NHS
Purchasing and Supply Agency

Centre for Evidence-based Purchasing

Market review

Pulse oximeters in primary and prehospital care

CEP10066

March 2010

Informing procurement - Encouraging innovation

Contents

Introduction 3

Key device considerations 6

Fingertip pulse oximeters 7

Handheld pulse oximeters 16

Wrist-worn pulse oximeters 26

Bedside / desktop pulse oximeters 28

Choosing a pulse oximeter 34

Acknowledgements 37

References 40

Appendix 1: Supplier contact details 45

Appendix 2: Summary of clinical trials 49

Author and report information 91

Introduction

CEP market reviews provide comparative product specifications for healthcare products available to the UK market within a defined category. They supplement CEP buyers' guides, which offer more general advice on the technical, operational, and economic considerations to be taken into account when selecting an appropriate product.

This market review is intended to assist in the selection of pulse oximeters for use within primary and prehospital care. However, some or all of the devices may also be of use in secondary care.

Scope

This market review provides information on pulse oximeters that can be used across healthcare services, particularly within primary and prehospital care. The 85 pulse oximeter models in this review are representative of the UK market at the beginning of 2010. They were grouped into four categories:

- **Fingertip:** a pulse oximeter with an integrated fingertip probe which incorporates a display and records results (list price range £50.00 - £415.00).
- **Handheld:** a pulse oximeter that displays and records results and is intended to be held in the hand during normal use. Probes are connected to the unit via a cable (list price range £143.10 - £5800.00).
- **Wrist-worn:** a pulse oximeter that displays and records results and is intended to be worn on the wrist during normal use. Probes are connected to the unit via a cable (list price range £558.57 - £695.00).
- **Bedside/desktop:** a pulse oximeter that sits on a desk or is supported by a stand during normal use. Probes are connected to the unit via a cable or wireless link (list price range £785.00 - £2703.75).

No multi-parameter monitors (*ie* vital sign monitors and patient monitors) are included in this market review, as these systems are predominantly used in secondary care. Hospital grade non-invasive blood pressure monitors with pulse oximetry were included in a previous buyers' guide [1]. Fetal oximeters, cerebral oximeters, oximetry recorders and oximeters intended for non-NHS markets (*eg* sports, aviation and consumer-use) were also excluded from this market review.

This market review is concerned with the monitoring of oxygen saturation non-invasively. Direct arterial oxygen saturation is measured invasively using co-oximetry, covered in previous CEP reports [2, 3].

This market review should be read in conjunction with the associated buyers' guide [4].

Introduction

The clinical and cost effectiveness of pulse oximeters in primary and prehospital care have been previously reviewed by CEP [5].

Method

Product identification

During 2009/10 we carried out a review of pulse oximeters available on the UK market that could be used in primary and prehospital care, drawing on information from medical literature, marketing literature from known suppliers and internet searches. We identified 85 models from 21 manufacturers. These comprised:

- 28 fingertip pulse oximeters
- 34 handheld pulse oximeters
- 3 wrist-worn pulse oximeters
- 20 bedside/desktop pulse oximeters

Collation of product information

Product information was derived from the manufacturers' and suppliers' product brochures or from specifications published in user manuals. We have presented this information (tables 2, 4, 6 and 8) in a common, consistent format to allow easy comparison between devices. Devices are ordered alphabetically by manufacturer and by model. Where the manufacturer or supplier did not provide data *not specified* is shown.

Evidence of accuracy

The performance of pulse oximeters is defined in the standard BS EN ISO 9919:2009 [6], which specifies that accuracy should be supported by a clinical trial. The standard originated in 1992 [7], but no specification for SpO_2 accuracy was defined. However, it did state that manufacturers must disclose accuracy and test methods upon request. Specifications for SpO_2 accuracy were introduced in the 2005 revision [8].

We searched for peer-reviewed literature relating to the performance of the pulse oximeters included in the market review. The following questions were considered:

- Has the accuracy of the pulse oximeter been determined as specified in BS EN ISO 9919:2009 (or an earlier version)?
- Has the performance of the pulse oximeter been compared with other pulse oximeters and/or the gold standard analysis of arterial blood using co-oximetry?

A literature search on MEDLINE was completed in January 2010 using pulse oximeter makes, models and technology as search terms. Relevant literature was also requested from manufacturers and suppliers.

Twenty-nine peer-reviewed articles were identified: 13 considered the accuracy of pulse oximeters [9-21] and 16 considered the performance of pulse oximeters [22-37]. Accuracy testing is where SpO_2 measurements made by the pulse oximeter under test are directly compared with SaO_2 measurement made using a co-oximeter. Performance testing is where pulse oximeters are compared against each other.

In addition to peer-reviewed articles, manufacturers / suppliers were asked to provide any unpublished or non-peer reviewed evidence (including meeting abstracts and conference papers) on accuracy of pulse oximeters. Nine unpublished reports [38-46] and nine non-peer reviewed abstracts [47-55] were received.

The evidence relating to accuracy and performance of pulse oximeters has been summarised in tables 11-17, appendix 2. Where models are claimed to use the same pulse oximetry (SpO_2) technology as a device for which accuracy and/or performance has been demonstrated in the literature, equivalent performance has been assumed.

Key device considerations

Table 1 contains device characteristics to be considered when purchasing pulse oximeters. This table should be used in conjunction with the comparative product information tables (tables 2, 4, 6 and 8).

Table 1. Device considerations

Feature	Description
SpO_2 technology	Manufacturers have developed different algorithms to determine SpO_2 from the measured absorbance of red and infrared light. Algorithms use different and usually proprietary methods to reduce the effect of low amplitude and artefact, such as movement and ambient light, on measurement accuracy.
Sensor wavelengths	Red and infrared (or near infrared) light wavelengths used to determine SpO_2.
SpO_2 range and accuracy	The range of oxygen saturation for which the pulse oximeter measures within the stated accuracy. BS EN ISO 9919:2009 [6] states that SpO_2 accuracy should be less than ±4% over the range of 70% to 100%. Accuracy should be supported by a clinical study where SpO_2 measurements have been compared with SaO_2 measurements made using a co-oximeter.
Pulse rate range and accuracy	The range of pulse rate or heart rate for which the pulse oximeter measures within the stated accuracy. BS EN ISO 9919:2009 [6] states that pulse rate accuracy should be supported by evidence of comparison with a reference method of measuring heart rate, *eg* electronic pulse simulator or ECG heart rate.
Display type	This can be an integrated LED or LCD display. Some displays are monochrome whilst others are colour. Purchasers should consider whether high visibility or brightly coloured displays are important for their application.
Power supply	Devices in this review are powered by mains or battery, some of which are rechargeable by connecting to a mains adaptor or via USB.
Battery capacity	Typical length of continuous operation with new or fully charged battery.
Other features	Other features such as display of plethysmograph waveform, memory options, software, automatic power off *etc*.
Size and weight	These factors are important when considering the environment the device is to be used in, *eg* in GP surgery, by paramedic in the field *etc.*
List price	We have shown the list price excluding VAT as a guide only; price paid will depend on various commercial factors.
Accessories and prices	Accessories include sensors, mains adaptor or charger, printer options, carry case *etc*. We have shown the current accessory list prices excluding VAT. For some manufacturers/suppliers, prices vary depending on quantity. Most oximeters have a wide range of sensors which could not be listed due to space limitations. Users should contact suppliers to establish the full list of accessories available.

Table 2. Fingertip pulse oximeters

	Beijing Choice MD300-C	Beijing Choice MD300-C5	Beijing Choice MD300-D	Beijing Choice M-Pulse
				
SpO_2 technology	Beijing Choice	Beijing Choice	Beijing Choice	Beijing Choice
Sensor wavelengths	not specified	not specified	not specified	not specified
SpO_2 range & accuracy	100%-0% 99%-75%: ±2%; 74%-50%: ±3%; <50% unspecified	99%-70% ±2%	99%-70% 99%-80%: ±2% 80%-70%: ±3% <70% unspecified	99%-0% 99%-80%: ±2% 80%-70%: ±3% <70% unspecified
Pulse rate range & accuracy	30-240 bpm ±2 bpm	30-235 bpm ±2 bpm	30-235 bpm ±2 bpm	0-254 bpm ±2 bpm or ±2%
Display type	LED	dual colour OLED	dual colour OLED	dual colour OLED
Power supply	2 x AAA alkaline batteries	2 x AAA alkaline batteries	2 x AAA alkaline batteries	2 x AAA alkaline batteries
Battery capacity	30 hours	30 hours continuous use	30 hours continuous use	approx. 30 hours
Other features	8 second auto power off	rotatable display; plethysmogram waveform display; 8 second auto power off; 10 level adjustable brightness	4 way rotatable display; plethysmogram waveform display; 8 second auto power off; 10 level adjustable brightness	finger size range: 8-26mm; plethysmogram waveform display; 10 level adjustable brightness
Size (H x W x D)	58 x 34 x 32 mm	50 x 28 x 28 mm	58 x 34 x 32 mm	58 x 32 x 34 mm
Weight	0.080 kg (inc. battery)	0.042 kg	0.090 kg	0.050 kg (inc batteries)
List price (exc. VAT)	£50.00	£90.00	£80.00	£77.50
Accessories & prices				carry case £4.95

Table 2. Fingertip pulse oximeters (continued)

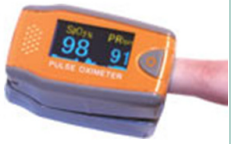
	Beijing Choice M-Pulse Lite	Comdek MD-650P Traveler II	Daray V407	Daray V408
				
SpO_2 technology	Beijing Choice	Comdek	Daray	Daray
Sensor wavelengths	not specified	not specified	not specified	not specified
SpO_2 range & accuracy	99%-70% 99%-80%: ±2% 80%-70%: ±3%	100%-0% 100%-80%: ±2% <80% unspecified	99%-35% ±1%	range not specified 100%-70%: ±2% <70% unspecified
Pulse rate range & accuracy	30-235 bpm ±2 bpm or ±2%	30-250 bpm ±1% of full scale	range not specified ±1 bpm	range not specified ±2 bpm
Display type	LED	LED	OLED	LED
Power supply	2 x AAA alkaline batteries	3 x AAA batteries	2 x AAA alkaline or rechargeable batteries	2 x AAA alkaline or rechargeable batteries
Battery capacity	not specified	not specified	not specified	approx. 100 hours
Other features		10 seconds auto power off	adjustable brightness; auto power off; plethysmogram waveform display	8 second auto power off
Size (H x W x D)	58 x 32 x 34 mm	73 x 45 x 43 mm	not specified	not specified
Weight	0.050 kg (inc batteries)	0.060 kg	not specified	<0.050 kg
List price (exc. VAT)	£65.00	£123.20	£149.00	£69.00
Accessories & prices	carry case £4.95			

Table 2. Fingertip pulse oximeters (continued)

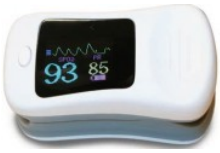
	Daray V409	Daray V501	Edan H10	Konica Minolta Pulsox-1
				
SpO_2 technology	Daray	Daray	Edan	Konica Minolta
Sensor wavelengths	not specified	not specified	not specified	red 659-677 nm infrared 900-990 nm
SpO_2 range & accuracy	99%-35% 99%-70%: ±2% <70% unspecified	99%-35% ±2%	99%-35% 99%-80%: ±2% 79%-70%: ±3% <70% unspecified	100%-0% 100%-70%, 1sd: ±2% <70% unspecified
Pulse rate range & accuracy	range not specified ±2 bpm	range not specified ±2 bpm	30-240 bpm ±3% or ±2 bpm	30-230 bpm 30-100 bpm: ±2 bpm 101-230 bpm: ±2% of reading
Display type	OLED	OLED	128 x 64 pixel dual colour OLED	backlit LCD with light sensor
Power supply	2 x AAA alkaline or rechargeable batteries	2 x AAA batteries	2 x AAA alkaline batteries	1 x AAA alkaline battery
Battery capacity	approx. 100 hours	50 hours	25 hours continuous	approx. 55 hours
Other features	rotatable display; 8 second auto power off; plethysmogram waveform display	auto rotation display; 8 second auto power off	rotatable display; auto power off; plethysmogram waveform display; 10 level adjustable brightness	1 minute display hold; neck strap included
Size (H x W x D)	not specified	not specified	57 x 32 x 31 mm	56 x 35 x 33 mm
Weight	<0.050 kg	approx. 0.050 kg	0.060 kg (inc. batteries)	0.049 kg (inc. battery)
List price (exc. VAT)	£99.00	£149.00	£58.61	£220.00
Accessories & prices				

Table 2. Fingertip pulse oximeters (continued)

	Konica Minolta Pulsox-2	Mediaid 100 / 100C	Nissei BO-800	Nonin 9500 Onyx
				
SpO_2 technology	Konica Minolta	Mediaid	Nissei	Nonin PureSAT®
Sensor wavelengths	not specified	red 660 nm infrared 910 nm	not specified	red 660 nm infrared 910 nm
SpO_2 range & accuracy	100%-0% 100%-70%, 1sd: ±2% <70% unspecified	100%-20% 100%-70%: ±2% 69%-60%: ±3% <60% unspecified	100%-0% accuracy not specified	100%-0% 100%-70%: ±2 digits <70% unspecified
Pulse rate range & accuracy	20-250 bpm ±2 bpm	25-250 bpm 25-200 bpm: ±2 bpm or 2%, whichever is greater >200 bpm: ±3%	30-240 bpm accuracy not specified	18-300 bpm ±3% ±1 digit
Display type	backlit LCD	LED	backlit LCD	LED
Power supply	2 x AAA alkaline batteries	1 x AA alkaline battery	2 x AAA batteries	2 x AAA alkaline batteries
Battery capacity	72 hours	approx. 1200 spot checks	up to 200 hours (without backlight); 18,000-24,000 spot checks	up to 18 hours (continuous); 1600 spot checks
Other features	integrated finger sensor; neck strap included	model 100: integrated finger sensor; model 100C has an additional cable adaptor module & sensor, 11.5 hour, 20 patient internal memory; infrared interface & PC software	auto power off	finger size range: 8-26mm; auto power off
Size (H x W x D)	69 x 60 x 28 mm	120 x 47 x 25 mm	51 x 30 x 26 mm	57 x 33 x 33 mm
Weight	0.057 kg (exc. batteries)	0.098 kg	0.046 kg (inc. batteries)	0.060 kg (inc. batteries)
List price (exc. VAT)	£311.95	100: £215.00 100C: £415.00	£169.00	£169.00
Accessories & prices				carrying case

Table 2. Fingertip pulse oximeters (continued)

	Nonin 9550 Onyx II	Nonin 9560 Onyx II	Nonin GO_2	Nonin Medair OxyCheck
				
SpO_2 technology	Nonin PureSAT®	Nonin PureSAT® with SmartPoint™ technology	Nonin PureSAT®	Nonin PureSAT®
Sensor wavelengths	red 660 nm infrared 910 nm	red 660 nm infrared 910 nm	red 660 nm infrared 910 nm	red 660 nm infrared 910 nm
SpO_2 range & accuracy	100%-0% 100%-70%: ±2 digits <70% unspecified	100%-0% normal & low perfusion: 100%-70%: ±2 digits <70% unspecified	100%-0% normal & low perfusion: 100%-70%: ±2 digits <70% unspecified	100%-0% 100%-70%: ±2 digits <70% unspecified
Pulse rate range & accuracy	18-321 bpm 20-250 bpm: ±3%	18-321 bpm 20-250 bpm: ±3 digits low perfusion: 40-240 bpm: ±3 digits	18-321 bpm 20-250 bpm: ±3 digits low perfusion: 40-240 bpm: ±3 digits	18-321 bpm 20-250 bpm: ±3 digits low perfusion: 40-240 bpm: ±3 digits
Display type	LED	LED	backlit LCD	LCD
Power supply	2 x AAA alkaline batteries	2 x AAA alkaline batteries	1 x AAA alkaline battery	2 x AAA alkaline batteries
Battery capacity	approx. 21 hours (continuous); 2500 spot checks	approx. 600 spot checks	approx. 21 hours (continuous); 2400 spot checks	approx. 18 hours (continuous); 1600 spot checks
Other features	finger size range: 8-26mm; auto power off	remote patient monitoring via Bluetooth® 2.0 wireless technology; range up to 100m; minimum 20 measure-ment internal memory	auto on/off; 3 colours (blue, orange or green)	finger size range: 8-26mm; auto on/off;
Size (H x W x D)	56 x 33 x 32 mm	not specified	not specified	not specified
Weight	0.054 kg (inc. batteries)	0.060 kg (inc. batteries)	not specified	not specified
List price (exc. VAT)	£229.00	£399.50	£89.50	£69.50
Accessories & prices	carrying case		carrying case; 20” lanyard; clip holder	soft carry case £8.50

Table 2. Fingertip pulse oximeters (continued)

	Rossmax SB-220	SeQual SmartPulse	Smiths Medical BCI Digit	SPO Medical PulseOx 5500
				
SpO_2 technology	Rossmax	SeQual	BCI	SPO Medical Reflective Pulse Oximetry (RPO) technology
Sensor wavelengths	red 660 nm infrared 880-905 nm	not specified	not specified	not specified
SpO_2 range & accuracy	99%-35% 99%-70%: ±2% 69%-35% unspecified	99%-9% 8 pulse averaging 99%-70%: ±2% <70% unspecified	99%-0% 8 beat averaging 99%-70%: ±2% <70% unspecified	99%-40% 99%-70%: ±2% or ±2 digits <70% unspecified
Pulse rate range & accuracy	30-250 bpm ±3 bpm	30-254 bpm 8 pulse averaging ±2% or ±2 bpm, whichever is greater	30-254 bpm 8 second averaging ±2% or ±2 bpm, whichever is greater	40-250 bpm ±3% or ±3 digits
Display type	dual colour OLED	multi-colour LED	LED	backlit LCD
Power supply	2 x AAA alkaline batteries	2 x AAA alkaline batteries	2 x AAA alkaline batteries	1 x ½AA 3.6V lithium battery
Battery capacity	approx. 16 hours (continuous)	50 hours (continuous)	approx. 16 hours (continuous); 1400 spot checks	approx. 1000 hours or 40 days continuous use
Other features	SpO_2 <90% alarm; auto power off	8 second auto power off; audio & visual alerts; detachable lanyard & carry case	8 second auto power off	automatic on/off; includes lanyard
Size (H x W x D)	63.5 x 35 x 34 mm	60 x 56 x 30 mm	57 x 43 x 38 mm	74 x 41 x 40 mm
Weight	0.037 kg	0.050 kg (inc. batteries)	0.085 kg (inc. batteries)	0.055 kg (inc. battery)
List price (exc. VAT)	£84.25	£164.52	£145.00	£115.00
Accessories & prices				belt pouch £7.50

Table 2. Fingertip pulse oximeters (continued)

	SPO Medical PulseOx 6000	Viamed VM-2101	Viamed VM-2105
			
SpO_2 technology	SPO Medical Reflective Pulse Oximetry (RPO) with AutoSpot™ technology	Viamed	Viamed
Sensor wavelengths	not specified	red 660 nm infrared 905 nm	red 660 nm infrared 905 nm
SpO_2 range & accuracy	99%-40% 99%-70%: ±2% or ±2 digits <70% unspecified	100%-0% 100%-70%: 1sd: ±2%; A_{rms} = <3% <70% unspecified	100%-0% 100%-70%: 1sd: ±2%; A_{rms} = <3% <70% unspecified
Pulse rate range & accuracy	40-250 bpm ±3% or ±3 digits	20-300 bpm ≤100 bpm: ±1 bpm >100 bpm: ±1%	20-300 bpm ≤100 bpm: ±1 bpm >100 bpm: ±1%
Display type	backlit LCD	128 x 96 pixel multi-colour OLED	128 x 96 pixel multi-colour OLED
Power supply	1 x ½AA 3.6V lithium battery	2 x AAA alkaline batteries	2 x AAA alkaline batteries
Battery capacity	approx. 500 hours continuous use	approx. 24 hours continuous use	approx. 24 hours continuous use
Other features	180° bi-directional display; automatic on/off; includes lanyard & belt pouch	4 way rotatable display; plethysmogram waveform display; adjustable brightness; includes lanyard	soft silicone housing; 4 way rotatable display; plethysmogram waveform display; adjustable brightness; includes lanyard
Size (H x W x D)	74 x 41 x 30 mm	57 x 33 x 27 mm	65 x 50 x 34 mm
Weight	0.050 kg (inc. battery)	approx. 0.050 kg (inc. batteries)	approx. 0.049 kg (inc. batteries)
List price (exc. VAT)	£135.00	£120.00	£225.00
Accessories & prices		lanyard £2.00; hard carry case £4.00; soft carry case £4.00	

