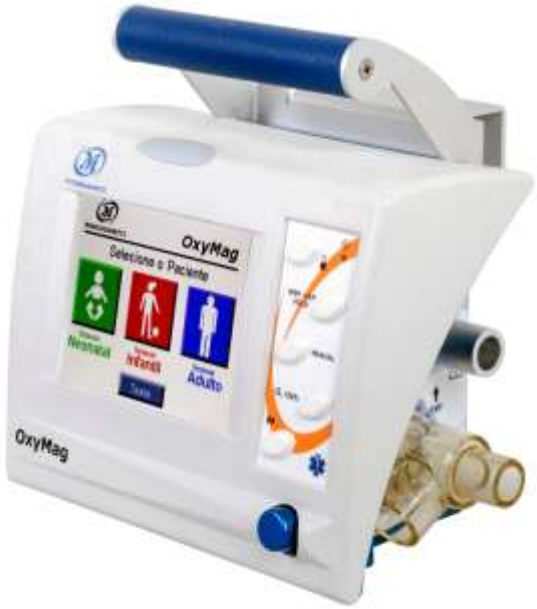
MAGNAMED



Operation Manual

OxyMag – Transport and Emergency Ventilator

CE 2460

ANVISA Registration nº 80659160004

Magnamed Tecnologia Médica S/A
Rua Santa Mônica 801/831 – Capuava
CEP: 0671-865 – Cotia – SP – Brazil
Phone/Fax: +55 (11) 4615-8500
E-mail: magnamed@magnamed.com.br
Website: www.magnamed.com.br
CNPJ: 01.298.443/0002-54
State Registration: 149.579.528.111

Technical Responsible: Tatsuo Suzuki
Registration at CREA-SP: 0600629049
Legal Responsible: Tatsuo Suzuki

1600185-10: OxyMag – Version 3.n

Analytical Index

Definition and Care

a. Definitions

WARNING

- ***It 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

- It 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 read the instruction manual for more details, this manual should be read in its entirety, CAREFULLY, for correct and safe use of the equipment and to provide maximum safety and 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 Intended Use in conjunction with appropriate monitoring;***
- ***This equipment must be operated only by qualified professional in the health care area with expertise in mechanical ventilation qualified and trained in its use, who should watch closely during its use. Including ventilation limited to volume.***
- ***This equipment and the parts should go through a cleaning process each time it is used, including the first use, as indicated in chapter 10 Cleanning and Sterilization.***
- ***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 6 Checks Before Use.***
- ***This equipment must remain ALWAYS connected to a power grid so that there is enough charge during a power outage.***
- ***This equipment must issue three beeps when started, demonstrating the correct operation of audible signal.***
- ***This equipment, parts and accessories must be disposed according to chapter 13 Disposal;***
- ***This equipment must be switched off with the patient disconnected on the on/off switch.***

- *This equipment should not be used with transmission devices in the vicinity of the transport ventilator, such as mobile phones, point-to-point radio transmission, cordless phones, pagers, high-frequency surgical equipment, defibrillators, short-wave therapies, which could stop operation of the ventilator.*
- *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 in areas containing harmful substances, because it aspirates ambient air to ventilate the patient, once set at less than 100% O2 concentrations.*
- *This equipment should not be used with flammable anesthetic agents because there is risk of explosion.*
- *This equipment should not be used in hyperbaric chambers, as this may affect the operation of the equipment and cause adverse effects to the patient.*
- *After prolonged use of the equipment in environments with particulate matter in suspension, replace the filter as indicated in chapter 12.5 Replacing the Ambient Air Filter.*
- *Parts applied to transport ventilator support defibrillation.*
- *Alarms and Alerts should be treated promptly in order to maintain the operation integrity of the equipment and patient safety, as indicated in chapter Alarms Available.*
- *Do not use hoses or antistatic or electrically conductive tubes.*
- *After starting ventilation, check if the ventilation parameters indicated by the monitoring display are appropriate.*
- *Use only parts, pieces and accessories specified by MAGNAMED listed in this manual, which have been tested and approved for use in conjunction with this equipment; otherwise, it can jeopardize the operation endangering the patient or user.*
- *During the prolonged use of the equipment in patients with excessive secretion or breathing circuits using heated humidifier, cleaning of flow sensors should be often checked.*
- *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 inform the type of patient and this will set the proper ventilation. Connect the flow sensor with the type of patient informed so that ventilation is properly monitored.*
- *All parts applied to Oxymag are made of non-toxic material, latex-free, do not cause irritation or allergy to the patient.*
- *Use MASKS specified by MAGNAMED with local registration;*
- *Use MASK 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.*
- *Have available a manual ventilation equipment, for the case of full battery discharge, lack of gases to the operation of the device or general failure of the transport ventilation.*
- *Test Sequence must be performed with the patient disconnected*
- *Do not expose the product to extreme temperatures beyond the specified in item 15.3.3 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, HEPA filter and airway adapter are single use. The reuse of these accessories may cause cross contamination.*

c. Caution

Caution

- Oxymag do not emit electromagnetic waves that interfere with the equipment operation in the vicinity.
- Oxymag must pass annual periodic maintenance or according the hours of use as specified, whichever comes first.
- Oxymag must have the ambient air intake filter replaced every 500 hours of use, or at shorter intervals, if the environment in which it is used contains too much particulate matter in suspension.
- Oxymag should have their maintenance only carried out by a qualified, trained technician duly authorized by MAGNAMED.

d. Notes

Notes

- There are additional contraindications, in addition to those specified in Warning items in page 7 of this manual. It remains the responsibility of the trained operator the choice and selection of suitable respiratory mode to each patient.
- 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

- 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 13 Disposal.

1. Description

1.1 Intended Use

Oxymag MAGNAMED's Transport and Emergency Electronic Ventilator – belong to the family of equipment for ventilatory support of neonatal, pediatric and adult patients with respiratory failure, with controlled volume, pressure and time cycled. Intended for use in patients from neonatal, pediatric, adult and adults with morbid obesity.

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. 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);
- PLV – Pressure Limited Ventilation (can be Assisted) – Available Weight ≤ 6.0Kg (Neonatal);
- 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;
- DualPAP – Ventilation at two CPAP levels (with or without Support Pressure). Adjustments can be performed through this modality in order to obtain APRV mode (Airway Pressure Release Ventilation);
- Noninvasive ventilation (NIV) by mask can be activated in all ventilation modes with leakage compensation.

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

WARNING

- ***This device should be operated only by healthcare professional with expertise in mechanical ventilation and qualified and trained in its use.***
- ***In CPAP/PSV and DUALPAP modes △PS = OFF should be set to deactivate the support pressure and BACKUP should be set to OFF to deactivate backup ventilation. Be aware that when adjusting parameter BACKUP to OFF backup ventilation will be INACTIVE during APNEA.***

Pulmonary ventilation may be performed in the following conditions:

- In emergency medicine for service in the field, primary care, rescue in which the patient can be transported by land or air, including helicopters;
- Postoperatively, in the post-anesthetic recovery room (PACU);
- Intra-hospital transportation: The patient can be transported internally, from one to another department;
- Inter-hospital transportation: The patient can be transported by road or air.

1.2 Optional items compatible with the products

This equipment is compatible with the following items:

- Nasal prong for neonatal CPAP and its breathing circuit, both must comply local legal government requirements;
- Breathing circuits with trachea, which resistance is less than 0.3 mbar/(L.s-1) that comply local legal government requirements;
- Blender with flow 120ml/min and outlet pressure 60psi that complies local legal government requirements;
- Adult, Pediatric and Neonatal Simple Facial Masks that comply local legal government requirements;
- HME filter that complies local legal government requirements (to be used in accordance with the patient being ventilated);
- Aluminum cylinder for oxygen M9 for carrying case, that complies local legal government requirements, namely:
    - Diameter = 11.13 cm;
    - Height = 27.20 cm;
    - Volume = 1.7L;
    - O2 Capacity = 255L.

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 carrier and MAGNAMED and DO NOT open the package.
- ✓ Open the package carefully observing the signs in the box;
- ✓ Check the content in accordance with the following list of components.

Table 1: List of components for Oxymag

List of components for Oxymag	
 OXYMAG TRANSPORT AND EMERGENCY VENTILATOR Part Number 1600185 Quantity: 1 unit	 POWER OUTLET 12V WITH 4-WAY CONNECTOR Part Number 2402568 Quantity: 1 unit
 AC CABLE 3 WAYS 1,5 M Part Number 2802612 Quantity: 1 unit	 BREATHING CIRCUIT ADULT [1] 1,2m AUTOCLAVABLE Part Number 1703218 Quantity: 1 unit
 O2 EXTENSION DISS X2 2 M Part Number 3902647 Quantity: 1 unit	 EXHALATION VALVE WITH STABILIZING RING Part Number 3804865 Quantity: 1 unit
 DIAPHRAGM OF EXHALATION VALVE MAGNAMED Part Number 3800248 Quantity: 1 unit	 ENVELOPE WITH 3 ENVIRONMENT FILTERS Part Number 1702656 Quantity: 1 unit

KIT FLOW SENSORS
ADU PED NEO AUTOCLAVABLE
03 Silicon line, 03 Flow sensors (1 Adult; 1 Pediatric, 1 Neonatal)

Part Number 5001748
Quantity: 1 unit

OPERATION MANUAL

Part Number 1600185-NE-22-RR
Quantity: 1 unit

QUICK GUIDE
OXYMAG FAMILY

Part Number 7006467
Quantity: 1 unit

1 Accessories not available for European Union

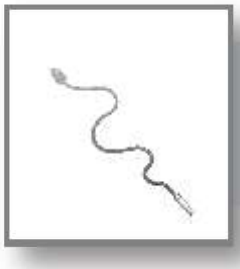
2.2 Parts and Accessories

Caution

- Always use original parts and accessories to ensure the safety and effectiveness of the equipment.

2.3 Optional accessories that can be purchased for Oxymag

Table 2: List of optional components for Oxymag.

List of optional accessories for Oxymag	
	STAND WITH CASTERS FOR OXYMAG Part Number 3802668
	ARTICULATED ARM WITH SUPPORT FOR BREATHING CIRCUITS Part Number 1704414
	PEDIATRIC BREATHING CIRCUIT 1.2M AUTOCLAVABLE [1] Part Number 1702654
	NEONATAL BREATHING CIRCUIT 1.2M AUTOCLAVABLE [1] Part Number 1702655
	POWER CORD DC 12V 4-WAY WITH CAR PLUG Part Number 2802671
	VERTICAL SUPPORT FOR AMBULANCE OR HELICOPTER WITH SAFETY LATCH Part Number 1702496
	CARRYING BAG FOR PARA OXYMAG Part Number 1702875
	CARRYING BAG FOR OXYMAG WITHOUT CYLINDER Part Number 1704784

KIT ADULT FLOW SENSORS AUTOCLAVABLE

- 03 Silicone Line
- 03 Adult Flow Sensors Autoclavable

Part Number 5001747

KIT PEDIATRIC FLOW SENSORS AUTOCLAVABLE

- 03 Silicone Line
- 03 Pediatric Flow Sensors Autoclavable:

Part Number 5001746

KIT NEONATAL FLOW SENSORS AUTOCLAVABLE

- 03 Silicone Line
- 03 Neonatal Flow Sensors Autoclavable

Part Number 5001745

ADULT FLOW SENSORS AUTOCLAVABLE

- 05 Silicone Lines
- 05 Adult Flow Sensors Autoclavable

Part Number 5001495

PEDIATRIC FLOW SENSORS AUTOCLAVABLE

- 05 Silicone Line
- 05 Pediatric Flow Sensors Autoclavable

Part Number 5001494

NEONATAL FLOW SENSORS AUTOCLAVABLE

- 05 Silicone Line
- 05 Neonatal Flow Sensors Autoclavable

Part Number 5001493

AIRWAY SENSOR IRMA CO2 WITH 5-WAY CONNECTOR

CE 0413

Part Number 1704396

IRMA CO2 GAS ANALYZER (EtCO2)

CE 0413

Part Number 1704388

IRMA AIRWAY ADAPTER, INFANT
CE 0413
Part Number 1704394

IRMA AIRWAY ADAPTER, ADULT/PEDIATRIC
CE 0413
Part Number 1704395

SPO2 – ADULT PEDIATRIC PULSE OXIMETER SENSOR AND CABLE ADAPTER
CE 0123
Part Number 1704409

SPO2 – NEO PULSE OXIMETER SENSOR AND CABLE ADAPTER
CE 0123
Part Number 1704410

HME FILTER STERILE
CE 2460
Part Number 1705143

HEPA FILTER FOR MECHANICAL VENTILATION
CE 2460
Part Number 3905085

1 Accessories not available for European Union

2.4 Identification of Components

2.4.1 Components of transport ventilator

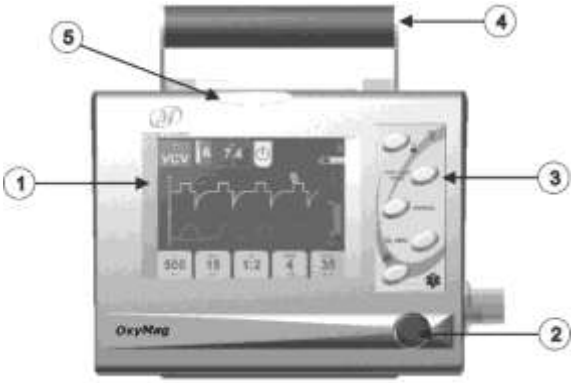


Figure 1: Frontal Panel of transport ventilator.

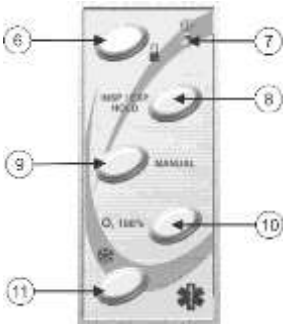


Figure 2: Side Keyboard

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

Components of Figures 1 and 2
1. LIQUID CRYSTAL DISPLAY WITH TOUCH SCREEN Visual and graphical presentation of the setting parameters with touch screen.
2. 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.
3. KEYBOARD The keypad buttons allow quick access to the ventilator functions.
4. HANDLE This handle allows to carry the ventilator during rescue and emergency operations. At the rear of the ventilator, there is a support that can be easily adapted to the patient stretcher.
5. 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.
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 for 2 seconds to release them. 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

Components of Figures 1 and 2
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 actuating this key will be visible for 5 seconds; after this period, the monitoring upper are will again display the parameter previously displayed.
9. MANUAL KEY This key triggers an inspiratory cycle of support pressure. And is active in the VCV, PCV, V-SIMV, CPAP/PSV, P-SIMV, DUALPAP, PLV modes.
10. O2 100% KEY By pressing key to "O2 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. When the ventilator is in STAND-BY, 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 change the value of the desired flow.
11. FREEZE KEY Freezes the graph layout to allow the analysis of the curves.

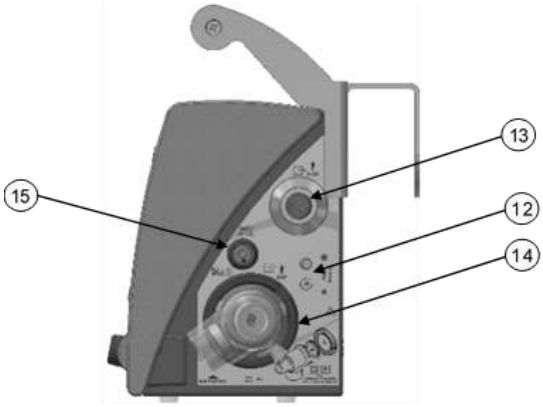


Figure 3: Right side view

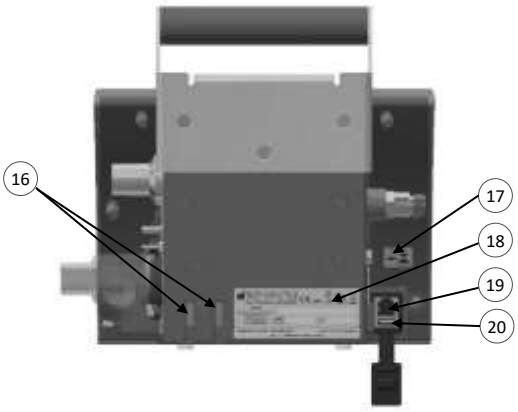


Figure 4: Back view

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

Description of the items in Figure 3 and 4	
12. FLOW SENSOR CONNECTIONS These connectors are used to connect the flow sensor.	**16. PLUG OF POWER SUPPLY – BASE** This plug is used together 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.
13. CONNECTOR 22M/15F OF INSPIRATORY FLOW Standard connection of the inspiratory flow to the breathing circuit of the patient	**17. LABELING TAG** This is the INMETRO seal of compliance and safety.
14 EXHALATION VALVE Connection of the expiratory limb of the breathing circuit of the patient.	

Description of the items in Figure 3 and 4	
15. CONNECTOR TO THE CO2 SENSOR or SpO2 SENSOR Connection to the CO2 sensor of PHASE IN or MASIMO SpO2 sensor (these sensors are optional)	**18. LABELING TAG** This labeling tag brings MAGNAMED information, European Authorized Representative, Registration number at ANVISA, month and year of manufacture and serial number.
19. ETHERNET RJ-45 CONNECTOR (optional) RJ-45 Ethernet Standard Connector Used to send data to an electronic health recorder and to share information on monitored parameters, waveforms and alarms. It is not possible to control the equipment remotely through this port.	**20. USB CONNECTOR (optional)** The UBS port is for maintenance purposes only and should be accessed by trained and authorized MAGNAMED personnel only.

Attention

- Use an ANSI / TIA / EIA-568 or higher CAT 5E cable category with a maximum length of 3 meters to connect to the ventilator's network port.
- Use only certified cables on the equipment's connectors.
- Connecting the ventilator to an IT network may result in risks to the patient, operator, or others not previously identified. The responsible organization must identify, analyze, assess and control these risks.
- Subsequent changes to the IT network may introduce new risks and require additional analysis by the responsible organization. Changes to the IT network include configuration changes, connection of additional items, disconnection of items, upgrading of equipment connected to the IT network, and enhancement of equipment connected to the data communication port.
- Failure to implement the communication protocol will result in failure to send data to other equipment.

2.4.2 Protocol used for data communication with external devices

The Ethernet port can be used to share ventilator data such as set parameters, monitored parameters, waveforms and alarm logging to electronic health recorders. Data has an average delay of 8 seconds from the time of data generation to the data output connector.

To send data to electronic health recorders, the IT network must be scalable, with high availability and low data propagation delay.

Required network configurations include a Dynamic Host Configuration Protocol (DHCP) enabled network server so that SEMP receives a valid Internet Protocol (IP). Communication is performed through the TCP protocol in the IT network. For communication with the electronic health recorder, an appropriate communication protocol must be implemented. For the communication protocol implementation guide, contact MagnaService.

