

LUCASTM

Chest Compression System Instructions for Use

US version



LUCASTM
Chest Compression System





Important user information

All users must read and fully understand the entire Instructions for Use before operating LUCAS™ Chest Compression System.

The Instructions for Use should always be easily accessible to the users of LUCAS.

Always follow local and/or international guidelines for CPR when using LUCAS.

The use of other medical equipment or drugs in conjunction with external chest compressions may reduce the effect of compressions. Always consult the instructions for use for other equipment or drugs to check that they are appropriate to use in conjunction with the treatment and compressions being performed with LUCAS.

When LUCAS is used on a non intubated patient the device can safely be stopped to allow intermittent manual ventilation. Switch off the device by turning the ON/OFF knob to the *Lock*  position, ventilate and turn the ON/OFF knob back to the *Active*  position again. See Section 1.5 on page 7 for information about the ON/OFF knob positions.

REQUIRED SKILLS

JOLIFE AB **strongly recommends** that LUCAS Chest Compression System is only used by persons with basic medical skills such as:

First responders, ambulance personnel, nurses, physicians or medical staffs, who have:

- completed a CPR course according to the American Heart Association or equivalent, AND
- received training in how to use LUCAS

LUCAS can only be bought by or on the order of a licensed medical practitioner.

TRADEMARKS

LUCAS™ is a trademark of JOLIFE AB.

DECLARATION OF CONFORMITY

LUCAS Chest Compression System complies with the requirements of the European Medical Device 93/42/EEC. It is marked with the CE-symbol:

 0434

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LUCAS Chest Compression System, Instructions for Use
[ENGLISH \(US\)](#)

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1 Introduction

1.1 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 absence of spontaneous breathing and pulse, and loss of consciousness.

LUCAS must only be used in cases where manual chest compression would be used. LUCAS is only intended for temporary use.

1.2 CONTRAINDICATIONS

Do **NOT** use LUCAS Chest Compression System in the following cases:

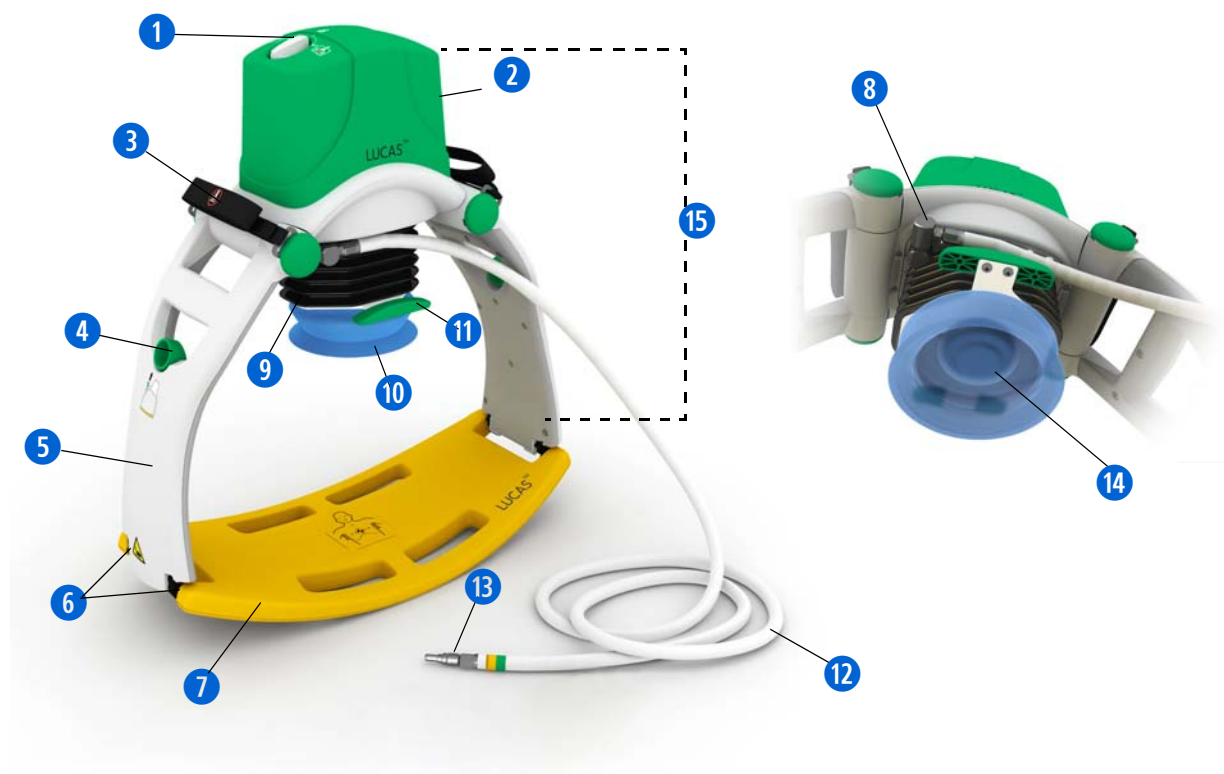
- **Too small adult patient:** The suction cup is not being completely compressed when it is lowered as far as possible.
- **Too large patient:** The support legs of LUCAS cannot be locked to the back plate without compressing the patient.
- **Patient is a child.**
- **Patient with traumatic injury** (wounds resulting from sudden physical injury or violence).
- **Pregnant patients.** The woman has to lie 10–15° to one side to prevent vena cava syndrome (impaired venous return to the heart as the uterus compresses the inferior vena cava).
- **If there is no indication that chest compression is likely to help the patient.**

1.3 LUCAS CHEST COMPRESSION SYSTEM

LUCAS is a portable device for external cardiac compressions. It is stored and easily carried in a backpack, giving the user free hands until the device is needed.

The components of LUCAS are shown in the illustration in Section 1.4.




1.4 LUCAS COMPONENTS

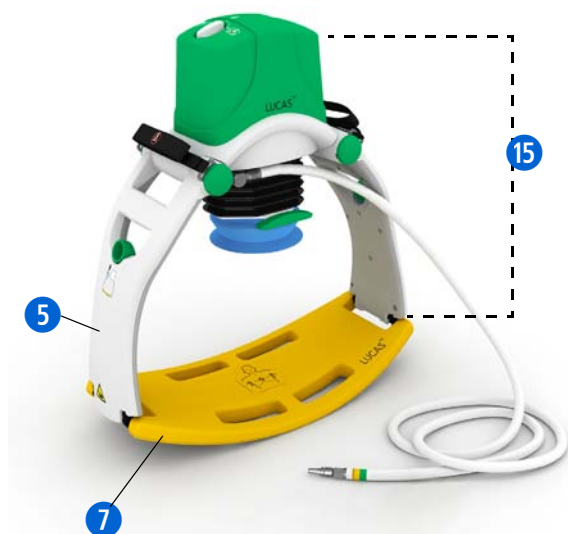


1. **ON/OFF** Knob
2. Hood
3. Patient strap
4. Release ring
5. Support leg
6. Claw lock
7. Back plate
8. Hose attachment
9. Bellows
10. Suction cup
11. Height adjustment handle
12. Air hose
13. LUCAS unique connector
14. Pressure pad
15. Upper part

1.5 ON/OFF-KNOB, POSITIONS



1. **Adjust:** The suction cup can be adjusted to fit the patient, using the height adjustment handles. 
2. **Lock:** The compression mechanism is locked. This is used during defibrillation and when moving the patient. 
3. **Active:** This is the operating position. When LUCAS Chest Compression System is connected to an air supply of specified capacity, it performs compressions at a rate of about 100 per minute. 



1.6 DESCRIPTION

1.6.1 MAIN PARTS

LUCAS consists of an upper part (15) and a back plate (7). The back plate is placed underneath the patient to form a support for the external chest compressions.

The upper part contains a pneumatically driven piston rod, which acts on the patient's chest via a pressure pad. The pressure pad is surrounded by a suction cup.

The support legs (5) of the upper part are fastened to the back plate prior to starting compressions.

