



VIAMED

BW/SW. JSC
Design Review 19/12/02

Viamed SpO₂ Clip

Plastic moulding re-viewed
In strength of spring retainer
2 colour 2 texture of plastic

Send O.R.M. Plastic to be
analysed

g

Viamed Limited · 15 Station Road · Cross Hills
Keighley · West Yorkshire · BD20 7DT · United Kingdom
Tel: +44 (0)1535 634542/636757 Fax: +44 (0)1535 635582
Email: info@viamed.co.uk Website: www.viamed.co.uk



BS EN ISO 9001 BS EN 46001
Company registered in England, No. 12917565

	Design Review	QC 24
--	----------------------	--------------

QC 24

Project: Pulse Oximeter Probes

[illegible]

Areas to be addressed

Medical Cables

Total QA ISO900/EN4600

FDA 510K

CE Mark & EMC

Documentation : Design Files: Manufacturing Files: Serial Numbers: Lot Numbers

Leaflets USA,

Labeling: Containers: Probe identification (e.g. Use only on Nellcor)

Manufacturers Product Liability

Probe Testing & QA

It is assumed that every probe leaving UDT will have been tested and the results logged and preferably a copy included with the probe.

This probably means original manufacturers equipment is required for the final tests.

I assume it will be the responsibility of UDT to acquire this equipment locally. Used equipment is available locally in the USA.

Viamed

Leaflets: Local languages

Local standards: World-Wide standards ex USA

Clinical Trials

Pricing

Need to establish pricing from UDT to Medical Cables on finished product and parts.

Pricing to Viamed on finished products and parts

Pricing to Master Distributors

Master Distributors need 15% off International Price List

Pricing to Sub distributors at International List

Pricing to customers

Need one International Distributors Price list

Target for Distributors to be able to sell at 30% less than OEM (Nellcor, Ohmeda etc. and make 25-30% GP. We will price to Distributors at Epic prices less 5% conditional on 30-45 day payment.

Warranty

There will be failures during the warranty period. Currently 12 months. I estimate this to be a maximum of 10%.

Most warranty failures will be traced back to user mistreatment but as a sales policy will still be repaired or replaced free of charge.

We would expect our distributors to keep the customer happy by giving an immediate exchange. The failed probe would then be repaired either locally or in the UK. I do not envisage return to the USA.

Do you have this factor built into your pricing or do you want it to be our total responsibility

Warranty from UDT

Warranty repairs carried out at local service centers at whose costs
Warranty products to be returned to Viamed or Medical Cables at whose cost
% of the pricing to include warranty costs
Third world No returns to USA or EEC
Testing of Probes by distributors

Payments

UDT 58 days
Master Distributors 30 days LC
Sub Distributors 30 days
Viamed and MC flexible by agreement
Packaging
Viamed was planning to receive the product in plastic bags and re-package in UK.
The preferred choice was a polypropylene plastic box:
This reduces freight and costs of packing are comparable to UDT cardboard boxes.
Drop shipping packaging
Product and packaging are subject to EEC legislation on labels
Also subject to re-cycling and re-usable legislation coming into effect soon (2000AD))

Inserts & Instructions

Viamed planning to print inserts in local languages.
Label product with Distributor labels
Drop shipments would place this burden on Master distributors
Drop shipments
Could be better to ship direct from USA to Master distributors the large quantities and small quantities from UK.
Invoicing from UK but copies need to be included in Packing for customs. Possible modem link to UK to print dispatch notes with pricing
Grey Imports Product can be purchased in the USA and shipped to other countries or purchased in Europe and shipped to the USA.
When it appears it causes problems.
Distribution contracts between Viamed and Distributors stipulate regions of sales responsibility
Viamed draft is available

OEMs

Manufacturers of Equipment: Low selling price
Joint venture decision Medical Cables & Viamed
Suggest Local Distributor is paid a nominal sum to look after our interests.
O.E.M's Re-labeling of the product range : very low selling price

Future Products

How do we finance future moulds : wrap round

Disposables

Disposables: Aristo cannot meet nellcor prices

Component prices

Need prices for all the components. including Flexible probe components, & wrap round. Repair of probes is a valuable and essential feature of the programme.

Extension Cables

Which types of cables will be available

Which samples to you have to reproduce.?

Need prices of the extension cables and the quantities to be ordered.

It is possible that this part of the range could be manufactured to order in the UK. This would reduce substantially the inventory costs.

Clip tool

Is the clip still required on extension cables using DB9 connectors. How far have we progressed

Need prices and quantities for this item. Is it universal and able to fit on all our cables.

Repairs

Our existing repair facility is purchasing components from Epic and it is essential that we second source all components prior to our product launch. We believe we have just been cut off.

