



An Introduction to Human Factors in Medical Devices

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FOREWORD

The Center for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA), develops and implements national programs and regulations to protect the public with respect to devices and radiological health. These programs are intended to assure the safety, effectiveness, and proper labeling of medical and radiation-emitting devices.

An emerging concern of great importance to the Agency is the implementation of good human factors practices in the design of medical devices. If device operation is overly complex or counter-intuitive, safe and efficient use of a medical product can be compromised. Both CDRH databases and research findings indicate that lack of attention to human factors during product development may lead to errors that have the potential for patient injury, or even death. The application of user interface design principles and participation of healthcare practitioners in design analyses and tests are very important. In addition to increased safety, an added benefit of such practices is the likelihood that good user interface design will reduce training costs to healthcare facilities. This document offers guidance intended to increase the understanding of human factors in device design.

The Center publishes the results of its work in scientific journals and in its own technical reports. Through these reports, CDRH also provides assistance to industry and to the medical and healthcare professional communities in complying with the laws and regulations mandated by Congress. The reports are sold by the Government Printing Office (GPO) and by the National Technical Information Service (NTIS). Many reports are also available on the Internet/World Wide Web.

We welcome your comments and requests for further information.



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PREFACE

Human factors is a discipline that focuses on those variables that affect the performance of individuals using equipment. The subject of this primer is the impact of design upon safe and effective use of medical devices. Errors in the use of such devices often are caused, at least in part, by the design of the user interface, i.e., those features with which healthcare practitioners and lay users interact. Mistakes made during device operation not only can hamper effective patient treatment, monitoring, or diagnosis but in some cases can lead to injury or death. It is important that medical devices be designed with consideration of the impact of design on safe use. This primer discusses human factors problems, general design principles, and human factors engineering methods and uses examples and illustrations for clarification.

The Food and Drug Administration (FDA) believes that this information is important because of its implications for patient and user safety. Reports received throughout the Medical Device Reporting (MDR) system, recall data, and other postmarket information indicate that device design and related use errors are often implicated in adverse events. As implied in the language of the design control section of the Quality System Regulation (“...design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient.”), human factors is an important consideration in quality assurance programs. Additionally, good human factors design is an important consideration in submissions to the Agency prior to device marketing.

While this guidance represents a final document, comments and suggestions about *Do It By Design* may be submitted at any time for Agency consideration by writing Dick Sawyer, Office of Health and Industry Programs, HFZ 230, 1350 Piccard Drive, Rockville, MD 20850. For inquiries about the Quality System Regulation, call Kimberly A. Trautman, Office of Compliance, at 301-594-4648.

This guidance is available through Internet/World Wide Web at <http://www.fda.gov> and after January, 1997, from the National Technical Information Service, Springfield, Virginia 22161, telephone number 703-487-4650.



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Where this document reiterates a requirement imposed by statute or regulation, the force and effect as law of the requirement is not changed in any way by virtue of its inclusion in this document.

INTRODUCTION

The purpose of this primer is to encourage manufacturers to improve the safety of medical devices and equipment by reducing the likelihood of user error. This can be accomplished by the systematic and careful design of the *user interface*, i.e., *the hardware and software features that define the interaction between users and equipment*. This document contains background information about human factors as a discipline, descriptions and illustrations of device problems, and a discussion of human factors principles and methods. In addition, the final section of this document contains recommendations for manufacturers and healthcare facilities.

The primer is directed to the following audiences:

- Manufacturers
- Employees of the Food and Drug Administration (FDA)
- Healthcare professionals

Because many designers, engineers, scientists, and healthcare professionals may be unfamiliar with human factors, this primer is written as a basic educational tool and assumes little background in the subject. At the same time, much of the content may serve as a resource for those individuals who have had experience with human factors issues.

The information in this document will be useful in planning human factors programs that involve testing, incident analysis, or staff training. In addition to providing technical information, it also discusses various human factors resources.

Good user interface design is critical to safe and effective equipment operation, installation, and maintenance. Human factors should be considered early in the design process, and systematic analysis and hands-on testing should be conducted throughout development stages and involve participants from the end-user population. It is *not* simply a matter of “fine tuning.” Thorough attention to design will result in safer, more usable devices and, correspondingly, fewer accidents, reduced training costs, fewer liability problems, and less trial-and-error during device development.

Because poor user interface design greatly increases the likelihood of error in equipment operation, *Do It By Design* encourages readers to think critically about the impact of device design upon the ability of healthcare professionals to treat patients safely and effectively. On a positive note, attention to human factors design principles and methods will help greatly in the development of a product that meets the users’ needs. Consider this primer a starting point. One should supplement this information with more detailed data, principles, and methodologies from guidelines, standards, texts, and articles (some of which are listed in the References for Further Reading).

HUMAN FACTORS: AN HISTORICAL PERSPECTIVE

Human factors is a discipline that seeks to improve human performance in the use of equipment by means of hardware and software design that is compatible with the abilities of the user population. The terms "human engineering," "usability engineering," and "ergonomics" are often used interchangeably for the process utilized to achieve highly usable equipment.

Historically, human factors can be traced to early efforts by industrial engineers, psychologists, and efficiency experts to streamline manufacturing operations and equipment for better worker efficiency. In World War II, emphasis shifted from production to personnel safety. A special focus was cockpit design of aircraft. Poor design of controls and displays often induced pilot errors, sometimes leading to crashes. Human factors analyses and tests became routine in the design of military and commercial cockpits. Through the 1970s, the most notable applications of human factors were highly costly, complex systems regulated by the Federal government, such as military and transportation systems. Media coverage of user-related accidents, like the Three-Mile Island nuclear power plant meltdown, has done much to increase the recognition of human factors.

Such disaster stories are by no means a thing of the past. Recently, a nationally aired television program presented findings related to a disastrous airline crash. The investigators concluded that difficult-to-distinguish operating modes of the guidance system and confusing data displays misled the pilots. They thought they were viewing angle-of-descent information when, in fact, they were viewing vertical drop-in-altitude data. The plane crashed short of the runway without the crew attempting corrective action.

Human factors principles increasingly are being applied to commercial products. Examples include "ergonomically-designed" automobiles and the development of "user friendly" computer hardware, software, and communications products. Although some manufacturers now integrate human factors design into their medical devices, there exists a need for more widespread applications.

WHY HUMAN FACTORS ENGINEERING IS IMPORTANT

Design-induced errors in the use of medical devices can lead to patient injuries and deaths. A user's behavior is directly influenced by operating characteristics of the equipment; user interfaces that are misleading or illogical can induce errors by even the most skilled users. A brief discussion of device users, operating conditions, adverse events, and design implications will show the need for medical device designs that accommodate the necessary range of user capabilities.

THE INTERACTION OF USERS, DESIGN, AND OPERATING ENVIRONMENT

Healthcare practitioners vary greatly in their physical, sensory, and mental abilities. Lay people, who represent an increasing proportion of medical device users, are even more variable. Medical devices are used in many environments, including operating rooms, emergency rooms, patient units, x-ray departments, laboratories, emergency vehicles, critical care facilities, clinics, and homes. Performance often is compromised by noise, poor lighting, glare-producing surfaces, heat, dirt, improper cleaning products, electrical interference, humidity, and moisture. Poorly written procedures, stress, and fatigue can also degrade performance. Compounding the situation is the wide array of equipment that a healthcare practitioner operates.

A medical device can be used safely and effectively only if the interaction between the operating environment, user capabilities, stress levels, and device design is considered when the manufacturer designs the device. The following dimensions of human capability are basic to an understanding of human factors.

Physical and Sensory Characteristics

A person's most basic physical and sensory capacities include vision, hearing, manual dexterity, strength, and reach. A number of related design factors can interact with them to influence human performance: the legibility and discriminability of displayed symbols, audibility and distinctiveness of alarms, the strength required to make connections, and the requirements for reaching controls.

Perceptual and Cognitive Abilities

Perception is the ability to detect, identify and recognize sensory input. Understanding human limitations and exploiting human strengths in this area is crucial for safe design of equipment. Perceptual characteristics are important in the design and arrangement of controls, keypads, displays, information presentation, and alarms. Cognition refers to higher level mental phenomena such as memory, information processing, use of rules and strategies, hypothesis formation, and problem solving. For example, the multiple hierarchical pathways and seemingly unlimited information often found in computerized devices can rapidly exceed the user's memory limits.

Therefore, a designer should develop easy-to-use retrieval systems, taking advantage of well-established semantic and symbolic techniques for screen and menu design.

Expectancies: People are predisposed to react to new situations according to established habits. Designers can take advantage of existing conventions (“population stereotypes” such as the color red equals danger) in the general population, as well as the standards and conventions of the medical community. Designs consistent with ingrained habits will facilitate performance and reduce training time. Designs that conflict with such habits can lead to errors.

Mental Models: Based on experience, people form abstract concepts about how complex phenomena actually work. For example, anesthesiologists, form mental representations of patient status based on information about respiration, heart rate, oxygen levels, and other bodily processes. Monitors should present such information in a manner consistent with such models. There is a need for thorough assessment of how users conceptualize device operation in patient treatment and monitoring. This is a complex issue, because individuals differ in how they mentally integrate and conceptualize data that change over time.

