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Nellcor™ Pulse Oximetry Performance in Challenging Conditions

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Background

Pulse oximetry noninvasively measures blood oxygenation by estimating the fraction of hemoglobin bound to oxygen in pulsing arterial blood (SpO_2). This parameter primarily reflects oxygen transfer from the lungs to tissues via the blood and provides an early indication of oxygenation issues. Pulse oximetry is quantitative, accurate, continuous, and convenient.[1] Today, pulse oximetry is considered a standard of care and is often relied upon to ensure patient safety.[2,3]

Pulse oximetry performance and reliability is necessary across patients with diverse demographics and challenging physiological conditions and co-morbidities. Common challenging conditions for pulse oximetry include low sensor-site perfusion and motion artifact. Low perfusion is often encountered in patients with sepsis, shock, and other vascular conditions, and motion artifact can occur in a variety of circumstances, ranging from the involuntary movement of a neonate to a hospitalized adult eating lunch.[3-5] These conditions can occur in all care settings (ED, OR, ICU, GCF, L&D, NICU, etc.), and can impact clinical workflow due to difficult sensor placements and nuisance alarms. A pulse oximeter that can accurately measure pulse rate and SpO_2 is necessary in cases in which a patient presents with one or more conditions that make pulse oximetry challenging, both to ensure patient safety and to maintain efficient clinical workflow.

The purpose of this paper is to review key literature examining Nellcor™ pulse oximetry performance in challenging clinical conditions. Key technical features important in challenging clinical conditions include pulse rate accuracy, SpO_2 accuracy, and alarm management.

Low Sensor-Site Perfusion

Patients with low sensor-site perfusion have a smaller pulse amplitude, due to vasoconstriction or hypotension, that can result in artifact and inaccurate readings.[3] Low sensor-site perfusion is common in patients with peripheral vascular disease, sepsis, hypothermia, or shock, making pulse oximetry more challenging.[3,5] To evaluate pulse oximetry performance during low sensor-site perfusion, both clinical studies and healthy volunteer studies have been performed. While controlled volunteer studies often create low sensor-site perfusion using cold temperatures or partial arterial occlusion, prospective clinical studies have focused on critically ill patients and transport conditions in which low perfusion occurs.

Healthy Volunteer Pulse Oximetry Low Perfusion Studies

Oximetry performance during low sensor-site perfusion has also been evaluated in volunteer studies of diverse designs, using reproducible protocols and distinct challenges, such as cold or occlusion, to represent non-ideal pulse oximetry conditions. In this section, we summarize the results of several healthy volunteer pulse oximetry studies.

Study 1

In one prospective study, 18 anesthetized volunteers underwent induced apnea, along with reduced finger perfusion by compressing the axillary artery.[6] Circulatory delay was evaluated using Nellcor™ pulse oximetry monitors connected to Nellcor™ pulse oximetry digit (MAXA) and forehead (MAXFAST) sensors. The forehead is a uniquely robust pulse oximetry site, for which the Nellcor™ MAXFAST pulse oximetry sensor was designed. Because forehead arterial supply also feeds the brain, this site is not susceptible to vasoconstriction.[7] However, because veins in the head lack one-way valves, the forehead may be prone to venous pulsation, particularly if the head is below the heart (Trendelenberg) or the patient condition or surgical procedure impedes venous return.[5] The primary mitigation is proper headband application to provide ample pressure to restrict venous pulsation, with secondary mitigation in the monitor's signal processing that was designed for such conditions.

In their low perfusion study, Sugino et al found that, as hypothesized, axillary compression induced a modest incremental circulatory delay for digit SpO_2 relative to forehead SpO_2 (6.3±4.9 seconds), whereas the response at both sensor sites was essentially equal before axillary compression.[6] Therefore, the forehead sensor demonstrated reduced time to detect the changes caused by induced apnea.

Study 2

In another prospective, healthy volunteer, low perfusion study, Addison et al performed a cold-room (13°C) motion hypoxia study with 12 volunteers of varied skin pigmentation.[8] This study was conducted and sponsored by Medtronic. The study demonstrated excellent pulse rate accuracy versus ECG (1.6 per minute) on the non-motion digits using Nellcor™ pulse oximetry, indicating that during reduced perfusion with no motion, the pulse oximeter is accurate.

