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Procedia Computer Science 219 (2023) 1232–1239

Procedia Computer Science

www.elsevier.com/locate/procedia

CENTERIS - International Conference on ENTERprise Information Systems / ProjMAN - International Conference on Project MANagement / HCist - International Conference on Health and Social Care Information Systems and Technologies 2022

Heuristic Evaluation of the Usability of a Mechanical Ventilator Interface through a Simulator

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Abstract

Determining the usability of mechanical ventilator interfaces is vital in ensuring correct usage under critical procedures that can place patients' health in danger. Heuristic evaluation has been used to evaluate usability in many different areas, including medical devices. The objective of this study is to evaluate the usability of a mechanical ventilator using the heuristic evaluation method. The evaluation of a mechanical ventilator simulator (Drager's Evita V500) was performed using the Heuristic Evaluation System Checklist (HESC). Three evaluators took part in the experiment in assessing the usability through HESC. The results show that of the 292 checklist sub-heuristics included in the HESC Checklist, 127 were compliant (had no flaws), 75 were not compliant (had flaws) and 95 were not applicable. The results point out that the mechanical ventilator interfaces should be improved to avoid human error due to usability issues. The results also show that heuristic evaluation generates a large quantity of objective information, which provides an exhaustive identification of aspects that should be improved.

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1877-0509
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Peer-review under responsibility of the scientific committee of the CENTERIS – International Conference on ENTERprise Information Systems / ProjMAN - International Conference on Project MANagement / HCist - International Conference on Health and Social Care Information Systems and Technologies 2022
10.1016/j.procs.2023.01.406

Keywords: Usability, Ventilator, Heuristic Evaluation, Medical devices, Human-Computer Interaction

1. Introduction

The general definition for an Intensive Care Unit (ICU) is “a specially staffed and equipped, separate and self-contained area of a hospital, dedicated to the management of patients with life-threatening illnesses, injuries and complications and to the monitoring of potentially life-threatening conditions” [1]. Among the various devices used in an ICU, there are invasive or non-invasive ventilators, that guarantee patient life support through mechanical ventilation, which is the medical term for artificial ventilation where mechanical means are used to assist or replace spontaneous breathing. It is indicated when the patients’ spontaneous ventilation is inadequate to maintain life. When a ventilator is in use, the airway and respiratory circuit pressure must be monitored continuously, and prompt warning should be given in cases of over or under pressure [2]. The interface of a mechanical ventilator should include waveforms that represent clinical parameters such as pressure, airflow, volume or respiratory rate.

The usability and functionality of these systems must be very clear and perfectly functional as one error has the potential to be fatal. Therefore, it is crucial to understand the usability of this type of systems to provide good scientific information to manufacturers so that they can redesign or design new medical products.

The term usability generally refers to the ability of a product or computer system to be easily used; however, the concept is broader, since it can be expressed by the scope of action of a product and can be employed for different groups of users or users with specific goals, with effectiveness, efficiency, and satisfaction, in a context of particular use [3,4].

A system or product is considered with good usability when it offers its users several benefits, among which the reduction of the error rate, and consequently, better acceptance and increased efficiency and productivity [5,6].

To determine a system’s usability there are several methods that can be empirical (involving real users) or analytical (involving experts) [7].

The most used analytical method is the heuristic evaluation which allows the evaluation of the interface of a system, based on a set of heuristics, which are a set of rules that guide the evaluation of the system’s usability [3]. It is recommended for at least 3 to 5 evaluators to take part in a heuristic evaluation [8]. The usage of heuristic evaluation does not implicate the replacement of user testing, as user testing manages to find problems often overlooked during a heuristic evaluation. However, heuristic evaluation tends to find serious usability problems at a fraction of the cost and at an early stage.

This paper reports the heuristic evaluation of a mechanical ventilator simulator (i.e., the Evita V500 (Drager)), whose objective was to assess the adequacy of the heuristic evaluation to determine potential usability problems of commercial ventilators. After this first section with the introduction, the rest of the paper is organized as follows: the related work, the methods that were applied and the respective results, and, finally, a discussion.