Home-use

Lay people increasingly use medical devices. Because of illness, poor reading ability, inadequate facilities, insufficient assistance, and inexperience, this population often represents a special challenge to designers. Decrements in vision, hearing, strength, manual dexterity, and memory are to be expected with age and illness. Also, many patients often are unfamiliar with automated devices and may be afraid to use them. An additional concern is the potential effects of medications upon a patient’s use of medical equipment. For these reasons, as well as lack of medical training, the lay user’s operation of highly complex devices is problematic. Some devices that are difficult for physicians and nurses to operate find their way into the home, where the problems are further compounded by power outages, insufficient electrical outlets, electromagnetic interference, narrow doors, the use of accessories (e.g., batteries), and other factors.

DESIGN IMPLICATIONS

Obviously, completely “designing out” all problems associated with human limitations, environmental factors, and stress is impossible. Regardless, the cumulative and interactive effects of user errors can be serious and even disastrous. Designing the interface with the user in mind usually will result in a device that:

- accommodates a wide range of users working under variable, often stressful conditions;

- is less prone to user error; and
- requires less user training.

In general, human capability and limitations are extremely important considerations in device design. The next section describes the kinds of user-interface issues frequently encountered with medical devices.

THE USER INTERFACE

This section describes and discusses problems related to human factors. Hopefully, the material will foster an appreciation of the impact of considering the user-interface during design and provide the reader with the rationale and basic principles of human factors. Brief summaries of serious incidents taken from the Food and Drug Administration's Medical Device Reporting (MDR) system illustrate the problems. The summary principles found in the "Rules of Thumb" in each subsection are by no means exhaustive, e.g., no detailed data on control dimensions and forces, body dimensions, audition, vision, or menu and screen design are included. Consult guidelines, textbooks, articles, and conference proceedings such as those listed in the References for Further Reading. Finally, design principles alone do not solve every user interface problem; the human engineering process, discussed later, is vital to such solutions.

CONTROL/DISPLAY ARRANGEMENT AND DESIGN

Many devices have large consoles with rows of mechanical controls and displays. The designer should consider the ability of users to: quickly and properly identify controls, switches, and displays; reach and accurately set controls; read displays accurately; and associate controls with their related displays. Desirable features include functional grouping of controls and displays, unambiguous labels, and easy-to-operate keys. Clear instructions and effective warnings also are important.

Examples of Errors Related to Hardware Design

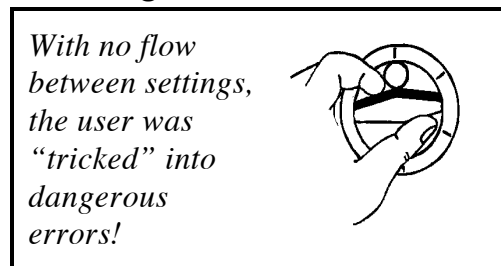
The following three examples of problems were abstracted from the Medical Device Reporting (MDR) system and FDA device recalls.

- A physician treating a patient with oxygen set the flow control knob, as show in Figure 1, between 1 and 2 liters per minute, not realizing that the scale numbers represented discrete, rather than continuous, settings. *There was no oxygen flow between the settings, yet the knob rotated smoothly, suggesting that intermediate settings were possible.*

The patient, an infant, became hypoxic before the error was discovered. One solution would have been a rotary control that snaps into a discrete setting. Some indication of flow also should have been provided.

- There have been numerous reports and recalls associated with defibrillator design. These include paddles that are hard to remove from

Figure 1 - Controls



their retaining wells and confusing arrays of poorly-labeled controls and displays that inhibit safe, efficient use.

- There have been cases in which patients were seriously injured when a nurse over infused a patient after reading the number 7 as a 1. Because the flow rate readout was recessed in the infusion pump display panel, the top of the 7 was blocked from view by the display surface, even at modest vertical viewing angles. There have been similar reports of flow rates which had been misread when viewed from the side; for example, 355 ml read as 55 ml.

These few examples illustrate the fact that seemingly small design flaws can result in serious problems. Tailoring a few general human factors guidelines, such as those below, to particular devices will decrease the risk of such problems. Following are some rules of thumb for designing the user interface.

Rules of Thumb

- Make all facets of design as consistent with user expectations as possible. Both the user's prior experience with medical devices and well-established conventions are important considerations.
- Design workstations, controls, and displays around the basic capabilities of the user, such as strength, dexterity, memory, reach, vision, and hearing.
- Design well-organized and uncluttered control and display arrangements. Ensure that the association between controls and displays is obvious. This facilitates proper identification and reduces the user's memory load.
- Ensure that the intensity and pitch of auditory signals allow them to be heard easily by device users. Consider the effects of ambient noise.
- Ensure that the brightness of visual signals is sufficient to be perceived by users working under various conditions of ambient illumination. Also, brightness contrast and color contrast can help to optimize legibility.
- Make labels and displays so that they can be easily read from typical viewing angles and distances. Symbol size, contrast, color, and display depth are important considerations.
- Ensure that the abbreviations, symbols, text, and acronyms placed on, or displayed by, the device are also used consistently in the instructional manual. They also should correspond to standard nomenclature, if possible.

- Design control knobs and switches so that they correspond to the conventions of the user population (as determined by user studies and existing medical device standards).
- Arrange and design knobs, switches, and keys in a way that reduces the likelihood of inadvertent activation.
- Use color and shape coding, where appropriate, to facilitate the rapid identification of controls and displays. Colors and codes should not conflict with universal industry conventions.
- Space keys, switches, and control knobs sufficiently apart for easy manipulation. This will also reduce the likelihood of inadvertent activation.
- Make sure that controls provide tactile feedback.

Summary

In summary, the layout and design of controls and displays greatly affect the user's ability to successfully perform functions and extract information during operation of a device, especially during critical events. The next section discusses the logic of such user-device interactions.

DEVICE LOGIC AND MICROPROCESSING

With modern automation, the logical, temporal, and informational characteristics provided via software are increasingly crucial and error-inducing. For instance, data presented imprecisely, ambiguously, or in a difficult-to-read format are likely to be misread. Examples are crowded CRT displays, cryptic abbreviations, or time lags between user input and displayed feedback. Such design may overtax the user's memory and decision-making capability.

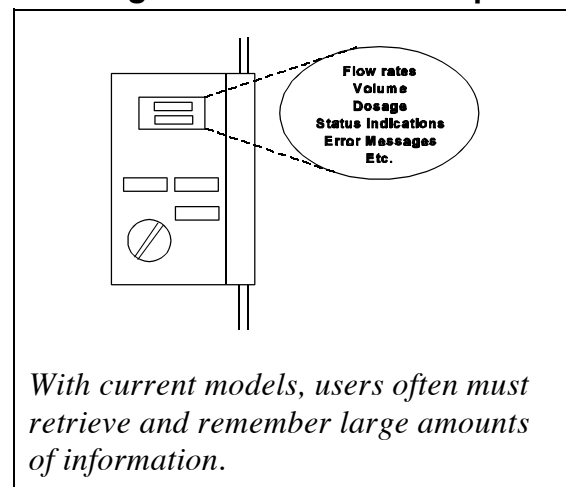
Characterizing the Shift to Software

With a large number of controls and displays, the user must identify and integrate spatially disparate information. Although such designs are still common, the trend is to assign more functions to software. This reduces the number of controls and displays, but it can increase the burden on the user in other ways. This is the case with many infusion pumps, as shown in Figure 2 on the following page. Although there are few controls and displays, the large amounts of information impose heavy demands on the user's memory. Most information must be recalled in sequence, thereby precluding simultaneous viewing of related data. Users can become lost in the system if sufficient prompts and roadmaps are absent. Also, users may misinterpret displayed data and respond inappropriately if not given precise feedback and indications of functional status.

Product developers often incorporate multiple of functions into a device to provide flexibility and to serve a wider user community. However, extensive functional capability may well impose an unreasonable cognitive load on the user, unless considerable effort is devoted to the design of the user interface. The following are some problems that apply to many medical devices and can lead to errors:

- illogical or cumbersome control sequences;
- unfamiliar language, symbols, or codes;
- inconsistencies among display formats;
- conventions that contradict user expectations;
- uncertain or no feedback after input;
- functions that are hidden from the user;
- missing or ambiguous prompts, symbols, or icons;
- unsignalled resets or defaults;
- no status information;
- missing lock-outs or interlocks; and
- requirements for complex mental calculations.

Figure 2 - Infusion Pump



Examples of Errors Related to Software Design

Many use errors induced by software design are incorrectly attributed to other factors, because such errors are not easily remembered or recreated for post hoc analysis or correction. Also, software-related errors can be subtle. For example, users become frustrated by cumbersome data entry steps and make errors not directly related to those steps. Ambiguous acronyms or abbreviations used in the command structure or on menus may also lead to serious errors. Below are examples gathered from incident files, recalls, and analyses:

- There have been incidents with radiation treatment devices because users failed to enter dosage levels if the device software did not prompt the user for

the data. Instead, the device automatically defaulted to a given value without signaling this value.

- A cardiac output monitor alarm was disabled without the operator's knowledge when the control buttons were pushed in a specific sequence.
- There have been serious infusion pump incidents and recalls involving such deficiencies as poorly signaled operating modes, cumbersome operating steps, and the presentation of unanticipated warning data on displays normally reserved for other critical information.

Below are some general considerations that, if implemented, can prevent many software-related design errors.

Rules of Thumb

- Do not contradict the user's expectation. Rather, exploit their prior experience with computerized equipment and consider conventions related to language and symbols.
- Be consistent and unambiguous in the use and design of headings, abbreviations, symbols, and formats.
- Always keep users informed about current device status.
- Provide immediate and clear feedback following user entries.
- Design procedures that entail easy-to-remember steps.
- Use prompts, menus, etc. to cue the user regarding important steps; do not "strand" the user.
- Give users recourse in the case of an error. Provide conspicuous mechanisms for correction and troubleshooting guides.
- Do not overload or confuse users with information that is unformatted, densely packed, or presented too briefly.
- Consider the use of accepted symbols, icons, colors, and abbreviations to convey information reliably, economically, and quickly.
- Do not over use software when a simple hardware solution is available, e.g., a stand-alone push button for a high priority, time-driven function.

