PHYSIO CONTROL

PHYSIO-CONTROL
TRAINING

LUCAS® 3 Chest Compression System

Instructor Guidebook

Classroom and Hands-On Training

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Classroom and Hands-On Training

Physio-Control, Inc.
Redmond, Washington

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Instructor Notes:

This Instructor Guidebook is an introduction to the basic operations of the LUCAS 3 chest compression system and acts as a guide for conducting classroom and hands-on training in a manner consistent with training provided by Physio-Control.

Refer to the *Instructions For Use (IFU)* for complete directions for use, indications, contraindications, warnings, cautions and technical specifications. The IFU is included with each device.

All operators must read the complete IFU before operating the LUCAS chest compression system.

Chapter 1: Instructor Training Preparation

Instructor Training Preparation

THINGS TO KNOW BEFORE EACH TRAINING SESSION

Who is your audience?

There may be a combined audience of both prehospital and hospital providers. It is helpful to know whether the audience you will be instructing will be EMTs, Paramedics, Nurses, etc., to tailor your examples and discussion to be the most relevant for the audience present.

How large is your audience?

- In order for the hands-on training to be the most effective, it is important to maintain an instructor to student ratio of 1:6 (one instructor to six students).
- Determine the need for additional trainers and make arrangements for resources such as LUCAS devices, manikins and training materials accordingly, prior to the training session.

FACILITY PLANNING AND LOGISTICS

Each training session will require a classroom setting for the “Introduction and Device Overview” large enough to accommodate the audience attending. In addition, there needs to be ample space for multiple small groups, with an instructor to student ratio of 1:6, to perform small group hands-on training and application practice. This may require reserving a second room for the hands-on training depending on space available in the classroom.

Training should follow the timing outlined below:

15 min.	Introduction
45 min.	Classroom Training
10 min.	Break
120 min.	Small Group Hands-On Training and Application Practice
5 min.	Break
30 min.	Training Evaluation
15 min.	Q&A/Additional Hands-on (as needed)

Room layout

- Basic classroom layout should include tables and chairs for students to take notes and complete evaluations at the conclusion of the training.
- For the small group hands-on training, ensure enough floor space for hands-on training with a manikin.

Audio/Visual needs

- There are several videos that will be played at the beginning of the classroom session. The room will need to be set up with a projector. A computer with internet access will allow streaming of the videos. If internet access is slow or limited the videos can be downloaded ahead of time.

Power

Ensure there is an adequate power supply and power strips for A/V equipment or in the event that LUCAS devices need to be charged.

WHAT YOU NEED

Devices, accessories, manikins

- At least one LUCAS device and one manikin for every 6 students (e.g., class of 40 will require seven devices/manikins)
- Each LUCAS device in Carrying Case should have the following present:
  - Suction Cup mounted to the Piston
  - Patient Straps (wrist straps), attached to Support Legs
  - Stabilization Strap, present in Carrying Case with two Support Leg straps that buckle to Support Legs
  - Two charged batteries, one installed in device with spare in Carrying Case compartment
  - External Power Supply Cord, present in case compartment
  - LUCAS Back Plate
  - One additional Suction Cup
- One manikin for each LUCAS device

Training materials and handouts (Copies available: www.physio-control.com/LUCAS)

- LUCAS 3 Device Fits Large Patients
- LUCAS 3 User Performance Evaluation form
- LUCAS 3 Chest Compression System Training Quiz
- LUCAS 3 Device Training Answer Key and Annotated Test
- LUCAS 3 Device - First Use Preparation Video
- LUCAS 3 Device - Prehospital Application Video
- LUCAS 3 Device - Hospital Application Video
- LUCAS Report Generator - Quick User Guide
- LUCAS 3 Quick Reference Guide - Trifold
- Information on Defibrillation and Ventilation with LUCAS
- LUCAS 3 Instructor Guidebook

DEVICE PREPARATION AND READINESS

Prior to each training session, ensure all LUCAS devices are checked and ready for use. Always complete device preparation to allow at least four hours for charging batteries.

1. Make sure a Suction Cup is attached to the Piston.
2. Make sure the Patient Straps are attached.
3. Make sure the two Support Leg Straps of the Stabilization Strap are buckled around the Support Legs with the buckles on the inside.
4. Make sure batteries are fully charged. When the LUCAS device is in the OFF mode, push the **MUTE** button. The battery indicator illuminates and shows the battery charge status.
5. Push and hold the **ON/OFF** button to turn on the device so the LUCAS device does a self-test. Make sure the **ADJUST** **.** LED illuminates with no alarm or warning LED.
6. Push and hold the **ON/OFF** button for one second to power down the LUCAS device again.
7. Charge LUCAS batteries as needed.
    - Installed in LUCAS device (power supply cord) – less than two hours
        - Put battery in the slot in the Hood of the LUCAS device
        - Connect the Power Supply to the DC input on the side of the LUCAS device
        - The LUCAS device can be charged using the charge port in the back of the Carrying Case
        - Connect the Power Supply to the wall outlet
    - In the external LUCAS Battery Charger (if available) – less than four hours
        - Put the battery in the slot of the battery charger
        - Connect the battery charger power cord to the wall outlet

Chapter 2: Classroom Training Introduction and Overview

Classroom Training—Introduction and Overview

INTRODUCTIONS

Introduce lead trainer and support staff.

Confirm your audience (e.g., “By a show of hands, how many of you are EMTs? Paramedics? Nurses?” etc.)

AGENDA REVIEW

Provide brief overview of the agenda for the training session:

- **Introductions**
- **Videos**
- **Introduction and Overview of LUCAS device**, including intended use, indications and contraindications for use, main parts, etc.
- **Comprehensive device and operation overview**
- **Break** (15 minutes)
- **Small groups hands-on training and application practice**
- **Training evaluations**
- **Q&A**

VIDEOS

There are three videos that can be played at the beginning of each training session. Have the videos prepared prior to starting the class. All videos available for streaming and downloading at ***www.physio-control.com/LUCAS.***

LUCAS 3 Chest Compression System - First Use Preparation

- This video provides an overview of the LUCAS device first time assembly, standard and optional accessories and device storage.

LUCAS 3 Chest Compression System - Prehospital Application

- This video provides an overview of LUCAS device application in the EMS setting.

LUCAS 3 Chest Compression System - Hospital Application

- This video provides an overview of LUCAS device application in the hospital setting.

DEVICE OVERVIEW

LUCAS Chest Compression System

The LUCAS Chest Compression System is a portable tool designed to overcome problems identified with manual chest compressions. The LUCAS device assists rescuers by delivering effective, consistent and continuous chest compressions as recommended in the American Heart Association Guidelines for CPR[1] and the European Resuscitation Council guidelines[2]. Both human[3, 4] and experimental[5, 6] studies have shown that the LUCAS device can produce coronary perfusion pressures (CPP) of over 15mmHg during prolonged CPR, better than manual CPR.

Intended Use

LUCAS Chest Compression System is to be used for performing external cardiac compressions on adult patients who have acute circulatory arrest defined as an absence of spontaneous breathing and pulse, and loss of consciousness.

The LUCAS device must only be used in cases where chest compressions are likely to help the patient.

The LUCAS 3 device is for use as an adjunct to manual CPR when effective manual CPR is not possible (e.g., transport, extended CPR, fatigue, insufficient personnel). (US Only)

Contraindications

Do NOT use the LUCAS Chest Compression System in these cases:

- If it is not possible to position the LUCAS device safely or correctly on the patient's chest.
- Too small patient: if the LUCAS device alerts with 3 fast signals when lowering the Suction Cup, and you cannot enter the **PAUSE** mode or **ACTIVE** mode.
- Too large patient: If you cannot lock the Upper Part of the LUCAS device to the Back Plate without compressing the patient's chest.

Always follow local and/or international guidelines for CPR when you use the LUCAS chest compression system.

Personnel

It is recommended the LUCAS device is only used by persons with medical skills such as: first responders, ambulance personnel, nurses, physicians or medical staff, who have:

- Undertaken a CPR course according to the resuscitation guidelines (e.g., American Heart Association, European Council Resuscitation or equivalent)

- AND received training in using the LUCAS device

Side Effects

The International Liaison Committee on Resuscitation (ILCOR) states these side effects of CPR:[7]

> *"Rib fractures and other injuries are common but acceptable consequences of CPR given the alternative of death from cardiac arrest. After resuscitation, all patients should be reassessed and re-evaluated for resuscitation-related injuries."*

Apart from the above, skin abrasions, bruising and soreness of the chest are common during the use of the LUCAS Chest Compression System.

Clinical as well as autopsy studies have shown that LUCAS compressions are safe for the patient[8–11, 13] with the same type of side-effects as for manual CPR.

Main Components

The main parts of the LUCAS Chest Compression System include;

- A **Back Plate** which is positioned underneath the patient as a support for the external chest compressions.
- An **Upper Part** which contains the proprietary and rechargeable LUCAS Battery and the compression mechanism with the disposable Suction Cup.
- A **Stabilization Strap** which helps to secure the position of the device in relation to the patient.
- A **Carrying Case.**

Each part of the LUCAS device and its operation will be covered in the next section, Comprehensive in-depth device and operation overview.

