# Human Factors in Medical Device Design

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# Human Factors in Medical Device Design

## Methods, Principles, and Guidelines

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**KEYWORDS**

• Intensive care unit • Human factors • Adverse events • Medical devices • Usability

**KEY POINTS**

- A total of 400,000 to 500,000 patients die in intensive care units (ICUs) each year, largely because ICUs care for the sickest patients.
- On the other hand, factors such as workload, shift changes, handoffs, alarm fatigue, inadequate team communication, and difficult-to-use medical devices contribute to the problem.
- This article focuses on the human factors of those medical devices, a significant cause of adverse events in the ICU.

## INTRODUCTION

There are approximately 6000 intensive care units (ICUs) across the United States,[1] caring for nearly 55,000 patients every day.[2] This accounts for approximately 10% of all hospital beds and 1.5% of US gross national product,[3] numbers that will only increase as the population ages.

More important, 400,000 to 500,000 patients die in ICUs each year,[1] largely because ICUs care for the sickest patients. On the other hand, factors such as workload, shift changes, handoffs, alarm fatigue, inadequate team communication, and difficult-to-use medical devices contribute to the problem. For example, Donchin and colleagues[4] estimate 1.7 errors per patient per day in ICUs, with 29% of these errors having potential to cause significant harm or death. This article focuses on the human factors (HF) of those medical devices, a significant cause of adverse events in the ICU.[5]

## HUMAN FACTORS

The most complex part of any medical device is the person using it. Unless the device operates entirely on its own, the user's behavior, capabilities, and limitations

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are key to its effectiveness and safety. HF applies scientific knowledge about human behavior, capabilities, and limitations to design.[6] By understanding how humans think, decide, and act under stress, we can engineer products that humans can use safely, correctly, and reliably.[7] Because people are complex and multifaceted, HF includes practitioners from cognitive psychology, sociology, anthropology, industrial engineering, industrial design, medicine and related health sciences, biomechanics, and more. The common denominator is that each focuses on human behavior, capabilities, and limitations. This focus not only improves the performance and satisfaction of health care providers, but also improves patient safety.

It is also important to describe what HF is not, articulated by Lee and colleagues[6] who point out that HF is not simply applying a checklist to determine if a product is easy to use. The variability of people, situations, tasks, technologies, and environments make creation of such a checklist impossible. Second, HF is not simply using oneself as a model of the end user. There are sizable person-to-person variations in size, strength, reading ability, stress, exhaustion, technical sophistication, and so on. This requires design for a wide range of users, rather than just one "type." Unfortunately, organizations may believe that good HF is easy or "common sense," but if that were true, the world would be chock full of easy-to-use medical devices. Personal experiences of health care providers, as well as numerous product recalls and adverse events, suggest quite the opposite.

## USABILITY

Usability[8] is a term so closely related to HF that it is often treated as a synonym. Rubin and Chisnell[9] argue that "a usable product enables users to do what they want to do, in the way they expect to be able to do it, without hindrance or questions." Usability is defined along 5 dimensions.

- *Learnability* refers to users' ability to begin using a new system quickly and correctly, and to develop proficiency within a reasonable time frame.
- *Efficiency* refers to whether the system allows users to complete tasks more easily than working without the product.
- *Memorability* refers to how easily users can return to the system after a period of inactivity and recall important functions, features, and interactions.
- *Error resistance and remediation* refers to how well a system prevents errors or handles errors when they occur.
- S*atisfaction* refers to how pleasant the system is to use. Users desire products that are not merely functional, and systems that cause individuals to be miserable are less usable.[10,11]

Two approaches to improving medical device HF are described in the following sections. The first is a design philosophy called human-centered design. The second is a set of design principles, derived from research in cognitive and biological sciences, such as perception, attention, memory, learning, and emotion. These approaches should be used in tandem.

## USER-CENTERED DESIGN

The International Organization for Standardization states that user-centered design involves the active involvement of users, clear understanding of user and task requirements, correct allocation of functions between users and technologies, iterative design solutions, and multidisciplinary design.[12] Gould and Lewis[13] articulated 3 tenets for user-centered design:

- An early and constant focus on the users and their tasks.
- Reliance on human-system performance and behavioral data to guide design decisions. Commonly, these data are generated by usability tests, which collect measures such as success and failure rate, error rate, timing, self-report, and user perceptions to reveal problems and barriers.
- Iteration. Good design entails many rounds of design and testing until success rates, error rates, and other outcomes are brought to acceptable levels.

