CCSC

MEDICAL CABLES™

1340 LOGAN AVENUE, COSTA MESA, CA 92626-(714) 545-3400-(800) 628-1899-FAX (714) 545-7212

To : Mr. Tom Hickman
Managing Director
Opto Sensors (M) Sdn. Bhd.
No. 8 Jalan Firma 2/2
Kawasan perindustrian Tebrau I
Johir Bahru, Johor,
Malaysia

COPY

CC: Jack Kimbro, Tammy Conway, Chris Chin, John Lamb, C. Fontana, P. Bonin

Ref.: Christopher Fontana, communication 7/22/99

Date 23rd. July 1999

Dear Mr. Hickman,

With reference to the above letter, as copied to me by Mr. Fontana, please allow me to make the following comments.

The letter mentioned that ' the move to " crimp type " pins was approved by Chris Chin as part of the corrective action for the blisters on ——'. Medical Cables recognizes and appreciates the institution of appropriate corrective action to a serious problem by OSM, but because of the lack of communication between UDT and Medical Cables, this 'unofficial' change was unfortunately brought to our attention by one of our premier but disappointed customers in the UK. This 'unofficial' change is unacceptable by Medical Cables.

Medical Cables and UDT are signatories to a Quality Assurance Agreement, see fax No. 11168, Medical Cables, dated May 13th 1998 to UDT, that includes and describes how revisions or changes are to be carried out. Clause 9 of the Quality Agreement between UDT and Medical Cables specifically states that " If UDT plans to make a change, e.g. to use some other material or alter drawings or the production process which leads to a change in the written specifications, Medical Cables must be informed as soon as possible. These changes in written specification of the article must be accepted in writing by Medical Cables." Clause 9 further describes pre production samples, process validation, testing and other relevant common and accepted practices in the medical device industry. We regret the fact that absolutely no communication was forwarded to Medical Cables describing this change before being approved by Chris Chin of UDT. I believe that a review of the Quality Assurance Agreement is needed in order to shed some light on this preventable event.

I sincerely hope that this information will serve as additional input to a most serious infringement of the Quality Agreement between UDT and Medical Cables.

Yours truly,

Robert Hilmian
Quality Assurance / Regulatory Affairs.

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.

older.

**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.

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

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

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.

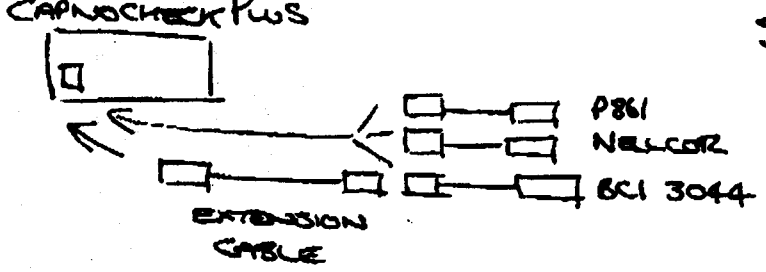
THE MONITOR WAS TESTED WITH ITS ORIGINAL PROBE, PROBE MODEL NUMBER 3044 AND WORKED FINE, OUR PROBE (P861) WAS THEN FITTED AND THIS ALSO WORKED FINE, MR BARRY DIDN'T KNOW THE REASON WHY BUT HAS A NUMBER OF THESE MONITORS AND WILL CHECK THEM ALL TO FIND OUT IF THE ODD UNIT HAS A PROBLEM. I WILL CONTACT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



VIAMED

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Kind Regards,

John S. Lamb.

CC Medical Cables Inc.

cc JSL

MEDICAL CABLES™

1340 LOGAN AVENUE, COSTA MESA, CA 92626-(714) 545-2469-(800) 626-1999-FAX (714) 545-7212

To : Mr. Tom Hickman
Managing Director
Opto Sensors (M) Sdn. Bhd.
No. 8 Jalan Firma 2/2
Kawasan perindustrian Tebrau I
Johir Bahru, Johor,
Malaysia

COPY

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Robert Hillman
Quality Assurance / Regulatory Affairs.

MEDICAL CABLES™

1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-3469•(800) 828-1599•FAX (714) 545-7212

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

6th. July 1999

Reference: Quality Issues

CC: Tom Hickman OSM, Peter Williamson UDT, and John Lamb Viamed, Ltd.

Dear Jack,

As of late, especially over the last six months, the quality of the pulse oximeter probes has been besieged by very serious quality flaws. This deterioration in quality alarms us greatly, and even more so, we feel that UDT, or OSM, is lacking in forthrightness in sharing with Medical Cables the results of investigations as to the cause of problems or failures. Medical Cables is interested in the results of the investigations in order to anticipate the occurrence of future deficiencies and to plan ahead. We, at Medical Cables feel that perhaps improvements are needed in design specifications in order to achieve optimum quality of product. Medical Cables ultimately bears responsibility to the consumer, albeit all of us benefit from a successful, widely used, reliable and safe product.

Notwithstanding, Medical Cables is very appreciative of the fact that UDT has taken corrective actions such as, steps to prevent duplication of serial numbers and recently, corrective action at OSM and the submission of inspection criteria for Cable Inspection. It is noteworthy that the Cable Inspection criteria constitute standard training for manufacturing and inspection personnel and that these criteria, as stated, have been and will continue to be the UDT and OSM standard. It was very disappointing to note that despite those stringent measures, the defects regulated and controlled by those inspection criteria turned up in such large numbers indeed. Fortunately, no such defects have been found in recent shipments or products returned for warranty or complaints. However, failure analyses and investigation results from UDT and OSM have been very much lacking, and we look forward to getting at least some in the future. To the FDA, as specifications developers and re-packagers and re-labelers, we, Medical Cables, have a responsibility to provide failure analyses, especially if they are consumer/user complaints. Medical Cables does not comply with regulatory requirements if we state that faulty, especially class II, product has been returned for warranty and replaced to the customer/user, without Medical Cables investigating and providing a reason for the failure.

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I have listed below the major quality issues that have surfaced during the last six months:

1. The numerous rejections by Medical Cables and Viamed Ltd. of probes with unsightly blue stains, smears, smudges on cables and at times, connectors despite the cable inspection criteria being standard and in place.
2. The numerous rejections by Medical Cables and Viamed Ltd. of probes with bubbles on connectors despite cable inspection criteria being standard and in place.
3. The present issue of substitution of connector pins with substandard connector pins as observed by Viamed Ltd.
4. The continuing lack of failure analyses, or the absence of efforts in initiating such an investigation. Even our customers return product with a finding or an opinion!
5. This leads to the next related issue, now that the issue of blue stains and bubbles has abated. The majority of warranty returns, failures and complaints are now for electronic failures involving emitters, sensors and continuity of circuitry, and Medical Cables has yet to receive a failure analysis from either UDT or OSM on any failure. The incidence fortunately is low, nevertheless, isn't the object of this exercise - zero defects? It could be deemed an acceptable failure rate of the assembly process and missed by a random sample for electronic testing, if electronically tested at all?
6. Last year it was a duplication of serial numbers, this year we had product without serial numbers (2). The problem has been resolved, and we presume that an internal corrective action had been instituted as we were queried on the inspector stamps on the accompanying documentation. We are awaiting the return of the two re-serialized probes.

It is with regret that Medical Cables has to present these quality issues, but we feel that since these issues have a profound impact on our present and future customer base, we feel that product quality needs to be restored if not, improved.

C. Fontana V. P.

MEDICAL CABLES™
1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-2400•(800) 828-1899•FAX (714) 545-7212

# Facsimile Transmittal

To: Stephen Nixon — Fax: 44 1535 635582

Company: Viamed Ltd. — Date: 9 / 6 / 00

From: Robert Hilman — Pages: 3

Re: Copy of request for RMA to OSM and inquiry as to Quality and Serial numbers of direct shipment.

---

Dear Stephen,

How are you ? How is John doing ? I hope this note finds you both well!
I am herewith faxing you a copy of a letter that we sent to OSM inquiring as to the quality of product and the longstanding problem of lacking to send us a copy of the shipper showing serial numbers that were sent to your facility in the UK. ( Half of the P856RA's on MCI RGA#1251 cannot be accounted for and these were out of total about 82 returned probes ) A list of model and serial numbers would not only assist us in our trace ability efforts, but would also greatly support our accounting department as to warranty replacements. We would be then more confident to issue warranty replacements if we knew that they indeed had been sent out by the shipper.

Thank you and
kind regards

Robert Hilman

Cc: C Fontana

MEDICAL CABLES

1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 848-2488•(800) 826-1899•FAX (714) 848-7212

To: Ms Lily Rozeimah
Opto Sensors Manufacturing (OSM) Sdn. Bhd.
No. 8 Jalan Firma 2/2
Kawasan perindustrian Tebrau I
81100 Johor Bahru
Malaysia.

COPY

Subject: Request for RMA's for MCI RGA# 1251

27th August 2000

Dear Ms Lim

I am herewith sending you the serial number list of the 76 P856RA's and 6 P858RA's that were rejected by our customer with the complaint : all the items returned have non functioning emitters? Would you be so kind as to furnish us with an RMA number for these items.

The serial numbers for the returned P856RA's and P858RA's are as follows:

P856RA's (76 UNITS )

OD26213, OD26215, OD26219, OD26229, OD26235, OD26350, OD26375, OD26466, OD26474, OD26484, OD26491, OD26492, OD26494, OD26495, OD26500, OD26501, OD26518, OD26519, OD26521, OD26528, OD26529, OD26542, OD26560, OD26561, OD26570, OD26571, OD26573, OD26576, OD26578, OD26582, OD26583, OD26584, OD26597, OD26598, OD26599, OD26600, OD26601, OD26604, OD26605, OD26613, OD26617 OD26620, OD26621, OD26630, OD26633, OD26637, OD26640, OD26647, OD26650, OD26653, OD26654, OD26655, OD26665, OD26667, OD26678, OD26680, OD26691, OD26692, OD26693, OD26695, OD26696, OD26698, OD26700, OD26704, OD26708, OD26714, OD26717, OD26729, OD26730, OD26738, OD26831, OD26837, OD26842, OD26845, OD26846, OD26852,

(From OD26597 onwards we have absolutely no records of the Serial Numbers as they were directly shipped to the UK. This is one of the obstacles that we face for warranty replacements-billing-replacement warranty charges)

MEDICAL CABLES™

1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-3469•(800) 826-1699•FAX (714) 545-7212

P858RA's ( 6 UNITS )

COPY

9H23388, 9H23326, 9H23311, 9H23373, 9H23101, 9H23666.

