

INSTRUCTIONS FOR USE

MGPV

**(MILITARY GRADE PULMONARY
VENTILATOR)**

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1. INTRODUCTION

1.1 Introduction to the MGPV device

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 device can be used both in hospitals and in the patient's home. In the latter case, the patient is constantly monitored by doctors and nurses.



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.



1.2 Introduction to the manual

This manual is an integral part of the MGVP medical device equipment, constitutes documentation and support for use and is not intended for sale.

Reproduction, even partial, is forbidden without the explicit authorization of the manufacturer. It is made by the technical office of the manufacturer for its exclusive use with MGVP lung respirator equipment.

It is guaranteed that the manual delivered is that relating to the equipment. Corrections will be included in the new editions.

All the information contained can be subject, without notice, to changes by the manufacturer for reasons of technical or commercial improvement.

The use of the MGVP lung ventilator implies the knowledge of this manual in all its parts. The use, which does not comply with what is indicated in the manual, automatically invalidates the warranty and liability on the part of the manufacturer for what follows.

1.3 Safety precautions and warnings

❗ Before connecting the MGPV medical device to the main power supply it is necessary to ensure that it has the following characteristics:

- Main voltage 100-240 V (+/- 10%)
- Main frequency 50-60 Hz
- Power absorption 80 VA

❗ The environmental conditions must be as follows:

- Environmental temperature from +5 ° C to +40 ° C
- Relative humidity from 10% to 95% non condensed
- Atmospheric pressure from 600 to 1100 hPa

❗ The environmental conditions of storage must be the following:

- Environmental temperature from -40° C to +70 ° C
- Relative humidity from 10% to 95% non condensed
- Atmospheric pressure from 500 to 1100 hPa

❗ Installation of the equipment should be avoided in the following cases:

- Near heat sources
- Exposed to rain or moisture
- Exposed to direct sunlight



- Power supply not compliant with what previously described
 - Unsuitable environmental conditions
 - Inappropriate use of the medical device, compared to what is reported in the User Manual
-
- ❗ Do not use the device:
 - In the presence of combustible gases, flammable vapors, in chambers with oxygen or in a detonating atmosphere
 - In the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide
 - Near equipment with strong electromagnetic emission or equipment sensitive to electromagnetic emissions
 - Near or on top of other appliances
 - ❗ Keep the appliance away from splashes of water, even accidental.
 - ❗ Portable and mobile radio communication equipment can affect the operation of the medical device.
 - ❗ The product must be used only by medical personnel trained in the use of this product, with the necessary clinical knowledge of artificial ventilation in order to correctly set the values available on the device based on the patient's clinical status.
 - ❗ The adjustment of the ventilation parameters must only be carried out by qualified medical personnel.
 - ❗ Do not block or obstruct the gas inlets and the emergency air inlet, thus interfering with the patient's ventilation.
 - ❗ The use of the medical device for any other use other than that described in the User manual is prohibited.
 - ❗ The product must not be subjected to any tampering (modification, retouching, addition, repair), otherwise no responsibility will be accepted for incorrect operation or for any damage caused by the product itself.
 - ❗ The correct functioning of the pulmonary ventilator can be compromised if original Periso SA spare parts and accessories are not used.
 - ❗ Using the device, position and adjust it so as not to hinder operator operations and the use of any other equipment.
 - ❗ Make sure that you have taken every precaution to avoid dangers deriving from contact with blood or body secretions.
 - ❗ Do not allow the patient to remain connected to the ventilator when ventilation is stopped, because a significant amount of expiratory gas, mainly carbon dioxide, can be inhaled by the patient. Inhalation of carbon dioxide can cause insufficient ventilation, suffocation, serious injury or death.
 - ❗ You must always have immediate access to an alternative means of ventilation, ready to use, to avoid patient death or serious injury. Do not start ventilation until you are sure that the device is properly assembled, that the air inlet filter is installed correctly and unobstructed, and that there is adequate space around the unit. Make sure that the patient circuit is properly connected to both the ventilator and the patient and that it is not damaged or obstructed.
 - ❗ A patient dependent on the ventilator must always be monitored by a trained doctor and competent personnel to deal with the possibility that the ventilator identifies an alarm condition or encounters a problem.

