CellAED®

The latest development in defibrillation technology and therapy

HOW CellAED® DELIVERS EFFECTIVE SHOCKS WITH OPTIMISED ENERGY

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CellAED® IS A PRODUCT OF Rapid Response Revival®

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Executive Summary

Between seven and nine million people die from sudden cardiac arrest (SCA) each year.[1] Most SCAs occur out-of-hospital with up to 80% occurring in the home.[2] For each minute cardiopulmonary resuscitation (CPR) and defibrillation are delayed, the chances of survival decrease by 10%.[3]

While public access defibrillators aim to increase the survival rates from SCA, there are many barriers that prevent them from being used in most SCA occurrences. These include lack of accessibility, inexperience, and inadequate user knowledge. Further, conventional automated external defibrillators (AEDs) are too expensive and bulky to be carried by individuals or to have in their home.

CellAED® was designed for everyone, regardless of medical or first-aid experience, to make portable defibrillators affordable, accessible, effective, and easy-to-use in the event of an out-of-hospital cardiac arrest (OHCA).

Through sophisticated engineering and the development of a patented low-energy biphasic waveform, CellAED® is an ultraportable and affordable personal AED that uses less energy (joules) to deliver a peak current that is equivalent to that of conventional AEDs.

Key points

- A defibrillator is a medical device that provides an electrical shock (or multiple shocks if required) to "terminate" fibrillation and restore a normal heart rhythm during SCA.
- AEDs are designed to be used in OHCAs by minimally trained people.
- Publicly accessible AEDs are successfully used in only a small number of OHCAs due to problems with access, and lack of experience and knowledge amongst the public.
- Designed to overcome these barriers, sophisticated engineering of the conventional biphasic waveform resulted in the ultraportable and affordable design of CellAED®, delivering an effective shock using less energy.
- CellAED® is the next step in the evolution of AED technology, requiring around 75 joules of energy to deliver an equivalent current to that of conventional AEDs.
- Although joules have traditionally been used to describe and compare shock dose in defibrillators, it is the current (Amperes), and how it is delivered, that determines whether a shock is effective or not.
- Different shock waveforms require different energy to deliver effective defibrillation.
- Unlike most conventional defibrillators, CellAED® delivers a patented low-energy biphasic waveform that is balanced between phases, creating a waveform with equal peak current and voltage in both phases.
- This carefully balanced waveform minimises the residual effect of defibrillation upon the heart cells, optimising the energy required and reducing the chances of re-entering SCA after the shock.

Introduction

Sudden cardiac arrest

SCA is a medical emergency that occurs when the heart suddenly stops beating effectively, preventing blood from being pumped around the body.

Within seconds, a person in SCA will collapse, become unresponsive, and stop breathing normally. In the early minutes of a SCA, some people will have an abnormal gasping breathing pattern known as agonal breathing. The most critical initial steps in the treatment of SCA include calling emergency services, starting CPR, and retrieving a defibrillator.[4] While CPR helps to keep some blood circulating to vital organs, defibrillation with an AED is required to get the heart pumping again.

Between seven and nine million people experience SCA each year,[1] with a survival rate of less than 1% worldwide.[1] Most SCAs occur out-of-hospital with up to 80% of these occurring at home.[2] For each minute CPR and defibrillation are delayed, the chances of survival decrease by 10%.[3] Unfortunately, in the event of a SCA, few people have access to an AED and many people die because they do not receive rapid defibrillation.[5]

How automated external defibrillators work

The heart is composed of specialised muscle cells that are called "excitable cells", meaning they respond to external electrical stimuli to contract or expand. The sinoatrial (SA) node is an area of specialised tissue in the heart that acts as the heart's natural pacemaker. It generates electrical stimuli that spreads throughout the heart's electrical network in an organised manner, which results in a "normal sinus rhythm". The SA node keeps the heart beating in a regular and organised rhythm. During many cases of SCA the heart's electrical behaviour can become irregular and chaotic. When this happens, the heart stops beating effectively.

By delivering a controlled electrical shock, defibrillation interrupts the abnormal chaotic electrical activity by "resetting" (depolarising) the heart cells. This depolarisation returns the fibrillating cells to a rest state and provides an opportunity for the SA node to regain control and initiate a coordinated organised rhythm.[6]

Manual defibrillators have been used in the hospital setting by medical professionals since 1947[7] and require specialised medical training to operate. Defibrillators first became usable by lay people in the 1980s with the creation of AEDs.

