FAX REF. :

DATE 20 May 1997

Jack Kimbro
UDT Sensors Inc.
12525 Chadron Ave.: Hawthorne. CA 90250 . USA

Dear Jack,

Samples of Ohmeda Probes

We are testing your samples of Ohmeda probes with our tester and are finding inaccuracies of around 2% low at 99% and 2% High at 60%.

This could be because you have matched LED's to a probe with 56K ohm resistors.

Most Ohmeda appear to have 68K.

NB We have simulated a resistor change from 20K to 94K (limits our Ohmeda instrument accepts) we can change the accuracy by about 5% at 60% but only 0.5% at 98%.

Tomorrow we are going to test the probes on a Oximeter tester and on a Bio-Tec Index.

Is there any chance you can build a probe using an Ohmeda with a 68K?

We need to find a combination that not only works on the patient but works with the simulators.

If you cannot obtain a sample please let us know.

Kind Regards,

John S. Lamb.

CC Medical Cables Inc.

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 Jan 2002	P867RA assembled using high output infrared LED from Dai Shin - read on finger, doesnot work on DL-3000. 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 : 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.

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.	

P867RA underead 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.

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,
	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,	

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.

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.

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. < 1µA.	907mV, 53µA. 948mV, 142µA.	< 3.2mV. < 3.2mV.	907mV, 34.7mV. 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.	

VIAMED

Variation in product specification

P856RA Nellcor compatible

S/N 941568 ME to 941667 ME

Variation from Viamed specification:

During the design of this probe a range of Nellcor probes was tested for resistor value.

Nellcor use this resistor for two purposes.

1) It informs the instrument that a probe exists

2) Disposables probes use 8K23 - 8K03

3) Y use 7k97

It became apparent that a 7K5 ohm resistor was being used by Nellcor finger probes although no actual specification has been actually published. A wide variation around this value did not effect the accuracy of the probes.

However it was decided that Viamed would use 7K5 ohm +/- 1%

Although this increased the expense it was felt that it would be better to be as accurate as possible leaving a larger margin for errors.

This batch appear to be using a +/- 5% tolerance resistor.

Although accuracy should not be compromised the supplier has been advised that in future the correct specification for this resistor must be used.

This batch have all been tested and released on my authority

J.S.Lamb

Managing Director

19 May 1999

upplier ref	P/N	S/N	Text S/N	Link	Status	Date
9619	P856RA	941568	ME	L	Printing	18/05/9
9619	P856RA	941569	ME	L	Printing	18/05/9
9[illegible]	P856RA	941570	ME	L	Printing	18/05/9
9619	P856RA	941571	ME	L	Printing	18/05/9
9619	P856RA	941572	ME	L	Printing	18/05/9
9619	P856RA	941573	ME	L	Printing	18/05/9
9619	P856RA	941574	ME	L	Printing	18/05/9
9619	P856RA	941575	ME	L	Printing	18/05/9
9619	P856RA	941576	ME	L	Printing	18/05/9
9619	P856RA	941577	ME	L	Printing	18/05/9
9619	P856RA	941578	ME	L	Printing	18/05/9
9619	P856RA	941579	ME	L	Printing	18/05/9
9619	P856RA	941580	ME	L	Printing	18/05/9
9619	P856RA	941581	ME	L	Printing	18/05/9
9619	P856RA	941582	ME	L	Printing	18/05/9
9619	P856RA	941583	ME	L	Printing	18/05/9
9619	P856RA	941584	ME	L	Printing	18/05/9
9619	P856RA	941585	ME	L	Printing	18/05/9
9619	P856RA	941586	ME	L	Printing	18/05/9
9619	P856RA	941587	ME	L	Printing	18/05/9
9[illegible]	P856RA	941588	ME	L	Printing	18/05/9
9619	P856RA	941589	ME	L	Printing	18/05/9
9619	P856RA	941590	ME	L	Printing	18/05/9
9619	P856RA	941591	ME	L	Printing	18/05/9
9619	P856RA	941592	ME	L	Printing	18/05/9
9619	P856RA	941593	ME	L	Printing	18/05/9
9619	P856RA	941594	ME	L	Printing	18/05/9
9619	P856RA	941595	ME	L	Printing	18/05/9
9619	P856RA	941596	ME	L	Printing	18/05/9
9619	P856RA	941597	ME	L	Printing	18/05/9
9619	P856RA	941598	ME	L	Printing	18/05/9
9619	P856RA	941599	ME	L	Printing	18/05/9
9619	P856RA	941600	ME	L	Printing	18/05/9
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9619	P856RA	941620	ME	L	Printing	18/05/9
9619	P856RA	941621	ME	L	Printing	18/05/9
9619	P856RA	941622	ME	L	Printing	18/05/9
9619	P856RA	941623	ME	L	Printing	18/05/9
9[illegible]	P856RA	941624	ME	L	Printing	18/05/9
9619	P856RA	941625	ME	L	Printing	18/05/9
9619	P856RA	941626	ME	L	Printing	18/05/9

upplier ref	P/N	S/N	Text S/N	Link	Status	Date
9619	P856RA	941627	ME	L	Printing	18/05/9
9619	P856RA	941628	ME	L	Printing	18/05/9
96	P856RA	941629	ME	L	Printing	18/05/9
9619	P856RA	941630	ME	L	Printing	18/05/9
9619	P856RA	941631	ME	L	Printing	18/05/9
9619	P856RA	941632	ME	L	Printing	18/05/9
9619	P856RA	941633	ME	L	Printing	18/05/9
9619	P856RA	941634	ME	L	Printing	18/05/9
9619	P856RA	941635	ME	L	Printing	18/05/9
9619	P856RA	941636	ME	L	Printing	18/05/9
9619	P856RA	941637	ME	L	Printing	18/05/9
9619	P856RA	941638	ME	L	Printing	18/05/9
9619	P856RA	941639	ME	L	Printing	18/05/9
9619	P856RA	941640	ME	L	Printing	18/05/9
9619	P856RA	941641	ME	L	Printing	18/05/9
9619	P856RA	941642	ME	L	Printing	18/05/9
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9619	P856RA	941644	ME	L	Printing	18/05/9
9619	P856RA	941645	ME	L	Printing	18/05/9
9619	P856RA	941646	ME	L	Printing	18/05/9
96	P856RA	941647	ME	L	Printing	18/05/9
9619	P856RA	941648	ME	L	Printing	18/05/9
9619	P856RA	941649	ME	L	Printing	18/05/9
9619	P856RA	941650	ME	L	Printing	18/05/9
9619	P856RA	941651	ME	L	Printing	18/05/9
9619	P856RA	941652	ME	L	Printing	18/05/9
9619	P856RA	941653	ME	L	Printing	18/05/9
9619	P856RA	941654	ME	L	Printing	18/05/9
9619	P856RA	941655	ME	L	Printing	18/05/9
9619	P856RA	941656	ME	L	Printing	18/05/9
9619	P856RA	941657	ME	L	Printing	18/05/9
9619	P856RA	941658	ME	L	Printing	18/05/9
9619	P856RA	941659	ME	L	Printing	18/05/9
9619	P856RA	941660	ME	L	Printing	18/05/9
9619	P856RA	941661	ME	L	Printing	18/05/9
9619	P856RA	941662	ME	L	Printing	18/05/9
9619	P856RA	941663	ME	L	Printing	18/05/9
9619	P856RA	941664	ME	L	Printing	18/05/9
96	P856RA	941665	ME	L	Printing	18/05/9
9619	P856RA	941666	ME	L	Printing	18/05/9
9619	P856RA	941667	ME	L	Printing	18/05/9

VIAMED

From: "Medivent Ltd." <medivent@indigo.ie>
To: <info@viamed.co.uk>
Subject: Nellcor Compatible MCI Finger Probes
Date sent: Fri, 24 Apr 1998 12:55:23 +0100

Dear John,

I have just been speaking to Andrew Kennedy, Bio-Medical Engineer, Mater Hospital, Dublin regarding the Nellcor compatible MCI Finger Probe which they are evaluating.

