MAGNAMED

Operation Manual

OxyMag – Transport and Emergency Ventilator

Rx ONLY

US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

MAGNAMED

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1606880-01: OxyMag

Review of this operation manual: 07

Table of Contents

Definition and Care

a. Definitions

WARNING

- ***This header is to inform the user of the possibility of injury, death or other serious adverse reaction associated with the use or misuse of the equipment.***

Caution

- This header is to inform the user of the chance to occur failure in the equipment associated with the use or misuse, such as equipment malfunction, equipment damage, or damage to third's property, and indirectly, injury to a patient.

Note

- Important information.

b. Warning

WARNING

- ***Where there is the ⚠ symbol, please read the instruction manual for more details, this manual should be read in its entirety and CAREFULLY, for the correct and safe use of the equipment and to provide maximum safety and to provide the best resources to patients. Check all Warnings and Cautions in this manual and on the labeling of the equipment.***
- ***This equipment should be operated only for the purpose specified in 1.1 in conjunction with appropriate monitoring.***
- ***This equipment must be operated only by qualified professionals in the health care area with expertise in mechanical ventilation qualified and trained in its use, who should be monitoring its use closely, including ventilation limited to volume.***
- ***This equipment and the parts should go through a cleaning and disinfection process, as indicated in chapter 8 Cleaning and Disinfection.***
- ***This equipment should pass the "Basic adjustments and checking procedures" to ensure the effectiveness of the equipment and the safety of***

the operator and patient, as indicated in chapter 5

- ***Inspection Before Use.***
- ***This equipment should remain connected to a grid power supply as long as it is possible, to ensure there is sufficient charge during a power outage or to transport the patient.***
- ***This equipment must beep three times when turned on, demonstrating the correct operation of audible signal. If you do not hear the three "BEEP" sounds or do not see the flashing light alarm, avoid the use of the equipment, because there will be no audible or visual indication of alarms.***
- ***This equipment, parts and accessories must be disposed according to chapter 10 Disposal;***
- ***This equipment must be switched off when there is no patient connected to the equipment.***
- ***This equipment should not be used with transmission devices in the vicinity of the transport ventilator, such as point-to-point radio transmission, cordless phones, pagers, high-frequency surgical equipment, defibrillators, short-wave therapies, which could stop the operation of the ventilator. All the transmission devices, including cellphones shall be 0.73 m (2.4 ft) away from the equipment to avoid unexpected or adverse outcomes.***
- ***This equipment should not be used during a magnetic resonance imaging (MRI, NMR, NMI), because this could cause interference, and can cause adverse effects to the patient.***
- ***This equipment should not be used with flammable anesthetic agents because there is risk of explosion.***
- ***The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.***
- ***After 500 hours of use, replace the ambient filter as indicated in chapter 9.4 Replacing the Ambient Air Filter.***
- ***Alarms and Alerts should be treated promptly in order to maintain the operation integrity of the equipment and patient safety, as indicated in chapter 7.***
- ***Do not use antistatic or electrically conductive hoses or tubing.***
- ***After starting ventilation, check if the ventilation parameters indicated by the monitoring display are appropriate.***
- ***Only use power supply, hose and breathing circuit (including exhalation valve, diaphragm, HME filter, flow sensor and flow sensor line) supplied by Magnamed which were tested and approved for use in conjunction with this equipment; otherwise, this can jeopardize the operation endangering the patient or user. For masks and nebulizer which are supplied by third part, follow the specifications of chapter 2.4.***
- ***It is essential for ventilation monitoring that the flow sensor is correctly connected and unblocked; therefore, this sensor must be frequently checked during operation.***

- ***When turning on the ventilator, please choose the type of patient on the home screen and this will set the proper ventilation.***
- ***Oxymag and all parts applied to it are made of non-toxic material, latex-free, and do not cause irritation or allergy to the patient. Applied parts is ventilation breathing circuit.***
- ***Use masks as specified in chapter 2.4 with FDA clearance.***
- ***Use MASK suitable for patient type.***
- ***Use endotracheal tube suitable for patient type.***
- ***Always use oxygen cylinders officially approved and pressure reducing valves that meet local government requirements.***
- ***Consider the dead space of the breathing circuit to make adjustment in the ventilator, especially for small tidal volumes.***
- ***Ensure to have a manual ventilation equipment available, for the case of a full battery discharge, lack of gases to the operation of the device or any general failure of the transport ventilator. Failure to have an alternative means of ventilation such as a self-inflating, manually powered resuscitator with mask can result in PATIENT death if the VENTILATOR fails.***
- ***Initial procedures (daily check) shall be performed with the patient disconnected from the equipment.***
- ***Do not expose the product to extreme temperatures beyond the specified range in chapter 12.3.3 Physical and Environmental Specifications during its use. The equipment performance may be adversely affected if the operating temperature is beyond the specified limits.***
- ***HME filter and breathing circuit (including flow sensor, flow sensor line, exhalation valve, and diaphragm) are single use. The reuse of these accessories may cause cross contamination between patients.***
- ***HME filter and breathing circuit (including flow sensor, flow sensor line, exhalation valve, and diaphragm) are disposable and shall be replaced after 24 hours of use and at each patient change.***
- ***During prolonged use of the equipment in patients with excess secretion, the condition of the flow sensor should be checked frequently, seeking to drain accumulated fluid out of the breathing circuit as needed.***
- ***Do not block the gas intake port, which would interfere with patient ventilation.***
- ***When components of the respiratory circuit or any other components/ subassemblies are added to the respiratory system of the ventilator, the pressure gradient across the respiratory system, measured relative to the patient's attachment port, may increase, adversely affecting the performance of the ventilator.***
- ***When using nebulization, breathing system filters as well as heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.***
- ***The ventilator shall not be used with nitric oxide. Such use might cause the ventilator to not function correctly, causing patient death or serious***

deterioration of health.

- ***The ventilator shall not be used with inlet gases, which are not specified for use (e.g., helium or mixtures with helium). Such use might cause the ventilator to not function correctly, causing patient death or serious deterioration of health.***
- ***The accuracy of the ventilator can be affected by the gas added to the ventilator breathing system by use of a pneumatic nebulizer. Only use nebulizer as specified in chapter 2.4.***
- ***The expiratory branch may become contaminated with bodily fluids or expired gases during use of the equipment under normal conditions and under a single fault.***
- ***Do not add any attachments or accessories to the ventilator that contravene the instructions for use of the ventilator or accessory, as the ventilator might not function correctly, leading to the risk of patient death or serious deterioration of health.***
- ***It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.***
- ***Do not cover the ventilator or place in a position that affects proper operation.***
- ***This ventilator is intended to be continuously attended by an operator. Failure to be in close proximity to this ventilator can contribute to patient death or serious injury.***
- ***Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or additional deterioration of health.***
- ***Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the instructions for use of the ventilator or accessory, as the ventilator might not function correctly leading to the risk of patient death or additional serious deterioration of health.***
- ***Do not use the ventilator in explosive environments. Such use might cause an explosion.***

c. Caution

Caution

- Oxymag does not emit electromagnetic waves that interfere with the equipment operation in the vicinity.
- Oxymag must have the ambient air intake filter replaced every 500 hours of use.
- Oxymag should only have their maintenance carried out by a qualified, trained technician duly authorized by MAGNAMED.
- All service, modification or maintenance on the ventilator can only be carried out by a qualified technician, trained, and duly authorized by MAGNAMED.

d. Note

Note

- There are additional contraindications, in addition to those specified in Warning items in page 6 of this manual. It is the responsibility of the trained operator to choose and select the suitable respiratory mode for each patient.
- The technical characteristics of MAGNAMED Products are subject to change without notice.
- All ventilator parts, pieces and accessories that are subject to disposal must comply with the recommendations of Chapter 11 Disposal.
- Oxymag does not generate sub atmospheric pressure during the expiratory phase.
- Pressure units:

1 mbar (millibar) = 1 hPa (hectoPascal) = 1.016 cmH2O (centimeter of water)

In practice, these units are not differentiated and can be used as:

1 mbar = 1 hPa ≈ 1 cmH_2O

1. Description

1.1 Device Description

Oxymag provides a mixture of ambient air and oxygen at concentrations adjusted by the operator using the accurate oxygen concentration System using the venturi principle. O_2 concentration is obtained through a galvanic cell by passing gas through the sensor. In addition, it performs the control of flows and pressures in the respiratory circuit to provide the ventilation modalities appropriate to the patient's condition.

The possible ventilation modes of this ventilator are:

- VCV – Volume Controlled Ventilation (can be Assisted);
- PCV – Pressure Controlled Ventilation (can be Assisted);
- P-SIMV – Synchronized Intermittent Mandatory Ventilation with Pressure Controlled cycle;
- V-SIMV – Synchronized Intermittent Mandatory Ventilation with Volume Controlled cycle;
- CPAP /PSV – Continuous Pressure Ventilation with Pressure Support.
- CPAP/PSV (NIV) – Non-invasive ventilation by mask can be activated in spontaneous mode (CPAP) adjusting parameter NIV to ON in parameters adjusts.

WARNING

- ***This device is not approved for long-term ventilation more than 24 hours. The device is only indicated for transport and emergency situations, and it is contra-indicated to be used in prolonged therapies and ICU.***
- ***This device is not approved for use with humidifier.***
- ***This device should only be operated by healthcare professionals with expertise in mechanical ventilation and qualified and trained in its use.***
- ***In spontaneous mode, be aware that when adjusting parameter BACKUP to OFF backup ventilation will be INACTIVE during APNEA.***
- ***In CPAP (NIV) mode, the exhaled volume and exhaled CO_2 of the PATIENT can differ from the measured exhaled volume and exhaled CO_2 due to leaks around the mask. The equipment will compensate leaks of approximately 40L.min^{-1}, depending on the ventilator settings.***

Note

- During ventilation in CPAP/PSV a backup ventilation can be established in the case of APNEA; this ventilation can be chosen between VCV, PCV or OFF.

1.2 Intended Use

Oxymag is a controlled volume, pressure and time cycled emergency and transport ventilator. It is intended for use with infant, child, and adult patients with a tidal volume from 50 ml upwards who are in respiratory and/or cardiac arrest or respiratory distress and who require the ventilatory support.

It is intended for pre-hospital and hospital use including intra-hospital, inter-hospital and transport settings.

Pulmonary ventilation may be performed in the following conditions:

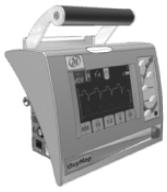
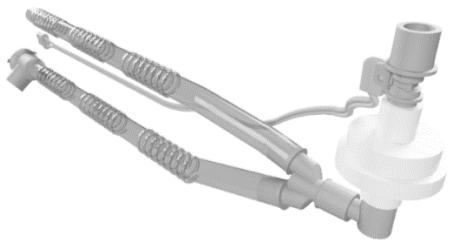
- In emergency medicine for service in the field, rescue in which the patient can be transported by land;
- Intra-hospital transportation: The patient can be transported internally, from one to another department;
- Inter-hospital transportation: The patient can be transported by ambulance between hospitals.

2. Unpacking the Product

2.1 Initial Checks

- ✓ Make sure the packaging is intact checking for dents, holes, or other damage.
- ✓ If the package is found damaged, please report immediately the Responsible courier and MAGNAMED. DO NOT open the package.
- ✓ Open the package carefully observing the symbols in the box.
- ✓ Check the content in accordance with the following list of components.

Table 1: List of components for Oxymag

Part Number	Description	Qty	Image
1606880	OXYMAG - TRANSPORT AND EMERGENCY VENTILATOR	1 unit	
2402568	POWER OUTLET 12V/3,34A MEDICAL DEGREE	1 unit	
2807837	AC CABLE - 3 WAYS 3,0 M (hospital grade)	1 unit	
1707816	KIT DISPOSABLE RESPIRATORY CIRCUIT • 1 Breathing circuit • 1 Exhalation valve • 1 Diaphragm • 1 Flow sensor • 1 Flow sensor line • 1 filter	1 unit	
3907836	O_2 EXTENSION DISS X2 - 2 M	1 unit	

Part Number	Description	Qty	Image
1702656	ENVELOPE WITH 3 ENVIRONMENT FILTERS	1 unit	
1710058	ENVELOPE WITH 3 COOLER FILTER	1 unit	---
7006467	QUICK GUIDE	1 unit	---
1606880-NE-22-RR	OPERATION MANUAL	1 unit	---

2.2 Parts and Accessories

Caution

- Always use original parts and accessories to ensure the safety and effectiveness of the equipment.
- Parts and pieces indicated in these instructions for use may be used in the patient environment.
- Before use the equipment and accessories, open the packages carefully and remove the items from their packages.

2.3 Optional accessories that can be purchased for Oxymag

Table 2: List of optional components for Oxymag.

Part Number	Description	Qty	Image
1702496	VERTICAL SUPPORT FOR AMBULANCE WITH SAFETY LATCH	1 unit	

2.4 Third-party accessories compatible with Oxymag

2.4.1 Nebulizer

- Aeroneb® Solo Nebulizer System (K133360)

2.4.2 Facial mask

- Adult mask:

Indications for use	Non-invasive ventilation in transport environment
Patient weight	> 36.6 kg
Patient usage type	Single use
Pressure source action body site	Mouth and Nose
Breathing Tube connection	22 mm conical connector
Operating environment	According to section 13.3.3 Physical and Environmental Specifications
Anti-asphyxia valve	Not needed
Mask size	Suitable to the patient, according to manufacturer specification

- Pediatric mask:

Indications for use	Non-invasive ventilation in transport environment
Patient weight	12.4 kg < P ≤ 36.6
Patient usage type	Single use
Pressure source action body site	Mouth and Nose
Breathing Tube connection	22 mm conical connector
Operating environment	According to section 13.3.3 Physical and Environmental Specifications
Anti-asphyxia valve	Not needed
Mask size	Suitable to the patient, according to manufacturer specification

- Infant mask:

Indications for use	Non-invasive ventilation in transport environment
Patient weight	6 kg ≤ P < 12.4 kg
Patient usage type	Single use
Pressure source action body site	Mouth and Nose
Breathing Tube connection	22 mm conical connector
Operating environment	According to section 13.3.3 Physical and Environmental Specifications
Anti-asphyxia valve	Not needed
Mask size	Suitable to the patient, according to manufacturer specification

2.5 Components of transport ventilator

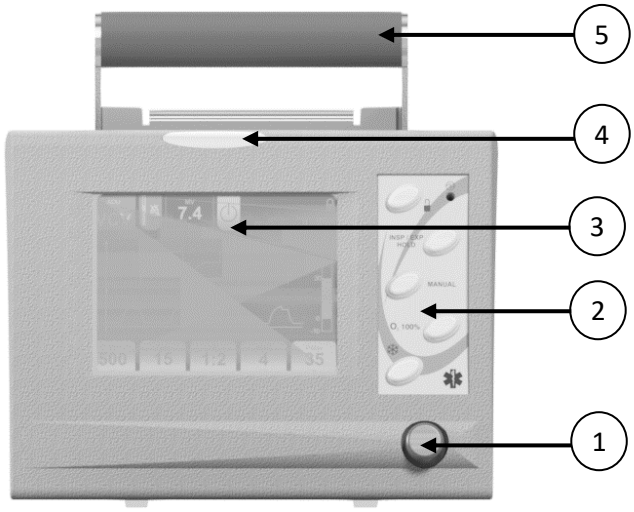


Figure 1: *Frontal Panel of transport ventilator.*

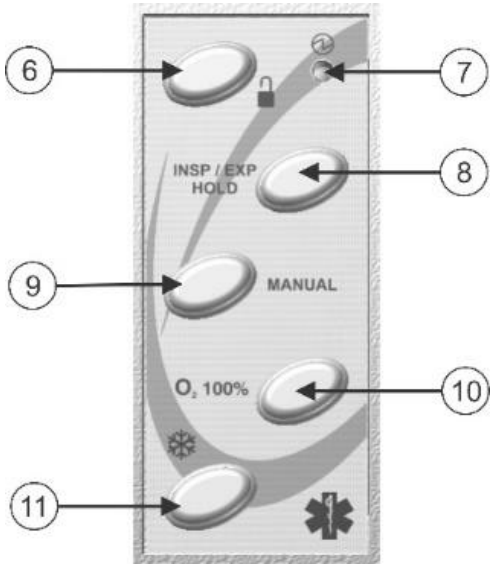


Figure 2: *Side Keyboard*

Table 3: Description of the frontal panel and the side keyboard components of the transport ventilator

Components of Figures 1 and 2
1. KNOB BUTTON This button is used for most of the adjustments to be made in the Transport Ventilator Oxymag. • Select the parameters to be set on the display by directly touching the corresponding button; • The selected button will change color to YELLOW allowing the change of values or adjustments; • Set the desired value by turning the knob clockwise or counter-clockwise; • To confirm press the button When the button returns to its original color the parameter set will be in effect.
2. KEYBOARD The keypad buttons allow quick access to the ventilator functions.
3. LIQUID CRYSTAL DISPLAY WITH TOUCH SCREEN Visual and graphical presentation of the setting parameters with touch screen.
4. ALARM INDICATOR LIGHT – RED The alarm indicator light flashes when an alarm condition of high priority occurs. When in silent mode, it remains activated indicating the alarm condition.

Components of Figures 1 and 2

5. HANDLE

This handle allows the user to carry the ventilator during rescue and emergency situations. At the rear of the ventilator, there is a support that can be easily adapted to a patient stretcher.

6. LOCK TOUCH SCREEN

This key allows to lock or unlock the touch screen. When the commands on the display are locked, press this key and a pop-up will be displayed. To unlock the screen, press "✓". To lock again simply press this key once or wait 60 seconds without touching the screen.

7. GREEN LED – CONNECTION TO MAINS

The GREEN LED will bel it when the DC power inlet or power supply 12VDC inlet are connected

8. HOLD KEY (PAUSE)

This key allows to suspend inspiration maneuvers, often used in cases of chest X-ray and maneuvers to extend the time of expiration (extend the expiration time).

If pressed during the inspiratory time of the respiratory cycle, the inspiration will be prolonged for 5 seconds; after this period, parameter Cest will be displayed in the monitoring area at the top center of the screen. If this key is pressed during the exhalation time, expiration will be extended for 5 seconds; after this period, the parameter PEEPi will be displayed in the monitoring area in the top center of the screen.

The parameters displayed after pressing this key will be visible for 5 seconds; after this period, the monitoring will again display the parameter previously displayed.

9. MANUAL KEY

This key trigger an inspiratory cycle of support pressure. And is active in the VCV, PCV, V-SIMV, CPAP/PSV, P-SIMV modes.

10. O_2 100% KEY

By pressing key to "O_2 100%" the oxygen concentration will remain at 100% during the next 90 seconds. This feature can be used for pre-aspiration and post-aspiration procedures of secretions from the airways. Use with an aspiration catheter may be performed in any mode and does not require a specific adjustment.

When the ventilator is in STAND-BY, and after pressing this button for 2 seconds, an oxygen flow meter will be displayed in the ventilator screen. At the top of the screen, the set value of the flow meter is displayed, and at the bottom the value measured of the flow delivered is displayed. Use the button "Set and Confirm" to

Components of Figures 1 and 2
change the value of the desired flow.
11. FREEZE KEY Freezes the graph layout to allow the analysis of the curves.

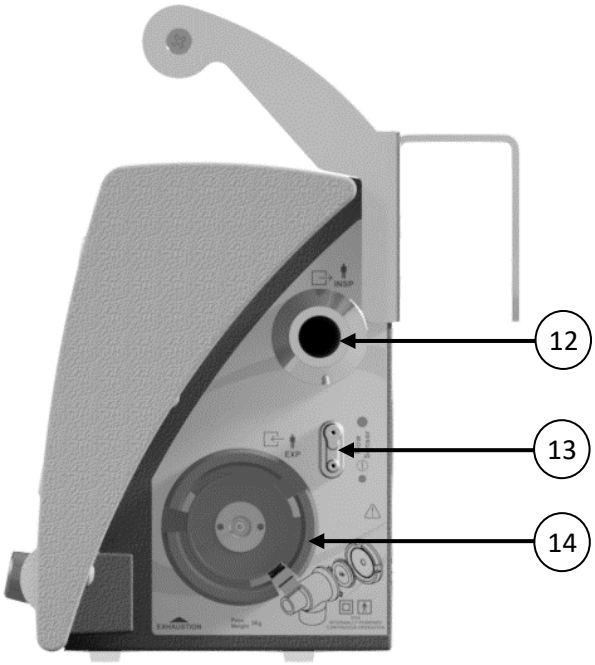


Figure 3: Right side view

Table 4: Description of components of the right side of the transport ventilator.

Components of Figure 3
12. CONNECTOR 22M/15F OF INSPIRATORY FLOW Standard connection of the inspiratory flow to the breathing circuit of the patient
13. FLOW SENSOR CONNECTIONS These connectors are used to connect the flow sensor.
14. EXHALATION VALVE Connection of the expiratory limb of the breathing circuit of the patient.

