List of Titles

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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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

Approved 2 May 2001 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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AAMI Standard

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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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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.

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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.

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);

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).

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).

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.

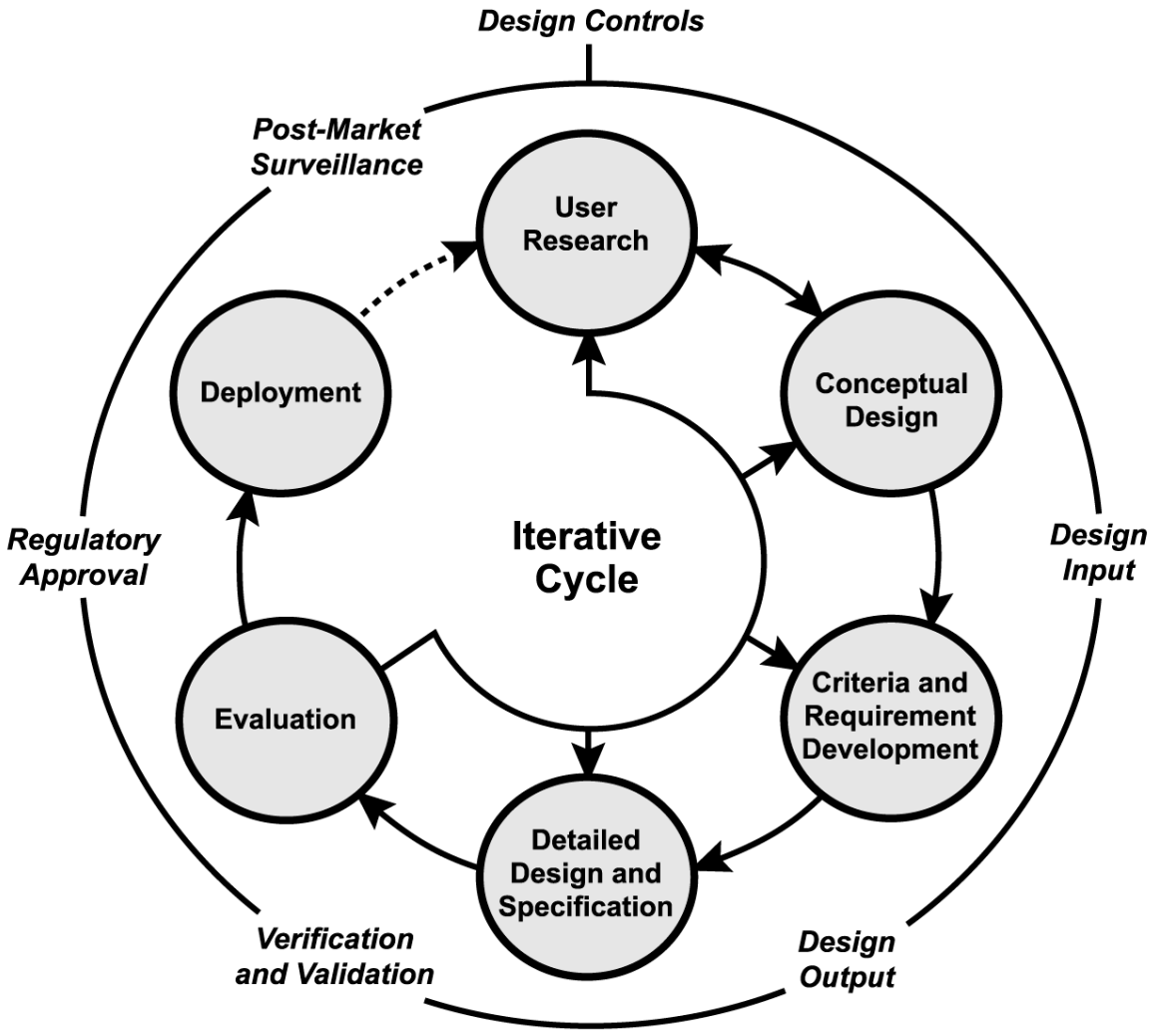

Figure 1—A human factors engineering user interface design cycle

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

For each step in the cycle, the HFE team must use evidence, judgment, and experience to determine the appropriate HFE activities and effort. Thus, a fundamental goal of this document is to provide guidance on how to make decisions about the nature and magnitude of HFE activities.

The same HFE tools and techniques may be successfully used at several different steps in the HFE cycle. For example, an analysis of the tasks a user performs when interacting with a device (i.e., task analysis) may be equally appropriate during early conceptualization of a new device, when developing specific device design criteria and requirements, and when evaluating a fully functional prototype. However, the type of task analysis employed *and* the method in which it is performed will likely vary to fit the specific goals of the HFE process at each of these steps.

4.1 Iterative nature of the HFE cycle

People who are familiar with systems engineering will appreciate the similarity of the depicted cyclical HFE process with other types of process or product development cycles. A fundamental attribute is that, as a product evolves throughout its life span, it will go through many such cycles. With respect to medical devices, particularly when one considers not only HFE activities but also other risk management and design control processes, every step in the cycle must be addressed at least once in any device development process.

Additionally, the HFE cycle depicted in Figure 1 emphasizes the iterative nature of the development process. Not only do the outcomes (or outputs) of one step feed (i.e., provide input to) the next step, but also, invariably, the output of some steps feeds back to prior steps. For example, during device evaluation, issues raised by design verification activities (i.e., ascertaining whether device design meets previously established design requirements) frequently lead to design changes. Similarly, issues raised during design validation activities (i.e., ascertaining whether the device adequately addresses established user needs) may precipitate subsequent modifications in design requirements or even in device conceptualization.

The description of the HFE process as a cycle of steps may give the misleading impression that user interface development is always a serial process. In fact, many of these activities commonly occur in parallel. Interaction between steps occurs frequently, rapidly, and often seamlessly. For example, in medical software design, an HFE practitioner may accomplish elements of design criteria and requirement development (e.g., usability goals), device design (e.g., rapid prototyping), and design verification (e.g., usability testing) concurrently.

Figure 1 suggests that the design cycle typically begins with user-driven design conceptualization (User Research and Conceptual Design; the two connected, upper-right steps). Whether one is considering a revolutionary new device or evolutionary modifications to an existing device, design conceptualization may be driven not only by user ideas or needs but also by entrepreneurial creativity or even new technologies searching for useful application. Practically, however, the HFE design cycle may be entered at any step. For example, the development of a new, more cost-effective manufacturing process may lead to proposed device design changes that affect user interface design specifications. In this circumstance, every step in the HFE design cycle is likely to be addressed, some steps perhaps more explicitly than others.

4.2 User research

Involving users at the earliest stages of device development is critical. For example, people with disabilities who use devices in their homes have special requirements that may be fully appreciated only after careful user research. User needs should be a primary motivating force behind both new product conceptualization and existing product enhancements.

User input can be obtained in a variety of ways, and HFE includes many structured tools and techniques to obtain this critical information effectively. A systems approach to medical device development, as advocated in this document, necessitates an understanding of how users will interact with the device in the actual use environment. This understanding can come only from user input and observation. Formal user testing in an actual or simulated setting is commonly an integral part of the medical device development process.

Efforts to get to know users better can be integrated with market research activities. However, market research often focuses on a broader set of issues such as the benefits of alternative feature sets, competitive pricing, and customer service. Additionally, most market-focused efforts to elicit user preferences (e.g., focus groups) are unacceptable substitutes for appropriately designed HFE testing and evaluation. However, marketing groups can facilitate relationships between prospective users and designers and engineers.

4.3 Design concept development (conceptual design)

The concept for a medical device can come about in many different ways. Most often, a clinical need is identified, and this need leads to a new or modified device that addresses the need. In many cases, a very broad need is identified, and substantial time and effort must then be devoted to developing this need into a concept that evolves into a commercially viable device.

During the earliest phases of design, user needs should be defined as clearly and specifically as possible—often a difficult task. Users may have difficulty articulating their needs precisely and sometimes do not really know what they need. The results of focus groups and user interviews can be misleading, causing designers to solve the wrong problems and meet perceived as opposed to actual needs. Therefore, other techniques for needs assessment such as observing the use of precursor systems in the operational environment are useful in validating the expressed user needs prior to design.

Case Study 1—Evolutionary development of pulse oximetry

Although the advent of new technologies can lead directly to a new medical device, more commonly, medical devices that evolve from efforts to address well-understood clinical needs are more successful than those that are technology driven. For example, pulse oximetry became commercially available in the United States in the mid-1970s. However, not until 10 years later, when the anesthesiologist's need for an easy-to-use, continuous, noninvasive monitor of oxygenation was recognized, did the pulse oximeter become a commercially successful medical device. Pulse oximetry's acceptance required manufacturers to have a sufficient understanding of the end user's needs before they could adapt the existing technology successfully, develop new enabling technologies, and design appropriate user interfaces.

In recent years, pulse oximeters have undergone evolutionary changes. Once again, these changes have stemmed from the appreciation of user needs. Manufacturers recognized that signal artifact (whether because of patient motion, peripheral vasoconstriction, ambient light, or mechanical factors) was responsible for significant numbers of usability and reliability complaints. As a result of this user input, a variety of design conceptualizations have evolved. Resulting design requirements have focused on reducing the effect of signal artifact, thereby improving reliability and reducing the number of false alarms. The software- and hardware-based design solutions have made pulse oximeters less motion sensitive, better able to detect signals under low-blood-flow conditions, or more resistant to ambient light and other factors.

4.4 Design criteria and requirements development

The development of design criteria and requirements can begin once user needs and the consequent concept of the device have been well defined. The design criteria/requirements define the intended operating conditions, user characteristics, functions, and potential hazards of the device. Typically, the design criteria and requirements, the embodiment of the design input, undergo substantial revision and refinement as the device design matures, progressing from rather general statements to highly specific and technical requirements.

Design criteria and requirement development requires substantial analysis to determine the sufficiency of possible design solutions as well as to address user needs, technical and manufacturing constraints, and market realities. The HFE team concurrently interprets user input, develops HFE requirements, and provides feedback to other engineers on the HFE implications of design decisions. The HFE team should play a critical role in decisions with respect to features and user interface attributes.

