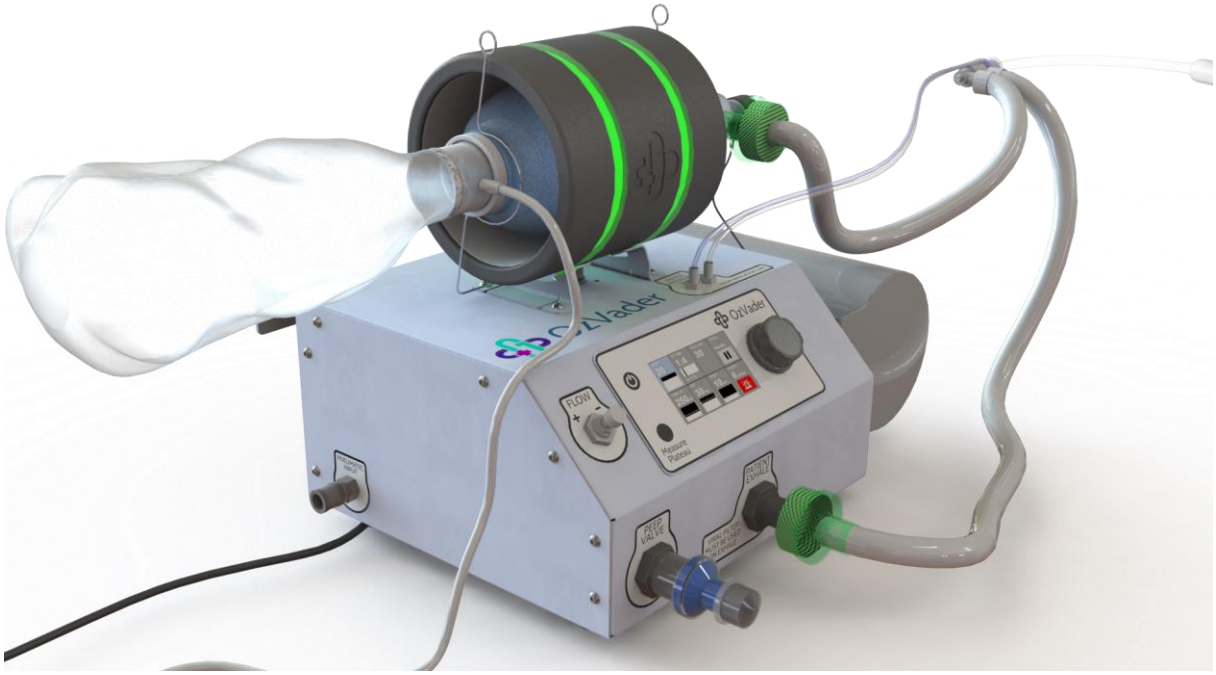
OzVader

OzVader V1

Ventilator System



Product Brochure

V.3

April 2020

POWERED BY OLITEK

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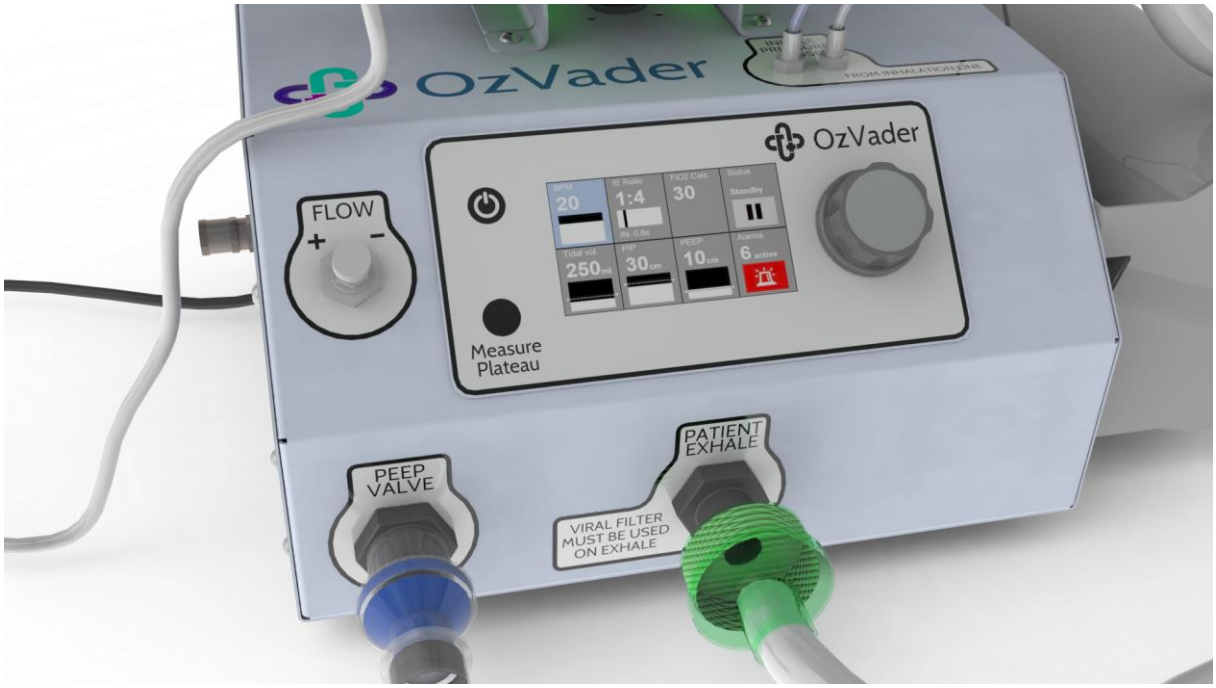
OzVader V1 is an Australian designed intermittent mandatory ventilator (IMV) that safely meets the needs of ICU clinicians.

The OzVader ventilator complies with all mandatory technical requirements of the Australian Government's Therapeutic Goods Administration (TGA) Specification for COVID-19 Ventilators - Revision 1.0, 07APR2020



OzVader – saving lives, safely.

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OzVader V1 Ventilator

- The OzVader V1 is an intermittent mandatory ventilator (IMV) specifically designed for the COVID-19 pandemic.
- The device was designed by an Australian engineering and manufacturing team in collaboration with an expert medical advisory panel.
- The OzVader utilises intermittent mandatory ventilator (IMV) mode to achieve safe patient gas exchange and acid-based balance to sustain life.

Australian Therapeutic Goods Administration (TGA)

The TGA is part of the Australian Government Department of Health and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

In response to the anticipated demand for invasive ventilator medical devices to treat patients requiring respiratory support as a result of infection with COVID-19, an Australian Government taskforce was established to identify domestic manufacturing capability of these devices.

Australia's Chief Scientist, Dr Alan Finkel, led these efforts and, with support from an expert panel of ICU medics from across Australia, compiled ***Ventilator for COVID-19 use in Australia***. This document details the minimum technical requirements for invasive ventilators that would be suitable for supply to and use in Australian hospitals during the COVID-19 emergency.

OzVader V1 ventilator complies with all mandatory requirements for invasive ventilators as detailed in TGA specification document: *"Ventilator for COVID-19 use in Australia" Revision 1.0, 07APR2020.*