COMPREHENSIVE IN-DEPTH DEVICE AND OPERATION OVERVIEW

Instructor Notes:
Begin with a complete LUCAS chest compression system packed in the Carrying Case on a table at the front of the room and visible to the attendees. As you review each component and aspect of operation, physically remove the component from the case and demonstrate to the audience.

Carrying Case

The LUCAS Carrying Case was designed to be compact, portable, durable and easy to deploy.

Instructor Notes:
Begin by demonstrating the key components of the case; the hard shell, the Top Window and the rear Charge Port. Next demonstrate how to open the Carrying Case and turn on the device while still in the case.

While the LUCAS chest compression system is still in the case, push the power **ON** button for one second to allow the device to perform a self-test to make sure it is ready to operate before applying it to the patient. The case and power on procedure will be reviewed in more detail later during the *Application Demonstration.*

Back Plate

Instructor Notes:
Remove the Back Plate from the case, explain what the picture on the Back Plate means and where the claw locks attach.

The graphic on the Back Plate is intended to provide a reminder of where to orient the Back Plate in relation to the patient, and where to position the Piston and Suction Cup. (Positioning of the Piston and Suction Cup will be explained when reviewing the Upper Part of the LUCAS chest compression system.)

The Back Plate should be placed under the patient, immediately below the arm pits, either by lifting the patient's upper body a small distance or by rolling the patient from side to side. Accurate positioning of the Back Plate makes it easier and faster to position the Upper Part and Suction Cup correctly.

The rods on each end of the Back Plate are where the Claw Locks on the Support Legs attach the Upper Part to the Back Plate.

The LUCAS device is specifically designed to be used with the LUCAS Back Plate. It cannot be applied directly to any other backboard or transportation device.

Carrying Case Contents

Instructor Notes:
Set the Back Plate aside. Remove the Upper Part from the Carrying Case and set aside to review contents of the bag. Show the audience where each component is located in the Carrying Case.

In addition to the Back Plate and the Upper Part (including battery), the LUCAS device is delivered with:

- Two disposable Suction Cups—one will be attached to the LUCAS device, and one will be packaged and in the mesh storage compartment.

There is a storage compartment in the middle of the Carrying Case that can hold a spare battery and a battery charger.

The Stabilization Strap is also placed in the bag where it can be easily accessed. When returning the Stabilization Strap to the Carrying Case, loosen the strap and roll it for the next use.

Upper Part

Instructor Notes:
Highlight all of the components of the Upper Part of the LUCAS device. Point out each component and demonstrate. Note: some parts, such as the control panel, may be difficult to see from a distance. Explain that attendees will have a chance to review all of these components up close during the hands-on portion of the training.

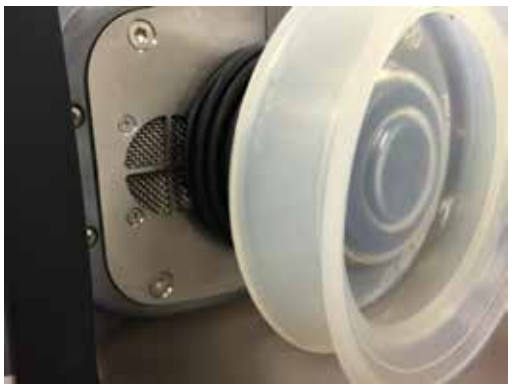
The Hood of the LUCAS device contains the Battery and the User Control Panel. Internally, the Hood houses the compression module and all of the electronics of the LUCAS device.

Do not immerse the LUCAS device in liquid. The device can be damaged if liquid enters the Hood.

Underneath the Hood of the LUCAS device are the Vent Holes. Do not block the Vent Holes as this can cause the device to become too hot.

The LUCAS device has an IP43 rating, which is the level of ingress protection against particulate matter (first number) and liquid (second number). A rating of 3 for liquid indicates protection against spraying water, such that water falling as a spray at any angle up to 60 degrees from the vertical will not have a harmful effect. This is consistent with what you would expect from rainfall.

Instructor Notes:
After showing the Vent Holes under the Hood, point out the Pressure Pad at the end of the Piston and Suction Cup.



Underneath the Hood is the Piston, which contains the Pressure Pad and the Suction Cup.

The Pressure Pad is at the end of the Piston. The Pressure Pad acts as the heel of your hand when performing manual CPR, it is what makes contact with the chest when performing compressions. The compression point should be in the middle of the chest, at the same spot as for manual CPR and according to current Guidelines.

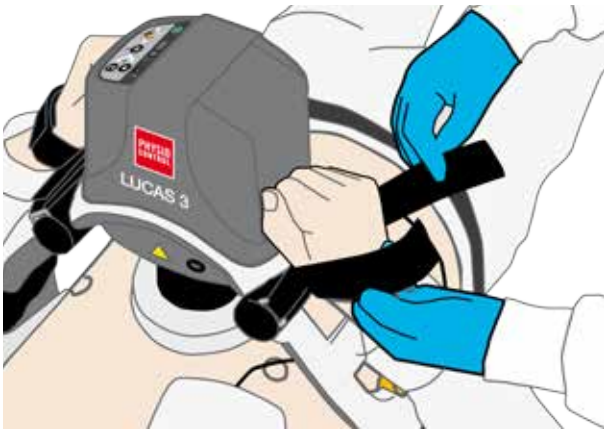
When the Pressure Pad in the Suction Cup is in the correct position, **the lower edge of the Suction Cup is immediately above the end of the sternum bone. The lower edge of the Suction Cup should not be placed over the tip of the sternum (xiphoid process), but over the lower edge of the main body of the sternum.**

If the Pressure Pad is not in the correct position, there is an increased risk of damage to the rib cage and the internal organs. Also, the patient's blood circulation is compromised.

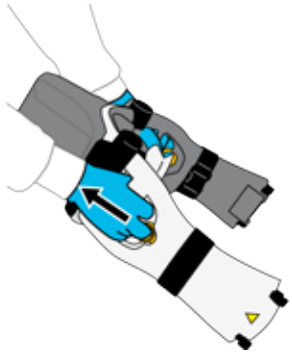
The Suction Cup is disposable and should be replaced after each use. To replace the Suction Cup, pull it off the black mounting tube and discard it. Bend a new Suction Cup back onto the tube and make sure it is safely attached.

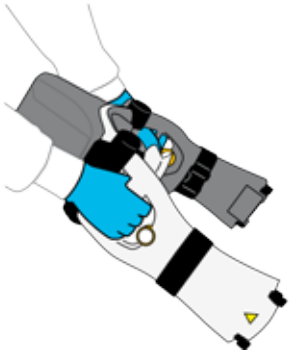
The **Support Legs** contain several components:

- The **Patient Straps** – When you move the patient, you can secure the patient's arms with the Patient Straps on the LUCAS device. This makes it easier to move the patient. Do not use the straps for lifting, and make sure that IV access is not obstructed.



- The **Release Rings** – The Release Rings operate the **Claw Locks**, which attach the Upper Part to the Back Plate. These are used for removing the LUCAS device from the Back Plate. However, before applying the Upper Part, you should pull the Release Rings once to make sure the claw locks are open, then release the Rings.





It is important you release the Rings when attaching the Upper Part to the Back Plate so the Claw Locks can click onto the Back Plate. Listen for the click and make sure the parts are correctly attached by pulling up on the device.

Instructor Notes:
Point to the Claw Locks and demonstrate opening a closed Claw Lock by pressing one side closed, and pulling the Release Rings once to demonstrate opening the Claw Locks.

- **Support Leg Strap for the Stabilization Strap** – The Stabilization Strap helps secure the correct position during operation. Apply it while the LUCAS device is active to keep interruptions to a minimum. Delay the application of the Stabilization Strap if it prevents or delays any medical treatment of the patient.
- Once the device is active:
  - Remove the Stabilization Strap from the Carrying Case and extend the strap fully at the buckles.
  - Carefully position the cushion of the Stabilization Strap behind the patient's neck, as close to the patient's shoulders as possible.
  - Connect the Buckles on the Support Leg straps to the Buckles on the Stabilization Strap. Make sure straps are not twisted.
  - Hold the LUCAS device Support Legs stable and tighten the Stabilization Strap. Only tighten as much as needed to secure the device. Be careful not to pull the device out of position.

Instructor Notes:
Attach the Upper Part of the LUCAS device to the Back Plate. In the next section you will demonstrate the too small patient alarm and explain the control panel.

Control Panel

The Control Panel is intended to be simple and easy to use, and after you turn the device on, the steps are numbered 1 through 3.

The **ON/OFF** button is in the top left of the Control Panel in the gray bar. Push and hold this button for one second to power up or power down the LUCAS device. When the device powers up, it automatically does a self-test of the functions and the protective system. When the self-test is complete, the green LED beside the **ADJUST** key illuminates. This takes approximately three seconds.

- When you are using the LUCAS device, the very first thing you do, even before taking it out of the Carrying Case, is to press the **ON/OFF** button and turn the device on.

