CellAED®

AUTOMATED EXTERNAL DEFIBRILLATOR

USER MANUAL

Read the User Manual carefully before using your CellAED® and keep it for future reference

EN

REF 100-2.2-094

CE 0297

TABLE OF CONTENTS

01 SYMBOLS


Caution


Refer to Instructions for Use

Automated External Defibrillator


Expiry Date


Date of manufacture

Serial Number

Batch code

Catalogue Number


Consult instructions for use


Do not re use


Do not use if package is damaged


Keep dry


Keep away from sunlight


Do not damage


Keep from high heat

Storage temperature range

Storage humidity range


Separate collection for waste of electrical and electronic equipment


General Prohibition Sign


Warning, high voltage


Fragile, handle with care


Electromagnetic interference


Manufacturer

IP 22
Ingress protection rating


Regulatory Compliance Mark (RCM)

Medical device

European Authorised Representative


Type BF applied part

Patent

CE 0297
CE registration mark with notified body number


Defibrillation proof type BF Applied Part


Defibrillation proof type CF Applied Part


Voice instruction

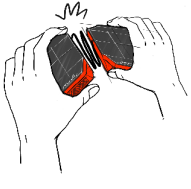

Analysing heart rhythm


Important information

02 GETTING TO KNOW YOUR CellAED®

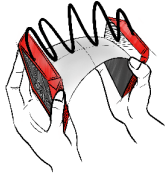
CellAED® is an automated external defibrillator (AED) designed for single patient event use.

CellAED® is designed for use by minimally trained* individuals with its patented 3-step activation process - Snap Peel Stick™. It can be applied to someone in seconds:



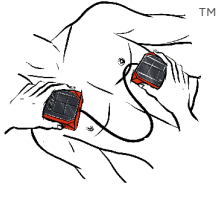
SNAP

Snap the device to turn on and start voice instructions



PEEL

Peel to separate the two electrode gel pads



STICK

Stick the pads to the bare chest

CellAED® is ultraportable, weighing only 450g. It is small enough to carry, making it accessible wherever you may witness a sudden cardiac arrest.

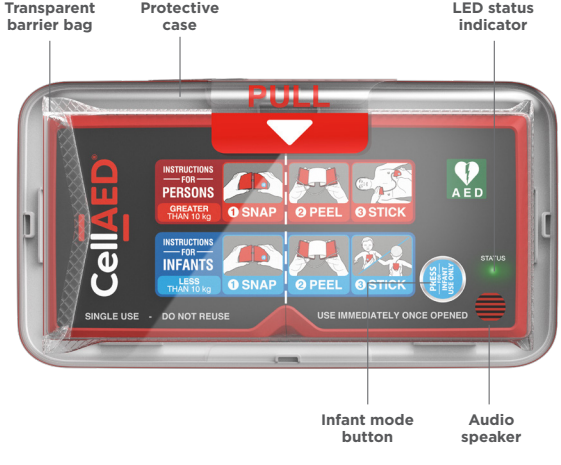
The CellAED® package contains:

- One CellAED® single-use automated external defibrillator sealed inside a transparent bag and enclosed in a protective outer case.
  DO NOT open the protective case until required to use your CellAED® in an emergency.
- A user manual containing instructions for operating your CellAED®.
- A supplementary information sheet.
- A monthly product inspection checklist.

IMPORTANT: It is important you deactivate your device after emergency use. Stick the pads together with the gel sides touching. The voice instructions or beeps may continue for up to 2 minutes before you hear *"device deactivated".*

**Minimally trained is defined as a user who has read the CellAED® User Manual or watched the CellAED® instructional video.*

Important features about your CellAED®



DO NOT OPEN the tamper evident seal. Keep in protective case until needed in emergency.

Specifications are subject to change without notice and may vary in different countries and regions.

CLINICAL BENEFITS

A sudden cardiac arrest means that the heart has unexpectedly stopped beating effectively. When this happens, the heart stops pumping blood and within seconds the person falls unconscious. They may be breathing abnormally, gasping for breath or may stop breathing altogether. Sudden cardiac arrest can occur in anyone, from infants to adults.

First, Emergency Medical Services need to be called and cardiopulmonary resuscitation (CPR) started. Without immediate treatment to restore blood flow, people who experience sudden cardiac arrest will die in a matter of minutes. In combination with CPR, defibrillation is the most effective treatment.

If you witness a sudden cardiac arrest:

1. Call Emergency Medical Services

2. Begin CPR

3. Grab your CellAED® or have someone grab it for you

WHEN TO USE YOUR CellAED®

Your CellAED® is a single-use, portable, transit-operable, fully automated external defibrillator, intended for use by minimally trained individuals to treat sudden cardiac arrest in conjunction with chest compression CPR until Emergency Medical Services arrive.

Your CellAED® is designed to be used on a person of any age, who is experiencing a sudden cardiac arrest. A person in sudden cardiac arrest is:

- Unconscious
- Unresponsive
- Not breathing or not breathing normally

Any person who needs CPR should also have CellAED® used.

If you are unsure what to do, follow the instructions from the emergency operator. The operator will stay on the phone until Emergency Services arrive at your location.

CellAED® is intended to treat sudden cardiac arrest only. Always consult a Healthcare Professional for any health concerns (e.g., chest pain).

