Clinical Summary

AED Comparison Usability Study

Background:

It is critical an Automated External Defibrillator (AED) is well-designed so lay users can use it safely and effectively to achieve the desired clinical outcome. While many brands of AEDs are currently available on the market, the level of usability varies significantly among defibrillators. This is especially evident in a study that compares lay user performances using four different models of AEDs, where the success rate of delivering a shock ranged from 44% to 100%, and the time from test users room entry to shock delivered ranged from 93 to 210 seconds.[1]

Defibrillation within 3–5 minutes of collapse can produce survival rates as high as 50–70%.[2] Thus, the performance differences observed in the study could have led to significantly different patient outcomes in the real world.

To obtain the best patient outcomes, defibrillation needs to be combined with CPR. According to the Public Access Defibrillation (PAD) Trial, survival rates doubled when bystanders provide CPR and use an AED to deliver a shock.[3] Accordingly, many AEDs now provide instructions on how to perform CPR, and CPR quality has become an important criteria used to evaluate the effectiveness of an AED.

The LIFEPAK® CR2 Defibrillator manufactured by Physio-Control (Redmond, WA) is an AED designed for lay operator use in workplace and community settings. It incorporates a number of features such as emergency response guidance, CPR coaching and detection technology, ECG analysis during CPR and variable sound tones and voice prompts to facilitate device use and patient resuscitation.

Purpose

This study aimed to gather objective data regarding device usability and CPR performance on the following four AED models:

- Physio-Control LIFEPAK® CR2 Defibrillator
- Physio-Control LIFEPAK CR® Plus AED
- Philips HeartStart OnSite AED
- ZOLL® AED Plus®

Methods

Device usability was evaluated through simulated use testing, in which a lay operator used an AED to help a patient (manikin) in sudden cardiac arrest.

Data was collected from June 8 through July 31, 2015 (for Physio-Control LIFEPAK CR Plus AED, Philips HeartStart OnSite AED, and ZOLL AED Plus), and on July 6, 2016 for (Physio-Control LIFEPAK CR2 Defibrillator). Evaluation was performed by human factor engineers with assistance from clinical specialists and a human factor consultant.

Sixty-one lay users (participants), recruited through Physio-Control's own outreach effort (in 2015) and through a third-party recruiting agency (in 2016), participated in the current study. Overall, participant demographics, including gender, age, education, and CPR training, were comparable amongst the four different device groups. The only exception was that fewer participants who tested the ZOLL AED Plus had previous AED training (33% vs. 70% for the other three devices). Because of this, the ZOLL AED Plus test results were further examined according to participants' previous AED training. The test devices were randomly assigned (ZOLL AED Plus, Philips HeartStart OnSite AED, Physio-Control LIFEPAK CR Plus AED). The *CR2* testing was conducted in one day.

The test scenario lasted a total of 5 minutes and included:

- Connecting AED to manikin (time to achieve varied with each participant).
- Delivering a shock
- Performing 2 minutes CPR
- Delivering second shock
- Performing 2 minutes CPR
- Delivering third shock
- Performing CPR until end of scenario (time for this segment varied due to time used to connect AED).

Equipment

All devices were set to a single language (English) setting and were of a semi-automatic type. The devices were slightly modified to allow for connection to a patient simulator for sensing electrode pad placement on the manikin and for shock delivery. This modification included the attachment of a six-foot (182.88cm) cable to the back of each device while other aspects of the user interface remained intact.

A Laerdal Resusci Anne® with QCPR manikin, with a shirt and jacket on its upper body, was used to simulate an adult male patient. During testing, the manikin was connected to a SimPad® SkillReporter™, a hand-held device which collected CPR performance data including compression depth, rate and compression fraction (the amount of time CPR was performed over the test case time, i.e., 5 minutes). The manikin and the SimPad SkillReporter were measured prior to the start of data collection (first in 2015 and again in 2016) so the measuring errors between the actual chest compression depths on the manikin and the SimPad SkillReporter readout were recorded and later used to adjust the CPR depth measurement in the raw SimPad SkillReporter data files. The CPR depth data reported here are adjusted depths.

The LIFEPAK CR2 AED is not available for sale in the U.S.

