EVALUATING THE HUMAN ENGINEERING OF MICROPROCESSOR-CONTROLLED OPERATING ROOM DEVICES

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ABSTRACT. Although human engineering features are widely appreciated as a potential cause of operating room incidents, evaluating the human engineering features of devices is not widely understood. Standards, guidelines, laboratory and field testing, and engineering discipline are all proposed methods for improving the human engineering of devices. New microprocessor technology offers designers great flexibility in the design of devices, but this flexibility is often coupled with complexity and more elaborate user interaction. Guidelines and standards usually do not capture these features of new equipment, in part because technology improvements occur faster than meaningful guidelines can be developed. Professional human engineering of new devices relies on a broad, user-centered approach to design and evaluation. Used in the framework of current knowledge about human operator performance, these techniques offer guidance to new equipment designers and to purchasers and users of these devices.

KEY WORDS. Equipment: standards; computers. Measurement techniques: computer; cognitive engineering; human factors.

Quality human engineering of operating room devices is a clearly desirable goal. But what does it mean to say that a device is well designed for a human operator? How does the designer know when the design is good or the user know that the device is well designed? The evaluation of human engineering features is a complex activity conducted by professionals. They call on experience with classical human factors, human-computer interaction, and cognitive engineering and employ many different techniques to evaluate the nature of devices and systems. These techniques span a wide range. At one end is the application of written criteria as a static review of device design. The criteria may be formal standards or more informal checklists or guidelines, for example, the Association for the Advancement of Medical Instrumentation (AAMI) *Human Factors Engineering Guidelines and Preferred Practices for the Design of Medical Devices* [1]. Guidelines contain lists of features or elements that should or should not be included in order for the design to be "human factored." At the other end of the scale are methods that rely heavily on testing in laboratory or controlled field conditions, analysis of user interactions with the device under realistic conditions, and interactions of the device with other devices in the environment. All techniques have limitations that depend critically on the nature of the device and the stage in the design process at which they are applied.

Over the past 10 years technology has shifted the characteristics of devices in many fields including the operating room. Many microprocessor-based devices

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have appeared. These include drip-rate controllers, fluid pumps, a wide variety of monitors, diagnostic equipment (e.g., transesophageal Doppler echocardiographs), ventilators, and patient stimulators (e.g., continuous passive motion devices). Some devices are new and intrinsically dependent on the microprocessor (e.g., pulse oximeters) while others are modifications of non–microprocessor-based predecessor devices. This technologically induced change shows no signs of abating; indeed, the first generation of high integration patient monitors is now being installed in hospitals throughout North America.

Our purpose is to demonstrate the limitations of checklist-based guidelines and to point to other techniques used by human factors professionals to ensure quality human factors in device design. We performed both sorts of assessments on a small operating room device. These evaluations produce lists of human engineering deficiencies (HEDs), that is, identifiable features that are more or less likely to lead to problems in their use. We show representative examples of the sorts of HEDs revealed and some of their likely consequences for human users. We also provide some justification for concluding that the differences between the styles of assessment are important and try to map out the broader space of human factors evaluations.

Such a demonstration requires a device, preferably a simple one with an easily understood purpose. The test device chosen for this evaluation was the Marquest SCT 2000 Servo Controlled Tracking Heated Humidification System. In our hospitals it replaced the Bird heated humidifiers that had been in use for many years. The Bird devices required substantial setup effort, were difficult to maintain, and produced annoying condensation in the proximal circuit limb ("rainout"). The timing of introduction of the new device allowed us to observe the manufacturer's in-service training session and early as well as later use. In principle, the device should be easy to understand and straightforward to operate. The device is also used independently of other devices and, except that it is in the anesthesia circuit, does not have much potential for interaction with other devices. The device was developed before the AAMI guidelines were published. We wish to draw attention not to this particular device but rather to the general problem of doing human engineering reviews of new microprocessor-based devices. Users in our hospitals clearly prefer the new device to its predecessor, based on reduced setup time, reduced maintenance, and fewer problems with rainout.

Following a brief description of the specific device, this article presents the methods and results of two different engineering reviews, one based on application of guidelines and the other a broader approach, and then discusses the nature of human engineering reviews of operating room equipment.