- Consider using dedicated displays or display sectors for highly critical information. In such cases, *do not display other data in these locations*.

Summary

Microprocessing offers outstanding capabilities – ready data access, manipulation, computation, speedy accomplishment of functions, and information storage. Technological sophistication, however, can work to the user's disadvantage if the software design is done without a thorough understanding of the user. At a minimum, designers are advised to utilize guidelines for human computer interface (HCI), do a thorough analysis, and conduct usability testing during software development. A thorough knowledge of the user population is necessary. Finally, software designers need to coordinate their efforts closely with hardware designers.

COMPONENT INSTALLATION

Among the most common errors reported to FDA are improper installations of device accessories. Although erroneous installation often is not obvious before an accident, design-related installation problems frequently can be detected upon examination following an accident. Proper installation is critical to safe device operation.

Problems and Examples

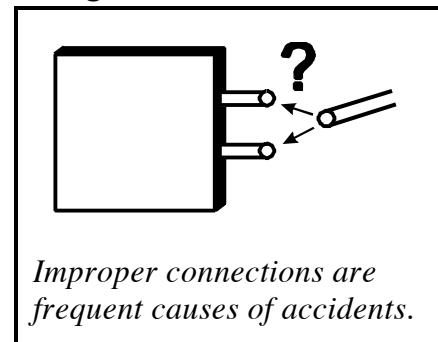
Some commonly reported errors are tubing connected to the wrong port; loose connections; accidental disconnections; electrical leads inserted into an improper power source; batteries or bulbs inserted incorrectly; and valves or other hardware installed backward or upside-down. The following MDR reports are illustrative:

- A component of an oxygen machine was installed upside-down, resulting in a patient death because of impeded air flow.
- A ventilator was recalled after a low-pressure alarm had short circuited on several occasions. The failures were traced to misinstalled batteries resulting from design of the battery ports.
- Three deaths were reported due to the introduction of a feeding solution from an enteral feeding tube into an IV tubing used for medication. This happened because an adaptor intended to introduce medication from an IV tube into the enteral feeding system permitted the reverse operation.
- Several injuries and deaths occurred because users inserted a cassette from one infusion pump model into a different model for which the set was not compatible. The resultant medication volumes were incorrect, although pump operation and data display did not reflect this error.

- Numerous injuries, deaths, and "near-misses" with ventilators have occurred because of disconnections of the breathing tubes due to poor tube and connector design.

The situation is exacerbated because many manufacturers sell a wide range of accessories for a given type of device. There are a great variety of cables, leads, connectors, valves, and tubing on the market. Accessories for different models are often similar in appearance and/or difficult to install, leading to misinstallations and disconnections. Figure 3 illustrates the kinds of confusion that can lead to installation errors. However, such accidents can often be prevented through design solutions. When conducting user studies, tests, and simulations, it is *crucial that device components and accessories be regarded as part of a system, not isolated elements.*

Figure 3 - Connectors



Rules of Thumb

The following are general considerations for reducing the likelihood of confusion between similar components and accessories and making improper connections.

- Cables, tubing, connectors, leuers, and other hardware should be designed for easy installation and connection. If properly designed, incorrect installations should be impossible, extremely difficult, or so obvious that they can be easily detected and remedied.
- User instructions should be understandable, and warnings conspicuous.
- If a hazard cannot be eliminated by a design solution, color codes or other markings will help the user achieve proper connections and component or accessory installation.
- Positive locking mechanisms are desirable whenever the integrity of connections may be compromised by such factors as component durability, motion, or casual contact.
- Protected electrical contacts (e.g., the conductors are recessed) are necessary for body leads that can be inadvertently introduced into outlets, power cords, extension cords, or other common connectors. If possible, exposed contacts should be avoided.
- Components and accessories should be numbered, so that defective ones can be replaced with the proper items.

- Textual complexity in maintenance manuals should be reduced by adding graphics.

Summary

There is a variety of device components and accessories. Potential hazards should be identified, and appropriate design and coding techniques should be used to prevent misinstallation.

ALARMS

Alarms and related advisories are intended to alert device users about problems with the patient and device status. This seemingly straightforward function often is complex. In some environments, alarms sounding simultaneously or intermittently on one or more devices make proper identification difficult, and staff may become distracted. Alarms may be considered a nuisance or part of the background; they also can induce stress. Ambient noise and numerous visual displays can mask the output from a particular auditory or visual display; overly loud alarms can mask other alarms. Compounding the above problems are alarm failures and false alarms due to electro-magnetic interference (EMI), static electricity, or over-sensitivity. It is critical to test alarms in the environments in which they will be activated.

Problems and Examples

Alarm problems include the following: false alarms, delayed alarms, too sensitive or insensitive alarms, alarms drowned out by noise, ambiguous meanings, inappropriate silencing, and accidental disabling. The two incidents below resulted from relatively common problems.

- A patient receiving oxygen died when a concentrator pressure hose loosened. The alarm was not loud enough to be heard over the drone of the device.
- A patient on a ventilator died following accidental detachment of the breathing tube from the humidifier. The alarm did not sound, because the pressure limit setting apparently was so low that it was essentially non-functional.

Variations of these scenarios are common. Low alarm intensity, high ambient noise, low battery conditions, inappropriate alarm settings, and other factors combine to create potentially dangerous situations.

Rules of Thumb

- Consider the wide spectrum of operating environments when designing and testing alarms, including other equipment in simultaneous use.

- Be sure that visual and auditory alerts and critical alarms are included in the design requirements for the device.
- Carefully consider the effects of over-sensitivity, electromagnetic interference, and static electricity on alarm functioning.
- Design alarms so they meet or exceed normal hearing and visual limits of the typical user.
- Make sure that both brightness contrast and color contrast are sufficient for legibility under a variety of lighting conditions.
- Use codes, such as color, that correspond to established conventions.
- Design alarms to be distinguishable from one another and, to the extent possible, from alarms on other devices used in the same setting.
- Design alarms to activate immediately following the onset of a critical problem. It is important that alarms identify the source of the problem.
- Consider giving a priority status to critical alarms. Critical alarms should provide redundant auditory and visual signals.
- Design alarms so that when they are silenced, they remain silent temporarily. They ideally will have visual indicators to indicate status and a mechanism for querying the reason for the alarm.

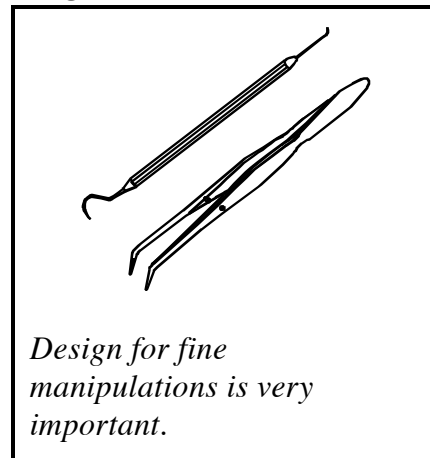
OTHER IMPORTANT ISSUES

Dimensions, Forces, and Angles

Workstations, seating, and consoles associated with medical devices should fit the user population. Data on body dimensions of various populations, including arm length, body height, leg length, and numerous other bodily specifications, are collected and published in a variety of documents. Such data, in conjunction with dynamic fitting trials, are important in designing equipment, so that controls are within reach and seating arrangements are comfortable. There are important implications for anesthesia workstations, prosthetics, and rehabilitative devices; these data apply to many home-use devices, such as wheelchairs, in which portability, compatibility with structures, and compactness are important. Knowledge of the clinical or home use environments is extremely important.

Important, but more elusive, are the biomechanical characteristics of tools such as hammers, dental tools, surgical instruments, control knobs, keyboards, and other devices that require substantial dexterity or strength and/or involve repetitive motions. For example, instruments such as those shown in Figure 4 can be difficult to use if they are not tested with users. Physicians and dentists often must precisely manipulate instruments in limited spaces. There may be problems associated not only with demands on dexterity and strength but those related to visibility, reach, and compatibility with other equipment.

Figure 4 - Medical Tools



Transfer of Training

Product developers often are encouraged to design products that incorporate unique, distinctive features. These can have performance and training impacts upon users in hospital units, where physicians and nurses have become accustomed to a particular device model. For example, if two models have very similar (“look-alike”) user interface configurations but require conflicting operator actions, habits established with one device can interfere with user performance on the other. This greatly increases the likelihood of errors. For example, if the ON/OFF switch positions are reversed on two very similar devices, a user transferring from one to the other could easily revert to the switch operation habits learned with the first device. The same concern applies to a device that is retrofitted or redesigned. This discussion is not intended to discourage innovation but rather to encourage designers to carefully evaluate the impact of user interface changes on user performance.

Device Maintainability

Medical devices should be designed for simple maintenance, because poor maintenance can hinder safe, reliable operation. Maintenance personnel often encounter the following problems:

- poor component labeling, coding, or numbering;
- inadequate self-diagnostic capability;
- parts that are hard to locate visually or by touch;
- screws and other parts that are difficult to reach or manipulate;
- confusing component arrangements;

- requirements for difficult-to-find tools;
- inadequate design for easy cleaning; and
- materials that are not durable and degrade the user interface.

