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Standard Guide for Hazards for Consideration when Designing Exoskeletons[1]

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1. Scope

1.1 This guide lists typical hazards that should be considered by exoskeleton producers when analyzing and managing potential risks related to exoskeletons.

1.2 Where possible, this guide provides references to agency standards, regulations, or guidelines for assessment of risks related to these hazards and for application of risk reduction measures.

1.3 This guide applies to all exoskeleton types, regardless of the applications of the technology such as consumer, industrial, medical, military, and emergency management services.

1.4 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

C1055 Guide for Heated System Surface Conditions that Produce Contact Burn Injuries

C1057 Practice for Determination of Skin Contact Temperature from Heated Surfaces Using a Mathematical Model and Thermesthesiometer

D1230 Test Method for Flammability of Apparel Textiles

F2808 Test Method for Performing Behind-the-Knee (BTK) Test for Evaluating Skin Irritation Response to Products and Materials That Come Into Repeated or Extended Contact with Skin

F3323 Terminology for Exoskeletons and Exosuits

F3392 Practice for Exoskeleton Wearing, Care, and Maintenance Instructions

F3427 Practice for Documenting Environmental Conditions for Utilization with Exoskeleton Test Methods

F3474 Practice for Establishing Exoskeleton Functional Ergonomic Parameters and Test Metrics

2.2 *ANSI Standards:*[3]

ANSI/ASA S2.70 Guide for the Measurement and Evaluation of Human Exposure to Vibration Transmitted to the Hand

ANSI C18.2M Part 2 American National Standard for Portable Nickel Rechargeable Cells and Batteries – Safety Standard

ANSI C63.4-2014 American National Standard for Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz

ANSI Z535.4 Product Safety Signs and Labels

2.3 *BSI Standards:*[4]

BS EN 13921 Personal protective equipment. Ergonomic principles

EN 50581:2012 Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

2.4 *CEN Standards:*[5]

CR 1030-1 Hand-arm Vibration – Guidelines for Vibration Hazards Reduction – Part 1: Engineering Methods by Design of Machinery

2.5 *IEC Standards:*[6]

IEC 60529 Degrees of protection provided by enclosures (IP Code)

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] Available from British Standards Institution (BSI), 389 Chiswick High Rd., London W4 4AL, U.K., http://www.bsigroup.com.

[5] Available from European Committee for Standardization (CEN), Avenue Marnix 17, B-1000, Brussels, Belgium, http://www.cen.eu.

[6] Available from International Electrotechnical Commission (IEC), 3, rue de Varembé, 1st floor, P.O. Box 131, CH-1211, Geneva 20, Switzerland, https://www.iec.ch.

IEC 60601 Series of technical standards for the safety and essential performance of medical electrical equipment
IEC 60825-1 Safety of Laser Products - Part 1: Equipment classification and requirements
IEC 61000-1-2 Electromagnetic Compatibility (EMC) – Part 1-2: General – Methodology for the Achievement of Functional Safety of Electrical and Electronic Systems including Equipment with Regard to Electromagnetic Phenomena
IEC 61000-6-1 Electromagnetic Compatibility (EMC) – Part 6-1: Generic Standards – Immunity Standard for Residential, Commercial and Light-industrial Environments
IEC 61000-6-2 Electromagnetic Compatibility (EMC) – Part 6-2: Generic Standards – Immunity Standard for Industrial Environments
IEC 61000-6-3 Electromagnetic Compatibility (EMC) – Part 6-3: Generic Standards – Emission standard for equipment in residential environments
IEC 61000-6-4 Electromagnetic Compatibility (EMC) – Part 6-4: Generic Standards – Emission Standard for Industrial Environments
IEC 61032 Protection of Persons and Equipment by Enclosures – Probes for Verification
IEC 61508 Functional safety of electrical/electronic/programmable electronic safety-related systems
IEC 62061 Safety of Machinery – Functional safety of safety-related control systems
IEC 62133-2 Secondary Cells and Batteries Containing Alkaline or Other Non-Acid Electrolytes – Safety Requirements for Portable Sealed Secondary Lithium Cells, And for Batteries Made from Them, For Use in Portable Applications – Part 2: Lithium Systems
IEC 62366-1 Medical devices – Part 1: Application of Usability Engineering to Medical Devices
IEC 62471 Photobiological Safety of Lamps and Lamp Systems
IEC 63000:2018 Technical Documentation for the Assessment of Electrical and Electronic Products with Respect to the Restriction of Hazardous Substances
IEC 80601-2-78 Medical electrical equipment — Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation

2.6 *ISO Standards:*[3]

ISO 447 Machine Tools – Direction of Operation of Controls
ISO 1996-1 Acoustics – Description, Measurement, and Assessment of Environmental Noise – Part 1: Basic Quantities and Assessment Procedures
ISO 2919 Radiological Protection – Sealed Radioactive Sources – General Requirements and Classification
ISO 3740 Acoustics – Determination of Sound Power Levels of Noise Sources – Guidelines for the Use of Basic Standards
ISO 3864-2 Graphical Symbols – Safety Colours and Safety Signs – Part 2: Design principles for product safety labels
ISO 3925 Unsealed Radioactive Substances – Identification and Documentation
ISO 4413 Hydraulic fluid power — General rules and safety requirements for systems and their components
ISO 4414 Pneumatic fluid power — General rules and safety requirements for systems and their components
ISO 5349-5 Mechanical vibration and shock-evaluation of human exposure to whole body vibration - Part 5: Method for evaluation of vibration containing multiple shocks
ISO 6385 Ergonomics Principles in the Design of Work Systems
ISO 7000 / IEC 60417 Graphical Symbols for Use on Equipment
ISO 7212 Enclosures for Protection Against Ionizing Radiation – Lead Shielding Units for 50 mm and 100 mm Thick Walls
ISO 8041-1 Human Response to Vibration – Measuring Instrumentation – Part 1: General Purpose Vibration Meters
ISO 9241 Series of Ergonomic Requirements for Office Work with Visual Display Terminals
ISO 9355-1 Ergonomic Requirements for the Design of Displays and Control Actuators – Part 1: Human Interactions with Displays and Control Actuators
ISO 9355-3 Ergonomic Requirements for the Design of Displays and Control Actuators – Part 3: Control Actuators
ISO 9886 Ergonomics – Evaluation of Thermal Strain by Physiological Measurements
ISO 10551 Ergonomics of the Physical Environment – Subjective Judgement Scales for Assessing Physical Environments
ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and skin sensitization
ISO 11200 Acoustics – Noise Emitted by Machinery and Equipment – Guidelines for the Use of Basic Standards for the Determination of Emission Sound Pressure Levels at a Workstation and at Other Specified Positions
ISO 12100 Safety Of Machinery – General Principles For Design – Risk Assessment And Risk Reduction
ISO 13482 Robots and robotic devices – Safety requirements for personal care robots
ISO 13732-1 Ergonomics of the Thermal Environment — Methods for the Assessment of Human Responses to Contact with Surfaces — Part 1: Hot Surfaces
ISO 13732-3 Ergonomics of the Thermal Environment — Methods for the Assessment of Human Responses to Contact with Surfaces — Part 3: Cold Surfaces
ISO 13849-1 Safety of machinery – Safety-related Parts of Control Systems – Part 1: General Principles for Design
ISO 13854 Safety of machinery – Minimum Gaps to Avoid Crushing of Parts of the Human Body
ISO 13857 Safety of Machinery – Safety Distances to Prevent Hazard Zones being Reached by Upper and Lower Limbs
ISO 14123-1 Safety of Machinery — Reduction of Risks to Health Resulting from Hazardous Substances Emitted by