DESCRIPTION OF THE DEVICE

The new device uses a pass-over hot plate humidification chamber and a heated wire circuit to control the temperature and humidity of the gas (Fig 1). As the gas flows over heated water, it becomes saturated with water vapor. To prevent condensation in the inspiratory limb of the breathing circuit (rainout), the heated wire circuit maintains the temperature of the gas between the chamber and the patient. Temperature probes at each end of the inspiratory limb of the circuit provide feedback to a microprocessor that controls the heater plate and heated wire. The device has no moving parts such as floats or valves. It uses a disposable see-through canister and tubing.

The delivered gas temperature is displayed on a three-digit light-emitting diode (LED) display. The operator may change the set point for temperature of the delivered gas from its default value of 37°C. In addition, the relative humidity (RH) may be changed from its default value of 6 (on a scale from 1 to 10). These changes are accomplished through controls on the front of the device. The device is a "closed loop" controller, where the measurements of temperature are used to control the device function. Several alarms possible during device operation are presented on an eight-character dot matrix LED display. These include low temperature (delivered gas temperature too low), high temperature, heater wire malfunction, temperature probe malfunction, and "service." Both heating elements are disabled during the high-temperature alarm conditions.

Fig 1. Overview of the heated humidification system investigated.

EVALUATION BASED ON AAMI HUMAN FACTORS GUIDELINES

We performed a device evaluation using the AAMI guidelines and consisting of a static review of features as if done by a person with little or no knowledge of the human factors profession. Since Van Cott and Kinkade [2] and Woodson and Conover [3] began to establish human engineering guidelines for systems designers, similar guidelines, design criteria, and standards have been customized for particular contexts (e.g., [4–7]). The AAMI guidelines are also based on these earlier human engineering guidelines. The goal of the guidelines is to provide ergonomic information and human factors engineering guidelines so that optimum user and patient safety, system safety and performance, and operator effectiveness will be reflected in design of the medical device [1].

Table 1 lists the various sections of the AAMI guidelines. The guidelines emphasize hardwired devices (e.g., control/display relationship, spacing between controls) rather than issues related to computer-based systems such as multifunction keys, multiple displays, and complex dialogue between person and computer. Some of the guidelines are broad generalizations that are difficult to evaluate. For example, the guideline for standardization reads [1]: "3.1 Standardization. Design standardization of controls, displays, markings, codings, and arrangement schemes for consoles and instrument panels is encouraged." Nevertheless, given a device, it is possible to read the sections of the guidelines and assemble a list of items that apply. The guidelines contain about one hundred eighty specific, testable criteria that might be applied to a device. Not all of these items apply to every device. The example device is small and the guidelines section regarding consoles does not apply. Similarly, large portions of the section on controls do not apply because the device lacks the type of control referred to in the guidelines, for example, foot switches.

Table 1. Section Contents of the Guidelines of the Association for the Advancement of Medical Instrumentation [1]

Contents
1. Scope of the guidelines
2. Purpose of the guidelines
3. General recommendations
4. Controls
5. Visual displays
6. Audio signals
7. Consoles
8. Bibliography

The humidifier was evaluated for the one hundred eighty objective issues addressed by the guidelines. Of sixty found applicable, all but eight were met by the device. Table 2 provides a summary of the HEDs identified by the guidelines. These HEDs relate primarily to control positioning relative to displays, the coloring of messages, and some details about legibility of warning notices. In some cases, several guidelines apply to one deficiency and in others one guideline helps identify several deficiencies.

The AAMI guidelines indicate several HEDs in the device design, all of which are based on elementary human factors principles. However, only minor alterations would be needed to produce compliance with the guidelines. The remedial actions necessary to eliminate the deficiencies range from straightforward changes in color coding and warning legibility to slightly more complicated changes in the functions of controls and format of information presented. These changes would not significantly affect operational use of the device. The fact that only one third of the guideline items apply is an indication of the broad coverage of the guidelines and is typical of this type of standard.

This type of evaluation can be accomplished by a straightforward review of the device, does not require any significant laboratory testing, and can be accomplished at any stage of development, from conceptual design to final production.

