MAGNAMED

Operation Manual

OxyMag Agile – Transport and Emergency Ventilator

This instructions for use applies to Oxymag Agile – Transport and Emergency Ventilator - 1603855-01: OxyMag Agile, developed and manufactured by Magnamed Tecnologia Médica S/A.

Review of this instructions for use: nº 06

Software version: 1.n

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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

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Safety Notes

a. Definitions

WARNING

- ***It is meant 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 meant to inform the user of the chance of a failure in the equipment associated with its use or misuse, such as equipment malfunction, equipment damage, or damage to a third party, and an indirect injury to a patient.

Note

- Important information.

b. Warning

WARNING

- ***Where there is this 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 the best resources to patients. Check all Warnings and Cautions in this manual and on the labeling of the equipment.***
- ***This equipment should be operated only for the purpose specified in 1.1 Intended Use in conjunction with appropriate monitoring.***
- ***This equipment must be operated only by a qualified professional in the health care area with expertise in mechanical ventilation, qualified and trained in its use, who should be closely monitoring 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 8 Cleaning and .***
- ***This equipment shall pass the "Basic adjustments and inspection procedures" to ensure the effectiveness of the equipment and the safety of the operator and patient, as indicated in chapter 5 Inspection Before Use.***
- ***This equipment must ALWAYS remain connected to a power grid when possible, so that there is enough charge during a power outage.***

- *This equipment must issue three beeps when turning on, demonstrating the correct operation of the audible signal.*
- *This equipment, parts, and accessories must be disposed according to chapter 10 Disposal;*
- *This equipment must be switched off with the patient disconnected, using 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, all of which could interrupt operation of the ventilator.*
- *This equipment should not be used during 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, if it is set at less than 100% O_2 concentrations.*
- *This equipment should not be used with flammable anesthetic agents because there is a risk of explosion.*
- *The ventilator shall not be used in a hyperbaric chamber. Such use might cause the ventilator to not function correctly, causing patient death or additional serious deterioration of health.*
- *After prolonged use of the equipment in environments with suspended particulate matter, replace the filter as indicated in chapter 9.5 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 7 Available.*
- *Do not use antistatic or electrically conductive hoses or tubing.*
- *After starting ventilation, check if the ventilation parameters indicated by the monitoring display are appropriate.*
- *Only use 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.*
- *When turning on the ventilator, please inform the patient type and this will set the proper ventilation.*
- *Oxymag Agile and all parts applied to it are made of non-toxic material, latex-free, and do not cause irritation or allergy to the patient. Applied parts are: patient breathing circuit, and exhalation valve.*
- *Use MASKS specified by MAGNAMED with local registration;*
- *Use MASK suitable for patient type.*
- *Always use oxygen cylinders that are 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 manual ventilation equipment available, in case of complete battery discharge, lack of gases for*

the device to function, or any general failure of the transport ventilator.

- ***The Initial Test Sequence must be performed with the patient disconnected from the equipment.***
- ***Do not expose the product to extreme temperatures beyond the specified range in item 12.3.3 Physical and Environmental Specifications during its use. The equipment's performance may be adversely affected if the operating temperature is beyond the specified limits.***

c. Caution

Caution

- Oxymag Agile does not emit electromagnetic waves that interfere with the operation of equipment in its vicinity.
- Oxymag Agile must pass annual periodic maintenance, or according to the hours of use as specified, whichever comes first.
- Oxymag Agile 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 suspended particulate matter.
- Oxymag Agile should only have its maintenance performed by a qualified, trained technician duly authorized by MAGNAMED.

d. Notes

Note

- There are additional contraindications, in addition to those specified in Warning items in page 5 of this manual. It remains the responsibility of the trained operator to make the choice and selection of suitable respiratory mode for each patient.
- The technical characteristics of MAGNAMED Products are subject to change without notice.
- All ventilator parts, pieces, and accessories that are subject to disposal must comply with the recommendations of Chapter 10 Disposal.
- Pressure units:

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

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

1 mbar = 1 hPa ≈ 1 cmH_2O

1. Description

1.1 Intended Use

Oxymag Agile – MAGNAMED's Transport and Emergency Electronic Ventilator – belongs 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 that are neonatal, pediatric, adult and adults with morbid obesity. Oxymag Agile interacts with the patient through an invasive or noninvasive interface that supplies ventilator air to the patient's airway.