Possible signs of inadequate attention to human factors include improperly connected wires, stripped threads, unreliable operation, dirty displays, and sticking keys. Not only are devices that are difficult to maintain usually out of use for long periods of time, but maintenance personnel may modify the devices to compensate for deficiencies, possibly creating new problems for the user.

Device Packaging

Packaging sometimes affects operation of a device. For example, there have been incidents resulting from packaging materials enclosed in such a way that users failed to detect and remove them. In some cases, this impaired functioning of the device. With one infusion pump, serious accidents occurred when unremoved packaging materials increased flow rates. On the other hand, packaging also can be designed to facilitate removal of devices or accessories and/or to make storage easier.

Sometimes, package design can reduce the likelihood of error. For example, catheters and compatible guide wires usually are packaged together. The same is true of needles and syringes, some infusion pumps and dedicated administration sets, and various contact lens accessories. A unique example is a customized container cover having an integral spacer that separates heart valve leaflets. Originally, cotton was used to accomplish this separation, but in a number of instances surgeons had neglected to remove the cotton spacer prior to installing the heart valve. There were several deaths due to the formation of massive clots associated with residue from the cotton. The integral spacer precludes such accidents.

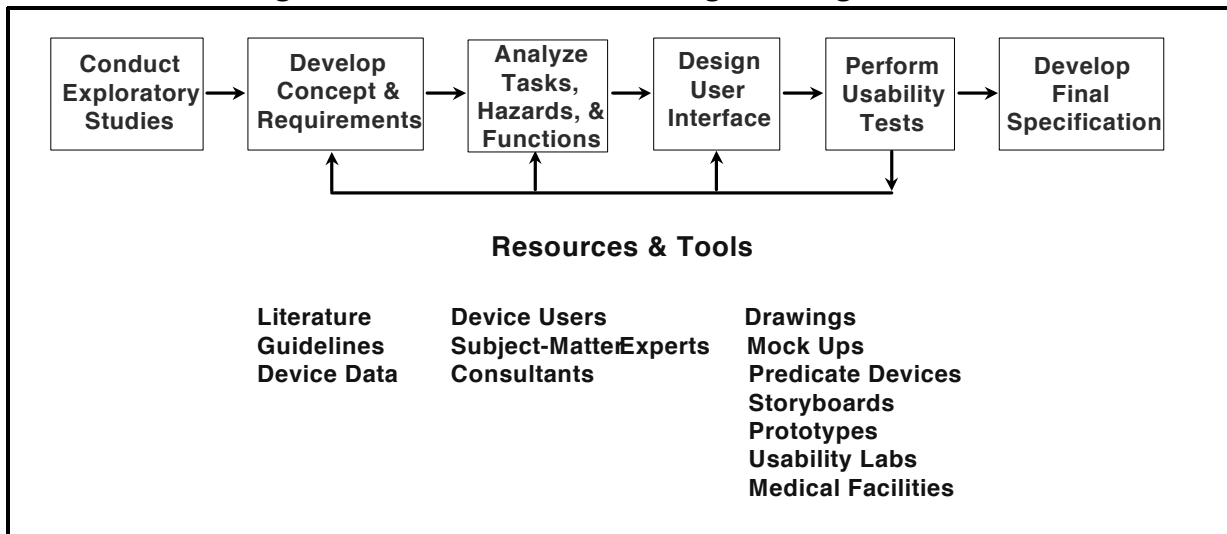
Summary

Implicit in the discussion of errors is the importance of implementing good design principles. Rarely do human factors principles fully cover all design situations. Good design practice entails the involvement of medical device users in studies, analyses, and tests to achieve optimal design. The next section, on human factors engineering discusses these methods.

HUMAN FACTORS ENGINEERING

Human factors engineering is a methodology that is crucial to effective user-interface design; it entails the iterative application of various procedures and tools throughout the design cycle, as illustrated in Figure 5. Participation of individuals from the user population is integral to this process. The developers of high technology products have adopted and refined such methods, calling their approach *usability engineering*. Of particular note is their emphasis on user studies and computerized testing prototypes.

Figure 5 - Human Factors Engineering Process



The rationale embodied in Figure 5 may be characterized as “designing in the user”. Designers usually are *too familiar with, and too close to*, their designs to understand all of the potential impacts upon users. Early consultation with the user population is necessary for assessing needs and developing requirements. Users also are critical for analytical work and testing throughout product development. With marketed products, field testing and feedback to manufacturers are highly desirable.

Ideally, hardware and software designers, engineers, human factors practitioners, document writers, and clinical staff coordinate their efforts to achieve a user interface design that lends itself to safe device assembly, installation, operation, and maintenance. The following factors will influence the flow of a given project:

- pre-existing data;
- complexity of the device;
- criticality of errors;
- human factors expertise;

- experience with other devices ;
- similarity of a product to an existing one;
- organizational culture; and
- competitive market pressures.

When developing a device that automates previously manual tasks, one might start by analyzing the performance of such tasks by healthcare professionals in a clinical setting. A competitive “benchmark” test of already-marketed models also might be conducted to uncover strengths and weaknesses of existing designs. Or, a project could start with an examination of existing devices and manuals for design modifications, markings, or notations. These may indicate that users attempted to compensate for design deficiencies.

Sometimes, a new design represents a small departure from an existing one, as in many product improvement efforts. However, even small hardware or software changes may have substantial impacts on the user interface. Therefore, potential impacts of change are important, even when the use history of the predecessor device is indicative of good design.

Although there is latitude with respect to what analyses, tests, and tools are implemented, the process should not be haphazard. The rationale for human factors engineering lies in the repetitive analysis, testing, and refinement of design concepts – all with input from users. There is some trial-and-error, but the bigger problems are detected and eliminated during the earlier stages before the design is “frozen.”

Finally, information collected during these efforts can help reduce errors, time, and costs in future projects involving similar products. The development of an in-house human factors guidance notebook for a family of devices should be considered.

The remainder of this section describes methods used by human factors professionals in designing user interfaces for equipment.

DOCUMENT REVIEWS

Studying documents about human factors and related device issues is valuable early in the development of a product. Such information is easy to obtain and is useful in understanding user interface issues and human factors methods.

The Literature

Human factors articles, technical reports, and textbooks offer substantial information. Numerous journals, magazines, and newsletters report studies and surveys on the combined effects of design, environment, and work conditions upon

device operation. Also of value are design case studies and product evaluations. Research, design, and conceptual articles of value also can be found in such human factors publications as: *Human Factors*, *Ergonomics*, *Ergonomics in Design*, *The Journal Of Applied Ergonomics*, and the *Proceedings of the Human Factors and Ergonomics Society (HFES) Annual Meetings*. The proceedings of sessions conducted by the Human Factors and Ergonomics Society (HFES) Medical Systems and Rehabilitation Technical Group are especially relevant, as are those of the Human Engineering Division (#21) of the American Psychological Association. Textbooks offer a broader view of human factors principles, design process, environmental factors, and humans as device operators. Finally, technical reports, standards, and guidelines from government and military agencies are useful.

Complaints and Recall Data

A company's recall and device experience data can provide historical information that may lead to important insights about potential problems and design solutions relevant to new product development. Reports in FDA's MDR system about problems across a device area may also be enlightening. Although use errors and design traditionally have been treated as separate issues, one can glean substantial information from this source via careful analysis. Such information may identify potential problems during the feasibility phase of a new development project.

Guidelines

Guidelines provide principles, data, and human factors engineering methods. An example of a principle might be the following: "There usually should be feedback displayed immediately following a user input via a control, key, switch, or other input device." Data may include anthropometric, dimensions, visual and auditory limits, etc. The most widely recognized guidelines in the medical device community are the ANSI/AAMI *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices (1993)*. Other guidelines published by government agencies include guidelines and military standards. They contain useful information about principles and methodology. Many textbooks on human factors, usability testing, and human-computer interface (HCI) design also are applicable.

Guidelines must be used judiciously. They are *not intended as "cookbooks."* The effectiveness of a guideline is in part determined by the education and skill of the person using it. Understanding the rationale behind principles is important, because the applicability of some principles may depend in part on the specific design in question, as well as analytical, research, and test data.

Manuals

Review of user instruction manuals may provide information about pitfalls to avoid and possible features to include when considering the development of a new product. For example, a warning such as "be careful of automatic flow rate defaults" may

indicate that such defaults are not clearly signaled or, possibly, may not be desirable in the first place. The review and comparison of the written operating procedures and control panel illustrations may also point to a number of strengths or weaknesses in key layout, operating logic, and other user interface concerns during new product development.

Ideally, once the user interface concept begins to take shape, concurrent work on the instruction manual should begin. Manual development should not be delayed until after the design effort is well under way or completed. If manual development is coordinated closely with the design effort, the very process of developing the new manual may uncover design problems.

Summary

Review of the above types of documents can provide a clearer picture of the following:

- sensory, perceptual, physical and cognitive capabilities and limitations of individuals;
- environmental interactions with human performance, especially as mediated by user interface design;
- human factors principles and methods;
- generic problems associated with types of devices; and
- strengths and weakness of existing devices and the one under development.

Document reviews help one to ask the right questions, avoid pitfalls, and get the product design process off on the right track.

EXPLORATORY STUDIES

Obtaining first-hand information from physicians, nurses, and lay-users is important in assessing the strengths and weaknesses of a device design. Other potential participants to consider are risk managers, clinical engineers, maintenance personnel, trainers, and supervisors. Questionnaires, on-duty observations, interviews, and focus groups are ways to assess design concepts, mockups, or predicate devices.

Why Do Such Studies?

