CellAED®

USER MANUAL

AUTOMATED EXTERNAL DEFIBRILLATOR

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

SNAP PEEL STICK™

AED

SINGLE-USE AED ②

REF 100-2.2-094

RMDOC0007v4

TABLE OF CONTENTS

Read the Operating Instructions carefully before using the CellAED® and keep it for future reference.

1.1 NOTICE

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1.3 REGARDING THIS MANUAL

All efforts have been made to ensure that the contents of this manual are correct. If for any reason the user suspects an error, please do not hesitate to contact RRR at the address shown on **Section 12, page 69.**

1.4 LIMITS TO MANUFACTURER'S RESPONSIBILITIES

To the maximum extent permitted by law, RRR Manufacturing Pty Ltd. is not responsible for the safety and reliability of the CellAED® if the CellAED® is not used in accordance with all Instructions and danger, warning and caution notices in this manual.

1.5 INDEMNIFICATION

RRR Manufacturing Pty Ltd. provides the following indemnity to persons or legal entities that have purchased a CellAED® from RRR or an authorized distributor appointed by RRR (hereafter referred to as "the Purchaser").

RRR will, at its cost, defend, indemnify, and hold harmless the Purchaser from third-party claims or legal actions for liability or damages resulting from bodily injury or death caused by a mechanical or electrical failure of the CellAED®, or the malfunction of the CellAED® due to a defect in its design or manufacture.

This indemnity does not extend to, or cover, any claim or legal action for liability or damages in connection with the use of the Purchaser's CellAED® caused by:

- Negligent operation of the CellAED®, or failure to follow the sequential operating instructions for use of the CellAED®, or:

- Failures or malfunctions of the CellAED® that are due to improper maintenance, including, without limitation, malfunctions of electrode pads or batteries that occur after expiration of their shelf life, or malfunction of repairs, replacement parts, pads, or batteries that were not provided by RRR. This indemnification is expressly conditioned on the Purchaser's fulfilling the following obligations with respect to any claim for which indemnification will be requested (hereafter referred to as "the Claim"). The Purchaser will send it to an authorized distributor, or RRR at the contact address shown in **Section 12, page 69** with written notice of the Claim, promptly after the Purchaser obtains knowledge of the Claim.

The Purchaser also will provide to RRR all assistance reasonably requested for evaluation of the Claim or Defense of the Claim. Such assistance will include:

- Transferring possession of the CellAED® involved in the Claim to RRR and/or distributor (including any electronic records created by the CellAED® of the event involved in the Claim) for analysis of the cause of any failure, and providing to RRR and its counsel all other evidence relevant to the Claim, whether in the form of documents or testimony. RRR will promptly notify the Purchaser in writing if RRR determines that the Claim is not covered by this indemnity, and RRR shall have the unrestricted authority to defend or settle any Claims for which indemnification is required by this agreement. However, the Purchaser shall retain the right to participate, at its own expense, in the defense or settlement of any Claim that is covered by this indemnity.

All claims in respect of the above must be sent in a timely manner by registered mail or by electronic mail (email) to an authorized distributor or the manufacturer at the contact address in **Section 12, page 69**.

1.6 COMPLIANCE WITH LOCAL REGULATIONS

All users must comply with any statutory and local regulations and requirements associated with ownership and use of a defibrillator in the region where it is to be used; check with the Government Health Department for this information. In case of a difference between the regulations and these operating instructions, comply with the regulations in the region of use.

02 GLOSSARY

This document contains some terms that may be unfamiliar. This table includes the terms that you need to be familiar with to use the CellAED®.

TERMINOLOGY / ACRONYMS	DESCRIPTION
AED	Automated external defibrillator. A device that evaluates the patient's heart rhythm and delivers an electrical shock to the heart if a shockable rhythm is detected.
AMA	American Medical Association
Agonal breathing	Irregular gasping or labored breathing, accompanied by strange vocalizations and involuntary, irregular (lacking rhythm) muscle spasms that resemble seizures.
Asystole	Asystole is the state characterised by a lack of heart rhythm, commonly known as flatlining. It occurs when the heart has stopped beating and there is no electrical activity in the heart.
Cardiac arrest	The termination of the heart's pumping action, resulting in lack of heartbeat, pulse and/or normal breathing.
CellAED®	The CellAED® is a single-use, portable, transit-operable, fully automated external defibrillator (AED), intended for use by minimally trained individuals to treat sudden cardiac arrest (SCA), in conjunction with chest compression cardiopulmonary resuscitation (CPR) until Emergency Services arrive.
CPR	Cardiopulmonary resuscitation involves the delivery of chest compressions to a patient in SCA to keep their blood circulating.
Defibrillation	Delivery of an electrical shock to the heart for the purpose of reversing ventricular fibrillation and ventricular tachycardia.

ECG	Electrocardiogram. A composite picture of what is occurring electrically in the heart.
Fibrillation	Chaotic activity of the heart's electrical system. This condition can occur in the atria or the ventricles. When it occurs in the ventricles, they quiver in a rapid, chaotic manner, preventing them from pumping blood to the body.
Heart attack	A non-specific term referring to the death of heart muscle tissue resulting from interruption of blood supply, often confused with cardiac arrest.
LED	Light emitting diode
Non-shockable rhythm	A heart rhythm that is detected by the CellAED® that does not need a shock, but may need CPR.
Normal sinus rhythm (NSR)	The rhythm that originates from the heart's natural pacemaker and describes the characteristic rhythm of the healthy human heart. The rate in NSR is generally regular but will vary depending on autonomic inputs into the heart's natural pacemaker.
Patient	In this manual, the person suffering from sudden cardiac arrest.
RRR	RRR Manufacturing Pty Ltd
Shockable rhythm	A heart rhythm that is detected by the defibrillator as requiring a shock, for example, ventricular fibrillation.
Sudden cardiac arrest (SCA)	A sudden cardiac arrest occurs when the heart stops pumping blood. It can be caused by an electrical or mechanical problem with the heart.
Ventricular fibrillation (VF)	A life-threatening, chaotic heart rhythm originating in the ventricle.
Ventricular tachycardia (VT)	A life-threatening, rapid heart rhythm originating in the ventricle.

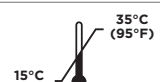
03 SYMBOLS USED IN THIS MANUAL/DEVICE

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**Manufacturer**	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements ISO 7000-3082 — Graphical symbols for use on equipment.
	**Date of Manufacture (yyyy-mm-dd)**	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (5.1.3)
	**Automated External Defibrillator**	AS 1319-1994 Emergency Information Signs. Emergency Signs indicate the location of life saving equipment.
	**Authorised Representative in the European Community**	ISO 15223-1:2016 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements (5.1.2)

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
CE 0297	**CE marking and Notified Body Number related to CE conformity**	Hereby, RRR Manufacturing Pty Ltd declares that the CellAED® meets the provision of the following Union harmonisation legislation: Council Directive 93/42/EEC, Radio Equipment Directive 2014/53/ EU (radio equipment type class 1), RoHS Directive 2011/65/EU, WEEE Directive 2012/19/EU. The full text of the EU declaration of conformity is available at the following internet address: cellaed.info/declaration-of-conformity
	**Regulatory Compliance Mark related to electrical safety and EMC requirements**	Hereby, RRR Manufacturing Pty Ltd declares that the CellAED® meets the AS/NZS 4417.1:2012 Regulatory Compliance Mark for Electrical and Electronics Equipment Use of the Mark.
REF	**Catalogue or model number**	ISO 15223-1, Clause 5.1.6 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied ISO 7000- 2493 — Graphical symbols for use on equipment
SN	**Serial number**	ISO 15223-1, Clause 5.1.7 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. ISO 7000-2498 — Graphical symbols for use on equipment.
	**Refer to Operating Instruction Manual / Booklet**	ISO 7010-M002 — Refer to instruction manual / booklet

(Continued page 10)

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**Caution: Read all warnings and precautions in instructions for use. Refer to the Section about General Warnings, Alerts and Cautions for more information about the warnings and cautions.**	ISO 15223-1, Clause 5.4.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. IEC 60601-1-11:2015, Table D.1, Symbol 10 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance. ISO 7000-0434 — Graphical symbols for use on equipment.
	**Keep away from sunlight**	ISO 7000 — Graphical symbols for use on equipment — Registered symbols. To indicate that transport package shall not be exposed to sunlight. Reference No: 0624. Registration date: 2014-06-04. Status: Active.
	**Do not damage**	Do not damage or crush
	**Keep away from high heat**	Do not expose to high heat or open flame. Do not incinerate.

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**Do not open until ready for use**	ISO 7010 - Graphical symbols, safety colours and safety signs.
	**Do not re-use**	ISO 15223-1, Clause 5.4.2 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. ISO 7000-1051 — Graphical symbols for use on equipment.
	**Separate collection for waste of electrical and electronic equipment**	EN 50419 - Marking of Electrical and Electronic Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE). Recycle: Electronic Equipment DO NOT THROW IN TRASH.
	**Storage temperature range**	Indicates the temperature limits to which the medical device can be safely exposed. ISO 15223-1, Clause 5.3.7 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. ISO 7000-0632 — Graphical symbols for use on equipment.
	**Storage humidity range**	ISO 15223-1, Clause 5.3.8 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. Indicates the range of humidity to which the medical device can be safely exposed. ISO 7000-2620 — Graphical symbols for use on equipment.

(Continued page 12)

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**Keep dry**	ISO 15223-1, Clause 5.3.4 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. ISO 7000-0626 — Graphical symbols for use on equipment.
	**A potential or actual hazard exists. Warning, high voltage**	EN 60601-1-11 : 2015
	**Type BF applied part**	IEC 60417. Committee: IEC/SC 3C. Type BF applied part. Reference number: 5333. Type: For use on equipment.
	**Consult Instructions for Use**	ISO 15223-1, Clause 5.4.3 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. IEC 60601-1-11:2015, Table D.1, Symbol 11 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance. ISO 7000-1641 — Graphical symbols for use on equipment.
	**Patent**	rapidresponserevival.com/legal
	**Logo**	RRR Worldmark Logo

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**SNAP**	Visually represents the action required to activate the CellAED®. The CellAED® is separated along the centreline, into two halves. The SNAP simultaneously commences audio (voice) prompts, guiding the user through the next steps.
	**PEEL**	Visually represents the activation process of the CellAED®. The gel pad liner is removed completely by separation of the two halves of the CellAED®, exposing the adhesive gel pads and extending the electrical connecting cable.
	**STICK**	Visually represents the activation process of the CellAED®. Audio (voice) prompts instruct the user to apply the electrode gel pads of the CellAED® to the patient appropriately.
IP 22	**(Enclosure) Protected from tools & wires greater than 2.5 millimeters & water spray less than 15 degrees from vertical**	A two-digit number established by the International Electrotechnical Commission, is used to provide an Ingress Protection rating to a piece of electronic equipment or to an enclosure for electronic equipment. The protection class after EN 60529 are indicated by short symbols that consist of the two code letters IP and a code numeral for the amount of the protection.

(Continued page 14)

SYMBOLS	DESCRIPTION	RELATIVE SYMBOL REGULATIONS AND MORE INFORMATION
	**Electromagnetic Interference**	Interference may occur in the vicinity of equipment.
	**Batch code**	ISO 15223-1, Clause 5.1.5 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. ISO 7000-2492 — Graphical symbols for use on equipment.
	**Use-by Date as yyyy-mm-dd**	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (5.1.4) Indicates the date after which the medical device is not to be used. ISO 7000-2607 — Graphical symbols for use on equipment.
	**Do not use if package is damaged**	ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (5.2.8)
	**Fragile, handle with care**	ISO 15223-1, Clause 5.3.1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied. Indicates a medical device that can be broken or damaged if not handled carefully. ISO 7000-0621 — Graphical symbols for use on equipment.

This Section provides important information to help you safely operate your CellAED®. Familiarise yourself with safety terms (Danger, Warning and Caution) in this Section.

