

FIRST Clinical Trial: Frequently Asked Questions

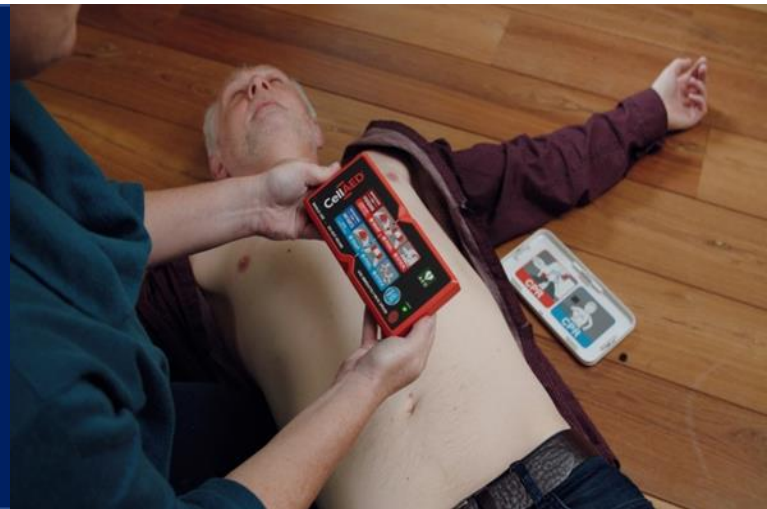


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Trial FAQs

Which patients should have the CellaED® applied?

All patients who are unresponsive with absent or ineffective breathing should be considered to be in cardiac arrest and should have CellaED® applied. As a rule of thumb, any patient who requires chest compressions, should also have the CellaED® applied. If in doubt, follow the recommendations of the Triple Zero (000) call-taker.

When not to apply the CellaED®

You should not apply the CellaED®, if:

- The patient is conscious or breathing normally.
- An automated external defibrillator (AED) has already been applied before your arrival and is functioning normally, or;
- You arrive on scene after paramedics or another emergency service with an AED.

Where is the best place to store my CellaED® ?

You should aim to store your device in a location that is readily accessible, such as near the front door of your home. We recommend that if you leave your home, you take the CellaED® with you as much as possible, as you may be called upon in public areas. See the storage section below for further details on storing your CellaED®.

Can I use the CellaED® if I witness a cardiac arrest, but I am not alerted by GoodSAM?

Yes. Although not the primary purpose of clinical trial, it would be detrimental to withhold defibrillation in these circumstances. We ask that you contact the FIRST team (see details below) to provide details of the incident and replacement of your device.

When will the trial start?

The trial will launch on 1st October 2022

How long will the trial last?

The trial will last for approximately 24 months

What are the contradictions/exclusion criteria?

The following patients **are excluded from the clinical trial and reflect** the existing exclusion criteria for GoodSAM dispatch (any of the following):

- Patients with a Do Not Resuscitate (DNR) order or Advanced Care Directive
- Cardiac arrests secondary to trauma or hanging
- Locations or events where scene safety issues apply

What is randomisation and how does it work?

Randomisation is a way of randomly allocating a patient to a treatment or intervention so that the groups are comparable without undue influence or bias. In this trial, we will randomise GoodSAM participants into two groups. One group will be given an ultraportable defibrillator called a CellaED®, and the other group will continue to retrieve the closest public access defibrillator in the community

when responding to a GoodSAM alert. Randomisation is computer-generated and the FIRST trial team do not have any influence on which GoodSAM responders are allocated to the intervention or control arm. Your group allocation cannot be changed over the life of the trial.

How do I register my interest in this trial?

Your local FIRST trial team will contact all frequent GoodSAM responders by email to register their interest in the trial.

What are the costs of participating in this trial?

There are no direct costs to participants for participation in this trial. There is a small-time cost of watching a 10minute video on how to use an CellaAED.

When will I receive the CellaAED®?

If you are allocated to the group that will receive the CellaAED®, you will receive your CellaAED® before the 1st of October 2022.

Who will contact me after using the CellaAED®?

After using the CellaAED®, you will be required to notify your local FIRST trial team to organise the return and replacement of your device. The GoodSAM management teams or FIRST trial teams may also contact you by phone or email following a GoodSAM alert.

About CellaAED®



What is the CellaAED®?

The CellaAED® is a single-use, portable, transit- operable, fully automated external defibrillator (AED), intended for use by minimally trained individuals to treat sudden cardiac arrest in conjunction with chest compression cardiopulmonary resuscitation (CPR) until emergency services arrive. It is intended for use in the First Responder Shock Trial (FIRST).

What are the dimensions and weight of the CellaAED®?

