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Guideline

Lung volume recruitment bags: An ACPRC technical standard

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Abstract

Introduction

Lung volume recruitment (LVR) is a technique used to reach maximum inspiratory capacity (MIC). Within the United Kingdom, LVR self-inflating bags have been distributed historically by two manufacturers (Intersurgical and Breas). The LVR bags are currently unavailable for purchase as a complete kit, but competent clinicians can assemble the component parts.

Aims

The aim of this technical standard is to support clinicians using LVR bags and considers assembly, usage, governance and patient information.

Content

An overview of LVR is given. A list of component parts required and a step-by-step assembly guide with accompanying figures are provided. Quality control and governance are also considered. Usage instructions include: indications, contraindications, considerations and prescription. Maintenance is advised upon. Staff training, as well as patient and carer training, are discussed.

Conclusion

This technical standard is not meant to serve as a guideline, but rather as support for addressing a clinical problem. Clinicians are responsible for their own practice and should apply clinical reasoning when implementing LVR.

PURPOSE

This technical standard aims to provide a comprehensive solution to practice for clinicians, managers and medical electronics technicians on the purpose, assembly, use and governance of lung volume recruitment (LVR) bags. This technical standard has been produced in response to multiple ACPRC members' queries regarding LVR bags following the withdrawal from the market of the LVR kits by Intersurgical and Breas.

SCOPE

This document is intended for use by clinicians, managers and medical electronics technicians involved in the care and management of patients requiring LVR. The document covers:

- Assembly: Step-by-step instructions for assembling LVR bags, including necessary components and quality control measures.
- Usage: Guidelines for the safe and effective use of LVR bags, including: indications, contraindications and maintenance procedures.
- Governance: Policies and procedures for the governance of LVR bags, including compliance with MHRA regulations and staff training requirements.
- Patient Information: Information to be provided to patients, including usage instructions and safety information.

This document does not cover detailed clinical protocols for specific patient conditions. It is written for those working in the United Kingdom (UK), and thus, whilst aspects may be applicable to other countries, the regulatory and governance considerations are specific to the UK. Whilst the LVR bag can be used in combination with other treatments, these are not covered in detail within this docu-

ment. This document does not discuss the evidence-base for the application of LVR. Readers should refer to the recent narrative review from Sheers et al.[1] for a comprehensive presentation of the evidence-base.

DEFINITIONS

CE mark: Conformité Européenne, a European mark of conformity with European health, safety and environmental protections.

LVR: Lung Volume Recruitment Bag, a medical device used to augment maximal inspiratory capacity.

MHRA: Medicines and Healthcare Products Regulatory Authority. The UK body responsible for regulation of medicines and medical devices.

MIC: Maximum inspiratory capacity. The maximum amount of air in the lungs on full inspiration.

System pack: A combination of medical devices used for their intended purpose to achieve a specific medical intervention.

UK CA mark: UK Conformity Assessed. A UK mark indicating that applicable requirements have been met for the sale of the product in the UK. The UK CA mark replaced the CE mark following the UK's exit from the European Union.

INTRODUCTION

WHAT IS LUNG VOLUME RECRUITMENT

Lung volume recruitment (LVR) is a technique used to reach maximum inspiratory capacity (MIC).[2] A LVR bag is a modified resuscitation bag adapted with an extension tube and one-way valve.[2] The one-way valve allows patients to breath stack in order to achieve MIC.[2] LVR bags are NOT resuscitation bags; the one-way valve means the patient cannot exhale, and thus, if used in a closed circuit, where gas does not enter or exit the circuit, LVR bags could cause a tension pneumothorax.