- *https://www.tga.gov.au/ventilator-covid-19-use-australia.*

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OzVader V1 Functionality

Specifications	
Ventilator modes	Intermittent Mandatory Ventilation (IMV) capable of: ▪ Volume Controlled Ventilation (VCV)
Operational summary	OzVader is a pneumatically actuated mechanical ventilator providing precise control over the patient side ventilation variables: ▪ Tidal Volume (Vt), ▪ Respiratory Rate, ▪ Flow, ▪ IE Ratio, ▪ Peak Inspiratory Pressure (PIP)
	Air Pump: 12V DC onboard high flow air pump
	Control System: powerful on-board micro-processor control system.
	User Interface: designed with ICU clinicians in mind for functionality & usability
	Sensors: OzVader's flow and pressure sensors constantly monitor ventilator and patient variables to ensure patient safety.
	Valves: electronic valves provide accurate control of air pressure and flow to ensure patient safety.
	OzVader's unique pressure chamber design suits all adult Bag-Valve-Mask types and is therefore supplier agnostic.
FI02	The OzVader V1 suggests a calculated oxygen flow rate based on measured air flow and display this on the electronic user interface. Clinician uses this to set the external wall/bottle mounted O2 flow control. The Fi02 is therefore infinitely adjustable between 0% and 100% There is an option for an integrated oxygen monitoring sensor that monitors 02 flow and %FI02 and is connected to the visual and audible alarm system.
Reliability	Designed for highest levels of reliability with minimal moving parts and inbuilt redundancy of power systems (240V, 12V, Battery, Compressed Air)
Tidal volume	Range 10ml to 950ml Infinitely variable
Respiratory rate	5 to 30 breaths per minute in increments of 2
Flow	30L/min to 60L/min preferred range. Up to 100lpm can be achieved when connected to hospital air supply.
Inspiratory rate	Inspiratory time adjustable from 0.5 seconds to 2 seconds
Inspiratory to expiratory time ratio (I:E)	Infinitely variable Adjustment of gas flow rates according to patient's lung compliance, pulmonary gas exchange status

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Peak inspiratory pressure (PIP)	Direct measurement of peak inhalation pressure Mechanical failsafe valve at 80cm H2O Inspiratory pause function/manoeuvre allowing setting of safe tidal volumes and PEEP (plateau pressure measurement). Target plateau pressures < 30 CmH2O and driving pressure < 15 Cm H2O Clinician override function of 35cm H2O PIP cut-off while performing procedures such as bronchoscopy
Positive end expiratory pressure (PEEP)	Adjustable PEEP between 2-25cm H2O Infinitely variable Compatible with standard disposable & re-usable PEEP valves
Ventilation circuit	Twin tube ventilation circuit 22 mm outside diameter (OD) 'male' standard connectors Separate inspiratory and expiratory limbs
ICU clinician functionality	PIP overpressure override function (ICU / endotracheal tube inspections etc.) Plateau pressure hold mode (10seconds)
Alarms	Refer to OzVader alarm systems
Power modes	240V AC 12V DC Compressed air (hospital grade) Compressed air (industrial compressor)
Battery	Backup 12V battery power supply 2 hours achieved via hot swappable 12V batteries or external compressed air tanks
Motive air requirements - when connected to hospital air	

Peak Consumption (lpm @ 4 BAR)	Average Flow (lpm @ 4 BAR)	Tidal (ml)	BPM
30	2.50	900	5
30	5.00	900	10
30	10.00	900	20
30	15.00	900	30
18	1.50	600	5
18	3.00	600	10
18	6.00	600	20
18	9.00	600	30
8	0.67	300	5
8	1.33	300	10
8	2.67	300	20
8	4.00	300	30