4.1 RESPONSIBILITY OF USER AND TRAINING REQUIREMENTS

The CellAED® is intended for use by minimally trained individuals (who have undergone training in the use of the CellAED®) to treat patients of suspected sudden cardiac arrest (SCA). It is the responsibility of our customers to ensure that any person who may use this CellAED® has access to the information in this manual, including this Safety Information Section.

Read this manual well before use, and take note of all instructions, cautions, warnings, dangers, and statements of intended use. Ensure that all potential users are familiar with the intended and correct use of this product, understand the material presented in this user manual, and receive appropriate training for the use of this product. Failure to do so may result in harm to the patient or user.

All potential users of the CellAED® should read this User Manual. Online access to a PDF of the User Manual and step-by-step video instructions are accessible by scanning the QR codes on the back of the outer packaging **(Figure 3B, page 25)** and protective case **(Figure 4A, page 26)**.

Operating instructions include chest compression cardiopulmonary resuscitation (CPR) guidance for hand placement, compression depth and timing on pages 35 - 43.

Do not use the CellAED® to treat any condition other than SCA. The CellAED® must be used in accordance with the instructions contained in this User Manual, the visual cues on the CellAED® and the instructional videos.

To the maximum extent permitted by law, RRR assumes no responsibility for any adverse results arising from improper use of this product.

4.2 CellAED® INTENDED USE

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

4.2.1 WHAT IS SUDDEN CARDIAC ARREST (SCA)?

A sudden cardiac arrest occurs when the heart stops pumping blood. It can be caused by an electrical or mechanical problem with the heart. SCA is caused by abnormal heart rhythms such as ventricular fibrillation (VF) and ventricular tachycardia (VT). SCA can occur in anyone, from infants to adults. If not treated immediately, SCA can lead to death.

In combination with CPR, defibrillation is the most effective treatment for SCA. The CellAED® is activated with a simple, three-part Snap Peel Stick™ action **(Figure 5 (b) and (c), page 34)**. After the CellAED® electrode pads are placed on the patient's exposed chest, the CellAED® analyses the patient's heart rhythm. If a shockable rhythm such as VF or VT is detected, the CellAED® will deliver an intense pulse of electricity (shock) through the electrode pads to the heart muscle, to attempt to restore the heart's electrical function to a normal sinus rhythm (NSR). The CellAED® will then instruct the user to commence chest compression CPR for 2 minutes. If a shockable heart rhythm is not detected, the CellAED® will not deliver a shock and will instruct

the user to commence chest compression CPR. The CellAED® automatically repeats this process. Once removed from the chest, placing the two pads together deactivates the CellAED®.

4.3 CellAED® INDICATIONS FOR USE

The CellAED® should be used on patients in SCA for the treatment of VF and VT. The fully integrated electrode gel pads can be applied to patients weighing greater than 10 kg (22 lbs) and infants weighing less than 10 kg (22 lbs).

A person in SCA is:

- **Unresponsive,**
- **Unconscious, and**
- **Not breathing or not breathing normally (including agonal breathing).**

Always consult a Healthcare Professional for any health concerns (e.g. chest pain). The CellAED® is intended to treat SCA only.

4.4 CellAED® CONTRAINDICATIONS

The CellAED® must not be used if a person is:

- **Responsive,**
- **Conscious, or**
- **Breathing normally (with no signs of agonal breathing)**

The CellAED® is not intended for use in the emergency medical services environment.

The CellAED® is not intended for use on injured skin.

4.5 SAFETY TERMS

You may encounter the following terms throughout this manual and while using the CellAED®:

Danger

Hazards that could result in immediate serious personal injury or death to the user and/or the patient.

Warning

Hazards or unsafe practices that could result in serious personal injury or death to the user and/or the patient.

Caution

Hazards or unsafe practices that could result in minor personal injury to the user and/or the patient, product damage, or property damage.

Please refer to Section 11, pages 64 - 68.

4.6 OPERATION WITH OTHER DEVICES

The CellAED® may cause interference with other medical equipment. While the CellAED® complies with radiated emission standards, some medical equipment may still be impacted by emissions from the CellAED®. If this occurs, move the impacted equipment away from the CellAED® until the CellAED® is no longer needed for the patient, or Emergency Services arrive.

DANGER

- User modification of, or interference with, the mechanical/electrical integrity of the CellAED® may affect the performance of the CellAED® and/or the electromagnetic emissions, which could compromise other equipment in close proximity.
- Using other manufacturers' cables or electrode pads may cause the CellAED® to perform improperly and invalidates the safety agency certification.

CAUTION

- The normal operation of the CellAED®, including the ability to correctly detect a shockable rhythm, may be impacted if it is operated near strong sources of electromagnetic interference (EMI) and/or radio frequency interference (RFI). This can include arc welders and radio transmitters. If it is safe to do so, keep a separation between the CellAED® and strong sources of EMI and RFI of at least 1.2m (4ft).

4.7 TERMS OF WARRANTY

The CellAED® is warranted against defects in material and manufacture for the duration of 2 years from date of manufacture, or until Use-by Date, whichever is occurs first.

Excluded from this guarantee is damage caused by an accident or as a result of mishandling. The warranty entitles free replacement of the CellAED®. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make any repairs or modifications.

For Australian consumers, our goods come with guarantees that cannot be excluded under the Australian Consumer Law. You are entitled to a replacement or refund for a major failure and compensation for any other reasonably foreseeable loss or damage. You are also entitled to have the goods repaired or replaced if the goods fail to be of acceptable quality and the failure does not amount to a major failure.

For New Zealand consumers, this warranty in no way limits or affects any rights you may have under the NZ Consumer Guarantees Act.

For United Kingdom customers, this warranty does not affect your statutory rights.

In case of a defect, cease using the CellAED® and contact the manufacturer at the contact address shown in **Section 12, page 69**. In the event of a warranty claim being made, RRR and the Purchaser will each bear their own expenses in relation to the preparation and assessment of any warranty claim.

4.8 MORE INFORMATION

Contact the manufacturer for additional information about the CellAED®. They will be happy to answer any questions you may have and to provide you with copies of the clinical summaries of several key studies involving the CellAED®.

Technical information about the CellAED® is also available online at cellaed.info/technical-specs

The CellAED® conforms to all mandatory clinical requirements in compliance with EN 60601-2-4:2011+A1:2019 and EN 60601-1-11:2015.
The unit complies with all relevant standards for patient's safety and operating conditions.

5.1 The CellAED®

The CellAED® is shipped ready-to-use with the pre-programmed CellAED® biphasic energy protocol.

It is a fully automated external defibrillation device to be used for patients weighing greater than 10 kg (22 lbs) or more, and with infants weighing less than 10 kg (22 lbs) when the Infant Mode button is pressed, prior to the arrival of Emergency Services.

When electrode pads are properly applied to the patient's exposed chest, the CellAED® automatically analyses the patient's heart rhythm. If a shockable rhythm is detected, the CellAED® automatically delivers an electrical pulse (shock) to the heart muscle with the aim of restoring NSR.

The CellAED® will only administer defibrillation when the heart exhibits VF and VT, as these are the heart rhythms associated with SCA. The CellAED® will not administer an electrical shock if it detects a healthy heart rhythm, such as NSR, or abnormal heart rhythms not associated with SCA, such as asystole and all other arrhythmias (refer to **Section 10.4, page 57**).

After shock delivery, the CellAED® will re-assess the patient's heart rhythm, and continue to instruct the User and deliver shocks in a timely and appropriate manner as necessary.

For use with an infant weighing less than 10 kg (22 lbs), the CellAED® requires the user to press the infant mode button twice to confirm and enable Infant Mode.

In both modes there are audio (voice) prompts that guide the user through the defibrillation process.

For detailed instructions for use, refer to Sections 6 - 8, pages 20 - 49.

5.2 CAPABILITIES AND KEY FEATURES

The following paragraphs introduce specific key features found in the CellAED®.

5.2.1 ACCESSORIES

No accessories provided.

5.2.2 SIMPLE SNAP PEEL STICK™ OPERATION

CellAED® is designed to enable minimally trained individuals to perform defibrillation in the event of a cardiac arrest with a quick and simple Snap Peel Stick™ action, as illustrated in **Figure 5, page 34,** prior to arrival of Emergency Services.

5.2.3 AUTOMATED OPERATION

The 'SNAP' action activates the CellAED®. It will commence audio (voice) prompt instructions to guide the defibrillation and chest compression CPR process.

When the CellAED® electrode pads are placed correctly on the patient, they automatically identify whether a shockable rhythm is present. If a shockable rhythm is detected, the CellAED® will commence charging the capacitors to release a shock.

There is an Infant Mode button that the user must press if the patient is an infant weighing less than 10 kg (22 lbs); this is a manual action taken when the CellAED® audio (voice) prompt invites them to "For infants, press infant button." The user must press the infant button a second time to confirm and enable Infant Mode.

The CellAED® will issue audio prompt warnings prior to shock delivery. Shock delivery is automated by the CellAED®.

If the patient is transferred to emergency medical personnel, the medical personnel can remove the CellAED® electrode pads and replace with their own defibrillation equipment, if available. The CellAED® must be removed before any alternative defibrillator is applied. To deactivate the CellAED®, stick the gel sides of the electrode pads together **for at least five seconds**. Audio (voice) prompts will acknowledge when the CellAED® has been deactivated. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

5.2.4 CONTINUOUS BATTERY DIAGNOSTIC

The CellAED® is constantly aware of the battery status and provides visual feedback to indicate the state of readiness.
A periodic flashing GREEN LED (every 30 seconds) indicates the CellAED® is fully operational and ready to use.

A periodic flashing AMBER LED (every 30 seconds) indicates that the battery is low and the CellAED® should be replaced immediately. Contact the manufacturer for a replacement.

No LED indicates that the battery has expired and the CellAED® should be replaced immediately. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

5.2.5 HEART RHYTHM ANALYSIS

The CellAED® evaluates the patient's heart rhythm. Refer to **Section 10.4, page 57** for further information.

5.2.6 DEFIBRILLATION WAVEFORM

The defibrillation shock, using patented CellAED® biphasic waveform technology, is a fully-discharging capacitator method for delivering an energy-efficient biphasic defibrillation waveform. The waveform is automatically adjusted to compensate for patient impedance. The CellAED® does not detect patient motion.

5.2.7 USE-BY DATE ⌛

Your CellAED® has an expiry date, after which it should be replaced. Please refer to the Use-by Date that is printed on the back of the protective case **(Figure 4A (c), page 26).**

Maintaining the CellAED® in an ideal storage condition (15°C – 35°C (59°F – 95°F)) is required to maximise the performance of the battery as well as the CellAED® expected shelf life (refer to **Section 6.4, page 28**).

The CellAED® package contains:

- **One CellAED® single-use automated external defibrillator sealed inside a transparent bag and a protective case – do not open these until the CellAED® is needed to treat SCA**
- **Instructions for operating the CellAED®**
- **A Monthly Product Inspection Checklist**

6.1 UNPACKING & INSPECTING THE CellAED®

To help ensure the integrity of the CellAED® and to verify that it is complete and ready for use, perform the following inspection **(Figure 1 - Figure 4B, pages 21 - 27)**:

1. **Inspect** the outer packaging for signs of damage that may have occurred during transport. If the packaging presents rips, cracks, bends, leakages, discolorations, or deformation, contact the manufacturer.
2. **Open** the outer packaging and remove the CellAED® in its protective case. Check that the tamper evident seal **(Figure 1 (b), page 21)** on the protective case has not been broken. Do not remove the tamper evident seal, and do not remove the CellAED® from the protective case and sealed transparent bag until required for emergency use **(Figure 1 (c) and (d), page 21).** If the tamper evident seal has been broken, contact the manufacturer.

Do not store the CellAED® in the outer packaging, as the LED indicator and expiry date will not be visible.