Study 3

In contrast to studies using a cold room or axillary artery compression to simulate low perfusion, MacLeod et al used a mild hypothermia model (water mattress 14°C, core temperature 36°C) to induce vasoconstriction.[9] In this prospective study of 10 volunteers, the mean finger circulatory delay was 215 seconds relative to co-oximeter with blood drawn from a radial artery catheter, while head sites demonstrated a fraction of this delay.[9] Out of 6 pulse oximeter sensor types evaluated (forehead, ear, and finger sensors), a statistical test of rank order found that the Nellcor™ MAXFAST sensor ranked first in response time in 28 of the 30 hypoxic challenges, and the four digit sensors showed equivalent digit circulatory delay, confirming that this delay is a function of physiology.[9] Table 1 shows the response times to hypoxic challenge (3 minutes at 11% FiO_2).[9]

Study 4

Although circulatory delay due to low sensor-site perfusion may not be readily apparent, a pulse oximeter cannot monitor a drop in oxygenation at the lungs (e.g. apnea) until blood reaches the sensor site. To evaluate the performance of Nellcor™ pulse oximetry during low perfusion, the data from 12 Medtronic-internal motion hypoxia studies performed with room temperature 13-15°C were retrospectively pooled and analyzed.[10]

Table 1. Response times (seconds) of pulse oximeters during hypoxic challenge in healthy volunteers.

Site and Monitor:	Forehead Nellcor™ MAXFAST	Earlobe Masimo	Finger Mean of 4 vendors	p-value
Normothermia	41±14 sec	60±16 sec	130±44 sec	p<0.001
Hypothermia	40±11 sec	60±36 sec	215±67 sec	p<0.001
Hypothermia + glyceryl trinitrate	22±11 sec	33±14 sec	188±77 sec	p<0.001

Among 369 forehead-digit sensor pairings (114 healthy volunteers), we observed an incremental circulatory delay for non-motion digit SpO_2 relative to forehead SpO_2 of 74±19 seconds. In response to cold, digit pulse signal amplitude varied by over an order of magnitude across the volunteer pool, as well as compared to normothermic studies on different dates (example: 4.18% in normal conditions and 0.11% in cold room). In this retrospective analysis, we found that digits with the smallest pulses had up to a two-minute circulatory delay compared to forehead pulse oximetry.[10]

Study 5

The Nellcor™ MAXFAST forehead sensor provides robust, accurate and timely oximetry monitoring with appropriate headband application. Table 2 shows the results of an 11-volunteer Medtronic-internal room-air study in Trendelenberg position, creating a venous pulsation challenge at the forehead.[11] It shows the bias and posting of the Nellcor™ MAXFAST sensor compared to the mean of four digits with Nellcor™ MAXA sensors. With the headband, the Nellcor™ MAXFAST sensor provided reasonable SpO_2 accuracy for tilts down to 20 degrees. However, without the headband, bias ± precision relative to digits at -20 degrees tilt was 6.40±8.38.[11]

Table 2. Bias, precision, and posting of the Nellcor™ MAXFAST sensor in Trendelenberg position with and without a headband.

Patient Position	SpO_2 Bias vs finger	SpO_2 Posting %
0 degrees, with headband	1.09±1.85	100%
-10 degrees, with headband	-0.17±2.30	100%
-15 degrees, with headband	-0.59±3.07	100%
-20 degrees, with headband	-1.28±3.61	100%
-20 degrees, without headband	-6.40±8.38	97%
-20 degrees, re-apply headband	-1.39±3.75	96%
Back to 0 degrees, with headband	0.05±1.85	100%

Clinical Pulse Oximetry Low Perfusion Studies

Pulse oximetry performance during low sensor-site perfusion has been evaluated across multiple clinical settings. In this section, we summarize the results of several clinical studies that examined pulse oximetry performance.

