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Alarm Evaluation of an Intensive Care Unit Vital Signs Monitor System Based in Usability Parameters

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Abstract **—**This article presents a test model for the usability of a vital signs monitoring system, specifically in Intensive Care Units (ICUs). This is because approximately 12% of annual failures occur in this area and 50% of these are due to usability problems. The model specifically measures the interaction between medical personnel with the equipment, beginning with a bibliographical review, then defining the equipment with which to work to later suggest and develop a protocol proposal which will enable evaluating its usability and thus suggest some changes to be implemented.

Keywords **—** ICU, supervision, system, usability.

Evaluación de las alarmas de un sistema de monitoreo para una unidad de cuidados intensivos y especiales basándose en criterios de usabilidad

Resumen **—**En este artículo se presenta la aplicación de un modelo de pruebas de usabilidad a un sistema de monitoreo de signos vitales usados específicamente en Unidades de Cuidados Intensivos (UCI) debido a que aproximadamente el 12% de los fallos anuales se presentan en esta área, en donde el 50% de estos fallos son el resultado de problemas de usabilidad. Este trabajo busca medir específicamente la interacción personal médico con el equipo, empezando con una revisión bibliográfica, luego definiendo el equipo a trabajar. Finalmente, se propone desarrollar una propuesta de protocolo que permita evaluar la usabilidad del mismo y así sugerir algunos cambios que se pueden implementar.

Palabras clave **—** Monitoreo, sistema, UCI, usabilidad.

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Avaliação dos alarmes de um sistema de monitorização para uma unidade de cuidados intensivos e especiais baseando-se em critérios de usabilidade

Resumo —Neste artigo apresenta-se o aplicativo de um modelo de provas de usabilidade a um sistema de monitorização de signos vitais usados especificamente em unidades de cuidados intensivos (UCI) como aproximadamente o 12% das falhas anuais apresentam-se nesta área, e o 50% destas falhas são devido a problemas de usabilidade, medindo especificamente a interação pessoal médico com o equipamento, começando com uma revisão bibliográfica, logo definindo a equipe a trabalhar para posteriormente propor e desenvolver uma proposta de protocolo que permita avaliar a usabilidade do mesmo e assim sugerir algumas mudanças que podem-se implementar.

Palavras-chave —Monitorização, sistema, UCI, usabilidade

I. Introduction

Usability enables the evaluation of equipment, as well as determining how user friendly it is, a key factor in the error tendency during the use of the device. This article presents an implemented methodology in order to achieve usability tests, its corresponding results, along with their analysis, to thus reach the project's conclusions.

When user criteria for equipment evaluation are taken into account, it guarantees the equipment will have easy interaction with the user, which in turn leads to a great reduction in errors that can occur with the day-to-day use of equipment [1]. Some countries have regulations for the implementation of usability in medical devices. Standards such as IEC 62366-1:2015 [2] establish processes for the evaluation of devices with usability parameters, focusing on patient safety. This project applied usability evaluations which were developed based on the heuristics evaluation established by Nielsen, which take into account the following at the time of evaluating components: learning ease, efficiency, efficacy, quality of remembrance and user satisfaction [3]. The intensive care unit (ICU) is a highly complex service whose objective is to offer complete care to persons in critical health conditions who were admitted there [4].

This is why usability oriented toward this type of equipment plays an important role, since even minimal error or minimum failure, whether due to equipment or medical personnel, puts the patient's life at risk [5]. In Patricia Mena's article "Medical errors and adverse events," the author establishes that when adverse events occur where patient safety is compromised, whether due to medical error or failure of the equipment or its usability, the medical equipment is responsible for its prevention, avoidance and timely identification, as well as, limiting damage to the patient [5]. As such, the need to have alarm controls grows, as well as control of the general use of medical equipment within a hospital and especially within an intensive care unit (ICU), looking at the most repetitive failures occurring within this location and posing possible solutions which range from training to changing the equipment used at said locations.

II. Methodology

For an evaluation in usability engineering (UE), it is necessary to take into account several considerations or aspects that should be included in the evaluation: users, environment and user interfaces [6]. A methodology was implemented in the project, which included all three. The selected users for testing had to work at SCUs or ICUs, which is the context environment for the above stated reasons, in addition to being close to the equipment to be evaluated. That is why the technician in charge of the ICU equipment was chosen, as well as, its nursing staff. These personnel are trained to perform tests and handle equipment in the unit. They must go through previous training in order to work at ICUs. Lastly, the user interface evaluated will be the vital signs monitor. The project development consisted of four stages:

1. Antecedents: The first step was determining what standardization is used in Colombia with relation to evaluation of medical equipment, as well as, which standard applies specifically to usability. The state of the art was established with regard to articles and studies on the topic. Lastly, we determined what percentage of failures in devices were related to usability, according to reports dating back three consecutive years from a Medellín hospital database which we had access to during this study.