3. **Check** and confirm the Use-by Date on the protective case has not expired **(Figure 4A (c), page 26)**. Verify that the green LED indicator is flashing. The green LED will flash approx. every 30 seconds **(Figure 5 (e), page 34)**, and is visible through the protective case **(Figure 1 (d), page 21)**. A green LED flashing means the CellAED® is ready for use. If the CellAED® has expired or the green LED is not blinking, contact the manufacturer.
4. **Save** the outer packaging and any inserts in case the CellAED® requires transporting in the future.

Contact the manufacturer with any questions about the CellAED®.

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

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

CAUTION: Once the unit is unsealed, the CellAED® must either be used in an appropriate manner or disposed of as per instructions from the manufacturer.

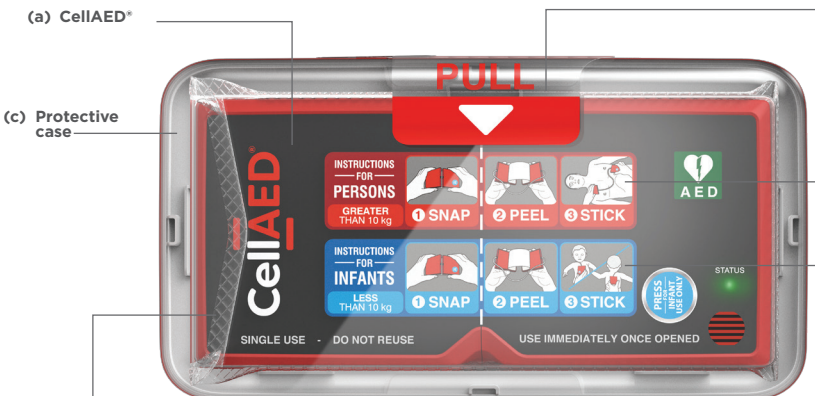


FIGURE 1: CellAED® protective case front

Images are representative only and may vary between regions

FIGURE 1B: Opening the tamper seal

(Continued page 22)

6.2 PACKAGING, INSTRUCTIONS, CONTROLS, INDICATORS AND LABELS

This Section introduces the packaging, instructions, controls, indicators, and labels of the CellAED®.

LABELS, INSTRUCTIONS AND WARNINGS

The outer packaging box **(Figure 3B, page 25)** and protective case **(Figure 4A, page 26)** feature storage and handling instructions, warnings, and the Date of Manufacture/ Use-by Date of the CellAED® on the back. QR codes **(Figure 3B, page 25 and Figure 4A (b), page 26)** provide online access to a PDF of the User Manual, and step-by-step video instructions for responding to a patient in SCA.

CellAED® PROTECTIVE CASE

For personal, home, public, or office use, the CellAED® is stored inside a hard protective case **(Figure 1 (c), page 21)**. The back of the case details additional environmental and operational safety requirements, and features a tamper evident seal **(Figure 1 (b), page 21).** The CellAED® operational label (as seen through the transparent bag and front of the transparent protective case) provides clear and simple operational instructions to follow when a patient has suspected SCA **(Figure 1 (e), page 21)**.

Do not open this case until the CellAED® needs to be used to treat SCA.

The CellAED® is sealed in a transparent bag with 'Tear here' tabs **(Figure 2B, page 23)**. These should only be torn open when the CellAED® will be used.

Each CellAED® has a unique Serial Number (SN) **(Figure 5 (g), page 34).** Each CellAED® also has a Unique Device Identification number (UDI) **(Figure 4A (a), page 26)**. The UDI is the combination of the Global Trade Item Number (GTIN), the manufacturing date, the expiry date, the batch number and the unique serial number. These identification numbers are located beside (01), (11), (17), (10), and (21), respectively.

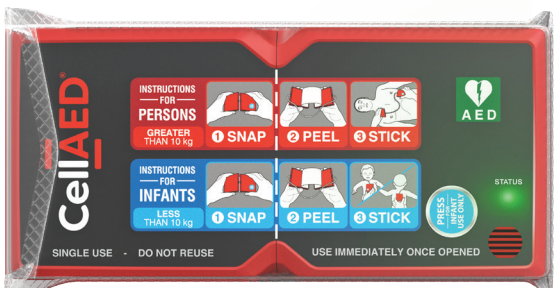


FIGURE 2A: CellAED® sealed transparent bag front

FIGURE 2B: CellAED® sealed transparent bag back

Images are representative only and may vary between regions

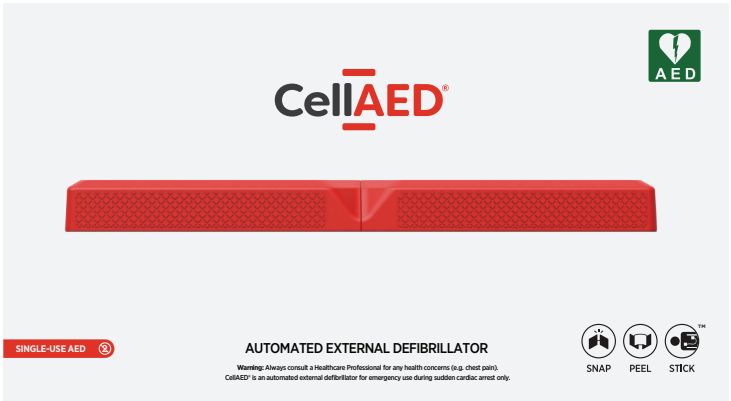


FIGURE 3A: CellAED® outer packaging front

Images are representative only and may vary between regions

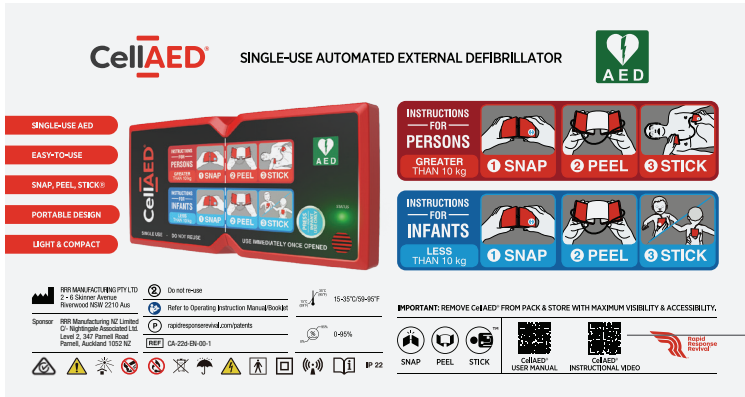


FIGURE 3B: CellAED® outer packaging back

Images are representative only and may vary between regions

FIGURE 4A: CellAED® protective case back & side

Images are representative only and may vary between regions

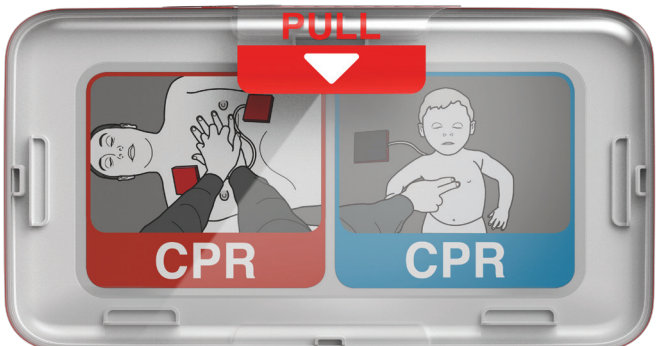


FIGURE 4B: CellAED® protective case inside

Images are representative only and may vary between regions

6.3 STORING THE CellAED®

CAUTION: Store the CellAED® out of reach of pets or children.

Store the CellAED® in its protective case in a location that is visible, easy to access, easy to remember, has good cellular connectivity and is free of obstacles. Avoid storing the CellAED® in areas that will expose the CellAED® to moisture, dust, or extreme temperatures. Consider locating the CellAED® near other emergency equipment, such as fire extinguishers and first-aid kits.

Position the CellAED® so that the LED Indicator **(Figure 5 (e), page 34)** on the front of the CellAED® is easy to see.

DANGER: Do not store or use the CellAED® near flammable gases (such as in an oxygen-enriched atmosphere) or in direct contact with flammable material. Store in a dry location away from any heat sources (including direct sunlight). Turn off local gas sources or move source away from patient during defibrillation. Failure to comply with any of these conditions presents a risk of explosion.

Although the CellAED® and electrodes are designed to withstand a range of temperatures, it is important to follow the recommended storage temperature as described in this manual. Failure to do so may result in damage to the CellAED® and improper operation.

WARNING: Extreme and fluctuating temperatures will reduce the life of the battery and electrodes contained within the CellAED®.

The CellAED® should be stored between 15° - 35°C (59° - 95°F). Temperatures exceeding 35°C (95°F) can permanently damage the internal battery.

6.4 MAINTAINING THE CellAED®

The CellAED® does not require routine maintenance.

Plan a monthly inspection of the CellAED® to:

1. Check the current date is within the CellAED® Use-by Date. If this date has passed, contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
2. Check the CellAED® packaging is in good condition; If damage, rips, cracks, discoloration, or foreign substances (e.g. oil, dirt or dust) are present, or if the tamper evident seal is compromised, contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

DANGER: Never use a compromised, damaged, expired, or pre-used CellAED®, as doing so may result in ineffective treatment or user injury.

DANGER: The CellAED® is a single-use device and cannot be re-used or recycled. If the packaging has been broken or damaged in any way, contact the manufacturer.

3. Observe the LED Indicator on the front of the CellAED® **(Figure 5 (e), page 34)**:
   - **A periodic flashing GREEN LED** (every 30 seconds) indicates that the CellAED® is fully operational and ready to use.
   - **A periodic flashing AMBER LED** (every 30 seconds) indicates that the battery is low and the CellAED® should be replaced immediately. Contact the manufacturer for a replacement.
   - **NO LED** indicates that the battery has expired and the CellAED® must be replaced immediately. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

   WARNING: Colourblind users may have difficulty differentiating between the GREEN and AMBER LEDs. Please seek assistance and be aware of the product's shelf life.

It is strongly recommended that useful items supporting the use of the CellAED® (towel, safety razor, and scissors) can be easily accessed.

Document your assessment in the Monthly Product Inspection Checklist included with the CellAED®:

HAVE YOU DONE YOUR 3 CHECKS?			
SN Serial Number:		Use-by Date*:	/ /

To complete the below checklist, simply start with present month and year and continue to check monthly until you reach the Use-by Date month.

YEAR	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec
20____												
20____												
20____												
20____												

SAMPLE

*CellAED® is a single-use, disposable product. Users must be aware of the Use-by Date to ensure your CellAED® is ready for use in an emergency situation. Highlight the month of expiry in the checklist with an asterisk.

DANGER: Damaged or expired equipment may result in ineffective treatment, or user injury.

The CellAED® may be damaged by mechanical or physical abuse, such as immersion in water or dropping the CellAED®. Avoid spilling any fluids on the CellAED® enclosure or its electrode pads. Do not clean with ketones or other flammable agents. In case of physical or mechanical abuse, contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

Do not attempt to service or modify the CellAED®. The CellAED® is not intended for maintenance or service by the user. Modification will void all warranties and present a serious risk of harm to the user and/or patient.

Maintaining ideal standby/storage environmental conditions (15° - 35°C (59° - 95°F)) is crucial to optimise the performance and maximise the shelf life of the CellAED®. Certain critical components, such as the battery and the electrode gel, can be influenced significantly by environmental conditions outside of the specifications of the CellAED®.

The CellAED® battery is non-rechargeable. As with all batteries, this battery will decay over time due to its natural self-discharge. Exposure to temperatures outside of the specifications of the CellAED® may permanently increase the self-discharge rate of the battery, which can ultimately lead to a significant reduction in the expected shelf life of the battery and the CellAED® accordingly.

Users are strongly encouraged to perform a regular inspection of their CellAED® and maintain a record. An example of an inspection record is also provided on page 29.

6.5 DISPOSING OF THE CellAED®

The CellAED® is designed to be single use and then disposed of as per the instructions from the manufacturer.

