



## Human Factors Engineering Series

# Conclusion: You Need Human Factors Engineering Expertise to See Design Hazards That Are Hiding in “Plain Sight!”

John W. Gosbee, M.D., M.S.

“I believe that much of the difficulties associated with the nonacceptance (sic) and possible rejection by physicians of this computerized system could have been avoided if human factors specialists had worked more diligently on the physician-computer interface problems... Unless some efforts are undertaken as a matter of routine in the development of future systems, I can assure you that other medical-computer systems will find hard going and, perhaps quick rejection.”<sup>1(p. xxiii)</sup>

In 1975, Maurice Rappaport wrote this prescient statement as a practicing physician and human factors engineering (HFE) professional in San Jose, California, after using one of the first hospital computer systems. Five years before, he had written about HFE and medicine.<sup>2</sup> I suspect that he was chagrined that the academics and industry professionals who were creating this computer system that he and his colleagues had to use had not heeded his article. In addition, I think we can all empathize with him about the opportunities for better patient care that might have been realized had the computer system been designed with HFE.

In the introduction to this HFE series in the *Joint Commission Journal on Quality and Safety*, I wrote that the basic ideas and tools from the discipline of HFE are needed to “help organizations go deeper in their analyses of adverse events and develop more effective and lasting remedies.”<sup>3(p. 215)</sup> I attempted to show how the understanding of human limitations and capabilities could be applied across a variety of design issues, ranging from labels and

## Article-at-a-Glance

**Background:** The Human Factors Engineering (HFE) series was launched to share the ideas and methods to aid deeper analyses of adverse events and provide tools to ensure more effective and lasting therapies. Articles in the series showed how human limitations and capabilities were important design issues in a variety of areas, ranging from labels and warnings to work place design and complex decision support systems.

**Remaining Questions:** After reading all the articles, one might ask a number of questions, such as who made all our “puzzle rooms?” How did it happen that so many device components “masquerade” as each other yet perform very distinct functions? What are the procurement systems that gave us medication containers, tubing, and connectors that are hard to see and easy to misconnect? Behind all those questions remains a key query: what stands in the way of developing or hiring the expertise to see and fix these catastrophic design hazards “hiding in plain sight?”

**Summary and Conclusion:** HFE has already found its way into health care organizations and industry. As with most large changes in professions and industries, many small steps will need to be taken toward applying HFE methods and principles to the large problems of patient safety. But there already ample incentives and tools to start transforming your health care delivery or manufacturing organization.

warnings to work place design and complex decision support systems.

After rereading the papers, which describe the application of HFE to computerized order entry systems, cardiac monitors, ambulance design, automatic epinephrine injectors, and other topics, I found that I still had a number of questions—Who made all our “puzzle rooms?” How did it happen that so many device components “masquerade” as each other yet perform very distinct functions? What are the procurement systems that gave us medication containers, tubing, and connectors that are hard to see and easy to misconnect? What was industry trying to do with alarm design, since wildly dissimilar devices provide alerts with similar sounds? What tools have hospitals created in their customized software that make it easy to do the wrong thing? Most importantly, what stands in the way of developing or hiring the expertise to see and fix these catastrophic design hazards “hiding in plain sight?”

Entire books have been devoted to answering questions about incorporating HFE (also known as *usability engineering*) into the computer industry and other domains.<sup>4</sup> Vicente<sup>5</sup> has considered the factors that influence change in the medical device industry, such as pressure by health care organizations purchasing devices and systems and by regulatory authorities. This final article in the series highlights some cases where HFE has already been incorporated into health care organizations and industry. These examples of successes should provide hope and incentive for you to *develop* or *hire* HFE expertise as a necessary component of a patient safety program or a health care system’s design team. More broadly, HFE methods should be increasingly tailored to health care settings, including the architecture of such settings, and should be integrated into patient safety education.

## Enlisting the “Front Line” to Report HFE Events and Issues

*An anesthesiology resident recently thanked me for arranging the sessions because they “really changed the way I think.” This resident went on to describe being more aware of the environment in which we work...*

These quotes are excerpts from a June 2004 e-mail to me from Kathy Rosen, M.D., faculty for the anesthesiology

residency program, West Virginia University. This feedback from residents came after I worked with her on several presentations and small-group exercises related to HFE and patient safety. These sessions are part of a patient safety curriculum, with a purposefully heavy emphasis on HFE, that is being launched across 100 of the 163 facilities in the Veterans Health Administration (VHA). The HFE curriculum-related activities at VHA and university-affiliate hospitals serves the following three purposes:

- It is the foundation for many patient safety activities and concepts
- It provides a conceptual structure to explain the many human-machine and human-computer glitches that residents see every day
- Learning and engaging in HFE methods helps turn residents’ brains around “180 degrees”<sup>7,8</sup>

Neilson, another series author,<sup>9</sup> has continued her HFE in-house training efforts as the safety professional in her health care organization. The initial work in training and working with biomedical and clinical engineers has expanded. Stakeholders from pharmacy, purchasing, education, and front-line nursing have been added to the HFE and “no problem found” task force. Nielsen and her colleagues are proposing expanding HFE training to their entire health care system within a year.