The weight of the unit is approximately 300g, or 450g including the case. The dimensions of the device are L19.6cm x W9.3cm x D1.7cm.

How many shocks is the CellaAED® capable of?

It is designed for a single event use and is pre-programmed to deliver a maximum of 20 shocks (international standard IEC 60601-2-4).



How many joules of energy does the CellaAED® deliver?

The CellaAED®'s innovative technology uses 85 joules, to deliver an equivalent shock to a traditional AED. Through the process of miniaturising a conventional AED to create the CellaAED®, Rapid Response Revival created a regulatory- approved biphasic waveform that enables effective defibrillation at a lower energy.

Is the CellaAED® reusable?

No. It is designed for single event use – meaning it will deliver multiple shocks, as required, in a single event, after which the entire unit is replaced. Contact the FIRST trial team for a replacement of your CellaAED®

Is the CellaAED® automated?

Yes. Once activated, the CellaAED® will begin delivering instructions to the user. When the pads have been applied to the chest, it will automatically determine if a shock is required, and act accordingly.

How does CellaAED® analyse a person's rhythm and determines when a shock is required?

The CellaAED® conducts an ECG analysis on the patient's heart rhythm and only delivers a shock if and when required. So, do not hesitate to use it on a person who is unconscious and not breathing or not breathing normally.

Will I need to recharge my CellaAED®?

No. Your CellaAED® comes with a non-rechargeable battery and will arrive pre-charged. A blinking LED on the front face of the device will inform you of the battery status.

- A blinking GREEN LED (every 30 seconds) on the front face of the device indicates that the device is fully operational and ready to use.
- A blinking AMBER LED (every 30 seconds) indicates that the battery is low, and the device should be replaced immediately.
- NO LED indicates that the battery has expired, and the device must be replaced immediately.

Can I still use the CellaAED® if the LED is blinking Amber?

When the battery status LED blinks AMBER, this indicates that the battery is low, and the device should be replaced immediately. Contact your local FIRST Trial team to organize a return and replacement.

What is the battery/shelf life of a CellaAED®?

The approved shelf life is currently 13 months.

Will I need replacement parts or servicing for the CellaAED®?

No. The CellaAED® is designed to work without needing servicing or any replacement parts during the approved shelf life.

Will I need to connect my CellaAED® to a network?

No. Your device will stay connected to the internet as long as it is kept in-range of a cellular signal. If you move the device out of range, it will automatically reconnect to the internet as soon as it detects a fresh signal.



Can I travel with my CellaAED®?

Yes, you can travel with your CellaAED® throughout Australia and New Zealand. For your participation in this trial, you are expected to live in your local area (Victoria, Australia, or New Zealand) over the next 2 years without any absences for longer than 3 months.

If you travel through an area with no mobile coverage, we will not be able to monitor your device, however, this will not impact your ability to use the device in an emergency.

What happens if I am in an area with low/no mobile coverage?

The CellaAED® uses a special data only SIM which typically works well in low mobile coverage areas. So, it is possible that even though you cannot get voice calls, we can still monitor your device. If there is no mobile coverage in your area, we will not be able to monitor your device. This will not impact your ability to use the CellaAED® in an emergency.

CellAED® FAQs

What comes with my CellaAED®?

The package contains:

- One CellaAED® sealed inside a transparent bag and protective case,
- Instructions for operation,
- Monthly inspection checklist, and
- Biohazard bag.

Save the outer box and any inserts to enable the return of your device.

How to unpack & inspect your CELLAED®

To help ensure the integrity of the CellaAED® and to verify that it is complete and ready for use, perform the following inspection:

1. **Inspect** the outer box for signs of damage that may have occurred during transport. If the packaging presents rips, cracks, bends, leakages, discolorations, or deformation, contact the FIRST trial team.
2. **Open** the outer box to reveal the CellaAED® in its protective case. Check that the tamper evident seal on the protective case has not been broken. Do not remove the tamper evident seal, and do not remove the device from the protective case and sealed transparent bag until required for emergency use. If the tamper evident seal has been broken, contact the FIRST trial team.
3. **Check** the Date of Manufacture/Use-by Date on the back side of the protective case. Confirm that the current date is within 13 months of the manufacturing date. The CellaAED® expires 13 months after manufacture. If it has expired, contact the FIRST trial team.
4. **Verify** that the green LED indicator is blinking. The green LED will blink every 30 seconds and is visible through the protective case. A green LED blinking means the CellaAED® is ready for use. If the green LED is not blinking or is blinking a different colour, contact the FIRST trial team.

