American National Standard

ANSI/AAMI HE74:2001/(R)2009

Human factors design process for medical devices

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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.

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Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

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American National Standard

ANSI/AAMI HE74:2001/(R)2009
(Partial revision of ANSI/AAMI HE48:1993)

Human factors design process for medical devices

Developed by
Association for the Advancement of Medical Instrumentation

Approved 2 May 2001 and reaffirmed 10 August 2009 by
American National Standards Institute, Inc.

Abstract: The purpose of this process-oriented standard is to provide ergonomic information and human factors engineering guidance so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in medical device design. This document describes a recommended human factors engineering process for use in fulfilling user interface design requirements in the development of medical devices and systems, including hardware, software, and documentation.

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

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Committee representation

Association for the Advancement of Medical Instrumentation

Human Factors Engineering Committee

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

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Foreword

In the course of the AAMI Human Factors Engineering Committee's most recent review of ANSI/AAMI HE48:1993, *Human factors engineering guidelines and preferred practices for the design of medical devices*, the committee decided that standards users would be better served if the document was divided into separate standards covering: (1) human factors *design process*, and (2) human factors *design principles*. The human factors design process (previously addressed in section 5 of the 1993 standard) is now addressed in the new American National Standard, *Human factors design process for medical devices*, and is designated ANSI/AAMI HE74:2001. Human factors design principles are being addressed in a new standard under development by the AAMI Human Factors Engineering Committee. The new ergonomics standard will be entitled *Human factors engineering—Design of medical devices* and will carry the designation HE75. Until that document is published, standards users should refer to ANSI/AAMI HE48:1993 for requirements with respect to human factors design principles.

NOTE—ANSI/AAMI HE74:2001, *Human factors design process for medical devices,* was originally designated ANSI/AAMI HE48:2001. It was later redesignated ANSI/AAMI HE74:2001.

This standard should be considered flexible and dynamic. As technology advances and new data are brought forward, the standard will be reviewed and, if necessary, revised. Within the context of this standard, "shall" indicates requirements strictly to be followed to conform to the standard. "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 standard. "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.

Suggestions for improving this standard 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 American National Standard*, Human factors design process for medical devices* (ANSI/AAMI HE74:2001).

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Introduction

The AAMI Human Factors Engineering Committee developed this process-oriented standard to provide manufacturers with a structured approach to user interface design. Additionally, the document will help manufacturers interpret and respond effectively to national and international regulations and standards pertaining to the design of user interfaces. The document describes design approaches and techniques that can be applied to the design of other aspects of device use, including training programs and learning tools. The committee's principal motivation to write a process-oriented standard was to help manufacturers respond to the increasing number of national and international human factors standards in the medical field and the promulgation of new governmental regulations (based on ISO 9001) pertaining to the medical device user interface design.

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Human factors design process for medical devices

1 Scope

By providing a structured approach to user interface design, this document can help manufacturers develop safe and usable medical devices. This document includes an overview of the human factors engineering (HFE) discipline, a discussion of the benefits of HFE, a review of the HFE process and associated analysis and design techniques, and a discussion of implementation issues and relevant national and international standards and regulations (see annex B). The document also incorporates a listing of applicable government documents and human factors engineering literature citations (see annex E).

For the purposes of this document, the user interface includes all aspects of a device with which users interact when operating the device. Instructions for use and device labeling are an integral part of the user interface. Users are defined as including operators, maintainers, cleaners, and other service personnel as well as other individuals directly affected by the use of the device. Thus, a user may be a caregiver (e.g., anyone who gives a diabetic his/her insulin injection); a patient (e.g., diabetics who administer their own insulin injections); or someone who provides support for either a caregiver or a patient (e.g., a diagnostic ultrasound technician). A caregiver may be a trained clinician or a layperson (e.g., a family member).

NOTE—This definition of user differs from that used in international standards that define a *user* as the "authority responsible for the use and maintenance of equipment," whereas the *operator* is defined as the "person handling the equipment."