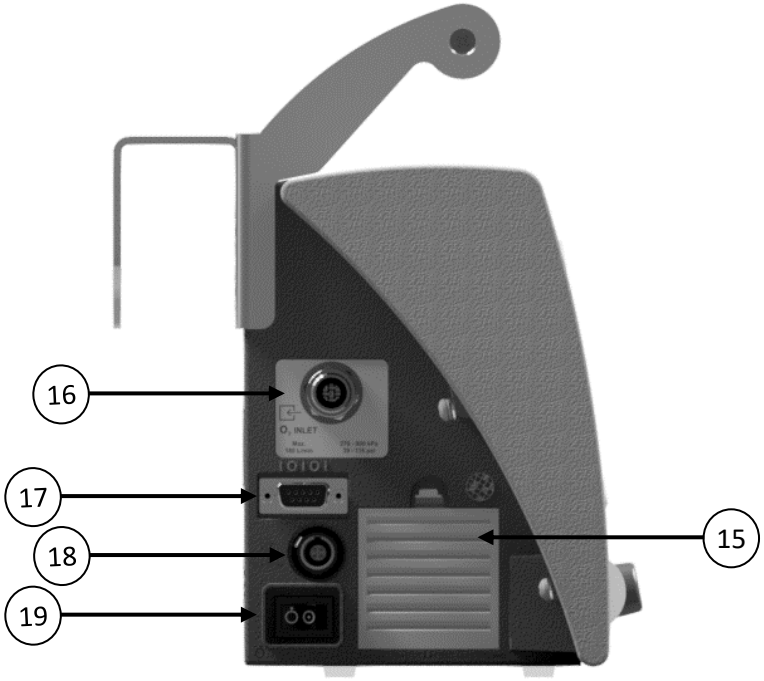


Figure 4: Left side view

Table 5: Description of the components found in the left side

Description of the items in Figure 4
15. Air Inlet Filter Ambient air intake filter, which is mixed with oxygen to provide oxygen concentrations less than 100%. Filter should be replaced according to the descriptive operations manual (9.4 Replacing the Ambient Air Filter).
16. OXYGEN INLET Connect oxygen. Inlet pressure should be in the range of 39 to 87 psi (280 to 600 kPa). Standard DISS connection (as per CGA V-5)
17. SERIAL CONNECTION Serial Communication – RS-232 – female DB-9 connector for software update. Only for technical assistance.
18. INLET +12VDC – External AC/DC Source Power supply input +12VDC – Connection to external AC/DC source through the plug
19. On/Off Switch On/Off Switch

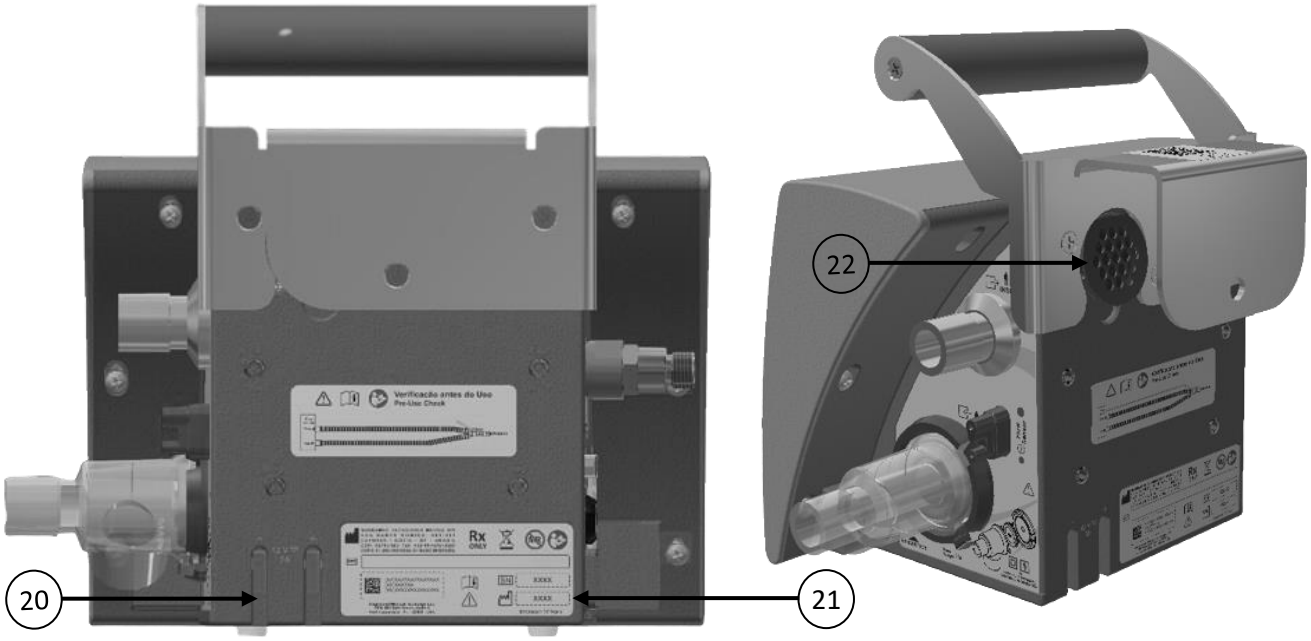


Figure 5: Back view

Table 6: Description of components of the back side of the transport ventilator.

Description of the items in Figure 3 and 4
20. PLUG OF POWER SUPPLY – BASE This plug is used along with the support base of Oxymag and the power supply system. The inlet is +12VDC. Note the polarity indication and the recorded voltage DC power.
21. LABELING TAG This labeling tag displays MAGNAMED information, European Authorized Representative, Registration number at ANVISA, month and year of manufacture and the serial number.
22. COOLER'S FILTER Cooler's filter should be replaced according to the descriptive operations manual (9.6 Replacing the cooler's filter)

The parameters are monitored based on the pressure and the FiO_2 measurements performed by oxygen monitor.

WARNING

- ***As with all medical equipment, position the cable on the patient in order to reduce the possibility of entanglement or strangulation.***

Caution

- If there is no confirmation by pressing the button, the parameter value will return to the previous value after 10 seconds.

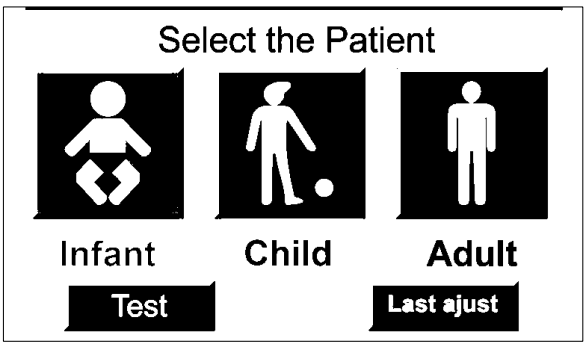
Note

- For electrical insulation of the ventilator circuits from the external source, only disconnect the power supply input+12VDC of the equipment.

3. Description of the Display

3.1 Home Screen

By starting the ventilator, the following screen will be displayed:



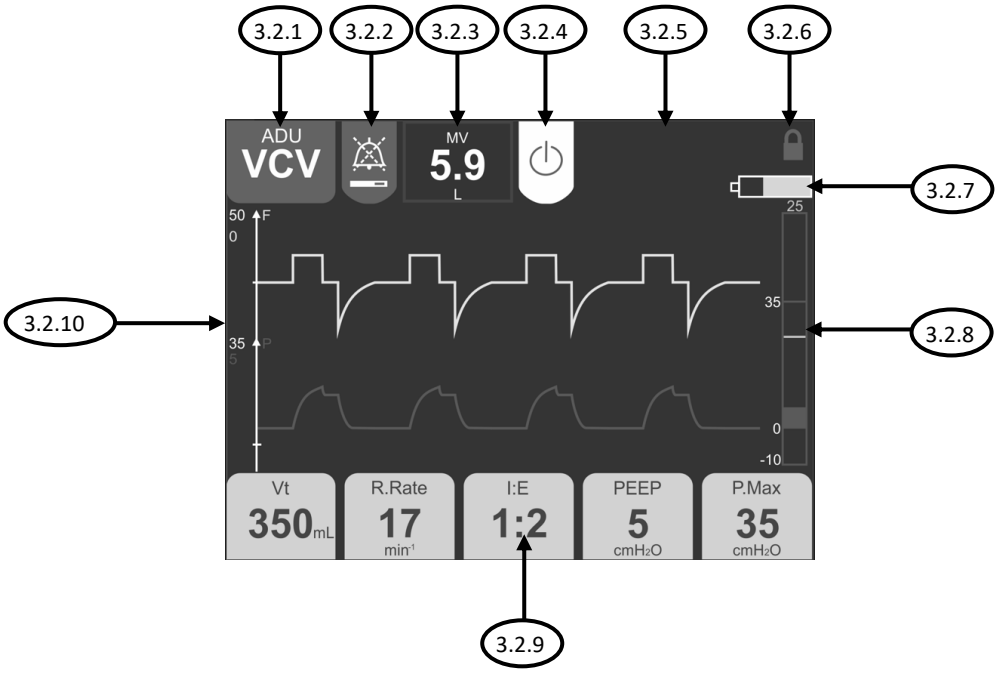
It is recommended to perform the autotest before starting the ventilation. To do this, press the button “Test” and follow the instructions on the screen. For more information, see chapter 5.2.2 - Test Sequence.

To start the ventilation, choose the patient and click on the corresponding button. For more information, see chapter 5.2 - Ventilator Settings.

To quickly start a ventilation with the same configuration of the previous ventilation, select the button “Last adjust”.

3.2 Main screen

By clicking on the patient in the previous step, the following screen will be displayed:



3.2.1 Modes

In the upper left corner, there is the indicator of:

- Type of patient selected: Adult; Child; Infant;
- Active Mode;
- NIV indication (CPAP mode).

By clicking on the button, it will be displayed the available ventilatory modes. To change the mode, click on the desired mode, and set the parameters that will blink in yellow.

3.2.2 Mute

By clicking on the mute button, the alarms will be muted for 2 minutes or until another alarm starts. When the alarm is muted, a bar indicating the mute time is shown.

3.2.3 Monitor

By clicking on this button, the following monitored parameters will be displayed: MV – Minute Volume Monitored, Vte – Volume Expired or PMax – Maximum Pressure. To change the parameter displayed, simply touch the screen on the parameter.

When performing the inspiratory or expiratory pause, in this area will be displayed the monitored Static Compliance (C.Stat) and the Intrinsic PEEP (PEEPi).

3.2.4 Standby

To put or remove the ventilation in standby, click on this button, and confirm the message displayed.

3.2.5 Lock

When the screen is blocked, the padlock icon will be displayed. To activate this function, see chapter 2.5 - 2.5Components of transport ventilator, item 6.

3.2.6 Alarms and messages

Alarms and alert messages will appear on this area when enabled.

3.2.7 Battery status

The remaining battery charge will be displayed on this icon.

3.2.8 Bar graph

The bar graph will show the instantaneous pressure in the breathing circuit and the value of maximal inspiratory pressure at the top.

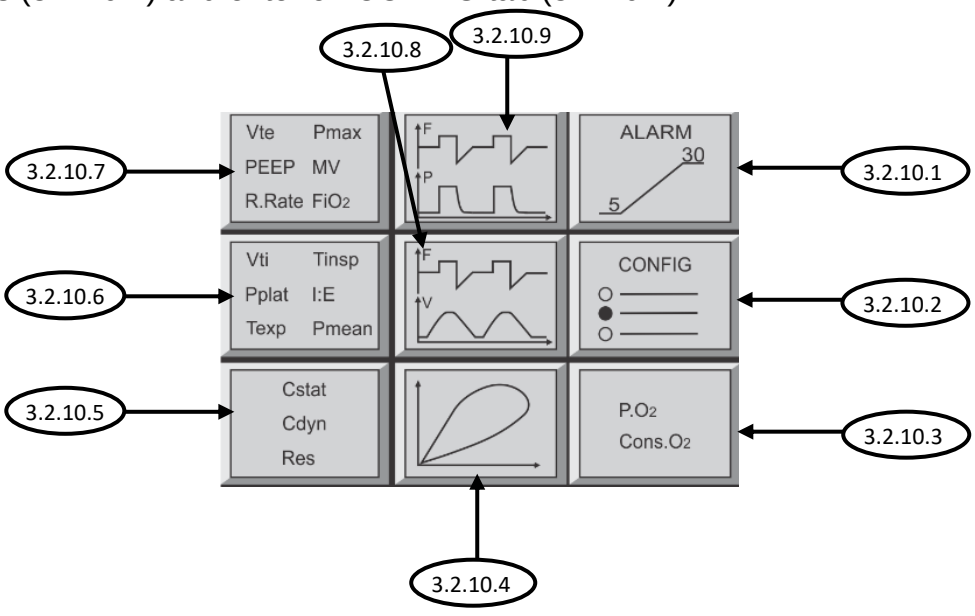
3.2.9 Set parameters

The available set parameters will be displayed on this area. To change the parameter, click on the desired parameter, adjust the value with the knob and click to confirm.

3.2.10 Graphic area

In this area will be displayed the graphics: flow and pressure (3.2.10.9), flow and volume (3.2.10.8) or loop (3.2.10.4), or the monitoring parameters: Volume tidal, Maximum pressure, PEEP, minute volume, respiratory rate, and FiO_2 (3.2.10.7), or inspired volume, inspiratory time, plateau pressure, I:E ratio, and expiratory time (3.2.10.6), or static compliance, dynamic compliance, and resistance (3.2.10.5) or Pipeline pressure, and O_2 consumption (3.2.10.3).

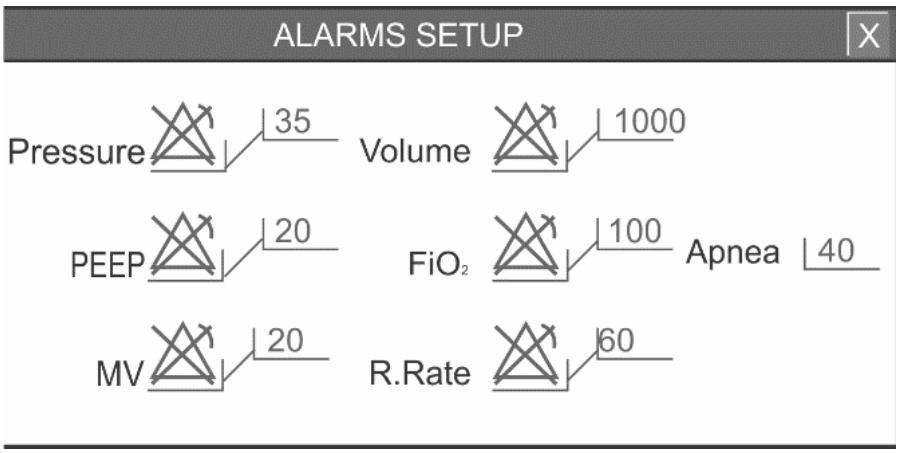
To change the graphic displayed, click on the graphic area. A menu will be displayed, and it will be possible to choose other graphic or monitor. In this menu is also possible to set the alarms (3.2.10.1) and enter on CONFIG tab (3.2.10.2).



3.2.10.1 Alarm menu

By accessing this menu, it is possible to set the alarm limits. To access the ALARM menu, press anywhere on the graph screen and select ALARM.

It will be displayed the alarm limits of Pressure, Volume, PEEP, FiO2, Minute Volume, Respiratory Rate, and Apnea Time. To set the limits, click on the area corresponding to the alarm that you want to set, turn the knob to change the parameter and press the knob to confirm.



3.2.10.2 CONFIG menu

Additional configurations may be selected by pressing on the CONFIG button. To access CONFIG menu, press anywhere on the graph screen and select CONFIG. This screen is divided into three tabs:

- In the **GENERAL tab** it is possible to:
  - Change the height of the Patient thereby defining the ideal weight (BMI 22), recalculating the default ventilatory parameters of the patient.
  - Turn on or off the “sigh” function. In this condition, there will be a “sigh” every 100 cycles in control modes.
  - Select the language of the equipment (English, Portuguese, Spanish).

Note

- “Sigh” function is only available in VCV and V-SIMV modes.

- In the **O_2 tab** it is possible to calibrate the O_2 cell by pressing the “Calibrate O2” button.

Note

- It is not necessary to discard calibration gases.

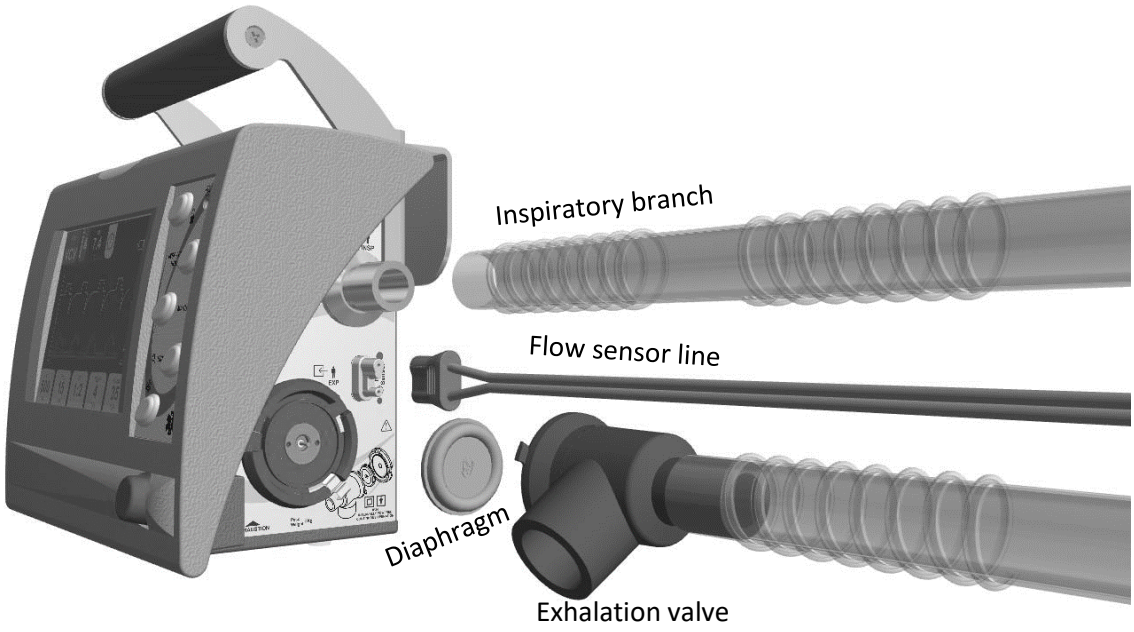
- In **VENTILATOR tab** it is possible to:
  - Set Audio volume – to set the alarm audio volume. Use the knob to change and confirm to make this adjustment. This parameter always starts in the maximum of 5.
  - Set the unit of Pressure – Select the desired unit (cmH2O, hPa or mbar);
  - View data of the last test performed: breathing system leakage, compliance and resistance done in the initial tests;
  - View the total hours of use of the equipment;
  - View the hours since the last maintenance.

4. Preparation for Use

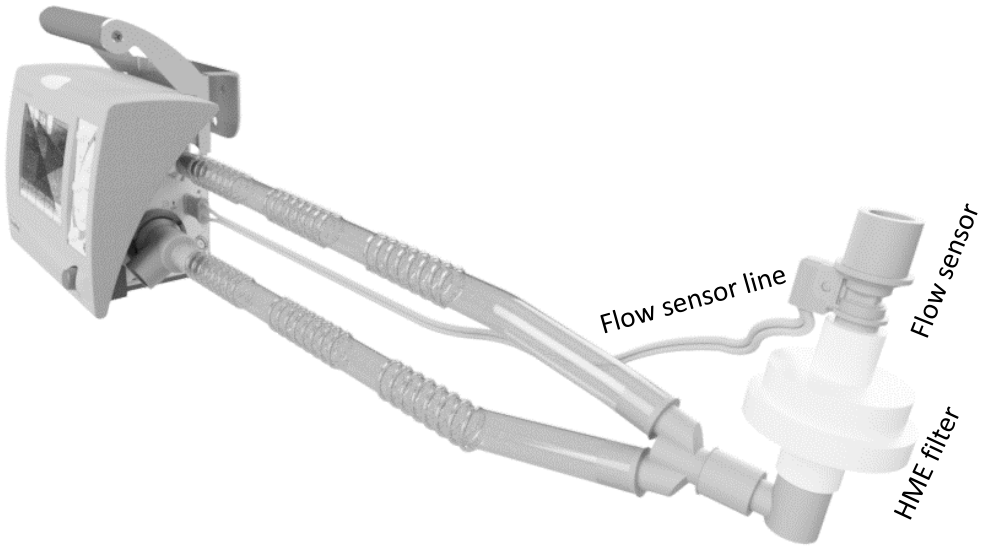
4.1 Assembling Oxymag – Transport Ventilation

Table 7 describes the steps that the operator should follow (health care professional, duly trained and authorized to use the equipment) to assemble and prepare the transport ventilator.

Table 7: Assembly Sequence of Oxymag

Assembly Sequence
1. Insert a diaphragm in the exhalation valve, then insert the assembly into the base and press firmly and rotate clockwise to lock. **Caution** • To unlock the valve, press the locking valve and turn the valve counterclockwise. • Ensure that the connection of the exhalation valve is secure. It is important that the diaphragm is installed properly. 2. Firmly connect the breathing circuit to the 22M/15F connector of inspiratory flow. 3. Connect the flow sensor line in the flow sensor connector.   

Assembly Sequence

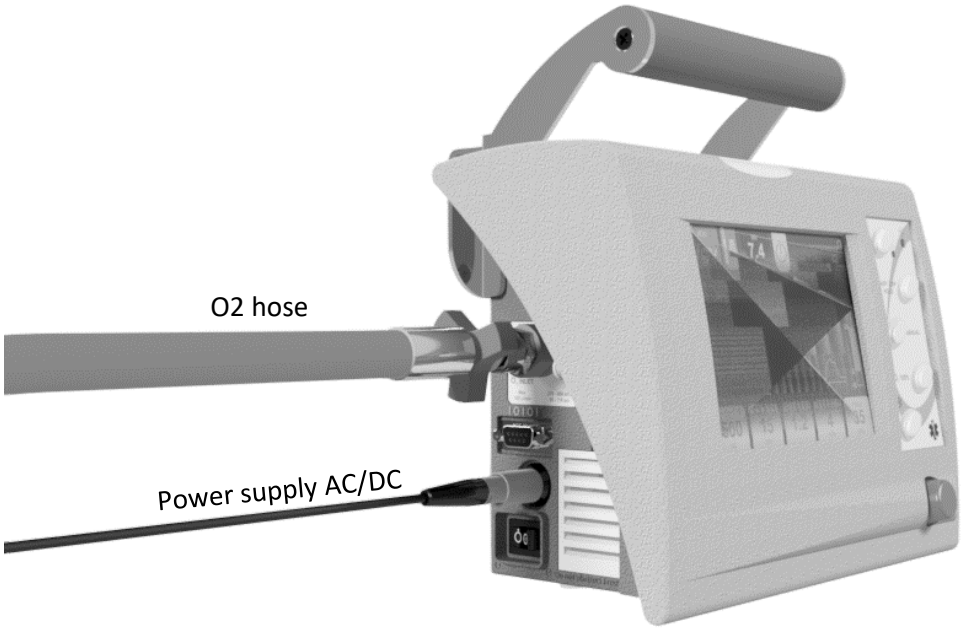


Caution

- Securely check the connection of the breathing circuit and the flow sensor.

