When Every Minute Counts, All Automatic External Defibrillators Are Not Created Equal

Anthony D. Andre, Ph.D.

A recent study, published in the New England Journal of Medicine, documented the ability of innocent bystanders with no defibrillator training to use an automated external defibrillator (AED) in actual cardiac arrest incidents. In the present study, sixty-four adults with no prior exposure to, training with, or understanding of AEDs were asked to rush into a room, one at a time, and attempt to use an AED to resuscitate a victim of sudden cardiac arrest. Each of four different AEDs available in the United States was used by a different group of sixteen participants. From our results we conclude that the Philips HeartStart OnSite device is appropriate for use in public settings where laypersons and innocent bystanders are expected to use these devices in an unexpected emergency. With some reservation, we also conclude that the Medtronic CR+ AED is appropriate for this context; however, we do have a concern regarding the high number of instances where users inaccurately placed the Medtronic defibrillator pads, which could result in degraded shock effectiveness, and the propensity of the pad plug to become detached from the Medtronic device during use. Finally, we conclude that the Cardiac Science Power Heart and Zoll AED Plus devices are not suited for use by untrained laypersons in public settings. Simply stated, these devices do not provide a sufficient amount of guidance and specific instructions required in the context of public use. This study, the most comprehensive and quantitative comparative AED study to date, clearly demonstrates that all AEDs are not equally usable by untrained laypersons.

Introduction

Sudden cardiac arrest is a leading cause of death in the United States. The American Heart Association (AHA) estimates that about 250,000 people die of coronary heart disease before reaching the hospital each year.¹ Unlike many other life-threatening illnesses and conditions, sudden cardiac arrest often occurs outside of a medical setting. In such settings, the victim's only chance for survival rests with the arrival of an emergency medical service – often unavoidably delayed beyond the critical first few minutes – and the use of a defibrillator, a device that delivers a shock to the heart.

During sudden cardiac arrest the heart abruptly stops pumping, usually due to an electrical malfunction, and the victim collapses and quickly loses consciousness. Death quickly ensues unless a normal heart rhythm can be restored in a matter of a few minutes. Because effective treatment for sudden cardiac arrest – defibrillation of the heart – cannot routinely be delivered within three to five minutes of the victim's collapse, the estimated survival rate is less than five percent. During sudden cardiac arrest, every minute counts. In fact, for every minute that goes by without defibrillation, the chance of survival decreases by about 7% to 10%.²

Recently, there has been a surge of interest in the placement of automated external defibrillators (AEDs) in public environments. For example, in separate incidents, one in Georgia and one in California, during the month of April 2003, two young boys died from sudden cardiac arrest after being hit in the chest with a baseball. In both cases, CPR was applied to no avail, and the victims died within a few minutes. The victims' families, supported by community members, medical professionals, and politicians, called for implementation of AEDs at sporting events. These and other, similar tragic events have led to an increased proliferation of AEDs in public and corporate environments. For example, AEDs can now be found in airplanes, airports, schools, shopping malls, and various workplaces. In most of these environments, selected individuals (e.g., flight attendants) are trained to use the devices. However, it is clearly the case that in order to make a significant impact on the sudden cardiac arrest mortality rate, these devices must be accessible to, and usable by, untrained bystanders, often referred to as lay responders.

The Usability Factor

Of course, in order for these devices to be practical for broad public use, they must be designed in a way that allows untrained "ordinary" people to use them quickly, easily, and effectively in the context of an unexpected and dramatic emergency medical situation. This premise represents a significant challenge to AED manufacturers, many of whom have historically designed devices to be used by trained medical professionals (e.g., nurses, EMTs) and, more recently, by selected and trained lay individuals (e.g., flight attendants, lifeguards, airport personnel).