Small, describing the need for HFE training approaches in health care,<sup>10</sup> cites numerous problems with the existing systems to find and analyze medical device adverse events, many of which involve HFE components. Surveillance using event reports, clinical software data, or administrative data (for example, International Classification of Diseases-9th revision [ICD-9] codes), is limited, whereas clinical engineering logbooks, which enable deeper analysis of usability issues and case-based training about device-associated issues, have “great potential to enhance the safety of medical devices.”<sup>p. 369</sup>

## HFE Methods and the Procurement Process

Many HFE methods, such as those described in the introductory article to this series, can be used to assist in proactive risk assessment efforts during procurement or in-house development of devices, software, and other clinical systems.<sup>3</sup> For example, one HFE-related facility can be found at The Centre for Global eHealth Innovation, which

was developed as a joint initiative of University Health Network (Toronto, Canada) and the affiliated University of Toronto. At the heart of The Centre is a usability testing facility, which is designed to test and develop electronic health innovations. This facility has enabled University Health Network to build on earlier usability work done to aid in evaluating medical devices. Whereas the earlier HFE work was conducted in informally assembled laboratories, the new facility, which features a multitasking simulation laboratory capable of being transformed into many health-related environments, allows for more sophisticated data collection. The laboratory is equipped with numerous cameras and microphones to capture fine level of detail, including key presses, facial expressions, and task sequences from multiple viewpoints, such as in the simulated use of an infusion pump.<sup>11</sup> Another usability lab for patient safety and improved medical device design, a Healthcare Product Usability Lab at the Miami Center for Patient Safety (Miami), is designed to evaluate devices regarding patient safety and work with companies to refine or fix products. As the Web site states:

Usability Testing is a powerful analytical procedure that lets us look at whether or not a typical user will make errors when using a given product, when that product is put into actual use. With the Usability Testing tool we can predict behavior. This is an important building block in the development of safer medical products.<sup>12</sup>

Matthew Scanlon, the patient safety officer for Children's Hospital of Wisconsin and author of the third HFE series article,<sup>6</sup> has worked with colleagues, especially biomedical engineering and hospital information systems department personnel, to make a business case for evaluating devices with various proactive risk assessment techniques, especially usability testing. Along with colleagues in the outcomes research group, he is planning another approach to incorporating HFE and usability testing methods—by starting much more informally and trying to make a business case by integrating the process into overall technology assessment.

## Increased HFE Activity in Medical Device Industry

It is beyond the scope of this article to address whether HFE activity and the number of HFE jobs in the medical device industry have increased, but it is of interest that a

recent job posting from “a leader in developing, manufacturing, and distributing medical devices for the global cardiovascular market” lists the following responsibilities for the human factors engineer:

- Create interaction design solutions for life-saving medical products
- Document, communicate, and advocate for design solutions
- Plan and conduct field research as well as usability benchmarking with customers
- Develop graphical user interface (GUI)
- Designs and interactive prototypes for usability testing
- Conduct usability tests and apply customer feedback toward improved concepts

In the HFE series in the *Journal*, more than one author has highlighted HFE issues with infusion (IV) pumps.<sup>13</sup> Another author (Ed Israelski, Abbott Laboratories, Abbott Park, Illinois) has worked with AdvaMed, a medical technology association, and IV pump manufacturers to create universal IV pump usability requirements.<sup>14</sup> For example, their draft document might state that 95% of all nurse end-users can power on the IV pump with no training in less than 5 minutes or that 90% of all nurse end-users can program the main functions with no training in 15 minutes. The final document, which will likely be published by a national medical devices standards group, is likely to not only be a groundbreaking step for the IV pump industry but also provide a model for all medical device companies. For example, perhaps the work with defibrillators noted in this series by Fairbanks<sup>15</sup> will jumpstart activity in this area.

## The Future of HFE and Patient Safety

In 2010, a 14-year old girl is being brought into the magnetic resonance imaging (MRI) room for minimally invasive surgery. All her cardiovascular monitoring wires and IV tubes need to be moved over to special, nonferromagnetic medical devices, and these medical devices have to be programmed anew. Her anesthesiologist and surgeon are working with many specialized technicians to arrange the video screens, gas lines, surgical instruments, and other equipment. Because of the invisible magnetic and electrical fields, and the space constraints of the MRI equipment and room, everything and everyone needs to be in a particular place.

Today, you are the HFE officer. What kinds of things should you have done to ensure that multiple things would not go wrong? What are the optimal HFE methods to procure the best MRI-compatible devices? What about the hundreds of “little” devices, hand tools, and maintenance items that are nearly anonymous—and for which the vendor is switched every two years? How have you addressed the intractable problem of line and tubing management to avoid cross connections and misconnections? Where were you when the architects and builders developed the new MRI floor plans? Finally, should you be nervous that your education was provided by professors who research HFE in aviation and that your master’s degree did not require an internship?

Fortunately, many professionals and organizations are working on these issues. Some are adapting HFE methods for use in health care settings. Series authors developed HFE methods to apply to the health care safety issues of wrong site surgery<sup>16</sup> and adverse drug events.<sup>17</sup> A group has applied and evaluated the use of usability testing of home medical care information technologies.<sup>18</sup> Other professionals are looking at cost effectiveness of HFE methods such as heuristic (expert) evaluations of IV pumps.<sup>19</sup> Professional societies and patient safety experts have provided recommendations for HFE and health care architecture<sup>20</sup> in general and for specialized areas, such as MRI.<sup>21</sup> Most importantly, there is definitive movement to create innovation in HFE and patient safety education. For example, at the University of Wisconsin, professionals from health care schools and engineering schools work together to develop the cross-disciplinary expertise<sup>22</sup> needed to answer the difficult rhetorical questions posed to the HFE officer.

## Summary and Conclusion

As with most large changes in professions and industries, many small steps will need to be taken toward applying HFE methods and principles to the large problems of patient safety. The series authors have used case

studies to provide examples of the problems HFE can help solve. Some of the analyses were conceptual, where other articles described the HFE solutions that were actually put into place. Other cases illustrate where progress is being made and where challenges remain to adapt the HFE methods to health care and build a workforce capable of their effective application. But there are already ample incentives and tools to start transforming your health care delivery or manufacturing organization.