CAUTION: Do not open the sealed tamper-proof and protective packaging of the CellaAED® unless you intend to use the device. This packaging protects the device from accidental activation, and from environmental elements such as water, heat and dust. Opening the package can expose the device to environmental contaminants and compromise its effectiveness.

CAUTION: Only open the sealed packaging and activate the CellaAED® prior to immediate use.

CAUTION: Once the unit is unsealed, the CellaAED® must either be used in an appropriate manner and/or returned to FIRST clinical trial team for replacement.

Maintenance of your CELLAED®

The CellaED® does not require routine maintenance. Plan a monthly inspection of the CellaED® to:

1. **Check** the current date is within the use by period. If this date has passed, contact the FIRST trial team for a replacement and to organise return of your device.
2. **Check** for damage, discoloration, or presence of foreign substances such as oil, dirt, or dust within the packaging. Assess the tamper evident seal and the CellaED® for any damages. If present, contact the FIRST trial team for a replacement and to organise return of your device.
3. **Observe** the LED indicator on the front of the CellaED®:
 - A blinking GREEN LED (every 30 seconds) indicates that the device is fully operational and ready to use.
 - A blinking AMBER LED (every 30 seconds) indicates that the battery is low, and the device should be replaced immediately. Contact the FIRST trial team to organize return and replacement.
 - NO LED indicates that the battery has expired, and the device must be replaced immediately. Contact the FIRST trial team to organize return and replacement.

Storage of your CELLAED®

What are the recommended storage temperature and conditions?

Keep your device away from moisture, dust, and extreme temperatures. It should be stored between 15-35°C (59-95°F). Exposure to temperatures outside this range will reduce the life of the battery. The shelf life of the device is impacted by higher and lower temperatures, so it is important that it is not exposed to extreme temperatures for long periods of time.

Can I keep the CellaED® in my car/backpack?

The CellaED® is small and portable and can easily be taken with you, however, it is important that the device is not exposed to extreme temperatures as this will reduce the life of the battery. Accordingly, we do not recommend that you store it in your car or in other places that may get very hot or very cold.

Does storage near electrical and magnetic fields affect the functioning of the CellaED®?

No. The device underwent rigorous Electromagnetic Compatibility (EMC) testing to ensure that it will operate safely and effectively in its conditions of use.

What happens if I drop my CellaED®, or my CellaED® is damaged?

If you drop or damage your device, or you suspect it is faulty, contact your local FIRST trial team to organise a return and replacement.

What happens if I accidentally activate my CellaED®?

The CELLAED® is a single use device. If you accidentally activate the device, deactivate it by placing the gel sides of the electrode pads together for at least five (5) seconds. Audio (voice) prompts will acknowledge when the device has been deactivated. Wrap the electrode cable around the deactivated unit and contact the FIRST trial team for a return and replacement.

How to return your CellaED®

After your device has been deactivated, place it in the biohazard bag provided with your CellaED® package and seal the bag. Place the device, as well as all other materials included with your CellaED® into the outer box provided with your device. Affix the provided return label to the exterior of the packaging and follow postage instructions.

CellAED® USAGE

Can I use the CellAED® on a person with a pacemaker?

Yes. If the patient has a pacemaker, which looks like a raised bump beneath the skin, ensure that the electrode pad is placed at least 2.5cm (1") away from the bump. **Never stick the pad directly over the pacemaker as this will reduce the effectiveness of the device.**

Can I use the CellAED® on children/infants?

Yes. The CellAED® has a blue button located on the front of the device that allows you to select Infant Mode. This feature is designed for application on infants less than 10kg (22lbs). On average, children under 1 year of age fall within this weight range. For children greater than 10kg, the device can be used as normal.

Where do I place the CellAED® electrode pads?

For adults and children greater than 10kgs, stick one pad firmly onto the patient's skin at the top right-hand side of their chest and stick the second pad, featuring the blue infant button onto the bottom left-hand side of the patient's chest, as per the pictorial instructions on the device. When placed correctly, the cable of the device should be aligned with the patient's nipples where it exits the device. The apical pad of the CellAED® is placed more anteriorly than that of a traditional AED.

To apply the unit to an infant weighing less than 10kg, place the electrode pad with the blue button in the centre of the infant's chest and place the other pad on the centre of the infant's back. To perform CPR on an infant, it is important to first remove the device gel pad from the front of the infant's chest. Lay it gel pad side up alongside the infant before conducting CPR. The gel pad can be returned to the infant's chest when required and prompted.

How do you remove the CellAED® from its protective packaging?

To remove the CellAED® from its packaging when responding to a cardiac arrest:

1. Open the tamper evident seal by lifting the red tab and peeling the red seal from the edges of the protective case.
2. Remove the sealed transparent bag and the CellAED®.
3. Tear open the sealed transparent bag where the bag reads 'Tear here' and remove the CellAED®.

