# **Technical Information Sheet**

From:

**Epic Medical Equipment Services** 

**Jeff Secunda Technical Operations** 

Subject E100A Accuracy using the Bio-Tek Index SpO2
Simulator

## **Problem:**

Customers who use the Bio-Tek "Index" SpO2 simulator will get erroneous numbers when testing the Epic E100A on a Nellcor pulse oximeter.

## Cause:

The Bio-Tek simulator does not contain, in its memory, the necessary "R-curve" for the Epic E100A sensor. The "R-curve" translates the electronic values measured by the pulse oximeter into SpO2 values % saturation)

## **Response:**

Bio-Tek has developed an "R-curve" for the Epic E100A which will allow the Nellcor pulse oximeter to display the appropriate SpO2 values.

### How:

Bio-Tek will make the "Epic/Nellcor" R-curve available to customers through their "Electronic Bulletin Board" (within 30-60 days)

Bio-TEk is also evaluating the performance of Epic sensors with other pulse oximeter OEMs when using the Bio-Tek Index simulator, and will create the necessary R-curves for these proproducts.

**July 1996** 

Please Advise receipt of this Information sheet.

There is no reason why this sheet cannot be

# Compatible SpO<sub>2</sub> Finger Probe Cross Reference

Origional Equipment Manufacturer.	Identification Model or Part Number	Lengt h (Ft)	MCI No
Baxter	600333-003 ASAT	12	P860RA
Baxter	Explorer Monarch		P856RA
Biochem (BCI)	3044 3300 3301 3302 3044		P861RA
Bruker	Bruker		P861RA
Corometrics	556	3	P856RA
Criticare	511SD/934 1100 1100-3 501 503 504 507 508 581 Poet Plus	12	P862RA
Critikon	9084 8700 Series	12	P870RA
Critikon	8997 Dinamap Oxytrak	3	P877RA
Critikon	9700 Series	3	P856RA
Critikon	9700 Series	11	P858RA
Datascope	0600-00-0026-01 Accusat	12	P864RA
Datex	878579-1 SAS-F4 CG-2CS CH-S CH-RS ULTSIO ULTSVI AS/3 OSP-200 CH-2S Satlite ULTS00 Oscar II M-ESTPR CH-RS ULTSVO Cardoicap II	12	P872RA
Draegar	Vitalert 1000 Narkomed Cicero	3	P856RA
Elmed	6006194 PSO1000	3	P861RA
Entri Medical	Propaq 102 104 106	3	P856RA
Fukuda Denshi	HG302 Module	3	P856RA
Gambro	BP806	3	P856RA
Hewlett Packard	Miracle Adult System Merlin M1020A Neonatal	3	P856RA
Invivo	4500+2	3	P856RA
Ivy Medical	405A	3	P856RA
Marquette	Tram System Modular System	12	P867RA
Marquette	Eagle 3100	3	P856RA
Medical Data	2800-50 OP11A OP30 Escort 100 Escort II	3	P856RA
Mennen	800-060-540 Horizon XL (Ohmeda)	12	P867RA
Mennen	800-060-730 Horizon XL (Nellcor)	3	P856RA
Nellcor	N6000 N180E N180	11	P858RA
Nellcor	C-13-200M N-200 DS100A	3	P856RA
Novametrix	8774 8776 505 511 515 520 7000 Oxypleth	12	P876RA
Novametrix	8660 500 Series	12	P875RA
Ohmeda	380-1000-042 6051-0000-049 Oxystat Modular CD Anaes 3700 4700	12	P867RA

	Oxysta Plus		
Propaq	Propaq	3	P856RA
S & W Vickers	4621643 4700708 DSNT	3	P856RA
Sensor Medics	766721 767367 Oxyshuttle Omnistat	3	P865RA
Siemens	1281	3	P856RA
Simed	S-100e	12	P860RA
Spacelabs	015-0130-00 90651A-08 90419-01 90489 90467 90466 90465 90351- D/G (Ohmeda)	12	P876RA
Spacelabs	015-0150-00 90489 90465 90466 90467 90651A-08 (Nellcor)	3	P856RA
Spacelabs	369-083-001 90419 90501 90651A-03 (Novametrix)	12	P875RA
Spacelabs	90651A-08	12	P857RA

All original manufacturers' trademarks and registered names recognised.

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Available From: Viamed Ltd. 15, Station Road, Crosshills, Keighley ,West Yorkshire. BD20 7DT. Telephone 01535 634542 Fax: 01535 635582. EMail: info@Viamed.co.uk

#### Rework Instructions for Connectors on Ohmeda Type Probes

Rework instructions for Connectors on Chineda Type Frodes
The shielding on some reworked Ohmeda type probes may require upgrading if they are to be used in the presence of surgical diathermy equipment. The following instructions show how to check if any work needs to be carried out and how this work can be done. This only applies to a small number of probes done by one technician who was following an incorrect procedure. Any probes which have the original Ohmeda connector will not require reworking, only probes with the unscrewable type replacement connector will need to be checked.  After the probe has been upgraded no problem will arise from its use in Theatres.
Open the connector by unscrewing the collet nut on the back whilst holding the barrel of the plug. Slide the barrel off.
Pull the body of the connector and the strain relief back along the cable to expose the wiring.

Check the connection between the shield and the resistor, if the shield is not soldered or the solder connection is such that the shield is able to slide along the resistor then it will need to be resoldered.

After ensuring a good solder connection the body of the connector and the strain relief can be pulled back along the cable to cover the wiring. The barrel of the connector can then be put back on, noting that this will only be achieved if the barrel is correctly aligned. Screw the collet nut back on.

