

ADVANCED CPR SOLUTIONS™

EleGARD™ Patient Positioning System

INSTRUCTIONS FOR USE



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1 Important User Information

The information in these Instructions for Use applies to the EleGARD™ Patient Positioning System, also referred to as EleGARD System or simply EleGARD. See below for the components making up the EleGARD System.

All operators must read the complete Instructions for Use before operating the EleGARD.

The Instructions for Use must always be easily accessible to the operators of the EleGARD.

Always follow your service's protocol or approved procedures for cardiopulmonary resuscitation (CPR) when you use the EleGARD.

Trademarks

EleGARD™ is a trademark of AdvancedCPR Solutions™

ElevatedCPR™ therapy is a trademark of AdvancedCPR Solutions

LUCAS™ is a registered trademark of Stryker Corporation

ResQCPR™ System is a trademark of ZOLL Medical Corporation

Use of EleGARD is classified by the US FDA as: **Rx ONLY**

This Instructions for Use Document describes the EleGARD System, catalog number: SYS-ELG-001.

The EleGARD System, SYS-ELG-001, consists of the following packaged together in two shipping containers:

Container 1:

- 1 EleGARD device, catalog number DEV-ELG-001
- 1 LUCAS 3, backplate, catalog number ACC-ELG-004
- 2 Batteries, catalog number ACC-ELG-002
- 1 Battery Charger, catalog number ACC-ELG-003
- 1 Copy of this Instructions for Use document

Container 2:

- 1 Carrying Case, catalog number ACC-ELG-001

Intended Use

Intended to assist in elevating the head and the thorax of a patient from a supine position into a multi-level elevated position with the head above the thorax and the thorax above the lower body and extremities, and may be used during various procedures, i.e., airway management procedures, CPR, etc.

The environment of use is pre-hospital and hospital.

EleGARD™ Patient Positioning System Overview

The EleGARD Patient Positioning System is a portable tool designed to elevate a patient's head and thorax. It can be used to help maintain the sniffing position. There are three different adjustable head and neck angle positions. The EleGARD can be used whenever elevation of the head and thorax is clinically indicated, including during CPR and patient transport.

The EleGARD can be used during manual CPR, manual active compression decompression CPR (ResQCPR System), and CPR with the LUCAS Chest Compression System.

Contraindications

DO NOT use the EleGARD:

- When it is not possible to position the patient safely or correctly on the EleGARD
- If the patient weighs more than 350 pounds

EleGARD Patient Positioning System



Figure 1.

- 1. Base with Circumferential Handles
- 2. Lower Back and Thoracic Plates
- 3. Adjustable Head and Neck Support
- 4. Neck and Shoulder Stabilizer Cushion
- 5. Control Panel
- 6. Back Plate Holder
- 7. Back Plate Release Knob
- 8. The Battery
- 9. Carrying Case

See Figure 1.

1 Base with Circumferential Handles

The Base with Circumferential Handles is designed to stabilize the patient and allow rescuers to lift the patient's upper body as needed. The base is designed to be used with portable patient litters or portable transport units and fit onto most stretchers and beds.

2 Lower Back and Thoracic Plates

The Lower Back and Thoracic Plates are designed to stabilize the patient's lower back and thorax in the lowest and highest positions, and when elevating the head and thorax. The lower back and upper thoracic plates are designed to accommodate almost all adult body sizes by extending lengthwise, as needed, to reduce the likelihood the head and thorax will curl forward with elevation of the head and thorax.

3 Adjustable Head Support

The Adjustable Head Support is designed to support the head in the lowered and elevated positions. The head can be tilted back to help prevent airway closure and to help maintain the sniffing position. The head and neck angle can be adjusted using the red handle. There are three different head and neck angles, which can be adjusted as needed for each patient. The device should be stored with the head and neck in the middle position. NOTE: The outer squeeze handle is colored red to alert the user that it is not to be used as a handle when lifting the patient. The red and gray handles are designed to adjust the head and neck support and should NOT be used when lifting the EleGARD when the patient is on the unit.

4 Neck and Shoulder Stabilizer Cushion

The Neck and Shoulder Stabilizer Cushion is designed to help prevent the patient from slipping downward with elevation of the head and neck and to help maintain the sniffing position. If a patient requires a neck collar, the neck and shoulder stabilizer cushion should be removed to allow room for the patient's head and neck, with the neck collar in place, on the EleGARD. To remove the Neck and Shoulder Stabilizer Cushion, stretch and detach the tether at each end of the cushion assembly and remove the cushion assembly. To replace the cushion assembly, center it on the EleGARD and re-attach the tether to each end.