How do you apply the CellAED® to patients weighing more than 10kg?

To activate the CellAED®, perform the SNAP, PEEL, STICK® actions depicted in the pictorial instructions on the device.

1. Hold the device with two hands, with the label side facing up and the side featuring 'THIS SIDE FACE DOWN' facing down.
2. SNAP the device into two separate pads along the centreline by applying downwards pressure in a snapping or folding motion. This activates the device to deliver audio (voice) prompts to guide you in using the device.
3. Pull the two pads apart and PEEL off the protective liner from the bottom marked 'THIS SIDE FACE DOWN'. It should be completely removed so that the adhesive pads are exposed and ready to apply to the patient.
4. You may need to apply one electrode pad to the patient before manually removing the remaining liner from the other gel pad.
5. Fully extend the cable connecting the two pads.
6. STICK one pad firmly onto the patient's exposed skin just below their right collar bone, above the breast. STICK the other pad onto the patient's exposed skin on their left side, below or under the breast. Press firmly so that the entire pad adheres to the patient's skin. The apical pad of the CellAED® is placed more anteriorly than that of a traditional AED.

7. Follow the audio (voice) prompt instructions as directed and do not touch the patient unless instructed to do so. If the heart rhythm analysis determines that a shock is needed, the audio (voice) prompts will announce SHOCK ADVISED and then instruct DO NOT TOUCH PATIENT, followed by STAND CLEAR FOR SHOCK. Do not touch the patient when these prompts are heard and whilst the LED is illuminated. The CellaED[®] will advise when to commence chest compression CPR. Deliver chest compression CPR when instructed by the audio (voice) prompts. The device will issue an audio metronome to guide the user in providing chest compressions at the correct rate.

How do you apply the CellaED[®] to infants weighing less than 10kg?

To apply the CellaED[®] to an infant weighing less than 10kg

1. STICK the pad featuring the blue Infant Mode button firmly onto the infant's exposed skin on the chest between the nipples. Press firmly so that the entire pad adheres to the skin.
2. Grasp the infant's shoulder to turn them and expose their back, supporting their head where necessary, and STICK the other pad firmly to their back in the centre. Press firmly so that the entire pad adheres to the skin and return them to their back.
3. When prompted, press the infant button. Press the infant button a second time to confirm and enable INFANT MODE.
4. Follow the audio (voice) prompt instructions as directed and do not touch the infant unless instructed to do so.
5. When the audio (voice) prompts to begin chest compression CPR is heard, remove the front electrode pad, and set it aside carefully. The device will issue an audio metronome to guide the chest compression rate. Replace the front pad for heart rhythm analysis when instructed.

DANGER: Take care to place the electrode pad gel-side up when removed. Do not touch the exposed electrode or stick the pad to any object, as this may contaminate the electroconductive gel and compromise the performance of the CELLAED[®].

When do you remove the CellaED[®]?

The device may be removed if more advanced medical equipment is present and/or it interferes with advanced medical care. Do not remove the device until advised by emergency medical services.

How do you deactivate the CellaED[®]?

To deactivate the CELLAED[®], stick the gel sides of the electrode pads together for at least five (5) seconds. Audio (voice) prompts will acknowledge when the device has been deactivated. Wrap the electrode cable around the deactivated unit.

CeIAED® TRAINER



What is the CellaED® Trainer?

The CellaED® Trainer is a dedicated training unit that allows the user to practice the defibrillator activation and application process. The CellaED® Trainer is reusable and does not need maintenance or replacement parts.

How can I tell the difference between the CellaED® and CellaED® Trainer?

The CellaED® is an automated external defibrillator that is red in colour with a predominantly black label. The CellaED® has a blinking LED indicating its status. It is single use and for **EMERGENCY USE ONLY**.

The CellaED® Trainer is a dedicated training unit that is the same size, shape, and weight as the CellaED®. It is white in colour with a predominantly yellow label. There are no electrical components in the CellaED® Trainer. It is a reusable device and for **TRAINING PURPOSES ONLY**.

What is the CellaED® Trainer App?

The CellaED® Trainer App is a mobile application designed for use with the CellaED® Trainer. It contains instructional videos on the use of the CellaED® and CellaED® Trainer as well as a variety of training modes to assist the user in familiarising themselves with the CellaED®.

Where can I download the CellaED® Trainer App?

The CellaED® Trainer App is free to download from the Apple App Store and Google Play Store.

CONTACT US

If you have any further questions or concerns, or if you believe your device is damaged or faulty, please contact FIRST clinical trial team below:

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