IN THE MATTER OF VIAMED LIMITED AND EPIC MEDICAL EQUIPMENT (UK) LIMITED

# INSTRUCTIONS FOR COUNSEL TO ADVISE IN CONFERENCE ON WEDNESDAY 26 TH MARCH 1997 CONCERNING RESTRICTIVE COVENANTS AND CONFIDENTIALITY AGREEMENTS

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IN THE MATTER OF VIAMED LIMITED AND

EPIC MEDICAL EQUIPMENT (UK) LIMITED

# INSTRUCTIONS FOR COUNSEL TO ADVISE IN CONFERENCE ON WEDNESDAY 26 TH MARCH 1997

# CONCERNING RESTRICTIVE COVENANTS AND CONFIDENTIALITY AGREEMENTS

Left herewith are:-

- 1. Product information
- 2. Consultancy Agreement
- 3. Confidentiality Agreement
- 4. Share Sale Agreement
- 5. **Supply** Agreement
- 6. Letter

Counsel is asked to advise in conference concerning the enforceability of restrictive covenants and confidentiality agreements in relation to the sale but more particularly to the repair of Pulse Oximeter Finger Probes ('probes') (herewith 1)

Instructing Solicitors act for Viamed Limited ("Viamed'), a company

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which has been in business for some twenty years selling equipment to the medical services.

The principal Directors and Shareholders are John and Jean Lamb ("John" and "Jean").

Instructing Solicitors also act for Epic Medical Equipment (UK) Limited

("Epic UK") which started off as an off-the-sheif company incorporated in

October 1995. It was acquired in November 1995 in the circumstances referred to below, for the purpose of dealing with the sale and repair of probes produced by IOC (referred to below). The principal Directors and Shareholders of the company are now John and Jean and Derek Lamb

("Derek") the son of John and Jean, and Stephen Hardaker ('Steve"), an employee of Viamed.

The other parties to whom reference will be made are as follows: -

**Epic Medical Equipment Services Inc.** ('EPIC INC.") - a company owned or under the control of Ken Perdue ("Ken") and/or his grandson Todd Daniels ("Todd") and/or a subsidiary of IOC and which is mainly concerned with carrying out, in the United States, repair work to probes.'

International Oxymetry Sensors and Cabies Inc. ("IOC") also under the ownership or control of Ken and/or Todd, which is concerned with the manufacture of probes.

**DD DeMichlyn Co. Ltd.** ('DD"), a company registered in the Bahamas and being under the control or direction in part or wholly of Todd and/or Ken and/or a subsidiary of IOC.L

**Teledyne-Brown Engineering** ('Teledyne") a companylbusiness based in Caiifornia USA at one time a distributor of IOC probes.

The enclosures (h	nerewith 1	- 6) are as	follows: -
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- 1. A recent leaflet which shows some probes and lists equipment for which available
- 2. Consultancy Agreement, believed to be the same date as the Confidentiality

  Agreement referred to above, dated 3 oth November 1995, made between DD and Viamed

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DD was to supply the services required by Viamed during the consultancy period, which started with the commencement date and finished on the termination date.

Clause 5 relates to restrictive covenants,

5. 1 (a) gave the period as three years after Completion or one year after Termination when Viamed were (inter alia) not to be concerned 'n the bus'

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of repairing and/or manufacturing probes. The Completion date is not defined.

(b) during a period of twelve months from the termination date not to have connection with any customer of the Consultant.

(d) deais with trade names and marks		
5.2 Not to divulge information		
5.3 Acknowledgement that the above covenants are to protect the		
Consultant's goodwill		
5.4 Each restliction can be construed separately		
5.5 Provisions for modification		
It also contains under Clause 6 the confidentiality provision		
The Consuitancy Agreement calculations are referred to in Schedule 2.		
3. Confidentiality Agreement <b>30th</b> November 1995 made between DD		
and Viamed, referred to above		
4. Share Sale Agreement gth February 1996, made between DD and		
Viamed.		

5. Supply Agreement undated, but believed to be dated the same date as the Share Sale Agreement, gth February 1996, made between IOC and Epic UK.

It contains Restrictions under Clause 6 and confidentiality obligation under Clause 7.

It provides under Clause 9 for payment of 25% of gross revenue fees of Epic UK.

6 Letter dated 1 7th January 1996 confirming the salelpurchase of the Epic UK shares.

1 oth

It all started on October 1994 when John visited a Trade Exhibition in Las Vegas U.S.A. where Ken and Todd had a booth offering their products, including the probes. john expressed his interest in buying the probes for the UK market and the meeting resulted in Viamed placing its first order with IOC or on 22nd December 1994.

Viamed has for over twelve years soid Patient Monitors to various medical establishments, part of which included a module to which were attached non-invasive probes for checking oxygen levels in patients' blood. These probes were easily broken or damaged, and the practice

had been for the users to buy replacements from the manufacturers of the module. These probes could cost up to £300 each, which worked out to be very expensive, given the frequency that damage occurs (.without imputing an excessive degree of roughness on the part of the nurses or other medical staffi.

What John had seen at the exhibition in Las Vegas, was what he had been seeking for a long time, namely, a comparatively inexpensive probe which could be used with most, if not ail, modules. At the same time Ken put in mind the introduction into UK of a repair service for damaged probes.

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Following discussions between John and Todd, during the course of 1995, and at a meeting on 30th October 1995 it was proposed that Todd would set up a company in UK under the name of Epic. The intention at that stage was that the new company would operate fi-om Viamed premises and hire Viamed staff to do the repairs. It was to be a joint venture between IOC and Viamed personnel as directors. However the following day Todd told John that, having spoken to Ken, it had been decided that the directors would be Todd and Ken with Jean as Company Secretary and it would involve signing a Supply Agreement.

In fact it was the Consultancy and Confidentiality Agreements (herewith 2 and 3) that were entered into.

As referred to above Epic UK was acquired in November 1995 with DD as owner of ail of the shares; Todd as principal director and Jean as secretary. However at a meeting on 16 Ih January 1996 between Ken Todd John and Jean it was agreedlthat Epic UK should be sold to John and Jean. An agreement was signed dated glh February 1996 (Herewith 4)

In Aprii 1996 work actually commenced on the repair of probes with Viamed labour being hired to Epic UK

Derek and Steve were interested in becoming heavily involved in the development of the probe repair service, and went to the States on 4 th February 1996. They were required to sign Confidentiality Letters.

Including taking over the shares in Epic UK Viamed was required to buy a Test Box from DD/IOC for S3000 together with additional Puise Oximeters at total outlay of \$1 0,000.