As their name states, AEDs are *automated*, meaning they analyse and diagnose the heart rhythm without any input from the user; they're *external* in that they involve electrode pads placed outside of the body on the chest; and they *defibrillate* by passing an electric current through the heart.[6]

Importantly, AEDs are as effective as manual hospital defibrillators at treating SCA, but with a simplifed user interface. This allows them to be used by minimally trained people in an out-of-hospital setting.

Barriers to public access AED use

Cost[5] and portability prevent most individuals from securing AEDs for personal use. For this reason, the only way that people can access an AED in an emergency is by locating and retrieving a public access defibrillator. Despite conventional public access AEDs being available in many public locations such as airports, train stations, schools, and workplaces, they are rarely used during OHCAs.[5] Barriers to the use of public access AEDs include:[5,8]

Accessibility
Public access AEDs are not easily accessible to people at the scene. They may be too far away or stored in a location that is only accessible at certain times of the day.

Inexperience
People may hesitate in using the device due to inexperience, unfamiliarity and/or reluctance to be responsible for the outcome.

Knowledge
People at the scene of an OHCA do not think to retrieve an AED, do not know what an AED is, or do not know how to use one.

Location
People at the scene of an OHCA are unaware of where the nearest public AED is located.

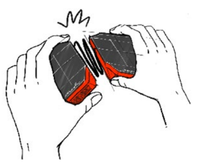
In recognition of these barriers, CellAED® was engineered to make personal defibrillators affordable, accessible, effective, and easy-to-use in the event of an OHCA.

A new class of AED to address these barriers

CellAED® signifies the most substantial leap in AED technology since the introduction of biphasic AEDs in the 1990s. Designed as a personal AED, CellAED® is significantly smaller and lighter than conventional AEDs. The easy-to-use, integrated design houses the technology and parts required to deliver an effective shock, including the battery and the electrode pads, in one compact unit. This eliminates the need for separate consumables required by conventional AEDs, such as electrode pads and batteries, which are also associated with additional packaging and cost of replacement.

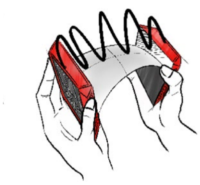
The innovative engineering of the CellAED® waveform has allowed for the ultracompact and ultraportable design of CellAED®. The device weighs only 450 g including its protective case and is small enough to carry in a handbag or backpack. The improved portability of CellAED® helps to address accessibility barriers.

CellAED® has improved the simplicity of using an AED for minimally trained individuals with its proprietary 3-step activation process: Snap Peel Stick™. With this innovation, CellAED® is helping to address barriers of inexperience and user knowledge and it can be applied to a person in seconds.



SNAP

Snap the device to turn on and start voice instructions



PEEL

Peel to separate the two electrode gel pads

STICK

Stick the pads to bare chest

> **CellAED® has improved the simplicity of using an AED for minimally trained individuals with its proprietary 3-step activation process: Snap Peel Stick™.**

Clinical trials

The radical innovation of CellAED® meets all relevant regulatory requirements for AEDs in jurisdictions where it is sold.

CellAED® is also being used in several clinical trials around the world, led by independent researchers. Preliminary data from these trials at the time of writing confirm that CellAED® consistently delivers therapy and has terminated ventricular arrythmias to facilitate return of pulses (i.e., return of spontaneous circulation) with no reported safety issues or adverse events.

Clinical trial register
For further information see: https://www.anzctr.org.au/

A multi-centre, prospective, safety and efficacy evaluation study of automated external defibrillation (CellAED®) in patients with cardiac arrythmias.

A study on patients in cardiac arrest to determine the effect of equipping GoodSAM responders with an ultraportable defibrillator on 30-day survival.

Energy requirements for defibrillation

An AED is intended to "reset" the chaotic electrical activity of the heart cells, ending ventricular arrhythmia and allowing the heart to naturally restart with a normal rhythm. For this to happen, the energy applied by an AED must generate enough current through the heart (transmyocardial current), while minimising injury to the heart. A shock will not terminate the arrhythmia if the current is too low, but physical damage to the heart may occur if the energy applied to the heart is too high.[11]

Therefore, the most efficient and effective defibrillation waveform is one that delivers sufficient current (Amps) with the lowest total energy (joules). This allows for effective defibrillation with the least amount of damage to the heart tissue.