Given that success with untrained users is a critical goal for the broad public deployment of AEDs, it is important to determine if AEDs can be used effectively, and without undue difficulty and stress, by the average person. Previous studies suggest that this is possible with some AEDs. For example, the majority of patients who survived a sudden cardiac arrest in Chicago airports over a two-year period were saved by persons who had no duty to act and no prior training in the use of automated external defibrillators.³ Another study showed that untrained persons as young as sixth grad-



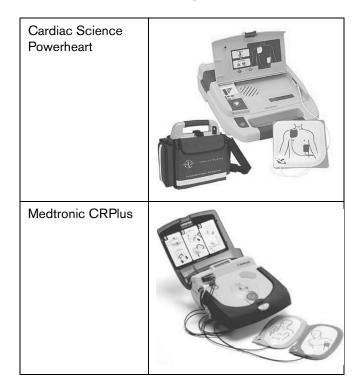
INTERFACE ANALYSIS ASSOCIATES 16275 S. MONTEREY STREET SUITE S MORGAN HILL, CA 95037 408.782.6006 ers can indeed successfully employ some AEDs.⁴ However, it is not known if all AEDs can equally support the successful use by untrained persons.

As usability professionals, we make a clear distinction between a product's functionality (what a product can do) and its usability (what users can do with the product). While all AEDs share a common set of functionality and, if used correctly, result in the delivery of a shock to the victim, the objective and subjective experiences of the users are likely to vary based on the presence or absence of critical usability design attributes. Usability evaluations typically involve a comprehensive set of measures that fall into four main categories: 1) *intent* (What are the users trying to do?), 2) *behavior* (How are they trying to do it?), 3) *performance* (Are they succeeding? How long does it take?), and 4) *impact* (Was it difficult or stressful? Was it safe?).

Given the growing media attention being paid to all AEDs as part of the same general class of product, it is critical to advise the public as to specific differences that might exist among AEDs in terms of their usability. It might well be the case, and it is true of most products, that only some AEDs are designed to be intuitive enough to be effectively used by untrained laypersons, while others are not. To date, there is little if any empirical information on usability differences between AEDs intended for public use.

A Comparative Study

To address this concern, Interface Analysis Associates, at the request of Philips Medical Systems, recently conducted an independent, comprehensive, and comparative study of four leading AEDs, all marketed for public use. The four devices included in the study were:



Philips HeartStart OnSite	
Zoll AED Plus	

The study was conducted in the context of a scenario where AEDs are available in a variety of public settings such as shopping malls, schools, parks, sporting events, government buildings, hotels, convention centers, large corporate offices, and other public environments.

Sixty-four adult participants, ages 35 to 55, and representing a variety of occupations, were asked to rush into a room and attempt to use an AED to resuscitate a victim of sudden cardiac arrest. None of the participants worked in medical or related fields, nor did they have any exposure to, prior training, or familiarity with AEDs. In this study they were provided only basic information about the main functions of an AED prior to their entering the room, where they found a fully clothed manikin (Resusci Anne, Laerdal Medical) on the floor and one of the four AEDs nearby. The manikin was wired with a simulator that allowed it to transmit signals to the electrode pads of each AED, which prompted the unit to advise a simulated shock to the manikin (under conditions similar to those that would produce a shock command in actual use).

Each of the four AEDs was used by a different group of sixteen participants. A comprehensive variety of quantitative, behavior, and subjective measures was collected and analyzed. Selected electrode pad placement measures were confirmed by an independent reviewer.*

What We Found

The results showed significant statistical differences among the four products across most measures. Below we present a brief summary and discussion of the main performance, behavior, and subjective measures.

Dr. Jeanne E. Poole, Associate Professor of Medicine, Acting Director of the Arrhythmia Service and Electrophysiology Laboratory, and Attending Physician, University of Washington Medical Center

Failure to Deliver Therapy

Clearly, the most important measure was the frequency with which untrained users could deliver a shock with the AED. Most noteworthy was the finding that 9 of the 16 Zoll users (56%) and 4 of the 16 Cardiac Science users (25%) failed to administer a shock to the simulated victim. In contrast, the Philips and Medtronic users were successful in delivering a shock in all completed trials. (See Figure 1.)