4. Connect the power supply AC/DC to the equipment and then to the power grid.

5. Connect the oxygen hose to the transport ventilator.



Note

- There is an indication with a larger circle and a smaller circle in the ventilator showing the fitting position of the pressure line in the equipment.
- There is no specific position for the disposition between the operator and the patient, as long as the breathing circuit is mounted properly.
- For electrical insulation of the ventilator circuits from the external source, just disconnect the power supply input +12VDC from the equipment.

4.2 Non-invasive ventilation mask

Use of the breathing circuit for NON-INVASIVE VENTILATION (NIV).

A. Mask without an HME filter;

Figure 6: Assembly of the non-invasive mask without HME filter

B. Mask with an HME filter

Figure 7: Assembly of non-invasive mask with HME filter

WARNING

- ***Correctly position the diaphragm and the exhalation valve to prevent obstruction of the expiratory branch;***
- ***The correct connection of the pressure lines and the absence of all obstruction are extremely important for the proper functioning of the patient's ventilation monitoring and, therefore, it should be checked frequently during the course of ventilation of the patients.***

- ***Never obstruct the pressure port. The measured pressure in these points are used by the patient ventilation monitoring system.***
- ***All connections must be FIRMLY secured to prevent leakage.***
- ***PROPER connection of these pressure lines are extremely important for monitoring patient ventilation.***
- ***When using the Oxymag for an extended time on battery, an alarm occurs whose message is LOW BATTERY. Provide IMMEDIATE connection of power supply to the power grid, and if DISCONNECTING the equipment from the patient is not possible, the user must provide appropriate means of ventilatory support.***
- ***When using oxygen cylinder, check if the pressure reducing valve is set to deliver oxygen flow with pressure according to 15.3.2 Connecting to the Oxygen Supply. Pressures greater than those specified may damage the equipment.***

4.3 Power Connection

The equipment must be connected to 3-way AC CABLE.

The internal battery of the equipment must always be charged and ready for use in a failure of the power grid or for use in external operations; thus, your power supply should be always connected to the power grid to keep the battery charged, even if the equipment remains off.

After prolonged use of the equipment with only the internal battery, a full recharge is required to prepare the equipment for extended use.

If the equipment remains unplugged for more than a month, the battery should be fully recharged.

Caution

- Do not position the equipment so that it is difficult to operate the device when disconnected from power supply.

Note

- If the power supply has been unplugged and then restored while the equipment is operating, equipment performance will not be affected, and accuracy will be maintained so long as the internal battery is fully charged
- After a long period of disconnection from the power supply, reconnect the equipment to the power grid, switch on the equipment and leave on for 30 minutes. Perform all necessary calibrations and a self-test.
- Fully recharge the batteries after an extended period of storage.
- Recharge the batteries before the next use, otherwise, any electrical power failure may interrupt the operation of the ventilator.

4.4 Mounting the vertical support

Wall Support (1702496) is an optional item and can be used in ambulances or walls of hospital environment facilities.

Below is the procedure to assemble the wall support onto the wall.

1. Install the fixed support with +12V DC power (3803835) onto the wall (room, ambulance) using 4 screws (3003446) to the side and 4 fixing bolts (3003447), if required.

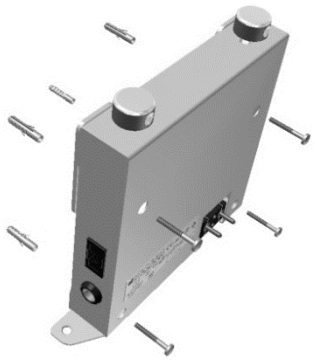


Figure 8: Installation of the fixed support

2. To place the ventilator on the support, follow the procedure below:
   a. Pull the handle bracket on the wall, just above the fixed support;
   b. Slide Oxymag down until it clicks into place;
   c. Press the safety lock of the ventilator turning the two eccentric buttons from the top until the red dots are no longer visible;
   d. Make sure that Oxymag is fixed in place;
   e. To remove Oxymag, perform the procedure in reverse.

Figure 9: Connection of the ventilator to the fixed support

Below the procedure to assemble the support on the bench:

1. Install the fixed support with +12V DC power (3803835) on the bench using 2 screws (3003446).

Figure 10: Installation of the fixed support on the bench

2. To place the ventilator on the support, follow the procedure below:

a. Insert the handle holder in the support above the fixed support;
b. Slide Oxymag down until it clicks into place;
c. Activate the safety lock of the ventilator turning both eccentric buttons from the top until the red dots are no longer visible;
d. Make sure that Oxymag is fixed in place;
e. To remove Oxymag, perform the procedure in reverse.

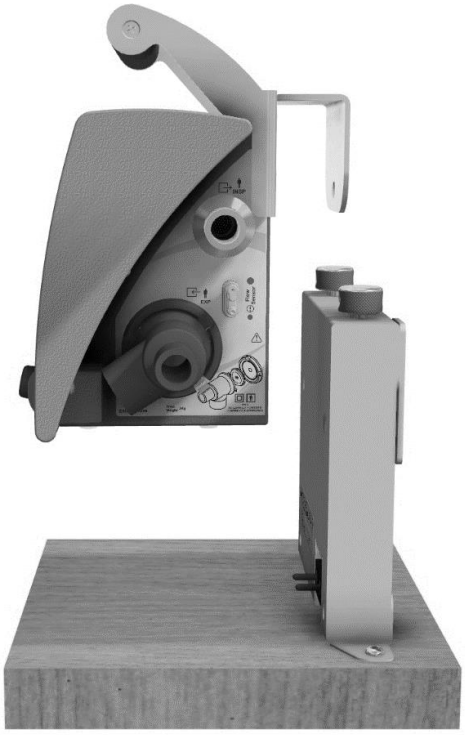


Figure 11: Connection of the ventilator to the support

4.5 Nebulizer assembling

To connect the nebulizer, remove the HME filter from the breathing circuit and connect the tee adaptor in the inspiratory branch (1). Connect the Aerogen solo® (2) to the tee adaptor. Connect the Y (3). Connect the flow sensor and mask after Y (4) as shown in Figure 12.

Figure 12: Nebulizer assembly

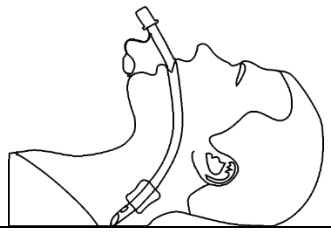
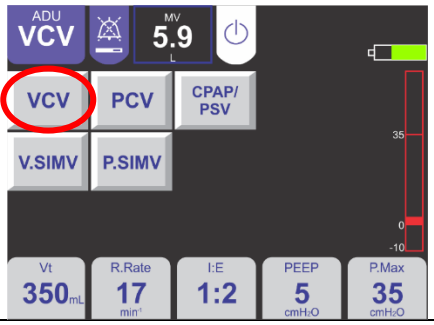
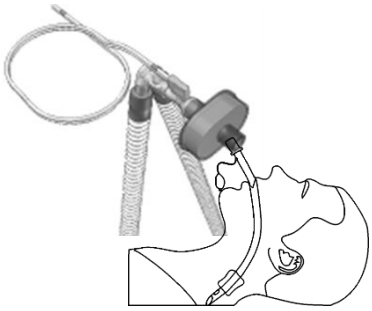
WARNING

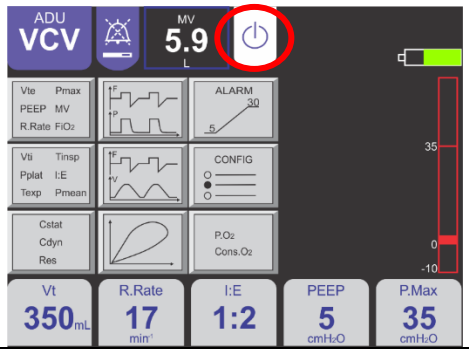
- ***Only nebulize drugs in a manner consistent with what the drug has been cleared for by the FDA.***
- ***Only nebulize drugs in the route of administration (e.g., oral, tracheal) that is consistent with what the drug has been cleared for by the FDA.***

Caution

- Only use nebulizer with FDA clearance.

4.6 Changing from non-invasive mode to invasive mode

Disconnect the facial mask from the breathing circuit	
Connect the suitable endotracheal tube on the patient	
Configure invasive mode according to the patient's need	
Connect the endotracheal tube to the breathing circuit	

Start the invasive mode ventilation	

5. Inspection Before Use

The purpose of this inspection routine is to guide the user in performing a simple and quick set of procedures to test the equipment before each use or at least at the beginning of each work period.

WARNING

- ***This equipment must pass the "Basic Adjustments and Checking Procedures" to ensure the effectiveness of the equipment and the safety of both the operator and patient*.**

5.1 Initial procedures – Daily check

This equipment must pass the "Basic Adjustments and Checking Procedures" before connecting the patient to ensure the effectiveness of the equipment and the safety of the operator and the patient, as the following sequence:

- Ensure that the equipment is off;
- Clean and disinfect the equipment according to Chapter 8;
- Check that the battery is fully charged;
- Assemble the accessories according to Chapter 4;
- Check the pressure in the cylinder gauge (where applicable);
- Perform the Auto Test on the ventilator's main menu by following the instructions.

The equipment is ready for use immediately after been turned on.

WARNING

- ***This equipment must make three beeps when started, to ensure the audible signal is functioning properly. If you do not hear the triple "BEEP" sounds or do not see the light flashing alarm, avoid the use of the equipment, because there will be no audible or visual indication of alarms.***
- ***Daily check should be performed with the patient disconnected.***

5.2 Ventilator Settings

The ideal weight of the patient is used to calculate the ventilator parameters to provide the best approximation to ventilate the patient. This value is calculated using the height of the patient, considering the Body Mass Index (BMI) of 22. The following will be calculated according to the weight:

- Volume – calculated based on 7 mL/kg;
- Respiratory rate – according to the internal calculation to the system;
- Ratio I:E - 1:2;
- Inspiratory Flow – calculated according to TINS obtained;
- Maximum Pressure – 30 hPa (cmH2O)
- PEEP – 5 hPa (cmH_2O)
- Plateau Pressure – 30 % de T_{INS}
- Flow – Square

The following table shows the modes available for each type of patient:

Table 8: Modes available for the types of patients

Patient type	*Modes available*
INFANT	VCV, V-SIMV, PCV, CPAP / PSV, P-SIMV
CHILD	
ADULT	

When selecting the type of patient at the startup of the equipment, the values of ideal height and weight assumed by the equipment.

Table 9: List of values adopted by the equipment when selecting a patient

Startup button	Patient type	Height	Ideal Weight P
	***INFANT***	*0.64 m (2.09 ft)*	*9.0 kg (19.8 lbs)*

Startup button	Patient type	Height	Ideal Weight P
	***CHILD***	*0.95 m (3.12 ft)*	*19.8 kg (43.7 lbs)*
	***ADULT***	*1.50 m (4,92 ft)*	*49.5 kg (109.1 lbs)*

After startup, it is possible to change the height value within the adjustment range of the patient type by clicking on the chart area and menu and select the Settings button (General Tab). The settings range are found in the table below:

Table 10: List of adjustment range for height and weight

Patient Type	Height Adjustment		Ideal Weight P
	Min.	Max.	
INFANT	0.53 m (1.74 ft)	0.75 m (2.46 ft)	6.0 kg (13.2 lbs) < P ≤ 12.3 kg (27.1 lbs)
CHILD	0.76 m (2.49 ft)	1.29 m (4.23 ft)	12.4 kg (27,3 lbs) < P ≤ 36.6 kg (80,7 lbs)
ADULT	1.30 (4,27 ft)	2.5 (8.20 ft)	> 36.6 kg (80,7 lbs)

The weight of the patient considered by the equipment is the ideal body weight, calculated according to the height of the patient.

Height adjustment of the patient does not save after turning off the equipment. It is only possible to change the height within the range of values corresponding to the type of patient selected.

Note

- The selection of the patient type on startup will perform the initial calculations of the transport ventilator and issue certain ventilation modes as options.
- Body Mass Index Formula:

$$BMI = \frac{\text{Weight [kg]}}{(\text{Height [m]})^2}$$

5.2.1 Normal Startup Sequence

1. Oxymag Main Menu – Turn on the ventilator with the on-off switch on the left side of the equipment. Once it turns on, notice if a triple “beep” occurs in conjunction with the light alarm indicator. This means that the audible and visual alarm are operational.

WARNING

- ***If you do not hear a triple “BEEP” sound or do not see the light alarm indicator flashing, avoid the use of the equipment, because there will be no indication of any audible or visual alarm.***

2. Choose the type of patient to be ventilated and connect the flow sensor in the patient’s breathing circuit. The ventilator will be initialized in the mode indicated in Table 8: Modes available for the types of patients.
3. Last Adjust Option – This brings back the last parameters set when the equipment was switched off the last time. These settings are automatically saved (optional).
4. By choosing INFANT, the ventilator will start the ventilation with the following parameters:

Table 11: List of parameters in the INFANT mode

PCV	Default
Pcontrol	10 cmH2O
Rate	24 min^{-1}
Ratio I:E	1:2

PCV	Default
PEEP	5 cmH2O
FiO_2	60%
Flow Trigger	OFF
Pressure Trigger	OFF
Rise Time	0,1s

5. By choosing CHILD, the ventilator will start the ventilation with the following parameters:

Table 12: List of parameters in the CHILD mode

PCV	Default
Pcontrol	10 cmH2O
Rate	22 min^{-1}
Ratio I:E	1:2
PEEP	5 cmH2O
FiO_2	60%
Flow Trigger	OFF
Pressure Trigger	OFF
Rise Time	0,1s

6. By choosing ADULT, the ventilator will start the ventilation with the following parameters:

Table 13: List of the parameters in the ADULT mode

VCV	Default
Vt	350 mL
Rate	17 min^{-1}
Ratio I:E	1:2
PEEP	5 cmH2O
Pmax	35 cmH2O

VCV	Default
Pause	0%
FiO_2	60%
Flow Trigger	3.0
Pressure Trigger	OFF
Wave Flow	Square

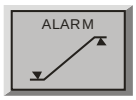
7. After the startup sequence, the equipment will display the graph screen of the ventilator. Audible alarms will be disabled in the first 2 minutes. Note that the white bar next to the alarm silence symbol is reduced over time. After 2 minutes the audible alarm will be reactivated.
8. Select the ventilation mode button 

to bring up the ventilation mode selection screen. This will allow you to change between different ventilations.
9. Select the desired mode and after confirmation of adjustment parameters required for the selected ventilation mode, the ventilation will immediately start.
10. To change a parameter, select it on the screen. The parameter will become YELLOW indicating that is selected, allowing for changes to happen. Turn the knob clockwise to increase the value and counterclockwise to decrease. To confirm the change, press the knob or tap on the parameter on the screen.

Note

- Volume and respiratory rate parameters may also be set by selecting the CONFIG menu and setting the patient's height. The software will calculate these parameters by considering the ideal weight obtained according to the new inputted height.
- To access CONFIG menu, press anywhere on the graph screen and select CONFIG.

Press anywhere on the graph screen to bring up the secondary menu. A panel of buttons will be displayed for selection including graphs, measurements, settings, and alarms.

11. Press the ALARM button 

and the Alarm Setting screen will appear. Select the alarm to be set and use the knob and to change the value. When the desired value is set confirm pressing the knob. To return to the secondary menu with the selection of graphs, measurements, settings, and alarms, press the  button.

5.2.2 Test Sequence

These tests are essential to ensure that the equipment is operating as expected and to adjust for the best possible performance. Remember to conduct the initial tests before starting any ventilation.

WARNING

- ***Test Sequence must be performed with the patient disconnected.***

---

1. Home screen - Press the Test button and the sequence of auto tests will begin. Follow all the instructions on the screen.
2. Upon entering the home screen of the test sequence, you should hear a sequence of “beeps” in conjunction with the lighting of the light alarm indicator. If you do not hear the audible signal or do not see the light signal above the liquid Crystal display, press key NO; otherwise press YES to proceed to the next test.
3. By pressing the key “NO”, the message: “Device Failure” – Contact Technical assistance will appear. The equipment requests the connection of a y-connector and the flow sensor corresponding to the last patient type ventilated. Press Ok when this condition is carried out.
4. Tests will be carried out sequentially; and after each item, there is a report of pass (OK message) or fail (Failure message).

WARNING

If any test shows Failure perform the required repair (see

Table 34).

---

5. After the test phase of the proximal sensor, press NEXT to continue.
6. Occlusion of the breathing circuit in the “Y” after the flow sensor will be requested. Press OK to confirm that the circuit is properly occluded.

   Make sure that all the test items are APPROVED and check if the data for compliance, breathing circuit resistance and leakage value are suitable for use in the ventilator.

7. Select END to complete.
8. The system will automatically return to the home screen of the ventilator. From this point on, proceed with the normal startup of the ventilator.

5.2.3 Failure Diagnosis

Table *14:* shows the actions that can be taken to remedy any failures indicated in the test sequence. The consequence column indicates what may occur if the equipment is used with failure.

WARNING

- ***If “Device Failure” is indicated, the use of equipment with the presence of this failure is expressly not allowed; you should then contact the technical service to solve the problem.***

Note

- After performing repairs, you should restart the equipment and perform the sequence test again; if failure persists, contact technical assistance.

Table 14: Indications of fault diagnosis

Fault	Action	Consequence
O_2 Flow	Ensures that the oxygen supply pressure is according to the specification 15.3.2 Connecting to the Oxygen Supply	Lack of flow, use not allowed

Fault	Action	Consequence
Internal Sensor	Contact Technical Assistance	Failure in flow control, use not allowed
Air Flow+ O_2	Ensures that the oxygen supply pressure is according to the specification 15.3.2 Connecting to the Oxygen Supply	Lack of flow, use not allowed
O_2 Cell	Contact Technical Assistance	No warranty for O_2 Cell, use not allowed
Exhalation Valve	Check the positioning of the diaphragm in the Exhalation Valve	Failure in the pressure monitoring and control, use not allowed
Pressure Sensor	Check the positioning of the diaphragm in the Exhalation Valve, check leakage in breathing system	Failure in the pressure monitoring control, use not allowed
Proximal Sensor	Check connections of breathing circuit and flow sensor	- Alarm “Flow Sensor OFF” will be displayed when connection of this sensor is not identified; - There will be variation of up to 10% in the volume measures delivered; - Only monitors the parameters: Pmax, PEEP, Pplat., Pmean and Pressure x time chart; - Parameter flow trigger will be inactive;

6. Description of Modes

6.1. VCV – Volume Controlled Ventilation

Description:
In this mode, the ventilator controls the volume flow and cycle, i.e., at each inspiratory cycle the ventilator delivers a precise volume to the patient, so long that the pressure is not limited.

Set Parameters:

- VOLUME;
- R.RATE;
- RATIO I:E;
- PEEP;
- MAXIMUM PRESSURE;
- PAUSE INSP (%);
- FiO_2;
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- FLOW WAVE

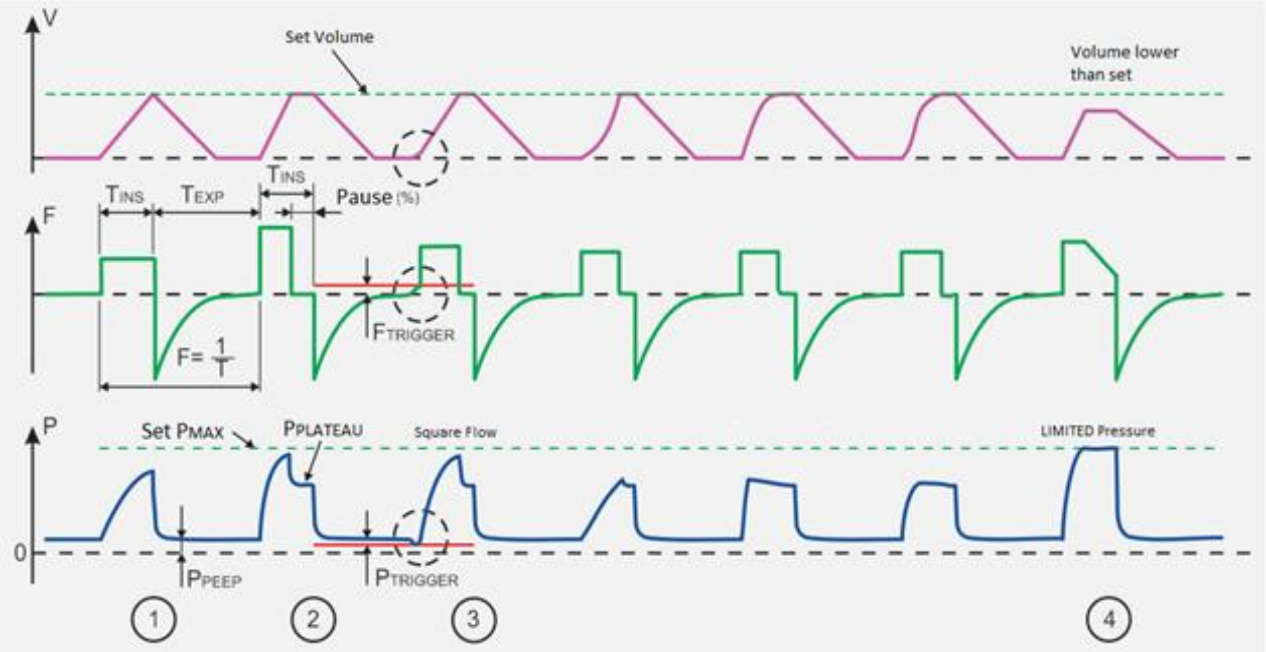


Figure 13: VCV Curves

Once all ventilation parameters are received by the ventilator, it calculates TINS, TEXP, TPAUSE, FINS based on Ratio I:E, Pause and Respiratory rate, thus obtaining all the ventilation control times.

