



LifeVent Medical Limited

White Paper

Summary

Early Intervention with CPAP improves patient outcome.

CPAP is an effective treatment for respiratory failure resulting from COPD or Pulmonary Oedema. There is positive evidence to suggest that CPAP may be useful in the treatment of other causes of respiratory failure, especially in selected subgroups of patients.

CPAP has also been shown to be useful in the treatment of other conditions like recovery from Coronary Artery Bypass Graft operations and major abdominal surgery. CPAP is an established therapy in the area of premature infant respiratory support. It is also useful in weaning patients from Endo Tracheal Intubation ventilation.

CPAP treatment's greatest advantage is that it has been shown to significantly reduce the need for Endo Tracheal Intubation. This has a multitude of advantages, the most significant being to the patient. ETI is an unpleasant procedure at the best of times. CPAP allows a significant percentage of patients to avoid ETI without compromising therapeutic goals. It also allows the patients to talk to their families without the interference of a tube in the throat. This is particularly important in the terminally ill whose time is even more precious.

In terms of the health system, the avoidance of ETI means that less ICU beds are utilized as CPAP can be delivered in a medical ward. CPAP is also associated with a much lower rate of nosocomial infection which means the CPAP treated patient utilizes lower volumes of antibiotics and specialist time, which in turn leads to shorter hospital stays and savings. In some cases the Length of ICU Stay and Length of Hospital Stay can be reduced as well. All of this contributes to CPAP being a cost effective treatment method which has the advantage of being patient friendly in most cases.

This white paper introduces the LV300 Low Flow CPAP device as an effective provider of effective CPAP hospital wide and illustrates its portability and simplicity of use for clinicians who understand the wider applications of CPAP.

The Scenario

Emergency Department

A patient presents in Emergency Department with respiratory distress and their symptoms may be typical of acute exacerbation of Chronic Obstructive Pulmonary Disease, Acute Pulmonary Oedema or other causes. The Clinicians early assessment of the patient is key to determining what treatment to prescribe and the clock is ticking as the patient is acutely ill.

What intervention to maintain the airway? How do I achieve optimum respiratory function with the patient?
How do I treat the hypoxia?

Taking an active step in improving this patients outcome and maintaining their respiratory function would be to prescribe low flow portable CPAP.

Taking this important step by administering CPAP early can improve their patient journey but to date there has not been a hospital wide portable CPAP solution available leaving clinicians with limited respiratory care choices.

Recovery Department

A patient presents in Post Operative Recovery Department with Hypoxaemia and their symptoms may be typical of Post Operative atelectasis following major abdominal surgery or post anaesthetic respiratory difficulties due to Obstructive Sleep Apnoea. The Clinicians early assessment of the patient post operatively is key to determining what treatment to prescribe and the clock is ticking as the patient is acutely ill.

What intervention to maintain the airway? How do I achieve optimum respiratory function with the patient? How do I treat the hypoxia?

Critical decisions need to be made now to keep this patient alive. The decision needs to be a reasoned evidence based justifiable decision and it needs to be correct.

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History

Negative pressure ventilators (iron lungs) were developed in the early 20th century to assist victims of poliomyelitis. However during Copenhagen's polio epidemic in 1952 there was a shortage of negative pressure ventilators. Rather than let children die of respiratory failure, they were ventilated by medical students providing positive pressure through an endotracheal tube. This new approach caused the patient survival rate to improve from 10 to 90 percent. The advantages of positive pressure ventilation became abundantly clear causing a paradigm shift in the management of acute respiratory failure.

Today CPAP has been used in the acute care hospital setting for the last three decades and the efficacy of the applications is well documented. CPAP is now being regarded as being a basic standard of care in patients with acute heart failure and refractory hypoxemia due to pulmonary oedema.

CPAP may also have some benefit in patients with postoperative pulmonary complications, or in the early stages of acute respiratory distress syndrome (ARDS). It is also used as an adjuvant to physiotherapy in patients with secretion retention and focal areas of lung collapse.

The CPAP acute care applications have almost exclusively been confined to the acute care facilities. This restriction has been due to the characteristics of the equipment (bulky, high gas flow, non-portable) and the availability of trained personnel to operate the equipment. However, recent research has demonstrated the efficacy of using CPAP in the pre-hospital setting by Emergency Medical Services. The results of these studies have shown:

A significant decrease in the need for endotracheal intubation and artificial ventilation after CPAP by face mask was introduced for patients suffering from acute respiratory failure secondary to congestive heart failure/cardiac pulmonary oedema.

A decrease in mortality rate and the length of admission for patients treated with CPAP.

