

Reliance Medical Ltd
Risk Analysis

Step 1 – Description of Product & Intended Use

Product Name	RELIBURN
Product Code	

Description and outline of intended use
<p>Convenient burns dressing. Provides on the spot cooling effect for small burn areas . It adsorbs and dissipates heat. Safe for use on all burns.</p> <p>For use by trained or untrained personnel.</p> <p>Contents .Gel & water</p>

Assessment carried out by:

Name	Position	Sign	Date
Nigel Hargreaves	QA Manager		7/03/07

Recommendations raised	No recommendations from this risk analysis
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Step 2 – Identify Person(s) / Groups of Persons at Risk

Consideration must be given to how each hazard and risk identified will affect the different person(s) / groups of persons who may come into contact with the medical device.

Some examples: - Patient - Members of the Public

Table 1A – Person(s) / Groups of Persons Considered to be at Risk	
<ul style="list-style-type: none"> • Members of the Public • Patients • Person administering the first aid • Sportsmen and women 	

Step 3 – Identify Known or Foreseeable Hazards & Estimate Risk Rating

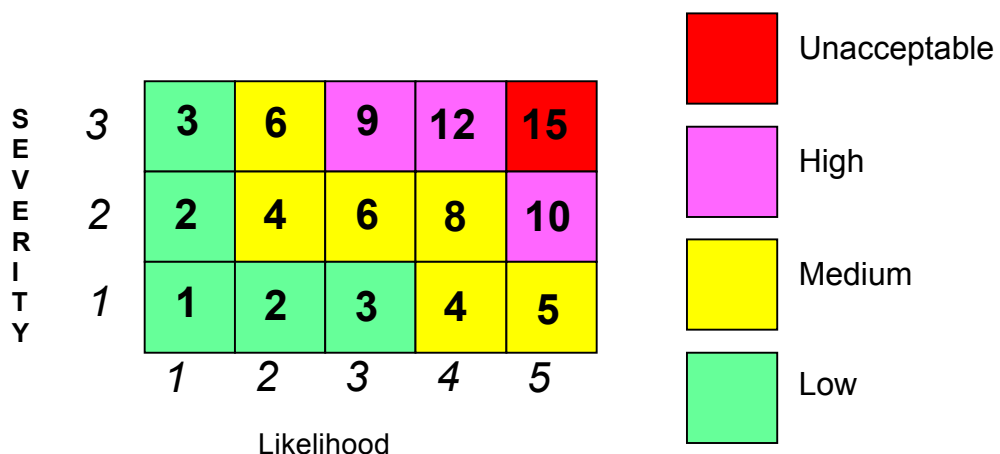
For each person / groups of persons outlined in table 1a identify any known or reasonably foreseeable hazards and taking into consideration any existing risk control measures assess the residual risk(s) using the risk rating chart shown in figure 1 below.

Figure 1 – Risk Rating Chart

Risk = Likelihood x Severity

Likelihood	
1	Unlikely
2	Possible
3	Likely
4	More Than Likely
5	Certain

Severity	
1	Minor Injury
2	Major Injury
3	Death



Use the following tables to record the details of your assessment

Annex A – Impact on Safety

A.2.1 – What is the intended use / purpose and how is the medical device to be used?
Refer to page 1 – description and outline of intended.

A.2.2 – Is the medical device intended to contact the patient or other person?
The product is intended to come into contact with the patient or user, refer to user instructions.

A.2.3 – What materials and / or components are incorporated in the medical device or are used with, or are in contact with, the medical device?
The product utilizes widely available components that are compatible with use on the skin using well developed industry technology.

A.2.4 – Is the energy delivered to and / or extracted from the patient?
Yes thermal energy is dissipated from the patient.

A.2.5 – Are substances delivered to and / or extracted from the patient?
n/a

A.2.6 – Are biological materials processed by the medical device for subsequent re-use?
n/a

A.2.7 – Is the medical device supplied sterile or intended to be sterilised by the user, or are other microbiological controls applicable?
Sterile , by gamma irradiation.

A.2.8 – Is the medical device intended to be routinely cleaned and disinfected by the user?
n/a single use.

A.2.9 – Is the medical device intended to modify the patient environment?
The device is intended to alleviate the condition.

A.2.10 – Are measurements taken?
n/a

A.2.11 – Is the medical device interpretative?
n/a

A.2.12 – Is the medical device intended for use in conjunction with medicines or other medical technologies?
n/a

A.2.13 – Are there unwanted outputs of energy or substances?
n/a

A.2.14 – Is the medical device susceptible to environmental influences?
Correct storage conditions are detailed on the label.

A.2.15 – Does the medical device influence the environment?
n/a

A.2.16 – Are there essential consumables or accessories associated with the medical device?
n/a

A.2.17 – Is maintenance and / or calibration necessary?
n/a

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A.2.18 – Does the medical device contain software?

n/a

A.2.19 – Does the medical device have restricted shelf – life?

Refer to the expiry date on the packaging. 5 years.

A.2.20 – Are there any delayed and / or long term use effects?

Provided all instructions are followed this product is not expected to produce either short or long term effects. If adverse effects occur stop using the product.

A.2.21 – To what mechanical forces will the medical device be subjected?

n/a

A.2.22 – What determines the life time of the medical device?

The shelf life of the packaging components

A.2.23 – Is the medical device intended for single use only?

Yes, single use.

A.2.24 – Is safe decommissioning or disposal of the medical device necessary?

Dispose of safely, considering good hygiene practice.

A.2.25 – Does installation or use of the medical device require special training?

No, follow on pack instructions.

A.2.26 – Will new manufacturing processes need to be established or introduced?

No

A.2.27 – Is successful application of the medical device critically dependant on human factors such as the user interface?