Machinery — Part 1: Principles and Specifications for Machinery Manufacturers
ISO 14152 Neutron Radiation Protection Shielding – Design Principles and Considerations for the Choice of Appropriate Materials
ISO 14159 Safety of Machinery – Hygiene Requirements for the Design of Machinery
ISO 14971 Medical devices — Application of risk management to medical devices
ISO 15537 Principles for Selecting and Using Test Persons for Testing Anthropometric Aspects of Industrial Products and Designs
ISO 15667 Acoustics – Guidelines for Noise Control by Enclosures and Cabins
ISO 19353 Safety of Machinery – Fire Prevention and Protection
ISO 22523 External limb prostheses and external orthoses — Requirements and test methods
ISO 26262 Road Vehicles – Functional Safety
ISO 31000 Risk management — Guidelines
ISO/AWI 2631-1 Mechanical Vibration and Shock – Evaluation of Human Exposure to Whole-body Vibration – Part 1: General Requirements
ISO/DIS 13482 Robots and robotic devices — Safety requirements for non-industrial robots — Non-medical personal care robot
ISO/IEC Guide 51 Safety aspects — Guidelines for their inclusion in standards
ISO/IEC 27000 Series of Information Technology – Security Techniques
ISO/PAS 21448 Road Vehicles - Safety of The Intended Functionality
ISO/TR 11688-1 Acoustics. Recommended Practice for the Design of Low-Noise Machinery and Equipment. Introduction to the Physics of Low-Noise Design
ISO/TS 13732-2 Ergonomics of the Thermal Environment — Methods for the Assessment of Human Responses to Contact with Surfaces — Part 2: Human Contact with Surfaces at Moderate Temperature
ISO/TS 15066 Robots and Robotic Devices – Collaborative Robots
ISO/TS 15666 Acoustics – Assessment of Noise Annoyance by Means of Social and Socio-Acoustic Surveys

2.7 *NFPA Standards:*[7]
NFPA 70 National Electrical Code
NFPA 701 Standard Methods of Fire Tests for Flame Propagation of Textiles and Films

2.8 *OSHA Standards:*[8]
OSHA 29 CFR 1910.95 Occupational Noise Exposure
OSHA 29 CFR 1910.147 The Control of Hazardous Energy (Lockout/tagout)
OSHA 29 CFR 1910.331-335 Occupational Safety and Health Standards – Electrical
OSHA 1910.242(b) Hand and Portable Powered Tools and Equipment, General

2.9 *UL Standards:*[9]
UL 94 Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
UL 508A Industrial Control Panels
UL 991 Standard for Tests for Safety-Related Control Employing Solid-State Devices
UL 2054 Standard for Household and Commercial Batteries

2.10 *Federal Regulations:*[10]
49 CFR § 571.101 Standard No. 101 Controls and Displays
49 CFR § 571.118 Standard No. 118 Power-Operated Window, Partition, and Roof panel systems
FCC CFR 47 Part 15, Subpart B Radiated Emissions and Conducted Emissions (Sections 15.107 and 15.109)

2.11 *Military Standards:*[11]
MIL-HDBK-310 Global Climatic Data for Developing Military Products
MIL-STD 810 Environmental Engineering Considerations and Laboratory Tests
MIL-STD-1246 Military Standard: Product Cleanliness Levels Contamination Control Program
MIL-STD-1472 Department of Defense Design Criteria Standard: Human Engineering

3. Terminology

3.1 Many terms used within this document are defined as in Terminology F3323. The following terms and definitions are used within this document and are not defined within Terminology F3323.

3.2 *Definitions:*

3.2.1 *harm scenario, n*—circumstance in which people, property or the environment is/are exposed to one or more hazards.

3.2.1.1 *Discussion*—Equivalent to "hazardous situation" defined in ISO/IEC Guide 51.

3.2.2 *injury, acute, n*—an injury that is obvious and has immediate impact on a person's general health and well-being.

3.2.3 *injury, chronic, n*—an injury having a hidden, cumulative or long term impact on a person's general health and well-being.