Procedure

Participants were tested individually following the same procedure:

- Test moderator first described the test scenario to the participant outside of the testing room.
- Participant entered the testing room and performed the task while test moderator and test assistant in the same room observed and took note of any issues.
- After participant completed the task, test moderator conducted post-test interview to obtain participant's subjective responses as well as answers to open-ended questions.

During each test session, test moderator used a moderator's guide to ensure interactions with all participants were consistent and the same information was obtained from each participant. In addition, each test session was video recorded and photographed for review for more granular data analysis.

Data Analysis

Data analysis was conducted immediately after data collection on each brand was complete, and focused on the following:

- AED use time profile—One individual, the Senior Human Factors Engineer who moderated all test sessions, reviewed video recordings of all study sessions to obtain time stamps for turning on device, placement of both pads on patient, delivery of first shock and start of CPR for each participant.
- A Principal Clinical Specialist reviewed photographs of the placement of electrode pads on the manikin by each participant to determined whether or not the placement would lead to clinically effective shocks.
- The same Senior Human Factors Engineer analyzed CPR performance data based on SimPad SkillReporter data files with adjustment for measuring errors.

Task Success Rate

The overall criteria for task success was that the participant was able to deliver the first shock deemed clinically effective. The table below summarizes the number of participants who succeeded with each device:

	# Participants	# Who Delivered First Shock before CPR	# Who Delivered First Shock during 5-min CPR	# Who Never Delivered Shock
LIFEPAK CR2 Defibrillator	15	15 (100%)	0	0
LIFEPAK CR Plus AED	16	16 (100%)	0	0
Philips Onsite AED	15	15 (100%)	0	0
ZOLL AED Plus	15	7 (47%)	5 (33%)	3 (20%)
	AED trained: 5 Not AED trained: 10	3 (60%) 4 (40%)	2 (40%) 3 (30%)	0 3 (30%)

While all participants using the LIFEPAK CR Plus AED, Philips HeartStart OnSite AED and the LIFEPAK CR2 Defibrillator were able to deliver a clinically effective shock before starting CPR, only 7 of 15 participants (47%) using the ZOLL AED Plus device were able to do so.

Time Measures

The table above right shows the median times taken by participants to turn on the device, place pads on the manikin, deliver the first shock and start CPR. For the ZOLL AED Plus, time to open the device lid (after turning on the device) also is provided. The timer started when a participant entered into the camera view ready to reach for the device. Measurement errors are within 1-2 seconds.

	# Participants	Turn On Device (Seconds)	Open Lid (Seconds)	Place Pads (Seconds)	Deliver Shock (Seconds)	Start CPR (Seconds)
LIFEPAK CR2 Defibrillator	15	10.4	N/A	55.3	77.7	86.8
LIFEPAK CR Plus AED Note: Pressing ON button opens lid and starts device	14a	7.1	N/A	67.8	93.2	102.5
Philips OnSite AED	12a	10.1	N/A	79.1	102.1	131.6
ZOLL AED Plus	7b 5c	6.1 5.1	15.2 41.6	84.3 224.2	112.7 271.8	118.1 127.0d

a Participant attrition in the *CR Plus* and OnSite AED groups was due to 5 participants who started by performing CPR first (following their CPR training); therefore, their data were excluded from this analysis.

b Participants who delivered the first shock before CPR.

c These five users were not able to place electrodes on manikin before starting CPR (after being prompted by the device). After 2 minutes of CPR, device voice prompts instructed user to attach electrodes to manikin. These users eventually applied electrodes to manikin and delivered the first shock. Afterwards they resumed CPR following device voice prompts.

d For these five participants, the median time to start CPR (without delivering the first shock) was 127.0 seconds, and the median time to resume CPR after the first shock was 276.7 seconds.

CPR Performance

Key CPR performance data includes compression depth, rate and compression fraction. Current ERC/AHA Guidelines recommend a compression rate of 100-120min beats per minute and depth 5-6cm (2.36 inches).[4,5] Participants' CPR performances are summarized below, with numbers representing the medians of each performance variable for each device (numbers in parentheses are ranges on a variable):

	# Participants	Compression Depth (mm)	Compression Rate (beats/minute)	Compression Fraction (%)
LIFEPAK CR2 Defibrillator	15	51.0	103 (85 – 106)	89 (87 – 92)
LIFEPAK CR Plus AED	14[a]	45.5	112 (65 – 144)	52 (34 – 67)
Philips OnSite AED	15	43.0	99 (94 – 149)	82 (26 – 85)
ZOLL AED Plus	15	59.0	101 (50 – 150)	74 (11 – 85)

e Due to a technical malfunction, CPR data were not collected for two participants in the LIFEPAK CR Plus AED group.

