cc
JC

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.

www.ebme.co.uk

Author	Topic: Massimo Probe Prices

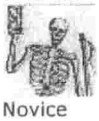
Simon Brooke
Newbie
Member # 772

posted 28. January 2004 01:45 PM

Hello
Has anyone found a supplier of Massimo Spo2 probes at reasonable prices? We currently buy from Datascope at £180 for the fingerclip and £148 for the instrument cable. I know Ultramedic supply them for alot less but only if you buy one of their monitors. There are many suppliers out there, who is the cheapest?
Simon

Posts: **4** | From: **James Paget Hospital** | Registered: **Jun 2003** | IP: Logged | Report Post

Frank



Novice
Member # 970

posted 28. January 2004 02:36 PM

Try sending your "dead" ones to Viamed 01535 633705 they do a pretty good repair service on SPO2 & ECG leads

Posts: **13** | From: **York** | Registered: **Jan 2004** | IP: Logged | Report Post

andyj81

Dreamer
Member # 88

posted 28. January 2004 03:13 PM

Hello.

Viamed do repair probes and do a good job, with a god service.
However Artema Medical, when I last ordered I could get supplied finger probe : £145 4ft lead at £110 8ft at £115 and a 12ft at £127

I have a number etc should you require this.

Regards.

Posts: **25** | From: **Airedale General Hospital** | Registered: **Nov 2000** | IP: Logged | Report Post

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.

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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.

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.

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

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

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

cc JSL SF

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

Report : Underread of P867RA on Ohmeda 3700e oximeter.

05-07-02.

Three probes tested: CF61092252, CF61092262, CF61092263.

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.

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).

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).

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).

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).

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).

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).

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:

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.

Report.

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

Contents.

Appendices.

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.
AE	Test of failed P867RA (production) from batch CB5953 after rework.
AF	Test of batch of 10 P867RA (prototype) manufactured (CD6031).
AG	Test of electrical characteristic of Ohmeda Adult reuseable finger probe.
AH	10 x LEDs selected based on 14.00mA forward IR diode current at 1200mV. Batch of 10 P867RA (prototype) manufactured.
AI	Data to support adapter cable constructed to boost IR diode forward current. Specification drawn up of new LED to cure the underread problem.
AJ	New LEDs received, PDI-E8078. 2 x 10 P867RA (prototype) built and tested.
AK	Test of above P867RA (prototype) with 43.0 kohm resistors.

Introduction.

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

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

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

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

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

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

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

The theory of pulse oximetry.

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

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

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

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

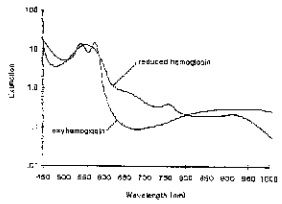

Figure 1: Diagram showing absorption (extinction coefficient) versus wavelength for oxy-haemoglobin($Hb0_2$) and deoxy-haemoglobin(Hb).

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 oxy-haemoglobin ($Hb0_2$) 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 lesser amount of transmitted light passes through the site unobstructed. The relatively high absorption of red light as it passes through blood with low dissolved oxygen content is the reason why deoxygenated venous blood appears to the human eye to be dull red in colour.

This is shown schematically in Figure 2 - as percentage saturation increases from left to right across the horizontal axis, absorption of red light at 660nm decreases. The relationship is linear throughout the entire range of 0% $Hb0_2$, 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.

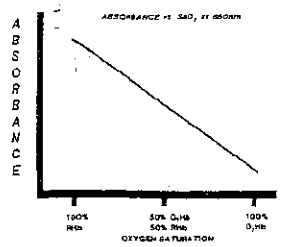

Figure 2: Absorption of red light at 660nm compared to the level of blood saturation.

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 $Hb0_2$.

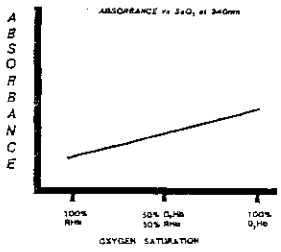

Figure 3: Absorption of red light at 930nm compared to the level of blood saturation.

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,

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

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

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

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

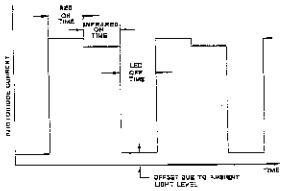

Figure 4: Diagram showing the sequence of pulses of red and near infrared and measurement of ambient light (neither red nor infrared on).

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

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

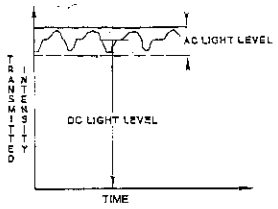

Figure 5: Schematic representation of AC signal and DC level produced by transmission of the given wavelength of light through living tissue.

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

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

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

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

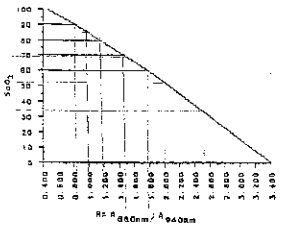

Figure 6: Diagram showing the relationship between R ratio derived and displayed spO_2.

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

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

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

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

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

Construction of the P867RA.

