American National Standard

ANSI/AAMI HE75:2009/(R)2013

Human factors engineering – Design of medical devices

AAMI
Advancing Safety in Medical Technology

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

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Human factors engineering – Design of medical devices

Developed by
Association for the Advancement of Medical Instrumentation

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Abstract: This recommended practice covers general human factors engineering (HFE) principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE (e.g., connectors, controls, visual displays, automation, software–user interfaces, hand tools, workstations, mobile medical devices, home health care devices).

Keywords: anthropometry, design process, ergonomics, human factors engineering, medical device

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Glossary or equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2002	ANSI/AAMI DF80:2003	Major technical variations
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC/TR 80002-1:2009	ANSI/AAMI/IEC TIR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2004	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2004	ANSI/AAMI RD16:2007	Major technical variations
ISO 8638:2004	ANSI/AAMI RD17:2007	Major technical variations
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:1999	ANSI/AAMI/ISO 10993-9:1999/(R)2005	Identical
ISO 10993-10:2002 and Amendment 1:2006	ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008	Minor technical variations Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:1998	ANSI/AAMI/ISO 10993-13:1999/(R)2004	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:1997	ANSI/AAMI/ISO 10993-16:1997/(R)2009	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical

International designation	U.S. designation	Equivalency
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006	Identical
ISO 11137-2:2006 (2006-08-01 corrected version)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006	Identical
ISO 11138-1: 2006	ANSI/AAMI/ISO 11138-1:2006	Identical
ISO 11138-2: 2006	ANSI/AAMI/ISO 11138-2:2006	Identical
ISO 11138-3: 2006	ANSI/AAMI/ISO 11138-3:2006	Identical
ISO 11138-4: 2006	ANSI/AAMI/ISO 11138-4:2006	Identical
ISO 11138-5: 2006	ANSI/AAMI/ISO 11138-5:2006	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006	Identical
ISO 11737-1: 2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 14155-1:2003	ANSI/AAMI/ISO 14155-1:2003/(R)2008	Identical
ISO 14155-2:2003	ANSI/AAMI/ISO 14155-2:2003/(R)2008	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15225:2000 and A1:2004	ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006	Identical
ISO/TS 19218:2005	ANSI/AAMI/ISO 19218:2005	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Human Factors Engineering Committee

This recommended practice was developed by the AAMI Human Factors Engineering Committee. Committee approval of the recommended practice does not necessarily mean that all committee members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this recommended practice does not constitute endorsement by the federal government or any of its agencies.

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Foreword

In the course of the AAMI Human Factors Engineering Committee's review of ANSI/AAMI HE48:1993, *Human factors engineering guidelines and preferred practices for the design of medical devices,* the committee decided that users would be better served if the document was divided into two separate standards covering (1) human factors *design processes* and (2) human factors *design principles.* A structured approach to human factors design in medical devices is addressed in the American National Standard, ANSI/AAMI HE74:2001, *Human factors design process for medical devices*. ANSI/AAMI HE74 formed the basis of an international collaboration that led to the creation of IEC 62366:2007, *Medical devices–Application of usability engineering to medical devices*. The relationship between human factors engineering and risk management to reduce use error is addressed in IEC 62366. The content of ANSI/AAMI HE74 is provided in Appendix G of IEC 62366. ANSI/AAMI HE75 is the committee's effort to provide comprehensive human factors design principles for medical devices.

This recommended practice should be considered flexible and dynamic. As technology advances and new data are brought forward, this document will be reviewed and, if necessary, revised.

Within the context of this recommended practice, "shall" indicates requirements that must be strictly followed to conform to this document's guidance. "Should" indicates that among several possibilities, one approach is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" indicates that a course of action is permissible within the limits of the recommended practice. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

AAMI and ANSI procedures require that standards and recommended practices be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

Suggestions for improving this recommended practice are invited. Comments and suggested revisions should be sent to AAMI, 1110 N Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This foreword does not contain provisions of the AAMI recommended practice, *Human factors principles for medical device design* (ANSI/AAMI HE75:2009), but it does provide important information about the development and intended use of the document.

Human factors engineering – Design of medical devices

Introduction

Human factors engineering

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. HFE might also be called human factors, ergonomics, human engineering, usability engineering, or human–computer interaction (HCI). HFE involves the use of behavioral science and engineering methodologies in support of design and evaluation.

Successful development of safe and usable medical devices and systems requires the application of HFE principles and processes throughout the product design cycle. Doing so can help reduce use error, enhance patient and user safety, improve product usability and efficiency, and enhance user satisfaction. The relationship between HFE and risk management in reducing use error is addressed in International Electrotechnical Commission (IEC) 62366:2007, *Medical devices–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., inadvertent control activation).

