Underread of P867RA probes on Ohmeda 3800 pulse oximeter : 02-03-01 : SW.

2nd P867RA prototype based upon Aristo neonatal disposable optics built into Viamed clip - labelled Proto A5.

Both prototypes A2 & A5 evaluated by SW and independently by RT - results as follows :-

SW.

A2	3700	97	90	80	70	60	- Target DL3000.
		97	91	81	71	62	- Displayed SpO2.
	3800	97	90	80	70	60	- Target DL3000.
		97	90	80	70	59	- Displayed SpO2.
Finger	3700	100 (aligned)	98 (mis-aligned)				
	3800	99 (aligned)	98 (mis-aligned)				
A5	3700	97	90	80	70	60	- Target DL3000.
		97	90	81	71	61	- Displayed SpO2.
	3800	97	90	80	70	60	- Target DL3000.
		96	89	79	69	59	- Displayed SpO2.
Finger	3700	100 (aligned)	99 (mis-aligned)				
	3800	98 (aligned)	98 (mis-aligned)				

RT.

A2	3700	97	90	80	70	60	- Target DL3000.
		97	91	82	71	60	- Displayed SpO2.
	3800	97	90	80	70	60	- Target DL3000.
		97	90	81	70	60	- Displayed SpO2.
Finger	3700	97 (aligned)	98 (mis-aligned)				
	3800	98 (aligned)	97 (mis-aligned)				
A5	3700	97	90	80	70	60	- Target DL3000.
		97	90	80	70	61	- Displayed SpO2.
	3800	97	90	80	70	60	- Target DL3000.
		96	90	79	69	59	- Displayed SpO2.
Finger	3700	98 (aligned)	97 (mis-aligned)				
	3800	98 (aligned)	96 (mis-aligned)				

Test of 1st batch of Southmead spec probes : SW : 11-5-01.

1st batch of 25 probes tested on both 3700e & 3800 oximeters - details as per original document held in Southmead folder.

Test of MCI prototype P867RA's : SW : 25-6-01.

4 x prototype P867RA's received from MCI and tested against the Ohmeda 3800 oximeter on 14-6-01. Probes labelled 1,2,3 & 7 for reference.

Probes tested in comparison to known good simulator signals from DL-3000 SpO2 simulator and on a human subject.

Results as follows :-

Probe 1.

Human	Sim : 97%	Sim : 90%	Sim : 80%	Sim : 70%	Sim : 60%
98	94	87	77	68	57

Probe 2.

Human	Sim : 97%	Sim : 90%	Sim : 80%	Sim : 70%	Sim : 60%
98	94	88	79	68	58

Probe 4.

Human	Sim : 97%	Sim : 90%	Sim : 80%	Sim : 70%	Sim : 60%
97	94	88	77	67	57

Probe 7.

Human	Sim : 97%	Sim : 90%	Sim : 80%	Sim : 70%	Sim : 60%
98	94	87	77	67	57

Conclusion.

Probes read generally 2-3% low on this oximeter and are hence unsuitable.

P867 underead : Dai shin prototype : SW : 05-07-01.

P867RA prototype constructed using Dai Shin samples, results as follows :-

Probe tested on same hand to both oximeter models. 3800 reads 2% lower than 3700 independent of clip site, in comparison to Ohmeda original finger probe.

Conclusion : Unsuitable.

Exact part nos not known.

P867RA underread : Doklphin prototypes : SW : 02-07-01.

Optics taken from Dolphin Ohmeda compatible disposables and fitted (minus metal grid screens) into Viamed clips for evaluation. Results as follows :-

Serial no. 0016-1.

3700 oximeter.

DL3000 target :	98	94	80	70	60
Displayed :	98	94	80	71	62

3800 oximeter.

DL3000 target :	98	94	80	70	60
Displayed :	95	92	78	68	58

Serial no. 0103-2.

3700 oximeter.

DL3000 target :	98	94	80	70	60
Displayed :	98	94	80	71	61

3800 oximeter.

DL3000 target :	98	94	80	70	60
Displayed :	98	94	80	70	61

* Both probes tested on same hand to both oximeter models. 3800 reads 2% lower than 3700 independent of clip site, in comparison to Ohmeda original finger probe.

Conclusion : Both unsuitable.

P867RA underread : SW : 27-07-01.

Viamed optics fitted into Viamed shells / pad etc with O ring immediately infront of LED and Detector packages. Probe tested on DL-3000. Results as follows :-

3700 oximeter.

Target DL3000 Spo2 value	98	94	80	70	60
Displayed Spo2 value	Insufficient light on all values				

3800 oximeter.

Target DL3000 Spo2 value	98	94	80	70	60
Displayed Spo2 value	968	92	80	71	60

Test results of P867RA fitted with Ohmeda components : SW : 02-08-01.

3 probes built using Ohmeda original components / PDI components, results as below :-

PDI LED, PDI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	62
DL target	98	94	80	70	60
3800	96	92	79	69	59

PDI LED, Ohmeda sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	61
DL target	98	94	80	70	60
3800	95	91	79	70	60

Ohmeda LED, Ohmeda sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	61
DL target	98	94	80	70	60
3800	98	94	80	70	60

Ohmeda LED, PDI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	61
DL target	98	94	80	70	60
3800	98	94	80	69	59

Conclusion - Change of LED package cures or compensates for cause of 2% underread.

Results of tests on Dai Shin prototype (2 x Infrared emitters) based P867RA : SW : 15-08-01.

As stock, 12 ft length, 68k resistor, no windows, labelled "Dai Shin proto 2 x IR's".

Shows "probe failure" when test attempted on DL-3000, 3800 (frac).

On Human (SW):-

3700	Original Ohmeda Lot 27299	98
3800	Dai shin prototype	95
3700	Dai shin prototype	95
3800	Original Ohmeda Lot 27299	98

Conclusion.

Unsuitable.

Results of test of MCI P867RA fitted with Ohmeda original cable : SW : 03-08-01.

P867RA constructed using MCI optics, our connector, shells, pads etc, using Ohmeda original cable. Fitted with a 23.2k resistor. 10ft length. Pin out as MCI.

Results as below :-

DL target	98	94	90	80	70	60
3700	98/97	94/93	90	80/79	70	60
DL target	98	94	90	80	70	60
3740	98	95/94	91	81	72	63
DL target	98	94	90	80	70	60
3800	98	94	90	81	72	63

Conclusion.

Change of resistor to value in the lower region of acceptable range gives extra 1% in displayed SpO2 for high 90's using the 3800. It doesnot adversely affect the lower SpO2 values.

Change of resistor causes change in the lower SpO2 values for the 3700 & 3740, values remaining within +/- 3%.

Probe component changes compensate or cure previous 2% underread.

Results of tests on MCI based P867RA (special) : SW : 15-08-01.

As stock except shortened to match comparson and resistor change.

Wavelength (red) : 654.7-658.0nm.
Wavelength (infrared) : 931.5-934.8nm.
resistor : 21.997kohm.
Length :
Forward diode voltage (red) : 1.5V.
Forward diode voltage (infrared) : 1.0V.
Forward diode voltage (detector) : 0.4V.
DL3000 module returns (attenuated setting) : Red, 17, Infrared, 16.
Reads 97% on 3800 against DL3000.
Human : SW : 97%.

Test of emitters and detector (voltages and currents measured at connector).
Detector test c/o sheilded from ambient light.

Red current at measured voltage .	Infrared current at measured voltage.	Detector voltage in response to red.	Detector voltage in response to infrared.
< 1µA.	700mV, 1µA.	< 5.2mV.	700mV, < 4.0mV.
< 1µA.	752mV, 2µA.	< 5.2mV.	752mV, 4.0mV.
< 1µA.	804mV, 7µA.	< 5.2mV.	803mV, 4.3mV.
< 1µA.	846mV, 16µA.	< 5.2mV.	854mV, 8.3mV.
< 1µA.	897mV, 43µA.	< 5.2mV.	906mV, 34.7mV.
< 1µA.	949mV, 116µA.	< 5.2mV.	947mV, 102.5mV.
< 1µA.	1000mV, 326µA.	< 5.2mV.	998mV, 171.6mV.
< 1µA.	1047mV, 896µA.	< 5.2mV.	1040mV, 214.2mV.
< 1µA.	1101mV, 2743µA.	< 5.2mV.	1099mV, 263.2mV.
< 1µA.	1143mV, 5482µA.	< 5.2mV.	1141mV, 288.6mV.
1200mV, 1µA.	1202mV, 11574µA.	< 5.2mV.	1200mV, 317.0mV.
1250mV, 1µA.		< 5.2mV.	
1302mV, 2µA.		< 5.2mV.	
1342mV, 4µA.		1346mV, 5.0mV.	
1392mV, 11µA.		1391mV, 6.7mV.	
1451mV, 32µA.		1450mV, 18.1mV.	
1501mV, 79µA.		1499mV, 76.0mV.	
1549mV, 199µA.		1548mV, 153.4mV.	
1601mV, 609µA.		1604mV, 215.7mV.	
1650mV, ----µA.		1657mV, 257.4mV.	
1696mV, 4594µA.		1704mV, 288.7mV.	
1754mV, 9949µA.		1752mV, 310.5mV.	
1802mV, 15370µA.		1800mV, 325.0mV.	

Results of tests on stock MCI P867RA's : SW : 08-08-01.

Stock MCI based P867RA taken from stock. Tested on 3800 / DL3000 - proven to read 2 to 3% low. 12ft long, 68k resistor.

Led removed and old style CSI Led fitted with 2 x infrared Leds on single ceramic -
unable to get probe to read on 3800 using DL3000.

Stock MCI based P867RA taken from stock. Tested on 3800 / DL3000 - proven to read 2 to 3% low. 12ft long, 68k resistor.

Sheilds shorted together at clip, both sheilds commoned to resistor at connector -
no change when tested.

Sheilds shorted together at clip, inner sheild connected to resistor at connector -
no change when tested.

Sheilds shorted together at clip, outer sheild connected to resistor at connector -
no change when tested.

Sheilds opened at clip, only inner sheild connected to resistor at connector -
no change when tested.

Sheilds opened at clip, only outer sheild connected to resistor at connector -
no change when tested.

Sheilds opened at clip, inner sheild connected to resistor at connector, outer to yellow (common anode) -
no change when tested.

Sheilds opened at clip, inner sheild connected to resistor at connector, outer to red (red cathode) -

no change when tested.

Sheilds opened at clip, inner sheild connected to resistor at connector, outer to orange (infrared cathode) -
no change when tested.

100k variable resistor connected across red led -
Occasionally reads 1% lower when tested, unable to show this happens at a given resistor setting.

100k variable resistor connected across infrared led -
no change when tested.

Jacket & outer sheild stripped and heatshrink tube used to simulate jacket, inner screen connected to resistor at connector -
reads 1% low when tested.

Ohmeda finger probe, lot 27299 : SW : 02-08-01.

