Product Description:Pulse Oximetry Probe

Risk Analysis Report.

This product has been in continual use since 1987 without any recorded adverse effects.

Where hazards have been identified, solutions have been implemented to reduce any known risks:

General

The sensors use two LED emitters to measure the light absorption of the tissue and by suitable electronics converts the measurement into a value related to arterial oxygen.
They are intended for use by suitable health care employees. These products are sufficiently in widespread use throughout the world that only simple device labelling is required

The sensors are accessories compatible with the Original Manufacturers product.
They are therefore subject to the same restraints and warnings as the originals.
They do not deviate from tried and tested methods and are not innovative.
Each sensor is typed and families of sensors are colour coded.
Many manufacturers use identical sensors with different connector configurations.
The sensor should only be connected to equipment designated for use on the enclosed leaflet.
Damage could result if the main instrument fails or the sensor is incorrectly fitted to the instrument or fitted to the wrong instrument.
The sensors measure transmitted IR and visible light and should be used in conjunction with the manufactures advice as they can be affected by: extraneous light, position, and movement.

Specific use
The sensor delivers IR and visible light to the patient and records the differential light absorbance of the tissue and the pulsating arterial component to produce a clinical value for oxygenation. The oximeter sensor will detect an approximated value of arterial oxygen saturation SpO2 and pulse rate by means of a continuous, non-invasive method. The method and relative merits and accuracy has been the subject of several independent reports some have been included in the CE File for reference.
The intended environment of the device is for hospitals and clinics. The device labeling is self explanatory for installation and operation. Special attention is to be paid to individuals with perfusion problems in limbs and tissue.

It is intended that the product come in contact with patients

Re-usable Oximeter Sensors are applied to a patient's extremity such as "Finger or Ear". The spring incorporated within the clip allows for the unit to remain attached to the patient in a static position. The sensor must be re-positioned every 4 Hours.
Disposable Oximeter sensors are applied to the patient with the use of tape. The tape is wrapped around the sensor and the measurement site (patient limb). Generally the sensor comes in contact with patient and healthcare provider only. The sensor site must be checked every eight (8) hours for tissue abnormalities. The sensor must be repositioned every 24 hours.

Materials and components used.
Oximeter sensor consists of the following components:
LED's (Light Emitting Diodes) Red & IR
Photo-detector (Silicon Photodiode)
Adhesive Tape (Non-allergenic)
Medical Grade PVC, white cable and connector (5 wire conductor cable, PVC insulation)
Solder Paste (Tin, Lead, Silver component)
Silicon /Adhesive (Liquid Silicone rubber)
ABS clip

No substances are supplied or removed from the patient

The product is not Sterile when supplied.
Sterilization is not recommended Instructions are given for disinfecting the sensors are supplied Clean but not Sterile. If used on different patients there is a risk of cross infection if well-established basic medical techniques are not followed correctly.

The product is not intended to change the patient environment?

Measuring function
The sensor does not measure but is an accessory to a measuring instrument. Each sensor group is matched accurately to the original sensor it is replacing by using matched components.

Product explanations
The user is given general guidelines in the information leaflet and is referred to the original manufacturers specific guidance notes. Compatibility labels (Flag tags) are attached to each sensor cable.

The product is not intended for the control of or interaction with, other products or medication?

The Product produces visible and infrared light
Light is absorbed by the patient's tissue. The level of light is controlled by the monitor and depends on the type and pigmentation of the tissue.
Heat from the sensor should only be a problem if the sensor is left in-situ beyond the manufacturers guidance information, or when it is connected to non-compatible Oximeter monitor. Current levels to sensor may be of higher or lower levels than required if connected to non-compatible Oximeter Monitors. The sensors are colour coded to reduce this possibility and are flagged.

The product can be sensitive to outside influences
Product literature specifies the use of sensor within the areas of ambient light, which may influence the photo-detectors absorption of infrared light and give false data to the Oximeter monitor. The literature recommends that the original manufacturer's methods should be followed.

Product does not require any consumables or accessories
Flexible probes will require wrap rounds and/or Ear-clips.