The above matters are more concerned with repairs to the probes than their safe which concerns Teledyne involvement and a summary of events concerning Viamed, Teledyne, Epic 1nc and IOC is set out below.

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On 10'hDecember 1995 Ed Avila of Teledyne met Ken at an exhibition in Florida where Ken offered Teledyne the rights to purchase probes for sale throughout the world except USA, Canada, and the UK and this is believed to have been agreed eady in 190@

On is'January 1996 Viamed were appointed "Master Distributors in Europe" for other Teledyne products following discussions over previous months and meeting, individually, most of Teledyne existing European distributors, in Dusseldorf, during the exhibition week of 20lh November 1995.

On 8th February 1996 as Viamed now had two suppliers of probes it relinquished the right +,o purchase from IOC in order to make all purchases from Teiedyne for UK and the rest of Europe distribution

During the course of 10M@ 996 relationships between IOC and Teledyne personnel deteriorated

At the exhibition in Dusseldorf in mid November 1996 Teledyne and Viamed jointly held nightly receptions for their distributors as well as having individual meetings during the daytime.

IOC had their own booth at the exhibition where they distributed forms inviting anyone to apply to be their agents. When existing Teledyne/Viamed distributors introduced themselves they were taken into back office; offered direct sales at better prices than through Teiedyne/Viamed and were asked not taik to John or Ed Aviia about the offer. When John and Jean visited the booth they were treated cordially but no discussion of changes In distributorship

took place

On 25 th November 1996 IOC gave Teledyne 30 days notice terminating They're sales agreement, copying notification to Viamed and some of other existing purchasers around the world. On the same date Viamed was offered

direct

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sales again, but put off making a decision

On 5 h March 1997 Viamed were notified that IOC had appointed a new distributor in the U.K.

Duhng the course of 1996 Teledyne have succeeded in finding another source of supply for the same type of product which will be formally introduced to the distributorship network at a seminar to be held at the end of May 1997.

In fact, Viamed soitcits all of the custom and does all of the work and passes the required amount on to Epic UK which then pays iOC. So far, a total of £ 1 0999 has been paid to IOC, with a further amount due of £7170 for the period December 1996 to February 1997.

Viamed/Epic UK want to operate throughout UK and mainland Europe, both in the field of

selling and repairing Probes without having to make any payments to DD or IOC. They, and both Derek and Steve, would like to know to what extent they would run the risk of DD or IOC successfully stopping them as a whole or individually from providing sales and services in connection with Probes, whether or not they have been manufactured or supplied by DD or IOC.

In addition, Derek and Steve would like to know to what extent they could be restrained from passing on the information they received in their training by DD/IOC, together with knowledge and experience gained whilst carrying out their work during 199617

It should be borne in mind that DD/IOC are not the only suppliers of modules or Probes, ail of which are of a similar pattern

JPMMISDS/M5 21 March 1997

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Please find enclosed our information on Pulse Oximeter Probes as promised
On the leaflet with picture and side text only, we can print anything you like in any language (both sides). If you want us to supply this, all we request is that you send the text you require on plain paper in a large font. If necessary, you can also supply a sketch on a separate piece of paper indicating how you want the text laid out.
We can also supply A5 reply cards with your own text. A sample of which is enclosed for your reference.
Regards
Peter Lamb

Dear

# UK Strategy for the Introduction of Compatible SpO<sub>2</sub> Finger probes

This strategy may be unique to the UK market but it has worked.

- 1) The most common finger probes in use in UK hospitals were investigated.
- 2) The List prices and discount deals on these probes were obtained.
- 3) Five equivalents of the most popular two manufactures were obtained from the supplier.
- 4) These were circulated to hospitals with a close relationship to Viamed.
- 5) The most likely people to buy finger probes were located and given demonstrations.
- 6) The big buyers were left samples to try.

7) The Viamed prices were established to be 30% below the existing manufacturers prices.

This has meant on one or two reducing the gross profit. The number of sales achieved has proved this risk to be worth while.

8) A full 12 month warranty was offered. This has risks, as most breakage's are due to

the customer mistreating the probe. However the response in sales far outweighed the costs

of warranty. Viamed repairs Free of Charge your warranty failures.

- 9) Discounts are offered to the end user for quantity purchases,
  - a) 10 more less 5%
  - b) 20 or more less 10%
  - c) Call off orders 10 or more less 5%
  - d) Mixed types of probes qualify for discounts.
- 10) The "one stop shop" supplying Teledyne Oxygen sensors SpO2 probes has been

exploited.

11) Having established a market and determined the most popular types of probes in the UK

Mail shots to users are now being sent out in large quantities.

12) Viamed has now brought onto line a Repair service for most types of existing finger

probes

We can only repair Finger Probes

We cannot always repair OEM. cables with moulded plugs.

The cost to you is \$85 per repair

We warranty the parts repaired for 6 months.

The probes should be decontaminated before you handle them.

# Advertising

# Leaflets

We are continually asked for a leaflet on the finger probes even though all of our sales people have an almost unlimited range of demonstration samples. I am therefore printing a European leaflet.

The front is in colour similar to our UK leaflet

The words can be added in your language later by laser printer if you can translate it for me.

Your Address can also be laser printed on or use can use your own label

If you translate your requirements we can laser print small quantities for you.

Alternatively we can supply the photograph

# **Comprehensive Conversion Chart**

A comprehensive conversion chart has been built up in the database Approach.

It is never fully up to date as we are continually adding new information as we receive it.

We appreciate any information on Oximeters and

probes you can send us.

# **Customer "Feel Good Factor"**

This is the contents of a letter sent to UK Hospitals who query the Probes or have been frightened by the OEM's verbal references to warranty infringements etc.

#### **Pulse Oximeter Probes**

#### The SpO2 Probe

The probe consists of two Light Emitting Diodes (LED) with specific transmission frequencies. These LED's are manufactured by several electronic component companies world-wide to standard specifications for industrial use and are not specific to the medical field. We are using diodes with the same specication and wavelengths.

There is no way the probe can damage the module or measuring instrument.

#### Liability

The product is guaranteed equivalent to the probe it is replacing and is backed with full product liability insurance. Viamed as the importer into the EEC legally must carry this liability and are therefore insured to do so.