6 core cable, red, brown, green, orange, black, white.

black / white form twisted pair enclosed in twisted inner sheild.

pin	1	orange	infrared cathode
	2	green	red cathode
	3	not used	
	4	brown/red	common anode
	5	resistor	51.14 kohm
	6	not used	
	7	sheild/resistor	common point
	8	black	detector anode
	9	white	detector cathode

emitters tested at 651.5nm (*) & 931.5nm respectfully.

(*) Not 660nm as previously thought.

Results of tests on Ohmeda original finger probe, Lot 27299 : SW : 15-08-01.

Wavelength (red) : 651.5nm. (*) Not 660nm as previously thought.
Wavelength (infrared) : 928.3-931.5nm.
resistor : 50.8kohm.
Length :
Forward diode voltage (red) : 1.5V.
Forward diode voltage (infrared) : 1.0V.
Forward diode voltage (detector) : 0.4V.
DL3000 module returns (attenuated setting) : Red, 19, Infrared, 50.
Reads 97% on 3800 against DL3000.
Human : SW : 97%.

Test of emitters and detector (voltages and currents measured at connector).

Red current at measured voltage .	Infrared current at measured voltage.	Detector voltage in response to red.	Detector voltage in response to infrared.
< 1µA.	700mV, 1µA.	< 17.6mV.	700mV, 16.0mV.
< 1µA.	754mV, 3µA.	< 17.6mV.	752mV, 16.3mV.
< 1µA.	803mV, 7µA.	< 17.6mV.	803mV, 18.1mV.
< 1µA.	854mV, 19µA.	< 17.6mV.	854mV, 30.9mV.
< 1µA.	897mV, 43µA.	< 17.6mV.	906mV, 100.7mV.
< 1µA.	957mV, 147µA.	< 17.6mV.	947mV, 169.8mV.
< 1µA.	9990mV, 341µA.	< 17.6mV.	998mV, 228.9mV.
< 1µA.	1059mV, 1234µA.	< 17.6mV.	1040mV, 269.2mV.
< 1µA.	1100mV, 2800µA.	< 17.6mV.	1099mV, 320.4mV.
< 1µA.	1142mV, 5927µA.	< 17.6mV.	1141mV, 348.0mV.
1200mV, 1µA.	1196mV, 11900µA.	< 17.6mV.	1200mV ,378.0mV.
1248mV, 2µA.		< 17.6mV.	
1298mV, 5µA.		1291mV, 17.6mV.	
1348mV, 12µA.		1351mV, 18.7mV.	
1396mV, 30µA.		1401mV, 27.0mV.	
1447mV, 76µA.		1450mV, 75.0mV.	
1496mV, 192µA.		1498mV, 158.7mV.	
1557mV, 602µA.		1558mV, 222.3mV.	
1610mV, 1193µA.		1607mV, 262.4mV.	
1645mV, 2399µA.		1647mV, 288.3mV.	
1703mV, 4696µA.		1704mV, 316.5mV.	
1751mV, 7132µA.		1752mV, 333.0mV.	
1802mV, 10076µA.		1801mV, 349.0mV.	

Results of test of PDI based P867RA fitted with Ohmeda original cable : SW : 06-08-01.

P867RA constructed using PDI optics, our connector, shells, pads etc, using Ohmeda original cable. Fitted with a 22k resistor. Approx. 10ft length. Pin out as Ohmeda original.

Results as below :-

DL target	98	94	90	80	70	60
3800	98	94	90	80	71	61
DL target	98	94	90	80	70	60
3740	98	94	90	80	71	61
DL target	98	94	90	80	70	60
3700	98	94	90	81	72	63

Conclusion.

Change of resistor to value in the lower region of acceptable range gives extra 1% in displayed SpO2 for high 90's using the 3800. It doesnot adversely affect the lower SpO2 values.

Change of resistor causes change in the lower SpO2 values for the 3700 & 3740, values remaining within +/- 3%.

Probe component changes compensate or cure previous 2% underread.

Results of tests on MCI based P867RA : SW : 15-08-01.

As stock except shortened to match comparison & resistor change.

Wavelength (red) : 654.7-658.0nm.
Wavelength (infrared) : 931.5nm.
Resistor : 21.889kohm.
Length :
Forward diode voltage (red) : 1.5V.
Forward diode voltage (infrared) : 1.0V.
Forward diode voltage (detector) : 0.4V.
DL3000 module returns (attenuated setting) : Red, 39, Infrared, 26.
Reads 96% on 3800 against DL3000.
Human : SW : 97%.

Test of emitters and detector (voltages and currents measured at connector).
Detector test c/o sheilded from ambient light.

Red current at measured voltage .	Infrared current at measured voltage.	Detector voltage in response to red.	Detector voltage in response to infrared.
< 1µA.	700mV, 1µA.	< 3.2mV.	700mV, < 4.0mV.
< 1µA.	742mV, 2µA.	< 3.2mV.	750mV, 4.0mV.
< 1µA.	805mV, 7µA.	< 3.2mV.	795mV, 4.3mV.
< 1µA.	856mV, 19µA.	< 3.2mV.	856mV, 8.3mV.
< 1µA.	907mV, 53µA.	< 3.2mV.	907mV, 34.7mV.
< 1µA.	948mV, 142µA.	< 3.2mV.	948mV, 102.5mV.
< 1µA.	999mV, 310µA.	< 3.2mV.	998mV, 171.6mV.
< 1µA.	1040mV, 684µA.	< 3.2mV.	1040mV, 214.2mV.
< 1µA.	1100mV, 2135µA.	< 3.2mV.	1099mV, 263.2mV.
< 1µA.	1140mV, 4.018µA.	< 3.2mV.	1141mV, 288.6mV.
1202mV, 0µA.	1200mV, 8751µA.	< 3.2mV.	1200mV, 317.0mV.
1253mV, 1µA.		< 3.2mV.	
1302mV, 2µA.		1300mV, 3.1mV.	
1342mV, 4µA.		1348mV, 4.5mV.	
1401mV, 11µA.		1399mV, 7.7mV.	
1451mV, 28µA.		1448mV, 33.6mV.	
1500mV, 67µA.		1497mV, 118.1mV.	
1549mV, 169µA.		1554mV, 193.7mV.	
1599mV, 493µA.		1604mV, 242.8mV.	
1656mV, 1883µA.		1652mV, 283.3mV.	
1705mV, 4585µA.		1701mV, 314.7mV.	
1753mV, 8452µA.		1749mV, 336.0mV.	
1802mV, 13094µA.		1798mV, 353.0mV.	

Test results of P867RA fitted with Ohmeda components : SW : 20-08-01.

2 probes built using Ohmeda original LEDs and MCI / PDI detectors. Both probes constructed as per stock supplied MCI P867RA's. Results as below :-

Ohmeda LED, PDI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	61
DL target	98	94	80	70	60
3800	98	94	80	69	59

Human (SW) : 3700, Ohmeda original : 97 3700, Probe as above : 97
3800, Probe as above : 96 3800, Ohmeda original : 97

Ohmeda LED, MCI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	60
DL target	98	94	80	70	60
3800	98	94/93	80/79	69	59

Human (SW) : 3700, Ohmeda original : 98 3700, Probe as above : 97
3800, Probe as above : 98 3800, Ohmeda original : 97

Conclusion.

Only change in these probes to stock MCI P867RA's is change of LED package.

Based on current understanding of the DL-3000, LED package change should not have an effect on derived SpO2 values as the DL-3000 should continue to produce identical red to infrared ratios regardless of the change.

The only difference identified between the packages fitted above and MCI/PDI LED packages is the red wavelength : Ohmeda 650.5nm, MCI 658.0nm and PDI 658.0nm.(measured on Prema 9001).

Action : Build prototype using 650nm red emitter to eliminate this as source of underread. Samples requested to be sourced by SN from Dai Shin or alternative supplier at 650nm / 930nm respectively.

Test results of P867RA fitted with Ohmeda components : SW : 20-08-01.

2 probes built using Ohmeda original LEDs and MCI / PDI detectors. Both probes constructed as per stock supplied MCI P867RA's. Results as below :-

Ohmeda LED, PDI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	61
DL target	98	94	80	70	60
3800	98	94	80	69	59

Human (SW) : 3700, Ohmeda original : 97 3700, Probe as above : 97
3800, Probe as above : 96 3800, Ohmeda original : 97

Ohmeda LED, MCI sensor.

DL target	98	94	80	70	60
3700	98	94	80	70	60
DL target	98	94	80	70	60
3800	98	94/93	80/79	69	59

Human (SW) : 3700, Ohmeda original : 98 3700, Probe as above : 97
3800, Probe as above : 98 3800, Ohmeda original : 97

Conclusion.

Only change in these probes to stock MCI P867RA's is change of LED package.

Based on current understanding of the DL-3000, LED package change should not have an effect on derived SpO2 values as the DL-3000 should continue to produce identical red to infrared ratios regardless of the change.

The only difference identified between the packages fitted above and MCI/PDI LED packages is the red wavelength : Ohmeda 650.5nm, MCI 658.0nm and PDI 658.0nm.(measured on Prema 9001).

Action : Build prototype using 650nm red emitter to eliminate this as source of underread. Samples requested to be sourced by SN from Dai Shin or alternative supplier at 650nm / 930nm respectively.

Test results of shortened MCI based P867RA's: SW : 03-09-01.

1 x MCI P867RA progressively shortened to a length where it was found to read correctly on the Ohmeda 3800 - 8 feet in length.

2 x further MCI P867RA's shortened to 8 ft - results for all 3 probes as below.

probes built using Ohmeda original LEDs and MCI / PDI detectors. Both probes constructed as per stock supplied MCI P867RA's. Results as below :-

#1B25730.

DL target	98	94	90	80	70	60	
3700	98	94	91	81	71	62	Human : 98.
3740	98	94	91	80	71	61	Human : 98.
3800	98	94	90	80	70	60	Human : 98.

#1B25733.

DL target	98	94	90	80	70	60	
3700	98	94	90	81	71	61	Human : 97.
3740	98	94	90	80	70	61	Human : 98.
3800	98	94	90	80	70	59	Human : 98.

#1B25748.

DL target	98	94	90	80	70	60	
3700	98	94	90	81	70	61	Human : 98.
3740	98	94	90	80	71	61	Human : 98.
3800	98	94	90	80	70	60	Human : 98.

Conclusion : Suitable modification to eliminate underread problem.

Test results of shortened MCI based P867RA's: SW : 03-09-01.

1 x MCI P867RA progressively shortened to a length where it was found to read correctly on the Ohmeda 3800 - 8 feet in length.

2 x further MCI P867RA's shortened to 8 ft - results for all 3 probes as below.

probes built using Ohmeda original LEDs and MCI / PDI detectors. Both probes constructed as per stock supplied MCI P867RA's. Results as below :-

#1B25730.

DL target	98	94	90	80	70	60	
3700	98	94	91	81	71	62	Human : 98.
3740	98	94	91	80	71	61	Human : 98.
3800	98	94	90	80	70	60	Human : 98.