The information goes as follows: Oxymag sends the data to the answering electronic health recorder it has received. The electronic health recorder may ask questions or request data to Oxymag who immediately responds or confirms the request.

Attention

- For the communication protocol implementation guide, contact MagnaService.
- This implementation should be performed on a network with the characteristics described in 2.4.1 by an IT specialist.
- IT network failures to provide the required characteristics may lead to delays in data communication or incorrect, incomplete or corrupted data transmission, resulting in incorrect information to the user.

WARNING

- ***Only rely on the ventilator for alarm signal generation and information. The IT network is not reliable for receiving alarm signals. Therefore, do not use a distributed alarm system as the only means to recognize alarm signal generation.***

The parameters are monitored based on the pressure and the FiO2 measurements performed by oxygen monitor.

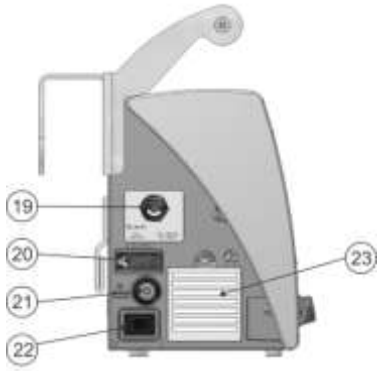


Figure 5: Left side view

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

Description of the items in Figure 5
19. OXYGEN INLET Connect oxygen. Inlet pressure should be in the range of 39 to 87 psi (270 to 600 kPa). Standard DISS connection (ABNT NBR-11906:1992).
20. SERIAL CONNECTION Serial Communication – RS-232 – female DB-9 connector for software update.
21. INLET +12VDC – External AC/DC Source Power supply input +12VDC – Connection to external AC/DC source through the plug
22. On/Off Switch On/Off Switch
23. 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 (12.Replacing the Ambient Air Filter).

WARNING

- ***Only use power supply, parts, pieces and accessories specified by MAGNAMED listed in this manual, which were tested and approved for use in conjunction with this equipment; otherwise, this can jeopardize the operation endangering the patient or user.***

Caution

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

Notes

- 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 Modes

In the upper left corner there is the indication:

- ✓ Type of patient selected: ADU→Adult; PED→Pediatric; NEO→Neonatal;
- ✓ Active Mode;
- ✓ NIV activation indication, this will have offset of leaks.

3.2 Alarms, Monitor and Status

- At the top of the screen, next to the mode indication, there is the alarm muting button for 2 minutes, as symbol below:

- When activated the alarm silencing, a bar indicating the silencing time is shown
- At the top center, there is the display are of the parameter always visible; this can display one of the parameters: MV – Minute Volume Monitored, VEXP – Volume Expired or PMAX – Maximum Pressure. To change the parameter displayed, touch on this screen position.
- At the top center, there is the STAND-BY button. By pressing this button for at least 2 seconds, the ventilator enters standby mode suspending mechanical ventilation. The word 'STAND-BY' will remain flashing while the equipment is in this condition. By continuing pressing the button, the sidebar will fill until complete 2 seconds. Stand-by button is shown with the symbol below:

- At the right top of the screen, there is the battery charge status. As shown below:

- At the top right of the screen, there is the area of alarm and alert messages;
- At the top right of the screen, a padlock will appear indicating that the touchscreen is disabled. Press LOCK button for at least 2 seconds, and the touch screen is enabled.

3.3 Monitor, Menus and Charts

- On the right side there is a "Bargraph" for pressure, a bar graph showing the instantaneous pressure in the breathing circuit and the value of maximal inspiratory pressure at the top of the bar graph in yellow.
- In the center of the screen there is the menu display area, numerical ventilation parameters and graphics

3.4 Setting the ventilation parameters

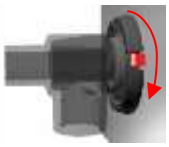
- On the bottom, there is a setting bar of the ventilation parameters

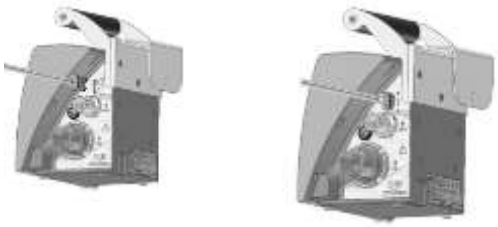
4. Preparation for Use

4.1 Assembling Oxymag – Transport Ventilation

Table 6 describes the steps to be followed by the operator (health care professional, duly trained and authorized to use the equipment) to assemble and prepare the transport ventilator.

Table 6: Assembly Sequence of Oxymag

Assembly Sequence	OK	Figure
1. Insert the ambient air filter into the appropriate slot on the left side of the ventilator. See chapter 12.5 Replacing the Ambient Air Filter.	☐	
2. Insert a diaphragm in the exhalation valve, then insert the assembly into the base as shown in the figure and press firmly and rotate clockwise to lock. **Attention** • To unlock the valve, press the locking valve and turn the valve counterclockwise.	☐	  
3. Prepare the patient breathing circuit, firmly connecting the inspiratory limb to the flow mixing gas supply.	☐	
4. The expiratory limb of the circuit should be securely connected to the exhalation valve.	☐	

Assembly Sequence	OK	Figure
5. Connect the power supply AC/DC to the equipment then to the mains.	☐	
6. Connect the oxygen hose to the transport ventilator.	☐	
7. Connect the appropriate flow sensor to the patient according to the figure.	☐	
8. Connect the flow sensor line as indicated in the figure on the right.	☐	

Notes

- There is an indication with a larger circle and a smaller circle in the ventilator showing the fitting position of the pressure line connector 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 Noninvasive ventilation mask

Use of the breathing circuit for NON INVASIVE VENTILATION (VNI or NIV – Non Invasive Ventilation).

A. Without HME filter;

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

B. With mask and HME filter

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

WARNING

- ***Use HME Filter and MASKs specified by MAGNAMED use appropriate MASKs for each type of patient.***
- ***Position correctly the diaphragm and the exhalation valve to prevent obstruction of the expiratory limb;***
- ***The correct connection of the pressure outlet tubes and the absence of 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 obstructe pressure port.The measured pressure in this points are used by the patient ventilation monitoring system.***
- ***All connections must be FIRMLY secured to prevent leakage.***
- ***Only use parts, pieces and accessories specified by MAGNAMED listed in this manual, which have been tested and approved for use in conjunction with this equipment; otherwise, it can jeopardize the operation endangering the patient or user;***
- ***PROPER connection of these pressure line tubes is extremely important for monitoring patient ventilation.***
- ***When using Oxymag for extended time in battery, an alarm occurs which message is LOW BATTERY, provide IMMEDIATE connection of power supply to the mains, if DISCONNECTING the equipment from the patient is not possible and provide***

appropriate means of ventilatory support.

- ***Use the appropriate breathing circuit to the patient.***
- ***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 specified may damage the equipment.***

4.3 Power Connection

The equipment must be connected to a three-pin grounded power outlet fulfilling ABNT NBR 13534 standard – "Electrical installations in health care facilities – Safety requirements".

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

After prolonged use of the equipment, using only the energy of the internal battery, full recharge is required preparing the equipment for the 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 from disconnecting of the power supply.

4.4 Mounting the vertical support

Support (1702496) is an optional item and can be used in ambulances, helicopters or walls of hospital environment facilities (emergency, post-anesthetic recovery rooms, ICU, etc).

Below is provided the sequence to assemble the support on the wall.

1. Install the fixed support with +12V DC power (3803835) on the wall (room, ambulance, helicopter, etc.) using 4 screws (3003446) item 1 of the figure to the side and 4 fixing bolts (3003447), if required (item 2 of the figure).

Figure 8: Installation of the fixed support

2. To place the ventilator on the support, follow the sequence 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 invisible;
d. Make sure that Oxymag is fixed in placed;
e. To remove Oxymag, perform the reverse procedure.

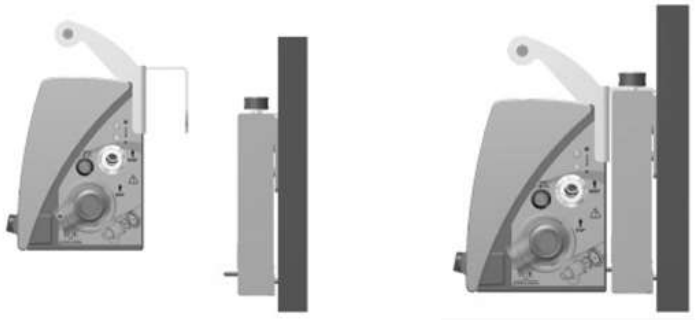


Figure 9: Connection of the ventilator to the fixed support

Below is provided the sequence to assemble the support on the bench:

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

Figure 10: Installation of the fixed support on the bench

2. To place the ventilator on the support, follow the sequence 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 invisible;
d. Make sure that Oxymag is fixed in place;
e. To remove Oxymag, perform the reverse procedure.

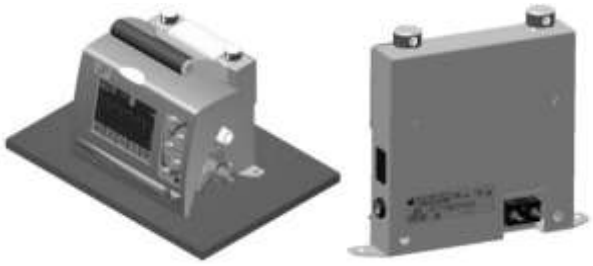


Figure 11: Connection of the ventilator to the support

5. Checks Before Use

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

WARNING

- ***This equipment must pass the "Checking procedures and basic settings" to ensure the effectiveness of the equipment and the safety of the operator and patient.***

5.1 Initial procedures

This equipment must pass the "Checking procedures and basic settings" to ensure the effectiveness of the equipment and the safety of the operator and the patient, as the following sequence:

- ✓ Make sure the equipment is off;
- ✓ Perform a visual inspection of the equipment and its components seeking to identify their full integrity;
- ✓ Check if all equipment components are connected and inserted correctly;
- ✓ Check the presence of the ambient air inlet filter;
- ✓ Ensure that the connection of the exhalation valve is secure. It is important to check the presence of the diaphragm;
- ✓ Check the secure connection of the breathing circuit and the flow sensor suitable for the patient to be ventilated;
- ✓ Check the tight connection of the oxygen hose;
- ✓ Check the pressure in the cylinder gauge, where applicable this should be according item 15.3.2 Connecting to the Oxygen Supply.
- ✓ Check the tight connection of the power supply, where applicable. The Ventilator can be operated on battery, lasting as specified;
- ✓ Turn on the ventilator and make sure that three beeps were issued and the alarm indicator light was triggered. This check ensures the functioning of the audible and visual alarm indicators;
- ✓ Select the type of patient with the corresponding figures shown on the display. The ventilator will immediately start ventilation. If you want to put on standby, press the button STAND-BY.

WARNING

- ***If you hear the triple "BEEP" signal 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.***

5.2 Ventilator Settings

The ideal weight of the patient is used to calculate the ventilator setting 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;
- Frequency – according to the internal calculation to the system;
- Ratio I:E - 1:2;
- Inspiratory Flow – calculated according to TINS obtained;

The other parameters will have the default value:

- 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 7: Modes available for the types of patient

Patient type	*Flow Sensor*	*Modes available (1)*
NEONATAL	NEO	PLV, CPAP/PSV, P-SIMV, DualPAP
PEDIATRIC	INF	VCV, V-SIMV, PCV, CPAP/PSV, P-SIMV, DualPAP
ADULT	ADU	VCV, V-SIMV, PCV, CPAP/ PSV, P-SIMV, DualPAP

(1) NVI (Non Invasive Ventilation) can be activated in all ventilation modes and when activated, it will compensate leaks

Below the patient selection button, there is an indication of the sensor to be used for each patient.

WARNING

- ***To obtain all monitored parameters available on the equipment, it is important to connect the correct flow sensor in the breathing circuit.***
- ***If required to use a breathing circuit different from the one indicated, use the indicated flow sensor.***

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

Table 8: List of values adopted by the equipment when selecting a patient

Startup button	Patient type	Height [m]	Ideal Weight P [kg]
	***NEONATAL***	*0,36*	*2,8*
	***PEDIATRIC***	*0,95*	*19,8*
	***ADULT***	*1,50*	*49,5*

After startup, it is possible to change the height value within the adjustment range of the patient type set by clicking on the chart area and menu and selecting the Settings button (General Tab). Setting is as table below:

Table 9: List of adjustment range for height and weight

Patient Type	Height Adjustment [m]		Ideal Weight P [Kg]
	Min.	Máx.	
NEONATAL	0,16	0,52	≤ 6,0
PEDIATRIC	0,53	1,08	6,0 < P ≤ 25
ADULT	1,09	2,5	> 25

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

Height adjustment of the patient does not remain 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.

WARNING

- ***USE THE FLOW SENSOR INDICATED. The correct ventilation monitoring depends on the flow sensor used in the breathing circuit.***
- ***Even if there is need to use breathing circuits different from the patients to be ventilated, the FLOW SENSOR SHOULD BE AS INDICATED.***

Notes

- The selection of the patient type on startup will perform the initial setting of the transport ventilator and release certain ventilation modes.
- There are three types of flow sensors
    - NEO – Neonatal – Range from -20 to +20 $L.min^{-1}$
    - PED – Pediatric – Range from -50 to + 50 $L.min^{-1}$
    - ADU – Adult – Range from -150 to +150 $L.min^{-1}$
- Body Mass Index Formula:

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

5.2.1 Normal Startup Sequence

1. Initial screen of Oxymag – Turn on the ventilator through on-off switch on the left side of the equipment. By turning on, note that a triple "beep" goes off in conjunction with the light alarm indicator, meaning 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 audible or visual alarm indication.***

2. Press the key corresponding to the type of patient to be ventilated and connect the flow sensor indicated in the patient's breathing circuit. The ventilator will be initialized in the mode indicated in *Table 7*: Modes available for the types of patient

3. Last Set Button – This button brings back the last parameters set and saved when the equipment was switched off for the last time. This saving is automatic (optional).

4. By pressing the key NEONATAL the ventilator will start ventilation with the following parameters:

Table 10: List of parameters in the Neonatal mode

PLV	Default
Pinsp	15 cmH2O
Rate	40 min^{-1}
Tinsp	0,5s
PEEP	5 cmH2O
Flow	6 $L.min^{-1}$
FiO_2	40%
Flow Trigger	OFF
Pressure Trigger	OFF

5. By pressing key PEDIATRIC the ventilator will start ventilation with the following parameters:

Table 11: List of parameters in the Pediatric mode

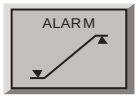
PCV	Default
Pinsp	15 cmH2O
Rate	22 min^{-1}
Ratio I:E	1:2
PEEP	5 cmH2O
FiO_2	50%
Flow Trigger	OFF
Pressure Trigger	OFF
Rise Time	0,1s

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

Table 12: 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
Pause	30%
FiO_2	50%
Flow Trigger	OFF
Pressure Trigger	OFF
Wave Flow	Square

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

to display the following screen to select the mode.
9. Press the desired mode button and after confirmation of adjustment parameter required for this ventilation mode and the ventilation will immediately start.
10. To change a parameter, press the corresponding button. The parameter will become YELLOW indicating that is selected, allowing the change. Turn the knob clockwise to increase the value and counterclockwise to reduce. To confirm the change, press the knob and confirm or tap on the parameter button to be set on screen to activate the new value.
11. Press ALARM button 

and the Alarm Setting screen will appear, the figures below follow the order of the conditions described in the previous item. Tap on alarm to be set and use the knob and confirm to set the value. When the desired value is set confirm pressing the knob and confirm.

To return to the screen with the button for selection of charts, data, settings and alarms press button  . To automatically adjust the alarm values select the parameter "Automatic" and choose the default limit: OFF, 10%, 20% or 30%. The alarm limits of ventilator parameters (Pressure, PEEP, MV, Volume, FiO2 and Frequency) will be automatically adjusted:

a) In the lower limit: for the value of the parameter currently measured minus the percentage selected in automatic;

b) In the upper limit: for the value of the parameter currently measured plus the percentage selected in automatic;

c) If OFF selected, these alarms return to the alarm default values for the type of patient set at startup;

To enable the automatic adjustment, it is required that the ventilator is not in STAND-BY.

12. By pressing SETTING button, you can:

- Change the height of the Patient thereby defining the ideal weight (IMC 22), recalculating the default ventilatory parameters of this patient;
- Turn on or off the NIV (Non Invasive Ventilation) using a mask. When NIV is activated, there will be compensation of leaks of approximately 40L.min-1, depending on the ventilator settings;
- Turn on or off the extern blender compensation. In this condition the device don't allow the FiO_2. The FiO_2 adjustment will be done directly in the blender[1];
- 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;
- Press O2/CO2 tab to perform calibration of O2 and CO2 meters. Press button "Calibrate FiO2" to calibrate the oxygen sensor. Press button "Calibrate CO2" to calibrate CO2 sensor.
- Press Ventilator tab to:
- **Set:**
    - Audio volume – to set the alarm audio volume. Use the button "knob and confirm" to make this adjustment. This parameter always starts in the maximum level 5.
    - Pressure unit – Press the desired unit;
- **View:**
    - Data of the last test performed: breathing system leakage, compliance and resistance done in initial tests;
    - Total hours of use of the equipment;
    - Hours past since the last maintenance;

13. Press the screen on chart area and menu. A panel of buttons will be displayed for selection of charts, data, settings and alarms. If no external sensor is connected to the equipment (capnography or oximeter) the respective button will not appear.

1 With extern Blender it is possible to adjust the FiO_2 from 21 to 100%.

5.2.2 Test Sequence

The tests are essential to check if the equipment is operating as expected and make adjustments for the best possible performance. Remember to conduct initial tests before starting ventilation.

WARNING

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

1. Home screen - Press the Test button and the sequence of internal tests will be activated. Follow 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: “Inoperative Device” – Contact Technical assistance will appear. The equipment requests the clearance of y-connector and the sensor connection corresponding to the last patient ventilated. Press Ok when this condition is carried out.

WARNING

- ***After a ventilation, to change the patient type in the test sequence, restart the equipment, select the type of patient desired and restart the equipment again, only then proceed to the test sequence.***

---

4. Tests will be carried out sequentially; 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 20)***

---

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. Press key 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

The *Table 13:* shows the actions that can be taken to remedy the shortcomings indicated in the test sequence. The consequence column indicated what may occur if the equipment is used with failure.

WARNING

- ***If “Inoperative Device” 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 fault persists, contact technical assistance.