Unfortunately the hospital users are experiencing the same problems as they had with previous MCI probes i.e. poor signal pick up/intermittent data readout. The probe is being used with H.P. Merlin systems on Post Cardiac Surgery Patients. They have been comparing the MCI probe's performance with original Boot Type H.P. Finger Sensors, Nellcor DS100A's and Aristo Probes.

As you are aware we previously had another complaint about the Nellcor compatible MCI Finger probe from a hospital who was also using the probe with H.P. Merlin systems. We have not been able to provide this user with the second probe you gave us for evaluation due to the Bioengineer being on an extended annual vacation. Instead we supplied it to a user of Siemens and Nellcor Monitors and they are happy with the Probe's performance. This may lead us to the conclusion that we have a problem using the MCI probe with H.P. systems. Consequently we may have to concentrate our marketing efforts on the new H.P. users until this issue is resolved.

As mentioned in my fax to you of 22 April please send on the seven Nellcor compatible MCI Probes due to us and we shall continue to sell these to the majority of out customers.

I look forward to receiving your comments at your convenience.

Best regards,

MEDIVENT LTD.

PHILIP STRICKLAND.

FS 28343 FS 28344

Viamed Limited, 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
Registration No 12917565 in England

CC-SN
JSL

MEDIVENT LTD.
UNIT 10, HILLS INDUSTRIAL CENTRE, LIFFEY BRIDGE, LUCAN, CO. DUBLIN, IRELAND.
Tel: + 353 1 6280338 (5 lines) Fax: + 353 1 6281904

FAX

TOTAL NUMBER OF PAGES INCLUDING COVER SHEET ..... ONE .....

IF YOU DO NOT RECEIVE ALL PAGES - PLEASE CONTACT SENDER, TEL: + 353 1 6280338

ATTN:	**MR. JOHN LAMB**	AT:	**VIAMED LIMITED**
FROM:	**PHILIP STRICKLAND**	CC:	
DATE:	**20 FEBRUARY 1998**	NO:	**0044 1535 635582**

Dear John,

As per our telephone conversation earlier this afternoon, a total of nine probes were sent back for evalutation/analysis and the serial numbers are as follows:

Serial No. 7J01728	*Supplied to Mater Hospital, Dublin.*
Serial No. 7J01729	*Supplied to Mater Hospital, Dublin.*
Serial No. 7J01730	*Supplied to Mater Hospital, Dublin.*
Serial No. 7J01732	*Supplied to Rotunda Hospital, Dublin.*
Serial No. 7J01734	*Supplied to Rotunda Hospital, Dublin.*
Serial No. 7J01735	*Medivent Sales Stock*
Serial No. 7J01736	*Medivent Sales Stock*
Serial No. 7J01737	*Medivent Sales Stock*
Serial No. 7J02026	*Medivent Sales Stock*

All probes were sent to you *per post on 17 February 1998. Please let me know when you have any feedback.*

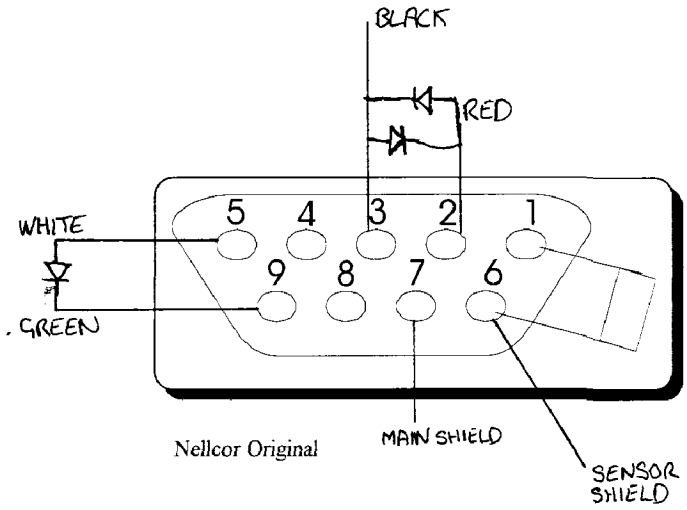
Best regards,

MEDIVENT LTD.,

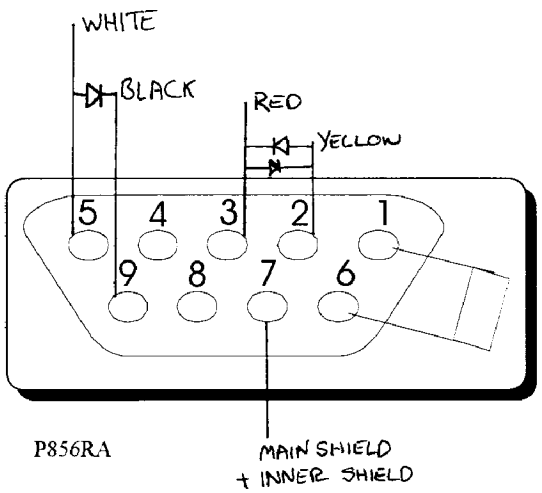
PHILIP STRICKLAND.