## Key Points

- A brief summary of various aspects of the HFE series reveals that it demonstrated the breadth and depth of HFE and patient safety
- Progress can be shown in many areas inside health care organizations and companies, including the following:
  - Usability testing and procurement
  - Improving analysis and reporting by teaching HFE to front-line practitioners and students
  - More HFE activity and nationwide guidance for the medical device industry
- The future of HFE and patient safety lies mainly within the following
  - Adapting existing HFE methods and providing better practical data about them (for example, cost/benefit)
  - HFE and architecture of rooms, units, and the entire health care building
  - Innovation in education to create true cross-disciplinary expertise to help us “see” design hazards hiding in plain sight . . . and for sustainable progress **I**

John Gosbee, M.D., M.S., an advisor to professional societies and patient safety organizations in academia and government, is Human Factors Engineering and Healthcare Specialist, Veterans Affairs (VA) National Center for Patient Safety, Ann Arbor, Michigan, and has served as Guest Editor of the HFE Series. Please address requests for reprints to John Gosbee, M.D., M.S., [John.Gosbee@med.va.gov](mailto:John.Gosbee@med.va.gov).

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# Evaluation of the User Interface Simplicity in the Modern Generation of Mechanical Ventilators

Yoshihiro Uzawa RRT RPT MSc, Yoshitsugu Yamada MD PhD, and Masayuki Suzukawa MD PhD

**OBJECTIVE:** We designed this study to evaluate the simplicity of the user interface in modern-generation mechanical ventilators. We hypothesized that different designs in the user interface could result in different rates of operational failures. **SETTING:** A laboratory in a tertiary teaching hospital. **DESIGN:** Crossover design. **SUBJECTS:** Twenty-one medical resident physicians who did not possess operating experience with any of the selected ventilators. **METHODS:** Four modern mechanical ventilators were selected: Dräger Evita XL, Maquet Servo-i, Newport e500, and Puritan Bennett 840. Each subject was requested to perform 8 tasks on each ventilator. Two objective variables (the number of successfully completed tasks without operational failures and the operational time) and the overall subjective rating of the ease of use, measured with a 100-mm visual analog scale were recorded. **RESULTS:** The total percentage of operational failures made for all subjects, for all tasks, was 23%. There were significant differences in the rates of operational failures and operational time among the 4 ventilators. Subjects made more operational failures in setting up the ventilators and in making ventilator-setting changes than in reacting to alarms. The subjective feeling of the ease of use was also significantly different among the ventilators. **CONCLUSION:** The design of the user interface is relevant to the occurrence of operational failures. Our data indicate that ventilator designers could optimize the user-interface design to reduce the operational failures; therefore, basic user interface should be standardized among the clinically used mechanical ventilators. *Key words:* user interface, mechanical ventilator, ventilator design, ergonomics, usability, operational failure. [Respir Care 2008;53(3):329–337. © 2008 Daedalus Enterprises]

## Introduction

Medical care has been faced with the issue of improving patient safety since a report titled *To Err Is Human* was released in 1999.<sup>1</sup> Medical incidents have been an important issue for our society and for medical practitioners.

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Yoshihiro Uzawa RRT RPT MSc is affiliated with Kameda Medical Center, Chiba, Japan. Yoshitsugu Yamada MD PhD is affiliated with The University of Tokyo School of Medicine, Tokyo, Japan. Masayuki Suzukawa MD PhD is affiliated with Jichi Medical School, Tochigi-ken, Japan.

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Ventilator dealers provided the ventilators used in this study.

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According to a study by Brennan et al,<sup>2</sup> adverse events in hospitals occur in 3.7% of hospitalizations. Within hospitals, intensive care units (ICUs) have been a site of higher rates of adverse incidents, mainly because of 3 factors: the highly sophisticated devices, work load of caregivers, and the severity of patient illnesses. As is human nature, human errors occur more frequently as the medical devices become more sophisticated and as the work load causes stress and negligence. Giraud et al have revealed that human errors are involved in 67% of the major complications and are associated with higher morbidity and mortality rates in the ICU.<sup>3</sup> Of all the human errors, mechanical-ventilator-related human errors happen with the highest frequency.<sup>4</sup> In order to reduce the mechanical-ventilator-

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Correspondence: Yoshihiro Uzawa RRT RPT MSc, Department of Rehabilitation Medicine, Kameda Medical Center, 929 Higashi Kamogawa, Chiba, 296-8602, Japan. E-mail: yoshiuzawa@yahoo.co.jp.

Table 1. List Used to Check Subject's Knowledge of Mechanical Ventilation\*

Ventilator Mode Terminology	
Volume-control continuous mandatory ventilation	
Pressure-control continuous mandatory ventilation	
Volume-control intermittent mandatory ventilation	
Pressure-control intermittent mandatory ventilation	
Pressure-control continuous spontaneous ventilation	
Ventilator Setting Terminology	
Tidal volume	
Respiratory rate	
Peak inspiratory flow	
Inspiratory time	
Inspiratory hold time	
Positive end-expiratory pressure	
Fraction of inspired oxygen	
Sensitivity (pressure, flow)	
Rectangular flow waveform	
Decelerating flow waveform	
Peak inspiratory pressure	
Mean airway pressure	

\*Each subject understood all of the listed items.

related human errors, researchers have proposed some strategies, such as education programs, initiation of interdisciplinary teams, and environmental maintenance.<sup>5</sup>

Although there are some ways to solve safety problems, little attention has been paid to the contribution of the sophisticated design of mechanical ventilators. How well the user interface is designed could be an important factor affecting human errors. Therefore, we hypothesized that different user-interface designs could result in different rates of operational failures, operational time, and the user's subjective feeling of difficulty of use. The results of the study can be used by ventilator designers in future development to improve safety, and by medical trainers to enhance training programs.