Table 13: Indications of fault diagnosis

Fault	Action	Consequence
O_2 Flow	Ensure that the oxygen supply pressure is according to the specification 15.3.2 Connecting to the Oxygen Supply	Lack of flow, use not allowed
Internal Sensor	Contact Technical Assistance	Failure in flow control, use not allowed
Ar Flow+ O_2	Ensure 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 O2 meter, use not allowed
Exhalation Valve	Check the positioning of the membrane in the Exhalation Valve	Failure in the pressure monitoring and control, use not allowed
Pressure Sensor	Check the positioning of the membrane 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	- Message “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 monitored the parameters: Pmax, PEEP, Pplat., Pmean and Pressure x time chart; - Parameter flow trigger will be inactive;

6. Capnography Sensor (EtCO2)

The mainstream sensor IRMA™ MASIMO was designed to monitor the respiratory gases of adult, pediatric and pediatric patients during anesthesia in places such as Intensive Care Unit (UCI), Operating Rooms and Emergency Room. The CO2 sensor is state of the art, in an assembly formed by a single way sensor with technology of up to 9 non-dispersive infrared (NDIR) channels to identify gas, a barometric pressure sensor, a voltage regulator and a microprocessor. The unit weighs less than 25g.Carbon Dioxide (CO2) concentrations are monitored together with other parameters, such as Respiratory Rate ("RR"), the waveform of the gas and concentration of each gas during inspiration and expiration.

The IRMA airway adapter fits perfectly to the IRMA gas sensor. This equipment uses window technology XTP™. The airway adapter should be positioned between the endotracheal tube and the breathing circuit allowing that XTP Windows positioned on the sides of the sensor to measure the concentration of gases.

By operating on a standard continuous voltage of low intensity, the CO2 sensor was designed to meet requirements of portability and low power consumption, typically below 1 Watt. It was designed to be extremely easy to integrate with any monitoring device, allowing real-time visualization of Information about gases.

6.1 Instructions for Use

The mainstream sensor IRMA was designed to be used connected to Oxymag ventilator and any other monitoring device compatible with this sensor. It has the function to monitor in real time the signal and the gas concentration.

The sensor must be connected to the patient breathing circuit in order to monitor the inhaled and exhaled gases during anesthesia, and when the patient is in the recovery room and on respiratory care. It should be used in Operating Rooms, Intensive Care Unit (ICU), Emergency Room and patient rooms. It is indicated for adult, pediatric and pediatric patients.

It should not be used as the sole means for patient monitoring. It should always be used in conjunction with other monitoring equipment of vital signs and this monitoring must be accompanied by an expert capable to analyze the patient condition. The CO2 sensor was designed to be used by trained and authorized health care professionals.

6.2 Assembling the Sensor

The following steps show how to assemble the gas monitoring sensor:

a) Connect the cable of the CO2 sensor to the ventilator Oxymag and turn on the device;

Figure 12: Fitting the capnography in Oxymag

b) Attach the airway adapter to the IRMA sensor. You can hear a click when the airway adapter fits correctly to the sensor;

Figure 13: Fitting airway sensor

c) green LED indicates that the CO2 sensor is ready for use.

Figure 14: LED indicates if the sensor is ready for use

d) Connect IRMA 15-mm adult airway adapter to the Y-piece of the breathing circuit;

Figure 15: Connection of the airway adapter to Y-piece of the Breathing Circuit

e) Connect IRMA 15-mm adult airway adapter to the Endotracheal Tube of the patient;

Figure 16: Connecting the Airway Adapter to Part Y to the Endotracheal Tube

f) If there is need to connect a Heat Moisture Exchanger (HME), place it between the CO2 sensor and the Endotracheal Tube. Placing the Moisture Exchanger in front of the sensor will protect the airway adapter from secretions and effects of steam, which eliminates the need to Exchange the adapter in use.

Figure 17: Scheme to assemble the Humidifier Filter

6.3 Positioning the Sensor

When connecting the CO2 sensor to the breathing circuit of an pediatric patient, it is extremely important to avoid direct contact between the CO2 sensor and the patient body.

If not possible, for any reason, the direct contact of the sensor with any part of the child body, an insulating material must be placed between the CO2 sensor and the body.

WARNING

- ***The CO_2 sensor must have direct contact with the patient during use.***

6.4 Procedure to Reset the Sensor

WARNING

- ***The incorrect reset of the sensor will result in incorrect Reading of the measured values.***

To ensure high accuracy in the values measured by IRMA sensors, the following resetting recommendations should be followed.

Resetting must be performed by connecting an airway adapter to IRMA sensor, without connecting them to the breathing circuit. When the gas monitoring signals have stable values, press the button to start resetting.

Special care must be taken to avoid any breathe near the sensor before or during resetting. The presence of ambient air (21% O2 and 0% CO2) in the airway adapter is of extreme importance for a successful resetting. If the error message “Recalibration required” appears immediately after the end of the resetting, this procedure must be repeated.

Resetting must be performed every time the airway adapter is replaced. It should be also performed whenever there is a shift of the baseline (offset) in any of the gas measures or when the error message “Accuracy of gas measures not determined” appears on the screen.

After turning on the sensor or replacing the airway adapter, wait at least one minute before starting the resetting procedure in order to allow heating of IRMA sensor. The green LED on the sensor will flash for 5 seconds while resetting process is in progress.

6.5 Information regarding LED

The following table shows the possible colors displayed on the LED found on the sensor and their meanings:

Table 14: Colors on the LED and their meanings

Color (Status)	Meaning
Green (lit constantly)	System OK
Green (flashing)	Resetting in progress
Blue (constantly lit)	Anesthetic Agent Found
Red (lit constantly)	Error in sensor
Red (flashing)	Check the adapter

6.6 Preventive Maintenance of $EtCO_2$ Sensor

The gas calibration must be checked at regular intervals by reference instrument.

WARNING

- ***The CO2 sensor is intended for the exclusive use of trained and authorized medical personnel;***
- ***The CO2 sensor should not be used with flammable anesthetic agents;***
- ***The CO2 airway adapters should not be reused. The reuse of a disposable airway adapter may cause cross infection;***
- ***Do not use the Adult/Pediatric airway adapter in pediatric patients, because the adapter adds a 6-ml dead space in the patient breathing circuit;***
- ***Do not use the Pediatric airway adapter in adult patients, because this adapter may add excessive resistance;***
- ***Measurements can be affected by Radio Frequency communication equipment or by mobile devices. The user must make sure that the sensor is used in environments according to the electromagnetic environment specifications expressed in this manual;***
- ***Do not connect the airway adapter between the Endotracheal Tube and the elbow of the breathing circuit, as this may cause the patient secretion to block the Windows of the adapter, causing improper sensor operation;***
-

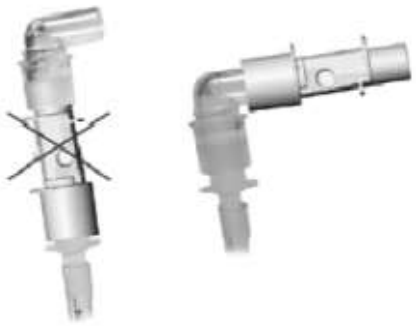


Figure 18: Incorrect and correct positioning of the airway adapter

- ***Do not use the airway adapter with inhaler with dosimeters or nebulized medications, because they can affect the light transmission within the sensor window;***
- ***The CO2 sensor was designed to be an adjunct device in patient monitoring. Its***

information must be analyzed together with other measurements and symptoms;

- ***Improper resetting can result in erroneous measurements;***
- ***Replace the airway adapter if there is condensation inside the adapter;***
- ***Use only airway adapters produced by PHASEIN;***
- ***The CO2 sensor should not come into direct contact with the patient during use.***

Caution

- Never sterilize or immerse the CO2 sensor in liquid;
- Do not apply voltage to the sensor cable;
- Do not use the CO2 sensor in environments which specifications are outside the limits stablished in the Technical Specifications (Temperature, Humidity, etc.)
- Airway adapters of the CO2 sensor are non-sterile accessories. Steam sterilization can damage these accessories.
- Never sterilize or immerse the CO2 sensor in liquid.

6.7 Technical Specifications of the Capnography

Table 15: Technical Specifications of the Capnography

Attribute	Specification
GENERAL	
Description	Mainstream monitoring sensor with infrared technology.
Dimensions (W x D x H)	IRMA CO_2: 38 x 37 x 34mm (1.49” x 1.45” x 1.34”)
Cable length	2.50m (± 0.02m)
Weight	< 25g (without cable); < 38g (with cable).
Mechanical Resistance	Withstands repeated 1-m falls on a hard surface. According to the standard requirements for ambulances (EN 1789:2004 – clause 6.4) and requirements against shock and vibration (ISO 80601-2-55 - ed.1).

Attribute	Specification
Electric Power Supply	IRMA CO_2: 4.5 – 5.5 VDC, Max 1.0W (power measured with 5V and less than 350mA during 200ms).
Surface Temperature (room temperature 23°C)	IRMA CO_2: Max: 41°C / 106°F.
Airway adapter	Adult/Pediatric (Disposable): Adds less than 6ml dead space; Pressure drop lower than 0.3cmH_20 at 30LPM. Pediatric (Disposable): Adds less than 1ml dead space; Pressure drop less than 1.3cmH_20 at 10LPM.
OUTPUTS	
Breathing Detection	Adaptive threshold, minimum 1% volume change in CO_2 concentration.
Respiratory Rate	0 - 150bpm. Respiratory Rate is shown every 3 breaths and the average value is updated every breath.
Fi and ET	Fi and ET are shown after a breath and their averages are continually updated. IRMA CO_2: CO_2.
Waveform	IRMA CO_2: CO_2.
Diagnostic Parameters	Atmospheric Pressure, review of software and hardware, serial number.
Information	Detection of New Breath, Apnea, Check Adapter, Accuracy Not Specified and Sensor Error.
CO_2 Gas Analyzer:	
Sensor	Gas analyzer with 2 - 9 NDIR (Non-Dispersive Infrared) Channels which measures in the range of 4 - 10µm. Makes correction of pressure, temperature and interference across the spectral range.
Calibration	Resetting recommended at each replacement of Airway Adapter. No need for specific infrared calibration.

Attribute	Specification
Warm-up	Information on the concentration is analyzed and sent every 10 seconds. Overall accuracy in measurements: 1 minute.
Rise time (at 10 l/min)	CO_2 ≤ 90ms.
Overall System Response Time	< 1s.

Table 16: Accuracy specifications of the Capnography

Precision / Accuracy of measurements (under standard conditions):		
Gas Type	**Gas Type**	**Gas Type**
CO_2	0 - 15 15 - 25	±(0.2 vol% + 2% reading) Not specified
Note: Gas concentration expressed in percent volume units.		
Gas Type		**Precision / Accuracy**
CO_2		±(0.3 vol% + 4% reading)

Note 1: Specification for precision is valid for any environmental condition specified, except in the cases expressed in the table below with "Effects of Gas and Steam Interference".

Table 17: Interference specifications in the Capnography

Effects of Gas and Steam Interference:		
Gases or Steam	Gas Level	CO_2
N_2O	60 vol%	--- (1 and 2)
HAL	4 vol%	--- (1)
ENF, ISO, SEV	5 vol%	+8% measurement read.. (3)
DES	15 vol%	+12% measurement read. (3)
Xe (Xenon)	80 vol%	-10% measurement read. (3)
He (Helium)	50 vol%	-6% measurement read. (3)
Propellant inhaler with dosimeter	Not designed for use with propellant inhaler with dosimeter.	

Effects of Gas and Steam Interference:			
C_2H_5OH (Ethanol)	0,3 vol%	--- (1)	
C_3H_7OH (Isopropanol)	0,5 vol%	--- (1)	
CH_3COCH_3 (Acetone)	1 vol%	--- (1)	
CH_4 (Methane)	3 vol%	--- (1)	
CO (Carbon Monoxide)	1 vol%	--- (1)	
NO (Nitrogen Monoxide)	0,02 vol%	--- (1)	
O_2	21 vol%	0% measurement read.	5.0 vol%(2)
	50 vol%	-2,76% measurement read.	4.9 vol%(2)
	70 vol%	-4,67% measurement read.	4.8 vol%(2)
	95 vol%	-7,05% measurement read.	4.7 vol%(2)

NOTE 1: NEGLIGIBLE INTERFERENCE. INTERFERENCE EFFECTS DO NOT CHANGE VALUES IN TABLE "PRECISION / ACCURACY OF MEASUREMENTS (UNDER ALL CONDITIONS)" ABOVE.

NOTE 2: VALUE SHOWN FOR ACTUAL CONCENTRATION OF 5.0% CO2

NOTE 3: INTERFERENCE AT THE GAS LEVEL INDICATED. FOR EXAMPLE, 50 VOL% HELIUM TYPICALLY LOWER THE VALUES READ AT CO2 6%. THIS MEANS THAT, IF THE MIXTURE CONTAINS 5.0 VOL% CO2 AND 50 VOL% HELIUM, THE CO2 CONCENTRATION WILL BE NORMALLY CALCULATED AS: (1 – 0.06) * 5.0 VOL% = 4.7 VOL% CO2.

7. Oximeter (Masimo)

The encapsulated pulse oximeter Masimo MS-2040 is a self-sufficient solution that enables the secure measurement even in motion and low perfusion to measure: SpO2, heart rate, perfusion index and PVI. This oximeter is compatible with all Masimo LNCS® sensors.

7.1 Operation Principle

The MS board of Masimo SET ® pulse oximeter is based on three principles:

1 Differential of oxyhemoglobin and deoxyhemoglobin absorption of red and infrared light (spectrophotometry).
2 Volume of arterial blood in the tissue and the light absorbed in blood changes (plethysmography).
3 Arteriovenous shunt is highly variable and its absorbance fluctuation by the venous blood is the most noise component during the pulse.
4 MS board of Masimo SET pulse oximeter as well as the traditional pulse oximeter determines SpO2 by passing red and infrared light into a capillary bed and changing the measurement during the pulsatile cycle. Red and infrared light emitting diodes (LED) in oximetry sensors serve as light source; the photodiode serves as a photodetector.

Traditionally, the pulse oximetry assumes that all pulsations in the light absorbance signal are caused by fluctuations in arterial blood volume. It is assumed that the blood flow in the sensor region passes entirely by the capillary bed rather than via some arteriovenous shunt. Traditional pulse oximetry calculates the ratio of pulsatile absorbance (AC) in relation to average absorbance (DC) in each of the two wavelengths, 660nm and 905nm:

$$S(660)=AC(660)/DC(660)$$

$$S(905)=AC(905)/DC(905)$$

The oximeter then calculates the ratio between these two signals of arterial absorbance pulse:

$$R=S(660)/S(905)$$

This R value is used to find the SpO2 saturation in a check table provided by the oximeter software. The values in this table are based on studies with human blood versus those from a co-oximetry laboratory in healthy adult volunteers in an induced hypoxia study.

The MS board of Masimo SET pulse oximeter assumes that the arteriovenous shunt is highly variable in the floating absorbance due to venous blood being part of the noise component during the pulse. The MS board decomposes S(660) and S(905) into an arterial signal plus a noise component and calculates the ratio of arterial signal without noise:

$$S(660)=S1+N1$$

$$3S(905)=S2+N2$$

$$R= S1/S2$$

Again, R is the ratio between two signals of pulsed arterial absorbance and its value is used to find the SpO2 saturation in an empirically derived equation in the oximeter software. The values in the equation empirically derived are based on studies on human blood versus those from a co-oximetry laboratory in healthy adult volunteers in a hypoxia-induced study.

The above equations are combined and a reference noise (N') is set:

$$N'=S(660)-S(950)xR$$

If there is no noise N'=0: then S(660) = S(905) x R, which is the same ratio that the traditional pulse oximeter.

The MS board software scans through all possible R values corresponding to SpO2 values between 1% and 100% and generates a N' value for each of these R values. The signals S(660) and S(905) are processed for each possible reference noise N' for an adaptive cancellation correlation (ACC) which produces a power output versus possible SpO2 value as shown in the following figure, where R corresponds to SpO2=97%..

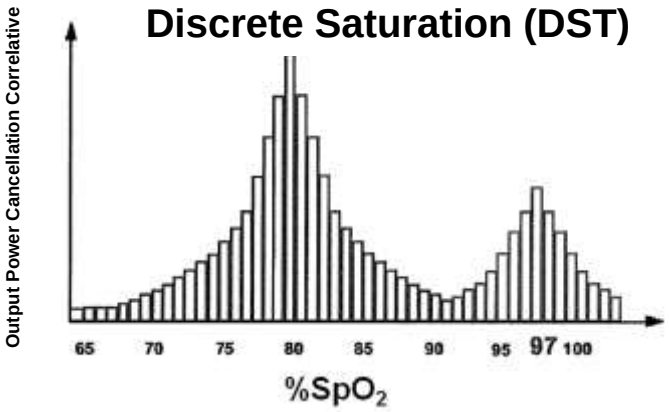


Figure 19: Discrete Saturation Curve (DST)

The DST curve has two peaks: one peak corresponding to higher saturation is selected as SpO2 value. All sequence is repeated every two seconds within the most recent four seconds of data received. Completing the SpO2 of the MS board corresponds to the analysis used for the arterial hemoglobin saturation updated every two seconds.

WARNING

- ***Risk of explosion. Do not use MS pulse oximeter in the presence of flammable anesthetics or other flammable substances in communication with air, oxygen- or nitrous oxide-rick environments.***
- ***The pulse oximeter should not be used as an apnea sensor.***
- ***The heart rate is based on optical detection of the peripheral pulse flow and, therefore, may not detect certain arrhythmias. The pulse oximeter should not be used as replacement or substitution for the arrhythmia analysis based on ECG***
- ***A pulse oximeter may be considered a previous warning device. As an indicator of tendency of patient deoxygenation, blood samples may be analyzed by a co-oximetry laboratory to complete the understanding of the patient condition.***
- ***The MS board of the pulse oximeter should be operated only by a qualified person. This manual, instructions for use, all precautionary information, and specifications should be read before use.***
- ***Risk of electric shock. Do not remove the monitor cover, except for battery replacement. The operator may perform maintenance procedures specifically described in this manual. Contact MAGNAMED technical assistance to repair this oximeter.***
- ***As with all medical equipment, position the patient cable in order to reduce the possibility of entanglement or strangling.***
- ***Interfering substances: Carboxyhemoglobin can erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present. Dyes, or any substances containing dye, changing usual pigmentation of arteries can cause read errors.***
- ***Do not use Masimo sensor during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The oximeter may affect the resonance image, and the resonance unit may***

affect oximetry measurements.