SN:	GLENFIELD	RESISTOR KΩ
	7J02234	7.468
	7J02236	7.481
	7J02224	7.464
	7J02227	7.454
	7J02235	7.473
	7J02237	7.469

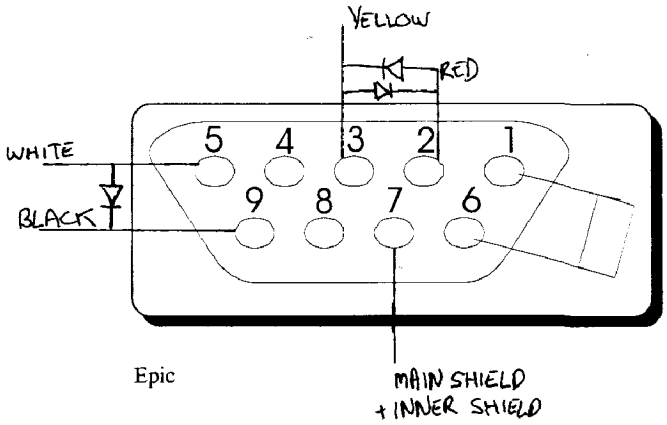
SN:	MEDIVENT	RESISTOR KΩ
	7J01737	7.474
	7J01730	7.472
	7J01736	7.458
	7J01728	7.482
	7J02026	7.475
	7J01734	7.469
	7J01729	7.481
	7J01732	7.470
	7J01735	7.478



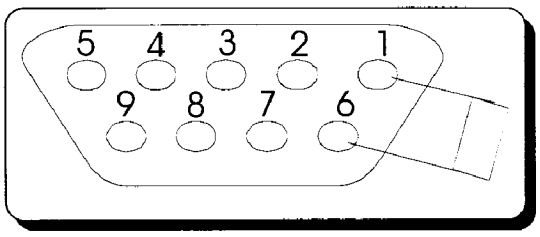
Nellcor Original



P856RA



Epic



Aristo

VIAMED

cc. JK

FAX REF. :
20 February 1998
Chris Fontana
MCI. 1340 Logan. Costa Mesa. CA 92626
Fax 001 714 545 7212

c.c. Jack Kimbro U.D.T.

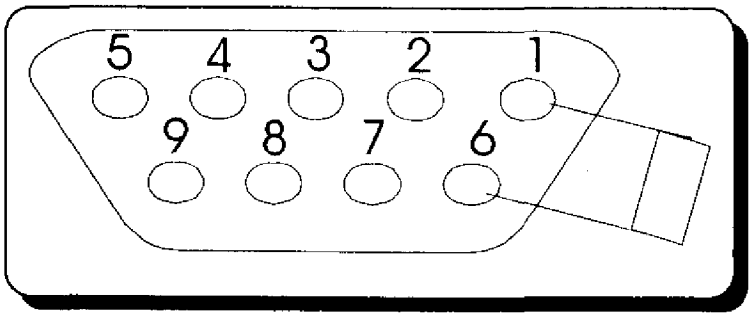
Dear Chris

URGENT

Potential problem with P856RA Possible HOLD on ALL Sales

We have had two problems notified to us this week regarding P856RA sensors. Batch **7J**

1. The sensors reportedley would not switch on an HP Merlin
   They were all tested prior to dispatch for continuity of Diodes.
2. Unreliable readings has occurred for a second time in Ireland. This time using Nellcor instruments ?.Not yet confirmed .
3. The P856RA continues to work on Nellcor instruments even under simulated (DL3000) poor conditions. We carried out tests on Nellcor instruments both here and in a local Hospital
4. So at present we are concentrating on the Merlin.
5. Please check URGENTLY at your end the current wiring diagram of the DB9 we believe there may be a difference between Nellcor and MCI. This is being checked out now and initial observations suggest we may need to re-wire a extra screen.
6. We are re-wiring a DB9 (Amp) splitting the screens and will test it on a Merlin.
7. We need to establish very quickly whether or not we have a wiring general problem or a batch problem.



The P856RA has inner and main screen connected to Pin 7. This is also true for Epic

The Original Nellcor has the inner screen separately connected to Pin 6. The inner screen is not connected at the finger clip end.

Kind regards

John S Lamb

cc J Kimbro UDT

Ajohn\MCI

FAXED 25.02.98 CLO

Viamed Limited, 15 Station Road, Cross Hills, Keighley, West Yorkshire BD20 7DT
Tel +44 (0)1535 634542/636757 Fax +44 (0)1535 635582
Email info@viamed.co.uk
Registration No 12917565 in England

Tank

SN.		RESISTOR KΩ
	8A03383	7.456
	8A03313	7.478
	8A03382	7.455
	8A03324	7.475
	8A03034	7.458
	8A03033	7.472

MEDIVENT LTD.

UNIT 10, HILLS INDUSTRIAL CENTRE, LUCAN, CO. DUBLIN, IRELAND.
TEL:+353 1 6280338 FAX: +353 1 6281904 E-mail: medivent@indigo.ie

CC SN JSL

Our Ref: PS/MCR Your Ref: Date: 17/02/98

Mr. John Lamb,
Viamed Limited,
15 Station Road,
Cross Hills,
Keighley,
West Yorkshire,
BD20 7DT
England.

Dear John,

I am sure you recall our recent discussions regarding the Mater Hospital, Dublin and their concerns about the quality of read out when using the new MCI Nellcor Compatible SP02 Finger Sensor, part no. P856RA. As we were unable to convince them that the MCI probe is as good or better than the original we ended up issuing them with a Credit Note and taking back the three units we supplied.

On 29 January 1998 the Bioengineering Department in the Rotunda Hospital, Dublin, a maternity facility, ordered for the first time 2 x MCI Nellcor Compatible Sensors, part no. P856RA and these we duly supplied. The Bioengineer received the probes and immediately supplied them on for use in the hospital. As soon as these were put in use he began receiving calls from the Nursing Staff complaining that the probes were not working correctly.

He collected the probes and called Medivent and we sent in two Engineers to investigate. Both Engineers confirmed that when placed on the finger, the MCI probes were less able to pick up signals in comparison to the Nellcor DS100A. Both Engineers concluded that the performance of the MCI probe was markedly inferior to the DS100A. They then tried brand new MCI probes, but found the same results.

MEDIVENT LTD.

UNIT 10, HILLS INDUSTRIAL CENTRE, LUCAN, CO. DUBLIN, IRELAND.
TEL:+353 1 6280338 FAX: +353 1 6281904 E-mail: medivent@indigo.ie

CC SN JSL

Our Ref: PS/MCR Your Ref: Date: 17/02/98

cont'd

As this is the second independent complaint regarding the MCI probe part no. P856RA I am sending you our stock of this probe type for evaluation. I have included new and returned probes. The Serial Numbers of the two originally supplied to the Rotunda are 7J01732 and 7J01734. Please let me have your comments as soon as possible.

Best regards,

MEDIVENT LTD.,

PHILIP STRICKLAND.

Ymddiriedolaeth GIG
Gogledd Orllewin Cymru
North West Wales NHS Trust

ADRAN ELECTRONEG/
ELECTRONICS DEPARTMENT
Ysbyty Gwynedd
~~Penrhosgarnedd~~
BANGOR
Gwynedd
LL57 2PW

Llinellau Uniongyrchol/Direct Lines: Ffôn/Tel: 01248 384358
Ffacs/Fax: 01248 370892

Ein Cyf / Our Ref: PCH/REG

11 October 1999

Mr J Lamb
Viamed
15 Station Road
Crosshills
KEIGHLEY
West Yorkshire
BD20 7DT

Dear John,

I have tried these probes on a Ohmeda 3800 picked at random and it is reading low 3%. Tried them on a Blox 3740 and they produced the correct reading.

Tried one of your existing probes on the 3800 and it read 3% low. They appear to be giving the same results as your old probes.

This problem obviously needs further investigation.

