

Risk Assessment

ECB LIMITED

INSTANTCRYO DEVICE

Document Reference: Risk Assessment.doc

Issue: 1

Date: [July 2021](#)

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1. Introduction

This risk assessment is compiled to assist in the safety compliance of the Instantcryo device.

The risk assessment process is an iterative process involving risk assessment and risk reduction, and shall include the following points:

- Determination of the limits of the product, including the intended use and any reasonably foreseeable misuse,
- Identification of the hazards that can be generated by the product and the associated hazardous situations,
- Estimation of the risks, taking into account the severity of the possible injury or damage to health and the probability of its occurrence,
- Evaluation of the risks, with a view to determining whether risk reduction is required, in accordance with the objectives of the Directive,
- Elimination of the hazards or reduction in the risks associated with these hazards by application of protective measures, in the order of priority as described in the 3 step method below.

The risk assessment process is shown in Figure 1.

Following the risk assessment, hazard elimination or risk reduction may be needed. This should be carried out in a 3 step process in the following order:

1. The hazard to be eliminated or the risk reduced by design or by the substitution through less hazardous materials and substances or by application of ergonomic principles.
2. The risk to be reduced by the application of safeguarding and complementary protective measures of a type that adequately reduces risk for the intended use and reasonably foreseeable misuse, and which are appropriate for the application.
3. When the application of safeguarding or complementary protective measures is not practicable or does not reduce the risk adequately, the information for use shall also include notice of any residual risk.

This information shall include but not be limited to

- a) operating procedures for the use of the machinery consistent with the expected ability of personnel who use the product or other persons who can be exposed to the hazards associated with the product,
- b) the recommended safe working practices for the use of the product and the related training requirements adequately described,
- c) sufficient information, including warning about residual risks for the different phases of the life of the product, and
- d) the description of any recommended personal protective equipment, including details as to the need for it, as well as of the training needed for its use.

2. Equipment

This risk assessment refers to the following machinery:

InstantCryo device

and includes the following variants and options:

Battery charger and uses liquid Carbon Dioxide (CO2) (CO2 Independently sourced by a regulated gas company)

3. Information

The following information has been used during the preparation of this risk assessment:

Manufacturer's experience in the design and construction of this type of device (years)	25 Years
The accidents known to the manufacturer are	None
There is a C-type transposed harmonised standard for the device	No
Other relevant standards (Also see TOC for other relevant standards)	See Declaration of Conformity

4. Expected Use and Limits of Use

The device is intended for the purpose of	Rapid cooling of the skin surface for mainly equestrian and human wellness uses
The foreseen misuse included and considered in design and instructions is	Use by persons who are not trained in its use and are not certified

The device is intended for use to process the following materials	To vaporize liquid carbon dioxide
The features of Material or workpieces e.g. maximum size / maximum weight	N/A
Mass and dimensions of machinery	L 25cm, W 10 cm d 4cm. Weight 780 grams / Hand held device
Maximum speed and travel in linear or rotational modes of machine or tools (each axis) or, maximum peripheral speed of rotating equipment.	N/A
The machinery is intended for use in an industrial environment that is:	Warm and dry, horse stabling, Clinics
The machinery requires the following services (ratings for electricity, air, etc.)	2 x 3.7v lithium ion battery pack, charged from mains electric 240v
The machinery is designed for a foreseen life of (years)	10 years
Skill or experience required for safe operation (see note 1)	Operator training is required for safe operation
Skill or experience required for installer / maintainer	Training is required for installer/maintainer
Are other (untrained) people exposed to risks from this machine e.g. general public, visitors	Untrained persons are not at risk from this device

Note 1: Prior to beginning work the first time, the operators are expected to have read and understood the safety section of the instructions that accompany the machinery, be familiar with the location and operation of each control, and have received appropriate training / competence assessment.

5. General safety rationale

EMC hazards are addressed by collating information to demonstrate that the device conforms to the Essential Requirements

Assessment of Hazardous Substances are addressed by conformance with BS EN IEC 63000:2018

6. Hazard Identification and Classification of Risk

Hazards should be assessed at all phases of the machine life i.e. construction, transportation, assembly, installation, commissioning, use, maintenance, dismantling & disposal. This may lead to a different risk rating for each activity. Risk is a function of the combination of the severity of injury, frequency of exposure and possibility of avoidance for a hazard.

A Risk Rating is calculated by multiplying: Severity of injury x Frequency of exposure x Possibility of avoidance using the following scoring system:

	Rating	Description	Score
Severity of injury	High	irreversible e.g. loss of limb, or fatality	3
	Medium	recoverable e.g. broken bone or deep cuts	2
SoI	Low	reversible, minor cuts and bruises	1
Frequency of exposure	High	frequent e.g. more than once every 10 minutes	3
	Medium	regularly e.g. once per hour	2
FoE	Low	infrequent e.g. once per week	1
Possibility of avoidance*	High	obvious and slow moving	1*
	Medium	can get out of the way with normal reactions	2*
PoA	Low	hazard not obvious and moving fast	3*

Risk Score	Risk Level	Risk Reduction
9-27	High	Risk reduction required
6-8	Medium	Risk reduction required
1-4	Low	Risk reduction if possible

* Note: The scoring for Possibility for avoidance is reversed from the other 2 categories.

