PHILIPS

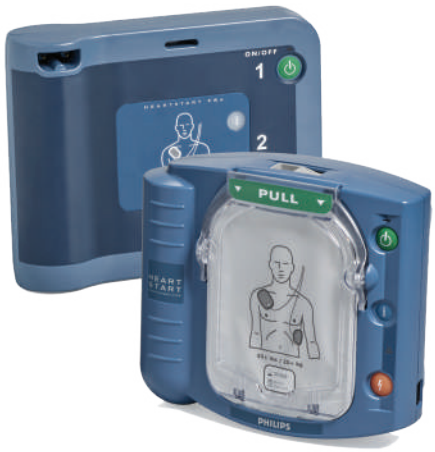
HeartStart AEDs

Why Philips AEDs?

Because the therapy is proven

43

published studies prove effectiveness of Philips AED therapy.



A shock from a defibrillator within three to five minutes of a sudden cardiac arrest (SCA) is widely recognized as the most reliable way to restore the heart's normal rhythm.[1] But which AED is the right choice for effective therapy?

The efficacy of Philips AED technology is supported by over 40 published peer-reviewed studies. Two of those studies showed 100% first shock efficacy.[2,3] Another demonstrated 96%.[4] No other AED manufacturer can claim superiority to Philips therapy. Our evidence was sufficiently compelling to make Philips technology the first Biphasic therapy to be recommended by the American Heart Association for a Class 3 designation, meaning "standard of care" and "intervention of choice".[4]

Discover how the Philips AED with SMART Biphasic technology can help you deliver effective therapy when responding to sudden cardiac arrest.

When every minute counts, Philips AED Solutions are **a partner by your side.**

Philips Healthcare pioneered biphasic AED therapy, the technology that is now the gold standard. But not all biphasic therapy is created equal. In fact, every manufacturer uses its own proprietary biphasic waveform.

So why is the Philips AED with SMART Biphasic therapy the right choice?

Fast. In the event of SCA, time is the enemy. With a Philips AED, your patient receives its highest peak current on the very first shock, as well as on every subsequent shock. Other AEDs hold back, escalating to higher levels only if necessary. Given this timing sequence with some other AEDs, patients may not get the therapy they need for as long as six minutes. And, with our proprietary Quick Shock technology, Philips AEDs are among the fastest in delivering shock treatment after CPR. Reducing time to shock after chest compressions by even a few seconds can improve shock success.[5]

Efficient. Current is the true measure of shock intensity.[5] Thanks to the unique Philips capacitor technology, Philips 150-joule shocks pack more peak current joule-for-joule than conventional higher-energy waveforms from other manufacturers.

Flexible. Philips AED with SMART Biphasic technology is proven to work for a wide range of patients. This includes children and infants, as well as those some claim are difficult to defibrillate – large, obese patients, those with high or low body resistance, people with recurring VF episodes, and those with a myocardial infarction.[6-9]

Effective. High energy and elevated joules do not necessarily lead to stronger shock or better outcomes. In fact, high energy may stun an already fragile heart.[10] Philips AED with SMART Biphasic therapy combines high current for effectiveness and low energy to reduce the risk of stunning a vulnerable heart.

Automated. Philips AED with SMART Analysis automatically assesses heart rhythm to determine if a shock is needed. This automated feature persists regardless of whether the shock button is pressed. Philips AEDs will adjust the shock intensity instantly based on the patient's body resistance, so escalating energy is not necessary.

Therapy you can count on. Philips HeartStart HS1 and HeartStart FRx AED both incorporate our SMART Analysis heart rhythm assessment and SMART Biphasic technology. You can learn more about our advanced defibrillation technology at **www.philips.com/healthcare**.

Philips—the first choice

The experts agree Philips AEDs with SMART Biphasic technology have received scores of awards from independent organizations and respected publications. Among these recognitions are an outstanding published review by ECRI, an objective, non-profit evaluator of medical equipment, and a favorable owner survey by the British Department of Health.