Subjective Responses

Participants provided ratings on a 7-point scale with regard to device ease of use, ease of hearing device voice prompts and their own confidence level respectively, with 1 being the most negative response and 7 the most positive. The following table shows participants' average ratings after device use (numbers in parentheses represent the range). Note averages rather than medians are presented because individual ratings congregated in a small number of rating categories, so the average is more sensitive and accurate than the median.

	# participants	Device Ease of Use	Ease of Hearing Voice Prompts	Confidence Level
LIFEPAK CR2 Defibrillator	15	6.7 (6 – 7)	6.7 (4 – 7)	5.5 (3 – 7)
LIFEPAK CR Plus AED	16	6.1 (4 – 7)	6.6 (5 – 7)	4.8 (3 – 6)
Philips OnSite AED	15	5.9 (4 – 7)	6.5 (5 – 7)	5.2 (3 – 7)
ZOLL AED Plus	15	3.5 (1 – 6)	6.2 (5 – 7)	4.0 (1 – 6)

Discussion

The current study aimed to gather objective data regarding AED device usability and CPR performance. Simulated use testing showed lay operators' use of an AED is directly impacted by device usability. On several key performance measures, participants using the LIFEPAK CR2 Defibrillator outperformed those using both competitive AED models currently available on the market.

Specifically, all participants using the LIFEPAK CR2 Defibrillator, LIFEPAK CR Plus AED and Philips OnSite AED successfully delivered the first shock even though 10 out of 46 participants did not have AED training. In comparison, only 47% of the participants using the ZOLL AED Plus were able to deliver a shock before CPR, and 3 of the 10 participants who did not have AED training never delivered a shock even after 5 minutes of CPR (during which the device paused CPR voice prompts to direct user to attach electrodes to patient). This suggests the first three AEDs are sufficiently intuitive and easy to use by lay users untrained on an AED, whereas for ZOLL AED Plus, previous AED training appears to be a prerequisite.

In sudden cardiac arrest resuscitation, time-to-shock is one of the most critical variables which determines the clinical outcome of defibrillation. Among the four devices tested in the current study, participants using the LIFEPAK CR2 Defibrillator delivered the first shock within 78 seconds after the test started, an advantage of 24 seconds over Philips OnSite AED and 35 seconds over ZOLL AED Plus (note only 47% of the ZOLL AED Plus participants were able to achieve this level of performance). A closer look at the time profile shows LIFEPAK CR2 Defibrillator's advantage was gained through reducing time spent placing electrodes on the patient and remained through the start of CPR (the advantage increased to 45 seconds when compared to Philips OnSite AED). The differences in times are the direct result of design features implemented in the devices.

With regard to CPR performance, participants using the LIFEPAK CR2 Defibrillator and ZOLL AED Plus reached median compression depth of at least 51mm (2 inches). Even though all four device groups had median compression rates within the 100 – 120 beats/minute range recommended by the 2015 AHA/ERC Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care, the *CR2* Defibrillator resulted in more consistent compression rates across participants than the other devices. This is likely due to the combination of the metronome and CPR coaching prompts. In addition, the LIFEPAK CR2 Defibrillator group also had the highest compression fraction (89%), with all 15 participants performing remarkably consistent on this measurement (ranging from 87% to 92%), whereas for other devices individual differences using the same device were as high as 74% for the ZOLL AED Plus.

Corresponding to objective behavioral data, participants' subjective responses were also clearly impacted by device usability. Specifically, participants using the LIFEPAK CR2 Defibrillator gave it the highest score on device ease of use (averaged 6.7 on a 7-point scale), and felt the most confident during patient resuscitation (5.5 on a 7-point scale). In comparison, participants who used the ZOLL AED Plus rated it negatively on the ease of use scale (3.5 on the 7-point scale) and reported the lowest confidence level (4.0 on the 7-point scale) amongst all the device groups.