Table 3. Evidence of clinical study to confirm accuracy of fingertip pulse oximeters

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Beijing Choice	MD300-C					no evidence
Beijing Choice	MD300-C5					no evidence
Beijing Choice	MD300-D					no evidence
Beijing Choice	M-Pulse					no evidence
Beijing Choice	M-Pulse Lite					no evidence
Comdek	MD-650P Traveler II					no evidence
Daray	V407					no evidence
Daray	V408					no evidence
Daray	V409					no evidence
Daray	V501					no evidence
Edan	H10					no evidence
Konica Minolta	Pulsox-1				✓ [45]	
Konica Minolta	Pulsox-2				✓ [45]	
Mediaid	100/100C				✓ [44]	
Nissei	BO-800					no evidence
Nonin	9500 Onyx	✓ [17, 23]			✓ [39-41]	
Nonin	9550 Onyx II	✓ [17, 23]			✓ [39-41]	
Nonin	9560 Onyx II	✓ [17, 23]			✓ [39-41]	
Nonin	GO_2	✓ [17, 23]			✓ [39-41]	
Nonin	Medair OxyCheck	✓ [17, 23]			✓ [39-41]	
Rossmax	SB-220					no evidence
SeQual	SmartPulse					no evidence
Smiths Medical	BCI Digit		✓ [37]			
SPO Medical	PulseOx 5500				✓ [41, 43]	
SPO Medical	PulseOx 6000				✓ [41, 43]	

Table 3. Evidence of clinical study to confirm accuracy of fingertip pulse oximeters (continued)

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Viamed	VM-2101					no evidence
Viamed	VM-2105					no evidence

Table 4. Handheld pulse oximeters

	Beijing Choice MD300K1-E	Bionet Oxy9	Bitmos Medizintechnik SAT 800	Bitmos Medizintechnik SAT 801
				
SpO_2 technology	Beijing Choice	Bionet	Masimo SET®	Masimo SET®
Sensor wavelengths	not specified	red 680 nm infrared 890 nm	red 660 nm infrared 940 nm	red 660 nm infrared 940 nm
SpO_2 range & accuracy	100%-70% 100%-80%: ±2% 79%-70%: ±3% ≤69%: unspecified	100%-80%: ±2% 80%-70%: ±3% 69%-40%: unspecified	adults & children - no motion: 100%-70%: ±2% 69%-0%: unspecified neonates - no motion: 100%-70%: ±3% 69%-0%: unspecified adults & children - with motion 100%-70%: ±3% 69%-0%: unspecified	
Pulse rate range & accuracy	30-235 bpm 30-100 bpm: ±2 bpm 101-235 bpm: ±2%	30-300 bpm ±1 bpm	25-240 bpm ±3 bpm (no motion) ±5 bpm (with motion)	
Display type	LED	monochrome LCD	backlit monochrome LCD	
Power supply	2 x AA alkaline batteries	3 x AA rechargeable NiMH batteries with external mains adaptor	2 x AA batteries	2 x AA batteries (battery version); rechargeable Li-Ion batteries (1.6Ah & 3.2Ah Li-Ion versions); external mains adaptor (optional on battery version)
Battery capacity	approx. 30 hours	12-20 hours	20 hours (typical)	20 hours (typical) (battery version); 15 or 30 hours (depending on Li-Ion version)
Other features	alarms; 100 patient, 72 hour internal memory; shock-proof & highly visible; carry case & IV pole strap		perfusion index; integrated rubber protectors; USB interface	as for Sat800 with additional prioritised alarms & internal memory with PC analysis software
Size (H x W x D)	130 x 61 x 30 mm	133 x 65 x 30 mm	128 x 85 x 46 mm	
Weight	not specified	not specified	0.230 kg	
List price (exc. VAT)	£249.00	price not provided	£499.00	£799.00
Accessories & prices			external mains adaptor; table stand	

Table 4. Handheld pulse oximeters (continued)

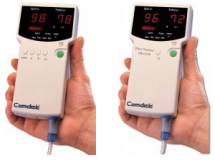
	Comdek MD-600P / MD-610P	Comdek MD-630P	Comdek MD-670P	Comdek MD-680P
				
SpO_2 technology	Comdek	Comdek	Comdek	Comdek
Sensor wavelengths	not specified	not specified	not specified	not specified
SpO_2 range & accuracy	100%-80%: ±2% 79%-0%: unspecified	100%-80%: ±2% 79%-0%: unspecified	100%-80%: ±2% 79%-65%: ±3% 64%-0%: unspecified	100%-80%: ±1% 79%-0%: unspecified
Pulse rate range & accuracy	30-250 bpm ±1% of full scale	30-250 bpm ±1% of full scale	30-250 bpm ±1%	30-250 bpm ±1% of full scale
Display type	LED	LED	backlit monochrome LCD	LED
Power supply	both models: 4 x AA batteries MD-600P only: 4 x AA rechargeable batteries with external mains adaptor	4 x AA batteries; 4 x AA rechargeable batteries with external mains adaptor	4 x AA batteries; 4 x AA rechargeable batteries with external mains adaptor	3 x AAA batteries
Battery capacity	20 hours	not specified	not specified	not specified
Other features	MD-600P only: alarms	built-in thermal printer; alarms; 24 hour internal memory; USB interface	alarms; 72 hour internal memory with trends; USB interface; PC analysis software	integrated finger probe; pulse rate alarm; 1 minute auto power off
Size (H x W x D)	172 x 90 x 36 mm	155 x 88 x 44 mm	170 x 88 x 44 mm	90 x 62 x 22 mm
Weight	0.240 kg	0.300 kg	0.250 kg	0.090 kg
List price (exc. VAT)	MD-600P: £316.80 MD-610P: £299.20	£519.20	£413.60	£158.40
Accessories & prices				

Table 4. Handheld pulse oximeters (continued)

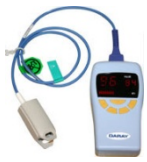
	Criticare 503DX miniSPO$_2$T	Daray V60	Daray V202	Edan H100B
				
SpO_2 technology	Criticare Systems Inc (CSI) DOX™	Daray	Daray	Edan
Sensor wavelengths	not specified	not specified	red 660 nm infrared 940 nm	not specified
SpO_2 range & accuracy	99%-1% 99%-70%: ±2% 69%-40%: ±3% <40%: unspecified	100%-0% adult/paed, no motion: 100%-70%: ±2% neonate, no motion: 100%-70%: ±3% 69%-0%: unspecified	99%-35% 99%-70%: ±2% <69%: unspecified	100%-0% adult: 100%-70%: ±2 digits neonate: 100%-70%: ±3 digits <70%: unspecified
Pulse rate range & accuracy	20-300 bpm ±1 bpm or ±1%, whichever is greater	25-250 bpm no motion: ±3 bpm	30-250 bpm ±2 bpm	30-254 bpm ±3 digits
Display type	LED	160 x 96 pixel 1.8” colour TFT LCD	LED	backlit monochrome LCD
Power supply	4 x AA alkaline batteries	2 x AA batteries	3 x AA alkaline or rechargeable batteries	4 x AA alkaline batteries or rechargeable NiMH battery pack
Battery capacity	24 hours	not specified	7 hours	48 hours (alkaline) or 36 hours (rechargeable)
Other features		alarms; display direction adjust; 24 hour internal memory; data transfer to PC software	3 minute auto power off; alarms	alarms; 300 hour internal memory; real-time clock display; graphical & tabular trends; auto power off; battery charger stand; serial interface for data transfer
Size (H x W x D)	146 x 91 x 33 mm	92 x 82 x 22 mm	120 x 63 x 32 mm	160 x 70 x 38 mm
Weight	0.280 kg	0.136 kg (inc batteries)	0.130 kg	0.165 kg
List price (exc. VAT)	£495.00	price not provided	£269.00	£143.10
Accessories & prices			adult sensor £85.00 paediatric sensor £85.00 neonatal sensor £85.00 ear clip sensor £85.00 additional batteries & charger £29.95	reusable paediatric finger sensor £52.00

Table 4. Handheld pulse oximeters (continued)

	GE Healthcare TuffSat	Huntleigh smartsigns MiniPulse	Masimo Rad-5 / Rad-5v	Masimo Rad-57
				
SpO_2 technology	GE TruTrak®	BCI	Masimo SET®	Masimo SET® upgradeable to Masimo Rainbow® SET
Sensor wavelengths	red 650-670 nm infrared 930-950 nm	not specified	red 660 nm infrared 940 nm	red 660 nm infrared 940 nm
SpO_2 range & accuracy	100%-0% 12 sec averaging 100%-70%: ±2 digits <70%: unspecified	99%-0% 8 sec averaging 99%-70%: ±2% <70%: unspecified	100%-1% Rad-5: 2, 4, 8, 10, 12, 14 or 16 sec averaging Rad-5v: 8 sec averaging 100%-70%: no motion: ±3 digits (adult/paed/neonate) motion or low perfusion: ±2 digits (adult/paed) ±3 digits (neonate)	100%-1% 2, 4, 8, 10, 12, 14 or 16 sec averaging 100%-70%: no motion or low perfusion: ±2 digits (adult/paed) ±3 digits (neonate) motion: ±3 digits (adult/paed/neonate)
Pulse rate range & accuracy	40-255 bpm 40-100bpm: ±2 bpm 100-255bpm: ±2%	30-254 bpm ±2 bpm or ±2%	25-240 bpm no motion & low perfusion: ±3 digits motion: ±5 digits	25-240 bpm no motion & low perfusion: ±3 digits motion: ±5 digits
Display type	backlit monochrome LCD	LED	LED	LED
Power supply	4 x AA alkaline batteries	4 x AA alkaline batteries (model MP1) or rechargeable NiMH cells & desktop charger (model MP1R)	4 x AA alkaline batteries	4 x AA alkaline batteries
Battery capacity	17-20 hours	>120 hours	>30 hours	>8 hours
Other features	pulse strength index; 5 minute auto power off; 64 minute internal memory; infrared printing; protective rubber bumper	alarms; auto power off; integrated probe storage	perfusion index; alarms Rad-5 only: FastSat® rapid change & Max indication; 72 hour internal memory with PC output; sleep mode; power-on user configuration	additional Rainbow® SET parameters: 57c carboxy-haemoglobin (%SpCO), 57m methaemoglobin (%SpMet) & perfusion index; alarms; 72 hour internal memory
Size (H x W x D)	150 x 70 x 30 mm	140 x 75 x 25 mm	158 x 76 x 36 mm	158 x 76 x 36 mm
Weight	0.257 kg	0.300 kg	0.320 kg	0.370 kg
List price (exc. VAT)	£555.00	MP1: £423.00 MP1R: £482.00	Rad-5 £550.00 Rad-5v £450.00	Rad-57c £2995.00 Rad-57m £2995.00 Rad-57cm £5800.00
Accessories & prices	infrared printer	protective cover; IV pole attachment; carry case; desk stand	reusable sensor range; protective boot with stand	reusable sensor range; 7 colour-choice protective rubber boot with stand

Table 4. Handheld pulse oximeters (continued)

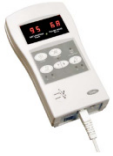
	Mediaid M34	Mediaid M5340	Mindray PM-50	Mindray PM-60
				
SpO_2 technology	Mediaid	Mediaid	Mindray	Mindray
Sensor wavelengths	red 660±2 nm infrared 910±10 nm	red 660 nm infrared 910 nm	not specified	not specified
SpO_2 range & accuracy	100%-0% 4 beat averaging 100%-70%: ±2% <70%: unspecified	100%-0% 100%-70%: ±2% 69%-60%: ±3% <60%: unspecified	100%-0% 100%-70%: ±2% (adult/paed) ±3% (neonate) 69%-0%: unspecified	100%-0% 7, 9 & 11 sec averaging (sensitivity: High, Med & Low) 100%-70%: ±2% (adult/paed) ±3% (neonate) 69%-0%: unspecified
Pulse rate range & accuracy	25-250 bpm ±2 bpm or ±2%, whichever is greater	32-250 bpm ±2 bpm	25-254 bpm ±2 bpm	18-300 bpm ±3 bpm (no motion) ±5 bpm (motion)
Display type	LED	LED	blue monochrome LCD	2.4” colour TFT LCD
Power supply	9V rechargeable lithium ion battery	rechargeable NiCad battery with external mains adaptor	4 x AA alkaline or rechargeable batteries	3 x AA batteries or rechargeable Li-ion battery with external charger stand
Battery capacity	21 hours (in sleep mode)	12 hours	approx. 15 hours	36 hours (standard) or 24 hours (rechargeable)
Other features	alarms; intermittent, automatic & sleep recording modes; up to 136 hour internal memory; data transfer to PC via USB or printer via infrared interfaces	alarms; data transfer via serial interface	100 patient, 200 measurement internal memory; auto power off; serial RS-232 data transfer	alarms; spot check & continuous modes; 96 hour, 99 patient, 4000 measurement internal memory; infrared data transfer
Size (H x W x D)	140 x 76 x 27 mm	197 x 105 x 38 mm	140 x 65 x 32 mm	120 x 55 x 30 mm
Weight	0.202 kg	0.516 kg	0.130 kg	0.300 kg
List price (exc. VAT)	£425.00	£395.00	£199.00	£299.00
Accessories & prices	reusable & disposable sensors; infrared printer; rubber boot £35.00; IV pole clamp £35.00	reusable & disposable sensors; table/wall mount; IV pole clamp £35.00		carrying case; protective cover; battery charger kit; pole mounting kit; data management kit

Table 4. Handheld pulse oximeters (continued)

	Nellcor Oximax N-65	Nonin PalmSAT 2500/2500A	Nonin 8500 series	Smiths Medical BCI 3301
				
SpO_2 technology	Nellcor OxiMax® with LoSat™	Nonin PureSAT®	Nonin PureSAT®	BCI
Sensor wavelengths	red 660 nm infrared 900 nm	red 660 nm infrared 910 nm	red 660 nm infrared 910 nm	not specified
SpO_2 range & accuracy	100%-1% 100%-70% (±1sd): adult & low perfusion: ±2 digits neonates: ±3 digits	100%-0% 100%-70%: no motion: ±2 digits (adult/paed) ±3 digits (neonate) motion or low perfusion: ±3 digits (adult/paed) ±4 digits (neonate)	100%-0% 100%-70% (adult): ±2 to ±4 digits (depending on sensors) 95%-70% (neonate): ±3 digits <70%: unspecified	99%-0% 8 beat averaging 99%-70%: ±2% <70%: unspecified
Pulse rate range & accuracy	20-250 bpm ±3 digits including low perfusion	18-300 bpm no motion: 18-300 bpm ±3 digits motion: 40-240 bpm ±5 digits low perfusion: 40-240 bpm ±3 digits	18-300 bpm ±3% ±1 digit	30-254 bpm 8 second averaging ±2% or ±2 bpm whichever is greater
Display type	blue monochrome backlit LCD	LED	LED	LED
Power supply	4 x AA alkaline or lithium batteries	4 x AA alkaline batteries or rechargeable NiMH battery pack or mains via external charging stand	6 x AA alkaline batteries	3 x C alkaline batteries or rechargeable NiCad batteries
Battery capacity	19 hours typical (alkaline) 40 hours typical (lithium)	2500: 100 hours (alkaline) 45 hours (rechargeable) 2500A: 60 hours (alkaline) 40 hours (rechargeable)	100 hours (maximum display brightness) 200 hours (minimum display brightness)	approx. 24 hours in continuous mode or 1500 spot checks (1 min on/2 min off)
Other features	alarms; perfusion value; infrared printer interface	alarms (2500A only); 72 hour internal memory; serial interface & data management software	spot check & continuous modes; optional alarms & memory	spot check & continuous modes; 1000 spot check, 99 patient internal memory; RS232C
Size (H x W x D)	158 x 73 x 35 mm	138 x 70 x 32 mm	150 x 80 x 20 mm	172 x 84 x 37 mm
Weight	0.290 kg	approx. 0.210-0.230 kg depending on model	0.280 kg	0.462 kg
List price (exc. VAT)	£811.13	2500 £499.00 2500A £556.00	8500 £349.00 with memory £399.00	£265.00
Accessories & prices	range of sensors; external printer; carry case	range of sensors; carry case	range of sensors; thermal printer; carry case; rubber bumper	disposable & reusable sensor range; carrying case; rubber boot

Table 4. Handheld pulse oximeters (continued)

	Smiths Medical BCI FingerPrint	Smiths Medical BCI MiniCorr	Smiths Medical SPECTRO$_2$ 10	Smiths Medical SPECTRO$_2$ 20
				
SpO_2 technology	BCI	BCI SAC (Serial Auotcorrelation)	BCI	BCI SAC (Serial Auotcorrelation)
Sensor wavelengths	not specified	not specified	not specified	not specified
SpO_2 range & accuracy	99%-0% 8 beat averaging 99%-70%: ±2% <70%: unspecified	99%-0% 4, 8 or 16 beat averaging 99%-70%: ±2% 69%-50%: ±3% <50%: unspecified	99%-0%; 8 beat averaging no motion or low perfusion: 70%-99%: ±2 A_{rms} (adult/paed); <70%: unspecified	100%-0%; 8 beat averaging no motion or low perfusion: 70%-100%: ±2 A_{rms} (adult/paed); ±3 A_{rms} (neo) motion: 70%-100%: ±3 A_{rms} (adult/paed); <70%: unspecified
Pulse rate range & accuracy	30-254 bpm 8 second averaging ±2% or ±2 bpm whichever is greater	30-254 bpm 8 or 16 second averaging ±2% or ±2 bpm whichever is greater	30-254 bpm; 8 second averaging 30-254 bpm ±2 A_{rms} low perfusion: 30-250 bpm ±3 A_{rms}	20-300 bpm; 8 second averaging ±2 A_{rms} low perfusion: 25-250 bpm ±3 A_{rms}
Display type	LED	LED	LED	
Power supply	4 x AA alkaline or rechargeable equivalent batteries	6 x AA alkaline batteries or optional external mains adaptor	4 x AA alkaline batteries, rechargeable lithium-ion battery pack, external mains adaptor/charger or external USB	
Battery capacity	14 hours (continuous printing) or 24 hours (no printing) or 2000 spot checks	24 hours (without printing)	32 hours (alkaline) 54 hours (rechargeable)	26 hours (alkaline) 31 hours (rechargeable)
Other features	integrated thermal printer; 14 hour, 30 second interval, 99 patient internal trend memory; auto power off; protective rubber boot included; PC interface; FingerPrint Sleep version	alarms; clinician, sleep & home modes; 12, 24 or 90 hour (4, 8 or 30 sec interval), 99 patient internal memory; protective rubber boot included ; infrared printer interface; RS232 serial PC interface	pulse amplitude index; 144 hour, 4 second interval, 99 patient internal memory; integrated sensor storage; USB interface	as for model 10 plus Nellcor sensor compatibility
Size (H x W x D)	167 x 70 x 36 mm	167 x 70 x 36 mm	155 x 84 x 43 mm	
Weight	0.369 kg	0.454 kg	0.340 kg	
List price (exc. VAT)	£285.00	£485.00	price not provided	price not provided
Accessories & prices	disposable & reusable sensor range; carrying case; printer paper	disposable & reusable sensor range; carrying case; mains adaptor	disposable & reusable sensor range; docking station; attachable printer; protective rubber boot (4 colours); mounting bracket	

Table 4. Handheld pulse oximeters (continued)

	Smiths Medical SPECTRO$_2$ 30	SPO Medical PulseOx 6100	Viamed VM-2160
			
SpO$_2$ technology	BCI SAC (Serial Auotcorrelation)	SPO Medical Reflective Pulse Oximetry (RPO) with AutoSpot™ technology	Viamed
Sensor wavelengths	not specified	not specified	red 660 nm infrared 905 nm
SpO$_2$ range & accuracy	100%-0%; 2 (sleep mode), 4, 8 or 16 beat averaging; no motion or low perfusion: 70%-100%: ±2 A_{rms} (adult/paed); ±3 A_{rms} (neo) motion: 70%-100%: ±3 A_{rms} (adult/paed); <70%: unspecified	99%-40% 99%-70%: ±2% or ±2 digits <70%: unspecified	100%-0% ±1SD = 2% A_{rms} = <3%
Pulse rate range & accuracy	20-300 bpm; 8 or 16 second averaging ±2 A_{rms} low perfusion: 25-250 bpm ±3 A_{rms}	40-250 bpm ±3% or ±3 digits	20-300 bpm ±1 digit (≤100 bpm) ±1% (>100 bpm)
Display type	LED	blue backlit monochrome LCD	128 x 160 pixel colour OLED
Power supply	4 x AA alkaline batteries, rechargeable lithium-ion battery pack, external mains adaptor or external USB	2 x AA alkaline batteries	3 x AA alkaline batteries
Battery capacity	17 hours (alkaline) 30 hours (rechargeable)	200 hours	>2 days continuous or approx. 5 days in economy power mode
Other features	as for model 20 plus alarms & clinician, sleep & home modes and 72 hour, 2-30 second interval internal memory	internal memory; auto power off	alarms; 15, 30 or 240 minute short term or up to 480 hour, 50 dataset internal memory; protective cover; USB 2.0 interface & PC software
Size (H x W x D)	155 x 84 x 43 mm	160 x 44 x 27 mm	118 x 60 x 25 mm
Weight	0.340 kg	0.085 kg	0.160 kg
List price (exc. VAT)	price not provided	£245.00	£345.00
Accessories & prices	as for SpectrO$_2$ 10 and SpectrO$_2$ 20		reusable sensor range; carrying bag £14.00; mounting options