Yours sincerely

PP

Peter Hughes
TECHNICAL MANAGER

PETER

6TH OCT 99

JUST A QUICK NOTE TO KEEP YOU UP TO DATE ON THE BANGOR PROBLEM.

AS YOU ALREADY KNOW THE PROBLEM STARTED WHEN TWO OF OUR PROBES FAILED TO GIVE CORRECT READINGS WHEN USED ON AN OHMEDA 3800.

THE PULSE OXIMETER WAS REPORTED FAULTY TO THE EBME DEPARTMENT, THE PULSE OXIMETER WAS GIVING LOW READINGS (SEE PREVIOUS REPORT). THE PULSE OXIMETER WAS SENT AWAY TO OHMEDA TO HAVE A CALIBRATION CHECK, THIS WAS DONE AS NO OTHER DEPARTMENT HAD REPORTED FAILURES WITH OUR PROBES. THE PULSE OXIMETER WAS RETURNED BY OHMEDA WITH NO FAULT FOUND, AT THIS POINT THE EBME DEPARTMENT CHECKED OUR PROBES (2) AGAINST ORIGINAL AND THE LOW READINGS WERE STILL BEING DISPLAYED SO THEY CONTACTED US WITH THE PROBLEM.

I CALLED INTO THE DEPARTMENT AND SAW THE PROBLEM FIRST HAND, THE PULSE OXIMETER UNDER QUESTION WAS TESTED WITH TWO OF OUR PROBES AND AN ORIGINAL OHMEDA ON THREE PEOPLE, IN ALL THREE TESTS THE READING ON OUR PROBES WERE VERY LOW. THE PULSE OXIMETER WAS LOANED TO ME SO AS I COULD DEMONSTRATE FAULT IN THE OFFICE, THIS WAS DONE BY STEVE AND MARK AND THEY AGREED THAT IT WAS NOT CORRECT.

HOSPITAL PULSE OXIMETER RETURNED TO THE HOSPITAL AFTER AN EXTENDED LOAN AND MESSAGE LEFT WITH TECHNICIAN EXPLAINING WHAT WE ARE GOING TO DO AND THAT I WOULD CONTACT MANAGER, MR HUGHES THE NEXT DAY. THE FOLLOWING DAY MR HUGHES PHONED THE OFFICE BEFORE I CONTACTED HIM TO COMPLAIN THAT IT WAS A BIT TO IMPORTANT PROBLEM TO DISCUSS WITH A TECHNICIAN, SPOKE TO STEVE IN THE OFFICE, I CONTACTED HIM THAT DAY AND SORTED OUT THE PROBLEM AND AGREED TO TAKE IN TEST PROBES IN A COUPLE OF WEEKS.

ON THE LAST VISIT TO THE HOSPITAL TO SEE MR HUGHES TO SHOW HIM NEW VERSION OF PROBE AND TO TEST IT, I LEFT BOTH PROBES FOR A WEEK DUE TO THE PRESSURE FROM THE CUSTOMER, ONE TO BE USED ON THE MAN WHO STARTED THE PROBLEM AS HE IS THE IDEAL PERSON, CONSTANT STAFF TO COMPARE THIS VERSION TO OLD ONE. THE SECOND IS FOR TEST IN THE HOSPITAL SO AS MR HUGHES CAN SEE IT WORKS.

BOTH PROBES WERE LEFT EVEN THOUGH STEVE ONLY SUGGESTED LEAVING ONE FOR THE PREVIOUS REASON, IT WAS POINTED OUT TO MR HUGHES THAT THE PROBES WERE FOR EVALUATION ONLY AND CARRIED NO SERIAL NUMBERS.

06 OCT. '99 21:59 01785248945 VIAMED NO. 002 PAGE 03

PETER 6TH OCT 99

TODAY I HAD TWO CALLS ON MY ANSWERPHONE FROM JOHN TELLING ME THAT THE PROBES IN BANGOR HAD TO COME OUT WITHOUT FAIL TODAY, THIS WAS FOLLOWED BY A SECOND SAYING NOT TO CONTACT BANGOR AS IT IS NOW SORTED.

I CONTACT JOHN AND HE TOLD ME THAT I SHOULD NOT HAVE LEFT THE PROBES IN BANGOR ALL I WAS MEANT TO DO WAS TO SEE IF THEY WORKED, I SAID THAT AS I UNDERSTOOD MY CONVERSATION WITH STEVE IT WAS ALRIGHT TO LEAVE ONE PROBE IF I HAD TO BUT TO TRY NOT TO LEAVE BOTH, JOHN TOLD ME I WAS WRONG AND THAT STEVE SAID NOT TO LEAVE ANY PROBES IN HOSPITAL, ONLY TWO PROBES OF THIS TYPE IN VIAMED SO THEY ARE NEEDED FOR TESTING, I'M SURE STEVE TOLD ME THAT WE HAD THREE PROBES OF THIS TYPE.

ANYWAY BANGOR ARE DOING THE TEST AND RETURNING THE PROBES DIRECT TO THE OFFICE EARLY NEXT WEEK.

STEVE

MEDICAL DEVICES AGENCY

Safeguarding Public Health

15/11/2001

MDA Ref 20011105.011-3

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

MDA ADVERSE INCIDENT CENTRE (Direct Tel / Fax: 020 7972 8080 / 8109)

Dear Mr Lamb,

We have recently received the attached report from BRADFORD HOSPITALS NHS TRUST BRADFORD ROYAL INFIRMARY (their ref:) concerning the following device:

Device MONITORS, PATIENT
Item SECTION TO ALLOCATE
Model Pulse Oximeter Finger Probe
Batch Number
Serial Number

Please could you investigate this matter and tell us of your findings and any action you propose taking, liaising with the reporter as necessary. We are content for them to release any samples or devices which may help your investigation. When requesting any samples, please could you show the reporter a copy of this letter. Unless we hear otherwise, we will be relaying your response to the reporter.

Unless you are already in correspondence with the MDA regarding the performance of this device model, could you please provide the following information for our ongoing risk analysis. Please provide answers as they become available: we realise that in some instances it will not be possible to provide accurate answers until the investigation is complete.

- is the device involved in this incident CE-marked under any of the medical devices Regulations?
- is the report relevant to any other CE-marked devices that you manufacture?
- have you received any similar reports involving this model in the UK / Europe / worldwide?
- how many of these devices have you sold in the last year in the UK / Europe / worldwide?
- (where applicable) has the analysis of the manufacturing records for this batch indicated any abnormalities?

If the report is relevant to a CE-marked device, and your investigation reveals that the incident led to, or could have led to, a death or serious deterioration in health then it will be dealt with under the requirements for medical devices vigilance.