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Waveforms

Conventional biphasic waveforms

Conventional biphasic AEDs deliver a shock using what is known as a biphasic truncated exponential (BTE) waveform. AEDs use capacitors, an electric component that stores electrical energy, to charge from the battery and discharge during shock delivery. Conventional biphasic AEDs use a single high voltage capacitor module, which is then discharged across the heart in two phases (Figure 1).

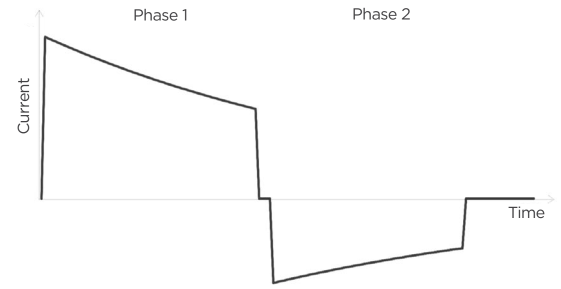

Figure 1: A conventional biphasic truncated exponential (BTE) waveform

During the first phase of the biphasic truncated exponential waveform, the voltage reduces as the stored energy is discharged in one direction (positive) over a specific time. Phase 1 ends with "truncation", an abrupt switch in the direction (negative) of current flow. The remaining voltage on the capacitor is then discharged, resulting in phase 2 of the waveform. In conventional biphasic waveforms, the starting voltage of phase 2 is equal to the end voltage of phase 1. This is because the voltage in the single capacitor module has been discharged over the first phase of the waveform. The result is that phase 2 peak current and voltage is substantially less than that of phase 1. In this way, the waveform is uneven between phases 1 and 2.

Not all waveforms are equal

An AED's shock is visually represented as a waveform. Early defibrillator technology delivered a monophasic waveform, with current travelling in one direction across the heart. Monophasic waveforms required up to 360 joules to deliver an effective shock. Over time, this has changed as defibrillation technology has evolved.

The first biphasic AED was introduced in 1996 as an improvement on monophasic technology. Biphasic defibrillators work by delivering current in two phases, each with a different direction of current flow between the electrode pads for a specific time interval.[12] The introduction of biphasic AEDs approximately halved the energy required to deliver an effective shock, when compared to the monophasic technology. Today, biphasic

Not all waveforms are equal

(continued)

AEDs typically use around 120 - 150 joules to deliver an effective shock.[13*] And now, CellAED® has halved that again, delivering an effective shock with 75 joules, which is due to its patented low-energy biphasic waveform.

Among other factors, the amount of energy (joules) required to deliver an effective shock is dependent on the amplitude and shape of the waveform. The shape of the waveform is determined by software and electrical components in the defibrillator, which adjust key parameters such as voltage and current over time. Importantly, the shape and duration of the waveform can differ between AEDs, even between AEDs of the same energy (Figure 2).[†]

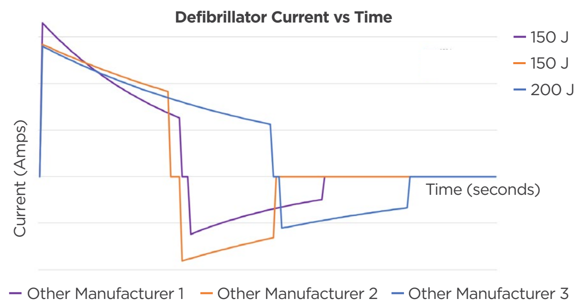

Figure 2: A comparison of conventional biphasic waveforms

As such, comparing different AEDs based on their energy usage (joules) is not a comparison of the effectiveness of their therapy. The most critical factor in determining shock effectiveness is the electrical current that flows through the heart. In other words, it is current, not energy that determines effective defibrillation.[14]

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An effective shock

The effectiveness of a shock relies on two critical factors, intensity and duration. Specifically, an effective defibrillation shock must ensure the electrical current is of adequate intensity to surpass the defibrillation threshold, and the duration of the shock is sufficient to ensure all the heart cells are depolarised. In other words, the electrical shock of an AED must be strong enough and applied over a suitable period to effectively defibrillate (Figure 3).