3.2.3.1 *Discussion*—Equivalent to "cumulative trauma injury" and "repetitive trauma injury."

3.2.4 *possible harm, n*—injuries that could result from encountering a hazard presented in harm scenario.

ISO/IEC Guide 51

3.2.5 *producer, n*—natural or legal person with responsibility for the design, manufacture, assembly, packaging, or labeling of an exoskeleton, or adapting an exoskeleton before it is placed on the market or put into service, regardless of

[7] Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169-7471, http://www.nfpa.org.
[8] Available from Occupational Safety and Health Administration (OSHA), 200 Constitution Ave., NW, Washington, DC 20210, http://www.osha.gov.
[9] Available from Underwriters Laboratories (UL), UL Headquarters, 333 Pfingsten Road, Northbrook, IL, 60062, http://www.ul.com.
[10] Available from U.S. Government Publishing Office (GPO), 732 N. Capitol St., NW, Washington, DC 20401, http://www.gpo.gov.
[11] Available from IHS, 15 Inverness Way East, Englewood, CO 80112, http://www.global.ihs.com.

whether these operations are carried out by that person or on that person's behalf by a third party.

3.2.5.1 *Discussion*—Legal person refers to a human or non-human entity that is treated as a person for limited legal purposes.

3.2.6 *risk, n*—combination of the probability of occurrence of harm and the severity of that harm. **ISO/IEC Guide 51**

3.2.6.1 *Discussion*—The probability of occurrence includes the exposure to a hazardous situation, the occurrence of a hazardous event and the possibility to avoid or limit the harm.

3.2.7 *risk analysis, n*—systematic use of available information to identify hazards and to estimate the risk. **ISO/IEC Guide 51**

3.2.8 *risk assessment, n*—overall process comprising a risk analysis and a risk evaluation. **ISO/IEC Guide 51**

3.2.9 *risk evaluation, n*—procedure based on the risk analysis to determine whether tolerable risk has been exceeded. **ISO/IEC Guide 51**

3.2.10 *risk reduction measures, n*—action or means to eliminate hazards or reduce risks. **ISO/IEC Guide 51**

3.2.10.1 *Discussion*—Equivalent to protective measure.

3.2.10.2 *Discussion*—Examples of risk reduction measures are: inherently safe design; protective devices; personal protective equipment; information for use and installation; organization of work; training; application of equipment; supervision.

4. Significance and Use

4.1 Development of exoskeleton technologies requires careful analysis of potential risks that may be associated with their use. Failure to adequately assess risks may give rise to hazardous situations at many instances of exoskeleton use, for example during completion of human trials, during exoskeleton demonstrations in trade shows, as well as during exoskeleton training, wear, operation, transportation, maintenance, and disposal.

4.2 This guide provides a minimum set of hazards that should be considered by producers when analyzing and mitigating risks related to exoskeletons. This set of hazards should be supplemented with other hazards that may reflect unique safety concerns relevant to the exoskeleton technology and application. The following sources may provide additional insight based on exoskeleton technology and application:

4.2.1 IEC 60601 series;

4.2.2 IEC 80601-2-78;

4.2.3 ISO/DIS 13482;

4.2.4 Product standards established by military agencies (examples are NATO standards and United States Military Standards).

4.3 For each listed hazard, one example of harm scenario and examples of possible harm are provided. These examples are used to illustrate potential safety consequences related to such hazards. They do not reflect a comprehensive list of all possible acute or chronic injuries that may result from exoskeleton use. Additionally, although this guide does not address hazards that may result in damage of objects, these should be considered as well during the risk analysis process.

4.4 This guide does not provide detailed guidance for application of risk management processes to exoskeletons. However, the producer should use a structured approach to identify and monitor hazards, and mitigate related risks throughout the exoskeleton life-cycle. Additional guidance on risk management can be found in the following standards:

4.4.1 ISO 31000;

4.4.2 ISO 14971.

4.5 This guide does not supersede any established laws or regulations of international, national, federal, state, tribal, local, or regional governments.

