Venn Brown
Investment Research & Advisory

Initiation of coverage

Rapid Response Revival

CellAED: Next generation AED

11th March 2024

Smallest, lightest, most affordable AED

Rapid Response Revival Research is the developer of the CellAED, the world's first personal, fully portable handheld automated external defibrillator (AED). CellAED is the smallest, lightest, most affordable and arguably easiest-to-use defibrillator on the market, costing just 25% - 35% of other AEDs.

Sudden cardiac arrest is #1 or #2 cause of premature death

Every year, sudden cardiac arrests (SCA) kill between 6 to 8 million people globally, killing more people in the US than breast cancer, cervical cancer, colorectal cancer, Alzheimer's, firearms, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer and suicides combined. One estimate puts the cost of SCA in Australia at around $51 billion a year.

Survival rates can be as high as 90% with early defibrillation but decreases ~10% with every minute that passes. CellAED is designed from the ground up to be available in people's homes, where 70-80% of all cardiac arrests occur.

Already one of Australia's best-selling AEDs

In its first year in Australia, CellAED outsold one of the world's most popular AED brands by eight times. CellAED is currently available in Australia, New Zealand, Ireland and the UK, with plans to launch in the US within three years. Since its launch in late 2022, RRR has sold more than 17,000 devices, generating more than $7 million in revenue.

Valuation: $314 - $345 million

By FY34, and with ~$80 million in funding, we believe RRR could capture ~1.1% of the 230 million device total addressable market (TAM) in just the five regions RRR is currently targeting, delivering $842 million in revenue and $208 million in free cash flow. Based on our forward estimates and the group's successful capital raise, we value RRR at $314 – $345 million ($200 - $220 per share).

Up to US$100 million capital raise

RRR is undertaking a capital raise of up to US$100 million. Our modelling assumes a raise of $80 million (~US$52 million) over the next two years.

Rapid Response Revival

Public unlisted

Sector	Medical Devices
Currency	Australian dollar (AUD)
Date	11th March 2024
Share price	$40.00
Market cap	$61.3m
Free float	-
Dividend	-
Yield	-

Year-end 30 June	FY22	FY23	FY24e	FY25e
Revenue	$3.8m	$9.5m	$14.4m	$25.7m
COGS	-	-$2.4m	-$4.2m	-$11.6m
Employees	-$7.5m	-$9.3m	-$11.2m	-$14.5m
Professional fees	-$4.4m	-$4.0m	-$4.6m	-$4.6m
Other costs	-$6.2m	-$9.8m	-$4.9m	-$6.5m
EBITDA	-$14.5m	-$13.0m	-$10.2m	-$13.3m
EBIT	-$15.5m	-$13.5m	-$10.7m	-$13.6m
Net profit	-$15.6m	-$13.7m	-$11.1m	-$13.6m
Earnings per share	-$9.64	-$7.24	-$7.27	-$9.82
Op. cash flow	-$13.2m	-$14.4m	-$15.6m	-$13.3m
Free cash flow	-$14.4m	-$14.5m	-$15.6m	-$14.6m
Cash / net debt	$0.7m	$0.3m	-$4.3m	$11.1m

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Venn Brown Pty Ltd has been engaged and paid by the company covered in this report for ongoing research coverage. Please refer to the disclaimers at the end of this report.

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Disclosure

Venn Brown provides the following additional disclosures to provide further details and context in which this report was written. Venn Brown's full disclaimers and disclosures are available at the end of this report. See *Disclaimers.*

1. Venn Brown has been engaged by Rapid Response Revival Research Limited (RRR) to investigate the company and prepare this equity research report.
2. Employees of Venn Brown either directly or indirectly own Rapid Response Revival shares.
3. RRR has not yet released its FY23 audited reports. According to management, the delay in releasing the accounts was due to delays with its auditors, Ernst & Young. RRR expects to have the financial reports released within a few weeks.
4. RRR does not intend to hold its FY23 AGM until it has its audited financial report. The company expects to announce the AGM's timing soon after management releases its accounts.
5. RRR must raise capital within eight months. The capital will most likely come from some form or combination of debt and equity raise but may come through business activities, including a joint venture partnership or licensing exclusive distribution rights for various regions. RRR is actively discussing these and other non-dilutive options with potential partners.
6. If RRR does not raise capital, it will most likely shut down.
7. RRR is still early in its commercialisation ramp-up phase. The timing of single events can have a meaningful impact on the company's short-term performance.
8. In May 2023, three independent board members resigned from the board.
9. **In writing this report, Venn Brown is aware of the financial challenges facing RRR. In determining the business outlook, including financial forecasts and valuation, Venn Brown has assumed that the business successfully raises $80 million in four tranches: $5m in late FY24, $10m in early FY25, $25 million in late FY25 and $40 million in FY26. This capital is sufficient for RRR to generate the returns outlined in this report. The timing of each raise will affect the timing of financial results.**

Business Overview

CellAED is the world's first personal defibrillator

Rapid Response Revival Research (RRR) is an Australian medical device company that developed the CellAED (www.cellaed.io), the world's first personal, fully portable handheld automated external defibrillator[1] (AED). CellAED is designed from the ground up to be available in people's homes, where 70-80% of all cardiac arrests occur. It is the smallest, lightest, most affordable[2] (just 25-35% of the upfront cost of most AEDs) and arguably easiest to use defibrillator on the market. RRR is currently selling CellAEDs in Australia, New Zealand, the UK, and Ireland, and they are approved for sale in South Africa and Malta.

Figure 1: The CellAED was designed from the ground up to maximise survival rates

CellAED is smaller, lighter & more affordable than any other AED[1]

Source: Rapid Response Revival

The CellAED is designed for home, business and mobile applications. CellAED is the first single-use AED and is designed to be small, lightweight, fully portable, and affordable.

- **Affordable:** 15-35% of the upfront cost of other devices
- **Lightweight:** 15% - 25% the weight of other devices.
- **Ultra-portable:** 10% - 20 % the size of other devices.
- **Easy to use:** Patented "Snap, peal stick", all-in-one design
- **No maintenance:** Single use, single piece, inbuilt pads

CellAED outsold ZOLL AEDs by 8x

In Australia, the CellAED costs $599[3] upfront, which includes a year's subscription to 'CellAED for Life' ($198/yr), which includes remote monitoring and a free replacement device when the existing device is used or expires (30 months from manufacture). This price compares to other devices, which cost $1,700 – $4,950 upfront, plus $50 – $100 in annual maintenance/servicing costs.

[1] Defibrillators are medical equipment that apply an electric current through a fibrillating heart to "shock" it back into a normal rhythm. Defibrillators can be applied externally (on the patient's skin) or internally (directly to the heart). Automated external defibrillators (AEDs) are designed to be used by untrained bystanders and once attached to the patient will operate automatically. Manual defibrillators are operated by medical professionals. See section 'Automated External Defibrillator (AED)' for more details.

[2] The Schiller FRED Easyport is similar in size and slightly heavier but costs A$4,950 compared to CellAED at A$599.

[3] Unless specified, all currency values are in Australian dollars.

Market intelligence indicates that in its first year, CellAED sold eight times as many AEDs in Australia as ZOLL, one of the world's top three AED brands. Since launching, RRR has sold 17,535 devices, generating $7.1 million in revenue.

Figure 2: RRR has sold 17,500 CellAEDs since launching

	Devices sold	Delivered	Revenue ($'000)[4]
FY22	2,039*		$0.5m
FY23	9,817	7,344	$3.5m
FY24	5,679	7,110	$3.1m
Total	**17,535**	**14,454**	**$7.1m**

* Pre-sales
Source: Rapid Response Revival

Sudden Cardiac Arrest is the #1 or #2 cause of premature death globally

Sudden cardiac arrest is the #1 or #2 cause of premature death globally

Across the western world, sudden cardiac arrest (SCA) is the leading or second leading cause of premature death, killing between six and eight million people every year.

In the US, sudden cardiac arrest kills roughly the same number of people each year as Alzheimer's, firearms, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer and suicides combined [5].

Table 1: Each year, sudden cardiac arrests kill between 6 - 8 million people

SCA kills more people than the top five cancers combined

Cause of Death	United Kingdom	United States	Australia	Germany	France
All Cancers	166,000	606,520	50,000	240,000	157,400
SCA	**95,153**	**356,000**	**25,000**	**65,000**	**48,945**
Dementia	66,000	122,019	14,000	59,500	33,500
Stroke	36,000	146,383	10,000	40,000	30,200
Lung Cancer	35,000	142,670	9,000	45,000	31,200
Colorectal cancer	16,000	53,200	5,300	25,700	17,400
Breast Cancer	11,500	2,170	3,000	18,570	11,900
Road Accidents	1,800	38,800	1,200	3,046	3,500
Firearms	115	39,682	229	815	1650
Deaths from all causes	616,014	2,854,838	169,301	939,520	613,900

Source: See *References - Mortality and Disease statistics*

[4] Unless specified, all currency values are in Australian dollars.
[5] https://cpr.heart.org/en/resources/cpr-facts-and-stats

SCA Survival Rates

Survival rates can be as high as 90% with early defibrillation

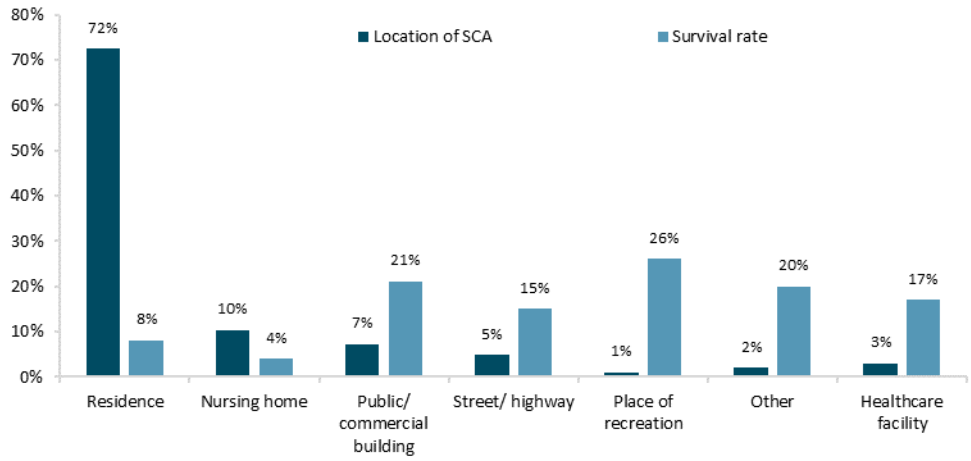
CPR can help extend the survival window of sudden cardiac arrest (SCA) patients, but defibrillation is required to revive most patients experiencing SCA with a shockable rhythm[6]. Among patients with shockable rhythms, SCA survival rates can be as high as 90% if defibrillation occurs within the first minute following the arrest.

If defibrillation occurs within 3-5 minutes, the survival rate can be as high as 70%, but as time passes, the chances of survival decrease rapidly. Survival rates reduce by approximately 10% for every minute without CPR or defibrillation, reaching effectively zero after ten minutes.

In the US in 2022, 72% of SCAs occurred in people's homes (80% in the UK[7]), the least likely place to find a defibrillator. Fewer than 15% of SCAs occur in public places where most public use automated external defibrillators are located.

The home is the deadliest place to have a SCA and it's where 70% - 80% occur

Figure 3: Between 70 - 80% of out-of-hospital cardiac arrests occur in the home



Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

Average ambulance response time across major global capital cities ranges from eight minutes forty seconds (London) to over sixteen minutes (Sydney)[8]. This delay and the lack of defibrillator availability results in the survival rate of at-home SCA being 8% (below the overall average of less than 10%).

Ambulance response times are not fast enough to save +90% of SCA victims

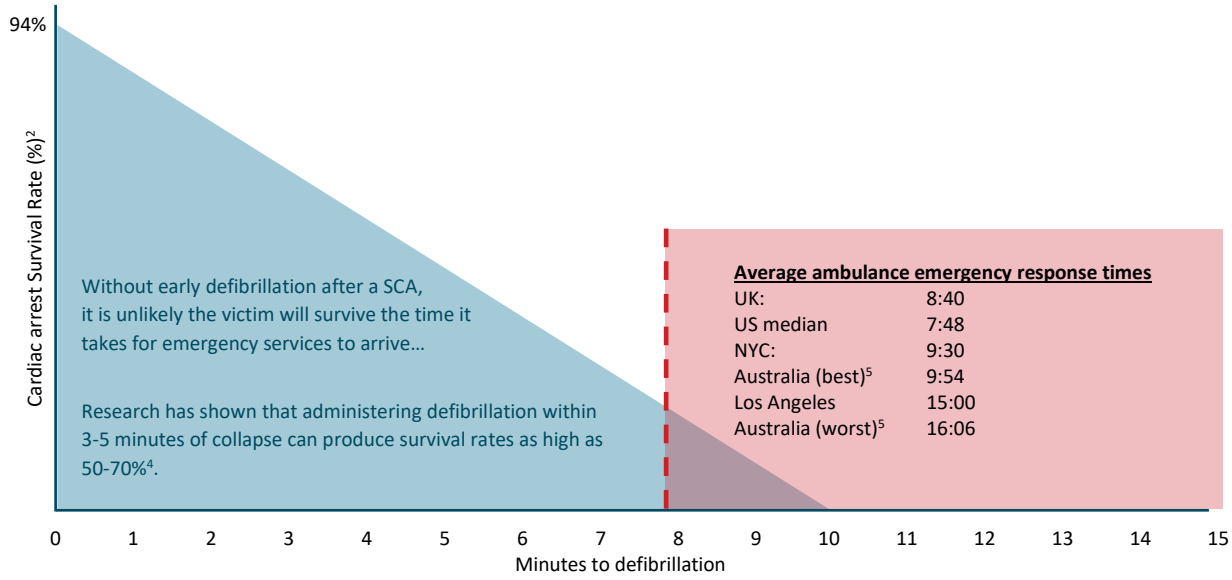
Eight minutes without defibrillation reduces survival rates to below 20%, and those who do survive suffer severe neurological impairment. At sixteen minutes, the survival rate is effectively zero.

[6] Every patient with a cardiac arrest should have an AED placed on their chest as soon as possible to identify patients with shockable rhythms. Only certain types of SCAs have heart rhythms that are shockable. However, some patients who don't initially have a shockable rhythm can later develop shockable rhythms after initial resuscitation, which an AED will detect and then treat. AEDs also help support bystanders in the provision of CPR.

[7] Out-of-Hospital Cardiac Arrest Outcomes (OHCAO) (2022)

[8] See *References - Ambulance response times.* Australian response times reported as median, compared to averages reported for other regions.

Figure 4: Ambulance response times largely exceed the SCA defibrillation window



Note: Australian response times reported as median, compared to averages reported for other locations.
Source: See *References - Ambulance response times*.

SCA costs Australia an estimated $51 billion each year

SCA costs Australia $51 billion a year

A report authored by Dr Anthony Ockwell of Economic Connections estimated the economic cost associated with deaths resulting from sudden cardiac arrest in Australia at around $51.2 billion per year. Dr Liz Paratz from the Baker Heart and Diabetes Institute looked at the direct impact of productivity losses caused by SCA on GDP. The report found the direct economic impact on Australia's GDP from lost productivity alone due to sudden cardiac arrest is $2 billion annually.

Total addressable market of 230 million in currently targeted regions

We believe a target market of 230 million devices exists in RRR's currently identified markets (Australia, New Zealand, the UK, the USA and the European Union).

In just 4 regions alone CellAED has a total addressable market of 230 million devices

The 230 million TAM doesn't include South America, Asia, the Middle East or Africa, nor applications including the military, hospitals, schools, taxis, hotels, new vehicles, government buildings, or the implementation of government regulations mandating AEDs.

Table 2: A conservative estimate puts CellAED's target market at 230 million

Category	Australia	UK	USA	France	Germany	Italy	EU-ex[9]	Size
Households w/ >=50yo	2.7m	11.3m	61.0m	14.0m	16.5m	9.5m	40.0m	155m
Businesses	2.6m	5.5m	33.2m	4.1m	5.3m	6.0m	15m	71m
Police Officers	80k	186k	708k	150k	290k	277k	883k	2.6m
Ambulance Vehicles	4,073	7,200	57,000	6,470	8,256	9,436	23,174	0.1m
Total	**5.4m**	**17.0m**	**95.0m**	**18.3m**	**22.0m**	**15.8m**	**55.6m**	**230m***

***Note:** New Zealand adds 1.1 million, bringing the total TAM to 230 million.

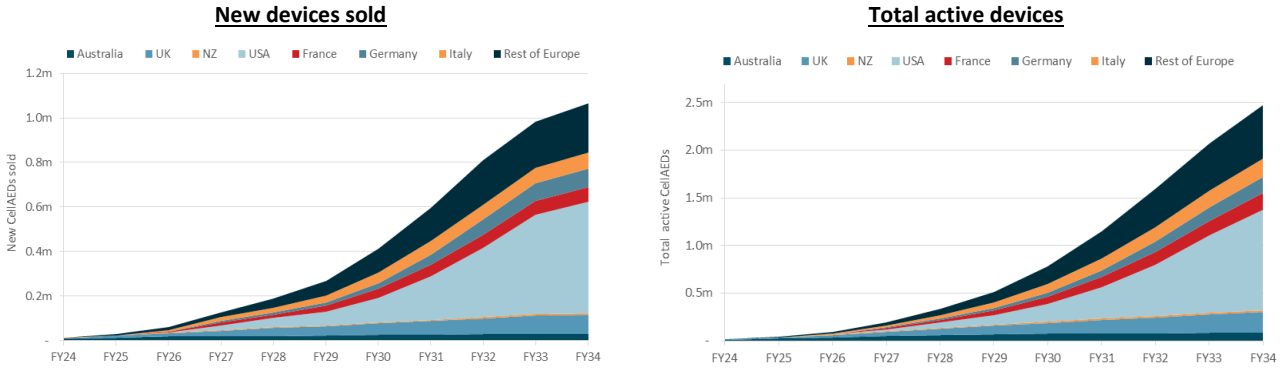
Financial returns & valuation

In FY34, RRR could generate $842 million in revenue and $208 million in free cash flow

With adequate funding (~$80 million over two years), we believe that by FY34, RRR can capture around 1.1% of its current target market, which equates to almost 2.5 million active devices. These figures would deliver around $842 million in revenue and $208 million in free cash flow.

We do not believe that these estimates are a stretch, nor do they include the +65% - 145% of additional TAM represented by other regions and use cases.

Figure 5: Capturing just 1.1% of TAM is an installed base of 2.5 million devices



Source: Venn Brown

CellAED for Life frees businesses from managing maintenance and testing schedules

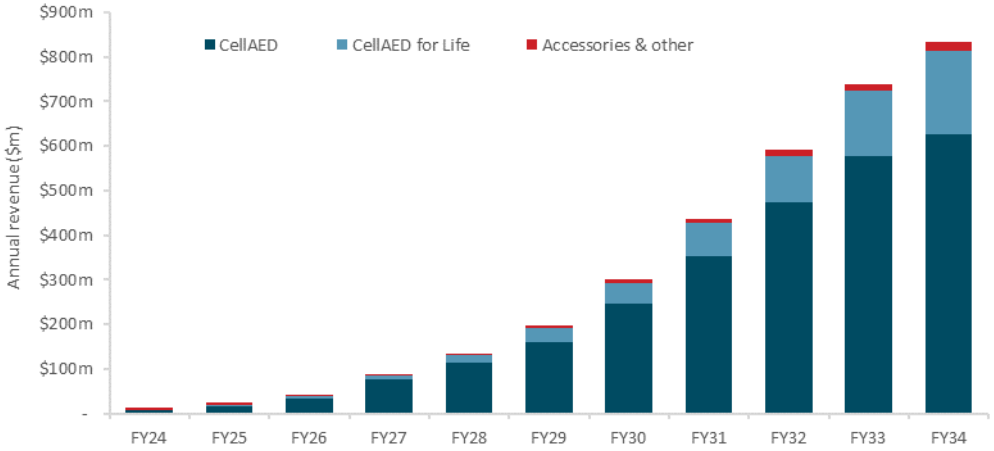
RRR reports that over 70% of CellAED buyers subscribe to the 'CellAED for Life' program. While we are cautiously forecasting a relatively high subscription churn (25% per year), the offering provides a steady, sticky and highly cash-generative revenue stream. It also offers huge upside as RRR steadily reduces its unit costs by as much as 50%. CellAED is an insurance product. Something that people buy, hoping never to use, but once they've decided to purchase one, we expect most will continue owning one, and the cheapest way is through CellAED for Life. For businesses, CellAED for Life is a set-and-forget program. With a subscription, managers don't need to manage regular testing and maintenance for individual parts (pads, batteries, and unit). Instead, RRR remotely monitors each device and emails a

[9] European Union excluding France, Germany, and Italy.

monthly status report. When the unit is about to expire or is used, RRR simply sends the business a replacement.

Figure 6: Unit sales and subscriptions will see revenue reach $832 million in FY34

CellAED and CellAED for Life are highly cash generative



Source: Venn Brown

In valuing RRR, Venn Brown assumes that it will successfully raise ~$80 million over the next two years. Without these funds, the company will either close or be unable to deliver our growth forecasts. Any early-stage company is difficult to value, and in doing so, we have used four different methodologies that converge on our fair value of $307 - $337 million, or $200 - $220 per share.

Table 3: Four valuation methodologies support a valuation of $307 - $337 million

We value RRR at $200 - $220 per share

	DCF	Private Equity 30%	Discounted EV/EBIT	Price to FY25 sales
Market cap	$316m	$389m	$381m - $490m	$310m - $412m
Per share	$206	$254	$249 - $320	$202 - $269

Source: Venn Brown

In accessing RRR, we also estimated an upside and downside case, both requiring additional capital. It's worth noting that the upside does not capture all the blue sky within the business and falls far short of the optionality management believes it can achieve.

Table 4: There is clear upside to our cash flow estimates and valuation

Our upside case doesn't include blue sky

	Market cap	Per share
Base case	$314m - $345m	$200 - $220
Downside	$92m - $107m	$60 - $70
Upside	$736m - $812m	$480 - $530

Source: Venn Brown

Growth capital

RRR needs at least $80 million to scale

Since its launch in 2018, RRR has raised $50 million in capital, a tiny amount, to bring a Class III[10] medical device to the market. Most companies would burn this capital simply during product development rather than designing, manufacturing, securing regulatory approval and commercialising a device.

RRR operates on a tiny budget and needs a proper injection of growth and scale capital to realise its full potential.

Management aims to raise US$100 million in capital over the next two to three years. This will allow it to achieve US FDA approval and commit to an appropriate marketing campaign. We've based our forward estimates on raising A$80 million over the next two years. Addition capital should accelerate the business's growth. RRR has achieved sales to date on a shoestring budget, which is insufficient to sell an entirely new consumer product in a completely new product category.

Wide protective moat

RRR has a 5 year head start on competitors

Given it's the most commonly asked question, it's worth addressing here. The idea that a competitor or new entrant could sell a cheap knockoff is impossible in any regulated market. The most effective protection CellAED has from competitors and new entrants is regulation. CellAED is regulated in more than five regions and has secured CE certification. AEDs are now Class III medical devices (the same category as pacemakers, heart valves, implantable cardioverter defibrillators (ICD), and Cochlear implants) and now require clinical trials (or in-market data) to secure CE or US FDA approval. The clinical trials alone cost millions of dollars and take *at least* two years to complete. Regulator approval adds at least another 2-3 years, giving RRR at least a five-year head start on anyone wishing to produce their own small, lightweight, ultra-portable, affordable personal defibrillator and sell it in the US or Europe.

CellAED's unique patented design makes it extremely difficult for competitors to reduce the size, weight, and cost of their devices. We expect competitors to emerge, but the innovative design and construction RRR uses will make it difficult for competitors to reduce the size, weight and price without impinging on RRR's intellectual property. We intentionally use "difficult" because once RRR proves the market for personal defibrillators exists, competitor devices will emerge.

As for a cheap Chinese knockoff, there are already a few Chinese AED manufacturers (including Mindray) that price their devices in line with US and European competitors. Mindray's AEDs sell for between A$1,900 - $2,500. If it was so easy to make a Chinese knockoff, would it not already have been done?

[10] The FDA upgraded AEDs to Class III (the highest level) in February 2020. The upgrade was first recommended in 2010 after a series of investigations found serious design and operation flaws is a meaningful percentage of AEDs in the market.

Sudden cardiac arrest

SCA is #1 or #2 leading cause of premature death worldwide

Across the western world, sudden cardiac arrest is the leading or second leading cause of premature death, killing between six and eight million people every year. Survival rates are around 10% but can be as high as 90% when CPR and defibrillation are applied within the first minute of the arrest.

Table 5: Sudden cardiac arrest at a glance

Factor	Outcome[11]
Gender split (male/female)[12]	66% / 34%
Age (average / median)	Male: 64/67 Female: 67/71
SCA occurs at home	74 - 80%
Witnessed by bystander*	37%
Receive bystander CPR*	~40%
Received bystander defibrillation	5.2%
Received bystander defibrillation in public SCA**	11.3%
Survival to hospital discharge	9%
% of survivors discharged with positive neurological outcomes (CPC 1–2)***	81%
Survival rate with defibrillator:	<1 min: 90% >10mins: ~0%
Average time taken for ambulance to arrive****	7:50 – 16:00

40% of SCA patients receive CPR

Only 5% of SCA patients receive bystander defibrillation

Note: Statistics vary between countries and years. Most figures are drawn from the US CARES 2022 Annual Report.
* A SCA is only considered witnessed if someone sees the attack occur. If someone finds the patient within seconds of the arrest, it is not considered witnessed.
** Only ~14% of SCAs occur in a public place. AED use by bystanders in private places occurs in less than 1-2% of cases. Most likely due to the lack of AEDs in private places.
*** CPC = Cerebral Performance Category. CPC 1 means the patient has good cerebral performance and can lead a normal life. CPC 2 means the patient has a moderate cerebral disability but can function independently. See *Appendix – Other notes Table 59* for more details.
**** See Figure 12 below
Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022, Out-of-Hospital Cardiac Arrest Outcomes (OHCAO) (2022)

Defibrillation is an essential part of the survival chain

Sudden cardiac arrest occurs when the heart unexpectedly stops beating effectively. When this occurs, blood ceases to flow around the body, and vital organs are starved of oxygen and energy. Sudden cardiac arrest can occur because of an interruption in the regular electrical impulses that occur in the heart to facilitate the pumping action, or it may involve a mechanical issue resulting in an ineffective pumping mechanism of the heart. In cases where the cardiac arrest is caused by abnormal electrical rhythms called ventricular fibrillation or pulseless ventricular tachycardia, a defibrillator can provide a counter-shock to stop the

[11] These are typical values, but they vary depending on numerous factors. Rarely are outcomes better than those shown.

[12] Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

abnormal rhythm, allow a normal rhythm to return, and restore normal pumping action of the heart.

SCA and Heart Attack: Serious but different

A heart attack is caused by a circulatory blockage preventing blood flow to the heart

Sudden cardiac arrest (SCA) and heart attack (myocardial infarction) are both serious medical emergencies but are different conditions and require different treatments. A heart attack occurs when blood flow to the heart itself is blocked, which can damage or destroy heart tissue. Heart attacks are often caused by plaque buildup in the arteries that supply blood to the heart muscle itself (ie the heart's blood supply, not blood flowing into the heart to be pumped around the body). Heart attacks can be fatal by causing cardiac arrest, but they are often treatable with medications, coronary artery interventions (like stents to reopen the blockage), and sometimes surgery. Heart attacks can occur without warning, but they can also come on slowly over several hours. Someone suffering a heart attack without cardiac arrest will have a beating heart and remain conscious, while a SCA will render the sufferer unconscious within seconds.

Table 6 below summarises the key differences between sudden cardiac arrest and heart attack.

Table 6: Sudden Cardiac Arrest versus Heart Attack

SCA is when the heart stops pumping blood effectively

	Sudden Cardiac Arrest	Heart Attack
Definition	The heart suddenly stops beating properly. Without blood flow to vital organs, death occurs in minutes without treatment.	Blood flow to the heart muscle is blocked. There is an injury to the heart muscle causing dysfunction. A heart attack is a circulation problem.
Symptoms	Loss of consciousness, absent or abnormal breathing, no pulse.	Chest pain, shortness of breath, nausea, light-headedness.
Treatment	CPR, defibrillation and treatment of the underlying cause.	Angiography and angioplasty (stents to open the blocked artery), medications and sometimes surgery
Survival rate	~90% if defibrillated within the first minute, declining at 10% per minute. Fewer than 10% overall.	Survival rates for people hospitalised with heart attacks are approximately 90%[13] - 97%[14].

[13] Recent trends in the incidence, treatment, and outcomes of patients with STEMI and NSTEMI. (2011)

[14] Heart failure after myocardial infarction in the era of primary percutaneous coronary intervention: Mechanisms, incidence and identification of patients at risk. (2017)

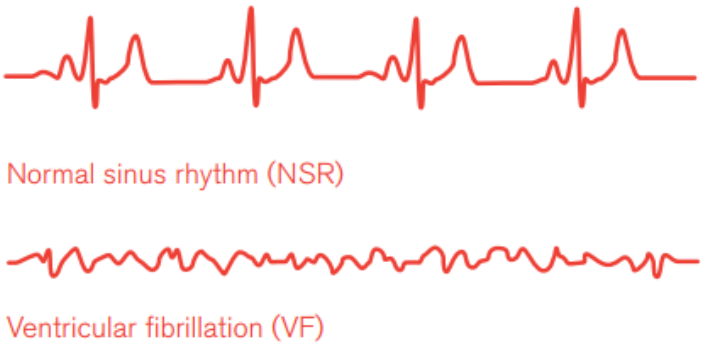
Most SCA are caused by an electrical malfunction in the heart

Most SCAs are caused by cardiac arrhythmia[15] , which is itself caused by an electrical malfunction in the heart. The heart is made of a specific type of muscle cell known as "excitable cells," which react to electric signals. Within the heart, a specialised region called the sinoatrial (SA) node serves as the heart's inherent pacemaker. This node produces electric impulses that systematically travel through the heart's electric system, maintaining a "normal sinus rhythm." This sinus rhythm coordinates the contraction and expansion of the heart's four chambers, thereby pumping blood around the body.[16]

In many instances of Sudden Cardiac Arrest (SCA), the heart's electric rhythm can turn erratic and disordered, leading to the heart's failure to beat effectively. The most common outcome resulting from a shockable SCA is the uncoordinated contraction of the ventricular cardiac muscles, causing the heart to tremble or spasm in an uncoordinated way, resulting in blood not being pumped around the body. The underlying cause of VF at the cellular level is not fully understood, but most VF cardiac arrest is caused by myocardial ischemia secondary to coronary artery disease.

During a SCA, the heart's chaotic rhythm is ineffectual at pumping blood around the body

Figure 7: The chaotic VF rhythm prevents the heart from pumping blood



Source: Philips

Age, sex, smoking and body weight are key SCA risk factors

A SCA can occur for a variety of reasons. The common causes include ischemic heart disease, myocardial infarction, primary arrhythmia, drug overdose, pulmonary embolism, and trauma. Ventricular fibrillation and, subsequently, cardiac arrest and death can also occur in what would be considered a healthy heart. There often aren't any warning signs before someone suffers a sudden cardiac arrest, and patients can go from appearing perfectly fine to collapsing unconscious in a matter of seconds.

[15] A cardiac arrhythmia, also known as an irregular heartbeat, is a condition where the heart beats abnormally due to a problem with the electrical signals that coordinate the heartbeats. This can cause the heart to beat too fast (tachycardia), too slow (bradycardia), or irregularly.
While many people with heart arrhythmias have no symptoms at all, some may experience palpitations, a sensation of the heart skipping a beat, a racing or slow heartbeat, or an irregular heartbeat. Arrhythmias can be caused by various factors including coronary heart disease, abnormal heart valves, cardiomyopathy, high blood pressure, thyroid problems, obstructive sleep apnoea, certain medications, heavy alcohol use and conditions that can be inherited or present at birth.

[16] The heart has four chambers (two atria and two ventricles) which contract in a sequenced and coordinated way to pump blood into the lungs and around the body. Blood enters the right atrium from the body, then passes into the right ventricle where it's then pumped into the lungs. In the lungs, blood picks up oxygen and releases carbon dioxide. The oxygenated blood returns to the left atrium then passes into the left ventricle where it is then pumped to the rest of the body. The SA node ensures that the four chambers expand and contract with the right timing and sequence to pump blood. If the contractions of each chamber don't occur in sequence, then the pump fails, and blood isn't moved around the body.

A SCA is often the first sign someone is at risk of a SCA

Numerous factors impact the likelihood of someone experiencing a sudden cardiac arrest; the most impactful ones are summarised in Table 7.

Table 7: Health and lifestyle factors can significantly increase your chance of SCA

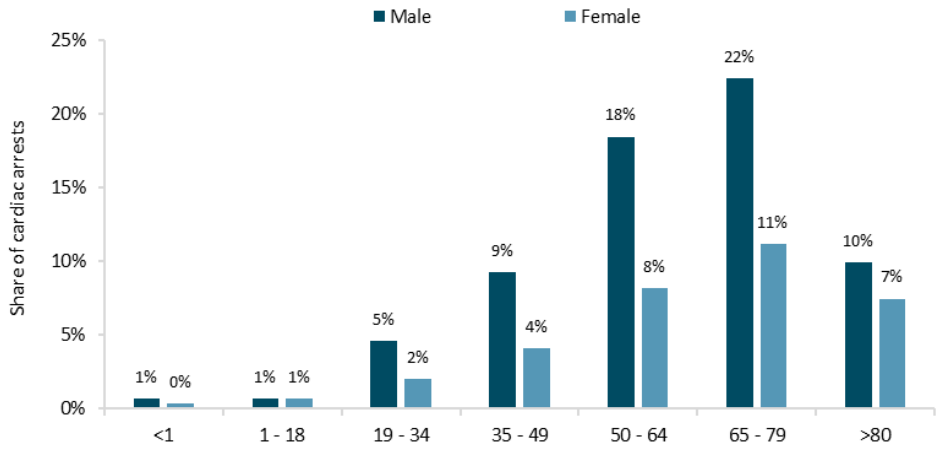
Risk factor	Details
Age	The risk of SCA increases with age, with 58% of SCA occurring in people aged 65 years old or above.
Sex	Men are almost twice as likely as women to have a SCA (66% vs 34%).
Family history	A family history of SCA or cardiac events such as heart attacks indicates a potential genetic predisposition to heart conditions that can lead to SCA.
Smoking	Smokers are three times more likely to die from SCA.
Obesity	Obese men are 2.6 times more likely to have a SCA compared to normal-weight men. Obese women are 5.8 times more likely than normal-weight women to have a SCA[17].
Other health issue	Other underlying health issues can increase the risk of SCA, including high blood pressure, high cholesterol, and diabetes. Lack of physical activity also increases the risk of SCA.

Before defibrillators, SCA were almost always fatal

The cause of cardiac arrest varies by population and age, most commonly occurring in those with a previous diagnosis of heart disease. Most cardiac arrests are sudden and unexpected, which, before the invention of defibrillators and CPR, were uniformly fatal. However, bystander cardiopulmonary resuscitation (CPR) and advances in emergency medical services have proven life-saving interventions. Despite these improvements, fewer than 10% of those who experience a cardiac arrest leave the hospital alive, and most who do will suffer some level of neurological impairment (see *SCA Survival Rates* below).[18]

Figure 8: Around 60% of sudden cardiac arrests occur in people aged 65 or older

~60% of SCA occur in people aged 65 or old



Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

[17] Sudden cardiac death and obesity (2014)

[18] Trends in Short and Long Term Survival Among Out-of-Hospital Cardiac Arrest Patients Alive at Hospital Arrival (2014)

Rates of sudden cardiac arrest

SCA kill around 356,000 Americans each year

Sudden cardiac arrest is the first or second highest cause of premature death in almost every developed country around the world. Every year, approximately 28,000 Australians, 365,000 Americans and 376,000 Europeans die from sudden cardiac arrest. Globally, SCA kills between six to eight million people annually. It's not surprising that the American Heart Association[19] considers cardiac arrest a public health crisis.

As shown in Table 8 and Figure 9 below, sudden cardiac arrest is the second highest cause of death (second only to all cancers), accounting for around 12 – 18% of all deaths in the US, UK, Australia, Germany and France. SCA kills more people than the five most prolific types of cancer combined (lung, colorectal, pancreatic, breast, prostate).

In the US, sudden cardiac arrest kills roughly the same number of people each year as Alzheimer's, firearms, breast cancer, cervical cancer, colorectal cancer, diabetes, HIV, house fires, motor vehicle accidents, prostate cancer and suicides combined [20].

Table 8: Each year, sudden cardiac arrests kill between 6 - 8 million people

SCA kill more people each year than the top five cancers combined

Cause of Death	United Kingdom	United States	Australia	Germany	France
All Cancers	166,000	606,520	50,000	240,000	157,400
SCA	**95,153**	**356,000**	**25,000**	**65,000**	**48,945**
Dementia	66,000	122,019	14,000	59,500	33,500
Stroke	36,000	146,383	10,000	40,000	30,200
Lung Cancer	35,000	142,670	9,000	45,000	31,200
Colorectal cancer	16,000	53,200	5,300	25,700	17,400
Breast Cancer	11,500	2,170	3,000	18,570	11,900
Road Accidents	1,800	38,800	1,200	3,046	3,500
Firearms	115	39,682	229	815	1650
All Deaths from all causes	616,014	2,854,838	169,301	939,520	613,900

Note: Figures are drawn from a wide range of sources across 2018 – 2020, and as much as possible, do not include the impact of COVID-19.[21]
Source: See References - Mortality and Disease statistics

Time taken to defibrillate is a critical factor in survival rates

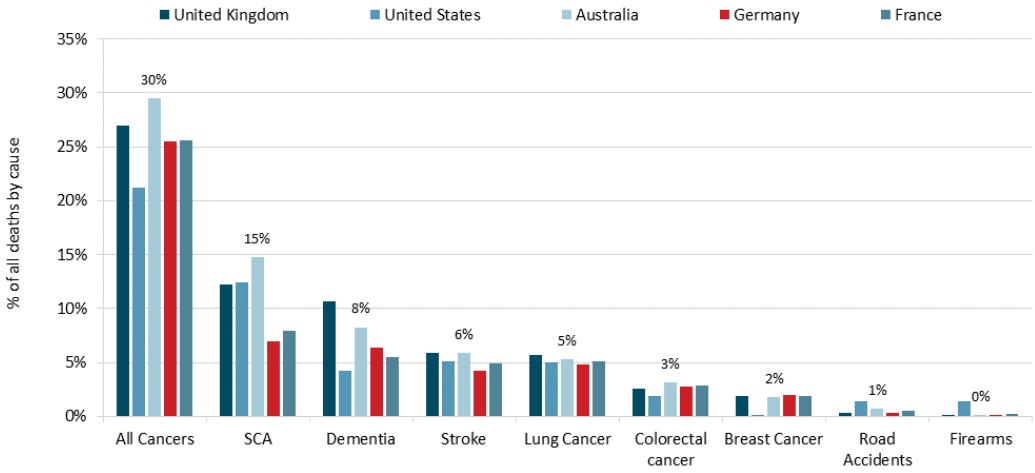
While there is some variation between countries and years, there is a persistent pattern with SCA appearing as the first or second highest cause of death across the developed world.

[19] Heart Disease and Stroke Statistics – 2022 Update: A Report from the American Heart Association

[20] https://cpr.heart.org/en/resources/cpr-facts-and-stats

[21] Inconsistences in the collection, reporting and categorising of medical incidents and causes of death complicates estimating the instances of OHCA. For instance, estimated deaths by OHCA in Australia vary depending on the source. Heart Foundation of Australia: ~25k, St John Ambulance of Victoria: ~30k, Heart Research Australia: >20k, Australian Genetic Heart Disease Registry: 22-33k, Medical Journal of Australia: >25k.

Figure 9: SCA is the highest or second-highest cause of premature death in most developed countries



Source: See *References - Population and demographic statistics*

SCA Survival Rates

Survival rates can be as high as 90% with early defibrillation

Rapid or immediate defibrillation and CPR are critical for the survival of someone suffering a sudden cardiac arrest. The biggest determinant of whether someone survives a sudden cardiac event is the time taken for them to receive defibrillation. According to a study published in the New England Journal of Medicine[22], a person experiencing sudden cardiac arrest needs to receive CPR and defibrillation within minutes[23] to maximise chances of survival.

*"**Decreasing the time to treatment is crucial for improving outcomes in cases of cardiac arrest.** As stated in American and European guidelines, the most important response measures that currently can be taken outside a hospital setting are recognising early that a cardiac arrest is occurring, placing an alarm call, performing cardiopulmonary resuscitation (CPR), and performing defibrillation.*

*The **main effect of CPR is probably indirect** in that it may prolong the time window for defibrillation. **The sooner defibrillation can be performed, the better the chance of survival."***

Source: Early cardiopulmonary resuscitation in out-of-hospital cardiac arrest (2015))

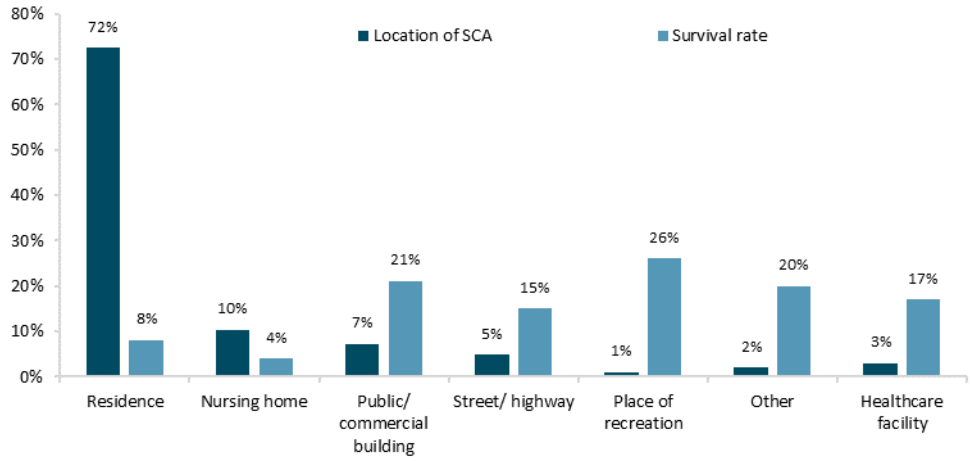
Better access to AEDs means more lives saved

Despite the vast majority of OHCAs occurring in the home, very few homes have a defibrillator. This is because, until now, no manufacturer has made an affordable, easy-to-use, easy-to-maintain AED for the home market.