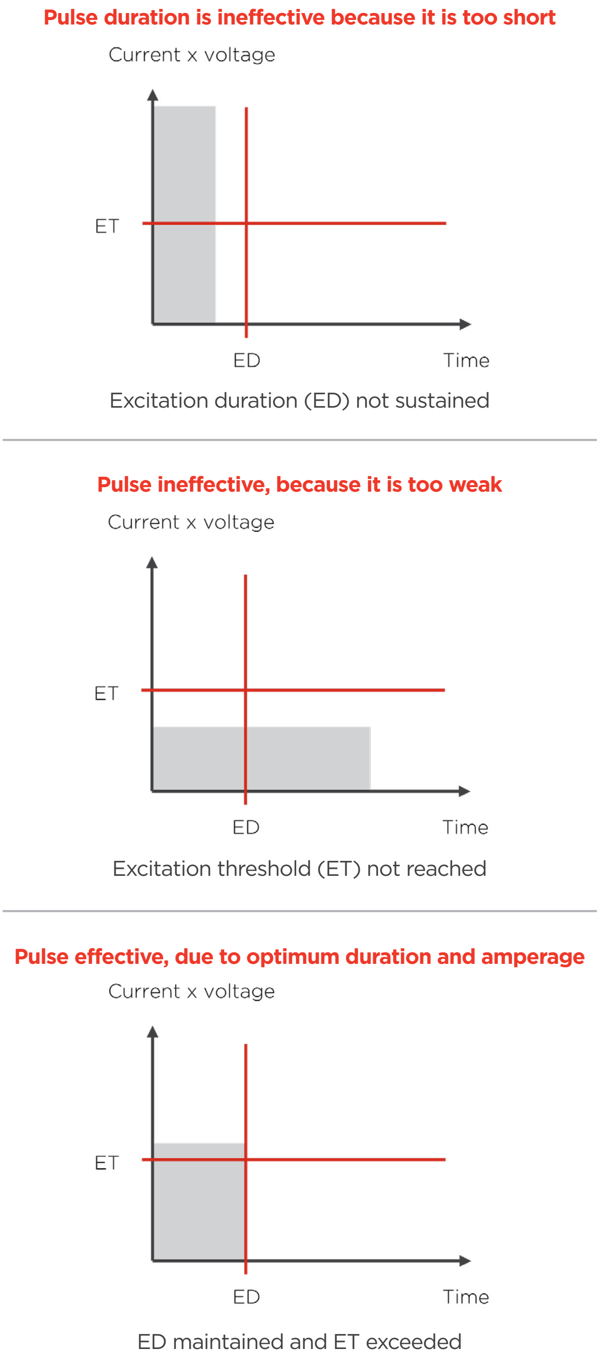

Figure 3: Effective pulses for defibrillation

For footnotes, see page 13

An effective shock (continued)

There is one other critical issue to consider in the design of a waveform, which is the electrical charge left on the cell membranes after the defibrillation shock, also known as the residual voltage. In biphasic waveforms, defibrillation is optimised when phase 2 leaves as little residual voltage on the heart cells as possible. Residual voltage is accumulated in heart cells during phase 1 of the waveform. So, in addition to "resetting" the heart cells across both phases of the waveform, residual voltage from phase 1 must be minimised in phase 2.[15] This requires careful design and balancing of the biphasic waveform.

When an electric shock is not balanced and has an uneven biphasic waveform, the current in phase 2 of the waveform can be below the minimum strength and duration required to effectively "reset" all the heart cells. If all the heart cells do not reset at the end of the shock, the abnormal rhythm can restart and spread to the rest of the heart. This is a recognised cause of failed defibrillation attempts. To overcome this issue, conventional biphasic AED waveforms start with higher energy to ensure that phase 2 in a single capacitor setup remains powerful enough to deliver an effective shock after depletion of the voltage from phase 1.

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Typically, the energy delivered by a defibrillator to a patient also varies with the impedance (electrical resistance) of the patient. As such, reported device specifications include the energy used by a defibrillator across a range of expected patient impedances. For some defibrillators, the energy can decrease by up to 36.5% from the lowest to highest impedance. For others, the same impedance range can have an opposite effect, resulting in an increase in energy of up to 26.9%.[16] The nominal rated energy delivered into a 50 Ohm patient is a standard reporting metric across defibrillators to facilitate comparisons. The rated energy of CellAED® for the delivery of a shock to an adult patient with an impedance of 50 Ohms is 75 Joules.

The innovation of CellAED®

Delivering an effective shock with 75 joules

CellAED® delivers an effective shock using 75 joules due to its patented low-energy biphasic waveform.*

Most conventional defibrillators store their energy within a single capacitor module, requiring truncation and a polarity switch to reverse the direction of current at the end of phase 1. In contrast, CellAED® uses a sophisticated array of capacitors, enabling each phase of the waveform to have dedicated independent energy storage. As a result, CellAED® does not truncate to produce a biphasic waveform (Figure 4).

