Viamed Pulse Oximeter Probe Design File

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30/3/00 samples of Clinipol pads & meeting with G Shaw

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FAX REF 5732 Page 1 of 2
DATE :17 December 1996
TO : Ed Avilla
: Teledyne
FROM : John S. Lamb

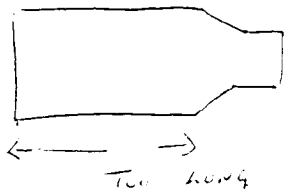
Dear Ed

First Comments on the New Finger Probe

1) Looks good and familiar to existing finger probe so should be readily acceptable to marketplace

2) Reads Low:
We have checked both finger probes on Phantom fingers and on ourselves.
They have been compared with both OEM original and EPIC compatibles. They read 3% low.
Even assuming +/-3 digit accuracy the underlying trend is low

3)The connector will not allow the clamp to close on an HP extension cable.
We can safely assume that the same problem will appear on Nellcor.
We are still trying to acquire a Nellcor interface cable



4) A solid cable grip is preferred for hygienic purposes.

5) The top of the finger probe should show the finger nail.

6) The spring is too tight.

7) There is no resistance in the plug. All Nellcor probes have approximately 7Kohm
How will a Nellcor Instrument know which R curve to use.?

Kind Regards

John S Lamb

Viamed Limited, 15 Station Road, Cross Hills,
Keighley, West Yorkshire BD20 7DT
Tel: +44 (0) 1535 634542/636757 Fax: +44 (0) 1535 635582
Registration No. 1291765 in England

Design & Development Job Progress

Job Number 960110 Pulse Oximeter probes **Date :** _____

Job Application		
Quote Preparation	**Preliminary Drawings**	**Design Compliance**
Purchasing	**Working Drawings**	**Construction**
March 98 Meeting JSL.SN.GGL.PL.DIL to decide to manufacture Viamed probes		
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August JSL DIL Envitec Wismar		
August SN JSL visit Whitby and chandler. Pad is to be compress moulded and cleaned.		
BICC discussios on cables		
Oct 1998 discussion with Goss components on springs. Springs and diagrams sent to Goss & subsequently ordered.		
Dec 1998 First batch of sensor medics probes using PDI detectors : production techniqques tested and changed see assembly manual		
Jan 1999 Visit to USA on fact finding on SpO2 probe components BetaBiomed; Production techniques,test equipment, component specs and sourcing,opto electronics, connectors clips, sub assemblies complete assemblies, quality control Photonic Detectors Inc;Production techniques,test equipment, component specs and sourcing,opto electronics, connectors clips, sub assemblies complete assemblies, quality control MCI; QA Advantage Medical;Production techniques,test equipment, component specs and sourcing,opto electronics, connectors clips, sub assemblies complete assemblies, quality control Medical Concepts; Production techniques,test equipment, component specs and sourcing,opto electronics, connectors clips, sub assemblies complete assemblies, quality control This visit brought new ideas and sources of new materials. Each company offered a different advantage		

QC24

Design & Development Job Progress

Job Number 230301 **Date :** 30/01/98

Job Application

Quote Preparation N/A	**Preliminary Drawings**	**Design Compliance**
Purchasing	**Working Drawings**	**Construction**

Progress : The product will be reversed engineered and constructed from materials of equal or better specification. Peliminary drawings and assembly procedures accompanied by photographs and diagrams will be collated and included in a finnished assembly procedure.

Each etension cable will have its own procedure.

Progress

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Pete Williamson
1.30 pm
(340 FD
Food Sampler.

Finger Probes

Manufacturing

Leaflets

Backup Information

Progress

14 April 1997

Teledyne Product Manufacture

1)No moulding of Connectors initially. Cable outlets need special attention to look good and substantial.
Discuss with Frances

Allows repair and re-ycling.

Enables specials (long cables to be faricated in UK)

UDT. Cables without connectors can be stored. OEM,s sometimes require them Smmc qty req.

A method is needed to code the probes to recognise the different types of LED.

Special attention has to e paid to the junction of the cable and connection to make it look right.

2)Choose the most common probes first

3)Flexible Probes may not require such a long lead time on moulds.

The BCI card wrap is a good idea. Not as disposable but as amethod of accurate placement.