The Nellcor 1 metre cable with integral DB9 and resistor is available I require prices for 100/250/500/and 1000 off. If the prices are right I probably have a market with other repair facilities throughout the world.

SpO2 Printed Circuit Boards

There is a need, presently satisfied by Nellcor and BCI, in certain countries to establish home produced monitors. Nellcor will only supply one probe per PCB so although the module is inexpensive the manufacturer only gets one probe. BCI are making a big impression into this market

Lead times

How long do you estimate it will take from the placing of a order to dispatch of product..

Some like Ohmeda/Nellcor/and Datex will be on monthly call off orders but most types will be either regular small orders or larger orders placed sporadically.

Lead time for small quantities?.

Generic probes without connectors available for both Finger and Flexible

It is important that we offer as many different types as possible at all times. Some of these can be prefabricated in the UK by using a generic probe and adding a connector.

Need a price for the Generic Probes

Complete Finger probes 4mtrs (13 ft) of cable no connector

Flexible Probes 4mtrs (13ft) of cable no connector

LED's

How many different types will there be

How long will it take to produce a new version from an original sample.

Packaging

We will be prepared to box the product in the UK and only require that you ship them in transparent bags with a label denoting Type and serial number.

Generic type probes should also have a serial number and some method of identifying the type of LED used

Clinical Trials

We have begun the process of locating in the UK a centre to carry out clinical trials

FAX REF. :

11/09/00

Page 1 of 1

Robert Hillman

Medical cables

1340 Logan. Costa Mesa. CA 92626

Fax 001 714 545 7212

Dear Robert

Many thanks for the copy of your letter to UDT and thanks for the personal enquiry.
Apart from growing older Jean and I are still going strong.
How is Pete?.

Back to business

On a recent audit I find that I am still missing the technical information on the Y ear clip.

I need to have information on

1. Manufacturer of the clip
2. Are they ISO9001/2 or EN46001/2? if not to what level are they working
3. Specifications of the materials used Plastic and spring
4. Diagrams
5. If different manufacturers we need the manufacturing route and information on each piece
6. Risk assessment. If this has not been done can you give me the most important points addressed
7. Material safety data sheets
8. Quality control carried out on the product.

This has now become urgent

I have assumed that the materials of the Y probe are identical to the finger probes.
However I do not have confirmation or the differences recorded in my files.
I am also short of the full diagrams and manufacturing routes .They were not included with the
finger probe information
These are again needed for the CE files

Kind regards and many thanks

John S. Lamb



Pete Williamson
1:30 pm
(340 FD
Food Samples)

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 Franck

Allows repair and re-cycling.

Enables specials (long cables to be fabricated in UK)

4DT.

Cables without connectors can be stored. OEM,s sometimes require them *3mm 277 RLR.*

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

Special attention has to be 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 a method of accurate placement.

Connectors as with 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 assessed. 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. *Disposables only*

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

On Probe:

Serial Number ✓

Lot Number *Disposables*

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. } ok

✓ Instructions for use ✓ *Posy.* *BGI*

✓ Accessories for better use | *< 50c*

Languages

Collection of different ~~ex~~

CK BY MAY 1ST

types of Probe by distribtors

Leaflets & Documentation

Sales Information

Basic sales leaflet for all products ✓

Finger probes, ✓

Flex probes ✓

Wrap around probes

Disposable Probes ✓

Accessories

For each family of products

Data Sheets specifications components used general i.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 values)

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 continuously updated and distributed.

Video,s: written procedures:CD ROMDS etc.

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

Subject : Cable assembly drawings
Date : Mon, 1 Jul 2002 14:33:00 +0100
Linked to: Billy Cheng
From : Jasvir Nirwan <info@viamed.co.uk>
To : Billy Cheng <bcheng@dolphinmedical.com>

Billy,

i have checked the drawings and found only one drawing that needed a slight modification. i am attaching the drawing back with the alteration made (length of cable) as well as a Viamed drawing sheet as you requested.

Jaz



VIAMED



FAX REF

5730

Page 1 of 2

DATE

: 17 December 1996

TO

: Ed Avilla

FROM

: Teledyne

: 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

GOSS COMPONENTS LTD

43 Fulbourne Road, London E17 4AF

Telephone (44) 0 181 527 5599

Fax (44) 0 181 527 1142

Internet <http://www.city2000.com/goss-components/>

Email goss.components@dial.pipex.com

16 September 1999

Viamed Ltd
15 Station Road
Cross Hills
West Yorkshire
BD20 7DT

Dear John

Due to technical problems with previous productions of your Part No. 0103-1 Wire Spring, we have reviewed our manufacturing process and have changed our methods of the stress relieving.