The orange button is the **ADJUST** button. It is also labeled with a “1”. When you turn the device on, it automatically enters the ADJUST mode, which is used to adjust the position of the Suction Cup. When you push this button, you can manually move the Suction Cup up or down. To adjust the start position of the Suction Cup, manually push down the Suction Cup, extending the Piston with two fingers onto the chest of the patient, ensuring the pressure pad touches the patient’s chest.

Press the **PAUSE** button, labeled with a “2”, to lock the Piston in the Start Position. Also, use this when you want to stop the device and temporarily pause compressions but still want to keep the Start Position of the Suction Cup.

There are two **ACTIVE** modes on the device. One is **ACTIVE (continuous)** and the other is **ACTIVE (30:2)**.

In **continuous mode** the device will perform continuous compressions at 102 ± 2 compressions per minute; use this setting if the patient is intubated. The green LED next to the button for continuous mode will blink ten times per minute to alert for ventilation during ongoing compressions.

When you push the **ACTIVE (30:2)** button, the device will perform 30 compressions, then temporarily stop for three seconds to allow for giving two ventilations, and continues this cycle. An intermittent LED in combination with an alarm signal sequence on the 28th, 29th and 30th compression will alert the operator before each ventilation pause.

On the top of the Control Panel, in the middle of the gray bar, are the **MUTE** button and the **Alarm indicator**.

Pushing the **MUTE** button will mute the alarm for 60 seconds. If you push this button when the device is powered OFF, the Battery indicator will show the charge status of the battery.

On the **Alarm Indicator**, a red LED and alarm signal indicate a malfunction. If there is a malfunction while the device is performing chest compressions, push **ON/OFF** for one second to stop the device, remove the device, and perform manual CPR immediately to minimize interruptions in compressions.

If your protocols allow, you can attempt to reset the alarm once by pushing **ON/OFF** , removing and replacing the battery and following proper steps to deploy the device in the **APPLICATION DEMONSTRATION** section of this guide.

TRANSMIT data: This key is used to transmit data after the use of the LUCAS device. The device must be in power OFF mode to transmit data.

More information about data will be covered in the **'LUCAS Report Generator - Quick User Guide'** flyer.

Caution - Radio frequency communications can affect other medical electrical equipment.

Battery

The Battery is in the Hood, opposite the Control Panel. The Lithium Polymer battery has a runtime of 45 minutes when fully charged. If the battery is fully depleted, it takes less than two hours to charge when the power supply cord is used, and less than four hours in the standalone battery charger.

In the center of the top row of the Control Panel is the **Battery indicator**. Three green LEDs show the charge status.

- Three green LEDs means the Battery is fully charged
- Two green LEDs means the Battery is 2/3 charged
- One green LED means the Battery is 1/3 charged

If you see one intermittent yellow LED and hear an intermittent alarm during operation, it means the Battery has less than 30% capacity, or approximately 10 minutes of operating capacity left. (For a complete list of Battery indicators, refer to the Instructions for Use.)

The status of the battery charge can be evaluated without removing the device from the Carrying Case. Simply pressing **MUTE** through the top window, will illuminate the battery indicator.

To minimize interruptions, having a charged spare LUCAS battery in the carrying case is always recommended. When the battery gets low during operation, it can be replaced by a new one without turning the device off. To change the battery during operation:

1. Press **PAUSE** to temporarily stop compressions
2. Pull the Battery out and then upwards to remove it
3. Install a fully charged spare and wait until the green **PAUSE** mode LED illuminates
4. Push either **ACTIVE (continuous)** or **ACTIVE (30:2)** to start chest compressions again

If the battery change takes less than 60 seconds, the LUCAS Smart Restart feature remembers the settings and Start Position for 60 seconds. If the battery change takes more than 60 seconds, the device does a self-test and you must adjust the Start Position again.

If there is no spare battery present, the device can be connected to the Power Supply in all operating modes. **The Battery must always be installed for the device to be able to operate, including when it is powered by the external Power Supply.** The Power Supply connects to the LUCAS device just below the Hood. The device can run for as long as needed on a nominal patient chest when connected to the Power Supply.

It is recommended to replace the battery every three to four years or after 200 uses of more than 10 minutes each time.

Instructor Notes:
Turn the LUCAS device on. Point out the self-test. Demonstrate moving the Piston up and down.

Patient Size

Remember, do not use the LUCAS device if the patient is too small (the LUCAS device alarms with three fast signals and you can't enter the **PAUSE** or **ACTIVE** modes) or if the patient is too large (you can't lock the Upper Part to the Back Plate without compressing the patient's chest).

Although the LUCAS device looks small, it can fit very large patients. When it was launched in the United States, a survey of four different EMS systems on the use of the device on over 300 patients showed that it fit 95% of patients. Of those who didn't fit, 3% were too large and 2% were too small.[12] This was also confirmed in the LINC Trial, a large, randomized controlled trial including 1,300 patients in Europe who received LUCAS chest compressions.[13]

The LUCAS device will fit patients with:

- Chest width up to 44.9 cm / 17.7 inches
- Sternum height of 6.7 to 17 - 30.3 cm / 11.9 inches

The use of the device is not restricted by patient weight.

If the device does not fit on the patient, remove the device and immediately perform manual CPR.

Instructor Notes:
Make sure the LUCAS device is on. Demonstrate the too small patient alarm by slowly pulling the Suction Cup down until device alarms with three fast signals. Slowly lift the Suction Cup until the signals stop and then leave the Suction Cup there to demonstrate the approximate sternum height of a patient that is too small for the device.

Preparation for Next Use

To remove the LUCAS device, press the **ON/OFF** button for one second to power off the device. If a Stabilization Strap is attached, remove the cushion of the Stabilization Strap from the Support Leg straps and loosen the Stabilization Strap for next use. Then, pull the Release Rings to remove the Upper Part from the Back Plate.

After each use you should remove the Suction Cup, and clean the device and straps and let it dry. You should also replace the Battery with a fully charged one and mount a new Suction Cup.

Clean all surfaces and straps with a soft cloth and warm water with a mild cleaning agent or disinfectant agent, e.g.

- 70% isopropyl alcohol solution
- 45% isopropyl alcohol with added detergent
- Quaternary ammonium compound
- 10% bleach
- Peracetic (peroxide) acid solutions

Follow the handling instructions from the manufacturer of the disinfectant.

When putting the device back in the Carrying Case, ensure the DC input is placed downward. Putting the LUCAS device in this position makes it possible to charge the device through the Carrying Case charger access port and to check Battery charge status through the Carrying Case top window. Loosen the Stabilization Strap and place it in the bag so it is ready to go the next time you deploy the device. Slide the Back Plate into the pocket in the lid of the Carrying Case. Close the lid of the case and zip it closed.

A full list of steps to prepare the LUCAS device for the next use is in the IFU.

APPLICATION DEMONSTRATION

Instructor Notes:
Put a half manikin (Brad™ CPR Manikin or comparable) on the floor or table and ask for a volunteer to help by performing manual chest compressions while you apply the LUCAS device.

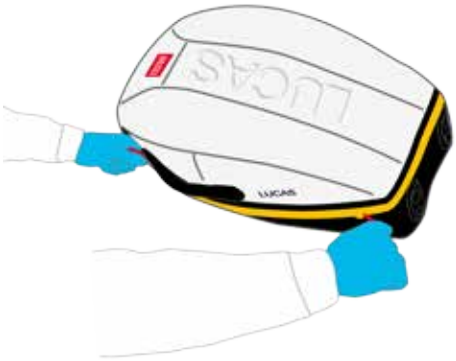
Arrival at the patient

After confirming the patient is in cardiac arrest, manual CPR should be started immediately until the LUCAS device is ready.

Unpack the LUCAS device

The LUCAS Carrying Case was designed to be quick and easy to deploy.

- Using the large zipper handles, unzip the case.



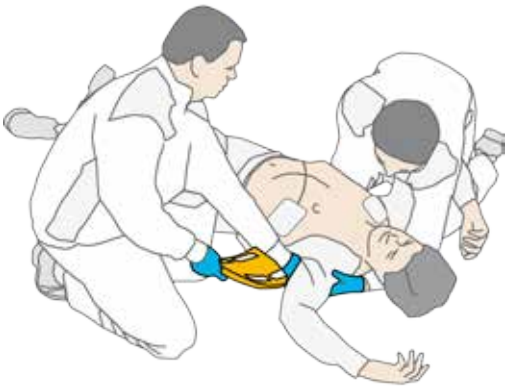
- While the device is still in the bag, push the **ON/OFF** button for one second to power on the device. You will hear a few tones while the device does its self-test to make sure it's ready to operate before applying to the patient.

Apply LUCAS device to the patient

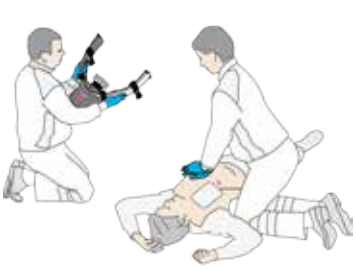
Always apply the device with minimal interruptions in compressions. This can be done in two brief pauses.