#### **Quality Assurance**

Viamed already has BS ISO EN 9002 and should achieve ISO 9001 EN4601 by the end of 1996. We are working with MCI so that they can also achieve ISO 9001/EN 46001. MCI already have a GMP system installed which satisfies the USA FDA. All their products will in the future carry the CE mark. Test procedures are available on request . Every probe is serialised and Viamed MCI have total traceability.

#### O.E.M's

Very few equipment manufacturers actually manufacturer their own probes and these items are bought in and re-labeled. This is exposed by the number of manufacturers we can cover with a minimum of probe types. As most manufacturers are using Nellcor or Ohmeda, Hospitals which have a number of different types of SpO2 modules may be able to purchase the same MCI probe for them all thereby either purchasing in quantity at a lower price or reducing their stocking requirements.

#### Warranty

All MCI products have a 12 month warranty unless physically damaged by the user.

#### **Pricing**

Ten or more less 5% 20 or more less 10%

John S. Lamb

# Viamed SpO<sub>2</sub> Finger Probe Recycle Programme

Viamed has now brought onto line a Repair service which will allow most types of existing finger probes to be repaired and re-cycled

The aim is to return to the user a Finger probe that looks new and has not just been glued together or spliced and covered with heatshrink tubing. Our object is to re-cycle as much as possible of the existing finger probe instead of consigning it to the waste bin.

These probes are used in critical care areas and it is our intention not only to repair them but to return them clean and professionally finished so they look the part. Our warranty covers the parts and labour used to repair your probe. i.e. if we replace the clip and the clip breaks in 6 months we repair it free. However if we repair the clip then later the instrument plug develops a fault this is treated as a separate repair.

Viamed is ISO9002 certified and all repairs will be carried out in accordance with these procedures. All repaired probes will be tested before dispatch as well as having the LED's electronically analysed.

# Our repair Policy is :-

We will endeavour to provide quality repairs
All repairs are made using new parts
manufactured for Viamed's repair programme
Prompt service and fast turn around
Six months warranty on all repairs
There is a fixed cost regardless of type of cable
or extent of repair

We can usually only repair Finger Probes at present

We cannot always repair OEM cables with moulded plugs although we try.

If we cannot repair a probe a service replacement will be offered.

The probes should be decontaminated before they are returned to us.

This is the contents of a letter sent to UK Hospitals who query the Probes or have been frightened by the O.E.M.'s verbal references to warranty infringements etc.

#### **EPIC Pulse Oximeter Probes**

#### The SaO2 Probe

The probe consists of two Light Emitting Diodes (LED) with specific transmission frequencies. These LED's are manufactured by several electronic component companies world-wide to standard specifications for industrial use and are not specific to the medical field. Epic are using these same diodes in their probes.

There is no way the probe can damage the module or measuring instrument.

#### Liability

The product is guaranteed equivalent to the probe it is replacing and is backed with full product liability insurance. Viamed as the importer into the EEC legally must carry this liability and are therefore insured to do so.

#### **Quality Assurance**

Viamed already has BS ISO EN 9002 and should achieve ISO 9001 EN4601 by the end of 1996. We are working with EPIC so that they can also achieve ISO9001/EN46001. Epic already have a GMP system installed which satisfies the USA FDA. All their products will in the future carry the CE mark. A customer copy of Epic Q.A. tests accompanies every probe. Copies of Epic test procedures are available on request .Every probe is serialised and Viamed/Epic have total traceability.

#### O.E.M's

Very few equipment manufacturers actually manufacturer their own probes and these items are bought in and re-labeled. This is exposed by the number of manufacturers we can cover with a minimum of Epic types. (see equivalent chart). As most manufacturers are using Nellcor or Ohmeda, Hospitals which have a number of different types of SaO2 modules may be able to purchase the same Epic probe for them all thereby either purchasing in quantity at a lower price or reducing their stocking requirements.

#### Warranty

All Epic products have a 12 month warranty unless physically damaged by the user.

#### Pricing

Ten or more less 5% 20 or more less 10%

John S .Lamb**Date** 8th November 1995 (Epicqa)

# Viamed SpO<sub>2</sub>Pulse Oximeter Finger Probes

Please find enclosed our latest literature on Pulse Oximeter Finger probes. It was with a certain amount of trepidation we introduced these probes during the early part of 1995. However the market response has been tremendous and they have proved in use to be not only compatible with the original equipment suppliers versions but reliable, accurate, and durable.

We offer a 12 month warranty on all probes and with most probes a substantial saving in cost. You can now order from one company several different types and save more by multiple or call-off purchases: Ten or more less 5%: 20 or more less 10%

#### The SpO<sub>2</sub> Probe

There is no way the probe can damage the module or measuring instrument.

The probe consists of two Light Emitting Diodes (LED) with specific transmission frequencies. These LED's are manufactured by several electronic component companies world-wide to standard specifications for industrial use and are not specific to the medical field.

#### Liability

The product is guaranteed equivalent to the probe it is replacing and is backed with full product liability insurance. Viamed as the importer into the EEC legally must carry this liability and are therefore insured to do so. This liability is supported by Teledyne and the manufacturer.

#### Quality Assurance

Viamed already has BS ISO EN 9002/ EN4601 . We are working with the manufacturer so that they can also achieve ISO9001/EN46001. All  $SpO_2$  products will in the very near future carry the CE mark. Copies of test procedures are available on request . Every probe is serialised and Viamed have total traceability.

#### O.E.M's

Very few equipment manufacturers actually manufacturer their own probes and these items are bought in and/or re-labelled. This is exposed by the number of manufacturers we can cover with a minimum of Epic types. (see equivalent chart). As most manufacturers are using Nellcor<sup>R</sup> or Ohmeda R, Hospitals which have a number of different types of SpO2 modules may be able to purchase the same Viamed SpO<sub>2</sub> probe for them all thereby either purchasing in quantity at a lower price or reducing their stocking requirements.

#### Warranty

All Viamed SpO<sub>2</sub> products have a 12 month warranty unless physically damaged by the user.

As the number of manufacturers of finger probes grows so does our range of compatible probes. If it is not on the cross-reference chart telephone us. If it is not available now your request could enable us to add it.

