CellAED®

Automated External Defibrillator

Operating Instructions

Manual 91808 Rev A, 2019-02
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CONTENTS

Contact and Support:

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Important

Read this manual carefully, take note of all warnings and ensure that you are familiar with the intended and correct use of this product before using it.

Register your Product (Required)

*Rapid Response Revival and its distributors are required by national regulatory agencies to maintain a record of all end-users that purchase a **CellAED®**.*
Please provide the information required at www.cellaed.io to comply with these tracking requirements and enable us to notify you promptly if there is an update or service requirement. Unregister a device at: +611300 727 580 in the event a CellAED® has been disposed of or lost. CellAED® provides approximately 2 years of standby performance, depending on environmental conditions. Notice of expiry is provided via email, SMS, red warning light, and to the owner's registered web portal login.

Limits to Manufacturer's Responsibilities

Rapid Response Revival is responsible for the safety and reliability of the CellAED®, only if the CellAED® is used in accordance with all Instructions and Warnings in this manual.

Indemnity

Rapid Response Revival Automated External Defibrillators (CellAED®) provides the following indemnity to persons or legal entities that have purchased a CellAED® from Rapid Response Revival or an authorized distributor appointed by Rapid Response Revival (hereafter referred to as "the Purchaser").
Rapid Response Revival 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 Rapid Response Revival AED caused by:
1. Negligent operation of the Rapid Response Revival AED, or failure to follow the sequential operating instructions for use of the Rapid Response Revival AED, or:
2. Failures or malfunctions of the Rapid Response Revival AED that are due to improper maintenance, including, without limitation, malfunctions of pads or batteries that occur after expiration of their shelf life; or malfunctions of repairs, replacement parts, pads, or batteries that were not provided by Rapid Response Revival.
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 to Rapid Response Revival, at the address shown below, written notice of the Claim, promptly after the Purchaser obtains knowledge of the Claim. The Purchaser also will provide to Rapid Response Revival all assistance reasonably requested for evaluation of the Claim or defense of the Claim. Such assistance will include:
Providing to Rapid Response Revival possession of the Rapid Response Revival AED involved in the Claim (including any electronic records created by the Rapid Response Revival AED of the event involved in the Claim) for analysis of the cause of any failure, and providing to Rapid Response Revival and its counsel all other evidence relevant to the Claim, whether in the form of documents or testimony. Rapid Response Revival will promptly notify the Purchaser in writing if Rapid Response Revival determines that the Claim is not covered by this indemnity, and Rapid Response Revival 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 to RRR Manufacturing Pty Ltd.

WARNINGS

Shock Hazard

Disconnect other electrical equipment from the patient before defibrillating.

Properly place defibrillation pads. Do not allow defibrillation pads to touch each other or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause patient skin burns during defibrillation and may divert defibrillating current away from the heart.

Defibrillation current can cause injury. Do not touch the patient during defibrillation. Do not touch equipment connected to, or metal objects in contact with, the patient during defibrillation.

Burns

Remove excessive body hair, which may cause skin burns or ineffective energy transfer.

Do not use alcohol, iodine, or other skin preparations. These can dry the skin and may cause the ***CELLAED®*** to function improperly or may cause skin burns.

Large Magnetic Fields

ECG electrodes and cables contain ferromagnetic materials. They must not be used in the presence of large magnetic fields created by magnetic resonance imaging (MRI) equipment. The large magnetic fields generated by an MRI device could move ferromagnetic equipment with an extremely violent force that could cause serious personal injury or death to persons between the equipment and the MRI device.

Electrical Energy

CELLAED® can deliver 150 joules of electrical energy. Disconnect any medical electronic device that is not labeled “defibrillation protected” from the patient. If this electrical energy is not discharged properly, it could cause personal injury or death to the operator or bystander. During defibrillation, the operator and all other people must stand clear of the patient, bed, and all conductive surfaces in contact with the patient.

WARNINGS (continued)

ECG Failure

Properly place defibrillation pads. Improperly placed pads may produce incorrect analysis and an inappropriate shock, or a no-shock decision.

Do not move patient.

Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis.

Cardiac Pacemakers

Cardiac pacemakers may affect rhythm analysis. Patient pacemakers may reduce the sensitivity of the ***CellAED®*** analysis and create errors in detecting shockable rhythms.

Radio Frequency Interference

Do not operate ***CellAED®*** in conjunction with electrocautery or diathermy equipment. Any equipment that emits strong radio frequency signals can cause electrical interference and distort the ECG signal and cause inaccurate interpretation of rhythms.

Explosion

Possible explosion hazard if used in the presence of concentrated oxygen or flammable anesthetics.

Repairs or Upgrades

Do not open unit, remove covers, or attempt to repair ***CellAED®***.

Improper Use or Failed Discharge

The ***CellAED®*** has an automatic disarm function for stored energy. If the operator has not delivered the stored energy to a patient or a test load, an internal timer will disarm this stored energy. Stored electrical energy can potentially cause death or injury, if discharged improperly.

Water and Humidity

Do not immerse or expose ***CellAED®*** in water or other liquids. Do not use the defibrillator if the unit has been immersed in liquid or if excessive condensation is visible on the device.

WARNINGS (continued)

Grounding

Conductive parts should not contact other conductive parts, including the earth.

Avoid Pressure on Pads

Do not perform chest compressions (CPR) or apply pressure through defibrillation pads. This may damage the ***CellAED®*** and/or cause them to function improperly.

Care and Storage

- Replace the ***CellAED®*** every 2 years.
- Only 'Snap' open and activate ***CellAED®*** when the defibrillator is to be used on a patient. Do not activate ***CellAED®*** during nonemergency situations.
- If the ***CellAED®*** is subjected to excessively cold or hot temperatures, near or outside of its operating or storage limits, its life expectancy may be adversely affected.

INTRODUCTION

CellAED® is a single use, disposable, Automated External Defibrillator (AED), used as remedy in the event of a cardiac arrest. It performs all mandatory clinical requirements in compliance with ANSI/AAMI/ IEC 60601- 2-4:2010/ (R)2015 and IEC 60601-1:2005.

Key Features

- ◊ Snap, Peel, and Stick operation
- ◊ Disposable, one-time use
- ◊ Extensive voice and sound prompts
- ◊ Event logging
- ◊ Periodic status self-checks
- ◊ Biphasic waveforms to suit transthoracic impedance
- ◊ ECG analysis – AMSA (Amplitude Spectral Analysis)
- ◊ Transcutaneous impedance calculation

INTRODUCTION *(Continued)*

CellAED® is designed to enable any operator to perform defibrillation, in the event of a cardiac arrest, with a quick and simple "**Snap, Peel and Stick**" action, as illustrated.

The operator will be guided through the various steps required by audio prompts, as the device assesses the condition of the subject in arrest, and prior to applying shocks to the chest area if the device deems them necessary and safe.

The ***CellAED®*** is a safe and easy-to-use defibrillation device intended to be used by any available bystander in conjunction with CPR and prior to the arrival of Emergency Services.

When connected to a patient that is **not breathing**, is **unconscious**, and is **unresponsive**, ***CellAED®*** analyses the patient's heart rhythm, and, based on its analysis, will provide Audio Instructions to the user or operator.

Once the device has established a shockable situation, and if appropriate, it will automatically shock the patient.

CellAED® will them reappraise the condition of the subject and if necessary, reapply shocks in a timely and appropriate manner; meanwhile instructing the operator as necessary.