## Methods

### Subjects

The study was conducted with medical residents. The enrollment criteria included the number of years of residence, knowledge of mechanical ventilation, and experience with commercial ventilators. To be eligible for enrollment a subject had to be in the first 3 years of the residency program after graduation, and had to demonstrate basic knowledge of mechanical ventilation by attaining a satisfactory score on a test that used a check sheet (Table 1). The check sheet contained the medical terms that would be used throughout the study, such as modes of

ventilation, trigger sensitivity, and alarm parameters. The subjects were also asked about their experience with commercial ventilators, and only those who did not possess operating experience with any of the selected ventilators in this study were chosen for participation. Twenty-one residents satisfied the enrollment criteria and were enrolled in the study. All subjects understood the purpose of the study; written informed consent was obtained. Our institutional review board approved this study.

### Equipment

Four modern mechanical ventilators were selected and used to test the hypothesis of the study: Evita XL (software version 5.1, Dräger Medical, Telford, Pennsylvania), Servo-i (version 1.2, Maquet, Bridgewater, New Jersey), e500 (version WWR2.1, Newport Medical Instruments, Newport Beach, California), and 840 (version H, Puritan Bennett, Pleasanton, California). These 4 ventilators were chosen not only because they represent the new generation of mechanical ventilators, but also because of their different approaches in user-interface design. The Evita XL and 840 use a fully graphic user interface. The Servo-i and e500 use a hybrid of analog and graphic user interface. The e500 uses an analog user interface in the controls and alarms, but uses a graphic user interface in the monitoring. The Servo-i uses a graphic user interface in every area except the most commonly used control settings, such as tidal volume and oxygen concentration.

Each ventilator was equipped with a standard dual-limb breathing circuit with heated wires; the color of the circuit was the same for both inspiratory and expiratory limbs. The heated humidifier (MR730, Fisher and Paykel Healthcare, Irvine, California) was connected in-line on the inspiratory limb. The breathing circuit was connected to a test lung (TTL, Michigan Instruments, Grand Rapids, Michigan), with a lung compliance of 50 mL/cm H<sub>2</sub>O and airway resistance of 5 cm H<sub>2</sub>O/L/s.

### Test Tasks

Each subject was asked to perform a total of 8 tasks, which were divided into 3 categories of work. The 3 categories of work were: setting up the ventilator (2 tasks), adjusting the control settings and modes (4 tasks), and reacting to alarm conditions (2 tasks) (Table 2).

### Protocol

With each subject the 4 test ventilators were evaluated in a randomized order. A test ventilator was placed in the room. Each subject was given an abbreviated version of the operating manual. In Japan there is a government requirement that every ventilator should have a simplified

## EVALUATION OF VENTILATOR USER INTERFACES

Table 2. List of Tasks and Classification of Procedure Time in the Categories

Task Category	Number of Tasks	Task	Directions	Classification of Time (s)		
				Ideal	Acceptable	Unacceptable
Setup	2	Start the ventilator	Plug in the power cord and turn on the ventilator.	< 120	120–300	> 300
		Assemble all the accessories	Assemble the breathing circuit and heated humidifier, and get the ventilator ready for use.	< 180	180–300	> 300
Changes of settings and modes	4	Change ventilator settings and modes	Change setting from VC-CMV to VC-IMV.	< 120	120–300	> 300
			Change setting from VC-IMV to PC-CMV.	< 120	120–300	> 300
			Change setting from PC-CMV to PC-CSV.	< 120	120–300	> 300
			Change setting from PC-CSV to VC-CMV.	< 120	120–300	> 300
Alarm setting and reaction	2	Set alarms*	Set alarms.	< 120	120–300	> 300
		Respond to alarms†	Respond to, recognize, and silence alarms.	< 30	30–60	> 60

\*Alarms: high and low pressure, high and low minute volume, and high respiratory rate  
†Alarms: high and low pressure, apnea, and increase respiratory rate  
VC-CMV = volume-control continuous mandatory ventilation  
VC-IMV = volume-control intermittent mandatory ventilation  
PC-CMV = pressure-control continuous mandatory ventilation  
PC-CSV = pressure-control continuous spontaneous ventilation

operating manual present with each ventilator. It allows the users to get most commonly needed information within 5 minutes or so. Therefore, the subjects were allowed 5 minutes to read the abbreviated version of the operating manual before each series of tasks was started. The subjects were also allowed to refer to the operating manuals at any time throughout the study.

Immediately before each test, an investigator stood beside the ventilator and showed the written task to the subject. The subjects were allowed to ask the investigator any question that served the purpose of clarifying the understanding of the requirement. The investigator explained the requirement until the subject had a clear understanding.

Subjects were allowed to begin operating the ventilator when the investigator gave a verbal signal. When the subject finished the task, they informed the investigator. The investigator then checked the subject's performance and determined whether the given task had been properly completed. When the performance was successfully completed, the subject was allowed to advance to the next task. If the investigator found any mistake, the subject was asked to correct it. If the correction was completed, the subject was allowed to proceed to the next task. If the subject did not complete the task within 10 minutes or the subjects gave up the task before 10 minutes, the subject was allowed to move to the next task. Operation time was measured with

a stopwatch, until the subject completed each task. The time during which the investigator checked and communicated was not counted in the operation time.

With each ventilator, each subject performed a series of 8 tasks. After these 8 tasks were finished, the subject moved to the next mechanical ventilator. The subjects were allowed to rest between tasks, as needed.