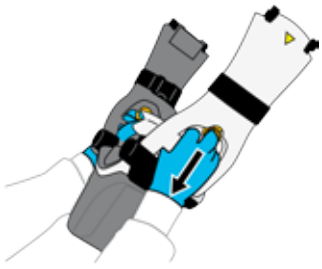
1. Remove the Back Plate from the Carrying Case.

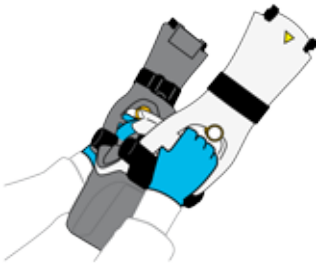
2. Temporarily stop manual CPR while placing the Back Plate under the patient, immediately below the armpits. You can use several procedures to do this: either lift the patient's torso and slide the Back Plate under from the head, or log roll the patient and slide the Back Plate in from the side.



3. Start manual CPR again.
4. Hold the handles on the Support Legs to remove the LUCAS Upper Part from the case. Pull the Release Rings once to make sure that the Claw Locks are open, then let go of the Release Rings.







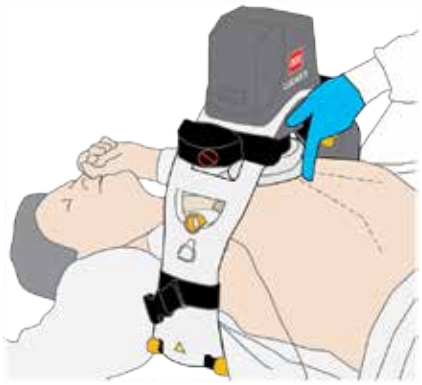
5. Attach the Support Leg that is nearest you to the Back Plate.

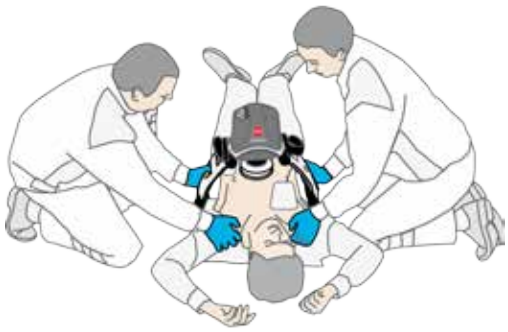
6. Move the other Support Leg through the arms of the responder doing manual CPR and stop manual CPR while you attach the Support Leg to the Back Plate. Ask your partner to assist with attaching the second Support Leg if needed. Listen for a click.
7. Pull up once to make sure the parts are correctly attached.

Adjustment and Operation

Remember, the compression point should be at the same spot for manual CPR according to the Guidelines. When the Pressure Pad in the Suction Cup is in the correct position, **the lower edge of the Suction Cup is immediately above the end of the sternum, but not over the xiphoid process.**

1. Use your finger to make sure the Suction Sup is immediately above the end of the sternum. If necessary, move the device by pulling the Support Legs to adjust the position.





2. Adjust the height of the Suction Cup to set the Start Position. This is the position where the LUCAS device will start its two-inch compressions, and the point where it will return the chest for full recoil.

- Make sure the LUCAS device is in **ADJUST** mode
- Push the Suction Cup down with two fingers until the Pressure Pad touches the patient's chest without compressing it
- Push **PAUSE** to lock the start position.
- Check for proper position. If you need to reposition:
    - Push **ADJUST**, pull the Suction Cup up, move the device by pulling the Support Legs, push the Suction Cup down until the Pressure Pad touches the chest, then push **PAUSE** once back in place
- Push either **ACTIVE (continuous)** or **ACTIVE (30:2)**.

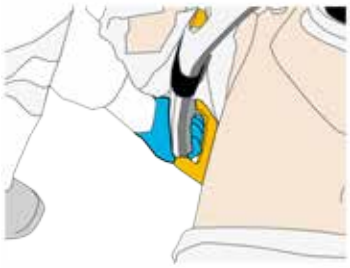
Notes:

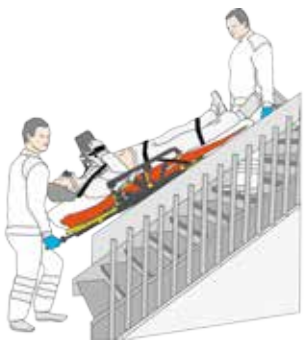
- The LUCAS device has a "quick fit" feature, so if the Pressure Pad is pushed down too hard, or not touching the chest fully, the device will adjust the Pressure Pad by up to 30 mm /1.2 inches in either direction to the correct start position.
- Some users will use a marker to draw a line on the chest around the top and/or bottom of the Suction Cup to help monitor placement during operation.

The LUCAS Stabilization Strap helps secure the correct position during operation. Apply it while the LUCAS device is active to keep interruptions to a minimum. Delay the application if it delays any medical treatment of the patient. The Stabilization Strap is not a neck Stabilization Strap but a device Stabilization Strap. The Stabilization Strap can fit and be put on the outside of a c-collar.

Moving the Patient

When you move the patient, you can secure the patient's arms by placing their wrists in the Patient Straps on the LUCAS device. This makes it easier to move the patient, but DO NOT lift the patient by the Patient Straps. Make sure that IV access is not obstructed.





To move a patient, the LUCAS device can be used on a backboard, carrying sheet or other transportation device. After you have made a decision about what equipment you will use and where to put the transportation device, you can prepare to lift the patient.
(**Note:** The LUCAS device cannot be connected directly to a backboard. The LUCAS Back Plate must be used. The whole system can be used on top of a backboard or other transportation device.)

Those at the patient's side can put one hand below the Claw Locks under the Support Leg and with the other hand, hold the patient's belt, pants or under the thigh.

To lift the patient:

1. Push **PAUSE** to temporarily stop compressions.
2. Lift and transfer the patient to a stretcher or other transportation device (backboard, carrying sheet, vacuum mattress or similar).
3. Make sure the Suction Cup is in the correct position on the patient's chest.
4. Push one of the **ACTIVE** buttons to start compressions again.

The device can be active when you move the patient, including at an angle, as long as the device and the patient are safely positioned on the transportation device and the device stays in the correct position and angle on the patient's chest.

Always monitor the position of the Suction Cup. If the position changes during movement, immediately push **ADJUST** to adjust the position. Always use the Stabilization Strap to help secure the correct position.

Defibrillation

Defibrillation can be performed while the LUCAS device operates.

- **Note:** Chest compressions interfere with ECG interpretation. Push **PAUSE** to temporarily stop compressions before you perform a rhythm check with a manual defibrillator or analysis with an AED. Once ECG rhythm check or AED analysis is complete, you can immediately press either **ACTIVE (continuous)** or **ACTIVE (30:2)** .to continue compressions to help make the interruption as short as possible.
- You can apply the defibrillator electrodes before or after the LUCAS device has been put in position, but you should never delay defibrillation of a shockable rhythm to apply the device.
- Position the electrodes and wires so they are not underneath the Suction Cup. If there are already electrodes on the patient, make sure they are not under the Suction Cup. If they are, apply new electrodes.
- Perform defibrillation according to the instructions from the defibrillator manufacturer.

After defibrillation, make sure the Suction Cup is still in the correct position. If necessary, adjust the position.

Always follow your protocols regarding defibrillation.

Note: Chest compressions interfere with ECG interpretation. Push **PAUSE** to temporarily stop compressions before you perform a rhythm check with a manual defibrillator or analysis with an AED. Once ECG rhythm check or AED analysis is complete, you can immediately press either **ACTIVE (continuous)** or **ACTIVE (30:2)** .to continue compressions to help make the interruption as short as possible.

Ventilation

The optimal method of managing the airway during cardiac arrest will vary depending on the provider experience, EMS or healthcare system protocols, and the patient's condition.

With a non-secured airway (e.g., bag-valve-mask), use the **ACTIVE (30:2)** mode so the LUCAS device performs 30 compressions then pauses for three seconds to allow for two ventilations. With a secured airway (e.g., endotracheal tube), ventilation and chest compressions do not need to be synchronised and ventilations can be provided without pausing compressions. Use the **ACTIVE (continuous)** mode. A green LED will blink 10 times per minute to alert for ventilation. Current AHA and ERC Guidelines[1, 2] recommend 10 ventilations per minute and limited tidal volume to achieve chest rise. Avoid rapid or forceful breaths.

Always follow your protocols regarding ventilations for patients with a secured airway in place.

Q&A, 15 minute break

Instructor Notes:

Prepare for transition to small group hands-on training and application practice.

Depending on the number of students, divide the room into groups of no more than six students for every instructor by counting off around the room sequentially up to the number of groups (e.g., if there are 36 people in the class, there will be six groups of six, so have each person count sequentially up to six, then start over). The numbers correspond to the group they will be in after the break.

Chapter 3: Small Group Hands-on Training and Application Practice

Small Group Hands-on Training and Application Practice

The small group hands-on training and application practice is intended to ensure each student exhibits competency and is comfortable with the operation and application of the LUCAS device to be able to reproduce the hands-on training for their peers.