Yours sincerely

RS

Tony Sant
Manager, Adverse Incident Centre

PLEASE ACKNOWLEDGE RECEIPT

MEDICAL DEVICES AGENCY - *An Executive Agency of the Department of Health*
Hannibal House, Elephant & Castle, London SE1 6TQ. Tel: 020 7972 8000 Fax: 020 7972 8108
E-mail: mail@medical-devices.gov.uk Internet: http://www.medical-devices.gov.uk

15/11/01 ☑001

20011105; 011-5

Jeff Ali
0207 412 8019

ADVERSE INCIDENT REPORT

Relating to Medical Devices

This form should be used for reports of adverse incidents concerning medical devices, under the terms defined in HSG(93)13. HSG(93)26 and Safety Notice MDA SN9401 and SN9601. It should be completed and submitted without delay to the MEDICAL DEVICES AGENCY'S ADVERSE INCIDENT CENTRE at the address given below.

[Bradford Royal Inf]

1. ORIGIN OF REPORT

Trust/Hospital/Unit: BRADFORD HOSPITALS TRUST

Person making report: GARY L HIRD.

Position: Manager - Electro-Medical Equipment Services

Telephone/Fax No: 01274 364147 / 364134

Date and time of incident: Mon 29th Oct.

Alternative contact: Mr STEPHEN KASSIM

2. DETAILS OF MEDICAL DEVICE INVOLVED

Generic type of medical device: Pulse oximeter finger probe

Brand name: REPAIRED 'OHMEDA' Probe with new

Model/Size: Finger clip shell, used with

Serial/Product Code No: OHMEDA 3775 oximeter.

Batch/Lot No: TYPE - OHMEDA (orgually) FINGER CLIP

Manufacturer/Supplier: VIAMED.

Contact: SIMON WATMUFF.

Telephone No: 01535 634542

Does the device or its labelling bear the 'CE'marking (YES) / NO / NOT KNOWN

Date of manufacture: ——

Date put in use: July 2001.

Quantity defective: —— ALL

Location of device now: MEDICAL PHYSICS DEPT.

3. ADDRESS FOR COMPLETED FORMS OR ADVICE

Medical Devices Agency, Adverse Incident Centre, Hannibal House, Elephant and Castle, London SE1 6TQ

Direct Line: 0171 972 8080 (message service on this number outside office hours)

Fax: 0171 972 8109

Medical Devices Agency

2 - NOV 2001

Please see over page

Adverse Incident Centre

4. NATURE OF INCIDENT OR DEFECT

Was any injury caused? YES (NO)

To whom: PATIENT/STAFF/OTHER

Nature of injuries and treatment:

Consultant in charge (if known)

Details of incident or defect and local action taken:

Finger probe can be placed on the finger in a position where low O_2 saturations are indicated = 92%. Administration of O_2 to patients inappropriately. Manufacturer have now supplied instruction leaflet with specific instructions to place sensor LED/detector with over the finger nail area, this did cure the problem however this instruction was not supplied with the repaired product.

5. IMPORTANT

Devices which are the subject of this report and/or have been involved in adverse incidents should not be interfered with except for reasons of safety or to prevent loss of patient related data. Dial settings, position of taps, switches etc., and other relevant information should be recorded.

Where the device(s) has/have been used, it/they should be decontaminated, unless this would destroy material evidence in which case the device(s) should be enclosed in a suitable container to reduce the risk of infection. ***Contaminated items should not be sent through the post.*** *Advice on decontamination is given in HSG(93)26 and HC(91)33.*

For single use devices or consumables all material evidence, including wrapping materials and containers, should be preserved and suitably labelled.

The manufacturers of the devices (or their agents) may be allowed to inspect them in the presence of a responsible officer but must not be allowed to interfere with them, or remove any part, at this stage.

Further advice on decontamination, devices held in quarantine, manufacturer access to devices or other related matters may be obtained from the address overleaf. If you wish to send samples to the MDA, please sign the declaration below.

6. TRANSFER OF DEVICE TO MDA (IF RELEVANT)

I am sending this/these device(s) to you for investigation. The device(s) is/are safe to handle and relevant information is included on this form or on the attached sheet(s).

Method of decontamination used:

Signed:

Date:

CCJL

MEDICAL DEVICES AGENCY

Safeguarding Public Health

13/12/2001

Mr J Lamb
Viamed Ltd
15 Station Road
Cross Hills
Keighley
BD20 7DT

Your Re
MDA Ref20011105.011-3

MDA ADVERSE INCIDENT CENTRE (Direct tel / Fax: 020 7972 8080 / 8109)

Dear Mr Lamb

Thank you for your report in connection with the following device:

Device MONITORS, PATIENT
Item SECTION TO ALLOCATE
Model Pulse Oximeter Finger Probe
Batch
Serial Number

So far as we are concerned, the file on this report is now closed. However, we shall continue to monitor the situation and would welcome details of any additional or similar incidents.

Many thanks for your help in bringing this matter to a conclusion.

Yours sincerely

Sandra Draper

Tony Sant
Manager, Adverse Incident Centre

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

Customer Complaint Report

		CCR	
		Date	25/07/01
Customer	MARINE DENTAL PRACTICE	P.O	
File Number	11405	Invoice	
Address	36 MARINE PARADE		
Product	REPAIR		
Serial Number/s	SRN 25771	Dispatched	
Manufacturer/Supplier			
Nature of Complaint	RETURNED TO VIAMED 3 TIMES		
Result of Investigation	POSSIBLE RESISTOR PROBLEM - [redacted]. RESISTOR REPLACED. PROBE DETERMINED TO BE POOR TO PICK UP SpO_2 & HEARTRATE - PROBE REPLACED WITH NEW FROM STOCK 1866RA FOR SIMED S-100 MONITOR.		
Signed		Date 13/8/01	
Corrective Action			
External			
Internal	The problem was eventually traced to an intermittant fault in the instrument This is not re-pairable by Viamed Unit returned and invoices cancelled 17/8/01		
Signed		Date	17/8/01
MDA Informed	NO YES		QC12

Customer Complaints, User Feedback and Clinical Trials

Customer complaints and feedback information is held:

1. Complaints file.
2. Complaints file Paperport.
3. Repairs file (Approach).
4. Individual customer files.
5. Goldmine customer files.
6. Archives (up to 25years).

PETER / STEVE / JOHN

PL

14-4-98

TODAY I CALLED INTO YEOVIL DISTRICT HOSPITAL TO SEE MR ROBIN PARRY WHO IS THE SODA.

THE REASON FOR THE VISIT WAS AT JOHN'S REQUEST AS MR PARRY WAS HAVING TROUBLED WITH A SAO^2 PROBE THAT HE PURCHASED FROM US TO GO INTO HIS CAPNOCHECK PLUS MACHINE, THE PROBE DIDN'T WORK ON THE UNIT TO START WITH, IT WAS THEN RETURNED TO THE OFFICE FOR TEST, THE PROBE (P861) WORKED FINE, SO MY VISIT WAS TO FIND OUT WHATS GOING ON.

THE MONITOR IN QUESTION IS A BCI, CAPNOCHECK PLUS, MODEL 9004, IT HAS SAO^2, FIO^2 AND PULSE ON BOARD, O^2 IS ALSO THROUGH RIS CELL.