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

The possible ventilation modes of this ventilator are:

- VCV – Volume Controlled Ventilation (can be Assisted);
- PCV – Pressure Controlled Ventilation (can be Assisted);
- 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 only be operated by healthcare professional with expertise in mechanical ventilation and are qualified and trained in its use.***
- ***In CPAP/PSV and DUALPAP modes, ∆PS should be set to OFF 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 care unit (PACU);
- Intra-hospital transportation: The patient can be transported internally, from one department to another.
- Inter-hospital transportation: The patient can be transported by road or air between hospitals.

1.2 Optional items compatible with the products

This equipment is compatible with the following items:

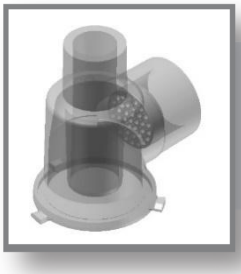
- Nasal prong for neonatal CPAP and its breathing circuit, both must comply local legal government requirements.
- Breathing circuits with trachea, which resistance is less than 0.3 mbar/(L.s-1) that comply local legal government requirements;
- Blender with flow 120ml/min and outlet pressure 60psi that 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 Oxymag Agile

2.1 Initial Checks

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

Table 1: List of components for Oxymag Agile

List of components for Oxymag Agile	
OXYMAG AGILE TRANSPORT AND EMERGENCY VENTILATOR Part Number 1603855 Quantity: 1 unit	POWER OUTLET 12V/3,34A MEDICAL DEGREE Part Number 2402568 Quantity: 1 unit
AC CABLE 3 WAYS 1,5 M Part Number 2802612 Quantity: 1 unit	ADULT BREATHING CIRCUIT 1,2m AUTOCLAVABLE Part Number 1703218 Quantity: 1 unit
QUICK GUIDE OXYMAG FAMILY Part Number 7006467 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

	USER MANUAL Part Number 1603855-NE-171-RR Quantity: 1 unit

2.2 Parts and Accessories

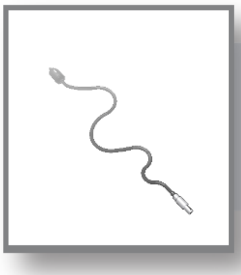
Caution

- Always use original parts and accessories to ensure the safety and effectiveness of the equipment.
- Parts and pieces indicated in this instruction for use may be used in the patient environment.

2.2.1 Optional accessories that can be purchased for Oxymag Agile

Table 2: List of optional components for Oxymag Agile.

List of optional accessories for Oxymag AGILE	
	STAND WITH CASTERS FOR OXYMAG Part Number 3802668
	ARTICULATED ARM WITH SUPPORT FOR BREATHING CIRCUITS Part Number 1708046
	PEDIATRIC AND NEONATAL BREATHING CIRCUIT 1.2M AUTOCLAVABLE Part Number 1702654
	VERTICAL SUPPORT FOR AMBULANCE OR HELICOPTER WITH SAFETY LATCH Part Number 1702496



POWER CORD DC 12V 4-WAY WITH CAR PLUG

Part Number 2802671

CARRYING BAG FOR OXYMAG WITHOUT CYLINDER

Part Number 1704784

CARRYING BAG FOR OXYMAG

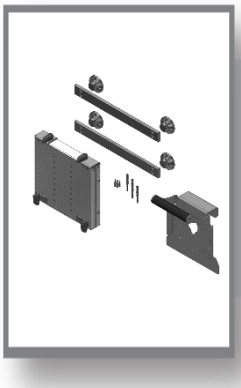
Part Number 1702875

KIT DISPOSABLE BREATHING CIRCUIT ADU – OXYMAG AGILE
Part Number: 1709766
Quantity: 1 unit