DYNAMIC TESTING WITH RESPECT TO HUMAN-COMPUTER INTERACTION PRINCIPLES

The second evaluation differed from the first in three important ways. First, the participants in the evaluation (the authors) included human factors professionals and potential users. Second, the device was tested dynamically, varying many operational variables and introducing faults in the laboratory. The variables included gas flow rate, temperature and humidity settings, disconnections of temperature sensors, and initial water temperature. The effect of device states, especially alarm states, was evaluated carefully, since this aspect is critical in human interaction in highly automated systems. Note that the purpose of this evaluation was not to assess whether the device performs "correctly" in some clinical or legalistic sense. Rather, the evaluation sought to map out device performance under the widest possible conditions of operator interaction.

Third, system performance was assessed using human-computer interaction guidelines, principles, and knowledge (e.g., [8–10]). This evaluation was based in part on mapping the various device states and the possible user interactions for each state. An example of the

Table 2. Summary of Human Engineering Deficiencies Identified by Guidelines of the Association for the Advancement of Medical Instrumentation [1][a]

Guidelines Section/Contents	Human Engineering Deficiency
Arrangement of controls and displays	
4. Controls	
4.7. Control location/display relationship	
4.7.2. Arranging related controls and displays	Although the temperature display can be read during control operation, the lower LED indicating the function being set (either SET TEMP or SET RH) lies below the push button controls and is blocked from view by the operator's hand.
(1) Each control should be located directly below its related display.	
4.7.3. Arranging controls on the console	
(7) Controls that must be manipulated while the operator is monitoring a display should be placed close to and directly below that display.	
5. Visual displays	
5.8. Transilluminated displays	
5.8.2. Location. When a transilluminated indicator is associated with a control, . . . the light should be visible to the operator during control operation.	(same as above)
Integration of controls and displays	
4. Controls	
4.4. Integration. Controls and displays should be integrated so that the relationship between a control and its related display is unambiguous, a control's direction of movement is consistent with its display's setting and direction of movement, and the control/display amount-of-movement ratio is appropriate.	The alarm mute button has two functions, but only one is indicated by labeling. The device labels do not show how to use it for its secondary purpose (pressing it simultaneously with SET button permits changing of RH).
Hazard warnings	
4. Controls	
4.10. Markings and symbols. Controls and displays should be appropriately and clearly marked; . . . hazard warnings should be prominent and understandable.	
4.10.5. Hazard warnings. Operators and maintenance personnel should be warned of possible fire, radiation, explosion, shock, or other hazards that may be encountered during the use . . . of the device.	The warning for the heater plate consists of small, uncolored, raised lettering on the white casing. This is not easily seen as it does not provide any contrast.
Brevity of markings and symbols	
4. Controls	
4.10. Markings and symbols	
4.10.6. Qualities of markings and symbols	
4.10.6.1. Brevity. Markings should be as concise as possible without distorting their meaning. The meaning of abbreviations and symbols should be obvious to the intended user and should be consistent with the terminology used in manuals and on instruction sheets. All information should be unambiguous without being redundant.	The SET button does not describe what is being set and is used for two different setting functions, temperature and humidity. When the SET button is pressed, the user receives feedback from the LED display, but this does not clearly meet the requirement that the labeling be "obvious."
Separation of Controls	
4.11. Separation of controls. Suggested criteria for the minimum distance between controls are summarized in Table 6 [a table that presents minimum separation distances for various controls]. For ease of operation, control separation should equal or exceed these values, although some operational situations will necessitate distances less than those recommended in the table; . . . the spacing of controls should be based on whether or not the controls need to be used sequentially or simultaneously.	In order to set RH, the SET and alarm mute buttons need to be pressed simultaneously, which, based on their arrangement, is not easily accomplished.

Table 2. (Cont.)