5 Control Panel

The Control Panel is designed to control the head and thorax elevation height and the digital timer. There is a power OFF/ON switch. There is a way to determine the Battery charge status. There are switches to elevate the head and thorax, lower the head and thorax, and stop the upward or downward movement of the head and thorax. The order of operation is shown by the numbers 1, 2, and 3. Pressing 1 will power on the device. Pressing 2 will start the timer. The timer provides the rescuer with a real-time clock. The time will start when the timer Start button is pressed. The timer light will start flashing after 2 minutes and it will continue to flash and count thereafter. Pressing 3 will elevate the head and thorax over a 2 minute period of time. The Battery lights will flash off and on in an upward cascade as the head and thorax are being elevated.

6 Back Plate Holder

The EleGARD is designed to securely hold a LUCAS 3 Series Chest Compression System standard back plate in place. During normal use, the LUCAS 3 Series back plate should be securely attached to EleGARD. In this manner, a patient can receive conventional manual CPR, ACD CPR with the ResQCPR System, or CPR with a LUCAS 2.0 or 3 Series Chest Compression System while on the EleGARD according to the protocol or standard procedure of the service or hospital.

7 Back Plate Release Knob

The LUCAS 3 back plate can be easily released by pulling the Back Plate Release Knob outward (see Figure 2) and then lifting the back plate out. The LUCAS 3 back plate can be readily inserted back into the EleGARD by first placing the lower end of the back plate, and then the upper end of the back plate, into the EleGARD LUCAS 3 back plate locking system.



Figure 2. Back Plate Release Knob

8 Battery and Battery Charger

The Battery powers the unit and needs to be charged before use (see Figure 3). The amount of electricity remaining in the Battery can be checked by looking at the charge indicator on the Control Panel. The Battery can be easily removed by opening the Battery Compartment and removing the Battery (see Figure 4). The EleGARD comes with two Batteries to enable one to be used and one Battery carried as a spare.

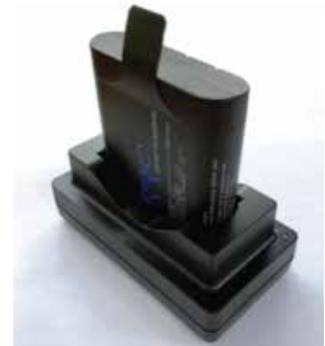


Figure 3. Battery and Battery Charger

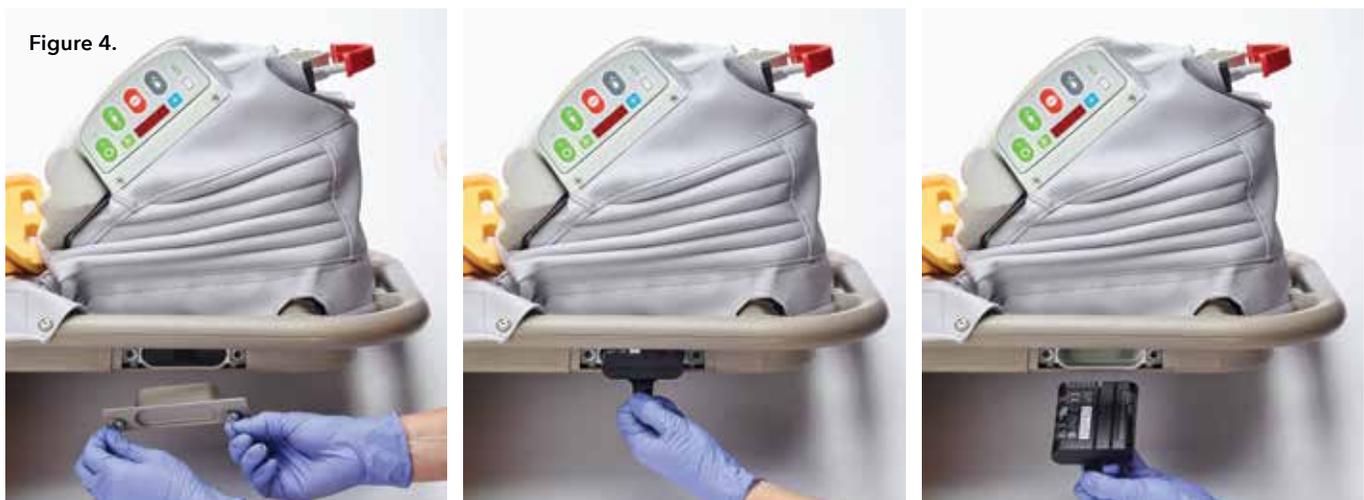


Figure 4.