The HFE process for medical device design and evaluation is discussed in detail in ANSI/AAMI HE74:2001/(R)2009, *Human factors design process for medical devices,* and in comparable international standards. HFE is not blind adherence to a set of guidelines; it is the sum of several processes:

a) An analytic process that directs the use of available user-interface design guidance

b) A design and development process that tailors that guidance to the specific application

c) A test and evaluation process that verifies that the design and development process has resolved issues identified during the analytic process

The primary HFE concern for medical devices is to ensure that medical devices can be used safely. Devices that are not designed with usability in mind are frequently unsafe, prone to use error, difficult to use, difficult to learn to use, or detract from user efficiency or satisfaction.

HFE applies to all aspects of a device with which a human interacts and to all of the tasks that a human might perform with the device, including all hardware and software interfaces that support all user tasks. Primary usability questions include the following:

a) How easy is it to learn to use the device? How soon will the intended user feel comfortable using the device?

b) Once learned, how efficiently can the device be used?

c) Do users remember how to use the device after several days, weeks, or months of non-use?

d) Does the device prevent users from making errors or help users recover from their errors?

e) Are users satisfied with the device?

f) Is the device design appropriate for the capabilities and limitations of users?

HFE-based medical device designs offer numerous benefits. They increase safety, reduce use error and facilitate recovery from use error, decrease training time, increase ease of use, improve task performance and optimal device use, enhance user satisfaction, improve patient outcomes, reduce product liability risks, facilitate the regulatory approval process, and increase the chance of commercial success.

Purpose of this recommended practice

The purpose of this document is to provide a relevant source of HFE information, design criteria, and guidelines for medical devices. The human factors design information and methodologies described here may 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 device requirements and refined into detailed usability specifications. As the device design evolves and as usability testing is conducted, the initial requirements or usability specifications will need to be refined further.

NOTE—In regard to "user" and "operator" nomenclature, international (IEC, International Organization for Standardization [ISO], and European Committee for Standardization [CEN]) standards have used a convention set by IEC 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, including ANSI/AAMI HE74:2001/(R)2009, "user" encompasses both groups; however, the term usually refers to the person using the medical device. In the 3rd edition of IEC 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 IEC 62366.

Objectives of this recommended practice

These guidelines are 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.

These guidelines will help medical device manufacturers

a) understand the concept of HFE;

b) understand how different concepts and techniques can and should be used during all device design and development phases;

c) develop devices that solve problems in today's clinical environment;

d) make medical devices easier to use;

e) understand that risk management alone cannot address use errors that lead to safety problems;

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

g) adapt designs for environmental and clinical contextual considerations;

h) recognize the importance of consistency in design, as well as in the use of signs, symbols, and markings;

i) assess a variety of cognitive and physical human capabilities and limitations;

j) develop an awareness of various user-interface design issues; and

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

Use of this recommended practice

Prospective uses: Medical device manufacturers can use these guidelines when designing and manufacturing their products. Health care facilities can apply the concepts in these guidelines when evaluating devices, trying to prevent use errors, or analyzing use errors that have occurred. Regulators and other organizational entities can use these guidelines to assess the design of medical devices both in isolation and as part of larger systems. Students can use these guidelines 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, courses, and experience. Special efforts have been applied to the "human factors/usability" of this document, following the guidelines in this document and in ANSI/AAMI HE74:2001/(R)2009. Many of this document's major sections are interrelated and use similar methodology and terminology.

Topic completeness: The authors strove to make the topic coverage relevant and sufficiently detailed to provide the groundwork for skillful 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 to reference a different section for 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 recommended practice

This document is divided into three main parts: "General Considerations and Principles," "Design Elements," and "Integrated Solutions." References are provided at the end of each section. Section 3 (Definitions) is a good place to become acquainted with the HFE terminology used in these guidelines.

NOTE—The first section below is Section 4. Sections 1 through 3 are not listed because they are part of the general framework of the recommended practice.

General considerations and principles: This part provides general HFE background upon which the remainder of this recommended practice is built.

Section 4 (General principles) summarizes best practices for general design (from making devices simple to being consistent with rules of design), which apply to all sections and devices.

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 IEC 62366:2007 and ISO 14971:2007, *Medical devices—Application of risk management to medical devices*. 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. This section is relevant to the content of many other sections and has broad implications for many other sections and for the design of all devices.

Section 7 (Anthropometry and biomechanics) describes the extent of 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 tool design), Section 23 (Workstations), and Section 24 (Design of mobile medical devices).

Section 8 (Environmental considerations) presents special circumstances regarding the overall 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) provides detailed methods of planning and conducting evaluations that generate valid and reliable usability data. This section expands on material found in ANSI/AAMI HE74:2001/(R)2009 and is relevant to the evaluation of all medical devices.

