

Documented Accuracy in Independent Clinical Studies:

Comparing Masimo SET and Nellcor OxiMax Technology

Performance Claim	Nellcor Pulse Oximeters: N-595 / N-600 / N-600x [‡]			Masimo Radical Pulse Oximeters:			Published Research Details		
	Accuracy Claim	Actual Reported Accuracy: (A _{RMS}) [*]	Meets Spec?	Accuracy Claim	Actual Reported Accuracy: (A _{RMS}) [*]	Meets Spec?	Study Population	Nellcor Device	Relevant Footnote
SpO₂ Accuracy (70-100%)									
Adult/Pediatric (digit)	±2 digits	2.26	Yes	±2 digits	2.00	Yes	100 ICU patients	N-600 n/a	1
Neonate (hand/foot)	±3 digits	3.70	No	±3 digits	3.13	Yes	17 newborns	N-600 n/a	2
Forehead Sensor	±2 digits	4.91	No	±2 digits	0.51	Yes	24 Pediatric Surgery Patients	N-595 p<0.006	3
Forehead Sensor	±2 digits	6.42	No	±2 digits	0.85	Yes	44 Adult Surgical Patients	N-595 p<0.00003	4
Fragile Skin	±2 digits	No studies	No	±3 digits	2.50	Yes	56 term & preterm infants	n/a	5
SpO₂ Accuracy (60-80%)									
Adult/Pediatric (digit)	±3 digits	7.69	No	±3 digits	2.52	Yes	7 CCHD Peds	N-595 p<0.0001	6
Infant (toe/thumb)	±3 digits	6.49	No	±4 digits	3.97	Yes	12 CCCL Infants	N-600 p<0.001	7
Infant (toe/thumb)	±3 digits	9.26	No	±3 digits	2.31	Yes	6 Cyanotic Infants	N-550 n/a	8
Neonate	±4 digits	5.71	No	±3-4 digits	3.83	Yes	8 CCCL Infants	N-600 p<0.0001	9

* ARMS is what is accepted by the FDA and ISO standards for pulse oximetry (ISO 9019) when manufacturers provide accuracy data for market clearance of a device. $ARMS = \sqrt{[(bias)^2 + (precision)^2]}$ where bias = mean difference between SaO₂ and SpO₂ and precision = standard deviation of the differences.

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[‡] Per Nellcor's website, "the OxiMax N-600x pulse oximeter has the same signal processing technology as the OxiMax N-600™ pulse oximeter."

Product Specification Performance Comparison:

Manufacturers Claims vs. Market Data

Published Accuracy Specifications*

Performance Claim	Nellcor®-N600™ / N-600x ⁺ Pulse Oximeter ¹	Masimo® Radical® Pulse Oximeter	Masimo® Radical-7™ Pulse CO-Oximeter
SpO₂ Accuracy (70-100%)			
Adult/Pediatric (No Motion)	±2 digits	±2 digits	±2 digits
Adult/Pediatric (Motion)	Not Available	±3 digits	±3 digits
Neonate (No Motion)	±2 digits	±3 digits	±2 digits
Neonate (Motion)	Not Available	±3 digits	±3 digits
Perfusion Range	0.03% - 20%	0.02% - 20%	0.02% - 20%
Accuracy in Low Perfusion	Adult ±2 Neo ±2 digits	Adult ±2 Neo ±3 digits	Adult, Pediatric ±2 digits Neo ±3 digits
Forehead Sensor	MAX-FAST ±2 digits	TF-I ±2 digits	TF-I ±2 digits
Ear Sensor	D-YSE ±3.5 digits	TC-I ±3.5 digits	TC-I ±3.5 digits
Fragile Skin non-adhesive (No Motion)	SoftCare ±2 digits	SofTouch ±3 digits	SofTouch ±3 digits
Fragile Skin non-adhesive (Motion)	Not Available	SofTouch ±3 digits	SofTouch ±3 digits
SpO₂ Accuracy (60-80%)			
Adult/Pediatric (No Motion)	±3 digits	Not Currently Claimed ²	±3 digits ³
Infant (No Motion)	±3 digits		±3 digits ³
Neonate (No Motion)	±3 digits (N-600x) ±3 digits (N-600)	60% - 80% ±4 digits ⁴ 70% - 100% ±3 digits ⁴	60% - 80% ±4 digits ⁴ 70% - 100% ±3 digits ⁴
Congenital Cyanotic Cardiac Defects (No Motion)	Not Available	80% - 100% ±3 digits ⁴	70% - 100% ±3 digits ⁴ 80% - 100% ±3 digits ⁴
Forehead Sensor	±3 digits	Not Available	Not Available
Pulse Rate Accuracy (70%-100%)			
Pulse Rate (No Motion)	20 - 250 bpm ±3 digits	25 - 240 bpm ±3 digits	25 - 240 bpm ±3 digits
Pulse Rate (Motion)	Not Available	25 - 240 bpm ±5 digits	25 - 240 bpm ±5 digits
Pulse Rate - Low Perfusion	20 - 250 bpm ±3 digits	25 - 240 bpm ±3 digits	25 - 240 bpm ±3 digits
Carboxyhemoglobin Saturation (%SpCO) Accuracy (No Motion)	Parameter Not Available	Parameter Not Available	1% - 40% ±3 digits
Methemoglobin Saturation (%SpMet) Accuracy (No Motion)	Parameter Not Available	Parameter Not Available	1% - 15% ±1 digit

* See reverse side for summary of independent clinical research revealing actual accuracy of above instruments when testing is performed on clinical populations

1. According to Nellcor, the FDA granted Nellcor clearance to drop the +1 digit for MAX-N, SC-PR and SC-NEO, because enough convenience sample data was submitted to support the claim.

2. Clinical need not established to justify submission

3. Validated with Rainbow adhesive sensors; testing including 60 - 80% SpO₂ accuracy was recently completed on a clinical population with balanced distribution of SpO₂ values between 60-80%

4. Validated with LNOP Blue Sensor