Motion Performance Comparison of New Generation Pulse Oximeters

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INTRODUCTION

The purpose of this paper is to summarize testing that compares the motion performance of Masimo SET® Radical® (V3.1), Nellcor N-595 (V2.4.5.0), and Nellcor N-395 (V1.6.3.0) pulse oximeters.

METHODS

Testing was performed in a room cooled to 18° C. The motion test sensors were attached to the right hand of the volunteers, and optically shielded to prevent cross-talk. Two reference pulse oximeters (N395 and Masimo SET Radical) were connected to the left hand. All motions were performed with the right hand of the subjects, keeping the left hand still. Four volunteers were instructed to perform different types of persistent erratic/random motions: tapping, rubbing, waving, and scratching. These motions were performed in room air, as well as during hypoxic episodes. Episodes that were started with the patient cable disconnected from the test units then reconnected are referred to as T=0 tests. Accuracy results were compared to the published accuracy specifications for saturation and pulse rate. All three units claim the same specifications for saturation and pulse rate accuracy.

RESULTS

False Low Saturation Alarm and Missed Desaturation Event analyses are shown in Table I.

Volunteer Motion Performance Comparison Masimo SET Radical, Nellcor N-595, and Nellcor N-395			
Oximeter	Masimo SET Radical	Nellcor N-595	Nellcor N-395
Motion Episode Count	39	39	39
False Low Saturation Alarm Count	4	17	11
False Low Saturation Alarm %	10.3%	43.6%	28.2%
Desaturation Event Count	13	13	13
Missed Desaturation Event Count	1	6	4
Missed Desaturation Event %	7.7%	46.2%	30.8%

Table I: False Alarm and Missed Event Comparison

Accuracy analysis correlating the SpO_2 readings of the subject's test and reference hands was deemed inappropriate for three of the four files reported above due to reading delays from test hand to reference hand associated with their very low perfusion. The correlation for the file obtained without such delay is shown in Table II.

Motion Performance Comparison Masimo SET Radical, Nellcor N-595 and Nellcor N-395		
Oximeter	Saturation Accuracy	Pulse Rate Accuracy
Published Accuracy Specification[1, 2]	3.0	5.0
Masimo SET Radical	1.3	3.1
Nellcor N-595	6.0	11.0
Nellcor N-395	3.8	6.2

Table II: Motion Performance Comparison

DISCUSSION/CONCLUSIONS

The Masimo SET instrument showed better False Alarm and Missed Event performance than either Nellcor unit. The Nellcor N-595 showed False Alarms with nearly 44% of the motion episodes, while missing more than 36% of the desaturation episodes. The correlation analysis showed the Masimo SET instrument to be within the published saturation and pulse rate accuracy specifications. Neither Nellcor instrument met the accuracy specification for saturation or pulse rate during motion. The accuracy results of the N-595 in our testing confirm the accuracy results of the N-595 reported in an abstract by Tyco Healthcare[3].

[1] Radical Signal Extraction Pulse Oximeter Operator's Manual, p. 49
[2] Nellcor OxiMax N-595 Pulse Oximeter Operator's Manual, pp. 125-126
[3] Pulse Oximetry Accuracy and Performance During Combined Motion and Low Perfusion, Cook CM, et al. American Journal of Critical Care; 2002; 11(3):294