Table 5. Evidence of accuracy and performance of handheld pulse oximeters

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Beijing Choice	MD300K1-E					no evidence
Bionet	Oxy9					no evidence
Bitmos Medizintechnik	SAT 800	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Bitmos Medizintechnik	SAT 801	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Comdek	MD-600P/MD-610P					no evidence
Comdek	MD-630P					no evidence
Comdek	MD-670P					no evidence
Comdek	MD-680P					no evidence
Criticare	503DX miniSPO_2T	✓ [9]				
Daray	V60					no evidence
Daray	V202					no evidence
Edan	H100B					no evidence
GE Healthcare	TuffSat		✓ [37]			
Huntleigh	smartsigns MiniPulse		✓ [37]			
Masimo	Rad-5/Rad-5v	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Masimo	Rad-57	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]	✓ [48]		
Mediaid	M34				✓ [44]	
Mediaid	M5340				✓ [44]	
Mindray	PM-50					no evidence
Mindray	PM-60					no evidence
Nellcor	Oximax N-65			✓ [50-55]		

Table 5. Evidence of accuracy and performance of handheld pulse oximeters (continued)

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Nonin	PalmSAT 2500/2500A		✓ [17, 23]		✓ [39-41]	
Nonin	8500 series		✓ [17, 23]		✓ [39-41]	
Smiths Medical	BCI 3301		✓ [37]			
Smiths Medical	BCI FingerPrint		✓ [37]			
Smiths Medical	BCI MiniCorr		✓ [37]			
Smiths Medical	SPECTRO$_2$ 10		✓ [37]			
Smiths Medical	SPECTRO$_2$ 20		✓ [37]			
Smiths Medical	SPECTRO$_2$ 30		✓ [37]			
SPO Medical	PulseOx 6100				✓ [41, 43]	
Viamed	VM-2160					no evidence

Table 6. Wrist-worn pulse oximeters

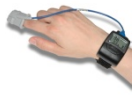
	Konica Minolta Pulsox-300	Konica Minolta Pulsox-300i	Nonin 3100 WristOx
			
SpO_2 technology	Konica Minolta		Nonin PureSAT®
Sensor wavelengths	red 665 nm infrared 880 nm		red 660 nm infrared 910 nm
SpO_2 range & accuracy	100%-0%; 5 second averaging 100%-70%: ±1sd: ±2% <70% unspecified		100%-0% 100%-70%: ±2 digits <70% unspecified
Pulse rate range & accuracy	30-230 bpm 5 second averaging 30-100 bpm: ±2 bpm 100-230 bpm: ±2% of reading		18-300 bpm ±3%
Display type	LED	backlit LCD	LCD
Power supply	1 x AAA alkaline battery		2 x size N alkaline batteries
Battery capacity	approx. 16 hours	approx. 30 hours	at least 24 hours continuous
Other features	alarms Pulsox-300i only: up to 300 hour, 1 second interval internal memory; USB interface and PC analysis software with 0.1% resolution		3 activation modes (spot check, sensor activation & programmed); 33, 16 or 8 hour (4, 2 or 1 second interval) internal memory; 3 minute auto power off; serial interface with PC analysis software
Size (H x W x D)	68 x 58 x 15 mm		51 x 44 x 19 mm
Weight	0.056 kg (including battery)		0.025 kg (excluding battery)
List price (exc. VAT)	£558.57 with finger probe £350.00 without finger probe	£607.57 with finger probe £399.00 without finger probe	£695.00 inc. reusable finger sensor
Accessories & prices	range of sensors	PC software with USB adaptor & cable set £399.00 range of sensors	PC software £379.00 serial interface cable £89.70 carrying bag £19.95 range of sensors

Table 7. Evidence of clinical study to confirm accuracy of wrist-worn pulse oximeters

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Konica Minolta	Pulsox-300				✓ [43, 46]	
Konica Minolta	Pulsox-300i				✓ [43, 46]	
Nonin	3100 WristOx				✓ [40, 43]	

Table 8. Bedside / desktop pulse oximeters

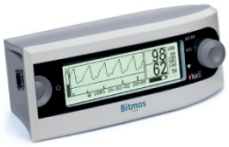
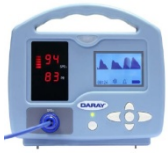
	Bitmos Medizintechnik SAT 805	Criticare 504DX	Daray V450	GE Healthcare 3800
				
SpO_2 technology	Masimo SET®	Criticare Systems Inc (CSI) DOX™	Daray	GE TruTrak®+
Sensor wavelengths	red 660 nm infrared 940 nm	not specified	red 660 nm infrared 940 nm	red 650-670 nm infrared 930-950 nm
SpO_2 range & accuracy	100%-1% adults & children - no motion: ±2 digits neonates - no motion & adults & children - with motion: ±3 digits 69%-0% unspecified	99%-0% 99%-70%: ±2% 69%-40%: ±3% <40% unspecified	100%-35% 100%-70%: ±2% 69%-0% unspecified	100%-0% 3, 6 or 12 second averaging no motion: 100%-70%: ±2 digits with motion: 100%-70%: ±3 digits <70% unspecified
Pulse rate range & accuracy	25-240 bpm no motion: ±3 digits with motion: ±5 digits	20-300 bpm ±1 bpm or ±1%, whichever is greater	30-250 bpm ±2 bpm	30-255 bpm ±2 bpm or ±2%, whichever is greater with motion: unspecified
Display type	backlit LCD	LED (numerics) & LCD (text)	LED (numerics) & blue monochrome backlit LCD (waveform & settings)	LED (numerics) & orange monochrome backlit LCD (waveform & settings)
Power supply	internal rechargeable 7.2V lithium ion battery with external mains adaptor & charger	internal rechargeable sealed lead acid battery with external mains charger	internal rechargeable lithium battery; external mains adaptor or 5 x AA alkaline or rechargeable batteries	internal rechargeable 8V sealed lead acid battery with integrated mains
Battery capacity	15 hours (minimum) 18 hours (typical)	6 hours (typical)	15 hours (lithium) >5 hours (AA)	approx. 5.5 hours
Other features	alarms & trends; 2 MB, 160 hour internal flash memory card; plethysmogram waveform; analogue & nurse call outputs; infrared interface with PC analysis software	alarms; 24 hour, 4 second interval internal memory; RS232-compatible serial interface with sleep study software	alarms & trends; 36 hour internal memory; auto power off; plethysmogram waveform; serial interface with PC analysis software; temperature model available (V450T)	alarms; 12 hour internal memory; perfusion index value; plethysmogram waveform; serial interface
Size (H x W x D)	92 x 240 x 104 mm	144 x 178 x 122 mm	148 x 160 x 85 mm	94 x 244 x 225 mm
Weight	0.900 kg (including battery)	1.520 kg (inc. battery & printer)	0.420 kg	2.800 kg
List price (exc. VAT)	£999.00	£995.00	£399.00 £449.00 (V450T)	£1534.00
Accessories & prices		integrated thermal printer option; reusable & disposable sensor range	adult, paediatric & neonate sensors £85.00	reusable & disposable sensor range

Table 8. Bedside / desktop pulse oximeters (continued)

	GE Healthcare 3900/3900P	GE Healthcare TruSat	Masimo Radical-7	Masimo Rad-8
				
SpO_2 technology	GE TruTrak®+	Ohmeda TruSignal®	Masimo SET® upgradeable to Masimo Rainbow SET®	Masimo SET®
Sensor wavelengths	red 650-670 nm infrared 930-950 nm	red 650-670 nm infrared 930-950 nm	red 660 nm infrared 940 nm	
SpO_2 range & accuracy	100%-0% 3, 6 or 12 second averaging no motion: 100%-70%: ±2 digits with motion: 100%-70%: ±3 digits <70% unspecified	100%-1% 10 second averaging no motion & low perfusion: 100%-70%: ±2 digits with motion: 100%-70%: ±3 digits <70% unspecified	100%-0% 2, 4, 8, 10, 12, 14 or 16 second averaging 100%-70%: no motion & low perfusion: ±2% with motion & neonates: ±3% 80%-60%: no motion: ±3% (Radical-7); ±4% (Rad-8) for LNOP® blue adhesive sensors	
Pulse rate range & accuracy	30-255 bpm ±2 bpm or ±2%, whichever is greater with motion: unspecified	30-250 bpm no motion: ±2 bpm or ±2%, whichever is greater low perfusion: ±3 bpm with motion: ±5 bpm	25-240 bpm no motion & low perfusion: ±3 bpm with motion: ±5 bpm	
Display type	LED (numerics) & orange monochrome backlit LCD (waveform & settings)	orange monochrome backlit LCD	multi-colour or blue monochrome TFT LCD	LED
Power supply	internal rechargeable 8V sealed lead acid battery with integrated mains	internal rechargeable 12V NiMH battery with external mains charger	internal rechargeable NiMH battery with integrated mains	internal rechargeable sealed lead acid battery with integrated mains
Battery capacity	approx. 5.5 hours; 4 hours (continuous printing)	30 hours; 20 hours (with trend download (TD) option)	4 hours (10 hour option)	up to 7 hours
Other features	alarms & trends; 24 hour internal memory; perfusion index value; plethysmogram waveform; analogue output; serial interface with PC software; integrated thermal printer model (3900P)	alarms; perfusion index value; 20 minute auto power off; TD option: 48 hour, 4 second interval trend memory & download with RS-232 serial interface & PC software	handheld or docking station configuration; perfusion index value; alarms; display rotation; 72 hour, 2 second interval trends; serial, analogue, nurse call & interface options	home & sleep modes; perfusion index value; alarms; 72 hour, 2 second interval trends; serial, nurse call & interface options
Size (H x W x D)	94 x 244 x 225 mm; 104 x 244 x 225 mm (with printer)	103 x 218 x 115 mm	89 x 226 x 53 mm 267 x 89 x 196 mm (in docking station)	76 x 208 x 152 mm
Weight	2.800 kg; 3.200 kg (with printer)	1.250 kg; 1.47 kg (with TD option)	0.540 kg (handheld) up to 1.950 kg	0.908 kg
List price (exc. VAT)	£1903.00 printer upgrade £826.00	£1200.00 £1350.00 with TD option	£1100.00 (blue) £1600.00 (colour)	£800.00
Accessories & prices	reusable & disposable sensor range	reusable & disposable sensor range; printer kit £564.00	reusable sensor range	reusable sensor range

Table 8. Bedside / desktop pulse oximeters (continued)

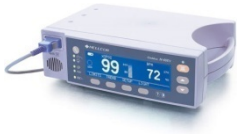
	Masimo Rad-87	Nellcor Oximax N-560	Nellcor Oximax N-600x	Nonin 7500/7500FO
				
SpO_2 technology	Masimo SET® upgradeable to Masimo Rainbow SET®	Nellcor OxiMax® with LoSat™		Noni PureSAT®
Sensor wavelengths	red 660 nm infrared 940 nm	red 660 nm infrared 900 nm		red 660 nm infrared 910 nm
SpO_2 range & accuracy	100%-0% 2, 4, 8, 10, 12, 14 or 16 second averaging 100%-70%: no motion & low perfusion: ±2% with motion & neonates: ±3% 80%-60%: no motion: ±3% for LNOP® blue adhesive sensors	100%-1% 100%-70% (±1sd): adult-neonate & low perfusion: ±2 digits 80%-60% (±1sd): adult-neonate: ±3 digits		100%-0% 100%-70% (±1A_{rms} = 68% of measurements): no motion: adult/paed: ±2 digits neonate: ±3 digits motion: adult/paed: ±2 digits neonate: NA
Pulse rate range & accuracy	25-240 bpm no motion & low perfusion: ±3 bpm with motion: ±5 bpm	20-250 bpm ±3 digits including low perfusion		no motion: 18-300 bpm motion & low perfusion: 40-240 bpm no motion & low perfusion: ±3 digits with motion: ±5 digits
Display type	LED	LED	blue monochrome backlit LCD	LED
Power supply	internal rechargeable sealed lead acid battery with integrated mains	internal rechargeable 9.6V NiMH battery with integrated mains	internal rechargeable sealed lead acid battery with integrated mains	internal rechargeable 7.2V NiMH battery with external mains charger
Battery capacity	up to 4 hours	8 hours minimum	7 hours typical	16 hours minimum
Other features	alarms; wireless network communication; perfusion index value; 72 hour, 2 second interval trends; serial, nurse call & interface options	alarms; 24 hour trend; nurse call; serial output	fast averaging mode; alarms; on-screen 24-48 hour trends; nurse call; serial and analogue outputs	7500FO (fibre optic sensors) designed for MRI use; alarms; 70 hour internal memory; analogue output; serial interface with PC software
Size (H x W x D)	76 x 208 x 152 mm	75 x 230 x 128 mm	84 x 264 x 173 mm	92 x 219 x 142 mm
Weight	0.908 kg	1.390 kg	2.600 kg	approx. 0.900 kg (inc. battery)
List price (exc. VAT)	£1000.00	£1460.03	£2703.75	7500 £795.00 7500FO £1395.00
Accessories & prices	reusable sensor range	range of OxiMax sensors		carry case £78.20 PC software £279.00 range of sensors

Table 8. Bedside / desktop pulse oximeters (continued)

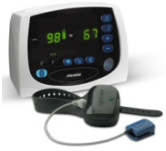
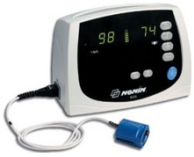
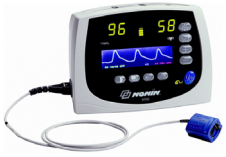
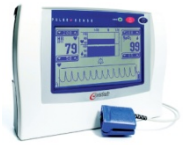
	Nonin Avant 4000	Nonin Avant 9600	Nonin Avant 9700	Nonin Medair PulseSense
				
SpO_2 technology	Noni PureSAT®			
Sensor wavelengths	red 660 nm infrared 910 nm			
SpO_2 range & accuracy	100%-0% 100%-70%: adults with finger clip sensor: ±2 digits adults with flex sensor: ±3 digits	100%-0% 100%-70% (±1sd): motion, no motion & low perfusion: adult/paed: ±2 digits neonates: ±3 digits		100%-0% adult/paediatric: ±2 digits
Pulse rate range & accuracy	18-300 bpm ±3%	18-300 bpm no motion 18-300 bpm & low perfusion 60-240 bpm: ±3 digits motion 60-240 bpm: ±5 digits		18-255 bpm ±2 digits low perfusion: 40-240 bpm: ±3 digits
Display type	LED	LED	LED (numerics) backlit colour LCD (waveform)	touchscreen blue mono-chrome backlit LCD
Power supply	main unit: internal rechargeable 7.2V NiMH battery pack with external mains adaptor wireless sensor: 2 x AA batteries	internal rechargeable 7.2V NiMH battery pack with external mains adaptor		internal rechargeable lithium ion battery with external mains adaptor
Battery capacity	main unit: 18 hours minimum wireless sensor: 120 hours minimum	12 hours minimum	12 hours (LCD backlight off) 8 hours (LCD backlight on)	approx. 12 hours
Other features	Bluetooth® wireless wrist-worn sensor; alarms; 33.5 hour internal memory; RS-232 serial interface with PC software	alarms; 115 hour internal memory; nurse call; RS-232 serial interface with PC software	as for 9600 with additional colour-change (green/amber/red) plethysmogram waveform	alarms; plethysmogram waveform; 1.5 hour internal trend memory with on-screen display; RS-232 serial interface with PC software
Size (H x W x D)	140 x 184 x 114 mm			135 x 200 x 50 mm
Weight	1.000 kg (main unit) 0.125 kg (sensor)	1.000 kg	1.100 kg	0.800 kg
List price (exc. VAT)	£1595.00	£995.00	£1445.00	£850.00
Accessories & prices	carry case £89.50 PC software £279.00 range of sensors			download kit £259.00 range of sensors

Table 8. Bedside / desktop pulse oximeters (continued)

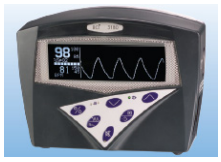
	Smiths Medical BCI 3180	Smiths Medical BCI Autocorr
		
SpO_2 technology	BCI	BCI SAC (Serial Autocorrelation)
Sensor wavelengths	not specified	not specified
SpO_2 range & accuracy	100%-0% 4, 8 or 16 beat averaging 100%-70%: adult/paed: ±2% neonate: ±3% <70% unspecified	100%-0% 4, 8 or 16 beat averaging 100%-70%: no motion: ±2% motion: ±3% 69%-50%: no motion: ±3%
Pulse rate range & accuracy	30-254 bpm 8 or 16 second averaging ±2 bpm or ±2%, whichever is greater	30-254 bpm 8 or 16 second averaging no motion: ±2% motion: unspecified
Display type	blue monochrome backlit LCD	LED
Power supply	internal rechargeable 6V sealed lead acid battery with integrated mains	internal rechargeable sealed lead acid battery with external mains adaptor
Battery capacity	approx. 4 hours	approx. 4.5 hours continuous
Other features	alarms; plethysmogram waveform; 30 hour internal trend memory with on-screen display; serial infrared printer output	alarms; printer output; digital, analogue & nurse call outputs
Size (H x W x D)	165 x 203 x 127 mm	82 x 216 x 140 mm
Weight	2.000 kg	0.850 kg
List price (exc. VAT)	£1042.36	£785.00
Accessories & prices	disposable & reusable sensor range	disposable & reusable sensor range

Table 9. Evidence of clinical study to confirm accuracy of bedside/desktop pulse oximeters

Manufacturer	Model	Peer-reviewed article (comparison with co-oximetry)	Peer-reviewed article (comparison with other pulse oximeters)	Non-peer reviewed article	Unpublished report	Comment
Bitmos Medizintechnik	SAT 805	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Criticare	504DX	✓ [9, 21]	✓ [26]			
Daray	V450					no evidence
GE Healthcare	3800				✓ [38]	
GE Healthcare	3900/3900P				✓ [38]	
GE Healthcare	TruSat				✓ [56, 57]	
Masimo	Radical-7	✓ [13-16, 18-20]	✓ [22, 24, 27-36]	✓ [47, 49-55]	✓ [42]	
Masimo	Rad-8	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Masimo	Rad-87	✓ [13-15, 18]	✓ [22, 24, 27-31, 33-36]			
Nellcor	Oximax N-560			✓ [50-55]		
Nellcor	Oximax N-600x			✓ [50-55]		
Nonin	7500/7500FO				✓ [40]	
Nonin	Avant 4000				✓ [40]	
Nonin	Avant 9600				✓ [40]	
Nonin	Avant 9700	✓ [19]		✓ [49]	✓ [40, 42]	
Nonin	Medair PulseSense				✓ [40]	
Smiths Medical	BCI 3180		✓ [37]			
Smiths Medical	BCI Autocorr		✓ [37]			

Choosing a pulse oximeter

The product information presented in this market review should be used with the following questions to shortlist pulse oximeters that best meet purchasers requirements. Under each question is a list of relevant features to consider.

1. In what setting is the pulse oximeter to be used (*eg* GP surgery, ambulance)?
    - Display type
    - Power supply
    - Other features
    - Size
    - Weight

2. What are the lifetime costs of the device?
    - Battery capacity
    - List price
    - Accessories and prices

3. How accurate is the pulse oximeter and does it comply with the BS EN ISO 9919:2009 [6]?
    - SpO_2 range and accuracy – table 10 lists the pulse oximeters in the market review for which we found evidence of accuracy testing; for the level of evidence see tables 3, 5, 7 and 9.
    - Pulse rate range and accuracy

We recommend that only those devices with evidence of accuracy testing (table 10) be considered for shortlisting.

Once a shortlist of devices has been created, we recommend that demonstrations or short term loans are arranged with suppliers. The loan period should be used to assess qualities that have not been considered in this market review, such as usability, build quality and ergonomic features.