#1B25733.

DL target	98	94	90	80	70	60	
3700	98	94	90	81	71	61	Human : 97.
3740	98	94	90	80	70	61	Human : 98.
3800	98	94	90	80	70	59	Human : 98.

#1B25748.

DL target	98	94	90	80	70	60	
3700	98	94	90	81	70	61	Human : 98.
3740	98	94	90	80	71	61	Human : 98.
3800	98	94	90	80	70	60	Human : 98.

Conclusion : Suitable modification to eliminate underread problem.

Summary of investigation into P867RA underread on 3800 oximeter.

Start of investigation into this problem Jan 02.

From this date the following prototypes have been constructed and tests carried out :-

Jan 2001	Aristo disposable range of probes evaluated on 3700 & 3800 pulse oximeters. Aristo Disposable (neonatal) gave best results and optics used from these probes until stocks exhausted.
May 2001	Other aristo disposable optics giving favourable results assembled into Viamed probes but prove to read low.
June 2001	4 x MCI supplied prototypes evaluated - all read low.
July 2001	P867RA assembled and tested using Dai Shin samples - reads low.
July 2001	P867RA's assembled using Dolphin disposable optics - all read low .
July 2001	P867RA assembled using O ring in front of the detector - reads low.
July 2001	P867RA's assembled using LED, detector or both from Ohmeda originals - conclude that change of LED to Ohmeda cures or compensates for underread. CSI LED with 2 x infrared emitters fitted - doesnot read on DL-3000.
Aug 2001	P867RA assembled using Dai Shin samples - LED with 2 x IR emitters on board - doesnot work on DL-3000, underreads on both 3700 & 3800 oximeters.
Aug 2001	P867RA assembled using MCI optics, Ohmeda original cable, 23k2 resistor and our remaining parts - component changes cure or compensate for the underread on the 3800.
Sept 2001	3 x MCI built P867RA's progressively shortened with regular testing - found that all three probes read correctly when reduced to 8 ft. - also found that the physical removal of cable outer screen cures the underread on probe at 12 ft length. Recommendation made that all P867RA's supplied as new or repaired as of this date are shortened to 8ft. Cable comparison made between ours and Ohmeda. Pin to pin checks carried out between good and bad probes for capacitance - unable to identify a difference between cable / probe types with only 12 ft lengths to examine. Cable samples provided to SN to be externally checked.

	- Results suggest change of cable to that with greater conductor cross sectional area. Cable ordered, one as above and standard cross sectional area sample without outer screen.
Oct 2001	P867RA assembled using high output infrared LED from Dai Shin - read on finger, doesnot work on DL-3000.
Jan 2002	2 x P867RA's assembled using new cables - both read accurately throughout the range. - prototype with inner screen only earmarked as modification to be embodied into further manufactured P867RA subject to satisfactory testing.
Jan 2002	Both prototypes further evaluated - Results good - both probe prototypes return the target Spo2 value in the range 100 - 80%. - Maximum error - +/- 1% below 80%. - Spo2 values displayed alter by -1% when correctly aligned compared to incorrectly aligned. Ohmeda original finger probe - displayed Spo2 doesnot alter. - Recommend optics are moved forward such that the probe cannot be placed on the finger incorrectly, fingertip against end stop, probe optics above and below finger nail.
Jan / Feb 2002	Prototype probes to be tested and tables generated comparing displayed Spo2 to probe resistor value for the three Ohmeda models available (3700, 3740 & 3800).

Investigation carried out by S Watmough, Technical Engineer, Viamed Ltd.

Report.

Investigation into Viamed P867RA Adult Finger Probe under read on Ohmeda 3800 oximeter.

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AC	Test of 3 x P867RA (production) from the above batch after reworking to become P867RA (prototype) attempting to establish the cause of the under read.
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AF	Test of batch of 10 P867RA (prototype) manufactured (CD6031).
AG	Test of electrical characteristic of Ohmeda Adult reuseable finger probe.
AH	10 x LEDs selected based on 14.00mA forward IR diode current at 1200mV. Batch of 10 P867RA (prototype) manufactured.
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AJ	New LEDs received, PDI-E8078. 2 x 10 P867RA (prototype) built and tested.
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Introduction

Viamed Ltd specialise in pulse oximetry probes and have successfully developed, marketed and supported these types of products for over 25 years. A comprehensive range of probes, are available, both as finger type probes and as 'Y' probes.

The Viamed, Ohmeda compatible adult finger probe, the P867RA, has been supplied worldwide with no inaccurate readings reported whilst this type of probe has been used with Ohmeda 3700, 3700e and 3740 model pulse oximeters. After release of the Ohmeda 3800 pulse oximeter in mid 1999, a number of customers (initially Ysbytygwynedd Hospital (Bangor), Southmead General Hospital (Bristol) & Northern General Hospital (Sheffield) reported that the P867RA could read up to 2% lower than the equivalent Ohmeda adult finger probe.

The disclosed accuracies for the Ohmeda 3800 pulse oximeter are, (80 - 100%) +/-2%, (60-79.9%) +/- 3%, (below 60%) unspecified. It is considered that a typical reading from a Viamed P867RA still falls within the accuracy tolerance of a 3800 oximeter and Ohmeda original probe.

In the interest of resolving customer queries, an investigation was initiated to establish why there should be any discrepancy between a displayed SpO_2 reading derived from an Ohmeda original adult finger probe and the P867RA.

This report intends to document the investigation to date and to record the sequence of events in order to satisfy the following goals:

1. To develop an Ohmeda compatible pulse oximetry probe which derives displayed oxygen saturation readings of at least equivalent value in comparison to a typical Ohmeda original adult finger probe when on a human finger using the 3700, 3700e, 3740 and 3800 model pulse oximeters.
2. To ensure that the finger probe developed to satisfy point (1) also derives a displayed oxygen saturation reading of at least equivalent value in comparison to a typical Ohmeda original adult finger probe when on the DL-3000 simulator(*) using the 3700, 3700e, 3740 and 3800 model pulse oximeters.
3. To scientifically prove the root cause of the difference in reading and support a new design P867RA satisfying points (1) and (2) with documentary evidence of accurate readings derived from it and it's compatibility with the Ohmeda series of pulse oximeters.

(*). The DL-3000 SpO_2 simulator is a piece of test equipment developed by Viamed Ltd and allows a given oximeter and probe combination to be tested throughout the clinical range of saturations (100% - 60%). It produces a calibrated output in response to the signals from the oximeter under test, in order to produce a displayed saturation on that oximeter. It is not intended to be an infallible test, however simulators in general are being more increasingly used as a means of evaluating the performance of probes prior to release into mainstream use.

The theory of pulse oximetry.

A pulse oximeter and probe relate the arterial oxygen concentration of blood to a displayed percentage oxygen reading known as SpO_2.

SpO_2 is defined as the percentage arterial haemoglobin saturation with oxygen as measured by a pulse oximeter and displayed as a percentage.

As most people know, the colour of blood alters as a function of the level of dissolved oxygen it contains, irrespective of the person being tested. As blood deoxygenates, it becomes increasingly less impermeable to red light. The tissue loses its pinkish appearance, taking on a blue tint. The pulse oximeter measures the "blueness" of arterial blood, whilst ignoring the patient's natural pigmentation, the venous blood and any other major absorbers, and displays this blueness in terms of saturation.

The colour of blood is dependent on the optical properties of haemoglobin, in particular, the difference in optical properties of a haemoglobin molecule when carrying oxygen compared to when it is not. Figure 1 below shows the extinction curves resulting from the presence of oxy-haemoglobin (HbO_2) and reduced haemoglobin (Hb) in comparison to wavelength.

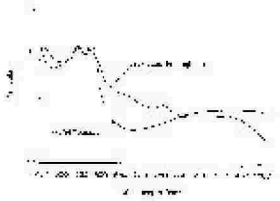

Figure 1: Diagram showing absorption (extinction coefficient) versus wavelength for oxy-haemoglobin(HbO_2) and deoxy-haemoglobin(Hb).

Note: Logarithmic scales are used up the vertical axis and a higher extinction coefficient at a given wavelength indicates that more transmitted light will be absorbed than otherwise.

At 660nm (typical wavelength of red light), the extinction coefficient of oxy-haemoglobin (HbO_2) is at it's lowest, whereas the extinction coefficient of reduced haemoglobin (Hb) is high. At 930nm (typical wavelength of near infrared light), the extinction coefficient for oxy-haemoglobin (HbO_2) is high compared the extinction coefficient of reduced haemoglobin (Hb), which is lower.

When red light with a typical transmission wavelength of 660nm, is passed through a tissue site supplied with healthy arterial blood with high dissolved oxygen content, large amounts of light pass through the site unobstructed due to the presence of majority HbO_2. A relatively small amount of "transmitted light" is absorbed by the minority Hb present. Relatively obstructed red light being allowed to pass through blood with high dissolved

oxygen content is the reason why highly oxygenated arterial blood appears to the human eye to be bright red in colour.
Should HbO_2 present decrease, absorption of red transmitted light at 660nm wavelength increases due to the increasing presence of Hb - the extinction coefficient of Hb is approximately 10 times that of HbO_2 at 660nm. When transmitted light at this wavelength is passed through a site supplied with healthy venous blood with relatively low dissolved oxygen content, a lesser amount of transmitted light passes through the site unobstructed. The relatively high absorption of red light as it passes through blood with low dissolved oxygen content is the reason why deoxygenated venous blood appears to the human eye to be dull red in colour.

This is shown schematically in Figure 2 - as percentage saturation increases from left to right across the horizontal axis, absorption of red light at 660nm decreases. The relationship is linear throughout the entire range of 0% HbO_2, 100% Hb to 100% HbO_2, 0% Hb. The extent of negative gradient of the line is a indication of the difference in absorption levels for the two types of haemoglobin at this wavelength.

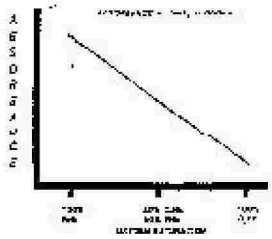

Figure 2: Absorption of red light at 660nm compared to the level of blood saturation

When infrared light of typical transmission wavelength of 930nm, is passed through a tissue site supplied with healthy arterial blood with high dissolved oxygen content, a large proportion of "transmitted light" is absorbed by the majority HbO_2.

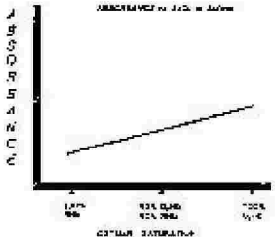

Figure 3: Absorption of red light at 930nm compared to the level of blood saturation

Should HbO_2 present decrease, absorption of infrared transmitted light decreases due to increasing levels of Hb - the absorption coefficient of Hb is approximately 1.5 times that of HbO_2 at 930nm. When transmitted light of 930nm is passed through a tissue site supplied with healthy venous blood with low dissolved oxygen content, a smaller proportion of transmitted light is absorbed by the presence of Hb.