- ❗ When an alarm is triggered or a fault is present, always examine the patient before the ventilator.
- ❗ Periso SA declines all civil or penal liability in the following cases:
 - Use of the pulmonary ventilator in conditions and for purposes that do not comply with the provisions of this manual.
 - Use of the lung ventilator by unqualified personnel.
 - Omitted periodic maintenance as foreseen in this manual.

- Connection with equipment that does not comply with current safety standards and is not suitable for the intended purpose.
- For direct or indirect damage to people or things deriving from unauthorized technical interventions or from improper use of the lung ventilator.

Power connection

The connection of the equipment to the power supply is simple and immediate and must be carried out by using the power cable following the instructions below (Chapter 3).

- ❗ To avoid the risk of electric shock, this appliance must only be connected to grounded power supply networks.
- ❗ If the power cable is damaged, it must be replaced only by the manufacturer or by personnel suitably trained by the manufacturer.
- ❗ Any repair of the MGVP device must be carried out by the manufacturer or by personnel suitably trained by the manufacturer.
- ❗ The device is not permanently installed and uses the power plug as a means of isolation from the main power supply.

1.4 Shipping damage

The equipment and all its components and accessories are subject to careful and accurate testing by the quality control office, which certifies its integrity and perfect functioning. Any damage and / or failure or incorrect functioning of the same must therefore be promptly communicated to the manufacturer and to be attributed exclusively to serious negligence on the part of the transporter. The original packaging must be kept for the purpose of any future consignments to / from the manufacturer.

1.5 Contents of the packaging

The MGVP device is carefully packaged and shipped with all the accessories and the manual, provided in the basic equipment. Below is a list of the objects included in the shipping package.

| Quantity | Description |
|----------|--|
| 1 | Instructions for use |
| 1 | Pulmonary ventilator |
| 1 | Power cord |
| 1 | Tablet |
| 1 | Tablet stand |
| 1 | Mucus drainage system |
| 1 | Tracheal tube (optional – on request) |
| 1 | Antibacterial and antiviral filter (optional – on request) |

1.6 Warranty Conditions

Periso SA guarantees a 2-year guarantee on the medical device starting from the date of purchase. The expected service life for the MGVP device is 10 years.

- ❗ The warranty seals, if present on the product, must not be removed; otherwise the Manufacturer no longer recognizes the product warranty and declines any responsibility for incorrect operation or for any damage caused by the product itself.

1.7 Jurisdiction

For any dispute concerning these conditions, the exclusive jurisdiction is that of Lugano.

2. GLOSSARY OF SYMBOLS AND CONVENTIONS OF WRITING

2.1 Label symbols

| | | | |
|---|---|---|--|
|  | CE mark. |  | Temperature limits. |
|  | Indicates the name and address of the manufacturer of the medical device. |  | Humidity limits. |
|  | Consult the instructions for use. |  | Atmospheric pressure limits. |
|  | Type BF applied part. |  | Keep away from sunlight and heat sources. |
|  | It is mandatory to read the instructions for use.. |  | Keep away from moisture and rain. |
|  | Lot number. |  | ESD antistatic product. |
|  | Serial number. |  | Waste electrical and electronic equipment. |
|  | Non-ionizing emissions. |  | It is forbidden to push the device sideways. |
|  | It is forbidden to go up. | | |

2.2 Writing conventions



Underline and / or bold

It highlights some parts of the document, of particular importance or in any case worthy of note.



Note

The notes highlight important information for specific use.



Attention

These messages appear before the description of operations that if not observed can cause damage to the equipment or its accessories, and to people.



Prohibition

This message is placed before operations that must never be performed.

3. INSTALLATION

3.1 Installation instructions

The MGPV medical device, once removed from the packaging paying close attention, is ready for use.

In fact, the device arrives partially assembled, the only operations to be performed are:

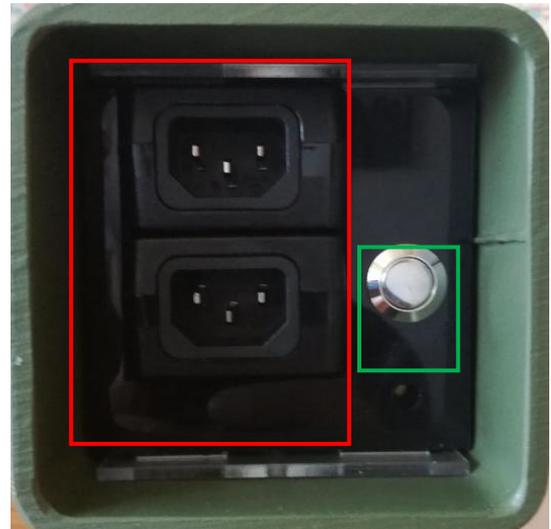
- Connect the lung ventilator to a pressure gauge
 - Connect the medical device to the oxygen source (hospital line or oxygen tank)
 - Connect the antibacterial and antiviral filter
 - Connect the mucus drainage system
 - Connect the power cable to the power supply
- !** MGPV fan must work in the pressure range between 4 and 8 bar.
- !** The use of extension cords and / or multiples between the mains socket and the power cable is always discouraged as their possible malfunction could cause damage to the system.
- !** The device must be positioned in such a way that it is feasible to operate on the plug or on the switch if there is a need to interrupt the connection with the electrical network.