Table 10. Pulse oximeters with evidence of accuracy and performance testing

Device	Handheld	Fingertip	Bedside/desktop	Wrist-worn
Bitmos Medizintechnik SAT 800	✓			
Bitmos Medizintechnik SAT 801	✓			
Bitmos Medizintechnik SAT 805			✓	
Criticare 503DX miniSPO_2T	✓			
Criticare 504DX			✓	
GE Healthcare 3800			✓	
GE Healthcare 3900/3900P			✓	
GE Healthcare TuffSat	✓			
GE Healthcare TruSat			✓	
Huntleigh smartsigns MiniPulse	✓			
Konica Minolta Pulsox-1		✓		
Konica Minolta Pulsox-2		✓		
Konica Minolta Pulsox-300				✓
Konica Minolta Pulsox-300i				✓
Masimo Rad-5/Rad-5v	✓			
Masimo Rad-57	✓			
Masimo Radical-7			✓	
Masimo Rad-8			✓	
Masimo Rad-87			✓	
Mediaid 100/100C		✓		
Mediaid M34	✓			
Mediaid M5340	✓			
Nellcor Oximax N-65	✓			
Nellcor Oximax N-560			✓	
Nellcor Oximax N-600x			✓	
Nonin PalmSAT 2500/2500A	✓			
Nonin 3100 WristOx				✓
Nonin 7500/7500FO			✓	
Nonin 8500 series	✓			
Nonin 9500 Onyx		✓		
Nonin 9550 Onyx II		✓		
Nonin 9560 Onyx II		✓		
Nonin Avant 4000			✓	

Table 10. Pulse oximeters with evidence of accuracy testing (continued)

Device	Handheld	Fingertip	Bedside/desktop	Wrist-worn
Nonin Avant 9600			✓	
Nonin Avant 9700			✓	
Nonin GO_2		✓		
Nonin Medair OxyCheck		✓		
Nonin Medair PulseSense			✓	
Smiths Medical BCI 3180			✓	
Smiths Medical BCI 3301	✓			
Smiths Medical BCI Autocorr			✓	
Smiths Medical BCI Digit		✓		
Smiths Medical BCI FingerPrint	✓			
Smiths Medical BCI MiniCorr	✓			
Smiths Medical $SPECTRO_2$ 10	✓			
Smiths Medical $SPECTRO_2$ 20	✓			
Smiths Medical $SPECTRO_2$ 30	✓			
SPO Medical PulseOx 5500		✓		
SPO Medical PulseOx 6000		✓		
SPO Medical PulseOx 6100	✓			

Acknowledgements

We should like to thank the following for their contribution to this market review.

Manufacturers and suppliers

John Allen, Lead Clinical Scientist, Microvascular Diagnostics, Freeman Hospital, Newcastle upon Tyne

Glossary

A_{RMS}	accuracy of pulse oximeter stated in terms of the RMS difference between measured SpO_2 values and SaO_2 reference values
bpm	beats per minute
CO_2	carbon dioxide
ECG	electrocardiograph
FIO_2	fraction of inspired oxygen
HbO_2%	percentage of oxyhaemoglobin
HR	heart rate
Hypobaric	below normal pressure (applied to gases less than atmospheric pressure)
ICU	intensive care unit
LCD	liquid crystal display
LED	light emitting diode
NHS	National Health Service
NICU	neonatal intensive care unit
nm	nanometre
Normoxia	normal levels of oxygen
OLED	organic light emitting diode
OT	operating theatre
PACU	postanesthesia care unit
PC	personal computer
PCO_2	partial pressure of carbon dioxide
pH	a measure of the acidity of a solution
PO_2 or PaO_2	partial pressure of oxygen
PR	pulse rate
$P_{Tc}O_2$	transcutaneous partial pressure of oxygen
R/IR	red to infrared ratio
RMS	root mean squared
SaCO	arterial carbon monoxide saturation
SaO_2	arterial oxygen saturation
SD	standard deviation

Glossary

SpCO	carbon monoxide saturation measured non-invasively, which is an approximation of SaCO
SpO_2	oxygen saturation (via pulse oximeter); SpO_2 is an approximation of SaO_2 when oxygen saturation is good (generally less that 3% discrepancy when SpO_2 is above 70% [58])
SET	signal extraction technology
USB	universal serial bus
VO_{2max}	maximum amount of oxygen in millilitres used in one minute per kilogram of body weight

References

1. Reay CA, Menes JA, Bousfield DR, Colechin ES and Sims AJ. CEP 08018 Buyers' guide: Hospital grade non-invasive blood pressure monitors. www.dh.gov.uk/cep, 2008.

2. Nayyar P, Batki AD and Thomason H. CEP09043 Buyers' guide: Blood gas analysers. www.dh.gov.uk/cep, 2009.

3. Thomason HL, Batki AD and Nayyar P. CEP09044 Market review: Blood gas analysers. www.dh.gov.uk/cep, 2009.

4. Colechin ES, Bousfield DR, Reay CJ and Sims AJ. CEP10065 Buyers' guide: Pulse oximeters in primary and prehospital care. www.dh.gov.uk/cep, 2010.

5. Colechin ES, Reay CA, Bousfield DR and Sims AJ. CEP10064 Evidence review: Pulse oximeters in primary and prehospital care. www.dh.gov.uk/cep, 2010.

6. British Standards Institute. BS EN ISO 9919: Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. 2009.

7. International Organisation for Standardization. ISO 9919: Pulse oximeters for medical use - Requirements. 1992.

8. British Standards Institute. BS EN ISO 9919: Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. 2005.

9. Clayton DG, Webb RK, Ralston AC, Duthie D and Runciman WB. A comparison of the performance of 20 pulse oximeters under conditions of poor perfusion. *Anaesth* 1991 46(1):3-10.

10. Trivedi NS, Ghouri AF, Shah NK, Lai E and Barker SJ. Effects of motion, ambient light, and hypoperfusion on pulse oximeter function. *J Clin Anesth* 1997 9(3):179-83.

11. Wood RJ, Gore CJ, Hahn AG, Norton KI, Scroop GC, Campbell DP, Watson DB and Emonson DL. Accuracy of two pulse oximeters during maximal cycling exercise. *Aust J Sci Med Sport* 1997 29(2):47-50.

12. Chiappini F, Fuso L and Pistelli R. Accuracy of a pulse oximeter in the measurement of oxyhaemoglobin saturation. *Eur Respir J* 1998 11(3):716-9.

13. Bohnhorst B, Peter CS and Poets CF. Detection of hyperoxaemia in neonates: data from three new pulse oximeters. *Arch Dis Child Fetal Neonatal Ed* 2002 87(3):F217-9.

14. Durbin CGJ and Rostow SK. More reliable oximetry reduces the frequency of arterial blood gas analyses and hastens oxygen weaning after cardiac surgery: a prospective, randomized trial of the clinical impact of a new technology. *Crit Care Med* 2002 30(8):1735-40.

15. Durbin CGJ and Rostow SK. Advantages of new technology pulse oximetry with adults in extremis. *Anesth Analg* 2002 94(1 Suppl):S81-3.

16. Torres AJ, Skender KM, Wohrley JD, Aldag JC, Raff GW, Bysani GK and Geiss DM. Pulse oximetry in children with congenital heart disease: effects of cardiopulmonary bypass and cyanosis. *J Intensive Care Med* 2004 19(4):229-34.

17. Bickler PE, Feiner JR and Severinghaus JW. Effects of skin pigmentation on pulse oximeter accuracy at low saturations. *Anesthesiol* 2005 102(4):715-9.

18. Murthy TVSP, Goyal R and Singh VP. Masimo - a new reliable non invasive method of detecting oxygen saturation in critically ill. *Indian J Anaesth* 2005 49(2):133-6.

19. Feiner JR, Severinghaus JW and Bickler PE. Dark skin decreases the accuracy of pulse oximeters at low oxygen saturation: the effects of oximeter probe type and gender. *Anesth Analg* 2007 105(6 Suppl):S18-23.

20. Levrat Q, Petitpas F, Bouche G, Debaene B and Mimoz O. Usefulness of pulse oximetry using the SET technology in critically ill adult patients. *Ann Fr Anesth Reanim* 2009 28(7-8):640-4.

21. Iyer P, McDougall P, Loughnan P, Mee RB, Al-Tawil K and Carlin J. Accuracy of pulse oximetry in hypothermic neonates and infants undergoing cardiac surgery. *Crit Care Med* 1996 24(3):507-11.

22. Dumas C, Wahr JA and Tremper KK. Clinical evaluation of a prototype motion artifact resistant pulse oximeter in the recovery room. *Anesth Analg* 1996 83(2):269-72.

23. Macnab AJ, Smith M, Phillips N and Smart P. Oximeter reliability in a subzero environment. *Aviat Space Environ Med* 1996 67(11):1053-6.

24. Barker SJ and Shah NK. The effects of motion on the performance of pulse oximeters in volunteers (revised publication). *Anesthesiol* 1997 86(1):101-8.

25. Grieve SH, McIntosh N and Laing IA. Comparison of two different pulse oximeters in monitoring preterm infants. *Crit Care Med* 1997 25(12):2051-4.

26. Rheineck-Leyssius AT and Kalkman CJ. Advanced pulse oximeter signal processing technology compared to simple averaging. I. Effect on frequency of alarms in the operating room. *J Clin Anesth* 1999 11(3):192-5.

27. Bohnhorst B, Peter CS and Poets CF. Pulse oximeters' reliability in detecting hypoxemia and bradycardia: comparison between a conventional and two new generation oximeters. *Crit Care Med* 2000 28(5):1565-8.

28. Malviya S, Reynolds PI, Voepel-Lewis T, Siewert M, Watson D, Tait AR and Tremper K. False alarms and sensitivity of conventional pulse oximetry versus the Masimo SET technology in the pediatric postanethesia care unit. *Anesth Analg* 2000 90(6):1336-40.

29. Barker SJ. "Motion-resistant" pulse oximetry: a comparison of new and old models. *Anesth Analg* 2002 95(4):967-72.

30. Gehring H, Hornberger C, Matz H, Konecny E and Schmucker P. The effects of motion artifact and low perfusion on the performance of a new generation of pulse oximeters in volunteers undergoing hypoxemia. *Respir Care* 2002 47(1):48-60.

31. Hay WWJ, Rodden DJ, Collins SM, Melara DL, Hale KA and Fashaw LM. Reliability of conventional and new pulse oximetry in neonatal patients. *J Perinatol* 2002 22(5):360-6.

32. Irita K, Kain Y, Akiyoshi K, Tanaka Y and Takahashi S. Performance evaluation of a new pulse oximeter during mild hypothermic cardiopulmonary bypass. *Anesth Analg* 2003 96(1):11-4.

33. Sahni R, Gupta A, Ohira-Kist K and Rosen TS. Motion resistant pulse oximetry in neonates. *Arch Dis Child Fetal Neonatal Ed* 2003 88(6):F505-8.

34. Robertson FA and Hoffman GM. Clinical evaluation of the effects of signal integrity and saturation on data availability and accuracy of Masimo SET and Nellcor N-395 oximeters in children. *Anesth Analg* 2004 98(3):617-22.

35. Workie FA, Rais-Bahrami K and Short B. Clinical use of new-generation pulse oximeters in the neonatal intensive care unit. *Am J Perinatol* 2005 22(7):357-60.

36. Richards NM, Giuliano KK and Jones PG. A prospective comparison of 3 new-generation pulse oximetry devices during ambulation after open heart surgery. *Respir Care* 2006 51(1):29-35.

References

37. Mathes AM, Kreuer S, Schneider SO, Ziegeler S and Grundmann U. The performance of six oximeters in the environment of neuronavigation. *Anesth Analg* 2008 107(2):541-4.

38. Anonymous. Datex-Ohmeda TruTrak+ Oximetry Technology; A 663 patient, multi-site performance evaluation during clinical motion. GE Healthcare. http://www.gehealthcare.com/usen/oximetry/docs/OS3959.pdf 2002.

39. Severinghaus JW. SpO_2 accuracy of PureSAT signal processing technology - The ONYX II. University of California at San Francisco Hypoxia Research Laboratory. http://www.nonin.com/documents/TechnicalBulletin-ONYXII.pdf 2005.

40. Nonin. Accuracy and superior performance of Nonin PureSAT and PureLight oximetry technologies. University of California San Francisco Hypoxia Research Laboratory. http://www.nonin.com/documents/Technical_Bulletin_OEM_III.pdf , 2006.

41. Nonin. Accuracy of Nonin Onyx 9500 fingertip pulse oximeter is superior to competitor's device. University of California San Francisco Hypoxia Research Laboratory. http://www.nonin.com/documents/Avant%209600-9700%20Study%20Data.pdf 2007.

42. University of California San Francisco. The effect of dark skin pigmentation and low saturation in oximetry. University of California San Francisco. http://www.nonin.com/documents/M-5407%20Skin%20Pigmentation%20II%20Tech%20Bulletin.pdf , 2008.

43. University of California San Francisco Hypoxia Research Laboratory. Nonin PureSAT oximetry technlogy shown to have superior accuracy. University of California San Francisco. http://www.nonin.com/documents/M-6208%20WristOx%20Comparison%20Tech%20Bulletin.pdf , 2009.

44. Mediaid. Mediaid Oximetry Technology. 2006.

45. Feiner JR, Bickler PE and Severinghaus JW. Pulse oximeter report for Minolta - Pulseox-2. Hypoxia Research Laboratory, University of California, San Francisco. 2002.

46. Feiner JR, Bickler PE and Severinghaus JW. Pulse oximeter report for Konica Minolta Sensing, Inc. - P300i. Hypoxia Research Laboratory, University of California, San Francisco. 2005.

47. Goldstein MR, Louie N, Lawas-Alejo P, Pernia ML and Martin GI. Comparison of two new generation pulse oximeters: The Masimo Radical and the Philips Viridia. *Anesthesiol* 2003 99:A554.

48. Mottram C, Hanson LJ and Scanlon PD. Comparison of Masimo Rad-57 pulse oximeter with SpCO technology against a laboratory CO-oximeter using arterial blood. *Respir Care* 2005 50(11):1471.

49. Shah N, Taleghani A, Chitkara A and Miller JM. A comparison of accuracy of three new generation pulse oximeters (POs) during motion and low perfusion in human volunteers. *Anesthesiol* 2005 103:A1168.

50. Ahrens TS and Ott K. Comparison of three new generation pulse oximeters in a medical intensive care unit. Barnes Jewish Hospital. http://www.nellcor.com/clin/List.aspx?S1=CLN&S2=POX 2006.

51. Sautel M. Comparison of two newer-generation pulse oximeters in the neonatal intensive care unit (NICU). Children's Memorial Hospital. http://www.nellcor.com/clin/List.aspx?S1=CLN&S2=POX 2006.

52. Shah N and Estanol L. Impact of motion and low perfusion on SpO_2 and pulse rate in three new generations of POs in volunteers. *Anesthesiol* 2006 105:A1433.

53. Shah N and Estanol L. Comparison of three new generation pulse oximeters during motion and low perfusion in volunteers. *Anesthesiol* 2006 105:A929.

54. Cox PN. New pulse oximetry sensor with low saturation accuracy claims - a clinical evaluation. *Anesthesiol* 2007 107:A1540.

55. Lussky RC, Cifuentes RF, Kaester K, Stanek G and Geppert J. A comparison of newer generation pulse oximeters for accuracy and drop-out rate in neonatal intensive care. Hennepin County Medical Center. http://www.nellcor.com/clin/List.aspx?S1=CLN&S2=POX 2007.

56. Raley DM. Results of SpO_2 accuracy of Datex-Ohmeda TruSat™ pulse oximeter with OxyTip+ sensors during low perfusion conditions as compared to co-oximetry. Datex-Ohmeda Inc. 2004.

57. Raley DM. Results of oxygen saturation test of TruSat™ pulse oximeter during motion and non-motion conditions compared to arterial blood co-oximetry. Datex-Ohmeda. 2004.

58. Design of pulse oximeters. Webster JG (Ed.). Bristol: Institute of Physics Publishing Ltd, 1997.

59. Barker SJ and Shah NK. Effects of motion on the performance of pulse oximeters in volunteers. *Anesthesiol* 1996 85(4):774-81.

Charter Kontron	***(Supplies: Bitmos Medizintechnik)***
Avant Business Centre 21 Denbigh Road Denbigh West Milton Keynes MK1 1DT	Tel: 01908 646070 Fax: 01908 646030 website: www.charter-kontron.com email: info@charter-kontron.com

Covidien	***(Supplies: Nellcor)***
Respiratory and Monitoring Solutions 154 Fareham Road Gosport Hampshire PO12 0AS	Tel: 01329 224114 Fax: 01392 224336 website: www.nellcor.com email: uksales@emea.tycohealthcare.com

Daray Ltd	
Marquis Drive Moira Swadlincote Derbyshire DE12 6EJ	Tel: 0800 804 8384 Fax: 0333 321 0974 website: www.daray.co.uk email: sales.team@daray.co.uk

DeVilbiss Healthcare	***(Supplies: Konica Minolta)***
Sunrise Medical Ltd High Street Wollaston Stourbridge West Midlands DY8 4PS	Tel: 01384 446868 Fax: 01384 446628 website: www.devilbisshealthcare.com email: sunmail@sunmed.co.uk

Dolby Medical Ltd	***(Supplies: Criticare Systems Inc)***
Monitor House Kerse Road Stirling FK7 7RZ	Tel: 0800 111 4415 Fax: 01786 446630 website: www.dolbymedical.com email: sales@dolbymedical.com

GE Healthcare	
Clinical Systems Devices 71 Great North Road Hatfield Hertfordshire AL9 5EN	Tel: 01707 263570 Fax: 01707 260065 website: www.gehealthcare.com/uken/ email: via form on website

Huntleigh Healthcare Ltd	
Diagnostic Products Division 35 Portmanmoor Road Cardiff CF24 5HN	Tel: 029 2048 5885 Fax: 029 2049 2520 website: www.huntleigh-healthcare.com email: sales@huntleigh-diagnostics.co.uk

Inspiration Homecare Ltd	***(Supplies: Comdek and SeQual)***
Gildor House West Street East Shilton Leicester LE9 7EJ	Tel: 01455 849187 Fax: 01455 846789 website: www.inspiration-homecare.co.uk email: info@inspiration-homecare.co.uk

Masimo	
Unit Q Lodden Business Centre Roentgen Road Basingstoke Hampshire RG24 8NG	Tel: 01256 479988 Fax: 01256 473684 website: www.masimo.co.uk email: uksales@masimo.com

Medical Physics International Ltd	***(Supplies: Bionet)***
Bolton Technology Exchange Spa Road Bolton BL1 4AY	Tel: 01204 555900 Fax: 01204 555909 website: www.medphysics.co.uk email: enquires@medphysics.co.uk

Mindray (UK) Ltd	
3 Percy Street St John's Park Huntingdon Cambridgeshire PE29 6SZ	Tel: 01480 416840 Fax: 01480 436588 website: www.mindray.com email: unknown

PMS (Instruments) Ltd	***(Supplies: Mediaid and RossMax)***
Waldeck House Waldeck Road Maidenhead Berkshire SL6 8BR	Tel: 01628 773233 Fax: 01628 770562 website: www.pmsinstruments.co.uk email: sales@pmsinstruments.co.uk

Proact Medical Ltd	***(Supplies: Nonin)***
9-13 Oakley Hay Lodge Great Folds Road Great Oakley Northamptonshire NN18 9AS	Tel: 0845 051 4244 Fax: 0845 051 4255 website: www.proactmedical.co.uk email: sales@proactmedical.co.uk

Pulmolink	***(Supplies: SPO Medical)***
Redwood House Canterbury Road Charing Kent TN27 0EU	Tel: 01233 713070 Fax: 01233 713859 website: www.pulmolink.co.uk email: sales@pulmolink.co.uk

Pulse Medical Ltd	***(Supplies: Edan Instruments)***
West Lea Fosters Lane Knaphill Woking Surrey GU21 2PW	Tel: 01483 473803 Fax: 01483 326025 website: www.pulsemedical.co.uk email: sales@pulsemedical.co.uk

Smiths Medical International (UK) Ltd	
Colonial Way Watford Hertfordshire WD2 4LG	Tel: 01923 246434 Fax: 01923 231595 website: www.smiths-medical.com/uk/ email: ukcs@smiths-medical.com

Viamed Ltd	***(Supplies Viamed and Beijing Choice MD300-C, MD300-C5 and MD300-D)***
15 Station Road Cross Hills Keighley West Yorkshire BD20 7DT	Tel: 01535 634542 Fax: 01535 635582 website: www.viamed.co.uk email: enquires@viamed.co.uk