2. Related Work

The literature presents the usability evaluation of ventilators using techniques such as focus groups or observation [9-12]. While numerous studies have been conducted to access ventilator usability, the studies tend to focus on interpreting faults within the ventilator by either failure to accomplish a given task or exceeding the amount of time given in the experiments [9,13,14]. A general issue would be known to occur when performing a specific task, but not exactly what is wrong with it. In this sense, this paper aims to present the results of a heuristic evaluation of a mechanical ventilator.

According to Giraud et al. [10] 67% of complications present in the ICU are human errors, 50% of them being classed as major complications (within these complications are severe hypotension, respiratory distress, pneumothorax, and cardiac arrest). To tackle the design of systems, there are multiple paradigms to consider, especially on the side that concerns the human element [15]. Regarding what concerns with mechanical ventilators, the following aspects must be considered [16]:

- Tasks to perform including: i) time available to perform the tasks, ii) tools available, iii) complexity of the tasks, and iv) complexity in recognizing alarms/interface elements.
- Individual issues including: i) knowledge of mechanical ventilation, ii) experience operating mechanical ventilators, iii) stress, and iv) fatigue.
- Organizational issues including: i) procedures to follow, and ii) number of staff.

These factors by themselves don't lead to patient safety or reduction of errors in any way, but it is the complex work between them that leads to fruitful outputs (reduced harm) or less than positive outcomes (decreased patient safety).

Across different usability studies with mechanical ventilators, the tasks that were studied were: i) starting the ventilator, assembling the ventilator, changing/monitoring ventilation modes and parameters and evaluating alarms/shutting alarms/responding to alarms. In those studies, most errors were found to be in changing ventilator parameters and starting the ventilators [9,17].

3. Methods

3.1. Mechanical Ventilator Simulator

The mechanical ventilator simulator considered for the usability evaluation reported by this paper was the Evita V500 (Drager). The mechanical ventilator simulator was designed to mimic the real-life counterparts, operating in ICU-like environments, and offering a wide range of ventilation modes and breath delivery options.

Evita V500, designed by Drager, is a ventilation unit that is incorporated within the Drager Infinity C series Medical Cockpits. The ventilator aims to provide respiratory support across different timeframes, as well as different types of therapy to be applied (Non-Invasive Ventilation via Mask, Oxygen Therapy, Invasive Ventilation via Endotracheal Tube). Along with this, the mechanical ventilator provides options for defining different ventilation modes, divided mainly into three categories: i) Volume-Controlled Ventilation; ii) Pressure-Controlled Ventilation and iii) Spontaneous Breathing Ventilation

For interaction with the ventilator, the user uses a GUI display, named Infinity C500. On display, the user has access to different graphs pertaining to the patient's condition, menus, and system variables. The GUI is touchscreen-based, and most changes performed via the monitor must be confirmed by pressing an analogic knob attached to the Infinity C500. The knob in the system is designed to allow the user to change parameter values, while simultaneously serving as a confirm button.

When abnormalities are detected within the ventilator, alarms are issued as well as the severity of the alarm. Figure 1 shows Evita V500 and the simulated interface.

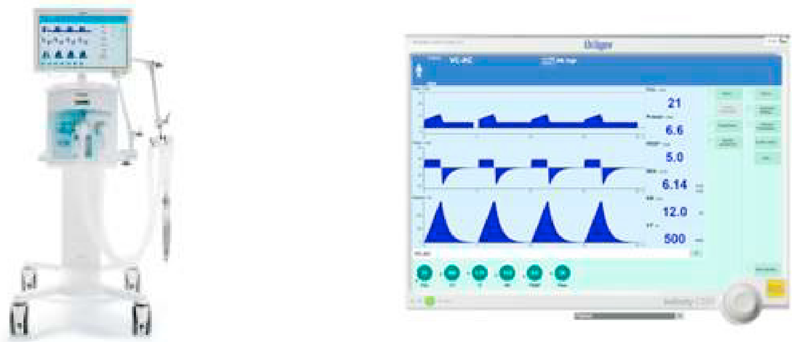

Fig. 1. Drager Evita V500 (a); Interface (b).