1.6.2 CONNECTION TO AIR SUPPLY

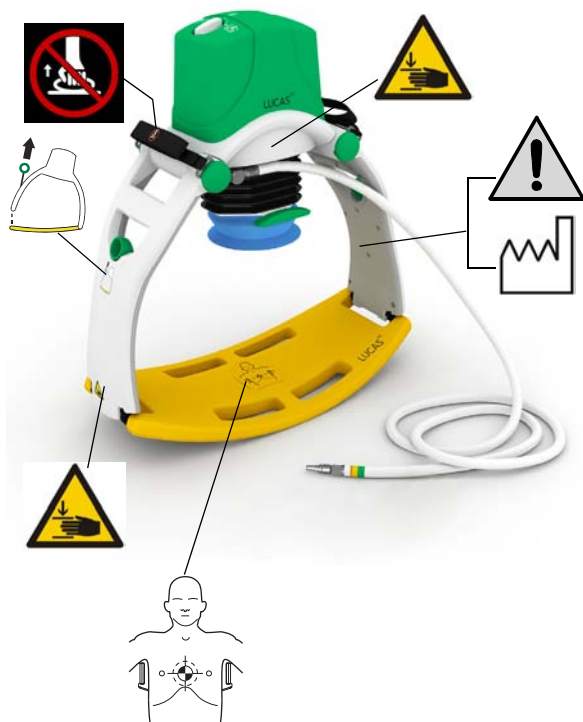
LUCAS is powered by compressed air from a wall outlet or a cylinder. See Section 6 for specification of air sources.

The air hose is permanently mounted on LUCAS, and has a unique male connector at the open end. A suitable pressure regulator is delivered with LUCAS.

LUCAS requires no electrical supply and has no conducting parts on the outside, except the hose attachment, the claw lock bar, and the upper attachment of the bellows.

1.6.3 LUCAS STABILIZATION STRAP

LUCAS Stabilization Strap (16) is an accessory which is attached to LUCAS to prevent downward movement of LUCAS during operation. Please see Appendix B for instructions for use of LUCAS Stabilization Strap.



1.7 SYMBOLS ON THE DEVICE

Symbol/ Location	Meaning
	Caution – see instructions for use. All users must read the entire Instructions for Use before operating LUCAS Chest Compression System.
	Year of manufacture.
	WARNING – Crushing hazard. The pressure pad and suction cup are drawn into the bellows with high force when LUCAS is connected to an air supply. Keep all body parts away from the suction cup, the bellows and the height adjustment handles when connecting the air hose, and during operation.
	WARNING – Crushing hazard. Keep your fingers away from the claw locks when attaching the upper part to the back plate.
	Caution – Do not lift by the straps. The straps are only intended for securing the patient's arms to LUCAS.
	Place the suction cup immediately above the end of the sternum, as indicated in the figure. The suction cup should be centred over the sternum.
	Pull up the release rings to release the support legs from the back plate.

1.8 DELIVERED ITEMS

Before using LUCAS Chest Compression System, make sure that the following items are delivered:

1. LUCAS in carrying bag together with Instructions for Use.
2. Pressure regulator.
3. LUCAS Stabilization Strap (packed in carrying bag).

1.9 THE LUCAS TEAM

It is strongly recommended that qualified personnel work in teams of two. This enables one person to perform cardiopulmonary resuscitation (CPR) while the other person unpacks LUCAS Chest Compression System.

The Instructions for Use will refer to "The LUCAS team" (Figure 1), consisting of two people who have the required skills stated on page 2.





1.10 BACKGROUND

The single most common cause of death in western society is cardiovascular disease either on its own or as a contributory factor.

There is only a short space of time after the heart stops during which it is possible to reverse the situation and restore spontaneous circulation.

If the heart is not started quickly, the two most important organs, the heart and brain, will be damaged by the lack of oxygen.

Effective chest compressions can restore circulation to a level, which may be sufficient to prevent heart and brain damage during a short period of time.

For optimal results the compressions should be performed in such a way that the rib cage is held down for approximately half of the time, and subsequently released for the remaining half of the time¹.

It is very difficult to perform manual chest compressions effectively, even for experienced CPR practitioners, and especially in a vehicle, moving ambulance, during transport or when there is no firm surface under the patient^{2 3}.

1.11 CHEST COMPRESSIONS USING LUCAS

In situations where it is possible to use LUCAS Chest Compression System, many of the problems with manual chest compressions can be eliminated.

LUCAS works by pressing down very quickly on the rib cage and holding it down for 50% of the period/cycle.

When following normal routines for CPR, the use of LUCAS has the following advantages over manual chest compression:

- The device maintains consistent chest compression over a long period of time.
- One person becomes free to provide other care.
- It is possible and safer for the user to give effective chest compression even in a moving vehicle.

1.12 SIDE EFFECTS

Bruising and soreness of the chest is common during use of LUCAS External Cardiac Compressor.

The International Liaison Committee on Resuscitation (ILCOR) states the following side effects of CPR⁴:

- 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.

¹ American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation 2005;112: 24, Supplement; December 13, 2005.

² Hightower D, Thomas SH, Stone CK et al. Decay in Quality of Closed-Chest Compressions Over Time. Ann Emerg Med 1995;26:300-303.

³ Sunde K, Wik L, Steen P A: Quality of Mechanical, manual Standard and active compression-decompression CPR on the arrest site and during transport in a manikin model. Resuscitation 1997;34:235-242.

⁴ 2005 International Consensus on Cardiopulmonary Resuscitation and Emergency Cardiovascular Care Science with Treatment Recommendations. Resuscitation 2005;67:195.

2 Warnings and precautions

Important

This section contains safety information. All users must read this section before using LUCAS Chest Compression System and observe the safety information at all times during use.

Sections 2.1 to 2.5 summarize warnings and precautions during assembly and use of LUCAS Chest Compression System.

Additional hazards are described in relevant sections of the Instructions for Use. All users must observe the safety information in **Warnings** and **Cautions** during use of LUCAS Chest Compression System.

2.1 ASSEMBLY

WARNING – LETHAL PINCH HAZARD

If the air is connected during the assembly procedure, and the ON/OFF-knob is in the *Active* position, the compressions may seriously injure the patient or create conditions leading to death of the patient.

Always follow the described sequence of air connection and assembly.

Caution – Keep hose and connectors clean

The mechanical parts of LUCAS may be damaged if sand or soil enters the air hose, resulting in reduced performance.

Always keep the hose and connectors clean, do not leave these parts on the ground.

2.2 USING LUCAS CHEST COMPRESSION SYSTEM

WARNING – IMPROPER USE

Improper use of the device can cause serious injury to the patient and ineffective chest compressions.

JOLIFE AB strongly recommends that the equipment only be used by personnel who have undertaken training in use and handling of LUCAS Chest Compression System.

Other personnel may assist those with the necessary training in using LUCAS.

WARNING – DEVICE STATUS

If your LUCAS unit does not appear as in the illustration in Section 1.4, or if the device does not function in the same way as in training, or according to specification:

Discontinue use and continue with manual chest compressions.

WARNING – MALFUNCTION

If there is air leakage, interruption in compressions or insufficient compressions, if the frequency is wrong, or there is jarring, or there is something else that cannot be classified as normal running:

Disconnect the air hose immediately, turn the ON/OFF knob to *Adjust* and remove the device. Start manual chest compressions.

WARNING – SUCTION CUP SLIDING ON GEL

If there is gel on the patient's chest (e.g. from ultrasound examination), the position of the suction cup may change during use.

Remove any gel left before applying the suction cup.

WARNING – PATIENT INJURY OR DEATH

Do not leave the patient or device unattended while LUCAS Chest Compression System is active.



2.3 CONNECTION TO AIR SUPPLY

WARNING – INTERRUPTING AIR SUPPLY TO LIFE SUPPORT DEVICES

If other life support equipment is disconnected from the air supply, serious injury or death may result.

Never remove attachments to air outlets without first checking that this will not put a patient at risk.

WARNING – EMPTY AIR SUPPLY

When the air in the cylinder runs out, the pressure falls and compressions delivered by LUCAS lose force.

Immediately start manual chest compressions and ensure that the air cylinder is exchanged. Always change air cylinder if the pressure gauge is on red.

2.4 ADJUSTING LUCAS TO THE PATIENT

WARNING – INCORRECT HEIGHT ADJUSTMENT

If the suction cup presses down too hard or too lightly on the rib cage, the patient's circulation will be compromised.