- *If the faithfulness of any measurement does not seem reasonable, first check the vital signs of the patient by alternative measures and check if the oximeter is working properly.*
- *The oximeter may be used during defibrillation, but the readings may not be accurate by a short period of time.*
- *Before use, carefully read the operating instructions of LNOP®/LNCS® sensors.*
- *Use only Masimo oximetry sensors for SpO2 measurements.*
- *Tissue can be damaged by incorrect application or use of LNOP®/LNCS® sensor; for example, by attaching too tight LNOP®/LNCS® sensors. Inspect the sensor site as directed in the instructions for use to ensure skin integrity and correct sensor positioning and attachment.*
- *Do not use damaged LNOP®/LNCS® sensors. Do not use LNOP®/LNCS® sensors with exposed optical components.*
- *Do not immerse the sensor in water, solvent or cleaning solution (sensors and connectors are not waterproof). Do not use irradiation, steam or oxide sterilization. See cleaning instructions in the instructions for use of reusable Masimo LNOP®/LNCS® sensors.*
- *Do not use damaged patient cables. Do not immerse the patient cable in water, solvent, or cleaning solution (patient cables are not waterproof). Do not use irradiation, steam or oxide sterilization. See cleaning instructions for reusable Masimo LNOP®/LNCS® patient cables.*

Caution

- *Cleaning*
    - *Do not sterilize by steam, pressure or gas.*
    - *Do not wet or immerse the monitor in any liquid.*
    - *Use sparingly the cleaning solution. Excessive amount of solution may drip inside the monitor and cause internal damage to the components.*
    - *Do not use petroleum- or acetone-based solutions, or other harsh solvents to clean the oximeter. These components attack the materials of the device and may even result in failure.*
- *Inaccuracy in the measurements may have been caused by:*
    - *Misapplication or misuse of the sensor*
    - *Significant level of hemoglobin dysfunction (e.g., carboxyhemoglobin or methemoglobin).*
    - *Intravascular dyes, such as green indocyanine or methylene blue.*
    - *Exposure to excessive light, as well as surgical lamps (particularly those with xenon light source), lamp for bilirubin, fluorescent light, infrared heating lamps, or direct sunlight (exposure to excessive light can be corrected by covering the sensor with a dark or opaque material).*
    - *Excessive patient motion.*
    - *Venous pulsation*
    - *Positioning the sensor at one end with a blood pressure cuff, arterial catheter or intravascular line.*
- *Loss of pulse signal can occur due to any of the following:*
    - *The sensor is too tight*

- ***There is excessive illumination from light sources, such as surgical lamp, bilirubin lamp or sunlight.***
- ***Blood pressure cuff is inflated at the same end where the SpO2 sensor is positioned.***
- ***The patient has hypotension, severe vasoconstriction, severe anemia or hypothermia.***
- ***There is arterial occlusion near the sensor.***
- ***The patient is in cardiac arrest or shock***

7.2 Sensor assembly

Connect the oximetry sensor to the Oxymag as shown in the figure:

Figure 20: Oximeter sensor assembly

8. Description of modes

8.1 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, provided that the pressure is not limited. Waveform of the flow can take square, descending, sine and ascending shapes

Note

- This ventilation mode is not available for NEONATAL patients (weight < 6,0 kg).

Set Parameters::

- VOLUME;
- RATE;
- RATIO I:E;
- PEEP;
- MAXIMUM PRESSURE;
- PAUSE INSP (%);
- FiO2;
- TRIGGER FOR FLOW;
- TRIGGER FOR PRESSURE;
- FLOW WAVEFORM

Figure 21: VCV Curves

Once all ventilation parameters are received by the ventilator, it calculates TINS, TEXP, TPAUSE, FINS based on Ratio I:E, Pause and Frequency, thus obtaining all 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 stopped 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 time.

Note

- When the patient begins to demonstrate inspiratory effort and the ventilator is with 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.

4. ASCENDING (or accelerated) waveform of the flow.
5. DESCENDING (or decelerated) waveform of the flow.
6. SINE waveform of the flow.
7. Representation of Pressure Limitation. In this situation the ventilator limits the pressure at the set value and as a result of factors such as lung compliance of the patient and pressure limit imposed, the set volume IS NOT DELIVERED and this condition is reported in the status area and screen messages (message LIMITED PRESSURE).

WARNING

- ***Upon reaching the pressure limit set in the Maximum Pressure setting (Message LIMITED PRESSURE) the Volume Set IS NOT DELIVERED.***
- ***Default values are only initial reference. Reset the ventilation parameters as needed by the patient.***
- ***Volume limited ventilators must not to be used in patients without supervision.***

8.2 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.

Note

- This ventilation mode is not for NEONATAL patients (reported weight ≤ 6.0 kg).

Set Parameters:

- INSP PRESSURE;
- RATE;
- RATIO I:E;
- PEEP;
- FiO2
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- RISE TIME;

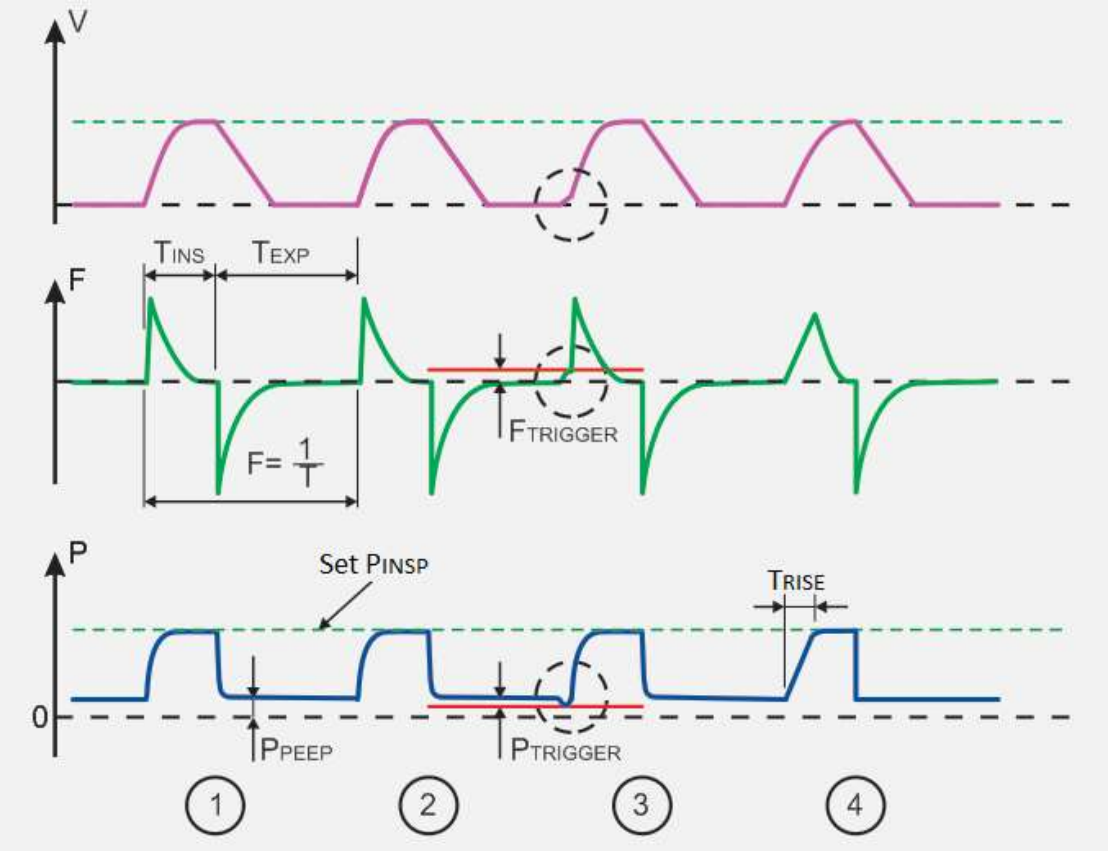


Figure 22: PCV Curves

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.

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.***

8.3 PLV –Limited Pressure Ventilation

Description:

In this continuous flow mode, the ventilator limits 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 which decreases over time.

Note

- This ventilation mode is available only for NEONATAL patients (reported weight ≤ 6.0 kg).

Set Parameters:

- INSP PRESSURE;
- RATE;
- INSPIRATORY TIME;
- PEEP;
- FLOW ( );
- FiO2
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE

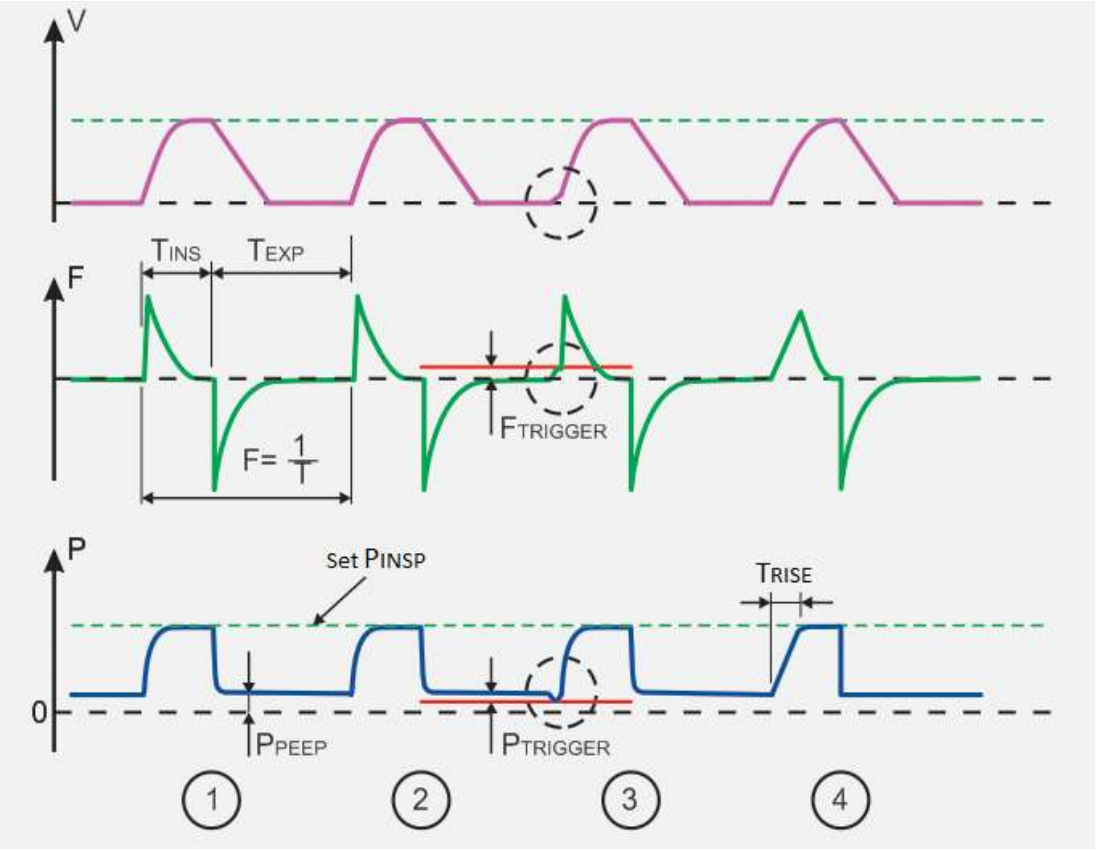


Figure 23: PLV Curves

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

1 e **2** Pressure Limited Ventilation – The ventilator seeks to achieve the set inspiratory pressure, and this is accomplished by occlusion of the exhalation valve. It is important to note that the pressure rise time is dependent on the set continuous flow. The Volume delivered to the patient is the result of the resistance and compliance of his breathing circuit. The ventilator remains at the level of set inspiratory pressure during TINS after which cycles to exhalation, maintaining the set PEEP pressure.

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

WARNING

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

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 an assisted-controlled ventilation, the respiratory rate monitored can be higher than the respiratory rate set.
- BASE FLOW is an existing flow during the exhalation phase to eliminate CO2 from the respiratory circuit, in addition to reduce undesirable PEEP.

8.4 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).

Note

- This ventilation mode is not available for NEONATAL patients (weight reported ≤6.0 kg).

Set Parameters:

- VOLUME;
- RATE;
- INSPIRATORY TIME;
- PEEP;
- MAXIMUM PRESSURE;
- PAUSE (%);
- FiO2
- ΔPS (Pressure support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- WAVEFORM OF THE FLOW;
- CYCLING BY FLOW (% FLOW);
- RISE TIME;
- FLOW (- only to NEONATE);

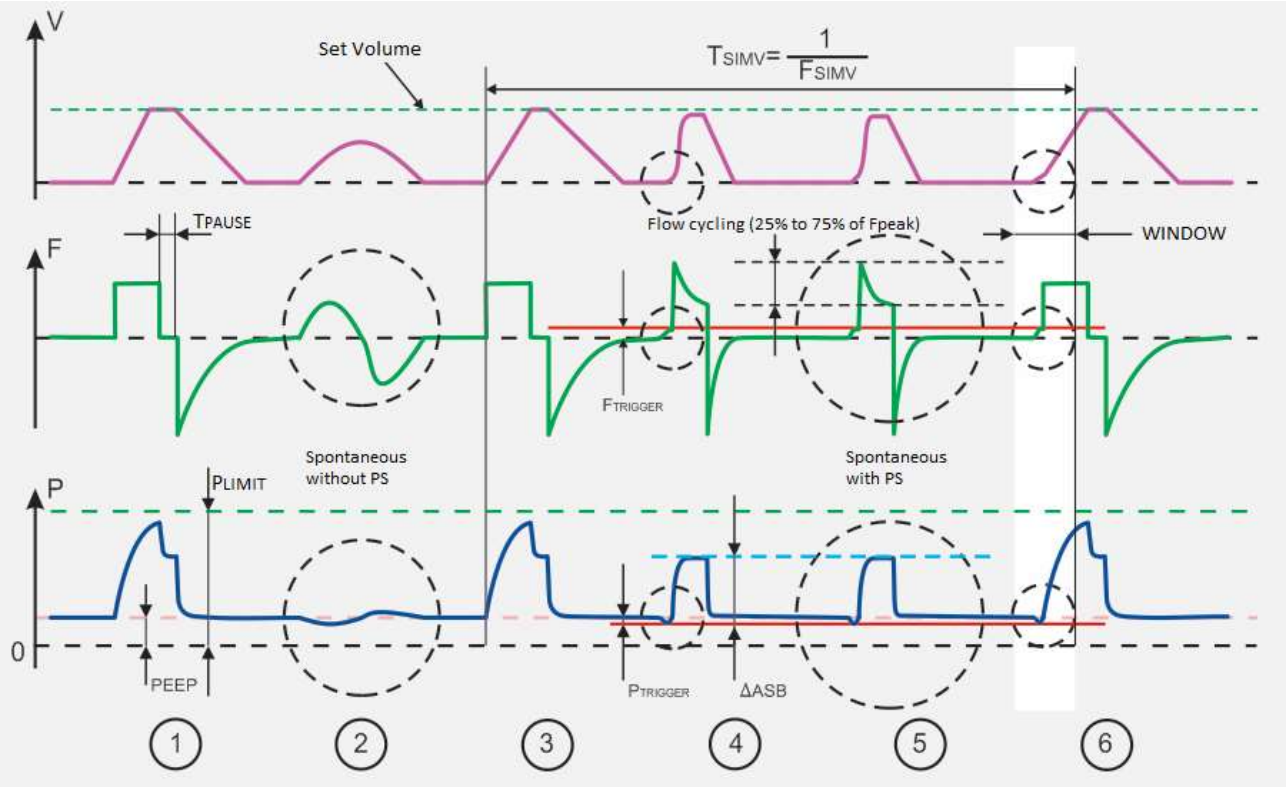


Figure 24: V-SIMV curves

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 limited ventilation must not to be used in patients without supervision.***

8.5 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:

- INSP PRESSURE;
- RATE;
- INSPIRATORY TIME;
- PEEP;
- FiO2
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- CYCLING BY FLOW (% FLOW);
- RISE TIME;
- FLOW (- only to NEONATE);

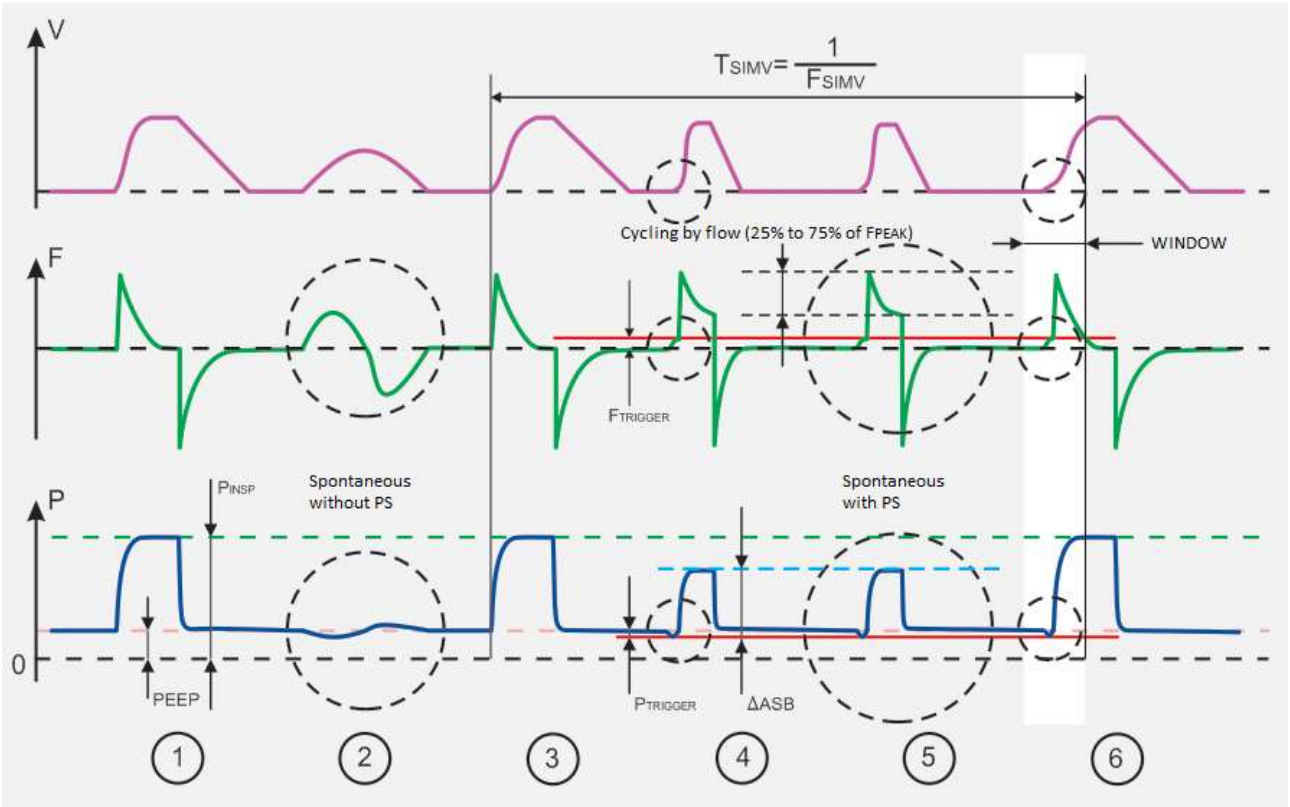


Figure 25 - P-SIMV Curves

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.

8.6 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.