The CellAED® is non-rechargeable. When the battery is low, the LED will flash AMBER to indicate the need to replace the CellAED®. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

DANGER: The CellAED® battery is not rechargeable. Do not attempt to recharge, open, crush, or burn the battery, as these actions present a risk of explosion or fire and can cause harm to the user. If the battery is depleted, the CellAED® needs to be replaced. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

DANGER: Keep a snapped CellAED® out of the reach of children, as the cable presents a risk of strangulation. After use, contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

CAUTION: After the CellAED® has been used, is expired, is damaged, or you have doubts about the condition of the CellAED®, contact the manufacturer, who will provide instructions for the disposal of the CellAED®. Correct disposal procedure must be observed to ensure that no dangerous substances are released, which may adversely impact human and/or environmental health.

Return the CellAED® to an authorized distributor or the manufacturer to ensure that the correct disposal procedure is implemented.

WARRANTY: The Manufacturer provides a Warranty for the battery. For more details, please refer to **Section 4.7 (Terms of Warranty, page 17).**

The CellAED® is designed to enable minimally trained individuals to perform defibrillation in the event of SCA, prior to arrival of Emergency Services. The use of the CellAED® involves a three-step process, as illustrated in **Figure 5 (page 34)**:

1. SNAP - Snap the CellAED® to activate it.

2. PEEL - The user must peel the protective liner from the electrode gel pads.

3. STICK - The user places the electrode gel pads firmly on the patient.

The CellAED® can be used on patients weighing greater than 10 kg (22 lbs) and infants weighing less than 10 kg (22 lbs) (typically less than 1 year old). The electrode pads must be positioned appropriately (refer to **Section 7.1 and 7.2, page 32**). For infants weighing less than 10 kg (22 lbs), the CellAED® will deliver an adjusted treatment during defibrillation.

DANGER: The CellAED® has a differentiated use for infants weighing less than 10 kg (22 lbs). You must use the Infant Mode on infants weighing less than 10 kg (22 lbs). Failure to do so may result in ineffective treatment. Activate the CellAED® Infant Mode by pressing the Infant Mode Button when prompted by the audio (voice) prompts **(Figure 5 (d), page 34)** only for infants that weigh less than 10 kg (22 lbs), or typically less than 1 year old.

CAUTION: If an infant's age or weight is unknown, make a reasonable estimation. The World Health Organisation advises that an average 12-month (1 year) old infant weighs 10 kg (22 lbs), meaning that an infant younger than 1 year old can be assumed to be less than 10 kg (22 lbs) in weight.

7.1 PAD PLACEMENT AND CHEST COMPRESSION CPR DELIVERY FOR PATIENTS WEIGHING GREATER THAN 10 kg (22 lbs)

Both electrode pads are placed on exposed skin on the front of the patient. 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 **(Figure 9B, page 37).**

Chest compressions are delivered between shocks, with both hands placed on top of each other over the sternum (center of the chest) and are used to deliver chest compressions to a depth of no more than one third of the patient's chest cavity.

7.2 PAD PLACEMENT AND CHEST COMPRESSION CPR FOR INFANTS WEIGHING LESS THAN 10 kg (22 lbs)

For infants less than 10 kg (22 lbs), one of the CellAED® electrode gel pads is placed on the front of the chest between the nipples, and the other in the centre of the back **(Figure 14, page 42)**. For infants weighing less than 10 kg (22 lbs), remove the front chest pad, if applied, before delivering chest compressions. Chest compressions are delivered with two (2) fingers over the sternum (center of the chest) (refer to **Figure 12, page 41**) in between shocks. This is to control the pressure applied; the user must deliver chest compressions to a depth of no more than one third of the infant's chest cavity.

7.3 WHAT HAPPENS WHEN I ACTIVATE THE CellAED®?

The CellAED® label provides images that represent cues for action **(Figure 5, page 34)**.

i) The series of images at the top demonstrates the CellAED® Snap Peel Stick™ actions for a patient weighing greater than 10 kg (22 lbs). The series of images at the bottom demonstrates the CellAED® Snap Peel Stick™ actions for an infant weighing less than 10 kg (22 lbs).

ii) Once the CellAED® has been snapped apart into two parts along the perforated Label Mark for snapping **(Figure 5 (a), page 34)**, the audio (voice) prompts are activated to guide the user.

iii) The audio (voice) prompts instruct the user to apply the electrode pads for a patient weighing greater than 10 kg (22 lbs) or for an infant weighing less than 10 kg (22 lbs) **(Figure 5 (b) and (c), page 34)**. Peeling the lining from the bottom of the electrode pads enables the pads to be applied to the patient's skin.

iv) If the patient weighs less than 10 kg (22 lbs), press the infant button **(Figure 5 (d), page 34)** when prompted. Press the infant button a second time to confirm and enable Infant Mode when prompted.

v) If a shockable rhythm is detected, the CellAED® will start charging the electrodes for defibrillation. The red LED will turn on to indicate the CellAED® is charging, and the audio (voice) prompts notify the user not to touch the patient and to stand clear of the patient.

vi) The CellAED® uses audio (voice) prompts to advise the user when to perform chest compression CPR in between shocks, emits a metronome to guide the chest compression rate, and advises the user when to discontinue chest compression CPR. **Section 8, pages 44 - 49,** describes the audio (voice) prompt instructions and provides a step-by-step reference to using the CellAED®.

vii) The CellAED® defibrillation and audio (voice) prompt functions can be deactivated by pressing the gel sides of the electrode pads together for **at least five seconds** (refer to **Figures 16A and 16B, pages 46-49**).

DANGER: Do not remove the electrode pads from the patient during or after rhythm recognition, during charging, or while the shock is being delivered. The shocks delivered by the CellAED® can cause serious harm to user(s) or bystanders if the instructions are not followed.

WARNING: Do not handle or transport the patient while the CellAED® is attached to the patient and analysing the heart rhythm, as this can cause incorrect or delayed diagnosis. Keep the patient as still as possible while the CellAED® is attached.

WARNING: The CellAED® cannot abort a shock once a shockable rhythm has been detected. The CellAED® delivers up to 85 Joules of electrical energy with every electrical pulse (shock).

WARNING: Do not attempt to operate the CellAED® unless thoroughly familiar with this manual and the functions of all controls, indicators and of the electrode pads.

WARNING: Do not insert any object into the CellAED®.

WARNING: Do not place the electrode pads together when in use, as this may deactivate the CellAED® functions including audio (voice) prompts, heart rhythm detection and classification, capacitor charge and discharge, and render the CellAED® unusable.

(Continued page 34)

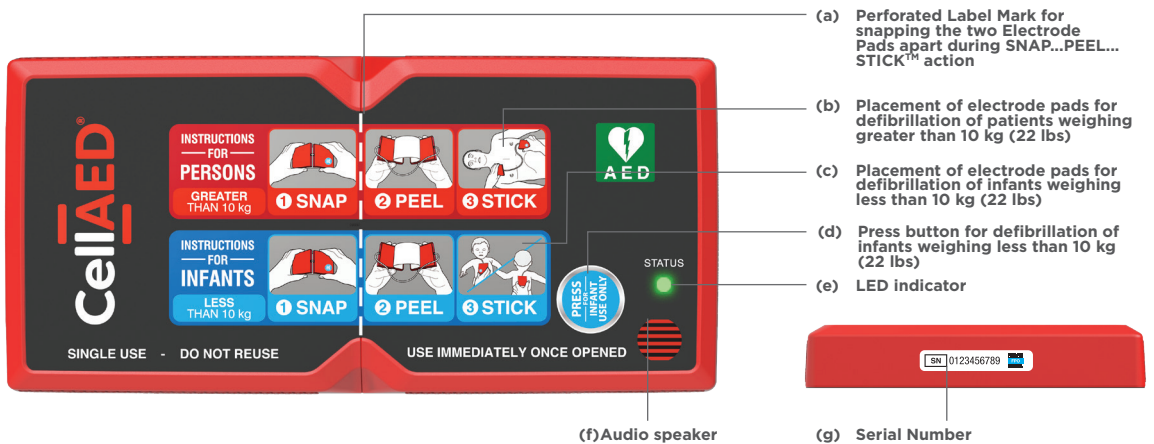


FIGURE 5: CellAED® enclosure with cues for action

Images are representative only and may vary between regions

7.4 RESPONDING TO A SUDDEN CARDIAC ARREST USING THE CellAED® ON A PATIENT WEIGHING GREATER THAN 10 kg (22 lbs)

STEP 1 ASSESS SAFETY OF LOCATION

Ensure that no obvious danger is present, and that the area is safe for you to provide chest compression CPR and administer the CellAED®.

DANGER: Do not use the CellAED® while the patient is in or is near a pool of water or on any other conductive surface(s). Carefully remove the patient if necessary. Ensure that the patient is dry before using the CellAED®.

STEP 2 DETERMINE WHETHER THE PATIENT IS IN SUDDEN CARDIAC ARREST

A patient in SCA is typically:

- Unconscious,
- Unresponsive when you talk to, shout at, touch, or gently shake them **(Figure 6, page 35)**, and
- Not breathing or taking occasional gasping breaths, accompanied by strange vocalizations and muscle spasms (agonal breathing).

FIGURE 6: Check if the patient is responsive

STEP 3 CALL EMERGENCY SERVICES IMMEDIATELY AND RETRIEVE THE CellAED®

If the patient is unconscious, unresponsive, and not breathing normally, or if you are unsure whether they are in SCA, call or have a bystander call Emergency Services. Send a bystander to retrieve the CellAED®, or if you are alone, retrieve the CellAED® before commencing chest compression CPR (for instructions, see STEP 4).

If the patient is between 1-8 years old, you are alone, and a telephone is not close by, commence chest compression CPR (for instructions, see STEP 4) for 1 minute (60 seconds), before retrieving a telephone and calling Emergency Services, and retrieving a CellAED®. Inform Emergency Services that you have a CellAED® and follow their instructions.

STEP 4 START CHEST COMPRESSION CPR

Start chest compression CPR to keep the patient's blood flowing. To perform chest compression CPR on a patient weighing greater than 10 kg (22 lbs) **(Figure 7, page 36)**, complete the following:

i) Place the heel of one hand over the sternum, in the centre of the patient's chest. Place your other hand on top of the first and interlock your fingers.

ii) Position yourself above the patient's chest.

iii) Keeping your arms straight, press straight down on their chest and deliver chest compressions of no more than one third of the patient's chest cavity.

iv) Release the pressure. Pressing down and releasing is 1 compression.

Perform chest compression CPR at a rate of 120 per minute (twice per second) for 1 minute (60 seconds).

(Continued page 36)

FIGURE 7: Chest compression CPR

STEP 5 **PREPARE THE PATIENT FOR TREATMENT WITH THE CellAED®**

The CellAED® has been designed for use on people who are unconscious, unresponsive, and who have ceased breathing or have abnormal (agonal) breathing associated with SCA.

DANGER: Do not store or use the CellAED® near flammable gases (such as in an oxygen-enriched atmosphere) or in direct contact with flammable material. Store in a dry location away from any heat sources (including direct sunlight). Turn off local gas sources or move source away from patient during defibrillation.

WARNING: The CellAED® should not be used if the patient is conscious, responsive, or breathing normally. No shockable rhythm will be detected and the CellAED® will not provide shocks. Call Emergency Services if symptoms of concern are present.

If you are unsure whether a sudden cardiac arrest is occurring, use the CellAED®.

If the patient remains unconscious, unresponsive, or not breathing normally after 60 seconds, obtain the CellAED® and prepare the patient for treatment.

- Remove clothing and jewellery and expose the patient's chest **(Figure 8, page 36)**. Cut through clothing with scissors if necessary.
- Shave any excessive hair in the areas where you will place the pads.
- If the chest is dirty or moist, wipe the chest with a towel to make the skin dry and clean for good pad contact.
- Remove any medicine patches on the patient's chest.
- Remove any electronic devices or equipment attached to the patient that do not feature the 'defibrillation-proof' mark.