I would like to request that you forward a copy of this letter to Mr Siow Kian Tek in order to initiate an investigation into this matter as a complaint report has been forwarded to us by our customer. We are very surprised at this sudden surge in electrical failures, and as you can verify with Mr Hermen Gilbert, we are inquiring for more ( 750 ) of the P856RA's and P858RA's to be shipped to us ASAP. We are anxious to know as to what corrective actions you will take after investigation of this matter has been completed. I am sure that you will continue to supply Medical Cables with products of the highest quality and we wish you well in your efforts to maintain quality.

Thanking you for your attention, I remain

Yours truly

Robert Hilman
Quality / Regulatory Affairs

cc: C. Fontana, VP
K. T. Siow, OSM QA Mgr.

# 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,

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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.

RS 28343 RS 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.*

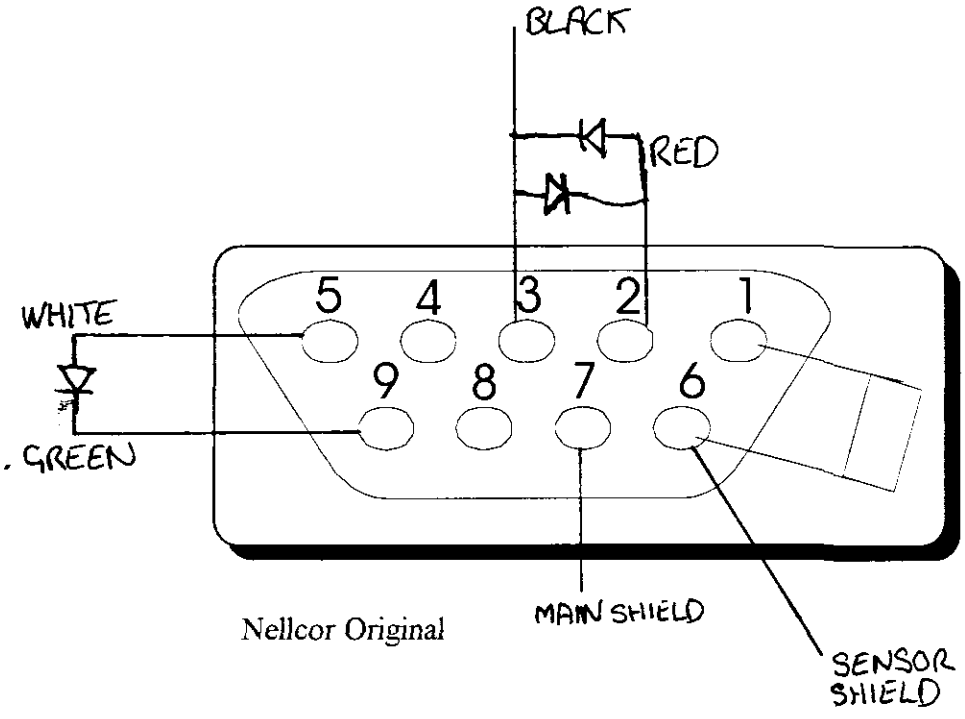
*Best regards,*

***MEDIVENT LTD.,***

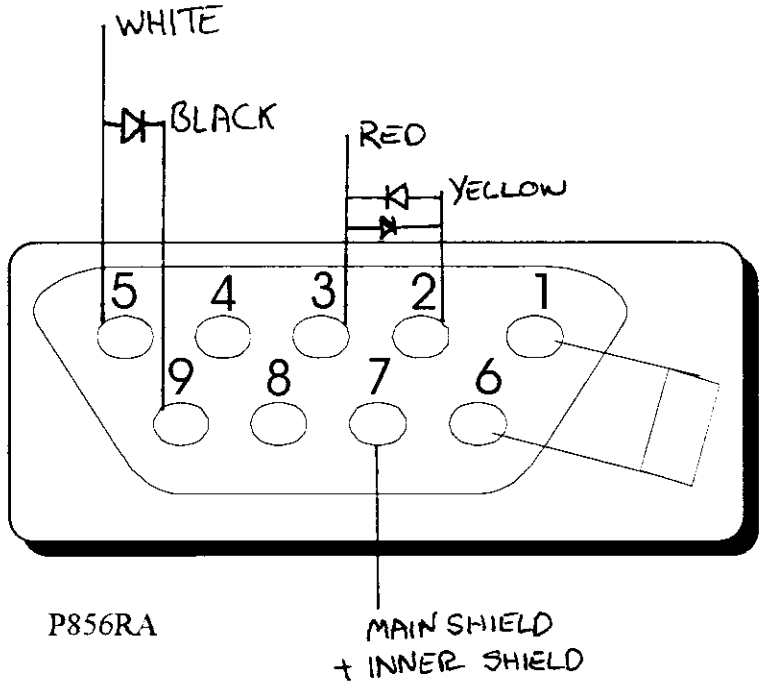
***PHILIP STRICKLAND.***

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

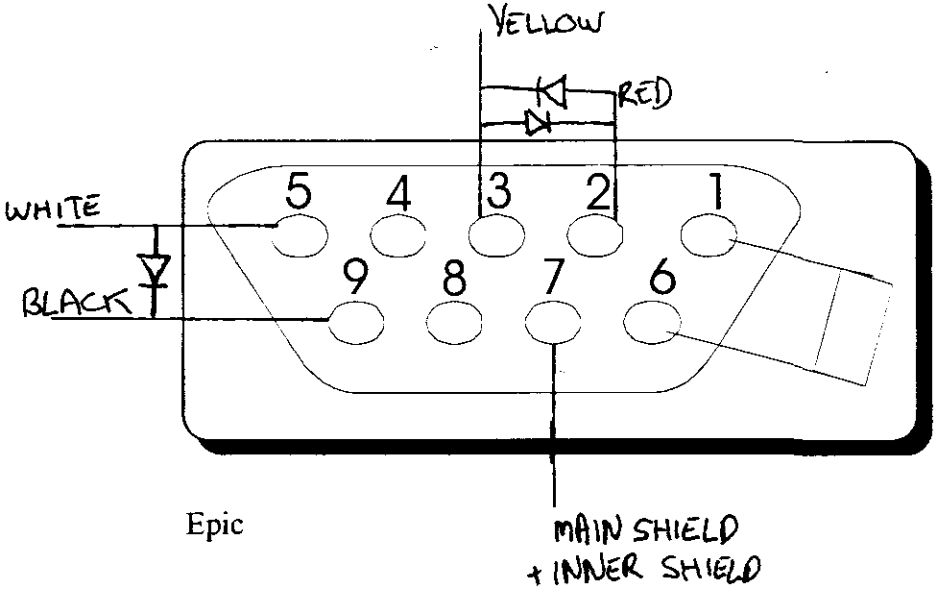
| MEDIVENT | RESISTOR KΩ |
|---|---|
| SN: 7J01737 | 7.474 |
| 7J01730 | 7.472 |
| 7J01736 | 7.458 |
| 7J01728 | 7.482 |
| 7J02026 | 7.475 |
| 7J01734 | 7.469 |
| 7J01729 | 7.481 |
| 7J01732 | 7.470 |
| 7J01735 | 7.478 |



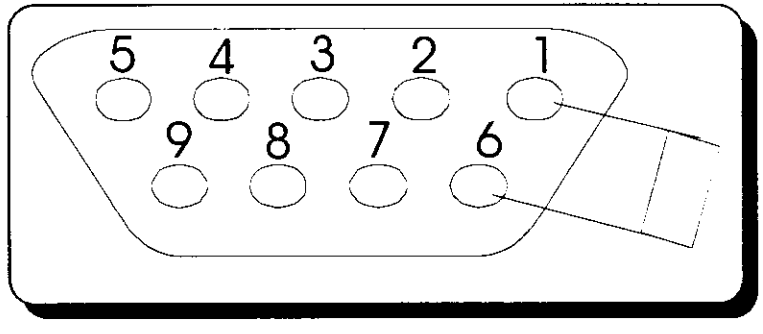

Nellcor Original




P856RA




Epic




Aristo

# VIAMED

cc. JL

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



cc. Jack Kimbro U.D.T.

---

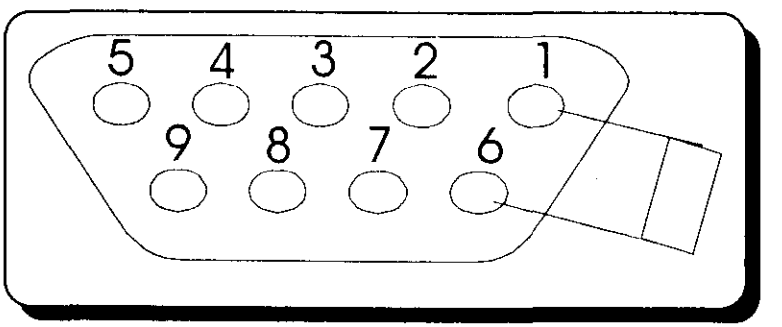
Dear Chris

## 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

Tech

RESISTOR KΩ

| SN. | | |
|---|---|---|
| | 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.

