

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

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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 1999.¹ Medical incidents have been an important issue for our society and for medical practitioners.

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According to a study by Brennan et al,² 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.³ Of all the human errors, mechanical-ventilator-related human errors happen with the highest frequency.⁴ In order to reduce the mechanical-ventilator-

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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.⁵

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 H₂O and airway resistance of 5 cm H₂O/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 100.⁶ 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).

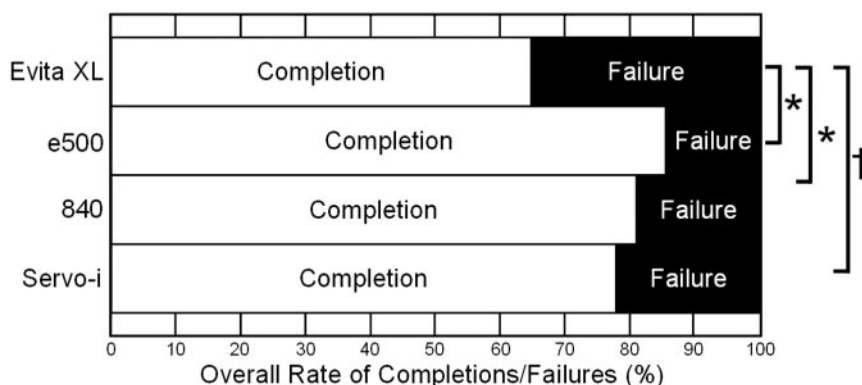


Fig. 1. Comparison of the number of completions and operation failures of tasks among ventilators. Chi-square test p < 0.001. Post hoc analysis was via Tukey's test. * p < 0.01. † p < 0.05.