Open the Battery Compartment.

Grab the black tab.

Remove the Battery.

9 Carrying Case

The Carrying Case is designed to store the EleGARD and is also used to easily carry the EleGARD to the patient. It can be carried on the back by using the shoulder straps or it can be carried using the handle. It can be opened in seconds by unclipping the two snap fit latches and pulling upward on the cover with one hand while holding down the base portion of the cover with the other hand. The zipper is designed to open when using a single smooth upward motion (see Figure 5).



Figure 5. EleGARD Carrying Case

Control Panel Operating Instructions

A keypad is used to operate the EleGARD (see Figure 6).



Figure 6. Control Panel

This keypad includes the following:

Component:

Description:



Power Button

Enables up/down motion and timer operation.

Press briefly to power the EleGARD. The Timer will initially show 00:00.

Press and hold the Power Button for 2 seconds to turn off the power.



Timer

A stopwatch-type timer counts seconds and minutes starting with 00:00 and flashes starting at 2 minutes and continuously thereafter. It continues to count until the Timer Stop button is pressed.

Press the Timer Start Button () to begin elapsed time counting by minutes and seconds. At the 2 minute point, the timing lights will begin to flash to alert the rescuer. The lights will continue to flash and provide the time in minutes and seconds from when the Timer Start Button was pressed.

Press the Timer Stop Button () to stop the count at the current time displayed.

Press the Timer Start Button to continue elapsed time counting.

Press and hold the Timer Stop Button for 2 seconds to reset the Timer display to 00:00.



Up Button

Raises the lower back and thoracic plates into their fully elevated positions. Requires approximately 2 minutes for the head and thoracic pieces to fully raise into position.



Down Button

Lowers the lower back and thoracic plates into supine position in about 6 seconds.



Stop Button

Stops the elevation of the unit when pressed. Unit can resume the elevation cycle when the UP Button () is pressed. If the Down Button () is pressed, the EleGARD will return to the fully lowered position in about 6 seconds



Battery and Upward Motion Indicator

Three green LEDs show the battery charge status when the Battery Button is pressed. The Battery is fully charged when all 3 LEDs are illuminated. Similarly, the Battery is 2/3 charged when 2 LEDs are illuminated and 1/3 charged when 1 LED is illuminated. See Figures 7, 8, and 9 below.

In addition to indicating Battery life, the 3 green LEDs cascade upward when the Up Button () has been pressed to indicate that upward motion is in progress. See Figure 10 below. When the LED stops the cascading motion, the EleGARD is in the fully raised position.



Figure 7.
Fully Charged Battery



Figure 8.
2/3 Charged Battery



Figure 9.
1/3 Charged Battery



Figure 10.
Cascading Motion Indicator

3 Safety Precautions

Conventions Used in Instructions for Use

The following conventions are used throughout these Instructions for Use:

⚠ Warning: Indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury.

⚠ Caution: Indicates a hazardous situation, which, if not avoided, may result in minor or moderate injury.

Notice: Indicates a hazard, which may result in product damage.

Personnel

These Instructions for Use and the equipment it describes are for use only by qualified professionals trained in the particular technique and procedure to be performed.

General Safety Precautions

⚠ Caution: Use Only Approved Accessories

Use only AdvancedCPR Solutions™-approved accessories with the EleGARD™ Patient Positioning System. The EleGARD may not operate correctly if you use accessories that are not approved. Use only EleGARD Batteries and the EleGARD power supply that are designed for use with the EleGARD. If you use other batteries or power supply, you may cause permanent damage to the EleGARD.

⚠ Caution: Standing Water

Do not place the EleGARD in standing water or snow. The system can be damaged from liquid entry.

⚠ Caution: Keep Battery Installed

Do not use the EleGARD in standing water or snow. The system can be damaged if liquid enters the Battery Compartment.

Battery

⚠ Warning: Low Battery

When the Battery indicator shows no or only the lower LED illuminated, replace the Battery with one that is fully charged.

Operation

⚠ Warning: Patient Position

Use the EleGARD only on a flat surface.