No routine servicing or calibration is necessary

Product does not contain software

Some versions of the product have a limited shelf life
This is clearly stated on the labels.
Products have serial numbers and lot numbers

Product has no known long-term effects

Product Description: Pulse Oximetry Probe

Risk Analysis Report.

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General

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Specific use

The sensor delivers IR and visible light to the patient and records the differential light absorbance of the tissue and the pulsating arterial component to produce a clinical value for oxygenation. The oximeter sensor will detect an approximated value of arterial oxygen saturation SpO2 and pulse rate by means of a continuous, non-invasive method. The method and relative merits and accuracy has been the subject of several independent reports some have been included in the CE File for reference. The intended environment of the device is for hospitals and clinics. The device labeling is self explanatory for installation and operation. Special attention is to be paid to individuals with perfusion problems in limbs and tissue.

It is intended that the product come in contact with patients

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Disposable Oximeter sensors are applied to the patient with the use of tape. The tape is wrapped around the sensor and the measurement site (patient limb). Generally the sensor comes in contact with patient and healthcare provider only. The sensor site must be checked every eight (8) hours for tissue abnormalities. The sensor must be repositioned every 24 hours.

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No routine servicing or calibration is necessary

Product does not contain software

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Product has no known long-term effects

Risk Analysis Report

General

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The sensors measure transmitted IR and visible light and should be used in conjunction with the manufactures advice as they can be affected by extraneous light,position, and movement.

Specific use

The sensor delivers IR and visible light to the patient and records the differential light absorbance of the tissue and the pulsating arterial component to produce a clinical value for oxygenation. The oximeter sensor will detect an approximated value of arterial oxygen saturation SpO2 and pulse rate by means of a continuous, non-invasive method..The method and relative merits and accuracy have been the subject of several independent reports some have been included in the CE File for reference.
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It is intended that the product come in contact with patients
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Materials and components used.
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ABS clip

No substances are supplied or removed from the patient

The product is not Sterile when supplied.
Sterilization is not recommended Instructions are given for disinfecting The sensors are supplied Clean but not Sterile. If used on different patients there is a risk of cross infection if well established basic medical techniques are not followed correctly.

The product is not intented to change the patient environment?

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The sensor does not measure but is an accessory to a measuring instrument. Each sensor group is matched accurately to the original sensor it is replacing by using matched components.

Product explanations
The user is given general guidelines in the information leaflet and is referred to the original manufacturers specific guidance notes. Compatibility labels (Flag tags) are attached to each sensor cable.

The product is not intended for the control of or interaction with, other products or medication?

The Product produces visible and infrared light
Light is absorbed by the patients tissue . The level of light is controlled by the monitor and depends on the type and pigmentation of the tissue.
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The product can be sensitive to outside influences
Product literature specifies the use of sensor within the areas of ambient light which may influence the photodetectors absorption of infrared light and give false data to the Oximeter monitor. The literature recomends that the original manufacturers methods be followed.

Product does not require any consumables or accessories
Flexible probes will require wrap rounds and/or earclips.

No routine servicing or calibration is necessary

Product does not contain software

VIAMED

Some versions of the product have a limited shelf-life
This is clearly stated on the labels.
Products have serial numbers and lot numbers

Product has no known long term effects

Product Description: **Pulse Oximetry Probe**

Risk Analysis Report.

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Product does not contain software

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IR= Initial Risk RR = Residual Risk

Risk Analysis Report

Date 18 February 1998

Product

(In accordance with pr EN 1441:1997)

We hereby declare that the statements made herein are correct and valid

Company: Viamed Ltd. 15, Station Road, Crosshills, Keighley, West Yorkshire, BD20 7DT. UK