Connectors as wih finger probes

For Europe Nelcor, Ohmeda, Datex see latest predictions

4)Wrap round probe similar to Flexible Probes The moulds for these are probably available

Simultaneous action

Legal Documentation

1)EMC

2)CE mark

These two items are easily achieved as they are Self assesed. Teledyne has ISO9000

3)Compatibility

This is a statement by the manufacturer.To be backed up with independent Tests for real credibility

4)Accuracy

Figures are needed by an independent body.

Comparisons with as many manufacturers as possible.

it is now apparent to us in Viamed that a large number of OEM,s are using standard Nellcor technology. The difference is in the connectors and cables. In this connection it is possible to have interconnecting cables between the sensor and the OEM equipment. Where we can prove this is correct

Nellcor publish a list of companies using their technology. We have many types of SpO2 monitor. Only the comparisons for Nellcor are required.

5)BioTek needs to be approached regarding the Index compatibility.

Viamed are close to manufacturing a SPO2 probe/monitor test & possibly calibration system.

This could be sold as a separate product. The accuracy claimed is far in excess of existing instruments.

6)FDA This should be seen as urgent as CE marks as it is required in many areas outside Europe.

This may be relatively easy considering work already completed

Packaging

Containers

Size should be as small as possible to reduce the transit of air. They should be stackable like cell boxes

For Europe they can be shipped loose and packed over here.

Labelling:-

On container:

If boxes are used Type and Serial number should be on the side which is visible when stacked.

Serial numbers are essential for tracking purposes.

Use by dates if required. Disposable only

Label for Re-cycle & re-use of container.

On Probe:

Serial Number

Lot Number

Product Type

Use only with: Manufacturers products (compatibility)

Manufactured by:

Product Life/use by date if applicable

Do not discard label

Inserts

Re-cycle/Re-use information

Information sheet for user. Refer to manufacturers instructions.

Instructions for use Posy. BGT

Accessories for better use < 50c

Languages

Collection of different ~~by~~ types of Probe by distribtors CK BY MAY 1ST

Leaflets & Documentation

Sales Information

Basic sales leaflet for all products

Finger probes,

Flex probes

Wrap around probes

Disposable Probes

Accessories

For each familly of products

Data Sheets specifications components used generali.e.

Materials

LED,s

Accuracy

Compatibility statements.

Brief cross reference.on Rear.

Languages

User Information

* Translations

French, German, Spanish, Italian.

Viamed can print in UK and add as required.

A full and comprehensive cross reference chart should be made available to distributors.

Database exists

Paper

Floppy Disk

Repairs: PRICES & AVAILABILITY OF PARTS

As this will be the best introduction world-wide all parts need to be available

Finger Clips

Springs

Pads

LED,s

IR Diodes

Photo Diodes

Cable grips

Retainers

Cable

Connectors.

We also require the 9pin connectors pre-moulded onto cables (Check Nellcor resistance valus)

Other manufactures have similar cables.

At present we cut our the middle connector and create a one-piece cable

Assuming Viamed can extract itself from the Epic repair side we can help to set up Teledyne repair centres world-wide.

Most of the non Epic information is widely available and is therefore in the public domain.

The areas to be addressed by Teledyne distributors are:-

Training to dismantle and re-build probes. UDT training can be applied to any probe manufactured.

Test equipment:

Under ISO9000 all probes should be tested on an OEM instrument or a calibrated instrument traceable to a Test certificate before dispatch.

Background information on wiring diagrams and procedures should be continuosly updated and distributed.

Video,s: written procedures:CD ROMDS etc.

Each distributor should have a system for traceability of all repairs.

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FAX REF. : 7535

DATE 7 May 1997

Peter Williamson
UDT Sensors Inc.
12525 Chadron Ave.: Hawthorne. CA 90250 . USA

Dear Peter,

Extra Tooling Required

We realise the $25K is needed to finish the current tooling project are any further costs anticipated to produce Nellcor and Ohmeda finger probes.

Flexible probes will be required what are the estimated costs and delivery times?

The range of flexible probes will probably mirror that of finger probes although start up quantities could be smaller.

What is required before we can release disposables.

Kind Regards,

John S. Lamb.

UDTFax 001 310 644 1727

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Tel: +44 (0) 1535 634542/636757 Fax: +44 (0) 1535 635582
Registration No. 1291765 in England