Rewards and recognition include:

- MD Buyline Highest Rating
- Best of What's New 2003, Popular Science
- Most Loved Products of 2004, Amazon.com
- Readers' Choice Award 2004, Today's Facility Manager
- Medical Design Excellence Award, 1997, 2003
- Best Products of 2004, Fortune
- Forbes Ten Years/Ten Disruptors
- External Defibrillator Business Development Strategy, Leadership of the Year 2005, Frost & Sullivan
- EMS Today 2012 Hot Products

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Emergency Care and Resuscitation

This research summary brought to you by Philips

Effects of AED Device Features on Performance by Untrained Laypersons

Mosesso Jr, V.N. et al. *Resuscitation* 2009.07.016

Device features associated with increased performance rate were not always associated with shorter times to shock. This may reflect benefit of more detailed instructions for untrained users.

Objective

The study evaluates the impact of features of automated external defibrillators (AEDs) on the performance and speed of untrained laypersons to deliver a shock and initiate CPR after a shock. It assesses how these features affect the ease and speed with which a layperson performs a simulated cardiac arrest rescue.

Methodology

A prospective, randomized observational evaluation of six different AED models in a simulated cardiac arrest using trainer AEDs on manikins. Models include Cardiac Science PowerHeart AED G3, Heartsine Samaratan PAD, Medtronic CR Plus, Philips HeartStart Onsite, Welch Allyn AED 10 and ZOLL AED Pro. Subjects had no previous AED or advanced medical training.

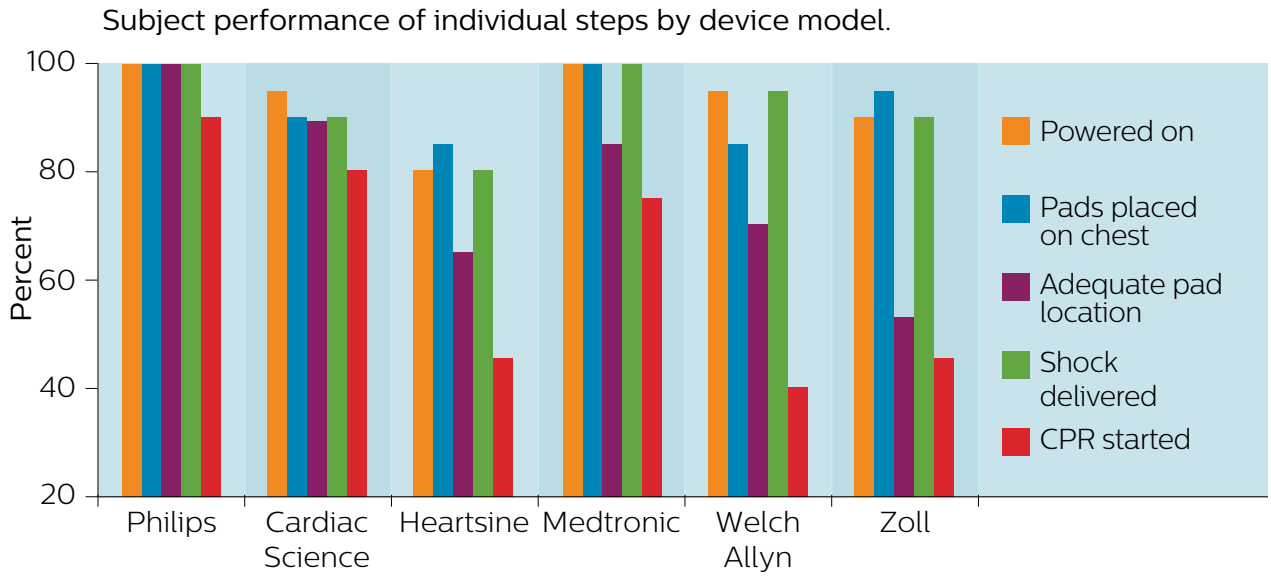

Figure 1: Many cardiac arrest victims who now die can be saved with prompt defibrillation.[1] Note that Philips led in observed performance in all categories. Note also the wide variability in pad placement accuracy and starting CPR. Based on table 3 of the manuscript.

