

THE DANGER IS IN THE DETAILS: HUMAN FACTORS EVALUATION OF AUTOMATIC EXTERNAL DEFIBRILATORS

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INTRODUCTION

Because chances of survival following a sudden cardiac arrest decline by 7-10% for each minute that passes before resuscitation (Cummings, 1989), the American Heart Association recommends the use of Automated External Defibrillators (AEDs) in the hospital setting, as a way to facilitate an early response to an arrest situation (*Circulation*, 2005).

In order to improve their resuscitation response times, The University Health Network and Mount Sinai Hospital in Toronto, Canada, plans to introduce AEDs into their sites as an adjunct to fully equipped crash carts with conventional defibrillators.

A number of studies have been conducted evaluating the performance of lay people with AEDs in public scenarios. (Fleischhackl, et al., 2004; Andre et al., 2004; Beckers et al., 2005; Callejas et al., 2004; Eamses et al., 2003). While AEDs are meant to be simple to use with minimal training, these studies yielded mixed results with respect to the usability of the devices evaluated.

Usability evaluations of AEDs to be purchased for in-hospital use were therefore conducted to increase the likelihood of an improved response to sudden cardiac arrest.

As part of the product procurement process a three-part analysis was conducted to evaluate each of the AEDs with the intention of determining the product features that are best suited to providing the quickest response.

METHODS

Heuristic Evaluation

A heuristic evaluation of each AED was conducted according to the 14 patient-safety usability heuristics identified by Zhang, Johnson, Patel, et al. (2003). These heuristics were applied to the following features of each device:

- Device handle
- Device case
- Shoulder strap
- Electrode pad package
- Electrode pads
- In-case instructions
- Buttons
- Screen
- Status indicator
- Audio quality

For each AED, features were rated on a scale from one to five depending on whether they adhered to or violated the Zhang heuristics (1 being unacceptable from a usability perspective, and 5 being exceptional). Each feature evaluated was weighted equally in this evaluation.

User Testing

The user testing assessed the ease of use of the AEDs in two realistic resuscitation scenarios:

1. A patient is in ventricular fibrillation, and can be defibrillated. The patient recovers after 3 shocks.

2. A patient is asystolic and requires Cardiopulmonary Resuscitation (CPR). Following CPR, the patient is then in ventricular fibrillation and can be defibrillated. The patient recovers after 2 shocks.

During each of the scenarios the following aspects of the AEDs were evaluated:

- Handling the device
- Handling the electrode pad package
- Placing the electrode pads
- Turning the device on
- Visibility of ECG on the screen
- Visibility of text on the screen
- Audibility of voice prompts
- Quality of instruction in voice prompts
- Performing chest compressions when using the device
- Turning off the device

Eight representative end-users (six nurses, two respiratory therapists) were recruited to participate in the user testing after the project was granted Ethics Review Board approval. These participants had no prior experience with AEDs.

Prior to starting, each participant was provided 10 minutes of training that introduced the goals of the usability evaluation and generally described the use of AEDs for resuscitation in a 5 minute video.

A Laerdal human simulator (SimMan) (Laerdal Medical AS, Stavanger, Norway) was used as the patient in a simulated hospital room environment. The simulator was programmed to mimic the respiration and heart rate changes consistent with the above two scenarios. In order

to resuscitate him, participants used the apex and lateral chest conductors for defibrillation.

During each scenario, participants were asked to comment aloud on their experiences while being observed and video recorded. This process was repeated each of the three AEDs evaluated and the order of device evaluation and scenarios was randomized to minimize the effects of learning.

Following the user testing, the observations were analyzed for errors and patient safety concerns. The severity of each issue identified was rated on a scale from one to five, with one being unacceptable from usability and patient safety perspective, and five being exceptional.

Failure Modes and Effects Analysis (FMEA)

An FMEA was performed to identify significant risks associated with AED usability issues and gain insights into methods of preventing failures. The severity of each risk was rated on a scale from one to five, with one being the least severe, and five being the most severe, from a patient safety perspective. The probability of the issue occurring was assigned using a scale from one to five, with one being not likely, and five being very likely. The current design of each AED was then assessed from the likelihood of detecting the problem which was rated on a scale from one to five, with one being likely the design would catch the issue, and five being the design would not likely to catch the problem.

The risk priority numbers (RPN) were then computed. These are the mathematical product of the numerical severity, probability, and detection ratings. These RPN were used to identify the significant usability risks that require attention.

RESULTS

Heuristic evaluation

AED A had a total score of 43/50 for the features assessed. The main problems encountered were electrode pads that were not pre-connected to the device, the vague instructions provided

inside of the case, and the unintuitive device status indicator.

AED B had a total score of 38/50 for the features assessed. AED B had a simple two-zipper opening and a heart symbol on the case for ease of identification. Problems included the electrode pad packaging remaining attached to the cabling during use, unclear instructions provided with the device, and an audio cadence rhythm that was confused as an alarm during CPR.

AED C had a total score of 31/50 for the features assessed and was the most problematic device. The primary issues included:

- The handle and shoulder strap location obstructed the zipper
- The black case did not have any distinguishing symbols
- The double zipper made the case difficult to open
- The electrode pad package and electrode pads had poor instructions
- No in-case instruction were provided

User Testing

Assessments of the ease of use of the features were made directly from observing user interaction with the devices during the evaluation.