5. General

5.1 Sections 6 – 20 list hazards that are typical to exoskeletons. Harm scenarios and possible harm examples are provided. These examples are not all inclusive, only one example is provided for each hazard. Where possible, this guide references common agency standards, regulations, and guidelines that provide greater detail for definition, measurement, assessment, and reduction of risks associated with these hazards. Table 1 illustrates the allocation of hazards in the sections of this guide.

6. Moving Parts

6.1 Exoskeletons typically comprise many moving parts, such as pivots, rotating elements, and cables which can pose a risk of minor to severe injuries to the exoskeleton user and personnel in proximity to the user. Hazards related to moving parts are listed.

6.2 *Pinching:*

6.2.1 *Harm Scenario*—Exoskeleton pivots are not safeguarded against access by body parts, for example, hands, and create a pinch point during operation.

6.2.2 *Possible Harm*—Abrasion, blunt trauma, laceration, traumatic amputation.

6.2.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

6.2.3.1 ISO 13854;

6.2.3.2 IEC 61032;

6.2.3.3 ISO 13857;

6.2.3.4 49 CFR § 571.118.

6.3 *Rubbing:*

6.3.1 *Harm Scenario*—Movement of exoskeleton parts induce friction between the device and user.

6.3.2 *Possible Harm*—Abrasion, heat burn.

6.4 *Entanglement:*

6.4.1 *Harm Scenario*—Unsecured cabling or similar exoskeleton tethers restricts movement or causes a fall, resulting in user entanglement within the cabling.

6.4.2 *Possible Harm*—Strangulation, laceration, blunt impact.

6.5 *Hazardous Acceleration and Deceleration of Parts:*

6.5.1 *Harm Scenario*—Exoskeleton design requires user to apply excessive force or effort to control movements resulting in strain on body joints.

TABLE 1 Summary of Sections and Listed Hazards

No.	Section Name	Listed Hazards
6	Moving Parts	Pinching, rubbing, entanglement and acceleration
7	Ergonomic Parameters	Hazardous kinematic and kinetic patterns, body posture and fit, obstruction of vision, smell, tactile senses, hearing, and proprioceptive response
8	Surface Finishes	Rough or sharp edges, surfaces, and projections
9	Mechanical Failure	Fastener failure, stress, fatigue, and corrosion
10	Noise and Vibration Emissions	Hazardous noise and vibration
11	Thermal Emissions	Hot or cold surfaces, liquids or gases, and fire
12	Stored Potential Energy	Springs and elastic elements Pressurized gas or liquids
13	Stored Electrical Energy	Battery failure, capacitor failure, electrical failure (fire), arcing, exposed conductors, short circuits, loss of power, electrostatic discharge
14	Chemical and Biological Agents	Hazardous substances and fluids, infectious diseases, and related biohazards
15	Control Systems	Erroneous mode activation, misunderstanding of system labels, unintentional access to controls, incorrect functionality, excessive torque, inappropriate output, loss of function, control system error, failure of emergency stop function, and system hacking
16	Gravity and Inertia	Entrapment, inertial loading, shock loading, mass distribution, fit instability, and pressure
17	Physical Environment	Collisions with objects and living beings, entrapment, and functional degradation
18	Emergencies	Emergency exoskeleton doffing and building evacuation
19	Clothing and Personal Protective Equipment (PPE)	Inability to wear and incompatibility with PPE
20	Radiation	Non-ionizing and ionizing radiation

6.5.2 *Possible Harm*—Musculoskeletal injuries.

