



Designation: F3527 – 21

Standard Guide for Assessing Risks Related to Implementation of Exoskeletons in Task-Specific Environments¹

This standard is issued under the fixed designation F3527; 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 reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 When implementing exoskeletons in real-world work environments, exoskeleton interaction with various components of a given task and its environment can generate a number of risks. This guide provides guidance for conducting contextual risk assessment. A working document is provided in **Appendix X1** to allow initiation of the risk assessment process. It can be used to describe tasks, break the tasks down into task elements, anticipate related harm scenarios (a series of typical harm scenarios are provided), assess related risks, and detect scenarios that may require further analysis or implementation of risk reduction measures.

1.2 This guide applies to exoskeletons administered by employers to paid workers or professionals to support work-related tasks and activities.

1.3 This guide addresses risks that may result in acute and observable injury and harm. This guide does not address the following topics and concerns related to exoskeleton use:

1.3.1 Assessment and prevention of risk factors that can lead to chronic, cumulative, or long-term injuries;

1.3.2 Use of exoskeletons to support rehabilitation and return to work;

1.3.3 Risks related to storage and use of personal information;

1.3.4 Risks that may result in damage of objects; and

1.3.5 Financial risks.

1.4 **Units**—The values stated in SI units are to be regarded as the 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 standard-*

ization 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

F3323 Terminology for Exoskeletons and Exosuits

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

F3444/F3444M Practice for Training Exoskeleton Users

2.2 Other Standards:

EN 13921 Personal Protective Equipment - Ergonomic Principles³

ISO/IEC Guide 51 Safety aspects — Guidelines for their inclusion in standards⁴

ISO 31000 Risk Management — Guideline⁴

ISO 14971 Medical Devices — Application of Risk Management to Medical Devices⁴

3. Terminology

3.1 Many terms used within this guide are defined as in Terminology **F3323** – 20. The following terms and definitions are used within this guide and are not defined within Terminology **F3323** – 20.

3.2 Definitions:

3.2.1 **harm, n**—injury or damage to the health of people, or damage to property or the environment. **ISO/IEC Guide 51**

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

3.2.2.1 **Discussion**—Equivalent to “hazardous situation” defined in ISO/IEC Guide 51.

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

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

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.

Current edition approved Sept. 1, 2021. Published October 2021. DOI: 10.1520/F3527-21.

3.2.3 *implementer*, *n*—natural or legal person responsible for purchase, administration and/or implementation of exoskeletons in task-specific environments.

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

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

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

3.2.5 *residual risk*, *n*—risk remaining after risk reduction measures have been implemented.

Adapted from ISO/IEC Guide 51:2014

3.2.6 *risk*, *n*—combination of the probability of occurrence of harm and the severity of that harm.

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 (definition and discussion adapted from ISO/IEC Guide 51:2014).

3.2.7 *risk analysis*, *n*—systematic use of available information to identify hazards and to estimate the risk.

Adapted from ISO/IEC Guide 51:2014

3.2.8 *risk assessment*, *n*—overall process comprising a risk analysis and a risk evaluation.

Adapted from ISO/IEC Guide 51:2014

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

Adapted from ISO/IEC Guide 51:2014

3.2.10 *risk reduction measure*, *n*—action or means to eliminate hazards or reduce risks.

Adapted from ISO/IEC Guide 51:2014

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, and supervision.

3.2.11 *safety*, *n*—freedom from risk which is not tolerable.

Adapted from ISO/IEC Guide 51:2014

3.2.12 *task element*, *n*—a component or constituent of a task to describe a certain part or the entire entity of the task.

3.2.12.1 *Discussion*—Equivalent to task component.

3.2.13 *task-specific environment*, *n*—the overall context in which a task is executed.

3.2.13.1 *Discussion*—Equivalent to operating environment.

3.2.14 *tolerable risk*, *n*—level of risk that is accepted in a given context based on the current values of society.

Adapted from ISO/IEC Guide 51:2014

3.2.14.1 *Discussion*—Equivalent to acceptable risk.

3.2.14.2 *Discussion*—Opposite to unacceptable risk.

4. Significance and Use

4.1 There is evidence to support use of occupational exoskeletons to support work tasks and activities. It is recognized that organizations, job responsibilities, and working contexts vary widely. Additionally, a wide array of exoskeletons are becoming available on the market. Exoskeletons vary in terms of complexity, form and mass, body coverage, and function. Certification programs for occupational exoskeletons are not available at this time. As such, at the present time no mechanisms exist to guarantee that circumstantial risk evaluation was performed on exoskeletons or whether these evaluations reflect the real working context in which exoskeletons will be implemented.

4.2 This guide provides a minimum baseline for assessing risks that may arise from exoskeleton interaction with existing and task-specific environments. The working document presented in **Appendix X1** can be used to support decision making at different stages of exoskeleton implementation, such as:

4.2.1 *Purchase*—It can highlight safety concerns that may arise from introduction of a given exoskeleton technology in a specific work context;

4.2.2 *Implementation of Risk Reduction Measures*—It can highlight residual risks that require risk reduction measures;

4.2.3 *Detection of Unknowns*—It can lead to definition of additional steps that are needed to satisfy risk assessment for potentially hazardous situations;

4.2.4 *Risk Monitoring*—It can be used as a “living document” to monitor residual risks throughout the use period of the exoskeleton.

4.3 Harm scenarios described in this guide primarily reflect situations that may result in acute and observable injury or harm to a person. This guide is not suited for assessment of potential exoskeleton-to-task incompatibilities that may result in chronic, cumulative, or long-term injuries. However, these should be considered as part of any exoskeleton selection and implementation process. Guidelines on evaluation of risk factors that may lead to such injuries are currently under development and not yet published.

4.4 The user of this guide should evaluate the applicability of this guide for the given job context. The tool provided in **Appendix X1** can be used as presented, can be adapted to reflect additional safety concerns, or elements of it can be used to supplement risk assessment tools existing in the enterprise where an exoskeleton is implemented.

4.5 The questions, statements, and harm scenarios provided in **Appendix X1** are primarily targeted for assessment of risks that may endanger primary exoskeleton users. These can be modified to assess risks that may endanger secondary users, such as maintenance personnel, trainers, adjustment personnel, etc. It is recommended that risk assessment be conducted separately for each user type.

4.6 This guide can be used by non-specialized personnel to perform preliminary risk assessment, to aid, for example, pre-selection of exoskeleton models for purchase options. However, prior to implementing an exoskeleton in real-world