Some common user-centered research methods are described as follows. Some, such as contextual inquiry[14] and ethnography,[15] are aimed at gathering and analyzing user requirements. Broadly, contextual inquiry and ethnography refer to observing and interviewing research participants in their natural place of work (eg, surgical suite, examination room).

Some usability problems can be discovered via systematic inspection of user interfaces and functions without the assistance of authentic end-users (ie, similar to how programmers review and inspect code). These can be implemented quicker and less expensively than full usability tests, and yet enable designers to identify many design flaws early in development. Inspection methods are considered an informal usability evaluation method, because they rely on heuristics and the knowledge of the evaluators. In contrast, empirical techniques assess usability by testing an interface with real users.

One popular usability inspection method is *heuristic evaluation*.[8,16] In heuristic evaluation, 1 or more members of the development team evaluate a product against a list of design principles or rules of thumb. Examples of heuristics, which are particularly useful for medical devices, are provided by Zhang and colleagues,[17] and Graham and colleagues.[18] Evaluations from all reviewers can be aggregated to identify the most common problems and discuss ways to mitigate them. This method has become popular in usability evaluation due to its low cost, low time commitment, and ease of application.

Cognitive walkthrough[19,20] is a method for inspecting the learnability and usability of a system via naturalistic exploration. Developers take on the role of typical users to complete tasks within the system. During the walkthrough, individuals or groups of reviewers reflect on the actions required to complete the tasks and any barriers or confusion encountered. Reviewers might ask questions such as "what would the user be doing at this point?" and "what features in the interface are available to do this?" Importantly, a functional version of the system is not necessary; cognitive walkthroughs can be performed using detailed description of the interface, a mockup, or a working prototype, along with a task scenario or prespecified sequence of actions.[7,21]

Usability testing,[9,22,23] derived from applied experimental psychology, identifies insights about how people use a product or prototype. These expose usability deficiencies, which in turn improve system design. A usability test consists of a series of tasks conducted by authentic end-users or participants who are similar to the target user.[24] Researchers record and analyze objective performance data such as success and failure rate, error frequency, deviation from ideal task path, and task completion time. Additionally, several self-report measures of perceived usability have been developed and used widely.[25]

Usability testing can be used for a variety of purposes depending on the current design stage, including exploration, assessment, comparison, and validation.

- *Exploratory testing* occurs during initial stages of development to evaluate the promise of preliminary concepts. In general, an exploratory test focuses on high-level aspects of the information architecture rather than on fine detail.[9]
- *Formative tests* are conducted early or midway through the development process, usually after high-level design decisions have been made. Formative tests seek to identify and fix usability issues at a detailed level. Tests at this stage typically rely on mockups, prototypes, and tasks that more closely match final products (ie, higher fidelity).
- Comparative tests. When multiple or competing versions are available, *comparison tests* evaluate one design against another. Comparisons can happen at any point in the product development cycle.
- Validation tests. Finally, *validation testing* is usually conducted late in the product development cycle to confirm that features and systems meet predefined standards and benchmarks.

When designing, it is helpful to consider the ways people process information, so that we can present the information and tasks in the most appropriate way. The following sections describe important stages of human information processing, and corresponding design principles and guidelines. For more information on principles and guidelines, see Lee and colleagues,[6] Nielsen,[8] Shneiderman and colleagues,[26] and Zhang and colleagues.[17]

## DESIGN PRINCIPLES

### *Perception*

Perception refers to the ability to see, hear, become aware of, and recognize stimuli in our surroundings.[27] Perception relies on more than just sensory organs, such as eyes and ears (bottom-up processing), but it also relies on stored knowledge, experiences, memories, and expectancies (top-down processing). Perception then involves reconciling what our senses tell us with what our brain knows and expects. We can facilitate bottom-up processing in various ways. For example, we can make controls, displays, labels, and text legible from the distance of use. This means that the text must be large enough and provide adequate contrast. Contrast enables us to discriminate between the figure and the background, and is maximized with black text on a white background, although often aesthetics requires another configuration. Use light backgrounds for main areas of displays. Good examples include off whites and grays.[28] It is important that text can be read quickly and easily. Also, for improved perception, not all text is created equal. The perception of text is improved, and the device made more usable, when a familiar and unadorned font is used, when mixed case (rather than all capitals) text is used, and when sans-serif fonts are used on computerized displays and serif fonts are used for hard copy, such as instructions for use.[6,29,30] Finally, include labels on your icons. This reduces ambiguity and speeds recognition.[31]