Switching on and off

Connect the medical device to the power supply by inserting the supplied power cable into one of the two connectors (highlighted in red). The two connectors are identical and the MGVP system allows, if one of the two stops working, to pass to the second working connector.

By inserting the power cable into one of the two connectors, the device turns on.

The device is equipped with a very rapid ignition system: after 1.5 seconds from the ignition, the medical device begins to supply air to the patient.



By pressing the button highlighted in green, the minimum functional ventilation parameters that the machine uses when it is switched on are set. These parameters can be used in most cases.

- ❗ The MGPV device does not use batteries. It is connected directly to the power supply or to a UPS (Uninterruptible Power Source).

Tube connections to the medical device



Connection to source of oxygen

Patient's circuit

Valve to adjust the oxygen pressure value to be supplied to the patient

Pressure gauge for reading the pressure of the oxygen supplied

It is possible to change the air pressure using the black valve (shown in the image above). The recommended settings are present on the label applied on the device itself. At a later stage, after

the patient has been intubated and is out of danger, the parameters can be adjusted using the tablet software.

The pressure gauge present allows you to view the oxygen pressure value (bar) that the medical device is delivering, depending on the type of patient.

 The label applied on the MGPV device reports all the steps to follow to set the correct pressure.

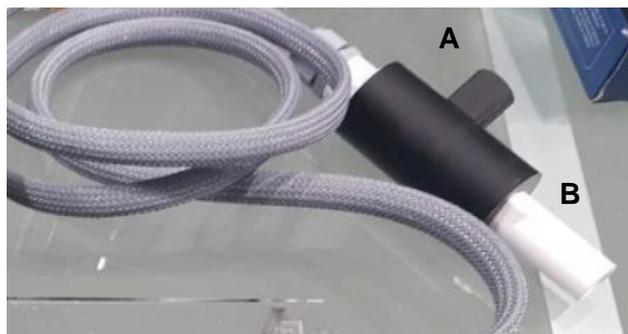
As reported on the device label, the recommended pressure values are:

- **1.5 bar** children 40-70 kg
- **1.8 bar** adults 60-80 kg
- **2.0 bar** adults with breathing difficulties

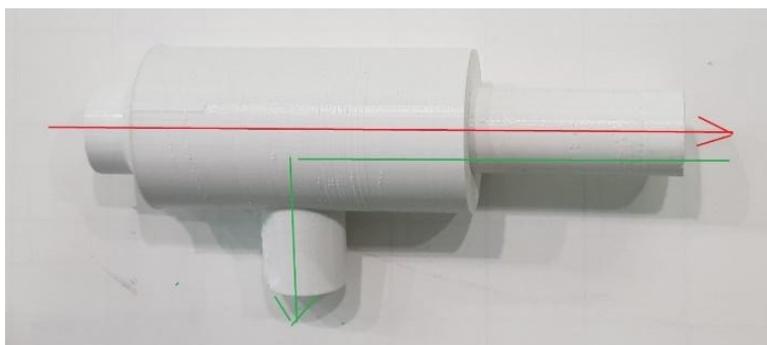


Handpiece and mucus drainage system

The figure shows the mucus drainage system. For the correct elimination of mucus from the airways, a system is used that creates an obstacle to the escape of air from the bronchial tree, maintaining positive pressure throughout the expiratory phase. This allows you to keep the bronchi with the thinner wall open, which can be crushed by expiratory chest pressure by trapping the air left downstream. This avoids air trapping. In addition, an increase in expiratory pressure allows air to enter, through collateral ventilation, also in the areas downstream of the bronchial obstruction due to mucus, allowing its elimination. The system is equipped with a valve (A) and a respiratory resistance (B).



