

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

ID	Clause	Applicable	Traces to risk relevant items / Qualification / Comment
RIC 22	9.2.1 Hazards associated with moving parts - General Demonstrate the assessment of risks associated with moving parts and if applicable how they are prevented from harming the operator/patient. This include assessing reasonably foreseeable misuse.	Yes	HZA 1 : User squeezes hand when reaching inside the device. File: UCC-564-331 Complexis Risk Assessment Document.docx
RIC 23	9.2.4 Emergency stopping devices Demonstrate how the emergency stop reduces risk to an acceptable level. 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.	No	There is no emergency stop.
RIC 24	9.2.5 Release of patient 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.	Yes	HZA 2 : User cannot get released from harness. File: UCC-564-331 Complexis Risk Assessment Document.docx
RIC 25	9.5.1 Protective means of expelled parts Demonstrate the assessment of risks associated with expelled parts from the device.	No	No parts can get expelled from device.
RIC 26	9.6.2.2 Infrasound and ultrasound energy Demonstrate the risks associated with infrasound and ultrasound.	To be assessed	

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Table of Contents Iec 60601 1 Checklist

1. Understanding the eBook Iec 60601 1 Checklist
 - The Rise of Digital Reading Iec 60601 1 Checklist
 - Advantages of eBooks Over Traditional Books
2. Identifying Iec 60601 1 Checklist
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Iec 60601 1 Checklist
 - User-Friendly Interface
4. Exploring eBook Recommendations from Iec 60601 1 Checklist
 - Personalized Recommendations
 - Iec 60601 1 Checklist User Reviews and Ratings
 - Iec 60601 1 Checklist and Bestseller Lists
5. Accessing Iec 60601 1 Checklist Free and Paid eBooks
 - Iec 60601 1 Checklist Public Domain eBooks
 - Iec 60601 1 Checklist eBook Subscription Services
 - Iec 60601 1 Checklist Budget-Friendly Options
6. Navigating Iec 60601 1 Checklist eBook Formats

-
- ePub, PDF, MOBI, and More
 - Iec 60601 1 Checklist Compatibility with Devices
 - Iec 60601 1 Checklist Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Iec 60601 1 Checklist
 - Highlighting and Note-Taking Iec 60601 1 Checklist
 - Interactive Elements Iec 60601 1 Checklist
 8. Staying Engaged with Iec 60601 1 Checklist
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Iec 60601 1 Checklist
 9. Balancing eBooks and Physical Books Iec 60601 1 Checklist
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Iec 60601 1 Checklist
 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
 11. Cultivating a Reading Routine Iec 60601 1 Checklist
 - Setting Reading Goals Iec 60601 1 Checklist
 - Carving Out Dedicated Reading Time
 12. Sourcing Reliable Information of Iec 60601 1 Checklist
 - Fact-Checking eBook Content of Iec 60601 1 Checklist
 - Distinguishing Credible Sources
 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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