CC SN
JSL

UNIT 10, HILLS INDUSTRIAL CENTRE, LUCAN, CO. DUBLIN, IRELAND.
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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.**

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

| Supplier 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 |

CABLES
1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-3469•(800) 826-1599•FAX (714) 545-7212

cc JSL SL

# FAX TRANSMISSION

Date : 14th April, 1999

From : Robert Hilman

To : Mr John Lamb
VIAMED Ltd.
15 Station Road
Cross Hills Keighly
West Yorkshire BD20 7DT
U.K.

Subject: Fax Hard silicon rubber pad

Dear Mr. Lamb,

With reference to your fax describing your findings concerning the difference in appearance of the material used in the hard finger pad, I am herewith bringing to your attention the following comments as forwarded by UDT to Medical Cables.

UDT has made no change in material, or in the tooling , and they have not changed vendors for the silicone rubber pads used in the finger clip pulse ox probes. Any difference noticed can only be attributed to lot variations. Liquid silicone rubber color may vary slightly from lot to lot due to molding and / or base material mixing. Many different suppliers such as Dow Chemical, Meghan, Nusil and Applied Silicone, produce this material. This is medical implant grade material of the highest quality . Should you need additional information, please feel free to contact me at 714 545 3469

Thanking you for your kind attention, I remain

Yours truly

Robert Hilman

cc: Chris Fontana VP.

FAX REF. :
15/04/99 Page 1 of 1
Robert Hillamn
MCI. 1340 Logan. Costa Mesa. CA 92626
Fax 001 714 545 7212

---

Dear Robert

**Silcon Pads**

Thanks for you quick reply. Unfortunately this may not answer the problem.

The variation in colour affects the transmission properties and therefore the response of the pulse oximeter.

We would expect this to be queried by our MDA.

Can you please obtain from UDT the part numbers and descriptions of the materials supplied by the different manufacturers.

If UDT cannot supply the tolerances we will need to contact the manufacturers direct from here.

I cannot stress too strongly how important this information is.

Kind regards

John S. Lamb

f:main\Ajohn\MCI

**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.

# 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
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

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
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

Tony Sant
Manager, Adverse Incident Centre

15/11/01

20011105:011-5

Jeff Ali
02079428019

# 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 loss 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:

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.

# 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.

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.

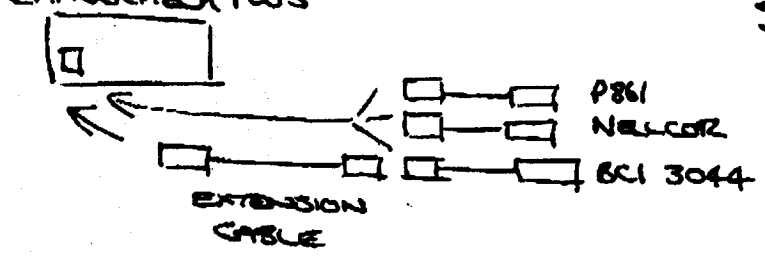
THE MONITOR WAS TESTED WITH ITS ORIGINAL PROBE, PROBE MODEL NUMBER 3044 AND WORKED FINE, OUR PROBE (P861) WAS THEN FITTED AND THIS ALSO WORKED FINE, MR BARRY DIDN'T KNOW THE REASON WHY BUT HAS A NUMBER OF THESE MONITORS AND WILL CHECK THEM ALL TO FIND OUT IF THE ODD UNIT HAS A PROBLEM. I WILL CONTACT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



## 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).

# 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 SpO2 & HEARTRATE - PROBE REPLACED WITH NEW FROM STOCK 1866RA FOR SIMED S-100 MONITOR. | | |
| Signed | [signature] | Date 13/8/01 | |
| Corrective Action | | | |
| External | | | |
| Internal | The problem was eventually traced to an intermittent fault in the instrument. This is not re-pairable by Viamed and returned and invoices cancelled. [signature] 17/8/01 | | |
| Signed | [signature] | Date | 17/8/01 |
| MDA Informed | NO YES | | QC12 |

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 UPTO 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 PAR 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.

3 of 3

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

# 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.*

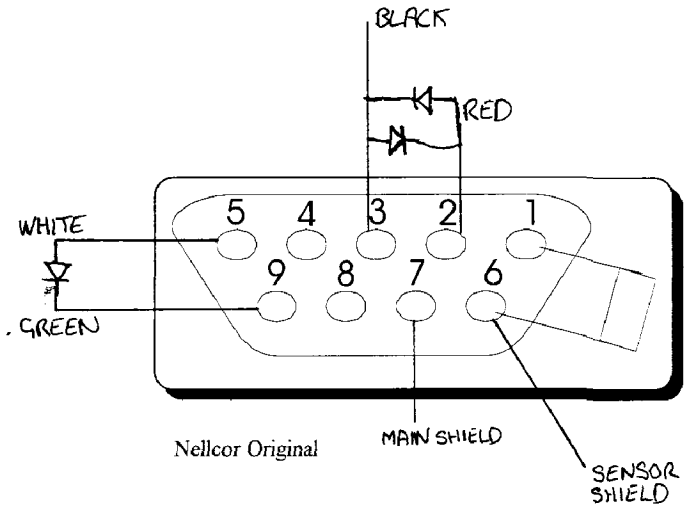
*Best regards,*

***MEDIVENT LTD.,***

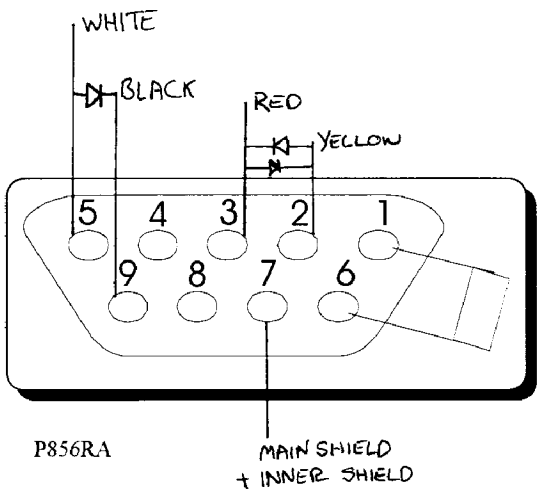
***PHILIP STRICKLAND.***

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

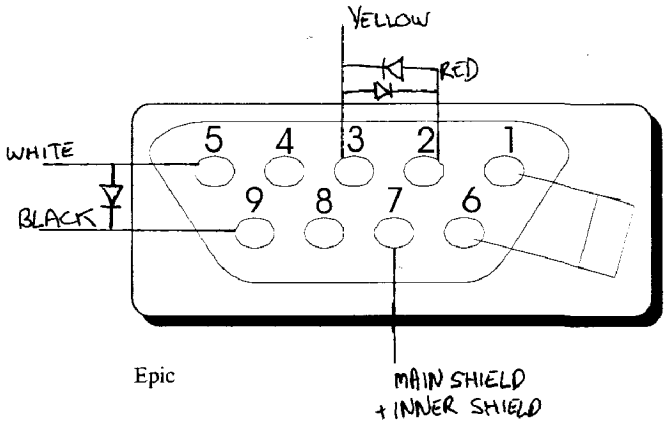
| MEDIVENT | RESISTOR KΩ |
|---|---|
| SN: 7J01737 | 7.474 |
| 7J01730 | 7.472 |
| 7J01736 | 7.458 |
| 7J01728 | 7.482 |
| 7J02026 | 7.475 |
| 7J01734 | 7.469 |
| 7J01729 | 7.481 |
| 7J01732 | 7.470 |
| 7J01735 | 7.478 |



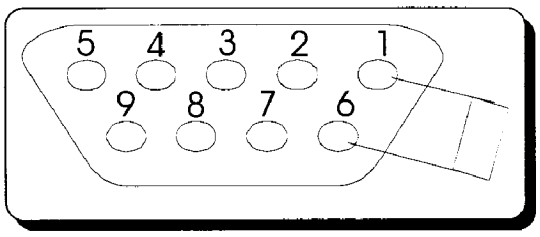

Nellcor Original




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



cc. Jack Kimbro U.D.T.

---

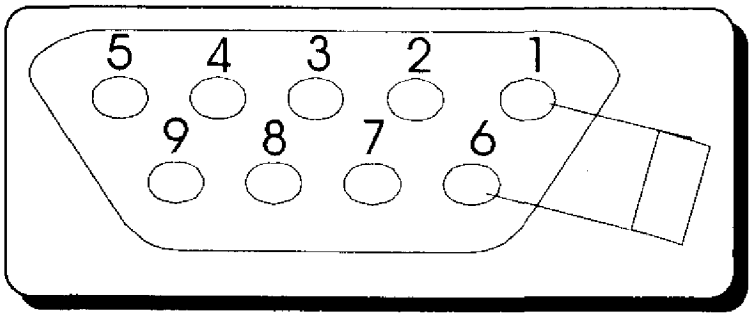
Dear Chris

## 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.**

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 |
| 96 | 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 |
| 96 | 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 |
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| 9619 | P856RA | 941603 | ME | L | Printing | 18/05/9 |
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| 9619 | P856RA | 941619 | ME | L | Printing | 18/05/9 |
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| 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.

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.