As shown below in Figure 10, in the US in 2022, 72% of SCAs occurred in people's homes (80% in the UK[24]), the least likely place to find a defibrillator. Fewer than 15% of SCAs occur in public places where most public use automated external defibrillators are located.

[22] Early cardiopulmonary resuscitation in out-of-hospital cardiac arrest (2015)
[23] Outcomes of Rapid Defibrillation by Security Officers after Cardiac Arrest in Casinos (2000)
[24] Out-of-Hospital Cardiac Arrest Outcomes (OHCAO) (2022)

Figure 10: Between 70 - 80% of out-of-hospital cardiac arrests occur in the home



Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

70% - 80% of cardiac arrests occur at home

Survival rates for people who experience sudden cardiac arrest (SCA) vary widely depending on several factors, but defibrillation is a crucial part of the chain of survival. Among patients with shockable rhythms, SCA survival rates can be as high as 90% if defibrillation occurs within the first minute following the arrest. If defibrillation occurs within 3-5 minutes, then the survival rate can be as high as 70%[25 & 26], but as time passes, the chances of survival decrease rapidly. Survival rates reduce by approximately 10% for every minute without CPR or defibrillation, reaching effectively zero after ten minutes. As shown in Figure 11 below, aside from nursing homes (where age plays a major factor in mortality rates), a person's home is the most dangerous place to suffer a SCA. This is especially concerning given that 70-80% of all SCAs occur at home (see Figure 10).

The importance of ready access to automated external defibrillators (AEDs) in the event of a SCA is probably most evident when looking at Figure 11 below. Despite patients who have cardiac arrests at home receiving similar rates of CPR (34%) as those in other public locations (transport centres (39%), and street or highway (27%)), the survival rate of at-home SCA is just 8%, less than half the rate of SCAs occurring in transport centre (20%) and around half of those occurring on the street (15%). The key difference is the availability of public access AEDs in these public locations compared to in the home.

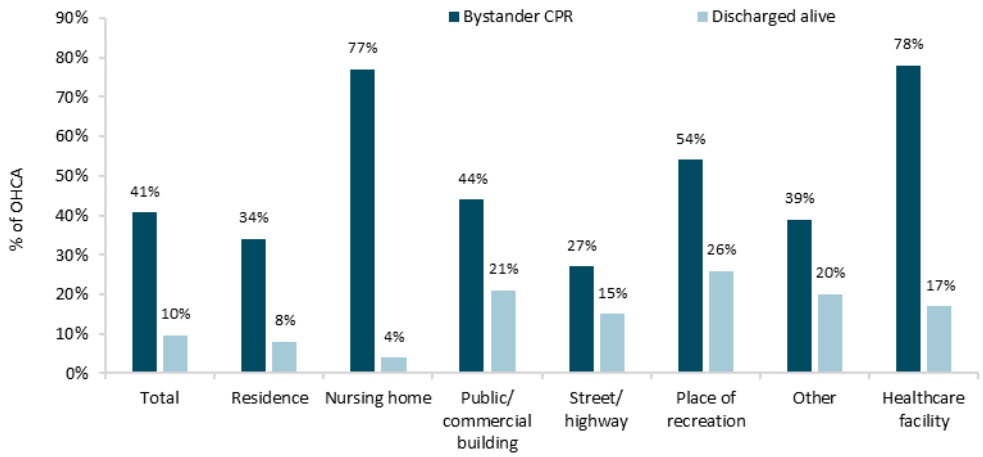
SCA survival rates decrease ~10% for every minute without defibrillation

While some of the higher out-of-home survival rates might be due to a bias towards healthier, more mobile people (and therefore making them more likely to survive a SCA) in these outdoor settings, when adjusting for age (thereby reducing the over-representation of nursing home morbidities), it is clear that the most dangerous location to suffer a SCA is at home.

[25] The overall health of the individual, the cause of the cardiac arrest, and any pre-existing conditions can influence survival rates. Some underlying medical conditions may reduce the likelihood of survival.

[26] Ibrahim WH. Recent advances and controversies in adult cardiopulmonary resuscitation. Postgrad Med J. 2007 Oct;83(984):649-54.

Figure 11: SCA survival rates are around 10%, but only 8% when they occur at home



Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

The home is the deadliest place to have a SCA

A critical factor that lowers survival rates of at-home SCA patients is the time taken to defibrillate patients, which is itself a result of:

1. The typical time taken for ambulances to respond to emergencies exceeds the 10-minute survival window (see Figure 12); and
2. Low rates of bystander defibrillation, primarily due to the unavailability of defibrillators in the home.

Ambulance response times are not fast enough to save +90% of SCA victims

As shown in Figure 12 below, the average ambulance response time across major global capital cities ranges from eight minutes forty seconds (London) to over sixteen minutes (Sydney)[27]. This delay and the lack of availability of defibrillators see the survival rate of at-home SCA at 8% (below the overall average of less than 10%).

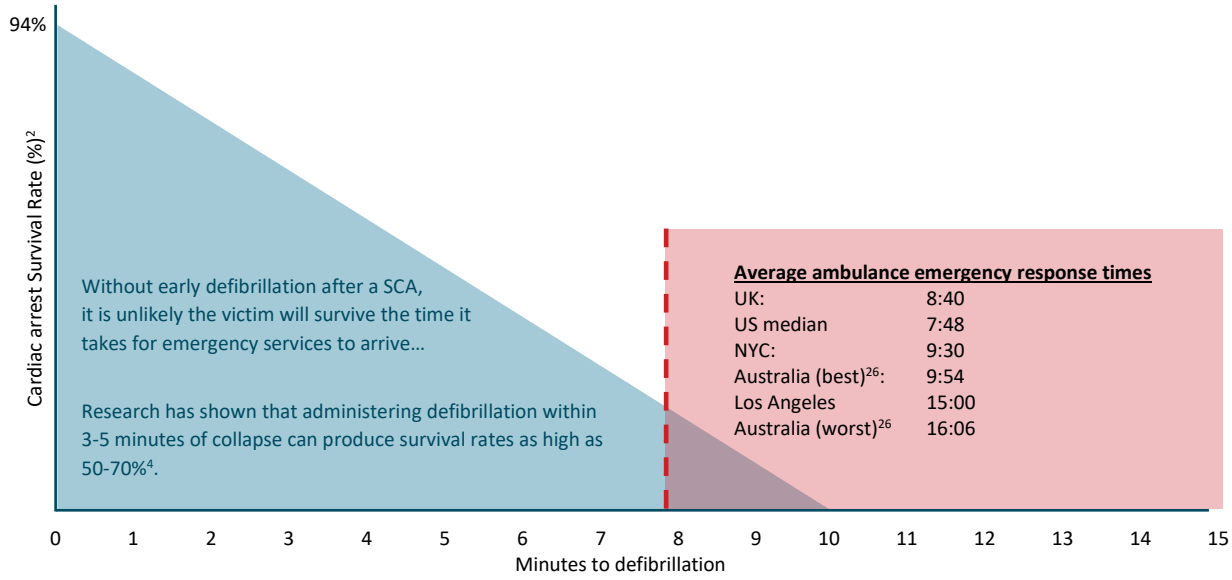
Eight minutes without defibrillation reduces survival rates to below 20%, and those who do survive suffer severe neurological impairment. At sixteen minutes, the survival rate is effectively zero.

"the greatest contribution that AEDs can make towards improving survival from cardiac arrest lies outside hospital-for use in public places by persons who are not healthcare professionals."[28]

[27] See *References - Ambulance response times*

[28] Public Use of AEDs in Europe: Where Are We Now and Where Are We Going? (2003)

Figure 12: Ambulance response times largely exceed the SCA defibrillation window



Note: Australian response times reported as median, compared to averages reported for other locations.
Source: See *References - Ambulance response times*. Also, see footnotes 29

Fewer than 30% of SCA patients receive in-field defibrillation

According to the CARES 2022 Annual Report, of the nearly 147,700 logged SCA events, only 29% of patients received in-field defibrillation (from either bystanders or first responders/EMS). This low figure is likely a combination of:

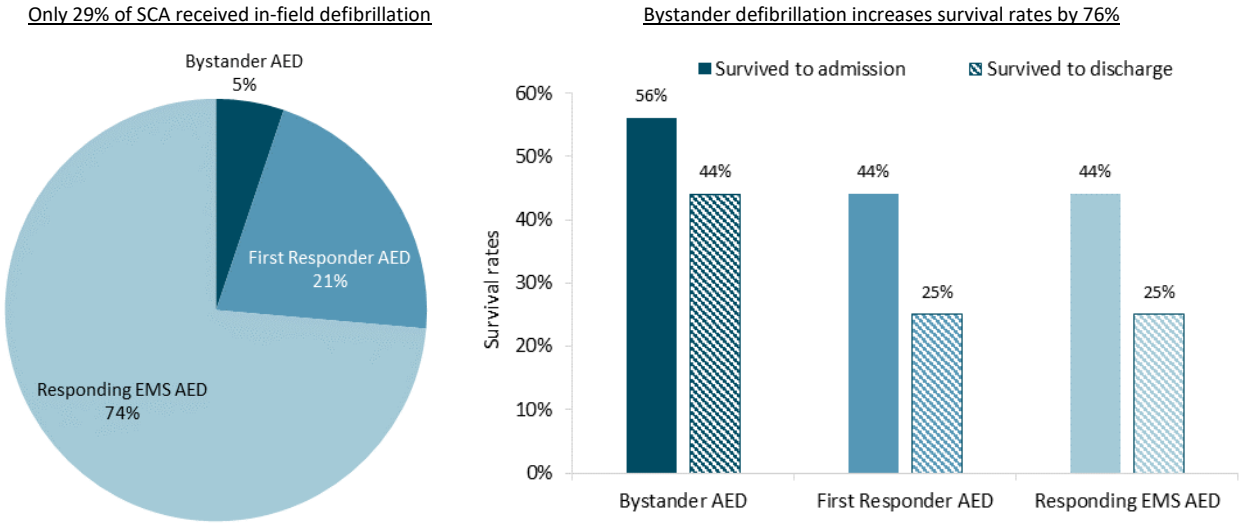
1. ambulances arriving too late to defibrillate;
2. bystanders not having access to an AED or not knowing an AED was nearby; or
3. bystanders being reluctant to use one.

Only 5% of SCA patients receive bystander defibrillation

As shown below in Figure 13, early defibrillation by bystanders increases survival rates by 76% to 44% compared to the majority who don't receive defibrillation until first responders or EMS personnel arrive. Unfortunately, of the patients defibrillated, only 5% were treated by bystanders, with the remaining 95% not treated until first responders or emergency medical personnel arrived on the scene. So, the survival rate of 95% of patients who receive in-field defibrillation is 25% (administered by EMS or first responders), but this increases to 44% for the 5% of patients who receive defibrillation by a bystander.

[29] See *References - Ambulance response* times. Australian response times reported as median, compared to averages reported for other regions.

Figure 13: Survival rates increase by 76% when bystanders apply defibrillation



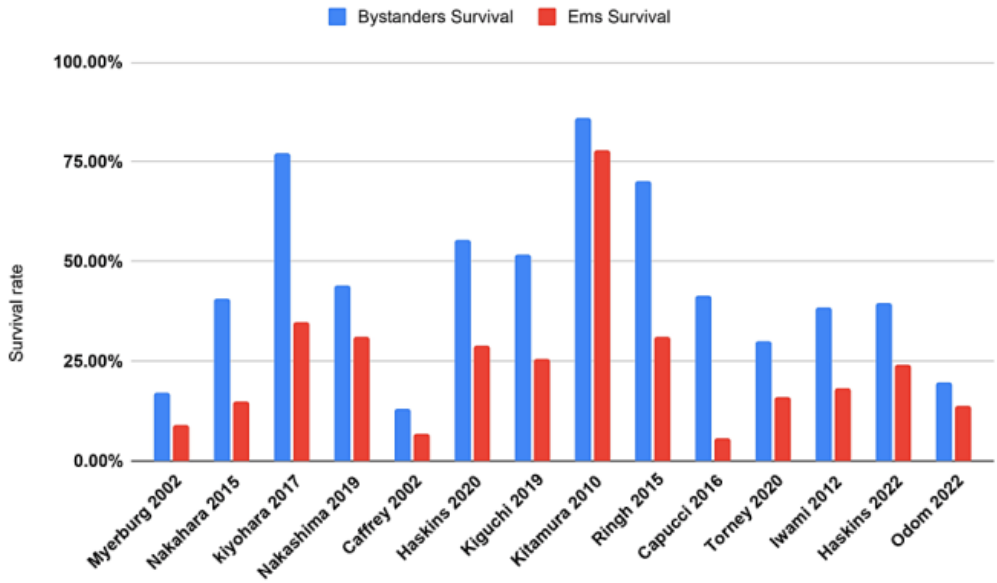
Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

Bystander defibrillation can increase survival rates by 2-3x compared to EMS defibrillation alone

The higher survival rates resulting from bystander-initiated defibrillation were confirmed in a comprehensive literature review published in the medical journal Cureus in October 2023 (The Role of Automated External Defibrillator Use (2023)). The paper conducted a systematic review of the data from 30 global studies published between 2001 and 2022 examining the role of bystander and emergency medical service (EMS) interventions during SCA, primarily focusing on the use of AEDs. The conclusion was that the rapid application of CPR and AEDs, especially by bystanders, can increase SCA survival rates by two to three times over EMS-applied defibrillation alone.

Figure 14: Bystander defibrillation can increase survival rates by 2-3 times

Australian study found the deployment of public access AEDs delivered a 5x increase in survival rates



Source: The Role of Automated External Defibrillator Use (2023)

These trends were further confirmed by an Austrian study published in March 2019 (Automated external defibrillator use in out-of-hospital cardiac arrest: Current limitations and solutions (2019)). The outcome of out-of-hospital cardiac arrests (OHCA) was observed before and after the deployment of public access AEDs and recorded a more than five-fold increase in survival at hospital discharge, from 4.3% before the installation of AEDs to 27% afterwards.

Critically, survivors of SCA often suffer ongoing health impairment. The longer the period before defibrillation, the greater the likelihood the patient experiences severe adverse health effects associated with cardiac arrest. These include severe physical or cognitive impairment, such as:

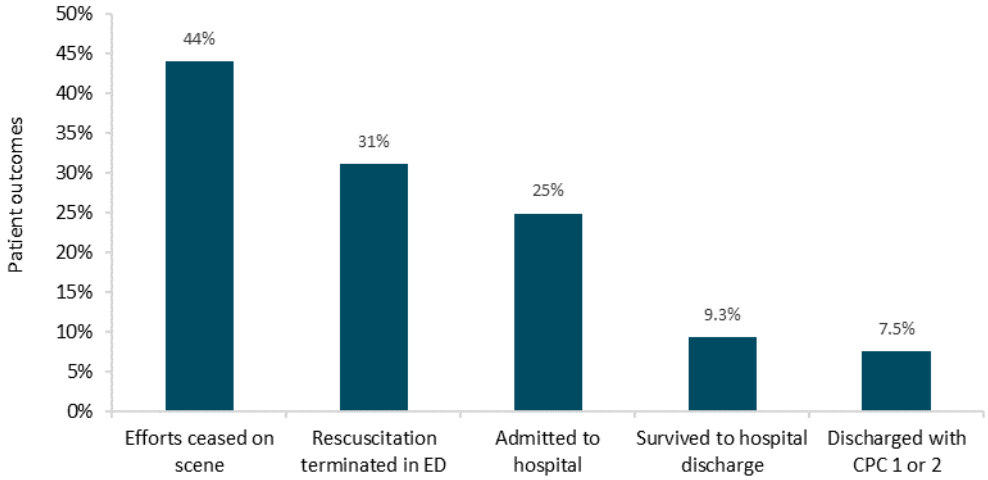
Early defibrillation improves long term health outcomes

- movement disorders;
- memory loss or deficiency;
- speech difficulties;
- weakness or immobility; and
- problems with attention, concentration, and visual-motor skills.

It's estimated that more than half of the patients who survive cardiac arrest and are discharged from the hospital are affected by a decrease in physical or neurological abilities. As shown in Figure 15 below, according to the CARES 2022 Annual Report, of the 9.3% of SCA patients discharged from hospital, 20% suffered severe cerebral disability, with the remaining 80% being classified as CPC 1 or 2, indicating either normal cerebral function or moderate cerebral disability (see *Appendix – Other notes Table 59* for more details).

Figure 15: Delayed defibrillation leads to permanent neurological damage

Early defibrillation reduces negative neurological outcomes



Note: CPC = Cerebral Performance Category. CPC 1 means the patient has good cerebral performance and can lead a normal life. CPC 2 means the patient has a moderate cerebral disability but can function independently. See Appendix – Other notes Table 59 for more details.
Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

In summary, the survival rates for people who experience sudden cardiac arrest are highly dependent on the time it takes to apply defibrillation. Immediate defibrillation significantly improves the chances of survival and reduces adverse neurological outcomes. While CPR and quickly responding emergency responders also play a role, the most consequential and impactful factor is the rapid application of a defibrillator. Given the vast majority of SCAs

occur in homes, a critical way to improve SCA survival rates is to have AEDs readily accessible for all cardiac arrests when they occur, especially in or around people's homes.

What role does CPR play?

Within minutes of losing oxygenated blood flow, the body's organs begin to sustain serious (and eventually catastrophic) damage. The heart and brain are particularly susceptible, with brain cell death and permanent cognitive damage starting approximately two minutes after losing blood flow.

CPR extends the defibrillation survival window

Despite what you see in films and television, CPR alone is unlikely to revive someone suffering a sudden cardiac arrest and heart fibrillation. That said, CPR is important for all cardiac arrest victims, even those without shockable rhythms and can help delay the onset of cell damage and death, effectively buying the patient more time before defibrillation is applied. Current resuscitation guidelines[30] recommend CPR be started immediately and be immediately recommenced after a defibrillation shock.[31] A defibrillator should be attached and activated as soon as it's available, as they actually support the provision of CPR with voice prompts and metronomes to keep attendees pushing at the correct rate. Additionally, sometimes, patients with an initial non-shockable cardiac rhythm can develop a shockable rhythm with good-quality CPR.

All AEDs now provide voice prompts to guide operators on how and when to do CPR, which is a critical component of the chain of survival. Only certain heart rhythms are shockable, but all SCA patients benefit from CPR.

The role of public access defibrillators

The effectiveness of public-access defibrillators is a topic of debate within the industry. There are circumstances where they reliably save lives, specifically in locations such as restaurants, bars and airports, with staff or officials trained in their use. Figures vary, but industry experts estimate that between 10-35% of public AEDs are not in working order[32], with the most common cause being a flat battery.

10-35% of public AEDs don't work

The other major challenge of public access AEDs is that bystanders don't know where they are. If it's a choice between starting CPR and running off to find an AED, most people will start CPR. A senior emergency physician told Venn Brown that if an AED isn't in line-of-sight of an incident, then it's very unlikely to be retrieved and used. Quite simply, there aren't AEDs in the vicinity of over 85% of OHCAs.

[30] Guideline 7 – Automated External Defibrillation in Basic Life Support (2021)

[31] Some research suggestions the immediate recommencement of CPR following an AED shock actually induces a return of ventricular fibrillation (VF). See Chest Compressions Cause Recurrence of Ventricular Fibrillation After the First Successful Conversion by Defibrillation in Out-of-Hospital Cardiac Arrest (2009). Almost every national guidelines committee in the world has debated this point, assessed the science suggesting this may be a thing, and then recommended that CPR be initiated after each shock from a defibrillator. According to experts it is very clear that pauses in CPR caused by people checking for a pulse after shocking are far more deleterious than any occurrence of VF recurrence that may or may not occur with CPR.

[32] In the US, between 2005 and 2009, the annual number of problems reported with AEDs increased by 85%. Medical-device reports are issued by manufacturers whenever they think one of their units may have malfunctioned, contributing to a death or serious injury. In that five-year period there were more than 28 000 such report, one malfunction for every 50 devices in the US. More than 750 of the reports followed a death. https://spectrum.ieee.org/the-shocking-truth-about-defibrillators

CellAED aims to change this paradigm. The CellAED is designed to be in people's homes, businesses, cars, and backpacks when they travel. It's affordable, small, lightweight, and completely mobile. RRR designed the CellAED to not only be on site where 80% of SCAs occur, but it can also be swiftly taken to an incident near someone's home or place of work, or neighbourhood as in the case of GoodSAM (see *Clinical trial: FIRST*). Existing AEDs have not been marketed to consumers for personal use as they are expensive, large, heavy, intimidating, and require regular maintenance.

The cost of sudden cardiac arrests

The estimated economic cost to Australia of SCA is $51-60 billion per year

A report authored by Dr Anthony Ockwell of Economic Connections, supported by the Heart of the Nation charity[33], estimated the economic cost associated with deaths resulting from sudden cardiac arrest in Australia at around $51.2 billion per year. This was based on the 22,689 deaths from the 25,413 SCAs in Australia in 2017-18. Dr Ockwell calculated this figure by applying the same methodology used by the Australian government's National Road Safety Strategy 2011-2020, which estimated the cost to society of trauma and death arising from road accidents.

Table 9: Estimated annual cost to Australia of SCA is $50-60 billion

Study	Region	Cost
Economic Connections	Australia	$51.2 billion
Australian Government - Value of life year	Australia	$60.2 billion
Baker Heart and Diabetes Institute	Australia	$2 billion (GDP only)
Baker Heart and Diabetes Institute	US, UK, Australia, Germany & France	$46 billion (GDP only)

SCA is estimated to have a $2 billion direct impact to annual Australian GDP

Another approach is to apply the value of life statistics published yearly by the Australian government's The Office of Impact Analysis[34]. Using the value of a statistical life year of $235,000 and a discount rate of 3% (both published in the Office's most recent October 2023 update[35]) and the average premature death of 12 years (age life expectancy less median age of SCA)[36], the value of each life lost is approximately $2.4 million, putting the total annual cost of lives lost to SCA each year at $60.2 billion.

Another study led by cardiologist Dr Liz Paratz from the Baker Heart and Diabetes Institute (The economic impact of sudden cardiac arrest (2021)) published in the journal 'Resuscitation' looked at the direct impact on GDP of productivity losses caused by SCA. The report found the direct economic impact on Australia's GDP from lost productivity due to sudden cardiac arrest is $2 billion annually. Dr Paratz attributes the significant economic impact to the high rates of cardiac arrest, the meagre survival rates and that the condition often affects people during their working lives. Extrapolating this $2 billion cost across just the US, UK, Australia,

[33] Heart of the Nation was founded by the "Original Yellow Wiggle" Greg Page, after he survived a SCA. Greg's survival was in part due to the rapid application of a defibrillator.

[34] The Office of Impact Analysis is under the Department of Prime Minister and Cabinet.

[35] https://oia.pmc.gov.au/resources/guidance-assessing-impacts/value-statistical-life

[36] Out-of-Hospital Cardiac Arrest Outcomes (OHCAO) (2022)/)

Germany, and France suggests that SCA's direct productivity cost to GDP is around $46 billion a year.

During Dr Liz Paratz's group's study period, they found just 7% of SCA patients survived to leave hospital, with only 6.5% surviving 12 months beyond the arrest.

The report identified the following activities as having led to improvements in survival around the globe:

1. successful public resuscitation campaigns;
2. clinical quality registries
3. standardised chain of survival protocols
4. availability of public AEDs; and
5. advances in clinical care.

Automated External Defibrillator (AED)

AEDs are just 1 of 5 main types of defibrillator

Anyone who's watched a medical drama on television has seen a doctor yell "Clear!" and then use the paddles of a defibrillator to shock a patient to restart their heart. Medical shows tend to show manual external defibrillators - MED. An Automatic External Defibrillator (AED) is a simplified, automated, portable, and more affordable version designed to be used outside of hospitals by laypeople with little or no training.

Figure 16: There are more than 60 AEDs on the market across the US and Europe

Note: Images are not to scale. The CellAED is a fraction of the size of all other devices.
Source: FDA.gov, manufacturer websites

Defibrillation involves passing a controlled electrical current through a patient's heart to interrupt the arrhythmia and return the heart to its normal rhythm. AEDs deliver the shocks (which generate the current) via two sticky pads (electrodes) attached to the patient's chest. The pads replace the paddles you've seen on television.

There are five main types of defibrillators:

1. **Manual external defibrillators (MED)**. These devices are designed to be used by medical personnel with special training. They allow healthcare professionals to see the electrical rhythm of the patient's heart and make their own determination of

rhythm type. Users determine when to deliver electrical therapy and at what energy level. These devices can provide defibrillation in patients with cardiac arrest and electrical cardioversion for patients with arrhythmias who are not in cardiac arrest.

Most public AEDs are full-automated requiring little interaction once attached to the patient

2. **Manual internal defibrillators:** Similar in concept to manual external defibrillators, only they're designed for internal use, typically during open heart surgery, with electrodes (paddles) applied directly to the patient's heart.
3. **Semi-automated:** Semi-automated AEDs analyse the heart's rhythm. If an abnormal heart rhythm is detected and the rhythm is deemed shockable, it prompts the user to push a button, sending an electrical defibrillating shock to the patient.
4. **Fully automated defibrillators**: Fully automated AEDs analyse the heart's rhythm, and if an abnormal heart rhythm is detected and the rhythm is deemed shockable, the device will automatically deliver a defibrillation shock to the patient. Once the adhesive pads/electrodes are attached to a patient, a fully automated defibrillator does not require any manual intervention. CellAED is a fully automated AED.
5. **Implantable cardioverter defibrillator**: An ICD is a battery-powered device placed under the skin that keeps track of your heart rate. If an ICD detects a heart rhythm that is chaotic or much faster than normal, it will send an electrical shock to the heart to bring the rhythm back to normal. An ICD is like an implantable, fully automated AED.

AEDs will repeat analysis every 2 minutes to check for a shockable rhythm. This will continue until either a non-shockable rhythm is detected, the device is deactivated, or the battery is drained.

A common misconception about defibrillators is that their primary purpose is to restart a stopped heart. In fact, defibrillators are designed to stop abnormal electrical rhythms in the heart, allowing the normal innate electrical rhythm of the heart to return.

How does an AED deliver the electric shock?

AEDs deliver a shock voltage 10x higher than a wall socket

The principles behind generating the shock delivered by a defibrillator are fairly simple, with the complexity stemming from the need for reliability, accurate patient assessment and automation. The key components of defibrillators that generate the therapeutic shocks are:

1. **Battery:** Many AED models use batteries similar to conventional batteries found in TV remotes, smoke detectors, and remote-control cars. These AEDs can use a 9-volt battery or several 1.5 or 3-volt batteries connected together. The voltage of AED batteries typically ranges between 9 – 12 volts.

Figure 17: ZOLL AED Plus uses ten 3-volt batteries

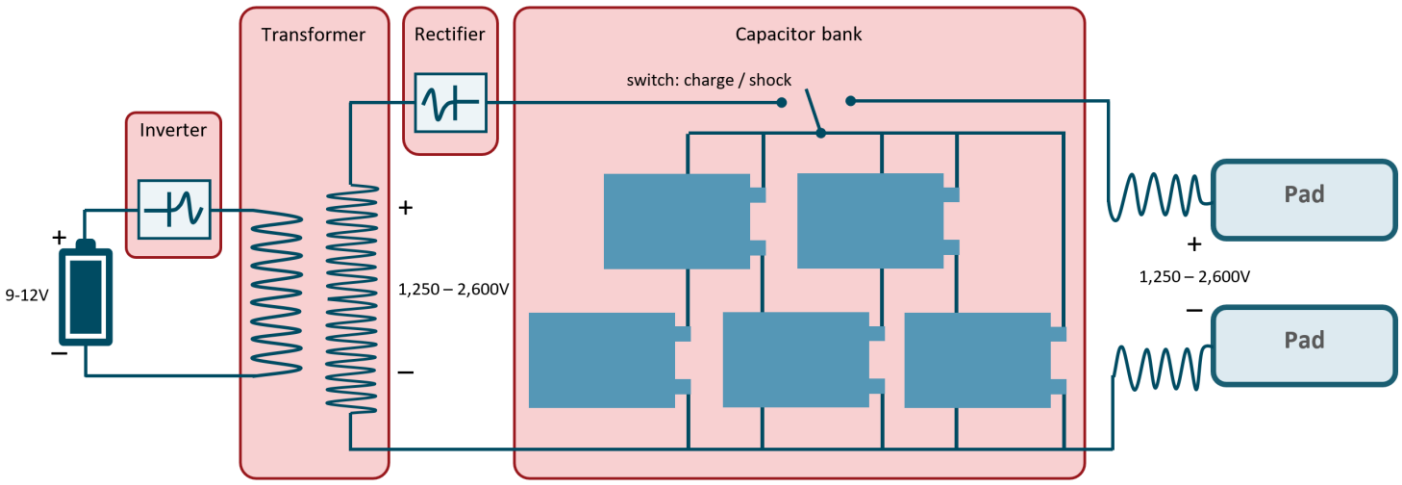
Source: ZOLL Medical, St John Western Australia

2. **Inverter:** Converts the direct current (DC) from the battery to an alternating current (AC). This is necessary for the voltage to be increased by the transformer.
3. **Transformer:** The transformer increases the battery voltage from 9-12 volts up to 1,250 – 2,600 volts. For comparison, the voltage coming from wall sockets is 240V (in the US, it's 110 volts)
4. **Rectifier:** The rectifier is the reverse of an inverter, converting the alternating current from the transformer back to direct current while maintaining the high voltage.

Capacitors are like batteries that can discharge in milliseconds

5. **Capacitors:** Capacitors are like batteries that can be charged and discharged quickly (within milliseconds). The capacitors are charged to the high voltage generated by the transformer. The capacitors and not the batteries deliver the shock to the patient. The type and layout of the capacitors in the CellAED are crucial to its size and affordability.
6. **Electrodes/pads:** The AED delivers the shock to the patient via sticky pads attached to the patient's chest. The side of the pads stuck to the patient has a special gel that reduces the resistance between the electrode and the skin, allowing more current to pass to the patient. This gel is a particularly poorly understood part of AEDs and one we will discuss later.

Figure 18: The core components of the shock delivery systems are remarkably simple



Source: Venn Brown

When an AED is first turned on, it measures the patient's heart rhythm via the pads. If the patient has a shockable rhythm, the AED connects the battery to the capacitors and charges them. Charging typically takes between 5 and 20 seconds, depending on the device. Once charged, the device is ready to deliver the shock. At this point, a semi-automatic AED will tell the user to push the button, which flips the switch, allowing the charge from the capacitors to deliver the shock.

AED's shock delivery system is remarkably simple

A fully automatic AED will warn bystanders to step back before automatically flipping the switch, connecting the capacitors to the pads, and shocking the patient. The length of the shock varies but is generally between 15 – 30 milliseconds. The duration depends on the electrical resistance of the patient.

This is a high-level explanation of how an AED works. The machines have complicated control electronics to ensure they operate correctly and only shock patients with shockable heart rhythms.

A single shock will completely drain the capacitors, after which the AED will guide the operator in CPR for a period of time (this varies but is typically 2 minutes), after which the control circuitry will again analyse the patient's heart rhythm to determine if another shock is required. Most AEDs can produce well over ten shocks on a single charge (most devices will deliver more than 50+ shocks on a new, fully charged battery). It is rare to use more than ten shocks in a typical resuscitation scenario.

CellAED – Next-generation AED

CellAED is the first personal, full-portable handheld defibrillator

The CellAED is the world's first personal, fully portable, handheld defibrillator. It's designed from the ground up to be available in people's homes, where 70-80% of all cardiac arrests occur. It is the most affordable defibrillator on the market (70 – 85% cheaper than most models) and the smallest, lightest and arguably easiest to use.

The genesis for the development of CellAED and the launch of Rapid Response Revival occurred in 2014 when Sarah Walke, the partner of founder and CEO Donovan Casey, suffered a sudden cardiac arrest at home. As a former professional parachute instructor, Donovan knew CPR and kept Sarah alive until an ambulance (which was fortunately nearby) arrived. Paramedics took over the CPR and applied a defibrillator to shock Sarah's heart back into its correct rhythm. Sarah survived, making her one of the lucky 10%. Had the paramedics not been so close, the outcome would have likely been quite different.

Figure 19: The CellAED was designed from the ground up to maximise survival rates

Source: Rapid Response Revival

The CellAED design was driven by a real world experience with cardiac arrest

That incident motivated Donovan to invent a new AED. CellAED is purpose-built to be in the places where AEDs are most likely to save the most lives. The seemingly audacious aim of Rapid Response Revival is to make it possible for there to be an AED within reach of where 70-80% of all sudden cardiac arrests happen, namely at home and at work. CellAED is the first AED on the market designed for the home market, which also means that it's perfect for mobile applications as well.

Freed from all legacy constraints, Donovan and his team worked from first principles to develop an entirely new device with the aim of maximising survival rates from sudden cardiac arrest. In order to do this, they needed to focus on maximising:

1. **Availability:** Speed to defibrillation is a major factor in survival rates; and
2. **Usability:** There is high reluctance within the public to use AEDs, resulting in bystanders using defibrillators in only around 5-11% of SCAs that occur in public.
3. **Ease of maintenance:** CellAED is a single-use device. The pads and batteries are integrated within the unit. At the end of its life, the entire device is replaced as a single unit.

Some of CellAED's unique features include:

Table 10: CellAED's offers several unique features

Features	Details
Single-use	CellAED is the world's first single-use AED, greatly reducing costs.
Lightweight	CellAED is 15% - 25% the weight of most other devices.
Ultra-portable	CellAED is 10% - 20 % the size of other devices.
Single-piece design	The world's first single-piece AED, with the defibrillator pads integrated into the device. This enables the small volume and simple, unintimidating and intuitive design.
Easy to use	The device has an intuitive, unintimidating, simple 3-step activation and application process: "Snap Peel Stick"® (see Figure 20).
Universal pads	Most AEDs require separate pads for use on infants and small children. Although out-of-hospital cardiac arrests are very rare in infants and small children, having universal pads not only saves money (usually US$70 - $150) but also simplifies use and maintenance.
Mobile network connectivity & IoT	CellAED is one of the few AEDs offering mobile network connectivity. Other connected AEDs mostly use Bluetooth or Wifi, severely limiting their connectivity and portability. Each CellAED contains an integrated SIM that automatically connects to the local 2G and 3G networks, making it truly mobile. The device will connect to the local network, even when travelling internationally (see *3G switch off in Australia*). Currently, this connectivity is used for remote monitoring (ensuring correct operational status), incident reporting and data capture. However, given that the connectivity and data capture infrastructure are already in place, it opens up significant opportunities for far broader and more innovative future internet-of-things (IoT) features and functionality. RRR reports that CellAED's connectivity and IoT functionality received much attention at the Arab Health conference[37] held in late January 2024, opening significant opportunities for feature expansion, including the UAE's 'Safe City' initiative.
Location monitoring	CellAED is one of the few AEDs with location monitoring. CellAED uses cellular location and triangulation to generate location data. Combining this with mobile connectivity opens the CellAED to support several new advanced features, including fleet monitoring and enhanced incident reporting. With the device functionality and backend infrastructure already in place, RRR has already overcome the most complicated aspects of extending the device's functionality.

CellAED is the smallest, lightest, most affordable AED

CellAED is the first single-use AED

CellAED is one of the first AEDs to connect to mobile phone networks

[37] The Arab Health conference is the largest healthcare trade show in the Middle East, each year attracting over 110,000 professionals, 3,450 exhibiting companies, from around 180 countries.

Features	Details
Incident reporting	Immediately after an incident and device de-activation, CellAEDs automatically send all incident data, including heart rhythm and shock pattern information, to RRR. RRR can share this data with treating physicians, hospitals, and medical researchers. Soon, RRR will have the world's largest database of real-time SCA incident data, which it will use to improve the CellAED and can make available to SCA and cardiac researchers.

CellAED is the complete reimagining of AEDs

The internal workings of the CellAED brings numerous modern innovations to a technology that has seen very few advancements over the last 30 years. To users, the CellAED offers an unintimidating, easy-to-use, all-in-one design. Measuring just larger than a family block of chocolate, the CellAED comes in a single piece with the pads integrated into the device's body. The three-step instructions are displayed on the front of the device (see Figure 19), and voice prompts guide users through the application process. Critically, there is no complicated interface that requires users to make decisions, which can delay response times or lead to mistakes. Users must only decide whether the patient weighs less than 10kg. Aside from this, the CellAED operates automatically and is activated immediately upon being "snapped".

Table 11: Despite being lower cost and more compact, CellAED is a feature-rich AED

CellAED is smaller, lighter, more affordable and simpler to maintain

Features	CellAED	Competitors[38]
Price	US$420	US$1,400 – US$4,500
Shelf life	2 years[39]	5-8 years
Pad shelf life	2 years	2-4 years
Replacement pads	No	US$100 - $240[40]
Battery shelf life	2 years	2-5 years
Replacement battery	No	Most US$150 - $500
Rechargeable battery	No	Avive (US only)[41]
Self-monitoring and reporting	Yes	Some
Cellular connectivity	Yes	A few
Location monitoring	Yes (via cellular location)	Some
Wifi connectivity	No	Some
Integrated device & pads	Yes	No

[38] Features vary between devices. The table provides an overview of CellAED's key competitors

[39] CellAED's proven and regulatory approved shelf life is 30 months, but this official life could be extended as post market surveillance demonstrates it will last longer. The advertised two year shelf life ensures enough buffer for logistical delays and for resellers to hold and move inventory.

[40] HeartSine SAM uses combined battery and pad pack which costs US$249 (adult) and US$270 (child). LIFEPAK battery and pad pack cost $396.

[41] Until early 2024 Avive (www.avive.com) was the closest AED to CellAED in price and target market. It's only currently available in the US and recent price and marketing changes indicate they're no longer going after the home market.

Features	CellAED	Competitors[38]
Screen	No	Some
Emergency services connection	Not yet[42]	Only Avive (US only)[43]
Separate child pads	No	Most require separate pads (sold separately US$70 – $250)
Training device	US$92	Most US$200 - $900[44]
Voice prompts	Yes	All
CPR voice prompts	Yes	All
CPR movement detection[45]	No	Some
Multi-language	Being developed	A few

Note: All prices are in US dollars. Competitor price ranges are based on recommended retail prices and generally exclude the most expensive machines and accessories.
Source: Rapid Response Revival, company and reseller websites

The integrated pads work for both adults and infants

Key design considerations make CellAED an affordable consumer product

Size, weight and affordability were the key design drivers

To address these two key requirements of availability and useability, Rapid Response Revival designed the CellAED with the following drivers in mind:

1. **Affordability:** Most AEDs on the market have an upfront cost of between US$1,600 – $3,400, plus an ongoing maintenance cost of between US$200 – $400 every 2-3 years. CellAED has an upfront cost of US$420 (A$599), which is 15% - 35% of the cost of other devices. The 'CellAED for Life' program costs US$130 (A$198) per year, which provides ongoing remote monitoring, free device replacement if the CellAED is used in an emergency, and a new replacement device upon expiry (currently every two years). Looking over a full 10-year period, CellAED is 30-40% of the cost of other devices.

   Most other devices also need separate child/infant pads (US$100 – $400) every 2-4 years, while the complexity of maintenance requirements has created AED maintenance services, which typically charge US$100 – $200 per year[46].

[42] RRR has built much of the functionality into the device but have not enabled it due to logistically complexities of support the feature in multiple countries.

[43] While great for marketing, Avive's emergency services connection currently only works in three US counties with a total population of fewer than 600,000 people. The connectivity is provided by a third party service provider and is open for AEDs to also use. There is much speculation within the industry and amongst emergency services personnel as to the value it will provide.

[44] Avive's (USA only) training cartridge is US$74.

[45] A few AED measure the rate and depth of CPR being performed and provide feedback to operators if they need to change their speed or the force of each compression.

[46] Maintenance requirements are a critical factor for AEDs. It's estimated the between 10-35% of all public access AEDs don't work, mostly due to dead batteries. Another factor often overlooked is the rapid aging of the pad's contact gels. These gels are critical for enabling the shock to pass into the patient. These gels typically last 2 years but must be kept within a fairly tight temperature and humidity range.

In November 2023, RRR increased its prices and simplified its product offering to those shown in Table 12. RRR reports they saw no change in conversion or demand despite increasing the outright purchase price by $100 (+20%) and the CellAED plus CellAED for Life price by $42 (+7.5%). See Table 13 for a comparison with other AEDs.

