

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