Format of visual information 5. Visual displays 5.1. General information 5.1.1. Format. Information should be presented to the operator in a directly usable form and should be limited to that which is necessary for specific actions or decisions. Designs requiring the operator to transpose, compute, interpolate, or mentally translate units of measurement should be avoided.	RH information is presented on a scale of 1 to 10, which does not directly translate into humidity level. In fact, this may foster the perception of a 0 to 100 scale, which is incorrect. There is no indication of the actual humidity level delivered at any of the settings.
Color coding of displays 5. Visual displays 5.7. Coding. Displays may be coded by color, size, location, shape, or flashing lights. Coding techniques should be used to help discriminate among individual displays and to identify functionally related displays, the relationship among displays, and critical information within a display. 5.8. Transilluminated displays 5.8.5. Color coding of displays. Transilluminated displays and indicators should conform to Table 7 [a table that relates color coding to meaning].	Sections 5.7 and Table 7 indicate that green should be used to indicate normal or ready condition, while red should be reserved for warning or danger. Red LED displays for alarms are acceptable, but green should be used to indicate normal operating conditions.

[a]LED = Light-emitting diode; TEMP = temperature; RH = relative humidity.

state transitions possible for this device are from warm-up to operating mode, from operating mode to high temperature alarm, etc. The principles for effective human-computer interaction place great importance on making it possible for the user to (1) determine the current state of the device, (2) identify easily which controls can be used to alter the state of the device, and (3) maintain a conceptual model of the device operation that corresponds to the actual operation of the device. On the basis of this review, we identified several additional HEDs in the device.

MODES OF OPERATION

The device has two modes of operation. A mode is a device state in which controls or displays function in a distinct way or have distinct meaning. At start-up, the system is in warm-up mode for a certain period (7–10 min) while the mass of water is heated to achieve the set temperature. After this period, the device switches to normal mode. In addition, the device changes from normal mode to warm-up mode whenever the temperature or humidity settings are adjusted. The meaning of alarm messages and the effect of controls are different in these two modes.

Mode error, a classic human factors problem, occurs when an operator takes an action that is appropriate for one mode when the device is in another mode. For example, an automobile transmission has several modes, among them forward, reverse, and neutral. The effect of pressing down on the accelerator is different in each mode. If the driver presses on the accelerator believing the transmission to be in forward when it is in fact in reverse, a mode error occurs. In the present device neither the current mode nor a change in mode are indicated to the operator. This is one factor that increases the likelihood of mode errors [11,12].

ALARMS AND THE MEANING OF ALARM MESSAGES

While in normal mode, the high- or low-temperature alarm messages appear whenever the distal temperature (that nearest the patient) deviates from the set temperature by a fixed amount. During warm-up mode, however, the high- and low-temperature alarms sound whenever insufficient progress toward the desired temperature is achieved (i.e., in warm-up mode the alarm is a rate alarm). Thus, four distinct alarm-triggering conditions are mapped onto two alarm messages (HI TEMP and LO TEMP) so that the same message has different meanings depending on the operating mode. In order to understand the internal condition that caused the message to be displayed, that is, to determine the unique device state, the user must infer which malfunction is being indicated by the alarm.