3.2. Study Design

The experiment was conducted through the application of the Heuristic Evaluation of a mechanical ventilator simulator, namely Evita V500 (Drager). The heuristic evaluation was performed using the Heuristic Evaluation System Checklist (HESC) [18]. This checklist consists of 292 sub-heuristics that help the evaluator to thoroughly review the system. The HESC covers the ten original Nielsen heuristics and includes three heuristics related to user skills, pleasurable user experience and privacy. Each sub-heuristic is posed in the form of a question, which then must be checked throughout the system for any case which might invalidate the sub-heuristic. To state which current sub-heuristic is being referenced, it is first referenced the heuristic, then the sub-heuristic itself (1.1 would be Heuristic 1. Sub-heuristic 1).

As the present experiment dwells with a simulated software, errors that could be found regarding the user's interaction with the physical ventilator are not covered. (e.g., setting up the ventilator system).

Before initiating the experiment, three evaluators were selected for the study. Two of the evaluators have vast experience in the fields of user experience and human factors and have conducted research for over 10 years. The other evaluator is a student in Computer engineering, with no prior research experience.

The evaluators went through each of the simulated ventilator interfaces based on the heuristics, to check and note the flaws found and their location on the interface.

Once this phase was concluded, the evaluators compared the results of their individual evaluations and established a consensus regarding the sub-heuristics in which there was disagreement. When the clarification process was concluded, a list of problems was generated based on the usability problems found during the initial evaluation / post-discussion.

The method application requires picking a sub-heuristic and analysing every screen within the system, which quickly adds up to the complexity of evaluating systems with many different screens to navigate, as well as increasing the time needed to evaluate a particular sub-heuristic. Upon finishing looking over a sub-heuristic, the evaluator decides if the sub-heuristic is applicable or not and if it is compliant with the sub-heuristic in question.

When the system does not comply with a given sub-heuristic, it is noted down. Additional comments are sometimes provided as to where the usability issue was found and possible fixes to the issue, as well as print screens detailing the usability issue.

The procedures performed to carry out the Heuristic Evaluation are detailed below:

1. Exploratory phase of the Simulator - The evaluators explored the mechanical ventilator simulator to become familiar with the interface, the functionalities, and the mapping of the interface.
2. Initial Evaluation of the Simulator - The evaluators performed the heuristic evaluation using the HESC by checking each individual interface element, indicating the non-applicable heuristics, those verified without problems and those with problems. In case of flaws the evaluators noted down in the HESC the respective sub-heuristic and, if needed, write additional comments. Prints of the screen were taken to signal where the usability issue was found.
3. Discussion - The evaluators compared the results of their individual evaluations and established a consensus regarding the sub-heuristics in which there was disagreement.
4. List of Usability Problems -The evaluators discussed the main usability problems found and their locations with basis on the heuristic evaluations performed and generated a usability problem list.

4. Results

The results of the heuristic evaluation of the Drager's Evita V500 indicate that, of the 292 checklist sub-heuristics included in the HESC Checklist, 127 were compliant (had no flaws), 75 were not compliant (had flaws) and 95 were not applicable.

For a sub-heuristic to not be applicable, the question it poses must not be relevant to the type of system it is being currently being analysed. For example, it is not possible to use function keys in a mechanical ventilator, as it does not provide support for keyboard. Then, any sub-heuristic related to function keys makes no sense to be evaluated, such as 1.15 (Is there feedback when function keys are pressed?), 2.24 (Are function keys labelled clearly and distinctively, even if this means breaking consistency rules?), 3.20 (Do function keys that can cause serious consequences have an undo feature?).

Table 1 presents the number of compliant sub-heuristics, the number of non-applicable sub-heuristics, the amount of sub-heuristic flaws found in the mechanical ventilator simulator and the number of screens existing in the system.

Table 1: Heuristic Evaluation Results Report, an overall view of the results obtained in the evaluation of the ventilator.

Heuristic Evaluation Results Report				
Mechanical Ventilator	Compliant sub-heuristics	Non-Compliant sub-heuristics	Unapplicable sub-heuristics	Number of Screens
Evita V500	127	75	95	94

Table 2 presents of the amount of compliant, non-compliant and unapplicable sub-heuristics present within each of the 13 heuristics present in the HESC. The heuristic that showed the most flaws was heuristic 4, (Consistency and Standards), with failure in 19 sub-heuristics, that are mainly related to the lack of uniformity of some features in the system and the absence of acronyms description and labels followed by the heuristic 7 (Recognition Rather Than Recall) and heuristic 10 (Help and Documentation) both with failure is 11 sub-heuristics.