LEARNING OBJECTIVES

Upon completion of the small group hands-on training, students will be able to:

- Locate all buttons and indicators on the Control Panel and describe their function
- Explain the difference between the two Active operating modes of the LUCAS device
- Demonstrate proper placement of the LUCAS Back Plate
- Understand how to minimize interruptions to manual CPR during LUCAS device application
- Apply the Upper Part of the LUCAS device to the Back Plate and demonstrate proper positioning of the Suction Cup
- Demonstrate how to adjust the position of the Suction Cup if necessary
- Describe the function of the Stabilization Strap and demonstrate its application
- Demonstrate how to change the LUCAS Battery during operation
- Verbalize/demonstrate post-use data transmission, including what tool is used and what data is captured
- State the considerations for defibrillation when using the LUCAS device
- Understand the importance of resuming manual CPR if the device alarms or does not operate properly
- Successfully complete the LUCAS 3 User Performance Evaluation
- Reproduce the hands-on training for their own staff

ROLES, RESPONSIBILITIES AND EXPECTATIONS

Instructors:

Instructors will lead a group of no more than six students and evaluate their performance as they apply the LUCAS device. Instructors should emphasize that high-quality CPR with minimal interruptions is the goal, and the device should always be complemented by minimally interrupted high-quality manual CPR before and during application. Instructors are expected to demonstrate the application of the device according to the following guide and the *User Performance Evaluation*. The instructor will complete a *User Performance Evaluation* for each student once the student feels confident applying the device and has demonstrated device application at least three times. The instructor will provide feedback on each student's performance, including any steps in the *User Performance Evaluation* that were missed or performed incorrectly, and will require the student starts from the beginning until all steps are completed.

Students:

Students are expected to be engaged and actively participate in the small group hands-on training. They will be expected to ask questions during the detailed overview if clarification is necessary. Students are required to apply the LUCAS device until they exhibit competency and confidence in the operation and application of the device after no less than three times applying the device. Finally, they will take the role of instructor to demonstrate their ability to train others in the application of the device.

Instructor Notes:

Each instructor for the small group hands-on training will need the following materials:

- One LUCAS device with all of the accessories included in the Carrying Case
- One Brad CPR manikin (or comparable training manikin)
- Handouts for each student:
  - LUCAS 3 Device Fits Large Patients
  - LUCAS 3 User Performance Evaluation form
  - LUCAS 3 Chest Compression System Training Quiz
  - LUCAS 3 Device Training Answer Key and Annotated Test
  - LUCAS 3 Device - First Use Preparation Video
  - LUCAS 3 Device - Prehospital Application Video
  - LUCAS 3 Device - Hospital Application Video
  - LUCAS Report Generator - Quick User Guide
  - LUCAS 3 Quick Reference Guide - Trifold
  - Information on Defibrillation and Ventilation with LUCAS
  - LUCAS 3 Instructor Guidebook

DETAILED STEP-BY-STEP OVERVIEW

The following outline is intended to help guide instructors through the key points to be covered during the demonstration.

- General Overview
  - User Control Panel
  - Active operating modes
  - Battery and battery indicator, external power
  - Removing the LUCAS device, replacing Suction Cup
  - Data capture and review
- Operation
  - Case placement, powering ON the device, and applying the Back Plate
  - Removing Upper Part from case and attaching to Back Plate
  - Adjusting/Readjusting the Suction Cup and positioning on chest
  - Active modes and associated prompts
  - Stabilization Strap
  - Defibrillation
  - Patient transportation
  - Changing Battery during the LUCAS device operation
  - Data transmission and review

Instructor Notes:
With users following along on the *User Performance Evaluation,* walk through each step before doing a live action, full-speed demonstration.

Each numbered step below corresponds with a step in the *User Performance Evaluation.*

Start with the LUCAS device in the Carrying Case, next to the Brad manikin and ask for a volunteer to perform manual CPR on the manikin:

1. Opens case; presses **ON/OFF** for one second to start self-test and power up the LUCAS 3 chest compression system.

- **Key points:**
  - Carrying Case was designed to be fast and easy to deploy.
  - To open, grab the zipper handles and unzip the case.
  - Make sure users see how the device is oriented in the bag, point out that the charge port is facing down to ensure the device can be charged while in the case, and where the **ON/OFF** button is located.
  - You'll hear several tones when the device is turned on. These sounds are a self test.
  - Note: The LUCAS device powers down automatically after 5 minutes in the **ADJUST** mode.

2. Removes Back Plate from the case
3. Verbalizes "stop manual CPR" to other rescuer
4. Places Back Plate under patient, immediately below patient's armpits

- **Key points:**
  - Reiterate the Back Plate can be oriented in either direction and the graphic is only intended to provide a reminder of where to orient the Back Plate in relation to the patient, and where to position the Piston and Suction Cup.
  - To place the Back Plate, you can either lift the patient's torso and slide the Back Plate under from the head or log-roll the patient and slide the Back Plate in from the side.
    - If using a Brad manikin (or comparable), demonstrate lifting the torso
  - Explain that an accurate position of the Back Plate makes it easier and faster to position the Suction Cup correctly.

5. Verbalizes "Resume manual CPR" to other rescuer
6. Lifts Upper Part of LUCAS 3 device from case and pulls once on the Release Rings to check the claw locks are open, then lets go of Rings

- **Key points:**
  - **Let go of the Release Rings when attaching the Upper Part to the Back Plate.** Pulling them once is only to ensure that the Claw Locks are open and will snap onto the Back Plate. To demonstrate why you pull the Release Rings before attaching the Upper Part, manually close one of the Claw Locks and show what happens when the Release Rings are pulled.
  - Demonstrate that an effective way to remove the LUCAS device from the Carrying Case is for the user to place their thumbs in the top opening of the handle, and while grasping the handle, one finger can be placed in Release Rings so that removing the device and ensuring the Claw Locks are open can be done in one fluid motion.

7. Connects the Upper Part to the backboard – starting on the side closest to user. Listens for click.

- **Key points:**
  - The purpose of attaching the side closest to the user first is to allow manual compressions to continue with minimal interruptions while the person applying the LUCAS device swings the other Support Leg through the other rescuer's arms.
  - If necessary, the other rescuer, when they are stopping manual CPR, can grab the Support Leg and help guide it into position.

8. Pulls up once to ensure attachment
9. Positions the Suction Cup immediately above the end of the sternum in the center of the chest and adjusts if necessary.

- **Key points:**
  - Demonstrate physically feeling for the end of the sternum and guiding the Suction Cup into place.
  - Demonstrate how to adjust the position of the Suction Cup by grasping both sides of the Suction Cup and lifting when device is in **ADJUST** mode.

10. Pushes the Suction Cup down using two fingers with the device in **ADJUST** mode until the pressure pad inside the Suction Cup touches the patient's chest.
11. Pushes **PAUSE** to lock start position
12. Presses **ACTIVE (30:2)** .or **ACTIVE (continuous)**

- **Key points:**
  - Reiterate that 30:2 should be used with an unsecured airway (i.e., using a Bag Valve Mask) and users can switch to continuous without having to pause compressions once an advanced airway is in place.

13. Fully extends the Stabilization Strap at the buckles
14. Places the cushion of the Stabilization Strap under patient's neck
15. Connects buckles on support cushion straps to device straps
16. Tightens support cushion straps firmly

- **Key points:**
  - Reiterate the purpose of the Stabilization Strap is to help secure the correct position during operation, and should not be tightened more than needed.
  - Delay the application of the Stabilization Strap if it prevents or delays any medical treatment of the patient.

17. Checks for proper position of Suction Cup, adjusting if needed

- **Key points:**
  - Some people will use a marker and draw a line on the chest around the top and/or bottom of the Suction Cup to help monitor placement during operation.
  - The rescuer managing the airway can help inspect the position of the Suction Cup from the head, making sure it is centered on the chest.

Instructor Notes:
After walking through each step, with LUCAS device still applied to the manikin, demonstrate changing the battery during operation (hot swap) and where the external Power Supply is connected if necessary.

With LUCAS device operating in one of the ACTIVE modes:

1. Retrieve a charged spare from the carrying bag
2. Pause the compressions and remove the battery
3. Insert the new Battery and press **ACTIVE** once the green LED next to the **PAUSE** button is lit

- **Key points:**
  - Point out the port for the external power supply
  - Explain the device can operate for prolonged periods while on external power but emphasize that a Battery always needs to be installed in the device for it to operate
  - Explain you must detach the power supply cord by pulling back on the plastic connector. Do not pull the cable directly as this can damage the charging port.

Instructor Notes:
After demonstrating changing the Battery during operation, pause compressions and discuss the considerations for defibrillation while using the LUCAS device.

With LUCAS device paused, emphasize the following:

1. Make sure no pads or wires are under the Suction Cup. If the patient already has pads applied they may need to be replaced.
2. During a rhythm check or AED analysis you'll need to stop compressions by pressing the **PAUSE** button (manual or mechanical compressions interfere with rhythm analysis).
3. To minimize interruptions and resume CPR as soon as possible, you can charge and defibrillate the patient without removing the LUCAS device and while compressions are ongoing.