2. Definition of equipment to work with: For this stage, it was decided to perform an evaluation of a complete monitoring system which includes a vital signs monitor and the monitoring station in charge of supervising it. Using criteria such as time for task completion steps,

remembrance quality, service effectiveness, interface quality and how intuitive this is.

3. Protocol proposal and tests to be performed: Different tests were performed related to the usability developed based on "Usability evaluation for a vital signs monitor prototype" [7].

- Characterization of vital signs monitor alarms used within the ICU
- Comparison of alarm configuration in a Medellín clinic versus manufacturer determined configuration
- Observation of alarm management at an ICU
- Testing of alarm management on nursing staff

4. *Results analysis:* With the results obtained, the usability of the equipment and the center was evaluated. Also, some changes are suggested that could be implemented in the ICU.

III. Results

Characterization of vital signs monitor: A vital signs monitor in the ICU was used, which possesses a monitoring platform PiCC02, ScvO2 and BISx/x4, as well as, clinical tools such as spider diagram and spectral density matrix and a totally modular design which enables the simultaneous measuring and operation.

The HL7 protocol and the communication gateway allow the monitor in the ICU to perfectly interact with the hospital information system or with a clinical information system. The admission of patients is carried out simply. In addition, important data about the vitals constants can be transferred to the patient record. This efficient procedure, performed without any paperwork, improves productivity and reduces the risk of transcription errors.

With the plug and play BeneLink module, up to four devices can be connected to the monitor, such as ventilators and anesthesia machines, which increases the amount of information provided [8].

To this, a characterization was performed taking into account usability parameters. The first to be evaluated is the color system, which, if adequate greatly eases the monitor's connection, making it more intuitive for the user, as can be seen in Fig. 1.

Table 1. Specifications, vital signs monitor

Monitor	Specifications
 **Fig. 1.** Module for UCI monitor connections	• Modular monitor • Entrance pins with labels according to function • Entrance pins with specific colors per corresponding connection

Specifications in Table 1 are beneficial for the usability of the equipment, thus contributing to the reduction of errors at the time the connection was carried out.

Monitoring Station Characterization: The center was located in the Special Care Unit (SCU), strategically located so as to be viewed from all cubicles. The station has access to the variables given off by the vital signs monitor. This information can be constantly viewed on a screen, as Fig. 2 shows.

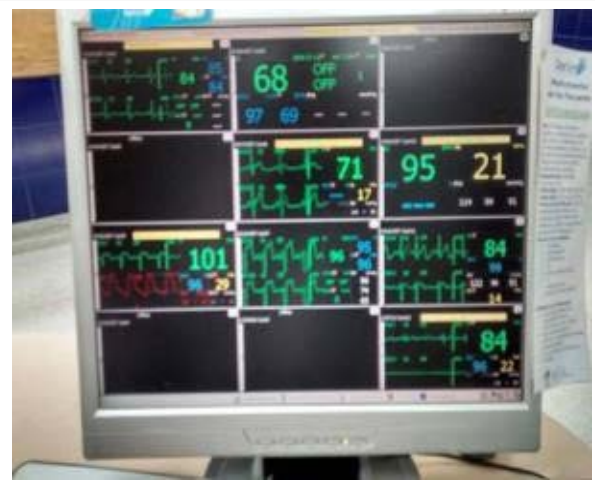

Fig. 2. View of physiological parameters from monitoring center

The center has a system that relates a hospital bed's own direction and assigns it to the monitor. This way, the monitor sends its information, specifying which direction it comes from. This direction appears in the upper part of each one of the corresponding divisions of each of the vital signs monitor. The monitoring station characterized in this study was set up according to the central monitoring

system protocol [9], where the protocol for the cable network was used.

***Characterization of alarms monitor**:* Table 2 shows a classification of alarms according to priority levels.

Table 2. ICU monitor alarm levels

Level	Physiological alarms	Technical Alarms
High	Situation where patient life is in danger	Serious device failure in which monitor cannot detect patient's critical state
Medium	Patient constants are abnormal	Device failure which does not put patient's life at risk
Low	Patient constants are abnormal	Poor device operation but does not put patient's life at risk

Table 3 shows the different alarm indicators with light, which show the differences in light, color and frequency, depending on the priority level of the alarm.

