Risk Assessment iaw EN ISO 14971:2000 Annex D : Possible hazards with medical devices.

Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Document referenced.	Sev of Haz.	Like 0f Haz.	Risk.
D.2	**Energy hazards and contributory factors**									
D.2.1	Electricity	N/A	1	1	1			1	1	1
D.2.2	Heat	N/A	1	1	1			1	1	1
D.2.3	Mechanical force	Light Shield	1	2	2	Recommendation not to lean on cover when in use. If damaged, user to assess level of damage / sharp edges before re-use	F. User Instructions / label	1	2	2
D.2.4	Ionising radiation	N/A	1	1	1			1	1	1
D.2.5	Non ionising radiation	N/A	1	1	1			1	1	1
D.2.6	Moving parts	N/A	1	1	1			1	1	1
D.2.7	Unintended motion	N/A	1	1	1			1	1	1
D.2.8	Suspended masses	N/A	1	1	1			1	1	1
D.2.9	Patient support failure	N/A	1	1	1			1	1	1
D.2.10	Pressure (vessel rupture)	N/A	1	1	1			1	1	1
D.2.11	Acoustic pressure	N/A	1	1	1			1	1	1
D.2.12	Vibration	N/A	1	1	1			1	1	1
D.2.13	Magnetic fields (eg. MRI)	N/A	1	1	1			1	1	1
D.3	**Biological hazards and contributory factors**									
D.3.1	Bio-contamination	Light Shield	1	2	2	Construction / polished surfaces – easy to clean	E. Risk analysis report	1	2	2
D.3.2	Bio-incompatibility	Light Shield	1	1	1	Perspex/acrylic sheet,	Manufacturers data	1	1	1
D.3.3	Incorrect formulation (chemical composition)	N/A	1	1	1		Manufacturers data	1	1	1
D.3.4	Toxicity	N/A	1	1	1		Manufacturers data	1	1	1

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.3.5	Allergenicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.6	Mutagenicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.7	Oncogenicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.8	Carcinogenicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.9	Re and/or cross infection	Light Shield	1	1	1		Manufacturers data	1	1	1
D.3.10	Pyrogenicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.11	Inability to maintain hygienic standards	Light Shield	4	2	8	Construction/polished surfaces – easy to clean. Cleaning recommendation in user manual / label	F. User Instructions / label E. Risk analysis report	1	2	2
D.3.12	Degradation	Light Shield	1	1	1	Care instructions given in the user instructions	F. User instructions	1	1	1
D.4	**Environmental hazards and contributory factors**									
D.4.1	Electromagnetic fields	N/A	1	1	1			1	1	1
D.4.2	Susceptibility to electromagnetic interference	N/A	1	1	1			1	1	1
D.4.3	Emissions of electromagnetic interference	N/A	1	1	1			1	1	1
D.4.4	Inadequate supply of power	N/A	1	1	1			1	1	1
D.4.5	Inadequate supply of coolant	N/A	1	1	1			1	1	1
D.4.6	Storage / operation outside prescribed environmental conditions	Light Shield	1	2	2	Environmental storage / operating conditions in user manual / labelling	F. User instructions / label E. Risk analysis report	1	2	2
D.4.7	Incompatibility with other devices with which the product is intended to be used	N/A	1	1	1			1	1	1