1. Ventilation without Inspiratory Pause: after TINS, the ventilator cycles to exhalation. The inspiratory pressure achieved is a consequence of the volume delivered and the resistance and compliance of the patient's breathing circuit.
2. Ventilation with Inspiratory Pause: after delivery of the set volume, the ventilator maintains the exhalation paused until complete TINS, after which the ventilator cycles to exhalation. The feature is the pressure plateau formation (gap between peak and plateau depends on the airway resistance).
3. If the pressure or flow trigger is enabled, then the ventilator tries to synchronize the beginning of the next inspiration with patient effort, according to the levels established. The information of what type of trigger activated the inspiratory cycle is reported in the area of status and messages. The detection of patient's inspiratory effort for synchronization occurs at any time of the exhalation.

Note

- When the patient begins to demonstrate inspiratory effort and the ventilator has flow or pressure triggers activated, it starts to "assist" the patient. This situation is often called Assisted-Controlled Ventilation.
- In Assisted-Controlled Ventilation, the respiratory rate monitored can be higher than the respiratory rate set.
- In this mode, the inspiratory flow values depend on the settings of Vt, Rate and I:E. The Insp time values depend on the Rate and I:E adjustments.

4. Representation of Pressure Limitation. In this situation, the ventilator limits the pressure at the set value and as a result of factors such as the lung compliance of the patient and pressure limit imposed, the set volume IS NOT DELIVERED. This condition is reported in the status area and screen messages (message states PRESSURE LIMITED).

WARNING

- ***Upon reaching the pressure limit set in the Maximum Pressure setting (Message PRESSURE LIMITED) the Volume Set IS NOT DELIVERED.***
- ***Default values are only initial reference. Reset the ventilation parameters as needed by the patient.***

6.2. PCV – Pressure Controlled Ventilation

Description:

In this mode, the ventilator controls pressure and cycles on time, i.e., at each inspiratory cycle. The ventilator reaches the set pressure and remains at this level until the inspiratory time set has elapsed, the volume is, therefore, result of the physiology of the patient's lung (compliance and resistance). Usually when analyzing the flow curve, a flow peak is seen that decreases over time.

Set Parameters:

- PRESSURE CONTROL;
- R.RATE;
- RATIO I:E;
- PEEP;
- FiO_2;
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- RISE TIME;

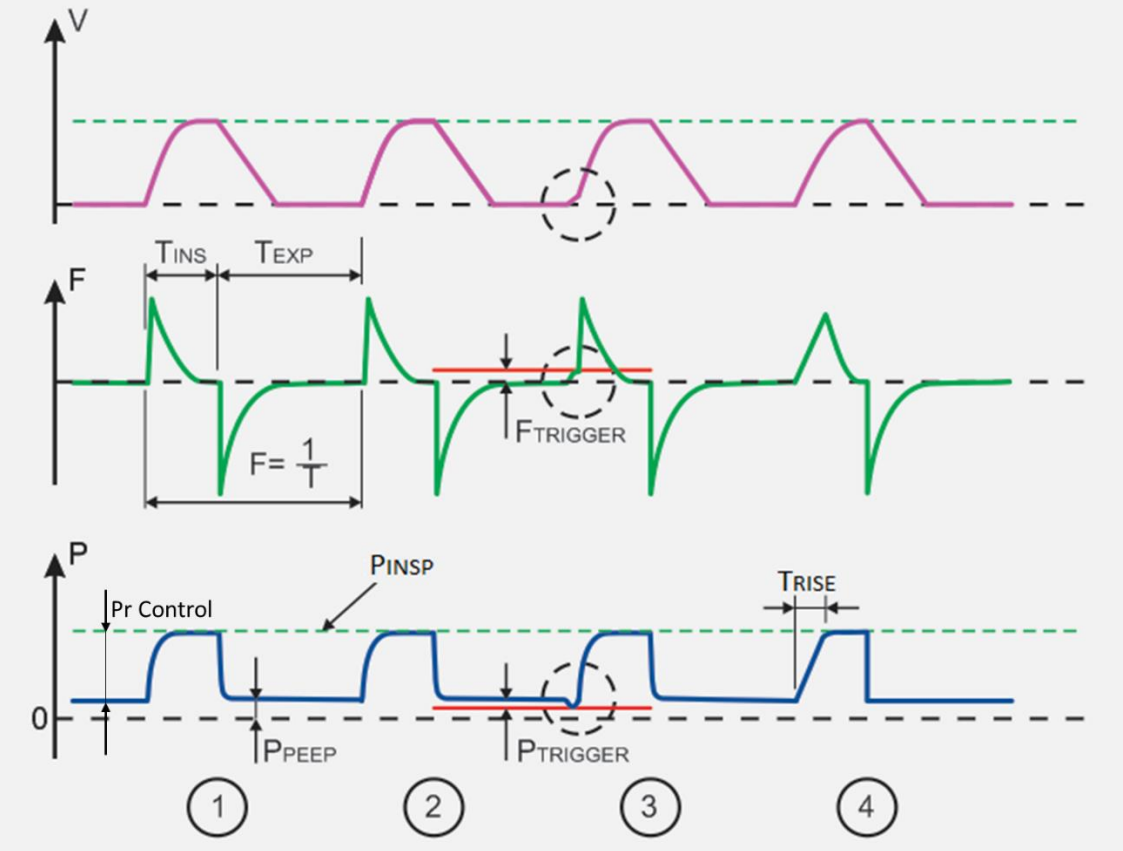


Figure 14: PCV Curves

Once all ventilation parameters are set on the ventilator, it calculates TINS, TEXP based on Rate and Ratio I:E; thus obtaining all ventilation control times.

1 and **2** Pressure Controlled Ventilation – The ventilator achieves the inspiratory pressure set in the shortest time possible, and this is accomplished by controlling the inspiratory flow. Volume delivered to the patient is the result of resistance and compliance of his breathing circuit. The ventilator remains at the inspiratory pressure level set during TINS after which cycles to exhalation, maintaining the PPE pressure set.

3 If the trigger by pressure or flow is activated, then the ventilator tries to synchronize the beginning of the next inspiration with the patient effort, according to the levels set. The information of what trigger activated the inspiratory cycle is reported in the status area and screen messages. The detection of patient's inspiratory effort for synchronization occurs at any time of the exhalation time.

Note

- When the patient begins to demonstrate inspiratory effort and the ventilator is with triggers by flow or pressure activated, it starts to "**assist**" the patient. This situation is often called Assisted-Controlled Ventilation.
- In Assisted-Controlled Ventilation, the monitored respiratory rate can be higher than the respiratory rate set.
- In this mode, the inspiratory time values depend on Rate and I:E adjustments.

---

4 The rise time for pressure can be adjusted by TRISE TIME, the initial peak flow is generally smaller than that in TRISE TIME=0 (depending on the resistance and compliance of patient breathing circuit).

WARNING

- ***Default values are only for initial reference. Reset the ventilation parameters as needed by the patient.***

6.3. V-SIMV – Synchronized Intermittent Mandatory Ventilation – Volume Controlled Cycle

Description:

In this mode, the patient can breathe spontaneously between the controlled cycles, with or without the use of pressure support. Controlled cycles are VCV (Volume Controlled).

Set Parameters:

- VOLUME;
- R.RATE;
- INSPIRATORY TIME;
- PEEP;
- MAXIMUM PRESSURE;
- PAUSE (%);
- FiO_2;
- ΔPS (Pressure support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- FLOW WAVE;
- CYCLING BY FLOW (% FLOW);
- RISE TIME

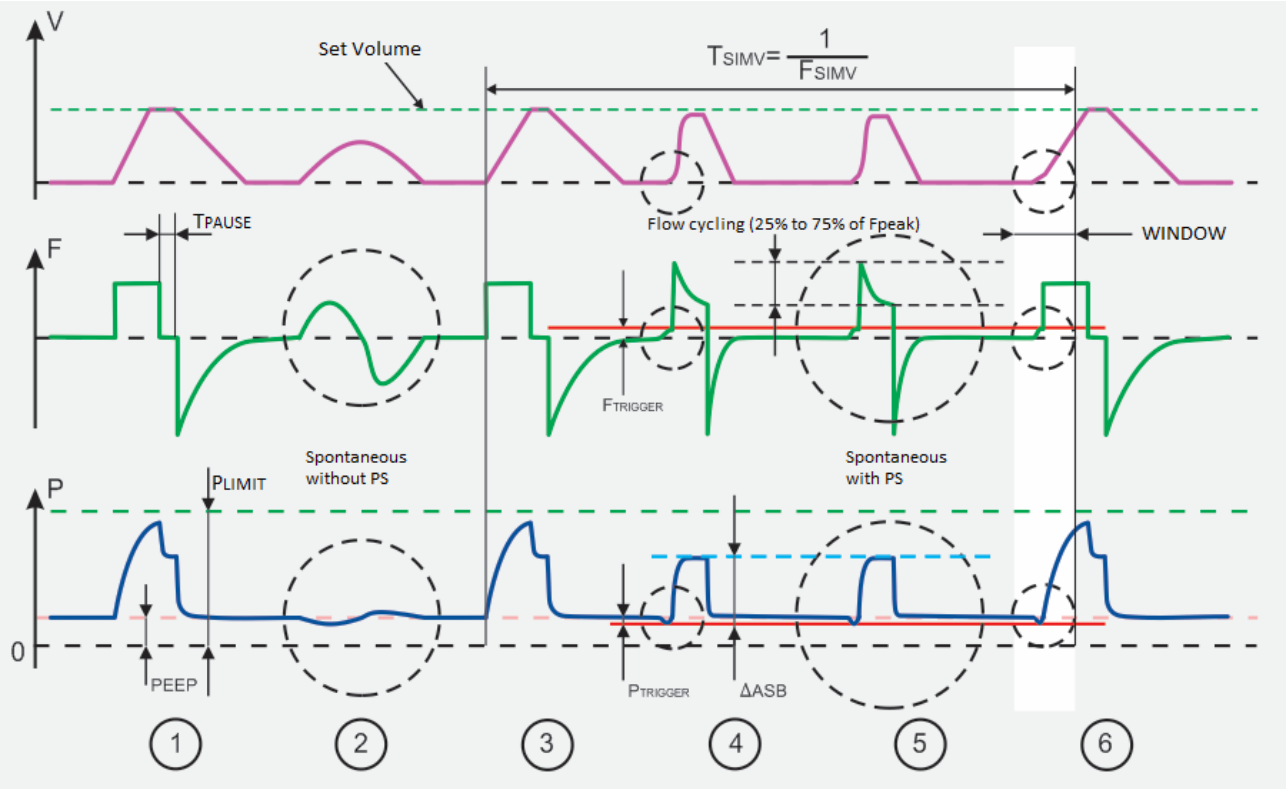


Figure 15: V-SIMV Curves

Once all ventilation parameters are set on the ventilator, it calculates TEXP and FINS based on Inspiratory Time, Pause and Rate, thus obtaining all ventilation control times.

1 Represents a VCV (volume controlled) cycle with inspiratory pause;

2 Represents a spontaneous breathing cycle of the patient WITHOUT PRESSURE SUPPORT;

3 Represents a VCV (volume controlled) cycle with SIMV Period elapsed;

4 and **5** Represents spontaneous breathing cycle of the patient WITH PRESSURE SUPPORT, with cycling occurring by flow, when this reaches a value between 5% and 80% of the peak value read. Peak flow percentage at which cycling of inspiratory phase occurs to the expiratory phase is programmable. The rise time (TRISE TIME) also applies to pressure support (see PCV).

6 If the patient performs inspiratory effort, at the end of the SIMV period (TSIMV), there is a window to the timing of controlled ventilation cycle, which is 'open' from 0.75 x TSIMV, i.e., the last quarter of SIMV Period a timing window opens for the mandatory ventilation cycle. The information of what type of trigger activated the inspiratory cycle is reported in the message area and screen status.

Note

- Respiratory rate monitored can be higher than respiratory rate set, because the patient can breathe spontaneously during the mandatory ventilation cycles.
- Pressure support (ΔPS) is a value above PEEP and can be adjusted between 5 cmH2O and PMAX-PEEP.

WARNING

- ***Default values are only for initial reference. Reset ventilation parameters as needed by the patient.***
- ***Volume ventilation must not to be used in patients without supervision.***

6.4. P-SIMV – Synchronized Intermittent Mandatory Ventilation – Pressure Controlled Cycle

Description:

In this mode, the patient can breathe spontaneously between the controlled cycles, with or without the use of pressure support. The controlled cycles will be PCV (Pressure Controlled).

Set Parameters:

- PRESSURE CONTROL;
- R.RATE;
- INSPIRATORY TIME;
- PEEP;
- FiO_2;
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- CYCLING BY FLOW (% FLOW);
- RISE TIME;

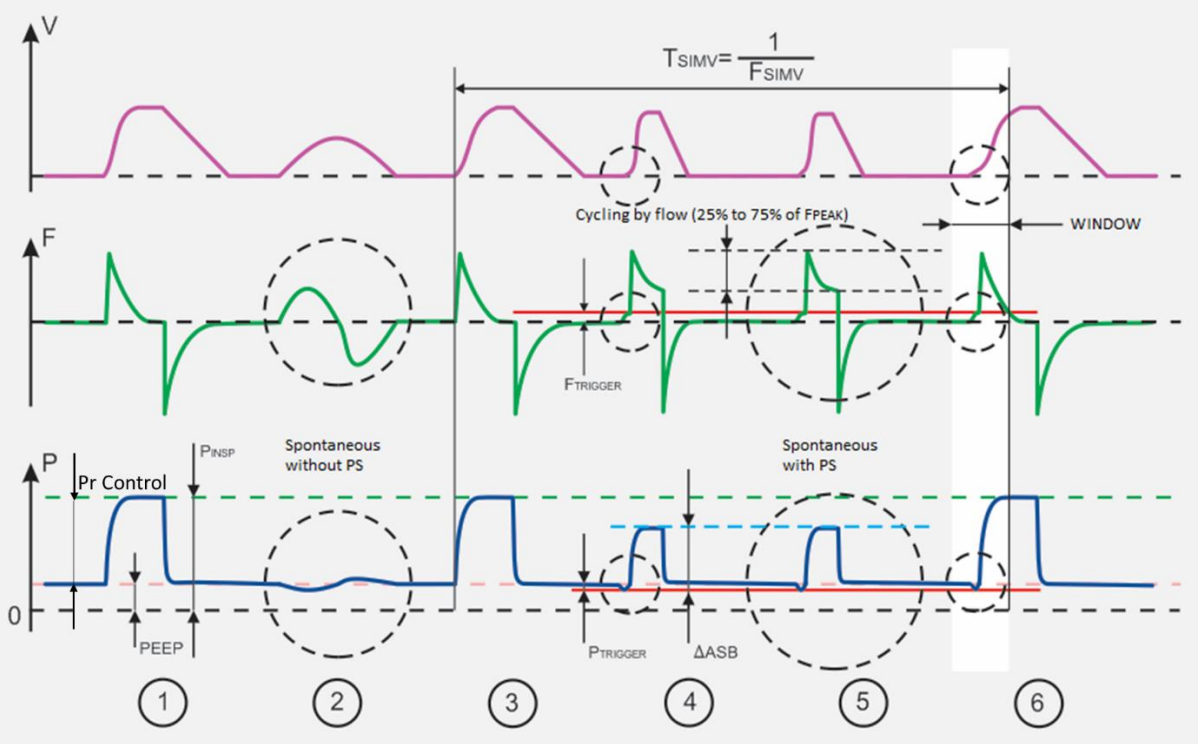


Figure 16 - P-SIMV Curves

Once all ventilation parameters are set on the ventilator, it calculates TEXP based on TINS and Rate, thus obtaining all ventilation control times.

1 Represents a PCV (pressure controlled) cycle during TINS;

2 Represents a spontaneous breathing cycle of the patient WITHOUT PRESSURE SUPPORT;

3 Represents a PCV (pressure controlled) cycle when SIMV Period has elapsed;

4 and **5** Represents the spontaneous breathing cycle of the patient WITH PRESSURE SUPPORT, with cycling occurring by flow, when this reaches a value between 5% and 80% of the peak value read. Percentage of peak flow in which cycling occurs from inspiratory phase to expiratory phase is programmable. Rise time (TRISE TIME) also applies to pressure support (see PCV).

6 If patient performs inspiratory effort, in the end of SIMV period (TSIMV), there is a timing window of the controlled ventilation cycle, which is 'open' from 0.75 x TSIMV, i.e., in the last quarter of SIMV Period, a timing window opens for the mandatory ventilation cycle. The information of what type of trigger activated the inspiratory cycle is reported in the message area and screen status.

WARNING

- ***Default values are only for initial reference. Reset ventilation parameters as needed by the patient.***

Note

- Respiratory rate monitored can be higher than respiratory rate set, because the patient can breathe spontaneously during mandatory ventilation cycles.
- Pressure support (ΔPS) is a value above PEEP and can be adjusted between + 5 cmH2O and PINSP - PEEP.

6.5. CPAP/PSV – Continuous Pressure Ventilation with Pressure Support

Description:

In this mode, the patient breathes spontaneously on a continuous positive pressure and breathing is assisted by a Pressure Support (ΔPS). Usually when analyzing the flow curve, a flow peak is seen which decreases over time.

Cycling occurs by flow, is adjustable between 5% and 80% peak inspiratory flow measured.

If the Pressure Support (ΔPS) value is set to 0 (ZERO) or both cycle trigger ways (pressure or flow) are disabled, pure CPAP mode will be activated, i.e., without pressure support. In this condition, PEEP parameter will be displayed as CPAP.

In this mode it is also possible to turn on the non-invasive ventilation by adjusting parameter NIV to ON in parameters adjust.

Set Parameters:

- PEEP or CPAP;
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- FiO_2;
- CYCLING BY FLOW (% FLOW);
- RISE TIME;
- BACK-UP MODE (VCV,PCV or WITHOUT BACK-UP)
- R.RATE (back-up VCV and PCV);
- RATIO I:E (back-up VCV and PCV);
- MAXIMUM PRESSURE (back-up VCV);
- VOLUME (back-up VCV);
- PAUSE (back-up VCV);
- FLOW WAVE (back-up VCV);
- PRESSURE CONTROL (back-up PCV)
- NIV (ON or OFF)

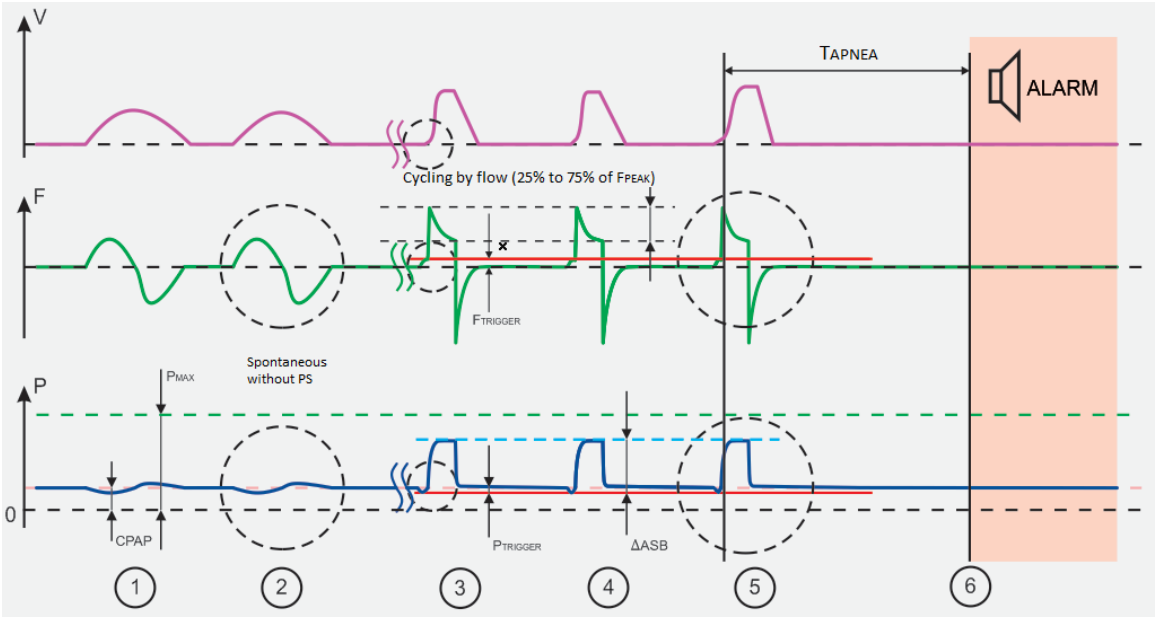


Figure 17: PSV (CPAP + ΔASB) Curves

1 and **2** Represent spontaneous cycles with pressure support at ZERO.

3, **4** and **5** Represent spontaneous breathing cycles of the patient with pressure support different from zero. RISE TIME of pressure support may be adjusted so that initial flow is smoothed.

6 If the patient enters in apnea, after TAPNEA (s) the ventilator will show this condition with alarm in its message area and alarms on screen and will initiate backup ventilation selected as settings and parameters programmed.

WARNING

- ***If backup ventilation selected is NO BACK-UP, the equipment operator must be aware of this situation (INDICATING ON DISPLAY).***
- ***Default values are only for initial reference. Reset the ventilation parameters as needed by the patient.***

Note

- Pressure support (ΔPS) is a value above PEEP and can be adjusted between + 5 cmH2O and PMAX - PEEP.
- To obtain CPAP mode with backup ventilation, select option CPAP/PSV, set ΔPS=OFF and select backup ventilation.

7. Alarms Available

All alarm setting referenced here is found in the technical specification chapter.

WARNING

- ***Alarms and Alerts should be treated promptly in order to maintain the operation integrity of the equipment and patient safety, as indicated in chapter 7.***
- ***While the audio volume is set to below the maximum level (5), if there is an alarm, the audio volume will gradually increase every 15 seconds until it reaches its maximum level.***
- ***Make sure that the volume adjusted for the audio of the alarms is compatible with the distance that the equipment will be from the clinicians.***

Note

- Whenever the equipment turns off and on, either in the end of the battery autonomy (after 4 hours in battery operation) or by user action, the alarm system returns to default values.