7. Ergonomic Parameters

7.1 Ergonomic design relates to the exoskeleton fitting the needs and abilities of the user, allowing the user to operate the exoskeleton and adapt the exoskeleton function for a given task. Natural human kinematics and kinetics should inform exoskeleton kinematic and kinetic patterns. Modifications to the user's kinematics or kinetics may lead to accidents or injuries. Anthropometric data of the target user population should inform the size, shape, form, and strength of the exoskeleton, to reduce the likelihood of inappropriate interaction between exoskeleton and user, and consequently, risk of injury. Obstruction of any senses (vision, hearing, proprioception, tactile sense, smell, and taste) may lead to accidents. Body coverage and heat emissions may have negligible to severe effects on the user's thermoregulation.

7.2 *Hazardous Kinematic and Kinetic Patterns:*

7.2.1 *Harm Scenario*—Insufficient degrees of freedom in exoskeleton kinematic chain imposes awkward movement patterns.

7.2.2 *Possible Harm*—Musculoskeletal injury.

7.2.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.2.3.1 Practice F3474.

7.3 *Hazardous Body Posture:*

7.3.1 *Harm Scenario*—Volume of exoskeleton parts causes user to adopt a particular and unusual posture to complete a drilling task, resulting in dust falling in user's eyes.

7.3.2 *Possible Harm*—Temporary or permanent eye injury.

7.3.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.3.3.1 Practice F3474;

7.3.3.2 MIL-STD-1472.

7.4 *Hazardous Fit:*

7.4.1 *Harm Scenario*—Poor alignment or incorrect orientation of joints, such as exoskeleton joint axis of rotation misaligned with anatomical joint axis of rotation, causing strain to user's joints.

7.4.2 *Possible Harm*—Musculoskeletal injury.

7.4.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.4.3.1 ISO 15537.

7.5 *Obstruction of Vision:*

7.5.1 *Harm Scenario*—Inability to see or avoid approaching hazard or to identify emergency signal in a timely manner, resulting in a fall.

7.5.2 *Possible Harm*—Blunt trauma, fracture.

7.5.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.5.3.1 MIL-STD-1472.

7.6 *Obstruction of Smell:*

7.6.1 *Harm Scenario*—Product odor masks environmental odor related to emergency, for example, gas leakage, burning material, resulting in failure to avoid or evacuate dangerous environment.

7.6.2 *Possible Harm*—Chemical burn, heat burn.

7.7 *Impairment of Tactile Senses:*

7.7.1 *Harm Scenario*—Numbness in hands or feet caused by fitment or contact with product preventing user from identifying pain signals.

7.7.2 *Possible Harm*—Blunt trauma, laceration.

7.8 *Obstruction of Hearing:*

7.8.1 *Harm Scenario*—Product noise masks environmental sounds related to emergency, for example, gas leakage, burning material, resulting in failure to avoid or evacuate dangerous environment.

7.8.2 *Possible Harm*—Chemical burn, heat burn.

7.8.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.8.3.1 MIL-STD-1472;

7.8.3.2 ISO/TR 11688-1.

7.9 *Hazardous Proprioceptive Response:*

7.9.1 *Harm Scenario*—Inability to sense self-movement and body position, resulting in collision with environment or fall.

7.9.2 *Possible Harm*—Blunt trauma, fracture.

7.10 *Heat Stress:*

7.10.1 *Harm Scenario*—Hot environment resulting in elevated body core temperature of user.

7.10.2 *Possible Harm*—Heat-related illness (heat exhaustion, stroke).

7.10.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

7.10.3.1 ISO 9886;

7.10.3.2 ISO 10551;

7.10.3.3 MIL-HDBK-310.

8. Surface Finishes

8.1 Inadequate exoskeleton surface finishes, including inner surface (in contact with the user) and outer surfaces may injure the user, maintenance personnel or personnel in proximity to the exoskeleton. Hazards related to surface finish are listed.

8.2 *Rough or Sharp Edges, Surfaces, and Projections:*

8.2.1 *Harm Scenario*—Metal component with an exposed sharp edge cuts exposed skin during normal operation or maintenance.

8.2.2 *Possible Harm*—Abrasion, laceration.

