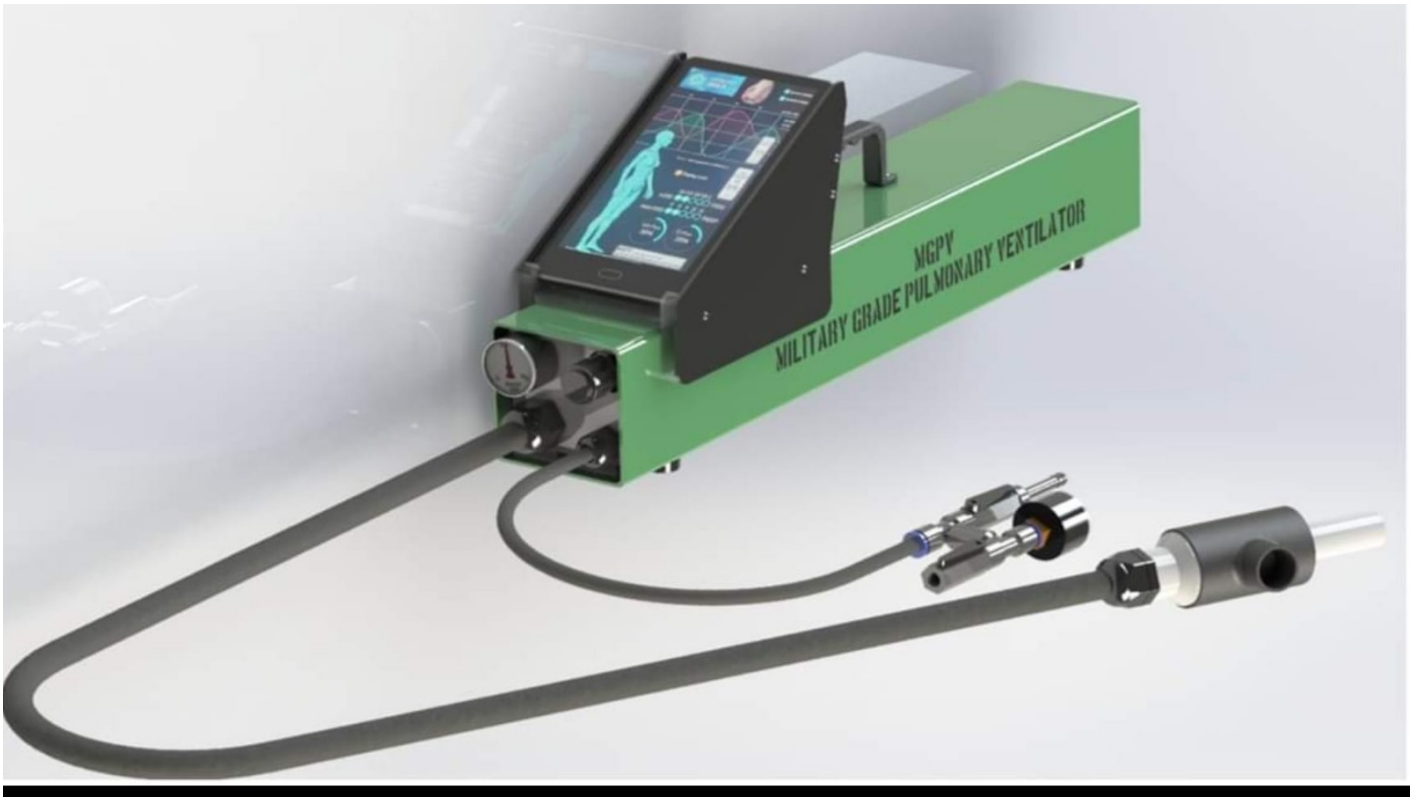
Portfolio Portugal

MGPV (R)

Military Grade Pulmonary Ventilator



SWISS MADE

MGPV Military Grade Pulmonary Ventilator

MGPV is a patented new generation pulmonary ventilator designed to be used on adults and pediatric subjects for whom is needed lung ventilation in critical condition or to prevent the critical situation.