This is shown schematically in Figure 3 - as percentage saturation increases from left to right across the horizontal axis, absorption of infrared light at 930nm increases. The relationship is linear throughout the entire range of 0% HbO_2, 100% Hb to 100% HbO_2, 0% Hb. The extent of positive gradient of the line is a indication of the difference in absorption levels for the two types of haemoglobin at this wavelength.

SpO_2 measurement relies on two essential facts,

1. Oxygenated and deoxygenated haemoglobin absorb uniquely different amounts of different wavelengths of light.

2. By Beers Law, at least n wavelengths are required to identify any one absorber in a system of n absorbers.

It has already been shown that the two types of haemoglobin we wish to identify do indeed have unique extinction curves. By Beers Law, to identify a single absorber in a system of two absorbers requires two transmission wavelengths. Red and near infrared light sources are normally selected, giving a large difference in absorption levels.

An SpO_2 finger probe contains a red and infrared light source on one side of the clip, normally in the form of a dual LED package. Immediately opposite a detector is sited, normally a photodiode. The pulse oximeter activates the two light sources in an alternating sequence. When measuring the return from the detector due to the pulses of red and infrared light striking it, the oximeter can determine the level of red and infrared light absorbed through the patients' tissue. Some pulse oximeters have a period when both light sources are off which is used to assess the level of ambient light striking the detector as shown below in Figure 4.

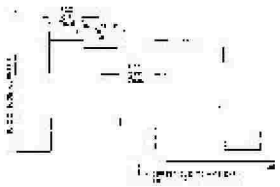

Figure 4: Diagram showing the sequence of pulses of red and near infrared and measurement of ambient light (neither red nor infrared on).

The SpO_2 value of interest is that of the arterial blood supply. The pulse of arterial blood during the heartbeat varies the level of light absorption. The detector produces a voltage dependent on the level and wavelength of light falling on it. There are four elements present in the output from the detector; an AC signal during the red pulse, a DC level during the red pulse, an AC signal during the infrared pulse and a DC level during the infrared red pulse. AC components of the detector output are derived from the movement of the blood during the pulses of arterial flow and the DC levels are due to tissue, bone

and relatively stationary venous blood. Refer to Figure 5. The amplitude of both AC signals and DC levels are dependent on the intensity of light transmitted.

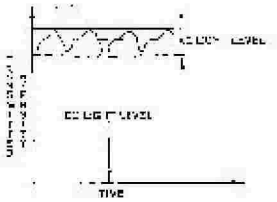

Figure 5: Schematic representation of AC signal and DC level produced by transmission of the given wavelength of light through living tissue.

Modern day pulse oximeters then derive what is known as an 'R' ratio. In order to do this, they firstly derive 'corrected AC' by dividing the AC component of the detector signal by the DC component for each transmission wavelength. This eliminates the need to monitor the initial transmission intensity as had to be done with early generation pulse oximeters. The corrected AC is a function of only the extinction curves of the two types of haemoglobin and the path length of the arterial blood through which the light has passed.

When corrected AC (red), is divided by the corrected AC (infrared), the 'R ratio' is obtained:

$$\text{The 'R ratio'} = \text{Corrected AC (red)} \div \text{Corrected AC (infrared)}$$

$$= \frac{AC_{RED}}{DC_{RED}} \div \frac{AC_{INFRARED}}{DC_{INFRARED}}$$

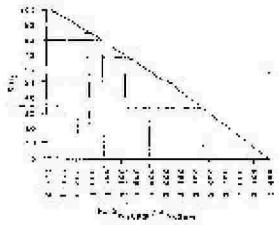

Figure 6: Diagram showing the relationship between R ratio derived and displayed spO_2.

In many pulse oximeters, when the calculation for R ratio equals 1.00, the value of SpO_2 is 85%. R ratio values of less than 1.00 indicate above saturations above 85% and R ratio values greater than 1.00 indicate saturations below 85%. These can be seen in Figure 6.

When the R ratios for all spO_2 readings are put together, practically from 60% to 100%, the 'R-curve' is formed. The R-curve value derived allows the detector returns to be related to the spO_2 reading displayed to the value of blood oxygenation obtained by blood

gas analysis. Since the relationship as shown in Figure 6 is non-linear, a cross reference table is held within the oximeters memory allowing the R curve value derived at a given time to be converted into the displayed spO_2 value.

R curve values are dependent on the returns from the probe detector and the exact method of calculation or software algorithm employed.

More recent models of pulse oximeter, such as the Ohmeda 3800, have made a distinction between 'functional' and 'fractional' measurement of SpO_2. Functional spO_2 measurement is oxygenated haemoglobin expressed as a percentage of haemoglobin capable of carrying oxygen. Fractional spO_2 is the percentage of oxygenated haemoglobin when compared to all types of haemoglobin.

Construction of the P867RA

Shown in Figure 7 is a schematic wiring diagram of the Viamed P867RA, Ohmeda compatible adult pulse oximetry finger probe.

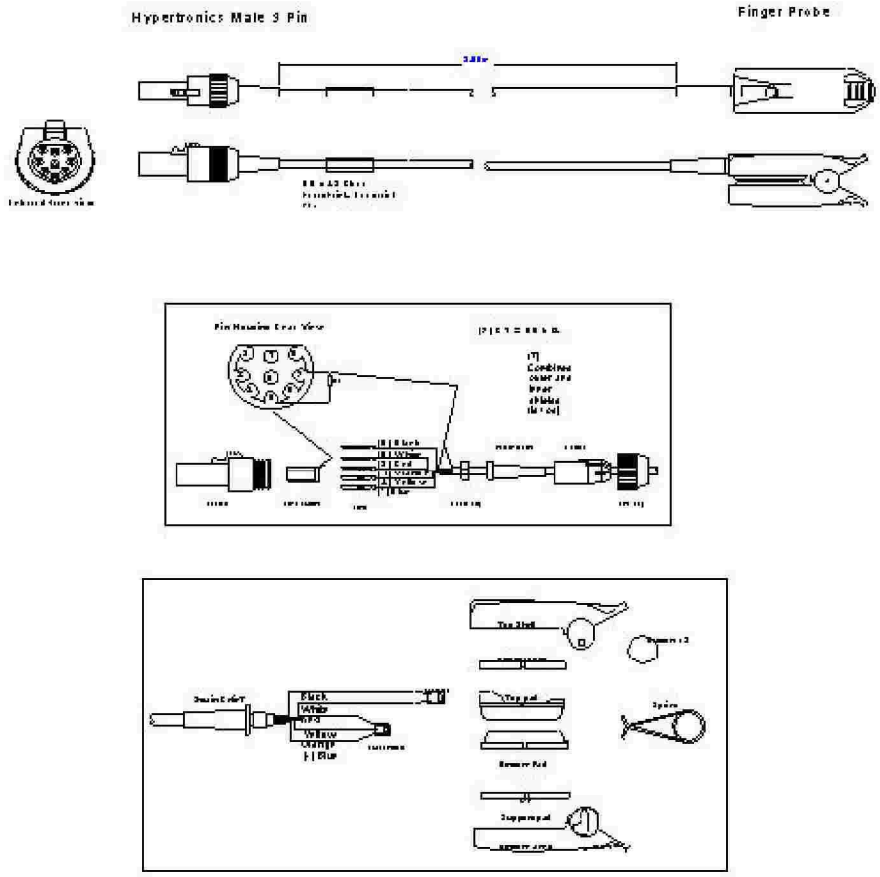

Figure 7: Schematic diagram of Viamed P867RA adult re-useable pulse oximetry finger probe.

This type of finger probe is constructed from a number of individual parts. Those parts through which electrical signals pass are felt to be the most likely cause of a difference of 2% in readings. It would be premature to conclude that a single component part of the P867RA would cause the problem being investigated. It is felt that it is more likely that the 2% difference in readings is as a result of the cumulative action of a number factors and that any differences highlighted through the investigation should not be dismissed as being negligible.

Possible factors resulting in a difference in displayed spO_2 readings.

The only signal which can be monitored by the connected oximeter is the return from the detector. Any change in the properties of the probe which affects the return from the detector has the potential to alter the displayed spO_2 reading.

It is felt that the most likely cause of the discrepancy in reading is a change in overall resistance or capacitance of the electrical aspect of the probe or change in wavelength / optical properties of the emitters / detectors.

Optical components:	Change in wavelength.
	" " transmission intensity.
	" " $Vf_{(RED)}$.
	" " $Vf_{(INFRARED)}$.
	" " $Vf_{(DET)}$.
	" " leakage currents.
	" " shunt resistance.
Cable:	Change in resistance per unit length.
	" " capacitance per unit length.
	" " performance of shields.
	" " material of conductors.
	" " no. of conductors per bunch.
	" " cross sectional area of conductors.
	" " coatings on conductors.
	" " bunch jacket thickness or material.
	" " cable jacket thickness or material.
Connector:	Change in resistance of pin material per unit length.
	" " effectiveness of connection from male probe pin to oximeter female socket, coating on pins.
Resistor:	Change in value of resistor.
Other factors:	Change in effectiveness of solder joints.
	" " type of solder used.
	" " clarity of probe windows.
	" " electrical properties of clear silicon.
	" " optical properties of backing silicon.
	" " external influence. i.e. electro-magnetic interference etc,
	" " any effect of cable clamp.
	" " external temperature

Table 1: Listings of most likely factors to result in a discrepancy in spO_2 reading.