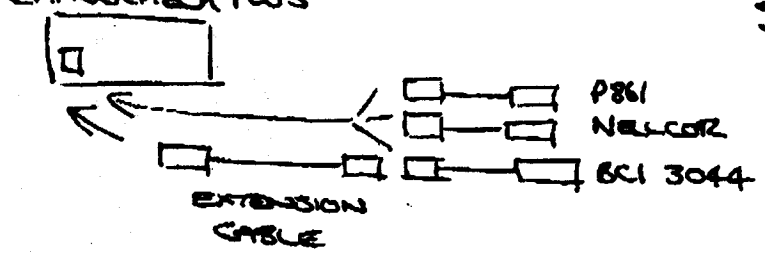
THE MONITOR WAS TESTED WITH ITS ORIGINAL PROBE, PROBE MODEL NUMBER 3044 AND WORKED FINE, OUR PROBE (P861) WAS THEN FITTED AND THIS ALSO WORKED FINE, MR BARRY DIDN'T KNOW THE REASON WHY BUT HAS A NUMBER OF THESE MONITORS AND WILL CHECK THEM ALL TO FIND OUT IF THE OLD UNIT HAS A PROBLEM. I WILL CONTACT NEXT WEEK.

ONE INTERESTING POINT FROM THIS IS THAT THE UNIT WILL ALSO WORK USING A STANDARD NELLCOR PROBE EITHER INTO EXTENSION CABLE OR DIRECT INTO UNIT.

POINT AGAINST WAS THAT THE RETAINING CLIP ON THE EXTENSION CABLE WOULD NOT GO OVER THE TOP OF THE PROBE PLUG, PLUG IS ABOUT 3MM TO LONG, NELLCOR IS THE SAME LENGTH AS OURS AND WON'T FIT EITHER.

REGARDS

STEVE H



Analysis of Complaints and Customer Feedback

Ohmeda P867RA: Failed on some very thin patients. Light transmitted through the Finger Pad was sufficient to fool the electronics into a "No Probe Connected" Unit failed safe.

Pads Changed to Black – Problem solved.

Electronically the Probes were identical with OEM.

Clinical Trials for Long-term use are ongoing.

Datex P872RA: Original Probes have had many user problems, which the compatible has tried to correct.

The use of better screening and a high quality cable has been successful.

The P872RA does not work well on the Cardiograph II.

Datex now have another new version, which is better.

The P872RA is matched to the latest Datex Probe.

Nellcor P856RA: Some problems using Nellcor on older HP Merlin have been encountered with the very thin patients.

Nellcor has in the past experienced problems with SpO2 Probes, which did not work on all patients.

The P856RA problem whereby the Nellcor monitor does not see the probe seems to be restricted to one batch (7J), with thin patients on old versions of Hewlett Packard Merlin Monitors.

Hewlett Packard has introduced a software upgrade, which appears to have eliminated the problem.

So far no problems have been serious, or involved with inaccuracies. In all instances, the instruments have failed to detect the probe.

Space Labs P857RA: Some problems arose with connection to Space Labs equipment.

After consultation with the original MCI, it was found that the configuration of these probes is not compatible with the following monitors.

90465 / 90466 / 90467

The problem was corrected by changing the P857RA to Nellcor technology.

Nellcor P856RA: A complaint was received with regard to connectors being supplied moulded 9 Pin.

After consultation with MCII it was found that due to a cable shortage, an alternative supplier was temporarily used. This problem has now been corrected.

The probes in question were returned and replaced. No further problems were reported.

Various: A number of differing faults have been reported with various probes.

The probes were tested to evaluate these faults, and a report created.

The probes were returned to MCI who undertook their own investigation. Their report indicated that they could not duplicate the problems. Their statement showed No Fault Found.

The repairs were then undertaken by Viamed to ensure correctness to specifications.

Ohmeda P867RA: A problem was found with the Hypertronics connectors not fitting the monitor socket.

The connectors were measured and some were found to be slightly oversize. Greater inspection was implemented.

The manufacture replaced the shells with correct size, and implemented tighter inspection / Q.A. controls.

Ohmeda P867RA: A problem has arisen with Low Saturation of these probes.

The MDA were involved with an Adverse Incident. Viamed responded with a letter stating our position in regard to Instructions with repaired probes. The MDA were happy with this response and subsequently closed the file.

Labels are also to be added to the repaired items.

Customer Complaint Report

		CCR	97
		Date	16.11.01
Customer	BRADFORD ROYAL INF.	P.O	
File Number	E20	Invoice	
Address	SMITH LANE, BRADFORD		
Product	OHMEDA REPAIR		
Serial Number/s	NIK	Dispatched	
Manufacturer/Supplier			
Nature of Complaint	OHMEDA SENSOR INDICATED LOW SATURATIONS. INSTRUCTION LEAFLET NOT SUPPLIED INITIALLY WHICH STATES TO PLACE OVER FINGER NAIL.		
Result of Investigation	JOHN, SPOKE TO JEFF ALL AT BRADFORD AND WILL ADDRESS THE PROBLEM WHEN HE RETURNS FROM MEDICA.		
Signed		Date	
Corrective Action			
External	See MDA Correspondence labels to be added to Repairs		
Internal			
Signed		Date	17/12/01
MDA Informed	NO YES		QC12

CCJL

MEDICAL DEVICES AGENCY

Safeguarding Public Health

13/12/2001

Mr J Lamb
Viamed Ltd
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Keighley
BD20 7DT

Your Re
MDA Ref20011105.011-3

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Serial Number

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Many thanks for your help in bringing this matter to a conclusion.

Yours sincerely

Sandra Draper

Tony Sant
Manager, Adverse Incident Centre

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

30/11/01. 82

Geoff Ali
@ Medical Devices Agency

Telephoned ref:- adverse incident investigation on probe. He has received your letter & said that they are closing investigation & will pass back to the Manufacturer. He will write to you shortly. RYH.

MEDICAL DEVICES AGENCY

Safeguarding Public Health

15/11/2001

MDA Ref 20011105.011-3

Mr J Lamb
Viamed Ltd
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Keighley
BD20 7DT

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Yours sincerely

Tony Sant
Manager, Adverse Incident Centre

15/11/01

20011105:011-5

Jeff Ali
02079428019

ADVERSE INCIDENT REPORT

Relating to Medical Devices

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[Bradford Royal Inf]

1. ORIGIN OF REPORT

Trust/Hospital/Unit: BRADFORD HOSPITALS TRUST

Person making report: GARY L HIRD.

Position: Manager - ELECTRO MEDICAL EQUIPMENT SERVICES

Telephone/Fax No: 01274 364147 / 364434

Date and time of incident: Mon 29th Oct.

Alternative contact: Mr STEPHEN KASSIM

2. DETAILS OF MEDICAL DEVICE INVOLVED

Generic type of medical device: Pulse oximeter finger Probe

Brand name: REPAIRED 'OHMEDA' Probe with new

Model/Size: Finger clip Shell, used with

Serial/Product Code No: OHMEDA 3775 oximeter.