Sensible grouping of display items and controls facilitates top-down perception. For example, it is advisable to place similar, related, and items used to complete the same task in sequence, close together.[32] Usually white space is helpful to separate display items between groups, but you could also use boxes, borders, color coding, or shape coding. One key is to adhere to user expectancies. Based on experience, people often expect to find items in certain places on a device or screen. It is important to match those expectancies as closely as possible.

Because perception is about recognizing components and groups on a device, we must try to make items as easy to recognize as possible. There are a few ways to do this. One is called pictorial realism.[33] Specifically, it means that a display, icon, or sign should look like the thing it represents. An example of pictorial realism is a print icon that looks like a printer. It is easier to recognize because it looks like the concept it represents. Another tip is to use redundancy gain,[34] which refers to expressing the same information in more than one way. An example is a stop sign, which is red in color, hexagonal in shape, and says STOP. Three cues combine to make the sign more recognizable than any one cue alone.

Finally, perception refers to more than just vision. It is important that auditory alarms, messages, and warnings can be heard in ambient conditions of use.[35] This is difficult these days when so many devices have their own auditory warnings. It should be mentioned that auditory warnings have many qualities, which can be manipulated to make them discriminable. These include volume, frequency, tempo, envelope (for example rising sound or falling sound), and others.[35] This is particularly relevant to the ICU, where health care providers are exposed to numerous technologies all at once,[21] and in which the sheer number of false alarms often causes alarm fatigue.[36] The key is to treat auditory displays such as these with the same attention provided to visual displays.

### *Attention*

The fact that we use the phrase "pay attention" suggests that attention is limited and valuable. Despite our best efforts, we have only so much attention to go around, so we allocate it in ways that help us achieve our goals. You can think of attention as a spotlight. It can be wide and diffuse, shedding a little light on a lot of things, or it can be focused, shedding lots of light on just a few things,[37] but it cannot be both at once. Here are some ways to help users to pay attention to the right things to complete their tasks.

The first approach is to design for minimalism. In 1939, well before many health care technologies, Antoine de Saint-Exupery[38,39] wrote, “a designer has reached perfection not when there is nothing left to add, but when there is nothing left to take away.”[a] This captures the essence of minimalist design, encouraging us to avoid clutter, placing only necessary information on the display, because everything else is distracting. Further, color should be used sparingly and consistently. In fact, many designers suggest no more than 4 colors per screen on visual displays,[6,40] and very few colors in icons. The issue is that icons are so small that it is hard to discriminate where one color ends and another begins. This gives it a fuzzy look that makes it hard to recognize.

The best way to get people to pay attention to an item that you want them to notice is through conspicuity[41]; that is, items tend to pop out and capture attention when they differ from their surroundings. These differences can include different shapes, colors, and brightness. On the most rare occasion, for example, an emergency situation, blinking or movement on the display attracts attention strongly. Because it is so distracting though, it should be used only in the most serious situations.

### *Learning*

In a perfect world, all devices would enable us to simply walk up and use them. In this world though, devices often need to be learned. Because humans manage complexity by placing things in categories and hierarchies, learning is facilitated by organization.[42] For example, good graphical user interfaces place items that are related to

[a] Actually he wrote “In anything at all, perfection is finally attained not when there is no longer anything to add, but when there is no longer anything to take away.” The design profession appropriated and modified the quote slightly.

each other, either because they are similar or are used together in the completion of a task, in close proximity. This enables the user to look at the layout of items and learn the underlying model of the device. Additionally, people spontaneously search for similarities between new situations and previously encountered situations. For this reason, learning is facilitated by analogy and metaphor.[43–45] Indeed, one of the reasons for the success of Apple's Macintosh user interface was because it used the familiar metaphor as a desktop, with files, file folders, and other objects people were already familiar with from the office environment.[46]

Devices are easier to learn when they are consistent, using consistent labeling, placement of information, and color coding.[47] They are also easier to learn if they behave similar to other medical devices used in the same environment and for related tasks. Further, devices are made easier to use when the user is provided with informative feedback, enabling them to understand the device's status at all times.

