Designation: ~~F3392 – 19~~ F3392 – 20

Standard Practice for Exoskeleton Wearing, Care, and Maintenance Instructions[1]

This standard is issued under the fixed designation F3392; 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 describes the ~~recommended~~required minimum information to be conveyed by the manufacturers to buyers or end users for the wearing, care, and maintenance of exoskeletons.

1.1.1 This practice does not cover specific instructions for how to select and when to use exoskeletons or design requirements.

1.2 *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.*

1.3 *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]

D5489 Guide for Care Symbols for Care Instructions on Textile Products

F2061 Practice for Chemical Protective Clothing: Wearing, Care, and Maintenance Instructions

F3358 Practice for Labeling and Information for Exoskeletons

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

21 CFR 890.3480 Powered lower extremity exoskeleton

2.3 *Other Standards:*

ANSI Z535.4 Standard for Product Safety Signs and Labels[4]

ISO 7000 / IEC 60417 Graphical symbols for use on equipment[5]

3. Terminology

3.1 *Definitions:*

3.1.1 *care, n*—procedures for cleaning, sterilization, decontamination, and storage of the exoskeleton.

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[1] This practice is under the jurisdiction of ASTM Committee F48 on Exoskeletons and Exosuits and is the direct responsibility of Subcommittee F48.04 on Maintenance and Disposal.

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

[5] 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.

3.1.2 *contamination, n*—the addition of an undesired substance to the exoskeleton.

3.1.3 *decontamination, n*—the reduction, removal, or neutralization of a contaminant or contaminants from the exoskeleton to the extent necessary to safely permit the exoskeleton to be doffed (taken off), reused, or discarded.

3.1.4 *degradation, n*—a deleterious change in one or more properties of a material.

3.1.5 *disinfection, n*—a process that destroys or irreversibly inactivates fungi, viruses, and bacteria, but not necessarily their spore, on inanimate surfaces and objects.

3.1.6 *end user, n*—the entity or organization whose employees ultimately wear the exoskeleton.

3.1.7 *maintenance, n*—procedures for inspection, service, upgrades, and repair of the exoskeleton, including the determination for removal from service.

3.1.8 *manufacturer, n*—party responsible for the manufacturing of the exoskeleton and assumes the liability or provides the warranty for the exoskeleton.

3.1.9 *sanitization, n*—a process that reduces, but not necessarily eliminates, microorganisms from the inanimate environment to levels considered safe as determined by public health codes or regulations.

3.1.10 *storage life, n*—the length of time that an exoskeleton can remain in storage, presuming that the exoskeleton has undergone proper care and maintenance in accordance with the manufacturer's instructions but has not been used either in training or on the job.

3.1.11 *wearing instructions, n*—procedures for donning, doffing, fitting, and adjusting an exoskeleton and preparing the exoskeleton for use.

4. Significance and Use

4.1 This practice describes the minimum information to be provided by the manufacturer to the end user related to the wearing, care, and maintenance of an exoskeleton. Adherence to this practice allows written information to be provided with the exoskeleton to ~~purchasers by means of labels (such as labels complying with Practice~~ purchasers.~~F3358), pamphlets, or other documents.~~

4.2 Not every element of this practice may be applicable to all exoskeleton components or configurations. It is the manufacturer's responsibility to determine which portions of this practice, and the corresponding requirements, are applicable to their exoskeletons. For informational requirements that are not applicable because of the nature of the product and intended use, the manufacturer ~~is to~~ shall indicate and describe those portions or requirements that are not applicable.

4.3 All information related to wearing, decontamination, care, and maintenance ~~are required to~~ shall be written in a manner so that the end user can readily understand the details. To emphasize important limitations, bold lettering and explicit warning terminology (for example, signal words such as 'danger,' 'warning,' and 'caution' (described in ANSI Z535.4)) ~~are to~~ shall be used. Where possible, pictograms and illustrations ~~are required~~ may be used to convey specific instructions. In addition, the use of symbols, such as those provided in the care of textile products in Guide D5489, are appropriate for indicating specific care procedures used in cleaning an exoskeleton where applicable.