If a LUCAS Chest Compression System is to be used, ensure the LUCAS 3 back plate is securely fastened to the EleGARD and the patient is positioned properly on the LUCAS Chest Compression System. Refer to the LUCAS Chest Compression System Instructions for Use for proper patient positioning and use of the LUCAS Chest Compression System.

⚠ Warning: Patient Injury

Do not let the patient or the system stay unattended when the EleGARD is in use.

Service

⚠ Warning: Do Not Open or Remove the EleGARD's Cover

*Never open or remove the vinyl cover encasing the EleGARD.
Do not change or modify external or internal parts of the system.*

All servicing and repairs must be done by service personnel that are approved by AdvancedCPR Solutions.

Replacement of the vinyl cover and Neck and Shoulder Stabilizer Cushion is allowed only when using the AdvancedCPR Solutions replacement components in accordance with their instructions.

Contact an Authorized EleGARD Service Center for repair, if needed as described in the Technical Description section at the end of this Instructions for Use document.

4 First Use Preparation

List of Materials

The EleGARD™ Patient Positioning System is supplied with the following:

- EleGARD Device
- Rechargeable EleGARD Battery
- Extra EleGARD Battery
- External Battery Charger
- EleGARD Carrying Case
- Instructions for Use

The Battery

The proprietary Lithium Polymer Battery is the exclusive power source for the EleGARD Patient Positioning System. You can remove the Battery from the EleGARD Case and recharge it. The front end of the Battery has connections for power transfer from the Battery Charger and to supply power to the EleGARD when installed properly.

Charge the Battery

To charge the EleGARD Battery in the Battery Charger:

1. Put the Battery into the slot of the Battery Charger. See Figure 11.
2. Connect the Battery Charger power cord to the mains wall outlet.



Figure 11. Charging the Battery

Note: Optional chargers are available for charging either 2 or 4 Batteries at a time.

⚠ Caution: Keep a Battery Installed

A charged Battery must always be installed to operate the EleGARD quickly when needed.

Prepare the Carrying Case



Figure 12. EleGARD Carrying Case



Figure 13. Closing the EleGARD Carrying Case

1. Install a fully charged EleGARD Battery into the Battery Compartment of the EleGARD.
2. Insert the EleGARD into the Carrying Case. See Figure 12.

Notice: (refer to Figures 12 and 13)

Putting the EleGARD in this position makes it possible to check the charge level of the installed Battery through the clear windows of the Carrying Case by pressing the Battery Button and observing the 3 green LEDs.

3. Put a charged spare EleGARD Battery in the pocket on the front of the Carrying Case.
4. Close the Carrying Case by zipping both zippers fully up and snapping the two snap fit latches (see Figure 13).

5 Using the EleGARD™

Arrival to the Patient

When you arrive at the patient, provide CPR per your service's cardiac arrest and resuscitation protocol or standard procedure.

Minimize interruptions to manual chest compressions during the preparation and application of the EleGARD Patient Positioning System.

Unpacking the System

1. Open the Carrying Case. See Figure 14.
2. Carefully remove the EleGARD and place on a dry surface.



Figure 14. Opening the EleGARD Carrying Case



⚠ Caution: Keep Battery Installed

The Battery must always be installed for the EleGARD to operate.

Positioning the Patient

When positioning the patient on the EleGARD during CPR, keep interruptions to chest compressions to a minimum.

1. Minimize interruptions to manual CPR by planning for and coordinating the placement of the patient on the EleGARD.
2. Make sure to support the patient's head.

3. Pause manual CPR briefly (< 10 sec), lift the patient from the arms/shoulders and slide the EleGARD into place underneath the patient's torso (see Figure 15), and then resume CPR immediately thereafter.
4. Position the patient properly over the LUCAS 3 back plate as directed in the LUCAS Chest Compression System's Instructions for Use (see Figure 16).