# Viamed Finger Probe Re-Cycle programme

This year will see the introduction of EEC legislation regarding recycling of waste and as an medical engineering based company we understand the frustration of broken pulse oximeter probes collecting dust whilst you earnestly wish you could repair them.

This is now possible as Viamed have brought onto line a finger probe re-cycling service and we are able to repair most probes. Moulded connectors obviously cause problems and may prevent us effecting a clean profession repair. We also have a learning curve and therefore with less popular versions of finger probes we may exceed our target of a maximum 7 day turn around.

The aim is to return to the user a finger probe that looks new and has not just been glued together or spliced and covered with heatshrink tubing. Our object is to re-cycle as much as possible of the existing finger probe instead of consigning it to the waste bin. Where required new parts will be fitted. These probes are used in critical care areas and it is our intention not only to repair them but to return them clean and professionally finished so they look the part.

Our warranty covers the parts and labour used to repair your probe. i.e. if we replace the clip and the clip breaks in 12 months we repair it free. However if we repair the clip then later the instrument plug develops a fault this is treated as a separate repair.

Viamed is ISO9002/EN46002 certified and all repairs will be carried out in accordance with these procedures. Before despatch Every re-cycled finger probe is tested electronically and in many cases on the original manufacturers equipment. As the number of different types of probe we repair increases so does the number of O.E.M' SpO2 instruments we acquire. Full reports and tests carried out are documented and supplied with each probe.

The proof is always easy to establish by trying us out at no risk. If we cannot repair to your satisfaction there is no charge. If we are not satisfied, under our BS EN ISO 9002/EN46002 registration, with the

finished product or its accuracy we will not claim to have repaired it.

Our repair Policy is:-

We will endeavour to provide quality repairs

All repairs are made using, when required, new replacement parts

Prompt service and fast turn around Six months warranty on all repairs

There is a fixed cost regardless of type of cable or extent of repair

We can usually only repair Finger Probes at present

We cannot always repair OEM cables with special moulded plugs although we try.

If we cannot repair a probe a service replacement will be offered at 20% off our list price.

Most Finger Probes can be re-cycled

The probes should be decontaminated before they are returned to us in accordance with the official recommendations.

The fixed cost of the repair/re-cycle service is £80.00. + VAT & Carriage

John S. Lamb 23 January 1997 FAX REF: NOS. OF PAGES: 1

DATE 8 May 1997 TO Mr. K. Perdue

Epic

FROM John S Lamb

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Dear Mr Perdue,

Please do not insult me.

I have been in the Medical business for thirty years and have achieved an untarnished reputation for honesty and high ethical standards. I have no intention now of breaking a signed agreement.

However your unilateral actions and underhand methods last year have forced me to protect the ability of our companies to continue trading. I have therefore made extensive contacts with Manufacturers of Pulse Oximeter products, Pulse Oximeter and probe repair centres, suppliers of Pulse Oximeter accessories and components world-wide. It is therefore not suprising that we should stumble upon your manufacturer and supply chain. You forget how small the world has become.

I do not believe this is of any concern of yours as I repeat I will abide by every agreement I have signed to the letter.

John S Lamb

# **Epic Advertising**

#### Leaflets

We are continually asked for a leaflet on the finger probes even though all the sales people have samples.

I have therefore printed a European leaflet.

The front is in colour similar to our UK leaflet

The words "REPLACEMENT PULSE OXIMETER FINGER PROBES"

can be added in your language later by laser printer. if you can translate it for me.

Your Address can also be laser printed on or use can use your own label

If you translate your requirements we can laser print small quantities for you.

The reverse is the Epic conversion chart.

Alternatively we can supply the photograph

#### **Demonstration Kits**

Pt.No. E1114

I have some special Epic demonstration kits which are available at \$400.

The kit in a foam lined presentation box contains short versions of :

- (1) E100A sensor for Nellcor
- (1) E3000 sensor for Ohmeda
- (1) EN300 patient module for Nellcor probe
- (1) E100SL sensor for Spacelabs. This item fits the Oximeter direct.

# **Comprehensive Conversion Chart**

A comprehensive conversion chart has been built up in the database Approach.

It is never fully up to date as we are continually adding new information as we receive it.

We can supply

- 1) A Floppy disk with the Database in Approach
- 2) A Floppy disk with the Database in another standard format
  - 3) Hard copy on paper

# SpO2 Finger Probe Re-Cycle programme

We are now seeing the introduction of EEC legislation regarding re-cycling of waste and as a medical engineering based company we understand the frustration of broken pulse oximeter probes collecting dust whilst you earnestly wish you could repair them. This is now possible as Viamed have brought onto line a finger probe re-cycling service and we are able to re-cycle most probes. Moulded connectors obviously cause problems and may prevent us effecting a professional repair.

Our aim is to return to the user a finger probe that looks new and has not just been glued together or spliced and covered with heatshrink tubing. Our object is to re-cycle as much as possible of the existing finger probe instead of consigning it to the waste bin. We carefully dismantle the finger probe and rebuild it using as many as possible of the original manufacturers components. Where damage or aesthetic reasons dictate components be replaced we do so with components which are manufactured utilising the same materials in a comparable manner as the original manufacturer.

Our warranty covers the parts and labour used to repair your probe. i.e. if we replace the clip and the clip breaks in 6 months we repair it free. However if we repair the clip then later the instrument plug develops a fault this is treated as a separate repair. We cannot offer a comprehensive warranty on the original manufactures product or materials. Every re-cycled finger probe is tested on a proprietary tester and in most cases on the original manufacturers instrument. As the number of different types of probes we repair increases so does the number of O.E.M's SpO2 instruments we acquire. Full reports and tests carried out are documented and supplied with each probe.

Viamed is ISO9002/EN46002 certified and all repairs will be carried out in accordance with these procedures.

#### Our repair Policy is :-

We will endeavour to provide quality repairs

All repairs are made using, when required, new replacement parts manufactured for Viamed's recycle programme

Prompt service and fast turn around (Depends on the numbers being returned) Target 7 days

Six months warranty on all repairs

There is a fixed cost regardless of type of cable or extent of repair

We can usually only repair Finger Probes at present

We cannot always repair OEM cables with special moulded plugs although we try.