Content:
1707787 - Disposable breathing circuit 22 mm x 1,5 m (CE: 1984)
3201486 - Exhalation valve 22 mm
3800248 - Diaphragm

KIT DISPOSABLE BREATHING CIRCUIT PED-NEO – OXYMAG AGILE
Part Number: 1709767
Quantity: 1 unit

Content:
1707786 - Disposable breathing circuit 22 mm x 1,5 m (CE: 1984)
3201486 - Exhalation valve 22 mm
3800248 - Diaphragm



OXYMAG AIRCRAFT SUPPORT[1]

- 1 Aircraft Support Kit (1710071)
- 1 Rail Kit (1710121)[2]

Part Number: 1710130

1 Accessories not available for the European Union

2 According to ISO 19054

2.3 Components of transport ventilator

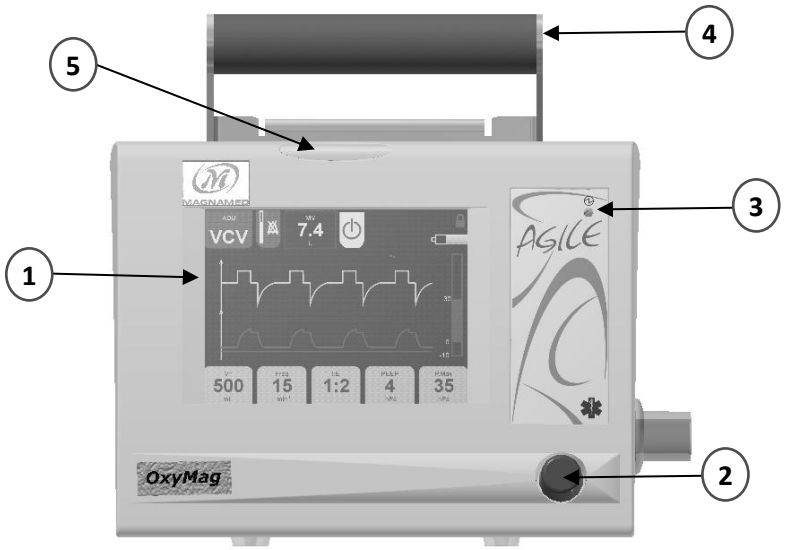


Figure 1: Front Panel of Oxymag Agile

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

Components of Figures 1
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 Agile. • 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 counterclockwise. • To confirm press the button When the button returns to its original color the parameter set will be in effect.
3. GREEN LED – CONNECTION TO MAINS The GREEN LED will bel it when the DC power inlet or power supply 12VDC inlet are connected
4. HANDLE This handle allows you 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's stretcher.
5. ALARM INDICATOR LIGHT – RED The alarm indicator light flashes when an alarm condition of high priority occurs. When in silent mode, this remains activated, indicating the alarm condition.

