American National Standard

ANSI/AAMI HE74:2001

Human factors design process for medical devices

AAMI Association for the Advancement of Medical Instrumentation

The 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.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a fume of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards health care professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decisionmaking.

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.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the Manager for Technical Development. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News.* The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News.*

American National Standard

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

Human factors design process for medical devices

Developed by
Association for the Advancement of Medical Instrumentation

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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

AAMI Standard

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Contents

Annexes

Tables

Figures

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

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).

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.

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.