Batch/Lot No: TYPE - OHMEDA (orgually) Finger clip

Manufacturer/Supplier: VIAMED.

Contact: Simon WATMUFF.

Telephone No: 01535 634542

Does the device or its labelling bear the 'CE'marking (YES) / NO / NOT KNOWN

Date of manufacture: ——

Date put in use: July 2001.

Quantity defective: —— ALL

Location of device now: MEDICAL PHYSICS DEPT.

3. ADDRESS FOR COMPLETED FORMS OR ADVICE

Medical Devices Agency, Adverse Incident Centre, Hannibal House, Elephant and Castle, London SE1 6TQ

Direct Line: 0171 972 8080 (message service on this number outside office hours)

Fax: 0171 972 8109

Medical Devices Agency

2 - NOV 2001

Please see over page

Adverse Incident Centre

4. NATURE OF INCIDENT OR DEFECT

Was any injury caused? YES (NO)

To whom: PATIENT/STAFF/OTHER

Nature of injuries and treatment:

Consultant in charge (if known)

Details of incident or defect and local action taken:

Finger probe can be placed on the finger in a position where low O2 saturations are indicated = 92%. Administration of O2 to patients inappropriately. Manufacturer have now supplied instruction leaflet with specific instructions to place sensor LED/detector window over the finger nail area, this did cure the problem however this instruction was not supplied with the repaired product.

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Method of decontamination used:

Signed:

Date:

Mr T Sant,
Manager,
Adverse Incident Centre,
Medical Devices Agency
Hanibal House,
Elephant & Castle,
London,
SE1 6TQ.

27 November 2001

MDA Ref 200011105.011-3

Dear Mr Sant.

We are somewhat confused concerning the above reported adverse incident.

This incident concerns an accessory which was returned to us for repair. If the object concerned was current it would bear the original manufacturers CE mark. The advice we have been given and our interpretation of the MDD has led us to believe that we cannot add our CE mark to a repaired product of another manufacturer.

We also believe that if we add "Viamed" instructions to a repaired product which could in any way be interpreted by the original manufacturer as incorrect we would leave ourselves open to litigation.

In over 35 years of medical equipment/accessory repair I have never included instructions with the repaired product unless the manufacture's instructions had been originally supplied by the user with the product sent in for repair. It has always been our belief that Hospitals were obliged to have procedures in place to ensure that the user was fully trained to use the equipment purchased. If you interpret this situation differently please let me know.

The Viamed repair facility was first audited by BSI in June 1994 when we gained BS5724 BS EN ISO 9002 and specifically covers the "Repair, maintenance, and servicing of medical monitoring, ventilation, and anaesthetic equipment, including that carried out on customer premises"

This was upgraded in 1998 to include EN46002, and both were upgraded in 1999 to BS EN ISO 9001/EN46001 where design was added to the scope. The relevant technical/design/customer complaint/ and post market surveillance files are in position and active.

As to the repair of Pulse oximeter probes we have always attempted to recycle as many of the components as possible from the original manufacturer, specifically the active devices.

The problem relating to placement has been well known with oximetry users and manufacturers for almost 20 years and is a function of human physiology.

We have re-examined the problem and believe it may be of assistance to include labels which state

" Please refer to the original manufacturers instructions"

" For best results from pulse oximetry the finger sensor LED's and detectors should be aligned over the finger nail".

These labels we feel are general and do not contradict or vary from information supplied continually by the manufacturers since pulse oximetry was introduced.

Concerning the probes we manufacture. These probes are compatible with the original manufacturer, carry a CE mark, have instructions included to follow the original manufacturers instructions,

Yours sincerely

John S. Lamb
Managing Director.

Mr T Sant,
Manager,
Adverse Incident Centre,
Medical Devices Agency
Hanibal House,
Elephant & Castle,
London,
SE1 6TQ.

27 November 2001

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Yours sincerely

John S. Lamb
Managing Director.

VIAMED

Variation in product specification

P856RA Nellcor compatible

S/N 941568 ME to 941667 ME

Variation from Viamed specification:

During the design of this probe a range of Nellcor probes was tested for resistor value.

Nellcor use this resistor for two purposes.

1) It informs the instrument that a probe exists

2) Disposables probes use 8K23 - 8K03

3) Y use 7k97

It became apparent that a 7K5 ohm resistor was being used by Nellcor finger probes although no actual specification has been actually published. A wide variation around this value did not effect the accuracy of the probes.

However it was decided that Viamed would use 7K5 ohm +/- 1%

Although this increased the expense it was felt that it would be better to be as accurate as possible leaving a larger margin for errors.

This batch appear to be using a +/- 5% tolerance resistor.

Although accuracy should not be compromised the supplier has been advised that in future the correct specification for this resistor must be used.

This batch have all been tested and released on my authority

J.S.Lamb

Managing Director

19 May 1999

upplier ref	P/N	S/N	Text S/N	Link	Status	Date
9619	P856RA	941568	ME	L	Printing	18/05/9
9619	P856RA	941569	ME	L	Printing	18/05/9
9[illegible]	P856RA	941570	ME	L	Printing	18/05/9
9619	P856RA	941571	ME	L	Printing	18/05/9
9619	P856RA	941572	ME	L	Printing	18/05/9
9619	P856RA	941573	ME	L	Printing	18/05/9
9619	P856RA	941574	ME	L	Printing	18/05/9
9619	P856RA	941575	ME	L	Printing	18/05/9
9619	P856RA	941576	ME	L	Printing	18/05/9
9619	P856RA	941577	ME	L	Printing	18/05/9
9619	P856RA	941578	ME	L	Printing	18/05/9
9619	P856RA	941579	ME	L	Printing	18/05/9
9619	P856RA	941580	ME	L	Printing	18/05/9
9619	P856RA	941581	ME	L	Printing	18/05/9
9619	P856RA	941582	ME	L	Printing	18/05/9
9619	P856RA	941583	ME	L	Printing	18/05/9
9619	P856RA	941584	ME	L	Printing	18/05/9
9619	P856RA	941585	ME	L	Printing	18/05/9
9619	P856RA	941586	ME	L	Printing	18/05/9
9619	P856RA	941587	ME	L	Printing	18/05/9
9[illegible]	P856RA	941588	ME	L	Printing	18/05/9
9619	P856RA	941589	ME	L	Printing	18/05/9
9619	P856RA	941590	ME	L	Printing	18/05/9
9619	P856RA	941591	ME	L	Printing	18/05/9
9619	P856RA	941592	ME	L	Printing	18/05/9
9619	P856RA	941593	ME	L	Printing	18/05/9
9619	P856RA	941594	ME	L	Printing	18/05/9
9619	P856RA	941595	ME	L	Printing	18/05/9
9619	P856RA	941596	ME	L	Printing	18/05/9
9619	P856RA	941597	ME	L	Printing	18/05/9
9619	P856RA	941598	ME	L	Printing	18/05/9
9619	P856RA	941599	ME	L	Printing	18/05/9
9619	P856RA	941600	ME	L	Printing	18/05/9
9619	P856RA	941601	ME	L	Printing	18/05/9
9619	P856RA	941602	ME	L	Printing	18/05/9
9619	P856RA	941603	ME	L	Printing	18/05/9
9619	P856RA	941604	ME	L	Printing	18/05/9
9619	P856RA	941605	ME	L	Printing	18/05/9
9[illegible]	P856RA	941606	ME	L	Printing	18/05/9
9619	P856RA	941607	ME	L	Printing	18/05/9
9619	P856RA	941608	ME	L	Printing	18/05/9
9619	P856RA	941609	ME	L	Printing	18/05/9
9619	P856RA	941610	ME	L	Printing	18/05/9
9619	P856RA	941611	ME	L	Printing	18/05/9
9619	P856RA	941612	ME	L	Printing	18/05/9
9619	P856RA	941613	ME	L	Printing	18/05/9
9619	P856RA	941614	ME	L	Printing	18/05/9
9619	P856RA	941615	ME	L	Printing	18/05/9
9619	P856RA	941616	ME	L	Printing	18/05/9
9619	P856RA	941617	ME	L	Printing	18/05/9
9619	P856RA	941618	ME	L	Printing	18/05/9
9619	P856RA	941619	ME	L	Printing	18/05/9
9619	P856RA	941620	ME	L	Printing	18/05/9
9619	P856RA	941621	ME	L	Printing	18/05/9
9619	P856RA	941622	ME	L	Printing	18/05/9
9619	P856RA	941623	ME	L	Printing	18/05/9
9[illegible]	P856RA	941624	ME	L	Printing	18/05/9
9619	P856RA	941625	ME	L	Printing	18/05/9
9619	P856RA	941626	ME	L	Printing	18/05/9