### Variables and Data Collection

Two objective variables and one subjective variable were measured to determine the simplicity of the user interface. The 2 objective variables were the number of successfully completed tasks without operational failures and the operational time. A completed task was defined as a task completed without any mistakes within 10 minutes. On the other hand, operational failure was defined as one of the following situations: the subject completed a task with at least one mistake; the subject needed more than 10 minutes to complete the operation; or the subject gave up attempting to complete the task due to difficulty.

The operational time was divided into 3 categories: ideal, acceptable, and unacceptable. We divided these categories somewhat arbitrarily, based on the time for a competent operator performance with the consideration of the complexity of the tasks and the potential unfavorable impact to the patient safety due to the delayed operation. The clas-

Table 3. Rate of Completion and Operational Failures During the Operation of the 4 Ventilators

Task Category	Completion n (%)	Operational Failure n (%)	Total n (%)
Setup	117 (70)	51 (30)	168 (100)
Change settings and modes	244 (73)	92 (27)	336 (100)
Alarm setting and reaction	159 (95)	9 (5)	168 (100)
Totals	520 (77)	152 (23)	672 (100)

sification of these categories is shown in Table 2. At the end of the evaluation of each ventilator the subject was asked to evaluate subjectively how easily they were able to operate the ventilator. A 100-mm visual analog scale was used to evaluate the subjective feeling of simplicity versus difficulty. Subjects marked the location on the 100-mm line that corresponded to the feeling of difficulty of use they experienced with each ventilator. Visual analog scale data from this study were recorded as the number of millimeters from the left on the line, with the range 0 to 100.<sup>6</sup> A higher visual analog scale score was used to indicate a subjective feeling that the ventilator was more difficult or confusing to use.

**Statistical Analysis**

The analyses were performed with a commercially available statistical package (SPSS version 11.0, SPSS, Chicago, Illinois). The successful completion and the procedure time were compared with chi-square tests. In the comparison of successful completion and operational failures the Tukey test was applied for post hoc analysis to determine the significant differences within the group. The visual analog scale scores were compared with nonparametric analysis (Friedman test), because the number of subjects was not large enough and the obtained data did

not show the normal distribution. The Steel-Dwass test was used for post hoc analysis. A p value of < 0.05 was considered statistically significant.

**Results**

**Operational Failures**

For all tasks, all the subjects made 23% of operational failures, which indicates that they made one failure in every 4 operational tasks when they operated a ventilator with which they had no practical experience (Table 3). There was a significant difference in operational failure occurrences among studied ventilators in all tasks (Fig. 1). The failures happened more frequently during ventilator setup and during the adjustment of settings and modes than during reactions to alarms (Fig. 2). All 4 ventilators showed a similar degree of simplicity in the alarm user interface, as evidenced by the rates of completed tasks that were not statistically different among these ventilators (see Fig. 2). However, there were significant differences in the rates of completion of the setup tasks and of the setting-adjustment tasks without operational failures. There was no significant difference among the other 3 ventilators (see Fig. 2).

**Operational Time**

In operational time, there was a significant difference among the 4 ventilators throughout the tasks (Fig. 3). More subjects had an unacceptable operation time in the setting-adjustment tasks with the Evita XL than with the other 3 ventilators, whereas the e500 had the fewest unacceptable operation times in the change-settings-and-modes tasks. In the alarm-setting-and-response tasks the Evita XL had no unacceptable operation times (Fig. 4).

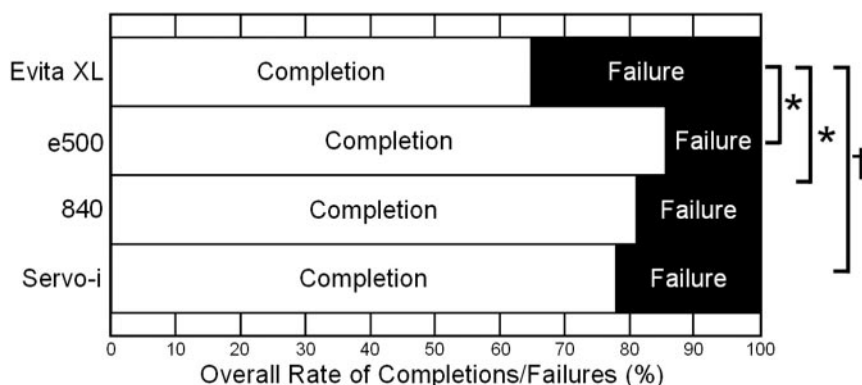


Fig. 1. Comparison of the number of completions and operation failures of tasks among ventilators. Chi-square test p < 0.001. Post hoc analysis was via Tukey's test. \* p < 0.01. † p < 0.05.

