

MVM - MECHANICAL VENTILATOR MILANO



- HEALTH CANADA COVID-19 MEDICAL DEVICE AUTHORIZATION FOR IMPORTATION OR SALE
- FDA CLASSIFICATION EMERGENCY USE AUTHORIZATION (EUA)

PRODUCT OVERVIEW

The MVM is an electrically operated, microprocessor controlled, pneumatically driven ventilator. It is designed for the treatment of adult patients suffering from respiratory failure due to Covid19 who require temporary or longer-term invasive ventilatory support. The touchscreen panel color LED provides real time graphic displays and digital monitoring capabilities. The touch screen is designed for easy interaction for setting the modes, parameters and alarms.

The ventilator requires electrical source (100-240V) and a high-pressure air and oxygen source which connects to a built in blender providing adjustable FIO2, ranging between 21 and 100%. A battery provides 2 hours of power

FEATURE MODES

The MVM features two basic modes: Pressure controlled ventilation (PCV) for patients requiring a controlled ventilation strategy and pressure-support ventilation (PSV) a mode that provides a supported approach, suitable for the weaning phase of intubated patients.

PRESSURE CONTROLLED VENTILATION (PCV)

PCV is a time-cycled ventilation mode in which the operator sets the desired inspiratory pressure level, a positive end expiratory pressure, the length of the inspiratory time, the number of breaths per minute and trigger criteria. A new inspiration begins when the timed respiratory rate is met or when the patient initiates a breath.

PRESSURE SUPPORTED VENTILATION (PSV)

PSV is a mode in which the operator sets the desired inspiratory pressure level, a positive end expiratory pressure, and a cycle criteria to end inspiration. The patient controls the number of breaths per minute. PSV is not suitable for patients unable to breathe spontaneously.

The MVM has 12 different alarm capabilities and can monitor up to 9 patient and parameter data.

KEY FEATURES

This ventilator is a low cost solution for providing ventilatory support for patients suffering from COVID-19.

- LARGE SCALE PRODUCTION
- LOW COST
- SIMPLICITY OF CONSTRUCTION
- CONVENIENCE OF DEPLOYMENT

- CUSTOMIZABILITY
- COMPACT UNIT
- USER FRIENDLY
- EASY SET UP



GENERAL SPECIFICATIONS

| DIMENSION UNIT MVM | 266 w x 256 d x 146 h mm |
|------------------------|--|
| WEIGHT | 6 kg |
| ALARMS | Adjustable alarm sound level (65 - 85 dBA at 1 meter) Distributed alarm system output |
| | |
| DIMENSION POWER SUPPLY | 210 w x 133 d x 75 h mm |
| WEIGHT | 3 kg |

ENVIRONMENT SPECIFICATIONS

| OPERATING TEMPERATURE | +10° C to +40° C |
|-----------------------------------|---------------------|
| OPERATING HUMIDITY | 10% to 95% RH |
| OPERATING ATMOSPHERIC PRESSURE | 700 hPa to 1060 hPa |
| MAX ALTITUDE | 3000 m |
| | |
| STORAGE TEMPERATURE | -25° C to +70° C |
| STORAGE HUMIDITY | 10% to 95% RH |
| STORAGE ATMOSPHERIC PRESSURE | 500 hPa to 1060 hPa |

ELECTRICAL CHARACTERISTICS

| POWER SUPPLY | 100 – 240 Vac |
|----------------------------------|--|
| FREQUENCY | 50/60 Hz |
| POWER CONSUMPTION | 60 VA |
| APPLIED PARTS | TYPE B |
| INTERNAL BATTERY | Yes |
| AUTONOMY TIME IN BATTERY MODE | 2 hours |
| EXTERNAL CONNECTION | USB compatibility for flash memory 2.0 |

PERFORMANCE SPECIFICATION FOR PCV - PRESSURE CONTROLLED VENTILATION

| CONTROL PARAMETER | RANGE |
|--|---|
| RESPIRATORY RATE | 4-50 rpm |
| INSPIRATORY TIME INSPIRATORY - EXPIRATORY RATIO | 0.4-1.5 s 1:1-1:4 |
| PEEP* | 5-20 cm H ₂ O |
| MAX INSPIRATORY PRESSURE | 68 cm H ₂ O |
| Inspiratory Trigger Sensitivity | 1-9 cmH ₂ O/sec ² |
| FiO ₂ | 21-100% |
| BATTERY | OBSTRUCTION |

^{*}via spring-loaded PEEP valves

PERFORMANCE SPECIFICATION FOR PSV - PRESSURE SUPPORT VENTILATION

| CONTROL PARAMETER RANGE | | |
|---|-----------------------------|--|
| *PEEP | 5-20 cm H ₂ O | |
| INSPIRATORY PRESSURE 2-50 cm H ₂ O | | |
| Expiratory Trigger Sensitivity | 5-60% | |
| Inspiratory Trigger Sensitivity | 1-9 cmH ₂ O/sec2 | |
| FiO ₂ | 21-100% | |
| Apnea Backup Ventilation | | |
| ALARM PARAMETER | | |
| HIGH/LOW - PRESSURE | HIGH/LOW - TIDAL VOLUME | |
| NSPIRATORY TIME HIGH/LOW - MINUTE VOLUI | | |
| LOW - PEEP | APNEA | |
| FIO ₂ | GAS FAILURE | |

^{*}via spring-loaded PEEP valves



ADDITIONAL SAFETY FEATURE

Another adjustable pressure limiting valve is connected to the inspiratory line and ensures that the maximum pressure delivered does not exceed the pre-set value.





A front 7" wide TFT Touch screen display is the user interface for data entry and monitoring functions.

The display shows numerical and graphical data and trends in real time, as well as current alarm and ventilator settings.





REFERENCE STANDARDS

| NUMBER | TITLE |
|-------------------|---|
| ISO 14971 | Medical devices - Application of risk management to medical devices |
| ISO 80601-2-80* | Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency |
| EN 60601-1 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| EN 60601-1-2 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests |
| EN 60601-1-6 | Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability |
| EN 60601-1-8 | Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems |
| ISO 18562-1/2/3/4 | Biocompatibility of breathing gas pathways in healthcare application |

 $^{^*}$ "Emergency Use Vantilator Design Guidance, modeled upon ISO 80601-2-80:2018 presuming usage in traditional healthcare facilities.

ACCESSORIES

| CONSUMABLE ASSESSORIES INVASSIVE VENTILATION |
|--|
| Patient circuit item: DEAS 04775 NS |
| Respiratory system Filter items (antibacterial and viral): DEAS HMEF8 DEAS HMEF7 AIRLIFE 001851 |
| Patient Connection Adaptor: DEAS 1510TG (rotatable) DEAS 22xxDV (straight) |
| Flex tube items: DEAS ETANXXC02 DEAS ETSLXXC02 |
| PEEP Valve items: DEAS 03986 NS LAERDAL 845240 |



ACCESSORY

TROLLEY SUPPORT FOR MVM MEDICAL DEVICE AND POWER SUPPLY



TO LEARN MORE

For additional information, please contact

call: Toll Free: **844-300-7680**

Email: vexos-support@valleyassociates.com

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