Yes, refer to user instructions.

A.2.27.1 – Does the medical device have connecting parts or accessories?

No

A.2.27.2 – Does the medical device have a control interface?

No

A.2.27.3 – Does the medical device display information?

No

A.2.27.4 – Is the medical device controlled by a menu?

No

A.2.28 – Is the medical device intended to be mobile or portable?

Yes by nature the product range is portable

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Table 2A – Energy Hazards & Contributory Factors			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Electricity	N		
2. Heat	N		
3. Mechanical Force	N		
4. Ionising Radiation	N		
5. Non Ionising Radiation	N		
6. Moving Parts	N		
7. Unintended Motion	N		
8. Suspended Masses	N		
9. Failure of Patient Support Device	N		
10. Pressure i.e. vessel rupture	Y		1 x 1 = LOW
11. Acoustic Pressure	N		
12. Vibration	N		
13. Magnetic Fields i.e. MRI	N		

Table 2B – Biological Hazards & Contributory Factors			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Bio-contamination	N		
2. Bio-incompatibility	N		
3. Incorrect Formulation (chemical composition)	N	Specification controlled	1 x 1 = LOW
4. Toxicity	Y		1 x 1 = LOW
5. Allergenicity	N		
6. Mutagenicity	N		
7. Oncogenicity	N		
8. Teratogenicity	N		
9. Carcinogenicity	N		
10. Re and/or cross infection	N	These products are for single use only.	1 x 1 = LOW
11. Pyrogenicity	N		
12. Inability to maintain hygienic safety	Y	The products are protected in the primary double sealed plastic packaging.	1 x 1 = LOW
13. Degradation	Y	The shelf life is on individual product / packaging	1 x 1 = LOW

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Table 2C – Environmental Hazards & Contributory Factors			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Electromagnetic Fields	N		
2. Susceptibility to Electromagnetic interference	N		
3. Emissions of electromagnetic interference	N		
4. Inadequate power supply	N		
5. Inadequate supply of coolant	N		
6. Storage or operation outside prescribed environmental conditions	N		
7. Incompatibility with other devices with which it is intended to be used	Y	The device is intended to be used with a cloth barrier for protection against ice burns.	1 x 1 = LOW
8. Can be subject to accidental mechanical damage	Y	Products can be damaged during manufacture, and transportation .Each product is inspected before final packing. Strong shippers are used to protect the product and have the correct warning/handling symbols on the pack.	2 x 1 = LOW
9. Contamination due to waste products (chemical)	Y	Only occurs if the pack is ruptured. Double seals give the pack better seal integrity.	1 x 1= LOW

Table 2D – Hazards From Incorrect Output of Energy & Substances			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Electricity	N		
2. Radiation	N		
3. Volume	N		
4. Pressure	N		
5. Supply of medical gases	N		
6. Supply of anaesthetic agents	N		
7. Thermal	Y	Instructions call for use of a cloth to act as a barrier against thermal burns	1 x 1 = LOW

Table 2E – Hazards Relating to the Use of the Device			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Inadequate labelling	Y	All products are labelled according to MDD 93/42/EEC and in accordance with any specific product standard.	1 x 1 = LOW No action required
2. Inadequate operating instructions	N		
3. Use by unskilled or untrained personnel	Y	Products are used by the public.	1 x 1 = LOW
4. Reasonably foreseeable misuse	N	To follow the on pack instructions.	
5. Insufficient warning of side effects	N		
6. Inadequate warnings of dangers from the re-use of a single use device	Y	All single use only products are labelled as such	1 x 1 = LOW
7. Incorrect measurements or other metrological aspects	N		
8. Incompatibility with consumables, accessories or other devices	Y	Refer to table 2C point 7	1 x 1 = LOW
9. Sharp edges or points	N		

Table 2F – Hazards from Complicated / Inadequate user Interface			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Mistake & judgement errors	N		
2. Lapses & cognitive recall errors	N		
3. Slips & blunders (mental or physical)	N		
4. Violation or abbreviation of instructions or procedures	N		
5. Complex or confusing control system	N		
6. Ambiguous or unclear device state	Y	Not a complex product	1 x 1 = LOW
7. Ambiguous or unclear presentation of settings, measurements	N		
8. Misrepresentation of results	N		
9. Insufficient visibility, audibility or tactility	N		

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Table 2G – Hazards Arising From Functional Failure, Maintenance or Ageing			
Hazard	Hazard Identified Yes / No	Existing Controls	Risk Rating (use fig.1 above)
1. Erroneous data transfer	N		
2. Lack of or inadequate maintenance specifications	N		
3. Inadequate maintenance	N		
4. Lack of adequate determination of end of life of device	Y	Expiry date is displayed on every product.	1 x 1 = LOW
5. Loss of electricity / mechanical integrity	N		
6. Inadequate packaging	Y	Compatibility and ease of use are considered when packaging is chosen.	1 x 1 = LOW
7. Re-use & improper re-use	N		
8. Deterioration in function i.e. gradual occlusion of fluid / gas or change in resistance to flow, electrical conductivity from repeated use	N		

Step 4 – Identification of Additional Control Measures

Where any hazards & risks identified above are not as low as is reasonably practicable, additional control measures must be identified and implemented.

Additional Control Measures		
Hazard	Additional Control	Expected Revised Risk Rating
n/a		

Step 5 - Risk Analysis Review

Where any changes to the design, specification and intended usage of the device takes place or where an accident, incident or near miss occurs involving the device, the risk analysis must be reviewed. The details of any such review should be recorded below.

Risk Analysis Review				
Reason for Review	Action Taken	Expected Revised Risk Rating	Date	Signature
n/a				