In the following picture the red and green arrows described the direction of the inspiratory flow and the direction of the expiratory flow (with mucus drainage).



Antibacterial and antiviral filter

The antibacterial and antiviral filter is a medical device used in ventilation systems and respiratory circuits to allow the filtering of air by pathogens, having a bacterial and viral filtration efficiency of 99.999%. This also allows you to protect patients, equipment, the environment and healthcare professionals from cross-contamination. The filter is disposable, single-patient and supplied in a sterile package.



| Component | Shelf life | Features |
|----------------------------------|-------------------|---|
| Mucus drainage system | 2 years | Disposable, single-patient and supplied in a sterile package. |
| Antibacterial / antiviral filter | From 2 to 5 years | Disposable, single-patient |

Antibacterial / antiviral filter - mucus drainage system connection

The following image shows the correct connection of the two components.

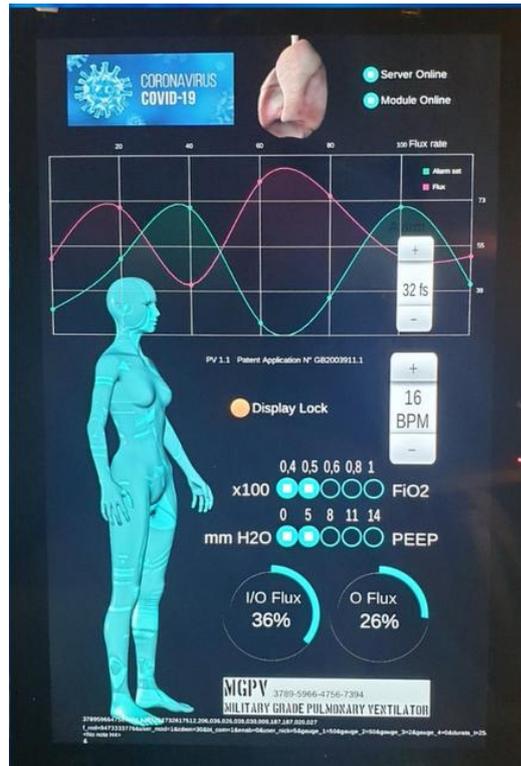


- ❗ The tracheal tube is not included (optional). The component is disposable, single-patient supplied in a sterile package.

Graphical interface (tablet)

Once the patient has been intubated and is no longer in an emergency due to the inability to breathe, the supplied tablet can be connected to the medical device.

The software on the tablet is simple and intuitive. The tablet shows the screen, shown in the figure, and allows medical personnel to modify the ventilation parameters to best adapt them to the patient.



- ⊙ No modification of the medical device is allowed.
- ! Never turn off the device by unplugging the power cord, to avoid anomalies in the operation of the software or possible damage.
- !

- ! The device must be disposed of in accordance with the WEEE disposal regulations.



Based on Art. 28 of Legislative Decree 14 March 2014, n. 49 all electrical and electronic equipment to be placed on the market after August 13, 2005 must bear a trademark, which must be visible, legible and indelible, which makes it possible to unequivocally identify the manufacturer of the EEE and the symbol indicating that the product must be disposed of separately.

Information to users regarding the disposal of WEEE waste

According to the provisions of the Ordinance concerning the return, recovery and disposal of electrical and electronic appliances, January 14, 1998 (ORSAE), this equipment cannot be disposed of as mixed urban waste but separate collection must be carried out. The electrical and electronic appliances are those contemplated. The Ordinance obliges traders, manufacturers and importers to take back - without additional costs - the appliances included in their assortment. In turn, consumers are obliged to return the appliances they intend to discard.

In fact, used appliances must not be disposed of together with municipal waste or bulky waste but must be delivered, free of charge, to all SENS and SWICO sales points or official delivery centers for their disposal.

With regards to disposal at countries outside Switzerland, the user and the distributor must comply with the legislation in force in the country of use of the device.