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OzVader V1 Alarm Systems

Alarm	Trigger / Cause	Machine Action	Clinician Action
System Pressure Low	The charge chamber is not reaching pressure probably due to pump failure or lack of system air / leakage	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	This is a mechanical failure; the pump may need replacing or connect to hospital air or fix system leak
System Pressure High	The pressure in the system pressure line is too high	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	Check the system pressure regulator
Ventilation Fail Alarm	The flow meter doesn't see the expected airflow through the patient's airway	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	Check airway circuit, check flow meter, check BVM
PIP high	The inspiration pressure is higher that the set limit	Stop Inspiratory cycle at PIP, Red Beacon Flashing, Audible Alarm – Continue to Ventilate. Auto Reset if next breath is under PIP, hold alarm for each breath at PIP Display Alarm on Screen	Attend to patient and make suitable adjustments
Main power supply failure	Loss of power on the main power supply	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	If this fault is not due to a known cause (moving patient etc.) then check power
Battery charge failure	Internal battery charge voltage is low when the system is under normal power	Continue to Ventilate - Display Alarm on Screen	Check the condition of the battery and charge circuit, avoid losing mains power to the ventilator until it has been resolved
Low Battery	Battery voltage is low / battery flat	Continue to Ventilate - Display Alarm on Screen	Connect an alternative power supply, power drain on battery by connecting air supply to eliminate internal pump discharging battery