WARNING: Certain materials making contact with the electrode pads during defibrillation can cause electrical sparks, skin burns, and divert electricity away from the heart. Do not allow the electrode pads to touch each other or any metal parts or objects (such as a bed frame or stretcher); medication patches; dressings; or any other material on the patient's chest or in contact with the patient.

- Continue to provide chest compression CPR.
- If possible, call for assistance as you prepare the CellAED® for use.

FIGURE 8: Expose chest for defibrillation

STEP 6 **REMOVE THE CellAED® FROM THE PACKAGING**

i) Open the tamper evident seal by lifting the red tab and peeling the red seal from the lateral edges of the protective case **(Figure 1, page 21)**

ii) Remove the sealed transparent bag and the CellAED®.

iii) Tear open the sealed transparent bag where the bag reads 'Tear here' and remove the CellAED® **(Figure 2B, page 23)**.

STEP 7 **DEFIBRILLATE USING THE CellAED®**

To activate the CellAED®, perform the Snap Peel Stick™ actions as shown in **Figure 9A, page 37**.

i) Hold the CellAED® with two hands with the label side facing up and side featuring 'THIS SIDE FACE DOWN' facing down.

ii) SNAP the CellAED® into two separate pads along the center line, by applying pressure downwards in a snapping or folding motion.

iii) This activates the CellAED® to deliver audio (voice) prompts **(Section 8, pages 44 - 49)** to guide you in using the CellAED®.

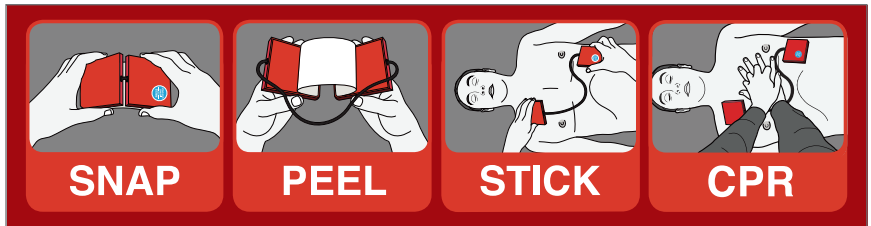


FIGURE 9A: Instructions for patients weighing greater than 10 kg (22 lbs)

iv) 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.

v) Fully extend the cable connecting the two pads.

vi) 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 **(Figure 9B, page 37)**. Press firmly so that the entire pad adheres to the patient's skin.

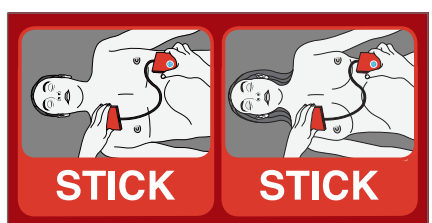


FIGURE 9B: STICK placement for adult males & females

(Continued page 38)

DANGER: Correct pad placement and good pad contact with the skin is critical (refer to **Figure 9A, page 37** for patients weighing greater than 10 kg (22lbs)).

WARNING: Air pockets between the skin and electrode pads can cause ineffective treatment. Make sure electrode pads are completely adhered to the skin. If necessary and possible, shave hair from the area to ensure good contact. Do not use damaged, expired, or dried out electrode pads.

vii) If the patient has a pacemaker (indicated by a raised bump under their skin), position the pads at least 2.5 cm (1") from the device.

WARNING: If a patient has a pacemaker, never stick an electrode pad over the pacemaker, as it may reduce the accuracy of analysis, generate errors in detecting shockable rhythms, and result in ineffective treatment.

viii) Follow the audio (voice) prompt instructions as directed and do not touch the patient unless instructed to do so.

If the CellAED® 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 red LED is illuminated. The CellAED® will advise when to commence chest compression CPR.

DANGER: Do not remove the electrode pads from the patient during or after rhythm recognition, during charging, or while the shock is being delivered. The shocks delivered by the CellAED® can cause serious harm to user(s) or bystanders if the instructions are not followed.

WARNING: The CellAED® cannot abort a shock once a shockable rhythm has been detected. The CellAED® delivers up to 85 Joules of electrical energy with every electrical pulse (shock).

WARNING: The energy emitted by the CellAED® can be conducted through the patient or conductive matter touching the patient. Therefore:

- Do not touch the patient, electrode pads, metal objects such as a bedframe or stretcher in contact with the patient, or any other material in contact with the patient while the shock is being delivered. These shocks can cause serious harm to user(s) or bystanders if the instructions are not followed.
- Do not use the CellAED® when the patient is in or is near a pool of water or on any other conductive surface(s). Carefully remove the patient if necessary. Ensure the patient is dry before using the CellAED®.

Deliver chest compression CPR when instructed by the audio (voice) prompts. The CellAED® will issue an audio mentronome to guide the user in providing chest compressions at the correct rate (120 per minute). Continue chest compression CPR until:

- The patient recovers and is breathing normally, or
- Qualified medical help is ready to take over, or
- A healthcare professional instructs you to stop, or
- It is physically impossible to continue, or
- The CellAED® advises the user to stop chest compression CPR.

If the patient starts moving, coughing, or breathing regularly, place the patient in the recovery position **(Figure 10, page 39)** and keep them as still as possible until Emergency Services arrive.

DANGER: Pregnant women must be lain on their left side in the recovery position.

CAUTION: Temporary redness of the skin may occur where the electrodes were attached. This is not concerning unless the patient experiences pain, in which case inform the patient's healthcare provider so that the patient can receive the appropriate care.

When finished using the CellAED®, stick the gel side of the pads together **for at least five seconds**. This will deactivate the CellAED® defibrillation functions and audio (voice) prompts.

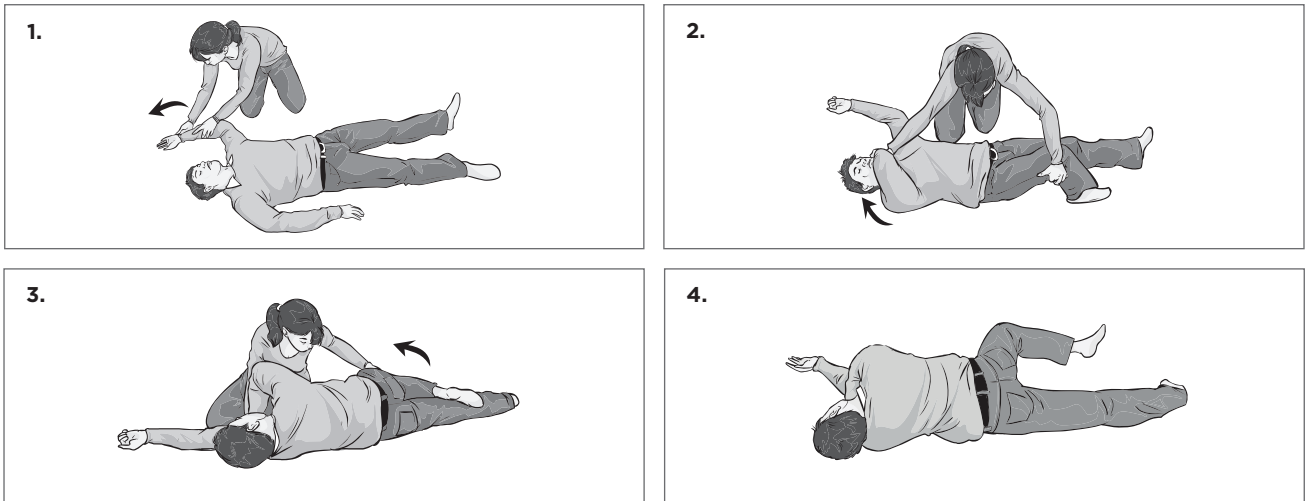


FIGURE 10: Move patient into recovery position

(Continued page 40)

7.5 RESPONDING TO A SUDDEN CARDIAC ARREST USING THE CellAED® ON AN INFANT WEIGHING LESS THAN 10 kg (22 lbs)

DANGER: Infant Mode can only be enabled at the correct time. See **Step 7, page 42.**

STEP 1 ASSESS SAFETY OF LOCATION

Ensure that no obvious danger is present, and that the area is safe for you to provide chest compression CPR and administer the CellAED®.

DANGER: Do not use the CellAED® while the infant is in or is near a pool of water or on any other conductive surface(s). Carefully remove the infant if necessary. Ensure that the infant is dry before using the CellAED®.

STEP 2 DETERMINE WHETHER THE INFANT IS IN SUDDEN CARDIAC ARREST

An infant in SCA is typically:

- Unconscious,
- Unresponsive when you talk to, touch, or tickle their feet/under their arms **(Figure 11, page 41)**, and
- Not breathing or taking occasional gasping breaths, accompanied by strange vocalizations and muscle spasms (agonal breathing).

STEP 3 CALL EMERGENCY SERVICES AND RETRIEVE THE CellAED®

If the infant is unconscious, unresponsive, and not breathing normally, or if you are unsure whether they are in SCA, remain with the infant and call or have a bystander call Emergency Services. Send a bystander to retrieve the CellAED®. Inform Emergency Services that you have an automated external defibrillator (AED) and follow their instructions.

If you are alone, and a telephone is not close by, commence chest compression CPR (for instructions, see STEP 4) for 1 minute (60 seconds), before retrieving a telephone and calling Emergency Services, and retrieving a CellAED®. Inform Emergency Services that you have an automated external defibrillator (AED) and follow their instructions.

STEP 4 START CHEST COMPRESSION CPR

Start chest compression CPR to keep the infant's blood flowing. To perform chest compression CPR on an infant weighing less than 10 kg (22 lbs) **(Figure 12, page 41)**, complete the following:

i) Place 2 fingers over the sternum, in the centre of the patient's chest.

ii) Press straight down on their chest and deliver chest compressions of no more than one third of the infant's chest cavity.

iii) Release the pressure. Pressing down and releasing is 1 compression.

Perform 5 chest compression CPR and check for breathing **(Figure 12, page 41)**. If the infant remains unresponsive and not breathing normally, commence chest compression CPR at a rate of 120 per minute (twice per second) for 1 minute (60 seconds).

STEP 5 PREPARE THE INFANT FOR TREATMENT WITH THE CellAED®

The CellAED® has been designed for use on people who are unresponsive and unconscious, and who have ceased breathing or have abnormal (agonal) breathing associated with SCA.

DANGER: Do not store or use the CellAED® near flammable gases (such as in an oxygen-enriched atmosphere) or in direct contact with flammable material. Store in a dry location away from any heat sources

(including direct sunlight). Turn off local gas sources or move source away from patient during defibrillation.

WARNING: The CellAED® should not be used if the infant is conscious, responsive, or breathing normally. No shockable rhythm will be detected and the CellAED® will not provide shocks. Call Emergency Services if symptoms of concern are present.

If you are unsure whether a sudden cardiac arrest is occurring, use the CellAED®.

If the infant remains unconscious, unresponsive, or not breathing normally after 60 seconds, obtain the CellAED® and prepare the infant for treatment.

- Remove clothing and jewellery and expose the infant's chest **(Figure 13, page 41)**. Cut through clothing with scissors if necessary.
- If the chest is dirty or moist, wipe the chest with a towel to make the skin dry and clean for good pad contact.
- Remove any medicine patches on the infant's chest.
- Remove any electronic devices or equipment attached to the patient that do not feature the 'defibrillation-proof' mark.

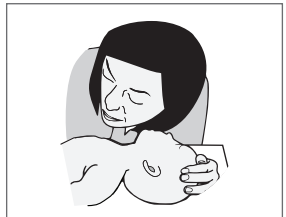


FIGURE 11: Check if infant is responsive or normal breathing

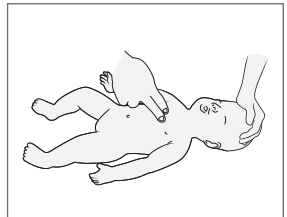


FIGURE 12: Chest compression

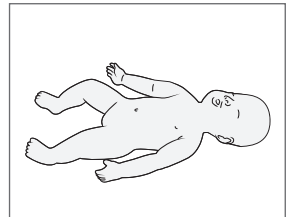


FIGURE 13: Expose chest for defibrillation

WARNING: Certain materials making contact with the electrode pads during defibrillation can cause electrical sparks, skin burns, and divert electricity away from the heart. Do not allow the electrode pads to touch each other or any metal parts or objects (such as a bed frame or stretcher); medication patches; dressings; or any other material on the patient's chest or in contact with the patient.

