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Human factors engineering—Design of medical devices

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Advancing Safety in Health Technology

Human factors engineering—Design of medical devices

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Abstract: This standard addresses a broad range of human factors engineering topics as they relate to the design and evaluation of medical devices. This document is expected to be useful to human factors and usability engineering specialists, software developers, industrial, biomedical, mechanical, and electrical engineers, and other development personnel.

Keywords: human factors engineering, HFE, design, usability, user-interface

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Foreword

The following verbal forms are used within AAMI documents to distinguish requirements from other types of provisions in the document:

- "shall" and "shall not" are used to express requirements;
- "should" and "should not" are used to express recommendations;
- "may" and "may not" are used to express permission;
- "can" and "cannot" are used to express possibility or capability;
- "might" and "might not" are used to express possibility;
- "must" is used for external constraints or obligations defined outside the document; "must" is not an alternative for "shall."

Suggestions for improving this document are invited. Comments and suggested revisions should be sent to Standards, AAMI, 901 N. Glebe Road, Suite 300, Arlington, VA 22203 or standards@aami.org.

NOTE This foreword does not contain provisions of ANSI/AAMI HE75:2025; *Human factors engineering—Design of medical devices*, but it does provide important information about the development and intended use of the document.

Introduction

Human factors engineering (HFE) is the application of knowledge about human capabilities (physical, sensory, emotional, and intellectual) and limitations to the design and development of tools, devices, systems, environments, and organizations. Related terms for and sub-specialties of HFE include human factors, ergonomics, human engineering, usability engineering, or human–computer interaction (HCI). HFE involves the application of behavioral science and engineering methodologies to medical device design and evaluation.

The primary HFE concern for medical devices is to ensure they can be used safely and effectively by the intended users for the intended uses in the intended use environments. Successful development of safe and usable medical devices and systems requires the application of HFE principles and processes throughout product development and the product's life cycle. Doing so can help reduce use error, enhance patient and user safety, improve product usability and efficiency, and enhance user satisfaction. The HFE process for medical device design and evaluation, and the relationship between HFE and risk management in reducing use error, are addressed in ANSI/AAMI/IEC 62366-1, *Medical devices–Part 1: Application of usability engineering to medical devices*.

Many decades of basic and applied research, as well as practical experience, have generated a substantial base of scientific knowledge about people and their interactions with each other, with technology, and with their environment. For example, extensive data are available on the size and shape of the human body (anthropometry), how people sense the world (perception), how people think (cognition), and how they act (sensory/motor performance). These data and related principles governing their application are available in numerous textbooks, technical articles, standards and guidelines, and specialized design tools.

Knowledge of HFE methods and principles is critical to the design of safe and effective medical devices. It allows device designers to choose wisely among design alternatives. It also allows designers to validate that a design is appropriate for use in a clinical context. HFE areas of special importance relate to understanding the factors that affect human performance, the nature of human error and human fallibility, the role of humans in complex systems, and the causes of use errors (e.g., a poor arrangement of controls can result in inadvertent control activation).

Practicing HFE does not mean blind adherence to a set of guidelines; it is the sum of several processes:

- an analytical process following a rich variety of available assessment tools and user interface design guidance;
- a design and development process that tailors that guidance to the specific medical device application; and
- an evaluation and testing process that verifies that the design and development process has resolved issues, particularly those involving use-related risk, identified during the analytical process.

Devices that are not designed with the users in mind are sometimes unsafe, prone to use error, difficult to use, difficult to learn to use, or detract from use efficiency or user satisfaction. As HFE applies to all aspects of a device with which a human interacts and to all the tasks that a human might perform with the device, designers should ask the following primary human factors questions.

- Is the device design appropriate for the capabilities and limitations of users?
- How easy is it to learn to use the device?
- Once learned, how efficiently can the device be used?
- Do users remember how to use the device (i.e., is the way to use the device correctly memorable) after several days, weeks, or months of non-use?
- Does the device prevent users from making errors or help users recover from their errors?
- Are users satisfied with the device?