Though subjects were instructed to attempt to use a device to "rescue" a manakin simulating a Sudden Cardiac Arrest (SCA) victim, they were not provided with instructions on how to use the device. Each subject used only one device. There were twenty subjects per device.

A scenario was stopped when the subject started performing CPR, or 5 minutes had elapsed, or the subject expressed a desire to stop. The subject then completed a questionnaire about device operation, ability to locate and place pads, and voice, text and graphic prompts.

Primary endpoints were shock delivery and elapsed time from start of scenario to shock. Secondary endpoints included time to power-on, time from second rhythm analysis to initiation of CPR, adequacy of pad placement and subject survey responses.

References

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Results

- Philips led all devices in observed device operation success (Figure 1)
  - Only Philips users demonstrated 100% success in turning the device on, attaching the pads on the chest, placing them accurately, and delivering a shock
  - Only Philips achieved a 90% success rate in starting CPR
- Devices that do not provide detailed CPR instructions (Heartsine, Welch Allyn, and Zoll) had lower success rates at starting CPR. Approximately half the responders using those devices did not perform that critical step (26/51)
- Cardiac Science and Zoll subjects were significantly slower to deliver a shock
- Device features associated with rescue success were not always associated with faster time-to-shock. This may be indicative of the benefits of more detailed instructions for untrained users

Conclusion

In a simulated cardiac arrest, most untrained users can successfully deliver a shock within three minutes, however pad placement is often inadequate, and CPR is often not started. Device ergonomic features have the greatest impact on three actions: powering on device, proper pad placement, and starting CPR after shock.

Philips Commentary

These results are consistent with those of three other AED ease-of-use studies,[2,3,4] in which the Philips device also led in observed mission success. These studies demonstrate Philips ease of use compared to other manufacturers.

The authors point out that inexperienced lay-responders benefit from device features that better ensure that rescuers actually perform steps critical to survival. Philips detailed instructions, paced to the responder's speed, are helpful in ensuring consistent and correct execution of the rescue. This is important for stressed, inexperienced responders because a shock not delivered or CPR not performed seriously compromises survival. And pads placed inaccurately compromises the effectiveness of the shock.[5]

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PHILIPS

Automated External Defibrillator

HeartStart AEDs

The Philips Difference

HeartStart AEDs are ready to go – on wet or metal surfaces.

Be ready for the real world

You never know when or where sudden cardiac arrest will strike. It could happen in the driving rain, sleet, or snow. At poolside, a marina, an ice rink, or the health club shower. The victim might be lying on a highly conductive metal surface like a loading dock, freight elevator, storefront grid, or grated walkway.

No matter where SCA takes place, you're ready and able to help save a life – with Philips HeartStart AEDs.

One of a kind

All AEDs should be safe to use anywhere, at any time. But that's simply not the case. Many manufacturers sell AEDs with specific warnings to move patients from wet or metal surfaces before using. Or to avoid rain and extreme moisture.

Philips AEDs are a breed apart because they're proven in real-life environments. Studies show that shocking a patient with a HeartStart AED on wet concrete poses a particularly low risk.[1] And treating SCA victims lying on metal surfaces is just as safe with our family of AEDs.

No rain delays

When every second counts, delaying treatment to move a patient off a wet or metal surface can be a matter of life or death. More than half the victims of the most common cause of SCA can survive when treated with CPR and shock from a defibrillator within 3 to 5 minutes of collapse.[2] So you can't afford to wait.