Table 12: RRR increased and simplified Australian pricing without impacting sales

Retail Pricing	Australian (A$)	United Kingdom (£)	New Zealand (NZ$)	Ireland (€)	USA (US$)*
CellAED outright	$599	£340	$521	€390	$420
CellAED + 1yr CellAED for Life	$599	£445	$635	€511	$550
CellAED for Life (yrly)	$198	£105	$201	€121	$130
Wall mount	$63	£60	$69	€70	$80
Trainer	$90	£73	$100	€85	$92
Starter pack	$668	£580	$760	€650	$700

***Note:** CellAED is not yet available in the US. For comparison, we've applied Australian prices with a USD/AUD exchange rate of $0.65.
Source: Rapid Respond Revival

2. **Portability:** As shown below in Table 13**,** the CellAED is the smallest and lightest AED on the market. It's roughly 1cm longer and 2cm wider than a block of chocolate and weighs just 450g, including its protective case.

CellAED is truly portable

Current AEDs on the market are designed for public use, generally weighing between 1.2 - 3kg and are 5 – 11x the size of a CellAED. CellAED's portability is a key competitive advantage that RRR achieved through innovations not only in the construction and design of the internal circuitry and all-in-one casing but also in the development of the CellAED's optimised therapeutic waveform (see *What is an AED waveform, and why should I care?*). As discussed below, it will take time for competitors to reduce their devices down to match CellAED.

Meanwhile, Rapid Response Revival is looking to reduce the size further to have the CellAED no larger than a mobile phone. As discussed in further detail below, this fully mobile design opens CellAED up to markets and use cases otherwise impractical for typical AEDs.

3. **Ease of use:** Donovan Casey (RRR CEO) discovered firsthand how adrenaline, fear, and panic drive everything from your mind (including your name, address, and phone number[47]), so designing an intuitive device that someone without training could pick up and use was paramount. Unlike every other AED on the market, CellAED uses an all-in-one design where the AED body becomes the electrode pads. All other models have a body and separate pads. CellAED provides easy-to-following illustrative instructions that have been successfully followed at least 20 times in real emergencies. CellAED requires users to make only one decision: does the patient weigh less than 10kg? If so, then the infant mode is enabled with the push of a single button.

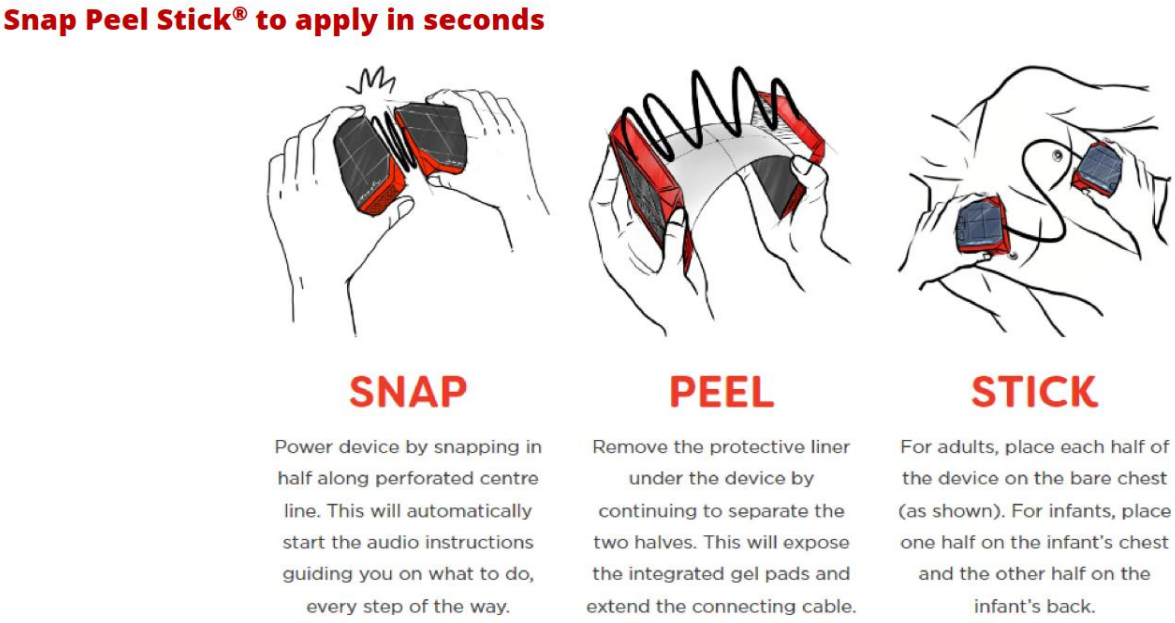
Ease of use if critical for patient survival

[47] CellAED come with wall stickers which provide easy to follow instructions on what to do in an emergency and include a place for users to write their address.

Rapid Response Revival's trademarked SNAP PEEL STICK® activation process is the simplest application and activation process of any AED. Venn Brown also suspects (but has not confirmed) that people find the simplicity of the design and the small size of the CellAED less intimidating. It bears no resemblance to the defibrillators seen in television dramas, and its unassuming, lightweight, handheld nature hides the power it generates.

As discussed in more detail below (see *Usability saves lives* below), ease of use reduces the time to first shock and the likelihood of user error and increases the likelihood that bystanders will use the device as they don't find it intimidating.

Figure 20: The 3-step "Snap Peel Stick"® makes CellAED one of the easiest AEDs to use



Source: Rapid Response Revival

10% - 35% if public access AEDs don't work

4. **Reliability:** Estimates range, and definitive figures are difficult to come by, but industry sources report that between 10-35% of public AEDs fail to operate as they should. The number one cause is a flat or missing[48] battery. Batteries can last between one and five years, depending on the model and the conditions and environment in which they're stored. Batteries are not only impacted by the use of the AED and environmental conditions (extreme hot and cold temperatures impact battery usage and life), but for those with remote monitoring (usually via Wi-Fi), the strength of the signal can also impact battery life as regular dropouts require the device to repeatedly attempt to reestablish a connection.

   The CellAED for Life plan provides ongoing remote device monitoring. The CellAED will report its status to Rapid Response Revival every 30 days. RRR then emails the registered owners (see below for full program details), confirming the device is functioning correctly or warning them it needs attention.

[48] There have been numerous cases of staff or volunteers responsible for maintaining public AEDs removing batteries, so they don't drain, only for people to grab the AED in an emergency and not also take the batteries.

While some devices offer remote monitoring, CellAED and Avive are the only AEDs on the market using mobile/cellular phone networks (2G and 3G - see *3G switch off in Australia* below) to facilitate remote monitoring. CellAED has removed another point of failure by eliminating the reliance on Wi-Fi connectivity. This feature makes the CellAED truly mobile, even across international and intercontinental borders.

CellAED is a single unit with no separate parts to maintain

5. **Low maintenance:** As suggested by Table 13, most AEDs require regular and ongoing maintenance, with different components following different maintenance schedules. Most pads need replacing every two years (or after use), batteries every one to five years (depending on various factors that can be difficult to monitor, such as Wi-Fi signal strength), and most AEDs' warranties last between five and eight years. Maintenance is seen as such a complex requirement that it has created an industry of AED maintenance companies that charge between US$100 -$200 per year to maintain a single AED. This cost and complexity impeded the widespread adoption of AEDs.

   RRR designed the CellAED to remove this complexity of ownership entirely. Neither consumers nor businesses want the complexity of maintaining a maintenance schedule for a device they hope never to use, which could fail if the schedule isn't followed.

CellAED for Life replaces a used device for free

   CellAED's all-in-one design and replacement cycle removes this complexity. Upon expiry (CellAED's current approved life is 30 months, which Venn Brown expects will be extended in future releases), the entire device is simply replaced with a new one. As mentioned above, the 'CellAED for Life' plan provides remote device monitoring. The plan also provides a free replacement device if a CellAED is used in an emergency.

Table 13: CellAED is small, lighter, cheaper and easier to use than existing AEDs

Model	Price*	Avg annual maintenance	Total 8yr cost	Dimensions	Weight	Shelf life	Replacement battery	Replacement pads - adult
CellAED (subscription & outright options)	**$550**	**$130**	**$1,280**	**21 x 11 x 3cm[49]**	**450g[49]**	**AED: 2yrs Battery: 2yrs Pads: 2yrs**	**Included in $130/yr CellAED for Life. Replaced upon expiry. Currently, every 30 months.**	
	$420	**n/a**	**$1,680**				**Replace whole unit every 2 years**	
Avive[50] (subscription & outright options)	$900	$450	$4,050	14 x 16 x 7cm	953g	AED: 5-8yrs Battery: 5-8yrs Pads: 2yrs	Rechargeable	Included in $450 annual subscription
	$1,650	$50	$3,600					$100
Cardiac Science Powerheart G5	$2,064	$100	$2,767	30 x 23 x 9cm	2.6kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$460	$81
Defibtech Lifeline/Revive	$1,545	$86	$2,145	22 x 30 x 7cm	2.0kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$375	$68
Philips HeartStart OnSite	$1,479	$61	$1,905	19 x 21 x 7cm	1.5kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$189	$79
Stryker HeartSine SAM 350P	$1,738	$118	$2,563	20 x 18 x 5cm	1.1kg	AED: 8yrs Battery: 4yrs Pads: 4yrs	Combined battery & pads: $228 adult	
ZOLL AED 3	$2,144	$389	$4,864	24 x 25 x 13cm	2.5kg	AED: 5-8yrs Battery: 1-5yrs Pads: 2yrs	$186	$204

***Note:** All prices are in US dollars. Prices are recommended retail prices without discounting. Prices vary between suppliers, and the last four months have seen significant discounting across all major brands in Australia, the US, and the UK.
Source: Rapid Response Revival, Avive, Cardiac Science, Defibtech, HeartSine, HeartStart & ZOLL

The last 30yrs has seen very little innovation in AED therapy

Table 13 and Figure 21 show details of six of the leading AEDs in the market. These are only a small subset of the more than 60 individual units we surveyed, including, where possible, pricing in the US, UK, and Europe. As discussed in more detail in *What is an AED waveform, and why should I care*?, the startling truth about the AED industry is that in the last 30 years, there has been very little development in defibrillator therapy; instead, the majority of manufacturers have focused on putting the same electronics in new boxes and adding extraneous features which may or may not improve patient outcomes.

[49] Includes carry case. CellAED without the case measures 19.6 x 9.6 x 1.7cm and weighs <300g

[50] Avive can also be bought outright for $1,650.

Figure 21: More than 60 individual AED models exist in the market

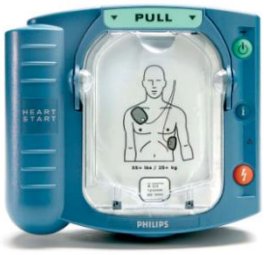
Most AEDs are 3-6x bigger and 3-5x heavier than CellAED

Avive

Powerheart G5 AED

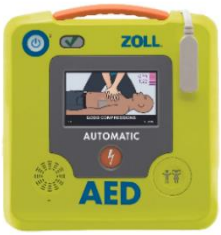
Defibtech Lifeline/Revive

Philips HeartStart OnSite



HeartSine SAM 350P

ZOLL AED 3



Source: Manufacture websites

CellAED for Life™

Along with CellAED and the subscription/membership plan 'CellAED for Life', RRR also sells a reusable CellAED trainer and a wall mount.

Figure 22: RRR also sells a CellAED trainer and wall mount

Source: Rapid Response Revival

CellAED for Life is a subscription or "membership" program that costs A$198 per year (approximately US$130)and includes:

CellAED for Life provides RRR a valuable annuity stream

1. Ongoing remote device monitoring, with monthly status notifications
2. Up to one replacement device a year if used in an emergency
3. A new CellAED upon expiration of the existing device (two years).

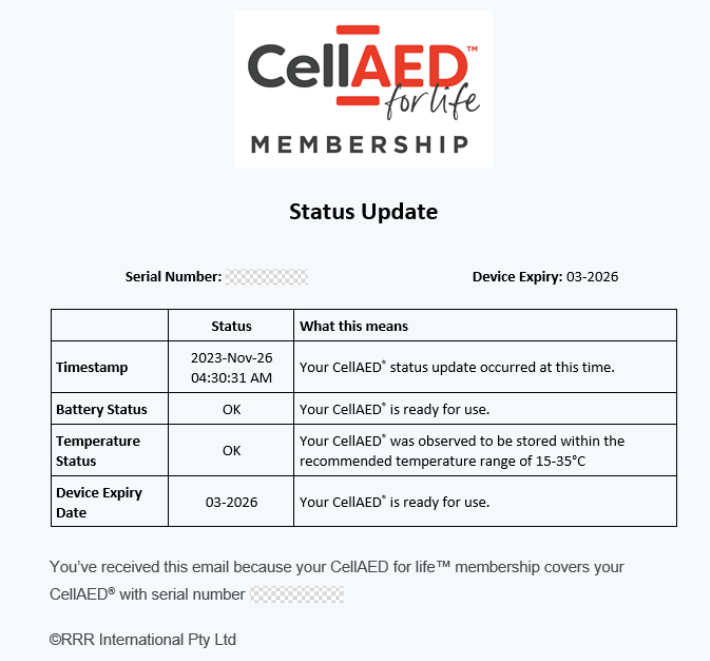
Rapid Response Revival offers the CellAED as a one-off purchase (but RRR will likely discontinue this), but sales for the first twelve months saw >70% of customers purchasing

CellAED for Life. Recently, RRR increased the one-off purchase price to include a free first-year membership to CellAED for Life. Along with the ongoing monitoring and replacement benefits, CellAED for Life gives consumers a lifetime of cheaper replacement devices once their existing device expires, something the majority of customers value. The benefit for Rapid Response Revival is an ongoing growing annuity stream, high total customer lifetime value and lifelong engagement with customers.

CellAED for Life provides a maintenance & worry free AED ownership

Under CellAED for Life, after the initial US$420 (A$599) purchase, each replacement CellAED costs US$260/A$396 (two years at US$130/A$198). It's too early to tell how sticky the offering is, but one would expect that once someone has decided to purchase a CellAED, it's a much lower hurdle for them to continue to own one at a meaningfully discounted price. The program is also a highly attractive offering for companies and government agencies looking for a simple solution to managing a fleet of devices.

Figure 23: CellAED for Life subscribers receive monthly email confirming device status



Source: Rapid Response Revival

3G switch off in Australia

As mentioned previously, CellAED has a communication chip that connects to 2G and 3G networks. Australia shut down its 2G network in 2018. Vodafone shut its 3G network in January 2024 (it was scheduled for August 2023 but was delayed). Telstra and Optus are scheduled to shut down their 3G mobile networks by the end of June 2024 and September 2024, respectively. Australia is the only country within RRR's sales region with neither 2G nor 3G networks.

RRR is releasing a 4G enabled CellAED within a few months

Once the 3G network is closed, RRR will no longer be able to perform remote monitoring of its current version devices. There are more than 11,000 devices in Australia which all use the 3G network. Only those with an active CellAED for Life subscription are eligible for remote

monitoring service. RRR expects to release a 4G operable CellAED by June, but the existing devices already on the market will lose remote monitoring.

The company is currently working on its strategy to handle this situation. Telstra or Optus may delay their switch-off, but it still leaves some devices in the market without remote monitoring. While not ideal, given the small number of devices affected, we believe that RRR can manage the situation by either crediting customers' subscriptions, refunding the subscription or replacing non-functioning older devices with new ones.

Usability saves lives

Speed to apply pads of competitor AEDs ranged from 55 seconds to 3mins & 40 seconds

The importance of making an AED intuitive and easy to use should not be underestimated. A survey conducted by the Australian Heart Foundation found that only 41% of Australians feel confident using an AED (52% of Australians would not feel confident using an AED). An AED's usability, including how complicated and intimidating it appears, can dramatically impact the likelihood of a bystander using it in an emergency.

Rapid Response Revival designed the CellAED (with Donovan's firsthand experience) to be as simple, intuitive, and non-intimidating as possible while minimising the number of decisions users need to make. These design considerations literally save lives.

A study by Stryker, one of the world's largest AED manufacturers, found the time-to-first-shock can vary enormously between different devices. As shown in Table 14 below, study participants took between 78 seconds and 272 seconds to deliver the first shock when asked to apply an AED to a manikin. Considering that survival rates drop by ~10% per minute, less than optimal usability design will cost lives.

Table 14: The complexity of an AED can increase time to first shock by more than 3 minutes

	Participants	Turn on device	Open lid	Place pads	Deliver shock	Start CPR
Lifepak CR2 defibrillator	15	10.4	N/A	55.3	77.7	86.8
Lifepak CR2 Plus AED#	14[a]	7.1	N/A	67.8	93.2	102.5
Philips OnSite AED	12[a]	10.1	N/A	79.1	102.1	131.6
ZOLL AED Plus	7[b] 5[c]	6.1 5.1	15.2 41.6	84.3 224.2	112.7 271.8	118.1 127.0[d]

Note: All time shown in seconds

[#] Pressing the ON button opens the lid and starts the device

[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 was excluded from this analysis.

[b] Participants who delivered the first shock before CPR.

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

[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.

Source: AED comparison usability study (2019)

Affordable AED trainer increases device familiarity and is a great marketing tool

CellAED trainers are a great marketing and sales tool

One of the only ways non-first responders can access AEDs is through first-aid training courses. Historically, training organisations do not give participants an opportunity to train with AEDs due to the prohibitive cost of the devices and AED trainers. Of the more than 60 models we surveyed, most trainer units cost between US$440 and US$600. The exception was Avive, which offers a separate trainer cartridge for US$75.

CellAED's reusable trainer costs just A$99, allowing training organisations and even large corporations that provide first aid training to staff (mining, construction, utilities, remote workers) to give simulated training with a training device that is physically identical to the actual device. The CellAED training app provides audible instructions for training situations. The affordable price of CellAED also means training organisations can sell CellAEDs to course participants, which is unrealistic considering that existing devices cost at least $1,700. Greater access to trainers is always an effective way of reducing the reluctance of the ~50% of the public who report they are uncomfortable using an AED.

Figure 24: An affordable trainer means more people can become comfortable using the CellAED

Source: Rapid Response Revival

Life time cost of ownership

CellAED has the lowest upfront and life-time ownership cost

As discussed above, the CellAED's upfront price is around 18-25% of the price of the five most popular selling AEDs in the US and UK markets and around 61% of the price of the new Avive[51] AED (which is only available in the US). If bought outright, CellAED is 25% of the cost of Avive. In addition to the substantial initial purchase price, AEDs require ongoing maintenance, with pads and batteries needing replacing every 2-5 years, depending on the model. Pads range in price from US$100 - $240, with most devices also requiring a separate infant/child set of pads[52]. Replacement batteries range in price from US$140 to $500 and need replacing on average every 4-5 years, with some devices needing more regular changes depending on the environment in which the device is stored. Most devices have an 8-year warrantee, but five and seven-year warrantees also exist.

[51] Avive is only available at this price on a five-year contract of $900 upfront plus $450 per year. Outright, Avive costs US$1,650

[52] Infants represent only ~2% of all incidents of cardiac arrest and the vast majority of these occur within a hospital. Most publicly available AEDs do not have infant pads.

The longer someone owns a CellAED the more they save

As shown in Table 15, ongoing maintenance requirements mean the total 8-year ownership of competing AEDs ranges from 1.5x to 2.4x more than CellAED. Given the high upfront costs of competing AEDs, the cost of ownership gap widens every complete life cycle, which is typically eight years. After 16 years, the cost of ownership increases to between 1.6x to 2.7x the cost of CellAED. This price gap also does not capture the added benefits included in 'CellAED for Life'.

In addition to the device costs, as we've mentioned above, AED maintenance firms charge US$100 - $200 per year to maintain other AEDs. This gap also doesn't reflect the time and maintenance effort saved with CellAED's single-use design (meaning used devices don't need to be retrieved from hospitals or first responders and used parts replaced) nor the cost saving of CellAED's free replacement offering.

Table 15: Ongoing maintenance can more than double the initial price of AEDs

	Initial price	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Total	Total vs CellAED
CellAED - outright	$420		$420		$420		$420		$1,680	1.2x
CellAED for Life	**$550**	**$130**	**$130**	**$130**	**$130**	**$130**	**$130**	**$130**	**$1,460**	**1.0x**
Avive[51]	$900	$450	$450	$450	$450	$450	$450	$450	$3,600	2.5x
Avive – outright	$1,650		$100		$100	$1,650		$100	$4,049	2.8x
Cardiac Science Powerheart G5	$2,064		$81		$541		$81		$2,767	1.9x
Defibtech Lifeline/Revive	$1,545		$75		$75	$375	$75		$2,145	1.5x
Philips HeartStart OnSite	$1,479		$79		$268		$79		$1,905	1.3x
Stryker - HeartSine SAM 350P	$1,738		$298		$228		$298		$1,966	1.3x
ZOLL AED 3	$2,144		$204	$186	$204		$204	$186	$3,128	2.1x

Note: Prices shown are the recommended retail price in US dollars
Source: Rapid Response Revival, manufacturer websites

How is CellAED so small and affordable?

Design innovation lead to CellAEDs size, weight and cost savings

Getting an AED in people's homes has been the primary motivation of RRR. The team realised that the only way to achieve this was to make a portable and affordable AED, resulting in the CellAED's four key driving axioms: efficacy, affordability, size and weight.

As shown above, in Figure 17 and below in Figure 25, the largest components of traditional AEDs are the capacitors and batteries, so these were the most obvious targets for innovation.

1. **Battery size:** Since most existing AEDs were first developed, revolutionary advancements have been made in battery technology driven by mobile phone innovations. RRR put these advancements to good use while extending them further by minimising battery drain, using non-rechargeable batteries and not trying to extend battery life to 5-8 years. CellAED's approved battery life is 30 months[53]. These

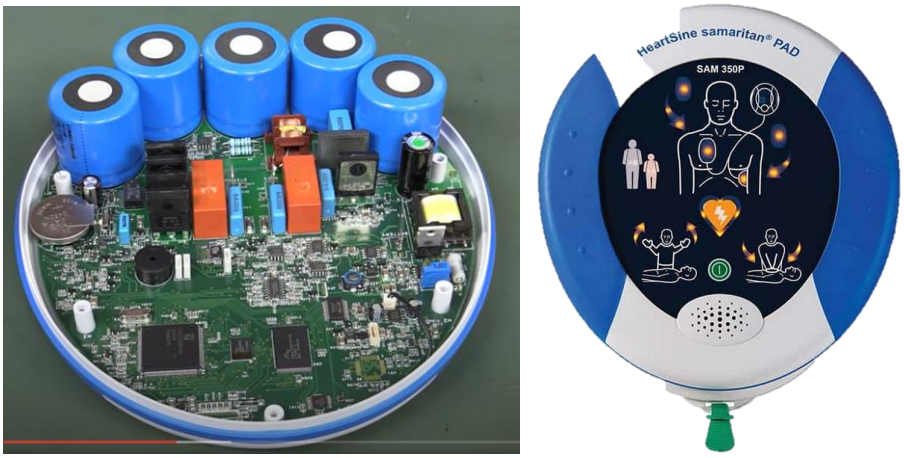
[53] The approved battery life can only be as long as proven in real, operating devices. When first launched the approved battery life was only twelve months since RRR could only show its devices were still operating after twelve

factors mean that CellAED's battery is similar in size to those found in mobile phones, thereby offering huge space savings.

Smaller capacitors reduce size and cost

2. **Capacitor size:** RRR completely redesigned the capacitor configuration. Instead of using the four to six large capacitor arrangement of other manufacturers, CellAED generates its therapy using an array of smaller capacitors that combine to provide a larger capacitance (in the same way that several small batteries can be chained together to increase voltage or power). CellAED's capacitor arrangement makes the device much smaller and cheaper as capacitors are exponentially more expensive the larger and higher power they are.

Figure 25: The capacitor size limits how small an AED can be



Note: The figure on the left shows an older model device, which may have changed. It has the same size and styled outside casing as the current model shown on the right.
Source: YouTube, HeartSine

Capacitor capacitance optimises the CellAED waveform

3. **Capacitor capacitance:** One of the revolutionary innovations RRR made with the CellAED was reducing the capacitance (energy storage capacity) of the capacitors, which allowed them to reduce the number and physical size of the capacitors even further.

   While most AEDs use four to six capacitors to provide a total capacitance of between 100 – 200 microfarads (most are 150 – 200 microfarads), CellAED uses two separate banks of small capacitors providing a total capacitance of around 75-100 microfarads (for commercial reasons RRR doesn't disclose actual values). The first bank has around 50-60 microfarads provided by approximately 10-12 capacitors, and the second bank consists of 5-6 capacitors, providing about 25-40 microfarads of capacitance. Figure 26 shows a simplified illustration of CellAED's configuration, which compares to the more typical configuration shown in Figure 18.

months. As more devices enter the market and demonstrate longevity, we expect to see the approved shelf life of CellAED extended. We expect CellAED version 2.0 will have a life of three, even four years, with the obviously significantly profit margin benefits this provides.

Through its innovative design, RRR reduced the size and number of capacitors while providing the equivalent[54] or better therapeutic output. The reduced capacitance is partially enabled by CellAED's optimised therapeutic waveform.

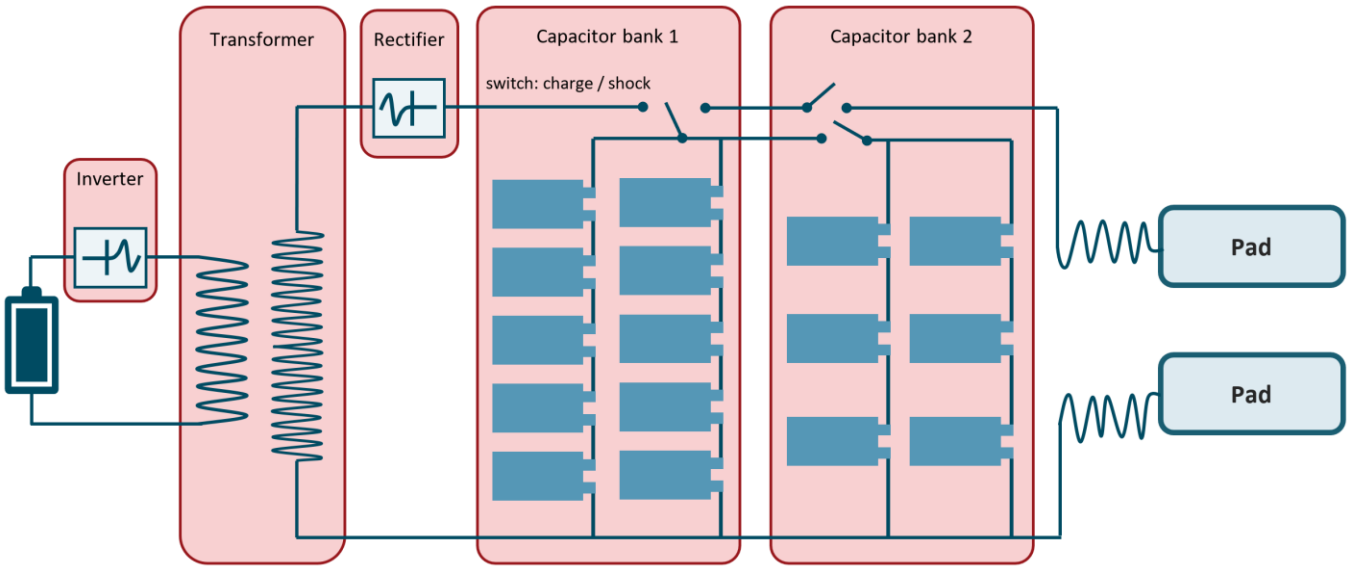
CellAED's innovation is driven by 30 years of research largely ignored by other manufacturers

RRR's innovative capacitor configuration and lower capacitance is responsible for CellAED's optimised waveform[55], which:

1. Maximises peak-to-peak current;
2. Provides a near-symmetrical amplitude two-phase waveform; and
3. Reduces the waveform energy output

As discussed below, it is believed these properties lead to beneficial therapeutic outcomes.

Figure 26: By changing the capacitor configuration, RRR has dramatically reduced CellAED's size and cost



Note: This is illustrative only. We estimate that capacitor bank 1 has around 10-12 capacitors, while bank 2 has around 5-6 capacitors**.**
Source: Venn Brown

A defining feature of CellAED's configuration is the use of the second capacitor bank to generate the negative wave cycle/phase (see Figure 27). While all other AEDs use a single capacitor bank and generate the negative cycle by inverting the current during discharge, CellAED has two separate capacitor banks that deliver near equal but opposite peak currents. The first bank generates the positive cycle, and once discharged, the second bank generates the negative cycle. This configuration creates the optimised waveform shown below in Figure 27.

[54] Within medical device regulation "equivalence" refers to a device being substantially equivalent to an existing approved device (predicate device) in terms of safety and effectiveness for a specific intended use. If a device is deemed equivalent it can gain approval after undergoing a less rigorous review process (for instance the US FDA 510(k) clearance process). This means the new device is compared to a predicate device to demonstrate it has the same intended use and is as safe and effective as the predicate. The new US FDA and CE MDR processes have removed the equivalence pathways for new AEDs. See the *Regulation* section for more details.

[55] Waveform describes the shape (voltage or current over time) of the electric discharge an AED applies to a patient. See examples in Figure 27.

What is an AED waveform, and why should I care?

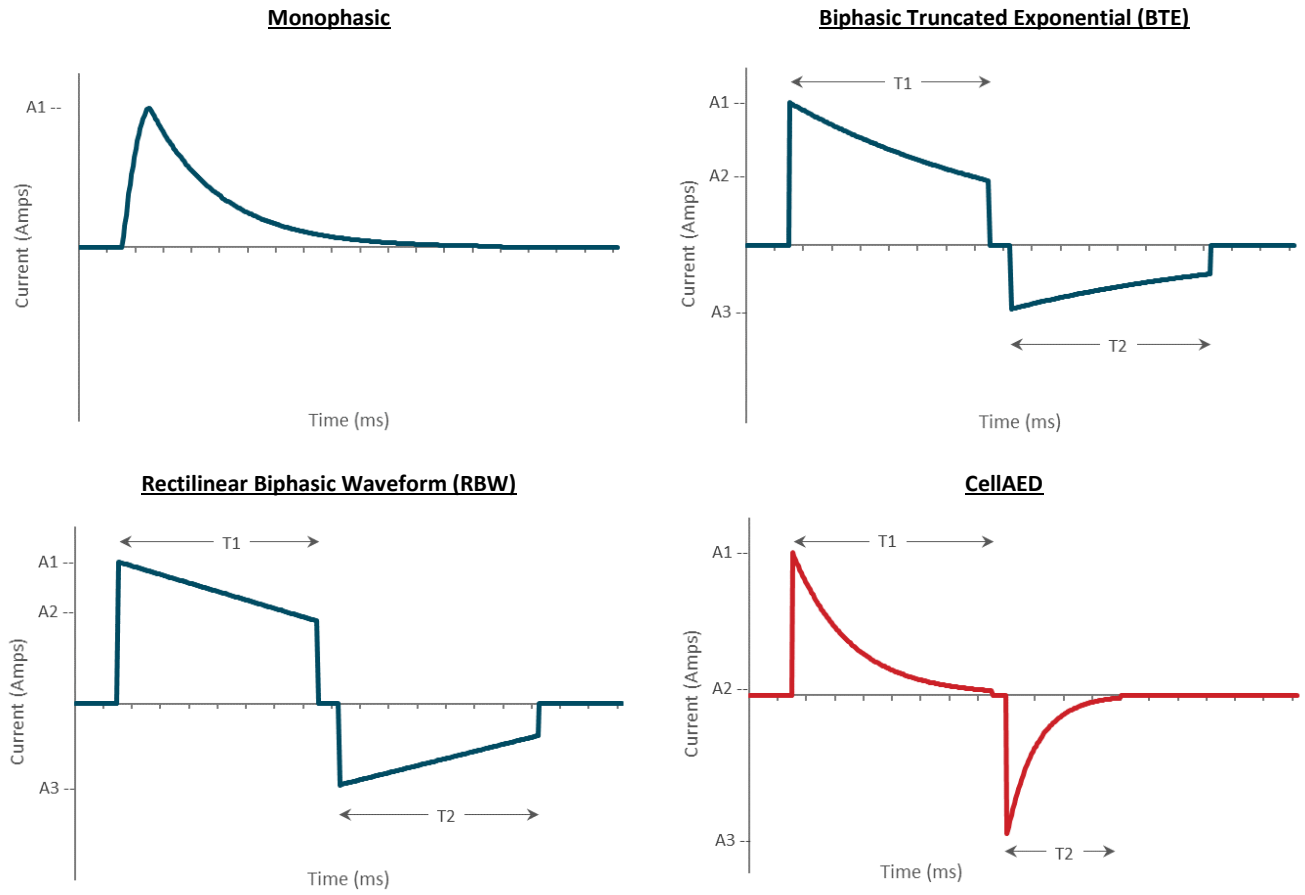
Waveform describes the timing and amplitude of the electric shock

Within the world of AEDs, the term "waveform" describes the shape (the change in voltage and current over time) of the electric shock an AED applies to a patient. After centuries[56] of using monophasic waveforms (one phase), in recent decades, defibrillators have started using biphasic waveforms (two phases), with the two most common biphasic waveforms being:

1. Biphasic Truncated Exponential (BTE) – most common; and
2. Rectilinear Biphasic Waveform (RBW) – exclusively ZOLL;

Biphasic waveforms became the norm in AEDs in the 1990s[56,] and there have been very few significant changes since then. We didn't find any AEDs for sale that use a monophasic waveform.

Figure 27: CellAED's waveform is one of the first major advances since 1990s



Source: Venn Brown

Figure 27 shows the three basic AED waveforms and how they compare to CellAED's waveform. The actual magnitudes of the currents shown in the figures vary between manufacturers and patients, as the resistance of the patient's body impacts current and

[56] The first time electricity was used to restart a heart was in 1775 by a Dutch veterinarian who restarted a chicken's heart. See Appendix – Brief timeline of AEDs for more information.

voltage.[57] Given the resistance of a patient's body is effectively constant during treatment, the voltage and current waveforms have the same shape[58].

There are three related features that optimise CellAED's waveform:

CellAED's innovation improve size, weight, affordability and therapy

1. **Peak currents almost identical:** The magnitude of CellAED's current at A3 is only slightly less than at A1, thereby maximising the peak-to-peak current difference (A3 is negative) compared to other waveforms, even if the magnitude of A1 is lower than other waveforms. For most AEDs, A2 is approximately 60-70% of A1, so their peak-to-peak current is ~1.6 x A1. In CellAED's case, the peak-to-peak current is close to 2x A1.

   All other AEDs we found used a single capacitor bank, with a simple switch to invert the polarity once the waveform decayed to a set point, thereby making the current A3 equal to the negative of the current A2.

   Various scientific papers (see footnote 60) published since 1998 have found that the peak-to-peak current is a crucial determinant of the shock's therapeutic value rather than the shock's energy. Studies also found that higher voltage changes during the waveform inversion are beneficial, which CellAED achieves with the second capacitor bank providing a full charge.

2. **Faster decay:** The CellAED's lower capacitance means the device's waveform decay rate is faster than other AEDs (see Figure 27). The benefit of this is that the shock provides the same (equivalent[54] or better) therapeutic benefit but with less energy (see Figure 29). Given electrical energy causes cell damage (see 'A word about energy' below), especially to sensitive tissue like heart cells, a lower energy waveform with the same defibrillating outcome is preferable.

3. **Shorter second pulse:** The duration of the second pulse is approximately half that of the first, a result of the lower capacitance of the CellAED's second capacitor bank. This also reduces the energy discharged into the body.

Table 16 below shows the typical voltages[59] delivered during a shock, assuming a resistance of 75 Ohms[57] (which is a typical resistance between electrodes when connected to a human).

[57] Devices are designed to operate with resistances ranging from 25 Ohms to 175 Ohms. A few devices are designed to keep the voltage and current the same for every patient irrespective of the electrical resistance (resistance) of the patient's body.

[58] Voltage = current x resistance.

[59] Most manufacturers provide voltage specifications rather than current.

Table 16: CellAED delivers the same peak-to-peak current with half the energy

	A1	A2	A3	Peak to peak	T1	T2	Energy
Monophasic	67 amps	-		A1			360-450 J
Biphasic Truncated Exponential	24 – 33 amps	30-50% of A1	same as -A2	1.3 – 1.5 x A1	10-20 ms	same as T1	200-300 J
Rectilinear Biphasic Waveform*	21 – 26 amps	9 – 18 amps	12 – 19 amps	31 – 47 amps	6 ms	4 ms	200 J
CellAED (at 75 ohms)	**15.8 amps**	**~0 amps**	**15.6 amps**	**31.4 amps**	**14.2 ms**	**7.0 ms**	**78 J**

Note: Most device manufacturers only provide voltage and not the current specification. Voltage and current are directly proportional, so we've assumed a resistance of 75 Ohms when converting voltage to current.
* The Rectilinear Biphasic Waveform data is from the ZOLL AED 3 specification. The ranges are the values for resistance of 50 and 100 ohms.
Source: Various AED manufacturers, Rapid Response Revival

Competitor's waveforms were not found through rigorous scientific testing

The history of AED development is not one of manufacturers testing tens or hundreds of different waveforms to find the ones with the highest efficacy. While manufacturers have done some development (especially when moving from monophasic to biphasic), the process was largely akin to finding one that worked and then copying it (Phillips, ZOLL, and Schiller have done more significant research and tested some variations of the established waveform cycles with varying degrees of success). This limited advancement in therapies is despite several studies[60] showing that more optimal waveforms exist. Indeed, ZOLL claims that it is the only manufacturer with US FDA approval to claim that its biphasic waveform is better than monophasic waveforms, even though biphasic waveforms became the norm for internal defibrillators around 1990 and external defibrillators in the early 2000s.

Most AED brands license existing waveforms for the major manufacturers and secure regulatory approval simply by demonstrating their waveform is the same as those already approved. Importantly, as discussed in more detail later (see '*Regulation - Recent changes to regulation widens CellAED's protective moat*' below), both the US FDA and CE have closed the equivalency pathway.

Prior to the release of CellAED, the more optimally designed waveforms never seemed to make it from laboratory to commercialisation, but these research papers (footnote 60) formed the basis on which CellAED's waveform was designed.

The key findings of the papers were:

Current not energy determines therapeutic outcomes

1. **Current not energy:** Current not energy drives the key therapeutic outcomes of defibrillation
2. **Peak-to-peak current:** Increasing the peak-to-peak current between phases (A1 + A3 in Figure 27) can increase the efficacy of defibrillation, thereby achieving defibrillation at lower energy levels
3. **Lower capacitance:** Given various factors within the range of typical patients and defibrillation use cases, the optimal capacitance for defibrillation is between 40-80 microfarads (similar to what CellAED uses). This compares to the 150 – 200 microfarad capacitance of most defibrillators.

[60] Waveform analysis of biphasic external defibrillators (2001), Optimal Small-Capacitor Biphasic Waveform (1998), Optimal biphasic waveforms for internal defibrillation (2003), Fully Discharging Phases: A New Approach to Biphasic Waveforms for External Defibrillation (1999), Large Change in Voltage at Phase Reversal Improves Biphasic Defibrillation Thresholds (1996)

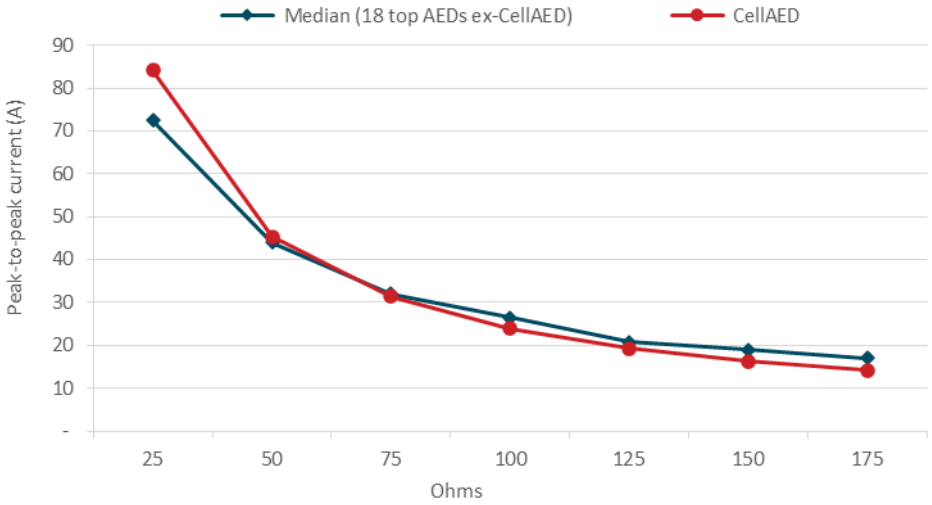
4. **Asymmetrical phase time:** The optimal "phase tilt" (the ratio T1 to T2 in Figure 27) is around 70%, ie T1= 70% of full cycle, T2 = 30% of full cycle.
5. **Symmetrical phase current:** Symmetrical positive and negative cycles can increase defibrillation success.

As with most research papers, each finding comes with caveats. The results were found under specific conditions and don't necessarily replicate across all situations. The experiments were performed using theoretical models, benchtop testing or animal experiments and may not translate to humans. However, we believe that these studies and papers, and probably many others, formed the basis on which RRR developed its optimised waveform.

Using data from a research paper[61] published in the journal 'Resuscitation' we calculated the approximate median peak-to-peak current for 18 of the most popular AEDs. As shown in Figure 28, despite its significantly lower energy rating, CellAED generates the same peak-to-peak current as the median of the top 18 AEDs on the market.