Turn the ON/OFF knob to *Adjust* and adjust the height of the suction cup immediately.

WARNING – INCORRECT POSITION

If the suction cup is not positioned correctly in relation to the sternum, there is an increased risk of damage to the rib cage and internal organs. In addition, the patient's circulation will be compromised.

Make sure that the suction cup is positioned according to instructions in Section 3.4 before starting compressions.

If the position changes during operation, immediately turn the ON/OFF knob to *Adjust* and adjust the position of the suction cup.

2.5 HANDLING LUCAS CHEST COMPRESSION SYSTEM

WARNING – CRUSHING HAZARD

Avoid placing your hands or other body parts on, or below the suction cup, when LUCAS is active.

WARNING – CRUSHING HAZARD

Keep your fingers away from the claw locks, particularly when lifting the patient from the floor to the stretcher with LUCAS in position.

3 Using LUCAS



LUCAS Chest Compression System should be used to treat patients following the same routines as for manual CPR.

This section describes the use of LUCAS. It is divided into nine steps:

1. Arrival at the patient
2. Unpacking and connecting the air
3. Assembly
4. Adjustment
5. Operating
6. Defibrillation
7. Transporting the patient
8. Changing air sources
9. Removing LUCAS from the patient

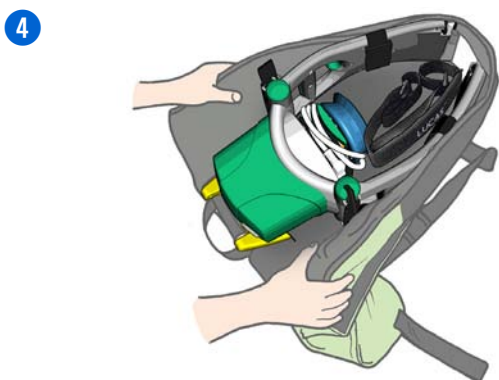


3.1 ARRIVAL AT THE PATIENT

Upon arrival at the patient, confirm cardiac arrest by determining level of consciousness, breathing and pulse (Figure 2).

If the patient has suffered a cardiac arrest, commence cardiopulmonary resuscitation (CPR) with the LUCAS team immediately.

If CPR is already being carried out when you arrive, assist as required. Do not interrupt CPR.



3.2 UNPACKING AND CONNECTING THE AIR

On arrival, one of the LUCAS team members should immediately start to unpack and connect LUCAS Chest Compression System.

3.2.1 UNPACKING LUCAS

1. Place the bag on the floor/ground with the straps downwards and the top opposite you (Figure 4).
2. Take hold of the straps on the side of the cover and open up the cover so that the entire bag unfolds (Figure 4).



3.2.2 CONNECTING THE AIR

WARNING – INTERRUPTING AIR SUPPLY TO LIFE SUPPORT DEVICES


If other life support equipment is disconnected from the air supply, serious injury or death may result.

Never remove attachments to air outlets without first checking that this will not put a patient at risk.

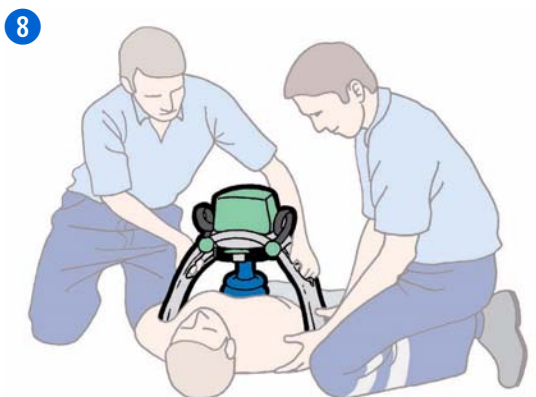
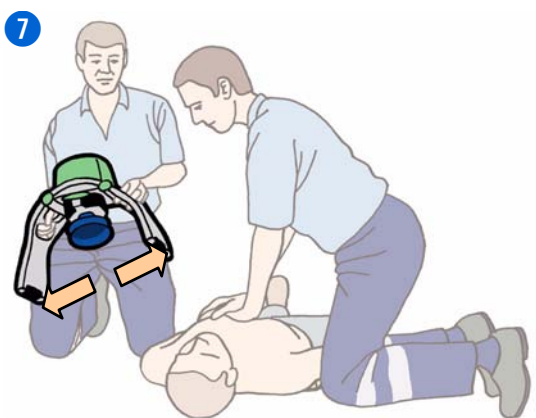
WARNING – CRUSHING HAZARD

The suction cup is drawn into the bellows with high force when the air hose is connected.

Keep all body parts away from the suction cup, the bellows and the height adjustment handles when connecting the air hose.

1. Confirm that the **ON/OFF** knob is in the **Adjust**  position.
2. If not already connected, attach the air hose to the connector.
3. Attach the connector to a wall outlet or to a portable air cylinder.
4. If using a pressure regulator, open the air valve.

3.3 ASSEMBLY



WARNING – LETHAL PINCH HAZARD

If the air is connected during the assembly procedure, and the ON/OFF-knob is in the *Active* position, the compressions may seriously injure the patient or create conditions leading to death of the patient.

Always follow the described sequence of air connection and assembly.

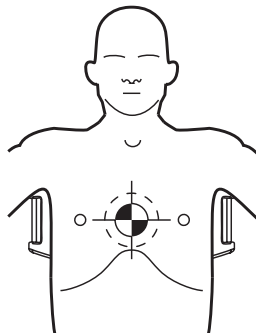
1. Take the back plate out of the bag and approach the patient (Figure 5).
2. Instruct those carrying out CPR to interrupt chest compression.
3. Work in a pair, one person on each side of the patient.
4. Take hold of the patient's arms. One of the LUCAS team should support the patient's head.
5. Lift up the patient's upper body and lay the back plate below the armpits. Ensure that the patient's arms are outside the back plate (Figure 6).
6. Continue manual chest compressions.
7. Take the upper part of LUCAS out of the bag. Lift it out by holding on to the handles of the support legs. Ensure that the support legs have reached their outer position (Figure 7).
8. Pull up once on the release rings to check that the claw locks are open.
9. Interrupt manual chest compression.
10. Place the upper part of LUCAS over the patient's chest so that the claw locks of the support legs will engage with the back plate (Figure 8).
11. Start by pressing on the support leg nearest to you and then the one on the other side so the support legs lock against the back plate.
12. Check by pulling upwards, that both support legs have locked against the back plate.



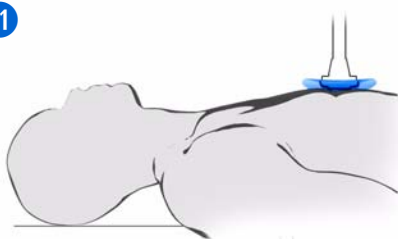
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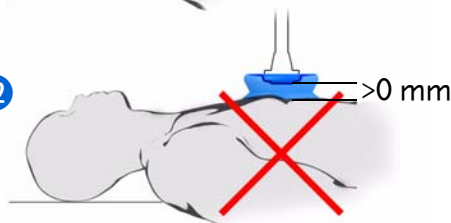
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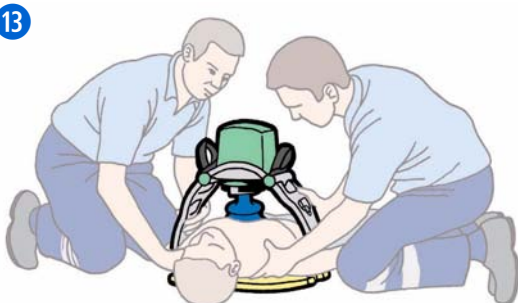
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3.4 ADJUSTMENT

3.4.1 INTRODUCTION

To achieve effective compressions, it is very important that the suction cup is positioned correctly on the patient (Figure 9).

The lower edge of the suction cup should be positioned immediately above the end of the sternum. The suction cup should be centred over the sternum (Figure 10).


3.4.2 ADJUSTMENT PROCEDURE

WARNING – MINIMUM PATIENT SIZE

If the suction cup cannot be completely compressed and lowered enough to make the pressure pad touch the patient's chest, the patient is too small for LUCAS to be used.

