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. Enclosures to enable; oxygen enriched air and humidity to be supplied to the patients head only		
	Diagnosis?	N	N
	Prevention?	Y	Y
	Monitoring?	N	N
	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. Enclosures to enable; oxygen enriched air and humidity to be supplied to the patients head only		
	Life sustaining?	N	N
	Life supporting?	N	N
A.2.1	Q. How is the medical device to be used? A. Place Headbox over patient and feed in enriched / humidified gas via pressure regulator / flow meter		
	The patient can control the use?	N	N
	The patient can influence the use?	N	N
	Mental abilities of the user ?	N	N
	Physical abilities of the user?	N	N
	Skill of the user?	N	N
	Training of the user?	N	N
	Used by handicapped persons?	N	N
	Used by the elderly?	N	N
	Used by children?	N	N
	Used by individuals with various skill levels?	Y	Y
	Used by individuals from various cultural backgrounds?	Y	N
A.2.2	Q. Is the medical device intended to contact the patient or other persons? A. Not in normal use		
	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	Y	Y
	The frequency of contact	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? A. Perspex / acrylic sheet & rubber gaiter around neck door	Y	Y
A.2.4	Q. Is energy delivered to and/or extracted from the patient? A. No	N	N
A.2.5	Q. Are substances delivered to and/or extracted from the patient? A. Oxygen	N	N
	Single substance?	Y	N
	Range of substances?	N	N
	The maximum and minimum transfer rates and control thereof? A. 6 litres / min, pressure	N	N
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? A. No	N	N
	The shelf life?	N/A	N/A
	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? A. Enriched /humidified gas & Light (amber head-boxes)	N	N
	Temperature?	N	N
	Humidity?	Y	N
	Atmospheric gas composition?	N	N
	Pressure and light?	N	N
	Light?	Y	N
A.2.10	Q. Are measurements taken?	N	N
	The variables measured?	N/A	N/A
	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?	N	N
	Conclusions are presented by the medical device from input data?	N/A	N/A
	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?		
A.2.12	Q. Is the medical device intended for use in conjunction with medicines or other medical technologies? A. Oxygen regulators	Y	N
A.2.13	Q. Are there unwanted outputs of energy or substances?	N	N
	Noise?	N/A	N/A
	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?	N	N
	Operational?	N/A	N/A
	Transport storage environments?		
	Light?		
	Temperature?		
	Vibrations?		
	Spillage?		
	Susceptibility to variations in power?		
	Susceptibility of cooling supplies?		
	Electromagnetic interference?		

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?	N/A	N/A
	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?	N/A	N/A
	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?	N/A	N/A
	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?	N/A	N/A
	Indicators?		
	The disposal of such medical devices?		
A.2.20	Q. Are there any delayed and/or long-term use effects?	N	N
	Ergonomic?	N/A	N/A
	Cumulative effects?		
A.2.21	Q. To what mechanical forces will the medical device be subjected? A. Negligible in normals use.	N	N
	Under the control of the user?	N/A	N/A
	Controlled by interaction with other persons?		
A.2.22	Q. What determines the lifetime of the medical device? A. Clarity and damage to plastics	Y	N
	Ageing?	Y	N
	Battery depletion?	N	N
	User care?	Y	N
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?	N/A	N/A

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?	N	N
	Connections?	N/A	N/A
	Connection force?		
	Feedback on connection integrity?		
	Over tightening?		
	Under tightening?		
	Spacing?		
	Coding?		
	Grouping?		
A.2.27.2	Q. Does the medical device have a control interface?	N	N
	Mapping,	N/A	N/A
	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?	N/A	N/A
	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?	N/A	N/A
	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? A. Portable	Y	N
	Grips?	N	N
	Handles?	N	N
	Wheels?	N	N
	Brakes?	N	N
	Mechanical stability?	Y	N
	Mechanical durability?	Y	N

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