- **Key points:**

- Compressions cause artifact in the rhythm – as soon as rhythm check or AED analysis is complete, compressions can be resumed.
- After shock is delivered, you should always check placement of the Suction Cup to make sure it hasn't moved out of place. This is why using a marker to mark the placement of the Suction Cup can be helpful.

Instructor Notes:
Before placing LUCAS device back into the Carrying Case to prepare for student applications, discuss cleaning and demonstrate how to remove the Suction Cup.

Press and hold ON/OFF for one second to power down the LUCAS device, and emphasize the following steps to prepare device for the next use:

1. Before placing LUCAS device back in the bag, clean it as necessary.

- **Key points:**
  - All surfaces and straps can be cleaned with a soft cloth and warm water with a mild cleaning agency or disinfectant agent, such as a 70% isopropyl alcohol solution.
  - A full list of cleaning solutions is found in the IFU.
  - Don't immerse the LUCAS device in liquid. It can be damaged if liquid enters the Hood.

2. To remove the Suction Cup, peel it off of the black mounting tube. Bend a new Suction Cup onto the black mounting tube and make sure it's fully seated and safely attached by spinning the Suction Cup and giving it a gentle tug.
3. To transmit post-event data from the LUCAS device, ensure it is turned off, then press the **TRANSMIT** button. Further instructions about data transmission can be found in the **'LUCAS Report Generator - Quick User Guide'** insert.
4. Remember to place the LUCAS device with the charge port facing down into the case. This ensures the battery status can be checked through the Top Window and the device can be charged while remaining in the Carrying Case.

REAL-TIME APPLICATION DEMONSTRATION

Instructor Notes:
After providing the detailed, step-by-step demonstration of the LUCAS device, demonstrate the entire application process without explaining each step so students can see the application in real-time.

After the full speed demonstration, each student will take turns applying the device. When students exhibit competency and confidence in the operation and application of the device after no less than three applications, use the student's User Performance Evaluation to evaluate their performance.

STUDENT DEVICE APPLICATION

Each student will take turns practicing applying LUCAS device with a partner performing manual CPR during the initial steps of device application.

Each student should apply LUCAS device at least three times, and until they are comfortable and confident applying the device.

After each student has applied LUCAS device at least three times, confirm whether they feel comfortable and confident applying device. If there are any aspects of device application the students are not comfortable with, review and demonstrate them again with the group.

COMPLETING THE USER PERFORMANCE EVALUATION

Instructor Notes:
Emphasize to the group the form is intended to provide constructive feedback on their LUCAS device application and is not meant to be punitive. The goal is to prepare instructors for their peers, by ensuring knowledge and competency with the LUCAS device.

For students who need extra time or assistance, inform them there will be an opportunity at the end of the training to spend extra time practicing LUCAS device application.

Ask each student to provide you with their *LUCAS 3 User Performance Evaluation form*.

As each student demonstrates applying the LUCAS device, follow along on their *User Performance Evaluation form* and mark whether each step was completed.

Using a stopwatch or the stopwatch feature on a cell phone, time the student's application of the device, starting the timer right after Step 6 when manual compressions stop for attachment of the upper part. Stop the timer at Step 12, as soon as they press either **ACTIVE (30:2)** or **ACTIVE (continuous)** and start LUCAS compressions. **The goal is to complete steps 7 through 12 in less than 20 seconds to minimize interruptions to chest compressions at device application.** Note this time on the form. If the time is >20 seconds, repeat the evaluation of the student.

After each application, review the steps the student did well, then provide positive, constructive feedback on any steps they did not complete. After reviewing any missed steps, give the student the option of repeating the application again or waiting until others have completed their evaluation before making another attempt.

Note: There will be extra time at the end of the training for additional practice for those who are not comfortable or who were unable to complete Steps 7 through 12 in less than 20 seconds.

After completing the *LUCAS 3 User Performance Evaluation form* for each student, they will now take the role of instructor and teach the instructor how to apply the LUCAS device.

Student Teach-Back

Students must demonstrate their ability to perform the detailed step-by-step overview

of how to apply the LUCAS device prior to the end of the hands-on training and application practice.

Each student will take turns acting as the instructor while the instructor takes the role of the student.

Instructor Notes:
As each student teaches LUCAS device application, ask questions as needed to ensure the student covers each step appropriately.

At the conclusion of the hands-on training and application practice, return to the classroom for training evaluation.

Chapter 4:
Training Evaluation

Training Evaluation

Instructor Notes:
Before the training evaluation begins, distribute copies of the Training Evaluation and Feedback Form and the LUCAS device training quiz.

The Training Answer Key and Annotated Test should be distributed once the quiz has been completed and answers reviewed with the class.

The training evaluation includes each student completing an evaluation and feedback form and training quiz, and receiving an annotated answer key and performance evaluation.

LUCAS 3 Device Training Quiz: This is a 20 question quiz, including 10 multiple choice and 10 True/False questions related to important information covered during the training. Students must complete the quiz individually.

When all quizzes have been completed, review the answers to the quiz as a group, using the Answer Key as a guide. The students will also be provided with a **LUCAS 3 Device Training Answer Key and Annotated Test**. This is a version of the training quiz that includes the correct answers highlighted in yellow. Under each question there is an explanation of the answer from the IFU, including the page numbers where the answers can be found.

LUCAS Device Training Evaluation and Feedback Form: Students are strongly encouraged to complete this form and leave it with the instructor (or other person designated on the day of the training) prior to departing to provide feedback on the training conducted and offer comments and/or suggestions for improvements.

Students are encouraged to do refresher trainings at least once a year.

Appendix A:
Important Contacts

Physio-Control Customer Service

Phone: 1.800.442.1142 (U.S.), 800.895.5896 (Canada)
Hours of operation: 5:00 AM to 4:00 PM PST
Web: www.physio-control.com > Service & Support > Customer Service

Physio-Control Technical Support

Phone: 1.800.442.1142
Hours of operation: 6:00 AM to 4:00 PM PST
Web: www.physio-control.com > Service & Support > Technical Support

Sales and Service Support

For sales and service related needs, please contact your local Physio-Control representative. You can use the “Find a Sales Rep” feature on our website (www.physio-control.com > Service & Support > Find a Sales Rep).

General LUCAS 3 Device Inquiries

Product Manager, LUCAS Chest Compression System
LUCAS3@physio-control.com

Appendix B:
Frequently Asked Questions

Frequently Asked Questions

The following are frequently asked questions related to the LUCAS device. For all pricing or ordering-related questions, refer to Appendix A: Important Contacts and contact your local Physio-Control representative. For product-related questions not addressed below, please contact: http://www.physio-control.com. Select your country at the top of the page and select 'contact us' or send an email to the LUCAS Product Manager at LUCAS3@physio-control.com.

Q: Can the LUCAS device be used on pediatric patients?

A: The LUCAS device is not indicated for use on pediatric patients. It is indicated for "performing external cardiac compressions on adult patients who have acute circulatory arrest…" The LUCAS device fits a broad range of patients, including smaller patients. Patients eligible for treatment with LUCAS device include adult patients who fit the device, with a sternum height of 17.0 to 30.3 cm / 6.7 to 11.9 inches.

Always follow local protocols for definition of adult versus pediatric patients.

Q: Can the LUCAS device be used on a pregnant patient?

A: In case of special circumstances such as pregnant women, there are no specific LUCAS device recommendations but the rescuer should refer to the current Guidelines (AHA or ERC).

The 2010[15]/2015[1] AHA Guidelines state:

- Priorities for the pregnant woman in cardiac arrest are a provision of high-quality CPR and relief of aortocaval compression. (2010)
- If left-lateral tilt is used to improve maternal hemodynamics during cardiac arrest, the degree of tilt should be maximized. However, at a tilt greater than or equal to 30° the patient may slide or roll off the inclined plane, so this degree of tilt may not be practical during resuscitation. (2010)
- Two studies in pregnant women not in arrest found that manual left uterine displacement, which is done with the patient supine, is as good as or better than left-lateral tilt in relieving aortocaval compression. (2010)
- Chest compressions should be performed slightly higher on the sternum than normally recommended to adjust for the elevation of the diaphragm and abdominal contents caused by the gravid uterus. (2010)
- Therefore, the critical importance of high-quality CPR has been further supported. Alternative strategies to relieve aortocaval compression do not seem to be compatible with delivery of high-quality CPR, the recommendation to perform left uterine displacement during CPR was strengthened. If the fundus height is at or above the level of the umbilicus, manual left uterine displacement can be beneficial in relieving aortocaval compression during chest compressions (2015, Class IIa, LOE C-LD).

Always follow local protocols and/or international guidelines for CPR when you use the LUCAS device.

Q: Can the LUCAS device be used on trauma patients?

A: There is no contraindication for trauma. Traumatic injuries can be of varying types and severities, so the professional rescuer who is treating the individual patient must use clinical judgment to determine when or when not to provide chest compressions.

The LUCAS device must only be used in cases where chest compressions are likely to help the patient.

Q: Is it OK to use the LUCAS device if the patient is a woman with breast implants?