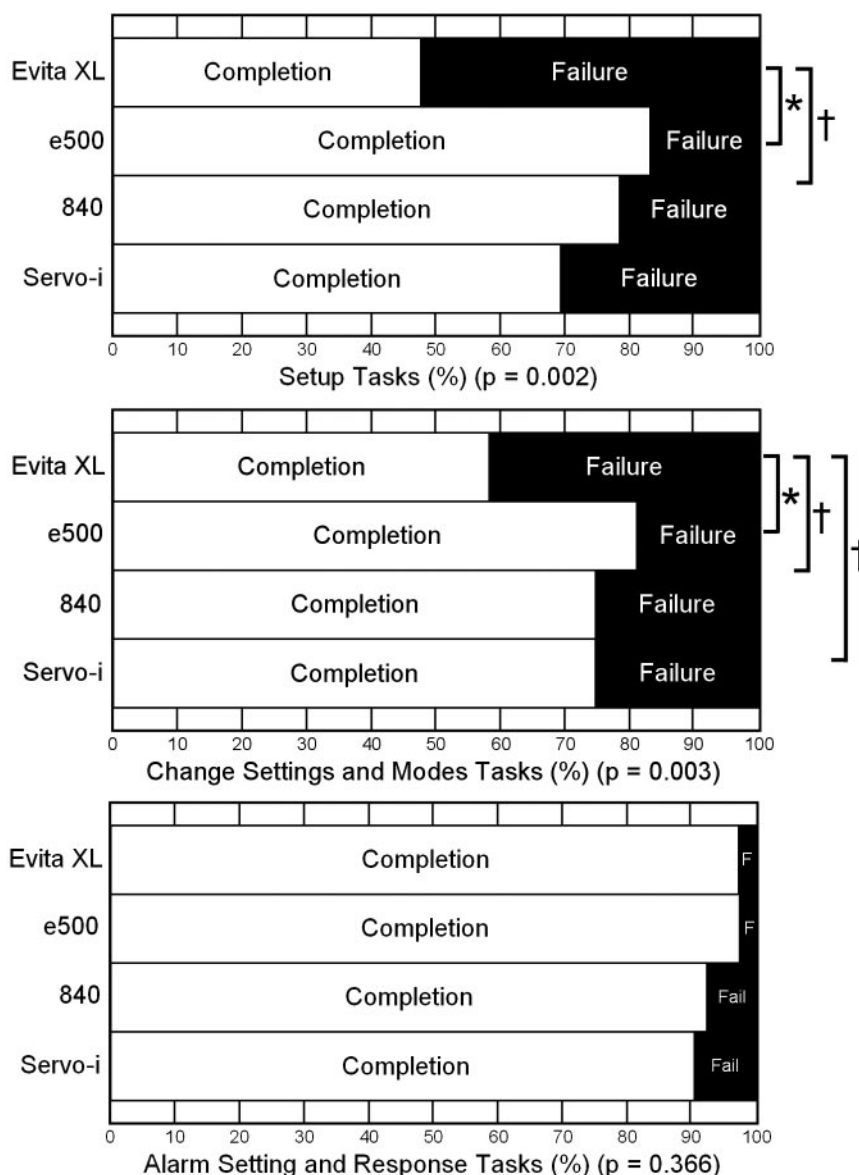


Fig. 2. Comparison of the number of completions and operational failures among ventilators in each task category. Post hoc analysis was via Tukey's test. * $p < 0.01$. † $p < 0.05$.

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-

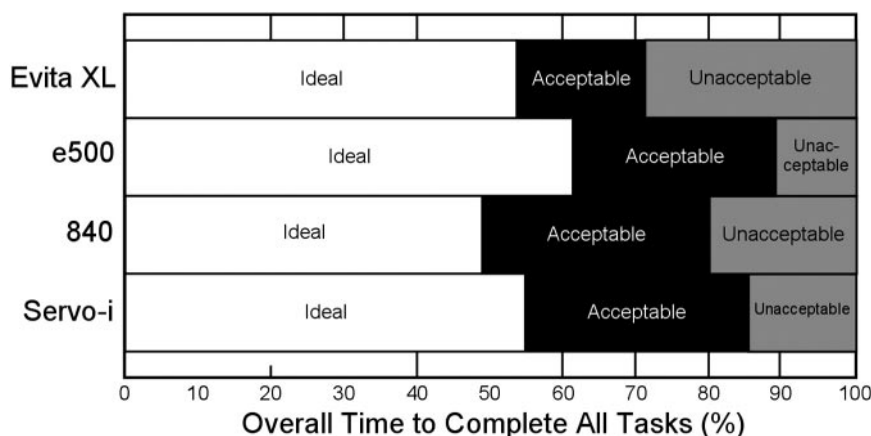


Fig. 3. Comparison of the time during operation of tasks among ventilators. Chi-square test $p < 0.001$.