WHEN NOT TO APPLY YOUR CellAED®

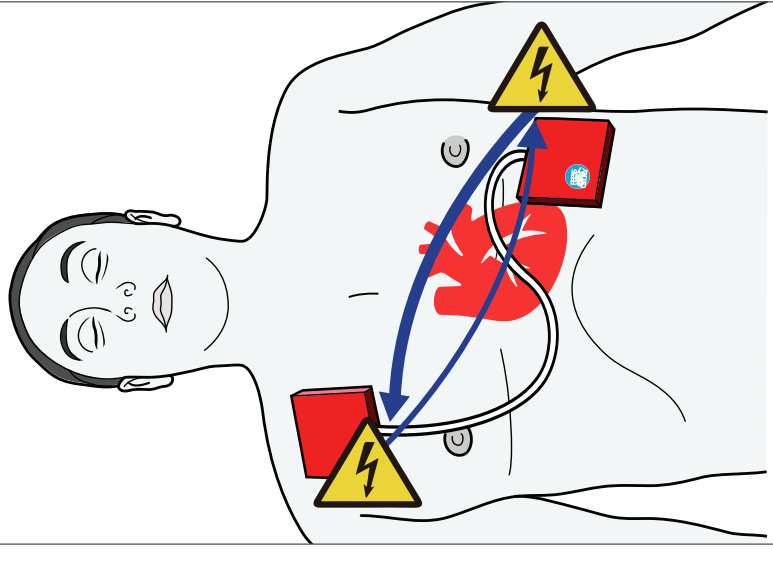
You must not use CellAED® on someone who is conscious (awake), responsive, or breathing normally.

USE CellAED® WHEN SOMEONE IS	DO NOT USE CellAED® WHEN SOMEONE IS
Unconscious	Awake
Unresponsive	Responsive
Not breathing or not breathing normally	Breathing normally

A defibrillator delivers an electrical current (shock) through the heart.

This shock attempts to reset the heart to help it return to a normal rhythm.

Ventricular tachycardia (VT) and ventricular fibrillation (VF) are treatable with defibrillation.



How your CellAED® works

HOW YOUR CellAED® WORKS

Your CellAED® is a fully automated external defibrillator (AED).

Automated: Analyses the heart rhythm automatically.

External: Electrode pads placed on the exposed bare chest.

Defibrillator: Passes an electric current through the heart to deliver a shock.

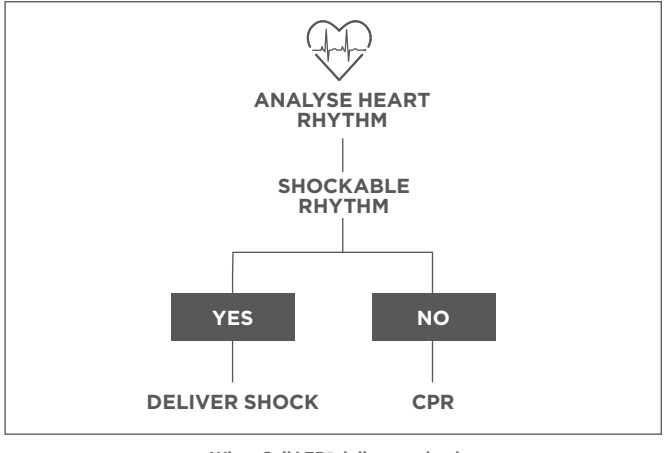
If a shockable rhythm is detected, your CellAED® will:

- Automatically deliver a shock through the electrode pads across the heart without you needing to press a button
- Instruct you when to begin CPR and provide a metronome tone for correct pace of chest compression CPR

If a shockable heart rhythm is not detected, your CellAED®:

- WILL NOT deliver a shock
- Will instruct you when to begin CPR and provide a metronome tone for correct pace of CPR pushes

Your CellAED® automatically repeats this process with instructions and will continue until Emergency Medical Services arrive and take over treatment, the device is deactivated, or the battery depletes.



When CellAED® delivers a shock

Your CellAED® is pre-programmed to deliver a maximum of 20 defibrillation cycles or 20 shocks, which is equivalent to approximately 45 minutes of therapy.

04 WARNINGS & CAUTIONS

This is a summary of warning and caution messages related to using and storing your CellAED®. For convenience, warnings and cautions also appear throughout the rest of this user manual beside their associated actions.

If any serious incidents occur, please contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller.

WARNING	MORE INFORMATION
CellAED® is designed for single patient event use.	Once your CellAED® has been activated, it must be used immediately. It cannot be turned off and used at a later time.
CellAED® is not intended for use on injured skin.	It is important to have good adhesion of the electrode pads to the skin to analyse the heart rhythm and to deliver an effective shock. Direct contact of the electrode pads with open wounds or injury can increase the risk of infection or further injury. Sudden cardiac arrest is a life-threatening condition. DO NOT delay treatment if skin is injured.
DO NOT open protective case until ready to use in an emergency.	Removing your CellAED® from its protective case can increase the risk of damaging the transparent barrier bag or damaging the device.