By implementing HFE early in and throughout the device development process, medical device manufacturers can do the following:

- identify potential use errors;
- reduce the occurrence of use error;
- control use related risk;
- increase patient and user safety;
- improve patient outcomes;
- improve task performance and optimal device use;
- decrease training time;
- enhance user satisfaction;
- reduce product liability risks;
- facilitate the regulatory clearance and approval process; and
- increase the chance of commercial success.

Purpose of this standard

The purpose of this document is to provide relevant and useful HFE information, design criteria, and guidelines for medical devices. The information and methodologies described here can be used during every phase of device design and development, from initial conceptualization through post-market surveillance. The sooner HFE design criteria are incorporated into device requirements, the more significant the impact will be. For example, basic HFE principles should be incorporated into initial user needs that support the definition of device requirements and refined into detailed user interface specifications. As the device design evolves and as usability testing is conducted, the initial user needs, device requirements, and user interface specifications might need further refinement. The contents of this document are intended to support device definition, development, and evaluation, with the goal of optimizing the safety and effectiveness of the device and also the patient/user experience.

NOTE In regard to “user” and “operator” nomenclature, international standards (International Electrotechnical Commission [IEC], International Organization for Standardization [ISO], and European Committee for Standardization [CEN] standards) have used a convention set by ANSI/AAMI ES 60601-1 many years ago. By that convention, “user” referred to the owner of a medical device, whereas “operator” referred to the person who actually uses that medical device. In human factors documents, “user” encompasses both groups; however, the term usually refers to the person using the medical device. In the 3rd edition of ANSI/AAMI ES 60601-1, an attempt was made to resolve this difference by changing “user” to “responsible organization.” This new and more useful convention has been retained in ANSI/AAMI/IEC 62366-1.

Objectives of this standard

The information in this document is meant to supplement the myriad of books, databases, and references that support HFE, with a particular emphasis on the design and evaluation of medical devices. This document should be used with participation by individuals with formal human factors training and expertise.

This document will help medical device manufacturers do the following:

- understand the concept of HFE;
- understand how different concepts and techniques can and should be used during all device design and development phases;

— understand that risk management provides a foundation for HFE, and risk management and HFE work together to address use errors that could lead to harm;

— assess a medical device's user interface and its adequacy for use by individuals with a variety of cognitive and physical capabilities and limitations;

— recognize the value of incorporating the user's voice in device development;

— develop an awareness of various user interface design considerations;

— adapt designs for specific environmental and clinical contexts;

— develop an understanding, from an HFE perspective, of the appropriate role of new technologies (e.g., speech recognition, speech synthesis) in device design; and

— make medical devices that are safe, effective, and usable.

Use of this standard

Prospective uses: Medical device manufacturers can use this document when designing and manufacturing their products. Health care facilities can apply the concepts in this document when evaluating devices, developing strategies to minimize use errors or analyzing use errors that have occurred. Regulators and other organizational entities can use this document to assess the design of medical devices both in isolation and as part of larger systems. Students can use this document to learn more about HFE and good practices in medical device design.

Format and style: The style follows the document structure required for ANSI/AAMI standards. The format is intended to help users navigate, locate, and use the information they need.

Guideline philosophy: The material covered in this document is fundamental to good design. This document is meant to complement other learning avenues such as books, education, and experience. Many of this document's major sections are interrelated and use similar (if not always identical) methodology and terminology. Special efforts have been applied to ensure that this document is "usable," following the guidelines in this document and in ANSI/AAMI/IEC 62366-1.

Topic completeness: The authors strove to make the topic coverage relevant and sufficiently detailed to provide the groundwork for excellent HFE in medical device design and manufacturing. However, none of the topic presentations is comprehensive. References are provided to expand on the material presented and to help users address design problems germane to that section. Importantly, this document is not a replacement for the skillful application of HFE by trained and experienced practitioners.

Redundancy and references: In most cases, any redundancy in content across sections is intentional and meant to reduce the need for the reader to reference a different section to obtain critical information. References are made to other sections when a topic is covered there in more detail or from a different perspective.

Overview of this standard

Background: The first three sections of this document provide general information that will support the reader to understand of the rest of the document.

Section 1 Scope defines the topics that are covered in this document.

Section 2 Normative references identifies the key international and US standards and FDA guidance documents that can inform the reader about HFE for medical devices.

Section 3 Terms and definitions acquaints the reader with the HFE terminology used in this document.