Table 2: Heuristic Evaluation Results Report, view of the results divided into 13 heuristics.

Heuristics	**Compliant sub-heuristics**	**Non-Compliant sub-heuristics**	**Unapplicable sub-heuristics**
Heuristic 1 - Visibility of System Status	18	6	5
Heuristic 2 - Match between System and Real-World	8	7	9
Heuristic 3 - User Control and Freedom	6	2	15
Heuristic 4 - Consistency and Standards	23	19	9
Heuristic 5 - Help users Recognize, Diagnose, and Recover from Errors	11	5	5
Heuristic 6 - Error Prevention	1	4	10
Heuristic 7 - Recognition Rather Than Recall	19	11	10
Heuristic 8 - Flexibility and Minimalist Design	3	1	12
Heuristic 9 - Aesthetic and Minimalist Design	8	2	2
Heuristic 10 - Help and Documentation	8	11	4
Heuristic 11 - Skills	8	4	9
Heuristic 12 - Pleasurable and Respectful Interaction with the User	8	1	5
Heuristic 13 - Privacy	1	2	0

In 1.27 (Do GUI Menus make obvious which menu has been selected?), we found that selecting any of the lateral menu buttons does not change colour to indicate it is in fact selected, even though the window remains active.

The sub-heuristic 2.1 (Are icons concrete and familiar?), we find numerous unfamiliar icons such as the alarm icons (represented in the interface as a triangle instead of the familiar bell), the trends/data icon (represented as a square magnifying lens, instead of a plotted chart for instance).

In sub-heuristic 3.21 (Can users easily reverse their actions?), it is simply not possible due to the fact there is no possibility of using undo (lack of keyboard and system functionality), so if there is a change in ventilation settings in a mode, it is not possible to simply revert to previous parameters at a press of a button. Likewise, there is no implementation of a “Drager Default” button like in System Setup > Ventilation > Start up Settings to reset back to Mode’s Default settings present near Ventilation setting parameters.

In sub-heuristic 4.31 (Is a legend provided if colour codes are numerous or not obvious in meaning?), in Alarms > Current History/Alarm History, exclamation marks are used to represent priority instead of clear text. A suggestion would be since there are three levels of Alert priorities, it could be divided into Maximum, Medium and Low (Max, Med, Low to fit in the current priority box).

In the sub-heuristics 5.17 (Do error messages suggest the cause of the problem) and 5.20 (Do error messages indicate what action the user needs to take to correct the error), the alarm messages are extremely brief and do not underly the cause of the problem (e.g., “MV low”). The user is not informed of ways to correct these alarms other than prior technical knowledge. This is a severe problem given that users have often little time to waste on Critical-level alarms, so the lack of information on what possible parameters could be used to tackle the anomaly is an issue that would need to be fixed.

In the sub heuristic 6.11 (Does the system prevent users from making errors whenever possible), one finds that indeed the system has warnings when attempting to go upper limits in certain crucial parameters such as Tidal Volume (Vt) will throw a warning (i.e., Vt < Vt high!). This is not the case when lowering the Tidal Volume to minimum settings (Vt = 100ml), which is equally as dangerous, since not only will it inevitably trigger a low minute volume alarm, but also be a factor in causing atelectasis (lung collapse) [19].

In sub heuristic 7.12 (Have items been grouped in logical zones, and have headings been used to distinguish between zones), the system does organize the zones into sections, however, these have no headings of any sort (save for the current active ventilation mode in the bottom-left and new window titles).

In sub heuristic 8.1 (If the system supports both novice and expert users, are multiple levels of error message detail available), error messages have the same message regardless of the customization one undergoes through in the system setup.

In sub heuristic 9.10 (Is each lower-level menu choice associated with only one higher level menu), the system has a Smartcare side menu present in all 4 submenus of Trends/Data (Trends, Values, Logbook, Export Data). A suggestion would be to create a Smartcare submenu of Trends/Data and remove the menu choice from everywhere else.