Please find enclosed some samples which we would like you to check and confirm their suitability.

I would also be grateful if you could send a report detailing your inspection methods and if possible any type of inspection jig used, as this would be a great help to our inspection department.

Regards,

Tim Ford
Quality Department.

John/Derek.

8
2.12.97

Meeting with GERALD BULLIVANT
of LIP (LABPLAST) to discuss
manufacture of SpO₂ probe
cable strain relief.

10.00 am ~~on~~ on the 12/12/97
Synchronise Pscions!

Home tel: 01733 326359

Mobile: 0468 038763

Office: 01274 597403

Map and address to follow.

Steve

FAX REF 6047

TO

FROM

4 February 1997

Ed Avila

Teledyne

John S. Lamb

Page 1 of 1

Dear Ed,

We have tested almost 100 Nellcor SpO2 cables from repaired Nellcor probes

The Resistor values are as follows

7.44Kohm	1
7.45	2
7.46	9
7.47	15
7.48	13
7.49	21
7.50	14
4.51	9
7.52	4
7.53	3
7.54	1
7.68	1

This is a typical distribution curve around a resistor value of 7.5Kohm with a +/- 1% tolerance.

It would therefore appear that Nellcor are no longer matching LED's to a resistor value on Finger probes.

We tested 1 Dura Y @ 7.97Kohm

Two Disposable 8.03 Kohm & 8.23 Kohm

These tests are too few in number to be meaningful but it appears that the disposable with a difference of 2% may be using a different or even wider tolerance LED's.

NB

If a 7.5Kohm resistor is added to a BCI probe it will work on a Nellcor instrument

Investigation has shown that on a Nellcor connector Pins 1 & 2 are joined by a 7.5Kohm resistor.

Pin 7 is a screen

On a BCI pins 1, 6 & 7 are shorted out to a screen

We are looking at other DP9 connectors on other models and will keep you informed. However the above information should make life easier for UDT. i.e.

Kind Regards,





VIAMED



FAX REF
TO

:5 February 1997

Page 1 of 1

:Ed Avila

:Teledyne

FROM

:John S. Lamb

Dear Ed,

These are my personal thoughts on the Resistors in SpO2 probes.

Originally it was necessary to use a wide range of LED's in probes to keep the cost down. Nellcor & Ohmeda have used resistors to code the LED to an R curve.

To my knowledge and understanding this resistor is not used to adjust the LED output or input.

On examination of 100 Nellcor finger probes we have scientifically established that only one resistor is now being used i.e. 7.5Kohm. The resistor variations all lie within +/-1% of this value which suggests they are using a 1% tolerance.

Ohmeda still use a range of about 19 resistors.

As this resistor was added in the original designs a resistor is now required in present probes not to adjust the R curves but to tell the instrument a probe is actually present.

Other manufacturers who are using close tolerance LED's do not use resistors.

For instance BCI probes are identical to Nellcor but have a short circuit to the screen across the pins where the resistor would be in a Nellcor. If the resistor is removed from a Nellcor it will work in a BCI monitor.

Other manufacturers use wire links between pins to let the instrument know that a probe is present.

Theoretically it is impossible to join two pins with wire and have zero resistance.

This is not unique to SpO2 probes and is a well used device for differentiating between no signal and a disconnect. It is in fact used by Teledyne on the R22 sensor.

Nellcor Disposables appear to use a range of resistors possibly because for some disposables they claim a +/- 2 Digit accuracy. Finger probes +/- 3 Digits and the Y +/- 4 for Neonates, & +/- 3.5 for the Earclip.

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

5 October 1999

SpO₂ finger probe spring:

I attended a site meeting at Goss Components with Gerry Barton. The problem with the initial batches of the springs is lack of tension. The week prior to this visit we arranged for sample springs to be made out of a different grade of stainless steel (032). Initially Goss Component over specified the material used by using a medical grade of stainless steel which we found to be too soft and not appropriate for our application.

With the new grade of steel, besides being stronger it is also possible to temper the springs at higher temperatures, so increasing the tension of the spring.

The lengths of the spring legs were adjusted so that they were exactly the same length, since one was found to be slightly shorter. Even after this adjustment both legs of the springs were increased again by a further 1 mm. This is to make it more compatible with the original spring and also to ensure the aesthetic look of the springs once it has been assembled into the finger clip. The diameter of the spring coil is compatible with the clip buttons, and the end of the spring is flush with the outside of the buttons.

On initial tests the spring was found to be as good, if not better than the original. The tension is good so as to ensure consistent readings, without being too tight so as to adversely effect the perfusion of the patient. Aesthetically once the clip has been opened and extended the clip retains it's original position, so that there is not a gap between the button and the lower part of the clip assembly.