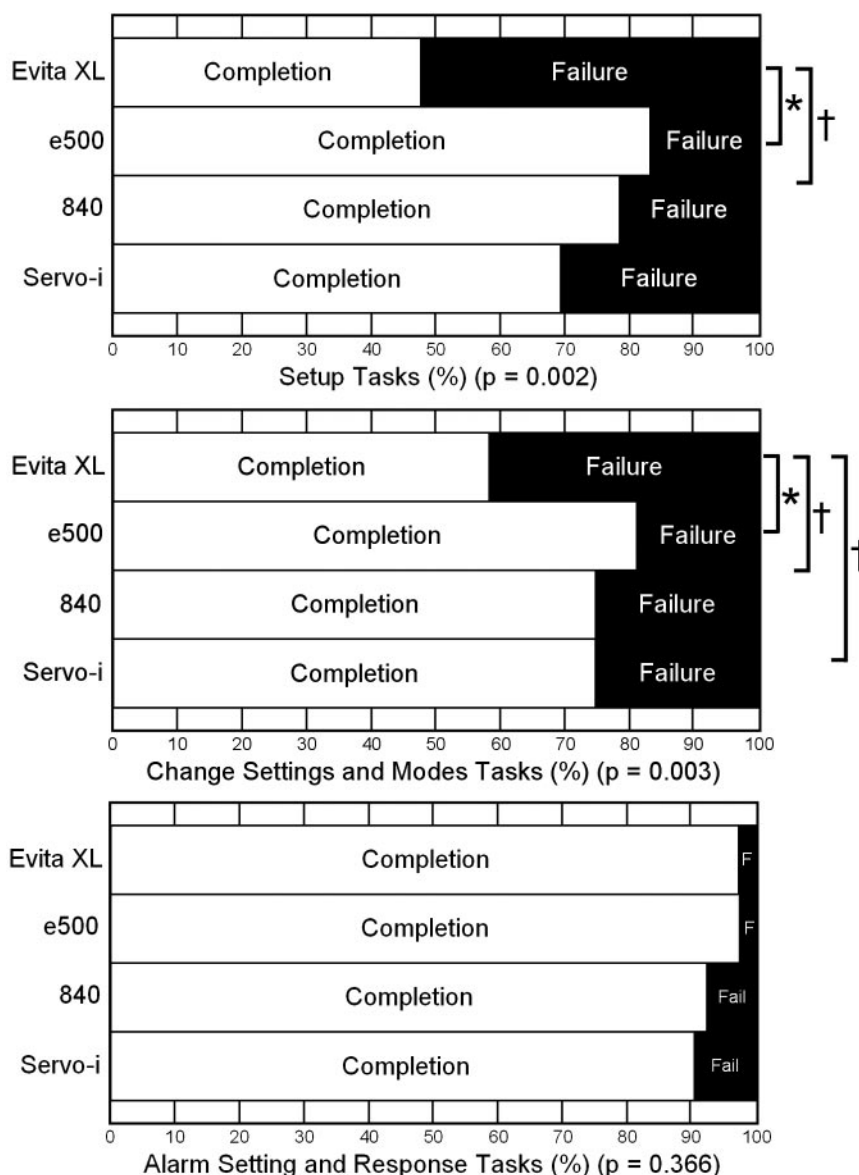


Fig. 2. Comparison of the number of completions and operational failures among ventilators in each task category. Post hoc analysis was via Tukey's test. \*  $p < 0.01$ . †  $p < 0.05$ .

### Subjective Feeling of the Ease of the User-Interface Operation

There were significant differences among the ventilators (Fig. 5). The subjects felt the user interfaces of the e500 and Servo-i were easier than those of the Evita XL and 840.

### Discussion

The resident physicians made one operational failure in every 4 operational tasks when they operated these ventilators with which they had no practical experience. The

operational failure rates and procedure times differed among the ventilators, which indicates that the man-machine interface design is relevant to the occurrence of insufficient operation.

### User Interfaces of the Existing Ventilators

**Type of the User Interface.** Overall, each of these approaches in the user-interface design seemed to be relatively acceptable in the alarm-setting and reaction to alarms, as evidenced by the low rate of the operational failures with all the ventilators (see Fig. 2) and less time in completing the alarm tasks (see Fig. 4). However, in the ven-

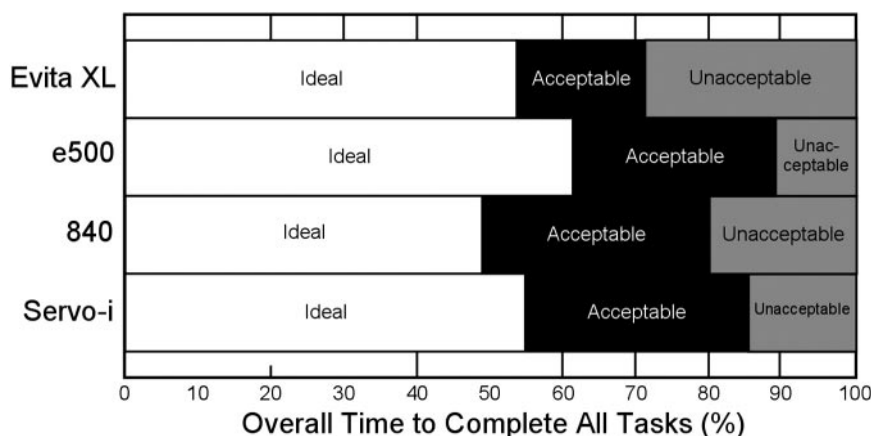


Fig. 3. Comparison of the time during operation of tasks among ventilators. Chi-square test  $p < 0.001$ .

tilator-setup and in the setting-changes, the user-interface designs seemed to cause some degree of difference in how accurately the subjects operated the ventilators. Among the selected 4 ventilators, the Servo-i adopts a graphic user interface but keeps a few of the most frequently used controls accessible via direct analog knobs. The e500, on the other hand, uses graphic user interface for all the monitor functions, but uses analog interface for all the control settings. On the Evita XL and 840, all tasks in controls and monitors are done via graphics. Although the data are not conclusive, the analog interface design for the setting-changes seems to be associated with better outcomes in accurately and quickly operating the ventilators. The graphic user interface of the Evita XL seemed to be less intuitive for the selected subjects and affected the rate of operational failures. Setting-changes are frequently done through a colorful graphic interface. However, a graphic user interface often comes with multiple layers in the menus, and it sometimes takes a long time to browse or search for a specific control button through the multiple layers. In order to ease the operation, some ventilators have developed a hybrid of graphic interface with analog interface.