5. General Information and Information Related to Wearing Instructions

5.1 *Address and Point-of-Contact Information*—The manufacturer shall provide an address, a contact telephone number, and means of electronic communication, as applicable, for questions concerning the proper use, limitations, decontamination, care, and maintenance of the exoskeleton. Provision of a toll-free emergency number is encouraged but not required.

5.2 *Safety Considerations, and Limitations of Use, and Warranty Information*—The manufacturer shall provide a list of considerations for the safe use of the exoskeleton and describe specific limitations for the use of the exoskeleton. As appropriate

for the intended use of the exoskeleton, the manufacturer shall provide appropriate warnings related to the use of the exoskeleton (for example, CONDUCT A HAZARD AND RISK ASSESSMENT TO DETERMINE THE SUITABILITY OF THIS EXOSKELETON FOR ITS INTENDED USE; FAILURE TO FOLLOW THESE INSTRUCTIONS MAY RESULT IN SERIOUS INJURY OR DEATH). It is recommended that warnings be highlighted using bold text and explicit terminology, such as the signal words 'danger,' 'warning,' and 'caution,' as described in ANSI Z535.4.

5.2.1 *Materials Compatibility*—The manufacturer shall provide a list of the types of materials used in the exoskeleton.

5.2.2 *Warranty*—The manufacturer shall provide the warranty statement and any associated information for the exoskeleton.

5.3 *Pre-Use Information*—The manufacturer shall provide information on how to mark the exoskeleton for purposes of identification by the end user organization, recommended undergarments and associated equipment to be worn with the exoskeleton, as applicable.

5.4 *Sizing Information*—The manufacturer shall indicate the types and number of sizes available for the exoskeleton and provide information for the selection of the correct size of the exoskeleton by the end user and describe any adjustments that can be made for properly sizing the exoskeleton.

5.5 *Donning and Doffing Instructions*—The manufacturer shall provide instructions to the end user on the proper donning (putting on and wearing) and doffing (removal) of the exoskeleton. ~~The~~ If applicable to the exoskeleton design, the manufacturer shall provide alternative instructions as needed for removal of the exoskeleton when contaminated with hazardous substances.

5.6 *Tools Required Instructions*—The manufacturer shall provide information about the necessary tools and equipment necessary for the proper wearing, care, and maintenance of the exoskeleton.

5.7 *Exoskeleton Domain*—The manufacturer shall indicate the domains of exoskeleton use. Such domains may include: consumer, industrial, medical, military, or all. This list is not exhaustive and domains beyond the prior shall be indicated as applicable.

5.8 *Power Source*—The manufacturer shall indicate the type of power source used by the exoskeleton. The power source refers to any device that stores and releases mechanical, electrical, pneumatic, or a combination thereof of energy. This list is not exhaustive and power sources beyond the prior shall be indicated as applicable.

6. Information Related to Care Instructions

6.1 *Information Related to Cleaning:*

6.1.1 *Cleaning Instructions*—The manufacturer shall provide specific instructions for the end user to properly clean, launder, or refurbish the exoskeleton, if the exoskeleton is designated by the manufacturer as able to be cleaned. This information shall include instructions for washing (for example, specific washing method, type of washing machine, machine cycle or formulation, detergents or cleaning agent, wash temperature, and pretreatment options) and drying (for example, the drying method, drying temperature, and length of time required).

6.1.2 *Cleaning Precautions and Limitations*—Warnings for limitations on the cleaning of an exoskeleton, such as loss of physical integrity or other forms of degradation, shall be included in this section. Additionally, the manufacturer shall describe methods to inspect or test for damages to the exoskeleton caused by cleaning or other maintenance, as applicable. As part of these precautions and limitations, the manufacturer shall provide a statement advising end users not to use an exoskeleton that is not thoroughly cleaned and dried.

~~6.1.2.1 Where testing is specified, the manufacturer shall provide procedures that specify the type of equipment to be used, the steps in the testing, the results to be reported, and how the results of the testing are interpreted.~~

6.2 *Information Related to Decontamination and Sanitization or Disinfection:*

6.2.1 *Decontamination Instructions*—The manufacturer shall provide specific instructions for removing various forms of anticipated contamination, if decontamination is recommended. These instructions shall include descriptions of acceptable processes, the types of contaminants that can be safely removed, the means of handling contaminated exoskeletons, the limitations