Report.

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

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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.

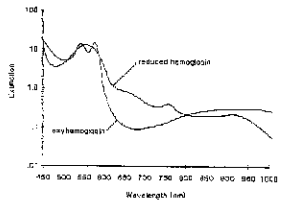

Figure 1: Diagram showing absorption (extinction coefficient) versus wavelength for oxy-haemoglobin($Hb0_2$) and deoxy-haemoglobin(Hb).

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.

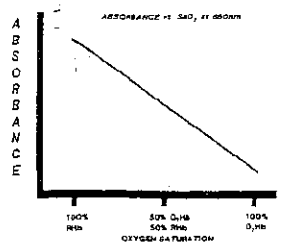

Figure 2: Absorption of red light at 660nm compared to the level of blood saturation.

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 $Hb0_2$.

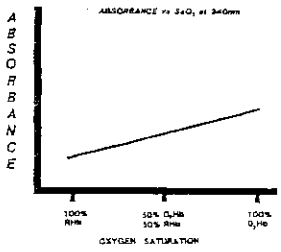

Figure 3: Absorption of red light at 930nm compared to the level of blood saturation.

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.

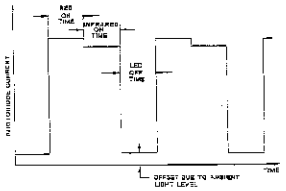

Figure 4: Diagram showing the sequence of pulses of red and near infrared and measurement of ambient light (neither red nor infrared on).

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.

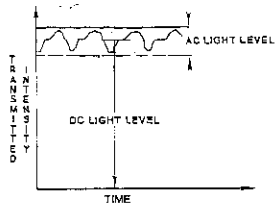

Figure 5: Schematic representation of AC signal and DC level produced by transmission of the given wavelength of light through living tissue.

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:

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

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

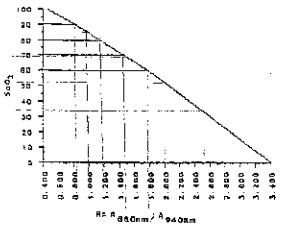

Figure 6: Diagram showing the relationship between R ratio derived and displayed spO_2.

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.

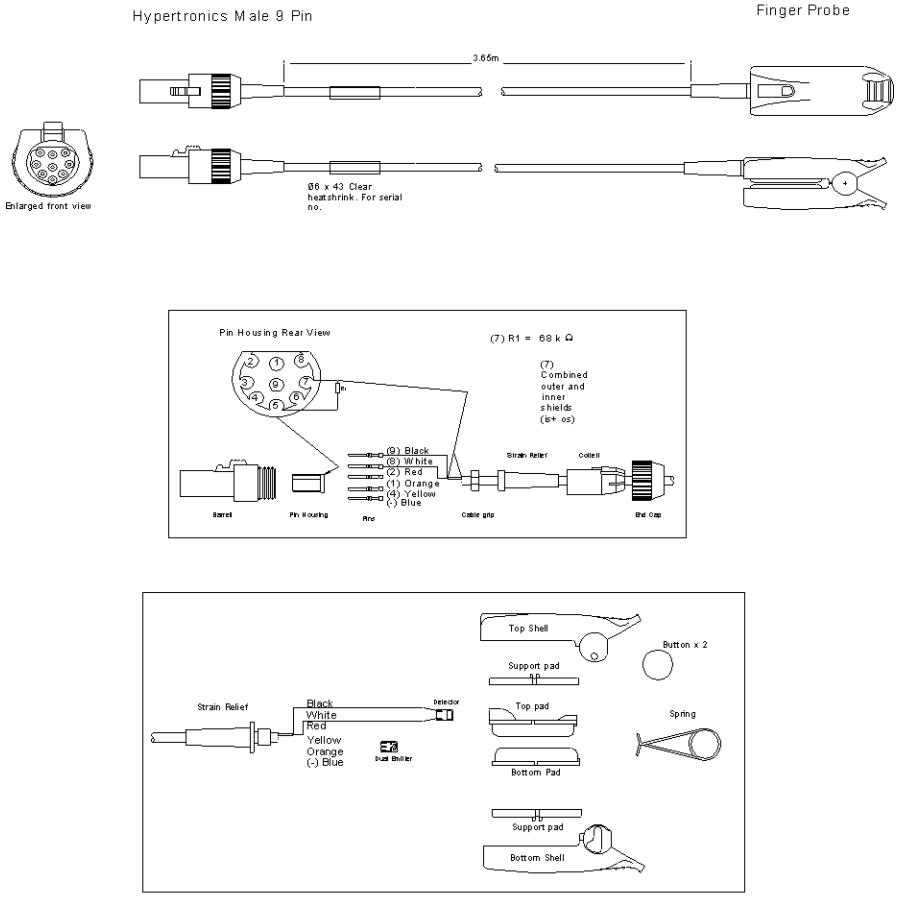

Figure 7: Schematic diagram of Viamed P867RA adult re-useable pulse oximetry finger probe.

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.