WARNING	MORE INFORMATION
DO NOT stick electrode pads on top of a pacemaker or another implantable device.	If the patient has a pacemaker, indicated by a raised bump under their skin, and if this is positioned on the right side of their chest, place the electrode pad below the collar bone and at least 2.5cm or 1 inch away from the bump. DO NOT stick an electrode pad over a pacemaker, as it may result in ineffective treatment.
Stick electrode pads to exposed chest and ensure good adhesion.	It is important to have enough exposed skin to stick the electrode pads on the bare chest for it to analyse the heart rhythm and to deliver an effective shock. Ensure skin is dry and excessive hair is shaved. DO NOT delay treatment if shaving is not possible.
Remove all other medical equipment from the patient (unless defibrillator proof) before sticking electrode pads on the bare chest.	If the patient has other medical equipment applied that does not feature a defibrillator-proof mark, remove it before applying CellAED® as this could interfere with the effectiveness of CellAED®.  **Defibrillation proof type BF Applied Part**  **Defibrillation proof type CF Applied Part**
Remove other electrodes or metal objects.	Ensure patient is clear from metal objects (e.g., bed frames/stretchers) and medicine patches or other materials (e.g., bras/piercings) are removed from the patient's chest before using CellAED®.
Remove patient from conductive surfaces.	DO NOT use CellAED® if a patient is in or near a pool of water or any other conductive surface(s) such as metal.

WARNING	MORE INFORMATION
Once infant mode has been enabled you CANNOT change to adult mode or vice versa.	Once you select a patient mode, you cannot change between modes. Infant mode is used on patients weighing less than 10kgs / 22lbs. Adult mode is used on patients weighing greater than 10kgs / 22lbs. DO NOT delay treatment to determine exact weight of patient. If you are unsure, use adult mode.
Your CellAED® CANNOT cancel a shock once started.	Stand clear and DO NOT touch the patient.
DO NOT touch the patient while your CellAED® is analysing the heart rhythm.	Stand clear and DO NOT touch the patient, your CellAED®, or anything that is in contact with them.
DO NOT touch the patient during shock delivery.	This may result in serious harm. Avoid all contact with the patient, as well as any conductive fluids or surfaces (blood, gel, water, metal) or any metal objects (beds, stretchers, zipper, or studs on clothing).
Keep your CellAED® AWAY from explosive or flammable products or oxygen enriched environments during storage and use.	This may result in a fire or explosion.
Radio-frequency interference (RFI) and electromagnetic interference (EMI) can cause improper CellAED® function.	CellAED® should be used at least 1.2m (4ft) away from strong sources of RFI and EMI such as arc welders and radio transmitters.

WARNING	MORE INFORMATION
Keep a used CellAED® out of the reach of children.	The 1-metre-long cable presents a risk of strangulation. After use, deactivate your CellAED® by sticking the two gel sides together and wrap the cable around the device. Contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller for instructions on how to dispose of CellAED®.
DO NOT use a damaged or expired CellAED®.	Your CellAED® may not work as intended.
DO NOT open the transparent barrier bag until ready to use in an emergency.	This will damage and dry out the gel on the electrode pads.
DO NOT store in hot environments such as an unattended vehicle.	This will damage the battery and dry out the gel on the electrode pads. Always keep your CellAED® within the recommended storage temperature: 15° – 35° C (59° – 95° F)
DO NOT modify or service your CellAED®.	The use of accessories, detachable parts, and materials with CellAED® that are not described in this user manual may be unsafe. This may cause irreversible damage.
Colourblind users.	Follow the Monthly Product Inspection Checklist and be aware of your CellAED® expiry date. Colourblind users may have difficulty differentiating LED status colours. Please seek assistance.

05 STORING & CARING FOR YOUR CellAED®

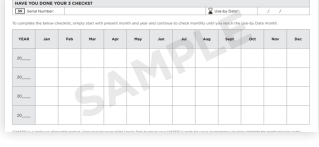
STORING YOUR CellAED®

- Store your CellAED® in a place where you can see it and get to it quickly, there is good cellular connectivity, and is free from obstruction.
- Ideal locations include near the front door of your home, or in a central spot, like your kitchen.
- Consider storing near other emergency equipment, such as a fire extinguisher, fire blanket and first aid kit.
- Keep other useful items nearby, e.g., razor, towel, and scissors, which may be helpful when using your CellAED®.
- Store away from direct sunlight.
- Keep away from extreme heat e.g., hot car or work shed, above stove tops or in-use kitchen appliances.

Keep your CellAED® inside its protective case until you are ready to use in an emergency.

CARING FOR YOUR CellAED®

Your CellAED® does not require regular maintenance. However, it is recommended you follow the Monthly Product Inspection Checklist provided with your CellAED®.



RETURNING YOUR EXPIRED CellAED®

It is important your expired CellAED® is not left in the community. If it has expired, it is important it is returned to the manufacturer in its protective case with the tamper evident seal intact.

Please contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller for instructions on how to return your device.

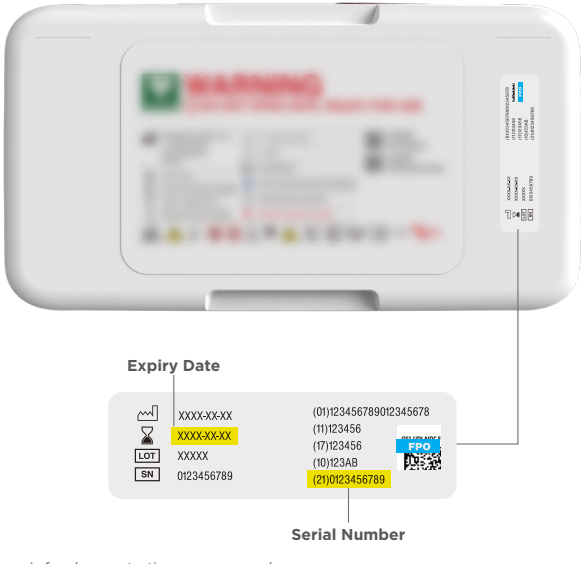


Image is for demonstration purposes only.

