Contents
960110 Pulse Oximeter Probes

DESIGN PROCESS ENCLOSURE CHECK LIST

Job Number /Description_960110 Pulse Oximeter Probes_

SPECIFICATION & QUOTATION

Viamed/Client specification/brief available and enclosed?	Yes
Preliminary activity assigned on Job Progress Form and enclosed?	Yes[ ]
Design Compliance Form completed and enclosed?	Yes
Appropriate standards available?	No
Preliminary drawings completed and enclosed?	Yes
Quotation completed and enclosed	N/A
Quotation acceptance recorded?	N/A

CONSTRUCTION:

Working drawings enclosed?	Yes
Materials information recorded on Service Report?	Yes[ ] N/A[ ]
Progress meetings/reports and personnel involved recorded on Job Progress Form?	Yes
All design changes recorded and approved by client on Job Progress Form?	Yes[ ] N/A[ ]
Final inspection and test results recorded	Yes[ ]
Final costings recorded	Yes[ ]
Client acceptance recorded	Yes[ ]
Post trial minor modifications recorded on additional Job Progress Forms?	Yes[ ] N/A[ ]
Photographs enclosed?	Yes[ ] N/A[ ]
Project validation Form completed and enclosed?	Yes[ ]

Expenditure Log

Project Name 969110 Pulse Oximeter Probes

Date	Reason for Purchase	Supplier

Design projects Time Scale

Project:960110 Pulse Oximeter Progress report:

Date Months	Date	
Project		
1 Evaluation & Description	August 1996	E Avila TELEDYNE
Specification	Aug 1996	Original manufacturers specification
2 **Responsibilities**		
2 Initial Design	Aug 1996	Teledyne /UDT/JSL
Final Design	Dec 1996	UDT/Teledyne
3 Prototypes		UDT
Pre-production		UDT
Production		UDT
4 Initial Tests		JSL/Teledyne
Final Tests		JSL/Teledyne
Clinical Evaluation		JSL/Teledyne
5 Component sourcing		UDT
Bio-compatibility		UDT
Suitability		UDT
Datasheets		JSL/Teledyne
Testing		JSL/Teledyne
6 Manufacturing Route		UDT
Contractors		Employed by UDT

Work Log

Project 960110 Pulse Oximeter Probes

Name

Date	Action	Hours

Jan 1997

Design Changes

Project	
Date	**Description of Change**
Nov 1996	Re-designed finger clip JSL/Teledyne
Jan 1997	Resistors added JSL/DIL
Junee 1997	Bleck Finger pads for Ohmeda
March 1998	Strain relief redesigned for Viamed
Oct 1998	New strain releif designed
Nov 1998	Finger clip re-designed for Viamed
Nov 1998	Pads redesigned for Viaamed
Jan 1999	New LEDs
Jan 1999	New connectors

Job Number/Description **960110 Pulse Oximeter Probes**

Requested By Date	Position
Location	Telephone No.

To reverse engineer existing pulse oximeter probes and manufacture compatibles. UDT have been manufacturing originals for many years so had access to originaal technology and components with a ready made assembly line.
UDT manyufactured the original 6 types and some Nellcor style extension cables. Viamed will use the standard types and by changing connectors wiil manufacture a more comprehensive range.
Specials will need to be made in Viamed due to small quantities involved.
This will involve manufacturing similar to repair fubction using existing components and original LED's

Mar 1998 It has become necessary to prepare to manufacture the total range in Viamed.

This will involve
New clips Pads Strain reliefs, cables connectors and LED
The product will be based on the work already completed by UDT/Teledyne and will utilise the original diagrams suitably modified in the light of experience gained in 1998

1998 will be a period of component sourcing .
1999 the start of production.

The end product should not require testing as the parameters are identical to original work carried out.

Design & Development Compliance

Job Number 960110 Pulse oximeter probes_

(a) The solutions adopted for the design and construction of the devices must conform to safety principles to eliminate or reduce risks as far as possible (inherently safe design and construction). The device must be designed in such a way that, when used under the conditions and for the purposes intended, it will not compromise the safety of patients, or the safety and health of users or, where applicable, other persons.	IEC601 compatibility to original manufacturers probes
The device must be designed with particular attention to: • Electrical Safety • Moving Parts • Enclosures • Stability • Expelled parts • Vibration and noise	proven design no enclosure N/A No expelled paarts No noise or vibration
(b) Where modification of other manufactured devices is required, written approval will be sought from the manufacturer, otherwise concessionary status will be sought.	
(a) If the device is intended for use in combination with other devices or equipment, the whole combination, including connection system must be safe and must not impair the specified performance of the device.	Tested with original device
(b) The device must be designed in such a way that they can be used safely with the materials, substances and gasses with which they enter contact with during their normal use or during routine procedures.	N/A
(c) Accessible parts of the device (excluding parts or areas intended to supply or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.	N/A
(d) Devices must be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use. Particular attention must be paid to devices whose intended use includes exposure to flammable substances or to substances which could cause combustion.	N/A
(e) Devices must be designed and manufactured in such a way as to minimise the risks connected with environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration.	IEC 60601-1 &60601-2