- Continue to provide chest compression CPR.
- If possible, call for assistance as you prepare the CellAED® for use.

STEP 6 **REMOVE THE CellAED® FROM THE PACKAGING**

i) Open the tamper evident seal by lifting the red tab and peeling the red seal from the lateral edges of the protective case **(Figure 1, page 21)**.

ii) Remove the sealed transparent bag and the CellAED®.

iii) Tear open the sealed transparent bag where the bag reads 'Tear here' and remove the CellAED® **(Figure 2, page 23)**.

(Continued page 42)

STEP 7 **DEFIBRILLATE USING THE CellAED®**

To activate the CellAED®, perform the Snap Peel Stick™ actions **(Figure 14, page 42)**.

i) Hold the CellAED® with two hands with the label side facing up and side featuring 'THIS SIDE FACE DOWN' facing down.

ii) SNAP the CellAED® into two separate pads along the center line, by applying pressure downwards in a snapping or folding motion.

iii) This activates the CellAED® to deliver audio (voice) prompts **(Section 8, pages 44 - 49)** to guide you in using the CellAED®.

iv) 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 infant.

v) Fully extend the cable connecting the two pads.

vi) STICK the pad featuring the blue Infant Mode button firmly onto the infant's exposed skin on the chest between the nipples **(Figure 14, page 42)**. Press firmly so that the entire pad adheres to the infant's skin.

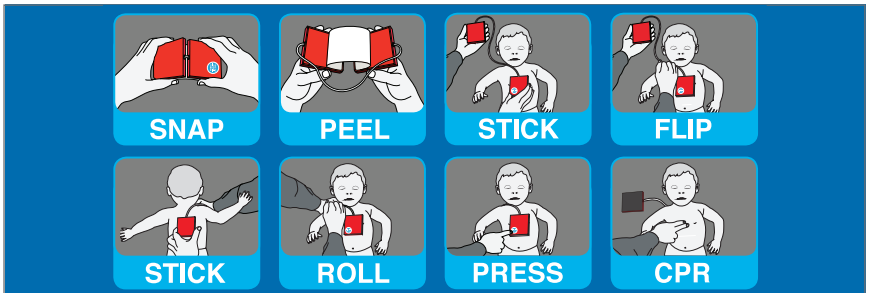


FIGURE 14: Instructions for infants less than 10 kg (22 lbs)

vii) Grasp the infant's shoulder to roll them onto their front, supporting their head where necessary, and STICK the other pad firmly to their back in the center. Press firmly so that the entire pad adheres to the infant's skin and roll them back onto their back.

DANGER: Correct pad placement and good pad contact with the skin is critical (refer to **Figure 14, page 42** for Infants weighing less than 10 kg (22 lbs)).

WARNING: Air pockets between the skin and electrode pads can cause ineffective treatment. Make sure electrode pads are completely adhered to the skin. Do not use damaged, expired, or dried out electrode pads.

viii) When prompted, press the infant button. Press the infant button a second time to confirm and enable INFANT MODE.

ix) Follow the audio (voice) prompt instructions as directed and do not touch the infant unless instructed to do so.

If the CellAED® heart rhythm analysis determines that a shock is needed, the audio (voice) prompt 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 red LED is illuminated. The CellAED® will advise when to commence chest compression CPR.

DANGER: Do not remove the electrode pads from the patient during or after rhythm recognition, during charging, or while the shock is being delivered. The shocks delivered by the CellAED® can cause serious harm to user(s) or bystanders if the instructions are not followed.

WARNING: The CellAED® cannot abort a shock once a shockable rhythm has been detected. The CellAED® delivers up to 45 Joules of electrical energy in Infant Mode with every electrical pulse (shock).

WARNING: The energy emitted by the CellAED® can be conducted through the patient or conductive matter touching the patient. Therefore:

- Do not touch the patient, electrode pads, metal objects such as a bedframe or stretcher in contact with the patient, or any other material in contact with the patient while the shock is being delivered. These shocks can cause serious harm to user(s) or bystanders if the instructions are not followed.
- Do not use the CellAED® when the patient is in or is near a pool of water or on any other conductive surface(s). Carefully remove the patient if necessary. Ensure the patient is dry before using the CellAED®.

When the audio (voice) prompts to begin chest compression CPR is heard, remove the front electrode pad and set aside carefully. The CellAED® 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®.

Continue chest compression CPR until:

- The infant recovers and is breathing normally, or
- Qualified medical help is ready to take over, or
- A healthcare professional instructs you to stop, or
- It is physically impossible to continue.
- The CellAED® advises the user to stop chest compression CPR.

If the infant starts moving, coughing, or breathing regularly, place the infant in the recovery position **(Figure 15, page 43)** and keep them as still as possible until Emergency Services arrive.

CAUTION: Temporary redness of the skin may occur where the electrodes were attached. This is not concerning unless the infant experiences pain, in which case inform the infant's healthcare provider so that the infant can receive the appropriate care.

When finished using the CellAED®, stick the gel side of the pads together **for at least five seconds**. This will deactivate the CellAED® defibrillation functions and audio (voice) prompts.

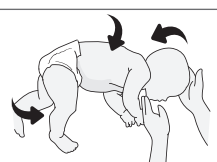


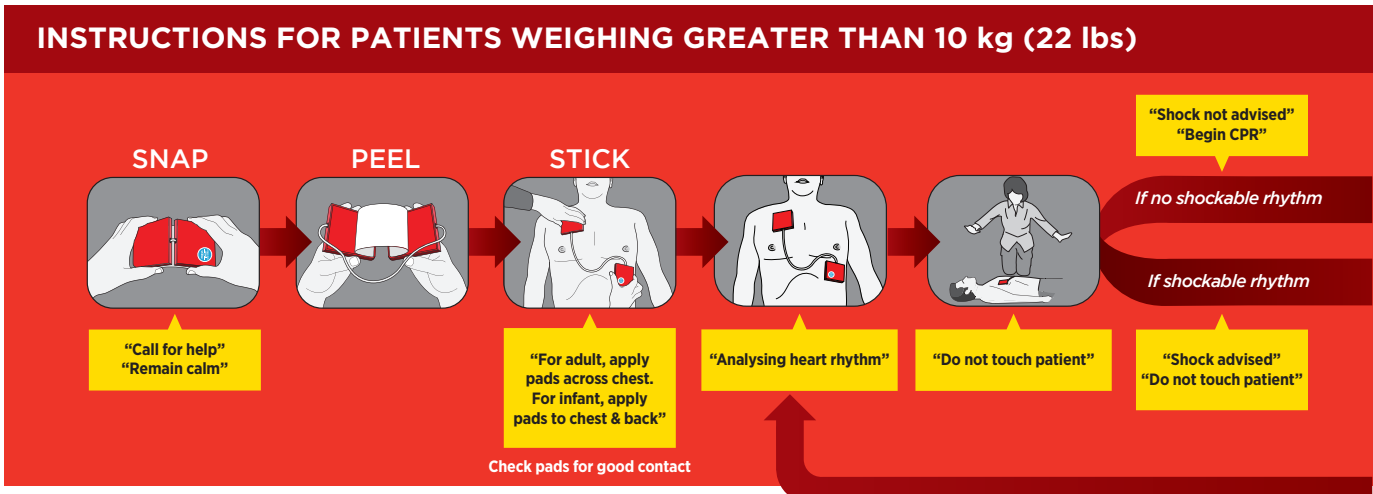
FIGURE 15: Infant recovery position

08 VOICE PROMPT INSTRUCTIONS

AUDIO (VOICE) PROMPT INSTRUCTIONS	
CALL FOR HELP. REMAIN CALM.	Call your local emergency services, or if possible, have a bystander call the local emergency services. Remain calm.
FOR ADULT, APPLY PADS ACROSS CHEST. FOR INFANT, APPLY PADS TO CHEST AND BACK.	Apply the electrode pads as instructed. Be prepared beforehand to place the electrode pads correctly. Take note of the difference between patients weighing greater than 10 kg (22 lbs) (both pads applied to the chest) and infants weighing less than 10 kg (22lbs) (one pad applied to the chest and one applied to the back) (refer to **Figure 9A (page 37)** for patients weighing greater than 10 kg (22lbs) and **Figure 14 (page 42)** for infants weighing less than 10 kg (22lbs)).
FOR INFANTS, PRESS INFANT BUTTON	For infants weighing less than 10 kg (22 lbs) (typically less than 1 year old), press the infant button **(Figure 5(d), page 34)** within 10 seconds of this audio (voice) prompt to provide the correct therapy. If the button is not pressed, the audio (voice) prompt is repeated once. Failure to use the correct setting may result in harm to the patient and/or ineffective treatment.
PRESS INFANT BUTTON TO CONFIRM INFANT MODE	For infants weighing less than 10 kg (22 lbs) (typically less than 1 year old), press the infant button **(Figure 5(d), page 34)** within 5 seconds of this audio (voice) prompt to confirm and enable Infant Mode. Failure to use the correct setting may result in harm to the patient and/or ineffective treatment.
INFANT MODE ENABLED	Infant Mode has been enabled. The CellAED® will automatically adjust its therapy. No operator or user action is required.
ANALYSING HEART RHYTHM	The CellAED® has begun automatically analysing the patient's heart rhythm. Do not touch the patient during the analysis.
DO NOT TOUCH PATIENT	Remove all contact of yourself and anyone else touching any part of the patient. Failure to do so may result in ineffective treatment and/or harm to the operator or patient.

SHOCK NOT ADVISED	The CellAED® has not detected a shockable rhythm (VF or VT). No operator or user action is required.
SHOCK ADVISED	The CellAED® has detected a shockable rhythm (VF or VT) and the CellAED® is preparing to defibrillate the patient. The red LED will turn on to indicate the CellAED® is charging. Do not touch the patient during this time.
STAND CLEAR FOR SHOCK	Remove all contact of yourself and anyone else touching any part of the patient. Failure to do so may result in ineffective treatment and/or harm to the operator or patient.
SHOCK DELIVERED	The CellAED® has discharged an electric shock to the patient. No operator or user action is required.
BEGIN CPR	Immediately begin chest compression CPR at the rate provided by the audio metronome. For instructions on performing chest compression CPR on patients weighing greater than 10 kg (22 lbs), see **Section 7.4, Step 4, page 35**. For instructions on performing chest compression CPR on infants weighing less than 10 kg (22 lbs), see **Section 7.5, Step 4, page 40**.
CONTINUE CPR	Continue chest compression CPR at the rate provided by the audio metronome.
STOP CPR	Stop performing chest compression CPR.
DEVICE DEACTIVATED	The CellAED® has been deactivated. Carefully set aside. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

FIGURE 16A: Step-by-Step CellAED® Audio instructions (Patients weighing greater than 10 kg (22 lbs))