Inspiration Valve Fault	Fault in the charge valve circuit	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	Needs an internal inspection to check the connections of the charge valve or replace the motherboard
Exhalation Valve Fault	Fault in the exhalation valve	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	Needs an internal inspection to check the connections of the charge valve or replace the motherboard
Pump Fault	Fault in the pump motor circuit	Red Beacon Flashing, Audible Alarm – Continue to Ventilate Display Alarm on Screen	Needs an internal inspection to check the connections of the charge valve or replace the motherboard
PEEP Alarm	Set PEEP value is not achieved by 10% too low or too high	Red Beacon Flashing, Audible Alarm – Continue to Ventilate. Reset alarm if PEEP returns within threshold of set value Display Alarm on Screen	Check patient or adjust the PEEP settings
Tidal Volume Alarm	Inspiratory tidal volume is exceeded by 10% or expiratory tidal volume is not achieved by 10%	Red Beacon Flashing, Audible Alarm – Continue to Ventilate. Reset if Tidal volume returns within threshold of set value. Display Alarm on Screen	Check patient or adjust the TV settings or flow settings
Machine switched off during mandatory mode	Attempts to turn machine off without disabling mandatory mode	Display Warning on Screen	Switch machine out of mandatory mode before attempting to power down
Control system watchdog	In the event of a control system failure, an independent watchdog function alarms Red Beacon Flashing, Audible Alarm		
Oxygen Low Alarm	**(Optional)** Oxygen flow and content sensor integrated to audible and visual alarms.		

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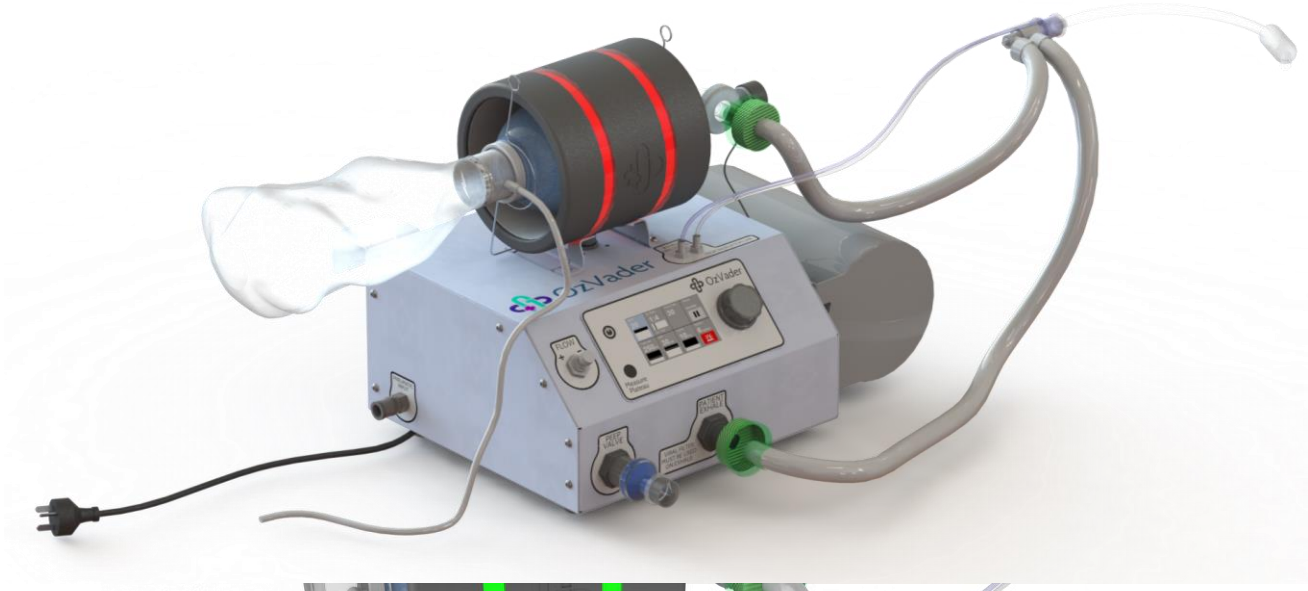
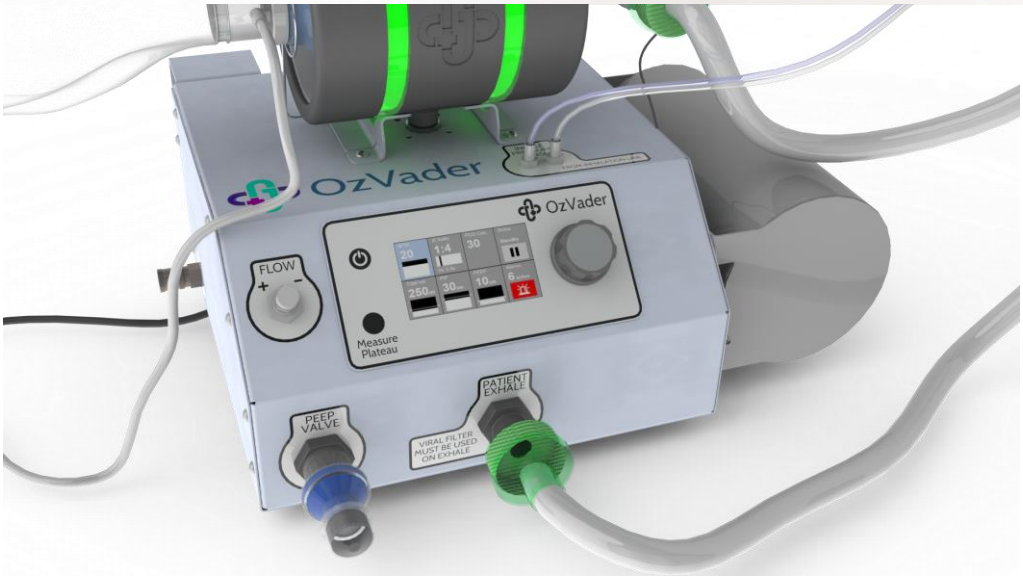
OzVader V1 Ventilator Images