4.5 Detailed design and specification

The design requirements at the beginning of this stage must provide sufficient detail to allow hardware and software designers to create the desired product. Equally important, the requirements must include measurable test criteria that can be used to ensure that the resulting product will meet its intended user needs. Thus, as the design process proceeds, rigorous statements of desired device attributes are converted to engineering or software specifications that enable construction of these attributes, first in prototypes and ultimately, after design evaluation, in the final product. Throughout this process, the HFE team should work closely with engineers, industrial designers, and learning-tool developers. The resulting design specifications (see Table 2) are sometimes called the "design output."

An important role of HFE team members is to apply HFE technical information to the relevant human factors questions that inevitably emerge as the design is refined. In doing so, the HFE practitioner relies on published research or collects new data on human capabilities, limitations, and tendencies, both physical (e.g., anthropometry and biomechanics) and cognitive (e.g., error tolerances, reaction time).

Table 2—Examples of HFE specifications

General	Make sure read-only displays differ visually from displays that allow users to edit data.
	Read-only text will be displayed as black text on a white background, whereas text that can be edited will be white text on a black background display.
List boxes	Selected item in list box is highlighted by reverse video.
	Box must be long enough to view four choices without scrolling.
	All menus have a title.
Menus	Menu items are left justified.
	The upper left corner of the screen shall be reserved for the alarm silence indicator.
Displays	The luminance of the display will be greater than 35 cd/m^2. Contrast will not be less than 7:1.
Control devices	Control panel buttons will be 0.5" square with center-to-center spacing of 0.75".
	The keyboard will be adjustable in height, ranging (measured from floor) from 945 mm to 1190 mm.

Case Study 2—Public access defibrillators

Design concept development and user research. Even with increasing use of manual cardiopulmonary resuscitation (CPR), most people who suffer life-threatening arrhythmias outside the hospital do not survive. Early defibrillation is thought to be the key intervention to improve the survival rate. Therefore, the concept for public-access automated external defibrillators (AEDs) developed.

HFE methods such as context-dependent observation, prototyping, and error analysis were used in the design of AEDs. The first prototypes were designed through observing defibrillator use in context at fire stations. Storage and access were identified as key issues and were addressed in the first iteration of design requirements.

Design criteria and requirement development. Through research, HFE personnel determined that the units must be lightweight and portable (briefcase size), easy for people with minimal training to use, and appropriate for use in public facilities (airplanes, casinos, hotels, etc.).

Design evaluation. User input and observation on early prototypes detected problems such as misplacement of electrode pads and unnecessary defibrillation. People were timed doing rescues with different models and labeling (behavioral prototyping). It was discovered that labeling steps sequentially (i.e., 1, 2, 3) improved performance. Error analysis led to strategies to minimize errors such as forgetting to turn the device on or not fully connecting the electrodes.

Device implementation and deployment. Since AEDs entered the market, tens of thousands of units have been sold to airlines, police departments, hotels, casinos, schools, and hospitals. However, about one-fourth of the buyers may be individuals who carry them or have them at home. Sixth graders can use commercial AEDs successfully after only 90 seconds of instruction.

4.6 Design evaluation

Only structured evaluation of the resulting device design can ensure that the design is technically sound and that it also meets the user's needs. The former goal, ensuring that the design output meets the design input requirements, is often called *design verification*. The latter goal, which ensures that the design output addresses the user's needs and intended uses, is called *design validation*. Thus, all design changes must go through the design evaluation step to ensure that the required verification and validation activities occur. In essence, design verification and validation serve as the checkpoints for a good design.

Both validation and verification activities should be initiated early in the design cycle. For example, risk analyses should be conducted initially during design conceptualization, repeated (or refined) as the design evolves, and finalized during design validation. Other design validation activities typically require substantial user involvement.

For a device to be well designed, its instructions for use and labeling should be clear, be consistent, and help to reduce potential use error. Thus, device instructions and labeling should undergo the same rigorous evaluation as other user interface elements.

4.7 Design implementation and deployment

The only step in the cycle that is not solely a part of product development is device implementation and deployment. This step includes manufacturing, marketing, sales, and regulatory affairs. *Design transfer* refers to the use of final design specifications to manufacture (and obtain approval to sell) the device. Design changes occurring after design transfer that deviate from the design specifications require that the entire design go through the complete design cycle again.

Design evaluation does not stop after sale of the device. Postmarket surveillance and vigilance reporting provide critical data with respect to design strengths and shortcomings. Review of these reports and other types of user feedback brings the HFE aspects of medical device design full circle. The result is revised device designs and ideas for new devices that address the issues raised.

5 Planning the HFE process

5.1 Assuring adequate HFE involvement in the design team

HFE professionals should become involved at a project's inception, although the team and its role may evolve throughout the design and development process. Early in the design process, once the initial concept has been defined, the range of necessary HFE expertise can be identified, and personnel can be recruited. The HFE effort will differ depending on the type of device, its HFE requirements, and the company's organizational structure and culture. In some cases, the HFE "team" may consist of one experienced practitioner who concurrently participates in a number of projects. In other cases, a number of HFE practitioners are part of a multidisciplinary design team. HFE practitioners can be employees of the organization or outside consultants. Some organizations' HFE practitioners are autonomous, whereas others are embedded within another discipline's department (for example, marketing, engineering, industrial design, or software development).

The success of HFE efforts requires strong leadership to advocate appropriate HFE during development and to manage design efforts. More specifically, an HFE leader must be designated who is empowered by management and is able to work productively and pragmatically with related disciplines while still pursuing user interface design excellence.

In addition to including a person or people with HFE expertise, design teams are generally improved by including individuals who possess the following qualifications:

a) Are responsible for developing the learning tools that are integrated with or that accompany medical devices (for example, on-line help, user manuals, and quick-reference guides);

b) Are responsible for developing device training courses;

c) Can communicate with engineers and developers on a technical level;

d) Can build (or manage the building of) computer-based user interface prototypes; and

e) Can effectively communicate with the relevant user population(s).

5.2 Scaling the HFE effort

Similar to other elements of any engineering or design process, HFE warrants proper scaling. In all circumstances, the goal is to perform sufficient HFE to ensure the safety, effectiveness, and usability of the final product in a traceable manner.

More vigorous human factors efforts may be indicated if one is:

a) Developing a new device rather than making minor changes to an existing design;

b) Developing a device involving extensive or complex user interactions as opposed to a simple device involving simple user interactions;

c) Developing a device that performs a critical, life-sustaining function versus one that performs less critical functions; and

d) Introducing an entirely new technology or method that is unfamiliar to users, as opposed to one with which people are experienced.

Conversely, if a product requires limited user interaction, then substantially less human factors work may be warranted. When one is initiating an evolutionary development effort (i.e., modifying or updating an existing device), it may be appropriate to leverage past HFE efforts such as the results of usability testing or post-market surveillance. For example, presuming no changes were made to a device's alarm system and no changes occurred in the types of users and use scenarios, one could justifiably verify that aspect of the new device by citing past HFE work (e.g., prior usability testing). However, unrelated design changes may warrant HFE evaluation. Leveraging past HFE work is an appropriate but complex matter that poses a trade-off between the potential savings and the extra effort required to justify and document the decision.

Case Study 3—Designing minor modifications of a simple device

Consider minor modifications to the design of a simple device involving established technology such as a syringe pump. In addition to the requisite task of creating an actual user interface design, a responsive HFE program might also include the following activities:

— Conduct structured interviews (individual or group) with representative users with respect to not only the company's current device but also several competing devices.

— Review reports of adverse device events and revise the device's hazard analysis to identify human error risks that could lead to patient injury or death, as well as to property damage. Then, ensure that the proposed design addresses these kinds of errors.

— Apply established HFE principles and guidelines during the design process; then ensure compliance by conducting an HFE design audit.

— Conduct a usability test of an early prototype (computer simulation or working model) to determine whether the prototype meets safety and usability goals and to identify opportunities for design improvement.

— Conduct a second usability test to validate the refined, near-final design.

Notice that the primary theme of these activities is early and continued involvement of representative end users, although the actual number of users involved may be limited, at least in the case of a simple device.

Some devices perform a new medical function, combine functions from separate devices, or automate previously manual functions. The inherent complexity of a new product or system may require a relatively large-scale HFE effort. Generally, the HFE effort in products with new technology will be much more substantial than the effort involved in device modification—from the initial research to conceptualization through final validation. Also, there will typically be relatively little existing data (e.g., adverse events or hazard analysis information) from which to establish baseline conditions.

5.3 Documenting the HFE activities

HFE documentation should state precisely the requirements to be met and should be written in a language and manner most useful to the specification's end users, who are often engineers and software developers.

HFE should be incorporated into existing design control processes and addressed within the specification, design, documentation, and hazard analysis processes as appropriate. Documentation shall be generated and maintained in accordance with applicable standards such as ISO 9001, ISO 9002, ANSI/AAMI/ISO 13485, ANSI/AAMI/ISO 13488, and ANSI/AAMI/ISO 14971.

The U.S. Food and Drug Administration (FDA) rules for Current Good Manufacturing Practice (CGMP) for medical devices are compatible with the design control requirements of international quality systems standards (see annex B). Thus, a manufacturer that complies with the CGMP requirements also meets the design control requirements of these other standards.

Early in a project, an HFE plan should be initiated and documented. The plan should be updated as needed throughout the project. A typical HFE plan might include the following:

a) Scope;

b) Key user interface design issues;

c) Planned HFE analyses and studies;

d) User interface design process and planned use of HFE tools and techniques (e.g., observational studies, usability testing, design reviews);

e) Use of national, international, or corporate user interface standards and guidelines (e.g., ANSI/AAMI HE74);

f) A method for tracking and resolving HFE issues;

g) HFE deliverables (see Table 3);

h) Schedule and milestones; and

i) Personnel and required resources.