Study 1

In a prospective study performed at a large university-affiliated medical center, Schallom et al measured SpO_2 accuracy in 30 critically ill surgical/trauma patients, versus co-oximeter.[5] Table 3 summarizes results for Nellcor™ pulse oximetry with OxiMax™ technology, which found that Nellcor™ pulse oximetry has low mean error and precision, particularly when using the Nellcor™ MAXFAST sensor.

Table 3. Nellcor™ pulse oximetry performance in critically ill surgical/trauma patients.

Site	Forehead	Digit	Digit
Monitor	Nellcor™	Nellcor™	Philips
Technology	OxiMax™	OxiMax™	OxiMax™
Sensor	MAXFAST	MAXA	MAXA
Measurements	89	89	89
Measurement failures	1 (1%)	6 (7%)	9 (10%)
Mean error ± precision	-1.39±1.28	-2.61±3.61	-3.84±6.91
R^2 versus catheter	0.834	0.433	0.254

Study 2

In a separate prospective clinical study, 52 patients were evaluated with Nellcor™ and Masimo pulse oximetry monitors, using both sensors on the same hand, with randomized digit selection, during ambulance transport in cold weather (Vienna, Austria, October-November).[12] Twenty patients had blood pressure ≤ 100/60. The incidence of "malfunctions" (no reading) was 0.13 and 0.21 per patient for Nellcor™ and Masimo pulse oximetry, respectively, which was statistically equivalent. Root-mean-square difference (RMSD) between the two oximeters was 1.69% SpO_2 and 4.48 BPM, implying acceptable accuracy and performance for both monitors. Overall, a systematic review of pulse oximetry accuracy in adult patients with low site perfusion at digit and forehead sensor sites concluded that "Oximeters are accurate in poorly perfused patients, especially newer oximeter models.".[3]

Study 3

Consider the following case report, which exemplifies the robustness of the forehead site: A coronary artery bypass graft (CABG) surgery was performed in 2002 on a 106 Kg dark-pigmented patient.[13] As seen in Figure 1, the combination of the Nellcor™ MAXFAST sensor and Nellcor™ pulse oximetry with OxiMax™ technology provided the earliest indication that the patient's heart had been restarted. Pulse amplitudes (normally 0.5 – 2.0% for the forehead) were 0.04%, increasing to 0.06% when pulse beeps became regular. When blood pressure display resumed, pulse pressure was still only 3 mm Hg, compared to normal pulse pressure of 40 mm Hg. This example is consistent with the high sensitivity and accuracy of Nellcor™ pulse oximetry across multiple clinical studies.[5,6,8,9,12]

Motion Artifact

A second key challenge for pulse oximetry is motion artifact, which occurs in all areas of care. In a review of pulse oximetry and the effect of motion, Petterson et al recognized that the invention of pulse oximetry was based on two principles:[14]

1. The light absorbance of oxygenated hemoglobin is different from that of reduced hemoglobin at the two wavelengths used in pulse oximetry (red and infrared).
2. The absorbances at both wavelengths have a pulsatile, or oscillating (AC) component, which is the result of the volume change, normally from arterial blood, occurring between the emitter and the detector of the sensor.

Petterson et al then enumerate the following implicit assumptions:[14]

1. All the hemoglobin present is either oxyhemoglobin or reduced hemoglobin.
2. There are no other absorbers between the emitter and detector other than those present during the empirical calibration. The absorption characteristics of these "other absorbers" are the same as during the empirical calibration.
3. All the blood that "pulsates" is arterial blood.

Motion artifact violates the second and third assumptions, both through the movement of venous blood and by modulating non-blood tissue and its physio-optics. Squeezing a fingertip visibly changes its optical characteristics, resulting in modulations that are much larger than those caused by arterial pulses. Pulse oximetry studies focused on motion artifact are often healthy volunteer studies, with heterogeneous methods and results.

Figure 1. Nellcor™ pulse oximetry during coronary artery bypass graft surgery.