1. Check your CellAED® expiry date on the back of the protective case.

   If your CellAED® has reached its expiry date it may no longer work as intended. Replace your CellAED® immediately.

2. Check your CellAED® protective case is in good condition but DO NOT open the protective case to do this.
   a. Check the tape around the case has not been opened (e.g., tamper evident seal is not broken).
   b. Check the transparent barrier bag is sealed without rips or tears.
3. Check the colour of the status LED periodically flashing* on the front of your CellAED®.

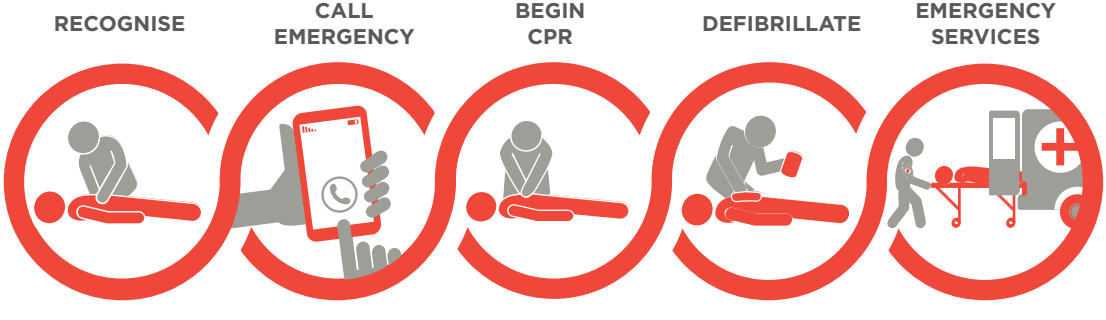
Green	Ready for use if your CellAED® is within expiry date.
Amber	Battery is low and your CellAED® should be replaced immediately. Until replacement arrives, your CellAED® should still be used in an emergency.
No LED	Battery has expired. Replace immediately.

*Flashing approximately every 30 seconds

06 HOW TO USE YOUR CellAED® IN AN EMERGENCY

Once you recognise someone is unconscious, unresponsive and not breathing or not breathing normally (gasping for air), follow the chain of survival. Following these steps gives a person experiencing a sudden cardiac arrest the best chance of surviving.

CHAIN OF SURVIVAL



You should start CPR as soon as possible and continue if another person is able to get your CellAED®. If you are on your own, get your CellAED® first and follow your CellAED® voice instructions.

USING YOUR CellAED®

STEP 1: Expose bare chest

Remove the patient's clothing to expose their bare chest, including bras.

STEP 2: Open your CellAED®

To open the protective case, pull the plastic tab that says "pull" to break the tamper evident seal and remove the red tape.

Tear open the transparent barrier bag where it is labelled "tear here" and remove your CellAED®.

STEP 3: Turn on and apply your CellAED®

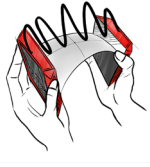
SNAP

Snap to turn on and start voice instructions.

"Call for help. Remain calm."

PEEL

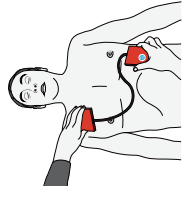
Peel to separate the two electrode pads.



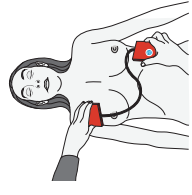
"For adult, apply pads across chest. For infant, apply pads to chest and back."

STICK

Stick the pads to the patient's bare chest.



OR



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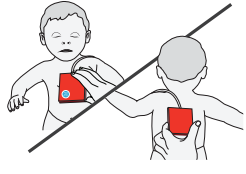


Push down firmly and make sure the surface of each pad sticks to the skin. If both pads are not stuck to the skin, your CellAED® will continue to repeat the voice instruction:

"For adult, apply pads across chest. For infant, apply pads to chest and back."

If patient is wet, dry any moisture from the chest.

Shave any excessive hair. DO NOT delay treatment if a razor is not available.

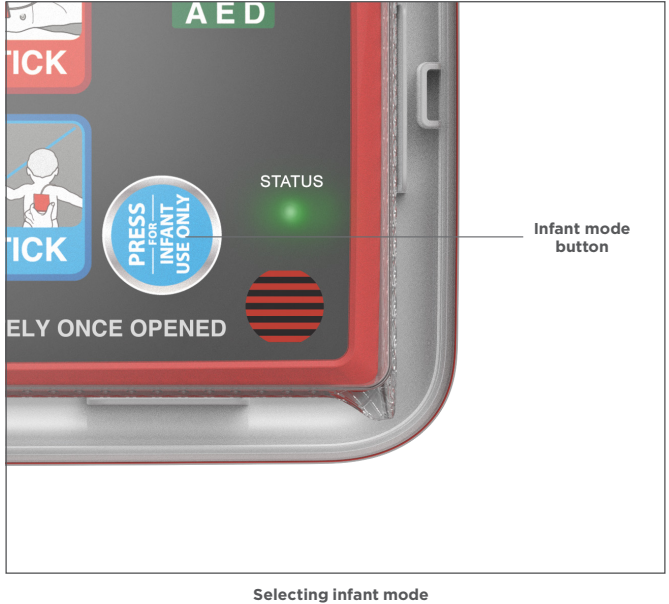
For an infant, stick the pad with the **blue infant button and speaker** in the centre of the chest and the other pad in the centre of the back.