LVR bags are beneficial for individuals with weak respiratory (inspiratory and expiratory) muscles due to neuromuscular conditions (such as motor neurone disease,[3,4] muscular dystrophy[5] and spinal cord injury[6]) and is used to augment an effective cough.[7,8] LVR bags can also aid in increasing lung volume, maintaining and increasing chest wall compliance, reducing atelectasis[9] and increasing speech volume. Without cough augmentation, patients with weak respiratory muscles often develop a weak and ineffective cough, which leads to sputum retention, risk of respiratory infection and respiratory failure.[1,4,7,8,10-12]

Within the UK, LVR bags have been distributed historically by two manufacturers, Intersurgical (United Kingdom) and Breas (Sweden). The LVR bags are currently unavailable for purchase as a complete kit, but competent clinicians can assemble the component parts.

The current (2025/2026) cost of the component parts is circa £10. The alternative to an LVR bags is a mechanical insufflation:exsufflation (MI:E) device. MI:E devices costing circa £5,000. As well as augmenting MIC through positive inspiratory pressure (insufflation), MI:E devices also augment expiratory flow through negative expiratory pressure (exsufflation). Currently, MI:E devices are not routinely available for all patients requiring MIC and cough augmentation, and the provision is dependent upon local commissioning and geographical provision.[13]

GOVERNANCE

All component parts of an LVR bag have a UK CA/CE mark, which are being used for their intended purpose. By combining these existing components to achieve a specific medical purpose, a LVR bag becomes a "systems pack" (The Medical Devices Regulations 2002 (SI 2002 No 618, as amended)). The assembly of the systems pack by healthcare professionals falls under the healthcare institution exemption.[14] Following the exit of the UK from the European Union, MHRA guidance is regularly updated. Readers take responsibility for ensuring this information is still valid. Please refer to the MHRA roadmap for "future implementation of the future regulations" for guidance on when intended updates will be published.[15] Certain regulations need to be adhered to when assembling the LVR systems pack:

1. Quality Management: a quality management system must be implemented locally to ensure the assembled packs meet safety and performance standards. A record should be kept of patients who have been issued with a LVR bag, including the date of issue, name of issuing clinician and batch numbers of component parts.
2. Documentation: Maintain detailed records of the assembly process, including components used, assembly instructions and quality checks. This technical standard could be included along with a local standard operating procedure.
3. Compatibility: Ensure that all components used in the system pack are compatible with each other and intended for their specific medical purposes.
4. Sterilisation: If sterilisation is required, it must be performed according to the manufacturer's instructions for each component.
5. Labelling and Instructions: Provide clear labelling and instructions for use to ensure safe and effective use of the system pack.

TECHNICAL SPECIFICATIONS

COMPONENT PARTS

Table 1. provides a list of the components needed to assemble a LVR bag in the UK. The product codes are for Intersurgical and are correct at the time of publication (May, 2025). Individuals assume responsibility for cross-checking the accuracy of product names and codes when operationalising this technical standard.

Table 1. List of component parts for the LVR bag

Product name	Intersurgical product code (Correct May 2025)
Bag valve mask OR bag valve mask with pressure relief valve	7152000 7152060
Low volume bacterial viral filter	1644007
22F-22F connector	1967000
22M-22M one way valve	1950000
Catheter mount with elbow	3506000
Anaesthetic Masks Soft Seal Size 3 Size 4 Size 5	1514111 1515111 1516111
Alternatives to Anaesthetic Masks soft seal are Anatomical Seal Size 3 Size 4 Size 5	7293001 7294001 7295001
Mouthpiece	1931000
Sponge nose clip	1435000

ASSEMBLY INSTRUCTIONS

STEP-BY-STEP INSTRUCTIONS

The LVR bag is assembled as follows and as per Figures 1 and 2.[2,7,10]

1. The self-inflating bag used within an LVR differs from those used for resuscitation as the oxygen reservoir and tubing should be removed; this is for simplicity and also prevents the LVR bag from being mistaken for a resuscitation bag in the event of an emergency.
2. A low-volume bacterial filter should be placed between the self-inflating bag and the rest of the circuit to prevent sputum and other secretions from entering the bag.
3. The 22F-22F connector is placed between the bag and the one-way valve; it acts solely as a connector.
4. The one-way valve must be placed in the correct orientation to allow air to flow towards the patient.
5. The catheter mount is used to increase the length of the circuit to make it easier for the user and allow different positions of use.
6. Interfaces (Figure 3): A mouthpiece with or without a nose clip (Figure 3.b) can be used. Often, users need to use the nose clip in the initial phase of using the LVR bag. Once they have control of the soft pallet, some users may find they are able to use the mouthpiece alone. An anaesthetic mask can be used, but requires two hands to ensure an adequate seal is achieved. Either a soft seal (Figure 3a) or anatomical anaesthetic mask (Figure 3c) can be used; this is dependent upon the user's preference.