If we cannot repair a probe a service replacement will be offered at 20% off our list price.

All Epic Finger Probes can be re-cycled

The probes should be decontaminated before they are returned to us in accordance with the recommendations.

official

The fixed cost of the repair/re-cycle service is £80.00. + VAT & Carriage

The proof is always easy to establish by trying us out at no risk. If we cannot repair to your satisfaction there is no charge and if we are not satisfied, under our BS EN ISO 9002/EN46002 registration, with the finished product or its accuracy we will not claim to have repaired it.

John S. Lamb Director.

#### Sales of Special SpO2 cables to Original Equipment Manufacturers

The main market area that we as distributors are targeting with the SpO2 finger probes is the Hospital end user .

Epic in line with most manufacturers would prefer to deal direct with the equipment manufacturer so their prices can be very keen.

If these cables came through Teledyne ,Viamed and the local Distributor on the way to the Manufacturer they would become too expensive.

In my opinion however these manufacturers are your customers

I believe that in order to gain credibility in the end user market and to retain any local market share we obtain it is preferable for you the local distributor to encourage your local manufacturers to use Epic products as well as Teledyne.

In order to achieve this end I have encouraged Epic to sell at a very low price on condition we also keep our prices very low.

We all have to view this as an investment in the future market for replacements and repairs.

We are intending to use our UK Finger probe repair company (Epic UK) in order to supply you with the finger probes direct at the lowest possible prices.

Epic USA will sell to Epic UK direct.

Epic UK will pay freight (4%) and Duty (2.1%). Epic UK will add on 5% for administration.

You will be invoiced in US\$ by Epic UK.

We expect the distributor only to add on the small freight from the UK and 5% to cover his administration.

Due to the low costing Epic UK is on 30 day payment with Epic USA so we must also be paid in 30 days. If this causes any problems please let me know. If you need to increase your selling price to handle extended local payments please let me know.

It is important that this exercise be a partnership and all parties know and understand what is happening.

I have chosen the following two Finger Probes which have been requested by an OEM without connectors

E100A Nellcor compatible finger probe with 4 mtr cable Pt. No. E4100A-601 E3000 compatible finger probe with 4 mtr cable Pt.No. E4300-601

#### Only supplied in lots of 25 minimum

\$85	\$80	\$75
		14.5
\$90.26	\$84.95	\$79.64
\$94.77	\$89.20	\$83.62
\$99.51	\$93.66	\$87.8
	\$94.77	\$94.77 \$89.20

These prices should enable us to approach the OEM's with confidence. I do not think we can press Epic much further but if we are still un-competitive we must inform Epic. My information suggests we are in the correct price region.

The only problem that remains is the potentential of the OEM to purchase cables at a low price add plugs then compete against you in your own market place. Your agreement with the OEM should include the agreement to supply only one cable for every oximeter or module he manufactures . This must remain your responsibility. Problems will arise if the OEM sells replacement probes in other countries.

Technically the Finger probe requires resistors in the instrument plug to match the probe to the oximeter. This must be the responsibility of the OEM unless he chooses to purchase complete finger probe cables.

We also need to know what the OEM is adding so that we can offer replacement cables.

Our warranty will only apply to the finger probe end and failure directly attributable to a faulty component or Epic workmanship. With such low margins we cannot use our normal warranty which we bend to cover problems caused by the user ( broken cables). Broken cables or damage by user misuse will be charged for.

John S Lamb

E	Product Line	Length	In Feet	OEM	OEM
			Niuma la a	 Number	Numb
					1.0
	1 =	0 3	= 3	01 = N	ellcor
		Feet (1)	Mtr)		
	Sensor				
	2 =		=12	02 = 01	nmedaa
	Flexi-	Feet (4	Mtr)		
	site				
	3 = Pre			03 = N	ovametri
	Amp				
	4 =			$04 = S_1$	pacelabs
	Cables				
				 05 = C	SI
				06 = B	CI
				07 = D	atascope
				08 = N	onin
				09 = D	atex
				10 = C	ritikon

		12 = Bianctoc
		13 = Kontron
		14 = Invivo

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## Competition Pulse Oximeter Probes

#### **Datex E8785**

Purchase Price from TED \$156

landed Price UK \$166 =£110.43

Distributor Buying price \$182

#### **DENMARK**

Exchange Rate US\$ 5.71

Exchange Rate £ 8.57

Prices	Local Currency Dk	US\$	£
OEM Price	1980	346	231
Ideal Epic Price	1386	243	162
Dist. Buying Price	1039	182	121
Dist. G.P.	347	61	41
GP %	25		

# **ENGLAND**

Prices	Local Currency £	US\$	£
OEM Price	170	255	
Ideal Epic Price	126	189	
Dist. Buying Price	111	167	
Dist. G.P.	15	22	
GP %	12		

### **Simed**

E333

Purchase Price from TED \$144

landed Price UK \$153 = £102

Distributor Buying price \$168

**BELGIUM Lameris** 

OEM selling to Distributor \$150

#### UK

Prices	Local	US\$	£
	Currency £		

OEM Price		
Ideal Epic Price		
Dist. Buying Price		
Dist. G.P.		
GP %		

Purchase Price from TED
landed Price UK \$ =\mathbb{\x}
Distributor Buying price \$
Exchange Rate US\$
Exchange Rate \mathbb{\x}

Prices	Local Currency £	US\$	£
EM Price			
Ideal Epic			

Price		
Dist. Buying Price		
Dist. G.P.		
GP %		

Purchase Price from TED

landed Price UK  $\$ = \pounds$ 

Distributor Buying price \$

Exchange Rate US\$

Exchange Rate £

Prices	Local Currency £	US\$	£
OEM Price			
Ideal Epic Price			
Dist. Buying Price			
ist. G.P.			