**Terminology Confusion.** In the setting-change tasks there were significant differences among ventilators in the operational failures, in part due to the result of the confusion in terminologies that each ventilator uses. For instance, the mode of spontaneous breathing with continuous positive airway pressure is expressed as CPAP on some ventilators, but as SPONT on others. Pressure-control ventilation is labeled as BIPAP in one ventilator but as PCV in others. When pressure-control ventilation is used and a level of pressure control is set, some ventilators target the peak pressure as the set level of pressure control, whereas others target the peak pressure as the set level of pressure control plus the positive end-expiratory pressure. These differences caused unnecessary confusion to the operators and increased the operational failures and the time

to complete the tasks. It would seem more logical to have the terminology standardized across the ventilator industry through an international body such as the International Standards Organization (ISO) TC121 Committee.

**Differences in the Layout of the User Interface.** The locations of the inspiratory outlet port and the expiratory port are different among the ventilators. In some ventilators the inspiratory port is located on the left side of the ventilator and the expiratory port on the right side. On other ventilators the locations are opposite. This caused confusion and errors; some subjects connected the inspiratory limb to the expiratory port. Similarly, the power button was located on the front of the machine on some ventilators, but on others it was on the back. Although there is no rationale to have any specific location from the end-user perspective, it would make sense to have the relative locations standardized internationally across the ventilator industry. The standardization could also include the relative locations of the frequently used functions, such as the manual breathing button, the fraction of inspired oxygen, alarm silence, et cetera. An international body such as the ISO TC121 could assume this coordinator role.

#### Rationale for the Selection of Subjects and the Limitations of the Study

Although in an ideal situation ventilator users should have sufficient pre-training before using a ventilator, that is not the case in many countries where respiratory therapists are not available. Frequently, a resident physician who is on night shift and has not had thorough training on the ventilator operates the ventilator. Japan does not have respiratory therapist as a government-recognized profession; many countries (with the exception of the United States, Canada, and a few other countries) are in this same

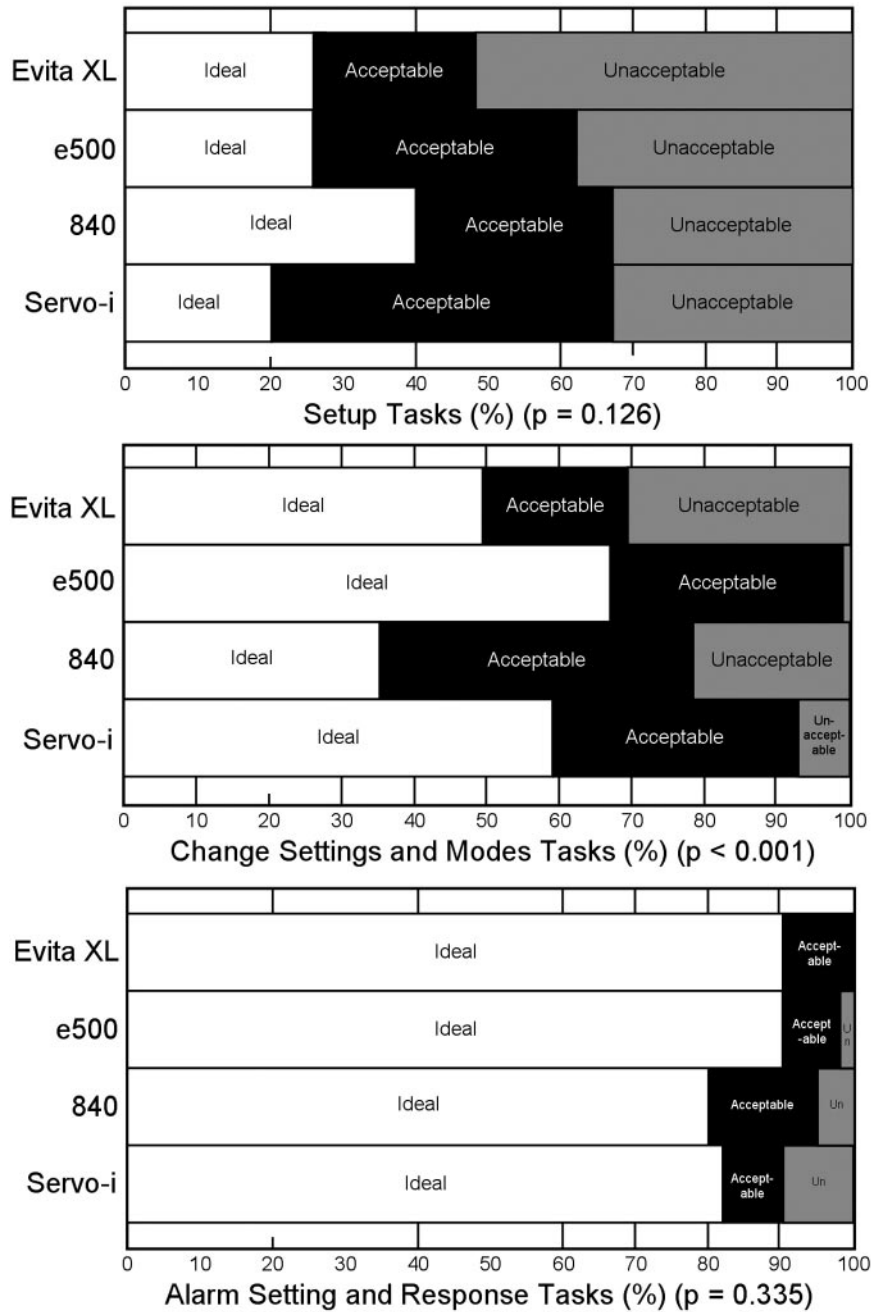


Fig. 4. Comparison of the time during operation of tasks in each task category.

situation. It is common that residents may operate a ventilator without sufficient training on the specific ventilator model, although they usually possess reasonable basic knowledge in mechanical ventilation. They are usually the front-line workers in response to medical conditions of ICU patients on the night shift. They have to quickly react to changes in the patient's condition. For these reasons we selected our subjects to be residents with only 3 years of training and only gave them 5 minutes to read the abbrevi-

ated version of the operating manuals before each test began with each ventilator.

