Contents
950101 Oxycal

DESIGN PROCESS ENCLOSURE CHECK LIST

Job

Number /Description_950101 Oxycal

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?	N/A
Preliminary drawings completed and enclosed?	No
Quotation completed and enclosed?	N/A
Quotation acceptance recorded?	N/A

CONSTRUCTION:

Working drawings enclosed?	Yes
Materials information recorded on Service Report?	No
Progress meetings/reports and personnel involved recorded on Job Progress Form?	No
All design changes recorded and approved by client on Job Progress Form?	No
Final inspection and test results recorded	No
Final costings recorded	No
Client acceptance recorded	N/A
Post trial minor modifications recorded on additional Job Progress Forms?	No
Photographs enclosed?	No
Project validation Form completed and enclosed?	No

Expenditure Log

Project Name: 950101 Oxycal

Date	Reason for Purchase	Supplier

Design projects Time Scale

Project: 950101 Oxycal :NO TIME SCALE

Date Months	Date	
Project		
1 Evaluation & Description	1990	Device based on the Teledyne J-1 simulator . To be extended to be used on R17 and T-7
Specification		

Work Log

Project 950101 Oxycal

Date	Action	Hours

Job Number/Description 950101 Oxycal _____

Requested By JSL Date 01/01/95	Position MD
Location	Telephone No.

A device to produce outputs that can be used as calibration sources for Oxygen analysers

Based on the Teledyne J-1 simulator

Tests to be carried out on analysers.

QC22

Design & Development Compliance

Job Number _

(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.	Not patient connected
The device must be designed with particular attention to: • Electrical Safety • Moving Parts • Enclosures • Stability • Expelled parts • Vibration and noise	9v battery No moving parts ABS enclosure N/A No expelled parts 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.	Teledyne final check
(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.	N/A
(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.	N/A (may require EMC??)

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.	N/A
(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.	N/A
(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.	N/A
(b) The surface finishes shall be suitable for the intended purpose of the device.	Standard ABS electronic enclosure
(c) The materials selected shall be appropriate for any sterilisation / disinfection / cleaning requirements.	N/A
(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.	N/A
(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.	Will need instruction manual if more than one sensor output is included
(b) Where appropriate, this information should take the form of symbols. Any symbol or identification colour used must conform to the harmonised standards.	N/A
The label must bear the following particulars: Identification of Viamed as the Manufacturer. If the device is custom made the words "Custom-made device"	Yes
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.	N/A N/A N/A N/A

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
(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.	

QC23c

None	Possibly IEC 601 IEC 60601-1 & 606001-2 EMC

Against analysers

Name N/A	Date

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

Authorised by N/A

Position

Please return to: Viamed Ltd

QC23d

Design & Development Job

Job Number 950101 Oxycal **Date :**01/01/95

Job Application		
Quote Preparation	**Preliminary Drawings**	**Design Compliance**
Purchasing	**Working Drawings**	**Construction**
Prototypes manufactured 1990		
Project not a high priority used internally for checking instruments		

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Design and Development Quotation

Job Number 950101 Oxycal

Title

Requested By JSL	Position MD
Department	Telephone No.
[redacted]	
For details see MPS File	
[redacted]	
For details see MPS file	
[redacted]	
All by Tewlephone	N/A
[redacted]	
	N/A

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Project Validation

Project 950101 Oxycal

	Subject	Y/N	Comments
1	Does the finnesed product meet the original specification	Y	
2	Is the quality of construction satisfactory	Y	
3	Will the equipment be durable	Y	
4	Does it comply with safety standards		
5	Does it comply with MDD		
6	Has the project remained in Budget		
7	Can the product be improved	Y	
8	Can the product be extended	Y	Moretypes of sensor