NASCOR
NEONATAL
AUSTRALIA

NASCOR PTY LTD

RISK ASSESMENT/ HAZARD ANALYSIS

Contents

General

3.GENERAL

The purpose of this document is to describe the risk analysis process that has been performed on the Nascor Biliband phototherapy mask.

3.2 RISK ANALYSIS TEAM

The members of the risk analysis team were assembled so as to provide a multidisciplinary approach to the task and to provide the necessary management support to implement any changes to the product to reduce risk.

Name	Role in Analysis Team	Qualifications
Dr Howard Chilton	NASCOR management representative Biomedical analysis	Neonatologist
Sue McNeil	Design Analysis	B.E. Ind design
Kwee Bee	Neonatal Nurse Practitioner	R.N.
Lindrea		

3.3 PRODUCT DESCRIPTION

The Nascor BILIBAND™ is a device to protect the eyes of the neonata during phototherapy from the effects of the bright light.

3.4 INTENDED USE OF THE PRODUCT

The Nascor BILIBAND™ is used by placing the eyepads over the eyes of the babies when under phototherpay. The pads provide enough attenuation of the light to prevent any theoretical damage to the eyes. It may be used by neonates of all weights and sizes.

3.5 METHODOLOGY

The method used evaluate the NASCOR BILIBAND™ is as follows-

1. The various entities that may potentially be subjected to a device hazard were identified.
2. For each entity all the potential hazards are identified and entered into the table. Reviewers from the risk analysis team evaluate the completeness of the list.
3. For each hazard its potential causes were identified and listed.
4. For each hazard and potential cause a severity and the likelihood rating was produced.

5. An acceptability rating based on the of hazards posed by the transport, storage or use of the NASCOR BILIBAND™ as "intended" (as defined in Section 0) was calculated.

3.2.1 Severity Categorisation

The severity of hazards, for the purpose of this document, is based on the classifications used with IEC 60601-1-4, Annex CCC. 4 classes for severity are defined below-

1. Negligible little or no potential of injury.
2. Marginal potential of injury.
3. Critical potential of death or serious injury.
4. Catastrophic potential of multiple deaths or serious injuries.

For the definition of 'serious injury' the FDA document-

" Guidance for the Content or Premarket Submission for Software Contained in Medical Devices" May 29, 1998"

Section 2.2.1 was used as a guide.

Serious injury means an injury or illness that:

-is life threatening
-results in permanent impairment of a body function or permanent damage to a body structure or
-Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

-For the purpose of this subpart, permanent means irreversible impairment or damage to a body structure or function excluding trivial impairment or damage.

3.2.2 Likelihood Estimation

The likelihood of occurrence is classified into a number of classes as per IEC 60601-1-4 Annex CCC.

6 frequent
5 probable
4 occasional
3 remote
2 improbable
1 incredible

These categories were further defined, using the following paper as a guide.

ISO/TC 210-IEC/SC 62A Joint Working Group "Application of Risk Management to Medical Devices" - provided in draft ISO/IEC JWG-RM N10 of Feb 1997.

	Category	Likelihood (event per year and device)
6	Frequent	>1
5	Probable	$1\text{-}10^{-1}$
4	Occasional	$10^{-1}\text{-}10^{-2}$
3	Remote	$10^{-2}\text{-}10^{-4}$
2	Improbable	$10^{-4}\text{-}10^{-6}$
1	Incredible	$<10^{-6}$

The likelihood calculation will be based on reported incidents and failure statistics as derived from post market surveillance.

Where there is no statistical information available to calculate the likelihood general assumption based on engineering experience were used

3.2.3 Combination of severity and likelihood.

The severity and likelihood information are combined to form an acceptability rating. The technique used to achieve the rating is the one proposed in IEC 60601-1-4. In this method a combination severity and likelihood will result in risk being deemed-

i Acceptable (Acc)
ii Not acceptable (NAcc)
iii As Low As Reasonable Possible (ALARP)

The following table indicated the method for cabining.

Likelihood	Severity 1 Negligible	2 Marginal	3 Critical	4 Catastrophic
6 frequent	ALARP (6)	Nacc (12)	NAcc (18)	NAcc (24)
5 probable	ALARP (5)	ALARP (10)	NAcc (15)	NAcc (20)
4 occasional	ALARP (4)	ALARP (8)	ALARP (12)	NAcc (16)
3 remote	Acc (3)	ALARP (6)	ALARP (9)	ALARP (12)
2 improbable	Acc(2)	Acc (4)	ALARP (6)	ALARP (8)
1 incredible	Acc (1)	Acc (2)	Acc (3)	Acc (4)

Note: The number after the acceptability rating is a multiplication of the severity and Likelihood ranking number from the table. This results in acceptability based on the following scores.

Score	Acceptance Rating
1-3	Acceptable
4	Overlap of Acceptable and ALARP (decision based on region)
5-12	ALARP
13-24	Not Acceptable

3.2.4 Criteria for acceptability of a risk level

For each of the hazards defined in the report only those that receive a score of "Acceptable" will require no further action.

A rating of ALARP will require a justification as to why the risk cannot be reduced any further.

A final rating of "Not Acceptable will result in the immediate modification of all existing and future units based on this design.

3.2.5 Validation

For each of the potential hazards, causes, severity and risk defined in the report a review and validation was completed by the risk analysis team.