MGPV was designed specifically in case of COVID-19 infection. The virus produces an excess of mucus in the lungs, hard to expel, sometimes a traditional ventilator is not completely efficient. MGPV by solving the problems related to the clogging of the tubes caused to mucus, the expulsion of the mucus from the circuits, the evolution of the complication from bilateral interstitial pneumonia determined by COVID 19 ,will make the mechanism completely efficient.

MGPV is a small size object, simple to install and has a very fast ignition: after 1,5 seconds the ignition from the main power supply the system starts to give air to the patient. MGPV aggregates the monitoring data and represents them as intuitive graphs. The images offer a quick overview of the current patient ventilation, and a reliable basis for the therapeutic decision.
In case of emergency the device can work without a human interface (tablet + software) with pre-set standard values.

An immediate information management system, through the displaying on a single MENU software screen, allows the operator to set alarms, collect data on the progress of the operating parameters (TREND) and all the EVENTS on the ventilator.

The same system allows to set the type of patient and the body size for an automatic analysis of the data and their use in the phase of treatment.

The ventilation system MGPV release controlled or spontaneous ventilations with a resettable level of pression at the end of the expiration (PEEP) and of oxygen concentration.

It is suitable for ventilation of adult and pediatric patients, thanks to a current volume adjustable from 2 ml to 3000 ml.
When the device is switched on is set on the parameters for an adult ,but it's possible to choose the type of the patient by setting automatically the related respiratory default parameters.
In spontaneous ventilation it allows inspiratory flows up to a maximum of 190 L / min, with or without support pressure.

MGPV is a medical device for mechanical ventilation, or artificial ventilation, it allows breathing support for patients unable to breathe spontaneously due to particular critical conditions.

The MGPV device is therefore a life-saving medical support which can replace the spontaneous breathing of unconscious and intubated patients in the intensive care unit.

The MGPV medical device is an extremely innovative system that differs from traditional lung ventilation. In fact, it does not use mechanical systems for closing and opening the valves, but patented dynamic flow valves. There is no movement of mechanical parts inside the medical device, except for the solenoid valves.

The MGPV medical device has a simple and intuitive user interface that allows you to define the optimal parameters for the individual patient. However, in situations of serious emergency and urgency, the medical device is able to work even without the user interface, thanks to default values defined by the software that allow to replace the patient's breathing in an optimal way.

The graphical interface does not represent a critical part of the device but an additional aspect useful for medical personnel, allowing you to modulate the various parameters of ventilation as needed.

The ventilator is equipped with a mucus drainage system if the patient is in a very critical medical condition.

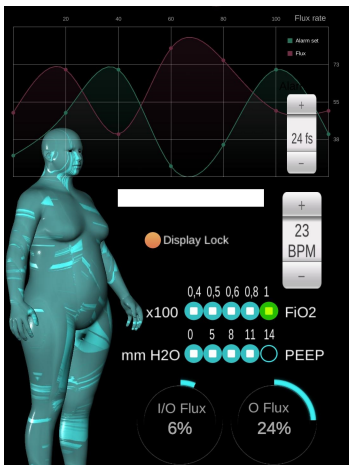
In an emergency, the device works without a human interface (tablet + software) with preset standard values and is very robustly designed for crisis use. The user interface (tablet) is not a critical part of the device.

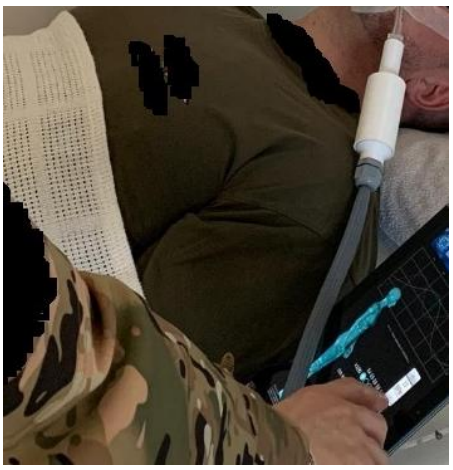
The device should initially only be adjusted with the manual regulation on the device. You find the settings on the label on the device. At a later point in time, the fine adjustment can then be carried out via the software.