This document addresses the needs of a diverse group of professionals who handle the planning, funding, management, and performance of research, design, and testing activities related to the safety and usability of medical devices, including:

a) Company, department, project, and product managers;

b) Design and engineering professionals (e.g., human factors engineers, industrial designers, technical writers, information designers, software developers, mechanical engineers, electrical engineers, packaging engineers);

c) Medical researchers and other interested clinicians; and

d) Marketers and other business professionals in the medical device industry.

This document is not intended as a sole source for HFE guidance or as a substitute for human factors expertise. Rather, it is intended to provide readers with a general understanding of how to perform HFE work in an effective way, drawing extensively on related documents (see annex E).

HFE practice varies widely. This variation is partly because of the diversity of its practitioners, who may have backgrounds in fields such as engineering, psychology, or design. Practice differences occur because of the wide variety and complexity of medical devices, which range from simple syringes to complex imaging systems, and which may be used in hospitals, clinics, or the home by various professionals and laypersons.

Thus, it is impossible to prescribe a single set of HFE methods that will be optimal for all design projects. Instead, this document describes an HFE process that requires additional shaping and scaling to suit practitioners' experience and style, as well as project specifications. The document's ultimate goal is to ensure that manufacturers approach user interface design in a rigorous, effective manner.

1.1 The benefits of HFE

The primary goal of an HFE program that is tailored to medical devices should be making devices safer, more effective, and easier to use. Well-established HFE tools and techniques support the analysis, design, testing, and evaluation of both simple and complex systems. These techniques have been successfully applied for many years in such diverse areas as consumer products, military applications, aviation equipment, and nuclear power systems. An integrated and structured HFE program can help medical device developers make their devices safer and easier to use.

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1.2 Avoiding design-induced error

Device-related errors usually result from multiple interrelated factors. Adverse event reports confirm that the device itself often contributes to use errors, most commonly because of user interface design flaws. Table 1 provides examples of design flaws and associated use errors. Good design should not only reduce the likelihood of use errors but also, when use errors do occur, increase the likelihood of their detection and correction and increase the ability to mitigate their consequences.

The systematic application of HFE design principles, reinforced by tests involving end users, is an effective means of identifying and resolving such design flaws. For example, adherence to established design standards that specify the minimum separation distances between controls helps prevent inadvertent user activation of adjacent controls. A thorough understanding of the environment in which the device is used that is garnered by site visits, field interviews, and usability tests (conducted in a laboratory or in the field) could reveal other design flaws that contribute to use error. Field observations conducted in the earliest phases of the design process may identify potential device interaction problems (for example, the possibility of incorrect, perhaps dangerous, tubing connections due to common physical fit and appearance). Usability tests using device mock-ups or simulations could identify the possibility of incorrect tubing connections resulting from uncommon physical fit and appearance, unnecessarily complex input sequences, or ambiguous messages.

Table 1—Sample of design flaws and associated use errors

Example of design flaw	Possible resultant use error
Push buttons on a control panel are too closely spaced.	User presses the wrong button.
Two icons on a software screen look too similar.	User misinterprets the icon and selects the wrong function.
A user interface requires a complex, lengthy, and arbitrary sequence of button pushes to initiate an infusion.	User enters incorrect sequence and fails to initiate infusion.
Infusion pump displays misleading “Open Door-Reset” message when air is in the infusion line.	User repeatedly opens the door and presses the reset key instead of clearing air from the infusion line.
User-adjusted high and low alarm limits on a heart-rate monitor are not continuously displayed.	User fails to detect a dangerous increase in heart rate because alarm limit is set too high and user is over-reliant on alarm system.
Typical user-applied force exceeds breaking strength of catheter connector.	User cracks catheter connector when tightening.