We required the subjects to have no operational experience with the specific ventilator models that were included in the study, because we could thus eliminate any bias or prejudice toward any specific ventilator model and enhance the comparability among the various ventilator designs. However, some subjects had experience with the operation of ventilators such as the Puritan Bennett 7200

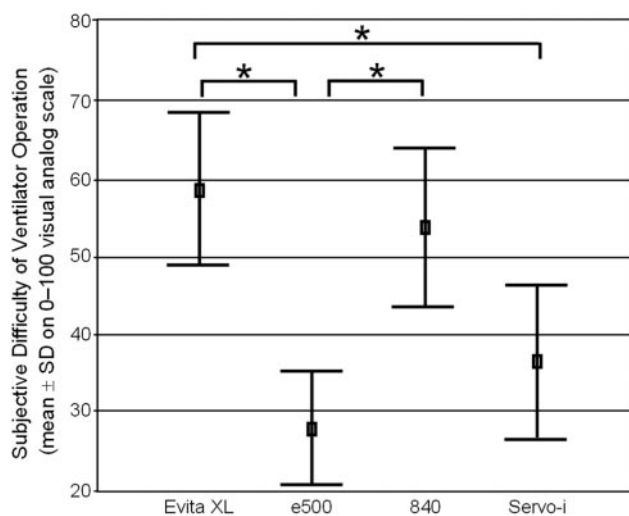


Fig. 5. Subjective feeling of difficulty to operate mechanical ventilators, measured with a visual analog scale (100 mm).  $n = 21$ . Friedman test ( $p < 0.001$ ). Stoll-Dwass used for multiple comparison. \*  $p < 0.05$ .

and the Bird 8400. The Puritan Bennett 7200 uses a multi-layer design, whereas Bird 8400 uses an analog design. The designs are different and they are not modern types such as we selected in this study, so this should have had a minimal effect.

The rate of operational failures in this study was high, in part probably due to the way we selected the subjects. Obviously, this absolute rate of operational failures cannot be extrapolated to a hospital where practical training is a prerequisite for operating a ventilator, or to a country that has credentialed respiratory therapists. We could reasonably expect that the operational failure rate would be lower if the operators had experience with the ventilator models that they were presented. The intent of our study was to test whether the current user interfaces of the ventilators are sufficiently intuitive and whether the user-interface designs result in different rates of operational failure. Therefore this study was conducted with a test lung in an isolated room, to avoid unnecessary pressure on the subjects. Then they were able to pay attention to the operation of the unfamiliar ventilators.

### Importance of the Study Results to Trainers and Designers

Our results demonstrate the necessity of sufficient training of the medical practitioners on the ventilator models that they select. Understanding mechanical ventilation does not guarantee the capability of operating mechanical ventilators without operational failures. Likewise, understanding the operation of a specific ventilator model does not assure accuracy in operating a different ventilator model.

Thus, it is very important for the medical institution to carry out a training program that is tailored to their personnel and the specific ventilator models they use.

Our data could be useful for ventilator designers when they design the user interface of their next generation of ventilators. Dozens of different approaches could be taken to achieve the same operational goal; however, the consequence of the ease of use could be widely different. Ventilator designers should pay more attention to the simplicity of the user interface to minimize confusion and to achieve patient safety. Gonzalez-Bermejo et al evaluated the user-friendliness of home mechanical ventilators with ICU physicians without practical experience.<sup>7</sup> They reported that mistakes occurred in close to 50% of cases during the ventilator-mode and setting-recognition test, which indicated that improving home ventilator user-friendliness was important. Chatburn presented a proposal for standardization of classification of mechanical ventilators. He emphasized confusion with the current nomenclature of ventilation modes and proposed a standard classification system.<sup>8</sup> In other medical fields the usability of medical equipment has been evaluated,<sup>9-12</sup> and those devices have been modified for user-safety reasons. To a greater degree for the ventilator industry, research on the user interface may be more important than the release of new breath modes, since the safety of mechanical ventilators has become a real concern for many government agencies and for our society.

### Conclusions

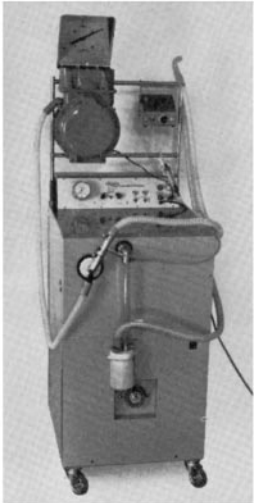
The design of the user interface is relevant to the occurrence of operational failures. Our data indicate that ventilator designers could optimize the user-interface design to reduce operational failures; therefore, the basic user interface should be standardized among the clinically used mechanical ventilators. It is our belief that the ventilator user interface should be designed in an intuitive manner. For all the basic operational tasks (as described in this study), the operator should have no need to refer to the operating manual. The user interface should be designed in a straightforward manner. We also suggest that medical training should be tailored to the operational knowledge of the specific ventilators used.

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