Direct contact with the user population is essential for good human factors work. It should be initiated in the earliest stages of product design. Observations, remarks,

and anecdotal comments about existing devices, desirable design features, and working conditions can provide the following:

- a snapshot of how healthcare professionals use devices;
- a picture of how operating conditions, including the multi-device environment, affect use;
- a snapshot of what problems are encountered;
- anecdotal reports or comments;
- a sampling of the user population with respect to individual differences;
- ideas for new designs and reactions to design concepts; and
- information necessary for establishing performance test protocols and performance criteria.

Early studies, along with document reviews and task analyses, are very important. They engender creative thinking and reduce the likelihood of major mistakes in the design process.

Study Methods

Below are some techniques frequently used in early studies. They are not independent of one another, and techniques discussed elsewhere, such as task analysis, may also be integrated into these approaches.

Observations: In a medical facility, the operating rooms, emergency rooms, and critical-care units are fertile areas for observational studies of associated devices. These include the observation of ongoing operations and the inspection of devices following operation, especially after prolonged use. There are implications for areas such as maintenance, cleaning, installation, and the effects of environmental conditions upon the user interface. In the operating environment, substances such as dirt, water, saline solutions, alcohol, blood, and coffee often impede proper use of a device, as well as its functioning.

Non-intrusive and systematic observations are best. They can be recorded as narrative descriptions and/or as entries on data sheets formatted with predetermined data categories. Demographic and device information are desirable. When videotaping a session, the tapes can be indexed by critical events and times in order to avoid a time-consuming review. Another issue is the sampling of participants and operating conditions. Within the scope of time and resources available, observing different users under varying work conditions is desirable to ensure the generality of the observations.

Interviews: Interviewing is a flexible way of obtaining opinions about specific devices, problems, and user preferences and ideas about improving user-interface design. Interviews also can be conducted quickly and in conjunction with observations. Below are a few ideas about interviewing personnel in medical facilities.

Interviewing Users: Healthcare practitioners and lay users often hold perceptions that differ greatly from those of the designer. Valuable data can be obtained by having physicians, nurses, or home users do the following:

- walk through the operational steps;
- compare relative strengths and weaknesses of different models;
- describe "critical incidents" involving a device;
- if needed, recommend device changes; and
- assess a new device concept.

Remember that interviewees usually will not be able to visualize design concepts in the abstract.

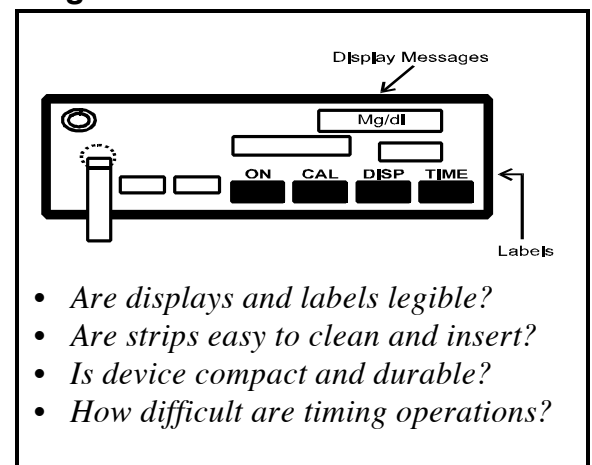
They react best to existing devices, mockups, or pictorial drawings of a device interface. In the latter instance, the operational logic should be clear. Allowing people to react to something tangible will provide a wealth of ideas. Questions, such as those in Figure 6, can help target problems with design.

Interviewing Supervisors, Trainers, and Risk Managers: Most healthcare supervisors have fairly broad views of device strengths and weaknesses. They are aware of serious incidents and device characteristics that are substantial impediments to productivity. Training staffs often have detailed knowledge of the effects of design on training time, as well as recommendations for instructional manuals. Risk managers document incidents that can shed light on specific design problems.

Interviewing Maintenance Personnel: Maintenance personnel may have a unique perspective about device problems. Users often bring to them "broken" devices that, in fact, are functional but difficult to use. For example, poor design-for-installation and examples of misinstalled components may come to light. In addition, a damaged device may signal a user-related problem. Finally, since recalled devices often are modified on site, technicians will know of both hardware and software fixes related to deficiencies in the user interface.

Conducting Focus Groups: Focus group sessions are group interviews of a few individuals from a specified population. The sessions are conducted to obtain opinions

Figure 6 - Blood Glucose Monitor



and ideas regarding a product concept. A focus group typically consists of about six to eight healthcare practitioners or lay users. These individuals should be prospective users of the new device under consideration. Such sessions are best conducted by experienced moderators working from scripts prepared in concert with the design team. Well-conducted sessions yield numerous ideas about user-interface design alternatives and user requirements. Remember that users generally have limited knowledge of design alternatives and principles. Thus, the best approach is to weigh subjective data against known interface characteristics, human factors expertise, and user performance data. Finally, because dominant individuals can bias findings, it may be wise to also consider one-on-one sessions.

Physical Measurements: Measuring sound and light will help in the assessment of such design-moderated factors as glare, contrast, and masking by ambient noise. Also, measurements of both physical reach and visual envelopes are necessary in workstation design. Samples from different facilities will produce data to profile typical work environments.

Summary

Observational studies and interviews can pay handsome dividends. The design team gains a better appreciation of the user population, the working environment, potential hazards, problems with predicate devices, and viable alternatives for new designs.

ANALYSES

Analyses of functions, tasks, and hazards are important to good design and will help shape the user interface by providing information about:

- user requirements and usability goals;
- other devices in the users' environment;
- bottlenecks to potential performance and error-inducing factors;
- possible hazards;
- device impact on user training; and
- device operating logic.

Analyses merit careful attention and should be woven into the development process.

Functions and Tasks

The user and a finished device work together as a system. Primary functions are device installation, maintenance, operation, and monitoring. The user's functional

contributions are referred to as tasks. Increasingly, devices are multi-functional in order to accommodate a wider range of users and to increase the flexibility of applications of the device. Such increased capability can impede ease of use, unless the respective assignments of functions to the device and tasks to the user are carefully weighed. Machines are good at storage and retrieval of coded data, rapid computation, timing, and deductively-based activities. People perform better in sensory, judgmental, interpretative, and non-routine tasks. The number of functions and relative device/user allocations have important implications for the user interface.

As a hypothetical example, suppose that an infusion pump designer decided to provide the user with the capability to "stack" flow rates, i.e., to program a sequence of rates that will apply to successive patient administrations. A number of questions arise: Should flow rate retrieval and administration functions be automatic or manual? What happens if one of the queued flow rates is accidentally deleted, defaulting to the next flow rate? How does the user identify and track the flow rates? How does the user access and change a specific flow rate? If such questions are addressed early in the product's development, the answers will help shape the functional design, which in turn will help determine the user-interface alternatives.

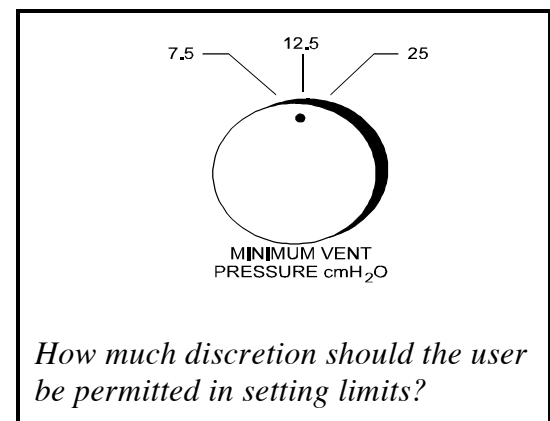
Some functional issues are complicated by medical practice, operating conditions, and the preferences of individual healthcare practitioners. An example is the degree to which ventilator or anesthesia machine pressure-limit alarm settings, illustrated in Figure 7, should be under the user's control. Many practitioners prefer a wide latitude in setting alarms. However, a very low alarm setting permits the user to effectively disable the alarm. Safety implications should be carefully weighed against the user's preferences.

In summary, too many functions or too much/little automation can be problematic, depending upon the user population and working environment. The appropriate tradeoffs should be considered at an early stage in the evolution of the design concept.

Analyzing Tasks

Task analysis is critical to good human-factors engineering and can be performed throughout the development phase. At various points, the design team should perform detailed sequential analyses of those tasks that comprise assembly, installation, operation, and maintenance. In the early conceptual stages, critical tasks can be identified and described by observing and/or questioning healthcare professionals who use the type of device under development. When design concepts are initially formulated, the analyses should be conducted as paper-and-pencil exercises. As

Figure 7 - Ventilator Alarm Control



development progresses, analyses can be performed with such tools as device descriptions, drawings, existing devices and prototypes. There are many methodological variations, but task analysis is basically straightforward. Depending upon the scope and purpose, the analyst usually will do some, or all, of the following:

- list the major tasks, such as calibration, entering operating parameters, attaching the device to patient, and cleaning parts;
- describe the necessary information for each task, user actions, required decisions, and related accessories;
- describe the device response for each action or step;
- record observations and inferences about design factors which potentially impact the user;
- list the effects of environmental conditions and other devices on the user interface and performance; and
- list the impact of the user interface on training requirements.

The following table shows a few steps from an analysis of a marketed infusion pump conducted by FDA. The analysts were “troubleshooting” the user interface design.