9. Mechanical Failure

9.1 Exoskeleton use may become a hazard if it is not ruggedized for the use scenario and duration. Mechanical failure modes are fastener failure, over-stress, over-fatigue, and corrosion-induced failure. Hazards related to mechanical failure are listed.

9.2 *Fastener Failure:*

9.2.1 *Harm Scenario*—A fastener nut, when not secured properly, could result in disassembly during exoskeleton use, causing loss of function or fall.

9.2.2 *Possible Harm*—Blunt trauma, fracture, musculoskeletal injury.

9.3 *Over-Stress:*

9.3.1 *Harm Scenario*—Inadequate design factor of safety results in exoskeleton joint assembly failure under load, causing loss of function or fall.

9.3.2 *Possible Harm*—Blunt trauma, fracture, musculoskeletal injury.

9.3.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

9.3.3.1 ISO 22523.

9.4 *Over-Fatigue:*

9.4.1 *Harm Scenario*—Cyclical loading of exoskeleton components results in failure, for example, bearing failure, and causes loss of function or fall.

9.4.2 *Possible Harm*—Blunt trauma, fracture, musculoskeletal injury.

9.4.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

9.4.3.1 ISO 22523.

9.5 *Corrosion:*

9.5.1 *Harm Scenario*—Corrosion of exoskeleton material results in fastener or part failure, causing loss of function or fall.

9.5.2 *Possible Harm*—Blunt trauma, fracture, musculoskeletal injury.

10. Noise and Vibration Emissions

10.1 Any exoskeleton has a certain mass, which may substantially increase not only static loads on the whole body or body segments, or combinations thereof, but also their dynamic loads, especially when the exoskeleton user is exposed to vibration. In addition, exoskeletons may produce noise and vibration, and active exoskeletons are likely to emit higher levels of both. Body exposure to vibration is a risk factor for musculoskeletal degenerative diseases. Vibration-related health risks are dependent on vibration magnitude, direction, frequency, exposure duration, and exposed body part. Exposure to high levels of noise may result in immediate hearing injury, while prolonged exposure to medium and low-level noise may result in degenerative hearing loss, high blood pressure, anxiety, and depression. Both vibration and noise may also cause user discomfort, stress, sleep disorders, poor concentration, and inattention, leading to accidents. Hazards related to vibration and noises are listed.

10.2 *Hazardous Noise:*

10.2.1 *Harm Scenario*—Exoskeleton user is exposed to loud or high frequency noise emitted from electronics for extended periods.

10.2.2 *Possible Harm*—Hearing loss, psychological trauma.

10.2.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

10.2.3.1 ISO 3740;

10.2.3.2 ISO 11200;

10.2.3.3 ISO/TS 15666;

10.2.3.4 ISO 1996-1;

10.2.3.5 ISO 15667;

10.2.3.6 OSHA 29 CFR 1910.95.

10.3 *Hazardous Vibration:*

10.3.1 *Harm Scenario*—Exoskeleton user is exposed to excessive limb or whole-body vibration for extended periods.

10.3.2 *Possible Harm*—Neural damage, musculoskeletal injury, psychological trauma.

10.3.3 *Major Agency Standards*—Relevant major standards and guidelines are listed for use, if applicable.

10.3.3.1 ISO 5349-5;

10.3.3.2 ANSI/ASA S2.70;

10.3.3.3 Directive 2002/44/EC of the European Parliament and of the Council of 25 June 2002 (**1**).[12]

10.3.4 *Auxiliary Agency Standards*—Additional relevant standards and guidelines are listed for use, if applicable.

10.3.4.1 ISO/AWI 2631-1;

10.3.4.2 ISO 8041-1;

10.3.4.3 ISO 5349-1;

10.3.4.4 CR 1030-1;

10.3.4.5 ACGIH – Hand-Arm Vibration: TLV Physical Agents Documentation (**2**);

10.3.4.6 ACGIH – Whole-Body Vibration: TLV Physical Agents Documentation (**3**).

10.3.5 *Cautions in the Application of Standards and Guidelines*—The exposure limits and action values specified in these standards or regulations should be used with cautions for the following reasons:

10.3.5.1 The additional mass of an exoskeleton on the body was not considered when the standards and guidelines were developed.