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.4.8	Accidental mechanical damage	Light Shield	1	1	1	Relatively robust material used. Glued joints used. If damaged, user to assess level of damage / sharp edges before re-use	F. User instructions / label	1	1	1
D.4.9	Contamination due to waste products and/or device disposal	Light Shield	1	2	2	No special disposal required	F. User instructions / label E. Risk analysis report	1	2	2
D.5	**Hazards resulting from incorrect output of energy and substances**									
D.5.1	Electricity	N/A	1	1	1			1	1	1
D.5.2	Radiation	N/A	1	1	1			1	1	1
D.5.3	Volume	N/A	1	1	1			1	1	1
D.5.4	Pressure	N/A	1	1	1			1	1	1
D.5.5	Supply of medical gases	N/A	1	1	1			1	1	1
D.5.6	Supply of anaesthetic agents	N/A	1	1	1			1	1	1
D.6	**Hazards related to the use of the medical device and contributory factors**									
D.6.1	Inadequate labelling	User manual / label	2	1	2	Product easy to use - label	F. Label	1	1	1
D.6.2	Inadequate operating instructions	User manual	2	1	2	Product easy to use – User manual	F. User Instructions	1	1	1
D.6.3	Inadequate specification of accessories		1	1	1			1	1	1
D.6.4	Inadequate specification of pre-use checks	User manual / label	2	2	4	Product easy to use User manual / inserts	F. User instructions / label	2	1	2
D.6.5	Over-complicated operating instructions	User manual	2	1	2	Product easy to use User manual / label	F. User instructions / label	1	1	1
D.6.6	Inadequate specification of service and maintenance	N/A	1	1	1	No service required except external cleaning	F. User instructions / label	1	1	1
D.6.7	Use by unskilled / untrained personnel	Light Shield	2	1	2	Product easy to use User manual / label	F. User instructions / label E. Risk analysis report	2	1	2

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.6.8	Reasonable foreseeable misuse	Light Shield	1	1	1	Product easy to use User manual / label	F. User instructions / label E. Risk analysis report	1	1	1
D.6.9	Insufficient warning of side effects	N/A	1	1	1			1	1	1
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices	N/A	1	1	1			1	1	1
D.6.11	Incorrect measurement and other metrological aspects	N/A	1	1	1			1	1	1
D.6.12	Misrepresentation of results	N/A	1	1	1			1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	Light Shield	1	1	1	Suitably sized cut-outs used.		1	1	1
D.6.14	Sharp edges or points	Light Shield	2	2	4	If damaged, user to assess level of damage / sharp edges before re-use	F. User instructions / label E. Risk analysis report	2	1	2
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors	N/A	1	1	1			1	1	1
D.7.2	Lapses and cognitive recall errors	N/A	1	1	1			1	1	1
D.7.3	Slips & blunders (mental or physical)	N/A	1	1	1			1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc	N/A	1	1	1			1	1	1
D.7.5	Complex or confusing control system	N/A	1	1	1			1	1	1

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.7.6	Ambiguous or unclear device state	N/A	1	1	1			1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	N/A	1	1	1			1	1	1
D.7.8	Misrepresentation of results	N/A	1	1	1			1	1	1
D.7.9	Insufficient visibility, audibility or tactility	N/A	1	1	1			1	1	1
D.7.10	Poor mapping of controls to action or of displayed information to actual state	N/A	1	1	1			1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment	N/A	1	1	1			1	1	1
D.8	**Hazards arising from function failure, maintenance and ageing and contributory factors**									
D.8.1	Erroneous data transfer	N/A	1	1	1			1	1	1
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests	N/A	1	1	1			1	1	1
D.8.4	Inadequate maintenance	N/A	1	1	1			1	1	1
D.8.5	Lack of adequate determination of end of device life	Light Shield	1	1	1	User decision based on clarity of plastic & tolerable damage to light shield	E. Risk analysis report	1	1	1
D.8.6	Loss of electrical integrity	N/A	1	1	1		E. Risk analysis report	1	1	1

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.8.7	Loss of mechanical integrity	Light Shield	1	1	1	User decision based on clarity of plastic & tolerable damage to light shield	E. Risk analysis report	1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	Light Shield	2	2	4	Often exact design specified by customer – product hand packed for despatch by courier	E. Risk analysis report M. Packaging	1	1	1
D.8.9	Re-use and/or improper re-use	Light Shield	1	1	1	User decision on suitability for next use based on clarity of plastic & tolerable damage	E. Risk analysis report	1	1	
D.8.10	Deterioration in function (gradual occlusion of fluid / gas path or change in resistance to flow, electrical conductivity) as a result of repeated use	Light Shield	1	1	1	User decision based on clarity of plastic & tolerable damage to light shild	E. Risk analysis report	1	1	

Severity of hazard: 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Probability of event: 1 = Improbable, 2 = Occasional, 3 = Likely, 4 = Highly likely.
Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.