Section 10 (Signs, symbols, and markings) 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 (User documentation), Section 19 (Visual displays), and Section 23 (Workstations).

Section 11 (User documentation) provides guidelines for creating easy-to-use and effective hard-copy or electronic device instructions, including multimedia. For additional information on device labeling, Section 10 (Signs, symbols, and markings) and Section 12 (Packaging design) should be consulted.

Section 12 (Packaging design) describes the design of medical device packaging, with emphasis on ease of access, shipping, integrity, and sterilization. Excluded are device enclosures and mobile accessories. Relevant additional material can be found in Section 10 (Signs, symbols, and markings) and Section 13 (Design for post-market issues).

Section 13 (Design for post-market issues) discusses principles relevant to the maintenance, reuse, disposal, and obsolescence of devices. This section has implications for all medical devices.

Section 14 (Cross-cultural/cross-national design) highlights usability issues 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 interface design.

Section 15 (Alarm design) presents guidance about the design of alarm systems, warning signals, and similar notification mechanisms in medical devices. This section complements IEC 60601-1-8:2006, *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*.

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 (Home health care).

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

Section 17 (Connectors and connections) discusses the physical design of medical device connectors. Specific issues addressed include the prevention of wrong connections, failed connections, and 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 (Signs, symbols, and markings), Section 19 (Visual displays), and Section 23 (Workstations). Controls related to hand tool design are addressed in Section 22.

Section 19 (Visual displays) contains guidelines for dynamic output devices, excluding those used to notify users of alarm conditions. This section discusses design trade-offs 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 (Signs, symbols, and markings).

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

Section 21 (Software–user interfaces) is a comprehensive description of all electronic user-interface elements and their respective design considerations. This section complements material presented in Section 10 (Signs, symbols, and markings), Section 18 (Controls), Section 19 (Visual displays), and Section 23 (Workstations).

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

Section 22 (Hand tool design) describes HFE factors relevant 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 (Signs, symbols, and markings), and Section 18 (Controls).

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

Section 24 (Design of mobile medical 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 (Home health care).

Section 25 (Home health care) covers the unique attributes and challenges of designing devices for lay users that are used outside of clinical environments. Other sections that cover relevant material include Section 8 (Environmental considerations), Section 16 (Accessibility considerations), and Section 24 (Design of mobile medical devices).

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 and useful medical device or in evaluating the safety and usability of a medical device.

1 Scope

1.1 General

This recommended practice addresses a broad range of human factors engineering (HFE) topics in a structured format. Examples are provided, as are references to more detailed information. The material emphasizes adoption of a user-centered focus throughout the product design and development process, with the goal of making medical devices easier to use and less prone to use error.

The presumed users of this document are human factors and usability specialists, software developers, industrial, biomedical, mechanical, and electrical engineers, and other development personnel. Other users might include clinicians, clinical and biomedical engineers, and others who evaluate devices before purchase or after use errors have occurred, regulatory agencies, purchasing entities, and others interested in assessing the usability of medical devices.

1.2 Inclusions

This recommended practice covers general HFE principles, specific HFE principles geared towards certain user-interface attributes, and special applications of HFE (e.g., hand tool design).

1.3 Exclusions

This recommended practice does not provide detailed recommendations on all aspects of the human factors medical device design process (see ANSI/AAMI HE74:2001/(R)2009).

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this AAMI recommended practice. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this AAMI recommended practice are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

2.1 Association for the Advancement of Medical Instrumentation. *Human factors design process for medical devices.* 1st ed. ANSI/AAMI HE74:2001/(R)2009. Arlington (VA): AAMI, 2001.

2.2 Association for the Advancement of Medical Instrumentation. *Medical devices—Quality management systems—Requirements for regulatory purposes.* 2nd ed. ANSI/AAMI/ISO 13485:2003/(R)2009. Arllngton (VA): AAMI, 2003.

2.3 Association for the Advancement of Medical Instrumentation. *Medical devices—Application of risk management to medical devices*. 3rd ed. ANSI/AAMI/ISO 14971:2007. Arlington (VA): AAMI, 2007.

2.4 International Electrotechnical Commission. *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.* IEC 60601-1-8:2006. Geneva (Switzerland): IEC, 2006.

2.5 International Electrotechnical Commission. *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.* IEC 60601-1-11:2010. Geneva (Switzerland): IEC, 2010.[1]

2.6 International Electrotechnical Commission. *Medical devices—Application of usability engineering to medical devices.* IEC 62366:2007. Geneva (Switzerland): IEC, 2007.

2.7 U.S. Food and Drug Administration. Quality Systems Regulation. *Code of Federal Regulations*, Title 21, Part 820.

[1] IEC/FDIS 60601-1-11 was circulated for final voting on 12 February 2010. If approved, the document should be published by IEC around June 2010.