It is anticipated that a sample batch of the new springs will be received on the 6 October. If these are satisfactory they will be officially approved by both Viamed and Goss Components. Goss Components will then supply appropriately amended drawings. Goss component will also manufacture two test jigs, one for Goss to test each spring; and one for Viamed in order to carry out QA batch tests.

A matter that needs to be resolved is what do we do with the 714 springs of lower tension that are presently in stock. I suggest that we keep these (suitably marked) in case we ever have customers who require lower tension springs.

Goss also have a stock of the softer medical grade stainless steel which they would like us to pay for, the price of this will be approximately £300.

If necessary the spring can be further adjusted or redesigned i.e. by altering the diameter of the coil, the angle of the return, or the length of the legs.

S Nixon



UDT SENSORS, INC.

12525 Chadron Ave., Hawthorne, CA 90250
(310) 978-0516 • FAX (310) 844-1727

FAX

TO: VIAMED

Attn: JOHN LAMB

FAX No.: 011 441 535 635582

FROM: JACK KIMBRO

SUBJ: CABLE ASSEMBLIES

REF: _____

OUR REF # _____

DATE: May 13, 1999

NO. OF PAGES: 1

COPIES TO: _____

Dear John:

I have received your drawing and request for 1500 ea. of 9905101 cable assembly.

I take exception to the term FDA approved. We will use medical grade materials but offer no FDA approvals. Also we will put 30 micro inches of gold rather than 30 inches on the pins.

We have cable in stock but no open tooling that will meet your requirement. Tooling will take 4 weeks unless we can persuade MCI to allow us to use theirs. If not, then add 3 more weeks to run the lot.

If we can get MCI's permission to use their tool the price will be \$8.95. as before.

If UDT has a new tool made the price will be \$10.50 for the first 1500 and \$8.95 thereafter. The tool will then belong to both UDT and Viamed. By the way, \$8.95 is the 10K-piece price.

John, on another subject, I think Mr. Bonin will be calling you tomorrow. He did not get his bank financing and may be ready to discuss the option of you buying direct from us. I will call you as well to discuss the cables and this situation.

Best regards

From: John Lamb <info@viamed.co.uk>
To: Billy Cheng <BCheng@udt.com>
Cc: Jack Kimbro <jackk@udt.com>
Date: 24 May 1999 12:10
Subject: Re: Cable Assembly Viamed p/n 9905101

Billy,

Thank you for your observations. I appreciate your concern.
Our diagram for 9905101 is correct.
Outer shield to Pin 7
Inner shield to Pin 6

John S Lamb
Managing Director
Viamed Ltd
<http://www.viamed.co.uk>

-----Original Message-----

From: Billy Cheng <BCheng@udt.com>
To: 'info@viamed.co.uk' <info@viamed.co.uk>
Cc: Jack Kimbro <JackK@udt.com>; Chris Chin <Chin@udt.com>
Date: 21 May 1999 19:38
Subject: Cable Assembly Viamed p/n 9905101

>Mr. Lamb :

>

>I am working on the 9905101 cable assembly and I notice there is a small
>different between the wiring of your cable and a typical Nellcor cable.

>According to your drawing 9905101, the outer shield of the cable is
>connected to pin 7 while the inner shield of the cable is connected to pin
>6. On a typical Nellcor cable, the inner shield and the outer shield of
the

> cable are connected to pin 7 together.

>

>I am going forward with that cable assembly using the wiring of a typical
>Nellcor cable. Please let me know if you have comment.

>

>

>Regards,

>

>Billy Cheng
>Design Engineer
>UDT Sensors Inc.

>

FAX REF. :

Page 1 of 1

DATE

20 May 1997

Jack Kimbro

UDT Sensors Inc.

12525 Chadron Ave.: Hawthorne. CA 90250 . USA

Dear Jack,

Samples of Ohmeda Probes

We are testing your samples of Ohmeda probes with our tester and are finding inaccuracies of around 2% low at 99% and 2% High at 60%.

This could be because you have matched LED's to a probe with 56K ohm resistors.

Most Ohmeda appear to have 68K.

NB We have simulated a resistor change from 20K to 94K (limits our Ohmeda instrument accepts) we can change the accuracy by about 5% at 60% but only 0.5% at 98%.

Tomorrow we are going to test the probes on a Oximeter tester and on a Bio-Tec Index.

Is there any chance you can build a probe using an Ohmeda with a 68K?

We need to find a combination that not only works on the patient but works with the simulators.

If you cannot obtain a sample please let us know.

Kind Regards,

John S. Lamb.

CC Medical Cables Inc.