7.1. Description of alarm control

The alarm system of the Oxymag family ventilators is classified according to the degree of priority (low, medium, and high priority) as shown in table.

Table 15: Classification of alarms according to the priority level

HIGH PRIORITY	Delay Time	Description
Low Battery	< 1 second	It is triggered when the internal battery is with the charge in the end. The alarm is triggered at least 10 minutes before the battery ends. Provide appropriate means of ventilatory support to the patient
Apnea	< 1 second	It is triggered when the time elapsed since the last inspiration is greater than the value set for apnea alarm

HIGH PRIORITY	Delay Time	Description
Low Supply Press.	< 1 second	It is triggered when pressure of oxygen network is insufficient for equipment operation.
Obstruction	< 2 cycles	It is triggered when there is obstruction in the breathing circuit that prevents the complete expiration by the patient
Disconnection	< 5 cycles	It is triggered when there is disconnection of the breathing circuit, which prevents proper ventilation of the patient
High Airway Press.	< 2 cycles	It is triggered when the ventilation pressure exceeded the set alarm value as the upper limit of pressure
Low Airway Press.	< 2 cycles	It is triggered when the ventilation pressure is below the set alarm value as the lower limit of pressure
High Volume	< 3 cycles	It is triggered when the measured volume exceeded the alarm value set as the upper limit of volume
Low Volume	< 3 cycles	It is triggered when the measured volume exceeded the alarm value set as the lower limit of volume
FiO_2 below 18%	< 3 cycles	It is triggered when FiO_2 measured is lower than 18%
HW: High O2 int.	< 3 second	It is triggered when the internal Oxygen concentration rises above 25%, due to failure or leakage of any component

MEDIUM PRIORITY	Delay Time	Description
High MV	< 3 cycles	It is triggered when the minute volume of the patient has exceeded the alarm value set as upper limit of minute volume
Low MV	< 3 cycles	It is triggered when the minute volume of the patient is below the alarm value set as lower limit of minute volume
High R. Rate	< 3 cycles	It is triggered when the respiratory rate of the patient has exceeded the alarm value set as upper limit of the respiratory rate
Low R. Rate	< 3 cycles	It is triggered when the respiratory rate of the patient is below the alarm value set as lower limit of the respiratory rate
High PEEP	< 3 cycles	It is triggered when the pressure in the end of exhalation (PEEP) has exceeded the alarm value set as upper limit of PEEP
Low PEEP	< 3 cycles	It is triggered when the pressure in the end of exhalation (PEEP) is below the alarm value set as lower limit of PEEP
High Intern. Temp.	< 3 seconds	It is triggered when the internal temperature is above 50ºC (122 °F).
Low Intern. Temp.	< 3 seconds	It is triggered when the internal temperature is below --20°C (-4°F).
High FiO2	< 3 cycles	It is triggered when the measured FiO2 has exceeded the alarm value set as the upper limit of FiO2
Low FiO2	< 3 cycles	It is triggered when the measured FiO2 has exceeded the alarm value set as the lower limit of FiO2

LOW PRIORITY	Delay Time	Description
AC input fail	< 1 second	It is triggered when the equipment is disconnected from the electric mains and the power is switched to internal power supply.
Flow Sensor Off	< 3 cycles	It is displayed when the proximal flow sensor is disconnected. In this case, all monitoring depending on this sensor (VT, MV, Rate, Vins, Tinsp, I:E, T exp, Cest, Cdin, Res, τ , iT, Volume Leakage, VxTime Chart) will NOT be provided. In the volume-controlled ventilatory modes, the volume delivered by the equipment will have a variation of up to ±10%

Note

- When CPAP/PSV mode is configured with pressure support and apnea condition occurs, audible and visual alarm will be triggered; audible alarm will sound only two sequences of high-priority alarms; however, the visual alarm will continue to identify this condition while this exists.

Among the existing alarm conditions, there are alarms with non-adjustable parameters; these have unique characteristics for their activation, which will be described in the following topics.

a) Battery Alarm

This alarm is triggered when the internal battery has low charge left. In this condition, the value of voltage found in the internal battery is below the limit established as essential for the proper operation of the equipment. In this case, an alternative energy source must be provided immediately. The alarm will be re-initialized when connected to a source of A.C. power or external D.C.

Note

- The actual remaining time will depend on the battery condition and parameters used in the ventilator.

b) Disconnection alarm

The disconnection alarm is triggered when any kind of disconnection from the breathing circuit occurs, which would prevent proper ventilation to the patient. In this case, there are two criteria to check the disconnection. The first criterion is based on the measured values of positive end-expiratory pressure (PEEP). When the airway pressure during exhalation is below the value set for PEEP, the ventilator records the measured values and, when reaching a threshold value, triggers the disconnection alarm. The second criterion for this alarm is based on the measured values for compliance. In this case, the alarm goes off when compliance records a value above the maximum allowed (200 mL/cmH20) or does not identify when a variation of natural internal pressure occurs when delivering a certain volume of air to a breathing circuit.

c) Obstruction alarm

The obstruction alarm is triggered when there is some form of obstruction in the breathing circuit preventing full exhalation of the patient. The criterion to trigger this alarm is based on the ratio of average values from PEEP and pressure limit (Pmax). When the pressure value is above the average of the reference parameters (PEEP and Pmax), the alarm is triggered.

d) O_2 pressure alarm

The O_2 pressure alarm is triggered when the pressure in the oxygen network is below than 30 psi (207 kPa).

Table 16: Alert Messages

Alert	Delay Time	Description
PRESSURE LIMITED	< 1 second	It is displayed when the monitored pressure reaches the set maximum pressure. In this case, the volume delivered by the ventilator will not reach the set volume
Assist. Fl. Trig	< 1 second	It is displayed in the event of an assisted trigger generated by a flow trigger
Assist. Pr. Trig	< 1 second	It is displayed in the event of an assisted trigger generated by a pressure trigger
Assist. Man. Trig	< 1 second	It is displayed in the event of an assisted trigger generated by a Manual trigger

Alert	Delay Time	Description
Spont. Fl. Trig	< 1 second	It is displayed in the event of a spontaneous trigger generated by a flow trigger
Spont. Pr. Trig	< 1 second	It is displayed in the event of a spontaneous trigger generated by a pressure trigger
Spont. Man. Trig	< 1 second	It is displayed in the event of a spontaneous trigger generated by a Manual trigger

WARNING

- ***The default values of alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***Automatic Adjustment of alarm limits set the alarms to a percentage calculated on the value monitored during ventilation; thus, it can only be adjusted when the ventilator is NOT in standby mode.***
- ***Do not use the equipment if a problem cannot be resolved.***

Note

- In CPAP/PSV mode apnea OFF is not available.

Table 17: Troubleshooting

Problem	Possible Causes	Solutions
Low Battery Alarm	1. End of charge of the internal battery after use without mains;	1. Immediately restore the connection of the equipment to a power grid or turn off the equipment and provide means of ventilatory support to the patient;
		2. If is not possible to connect the equipment to a power grid or if there is no power grid for long periods, the user has at least 10 minutes of battery autonomy to provide alternative means of ventilation. In this case, provide an ambu bag to ventilate the patient or use another ventilator with the internal battery full charged.
	2. Failure in the charging system of the internal battery, even with the presence of electric power;	1. Provide an ambu bag to ventilate the patient or use another ventilator with the internal battery full charged.
		2. Contact Technical Assistance / Magnamed;
AC input fail alarm	1. Disconnection to the power cord;	1. Restore connection of the equipment to a power grid or use the equipment with internal battery for transportation;
	2. Failure in the electrical grid;	2. Restore power grid;
		2. If is not possible to connect the equipment to a power grid or if there is no power grid for long periods, the user has 6,5 hours of battery autonomy to provide alternative means of ventilation. In this case, provide an ambu bag to ventilate the patient or use another ventilator with the internal battery full charged.

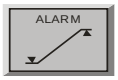
Problem	Possible Causes	Solutions
Device Failure Alarm	Electronic failure	Contact Technical Assistance / Magnamed
Disconnection Alarm	1. Disconnection in the breathing circuit;	1. Locate the disconnection and connect securely;
	2. Lack of Inspiratory Flow;	2. Check if there is inspiratory flow and increase, if necessary;
	3. Change in the Patient's Respiratory Mechanics;	3. Set new parameters for ventilatory support;
	4. Diaphragm of exhalation valve mounted incorrectly or damaged;	4. Replace the diaphragm in the correct position or replace diaphragm with a new one;
	5. Failure in the electronic system of pressure control;	5. Contact Technical Assistance / Magnamed
	6. Circuit integrity	6. Check circuit integrity and replace circuit if necessary
Low Airway Press. Alarm	1. Change in Patient's Respiratory Mechanics;	1. Set new parameters for ventilatory support;
	2. Excessive leakage in the breathing circuit;	2. Locate the leak and correct it;
High Airway Press. Alarm	1. Change in the Patient's Respiratory Mechanics;	1. Set new parameters for ventilatory support;
	2. Obstruction in the expiratory limb of the breathing circuit or exhalation valve;	2. Clear it;
	3. Obstruction of the airway of the patient;	3. Clear or aspirate the airway of the patient;

Problem	Possible Causes	Solutions
Apnea alarm	1. Spontaneous breathing of the patient was interrupted 2. Adjusted apnea time is greater than the patient's respiratory rate.	1. Change the ventilation mode from spontaneous to assisted-controlled. 2. Increase the adjusted apnea time or decrease the patient's respiratory rate.
Low Supply Press. alarm	1. Pressure of the O_2 supply is low 2. O_2 hose is not connected to the equipment 3. O_2 Pressure Sensor Failure	1. Increase the O_2 supply pressure or change the O_2 cylinder. 2. Connect the O_2 hose to the device. 3. Contact Magnamed Technical Assistance.
Obstruction alarm	1. Inspiratory or expiratory branch obstructed 2. Patient's airway obstruction	1. Clear it; 2. Clear or aspirate the patient's airway.
High Volume alarm	1. Expired volume is greater than the set alarm limit. 2. Flow sensor is out of calibration.	1. Change the parameters set in ventilation mode or set the upper limit of the volume alarm. 2. Perform self-test.
Low Volume alarm	1. Expired volume is less than the set alarm limit. 2. Flow sensor is out of calibration.	1. Change the parameters set in ventilation mode or adjust the lower limit of the volume alarm. 2. Perform self-test.
High FiO_2 alarm	1. FiO_2 adjust is above alarm limit; 2. O_2 cell is out of calibration; 3. Damaged O_2 cell.	1. Change the set FiO_2 or upper alarm limit; 2. Calibrate O_2 cell; 3. Contact Magnamed Technical Assistance.
Low FiO_2 alarm	1. FiO_2 adjust is below alarm limit; 2. O_2 cell is out of calibration; 3. Damaged O_2 cell.	1. Change the set FiO_2 or lower alarm limit; 2. Calibrate O_2 cell; 3. Contact Magnamed Technical Assistance.

Problem	Possible Causes	Solutions
FiO_2 below 18% alarm	1. O_2 concentration delivered to the inner patient at 18%. 2. Unbalanced O_2 cell. 3. Damaged O_2 cell.	1. Check the O_2 net or cylinder. 2. Calibrate O_2 cell. 3. Contact Magnamed Technical Assistance.
High MV alarm	1. Volume delivered and delivered respiratory rate are above alarm limit.	1. Change the adjusted parameters of the ventilation mode or set the upper limit of the minute volume alarm.
Low MV alarm	1. The delivered volume ratio and respiratory rate are below the alarm limit.	1. Change the adjusted parameters of the ventilation mode or adjust the lower limit of the minute volume alarm.
High R. Rate alarm	1. Patient's respiratory rate is above alarm limit. 2. Adjusted sensitivity is causing self-triggering.	1. Change the set respiratory rate or change the upper alarm limit. 2. Change the trigger setting.
Low R. Rate alarm	1. Patient respiratory rate is below alarm limit. 2. Adjusted trigger is too high and the ventilator does not recognize patient effort.	1. Change the adjusted respiratory rate or change the lower alarm limit. 2. Change the trigger setting.
High PEEP alarm	1. Monitored PEEP is above alarm limit. 2. Obstruction in the patient's breathing circuit.	1. Change the adjusted PEEP or change the upper alarm limit. 2. Clear it.
Low PEEP alarm	1. Monitored PEEP is below alarm limit. 2. Leak in patient circuit.	1. Change the adjusted PEEP or change the lower alarm limit. 2. Locate the leak and correct.
High internal temperature	1. The ventilator is placed in an environment above 50 °C (122 °F). 2. Microcontroller is overheated.	1. Move the equipment to a cooler environment. 2. Contact Magnamed Technical Assistance.
Low internal temperature	1. The ventilator is placed in an environment below -20°C (-4°F).	1. Move the equipment to a warmer environment.

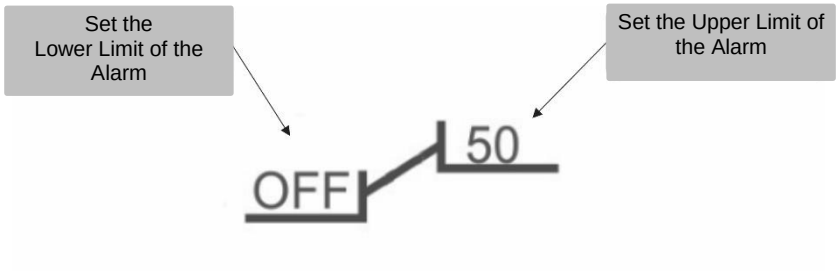
Problem	Possible Causes	Solutions
HW: High O2 int.	1. Cooler's filter is saturated 2. Internal leakage of O2	1. Replace the cooler's filter 2. Contact Magnamed Technical Assistance

7.2. Setting Alarms

To enter the alarm setting screen, press ALARM button 

on the secondary menu screen. One of the screens of the following table will be presented:

1. Position of the settings of lower and upper limits on the alarm screen:



To change the alarm values just select the area corresponding to the alarm limit to be set. The parameter selected will be highlighted indicating that is ready to change; in this case, use the knob button to set the desired value and confirm by pressing this button or by touching again on the selected parameter.

7.3. Alarm Test

7.3.1. Adjustable Alarm Test

To perform the alarm testing, a breathing circuit and a lung simulator balloon are required.

Caution

- Never perform alarm testing with the patient connected to the equipment.

7.3.1.1. Pressure alarm

To test the high-pressure alarm, enter PCV mode, set PEEP to zero, Pr insp to 5 and set the upper limit of the Ppeak alarm to 5. Set up the complete circuit, ventilate and press the test balloon so that the monitored pressure is greater than the set pressure. To test the low-pressure alarm, set the lower limit of the pressure alarm so that it is higher than the pressure monitored on the device.

7.3.1.2. PEEP alarm

To test the high PEEP alarm, set the upper PEEP alarm limit so that it is lower than the PEEP monitored on the device. To test the low PEEP alarm, set the lower limit of the PEEP alarm so that it is higher than the PEEP monitored on the device.

7.3.1.3. Minute volume alarm (MV)

To test the operation of the high minute volume alarm, set the upper limit of the minute volume alarm so that it is less than the minute volume monitored on the unit. To test the operation of the low minute volume alarm, set the lower limit of the minute volume alarm so that it is greater than the minute volume monitored on the unit.

7.3.1.4. Respiratory Rate alarm

To test the operation of the high respiratory rate alarm, set the upper limit of the respiratory rate alarm so that it is lower than the monitored respiratory rate on the device. To test the operation of the low respiratory rate alarm, set the lower limit of the respiratory rate alarm so that it is higher than the respiratory rate monitored on the device.

7.3.1.5. Volume alarm

To test the high-volume alarm, set the upper limit of the volume alarm so that it is lower than the tidal volume set on the device. To test the low volume alarm, set the lower limit of the volume alarm so that it is higher than the inspiratory volume monitored on the device.

7.3.1.6. Apnea alarm

To test the apnea alarm, set the apnea alarm time to 3 seconds and in ventilatory mode, a low respiratory rate. Place the ventilator in normal operation and wait for the time set for the alarm to occur.

7.3.1.7. FiO_2 alarm

To test the high FiO_2 alarm, set the upper limit of the FiO_2 alarm so that it is lower than the FiO_2 set on the device. To test the low FiO_2 alarm, set the lower limit of the FiO_2 alarm so that it is higher than the FiO_2 monitored on the device.

7.3.2. Critical alarm test

7.3.2.1. Disconnection

To test the disconnection alarm, select the patient and set the desired mode. Start ventilation and disconnect any point in the patient's circuit: inspiratory branch, expiratory branch, or Y connector. The high priority disconnection alarm should occur.

7.3.2.2. No AC power

To test the alarm without a power supply, put the ventilator in normal operation and disconnect the device from the power supply. The alarm without a low priority mains voltage should occur.

7.3.2.3. Low battery

To test the low battery alarm, put the ventilator in normal operation and disconnect the device from the mains and start ventilation. Wait until the battery level reaches a critical level for low battery, high priority alarm to occur.

7.3.2.4. Obstruction

To test the obstruction alarm, place the ventilator in normal operation and press the expiratory branches of the patient circuit in order to simulate the obstruction and observe the activation of the high priority alarm.

7.3.2.5. Low Supply Press.

To test the low O_2 pressure alarm, put the ventilator in normal operation, disconnect the oxygen source from the ventilator and observe the activation of the high priority alarm.

7.4. Manual Ventilation of the Patient

To perform manual ventilation to a patient, the ventilator must be on STAND-BY. In this situation, if the flow sensor is connected to the patient's breathing circuit, the monitoring of ventilation will be fully operational, including its alarm system.

8. Cleaning and Disinfection

8.1. Introduction

This chapter provides information about ventilator maintenance procedures, as well as cleaning and disinfection instructions. All the procedures in this chapter are to be performed by the operator.

The breathing circuit should be disassembled and discarded after each patient use or as needed, and the ventilator should be cleaned, and then disinfected, using the cleaning methods and specifics solutions as indicated in chapter 9. All the process can take approximately 20 minutes.

WARNING

- ***After cleaning and decontaminating parts, be sure to perform all required tests as described in chapters 4 and 5.***

8.2. Equipment cleaning

External ventilator surfaces of the Oxymag, supply hose, touch screen, power supply and power cables, should be cleaned with a clean, soft cloth moistened with enzymatic detergents (e.g., Empower), after each patient use, or as needed.

To clean the equipment parts:

1. Disassemble all detachable parts

a) Disconnect the Expiratory Valve and the diaphragm with the expiratory limb.

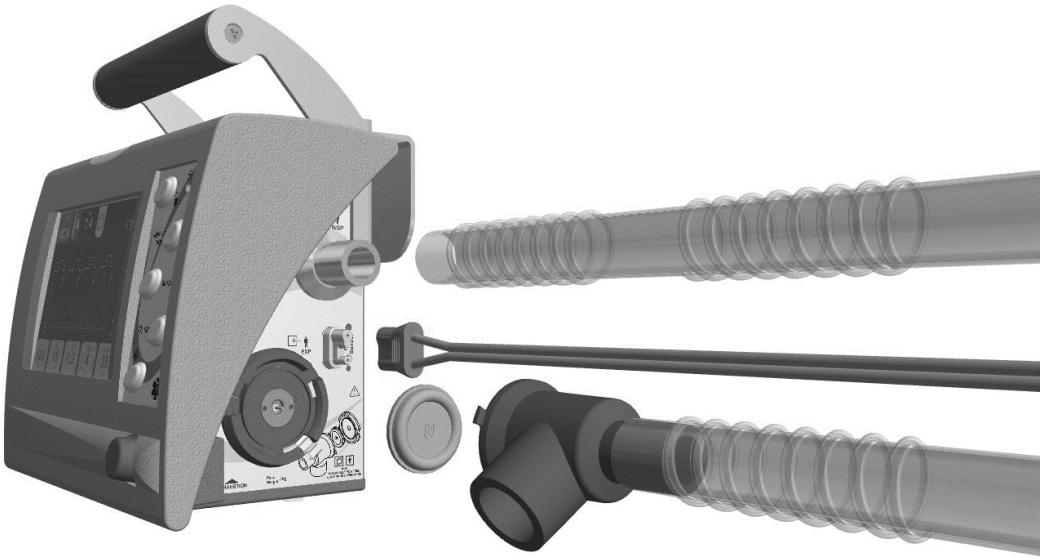
Caution

- To unlock the valve, press the locking valve and turn the valve counterclockwise.

b) Disconnect the inspiratory limb.

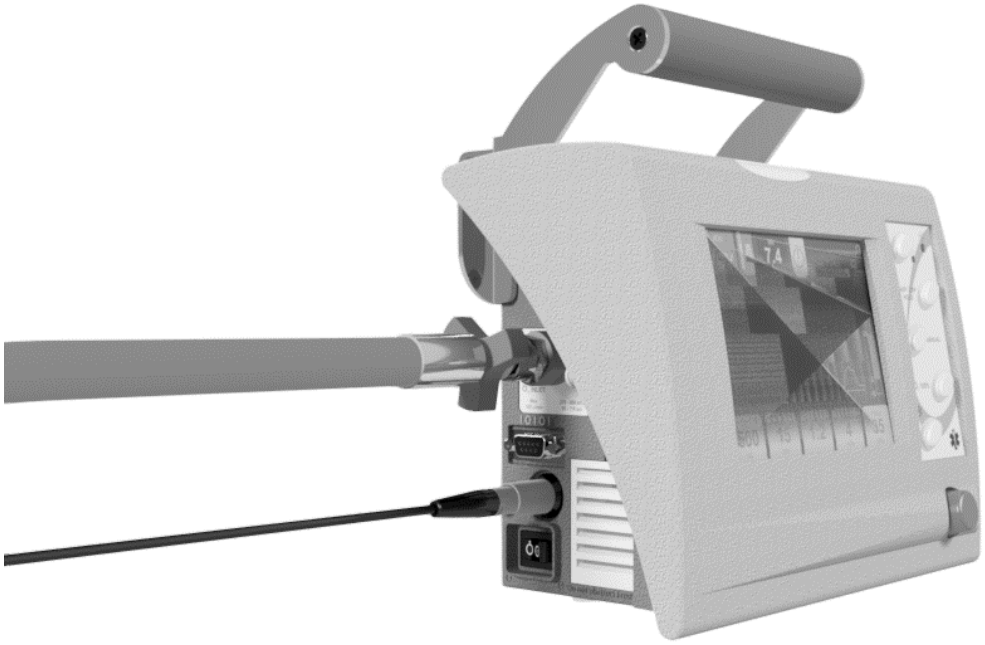
c) Disconnect the flow sensor line.

d) Discard all parts of the breathing circuit.



d) Disconnect the oxygen hose.

e) Disconnect the power supply AC/DC.