At the conclusion of a project's HFE activities, the project file should include the HFE plan, documentation of the HFE design criteria, hazards to be mitigated by means of the user interface, a description of the user tests performed, results of the tests, and the final user interface specification. Other documents, notes, review records, videotapes, completed questionnaires, and preliminary design mock-ups often are also included in the project file.

Case Study 4—Initiating the design of a complex device that incorporates new technologies

Consider the development of a mammography unit for taking breast X-rays. Such a system contains mechanically driven paddles for positioning the patient's breast and a number of controls and displays for setting various X-ray parameters and actuating the device. The development of such a system might involve the following steps:

— *Conduct a thorough requirements development effort, including appropriate research (e.g., task analysis) on device performance characteristics, user populations, operating environment, reliability, and safety issues.* Individuals from the intended use population (technicians, patients, and physicians) should be involved in this effort and in all successive testing. If possible, interviews and observations should be conducted in the intended environment of use. Also, relationships with other devices must be considered. At this stage, the HFE practitioner or team should have a detailed specification of the user interface requirements and a preliminary, step-by-step summary of the procedures that will be carried out.

— *Determine allocations of functions between operators and equipment to ensure that division of labor between manual and automated tasks is consistent with both human and machine capabilities.* In the example of the mammography system, important tasks would be to determine what aspects of the procedures would be automated, where manual overrides are necessary, what type of feedback users need at what stage of the process, and so forth. The result might be a list of functions accompanied by a specification of how each function is controlled and what form of information is to be provided at each stage of the various processes.

— *Conduct a complete risk analysis that incorporates the risk of use error, and develop design solutions to prevent or mitigate the risks that are identified.* A prudent assumption is that every possible mistake will be made by some users some of the time. This analysis should be updated throughout the development process.

— *Conduct a full-scale design and development effort, using the design and evaluation techniques described in sections 6 and 7.* These techniques include modeling, performing task analyses, prototyping, and conducting usability tests. Using iterative design and simulation can prevent costly retrofits later. Low-fidelity models are typically used during concept and early development work to examine alternative design concepts. As development progresses, prototypes of increasing fidelity facilitate cost-effective design evaluation. In this X-ray system example, one might initially create static screen simulations of the controller interface and rough physical mock-ups of the system. Early stage evaluation might include hypothetical walkthroughs with users in the intended use environment. However, as the designs of the various components become more refined and the prototypes more realistic, verification research should progress to more objective usability testing. Here, a technician might be given a series of tasks to perform on a touch-screen prototype and/or a working mock-up of the system. The results of all evaluations should be incorporated into the next design iteration so that errors are eliminated and users require less instruction.

— *Computerized prototypes are especially valuable for testing alternative user interface designs before the production of operational models.* Designers normally prefer to use rapid prototyping tools for software interfaces. The faster that prototypes can be created and modified, the more likely it is that user test results will have a real effect on the product's design.

— *Once high-fidelity prototypes or early production models are available, validation tests are performed to ensure that the device meets the users' and patients' needs.* At this point, users should be able to safely and efficiently proceed through each required step; for example, positioning the patient, setting the X-ray parameters, taking the X-ray, repositioning the breast for the next X-ray, and so forth.

Table 3—Typical deliverables

Design control component	HFE process step	Example deliverables
Design conceptualization	User research	HFE plan User profiles, task analyses, descriptions of use environments HFE analyses of precursor systems
	Design concept development	System usability requirements (goals) Usage scenarios, storyboards
Design input	Design criteria and requirement development	Use error analyses User interface design requirements
Design output	Device design and refinement	User interface models, prototypes User interface design specifications
Design verification and validation	Design evaluation Device implementation and deployment	Usability testing reports HFE inputs to design change requests

6 The HFE process: A systems approach

The HFE process recognizes that every medical device is part of a larger complex system (see Figure 2). At a minimum, these systems include the physical environment where the device is used, the device users, the patient, and other devices or ancillary equipment. A thorough understanding of the system of which the device is one element is integral to the HFE process. The relationships among system elements, first considered early in the design process, is essential to planning subsequent HFE efforts, especially design evaluation.

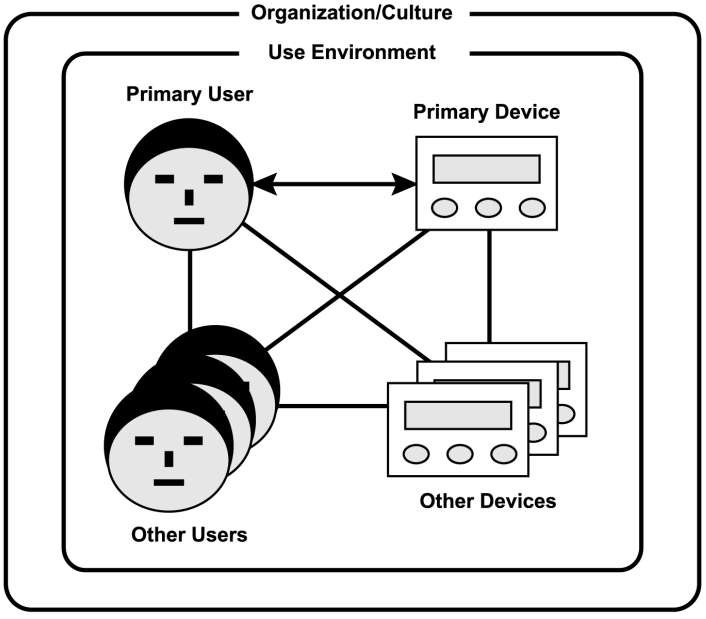

Figure 2—Medical device systems

All medical devices must be considered within the context of the larger system in which they are used.
This system includes the user, patient, other devices, the immediate environment of use, and the larger organizational milieu.

Early in the HFE process, the system elements that will be considered in the design should be defined. Broader system definitions tend to produce devices that better meet actual system needs. Also, broader system descriptions are more likely to result in devices that are revolutionary as opposed to evolutionary. However, in many design projects, broad system definitions may be impractical or unnecessary.

Case Study 5—Infusion pumps

Infusion pumps regulate the volume and rate of fluid or medication delivered to the patient and notify care providers of events or problems in the process. Depending on where the system boundaries are drawn, other system elements might include the care providers who use the device, the patient, patient visitors, other patients, related devices (e.g., tubing sets), other equipment such as physiological patient monitors, and the physical environment (which is relevant to device design because of issues such as illumination and noise level). If an evolutionary infusion pump is being developed (e.g., one with modified controls, displays, or functions), it may be unnecessary and impractical to define the system this broadly. However, a device that would revolutionize the fluid medication delivery system in hospitals would require thorough examination of all system elements, which could include hospital pharmacy practices, drug labeling, and even drug distribution methods.

Under these circumstances, the boundaries of the system might include the prescribing physician, the pharmacy, the transcriptionist, other hospital personnel (e.g., aides, bioengineers, maintenance personnel, technicians), hospital administrative procedures, the social and cultural environment of the people in the system, and the cultural environment of the hospital. One might even include other device manufacturers and the services they provide, the patient's visitors, and drug manufacturers, because their products and actions affect or define system elements.

Fundamentally, the HFE process is a user-centered process. That is, it is driven by users' actual needs and is based on the premise that the user is always a critical element of the system. At a minimum, research should evaluate how a person uses, or might use, a device in a specific clinical setting (e.g., a doctor's office, home, or emergency department). Research should also evaluate the anticipated environments of use, such as where a caregiver administers treatment, where the device is maintained, where support personnel interact with a device (e.g., a transporter in an elevator), or where the patient uses the device.

HFE research generally addresses one or more of the following concerns:

a) *Function.* What function or functions does the device perform (e.g., how does this device augment the caregiver's abilities to care for the patient)?

b) *Users.* Who will use (both directly and indirectly) the device and/or its data? This question includes consideration of the cultural, sociological, educational, and experiential characteristics of the potential users. If the device is to be used by a team of people, then issues include effects on team function and team training.

c) *Context of use.* In what clinical use environments will this device operate? What are the characteristics of each of the potential use environments (e.g., home, urgent care center, hospital ward, or operating room)? What other devices are commonly used in this clinical environment, and how might the use of this device affect the use of these other devices?

d) *Workload.* What are the cognitive and/or physical efforts associated with using the device?

e) *Safety.* What attributes of the system could compromise safe device use? How will other devices within the system affect device safety?

f) *Use and misuse.* What attributes of the system would prevent misuse, provide guidance, and allow for easy and safe correction if misuse occurs?

A concerted effort should be made to consider as many use environments as possible. It is important to consider that the range of use environments typically expand during the product's life span. By anticipating additional use environments, companies can reduce the need for expensive redesign, enhance marketability, and yield substantial long-term savings. For example, many devices designed for hospital use are now also being used in the home, often without the manufacturer's knowledge or intent. When devices are used in ways that fall outside the scope of the original design, safety and usability can be seriously compromised.

6.1 User input

User input must be part of an iterative process that begins in the early design phase and progresses throughout the design cycle. Considering user input early in the design process may prevent costly design errors. User involvement should include both end users and maintainers as well as patients and patients' families, when appropriate. Subjective data from users should include their ideas on features and appearance, as well as feedback on how the device could be made safer, more usable, and more effective. Both positive and negative reactions to the device should be sought. Objective data is generally superior to anecdotal opinions because it aids follow-up testing, ensuring design improvement. Examples of objective (i.e., measurable) user input include user performance problems, issues identified by field or customer service personnel, reported error incidents, and the results of laboratory tests of user performance.

A solid understanding of users' characteristics, capabilities, needs, and preferences is key to designing for safer and more effective use. There are many ways to obtain this information (see also section 7) including:

a) Collecting user interface-related information and opinions;

b) Unobtrusively observing people performing the relevant tasks associated with the device or a similar device;

c) Discussing design issues with small groups of users with the goal of generating ideas or reaching consensus;

d) Conducting formal studies of users performing relevant tasks under actual or simulated conditions; and

e) Reviewing HFE technical information.