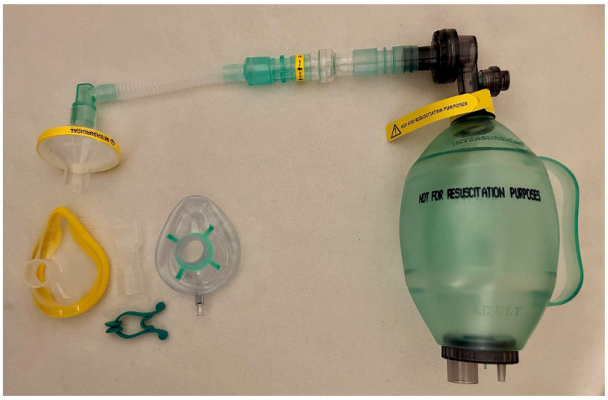

Figure 1. An overview of the LVR bag components

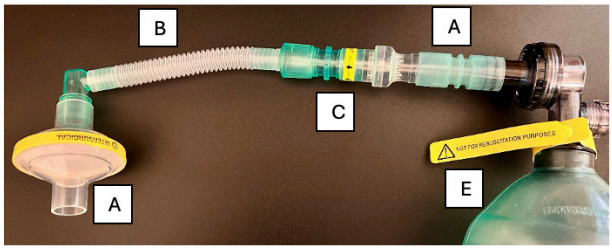

Figure 2. Close up of the LVR bag circuit.

A: Bacterial filter, B: Catheter mount,

C: 22M-22M one way valve, D: 22F-22F connector

E: Not for resuscitation purposes label

QUALITY CONTROL

- Check all component parts are within date
- Document the batch numbers of all component parts
- Check the one-way valve is correctly orientated; use a hand to ensure airflow can be felt going towards the user

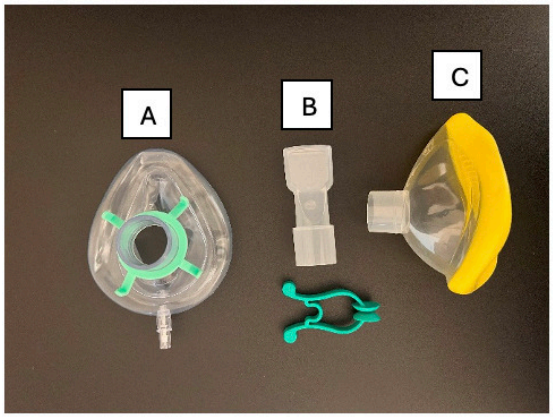

Figure 3. Interface options for use with the LVR bag.

A: Soft seal anaesthetic masks

B. Mouthpiece and nose clip

C. Anatomical seal mask

- Maintain a database of LVR bag users, date of LVR bag issue, LVR bag identifier number and date the next replacement LVR bag is due
- Report all patient safety incidents, including near misses on the national patient safety database
- Ensure the LVR bag is labelled as "not for resuscitation purposes"

USAGE INSTRUCTIONS

INDICATIONS

Clinicians are accountable for their own practice and should use clinical reasoning when applying LVR in the context of each individual clinical scenario.

Indications to LVR are listed below[2,7,8,10]

- Peak cough flow <270L/min
- Low vital capacity
- Risk of atelectasis
- Sputum retention
- Patients with a neuromuscular disease diagnosis

ABSOLUTE CONTRAINDICATIONS

An absolute contraindication refers to a situation or condition where a particular treatment, procedure, or medication must not be used under any circumstances, because it could result in life-threatening harm or severe adverse effects.