Generally, people are not motivated to learn how to use a new device; instead, they are motivated to actually use it. Consequently, training and tutorials are most effective if they take place in the context of real work and real tasks. This is one of the benefits of simulation training,[48] designed to re-create the context of use. Each realistic component of the simulation serves as a memory recall aid for during a subsequent actual event. Further, tutorials and documentation should be situated and available during the conduct of these real-world tasks, and easy to find, searchable, and should avoid jargon.

### *Memory*

Peoples' memories are far from perfect.[49] People tend to forget information when they conduct complex tasks, especially if they are distracted or stressed, as they often are in the ICU. Additionally, they tend to forget when trying to integrate information between screens, or even when trying to integrate information from far away on the same screen. It is helpful to provide placeholders for sequential tasks to indicate what step users are on. Also, allow side-by-side comparisons, and do not require users to remember information between screens.

Peoples' ability to recognize information is better than their ability to recall it.[50] So, it is important to avoid command-based systems, which rely on people recalling command names and syntax. Instead provide see-and-point rather than remember-and-type. Provide lists of choices and enable the user to pick from the list.

### *Language and Communication*

Although there are important differences, using a device is similar to communicating with another person. You need to make your intentions known, ask the device to do something for you, interpret what the device did, and then see if it has helped you get closer to your goal. There are some ways to make this communication easier and more satisfying. One way is to use simple and natural dialogue, eliminating extraneous words and graphics as well as unfamiliar or technical terms.[17] Provide text that can be read quickly. This, of course, is related to the notion of minimalism described previously. Another is to use words rather than abbreviations, because abbreviations can be confusing. Finally, be brief and concise, use short words and sentences, and use active voice.

A special type of communication and feedback involves error messages. Error messages are designed to help the user diagnose and recover from problems, informing them of potential failures. It is best to help the user avoid errors to begin with by providing obvious ways to undo, cancel, and redo actions, as well as by providing clearly marked exits. However, when it is necessary to use error messages, they should have the following characteristics[6]:

- Be polite, avoid negative wording, and never blame the users. Avoid intimidating language such as "Catastrophic Failure," or "A Fatal Exception Occurred," or "The Application Will Be Terminated."
- Design the error message for simple step-by step reading (eg, first do this then do that). Put most important information at the beginning of the message. All information should appear in a natural and logical order. Error messages should have 4 components:
  - Describe the problem
  - Describe why it happened
  - Describe a solution
  - Provide access to help and more information

### *Emotion and Motivation*

Typically, when using a medical device, users are trying to be as efficient as possible. They want to feel confident that they are progressing toward their goals of taking care of their patient. To this end, it is important to anticipate the users' needs, providing the information they need, when they need it, and in a helpful format. It is important to simplify task sequences, organizing tasks so that information is easy to find and use. Designers should organize information and functionality by importance of use, frequency of use, and relatedness of meaning. Specifically, important and frequent functions and information should be placed closest to the user. Information and functions that are related to each other, or are used in completion of the same task, should be arranged in close proximity. Finally, choose appropriate defaults,[6] making sure that default values are the ones expected by the user, and do not increase the likelihood of losing data.

It is important, also, to make the user feel in control. Provide a clear beginning and end (closure) for each task. Provide shortcuts for experienced users and frequent operation. These can include function keys, hot keys, command keys, aliases, templates, type-ahead, bookmarks, hot links, history, default values, and so on. Avoid surprising actions, unexpected outcomes, and tedious sequences of actions. Provide informative feedback. Limit interruptions and distractions.

## INFORMATION PROCESSING STAGES, DESIGN PRINCIPLES, AND GUIDELINES

Cognitive psychology's information processing stages provide a convenient structure for organizing various design principles and heuristics identified by previous investigators.[6,8,17,26] The principles and guidelines in **Table 1** are ones that the author has found particularly useful in application to medical device design. Most of the principles and guidelines come from Lee and colleagues[6] and Zhang and colleagues.[17] **Table 1** places them into the proper cognitive psychology information processing stages.