6.1.1 Sampling users

User research activities should involve people who accurately represent the user population. For example, a development team modifying an existing ventilator might gather design input from nurses, respiratory therapists, and physicians who treat ventilated patients. User populations typically vary across multiple dimensions such as age, gender, physical capabilities, experience, and expectations, as well as across social standing and geographic location. If appropriate sampling strategies are used, results from the subject population are likely to generalize to the final user population. The appropriate number of subjects depends on the objectives of the research, the diversity of the user population, the complexity of the issues to be addressed, and the desired level of confidence in the findings.

6.1.2 Research protocols and informed consent

The goals of the user research will dictate the research methods. User research may range from broad information-gathering processes, focused brainstorming, problem-oriented sessions, or more rigorous, hypothesis-based approaches. Regardless of the approach, the use of written scripts or other structured guidance documents will ensure a uniform process and enhance resultant data quality. Research protocols are usually desirable and are sometimes a legal requirement. The protocol typically stipulates the rationale for the research, the nature of the subject population, the methods to be employed, and how the resultant data is to be analyzed and interpreted.

Subject consent should be obtained if any risk of injury exists, if the research makes appreciable time or other demands on the subject, or if the results may appear in a peer-reviewed publication. Under some circumstances, state or federal regulations may require oral or written informed consent of subjects. Federally funded research must comply with Title 45 of the *Code of Federal Regulations* (CFR), Part 46 for the protection of human research subjects. Additionally, FDA regulations stipulate that studies involving human subjects abide by 21 CFR, Parts 50 and 56, pertaining to informed consent and standards for Institutional Review Boards (IRBs), respectively.

6.2 Design criteria and requirement development

Analysis of user input, observation, and research can identify user needs. An accurate needs assessment not only is critical to successful design criteria and requirement development but also ultimately influences commercial success. Establishing user interface design requirements helps place HFE considerations on an equal footing with other engineering considerations because documented goals carry greater weight. Moreover, it helps to focus the design process, aids trade-off decisions involving other disciplines, and establishes criteria for design acceptability.

Initially, design requirements may be in the form of broad and general vision statements, but as the design progresses, requirements become more detailed and specific. Iterative refinement of design requirements permits evolution of the design. Some requirements will be expressed as system usability goals such as ease of use and ease of learning (see Table 4), whereas others will address more detailed design components such as display brightness, portability, or durability (see Table 5).

Table 4—Examples of objective and subjective system usability goals

Objective	Subjective
80 % of users shall successfully calibrate the device within 5 minutes on their first try.	Two-thirds of users shall prefer the next generation infusion pump to the existing device upon programming a single channel infusion.
After reading the quick reference guide, 90 % of users shall be able to configure the display correctly to show two ECG lead traces on the first try.	On average, 80 % of users shall rate the monitor's display as easy to read (as 5 or better on a scale of 1 to 7, with 1 = very hard to read and 7 = very easy to read).

Table 5—Examples of detailed user interface design requirements

The display shall be visible at a distance of 25 inches to three people standing side by side, with all able to detect color and read text.
The system, when being carried, shall have no edges, corners, or protrusions that catch on stockings or other clothing.
The system shall be capable of producing a loudness of 85 dBA as measured 4 feet in front of the system.
The stylus shall activate software controls on the screen when used at an angle between 20 and 90 degrees.

User interface requirements are ultimately expressed in the form of explicit design specifications that may incorporate subjective or objective performance measures (see Table 2). Detailed usability requirements should be measurable and should be based on attributes that are important to users and safety. So that requirements are realistic and credible, performance criteria should be based on the results of benchmark usability testing of comparable products, a detailed estimate based on experimentation, or a working hypothesis. However, requirements based on estimates or hypotheses must be modified as appropriate during ongoing, iterative design and evaluation, and must take into consideration users' actual needs in the intended use environment.

6.3 Device design

No single best method has been formed for transitioning from developing user interface design requirements to achieving an effective design solution. A great deal depends on the designer or design team's capabilities and the type of device. Moreover, user interface design has a creative aspect that defies strict definition and control.

During the design stage, studies may be needed to make informed decisions about discrete design elements. For example, one may appropriately compare cursor positioning devices to select the best one for use in conjunction with an ultrasound workstation, or one might conduct a comparison study of handgrips on surgical instruments to determine which one is the most comfortable or enables the most precise movement.

6.3.1 Structuring an approach to design

The effective design team will commit to a structured approach. Elements typical of a structured approach include the following:

a) Consideration of several design alternatives. For example, design teams may start with a dozen or more user interface design concept sketches, select as many as five concepts for more detailed consideration, and model and test two or three concepts before converging on a final, preferred design. The initial consideration of several design alternatives, including some that might seem quite radical, is key to innovation, particularly when developing a next-generation device.

b) Development of simple conceptual models of user interface elements and of user-device interactions. Such models give designers a conceptual reference point that ultimately helps limit design complexity (e.g., Figure 3 demonstrates how a device's user interface may be modeled at the highest level as five basic elements: three major functions, a menu system, and a set of quick actions).

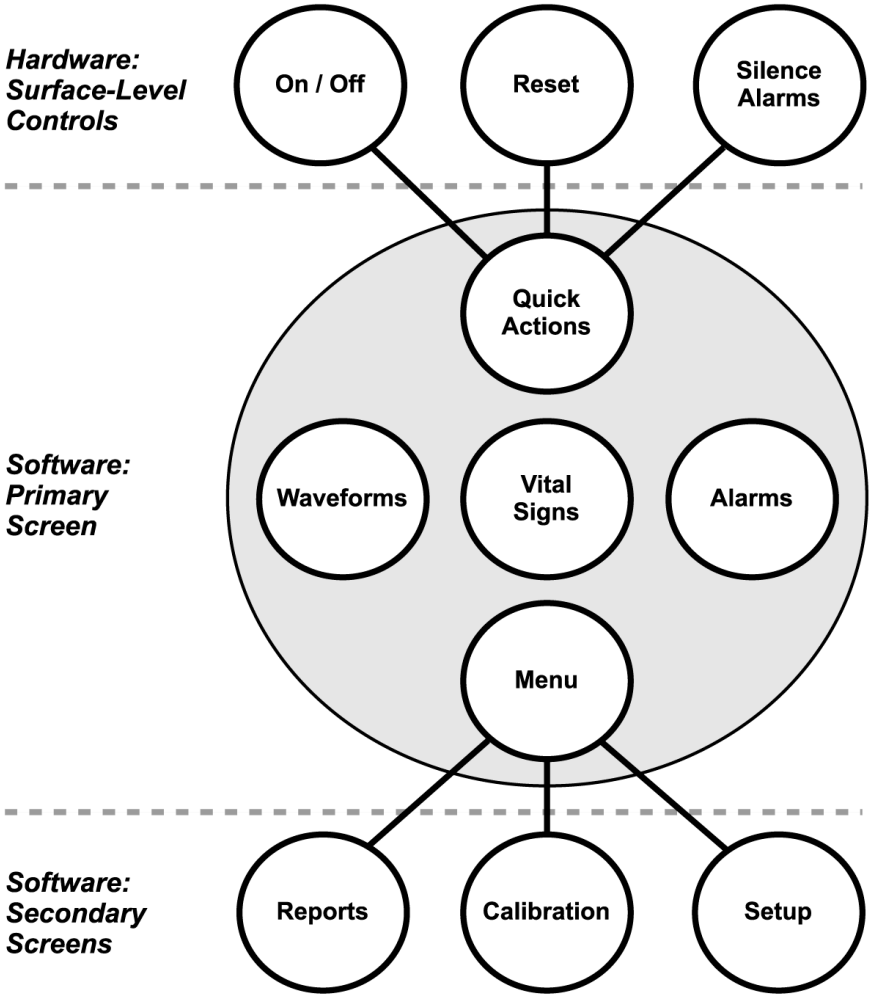

Figure 3—Bubble diagram of the conceptual model of a physiological monitor

c) Prospective application of established design principles and practices (see applicable sections of ANSI/AAMI HE48) as appropriate. Preventing a design flaw is easier and more practical than correcting a flaw that was uncovered in a retrospective design evaluation.

d) Consideration of task frequency, urgency, and criticality as a basis for making human–machine and hardware–software task allocations, as well as decisions about display and control organization and layout. These decisions require a thorough understanding of how the device actually will be used.

e) Enforcement of established design requirements to avoid inappropriately compromising user interface quality for the sake of other engineering goals.

f) Construction of user interface models (see 6.3.2) such as interactive prototypes to enable realistic usability tests and other evaluations involving end users.

g) Use of iterative testing to select a preferred design concept and then to refine it.

h) Involvement of end users throughout the design process.

6.3.2 Modeling the user interface

Modeling the user interface at different levels of fidelity during progressive design stages is useful (see Table 6). Modeling should be built early and continuously throughout the design process as a basis for collecting end-user feedback and evaluating the success of the design. Early in the design process, sketches, simple block models, or low-fidelity, computer-based renderings or interactive simulations (also called prototypes) are usually sufficient. Later in the process, it may be appropriate to work with refined renderings, appearance or working models, and high-fidelity, computer-based simulations. Figure 4a shows a computer-based simulation of an operating room ventilator, and Figure 4b shows the actual commercial product.