Investigation

App'x	Date	Details
B	Jan 01	Accuracy of R curves installed in the DL-3000 simulator checked using latest generation Ohmeda adult finger probe and displayed spO_2 readings taken on the 3700e, 3740 & 3800 oximeters. Conclusion: Results taken for comparison.
C	Jan 01	Customer reports checked - typical P867RA SN 0G24898 taken from stock reads low; 2% against the DL-3000 simulator and 1% on the human finger. Conclusion: Valid customer reports.
D	Jan 01	Disconnection of probe shields found to cause error message of "probe failure" using the 3800 oximeter. Conclusion: 3800 model oximeter is more sophisticated in it's monitoring of probe detector return than previous models.
E	Jan 01	Aristo disposable range of probes evaluated on 3700 and 3800 model oximeters. Displayed spO_2 readings derived from Aristo disposable (neonatal) prove to be most accurate against the DL-3000 simulator and on the human finger. Conclusion: Aristo disposable (neonatal) selected as most suitable for further evaluation.
F	Jan 01	Aristo disposable (adult), Aristo disposable (neonatal), Aristo disposable (infant) and Aristo disposable (pediatric) as tested in Appendix D stripped of optics and built into Viamed P867RA (prototype)'s. Prototypes tested - accurate results from prototype using Aristo disposable (neonatal) optics. Conclusion: P867RA (prototype) using Aristo disposable (neonatal) optics selected for further evaluation.
G	Mar 01	Second P867RA (prototype) built using Aristo disposable (neonatal) optics. Both prototypes independently evaluated by two individuals producing accurate results. Both P867RA (prototype)'s sent to Southmead General Hospital for approval.
H	May 01	Full test of optics from Aristo disposables carried out. - Aristo disposable (neonatal) again prove most accurate. 2 x prototypes approved by Southmead General Hospital Batch of 25 P867RA's manufactured, proven to read accurately after testing and released (SN BE51423214 - BE51423238 inc.).
I	June 01	4 P867RA (prototype) from Medical Cables, Inc. received and tested. Prototype probes read 3% low when tested on the 3800 oximeter against the DL-3000 spO_2 simulator. Conclusion: Unsuitable.
J	July 01	Sample LED's and detectors received from Dai Shin and fitted into P867RA (prototype). Prototype tested but reads 2% low on the 3800 oximeter against the DL-3000 spO_2 simulator. Conclusion: Dai shin sample optics are unsuitable.
K	July 01	2 x P867RA (prototype) assembled using optics from Dolphin Ohmeda compatible disposables. Prototypes tested but under read by 2 to 3% on the 3800 oximeter against the DL-3000 spO_2 simulator and by 2% on the human subject. Conclusion: Dolphin disposable optics are unsuitable.
L	July 01	P867RA (prototype) constructed using Viamed optics (PDI) with an O ring immediately in front of LED and detector. Prototype reads 2% low on the 3800 oximeter against the DL-3000 spO_2 simulator. Conclusion: P867RA (prototype) is unsuitable.
M	July 01	P867RA (prototype)'s assembled and tested using LED, detector or both from Ohmeda originals and PDI optics. Conclusion: Change of LED to Ohmeda original allows prototype to read accurately against the DL-3000 and on a human subject.
N	July 01	P867RA (prototype) assembled and tested using salvaged CSI LED with 2 x infrared

		emitters but does not read on the DL-3000. Conclusion: CSI LED unsuitable and probably other LED's with 2 x IR emitters will prove unsuitable.
O	**Aug 01**	P867RA (prototype) assembled & tested using Dai Shin samples optics (LED with 2 x IR emitters) but proven not to read on 3700 & 3800 against the DL-3000. Conclusion: Dai Shin optics as above are not suitable.
P	**Aug 01**	P867RA (prototype) assembled as standard (MCI optics) except using Ohmeda original cable & tested - under read on 3800-oximeter model reduced to 1%. Conclusion: Change of cable to Ohmeda original improves under read on the 3800 oximeter.
Q	**Aug 01**	P867RA (prototype) assembled as standard (PDI optics) except using Ohmeda original cable & tested - under read on 3800 oximeter model reduced to 1%. Conclusion: Change of cable to Ohmeda original improves under read on the 3800 oximeter.
R	**Aug 01**	As detailed as possible comparison made between Viamed standard cable and two types of Ohmeda original cable (white & blue/grey) - Ohmeda original cable very different in construction and materials used. Conclusion: Samples of cable sent of for specialist evaluation and recommended new cable ordered.
S	**Sept 01**	P867RA (prototype) constructed as standard (MCI optics) and Viamed cable but with inner shield making connection between pin 9 and detector cathode - found to under read by 2% against the DL-3000 simulator on both the 3740 and 3800 model oximeter and to under read on the human finger by 2% to 3% on the 3800 oximeter. Conclusion: This prototype is not suitable.
T	**Sept 01**	P867RA (prototype) constructed as standard (MCI optics) and Viamed cable but with outer shield making connection between pin 9 and detector cathode - prototype does not work on either the 3700 or 3740 models and under reads on the 3800. Conclusion: This prototype is not suitable.
U	**Sept 01**	3 x P867RA's (MCI) shortened to a length where they were found to read correctly on the Ohmeda 3800 oximeter against the DL-3000 SpO2 simulator. Conclusion: Shortening the cable length of stock P867RA (MCI) proven to be a suitable modification to eliminate under-read problem. Unfortunately an 8ft version of the P867RA is not practical for use in operating theatres, therefore investigation to continue to find alternative solution to satisfy goals.
V	**Sept 01**	1 x P867RA's (MCI), serial no. 1B25743 stripped of outer jacket and outer shield and outer jacket substituted with heat-shrink tubing. P867RA (prototype) created evaluated. Conclusion: Removal of outer jacket and shield causes the reading shown on the 3800 oximeter to increase by 1%.
W	**Sept 01**	Pin to pin capacitance checks made on P867RA (prototype)'s serial nos. 1B25733 and 1B25743 against Ohmeda original adult finger probe, Lot27299 and as stock P867RA serial no. 1B25731 (proven to read 2% low on the 3800 oximeter against the DL-3000 simulator). Conclusion: Unable to pin point a difference in readings taken, that could be proven to cause the under read problem on the 3800 oximeter.
X	**Oct 01**	Dai shin sample optics embodied into P867RA (prototype), 3.6m, standard wiring connection. Conclusion: Dai shin sample LED transmits infrared on the incorrect wavelength. P867RA (prototype) does not read on the DL-3000 spO_2 simulator and is hence unsuitable.
Y	**Dec 01**	New cables received and P867RA (prototype)'s constructed based on PDI optics and each cable type (larger conductor cross sectional area with inner & outer screens & standard conductor cross sectional area with inner screen only). Conclusion: Both

		P867RA (prototype)'s derive displayed spO_2 reading for exactly the target spO_2 value against the DL-3000 spo2 simulator in the range 100 - 80%. P867RA (prototype) CA59318715 selected as most suitable probe.
Z	**Jan 02**	Batch of 50 P867RA (production) manufactured based on P867RA (prototype) CA59328715. Full DL-3000 test carried out of 50% of the batch at random. Conclusion: Good results from all P867RA (production) on the 3700e oximeter against the DL-3000 spO_2 simulator. Poor results from all P867RA (production) on the 3800 oximeter against the DL-3000 spO_2 simulator. Typical under-read of -3% at 98% simulated spO_2.
AA	**Jan 02**	2 x P867RA (production), serial nos. CB59538943 & CB59538947, taken from the above batch and proven to read 2% low on the DL-3000 spO_2 simulator. Both probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Conclusion: Accuracy of displayed spO_2 readings improved by using yellow / blue drive leads in parallel to LED common anode.
AB	**Feb 02**	3 x P867RA (production), serial nos. CB59538955, CB59538967 & CB59538971, taken from batch and proven to read 2% low on the DL-3000 spO_2 simulator. Both probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Standard workshop techniques used except soldering done at higher temperature. Conclusion: Displayed spO_2 readings improved by using yellow / blue drive leads in parallel to LED common anode against the DL-3000 simulator. SpO_2 readings taken on the human subject are also consistent.
AC	**Feb 02**	3 x P867RA (production), serial nos. CB59538959, CB59538965 & CB59538980 taken from batch and proven to read 2% low on the DL-3000 spO_2 simulator. Probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Completely standard workshop techniques used. Full evaluation in comparison to P867RA (prototype) serial nos. CB59538955, CB59538967 & CB59538971. Conclusion: Displayed spO_2 readings improved by using yellow / blue drive leads in parallel to LED common anode against the DL-3000 simulator. SpO_2 readings taken the human subject are also consistent for the three prototypes. Manufacture techniques used for rework P867RA (prototype)'s CB59538959, CB59538965 & CB59538980 as per standard workshop production. Results above sufficiently consistent to warrant rework of remaining 42 P867RA (production) in batch CC5953.
AD	**Mar 02**	Batch CB5953 P867RA (production) reworked based on improved results of P867RA (prototype)'s using two parallel connection from pin 4 to common anode. Full DL-3000 simulator and on-human tests carried out of the entire reworked batch. Conclusion: Good results from first 20 P867RA (reworked production) on the 3700e. Improved results from first 20 P867RA (reworked production) on the 3800 - current failure rate of 4 in 20, 20%.
AE	**May 02**	Failed P867RA (production) from batch CB5953 (after rework) examined to establish the cause of their under read. Conclusion: No major difference in any measured parameter can be pin pointed as a threshold between accurate and under reading P867RA (prototype)s.
AF	**July 02**	Batch of 10 P867RA (prototype) manufactured (CD60310539 - CD60310548) and tested on the DL-3000 spo2 simulator and on the human finger. Probes (either passed or

		failed) examined to establish component(s) causing the under read problem. Conclusion: Suspect low through current and or low IR light output of IR diodes leads is resulting in under read.
AG	**Sept 02**	Electrical characteristic of Ohmeda Adult re-useable finger probe measured for red and infrared emitters. Conclusion: Ohmeda original adult re-useable finger probe, Lot 27299 accepts a far greater IR forward diode current than a typical Viamed P867RA.
AH	**Nov 02**	10 x LED's selected based on go/no-go measurement of 14.00mA forward IR diode current at 1200mV. Batch of 10 P867RA (prototype) manufactured (CE60420655-CE60420664). Measurements redone after fit into wiring harness with connector and after clip fit. Probes tested on the DL-3000 spo2 simulator and on the human finger. Failed probes examined to establish component(s) causing the under read problem. Intensities of red and infrared emitters measured on all probes. Conclusion: Again, failed P867RA (prototype)s can be seen to have lower forward IR diode currents than P867RA (prototype)s which pass. However at this time, it cannot be concluded that the lower intensities of IR diodes on under reading probes is not the root cause on the problem.
AI	**Dec 02**	Adapter cable manufactured allowing LED common, IR diode cathode & red diode cathode to be tapped into. 3.3Ω resistor introduced in series into LED common, IR diode cathode & red diode cathode. Conclusion: 2nd IR diode introduced in parallel with probe IR diode proves that 3 x under reading P867RA (prototype) can be made to read accurately and implies that the electrical properties on the probe as sensed by the 3900 is more important than the intensity of IR emitted.
AJ	**Jan 03**	New LED's received, PDI-E8078, and assembled into 10 x P867RA (prototype), batch no. CL6261. Probes tested against the DL-3000 and on the human finger. LED characteristics recorded to see if any pattern could be seen to relate the diode impedance to displayed SpO_2 value. 30 LED's tested to plot forward diode characteristics. Further batch of 10 P867RA (prototype), batch no. DA6269, with diodes taken from the above 30 at random. Conclusion: P867RA (prototype), batch CL6261, show promising results with no more than -1% error at 98% against the DL-3000. Analysis of LED characteristics / emission wavelength does not reveal a physical property that causes an under read. P867RA (prototype), batch DA6269, show very consistant results with 97% @ 98% DL-3000 and 58% @ 60 % DL-3000 (care taken during testing of these probes to ensure that the alignment of the probe optics to test finger optics were as consistent as possible from probe to probe). Characteristics of LEDs 11 - 30 seem to be more consistent than characteristics of previously used PDI-E835. PDI-E8078 does not meet the specification drawn up in Appendix AI, however the part seems to improve the reading of displayed SpO_2 by 1% @ 98% against the DL-3000.
AK	**Jan 03**	P867RA (prototype), batch no. CL6261, fitted with 43.0kohm resistors. P867RA (prototype), batch no. DA6269, fitted with 43.0kohm resistors. Probes tested against the DL-3000 and on the human finger. anode. Probe LED current tested @ 1800mV (red) & 1200mV (IR). Conclusion: One under reading probe in batch CL6261 also with the lowest If (IR) of all the probes. No under reading probes in batch DA6269. Current failure rate of 5%.