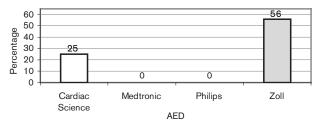


Figure 1. Percentage of failures to deliver a shock.

Perhaps even more disturbing was the user behaviors that resulted in these failures to deliver therapy. For example, two of the Zoll users and three of the Cardiac Science users never managed to open the electrode pad package. (See Figure 2.)



Figure 2. Electrode pads never removed from packaging during use of Zoll (left) and Cardiac Science (right) AEDs.

Another two Zoll users and four Cardiac Science users failed to remove the backings from one or both electrode pads. (See Figure 3.) Interestingly, three of the four Cardiac Science users who failed to remove one or both electrode pads from the backing still received a shock command. This occurred because the Cardiac Science pads have small holes in the back of the pad that allow a small fraction of the pad to contact the skin even with the backing left on. However, with the backing liner in place, the contact made by these pads clearly does not meet the minimum industry standard⁵ and would likely result in an ineffective shock.



Figure 3. Electrode pad backing not removed during use of Zoll (left) and Cardiac Science (right) AEDs.

Finally, another group of five Zoll users placed the electrode pads directly over the victim's clothes. (See Figure 4.)



Figure 4. Electrode pads placed over jacket (left) and shirt (right) with Zoll AED.

Time to Deliver Therapy

Managing to get the device to deliver a shock is a necessary but not sufficient goal, as the victim must be shocked within a short period of time from the point of collapse (usually three to five minutes maximum). Early defibrillation, in which an electric shock is quickly and safely delivered to the heart, is the most important predictor of survival among people who suffer sudden cardiac arrest.

In our study, the Medtronic and Philips devices were statistically equivalent in the time it took their users to deliver a shock, both averaging well under two minutes at 101.0 and 101.5 seconds, respectively. The other two devices were substantially slower, with the Cardiac Science AED averaging 151.6 seconds, just over 2.5 minutes, and the Zoll AED averaging 225.1 seconds, just under 4 minutes. (See Figure 5.)

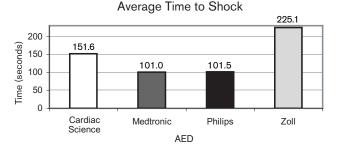


Figure 5. Average time to administer shock.

It is not surprising that the Zoll device resulted in the longest time to shock because it is the only unit that has to be manually turned on; the other three devices automatically turn on when their covers are opened. In fact, the average time taken by participants just to turn on the Zoll device was nearly equal to the average time taken by participants to administer a shock with the Medtronic and Philips devices. In other words, on average, by the time (or just shortly after) the AED had been turned on in the Zoll trials, the user had already delivered a shock in the Medtronic and Philips trials.

In all trials, there were no clinically significant instances of participants contacting the manikin during shock delivery.

Electrode Pad Placement

Pad placement has been well documented as the Achilles heel for lay responders and those with advanced training alike.^{6,7} Incorrect pad placement results in a reduced percentage of the current passing through the heart, thus reducing the chance of successful defibrillation.⁸ Failing to place pads on the skin or failing to remove backings from pads also results in an ineffective shock.⁹

As noted earlier, several Zoll and Cardiac Science users demonstrated difficulty in manipulating the electrode pads, either failing to remove them altogether from the package, failing to remove one or more backings, or placing the electrode pads over clothing.

For those users who managed to remove the electrodes from their package and place them on the victim's bare chest, the quality of the resultant shock was evaluated as a function of the following parameters: 1) percentage of pad contact with the skin, 2) the placement of the pads relative to the instructed position, 3) the distance between the pads, and 4) the relative alignment of the two pads. Table 1 shows how each AED fared across these measures.