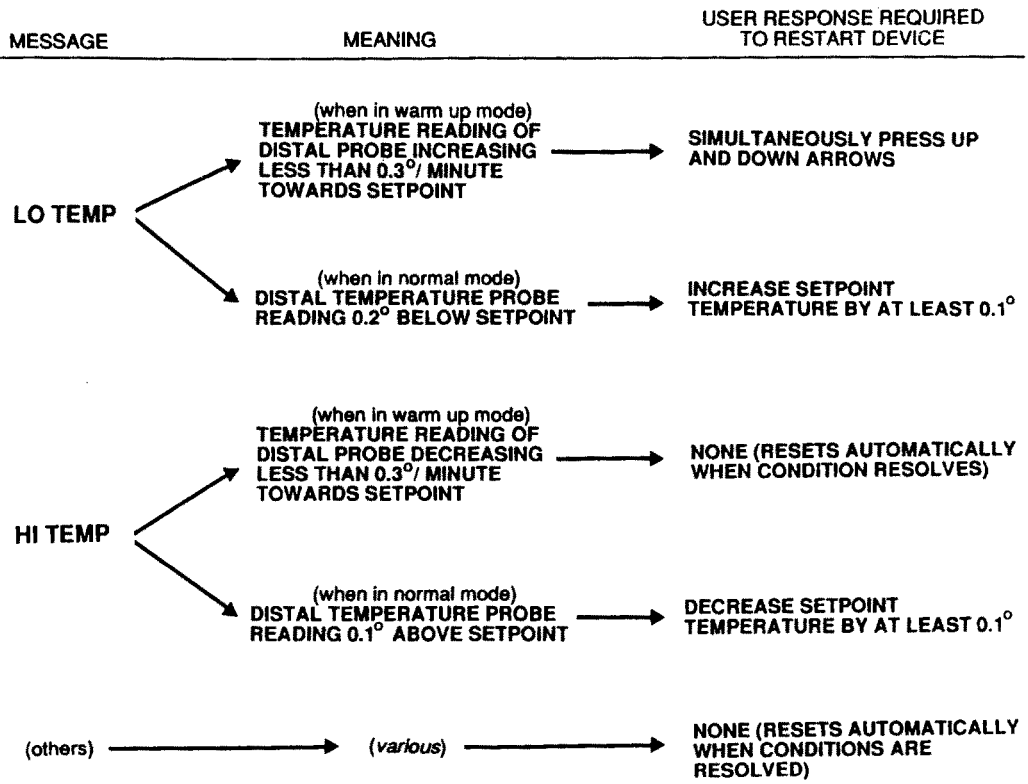

Fig 2. Inconsistent reset functions of the heated humidification system investigated.

ALARM CONDITION RESETTING

Responding to different alarms requires different actions. For some alarm conditions the device resumes operation automatically when the condition that caused the alarm is removed. For example, the device alarms when the heater wire is disconnected (the HTR WIRE message is displayed) and resets when the wire is reconnected. For other alarm conditions, however, the alarm state must be cleared manually. When a manual reset is required, the user must choose between various reset methods as shown in Figure 2. For some, but not all, alarms (those requiring manual reset), the heating elements are disabled until the reset procedure is carried out, but there is no clear indication that the device is disabled. The complex resetting procedures violate the principle of consistent signal-action mapping [13,14].

DEVICE SETUP

At least one aspect of the device setup is unclear. Setting "relative humidity" requires the user to press the set and alarm mute buttons simultaneously. There is nothing about the device, however, that indicates that this is the method for setting humidity. In fact, there is no reason for the user to associate the alarm mute button with humidity. This HED is a violation of the principle of correspondence between structure and function [15], that is, that the layout, labeling, and organization of controls should directly suggest what they do. Devices that have "hidden" features generally violate this principle.

The combination of ambiguous modes, multiple alarm message meanings, complex alarm resetting operations, and hidden controls increases the possibility that the user may be confused about device operation. In realistic settings users may not understand the complexity of the modes, alarms, and controls and seek to find alternative means for operating the device. Note that uncovering these HEDs depends critically on the three components of human-computer interaction described above. The user should be able to determine the current device state, identify readily which controls can be used to alter the current device state, and maintain a model of device operation that corresponds closely to the actual operation of the device.

The HEDs uncovered in this part of the evaluation can all be corrected. Correction would require changes in the device software; the relationship between displays and controls and the nature of messages, device states, and device operation are all in large part characteristics of the software rather than the functional hardware elements of the device.

ASSESSING THE IMPORTANCE OF HEDs

What is the effect on human performance of having a display below its control? How important is it that there are hidden modes of operation or that the relationships between controls and features are unclear? Or, to put it another way, what are the practical consequences of specific features of the HEDs identified in the different reviews?

One way to gauge the importance of HEDs is to test their effects on users' mental models. A mental model is defined as the representation or model that a user adopts to guide his or her actions and help in the interpretation of the device's behavior [16]. People form mental models of devices through experience, training, and instruction, largely by interpreting the device's behavior and its visible structure. Incoherent, incomplete, or inappropriate mental models (i.e., a mismatch between the mental model and actual device function) have been shown to lead to cumbersome operating sequences, long learning times, gaps in knowledge, and increased error rates [10].