Table 6—Examples of user interface modeling techniques

Technique	Description
Bubble diagram	Illustration of a user interface's conceptual model, with bubbles representing device functions and connecting lines to illustrate interrelationships (Figure 3)
Block model	Low-cost, unrefined physical model, typically constructed of a uniform material (i.e., high-density foam) that has little detail
Appearance model	Nonfunctional, physical model of the device that looks and feels real
Storyboard	Set of screen printouts that illustrates one or more task scenarios
User interface prototype	Functional, computer-based simulation of a device's user interface that enables representative users to perform realistic tasks
Working model	Functional, physical model of the product, which may or may not match the final design, that enables representative users to perform hands-on tasks
Device prototype	A near-final, working version of the device that can be used for its intended purpose

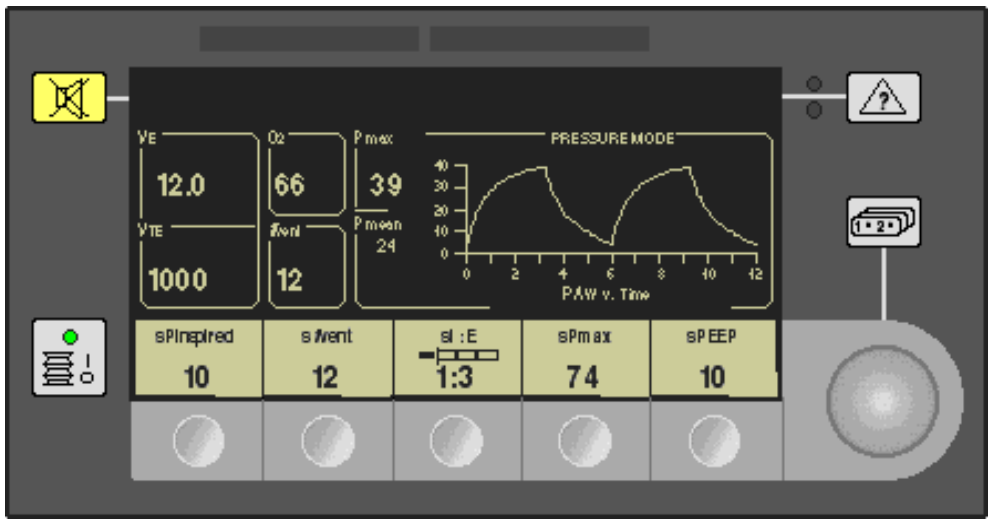

Figure 4a—Computer-based simulation

Courtesy of Datex–Ohmeda.

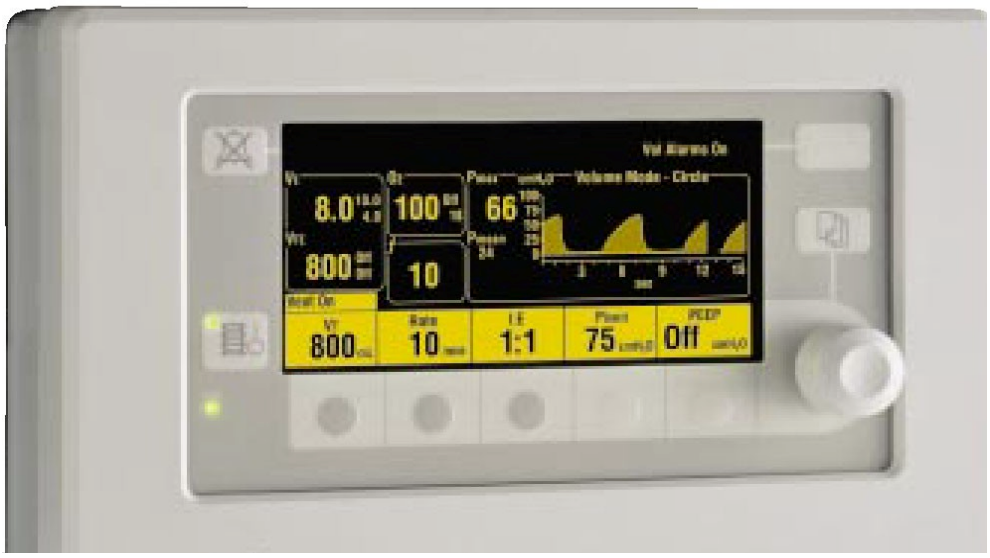

Figure 4b—Commercial product

Courtesy of Datex–Ohmeda.

When modeling a software user interface, it is useful to start with a usability test plan that delineates, among other things, the type of end-user feedback desired (see Table 7). For example, one may be most interested in how well prospective end users perform a set of urgent or frequent tasks. In this case, it may be most valuable to develop a partially functional prototype that enables users to perform only the tasks of interest.

Table 7—Characteristics of a typical usability testing effort

Test plan content	Logistics	Activities	Data
Purpose	Testing room (lab)	Orientation	Task times
Setting	6–8 participants	Self-exploration	Significant errors
Participants	1–2 staff	Directed tasks	Ratings
Staffing	2-hour sessions	Interview	Rankings
Recruiting activities	Videotaped		Verbal comments and questionnaires
Data collection			Videotapes
Data analysis			Photographs
Reporting			

An evaluation of hybrid devices that have both hardware and software components may warrant building a physical appearance model (i.e., a realistic-looking, three-dimensional model of the medical device) and an interactive, computer-based simulation.

6.4 Design specifications

A comprehensive and detailed user interface specification helps ensure user interface quality by reducing the chance that members of the development team will misinterpret design requirements. User interface specifications should be controlled and enforced with the same rigor as other kinds of engineering specifications.

The HFE team must carefully review proposed design changes resulting from engineering and manufacturing constraints to determine their potential effect on usability or safety. When significant HFE concerns arise, the relevant decision makers should have a candid discussion of issues and tradeoffs before any design changes are implemented.

6.4.1 Hardware user interface specifications

Specifications for the design of a hardware user interface might include the following:

a) A control panel layout drawing that shows the appearance and arrangement of device displays and controls. Such drawings are usually augmented by a written rationale that covers topics such as functional grouping, protection against accidental actuation of controls, and viewing angle considerations.

b) An anthropometric analysis diagram (a graphical analysis of the physical relationship between the device and individuals of varying size), which establishes the design's physical suitability for the intended user population.

c) A description of expected user interaction with the displays and controls (e.g., how controls and displays will change as a result of system events and user actions).

6.4.2 Software user interface specifications

Specifications for the design of a software user interface might include the following:

a) All screen and window layouts, including labeling, fonts, use of color, and graphics;

b) The appearance and behavior of all on-screen controls;

c) All dialog flow, including audible events;

d) All hard-copy report designs; and

e) A description of expected user interaction with the displays and controls (e.g., how controls and displays will change as a result of system events and user actions).

6.4.3 Other useful HFE tools

In the specifications for a user interface design, it may also be useful to produce the following:

a) A conceptual model diagram that illustrates a user interface's high-level structure (see Figure 3);

b) A user interface map—an illustration (typically a flowchart) showing the relationships among various screens;

c) A screen template—a generic layout for the computer screens;

d) A storyboard—a set of software screen printouts that may be cross-indexed to templates and written specifications; and

e) A style guide—a set of written rules that ensure consistency by governing the graphical composition of screens and means of interaction.

It is increasingly common to augment traditional, written specifications with physical simulations of the user interface such as appearance models and/or computer-based models. Microprocessor-controlled devices are particularly amenable to the use of functional prototypes. In this case, an interactive model of the device may include both a computer-based simulation of a screen-based user interface and the physical attributes of the proposed device (e.g., a syringe infusion mechanism for an infusion pump). It is useful to employ software tools that aid rapid prototyping to allow changes to be made at low cost.

6.5 Design evaluation

The products of each design activity shall be assessed throughout the development cycle. These activities are iterative and cumulative, and they should be applied to all interfaces (e.g., software, hardware, documentation) for all types of users (e.g., end users, maintainers, installers). The result will be a working model that will be subjected to final validation testing. The difference between verification and validation is that verification ensures that the design meets design requirements, whereas validation ensures that the final production model addresses the intended users' needs.

A comprehensive design evaluation shall be completed before finalizing the design. Typically, there is pressure to freeze a design prior to detailed engineering and software coding. Once the design is frozen, significant design changes are disruptive, time consuming, and costly. For example, unless a serious safety hazard was uncovered, a manufacturer would have difficulty justifying the cost of a major change to a control panel (e.g., rearranging or adding pushbuttons) after ordering expensive tooling. More likely, the specified design would remain frozen, and other options would be considered to address usability concerns, including special labeling, comments in the user documentation, or additional training. However, these types of fixes are often ineffective and are always less desirable than getting the design right the first time.

6.5.1 Design verification

The work products and other descriptive materials that characterize the design should be tested against criteria derived from the design requirements. These products, which can include drawings, task descriptions, mock-ups, and dynamic computer representations, serve as tools in task, storyboard, and heuristic analyses as well as in mock-up reviews and usability tests. Identified potential errors and/or device failures must be integrated into hazard analyses.

Without repetitive evaluation during development, the trial-and-error aspects of development will not be sorted out until product validation (discussed in the next section). During tests of production models, insufficient attention to verification activities may become apparent in the form of unsafe, inefficient device installation and operation (i.e., critical errors, performance bottlenecks, and slow task performance). The cost of correcting problems identified during verification will be much less than the cost of retrofitting production models.

Seemingly minor design changes can have a significant effect on ultimate device performance. Any significant design changes should be incorporated into revised risk analyses to ensure that such changes have not introduced any additional hazards.

The results of these evaluations often lead to design requirement refinements and will promote informed design decisions involving issues such as:

a) the allocation of functions to users, software, and hardware;

b) the logic, flow, and intuitiveness of task steps given the hardware–software user interface;

c) any design characteristics that could allow or induce errors;

d) potential hazards and alternative design solutions;

e) tasks that are overly time consuming;

f) markings or displayed information that are difficult to comprehend or are subject to misinterpretation; and

g) safeguards against reasonably foreseeable misuse (unintentional or intentional).

6.5.2 Production unit validation

Evaluation of production units must use methods to ensure that the device meets user needs and intended use (i.e., design validation). Testing may be conducted under actual or simulated conditions. The resulting data (e.g., task time, errors, observed bottlenecks) should pertain directly to safe, efficient performance. Normally, the device is evaluated before actual use on patients, although additional data may be gathered during clinical trials. Later field testing with marketed devices can provide useful feedback about design strengths and weaknesses.

During validation, all functions, rather than individual functions and their related user interface features, are scrutinized. Given a thorough verification effort, the user interface design will likely be substantiated during final validation. However, subtleties in operation that were not apparent during verification may emerge in final testing. Given a design based on a structured HFE approach, problems uncovered during validation are usually relatively minor and the required design changes modest.