STEP 4: Operating mode

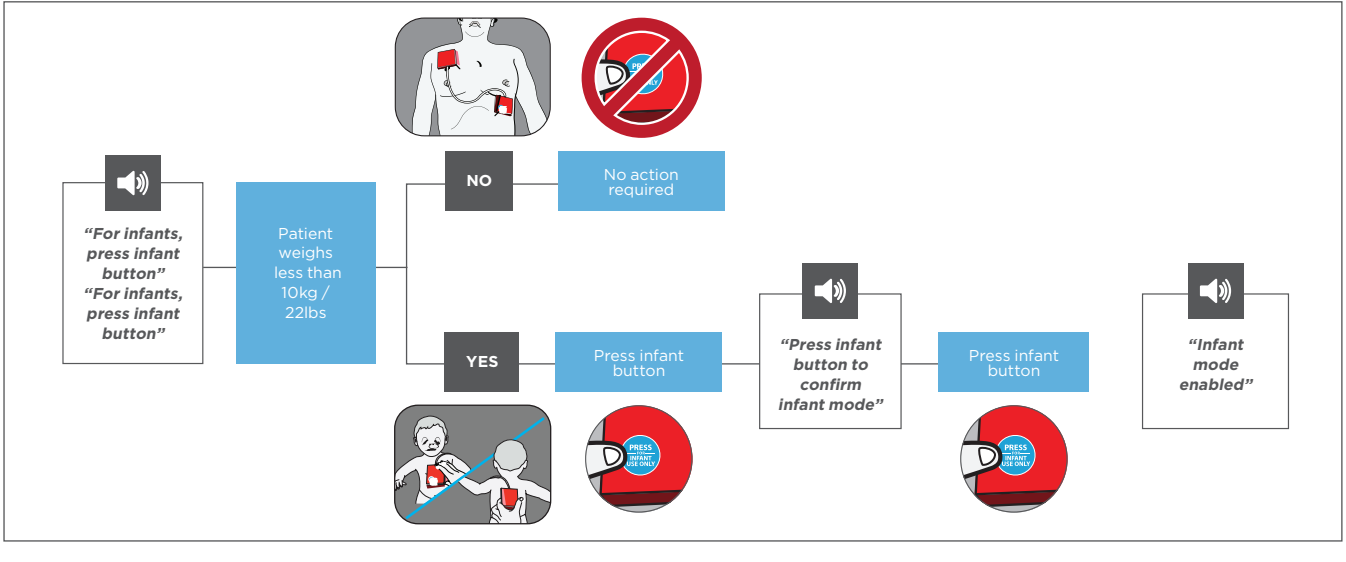
Your CellAED® has two operating modes. For an infant weighing less than 10kg / 22lb, press the infant button. The voice instructions will ask for confirmation of infant mode. Confirm by pressing the infant button again. The voice instructions will confirm ***"infant mode enabled."***

If the patient is more than 10kg / 22lbs no action is required and your device will automatically operate in adult mode.

DO NOT delay treatment to determine exact weight. Once infant mode has been enabled, you cannot change to adult mode. If you are unsure, use adult mode.

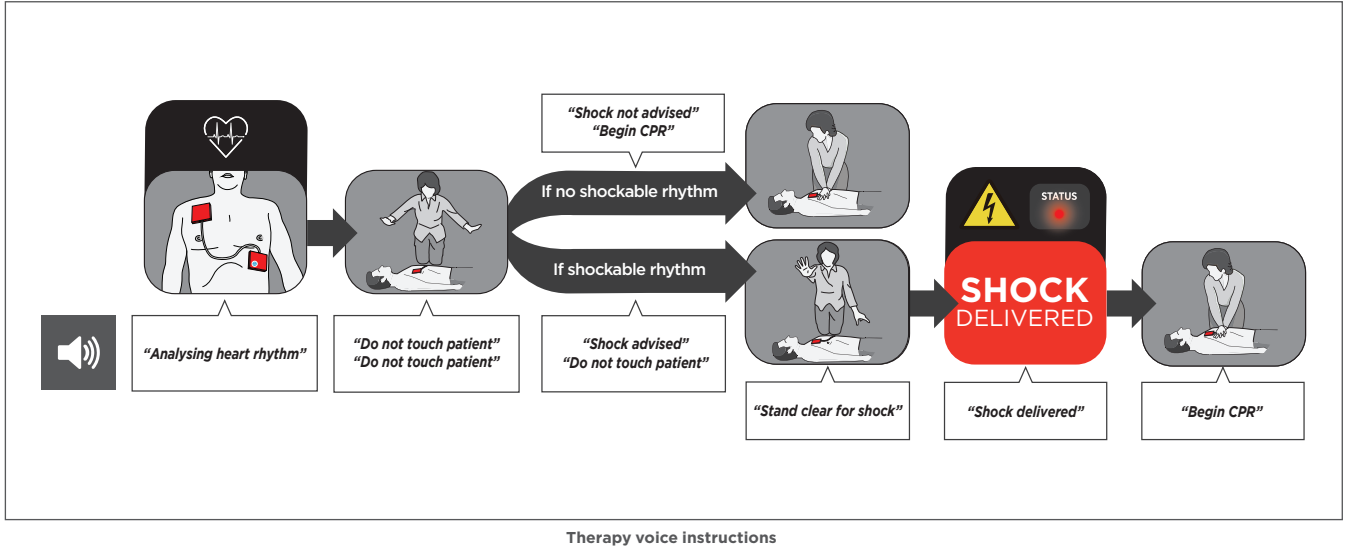


Selecting infant mode



Selecting the correct therapy mode

STEP 5: Heart rhythm analysis



Therapy voice instructions

It takes around 10 seconds for your CellAED® to analyse the heart rhythm.