Continue manual compressions.

To adjust the position of LUCAS:

1. Set the **ON/OFF** knob to **Adjust** .
2. Lower the suction cup with the height-adjustment handles until the pressure pad inside the suction cup touches the patient's chest without compressing the chest (Figure 11).
If there is a distance between the pressure pad inside the suction cup and the sternum, LUCAS cannot be used on the patient (Figure 12).
***Note:** By simultaneously holding up the outer rim of the suction cup you will more easily see or feel when the pressure pad touches the chest.*
3. If the suction cup is not correctly positioned in relation to the patient, adjust the position of LUCAS by pulling on the support legs (Figure 13). The person assembling the device determines whether the position is correct.

3.5 OPERATING LUCAS CHEST COMPRESSION SYSTEM

3.5.1 STARTING COMPRESSIONS

When the position of the suction cup is correctly adjusted according to Section 3.4, LUCAS can be switched on:

1. Turn the **ON/OFF** knob to **Active** (👤). LUCAS will now give chest compressions.

WARNING – PATIENT INJURY OR DEATH

Do not leave the patient or device unattended while LUCAS is active.

2. Check that the device is working as it should regarding frequency and compression.
3. When you want to stop chest compressions, turn the **ON/OFF** knob to the **Lock** 🔒 position, without changing the respective positions of the patient and device.

3.5.2 APPLYING LUCAS STABILIZATION STRAP

When LUCAS is applied to the patient and performing compressions under the supervision of one person of the LUCAS team, attach the Stabilization Strap to LUCAS (Figure 14). For detailed instructions, please refer to Appendix B.



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3.6 DEFIBRILLATION

WARNING – INCORRECT ECG ANALYSIS

Compressions interfere with ECG analysis.

Switch off LUCAS before ECG analysis. Make the interruption as short as possible

WARNING – INADEQUATE COMPRESSION

Patient's movements may change adjustment of suction cup.

Verify position of suction cup after defibrillation, re-adjust if necessary.

Note: Self-adhesive electrodes should be used during defibrillation as these make it easier to work with LUCAS. Position the defibrillator electrodes and wires so they are not under the suction cup; if electrodes are already on the patient, you may need to apply new electrodes.

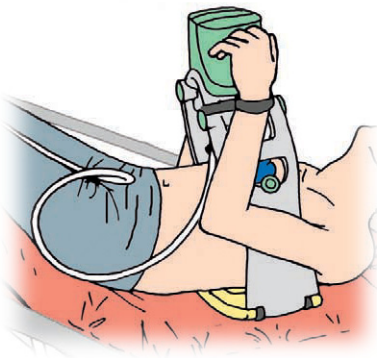
Defibrillation can be performed when LUCAS is applied to the patient (Figure 15).

1. Apply electrodes and perform the defibrillation according to manufacturer's instruction for the defibrillator.
2. After defibrillation or analysis of the outcome verify the position of the suction cup and re-adjust if necessary.

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3.7 TRANSPORTING THE PATIENT

3.7.1 SECURING THE PATIENT'S ARMS

The patient's arms can be fixed to the device during transport, using the straps on the support legs (Figure 16). This makes it easier to move the patient, especially if not in a hospital environment.

WARNING – BLOCKED INTRAVENOUS CATHETER

Do not tighten the patient strap/straps if drugs are administered to the patient via an intravenous catheter.

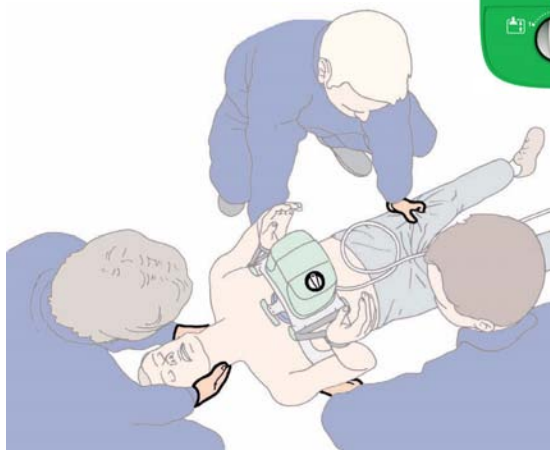
Caution – Do not lift by the straps

The straps are only intended for securing the patient's arms to LUCAS.

Apply the straps tightly enough to secure the arms, but do not overtighten as this may reduce blood circulation to the patient's hands.

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LOCK



3.7.2 LIFTING THE PATIENT

At least three people should lift the patient and LUCAS – one should support the patient's head and there should be one person on each side.

Plan carefully before lifting the patient. Consider which equipment needs to be moved and where to place the stretcher.



Those at the side should lift with one hand beneath the claw locks of the back plate. The other hand should be used to lift the patient's belt, trouser or under the thigh.

Use appropriate lifting technique to avoid injuries when lifting the patient (Figure 17).

WARNING – CRUSHING HAZARD

Do not insert your fingers in the claw locks.

To lift a patient:

1. Secure the patient's arms with the straps on the support legs.
2. Turn the **ON/OFF** knob to **Lock** , to pause compressions while lifting the patient, for example when:
 - lifting to a stretcher
 - moving from one stretcher to another
3. When the patient has been placed on the stretcher (or other surface), verify correct position of the suction cup on the patient.
4. Turn the **ON/OFF** knob to Active .

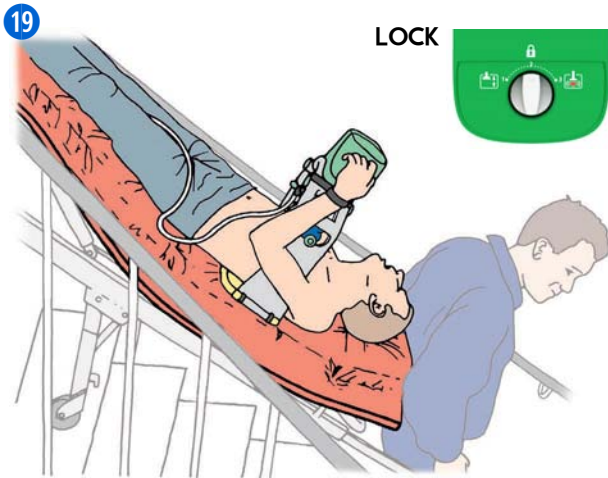
Once the patient is placed on the stretcher, LUCAS may be in active state during all **horizontal** lifts and movements.

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3.7.3 MOVING HORIZONTALLY

When the situation absolutely demands that the patient be moved while undergoing chest compression, the patient's chest should be horizontal throughout the entire movement (Figure 18).



3.7.4 MOVING PATIENT ON TILTED STRETCHER

In situations where conditions do not allow the chest to remain horizontal:

1. Turn the **ON/OFF** knob to **Lock** to pause compressions (Figure 19).
2. As soon as the patient is in horizontal position, check the position of the suction cup and adjust if necessary (see Section 3.4).
3. Turn the **ON/OFF** knob to **Active** .

3.7.5 AMBULANCE TRANSPORT

Make sure that the patient is fixed when using LUCAS Chest Compression System during ambulance transport. The ambulance cot should have four-point restraints for the patient's upper body in addition to the two lower-body restraints.

3.8 CHANGING AIR SOURCES

WARNING – INTERRUPTED COMPRESSIONS

There may be excessive changeover time if pressure regulators have to be mounted.


Always use reserve cylinders with pre-fitted pressure regulators.

To change air source:

1. Set the **ON/OFF** knob to **Adjust** .
2. Close the valve on the used air cylinder.
3. Disconnect the air hose from the air source.
4. Open the valve on the new air source.
5. Attach the air hose to the new air source.
6. Adjust the height of the suction cup on the patient's chest, as described previously on page 17.
7. Turn the **ON/OFF** knob to **Lock** .
8. Turn the **ON/OFF** knob to **Active** to continue compressions.