2. Prepare a solution with enzymatic detergent and warm water. Check the concentration in the manufacturer´s recommendations.

3. Dampen a lint-free cloth.

4. Wipe the surfaces areas on the product and parts and remove exterior impurities by carefully scrubbing the grooves in the screws, the hole of inspiratory flow connector and the expiratory flow connector with a soft cloth. Repeat the cleaning process if there are still any visible impurities.

5. Inspect all areas, and replace if it is damaged or if there is evidence of corrosion
6. Continue with the disinfection procedure. Examples of acceptable cleaning products: • Empower, Manufacturer: Metrex Research

WARNING

- ***Breathing circuit is single use. Do not reuse, because any reuse may cause cross contamination.***
- ***Do not allow blood or bodily fluids to dry on the equipment for more than 1 hour.***

8.3. Disinfection

External ventilator surfaces of Oxymag, the supply hose, touch screen power supply and power cables, should be cleaned with a clean, soft cloth moistened with a registered and approved Ethyl alcohol (70%) or disinfectant spray cleaner, after each patient use or as needed. The whole process can take approximately 20 minutes.

To disinfect the Equipment:

1. First, execute the cleaning process.
2. Do not re-assemble the detached parts
3. Use Ethyl alcohol (70%) or disinfectant spray cleaner and dampen a lint-free cloth. Or use disinfectant wipes ready for use.
4. Disinfect the surfaces areas on the product and parts.
5. Inspect all areas, and replace if damaged/corrosion
6. Reassemble, prepare, and perform all required tests described in Chapters 4 and 5.

Examples of acceptable disinfectant products:

- Caviwipes 1, Manufacturer: Metrex Research EPA Reg. No. 46781-13
- MetriGuard, Manufacturer: Metrex Research EPA Reg. No. 46781-6

These cleaning and disinfecting agents have been tested according to the manufacturers' guidelines. If you have any questions about the use of a particular cleaning or disinfection agent, contact the manufacturer of the cleaning agent.

Caution

- Ensure that no residue builds up in the connections of the equipment.
- Do not clean/disinfect the interior of the ventilator to avoid damaging any internal components.
- Be sure to only clean around the connection ports, not inside them.
- For touch screen cleaning, avoid using a gritty cloth.
- DO NOT clean/disinfect the interior of the ventilator.
- Make sure that the equipment is turned off prior to cleaning the display.

WARNING

- ***This equipment shall go through a cleaning and disinfection process every time it is used.***
- ***Do not reuse disposable parts. Reusing single use products can affect the product properties and may cause injury to the patient.***
- ***To prevent premature deterioration of parts, use only registered and approved cleaning and disinfection solutions, as recommended by the manufacturer in chapter 8.***

9. Preventive Maintenance

Caution

- Oxymag should only have maintenance performed by a qualified technician, trained, and authorized by MAGNAMED. Failure to comply will void the manufacturer's warranty and obligations regarding the ventilator.
- Oxymag must pass annual periodic maintenance (every 1 year) or after 5000 hours, whichever comes first. Failure to perform maintenance could affect the safety and performance of the ventilator.
- All maintenance shall be done with the patient disconnected from the equipment.

9.1. Indication of the need for periodic maintenance

The equipment will display on the home screen the preventive maintenance symbol  when 5000 hours or more had passed since the last maintenance.

9.2. Internal Lithium Battery

This battery is Responsible to power the equipment in the absence of electricity and its duration in normal operation is specified in 12.3.1 Electrical Characteristics.

WARNING

- ***This equipment shall remain connected to the power grid whenever it is possible, so that there is sufficient charge during a power outage or to transport the patient.***

Caution

- The battery must be replaced as indicated in the technical specifications so that capacity in normal operation.
- Replacement of internal battery should be performed only by a qualified technician, trained, and authorized by MAGNAMED.
- Battery should always be checked in periodic maintenance.

9.3. Internal Sensor of O_2 Concentration

The oxygen concentration sensor is a cell that generates electrical signal proportional to the oxygen concentration in the gas mixture administered to the patient and the intensity of this electrical signal is due to the chemical reaction.

Caution

- The galvanic O_2 cell undergoes less than 1% per month degradation in measurement accuracy.
- The oxygen concentration sensor should be replaced as indicated in the Technical Specification and shall be performed only by a qualified technician, trained and authorized by MAGNAMED.

9.4. Replacing the Ambient Air Filter

The ambient air filter shall be replaced after 500 hours of use. To replace the ambient air filter, follow the procedure below:

Figure 18: Example for exchanging air filter

(1) Remove the filter cover on the left side of the ventilator.
(2) Remove the old filter.
(3) Clean the filter area.

Caution

- Do not use compressed air for cleaning, as this may introduce dust and dirt in the gas mixing system.

(4) After drying, introduce a new filter.
(5) Install the filter cover and check that it is firmly closed.

WARNING

- ***The filter, when saturated, generates an increase in the resistance of the ambient air inflow and can lead to not satisfying the minimum concentrations. In this case, replace the filter.***
- ***Replace the filter when it is clogged so that it does not slow down the inlet flow of the equipment.***

Caution

- Do not operate the equipment without this filter, because it may damage the system controlling the air/oxygen mixture.

9.5. Shipping the Product to Repair Service

Products should be cleaned and disinfected as directed in this manual Cleaning and Disinfection (chapter 8) before being sent for repair service. Products showing signs of potential hospital contaminants will be returned without repair service so that it can be disinfected prior to the service.

WARNING

- ***When sending Oxymag for maintenance or repair services: closely follow the disinfection process.***
- ***Equipment visibly contaminated by patients' fluid will be returned without performing maintenance or repair service.***

9.6. Replacing the cooler's filter

The cooler's filter shall be replaced after 500 hours of use. To replace the cooler's filter, follow the procedure below:

Figure 19: Example for exchanging the cooler filter

(1) Remove the filter cover on the back side of the ventilator.

(2) Remove the old filter.

(3) Clean the filter area

(4) After drying, introduce a new filter.

(5) Install the filter cover and check that it is firmly closed.

10. Disposal

The Oxymag ventilator should be disposed of as any electrical equipment. Accessories and consumables should be disposed of as described in the instructions for use. Follow local government recommendations for proper disposal.

Caution

- When discarding ventilator components, treat components that might have been contaminated as biohazardous waste.
- Disposal of batteries shall comply with local regulations.
- Disposal of galvanic cells shall comply with local regulations.

11. Turning off the Equipment

The lung ventilator Oxymag is a life support equipment and MUST be disconnected from the patient to be turned off. The equipment should be turned off by pressing the on/off switch, identified in Figure 4. When the equipment is turned off, a continuous audio signal will be produced indicating that the equipment has been turned off. To end the continuous audio signal, press the turn-confirm knob/button, identified in Figure 1.

12. Technical Specification

12.1. Classification

- IEC – 60601

  Class II Equipment, energized internally, BF-type for continuous operation. Protected against the ingress of solid foreign objects > 2.5 mm or bigger and splash-proof equipment - IP34.

- FDA Regulation: 868.5925 – Powered emergency ventilator:
  Classification: Class II
  Identification: A powered emergency ventilator is a demand valve or inhalator intended to provide emergency respiratory support by means of a face mask or a tube inserted into a patient's airway.

12.2. Standards

- **ISO 5356-1** – Anesthetic and respiratory equipment – Conical connectors – Part1: Cones and sockets
- **ISO 14971:2019** - Medical devices — Application of risk management to medical devices
- **IEC 60601-1 Ed. 3.0 (2005) + Amd. 1 (2012) (EN 60601-1:2006 + A1: 2013)** – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **ISO 5359:2008/Amd 1:2011 (EN ISO 5359:2008+A1:2011)** – Low-pressure hose assemblies for use with medical gases
- **IEC 60601-1-2 Ed. 4.0 (2014) (EN 60601-1-2:2015)** – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- **IEC 62304:2006 +AMD1:2015 (EN 62304:2006/2008)** – Medical device software - Software life cycle processes
- **IEC 60601-1-8 Ed. 2.0 (2006)/A1:2012 (EN 60601-1-8:2007/A11:2017)** – 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

- **IEC 60601-1-6:2010 (EN 60601-1-6:2010)** – Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 62366:2007 (EN 62366:2008)** – Medical devices - Application of usability engineering to medical devices
- **EN 1041:2008** – Information supplied by the manufacturer of medical devices
- **ISO 15223-1:2016 (EN ISO 15223-1:2016)** – Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- **ISO 80601-2-55:2018** – Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- **60601-1-12 Ed. 1.0: 2015:** Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- **ISO 10993-1:2018 -** Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- **ISO 5367:2014** Anesthetic and respiratory equipment — Breathing sets and connectors
- **ISO 80601-2-12:2011** - Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators [Including: Technical Corrigendum 1 (2011)]
- **IEC 62133-1:2017 -** Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells and for batteries made from them for use in portable applications - Part 1: Nickel systems
- **IEC 60529:1989 + AMD1: 1999** - Degrees of protection provided by enclosures (IP Code)
- **AIM 7351731** - Medical Electrical Equipment and System Electromagnetic Immunity Test for RFID Readers

- **ISO 18562-1:2017** - Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process
- **ISO 18562-2:2017 -** Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 2: Tests for emissions of particulate matter
- **ISO 18562-3:2017 -** Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 3: Tests for emissions of volatile organic compounds (VOCs)
- **ISO 18562-4:2017 -** Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 4: Tests for leachables in condensate

12.3. Specifications

The transport electronic lung ventilator consists of the following components:

- 320 x 240 points color Liquid Crystal DISPLAY LCD 5.7” graphic with touch screen;
- Control Board with:
    - Data presentation on the display;
    - Serial interface RS-232C for software update;
    - Remote Diagnostics and Remote Assistance Magnamed (ARM);
    - Quick access keys for:
        - ✓ HOLD;
        - ✓ O_2 100%;
        - ✓ FREEZE;
        - ✓ MANUAL (Manual Trigger of Inspiratory Cycle);
        - ✓ LOCK (Lock key);
    - Pressure Reading in the breathing circuit;
    - Smart battery charger;
- Speaker for alarms and alerts;
- High brightness RED LED for quick Identification of alarms;
- GREEN LED indicator of connection to the electrical grid;
- Connection to AC/DC External Source (100-240 VAC – 47.5 – 63 Hz +12 VDC);
- On/off switch;

- Breathing Circuit
- Galvanic cell internal O_2;
- External source AC/DC converter AC/DC 100 – 240 VAC to +12 VDC;
- Plastic Cabinet in high impact ABS resistant to blows;
- PEEP valve integrated in the equipment.
- Automatic barometric pressure compensation.
- Gas supply reading
- Protection fuses for fixation support and pedestal: Voltage 250V; Current 3A; Operating speed: Medium; Breaking Capacity 100 A, Size: 5mm x 20mm, Quantity: 2.

12.3.1. Electrical Characteristics

Table 18: AC/DC Converter Source – External (2402568 – POWER SUPPLY 12V WITH 4-WAY CONNECTOR)

Item	Parameter	Specification	Tolerance	Unit
1	Power Grid (47.5/63Hz)	100 – 240	± 10%	V_{AC}
2	Maximum Power Consumed	40	± 10%	W
3	Output 12V_{DC} – 4 -way	12	± 10%	V_{DC}
4	Current	3.34	---	A

Table 19: Internal Li-Ion Battery

Item	Parameter		Specification	Tolerance	Unit
1	Internal Li-Ion Battery 11.8V_{DC}		4000	± 15%	mAh
2	Run time (with full load and normal use)		390	± 15%	Min
3	Charging time (module under operation) (1) (2)		240	± 15%	Min
4	Dimensions	Height	36	---	mm
		Width	68,1	---	mm
		Length	54	---	mm
5	Number of charge cycles		500	---	cycles

Item	Parameter	Specification	Tolerance	Unit
6	Service life	2	---	years

(1) The battery should be charged at room temperature, 5 - 35 ºC (41 °F – 95 °F).
(2) During the charge of the battery, the performance of the equipment is not affected.

Table 20: Run time for adult, child and infant conditions

Patient	Condition	Run time	Tolerance
Adult	Volume Tidal 500ml, Set rate 10 min-¹, Relation I:E 1:2, BAP 10cmH2O, Resistance 5hps (l/s)-¹ , Compliance 50ml hPa -¹	406 minutes	± 15%
Child	Volume Tidal 150ml, Set rate 20 min-¹, Relation I:E 1:2, BAP 10cmH2O, Resistance 20hps (l/s)-¹ , Compliance 20ml hPa -¹	398 minutes	± 15%
Infant	Volume Tidal 50ml, Set rate 30 min-¹, Relation I:E 1:2, BAP 10cmH2O, Resistance 50hps (l/s)-¹ , Compliance 1ml hPa -¹	415 minutes	± 15%

- Electromagnetic Compatibility:
  - Immunity: IEC 60601-1-2
  - Emission: CISPR11
  - Approvals: OS/IEC 60601-1
- Class IIb – According to CE/93/42/CEE annex IX;
- Protection Class of Breathing Accessories (Disposable or Reusable): BF type  (Body Floating).

12.3.2. Connecting to the Oxygen Supply

- Oxygen Inlet – DISS as per CGA V-5
  - OPTIONAL –NIST Thread
- Gas pressure: 39 - 87 psi (280 - 600 kPa) (1)
- Hoses and Extensions: As per EN ISO 5359:2008/A1:2011
- The aluminum cylinder for oxygen (1.7 LITERS) has autonomy of 40 minutes with the equipment configuration as follows:
  - o Adult patient;
  - o VCV mode;

[1] For input pressure to 39 psi (280 kPa), the maximum flow is 100 L / min

- o Volume 500ml;
- o Rate 12rpm;
- o Ratio 1:2;
- o PEEP 5 cmH2O;
- o Pause 30%;
- o FiO_2 100%;
- o Square flow wave.

Note

- All materials composing the product are compatible with Oxygen, Air and Medicinal Compressed Air.

12.3.3. Physical and Environmental Specifications

Table 21: Physical and environmental specifications

Item	Parameter		Specification	Tolerance	Unit
1	Dimensions (basic unit)	Height (with handle)	176 (231)	± 2	mm
			6.9 (9.1)	± 0.08	inches
		Width	254	± 2	mm
			10	± 0.08	inches
		Depth (with handle)	134 (185)	± 2	mm
			5.3 (7.3)	± 0.08	inches
2	Weight		3	± 0,1	Kg
			7.16	± 0,2	lbs
3	Operation / Transient	Temperature	-20 to 50	---	°C
			-4 to 122	---	°F
		Barometric Pressure	600 to 1100	---	hPa (cmH2O)
		Relative Humidity (w/o condensation)	15 to 95	---	%
4			-25 to 75	---	°C

Item	Parameter		Specification	Tolerance	Unit
	Storage/ Transport	Temperature	-13 to 167	---	°F
		Barometric Pressure	500 to 1200	---	hPa (cmH2O)
		Relative Humidity (w/o condensation)	5 to 95	---	%
5	Life time		10	---	years
6	Time to heat or cool equipment stored at extreme temperatures to operate at 20 ° C		30	---	minutes

12.3.4. Internal volume of respiratory circuit components

INTERNAL VOLUME	
BREATHING TUBE	407,8 mL
Y 22MM	18,7 mL
FLOW SENSOR	8,4 mL

12.3.5. Extreme conditions

WARNING

- ***Do not store the ventilator in environments outside the range of temperature, humidity and pressure specified in 12.3.3 Physical and Environmental Specifications. Accuracy of equipment readings may be affected.***
- ***AC power grid supply with voltage values below 25% may result in a switching of power to the internal battery.***
- ***Power above 15% of the rated value may result in equipment AC / DC power failure, but the equipment will continue to operate normally due to switching to the internal battery.***
- ***AC power grid supply with frequency values 5% below or 5% above nominal may result in switching to using the internal battery, however, the equipment will maintain its normal operation.***

- ***Do not use the ventilator in environments outside the range of temperature, humidity and pressure specified in 12.3.3. Physical and Environmental Specifications Accuracy of equipment readings may be affected.***

Caution

- The temperature alarm will be triggered if the internal temperature of the equipment is below -10ºC (14 °F) or above 50ºC (122 °F) (low/high internal temperature – medium priority).

12.3.6. Ventilation Modes

Table 22: Ventilation modes

Modes (1)	Description	Mode in Apnea (BACKUP)(2)
VCV	Volume-Controlled Ventilation	AUTO
PCV	Pressure-Controlled Ventilation	AUTO
V-SIMV + PS	Volume Controlled Synchronized Intermittent Mandatory Ventilation with Pressure Support	IMV – Volume Controlled Intermittent Mandatory Ventilation
P-SIMV + PS	Pressure Controlled Synchronized Intermittent Mandatory Ventilation with Pressure Support	IMV – Pressure Controlled Intermittent Mandatory Ventilation
CPAP /PSV	Continuous Positive Airway Pressure Ventilation with Pressure Support	VCV, PCV , OFF. Programmable by the Operator

(1) Automatic compensation of compliance and small leaks in the breathing circuit.
(2) For the modes where backup ventilator is defined as “Auto”, when the set apnea time is reached, the ventilator starts one ventilator cycle, which configuration is based on current ventilator mode.

12.3.7. Setting Specifications of the Ventilation Parameters

Table 23: Setting specifications of parameters.

Item	Parameter	Specification	Resolution	Unit
1	Tidal Volume	50 to 2000	50 to 100: 5 100 to 2000: 10	mL
2	Respiratory rate	5 to 60	1	min^{-1}
3	Rise time	0 to 2,0	0,1	s
4	Pause	0 to 70	10	%
5	Maximum Limit Pressure	0 to 60	1	cmH_2O
6	Control Pressure	4 to 50	1	cmH_2O
7	Delta of support pressure (ΔPS)	OFF; 4 to 35	1	cmH_2O
8	PEEP	OFF; 4 to 20	1	cmH_2O
9	Assisted Sensitivity (Pressure)	OFF; -0,2 to -10	-0,2 to -2,0:- 0,2 -2 to -10:- 1	cmH_2O
10	Assisted Sensitivity (Flow)	OFF; 1 to 15	0,5	$L.min^{-1}$
11	Automatic Inspiratory Flow (1)	0 to 150	1	$L.min^{-1}$
12	Cycling by Flow at Pressure Support	20 to 80	5	%
13	O_2 Concentration	60 or 100	-	%
14	Inspiratory Time	0,2 to 9	0,2 to 0,7:0,01 0,7 to 1:0,05 1 to 9:0,1	s
15	Inspiratory Flow Wave	Square	---	---

Item	Parameter	Specification	Resolution	Unit
16	CPAP[2]	4 to 20	1	cmH_2O
17	Ratio	1:4 to 3:1[3]	1:0,1	-
18	Backup	OFF; PCV; VCV [4]	---	-
19	Time for Apnea Alarm	10 to 60	1	s
20	Flow (flow meter)	0 to 15	1	$L.min^{-1}$
21	Leak Flow Compensation	Pressure of 150 Volume of 40L.min- [5]	1	$L.min^{-1}$
22	Height [6]	0,53 to 2,50	0,53 to 1,08:0,01	m
			1,09 to 2,50:0,01	

[1] Inspiratory flow automatically obtained adjusting Volume, Rate, Ratio I:E / Inspiratory time and Pause

Example (1): Volume = 70 mL; Rate = 20 min-1; Ratio= 1:2; Pause = 30%

$$\text{Inspiratory Flow} = \frac{70 \times 20 \times (1+1/0.5)}{1000 \times (1-30/100)} = 6.00 \text{ L/min}$$

Example (2): Volume = 2000 mL; Rate = 12 min-1; Ratio 1:2; Pause = 30%

$$\text{Inspiratory Flow} = \frac{2000 \times 12 \times (1+1/0.5)}{1000 \times (1-30/100)} = 102.86 \text{ L/min}$$

Example (3): Volume = 2200 mL; Rate = 12 min-1; Ratio 1:3; Pause = 40%

$$\text{Inspiratory Flow} = \frac{2200 \times 12 \times (1+1/0.333)}{1000 \times (1-40/100)} = 176.00 \text{ L/min}$$

[2] In CPAP/PSV mode, if pressure support (ΔPS = zero or Pressure and Flow Sensitivity = zero) is disabled, CPAP parameter will be adjusted.