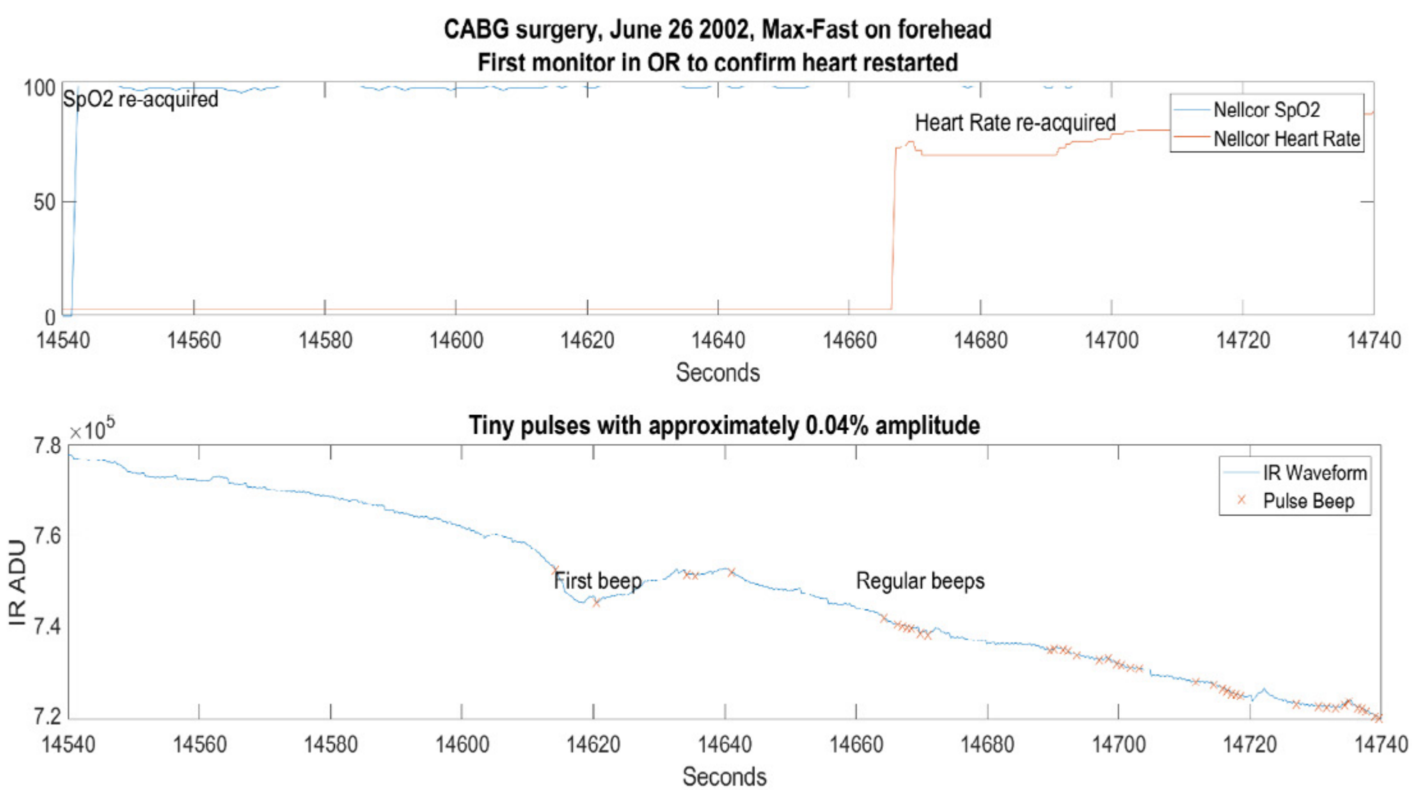

Table 4. Summary of health volunteer pulse oximetry study designs and results.