Set Parameters:

- PEEP or CPAP;
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- FiO2
- CYCLING BY FLOW (% FLOW);
- RISE TIME
- BACK-UP MODE (VCV,PCV, PLV-NEONATAL or WITHOUT BACK-UP)
- RATE (back-up VCV, PCV and PLV);
- RATIO I:E (back-up VCV and PCV);
- MAXIMUM PRESSURE (back-up VCV);
- VOLUME (back-up VCV);
- PAUSE (back-up VCV);
- FLOW WAVEFORM (back-up VCV);
- INSP PRESSURE (back-up PCV and PLV);
- INSPIRATORY TIME (back-up PLV);
- FLOW (- back-up PLV)

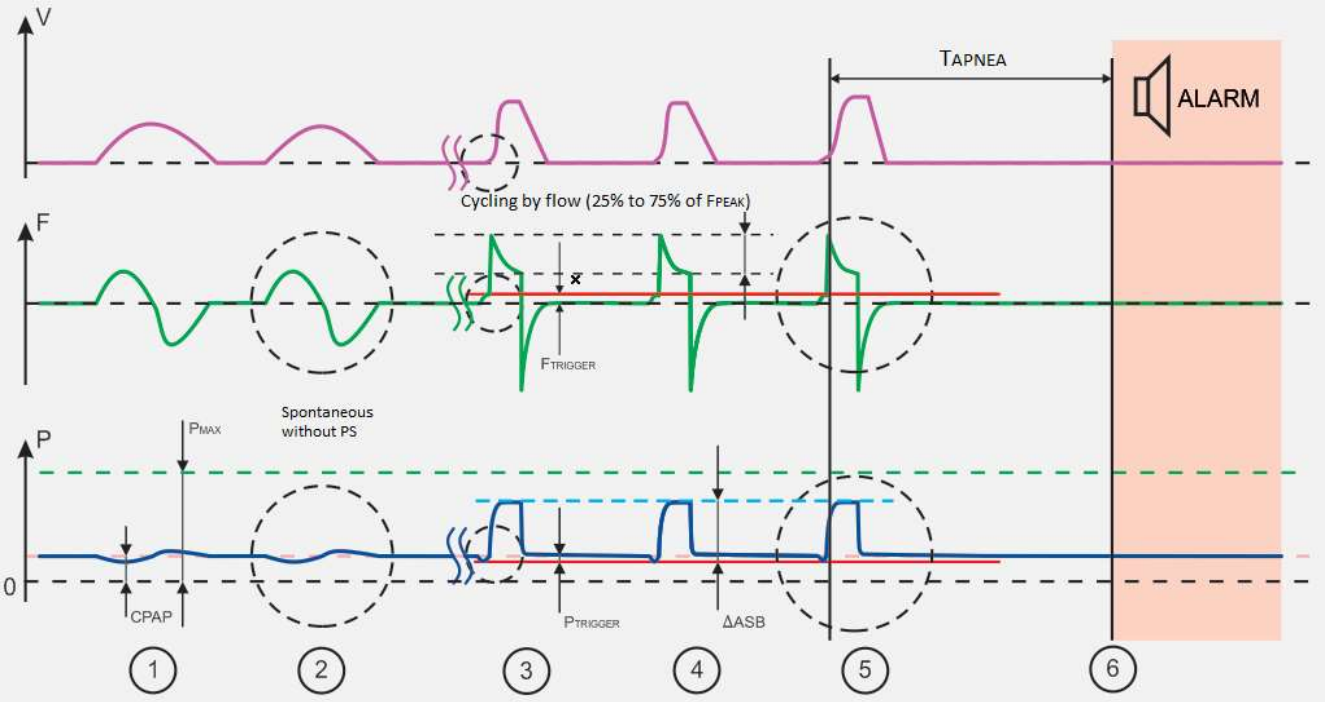


Figure 26: PSV (CPAP + ΔASB) Curves

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. TRISE 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

- ***Apnea alarm should be set to a safe value for the patient. However, apnea alarm can be RESET, in this condition, there will be no information or alarm for apnea condition and no backup ventilation in action. The equipment operator must be aware of the Apnea Alarm condition DEACTIVATED (OFF INDICATING ON DISPLAY).***
- ***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.

8.7 DualPAP – Bi-level Continuous Positive Airway Pressure Ventilation

Description:

In this mode, the patient breathes spontaneously on two continuous positive pressure and breathing may be assisted by a Pressure Support (ΔPS). Usually by analyzing the flow curve, a flow peak is seen which decreases over time. If the Pressure Support (ΔPS) value is set to 0 (ZERO) or both cycle trigger ways (pressure or flow) are disabled, pure DualPAP mode will be activated, i.e., without pressure support.

Cycling occurs by flow, adjustable between 5% and 80% inspiratory flow peaks measured. Depending on this, **APRV – Airway Pressure Release Ventilation can be obtained.**

Set parameters:

- P. HIGH;
- T. HIGH;
- P. LOW;
- T. LOW;
- FiO2;
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- CYCLING BY FLOW (% FLOW);
- RISE TIME
- MAXIMUM PRESSURE
- FLOW (- only to NEONATAL);
- BACK-UP MODE (VCV, PCV, PLV-NEONATAL or WITHOUT BACK-UP)
- RATE (back-up VCV, PCV and PLV);
- RATIO I:E (back-up VCV and PCV);
- VOLUME (back-up VCV);
- PAUSE (back-up VCV);
- FLOW WAVEFORM (back-up VCV);
- INSP PRESSURE (back-up PCV and PLV);
- INSPIRATORY TIME (back-up PLV);
- FLOW (back-up PLV);
- PEEP (back-up VCV e PCV)

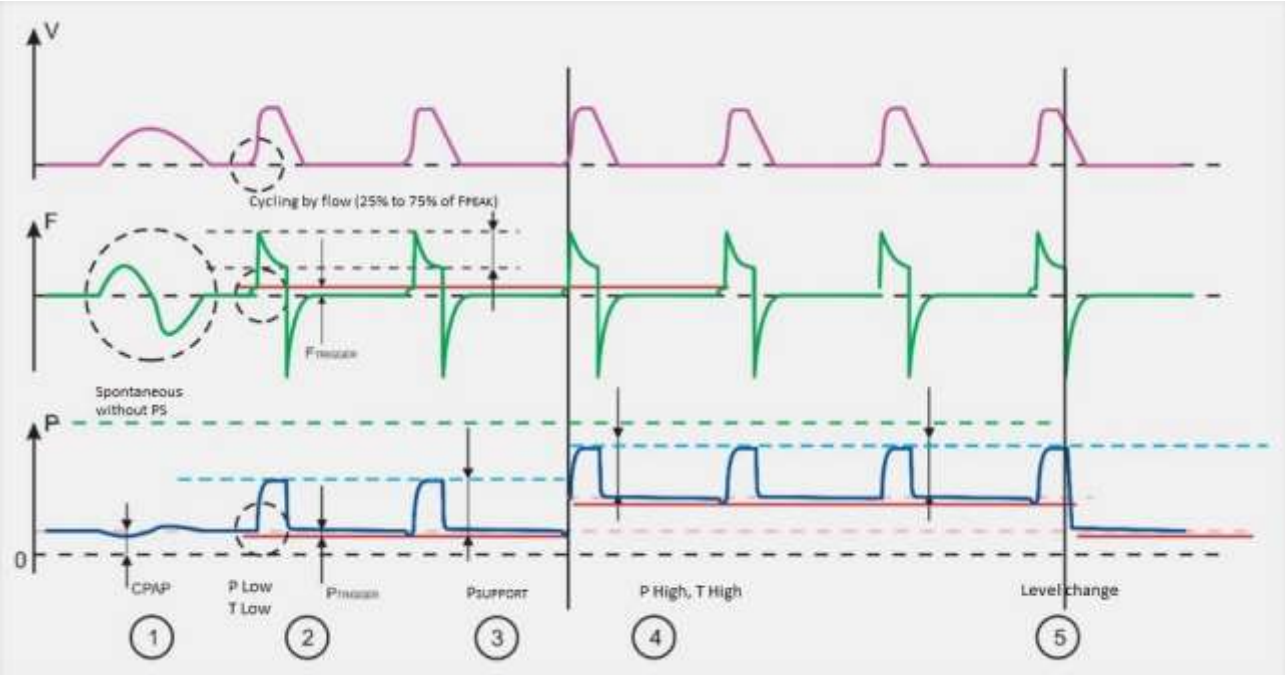


Figure 27 – DualPAP Curves

Once all ventilation parameters are set on the ventilator, the patient breathes spontaneously defining the ventilation control times.

1 Represents a spontaneous cycle without pressure support at P.Low (Low Continuous Airway Pressure);

2 Represents a breathing cycle with Pressure Support assist (above P.Low);

3 to **4** Represents a synchronized transition to P.High (High Continuous Airway Pressure);

5 Represents a transition from P. High to P. Low synchronized;

Transitions of levels from P.Low P.High or P.High P.Low occur in the final quarter of T.Low and T.High, respectively, by synchronizing with the effort of the patient. The information of what trigger activated the inspiratory cycle is reported in the message area and screen status.

WARNING

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

Note

- Respiratory rate monitored is result of the spontaneous breathing of the patient
- Pressure support (ΔPS) is a value above P.High or P.Low and can be adjusted between 5 cmH2O and PMAX - PHigh.
- Changes in pressure levels are synchronized.

8.8 APRV –Airway Pressure Release Ventilation (mode obtainied with inverted ratio in DUALPAP)

Description:

This mode allows spontaneous cycles on 2 levels of baseline pressure and can be achieved by appropriate adjustments in DualPAP mode;

For this mode selects inverted ratio in DUALPAP. With this adjustment is carried out a pressure relief airway, obtaining APRV – Airway Pressure Release Ventilation

Set parameters:

- P. HIGH;
- T. HIGH;
- P. LOW;
- T. LOW;
- FiO2;
- ΔPS (Pressure Support – PEEP);
- TRIGGER BY FLOW;
- TRIGGER BY PRESSURE;
- CYCLING BY FLOW (% FLOW);
- RISE TIME;
- MAXIMUM PRESSURE;
- FLOW (- only to NEONATAL)
- BACK-UP MODE
- (VCV, PCV, PLV-NEONATAL or WITHOUT BACK-UP)
- RATE (back-up VCV, PCV and PLV);
- RATIO I:E (back-up VCV and PCV);
- VOLUME (back-up VCV);
- PAUSE (back-up VCV);
- FLOW WAVEFORM (back-up VCV);
- INSP PRESSURE (back-up PCV and PLV);
- INSPIRATORY TIME (back-up PLV);
- FLOW (back-up PLV);
- PEEP (back-up VCV e PCV);

Figure 28: APRV Curves

Once all ventilation parameters are set on the ventilator, the patient breathes spontaneously defining the control times of ventilation.

1 and **2** Represent spontaneous cycles without pressure support at P. High (High Continuous Airway Pressure);

3 Represents the transition of P.High to P.Low (Low Continuous Airway Pressure) synchronously;

3 to **4** Represents the time T.Low in which airway pressure release is performed;

4 Represents transition from P.Low to P. High synchronously.

Transitions of levels from P. High P.Low or P.Low P. High occur in the final quarter of T. High and T.Low, respectively, by synchronizing with the patient's effort. 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 the ventilation parameters as needed by the patient.***
- ***To obtain DUALPAP mode with backup ventilation, select backup ventilation in the backup parameter.***

Note

- Respiratory rate monitored is result of spontaneous breathing of the patient
- Pressure support (ΔPS) is a value above P.High or P.Low and can be adjusted between PMax-P.High + 5 cmH2O e PMAX - P.High.
- Changes in pressure levels are synchronized.

9. Alarms Available

All alarm setting reference is found in the technical specification chapter.

WARNING

- ***Alarms and alerts should be promptly addressed in order to maintain the integrity of the operation of the equipment and patient safety.***
- ***While the audio volume is set to below the maximum level (5), if there is an alarm, the audio volume will increment gradually every 15 seconds until it reaches its maximum level.***
- ***Once ceased the situation that led to pause the audible alarm, you should re-enable it for patient safety.***

9.1 Description of alarm control

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

Table 18: 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. 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
Low O_2 Pressure	< 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 Maximum Pressure	< 2 cycles	It is triggered when the ventilation pressure exceeded the set alarm value as the upper limit of pressure
Low Maximum Pressure	< 2 cycles	It is triggered when the ventilation pressure is below the set alarm value as the lower limit of pressure

HIGH PRIORITY	Delay Time	Description
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
High FiO_2 (1)	< 3 cycles	It is triggered when the measured FiO_2 has exceeded the alarm value set as the upper limit of FiO_2
Low FiO_2 (1)	< 3 cycles	It is triggered when the measured FiO_2 has exceeded the alarm value set as the lower limit of FiO_2
High $EtCO_2$	< 3 seconds	It is triggered when the expired CO_2 has exceeded the alarm value set as the upper limit of $EtCO_2$
Low $EtCO_2$	< 3 seconds	It is triggered when the expired CO_2 is below the alarm value set as the lower limit of $EtCO_2$
CO_2i	< 3 seconds	It is triggered when the inspired CO_2 has exceeded the alarm value set as the upper limit of CO_2i
High FC	< 3 seconds	It is triggered when the heart rate has exceeded the alarm value set as upper limit of FC
Low FC	< 3 seconds	It is triggered when the heart rate is below the alarm value set as lower limit of FC
Low SpO_2	< 3 seconds	It is triggered when the Oxygen saturation is below the alarm value set as lower limit of SpO_2
⚠ IRMA Adapter	< 3 seconds	It is triggered when there is one of the conditions: the IRMA adapter of CO_2 sensor is not connected or must be replaced
Restart IRMA	< 3 seconds	It is triggered when IRMA CO_2 sensor must be disconnected and re-connected

[1] This alarm is only active when the blender option is enabled

HIGH PRIORITY	Delay Time	Description
Change IRMA	< 3 seconds	It is triggered when IRMA CO_2 sensor must be replaced.

MEDIUM PRIORITY	Delay Time	Description
High Minute volume	< 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 Minute volume	< 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 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 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
CO_2 out of range	< 3 seconds	It is triggered when IRMA CO_2 reading is incorrect
IRMA out of range	< 3 seconds	It is triggered in one of the situations with the CO_2 sensor: • Internal temperature of operation is out of scale or • Ambient pressure of operation is out of scale
IRMA zero required	< 3 seconds	It is triggered when there is need of Zero calibration of IRMA CO_2 sensor
Hight Temperature	< 3 seconds	It is triggered when the environment condition is above 50ºC.
Low Temperature	< 3 seconds	It is triggered when the environment condition is below -18°C.

LOW PRIORITY	Delay Time	Description
AC input fail	< 1 second	It is triggered when there is no electrical energy from the network
⚠ SpO_2 Sensor	< 3 seconds	It is triggered when SpO_2 Sensor is connected to the equipment, but is outside the finger
Check SpO_2	< 3 seconds	It is triggered when: • Oximeter has no sensor connected; • Sensor connected is defective; • Interference detected; • Excessive Ambient light; • Sensor unknown;
Check cable	< 3 seconds	It is triggered when the cable is disconnected
Low Perfusion	< 3 seconds	It is triggered when there is low perfusion
Looking for pulse	< 3 seconds	It is triggered when oximeter is looking for pulse
Activating SpO_2	< 3 seconds	It is triggered when oximeter is being activated
SpO_2 demo	< 3 seconds	It is triggered when the oximeter is generating a demo curve

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 the charge in the end. In this condition, the value of voltage found in the internal battery is below the limit established as essential to 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, in order to 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. In the **PEDIATRIC** and **ADULT** mode, 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.

In the **NEONATAL** mode, the obstruction alarm is triggered when airway pressure is above the PRESSURE SET + 5cmH2O. When an occlusion occurs in the breathing circuit, the ventilator triggers a valve system of overpressure that releases the pressure in the circuit in order to preserve the integrity of the patient's lungs.

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 19: Alert Messages

Alert	Delay Time	Description
LIMITED PRESSURE	< 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
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%
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
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

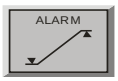
- ***The apnea time can be RESET; in this condition, there will be no apnea condition Information and no backup ventilation in action. The equipment operator must be aware of the DEACTIVATED Apnea Alarm condition (INDICATING ON DISPLAY).***
- ***The default values of alarms are only for initial reference. 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.***

Table 20: Troubleshooting

Problem	Possible Causes	Solutions
Ventilator Inoperative Alarm	Electronic failure	Contact Technical Assistance / Magnamed
Disconnection Alarm	1. Disconnection in the breathing circuit;	1. Locate the disconnection and connect securely;

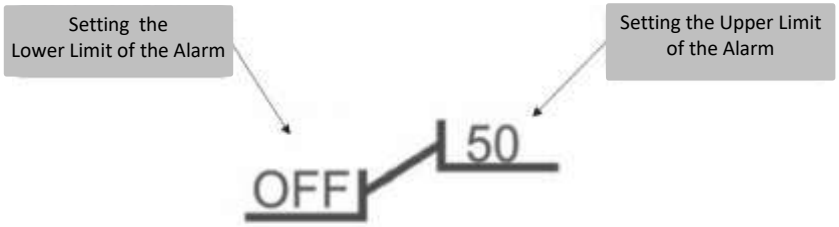
Problem	Possible Causes	Solutions
	2. Lack of Inspiratory Flow;	2. Check if there is inspiratory flow and increase, if necessary;
	3. Change in the Patient's Respiratory Mechanics;	3. Set new parameters for ventilatory support;
	4. Diaphragm of exhalation valve mounted incorrectly or damaged;	4. Replace 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
Low Pressure 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 Pressure 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;
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 mains or turn off the equipment and provide means of ventilatory support to the patient;
	2. Failure in the charging system of the internal battery, even with the presence of electric power;	2. Contact Technical Assistance / Magnamed;
Alert of Lack of Electric Power	1. Disconnection to the power cord;	1. Restore connection of the equipment to a mains or use the equipment with internal battery for transportation;
	2. Failure in the electrical grid;	2. Restore power grid;

9.2 Setting Alarms

To enter the alarm setting screen, press ALARM button 

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

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



2. Adjustable alarms of capnography will be visible if the capnography is connected to the ventilator, as well as the adjustable oximetry alarms will be visible when the oximeter is connected.

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

9.3 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.

WARNING

- ***During a manual ventilation, monitor the maximum pressure***
- ***During a manual ventilation, keep the alarm system active***

9.4 Alarm Test

To test the alarm use an Adult Circuit. Short circuit the inspiratory and expiratory ends. Select Neonatal patient with default adjust.

9.4.1 High pressure alarm:

Adjust the high pressure alarm to be lower than the inspiratory pressure adjusted in the equipment.

9.4.2 AC Input fail alarm:

Take off the power supply from the equipment.

9.4.3 FiO2 Alarm[2]:

The FiO2 alarm will be available only with external blender.

Adjust the desired FiO2 in the blender. In configuration menu check the blender option. In the alarm configuration menu set in the high part of FiO2 alarm a value lower than adjusted in the blender.

