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	Instrument Failure	2	1	2	Inherent Design features	Manufacturers Data	1	1	1
D.2.2	Heat	Instrument Failure	2	1	2	Inherent Design features Reflective Patch accessory	Manufacturers Data F. Instruction Leaflet	1	1	1
D.2.3	Mechanical force		1	1	1			1	1	1
D.2.4	Ionising radiation		1	1	1			1	1	1
D.2.5	Non ionising radiation		1	1	1			1	1	1
D.2.6	Moving parts		1	1	1			1	1	1
D.2.7	Unintended motion		1	1	1			1	1	1
D.2.8	Suspended masses		1	1	1			1	1	1
D.2.9	Patient support failure		1	1	1			1	1	1
D.2.10	Pressure (vessel rupture)		1	1	1			1	1	1
D.2.11	Acoustic pressure		1	1	1			1	1	1
D.2.12	Vibration		1	1	1			1	1	1
D.2.13	Magnetic fields (eg. MRI)	Potential component interference	2	1	2	Not for use within MRI scanning suites	F. Instruction Leaflet	1	1	1
D.3	**Biological hazards and contributory factors**									
D.3.1	Bio-contamination		1	1	1			1	1	1
D.3.2	Bio-incompatibility		1	1	1			1	1	1
D.3.3	Incorrect formulation (chemical composition)		1	1	1			1	1	1
D.3.4	Toxicity		1	1	1			1	1	1
D.3.5	Allergenicity		1	1	1			1	1	1
D.3.6	Mutagenicity		1	1	1			1	1	1
D.3.7	Oncogenicity		1	1	1			1	1	1
D.3.8	Carcinogenicity		1	1	1			1	1	1

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D.3.9	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instruction Leaflet	1	1	1
D.3.10	Pyrogenicity		1	1	1			1	1	1
D.3.11	Inability to maintain hygienic standards	General un-cleanliness	2	2	4	Cleaning Information	F. Instruction Leaflet	2	1	2
D.3.12	Degradation		1	1	1			1	1	1
D.4	**Environmental hazards and contributory factors**									
D.4.1	Electromagnetic fields		1	1	1			1	1	1
D.4.2	Susceptibility to electromagnetic interference		1	1	1			1	1	1
D.4.3	Emissions of electromagnetic interference		1	1	1			1	1	1
D.4.4	Inadequate supply of power		1	1	1			1	1	1
D.4.5	Inadequate supply of coolant		1	1	1			1	1	1
D.4.6	Storage / operation outside prescribed environmental conditions		1	1	1			1	1	1
D.4.7	Incompatibility with other devices with which the product is intended to be used		1	1	1			1	1	1
D.4.8	Accidental mechanical damage		1	1	1			1	1	1
D.4.9	Contamination due to waste products and/or device disposal		1	1	1			1	1	1
D.5	**Hazards resulting from incorrect output of energy and substances**									
D.5.1	Electricity		1	1	1			1	1	1

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D.5.2	Radiation		1	1	1			1	1	1
D.5.3	Volume		1	1	1			1	1	1
D.5.4	Pressure		1	1	1			1	1	1
D.5.5	Supply of medical gases		1	1	1			1	1	1
D.5.6	Supply of anaesthetic agents		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		2	1	2			1	1	1
D.6.2	Inadequate operating instructions		2	1	2			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		1	1	1			1	1	1
D.6.5	Over-complicated operating instructions		1	1	1			1	1	1
D.6.6	Inadequate specification of service and maintenance		1	1	1			1	1	1
D.6.7	Use by unskilled / untrained personnel	Inadequate site located	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.6.8	Reasonable foreseeable misuse		1	1	1			1	1	1
D.6.9	Insufficient warning of side effects		1	1	1			1	1	1
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices		1	1	1			1	1	1
D.6.11	Incorrect measurement and other metrological aspects	Technique Limited	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1

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D.6.12	Misrepresentation of results		1	1	1			1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	Alternative connections	2	2	4	Manufacturers use similar connectors	Colour spot identification labelling	1	1	1
D.6.14	Sharp edges or points		1	1	1			1	1	1
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.2	Lapses and cognitive recall errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instruction leaflet	1	1	1
D.7.3	Slips & blunders (mental or physical)		1	1	1			1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc		1	1	1			1	1	1
D.7.5	Complex or confusing control system		1	1	1			1	1	1
D.7.6	Ambiguous or unclear device state		1	1	1			1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information		1	1	1			1	1	1
D.7.8	Misrepresentation of results		1	1	1			1	1	1
D.7.9	Insufficient visibility, audibility or tactility		1	1	1			1	1	1

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D.7.10	Poor mapping of controls to action or of displayed information to actual state		1	1	1			1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment		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		1	1	1			1	1	1
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests		1	1	1			1	1	1
D.8.4	Inadequate maintenance		1	1	1			1	1	1
D.8.5	Lack of adequate determination of end of device life	Will fail to function	2	1	2	No end of life set		2	1	2
D.8.6	Loss of electrical integrity	Will fail to function	2	1	2	User decision of failure, cost effectiveness of repair	F. Instruction Leaflet	1	1	1
D.8.7	Loss of mechanical integrity	Will be visible to the user	2	1	2	Constant vigilance		1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)		1	1	1			1	1	1
D.8.9	Re-use and/or improper re-use		1	1	1			1	1	1

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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		1	1	1			1	1	1

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