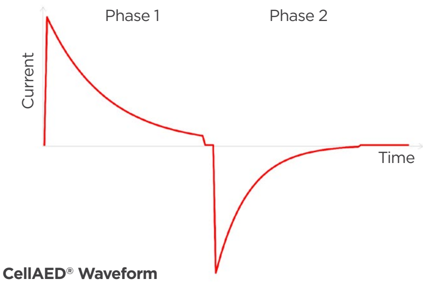

Figure 4: CellAED® Waveform

By removing the dependency between the voltage at the end of phase 1 and the start of phase 2, this technical innovation allows for the careful balancing of the two phases. As such, CellAED® delivers a fully discharging, equal leading-edge biphasic waveform with equal peak current and voltage in both phases, stimulating the heart cells with equal peak intensity in both phases. This balanced waveform minimises the residual effect of defibrillation on the heart cells and reduces the possibility of re-fibrillation of the heart.[15]

By virtue of its optimised and balanced waveform, CellAED® does not need higher energy to ensure there is sufficient voltage and duration of electric current in phase 2 to effectively "reset" all heart cells. The result of this is that CellAED® can use less energy to deliver an effective shock compared to most conventional AEDs.

Delivering an effective shock with 75 joules (continued)

This innovation in capacitor application also reduces space (less parts) and energy requirements for CellAED®, resulting in improved affordability, portability, effectiveness, and ease-of-use.

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The differences in energy between a typical biphasic waveform and the CellAED® waveform are shown in Figure 5. The shaded areas are an indication of the energy of each waveform, with the grey area clearly demonstrating the difference in energy expended by CellAED® in both phases. While the energy is different, the key parameters that are required to deliver an effective shock, namely peak current and voltage over time, remain comparable.

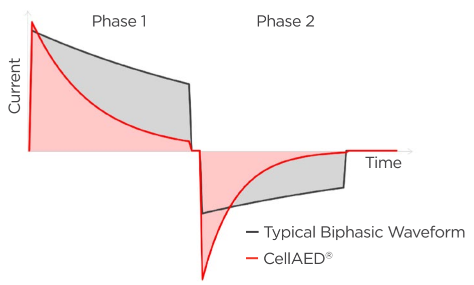

Figure 5: Typical biphasic waveform and CellAED® waveform, with energy comparison (shaded)

> **It is the balanced biphasic waveform of CellAED® that reduces the amount of energy expended while still maintaining the necessary strength and duration across both phases of the shock to effectively treat arrhythmias associated with SCA.**

Both the optimised biphasic waveform of CellAED® and the conventional biphasic waveform begin phase 1 with comparative peak current and voltage but begin to differ shortly afterwards. Due to its innovative technology, CellAED® begins phase 2 with the same peak current and voltage as phase 1, but in the opposite direction. Consequently, CellAED® efficiently defibrillates, providing comparative peak current and voltage over a similar duration to conventional technology, without delivering excess energy superfluous to effective defibrillation.

It is the balanced biphasic waveform of CellAED® that reduces the amount of energy expended while still maintaining the necessary strength and duration across both phases of the shock to effectively treat arrhythmias associated with SCA.

For footnotes, see page 13

Continued Innovation

CellAED® was created to make defibrillators more accessible and affordable, addressing the low survival rate associated with SCA. It is the result of continued innovation, which allows for more efficient power sources and systems in a small personal AED.

The design of CellAED® is ushering in a new age of personal AEDs and underscores several important points:

- Defibrillators cannot be compared solely based on energy (joules) delivered.
- Joules should not be relied upon as the only measure and predicator of effectiveness of a defibrillator waveform.
- It is current, not energy, that is the most important determinant of effective defibrillation.
- CellAED®, a personal AED, was designed to address barriers to public access AEDs.
- The patented low-energy biphasic waveform of CellAED® makes portable defibrillation affordable, accessible, effective, and easy-to-use by witnesses with limited training in the event of a SCA.
- By addressing these barriers, CellAED® empowers people with the ability and confidence to act in the event of an OHCA.