3.9 REMOVING LUCAS FROM THE PATIENT

To remove LUCAS Chest Compression System from the patient after treatment:

1. Switch off the device by turning the **ON/OFF** knob to **Adjust** .
2. Raise the suction cup and place the height adjustment handle in its uppermost position.
3. If available, close the air valve, and disconnect the air hose from the air source.
4. To detach LUCAS Stabilization Strap, disconnect the support cushion straps from the device straps.
5. Disconnect the upper part of LUCAS by placing one finger in each release ring of the handles on the support legs and pulling these up so the upper part releases from the back plate. Lay the upper part carefully on the floor.
6. If the patient's condition allows it, remove the back plate.

Before packing LUCAS or LUCAS Stabilization Strap into the carrying bag, clean and, if required, disinfect the product(s). See instructions in Section 4.

4 Care after use

This section describes the routines that should be performed by the user after each application of LUCAS Chest Compression System, before packing it into the carrying bag. In addition, LUCAS should be serviced once a year by service personnel authorised by JOLIFE AB.

4.1 CLEANING ROUTINES

Caution – Do not immerse in water or disinfectant

The compression mechanism may be damaged by liquid entering the hood. Do not immerse the device in water or disinfectant. Do not splash liquid over the hood.

4.1.1 NORMAL CLEANING PROCEDURE

1. Attach the upper part to the back plate.
2. If a LUCAS Stabilization Strap has been used, clean it according to its Instructions for Use.
3. Clean all outer surfaces of LUCAS with a soft cloth, wetted in warm water containing a mild cleaning agent.
4. If necessary, remove the patient straps and clean separately (see Section 4.1.2).
5. Remove the upper part. Clean the claw locks on the support legs and the back plate.
6. Wipe all surfaces with a clean moist cloth.

4.1.2 REMOVING THE PATIENT STRAPS

To remove the patient straps from the support legs:

- Open the velcro lock and pull out the strap from the retaining rings on the support leg.

To re-attach the patient straps:

1. Thread the patient strap through the rings on the support leg.
2. Fold the patient strap so that the symbol is visible as shown in the illustration in Section 1.4.
3. Press the strap parts firmly together.



4.1.3 DISINFECTION

WARNING – HAZARDS DURING DISINFECTION

Always wear appropriate protective clothing during disinfection of LUCAS. Follow the handling instructions from the manufacturer of the disinfectant.

The normal cleaning procedure is sufficient after "normal" soiling. If LUCAS is blood-stained or if an infectious patient has been treated, the device should also be disinfected using 45% isopropyl alcohol with added detergent.


4.1.4 DISINFECTION PROCEDURE

After cleaning LUCAS, disinfect it using the following procedure:

1. Wipe all outer surfaces of the device using a cloth wetted with the disinfectant solution.
2. Allow LUCAS to dry before packing into the bag.

4.2 ROUTINE CHECKS

After each use and once a week the following checks should be performed. Sign each item on the sheet attached in Appendix A:

1. Check that the device is clean.
2. Check that the air hose does not have any cracks and fits tightly to LUCAS.
3. Check that the connector(s) is/are present and undamaged.
4. Check that the **ON/OFF** knob is in the **Adjust**  position.
5. Pull up the release rings so that the claw locks are open for assembly. Attach the upper part to the back plate.
6. Check that the compression mechanism can be adjusted from the uppermost to the lowermost position without any jarring or sluggishness.
7. Attach the air hose to a air supply and switch the device on for 1-2 minutes. Check that it is operating normally. Calculate the number of compressions per minute. 100 compressions/min ± 10 is acceptable.

4.3 STORAGE

Store LUCAS in the carrying bag, in a location where it is easily accessible to all those who know how to use the device (see packing instructions in Section 5). The device should not be exposed to dirt or moisture during storage.

4.4 SERVICE

LUCAS should be serviced once a year to check that it is functioning properly. Use the original package when sending LUCAS. For this purpose, store the package and padding that came with LUCAS when you first received it.

WARNING – DO NOT OPEN

Do not, under any circumstances, open the casing of LUCAS, change or modify any external or internal parts of LUCAS.

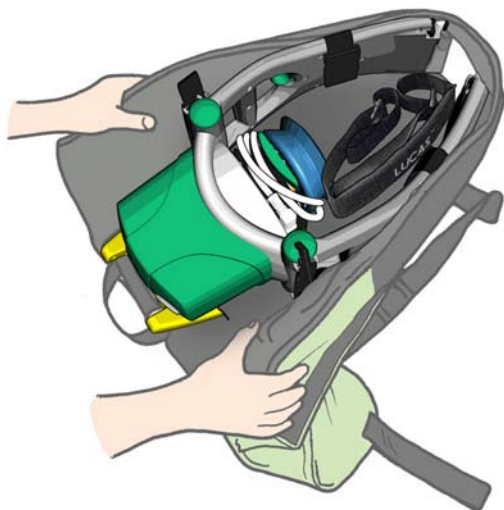
Unless otherwise stated, all service and repairs must only be done by service personnel authorised by JOLIFE AB.

If the above conditions are not adhered to, this may lead to patient or user injury or death.

Contact your distributor or the manufacturer for current information on where to send LUCAS for maintenance (see page 2 for addresses).

5 Packing away the device

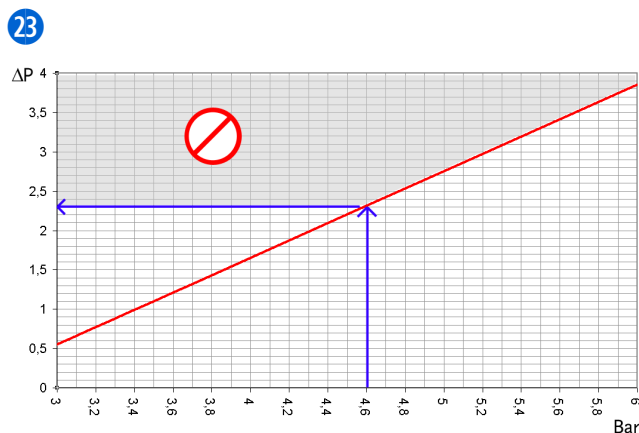
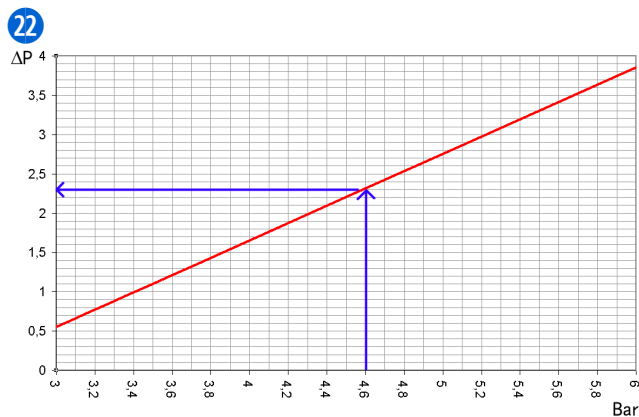
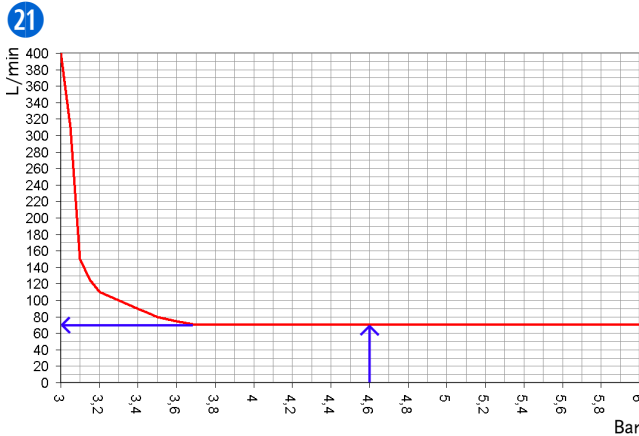
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After cleaning and, if necessary, disinfection, pack LUCAS Chest Compression System into the carrying bag:

1. Place the back plate in the larger pocket at the bottom of the bag.
2. Lay the upper part in the bag with the hood towards the open end.
3. Place the support cushion of LUCAS Stabilization Strap in front of the suction cup.
4. Roll up the air hose and place it on top of the device (Figure 20).
5. Close the bag.

