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	Manufacturers Data	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
D.3.9	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instruction Leaflet	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.3.10	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
D.5.2	Radiation		1	1	1			1	1	1

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Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

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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Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.7.10	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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Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.8.10	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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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	Manufacturers Data	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

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.3.8	Carcinogenicity		1	1	1			1	1	1
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

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D.5	**Hazards resulting from incorrect output of energy and substances**									
D.5.1	Electricity		1	1	1			1	1	1
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

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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
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

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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
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

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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
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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Ref.	Hazard.	Related part / Component posing risk.	Sev of Haz.	Like of Haz.	Risk.	Solution.	Documer
D.2.1	Electricity	Instrument Failure	2	1	2	Inherent Design features	Manufactur
D.2.2	Heat	Instrument Failure	2	1	2	Inherent Design features	Manufactur
D.2.3	Mechanical force		1	1	1		
D.2.4	Ionising radiation		1	1	1		
D.2.5	Non ionising radiation		1	1	1		
D.2.6	Moving parts		1	1	1		
D.2.7	Unintended motion		1	1	1		
D.2.8	Suspended masses		1	1	1		
D.2.9	Patient support failure		1	1	1		
D.2.10	Pressure (vessel rupture)		1	1	1		
D.2.11	Acoustic pressure		1	1	1		
D.2.12	Vibration		1	1	1		
D.2.13	Magnetic fields (eg. MRI)	Potential component interference	2	1	2	Not for use within MRI scanning suites	F. Instructio
D.3.1	Bio-contamination		1	1	1		
D.3.2	Bio-incompatibility		1	1	1		
D.3.3	Incorrect formulation (chemical composition)		1	1	1		
D.3.4	Toxicity		1	1	1		
D.3.5	Allergenicity		1	1	1		
D.3.6	Mutagenicity		1	1	1		
D.3.7	Oncogenicity		1	1	1		
D.3.8	Carcinogenicity		1	1	1		
D.3.9	Re and/or cross infection	User error	2	2	4	Cleaning Information	F. Instructio
D.3.10	Pyrogenicity		1	1	1		
D.3.11	Inability to maintain hygienic standards	General un-cleanliness	2	2	4	Cleaning Information	F. Instructio
D.3.12	Degradation		1	1	1		
D.4.1	Electromagnetic fields		1	1	1		
D.4.2	Susceptibility to electromagnetic interference		1	1	1		

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Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.4.3	Emissions of electromagnetic interference		1	1	1		
D.4.4	Inadequate supply of power		1	1	1		
D.4.5	Inadequate supply of coolant		1	1	1		
D.4.6	Storage / operation outside prescribed environmental conditions		1	1	1		
D.4.7	Incompatibility with other devices with which the product is intended to be used		1	1	1		
D.4.8	Accidental mechanical damage		1	1	1		
D.4.9	Contamination due to waste products and/or device disposal		1	1	1		
D.5.1	Electricity		1	1	1		
D.5.2	Radiation		1	1	1		
D.5.3	Volume		1	1	1		
D.5.4	Pressure		1	1	1		
D.5.5	Supply of medical gases		1	1	1		
D.5.6	Supply of anaesthetic agents		1	1	1		
D.6.1	Inadequate labelling		2	1	2		
D.6.2	Inadequate operating instructions		2	1	2		
D.6.3	Inadequate specification of accessories		1	1	1		
D.6.4	Inadequate specification of pre-use checks		1	1	1		
D.6.5	Over-complicated operating instructions		1	1	1		
D.6.6	Inadequate specification of service and maintenance		1	1	1		
D.6.7	Use by unskilled / untrained personnel	Inadequate site located	2	2	4	For use by trained / skilled personnel	F. Instructio

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		1	1	1		
D.6.9	Insufficient warning of side effects		1	1	1		
D.6.10	Inadequate warnings of hazards likely with re-use of single use devices		1	1	1		
D.6.11	Incorrect measurement and other metrological aspects	Technique Limited	2	2	4	For use by trained / skilled personnel	F. Instructio
D.6.12	Misrepresentation of results		1	1	1		
D.6.13	Incompatibility with consumables / accessories / other devices	Alternative connections	2	2	4	Manufacturers use similar connectors	Colour spot labelling
D.6.14	Sharp edges or points		1	1	1		
D.7.1	Mistakes & judgement errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instructio
D.7.2	Lapses and cognitive recall errors	Personnel attributes	2	2	4	For use by trained / skilled personnel	F. Instructio
D.7.3	Slips & blunders (mental or physical)		1	1	1		
D.7.4	Violation or abbreviation of instructions, procedures etc		1	1	1		
D.7.5	Complex or confusing control system		1	1	1		
D.7.6	Ambiguous or unclear device state		1	1	1		
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information		1	1	1		
D.7.8	Misrepresentation of results		1	1	1		
D.7.9	Insufficient visibility, audibility or tactility		1	1	1		

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Risk calculated as severity of hazard x probability of event, 1 – 16. Further explanation of risk management policy – see Risk Management Policy & Definitions.

D.7.10	Poor mapping of controls to action or of displayed information to actual state		1	1	1		
D.7.11	Controversial modes or mappings as compared to existing equipment		1	1	1		
D.8.1	Erroneous data transfer		1	1	1		
D.8.2	Lack of, or inadequate specification for maintenance including post maintenance functional tests		1	1	1		
D.8.4	Inadequate maintenance		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	
D.8.6	Loss of electrical integrity	Will fail to function	2	1	2	User decision of failure, cost effectiveness of repair	F. Instructio
D.8.7	Loss of mechanical integrity	Will be visible to the user	2	1	2	Constant vigilance	
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)		1	1	1		
D.8.9	Re-use and/or improper re-use		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		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.

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.	Documer
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.3.1	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						
D.3.10	Pyrogenicity						
D.3.11	Inability to maintain hygienic standards						
D.3.12	Degradation						
D.4.1	Electromagnetic fields						

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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.5.1	Electricity						
D.5.2	Radiation						
D.5.3	Volume						
D.5.4	Pressure						
D.5.5	Supply of medical gases						
D.5.6	Supply of anaesthetic agents						
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						

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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 consumables / accessories / other devices						
D.6.14	Sharp edges or points						
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						

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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 existing equipment						
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						

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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						

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