



Designation: F3540 – 21

Standard Guide for Hazards for Consideration when Designing Exoskeletons¹

This standard is issued under the fixed designation F3540; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reappraisal. A superscript epsilon (ε) indicates an editorial change since the last revision or reappraisal.

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)

¹ This guide is under the jurisdiction of ASTM Committee F48 on Exoskeletons and Exosuits and is the direct responsibility of Subcommittee F48.02 on Human Factors and Ergonomics.

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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 Varembe, 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