Philips Medical Systems

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AEDs that Shock By Themselves

Philips' Position on Current AEDs that Automate Shock Delivery

There are two types of Automated External Defibrillators (AEDs) on the market today. Most, including those from Philips, only deliver shocks if the user presses a shock button when instructed by the device and after the user has confirmed that everyone is safely clear of the patient. Then there are those models that deliver shocks *of their own volition,* without responder control. The manufacturers of these devices portray machine-controlled shock delivery as a contributor to ease of use, and as a way to mitigate the risk of a responder "freezing" and not delivering a shock due to fear or confusion. Conceptually, a well-implemented automated shock delivery is intriguing. However, Philips is concerned that the current implementations on the market risk responder confusion, injury, and may compromise patient care.

Maximum *overall* ease of use is a vital criterion for choosing an AED. Others are *safety* for the responder, patient, and bystander, and *effectiveness* of the therapy provided to the patient. Below is a discussion of each of these attributes, as they apply to Philips devices and those that shock by themselves.

Ease of Use: Philips is Unsurpassed

When evaluating a defibrillator for ease of use, the informed decision maker assesses *overall* ease of use *throughout the rescue*, and does not focus all their attention on a single feature that impacts one already-easy step in the rescue. It is particularly important that the AED help the responder through the more complex aspects of a rescue, such as applying the pads correctly and performing CPR. Good AED design anticipates areas where a responder may stray off track and provides ways to sidestep them or to gracefully bring the responder back on course with minimum stress and disruption.

Philips AEDs are designed to be easy to use by minimally trained, inexperienced responders, according to a number of published, peer-reviewed studies.[1,2,3,4,5] The HeartStart HS1 in particular has been compared to other manufacturers in several ease of use studies, and has demonstrated consistently unsurpassed performance.

Over the course of 3 such studies, 53 out of 53 test-subjects were successful in pressing the HeartStart shock button to deliver a shock when instructed by the device.[1,2,3] In use on real patients, there are no reported cases in which a Philips AED user "froze", unable to press the shock button when instructed to by the device because of fear or lack of understanding of instructions. The ability to press a flashing shock button when instructed has simply not been an issue.

When these studies assessed responder performance of the more complex rescue steps, the HS1 led in successfully encouraging responders to perform CPR,[1] and in helping users apply the pads to the patient correctly.[2,3] It also led in favorable subjective user evaluations.[3]

The HS1 and FRx offer detailed CPR coaching. And the FRx is the only AED with an Infant/Child key, designed to simplify the particularly stressful task of rescuing a young child in cardiac arrest. In the United States, Philips

devices are the only ones that can be purchased over-the-counter, without a prescription. Philips designs AEDs to be easy to use in rescues that progress smoothly, as well as those at risk of going off track.

On the other hand, Philips considers the implementation of current AED models that deliver shocks of their own accord to be sub-optimal from the perspective of *overall* ease of use. They lack features like CPR coaching. Also, the act of aborting an ill-advised shock may disrupt the flow of the rescue, and could lead to responder confusion or panic. One such model does not instruct on how to abort a shock at all.[6] Another advises pads connector removal or powering down the device.[7] Both courses of action risk leaving the responder at a loss as to what to do next. Powering off the device leaves the responder without the reassuring AED "voice" to guide the rescuer on next steps, potentially wasting valuable time or causing an inexperienced responder to panic at being "abandoned". But why would a responder *want* to abort a shock? For safety reasons.

Is it Safe for a Machine to Take Control of Shock Delivery?

When delivering high voltage therapy to a patient in a stressful, chaotic setting, it is important that the scene be safe, and that all responders and bystanders not be touching the patient. Responders are trained to double-check that no one is touching the patient before delivering a shock. The current implementation of AED models that deliver shocks on their own violate this fundamental safety principle in that they are incapable of checking that no one is touching the patient. If these AEDs decide a heart rhythm should be shocked, they *will* unleash their shock "ready or not", risking injury to a responder or bystander. A review of publicly available incident records shows that this has happened, even with professional responders. A responder, in their zeal to prevent a poorly timed and unsafe shock, may react by quickly pulling the pads off the patient, risking responder injury if the shock goes off at that particular instant.