In this example, the human factors team found that performing the initial setup steps was quite easy; but, shortly into the exercise, problems arose. First, the team had been operating on the assumption that the pump was plugged in when, in fact, it was not. Because the battery and AC power icons were poorly located and very small, they appeared as tiny “dots” at normal viewing distances and angles. Therefore, they were easily overlooked. The team also discovered that users could miss important status information and prompts due to a very brief display of data. When the keys for entering flow rates were depressed for more than a fraction of a second, the values scrolled past the desired one. In addition, there was auditory feedback only after the initial key press, not following each of the scrolled values. Inconsistencies across operating modes in the operation of a double function key were found, and these could be very confusing to the user.

Sample of Task Analysis Steps from Analysis of an Actual Pump: Troubleshooting the User Interface

User Action	Device Response	Observed Problem
1. Push "On" button.	If unplugged, battery light (icon) glows. If plugged in, power light glows. "Select Mode" message appears for brief interval of 3 seconds Flow rate and volume displays show "0" even if there is a default value.	Battery and power lights are so small and poorly positioned that the user probably will not notice power status. User likely will miss mode indication and leave device in previous (default) mode. Many other pumps show default value from last use. User may assume no default value with this pump (see step #3).
2. Press pump mode button.	Mode light glows.	Mode lights do not blink, are small, and can easily be missed. Each is close to a key with no functional relationship. Incorrect association is very possible.
3. Press rate button.	Flow rate displays default value from previous administration.	User experienced with another pump may assume a "0" value by this point and miss default value (see step # 1).
4. Enter flow rate values in ml per hour.	As first value (e.g., 100 ml) is entered, device "beeps" and 100 is displayed. User can scroll in increments of 100, and successive values are displayed - but no more "beeps". With constant pressure on key, values may scroll up to 300 ml, for example, in 1 sec.	A distracted user, not observing display, may intentionally or accidentally enter more values without any auditory feedback to indicate entry.

The research team visited a hospital after performing this analysis, and, by chance, this pump was used in the unit visited. The head nurse stated that she had selected it because it seemed "user friendly." Unfortunately, the unit staff found it so difficult to use that the head nurse now considers the pump not only an inconvenience to users but an impediment to safety and effectiveness.

If task analyses had been performed in the preceding example, a set of guiding principles for pump setup might have emerged, such as the following:

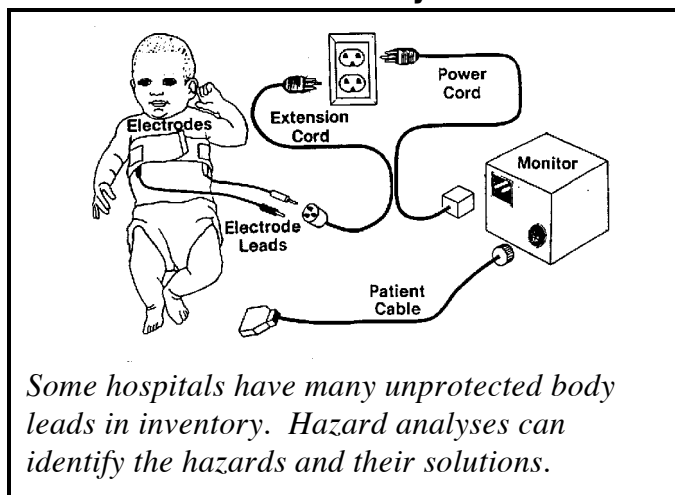
- Status indication and feedback should be precise and unambiguous.
- Displayed alerts should be attention-getting and in view until an action is taken.
- Flow rate and volume-entry mechanisms should be convenient for the user, without sacrificing accuracy (e.g., over-scrolling).
- Specific keys should operate in a consistent manner across modes.

Hazard Analyses

Human factors should be integrated into procedures used to isolate hazardous device failures. Although these analyses conventionally deal with electrical and mechanical problems, potential hazards associated with the user also should be evaluated. One should assume that if errors can occur, they will occur and that design may be a factor. Hazard analysis meetings provided an excellent collection point for possible hazards uncovered from complaint files during earlier studies, as well as from tests, user studies, and task analyses. As a first step, by considering errors as “failures” analysts can hypothesize what errors are possible. Then, they can analytically pinpoint potential causes and draw conclusions about consequences and appropriate design solutions. This information may be tabulated to provide a concise overview for further analysis and/or input into the design concept and requirements.

The utility of such an approach is illustrated by electrocutions of infants resulting from the insertion of patient electrode leads into AC power cords by parents, siblings, and healthcare professionals (see Figure 8). If analysts had considered the use environment, user populations, and potential errors, the hazard probably would have been identified and the appropriate solution, such as recessed body leads, implemented. One should note that *hazard analyses may pinpoint low-frequency errors not discovered in prototype tests involving users.*

Figure 8 - Electrical Leads & Hazard Analysis



Other Analyses

Other techniques include time lines and workload analysis. Time lines represent sequential and simultaneous responses required of the user which are graphed over time. Workload analysis can produce measures ranging from estimated expenditures of energy for physical tasks to subjective and performance measures of the performance requirements imposed on operators. Both of these methods are useful in multi-task situations which involve the use of more than one device by the user.

Summary

Thorough and continuous analysis is a powerful tool and is necessary throughout the design process. Overall, the findings can be combined with drawings, diagrams, user profiles, and various other data summaries to help shape alternative user-

interface designs, elucidate flaws in design, and provide the focus for human-factors tests.

USABILITY TESTING

Testing for ease and accuracy of use is the only way to ensure that users can safely and effectively operate, install, and maintain devices. By means of *iterative prototyping*, individual concepts of design can be tested, refined, and retested throughout the development process. This process culminates with *full testing* of a model embodying all the user-interface characteristics for both hardware and software of a fully functioning device.

Developing Prototypes

Prototypes simulate the user interface as defined by both the hardware and software; they are used to select alternative designs and uncover problems. A prototype's fidelity, or resemblance to a working device, is determined by its physical and/or conceptual attributes. If installation, control and display layout, or manual operation (e.g., of surgical tools) are of special interest, mock-ups should be used for physical simulations, or "games playing". Users can perform the procedural steps to confirm or repudiate the design or layout details. If underlying machine logic and information presentation are of concern, story boards, screen prints, interactive computer models, and working models can be used to evaluate user efficiency with a given interface design. An early test might consist of users completing tasks by performing data entry operations on a sequence of screen prints. The test participants would indicate their selected keys, while verbally describing each action. Each user input is followed by the presentation of a new print showing the appropriate feedback, prompts, or status change.

With more sophisticated, computerized prototypes, key panels and controls are represented graphically on a computer with the program having limited functionality. Thus, for example, a finger press on a specific "button" simulated on a touch screen results in apparent button movement, followed by displayed feedback. The program then sets up the contingencies for the next operator response. "Horizontal" prototypes present an overview of top-level features but do not permit much operational depth. "Vertical" approaches allow more in-depth operation of fewer functions and greater data access. "Scenario" prototypes combine features of both approaches, allowing test participants to perform a limited number of tasks of particular interest at a given point in development. Based on the findings, the design is refined, and the prototype is then retested. Such prototypes permit a great deal of flexibility in evaluating alternative designs prior to the final stages of development.

Developing Scenarios

Written scenarios help provide the structure for what test participants actually will do. A scenario generally is a written description of what the participants are expected

to accomplish and may be narrow or broad in focus, depending upon the purpose of the test and the functionality of the prototype. For example, the participant might be asked to turn on an infusion pump and set it up for drug administration by keying in the appropriate flow rate and volume-to-be-infused parameters. A more advanced scenario might include other tasks, such as installing the administration set, performing primary and secondary infusion, changing parameters, and reacting to an emergency. In all cases, scenarios should be clearly written to help ensure consistency across participants and test conditions. Healthcare professionals are of great use in creating scenarios and checking them for realism and accuracy.

Requirements and Measures

User requirements are based primarily on earlier interviews, observations, manufacturer's experience, analyses, and literature reviews. Some requirements are specific, such as "installation should take no more than 30 minutes." At the conclusion of the test, the actual performance times can be compared to these criteria. In other instances, initial requirements will be broader, such as "novice users should reach high levels of efficiency after a few hours of training." Efficiency, in terms of errors and time, can be hard to determine while the design concept is in flux. At some point in development a clearer picture of expected performance levels will emerge, and detailed performance criteria need to be defined. If possible, these should be quantitative and should be linked to safe use and any other goals important to the manufacturer and user population. In addition to specific strengths and weakness in device operation, a number of other design-related measures may be important, such as calibration time, accuracy, changes in error probability, and other measures.

Various measures are used in testing. Errors may be recorded by direct observation, videotaping, or electronic data logging. Speed of operation is based on completion times of tasks, and other objective measures may be used, such as the number of times the user must refer to the device manual. Verbal responses also are important and can be obtained by interviews or by having users state the rationale for their actions as they progress through task sequences. Also, subjective impressions of usability and potential safety problems are important.

Facilities

Depending on resources and the nature of the test, a modest usability laboratory may suffice. A limited facility might consist of a room containing a table, chairs, electrical outlets, and adequate lighting. An increasingly elaborate setup would include a one-way mirror, observation room, video camera(s), adjustable lighting, tape player for noise presentation, an automated data-logging system, a microphone, and other medical equipment. Finally, testing in medical facilities is another possibility.

Test Participants

In the case of small, iterative, prototype evaluations conducted throughout development, two or three participants per test may be sufficient. Employees such as clinical staff may be used, although repeated use of the same individuals can bias the findings. Full usability tests require larger samples drawn directly from the user population. If a device is intended for a fairly homogenous population, data obtained with about 10 individuals representative of that population *may* be sufficient to eliminate most problems. However, it is important to note that the cumulative number of participants over the course of development can be substantial, given the iterative small tests mentioned earlier.

