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									
D.2.2	Heat									
D.2.3	Mechanical force									
D.2.4	Ionising radiation									
D.2.5	Non ionising radiation									
D.2.6	Moving parts									
D.2.7	Unintended motion									
D.2.8	Suspended masses									
D.2.9	Patient support failure									
D.2.10	Pressure (vessel rupture)									
D.2.11	Acoustic pressure									
D.2.12	Vibration									
D.2.13	Magnetic fields (eg. MRI)									
D.3	**Biological hazards and contributory factors**									
D.3.1	Bio-contamination									
D.3.2	Bio-incompatibility									
D.3.3	Incorrect formulation (chemical composition)									
D.3.4	Toxicity									
D.3.5	Allergenicity									
D.3.6	Mutagenicity									
D.3.7	Oncogenicity									
D.3.8	Carcinogenicity									
D.3.9	Re and/or cross infection									

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.3.10	Pyrogenicity									
D.3.11	Inability to maintain hygienic standards									
D.3.12	Degradation									
D.4	**Environmental hazards and contributory factors**									
D.4.1	Electromagnetic fields									
D.4.2	Susceptibility to electromagnetic interference									
D.4.3	Emissions of electromagnetic interference									
D.4.4	Inadequate supply of power									
D.4.5	Inadequate supply of coolant									
D.4.6	Storage / operation outside prescribed environmental conditions									
D.4.7	Incompatibility with other devices with which the product is intended to be used									
D.4.8	Accidental mechanical damage									
D.4.9	Contamination due to waste products and/or device disposal									
D.5	**Hazards resulting from incorrect output of energy and substances**									
D.5.1	Electricity									
D.5.2	Radiation									
D.5.3	Volume									

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D.5.4	Pressure									
D.5.5	Supply of medical gases									
D.5.6	Supply of anaesthetic agents									
D.6	**Hazards related to the use of the medical device and contributory factors**									
D.6.1	Inadequate labelling									
D.6.2	Inadequate operating instructions									
D.6.3	Inadequate specification of accessories									
D.6.4	Inadequate specification of pre-use checks									
D.6.5	Over-complicated operating instructions									
D.6.6	Inadequate specification of service and maintenance									
D.6.7	Use by unskilled / untrained personnel									
D.6.8	Reasonable foreseeable misuse									
D.6.9	Insufficient warning of side effects									
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices									
D.6.11	Incorrect measurement and other metrological aspects									
D.6.12	Misrepresentation of results									
D.6.13	Incompatibility with									

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	consumables / accessories / other devices									
D.6.14	Sharp edges or points									
D.7	**Inappropriate, inadequate or overcomplicated user interface (man/machine communication)**									
D.7.1	Mistakes & judgement errors									
D.7.2	Lapses and cognitive recall errors									
D.7.3	Slips & blunders (mental or physical)									
D.7.4	Violation or abbreviation of instructions, procedures etc									
D.7.5	Complex or confusing control system									
D.7.6	Ambiguous or unclear device state									
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information									
D.7.8	Misrepresentation of results									
D.7.9	Insufficient visibility, audibility or tactility									
D.7.10	Poor mapping of controls to action or of displayed information to actual state									
D.7.11	Controversial modes or mappings as compared to									

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	existing equipment									
D.8	**Hazards arising from function failure, maintenance and ageing and contributory factors**									
D.8.1	Erroneous data transfer									
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests									
D.8.4	Inadequate maintenance									
D.8.5	Lack of adequate determination of end of device life									
D.8.6	Loss of electrical integrity									
D.8.7	Loss of mechanical integrity									
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)									
D.8.9	Re-use and/or improper re-use									
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									

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