Figure 15. Placing Patient on the EleGARD

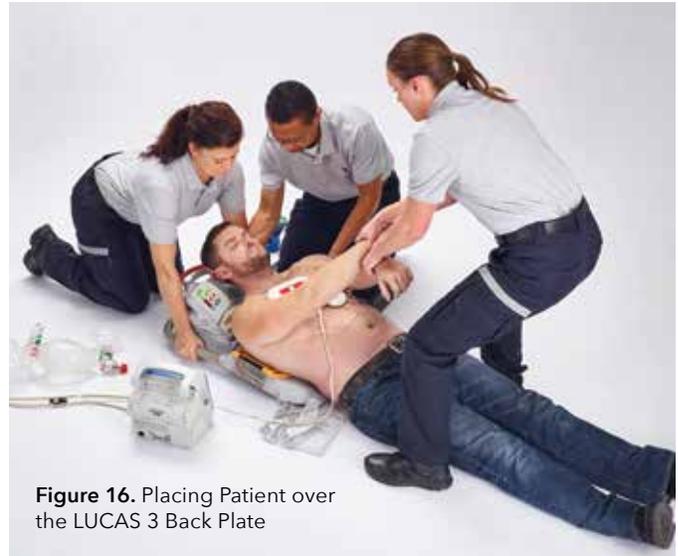


Figure 16. Placing Patient over the LUCAS 3 Back Plate

5. Place the Neck and Shoulder Stabilizer Cushion under the patient's cervical spine at the level of C6-C7 (see Figure 17). Ensure that the patient's head rests properly in the headrest. Pull outward on the gray handle behind the head support to extend the headrest, if needed, to make sure the head and neck are properly positioned while the EleGARD is in its fully lowered position. The midportion of the back of the neck should rest on the top of the Neck and Shoulder Stabilizer Cushion. Adjust the angle of the head and neck such that the head is in the 'sniffing' position. The mid-position is adequate for most patients.



Figure 17. Neck and Shoulder Stabilizer Cushion

6. Continue CPR as specified in your service's protocol or standard procedure for resuscitation.
7. Turn the power ON by pressing the #1 Button (see Figure 18).



8. Press the #2 Button, TIMER START, to start timer operation.
9. The TIMER will count up until stopped or reset by the caregiver.

⚠ Caution: Patients with Cervical Collars or Bullneck

The Neck and Shoulder Stabilizer Cushion may be removed for patients wearing cervical collars or with bullneck features not compatible with the Neck and Shoulder Stabilizer Cushion.

10. If the patient needs to be further adjusted into the sniffing position for airway management procedures, grasp the red handle on the Headrest and tilt the head to the desired position (see Figure 19).



Figure 19. Headrest Adjustment

11. If the ResQCPR System or the LUCAS Chest Compression System is to be used, you should switch from conventional manual CPR to the ResQCPR System or to LUCAS automated chest compressions as directed by your service's cardiac arrest resuscitation protocol or standard procedure.
12. When your service's protocol or standard procedure calls for elevation of the patient into the raised positions, press the #3 Button, UP (see Figure 20). The EleGARD will rise gradually over about 2 minutes.

To verify that the EleGARD is raising, view the Battery/Upward Motion green LEDs. The LEDs will cascade upward indicating that upward motion is in progress. The LEDs will stop cascading when the fully raised position is reached (see Figure 21).

If you do not want to elevate the head to the fully raised position, push the STOP Button at the desired elevation, and the EleGARD will not elevate the patient any further until you push the UP Button again.

13. Continue resuscitation as directed by local protocol.



Figure 20. EleGARD Control Panel



Figure 21. EleGARD in Fully Raised Position

Moving the Patient

1. Refer to local protocol or standard procedure for moving the patient.
2. Follow the procedure for when and how to move the patient that your service or patient care unit has developed as part of its resuscitation protocol, algorithm, or standard procedure.

Removing the Patient from the EleGARD

1. Press the DOWN Button on the keypad. The EleGARD will lower to the lowermost position in about 6 seconds.
2. If the LUCAS Chest Compression System has been used, remove the LUCAS device and accessories per LUCAS Instructions for Use.
3. Lift the patient off the EleGARD, making sure to support the patient's head.

6 Preparation for Next Use

Cleaning Routines

After every use, clean the EleGARD and let it dry before returning it to the Carrying Case.

⚠ Warning: Liquid

Do not immerse.

⚠ Caution: Cleaning Fluids

Do not allow water or cleaning fluids to enter the EleGARD. Use cleaning liquids on a dampened cleaning cloth. Avoid liquid pooling on the EleGARD.

⚠ Caution: Abrasive Cleaners

Abrasive powders, steel wool, industrial strength or solvent cleaners, and vinyl "conditioners" or "protectors" and isopropyl alcohol (IPA) solutions greater than 40% concentration should be avoided. Undiluted bleach, IPA, or lacquer can dull or damage the product. If in doubt about a detergent or cleaner, test a patch in an inconspicuous place before applying in a larger place.