The ventilator works safely even when all sensors fail.

The device is designed for unconscious and intubated patients (patients undergoing intensive therapy), fully automatically without a breath trigger.

Ultrafast power on: 1.5 seconds after the main power is turned on, the system begins to supply the patient with air.





MAIN CHARACTERISTICS

From a scientific point of view

MGPV uses a kinetic energy converter for the acceleration of the gases and the functioning of the device.
This characteristic makes the device very efficient and dynamic, with a simple hardware to build and to maintain.

Due to the particular conformation of the device moving mechanic valves are not used but are used fluid valves that it is the same air that open an closes with its kinetic energy the barriers that allows the entrance and the exit of the air.

Also, it has a system for monitoring the management of the parameters that uses an adaptive filtering model.
The technology MGPV uses a predictive model that makes the sensors very performing and with the use of a few sensor parameters the device can reconstruct a complete image of its own functioning and patient parameters.

From the point of view of the user, MGPV stands out because:

It is easy and intuitive to use in case the user has little experience with pulmonary ventilators

It is possible to use MGPV even in places that are not hospitals, for example at the patient home in case of specific necessity.

MGPV has a very fast ignition (1,5 Seconds and it is completely operating)

It provides a fast access through the pre-standard basic parameters that activates without the use of the user interface but directly from the ventilator block.

It allows the mucus to be expelled and not to block the tubes

It can be used both for intubating completely the patient and in force ventilation mode without intubation

The MGVP medical device emits an audible alarm signal in the following cases:

- Insufficient volume of air entering the lungs
- Low air velocity directed to the lungs
- Low air pressure directed into the lungs
- Difference between the air entering and leaving the lungs
- Air leaks
- Poor mechanical lung compliance
- Absence or low pressure of O2 from the fuel system
- Lack of electricity

TECHNICAL FEATURES:

ENVIRONMENTAL CONDITIONS

Relative operation humidity: 30 - 95% without condensation

Temperature: from +10 to + 40 ° C

Operating atmospheric pressure: 600hPa - 1200hPa

Relative storage humidity: <95%

Storage temperature: -25 to + 70 ° C

Atmospheric pressure for storage: 200hPa - 1200hPa

TECHNICAL DATA

Dimensions (W x H x D): 100 x 100 x 600 mm

Weight: 12 kg

Power supply: 100 - 240Vac / 50 - 60Hz

Max power consumption: 60 VA

External electrical connections: Double 220Vac power connector, connection and double oxygen cell with taps

The device can be connected to 2 circuits (triple redundancy of 2x110Vac 1x12Vdc) and 2 air supplies.

Patient connections: male conical fittings 22 mm (according to EN ISO 5356-1: 2015)

Pneumatic supply (O2): High pressure (4 - 6 bar) Max flow required (O2): 100 l / min (minimum)

IP protection degree: IP21

FUNCTIONAL CHARACTERISTICS OF THE MGPV

Intended use: Intensive care ventilator suitable for ventilation of adult patients and children.

Principle of operation:

• Constant volume time cycle

• Microprocessor controlled flow

• Spontaneous breathing

• Automatic loss compensation: Max. 60 l / min

Leak alarm: Present

Respiratory parameters default setting: Present (Adult)

Ventilation rate: from 1 to 60 bpm

Inspiratory time in SIMV: 0.2 to 5.0 sec.

Flow volume (Vt): 100 to 3000 ml (Adults)

IE ratios: 1:10 to 4: 1

Inspiratory pause: 0 to 60% of the inspiratory time

Pinsp inspiratory pressure limit: from 2 to 40 cmH2O

PEEP: From OFF, 2 to 10 cmH2O

O2 concentration: Adjustable from 40 to 100% with integrated electronic mixer

Trigger detection method: not present

Patient circuits: tube 150 cm

PARAMETER:

The ventilator works safely even when all sensors fail. The device is designed for unconscious and intubated patients (patients undergoing intensive therapy), fully automatically without a breath trigger. Ultrafast power on: 1.5 seconds after the main power is turned on, the system begins to supply the patient with air.