Signature

Name J.S.Lamb Director Date

IR= Initial Risk RR = Residual Risk

Ref	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C2	**ENERGY**					
C2.1	Electricity	Instrument & Sensor failure	3		3	
C2.2	Heat	Instrument & Sensor failure	3		3	
C2.3	Mechanical Force		4		4	
C2.4	Iononizing Radiation		4		4	
C2.5	Non Ionising Radiation		4		4	
C2.6	Electromagnetic Fields		4		4	
C2.7	Moving Parts		4		4	
C2.8	Suspended Masses		4		4	
C2.9	Patient Support Failure		4		4	
C2.10	Pressure (Vessel rupture)		4		4	
C2.11	Acoustic pressure		4		4	
C2.12	Vibration		4		4	
C2.13	Magnetic Fields (MRI)		4		4	
C3	**BIOLOGICAL**		4		4	
C3.1	Bio-Burden		4		4	
C3.2	Bio-Contamination		4		4	
C3.3	Bio-Incompatibility		4		4	
C3.4	Incorrect Output (Substance/energy)		4		4	
C3.5	Incorrect Formulation (Chemical Composition)		4		4	
C3.6	Toxicity		4		4	
C3.7	Cross Infection	User error	4		4	
C3.8	Pyrogenicity		4		4	
C3.9	Inability to Maintain Hygienic Standards		4		4	
C3.10	Degradation		4		4	
C4.	**ENVIRONMENTAL**		4		4	
C4.1	Electromagnetic Interference		4		4	
C4.2	Inadequate supply of Power or Coolant		4		4	
C4.3	Likelihood of Operation outside Prescribed Environmental Conditions		4		4	

IR= Initial Risk RR = Residual Risk

Ref.	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C4.4	Incompatibility with other Devices		4		4	
C4.5	Accidental Mechanical Damage		4		4	
C4.6	Contamination due to Waste Products and or Device Disposal		4		4	
C5	**DEVICE USE**		4		4	
C5.1	Inadequate Labelling		4		4	
C5.2	Inadequate Operating Instructions		4		4	
C5.3	Inadequate Specification of Accessories		4		4	
C5.4	Inadequate Specification of Pre-Use Checks		4		4	
C5.5	Over-complicated Operating Instructions		4		4	
C5.6	Unavailable or Separated Operating Instructions		4		4	
C5.7	Use by Unskilled /untrained Personnel		4		4	
C5.8	Reasonable Foreseeable Abuse		4		4	
C5.9	Insufficient Warning of Side Effects		4		4	
C5.10	Inadequate Warnings of Hazards Likely With Re-use of Single Use Devices		4		4	
C5.11	Incorrect Measurement and other Metrological Aspects	Technique limited	3		3	
C5.12	Incorrect Diagnosis		4		4	
C5.13	Erroneous Data Transfer		4		4	
C5.14	Misrepresentation of Results		4		4	
			4		4	
Ref.	**Hazard**	**Part of Equipment which pose risks**	4	**Design solution Adopted**	4	**Document referenced**

C5.15	Incompatibility with Consumables /accessories / other Devices	Manufacturers use similar connectors	3	Colour spot identification Labelling	4	
C6	**FUNCTIONAL FAILURE MAINTENANCE and AGEING**		4		4	

Product Description

Pulse Oximeter Compatible Finger Probes

C6.1	Inadequacy of Performance Characteristics for the Intended Use		4		4	
C6.2	Lack of ,or Inadequate Specification for Maintenance including Post Maintenance Functional Tests		4		4	
C6.3	Inadequate maintenance		4		4	
C6.4	Lack of Adequate Determination of End of Device Life	Will fail to function	4		4	
C6.5	Loss of Mechanical Integrity	Will be visible to the user	4		4	
C6.6	Inadequate Packaging (contaminationand/or Deterioration of the Device)		4		4	
C6.7	Improper Use		4		4	

IR= Initial Risk RR = Residual Risk

Product Type

MDD Class IIa

SpO_2 Probes

Model Type Various

Product Description

Pulse Oximeter Compatible Finger Probes

Manufacturer Address

Viamed Ltd.,

15 Station Road,

Crosshills

Keighley ,

West Yorkshire BD20 7DT. UK

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Risk Analysis Report

Date 18 February 1998

Product

Product Type	MDD Class IIb
SpO_2 Probes	

Model Type Various

Product Description

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(In accordance with pr EN 1441:1997)