WARNING

- ***The Alarm should be tested without a connection to the patient.***
- ***In case of failure see the Description of alarm.***
- ***Do not use the equipment if the test fail.***

Note

- Use a gas inlet with recommended pressure.

[2] Avaiable with external blender

10. Cleanning and Sterilization

10.1 Equipment cleaning

10.1.1 External ventilator surfaces

External ventilator surfaces of Oxymag should be cleaned with a clean, soft cloth moistened with the enzymatic detergent.

Caution

- Ensure that no residue builds up in the equipment connections.
- For cleaning do not use non-compliant products to polymer
- For touch screen cleaning avoid:
  - Use substances other than glass cleaner and do not use solutions vinegar base.
  - Use the dirty cloths and handle the display carefully.
- Not to be used for cleaning or disinfecting the phenol (> 5%) ketone, formaldehyde, hypochlorite, chlorinated hydrocarbons, aromatic hydrocarbons, inorganic acids, and quaternary ammonium compounds.

10.1.2 Respiratory circuit, proximal flow sensor and exhalation valve

The components that come in directly contact with respiratory gases must be periodically disassembled for cleaning, disinfection or sterilization.

Circuits and parts of silicone should be cleaned according the following steps:

10.1.2.1 Wash

a) Always use potable water for this procedure;

b) Use neutral and enzymatic detergent. Dilution should be performed as recommended by the manufacturer.

c) Immerse the entire body of the flow sensor and the silicone line in the detergent solution, keeping the solution in contact with the accessories for at least 3 minutes;

d) The external parts of the parts should be cleaned with a clean, soft cloth moistened with the enzymatic detergent. The internal parts must be cleaned by immersion.

10.1.2.2 Rinse

a) Always use potable water for rinsing;

b) Thoroughly rinse the external surface of the accessories with potable water.

c) Rinse the internal surface by injecting potable water under pressure at least 5 times.

Caution

- Not to be used for cleaning or disinfecting the phenol (> 5%) ketone, formaldehyde, hypochlorite, chlorinated hydrocarbons, aromatic hydrocarbons, inorganic acids, and quaternary ammonium compounds.
- Never use saline solutions, especially sodium hypochlorite (bleach) and saline, disinfectants, hydrogen peroxide for cleaning or rinsing the accessories.

10.1.2.3 Drying

Drying of the external parts should be done with a clean, soft and dry cloth and the drying of the internal parts should be done so that the solution drains by gravity.

10.2 Disinfection

10.2.1 External Parts

The external part should be disinfected using a clean cloth moistened with alcohol 70 º.

10.2.2 Respiratory circuit, exhalation valve, proximal flow sensor and silicone line

After cleaning, the items should be disinfected with alcohol 70º. The external part should be disinfected using a clean cloth moistened with alcohol 70 º and internal part by immersion. Important: Do not soak the items to be disinfected with alcohol as it can damage the material.

After disinfection, the external parts should be dried with a clean, soft and dry cloth and the internal parts should be dried so that the solution drains by gravity.

10.3 Sterilization

- The components that get in touch with the respiratory gases must be removed for cleaning and sterilization;
- Do not use abrasive agents to carry out cleaning;
- Do not use alcohol to clean the plastic parts;
- Do not immerse the Oxymag in any liquid;

WARNING

- ***When sending the Oxymag for maintenance or repair strictly observe the disinfection process.***
- ***Equipment visibly infected by patients fluid will be returned without performing maintenance or repair service.***
- ***This equipment and the parties must go through a cleaning process every time it is***

even used in the first use.

Caution

- The accessories and components removable from Oxymag undergoing repeated operations of sterilization and cleaning may be degraded and should be replaced with new ones.

10.4 Processing methods

Component	Processing methods		
	Steam sterilization 135ºC for 5 min	Antimicrobial disinfectant	Alcohol 70°
Ventilator surface	x	✓	x
Touch screen display	x	✓	✓
Silicone respiratory circuit	✓	✓	✓
Silicone sensor line	✓	✓	✓
Exhalation valve	✓	✓	✓
Diaphragm	✓	✓	x
Proximal flow sensor (Adu, Ped and Neo)	✓	✓	✓
SpO2 sensor	x	✓	x
EtCO2 sensor	x	✓	x

11. Preventive Maintenance

Caution

- O Oxymag should have their maintenance performed only by a qualified technician, trained and authorized by MAGNAMED

11.1 Indication of the need for periodic maintenance

The equipment displays in the home screen the preventive maintenance symbol  when 5000 hours or more had passed since the last maintenance.

11.2 Daily checks and/or prior to use

- Cleaning the equipment;
- Integrity of the power cord of the AC/DC converter;
- Correct operation of the visual and audible alarm system;
- Installation and cleaning of filters;
- Correct display of the screen;
- Correct use of touch screen;
- Full battery;
- Correct operation of the equipment panel keys;
- Correct operation of the knob and confirm button;
- Correct installation of the breathing circuit (including the existence of diaphragm of the exhalation valve).

WARNING

- ***Daily check should be performed with the patient disconnected.***

11.3 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 15.3.1 Electrical Characteristics.

WARNING

- ***This equipment must ALWAYS remain connected to the mains so that there is sufficient charge during a power outage.***

Caution

- The battery must be replaced as indicated in the technical specifications so that capacity in normal operation is as specified.
- 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.

11.4 Internal Sensor of O2 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. The length of the cell, as specified by the original manufacturer is 10,000 hours at 100% O2, i.e., more than one year of continuous use.

Caution

- The oxygen concentration measuring cell should be replaced as indicated in the Technical Specification (chapter 15).
- Replacement of the oxygen concentration measuring cell should be performed only by a qualified technician, trained and authorized by MAGNAMED.

11.5 Replacing the Ambient Air Filter

To replace the ambient air filter, follow the procedure below:

Figure 29: Example for exchanging air filter

(1) Remove the filter cover on the left side of the ventilator, item 2 of the figure.
(2) Remove the old filter, item 1 of the figure.
(3) Clean the seating area of the filter with a cotton ball soaked in water and mild soap solution.

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 if the set is firmly closed.

WARNING

- ***Use only filters, parts, pieces and accessories specified by MAGNAMED listed in this manual, which have been tested and approved for use in conjunction with this equipment; otherwise, this can jeopardize the operation endangering the patient or user;***
- ***filter when saturated generates an increase in the resistance of the ambient air inflow and can make the minimum concentrations (35% O2) to not be met. In this case, replace the filter.***

Caution

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

11.6 Forwarding the Product to Repair Service

Products before being sent to repair service should be cleaned and disinfected as directed in this manual Cleanning and Sterilization (capítulo 11). Products showing signs of potential hospital contaminants will be returned without repair service in order to be disinfected prior to the service.

WARNING

- ***When sending Oxymag for maintenance or repair services: check closely the disinfection process.***
- ***Equipment visibly infected by patient fluids will be returned without carrying out maintenance or repair service.***

12. Disposal

Discard the removed parts of the equipment according to the protocol for disposal of parts and pieces of your institution and follow the local government recommendations regarding environmental protection, especially in the case of electronic waste or electronic parts (e.g., batteries).

Caution

- When the need to discard parts of the ventilator may be potentially contaminated indicated as potentially infected hospital waste.

13. Turning off the Equipment

The lung ventilator Oxymag is a life support equipment and must be MANDATORILY disconnected from the patient to be turned off. The equipment should be turned off in the on/off switch, identified in Figure 5.

14. Technical Specification

14.1 Classification

- NBR – IEC – 60601

Class II Equipment, energized internally, BF-type for continuous operation. Protected against the ingress of solid foreign objects with 12,5mm diameter or bigger and Splash-proof equipment - IP24.

- Annex IX Directive 93/42/EEC, Rule 11

Class IIB – All active devices intended to administer and/or remove medicines, body fluids or other substances to or from the human body are Class IIa, unless this is done in a potentially hazardous way, given the nature of the substances and the body part involved, and the mode of application, in which case they are Class IIb.

- RDC 185/01 – Classification Rule 11

Class III – All active medical devices intended to administer medicines, body fluids or other body substances or to extract them from this, fall under Class II, unless this is done in a potentially hazardous way, given the nature of the substances, body part involved and mode of application, in this case, then they fall under Class III.

14.2 Standards

- **ISO 10651-3** – Lung Ventilators for Use Medical Part 3: Particular Requirements for Emergency and Transport Ventilators
- **ISO 5356-1** – Anesthetic and respiratory equipment – Conical connectors – Part1: Cones and sockets
- **ABNT NBR 11906** – Conexões roscadas e de engate rápido para postos de utilização dos sistemas centralizados de gases de uso medicinal sob baixa pressão
- **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
- **EN 794-3:1998+A2:2009** - Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
- **EN 1789:2007+A1:2010** - Medical vehicles and their equipment - Road ambulances
- **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. 3.0 (2007) (EN 60601-1-2:2007) -** 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 60601-1-4: 1996/A1:1999 (EN 60601-1-4: 1996/A1: 1999)** - Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical 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 ISO 17665-1:2006** - Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- **EN ISO 17664:2004** - Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable 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 80601-2-61:2011 (EN ISO 80601-2-61:2011)** – Medical electrical equipment: Particular requirements for basic safety and essential performance of pulse ox equipment
- **ISO 80601-2-55:2011 (EN 80601-2-55: 2011)** - Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

14.3 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%;
        - ✓ CONGELA;
        - ✓ MANUAL (Manual Trigger of Inspiratory Cycle);
        - ✓ LOCK (Lock keys);
    - Pressure Reading in the breathing circuit;
    - Regulated pressure reading;
    - 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 – 50 – 60 Hz +12 VDC);
- On/off switch;
- Adult breathing Circuit [1]
- Pediatric and Neonatal breathing circuit, optional;[1]

- Galvanic cell internal O2 ;
- External source AC/DC converter AC/DC 100 – 240 VAC to +12 VDC;
- Plastic Cabinet in high impact ABS resistant to blows;
- Carrying Case with Oxygen Cylinder, optional.
- Carrying Case without Oxygen Cylinder, optional.
- Pedestal for Oxymag, optional.
- Kit blender, optional.

1 Accessories not available for European Union

14.3.1 Electrical Characteristics

Table 21: AC/DC Converter Source – External (2402568 – POWER SUPPLY 12V WITH 4-WAY CONNECTOR)

Item	Parameter	Specification	Tolerance	Unit
1	Mains (50/60Hz)*	100 – 240	± 10%	V_{AC}
2	Maximum Power Consumed	50	± 10%	W
3	Output 12V_{DC} – 4 -way	12	± 10%	V_{DC}
4	Current	2,5	---	A

* 3(three)-pin connector, NBR-14136:2002, where center pin is ground

Table 22: Internal Li-Ion Battery

Item	Parameter	Specification	Tolerance	Unit
1	Internal Li-Ion Battery 11.8V_{DC}	4000	± 15%	mAh
2	Autonomy of Internal Battery (with full load and normal use)	390	± 15%	Min
3	Time to recharge to full load (module operation)(1)	4,0	± 15%	H

(1) The battery should be charged at room temperature, 5 - 35 °C

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

14.3.2 Connecting to the Oxygen Supply

- Oxygen Inlet –DISS male thread 9/16” 18 wires, as per ABNT NBR 11906
    - OPTIONAL –NIST Thread
- Gas pressure: 39 - 87 psi (270 - 600 kPa) [3]
- 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:
    - Adult patient;
    - VCV mode;
    - Volume 500ml;
    - Rate 12rpm;
    - Ratio 1:2;
    - PEEP 5 cmH2O;
    - Pause 30%;
    - FiO2 100%;
    - Square flow wave.

Note

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

14.3.3 Physical and Environmental Specifications

Table 23: Physical and environmental specifications

Item	Parameter		Specification	Tolerance	Unit
1	Dimensions (basic unit)	Height (with handle)	176 (231)	± 2	mm
		Width	254	± 2	mm
		Depth (with handle)	134 (185)	± 2	mm
2		Weight	3.25	± 0,1	kg
3	Operation	Temperature	-18 - 50	---	°C
		Barometric Pressure	600 - 1100	---	hPa
		Relative Humidity (w/o condensation)	15 - 95	---	%
4	Storage	Temperature	-25 - 75	---	°C
		Barometric Pressure	500 - 1200	---	hPa

[3] For input pressure to 39 psi (270 kPa), the maximum flow is 100 L / min

Item	Parameter		Specification	Tolerance	Unit
		Relative Humidity (w/o condensation)	5 - 95	---	%
5	Oxygen Consumption of the Cylinder under the conditions: • Vol tidal = 500 mL • Frequency = 12 min^{-1} • O_2 Concentration= 40%		92	± 10%	$min/L_{O2-CYLINDER}$
6	Life time		10	---	years

14.3.4 Extreme conditions

WARNING

- ***Do not expose to extreme temperatures and pressures than specified in item 15.3.3. Physical and Environmental Specifications during use. The performance of the equipment may be adversely affected if the temperature and / or operating pressure are beyond the specified limits.***

Caution

- The temperature alarm will be triggered if the environmental condition is below -10ºC or above 50ºC (low/high temperature alarm – medium priority).

14.3.5 Ventilation Modes

Table 24: Ventilation modes

Modes[1][2][3]	Description	Mode in Apnea (BACKUP)[4]
VCV	Volume-Controlled Ventilation	AUTO
PCV	Pressure-Controlled Ventilation	AUTO
PLV	Pressure Limited Ventilation Cycled by Time for ventilator in neonatal setting (may have assisted cycles)	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

Modes[1][2][3]	Description	Mode in Apnea (BACKUP)[4]
DualPAP[5]	Bi-level Positive Airway Continuous pressure with Pressure Support	VCV, PCV (adult and pediatric) / PLV (neonatal), OFF. Programmable by the Operator
CPAP/PSV	Continuous Positive Airway Pressure Ventilation with Pressure Support	VCV, PCV (adult and pediatric) / PLV (neonatal), OFF. Programmable by the Operator

[1] Non-Invasive Ventilation by Mask can be activated in all ventilation modes and, in this case, there is compensation for leaks.
[2] Automatic compensation of compliance and small leaks in the breathing circuit.
[3] When the ventilator enters in Neonatal mode (IBW ≤ 6.0 Kg) only PLV, P-SIMV, CPAP/ PSV, DualPAP modes will be available
[4] For the modes where backup ventilator is defined as "Auto", always when the set apnea time is reached, the ventilator start one ventilator cycle, witch configuration is based on current ventilator mode.
[5] APRV (Airway Pressure Release Ventilation) mode can be obtained by DualPAP mode with appropriate adjustment of the times and pressures.

14.3.6 Setting Specifications of the Ventilation Parameters

Table 25: Setting specifications of parameters.

Item	Parameter	Specification	Resolution	Unit
1	Tidal Volume	20 to 2500	100 to 2500: 10 20 to 100: 5	mL
2	Respiratory rate	0 to 150[2]	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	Inspiratory Pressure	1 to 60	1	cmH_2O
7	Delta of support pressure (ΔPS)	OFF; 5 to 60	1	cmH_2O
8	PEEP	0 to 40	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; 0,5 to 30,0	0,5	$L.min^{-1}$
11	Automatic Inspiratory Flow [3]	0 to 150	1	$L.min^{-1}$
12	Inspiratory Flow (Neonatal)	4 to 20	1	$L.min^{-1}$
13	Cycling by Flow at Pressure Support	5 to 80	5	%

Item	Parameter	Specification	Resolution	Unit
14	O_2 Concentration	35 to 100	1	%
15	Inspiratory Time	0,1 to 10	0,1 to 0,7:0,01	s
			0,7 to 1:0,05	
			1 to 10:0,1	
16	Inspiratory Flow Waveform	Square, Decelerated, Accelerated, Sine	---	---
17	CPAP(4)	1 to 40	1	cmH_2O
18	High Pressure	5 to 55	1	cmH_2O
19	Low Pressure	0 to 40	1	cmH_2O
20	High Time	0,20 to 60,0	0,20 to 0,70:0,01	s
			0,70 to 1,00:0,05	
			1,00 to 10,0:0,10	
			10,00 to 60,0:1,0	
21	Low Time	0,20 to 60,0	0,20 to 0,70:0,01	s
			0,70 to 1,00:0,05	
			1,00 to 10,0:0,10	
			10,00 to 60,0:1,0	
22	Ratio	1:4 to 4:1(5)	1:0,1	-
23	Backup	OFF;PLV; PCV; VCV (6)	---	-
24	Time for Apnea Alarm	OFF; 5 to 60	1	s
25	Flow (flow meter)	0 to 15	1	$L.min^{-1}$
26	Leak Flow Compensation	Pressure of 150 Volume of 40L.min- (7)	1	$L.min^{-1}$
27	Height (8)	0,16 a 2,50	0,16 to 0,52:0,01	m
			0,53 to 1,08:0,01	
			1,09 to 2,50:0,01	

(1) Tidal Volume for values lower than 20ml is set adjusting pressure, monitoring the tidal volume in the display of the ventilator. This volume is the volume delivered to the ventilator outlet, and the user should check the absence of leaks".

(2) In CPAP/PSV mode adjusted without pressure support and without backup respiratory rate will be zero.

(3) 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%

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

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

(5) In VCV, adjustment allowed is in the range between 1:4 and 4:1

(6) Backup options for CPAP/PSV mode; for DUALPAP mode, backup options are: PLV for neonatal, PCV for adult or OFF. Setting OFF, mode will not enter in backup when time for apnea alarm is reached.

(7) For modes with controlled volume, maximum compensation is 100% flow adjusted automatically

(8) Depending on the type of patient set during startup, the ventilator will be set to operate according to the following table:

(Patients smaller than 0.16m or greater than 2.5m can be ventilated in this equipment)

Table 26: Ratio Mode x type of patient

Patient Type	Flow Sensor(1)	Initial Mode	Ideal Weight (IBW)	Height [m]
NEONATAL	NEO	PLV	2,8Kg	*0,36*
PEDIATRIC	INF	PCV	19,8Kg	*0,95*
ADULT	ADU	VCV	49,5Kg	*1,50*

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 27: Calculation of ideal weight x patient height

Patient Type	Height Adjustment [m]		Ideal Weight P [Kg]
	Min.	Máx.	
NEONATAL	0,16	0,52	≤ 6,0
PEDIATRIC	0,53	1,08	6,0 < P ≤ 25

Patient Type	Height Adjustment [m]		Ideal Weight P [Kg]
	Min.	Máx.	
ADULT	1,09	2,5	> 25

Caution

- Minimum Limit Pressure: 5 cmH2O
- Adjusted Maximum Pressure serves to limit the pressure in the breathing circuit.
- On VCV 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 this will be the pressure control limit.
- This ventilator DOES NOT GENERATE NEGATIVE PRESSURE IN THE EXPIRATION OF THE PATIENT.