7 Methods and techniques used in the HFE process

Many techniques, tools, and methodologies have been developed to help HFE practitioners design safer and more usable devices. No single method is best in all situations, and several different ones are typically used during device design. Decisions about which methods should be used at what stages in the design cycle are based on the HFE issues of the design and can best be made by HFE professionals. Methods that generate objective, auditable data is preferred. However, both objective and subjective data are important to a comprehensive understanding of a design's successful and less successful attributes. Regardless of the methods, the results are credible only when research participants are representative of the people who will perform the task(s) under evaluation. The following section briefly describes major HFE techniques and methods. For more information, please see the bibliography in annex E. These approaches can be used in addition to obtaining relevant data from the technical literature and applying it intelligently to a given problem. The techniques are listed alphabetically.

7.1 Cognitive walkthrough

Cognitive walkthroughs involve a structured review of user requirements for the performance of a sequence of predefined tasks. A cognitive walkthrough early in the design process permits evaluation of different preliminary design concepts. Later in the design process, when designs have become better defined, a cognitive walkthrough may still be productive (Nielsen, 1993).

7.2 Contextual inquiry and observation

Contextual inquiry generally involves unobtrusive observation of users performing relevant tasks associated with the devices or similar devices in the actual use environment (Brown, 1996; Holtzblatt and Jones, 1993). Observing and working with users in their normal environment permits a better understanding of the relevant tasks and workflow. This method is typically used early in the design process (during problem identification, requirements analysis, and device conceptualization) to understand users and their tasks. This technique generally does not reveal cognitive processes, attitudes, or opinions.

7.3 Design audits

In a design audit, the proposed attributes and components of the user interface are compared against a checklist of good design practices. The checklist itemizes characteristics that the user interface should possess along with some method of recording whether or not the interface meets the listed standards. Design audits are relatively quick and cost-effective but may yield only a superficial understanding of user interface issues.

7.4 Device comparisons and functional analysis

Alternative devices or alternative device concepts can be compared by arranging a list of devices and their attributes in a matrix format. Attributes of each of the device alternatives are assigned ratings or scored on a series of criteria. These comparisons can be useful for understanding which design approach best meets user needs. For example, one might develop a matrix of showing physical attributes (e.g., weight, dimensions, texture) of several comparable devices to aid cross-device comparisons.

7.5 Expert reviews

Expert reviews depend on the knowledge and experience of HFE specialists to identify design strengths and weaknesses and to recommend opportunities for improvement. An expert review can be performed on design-concept sketches and on working prototypes. Many serious design flaws can be detected early and without incurring costs for user testing. However, if used in isolation, this technique is unlikely to detect all of the design flaws.

7.6 Functional analysis

A functional analysis provides a representation of the functions and events required to meet system objectives. For example, important functions for brachytherapy are clinical evaluation, patient preparation, treatment planning, treatment delivery, posttreatment device removal, communication, record keeping, quality assurance, and maintenance (Callan et al., 1995). This type of analysis is used to determine the appropriate allocation of functions to humans vs. machines. Numerous types of functional analyses can be performed, including operational sequence diagrams and the Functional Analysis Systems Technique (FAST), as well as computer simulation and modeling techniques such as Systems Analysis of Integrated Network of Tasks (SAINT) (Laughery and Laughery, 1987; Sharit, 1997).

7.7 Heuristic analysis

Heuristic analysis is the evaluation by clinical or human factors experts of a device or system through the assessment of how it conforms to well-established user interface design rules (Nielson, 1993). It is particularly useful early in the design process for identifying problematic aspects of the user interface. Also, it is useful for comparing potential interface designs because the assessments for each rule can be compared across products. This method is usually quick and inexpensive. The weaknesses of heuristic analysis are that, generally, it is *not* applied in the actual use environment, and typical device users are usually not involved in the evaluation. Heuristic analysis often yields excellent design insights early in the development process. However, it should be used in conjunction with other techniques that acquire input from device users, especially when used later in the design process.

7.8 Interviews

Often, it is useful to discuss design issues with a small group of users, especially when the goal is to generate ideas or reach consensus. Interviews can also be conducted individually. This method is for information gathering, not for evaluation. Structured (or directed) interviews are useful in circumstances in which the goal is to uncover answers to specific questions, often when designers are fairly well along in the design process. In contrast, unstructured interviews are useful for gaining initial insights about designs under conditions in which the designer wants to avoid biasing the interviewee in any particular direction (Drury et al., 1990; Sinclair, 1990).

7.9 Participatory design

Participatory design involves providing potential users with tools that allow them to “become design team members.” Examples of the many tools available (Schuler and Namioka, 1993) include three-dimensional models of components that users might be asked to arrange in a preferred configuration, or two-dimensional representations that users arrange to represent their ideas about a product’s design. Similarly, users could be asked to direct the efforts of an illustrator to represent their ideas, or to manipulate options on a computer screen.

7.10 Prototyping

Prototyping involves creating device models that can be used in various evaluation activities. Models may vary from “looks-like, works-like” prototypes with a high degree of fidelity to the final product to low-fidelity, rough simulations that demonstrate only a subset of device attributes. Examples of simulation and prototyping methods include screen simulation software prototyping tools, physical models that are tethered to a computer, and physical models with embedded microprocessors (Ellis et al., 1997; Wiener and Nagel, 1988).

7.11 Questionnaires and surveys

User interface-related information and opinions are commonly collected by means of the telephone, the Internet, or written forms (Meister, 1985). One benefit of this technique is that data can be easily and cost-effectively collected from many users. This technique can be used early in the design process for broad user studies, during other testing to obtain subjective information, and later to collect evaluations of a fielded product.

7.12 Simulated clinical environments and field testing

Simulated clinical environments permit device evaluation in a controlled manner in a setting containing some or all of the essential attributes of the actual clinical environment for which the device is being designed. Simulations aid creation of worst-case scenarios and complex failures. High-risk devices or those involving more complex tasks may be tested in high-fidelity simulators such as a full-scale, simulated operating room (see Figure 5a) with manikin (see

Figure 5b). High-fidelity simulation allows the design team to evaluate dynamic interactions among multiple devices, personnel, and task constraints.

Ultimately, every medical device is "field tested" when it is marketed. However, usability issues raised at that time can adversely affect commercial success. Field testing of prototypes or preproduction models in the actual environment, although less controlled, is almost always informative. Although field testing may be most valuable for complex devices that demand extensive interactions with multiple users and other devices, even field testing of relatively simple devices can reveal unanticipated interactions, usability issues, and use errors (Ellis et al., 1997; Wiener and Nagel, 1988).

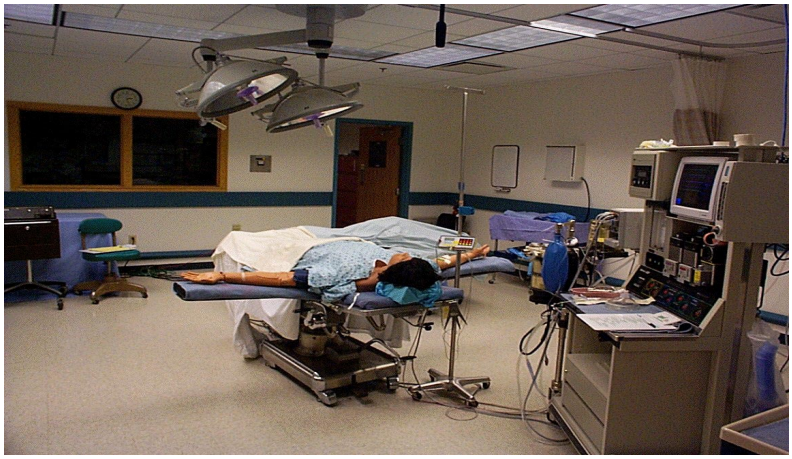

Figure 5a—Simulator with adjacent observation room

Courtesy of the Center for Medical Simulation, Boston, Massachusetts.

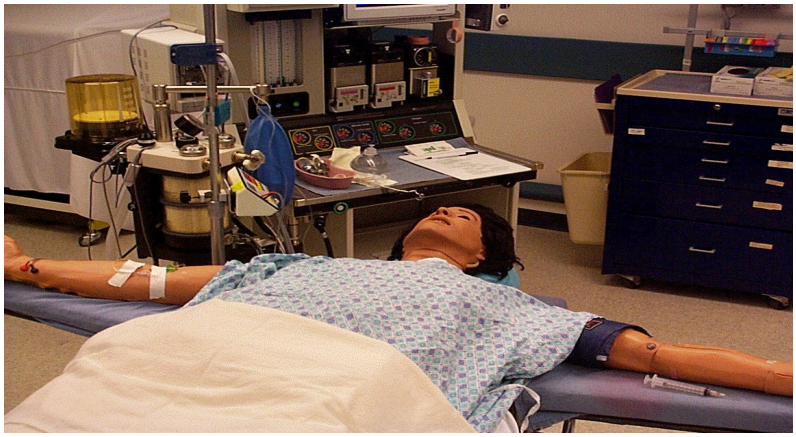

Figure 5b—Instrumented manikin

Courtesy of the Center for Medical Simulation, Boston, Massachusetts.

7.13 Task analysis

Task analysis is a family of systematic methods that produce detailed descriptions of the sequential and simultaneous manual and intellectual activities of personnel who are operating, maintaining, or controlling devices or systems. Task analysis can yield information about the knowledge, skills, abilities, and hazards associated with the completion of relevant tasks. Task analysis can be used as early as design conceptualization to aid understanding

and subsequent reengineering of an entire process. Later in the design cycle, task analysis can be used to evaluate a device prototype in actual or simulated use environments. The limitations of task analysis are that it can be time consuming, and the large amounts of data that can be generated are sometimes difficult to analyze and interpret (Fleishman and Quaintance, 1984; Kirwan and Ainsworth, 1992).

7.13.1 Time-and-motion studies

Time-and-motion studies, one of the earliest HFE techniques, document people's discrete actions over time. The technique can be used to identify interferences and opportunities for streamlining, to determine if actions can be completed within established time constraints, or to examine the effect of a device's use on processes and procedures (Loeb et al., 1993; Meister, 1985; Jonassen et al., 1989).

