Risk Assessment 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	Mains powered	3	3	9	Battery powered Designed to ISO 60601-1 & MDD requirements	(G) Technical manual (E) Risk analysis ISO 60601-1	1	1	1
D.2.2	Heat	If battery polarity reversed No direct heat	3	1	3	Protection diode added in circuit. Warning in user manual	(G1) Technical manual (Y.Z) Design file (F5) User manual	1	1	1
D.2.3	Mechanical force	N/A	1	1	1			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		2	3	6	Mounting screw	User Manual	1	2	2
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		2	3	6		(F5) User manual / inserts (E) Risk analysis	1	2	2
D.2.13	Magnetic fields (eg. MRI)	Instrument	4	4	16	Warning in user manual	(F5) User manual (E) Risk analysis	2	1	2
D.3	**Biological hazards and contributory factors**									
D.3.1	Bio-contamination		1	2	2		(F) User manual / inserts (E) Risk analysis	1	1	1
D.3.2	Bio-incompatibility	N/A	1	1	1		(T2) Manufacturers data	1	1	1
D.3.3	Incorrect formulation (chemical composition)	N/A	1	1	1		(T2) Manufacturers data	1	1	1
D.3.4	Toxicity	N/A	1	1	1		Manufacturers data	1	1	1

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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	N/A	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 / cable / sensor	4	2	8		Manufacturers data (F5) User manual (E) Risk analysis	1	2	2
D.3.12	Degradation	Instrument / cable through normal wear & tear	1	1	1	Care instructions given in the user manual	(F) User manual	1	1	1
D.4	**Environmental hazards and contributory factors**									
D.4.1	Electromagnetic fields	Instrument / cable / sensor	2	2	4	Circuit design & layout	(D) EMC report (Y16) Design reviews (E) Risk analysis	1	1	1
D.4.2	Susceptibility to electromagnetic interference	Instrument / cable / sensor	2	2	4	Circuit design & layout	(D) EMC report (Y16) Design reviews (E) Risk	1	1	1
D.4.3	Emissions of electromagnetic interference	Instrument / cable / sensor	2	2	4	Circuit design & layout	(D) EMC report (Y16) Design reviews (E) Risk analysis	1	1	1
D.4.4	Inadequate supply of power	Battery	2	3	6	Circuit design Battery low alarm Description in user manual	(Y16) Design reviews (F5) User manual	1	2	2
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 / cable / sensor	1	1	1	User manual / labelling	(F5) User manual (F7) Labels (E) Risk analysis	1	1	1
D.4.7	Incompatibility with other devices with which		3	2	6		(F7) Labels (F5) User manual	1	1	1

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	the product is intended to be used									
D.4.8	Accidental mechanical damage	Instrument / cable	1	1	1	Impact resistant case used Robust cable used	(T2) Manufacturers data	1	1	1
D.4.9	Contamination due to waste products and/or device disposal	Instrument / cable / sensor	4	2	8		(T2) Manufacturers data (F5) User manual / inserts (E) Risk	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	Radiated EM interference	1	1	1	Circuit design & layout	(D) EMC report (Y.Z) Design file	1	1	1
D.5.3	Volume	N/A	1	1	1			1	1	1
D.5.4	Pressure	N/A	1	1	1	Atmospheric Pressure	User Manual	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	Instrument	3	1	1	Product easy to use User manual / insert Labels	(F5) User manual & inserts (F7) Labels	1	1	1
D.6.2	Inadequate operating instructions	User manual & Insert	3	1	1	Product easy to use User manual & insert	(F5) User manual & inserts	1	1	1
D.6.3	Inadequate specification of accessories	User manual & insert	4	1	1	Product easy to use User manual & insert	(F5) User manual & inserts	1	1	1
D.6.4	Inadequate specification of pre-use checks	User manual & insert	3	1	1	Product easy to use User manual & inserts	(F5) User manual & inserts	1	1	1
D.6.5	Over-complicated operating instructions	User manual & insert	2	1	1	Product easy to use User manual & inserts	(F5) User manual & inserts	1	1	1
D.6.6	Inadequate specification of service and maintenance	User manual & inserts Technical manual	1	1	1	No service required except external cleaning of case & cable and battery replacement	(F5) User manual & inserts (G1) Technical manual	1	1	1