14.3.7 Specifications of the Monitoring Ventilation Parameters

Table 28: *Ventilation parameters*

Item	Parameter	Range	Resolution	Tolerance	Unit
1	Instant Pressure Measured	-20 to 100	1	± (1 cmH2O or 2% reading)	$cmH_2O^{(2)}$
2	Maximum Inspiratory Pressure	0 to 90	1	± (1 cmH2O or 2% reading)	cmH_2O
3	Measured Pressure	0 to 90	1	± (1 cmH2O or 2% reading)	cmH_2O
4	Plateau Pressure	0 to 90	1	± (1 cmH2O or 2% reading)	cmH_2O
5	PEEP - Pressure at the end of expiration	-20 to 90	1	± (1 cmH2O or 2% reading)	cmH_2O
6	Intrinsic PEEP at the end of expiration	-20 to 90	1	± (1 cmH2O or 2% reading)	cmH_2O
7	Flow Measured (Sensor Adult)	-150 to 150	1	± (2.0L.min-1 or 5% reading)	$L.min^{-1}$
8	Flow Measured (Sensor Pediatric)	-50 to 50	0,5	± (0.5L.min-1 or 5% reading)	$L.min^{-1}$

Item	Parameter	Range	Resolution	Tolerance	Unit
9	Flow Measured (Sensor Neonatal)	-20 to 20	0,2	± (0.2L.min-1 or 5% reading)	$L.min^{-1}$
10	Volume Measured (Sensor Adult – ADU) (3)	100 to 3000	100 to 995:5 1000 to 3000:10	± (20ml or 5% value measured)	mL
11	Volume Measured (Sensor Pediatric – INF)(3)	10 to 400	2	± (10ml or 5% value measured)	mL
12	Volume Measured (Sensor Neonatal – NEO)(3)	1 to 100	1	± (3ml or 5% value measured)	mL
13	Minute volume (Sensor Adult – ADU)	0,1 to 99,0	0,001	± (0.18L or 3% value measured)(4)	L
14	Minute volume (Sensor Pediatric – PED)	0,01 to 50,0	0,001	± (0.10L or 3% value measured)(4)	L
15	Minute volume (Sensor Neonatal – NEO)	0,001 to 20,0	0,001	± (0.06L or 3% value measured)(4)	L
16	Tidal Volume Inspired (3)	0,001 to 3000	0,01 to 3000:10	± (5% value measured)	mL
18	Inspiratory Time	0,05 to 60,0	0,01	± 0,01s	s
19	Expiratory Time	0,05 to 60,0	0,01	± 0,01s	s
20	Ratio I:E	1:100,0 to 100,0:1	1:0,1	± 2%	---
21	Respiratory Rate	0 to 200	1	± ($1min^{-1}$ or 1% value measured)	min^{-1}
22	Airway Resistance – R_{AW}	0 to 200	1	1	$cmH_2O/L/s$
23	Dynamic Compliance (C.Dyn)	0 to 200	0,1	± 1 mL.cmH2O $^{-1}$ or 10% value measured	$mL.cmH_2O^{-1}$
24	Static Compliance (C.Stat)	0 to 200	0,1	± 1 mL.cmH2O $^{-1}$ or 10% value measured	$mL.cmH_2O^{-1}$

Item	Parameter	Range	Resolution	Tolerance	Unit
25	FiO_2 (Oxygen Concentration)	12 to 110	0,1	±(1% in volume or 2% reading)	$\%O_2$
26	Flow (flowmeter)	0 to 20	0,1	± (0.2L.min-1 or 5% reading)	$L.min^{-1}$
27	Regulated Pressure	0 to 150	1	± 3.75 psi	psi
28	Oxygen Consumption (Cos. O_2)	0 to 160	0,1	±(1 L/min or 10% reading)	L/min
29	SpO_2	1 to 100	1	±2%	%
30	FC	25 to 240	1	±2%	bpm
31	CO_2[8]	0 to 25	0 to 15:1	±(0.2% in volume + 2% reading)	%vol
			15 to 25: Not Specified	Not Specified	

(1) When indicated two tolerances, 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 frequency of 12 , 20 and 30 rpm, respectively, for adult, pediatric and neonatal sensors. Tolerance is a function of the uncertainty of volume multiplied by frequency.

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

(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) CO2(mmHg)=CO2(%) x Patm(mmHg)x 0.75

14.3.8 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 the type of patient is changed, alarms will assume the default values in table 30 according to the type of patient.***
- ***Default values of the alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***Apnea Time can be RESET; in this condition, there will be no Information of the apnea condition and no backup ventilation in action. The equipment operator must be aware of the DEACTIVATED condition of the Apnea Alarm (INDICATING ON THE DISPLAY).***

- ***Automatic adjustment of the alarm limits (table 30) sets the alarms for a percentage calculated on the value monitored during ventilation; therefore, it can only be adjusted when the ventilator is NOT in STANDY-BY mode.***

The priority of the alarm condition is determined by the risk management process of the equipment and follows the description in Table 29: .

Table 29: *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 an 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 31.
- In the absence of high-priority alarms, the medium-priority alarms will be displayed alternately.

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

Table 30: *Alarm features*

Alarm	Feature	High Priority	Medium Priority
Visual	Color	Red	Yellow
	Intermittence frequency	1.42 hz	0.71 hz
Audible	*Number of saved pulses*	10 pulses	3 pulses
	Interval between saves	5.0 s	5.1 s
	Sound pressure range	63.5 dBA	62 dBA
	Pulse frequency	688 hz	687 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 to a distance of 4 m from the equipment.

Table 31: *Alarm set*

Item	Alarm	Setting	Limit	Standard Alarm[1]			Unit
				NEO	PED	ADU	
1	Maximum Pressure	OFF; 0 to 80	High	30	30	40	cmH_2O
			Low	OFF	OFF	OFF	
2	PEEP	OFF; 0 to 40	High	10	15	20	cmH_2O
			Low	OFF	OFF	OFF	
3	Total Volume	OFF; 0 to 3000	High	50 mL	500 mL	1.0 L	mL
			Low	OFF	OFF	OFF	
4	Minute volume	OFF; 0 to 99	High	5.0	10	20	L
			Low	OFF	OFF	OFF	
			High	OFF	OFF	OFF	
5	Time for Apnea Alarm	OFF; 5 to 60	Low	10	10	15	s
6	Respiratory Rate	OFF; 0 to 150	High	60	60	60	min^{-1}
			High	OFF	OFF	OFF	
7	FiO2	OFF; 35 to 100	Low	80	80	80	%
8	Automatic limit setting [3]	OFF, 10, 20 and 30	High	OFF			%
9	Heart Frequency [2]	OFF;25 to 240	Low	180	120	120	bpm
			High	80	40	40	
10	SpO_2 [2]	OFF; 1 to 100	Low	85	85	85	%
			High	OFF	OFF	OFF	
11	$EtCO_2$ [2]	OFF; 0 to 80	Low	45	45	45	mmHg
			High	OFF	OFF	OFF	
12	CO2 inspired [2]	OFF; 0 to 80	---	4	4	4	mmHg

[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 mains, the alarms will assume the default values indicated for each type of patient.

[2] Alarms available only with the use of optional external sensors.

[3] 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.***

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

Alarms related to the external sensors:

- Capnography Sensor
  - Caution IRMA adapter
  - Restart IRMA
  - Replace IRMA
  - CO_2 out of scale
  - Reading Error IRMA
  - Calibrate IRMA
- SpO_2 Sensor
  - Caution SpO_2 Sensor (Sensor out of Finger)
  - Check SpO_2
    - Check Cable
    - Low Perfusion
    - Looking for pulse
    - Enabling SpO_2
    - SpO2 demo

14.3.9 Concentration x Pressure in the breathing circuit curve

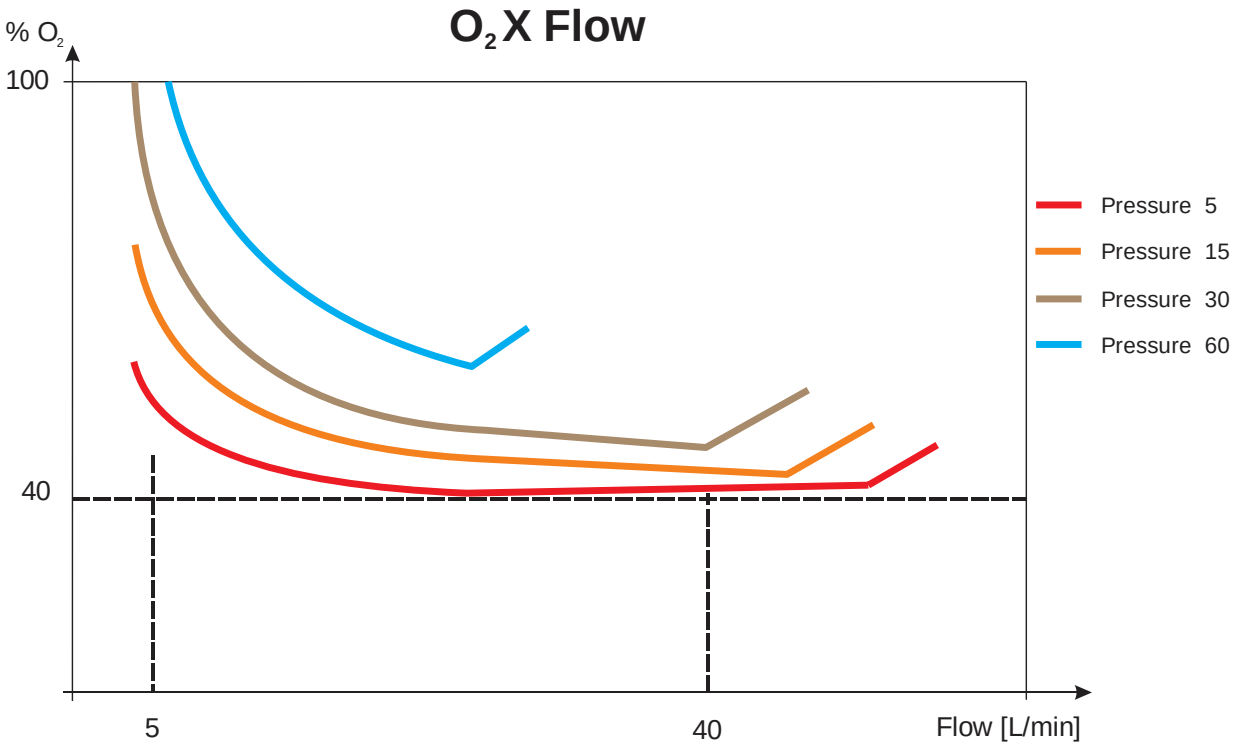


Figure 30: Concentration curve in function of pressur e in the breathing circuit

14.3.10 Performance Specifications

Table 32: *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)

14.3.11 Specifications for Maintenance and Calibration

Caution

- The processing time is after stabilizing at the specified temperature and pressure.
- Check the efficiency of sterilization through chemical or biological indicators.

Table 33: Specification for maintenance and calibration

Item	Description	Specification	Tolerance	Unit
1	Review and REPLACEMENT OF DIAPHRAGMA (3800248)	50 cycles of steam sterilization	---	Cycles
		10,000 h or 2 years	± 500	Hours
2	Review and REPLACEMENT OF O_2 CELL (3902020)	10,000 h or 2 years	± 500	Hours
3	Review and REPLACEMENT OF BATTERY (2702236)	10,000 h or 2 years	± 500	Hours
4	Exhalation Valve (3200251)	50 cycles of steam sterilization	--- ± 1 month	Cycles months
5	Breathing Systems Adult (1703218), Pediatric (1702654), Neonatal(1702655)			
6	Universal Connector with silicon line 1,3 m			

Item	Description	Specification	Tolerance	Unit
7	Autoclavable flow sensors Adult(3201100), Pediatric (3201099), Neonante (3201098)			
8	Review	1	± 1 month	Year
9	Calibration	500h(1)	± 50	Hours
10	Air intake filter	500h(1)	± 50	Hours

(1) If environment in which it is used contains excessive particulate matter in suspension, replace air filter at shorter intervals

14.3.12 Mask for Non-Invasive Ventilation

Specification	
Adult/ Pediatric connection	22 mm
Neonatal connection	15 mm

14.3.13 Breathing Circuit

Specification	
Adult/ Pediatric connection	22 mm
Neonatal connection	15 mm
Resistance	≤ 0.3 mbar/L.s^{-1}

14.3.14 HME Filter

Specification	
Adult/ Pediatric connection	22 mm
Bacterial Filtration Efficiency	99,999 %

14.3.15 Specifications for Resistance of the Expiratory Limb

Table 34: Expiratory Resistance in Function of Breathing Circuit and Accessories Aggregates

Breathing Circuit	Flow L x min^{-1}	Expiratory Resistance (hPa or cmH2O)			
		Circuit	Circuit + Flow Sensor	Circuit + Flow Sensor + HME Filter	Circuit + Flow Sensor + CO2 Sensor + HME Filter
Neonatal	5,0	0,2	1,1		
Pediatric	30,0	1,2	3,8	4,2	4,8
Adult	60,0	0,9	2,8	3,9	4,5

14.3.16 Pneumatic diagram

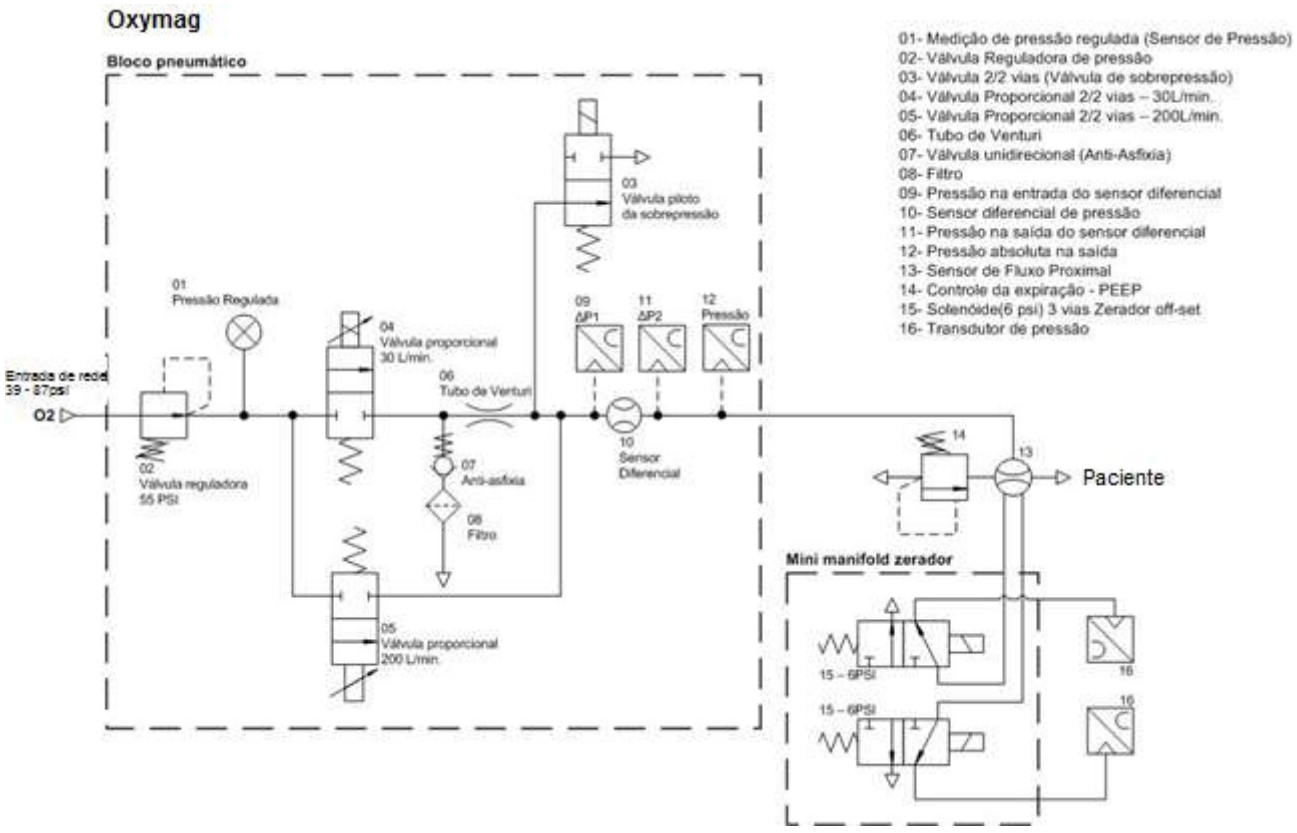


Figure 31: Pneumatic Scheme of the transport ventilator

14.3.17 Block Diagram of Control Electronics

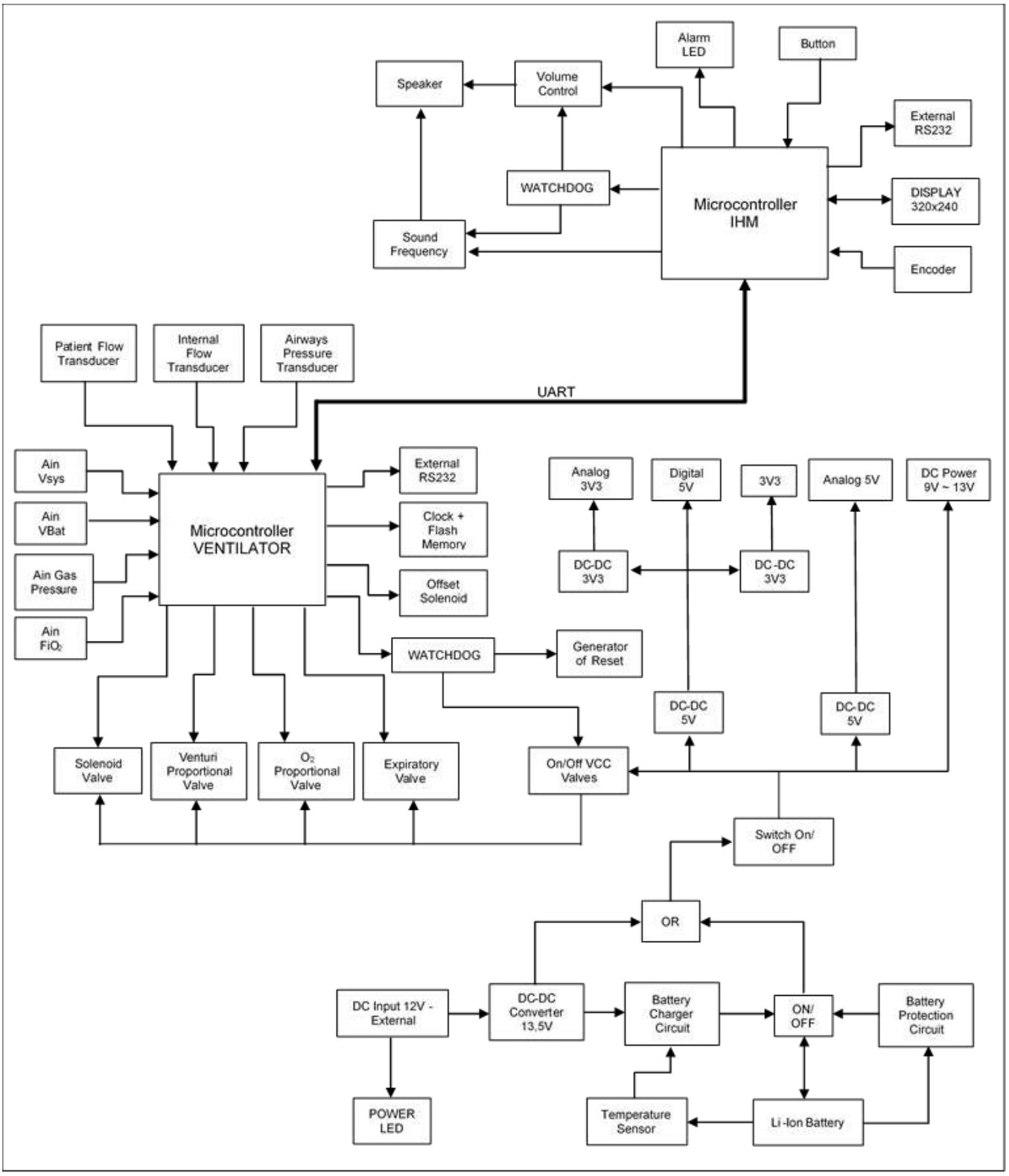


Figure 32: Block Diagram of Electronics

14.3.18 Electromagnetic Compatibility

Changes or modifications to this equipment not expressly approved by MAGNAMED can cause EMC problems with this equipment or another. 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.