Table 3. Alarm indicator

Level	Light	Color	Sound
High	Light blinks quickly	Red	Various
Medium	Light blinks slowly	Yellow	3 times
Low	No blinking	Yellow	1 time

Comparison of alarm configurations: When a vital signs monitor is assigned to a patient, it is simply appropriately connected to its corresponding cables for the variables to be measured, without needing to vary configurations between patients. The only different parameter found was the volume of the alarms. Manufacturer features of ICU monitors have the possibility of varying the volume of the alarm from a range between 2 and 10, and come programmed at the predetermined maximum level (10), the recommended volume level of the manufacturer. In spite of this, it was observed that the monitors were set at minimum volume levels (2) in the majority of those found in the ICU and SCU.

Alarm observations: For tracking, the alarm the monitor generated was taken into account, as well as, its level of importance and the time it took the nursing staff to tend to said alarm. Upon completing this observation, it was determined that it is very difficult to determine a reference or to reach a conclusion with this tracking. Within the alarms generated by the monitor, several are due to the fact the patient moves and causes some of the cables to disconnect. For this case, the monitor emits an alarm at low to mid level of importance. This can happen several times a day, depending on the patient. This is why personnel silence these alarms on many occasions, while they perform other activities, which represents a risk for the patient.

Usability test: For this test, an EKG simulator was connected to the monitor. Values above and below alarm limits were simulated in order to activate them and perform tests on hospital personnel. A usability test was performed on 6 nurses from the hospital ICU. Additionally, there was a reference evaluation which corresponded to the person in charge of the supervision and maintenance of the equipment found in the ICU.

Table 4. Usability test results

PERSON	TEST	TIME	NUMBER OF STEPS
Reference	2	0:07	1
	3	0:32	3
	4	0:29	3
1	2	0:45	5
	3	Did not know how	
	4	2:45	21
2	2	0:34	7
	3	1:50	12
	4	0:22	2
3	2	0:39	1
	3	0:30	3
	4	0:22	3
4	2	0:14	1
	3	0:39	4
	4	1:17	3
5	2	0:17	1
	3	0:52	8
	4	0:14	3
6	2	0:25	1
	3	0:40	8
	4	0:16	3

The tests consisted of four items:

1. Identifying the level of the alarm that was activated
2. Silencing the alarm
3. Changing the values of the limits of the alarm
4. Changing the volume of the alarm

The results obtained by the tests for points 2, 3 and 4 are abbreviated in Table 4.

Table 5 shows results for item 1, where the identification of the alarm is evaluated.

Table 5. Results of usability test (question 1)

ITEM 1	
PERSON	**ALARM LEVEL**
Reference	Medium
1	Low
2	Low
3	High
4	Medium
5	Medium-Low
6	High

IV. Discussion

Characterization of Monitoring Station. One of the inconveniences found regarding the usability of the monitoring station was the protocol used by the clinic for its set-up [1]. The station uses the protocol of a cabled monitoring station. It was found that during the rounds performed at the ICU, the connection of certain cables on the monitors or the entrance pins on the monitor located at the nurse's station was loosened, causing some patients' information to be un-viewable on the monitor. When this happens, the head nurse is in charge of informing the technician to verify connections or adjust cables, thus solving the problem. This could be due to a wear and tear of the cables over time, which reduces the usability of the station, since users have difficulties and are forced to call technicians to find solutions. This is why to increase the usability of this station, we propose trading out the current protocol for one carried out wirelessly, in order to eliminate possible alarms that might have gone unattended because the specific patient could not be viewed on the monitoring station.

Characterization of monitor alarms: Ignoring an alarm can place the life of a patient at risk, since these alarms are generated when there is a physiological parameter outside the recommended ranges. Earlier in this article we mentioned the levels and causes of the activation of these alarms. In the case of a high level alarm activating due to a monitor's technical failure as low battery, if the medical staff is not trained to understand and solve the problem, simply because the patient does not have his vital signals altered, it can cause the detention of the monitor and, as such, the visualization of the state of the patient, which can lead to an endless number of events, which could have been avoided by a good detection and solution of the alarm.