AED Device	Cardiac Science	Medtronic CR+	Philips Heart- Start OnSite	Zoll AED Plus
% Skin Contact	84%	94%	97%	76%
Rank	3	2	1	4
pad location error (average cm)	7.0	10.4	5.4	4.9
Rank	3	4	2	1
separation of pads (average cm)	10.4	9.0	14.7	13.9
Rank	3	4	1	2
% pads placed adjacent	0%	56%	6%	11%
Rank	1	4	2	3

Table 1. Pad Placement Measures

Skin Contact. Good skin contact is important in order to assure that the maximum surface area of the pad delivers electrical current. The Philips device resulted in the highest percentage of skin contact for both electrode pads, closely followed by the Medtronic and Cardiac Science devices, while the Zoll device resulted in the lowest percentage of skin contact.

Pad Location. Ideal pad location was determined by several independent observers based on the centerpoint of each manufacturer's recommended location, as depicted on the pad icon. The closer a pad is to the ideal location, the smaller the pad location error. For both the left and right pads, the Zoll and Philips devices facilitated more accurate pad placement than the Cardiac Science device, while all three devices considerably outperformed the Medtronic device.

Pad Separation. The closest distance between the two pads is another important dimension of pad placement, as pads placed too close to each other can cause shunting and/or reduce the efficacy of the defibrillation. Thus, a larger distance between pads is better. In our study, the Philips and Zoll devices showed the largest distances between electrode pads, followed by the Cardiac Science device and lastly the Medtronic device.

Relative Pad Alignment. A related measure to pad separation – the proportion of pads placed adjacent to one another (as opposed to placed on separate sides of the chest) – also shows a performance difference among the devices. Here we define adjacency as pads that are placed side-byside, and/or on the same side of chest, and/or at the same vertical level, and/or touching each other. Any of these arrangements is likely to result in shunting between the pads, and a less effective shock. Our results showed that the Medtronic device produced an inordinate number of these arrangements, with over 50% of the users placing the pads adjacent to each other. (See Figure 6.)

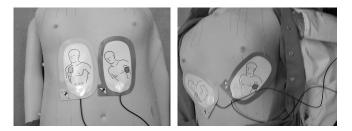


Figure 6. Electrode pads touching (left) and placed adjacent to each other (left and right) during use of Medtronic device.

Electrode Pad Plug Detachment

An astonishing 31% of the Medtronic users inadvertently pulled the pad connector plug out of its socket while attempting to open the pad package, causing them to spend precious time hunting for the place to put the plug back in. We attribute this frequent problem to both the design of the pad package (which encourages users to grasp a red handle and pull the entire package away from the device) and the ineffectiveness of the design of the cable strain relief. (See Figure 7.)

Use of Zoll Cover

Zoll users are instructed, via graphics, to use the device cover to help prop up the victim and open their airway. Of the sixteen participants, only two attempted to use the cover as described; one correctly and one incorrectly. (See Figure 8.)





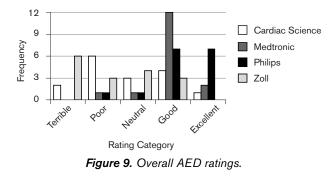
Figure 7. Electrode pad plug (circled) easily becomes detached during use of the Medtronic device.

Figure 8. Zoll device cover used incorrectly; obstructing, rather than opening the victim's airway.

Subjective Data

The Philips and Medtronic devices were consistently rated as easier to use, across a variety of dimensions, relative to the Cardiac Science and Zoll devices.

When asked to provide an overall rating of their experience with the device, more users rated the Philips device as "Excellent," the highest rating, and more users rated the Zoll device as "Terrible," the lowest rating. (See Figure 9.)