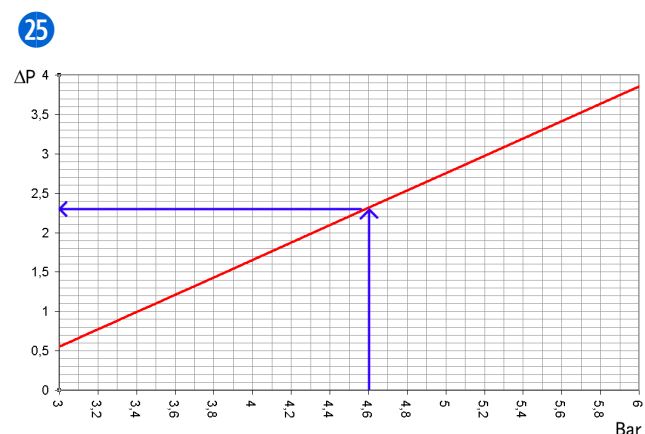
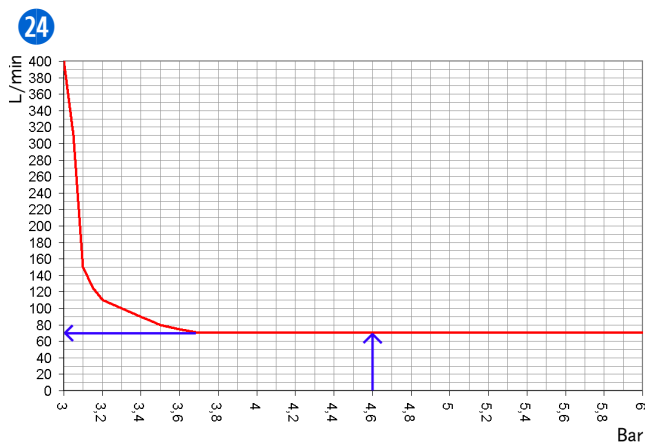
6 Technical specification



6.1 OPERATION

Power source	Air
Air consumption	13.7 gallons/minute (52 litres/minute)
Air hose	Permanently attached, 10.8 feet (3.3 m) in length, with unique male connector.
Approved air sources for use with LUCAS	<p>Pressure regulators or wall outlets for air (medical grade/breathing quality) should meet the following specifications:</p> <ol style="list-style-type: none"> 1. Nominal supply pressure: 46-87 PSI (3.17-6 bar). 2. Minimum required free flow rate in relation to nominal pressure according to Figure 21. Example shown: Nominal supply pressure 66.7 PSI (4.6 bar). 3. Pressure drop at minimum free flow rate obtained from Figure 21, must not exceed the value obtained from Figure 22. The shaded area in Figure 23 illustrates an unacceptably high pressure drop for nominal supply pressure 66.7 PSI (4.6 bar) and above. <p>The performance of the air supply should be verified according to the procedures in Section 6.1.1 and 6.1.2. If you do not know how to do this, please contact a clinical engineer or your distributor, for help.</p>

All pressure regulators supplied by your distributor are approved for use with LUCAS.



6.1.1 CHECKING A PRESSURE REGULATOR

If a flow rate performance diagram exists:

1. Check that the nominal output pressure for the pressure regulator is within 46-87 PSI (3.17-6 bar).
2. Find the regulator output pressure (**Bar**) in Figure 24 and obtain the minimum free flow rate (**L/min**) from the diagram. The example in Figure 24 shows a regulator output pressure of 66.7 PSI (4.6 bar).
3. From the flow rate performance diagram for the pressure regulator, obtain the output pressure for the regulator at the minimum free flow rate. Calculate the pressure drop.
4. Check that the calculated pressure drop does not exceed the maximum allowable pressure drop (ΔP) at the nominal pressure (**Bar**), obtained from Figure 25.

If no flow rate performance diagram exists, follow the instructions in Section 6.1.2 to check your pressure regulator.

6.1.2 CHECKING A WALL OUTLET

1. Measure and verify that the nominal supply pressure is within 46-87 PSI (3.17-6 bar).
2. Find the nominal supply pressure (**Bar**) in Figure 25 and obtain the minimum free flow rate (**L/min**) from the diagram. The example in Figure 25 shows a nominal supply pressure of 66.7 PSI (4.6 bar).
3. Measure the supply free flow rate and restrict the flow to the minimum required free flow rate obtained from Figure 25.
4. Measure the supply pressure at the minimum required free flow rate. Calculate the pressure drop.
5. Check that the calculated pressure drop does not exceed the maximum allowable pressure drop (ΔP) at the nominal pressure (**Bar**), obtained from Figure 25.



6.2 COMPRESSIONS

Patients suitable for treatment	Adult patients with a sternum height of 7.5 inches to 11.9 inches (190 to 303 mm) and a maximal width of 17.7 inches (449 mm) who fit into the device. The device is not suitable for use with children.
Depth of compression	Compresses the sternum by 2 inches (5 cm)
Frequency	90-110 comp/min. with air at +59 °F to +95 °F (+15 °C to +35°C)

6.3 ENVIRONMENT

Temperature range – operation	+41 °F to +104 °F (+5 °C to +40 °C)
Temperature range – storage	-22 °F to +140 °F (-30 °C to +60 °C)

6.4 DIMENSIONS AND WEIGHT


Dimensions in carrying bag	25.6 × 13 × 9.8 inches (H × W × D) (65 × 33 × 25 cm)
Weight	13.9 lbs (6.3 kg)

Appendix A

WEEKLY CHECK AND CHECK AFTER USE, LUCAS

Use this protocol for the weekly check on the device and the check after use. Store the completed checklist. Copying of this sheet is permitted.

Date:

Action	Approved signature	Adjustments carried out	Serious problem
Check that the device is clean.			
Check that the air hose is not cracked and fits tightly to LUCAS.			
Check that the connector(s) is/are present and undamaged.			
Check that the ON/OFF knob is in the Adjust  position.			
Pull the release rings so that the claw locks are open for assembly. Attach the upper part to the back plate.			
Check that the compression mechanism can be adjusted from the uppermost to the lowermost position without any jarring or sluggishness.			
Attach the air hose to a air supply. Switch the device on for 1–2 minutes. Check that it is operating normally. Calculate the number of compressions per 60 seconds. 100 compressions/min \pm 10 is acceptable.			

If any error cannot be corrected take the device out of operation and indicate the problem in the "Serious problem" column. Then immediately contact your distributor for advice or to order a new product (www.jolife.com).

When carrying out these checks always use air from a central air supply or separate air cylinder. Do not use up air from a air cylinder intended for use in emergency situations.



Appendix B - LUCAS Stabilization Strap

LUCAS Stabilization Strap Instructions for Use

US version

1 Introduction

1.1 OVERVIEW

LUCAS Stabilization Strap is intended to be used in conjunction with LUCAS Chest Compression System to provide means of stabilizing LUCAS relative to the patient when LUCAS is active.

LUCAS Stabilization Strap will prevent downward movement of LUCAS during operation.

LUCAS Stabilization Strap can be used in most situations where LUCAS Chest Compression System is used.

1.2 CONTRAINDICATIONS

Do **NOT** use LUCAS Stabilization Strap under circumstances where it is judged that it might obstruct or delay any medical treatment of the patient.

1.3 ASSOCIATED DOCUMENTATION

Refer to LUCAS Chest Compression System, Instructions for Use for details of LUCAS and instructions for its use.

1.4 LUCAS STABILIZATION STRAP

LUCAS Stabilization Strap is a portable product for stabilizing LUCAS Chest Compression System to the patient during compressions. It can conveniently be stored and transported in the same carrying bag as LUCAS. LUCAS Stabilization Strap is shown in Figure 1.

1.5 DESCRIPTION

LUCAS Stabilization Strap consists of a support cushion with two straps (called support cushion straps), and two separate device straps (see Figure 1). The device straps are attached to the support legs of LUCAS Chest Compression System with buckles.

An extra buckle on each of the device straps is used to connect to the support cushion straps. To minimize set-up time, the device straps should always be attached to the support legs of LUCAS Chest Compression System.