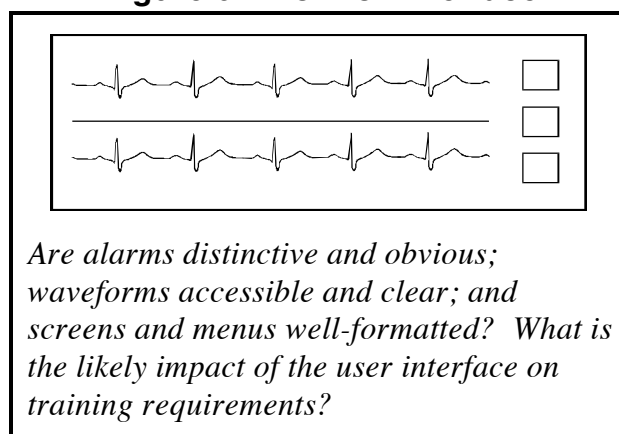
In general, the test team should consider the extent to which additional problems are uncovered as more participants are added and/or as more tests are run. With a more heterogenous population or in competitive device testing, larger samples are desirable. The user interface can be maximally stressed by using new healthcare practitioners. However, the preexisting habits of experienced individuals also may be an important concern, depending on the type of device and target population. With home-use devices, participants should be sampled from the lay-user population. In some cases, the effects of medication should be considered, provided that safety and ethical standards are met.

Conducting the Test

Below is a scenario that might be used in a fairly comprehensive assessment of the user-interface design of the arrhythmia monitor. It consists of narrative that requests the participants to perform various tasks. This will help the test team obtain data on errors, performance times, and impressions of device design features.

Evaluation of the data will answer the kinds of questions listed under the monitor in Figure 9. The participants might be given instructions such as the following:

Figure 9 - Monitor Interface



“Turn on the monitor and perform the basic setup tasks, such as checking and adjusting the calibration, amplitude, gain, and alarm limits. When prompted, retrieve waveforms and trend data as specified. Report any visual alarms such as disconnected lead wires or a low battery.”

Generally, the device users selected as test participants should be healthcare professionals who are not trained on the specific model. After participants become familiar with the monitor, the test team might have them run through the operations at their own pace, at any point probing with questions about bottlenecks or apparent

problems. If critical issues arise, the test can focus on these and less on others. In addition, because devices are often used in very intensive, novel situations, users can be stressed by minimizing their familiarization with the device and limiting the use of instruction manuals, which often are not readily available in real world situations. Also, consider the possibility of testing novice device users, in order to impose a greater burden on the interface.

Possible performance measures in the sample scenario include set-up times, number of errors, type of errors, changes in error rates, failures to detect and discriminate alarms, task completion time, and any observations that indicate performance obstacles. In addition, if the participants are asked to "think aloud" as they proceed through the tasks, it is important to develop a record of their remarks. Finally, pre- and post-testing questionnaires or interview comments, likes and dislikes about user interface elements, and other comments about overall device safety and usability are valuable. One caveat, however, is that users generally are inexperienced with design principles. Although their opinions generally are valuable, the subjective preferences of device users for various interface designs are most valuable when assessed in conjunction with performance data and expert opinion.

Testing in the "Real" Environment

The user interface should be tested under conditions that are as realistic as possible. Participants should be reminded that it is the *device*, not themselves, being tested.

Simulating Actual Conditions in the Laboratory: Some aspects of actual use conditions are relatively easy to simulate. For example, adjustable lighting and individual lamps of varying wattage and direction will produce variable levels of illumination and glare. Likewise, tape recordings from emergency rooms, operating rooms, and critical care facilities will reproduce decibel and frequency levels that challenge alarm audibility and the user's concentration. With home-use devices, it is important to simulate environmental constraints (e.g., space) that pertain to such device characteristics as placement and portability.

It is more difficult to simulate patient and device status, as well as the interactive effects of multiple devices. In the monitor example, changes in patient and device status could be simulated by programming in ECG changes and alarms. In multiple device scenarios, test participants might alternate between different devices they typically use on the job. Variables might include conflicting user-interface designs and problems associated with device attachments.

Simulations in Healthcare Facilities: Even without patients, performance testing in healthcare facilities adds substantial realism. If on-duty physicians and nurses are tested on devices that effectively simulate device interfaces and functions, the effects of stress and fatigue on use of the device can be assessed, especially if the tests are conducted at the end of shifts. Testing in emergency rooms, operating rooms, or

critical care facilities is difficult, if not impossible. Testing in many cases should be performed during breaks and be limited to especially problematic design issues. The exception would be a study in which a medical team performs a lengthy, simulated procedure. Then, the facility essentially becomes a laboratory.

Simulations in Homes: Medical devices intended for home use should be tested in that environment. This can be especially useful in assessing devices that pose problems associated with space, portability, availability of electrical outlets, lighting, noise, and operational complexity. Lay users should participate if possible.

Clinical Trials: Ideally, one could do full testing during clinical trials; however, there are definite limits. First, manipulating the healthcare practitioner's behavior by running scenarios would be disruptive and could endanger patients. Second, the user-interface design should be at least adequate *prior to* clinical trials. However, these factors do not preclude additional evaluation at this stage. Physicians and nurses can be alerted to design issues of special interest and interviewed after the completion of procedures. Likewise, observations by trained observers are valuable.

Field Studies: Studies of devices already in use offer an excellent opportunity to obtain valuable information once a device is marketed. Because there are few time constraints, data can be obtained from a wide variety of settings and user groups. Such studies can be modified at any point to accommodate changing circumstances. The findings will supplement and clarify complaint data, as well as provide unanticipated information pertinent to marketing and new development efforts. This data should be documented for current and future use.

Summary

Obtaining performance data from actual users is crucial. If test participants cannot safely and effectively use a device under test conditions, healthcare professionals definitely will have problems with it under actual conditions of use. Finally, the development of user requirements and thorough testing helps ensure that the final product addresses the needs of healthcare professionals and patients.

SPECIAL ISSUES

INITIATING A COMPANY HUMAN FACTORS PROGRAM

Personnel

No two product development projects are identical, and the same can be said of corporations. Size, organization, and culture vary from firm to firm; all will affect the implementation of a human-factors program. Whether relying primarily on consultants or staff experienced with human factors engineering, integrating them into project design teams is crucial.

Educating both technical and managerial staff about human factors also provides long-term benefits to the organization. The target audience for training should include engineers, designers, manual and training developers, risk managers, quality managers, and corporate executives. Staff should know what a human-factors program is and why it is important. One should consider having a human-factors professional give seminars which would include one or more of the following: (1) discussion of human factors principles, problems, and methods, (2) demonstrations, or (3) case studies. Involving a company's own designers and products will greatly increase the effectiveness of seminars. Likewise, the first-hand experience of human-factors practitioners with development efforts, design principles, liability issues, and the literature is valuable. There also are established professional short courses in human factors, and many universities offer degree programs in this discipline. There is a caveat, however: casual "armchair" approaches do not work; training and experience are necessary. Effective human factors programs consist of ongoing training that provides feedback for continuous improvement. Finally, depending on the manufacturer's capabilities and corporate resources, management should consider hiring human-factors staff. Trained human factors practitioners can expand solutions to problems in ways that others would not anticipate.

Resources

Some resources already have been discussed: the literature, guidelines, and expertise of current staff. Many manufacturers may also need a consultant's help in establishing a human-factors program. There are many highly qualified human-factors consultants available for such purposes. They currently apply their expertise to areas ranging from military systems, air-traffic control, and nuclear power plants to office equipment and, increasingly, medical devices. The basic rationale and methodology is the same in all of these areas. The societies listed below are clearing houses for consultants.

Ergonomics Society
University of Technology
Loughborough, LEIC LE11 3TU
England

Human Factors and Ergonomics Society (HFES)
P.O. Box 1369
Santa Monica, CA 90406

IEEE Systems, Man, and Cybernetics Society
345 East 47th Street
New York, NY 10017

Industrial Designers Society of America
1142-E Walker Road
Great Falls, VA 22066

Society for Information Display
8055 W. Manchester Avenue
Suite 615
Playa del Rey, CA 90293

Society for Technical Communications (STC)
Suite 904
901 North Stuart Street
Arlington, VA 22203

Special Interest Group on Computer
and Human Interaction (SIGCHI)
Association for Computing Machinery
P.O. Box 12115
Church Street Station
New York, NY 10249

Usability Professionals Association
American Airlines/STIN
P.O. Box 619616 MD 4230
DFW Airport, TX 75261-9616

Characterizing the Human Factors Effort

Despite substantial variability in human-factors engineering efforts, the following are essential:

- a designated individual in the design effort who is responsible for user-related issues;
- participants from the user population;
- requirements that the product be designed for safe use;

- studies, analyses, and tests that assess user performance and identify hazards; and
- data indicating whether or not the user interface meets requirements.

The best “advocate” for the device user is someone who works integrally with the design team. They participate in the planning and implementation of the appropriate studies, analyses, and tests. Test participants can be drawn from the company’s pool of clinical staff and outside healthcare professionals. Potential hazards, errors, and broader usability issues normally are defined from device records, user studies, and analyses. They will help shape initial requirements of the user, which will be refined throughout development and will help determine the test criteria and measures.

Although there is no formula for deciding how extensive a human-factors effort should be, consideration of some basic variables will help in making decisions. Weigh the following: the nature of the user-device interaction, the user population and use environment, the likelihood and criticality of errors, the feasibility of alternative user interfaces, and the company’s experience with predecessor devices.