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

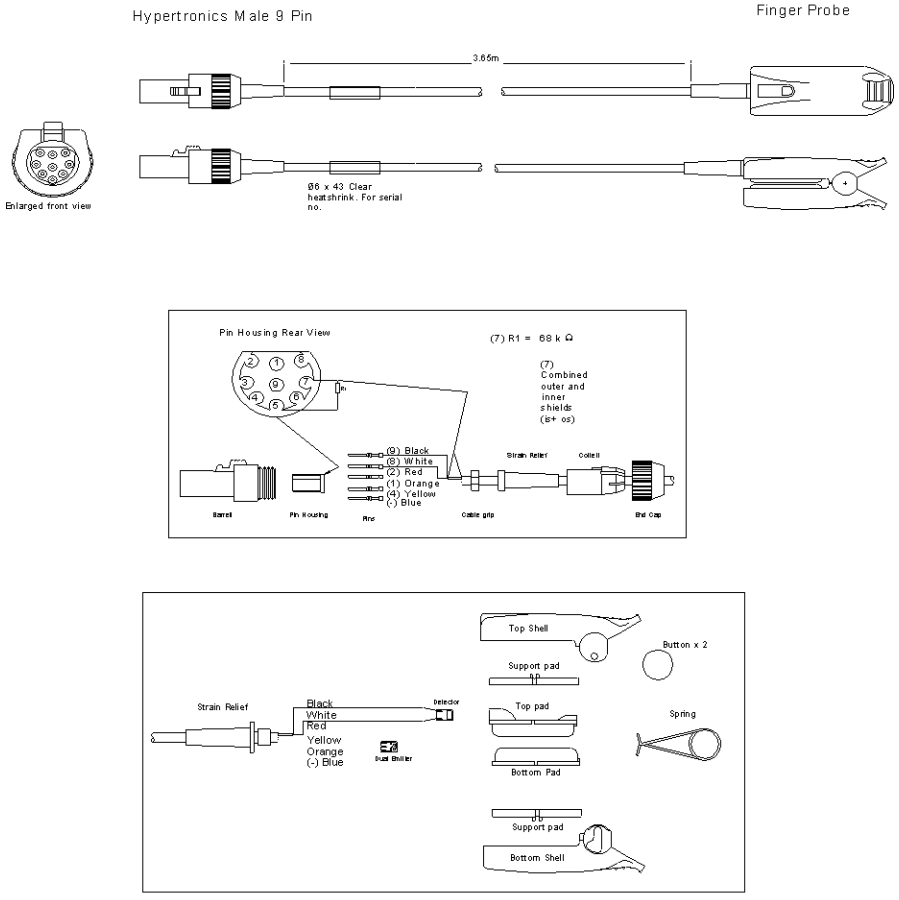

Figure 7: Schematic diagram of Viamed P867RA adult re-useable pulse oximetry finger probe.

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

Possible factors resulting in a difference in displayed spO_2 readings.

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

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

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

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

Investigation.

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

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

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

		on the DL-3000 spo2 simulator and on the human finger. Probes (either passed or failed) examined to establish component(s) causing the under read problem._ Conclusion: Suspect low through current and or low IR light output of IR diodes leads is resulting in under read.
AG	**Sept 02**	Electrical characteristic of Ohmeda Adult re-useable finger probe measured for red and infrared emitters. Conclusion: Ohmeda original adult re-useable finger probe, Lot 27299 accepts a far greater IR forward diode current than a typical Viamed P867RA.
AH	**Nov 02**	10 x LED's selected based on go/no-go measurement of 14.00mA forward IR diode current at 1200mV. Batch of 10 P867RA (prototype) manufactured (CE60420655-CE60420664). Measurements redone after fit into wiring harness with connector and after clip fit. Probes tested on the DL-3000 spo2 simulator and on the human finger. Failed probes examined to establish component(s) causing the under read problem. Intensities of red and infrared emitters measured on all probes. Conclusion: Again, failed P867RA (prototype)s can be seen to have lower forward IR diode currents than P867RA (prototype)s which pass. However at this time, it cannot be concluded that the lower intensities of IR diodes on under reading probes is not the root cause on the problem.
AI	**Dec 02**	Adapter cable manufactured allowing LED common, IR diode cathode & red diode cathode to be tapped into. 3.3Ω resistor introduced in series into LED common, IR diode cathode & red diode cathode. Conclusion: 2nd IR diode introduced in parallel with probe IR diode proves that 3 x under reading P867RA (prototype) can be made to read accurately and implies that the electrical properties on the probe as sensed by the 3800 is more important than the intensity of IR emitted.
AJ	**Jan 03**	New LED's received, PDI-E8078, and assembled into 10 x P867RA (prototype), batch no. CL6261. Probes tested against the DL-3000 and on the human finger. LED characteristics recorded to see if any pattern could be seen to relate the diode impedance to displayed SpO_2 value. 30 LED's tested to plot forward diode characteristics. Further batch of 10 P867RA (prototype), batch no. DA6269, with diodes taken from the above 30 at random. Conclusion: P867RA (prototype), batch CL6261, show promising results with no more than -1% error at 98% against the DL-3000. Analysis of LED characteristics / emission wavelength does not reveal a physical property that causes an under read. P867RA (prototype), batch DA6269, show very consistant results with 97% @ 98% DL-3000 and 58% @ 60 % DL-3000 (care taken during testing of these probes to ensure that the alignment of the probe optics to test finger optics were as consistent as possible from probe to probe). Characteristics of LEDs 11 - 30 seem to be more consistent than characteristics of previously used PDI-E835. PDI-E8078 does not meet the specification drawn up in Appendix AI, however the part seems to improve the reading of displayed SpO_2 by 1% @ 98% against the DL-3000.
AK	**Jan 03**	P867RA (prototype), batch no. CL6261, fitted with 43.0kohm resistors. P867RA (prototype), batch no. DA6269, fitted with 43.0kohm resistors. Probes tested against the DL-3000 and on the human finger. anode. Probe LED current tested @ 1800mV (red) & 1200mV (IR). Conclusion: One under reading probe in batch CL6261 also with the lowest If (IR) of all the probes. No under reading probes in batch DA6269. Current failure rate of 5%.

Conclusion of investigation.

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

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

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

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

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