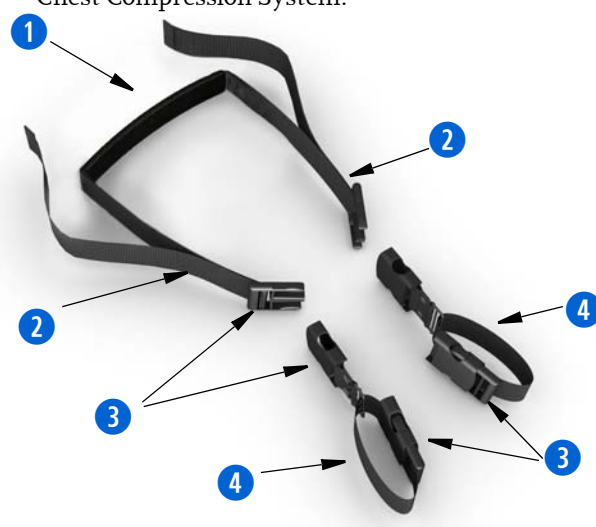


Figure 1. LUCAS Stabilization Strap.

LUCAS Stabilization Strap consists of the following parts (see Figure 1):

1. Support cushion
2. Support cushion strap
3. Buckle
4. Device strap

1.5.1 DELIVERED ITEMS

The LUCAS Stabilization Strap package contains the following items:

- One support cushion.
- Two device straps.
- Instructions for Use in relevant language versions.



1.5.2 USING LUCAS STABILIZATION STRAP

When compressions with LUCAS Chest Compression System have been started, the support cushion is placed under the patient's neck, and the support cushion straps are fastened to the device straps.

See instructions in Section 4.





Figure 2. LUCAS Stabilization Strap attached to LUCAS Chest Compression System.

1.5.3 STORAGE

LUCAS Stabilization Strap should be stored in the LUCAS carrying bag. See packing instructions in Section 6.

1.5.4 SYMBOLS ON THE DEVICE

Symbol	Meaning
	Caution – see instructions for use. All users must read the entire Instructions for Use before using LUCAS Stabilization Strap.
	Year of manufacture.

1.6 THE LUCAS TEAM

Two persons are required when attaching LUCAS Stabilization Strap, and at the same time monitoring the operation of LUCAS.

The Instructions for Use will refer to “The LUCAS team”, consisting of two people who have the required skills stated on page 2 of the Instructions for Use.

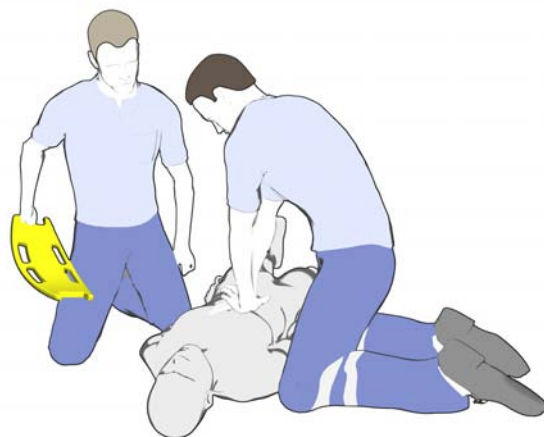


Figure 3. The LUCAS team.

2 Preparing LUCAS Stabilization Strap for use

Before the first use of LUCAS Stabilization Strap, attach both device straps to the support legs, using the following procedure:

1. Fold the device strap around the support leg.
2. Fasten the buckle on the inside of the support leg, and check that it is fixed.
3. Make sure that you can move the extra buckle on the device strap from side to side on the outside of the support leg.

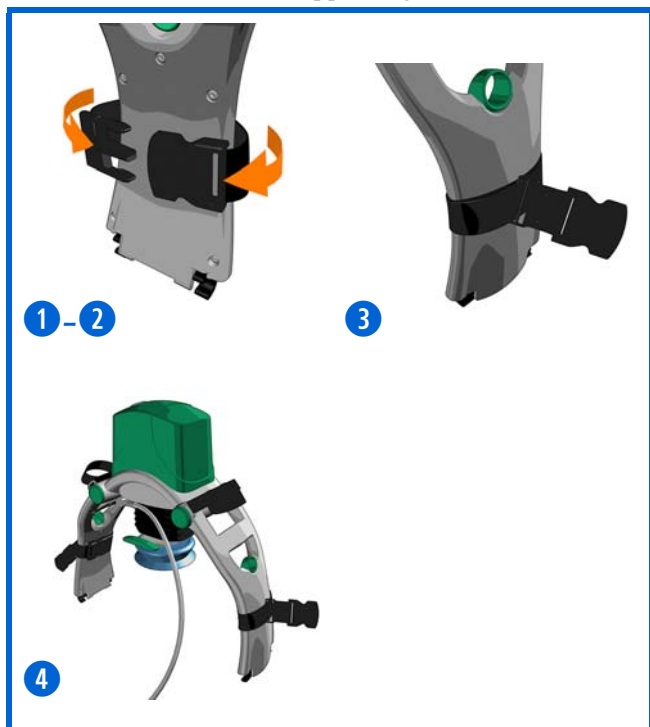


Figure 4. Attaching the device straps (1-3), LUCAS Chest Compression System with both device straps attached (4).

3 Warnings and precautions

Important

This section contains safety information. All users **must** read this section before using LUCAS Stabilization Strap and observe the safety information at all times during use.

Section 3.1 summarizes warnings and precautions during assembly and use of LUCAS Stabilization Strap.

Additional hazards are described in relevant sections of the Instructions for Use. All users must observe the safety information in **Warnings** and **Cautions** during use of LUCAS Stabilization Strap.

3.1 USING LUCAS STABILIZATION STRAP

WARNING – IMPROPER USE

Improper use of LUCAS Stabilization Strap can cause serious injury to the patient and ineffective chest compressions.

JOLIFE AB strongly recommends that LUCAS Stabilization Strap only be used by personnel who have undertaken training in use and handling of LUCAS Chest Compression System.

Other personnel may assist those with the necessary training in using LUCAS.

WARNING – PATIENT INJURY OR DEATH

The use of LUCAS Stabilization Strap does not mean that you can pay less attention to the patient.

Do not leave the patient or LUCAS Chest Compression System unattended while LUCAS is active.

Particularly, make sure that LUCAS does not move on the patient. If the position of LUCAS is changed, correct the position according to LUCAS Chest Compression System, Instructions for Use.

WARNING – IMPAIRED VENTILATION OF PATIENT

Do not use LUCAS Stabilization Strap if this impairs the ventilation of the patient.



4 Using LUCAS Stabilization Strap

4.1 INTRODUCTION

This section gives instructions for attaching LUCAS Stabilization Strap to LUCAS Chest Compression System during treatment of a patient with LUCAS.

Please refer to LUCAS Chest Compression System, Instructions for Use, for details on the use of LUCAS.

Always work in a pair, one person on each side of the patient.



Figure 5. The LUCAS team, working on each side of the patient.

4.2 ATTACHING LUCAS STABILIZATION STRAP

WARNING – DO NOT DELAY LIFE SUPPORT ACTIONS

Before unpacking and attaching LUCAS Stabilization Strap, make sure that all life-supporting actions have been taken. Particularly, LUCAS Chest Compression System must be applied to the patient and performing compressions under the supervision of one person of the LUCAS team.

If the application of LUCAS Stabilization Strap threatens to delay the treatment of the patient, it should be applied later or not at all.

Begin by taking out LUCAS Stabilization Strap from the LUCAS carrying bag. Follow the instructions below to attach the Stabilization Strap to LUCAS (see Figure 6).

1. Lift the patient's head carefully and place the support cushion under the patient's neck, as close to the patient's shoulders as possible.
2. Move the buckles on the device straps towards the patient's head.
3. Connect the buckles on the support cushion straps to the device straps. Make sure that the straps are not twisted.