AED A had a score of 45/50 for the features assessed during usability testing. The primary negative issue was the electrode pads did not come pre-connected to the device.

AED B had a score of 43/50 for the features assessed during usability testing. Its case was simple to open and the voice prompts were loud and instructive. The fact that the packaging remained attached to the cabling confused users, and many spent time trying to remove the packaging completely. Additionally, users did not correctly interpret the cadence sound that was intended to coach the user through performing chest compressions.

AED C had a score of 35/50 for the features assessed during usability testing. It was easy to turn the device on as well as view the information on the embedded screen. However, opening the case was difficult because the handle and shoulder strap obstructed the zipper. The electrode pads and packaging were also an issue, as it was difficult to open the peel-open package and the instructions provided for pad placement were not clear.

FMEA

The FMEA was used to identify the particular features or functions of each AED that posed significant patient safety risks. Potential failure modes of each feature or function that had an RPN score of over 50 were considered to be significant patient safety issues that needed to be addressed before the AED was used in the hospital setting. The issues, potential failure modes, and RPN scores are displayed in Table 1.

Following the FMEA, there were no issues identified with AED A that require immediate attention. All of the RPN were below the threshold of 50.

For AED B, the location of the electrode pad package, and the cadence sound that occurs during CPR both exceeded the threshold of 50 for the RPN (60 and 80 respectively).

The primary issues of concern with AED C were the case (RPN 60), the lack of in-case instructions (RPN 60), the peel-open electrode pad package (RPN 80), and the instructions on the electrode pads (RPN 60).

The FMEA identified the AED case, location and type of electrode pad packages, and audio quality as important features in the design of in-hospital AEDs. It quantitatively assessed the issues according to the risk they presented to patient safety.

Table 1: Issues and potential failure modes evaluated in FMEA

Issue	Potential Failure Modes	RPN AED A	RPN AED B	RPN AED C
1. Retrieve AED	Case identification	15	30	60
	Handle	4	12	36
	Shoulder strap	1	2	36
2. Open the case	Zipper	2	12	48
3. Follow instruction panel	In-case instructions	24	36	60
4. Retrieve pads	Location of pad package	45	60	15
	Pad package	12	12	4
5. Open pad package	Pad package	20	20	80
6. Place pads on patient	Instructions on pad package	16	16	32
	Instructions on pads	12	24	60
7. Connect pads to device	Device features	8	4	4
	In-case instructions	2	6	10
	Instructions on pad package	8	2	2
	Instructions on pads	8	2	2
	Audio prompt quality	15	15	15
8. Turn on device	In-case instructions	3	3	15
	Buttons	10	10	10
9. Follow prompts	In-case instructions	2	2	10
	Screen prompt quality	2	2	2
	Screen readability	2	4	4
	Audio prompt quality	25	25	50
	Audibility	16	16	48
10. Shock the patient	Audio prompt quality	20	20	20
	Audibility	16	16	48
	Buttons	9	9	9
11. Perform CPR	Screen prompt quality	20	80	20
	Screen readability	3	6	3
	Audio prompt quality	16	64	16
	Audibility	12	12	12
	Size of pads	8	8	16

DISCUSSION

The human factors evaluations resulted in the following design recommendations for AEDs intended for in-hospital use:

- The electrode pad package should be prominently placed inside of the device case and should come pre-attached to the device. A tear-open electrode pad package design that completely detaches from the electrode pads is desirable.
- Instructions on the electrode pads should be large and easy to read. Diagrams that clearly indicate the location of pad placement on the chest are best.
- The instruction panel inside the case should be prominent and should match the orientation of the device when in use.
- The screen should be easily viewable under a variety of lighting conditions and only contain information that is pertinent to the user during rescue.
- Labeled and color-coded buttons are the easiest to follow when using an AED. A

display panel with step-by-step instructions is useful in an emergency situation.

- Ambient noise levels in hospitals range from 50 dBA to 70dBA in multi-patient rooms (AAMI, 2000). Therefore, the voice prompts of the AED should have the volume level greater than 70dBA.
- The device handle should accommodate a hand circumference of 23.4 cm to serve 90% of potential rescuers (NASA, 2006). The handle and shoulder strap should be designed to avoid injury to the rescuer, and should not obstruct the opening or use of the AED.
- The case color should be distinctive and display a proper AED symbol in order to aid device identification during an emergency situation. A brightly colored single zipper tab makes the opening of the case quick and easy.
- The AED status indicator should present information through meaningful words, numbers, symbols, or abbreviations in order to be easily recognized (AAMI, 2000).

This study took place in a simulated hospital environment and approximated the scenario of a cardiac arrest rescue. Interruptions of the rescuer and disruptions in the room may not have been exactly as they would have during an actual resuscitation event. Therefore it is possible that more usability issues would be uncovered with the devices during actual use due to the additional stress placed on rescuers.

CONCLUSIONS

The usability and analysis methods utilized in this study can be applied to evaluating other devices used in healthcare settings.

The results of this study indicate that small details of the device design can play a large role in their successful use, and overshadow a device's extensive functionality. It is necessary to consider all aspects of medical device design in a practical sense to ensure the optimal usability and ultimately the overall performance of the device.

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Full analysis of the heuristic analysis, user testing, and FMEA can be obtained from the authors.

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