LUNG INSPIRATORY FLOW ENABLER

A continuous positive airway pressure ventilator

A project under the National Ventilator Programme, funded by the Solidarity Fund

Emergency ventilation device for Covid-19 only. | Not to be used post-pandemic

ABOUT CSIR L.I.F.E

The CSIR Lung Inspiratory Flow Enabler (L.I.F.E) was developed to support the South African government's response to the spread of COVID-19 infections. The Department of Trade, Industry and Competition has mandated the South African Radio Astronomy Observatory (SARAO) to manage the national effort required for the local design, development, production and procurement of respiratory ventilators to support the government's response to combat the COVID-19 (coronavirus) pandemic.

The ventilator is applied to a patient's face (non-invasive, non-intubated) and can thus be rapidly and easily utilised as emergency equipment, helping patients who are experiencing respiratory distress.

The system is based on existing ventilator technologies that supply a pressurised mixture of air and oxygen to the patient through a mask. A mild level of air pressure keeps the airways open and sustain lung pressure.

The device conforms to the licence requirements set out by the South African Health Products Regulatory Authority and conforms to World Health Organization guidelines for these type of products.

HOW IT WORKS

The device is based on the principles of Continuous Positive Airway Pressure (CPAP) ventilation by which a constant level of pressure above atmospheric pressure is maintained in the airway during the expiration cycle. The pressurised gas keeps the lung pressure elevated above ambient air pressure and the lung alveoli recruited and operating effectively.

The inspired oxygen proportion of the gas supplied to the patient can be adjusted.

FEATURES

The system consists of a stand-alone flow generator that is used in conjunction with a breathing circuit comprising hoses, filters and a mask.

The flow generator is a precision venturi device which is powered purely by oxygen – no electricity or medical air is required. Other features include:

- Uses standard oxygen supply as administered in hospitals;
- Can be supplied by compressed oxygen gas cylinders of sufficient capacity;
- Has separate on/off control switches;
- Features on-device flow adjustment; and
- Has a calibrated Fraction of Inspired Oxygen adjustment that does not require additional oxygen concentration sensors.

NOTE: The CSIR LIFE device is not suited to be used as a general life support system. It is only for use on adult patients and may only be administered by trained medical personnel. Devices are to be de-commissioned after the Covid-19 pandemic. Units need to be returned to the supplier or to the CSIR in PRETORIA.

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SPECIFICATIONS

SPECIFICATION	DESCRIPTION
Operating Temperature	5° to 35° C
Storage Temperature:	-20° to 60° C
Relative Humidity (operating & storage):	15 to 95% (non-condensing)
Atmospheric Pressure:	101 to 77 kPa (0 - 2286 m)
Physical Dimensions:	15.0cm x 5.0cm x 4.5cm (L x W x H) (CSIR L.I.F.E. ventilator only, excluding fittings and accessories) Package box: 40cm x 20cm x 20cm (L x B x H)
Weight:	Total packaged system is 1.5 kg Device: 500g
This device is designed to conform to the following standards to the degree accepted by SAHPRA	• ISO 80601-2-70 Sleep Apnoea Breathing Therapy Equipment • ISO 60601-2-12 Critical care ventilators ISO 10651-3 Emergency and transport ventilators • WHO Specification: Technical specifications for invasive and non-invasive ventilators for COVID-19 • MHRA Specification: Rapidly Manufactured CPAP System • (RMCPAPS)
IEC 60601-1	• Degree of protection against ingress of water: • Device: Drip proof, IP22 • Mode of Operation: 14-day continuous use cycles
Intake Port Pressure Range	Oxygen supply up to 400kPa
Intake Port Filters	• 0.027 µm viral filter on AIR INTAKE port • 0.027 µm viral filter on mask port • (Optional) Viral filter at OUT port of the air blender
Connector interfaces	• O2 IN port: 1/8 inch NPT threaded port • AIR IN port: Ø 22mm female port • OUT port: Ø 22mm male port
Dead space volume	250ml = mask volume
Patient mask volume	200ml – 300ml
Pressure limiting valve	20cmH_2O - 40cmH_2O
Inspiratory and expiratory resistances	• Inspiratory resistance – None • Expiratory resistance – PEEP value (20cmH_2O maximum)

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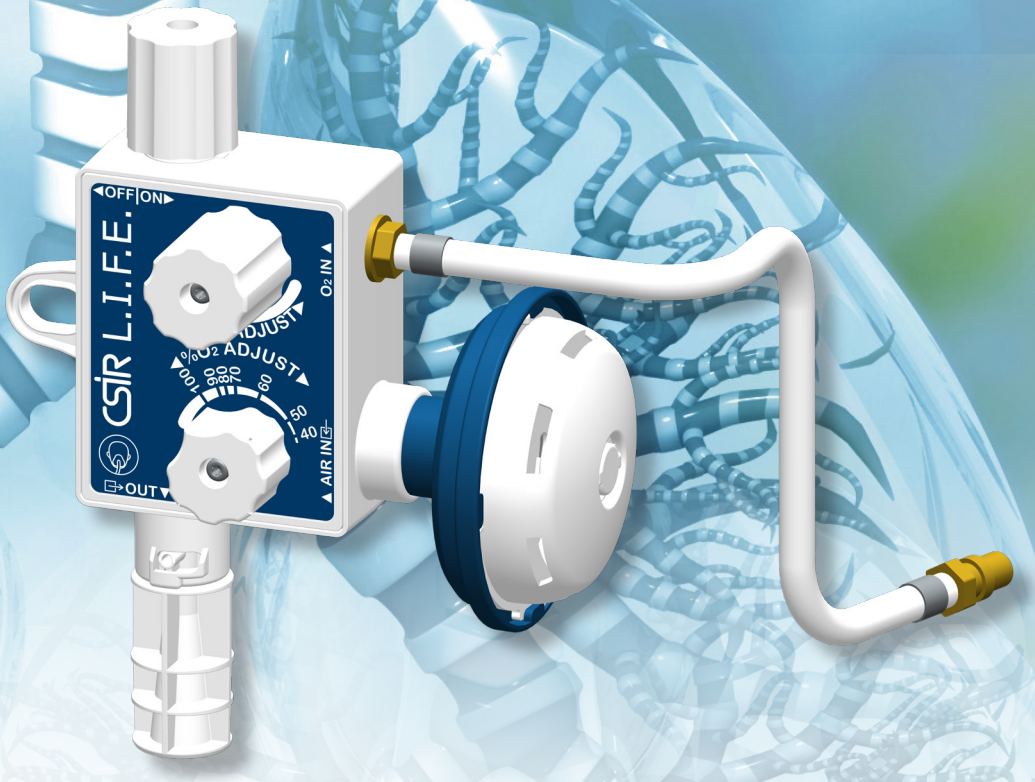

CONTRAINDICATIONS

When assessing the relative risks and benefits of using this equipment, the clinician must understand that this device can deliver pressures up to 20 cm H_2O under normal conditions. In the event of certain fault conditions, a maximum pressure of 40 cm H_2O is possible.

The following pre-existing conditions may **contraindicate** the use of CPAP therapy:

- Cavities or cysts in the lung (Bullous Lung Disease)
- Pathologically low blood pressure
- Bypassed upper airway
- Pneumothorax
- Decreased cardiac output
- Gastric distention

Caution should be used when prescribing CPAP for patients with, or with a history of:

- Cerebral spinal fluid leaks
- Abnormalities of the cribriform plate
- Pneumocephalus
- Head trauma, surgery to the brain, middle or inner ear, pituitary gland, or sinuses
- Middle ear infection, perforated ear drum or severe nosebleed

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