7.13.2 Cognitive task analysis

Cognitive task analysis focuses on users' cognitive processes such as their mental models of device or system operation (Cooke, 1994; Klein et al., 1993). This technique provides a formal evaluation of the cognitive demands placed on users as they perform the tasks that the device will replace, supplement, or require. Cognitive task analysis can also be used to evaluate how using the device will change how users think about the processes involved. In a related technique, cognitive modeling, task performance is predicted on the basis of an analysis of the basic task requirements, the capabilities of the person performing the task, the methods available to perform the task, and the process by which a user would select one of the available methods.

7.14 Usability testing

In usability tests, actual users interact with one or more device models, prototypes, or production units to assess ease of learning, ease of use, efficiency of use, ease of remembering, and user appeal (Nielsen, 1993). Usability tests can be performed in a laboratory setting, in a simulated environment, or in the actual environment of intended use. Usability testing, especially when conducted in the field, can detect use errors. However, because the subject populations are small, low probability errors may not be detected. For this reason, the use of additional techniques such as risk analysis (see 8.1) is essential.

7.15 Use error analysis

User interface designs should be evaluated throughout device development to determine the likelihood of specific use errors that could lead to reasonably foreseeable misuse, injury, or death. Analysis can include review of relevant vigilance reports, incident reports, adverse event reports, customer complaints, MedWatch data, closed claim data, postmarket surveillance data (e.g., CAPA—corrective action and preventive action; ISO 9001, Article 14), precursor analysis, or use of critical incident analysis techniques. Several empirical and computer-based techniques exist for error modeling and analysis. Both Rouse (1990) and Reason (1990) discuss use error analysis in more detail.

7.16 Workload assessment

User performance can be impaired by excessively high or low workloads. Device use can affect workload, and workload can affect how users interact with the device (Loeb et al., 1993; Weinger et al., 1997). Workload assessment aids in evaluating or predicting the worker's cognitive capacity for additional tasks. Workload can be measured using psychological techniques (e.g., subjective assessments, perhaps obtained with questionnaires), procedural techniques (e.g., effects on standardized performance metrics), or physiological techniques (e.g., changes in heart rate). Workload assessment methods must generally be validated and can be technically complex and difficult to analyze.

8 The complementary role of other types of analysis

8.1 Risk analysis

Analyses of use-related hazards should be integrated into overall efforts to assess device vulnerability to all types of failure (e.g., electrical or mechanical) from intended use and reasonably foreseeable misuse. Formal tools include Failure Modes and Effects Analysis (FMEA) and Fault Tree Analysis (FTA). It is critical that representatives from the HFE team participate in risk analysis, because the analysis is complementary to many HFE design evaluations. For example, possible errors identified in a task analysis should be incorporated in the risk analysis. It may be helpful for users to participate in these analyses, for example, to estimate the likelihood of errors and to assess the severity of their consequences. The results of risk analysis, which will often lead to both design and learning-tool modifications, must be formally documented (ANSI/AAMI/ISO 14971).

8.2 Cost-benefit analysis

Cost-benefit analysis (Bias and Mayhew, 1994) is a structured tool derived from traditional economic analysis for assessing how the potential benefits of a product or a subset of the product (e.g., a specific feature) compare to the

potential costs of designing, developing, incorporating, and manufacturing the product or feature. A rigorous cost-benefit analysis will provide information about the relative merits of critical design tradeoffs. Although both tangible and intangible costs and benefits should be included in the analysis, the intangibles are usually converted into approximate and comparable economic units. A rigorous analysis also incorporates the cost of time (e.g., delays to market because of necessary development milestones) and estimated probabilities of success or failure of different courses of action. A sensitivity analysis is usually then performed to test the importance of the many necessary assumptions (e.g., potential changes in sales with the addition of a specific feature). The values of individual assumptions are adjusted over a reasonable range, and the effects on the outcome of the larger analysis are examined.

Annex A
(informative)

Rationale for the development and provisions of this standard

A.1 Purpose

This document has two primary purposes:

a) To assist medical device manufacturers in implementing a systematic, user-centered approach to medical device design, the goals of which are to increase medical device usability and to reduce the likelihood of use errors that can lead to death, injury, or property damage; and

b) To help medical device manufacturers interpret and satisfy national and international regulations (e.g., FDA Design Controls) and standards (e.g., ISO 9001) pertaining to the application of human factors to the design of medical devices.

Regulations notably focus primarily on human factors engineering (HFE) as a means of increasing medical device safety. However, HFE efforts usually improve usability, an attribute that marketers can turn into a competitive advantage. As such, companies may be motivated to invest in HFE with the goal of increasing both safety and usability. Safety and usability are not mutually exclusive concepts; devices that are easier to use are generally safer to use. Therefore, this document takes an integrated view of safety and usability.

A.2 Historical background of the AAMI HFE guidelines

The Association for the Advancement of Medical Instrumentation (AAMI) originally published a document on the role of human factors in medical device design in 1988. That document, titled *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (AAMI HE:1988) was revised and expanded in 1993. A significant part of the 1988 document was derived from U.S. military standards for the design of military equipment, and it largely provided an abbreviated catalog of human factors design principles and practices. Notably, however, a new section was incorporated into the 1993 revision (section 5—The human engineering process), which outlined components of an HFE process.

The present document, written as a stand-alone standard for incorporating HFE into the design process of all medical devices, replaces section 5 of the 1993 guideline. Importantly, the present document takes a flexible view of the HFE design process, providing an overall framework for user interface design while leaving the selection and scaling of specific HFE activities to the manufacturer.

An updated version of the original *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* (ANSI/AAMI HE48:1993), in development at the time of publication of the present standard and redesignated HE75), provides specific human factors design principles and examples of their use in the medical domain.

A.3 Historical perspective on HFE

Human factors engineering (also called ergonomics) can trace its roots to early industrial engineering studies of work efficiency and task performance using, for example, time–motion techniques. HFE emerged as a recognized discipline during World War II while focusing primarily on military system performance, including problems in signal detection, workspace constraints, and optimal task training. Subsequently, the scope of human factors expanded to encompass a broad range of applications. The widespread recognition of the importance of applying HFE in the design of tools, devices, tasks, and other human activities is reflected in the increasing number of disparate professionals interested in human factors. Their work products can be found in lay and professional publications, standards, and other documents. Human factors activities have improved the quality of personal and professional life across many domains. Public and professional interest in patient safety issues (Kohn et al., 2000) has promoted increased application of HFE to the medical domain.

A.4 The science of HFE

Several decades of basic and applied research as well as hands-on experience have generated a substantial base of scientific knowledge about people and their interactions with each other and with technology. For example, extensive data is 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). This data and related principles governing its application are available in numerous textbooks, technical articles, standards and guidelines, and specialized design tools such as anthropometric analysis software (see annex E).

Design principles arise from the HFE knowledge base in experimental psychology, cognitive science, physiology, anthropometry, biomechanics, industrial engineering, medicine, computer science, and safety sciences, among others. But HFE is more than just design principles. HFE is also:

a) A collection of tools and techniques for analyzing and shaping the human role in systems;

b) A process for translating the specification of operator or user tasks into the design of human–machine interfaces, workspaces, workplaces, environments, and procedures; and

c) An iterative evaluation process in which the results of testing throughout the stages of system development feed back into design to improve the human–system interface and enhance human performance.

By applying design principles within the course of the dynamic design process, HFE can help reduce instances of use error, enhance patient and user safety, improve usability and efficiency, and reduce the occurrence of device failure.

A.5 The role of expertise in HFE

HFE requires the application of underlying principles, knowledge, and experience in a skillful manner to create a successful outcome. In this respect, HFE is analogous to other fields such as architecture where the experience and creativity of the practitioner influence the success of the process. In user interface design, designers must make complex trade-off decisions that transcend analytical decision making and require many subjective considerations. Creativity is important in user interface design. Structured process and design principles may be paramount to good design, but without insight and judgment, textbook-correct designs can fail miserably. Because skill plays such an important role in the successful application of HFE, individuals with sufficient HFE expertise must play an integral role in the design process.

Human factors practitioners may have training and/or experience in cognitive psychology, engineering, programming, training, education, or technical and science-related fields. HFE training and experience can be obtained in many ways. For example, HFE practitioners can obtain substantial on-the-job experience and participate in conferences, courses, and self-learning activities. Formally trained HFE professionals receive advanced degrees from accredited human factors programs within schools of engineering, psychology, or computer science. A few universities offer undergraduate HFE degrees. The Human Factors and Ergonomics Society provides a free copy of descriptions, requirements, and contacts for more than 70 HFE graduate programs in North American colleges and universities. Other information about program requirements, competencies, and diversity of HFE education is available from the International Ergonomics Association's Special Interest Group on Computer–Human Interaction or the Usability Professionals' Association.

A.6 HFE in medical device design

Numerous medical device companies have established HFE programs to ensure the usability and safety of their devices. These companies also believe that their HFE efforts enhance the marketability of their products. National and international regulations with respect to the safety of medical devices now require that HFE principles be applied to the design of medical devices, and that this process be documented (see, for example, annex B). Some companies have established in-house HFE teams that include trained professionals. Other companies achieve good results by identifying an HFE "champion" to coordinate the company's HFE efforts, drawing on additional external consulting support as required.

Annex B
(informative)

Current FDA regulations

The U.S. Food and Drug Administration (FDA) requires producers of medical devices to establish and follow design process procedures to ensure that their design activities are carried out in a rational and orderly manner (21 CFR Parts 808, 812 and 820—"Medical Devices: Current Good Manufacturing Practice (CGMP) Final Rule, Quality System Regulation"). This FDA regulation is compatible with the design control provisions of international quality systems standard ISO 9001, ANSI/AAMI/ISO 13485, *Quality systems—Medical devices—Particular requirements for the application of ISO 9001*), and ANSI/AAMI/ISO 14971, *Medical devices—Application of risk management to medical devices*.

When producers comply with the FDA requirements, they also comply with the design control provisions of ISO 9001. This compatibility between the FDA regulations and ISO 9001 is important to those engaged in global product marketing because ISO 9001 is a recognized quality systems standard that forms the basis for many national regulations. Certification to ISO 9001, for example, allows producers to market their products in the European Union.

B.1 CFR references to human factors activities

The following subparts of 21 CFR 820 have particular relevance to human factors design activities.