In the unlikely case that a device has virtually no user interface or functional integrity precludes interface design options, a substantial human engineering effort would not be warranted. However, most devices require substantial user/device interaction, and the complexity of the interface usually is an issue. The greater the impact of errors upon the health and safety of patients, the greater the need for thorough analysis and testing. If the user interface is similar to that of a previous model, the use history of the latter model and the potential impacts of any changes to the new model merit attention.

The Appendix offers points to consider regarding human factors engineering efforts.

ADVICE TO HEALTHCARE FACILITIES

Recognizing human-factors design problems with already purchased devices is important. The selection of new equipment that staff can operate safely and effectively also is important. This section deals with these issues.

Recognizing Problems

Healthcare professionals are more likely to blame themselves for errors than they are to blame the equipment. User interface flaws can be subtle, and a physician’s or nurse’s attention is focused on the patient, not the device. Also, a sense of professional responsibility often precludes healthcare practitioners from “blaming” the device; as a consequence, practitioners are often blamed for design-induced errors. Although problems with user interface do not negate one’s responsibility for proper training and careful operation of a device, poor design can greatly increase the

likelihood of errors. Such errors can have serious consequences and *cannot simply be trained away.*

If there are serious flaws with the design of a device, patterns may emerge. Ask users about operational problems they have experienced with a given device. Try to determine how widespread the problem is. Biomedical engineers and other maintenance personnel constitute a valuable source of information. In addition to individual interviews, try a focus group or questionnaire approach.

Evaluating Already-Purchased Devices

Below are some indications of problems.

Observations:

- Training has been slow and arduous.
- Only a few staff members seem able to use the device.
- Staff tends to modify the equipment or takes shortcuts.
- Staff refuses to use the device.

Installation Problem:

- Staff finds installation of accessories difficult, confusing, or overly time-consuming.
- Alarms and batteries often fail.
- Incorrect accessories sometimes are installed.
- Parts often become detached.

Complaints :

- Displays are difficult to read or understand.
- Controls are poorly located or labeled.
- Alarms are difficult to hear or distinguish.

- Device alarms are very annoying.
- Device operation is illogical and confusing.

Incidents :

- Accidents or “near-misses” can be a warning, especially if there are highly competent individuals involved. When questioning staff and examining implicated devices, look for types of problems mentioned above.

The December 1995 coding manual for Medical device reporting using mandatory MedWatch FDA Form 3500A contains a number of codes having implications for user interface design. These are found under the “Device-Related Terms”, “Results of Evaluation Codes”, and “Conclusion Codes.” They are valuable not only for device-reporting purposes but also for sensitizing staff to important human factors design issues.

Evaluating Devices Before Purchase

Before buying a new model, consider the means of assessing its usability, especially if it is a life-sustaining or life-supporting device. Following are some steps to consider:

- Determine whether or not the manufacturer conducted human factors/usability testing of the device in question.
- Check with staff, and possibly other facilities, about predecessor models made by the manufacturer.
- Check with other facilities that may also be using the new model.
- Check published evaluations of the new model.
- Request a trial period prior to the actual purchase of a new device.

Analyze and Test the Model

When doing analyses and tests on devices being considered for purchase or already in use, there are a few guidelines to keep in mind. Be careful not to bias the users. Staff should be told that it is the device, not the users, being tested. If this is not made clear, users may feel that their performance will be discussed with their superiors, and thus they will not be forthcoming about errors and deficiencies related to interface design. Also, should a device be evaluated during actual use on patients, data should be collected over a reasonable length of time, not just a day or two. In real

world settings, actual problems often emerge slowly and require repeated observations for identification. Findings may prove of great value to both healthcare facilities and manufacturers.

Final Comment: There is much one can do to assess devices already in use, as well as those being considered for purchase. Let the manufacturer know of uncovered strengths and weaknesses. Companies not only are responsive to their customers, but they want to market medical devices that meet customers' needs for functionality, safety, and effectiveness.

APPENDIX

Points to Consider

In considering the need for, and conduct of, human factors analysis and testing, there are a number of issues and questions to ask.

1. Does the device require user interaction with respect to operation, maintenance, cleaning, or parts installation? If so, do the technology and device functions permit alternative user interface designs?
2. Given the combination of user interface, user population, and operating conditions, are errors likely?
3. Could the consequences of error be serious for the patient or user?
4. In doing actual testing:
 - Is someone integral to the design team focusing on the user-related issues?
 - Are users involved?
 - Are hardware and software designers, technical writers, and others coordinating their efforts with respect to human factors?
 - Has a test plan been developed?
 - Have user requirements been developed, and are they being updated?
5. Has the design team checked the literature and company files for useful human factors information?
6. What studies, analyses, and test steps are being performed? Are staff examining all relevant issues related to the installation of accessories and operation of the device?
7. Has the project team done testing in simulated and/or actual environments?
8. Have user requirements been met?
9. User interface changes can be inadvertently introduced into production models during manufacturing. Have they been accounted for?

GLOSSARY

The definitions in this section are pertinent to this document. In some cases they are general and may not coincide with a specific usage or application.

Administration set (intravenous): A device used to administer fluids from a container to a patient's vascular system through a needle or catheter inserted into a vein. The device may include the needle or catheter, tubing, flow regulator, drip chamber, filter, stopcock, fluid delivery tubing, connectors, capped side tube to serve as an injection site, and hollow spike to penetrate and connect the tubing to an I.V. bag or other infusion fluid container.

Anthropometry: The field that involves the measurement of the dimensions and other physical characteristics of people and the application of this information to the design of things they use.

Blood glucose monitor: A device that quantitatively measures glucose concentrations in the blood.

Calibration: To check, adjust, or standardize systematically the graduations of a quantitative measuring instrument.

Cardiac monitor (including cardiometer and rate alarm): A device used to measure the heart rate from an analog signal produced by an electrocardiograph, vector cardiograph, or blood pressure monitor. This device may sound an alarm when the heart rate falls outside preset upper and lower limits.

Catheter: A tubular medical device for insertion into canals, vessels, passageways, or body cavities, usually to permit injection or withdrawal of fluids or to keep a passage open.

Coding: Identifying objects or events with the use of recognizable symbols, typically visual or auditory, utilizing readily apparent variables such as color, shape, size, direction, pitch, or duration.

Cognition: Processing information about the environment and oneself in conscious intellectual activity, as in thinking, reasoning, remembering, and imagining.

Default: Parameters that are automatically selected by a machine in case deliberate actions by the user do not occur.

DC-Defibrillator: A device that delivers an electrical shock for defibrillating (restoring to normal heart rhythm) the atria or ventricles of the heart or to terminate other cardiac

arrhythmias. The device delivers the electrical shock through paddles placed directly across the heart or on the surface of the body.

Enteral Feeding Tube: A tube for passing of food or medicines into the stomach.

Function: The action or accomplishment intended of a system where the system consists of a device and a user. Alternatively, individual *primary* functions, such as installation, maintenance, operation, and monitoring, are needed to accomplish the intended use of the user-device system.

Guide wire: A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

Human Factors: In the broadest sense, a discipline devoted to the effects of user interface design, job aiding, and personnel training in the operation, maintenance, and installation of equipment.

Heart valve leaflets: Any of the leaf-like flaps of the bicuspid or tricuspid valves of the heart.

Infusion pump: A device used to pump fluids into a patient in a controlled manner. The device may use a piston pump, roller pump, or a peristaltic pump and may be powered electrically or mechanically. The device may include means to detect a fault condition, such as air in, or blockage of, the infusion line and to activate an alarm.

Infusion pump cassette: That part of the set of intravenous tubing that fits into an infusion pump. Each cassette is “dedicated” or designed to fit a specific pump.

Iterative Prototyping: Successive small-scale tests on variations of a limited function prototype. Such tests permit continual design refinements based upon human performance.

Interlock: To prevent initiation of new operations until current operations are completed (computer science). To connect in such a way that no part can operate independently.

MedWatch Form 3500A: A form that must be completed by user facilities and manufacturers to report device-related adverse events to FDA under the medical device reporting (MDR) system (21 CFR, Parts 803 and 804).

Mockup: Usually a full-sized scale model of a structure, used for demonstration, study, or testing.

Negative transfer: Transfer of training that results in increased likelihood of human error, due to changes in the user interface or situations that are not obvious to the user.

Oxygen concentrator: A device that produces a high concentration of oxygen (85% to 95%) at clinically useful flow rates (up to 5 L/min) by physical separation of oxygen from ambient air. Oxygen concentrators are commonly used in home healthcare and occasionally in general anesthesia.

Screen print: A static image, represented on paper, which is used to show how a computer program will appear on a monitor.

Storyboard: One page in a series of paper representations of the sequence of actions possible in a system. Story boards representing a computer program could show keys, prompts, and changes in status.

Task: The steps or work activities required of the user in order to perform functions.

Task analysis: Identification and analysis of the key user tasks and steps for a device. The analysis may be conducted as a paper-and-pencil exercise for a device concept, or by running through the procedures on a prototype or actual device.

Transfer-of-training: The automatic application of skills, habits, or expectations to a new situation that appears similar to the one in which the skills and expectations were originally developed.

Usability Test: A test of either an actual device or an advanced prototype with a fully functional user interface. Data obtained includes user performance (time, errors, and accuracy) and subjective responses of test participants.

User performance data: Information describing human behaviors and responses during task performance. Examples of the criteria measured are frequency of accomplishing a task, time required for task accomplishment, and changes in performance with practice.

Ventilator: A continuous ventilator (respirator) is a device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas.

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