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D.6.7	Use by unskilled / untrained personnel	Instrument / cable / sensor	1	1	1	Product easy to use User manual & Insert	(F5) User manual & inserts (E) Risk analysis	1	1	1
D.6.8	Reasonable foreseeable misuse	Instrument / cable / sensor	1	1	1	Product easy to use User manual & Insert	(F5) User manual & inserts (E) Risk analysis	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		4	2	8		(F5) User manual & inserts (E) Risk analysis	1	1	1
D.6.11	Incorrect measurement and other metrological aspects		1	1	1		(F5) User manual & inserts	1	1	1
D.6.12	Misrepresentation of results	Instrument	1	1	1	Product easy to use Description / photos in user manual	(F5) User manual & inserts	1	1	1
D.6.13	Incompatibility with consumables / accessories / other devices		4	3	12	1.	(F5) User manual & inserts (E) Risk analysis (mask sensor & universal sensor)	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	Instrument / cable / sensor	1	1	1	Product easy to use User manual & insert	(F)5 User manual & inserts (E) Risk analysis	1	1	1
D.7.2	Lapses and cognitive recall errors	Instrument / cable / sensor	1	1	1	Product easy to use User manual & insert	(F5) User manual & inserts (E) Risk analysis	1	1	1
D.7.3	Slips & blunders (mental or physical)	Instrument / cable / sensor	1	1	1	Product easy to use User manual & Insert	(F5) User manual & inserts (E) Risk analysis	1	1	1
D.7.4	Violation or abbreviation of instructions, procedures etc	Instrument / cable / sensor	1	1	1	Product easy to use User manual & Insert	(F5) User manual & inserts (E) Risk analysis	1	1	1
D.7.5	Complex or confusing control system	Instrument	1	1	1	Description / photos in user manual	(F5) User manual	1	1	1

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D.7.6	Ambiguous or unclear device state	Instrument	1	1	1	Instrument specific LCD Description / photos in user manual	(F5) User manual	1	1	1
D.7.7	Ambiguous or unclear presentation of settings, measurement, or other information	Instrument	3	3	9	Instrument specific LCD Description / photos in user manual	(F5) User manual	1	1	1
D.7.8	Misrepresentation of results	Instrument	1	1	1	Breath rate only Description / photos in user manual	(F5) User manual	1	1	1
D.7.9	Insufficient visibility, audibility or tactility		1	3	3	Large LCD.	(Y16) Design review	1	2	2
D.7.10	Poor mapping of controls to action or of displayed information to actual state	Instrument	1	1	1		(F5) User manual	1	1	1
D.7.11	Controversial modes or mappings as compared to existing equipment	Instrument	1	1	1	Easy to use		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 / cable	1	1	1	No service required except external cleaning of case & cable, and battery replacement. Return to manufacturer for repair.	(F5) User manual & inserts (G1) Maintenance manual	1	1	1
D.8.4	Inadequate maintenance	Instrument / cable	1	1	1	No service required except external cleaning of case & cable, and battery replacement. Return to manufacturer for repair.	(F5) User manual & inserts (G1) Maintenance manual	1	1	1
D.8.5	Lack of adequate	Instrument / cable /	1	1	1	Oxygen Sensor depletion	(E) Risk analysis	1	1	1

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	determination of end of device life	sensor								
D.8.6	Loss of electrical integrity	N/A	1	1	1		(F5) User manual & inserts	1	1	1
D.8.7	Loss of mechanical integrity	Instrument / cable / sensor	1	1	1		(F5) User manual & inserts (E) Risk	1	1	1
D.8.8	Inadequate packaging (contamination and / or deterioration of the device)	Instrument / cable / sensors	2	2	4	Specifically designed packaging	(M) Packaging (M) Packaging manufacturers info (E) Risk	1	1	1
D.8.9	Re-use and/or improper re-use	Instrument / cable / sensors	1	1	1	.	(F5) User manual & inserts (E) Risk analysis	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 / cable	1	1	1	Failure of circuitry / cable likely to be obvious to user. Return instrument to manufacturer for repair.	(F5) User manual & inserts	1	1	1

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