Risk assessment iaw EN ISO 14971:2000 Annex A : Identification of medical device characteristics that could impact on safety.

Section	Question	Answer Y / N	Risk Y / N
A.2.1	Q. What is the intended use? A. Determine saturation of haemoglobin through tissue.		
	Diagnosis?	N	N
	Prevention?	N	N
	Monitoring?	Y	Y
	Treatment or alleviation of disease?	N	N
	Compensation for injury or handicap?	N	N
	Replacement or modification of anatomy?	N	N
	Control of conception?	N	N
A.2.1	Q. What is the intended purpose? A. Monitor the patient during determination.		
	Life sustaining?	N	N
	Life supporting?	N	N
A.2.1	Q. How is the medical device to be used? A. Attached to the patients finger & connected to the monitor		
	The patient can control the use?	N	N
	The patient can influence the use?	Y	Y
	Mental abilities of the user?	Y	Y
	Physical abilities of the user?	N	N
	Skill of the user?	Y	Y
	Training of the user?	Y	Y
	Used by handicapped persons?	N	N
	Used by the elderly?	N	N
	Used by children?	N	N
	Used by individuals with various skill levels?	N	N
	Used by individuals from various cultural backgrounds?	N	N
A.2.2	Q. Is the medical device intended to contact the patient or other persons? A. Yes – on the finger		
	Surface contact?	Y	Y

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

	The period of contact? A. Short term	Y	Y
	The frequency of contact? A. During required use.	Y	Y
	Invasive contact?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
	Implantation?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
A.2.3	Q. What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?	N	N
A.2.4	Q. Is energy delivered to and/or extracted from the patient?	N	N
A.2.5	Q. Are substances delivered to and/or extracted from the patient? A. No	N	N
	Single substance?		
	Range of substances?		
	The maximum and minimum transfer rates and control thereof?		
A.2.6	Q. Are biological materials processed by the medical device for subsequent re-use?	N	N
A.2.7	Q. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	N	N
	The shelf life?		
	Any limitation on the number of re-use cycles?		
	Any limitation type of sterilization process to be used?		
	Limitation on the number of cleaning cycles?		
	The effectiveness of routine cleaning and disinfection?		
A.2.9	Q. Is the medical device intended to modify the patient environment?	N	N
	Temperature?		
	Humidity?		
	Atmospheric gas composition?		
	Pressure and light?		
	Light?		
A.2.10	Q. Are measurements taken?	N	N
	The variables measured?		
	The accuracy?		
	The precision of the measurement results?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.11	Q. Is the medical device interpretative?		
	Conclusions are presented by the medical device from input data?	N	N
	Conclusions are presented by the medical device from acquired data?	Y	Y
	Conclusions are presented by the medical device from the algorithms used?	N	N
	Conclusions are presented by the medical device from input or acquired data, the algorithms used and confidence limits?	N	N
A.2.12	Q. Is the medical device intended for use in conjunction with medicines or other medical technologies?	N	N
A.2.13	Q. Are there unwanted outputs of energy or substances?	N	N
	Noise?		
	Vibration?		
	Heat?		
	Radiation?		
	Ionizing?		
	Non-ionizing?		
	Ultraviolet?		
	Visible?		
	Infrared?		
	Contact temperatures?		
	Leakage currents?		
	Electric fields?		
	Magnetic fields?		
	Discharge of chemicals?		
	Discharge of waste products?		
	Discharge of body fluids?		
A.2.14	Q. Is the medical device susceptible to environmental influences?		
	Operational?	N	N
	Transport storage environments?	N	N
	Light?	Y	Y
	Temperature?	N	N
	Vibrations?	N	N
	Spillage?	N	N
	Susceptibility to variations in power?	N	N
	Susceptibility of cooling supplies?	N	N
	Electromagnetic interference?	Y	Y

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.15	Q. Does the medical device influence the environment?	N	N
	The effects on power supplies?		
	The effects cooling supplies?		
	Emission of toxic materials?		
	The generation of electromagnetic interference?		
A.2.16	Q. Are there essential consumables or accessories associated with the medical device?	N	N
A.2.17	Q. Is maintenance and/or calibration necessary?	N	N
	Carried out by the operator?		
	Carried out by the user?		
	Carried out by a specialist? (Manufacturer)		
	Are special substances necessary for proper maintenance and/or calibration?		
	Is special equipment necessary for proper maintenance and/or calibration?		
A.2.18	Q. Does the medical device contain software?	N	N
	Is software intended to be installed?		
	Is software intended to be verified?		
	Is software intended to be modified?		
A.2.19	Q. Does the medical device have a restricted shelf-life?	N	N
	Labeling?		
	Indicators?		
	The disposal of such medical devices?		
A.2.20	Q. Are there any delayed and/or long-term use effects?	N	N
	Ergonomic?		
	Cumulative effects?		
A.2.21	Q. To what mechanical forces will the medical device be subjected? A. Fair wear & tear / possible drop.		
	Under the control of the user?	Y	Y
	Controlled by interaction with other persons?	Y	Y
A.2.22	Q. What determines the lifetime of the medical device? A. User care.		
	Ageing?	N	N
	Battery depletion?	N	N
	User care?	Y	Y
A.2.23	Q. Is the medical device intended for single use?	N	N
A.2.24	Q. Is safe decommissioning or disposal of the medical device necessary?	N	N
	Does it contain toxic material?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