Probe Information: P856RA

Standard Nellcor equivalent
Supplied as is from MCI

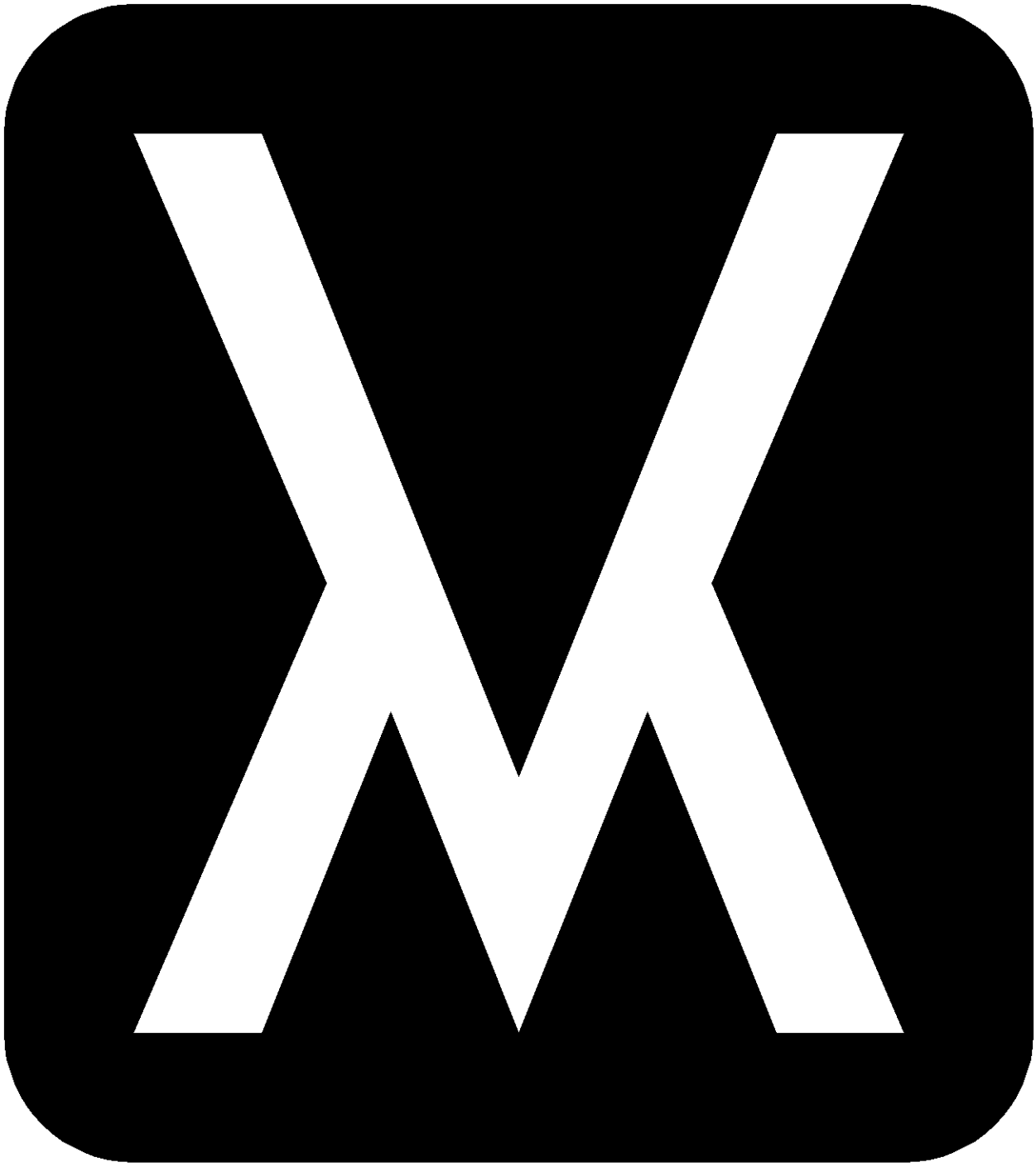
No problems currently Known

Connector
9 Pin D

# Report.

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

23rd April 2002



VIAMED

**Contents.**

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A : Effect of resistor value on displayed $SpO_2$ reading usinfg the Ohmeda 3700e, 3740, 3800 and 3900 model oximeters.

B : Test of Ohmeda adult finger probe, Lot 27299.

C : Test of P867RA serial no. 0G24898.

D : Test of P867RA serial no. 0G24898 after disconnection of inner & outer shields.

E : Test of Aristo range of probes as standard.

F : Test of P867RA (prototype)'s embodying optical components from Aristo disposable probes (adult, neonatal, infant & pediatric).

G : Test of second P867RA (prototype) embodying Aristo disposable (neonatal) optical components.

H : Test of P867RA (prototype)'s embodying optical components from Aristo range of disposable probes by Part & Lot number.

I : Test of P867RA (prototype)'s from Medical Cables, Inc.

J : Test of P867RA (prototype) embodying optical components from Dai Shin.

K : Test of P867RA (prototype)'s embodying optical components from Dolphin disposables.

L : Test of P867RA (prototype) embodying Viamed optical components (PDI) with O rings immediately infront of LED and detector.

M : Test of P867RA (prototype)'s embodying optical components from Ohmeda originals.

N : Test of P867RA (prototype) embodying CSI LED.

O : Test of P867RA (prototype) embodying Dai Shin optical components.

P : Test of P867RA (prototype) embodying MCI optical components and Ohmeda original cable.

Q : Test of P867RA (prototype) embodying PDI optical components and Ohmeda original cable.

R : Comparison of Viamed standard cable to two types of Ohmeda original cable (white & blue/grey).

S : Test of P867RA (prototype) using MCI optical components / Viamed cable and inner shield to connect pin 9 and detector cathode.

T : Test of P867RA (prototype) using MCI optical components / Viamed cable and outer shield to connect pin 9 and detector cathode.

U : Test of shortened P867RA's (prototype) using MCI optical components / Viamed cable.

V : Test of P867RA's (prototype) using MCI optical components / Viamed cable stripped of outer jacket and outer shield.

W : Pin to pin capacitance checks on satisfactory & non-satisfactory P867RA (prototype)'s in comparison to Ohmeda original adult finger probe.

X : Test of P867RA (prototype) embodying Dai shin sample optics.

Y : Test of P867RA (prototype)'s constructed based on PDI optics and each new cable type (larger conductor cross sectional area with inner & outer screens & standard conductor cross sectional area with inner screen only).

Z : Test of 25 from 50 P867RA (production) manufactured based on P867RA (prototype) CA59328715.

AA : Test of 2 x P867RA (production) from the above batch after reworking to become P867RA (prototype) attempting to establish the cause of the under read.

AB : Test of 3 x P867RA (production) from the above batch after reworking to become P867RA (prototype) attempting to establish the cause of the under read.

AC : Test of 3 x P867RA (production) from the above batch after reworking to become P867RA (prototype) attempting to establish the cause of the under read.

AD : Test of P867RA (production) reworked with parallel connection from pin 4 to LED common anode.

Introduction.

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

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

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

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

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

1. To develop an Ohmeda compatible pulse oximetry probe which derives displayed oxygen saturation readings of at least equivalent value in comparison to a typical Ohmeda original adult finger probe when on a human finger using the 3700, 3700e, 3740 and 3800 model pulse oximeters.

2. To ensure that the finger probe developed to satisfy point (1) also derives a displayed oxygen saturation reading of at least equivalent value in comparison to a typical Ohmeda original adult finger probe when on the DL-3000 simulator(*) using the 3700, 3700e, 3740 and 3800 model pulse oximeters.

3. To scientifically prove the root cause of the difference in reading and support a new design P867RA satisfying points (1) and (2) with documentary evidence of accurate readings derived

from it and it's compatibility with the Ohmeda series of pulse oximeters.

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

The theory of pulse oximetry.

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

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

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

The colour of blood is dependent on the optical properties of haemoglobin, in particular, the difference in optical properties of a haemoglobin molecule when carrying oxygen compared to when it is not. Figure 1 below shows the extinction curves resulting from the presence of oxy-haemoglobin ($Hb0_2$) and reduced haemoglobin(Hb) in comparison to wavelength.

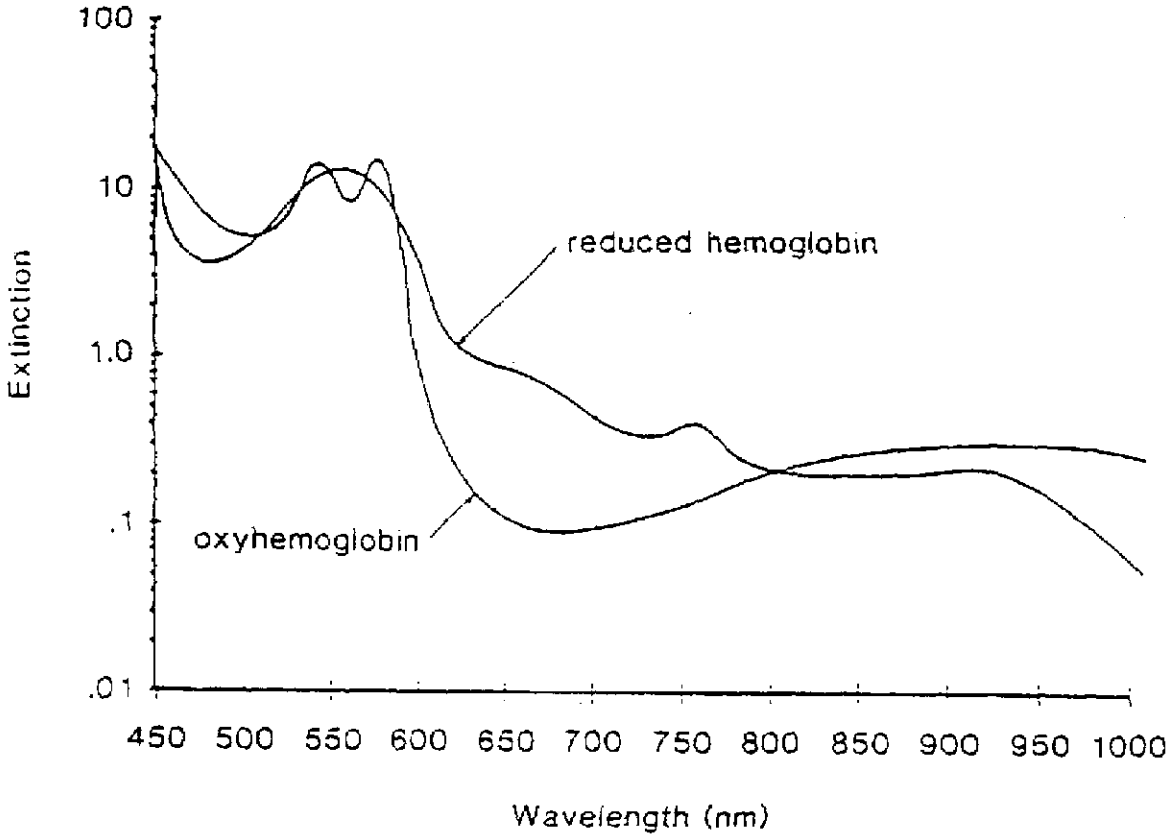


Figure 1 : Diagram showing absorption (extinction coefficient) versus wavelength for oxy-haemoglobin($Hb0_2$) and deoxy-haemoglobin(Hb).