1. Raise the EleGARD to the fully raised position to clean.
2. Manually pull the gray headrest handle to extend the slide as needed to flatten the pleats in a smooth surface as needed for cleaning.
3. Remove the foam Neck and Shoulder Stabilizer Cushion for cleaning. To remove the Neck and Shoulder Stabilizer Cushion, stretch and detach the tether at each end of the cushion assembly and remove the cushion assembly. To replace the cushion assembly, center it on the EleGARD and re-attach the tether to each end.
4. Disinfect all surfaces with a soft cloth and/or soft brush and disinfectant. NOTE: It is important to clean the EleGARD after disinfecting per the instructions for use of the disinfectants listed below. Recommended disinfectants include:
 - Cavicide or Cavi-Wipes
 - PDI Sani-Cloth AF3 Germicidal Disposable Wipes
5. Clean all surfaces with a soft cloth and/or soft brush dampened with warm water with a mild cleaning agent. Recommended cleaners include:
 - Formula 409 All-Purpose spray cleaner
 - Fantastik spray cleaner
 - Hand dishwashing soap and water

6. After cleaning, rinse all surfaces with a soft cloth dampened with water and then dry with a clean, lint-free cloth.

⚠ Caution: Chemical Residue

Failure to remove chemical residue may cause discoloration of the coated fabric surface to occur earlier in the life cycle of the product. Always clean after disinfecting.

Remove and Recharge the Battery

1. Replace the Battery with a fully charged Battery.
2. Recharge the Battery for future use. Refer to Section 4 for Battery charging instructions.

7 Maintenance

Routine Maintenance

After each use of the EleGARD™, do the following:

1. Make sure the system is clean.
2. Make sure the installed Battery is fully charged.
3. Make sure a spare Battery is fully charged and placed in the Carrying Case pouch.

Inspect the cover and Neck and Shoulder Stabilizer Cushion for wear or torn areas and contact the Service Center if replacement is needed.

Whenever specified by your service, run the EleGARD through the full use cycle to confirm proper raising, lowering, and timer operation.

8 Troubleshooting

Indications and Alerts During Normal Operation

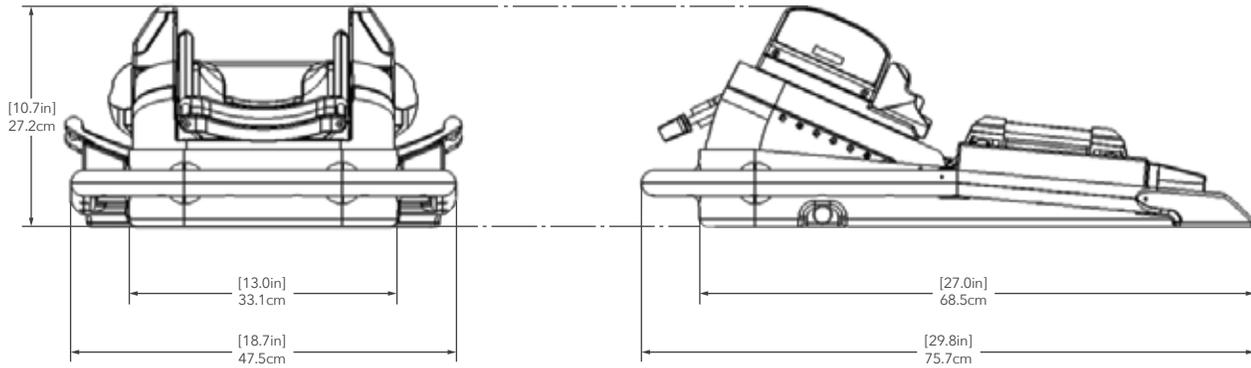
Refer to the table below to find the reason for LED alerts during normal operation.

Situation	Visual LED Indication	User Action
The EleGARD™ is in the ON mode and there is more than 2/3 battery capacity remaining.	Fully charged Battery: All green battery indication LEDs are illuminated.	None
The EleGARD is in the ON mode and there is 2/3 battery capacity remaining.	2/3 charged Battery: Two green battery indication LEDs are illuminated.	None
The EleGARD is in the ON mode and there is 1/3 battery capacity remaining.	1/3 charged Battery: One green battery indication LED is illuminated.	Replace Battery with charged Battery before next use.
The EleGARD is in the ON mode and there is less than 1/3 battery capacity remaining.	No LED illuminated or low Battery	Replace Battery with charged Battery before next use.
The EleGARD does not power on.	Control panel does not light up.	Ensure a Battery is installed. Ensure Battery is fully charged. Ensure Battery compartment is secured shut.
The EleGARD turns on but does not rise.	None	Ensure patient does not weigh more than 350 lbs. Ensure that installed Battery is charged.