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

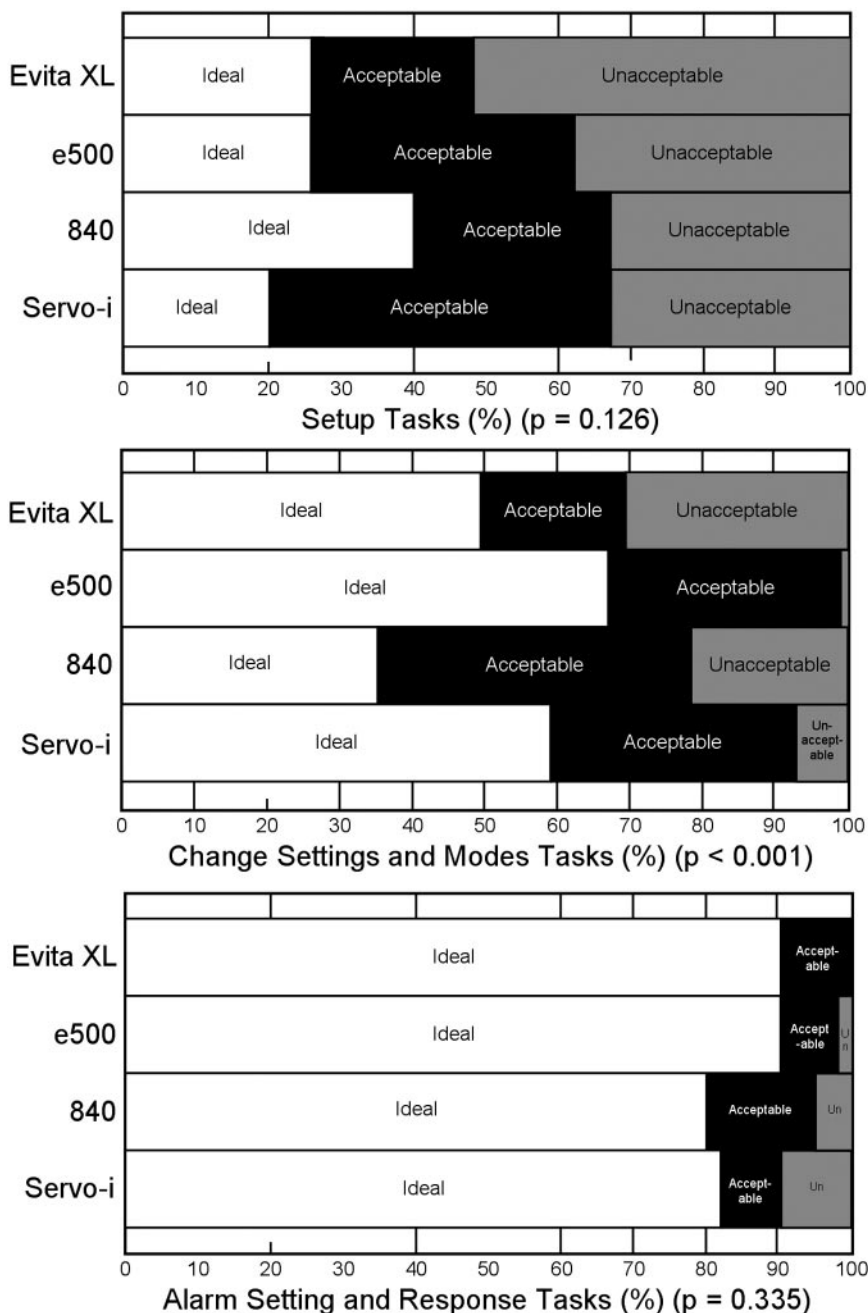


Fig. 4. Comparison of the time during operation of tasks in each task category.

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 abbre-

viated 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

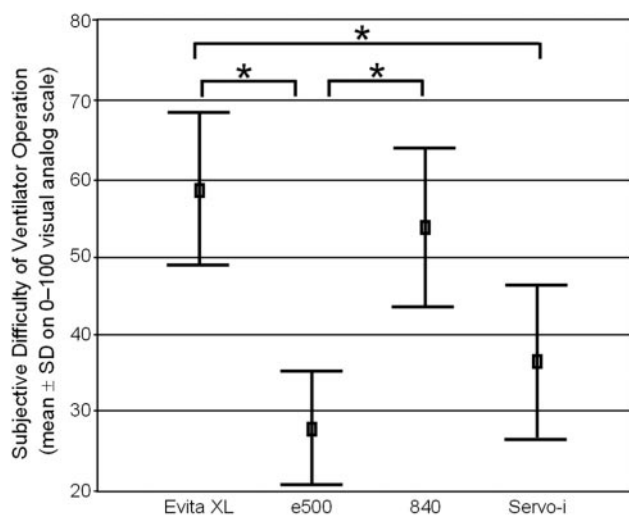


Fig. 5. Subjective feeling of difficulty to operate mechanical ventilators, measured with a visual analog scale (100 mm). $n = 21$. Friedman test ($p < 0.001$). Stoll-Dwass used for multiple comparison. * $p < 0.05$.

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.⁷ 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.⁸ In other medical fields the usability of medical equipment has been evaluated,⁹⁻¹² 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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