Risk Analysis Report

Product TC400 Date

Product Type	MDD Class IIb
Overhead Heater	

Model Type TC400

Product Description

Manual fixed height overhead heater

Manufacturer Address
Viamed Ltd.,
15 Station Road,
Crosshills
Keighley ,
West Yorkdhire BD20 7DT

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

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

Signature

Name J.S.Lamb Director Date 13 January 1998

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Risk Analysis Report

Ref	Hazard	Part of Equipment which pose risks	IR	Design solution Adopted	RR	Document referenced
C2	**ENERGY**		4		4	
C2.1	Electricity		4		4	
C2.2	Heat	Case	3	Warning label	4	
C2.3	Mechanical Force		4		4	
C2.4	Iononizing Radiation		4		4	
C2.5	Non Inonizing 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		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	

Ref.	Hazard	Part of Equipment which pose risks	4	Design solution Adopted	4	Document referenced
C4.3	Likelihood of Operation outside Prescribed Environmental Conditions		4		4	
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	

Ref.	Hazard	Part of Equipment which pose risks	4	Design solution Adopted	4	Document referenced
C5.11	Incorrect Measurement and other Metrological Aspects		4		4	
C5.12	Incorrect Diagnosis		4		4	
C5.13	Erroneous Data Transfer		4		4	
C5.14	Misrepresentation of Results		4		4	
C5.15	Incompatibility with Consumables /accessories / other Devices		4		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		4		4	
C6.5	Loss of Mechanical Integrity		4		4	
C6.6	Inadequate Packaging (contaminationand/or Deterioration of the Device)		4		4	
C6.7	Improper Use	Height	3	Warning label	4	

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Risk Analysis

TC400 Series Overhead baby Warmers

Intended Use

To create low level heat around a newborn baby to reduce heat loss from the patient. The heater is manually controlled and cannot exceed 400 Watts output.

There are four versions available all using the same heater module.
The structure is an electric Heater element in a metal enclosure
Behind the element is a reflector and in front a metal grill.

There are three areas of risk.

1) Electric Shock.

`This is only possible if;

a. The case is removed with the unit switche on
b. Wiring failure where wires are disconnected and comes into contact with the enclosure.
c. The element is touched. This can only happen with the use of a long thin conductor.

2) Patient Overheat.

This may occur on maximum power only if the warning labels are diregarded and the patient is placed to near to the heater
Warnings are attached to the stand.

3) User Overheat.

The distance between the heatr and the patient is also the working area and heat can effect the users head.
The grill can become hot to the touch
Warnings are placed on the heater unit.

4.Physical Injury

Due to the low distance between the the heater and the patient it is possible for the users head to come into contact with the heater enclosure.

5.Component failure

Failure of any component will leave the heater either OFF or at 100% output
The 400 watts at 100% at 27 ins has been shown to be safe.