A: We do not have any clinical data on how the LUCAS device affects breast implants. Anecdotally, we have heard of patients surviving long periods of LUCAS CPR with breast implants intact.

Q: Can we use the LUCAS device on a patient that has had a sternotomy?

A: The 2010 and 2015 AHA Guidelines have published the following recommendations (these recommendations were not changed in the 2015 Guidelines):

> *"For patients with cardiac arrest following cardiac surgery, it is reasonable to perform resternotomy in an appropriately staffed and equipped intensive care unit (Class IIa, LOE B). Despite rare case reports describing damage to the heart possibly due to external chest compressions, chest compressions should not be withheld if emergency resternotomy is not immediately available (Class IIa, LOE C)."*[15]

Taking this information and the LUCAS *Instructions for Use* into consideration, the physician or medical director can best determine whether it is appropriate to use the LUCAS device for patients with cardiac arrest after cardiac surgery.

Q: I've heard the LUCAS device provides such good circulation to the brain that patients can "wake up" while they are still in cardiac arrest. What do we do if this happens?

A: A potential consequence of high-quality CPR (correct depth, rate, minimum of interruptions) is increased blood flow to the brain and the heart, which may result in CPR-induced consciousness in individual patients.[21] There have been numerous anecdotal reports of patients becoming alert while still in cardiac arrest during LUCAS compressions, only to become unconscious again when the device is paused.

In circumstances such as this, there are no specific LUCAS device recommendations. You must follow your local protocols and/or medical direction.

The International Liaison Committee on Resuscitation (ILCOR) doesn't currently have any recommendations for either pharmaceutical or physical management of CPR-induced consciousness.[16] However, a recently published Dutch guideline for prehospital cardiac arrest suggested that agitation and/or pain during mechanical CPR can be treated with 2 µg/kg[1] of fentanyl IV (which can be titrated to 4 µg/kg[1]), and 2.5 mg of Midazolam IV (which can be titrated to 5 mg).[17]

Overall, the incidence and management of CPR-induced consciousness are not well described. A recent article published in *Resuscitation* reported the results of a systematic review that aimed to identify cases in published literature where CPR-induced consciousness is mentioned.[18] The review identified reports describing 10 patients who experienced CPR-induced consciousness, using both manual and mechanical CPR methods. In all of the cases, purposeful arm movements were observed. There were also reports of agonal breaths, eye opening and localizing painful stimuli. Cases also include both verbal and non-verbal communication with the rescuers. A few patients were even able to understand and adhere to instructions given to them, and there were also instances of agitation and attempts to push the rescuer away.

In four of the 10 cases, sedation was used; two didn't describe the drug or dose used; one stated "small doses" of morphine and diazepam; one case used 0.1 mg/kg[1] of Midazolam.

The conclusion of the literature review is as follows:

"*CPR may induce consciousness but this is infrequently reported in the medical literature. Treatment strategies for CPR-induced consciousness varied widely, and included physical restraint, administration of benzodiazepines and/or opiate, or no specific management. The incidence, implications and prognostic value of CPR-induced consciousness remains unknown. Increased awareness by rescuers of the presence of CPR-induced consciousness and development of consensus-based guidelines to treat this condition are required."*[18]

Always follow your local protocols.

Q: Can the LUCAS device be used at an angle, such as when going up and down stairs?

A: Yes. The LUCAS device can be used at an angle, as long as the device and the patient is safely positioned on the transportation device and device stays in the correct position and angle on the patient's chest (refer to IFU Section 5.6.4). If the position of the Suction Cup changes, immediately push **ADJUST** and adjust the position. Always use the LUCAS Stabilization Strap to help secure the correct position. Fixation/straps might be required. Always ensure the patient is properly strapped to the transportation device, according to locally approved procedures.

Q: Can the LUCAS device be used in a helicopter?

A: The LUCAS 3 device has been tested according to EN 13718-1:2014 Medical vehicles and their equipment - Air ambulances Part 1: Requirements for medical devices used in air ambulance. This includes random vibration and shock tests during operation, and stored in bag, in accordance with IEC 68-2-64 test Fh with RTCA/160G, section 8, category U/U2 as reference; and IEC 60068-2-29, test Eb with RTCA/160G, section 7 as reference, as well as drop and low pressure tests.

In addition, the LUCAS 3 device has also been tested according IEC 60601-1-2 for electromagnetic compatibility – which is a similar test as RTCA/DO-160F section 21 categories L, M and H tests done on the LUCAS 2 device.

The LUCAS 3 device retains the same form, fit and function as the LUCAS 2 device and tests done show the LUCAS 3 and LUCAS 2 devices have similar type of electromagnetic performance.

The LUCAS 2 device has been tested according to section 21 in the RTCA/DO-160F, environmental Conditions and Test Procedures for Airborne Equipment which is a standard for environmental test of avionics hardware. The LUCAS 2 device complies with the radiated emission (category L) and with the conducted emission (category L, M and H). This means the LUCAS 2 device does not influence nor is influenced by the flight environment in this test.

More tests might be required for use in different helicopters or within different organizations. In addition, the LUCAS 3 and LUCAS 2 devices have been tested in a number of other tests such as road ambulances and other set ups.

Q: Can we use the LUCAS device in the rain or snow?

A: The LUCAS device has an IP43 rating, which is the level of ingress protection against particulate matter (first number) and liquid (second number). As defined in international standard IEC 60529 (Ed. 2.1, clause 4.1) a rating of 3 for liquid indicates protection against spraying water, such that “water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect”. This is consistent with what you would expect from rainfall.

Do not immerse the LUCAS device in liquid. The device can be damaged if liquid enters the Hood.

Q: What do we do first, apply LUCAS device or defibrillate the patient?

A: The LUCAS device can be applied with minimal interruption to CPR, however, application of the device should preferably not delay defibrillation of a patient in a shockable rhythm or cause excessive interruptions in CPR. This should be considered when incorporating the LUCAS device into your cardiac arrest resuscitation protocol.

A growing number of protocols from LUCAS device users describe well-defined timing for the application of the device and steps to minimize CPR interruptions and avoid delays in defibrillation, including:

- Performing one or two full cycles of manual CPR prior to using the LUCAS device
- Requiring a defibrillator or AED to be applied before the LUCAS device
- Using a two-step application process (widely adopted by LUCAS device users globally), targeting longest pause of 10 seconds or less (placing the Back Plate during a planned pause, then attaching the Upper Part in a second planned pause)

Always follow your local protocols when using the LUCAS device.

Q: Do we need to pause the LUCAS device to intubate?

A: A manikin study has shown it is possible to intubate during LUCAS compressions.[22] Depending on skill level, experience and the individual patient, providers may be able to intubate without pausing the LUCAS device.

Q: Can the LUCAS device be attached directly to a backboard?

A: The device must be attached to the LUCAS Back Plate and cannot be directly attached to a backboard or stretcher. The LUCAS device is designed, tested and validated to be used only with the LUCAS Back Plate.

Q: How do we purchase extra Suction Cups, replacement Straps or other accessories?

A: Contact your local Physio-Control representative or Customer Service for replacement accessories.

Q: If the AHA or ERC guidelines change to recommend a different compression depth or rate, will the LUCAS device be updated?

A: Physio-Control is committed to implementing the latest standards of care in our products, and has a solid track record of offering updates to our products to meet the AHA/ERC Guidelines. Physio-Control will evaluate the feasibility and regulatory requirements of updates and changes on a case-by-case basis.

Q: How much force does the LUCAS device apply to the patient's chest?

A: Individual chests require different forces to be compressed 53 mm / 2.1 inches. LUCAS monitors each compression, senses and automatically adapts the force required to reach the correct compression depth on each patient.

Q: How quickly do the LUCAS Batteries deplete during storage?

A: Depletion time can vary and may be influenced by ambient temperature and the age of the Battery. To ensure the LUCAS device is always prepared for the next use, the Battery should be checked weekly and after each use to make sure it is fully charged. When the LUCAS device is OFF, press the **MUTE** button. The Battery Indicator illuminates and shows the Battery charge status.

Q: When the LUCAS device is not in use, can we leave the Power Supply Cord plugged into the device for extended periods of time without harming the Battery or device?

A: The LUCAS device can be left charging without harming the device or the Battery. When the Battery is fully charged, it will trickle charge.

Q: How long will the LUCAS device operate when running on the external power supply?

A: There is no specified limit. When operating on the external power supply on a typical patient, the LUCAS device can run continuously for as long as needed.

Q: What is the typical runtime for a fully-charged LUCAS Battery?

A: Typical runtime for a fully charged LUCAS Battery is 45 minutes.

Q: If unused, how long does the charge in a fully charged battery last when left in the Carrying Case?

A: About 1 year. However, you should always check the battery charge level at least weekly or after each use to ensure it is fully charged.

Q: If unused, how long does the charge in a fully charged battery last in the LUCAS device?

A: About 3 months. However, you should check the battery status and device weekly or after each use to ensure the device is ready for the next use.

Q: Can I deploy and turn on the LUCAS device in a grain silo?

A: No. Do not use the LUCAS device in conjunction with flammable agents.

Q: How do I keep the Back Plate from sliding on hard surfaces?