Our Conclusions

In this study, across nearly all measures of performance, behavior and subjective experience, the Philips AED showed superior performance over the three other devices. The Philips users typically showed significantly better compliance with instructions, more accurate pad placement, and higher subjective ratings relative to the users of the other AEDs. For example, none of the Philips users failed to place pads on the manikin and none of the Philips HeartStart OnSite connectors came out of the device, primarily because this device is designed so that the connector is inaccessible to the user, hidden inside the device. The Philips and Medtronic devices were roughly equivalent in terms of timing measures, such as time from entry into room until administration of shock.

Two design elements that were observed to have helped Philips users to achieve better pad placement performance are the voice instructions ("Look carefully at the pictures on the white adhesive pads... Place pads exactly as shown in the picture,") and the fact that both pads are shown on each pad icon, giving users a good sense of the relative placement of the two pads. (See Figure 10.) These two features often resulted in the users briefly pausing and explicitly reviewing the pad placement graphic.



Figure 10. Philips HeartStart OnSite AED depicts the relative placement of both pads on each pad graphic.

In addition, and perhaps most important, the Philips device includes sensor technology that detects the current action of the user and adjusts the instructions to match that action. Indeed, we observed many instances where the Philips users were aided by the intelligent pacing of the device's audio instructions. In contrast, we observed many instances with the other devices where the audio instruction and the user's current action were incongruent.

Recommendations for Public Deployment of AEDs

Defibrillators that are to be used by lay responders should be designed from a human-centered perspective. That is, they should provide useful and timely guidance, include effective and salient graphics, and induce acceptable levels of workload and stress. This study demonstrates that all automated external defibrillators are not alike; while all are potentially *useful*, only some are *usable*.

We conclude that the Philips HeartStart OnSite device is appropriate for use in public settings where laypersons and innocent bystanders with no prior exposure to, training with, or understanding of AEDs are expected to use the devices in an unexpected emergency. With some reservation, we conclude that the Medtronic CR+ AED is also appropriate for this context; however, we do have a concern with the lack of accuracy in the placement of Medtronic defibrillator pads (which could result in degraded shock effectiveness) and the propensity of the pad plug to become detached from the Medtronic device during use.

Finally, we conclude that the Cardiac Science Power Heart and Zoll AED Plus devices studied here are not suited for use by untrained laypersons in public settings. Simply stated, these devices do not provide a sufficient amount of guidance and specific instructions required of layperson users in the public-use context simulated during this study.

Anthony D. Andre, Ph.D. Founding Principal, Interface Analysis Associates June 2003

About Interface Analysis Associates

Interface Analysis Associates (IAA) is a successful human factors, ergonomics, and usability consulting firm, located in the Bay Area, CA. IAA provides workplace ergonomics, user interface design, usability evaluation, and usability testing services across a wide variety of product domains, with a focus on transportation, medical, software, input device and high-tech product domains. Since 1993, some of the largest and wellknown corporations and government agencies, such as Microsoft, Honeywell, Abbott Labs, Hewlett Packard, Kodak, Siemens, Logitech and NASA, have relied on IAA to conduct objective, independent and unbiased empirical evaluations of their products or services. Their unique usability testing facility, located in San Jose, CA, has been used to evaluate dozens of products using actual consumers.

Dr. Anthony D. Andre, IAA's founding principal and the lead investigator in this study, is the author of over

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100 publications on human factors and usability research and is an adjunct professor of Human Factors and Ergonomics at San Jose State University. There he teaches courses on cognitive engineering, professional ergonomics, research methods and usability testing.

Dr. Andre is a member of the Human Factors and Ergonomics Society (HFES), the Usability Professionals Association (UPA) and the Bay Area Chapter of the Association for Computer Machinery Special Interest Group on Computer-Human Interaction (BAYCHI).

For more information, please contact:

Dr. Anthony D. Andre Interface Analysis Associates 16275 Monterey St, Suite S Morgan Hill, CA 95037 Email: andre@interface-analysis.com Tel: (408) 782.6006

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A copy of this study is being made available by Philips Medical Systems. Defibrillator manufacturers recommend that defibrillator users receive appropriate training.