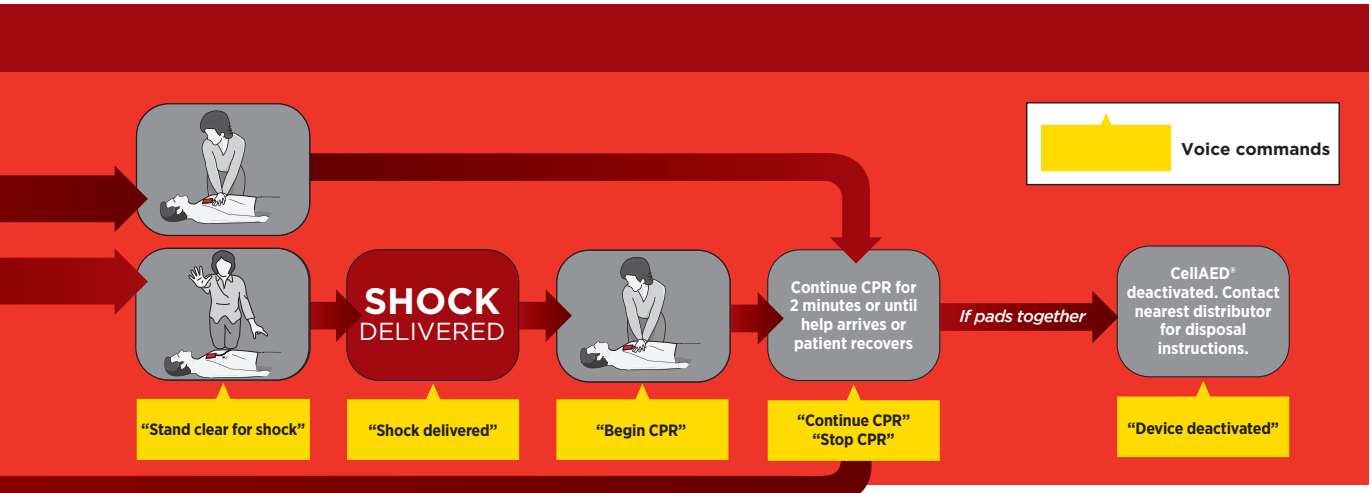
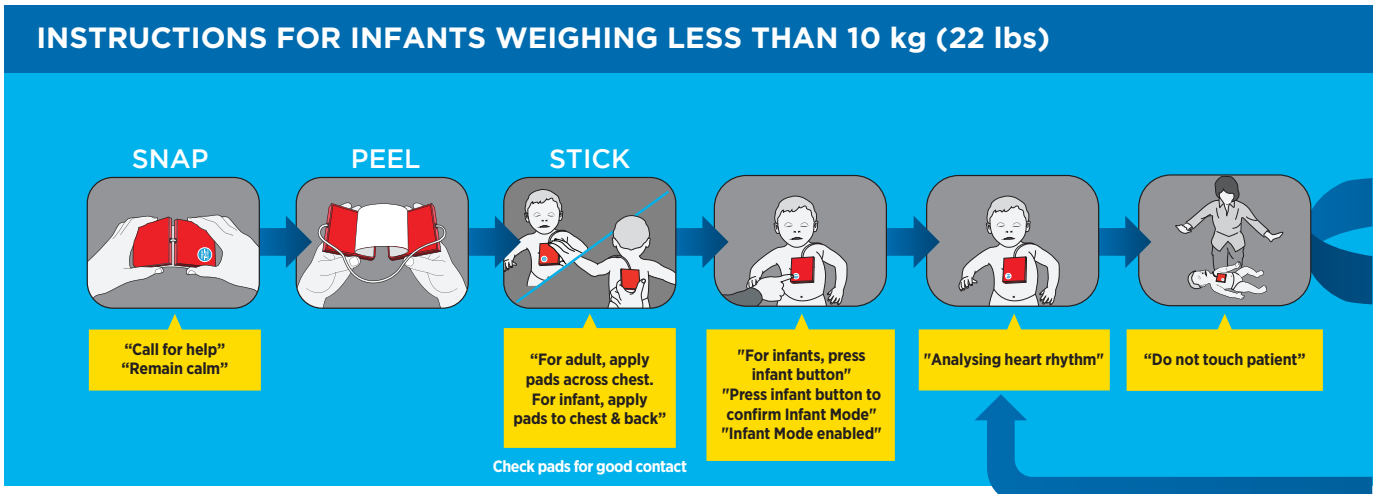
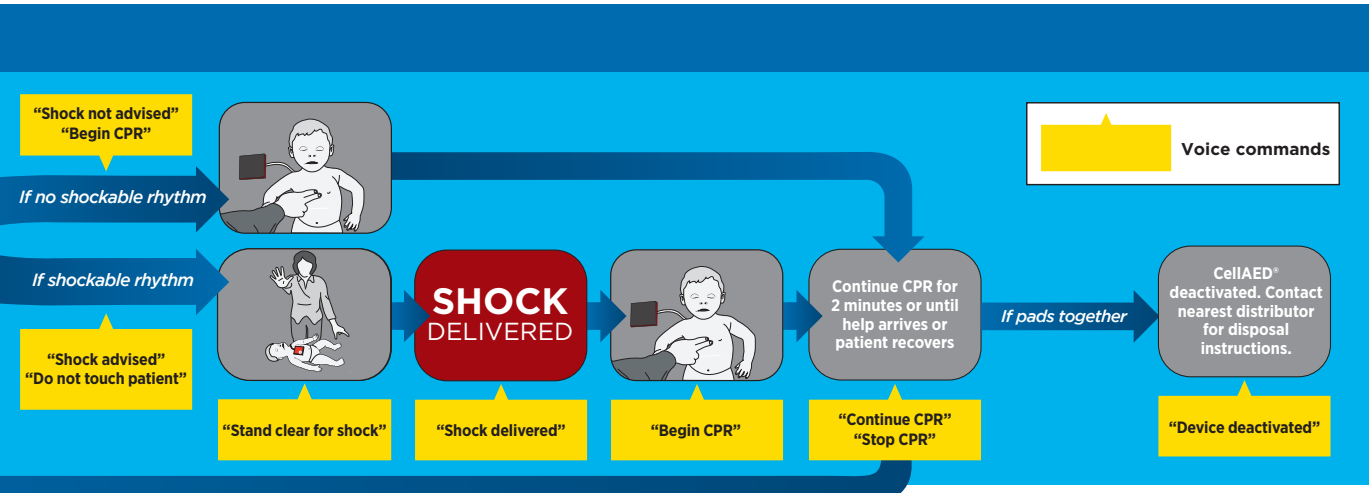

Voice commands
SHOCK
DELIVERED
Continue CPR for 2 minutes or until help arrives or patient recovers
If pads together
CellAED® deactivated. Contact nearest distributor for disposal instructions.
"Stand clear for shock"
"Shock delivered"
"Begin CPR"
"Continue CPR"
"Stop CPR"
"Device deactivated"

FIGURE 16B: Step-by-Step CellAED® Audio instructions (Infants weighing less than 10 kg (22 lbs))




"Shock not advised"
"Begin CPR"
If no shockable rhythm
If shockable rhythm
"Shock advised"
"Do not touch patient"
"Stand clear for shock"
SHOCK
DELIVERED
"Shock delivered"
"Begin CPR"
Continue CPR for 2 minutes or until help arrives or patient recovers
"Continue CPR"
"Stop CPR"
If pads together
CellAED® deactivated. Contact nearest distributor for disposal instructions.
"Device deactivated"
Voice commands

09 TROUBLESHOOTING

This Section explains problems you may encounter while using the CellAED®, its possible causes and what you should do in such an event. Immediately inform the manufacturer directly or through an authorised dealer about any malfunction of a CellAED®.

PROBLEM	POSSIBLE CAUSES	WHAT TO DO
The CellAED® does not activate or charge	Battery depleted	Administer chest compression CPR if the patient is not responding, not breathing normally, or not moving, until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
There is no LED status	Battery depleted CellAED® expired CellAED® is non-functional	Administer chest compression CPR if the patient is not responding, not breathing normally, or not moving, until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
Peeling or damaged sealed transparent bag on visual inspection	Expired CellAED® Damaged CellAED®	Administer chest compression CPR if the patient is not responding, not breathing normally, or not moving, until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
Cable is not extended completely	Cable stuck in enclosure	Pull the pads directly apart using mild force.

PROBLEM	POSSIBLE CAUSES	WHAT TO DO
Electrode pads are not adhering to the patient	Poor surface preparation Electrode pads expired	Clean, shave, and dry the patient's skin. Firmly press the pads on the patient's bare skin. Ensure that the entire pad adheres to the patient's skin. If poor detection persists, administer chest compression CPR if the patient is not responding, not breathing normally, or not moving until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
Audio (voice) prompt to apply pads to patient is continuing, after the operator has applied pads to patient	Poor pad contact to patient Poor surface preparation	Clean, shave, and dry the patient's skin. Firmly press the pads on the patient's bare skin. Ensure that the entire pad adheres to the patient's skin. If poor detection persists, administer chest compression CPR if the patient is not responding, not breathing normally, or not moving until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
Audio (voice) prompts sound faint or distorted	Speaker is covered Speaker failure Battery low CellAED® expired	If the Red LED is ON, do not touch patient and stand clear for shock as CellAED® will deliver an electric shock automatically. Ensure that the location of the speaker is not covered, which could muffle or dampen the audio (voice) prompts. If there is no improvement, administer chest compression CPR if the patient is not responding, not breathing normally, or not moving, until Emergency Services arrive. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

10.1 TECHNICAL TERMINOLOGIES/ACRONYMS

TERMINOLOGY/ ACRONYMS	DESCRIPTION
ABS	Acrylonitrile Butadiene Styrene
EIRP	Effective Isotropic Radiated Power
EMI	Electromagnetic Interference
EMS	Emergency Medical Services
ESD	Electrostatic Discharge
IEC	International Electrotechnical Commission
Impedance	Resistance to the flow of electrical current
IP	Ingress Protection
ISO	International Organization for Standardisation
ISTA	International Safe Transit Association
Joule (J)	The basic unit of energy delivered by a defibrillator. The amount of energy delivered during defibrillation in Watt-seconds
MIL-STD	Military Standard
RF	Radio Frequency
RFI	Radio Frequency Interference
SAR	Specific Absorption Rate

10.2 TECHNICAL CHARACTERISTICS AND SPECIFICATIONS

GENERAL SPECIFICATIONS	
ENCLOSURE	ABS/Polycarbonate fire retardant blend
DIMENSIONS (W X D X H)	196 mm x 93 mm x 17 mm
WEIGHT	Approximately 300 g
BATTERY	Non-rechargeable Lithium
FIRMWARE VERSION	1.x

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
TIME TO MAXIMUM ENERGY SHOCK AFTER ACTIVATION	< 50 seconds

(Continued page 54)

CLASSIFICATION OF MEDICAL ELECTRICAL EQUIPMENT	
EQUIPMENT CLASSIFICATION	Class II Internally Powered Type BF medical device
CONFORMITY (EU)	Council Directive 93/42/EEC, Radio Equipment Directive 2014/53/EU, RoHS Directive 2011/65/EU, WEEE Directive 2012/19/EU
CONFORMITY (AU)	Therapeutic Goods (Medical Devices) Regulations 2002, (AU) Telecommunications Act 1997
CONFORMITY (NZ)	Medicines Regulations 1984, (NZ) Telecommunications Act 2001, RoHS Directive 2011/65/EU
CONFORMITY (UK)	The Medical Devices Regulations 2002, UK Radio Equipment Regulations 2017, The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012, The Waste Electric and Electronic Equipment (WEEE) Regulations 2013
CellAED® INGRESS PROTECTION	IP 22
MODE OF OPERATION	Continuous, infrequent single event use only
ELECTRODE SPECIFICATIONS	
ELECTRICAL CONNECTING CABLE	1 m, 28 AWG
CONTACT AREA	Total combined area: 166 cm^2
ELECTRODE MATERIAL	Hydrogel
ELECTRODE DIMENSIONS	9 cm x 9.25 cm
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		
SHOCK/DROP/VIBRATION	Transit Operable, Portable Device (EN 60601-1-11:2015, EN 60601-1-6:2010+A1:2015)		
ESD/EMI (radiated and immunity)	See electromagnetic conformity tables **(Section 10.5, pages 58-61)**		
CELLULAR SPECIFICATIONS	**2G**	**3G (≤ SERIAL NUMBER 0000023640)**	**LTE Cat-M1† (≥ Serial Number: 0000023641)**
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
STANDARDS COMPLIANCE			
MEDICAL DEVICE	IEC 60601-2-4:2010+AMD1:2018, EN 60601-2-4:2011/A1:2019, IEC 60601-1-11:2015 & EN 60601-1-11:2015		
SYMBOLS	ISO 15223-1; UL61010		
RESTRICTION OF HAZARDOUS SUBSTANCE DIRECTIVE (RoHS)	EU Directive 2011/65/EU		
ESD/EMI	EN 60601-1-2:2015, EN 60601-2-4:2011+A1:2019, CISPR 11 Group 1 Class B, EN 61000-4-2 Severity Level 4 (Open air discharges up to 8 kV or Direct/Indirect contact discharges up to 6 kV)		
BIOCOMPATIBILITY	EN ISO 10993-1:2020		
TRANSPORTATION	ANSI ISTA Procedure 3A		

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

10.3 BIPHASIC EXPONENTIAL WAVEFORM

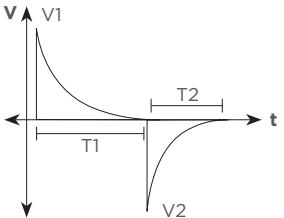
PATIENT WEIGHING GREATER THAN 10 kg (22 lbs)

IMPEDANCE (Ω)	ENERGY (J)	V_1 (V)	PEAK I_1 (A)	T_1 (ms)	V_2 (V)	PEAK I_2 (A)	T_2 (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)	V_1 (V)	PEAK I_1 (A)	T_1 (ms)	V_2 (V)	PEAK I_2 (A)	T_2 (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 shown above.