## DISCUSSION

This article introduced HF considerations in the design of medical devices. Because HF entails designing technology to match human abilities and limitations, and because humans are so complex, it is impossible to cover everything designers need to know in this short introduction. Instead, introducing HF, describing HF methods, discussing cognitive psychology's information processing stages and their implications for

**Table 1**
**Human factors principles and guidelines for medical devices**

| Category | Principle | Guideline |
|---|---|---|
| Perception | Visibility | Make items legible from the distance of use. |
| | | Design text of adequate size and contrast. |
| | | Use light (eg, off whites and very light gray) for the backgrounds for main areas of displays. |
| | Legibility | Ensure that text can be read quickly and easily. |
| | | Use familiar and unadorned font. |
| | | Use mixed case (rather than all capitals) text. |
| | | Use sans-serif fonts on computerized displays and serif fonts for hard copy. |
| | | Include labels on icons. |
| | Make items easy to recognize | Pictorial realism: make displays, icons, or signs look like the thing they represent. |
| | | Use redundancy gain: express the same information in more than one way. |
| | Grouping | Place similar, related, and items used to complete the same task close together. |
| | | Use white space, boxes, borders, color coding, or shape coding to distinguish groups. |
| | | Match user expectancies of item grouping and placement. |
| | Design good auditory displays | Design auditory alarms and messages to be heard in ambient conditions of use. |
| | | Use all components of sound design, such as volume, frequency, tempo, envelope, and others to make auditory displays discriminable. |
| Attention | Minimalism | Avoid clutter. |
| | | Use color sparingly. |
| | Conspicuity | Use uniqueness of color, shape, and so forth to make critical items stand out from the background. |
| | | For emergencies, use blinking or motion to attract attention. |
| Learning | Organization | Organize controls and displays in sensible categories and hierarchies. |
| | | Make use of analogies and design metaphors. |
| | Consistency | Be consistent in labeling, placement of information, color coding. |
| | | Use appropriate and expected defaults. |
| | | When possible, be consistent with other medical devices used in the same environment and for related tasks. |
| | Feedback | Provide informative feedback. |
| | | Ensure user is informed about the device's status at all times. |
| | Training and tutorials | Situate training and tutorials in the context of real work and real tasks. |
| | | Make training and tutorials easy to find, searchable, and without jargon. |
| Memory | Placeholders | Provide placeholders for sequential tasks to indicate what step you are on. |
| | Side-by-side comparisons | Allow side-by-side comparisons, and do not require users to remember information between screens. |
| | Use recognition over recall | Avoid command-based systems, which rely on recalling command names and syntax. |
| | | Provide see-and-point rather than remember-and-type. |
| | | Provide lists of choices and enable the user to pick from the list. |

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**Table 1**
**(*continued*)**

| Category | Principle | Guideline |
|---|---|---|
| Language and communication | Use simple and natural dialogue | Avoid unfamiliar or technical terms.<br>Eliminate extraneous words and graphics.<br>Provide text that can be read quickly.<br>Use words rather than abbreviations.<br>Be brief and concise. Use short words and sentences, and use active voice. |
| | Keep users informed | Inform users of progress toward task completion.<br>Make error messages polite.<br>Never blame the user.<br>Avoid intimidating language.<br>Design error messages for simple step-by-step reading (eg, first do this then do that).<br>Put most important information at the beginning of messages.<br>Write error messages with 4 components: (1) describe the problem; (2) describe why it happened; (3) describe a solution; and (4) provide access to help and more information. |
| Emotion and motivation | Confidence | Help users feel confident that they are progressing toward their goal.<br>Attempt to anticipate the users' needs by providing the information they need, when they need it, and in a helpful format. |
| | Simplify task sequences | Organize tasks so that information is easy to find and use.<br>Choose appropriate and expected defaults.<br>Organize information and functionality by importance of use, frequency of use, and relatedness of meaning. |
| | Provide feeling of control | Make the user feel in control.<br>Avoid surprising actions, unexpected outcomes.<br>Avoid tedious sequences of actions.<br>Provide informative feedback.<br>Limit interruptions and distractions.<br>Provide a clear beginning and end (closure) for each task.<br>Provide shortcuts for experienced users and frequent operation. |

design, and finally providing a table of design principles and guidelines will need to suffice.

Key to understanding HF is the insight that the most complex component of your medical device, and key to its success and safety, is the user attempting to operate it. This human component requires just as much attention (in fact probably more) than the mechanical, electrical, or other considerations. This requires early and constant focus on the user, evidence-based design decisions, and fast iteration.[13] In short, it requires user-centered design.

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