[3] In VCV, adjustment allowed is in the range between 1:4 and 4:1

[4] Backup options for CPAP/PSV mode

[5] For modes with controlled volume, maximum compensation is 100% flow adjusted automatically

[6] Depending on the type of patient set during startup, the ventilator will be set to operate according to the following table:

WARNING

- ***When the volume is set to 50 mL, the ventilator shall be equipped with a CO_2 sensor for the measurement of the expiratory carbon dioxide concentration prior to being put into service.***

Table 24: Ratio Mode x type of patient

Patient Type	Initial Mode	Ideal Weight (IBW)	Height
INFANT	PCV	9 Kg (19.8 lbs)	*0.64 m (2.09 ft)*
CHILD	PCV	19.8 Kg (43.6 lbs)	*0.95 m (3.11 ft)*
ADULT	VCV	49.5 Kg (109.1 lbs)	*1.50 m (4.92 ft)*

The ideal weight is calculated using BMI = 22 and patient height can be changed according to the type of patient set at startup as table below:

Table 25: Calculation of ideal weight x patient height

Patient Type	Height Adjustment		Ideal Weight P
	Min.	Max.	
INFANT	0.53 m (1.74 ft)	0,75 m (2.46 ft)	6.1 kg (13.4 lbs) < P ≤ 12.3 kg (27.1 lbs)
CHILD	0.76 m (2.49 ft)	1.29 m (4.23 ft)	12.7 kg (27.9 lbs) < P ≤ 36.6 kg (80.6 lbs)
ADULT	1.30 (4.26 ft)	2.5 (8.20 ft)	> 37.1 kg (81.7 lbs)

Caution

- Minimum Limit Pressure: 5 cmH2O
- Adjusted Maximum Pressure serves to limit the pressure in the breathing circuit.
- On VCV mode this will be the pressure limit, exhalation valve opens to the environment to maintain this maximum during the inspiratory cycle, exceeding this limit by 5 cmH2O, the ventilator cycles to the expiratory phase (pressure cycling).
- On PCV mode this will be the pressure control limit.
- This ventilator DOES NOT GENERATE NEGATIVE PRESSURE IN THE EXPIRATION OF THE PATIENT.
- For the calculation of ventilation parameters, the patient ideal weight obtained according to height is used. Therefore, there is no indication of specific body mass for the use of the product.

12.3.8. Specifications of the Monitoring Ventilation Parameters

The monitored parameters are calculated using the ordinary least squares (OLS) technique, which calculates the mean through the most recent values in a data series. Thus, for each value included in the averaging calculation, the oldest value is excluded.

Table 26: *Ventilation parameters*

Item	Parameter	Range	Resolution	Measurement Accuracy	Unit
1	Instant Pressure Measured	-20 to 100	1	(± 2 or ±10% of reading)	cmH_2O[(2)]
2	Maximum Inspiratory Pressure	0 to 90	1	(± 2 or ±10% of reading)	cmH_2O
3	Mean Pressure	0 to 90	1	(± 2 or ±10% of reading)	cmH_2O
4	Plateau Pressure	0 to 90	1	(± 2 or ±10% of reading)	cmH_2O
5	PEEP - Pressure at the end of expiration	-20 to 90	1	(± 2 or ±10% of reading)	cmH_2O
6	Intrinsic PEEP at the end of expiration	-20 to 90	0,1	(± 2 or ±10% of reading)	cmH_2O
7	Flow Measured	-150 to 150	1	± (50mL/min + 10 % of reading)	$L.min^{-1}$
8	Volume Measured [(8)]	1 to 3000	100 to 995:5 1000 to 3000:10	(±20 or ±15% of reading)	mL
9	Minute volume	0,001 to 99,0	0,001	(±20 or ±15% of reading)	L
10	Tidal Volume Inspired [(3)]	0,001 to 3000	0,01 to 1000:10 1000 to 3000: 50	(±20 or ±15% of reading)	mL

Item	Parameter	Range	Resolution	Measurement Accuracy	Unit
11	Inspiratory Time	0,05 to 60,0	0,01	(± 20% of reading)	s
12	Expiratory Time	0,05 to 60,0	0,01	(± 20% of reading)	s
13	Ratio I:E	1:100,0 to 100,0:1	1:0,1	(± 20% of reading)	---
14	Respiratory Rate	0 to 200	1	(±1 or ±10% of reading)	min^{-1}
15	Airway Resistance – R_{AW}	0 to 200	1	± (5cmH2O/L/s +20% of reading)	$cmH_2O/L/s$
16	Dynamic Compliance (C.Dyn)	0 to 200	1	± (1mL/cmH2O + 10% of reading)	$mL.cmH_2O^{-1}$
17	Static Compliance (C.Stat)	0 to 200	1	± (1mL/cmH2O + 10% of reading)	$mL.cmH_2O^{-1}$
18	FiO_2 (Oxygen Concentration)	12 to 110	0,1	(± 15% of reading)	$\%O_2$
19	Flow (flowmeter)	0 to 20	0,1	± (50mL/min + 10 % of reading)	$L.min^{-1}$
21	Oxygen Consumption (Cos. O_2)	0 to 160	0,1	± (50mL/min + 10% of reading)	L/min

(1) When two tolerances are indicated, consider the highest value.

(2) 1 mbar (milibar) = 1 hPa (hectoPascal) = 1.016 cmH2O (centimeter of water). In practice, these units are not differentiated and can be used as:

1 mbar = 1 hPa ≈ 1 cmH2O

(3) For airway resistance exceeding 150 cmH2O/L/s expiratory volume monitored will have tolerance changed to ±10%. In this condition, the inspired volume measured remains unchanged.

(4) Tolerance calculated for respiratory rate of 12, 20 and 30 rpm, respectively. Tolerance is a function of the uncertainty of volume multiplied by rate.

(5) 700 hPa corresponds to an altitude of 3048 m

(6) All monitoring data are considered at ATPD (Ambient, Temperature and Pressure Dry).
(7) The Ventilator does not generate negative pressure during expiratory phase.
(8) Volume, flow specifications associated with the ventilator respiratory system are expressed in BTPS with 50% oxygen concentration.

12.3.9. Specifications of the Safety and Alarm System

- Anti-asphyxia valve for fault protection in gas supply;
- Safety Release Valve 100 cmH2O – Basic standard of ventilators to avoid overpressure in the breathing circuit;
- Overpressure Valve ACTIVE – when detecting obstructions, it is activated to reduce pressure in the patient circuit.

WARNING

- ***Ventilation with cyclic pressure up to 100 cmH2O can add up to 2% tolerance error.***
- ***Parameter accuracy may be affected under the following conditions:***
  - ***Reuse of single use accessories;***
  - ***Secretion in the circuit and flow sensor;***
  - ***Uncalibrated oxygen cell and flow sensor;***
  - ***Condensation in circuit, flow sensor and gas inlet;***
  - ***Proximal flow sensor with tubes facing down.***
- ***To maintain ventilator accuracy, keep the flow sensor, breathing circuit, and gas inlet dry, clean, and free of condensation.***

12.3.10. Control accuracy

The following table shows the maximum error between the set value and the value applied by the ventilator.

Table 27 – Parameters accuracy

Item	Parameter	Accuracy (1)
1	Volume tidal (all range)	±20 or ±15% of reading
2	Inspiratory pressure	± 2 or ±10% of reading
3	PEEP	± 2 or ±10% of reading

Item	Parameter	Accuracy (1)
4	FiO_2	± 15% of reading

1. Volume and pressure accuracy is preserved for circuits with resistance up to 1.9 cmH2O with 15 LPM flow and compliance up to 5 mL / cmH2O.

   The accuracy of the parameters remains independent of the adjusted oxygen concentration.

2. Performance accuracies were determined in the worst-case configuration, with a respiratory circuit, and proximal flow sensor, because they have greater compliance and a greater number of potential leakage points.

Performance accuracies were determined using a test system with the measurement uncertainties described in the table:

Table 28 – Parameter Uncertainty

Item	Parameter	Uncertainty
1	Volume tidal	± 2,5%
2	Inspiratory pressure	± 2,0%
3	PEEP	± 2,0%
4	FiO_2	± 2,0%

12.3.11. Oxygen adjustment response time

The table below indicates the time required for oxygen concentration in the delivered volume to change from a fraction of 60% to 100% of the maximum oxygen concentration adjustable using the maximum internal volume respiratory system configuration.

Table 29 – Oxygen adjustment response time

Delivered volume (mL)	Maximum response time (s)
500	98
150	83

12.3.12. Specifications of the Safety and Alarm System

- Anti-asphyxia valve for fault protection in gas supply;
- Safety Release Valve 100 cmH2O – Basic standard of ventilators to avoid overpressure in the breathing circuit;
- Overpressure Valve ACTIVE – when detecting obstructions, it is activated to reduce pressure in the patient circuit.

WARNING

- ***When the ventilator is restarted or if the type of patient is changed, alarms will assume the default values in table 30 according to the selected type of patient. It is not possible to change the default alarm settings permanently.***
- ***Default values of the alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***The apnea time can be turned OFF in assisted-controlled modes. In this situation, there will be no apnea condition Information and no backup ventilation in action. The equipment operator must be aware of the DEACTIVATED Apnea Alarm condition (INDICATED ON DISPLAY).***
- ***Apnea time cannot be turned off in CPAP/PSV mode.***
- ***Adjusting the alarm limits to extreme values will make the alarm system useless.***
- ***If there is no image on the display when turning on, avoid using the equipment, as there will be no visual indication. If during use there is no image on the display, the ventilation configuration will be maintained, and the equipment must be replaced as soon as possible.***

The priority of the alarm condition is determined by the risk management process of the equipment and follows the description in Table 30.

Table 30: Priority of the alarm condition

Potential result of a failure to respond to the cause of the alarm condition	Beginning of potential injury (1)		
	Immediate (2)	Prompt (3)	Delayed (4)
Death or irreparable injury	HIGH PRIORITY	HIGH PRIORITY	MEDIUM PRIORITY
Repairable injury	HIGH PRIORITY	MEDIUM PRIORITY	-
Bruising or discomfort	MEDIUM PRIORITY	-	-

(1) *Beginning of the potential injury refers to the occurrence of the injury and not to its manifestation*
(2) *There is potential for the event to be developed over a period of time not usually sufficient for manual corrective action.*
(3) *There is potential for the event to be developed over a period of time usually sufficient for manual corrective action.*
(4) *There is potential for the event to be developed in a non-specified period not greater than that provided in "prompt".*

In this alarm system, there is no change in priority of the alarm condition and in the event of more than one alarm simultaneously:

- Alarm messages of high priority will be displayed alternately, following the priority described in
- Table 32.
- In the absence of high-priority alarms, the medium-priority alarms will be displayed alternately.

The alarm messages are displayed as soon as the alarm condition is detected; so, there is no delay to the messages display.

Table 31: Alarm features

Alarm	Feature	High Priority	Medium Priority	Low Priority
Visual	Color	Red	Yellow	Cyan
	Intermittence frequency	1.42 hz	0.71 hz	Constant
Audible	*Number of saved pulses*	10 pulses	3 pulses	1 pulse
	Interval between saves	5.0 s	5.1 s	59,4 s
	Sound pressure range	63.5 dBA	62 dBA	56,5 dBA
	Pulse frequency	688 hz	687 hz	686 Hz

Note

- It is recommended that the operator complies with the maximum distance of 1m to properly visualization and Identification of visual alarms; however, alarm signals are perceptible up to 4 m from the equipment.
- To identify the occurrence of an alarm, the operator should preferably be 1 meter in front of the equipment at an angle of 30° with the horizontal axis in the center of the monitor's viewing plane.
- Sound pressure levels of auditory alarm signals that are lower than ambient levels may prevent operator recognition of alarms.

Table 32: Alarm set

Item	Alarm	Setting	Limit	Standard Alarm[1]			Unit
				INF	CHILD	ADU	
1	Maximum Pressure	OFF; 1 to 60	High	30	30	40	cmH_2O
			Low	OFF	OFF	OFF	
2	PEEP	OFF; 1 to 20	High	10	15	20	cmH_2O
			Low	OFF	OFF	OFF	
3	Total Volume	OFF; 0 to 2000	High	50 mL	500 mL	1.0 L	mL
			Low	OFF	OFF	OFF	
4	Minute volume	OFF; 0,1 to 99	High	5.0	10	20	L
			Low	OFF	OFF	OFF	

Item	Alarm	Setting	Limit	Standard Alarm[1]			Unit
				INF	CHILD	ADU	
5	Time for Apnea Alarm	OFF; 10 to 60	Low	10	10	15	s
6	Respiratory Rate	OFF; 1 to 150	High	60	60	60	min^{-1}
			Low	OFF	OFF	OFF	
7	FiO_2	OFF; 18 to 100	High	OFF	OFF	OFF	%
			Low	OFF	OFF	OFF	

[1] Every time the equipment starts up or there is a change of patient type, or the battery power runs out without plugging the ventilator to the power grid, the alarms will assume the default values indicated for each type of patient.

[2] Only to be applied to the alarms related to basic ventilation parameters (Maximum Pressure, PEEP, Minute volume and Respiratory Rate).

WARNING

- ***Default values of the alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***It may be dangerous if different default alarm values are used for the same or similar equipment in the same area.***
- ***Setting the alarm limit to its extreme value may make the alarm system inadequate. Adjust the limits as needed by the patient.***

Note

- Oxygen monitoring is achieved accurately within 20 seconds of initialization.
- Alarm settings will not change when power is lost for 30 seconds or less. In this case, the equipment will be powered by the non-interchangeable internal battery.

Alarms related to the equipment and ventilation:

- Low Battery
- Low Network Pressure
- Disconnection from the Breathing Circuit
- Obstruction of the Breathing Circuit
- Apnea
- No AC power

12.3.13. Concentration x Pressure in the breathing circuit curve

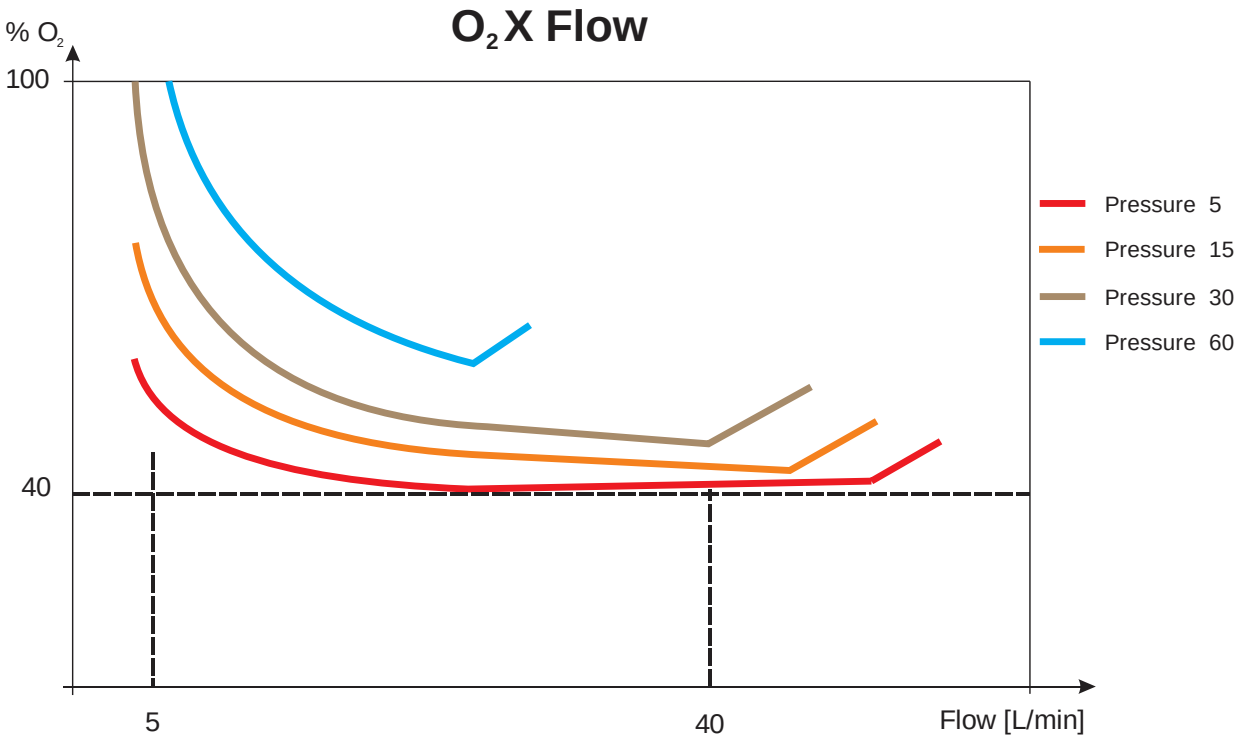


Figure 20: Concentration curve in function of pressure in the breathing circuit

Figure 20 shows the typical dependency of the resulting inspiratory oxygen concentration from the inspiratory flow at mean airway pressures of 5, 15, 30 and 60 hPa.

Because of the physical characteristic of the venturi principle, the oxygen concentration depends significantly on the inspiratory flow and the mean airway pressure. There is only a limited working range in which the oxygen concentration is on the desired constant level. At a low flowrate, the venturi is not able to intake sufficient air to achieve the desired oxygen concentration. At high flowrates, the performance limit of the venturi is reached. In both cases, the inspiratory oxygen concentration can rise significantly.

Depending on the parameters set by the user, the ventilator might not reach certain levels. In those situations, the operator should adjust the ventilation settings, such as I:E ratio and/or pause to increase the insufflation time and allow the system to reach the desired targets.

12.3.14. Performance Specifications

Table 33: *Performance specification*

Item	Parameter	Specification	Tolerance	Unit
1	Maximum Flow in Pressure Support or in cycles of controlled pressure	150	± 10%	$L.min^{-1}$
2	Control Principle	Cycled by Time, Constant Volume and Pressure Controlled	---	---
3	MTBF (Mean Time Between Failure)	5.000	---	hours (On) (POH)

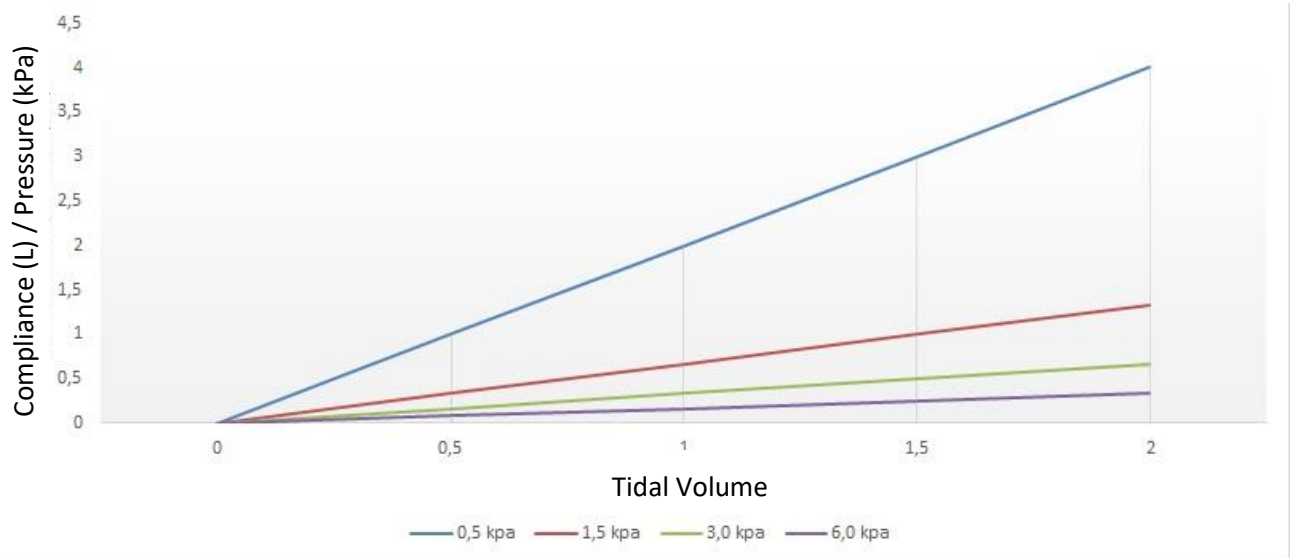


Figure 21: Influence of airway pressure on tidal volume (1)

(1) To check the influence of airway pressure on minute volume, the tidal volume applied by the monitored respiratory rate should be multiplied.

12.3.15. Specifications for Maintenance and Calibration

Each 5000h the proportional valves and linear actuator shall be reviewed and calibrated if needed to ensure that the flow and pressure are accurate.

Table 34: Specification for maintenance and calibration

Item	Description	Specification	Tolerance	Unit
1	Review and REPLACEMENT OF O_2 CELL (3902020)	10,000 h or 2 years	± 500	Hours
2	Review and REPLACEMENT OF BATTERY (2702236)	10,000 h or 2 years	± 500	Hours
3	Review	1	± 1 month	Year
4	Calibration	5000h	± 50	Hours
5	Air intake filter	500h	± 50	Hours
6	Review and replacement of O2 filter	5000h	± 50	Hours
7	Cooler filter	500h	± 50	Hours

12.3.16. Breathing Circuit

Specification	
Connection	22 mm
Resistance	≤ 0.3 mbar/L.s^{-1}

Table 35: Inspiratory and Expiratory Resistance specifications

Flow	Expiratory Resistance ((hPa/L.min^{-1} or cmH2O/L.min^{-1})

L x min^{-1}	Circuit	Circuit + Flow Sensor	Circuit + Flow Sensor + HME Filter
2.5	0.3	0.85(1)	
15.0	0.2	1.7	1.8
30.0	0.4	0.7	1.55

[1] Maximum resistance to assure the accuracy.

The operator should ensure that the inspiratory and expiratory resistance values are not exceeded when accessories or other components or subsets of the respiratory system are added.

Table 36: Respiratory circuit compliance specification

Circuit + Flow Sensor	Circuit + Flow Sensor + HME Filter	Maximum Compliance (2) (mL/cmH2O)
60 ± 3	2	5

[1] Default compliance will be used if the auto test is not performed or if a failure occurs.