White Medical	***(Supplies: Nissei)***
Sir Frank Whittle Business Centre Great Central Way Butlers Leap Rugby CV21 3XH	Tel: 01788 553904 Fax: 01788 560820 website: www.white-medical.co.uk email: enquires@white-medical.co.uk

Williams Medical Supplies Ltd	***(Supplies: Mindray and Beijing Choice M-Pulse,M-Pulse Lite and MD300K1-E)***
The Maerdy Industrial Estate Rhymney Gwent NP22 5PY	Tel: 01685 844739 Fax: 01685 844725 website: www.wms.co.uk email: sales@wms.co.uk

Table 11. Summary of peer-reviewed clinical trials

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Clayton *et al* 1991 [9]	• **Population:** 120 patients, who were sedated and undergoing intermittent positive pressure ventilation. • **Aim:** To compare the performance of 20 oximeters with *in vitro* measurements of haemoglobin saturation with a co-oximeter in patients after cardiac surgery involving cardiopulmonary bypass and hypothermia. • **Method:** – Patients were studied for 30 minutes to 2 hours. – Age, sex, operation, rectal temperature, systolic, diastolic and mean blood pressure and drug therapies of each patient were recorded. – Arterial pressures were monitored directly and continuously through radial artery cannulae. – Haemoglobin saturation and PR displayed on oximeters were recorded. Sample of arterial blood was taken from radial artery cannula. It was noted when pulse oximeters failed to give readings of saturation. – Oximeters tested included: Datex Satlite, Invivo 4500, Nellcor N-200, Novametrix 505, Ohmeda Biox 3740, Radiometer Oximeter, Datascope Accusat, Ohmeda Biox 3700, Nonin 8604D, Physio-Control 1600, Sensormedics Oxyshuttle, Simed S-100, Spectramed Pulsat, Biochem Microspan 3040, Criticare CSI 503, Criticare CSI 504, Engstrom Eos, Kontron 7840, Minoltan Pulsox 7 and Pulsemate Colin BX-5. – Oximeters were split into 3 groups and each patient was test with all the oximeters in one group. Each oximeter was tested on 40 different patients.	• Accuracy and precision of each pulse oximeter in respect to co-oximeter.	• Most oximeters failed to give a reading on a number of patients as a result of poor signal quality. • 5 of the 20 oximeters tested gave readings on all 40 patients. • The number of readings within 2% of the co-oximeter ranged from 11 to 32, while the number of readings with 3% ranged from 20 to 40. • The mean difference of the pulse oximeter differed by 0.1 to 4.5% of co-oximeter saturation measurement. • 16 oximeters tended to overestimate saturation whereas 4 underestimated. • The precision of the oximeters varied from 0.96% to 5.78%. • Only 2 of the 20 oximeters met the criterion of being within 1.96 SD of the true value. • Under conditions of poor perfusion only 2 oximeters (Datex Satlite and Criticare CSI 503) gave readings within 4% of reference co-oximeter. • 10 of the 20 oximeters failed to give readings at least 10% of the time. • Biochem Microspan ranked number 1 in terms of accuracy but number 18 in terms of precision. • Kontron 7840 ranked number 1 in terms of precision but number 19 in terms of accuracy.	• Oximeters were not tested on all 120 patients.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Dumas *et al* 1996 [22]	• **Population:** 50 patients who were generating alarms with their routine pulse oximeter monitoring. • **Aim:** To compare a prototype Masimo SET device with a conventional pulse oximeter in a postanesthesia care unit (PACU). • **Method:** – Conventional pulse oximeter was the Nellcor N-200. – SpO_2 and PR were recorded from both device every second using a computer. – 7 patients had arterial catheters to allow arterial blood sampling for blood gas analysis. – Accuracy was measured by SpO_2 values obtained during brief disturbances compared with baseline values and comparison of PR with HR measured on ECG or via arterial catheter.	• Artefact effect on measurements.	• 10 patients exhibited nonrhythmic motion. Masimo SET device failed to give a signal 3 times for an average of 10 ± 0.6 seconds, whereas the N-200 failed 14 times with a mean duration of 46 ± 66 seconds. • On 12 occasions the N-200 measured SpO_2 to be 10% lower than the Masimo SET SpO_2. During these episodes, the N-200 PR abruptly changed and/or did not agree with the ECG HR. • During episodes of tremor exhibited in 5 patients, 26 occasions were observed where N-200 SpO_2 was at least 10% lower than Masimo SET SpO_2 and these disturbances persisted for 75 ± 105 seconds. • During artefactual desaturations related to patient motion the Masimo SET PR remained consistent with the reference HR, whereas the N-200 PR had a much larger bias for the 3 types of motion. • Low perfusion due to fist clenching caused N-200 signal to be lost on 25 occasions compared with 9 for the Masimo SET. • Cool extremities resulted in complete signal loss in N-200. The Masimo SET device did give readings by with significant bias relative to arterial blood gas measurements. • The N-200 alarm frequency was once every 13 minutes, whereas the alarm frequency of the Masimo SET was a factor of 2 lower.	• Small population. • Comparison mainly between the 2 pulse oximeters. • Not all SpO_2 measurements were compared against blood gas analysis.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Iyer *et al* 1996 [21]	• **Population:** 25 infants undergoing major heart surgery under hypothermic cardiopulmonary bypass. • **Aim:** To assess the accuracy of pulse oximetry in newborn babies and young infants recovering from mild to profound hypothermia after open-heart surgery and to determine the relationships of skin temperature and probe site to the accuracy of the pulse oximeter. • **Method:** – Pulse oximetry readings were compared with simultaneous, directly measured arterial blood oxygen saturation using a hemoximeter. The pulse oximeter used was the Criticare 504. – All blood samples were collected anaerobically, stored on ice, and analysed within 0.5 hours of collection. Pulse oximeter readings at the time of sampling were collected. – Other observations recorded were peripheral temperature at probe site, core temperature, mean arterial blood pressure and details of medication administered.	• Effect on accuracy of temperature, probe location, haemoglobin type and medication.	• 151 observations were made using a hand probe and 148 observations were made using a foot probe. • The pulse oximeter did not give a reading in 14 of the 151 instances and in 8 of the 148 instances. • 3 of the oximeter readouts with the foot probe and 2 readings with the hand probe were <70%, so were exclude from analysis. • Temperature was shown to affect the accuracy of pulse oximetry measurements for both the foot and hand. When the foot temperature exceeded 29°C, 97.4% of observations were within the acceptable range of ±3%, whereas the difference between the pulse oximeter and hemoximeter tended to be much greater below this temperature. Similar observations were made with the hand. At very low peripheral temperatures, the proportion of oximeter readings with inacceptable bias was greatly increased at hand temperatures between 22°C and 27°C. • There was no significant difference between the two sites in terms of dropout rate or in terms of the proportion of readings with an abnormal bias. • Increase in carboxyhemoglobin or methemoglobin was not found to affect pulse oximetry measurements. • The administration of phenoxybenzamine was not found to statistically affect SpO_2 value pre- and post-injection.	• Small population. • Paediatric patients. • Study focused on affects on pulse oximeter accuracy more than the actual accuracy of pulse oximeter.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Macnab *et al* 1996 [23]	• **Population:** 26 children who were physiologically stable and normathermic in a intensive care unit. • **Aim:** To determine whether any of 3 commercially-available, battery-operated, portable pulse oximeters, used to monitor oxygen saturation during transport, provide reliable data for oxygen saturation and pulse rate in subzero environmental temperatures comparable to those encountered by inter-facility transport teams. • **Method:** – The 3 oximeters tested were Propaq 106EL monitor, Siemens Micro O_2 oximeter and Nonin 8500N oximeter. They were tested against a control unit, a Hewlett Packard Monitor M1166A. – To simulate subzero environment, the oximeters were packed in dry ice in a heavy duty polystyrene cooler. – The approximate internal temperature of each oximeter was calculated by measuring the temperature at the mid zone of the cooler at the surface of the oximeter screen and at the bottom of the cooler. – The oximeters were left in the dry ice for at least an hour prior to taking any SpO_2 measurements. – Readings from the oximeters were compared with simultaneous readings from the control unit, which was at room temperature. Data was collected immediately following simultaneous measurements using control unit and arterial blood gas sample. – Control unit data were considered acceptable only if SpO_2 value differed by 2% or less from co-oximetry measurement.	• Effect of device temperature on measurement.	• 26 pairs of SpO_2 readings from Propaq (temperature ≤-15°C at mid-point and ≤-30°C at bottom) and control unit were obtained. There was a significant correlation between the readings and an analysis of variance revealed no difference in mean levels. There was no difference evident in ECG reading from Propaq and control unit. • The Siemens oximeter repeatedly failed to give readings under the hypothermic test conditions and therefore no comparisons of data were made. • 18 pairs of SpO_2 readings from Nonin (temperature ≤-15°C at mid-point and ≤-30°C at bottom) and control unit were obtained. There was a significant correlation between the reading and an analysis of variance revealed no difference in mean levels. PR measurement compared with the PR measurements of the control unit.	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*). • Did not test devices in normal operating conditions.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Barker and Shah 1997 [24] *(Revised publication of Barker and Shah 1996* [59])	• **Population:** 10 healthy volunteers. • **Aim:** To compare the performance during standardised motion of three pulse oximeters: Nellcor N-200, Nellcor N-3000 and Masimo SET. • **Method:** – Each participant had a cannula placed in the radial artery of their nondominant wrist. The three oximeter sensors were attached to the test hand (opposite hand to radial cannula). – In addition N-200 and Masimo sensors were placed on the cannulated hand. – All sensors were provided by manufacturers of oximeters. – Data obtained from the test hand during various motion protocols were compared with simultaneous data from a similar oximeter on the stationary cannulated hand. – Standardised motions called *rubbing* and *tapping* were generated by a motor-driven tilt table. Various motion amplitude and frequencies were tested. – Arterial blood was drawn from the radial cannula at each stead-state condition of the study. Each sample was processed using a blood gas analyser for pH, PCO_2 and PO_2 and a co-oximeter for HbO_2%. – For hypoxaemia portions, participants breathed through a tight-fitting face mask connected to an anaesthesia machine, which was used to adjust the inspired oxygen fraction. Oxygen saturations were varied between 100% and 75%.	• Accuracy, dropout rate and performance index (PI).	• N-200 underestimated saturation by 5% to 18% during motion. • N-3000 failed to display SpO_2 after a disconnect-reconnection for both motions. • Masimo SET displayed SpO_2 at all times but underestimated saturation by 3% to 6% during hypoxemia and motion, • Masimo SET tracked the control SpO_2 well during desaturation but exhibited some lag during rapid resaturation. The other two oximeters did not tract control SpO_2 in this case. • The controlled hand motion had significant effect on accuracy and dropout rate of pulse oximeters. • The test condition of connecting the oximeters after beginning the motion proved more strenuous than that of starting motion after oximeters were connected and functioning. This incurred a higher dropout rate and lower performance index in the N-200 and N-3000. • Similar results were seen with rapid desaturation to 75%, the N-3000 exhibited a higher error rate and lower dropout rate. • Masimo SET exhibited much lower error rates and dropout rates that the other two oximeters during motions. • The lowest PI for Masimo was 95% compared with 46% for N-3000 and 68% for N-200. • For the alarm condition of SpO_2 <90%, there were no false negatives so the sensitivity for all devices was 100%. Specificity of 70% and 80% were reported for N-200 and N-3000.	• Small population. • Though data was measured, comparison to blood gases and co-oximetry was not made.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Grieve *et al* 1997 [25]	• **Population:** 16 infants in a neonatal unit. • **Aim:** To test the reliability and variation in the readings of Nellcor N-20 and Ohmeda Biox 3700. • **Method:** – Pulse oximeters were used simultaneously, with probes located on each foot. – ECG and transcutaneous oxygen tensions were monitored continuously by a multiparameter monitor. – All data was collected on one database. – Infants were observed while they were asleep, awake and whilst feeding. – Artefact on pulse oximetry tracings were determined by clinical observation, comparison with simultaneous transcutaneous PO_2 values and by correlation of PR from pulse oximeters with ECG HR.	• Comparison of Nellcor and Ohmeda measurements.	• Nellcor pulse oximetry was artefactual 19% of the total recorded time compared to 23% with Ohmeda oximetry. All these episodes were ascribed to infant movement. • Nellcor pulse oximeter showed an oxygen saturation level of 2.2 ± 2.3% above that of the Ohmeda. • The highest value measured by Nellcor was 99% on 5,536 occasions, whereas the Ohmeda measured a maximum value of 98% on only 40 occasions.	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Trivedi *et al* 1997 [10]	• **Population:** 8 volunteers. • **Aim:** To evaluate 5 of the most commonly used models of pulse oximeters and compared their accuracy during low perfusion states, motion of oximeter probe and interference by ambient light. • **Method:** – Each volunteer was continuously monitored with an ECG, automatic noninvasive blood press cuff and radial arterial cather, which was placed to measure blood pressure. – The 5 pulse oximeters were simultaneously attached to each subject. The oximeters used were Nellcor N-200, Nellcor with C Lock, Ohmeda 3740, Novametrix Oxypleth and Criticare 504-US. – Arterial blood samples were drawn simultaneously and a co-oximeter was used as a gold standard for measurement of SaO_2. – The effect of ambient light was assessed by shining a standard OT light on the pulse oximeter probes from a distance of 4 feet. Data was recorded for a period of 120 seconds for each subject. A SpO_2 value greater than 4% from SaO_2 value was defined as an error. HR errors were also determined, with error defined as a difference of 5%. – The effect of motion was studied using a motion generator to move hand. SpO_2 and HR errors were recorded. – The effect of low perfusion was studied by delivering a controlled pressure to each subject's brachial artery. Pressure was adjusted until the mean arterial pressure measure 50-60 mmHg. SpO_2 and HR errors were recorded.	• Effect of ambient light, motion and low perfusion on pulse oximeter accuracy.	• The Ohmeda and Nellcor N-200 had the highest total failure rates with respect to SpO_2 and HR due to ambient light interference. The Nellcor Clock, Novametrix and Criticare performed approximately equally well with regard to SpO_2 determinations, however, Nellcor C Lock was the best with regard to HR measurements. • Nellcor N-200 and C Lock were the most accurate with regard to SpO_2 during 2 Hz and 4 Hz motion. The Ohmeda and Criticare oximeters were most accurate in measuring HR during 2 Hz motion, however all oximeters failed at 4 Hz motion. • During states of low perfusion, the Nellcor N-200 and C Lock performed the best in terms of SpO_2 and HR. The Ohmeda and Novametrix failed approximately one-third to one-half of the time, while the Criticare oximeter failed 100% of the time.	• Small population.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Wood *et al* 1997 [11]	• **Population:** 20 men, 11 of whom were well-trained elite endurance cyclists. • **Aim:** to compare the performance of Ohmeda Biox 3700e and Criticare 504 USP pulse oximeters with arterial blood sampled during maximal cycling exercise. • **Method:** – Each subject performed two cycle ergometer VO_{2max} tests in a hypobaric chamber. The tests were conducted with a minimum of 24 hour rest interval between tests and all subjects were tested within 5 days. – The elite cyclists began cycling at 200 watts whilst non-elite cyclists began at 100 watts; both increased by 25 watts each minute until volitional exhaustion. The hypobaric chambers were set at 745 mmHg or 695 mmHg. – Before each test a catheter was inserted into the brachial artery. Samples were taken and immediately placed on ice and analysed within 20 minutes. – ECG was monitored via 3-lead ECG on Criticare monitor. – Arterial blood samples and oximetry recordings were taken simultaneously at rest, during final 30 seconds of the 7^{th} minute of exercise and during the last 30 seconds of the workload corresponding to VO_{2max}. – The clarity of the pulse waveform on each pulse oximeter was continually monitored to avoid effects of motion artefact and decreased perfusion. – HR was also monitored via a Polar Electro PE3000 Sportester. – Any SpO_2 measurement in which the HR from pulse oximeter did not correspond to Sportester HR ±10% was discarded from analysis.	• Correlation of SaO_2 and SpO_2 under different levels of exercise.	• At rest, the correlation between the SpO_2 and SaO_2 was weak for both pulse oximeters, but at the 7^{th} minute of exercise and at VO_{2max} the correlations were significant. • The bias (<3%) was relatively unchanged from rest to maximum exercise of both oximeters, while precision was worse during maximum exercise than during rest. • The highest correlations between co-oximetry and pulse oximetry vales was found when data from rest and exercise were combined, with Criticare oximeter have an higher correlation than the Ohmeda. The Ohmeda underestimated SaO_2 at all saturation levels, with the differences greater at lower saturation levels, while the Criticare slightly overestimated SaO_2 at all levels. • Both oximeters provided consistent estimates of oxygen saturation, though the Criticare oximeter was the better of the two models, with smaller bias and superior precision.	• Small population. • Male population.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Chiappini *et al* 1998[12]	• **Population:** 100 subjects. • **Aim:** To assess the accuracy of the Nellcor N-20P. • **Method:** – Arterial blood samples were collected according to the criteria of the British Thoracic Society. – Each sample was immediately any using a Radiometer ABL-330 and a IL-282 Co-oximeter. – During the collection of the blood sample, SpO_2 was measured with the pulse oximeter.	• Accuracy of SpO_2 measurements.	• The co-oximeter measured higher values of SaO_2 in comparison with N-20P oximeter, with a statistically significant difference when using the paired t-test. • The difference between the co-oximeter and pulse oximeter measurement was 1.56% and the limits of agreement ranged from 1.08 to 4.20. • Lack of accuracy of N-20P oximeter in comparison with a standard reference method is appreciable only for values at the extremes of the oxyhaemoglobin saturation range.	• Male dominated population.	Not specified.
Rheineck-Leyssius and Kalkman 1999 [26]	• **Population:** 53 patients. • **Aim:** To investigate the incidence of false alarms in the operator theatre (OR) generated by the Nellcor N-3000 compared with a conventional pulse oximeter (Criticare 504). • **Method:** – In each patient was simultaneously monitored with three pulse oximeters in the OR: Nellcor N-3000 and two Criticare 504 oximeters with different signal averaging times (21 seconds and 3 seconds). – SpO_2 alarms limits were set at 90%. – The anaesthesiologist recorded manually episodes of probable hypoxaemia together with the time of occurrence. – Criteria for detecting hypoxaemia was: cyanosis; alarm of at least one pulse oximeter and decreasing SpO_2 values of at least one of the two other pulse oximeters. – Alarm was considered to be caused by artefact and not hypoxaemia if the pulse oximeter was unable to determine the appropriate pulse when compared with ECG HR.	• Number of alarms. • Cause of trigger.	• The Nellcor and the Criticare with 21 second averaging both generated one false alarm (duration of 55 seconds and 5 seconds, respectively). • In 8 patients, the Criticare oximeter with 3 second averaging produced 20 false alarms (duration ranged from 5 to 95 seconds). • Nellcor generated *loss of pulse* alarm in 3 patients, whilst the Criticare oximeter with 21 second averaging generated *loss of pulse* alarm in 4 patients and with 3 second averaging in 5 patients. • 36 of the 53 patients experienced one or several episodes of hypoxaemia. All hypoxaemic episodes triggered the alarm of at least one monitor. • Hypoxaemia triggered the alarm of the Criticare oximeter with 3 second averaging more often than the alarms of the other two monitors. • 50 hypoxaemic events triggered the alarm of all three oximeters, 19 events two of the oximeters and 31 events just one of the oximeters.	• Small population. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Bohnhorst *et al* 2000 [27]	• **Population:** 17 spontaneously breathing unsedated preterm infants. • **Aim:** To determine whether the false alarm rates of the Masimo SET and Nellcor OXISMART might result in an increased proportion of missed true alarms such as an impaired detection of hypoxaemia or bradycardia. • **Method:** – 3 pulse oximeters were used: conventional pulse oximeter (Nellcor N-200), oximeter with OXISMART technology (Nellcor N-3000) and oximeter with SET technology (Masimo SET). – All sensors were shielded against ambient light and were resited in 4 hour intervals. – Postductal $P_{Tc}O_2$ was measured using a standard $P_{Tc}O_2$ monitor (Kontron 7640). – HR was recorded using a standard ECG monitor (Kontron 7271). – The SpO_2 and PR readings from the oximeters were recorded together with the data from the $P_{Tc}O_2$ and ECG monitor using purpose-written software. The raw red and infrared adsorption signal from the Masimo was also recorded. – Recording were analysed for all episodes during which $P_{Tc}O_2$ fell to <40 torr. Episodes were then analysed to see if a fall in SpO_2 <85% occurred within 2 minutes of fall in $P_{Tc}O_2$ to <40 torr. – Recordings were also analysed for the bradycardias that were not accompanied by a fall in $P_{Tc}O_2$ to <40 torr.	• Missed alarms of new technology for detection of hypoxaemia and bradycardia.	• 202 falls in $P_{Tc}O_2$ to <40 torr occurred, with a range of 1 to 34 episodes per infant. Of these, 174 were identified by all 3 oximeters. In 15 of these episodes the N-200 alarmed because of signal loss. This happened 4 times with the OXISMART and only once with Masimo SET. • Of the 28 episodes where an oximeter did not alarm, manual analysis of red-to-infrared ratios showed that SpO_2 had been <85% for <10 seconds or had not been <85% at all in 16 episodes. • 11 out of 185 true hypoxaemic episodes were missed by at least one oximeter. All 11 were identified by the conventional oximeter, whereas 10 were missed by Nellcor OXISMART and 1 was missed by the Masimo SET. • The mean interval between $P_{Tc}O_2$ falling to <40 torr and SpO_2 falling to <85% was -0.7 seconds for conventional oximeter and -0.4 seconds for both new generation devices. On average all 3 oximeters alarmed some 0.4-0.7 seconds before the $P_{Tc}O_2$ monitor reached the corresponding alarm threshold. • There were 54 bradycardias in 11 infants that were not accompanied by hypoxaemia. Only 14 of these were identified by all 3 oximeters. 37 were missed by the Nellcor OXISMART, 4 by Masimo SET (all had also been missed by OXISMART) and 17 by N-200 (14 of these had been missed by OXISMART).	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Malviya *et al* 2000 [28]	• **Population:** 75 children. • **Aim:** To compare the incidence and duration of false alarms between Masimo SET and conventional pulse oximeter in young children in the postanesthesia care unit (PACU). • **Method:** – Two probes were placed on hand of each child and connect to Nellcor N-200 (conventional pulse oximeter) and Masimo SET pulse oximeter. SpO_2 and HR were recorded continuously from these devices onto bedside computer. – Additional ECG HR was recorded continuously and simultaneously via SpaceLabs monitors. – Nurses were blinded to Masimo SET measurements and made all intervention decision and clinical observation on N-200. – A research assistant concurrently documented events such as removal of endotracheal tube or other airway device, patient motion, nursing interventions including placement of an artificial airway or oxygen administration, and blood pressure monitoring that could interfere with signal transmission. – All data was coded and analysed for frequency and duration of event: data dropout – complete interruption of continuous SpO_2; false negative – true alarm missed; false alarm – decrease in SpO_2 <90% that by expert clinical observation is considered incorrect; true alarm.	• Frequency and duration of events.	• The overall alarm frequency was once every 36minutes for N-200 and once every 30 minutes for the Masimo SET. • There were 27 true alarms, which were all identified by the Masimo SET. Only 16 of the true alarms were identified by the N-200. • Spurious desaturations and pulse rate changes triggered false alarms most commonly occurred with significant gross movement. There were more than twice the number of false alarms exhibited by the conventional pulse oximeter compared with the Masimo SET. • There were 52 data dropout events for the Masimo SET compared with 44 for the N-200. This difference was not deemed significant.	• Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Barker 2002 [29]	• **Population:** 70 healthy volunteers. • **Aim:** To compare the performance of recent version of motion-resistant oximeters during motion and hypoxaemia. • **Method:** – Each subject was monitored with 6 oximeter sensors: 3 on the moving *test* hand and 3 of the same make and model on the stationary *control* hand. – 20 different devices were tested: Masimo SET (V2), Philips HP Viridia 24C (Rev B), Philips HP CMS (Rev B), Datex-Ohmeda 3740, Datex-Ohmeda 3800, Datex-Ohmeda AS/3, Nellcor N-395 (v1620), Datex-Ohmeda 3900, Novametrix MARS (2000-10), Hewlett-Packard CMS, Nellcor N-180, Marquette 8000, Nellcor NPB-295, Novametrix 520A, Nellcor N-200, BCI 3304, Nonin 8600, SpaceLabs 90308, Nellcor NPB-190 and Criticare 5040. – The *test* hand was strapped to a motorised motion table, which produced repeatable, continuous hand motions. It could be configures so that the fingertips either tapped or rubbed on a smooth surface. The amplitude of the motion was ±2 cm and the frequency was either fixed or randomly varied within the range of 1 to 4 Hz. – After recording room air control values with both hands stationary, the motion table was activated and 2 min of data were recorded for each of the 2 motions. – Hypoxaemic episodes were measured during each motion by having the subject breath via an anaesthesia machine, where the amount of oxygen inspired could be controlled.	• Bias and precision of SpO_2 measurements. • Dropout rate. • Performance index (PI). • Sensitivity and specificity for the detection of hypoxaemia.	• There was a wide range of oximeter performance with PI values varying from 94% to 28%. The top 5 devices in PI were the Masimo SET (94%), the Philips Viridia 24C (84%), the Philips CMS (80%), the Datex-Ohmeda 3740 (80%) and the Datex-Ohmeda 3800 (79%). • Sensitivity to hypoxaemia ranged from 98% (Masimo) to 28% (BCI 3304) and specificity ranged from 93% (Masimo) to 15% (Criticare 5040). • The devices with lower sensitivity and specificity values had small dropout rate, meaning they continued to display a SpO_2 value that was grossly in error during motion. • The Masimo SET oximeter yielded the highest values of all the calculated performance statistics. • More recent pulse oximeters outperformed the older models in terms of both accuracy and reliability during motion. • Nellcor N-3000 was found to miss 5.4% of hypoxaemia episodes and 69% of bradycardia episodes, whereas the Masimo SET missed 0.5% and 7%, respectively.	• Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Masimo Corporation.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Bohnhorst *et al* 2002 [13]	• **Population:** 56 term and preterm infants who had been admitted to the neonatal intensive care unit. • **Aim:** To determine the sensitivity and specificity of three recently available pulse oximeters in the detection of hyperoxaemia. • **Method:** – The three devices studied were the Agilent Viridia M3, Masimo SET and Nellcor N-3000 Oximsmart. – Care was taken to ensure sensors had good contact with the skin and were shielded against each other and ambient light. – Whenever an arterial blood sample was taken for clinical purposes, the SpO_2 readings on the oximeters were recorded at the precise moment the blood was drawn. – Measurements were not timed specifically to include high PaO_2 values or exclude periods with motion and/or differences between HR and PR. But SpO_2 readings had to be stable for at least 20 seconds before arterial blood was drawn. – Blood samples were analysed of PaO_2 using blood gas analyser and SaO_2 using co-oximeter. – Sensitivity was calculated as the proportion of instances with a PaO_2 >80 mmHg that were associated with an SpO_2 above the threshold, divided by all instances with PaO_2 >80 mmHg. – Specificity was calculated as the proportion of PaO_2 readings ≤80 mmHg associated with an SpO_2 value below the threshold, divided by the number of instances PaO_2 ≤80 mmHg.	• Sensitivity and specificity for detection of hyperoxaemia. • Accuracy and precision of SpO_2.	• 280 SpO_2/SaO_2/PaO_2 determinations were performed for Agilent Viridia and 291 each for the Masimo SET and Nellcor N-3000. • 105 in 27 patients showed a PaO_2 >80 mmHg. • At an upper alarm limit of 95%, all three devices detected 93-95% of hyperoxaemic episodes (sensitivity). Specificity at this threshold values was more variable, ranging from 26% (Nellcor) to 46% (Masimo). • The two highest PaO_2 values that were >80 mmHg, but associated with an SpO_2 ≤95% (false negative) were 144 and 92 mmHg for Agilent, 169 and 98 mmHg for Masimo, and 141 and 95 mmHg for Nellcor. The lowest PaO_2 with SpO_2 >95% (false positive) was 46 mmHg for Agilent, 56 mmHg for Masimo and 50 mmHg for Nellcor. • Measurement precision was similar between the devices, while the bias was smaller with the Masimo and Agilent than with the Nellcor pulse oximeter.	• Small population.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Durbin and Rostow 2002 [15]	• **Population:** 13 postoperative adults patients in whom conventional pulse oximetry failed. • **Aim:** To test the ability of the Masimo SET technology to acquire and maintain reliable pulse oximetry signals in critically ill, postoperative patients in whom conventional pulse oximetry technology was unable to provide reliable monitoring. • **Method:** – Failure of conventional pulse oximetry was defined as complete inability of oximeter to obtain a pulse signal, or display of an obviously spurious saturation or inaccurate pulse rate value. – Immediately following failure, an oximeter incorporating Masimo SET (IVY 2000) was used in attempt to acquire a pulse oximetry signal. – When and if a stable pulse oximetry reading was obtained, an arterial blood gas sample was obtained for evaluation and validation of the SpO_2 and the pulse rate was confirmed by comparison with ECG HR.	