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

At 660nm (typical wavelength of red light), the extinction coefficient of oxy-haemoglobin ($Hb0_2$) is at it's lowest, whereas the extinction coefficient of reduced haemoglobin (Hb) is high. At 930nm (typical wavelength of near infrared light), the extinction coefficient for oxyhaemoglobin ($Hb0_2$) is high compared the extinction coefficient of reduced haemoglobin (Hb) which is lower.

When red light with a typical transmission wavelength of 660nm, is passed through a tissue site supplied with healthy arterial blood with high dissolved oxygen content, large amounts of light pass through the site unobstructed due to the presence of majority $Hb0_2$. A relatively small amount of transmitted light is absorbed by the minority Hb present. Relatively obstructed red light being allowed to pass through blood with high dissolved oxygen content is the reason why highly oxygenated arterial blood appears to the human eye to be bright red in colour.
Should $Hb0_2$ present decrease, absorption of red transmitted light at 660nm wavelength increases due to the increasing presence of Hb - the extinction coefficient of Hb is approximately 10 times that of $Hb0_2$ at 660nm. When transmitted light at this wavelength is passed through a site supplied with healthy venous blood with relatively low dissolved oxygen content, a lessor amount of transmitted light passes through the site unobstructed. The relatively high absorption

of red light as it passes through blood with low dissolved oxygen content is the reason why deoxygenated venous blood appears to the human eye to be dull red in colour.

This is shown schematically in Figure 2 - as percentage saturation increases from left to right across the horizontal axis, absorption of red light at 660nm decreases. The relationship is linear throughout the entire range of 0% $Hb0_2$, 100% Hb to 100% $Hb0_2$, 0% Hb. The extent of negative gradient of the line is a indication of the difference in absorption levels for the two types of haemoglobin at this wavelength.

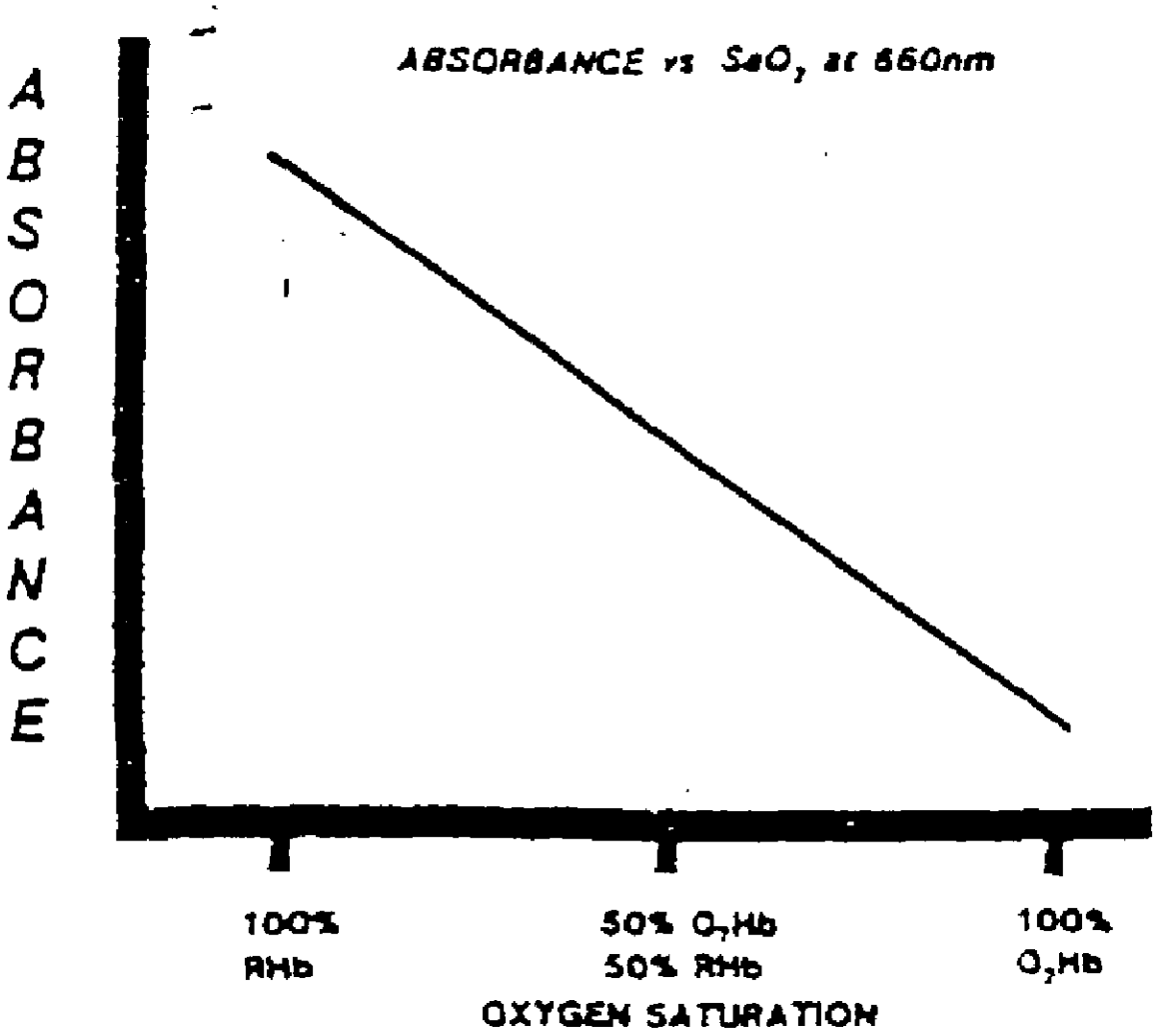


Figure 2 : Absorption of red light at 660nm compared to the level of blood saturation.

When infrared light of typical transmission wavelength of 930nm, is passed through a tissue site supplied with healthy arterial blood with high dissolved oxygen content, a large proportion of transmitted light is absorbed by the majority $Hb0_2$.

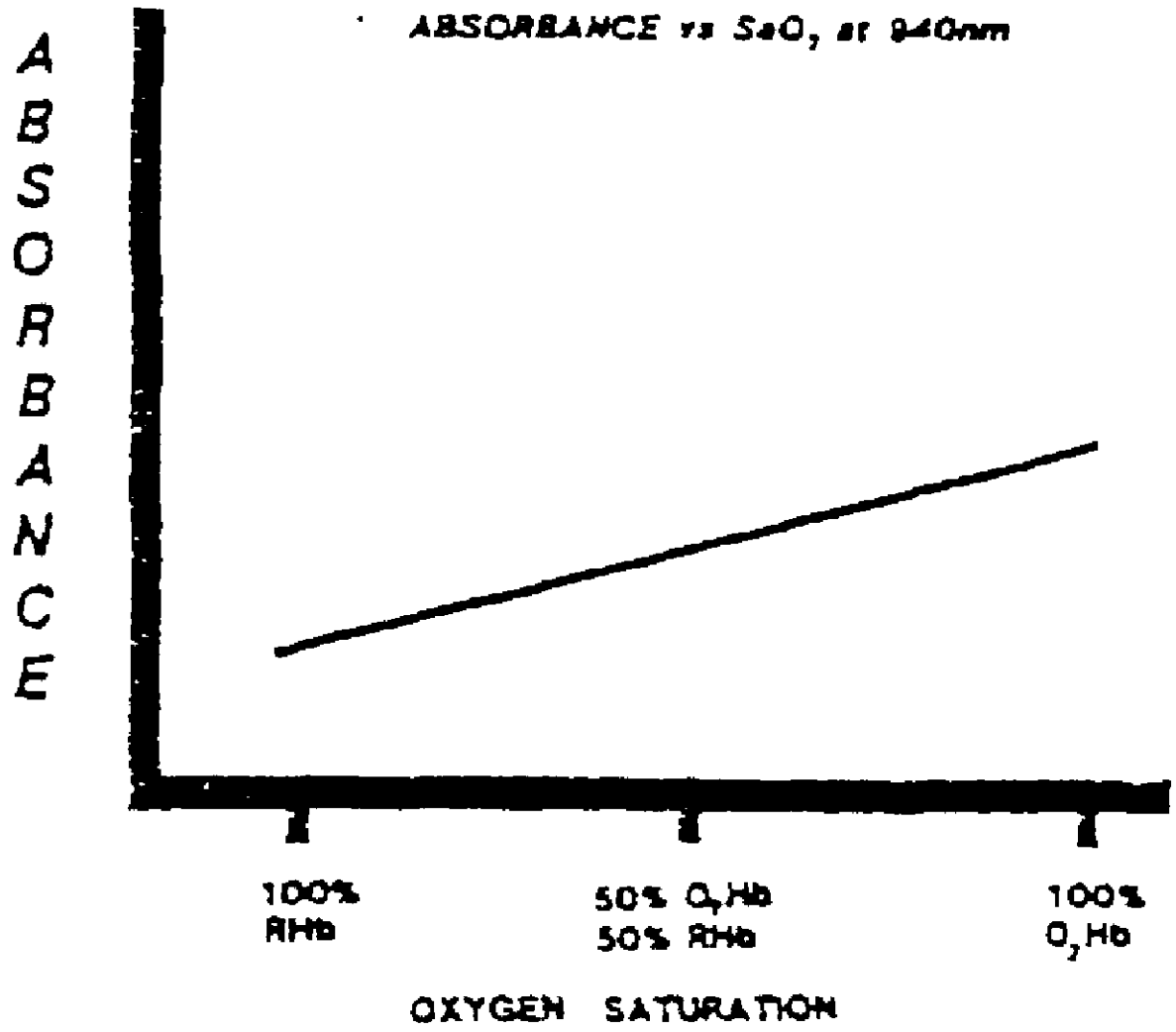


Figure 3 : Absorption of red light at 930nm compared to the level of blood saturation.