When your CellAED® is analysing the heart rhythm, stand clear and do not touch the patient, your CellAED®, or anything that is in contact with them.

After analysing the heart rhythm, the voice instructions will say ***"shock advised, DO NOT touch patient"*** or ***"shock not advised, begin CPR."***

If a shockable rhythm is detected, your CellAED® will:

- Automatically deliver a shock through the electrode pads across the heart without you needing to press a button
- Instruct you when to begin CPR and provide a metronome tone for correct pace of chest compression CPR

It takes less than 35 seconds for the ECG analysis and to deliver a shock. Subsequent shocks take around 20 to 25 seconds to charge.

When your CellAED® is delivering a shock stand clear and DO NOT touch the patient, your CellAED®, or anything that is in contact with them. When a shock is advised, the status LED will remain RED while charging and delivering a shock.

If a shockable heart rhythm is not detected, your CellAED®:

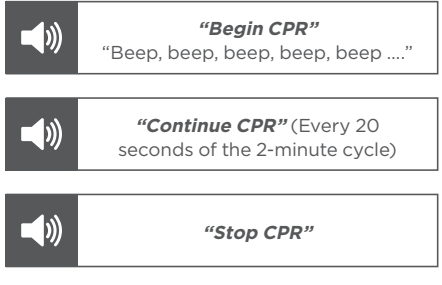
- WILL NOT deliver a shock
- Will instruct you when to begin CPR and provide a metronome tone for correct pace of CPR pushes

Your CellAED® automatically repeats this process with instructions and will continue until Emergency Medical Services arrive and take over treatment, the device is deactivated, or the battery depletes.

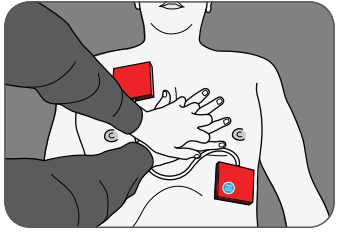
With a fully charged battery, your CellAED® is pre-programmed to deliver a maximum of 20 defibrillation cycles or 20 shocks, which is equivalent to approximately 45 minutes of therapy.

STEP 6: Performing CPR

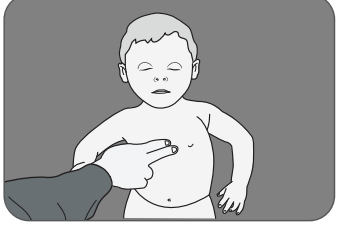
The voice instructions will tell you when to start and stop CPR. You will hear a metronome tone beeping at 120 beats per minute. Follow the rhythm of the beeps when performing CPR.



If both pads are not stuck to the bare chest after CPR you will hear the voice instruction ***"For adult, apply pads across chest. For infant, apply pads to chest and back"***. This will repeat until both CellAED® pads are on the chest.



For an adult: Overlap your hands and place them in the middle of the patient's chest. Keep your arms straight and push down to a depth of approximately one third (1/3) of the patient's chest. Follow the rhythm of the beeps, approximately 2 pushes per second.



For an infant: Remove the pad from the front of the infant's chest and place it on the ground with the sticky gel side facing upwards. Start CPR by placing two fingers in the middle of their chest just below the nipple line; DO NOT press on the end of the breastbone. Push down approximately 4 cm or 1.5 inches following the rhythm of the beeps. **When you are instructed to stop CPR you will need to place the front pad back onto the infants chest.**

If both pads are not stuck to the chest after CPR you will hear the voice instruction ***"For adult, apply pads across chest. For infant, apply pads to chest and back"*** this will repeat until both CellAED® pads are on the chest.

Your CellAED® will continue through the cycle from Heart Rhythm Analysis to CPR until your CellAED® is removed. It is important to continue CPR, where possible and safe to do so until:

- Emergency Medical Services arrive and instruct you to stop
- It is physically impossible to continue
- The patient recovers
- When your CellAED® voice instructions advise you to stop

If the patient starts moving, coughing, or breathing regularly, place the patient in the recovery position and keep them as still as possible until Emergency Medical Services arrive. DO NOT remove your CellAED®. Emergency Medical Services will advise you what to do on arrival.

STEP 7: Shutting down your CellAED®

Shut down your CellAED® once it is no longer needed. This will deactivate your device and the voice instructions will stop. Only do this step when instructed by Emergency Medical Services to do so.

Once your CellAED® has been removed from the patient, stick the pads together with the gel sides touching. The voice instructions or beeps may continue for up to 2 minutes before you hear ***"device deactivated".***

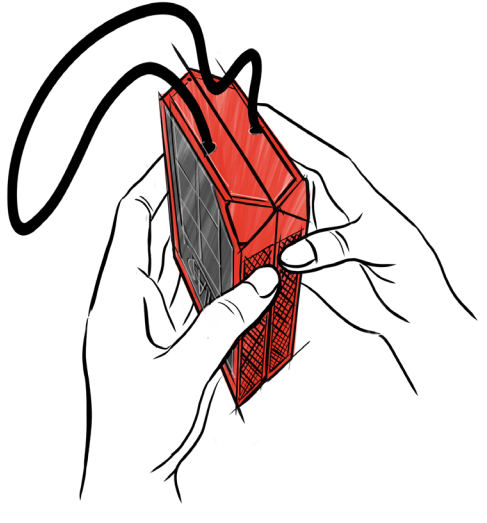
Once you deactivate your device, the event data recorded from your CellAED® will be sent to a secure cloud server if within cellular range.