I Risk	Measures taken to eliminate hazard or reduce risk	R Risk	Residual risks and warnings of residual risk
9-27	Measures taken to eliminate or reduce the original risk by design of equipment, such as guarding and speed limitation.	1-4	Describe residual risks after all practicable design measures have been taken and list of protective measures (operating procedures, labels, PPE warnings in manual) taken to allow those risks to be acceptable.
6-8	The measures taken should be evaluated to check if they have introduced any new hazards. The risk assessment process should be repeated until an acceptable risk level is achieved.	1-4	
1-4	For each hazard the objective is to get the residual rating (R Risk) to 4 or less . If the residual risk is higher than 4, then other actions such as procedural safeguards may be required. Even when the risk level is below 4, specific hazards may require warning labels / warnings in the manual.	1-4	

Risk reduction can be done by separately or simultaneously reducing each of the elements which determine the risk, SoI, FoE and PoA. Where access is not needed to the operational parts of the machine (general use) this might be achieved by guarding. Where access is required (e.g. setting) this might be achieved by setting limits such as a reduction in speed and hold-to-run operation.

No	EHSR	Hazard	Specific hazard, location and associated activity	S of I	F of E	P of A	IRisk	Measures taken to eliminate hazard or reduce risk	S of I	F of E	P of A	R Risk	Residual risks and warnings of residual risk
1		Battery charger	During use of CE marked charger	2	1	3	6	a) Must only use charger issued with the Device. b) The charger will supplied with the correct plug fitted for the country supplied to. c) Charger will accept 100-240v mains supply for various countries	1	1	2	2	Detailed on P25 of the Manual
2		Batteries	Replacing batteries	2	1	3	6	a) Batteries must only be replaced by trained personnel. b) Care must be taken to ensure batteries used are not damaged	1	1	2	2	Battery Safety detailed on P30 and P31 of the Manual
			Charging batteries	2	1	3	6	Charging must only be undertaken using the charger provided, no other charger may be used.	1	1	2	2	Warnings on P30 of the Manual
3		Carbon dioxide	Connection to the gas cylinder	2	1	3	6	a) There is an adaptor to be fitted to the gas cylinder. b) The Instantcryo hose, 'push and clicks' to fit safely to the adaptor, with push button release	1	1	2	2	Detailed on P19 and P20 of the Manual
			During use of the Device	2	1	3	6	a) The optimum distance from the treatment area is indicated by two visual laser points. b) A proximity sensor will show the optimum treatment distance and will stop the process when it is too close for user and patient safety. C) A high grade temperature sensor measures the surface temperature of the treatment area. Dual LED lights give a clear visual notification that the treatment area has reached the optimum range and the LED's turn from white light to blue light	1	1	2	2	Detailed P15 and P16 of the Manual

No	EHSR	Hazard	Specific hazard, location and associated activity	S of I	F of E	P of A	I Risk	Measures taken to eliminate hazard or reduce risk	S of I	F of E	P of A	R Risk	Residual risks and warnings of residual risk
			Safe use of carbon dioxide	3	1	3	9	a) Must only be used by certified trained personnel. b) The temperature sensor protects the treatment areas. c) Easy connection to the cylinder adaptor ensures safe supply. d) Safety warnings regarding condition of the treatment areas and never to spray onto eyes or open wound injuries	2	1	2	4	Noted on P5, P15, P19 and P30 of the Manual
4		Electromagnetic Compatibility Laser	At all working periods At all working periods	1 1	1 1	1 1	1 1	All information relating to EMC has been collated to ensure that the Device conforms to 2014/30/EU Component VL6180X has a Class1 laser which is safe at all times					
5		InstantCryo Device	At all working periods	3	2	3	18	a) The Device must only be used by certified trained personnel. b) Connection to the carbon dioxide is safe and secure c) The precision laser points give the optimum distance for safe use d) The temperature sensor accurately measures the treatment area e) The dual LED lights gives a clear visual notification, white light to blue light, when the optimum temperature is reached f) There is a section in the manual regarding the keypad functions g) There is a section in the manual regarding the use of the various nozzles h) There is a section for trouble shooting i) For transportation, there is a carry case for the hand device with a special foam insert, adapted to house the hand device ,charger and nozzles securely	1	2	1	2	The Manual is clear and concise and takes into account the general education and acumen that may be expected from trained personnel

No	EHSR	Hazard	Specific hazard, location and associated activity	S of I	F of E	P of A	I Risk	Measures taken to eliminate hazard or reduce risk	S of I	F of E	P of A	R Risk	Residual risks and warnings of residual risk