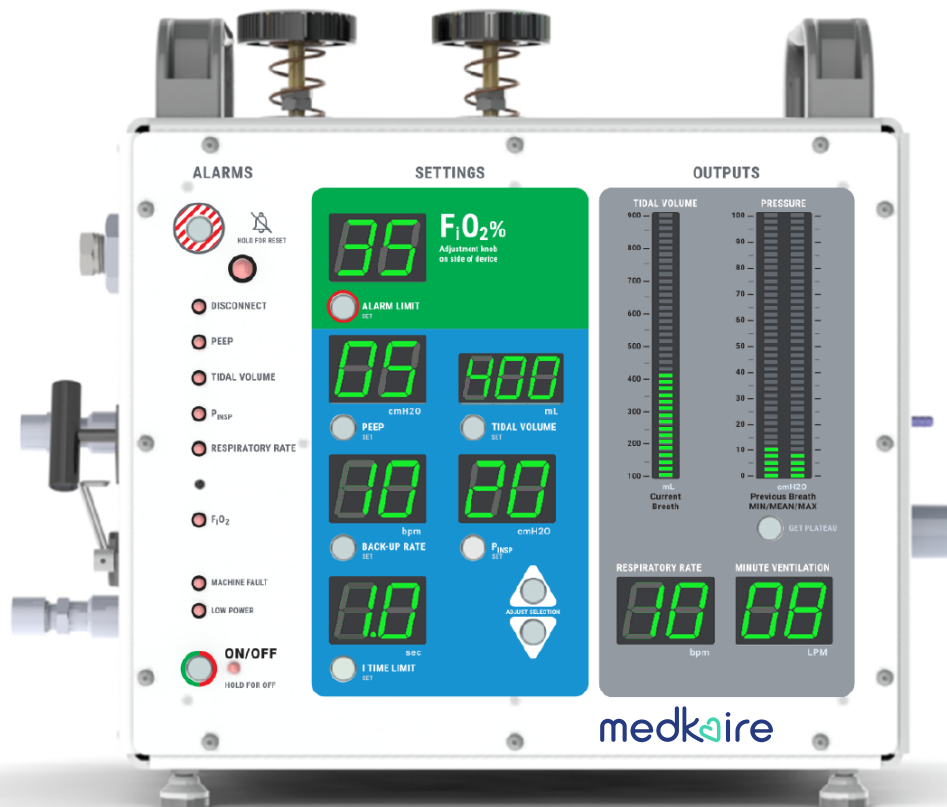




Medkaire Ventilator



**Medkaire Ventilator** is manufactured by K-One under licence from NASA-JPL of US. It is based upon the design of NASA-JPL's VITAL Ventilator which is approved by the Food & Drug Administration (FDA) in US for use under Ventilator Emergency Use Authorization (EUA). For Malaysia, the Medkaire Ventilator has been submitted to the Medical Device Authority (MDA) for approval which is pending. It shall only be commercially launched upon MDA's approval.

Similar to NASA-JPL's VITAL Ventilator, the Medkaire Ventilator is specifically developed and suitable for use with COVID-19 patients. It has fewer parts than a traditional, high-end ventilator and can therefore be built faster and maintained more easily.

Like all ventilators, the Medkaire Ventilator requires patients to be sedated and an oxygen supply inserted into their airway to breathe. It is focused on providing air delicately to stiff lungs – a hallmark symptom of COVID-19. Stiff lungs have a harder time expanding, so patients struggle to get enough air to breathe. The Medkaire Ventilator is meant to provide enough air pressure to patients to inflate their lungs but not so much that the lungs over-expand. It also works to ensure the lungs do not completely deflate either.

COVID-19 patients have lung damage that makes the sides of their lungs inflamed and sticky. If all the air goes out of their lungs and the sides touch each other, they might stick together and make it even harder to open back up again. So, the Medkaire Ventilator tries to keep the lungs slightly inflated whenever patients exhale.

## Features

### Low complexity ventilator

Volume-controlled ventilation

Assist-control trigger

Plateau (pause) pressure on demand

Interfaces with standard end circuits

### Alarm system

Create visual and audible alarms for a number of issues associated with the safety of the patient or issue with the device (9V alarm battery is included)

### Controlled with ease

Easy to learn and use with an intuitive and simple interface. Trained healthcare professionals will have easy access to all settings and important parameters through direct access knobs and buttons