• Whether Masimo SET could capture SpO_2 when conventional pulse oximetry was unable too. • Accuracy of Masimo SET SpO_2 and PR measurements.	• Masimo SET was able to obtain pulse oximetry readings in 12 of the 13 patients. • The SaO_2 to SpO_2 difference was 1.1% ± 1.0% (mean ± SD) for these patients. • Two patients exhibited SpO_2 values that were inaccurately high. The specific cause of errors was unclear. • In the one patient in whom a reliable reading with Masimo SET was not obtained, blood gas data could also not be obtained as the patient went into cardiac arrest.	• Small population.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Durbin and Rostow 2002 [14]	• **Population:** 86 patients undergoing coronary artery revascularisation surgery with good preoperative ventricular function. • **Aim:** To investigate whether improved oximetry would result in a measurable difference in patient care outcome variables compared with conventional less reliable oximetry. • **Method:** – Patients were monitored continuously with a Masimo SET pulse oximeter (innovative technology) and Ohmeda 3740 (conventional pulse oximeter). Data was recorded on a laptop. – Patients were randomised to have the output from one of the devices displayed for use by the bedside caregiver. – Pulse oximetry *failure percentage* was used as a measure of the efficiency of monitoring. Failure percentage was defined as percentage of total monitoring time when the monitor output was unreliable (no signal, obvious artefact or difference of >10% between SpO_2 and SaO_2 (calculated from PaO_2)). – Arterial blood gas determinations were used to calculate the accuracy and precision of oximeters.	• Patient care outcomes. • Reliability of oximeters.	• A total of 82 patients were available for analysis of clinical management: 43 had Masimo SET pulse oximetry data displayed and 39 has conventional pulse oximetry data displayed. • There was no difference in the time to extubation between the two groups, however, patients in the Masimo SET group were weaned to a FIO_2 of 0.4 an hour sooner and with significantly fewer arterial blood gas analyses. • Only 59 patients had adequate data for reliability evaluation. The conventional oximeter experienced almost 8 times more failure time than Masimo. • Comparison of Masimo with blood gas gave a bias of 0.53 ± 1.7 and for conventional oximeter -0.82 ± 2.8.	• Data was not available for all the patients enrolled in the study. • Accuracy determined by comparison with PaO_2 rather than SaO_2.	No specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Gehring *et al* 2002 [30]	• **Population:** 10 healthy volunteers. • **Aim:** To determine if new-generation oximeters improve the accuracy of tracking SpO_2 and PR during induced patient hypoxaemia in the presence of motion artefact and low perfusion. • **Method:** – The oximeters tested included: Datex Ohmeda 3900P, Agilent CMS, Nellcor N-395, Ivy SatGuard 2000 with Masimo SET and Nellcor N-3000. – The reference oxygen saturation was recorded on the right hand using 2 Nellcor N-3000 pulse oximeters. The left hand was subjected to motion and low perfusion. HR was recorded with an ECG, using electrodes place on the chest. – Participants breathed through a tight-fitting face mask connected to a Trajan 808 with fresh gas supply. Fraction of inspired oxygen was varied by adjusting oxygen and nitrogen. Inspiratory and expiratory oxygen and carbon dioxide concentrations and breathing patterns were continuously monitored. – Motion generator was used to move test hand in irregular patterns. Volunteers were also asked to perform a tapping motion for 120 seconds, followed 60 seconds later by a scratching motion for 120 seconds. – Low perfusion was induced by compression of the brachial artery in the upper arm. – The subject's oxygen saturation started at 100% and was decreased to 90%, where it was held for 1 minute. It was then decrease to 80%. It was then increased back to 100%. – SpO_2, PR and ECG HR were continuously recorded.	• Effect of motion and low perfusion.	• For desaturation with no motion and normal perfusion the differences between the oximeters were within ±3%. • The SpO_2 data from the various oximeters of the test and reference hand were in good agreement as perfusion changed. • In the period with motion and low perfusion, all oximeters tested showed high SpO_2 errors. • The maximum positive deviation between true SpO_2 and measured SpO_2 was 30% at the lowest saturation tested. • Datex-Ohmeda device exhibited the worst pulse indication performance followed by the Nellcor N-3000. There were no significant differences between the Agilent, Ivy and N-395. • Pulse oximeters reliably measured SpO_2 when movement was introduced as an artefact and when perfusion was reduced. Only during the clinically extreme condition of combined low perfusion and motion was the reliable detection of SpO_2 <63%. During combined reduced perfusion and motion, 3 of the oximeters proved to reliably show PR, whereas N-3000 and Datex-Ohmeda 3900P showed clear differences from ECG HR.	• Small population. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Agilent Technologies/Philips Medical Systems, Datex-Ohmeda and Nellcor/Tyco Healthcare Group.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Hay *et al* 2002 [31]	• **Population:** 26 neonates in initial study and 7 neonates in the follow-up study. • **Aim:** To evaluate the effects of motion on the incidence of SpO_2 and PR alarms in a neonatal population, comparing the results obtained from a conventional pulse oximeter (Nellcor N-200) to those of a Masimo SET pulse oximeter. • **Method:** – The Masimo sensor, LNOP Neo, and the Nellcor sensor, Oxisensor II N-25, were attached to different feet of each infant. To reduce effect of site bias, the sensors were switched to the opposite foot after 3 hours and monitored for an additional 3 hours. – The study was blinded to provide an objective comparison of pulse oximeter performance without affected routine care of the infant. – The ECG HR from a Datascope Passport monitor was collected to corroborate each pulse oximeter's PR. – Potential sources of artefact, including infant motion, nursing care and intervention, and parental handling and care, were logged by the research nurse. – Data were reviewed without knowledge of which pulse oximeter was used to determine how well each met the clinical indices for monitoring neonates, specifically, true and false desaturation, and bradycardic events. – Following initial study, the performance of three new-generation pulse oximeter (Nellcor N-395, Novametrix MARS and Philips Viridia 24C) was compared to Masimo SET. – The hypoxaemia alarm threshold was set at 85%. Bradycardia was defined as an ECG HR of ≤80 bpm	• Monitoring performance of Masimo SET compared with Nellcor N-200. • Comparison of performance of 4 new-generation pulse oximeters.	• Both Masimo SET and Nellcor N-200 pulse oximeters produced similar SpO_2 and PR values during nonmotion conditions. However, only the Masimo SET instruemtn recorded a stable value of SpO_2 and captured a PR similar to the ECG HR during motion conditions. • R/IR analysis found that the Masimo SET provided accurate measures of SpO_2 and PR. • The Nellcor N-200 had a total of 396.6 minutes of *zero outs* and false alarms (4.2% of operation) across all the infants. The Masimo SET pulse oximeter exhibited 31.3 minutes of *zero outs* and false alarms (0.3% of operation). • The Masimo SET had significantly fewer false alarms than the Nellcor and they were shorter in duration, resulting in 92% less total alarm time. • 8 infants had a total of 14 transient bradycardic episodes. Of these, the Masimo SET pulse oximeter caught significantly more, 12 compared to 2 for the Nellcor. • In the comparison of the f new-generation pulse oximeters, false desaturations totalled 86 (1, 10, 33 and 42 for Masimo, Nellcor, Philips and Novametrix, respectively), while missed desaturations were few (1, 4, 6 and 12 for Masimo, Nellcor, Philips and Novametrix, respectively). These new-generation devices differed greatly in their ability to detect changes in PR (*ie* the frequency of frozen PR during times of ECG HR change was 0, 6, 11 and 46 for Masimo, Nellcor, Philips and Novametrix, respectively).	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	National Institutes of Health GCRC Grant.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Irita *et al* 2003 [32]	• **Population:** 18 patients. • **Aim:** To compare the performance of a new-generation pulse oximeter with that of a conventional device during cardiopulmonary bypass under moderate hypothermia. • **Method:** – Nihon Kohden AY-900P was the conventional pulse oximeter used and the new-generation pulse oximeter was the Masimo SET Radical. – Pulse oximeter data was collected in real-time with a PC data acquisition system and handwritten notes. – Pulse oximeter failure was defined as failure to show no SpO_2 data and/or to display incorrect SpO_2 for longer than 3 minutes continuously. Incorrect SpO_2 was defined as <97% during bypass, because arterial saturation obtained with co-oximetry was >99%. The duration of pulse oximeter failure was calculated as the duration of no SpO_2 plus the duration of incorrect SpO_2. – The dropout rate corresponded to the percentage of time when the pulse oximeter shed no SpO_2 data. – Pulse oximeter performance was also examined from the standpoint of preoperative diuretic therapy and intraoperative hyperlactatemia.	• Pulse oximeter failure.	• Pulse oximeter failure developed in 14 patients with the AY-900P oximeter, whereas it developed in only 4 patients with Masimo. These 4 patients also had pulse oximeter failure for the AY-900P. • Pulse oximeter failure occurred immediately after the initiation of bypass 4 patients and just after aortic cross-clamping in 9 patients. • The duration of pulse oximeter failure was 36% ± 31% of the duration of bypass for AY-900P oximeter and 6% ± 15% for Masimo. The duration of pulse oximeter failure was 46% ± 43% of duration of aortic cross-clamping for AY-900P and 5% ± 15% for Masimo. • No SpO_2 was provided for 36% ± 39% of the duration of aortic cross-clamping for AY-900P and 4% ± 12% for Masimo. The observed pulse oximeter failure was mainly due to no SpO_2 rather than incorrect SpO_2. • Of 6 patients with preoperative diuretic therapy, 5 developed pulse oximeter failure in AY-900P, but only one in Masimo. • The incidence of pulse oximeter failure was similar between the AY-900P and Masimo among 12 patients without preoperative diuretic therapy. • Of the 9 patients with lactate less than 80 mg/dL, pulse oximeter failure developed in 3 patients with AY-900P and 2 with Masimo. • Of the 9 patients with lactate greater than 90 mg/dL, pulse oximeter failure developed in 8 patients with AY-900P and 2 with Masimo.	• Small population. • Did not consider accuracy or precision of SpO_2 measurements. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Sahni *et al* 2003 [33]	• **Population:** 15 healthy male infants. • **Aim:** To compare the effects of motion on measurements of SpO_2 and HR made with Masimo SET, with the same measurements made with the Nellcor N-200. • **Method:** – Continuous pulse oximetry and HR monitoring were performed using Masimo SET and Nellcor N-200 pulse oximeters and a standard HR monitor (Hewlett-Packard 3680). – Baseline data were collected for 10 minutes with the infant quietly asleep. Data collection was then continued during and after circumcision for a total duration of one hour. – Simultaneous minute by minute assessments of behavioural sleep and activity state were also made.	• Effect of motion of SpO_2 and HR.	• The incidence of artefact was significantly lower with the Masimo than with the Nellcor during and after circumcision. Even during baseline period when the infants were quietly asleep, there was a threefold higher incidence of artefact with the Nellcor. • Mean SpO_2 and HR values obtained for the Masimo were significantly higher than those obtained with the Nellcor, especially during circumcision, when extreme motion was likely. Similar differences were observed after circumcision. • The Masimo HR signal predicted the ECG HR more accurately, with lower residual error. • The HR and SpO_2 measured by Nellcor were lower and more variable during all behaviour states. The effects were more pronounced during behavioural activity states associated with excessive motion artefact. • Higher HR values were recorded by the Masimo during non-sleeping states; however, the Nellcor recorded not only much lower but more variable HR values during active sleep, awake and crying states than those recorded during quiet sleep. This was also reflected in the SpO_2 measurements, which remained stable for Masimo but were significantly lower for Nellcor during all behavioural activity states.	• Small population. • Paediatric patients. • Only male patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Robertson and Hoffman 2004 [34]	• **Population:** 27 patients (age range 2 days to 15 years) monitored in neonatal intensive care, paediatric intensive care unit, operating theatre and sleep laboratory. • **Aim:** To compare data availability, signal heuristics, and agreement of two new oximeter technologies compares with an older standard. • **Method:** – A blinded side-by-side comparison of Masimo SET, Nellcor N-395 and GE Marquette Solar 8000 oximeters. – The Masimo LNOP Neo sensor was used with the Masimo oximeter and Nellcor Oxisensor N-25 sensors were used with the N-395 and Solar 8000 oximeters. – Study tested the motion artefact, loss of pulse and signal quality indicators of the Masimo and N-395 oximeters. – Data from all oximeters were compared. – Co-oximetry data were not collected during the study.	• Time of data availability. • Measures of agreement. • Signal heuristics and warnings stratified by both signal integrity and SpO_2.	• 308,301 s of data acquired, with data reporting highest for Solar 8000 displaying data 98.7% of overall time, compared with 98.4% for the Masimo SET and Nellcor N-395. • Masimo reported data 97.1% of time overall with no signal heuristic flag. Nellcor N-395 reported data 84.7% of overall time with no signal heuristic flag. • Agreement between the devices deteriorated at a SpO_2 of less than 80% and grew progressively worse at lower saturations. • Under optimal signal conditions, with no signal heuristic displayed, there was little difference in precision and bias between the two newer technologies, but agreement between devices was significantly affected by signal quality, motion artefact and hypoxaemia. • Masimo device posted less questionable data that the Nellcor N-395 device. • The Solar 8000 detected all hypoxaemia episodes, whereas 5.4% were missed by the Nellcor N-395 and 0.5% by the Masimo device. • In the sleep laboratory, of 75 desaturation events not related to movement artefact, 98.6% of events were detected by Masimo oximeter, whereas Nellcor N-395 detected 45.3%.	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Torres *et al* 2004 [16]	• **Population:** 46 children: 25 children with congenital heart disease undergoing surgical repair or palliation using cardiopulmonary bypass; 21 children with cyanotic congenital heart disease. • **Aim:** To determine whether SpO_2 measured with the Nellcor N-395 and the Masimo SET Radical pulse oximeters were accurate and/or precise when compared with SaO_2 of the whole blood of children immediately recovering from cardiopulmonary bypass, a transient period of poor peripheral perfusion, or in children with persistent hypoxaemia (*ie* SaO_2 <90%). • **Method:** – SpO_2 displayed on each pulse oximeter at the time routine arterial blood SaO_2 measurements were recorded. SaO_2 was measured using a co-oximeter. – Cardiopulmonary monitor HR, pulse oximeter HR and failure of pulse oximeter to display SpO_2 at the time of blood gases measurement were also recorded.	• Bias and precision of pulse oximeters.	• In the postcardiopulmonary bypass group, Nellcor N-395 failed to measure SpO_2 during 41% of the SaO_2 measurements compared to 10% for the Masimo SET Radical. • There was a significant difference in bias ± precision (Nellcor 1.1 ± 3.3; Masimo -0.2 ± 4.1) but no significant difference in HR between oximeters (Nellcor 0.7 ± 6.9; Masimo -0.6 ± 1.9). • 17 of the 61 SaO_2 measurements in the bypass group were less than 90%. There was a significant difference in bias and precision when compare SaO_2 <90% versus SaO_2 ≥90% for the Nellcor N-395 and Masimo SET Radical. • In the cyanotic congenital heart disease group, there were no SpO_2 failures for either oximeter. There was no significant difference in bias ± precision between oximeters (Nellcor 2.9 ±4.6; Masimo 2.8 ± 6.2). The mean HR differences were not significantly different (Nellcor -0.1 ± 2.0; Masimo -0.05 ± 1.8). • There was a loss of accuracy and increase in scatter (increase of bias and precision) for both oximeters when SaO_2 <90%. • Masimo SET Radical and Nellcor N-395 pulse oximeters have an acceptable accuracy but unacceptable precision in children with congenital heart disease.	• Small population. • Paediatric patients.	Department of Pediatrics, University of Illinois College of Medicine.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Bickler *et al* 2005 [17]	• **Population:** 21 healthy, non-smoking subjects: 11 with dark pigmentation of skin and 10 light pigmentation. • **Aim:** To determine the affect of skin pigmentation on pulse oximeter accuracy. • **Method:** – Subjects were studied semisupine with a nose clip while deliberately hyperventilating air-nitrogen-CO_2 mixtures via a mouthpiece from a partial rebreathing circuit. – A radial artery catheter was placed to facilitate arterial blood sampling for measurement of SaO_2. – 5 oximeters were mounted on each subject: one Nellcor N-595, two Novametrix 513s and two Nonin Onyxs. Measurements from the Novametrix and Nonin oximeters were recorded manually. – The Nellcor oximeter was tested in all subjects and the Novametrix and Nonin oximeters were tested in 9 light- and 7 dark-skinned subjects. – A series of 10-12 stable target SaO_2 plateaus between 60 and 100% were sought by an operator adjusting the inspired air-nitrogen-CO_2 mixture breath by breath in response to an analogue meter displaying the estimated SaO_2. – At each level, arterial blood was sampled after a plateau of 30-60 seconds, followed by a second sample at the same plateau 30 seconds later.	• Affect of skin pigmentation.	• The mean of all 1,067 data points at all SaO_2 levels and all three types of oximeter indicated that SpO_2 read approximately 1% higher in dark- than in light-skinned subjects. The overall mean bias errors due to pigment were +0.4% with Nonin, +0.6 with Novametrix and +1.6% with Nellcor. • At lower oxyhaemoglobin saturation, greater differences in bias between light- and dark-skinned subjects were seen. • With all three devices the effect of skin pigmentation on bias increased approximately linearly as SaO_2 decreased. • In the range of 60-70% SaO_2, the mean difference in bias between light- and dark-skinned subjects was +1.4% (Nonin), +4.4% (Novametrix), and +4.3% (Nellcor). • Dark skin pigment-related bias was statistically significant with Nellcor in all SaO_2 decades and with Novametrix between 60 and 80%, but only in 70-80% range with Nonin. • Small but statistically significant differences were found between oximeters. The mean bias of Novametrix (1.40 ± 1.94%) was statistically higher than that of Nellcor (0.49 ± 2.18%) and Nonin (0.08 ± 1.45%). Small differences were also found within decadal SaO_2 intervals. • Dark skin pigmentation results in overestimation of arterial oxygen saturation, especially at low saturation in the 3 tested oximeters.	• Small population. • Study focused more on the cause of inaccuracy rather than which oximeter was most accurate.	UCSF Department of Anesthesia research fund.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Murthy *et al* 2005 [18]	• **Population:** 20 patients in whom clinicians could not get a conventional pulse oximeter signal. Patients ranged from neonates to elderly. • **Aim:** To evaluate the performance of Masimo SET in several conditions where conventional pulse oximeters exhibit a low or no signal alarm, comparing oxygen saturation values with that of arterial blood gas analysis. • **Method:** – Conventional pulse oximeter was Agilent M3046A M4. Conventional pulse oximeter declared as failed only after several attempts to get a signal were made. Sensor was left in place till end of study. – When a saturation reading and plethysmograph was established on Masimo oximeter an arterial blood sample was taken. – PR from conventional and masimo oximeters were recorded and compared to ECG HR.	• Correlation between Masimo and arterial blood gas analysis.	• Values measured by Masimo correlated well with those from blood gas analysis. • Motion disturbance could be seen on plethysmograph for Masimo but the oximetry readings remained constant and match blood gas analysis values. • The PR of the Masimo corresponded to the ECG HR in all patients, whereas the convention oximeter showed erratic readings.	• Small population. • Bias and precision not defined from results.	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Workie *et al* 2005 [35]	• **Population:** 36 neonates in a neonatal intensive care unit. • **Aim:** To compare Philips FAST pulse oximeter with the Masimo SET pulse oximeter to test the null hypothesis that there is no difference in the efficacy of these two new-generation motion-tolerant pulse oximetry devices. • **Method:** – The two pulse oximeters were used to simultaneously monitor each neonate. – Both oximeters were programmed for a signal averaging time of 10 seconds. – Readings were considered accurate only when the waveforms were of good quality and/or the pulse oximeter's pulse rate (PR) correlated with the ECG HR monitor. – Measurements were made every 5 minutes for a period of 2 hours on each patient. Potential sources of artefact such as patient motion, nursing care and parental handling were also noted. – Pulse oximeters were programmed to emit an alarm for episodes of hypoxaemia (SpO_2 ≤85%), bradycardia (HR ≤80 bpm) and tachycardia (HR ≥200 bpm). True alarms were defined as episodes that resulted in an alarm in the presence of a good waveform and correlation of pulse oximeter's PR with ECG HR. False alarms were episodes that occurred in the absence of a good waveform and had poor correlation. – Dropouts were instances when the pulse oximeter would emit an alarm due to an inability to isolate the arterial pulse and provide an oxygen saturation reading.	• Oxygen saturation measurement. • Number of true and false alarms. • Number of dropouts and their duration.	• One patient was removed from the study because of equipment failure. • 15 patients were ventilator dependent, 3 required respiratory support from nasal continuous positive airway pressure, 2 had nasal cannual, 1 had a tracheostomy collar with supplemental oxygen and 14 were receiving room air. 17 patients were also receiving some form of sedation. • The SpO_2 values for the Philips and Masimo pulse oximeters were 96.4 and 95.8%, respectively. There were no statistical difference between the two devices across all patients and time measurements. • The two pulse oximeters were similar in the number of true alarms and false alarms. • The Philips pulse oximeter had a markedly increased number of dropouts (247 versus 38 for the Masimo unit), which was statistically significant. The duration of dropouts was also three times longer with the Philips pulse oximeter (60.0 versus 20 minutes for the Masimo unit).	• Small population. • Paediatric patients. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Richards et al 2006 [36]	• **Population:** 36 adult patients admitted to the progressive-care unit after cardiac surgery. • **Aim:** To compare the clinical performance of 3 new-generation pulse oximeters with cardiac surgery patients during their first postoperative ambulation. • **Method:** – The 3 SpO_2 systems studied were the Philips FAST system used with the M3 patient monitor and M1191A adult finger sleeve sensor, the Masimo SET V2 used with the LNOP DCI adult clip sensor and the Nellcor N-3000 used with the DS1000A adult clip sensor. – Each patient was monitored continuously and simultaneously by all 3 pulse oximeters, as well as by a centralized cardiac telemetry monitor. – The amount of dropout and the number of false alarms were recorded manually during the ambulation period. – Data dropout was defined as a loss of signal initiating an alarm. A false alarm was defined as a spurious saturation of ≤90% with either an additional lack of correlation between the HR reading from oximeter and reading from ECG or a value that differed significantly from the other 2 devices when those devices were recording SpO_2 values >90%.	• Amount of data dropout. • Number of false alarms. • Heart rate correlation.	• The Nellcor had the highest percentage of data dropout per patient and the Masimo the least. • The Masimo had the most false alarms and the Nellcor the least. • The Masimo was functional for the greatest percentage (75.7%) of the time, the Philips 71.7% and the Nellcor 57.3%. • There were statistically significant differences in performance among the 3 device pairings for both data dropout and false alarms. • There were no differences in the mean device performance with regard to HR accuracy across any of the tested devices. • 70% of the readings for the Philips and Nellcor devices were within ±2 beats/min of the HR, compared to 60% of the reading for the Masimo.	• Small population. • Clinicians were not blinded to the oximeters. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Philips Medical Systems.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Feiner *et al* 2007 [19]	• **Population:** 36 healthy, non-smoking subjects, with a range of skin pigment. • **Aim:** To determine the effect of an range of human skim pigmentation on pulse oximeter accuracy at a range of SaO_2 from 70% to 100%; to determine whether gender affects pulse oximeter accuracy; and to determine whether probe type(adhesive disposable versus clip-on) affects the accuracy of SaO_2 estimates/SpO_2 values. • **Method:** – Each subject's skin was categorized as light, dark or intermediate, and confirmed in subject photographs by an observer blinded to saturation data/oximeter performance. – Subjects were studied while reclining in a semisupine position and deliberately hyperventilating air-nitrogen-CO_2 mixtures via a mouthpiece from a partial breathing circuit. – A radial artery catheter was placed to facilitate arterial blood sampling for measurements of SaO_2. – 3 oximeters using an adhesive disposable probe and a clip-type probe were mounted in each subject's fingers: Nellcor N-595, Masimo Radical and Nonin 9700. – A series of 11 stable target SaO_2 plateaus between 60% and 100% were achieved by an operator who adjusted the inspired air-nitrogen-CO_2 mixture breath by breath in response to the estimated SaO_2 derived from an oxyhaemoglobin dissociation curve determined for each subject. – Arterial blood was sampled after a plateau of 30-60 seconds. A second sample was taken at the same plateau 30 seconds later.	• Affect of skin pigmentation, gender and probe type on oximeter accuracy.	• 17 female and 19 male subjects participated. 17 were dark, 7 intermediate and 12 light skinned. • With the exception of the Masimo with adhesive probe, all device and probe combinations showed positive bias in intermediate- and dark-skinned subjects at low SaO_2. The greatest degree of bias was found with the adhesive probes. • At the extreme, the Nellcor adhesive and the Masimo clip-on read on average nearly 10 points differently in dark-skinned subjects at 60%-70% saturation and 7 point s at 70%-80% saturation. • Pulse oximeter bias was significantly influences by SaO_2 range for all oximeters and probe combinations. The pattern of bias varied according to oximeter configurations, will all except the Masimo with adhesive probe showing increasing positive bias at low SaO_2. • Gender is a statistically significant determinant of pulse oximeter bias, with the magnitude of gender bias difference varying with oximeter/probe type and SaO_2 range. With 5 of the 6 oximeter/probe combinations, females had greater bias in saturation estimates over the saturation range. • The Nonin with clip-on probe and Masimo with adhesive probe did not show an effect of skin pigment, although both had a significant gender effect. • Pulse oximeters general overestimated SaO_2 in hypoxic subjects (SaO_2 <80%). The bias was greatest in dark-skinned subjects. Though Masimo with adhesive probe underestimated.	• Small population. • Study focused more on the cause of inaccuracy rather than which oximeter was most accurate.	Research fund generated from the clinical testing of pulse oximeters.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Mathes *et al* 2008 [37]	• **Population:** 20 healthy, non-smoking volunteers. • **Aim:** To investigate the effects of neuronavigation on the performance of 6 different brands of pulse oximeters. • **Method:** – Each subject was monitored with the 6 pulse oximeters whilst breathing room air. The 6 oximeters used were: GE Healthcare Tuffsat, Philips FAST SpO_2 module, GE Healthcare Dash 3000 Pro patient monitor, Smith Medical BCI 3303 handheld oximeter, Siemens In vivo 4500 Plus and Dräger Infinity Delta patient monitor. – For each subject and monitor, HR, SpO_2 and signal quality were recorded. Signal quality was defined as: no pulse wave present during whole time of assessment (no signal detection); disruption of the signal for one or more episodes of >15 seconds (severe noise); one or more episodes of <15 seconds of signal interference (moderate artefact). – Cameras of a neurosurgical stereotactic guidance system were positioned 100 cm above subject's hands and neuronavigation system activated. Cotton blanket and aluminium foil were used to shield probes to reduce interference. – Measurements were recorded for 5 minutes with neuronavigation on and for 5 minutes with it off.	• Signal quality.	• All monitors displayed normal pulse oximeter signal at the beginning of the experiment. After activation of neuronavigation equipment, all monitors were at least partially affected by signal interference. The cotton blanket improved signal quality in all monitor except the Dash. Signal disturbance diminished further with aluminium foil for the Das, In vivo, Dräger and Philips pulse oximeters. • SpO_2 readings displayed normal values for all subjects at the beginning of the experiment. No significant differences were observed among the monitors. • After activation of neuronavigation system, 5 of the 6 monitors were unable to display SpO_2 in some of the subjects without shielding. The Dräger monitor was able to display SpO_2 in all subjects. Shielding with a cotton blanket improved saturation detection significantly for the Dash, In vivo and Tuffsat, BCI and Philips monitors. Aluminium foil improved detection in the Dash, In vivo and Tuffsat monitor. • When a SpO_2 reading was present, no statistical difference was noted between baseline values and the ones obtained during neuronavigation.	• Considered the effect of system of signal quality rather than the accuracy of the pulse oximeters. • Comparison between pulse oximeters and not with blood gases or co-oximetry (*gold standard*).	Not specified.