In sub-heuristic 10.9 (Is the help system interface (navigation, presentation, and conversation (consistent with the navigation, presentation, and conversation interfaces of the application it supports)), the ventilator does in fact offer a help manual, although it is confusing and differing in the general menu structure. It is hard to navigate given that there is no search function, and subitems in the help menus are not particularly organized (Alarms - Causes - Remedy is outside the Alarms segment and Description of Ventilation modes / Special procedures is outside of the Operation Segment). Within these subitems, it is possible to navigate even further inside the pages to different ones, although these are not listed within the Content page (Measurements > Measurement principles.)

In sub-heuristic 11.22 (Does the system correctly anticipate and prompt for the user’s probable next activity), in Start-up / Standby window, upon selecting a new patient, the next probable activity would be starting the ventilation unit, so the Ventilation unit field should have the Start button as yellow indicating that it is waiting for confirmation. Such is only the case when starting up the ventilator with Current Patient upon boot.

In sub heuristic 12.7 (Can users turn off automatic colour coding if necessary), the system has no option to do such in the System Setup.

In sub heuristic 13.1 (Are protected areas completely inaccessible?) and sub heuristic 13.3 (Is this feature effective and successful) the simulators do provide passwords to enter protected areas, but the system allows the ventilator to be able to connect to a local area network. If the ventilator is in fact connected to a network, a compromised element in the network could pose risks for patients. Some examples of these could be changes in device settings, false alarms / no alarms, as well as potential damage/loss of patient data. It is also possible to load custom applications via card in System Setup > Applications, offering a gateway to install malicious applications that could, for example, change hard-coded limits that cannot otherwise be changed in System Setup (Parameter minimums and maximums for instance).

Table 3 lists the sub-heuristics with flaws.

5. Discussion

The application of the heuristic assessment method to evaluate the Drager’s Evita V500 was effective in the exhaustive identification of system failures and allowed to list concrete aspects of the ventilator interface that are problematic and served as a basis for creating improvement suggestions.

Table 3. - List of sub-heuristics with flaws.