There are a variety of techniques in cognitive science for studying user mental models [16]. To examine the effects of deficiencies uncovered in the second evaluation, one of us (D.D.W.) asked five users (one staff member, one second-year and three third-year residents) to describe how they used the device, how the device worked, what alarms they had experienced, and how they responded to alarms. Each had been using the device in the operating room for between 1 and 2 months and had attended a manufacturer's introduction (in-service) on the device. Follow-up questions were used to explore parts or functions of the device that were not mentioned initially by the physicians and that had been identified in the second-stage evaluation as potentially error-prone. The actual device was not present during the interview, preventing the person from using the device as a memory-recall aid. Portions of the verbal reports were transcribed and analyzed to identify characteristics of the physicians' mental models. This technique is a simple method frequently used to test advanced prototypes for their human engineering features.

Those interviewed had major gaps, inconsistencies, and misconceptions in their models of device operation. They misunderstood the operation of the device, did not know there were two modes of operation, and did not understand the principles of operation. Although they knew there were some closed-loop features, they were unable to describe them in detail (Table 3). Only one user knew which of the two temperature probe values was displayed and controlled by changing the set point. One knew that the "humidity" was an adjustable variable of the device. Significantly, no one knew the reset procedures required to reactivate the device following an alarm. The device design completely obscured the fact that both heating elements are turned off following alarms. All users reported turning the device off (or off and then on again) in response to alarms, in effect creating their own reset button. Later, while conducting unrelated research in the operating room, we were able to observe the use of the device over an extended period. The only control ever operated under our observation was the power switch, which was used as a master reset button to respond to each alarm.

Although the users' comments indicated that they liked the device and that it performed most of the time, as they hoped it would, when it failed (alarmed) the failure was incomprehensible and, without a workable mental model, no diagnostic activity was likely to be successful. The inaccurate mental models presented in this section were predictable from the deficiencies discovered during the second-stage evaluation.

Inaccurate mental models can lead to erroneous actions, especially with respect to the diagnosis of difficult and unusual problems. For example, faulty mental models played a major role in the disasters at Three Mile Island and Chernobyl [17].

These results also parallel the results from other studies of mental models, especially where poor device design encourages the formation of weak or incoherent mental models [16]. The design of the human-computer interface affects the mental model of the device that the physician develops. Well-designed interfaces encourage and reinforce the formation of appropriate mental models.

DISCUSSION

Human factors engineers use various techniques to evaluate devices and systems. These include standards and guidelines but, in the era of microprocessor-based devices, rely heavily on mapping device states and display information organization and relating them to the dialogue that users carry on with the device, the real user requirements, and the limitations of the environment. Indeed, this is the common practice among knowledg-

Table 3. Basic Principles of Human-Computer Interaction and Their Effect on User Mental Models Demonstrated by Examples of User Statements Contrasted with Actual Device Characteristics