Despite its significantly lower energy waveform, CellAED's peak to peak current matches competitor

Figure 28: CellAED's peak-to-peak current approximates median

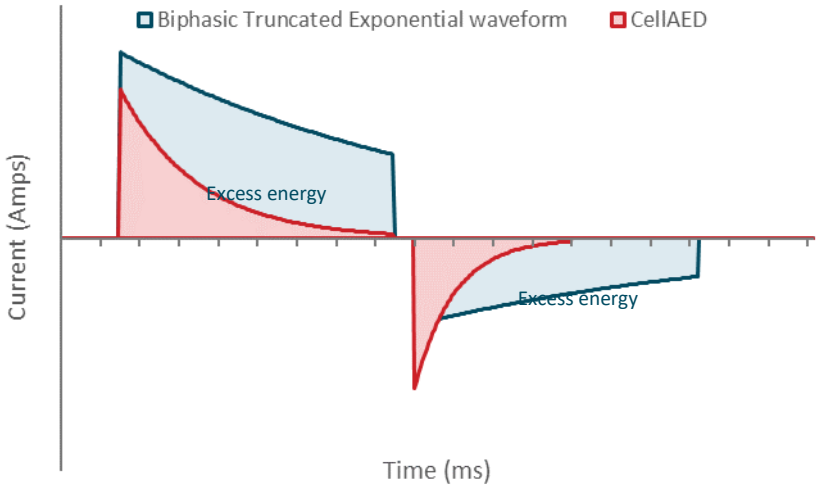


Source: Electrical features of eighteen automated external defibrillators: A systematic evaluation (2013), Rapid Response Revival

Given 1) the mounting evidence that current and peak-to-peak current is the driving therapeutic factor in defibrillation; and 2) electrical energy damages tissue, especially heart tissue, it seems logical that optimal defibrillation would minimise energy put into the patient while delivering the minimal effective current.

[61] Electrical features of eighteen automated external defibrillators: A systematic evaluation (2013)

Figure 29: CellAED delivers a higher peak-to-peak currency at lower energy



Source: Venn Brown, CellAED, various AED manufacturers

Excess energy provides no therapeutic value, but can cause more damage

A word about energy

Within the defibrillator industry, emergency services and emergency medicine, energy, measured in joules, is the shorthand used to measure or discuss the efficacy of defibrillators. This is both a combination of simplified marketing by defibrillator manufacturers and a byproduct of the controls on manual defibrillators reading in joules. Interestingly, for years, the major defibrillator manufacturers have tried to change the focus from energy and include detailed discussions in most of their literature and white papers on therapeutic outcomes being driven by current rather than energy. Unfortunately, it is taking a long time for practitioners to catch up, no doubt, because the equipment controls are still in Joules and not Amps.

Controls on manual defibrillators create confusion amongst clinicians and EMS staff

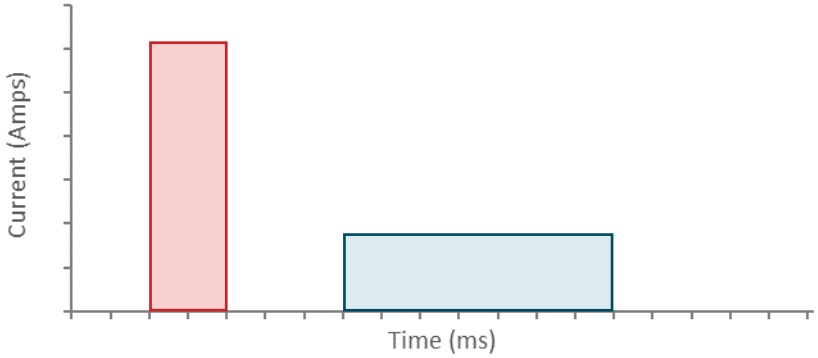
Within hospital settings (or first responder events) and with some AEDs, if an initial shock doesn't return the heart to its natural rhythm, medical staff or some devices will increase the energy of subsequent shock. While this often proves effective, in each instance, what's being tested is that a higher energy shock is more effective than a lower energy shock using the same waveform. Comparing AEDs by simply looking at their energy output is akin to comparing cars by only looking at their engine capacity. ZOLL has published its own paper discussing this point ('Rectilinear Biphasic Defibrillation: Separating Fact from Fiction').

As discussed above and investigated in numerous papers (see footnote 60), the efficacy of a defibrillator is not a simple measure of energy. Energy is a result of voltage, current and time and is represented by the area under waveform curves (Figure 27), as shown in Figure 29.

$$\text{Energy (J)} = \text{voltage (V)} \times \text{current (A)} \times \text{time (s)}$$

The two waveforms shown in Figure 30 have the same energy (measured as the area under the curve) but are not equally effective defibrillation waveforms. A very long waveform with a low current would be insufficient to break the heart's excitation threshold, and so would not defibrillate the patient's heart despite delivering the same energy as a short, high-current impulse waveform.

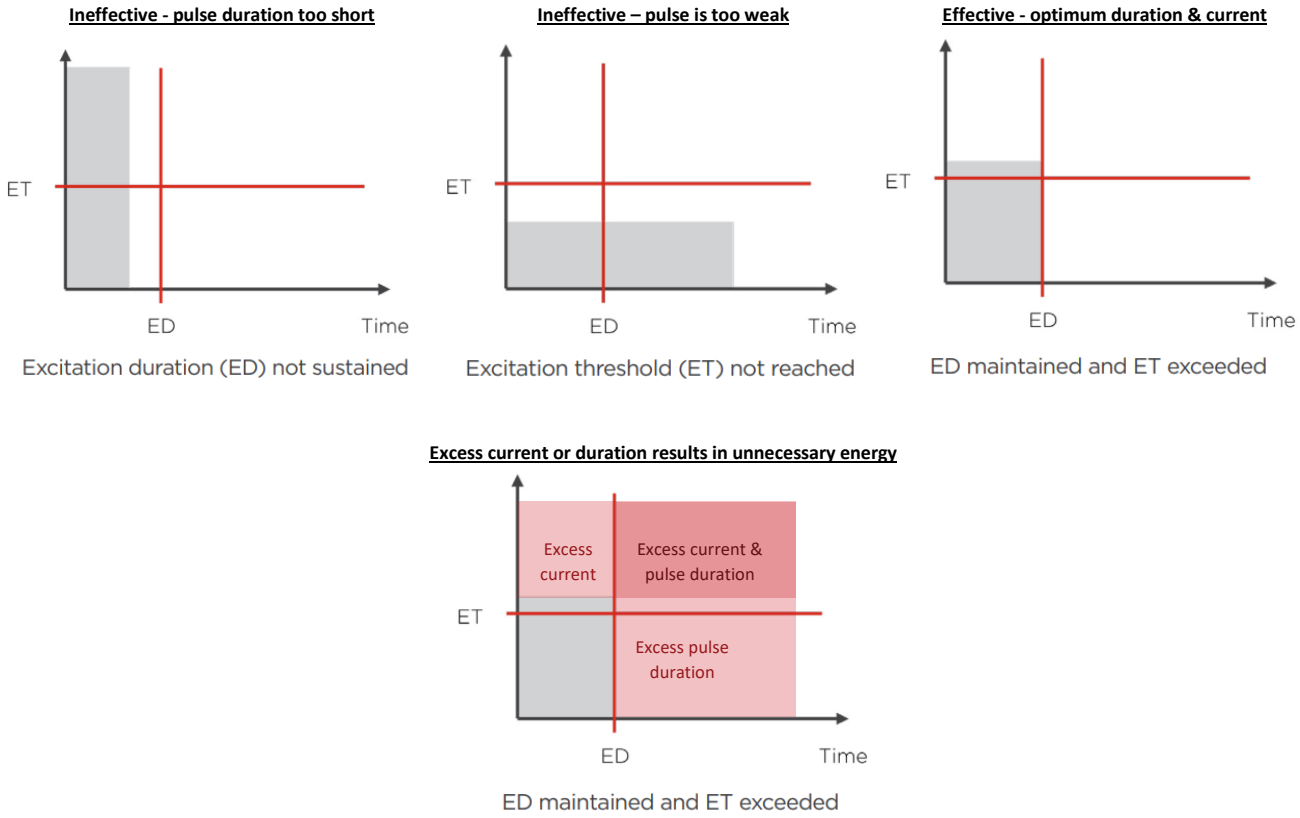
Figure 30: Energy is an imprecise metric for the efficacy of a waveform



Source: Venn Brown

This is not to say time is not a factor. The current pulse must also last long enough for the heart cells to depolarise. The depolarisation time is still a point of discussion within the scientific community, but it's generally accepted that it's shorter than the pulse duration of AEDs, which range from 5 – 20 milliseconds. The duration of most AEDs is 10 – 20 milliseconds (see Table 16), but again, this is an area that needs more research.

Figure 31: A successful excitation pulse is shorter than most AED phase cycles



Source: Schiller, Rapid Response Revival, Venn Brown

While there is overwhelming enthusiasm within the medical and emergency services industry for the arrival of CellAED, there are some who are cautious about its efficacy, given it uses a

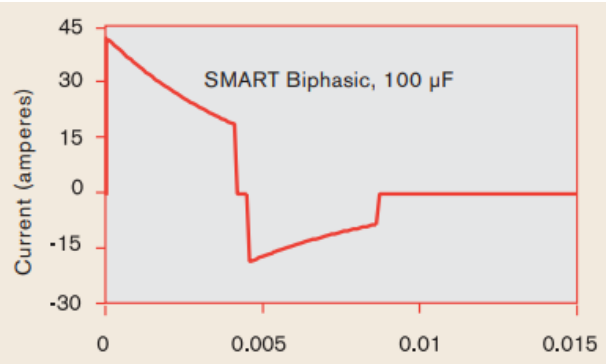
maximum of 85 joules of energy (usually ~80 joules) compared to other AEDs that use 150 – 250 joules (some go as high as 300 joules). While understandable, the focus on joules highlights the lack of understanding, even amongst practitioners, of how defibrillation works and the key therapeutic determinants. The focus on joules is understandable, given the controls of manual external defibrillators used by EMS and medical professionals allow users to increase the joules of the shock. We expect residual hesitation within the industry to somewhat dissipate (although not entirely, given competitors see CellAED as a threat) once the RAPID I clinical trial results are released, which the company is targeting for July (see '*Clinical Trials*' below). The results from the FIRST trial are not expected until 2025.

Philips' waveform is one of the most widely used in AEDs

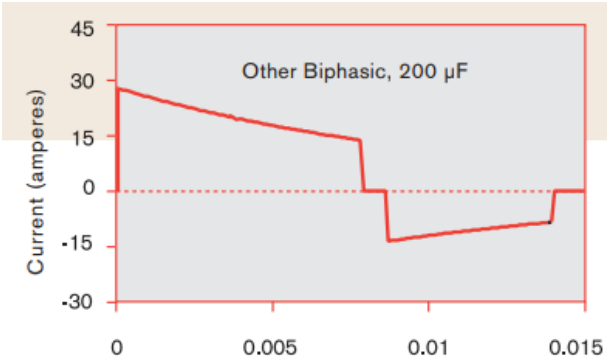
Philips, which probably has the most widely used waveforms (in their own devices and licensed devices, including Avive), has been using and championing low-energy and low-capacitance waveforms for almost 20 years. Several studies they quote[62] outline that wave shape (peak current, peak-to-peak current, and duration of cycle) all had a beneficial effect on patient recovery and patient health outcomes compared to simply waveform energy. Similarly, ZOLL has advocated its own lower energy Rectilinear Biphasic Waveform for several years, advocating that waveform shape is more important than the oversimplified energy measure.

Figure 32: Philips claims its low-energy biphasic waveform is more effective than other higher-energy waveforms.

Philips SMART Biphasic (150 J)



Other Biphasic (200 J)



Source: Philips

Unfortunately, given the cost, time, complexity and, until now, lack of financial incentive to undertake comprehensive clinical testing of various waveforms, it's still not understood what waveform is most effective or even exactly how defibrillation works.

What is widely understood, however, is that applying electrical shocks to the body damages heart tissue. It is in patients' best interest to minimise the energy of each shock and the number of shocks given. Again, the balance of energy versus the number of shocks is also unknown, but high-energy shocks cause permanent adverse health outcomes.

The European Resuscitation Council Guidelines say that:

[62] See https://www.aedbrands.com/wp-content/uploads/2020/11/philips-biphasic-energy.pdf

"The optimal energy for defibrillation is that which achieves defibrillation whilst causing the minimum of myocardial damage. Selection of an appropriate energy level also reduces the number of repetitive shocks, which in turn limits myocardial damage."

The guidelines continue:

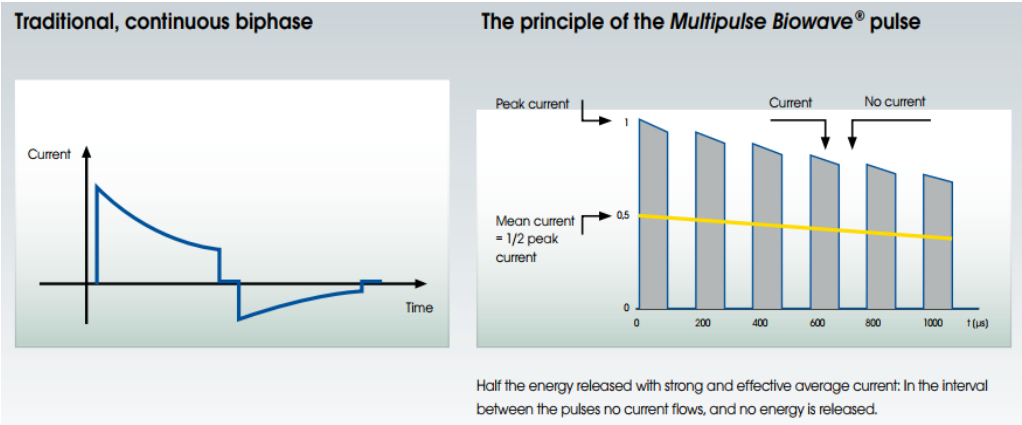
*"**Optimal energy levels for defibrillation are unknown**. The recommendations for energy levels are based on a consensus following careful review of the current literature. Although delivered energy levels are selected for defibrillation, **it is the transmyocardial current flow that achieves defibrillation**; the electrical current correlates well with successful defibrillation and cardioversion."*

"Optimal energy levels for defibrillation are unknown"

Schiller (another leading defibrillator manufacturer) is also a strong advocate for low-energy defibrillation waveforms and developed its Multipulse Biowave® with this goal in mind.

"Multipulse Biowave® emits highly efficient pulses that require less energy. Thanks to this, defibrillation is more successful and causes less damage to the victim. Less effective pulses (both monophasic and biphasic) compensate for the lack of effectiveness by releasing high energy (for example, increasing the first phase period to 10 ms when a patient requires a higher impedance) which is harmful. Especially in cases where the heart has had a previous ischemic injury and has received several shocks."[63]

Figure 33: Schiller's Multipulse Biowave operates at half the energy of a continuous biphase



ZOLL, Stryker, Philips, Schiller all advoke low energy waveforms

Source: Schiller (https://fhfd.dk/wp-content/uploads/2017/06/MultipulseBiowave_EN_frei.pdf)

That said, we expect energy output and the lack of understanding of its importance will likely be used by competitors and their distributors for sales and marketing purposes. This is especially easy now given the results of the clinical trials have not yet been published, and RRR is restricted from addressing these concerns or even reporting on actual lives saved by CellAEDs in the field less it interferes or be perceived to interfere with the First Responder Shock Trial (FIRST) that's currently underway(see '*Clinical Trials*').

[63] Schiller - https://schillerlatam.com/desfibrilacion-segura-y-eficiente-multipulse-biowave/

Awards and recognition

CellAED has won five international design, technology, and innovation awards in the two years since its launch. Along with these awards, the device is being positively received by first responders, emergency medicine professionals, first aid organisations and others in the resuscitation community who see the seismic shift in advancing cardiac arrest survival rates the device can achieve.

CellAED has been internationally recognised for design and innovation

2022

Winner in Life Science Design/Safety Designs

Winner in Life Science Design/Medical /Scientific Machinery

2023

Gold winner – Product Medical and Scientific

2023

Consumer Goods & Services of the Year

Health, Life Sciences and BioTech of the Year

2023

Winner – Red Dot Design Award - "*In the jury's opinion, the readily understandable design gives the user the confidence and security they need to use this device in an emergency.*"

2022

International Design Award - Silver in Industrial And Life Science Design/Medical/Scientific Machinery

Future products

Future projects offer upside to our forecast and valuation

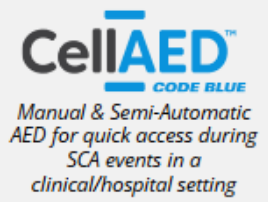
While not included in our cash flow forecasts or valuation, RRR has a roadmap to develop a portfolio of specialist and complementary products, the technology for which has largely already been designed or proven and, in some cases, already built. RRR is already in discussions with potential partners for several of these products, which could lead to significant development capital inflows, removing the need for additional capital raising.

The integration of IoT, location monitoring and mobile connectivity within CellAED opens up significant other opportunities beyond those listed below.

RRR could soon have the largest database of SCA event data in the world

AEDs

CellAED Force: a more robust tactical CellAED specifically developed for in-field military application. This includes modifications to improve protection from water, dust, impact, and extreme temperatures.



CellAED Code Blue: Manual CellAED designed specifically for hospitals. As already mentioned, every year, deaths occur in hospitals because staff cannot find or transport the hospital's limited, expensive, non-portable manual defibrillators to patients suffering cardiac arrests. As a more affordable and fully mobile option, CellAED Blue provides hospitals with a lifesaving device that they can have at every nursing station and within seconds of every patient. CellAED Blue requires minimum modification to the manual Investigational CellAED already used by interventional cardiologists in the RAPID I trial (see '*Clinical Trials*').

Clinical Data

DataAED: As CellAEDs become more widely adopted, RRR will collect a growing database of SCA incidence data. Very little data is currently available on heart rhythms and patient responses during SCA and defibrillation cycles. CellAEDs automatically record this data and communicate it to RRR once the event is complete. DataAED will soon have the most extensive and growing library of SCA data in the world, which can be used by clinicians, medical companies, researchers, and policymakers to help improve population and patient outcomes.

CellAED Mini: RRR researchers are already developing a miniaturised version of the CellAED. This will be another revolutionary step in AED advancement, with everyone able to carry a fully functional AED in their pocket.

Wearables

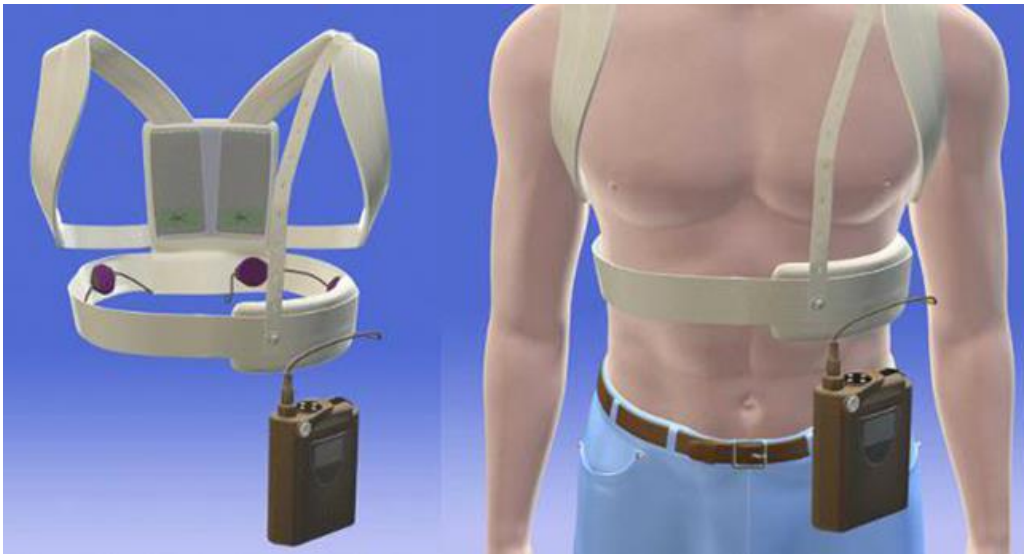
CellAED MEDIC
Wearable AED for out-patients at significant risk of SCA

CellAED Medic: ZOLL has already demonstrated the market for wearable AEDs with its ZOLL LifeVest (see Figure 34 below). The wearable vest is designed for out-patients at significant risk of SCA. At a cost of $3,370 per month, there is clearly an opportunity for the already lightweight, mobile CellAED to expand into this market. ZOLL claims that "tens of thousands of people around the world have protection from sudden cardiac death by wearing LifeVest." Element Science (https://elementscience.com) is also working on a wearable defibrillator called the Jewel. The Jewel is undergoing trials and has not yet secured regulatory approval.

CellAED ACTIVE
Sports wearable for monitoring and treatment of sporadic arrythmias

CellAED Active: A wearable with diagnostic and SCA treatment capabilities designed for athletes to monitor and respond to sporadic arrhythmias. The need for this has exploded (especially in the US) following the collapse and revival of Damar Hamlin (see '*Total Addressable Market - The Damar* & Christian Eriksen Effect' below), along with the wave of publicity that followed the recent collapses of several high school athletes across the US.

Figure 34: ZOLL LifeVest weighs ~1kg and costs US$40,440/yr to lease



Source: ZOLL Medical

Manufacturing & Capacity

As outlined in more detail below (see 'Regulation'), manufacturing Class III[64] medical devices is highly regulated and controlled. Regulators or their representatives conduct both scheduled and unscheduled inspections and audits. The entire manufacturing process must be auditable, with every device traceable back to the time and place of manufacture, the people involved in assembly and testing, the tests that were completed and their results, and the individual components used.

Perhaps surprisingly, the cost of equipment used in manufacturing the CellAED is not high, with most of the equipment available off the shelf. Given the appropriate space, RRR reports it can have new production lines in a new facility, with a production capacity of around 4,000 units per line per month, operating within 3 - 6 months with equipment costs of around $300,000 - $400,000. Additional lines can be added to an existing facility for around the same price within weeks. RRR can expand the capacity of a production line to more than 10,000 a month by operating two shifts a day, seven days a week. Given the small cost of equipment, it's more efficient to operate two lines at 4,000 a month than one line with two shifts.

RRR has set up a manufacturing line in Australia with room to expand. This line is not intended to produce large volumes but is used to optimise the manufacturing process, with efficiencies then passed to other facilities. RRR has another facility in Taiwan, with plans to open new facilities closer to demand as needed. We understand that several manufacturing partners have approached RRR to be involved, some of which also want distribution partnerships.

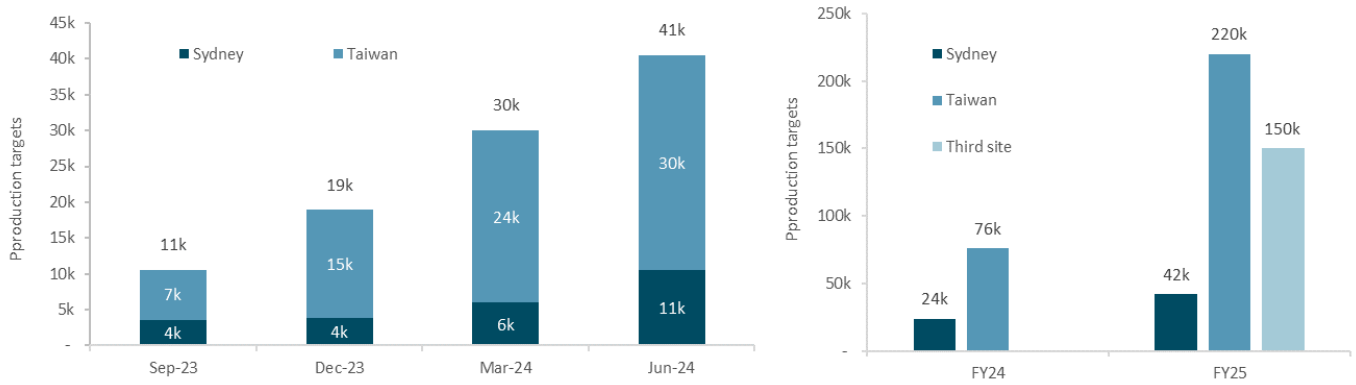
RRR's Sydney facility can produce 1,000 units per month but can ramp up to 4,000 within weeks by adding more people. The limiting factor is the time taken to find and train staff. The facility has sufficient space for more than five lines, with additional space available nearby.

RRR has partnered with a third-party provider in Taiwan for its manufacturing. The current capacity of the Taiwan facility is around 5,000 units per month, but it can rapidly expand to 15,000 units per month. Expanding beyond 15,000 is not complex, simply requiring a second production line, and RRR estimates it would take around three months.

Figure 35 shows RRR's production targets for calendar years 2024-25. The third manufacturing site planned for 2025 is contingent on one of several manufacturing and distribution contracts RRR is currently negotiating with international partners. While these negotiations have long lead times, RRR expects them to lead to sales volumes in the hundreds of thousands or millions of units over the following three to five years.

[64] AEDs became Class III from May 2021 under CE MDR and February 2020 under FDA.

Figure 35: RRR can rapidly ramp up manufacturing to support demand



Source: Rapid Response Revival

Total Addressable Market

Surprisingly, there is little publicly available information about the current AED market. Manufacturers are either large, multi-product companies (with the AEDs tending to provide a small component of total revenue) or private companies.

According to a 2022 report published by Prescient & Strategic Intelligence, in 2021, the global AED market was worth $1.7 billion and was expected to grow to $3.5 billion (CAGR +8.6%) by 2030. Other estimates put annual AED sales between US$2 - 3 billion[65], with aftermarket accessories and services worth $500 million to $ 1 billion.

Assuming an average sale price of $1,700 (which is the bottom end of the price range), a global market of $2 billion implies annual unit sales of 1.2 million. Lifting the sale price to the more realistic but still conservative average sale price of $2,100 implies annual unit sales of around 950,000. Comments by the President of ZOLL Medical support this range estimate.

ZOLL Medical, Philips and Stryker control 60-80% of the global AED market (*Competitive Landscape* below). In November 2023, ZOLL's president reported that the collapse of NFL player Damar Hamlin in January 2023 (see 'The Damar & Christian Eriksen Effect' below) caused a huge jump in US AED demand. The President reported that ZOLL had built more than 250 thousand devices year-to-date, double the number it manufactured three years ago.

Table 17: We estimate annual global AED unit sales of between 1.2 - 1.8 million

	$1,700	$2,100
US$2 billion	1.2 million	952,000
US$3 billion	1.8 million	1.4 million

Source: Venn Brown

With such a small existing market, it's not surprising the industry has seen limited innovation over recent decades. All but a few new entrants are targeting only a fraction of the potential customer base, namely hospitals, emergency services, large businesses and corporates, and the public access markets. This is entirely understandable, given aside from CellAED, current devices are significantly larger, heavier, more complicated, and more expensive.

CellAED: Creating a new market

While the CellAED is highly competitive in most of the existing AED applications – businesses, shopping centres, sports grounds, public places, nursing homes[66] - the device is creating an entirely new market focusing on the place where 70-80% of all SCA occur, the home. Despite only launching in mid-2022, over the last 12 months alone, CellAED has reportedly outsold all other AEDs in the Australian market, outselling marketing leading ZOLL AEDs by eight times.

[65] A Chinese research report claimed the global AED in 2022 was US$5.1 billion, with China representing US$1.6 billion, implying a global ex-China market of US$3.5 billion.

[66] CellAED won't replace manual or semi-automatic defibrillators used by medical professional. The planned future device CellAED Blue is being designed as backup defibrillator for medical professionals.

First responders have also purchased the device, and it is in trials with several first responder groups and corporate clients beyond the initially targeted home market.

Given the key characteristics of affordability, portability and simplicity of maintenance, we believe CellAED can find significant traction within the customer segments and use cases summarised in Table 18.

Table 18: CellAED can open up entirely new AED markets

Customers	Status
Homes	Currently selling
Small business	Currently selling
Corporates	Currently selling
Police	Trial with Leicestershire police[67], whose Police and Crime Commission said the CellAED would help "save lives", while others involved in the trial said the CellAED was a "game changer" for policing. Due to the patrol nature of policing, officers are more likely to be the first emergency service on a scene, ahead of ambulance and fire.
Emergency services	Conversations with ambulance officers have indicated they would support having the CellAED as a backup device in ambulances, as have other emergency service providers like the State Emergency Services (SES).
UK NHS Supply Chain	CellAED is an approved product on the UK NHS Supply Chain (National Health Service), which puts it in front of all healthcare professionals, agencies, and businesses in the UK. The NHS Supply Chain created an entirely new product segment for CellAED, "Personal Defibrillator", in which CellAED is the only product. In November, demonstrating an almost unprecedented level of support, the NHS Supply Chain released a press release stating: "Following recent clinical feedback, it was really great to see the scope of areas this product would benefit – from hospitals, at home, to the Ministry of Defence, emerging technology, and innovation can really tackle problems the NHS can face." And "Clinicians who have seen the handheld AED are very enthusiastic about the difference it could make. From anaesthetist assistants to GP Practice nurses and community nurses they have all said that **thanks to its small size they would carry one in their emergency bag so it's close at hand.**"
Government	Hertfordshire County Council (United Kingdom) has equipped its telecare vans with CellAEDs. Various government AED initiatives are underway in Australia, the UK, the US, Canada, Italy, UAE, and China. See Table 27.
Schools	Positive conversations with some schools in the UK where AEDs are now mandatory (legislation was passed in late 2023). An athletic trainer at an Ohio private high school said the record demand driven by the Damar Effect (see *The Damar & Christian Eriksen Effects)* has meant estimated wait times for AED batteries now stand at 25 weeks. A US based SCA awareness and training foundation called 'In a Heartbeat', which donates AEDs to schools and community groups, reports that in the seven months following Damar's collapse, they've received more than 70% more requests for AEDs than they received in the preceding seven years combined. 'USA Today' released Safer Sidelines, a multipart investigation that found more than 400 athletes died of sudden death in high school sports in the last 20 years. Sudden cardiac arrest is the number one killer of high school athletes. The investigation found that adding one traditional AED would cost less than $10 per sports participant for 99% of schools in Kentucky. The average cost statewide was $3.07 per participant. Using CellAEDs would reduce this figure by about 70%.

[67] **Note:** See *Protection & Competitive Advantages* section for more information.

Customers	Status
Hospitals	CellAED Blue, specifically designed for hospitals, is being developed. Every year, thousands of patients die in hospitals because staff can't find the few defibrillators on each floor or can't get them to the patients in time. CellAED is ~10% of the cost of current hospital AEDs, enabling hospitals to have backup AEDs in every ward. See 'Future products' above.
Vehicle manufacturers	Proposed but unconfirmed
Military	Some interest, but the device requires modifications to support infield conditions, including temperature variability, shock resistance and weather resistance. CellAED confirms these modifications are on the product roadmap but are not an immediate priority until they have strong interest from the military.
Community Volunteer Responders (CFRs)	RRR is providing CellAEDs to the Victorian ambulance service as part of a trial with GoodSAM (see *Clinical Trials* below). GoodSAM was founded in the UK in 2013 to radically change the response to Cardiac Arrests. Trained first aiders register with GoodSAM and are alerted of a cardiac emergency via the GoodSAM app. GoodSAM reports that over a million registered responders are using its app. Several first-aid training organisations have also become CellAED resellers. The GoodSAM app is now also active in NSW.
Remote workers	Currently selling to mine sites.
Sporting & leisure clubs	The Damar Effect (see *The Damar & Christian Eriksen Effects* below) is seeing a massive increase in US demand for AEDs by schools, sports teams, and administrators. The NSW government gave grants of up to $9,000 to sporting teams to fund AEDs (see Table 27)
Other activities	Occupational health with a CellAED carried in a mobile first aid kit, airline industry, where weight matters, hotels and cruise lines one for each guest suite or hallway. The applications seem nearly endless.

While we believe CellAED is competitive in most of the applications of existing AED, it is the home and SME market that CellAED is uniquely positioned to capture.

CellAED has a massive target market

The developers of the CellAED have a truly ambitious goal of making personal defibrillators as ubiquitous and widely adopted as fire extinguishers, fire blankets and smoke detectors, with one available in almost every home. Putting this in context, since 2004, fewer than 3,800 people have died each year in the US from fires, compared to the 350,000 who die each year from sudden cardiac arrest. The rollout (and, in some cases, the legislatively mandated rollout) of smoke detectors and fire extinguishers has no doubt helped reduce the number of fire-related deaths, so too could the widespread rollout of in-home AEDs help reduce the number of annual SCA deaths.

As mentioned previously, CellAED is already approved for sale in Australia, New Zealand, the UK, Ireland, Malta, and South Africa.

Table 19: CellAED is already available in six countries

Country	Status
Australia	Selling
New Zealand	Selling
United Kingdom	Selling
Ireland	Selling
Malta	Selling
South Africa	Selling
France	Negotiating – needs translation
Italy	Negotiating – needs translation
Germany	Negotiating – needs translation
UAE	We suspect negotiating[68]
Taiwan	Planned – needs translation
USA	Planned but needs FDA approval
China	Negotiating with interested distributors
India	Approached by interested distributors

While CellAED has secured a CE rating (Europe), to sell into each country, the device must provide instructions and audio commands in each local language. RRR reports that each localisation costs around A$300,000 - A$500,000 and will take around six months to develop and secure approval (this can happen concurrently). This cost and time frame will be reduced with future models as certain design decisions made in the early stages complicate localisation.

Rapid Response Revival is taking a strategic approach to this localisation, first selling into markets that require only English and waiting until it has sufficient demand or a distribution partner before undertaking the localisation.

In the following analysis, we look at the regions that we believe represent CellAED's largest and most immediate markets for the medium term. We have excluded the UAE and China from this analysis as we discuss those specific markets later.[69]

[68] RRR's Chief Research Officer Dr Atheer Nassir, is also listed as the Chief Executive Officer of Middle East and North Africa. No other geography has a regional head.

[69] The various demographic and population data used in this section was obtained from a variety of different sources include various departments of individual countries, the UN, WHO, the World Bank and several data aggregators. As such there are differences in collection methodologies, definitions, year of capture and classifications. We view the data as approximations only. See *Appendix: References - Population and demographic statistics* for a list of sources.

Table 20: There are close to 900 million people in CellAED's target geographies

	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Total
Population	26.5m	67.2m	332.9m	65.5m	83.8m	59.3m	239m	874m
Population >=40	12.4m	28.6m	161.9m	34.3m	47.2m	36.1m	133m	454m
Population >=50	9.1m	21.5m	120.8m	26.6m	41.6m	27.9m	93m	340m

Source: See *References - Population and demographic statistics*

As shown in Table 18, the population of the regions CellAED is targeting in the medium term is almost 900 million people. A more realistic market size is the 340 million people who are above 50 years of age. An AED is akin to an insurance policy. It's something no one wants to use, but they want to have it in case they need it. As such, given young people are both less likely to suffer a cardiac event, less likely to have ~US$250 to purchase a CellAED and less likely to consider themselves at risk of a SCA, we don't view them as a target market. That said, people in the 30-50 age range may purchase a CellAED for their parents or elderly relatives. Venn Brown is aware of several instances where this has already happened.

More relevant than the population is the number of households. Given that a household is unlikely to purchase more than one device, we looked at the number of households with at least one person over 50 and found approximately 115 million households within the immediate relevant geographies.

Table 21: There are 155 million households within CellAED's target geographies

	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Total
Households	9.3m	27.6m	139m	35.7m	41.8m	25.3m	107m	386m
Households w/ >=40	3.9m	15.5m	85.0m	19.5m	23.0m	13.5m	59.0m	219m
Households w/ >=50	**2.7m**	**11.3m**	**61.0m**	**14.0m**	**16.5m**	**9.5m**	**40.0m**	**155m**

Source: See *References - Population and demographic statistics*

The CellAED is also ideal for the SME market. Not only is it more affordable than other AEDs, but it requires no maintenance, and remote monitoring ensures it's continually operating correctly. The CellAED offers business owners a buy-and-forget option. Given the lower price, businesses can buy multiple devices for the same cost as a single competitor device, thereby having more devices available in each office across all their locations. We also expect there will be cross-selling with business owners or managers buying devices for their homes and businesses. We are aware of several instances where this has already occurred. There are approximately 71 million businesses within our specified region.

[70] European Union excluding France, Germany, and Italy.

Table 22: There are 71 million businesses within CellAED's target geographies

	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Total
Businesses	2.6m	5.5m	33.2m	4.1m	5.3m	6.0m	15m	71m

Source: See *References - Population and demographic statistics*

As discussed below (see *Clinical Trials* and *Sales, marketing and* traction), the CellAED is already in the hands of police and first responders. If the trial with Leicestershire Police is successful, CellAED could easily expand into the remaining 44 police forces across the UK, representing around 186,000 police officers.

CellAED is also already being used by Ambulance Victoria and St John Ambulance NZ as part of the GoodSAM trial (FIRST – see *Clinical trial: FIRST*). We have spoken with first responders who've said that the CellAED would be a good backup defibrillator for ambulances, and because of its size and weight, it could also be carried by first responders either operating on motorcycle or on foot where carrying the larger existing AEDs isn't practical. Logic also suggests CellAED is an ideal fit for volunteer responders like those using GoodSAM. It's small, lightweight, mobile and affordable. Upon being notified of an emergency, responders can grab their CellAED from the wall mount in their home or office and then run to the emergency and immediately apply the defibrillator, saving valuable minutes by not having to go via a public access AED (if one is close by and in working order) or wait for EMS to arrive. The results of the trial will be telling.

Table 23: First responders are another significant market opportunity

	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Total
Police Officers	80k	186k	708k	150k	290k	277k	883k	2.6m
Ambulance Vehicles[71]	4,073	7,200	57,000	6,470	8,256	9,436	23,174	115,610

Source: See *References - Population and demographic statistics*

Table 24 below summarises the size of the first mover target market within the markets into which Rapid Response Revival is already selling or is expected to enter within the next three to four years.

[71] The number of frontline operational emergency employees is more than double this: Australia – ~15,000, UK – 17,847, USA - 269,000. See *References - Population and demographic statistics*

Table 24: A conservative estimate puts CellAED's target market at 229 million

Category	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Size
Households w/ >=50	2.7m	11.3m	61.0m	14.0m	16.5m	9.5m	40.0m	155m
Businesses	2.6m	5.5m	33.2m	4.1m	5.3m	6.0m	15m	71m
Police Officers	80k	186k	708k	150k	290k	277k	883k	2.6m
Ambulance Vehicles	4,073	7,200	57,000	6,470	8,256	9,436	23,174	0.1m
Total	**5.4m**	**17.0m**	**95.0m**	**18.3m**	**22.0m**	**15.8m**	**55.6m**	**230m***

***Note:** New Zealand adds 1.1 million, bringing the total TAM to 230 million.

Several other future markets are open to CellAED, as listed in Table 18. As previously discussed, RRR has already designed a modified CellAED for hospitals. There are also military applications with a CellAED distributor reporting they are in discussions with military representatives. Opportunities also exist for safety-conscious car manufacturers to provide CellAEDs as an added feature. Each of these applications requires some modification to the existing device, but as shown below, each market represents a meaningful opportunity.

Table 25: New vehicles and hospitals provide opportunities for future sales

	Australia	UK	USA	France	Germany	Italy	EU-ex[70]	Total
Hospitals - Total	1,354	1,148	6,090	2,989	1,893	1,051	9,067	23,592
Hospital Beds - Total	98k	171k	920k	382k	480k	210k	1,273k	3,533k
New Vehicles Sold	1.1m	1.6m	13.9m	1.9m	2.6m	1.3m	5.5m	27.9m
Military medics[72]	4,000	12,200	73,000	14,232	18,000	11,731	-	133,163

Source: See *References - Population and demographic statistics*

Market Drivers

Several factors are increasing the overall risk and instance of SCA around the globe, thereby increasing the benefit of more readily available AEDs. This demand is being compelled by the steadily increasing awareness of SCA and the importance AEDs play in survival rates.

1. **Aging population:** Throughout the developed world and most of the rest of the world, the population is aging. Age is a major risk factor for SCA, with 58% of all incidents occurring in people over 65 (see Figure 8).
   According to the United Nations Department of Economic and Social Affairs, globally, in 2020, there were around 727 million people aged 65 years or above, and this number is projected to double by 2050, reaching more than 1.5 billion. The share of the older population is expected to increase from 9.3% in 2020 to 16.0% by 2050.

[72] Best estimates based publicly available information.

2. **Cardiovascular disease:** Cardiovascular disease (CVD) is a leading cause of SCA and is the leading cause of death amongst 40% of the G20+ countries[73] and the second leading cause of death amongst 55% of G20+ countries. In 2019, 18.6 million people died from cardiovascular disease. From 1990 to 2019, the worldwide prevalence of cardiovascular disease increased from 271 million people to a staggering 523 million people.[74] Table 26 below shows ten countries within the G20+ with the highest rates of cardiovascular disease. South Korea, Mexico, and Spain have the lowest rates of CVD amongst the G20+.

Table 26: Ten countries in G20+ with the highest rates of cardiovascular disease

Rank	Country	Cases per 100,000
1	European Union	11,647
2	Saudi Arabia	7,917
3	United States of America	7,617
4	Italy	7,499
5	Russia	7,453
6	Canada	6,799
7	South Africa	6,740
8	Australia	6,478
9	Turkey	6,241
10	China	6,177
….		
19	Spain	5,029
20	Mexico	4,977
21	South Korea	4,518

Note: According to the American College of Cardiology, over half the world's CVD deaths occur in Asia[75]
Source: The State of Cardiovascular Disease in G20+ Countries (2022)

3. **Rise in co-morbidities:** Other risk factors are also increasing, with rates of obesity and diabetes also steadily growing (see Table 7).
4. **COVID-19 aftereffects:** Studies have found that having COVID significantly increases one's risk of developing 20 cardiovascular problems for more than a year after infection. In one study, the risk of heart failure increased by 72%[76].
5. **Increased public awareness:** The very public collapse of several college and professional sports people (including Damar Hamlin, see below), along with the rise

[73] G20+ includes Argentina, Australia, Brazil, Canada, China, France, Germany, India, Indonesia, Italy, Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Turkey, the United Kingdom, the United States, the European Union and Spain.