	Does it contain hazardous material?		
	Does it contain recyclable material?		
A.2.25	Q. Does installation or use of the medical device require special training?	N	N
A.2.26	Q. Will new manufacturing processes need to be established or introduced?	N	N
A.2.27	Q. Is successful application of the medical device critically dependent on human factors such as the user interface?	N	N
A.2.27.1	Q. Does the medical device have connecting parts or accessories?		
	Connections?	Y	Y
	Connection force?	N	N
	Feedback on connection integrity?	Y	Y
	Over tightening?	N	N
	Under tightening?	N	N
	Spacing?	N	N
	Coding?	N	N
	Grouping?	N	N
A.2.27.2	Q. Does the medical device have a control interface?	N	N
	Mapping,		
	Modes of feedback?		
	Blunders?		
	Slips?		
	Control differentiation?		
	Visibility?		
	Direction of activation or change?		
	Are the controls continuous?		
	Are the controls discrete?		
	The reversibility of settings or actions?		
A.2.27.3	Q. Does the medical device display information?	N	N
	Visibility in various environments?		
	Orientation?		
	Populations and perspectives?		
	The clarity of the presented information?		
	Units?		
	Colour coding?		
	The accessibility of critical information?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.27.4	Q. Is the medical device controlled by a menu?	N	N
	Complexity?		
	Number of layers?		
	Awareness of state		
	Location of settings?		
	Navigation method?		
	Number of steps per action?		
	Sequence?		
	Clarity and memorization problems?		
	Importance of control function relative to its accessibility?		
A.2.28	Q. Is the medical device intended to be mobile or portable?	N	N
	Grips?		
	Handles?		
	Wheels?		
	Brakes?		
	Mechanical stability?		
	Mechanical durability?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. 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	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		

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.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		

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.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 A : Identification of medical device characteristics that could impact on safety.

Section	Question	Answer Y / N	Risk Y / N
A.2.1	Q. What is the intended use? A. Determine saturation of haemoglobin through tissue.		
	Diagnosis?	N	N
	Prevention?	N	N
	Monitoring?	Y	Y
	Treatment or alleviation of disease?	N	N
	Compensation for injury or handicap?	N	N
	Replacement or modification of anatomy?	N	N
	Control of conception?	N	N
A.2.1	Q. What is the intended purpose? A. Monitor the patient during determination.		
	Life sustaining?	N	N
	Life supporting?	N	N
A.2.1	Q. How is the medical device to be used? A. Attached to the patients finger & connected to the monitor		
	The patient can control the use?	N	N
	The patient can influence the use?	Y	Y
	Mental abilities of the user?	Y	Y
	Physical abilities of the user?	N	N
	Skill of the user?	Y	Y
	Training of the user?	Y	Y
	Used by handicapped persons?	N	N
	Used by the elderly?	N	N
	Used by children?	N	N
	Used by individuals with various skill levels?	N	N
	Used by individuals from various cultural backgrounds?	N	N
A.2.2	Q. Is the medical device intended to contact the patient or other persons? A. Yes – on the finger		
	Surface contact?	Y	Y