B.1.1 Design input

". . . the physical and performance requirements of a device that are used as a basis for device design." (21 CFR 820.3f)

Human factors relevance: The design requirements are based on users' needs and define the device functions, intended operating conditions, performance requirements, user characteristics, user interface, and potential hazards; the latter should include reasonably foreseeable use errors.

B.1.2 Design output

". . . the results of a design effort at each design phase and at the end of the total design effort." (21 CFR 820.3g)

Human factors relevance: The design output consists of such work products as the diagrams, flow charts, specifications, and materials that define and characterize the design (e.g., prototypes). Outputs relevant to operator-device interactions such as panel layouts, mock-ups, or computer prototypes should be verified (see below). The final output—the device itself—should be validated.

B.1.3 Design verification

". . . confirmation by examination and provision of objective evidence that specified requirements have been fulfilled." (21 CFR 820.3aa)

Human factors relevance: Manufacturers should conduct iterative human factors evaluations throughout the design process to verify that the evolving design products, or "outputs," are compatible with the established design requirements, or "inputs." These activities can include task–function analyses, user studies, usability tests, mock-up reviews, walkthroughs, and other techniques.

B.1.4 Design validation

". . . establishing by objective evidence that device specifications conform with user needs and intended use(s)." (21 CFR 820.3z-2)

Human factors relevance: Design validation demonstrates that users have the ability to safely operate and maintain the device, as well as to understand the accompanying labeling. Design validation should include risk analysis and testing of production models under actual or simulated use conditions.

B.2 Key elements of design control

Key elements of any design control procedure intended to ensure an adequate user interface include the following:

a) Establishing an HFE plan that describes all user interface design and implementation activities as well as associated organizational responsibilities. In addition to meeting the FDA's expectations, producing a plan

makes sense as a means to coordinate HFE activities with other engineering and design activities, and to determine budget and staffing requirements.

b) Organizing user-oriented requirements (i.e., design inputs) arising from various user and device studies in a consolidated document. Such requirements may be expressed in the form of a vision statement, a set of usability requirements and criteria (see 6.2), or a listing of functional requirements and their prospective allocations to the user or device.

c) Conducting design reviews at key stages to ensure that user interface design is proceeding according to the established plan and addressing user-oriented requirements properly.

d) Verifying that design solutions meet established user-oriented requirements. Such verification could be accomplished by conducting design audits and usability tests.

e) Preparing user interface specifications (i.e., design outputs) that ensure that the final user interface is carried out as designed.

f) Validating that the final manufactured device meets the user interface specifications. Such assurance can be accomplished by conducting design audits and usability tests of working prototypes. These tests may take place at the same time as in-house alpha testing or clinical trials.

Table B.1 links the processes involved in FDA design control to some of the HFE products that are discussed in this standard.

Table B.1—Design controls and associated HFE products

Design controls	**HFE products**
Design input	User research reports Vision statement Usability goals
Design reviews	Design reports
Design output	User interface specification
Design verification	Design audits (7.3), heuristic analysis (7.7), and task analysis (7.13) Usability test plan and report
Design validation	Usability test plan and report
Design transfer	User documentation and product labeling
Design changes	Memoranda
Design history file	File containing all HFE products

Ultimately, manufacturers should review the FDA regulations in detail to ensure design process conformance. Postmarket activities such as conducting field studies, reviewing complaint files, or reviewing the design of retrofits are beyond the scope of this document.

Issues or problems identified during design verification are usually addressed by design modifications. In contrast, serious issues or problems identified during design validation (see above) may also require modification of design criteria and requirements, or even of the device's conceptualization.

Annex C
(informative)

Helpful tips

The following lessons learned from the experience of others should promote a smooth transition to a more user-centered design process. The following lessons come from the experience of others trying to incorporate human factors engineering into their product development process. These "tips" are methods to deal with real-world roadblocks and competing interests. The practical advice ranges from the best ways to brief top management to communication tactics for software engineers and marketing personnel.

NOTE—Although many individuals have contributed to this annex, special recognition goes to Craig Hartley for providing most of these "Lessons Learned."

1. *Plan ahead.* An HFE program represents change, which may be threatening to related disciplines that normally would have control over the user interface design efforts. Planning ahead smoothes the transition to an HFE program and ensures that resources will be sufficient to accomplish the program goals.

2. *Popularize HFE as practical and cost-beneficial.* Because many people will be unfamiliar with HFE and the associated benefits, make efforts to educate members of the medical device development community. Emphasize motivating factors such as accident prevention achieved by identifying and resolving safety problems, and improved marketability resulting from systematically increased usability.

3. *Document success stories.* If HFE efforts lead to better devices that garner positive end-user feedback and potentially greater marketplace success, document these successes to promote greater HFE investment.

4. *Be flexible and pragmatic.* Although you should pursue user interface design excellence and ensure that the final device is safe, work closely and productively with other engineering disciplines. Compromise is an inevitable part of the process that leads to an optimal design. By contrast, an inflexible approach to HFE may do more harm than good. If HFE is treated as an afterthought in the design process, then HFE specialists will be perceived as creating barriers to meeting schedules, budgets, and design goals. HFE specialists should invite and remain receptive to input from other members of the design team.

5. *Learn as much as possible about other design disciplines.* If you have an exclusively HFE or social science background, you must understand the constraints imposed by other design disciplines so that you will not propose alternatives that conflict directly with other requirements.

6. *Blame yourself for communication problems.* If other design professionals misunderstand HFE recommendations, assume that you have a problem explaining the recommendations rather than that others have a problem understanding them. It is important to translate HFE concepts into the language of other design professionals rather than to expect engineers and designers to learn a new vocabulary.

7. *Be a user advocate.* Other design team members will fight for their particular design goals (e.g., low manufacturing cost, ease of sterilization); therefore, if the HFE professional fails to stand up for the user, HFE goals will inevitably be compromised. Of course, this advocacy has to be tempered by flexibility and pragmatism.

8. *Understand the nature, expectations, and structure of your organization.* The HFE professional is inevitably a "service provider" to internal "customers." Thus, to be effective, you must understand the dynamics of the organization and the needs and expectations of other design team members (i.e., make your services "usable" to *your* users).

9. *Make sure your efforts add value to the product.* It is important for the HFE professional to avoid engaging in efforts that do not add value to the final product (e.g., creating elaborate reports that are not really used).

10. *Don't expect immediate organizational change.* The successful HFE professional typically must work diligently and patiently to bring about organizational change. Expecting radical change immediately can be a prescription for disaster.

11. *Be helpful.* Keep your eyes and ears open for opportunities to answer questions posed by other design professionals.

12. *Stay involved.* Get involved in product development programs as early as possible and stay involved throughout. This strategy can reduce the degree to which your efforts might be viewed as "obstructionist," or can prevent your being told that it is too late to make changes.

13. *Establish lines of communication.* Communicate with management and with the professionals "in the trenches" as often as possible to get feedback on the usefulness of what you produce and to explain HFE.

14. *Be aware of cost and timing.* If you understand the cost and timing implications of your recommendations as well as the benefits, you will be a more effective advocate of HFE.

15. *Be responsive.* Provide a response by the deadline that is given. If necessary, let other team members know of the limitations of your answers, but provide something within whatever time frame is available.

16. *Scale your efforts to the appropriate level of effort.* Be prepared to provide what is needed and what can be done for a given project, even if the time and budget are severely restricted. If they need an answer in 30 seconds, give a best guess; in 15 minutes, consult a guideline; in 2 hours, do a paper-and-pencil study with internal employees; in 2 days, test a mock-up; in 2 weeks, test a prototype. An effort that is not as thorough as it could be in an ideal world is almost always better than no effort or one that relies purely on a seat-of-the-pants decision by an engineer.

17. *Try to make HFE free of charge.* If HFE services incur cross-charges, your efforts have less chance of success. If you offer your services for free, it is more difficult for others to refuse them. Arrange HFE funding to come out of overhead. An alternative is to tax the using departments; however, at the *individual project level*, HFE must be free, or appear to be.

18. *Try to do "out-of-box" studies.* One step forward could be to get a requirement to subject every product to an "out-of-box" study where uninitiated users must use the device "cold." Although it is too late at that point to have much effect on the design, the action can illustrate the need for HFE.

19. *Be willing to work on "pieces" of projects.* Teach people who use HFE services that you do not have to have the whole project or device together and working to be involved. Try to avoid waiting for "it" to be built before thinking of testing. If you wait too long for an all-up study, small but important findings are steamrolled or lost.

20. *Co-locate HFE people with the product teams they serve.* Informal questions and quick responses around a water cooler can win friends, fix problems, and build credibility.

21. *Build labs that give a direct view of what is going on in the room.* Don't rely on TV views. Design the lab so that observers can come and go as they please without light flashing through doors, and so forth. Build HFE labs co-located with the product teams so that engineers can drop in to see a test.

22. *Use project engineers as subjects in early iterative stage studies.* If engineers are usability study subjects for other projects, they will learn firsthand what the value can be and what it is that you do. Also, invite management to participate in or, at least, watch a study.

23. *Use video.* A three-minute video of a person struggling with a product can win over project teams more easily, in some cases, than a thorough report.

24. *Make all reports easily available in electronic form.* Paper reports may or may not be read. Prioritize problems and keep reports as short as possible.

25. *Sell yourself as a broad player.* HFE should be a consideration everywhere humans touch the system, from manufacturing through packaging, maintenance, service, operation, diagnostics, documentation, labeling, and even disassembly for recycling. All of those areas are potential HFE customers.

26. *Cultivate upper management support and project manager buy-in.* The best thing you can do is to have an incentive system tied to HFE results (e.g., track service calls for one year after the product ships and pay a big bonus if some criterion is met).

27. *Review HFE issues at each project review meeting.* Maintain the team's ongoing awareness of HFE, and don't let issues slip through the cracks.

Annex D
(informative)

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Annex E
(informative)

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ASSOCIATION FOR COMPUTING MACHINERY: Special Interest Group on Computer–Human Interaction. http://www.acm.org/sigchi