Please contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller for instructions on how to return your device.

STEP 8: Returning your device after use

Once your CellAED® has been used on someone and deactivated, wrap the cord around the electrode pads and keep the device for return to the manufacturer.

Do not throw your CellAED® away in normal waste. Your CellAED® contains a lithium battery. Please contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller for instructions on how to dispose of and return your device.



Shut down is permanent and your CellAED® will no longer operate.

07 TROUBLESHOOTING

	ISSUE	WHAT DOES IT MEAN	WHAT TO DO
Status LED	The status LED is flashing amber.	The battery is low. This will affect the number of shocks your CellAED® can deliver when in use.	Replace your CellAED® immediately. Until replacement arrives, your CellAED® should still be used in an emergency.
	The status LED is not flashing at all (no LED).	The battery has expired and your CellAED® will not work as intended.	Replace your CellAED® immediately.
Protective case or transparent barrier bag	The tamper evident seal has been opened.	The protective case has been opened and your CellAED® may not work as intended.	Please contact the manufacturer (Rapid Response Revival®) or your local Authorised Reseller.
	There is no transparent barrier bag. OR The transparent barrier bag has been opened, ripped, torn or damaged.	The gel on the electrode pads may dry out and your CellAED® may not work as intended.	Replace your CellAED® immediately.
	The protective case has cracked.	Internal components may be damaged and your CellAED® may not work as intended.	Replace your CellAED® immediately.

	ISSUE	WHAT DOES IT MEAN	WHAT TO DO
Shut down	CellAED® has been snapped and turned on. Voice instructions are coming from CellAED® and it won't turn off.	Your CellAED® is in operation mode and will need to be shut down.	Shut down your CellAED® by sticking the pads together with the gel sides touching until you hear ***"device deactivated."***
Expiry date and serial number	My CellAED® has reached the expiry date but the green LED is still flashing.	The expiry date of your CellAED® takes into consideration a range of internal components including the gel on the electrode pads. CellAED® may not work as intended after the expiry date.	Replace your CellAED® immediately.

08 TECHNICAL SPECIFICATIONS

GENERAL SPECIFICATIONS	
Dimensions (W x D x H)	CellAED® 19.5 x 9.3 x 1.7 cm Including protective case 21.2 x 11.2 x 2.8 cm
Weight	CellAED® approx. 300 g Including protective case approx. 450g
Battery	Non-rechargeable Lithium
Firmware version	1.x
Equipment classification	Internally Powered Type BF medical device as per IEC 60601-1
Ingress protection	IP 22*: Protected from objects greater than 12.5 mm and water spray less than 15 degrees from vertical.

* This rating applies to CellAED® in its most vulnerable state i.e., when removed from its protective packaging during its intended use. When not in use CellAED® is in a protective case and thoroughly sealed in an airtight transparent barrier bag that offers additional protection.

PERFORMANCE SPECIFICATIONS	
Pre-programmed maximum number of shocks	20 shocks
Number of maximum energy shocks delivered when low battery event occurs	> 3 shocks
Charging time to maximum energy with a new battery	< 25 seconds
Charging time to maximum energy with a battery after 6 shocks	< 25 seconds
ECG interpretation time with a new battery	< 8 seconds
ECG interpretation time with a battery after 6 shocks	< 8 seconds
Overall specificity	> 95%
Positive predictive accuracy	> 95%
False positive rate	< 1%
Time to maximum energy shock after activation	< 50 seconds

ENVIRONMENTAL SPECIFICATIONS	
Operating conditions	0 °C to 35 °C (32 °F to 95 °F), 0% to 95% RH (relative humidity) (non-condensing)
Standby/storage conditions	15 °C to 35 °C (59 °F to 95 °F), 0% to 95% RH (relative humidity) (non-condensing)
Transport conditions	0 °C to 35 °C (32 °F to 95 °F), 0% to 95% RH (relative humidity) (non-condensing)
Altitude	-100 m to 4,000 m
Atmospheric pressure	60 kPa to 102 kPa

CELLULAR SPECIFICATIONS	2G	3G	LTE CAT-M1†
Frequency* (MHz)	900, 1800	800, 850, 900, 1900, 2100	700, 800, 900, 1800, 2100
EIRP	900 MHz: 36 dBm 1800 MHz: 33 dBm	900 MHz: 22.65 dBm 2100 MHz: 26.48 dBm	LTE Cat-M1†: 26 dBm

*Bands may not be available in all regions; †LTE Cat-M1 is a category of 4G long-term evolution (LTE) technology for machines (M).