[74] The State of Cardiovascular Disease in G20+ Countries (2022)

[75] Source: https://www.acc.org/latest-in-cardiology/articles/2021/06/15/19/43/review-shows-over-half-of-cvd-deaths-worldwide-occur-in-asia

[76] Heart-disease risk soars after COVID - even with a mild case (2022)

in cardiac events during the COVID pandemic, have significantly increased public awareness of rates and risks of sudden cardiac arrests.

6. **Government programs:** Various governments around the world are initiating programs and legislation to address the growing rates of SCA (see 'Government legislative support' below).
7. **Launch of new products:** The launch of new AEDs aimed at the home or SME market will help lift public awareness, including CellAED, Avive (USA) and HeartHero (Europe).

The Damar & Christian Eriksen Effects

In January 2023, Damar Hamlin, the NFL player with the Buffalo Bills, collapsed mid-game with a SCA. Watched by 24 million viewers across the US and then replayed to tens of millions more in thousands of news broadcasts in the ensuing weeks, Damar collapsed and was then revived with an AED. This one incident saw demand for AEDs skyrocket overnight, in what the industry is now calling the 'The Damar Effect'.

"The world recognized if this can happen to an NFL superstar, it can happen to anybody," said Troy Pflunger, the vice president of sales for ZOLL. "It's turned up awareness and an eye to education.". As mentioned above, ZOLL is reporting a doubling of demand compared to three years ago, with a significant portion of the growth attributed to the Damar and similar effects.

In January, the US FDA reported that it expects shortages of AEDs will likely last through the summer of 2024. This is despite the agency's October 2023 update, which reported that it expected the AED shortage to end in 2023. The FDA said the shortages are largely due to increased demand for the devices.

A similar incident occurred in 2021 when Danish footballer Christian Eriksen collapsed with a cardiac arrest while playing Finland in the Euro 2020. Erisksen was resuscitated and made a full recovery. Industry contacts report demand in Denmark for AEDs doubled following the incident in what's now referred to as the "Christian Eriksen effect".

Government legislative support

Over the past several years, governments from around the world have enacted or reviewed legislation to reduce the huge number of lives lost or impacted each year by sudden cardiac arrest. Table 27 lists a sample of some of these programs, policies and legislative changes undertaken or being considered by just a few states or countries. Each of these changes looks to:

1. Increase government and public awareness of the risk and prevalence of SCA;
2. Increase funding to support measures to reduce rates of death and disability caused by SCA;
3. Increase the number and availably of AEDs; and
4. Provide funding for the purchase of AEDs.

Overall, the legislative and regulatory environments are moving in a favourable direction for CellAED. It's worth considering the precedence of smoke detectors and domestic fire blankets and extinguishers. In Australia, most places of business and rented residential apartments require smoke alarms. It's not out of the question that governments implement similar legislation mandating AEDs in schools, public buildings, businesses, apartment blocks and

perhaps even rental accommodation. Such regulation is now in place in parts of Italy and in Manitoba and Ontario in Canada.

Table 27: AEDs benefit from legislative initiatives

Country	Regulatory support
USA	Over 37 states have mandated the placement of AEDs in specific locations and have passed laws or adopted high-school curricula requiring hands-on, guidelines-based CPR and AED training. The bipartisan Cardiac Arrest Survival Act, introduced in February 2023, looks to save lives by establishing a uniform base of liability protection for businesses that acquire AEDs and the good Samaritans who use them.
USA	Lawmakers in several states, urged on by advocates, are pushing to require AEDs in schools.
USA	The federal Access to AED Act, which would mandate AEDs in schools, is in front of Congress.
South Australia (Australia)	The South Australian State Government recently passed a bill mandating that AEDs be installed in every commercial building of more than 6,458 square feet and on all public transport (trains & buses). The government will spend $9.1 million over three years to install defibrillators in all government buildings and vehicles, including public buses, trains, trams, and emergency vehicles.[77] When a member of the legislative council presented the bill, CellAED® was mentioned multiple times as an example of an affordable defibrillator.
New South Wales (Australia)	A spokesperson said the NSW government would "carefully monitor the roll-out of the SA legislation and glean any lessons that may be learned". The government also provided up to $9,000 in grants for sporting clubs to purchase AEDs.[77]
New South Wales (Australia)	In 2022, the NSW government spent $2.5 million bringing the GoodSAM smartphone app to NSW. GoodSAM is a program that alerts members of the community to a nearby cardiac arrest. GoodSAM also has the world's largest register of AED locations available to its volunteers in the event of a SCA. Last year, a global network of 1.5 million GoodSAM volunteers helped save the life of a cardiac arrest patient on average every three minutes.
Victoria (Australia)	The Victorian Ambulance Service is running a trial giving CellAEDs to GoodSAM responders (see *Clinical trial: FIRST*).
Europe	The 'Learnt to drive. Learn CPR' initiative is a collaboration between the European Resuscitation Council (ERC) and the European Driving Schools Association (EFA) to make learning CPR a compulsory part of learning to drive.
United Kingdom	The UK Government recently announced that it will provide all state-funded schools with defibrillators by late 2023. There is growing interest among policymakers in AEDs, as evidenced by the 100+ members ofparliament and staff who attended RRR's event hosted in Westminster, London.
United Kingdom	UK MPs have formed a Defibrillator All-Party Parliamentary Group (APPG). APPGs are informal, cross-party groups formed by MPs and Members of the House of Lords who share a common interest in a particular policy area, region, or country. The group provides a forum to discuss strategies and policies to improve SCA survival rates and outcomes and the roles defibrillators can play.

[77] https://www.smh.com.au/national/nsw/a-defibrillator-saved-this-wiggle-s-life-now-he-wants-them-everywhere-20230511-p5d7le.html

Country	Regulatory support
United Kingdom	Several British MPs have backed a campaign calling for purchases of automated external defibrillators (AEDs) for businesses and community groups to be zero-rated for VAT. The campaign to scrap the 'Heart Restart Tax' has been launched by the British Healthcare Trades Association. It is calling on the Government to remove the 20% VAT currently levied on defibrillators to widen defibrillator access in public spaces and thereby save lives.
United Kingdom	A bill has been presented to parliament to legislate the inclusion of AEDs in every development with more than ten houses.
Italy	In 2021, legislation came into effect that mandates the deployment of AEDs across all Italian cities in offices, schools, stations, airports, and ports. Public place administrators also need to maintain PAD (public access defibrillator) networks, and AED availability is mandatory. 'Good Samaritan Laws' were also introduced, reversing outdated laws which previously prevented untrained civiliansfrom using an AED in an emergency.
Canada	In November 2020, OHS Canada reported that the Defibrillator Registration and Public Access Act (Bill 141) was accepted by the government and is anticipated to increase public access to AEDs in the country.
Nova Scotia (Canada)	In March 2023, the Nova Scotia government announced a $700,000 investment to equip all public schools in Nova Scotia with automated external defibrillators. The government planned to purchase up to 350 units for a total investment of about $700,000 to ensure each school in the province had a device. About 70 schools already have a defibrillator – most of those have students with specialized healthcare plans requiring access to a defibrillator, while others have one as the result of fundraising, donation or based on a school community decision.
UAE	In 2022, the Dubai Health Authority launched its 'Dubai Heart Safe City' program. With support from the American Heart Association, the program intends to make Dubai one of the safest in the world in terms of response time to cardiac arrests by training 23,000 volunteers in CPR and placing 10,000 public access defibrillators across the city. It's worth noting that while Rapid Response Revival has not announced any projects in the Middle East, nor is it currently selling devices into the Middle East, its Chief Research Officer, Dr Atheer Nassir, is also listed as the Chief Executive Officer of the Middle East and North Africa. In November 2023, Dr Nassir represented RRR at the first Annual Arab Resuscitation Council Conference in Dubai. In January 2024, Dr Nassir and other members of RRR's leadership attended the Arab Health Conference in Dubai. Venn Brown is aware that Dr Nassir speaks fluent Arabic and has made several trips to the UAE over the last six months.
Saudi Arabia	In 2019, the Saudi Arabia Ministry of Health partnered with Philips on the 'Heart Safe City' project to increase SCA survival rates. In 2023, the Department of Emergency Medical Services partnered with several other ministries and institutions from Poland and Sweden to investigate the use of drones for streamlining disaster management and prehospital care in Saudi Arabia. The Occupational Safety and Health Governance Framework for Saudi Arabia's famous new NEOM city encourages all businesses to establish an AED program that puts an AED within 3-5 minutes of all employees.

Country	Regulatory support
China	In 2021, the National Health Commission (responsible for national health policies across China) issued new guidelines regarding the deployment of AEDs in public places, emphasising their significance in saving lives during SCA. The guidelines align with the 'Healthy China Action (2019 – 2030) initiative, which aims to enhance emergency equipment standards, including the need for health authorities to support AED deployments and conduct training to ensure effective utilisation and integration with pre-hospital emergency services. While China offers a huge potential market, most people don't recognise "AED" and have no first aid training or understanding. Despite this, encouraged by the national policy, several major cities are implementing plans to increase access and awareness of AEDs. It should be noted that several of these cities have populations of more than twelve million people. According to the National Health Commission's draft 'Technical Guidelines for the Configuration and Management of AEDs in Public Places,' the recommended quantity of AEDs should range from 100 to 200 units per 100,000 people. Across China, there are currently 16 devices per 100,000 people, with Shenzhen having the highest deployment of 30 devices per 100,000. With a population of 1.4 billion, 100 units per 100,000 people require 1.4 million devices. The Health Commission policy also encourages organisations, workplaces and "families or individuals with the means" are encouraged to acquire AEDs for personal use. • **Shenzhen:** goal to deploy 60,000 AEDs in 5-10 years • **Beijing:** 5,000 AEDs by the end of 2023

Sales, marketing and traction

CellAED is an insurance product that people hope never to use

When reviewing Rapid Response Revival's sales figures, it's important to consider the vapour-thin marketing budget the company has been working with. The challenge RRR faces is that despite the huge target market, CellAED is a new product in an entirely new product category. It will take time and a marketing budget to build awareness that a personal defibrillator exists. Additionally, CellAED is effectively an insurance product that people never want to use. As such, we expect the sales cycle and market recognition to follow a more delayed trajectory than a recreational consumer product.

All that said, in Australia, in its first twelve months, **CellAED sold eight times more devices than ZOLL**, one of the world's leading AED brands.

Other key achievements to date include:

1) Direct sales is the largest and fastest growth sales channel, delivering 75% of sales in the second half of 2023.
2) RRR reports no evidence of price elasticity after increasing prices in November.
3) Trading terms of offline sales: 20-50% upfront deposit, remainder once the order is shipped.

RRR generated $6.8 million in sales in its first 16 months

4) RRR has been approached by multiple groups looking to secure exclusive distribution rights to various countries, including China and parts of Europe.
5) Customers were purchasing CellAED even when notified of a three-month waitlist.
6) CellAED became an approved product on the UK NHS Supply Chain (National Health Service), which puts it in front of all healthcare professionals, agencies, and businesses in the UK. The NHS Supply Chain created an entirely new product segment for CellAED, "Personal Defibrillator", in which CellAED is the only product.

Despite these budgetary and other challenges (outlined below), RRR is achieving reasonable sales and steady growth with a stable and affordable acquisition cost of between A$100-$150. As with any new product, sales will benefit from public awareness and brand recognition. Having no direct competitors is obviously a huge advantage, allowing RRR to build a dominant market position. At the same time, acquisition costs should remain steady at worst or, as we expect, decline as RRR optimises its channels and messaging.

Figure 36: RRR has sold 17,500 devices since launching

	Devices sold	Delivered	Revenue ($'000)
FY22	2,039		$0.5m
FY23	9,817	7,344	$3.5m
FY24	5,679	7,110	$3.1m
Total	**17,535**	**14,454**	**$7.1m**

Source: Rapid Response Revival

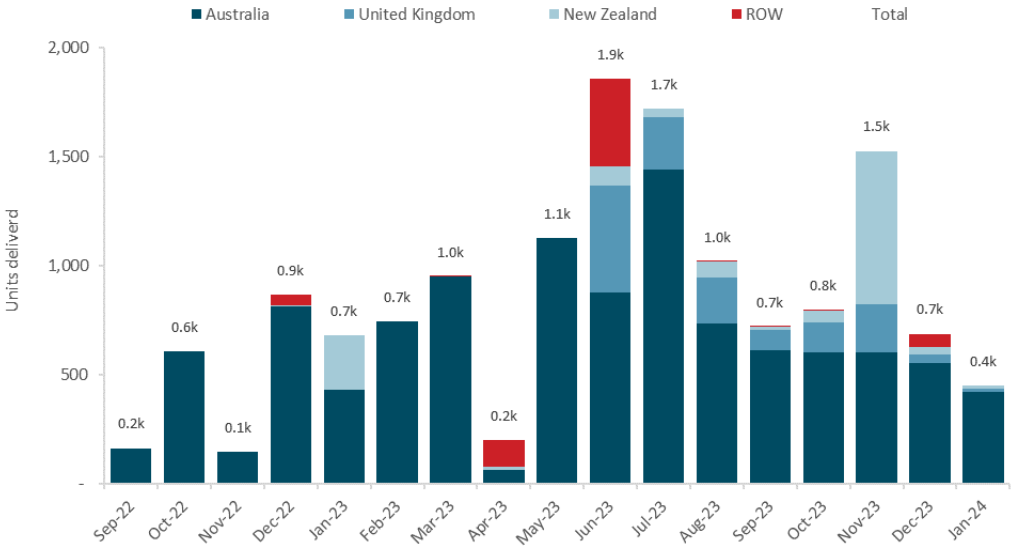
Rapid Response Revival began pre-sales in 2021 and started delivering devices in September 2022. Over that period to the end of January, RRR has sold 17,535 devices and generated $7.1 million in revenue.

CellAED's Australian sales outsold ZOLL by 8x

Figure 37 below shows monthly deliveries through January 2024. RRR started taking pre-orders in early 2022 and operated with a backlog of orders through to May 2023, when it brought its Taiwanese production online. In around March 2023, wait times peaked at approximately three months. Encouragingly, most customers continued to wait, with only a few requesting a refund. RRR worked through most of the backlog from May to July, which is why there was a spike in deliveries during this period, as shown in Figure 37.

Figure 37: Rapid Response Revival has delivered 14,454 CellAEDs

Sales are on track to hit 800 - 900 units in February



Source: Rapid Response Revival

Deliveries slowed in December and January due to a combination of seasonality, production shutdown over Christmas and production slowdown in late January, during which RRR undertook additional testing on a new batch of batteries. RRR reports that manufacturing is back operating at around 1,000 a month, and sales have picked up, with February expected to hit ~700 – 800 units.

Marketing – room to improve

Marketing is focused on online advertising and social media

There are significant improvements RRR can make to its sales and marketing efforts. The current sales results do not reflect what the group can achieve with the requisite marketing budget. RRR is still very much in learning mode, trialling and testing sales and marketing campaigns, messaging, target markets, channels and pricing. Having a longer cash flow runway will accelerate this process. When given the required budget, the marketing team has a long list of changes and updates it plans to make, and we believe these changes will lead to a step change in sales. As discussed in more detail in the *Financial performance* section, CellAED sales are cash flow positive at the gross profit level (including cost of acquisition). A proper marketing budget will see both cost of acquisition and cost of goods sold (COGS) reduced.

The one downside of no competition is that RRR can't leverage other parties' marketing efforts to raise awareness of the new product category. We expect to see a step change in sales once RRR has the additional capital to invest in sales and marketing properly.

RRR has focused its marketing budget on driving direct sales via its Australian website. The group mostly uses online and social media advertising while trialling specific small-scale campaigns in particular publications that they believe will reach first movers and have a high return on investment.

We expect a step change in sales once RRR has raised additional capital

RRR report that they have recently provided resellers with updated marketing collateral. The group is also being more targeted in terms of which resellers invest time. We also expect that the new pricing scheme, which includes higher retailer margins, should stimulate sales growth.

Direct sales channel is the largest and fastest-growing

Direct sales now account for ~75% of all sales

RRR sells CellAED and its accessories direct through its website (www.cellaed.io) and through resellers. Before launch, management expected resellers would account for 70% - 80% of sales, driving international sales. This has not been the case, with direct sales in Australia accounting for a growing majority of sales.

As shown in Figure 38, RRR quickly signed up an impressive number of resellers. The interest is sufficiently strong that customers agree to RRR's payment terms, with small orders paid upfront and larger orders requiring a 20-50% deposit, with the remainder paid upon dispatch. RRR does not give any suppliers credit. The fact that resellers and bulk purchasers agree to such terms demonstrates the strong demand for CellAED by those aware of the product.

Figure 38: RRR signed an impressive number of distributions to its reseller program

Australian Reseller/Distribution Partners

- Safety Supply Solutions Pty Ltd
- Kosmos Group Pty Ltd
- Ecovital Group Pty Ltd
- Evolution Medical Group Pty Ltd
- Citadel Medical Pty Ltd
- Ausnova Services Pty Ltd
- APL Group Pty Ltd (LivCor)

  + 113 Sub-resellers via LivCor
- DefibsPlus Pty Ltd
- Universal Medical International Pty Ltd
- 26 Referral Partners

New Zealand Reseller/Distribution Partners

- Defibs Plus NZ Limited
- Smart AED Limited
- HeartHQ Limited

United Kingdom Reseller/Distribution/Tender Partners

- CorMed-DX Ltd
- Seal Medical Supplies Ltd
- ProTrainings Europe Limited

  + 46 Sub-resellers via ProTrainings
- Black Space Technology Limited

Republic of Ireland Reseller/Distribution Partner

- Hibernian Healthcare Limited

Republic of South Africa Reseller/Distribution Partner

- Patient Medical Care (Pty) Ltd (t/a Zebra Medical)

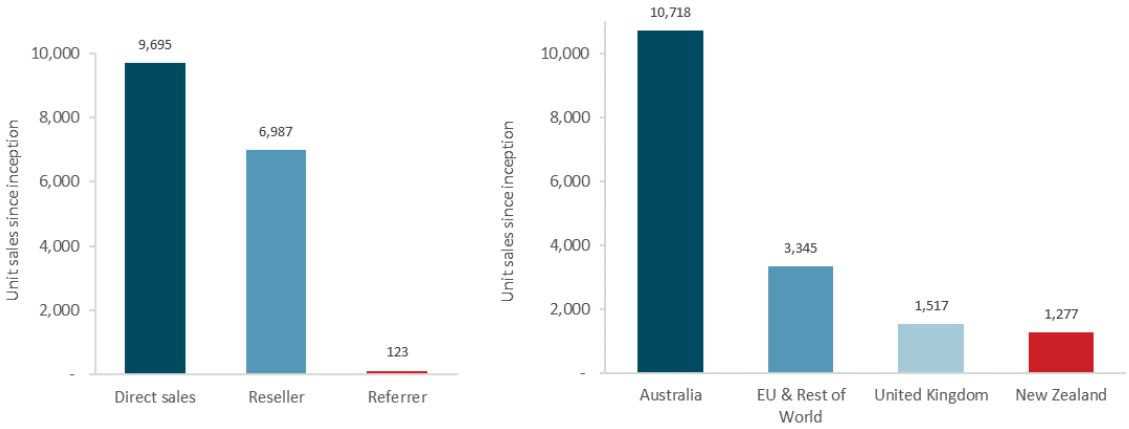
Source: Rapid Response Revival

RRR receives full payment before shipping, even bulk orders

Current resellers are dominated by medical device and defibrillator resellers, first aid training organisations and safety and tactical equipment providers. We see these as only the first movers in CellAED's retail distribution. In the medium and long term, as brand and product

awareness increases, we expect CellAEDs to be available in pharmacies, hardware stores, and anywhere you can buy a smoke detector or fire extinguisher.

Figure 39: Since inception, Australia and direct sales have dominated total sales



Source: Rapid Response Revival

RRR is helping resellers better sell and market CellAED

RRR has focused its direct marketing efforts on Australia, leaving resellers to drive international sales. We believe sales through resellers have been below expectations due to two main factors:

1) Inexperience of most resellers in actually selling products

   Most resellers are first-aid training organisations that have either never previously sold AEDs or have sold minimal quantities of high-margin, $1,700+ AEDs. Without sales training, it is difficult for resellers to sell a product that does not have a meaningful public profile. Also, to keep the sale price as low as possible, the margins initially offered to resellers (~$40 - $50 per unit) were probably insufficient to motivate most to put in much effort. RRR recently undertook a pricing review to address this issue, increasing retail prices by almost $100 and lifting the reseller margin to around $80.

2) Active campaign by a UK distributor to discredit CellAED

An active campaign to discredit CellAED has impacted UK sales

   Four or five main distributors dominate the UK AED market. One of these distributors, who reportedly initially wanted to be a CellAED reseller until they decided the retail margins were insufficient, has launched an unrelenting campaign to discredit CellAED. CellAED resellers report that these activities are affecting sales and allege that the distributor has even contacted CellAED customers (including councils and government organisations), attempting to dissuade them from using the devices and even claiming that it could expose them to litigation. The campaign has also caused the UK regulator and the NHS to retract their public support for CellAED. Press releases from both groups actively supporting CellAED are no longer available on their respective websites.

   We understand that RRR is seeking legal advice on the matter, and given the limited resources of the distributor and the volume of evidence posted on various social media sites and sent to the UK regulator, NHS and customers, we expect a remedy within the next six months.

The upside to this campaign is that the distributor clearly sees the potential disruption CellAED will bring to the market.

In the near term, RRR will continue focusing its direct marketing efforts in Australia, and the end of the attack campaign should result in an uplift in UK sales.

~70% of purchases include 'CellAED for Life'

In November last year, RRR simplified its product offering and pricing. This is partly motivated by the >70% take-up of CellAED for life, which is above the 50% level RRR had originally assumed.

The high takeup of CellAED for life is of enormous benefit to RRR and, as previously discussed, makes economic sense for purchasers. RRR increased its one-off purchase to A$599 and now offers the first year of CellAED for Life and shipping for free.

Table 28: RRR increased prices and simplified its product offering

Pricing	Jun-22	Nov-23
CellAED outright	$499	$599
CellAED + *CellAED for Life* (monthly)	$399 + $198 = $597	
CellAED + *CellAED for Life* (yrly)	$359 + $198 = $557	$599*
Wall mount	$69	$69
Trainer	$99	$99
Starter pack	$675	$675
Shipping	$24	$ -

*New $599 pricing includes one year of free *CellAED for Life* membership.

CellAEDs have already been use in at least 20 emergencies in Australia

Since launching sales only 18 months ago, CellAEDs have been used in at least 20 emergencies, and RRR reports that the devices functioned as designed in each instance. Unfortunately, several of these cases involved participants in the FIRST trial (see *Clinical trial: FIRST*), so the details can't be reported or advertised. Indeed, the operators of the trial actively monitor social media and request the removal of any content relating to incidents involving trial participants. Obviously, this is frustrating for RRR as it denies it the opportunity to leverage powerful free publicity to tell the story of how CellAED is saving lives. It also deprives them of real-life demonstrations of the efficacy of the device and waveform.

Figure 40: CellAEDs have been successfully used in at least 20 emergencies

30 NEWS

I DIED AT A FUNERAL

AND ONLY A MIRACLE BROUGHT ME BACK TO LIFE

Baby shake targeted

Licence go in a flash

Police wo faces cha

Why all farmers should invest in a CellAED

IN 2014, while studying for his MBA at home, Donovan Casey's life took an unexpected turn when he saved his wife Sarah from sudden cardiac arrest. A pivotal moment that inspired the invention of the world's first personal defibrillator, CellAED.

"I looked over and Sarah was making chucking sounds; that was her trying to breathe," Founder of Rapid Response Revival Mr Casey said. "You want someone to save you. I was on my own."

When the paramedics told him he had saved Sarah, Mr Casey wondered what might have happened if he had done nothing.

"When Sarah almost died, I was a customer for a product that didn't exist, so I invented it."

Since then, Donovan's mission has been to get an autonomed external defibrillator (AED) in every home, workplace, and community to increase the rate of survival from sudden cardiac arrest.

"We can't do anything about the unpredictability of sudden cardiac arrest (SCA), but we can be prepared."

According to the Australian Institute of Health and Welfare, the further a person lives and works from a metropolitan centre, the greater their risk of hospitalisation and death from cardiovascular disease.

People living and working in rural and remote areas are further away from emergency medical services and unable to access the help they need, when they need it.

This is particularly important when it comes to SCA, where for each minute CPR and defibrillation are delayed, the chances of survival decrease by 10 per cent.

Having a life-saving defibrillator on hand could mean the difference between life and death for people in rural communities. This is where CellAED is helping to bridge the gap.

SES volunteer in Gisborne South Denise Hoare said CellAED is faster than waiting for an ambulance and is affordable for areas where people aren't close to an AED.

Designed for everyone, regardless of medical or first-aid experience, the portable defibrillator is accessible, effective and easy-to-use.

The first few minutes are most critical in treating SCA and include calling emergency services, starting CPR and retrieving a defibrillator. Picture supplied

Source: The Sunday Telegraph, Stock Journal

A growing number of use cases

Police trial could lead to sales into UK's 45 separate police forces

The longer CellAED is in the market, the more use cases are proven. It has been reported[78] that Leicestershire Police are trialling giving its neighbourhood officers and members of the Rural Policing and motorbike teams CellAEDs to carry as part of their standard equipment. The county's Police and Crime Commissioner described the CellAED as a game changer that will help "save lives" as officers will be able to make use of the defibrillators much quicker when they come across a medical emergency, instead of having to try to find public access AED or wait for a police vehicle with one on-board.

There are 45 territorial police forces in the UK. If successful, the Leicestershire trial will be a valuable entry into the UK's remaining police forces.

Figure 41: Leicestershire Police are equipping its motorbike teams with CellAED

Source: harboroughfm.co.uk, CorMed-DX

[78] https://harboroughfm.co.uk/police-trial-hand-held-defibrillators/

One of RRR's largest distributors in the UK has created first aid and first responder packs for various professional applications, including first responders, military, elite sports and close personal protection.

Figure 42: Since launch, the market has validated various use cases

Source: CorMed-DX

CellAED is gaining traction with government and private organisations

While currently only in small quantities, there is growing confirmation of various use cases. Encouragingly, several government organisations are publicly announcing the use of CellAED (including Leicestershire Police and Hertfordshire County Council), which not only boosts awareness but also motivates similar organisations to examine CellAED.

- **Local council:** Hertfordshire County Council in the UK has put CellAEDs in all its telehealth vans, which install assistive technology equipment across the county area.
- **Utility:** A smart meter reading service has installed CellAEDs in their fleet of 140 vans across the UK.
- **Industrial applications:** Numerous Australian and UK industrial companies, including mining, wind turbine maintenance, oil rigs and high rope access companies, have purchased CellAEDs

Financial performance

Our modelling assumes RRR raisings A$80m in additional funding

Given the early stages of the business and that CellAED is effectively creating a new market, we've erred on the conservative side for all our assumptions, including total addressable market, growth rates, cost improvements, share of direct sales and churn. Our modelling assumes that RRR successfully raises A$80m in funding in four tranches.

1. Late FY24: $5m
2. Early FY25: $10m
3. Late FY25: $25m
4. Mid FY26: $40m

Failure to raise or a delay in raising this funding will impact the company's ability to meet Venn Brown's forecasts. We've assumed RRR raises these funds through the four equity issues and have adjusted our per-share returns (which feed our DCF valuation) accordingly. RRR is also working on several opportunities to raise at least a portion of these funds through non-dilutive means, including joint ventures, partnerships and licencing exclusive regional distribution rights. These non-dilutive means of raising funds would provide an upside to our estimates and valuation.

Table 29 and Table 30 below list the key assumptions driving our estimates.

Table 29: There is significant upside to our key driver assumptions

Improvements of any these drivers will lift revenue and margins

Driver	Value	Rational
Subscription uptake	70%	See below
Subscription churn	25%	See below
Wall mount sales	15%	RRR reports that wall mounts are sold with around 18% of new CellAEDs.
Trainer sales	2%	Currently, around 10% of sales also include a trainer. We expect this number to drop as consumers represent a larger proportion of purchasers. We expect industry, healthcare, EMS, military, and training organisations to be the main purchasers of trainers.
Shelf life	FY24-26: 2yrs FY27+: 3yrs	CellAED's current shelf life is 30 months, which supports resellers offering a two-year shelf life. RRR is confident of extending the CellAED's shelf life to at least three years. We assume a two-year shelf time for FY24-FY26 and a three-year life from FY27 forward.
Cost of acquisition	A$125	Growing at 5% pa from FY26. RRR is still refining its pricing and marketing strategy. As such, we believe they can significantly improve acquisition costs as 1) they optimise their activities; and 2) public awareness grows with more products in the market and more instances of CellAEDs saving lives.
CellAED for Life replacements	2%	CellAED for Life subscribers receive a free replacement if they use their CellAED in an emergency.

Extending CellAED's shelf life increases unit cashflow by >40%

Source: Venn Brown

Figure 43: We estimate 15% of CellAED sales will include a wall mount

Conservative assumptions leave significant upside to our valuation

Source: Rapid Response Revival

Unit Sales and Total Addressable Market

When modelling RRR's financial performance, we assume CellAED sales will follow a dampened "S" curve within each market. Venn Brown has only included in our estimates markets:

1) into which CellAED is already being sold;
2) from which potential buyers have already approached RRR; or
3) RRR has confirmed it plans to enter due to the obvious demand and market fit.

Table 30: Our model assumes after ten years, CellAED captures 1-2% of TAM

We assume only 1-2% of TAM captured after 10 years

Country	Start sales	TAM	10yr install base	% TAM	Direct Sales
Australia	FY23	5.4m	80k	1.5%	75%
UK	FY23	17.0m	187k	1.1%	15%
NZ	FY23	1.1m	16k	1.5%	40%
France	FY26	18.3m	180k	1.0%	-
Italy	FY26	15.8m	202k	1.3%	-
USA	FY27	95.0m	1,267k	1.3%	50%
Germany	FY27	22.0m	229k	1.0%	-
Rest of Europe	FY23	55.6m	474k	0.9%	-
Total			**2,634k**	**1.1%**	

***Note:** Includes Ireland, Malta, South Africa, and Rest of Europe.
Source: Venn Brown estimates

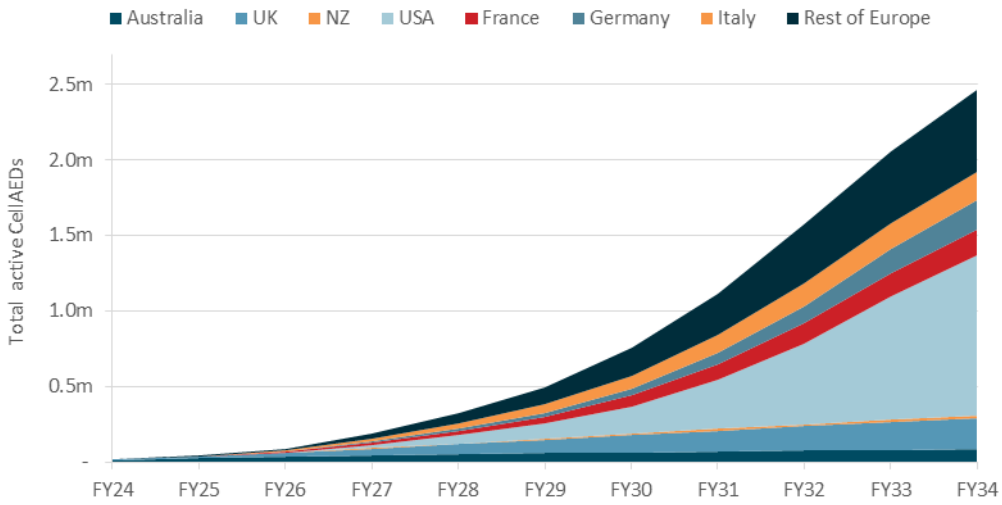
Table 30 lists the countries we've included in our financial model and the year we expect sales to commence. That table also shows our estimated total addressable market (TAM) for each region (as discussed above in '*Total Addressable Market')* and what proportion of the TAM we expect CellAED to have captured in its tenth year of sales (in that market). We've kept the ten-year market share capture for most markets at around 1%, with a few exceptions discussed below. Overall, we believe these targets of only ~1% TAM capture are conservative:

- **Australia – 1.5%:** The strong early sales support a more aggressive sales target, especially given the tight marketing budget that generated these sales.
- **United Kingdom – 1.1%:** Slightly higher target due to the strong support from councils, police and commercial buyers, despite the persistent negative attacks by a particularly aggressive competitor.
- **New Zealand – 1.5%:** Strong early support, boosted by the GoodSam program and early sales.
- **USA – 1.3%:** Record demand for existing AEDs stimulated by the Damar Effect (see '*The Damar* & Christian Eriksen Effect'). The presence and market awareness effort of Avive, which is raising awareness of the risks of SCA and the option of feature-rich and modern-looking AEDs, will assist CellAED's entry.
- **Italy – 1.3%:** Several government initiatives have led to Italy having a greater awareness and use of AEDs than most other countries[79]. RRR has also reported strong interest from several parties wanting to distribute CellAED in Italy.

New CellAED sales should reach ~1.0m by FY34

Figure 44 shows our unit sales expectations through to FY24. We expect sales to grow from just under 12,100 in FY24 to just over one million in FY34, representing an annual growth of around +56%. This may appear considerable, but it should be viewed in the context of sales in FY24 being almost exclusively from Australia (TAM of 5.4 million) compared to the TAM of 230 million in FY34.

Figure 44: Over time, the US will be the largest of RRR's existing targeted markets



Source: Venn Brown

[79] Progetto Vita is an Italian initiative aimed at enhancing public awareness and accessibility of Automated External Defibrillators (AEDs) through widespread training in CPR and AED usage. This program collaborates with local institutions to strategically place AEDs in public spaces and conduct educational campaigns, thereby improving the chances of survival following sudden cardiac arrests. Progetto Vita has been running since before 2001 and has been credited with saving hundreds of lives. It is the most comprehensive and long running SCA awareness and education program and resulting in the most comprehensive data for the effective treatment of OHCA of any public program. The data has had some surprising results especially the effectiveness of AEDs rather than CPR is saving lives. Community-based automated external defibrillator only resuscitation for out-of-hospital cardiac arrest patients (2015)

CellAED for Life Subscriptions

A new CellAED is 51% more expensive than a 'CellAED for Life' subscription

We measure the market capture in a given year as the total number of CellAEDs sold in that year plus the number of active CellAED for Life subscriptions. In the early years, revenue from new sales outpaces subscriptions, but as the user base grows, sales growth slows, and subscriptions provide an increasing share of revenue. The subscription model is an incredibly valuable asset for RRR and is unique to CellAED and Avive. By FY34, we expect 59% of active CellAEDs will be from CellAED for Life subscriptions. This share tends towards 37/63 due to churn and subscription uptake, with the slowing growth of subscriptions lagging behind the slowing growth of new sales.

We've made the following assumptions when modelling the growth and retention of CellAED for life:

- **Subscription uptake – 70%:** RRR reports that the uptake of the 'CellAED For Life' subscription is greater than 70%. This figure was before the November pricing changes, which lifted prices and introduced one year's free subscription. We expect these pricing changes to provide upside to the existing uptake rate.

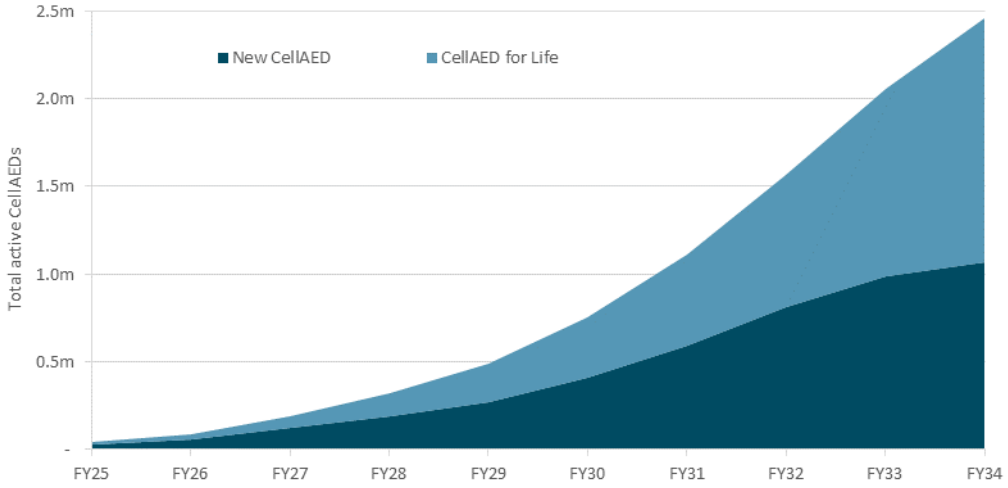
  As mentioned above, purchasing a CellAED is akin to purchasing an insurance policy. Once someone has decided to buy insurance, they are likely only to let it lapse if they find a cheaper option or can no longer afford it, especially given buying a new CellAED is 51% more expensive ($198 x 2 vs $599) than maintaining a subscription.

By FY34, 56% of active CellAEDs will be from subscriptions

- **Subscription churn – 25%:** A 25% churn implies the average user continues the subscription for four years. We believe this is conservative, given the reasoning above. That said, changes to life circumstances (old age, living alone, financial hardship) and simply changing one's mind will see subscription churn.

Figure 45: CellAED for Life subscriptions represent a growing share of active devices

There will be ~2.5 million active CellAED in FY34



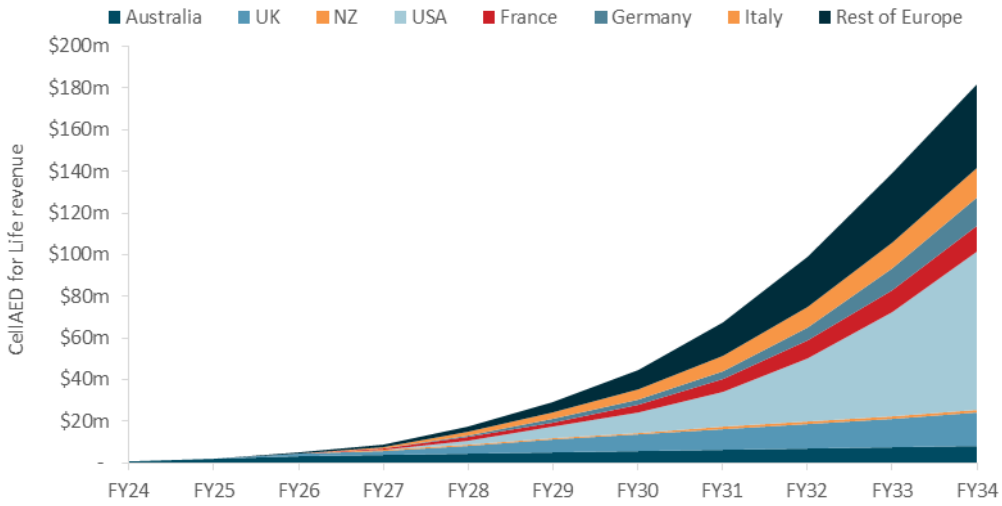
Source: Venn Brown

As shown above in Figure 45 (and below in Figure 46), by FY34, we estimate there will be just under 2.5 million active CellAEDs in the market, consisting of newly purchased devices and active CellAED for Life subscriptions. This figure represents just 1.1% of the total addressable market (assuming constant FY20-21 population and household figures). We believe this TAM

CellAED for Life provides a hugely valuable annuity stream

will grow for the reasons outlined in the 'Total Addressable Market' section, implying the 2.5 million figure is less than 1% of future TAM. The figures above and in our model do not include sales into other countries or regions, including Canada, South America, Eastern Europe, Asia or Africa. We believe these are highly conservative assumptions and expect RRR to commence sales into an expanded group of markets within the next five years.

Figure 46: The CellAED for Life program provides a hugely valuable annuity stream



Source: Venn Brown

Direct Sales

Resellers will dominate sales in international markets

In most international markets, we've assumed sales are 100% from resellers and distributors (see Table 30). We believe this is another conservative assumption based on existing sales patterns in both Australian and some international markets.

We've assumed direct sales continue to play a meaningful role in Australia (75%), NZ (40%), the UK (15%) and eventually the US (50%). For FY24, direct sales account for around 75% of total sales, with Australian sales almost exclusively direct. Venn Brown believes direct sales in New Zealand will also be strong and will grow in the UK.

The US is a large enough single market that we expect RRR to put a considerable sales and marketing effort focused on direct sales. Avive is showing that the direct sales model works with its devices only available through its website. While this may change with time, a move to indirect channels suggests sales will likely indicate total sales exceeding our targets (rather than cannibalising the direct channel), thereby outweighing the margin impact.

Unit costs

We expect COGS to reduce by 50% by FY29

We expect RRR to achieve significant unit cost savings over the coming years. We have assumed that over the next five years, RRR will reduce the input costs of CellAED, wall mount and trainer by around 40-50%, which leaves a significant upside if management achieves its targets of more than 60% reduction. Our model also assumes CellAED's shelf life is extended to three years by FY27. The shelf life has already been proven to be 30 months, and as more devices age in the market, they might demonstrate a longer shelf life than the existing model.

We believe these assumptions are fairly conservative and do not require all the optimisations outlined below, with upside if management achieves these targets.

Costs savings aren't speculative, but volume based

1) **Economies of scale:** Economies of scale will drive down both component and production costs. The price of most components drops by 60-70% when purchased in large quantities. These savings are not speculative but reflect volume-based list prices.
2) **Production and design efficiencies:** RRR did not design the current CellAED to optimise for ease and speed of mass production; instead, the focus was on designing, gaining regulatory approval and launching. There are significant improvements RRR has already planned for future versions, which will significantly reduce production time and cost. Appropriate manufacturing engineering alone can reduce production costs by at least 20%.
3) **Automation:** RRR's current production line is highly manual, which is appropriate for the current size and state of the company, but these lines will progressively become more automated, which will lower costs further.