Design & Development Compliance

(a) The device must be designed with particular attention to the choice of materials used, particularly as regards toxicity and where appropriate, flammability.	All materials compatible
(b) The device must be designed with particular attention to the compatibility between materials used and biological tissues, cells and fluids, taking account of the intended purpose of the device.	N/A
(c) The device must be designed in such a way as to minimise the risks posed by the unintentional ingress of substances into the device taking into account the device and the environment in which it is intended to be used.	Sealed with Silicone rubber
(d) The device must be designed with particular attention to reducing to a minimum the risks posed by substances leaking from the device.	N/A
(a) The materials used shall be appropriate for the intended purpose, taking account of strength, elasticity, melting point, porosity, conductance etc. (b) The surface finishes shall be suitable for the intended purpose of the device. (c) The materials selected shall be appropriate for any sterilisation / disinfection / cleaning requirements. (d) The characteristics and performance must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised when the device is subjected to the stresses which can occur during the normal conditions of use. i.e. ageing and corrosion.	
(a) Each device must be accompanied by the information needed to use it safely, taking account of the training and knowledge of the potential users. This information comprises details on the label and the data in the instructions for use.	Insert
(b) Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards.	Fingure symbol
The label must bear the following particulars: Identification of Viamed as the Manufacturer. If the device is custom made the words "Custom-made device"	
The label or instructions must contain the following instructions where appropriate: • Any special storage or handling precautions • Any special operating instructions • Any warnings and/or precautions to be taken. • Where appropriate, the method of sterilisation.	Yes Yes Yes Yes YES

QC23b

(a) The device must be designed in such a way as to eliminate or reduce as far as possible the risk on infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimise contamination of the device by the patient or vice versa during use.	N/A Not Sterile
(b) Devices delivered in a sterile state must be packaged in a non-reusable pack and remain sterile under normal transport and storage conditions, until the protective packaging is damaged or opened.	N/A
(c) Devices delivered in a sterile state must have been sterilised by an appropriate method.	N/A
(d) Devices that require sterilisation before use, but are supplied to the user in a non-sterile state, will be labelled to indicate this.	N/A
(e) The packaging for non-sterile devices must maintain the device cleanliness without deterioration, and minimise the risk of microbial contamination. The packaging system must be suitable, taking into account the method of sterilisation recommended.	N/A
(a) Devices must be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	N/A
(b) Where devices are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the omission, it must be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility and tolerance of relevant parameters.	N/A
(c) Where devices are intended to emit potentially hazardous visible and/or invisible radiation, they must be fitted, where practicable, with visual displayed and/or audible warnings of such emissions.	N/A
(d) Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to the emissions of unintended, stray or scattered radiation is reduced as far as possible.	N/A
(e) The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risk inherent in installation.	N/A

QC23c

IEC601	

IEC 601 IEC60601-1 IEC60601-2 Tests on OEM Tests on DL3000

Name N/A	Date

Drawings Enclosed **Yes [ ]** **No [ ]** **Not Applicable [ ]**

Authorised byN/A Position Date

QC23d

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		
March 98 DIL JSL visit LIP to assess manufacture of probe plastic parts		
Medilink visit to advise on local companies in plastic moulding		
March 1998 visit to Hi Tech Plastics to assess a probe design		
June 1998 JSL GGL visit Envitec discussed possiblity of joint project		
Met Envitec & S Gorsky from Imaginex(Daishin LED supplier and ex designer of Aristo.Heathrow airport		
Hammatsu visit to Viamed session on LED theory		
SN visit to Hamatsu offices in London		
Medilink visit to Viaamed concerning local suppliers		
SN visit to Medilink		
April 1998 JSL SN visit to Hi Tech order placed for Pips & strain relief		
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.		

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Design and Development Quotation

Job Number 960110 Pulse oximeter probes

to be assessed for each individual probe

Requested By	Position
Department	Telephone No.
[redacted]	
[redacted]	
[redacted]	
[redacted]	
[redacted]	

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