Should $Hb0_2$ present decrease, absorption of infrared transmitted light decreases due to increasing levels of Hb - the absorption coefficient of Hb is approximately 1.5 times that of $Hb0_2$ at 930nm. When transmitted light of 930nm is passed through a tissue site supplied with healthy venous blood with low dissolved oxygen content, a smaller proportion of transmitted light is absorbed by the presence of Hb.

This is shown schematically in Figure 3 - as percentage saturation increases from left to right across the horizontal axis, absorption of infrared light at 930nm increases. The relationship is linear throughout the entire range of 0% $Hb0_2$, 100% Hb to 100% $Hb0_2$, 0% Hb. The extent of positive gradient of the line is a indication of the difference in absorption levels for the two types of haemoglobin at this wavelength.

$SpO_2$ measurement relies on two essential facts,

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

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

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

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

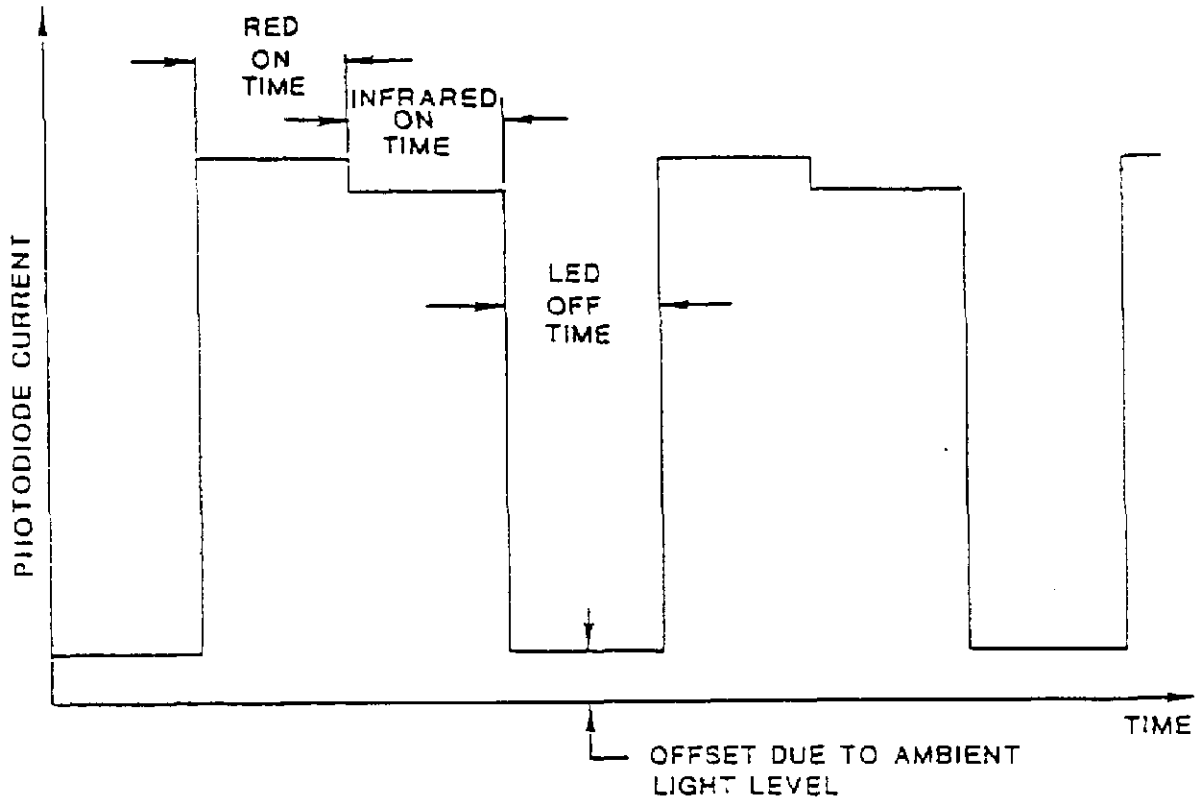


Figure 4 : Diagram showing the sequence of pulses of red and near infrared and measurement of ambient light (neither red nor infrared on).

The $SpO_2$ value of interest is that of the arterial blood supply. The pulse of arterial blood during the heartbeat varies the level of light absorption. The detector produces a voltage dependent on the level and wavelength of light falling on it. There are four elements present in the output from the detector; an AC signal during the red pulse, a DC level during the red pulse, an AC signal during the infrared pulse and a DC level during the infrared red pulse. AC components of the detector output are derived from the movement of the blood during the pulses of arterial flow and the DC levels are due to tissue, bone and relatively stationary venous blood. Refer to Figure 5. The amplitude of both AC signals and DC levels are dependent on the intensity of light transmitted.

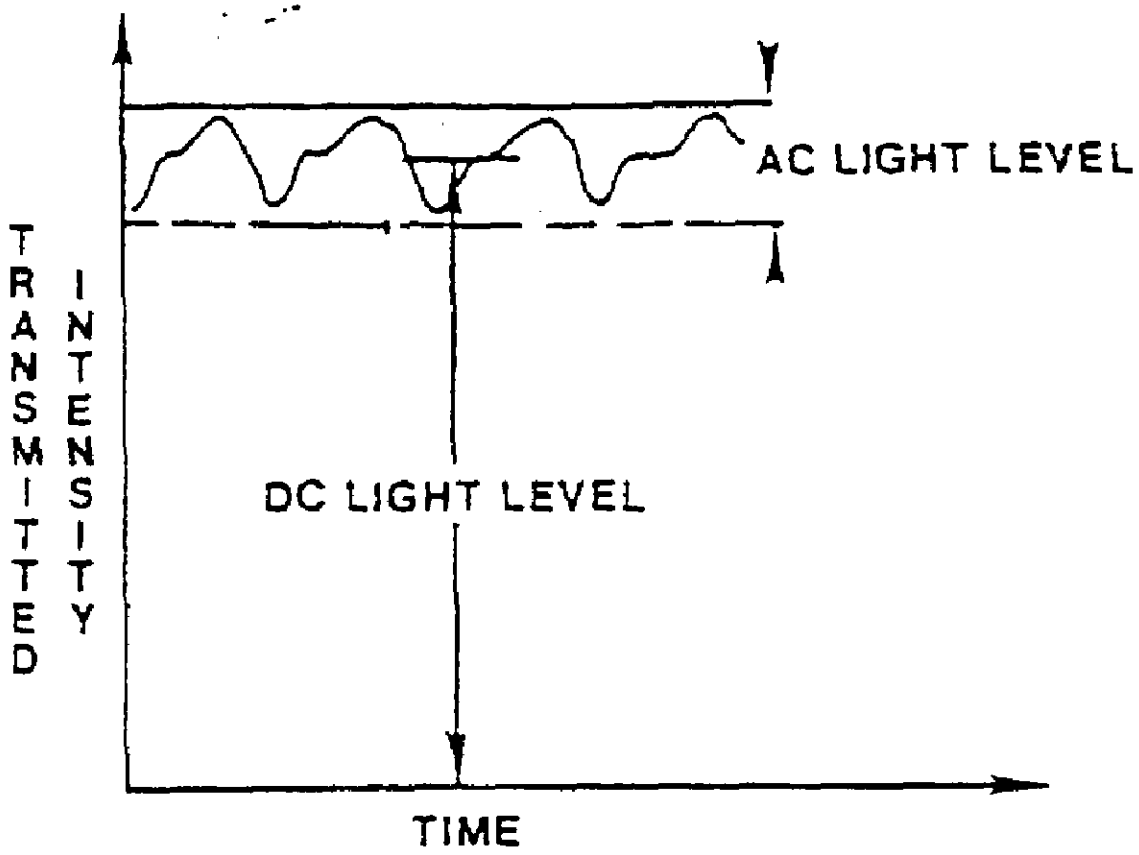


Figure 5 : Schematic representation of AC signal and DC level produced by transmission of the given wavelength of light through living tissue.