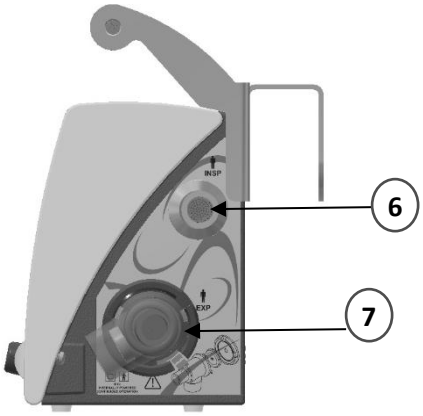


Figure 2: Right side view

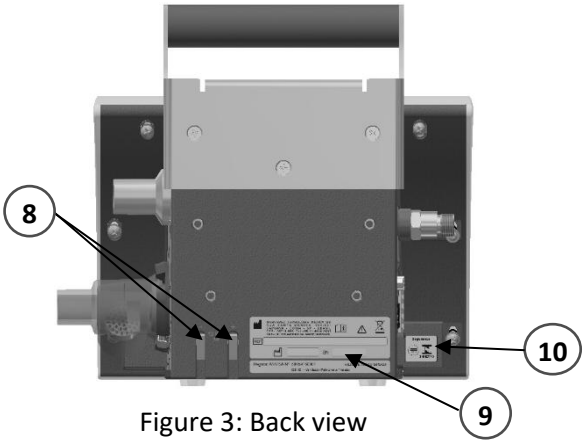


Figure 3: Back view

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

Description of the items in Figure 2 and 3	
6. 22M/15F CONNECTOR OF INSPIRATORY FLOW Standard connection of the inspiratory flow to the breathing circuit of the patient	**9. IDENTIFICATION LABEL** This identification label contains MAGNAMED and thier European Authorized Representative's information, the Registration number at ANVISA, month and year of manufacture, and serial number.
7. EXHALATION VALVE Connection of the expiratory limb of the breathing circuit of the patient.	**10. IDENTIFICATION LABEL** This is the INMETRO seal of compliance and safety.
8. . PLUG OF POWER SUPPLY – BASE This plug is used together with the support base of Oxymag Agile and the power supply system. The inlet is +12VDC. Note the polarity indication and the recorded voltage DC power.	

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

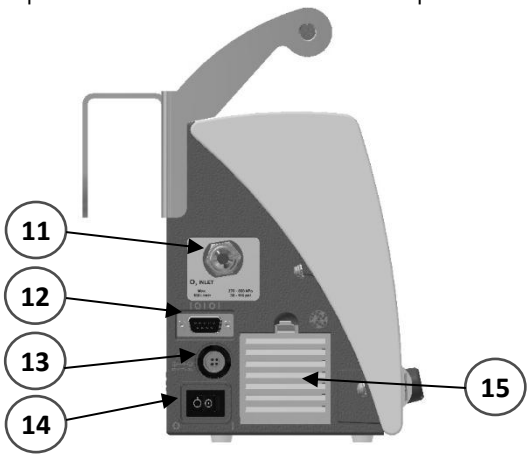


Figure 4: Left side view

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

Description of the items in Figure 4
11. OXYGEN INLET Connect oxygen. Inlet pressure should be in the range of 39 to 87 psi (270 to 600 kPa). Standard DISS connection (ISO 5359).
12. SERIAL CONNECTION Serial Communication – RS-232 – female DB-9 connector for software update and data export to external devices.
13. INLET +12VDC – External AC/DC Source Power supply input +12VDC – Connection to external AC/DC source through the plug
14. On/Off Switch On/Off Switch
15. Air Inlet Filter Ambient air intake filter which is mixed with oxygen to provide oxygen concentrations less than 100%. Filter should be replaced according to the descriptive operations manual (9.5 Replacing the Ambient Air Filter).

WARNING

- ***Only use the 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, the parameter value and the button will return to the previous state after 10 seconds.

Note

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

3. Description of the Display

3.1 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 leakage.

3.2 Alarms, Monitor and Status

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

- When the alarm muting is activated, a bar indicating the mute time is shown.
- At the top center, there is the display area of the parameter always visible; this can display one of the following 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/holding 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 to press the button, the sidebar will fill for the complete 2 seconds. Stand-by button is shown with the symbol below:

- At the right top of the screen, there is the battery 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 and hold the LOCK button for at least 2 seconds, and the touch screen is enabled.

3.2.1 Lock the touch screen

- On the upper right side there is a key that allows you to lock or unlock the touch screen. When the commands on the display are locked, press and hold this key for 2 seconds to release them. To lock just press this key once or it will automatically lock after 30 seconds without touching the screen.