[2] Maximum compliances to assure the accuracy

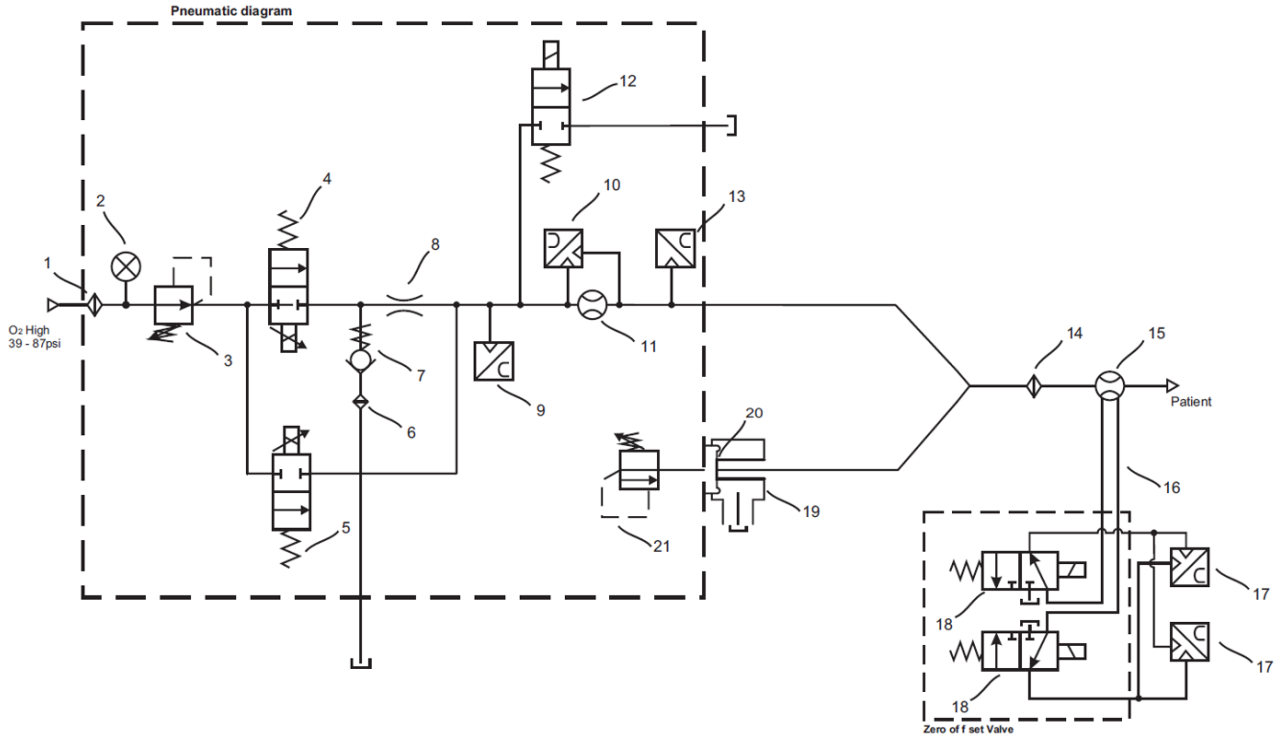
12.3.17. HME Filter

Specification		
Compliance	ISO 23328-1, ISO 23328-2, ISO 9360-1 and ISO 9360-2	
Connection	22 mm	
Bacterial Filtration Efficiency	99,999 %	
Resistance	30 L/min	2,02 cmH2O
	60 L/min	5,19 cmH2O
	90 L/min	9,37 cmH2O

WARNING

- ***To avoid cross contamination, a HME filter following the specifications in chapter 12.3.18, with local registration.***

12.3.18. Pneumatic diagram



1	Filter	12	Over-pressure Valve
2	High Pressure Sensor	13	Pressure Measurement Point
3	Poppet Valve	14	HME filter
4	30LPM Proportional Valves	15	Universal Flow Sensor
5	200LPM Proportional Valves	16	Universal Connector Silicon Line
6	Mesh Filter	17	Measurement point (proximal pressure differential)
7	Check Valve	18	Zero offset valve x-1 / 6 psi Solenoid valve
8	Venturi Tube	19	Exhalation Valve
9	Measurement Point Oxygen Cell	20	Diaphragm
10	Pressure Measurement Point	21	Linear actuator
11	Internal Flow Sensor		

Figure 22: Pneumatic Scheme of the transport ventilator

12.3.19. Block Diagram of Control Electronics

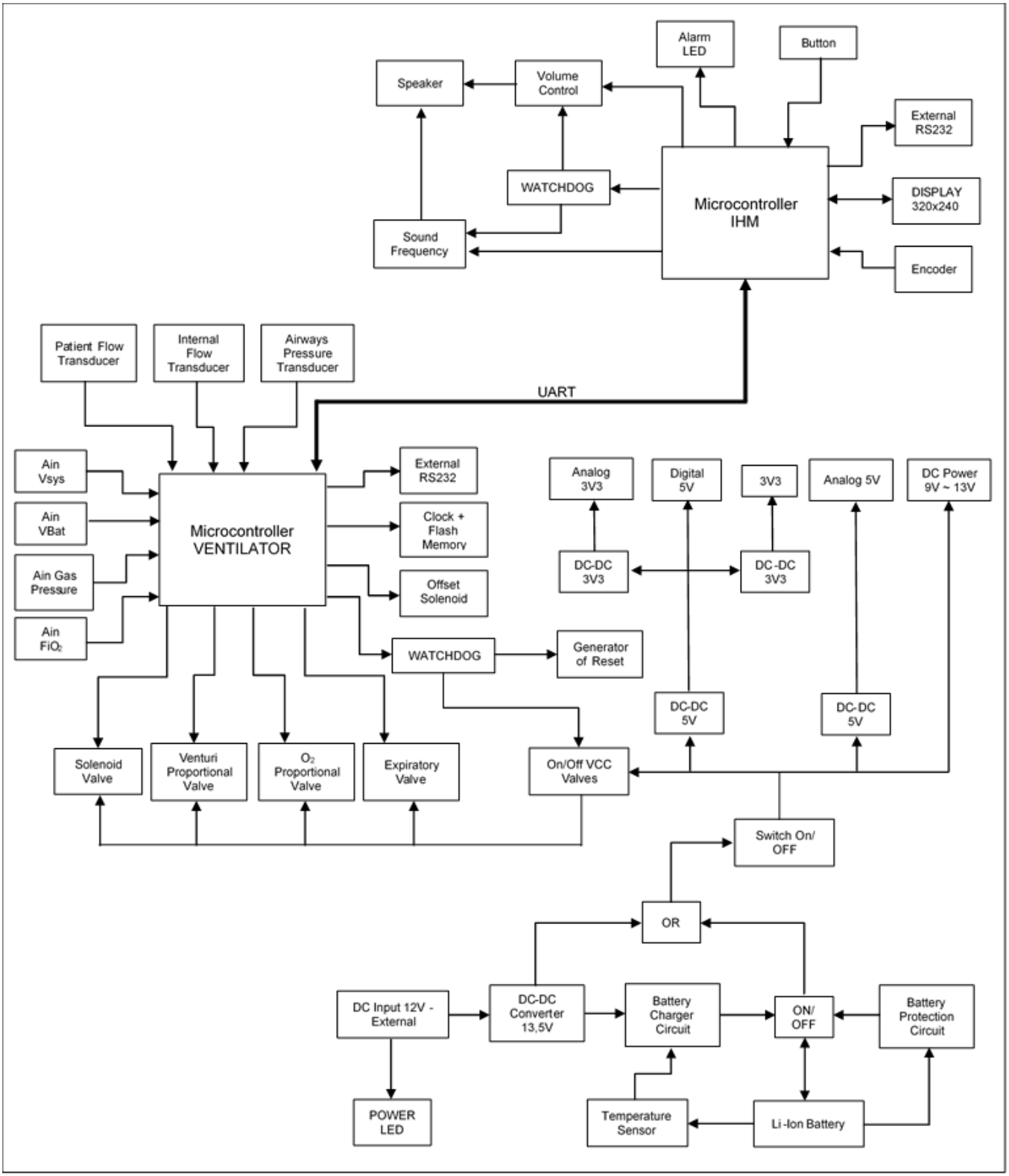


Figure 23: Block Diagram of Electronics

12.3.20. Electromagnetic Compatibility

Changes or modifications to this equipment not expressly approved by MAGNAMED can cause EMC problems with this equipment or others. Contact MAGNAMED to receive technical assistance. This equipment has been designed and tested to comply with applicable EMC standards as described below.

This equipment has been designed and tested to meet the following essential requirements: deliver ventilation to the patient connection port within alarm limits or generating an alarm condition; monitor oxygen concentration including high and low oxygen alarm; generate PEEP alarm above or below the alarm limit; generate obstruction alarm when airway pressure reaches the obstruction alarm limit; monitor expired volume and generate high priority alarm condition indicating high or low volume; generate alarm when there is a power failure and when the battery is low; generate high priority alarm when the oxygen network fails; generate high priority alarm when the high pressure limit for airway is reached; generate an alarm condition to indicate disconnection.

WARNING

- ***The use of cell phones or other radio frequency (RF) emitting devices near the system may cause unexpected or adverse outcomes. Monitor the operation if there are radio frequency emission sources in the vicinity.***
- ***The use of other electrical equipment in or around the system or may cause interference. Before use in a patient, you must check if the equipment works normally in the defined configuration.***
- ***Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be constantly observed to verify that they are operating normally.***
- ***Use of accessories, transducers, and cables other than those specified or supplied by Magnamed may result in high electromagnetic emissions or reduced electromagnetic immunity from this equipment and result in improper operation.***
- ***Portable RF communication equipment (including peripherals such as antenna cables and external antennas) should not be used within 30 cm of any part of Oxymag. Otherwise, performance degradation of this equipment may occur.***
- ***During the immunity testing below the device continued to ventilate normally.***
- ***Avoid exposure to known sources of EMI (electromagnetic interference) such as diathermy, lithotripsy, electrocautery, RFID (Radio Frequency Identification), and electromagnetic security systems such as anti-***

theft/electronic article surveillance systems, metal detectors. Note that the presence of RFID devices may not be obvious. If such interference is suspected, reposition the equipment if possible, to maximize distances.

A) Guidelines and manufacturer's statement – Electromagnetic emissions

The Oxymag is intended for use in pre-hospital and hospital use including intra-hospital transport.

Table 37: Specification of electromagnetic environment of use

Emission Test	Compatibility	Directive for Electromagnetic Environment
RF Emissions IEC CISPR 11	Group 1	The system uses RF energy only for its internal functions. However, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions IEC CISPR 11	Class B	The Oxymag is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics emission IEC 61000-3-2	Class A	
Emissions due to voltage fluctuation/ flicker IEC 61000-3-3	Complies	

B) Guidelines and manufacturer's statement – Electromagnetic immunity

Table 38: Electromagnetic environment for use of the system

Immunity Test	IEC Test Level - 60601-1-2	Compliance	Directive for electromagnetic environment
IEC 61000-4-2 – Electrostatic discharge (ESD)	± 8 kV by contact ± 15 kV by air	± 8 kV by contact ± 2, 4, 8, 15 kV by air	Floors should be wood, concrete, or ceramic. If floors are covered with synthetic material, relative humidity should be at least 30%
IEC 61000-4-4 – Electrical fast transient / Burst	± 2 kV at the power input interface c.a. ± 2 kV at the power input interface c.c.	± 2 kV at the power input interface c.a. ± 2 kV at the power input interface c.c.	Quality of power supply should be that of a typical commercial or hospital environment.
IEC 61000-4-5 - Surge	± 1 kV line(s) to line(s)	± 1 kV line(s) to line(s)	Quality of power supply should be that of a typical commercial or hospital environment.
IEC 61000-4-11 – Voltage dips, short interruptions and voltage variation on power supply input lines	0% UT; 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% UT; 1 cycle (single phase: at 0 °) 70% UT; 25/30 cycles (single phase: at 0 °)	0% UT; 0.5 cycle at 0 °, 45 °, 90 °, 135 °, 180 °, 225 °, 270 ° and 315 ° 0% UT; 1 cycle (single phase: at 0 °) 70% UT; 25/30 cycles (single phase: at 0 °)	Quality of power supply should be that of a typical commercial or hospital environment. If the user of the Oxymag requires continued operation during power mains interruptions beyond that provided by the battery, it is recommended that the Oxymag is powered from an uninterruptible power supply.

Immunity Test	IEC Test Level - 60601-1-2	Compliance	Directive for electromagnetic environment
Magnetic field of power frequency (50/60 Hz) IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Magnetic fields in the supply frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: UT is the a.c. supply voltage before application of the test level.

Electromagnetic Immunity			
The Oxymag is intended for use in the electromagnetic environment specified below. The customer or the user of the ventilator should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz	3 Vrms 6 V rms in ISM and amateur bands	The Oxymag is suitable for the electromagnetic environment of typical homes, commercial or hospital settings.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m	

Fields in the vicinity of RF wireless communication equipment			
The Oxymag cabinet interface has been tested as specified in the table below using the test methods specified in IEC 61000-4-3			
Band	**Freq. test**	**Modulation**	**Trial level**
[MHz]	**[MHz]**		**[V/m]**
380 to 390	385	Pulse, 18 Hz	27
430 to 470	450	FM, 1 kHz, Deviation from ± 5kHz	28
704 to 787	710 745 780	Pulse, 217 Hz	9
800 to 960	810 870 930	Pulse, 18 Hz	28
1.700 to 1.990	1.720 1.845 1.970	Pulse, 217 Hz	28
2.400 to 2.570	2.450	Pulse, 217 Hz	28
5.100 to 5.800	5.240 5.500 5.785	Pulse, 217 Hz	9

C) Electrical Safety

The following are the precautions that should be observed when combining these items (non-medical equipment) with the system.

WARNING

- ***Items that do not meet the requirements of standard IEC 60601-1 cannot be placed within 1.5 from the patient.***
- ***All items (electromedical or non-medical equipment) connected to the system with input/output signal cable must receive power from an AC source using separate transformer (according to standard IEC 60989) or provide additional earth protective conductor.***
- ***An additional multiple socket-outlet or extension cord shall not be connected to the system.***
- ***Do not directly connect the non-medical electrical equipment to an AC wall outlet. Use AC power supply with its own transformer. Otherwise, the leakage current will increase above the levels accepted by IEC 60601- under***

normal conditions and single-failure conditions. This may cause dangerous electrical shock to the patient or operator.

- ***After connecting any equipment into these outlets, the system should undergo a complete test for leakage current (according to standard IEC 60601-1).***
- ***The operator of the electromedical system must not touch the non-medical electrical equipment and the patient at the same time. This may cause dangerous electrical shock to the patient or operator.***
- ***Do not connect non-medical electrical equipment directly to the wall outlet. Use AC power supply with its own transformer. Otherwise, current leakage will increase above the levels accepted by IEC 60601-1 under normal conditions and single fault conditions. This may cause dangerous electrical shock to the patient or the operator.***

12.4. O_2 galvanic cell specification

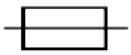
General specification	
Intended use	Measure the O_2 concentration delivered from the equipment to the patient
Measuring range	0 to 100%
Output sign	9 – 13 mV
Response time 90%	13 s
Accuracy	± 2%
Linearity	± 2%
Recommended flow rate	0.1 – 10 lpm
Data sampling rate	7 Hz
Method for calculating the gas level reading	Simple moving average (MMS) of 64 positions acquired every 140ms
Respiratory rate	The Respiratory Rate is shown every 3 breaths and the average value is updated with each breath.
Effects of gas and vapor interference	
Gases or Steam	**Gas Level**
Response to 80% NO	< 5%
Response to 7,5% Halothane	< 5%

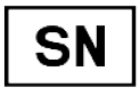
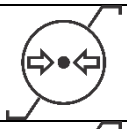
Response to 7,5% Isoflurane	< 5%
Response to 7,5% Enflurane	< 5%
Response to 9% Sevoflurane	< 5%
Response to 20% Desflurane	< 5%
Response to 10% CO_2	< 5%

13. Symbols

SYMBOLS / UNIFIED TEXTS	MEANING
	PATIENT
	CONTINUOUS TIDAL
	ALTERNATING CURRENT (POWER)
	ELECTRIC ENERGY
	WASTE – ELECTRICAL AND ELECTRIC EQUIPMENT SHALL BE COLLECTED AND RECYCLED IN ACCORDANCE WITH DIRECTIVE 2002/96/EC
	DC INPUT
	POWER PLUG
	ON
	OFF
INSP / EXP HOLD	INSPIRATORY/ EXPIRATORY HOLD
MANUAL	MANUAL TRIGGER
O_2 100%	OXYGEN 100%
	SERIAL
	TO IDENTIFY OR ADVISE CLEANING OR CHANGING A FILTER

SYMBOLS / UNIFIED TEXTS	MEANING
	KEYBOARD LOCK
	PERIODIC MAINTENANCE
	FREEZE
	PAGE
	AUDIO ALARM PAUSED
	ALARM
IP34	PROTECTED AGAINST THE INGRESS OF SOLID FOREIGN OBJECTS > 2.5 MM AND SPLASH-PROOF EQUIPMENT
	TYPE BF OF APPLIED PART
	CLASS II EQUIPMENT
	MANUFACTURE DATE
	MANUFACTURE
	EUROPEAN REPRESENTATIVE
	ATTENTION! SEE ACCOMPANYING DOCUMENTS
	OPERATING INSTRUCTIONS
	FRAGILE

SYMBOLS / UNIFIED TEXTS	MEANING
	THIS SIDE UP
	KEEP PROTECTED FROM MOISTURE
	SAFE STACKING QUANTITY
	TEMPERATURE LIMITS
	KEEP AWAY FROM HEAT
O_2 INLET	O_2 INLET
O_2	OXYGEN
	ALARM SETTING OFF
	STAND BY
INSP	INSPIRATORY
EXP	EXPIRATORY
	FUSE
 XXXX	CONFORMITY CE: INDICATES THAT THE SYSTEM IS IN ACCORDANCE WITH DIRECTIVE OF THE EUROPEAN COUNCIL 93/42
	INMETRO
	US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

SYMBOLS / UNIFIED TEXTS	MEANING
	USE BY DATE
	NON-STERILE
	DO NOT USE IF PACKAGE IS DAMAGED
	THE INSTRUCTION MANUAL MUST BE READ
	MANUFACTURER'S CATALOGUE NUMBER
	MANUFACTURER'S SERIAL NUMBER
	MANUFACTURER'S MATCH OR LOT CODE
	SINGLE USE
	GAS OUTPUT
	DRIVING GAS INPUT
	EXAUSTION
	PRESSURE GAUGE This measurement is a flow and volume reading technique. Airway pressure reading is performed internally.
	HUMIDITY LIMITATION Indicates the range of humidity to which the medical device can be safely exposed.
	ATMOSPHERIC PRESSURE LIMITATION Indicates the range of atmospheric pressure to which the medical device can be safely exposed.
	MR UNSAFE Oxymag poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.

14. Terms and Abbreviations

Table 39: List of terms and abbreviations with their descriptions

Terms and Abbreviation	Description
ADU	Adult
Backup	Apnea Mode Setting
BMI	Body Mass Index
C.Dyn	Dynamic Compliance
C.Stat	Static Compliance
CHILD	Child patient
Compliance	Circuit Compliance
Cons O_2	O_2 Consumption
CPAP	Continuous Positive Airway Pressure Ventilation
Cycl. PS	Cycling Percentage
Exp Valve	Expiration Valve
F.Base	Baseline Flow
FiO_2	O_2 Inspired Fraction
Fl Tig F.Trigger	Trigger (Sensitivity) to Flow
I:E	Ratio T.Insp by TExp
INF	Infant
Leakage	Circuit Leakage
Man Trig	Manual Trigger
MV	Minute Volume
NIV	Non-Invasive Ventilation
O_2 100%	Flash indication of O_2
P Mean	Mean Pressure
P. Insp	Setting of Inspiratory Pressure
P.Low	Low pressure
P.Max	Maximum Pressure in the Airways
P.Plat	Plateau Pressure
Pause	Inspiratory Pause
PCV	Pressure Controlled Ventilation
PEEPi	Intrinsic PEEP
Pr Trig P.Trigger	Trigger (Sensitivity) to Pressure
Prede	Network Pressure
P-SIMV	Controlled Pressure Synchronized Intermittent Mandatory Ventilation
PSV	Continuous Pressure Ventilation with Pressure Support
Rate	Total Respiratory Rate
Res	Airway resistance
Resistance	Circuit Resistance
Rise Time	Rise Time
T.Exp	Expiratory Time
T.Insp	Inspiratory Time
VCV	Volume Controlled Ventilation

Terms and Abbreviation	Description
V-SIMV	Synchronized Intermittent Mandatory Ventilation with Controlled Volume cycle
Vt	Adjusted Tidal Volume
Vti	Inspired Tidal Volume

Terms and Abbreviation	Description
Vte	Exhaled Tidal Volume
V	Tidal flow
ΔPS	Value to be added to PEEP pressure to obtain Pressure Support

15. Statement of Biocompatibility

In accordance with ISO 10993-1 and ISO 18562-1, the components of a ventilator are classified as indirect contact. Therefore, Oxymag was tested and approved in the following tests:

- Particulate matter emission
- Volatile organic compounds
- Ozone gas analysis
- Carbon monoxide and carbon dioxide gas analysis
- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogenicity

WARNING

- ***Common accessories purchased from third parties shall comply local legal government requirements.***

17. Technical Assistance

For maintenance, please contact our technical assistance who will indicate the service nearest you or visit our website.

WARNING

- ***Schedule preventive maintenance only with the authorized Magnamed Service.***

18. Training

To request training, please contact Magnamed product expert team who will indicate the authorized Representative nearest you.

19. Warranty

The manufactured Products and marketed by MAGNAMED TECNOLOGIA MÉDICA S/A are under warranty against material and manufacture defects throughout Brazil, as provided below.

The warranty period for the equipment is 12 months. For batteries and accessories, the warranty period is 3 months, provided that it retained its original state; this period starts on the date of purchase by the first purchaser of the product, as stated on the Sales Invoice of MAGNAMED TECNOLOGIA MÉDICA S/A.

The responsibility for warranty is limited to exchange, repair and hand labor for the defective parts or not meeting the specifications in the Product Operation Manual.

The warranty is limited to the product used under normal conditions and for the purposes for which it is intended, and which preventive maintenance and part replacements and repairs are carried out in accordance with the instructions in the Product Operation Manual, by personnel authorized by the manufacturer.

The warranty does not cover defects caused by misuse or inappropriately installed, accident, improper sterilization, service, installation, operation, or modification carried out by personnel not authorized by the manufacturer.

The disruption or absence of seals or warranty seals by unauthorized personnel results in the loss of product warranty.

Parts subject to wear or deterioration due to normal use, rough use, misuse, or accidents are not covered by warranty. Any costs and risks with transportation of the product are not covered by this warranty. There is no express or implied warranty than those set out above.

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