General considerations and principles: This part provides general HFE background information which provides a foundation upon which the remainder of this standard is built.

Section 4 General principles summarizes best practices for good HFE design, which apply to all medical devices and all sections of this document.

Section 5 Managing the risk of use error discusses the nature of use error and how HFE should be applied as part of risk management. This section expands on material found in ANSI/AAMI/IEC 62366-1 and ANSI/AAMI/ISO 14971. This section has implications for the design of all devices.

Section 6 Basic human skills and abilities presents information about the sensory, perceptual, cognitive, and physical attributes and abilities of users.

Section 7 Anthropometry and biomechanics describes human physical capabilities and limitations and includes data about human size, shape, posture, range of motion, and strength. Prevention of cumulative trauma is also discussed. This section complements Section 16 (Accessibility considerations), Section 22 (Hand tools and instruments), Section 23 (Workstations), and Section 24 (Transportable medical devices).

Section 8 Environmental, organizational, and structural issues presents special circumstances regarding the variety of environments in which health care occurs. Physical attributes, such as space, temperature, light, and noise are discussed. This section has implications for the design of all medical devices.

Section 9 Usability testing describes methods of planning and conducting evaluations that generate valid and reliable usability data to establish safe and effective use and other aspects of medical device usability. This section expands on material found in ANSI/AAMI/IEC 62366-1 and is relevant to the evaluation of all medical devices. Additionally, Annex A in this document (Statistical justification for sample sizes in usability testing) serves as a helpful resource.

Section 10 On-device labeling covers static on-device labels, icons, and mimics and their organization order, size, and optimal use conditions. Other sections with related material include Section 11 (Instructional and training materials), Section 19 (Visual displays), and Section 23 (Workstations).

Section 11 Instructional and training materials provides guidelines for creating understandable and effective hard-copy or electronic device instructions, including multimedia. For additional guidance on this topic, see Section 9 (Usability testing), Section 10 (On-device labeling), and Section 12 (Packaging).

Section 12 Packaging describes considerations for the design of medical device packaging, with emphasis on access, shipping, integrity, and sterilization. Excluded are device enclosures and mobile accessories. Relevant additional material can be found in Section 10 (On-device labeling) and Section 13 (Product lifecycle design considerations).

Section 13 Product lifecycle design considerations discusses principles relevant to the maintenance, reuse, disposal, and obsolescence of devices. This section has implications for all medical devices.

Section 14 Device design for global markets highlights considerations related to the design of devices intended for worldwide use. Different nations and cultures have different preferences, conventions, and expectations that can have substantial implications for user interface design.

Section 15 Alarms presents guidance about the design of alarm systems, warning signals, and similar notification mechanisms in medical devices. This section complements ANSI/AAMI/IEC 60601-1-8.

Section 16 Accessibility considerations highlights information related to designing medical devices to be accessible to users with temporary or permanent disabilities. Particular emphasis is placed on flexibility, adjustability, and multimodal access considerations. Related material can be found throughout this document, particularly in Section 6 (Basic human skills and abilities), Section 7 (Anthropometry and biomechanics), Section 23 (Workstations), and Section 25 (Devices used in non-clinical environments by laypersons).

Design elements: This part describes specific HFE principles geared towards certain user interface elements and attributes.

Section 17 Connectors and connections discusses the physical design components used to connect medical devices to inputs, outputs, or other medical devices. Specific issues addressed include the prevention of wrong connections, failed connections, and unintentional disconnections.

Section 18 Controls discusses decisions about the selection and design of a wide range of controls. Control design is also affected by issues discussed in Section 10 (On-device labeling), Section 19 (Visual displays), and Section 23 (Workstations). Controls related to hand tool design are addressed in Section 22 (Hand tools and instruments).

Section 19 Visual displays contains guidelines for dynamic output devices, excluding those used to notify users of alarm conditions. This section discusses design tradeoffs for various technologies and implementations. Display design is also affected by issues discussed in Section 18 (Controls) and Section 23 (Workstations). Static displays are discussed in Section 10 (On-device labeling).

Section 20 Automation discusses task allocation, automation, and feedback. Section 21 (Software user interfaces) covers some related issues.

