Design & Development Compliance

Job Number 960110 Pulse oximeter probes_

1 General	Report
(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. The device must be designed with particular attention to: • Electrical Safety • Moving Parts • Enclosures • Stability • Expelled parts • Vibration and noise (b) Where modification of other manufactured devices is required, written approval will be sought from the manufacturer, otherwise concessionary status will be sought.	IEC601 compatibility to original manufacturers probes proven design no enclosure N/A No expelled paarts No noise or vibration
2 Environment	**Report**
(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. (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. (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. (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. (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.	Tested with original device N/A N/A N/A IEC 60601-1 &60601-2

Design & Development Compliance

3 Biological Hazards	Report
(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
4 Material Physical Properties	**Report**
(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.	
5 User Information	**Report**
(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

6 Contamination	Report
(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

7 Radiation	Report
(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

Standards and Statutory requirements appropriate to this design	Requirement
IEC601	

Final Design Tests Proposed	Acceptance Criteria for Tests
IEC 601 IEC60601-1 IEC60601-2 Tests on OEM Tests on DL3000	

Quotation Authorised By	
Name N/A	Date

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

Client Acceptance
Authorised byN/A Position Date

QC23d

Design & Development Compliance

Pulse Oximeter Probes	960110

1. General	Report
(a) The solutions adopted for the design and construction of the devices must conform to safety principals 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 purpose intended, it will not compromise the safety of patients, or the safety and health of users or, where applicable, other persons. The device must be designed with particular attention to: • **Electrical Safety** • **Moving Parts** • **Enclosures** • **Stability** • **Expelled Parts** • **Vibration & Noise** (b) Where modification of other manufactured devices is required, written approval will be sought from the manufacturer, otherwise concessionary status will be sought.	IEC 601 Compatibility to original manufacturers probes Proven design No enclosure N/A No expelled parts No noise or vibration
2. Environment	**Report**
(a) If the device is intended for use in combination with other devices or equipment, the whole combination, including connection system, must be made safe and must not impair the specified performance of the device.	Tested with original device
(b) The devices must be designed in such a way that they can be used safely with the materials, substances and gases 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 for 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 that could cause combustion.	N/A
(e) Devices must be designed and manufactured in such a way as to	IEC 60601-1 & 60601-2

minimise the risks connected with environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration.	
3. Biological Hazards	**Report**
(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
4. Material Physical Properties	**Report**
(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 nd corrosion.	
5. User Information	**Report**
(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. 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 applicable:	Figure symbol
• **Any special storage or handling precautions**	Yes

• **Any special operating instructions**	Yes
• **Any warnings and / or precautions to be taken**	Yes
• **Where appropriate, the method of sterilisation**	Yes
6. Contamination	**Report**
(a) The device must be designed in such a way as to eliminate, or reduce as far as possible, the risk of 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
7. Radiation	**Report**
(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 emissions. 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 diplayed 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	N/A

of eliminating the risk inherent in installation.	

Standards and Statutory Requirements appropriate at this stage	Requirement
IEC 601	

Final Design Tests Proposed	Acceptance Criteria for Tests
IEC 601 IEC 60601-1 IEC 60601-2 Test on OEM Tests on DL3000 Simulator	

Quotation Authorised by:	
Name: N/A	Date:

Drawings Enclosed: Yes ( ) No ( ) Not Applicable ( )

Client Acceptance:
Authorised by: **N/A** Position: Date: Order Number: