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

Section	Main Question	Subsidiary questions	Answer Y / N	Risk Y / N
A.2.1	Q. What is the intended use ? A. Enclosures to enable oxygen enriched gas 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. To enable oxygen enriched gas 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
		The period of contact.	Y	Y

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16

		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. Yes, oxygen.	Single substance	Y	N
		Range of substances,	N	N
		The maximum and minimum transfer rates and control thereof.	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.	The shelf-life	N	N
		Any limitation on the number of re-use cycles	N	N
		Any limitation type of sterilization process to be used.	N	N
		Limitation on the number of cleaning cycles	N	N
		The effectiveness of routine cleaning and disinfection	N	N
A.2.9	Q. Is the medical device intended to modify the patient environment? A. Yes enriched / humidified gas & light (amber headboxes).	Temperature,	N	N
		Humidity,	Y	N
		Atmospheric gas composition	Y	N
		Pressure and light	N	N
		Light	Y	N

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16

A.2.10	Q. Are measurements taken? A. No	The variables measured : Breath rate	N	N
		The accuracy	N	N
		The precision of the measurement results	N	N
A.2.11	Q. Is the medical device interpretative? A. No.	Conclusions are presented by the medical device from input data,	N	N
		Conclusions are presented by the medical device from acquired data	N	N
		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?		Y	N
A.2.13	Q. Are there unwanted outputs of energy or substances? A. No.	Noise	N	N
		Vibration,	N	N
		Heat,.	N	N
		Radiation	N	N
		Ionizing,	N	N
		Non-ionizing	N	N
		Ultraviolet	N	N
		Visible	N	N
		Infrared	N	N
		Contact temperatures	N	N
		Leakage currents	N	N
		Electric fields	N	N
		Magnetic fields	N	N
		Discharge of chemicals	N	N
		Discharge of waste products	N	N
		Discharge of body fluids.	N	N

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16

A.2.14	Q. Is the medical device susceptible to environmental influences? A. No.	Operational,	N	N
		Transport storage environments	N	N
		Light,	N	N
		Temperature,.	N	N
		Vibrations	N	N
		Spillage	N	N
		Susceptibility to variations in power	N	N
		Susceptibility of cooling supplies,	N	N
		Electromagnetic interference	N	N
A.2.15	Q. Does the medical device influence the environment? A. No.	The effects on power supplies	N	N
		The effects cooling supplies,	N	N
		Emission of toxic materials	N	N
		The generation of electromagnetic interference.	N	N
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? A. No.	Carried out by the operator	N	N
		Carried out by the user	N	N
		Carried out by a specialist.	N	N
		Are special substances necessary for proper maintenance and/or calibration?	N	N
		Is special equipment necessary for proper maintenance and/or calibration	N	N
A.2.18	Q. Does the medical device contain software? A.No.	Is software intended to be installed,	N	N
		Is software intended to be verified	N	N
		Is software intended to be modified	N	N
A.2.19	Q. Does the medical device have a restricted shelf-life? A. No.	Labeling	N	N
		Indicators	N	N
		The disposal of such medical devices	N	N
A.2.20	Q. Are there any delayed and/or long-term use effects?	Ergonomic	N	N

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16

	A. No.	Cumulative effects	N	N
A.2.21	Q. To what mechanical forces will the medical device be subjected? A. Negligible, in normal use.	Under the control of the user	N	N
		Controlled by interaction with other persons	N	N
A.2.22	Q. What determines the lifetime of the medical device? A. Clarity mainly and damage to plastics.	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? A. No.	Does it contain toxic material,	N	N
		Does it contain hazardous material	N	N
		Does it contain recyclable material	N	N
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? A. No.	Connections	N	N
		Connection force	N	N
		Feedback on connection integrity,	N	N
		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? A. No.	Mapping,	N	N
		Modes of feedback,	N	N
		Blunders,	N	N
		Slips,	N	N
		Control differentiation,	N	N
		Visibility,	N	N

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16

		Direction of activation or change,	N	N
		Are the controls continuous	N	N
		Are the controls discrete,	N	N
		The reversibility of settings or actions	N	N
A.2.27.3	Q. Does the medical device display information? A. No.	Visibility in various environments,	N	N
		Orientation,	N	N
		Populations and perspectives,	N	N
		The clarity of the presented information,	N	N
		Units,	N	N
		Colour coding,	N	N
		The accessibility of critical information	N	N
A.2.27.4	Q. Is the medical device controlled by a menu? A. No.	Complexity	N	N
		Number of layers,	N	N
		Awareness of state,.	N	N
		Location of settings	N	N
		Navigation method,	N	N
		Number of steps per action,	N	N
		Sequence	N	N
		Clarity and memorization problems,	N	N
		Importance of control function relative to its accessibility	N	N
A.2.28	Q. Is the medical device intended to be mobile or portable? A. Yes	Grips,	N	N
		Handles,	N	N
		Wheels,	N	N
		Brakes,.	N	N
		Mechanical stability	Y	N
		Mechanical durability	Y	N

Explanation 1 = Insignificant 2 = Significant 3 = Tolerable 4 = Risk calculated as product 1 - 16