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 the system or around the system may cause interference. Before use in a patient, you must check if the equipment works normally in the defined configuration.***
- ***Use of this adjacent equipment or other equipment should be avoided as it may result in improper operation. If such use is required, this and other equipment should be 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, including Magnamed specified cables. Otherwise, performance degradation of this equipment may occur.***
- ***If essential performance is requested or degraded due to electromagnetic disturbance, the ventilator may stop ventilating. In this case, the operator should provide manual ventilation facilities.***

A) Guidelines and manufacturer's statement – Electromagnetic emissions

The system is intended for use in the electromagnetic environment specified below. It is recommended that the customer or user of the system ensures that it is used in such an environment.

Table 35: Specification of electromagnetic environment of use

Emission Test	Compatibility	Directive for Electromagnetic Environment
RF Emissions ABNT NBR 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 ABNT NBR IEC CISPR 11	Class B	The system may emit electromagnetic energy to perform its functions intended. Electronic equipment nearby may be affected.
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

The system is intended for use in the electromagnetic environment specified below. The customer or user of the system should ensure that it is used in such an environment.

Table 36: 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 ± 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. ± 1 kV at signal input / output parts	± 2 kV at the power input interface c.a. ± 2 kV at the power input interface c.c. ± 1 kV at signal input / output parts	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) ±2 kV line(s) to earth	± 1 kV line(s) to line(s) ±2 kV line(s) to earth	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.
Magnetic field of power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	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.

Table 37: *Radiated Immunity*

Immunity Test	Test Level ABNT NBR IEC 60601	Compliance	Electromagnetic environment – Guidelines Recommended separation distance
---	---	---	Portable and mobile RF communication equipment should not be used near any part of the system, including cables, with a separation distance shorter than the recommended, calculated from the equation applicable to the transmitter frequency.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside the ISM bands [a]	3 V	$d = 1,2\sqrt{P}$
---	10 Vrms 150 kHz to 80 MHz outside the ISM bands [a]	10 V	$d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-6	10 V/m	10 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz
---	80 MHz to 2,5 GHz	---	$d = 2,3\sqrt{P}$ 800 MHz to 2,7 GHz Where P is the declared maximum level of transmitter output power in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in meters (m) .b The field strength from RF transmitters, as determined by an electromagnetic field survey, should be less than the compliance level for each frequency range.d Interference may occur in the vicinity of the equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

---

a The industrial, scientific and medical (ISM) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13,553 MHz to 13,567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. Amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5 MHz. , 4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

b Compliance levels in the ISM frequency bands between 0.15 MHz and 80 MHz and in the 80 MHz to 2.7 GHz frequency range are set to reduce the possibility of mobile / portable RF communication equipment causing interference if inadvertently brought into patient areas. Therefore, an additional factor of 10/3 has been incorporated into the formulas used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strength from fixed transmitters such as telephone base stations (mobile or cordless) and mobile ground radios, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically with precision. . To assess the electromagnetic environment generated by fixed RF transmitters, an electromagnetic field survey should be considered. If the measured field strength at the location where Oxymag will be used exceeds the applicable RF CONFORMITY LEVEL set above, Oxymag should be observed to verify that it is operating normally. If abnormal performance is detected, additional measures may be necessary, such as reorienting or relocating Oxymag.

d Above the frequency range 0.15 MHz to 80 MHz, the field strength should be less than 3 V / m.

C) Recommended separation distance between portable and/or mobile RF communications equipment and the system

The system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the system can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communication equipment.

Table 38: Separation distance according to the transmitter frequency (m)

Maximum output power of the transmitter (W)	150 kHz - 80 MHz Out of the ISM bands	150 kHz - 80 MHz Within the ISM bands	80 MHz - 800 MHz	800 MHz – 2.5 GHz
	d = 1,2√P	d = 1,2√P	d = 1,2√P	d = 2,3√P
0,01	0,12	0,12	0,12	0,23
0,1	0,38	0,38	0,38	0,73
1	1,2	1,2	1,2	2,3
10	3,8	3,8	3,8	7,3
100	12	12	12	23

For transmitters with a stated maximum output power level not listed above, the recommended separation distance d in meters (m) can be determined using the transmitter frequency equation. Where P is the declared maximum transmitter output power in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 ISM bands (industrial, scientific and medical) between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13,553 MHz to 13,567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. Amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5 MHz. , 4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

NOTE 3 An additional factor of 10/3 has been incorporated into the formulas used to calculate the recommended separation distance for transmitters in the ISM frequency bands between 0.15 MHz and 80 MHz and in the 80 MHz to 2.7 GHz frequency range. , with the goal of reducing the possibility of mobile / portable RF communication equipment causing interference if inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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 [MHz]	Freq. test [MHz]	Modulation	Trial level [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

D) Electrical Safety

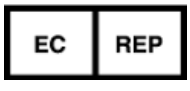
The following are the precautions that should be observed when combining these items (non-medical equipment) with the system.

WARNING

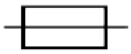
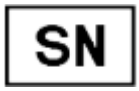
- ***Items that do not meet the requirements of standard IEC 60601-1 cannot be placed within 1.5 from the patient.***
- ***All items (electromedical or non-medical equipment) connected to the system with input/output signal cable must receive power from an AC source using separate transformer (according to standard IEC 60989) or provide additional earth protective conductor.***
- ***Multiple portable sockets with switch used on AC power supplies must comply with IEC 60601-1-1 and cannot be installed on the floor. Do not use more than one power strip with portable switch.***
- ***Do not connect directly 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.***

15. Symbols

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
	PACIENTE	PACIENTE	PATIENT
	CORRENTE CONTÍNUA	CORRIENTE CONTINUA	CONTINUOUS TIDAL
	CORRENTE ALTERNADA (REDE)	CORRIENTE ALTERNA (RED)	ALTERNATING CURRENT (POWER)
	ENERGIA ELÉTRICA	ENERGÍA ELÉCTRICA	ELECTRIC ENERGY
	RECOLHIMENTO DE EQUIPAMENTO ELÉTRICO/ELETRÔNICO FEITO DE FORMA SEPARADA	RECOGIMIENTO DE EQUIPO ELÉCTRICO ELECTRÔNICO HECHO POR SEPARADO	WASTE – ELECTRICAL AND ELECTRIC EQUIPMENT SHALL BE COLLECTED AND RECYCLED IN ACCORDANCE WITH DIRECTIVE 2002/96/EC
	ENTRADA DC	ENTRADA DC	DC INPUT
	CONEXÃO DE FORÇA	CONEXÃO DE FORÇA	POWER PLUG
	LIGA	ON	ON
	DESLIGA	OFF	OFF
INSP / EXP HOLD	PAUSA INSPIRATÓRIA/ EXPIRATÓRIA	PAUSA INSPIRATORIA/ ESPIRATORIA	INSPIRATORY/ EXPIRATORY HOLD
MANUAL	DISPARO MANUAL	GATILLO MANUAL	MANUAL TRIGGER
O_2 100%	100% OXIGÊNIO	100% OXIGENO	OXYGEN 100%
	SERIAL	SERIAL	SERIAL

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
	IDENTIFICAR OU ACONSELHAR LIMPEZA OU TROCA DE FILTRO	IDENTIFICAR O ASESORAR LA LIMPIEZA O EL CAMBIO DEL FILTRO	TO IDENTIFY OR ADVISE CLEANING OR CHANGING A FILTER
	TRAVAR TECLADO	TRABAR TECLADO	KEYBOARD LOCK
	MANUTENÇÃO PERIÓDICA	MANTENIMIENTO PERIÓDICO	PERIODIC MAINTENANCE
	CONGELA	CONGELA	FREEZE
	PÁGINA	PAGINA	PAGE
	ALARME AUDIO PAUSADO	ALARMA AUDIO PAUSADO	AUDIO ALARM PAUSED
	ALARME	ALARMA	ALARM
IP24	PROTEGIDO CONTRA RESPINGOS DE ÁGUA E ENTRADA DE PARTES SÓLIDAS MAIOR OU IGUAL A 12,5MM	PROTEGIDO CONTRA SALPICADURAS DE AGUA Y ENTRADA DE PARTES SÓLIDAS MAYOR O IGUAL A 12,5MM	PROTECTED AGAINST WATER SPRAYS AND THE INGRESS OF SOLIID PARTS OF 12,5MM OR BIGGER
	PARTE APLICADA TIPO BF	PARTE APLICADA TIPO BF	TYPE BF OF APPLIED PART
	EQUIPAMENTO CLASSE II	EQUIPO CLASE II	CLASS II EQUIPMENT
	DATA DE FABRICAÇÃO	FECHA DE FABRICACIÓN	MANUFACTURE DATE
	FABRICANTE	FABRICANTE	MANUFACTURE
	REPRESENTANTE EUROPEU	REPRESENTANTE EUROPEO	EUROPEAN REPRESENTATIVE
	ATENÇÃO! CONSULTAR DOCUMENTOS ACOMPANHANTES	ATENÇIÓN! CONSULTAR DOCUMENTOS QUE ACOMPANAN	ATTENTION! SEE ACCOMPANYING DOCUMENTS

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
	INSTRUÇÃO DE USO	MANUAL DE INSTRUCCIONES	OPERATING INSTRUCTIONS
	FRÁGIL	FRÁGIL	FRAGILE
	FACE SUPERIOR NESTA DIREÇÃO	LADO SUPERIOR EN ESTA DIRECCIÓN	THIS SIDE UP
	PROTEGER CONTRA UMIDADE	PROTEGER CONTRA LA HUMIDAD	FEARS HUMIDITY
	QUANTIDADE SEGURA DE EMPILHAMENTO	SOSTENIMIENTOS DE LA CANTIDAD DE AMONTANAR	SAFE STACKING QUANTITY
	LIMITES DE TEMPERATURA	LIMITES DE TEMPERATURA	TEMPERATURE LIMITS
	MANTENHA PROTEGIDO DO SOL	MANTENER PROTEGIDO DEL SOL	KEEP AWAY FROM HEAT
$EtCO_2$ / SpO_2	CONEXÃO DE ENTRADA DO SENSOR DE CAPNOGRAFIA / OXIMETRIA	CONEXIÓN DE ENTRADA DEL SENSOR DE CAPNOGRAFÍA / OXIMETRÍA	CAPNOGRAPHY / OXIMETRY SENSOR INPUT CONNECTION
O_2 INLET	ENTRADA DE O_2	ENTRADA DE O_2	O_2 INLET
O_2	OXIGÊNIO	OXIGENO	OXYGEN
	AJUSTE DE ALARME OFF	AJUSTE DE ALARMA OFF	ALARM SETTING OFF
	STAND BY	STAND BY	STAND BY
INSP	INSPIRATÓRIA	INSPIRATORIA	INSPIRATORY
EXP	EXPIRATÓRIA	ESPIRATORIO	EXPIRATORY

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
	FUSÍVEL	FUSIBLE	FUSE
	CONFORMIDADE CE: INDICA QUE O SISTEMA ESTÁ EM CONFORMIDADE COM A DIRETIVA 93/42/CEE	CONFORMIDAD CE: INDICA QUE EL SISTEMA ESTÁ EN CONFORMIDAD CON LA DIRECTIVA DEL CONSEJO EUROPEO 93/42/CEE	CONFORMITY CE: INDICATES THAT THE SYSTEM IS IN ACCORDANCE WITH DIRECTIVE OF THE EUROPEAN COUNCIL 93/42
	INMETRO	INMETRO	INMETRO
	A LEGISLAÇÃO FEDERAL DOS EUA RESTRINGE A VENDA DESTE DISPOSITIVO OU POR ORDEM DE UM MÉDICO	LA LEGISLACIÓN FEDERAL DE LOS ESTADOS UNIDOS RESTRINGE LA VENTA DE ESTE DISPOSITIVO O POR ORDEN DE UN MÉDICO	US FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN
	DATA DE VALIDADE	FECHA DE VALIDEZ	USE BY DATE
	NÃO ESTÉRIL	NO ESTERIL	NON-STERILE
	NÃO USAR SE A EMBALAGEM ESTIVER DANIFICADA	NO UTILIZAR SI EL PAQUETE ESTÁ DAÑADO	DO NOT USE IF PACKAGE IS DAMAGED
	O MANUAL DE INSTRUÇÕES DEVE SER LIDO	EL MANUAL DE INSTRUCCIONES DEBE SER LIDO	THE INSTRUCTION MANUAL MUST BE READ
	NÚMERO DO CATÁLOGO DO FABRICANTE	NÚMERO DE CATÁLOGO DEL FABRICANTE	MANUFACTURER'S CATALOGUE NUMBER
	NÚMERO DE SÉRIE DO FABRICANTE	NÚMERO DE SERIE DEL FABRICANTE	MANUFACTURER'S SERIAL NUMBER
	CÓDIGO DE LOTE DO FABRICANTE	CÓDIGO DE LOTE DEL FABRICANTE	MANUFACTURER'S MATCH OR LOT CODE
	USO ÚNICO	USO ÚNICO	SINGLE USE

16. Terms and Abbreviations

Table 39: List of terms and abbreviations with their descriptions

Terms and Abbreviation	Description	Terms and Abbreviation	Description
ADU	Adult	I:E	Ratio T.Insp by TExp
Backup	Apnea Mode Setting	BMI	Body Mass Index
C.Dyn	Dynamic Compliance	INF	Infant
CO_2i ↑	Alarm setting High CO_2 inspired	Man Trig	Manual Trigger
Compliance	Circuit Compliance	MV	Minute Volume
Cons O_2	O_2 Consumption	NEO	Neonatal
C.Stat	Static Compliance	NIV	Non-Invasive Ventilation
CPAP	Continuous Positive Airway Pressure Ventilation	O_2 100%	Flash indication of O_2
Cycl. PS	Cycling Percentage	Pause	Inspiratory Pause
DualPAP	Dual-level CPAP Ventilation	PCV	Pressure Controlled Ventilation
FiO_2	O_2 Inspired Fraction	PED	Pediatric
Freq	Total Respiratory Rate	PEEPi	Intrinsic PEEP
F.Base	Baseline Flow	P. Lower	Lower Pressure of DualPAP mode
Fspn	Spontaneous Frequency	P. Insp	Setting of Inspiratory Pressure
FI Tig F.Trigger	Trigger (Sensitivity) to Flow	PLV	Pressure Limited Ventilation
P Mean	Mean Pressure	P.Max	Maximum Pressure in the Airways
P.Plat	Plateau Pressure	T. Lower	Lower Time of DualPAP mode
Prede	Network Pressure	T. High	Upper Time of DualPAP mode
Pr Trig P.Trigger	Trigger (Sensitivity) to Pressure	Exp Valve	Expiration Valve
Prox	Next Page	Leakage	Circuit Leakage
P-SIMV	Controlled Pressure Synchronized Intermittent Mandatory Ventilation	VCV	Volume Controlled Ventilation

Terms and Abbreviation	Description
PSV	Continuous Pressure Ventilation with Pressure Support
P. High	High pressure of DualPAP mode
P.Low	Low pressure
Res	Airway resistance
Resistance	Circuit Resistance
Rise Time	Rise Time
SpO_2	Oxygen Saturation in the Blood
T.Exp	Expiratory Time
T.Insp	Inspiratory Time

Terms and Abbreviation	Description
VMspn	Spontaneous Minute Volume
V-SIMV	Synchonized Intermittent Mandatory Ventilation with Controlled Volume cycle
Vspn	Spontaneous Volume
Vt	Adjusted Tidal Volume
Vti	Inspired Tidal Volume
Vte	Exhaled Tidal Volume
ΔPS	Value to be added to PEEP pressure to obtain Pressure Support
$\dot{V}$	Tidal flow
HR	Heart Rate

17. Statement of Biocompatibility

This is to state, under our sole responsibility, that all materials used in parts (as defined in standard NBR IEC 60601-1) applied to Oxymag has been widely used in the medical field overtime, thus ensuring their biocompatibility.

And, according to standard ISO-10993-1 Biological evaluation of medical devices — Part 1: Evaluation and testing – clause 4.2.1 – the ventilator, its parts and accessories are classified as device without direct or indirect contact with the patient body; therefore, the ventilator, its parts and accessories are not included in the scope of this standard.

WARNING

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

18. Warranty

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

The warranty period for the equipment is 12 months. For batteries and accessories, the periods of 3 months, provided that retained their original features; this period is from 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 misinstallation, 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.

19. Technical Assistance

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

20. Training

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

Website: www.magnamed.com.br
Email: magnamed@magnamed.com.br

MAGNAMED

Manufacturer / Technical Assistance / Customer Service

Magnamed Tecnologia Médica S/A
Rua Santa Mônica, 801 - 831 – Bairro Capuava
CEP: 06715-865 – Cotia – SP – Brasil
Phone/Fax: +55 (11) 4615-8500
E-mail: magnamed@magnamed.com.br
Website: www.*magnamed*.com.br

CNPJ: 01.298.443/0002-54
State Registration: 149.579.528.111

EC REP **Europeu Representative**
CMC Medical Devices & Drugs S.L.
Adress: Horacio Lengo Nº 18, CP 29006, Málaga – Spain
Phone: +34951214054
Fax: +34952330100
E-mail: info@cmcmedicaldevices.com

Technical Responsibile: Tatsuo Suzuki
CREA-SP registration: 0600629049

Legal Responsible: Tatsuo Suzuki