Definitions

AED	Automated external defibrillator.
Arrhythmia	An abnormal heart rhythm. In this article, arrhythmia refers to pulseless ventricular tachycardia or ventricular fibrillation, which are types of arrhythmias seen in SCA that are treatable by defibrillation with an AED.
Capacitor	An electric component used to store and discharge electrical energy.
CPR	Cardiopulmonary resuscitation (CPR) is an emergency lifesaving procedure involving chest compressions to pump blood around the body.
Current	A measure of the flow of electricity, measured in amperes (Amps). In the context of the heart, current refers to the flow of electric energy current through cardiac tissue, which is delivered during defibrillation.
Depolarisation	In this article, the process by which the electrical polarity of a biological cell changes from a positively charged state to negatively charged state. Cells are normally negatively charged during their rest state, i.e., depolarised, and become polarised (positive) during cell activation.
Defibrillation	Terminating fibrillation during SCA to restore normal cardiac rhythm by depolarising the heart cells, potentially interrupting irregular, chaotic electrical activity.
Impedance	A measure of resistance to flow of electrical current, measured in ohms.
Joules	A unit of measurement of energy. A joule is equal to one amp of current passed through one ohm of resistance for one second. This is expressed as Energy (Joules) = Voltage (Volts) x Current (Amps) x Time (secs). In the context of defibrillation, joules are used to quantify the amount of energy delivered in the form of an electric shock.
Out-of-hospital cardiac arrest (OHCA)	An out-of-hospital cardiac arrest is when a cardiac arrest occurs outside a hospital setting.
Shock	In this article, "shock" refers to the electrical stimulus delivered by an AED to the chest.
Sudden cardiac arrest (SCA)	A sudden cardiac arrest is a medical emergency that occurs when the heart suddenly stops beating effectively, preventing blood from being pumped around the body. During some SCAs, the primary issue relates to chaotic and disorganised electrical signals in the heart (such as ventricular tachycardia or ventricular fibrillation), resulting in ineffective contraction of the heart. If left untreated, ventricular fibrillation and pulseless ventricular tachycardia lead to complete absence of electrical activity (known as asystole) and death.
Truncation point	In this article, the instant when the direction of current from a biphasic AED is reversed.
Voltage	The pressure from an electrical power source that pushes charged particles (electrons - current) through a conducting pathway.
Waveform	A graphical representation of the electrical signal (shock) from a defibrillator. Shown as a graph of Current or Voltage versus Time.

CellAED®

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Footnotes

*Current international guidelines acknowledge the optimal energy (joules) for defibrillation is not yet known. They recognise that traditional AEDs operate between 120-360 joules based on the manufacturer's recommendations, but also note that it is transmyocardial current flow (the movement of electrical current through the muscular tissue of the heart) that achieves defibrillation.

†The American Heart Association 2020 Guidelines state: "Currently, marketed defibrillators use proprietary shock waveforms that differ in their electric characteristics. These deliver different peak currents even at the same programmed energy setting, making comparisons of shock efficacy between devices challenging. Energy setting specifications for cardioversion also differ between defibrillators. Refer to the device manufacturer's recommended energy for a particular waveform."

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Rapid Response Revival
Original Design Engineer of CellAED® Concept

About CellAED®

CellAED® was designed to save lives from sudden cardiac arrest (SCA) by making personal defibrillators affordable, accessible, effective, and easy-to-use in the event of an out-of-hospital cardiac arrest.

SCA is a medical emergency that occurs when the heart suddenly stops beating effectively, preventing blood from being pumped around the body. It can happen to anyone, anywhere, at any time. Within seconds, a person in SCA will collapse, become unresponsive, and stop breathing normally. The most critical steps in the treatment of SCA include calling emergency services, starting CPR, and retrieving a defibrillator. For each minute CPR and defibrillation are delayed, the chances of survival decrease by 10%.

Every minute counts. With CellAED®, you can be prepared to help save the life of someone you care about in the event of a sudden cardiac arrest.

About Rapid Response Revival®

Rapid Response Revival® is a privately-owned start-up company based in Sydney, Australia, established in 2017. Its mission is to save lives from of out-of-hospital cardiac arrest.

Rapid Response Revival® was established by Donovan Casey, after his partner, Sarah, experienced a sudden cardiac arrest in their home. With a survival rate of less than 1% worldwide, Sarah was lucky to survive.

The Rapid Response Revival® flagship product is CellAED®, designed to make personal defibrillators affordable, accessible, effective, and easy-to-use in the event of an out-of-hospital cardiac arrest.

The world's first personal AED, CellAED® represents the first real improvements on AED technology in more than 30 years.

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