### Flexible

Can be easily mount on patient bed

## Intended patients

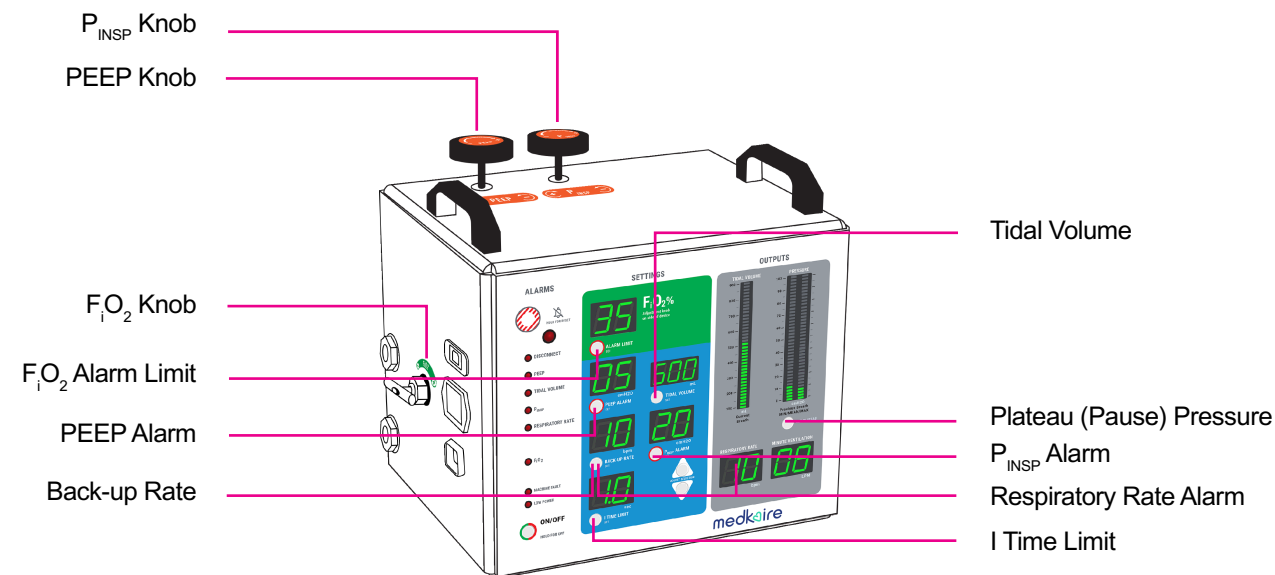
- Acutely ill patients suffering from Acute Respiratory Distress Syndrome (ARDS) caused by COVID-19.
- Patient is  $\geq 18$  years old; body weight  $\geq 50$  kg.
- Patients who are unable to maintain adequate/safe oxygen level with nasal or mask oxygen.
- Variety of clinical states including low compliance, high resistance, hypoxia, hypercapnia.
- Intubated and sedated.

## Intended use environment

Medkaire Ventilators are able to handle the dirt and dust of a field setting as target patient population may or may not have access to traditional hospital settings. Medkaire Ventilator can be used in the following environment:

- Healthcare facility.
- Stationary field setting – benign temperature and water exposure.
- Transit operable when used with Uninterruptible Power Supply (UPS).

ENVIRONMENTAL PARAMETER	ALLOWABLE RANGE
Temperature	16-27°C
Humidity	30-70% non-condensing
Local Atmospheric Pressure	70-110 kPa



**Dimensions** 393 mm (W) x 324 mm (H) x 250 mm (L)

**Weight** 8.2kg

**Connectivity** USB connector

## Facility resources requirements

SOURCES	REQUIREMENTS
AC (wall plug-in)	240V, 50Hz
Uninterruptible Power Supply (UPS)	≥70Wh rating will allow for operation of the ventilator for a minimum duration of 20 minutes.
Input gas types	Air & oxygen
Input O2 pressure	35-87 PSI
Input air pressure	35-87 PSI
Gas input connection type	Diameter Index Safety System (DISS) for oxygen and medical air

## Compatible patient circuit elements

CIRCUIT ELEMENT	COMPATIBLE HARDWARE
Universal Cuff Adapter	ISO standard 22mm interfaces (22mm OD Male and 22mm ID Female)
Nebtee	ISO standard 22mm interfaces
Gasp Valve	One-way valve with ISO standard 22mm interfaces
Patient Limb	Corrugated tubing, CPAP tubing or 22mm flexible tubing
Proximal Pressure Line	1.2mm inner diameter flexible tube with Luer fittings at ends
Exhalation Pressure Line	3mm inner diameter flexible tube
Check Valve	One-way valve with ISO standard 22mm interfaces
IPPB Exhalation Valve	Universal IPPB Circuit Kit
Heat and Moisture Exchange Filter (optional)	ISO standard 22mm interfaces with pressure drop of 3cmH <sub>2</sub> O or less
Exhalation Filter	ISO standard 22mm interfaces with pressure drop of 3cmH <sub>2</sub> O or less
Nebulizer (optional)	ISO standard 22mm interfaces
Humidifier (optional)	DeVilbiss Model DV5C or similar

## Verified device specification

PARAMETER	RANGE
Back-up rate (BPM)	4-40 bpm
Tidal volume (TV) (mL)	150-800 mL
Flow rate (L/min)	70 L/min
PIP (cm H <sub>2</sub> O)	up to 35 over PEEP (5-70)
PEEP (cm H <sub>2</sub> O)	5-30
Air source	Facility (35-87PSI)

**K-One MediTech Sdn. Bhd.**  
(formerly known as K-One Resources Sdn. Bhd.)

HQ : 66 & 68 Jalan SS22/21, Damansara Jaya, 47400 Petaling Jaya, Selangor, Malaysia  
Manufacturing centre : 68 Lengkok Rishah 2, Kawasan Perindustrian Silibin, 30100 Ipoh, Perak, Malaysia