4. INDICATIONS AND FUNCTIONAL CHARACTERISTICS

The MGVP medical device is intended for ICU patients who need a mechanical ventilation. The medical device is suitable for ventilation of adult patients and children (over 40 kg). The Assisted Ventilation provided by the medical device called MGPV, is indicated in all those pathological conditions characterized by severe forms of respiratory failure (inability to spontaneous breathing) of various origins, caused by:

- Severe and Acute Lung Disease, type Acute Respiratory Distress Syndrome (ARDS) e Acute Lung Failure Syndrome (ALF) and related causes, including bacterial, viral, intoxication, metabolic acidosis and others;
- Viral infection of lungs (for example caused by Covid-19);
- Severe thoracic trauma;
- Degenerative, vascular and traumatic diseases of the central nervous system;
- Neurological diseases: myasthenia gravis, Guillain-Barré syndrome, motor neuron diseases;
- Excessive respiratory work such as to induce tachypnea and respiratory distress;
- Arterial hypoxemia of various origins and of moderate / severe degree (partial pressure values oxygen (pO₂) lower than 60 mmHg);
- Severe sepsis hypotension, shock of various kinds and congestive heart failure.

More generally, the MGPV device is indicated in all those conditions in which there are: Respiratory rate > 30 / min., Inability of the respiratory system to maintain arterial oxygen saturation <90% with fractional inspired oxygen (FiO₂) > 0.60, for pCO₂ values > 50 mmHg and pH values <7.25.

The main features of the device are:

- ❗ Time volume constant cycling
- ❗ Microprocessor controlled flow
- ❗ Automatic loss compensation (max 60 l / min)

| | |
|--|--|
| Default setting of respiratory parameters | Present (adult) |
| Inspiratory time in SIMV | From 0.2 to 5.0 seconds |
| Tidal volume (V_t) | From 100 to 2000 ml ±(10 ml +15%) |
| Reports I: E | 1:10 to 4: 1 |
| Inspiratory break | From 0 to 60% of the inspiratory time |
| Inspiratory pressure limit (P_{insp}) | From 2 to 40 cmH ₂ O |
| PEEP | From 0 (OFF) to 14 cmH ₂ O |
| Trigger detection method | Not present. The device is not designed to recognize patient spontaneous breathing |
| Patient circuits | 150 cm tube |
| Oxygen concentration (FiO₂) | Adjustable from 0.4 to 1 (0.4 = 40%; 1 = 100%) with integrated electronic mixer |
| Respiratory rate | Adjustable from 12 to 32 bpm ±1 bpm |
| Flow control | Present |

SENSORS

The pulmonary ventilator incorporates a series of sensors designed to provide continuous monitoring of the patient, in particular a flow sensor placed on the expiratory line and a sensor placed on the inspiratory line that allow to measure the volumes exhaled / inspired by the patient.

ALARMS

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 pulmonary compliance
- Absence or low pressure of O₂ from the fuel system
- Lack of electricity

Alarms volume: 50 dBA to 80 dBA (Alarm volume setting MIN to alarm volume setting MAX)

Measurement uncertainty: ±3 dBA

5. TECHNICAL SPECIFICATIONS

MEDICAL DEVICE INFORMATION

| | |
|-----------------------------|--|
| Model | Military Grade Pulmonary Ventilator (MGVP) |
| Trading name | Pulmonary ventilator |
| IP protection degree | IP21 |
| Display | Tablet |

| | |
|----------------------|--|
| Medical class | Switzerland CHE-101.514.101 IVA II B |
|----------------------|--|

ELECTRICAL SPECIFICATION

| | |
|--|---|
| Supply | 100-240 Vac / 50-60 Hz |
| DC voltage supply | -10% to +10% of nominal |
| Absorbed power | 80 VA 430 BTUs per hour |
| External electrical connections | Double 220 Vac power connector, connection and double oxygen cell with taps |

PHYSICAL CHARACTERISTICS

| | |
|--|--|
| Patient connections | <ul style="list-style-type: none"> - Inspiratory limb connector: ISO 22 mm (OD) 15 mm (ID) conical - Exhalation limb connector (on exhalation block): ISO 22 mm (ID) conical - Oxygen inlet: female connector with valve - Exhalation pilot port: accommodates 3.2 mm to 4 mm ID tubing - Proximal pressure port: accommodates 5 mm to 6 mm ID tubing |
| Device airway volume | 2000 ml |
| Breathing circuit volume | 1150 ml – Adult patient 670 ml – Pediatric patient over 40 kg |
| Inspiratory bacteria filter requirement | Maximum allowable flow resistance: 4mbar at 60lpm |
| Dimensions with touch screen | 95 mm wide x 600 mm deep x 240 mm high |