A: Optional Back Plate grip tape is available from your sales representative.

Q: Our system often operates in very cold environments. Is there a temperature range the LUCAS device must operate in?

A: The temperature ranges for the device are as follows, and are also included in Section 9 of the IFU:

- Operating Temperature:
  - 0°C to +40°C, +32°F to +104°F
  - -20°C, -4°F for 1 hour after storage at room temperature
- Storage Temperature:
  - -20°C to +70°C, -4°F to +158°F

For complete device environmental specifications, see Section 9.4 of the IFU.

Q: Are the operating and storage temperatures of the Battery the same as for the LUCAS device?

A: The operating temperature of the Battery is the same as for LUCAS device when it is installed in the device. The storage temperature of the battery when not installed in the device is: 0°C to +40°C, +32°F to +104°F.

For complete Battery environmental specifications, see Section 9.6 of the IFU.

Q: Does the LUCAS device perform two-inch compressions on every patient that fits in the device?

A: LUCAS device will perform compressions at a depth of 53 ±2 mm, 2.1 ±0.1” on patients with a sternum height greater than 185 mm, 7.3”.

The smallest patients (patients with a sternum height of 170 to 185 mm, 6.7” to 7.3”) will receive 40 to 53 mm, 1.5” to 2.1” compressions.

Appendix C:
The LUCAS Device in the Cath Lab

The LUCAS Device in the Cath Lab

The LUCAS chest compression system facilitates the transportation of the patient to the cath lab, and allows for catheterization and cath lab intervention during ongoing LUCAS chest compressions. An emerging strategy for treating refractory VF cardiac arrest patients where there is a suspicion of the underlying STEMI, is to transport the patient directly to the cath lab for an emergency PCI. The LUCAS device is also used as a backup tool in the cath lab in the event a PCI patient goes into a refractory, CPR-requiring cardiac arrest during a coronary intervention.

THE 2010/2015 AHA/ERC GUIDELINES ON RESUSCITATION IN THE CATH LAB

Manual CPR during PCI is very difficult, involving compromises on circulation, intervention and/or rescuer safety. The ERC and AHA guidelines outline the difficulty in performing effective manual chest compressions on a patient in the cath lab while performing a potentially lifesaving PCI.

> *"During both elective and emergent percutaneous coronary intervention (PCI), there is risk of cardiac arrest."*
>
> *"Although high-quality chest compressions improve the chance of successful resuscitation and survival, it is difficult to perform effective, high-quality chest compressions during PCI."*
>
> *- AHA Guidelines 2010, part 12 Special Circumstances, p S849*[15]

The AHA has given the use of mechanical CPR during PCI a class IIb recommendation based on LUCAS publications alone, and the LUCAS device is designed for use in the cath lab.

> *"It may be reasonable to use mechanical CPR devices to provide chest compressions to patients in cardiac arrest during PCI" (Class IIb, LOE C-EO))*
>
> *- AHA Guidelines 2015, part 10 Special Circumstances, p S508*[1]
> *Cardiac Arrest during Percutaneous coronary intervention*

ERC writes in their latest guidelines:

> *"It is of extreme importance that chest compressions are not interrupted for angiography. On an angiography table with the image intensifier above the patient, delivering chest compressions with adequate depth and rate is almost impossible and exposes the rescuers to dangerous radiation. Therefore, early transition to the use of a mechanical chest compression device is strongly recommended."*
>
> *ERC Guidelines 2015, section 4 Special Circumstances, p 170*[2]

THE LUCAS DEVICE IN THE CATH LAB

The LUCAS device is mainly made of radiotranslucent materials (transparent to x-ray), except for the Hood and the Piston, and a fully radiotranslucent cath lab Back Plate that does not interfere with the angiogram is available.

The cath lab Back Plate is made out of carbon fiber, which is lightweight and very strong. It can be pre-positioned in unstable patients, without compromising angiographic imaging, and allowing for quick set up in case of refractory/non-shockable arrest. The standard yellow Back Plate can be used as well, however the ridges of the Back Plate design will appear as shadows in the imaging/views of the coronary arteries.

The anterior-posterior design of the LUCAS Piston means that cranial and caudal angulation views are necessary when performing angiography during the time the LUCAS device is in place. Because of its radiotranslucency except for the Hood and the Piston, the LUCAS device allows for all oblique projections except the straight anterior-posterior. This means the following projections can be obtained in monoplane:

- LAO Cranial/Caudal Oblique
- RAO Cranial/Caudal Oblique
- Straight Caudal
- Straight Lateral
- Straight Cranial

See the **Common Angiographic Views with LUCAS Device** section of this guide for examples of angiographic views obtained with LUCAS device in place.

Applying the LUCAS device on the Cath Lab Table

The LUCAS device is applied to the patient using the same steps as usual. Prior to placing the device into service in the cath lab, we encourage users to practice and familiarize themselves with maneuvering the imaging equipment while the LUCAS device is in place.

Continuing the Intervention During LUCAS Compressions

The interventionalist CAN catheterize, balloon and stent the patient during ongoing compressions. During stent positioning, LUCAS device might be paused to ensure a precise positioning.

LUCAS Device with Other Circulatory Supports Used in the Cath Lab

The LUCAS device can work as a "bridge" to left ventricular assist devices (LVADs) or other extracorporeal circulation support devices or surgery, such as extracorporeal membrane oxygenation (ECMO). This means it "buys time" for the patient, providing vital circulation while these other devices are set up for use.

Prolonged Resuscitation in the Cath Lab

The LUCAS device facilitates prolonged rescue attempts in the cath lab. The AC power cord can be used to prolong the operation time. There was a case out of Minneapolis, MN, in which the LUCAS device provided compressions on a patient for two hours and 45 minutes. The patient survived with no neurological deficits.[19]

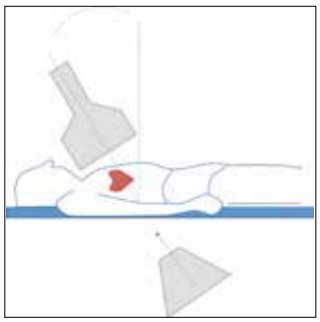
Common Angiographic Views with the LUCAS Device

The following images are from a test performed at Liverpool Hospital Cardiac Catheterization Lab in New South Wales, Australia.[20] The most common angiographic views were performed using Philips® Interventional Fluoroscopy System with a LUCAS 2 device, set up with the carbon fiber Back Plate. A Wire Heart (Bayer Pharmaceuticals) consisting of wire coronaries attached to a plastic aorta on a metal stand with plastic base was used to depict the coronary arteries. This test showed that the LUCAS 2 device provided clear working views in RAO-PA and RAO-PA Caudal planes with workable lateral views.

Although the photographs below show a LUCAS 2 Device, there is no difference in views as the LUCAS 3 device support legs and PCI plate are similar to those of the LUCAS 2 device.

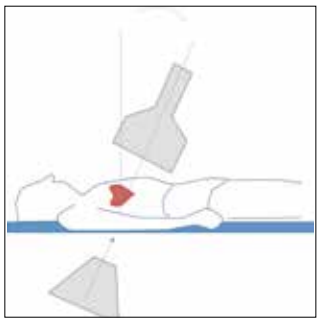
Cranial view

LUCAS 2 chest compression system allows for visualization of the coronary arteries in cranial views. The shadow of the Lucas Suction Cup may be partially visible.



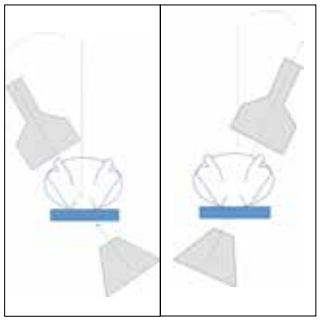
Caudal view

LUCAS 2 chest compression system allows for visualization of the coronary arteries caudal views.



Lateral view

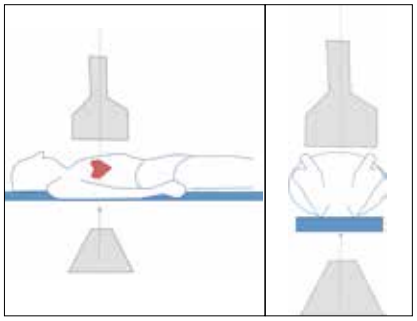
LUCAS 2 chest compression system Support Leg with screws causes minor artifact in lateral view.

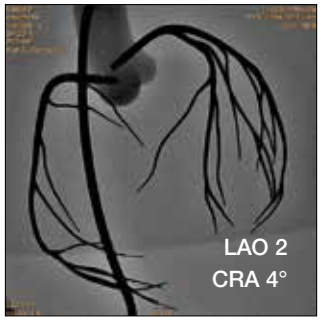


Straight posterior-anterior view

The straight posterior-anterior view cannot be used when the LUCAS device Upper Part is attached.

LUCAS PCI Back Plate (without Upper Part attached, in precautionary placement) allows for full visualization of arterial tree.





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This is not the complete instructions for use. Refer to Operating Instructions for complete device information including directions for use, intended use and warnings.

Physio-Control is now part of Stryker.

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