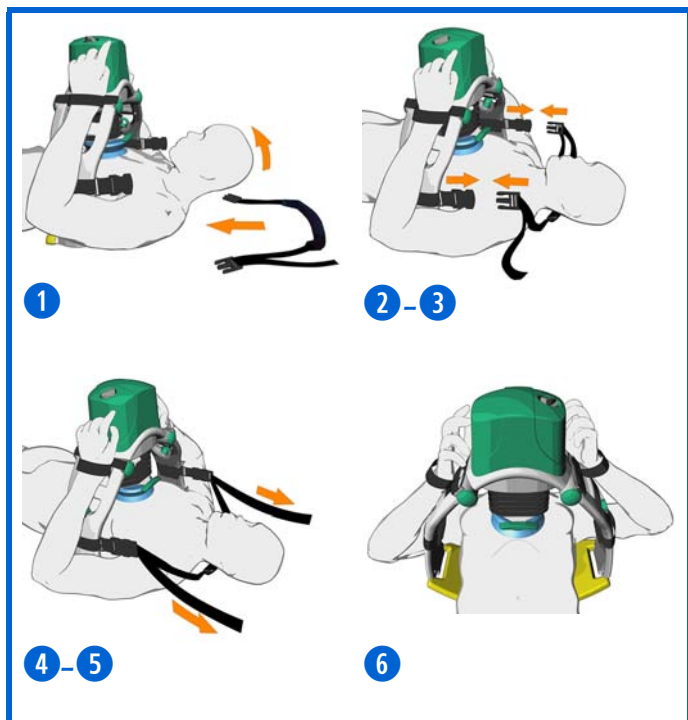


Figure 6. Attaching LUCAS Stabilization Strap to LUCAS.

WARNING – IMPAIRED VENTILATION OF PATIENT

Never tighten the support cushion straps so much that this impairs the ventilation of the patient.

4. Tighten the support cushion straps firmly, while holding the support legs of LUCAS. **Make sure that the position of LUCAS External Cardiac Compressor and the position of the suction cup on the patient, do not change.**
5. Verify that the support cushion straps are properly fastened to the support legs of LUCAS.
6. Visually check the position of the suction cup: The lower edge of the suction cup should be positioned immediately above the end of the sternum. The suction cup should be centered over the sternum. Refer to Section 4.2.1 if the suction cup needs to be adjusted

WARNING – LIFTING THE PATIENT


LUCAS Stabilization Strap must never replace a person supporting the patient's head. Always lift a patient and LUCAS according to LUCAS Chest Compression System, Instructions for Use.

WARNING – TRIPPING ON STRAPS

Mind your step to avoid tripping on the support cushion straps, or unintentionally tightening the straps, when lifting the patient.

4.2.1 IF THE POSITION OF THE SUCTION CUP IS NOT CORRECT

Refer to LUCAS Chest Compression System, Instructions for Use, for details on adjusting the position of LUCAS relative to the patient.

1. Turn the **ON/OFF** knob to the  (**Adjust**) position.
2. Release the support cushion straps from LUCAS.
3. Adjust to correct position of the suction cup on the sternum.
4. Start compressions.
5. Extend the support cushion straps by pulling the buckles to the end positions of the straps.
6. Re-attach LUCAS Stabilization Strap, see Section 4.2.

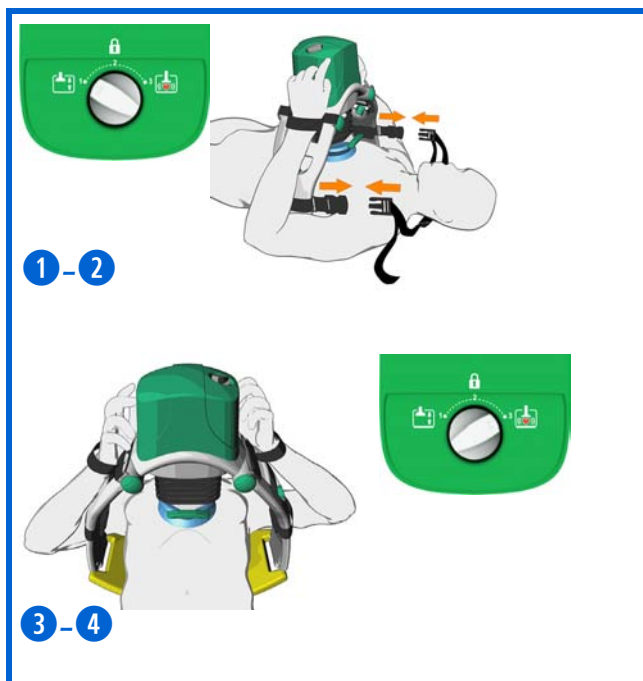


Figure 7. Adjusting the position of the suction cup.



5 Care after use

This section describes the routines that should be performed by the user after each use of LUCAS Stabilization Strap, before packing it into the carrying bag.

5.1 CLEANING ROUTINES

5.1.1 NORMAL CLEANING PROCEDURE

1. Clean all surfaces of LUCAS Stabilization Strap using a soft cloth, wetted in warm water containing a mild cleaning agent.
2. Wipe all surfaces with a clean moist cloth.
3. If necessary, remove the device straps from LUCAS and clean separately as described in step 1. After cleaning, re-attach the device straps to the support legs (see Section 2).

5.1.2 DISINFECTION

WARNING – HAZARDS DURING DISINFECTION

Always wear appropriate protective clothing during disinfection of LUCAS Stabilization Strap. Follow the handling instructions from the manufacturer of the disinfectant.

The normal cleaning procedure is sufficient after “normal” soiling. If LUCAS Stabilization Strap is blood-stained or if an infectious patient has been treated, the device should also be disinfected using 45% isopropyl alcohol with added detergent.

5.1.3 DISINFECTION PROCEDURE

After cleaning LUCAS Stabilization Strap, disinfect it using the following procedure:

1. Wipe all outer surfaces of the device using a cloth wetted with the disinfectant solution.
2. Allow LUCAS Stabilization Strap to dry before packing into the bag.

5.2 ROUTINE CHECKS

After each use and once a week, the following checks should be performed. Sign each item on the sheet attached in Appendix C:

1. Check that LUCAS Stabilization Strap is clean.
2. Verify that the device straps are fitted correctly as shown in Figure 4.
3. Make sure that the support cushion straps are extended, to speed up the next application of LUCAS Stabilization Strap.

5.3 STORAGE

Always store LUCAS Stabilization Strap together with LUCAS in the carrying bag (See packing instructions in Section 6). LUCAS Stabilization Strap should not be exposed to dirt or moisture during storage.

6 Packing away the Stabilization Strap

After cleaning and, if necessary, disinfection, pack LUCAS Stabilization Strap together with LUCAS in the bag:

1. Pack LUCAS according to instructions in LUCAS Chest Compression System, Instructions for Use.
2. To speed up the next application of LUCAS Stabilization Strap, extend the support cushion straps by pulling the buckles to the end positions of the straps.
3. Lift the air hose and place LUCAS Stabilization Strap in front of the suction cup. Put the rolled-up air hose back on top of the Stabilization Strap.
4. Close the bag.

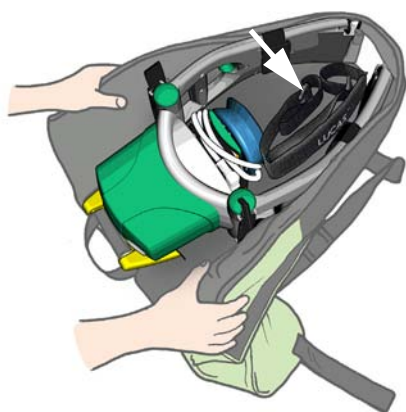


Figure 8. LUCAS Stabilization Strap packed with LUCAS.

7 Technical specification

7.1 PATIENTS SUITABLE FOR TREATMENT

Patients suitable for treatment	Refer to technical specifications for LUCAS Chest Compression System on page 27
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7.2 ENVIRONMENT

Temperature range – use	41 °F to +122 °F (+5 °C to +50 °C)
Temperature range – storage	-22 °F to +140 °F (-30 °C to +60 °C)



Appendix C

WEEKLY CHECK AND CHECK AFTER USE, LUCAS STABILIZATION STRAP

Use this protocol for the weekly check on LUCAS Stabilization Strap and the check after use. Store the completed checklist. Copying of this sheet is permitted.

Date:

Action	Approved, signature	Adjustments carried out	Serious problem
Check that all parts of the Stabilization Strap are clean.			
Verify that the device straps are fitted correctly as shown in Figure 2.			
Make sure that the support cushion straps are extended.			

If any error cannot be corrected, take LUCAS Stabilization Strap out of operation and indicate the problem in the "Serious problem" column. Then immediately contact your distributor for advice or to order a new product (www.jolife.com).