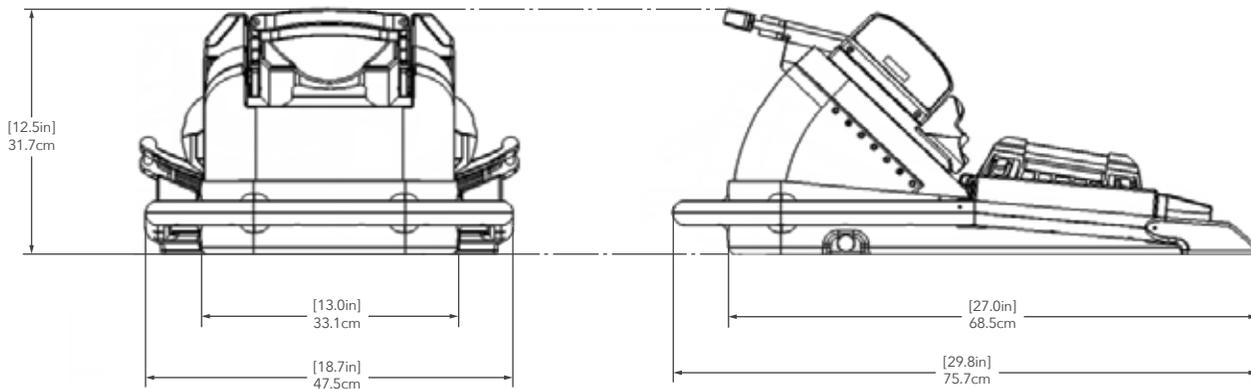
9 Technical Description

Physical Dimensions

Fully Lowered Position:



Fully Raised Position:



Weight

EleGARD™: 10.5 Kg [~23 lbs], with LUCAS 3 back plate installed and Battery inserted, without Carrying Case or spare Battery.

Carrying Case: 1.3 Kg [~2.9 lbs]

Spare Battery: 0.23 Kg [~0.5 lbs]

Operating Environment

Temperature: -20 to +40 °C [-4 to 104 °F]

Humidity: 15 to 90% relative humidity, non-condensing

Altitude: ≤3,000 meters [9,843 feet]

Atmospheric Pressure: ≤62 kPa

Transport and Storage Environment

Temperature: -20 to +70 °C [-4 to 158°F]

Humidity: <90% relative humidity, non-condensing

Power Input Requirements

Rechargeable Lithium-Ion Battery: 15V / 3.2 Ah / 48 Wh

Patent Positioning

Approximate measurements above ground level.

Measurement Point	Fully Lowered	Fully Raised
Top surface, center point of LUCAS back plate (back of torso).	7.2 cm [2.8in]	8.5 cm [3.4 in]
Center point of headrest surface (back of head), in position 1 (lowest) with slide adjusted for 50% human model.	13.5 cm [5.3 in]	21.5 cm [8.5 in]
Center point of headrest surface (back of head), in position 2 (middle) with slide adjusted for 50% human model.	14.5 cm [5.7 in]	23.2 cm [9.1 in]
Center point of headrest surface (back of head), in position 3 (highest) with slide adjusted for 50% human model.	16.1 cm [6.3 in]	25.3 cm [10.0 in]

Movement Timing

Time to fully raised position from fully lowered position: 120 +/- 10% seconds

Time to fully lowered position from fully raised position: 6 +/- 10% seconds

Duty Cycle/Capacity

Duty cycle: Maximum 6 actuations per hour

Capacity: Up to 20 actuations per fully charged Battery

Timer Feature

Elapsed time in seconds from 00:00 to 99:99 from press of Timer Start

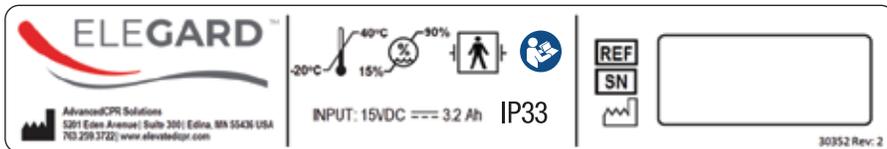
Flashing display beginning at 02:00 from press of Timer Start

Timer may be stopped/restarted

Timer resets to 00:00 on Power On or after holding the Timer Stop button for 2 seconds

Labeling

Name/rating label scheme:



An over-label as depicted above is located on the EleGARD back, underneath the headrest.