There is scope for significant costs savings beyond our assumptions

4) **Extend expiration:** As discussed previously, a medical device's maximum approved life expectancy cannot surpass the demonstrated period of its proven operational capability. CellAEDs currently have an approved proven life of 30 months. As more CellAEDs enter the market and show a longer working life, RRR can apply to extend their shelf life. Improvements in battery technology and adhesive gel[80] (on the CellAED's electrode pads) will also help extend the device's life. RRR believes that within a few years, the device's shelf life will extend beyond three years, which will effectively reduce the 'CellAED for Life' COGS by 33%. Table 31 below shows that an additional year shelf life lifts six-year cumulative cash flow by around 41%.
5) **Device recycling:** Although several years away, RRR sees significant opportunities to refurbish expired CellAEDs. The battery and adhesive gel are the limiting components of the device. Foreseeably, RRR could refurbish these components on expired devices returned under the 'CellAED for Life' plan and reissue them. Our financial model does not assume RRR achieves this, but if possible, it could lower the already reduced unit costs by another 20-40%. A refurbishing program is also a great ESG activity.

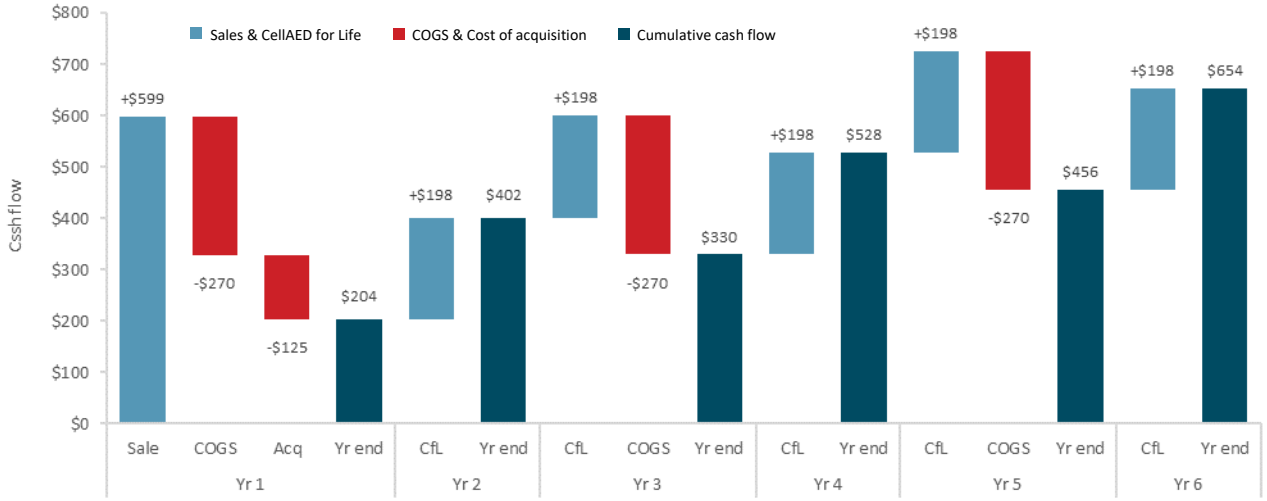
Unit Economics

Extending shelf life and device recycling will provide a step change in profitability

The high uptake and clear value proposition of the 'CellAED for Life' subscription model provide huge benefits for RRR and CellAED's unit economics. As shown in Figure 47, the longer customers maintain their subscription, the higher the margin and the better the unit economics of each device. The example below uses Venn Brown's estimated FY26 unit cost of $270, which is midway through RRR's cost reduction program. We've assumed a cost of acquisition of $125, the mid-point between RRR's reported acquisition cost of between $100-150 per unit (which we grow from 5% a year from FY26). The figure shows a positive unit cash flow of $204 (gross profit) in the first year, rising in a saw-tooth fashion (every second year, RRR replaces the CellAED), finishing the sixth year at $654.

[80] The conductive gel on AED pads is generally the first component to expire. Most gels only last 2 years which is what dirves the 2 year pad replacement cycle of most AEDs

Figure 47: Unit economics improves with every year of a CellAED for Life subscription



Source: Venn Brown

Table 31 highlights the cost and cash flow benefits of extending CellAED's battery life. The table shows the cash flow of a two-year and three-year shelf life, with the additional year adding $270 (the unit cost) or +41% to the cumulative cash flow in year six, up from $654 to $924. This pattern continues as long as the subscription is maintained, with the savings growing every 2-3 years.

We assume RRR reduces the subscription price, so when summed over the CellAED life, it provides a 20% discount to the outright CellAED purchase price.

Table 31: A one-year shelf life extension increases six-year cumulated cash by +41%

Extending shelf life will lift 6-year per unit cash flow by +41%

2-year shelf life	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
Revenue	$599	$198	$198	$198	$198	$198	$198
COGS	-$270		-$270		-$270		-$270
Cost of acquisition	-$125						
Cumulative	**$204**	**$402**	**$330**	**$528**	**$456**	**$654**	**$582**
3-year shelf life	**Yr 1**	**Yr 2**	**Yr 3**	**Yr 4**	**Yr 5**	**Yr 6**	Yr 7
Revenue	$599	$198	$198	$198	$198	$198	$198
COGS	-$270			-$270			-$270
Cost of acquisition	-$125						
Cumulative cash flow	**$204**	**$402**	**$600**	**$528**	**$726**	**$924**	**$852**
difference	-	-	82%	-	59%	41%	46%

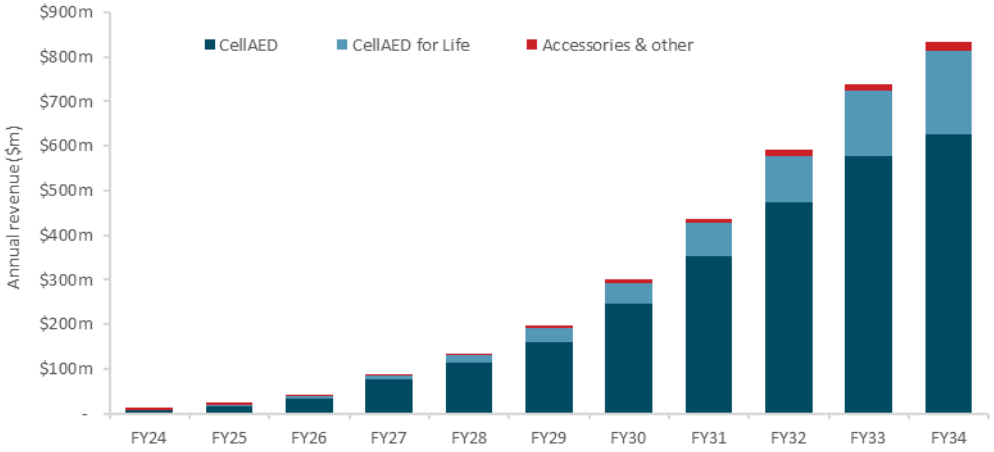
Source: Venn Brown

Financial performance

FY34 revenue will reach $840 million

Using the assumptions outlined above, we expect revenue from sales to grow from around $14 million in FY24 to just over $840 million in FY34, representing an annual growth of around 50%. These growth and sales expectations are a fraction of RRR's targets, as shown in Table 32.

Figure 48: Unit sales and subscriptions will see revenue reach $832 million in FY34



Source: Venn Brown

CellAED and CellAED for Life are highly cash generative

While the CellAED device and subscription model are highly cash-generative, we've assumed that for the next five years, RRR will direct all available cash into growth activities, including sales, marketing, geographic expansion, cost reduction, and manufacturing expansion and optimisation. As such, we don't expect RRR to be profitable until FY28 and free cash flow positive until FY29. This loss-making path is by choice, with the business able to turn profitable earlier by simply slowing growth activities.

Again, we believe this is a highly conservative assumption, with RRR's management team consistently demonstrating savant-like skills in stretching its budget to seemingly impossible lengths. RRR expects unit and revenue growth to far exceed our forecasts, with profitable and positive free cash flow achieved several years ahead of our projections.

Table 32: RRR has ambitious targets that would generate free cash flow in FY25

RRR's targets are far more ambitious than Venn Brown's

	FY24e	FY25e	FY26e
Units			
New CellAED	100,000	200,000	400,000
CellAED for Life	1,250	101,250	566,667
Revenue			
New CellAED	$44m	$88m	$176m
CellAED for Life	$13m	$53m	$133m
Total revenue	**$57m**	**$141m**	**$309m**
COGS	-$33m	-$58m	-$129m
Gross profit	**$24m**	**$84m**	**$181m**
margin	42%	59%	58%
Operating expenses	-$38m	-$50m	-$95m
EBITDA	**-$14m**	**$33m**	**$86m**

Note: RRR provided forecasts in USD. For ease of comparison, the figures were converted to AUD using an exchange rate of 0.65.
Source: Rapid Response Revival

Table 33 compares RRR and Venn Brown's expectations of key figures. RRR expects to generate $33 million in EBITDA in FY25 versus our -$14 million. Venn Brown's model has RRR generating its first positive EBITDA of $13 million in FY28.

Table 33: Venn Brown expects RRR to generate positive EBITDA in FY28

Venn Brown's model excludes countries representing almost 90% of the world's population

	FY24e	FY25e	FY26e
New CellAED			
RRR	100k	200k	400k
Venn Brown	12k	29k	60k
Revenue			
RRR	$57m	$141m	$309m
Venn Brown	$14m	$26m	$40m
EBITDA			
RRR	-$14m	$33m	$86m
Venn Brown	-$10m	-$13m	-$20m

Note: RRR forecasts converted to USD using USD/AUD exchange rate of 0.65
Source: Rapid Response Revival, Venn Brown

As shown in Table 34 below, we expect a combination of cost management and revenue growth over the next ten years will see RRR conservatively generating $301 million in EBIT and $209 million in free cash flow by FY34.

Table 34: RRR will use cash for growth activities, pushing profitability out to FY28

	FY24e	FY25e	FY26e	....	FY32e	FY33e	FY34e
Units							
CellAEDs	12k	29k	60k		809k	984k	1,066k
'CellAED For Life'	5k	12k	29k		760k	1,070k	1,394k
Total CellAED install base	**17k**	**41k**	**89k**		**1,569k**	**2,054k**	**2,461k**
growth		144%	116%		41%	31%	20%
Revenue							
CellAED	$7m	$17m	$34m		$481m	$591m	$641m
Subscription	$1m	$2m	$5m		$99m	$139m	$182m
Accessories	$0.1	$0.4	$0.8		$12.2	$15.1	$16.4
Other	$6.6	$6.6	$0.1		$1.3	$1.8	$2.0
Total Revenue	**$14m**	**$26m**	**$40m**		**$594m**	**$747m**	**$842m**
growth		79%	56%		38%	26%	13%
Gross Profit	$10.2m	$14.2m	$19m		$395m	$495m	$552m
margin	71%	55%	48%		66%	66%	66%
growth		39%	37%		38%	25%	12%
EBITDA	-$10m	-$13m	-$20m		$203m	$267m	$307m
margin					34%	36%	36%
EBIT	**-$11m**	**-$14m**	**-$20m**		**$198m**	**$262m**	**$301m**
margin					33%	35%	36%
growth					53%	32%	15%
NPAT	**-$11m**	**-$14m**	**-$20m**		**$138m**	**$183m**	**$210m**
Operating cash flow	-$16m	-$13m	-$20m		$144m	$189m	$217m
Free cash flow	**-$16m**	**-$15m**	**-$21m**		**$141m**	**$180m**	**$208m**
Free cash flow per share	-$10.17	-$7.82	-$10.14		$69	$88	$102
Cash / (net debt)	-$9m	$11m	$30m		$354m	$534m	$742m

Source: Venn Brown

Significant upside not included

As mentioned several times, we believe our estimates are conservative in most instances. We are confident in the long-term cash flows of the business, with the timing of the cash flows representing the biggest risk to our valuation, but here, too, we're assuming negative cash flows until FY28.

The recent pricing changes Avive has made give us confidence in the viability of CellAED and the personal defibrillator market. In January, Avive, which we believe is RRR's closest product competitor, significantly increased its prices. The annual fee was increased from US$350/yr to US$450/yr (on a five-year contract) plus an additional upfront US$450 "connection fee". Avive is now three times more expensive than CellAED over its five-year contract life.

Table 35: Avive is now one of the most expensive AEDs on the market

	Year 1	Year 2	Year 3	Year 4	Year 5	Total	vs CellAED
Jan-23	$350	$350	$350	$350	$350	**$1,750**	1.6x
Jan-24	$900	$450	$450	$450	$450	**$2,700**	2.5x

Note: We've compared Avive with our US pricing, which doesn't include the first year free CellAED for Life, which is currently only available in Australia. If the first year's membership were free, the comparison would be 1.9x and 2.9x.
Source: Avive

The greatest and most obvious upside to our forecasts is the total addressable market. Despite RRR reporting several conversations and even site visits from interested parties from Malaysia, The Philippines, China and India, we've not included sales from these countries in our forecasts. We've also not included sales from the Middle East or Africa despite RRR attending the annual Arab Health Conference for the last two years and appointing a Middle East and North Africa CEO.

Table 36 below lists the largest, most accessible and provable markets we've not included in our estimates. It's important to note that we don't consider the figures in Table 36 to represent 'blue sky' opportunities. Instead, these are markets into which we believe RRR will launch, but they were not included in our estimates because of the uncertainty of timing and size.

In addition to these figures, there are also 'blue sky' opportunities, which include:

1. the products discussed in *Future products;*
2. the expansion in the health and EMS connectivity provided by the CellAED's IoT capabilities; and
3. other countries and regions, including most of South East Asia, Eastern Europe and Africa.

Even without the blue sky, the opportunities listed in Table 36 increase our estimated TAM by 1.8 – 4x, adding significant upside to our forecasts and the company's long-term value.

Table 36: There is significant upside to our TAM and forward estimates

Market	Details	Potential TAM
Middle East	RRR has also attended the annual Arab Health Conference for the last two years and has a Middle East and North Africa CEO. Saudi Aradia, Qatar and the UAE have public "safe city" initiatives, which include IoT-connected public use AED programs. Saudi Arabia is also promoting the new NEOM (The Line) city as being the safest and most connected city, which presumably will include some configuration of EMS and AED infrastructure. One safe city project alone could involve 100,000 – 500,000 AEDs, which would most likely be on a CellAED for Life subscription and may also be connected to RRR DataAED product (see *Future products*). We expect that, at least initially, state-sponsored projects will drive the majority of Middle Eastern sales.	100,000 – 1,000,000 annual subscriptions (10-100% of FY34 new sales)
China	RRR has reported that it has been speaking with distributors interested in having exclusive rights to sell into China. We believe this is the ideal strategy, as it opens CellAED up to an entirely untapped market, frees RRR from having to navigate the Chinese regulatory process and de-risks that sales and distribution process. An exclusive deal would also provide a fresh, non-dilutive capital injection. China's middle class is estimated to be around 800 million, and the upper-middle class is around 30 million. Applying household ratios similar to those of other countries implies an additional 15-150 million TAM.	TAM: 15-150 m +7-65% of existing TAM
India	India has one of the fastest growing middle-class and upper-middle-class demographics in the world. The country's middle class is expected to almost double from 432 million in 2020 to 715 million in 2030-31. The country's current upper middle class is estimated to be around 58 million. Applying household ratios similar to those of other countries to the current population implies an additional 30-80 million TAM. In 2030, these figures are expected to increase to 50-130 million	TAM: 30-80m +13-35% of existing TAM
Japan	Population of ~122 million, with 20 million above middle class. Implies a TAM of 11 million	TAM: 11m +5% existing TAM
South Korea	Population of ~52 million, with 31 million in middle class. Implies a TAM of 6 million	TAM: 6m +3% of existing TAM
South America	Population of ~440 million, 92 million (~22%) upper and upper middle class, implies a TAM of around 21m	TAM: 21m +9% of existing TAM
Police	Venn Brown has heard unconfirmed reports that the trial with Leicestershire Police is nearing completion with positive results. We understand that other UK police forces have taken an interest in the trial, increasing the likelihood of a favourable outcome being extended beyond Leicestershire. There are more than 2.6 million police officers within the seven regions we've modelled. Extending this figure across the other regions listed above would increase this figure by at least 20 times.	TAM: 50m +22% of existing TAM

Vehicles	RRR also speaks of partnering with vehicle manufacturers to include CellAEDs as an optional extra for new car purchases. Within the seven regions, almost 29 million new cars are sold each year. Globally, the figure is around 80 million. Restricting the market to only luxury cars (RRP >US$80,000) brings the figure to around 1.6 million	TAM: 1.6m +1% of existing TAM
Hospitals	CellAED Blue (see *Future products)* has a very real and life-impacting use case that could save tens of thousands of lives each year. Within the seven regions, there are an estimated 3.3 million hospital beds. Extending these to other developed markets lifts the figure to over 15 million	TAM: 15m +7% of existing TAM
IoT connectivity and data collection	RRR has already built much of the connective infrastructure to support various IoT implementations, data collection and sharing. The R&D team have mapped out a product roadmap that enables the 'safe city' concept with a centrally connected and monitored fleet of AEDs positioned within a city so that one is always within a few hundred metres of every citizen. The functionality provides another revenue stream through remote monitoring, management and other functionality, including automatically connecting users with EMS upon device activation and building the world's largest database of real-life cardiac arrest data. The attention that Avive's '4-minute cities' functionality is garnering (see *Avive was going to be the* first real competitor) adds credibility to the contention of demand for functionality. This is further supported by the $100/yr price increase plus the $450 upfront 'connection fee' Avive implemented in January.	An entirely new revenue stream worth hundreds of thousands to millions a year in fees.
Total		**TAM: 150 – 335m 65% – 145% of existing TAM**

Valuation

In valuing RRR, Venn Brown assumes that it successfully raising ~$80 million over the next two years. Without these funds, the company will either fold or will not be able to deliver our growth forecasts.

Venn Brown has used four methodologies to value RRR. Our preferred methodology is a discounted cash flow (DCF), which best captures the growth potential and annuity-style cash flow provided by the CellAED for Life subscription. It also includes the five years of negative or near zero cash flow. We applied a 15% real discount and then discounted this by a further 30% to compensate for the business's unlisted and early-stage nature.

The results of the four valuations are shown in Table 37 below. These values validate each other and give us confidence in our **$200 - $220 per share valuation, which implies a company value of $307 - $337 million.**

We value RRR at $200 - $220 per share

Table 37: Four valuation methodologies support a valuation of $200 - $220 per share

	DCF	Private Equity 30%	Discounted EV/EBIT	Price to FY25 sales
Per share	$206	$254	$249 - $320	$202 - $269
Market cap	$315m	$389m	$381m - $490m	$309m - $412m

Source: Venn Brown

Table 38 below summarises our base, downside and upside cases. There is a wide range of values, but as discussed in previous sections, we believe the risk is to the upside with both our conservative cash flow estimates and fair valuation methodologies.

Table 38: There is clear upside to our cash flow estimates and valuation

	Per share	Market cap
Base case	$200 - $220	$307m - $337m
Downside	$60 - $70	$92m - $107m
Upside	$480 - $530	$736m - $812m

Source: Venn Brown

Method 1: Discounted Cash Flow

Venn Brown's DCF assumes a real discount rate of 15%. We believe this rate is appropriate given RRR's early stage of commercialisation and the cash flow uncertainty. We note that on balance, we believe the risk is to the upside of our cash flow forecasts and that management intends to list RRR within the next three years.

Our 15% real discount rate reflects uncertainty of cash flows

We calculated the DCF on a per-share basis to account for the dilution resulting from the four capital raisings expected in FY24, FY25 and FY26. As discussed previously, the size and price at which RRR completes these raisings will impact our DCF. It's also possible that one or all aren't needed if any of RRR's non-dilutive activities materialise.

We applied a 30% discount to the DCF to reflect illiquidity of shares

Based on the assumptions in Table 39 and forecasts in the section above (*Financial performance*), our DCF values RRR at $267 per share, with a total equity value of $410 million. We then discount this value by 30% to adjust for the illiquidity of the unlisted shares. The discount **results in a share value of $206 and a market cap of $315 million.**

For at least the last 18 months, there has been a disconnect between public and private markets, with private companies trading at 30% and up to a 50% premium to listed markets. This is contrary to historic norms and not what we assume in our valuation.

Table 39: Our DCF values RRR at $197 per share

DCF	Value
Real discount rate	15%
Real terminal growth rate	0%
Present value of terminal value	$43
Value per share	**$267**
Unlisted discount	30%
Discounted value per share	**$206**
Shares outstanding (current)	1,534,375
DCF market cap	**$315m**

Source: Venn Brown

Method 2: DCF + exit multiple

Our second methodology uses the typical private equity method of discounting cash flows with a 30% discount rate and assuming a 15x EV/EBIT exit in 2034. Given the business's growth potential and that our figures don't include any regional expansion beyond those already listed, we believe this is a more than fair multiple. **This methodology implies a fair value of $254 per share.**

Table 40: Private equity valuation implies a fair value of $254 per share

A DCF with 15x EV/EBIT exit in FY34 give a $254 share price

Driver	Value
Real discount rate	30%
Exit EV/EBIT multiple (FY34)	15x
Value per share	**$254**
Shares outstanding (current)	1,534,375
DCF market cap	**$389m**

Source: Venn Brown

Method 3: EV/EBIT multiple

Our third methodology applies the current trading multiples of listed medical device manufacturers to RRR. To normalise for the rapid growth phase RRR is entering, we used our FY34 EBITDA and EBIT estimates and discounted them back to present value (using the 30% real discount rate). Using this method, we found a valuation range of $249 to $398 per share, as shown below in Table 41.

Table 41: The DCF is supported by global medical device company trading multiples

Multiple	15x	20x	25x
EV/EBITDA	$253	$325	$398
EV/EBIT	$249	$320	$391

Source: Venn Brown

Peer multiples imply a valuation of $249 - $320 per share

We drew the multiples from the current and historical trading range of comparable listed medical equipment peers, a sample of which is shown in Table 42 below. There is no pure-play AED manufacturer, so the comparisons are not perfect. RRR is also still in its early stages and will likely still be in a high growth phase beyond FY34 (thereby understating the value given the maturity and more modestly growing peers), but the range provides confidence in our conservative and likely understated valuation.

Table 42 includes the three largest AED manufacturers, namely Stryker (owner of HeartSine and Physio-Control - 26x), Koninklijke Philips (maker of Philips - 11.2x) and Asahi Kasei (owner of Zoll and Cardiac Science – 12.7x). As discussed later (see section *Competitive Landscape*), all three companies' AED departments contribute only a small share of the companies' total earnings. Japan's Nihon-Kohden, maker of Defibtech, is also included, trading on a 12.7x multiple.

We use the EV/EBIT multiples of 15x and 20x, resulting in a value range of $249 - $320 per share.

Table 42: Trading multiples of most medical device companies range from ~14 – 25x

Ticker	Company	Mkt Cap (US$)	EV (US$)	EV/EBITDA	EV/EBIT	P/E
SYK-USA	Stryker	$135b	$145b	24.2x	26.0x	29.9x
MDT-US	Medtronic	$114b	$131b	13.5x	15.1x	15.7x
BSX-US	Boston Scientific	$98b	$107b	23.6x	25.8x	29.8x
EW-US	Edwards Lifesciences	$53b	$52b	24.7x	27.1x	31.9x
GEHC-USA	GE Healthcare	$41b	$48b	12.9x	15.2x	20.7x
RMD-USA	ResMed	$27b	$28b	18.4x	19.9x	24.8x
ZBH-US	Zimmer Biomet	$27b	$32b	11.9x	14.3x	16.0x
STE-US	STERIS	$23b	$27b	16.7x	19.4x	24.7x
COH-AU	Cochlear	$15b	$15b	36.5x	42.8x	57.4x
PHIA-NL	Koninklijke Philips	$18b	$25b	7.4x	11.2x	12.8x
3407-JP	Asahi Kasei	$9.7b	$15.0b	6.7x	12.7x	12.7x
PEN-US	Penumbra	$9.2b	$9.2b	55.3x	66.4x	84.2x
FPH-NZ	Fisher & Paykel	$8.9b	$9.0b	25.7x	32.5x	43.6x
GMED-US	Globus Medical	$7.6b	$7.6b	10.5x	15.2x	20.9x
IART-US	Integra LifeSciences	$3.5b	$4.9b	12.1x	13.6x	13.1x
CNMD-US	CONMED	$2.5b	$3.5b	12.3x	16.2x	18.6x
6849-JP	Nihon Kohden	$2.4b	$2.0b	10.8x	12.7x	21.2x
Mean				**19x**	**23x**	**28x**
Median				**14x**	**16x**	**21x**

Most listed medical device companies trade on an EV/EBIT multiple of 14-25x

Source: Factset

Method 4: Price to sales multiple

Venn Brown's fourth valuation methodology was to apply a price-to-sales multiple similar to that of relevant Australian healthcare companies. As shown in Table 44, the forward sales multiples of the relevant Australian peers range from 5x to 49x with an average of 17x. Applying a conservative range of 12-16x on our FY25 revenue estimate ($26 million) results in a price-to-sales price range of $202 - $269 per share (or $259 - $345 based on FY26 revenue).

Table 43: Current ASX-listed peers support our valuation

Price/Sales per share	FY25	FY26
12x	$202	$259
14x	$235	$302
16x	$269	$345

Australian healthcare price to sales multiples imply a value of $202 - $269

Source: Venn Brown

As shown in Table 43, Venn Brown's valuation is well within the range implied by the mid-point of the trading range of the ASX listed peers. While RRR is arguably a higher-risk business than most of its peers (simply because it's unlisted), it also offers significantly higher growth than most companies listed below.

Australian healthcare sector trades with an average price to sales multiple of 17x

Table 44: RRR offers greater growth opportunities than most listed peers

Ticker	Name	Market Value	Sales	Price / FY25 sales
COH	Cochlear	$14,398m	$1,445m	9.7x
TLX	Telix Pharmaceuticals	$2,525m	$334m	5.6x
PNV	Polynovo	$992m	$55m	14.7x
NAN	Nanosonics	$548m	$110m	5.0x
4DX	4DMedical	$176m	$1m	49.3x
IPD	Impedimed	$123m	$7m	15.6x
CYC	Cyclopharm	$111m	$17m	4.5x
GSS	Genetic Signatures	$69m	$7m	10.7x
OCC	Orthocell	$57m	$4m	14.6x
IIQ	Inoviq	$38m	$0m	36.5x
Mean				**17x**
Median				**13x**

Source: FactSet

Downside case - $60 - $70 per share

To look at the downside case, we removed all US sales, leaving only the countries into which RRR is already selling or has started obtaining local approval. The results are shown below in Table 45 and imply a fair value of between $60 and $70 per share. In this and the upside scenario, the price-to-sale valuation doesn't change since it's based on FY25 revenue, which isn't affected by US sales.

Downside model implies a $60 - $70 share price

Table 45: Downside scenario implies a fair value of $60 - $70 per share

	DCF	Private Equity 30%	Discounted EV/EBIT	Price to FY25 sales
Per share	$62	$56	$74 - $113	$202 - $269
Market cap	$94m	$86m	$113m - $173m	$309m - $412m

Source: Venn Brown

Upside case - $480 - $530 per share

For the upside case, we increased each country's targeted 10-year installed base to 1.5% of TAM, which is in line with Australia and New Zealand. We then assumed that in FY30, RRR would launch into new regions, thereby doubling the 10-year TAM target to 2.3% of the current TAM (sum of sales in each region ten years after launch).

Applying the same valuation methodologies, we arrived at a fair of between $480 – $530 per share. While we're not comfortable using this valuation at this stage in the company's growth path, we believe the cash flows the company will generate will more closely resemble the cash flows of this scenario, albeit more likely delayed by a few years. We also don't believe this captures the company's complete blue-sky optionality.

Upside model implies a $480 - $530 share price

Table 46: Upside scenario implies a fair value of $480 - $530 per share

	DCF	Private Equity 30%	Discounted EV/EBIT	Price to FY25 sales
Per share	$480	$687	$549 - $708	$202 - $269
Market cap	$735m	$1,054m	$842m - $1086m	$309m - $412m

Source: Venn Brown

Capital Raising

Having successfully brought CellAED to market, RRR is launching a new funding round to raise up to US$100 million to help accelerate the business's growth, strengthen its market position and capitalise on its first mover advantage. Table 47 below summarises RRR's intended use of funds for the US$100 million raise.

It should be noted that we're not assuming RRR successfully raises US$100 million. If it does, it will significantly accelerate the growth rates and financial performance we've calculated and presented in this report. We did, however, use the "use of funds" RRR provided as part of its capital raising plans (listed below in Table 47) to allocate the A$80 million raising that we're assuming RRR completes over the next two years.

RRR has additional capital available to it with the exercise of the 266,448 options it issued as part of the Entitlement issues (see Table 48 below). With a $180 exercise price and a September 2025 expiry, these options would raise A$48.0 million if exercised.

Table 47: RRR will use the new funds to accelerate its growth and strengthen its market position

Use of funds	US$
Staff & Professional	$31.5m
Sales & Marketing	$20.5m
Working Capital	$15.0m
IT & Software	$8.5m
General Operating Costs & Other	$5.5m
Approvals, Legal & Patents	$5.0m
IPO Related Costs	$5.0m
Patents & Intangibles	$5.0m
PPE	$4.0m
Total	**US$100m**

Source: Rapid Response Revival

RRR has undertaken several capital raisings since it launched in 2018. The company's history was made significantly more difficult due to the COVID outbreak that impacted every aspect of the business, including supply chain, manufacturing, R&D and regulatory approvals.

Over the last six years, RRR has raised $50.3 million in equity, with another $9.8 million in grants and tax incentives. The capital raising table shown below (Table 48) highlights that RRR has faced all the challenges non-SaaS Australian companies face when trying to raise capital, especially those with a multi-year pre-revenue development phase. It should not be understated how impressive it is that RRR has managed to get CellAED designed, built, approved by more than five international regulators and on the market in six countries (Australia, New Zealand, United Kingdom, Ireland, Malta and South Africa). Most companies aiming to design and commercialise a Class III medical device will raise hundreds of millions of dollars or, once proven, sell the device to an established manufacturer. Indeed, based on the

investment interest Avive has had, if RRR was based in the US, we expect they would have easily raised more than US$100 million and would have a US$1 billion-plus valuation.

For comparison, despite having a developed strategically weaker long-term product, our best estimate is that Avive has raised ~US$94.9 million, most recently closing a $40.9 million Series B round in early February 2024 (see Table 51). As discussed in greater detail below (see *Avive was going to be the* first real competitor), Avive has design constraints that give CellAED a significant competitive advantage. For instance, Avive:

1. uses a Phillips waveform[81];
2. uses Phillips therapeutic delivery (from what we can tell)[81];
3. is significantly larger, heavier and 3x more expensive, with limited options to reduce these while using the Phillips' therapy[81];
4. has only US FDA approval;
5. is only available in the US; and
6. has not undergone clinical trials.

Table 48: Rapid Response Revival has raised $50.3 million in equity since inception

Round	Year	Share price	Pre-raise valuation	Capital raised
Seed	2018	$1	$1.0m	$1.0m
Seed A	2018	$8	$8.0m	$0.1m
Series A	2018	$30	$30.0m	$0.2m
Series B	2019	$44	$45.0m	$1.3m
Series C & staff rights	2019	$90	$94.5m	$5.6m
Rights	2019	$90	$100.2m	$0.4m
Series D	2020	$90	$100.5m	$1.8m
Special	2020	$50	$52.3m	$4.6m
Capital reduction	2020	-		
Series E	2021	$90	$102.3m	$5.1m
Series E2	2022	$180	$215.0m	$12.7m
Entitlement 1	2022	$90	$113.9m	$12.2m
Entitlement 2	2023	$40	$56.0m	$5.3m
Sub-total				**$50.3m**
Tax incentives/grants	2019-23			$9.8m
Total				**$60.2m**
Shares outstanding				1,534,375
options				290,578

Source: Rapid Response Revival

[81] See *What is an AED waveform, and why should I care?* and *Competitive Landscape* for a detailed discussion of the importance and competitive advantage provided by CellAED's proprietary waveform and therapeutic delivery.

It should be noted that CEO and co-founder Donovan Casey cancelled 91,559 of his own shares to prevent the dilution of other shareholders as part of the 2020 Special raise at the start of the COVID pandemic. This is a highly unusual move for a founder and CEO and indicates Casey's commitment to seeing RRR a success.

Competitive Landscape

Venn Brown's survey of AEDs found almost 60 different devices for sale in the USA and Europe. The US FDA has only approved 32 devices from seven manufacturers (Avive, Cardiac Science, Defibtech, HeartSine, Philips, Physio-Control, and ZOLL) for sale in the US, several of which are no longer available. Most of the 60 models are available in Europe (Avive is only available in the US). Despite this number of individual units, Philips, ZOLL and & Stryker control between 60-80% of the AED market.

Figure 49: Philips, ZOLL and Stryker control 60-80% of the AED market

Source: Mordor Intelligence

For most manufacturers, AEDs represent only a small portion of group revenue and profit; this is especially true for the big three, which is another reason we suspect there has not been a lot of significant new development in the space since the 1990s.

The most significant change in defibrillation came in the 1990s, with the shift from using monophasic waveform to biphasic waveform, and since then, only CellAED and Schiller with its Multipulse Biowave®, have significantly changed waveforms (see '*What is an AED waveform, and why should I care?*'). Aside from these two manufacturers, product development has mainly involved putting the equivalent or similar therapeutic delivery into a new box and adding new ancillary features such as screens, easier controls, voice prompts, Wi-Fi, GPS and most recently, emergency services connectivity (despite the great marketing message, the current implementation is to three small cities within the US with several industry participants telling Venn Brown that emergency dispatch is unlikely to be feasible in most places.).

Table 49: There have been few developments in AED therapy since the 1990s

Corporate owner	Country HQ	Brand	Primary AED models
Major participants			
Asahi Kasei Corporation	Japan	ZOLL	AED 3 AED Plus
		Cardiac Science (bought by ZOLL in 2019)	Powerheart G5 Powerheart G3 Elite
Koninklijke Philips	Netherlands	Philips	HeartStart Home/Onsite HeartStart FR3 HeartStart FRx
Stryker Corporation	USA	HeartSine (bought by Physio-Control in 2015)	Samaritan PAD 360P Samaritan PAD 450P
		Physio-Control (bought by Stryker in 2016)	LIFEPAK 1000 defibrillator LIFEPAK CR Plus LIFEPAK CRa
Schiller	Switzerland	Schiller	Schiller Fred Easyport Schiller Fred Easyport Plus Schiller FRED PA-1
		Defisign	Pocket Plus Life
Other participants			
Nihon Kohden	Japan	Defibtech	Lifeline/Revive AUTO Lifeline/Revive VIEW
Mindray Medical International	China	Mindray	BeneHeart C1A BeneHeart C2
Mediana	Korea	Mediana	Mediana Heart On A15 Mediana Heart On A16
Metrax	Germany	Primedic	HeartSave Y HeartSave YA

Source: Manufacture websites

Figure 50: Despite the number of AEDs on the market, sales are remarkably small

Note: Images are not to scale. The CellAED is a fraction of the size of all other devices except for the $4,950 semi-automatic Schiller FRED EasyPort.
Source: Manufacturer websites

CellAED is not *yet* competing with established AEDs

As discussed previously, the most important unique features of the CellAED are its size, weight, and affordability. These features mean it's opened an entirely new market to AEDs in which all but the Avive AED can't compete. While we do see the CellAED being able to compete with existing AEDs in a lot of applications (SME, corporate and many public access applications), the CellAED has almost an open field where affordability and mobility are the primary factors: home, small business, and non-car/van-based emergency responders. As such, in the short and medium term, we do not expect CellAED to compete directly with established brands but instead sit alongside them and significantly broaden the coverage and awareness of AEDs.

Table 50: CellAED is small, lighter, cheaper and easier to use than existing AEDs

Model	Price (US$)	Avg annual maintenance (US$)	Total 8yr cost (US$)	Dimensions	Weight	Shelf life	Replacement battery	Replacement pads - adult
CellAED	$420	$130	$1,280	21 x 11 x 3cm[82]	450g[49]	AED: 2yrs Battery: 2yrs Pads: 2yrs	Included in $130/yr CellAED for Life. Replaced every 2 years	
Avive	$900	$450	$4,050	14 x 16 x 7cm	953g	AED: 5-8yrs Battery: 5-8yrs Pads: 2yrs	Rechargeable	Included in subscription
Cardiac Science Powerheart G5	$2,064	$100	$2,767	30 x 23 x 9cm	2.6kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$460	$81
Defibtech Lifeline/Revive	$1,545	$86	$2,145	22 x 30 x 7cm	2.0kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$375	$68
Philips HeartStart OnSite	$1,479	$61	$1,905	19 x 21 x 7cm	1.5kg	AED: 8yrs Battery: 4yrs Pads: 2yrs	$189	$79
Stryker HeartSine SAM 350P	$1,738	$118	$2,563	20 x 18 x 5cm	1.1kg	AED: 8yrs Battery: 4yrs Pads: 4yrs	Combined battery & pads: $228 adult	
ZOLL AED 3	$2,144	$389	$4,864	24 x 25 x 13cm	2.5kg	AED: 5-8yrs Battery: 1-5yrs Pads: 2yrs	$186	$204

Note: All prices are in US dollars. Prices are recommended retail price, without discounting. Prices vary between suppliers, and the last six months have seen significant discounting across all major brands in Australia, the US and the UK.
Source: Rapid Response Revival, Avive, Cardiac Science, Defibtech, HeartSine, HeartStart & ZOLL

The next generation

The last ten years have seen six companies attempt to launch a new generation of AED into the US or Europe. Most designs focused on reducing size and improving portability (see Table 51). Despite several registering patents and HeartHero even obtaining CE certification, only Avive has launched to market. As discussed below (see '*Recent changes to regulation widens CellAED's protective moat*') the changes to US FDA and CE MDR regulations mean that any device not already approved will require clinical trials, and so any device not already on the market is at least two more likely three or more years away from launching.

[82] Includes carry case. CellAED without the case measures 19.6 x 9.6 x 1.7cm and weighs <300g

Table 51: Only one new entrant had made it to market

Manufacturer	Certification	Price (US$)	Status	
Avive	US FDA	$450 + $450/yr for 5 yrs or $1,650	US base. Only available in the USA. In December, the founders were named in Forbes 2024 30 Under 30 in Health Space. We see Avive as CellAED's closest rival. It will be difficult for Avive to obtain CE certification as it would require clinical trials. Avive uses the Philips waveform. Has substantially increased pricing since first launching in late 2022.	
HeartHero	CE	Marketed as "affordable", but no pricing available	US based but has CE certification. Not for sale. Claim to be targeting the home market. Last website update November 2020, but posted on LinkedIn about securing a new patent in March 2024. Co-developed with the American College of Cardiology. Will require clinical trials to maintain CE certification under new MDR rules commencing in 2027. For the last 13 months HeartHero's home page has claimed the devices are sold out (but with a "Not currently approved in the United States" notice), but both the links to be added to the waiting list and to the online store open "403 Forbidden" error pages.	
Cardothrive	None	$1,300	US based. CardioThrive was founded in 2010. No certifications. No significant updates since May 2021. Has recently tried to raise investor funds but outcome unknown. In June 2020 the device was undergoing human-factors evaluation with the US FDA. Venn Brown has found no updates on the progress of the evaluation.	
Altrix Medical	None	Marketed as "affordable", but no pricing available	US based. Founded in 2013. AED is underdevelopment. Targeting the same home and other mobile markets as CellAED. It aims to develop a miniaturised AED that integrates with smartphones. The company claims the device is double the thickness of a phone. Was awarded $1 million in follow-on funding from the US National Science Foundation in October 2022.	
JoltzAED	None	$800 - $850	Advertised to be on the market by first quarter 2023 but no news since August 2022. Claims to be small, lightweight, and portable. Targeting similar market to CellAED, but close to double the price. Made by Rithem Life Sciences.	
Joule	None	Marketed as "affordable", but no pricing available	Not for sale but is currently hiring staff. Targeting home market like CellAED. Made by Ooono Medical, who's majority shareholder Ooono A/S is a "Danish scaleup known for smart mobility services aimed at improving traffic safety". The development of Joule is backed by 20 year old AED manufacturer CorScience. Joule aims to be the smallest AED on the market.	

Source: Manufacturer websites

Avive *was* going to be the first real competitor

Of all the products in the market, we saw Avive (www.avive.life) as the closest direct competitor. This was the case until the company significantly increased pricing in January. We have kept this section in the report because the company appears to be well-financed, innovative and willing to learn and pivot based on experience and the market response. As such, while they're currently in a very different price bracket and therefore focusing on a different market audience with a different value proposition, they could easily pivot again and become a more direct competitor again in the future.

Avive has attracted a lot of press coverage and serendipitously timed its market entry perfectly, given the growing awareness of SCA and the previously discussed "Damar effect". In November 2023, the three co-founders, who started working on the device while studying at MIT, were included in the 'Forbes 30 Under 30' (Healthcare) list.

Reports vary, but we believe Avive has raised US$90 – US$100 million in funding over the last five years, most recently raising ~US$40 million in February.

It's important to note that FDA filings suggest that Avive, like at least ten other competitors, uses the Philips waveform (and potentially Philips hardware), limiting its ability to innovate as it doesn't own the IP. Any significant changes would require re-applying for FDA certification which will require clinical trials. It also means that their capital has not been spent on developing therapeutic IP but instead on other activities.

