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	Instrument	2	1	2	"Will damage if dropped" in User Instructions	F. User manual / Technical manual	1	1	1
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	Instrument	2	2	4	Easy to clean – cleaning instructions in user manual	F. User manual / Technical manual	1	2	2
D.3.2	Bio-incompatibility	Instrument	1	1	1	No adverse materials used	Manufacturers data	1	1	1
D.3.3	Incorrect formulation (chemical composition)	N/A	1	1	1			1	1	1
D.3.4	Toxicity	N/A	1	1	1		Manufacturers data	1	1	1
D.3.5	Allergenicity	N/A	1	1	1		Manufacturers data	1	1	1

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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	Instrument & leads	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	Instrument	2	2	4	Easy to clean – cleaning instructions in user manual	F. User manual / Technical manual	2	1	2
D.3.12	Degradation	Instrument	2	1	2	Care instructions given in the user manual	F. User manual / Technical manual	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	Instrument	2	1	2	No specific environmental storage / operating conditions imposed		2	1	2
D.4.7	Incompatibility with other devices with which the product is intended to be used	Instrument	1	1	1	Standard fittings used – all push to fit		1	1	1

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D.4.8	Accidental mechanical damage	Instrument	2	1	2	"Will damage if dropped" in User Instructions .Robust materials used. If damaged, user to assess level of damage – return for repair or spares parts available.	F. User manual / Technical manual	1	1	1
D.4.9	Contamination due to waste products and/or device disposal	Instrument	1	1	1	No special disposal required.		1	1	1
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	Instrument	4	3	12	Warnings in User Instructions. For use by trained and qualified personnel only – training offered. Flow rate can be restricted.		3	2	6
D.5.5	Supply of medical gases	N/A	3	2	6	Routes medical grade oxygen – channels checked for debris – only Fomblin grease used		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	Label	2	1	2	No instruction label on instrument – Instructions for use attached	F. User manual / Technical manual	1	1	1

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D.6.2	Inadequate operating instructions	Instructions for Use	2	1	2	Instructions for use comprehensively cover the product. Instrument only for use by trained and qualified personnel.	F. User manual / Technical manual	1	1	1
D.6.3	Inadequate specification of accessories	N/A	1	1	1			1	1	1
D.6.4	Inadequate specification of pre-use checks	Instructions for Use	2	2	4	Instrument must be pre-use checked – Instructions for Use refer.	F. User manual / Technical manual	2	1	2
D.6.5	Over-complicated operating instructions	Instructions for Use	2	1	2	Instructions for use comprehensively cover the product. Instrument only for use by trained and qualified personnel.	F. User manual / Technical manual	1	1	1
D.6.6	Inadequate specification of service and maintenance	Instructions for Use	2	2	4	Instrument set up at manufacture. Instructions for use state service requirements.		1	1	1
D.6.7	Use by unskilled / untrained personnel	Instrument	3	2	6	Instrument only for use by trained and qualified personnel – training offered. Statement in Instructions for Use to "follow hospital protocol"	F. User manual / Technical manual	2	1	2
D.6.8	Reasonable foreseeable misuse	Instrument	3	2	6	Instrument has safety valve which cannot be inadvertently overridden.		2	1	2
D.6.9	Insufficient warning of side effects	N/A	1	1	1			1	1	1

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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	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual.	F. User manual / Technical manual	1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices	N/A	1	1	1			1	1	1
D.6.14	Sharp edges or points	Instrument	2	2	4	Only if damaged, user to assess level of damage – return for repair or spares parts available.	F. User manual / Technical manual	1	1	1
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual. Preuse check always before use.	F. User manual / Technical manual	1	1	1
D.7.2	Lapses and cognitive recall errors	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual. Preuse check always before use.	F. User manual / Technical manual	1	1	1

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D.7.3	Slips & blunders (mental or physical)	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual. Preuse check always before use.	F. User manual / Technical manual	1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual. Preuse check always before use.	F. User manual / Technical manual	1	1	1
D.7.5	Complex or confusing control system	N/A	1	1	1	No complex user interface		1	1	1
D.7.6	Ambiguous or unclear device state	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual. Preuse check always if device state unclear.	F. User manual / Technical manual	1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	N/A	1	1	1	No complex user interface		1	1	1
D.7.8	Misrepresentation of results	Instrument	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual.	F. User manual / Technical manual	1	1	1
D.7.9	Insufficient visibility, audibility or tactility	N/A	1	1	1	No complex user interface		1	1	1

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D.7.10	Poor mapping of controls to action or of displayed information to actual state	N/A	3	1	3	Only for use by qualified & trained personnel – warnings in user / technical manual.	F. User manual / Technical manual	1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment	N/A	1	1	1	No complex user interface		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	Instrument	1	1	1	Instructions for use state service requirements. Instrument will not pass preuse check if badly damaged.	F. User manual / Technical manual	1	1	1
D.8.4	Inadequate maintenance	Instrument	1	1	1	Instrument set up at manufacture. Instructions for use state service requirements. Instrument will not pass preuse check if servicing required.	F. User manual / Technical manual	1	1	1
D.8.5	Lack of adequate determination of end of device life	Instrument	1	1	1	User decision based on damage or cost effectiveness of repair. Instrument will not pass preuse check if badly damaged or requiring servicing.		1	1	1
D.8.6	Loss of electrical integrity	N/A	1	1	1			1	1	1

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D.8.7	Loss of mechanical integrity	Instrument	1	1	1	User decision based on damage or cost effectiveness of repair. Instrument will not pass preuse check if badly damaged.		1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	Instrument	1	1	1	Bubble wrapped and boxed prior to despatch.	L. Packaging	1	1	1
D.8.9	Re-use and/or improper re-use	Instrument	1	1	1	User decision on suitability for next use based on pre use check & tolerable mechanical damage.		1	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	Instrument	1	1	1	O rings have given life – O rings to be replaced at recommended service interval		1	1	1

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