1.3 Improving usability

Medical device users (e.g., physicians, nurses, therapists, technologists, patients, and service personnel) regard usability as one of a medical device’s most important design characteristics. They understand that a usable medical device is likely to reduce the amount of end-user training time and help clinicians be more productive. For devices intended for patients (e.g., home glucose monitors for diabetics), ease of use can affect whether the patient will be able to use the device at all. Medical device manufacturers will be well served by investing the necessary resources to improve usability. From a business standpoint, the potential payoffs of investing in improved usability may include:

a) Faster time to market (by avoiding user interface problems late in the development cycle);

b) Simpler user manuals and related learning tools;

c) Improved marketing through credible claims about a device’s usability and associated gains in user productivity;

d) Increased sales (attributable to enhanced user interface quality);

e) Reduced customer training and support requirements;

f) Extended market life;

g) Clearer compliance with regulatory requirements (see annex B);

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h) Reduced exposure to liability claims; and

i) Increased user satisfaction.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this AAMI standard. 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 possibility of applying the most recent editions of the standards indicated below.

2.1 ANSI/AAMI/ISO 13485:1996, *Quality systems—Medical devices—Particular requirements for the application of ISO 9001.*

2.2 ANSI/AAMI/ISO 13488:1996, *Quality systems—Medical devices—Particular requirements for the application of ISO 9002.*

2.3 ANSI/AAMI/ISO 14971:2000, *Medical devices—Application of risk management to medical devices.*

2.4 ISO 9001:1994, *Quality systems—Model for quality assurance in design, development, production, installation, and servicing.*

2.5 ISO 9002:1994, *Quality systems—Model for quality assurance in production, installation, and servicing.*

2.6 Title 21 CFR Part 50, *Protection of human subjects: Informed consent.* Washington, DC: Food and Drug Administration, June 18, 1991.

2.7 Title 21 CFR Part 56, *Protection of human subjects: Standards for institutional review boards for clinical investigations.* Washington, D.C.: Food and Drug Administration, June 18, 1991.

2.8 Title 45 CFR Part 46, *Federal Policy for the Protection of Human Subjects*. Washington, DC: Department of Health and Human Services, June 18, 1991.

3 Definitions

For the purposes of this AAMI standard, the following definitions apply.

3.1 anthropometry: Scientific measurement and collection of data about human physical characteristics as well as the application of this data to the design and evaluation of systems, equipment, and facilities (MIL-HDBK-1908B).

3.2 appearance model: Nonfunctional (i.e., static) mock-up of a device that realistically represents all of the device's physical characteristics in three-dimensional form.

3.3 conceptual model diagram: Graphical description of the underlying organization and relationships in a user interface design. A bubble diagram is one way to depict a conceptual model.

3.4 contextual inquiry: Process of observing and working with users in their normal environment to better understand the tasks they do and their work flow (Helander, Landauer, and Prabhu, 1997, p. 350).

3.5 criticality: Quality of a system element that, if it fails to meet system requirements, will most likely have adverse effects on system safety, reliability, efficiency, effectiveness, or cost.

3.6 fidelity: Degree of realism of models, simulations, or prototypes. Low-fidelity models share only a limited number of common elements with the actual system of interest, whereas high-fidelity models share many common elements with the actual system of interest (modified from Wiener and Nagel, 1988, p. 232).

3.7 hazard analysis: Use of available information to identify potential injury-causing events.

3.8 human factors engineering (HFE): Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of tools, machines, equipment, devices, systems, tasks, jobs, and environments to achieve productive, safe, comfortable, and effective human use (modified from Sanders and McCormick, 1993).

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3.9 labeling: (1) Act of describing the nature or contents of some device with respect to the name of the product, the manufacturer, the amount present, indications and instructions for use, or warnings associated with its use; (2) act of identifying display or control elements of a system with text or pictorial designators (modified from Stramler, 1993).

NOTE—The U.S. Food and Drug Administration defines *labeling* in Section 201(m) of the Food, Drugs, and Cosmetics Act as "all labels and written, printed, or graphic matter: (1) on the device or any of its containers, or (2) accompanying the device" (21 CFR Part 801, Labeling).

3.10 operator: Person handling a device for the purposes for which the device was intended (IEC 60601-1).