GP% Nellcor Purchase Price from TED landed Price UK =£ \$ Distributor Buying price Exchange Rate US\$ **ITALY** Medirex Mr Parisi Catania(Sicily)Price to Hosp L500,000 \$330 DiDedda DiDedda Milano(Ex Nellcor agent) L380,000 \$253 L470,000 £313 Lanzoni Milano " Hospimed Lconfirmed above Dima Manufacturer buys PCB+Probe Di Donna \$195 Meditec Lisi Nellcor distributor L400,000 \$400 Parma Burke & Burke Bonardini Milano Says Nellcor sells at L350,000 \$233 Disposable at L27,000 Aosta (Hospital) Milano Buys Nellcor Disp 33K-37K L450,000 Napoli(Hospital Cotugno) Buys Nellcor in gty

Sicily Hospital

1,000,000

666

Prices	Local Currency £	US\$	£
OEM Price			
Ideal Epic Price			
Dist. Buying Price			
Dist. G.P.			
GP %			

BCI

Samed Derosa Milano

Milano buys BC!

\$100

Purchase Price from TED

landed Price UK \$ =£
Distributor Buying price \$
Exchange Rate US\$
Exchange Rate £

Prices	Local Currency £	US\$	£
OEM Price			
Ideal Epic Price			
Dist. Buying Price			
Dist. G.P.			
GP %			

Purchase Price from TED
landed Price UK \$ =\mathbb{L}
Distributor Buying price \$

EPICCOP

# Exchange Rate US\$ Exchange Rate £

Prices	Local Currency £	US\$	£
OEM Price			
Ideal Epic Price			
Dist. Buying Price			
Dist. G.P.			
GP %			

#### **Epic Finger Probes background information**

Epic only manufacture at present Finger probes and extension cables which are available in a variety of forms to match the current user requirements.

#### **Nellcor**

Nellcor is the most popular finger probe in use and is used in many different manufacturers equipment.

The basic E100A offered by Epic is a finger probe with approximately 1 metre of cable to a connector.

Nellcor use an interface cable (or patient module ) which includes electronic circuitry between the probe cable and the instrument.

Nellcor also offer two extensions cables EC-4 (1 metre) & EC-8 (2. 25 metre)

Both Nellcor and Epic also offer a cable from finger to machine E180. Some OEM's like Hewlett Packard use Nellcor finger probes (E100A) but have thier own cable from the probe to machine. In this case we can usually only supply the probe end (E100A) See Epic conversion chart.

#### Marquette, Spacelabs, Mennen,

For some reason these companies have used different suppliers of SpO2

e.g. Mennen and Marquette have an option of Nellcor or Ohmeda. Spacelabs have an option of Nellcor and Novametrix.

Always request the Original manufacturers part numbers to save confusion. If in doubt Fax me with the original manufacturers part number and the equipment model number.

#### Other suppliers

Most of the other suppliers use the technology of Nellcor, Ohmeda, B.C.I. or Novametrix with there own cables and connectors. This is usually easy to sort out as they are straight forward conversion to Epic. If it is not on the chart we need samples working or not working to send to Epic

List Price	C1R	C2R	R13	R15	R17	R22	R23	R24	T1	T2	T4	T5	T7
-19	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
-1019	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
-2049	46.6	46.6	62.9	92.1	56	54.2	97.5	58.5	45.5	45.5	50.9	56.4	60.7
50+	45.5	45.5	62.9	86.7	53.8	52	97.5	58.5	44.4	44.4	50.9	56.4	60.7
					-				1				
Habel	48.8	48.8	62.9	97.5	60.5	58.8	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Lameris	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Medicoline	48.8	48.8	62.9	97.5	52	52	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Medith OY	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Int Process	45.5	48.8	62.9	97.5	52	52	82	58.5	47.7	47.7	50.9	56.4	60.2
KMT	48.8	48.8	62.9	97.5	60.5	58.5	77.5	58.5	47.7	47.7	50.9	56.4	60.7
DW Priess	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
VTG	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Gavala	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.2
Procustom	45.5	48.8	62.9	48.8	37.9	58.5	73.7	43.4	35.8	47.7	50.9	56.4	60.7
Elphymed	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
CK	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Portanje	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.2
Nycomed	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
MC Infort	48.8	48.8	62.9	54.2	53.8	52	77.5	58.5	39.8	47.7	50.9	56.4	60.7
Dansjo	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.7
Nufer	48.8	48.8	62.9	97.5	60.5	58.5	97.5	58.5	47.7	47.7	50.9	56.4	60.2

European Price List EPL22 5 April 1997

	Viamed	33	45	58	55	42	45	63	45	33	45	49		48
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European Price List EPL22 5 April 1997

# UK Strategy for the

Introduction of Epic SpO2 Finger probes
This strategy may be unique to the UK market but it
has worked.

- 1) The most common finger probes in use in UK hospitals were investigated.
- 2) The List prices and discount deals on these probes were obtained.
- 3) Five Epic equivalents of the most popular two manufactures were obtained from Epic.
- 4) These were circulated to hospitals with a close relationship to Viamed.
- 5) The most likely people to buy finger probes were located and given demonstrations.
- 6) The big buyers were left samples to try.

7) The Epic prices were established to be 30% below the existing manufacturers prices.

This has meant on one or two reducing the gross profit. The number of sales achieved has proved this risk to be worth while.

8) A full 12 month warranty was offered. This has risks, as most breakage's are due to

the customer mistreating the probe. However the response in sales far outweighed the costs of warranty. Viamed can now repair Free of Charge your warranty failures.

- 9) Discounts are offered to the end user for quantity purchases,
  - a) 10 more less 5%
  - b) 20 or more less 10%
  - c) Call off orders 10 or more less 5%
  - d) Mixed types of probes qualify for discounts.
- 10) The "one stop shop" supplying Teledyne Oxygen sensors & Epic SpO2 probes has been exploited.

11) Having established a market and determined the most popular types of probes in the UK

Mail shots to users are now being sent out in large quantities.

12) Viamed has now brought onto line a Repair service for most types of existing finger probes

We can only repair Finger Probes

We cannot always repair OEM. cables with moulded plugs.

The cost to you is \$99 per repair

We warranty the parts repaired for 6 months.

The probes should be decontaminated before you handle them.

Service Replacement Probes

A future potential problem area is the time delay and cost of shipping broken SpO2 probes into and out of the UK. We will try and complete the turn around in 7 days but obviously due to unpredictable returns we cannot at present guarantee this.