10.3.5.2 The vibration exposures considered in these standards and guidelines are primarily input to the human body through hands, seats, or feet, or combinations thereof. The vibrations generated by the exoskeletons may be transmitted to the body at some other locations and they may cause different effects.

11. Thermal Emissions

11.1 Active exoskeletons may comprise parts that heat up or cool down for proper function, such as motors and actuators. Storage and use environment can also heat or cool exoskeleton surfaces. Direct or indirect contact with hot and cold surfaces can cause minor to severe burns to the user and personnel in proximity depending on the surface temperature, surface composition, and contact duration. Exoskeletons may function with hot or cold gases or liquids. Gases and liquids may be emitted for proper functioning of exoskeletons, accidentally through damage, for example, leaking valve, or from a safety device, for example, relief valve. These gases and liquids may be emitted under pressure, increasing the likelihood of burns. Exoskeletons may comprise flammable materials, which can catch on fire and cause burns. Hazards related to thermal emission are listed.

11.2 *Hot and Cold Surfaces:*

11.2.1 *Harm Scenario*—Exposed skin comes into direct contact with extremely hot or cold surface.

11.2.2 *Possible Harm*—Heat burn, frostbite, hypothermia.

11.2.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

11.2.3.1 Practice C1057;

11.2.3.2 Guide C1055;

11.2.3.3 ISO 13732-1;

11.2.3.4 ISO/TS 13732-2;

11.2.3.5 ISO 13732-3.

11.3 *Hot and Cold Liquids and Gases:*

11.3.1 *Harm Scenario*—Hot liquid or gas is released during maintenance and contacts the skin of a technician.

11.3.2 *Possible Harm*—Chemical burn.

11.3.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

11.3.3.1 ISO 14123-1.

11.4 *Flammable Materials:*

11.4.1 *Harm Scenario*—Textile or coating ignites in the presence of a nearby flame.

11.4.2 *Possible Harm*—Heat burn.

11.4.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

11.4.3.1 UL 94;

11.4.3.2 Test Method D1230;

11.4.3.3 NFPA 701.

12. Stored Potential Energy

12.1 Exoskeletons may be designed with spring or elastic components, designed to store energy, and release it to provide additional torque to the user's joints. Exoskeletons may be designed with pneumatic or hydraulic systems, with potential energy stored in form of pressurized gas or liquid. The potential energy stored in such components may present a risk if released unintentionally. Hazards related to stored potential energy are listed.

12.2 *Springs and Elastic Elements:*

12.2.1 *Harm Scenario*—A spring-loaded component releases during normal operation or maintenance, causing exoskeleton parts to impact the user or a technician.

12.2.2 *Possible Harm*—Blunt impact, eye injury, laceration, traumatic amputation.

12.3 *Pressurized Gas or Liquid:*

12.3.1 *Harm Scenario*—Gas or liquid under pressure is released from a pressurized line because of a punctured conduit and contacts the eyes of a technician or of the exoskeleton user.

12.3.2 *Possible Harm*—Eye injury, abrasion.

12.3.3 *Agency Standards*—Relevant standards and guidelines are listed for use, if applicable.

12.3.3.1 ISO 14123-1;

12.3.3.2 OSHA 1910.242(b);

12.3.3.3 ISO 4414;

12.3.3.4 ISO 4413.

13. Stored Electrical Energy

13.1 Stored electrical energy may present a hazard if accidentally released due to failures of an exoskeleton electrical system. Hazards related to electrical safety are listed.

13.2 *Battery Failure:*

[12] The boldface numbers in parentheses refer to a list of references at the end of this standard.