Section 21 Software user interfaces provides a comprehensive description of electronic user interface elements and their respective design considerations. This section complements material presented in Section 10 (On-device labeling), Section 18 (Controls), Section 19 (Visual displays), and Section 23 (Workstations).

Integrated solutions: This part describes special medical device applications of HFE.

Section 22 Hand tools and instruments describes the application of HFE to the design of medical hand tools. Special attention is given to handle design. Other sections with related design guidance include Section 7 (Anthropometry and biomechanics), Section 10 (On-device labeling), and Section 18 (Controls).

Section 23 Workstations provides guidance on the large-scale integration of multiple devices in a single work environment. Topics include optimal control–display relationships and integration of furniture with medical devices. This section complements material covered in many other sections, including Section 4 (General principles), Section 7 (Anthropometry and biomechanics), Section 10 (On-device labeling), Section 16 (Accessibility considerations), Section 18 (Controls), and Section 19 (Visual displays).

Section 24 Transportable devices discusses the design of devices intended to be moved or to be used in environments that move (including beds, helicopters, and ambulances). It does not address implantable devices but does discuss wearable devices. Other sections with complementary material include Section 7 (Anthropometry and biomechanics), Section 23 (Workstations), and Section 25 (Devices used in non-clinical environments by laypersons).

Section 25 Devices used in non-clinical environments by laypersons covers the unique attributes and challenges of designing devices that are used outside of clinical environments by lay users. Other sections that cover relevant material include Section 8 (Environmental, organizational, and structural issues), Section 16 (Accessibility considerations), and Section 24 (Transportable devices).

Section 26 Integrated systems provides general considerations for designing devices to work together effectively as an integrated system, both in clinical and non-clinical settings. It also provides guidelines for making medical devices more likely to function well when networked with other medical devices, non-medical equipment, and, potentially, middleware and enterprise software applications.

Section 27 Combination products provides general considerations and design guidance to help combination product developers control the risks associated with use of a product that combines two FDA-regulated constituent parts, (e.g., a drug and a device). Many of these products are used by patients who self-treat themselves at home. Related and relevant information is provided in Section 5 (Managing the risk of use error), Section 9 (Usability testing), Section 10 (On-device labeling), Section 11 (Instructional and training materials),

Section 16 (Accessibility considerations), and Section 25 (Devices used in non-clinical environments by laypersons).

References are provided in the bibliography at the end of the document.

The authors hope that you find this document to be a useful resource for the application of HFE to the design of medical devices. We wish you success in designing a safe, effective, and useful medical device or in evaluating the safety and effectiveness of a medical device.

Human factors engineering—Design of medical devices

1 Scope

1.1 General

This standard addresses a broad range of human factors engineering (HFE) topics as they relate to the design and evaluation of medical devices. Examples are provided, as are references to more information. The material emphasizes adoption of a user-centered focus throughout the product design and development process, with the goal of making medical devices that are safe, effective, and also usable.

This document is expected to be useful to human factors and usability engineering specialists, software developers, industrial, biomedical, mechanical, and electrical engineers, and other development personnel. Other users might include clinical personnel and others who evaluate devices before purchase or after use errors have occurred, regulatory agencies, purchasing entities, and others interested in assessing the safety, effectiveness, and usability of medical devices.

1.2 Inclusions

This standard covers general HFE principles, specific HFE principles geared towards certain user- interface attributes, and applications of HFE to specific types of medical devices (e.g., hand tools).

1.3 Exclusions

This standard does not provide detailed recommendations on all aspects of the human factors medical device design process.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this AAMI standard are encouraged to investigate the appropriateness of applying the most recent editions of the standards indicated below.

NOTE Informative references are listed in the bibliography at the end of the document.

American National Standards Institute. *Medical devices—Quality management systems—Requirements for regulatory purposes.* ANSI/AAMI/ISO 13485:2016.

American National Standards Institute. *Medical devices—Application of risk management to medical devices.* ANSI/ISO 14971:2019.

American National Standards Institute. *Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.* ANSI/AAMI/IEC 60601-1-8:2006/A2:2021.

American National Standards Institute. *Medical electrical equipment—Part 1-11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.* ANSI/AAMI 60601-1-11:2015/A1:2021.

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