

Chapter 9 Protection against mechanical hazards from medical device equipment / systems

ID	Clause	Applicable	Traces to risk relevant items / Qualification / Comment
RIC 22	<p>9.2.1 Hazards associated with moving parts - General</p> <p>Demonstrate the assessment of risks associated with moving parts and if applicable how they are prevented from harming the operator/patient.</p> <p>This include assessing reasonably foreseeable misuse.</p>	Yes	<p>HZA 1 : User squeezes hand when reaching inside the device.</p> <p>File: UCC-564-331 Complexis Risk Assessment Document.docx</p>
RIC 23	<p>9.2.4 Emergency stopping devices</p> <p>Demonstrate how the emergency stop reduces risk to an acceptable level.</p> <p>Demonstrate how it is ensured that the emergency stop does not introduce any further hazards or interfere with the complete operation of necessary to remove the original hazard.</p>	No	There is no emergency stop.
RIC 24	<p>9.2.5 Release of patient</p> <p>Demonstrate how the restrained patient can be released quickly and safely in case of loss of power, emergency stop or breakdown of the device and, in general, situations where the patient is subjected to unacceptable risk.</p>	Yes	<p>HZA 2 : User cannot get released from harness.</p> <p>File: UCC-564-331 Complexis Risk Assessment Document.docx</p>
RIC 25	<p>9.5.1 Protective means of expelled parts</p> <p>Demonstrate the assessment of risks associated with expelled parts from the device.</p>	No	No parts can get expelled from device.
RIC 26	<p>9.6.2.2 Infrasound and ultrasound energy</p> <p>Demonstrate the risks associated with infrasound and ultrasound.</p>	To be assessed	

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