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

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

The 'R ratio' = Corrected AC (red) ÷ Corrected AC (infrared)

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

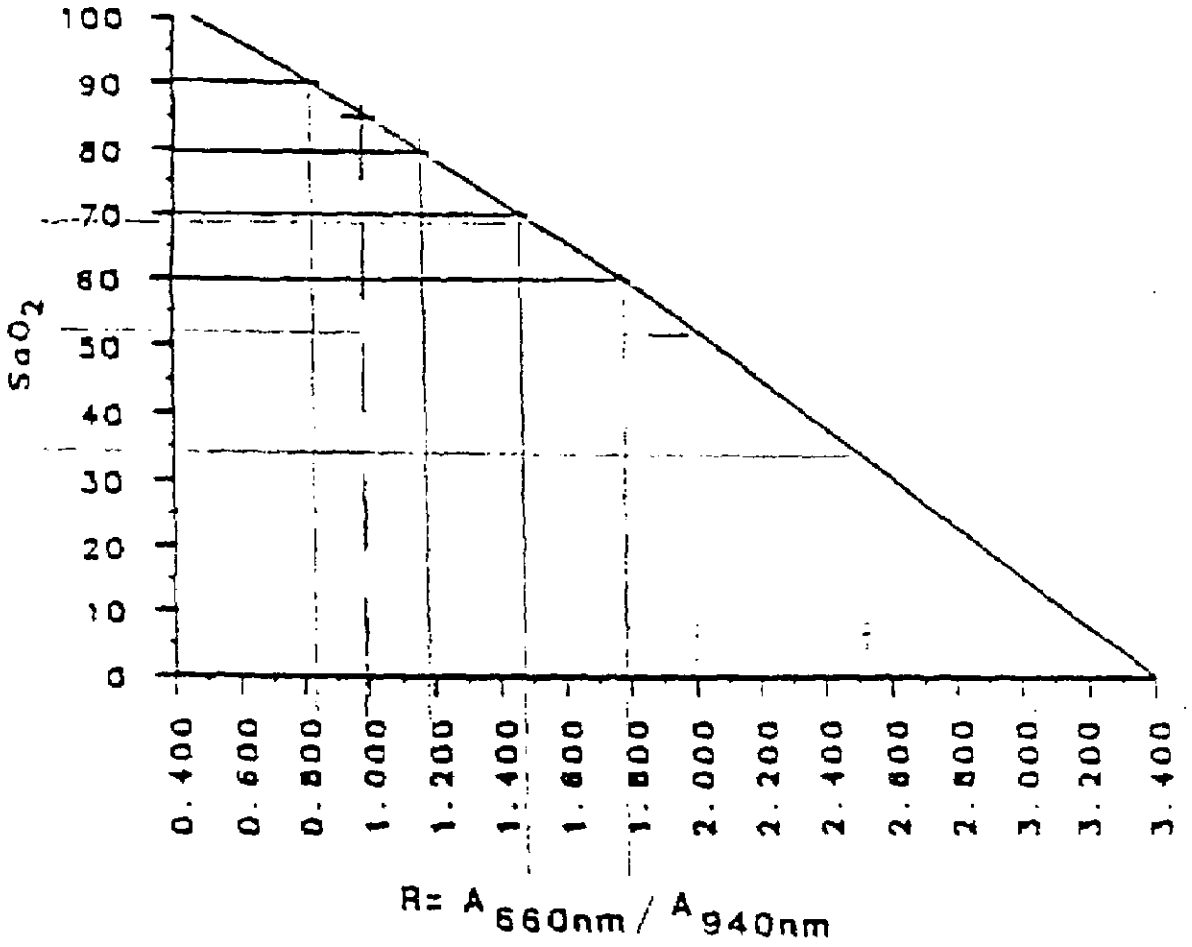


Figure 6 : Diagram showing the relationship between R ratio derived and displayed $spO_2$.

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

When the R ratios for all $spO_2$ readings are put together, practically from 60% to 100%, the 'R-curve' is formed. The R-curve value derived allows the detector returns to be related to the $spO_2$ reading displayed to the value of blood oxygenation obtained by blood gas analysis. Since the relationship as shown in Figure 6 is non-linear, a cross reference table is held within the oximeters memory allowing the R curve value derived at a given time to be converted into the displayed $spO_2$ value.

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

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

Construction of the P867RA.

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

Figure 7 : Schematic wiring diagram of the Viamed P867RA adult, Ohmeda compatible, pulse oximetry finger probe.

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

Possible factors resulting in a difference in displayed $spO_2$ readings.

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

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

Optical components : Change in wavelength.
- " " transmission intensity.
- " " $Vf_{(RED).}$
- " " $Vf_{(INFRARED).}$
- " " $Vf_{(DET).}$
- " " leakage currents.
- " " shunt resistance.

| | |
|---|---|
| Cable : | Change in resistance per unit length.<br>" " capacitance per unit length.<br>" " performance of shields.<br>" " material of conductors.<br>" " no. of conductors per bunch.<br>" " cross sectional area of conductors.<br>" " coatings on conductors.<br>" " bunch jacket thickness or material.<br>" " cable jacket thickness or material. |
| Connector : | Change in resistance of pin material per unit length.<br>" " effectiveness of connection from male probe pin to oximeter female socket, coating on pins. |
| Resistor : | Change in value of resistor. |
| Other factors : | Change in effectiveness of solder joints.<br>" " type of solder used.<br>" " clarity of probe windows.<br>" " electrical properties of clear silicon.<br>" " optical properties of backing silicon.<br>" " external influence. i.e. electro-magnetic interference etc,<br>" " any effect of cable clamp.<br>" " external temperature. |

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

Investigation.

| | | |
|---|---|---|
| Accuracy of R curves installed in the DL-3000 simulator checked using latest generation Ohmeda adult finger probe and displayed $spO_2$ readings taken on the 3700e, 3740 & 3800 oximeters. Conclusion : Results taken for comparison. | Jan 2001 | B |
| Customer reports checked - typical P867RA SN 0G24898 taken from stock reads low ; 2% against the DL-3000 simulator and 1% on the human finger. Conclusion : Valid customer reports. | Jan 2001 | C |
| Disconnection of probe shields found to cause error message of "probe failure" using the 3800 oximeter. Conclusion : 3800 model oximeter is more sophisticated in it's monitoring of probe detector return than previous models. | Jan 2001 | D |

| | | |
|---|---|---|
| Aristo disposable range of probes evaluated on 3700 and 3800 model oximeters. Displayed $spO_2$ readings derived from Aristo disposable (neonatal) prove to be most accurate against the DL-3000 simulator and on the human finger. Conclusion : Aristo disposable (neonatal) selected as most suitable for further evaluation. | Jan 2001 | E |
| Aristo disposable (adult), Aristo disposable (neonatal), Aristo disposable (infant) and Aristo disposable (pediatric) as tested in Appendix D stripped of optics and built into Viamed P867RA (prototype)'s. Prototypes tested - accurate results from prototype using Aristo disposable (neonatal) optics. Conclusion : P867RA (prototype) using Aristo disposable (neonatal) optics selected for further evaluation. | Jan 2001 | F |
| Second P867RA (prototype) built using Aristo disposable (neonatal) optics. Both prototypes independently evaluated by two individuals producing accurate results. Both P867RA (prototype)'s sent to Southmead General Hospital for approval. | Mar 2001 | G |
| Full test of optics from Aristo disposables carried out - Aristo disposable (neonatal) again prove most accurate. 2 x prototypes approved by Southmead General Hospital. Batch of 25 P867RA's manufactured, proven to read accurately after testing and released (SN BE51423214 - BE51423238 inc.). | May 2001 | H |
| 4 P867RA (prototype) from Medical Cables, Inc. received and tested. Prototype probes read 3% low when tested on the 3800 oximeter against the DL-3000 $spO_2$ simulator. Conclusion : Unsuitable. | June 2001 | I |
| Sample LEDs and detectors received from Dai Shin and fitted into P867RA (prototype). Prototype tested but reads 2% low on the 3800 oximeter against the DL-3000 $spO_2$ simulator. Conclusion : Dai shin sample optics are unsuitable. | July 2001 | J |
| 2 x P867RA (prototype) assembled using optics from Dolphin Ohmeda compatible disposables. Prototypes tested but under read by 2 to 3% on the 3800 oximeter against the DL-3000 $spO_2$ simulator and by 2% on the human subject. Conclusion : Dolphin disposable optics are unsuitable. | July 2001 | K |
| P867RA (prototype) constructed using Viamed optics (PDI) with an O ring immediately infront of LED and detector. Prototype reads 2% low on the 3800 oximeter against the DL-3000 $spO_2$ simulator. Conclusion : P867RA (prototype) is unsuitable. | July 2001 | L |
| P867RA (prototype)'s assembled and tested using LED, detector or both from Ohmeda originals and PDI optics. Conclusion : Change of LED to Ohmeda original allows prototype to read accurately against the DL-3000 and on a human subject. | July 2001 | M |
| P867RA (prototype) assembled and tested using salvaged CSI | July 2001 | N |

| | | |
|---|---|---|
| LED with 2 x infrared emitters but doesnot read on the DL-3000. Conclusion : CSI LED unsuitable and probably other LEDs with 2 x IR emitters will prove unsuitable. | | |
| P867RA (prototype) assembled & tested using Dai Shin samples optics (LED with 2 x IR emitters) but proven not to read on 3700 & 3800 against the DL-3000. Conclusion : Dai Shin optics as above are not suitable. | Aug 2001 | O |
| P867RA (prototype) assembled as standard (MCI optics) except using Ohmeda original cable & tested - under read on 3800 oximeter model reduced to 1%. Conclusion : Change of cable to Ohmeda original improves under read on the 3800 oximeter. | Aug 2001 | P |
| P867RA (prototype) assembled as standard (PDI optics) except using Ohmeda original cable & tested - under read on 3800 oximeter model reduced to 1%. Conclusion : Change of cable to Ohmeda original improves under read on the 3800 oximeter. | Aug 2001 | Q |
| As detailed as possible comparison made between Viamed standard cable and two types of Ohmeda original cable (white & blue/grey) - Ohmeda original cable very different in construction and materials used. Conclusion : Samples of cable sent of for specialist evaluation and recommended new cable ordered. | Aug 2001 | R |
| P867RA (prototype) constructed as standard (MCI optics) and Viamed cable but with inner shield making connection between pin 9 and detector cathode - found to under read by 2% against the DL-3000 simulator on both the 3740 and 3800 model oximeter and to under read on the human finger by 2% to 3% on the 3800 oximeter. Conclusion : This prototype is not suitable. | Sept 2001 | S |
| P867RA (prototype) constructed as standard (MCI optics) and Viamed cable but with outer shield making connection between pin 9 and detector cathode - prototype does not work on either the 3700 or 3740 models and under reads on the 3800. Conclusion : This prototype is not suitable. | Sept 2001 | T |
| 3 x P867RA's (MCI) shortened to a length where they were found to read correctly on the Ohmeda 3800 oximeter against the DL-3000 SpO2 simulator. Conclusion : Shortening the cable length of stock P867RA (MCI) proven to be a suitable modification to eliminate underread problem. Unfortunately an 8ft version of the P867RA is not practical for use in operating theatres, therefore investigation to continue to find alternative solution to satisfy goals. | Sept 2001 | U |
| 1 x P867RA's (MCI), serial no. 1B25743 stripped of outer jacket and outer shield and outer jacket substituted with heatshrink tubing. P867RA (prototype) created evaluated. Conclusion : Removal of outer jacket and shield causes the | Sept 2001 | V |