3.11 prototype: Model or preliminary version of a product developed for testing and evaluation purposes that is produced prior to manufacture of the production item (modified from Stramler, 1993).

3.12 requirement: Description of general or specific device characteristics that must be accounted for in the development of a device or product. An alternative term sometimes used in the context of usability testing is *usability design goals*.

3.13 risk analysis: Structured review of a system to identify undesirable events that can occur because of that system's use (including maintenance, etc.) and estimation of the likelihood and potential severity of those events. This term is often used synonymously with the term *hazard analysis*.

3.14 risk management: Systematic application of policies, procedures, and practices to the analysis, evaluation, and control of risks.

3.15 simulation: Conceptualization and use of an abstraction or model that behaves in a way similar to a real system (Salvendy, 1997).

3.16 specification: Technical descriptions that, taken together, explicitly describe the characteristics of a device's design. These technical descriptions are normally refined to whatever level of detail the users of these descriptions (e.g., the device's designers) deem appropriate. One purpose of these specifications is to allow someone to relate each requirement to specific details at each stage in design and implementation.

3.17 system: Composite of equipment, skills, and techniques capable of performing or supporting an operational role. A complete system includes all equipment, related facilities, material, software, services, and personnel required for its operation and support to the degree that it can be a self-sufficient unit in its intended operational environment (DOD-HDBK-1908B).

3.18 usability: Measure of the ease with which one can use or learn how to use a device (modified from Stramler, 1993).

3.19 usability goal: Desired quality of a user-device interaction that may be expressed in written form, stipulating a particular usability attribute (e.g., task speed) and performance criterion (e.g., number of seconds). Usability goals may address objective (observable) and subjective (opinion-based) aspects of interaction and can be used as a basis for planning and judging the results of usability tests.

3.20 usability test: Procedure for determining whether the usability goals have been achieved. Usability tests can be performed in a laboratory setting, in a simulated environment, or in the actual environment of intended use (modified from Helander, Landauer, and Prabhu, 1997, p. 669).

3.21 use error: Act or omission of an act that results in a different outcome than that intended by the manufacturer or expected by the user, which may result from a mismatch between user, man-machine interface, task, and/or environment.

3.22 use environment: The actual conditions and setting in which users interact with the device or system.

3.23 user: Person who interacts with a given device, piece of equipment, or system (modified from DOD-HDBK-1908B). Thus, users include operators, maintainers, cleaners, and other service personnel as well as other individuals directly affected by the use of the device. Patients or other laypersons can be users. This definition is different than that employed in international standards documents that define a *user* as the "authority responsible for the use and maintenance of equipment," whereas the *operator* is defined as the "person handling the equipment."

3.24 user interface: Means by which the human user and the device, piece of equipment, or system communicate information (modified from DOD-HDBK-1908B).

3.25 user profile: Summary of the mental, physical, and demographic traits of the end-user population as well as any special characteristics such as occupational skills and job requirements that may have a bearing on design decisions (from Wiklund, 1995, p. 6).

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3.26 validation: Confirmation that the device can perform its defined tasks and satisfy the user's needs, which is done by conducting a risk analysis and testing production models under simulated or actual use conditions (see annex B).

3.27 verification: Confirmation, usually by means of laboratory test and analysis, that work products and other descriptive materials that characterize the design meet the performance criteria derived from the design requirements (see annex B).

4 Overview of the HFE process

Regardless of whether one is designing a revolutionary new product or making minor modifications to an existing product, the associated HFE process will invariably include several specific HFE elements or steps. Figure 1 depicts the HFE aspects of medical device design as a cycle of steps. This does *not* imply that every design effort must follow a rigid prescription of development activities. On the contrary, the specific HFE activities at each step in the cycle (and the associated time, effort, and expense required) will vary with each development effort.