Oxygen concentration (FiO2)

FiO2 = 1.0 = 100% Adjustable from 0.5 to 1

PEEP (Positive End Expiratory Pressure)

From 0 to 14 mm H2O

Maximum inspiration pressure (Pmax)

No limit

Trigger

The device is not designed to recognize the patient's own breathing drive

Respiratory rate (fs)

Adjustable from 0 to 32

Flux monitoring

Available

1st stage operating pressure

min 2.5 bar

max 8 bar

optimally 4 bar

Air pressure 2nd stage

1.5 children 40-70 kg

1.8 adults 60 - 80 kg

2.0 adults with breathing difficulties

• The device triggers an alarm on the following events:

• low volume of lung intake air

• low speed of the lung air

• At a pressure above 30 mbar, the system cannot produce intrinsically safe more than 50 mbar

• Low pressure lung air

• Difference between inlet and outlet lung air

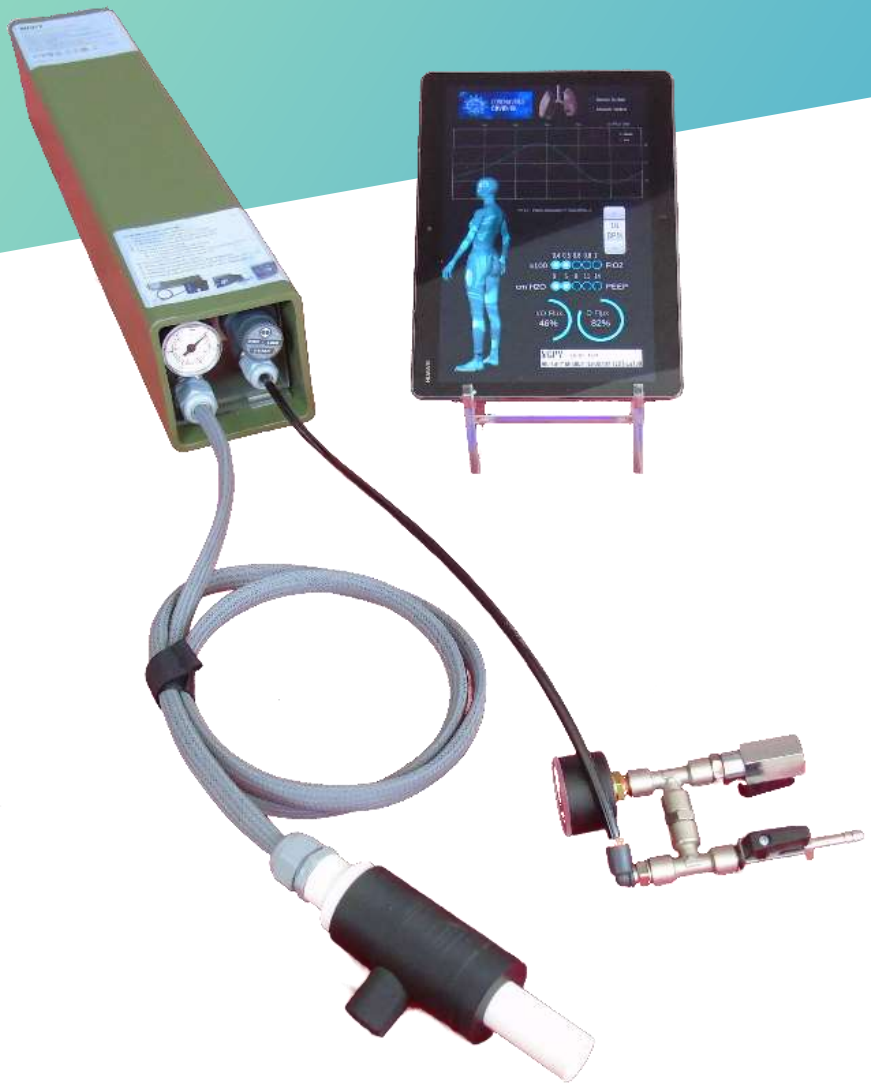
• poor mechanical lung compliance

• Air loss

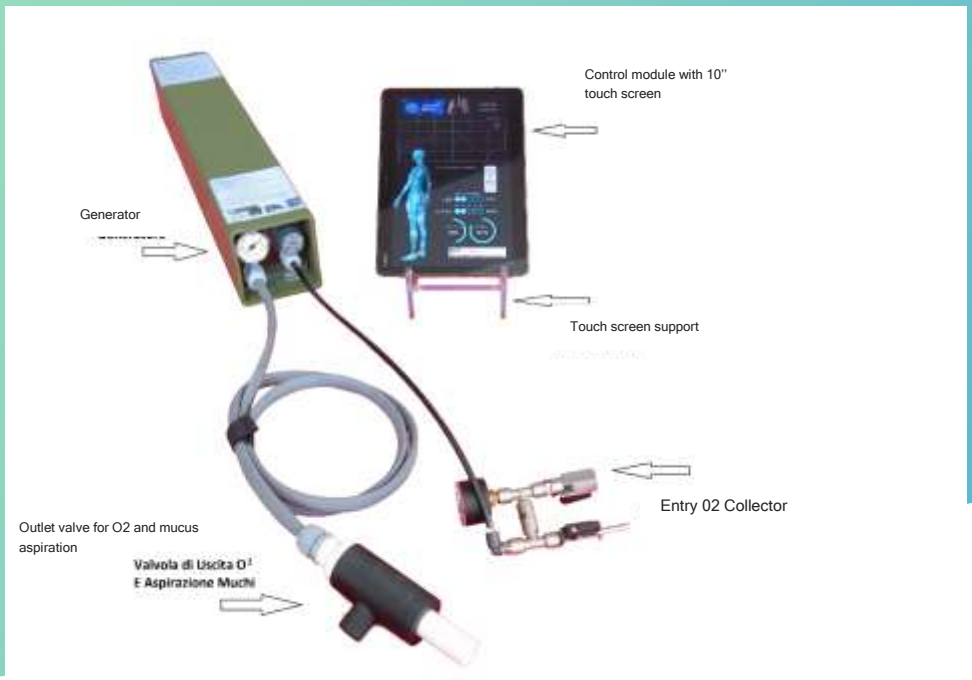
• Absence or low pressure O2 main supply

• Loss of electricity

View of the object:



Pulmonary ventilator for reanimation - Military Grade Pulmonary Ventilator - (equipped with a color monitor TFT 10'' touch screen);



cfr. 2.4	control module with 10'' touch screen
cfr. 2.3	Support for 10'' touch screen
cfr. 2.5	Generator
cfr. 2.6	Outlet valve for O2 and mucus aspiration

Control module with 10" touch screen

This paragraph describes the possible functions on the graphical use interface.
Important note: In case of emergency the device works without a human interface (control module + Software) with preset standard values.
The generator is designed to be very sturdy for use in crisis. The user's interface (control module) is not a critic part of the device.
The device must be regulated only with manual regulation present on the device. The base parameters are written on the label on the device.

Operating pressure
Min. 2.5 bar, Max 8 bar, and optimal 4 bar

Air Pressure
1.5 children 40-70 kg
1.8 Adults 60 - 80 kg
2.0 For adults with respiratory disabilities

With the generator comes a control unit with touch screen (CTS).

On the control unit there are all the informations needed for the ventilation of the patient among which:

- Selection of the operating mode;
- Respiratory parameter settings with visualization;
- Alarm signals.

These are between the principal informations showed.

The use of the touch screen permits the user to interact quickly with the pulmonar ventilator. The user's graphic interface is easy to use for the ones that don't have enough experience in the pulmonary ventilation field: the operator will find all the available features.

