Designation: F3358 – 20

Standard Practice for Labeling and Information for Exoskeletons[1]

This standard is issued under the fixed designation F3358; 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 This practice sets forth labeling and instruction guidelines for manufacturers of exoskeletons.

1.2 The values stated in SI units are to be regarded as standard. The values given in parentheses are mathematical conversions to inch-pound units that are provided for information only and are not considered standard.

1.3 *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.*

1.4 *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]

F2727 Guide for Manufacturers for Labeling Headgear Products

F1301 Practice for Labeling Chemical Protective Clothing

F3392 Practice for Exoskeleton Wearing, Care, and Maintenance Instructions

2.2 *U.S. Code of Federal Regulations:*[3]

21 CFR 890.3480 Powered lower extremity exoskeleton

2.3 *Other Standards:*[4]

ISO 7000 / IEC 60417 Graphical symbols for use on equipment

3. Terminology

3.1 *Definitions:*

3.1.1 *accompanying literature, n*—printed material or electronic records that accompanies the product when it is sold or distributed.

3.1.2 *contact information, n*—information that allows a user to contact the manufacturer of the product, such as name, telephone number, and website address.

3.1.3 *date of manufacture, n*—uncoded month and four-digit year during which the exoskeleton was manufactured.

4. Significance and Use

4.1 This practice contains the recommendations for minimal informational requirements for the identification of exoskeletons. It is intended to provide the user with some of the basic information necessary for the selection and use of the exoskeletons.

4.2 Additional information beyond the content recommended by this practice is permitted to be applied to the label.

5. Labeling Recommendations

5.1 Each exoskeleton should have a product label permanently and visibly attached, stamped, or printed.

5.2 Multiple label pieces should be permitted in order to carry all statements and information on the product label. Instructional manuals and promotional material are not considered part of the label.

5.3 All label text should be written at least in a language which the intended users can understand.

5.4 Symbols and other graphical information, such as ISO 7000 / IEC 60417 graphical symbols, should be permitted to be

[1] This practice is under the jurisdiction of ASTM Committee F48 on Exoskeletons and Exosuits and is the direct responsibility of Subcommittee F48.01 on Design and Manufacturing.

Current edition approved Sept. 1, 2020. Published September 2020. Originally approved in 2018. Last previous edition approved in 2018 as F3358 – 18. DOI: 10.1520/F3358-20.

[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 U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

[4] Available from International Organization for Standardization (ISO), ISO Central Secretariat, BIBC II, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, http://www.iso.org.

used to supplement text on the product label(s) and should be explained in the user documentation materials.

5.5 The label should include at least the following information. All letters should be at least 2 mm (1⁄16 in.) high:

5.5.1 Manufacturer's name, identification, or designation.

5.5.2 Model, style, or serial number, or combinations thereof.

5.5.3 Lot number or designation – may be incorporated in the serial number.

5.5.4 Date of manufacture – uncoded month and year.

5.5.5 Warnings, cautions, limitations, precautions, notes, contraindications, and information related to the necessary safeguards of the device, including warning against activities and environments that may put the user at greater risk. Detailed information regarding hazards and how to avoid them should be included in the information package.

5.6 If applicable, the certification organization's label, symbol, or the certification mark shall be legibly printed on the product label. All letters shall be at least 7 point (2.5 mm) high.

6. Accompanying Literature Recommendations

6.1 The manufacturer shall provide an information package in print, electronic media, through the use of an accessible online site, or any combination thereof, with each individual exoskeleton.

6.2 The manufacturer shall package the information with the exoskeleton in such a manner that its inclusion is readily apparent to the individual opening the package.

6.3 The information package should include specific instructions and the training needed for the safe use of the exoskeleton which includes, but is not limited to:

6.3.1 Proper care instructions, including maintenance, solutions for common issues or problems, cleaning, inspection guidelines and frequency, recommended storage practices, repair methods, and disposal where applicable,

6.3.2 Complete instructions on the setup or fitting, or both, of the exoskeleton,

6.3.3 Instructions on fitting the user and adjustment procedures,

6.3.4 Instructions for operating the user interface of the exoskeleton,

6.3.5 Instructions and explanation of all displays, controls, inputs, and outputs,

6.3.6 Instructions on system operation of the exoskeleton,

6.3.7 Instructions on all safety features of the exoskeleton,

6.3.8 Point(s) of contact information for product and warranty support, and

6.3.9 Information on how to report adverse events to manufacturers and regulators as applicable.

6.4 The manufacturer shall include the following, if applicable, in the user instructions:

6.4.1 Information on the intended user population,

6.4.2 Available options, accessories and sizes,

6.4.3 Information on electrical and thermal safety,

6.4.4 Information on electromagnetic compatibility,

6.4.5 Information on battery safety and performance,

6.4.6 Information on durability (for example, cycle loading), and

6.4.7 Information on flammability.

6.5 For exoskeletons intended for medical use, manufacturers shall follow applicable laws, regulations, and guidance.

7. Keywords

7.1 exoskeleton; labeling; wearable robotics