We hereby declare that the statements made herein are correct and valid

Company: Viamed Ltd. 15, Station Road, Crosshills, Keighley, West Yorkshire, BD20 7DT. UK

Signature

Name J.S.Lamb Director Date 18/2/98

IR= Initial Risk RR = Residual Risk

Ref	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C	**ENERGY**					
C2.1	Electricity	Instrument & Sensor failure	3		3	
C2.2	Heat	Instrument & Sensor failure	3		3	
C2.3	Mechanical Force		4		4	
C2.4	Iononizing Radiation		4		4	
C2.5	Non Ionising Radiation		4		4	
C2.6	Electromagnetic Fields		4		4	
C2.7	Moving Parts		4		4	
C2.8	Suspended Masses		4		4	
C2.9	Patient Support Failure		4		4	
C2.10	Pressure (Vessel rupture)		4		4	
C1	Acoustic pressure		4		4	
C2.12	Vibration		4		4	
C2.13	Magnetic Fields (MRI)		4		4	
C3	**BIOLOGICAL**		4		4	
C3.1	Bio-Burden		4		4	
C3.2	Bio-Contamination		4		4	
C3.3	Bio-Incompatibility		4		4	
C3.4	Incorrect Output (Substance/energy)		4		4	
C3.5	Incorrect Formulation (Chemical Composition)		4		4	
C3.6	Toxicity		4		4	
C3.7	Cross Infection	User error	4		4	
C	Pyrogenicity		4		4	
C3.9	Inability to Maintain Hygienic Standards		4		4	
C3.10	Degradation		4		4	
C4.	**ENVIRONMENTAL**		4		4	
C4.1	Electromagnetic Interference		4		4	
C4.2	Inadequate supply of Power or Coolant		4		4	
C4.3	Likelihood of Operation outside Prescribed Environmental Conditions		4		4	

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Ref.	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C	Incompatibility with other Devices		4		4	
C4.5	Accidental Mechanical Damage		4		4	
C4.6	Contamination due to Waste Products and or Device Disposal		4		4	
C5	**DEVICE USE**		4		4	
C5.1	Inadequate Labelling		4		4	
C5.2	Inadequate Operating Instructions		4		4	
C5.3	Inadequate Specification of Accessories		4		4	
C	Inadequate Specification of Pre-Use Checks		4		4	
C5.5	Over-complicated Operating Instructions		4		4	
C5.6	Unavailable or Separated Operating Instructions		4		4	
C5.7	Use by Unskilled /untrained Personnel		4		4	
C5.8	Reasonable Foreseeable Abuse		4		4	
C5.9	Insufficient Warning of Side Effects		4		4	
C 0	Inadequate Warnings of Hazards Likely With Re-use of Single Use Devices		4		4	
C5.11	Incorrect Measurement and other Metrological Aspects	Technique limited	3		3	
C5.12	Incorrect Diagnosis		4		4	
C5.13	Erroneous Data Transfer		4		4	
C5.14	Misrepresentation of Results		4		4	
			4		4	

IR= Initial Risk RR = Residual Risk

Ref.	Hazard	Part of Equipment which pose risks	4	Design solution Adopted	4	Document referenced
C 5	Incompatibility with Consumables /accessories / other Devices	Manufacturers use similar connectors	3	Colour spot identification Labelling	4	
C6	**FUNCTIONAL FAILURE MAINTENANCE and AGEING**		4		4	
C6.1	Inadequacy of Performance Characteristics for the Intended Use		4		4	
C6.2	Lack of ,or Inadequate Specification for Maintenance including Post Maintenance Functional Tests		4		4	
C6.3	Inadequate maintenance		4		4	
C6.4	Lack of Adequate Determination of End of Device Life	Will fail to function	4		4	
C6.5	Loss of Mechanical Integrity	Will be visible to the user	4		4	
C6.6	Inadequate Packaging (contaminationand/or Deterioration of the Device)		4		4	
C6.7	Improper Use		4		4	