How is the control unit divided into:

- Operative selection, patient info
- Visualize alarm signals
- Respiratory parameters settings
- Visualization area, loops, graphics, and measurement parameters
- Respiratory parameters monitoring

Touch screen display

The 10'' CTS permits to the user to interact with an intuitive graphic interface using the fingers, so the CTS is at the same time an inn and out device.
Because of it's characteristics, the CTS can substitute the functions of a keyboard or the use of one or more encoder knobs, this way it has a much wider interface

Next some examples of the use of the Touch screen; on the inside of the user manual will be shown various uses.

Starting of the device

The Military grade pulmonary ventilator has the characteristic that it can be used by people that didn't have a formation on how to use a pulmonary ventilator.
The device starts up with the pressure of a button on the back of the generator.

Bringing the button from position 0 to position 1 the respirator gets started automatically with some preset parameters.
NOTE- In case of problems press the RESET button, the generator sets on the standard parameters continuing to work without stopping.

Informations of the patients

For the operation of the device is not fundamental to put patient data.
For the best parametrization of the generator, you can intervene on the silhouette of the image that is on the left side of the CTS to determine the body size of the patient.
This variation is done with the simple sliding of the finger on the silhouette on the CTS with a downword movement (if the patient has a more or less robust body), upword (if the patient has a more or less thin body).

From this operation, the CTS does a series of parametrizations and settings of the generator.
Other actions that can be done for a better setting are:

- BMP (number of breaths/min of the patient) on a 1-5 scale, where 1 is 12 BMP (breaths per minute) and 5 is 30 BPM;
- FIO2 (partial pression of oxygen) on a 1-5 scale, where 1 is 100% and 5 is 0.5%;
- PEEP (residual pressure inside the lungs) on a 1-5 scale, where 1 is 0 mmH2O and 5 is 14mm H2O.

Visualizing of the graphics

- The operator can visualize different kinds of graphic rivelations: **loops/Graphics/measurements parameters.**

Visualizing of the alarms

Ventilator Block

The MGPV Generator is usable with or without the user's interface, and it's metallic structure making use extremely effective in every condition and situation.

Connection to the power supply

The electrical connection is a really important phase of the installation of the pulmonary ventilator, because incorrect connections or not suitable electric implant connections can compromise the patient and operator security.

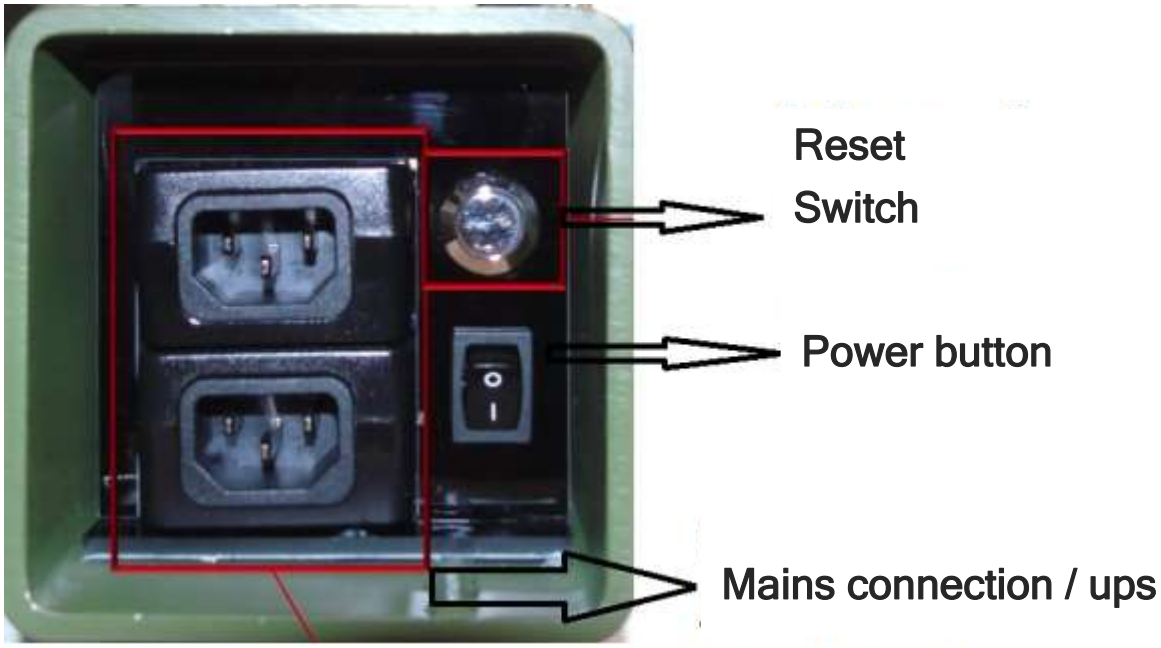
The electric implant must be conform to what has been pre-written on the norms CEI 64-8/7 regards the rooms used for type A medical use.
There are 2 types of power supply on the lung ventilator:

- via network line (100-240Vac / 50 ‘ 60Hz)
- via external power supply (12Vcc / 7°).

Main power connections

The mains supply voltage must match to the one on the identification plate (network tension, frequency and absorprion) on the pulmonary ventilator: 100 – 240Vac / 50 – 60Hz / 60 VA.

- Insert the plug of the power cable into the plug on the lung ventilator.
- Insert the plug of the power cable in the network plug.
- Place the principal switch (on the back of the pulmonar ventilator) in ‘’I’’ position.



Oxigen flux regulator

If the generator is used without the CTS user interface the device must be set only by the flux regulator, manually. Settings are on the device's label.

Operating preassure
Min. 2.5 bar, Max 8 bar, Optimal 4 bar

Air preassure regulation
1.5 Bar for children 40-70 kg
1.8 Bar for adults 60 - 80 kg
2.0 Bar for adults with respiratory disabilities

O2 inlet collector

Product identification labels

The product identification label reports the following data.

• Manufacturer

• Equipment model

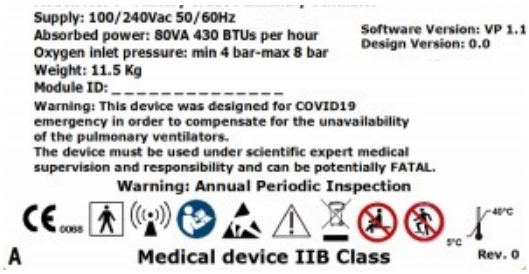
. Supply voltage

• Weight

• Reference regulations

• Serial number

Label sample:



Symbols (see description)

TECHNICAL SPECIFICATION – VENTILATOR
Patient adult/pediatric: Adult and pediatric patients (over 40 kg)
Display:
Display LCD /TFT: **Tablet**
Color: **Yes**
Minimum size 8": **Size 10"**
Range:
Tidal Volume 50 to 2000 mL: **from 300 to 1500 mL**
Respiratory rate 1 to 80 b/min: **from 12 to 32 bpm**
PEEP/CPAP 1 a 35 cmH2O/m Bar: **from 0 (OFF) to 14 cmH2O**
Inspiratory Pressure 5 – 60 cmH2O/mBar: **from 2 to 41 cmH2O**
FiO2 21 - 100%: **from 40 to 100%**
Trigger flow / Pressure trigger: **Not present**
Inspiratory time 0.1 - < 5 sec: **from 0.9 to 2.5 seconds**
Oxygen adjustable from 21% to 100%: **from 40 to 100%**
Inspiratory flow 10-100 L/min: **10-100L/min**
Base Flow, continuous or CPAP: **CPAP**
Optional: inspiratory pause: **no**
Optional: Expiratory pause **no**
General Characteristics:
Air/oxygen mixer – Internal: **no**
FiO2 Monitor internal: **no**
Flow sensor: **no**
Leakage compensation system: **Yes, leaks compensation up to 60 L/min**
Languages on the front and controls setting panel/screen Spanish: **No, English**
Optional: Air Turbine **no**
Monitoring parameters
Peak Inspiratory Pressure: **yes**
Airway mean Pressure: **yes**
Plateau Pressure: **yes**
PEEP / Auto PEEP: **yes**
Respiratory rate: **yes**
Expiratory Minute Volume: **yes**
I:E Ratio: **yes**
Tidal Volume: **calculated**
FiO2: **yes**
Distensibility: **no**
Resistance: **no**
Wave form at least two: Pressure/Time, Flow/ Time, Volume/Time: **Pressure/time**
Optional Pressure/Volume: **no**
Optional CO2 (Capnography, mainstream (volumetric) and side stream) : **no**
Capacity for save all the ventilations parameters, trends and events at least 24 h: **no**
Ventilation modes
Pressure and Volume mode: **Pressure mode**
SIMV Volume Control: **no**
SIMV pressure control: **no**
Pressure controlled and CPAP: **yes**