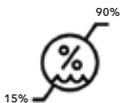
Information contained on this label includes:



Manufacturer name and contact information



Operating Temperature Range



Operating Range Relative Humidity (non-condensing)



Defibrillator-proof applied part type BF

NOTE: "applied part" for the EleGARD refers to the part of the vinyl cover and plastic and foam areas/components the patient may contact



Consult Instructions for Use (this document) for proper operations

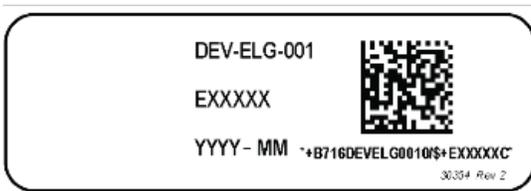
IP33

Ingress Protection: Protected against solid objects over 2.5mm e.g. wire, small tools, and sprays of water from above and up to 60° from vertical.



Battery DC input specifications

An under-label is placed under the clear window of the over-label. The under-label format is depicted below, shown by itself, and then in combination with the over-label.



Under-Label



Under Label + Over-Label Combined



Catalog Number



Serial Number



Date of Manufacturer

Accessories

Battery: ACS Catalog Number ACC-ELG-002

Battery Charger (single): ACS Catalog Number ACC-ELG-003

Battery Charger Input Requirements: 100-240V - 15% / +10%, 50/60Hz

Battery Charge Time (from fully depleted to 100%): Less than 8 hours (approx. 3 hours typical)

Carrying Case: ACS Catalog Number ACC-ELG-001

Disposal

The Battery is a Lithium Ion type and must be disposed of according to the rules/regulations of your health care organization and local authorities.

The EleGARD unit contains a motor and electronic circuits which must be disposed of according to the rules/regulations of your health care organization and local authorities.

Electrical Safety

The EleGARD™ System complies with the electrical safety standards 60601-1, 60601-2 and 60601-1-12.

Electromagnetic Compatibility

The EleGARD is suitable for the electromagnetic environment of typical homes, commercial, hospital and pre-hospital emergency medical equipment settings consistent with standard IEC 60601-1-12:2015 "Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment."

During the immunity testing described below, the EleGARD continued to function normally.

IMMUNITY

Electromagnetic Immunity			
The EleGARD is intended for use in the electromagnetic environment specified above. The customer or the user of the EleGARD should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air	The relative humidity should be in the range of 15% - 90%, non-condensing.
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	The EleGARD complies with the Radiated Electromagnetic RF Immunity test as noted. In addition, the EleGARD was tested and complies with RF immunity testing for wireless communications equipment in accordance with the standard.
Power Frequency H-Field Immunity IEC 61000-4-8	30 A/m 50 & 60 Hz	30 A/m	Complies with standard regarding immunity when exposed to power-line related fields. Note: The EleGARD is powered by a rechargeable 15 VDC Battery and not connected to AC Power.

EMISSIONS

Electromagnetic Emissions		
The EleGARD is intended for use in the electromagnetic environment specified above. The customer or the user of the EleGARD should assure that it is used in such an environment.		
Emission Tests	Compliance	Electromagnetic Environment - Guidance
RF emissions EN55011 CISPR 11	Group 1, Class B	The EleGARD is powered by a rechargeable 15 VDC Battery and is not connected to AC power. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Authorized EleGARD Service Center

The EleGARD contains no user-serviceable internal components. All servicing and repairs must be done by service personnel who are approved by AdvancedCPR Solutions™.

Replacement of the vinyl cover and Neck and Shoulder Stabilizer Cushion is allowed only when using the AdvancedCPR Solutions replacement components in accordance with their instructions.

For service, please contact the EleGARD Service Center at:

AdvancedCPR Solutions
763.259.3722
www.elevatedcpr.com/service

Patent Information

AdvancedCPR Solutions' products and methods for ElevatedCPR™ therapy are covered by issued patents.

See elevatedcpr.com/patents for the current listing of issued patents.

Additional US and Foreign patents pending.