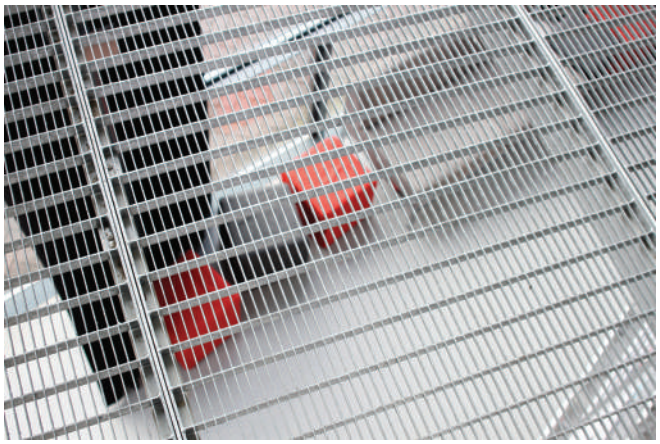
Be sure

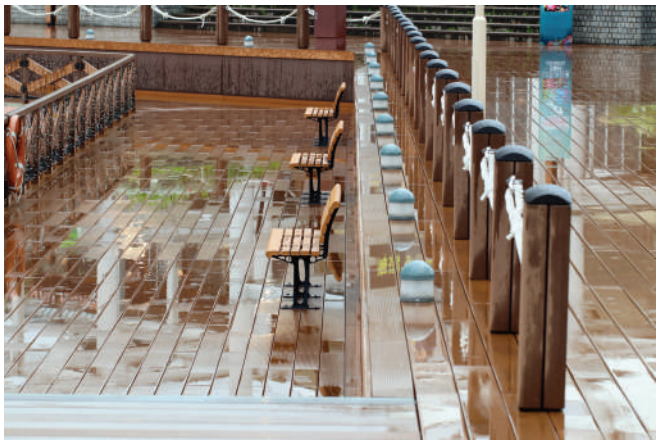
Count on Philips HeartStart AEDs to help you deliver the right therapy quickly and confidently – even on wet and metal surfaces.

The HeartStart AED family

Where can you use Philips HeartStart AEDs? Everywhere SCA happens.





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PHILIPS

Automated
External Defibrillator

HeartStart FRx

Side by side. Step by step.

Philips HeartStart FRx

To help save a life

For basic life support (BLS) trained responders, there's nothing more important than saving lives. When the need arises, it is important to quickly and confidently assess many unknowns:

What is the patient's condition?
What is the terrain like?
What is the treatment protocol?

It is crucial that AEDs be close at hand, ready to go, designed to be easy to use, lightweight and rugged.

More than half the victims of the most common cause of sudden cardiac arrest **can survive when treated within 3-5 minutes** of collapse with CPR and shock from a defibrillator.[1]

The HeartStart FRx defibrillator

- Is lightweight, rugged and reliable
- Includes features to help guide the treatment of sudden cardiac arrest with easy setup, real-time metronome and clear, step-by-step voice commands paced to your actions
- Provides CPR instructions for infants and children under 25 kg or 55 lbs or 8 years old, and adults and children over 25 kg or 55 lbs or greater than 8 years old
- Has an optional Infant/Child Key; simply insert it and the defibrillator adjusts instruction and therapy eliminating the need for additional infant/child pads
- Includes pre-connected SMART Pads II that can be used for both adults and children; SMART Analysis automatically assesses heart rhythm and only delivers a shock if the victim's rhythm is determined to be treatable by the Philips advanced algorithm, even if the Shock button is pressed
- Has Patented Quick Shock feature that allows the FRx to typically deliver a shock within 8 seconds after CPR[2]
- Performs a series of automatic self-tests, daily, weekly, and monthly to check pad readiness and verify functionality and calibration of circuits and systems