Because simulated use testing of the four models was conducted at different times by two sets of personnel in different locations, it is important to examine if any of the extraneous variables contributed to the different outcomes reported above. To that end, were compared the LIFEPAK CR2 Defibrillator results from the current study with the outcome of another LIFEPAK CR2 Defibrillator simulated use test conducted in April-May 2016. The earlier study was conducted in the same setting where the LIFEPAK CR Plus AED, Philips OnSite AED and ZOLL AED Plus were tested, by the same personnel (a Senior Human Factors Engineer and a Clinical Marketing Specialist), and with 17 lay user participants who met the same criteria. Data analysis was conducted by the same Senior Human Factors Engineer who conducted data analysis for the current study. The LIFEPAK CR2 Defibrillator tested in the earlier study resembled the LIFEPAK CR2 Defibrillator used in the current study, with identical device hardware and CPR coaching voice prompts. The results showed the device use time profile in the earlier study was similar to the LIFEPAK CR2 Defibrillator results from the current study. In particular, the times to turn on the device in the two studies (which was not impacted by voice prompts but a measure of how comparable the two studies are) were very similar (see data in below table). Therefore, we conclude that there is no evidence performance differences in the current study between the LIFEPAK CR2 Defibrillator and the other devices were caused by differences in study settings, administration staff, or schedules.[6]

	# Participants	Time to Turn on Device	
		Median	Mean
LIFEPAK CR2 Defibrillator in current study	15	10.4 seconds	9.9 seconds
LIFEPAK CR2 Defibrillator in earlier study	17	7.9 seconds	10.4 seconds

Conclusions

The current study compared Physio-Control's LIFEPAK CR2 Defibrillator with LIFEPAK CR Plus AED, Philips HeartStart OnSite AED and ZOLL AED Plus through a simulated use test by lay operators trained in CPR but not necessarily in AED use. The results showed participants using the LIFEPAK CR2 Defibrillator had the first time-to-shock and the fastest time to start CPR by large margins. CPR performance of participants using the CR2 Defibrillator met the AHA/ERC guidelines, with a median depth of 51mm (2 inches) and at a median rate of 103 compressions per minute over 5 minutes. In addition, these participants had the highest overall compression fraction (hands-on time) during CPR and performed in a remarkably consistent fashion.

Participants rated the LIFEPAK CR2 Defibrillator the easiest to use among all of the devices and reported a high level of confidence while using the device. The performance advantages and positive user experience offered by the LIFEPAK CR2 Defibrillator are the results of advanced device features and careful user interface design.

1 Andre A., Jorgenson D., Froman J., Snyder D., Poole, J. (2004). Automated external defibrillator use by untrained bystanders: can the public-use model work? *Prehospital Emergency Care*, 8(3), 284-291.

2 Perkins G, Handley A, Koster R, et al. European Resuscitation Council Guidelines for Resuscitation 2015. Section 2. Adult basic life support and automated external defibrillation. *Resuscitation*. 2015;95:83.

3 The Public Access Defibrillation Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *NEJM*. 2004;351:637-646.

4 Perkins GD, Handley AJ, Koster RW, et al. Section 2. Adult basic life support and automated external defibrillator. European Resuscitation Council Guidelines for Resuscitation 2015. *Resuscitation*. 2015;95:87.

5 Kleinman ME, Brennan EE, Goldberger ZD, et al. Part 5: Adult basic life support and cardiopulmonary resuscitation quality. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Care. *Circulation*. 2015;132(18 suppl 2):S419.

6 The LIFEPAK CR2 Defibrillator CPR coaching voice prompts remained the same over the course of the two studies. In the earlier study, participants' CPR compression depth was also similar to the results of the current study, with a median of 53.0mm and a mean of 51.7mm. The median and mean of compression depth in the current study were 51.0mm and 52.0mm respectively.

All claims valid as of June 2017.

Physio-Control is now part of Stryker.

For further information please contact your local Physio-Control representative or visit our website at www.physio-control.com

Physio-Control Headquarters
11811 Willows Road NE
Redmond, WA 98052
www.physio-control.com

Customer Support
P. O. Box 97006
Redmond, WA 98073
Toll free 800 442 1142
Fax 800 426 8049

Physio-Control Canada
Physio-Control Canada Sales, Ltd.
45 Innovation Drive
Hamilton, ON
L9H 7L8
Canada
Toll free 800 895 5896
Fax 866 430 6115

GDR 3333472_A