Table 11. Summary of peer-reviewed clinical trials (continued)

Authors	Study design	Outcomes	Results	Limitations	Source of funding
Levrat *et al* 2009 [20]	• **Population:** 25 patients admitted to ICU. • **Aim:** To compare the concordance between SaO_2 and SpO_2 measured using Masimo SET or conventional pulse oximeters in situations at risk of producing defective signals with the conventional technology. • **Method:** – Masimo SET Radical pulse oximeter and Philips M1020A pulse oximeter with Nellcor Oxymax sensor were used to simultaneous measure SpO_2. – Measurements were recorded when one of the two pulse oximeters did not display a value, when the difference between the values displayed by the oximeters was greater than five saturations points or at any time a blood gas analysis was done. – At each measurement the signal quality index, the presence of movement, the use of sedative, the use of norepinephrine, the patient temperature and the concomitant values of SaO_2 and SpO_2 were noted. – Four measurements were made per patient and a minimum period of 3 hours elapsed between measurements.	• Concordance of SpO_2 with SaO_2. • Capacity of pulse oximeter to display valid measurements in clinical situation.	• 83 measurements were recorded, including 62 in sedated patients, 51 in patients requiring norepinrphrine infusion, 19 in the presence of movements hindering the taking of SpO_2, 8 in patients with proven hypoxaemia and 8 in patients running a temperature below 36°C. • Display of SpO_2 values was more frequent with Masimo SET than with the conventional technology. • 89% of cases were considered valid with Masimo SET and only 66% were valid for conventional technology. • Comparison with SaO_2 found Masimo SET estimates of arterial oxygen saturation more accurate than the conventional technology. • Removing nonvalid measures from the results improved the performance of both oximeters, though Masimo SET still proved the more accurate estimations of arterial oxygen saturation. • For Masimo SET, in 95% of cases SpO_2 is within -3.1 and +3.2 saturation points of SaO_2. • For conventional technology, in 95% of cases SpO_2 is within -7.5 and +9.8 saturation points of SaO_2.	• Small population.	Not specified.

Table 12. Unpublished clinical trials for GE Healthcare pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Anonymous 2002 [38]	Datex-Ohmeda TruTrak+	• **Population:** 663 patients and healthy volunteers. • **Aim:** To compare the performance of the TruTrak+ technology to commercially available oximetry technology (with and without motion capability) and to arterial saturations measured by hemeoximetry. • **Method:** – Compared to traditional oximetry, Nellcor and Masimo motion oximetry, non-moving reference oximeters and Radiometer OSM-3 co-oximeters. – Testing took place in laboratories at Datex-Ohmeda and tat 5 hospitals in a wide variety of environments including NICU, paediatrics, ICU, OR, PACU and general wards. – Within the hospital environments, data was collected for 30 minutes to 5 hours. 2 or 3 oximeters were placed on each subject with simultaneous graphing of data. Pulse oximeter readings were compared to arterial blood gases when blood was drawn. No blood was drawn specifically for the purpose of the study. – In the laboratory, extremely low perfusion, motion (clinical and mechanically imposed) and a combination of motion with low perfusion were created in volunteers. Different desaturation episodes were created by subject's breathing a hypoxic mixture of nitrogen and oxygen.	• Two arterial samples were taken from the radial artery of non-moving had during each motion period. Subjects' saturation stated at about 95% and went down to 73%. The TruTrak+ closely agreed with co-oximeter measurement during periods of motion. The traditional pulse oximeter used was about 5% low. Masimo displayed similar readings to TruTrak+. • When TruTrak+ was compared to traditional oximetry in hospital, the traditional oximeter demonstrated less accuracy with more freezing, dashing and dropouts. • In the hospital comparisons to the Nellcor oximeter during low perfusion conditions, the TruTrak+ demonstrated greater accuracy with less dashing and freezing and fewer dropouts. • In the comparison of TruTrak+ with traditional and Masimo oximeters in laboratory clinical motion tests, TruTrak+ demonstrated greater accuracy in the ability to track a saturation change.	• Not peer-reviewed. • Not all comparisons were made to the *gold standard* of co-oximetry.

Table 12. Unpublished clinical trials for GE Healthcare pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Raley 2004 [56]	Datex-Ohmeda TruSat	• **Population:** 8 healthy, non-smoking subjects. • **Aim:** To evaluate the SpO_2 accuracy and precision of the Datex-Ohmeda TruSat pulse oximeter with OxyTip+ sensors over the SpO_2 range of 70-100% arterial blood oxygen saturations. • **Method:** – Comparison to functional oxygen saturation as measured by co-oximetry. – Each subject was cannulated with an indwelling catheter in the left radial artery. – The subject was moved to a cooled room (15-20 °C). The left side of the subject (side with arterial line) was kept warm with a blanket and a heat pad. The right side of the subject was cooled to a low perfusion level using the room temperature controls. – Lower perfusion was measured by the TruSat and cautions were taken so that the subject did not shiver. – Once subjects were cooled to an acceptable level, baseline data was recorded. Each subject was desaturated to various stable saturation levels of approximately 5% decrements from 95% to 70% returning to 100% SaO_2 by controlling the fraction of inspired oxygen. – SpO_2 values from pulse oximeters were collected simultaneously to blood being drawn from the arterial line.	• For ultra low to low perfusion, accuracy root mean square was 2.7, using data from 4 subjects. • For ultra low to impaired perfusion, accuracy root mean square was 2.5, using data from 7 subjects. • For ultra low to normal perfusion, accuracy root mean square was 1.9, using data from all 8 subjects. • The SpO_2 data collected showed that the TruSat pulse oximeter supports a claim of 3% SpO_2 accuracy under clinical low perfusion conditions.	• Not peer-reviewed. • Small population. • Level of perfusion determined by the pulse oximeter under test, rather than using an independent system.