Absolute contraindications to LVR are[2,10]:

- Haemoptysis/blood-stained secretions
- Recent or current barotrauma
- Significant hypotension
- Active vomiting
- Via an endotracheal tube or tracheostomy tube with an inflated cuff (one-way valve will mean the patient cannot exhale and there is a risk of tension pneumothorax)

RELATIVE CONTRAINDICATIONS

A relative contraindication is a situation or condition that makes a treatment or procedure potentially risky, but not entirely ruled out. It means caution is needed, and the treatment may still be used if the potential benefits outweigh the risks.

Relative contraindications to LVR are[2,10]:

- Bullous emphysema
- Severe obstructive pulmonary diseases
- Patient reporting chest pain
- History of pneumothorax
- Raised intracranial pressure
- Patient unable to follow instructions
- Reduced consciousness

PERFORMING LVR

The following should be considered when performing LVR[2,10]:

- LVR should be avoided for a minimum of 60 minutes after a meal to avoid the risk of reflux and discomfort for the patient. For those on gastrostomy feeding, feed should be stopped 60 minutes before LVR.
- Consider the need for personal protective equipment.
- LVR is best performed in an upright sitting position. It can be performed in other positions, especially if other techniques (e.g., postural drainage, manually assisted cough) are combined.
- Agree with the patient a signal/hand gesture they will use to indicate they have reached MIC.
- Place the mouthpiece in their mouth using a nose clip or mask over their nose and mouth and form a tight seal to minimise any air leak.
- Instruct the patient to take a full breath in while gently squeezing the bag. Careful coordination of inspiratory effort and compression of the LVR bag is required.
- Instruct the patient to try to hold their breath for 1-2 seconds, then try to take another breath on top of the previous breath, again squeezing the bag. Repeat this until they have reached MIC. This may take two to five breaths.
- Once MIC is achieved, instruct the patient to hold their breath for 3-5 seconds and then breathe out gently.
- The patient should rest between MIC breaths.
- The patients should be instructed to cough instead of exhaling if they feel they have respiratory secretions to clear.
- The patient should rest/stop if they feel lightheaded or dizzy.

There are a number of positions that can be adapted to deliver LVR, both for patients to deliver the LVR indepen-

Figure 4a. Place the LVR bag between knees and use knees to compress LVR bag

Figure 4b. Use hands to compress LVR bag

Figure 4c. Place LVR bag under arm and squeeze like a bagpipe to compress the LVR bag

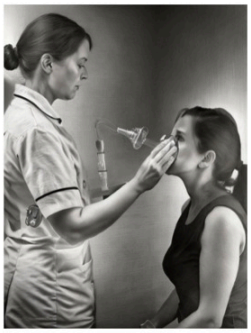

Figure 4d. If a carer assists, they should use two hands to hold the mask in place and place LVR bag under arm and squeeze like a bagpipe to compress the LVR bag

dently or with the assistance of a caregiver. See Figure 4 for examples of how to hold the LVR bag.

PRESCRIPTION

The prescription for LVR should be individualised to each patient.[1,10] The aim is to achieve MIC via breath stacking with multiple compressions of the LVR bag to augment inspiration. Usually, this takes three compressions of the bag, but this will vary between patients. One cycle usually consists of three-five breaths. A rest period is encouraged between cycles. A treatment session can comprise of two-three cycles. Patients should be encouraged to routinely perform LVR two to four times per day. At times of respiratory compromise, for example, a respiratory infection, they may need to undertake more frequent treatment sessions.[1, 10]

Other treatments can be used in combination with the LVR bag, for example manually assisted cough (MAC), positioning or suctioning.[1,10]

CONSIDERATIONS

- Some discomfort in the chest wall due to stretching of muscles and joints can occur during initial use.[10] It is appropriate to advise patients of this short-term side effect before commencing treatment.
- Some patients, especially those with spinal cord injury, may develop hypotension during MIC. The addition of an abdominal binder can assist with this hypotension response.[10]