Conclusion of investigation

Investigation into the under read shown by the Viamed P867RA adult re-useable pulse oximeter finger probe has taken some time to bear fruit. There have been a number of theories that seemed promising after initial trial but ultimately when in full production did not provide the solution required. Equally, misleading results caused the incorrect decisions to be made and delays incurred.

At the conclusion of the investigation, the present thoughts on the cause of the under read are that the forward electrical characteristic of the infrared diode has to be a certain sleepiness, it's exact shape remains unknown. It appears that probes with infrared diodes which conduct less that others at a given forward voltage, would be more inclined to under read than otherwise.

For example, probe CL62615122 shows a displayed spO_2 value of 96% against the DL-3000
spO_2 simulator set at 98%; a 2% under read. When the same probe is connected into an adapter cable boosting the current drawn by approximately 4mA at a Vf (IR) of 1200mV, the displayed spO2 rises to 98%; no under read. Components within the adapter cable can be set such that the displayed spO_2 when using the probe / extension combination improves by only +1%.

Whether the oximeter drives a 'faulty' LED differently or interprets the information returned from it's detector in the different way, the result is an under read. It cannot be established whether gradient of the forward electrical characteristic of the infrared diode at a point causes the under read or whether the overall shape over the entire range is the crucial factor.

At the present date, the current failure rate if P867RA (prototype) embodying PDI-E8078 LED's is 5%. With only 20 probes manufactured and tested, this failure rate may be as the result of the single rogue LED or a inherent problem. Either way, full scale production with testing of parts prior to fit, testing of completed probes on the component tester, followed by testing on the DL-3000 throughout the clinical range and finally testing on a human finger, should quickly highlight whether the PDI-E8078 LED produces a consistently accurate probe.

Report : Underread of P867RA on Ohmeda 3700e oximeter.

05-07-02.

Three probes tested: CF61092252, CF61092262, CF61092263.

Probe SN.	Test result against DL-3000 @ 97%.
CF61092252	Initially reads 93%. Increases to 95% in approx 5 seconds, then increases to stable 97% in approx 40 seconds.
CF61092262	Reads 95% for full duration of test.
CF61092263	Initially reads 93%, climbing to stable 97% in 5 seconds.

Probe SN.	λ (red) nm.	Λ (infrared) nm.	Ident resistor Kohms.
CF61092252	658.0	928.3	56.2
CF61092262	658.0	928.3	56.3
CF61092263	658.0	931.5	56.7

Spec: Red 660+/-3nm: All probes OK.
Infrared 940+/-10nm: All probes at very lowest wavelength to meet specs.

LED electrical characteristic: CF61092252 (probe alone).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	0.04
1400	0.00	900	0.07
1450	0.05	950	0.14
1500	0.11	1000	0.32
1550	0.27	1050	0.81
1600	0.81	1100	2.08
1650	2.48	1150	4.49
1700	5.79	1200	8.08
1750	10.36	--	--
1800	15.77	--	--

LED electrical characteristic: CF61092262 (probe alone).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	0.04
1400	0.00	900	0.08
1450	0.05	950	0.17
1500	0.08	1000	0.38
1550	0.20	1050	0.91
1600	0.66	1100	2.08
1650	2.25	1150	4.08
1700	5.54	1200	6.76
1750	10.30	--	--
1800	15.68	--	--

LED electrical characteristic: CF61092263 (probe alone).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	0.04
1400	0.00	900	0.07
1450	0.03	950	0.14
1500	0.07	1000	0.33
1550	0.19	1050	0.93
1600	0.51	1100	2.53
1650	1.96	1150	5.72
1700	4.99	1200	10.33
1750	9.32	--	--
1800	14.68	--	--

LED electrical characteristic: CF61092252 (probe with adapter fitted).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	2.45
1400	0.00	900	2.99
1450	0.05	950	3.58
1500	0.11	1000	4.30
1550	0.27	1050	5.33
1600	0.81	1100	7.16
1650	2.48	1150	10.12
1700	5.79	1200	14.28
1750	10.36	--	---
1800	15.77	--	--

LED electrical characteristic: CF61092262 (probe with adapter fitted).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	2.45
1400	0.00	900	3.00
1450	0.05	950	3.61
1500	0.08	1000	4.36
1550	0.20	1050	5.43
1600	0.66	1100	7.16
1650	2.25	1150	9.71
1700	5.54	1200	12.96
1750	10.30	--	--
1800	15.68	--	--

LED electrical characteristic: CF61092263 (probe with adapter fitted).

Vf (red) mV	If (red) mA	Vf (infrared) mV	If (infrared) mA
1350	0.00	850	2.45
1400	0.00	900	2.99
1450	0.03	950	3.58
1500	0.07	1000	4.31
1550	0.19	1050	5.45
1600	0.51	1100	7.61
1650	1.96	1150	11.35
1700	4.99	1200	16.53
1750	9.32	--	--
1800	14.68	--	--

Probes tested with adapter cable fitted:

Probe SN:	Test result against DL-3000 @ 97%.
CF61092252	96% for 3 seconds then stable 97%.
CF61092262	Reads 96% initially, increasing to 97/98% from then on.
CF61092263	Initially 96%, 97% in approx 1 second, then 98% from then on.

Conclusion:

Infrared emitters fitted in these probes do not conduct sufficiently high levels of current to be compatible with the Ohmeda 3700e, resulting in low readings of spO2.

Action req'd:

Alternatively:

1. Replace LED's with components capable of conducting higher levels of current for the infrared emitter.

2. Fit a series diode resistor combination in parallel to the infrared emitter to increase current with the driving 3700e thereby increasing displayed spO2.

Results of tests on MCI based P867RA (special) : SW : 17-08-01.

As stock except slightly shortened.

Wavelength (red) : 654.7-658.0nm.
Wavelength (infrared) : 931.5nm.
Resistor : 21.889kohm.
Length :
Forward diode voltage (red) : 1.5V.
Forward diode voltage (infrared) : 1.0V.
Forward diode voltage (detector) : 0.4V.
DL3000 module returns (attenuated setting) : Red, 39, Infrared, 26.
Reads 96% on 3800 against DL3000.
Human : SW : 97%.

Test of emitters and detector (voltages and currents measured at connector).
Detector test c/o sheilded from ambient light.

MCI LED removed.

Red current at measured voltage .	Infrared current at measured voltage.	Detector voltage in response to red.	Detector voltage in response to infrared.
	700mV,		700mV,
	750mV,		750mV,
	800mV,		800mV,
	850mV,		850mV,
	900mV,		900mV,
	950mV,		950mV,
	1000mV,		1000mV,
	1050mV,		1050mV,
	1100mV,		1100mV,
	1150mV,		1150mV,
1200mV,	1200mV,	1200mV,	1200mV,
1250mV,		1250mV,	
1300mV,		1300mV,	
1350mV,		1350mV,	
1400mV,		1400mV,	
1450mV,		1450mV,	
1500mV,		1500mV,	
1550mV,		1550mV,	
1600mV,		1600mV,	
1650mV,		1650mV,	
1700mV,		1700mV,	
1750mV,		1750mV,	
1800mV,		1800mV,	

As stock except Ohmeda LED fitted & slightly shortened.

Wavelength (red) : nm.
Wavelength (infrared) : nm.
Resistor : kohm.
Length :
Forward diode voltage (red) : V.
Forward diode voltage (infrared) : V.
Forward diode voltage (detector) : V.
DL3000 module returns (attenuated setting) : Red, , Infrared, .
Reads % on 3800 against DL3000.
Human : SW : %.

Ohmeda LED fitted.

Red current at measured voltage .	Infrared current at measured voltage.	Detector voltage in response to red.	Detector voltage in response to infrared.
	700mV,		700mV,
	750mV,		750mV,
	800mV,		800mV,
	850mV,		850mV,
	900mV,		900mV,
	950mV,		950mV,
	1000mV,		1000mV,
	1050mV,		1050mV,
	1100mV,		1100mV,
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1350mV,		1350mV,	
1400mV,		1400mV,	
1450mV,		1450mV,	
1500mV,		1500mV,	
1550mV,		1550mV,	
1600mV,		1600mV,	
1650mV,		1650mV,	
1700mV,		1700mV,	
1750mV,		1750mV,	
1800mV,		1800mV,	

Clinical Trials.

Extensive Clinical Trials have been carried out in a number of UK Hospitals, to assess the accuracy and compatibility of Viamed SpO_2 probes. Trials were carried out, collating information on SpO_2 levels against blood gas analysis, in patients undergoing a variety of treatments including administered drugs, arterial lines and %oxygen inhalation.

Dr A Cohen, Director of I.T.U, oversaw a major project, recording 588 readings at St James's University Hospital, Leeds. St James's is one of Europe's largest hospitals, having a substantial Intensive Care Unit.

Trials were also carried out at the University of Florida, an institution currently evaluating pulse oximetry techniques and the University College of Los Angeles.

It was felt that an 'Operational' trial was required, to effectively highlight a correlation between potential errors in SpO_2 measurement to patient treatment ongoing at the time. Data was taken from patients undergoing a variety of treatments, in the normal, 'day to day' hospital environment. The trial was **not** carried out on volunteers using artificial SpO_2 manipulation.

In all, hundreds of readings were taken, on which statistical and trend analysis was carried out. Tables of data are included overleaf. Graphical and statistical analysis of the data collated for the two probe types is shown overleaf.

The data should be interpreted with an understanding of the inherent inaccuracies of pulse oximetry. Pulse oximetry measures 'functional' SpO_2. Co-oximetry measures 'fractional' SpO_2 and blood gas analysis derives SaO_2 values. There may be a difference of $\pm(1 - 2)\%$ between pulse oximetry derived oxygen concentrations to that of co-oximetry and blood gas analysis.

Nellcor probes are quoted as having a SpO_2 accuracy of ($\pm$ 1 SD), 70 – 100% $\pm$ 2 digits.

The cumulative difference between pulse oximetry and other methods of oxygen concentration derivation is a combination of the original specification of the probe, differences between SpO_2 and SaO_2 and also errors induced due to the clinical condition of patients.

Published papers, which the reader may find relevant, are as follows:

1. **"Precision and Accuracy of Pulse Oxymetry".**

   Authors: P. Ahlburd M.D.,
   J. Norreslet M.D.,
   K. Knage M.D.,
   T. Nielson M.D.,
   J. B. Rasmussen M.D.,
   I. Brandsland M.D., DMSC.

   Department of Anaesthesia and Intensive Care and Department of Chemistry,
   Vejle Hospital,
   Denmark.