Figure 51: Since 2019, Avive has raised $90 – US$100 million*

Date	Amount raised (US$)	Total raised (US$)
December 2018	$3.4 million	$3.4 million
July 2019	$7.7 million	$11.1 million
June2020	$7 million	$18.1 million
March 2022	$35.9 million	$54.0 million
February 2024	$40.9 million	$94.9 million*

* Best estimate based on public data
Source: Forbes, CB Insights, Bizjournals.com, SEC.gov, tracxn.com

When it first launched in late 2022, Avive (only available in the US) was one of the most modern, affordable and portable AEDs on the market. However, in January 2024, Avive significantly increased its prices, making it one of the most expensive AEDs in its consumer space.

1. At launch (late 2022): US$350/yr for five years or $1,395 outright;
2. January 2024: US$900 upfront including US$450 'connection fee' + US$450/yr for the next four years or US$1650 outright.

Over a five-year period, Avive is now 2.5x more expensive than CellAED. The total cost over eight years (US$4,050) is 2.8x more than CellAED (US$1,460), making it one of the most expensive public access, consumer-focused AEDs on the market.

Avive's arrival in the market has enormous benefits for CellAED. Avive is doing a lot of marketing and gaining attention for its involvement in the '4-minute cities'[83] project. These activities are laying good groundwork for when CellAED enters the US market, raising public awareness of 1) sudden cardiac arrest; 2) the critical role of AEDs play in the survival chain; and 3) the availability of personal AEDs.

Given that the project aims to have AEDs within 4 minutes of any SCA, the more affordable, portable and low-maintenance CellAED is ideal. And given the price differential, city officials could deploy double or triple the number of AEDs with the same or smaller budget.

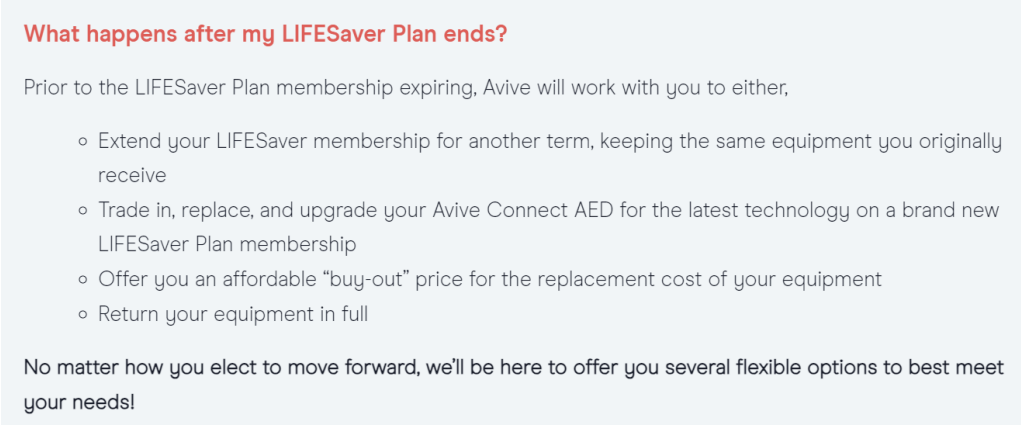
Table 52: Avive is now one of the most expensive AEDs on the market

	Year 1	Year 2	Year 3	Year 4	Year 5	Total	vs CellAED
Late-22	$350	$350	$350	$350	$350	**$1,750**	1.6x
Jan-24	$900	$450	$450	$450	$450	**$2,700**	2.5x

Note: All prices are in USD
Source: Avive

Avive is targeting businesses, corporations, schools, community groups, gyms, churches, and emergency services. Interestingly, what happens after the five-year subscription is unclear, with several options listed below but no prices mentioned.

Figure 52: Avive offers several end-of-life options, but pricing is unclear



Source: Avive (https://avive.life/lifesaver-or-one-time-purchase/#faqs)

As well as being smaller and lighter than traditional AEDs, Avive also has several other innovative features, including:

- **Rechargeable batteries:** Avive is a rechargeable unit that needs to be plugged into an outlet. This saves the maintenance and cost of battery replacement, with flat

[83] The "4-Minute City" program in the United States is an initiative aimed at significantly reducing the time to defibrillation in the event of a sudden cardiac arrest (SCA) to within 4 minutes of a 911 call. The program very much mirrors the "Safe City" program several Middle Eastern cities have discussed over the last six years. The program focuses on deploying Automated External Defibrillators (AEDs) through strategic, data-driven placement, including in homes, to ensure that an AED can be available within this critical time window. It also involves massive community training and awareness activities to enhance the capabilities of bystanders, integrating AEDs with 911 centres, and sharing valuable data with public safety and healthcare providers to improve overall care.

batteries being the most common cause of AED failure. The downside is that users must store the device near an outlet. That said, the company reports an unplugged battery will last more than eight and half months before it reaches the "low battery" condition, providing fewer than ten shocks and less than 20 minutes of continuous use.

- **Avive Connect AED:** Avive Connect AED is an AED management platform that helps users manage their AEDs. It provides up-to-date status and performance information (battery, pad life, active/inactive) and GPS location. This feature is especially useful for those trying to manage several AEDs, such as businesses, corporations, government organisations, first responders and emergency services.
- **Connected to 911:** Avive's "REALConnect" system is integrated into the 911 call centres of four[84] 4-minute cities, offering some innovative features. Avive will continue extending coverage, announcing this week that Carrollton, Texas, will become its fourth partner city. The fragmented structure of emergency services (especially in the US) makes this difficult. This is even more complex if Avive wants to expand internationally. As mentioned above, the upside is that all the effort Avive puts into the program and raising awareness of the importance of rapid response plays directly to CellAED's strength. Following their recent price rise, Avive is now 2.8x more expensive than CellAED, making it an even more obvious choice to maximise AED coverage across a city.
    - **Intelligent Response:** Developed in partnership with RapidSOS[85] (rapidsos.com), which operates similarly to the GoodSAM program. 911 call centres in the four connected cities can "dispatch" the nearby owners of Avive Connect AEDs to patients suffering a SCA and receive data from the AED during a rescue. It's not clear exactly how the AED is dispatched.
    - **QuickRescue – under development:** Once an Avive is activated in an emergency, the device automatically notifies the 911 call centre and sends its GPS location to emergency responders.
- **Incident reporting:** Upon activation, the Avive AED will record patient and shock data. This information can be accessed by emergency staff by scanning a QR code shown on the Avive screen following the SCA event.

[84] Avive's 4-minute cities are: Forsyth Country Georgia (260,200 people), Cumberland County Pennsylvania (263,000 people), Jackson Tennessee (68,000), and Carrollton Texas (133,251)

[85] RapidSOS is a connectivity platform that technology companies can use to send emergency data to safety agents, 911 and field responders. The platform can be linked to phone apps, devices, wearable, in home or in building security systems and can send data including location, emergency contact details, medical history, allergies, floor plans, door controls, video feeds, gunfire detection and more.

Figure 53: Avive Connect AED provides incident reporting to EMS

Source: Avive

- **English & Spanish:** Avive supports both English and Spanish, with a button to change between languages.
- **Trainer pads:** Rather than a separate training device, users can purchase a separate trainer pad cartridge that can be used to train users with the actual Avive device. Avive's training cartridge is similarly priced to CellAED's trainer and significantly cheaper than other AED's trainers.

As shown in Table 50 below, Avive offers several additional non-therapeutic features, which help with marketing if not actually relevant in saving lives. The trade-off is that Avive is larger, heavier and now far more expensive. For home users, it will be a trade-off between the cost and the value ascribed to these features. The 911 integration is a great selling point, but the current range reduces this value (coverage extends to three cities, totalling fewer than 730,000 people or ~0.2% of the US population). It's not clear how quickly Avive can extend coverage, but it's a great feature from a marketing perspective and also great for CellAED.

The rechargeable battery makes Avive less flexible for public access use since an outlet is required. However, the Connect AED platform is of great value for companies, government agencies and large organisations that need to manage a fleet of devices. We believe RRR intends to build an asset management system and policies specifically for fleet management, but the group's resources are currently focused on more immediate priorities. Importantly, the infrastructure in both the device and the backend monitoring and data collection are in place, meaning the main work will be in developing the front-end system.

CellAED has long-term strategic advantages

As discussed above in *What is an AED waveform, and why should I care?,* we believe that with current technology and electronic components, it will be difficult for Avive to reduce the size of its device much further without changing its waveform and hardware. As mentioned previously, any significant change to its waveform will require clinical trials, which will take at least 2-3 years.

This comparison is, of course, currently moot given Avive is only available in the US, and CellAED is not yet US FDA approved. Eventually, both devices will be in the same geographies

(which we believe will benefit both companies), but Avive's new pricing likely means CellAED will have the more prices sensitive consumer home market almost to itself.

Table 53: CellAED has several advantages that make it competitive against Avive.

RRR Advantages	RRR Disadvantages
1. Smaller and lighter 2. Significantly more affordable 3. 100% control over proprietary waveform and therapy delivery 4. Wide moat to protect size, weight and price advantage 5. Multiple regulatory approvals, including CE 6. First mover advantage in Europe, ROW 7. Undergoing two clinical trials	1. Not FDA approved 2. Several years behind Avive into US market 3. Fewer non-therapeutic but compelling marketable features 4. No fleet management capability (yet) 5. Limited marketing budget and access to capital 6. Non-US based 7. Missing huge AED demand and 'Damar Effect' tailwind

Figure 54: Avive offers far more non-therapeutic added features than CellAED

Feature	CellAED	Avive
Upfront cost	US$550 (inc. 1yr CellAED for life)	US$900
Annual subscription	US$130 (after first year)	US$450 (after first year)
8-year cost	US$1,290	US$4,050
Shelf life	AED: 2yrs Battery: 2yrs Pads: 2yrs	AED: 5-8yrs Battery: 5-8yrs Pads: 2yrs
Waveform	RRR proprietary biphasic exponential	Resistance compensating, biphasic truncated exponential (BTE) waveform[86]
Battery	24 months from purchase (30 months from manufacture)	Rechargeable
Dimensions	21 x 11 x 3cm[87]	14 x 16 x 7cm
Weight	450g[49]	953g
Screen	No	High-resolution colour touchscreen
Visual prompts	Visual instruction on the device	Image and motion graphics during emergency mode
Connectivity	Mobile	Mobile, Wi-Fi, Bluetooth
GPS	No – uses cellular location & triangulation	Yes
Data recording	Yes - not yet accessible outside RRR	Yes – access via QR code
Trainer	Separate device (US$65)	Separate pad cartridge (US$74.99)
Replacement pads	Not needed	US$99.95
Uses	Single	Multiple (each use requires users replace electrode pads)
Replacement policy	Replacement device if used in emergency[88] and also at expiry	Replacement pads, if used in an emergency[88]
End of device life plan	Yes (with subscription)	Not clear
Fleet management	Not yet	Yes
Bi-directional device communication	Device-to-cloud only	Bidirectional

Source: Rapid Response Revival and Avive

[86] We believe that Avive uses the same waveform as Philips and most like licences the waveform from Philips. Avive used the now expired Pre-Market Access (510(k)) (PMA) pathway to gain FDA approval which involved showing the applied therapy was the same or sufficiently similar to existing therapies. Avive used the Philips' resistance compensating, biphasic truncated exponential (BTE) waveform for its comparison.

[87] Includes carry case. CellAED without the case measures 19.6 x 9.6 x 1.7cm and weighs <300g

[88] Included as part of CellAED and Avive ConnectAED subscriptions. Not included without subscription.

Protection & Competitive Advantages

CellAED is a significantly different device compared with existing AEDs on the market. As such, under the new regulatory environments, the barriers to creating a comparative product that competes on size, weight and affordability are enormous for both existing AED manufacturers and new entrants. It's almost certain that any AED that attempts to match CellAEDs size will require human clinical trials, which will take at least 18-24 months and cost tens of millions of dollars to complete. Adding this to the time taken for regulatory approval along with time to design, test and manufacture a device, we are comfortable that CellAED has at least a four-year head start on any potential competitor.

RRR has a three-pronged strategy for protecting CellAED's market position:

1. **Regulation:** Regulation provides RRR with a powerful competitive advantage as well as protection from IP infringement. CellAED is the only single-use AED on the market. It is also the smallest, most portable, most affordable AED on the market.

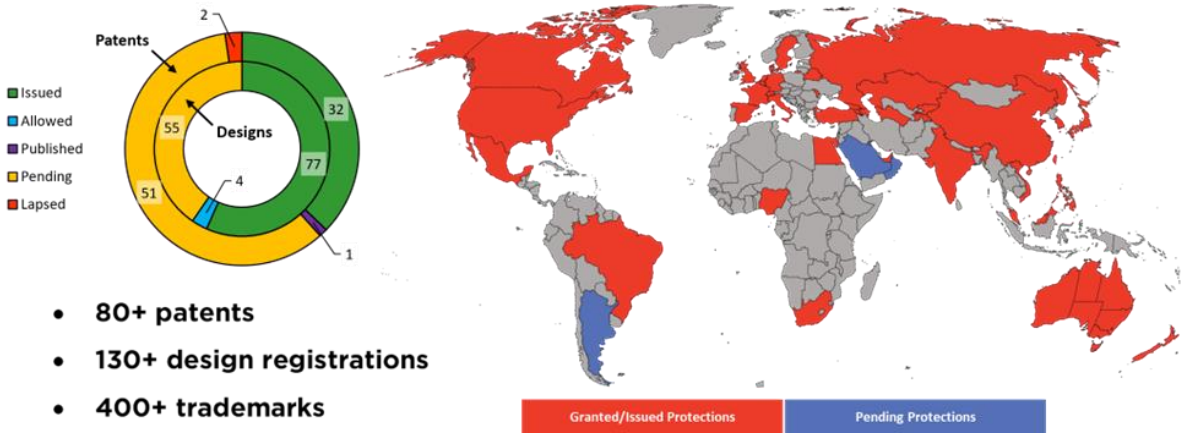
   As discussed above, changes to the CE certification framework require any new AEDs to undergo clinical trials before approval. The US FDA also require clinical trials on any device that isn't equivalent to an existing device, which means any device that comes to market trying to compete with CellAED's size, weight, portability, and affordability.

   Clinical trials take at least 18 months to conduct (more likely 24-30 months). The regulatory approval process takes at least 18 months (more likely 24 – 36 months), with individual approvals from the local regulators in each country then also required. This gives CellAED a head start of at least a 30-month (more like three to four year) on any manufacturer wishing to develop a device for the personal and ultra-portable market.

2. **Patents and registered designs:** The CellAED has more than 80 patents and more than 130 design registrations issued or pending. These protections cover several of the key elements of CellAED that enable it to be an ultra-small, portable, and affordable device, including the dual capacitor banks, single-use, inbuild pads and waveform, making it difficult for a competitor to build a device with these similar key characteristics.

   Intellectual property is only as powerful as one's ability to protect it but given that it relates to a Class III medical device, we expect the exposure of an infringement battle visible to both the public and regulators, adds another degree of protection.

Figure 55: Rapid Response Revival maintains 100% ownership



Source: Rapid Response Revival

3. **Trade secrets:** RRR is fiercely protective about several key aspects of its device. There are aspects of the design known by only a few people within the company, and in any partnerships (manufacturing or otherwise) RRR maintains total control over all IP. When RRR uses third-party manufacturers to assemble the devices, the programable logic boards are accessed and programmed remotely by RRR so that even manufacturing partners don't have access to the device's firmware.

   In future versions of CellAED, RRR intends to use more custom integrated components (Systems in Plastic – SiP). By integrating electronic systems directly into plastic, SiP creates a more intricate and compact design that is harder to dissect, analyse and reverse engineer. This integration can obscure the functionality and layout of electronic components, making it more challenging for competitors to replicate or understand the underlying technology, thus providing an additional layer of protection against reverse engineering efforts.

Other competitive advantages:

1. **Smallest, lightest, cheapest:** CellAED is the smallest, lightest and most affordable AED on the market. The device has created an entirely new market for ultra-portable, personal AEDs. Given the protections outlined above, it will be difficult for another manufacturer to beat CellAED on any one of these factors.

2. **First mover advantage:** Avive is CellAED's closest rival and the only product against which CellAED will directly compete within its core use case. For the moment, Avive is only available in the US, so the head-to-head matchup will only occur once CellAED gains FDA approval and commences selling in the US or if Avive expands into Europe. Even against Avive, CellAED offers meaningfully different features. CellAED is less than half the weight, 44% the size and 36% the price[89] of Avive.

   The downside to being the first mover is that CellAED must educate the market that personal AEDs exist. We see it advantageous that Avive exists in the market and is helping raise awareness of personal and portable AEDs.

3. **Subscription model:** CellAED's highly popular CellAED for Life offers all the advantages of a traditional subscription model. RRR maintains a direct relationship

[89] 36% of total price over 8 years. If bought outright, CellAED is 22% the price of Avive.

with customers while receiving an ongoing annuity revenue stream. Given the annual subscription is around a third of the initial purchase price, we expect churn to be low, as the cost of re-commencing a subscription (which is only possible by buying a new device), will provide users with a strong incentive to maintain their subscription.

RRR claim their design and manufacturing innovations, coupled with their IP protection and the newly enacted stricter regulatory requirements, give them a seven-to-eight-year head start. While possible, we're comfortable that once a competitor is confident CellAED has proven the market (which may have already happened), RRR comfortably has at least a three-to-four-year lead on anyone that hasn't started designing a competing product.

Can't I just copy, repackage & sell a knockoff CellAED?

Almost the only real pushback we hear on CellAED's market potential is that someone will undercut the device by reverse engineering it and making a cheap Chinese knock-off. Aside from the trade secrets and portfolio of patent and registered designs, regulation makes this impossible. As outlined above, it's not enough to simply have a working device; regulators want to see a complete, documented design history.

Conceivably, someone in China could reverse engineer the device and then use their political connections to secure regulatory approval in China (we believe this is extraordinarily difficult and highly unlikely), but there are already several Chinese-based AED companies (including Mindray) who would vehemently oppose such a move from either an existing competitor or new entrant. Approval in China also wouldn't allow a competitor to sell the device anywhere outside of China, including in Taiwan.

As for a cheap Chinese knockoff, Mindray AEDs have a recommended retail price of between A$1,999 - $2,500. If it was so easy to create a Chinese knockoff wouldn't they and other existing Chinese manufacturers already done so?

As discussed above, the regulatory approval process is immensely complicated, expensive, arduous, and ongoing, effectively preventing a company from simply reverse-engineering CellAED to create a cheaper version.

Management team

For a small and capital-constrained company, RRR has an impressive management team and medical advisory board. What becomes obvious when speaking with management and advisory board members, is how genuinely passionate and driven they are to materially improve SCA survival outcomes. Senior management are highly focused on saving millions of lives, and understand it requires they make and sell tens of millions of CellAEDs to do so.

Table 54: Founder Donovan Casey has assembled a high-calibre management team

Executive	Background
Donovan Casey CEO, Founder & Chairman	Donovan Casey is a successful entrepreneur with more than 25 years of experience across numerous industries. His deep experience spans new product and service development, business founding and growth, and generating profitable outcomes in both established and emerging markets. Casey founded Rapid Response Revival to develop the world's first miniaturised personal defibrillator, applying his proven track record of bridging the gap between a great idea and market viability. Casey has attracted and fostered an impressive team of dedicated staff who truly believe in his vision of meaningfully improving the global survival rates of sudden cardiac arrest. Donovan holds a Bachelor of Science in Pure and Applied Mathematics, Statistics and Data Analysis from the University of Sydney.
Alan Dworkin CFO	Alan has over 30 years of experience across a wide range of industries and geographies, including 16 years as a CFO. He is a qualified Chartered Accountant and a member of Chartered Secretaries Australia. Alan's most recent experience has been as CFO with ASX listed companies in the health and mining sectors. Alan has led and developed finance teams with positions at Medlab Clinical (ASX:MDC), BOD Science (ASX:BOD), Intercept Minerals (ASX:IZM) formerly Uramet Minerals, and FIT-BioCeuticals (acquired by Blackmores in 2012
Scott Casey COO & CTO	Scott Casey is an impressive executive with a formidable knowledge and understanding of the ever-expanding minutia across almost every aspect of RRR. Casey has over 15 years of experience in designing, developing, implementing, and maintaining systems, data engineering and analytics. Prior to Casey's appointment as Chief Operating Officer, he was one of Rapid Response Revival's foundation employees and has held dual roles as Chief Information Officer and Chief Technology Officer. Casey successfully led the software, systems, and engineering disciplines in achieving the company's first CE certification of CellAED in addition to overseeing the development of the manufacturing software, services, and tools. Scott holds a Bachelor of Business in Finance and a Bachelor of Science in Data Analytics from the University of Technology, Sydney.
Dr Atheer Nassir Chief Research Officer, CEO MENA	Dr Nassir is an award-winning researcher and business leader. After a decade in academic research, Dr Nassir moved into the corporate world and has over 15 years of international experience across Australia, Asia and the Middle East in a diverse array of industries, including healthcare and medical technology. Dr Nassir has been recognised for his expertise in successfully establishing and executing research projects and proven experience in cultivating, negotiating and maintaining strategic collaborations and partnerships. Dr Nassir has a PhD in Pharmacy from the University of Sydney and is fluent in English and Arabic.
Dr Steven Brooks Chief Medical Officer	Dr Brooks is a Clinician-Scientist and Professor in Emergency Medicine at Queen's University in Kingston, Canada and an Emergency Physician at the Kingston Health Science Centre. Dr Brooks is a member of the Resuscitation Advisory Committee of the Heart and Stroke Foundation of Canada, a Past Chair of the Science Subcommittee within the American Heart Association Emergency Cardiovascular Care Committee, and served as a task force member for the International Liaison Committee on Resuscitation (ILCOR). As a thought leader in resuscitation science and novel approaches to early defibrillation in cardiac arrest, Dr Brooks has been involved in the development of international emergency cardiovascular care guidelines for the last 20 years. As a resuscitation scientist, Dr Brooks has published 117 manuscripts that have been cited more than 11,000 times in the medical literature.

Executive	Background
Mark Hillebrand Chief Marketing Officer	Mark has more than 30 years of experience in marketing and advertising with clients including Citibank, Shell, Sidchrome, Nintendo, ANZ Bank, Isuzu, Nissan, and BMW. Mark's previous senior positions include Rapp Collins Worldwide Managing Partner (Melbourne), George Patterson Bates Direct Marketing Director, and Head of Marketing and Audience Relationships for the Australian Broadcasting Corporation (ABC). Mark's career took him to London for eight years, where he worked for the Grass Roots Group (a subsidiary of WPP plc), establishing a high-tech marketing service business delivering digital engagement and loyalty & insight programs for global clients including BlackBerry, Nikon, Tyco, and Microsoft. Mark holds a Bachelor of Business (Marketing) from Monash University and continues to mentor post-graduate IT students working on industry projects.

RRR's Medical Research Advisory Board consists of nine high-profile, public-facing medical clinicians and research professionals. The fact they, along with Chief Medical Officer Steven Brooks, are involved in the development and oversight of the CellAED should give anyone questioning its safety and efficacy pause to reconsider. Each of these professionals, who all have highly successful and prominent full-time careers outside of RRR, faces severe reputational and professional consequences if the CellAED fails to perform as prescribed.

Table 55: RRR's Medical Research Advisory Board consists of world-class medical clinicians and research professionals

Board Member	Background and qualifications
Dr Mavourneen Casey	Dr Mavourneen Casey is Chair of the Medical Research Advisory Board (MRAB). A Certified Advisory Board Chair and highly accomplished university academic, Mavourneen joined Rapid Response Revival in early 2019 as a key member of the research and scientific affairs team. With a PhD undertaken through the Research Centre for Clinical Epidemiology and Biostatistics (CCEB) at the Medical School of the University of Newcastle, Mavourneen has also completed a post-doctoral research fellowship at the Medical School of the University of Queensland. Prior to joining Rapid Response Revival, Mavourneen established a strong track record of academic research leadership, direction of multi-disciplinary research teams, and collaboration across academic and commercial contributors to research projects. Mavourneen's extensive experience in research management, governance, strategy, and policy make her well-suited to Chair the Rapid Response Revival Medical Research Advisory Board.
Professor Wendy Cross RN, MEd, PhD, FACN, FACMHN	Professor Cross is the Dean of the School of Health, Federation University, Australia. Wendy has held senior appointments within Australia and holds several honorary professorial appointments. With 40 years' experience as a clinician, academic and applied researcher (and Principal Investigator), Wendy has a focus on mental health, health services evaluation and workforce. Wendy has developed clinical best practices and workplace training on public health services, received more than $3M in research grants, and has written for more than 120 publications across all domains. Wendy is currently a registered TEQSA expert, a member of the NSW Health Ethics Advisory Panel, Director of the Australian Nursing and Midwifery Accreditation Council (ANMAC) and a Director of the Australian Osteopathic Accreditation Council (AOAC). Wendy has held numerous Board director positions, including community health services and at the Victorian Institute of TAFE. Wendy is the immediate past President of the Australian College of Mental Health Nurses, the immediate past Chair of the Council of Deans of Nursing and Midwifery (Australia & New Zealand), and a past Fellow of the Australian College of Nursing.

Board Member	Background and qualifications
Dr. Barry Gunn MB BS FACEM	Dr. Barry Gunn has been a Specialist Emergency Physician at Sunshine and Footscray Hospitals (part of Western Health) in Melbourne, Australia, since 2002. Barry graduated from the University of Melbourne in 1989 and obtained his Fellowship of the Australasian College for Emergency Medicine (ACEM) in 1999. His subsequent experience includes time spent in emergency medicine at St Michael's Hospital in Toronto, Canada. Barry is passionate about medical education and is actively involved with the teaching and training of the junior doctors he works with. Barry is also very committed to the development of the specialty of Emergency Medicine and has been actively involved with ACEM in several roles. Barry is the current Censor-in-Chief and Chair of the Council of Education, which oversees the training and education activities of ACEM. He is also a current ACEM Board member. As an Emergency Physician, Barry is passionate about finding solutions to the high rate of preventable death due to out-of-hospital cardiac arrest.
John Haines A.D.H.Sc (Ambulance), MICA Paramedic Cert	John Haines literally wrote the book on paramedicine and first aid. A MICA paramedic, flight paramedic and clinical educator at Ambulance Victoria from 1978 to 1993, John is also one of Australia's best-selling authors with his series of first aid guides and textbooks. In 1988, John developed what was to become known as "The HAINES Position", a recovery position for unconscious patients with suspected spinal injury. The High Arm in Endangered Spine (H.A.I.N.E.S.) recovery position was named by researchers at the University of Melbourne and featured in many published articles around the world. Also in 1988, he founded Australian First Aid, the country's first recognised first aid training provider of workplace and community education in medical emergency response. Now trading as LivCor, this work has continued to this day with John as Managing Director.
Dr. Adele Hosseini B.Pharm. M.Pharm, PhD	Dr Adele Hosseini is the Chief Scientific Officer at the pharmaceutical company, Bod Australia. Adele is a pharmacist with a PhD and over 30 years' of experience in leadership, global clinical research, regulatory affairs, and university lecturing. Adele's organisational experience spans pharmaceuticals, clinical research organisations, medical devices, and academia. Adele uses her cumulative experience across all facets of medical research gained over these years to lead and shape the scientific function of innovation biotech. An active contributor to industry thought leadership, Adele is dedicated to sharing knowledge and shaping the direction and future of the global pharmaceutical sector.
Charles Johnson MBBS (Singapore), FRCS (Emergency Medicine)	Charles Johnson is an Emergency and Flight Physician and Medical Director of Hope Medical Services, Singapore. An emergency physician, Charles graduated from the National University of Singapore (NUS) in 1992. In 2000, he was awarded a Fellowship of the Royal Society of Edinburgh (FRSE) from the Royal College of Surgeons in Edinburgh. In 2005, he helped establish Hope Medical Services to deliver private pre-hospital services dealing with basic- and advanced life support care on land, air, and sea. Since the onset of COVID-19, Charles's focus has been on the challenges of transferring pandemic patients internationally. Charles is passionate about first responder resuscitation and plays an active role in efforts to promote CPR and AED access to all.
Dr. Chandana Unnithan PhD (Digital Health), Mbus Computing, MBA	Dr Chandana Unnithan is Chief Security and Informatics Officer (CSIO), at Lifeguard Digital Health Canada. An expert scientist in digital health, Chandana pioneered and implemented novel technology solutions with socio-tech approaches in Australia and Canada, integrating Artificial Intelligence, IoT, Blockchain, Geo-spatial apps, Telehealth, and Health Informatics. Chandana is currently scaling a privacy-preserved, technology solution that is saving lives from opioid overdose deaths in Canada. Chandana is widely published with more than 140 scientific papers. She has previously held advisory positions with the World Health Organisation and the United Nations. A special focus on the health applications of blockchain has also resulted in Chandana holding expert advisory roles with Canada's Digital Technology Supercluster, and the University of British Columbia (UBC).

Regulation

For anyone outside the medical regulation industry, it's difficult to comprehend the complexity of gaining and retaining regulatory approval for a Class III medical device. Recent changes to the classification and approvals process of AEDs by the US Food and Drug Administration (US FDA) and the Conformité Européenne (CE) have made it significantly more difficult. Indeed, the process through which most AEDs on the market gained approval no longer exists, and we expect several devices reliant on CE registration will be withdrawn from the market when the existing device grandfathering period ends in December 2027.

The process of gaining regulation depends on the type of device and the jurisdiction in which the device is sold. The approval process for the CellAED was even more complicated as not only is it a medical device, but its telecommunication capabilities (GSM 2G and 3G mobile/cellular connectivity) require it to be approved under the Radio Equipment Directive (RED).

Until CE's new MDR framework came into place in May 2021 (replacing the previous MDD framework), the US FDA was regarded as having the strictest and most difficult regulatory process. Many jurisdictions around the world follow the lead of the US FDA or CE in granting their own approval or through Mutual Recognition Agreements (MRA).

While each regulator is different, the following provides the very high-level, broad steps in gaining regulatory approval for a Class III medical device. Each stage requires detailed auditable documentation with pages numbering in the several thousand and involves verification by the regulator or their representatives.

1. **Theory, development, and proof of concept:** Comprehensive documentation showing the entire development path from theory to concept to prototype, improvements, iterations, changes, motivation for changes, trials, failures, reasons for failures, learnings, to the final product. It's not enough to have a device that provably works; you must show why it works and how you got it to work. This is one of several reasons someone can't start selling cheap Chinese-made CellAED knockoffs.
2. **Quality Management System (QMS):** Establishing and maintaining a QMS compliant with ISO 13485 is crucial. The QMS ensures that every aspect of the manufacturing process, from design to distribution, adheres to standardised quality and safety protocols. The involvement of competent personnel and thorough documentation within the QMS is vital for transparency and accountability.
3. **Technical designs:** Provide the regulator with complete technical designs and specifications covering every aspect of the device, including each component within the device, failure rates, tolerances, manufacturing certainty, critical failure paths, impact of failure, redundancy, reliability, and contingency management.
4. **Risk Analysis and Clinical Evaluation:** A thorough risk analysis is required to identify and mitigate potential hazards associated with the AED's use. Simultaneously, a clinical evaluation must be conducted to affirm the device's safety and performance, supported by clinical data or literature. This includes rigorous testing for reliability under various conditions, evidence of effectiveness, adherence to design standards, and thorough user guides to ensure safe and proper operation.

5. **Functional testing:** Demonstrate the device works as intended within acceptable margins of error and failure contingencies. Functional testing occurs in stages and typically involves in-house laboratory testing, independent laboratory testing, animal testing and, at times, human testing. While not initially required for approval, RRR is undertaking clinical trials (see '*Clinical Trials*'), which will be needed for FDA approval and approval under CE's new MDR regulations, which come into effect in 2027 (see below).
6. **Supply chain:** Complete supply chain audit showing the source of each component (suppliers of critical paths must have regulatory approval themselves to provide components for medical grade equipment), failure rates, operation tolerance, potential substitutions and contingencies.
7. **Manufacturing:** A fully documented and implemented manufacturing process showing how consistency is maintained at every stage and for every component throughout the manufacturing process. This includes everything from how much solder is used to attach a component to how much force is applied to a screw and also the controls in place to ensure the correct procedure was followed.

   The manufacturing process requires a complete audit trail so that every device can be traced back to the batch of components it contains, the staff who put it together, the staff that tested it and each of the test results at every stage of its assembly. The documentation must also include staff training and ongoing compliance plans.
8. **Product testing:** The testing program includes testing during assembly and final product testing. It's not enough to test that the device works once fully assembled. Each device must be tested, and the results recorded at various stages throughout manufacturing. Again, these results, along with who ran them and when, must be kept both for regulatory audits and in the event of failure or an unexpected outcome.
9. **Post-market surveillance:** Manufacturers are required to maintain ongoing post-market surveillance studies to collect data on the safety and effectiveness of their devices. Data is collected from devices that work and fail. Manufacturers must report failures to regulators and investigate so causes can be found and rectified.
10. **Ongoing audits**: Manufacturers of medical devices must undergo regular scheduled and unscheduled audits showing documentation for every aspect outlined above. Regulators or their representatives can visit the company and manufacturing facilities to inspect them without warning. Every regulator has the right (and obligation) to do this. Given that CellAED has certification and registration from multiple regulators (see Figure 56), RRR is regularly audited by multiple independent parties, with more added as they continue to commercialise into new markets.

While each regulator needs similar information (with FDA and CE being the strictest), each requires the details in their specific format, adding another layer of administrative and reporting burden. This upfront and ongoing cost and administrative burden adds tens of millions of dollars in costs to get medical devices to market and several million a year to simply remain on market.

Table 56 outlines the regulatory certifications CellAED has achieved so far. Having been granted the CE approval, the process to gaining other regulatory approvals can be significantly easier. It's worth noting that even with CE approval, Rapid Response Revival must

still seek approval from each country's regulators in which they wish to sell CellAED. Compared to the CE process, it's far simpler and typically only requires applicants to submit paperwork to gain registration and certification in English-speaking countries. Otherwise, localisations (mostly language-related) are required before being able to sell into non-English speaking countries. Approval can take anywhere up to 12 months, depending on the country.

RRR reports that each localisation costs around A$300,000 - A$500,000 and takes around six months to complete. The long development time is partly due to specific design decisions made in this version of CellAED. Future designs will support faster and cheaper localisation.

Table 56: CellAED has already secured certifications for several regions, including Australia, NZ, UK & Europe

Period	Region/Country	Certification	Type	Details
4Q 2019	Global	QMS (ISO 13485)	General quality & safety including medical	Quality Management System (QMS) certification is a regulatory standard that verifies certain products are safe for sale and use. It ensures that the basic manufacturing practices and prerequisites necessary for the safety and quality of the product are effectively implemented.
2Q 2020	New Zealand	Medsafe	Medical	Medsafe is the New Zealand Medicines and Medical Devices Safety Authority. It is responsible for the regulation of medicines and medical devices in New Zealand, ensuring safety and efficacy. Medsafe is one of the easiest approvals to achieve.
4Q 2020	Global	RED	Radio equipment	The Radio Equipment Directive (RED) establishes a regulatory framework for placing radio equipment on the market. It ensures a single market for radio equipment by setting essential requirements for safety and health, electromagnetic compatibility, and the efficient use of the radio spectrum.
2Q 2021	Europe	CE	General quality & safety including medical	Conformité Européenne (CE) certification is a regulatory standard that verifies certain products are safe for sale and use in the European Economic Area (EEA). CE certification was previously the second most difficult certification to achieve, behind the US FDA. The recent changes discussed below, with the shift to the MDR system make CE the most difficult to attain. CE certification covers the EEA+4 countries[90]. Manufacturers place a CE mark on certified products to indicate that the product complies with European safety rules and can be traded freely within the EEA+4
3Q 2021	Australia	ARTG	Medical	In Australia, all medical devices, medical tests, custom-made devices, and systems or procedure packs must be registered with the Australian Register of Therapeutic Goods (ARTG) before they can be placed on the market.
4Q2021	United Kingdom	UK MHRA	Medical	The Medicines and Healthcare Products Regulatory Agency (MHRA) regulates medicines, medical devices, and blood components for transfusion in the UK. All medical devices require pre-market approval prior to entering the UK market.
1Q 2022	United Kingdom	QMS UKCA	General quality & safety, including medical	The UKCA (UK Conformity Assessment) mark is the new UK product marking that is required for certain products being placed on the market in Great Britain (England, Wales, and Scotland). It covers most products that previously required the CE mark. It will not be recognised in the EU market.
2Q 2022	Taiwan	Taiwan GMP	General quality & safety including medical	Good Manufacturing Practices (GMP) certification scheme provides independent certification to ensure that the basic manufacturing practices necessary for the safety and quality of food are effectively implemented in Taiwan.
2Q 2022	Taiwan	Taiwan NCC	Radio equipment	The NCC approval ensures the verification of the minimum legal requirements for radio technology products in Taiwan. All telecommunications products and other electronic products in the field of radio technology must meet regulatory and technical requirements in Taiwan to be approved for use in the market.

[90] EEA+4 refers to the 27 countries in the European Union plus Norway, Iceland, Liechtenstein, and Switzerland.

Period	Region/Country	Certification	Type	Details
3Q 2022	Taiwan	Taiwan FDA	Food and medical	The Taiwan Food and Drug Administration (TFDA) is Taiwan's equivalent of the US FDA. All imported medical devices must obtain a registration certificate from the TFDA before they can be imported into Taiwan.
3Q 2022	United Kingdom	UK CA	General quality & safety, including medical	The UK Conformity Assessed (UKCA) marking is a new UK product marking used for goods being placed on the market in Great Britain (England, Wales, and Scotland). It covers most goods that previously required a CE mark.

Source: Rapid Response Revival and respective regulatory bodies

For a more detailed overview of the FDA and CE regulatory processes, please see *Appendix – European CE Certification* and *Appendix – US FDA Certification*.

Figure 56: CellAED is an approved medical and radio equipment device

Source: Rapid Response Revival and respective regulatory bodies

Recent changes to regulation widens CellAED's protective moat

Both the FDA and CE had "equivalency" pathways for AEDs to gain regulatory certification. This required manufacturers to show evidence their device was equivalent to an already approved device. This was the cheapest and easiest path to gain certification and was used by most devices on the market.

In May 2021, CE reclassified AEDs from a Class IIb device to the highest classification, Class III device. The FDA made the same reclassification in 2013 but allowed AEDs to be assessed through the quicker and less stringent 510(k) process. In April 2019, the FDA closed the 510(k) pathway for new applicants, requiring all new AEDs to go through the lengthy and strict pre-market approval process (PMA). AEDs already in the 510(k) process had until February 2022 to gain approval. This reclassification and cancelling of the 510(k) process placed even more stringent regulatory controls on the devices, putting them in the same category as pacemakers, heart valves, implantable cardioverter defibrillators (ICD), breast implants, artificial joints, and Cochlear implants.

Under the reclassification change, the FDA requires all new AEDs that are not equivalent to existing devices to undergo human clinical trials to prove their safety and efficacy[91]. This simple requirement significantly lengthens the approval process by at least 18-30 months and adds a significantly higher cost burden for approval. These requirements also extend to all AED accessories, including spare batteries and pads.

The new CE certification is even more stringent, surpassing the US FDA as the strictest regulatory regime in the world. In May 2021 CE moved from the old Medical Device Directive (MDD) regime to the new Medical Device Regulation (MDR) regime (see '*Appendix – European CE Certification - Changes from MDD to MDR'*), which places far stricter testing and validation requirements on AEDs. Under the new regime, all AEDs (including those already on the market) must undergo clinical trials, completely removing the equivalency approval pathway. Most manufacturers can use their post market surveillance data to qualify their existing AEDs; however, any "significant"[92] changes they wish to make to their devices will require clinical trials, including evidence of the safety and efficacy of devices on humans. Devices already approved under MDD have been grandfathered into the regime but must satisfy the MDR requirements by December 2027.

Human-based clinical trials are time-consuming, costly, and ethically challenging. CellAED is already catching this safety and efficacy data through its two ongoing trials, RAPID I and FIRST (see '*Clinical Trials*'), and management reports that CellAED is almost CE MDR compliant and will require minimal engineering work to achieve the MDR certification.

As mentioned above, CE certification now surpasses the US FDA as the most difficult certification to gain. To understand the likely impact this change will have on the future development of AEDs, it's worth comparing the number of AEDs approved by the US FDA with those approved by CE. The FDA has only approved 32 devices from seven manufacturers. This compares to the 60+ devices from more than fifteen manufacturers with CE approval. In the lead-up to the expiry of MDD, manufacturers will need to decide if investing money to go through the MDR process is economically viable or if they're better off simply exiting the market.

The new regulations will also make it significantly more difficult and costly to advance AED development in both the US and Europe, thereby meaningfully widening CellAED protective moat from those wishing to develop an entirely new AED to compete in the personal, ultra-mobile and affordable market.

[91] The approval of Avive's AED suggests that these regulations either have some flexibility. Avive secured FDA approval in October 2022, after the grandfathering window had expired and yet the FDA's Summary of Safety And Effectiveness Data (PMA P210015) indicates that Avive used an equivalency test for approval rather than human trials: "The Philips adult wave form safety and effectiveness was supported through published clinical data for defibrillation" and "The analysis of safety was based on the comparison to the Philips adult defibrillation waveform as discussed above".

[92] Under the CE certification process for medical devices, a "significant change" refers to any alteration that could affect the safety or performance of the device. The definition is vague and broad requiring manufactures to access each change to determine if they believe it's significant. Significant changes must be reported to, and accesses by the authorising body before being implemented. Insignificant changes may be implemented and then reported to the authorising body at the yearly review.