V = Voltage t = Time

The waveform is automatically adjusted to compensate for patient impedance.

The CellAED® does not detect patient motion.

PERFORMANCE	
WAVEFORM	Equal leading-edge Biphasic Exponential
ENERGY OUTPUT & DELIVERY	Up to 85 Joules
RESISTANCE MEASUREMENT	25 to 175 Ohms, non-inductive (<2uH)
2-MINUTE STANDARD CPR	AMA standards
SHOCK DELIVERY	Fully Automatic
AUDIBLE VOICE PROMPTS	Up to 16 unique messages
AUDIO VOLUME	75 dBA

10.4 ECG INTERPRETATION AND PERFORMANCE

When placed on a patient meeting the indication for use criteria, the 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.

SENSITIVITY AND SPECIFICITY OF RHYTHM RECOGNITION DETECTOR	
Shockable Rhythm – VF	Meets IEC/EN 60601-2-4 requirement Sensitivity > 90%
Shockable Rhythm – VT	Meets IEC/EN 60601-2-4 requirement Sensitivity > 75%
Non-shockable Rhythm – Normal Sinus Rhythm	Meets IEC/EN 60601-2-4 requirement Specificity > 95%
Non-shockable Rhythm – Asystole	Meets IEC/EN 60601-2-4 requirement Specificity > 95%
Non-shockable Rhythm – all other rhythms	Meets IEC/EN 60601-2-4 requirement Specificity > 95%

The patient's transthoracic impedance is measured through the defibrillation electrode pads. If the baseline impedance is higher than 175 ohms, 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.

10.5 GUIDANCE AND MANUFACTURER'S DECLARATION – ELECTROMAGNETIC EMISSIONS AND IMMUNITY

10.5.1 ELECTROMAGNETIC EMISSIONS (IEC 60601-1-2:2014/EN 60601-1-2:2015 TABLE 201)

The CellAED® is intended for use in the electromagnetic environment specified below. The users must ensure that it is used in such an environment.

EMISSIONS TEST	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT
RF emissions CISPR 11	Group 1 Class B	The RF emissions of the CellAED® are unlikely to cause any interference in nearby electronic equipment. The 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.

10.5.2 ELECTROMAGNETIC IMMUNITY (IEC 60601-1-2:2014/EN 60601-1-2:2015 TABLE 202)

The CellAED® is intended for use in the electromagnetic environment specified below. The users must ensure that it is used in such an environment.

IMMUNITY TEST	IEC 60601-1-2:2014/EN 60601-1-2:2015 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT
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	±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 IEC 61000-4-8:2009/EN 61000-4-8:2009	30 A/m 50Hz	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.

(Continued page 60)

IMMUNITY TEST	IEC 60601-1-2:2014/EN 60601-1-2:2015 TEST LEVEL	COMPLIANCE LEVEL	ELECTROMAGNETIC ENVIRONMENT
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.

 (Continued page 61)

Note 1: At 80MHz 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 ISM (Industrial, Scientific and medical) bands between 150 kHz and 80 kHz 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 (Industrial, Scientific and Medical) 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 the CellAED® is used exceeds the applicable RF compliance level above, the 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.

10.6 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)

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

SEPARATION DISTANCE ACCORDING TO FREQUENCY OF TRANSMITTER (M)				
RATED MAXIMUM OUTPUT POWER OF TRANSMITTER	**150 KHZ TO 80 MHZ OUTSIDE ISM BANDS**	**150 KHZ TO 80 MHZ IN ISM BANDS**	**80 KHZ 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 MHz 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.

11 DANGERS, WARNINGS AND CAUTIONS

It is important to understand how to use the CellAED® safely. Please read the following danger, warning and caution notices carefully.

Danger describes hazards that could result in immediate serious personal injury or death to the user and/or the patient.

Warning describes hazards or unsafe practices that could result in serious personal injury or death to the user and/or the patient.

Caution describes hazards or unsafe practices that could result in minor personal injury to the user and/or the patient, product damage, or property damage.

If any serious incidents occur, please contact the relevant representative organization for your region (See Section 12, Page 69)

DANGERS	
Flammable gas	Do not store or use the CellAED® near flammable gases (such as in an oxygen-enriched atmosphere) or in direct contact with flammable material. Store in a dry location away from any heat sources (including direct sunlight). Turn off local gas sources or move source away from patient during defibrillation. Failure to comply with any of these conditions may present an explosion risk.
Battery	The CellAED® battery is not rechargeable. Do not attempt to recharge, open, crush, or burn the battery, as this may create an explosion risk or fire hazard and cause harm to the user. If the battery is depleted, the CellAED® needs to be replaced. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
Fluids	Avoid spilling any fluids on the CellAED® enclosure or its electrode pads. Do not clean the CellAED® with ketones or other flammable agents.
Use of the CellAED®	Do not attempt to operate the CellAED® unless thoroughly familiar with this manual and the functions of all controls, indicators and of the electrode pads. Users must ensure that they have read and understand the user manual before use. Use the CellAED® exactly as described in this manual.

Use of the CellAED®	Infant Mode can only be enabled at the correct time. Once Infant Mode is enabled, it cannot be reversed into Adult Mode.
	The CellAED® has a differentiated use for infants weighing less than 10 kg (22 lbs). You must use Infant Mode for an infant weighing less than 10 kg (22 lbs). Failure to do so may result in ineffective treatment.
	When using the CellAED® in Infant Mode and removing the front electrode pad to begin chest compression CPR, 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®.
	Correct pad placement and good pad contact with the skin is critical.
	Do not remove the electrode pads from the patient during or after rhythm recognition, during charging, or while the shock is being delivered. The shocks delivered by the CellAED® can cause serious harm to user(s) or bystanders if the instructions are not followed.
	Do not touch the pads to each other outside of deactivation protocol, as this may damage the electrodes. Do not stick the electrode pad to any object.
Patient handling	The energy emitted by the CellAED® can be conducted through the patient or conductive matter touching the patient. Therefore: • Do not touch the patient, electrode pads, metal objects such as a bedframe or stretcher in contact with the patient, or any other material in contact with the patient while the shock is being delivered. These shocks can cause serious harm to user(s) or bystanders if the instructions are not followed. • Do not use the CellAED® when the patient is in or is near a pool of water or on any other conductive surface(s). Carefully remove the patient if necessary. Ensure the patient is dry before using the CellAED®.
	Pregnant women must be lain on their left side in the recovery position.
Children	Keep a snapped CellAED® out of the reach of children as the cable presents a risk of strangulation. After use, contact the manufacturer for a replacement and instructions to dispose of the CellAED®.

Modification of the CellAED®	Do not attempt to service or modify the CellAED®. The CellAED® is not intended for maintenance or service by the user. Modifying the CellAED® in any way may result in ineffective treatment or cause death or injury. User modification of, or interference with, the mechanical/electrical integrity of the CellAED® may affect the performance of the CellAED® and/or the electromagnetic emissions, which could compromise other equipment in close proximity. Using other manufacturers' cables or electrode pads may cause the CellAED® to perform improperly and invalidates the safety agency certification. Modification will void all warranties and present a serious risk of harm to the user and/or patient.
Single-use	The CellAED® is a single-use device and cannot be re-used or recycled. If the packaging has been broken or damaged in any way, contact the manufacturer.
	Never use a compromised, damaged, expired, or pre-used CellAED®, as doing so may result in ineffective treatment or user injury. Contact the manufacturer for a replacement and instructions to dispose of the CellAED®.
WARNINGS	
Temperature	Extreme and fluctuating temperatures will reduce the life of the battery and electrodes contained within the CellAED®. It is important to follow the recommended storage temperature as described in this manual. Failure to do so may result in damage to the CellAED® and improper operation. The CellAED® should be stored between 15°C - 35°C (59°F - 95°F). Temperatures exceeding 35°C (95°F) can permanently damage the internal battery.
Electrical energy	The CellAED® cannot abort a shock once a shockable rhythm has been detected. The CellAED® delivers up to 85 Joules (45 Joules in Infant Mode) of electrical energy with every electrical pulse (shock).
	Do not insert any object into the CellAED®.

Use of the CellAED®	Air pockets between the skin and electrode pads can cause ineffective treatment. Make sure electrode pads are completely adhered to the skin. If necessary and possible, shave hair from the area to ensure good contact. Do not use damaged, expired, or dried out electrode pads.
	Certain materials making contact with the electrode pads during defibrillation can cause electrical sparks, skin burns, and/or divert electricity energy away from the heart. Do not allow the electrode pads to touch each other or any metal parts or objects (such as a bed frame or stretcher), medication patches, dressings, or any other material on the patient's chest or in contact with the patient.
	Do not place the electrode pads together when in use, as this may deactivate the CellAED® functions including audio (voice) prompts, heart rhythm detection and classification, capacitor charge and discharge, and render the CellAED® unusable.
	Do not handle or transport the patient while the CellAED® is attached to the patient and analysing the heart rhythm, as this can cause incorrect or delayed diagnosis. Keep the patient as still as possible while the CellAED® is attached.
	The CellAED® should not be used if the patient is conscious, responsive, or breathing normally. No shockable rhythm will be detected and the CellAED® will not provide shocks.
	If a patient has a pacemaker, never stick the electrode pad over the pacemaker, as it may reduce the accuracy of analysis, generate errors in detecting shockable rhythms, and result in ineffective treatment.
Storage	Colourblind users may have difficulty differentiating between the GREEN and AMBER LEDs. Please seek assistance and be aware of the product's shelf life.

CAUTION	
Storage	Store the CellAED® out of reach of pets or children.
Electromagnetic Interference and Radio Frequency Interference	The normal operation of the CellAED®, including the ability to correctly detect a shockable rhythm, may be impacted if it is operated near strong sources of electromagnetic interference (EMI) and/or radio frequency interference (RFI). This can include arc welders and radio transmitters. If it is safe to do so, keep a separation between the CellAED® and strong sources of EMI and RFI of at least 1.2m (4ft).
Packaging	Do not open the sealed tamper-proof and protective packaging of the CellAED® unless you intend to use it. This packaging protects the CellAED® from accidental activation, and from environmental elements such as water, heat and dust. Opening the packaging can expose the CellAED® to environmental contaminants and compromise its effectiveness.
	Only open the sealed packaging and activate the CellAED® prior to immediate use.
	Once the unit is unsealed, it should either be used in an appropriate manner or disposed of as per instructions from the manufacturer.
Disposal	After the CellAED® has been used, is expired, is damaged, or you have doubts about the condition of the CellAED®, contact the manufacturer, who will provide instructions for the disposal of the CellAED®. Correct disposal procedure must be observed to ensure that no dangerous substances are released, which may adversely impact human and/or environmental health.

12 CONTACTS

European Union (EU)	Australia (AU)	New Zealand (NZ)	United Kingdom (UK)
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