Table 12. Unpublished clinical trials for GE Healthcare pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Raley 2004 [57]	Datex-Ohmeda TruSat	• **Population:** 10 healthy, non-smoking subjects. • **Aim:** To evaluate the SpO_2 accuracy and precision of the Datex-Ohmeda TruSat pulse oximeter during motion and non-motion conditions over a wide range of arterial blood oxygen saturations as compared to arterial blood co-oximetry. • **Method:** – Each subject was cannulated with an indwelling catheter in the left radial artery. – The opposite hand was tasked with one of 3 defined motions: mechanically induced tapping, clinical rubbing motion randomised with the hand in the prone position or randomised motion with hand in the supine position. – 3 pulse oximeters were connected to finger sites on the motion hand using OxyTip+ sensors. 2 pulse oximeters and the desaturation control oximeter were attached to the stationary hand on the cannulated side. – Each subject was desaturated to various stable saturation levels of approximately 4% decrements from 95% down to 70% and back up to 100% SaO_2 by controlling the fraction of inspired oxygen. – SpO_2 values from pulse oximeters were collected simultaneously to blood being drawn from the arterial line.	• During stationary conditions, accuracy root mean square was 1.7. • During motion artefact, accuracy root mean square was 2.5. • The SpO_2 accuracy of the TruSat during stationary and motion artefact conditions was within specification as compared to co-oximetry.	• Not peer-reviewed. • Small population.

Table 13. Unpublished clinical trials for Konica Minolta pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Feiner *et al* 2002 [45]	Minolta Pulsox-2	• **Population:** 12 normal subjects. • **Aim:** To compare Pulsox-2 with co-oximetry. • **Method:** – Study undertaken by Hypoxia Research Laboratory at the University of California Medical Centre in San Francisco. – Each subject underwent a standard breath-down protocol of inducing hypoxaemia. Inspired gas mixtures were controlled to attain hypoxia plateaus between 70% and 100%. – Each plateau was maintained for at least 2 minutes while pulse oximeter readings and arterial blood samples were acquired simultaneously.	• Mean bias: 0.17 • Root mean square: 1.87	• Not peer-reviewed. • Small population. • Only a summary of the report was available.
Feiner *et al* 2005 [46]	Konica Minolta Pulsox-300i	• **Population:** 12 normal subjects. • **Aim:** To compare Pulsox-300i with co-oximetry and determine the effect of different probes. • **Method:** – Study undertaken by Hypoxia Research Laboratory at the University of California Medical Centre in San Francisco. – Each subject underwent a standard breath-down protocol of inducing hypoxaemia. Inspired gas mixtures were controlled to attain hypoxia plateaus between 70% and 100%. – Each plateau was maintained for at least 2 minutes while pulse oximeter readings and arterial blood samples were acquired simultaneously.	• Four probes were tested with the Pulsox-300i and the mean bias ranges from -0.35 to 0.23. • The root mean square for the four probes ranged from 0.95 to 1.73. • Combined the mean bias was -0.02 and the root mean squared was 1.28.	• Not peer-reviewed. • Small population. • Only a summary of the report was available.

Table 14. Meeting abstract of clinical trials for Masimo pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Goldstein *et al* 2003 [47]	Masimo Radical	• **Population:** 19 neonates. • **Aim:** To ascertain the clinical utility of the Masimo Radical and Philips Viridia. • **Method:** – Oximeter probes were placed according to manufacturer specifications. ECG HR was recorded to compare with oximeter's PR. – Criteria of for evaluation were: false desaturation (reading of <85% was not corroborated by other oximeter or physical findings); dropout (oximeter gave no SpO_2 and PR readings); changes in HR (PR differed by more than 25 bpm from ECG HR).	• Philips oximeter zeroed out and gave no signal for more than 10 times as many instances and more than 25 times as long as Masimo. • There were significant differences in the false desaturations of the two device, as well as significant differenced between the devices in erroneous PR as compare to ECG HR. In false desaturations and erroneous PR, Philips exceeded Masimo by greater than twofold instances and threefold duration.	• Not peer-reviewed. • Small population. • Paediatric population. • Did not consider the accuracy of the SpO_2 measurement of the 2 pulse oximeters, as no comparison with co-oximeter measurements (*gold standard*).
Mottram *et al* 2005 [48]	Masimo Rad-57	• **Population:** 31 subjects who required blood gas analysis for clinical evaluation. • **Aim:** To compare SpO_2 and SpCO measured by Rad-57 with SaO_2 and SaCO measured by a co-oximeter. • **Method:** – Measurement from Rad-57 were recorded when blood sample was being drawn. – Blood was analysed with 15 minutes using Radiometer ABL 725 analyser according to standard laboratory practice.	• SaO_2 measured 90.8 ± 5.4% (range 97.5-74.6%) compared with SpO_2 of 93.8 ± 1.8% (range 99-80%). Paired t-test gave a P-value of <0.001. • SaCO measured 2.0 ± 1.8% (range 9.3-0.8%) compared with SpCO of 2.5 ± 2.0% (range 11-1%). Paired t-test gave a P-value of <0.015.	• Not peer-reviewed. • Small population. • Bias and precision of SpO_2 and SpCO were not determined.

Table 14. Meeting abstract of clinical trials for Masimo pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Shah *et al* 2005 [49]	Masimo SET Radical	• **Population:** 9 volunteers. • **Aim:** to compare Masimo SET Radical, Philips CMS and Nonin 9700 under conditions of low perfusion and motion in hypoxic and normoxic states. • **Method:** – Low peripheral perfusion was induced by lowering the room temperature to 16-18°C. – Test hand was placed on motor-driven random motion table to induce rubbing and tapping motions. – Masimo ear sensor was used as a control during hypoxia studies. – Hypoxia was induced using a re-breathing circuit. – Data was recorded during normoxic and hypoxic conditions. False alarms were noted when SpO_2 dropped below 90% during normoxic conditions. A missed event was defined as the inability of the monitor to recover after desaturation, by the time the control monitor reached 100%.	• 189 motion tests during normoxia and hypoxia were performed. • Missed events were counted for the 54 events during hypoxia. Masimo had the fewest missed events (1/54) and Nonin had the greatest (22/54). • False alarms were counted for 135 room air motions. Masimo has the fewest false alarms (1/135) and Nonin had the greatest (18/135). • The sensitivity and specificity of the Masimo were significantly higher than the sensitivities and specificities of the Philips and Nonin.	• Not-peer reviewed. • Small population. • Did not consider the accuracy of the SpO_2 measurement of the 3 pulse oximeters, as no comparison with co-oximeter measurements (*gold standard*).

Table 14. Meeting abstract of clinical trials for Masimo pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Shah and Estanol 2006 [53]	Masimo Radical	• **Population:** 10 healthy volunteers. • **Aim:** To determine which of the Masimo Radical, Nellcor N-600 and Datex-Ohmeda TruSat were the most reliable and accurate during difficult patient conditions. • **Method:** – Each oximeter was connected the test hand and control hand of each subject. – Low peripheral perfusion was induced by lowering the room temperature to 16-18°C. – Motion was random self generated and machine generated with the test hand attached to a motion table. – A re-breathing circuit was used to induce desaturation to approximately 75%. – A missed event was defined as the inability of the pulse oximeter to detect desaturation and/or recover from a desaturation by the time the control reached 100%. – A false alarm was recorded during normoxic phase and defines as a SpO_2 ≤90% during motion.	• 160 motion tests were performed: 120 on room air and 40 during desaturation. Missed events were counted for the desaturation episodes and false alarms were counted for the 120 room air motions. • Masimo Radical missed the fewest events and had the lowest number of false alarms. • Datex-Ohmeda TruSat missed the most events. • Nellcor N-600 had the most false alarms.	• Not peer-reviewed. • Small population. • Did not consider the accuracy of the SpO_2 measurement of the 3 pulse oximeters, as no comparison with co-oximeter measurements (*gold standard*).

Table 14. Meeting abstract of clinical trials for Masimo pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Shah and Estanol 2006 [52]	Masimo Radical	• **Population:** 10 healthy volunteers. • **Aim:** To test the accuracy of the Masimo Radical, Nellcor N-600 and Datex-Ohmeda TruSat during motion and induced low perfusion in both normoxia and hypoxia. • **Method:** – Each oximeter was connected the test hand and control hand of each subject. – Low peripheral perfusion was induced by lowering the room temperature to 16-18°C. – During separate room air and desaturation events, motion consisted of random tapping and random rubbing. Motions were both machine and subject generated. – A computer recorded SpO_2 and PR data. Parameters analysed included: percentage of time SpO_2 was within 7% of control; percentage of time PR was within 10%; percentage of time SpO_2 and/or PR were zero or no signal; performance index.	• Masimo significantly outperformed the Nellcor and Datex-Ohmeda pulse oximeters. • Nellcor spent the greatest percentage of time with SpO_2 and PR measurements outside 7% and 10% of control. It also spent the greatest percentage of time with no signal or zero measurement for SpO_2 and PR.	• Not peer-reviewed. • Small population. • Did not consider the accuracy of the SpO_2 measurement of the 3 pulse oximeters, as no comparison with co-oximeter measurements (*gold standard*).
Cox 2007 [54]	Masimo SET Radical with LNOP Blue sensor	• **Population:** 12 paediatric patients. • **Aim:** To compare the accuracy of the Masimo Radical with LNOP Blue sensor and Nellcor N-600 with Max-I LoSat sensor with a traditional pulse oximeter on cyanotic cardiac lesion patients in ICU. • **Method:** – Arterial blood gases were obtained as clinically needed and compared with the pulse oximetry readings from the 3 devices. – SpO_2 and SaO_2 were compared using linear regression and accuracy in terms of RMS (A_{RMS}).	• 60 blood gas measurements were compared with SpO_2 in patient population. SaO_2 measured 72.3 ± 7.3% (range 85-56.1%). • For the Masimo, SpO_2 measured 70.5 ± 7.5% (range 87-52%). Bias was -1.91, precision 3.50 and A_{RMS} 3.97. • For the Nellcor, SpO_2 measured 75.9 ± 5.6% (range 89-61%). Bias was 3.81, precision 5.26 and A_{RMS} 6.49. • For the traditional pulse oximeter, SpO_2 measured 75.2 ± 6.4% (range 91-57%). Bias was 1.86, precision 6.24 and A_{RMS} 6.51.	• Not peer-reviewed. • Small population.

Table 15. Unpublished clinical trials for Mediaid pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Mediaid 2006 [44]	Mediaid technology	• **Population:** 12 normal subjects. • **Aim:** To compare Mediaid technology with co-oximetry. • **Method:** – Study undertaken by Anesthesia Research Laboratory at the University of California Medical Centre in San Francisco. – Each subject underwent a standard breath-down protocol of inducing hypoxaemia. Inspired gas mixtures were controlled to attain hypoxia plateaus between 70% and 100%. – Each plateau was maintained for at least 2 minutes while pulse oximeter readings and arterial blood samples were acquired simultaneously.	• Graph showing the correlation between the SpO_2 measurements made by Mediaid technology with SaO_2 measurements made by co-oximetry.	• Not peer-reviewed. • Small population. • A_{RMS} values not quoted.

Table 16. Posters of clinical trials for Nellcor pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Ahrens and Ott 2006 [50]	Nellcor OxiMax N-600	• **Population:** 100 critically ill patients in ICU. • **Aim:** To compare Nellcor OxiMax N-600, Masimo SET Radical and Philips Intellivue Fast pulse oximeters with co-oximetry. • **Method:** – SpO_2 and HR were compared for each pulse oximeter with co-oximetry and ECG HR. – Follow sensor placement SpO_2, PR and ECG HR were recorded under stable conditions prior and following arterial blood gas sampling for clinical care.	• There were no statistical differences between the three systems in the display of PR. • Bias and precision of Nellor measurements were 0.18% and 2.25%, respectively. • Bias and precision of Masimo measurements were 0.31% and 1.98%, respectively. • Bias and precision of Philips measurements were 0.19% and 2.58%, respectively.	• Not peer-reviewed.

Table 16. Posters of clinical trials for Nellcor pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Sautel 2006 [51]	Nellcor OxiMax N-600	• **Population:** 10 infants. • **Aim:** To compare the ability of Nellcor OxiMax N-600 and Masimo SET Radical used on NICU patients to post oxygen saturation and PR data during various conditions commonly encountered in the NICU environment. • **Method:** – Oximeters were attached to either foot of each patient. Measurements were recorded for 4 hours with 3 hour sensor rotation. – Data was capture via laptop. – Dropout rate was defined as the percentage of total monitoring time where data was not detected by pulse oximeter.	• SpO_2 mean difference and standard error between the Masimo and Nellcor was 1.46 ± 0.36, which was statistically significant. • PR mean difference and standard error between Masimo and Nellcor was -1.21 ± 0.74, which was not statistically significant. • Overall the Masimo dropout rate was statistically higher than the Nellcor. • SpO_2 and PR for both devices were less than 1% of the recorded time, but Masimo SpO_2 was 1.94 times more likely to drop out than Nellcor and Masimo PR was 1.55 times more likely to drop out than Nellcor.	• Not peer-reviewed. • Small population. • Paediatric patients. • Did not consider the accuracy of the SpO_2 measurement of the 2 pulse oximeters, as no comparison with co-oximeter measurements (*gold standard*).
Lussky *et al* 2007 [55]	Nellcor OxiMax N-600	• **Population:** 17 newborn infants with umbilical arterial line. • **Aim:** To establish accuracy and dropout rate for Nellcor OxiMax N-600 and Masimo SET Radical pulse oximeters for use in NICU. • **Method:** – SpO_2 was continuously measured by oximeters for 4 hours, with sensor rotation at 2 hours. – SpO_2 and PR data were exported to a laptop. – SaO_2 was measured using co-oximetry.	• There were statistically significant correlations found between SpO_2 measured by both oximeters and SaO_2, but no significant difference between the performance of oximeters. • Bias and precision of Nellcor was 1.76 ± 3.25%. • Bias and precision of Masimo was 1.39 ± 2.81%. • Nellcor has a statistically lower dropout rate than the Masimo.	• Not peer-reviewed. • Small population. • Paediatric patients.

Table 17. Unpublished clinical trials for Nonin pulse oximeters

Authors	Device/technology	Study design	Results	Limitations
Severinghaus 2005 [39]	Nonin ONYX II	• **Population:** 12 volunteers. • **Aim:** To compare the accuracy of Nonin PureSAT ONYX II with gold standard of co-oximetry. • **Method:** – Each subject was placed in a semi-supine position and allowed to breathe through a mouthpiece while nose was block with a nose clip. – Hypoxia was induced by subjects breathing mixtures of nitrogen, room air and carbon dioxide, with each desaturation level held at a stable plateau. – Each subject was exposed to 2 runs of 5 plateaus between 64% and 100%. – At each level SpO_2 and SaO_2 were measured. – Measurement of accuracy was presented as A_{RMS} and calculated according to ISO 9919:2005.	• Total number of samples was 253, giving an overall A_{RMS} of 1.31 %SpO_2, for an SaO_2 range of 70-100%. • The performance of the ONYX II was shown to be consistent over the oxygen saturation range.	• Not peer-reviewed. • Small population.

Table 17. Unpublished clinical trials for Nonin pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Nonin 2006 [40]	Nonin OEM III module (Nonin PureSAT)	• **Population:** 12 volunteers. • **Aim:** To compare the accuracy of Nonin PureSAT signal processing technology against the *gold standard* of co-oximetry during patient motion. • **Method:** – Each subject was placed in a semi-supine position and allowed to breathe through a mouthpiece while nose was block with a nose clip. – Hypoxia was induced by subjects breathing mixtures of nitrogen, room air and carbon dioxide, with each desaturation level held at a stable plateau. – Each subject was exposed to 2 runs of 5 plateaus between 60% and 100%. – At each level SpO_2 and SaO_2 were measured. – Rubbing and tapping motions were created by means of an industry-wide accepted protocol for generating motion. – Measurement of accuracy was presented as A_{RMS} and calculated according to ISO 9919:2005.	• A_{RMS} for SaO_2 ≥60% was 1.70. • A_{RMS} for SaO_2 ≥70% was 1.68. • At saturation levels below 80%, Nonin performed consistently. • SpO_2 measured by Nonin system correlated well with SaO_2 across changing levels. • No misleading data was observed.	• Not peer-reviewed. • Small population.

Table 17. Unpublished clinical trials for Nonin pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
Nonin 2007 [41]	Nonin Onyx 9500	• **Population:** 12 normal subjects. • **Aim:** To assess the accuracy of the Nonin Onyx 9500 and SPO Medical PulseOx 5500 compared to arterial blood saturation levels in normal subjects. • **Method:** – Hypoxia was induced to 5 levels of oxygen saturation between 70% and 100% by having subjects breathe a mixture of inspired gas. – Each level was held at each plateau for approximately 2 minutes whilst pulse oximeter readings and arterial blood gas samples were taken simultaneously. – 25 samples were obtained for each subject. – Accuracy was defined as the closeness of agreement between a test result and an acceptable reference value.	• A_{RMS} for Nonin and SPO was 1.4 and 4.2, respectively. • The accuracy of the Nonin was consistent throughout the range of 70% to 100% with no signal deterioration at the lower ranges of oxygenation. • The SPO oximeter's accuracy decreased at values less than 90%.	• Not peer-reviewed. • Small population.
University of California San Francisco 2008 [42]	Nonin Avant 9700	• **Population:** 36 normal subjects. • **Aim:** To compare the accuracy of Nonin Avant 9700, Masimo Radical and Nellcor OxiMax N-595 and determine the effect of dark skin on accuracy. • **Method:** – Each subject underwent a standard breath-down protocol to achieve arterial oxygen saturation between 70% and 100%. – Accuracy was reported as A_{RMS}.	• At 70% and 80% oxygen saturation, the mean bias in dark skin pigmentation was minimal for Nonin's oximeter at -0.6% ± 1.4, compared to a mean bias of 2.1% ± 2.9 for Masimo and 2.0% ± 2.1 for Nellcor. • A_{RMS} for Nonin, Masimo and Nellcor was 1.3, 3.6 and 2.9, respectively. • Nonin maintained acceptable variability in the most challenging environment of dark skin pigmentation and SaO_2 less than 80%.	• Not peer-reviewed. • Small population.

Table 17. Unpublished clinical trials for Nonin pulse oximeters (continued)

Authors	Device/technology	Study design	Results	Limitations
University of California San Francisco 2009 [43]	Nonin WristOx 3100	• **Population:** 12 normal subjects. • **Aim:** To compare the accuracy of Nonin WristOx 3100 with SPO 7500 and Minolta PULSOX 300i pulse oximeter. • **Method:** – Each subject underwent a standard breath-down protocol of induced hypoxaemia. Inspired gas mixtures were controlled to attain hypoxia plateaus between 70% and 100%. – Each plateau was maintained for at least 2 minutes while pulse oximetry readings and arterial blood samples were acquired simultaneously. – 25 samples were obtained for each subject.	• A_{RMS} for Nonin, SPO and Minolta was 1.7, 3.4 and 3.1, respectively. • The accuracy of the Nonin was significantly better than the other wrist pulse oximeters tested. • The accuracy of the Nonin was consistent throughout the range of oxygenation. Conversely, the accuracy of the other devices decreased at values less than 90%.	• Not peer-reviewed. • Small population.

Market review:
Pulse oximeters in primary and prehospital care

E S Colechin, D R Bousfield, C A Reay and A J Sims

Regional Medical Physics Department
Freeman Hospital
High Heaton
Newcastle upon Tyne
NE7 7DN

Tel: 0191 213 7787
Fax: 0191 213 0290
Email: rmpdfhevaluation@nuth.nhs.uk
Website: www.rmp.org.uk

About CEP

The Centre for Evidence-based Purchasing (CEP) is part of the NHS Purchasing and Supply Agency. We underpin purchasing decisions by providing objective evidence to support the uptake of useful, safe and innovative products and related procedures in health and social care.

CEP publications since 2002 are available from our website.

www.dh.gov.uk/cep