(excluding accessories)**Weight** ~11.5 kg**ENVIRONMENTAL REQUIREMENTS****Temperature**Operating: 5° to 40° C (from 41° F to 104° F) 20 minutes after conditioning at 23° CStorage: -40° to 70° C (from -40° F to 158° F)**Atmospheric pressure**Operating: 450 to 825 mmHg (600 to 1100 hPa; 8.7 to 15.9 psi)Storage: 375 to 825 mmHg (500 to 1100 hPa; 7.3 to 15.9 psi)**Altitude**Operating/storage: -500 ft to 13,000 ft (-152 m to 3962 m)**Humidity**Operating/storage: 10% to 95% RH non condensing**Combination temperature and humidity**Operating: 113° F (45° C) and 75% RH**PNEUMATIC SPECIFICATION****Oxygen inlet**

Minimum Flow: 100 l/min

Pressure: 400KPa max 800KPa (4-8 bar)

RANGE, RESOLUTION, AND ACCURACY**Tidal volume (Vt)**

Range: 100 ml to 2000 ml

Resolution: 10 ml

Accuracy: $\pm(10 \text{ ml} + 15\%)$ of setting

Default value: 500 ml

Pressure support (P Support)

Range: OFF or 5 mbar to 55 mbar in valve configuration

Range: 6 mbar to 30 mbar in leak configuration

Resolution: 1 mbar

Accuracy: $\pm(1 \text{ mbar} + 10\%)$ of P

Support + PEEP setting Default value: 15 mbar

Depends on: PEEP when Relative Pressure is set to YES

Respiratory rate (R-Rate)

Range: 12 bpm to 32 bpm in modes

Resolution: 1 bpm

Accuracy: ± 1 bpm

Default value: 13 bpm

PEEP

Range: OFF (0.5 mbar) to 14 mbar

Resolution: 1 mbar

Accuracy: $\pm(1 \text{ mbar} + 10\%)$ mbar

Default value: 5mbar

Fraction of Inspired Oxygen (FiO₂)

Range: 40 to 100%

Resolution: 10%

Default value: 40%

PERFORMANCE SPECIFICATION

| | |
|---|--|
| Working pressure | 5 mbar–55 mbar |
| Sound pressure level | 30 dBA (per NF EN ISO 17510-1 test conditions) Does not exceed 63 dBA per EN ISO 80601-2-72 test conditions |
| Maximum pressure limit | 90 mbar |
| Internal compliance (ventilator) | 0.0001 l/mbar 0.0001 l/cmH ₂ O |
| Alarm volume | 50 to 80 dBA ± 10% (as measured per IEC 60601-1-8) |
| Ventilator operating volume | 30 dBA + 10% |
| Ventilator airway resistance | |
| Inspiratory resistance | 1.0 cmH ₂ O at 30 lpm 3.7 cmH ₂ O at 60 lpm |
| Exhalation resistance | 0.5 cmH ₂ O at 30 lpm 1.1 cmH ₂ O at 60 lpm |
| Patient circuit inspiratory resistance | |
| Adult double branch circuit with exhalation valve | 2 cmH ₂ O at 60 lpm |
| Pediatric double branch circuit with exhalation valve | 2 cmH ₂ O at 30 lpm |

6. CLEANING AND MAINTENANCE

6.1 Cleaning

Failure to perform cleaning may result in the risk of infection due to the presence of secretions and / or residues. During all control and sanitation operations the operator must wear adequate personal protective equipment, such as gloves, goggles etc.

Before cleaning, carry out the following steps:

- Turn off the device
- Isolate it from the power supply (if connected)

External cleaning of the appliance can be carried out with the aid of special disinfectants for surfaces. All external panels and surfaces should be cleaned before and after each patient use and as often as necessary to keep the ventilator clean. Additionally the ventilator should be cleaned periodically, whenever it is soiled or dirty, before any maintenance operation and before storage.

Approved cleaning solutions for exterior ventilator surfaces are:

- Mild dishwashing detergent
- 70% isopropyl alcohol (rubbing alcohol)

- 10% chlorine bleach (90% tap water)
- Glutaraldehyde
- Hospital disinfectant cleaners
- Hydrogen peroxide
- 15% ammonia (85% tap water)
- Ammonia-based household cleaners
- Household cleaners

The inspiration block of the mucus drainage system (white part) is intended for single use by a single patient.

The exhalation block of the mucus drainage system (black part) is intended for single use by a single patient. It may periodically be cleaned, but it cannot be disinfected or sterilized. To maintain good measurement quality when used continuously, clean the exhalation block periodically. The exhalation block should be changed every 4 months and cannot be reused with any other patient.