Epic have suggested a scheme to me which they apply in the USA. and which you may like to think about and make suggestions or observations to me

Each distributor holds a stock (at Viamed/Epic expense) of consigned probes.

These probes will be service replacements.

The customer will send you a probe for repair You will replace it from your consignment stock.

When you have sufficient repairs you will send them to Viamed.

Viamed will repair and return to you.

You can either .:-

Exchange the probes again having treated the one you supplied as a loan probe. Very difficult to actually do in practice

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Charge as a service replacement and keep the repaired probes in your consigned stock.

The alternative is to continue repairing single probes and returning then to the original customer.

The number and types of probe consigned will depend entirely on the number of probes being returned for repair.

# **Epic Advertising**

### Leaflets

We are continually asked for a leaflet on the finger probes even though all of our sales people have an almost unlimited range of demonstration samples.

I have therefore printed a European leaflet.

The front is in colour similar to our UK leaflet

The words "REPLACEMENT PULSE OXIMETER FINGER PROBES"

can be added in your language later by laser printer. if you can translate it for me.

Your Address can also be laser printed on or use can use your own label

If you translate your requirements we can laser print small quantities for you. The reverse is the Epic conversion chart.

Alternatively we can supply the photograph

## **Demonstration Kits**

Pt.No. E1114

I have some special Epic demonstration kits which are available at \$400.

The kit in a foam lined presentation box contains short versions of :

- (1) E100A sensor for Nellcor
- (1) E3000 sensor for Ohmeda
- (1) EN300 patient module for Nellcor probe
- (1) E100SL sensor for Spacelabs. This item fits the Oximeter direct.

# **Comprehensive Conversion Chart**

A comprehensive conversion chart has been built up in the database Approach.

It is never fully up to date as we are continually

adding new information as we receive it. We can supply

- 1) A Floppy disk with the Database in Approach
- 2) A Floppy disk with the Database in another standard format
  - 3) Hard copy on paper

# Customer "Feel Good Factor" This is the contents of a letter sent to UK Hospitals who query the Probes or have been frightened by the OEM's verbal references to warranty infringements etc.

# **EPIC Pulse Oximeter Probes**

#### The SpO2 Probe

The probe consists of two Light Emitting Diodes (LED) with specific transmission frequencies. These LED's are manufactured by several electronic component companies world-wide to standard specifications for industrial use and are not specific to the medical field. Epic are using these same diodes in their probes.

There is no way the probe can damage the module or measuring instrument.

#### <u>Liability</u>

The product is guaranteed equivalent to the probe it is replacing and is backed with full product liability insurance. Viamed as the importer into the EEC legally must carry this liability and are therefore insured to do so.

#### **Quality Assurance**

Viamed already has BS ISO EN 9002 and should achieve ISO 9001 EN4601 by the end of 1996. We are working with EPIC so that they can also achieve ISO 9001/EN46001. Epic already have a GMP system installed which satisfies the USA FDA. All their products will in the future carry the CE mark. A customer copy of Epic QA. tests accompanies every probe. Copies of Epic test procedures are available on request . Every probe is serialised and Viamed/Epic have total traceability.

#### O.E.M's

Very few equipment manufacturers actually manufacturer their own probes and these items are bought in and re-labeled. This is exposed by the number of manufacturers we can cover with a minimum of Epic types. (see equivalent chart). As most manufacturers are using Nellcor or Ohmeda, Hospitals which have a number of different types of SpO2 modules may be able to purchase the same Epic probe for them all thereby either purchasing in quantity at a lower price or reducing their stocking requirements.

#### **Warranty**

All Epic products have a 12 month warranty unless physically damaged by the user.

#### **Pricing**

Ten or more less 5% 20 or more less 10%

John S .Lamb

#### **Conflict of Interests**

As a distributor, to survive, it is usually essential that several other agencies are carried.

Due to the nature of present day business it is highly likely that at some time there will be a potential conflict of interest.

With Teledyne Oxygen sensors we have a exclusive arrangement whereby the distributor may only stock and distribute Teledyne products.

If you also distribute for example a ventilator in which the manufacturer uses a competitive sensor we appreciate you may have no choice but to supply the new equipment with the sensor already factory fitted.

It is expected however that all replacement sensors supplied will be Teledyne.

With Epic finger sensors and other associated products about to be released it is appreciated that you may already be supplying Pulse Oximeters from another supplier.

We accept that you must continue to supply their finger probes and accessories as long as you continue to supply their hardware.

However no SpO2 supplier has a monopoly in any country and our market research shows the maximum penetration of any supplier is less than 50%. This leaves at least 50% of the market for Epics' other probes.

I hope this clarifies my interpretation of conflict of interests.

If you wish to discuss this in greater detail please

contact me

John S. Lamb

# Epic SpO2 Finger Probe Recycle Programme

EPICUKST 12 13/05/96

Viamed has now brought onto line a Repair service which will allow most types of existing finger probes to be repaired and re-cycled

The aim is to return to the user a Finger probe that looks new and has not just been glued together or spliced and covered with heatshrink tubing. Our object is to re-cycle as much as possible of the existing finger probe instead of consigning it to the waste bin.

These probes are used in critical care areas and it is our intention not only to repair them but to return them clean and professionally finished so they look the part.

Our warranty covers the parts and labour used to repair your probe. i.e. if we replace the clip and the clip breaks in 6 months we repair it free. However if we repair the clip then later the instrument plug develops a fault this is treated as a separate repair.

Viamed is ISO9002 certified and all repairs will be carried out in accordance with these procedures. All repaired probes will be tested before dispatch as well as having the LED's electronically analysed.

# Our repair Policy is :-

We will endeavour to provide quality repairs

All repairs are made using new parts manufactured for Epic's repair programme

Prompt service and fast turn around

Six months warranty on all repairs

There is a fixed cost regardless of type of cable or extent of repair

We can usually only repair Finger Probes at present

We cannot always repair OEM cables with moulded plugs although we try.

If we cannot repair a probe a service replacement will be offered.

The probes should be decontaminated before they are returned to us.