Visibility of System Status	**1**.9 After the user completes an action (or group of actions), does the feedback indicate that the next group of actions can be started?; 1.16 If there are observable delays (greater than fifteen seconds) in the system's response time, is the user kept informed of the system's progress? 1.24 High levels of concentration aren't necessary and remembering information is not required: two to fifteen seconds. 1.27 Do GUI menus make obvious which item has been selected? 1.28 Do GUI menus make obvious whether deselection is possible? 1.29 If users must navigate between multiple screens, does the system use context labels, menu maps, and place markers as navigational ai
Match between System and the Real World	2.1 Are icons concrete and familiar? 2.2 Are menu choices ordered in the most logical way, given the user, the item names, and the task variables? 2.9 On data entry screens, are tasks described in terminology familiar to users? 2.10 Are field-level prompts provided for data entry screens? 2.12 Do menu choices fit logically into categories that have readily understood meanings? 2.18 Have uncommon letter sequences been avoided whenever possible? 2.21 Does the system automatically enter commas in numeric values greater than 9999?
User Control and Freedom	3.7 Is there an "undo" function at the level of a single action, a data entry, and a complete group of actions? 3.21 Can users easily reverse their actions?
Consistency and Standards	4.2 Has a heavy use of all uppercase letters on a screen been avoided? 4.5 Are icons labelled? 4.7 Are there salient visual cues to identify the active window? 4.9 Are vertical and horizontal scrolling possible in each window? 4.11 Have industry or company standards been established for menu design, and are they applied consistently on all menu screens in the system? 4.15 Are menu items left-justified, with the item number or mnemonic preceding the name? 4.18 Are field labels and fields distinguished typographically? 4.19 Are field labels consistent from one data entry screen to another? 4.21 Do field labels appear to the left of single fields and above list fields? 4.24 Size: up to four sizes 4.27 Colour: up to four (additional colours for occasional use only) 4.30 Are there no more than four to seven colours, and are they far apart along the visible spectrum? 4.31 Is a legend provided if colour codes are numerous or not obvious in meaning? 4.32 Have pairings of high-chroma, spectrally extreme colours been avoided? 4.33 Are saturated blues avoided for text or other small, thin line symbols? 4.35 Are user actions named consistently across all prompts in the system? 4.37 Do field-level prompts provide more information than a restatement of the field name? 4.39 Are menu choice names consistent, both within each menu and across the system, in grammatical style and terminology? 4.45 Are abbreviated words all the same length?
Help Users Recognize, Diagnose and Recover from Errors	5.3 Do prompts imply that the user is in control? 5.12 Do messages place users in control of the system? 5.17 Do error messages suggest the cause of the problem? 5.20 Do error messages indicate what action the user needs to take to correct the error? 5.21 If the system supports both novice and expert users, are multiple levels of error-message detail available?
Error Prevention	6.2 Have dots or underscores been used to indicate field length? 6.4 Are menu choices logical, distinctive, and mutually exclusive? 6.6 If the system displays multiple windows, is navigation between windows simple and visible? 6.11 Does the system prevent users from making errors whenever possible?
Recognition Rather Than Recall	7.5 Are prompts, cues, and messages placed where the eye is likely to be looking on the screen? 7.11 Is white space used to create symmetry and lead the eye in the appropriate direction? 7.12 Have items been grouped into logical zones, and have headings been used to distinguish between zones? 7.13 Are zones no more than twelve to fourteen characters wide and six to seven lines high? 7.15 Are field labels close to fields, but separated by at least one space? 7.16 Are long columnar fields broken up into groups of five, separated by a blank line? 7.24 Is colour coding consistent throughout the system? 7.28 Is the first word of each menu choice the most important? 7.31 Have frequently confused data pairs been eliminated whenever possible? 7.32 Have large strings of numbers or letters been broken into chunks? 7.35 If the system has many menu levels or complex menu levels, do users have access to an on-line spatial menu map?
Flexibility and Minimalist Design	8.1 If the system supports both novice and expert users, are multiple levels of error message detail available?
Aesthetic and Minimalist Design	9.8 Are field labels brief, familiar, and descriptive? 9.10 Is each lower-level menu choice associated with only one higher level menu?
Help and Documentation	10.4 If menu choices are ambiguous, does the system provide additional explanatory information when an item is selected? 10.6 If menu items are ambiguous, does the system provide additional explanatory information when an item is selected? 10.9 Is the help system interface (navigation, presentation, and conversation) consistent with the navigation, presentation, and conversation interfaces of the application it supports 10.10 Navigation: Is information easy to find? 10.11 Presentation: Is the visual layout well designed? 10.13 Is the information relevant? 10.18 Navigational (Where am I?) 10.19 Is there context-sensitive help? 10.20 Can the user change the level of detail available? 10.21 Can users easily switch between help and their work? 10.23 Can users resume work where they left off after accessing help?
Skills	11.1 Can users choose between iconic and text display of information? 11.3 If users are experts, usage is frequent, or the system has a slow response time, are there fewer screens (more information per screen)? 11.4 If users are novices, usage is infrequent, or the system has a fast response time, are there more screens (less information per screen)? 11.22 Does the system correctly anticipate and prompt for the user's probable next activity?
Pleasurable and Respectful Interaction with the User	12.7 Can users turn off automatic colour coding if necessary?
Privacy	13.1 Are protected areas completely inaccessible? 13.3 Is this feature effective and successful.

The heuristic evaluation results showed an enormous lack of standardization between colours of alerts, fonts, and terminology. In this way, it is necessary to go in depth for the study of heuristic evaluation in other mechanical ventilators, as well as the one referred to in this study.

Some limitations in this study must be recognized. First, the heuristic shows only the point of view of the specialists. Even though important flaws were found such as 5.4 in which there is no more specific information regarding a problem when dealing with alarms, using formal methods with users along with heuristic evaluation would possibly allow finding more flaws within the system itself. Second, the experiments were conducted in a simulator based on a real ICU mechanical ventilator. Despite this, it is worth extending the study towards real environments, as the flaws found in this study prove the necessity of conducting investigations in evaluating the usability of mechanical ventilators.

One limitation of the method is the fact that HESC has many sub-heuristics that are similar to one another, despite sometimes being found in different heuristic groups. So, while an evaluator might evaluate that one sub-heuristic is compliant with the system, the other sub-heuristic which is closely related to it might deem it non-compliant. An example of this can be found in sub-heuristics 4.19 (Are field labels consistent from one data entry screen to another?) and 4.35 (Are user actions named consistently across all prompts in the system?).

It should be noted that, ideally, this type of assessment should be done before the system is tested with end users. vital, as this is a medical device on which the life of patients rely on, and any usability issue can be catastrophic.

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