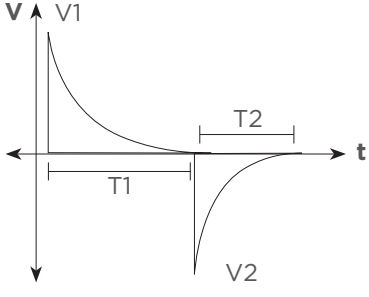
SENSITIVITY AND SPECIFICITY OF RHYTHM RECOGNITION DETECTOR	
Shockable Rhythm – VF	Sensitivity > 90%*
Shockable Rhythm – VT	Sensitivity > 75%*
Non-shockable Rhythm – Normal Sinus Rhythm	Specificity > 95%*
Non-shockable Rhythm – Asystole	Specificity > 95%*
Non-shockable Rhythm – all other rhythms	Specificity > 95%*
Overall specificity	I >95%
Positive predictive accuracy	I >95%
False positive rate	I <1%

* Meets IEC/EN 60601-2-4 requirement

BIPHASIC EXPONENTIAL WAVEFORM

PATIENT WEIGHING GREATER THAN 10 KG / 22 LBS							
IMPEDANCE (Ω)	**ENERGY (J)**	**V1 (V)**	**PEAK I1 (A)**	**T1 (ms)**	**V2 (V)**	**PEAK I2 (A)**	**T2 (ms)**
25	68	1050	42.0	5.2	1005	40.2	2.7
50	75	1150	23.0	9.7	1120	22.4	4.8
75	78	1183	15.8	14.2	1166	15.6	7.0
100	80	1204	12.0	18.8	1190	11.9	10.0
125	80	1212	9.7	20.1	1200	9.6	16.4
150	81	1224	8.2	20.0	1212	8.1	22.1
175	81	1235	7.1	20.0	1221	7.0	22.1
INFANT WEIGHING LESS THAN 10 KG / 22 LBS							
IMPEDANCE (Ω)	**ENERGY (J)**	**V1 (V)**	**PEAK I1 (A)**	**T1 (ms)**	**V2 (V)**	**PEAK I2 (A)**	**T2 (ms)**
25	36	762	30.4	5.2	743	29.8	3.1
50	40	835	16.7	9.6	824	16.5	5.5
75	42	861	11.5	14.1	855	11.4	8.0
100	43	876	8.8	18.5	872	8.7	10.6
125	43	885	7.1	20.1	880	7.0	15.6
150	43	891	5.9	20.1	888	5.9	21.9
175	43	896	5.1	20.1	892	5.1	22.2

The energy delivered is within +/- 15% of the nominal values show above.



V = Voltage t = Time

The waveform is automatically adjusted to compensate for patient impedance.

CellAED® does not detect patient motion.

ECG INTERPRETATION AND PERFORMANCE

When placed on a patient experiencing sudden cardiac arrest, CellAED® is designed to recommend a defibrillation shock when it detects proper pad impedance and one of the following shockable rhythms:

SHOCKABLE RHYTHMS

VF with peak-to-peak amplitudes of at least 200μV and VT (monomorphic and polymorphic) of at least 130 bpm and peak-to-peak amplitudes of at least 200μV.

NON-SHOCKABLE RHYTHMS

All other rhythms, including Normal Sinus Rhythms, fine VF with peak-to-peak amplitudes less than 200μV, some slow VT and Asystole.

The patient's transthoracic impedance is measured through the defibrillation electrode pads. If the baseline impedance is higher than a maximum limit, it is determined that the electrodes have not made sufficient contact, and ECG analysis and shock delivery are inhibited. In this instance, please check the electrodes and improve contact. The resistance measurement is 25 to 175 Ohms, non-inductive (<2uH).

ELECTROMAGNETIC EMISSIONS AND IMMUNITY

TEST	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT
RF emissions CISPR 11	Group 1 Class B	The RF emissions of CellAED® are unlikely to cause any interference in nearby electronic equipment. CellAED® is suitable for use in all establishments, including industrial establishments, domestic establishments and establishments directly connected to the public low-voltage power supply for domestic purpose.
Electrostatic Discharge (ESD) IEC 61000-4-2:2008, EN61000-4-2:2009	±2kV, ±4kV, ±6kV for Direct & Indirect Contact ±2kV, ±4kV, ±8Kv for Air Discharge	There are no special requirements with respect to electrostatic discharge.
Power-frequency magnetic field IEC 61000-4-8:2009/ EN 61000-4-8:2009	30 A/m 50Hz	Power-frequency magnetic fields should not be greater than magnitudes which are typical of commercial or hospital environments. There are no special requirements for non-commercial/non-hospital environments.
Radiated RF EM Fields IEC 61000-4- 3:2006/ A1:2007+A2:2010. 10 V/m, 20 V/m 80MHz to 2.5GHz	10V/m	Portable and mobile RF communications equipment should be used no closer to any part of the CellAED®, including cables, than is necessary. The recommended separation distance calculated from the equation applicable to the frequency of the transmitter is shown in the following table. Recommended separation distance d = 1.20 x √P, 80MHz to 800MHz d = 2.30 x √P, 800MHz to 2.5GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the symbol above.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

The Industrial, Scientific and Medical (ISM) bands between 150 kHz to 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

The compliance level in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into the area around the patient. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

If the measured field strength in the location in which CellAED® is used exceeds the applicable RF compliance level above, CellAED® should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CellAED®. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THE CellAED®
(IEC 60601-1-2:2014/EN 60601-1-2:2015 TABLE 205)

CellAED® is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of CellAED® can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and CellAED® as recommended below, according to the maximum output power of the communications equipment.

RATED MAXIMUM OUTPUT POWER OF TRANSMITTER	150 KHZ TO 80 MHZ OUTSIDE ISM BANDS	150 KHZ TO 80 MHZ IN ISM BANDS	80 MHZ TO 800 MHZ	800 MHZ TO 2.5 GHZ
(W)	d = [3.5/3] x √P	d = [12/10] x √P	d = [12/10] x √P	d = [23/10] x √P
0.01	0.17	0.12	0.12	.023
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.3
10	3.69	3.79	3.79	7.27
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MH to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

CellAED® IS A PRODUCT OF

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