Study Design	Population	Vendor	SpO_2 or Pulse Rate reference and results		Conclusions	Reference
20 body turns Room air	18 children Ages 6-10		**SpO_2 change during turn**	**ECG**	Both Nellcor™ and Masimo pulse oximeters report accurate heart rates, but Nellcor™ pulse oximetry had more stable SpO_2	Townshend 2006[15]
		Nellcor™	0.07±0.98[a]	1.11±4.08[a]		
		Nellcor™ forehead	-0.74±2.33	-0.46±7.40		
		Masimo	-0.04±2.25	0.53±8.94		
Voluntary motion + cool room (16-18°C)	10 adults		**Within 7% of non-motion digits**	**Within 10% of non-motion digits**	Using a performance index, both SpO_2 and HR measurements were not significantly different between Nellcor™ and Masimo pulse oximetry. Masimo had no dropouts.	Shah 2012[16]
		Nellcor™	73.1%[b]	60.3%[c]		
		Masimo	98.5%[b]	88.5%[c]		
Periodic and aperiodic voluntary motion + cold room (13°C)	12 adults		**ECG**		Across 5 types of voluntary motion, Nellcor™ pulse oximetry reported pulse rate error > 25 BPM 3.4% of the time, compared to Masimo, which exceeded the error threshold 27.6% of the time. The HR reported by Nellcor™ pulse oximetry was significantly superior to Masimo.	Addison 2013[8]
		Nellcor™	RMSD = 8.6			
		Masimo	RMSD = 25.2			
Motion + hypoxia, normal room temperature (28°C) Low perfusion categorized as Masimo PI<2% on non-motion hand	10 adults		**SpO_2 vs co-oximeter RMSD (95% CI)**		All pulse oximetry performed well during normal perfusion with motion, but only Nellcor™ and Nihon Kohden pulse oximetry performed well during low perfusion with motion	Louie 2018[17]
			Low perfusion	**Normal perfusion**		
		Masimo, non-motion hand	2.2 (1.9-2.6)	1.1 (1.0-1.3)		
		Masimo	7.4 (5.4-9.3)	3.1 (2.0-4.2)		
		Nellcor™	5.1 (3.5-6.8)	3.4 (2.5-4.3)		
		Nihon Kohden OxyPal Neo	2.3 (1.8-2.7)	2.2 (1.7-2.8)		
		Philips Intellivue MP5	7.8 (5.4-10.2)	4.0 (2.4-5.6)		
Voluntary motion + cold room (13-15°C)	115 adults 244 motion digits & 248 non-motion digits	Nellcor™	**SpO_2 Reference: Mean of non-motion digits**		Nellcor™ pulse oximetry is very consistent during low perfusion and has more variability during episodes of motion artifact with low perfusion.	Internal Medtronic studies[10]
			Low perfusion	**Low perfusion + motion**		
			RMSD=1.64	RMSD=7.68		

[a]Precision calculated from the 95% limits of agreement

[b]Difference between Nellcor™ and Masimo not statistically significant

[c]Difference between Nellcor™ and Masimo not statistically significant

Healthy Volunteer Pulse Oximetry Motion Studies

Healthy volunteer studies have evaluated oximeter performance during motion artifact, often including low sensor-site perfusion as part of the study design. Table 4 summarizes several pulse oximetry motion studies on digit sensors and illustrates the heterogeneity of both the study designs and the results. One common feature is that all adult studies included controlled hypoxia. In one study, Townsend et al noted, “All new generation pulse oximeters tested performed well to within 20 mmHg of total brachial artery occlusion, mimicking poor perfusion. Only the Nellcor™ 595 [with OxiMax™ technology] with finger sensor met all predefined criteria for accuracy during movement.”[15]

One important aspect of healthy volunteer studies examining pulse oximetry accuracy relates to the type of motion utilized in the study. While some studies utilize mechanical, repetitive movement to estimate the accuracy of pulse oximetry during motion, these results are not reflective of real-world conditions, in which patient movement is not mechanical, but random and unpredictable.[8] Pulse oximetry algorithms may be better equipped to adjust pulse rate and SpO_2 values measured during mechanical motion, making the results of these studies appear accurate, but in reality may be less applicable to real world conditions. In contrast, the healthy volunteer studies in which random motion is utilized generate data more reflective of real-world patient monitoring circumstances.[8] Importantly, out of the five pulse oximetry with motion studies summarized in Table 4, one prospective volunteer study sponsored by Masimo found equivalence between Nellcor™ and Masimo pulse oximetry performance,[16] two prospective volunteer studies concluded that Nellcor™ pulse oximetry provides superior SpO_2 measurements compared to Masimo,[15,17] and two Medtronic-internal studies, one prospective and one retrospective, concluded that Nellcor™ pulse oximetry has high accuracy in heart rate measurements, including superiority to Masimo in one study.[8,10] Together, these findings from a broad set of studies highlight that Nellcor™ pulse oximetry is accurate and reliable during motion.