Avoiding intubation negates complications from having to sedate or paralyze patients. Also once on a ventilator, patients have to be admitted to intensive care. Additional problems associated with intubation include increased risk of ventilator associated lung injury and barotraumas and nosocomial (hospital-acquired) infections. Intubation also causes agitation, anxiety and discomfort in awakened patients. The patients require additional treatment with sedative and analgesic drugs. Excess sedation has been shown to increase intensive care length of stay by up to 30%. There is little doubt that managing patients on ventilators poses significant risk, is expensive and very resource intensive

The cost savings associated with not intubating and mechanically ventilating patients is significant. Apart from eliminating the direct costs associated with implementing these modalities, additional cost savings can be realized due to a reduction in the length of hospital stay, morbidity and mortality. In one study it was concluded that there were significant benefits to using non-invasive ventilation in the treatment of chronic obstructive pulmonary disorders. These included a reduction in the need for endotracheal intubation by 66%, a 20% reduction in mortality and a reduction in the length of ICU stay of 19 days and a reduction in the length of hospital stay of 13 days.

The Portable Low Flow LV300™ CPAP Solution

LifeVent Ltd has developed and patented the technology for a new, compact, non-powered and portable CPAP device (LV300™). LV300™ needs oxygen gas flow rates of between 10-15 L/min compared with the 50-130 l/min gas delivery rates of incumbent devices. The low flow rates of the LV300™ CPAP now make it possible to produce a truly portable CPAP device. A standard C size oxygen cylinder (400L) will now last up to 40 minutes, instead of only 4-10 minutes using current technology.

LV300™ vs Existing CPAP

LifeVent CPAP Device	Incumbents
Portable <ul style="list-style-type: none"> • Low Gas Flows 15 l/min • Quiet Operation • Economical to run • Includes Venturi for air blending • More accessible 	Fixed <ul style="list-style-type: none"> • High Gas Flows 60-110 l/min • Noisy • Expensive to run and limited accessibility • Often requires additional air blender with piped air • Limited Access
Comfortable <ul style="list-style-type: none"> • Reduced pressure drop • Reduced need for humidifier • Low Imposed "Work of Breathing" 	Uncomfortable <ul style="list-style-type: none"> • Excessive air flow • Dehydrates patient • Increased need for humidifier

Features and Operating Principles of the LV300™

The LV300™ from LifeVent Medical Ltd is a continuous positive airway pressure (CPAP) device, i.e. a device for supplying oxygen or a mixture of air and oxygen at a pressure above atmospheric pressure to a spontaneously breathing patient.

The LV300™ has been specifically designed to be portable, to operate independent of electricity and the effects of gravity and to be efficient in terms of gas utilisation. It is anticipated that the LV300™ will be used in pre-hospital, post-operative/recovery and emergency room applications.

The LV300™ includes a Venturi to allow you to vary FIO₂ (fraction of inspired oxygen) from 33% to 100% depending on the CPAP level selected. It is not intended for life support or life sustaining applications.

The unique features of the LV300™ are:

Portability:	Lightweight, compact and non-powered.
Low gas flows:	Oxygen delivered at 15 l/min compared with the 50-130 l/min gas delivery rates of competitive devices. [Note: A standard D size oxygen cylinder (400L) will last for about 25 minutes, instead of the usual 4-10 minutes]. When operating the Venturi, only 10 l/min is required to operate the device.
Ease of use:	Efficient and intuitive mechanical operation.
Adjustable CPAP	Can deliver CPAP levels between 5 -15 cm of H2O.

The LV300™ testing shows:

Efficiency:	LV300™ can operate at very low flow rates without loss of performance [Work of Breathing].
Safety:	CPAP can be delivered safely at low gas flows.

How does CPAP work?

Under normal circumstances air sacs (alveoli) remain open at all stages during breathing. An important factor in maintaining normal lung function is surfactant. This is likened to a detergent that reduces surface tension in the alveolar walls preventing them from collapse. Many pulmonary conditions such as pneumonia and acute left ventricular failure are associated with loss or denaturation of surfactant. For example, left ventricular failure causes acute pulmonary oedema in which surfactant is "washed out" resulting in alveolar collapse. The mechanics of breathing and gas exchange are dramatically affected. Breathing becomes increasingly difficult and arterial blood oxygenation falls. This condition may develop very rapidly resulting in death if patients cannot obtain immediate medical assistance.

CPAP maintains constant pressure during both inspiration and expiration of a spontaneously breathing patient below which the pressures in the patient's airways are not allowed to drop. This keeps the smaller airways open and prevents the collapse of alveoli at the end of expiration, thereby minimizing the work of breathing. CPAP produces an increase in pressure inside the chest, including the surface surrounding the heart. This makes it easier for the left ventricle to eject blood and reduces cardiac work through a reduction in left ventricular preload. CPAP may be used in this way to assist patients with "weakened" hearts.