Significant changes include anything related to the therapy or delivery of therapy, changes in design, material, intended use, or manufacturing process. Any change that affects the therapy is considered significant including the waveform, or key components that are integral to delivering the therapy including the capacitors and their layout. Cosmetic changes are typically "insignificant", unless they affect how users might delivery the therapy.

Clinical Trials

While RRR has received the necessary regulatory approvals to make and sell CellAED, the company is submitting CellAED to two clinical trials to independently verify its safety, efficacy and effectiveness. As mentioned previously, CellAED's design allows for an optimised waveform that can deliver the equivalent therapy to existing devices but at a lower energy level. Understandably, as previously discussed (see *What is an AED waveform, and why should I care?*), the device has met some scepticism within the industry, which these trials should allay.

The trials will provide proof of CellAED's efficacy, and valuable feedback to the company for future product refinement. Both trials have passed the safety milestones.

Notably, most AEDs on the market have not undergone clinical trials but gained approval by demonstrating they are equivalent to existing and proven AEDs. As discussed above, this pathway is now shut in Europe and is considerably more complex in the US.

Figure 57: CellAED's trials involve various institutions in NSW, Victoria and New Zealand

Source: Respective company and organisation

Clinical trial: RAPID I

RAPID I is a multi-centre safety and efficacy evaluation study run by A/Prof Dion Stub from Alfred Hospital Heart Centre in Melbourne. The trial aims to test CellAED in hospital operating theatres by attaching the device to patients undergoing cardiac procedures during which they are likely to experience Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF).

Prior to their procedure, consenting patients have a CellAED attached to their chest. When a VT or VF occurs (either spontaneously or induced), the CellAED is used to defibrillate and return the patient to normal sinus rhythm. Under the study's design, only one attempt will be made for each patient before a backup defibrillator is used.

The study has a target sample size of 25 participants. The last trial update available to the public (see website below) was on the 20th June 2023, when 14 participants had completed the study. It's not unusual for the ANZCTR website to not be updated regularly. We expect that by now, more participants will have completed the trial, but we can't confirm this.

Organisers expect to complete recruitment by early 2024, with initial results made public in the second half of the year.

Seven hospitals are involved in the trial (four in Australia and three in New Zealand), including The Alfred, Prince of Wales, The Sutherland Hospital, Westmead Hospital, Auckland Hospital, Christchurch Hospital and Waikato Hospital.

As previously mentioned, the trial has passed its safety milestone, but until it's complete, we don't expect any more information to be made public.

More information is available on the Australia New Zealand Clinical Trials Registry (ANZCTR) website: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=381198

Clinical trial: FIRST

The First Responder Shock Trial (FIRST) is a cluster randomised controlled trial testing the effectiveness of equipping GoodSAM (Smartphone Activated Medic) responders with a CellAED on 30-day survival in out-of-hospital cardiac arrest (OHCA). GoodSAM is an international program that aims to deploy volunteer responders to cardiac arrests. Enabled through the GoodSAM app, responders are notified and dispatched to nearby potential out-of-hospital cardiac arrests (OHCA) to initiate CPR and defibrillation, usually arriving before professional emergency responders. The app also alerts volunteer responders of the location of nearby public access AEDs if they exist.

GoodSAM reports that hundreds of organisations and over a million people use the App. Through its community, GoodSAM now boasts the world's largest defibrillator registry and claims to deploy a trained responder to a cardiac arrest every three minutes.

Ambulance Victoria is co-ordinating the trial with St John Ambulance New Zealand. The study aims to recruit at least 714 cardiac arrest patients. As of the last update (October 2023) the study had recruited 281 patients. Data collection is expected to be completed by the end of September 2024, with results released in early 2025.

More information is available on the Australia New Zealand Clinical Trials Registry (ANZCTR) website: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=383697

It's worth noting that the success of FIRST could lead to a huge step up in sales with GoodSAM volunteers hearing of the life-saving benefit of having their own CellAED. GoodSAM's one million plus user base, most of whom are based in countries where CellAED is already being sold (the UK, Europe, Australia and New Zealand), presents RRR with a massive sale opportunity.

These results will also be relevant to other community first responder communities, including PulsePoint in the US, which has more than 1 million App users.

Risks

Table 57 below outlines the key risks Rapid Response Revival faces. This discussion should be read with the understanding that Rapid Response Revival is an early-stage medical device company that has only recently commercialised its product. The risk severity is assigned within the context that the company is still in its early ramp-up phase, has sold fewer than twenty thousand devices and has financial reserves. The company represents a far higher risk than a more mature and better-resourced business. Events that merely cause a temporary financial loss or delay for a more established company could be disastrous to RRR or even force the company to close.

Table 57: Risk factors and severity

Risk	Details	Severity
Cash flow	Rapid Response Revival's biggest and most immediate risk is its current cash flow position. RRR has minimum cash reserves and has been operating with anorexically tight budgets since its launch. The group has executed several successful capital raises, but each has only provided the company with a 6-12 month runway. Despite regularly hitting extremely challenging milestones, largely within tight deadlines, having massively de-risked itself, including already outselling legacy public access AEDs in Australia by more than a factor of eight, the biggest risk RRR faces is simply running out of cash.	Very high
Market fit	CellAED is effectively opening an entirely new and untapped market in that it's a mobile, personal AED designed for home users. This is an entirely different market segment and value proposition offered by existing public access AEDs. While current sales trends support the business's assessment that the in-home and mobile segments offer enormous sales potential, it's still very early days and RRR has only started down its sales and marketing journey. That said, evidence to date suggests RRR (and Avive) have found a new market with impressive sales volumes already outstripping existing public access AEDs manufacturers.	Medium
Marketing	CellAED is a consumer product. Moreover, it's a non-trivial priced product akin to insurance that no one ever wants to have to use. As with any new product (business or consumer), there is a learning curve that RRR must help consumers through, which is not entirely straightforward and will take time. It's still very early days, and RRR is far from having optimised its sales and marketing efforts. Given the calibre of RRR's team and the enormous size of the target market, Venn Brown is confident that, given time, RRR will drive efficiencies in its marketing and sales strategies. The primary risk is running out of cash before this is achieved.	Medium

Risk	Details	Severity
Competition	If RRR is right about the potential market size, there will be competition. As discussed above, the existing and incoming regulatory frameworks provide RRR with a significant head start on new or existing manufacturers trying to enter the new personal and mobile AED market. The size of the market is orders of magnitude larger than the existing public access market, which already supports more than 77 different products from around 55 manufacturers. Following the changes to CE regulations, Venn Brown expects the number of AEDs and manufacturers to shrink. CellAED's wholly-owned proprietary technology puts it years ahead of any player who has not yet gotten regulatory approval, and with the teams already working on versions 3 and 4 and (co-founders) Donovan and Erol already working on versions 5 and 6, it is unlikely the business will be left behind. Suffice to say that CellAED is a leading product, and there are more than enough customers to support several personal AED manufacturers. Securing a new cash injection will significantly accelerate and strengthen CellAED's market position.	Low
Regulatory weaponisation	As discussed above, we're already seeing a hostile UK AED distributor weaponising the UK regulator in an attempt to block CellAED and force the device from the UK market. This occurred much sooner and with greater ferocity than Venn Brown or the company expected, which is more likely than not a sign that these operators feel threatened and can see the impact CellAED could have on their businesses. Potentially, this opponent could be genuine in their concern for public safety, in which case, once the results of the RAPID clinical trial are released and demonstrate the CellAED's safety and efficacy, we would expect them to get behind CellAED. Given the opponent's refusal to engage directly with RRR in any public forum (aside from LinkedIn), including at medical conferences at which staff presented, we don't expect this to happen. While this risk has already materialised, it does have a shelf life, as once RRR has completed its clinical trials (assuming a positive outcome), it significantly reduces the opportunity for ongoing attacks. As discussed above, because CellAED uses an optimised waveform and generative method, its devices have been more closely scrutinised by regulators (and the industry). Unlike most other devices on the market, the CellAED is undergoing both clinical and field trials, the results of which the company and researchers cannot discuss to avoid any real or implied risk of results contamination.	High / Low
Key Person	RRR is operating on an extraordinarily tight budget. Given the volume of work being completed, the company is understaffed, and senior management is paid below market rates. There is likely no staff redundancy, which means the loss of a few key staff would dramatically impact several key aspects of the business, particularly manufacturing and regulation. Many of the staff joined the company and are motivated by both the company's vision (and ability to execute it) and by CEO Donovan Casey. Casey is a polarising character but has built a loyal and dedicated team. It's difficult to assess the likelihood of staff departures but at this stage, we would put it at low for the key players. That said, the consequence of a departure could be high.	Medium

Risk	Details	Severity
Regulation	Regulation is both a risk (mostly before approval) and a benefit (post-approval). As discussed at length in previous sections, the regulation of medical devices is incredibly complicated and ongoing. The initial approval involves the creation of literally thousands of pages of documentation. Ongoing compliance requires continued market surveillance and documentation across every aspect of the product, including manufacturing, change management, supply chain and testing. Each regulator also has the right (and obligation) to conduct annual as well as random spot audits on each manufacturing facility. The company has reporting obligations regarding any anomalies in product manufacturing or in field operation. Manufacturers must also provide answers (often tens or hundreds of pages) to answer questions raised by the regulator either directly or by "concerned parties", which may include the public, others in the industry or competitors (as discussed above). The CellAED is regulated by more than eleven different regulators and certifying bodies, several of which can conduct annual and spot audits and inspections and require ongoing post-market reporting. The number of regulators overseeing RRR will continue to grow as CellAED expands into new regions. Answering regulator inquiries is a cost and time burden for the company. Ongoing compliance is also costly and time-consuming (and wholly necessary). Any fault (potential or actual) can lead to consequences ranging from stoppage of manufacturing to product recall. As discussed above, regulation and the expensive and complicated process of getting approval also provide a significant barrier to entry for both new entrants and existing players attempting to innovate or significantly change their existing products.	Medium
Changes to regulation	Changes to regulation could have a dramatic impact on various markets, but RRR should be well insulated. Massive disruption is playing out in the European market as existing manufacturers decide whether to commit the capital to bring their devices up to comply with the far stricter CE MDR standards or exit the market in 2027. It's possible, but unlikely, that similar changes will occur again, given that AEDs are now Class III (the highest class) medical devices. Once CellAED has been certified under the CE MDR guidelines (which it is already close to complying with), it's unlikely to get stricter and more tightly controlled. Depending on timing, regulatory changes could benefit RRR. Once the company is established, manufacturing large volumes of devices and generating strong cash flow, it will likely be one of the best-positioned AED manufacturers to adapt to any changes.	Low
Product failure/recall	As with any manufactured product, a product failure or recall would be financially and reputationally costly. Without access to capital, a full product recall could force the business to close. RRR management regularly speaks of the importance of ensuring reliability to the point of being obsessive about quality. The team has already demonstrated its commitment to erring on the side of caution when it comes to potential problems. This has led to changes in production, testing, documentation, and monitoring. Ensuring consistency and efficacy of manufacturing requires ongoing effort, to which management has so far demonstrated an unwavering commitment.	Medium
Supply chain	As we all learned during the COVID pandemic, most of the world's electronics are provided by a very small number and geographically concentrated group of suppliers. RRR's management demonstrated impressive foresight in the months before the outbreak expanded beyond China to pre-order enough inventory of components to easily support production through the period. As discussed above, most of CellAED's components are standard and off the shelf. RRR maintains close and regular contact with suppliers of the few critical, more difficult-to-source and bespoke components and is working to diversify its supply to avoid the constraints that hit all but the most prepared manufacturers worldwide during the pandemic.	Low / Medium

Risk	Details	Severity
Technology / Manufacturing	Technology and manufacturing risk is unavoidable with any manufacturer. Working in RRR's favour is that it's forced to maintain incredibly high standards in the manufacture, testing, auditing, tracing, and surveillance of its products. This level of scrutiny means RRR requires a higher level of quality control throughout its production process, meaning it will be aware of issues earlier than most manufacturing processes. These high standards also mean that any errors, omissions or deviations from standards or protocols may have longer and further reaching impacts. Not only does each device need to be manufactured and tested properly, but each device must also have the necessary compliance paperwork and audit trail in place. Any lapse in any of these processes may render a device or batch of devices unable to be sold. This risk will reduce as RRR's production lines and facilities mature and the processes become more refined and embedded, staff trained and familiar with the requirements. Each new line or facility will cause a temporary uptick in risk. With its current low volumes, RRR can adjust production rates and inventory levels to navigate delays or interruptions, which will inevitably happen. RRR has been manufacturing for more than 18 months, with lines in two facilities in different countries. This has been a huge learning curve, which the company has successfully navigated despite expected setbacks and interruptions. Offsetting this, the CellAED is a single purpose, single use device with a small number of components (we estimate fewer than 150 individual components) >85% of which are readily available and off the shelf.	High
2G/3G switch off	The 3G mobile networks in Australia are scheduled to be shut down in 2024. Under the current schedule, Telstra will commence a gradual switch-off of its 3G network from 30 June 2024. Optus will follow suit from September 2024. Vodafone shut its network off in 2023. CellAED's monitoring services operate on 2G & 3G networks. Australia's last 2G network was shut down in 2018. Once the 3G network is closed, RRR will no longer be able to perform remote monitoring of its devices. There are more than 11,000 devices in Australia which all use the 3G network. Until RRR can release a new device that uses a 4G SIM, which they are currently working on, then the company has the liability of having sold CellAED for Life subscriptions, which include remote monitoring that they can't perform.	High
Environmental & sustainability	ESG is a growing area of concern for investors. RRR is actually well positioned to address these concerns given that they build an affordable lift-saving device, have an incredibly culturally diverse workforce, and are working on increasing the recyclability of their devices, thereby improving sustainability and waste. As discussed above, RRR has a long-term plan to implement device recycling and refurbishing, significantly reducing product waste.	Low

Appendix – Brief timeline of AEDs

The beginnings of modern AEDs can be traced back to Dutch veterinarian Peter Abildgaard who used electricity to revive the heart of a chicken.

1775: A Dutch veterinarian named Peter Abildgaard used electricity to stop and then revive the heart of a chicken.

1850: German physician Carl Ludwig documents electrically stimulated ventricular fibrillation in dogs.

1888: British physiologists John A Mac William suggests ventricular fibrillation might be the cause of sudden death.

1899: Jean-Louis Prevost and Frederic Batelli, two Swiss physiologists at the University of Geneva, conducted a series of successful defibrillation experiments confirming that strong currents applied directly to the heart could restart the heart of dogs.

1928: US Electrical Engineer William Bennett Kouwenhoven began developing defibrillators.

1933: Kouwenhoven, with US physiologist Orthello Langworthy, demonstrate internally applied electrical current reverses ventricular fibrillation

1940s: Soviet doctors Dr. Naum Lazarevich Gurvich and Dr. G.S. Yuniev proposed the first defibrillation waveform, now referred to as biphasic waveform technology.

1946: Gurvich and Yuniev completed the first closed-chest defibrillation on a mammal.

1947: US surgeon Claude S Beck is the first to save a human life through defibrillation, restoring his 14-year-old patient's heart beat during a surgical procedure.

1956: Kouwenhoven develops external defibrillators but during his experiments discovers and develops CPR, earning him the moniker of "Father of Cardiopulmonary Resuscitation". Harvard cardiologist Paul M ZOLL demonstrates the first closed chest (external) defibrillation.

1960: Portable DC-powered defibrillators are developed by Harvard's Bernard Lown and University of Washington's K William Edmark, allowing treatment outside hospitals for the first time.

1961: Bernard Lown and K William Edmark proved that a specific direct current (DC) waveform consistently reversed ventricular fibrillation, restoring a normal heart. They also confirmed direct current defibrillators had fewer adverse side effects and were more effective than alternating current defibrillators.

1966: In Northern Ireland, cardiologists J Frank Pantridge and John S Geddes are the first to install portable external defibrillators in an ambulance, creating the first Mobile Intensive Care Unit. Their first model weighed 70kg.

1969: The first non-medical personnel qualified to operate a defibrillator (Emergency Medical Technicians) are hired in Portland, Oregon

1978: the first Automated External Defibrillator is introduced, comprising sensors to detect in ventricular fibrillation. Crucially, the instructions are electronically provided, reducing the degree of training required to operate them.

1980: With computer enhancement, the sensitivity of the AED was further increased to help in sustaining lives.

1990: Biphasic waveforms become the standard for internal defibrillators.

1996: First biphasic external defibrillator developed in 1996

Early 2000s: The Workplace and Healthy standards highlighted the importance of AED's as essential equipment in the workplace.

Appendix – European CE Certification

The CE certification process for medical devices is a comprehensive and rigorous procedure aimed at ensuring the safety, performance, and reliability of products released into the European Economic Area (EEA). Conformité Européenne (European Conformity – CE), is governed by the European Commission and is a mandatory conformity mark that enables free movement of products within the European Economic Area. The certification process is guided by various directives, including the Medical Device Directive (MDD) 93/42/EEC for medical devices which in 2021, was superseded by the Medical Device Regulation (MDR) 2017/745. The MDR (and the MDD before it) provides a regulatory framework that manufacturers must adhere to, ensuring a standardised approach to quality and safety across diverse medical devices. As a life-saving medical device, AEDs undergo a stringent certification process to validate performance and reliability. The process involves multiple steps, ranging from device classification, scientific validation of claims and therapy, comprehensive documentation, testing, audits, QMS, to post-market surveillance. Each of these steps plays a crucial role in ascertaining that the device meets the high standards set by the MDR.

The entire CE certification process for an AED under MDD usually took two to three years, involving numerous parties, including the manufacturer, notified body (see below), suppliers, and quality assurance and regulatory affairs professionals. The new MDR requires AEDs to undergo clinical trials to prove their efficacy, thereby adding two to three years and several million dollars to the approval process.

Below is a brief summary of the steps involved in gain CE certification:

1. Notified Body

A notified body plays a pivotal role in the CE certification process for medical devices. It is an organisation designated by a European Union (EU) member state to assess whether a product, prior to being placed on the market, complies with the applicable CE marking directives. These directives set forth the safety and performance requirements necessary for medical devices sold within the EU.

During the CE certification process, the notified body is responsible for conducting a rigorous evaluation of the AED, scrutinising both its technical documentation, Quality Management Systems (QMS - see below) and the results of the clinical evidence. The notified body verifies that the manufacturer has adequately addressed all relevant risks associated with the device, ensuring its safety, performance, and conformity to the standards set forth by the MDR.

Upon successful completion of this evaluation, the notified body issues a CE certificate, attesting to the device's compliance and allowing the manufacturer to affix the CE mark, a visible indication of the device's conformity with EU regulations. However, the notified body's role does not end there.

Post-certification, the notified body remains actively involved, conducting periodic surveillance audits and inspections to ensure that the manufacturer continues to adhere to the required standards and maintains the integrity of their QMS. These audits included scheduled and unscheduled inspections of any and all sites involved in the manufacturing of the devices. Additionally, the notified body monitors post-market performance and safety data, ensuring that any emerging risks are promptly addressed.

In cases of non-compliance or when safety issues arise, the notified body has the authority to take corrective actions, which may include suspending or revoking the CE certificate, necessitating the removal of the device from the market until issues are resolved.

In essence, a notified body acts as an impartial third party and representative of the relevant EU member state, ensuring continuous adherence to safety and quality standards throughout the product's lifecycle, safeguarding public health, and instilling confidence in the CE marking process.

2. Classification

The first step is determining the device's classification under the MDR. AEDs are typically classified as Class III devices, the category for devices with the highest risk level. This classification influences the level of scrutiny and the type of conformity assessment procedure that the device must undergo. Under the MDR, Class III devices are subject to more rigorous clinical evaluation and quality control standards compared to the MDD. The classification process involves a detailed analysis of the device's intended use, the technology it employs, and the potential risks associated with its use. See below for more information on the differences between MDD and MDR.

3. Quality Management System (QMS) Implementation

Manufacturers must implement a Quality Management System (QMS) compliant with ISO 13485. This system ensures that every aspect of production, from design to manufacturing, meets stringent quality standards. The QMS covers product development, design control, manufacturing processes, product traceability, and post-market surveillance. Implementing a QMS helps in identifying and mitigating risks at every stage of the product lifecycle. It also involves regular audits and assessments to ensure ongoing compliance with the established standards.

4. Clinical Evaluation

A clinical evaluation is a systematic and planned process to collect, appraise, and analyse clinical data pertaining to a medical device. For AEDs, clinical evaluations must demonstrate the device's performance and safety. Under MDR this involves clinical investigations, literature reviews and clinical data. The MDR emphasizes a more robust clinical evidence requirement compared to the MDD, necessitating thorough and scientifically sound clinical evaluations. This step is crucial in proving the device’s efficacy and in identifying any potential risks associated with its use.

5. Technical Documentation Preparation

Technical documentation is a comprehensive compilation of data illustrating the device’s conformity with MDR requirements. This includes detailed descriptions of the device's design, manufacturing process, and intended use. It also encompasses the results of pre-clinical evaluations, clinical investigations, risk analysis, and instructions for use. This documentation must be meticulously prepared and maintained, as it will be subject to review by a notified body. It forms the basis of the assessment for CE marking and must be continually updated to reflect any changes in the device or relevant regulations.

The documentation phase is one of the most labour-intensive parts of the certification process. It requires meticulous attention to detail and an exhaustive compilation of various documents including the Technical File. The Technical File is a comprehensive document that encapsulates all relevant information about the AED. It serves as a proof of compliance with MDR requirements and includes:

1. **Device Description:** A detailed description of the AED, its components, and its intended use. This section elucidates how the device functions and the medical conditions it addresses.
2. **Design and Manufacturing Information:** Information on the design, materials used, and the manufacturing process. This part ensures transparency in production and helps in tracing any issues back to their source.
3. **Risk Management:** A thorough risk analysis that outlines potential hazards associated with the device, and the measures taken to mitigate these risks. This ensures that all conceivable risks have been considered and addressed.
4. **Clinical Data:** Clinical data proving the device's safety and performance. With the introduction of MDR, this is based on scientific literature and clinical trials, providing empirical evidence of the device's efficacy.
5. **Labels and Instructions for Use:** Clear and user-friendly manuals and labels that guide the user through the correct usage of the AED, reducing the risk of misuse.

6. Testing

Testing is a crucial phase where the AED is put through rigorous checks to validate its safety and performance. This includes:

1. **Electrical Safety Tests:** Ensuring the AED complies with established electrical safety standards, safeguarding users, and patients from electrical hazards.
2. **Performance Testing:** Assessing the AED's functionality across various scenarios, ensuring consistent performance and reliability.
3. **Environmental Testing:** Testing the device's resilience under different environmental conditions, ensuring its robustness and durability.
4. **Biocompatibility Testing:** Ensuring that the materials used in the AED are biocompatible and do not pose any risk of adverse reactions to patients.

7. Components and Suppliers

Securing quality components from reputable suppliers is pivotal in manufacturing a reliable AED. This entails:

1. **Supplier Evaluation:** Thoroughly vet suppliers to ensure they adhere to quality standards and provide reliable components.
2. **Component Specifications:** Maintaining detailed specifications for each component, ensuring they meet the required standards and contribute to the overall safety and performance of the AED.
3. **Supply Chain and Supplier Management:** Manufacturers need to have effective procedures in place for selecting and monitoring suppliers, ensuring the quality of purchased materials, and assessing the impact of any changes in the supply chain on the device's safety and performance.

8. Risk Management

Risk management under the MDR is an ongoing process throughout the device's lifecycle. Manufacturers must identify and analyse potential risks associated with the use of their AED. This involves not only the initial identification and mitigation of risks but also the continuous monitoring of the device once it is on the market. The risk management process must be documented and integrated into the QMS. It should include strategies for risk prevention, reduction, and management. This process ensures that the benefits of using the device outweigh any potential risks.

9. Conformity Assessment

The conformity assessment is a pivotal phase conducted by the notified body. It involves a comprehensive review of the Technical File and an audit of the QMS, ensuring that every aspect of the AED's design, production, and post-market plans comply with MDR requirements. Upon successful completion of the conformity assessment, the manufacturer issues a Declaration of Conformity. This document formally attests that the AED complies with all applicable MDR requirements.

10. CE Marking

With the Declaration of Conformity in hand, the manufacturer can now affix the CE Mark to the AED, along with the identification number of the notified body. This mark is a visible statement that the device complies with EU regulations and is safe for use.

11. Ongoing Post-Market Surveillance Compliance, Safety, and Auditing for CE Certified AEDs

Securing the CE certification for an AED under the MDR is an extensive process, and it is crucial to understand that obtaining the certification is not the endpoint. The manufacturer must commit to ongoing compliance, safety assurance, and regular audits to maintain the validity of the certification and ensure the continued reliability and safety of the AED.

By adhering to these ongoing compliance, safety, and auditing requirements, the manufacturer ensures that the AED continues to meet the stringent standards set by the MDR, safeguarding both the users and patients, and upholding the integrity of the CE certification. This ongoing diligence not only maintains regulatory compliance but also builds trust with healthcare providers and end-users, affirming the manufacturer's commitment to delivering safe and effective medical devices.

1. **Post-Market Surveillance and Vigilance:** The manufacturer is required to have a robust post-market surveillance system in place, ensuring the continuous monitoring of the AED's performance and safety once it is on the market. This involves collecting and evaluating data from various sources, including customer feedback, adverse event reports, and field performance data. The goal is to identify any potential safety concerns or trends that may necessitate corrective actions. In cases where serious incidents or potential safety risks are identified, the manufacturer must report these to the competent authorities and the notified body within the stipulated timeframes. This vigilance reporting is a critical component of the post-market surveillance system, ensuring that any emerging risks are promptly addressed and mitigated.
2. **Post Market Clinical Follow-up as part of the PMS:** The is a continuous process that updates the clinical evaluation and monitors the safety and performance of a medical device throughout its expected lifetime. This process involves collecting and analysing clinical data from the use of the device in practice, ensuring ongoing conformity with the general safety and performance requirements, and identifying any need for immediate corrective actions. PMCF should also aim to:
    a. Identify previously unknown side effects and monitor identified side effects and contraindications;
    b. Identify and analyze emergent risks on the basis of factual evidence;
    c. Ensure the continued acceptability of the benefit-risk ratio; and
    d. Identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.
3. **Quality Management System (QMS) Maintenance:** The manufacturer must maintain and continuously improve the Quality Management System (QMS) established during the certification process. This includes regularly reviewing and updating procedures, conducting internal audits, and ensuring that all employees are adequately trained on quality and compliance matters.

    Regular internal audits of the QMS and manufacturing processes are necessary to ensure ongoing compliance with the MDR and ISO 13485 standards. These audits help in identifying areas of improvement, ensuring that the QMS is effectively implemented and maintained.
4. **Recertification and Surveillance Audits by Notified Body:** The CE certification is not indefinite, and manufacturers need to undergo recertification audits by the notified body at specified intervals. Additionally, the notified body will conduct surveillance audits to ensure continued compliance with the MDR and other applicable standards.

    Manufacturers are required to keep the Technical File and all related documentation up to date, reflecting any changes in design, manufacturing, or post-market surveillance findings. The updated documentation must be readily available for review during audits by the notified body.
5. **Risk Management and Corrective Actions:** Ongoing risk management is integral to maintaining CE certification. The manufacturer must continuously assess and manage risks associated with the AED, implementing corrective and preventive actions as necessary. This proactive approach ensures that any potential issues are addressed before they can impact patient safety.
6. **Training and Competency:** Ensuring that all personnel involved in the design, production, and post-market activities of the AED are competent and adequately trained is crucial. Regular training on regulatory requirements, quality assurance practices, and risk management contributes to a culture of quality and compliance within the organization.

7. **Change Management:** Any changes to the AED, its components, or manufacturing processes must be meticulously evaluated for their impact on safety and performance. The manufacturer must follow a structured change management process, ensuring that all changes are validated, documented, and communicated to the notified body if necessary.
8. **Commitment to Safety and Compliance:** Ultimately, maintaining CE certification for an AED requires an unerring commitment to safety and compliance. Manufacturers must foster a culture of continuous improvement, regularly reviewing and enhancing practices to ensure the highest standards of safety and quality.

Changes from MDD to MDR

The Medical Device Regulation (EU) 2017/745, which came into full application in May 2021, is a legislative framework enacted to enhance the safety and performance of medical devices within the European market. The MDR was introduced to address the limitations and gaps identified in the MDD, incorporating stricter controls, enhanced transparency, and a more robust approach to ensuring device safety and efficacy. The regulatory overhaul was motivated by high-profile medical device failures and scandals, necessitating a revamp to restore public trust and ensure patient safety. It's up for debate whether the changes will improve the failures and incidents that motivated the change. It will certainly make new product development far more expensive and time consuming and will no doubt stifle innovation. CellAED would have needed far more capital to come to market under the MDR system, and as such it is now far better protected with a far higher barrier to entry for potential competitors.

Securing CE certification under MDR for AEDs involves adhering to significantly more stringent requirements, rigorous conditions and comprehensive evaluations compared to the MDD process, as outlined above. The process is distinctively more demanding than those mandated by the MDD. While the earlier MDD framework was considered to be less stringent than the US FDA certification process (discussed in the following Appendix), the MDR framework is considered stricter.

1. **Scope:** MDR has a larger scope, new requirements, more articles, and more annexes than MDD. There are 23 articles and 12 annexes over 60 pages in the MDD. The MDR contains 123 Articles and 17 Annexes in over 175 pages. While MDD is a set of guidelines that can be interpreted by each European Member State, the MDR is a law that is enacted directly for all European Member States, not subject to interpretation.
2. **More Rigorous Clinical Evidence and Evaluation:** MDR mandates a more comprehensive and rigorous clinical evaluation for AEDs. Manufacturers are required to provide substantial clinical data, ensuring that the device's performance and safety are well-substantiated. This may involve conducting clinical investigations, particularly for devices with novel technologies or where sufficient equivalence to existing devices cannot be established.
3. **Enhanced Post-Market Surveillance and Vigilance:** Post-market obligations under MDR are significantly more thorough. Manufacturers must establish a proactive post-market surveillance system, ensuring the continuous monitoring of AED performance and the prompt identification of potential safety issues. The MDR also introduces the requirement for a Periodic Safety Update Report (PSUR), providing a systematic overview of the device's safety and performance.
4. **Stricter Control Over Supply Chain:** MDR introduces stricter requirements for monitoring and verifying the compliance of suppliers and subcontractors. Manufacturers must have mechanisms in place to ensure that all components of the AED meet the necessary quality and safety standards.
5. **Increased Transparency and Traceability:** MDR enhances the transparency of medical device information through the establishment of the European Database on Medical Devices (EUDAMED). This database facilitates better traceability of devices, including AEDs, throughout their lifecycle.

Implications for AEDs Already Approved Under MDD

The transition from the Medical Devices Directive (MDD) to the new European Union Medical Devices Regulation (EU MDR) represents a shift towards more stringent regulation, with an increased focus on safety and post-market surveillance. The implication of the change to MDR are not insignificant and will impact existing devices and manufacturers as well as aspiring new entrants. AEDs that were CE certified under MDD before the full application of MDR are subject to transitional provisions. However, these devices cannot remain on the market indefinitely under their MDD certification.

1. **Transition Period and Certificate Validity:** AEDs that had acquired CE certification under MDD before the MDR came into full application in May 2021 are allowed to be placed on the market during a defined transition period, which lasts until December 2027 (the date has been delayed twice, most recently pushed back from May 2024) or until the expiry of their MDD certificate, whichever comes first. However, manufacturers cannot make any significant changes to the device's design or intended purpose during this period if they wish to continue selling the device under the existing MDD certification.
2. **Enhanced Scrutiny and Surveillance:** During the transition period, while AEDs are still on the market under MDD certification, manufacturers are not exempt from scrutiny. They are required to ensure compliance with certain MDR provisions, particularly those related to post-market surveillance and vigilance. This means that even before the AEDs are re-certified under MDR, manufacturers must elevate their surveillance and reporting practices to align with the more stringent requirements of the MDR.
3. **Preparation for Recertification:** Manufacturers of AEDs previously approved under MDD must proactively prepare for recertification under MDR. This involves a comprehensive review and update of all documentation, clinical evaluations, and quality management systems to ensure they meet the elevated standards of MDR. This preparation phase is critical to avoid any market access disruptions when the transition period ends.
4. **Addressing Supply Chain Challenges:** The MDR places a stronger emphasis on transparency and control over the entire supply chain. Manufacturers must ensure that every component of the AED, and every stage of its production, meets MDR requirements. This may require renegotiating contracts with suppliers, conducting additional audits, and implementing more robust quality control measures.
5. **Potential Re-Design and Innovation Inhibition:** Some AEDs approved under MDD may require design modifications to comply with MDR requirements. This poses a challenge, as any significant change would necessitate immediate compliance with MDR, even during the transition period.
6. **Economic and Market Impacts:** The transition from MDD to MDR has significant economic implications for manufacturers. The increased costs associated with compliance, potential delays in getting products to market, and the need for additional resources can strain manufacturers, particularly small and medium-sized manufacturers. We expect this will lead to a reduction in the diversity of AEDs available on the market, as some manufacturers might decide that the investment required for MDR compliance is not justified by the potential return.
7. **Training and Awareness:** Manufacturers must invest in training and awareness programs to ensure that all stakeholders, including employees, suppliers, and distributors, are aware of the changes brought about by MDR and are aligned in their efforts to ensure compliance.

The transition from MDD to MDR for AEDs already approved under the former directive is a complex process, laden with challenges but ultimately aimed at enhancing device safety and performance. Manufacturers must proactively plan for the recertification of their AEDs under MDR, ensuring that they meet all the additional requirements and enhanced scrutiny mandated by the new regulation. This may entail updating clinical evaluations, enhancing quality control processes, and ensuring full traceability of device components.

Appendix – US FDA Certification

Until the introduction of the European CE MDR requirements, the US FDA certification was regarded as the most difficult approval process for AEDs and most other medical devices. The FDA imposes stringent standards and comprehensive evaluation processes to ensure the devices are both safe and effective. Much of the documentation, processes, procedures, and requirements mandated under CE MDR are also required for FDA approval. The impact of the more stringent regulations is perhaps best demonstrated by noticing there are only 32 AEDs from seven manufacturers approved by the FDA, compared to the 60+ devices from more than 15 manufacturers approved under CE MDD.

In 2013, the US FDA reclassified AEDs as Class III devices, subject to the FDA's most stringent regulatory controls. AEDs had previously been Class IIb, but a series of well-publicised incidents[93]caused the FDA upgraded them to Class III. Other devices in this category include pacemakers, heart valves, implantable cardioverter defibrillators[94] (ICD), breast implants, artificial joints, and Cochlear implants.

Despite the reclassification, the FDA allowed AEDs to be assessed through the quicker and less stringent 510(k) process, which allowed manufacturers to use an equivalency test to prove efficacy and safety. Manufacturers could gain approval by showing their device provided the exact same therapy as an already approved device. This pathway was closed to new AEDs in April 2019 (AEDs already going through the pathway had until February 2022 to gain approval). From April 2019, all new AEDs have had to go through the lengthy and strict pre-market approval (PMA) process. Under the PMA, all new AEDs must provide extensive clinical data demonstrating their safety and efficacy and, in some cases, this requires human clinical trials. This requirement significantly lengthens the approval process by at least 18-30 months and adds a significantly higher cost burden for approval. These requirements also extend to all AED accessories, including spare batteries and pads.

Differences between FDA and CE MDR certification

While both the FDA and CE MDR certification processes share the common goal of ensuring AED safety and effectiveness, they embody distinct approaches, requirements, and oversight mechanisms. The FDA’s centralised, stringent, and often lengthier process ensures a comprehensive evaluation directly by the regulatory authority. On the other hand, the MDR introduces enhanced scrutiny, demanding ongoing clinical evidence and rigorous post-market surveillance facilitated through a network of Notified Bodies.

Table 58 below provides a high-level overview of the key differences between the FDA and CE (MDR) certification processes for an AED device.

[93] There were several well publicised incidents involving AEDs that failed to operate because of flat batteries. These incidents led to or at least contributed to the reclassification which seems nonsensical given the reclassification will do nothing to improvement people’s propensity to properly maintain their AEDs.
[94] ICDs are a combination pacemaker and internal defibrillator, with the ability to deliver shocks to the heart to restore a normal heartbeat in the event of a dysrhythmia event.

Table 58: Summary of key differences between FDA and CE certification process

Topic	FDA	CE MDR
Regulatory Approach and Oversight	The FDA operates under a centralized system, meaning that all decisions and evaluations are conducted directly by the agency. This approach ensures consistency in the interpretation and application of regulations. However, it can also lead to longer processing times, as the FDA deals with a large volume of applications across various medical device categories.	The MDR framework utilises a network of "notified bodies", which are independent commercial organisation designated by EU member states. This decentralised approach can lead to faster initial processing times as manufacturers can choose from various notified bodies. However, it introduces variability, as the rigor and speed of evaluations may differ between notified bodies.
Documentation and Clinical Data	The documentation required by the FDA is extensive, requiring detailed information on every aspect of the device, from design and manufacturing to exhaustive pre-clinical and clinical data. The FDA places a strong emphasis on clinical trials, often requiring more in-depth and longer-term studies to establish safety and efficacy.	The MDR also demands comprehensive documentation, with a particular focus on clinical evaluation and post-market surveillance. Manufacturers must provide substantial clinical evidence not only for initial certification but also as part of ongoing compliance. The MDR's increased requirements for clinical data aim to enhance device safety and performance throughout its lifecycle.
Post-Market Surveillance and Reporting	Post-market surveillance under the FDA is rigorous, with manufacturers required to promptly report any adverse events and implement corrective actions when necessary. The FDA actively monitors the post-market performance of devices and can initiate recalls or additional investigations if needed.	The MDR introduces more stringent post-market surveillance requirements, emphasizing proactive data collection and analysis. Manufacturers are obligated to continuously monitor the safety and performance of their devices, providing regular updates to Notified Bodies and taking corrective actions as needed.
Timeframes and Complexity	Obtaining FDA approval is often a time-intensive process, taking several months to years, depending on the complexity of the device and the quality of the submitted data. The centralized structure and the need for in-depth clinical trials contribute to the lengthy timelines.	The timeframes under MDR can vary significantly, influenced by the chosen notified body and the complexity of the AED. While the decentralised system has the potential for faster processing, the increased requirements for clinical data and ongoing compliance checks can extend the overall timeline.
Adaptation to Technological Advances and Global Harmonization	The FDA has established mechanisms to adapt to technological advances and continuously updates its guidelines and regulations to reflect the latest scientific knowledge and industry standards. Additionally, the FDA actively participates in global harmonization efforts to align its standards with international best practices.	The MDR represents a significant update from its predecessor, incorporating lessons learned and aiming to address previous shortcomings. It aims to enhance the adaptability of the regulatory framework to technological advances and improve alignment with international standards.
Cost Implications	The cost of obtaining FDA approval can be substantial, covering application fees, clinical trial expenses, and ongoing compliance costs. The investment in time and resources is significant, yet it is a critical component of ensuring device safety and market access.	Similarly, the costs associated with obtaining and maintaining MDR certification are considerable. The involvement of notified bodies, extensive clinical evaluations, and rigorous post-market surveillance requirements all contribute to the overall financial investment.

Appendix – Other notes

Table 59: Cerebral Performance Category (CPC) scores

CPC Score	Description
CPC 1	Good Cerebral Performance Conscious, alert, able to work and lead a normal life.
CPC 2	Moderate Cerebral Disability Conscious and able to function independently (dress, travel, prepare food), but may have hemiplegia, seizures, or permanent memory or mental changes.
CPC 3	Severe Cerebral Disability Conscious, dependent on others for daily support because of impaired brain function (in an institution or at home with exceptional family effort).
CPC 4	Coma, Vegetative State Not conscious. Unaware of surroundings, no cognition. No verbal or psychological interactions with environment.
CPC 5	Death

Source: Cardiac Arrest Registry to Enhance Survival (CARES) Annual Report 2022

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Population and demographic statistics

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Mortality and Disease statistics

For all countries, the World Health Organization's (WHO) Global Health Observatory would be a primary source. Other resources were used for specific diseases and where gaps in the data existed

a) Cancer Statistics:
   The Global Cancer Observatory (GCO)
   UK: Cancer Research UK and Office for National Statistics (ONS)
   USA: American Cancer Society and Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics
   Australia: Australian Institute of Health and Welfare (AIHW)
   Germany: Robert Koch Institute (RKI)
   France: Santé publique France and the French National Cancer Institute

b) Specific Disease and Condition Mortality:
   Dementia and Alzheimer's disease: Alzheimer's Disease International and respective national health databases.
   Road accidents: World Health Organization (WHO) and governmental transport departments.
   Stroke, cardiac arrest: World Stroke Organization, heart foundations, and national health services of the respective countries.

c) Violence and Injury Statistics:
   Gun-related deaths in the USA: Centers for Disease Control and Prevention (CDC), the Federal Bureau of Investigation (FBI), and other organizations like the Gun Violence Archive.

Ambulance response times

1. **Australia:** The median response ambulance response times vary between states and capital cities, ranging from 9.9 minutes in the ACT to 16.1 minutes in Sydney. Ambulance response times across Australia have been on an upward trajectory since 2013-14 (source: Report on Government Services 2023 - Ambulance services (2023)). Australian response times are reported as median, compared to averages reported for other locations.
2. **UK:** Average response times to emergency (Category 1) calls in the UK averaged 8:40 in 2021/22 (source: Why have ambulance waiting times been getting worse? (2022))
3. **New York City:** Average emergency response time was 9:30 in 2022 (source: Emergency response times by FDNY, NYPD increase (2022))
4. **Los Angeles:** In early 2022, the addition of new ambulances and staff saw ambulance response times reduce from 20 minutes to 15 minutes (source: LA Ambulance Response Times Improving, Says EMS Director (2022))

Notes

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