2. **"Potential Errors in Pulse Oximetry".**

   Authors: R. K. Webb, MB, BS, FFARACS,
   A. C. Ralston, BSc, BappSc,
   W. B. Runciman, BSc (Med), PhD.

   Department of Anaesthesia and Intensive Care,
   Royal Adelaide Hospital,
   Adelaide, Australia.

3. **"A Comparison of the Performance of 20 Pulse Oximeters under Conditions of Poor Perfusion".**

   Authors : D. G. Clayton, BSc, MB, BS, FFARCS,
   R. K. Webb, MB, BS, FFARACS,
   A. C. Ralston, BSc, BappSc,
   D. Duthie, MB, BCh, FFARACS,
   W. B. Runciman, BSc (Med), PhD.

   Department of Anaesthesia and Intensive Care,
   Royal Adelaide Hospital,
   Adelaide, Australia.

4. **"Oximetry Sensors: Factors that Impact Accuracy".**

   Published by Nellcor Puritan Bennett.

CLINICAL TRIAL REPORTS

Objectives

- To ensure that the SpO2 Probes perform to the same accuracy claimed by the manufacturer when used with the manufacturers instrument.
- To validate the claims that the probes are compatible with the original manufacturer's
- To collect sufficient data to satisfy the CE Mark requirements
- To collect sufficient data to satisfy F.D.A. 510K submission

Ongoing tests to ensure the quality of the sensor is consistent

Protocol

A comparison of readings will be provided between the SpO2 probe and blood gas values, readings to be logged at the time of blood sample being taken.

Using production type sensors a defined number will be loaned to a named hospital department with a named person of contact. The following information should be obtained.

a) Patients Ailment
b) Identification Number to Trace Original paperwork of Patient
c) Identity of Probe
d) Blood Gas reading
e) Probe reading
f) Dates
g) Notes on abnormalities
h) Is the equipment the original manufacturers for the probe used?

1. It is expected that each probe should be used in as wide a range of environments and situations as possible.
2. When a probe becomes unusable for any reason it should be returned to the supplier whereupon a replacement will be supplied free of charge.
3. The information gathered can be supplied on paper, hard disk or sent electronically.
4. The Hospital should retain all the original paperwork.

VIAMED

Clinical Trials & Compatibility Studies on SpO_2 Probes

Objectives

1. To ensure that the SpO_2 probes perform to the same accuracy claimed by the manufacturer when used with the manufacturers instrument.
2. To validate the claims that the probes are compatible with the original manufacturer's
3. To collect sufficient data to satisfy the CE mark requirements
4. To collect sufficient data to satisfy F.D.A. 510K submission

On-going tests to ensure the quality of the sensors is consistent.

PROTOCOL

A comparison of readings will be provided between the SPO_2 probe and blood gas values, readings to be logged at the time of blood sample being taken.

Using production type sensors a defined number will be loaned to a named hospital department with a named person of contact. The following information should be obtained

a) Patients Ailment:
b) Identification Number To Trace Original Paper Work Of Patient:
c) Identity of Probe
d) Blood Gas Reading
e) Probe Reading
f) Dates
g) Notes on abnormalities, environment etc.
h) Is the equipment the original manufacturers for the probe used?

1. It is expected that each probe should be used in as wide a range of environments and situations as possible
2. When a probe becomes unusable for any reason it should be returned to the supplier where upon a replacement will be supplied free of charge.
3. The information gathered can be supplied on paper ,hard disk or sent electronically
4. The hospital should retain all original paper work

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Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
Registration No 12917565 in England

Clinical Trials & Compatibility Studies On SpO2 Probes

REPORT DATE : 09/03/98

HOSPITAL : St James's University Hospital Leeds UK

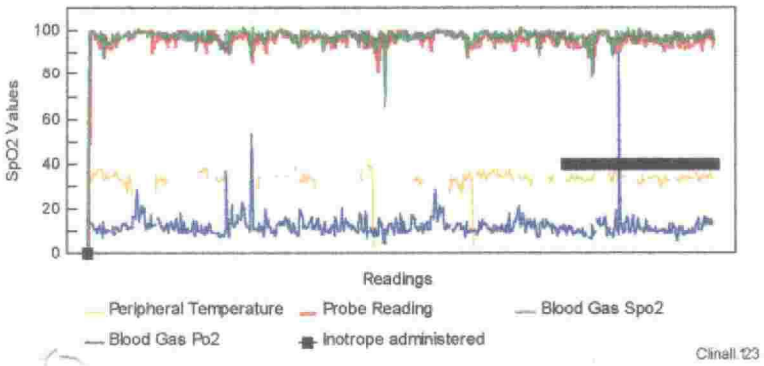
PR E DETAILS : P856RA (Nellcor Equivalent) Quantity In Use : 20 probes used on Mennen Medical HXL Patient Monitors

CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

Total Number Of Readings : 588

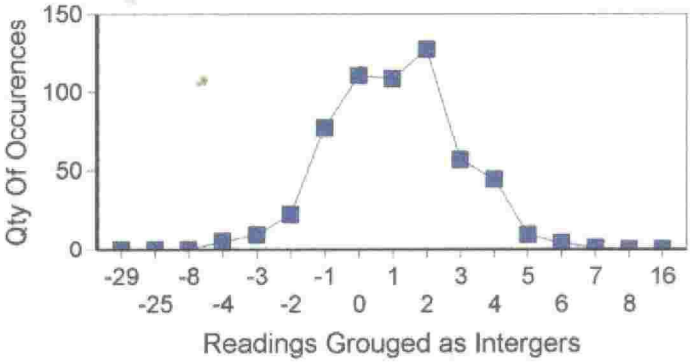
CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

This Page Details : All Readings



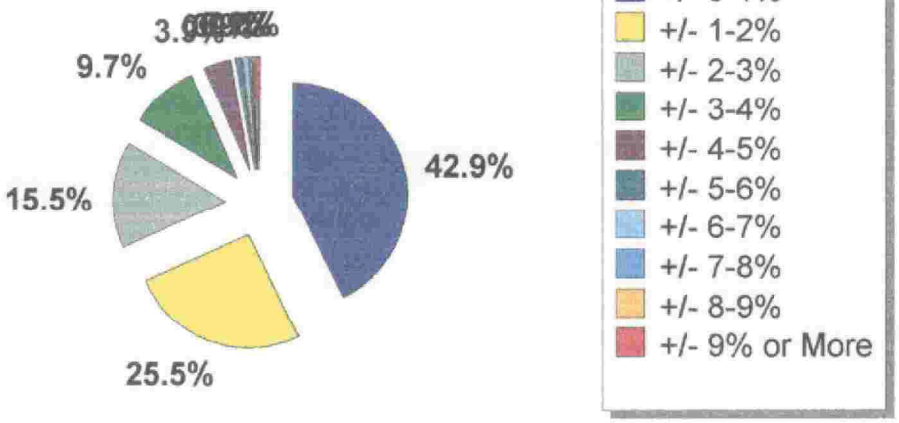
Standard Deviation

Difference in Readings between Probe & Blood Gas

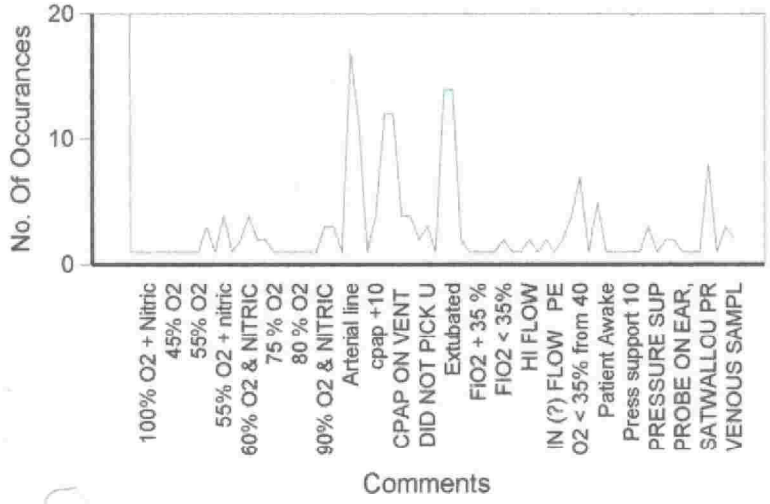


Difference

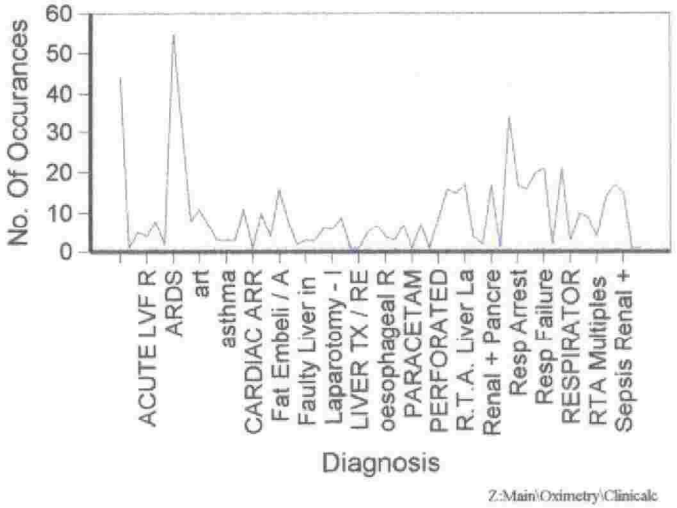
Between Probe & Blood Gas SpO2 Readings



Comments



Diagnosis



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Clinical Trials & Compatibility Studies On SpO2 Probes

REPORT DATE : 09/03/98

HOSPITAL : St James's University Hospital Leeds UK

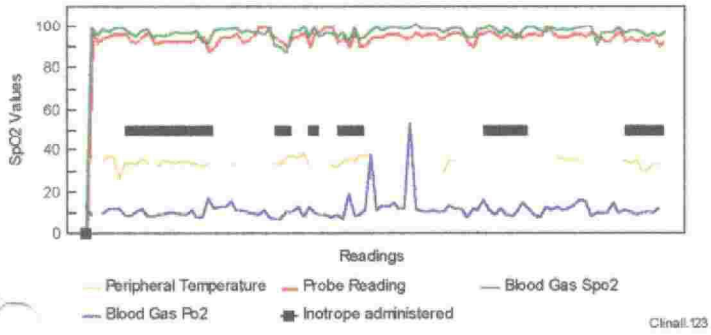
PROBE DETAILS : P856RA (Nellcor Equivalent) Quantity In Use : 20 probes used on Mennen Medical HXL Patient Monitors

CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

Total Number Of Readings : 186

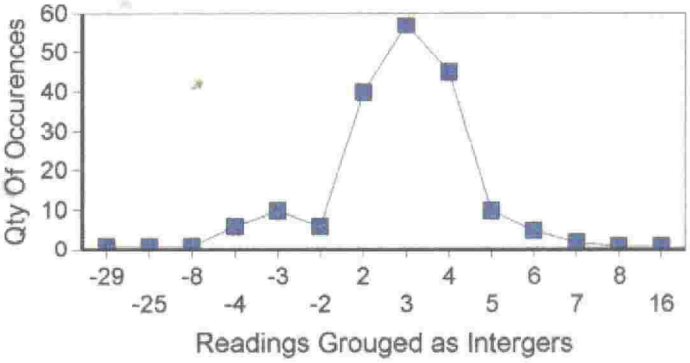
CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