Principle or Question (Q)/User or Physician Statement or Answer (A)	Device Function
Users transfer their mental models of past devices to try to explain the behavior of apparently similar new devices.	
"If I need a humidifier I always want it to be 39°C. So basically the fact that you turn it on and it comes on at 37° really isn't appropriate because there's heat loss through the tubing . . . so that by the time you get to your patient it's at the appropriate temperature." ". . . of course, if I don't have it at that temperature range, I won't be getting the full humidification. So I have to have it a little bit above 37°C so I get humidity. It's not so much temperature as how to get the humidity, . . ."	Accurate model of old device, but inaccurate model of new device (new device has a heater wire in the inspiratory limb to minimize rainout and also to maintain gas temperature).
User mental models develop based on experience with the behavior of the device.	
"It doesn't alarm on you except for the appropriate times. When patients are apneic or something like that, it will alarm. When you're trying to raise the CO_2[a] [the concentration of CO_2 in the lungs], . . . at the end of a case . . . so the patients start breathing on their own." Q: "Why is that an appropriate time for it to alarm?" A: "Well, I think any monitor should alarm at the right time when there is a danger to the patient. And I think apnea is definitely one of those. And if the humidifier is looking at that, in some way it must be because it seems to be the time when it alarms. [Later.] That one alarm I get when the patient's having trouble—it's actually performing a function, like counting respiratory rate or something."	Consistent but accidental association of a patient state with a device behavior leads to inaccurate mental model. A LO TEMP message alarm occurs when the gas flow rate ceases or decreases suddenly, a condition that occurs at the end of the case as patients return to spontaneous ventilation.
External appearance affects perception of device structure and function.	
Q: "What about humidity control?" A: "There isn't a control on that . . ." Q: "Can you do anything with it [humidity control]?" A: ". . . But I don't see any way to adjust the humidity unless you change the level of the water." "I can't remember exactly which buttons to do; I can probably figure it out if I had to."	Function associated with hidden display (pressing the alarm mute button and the temperature setting button allows the user to set the humidity value) is missed. Only one report demonstrated awareness of a humidity control, but user did not report ever having set the control.
Apparent simplicity leads users to be unaware of gaps/faults in their device model.	
"It's a very simple device to figure out and that's how I did it—was just figure it out." "I mean its pretty simple. I mean I think there's only two or three buttons on it—it doesn't have a lot of dials and numbers and stuff. I like that. Just simple, really." [Describing an alarm that occurred frequently.] "I know exactly what it is—it's because the patient has been, hasn't taken enough breaths or—I'm not sure exactly why."	
Users experiment to develop their own ways of using the device in the absence of good knowledge or cues to actual function.	
"When the alarm kept going off then we kept shutting it off [and on] and when the alarm would go off [again], we'd shut it off . . ." "When it's alarming, I haven't found a way to silence it other than shut it off." Q: "What do you do if there is any indication of trouble?" A: "If it gives me trouble, I turn it off . . ."	Complex mode dependent resetting sequences not understood and not apparent in device structure
Q: "So what do you do when the alarm keeps coming on?" A: ". . . so I just reset it to a higher temperature. So I kinda fooled it, so it was a higher temperature and whatever low temperature it was alarming at was above that. But I ran the risk of getting it too hot."	Uses inaccurate mental model to try to develop a way to stop a recurring alarm, given that resetting sequences are not understood and not apparent in device structure. The device is a closed loop controller that senses, displays, and controls the distal temperature.

[a] CO_2 = carbon dioxide.

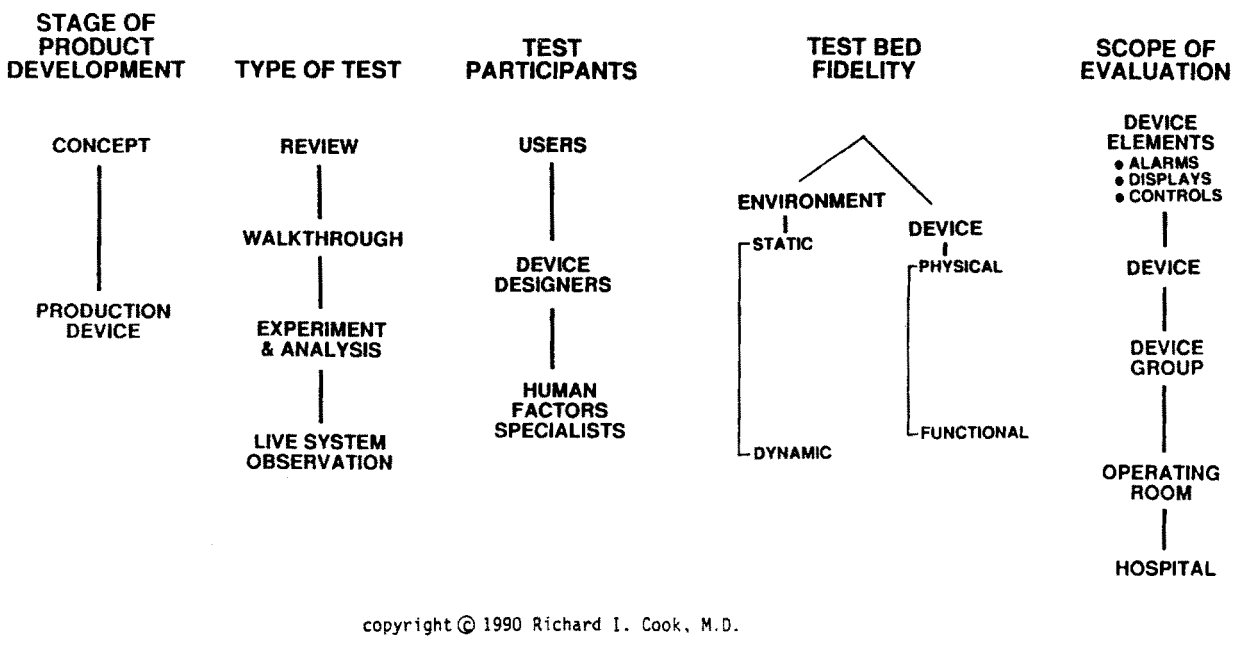

Fig 3. Human factors evaluation of devices.