One device is known to decide to shock some patients who should *not* be shocked. Cardiac Science reports results of a study of its patient analysis system showing 93.9% positive predictivity.[9] Simply put, 93.9% of its decisions to shock a patient are correct decisions. That means about 6% of its decisions to shock patients are wrong, and may result in shocks that are not warranted. Since the Cardiac Science G3 Powerheart Automatic controls if and when a shock is delivered, and does not instruct a responder on how to abort the shock, a responder unable to control that moment may watch as the AED shocks a patient who should not be shocked, and may even be awake and aware.

Effectiveness: Current Devices that Take Control of Shock Delivery Do So at a Cost to the Patient

Current science shows that CPR is particularly crucial to survival.[10,11] But once the responder stops CPR, the benefits fade with each passing second. Fast shock delivery after CPR is critical to shock success.[10,12,13] Reducing the time it takes to deliver a shock after CPR by even a few seconds can make a big difference in survival. In an animal study, survival dropped approximately 3% for every second of shock delay after CPR.[12] That's why Philips AEDs feature Quick Shock, the delivery of a shock in under 10 seconds (typical) after completion of CPR. No other manufacturer has it. For the HeartStart HS1 and FRx, a shock can be delivered in just 8 seconds (typical) after CPR. In contrast, the Cardiac Science G3 Automatic delivers a shock 23 seconds after CPR.[8] The Medtronic CR+ Auto delivers a shock almost 27 seconds after CPR.[8] The current implementation of devices that automatically deliver shocks take a long time to do it, squandering the benefits of CPR and potentially compromising patient survival.

Putting it all together

It is critical that any implementation of shock delivery automation not compromise ease of use throughout the rescue, safety, and effectiveness. When you combine Philips' demonstrated overall ease of use, a protocol that allows the responder to be in control of *safely* delivering a shock, and the therapeutic benefits of rapid delivery of a shock after CPR, Philips believes its approach results in a smoother, safer, more effective rescue, potentially reducing risk, compared to the current implementation of devices that shock on their own. The table below summarizes the above discussion.

		Advantage	
		Philips	**Current AEDs that shock on their own**
Ease of use	Simplify one action (shock delivery)		**X**
	Overall ease of use	**X**	
	Easy for a responder to control if and when a shock is delivered	**X**	
Safety during rescue & risk to organization	Avoid shocking a responder	**X**	
	Avoid shocking a bystander	**X**	
	Avoid shocking patient when considered inappropriate	**X**	
Therapy effectiveness	Patient receives CPR	**X**	
	Patient with shockable rhythm actually receives the shock	**X**	**X**
	Minimal time-to-shock after CPR for potentially better survival	**X**	

[1] Fleischhackl et al. Differing Operational Outcomes with Six Commercially Available Automated External. Circualtion 62 (2004) 167-174.
[2] Eames et al. Comparison of Ease of Use of Three Automated External Defibrillators by Untrained Lay People. Resuscitation 58 (2003) 25-30.
[3] Andre et al. Automated External Defibrillator Use by Untrained Bystanders: Can the Public Access Model Work? Prehospital Emergency Care. 8 (2004) 284-291
[4] Snyder. Time to Shock vs Voice Prompt Duration: Optimization of Defibrillators for Public Access and Home Deployment. 6th Scientific Congress of the European Resuscitation Council. October 2002.
[5] Gundry et al. Comparison of Naive Sixth-Grade Children With Trainer Professionals in the Use of an Automated External Defibrillator. Circulation. 1999; 100:1703-1707
[6] Cardiac Science G3 Powerheart Automatic Operation and Service Manual. PN 112-2025-005.
[7] Medtronic CR Plus Automatic Operating Instructions. PN 3201686-022.
[8] Timing information available from Philips upon request.
[9] Cardiac Science Powerheart Operation and Service Manual. PN 30282-003
[10] 2005 American Heart Association Guidelines for Cardiopulmonady Reuscitation and Emergency Cardiovascular Care. Circulation. Volume 112, Number 24 (2005).
[11] European Resuscitation Council Guidelines for Resuscitation 2005. Resuscitation Volume 67 Supplement 1 (2005).
[12] Yu et al. Adverse Outcomes of Interrupted Precordial Compressions during Automated Defibrillation. Circulation (2002); 106:368-372
[13] Eftestol et al. Effects of Interrupting Precordial Compressions on the Calculated Probability of Defibrillation Success during Out-of-Hospital Cardiac Arrest. Circulation. 2002; 105:2270-2273.