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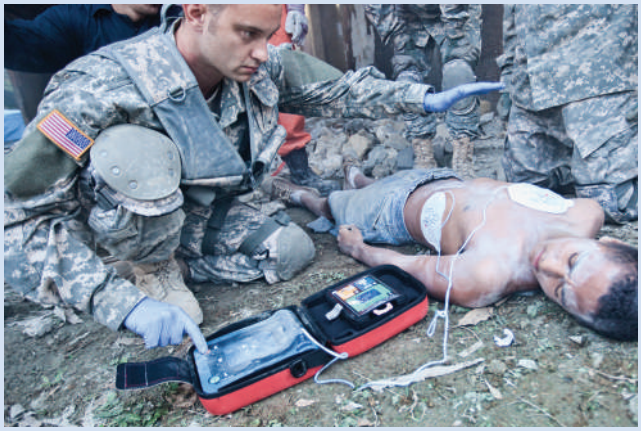
2. Nichol, G., Sayre, M. R., Guerra, F., & Poole, J. (2017). Defibrillation for Ventricular Fibrillation: A Shocking Update. *Journal American College of Cardiology*, 70(12), 1496-1509. doi:10.1016/j. jacc.2017.07.778

Expert guidance. Intuitive support.

The FRx defibrillator makes training easy. Simply insert the Training Pads II (available separately) to temporarily disable the FRx's energy delivery capability and switch into training mode. Eight realistic sudden cardiac arrest scenarios are designed to keep you and your team confident and prepared when the moment arises.



Designed to work where you need it

Lightweight, rugged and reliable, the Philips HeartStart FRx defibrillator can withstand rough handling, extreme temperatures, and dusty or wet surfaces. Designed for use in harsh settings, it can withstand up to 500 kg (1,100 lbs) and drops from 1.2 m (4 ft).

Patented technology. Proven therapy.

Real-time, step-by-step voice commands paced to your actions, and an audible metronome and CPR guidance assist the responder. When treating an infant or child, simply insert the optional infant/child key and the FRx adjusts instructions and therapy.

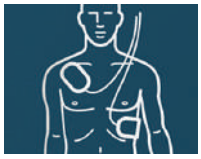
Ease of use

Pre-connected SMART Pads II can be used for both adults and children. Once installed and activated, the FRx is easy to maintain. It performs a series of automatic self-tests, daily, weekly, and monthly to check pad readiness and verify functionality and calibration of circuits and systems. It can last up to four years between battery replacements.

Easy as 1-2-3

1

Press the green On/Off button, which activates voice instruction and visual icons.



2

Place the pads on the patient as directed.

3

When advised by the device, press the orange Shock button.

HeartStart FRx defibrillator specifications

Defibrillator

Defibrillator family	Model Number 861304. Includes defibrillator, battery, SMART Pads II (1 set), Setup and Maintenance Guides, Owner's Manual, Quick Reference Guide, date sticker
HeartStart FRx Ready-Pack configuration	Order Option R01. Includes defibrillator, battery, carry case, SMART Pads II (1 pre-connected set, 1 spare set), Setup and Maintenance Guides, Owner's Manual, Quick Reference Guide, date sticker
Waveform	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance
Therapy	Adult defibrillation: nominal peak current 32 A (150 J nominal into a 50-ohm load) Pediatric defibrillation with optional FRx Infant/Child Key installed: nominal peak current 19 A (50 J nominal into 50-ohm load)
Protocol	Device follows preconfigured settings; defibrillation and CPR protocol can be customized using HeartStart Event Review Pro software

User interface

Instructions	Detailed voice prompts and visual icons guide responder through use of the defibrillator
CPR guidance	Verbal instructions for adult and infant/child CPR provides instructions and audio cues for the appropriate number, rate, and depth of chest compressions, as well as for each breath
Controls	Green On/Off button, blue-lit i-button, orange Shock button, optional Infant/Child Key
Indicators	Ready light, blue-lit i-button, caution light, illuminated pads, icons; Shock button lights up when shock is advised

Physical

Size	18 cm x 6 cm x 22 cm (7.1" x 2.4" x 8.8") H x D x W
Weight	Approximately 3.5 lbs (1.6 kg) with battery and pads installed