- ❗ When using the pulmonary ventilator for the first time, immerse mucus drainage system (white component) in a disinfectant solution. When using the lung ventilator for the first time, immerse the mucus drainage system (black component + O-ring) in an aqueous solution with alcohol at low temperature (75-80°C).
- ❗ Make sure that no sprays or liquids enter the medical device.
- ❗ Replace the antibacterial and antiviral filter with each use, making sure that it is sterile packed.
- ❗ The patient circuit is reusable.
- ❗ Never use pressurized water, as this can penetrate the device creating the risk of corrosion of the components as well as electrical leakage and short circuits.

6.2 Maintenance

The checks to be carried out before and after each commissioning are:

- General functionality of the device
- Device cleanliness status (please note that failure to perform cleaning operations can lead to risk of infection)
- Check that no structural part is deformed or compromised
- Integrity of the power cable and air pipes
- ❗ During all control, maintenance and sanitation operations, the operator must wear adequate individual protection devices, such as gloves, goggles, etc.
- ❗ The device must be overhauled every year by the manufacturer or by technicians suitably qualified by Periso SA.
- ❗ Do not attempt to open or repair the medical device. This could endanger the patient, damage the ventilator and / or void the warranty. Only authorized and qualified personnel of Periso SA can open or repair the medical device.
- ❗ Periso SA disclaims any responsibility for incorrect operation or for any damage caused by the use of devices not regularly overhauled.

MGPV components and Replacement Intervals

| | |
|--|---|
| Mucus drainage system | Single use Single patient |
| Bacteria/Virus Filter | Single use Single patient |
| Pressure sensor | 14 to 18 months or more often in case of persistent calibration failure |
| Oxygen solenoid valve | Every 15,000 hours of use |
| Cooling fan | Every 15,000 hours of use |
| Clean and disinfect inspiration block | Every two years |
| Measurements check | Every two years |
| Buzzer PCBA | Every two years |

6.3 Troubleshooting

| Problem | Reason | Solution |
|----------------------------|--|--|
| Lack of oxygen delivery | The ventilator is not connected to a source of compressed gas (oxygen) | Connect the ventilator to a source of medical gas |
| | The oxygen content in the cylinder is exhausted | Replace with another spare cylinder and prepare the filling of the empty cylinder |
| The patient cannot breathe | Patient valve positioned incorrectly or damaged | Check the patient valve assembly or replace it |
| High oxygen leakages | Oxygen loss greater than the maximum fan limit | Adjust the mask to the patient. If the problem persists put the device out of service, contact the manufacturer's qualified technician or contact the manufacturer immediately. |
| High pressure | Air circuit obstruction | Check the patient's trachea and remove the obstruction. If the filter is clogged, proceed with the replacement. |
| | Obstruction of the proximal part of the air tube or patient circuit | Clean the air pipes. |
| | Defect in the pulmonary ventilator or pressure sensor | Replace the medical device. The device must be immediately taken out of service and sent to the manufacturer for repair. |

| | | |
|---|--|--|
| High air flow | Hyperventilation condition of the patient | Remove condensate from the patient circuit. Check for leaks. If the problem persists put the device out of service, contact the manufacturer's qualified technician or contact the manufacturer immediately. |
| | Defect of the pulmonary ventilator or the flow sensor | Replace the medical device. The device must be immediately taken out of service and sent to the manufacturer for repair. |
| Low FiO ₂ | The oxygen value supplied to the patient is below the minimum value | Replace the medical device. The device must be immediately taken out of service and sent to the manufacturer for repair. |
| The pressure gauge does not indicate "0" when the fan is not running | The component is damaged | The device must be immediately taken out of service and sent to the manufacturer for repair. |
| The device is not working | Too low voltages have caused the microprocessor to freeze | Check the supply voltage. Switch the fan off and on again. If the problem persists, contact the manufacturer. |
| The quick clutch connector for the entry of medical gas is not stable | Damaged or worn clutch | The device must be immediately taken out of service and sent to the manufacturer for repair or contact the manufacturer's qualified technician. |
| The ventilator does not turn on | Anomalies in the internal electronic circuit | Take the device out of service, contact the manufacturer's qualified technician or contact the manufacturer immediately |
| The display is not well readable | The contrast adjustment is incompatible with the brightness of the environment | Contact customer service for support. |