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

	The period of contact? A. Short term	Y	Y
	The frequency of contact? A. During required use.	Y	Y
	Invasive contact?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
	Implantation?	N	N
	The period of contact?	N	N
	The frequency of contact?	N	N
A.2.3	Q. What materials and/or components are incorporated in the medical device or are used with, or are in contact with, the medical device?	N	N
A.2.4	Q. Is energy delivered to and/or extracted from the patient?	N	N
A.2.5	Q. Are substances delivered to and/or extracted from the patient? A. No	N	N
	Single substance?		
	Range of substances?		
	The maximum and minimum transfer rates and control thereof?		
A.2.6	Q. Are biological materials processed by the medical device for subsequent re-use?	N	N
A.2.7	Q. Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	N	N
	The shelf life?		
	Any limitation on the number of re-use cycles?		
	Any limitation type of sterilization process to be used?		
	Limitation on the number of cleaning cycles?		
	The effectiveness of routine cleaning and disinfection?		
A.2.9	Q. Is the medical device intended to modify the patient environment?	N	N
	Temperature?		
	Humidity?		
	Atmospheric gas composition?		
	Pressure and light?		
	Light?		
A.2.10	Q. Are measurements taken?	N	N
	The variables measured?		
	The accuracy?		
	The precision of the measurement results?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.11	Q. Is the medical device interpretative?		
	Conclusions are presented by the medical device from input data?	N	N
	Conclusions are presented by the medical device from acquired data?	Y	Y
	Conclusions are presented by the medical device from the algorithms used?	N	N
	Conclusions are presented by the medical device from input or acquired data, the algorithms used and confidence limits?	N	N
A.2.12	Q. Is the medical device intended for use in conjunction with medicines or other medical technologies?	N	N
A.2.13	Q. Are there unwanted outputs of energy or substances?	N	N
	Noise?		
	Vibration?		
	Heat?		
	Radiation?		
	Ionizing?		
	Non-ionizing?		
	Ultraviolet?		
	Visible?		
	Infrared?		
	Contact temperatures?		
	Leakage currents?		
	Electric fields?		
	Magnetic fields?		
	Discharge of chemicals?		
	Discharge of waste products?		
	Discharge of body fluids?		
A.2.14	Q. Is the medical device susceptible to environmental influences?		
	Operational?	N	N
	Transport storage environments?	N	N
	Light?	Y	Y
	Temperature?	N	N
	Vibrations?	N	N
	Spillage?	N	N
	Susceptibility to variations in power?	N	N
	Susceptibility of cooling supplies?	N	N
	Electromagnetic interference?	Y	Y

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.15	Q. Does the medical device influence the environment?	N	N
	The effects on power supplies?		
	The effects cooling supplies?		
	Emission of toxic materials?		
	The generation of electromagnetic interference?		
A.2.16	Q. Are there essential consumables or accessories associated with the medical device?	N	N
A.2.17	Q. Is maintenance and/or calibration necessary?	N	N
	Carried out by the operator?		
	Carried out by the user?		
	Carried out by a specialist? (Manufacturer)		
	Are special substances necessary for proper maintenance and/or calibration?		
	Is special equipment necessary for proper maintenance and/or calibration?		
A.2.18	Q. Does the medical device contain software?	N	N
	Is software intended to be installed?		
	Is software intended to be verified?		
	Is software intended to be modified?		
A.2.19	Q. Does the medical device have a restricted shelf-life?	N	N
	Labeling?		
	Indicators?		
	The disposal of such medical devices?		
A.2.20	Q. Are there any delayed and/or long-term use effects?	N	N
	Ergonomic?		
	Cumulative effects?		
A.2.21	Q. To what mechanical forces will the medical device be subjected? A. Fair wear & tear / possible drop.		
	Under the control of the user?	Y	Y
	Controlled by interaction with other persons?	Y	Y
A.2.22	Q. What determines the lifetime of the medical device? A. User care.		
	Ageing?	N	N
	Battery depletion?	N	N
	User care?	Y	Y
A.2.23	Q. Is the medical device intended for single use?	N	N
A.2.24	Q. Is safe decommissioning or disposal of the medical device necessary?	N	N
	Does it contain toxic material?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

	Does it contain hazardous material?		
	Does it contain recyclable material?		
A.2.25	Q. Does installation or use of the medical device require special training?	N	N
A.2.26	Q. Will new manufacturing processes need to be established or introduced?	N	N
A.2.27	Q. Is successful application of the medical device critically dependent on human factors such as the user interface?	N	N
A.2.27.1	Q. Does the medical device have connecting parts or accessories?		
	Connections?	Y	Y
	Connection force?	N	N
	Feedback on connection integrity?	Y	Y
	Over tightening?	N	N
	Under tightening?	N	N
	Spacing?	N	N
	Coding?	N	N
	Grouping?	N	N
A.2.27.2	Q. Does the medical device have a control interface?	N	N
	Mapping,		
	Modes of feedback?		
	Blunders?		
	Slips?		
	Control differentiation?		
	Visibility?		
	Direction of activation or change?		
	Are the controls continuous?		
	Are the controls discrete?		
	The reversibility of settings or actions?		
A.2.27.3	Q. Does the medical device display information?	N	N
	Visibility in various environments?		
	Orientation?		
	Populations and perspectives?		
	The clarity of the presented information?		
	Units?		
	Colour coding?		
	The accessibility of critical information?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

A.2.27.4	Q. Is the medical device controlled by a menu?	N	N
	Complexity?		
	Number of layers?		
	Awareness of state		
	Location of settings?		
	Navigation method?		
	Number of steps per action?		
	Sequence?		
	Clarity and memorization problems?		
	Importance of control function relative to its accessibility?		
A.2.28	Q. Is the medical device intended to be mobile or portable?	N	N
	Grips?		
	Handles?		
	Wheels?		
	Brakes?		
	Mechanical stability?		
	Mechanical durability?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

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Risk assessment iaw EN ISO 14971:2000 Annex A : Identification of medical device characteristics that could impact on safety.