upplier ref	P/N	S/N	Text S/N	Link	Status	Date
9619	P856RA	941627	ME	L	Printing	18/05/9
9619	P856RA	941628	ME	L	Printing	18/05/9
96	P856RA	941629	ME	L	Printing	18/05/9
9619	P856RA	941630	ME	L	Printing	18/05/9
9619	P856RA	941631	ME	L	Printing	18/05/9
9619	P856RA	941632	ME	L	Printing	18/05/9
9619	P856RA	941633	ME	L	Printing	18/05/9
9619	P856RA	941634	ME	L	Printing	18/05/9
9619	P856RA	941635	ME	L	Printing	18/05/9
9619	P856RA	941636	ME	L	Printing	18/05/9
9619	P856RA	941637	ME	L	Printing	18/05/9
9619	P856RA	941638	ME	L	Printing	18/05/9
9619	P856RA	941639	ME	L	Printing	18/05/9
9619	P856RA	941640	ME	L	Printing	18/05/9
9619	P856RA	941641	ME	L	Printing	18/05/9
9619	P856RA	941642	ME	L	Printing	18/05/9
9619	P856RA	941643	ME	L	Printing	18/05/9
9619	P856RA	941644	ME	L	Printing	18/05/9
9619	P856RA	941645	ME	L	Printing	18/05/9
9619	P856RA	941646	ME	L	Printing	18/05/9
96	P856RA	941647	ME	L	Printing	18/05/9
9619	P856RA	941648	ME	L	Printing	18/05/9
9619	P856RA	941649	ME	L	Printing	18/05/9
9619	P856RA	941650	ME	L	Printing	18/05/9
9619	P856RA	941651	ME	L	Printing	18/05/9
9619	P856RA	941652	ME	L	Printing	18/05/9
9619	P856RA	941653	ME	L	Printing	18/05/9
9619	P856RA	941654	ME	L	Printing	18/05/9
9619	P856RA	941655	ME	L	Printing	18/05/9
9619	P856RA	941656	ME	L	Printing	18/05/9
9619	P856RA	941657	ME	L	Printing	18/05/9
9619	P856RA	941658	ME	L	Printing	18/05/9
9619	P856RA	941659	ME	L	Printing	18/05/9
9619	P856RA	941660	ME	L	Printing	18/05/9
9619	P856RA	941661	ME	L	Printing	18/05/9
9619	P856RA	941662	ME	L	Printing	18/05/9
9619	P856RA	941663	ME	L	Printing	18/05/9
9619	P856RA	941664	ME	L	Printing	18/05/9
96	P856RA	941665	ME	L	Printing	18/05/9
9619	P856RA	941666	ME	L	Printing	18/05/9
9619	P856RA	941667	ME	L	Printing	18/05/9

VIAMED

Analysis of complaints & Customer Feedback

Ohmeda failed on some very thin patients.

Problem located in too much light transmitted through detector pads.

Pads changed to Black Problem resolved.

Electronically the probes were identical with OEM.

Clinical trials for long-term use are on going.

Datex original probes have had many problems which the compatible has tried to correct.

The use of better screening and a high quality cable has been sucessful.

Two version of Oximeter are available.

The P872RA does not work well on the Cardiograph II

Nellcor some problems using Nellcor on HP Merlin have been encountered.

FAX REF. :

DATE 20 May 1997

Jack Kimbro
UDT Sensors Inc.
12525 Chadron Ave.: Hawthorne. CA 90250 . USA

Dear Jack,

Samples of Ohmeda Probes

We are testing your samples of Ohmeda probes with our tester and are finding inaccuracies of around 2% low at 99% and 2% High at 60%.

This could be because you have matched LED's to a probe with 56K ohm resistors.

Most Ohmeda appear to have 68K.

NB We have simulated a resistor change from 20K to 94K (limits our Ohmeda instrument accepts) we can change the accuracy by about 5% at 60% but only 0.5% at 98%.

Tomorrow we are going to test the probes on a Oximeter tester and on a Bio-Tec Index.

Is there any chance you can build a probe using an Ohmeda with a 68K?

We need to find a combination that not only works on the patient but works with the simulators.

If you cannot obtain a sample please let us know.

Kind Regards,

John S. Lamb.

CC Medical Cables Inc.

VIAMED

Analysis of complaints & Customer Feedback

Ohmeda P867RA failed on some very thin patients. Light transmitted through the finger pad was sufficient to fool the electronics into a "no probe connected" Unit failed safe

Pads changed to Black Problem resolved.

Electronically the probes were identical with OEM.

Clinical trials for long-term use are on going.

Datex P872RA Original probes have had many user problems which the compatible has tried to correct.

The use of better screening and a high quality cable has been successful.

Two version of Oximeter are available.

The P872RA does not work well on the Cardiograph II

Datex now have another new version which is better .

The P872RA is matched to the latest Datex probe.

Nellcor P856RA some problems using Nellcor on HP Merlin have been encountered with very thin patients.

Nellcor has in the past experienced problems with SpO2 probes which do not work on all patients.

The P856RA problem whereby the Nellcor monitor does not see the probe seems to be restricted to one batch 7J , with thin patients on old versions of Hewlett Packard Merlin monitors.

Hewlett Packard have introduced a software upgrade which appears to have eliminated the problem.

So far no problems have been serious or involved with inaccuracies. In all instances the instruments have failed to detect the probe.