This Page Details : Readings with +/- 2% Difference in between Blood gas & probe



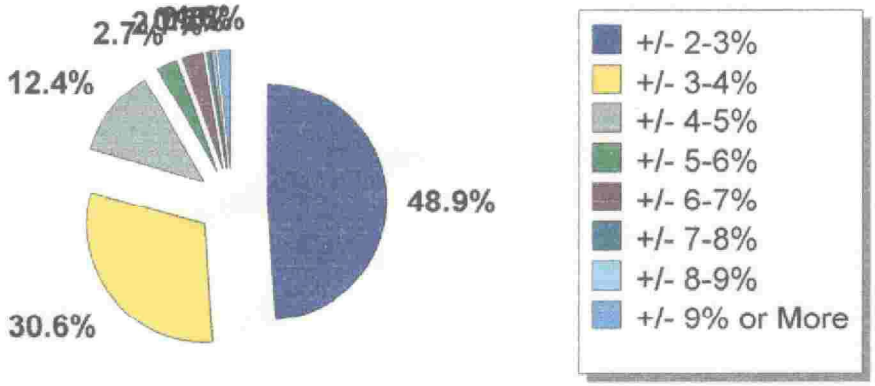
Standard Deviation

Difference in Readings between Probe & Blood Gas



Difference

Between Probe & Blood Gas SpO2 Readings



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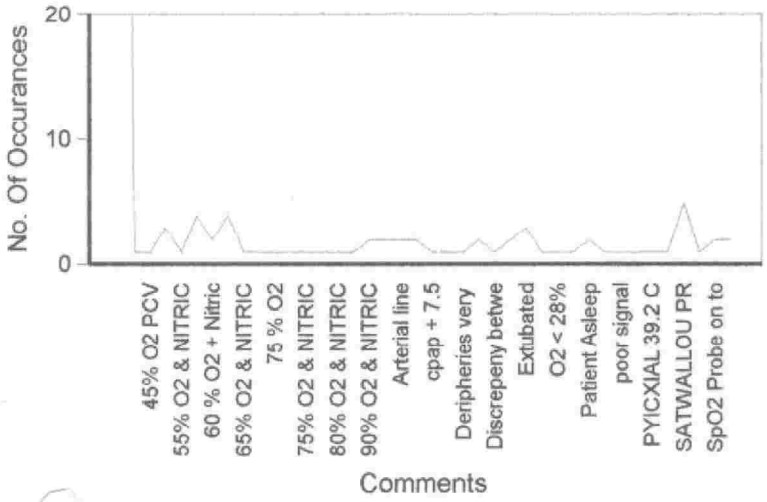
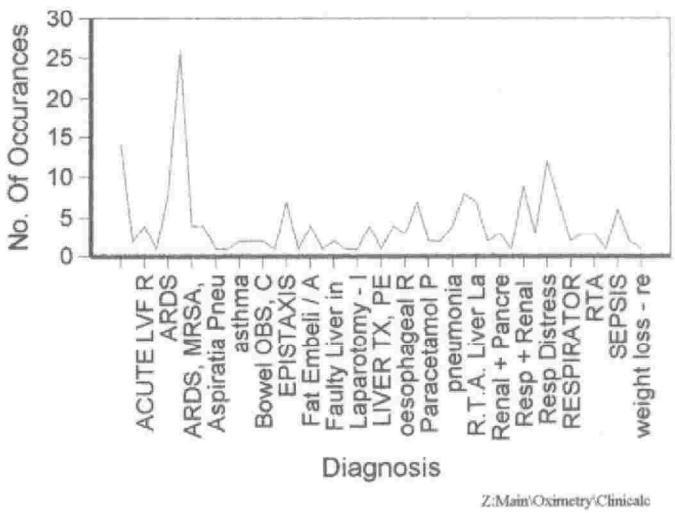


Diagnosis



Z:Main\Oximetry\Clinicalc

Clinical Trials & Compatibility Studies On SpO2 Probes

REPORT DATE : 09/03/98

HOSPITAL : St James's University Hospital Leeds UK

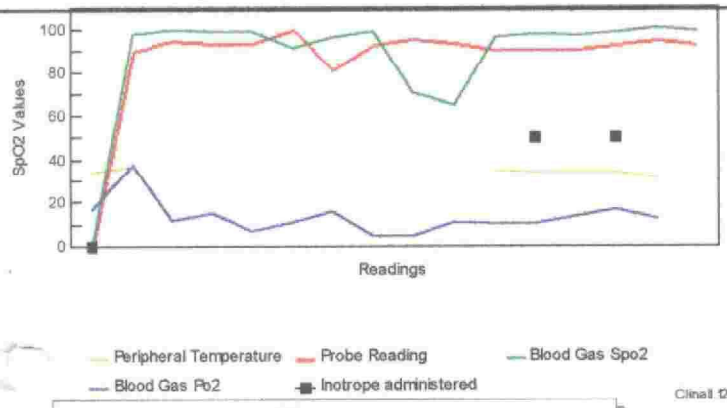
PROBE DETAILS : P856RA (Nellcor Equivalent) Quantity In Use : 20 probes used on Mennen Medical HXL Patient Monitors

CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

Total Number Of Readings : 15

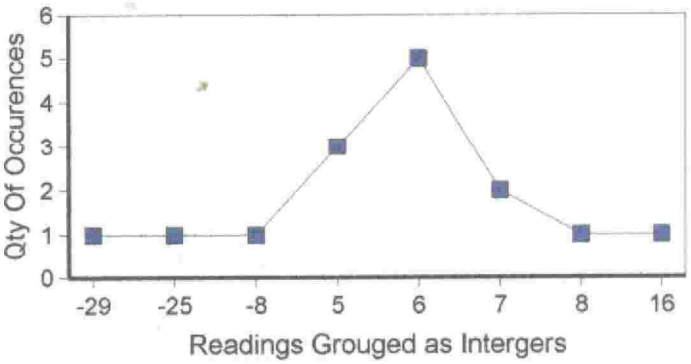
CONTACT : (ITU) Dr A Cohen Over looks project, Mrs J Thornton Completes the ground work. Tel 01132 06 433144 Bleep 5228

This Page Details : Readings with +/- 5% Difference in between Blood gas & probe



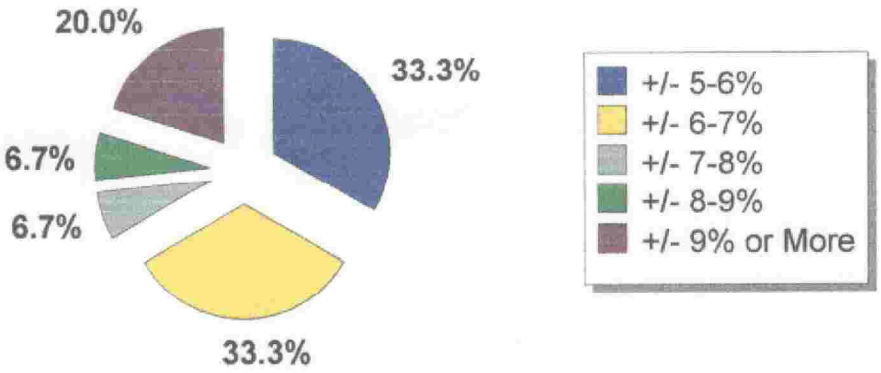
Standard Deviation

Difference in Readings between Probe & Blood Gas

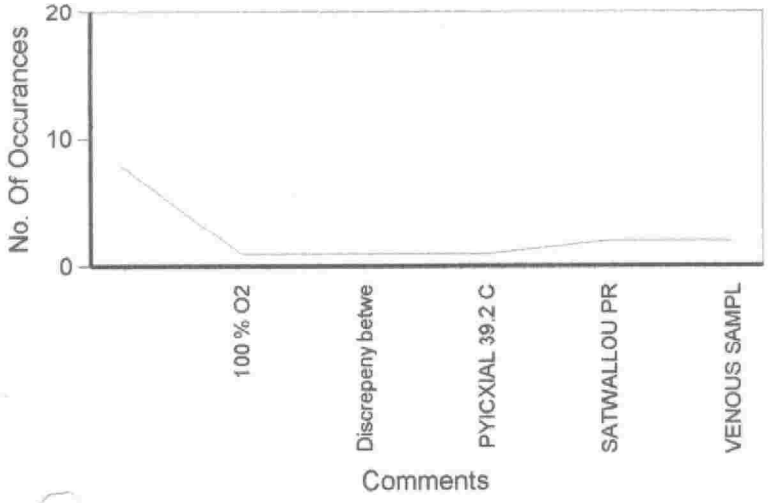


Difference

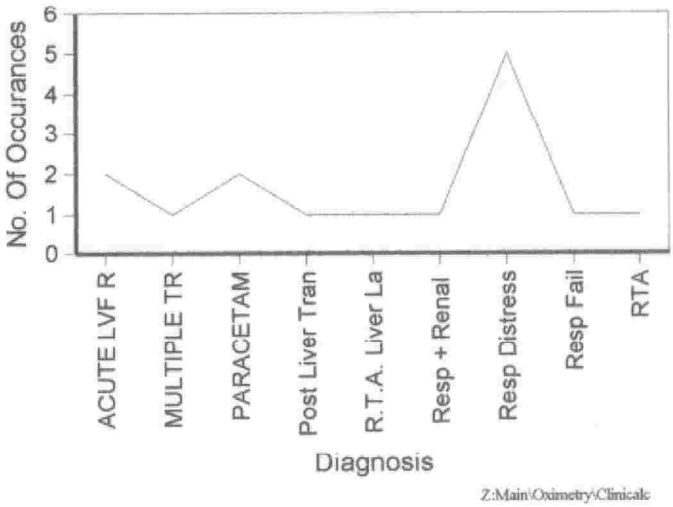
Between Probe & Blood Gas SpO2 Readings



Comments



Diagnosis



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Clinical Trials & Compatiblity Studies on

Sp02 Probes

Objective.. To produce data in order to compare **Viamed Sp02 Probes** with Blood Gas Readings.***Probe readings should be written in at the time of blood sample being taken.***

Probe Serial Number:.....\UKT Patient Initials..... Patient Study No. ..... Hospital.....

* If Patient is on low dose of Dopamine only **DO NOT SAY [Y]** in this column

Date	Sample Time	Diagnosis	Inotrope * Y/N	Peripheral Temperature	Probe Readings	Blood Gas Readings Sao2	P02	Comments

Please return all damaged probes to Viamed

Direct all queries to Peter Lamb at **Viamed** Tel 01535-634542 or your hospital contact .....