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Clinical Statement on Patient Safety

Intensive Care Specialist

M.B.B.S, PhD, FCCCM, FCICM

The OzVader design allows for safe ventilation in a sedated +/- paralysed patient.

Several risk mitigation strategies have been put in place:

1.Mitigating ventilator induced lung injury

- Ability to perform an inspiratory pause manoeuvre enables clinicians to set safe tidal volumes and PEEP while targeting plateau pressures < 30 CmH2O and driving pressure < 15 Cm H2O.
- This is very important to reduce mechanical power delivered to the lungs.

2.Mitigating high inflation pressures and barotrauma

- A peak pressure cut off at 35cm H2O will limit inflation pressures and any risks of barotrauma
- Clinicians will be able to override the 35cm H2O PIP cut off while performing procedures such as bronchoscopy.
- This is important to ensure tidal volume delivery in situations where procedures such as bronchoscopy increase PIP.

3. Ability to set I:E ratios

- This will enable clinicians to adjust gas flow rates according to patients changing lung compliance, pulmonary gas exchange status and in situations where there is increased resistance from small airways (e.g. bronchospasm)

4. Humidification

- HME filters can be safely placed in the circuit without increasing dead space or resistance.

5. Separate inspiratory and expiratory limbs

- This will minimise any risks of CO2 rebreathing and hypercapnia.
- Although devices that use one limb for both inspiration and expiration are acceptable in patients with near normal lungs, they may cause significant hypercapnia in patients with severely compromised lung compliance.

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OzVader Manufacturing

OzVader is manufactured by Olitek, a manufacturing company located in Brisbane that specialises in complex equipment fabrication involving automation & robotics.

Olitek's manufacturing facility is a large modern factory complete with CNC, clean room, final assembly and dispatch. As lead manufacturer for the OzVader ventilator, Olitek has partnered with key Brisbane manufactures for the provision of specialist micro-electronics & controls and rubber moulding & extrusions.

OzVader Manufacturing – Brisbane, Australia

The OzVader has been designed from the ground up for scalability, allowing OzVader to be manufactured in large numbers. Supply chains are constantly monitored to ensure we maintain access to key parts and materials.

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