The visual or acoustic indicators are a useful alternative at the time of classifying the alarm for its adequate attention, since identifying the color of the alarm will let one know how critical the solution to the situation is. Upon characterizing the alarms the equipment comes with and comparing them with the configurations with which they work at the care unit, we identified that the volume adjustment of the alarm to a low level can result in a dangerous situation for the patient, since a sudden change in the vital signs of a patient might not be heard by the staff in order to take measures. As mentioned before, the equipment comes from the manufacturer with the maximum volume level set at 10 and we observed that the equipment evaluated works with a minimum volume set at 2, being this a warning made by the manufacturer.

Usability tests: Upon performing the usability test, we observed that there is a variation in the data with respect to the reference data.

Regarding test 1, which consisted of saying which was the alarm level the monitor emitted, the answer was qualitative and no times nor steps used were monitored to complete said task. We found that only two of the six persons responded correctly to the question and this might be due to the fact low and medium alarm levels are activated in the same color and the only difference is in the sound and that they sometimes flicker. Regarding the persons who answered at a high level, they did not understand the question completely and were confused with the alarm limit of the vital signs, although not the level itself. However, knowing or not the level of the alarm, plays an important role at the time of making a decision of whether or not to consult the physician on call, since these levels tell us how serious the situation is and if the patient needs immediate attention.

Regarding test 2, which consisted of silencing an alarm previously emitted, the response reference is 1 step and took 7 seconds. According to table 4, we can see that the majority of the persons who took the test did so within the appropriate steps with respect to the reference. This behavior is due to the fact that the monitor has, in its interface, a button with which this action is carried

out immediately and is why it does not take much time or many steps to complete, and is possible to do in less than 1 minute.

Regarding test 3, which consisted in changing the parameters of the alarm limits of an EKG, reference time is 32 seconds and 3 steps to complete the task. We found that almost all the persons took more time and steps than the reference. This was due to the fact that these variables are never modified on the equipment, rather they work with those provided by the equipment manufacturer and this is why they are not familiar with this function. However, the importance of knowing and manipulating alarm limits are very important at the time of interpreting the illness of a patient, that is, some patients with pathologies related to heart disease must be given a major priority to the changes of the vital signs monitor and require a modification of this feature in order to better observe its variables and to be able to respond to any event on time.

Regarding test 4, which consisted of changing the monitor's volume level, reference time was 24 seconds and 5 steps. We observed that this task was the one that was most easily completed. As mentioned before, this parameter is modified from the manufacturer configuration and is why personnel is most familiar with this adaptation. However, this reinforces the fact his parameter should not be modified and could unleash a dangerous situation for the patient.

Based on the previous results, we recommend carrying out personnel training on the topic of ICU vital signs monitors, highlighting the importance of knowing features such as modifying the limit of alarms, since even though this is not very commonly done, personnel must be very familiar with the equipment and all its features. Additionally, the importance of identifying alarms must be emphasized since having not only different types of physiological but also technical alarms, personnel must know how to solve them to avoid adverse events. We found that, according to the colors and sounds that are particular to the ICU alarms monitor, there is much similarity on the low and medium level alarms, and the nursing staff evaluated showed difficulty in differentiating them. One possible solution could be to set the alarms to vary in color, as well in these three levels so that the distinction among them can be clearer. Due to a great number of alarms perceived daily in an intensive care unit, we evidenced that many monitors are silenced or configured at their lowest volume level, thus generating potentially risky situations for the patient. In addition to the many low and medium level alarms presented daily, the nursing staff has different jobs during their work days. The digitizing of all that occurs to a patient requires time. This is why when personnel detect an activation of a low level alarm, the decide to silence it while finishing other duties. Amid these intervals of time, there are spaces where a patient can be at serious risk.

A change in the implementation of the alarms of the monitor and the training of nursing staff could reduce the risks this represents.

V. Conclusions

- The Intensive Care Unit (ICU) is a system that requires adequate attention and management, since this is where the most critical patients are found, thus the importance of the timely detection of alarms emitted by the vital signs monitors. It must be noted that a minimal alteration in any of these parameters can cause the death of a patient.
- It is of vital importance that hospital units frequently carry out training where personnel interact with equipment and perform determined duties. This way personnel will be prepared for any damage, alarm, malfunction, among others, that can be immediately solved so as not to can put the life of a patient at risk.
- Alarms represent one of the critical points under the topic of patient safety. This is why it is necessary to evaluate usability of the equipment that emits alarms, as well as, the evaluation of said alarms for the purpose of proposing strategies that will help reduce errors in alarm handling.
- Tools such as usability tests can help establish a better picture regarding what measures to take with respect to the reduction of errors in a service, whether it be a change of equipment or more training of personnel. If the information regarding equipment usability exists, better focuses to understand and treat can be proposed.

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