Clinical Pulse Oximetry Motion Studies

Motion is to be expected in L&D and the NICU.[4] In a single-center prospective clinical study independent of manufacturers, Khoury et al monitored sixty newborns (55 with ECG, mean age 4 minutes) delivered by C-Section with Nellcor™ pulse oximetry with Nellcor™ MAXN sensors and Masimo Radical-7 with M-LNCS Neo sensors.[1] SpO_2 readings were defined as stable when consistent for at least three beats, as well as consistent with clinical appearance and ECG, if available. Nellcor™ pulse oximetry had a shorter time to stable reading and no false bradycardia episodes, as seen in Table 5.[1]

Table 5. Performance of Nellcor™ and Masimo pulse oximetry in newborns.

	Nellcor™ pulse oximetry	Masimo pulse oximetry
Stable SpO_2 reading achieved	60 / 60 (100%)	55 / 60 (92%)
Mean time to stable reading	15 seconds	27 seconds
Median time to stable reading	8.5 seconds	12 seconds
False bradycardia compared to ECG	0 / 55 (0%)	18 / 55 (35%)

For adult and pediatric patients, motion artifact is typically episodic restlessness, such as scratching or tapping, rather than continuous motion.[4] This still creates the possibility of false alarms that can interrupt clinical workflow. Nellcor™ pulse oximetry system with OxiMax™ technology includes Nellcor™ SatSeconds alarm management, to suppress audible alarms that are too shallow or transient (in combination) to result in interventions. After comparing Nellcor™ pulse oximeter alarms with and without Nellcor™ SatSeconds, Brostowicz concluded that “application of an integrated alarm system at 50 SatSeconds reduces the clinically insignificant pulse oximetry alarms by 40% and allows for a new alarm management feature to aid caregivers to respond to potentially clinically relevant alarms.”.[18]

Conclusion

The truly challenging patients are the “corner cases” in the patient population that interrupt clinical workflow with difficult sensor placements and nuisance alarms. For example, a sensor on the oversized dark-pigmented foot of a NICU patient who frequently vasoconstricts during neonatal abstinence syndrome may pose a triple challenge to the pulse oximeter, and the scenario in which a patient presents more than one challenge for pulse oximetry is quite realistic.

Nellcor™ pulse oximetry is consistently tested, using over 2,000 unique test conditions (infrared and red signal levels, pulse amplitude, SpO_2 and pulse rate) representing a full range of physiological conditions. Nellcor™ pulse oximetry can often acquire saturation and pulse rate for test points having a pulse amplitude of 0.03%, which is very difficult to create in a volunteer study, given that normothermic pulse amplitudes typically range from 0.5-2.0% on forehead and > 2% on digit sites. For low signals (e.g. dark pigment or thick sensor site), our systems can typically acquire pulses with amplitudes under 100 pico-amperes, which is 1000-fold smaller than the average pulse amplitude. Our extensive internal clinical data evaluation, along with independent clinical studies of Nellcor™ pulse oximetry performance, provide evidence that Nellcor™ pulse oximetry can provide reliable pulse rate and oxygen saturation readings in challenging monitoring conditions.[1,5,6,8-11,15]

Nellcor™ pulse oximetry with OxiMax™ technology demonstrates strong monitoring performance for patients with low sensor-site perfusion, and Nellcor™ pulse oximetry offers the Nellcor™ SpO_2 forehead sensor (MAXFAST) and headband as an alternative to a digit sensor. Nellcor™ pulse oximetry with OxiMax™ technology has a record of accurate, reliable monitoring during motion and low perfusion, as well as reducing nuisance alarms, which combined, can limit consequent disruption to clinical workflow while providing the critical information needed to support decision-making for patient care, even in the most challenging patient conditions.[1,4,5,8,15,17,18]

The Nellcor™ pulse oximetry monitoring system should not be used as the sole basis for diagnosis or therapy and is intended only as an adjunct in patient assessment.

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