

Underread of P867RA probes on Ohmeda 3800 pulse oximeter : 19-1-01 : SW.

Aristo range of probes evaluated on 3700 & 3800 pulse oximeters.
Recorded SpO2 as below.

Aristo Finger:	3700: 94% @ 97% (DL)	Human (SW): 100.
	3800: 94% @ 97% (DL)	Human (SW): 99.
Aristo Y probe:	3700: 95% @ 97% (DL)	Human (SW): 99.
	3800: 95% @ 97% (DL)	Human (SW): 97.
Aristo Disposable : (Adult)	3700: 95% @ 97% (DL)	Human (SW): 99.
	3800: 94% @ 97% (DL)	Human (SW): 99.
Aristo Disposable : (Neonatal)	3700: 97% @ 97% (DL)	Human (SW): 98.
	3800: 96% @ 97% (DL)	Human (SW): 97.
Aristo Disposable : (Pediatric)	3700: Can't test on DL	Human (SW): 99.
	3800: Can't test on DL	Human (SW): 99.
Aristo Ear Neonatal:	3700: 95% @ 97% (DL)	Human (SW): 99.
	3800: 94% @ 97% (DL)	Human (SW): 99.
Aristo D.O.T : (Adult)	3700: 95% @ 97% (DL)	Human (SW): 99.
	3800: 94% @ 97% (DL)	Human (SW): 98.
OSS Disposable:	3700: 97% @ 97% (DL)	Human (SW): 100.
	3800: 95% @ 97% (DL)	Human (SW): 98.

* Aristo disposable neonatal selected as most consistent SpO2 reading on simulator and human subject. Aristo disposable adult noted to have alternative detector, therefore selected also as a comparison. LED's & detectors from both probes removed and fitted into Viamed finger probes for further evaluation.

Prototype P867RA (Labelled A1, based upon Aristo disposable adult optics).

DL-3000 :	97	95	90	80	70	60
3700e :	95	93	89	80	71	62

DL-3000 :	97	95	90	80	70	60
3800 :	94	93	88	78	69	59

Human : 3700 : 98
 3800 : 96

Prototype P867RA (Labelled A2, based upon Aristo disposable neonatal optics).

DL-3000 :	97	95	90	80	70	60
3700e :	97	95	90	80	70	61

DL-3000 :	97	95	90	80	70	60
3800 :	97	95	90	80	70	60

Human (SW) 3700 : 99
 3800 : 99/98

Prototype P867RA (A1) shows inconsistent SpO2 readings, therefore rejected.
 Prototype P867RA (A2) shows consistent SpO2 readings, therefore further evaluated.

Test of Prototype P867RA (A2) on human subjects.

Subject 1 (MS)	3700 : 99/98	3800 : 99
Subject 2 (SW)	3700 : 99	3800 : 99/98
Subject 3 (AB)	3700 : 99/98	3800 : 98
Subject 4 (MFG)	3700 : 98	3800 : 98
Subject 5 (DB)	3700 : 98	3800 : 98
Subject 6 (JB)	3700 : 98	3800 : 98
Subject 7 (RT)	3700 : 98	3800 : 98
Subject 8 (SV)	3700 : 98	3800 : 98
Subject 9 (LN)	3700 : 97	3800 : 98
Subject 10 (MS)	3700 : 100	3800 : 100
Subject 11 (RA)	3700 : 99	3800 : 98/97
Subject 12 (AH)	3700 : 97	3800 : 96
Subject 13 (ML)	3700 : 96	3800 : 97/96
Subject 14 (RM)	3700 : 99	3800 : 99

Prototype probe (A2) seems to reproduce SpO2 values consistently (+/- 1%) on both 3700 & 3800 oximeters. Alignment problems minimised, as below, however recommend index marks to be introduced and optics moved forward more towards finger nail area.

A2 : Aligned	3700 : 100/99	3800 : 99
A2 : Misaligned	3700 : 98	3800 : 98

P867RA underread on 3800 : SW : 03-05-01.

4 Aristo lot no. / Part nos selected to be built up into Viamed clips - results as follows :-

Part no. 241-1, Lot no. 0038-1 (line 1 from table)

3700 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	98	97	96	95	90	86/85	81/80
Human :	98/97 (SW)						

3800 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	97	96	95	94	89	83	78
Human :	98 (SW)						

Conclusion : OK.

Part no. 241-1, lot no. 0031-2 (line 2 from table)

3700 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	97/96	96	95	94	90	85	81
Human :	96 (SW)						

3800 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	96	95	94	93	88	83	78
Human :	96 (SW)						

Conclusion : Unsuitable.

Part no. 241-1, lot no. 0027-3 (line 3 from table)

3700 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	97	96	95	94	89	85	80
Human :	97(SW)						

3800 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	96/95	95	94	93	88	83	78
Human :	96 (SW)						

Conclusion : Unsuitable.

Part no. 241-1, lot no. 0038-1 (line 15 from table)

3700 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	98	97	96	95	90	86	81
Human :	100 (SW)						

3800 oximeter.

DL3000 target :	98	97	96	95	90	85	80
Displayed :	98	97	96	95/94	89	84	79
Human :	99 (SW)						

Conclusion : OK.