Noninvasive modes: **yes**
Two levels ventilation: BIPAP o BILEVEL o DUOPAP: **no**
Apnea safety in all ventilation modes: **no**
Alarms
Visual and audible: **Only audible**
Low inspiratory Pressure: **yes**
Low PEEP: **yes**
Apnea: **no**
Minute Volume (High/ Low): **yes**
Respiratory Rate High: **no**
FiO2 Low/High: **yes**
Oxygen supply failed: **yes**
Power disconnection/ Failed: **yes**
Battery Low: **No battery**
Ventilator Failed: **yes**
Silence alarm: **yes for 1 minute**
Rechargeable battery (1 hour capacity): **No battery**
Electrical specifications 110 V CA +/- 10% /60 Hz: 100-240 Vac 50-60 Hz
Accessories
Patient tubing support arm: **no**
Trolley mounting system: **no**
Medical gas supply hoses: **yes**
Pressure regulator for every gas hoses: **yes**
100 patient ventilation tubing: **no**
Flow sensor: **no**
200 antibacterial high efficiency filters: **optional**

Reference standards for the construction of the MGPV device

MGPV device is designed and realized by reference (and subsequent updates) and standards of UNI EN ISO 13485:2016.

EN 60601-1 :2006/A1 :2011/A1 :2013	Electro-medical devices - Part 1: General rules for safety
EN 60601-1-2:2015	Electro-medical devices - Part 1-2: General requirements for basic safety and essential performance. Collateral standard. Electromagnetic disturbances. Requirements and tests
IEC 601-1-6:2013	Electro-medical equipments - Part 1-6: general prescriptions for basic safety and essential performance - Collateral standard: Usability
IEC 601-1-8:2012	Electro-medical devices - Part 1-8: General safety requirements – collateral standard standard: General requirements, tests and guidelines for alarm systems in electromedical equipment and electromedical systems
EN 62304:2006/AC:2016	Software medical devices- process of the software life cycle
ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62353:2014	Electro-medical devices - Periodic checks and tests to be carried out after repairs to electro-medical devices
IEC 601-2-12:2007	Electro-medical devices - Part 2-12: Particular rules for the safety of lung ventilators - Intensive care ventilators
ISO 80601-2-12:2011	Electro-medical devices - Part 2-12: Particular rules for the safety of lung ventilators - Intensive care ventilators
ISO 15223-1:2016	Medical devices - Symbols to be used on medical device labels, on the labeling and on the information that have to be provided - Part 1: General requirements
DIR. 2011/65/CE	RoHS Directive *(Restriction of the use of certain dangerous substances in electrical and electronic equipment)*
D.Lgs 49/2014	WEEE standard *(execution of Directive 2012/19 / EU on waste electrical and electronic equipment)*
ISO 14971:2012	Risk Management Requirements for Medical Devices
EN ISO 4135:2001	Pulmonary anesthesia and ventilation equipment - Vocabulary
DIR. 93/42/CEE (2007)	Medical devices

Uses: ICU (Intensive Care Unit), portable for use in helicopter, ambulance, and military vehicle. **Certifications:** Manufactured per FDA and EC standards. Currently used in Italian hospital, EC certification applied for and in progress, FDA certification in progress.

Availability: Up to 500 units/week.
Delivery: FOB Milan Airport (Italy)