Environmental/physical requirements

Sealing	Waterjet-proof IPX5 per IEC60529 Dust-protected IP5X per IEC60529
Temperature	Operating/Standby: 32° – 122° F (0° – 50° C) Transient operating (for 20 minutes or less, after rapid transition from 68° F [20° C]): -4° to 122° F (-20 to 50° C); under non-condensing humidity conditions.
Altitude	-400 to 4572 m (-1312 to 15,000 ft)
Aircraft	Meets RTCA/DO-160 Section 21 (Category M - Radiated Emissions) and Section 20 (Category M - Conducted Immunity, and Category D - Radiated Immunity).
Crush	500 kg (1100 lbs)
Drop	Withstands 1.22 m (4 ft) drop on any edge, corner, or face of the device onto masonry surface.
Vibration	Operating: meets MILSTD 810G Fig. 5146E-1, random. Standby: meets MILSTD 810G Fig. 5146E-2, swept sine (helicopter).
EMI (radiated/ immunity)	Meets CISPR 11 Group 1 Class B and IEC 61000-4-3

Data recording and transmission

Infrared	Wireless transmission of event data to a PC using the IrDA protocol
HeartStart Event Review Pro software	Data management software (optional) for download and review of data retrieved through defibrillator's infrared data port
Data stored	First 15 minutes of ECG and the entire incident's events and analysis decisions

Patient analysis system

Patient analysis	Evaluates patient ECG to determine if a rhythm is shockable. Rhythms considered shockable are ventricular fibrillation (VF) and certain ventricular tachycardias (VT) associated with lack of circulation. For safety reasons, some VT rhythms associated with circulation will not be interpreted as shockable, and some very low-amplitude or low-frequency rhythms will not be interpreted as shockable VF.
Sensitivity/ specificity	Meets AAMI DF80 guidelines and AHA recommendations for adult defibrillation
Shock advised	Able to deliver a shock as soon as the device indicates a shock is advised
Quick Shock	Able to deliver a shock after the last chest compression of a CPR interval, typically in 8 seconds
Shock-to-shock cycle time	Typically less than 20 seconds between shocks in a series
Artifact detection	Allows ECG analysis even in the presence of most pacemaker artifact and electrical noise sources; other artifacts are detected and corrective voice prompts issued

Battery

Item number(s)	Standard: M5070A Aviation: 989803139301 (TSO-C142, U.S. only)
Type	9 Volt DC, 4.2 Ah, lithium manganese dioxide, disposable long-life primary cell
Capacity	When new, a minimum of 200 shocks or 4 hours of operating time at 77° F (25° C)
Install-by date	Battery is labeled with an install-by date of at least five years from date of manufacture
Standby life	Typically, 4 years when stored and maintained according to directions provided in the Instructions for Use

SMART Pads II

Item number	989803139261
Active surface area	80 cm^2 (12.4″^{2}) each
Cable length	121.9 cm (48″)
Use-by date	Pads case is labeled with a use-by date of at least two years from date of manufacture
Infant/Child Key	Item # 989803139311

Training SMART Pads II

Item number	989803139271
Function	Special pads place HeartStart FRx into training mode and disable its energy delivery capability; features eight real-world training scenarios

Automated and user-activated self-tests

Daily automatic self-tests	Tests internal circuitry, waveform delivery system, pads, and battery capacity
Pads integrity test	Specifically tests readiness-for-use of pads (gel moisture)
Battery insertion test	Upon battery insertion, extensive automatic self-tests and user-interactive test check device readiness
Status indicators	Blinking green "Ready" light indicates ready for use; audible "chirp" indicates need for maintenance

* Refer to the HeartStart FRx Defibrillator Owner's Manual for detailed product instructions. All specifications based on 25° C unless otherwise noted. The defibrillator and its accessories are made of latex-free materials.

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