Question	Answer Y / N
Diagnosis?	
Prevention?	
Monitoring?	
Treatment or alleviation of disease?	
Compensation for injury or handicap?	
Replacement or modification of anatomy?	
Control of conception?	
Life sustaining?	
Life supporting?	
The patient can control the use?	
The patient can influence the use?	
Mental abilities of the user?	
Physical abilities of the user?	
Skill of the user?	
Training of the user?	
Used by handicapped persons?	
Used by the elderly?	
Used by children?	
Used by individuals with various skill levels?	
Used by individuals from various cultural backgrounds?	
Surface contact?	
The period of contact? A. Short term	
The frequency of contact? A. During required use.	
Invasive contact?	
The period of contact?	
The frequency of contact?	
Implantation?	
The period of contact?	
The frequency of contact?	

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

Single substance?	
Range of substances?	
The maximum and minimum transfer rates and control thereof?	
The shelf life?	
Any limitation on the number of re-use cycles?	
Any limitation type of sterilization process to be used?	
Limitation on the number of cleaning cycles?	
The effectiveness of routine cleaning and disinfection?	
Temperature?	
Humidity?	
Atmospheric gas composition?	
Pressure and light?	
Light?	
The variables measured?	
The accuracy?	
The precision of the measurement results?	
Conclusions are presented by the medical device from input data?	
Conclusions are presented by the medical device from acquired data?	
Conclusions are presented by the medical device from the algorithms used?	
Conclusions are presented by the medical device from input or acquired data, the algorithms used and confidence limits?	
Noise?	
Vibration?	
Heat?	
Radiation?	
Ionizing?	
Non-ionizing?	
Ultraviolet?	
Visible?	
Infrared?	
Contact temperatures?	
Leakage currents?	
Electric fields?	
Magnetic fields?	
Discharge of chemicals?	
Discharge of waste products?	
Discharge of body fluids?	

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

Operational?		
Transport storage environments?		
Light?		
Temperature?		
Vibrations?		
Spillage?		
Susceptibility to variations in power?		
Susceptibility of cooling supplies?		
Electromagnetic interference?		
The effects on power supplies?		
The effects cooling supplies?		
Emission of toxic materials?		
The generation of electromagnetic interference?		
Carried out by the operator?		
Carried out by the user?		
Carried out by a specialist? (Manufacturer)		
Are special substances necessary for proper maintenance and/or calibration?		
Is special equipment necessary for proper maintenance and/or calibration?		
Is software intended to be installed?		
Is software intended to be verified?		
Is software intended to be modified?		
Labeling?		
Indicators?		
The disposal of such medical devices?		
Ergonomic?		
Cumulative effects?		
Under the control of the user?		
Controlled by interaction with other persons?		
Ageing?		
Battery depletion?		
User care?		
Does it contain toxic material?		
Does it contain hazardous material?		
Does it contain recyclable material?		

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

Connections?	
Connection force?	
Feedback on connection integrity?	
Over tightening?	
Under tightening?	
Spacing?	
Coding?	
Grouping?	
Mapping,	
Modes of feedback?	
Blunders?	
Slips?	
Control differentiation?	
Visibility?	
Direction of activation or change?	
Are the controls continuous?	
Are the controls discrete?	
The reversibility of settings or actions?	
Visibility in various environments?	
Orientation?	
Populations and perspectives?	
The clarity of the presented information?	
Units?	
Colour coding?	
The accessibility of critical information?	
Complexity?	
Number of layers?	
Awareness of state	
Location of settings?	
Navigation method?	
Number of steps per action?	
Sequence?	
Clarity and memorization problems?	
Importance of control function relative to its accessibility?	
Grips?	
Handles?	
Wheels?	

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.

Brakes?
Mechanical stability?
Mechanical durability?

Explanation : 1 = Insignificant, 2 = Tolerable, 3 = Critical, 4 = Intolerable. Overall risk calculated as product 1 – 16. See Risk Management Policy & Definitions.