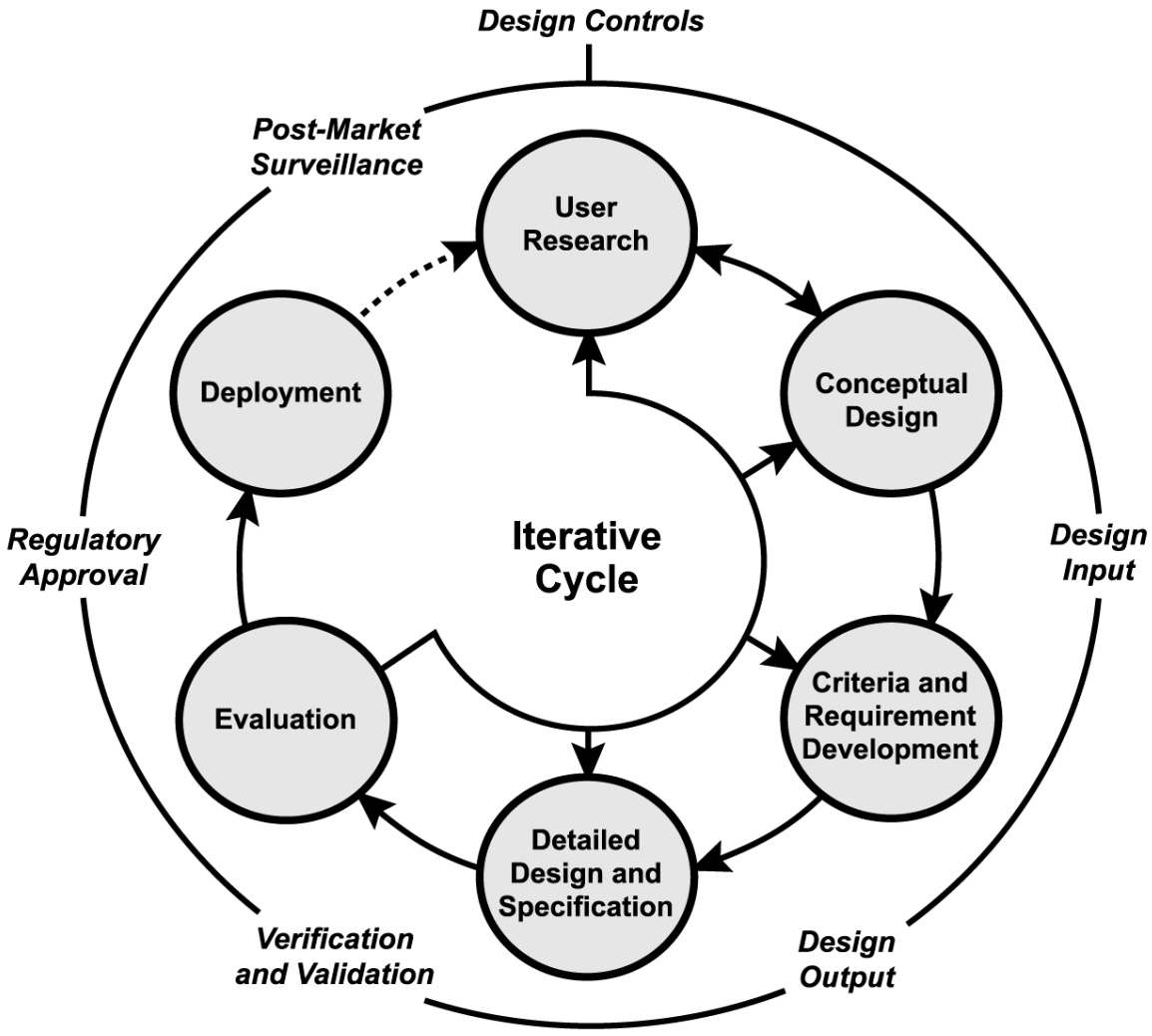

Figure 1—A human factors engineering user interface design cycle

Input from users is typically obtained at nearly every stage in the cycle.

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Full document details: HE74:2001, Human factors design process for medical devices