| | | |
|---|---|---|
| reading shown on the 3800 oximeter to increase by 1%. | | |
| Pin to pin capacitance checks made on P867RA (prototype)'s serial nos. 1B25733 and 1B25743 against Ohmeda original adult finger probe, Lot27299 and as stock P867RA serial no. 1B25731 (proven to read 2% low on the 3800 oximeter against the DL-3000 simulator). Conclusion : Unable to pin point a difference in readings taken, that could be proven to cause the under read problem on the 3800 oximeter. | Sept 2001 | W |
| Dai shin sample optics embodied into P867RA (prototype), 3.6m, standard wiring connection. Conclusion : Dai shin sample LED transmits infrared on the incorrect wavelength. P867RA (prototype) does not read on the DL-3000 $spO_2$ simulator and is hence unsuitable. | Oct 2001 | X |
| New cables received and P867RA (prototype)'s constructed based on PDI optics and each cable type (larger conductor cross sectional area with inner & outer screens & standard conductor cross sectional area with inner screen only). Conclusion : Both P867RA (prototype)'s derive displayed $spO_2$ reading for exactly the target $spO_2$ value against the DL-3000 spo2 simulator in the range 100 - 80%. P867RA (prototype) CA59318715 selected as most suitable probe. | Dec 2001 | Y |
| Batch of 50 P867RA (production) manufactured based on P867RA (prototype) CA59328715. Full DL-3000 test carried out of 50% of the batch at random. Conclusion : Good results from all P867RA (production) on the 3700e oximeter against the DL-3000 $spO_2$ simulator. Poor results from all P867RA (production) on the 3800 oximeter against the DL-3000 $spO_2$ simulator. Typical underread of -3% at 98% simulated $spO_2$. | Jan 2002 | Z |
| 2 x P867RA (production), serial nos. CB59538943 & CB59538947, taken from the above batch and proven to read 2% low on the DL-3000 $spO_2$ simulator. Both probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Conclusion : Accuracy of displayed $spO_2$ readings improved by using yellow / blue drive leads in parallel to LED common anode. | Jan 2002 | AA |
| 3 x P867RA (production), serial nos. CB59538955, CB59538967 & CB59538971, taken from batch and proven to read 2% low on the DL-3000 $spO_2$ simulator. Both probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Standard workshop techniques used except soldering done at higher temperature. Conclusion : Displayed $spO_2$ readings improved by using yellow / blue drive leads in parallel to LED common anode against the DL-3000 simulator. $SpO_2$ readings taken the | Feb 2002 | AB |

| | | |
|---|---|---|
| human subject are also consistent. | | |
| 3 x P867RA (production), serial nos. CB59538959, CB59538965 & CB59538980 taken from batch and proven to read 2% low on the DL-3000 $spO_2$ simulator. Probes checked in comparison to P867RA (prototype), serial no. CA59328715 and reworked to become P867RA (prototype) attempting to establish the cause of the under read. Completely standard workshop techniques used. Full evaluation in comparison to P867RA (prototype) serial nos. CB59538955, CB59538967 & CB59538971. Conclusion : Displayed $spO_2$ readings improved by using yellow / blue drive leads in parallel to LED common anode against the DL-3000 simulator. $SpO_2$ readings taken the human subject are also consistent for the three prototypes. Manufacture techniques used for rework P867RA (prototype)'s CB59538959, CB59538965 & CB59538980 as per standard workshop production. Results above sufficiently consistent to warrant rework of remaining 42 P867RA (production) in batch CC5953. | Feb 2002 | AC |
| Batch CB5953 P867RA (production) reworked based on improved results of P867ra (prototype)'s using two parallel connection from pin 4 to common anode. Full DL-3000 simulator and on-human tests carried out of the entire reworked batch. Conclusion : Good results from first 20 P867RA (reworked production) on the 3700e. Improved results from first 20 P867RA (reworked production) on the 3800 - current failure rate of 4 in 20, 20%. | March 2002 | AD |

Conclusion of investigation.

FAX REF. : Page 1 of 1

DATE 20 May 1997

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

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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.

**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,<br>800mV,<br>850mV,<br>900mV, | | 750mV,<br>800mV,<br>850mV,<br>900mV, |
| | 950mV,<br>1000mV, | | 950mV,<br>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,<br>750mV,<br>800mV, | | 700mV,<br>750mV,<br>800mV, |
| | 850mV, | | 850mV, |
| | 900mV, | | 900mV, |
| | 950mV, | | 950mV, |
| | 1000mV, | | 1000mV, |
| | 1050mV, | | 1050mV, |
| | 1100mV,<br>1150mV, | | 1100mV,<br>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, | |

**Underread of P867RA probes on Ohmeda 3800 Pulse Oximeter: 19-01-01**

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

| | DL | Human |
|---|---|---|
| Aristo Finger: | 3700: 94% @ 97% | 100 |
| | 3800: 94% @ 97% | 99 |
| Aristo Y Probe: | 3700: 94% @ 97% | 99 |
| | 3800: 94% @ 97% | 97 |
| Aristo Disposable: | 3700: 95% @ 97% | 99 |
| (Adult) | 3800: 94% @ 97% | 99 |
| Aristo Disposable: | 3700: 97% @ 97% | 98 |
| (Neonatal) | 3800: 96% @ 97% | 97 |
| Aristo Disposable: | 3700: Can't Test on DL | 99 |
| (Paediatric) | 3800: Can't Test on DL | 99 |
| Aristo Ear Neonatal: | 3700: 95% @ 97% | 99 |
| | 3800: 94% @ 97% | 99 |
| Aristo D.O.T.: | 3700: 95% @ 97% | 99 |
| (Adult) | 3800: 94% @ 97% | 98 |
| OSS Disposable | 3700: 97% @ 97% | 100 |
| | 3800: 95% @ 97% | 98 |

* Aristo disposable neonatal selected as the 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.**

| **DL3000:** | **97** | **95** | **90** | **80** | **70** | **60** |
|---|---|---|---|---|---|---|
| 3700: | 95 | 93 | 89 | 80 | 71 | 62 |
| 3800: | 94 | 93 | 88 | 78 | 69 | 59 |

**Human:** 3700: 98
3800: 96

**Prototype P867RA (labelled A2, based upon Aristo disposable neonatal optics.**

| **DL3000:** | **97** | **95** | **90** | **80** | **70** | **60** |
|---|---|---|---|---|---|---|
| 3700: | 97 | 95 | 90 | 80 | 70 | 61 |
| 3800: | 97 | 95 | 90 | 80 | 70 | 60 |

**Human:** 3700: 99
3800: 99/98

Prototype A1 shows "inconsistent" readings, therefore rejected
Prototype A2 shows "consistent" readings, therefore further evaluated

**Test of prototype A2 on Human subjects**

| **Subject** | **3700** | **3800** |
|---|---|---|
| **MS** | **99/98** | **99** |
| **SW** | **99** | **99/98** |
| **AB** | **99/98** | **98** |
| **MFG** | **98** | **98** |
| **DB** | **98** | **98** |
| **JB** | **98** | **98** |
| **RT** | **98** | **98** |
| **SV** | **98** | **98** |
| **LN** | **97** | **98** |
| **MS** | **100** | **100** |
| **RA** | **99** | **98/97** |
| **AH** | **97** | **96** |
| **ML** | **96** | **97/96** |
| **RM** | **99** | **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 the finger nail area.

| | | |
|---|---|---|
| Aligned: | 3700: 100/99 | 3800: 99 |
| Misaligned: | 3700: 98 | 3800: 98 |

**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<br>- all read low. |
| | |
| July 2001 | P867RA assembled and tested using Dai Shin samples<br>- reads low. |
| | |
| July 2001 | P867RA's assembled using Dolphin disposable optics<br>- all read low . |
| | |
| July 2001 | P867RA assembled using O ring in front of the detector<br>- reads low. |
| | |
| July 2001 | P867RA's assembled using LED, detector or both from Ohmeda originals<br>- conclude that change of LED to Ohmeda cures or compensates for underread.<br>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<br>- 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<br>- component changes cure or compensate for the underread on the 3800. |
| Sept 2001 | 3 x MCI built P867RA's progressively shortened with regular testing<br>- found that all three probes read correctly when reduced to 8 ft.<br>- also found that the physical removal of cable outer screen cures the underread on probe at 12 ft length.<br>Recommendation made that all P867RA's supplied as new or repaired as of this date are shortened to 8ft.<br>Cable comparison made between ours and Ohmeda. Pin to pin checks carried out between good and bad probes for capacitance<br>- unable to identify a difference between cable / probe types with only 12 ft lengths to examine.<br>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<br><br>Jan 2002 | P867RA assembled using high output infrared LED from Dai Shin<br>- read on finger, doesnot work on DL-3000.<br>2 x P867RA's assembled using new cables<br>- both read accurately throughout the range.<br>- 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<br>- Results good - both probe prototypes return the target Spo2 value in the range 100 - 80%.<br>- Maximum error - +/- 1% below 80%.<br>- Spo2 values displayed alter by -1% when correctly aligned compared to incorrectly aligned. Ohmeda original finger probe - displayed Spo2 doesnot alter.<br>- 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.

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

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

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

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

#1B25730.

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

#1B25733.

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

#1B25748.

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

Conclusion : Suitable modification to eliminate underread problem.

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

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

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

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

#1B25730.

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

#1B25733.

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

#1B25748.

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

Conclusion : Suitable modification to eliminate underread problem.