able human factors professionals. Exactly what kind of evaluation is performed depends on the stage of product development, the participants, the fidelity of the laboratory in which testing occurs, and the scope of evaluation (Fig 3). It is impossible to provide in a brief article, or even a large book [8], all the guidance necessary to do human engineering. It is somewhat easier to suggest ways in which computer-based designs frequently fail. Norman [10] presents a list entitled "How to do things wrong in designing computer-based devices." The list includes:

1. Make things invisible.
2. Be arbitrary. Computers make this easy.
3. Be inconsistent: change the rules. Let something be done one way in one mode and another way in another mode.
4. Make operations unintelligible. Use idiosyncratic labels and uninformative error messages.

The microprocessor-based device examined here demonstrates all of the above. Hidden modes of operation certainly make the device state invisible. Using the SET button and alarm silence button together to set the humidity is an arbitrary design decision. Inconsistency is demonstrated in the reset actions. Ambiguous alarm messages are idiosyncratic.

These features are not restricted to microprocessor-based devices, but they are more common in them because of the great flexibility the computer brings to equipment design and, especially, to user-device interaction. The traditional human factors concerns of sizing and arranging physical controls date back to the pre-computer era, when there was a mechanical and static relationship between controls, indicators, and actions. The microprocessor has eliminated the firm binding of control, display, and user action and made possible the production of internally complicated systems that give the outward appearance of simplicity. The new generation of high-integration monitoring equipment is potentially prone to just this sort of problem as multiple, discrete, hardwired devices are incorporated into a single shell under the aegis of supervisory software. What is absent from the AAMI guidelines, and from virtually all similar documents, is the guidance necessary to ensure that apparent simplicity corresponds to real simplicity. Devices that appear simple because they lack many controls may, in fact, be more complicated to use than their electromechanical predecessors, especially if designers assign multiple functions to single controls, hide system states from user view, and devise complex and arbitrary control sequences. Avoiding this hidden complexity requires a disciplined approach to design including appropriate human-computer interaction features.

These issues have particular implications for anesthesia safety. Anesthesia incidents are seldom single-point failures but rather represent the confluence of multiple events, each alone insufficient to cause an incident but in combination leading to disaster [18]. Introducing

unnecessary block box complexity through poor human-computer interface design creates one kind of latent failure [17] in the system of anesthetic care. The accumulation of latent failures has been shown to be the hallmark of systems prone to disaster [17]. Indeed, the user's observation that the device works well most of the time is characteristic of automated devices that fail in incomprehensible ways. Usually these failures have no lasting effect, but when they occur simultaneously with other system faults, the complexity of the overall system's interface with human operators may significantly delay diagnosis or even frustrate it altogether.

Human engineering is a large field [8], and quality cannot be reduced to a single checklist of factors or a cookbook of approaches [19]. Cooper [20] claims that more attention needs to be paid to human factors in the design of operating room equipment. The AAMI guidelines attempt to standardize some basic features of equipment, but in a world of microprocessor-based equipment it may not be possible to improve human factors simply by slavish attention to "guidelines" [19]. Traditional human engineering guidelines like those of AAMI may be only weak filters for identifying deficiencies. Human-computer interface knowledge can be used to prevent the omission of critical features, for example, a visible indication of mode. Dynamic evaluation, not in ideal conditions but in conditions that practitioners might face, is essential. Assessment of mental models can identify inconsistencies in perceived versus actual device function and pinpoint error-prone aspects of the man-machine system. While many microprocessor-based devices appear simple, human factors evaluations such as that performed here are crucial if these devices are to be simple in operation as well as in appearance.

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