MAINTENANCE

The LVR bag system pack should be replaced every three months. The low-volume bacteria filter prevents sputum and other fluid from entering the bag valve mask and one-way valve. If contaminated with fluid (e.g. respiratory secretions, saliva), the bacterial filter should be changed, and thus, the patient should be provided with spares and taught how to do this. Bacterial filters must not be washed as this will cause them to become blocked and air will not pass through. The interface (mouthpiece or mask) should be washed in warm soapy water daily. If the circuit is contaminated with sputum or other fluid, it should be rinsed with warm, soapy water and allowed to dry completely before use. Bacterial filters should be changed monthly. LVR bags should be changed if there are signs of damage.

STAFF COMPETENCE

Clinicians are responsible for practicing within their professional and individual scope of practice. Allied Health

professionals should refer to the Health and Social Care Professions Council's standards of conduct, performance and ethics and the standard of proficiency for their profession. Nurses should adhere to the Nursing and Midwifery Council's professional standards of practice and behaviour for nurses, midwives and nursing associates. Medics should adhere to the relevant General Medical Council's Professional Standards. Clinicians working in unregulated roles should refer to their local employer's standards. This technical standard is intended to assist in solving a clinical problem, not to act as a guideline. Clinicians are accountable for their own practice and should use clinical reasoning when applying LVR.

TRAINING REQUIREMENTS

Clinicians should undergo training and supervised practice to support the safe and effective assembly and use of LVR bags.

CAPABILITY ASSESSMENT FOR CLINICIANS

The following capabilities are suggested minimal standards for clinicians delivering LVR.

- Understand the physiology and pathophysiology of coughing and sufficient secretion clearance.
- Able to apply the LVR bag technique as described in this technical standard.
- Able to adapt the prescription and deliver LVR bag as described in this technical standard.
- Able to teach patients, their carers and other healthcare professionals how to apply LVR bag techniques.
- Able to adapt the prescription to individual patients.
- Able to assemble the LVR bag as described in this technical standard.
- Aware of the indications, absolute and relative contraindications for LVR bags.
- Aware of the quality control and governance procedures as described in this technical standard.

CARER TRAINING FRAMEWORK

- Understand the principles of lung volume recruitment and how the LVR assists in breathing.
- Understand that the LVR bag is not a resuscitation device and should not be used in emergencies.
- Able to apply the LVR bag technique as described in this technical standard.
- Able to assemble the LVR bag as described in this technical standard.
- Aware of the indications, absolute and relative contraindications for LVR bags.
- Knows when to stop the procedure and seek medical advice if the person experiences dizziness, chest discomfort, or pain.
- Ensure the LVR bag is kept clean and in good working order.

REVIEW AND APPROVAL

Reviewed by the MHRA for adherence to and information about their guidance in January 2025.

Endorsed by Specialists in Long-term Ventilation at Home (SiLVaH) network in February 2025.

Endorsed by Respiratory Information in Spinal Cord Injury (RISCI) group in February 2025

SAMPLE PATIENT INFORMATION SHEET

A sample patient information sheet is provided as a supplement to this technical standard. It is intended to act as a template for local adaptation.

Key points

- **Lung volume recruitment bags are designed to help increase the maximum amount of air a patient can inhale which, in turn, boosts cough strength and aids airway clearance in patients with neuromuscular diseases.**
- **Currently, these bags are available only as separate parts. This technical standard provides support for respiratory care professionals on how to assemble, use and manage lung volume recruitment bags.**

DECLARATION OF INTEREST

Nil to declare

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This work is unfunded

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SUPPLEMENTARY MATERIALS

Sample Participant information Sheet

Download: https://acprcjournal.scholasticahq.com/article/137799-lung-volume-recruitment-bags-an-acprc-technical-standard/attachment/283388.docx?auth_token=KR1VGvOU3Ly8sfWTbO19