3.2.2 Monitor, Menus and Charts

- On the right side there is a "Bar graph" for pressure, a 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.

3.2.3 Setting the ventilation parameters

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

a. Freeze key

- Freezes the graph tracing to allow for analysis of the curves, while keeping the monitoring active.

b. Manual key

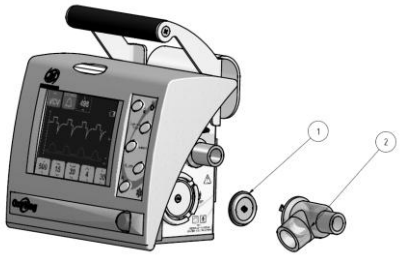
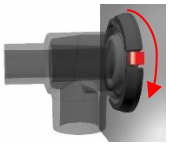
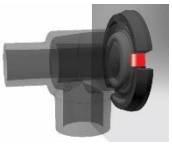
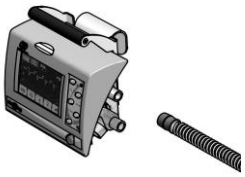
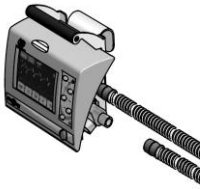
- This key triggers a pressure support inspiratory cycle. And it is active in VCV, PCV, V-SIMV, CPAP/PSV, P-SIMV, DUALPAP AND PLV modes.

4. Preparation for Use

4.1 Assembling Oxymag Agile – 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 Agile

Assembly Sequence	OK	Figure
1. Insert the ambient air filter into the appropriate slot on the left side of the ventilator. See chapter 11.5 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 AC/DC power supply to the equipment then to the power grid.	☐	
6. Connect the oxygen hose to the transport ventilator.	☐	

Note

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

WARNING

- ***Use HME Filter and MASKs specified by MAGNAMED and use appropriate MASKs for each type of patient.***
- ***Position correctly the diaphragm and the exhalation valve to prevent obstruction of the expiratory limb.***
- ***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 its operation, and in turn, endanger the patient or user.***
- ***When using Oxymag Agile for extended time on battery, an alarm occurs whose message is LOW BATTERY. Provide IMMEDIATE connection of the power supply to the power grid and if DISCONNECTING the equipment from the patient is not possible, the user must provide appropriate means of ventilatory support.***
- ***Use the appropriate breathing circuit for the patient.***
- ***When using an oxygen cylinder, check if the pressure reducing valve is set to deliver oxygen flow with pressure according to 12.3.2 Connecting to the Oxygen Supply. Pressures greater than that which is specified may damage the equipment.***

4.2 Power Connection

The equipment must be connected to a three-pin ground power outlet according to international standards.

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

After prolonged use of the equipment in battery mode, a full recharge is required to preparing the equipment for extended use.

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

Caution

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

Note

- If the power supply has been unplugged and restored while the equipment is operating, equipment performance will not be affected and accuracy will be maintained, so long as the internal battery is fully charged.
- After a long period of interruption to the power supply, connect the equipment to the mains, switch on the equipment and wait 30 min. Perform necessary calibrations and self-test.

4.3 Assembling the supports

4.3.1 Assembling the vertical support

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

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

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

Figure 5: Installation of the fixed support

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

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

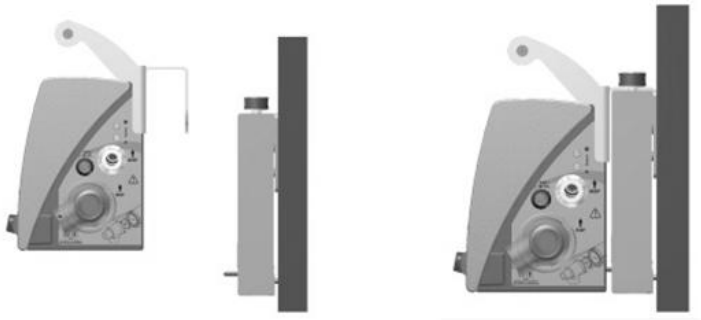


Figure 6: Connection of the ventilator to the fixed support

Below is the procedure to assemble the support on the bench:

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

Figure 7: Installation of the fixed support on the bench

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

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

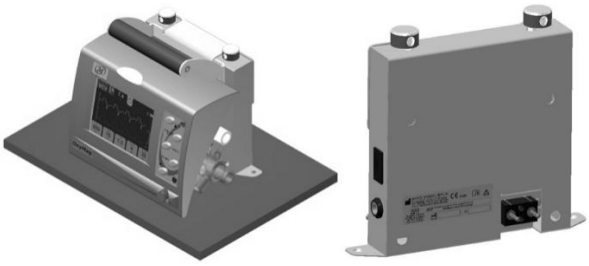
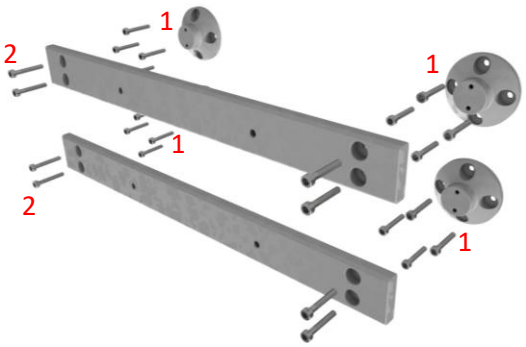


Figure 8: Connection of the ventilator to the support

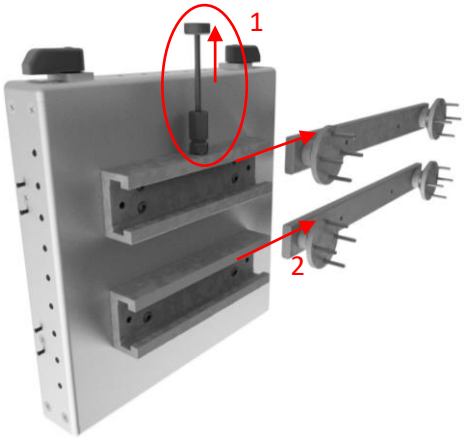
4.3.2 Assembling the support for air transport

The aircraft support (1710130) is optional and can be used on fixed-wing aircraft and helicopters. The sequence for assembling the support on the aircraft fuselage is shown below.

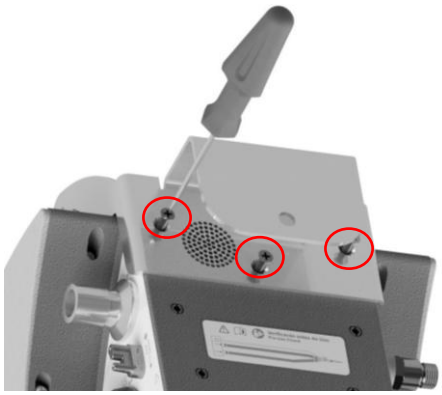
1. Install the rails to the aircraft fuselage by attaching 4 screws to each of the 4 flanges and 4 screws to each of the 2 rails:



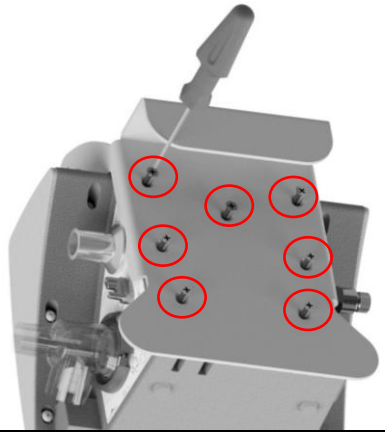
2. Pull the central lock and fit the support onto the rails. Release the lock to secure.



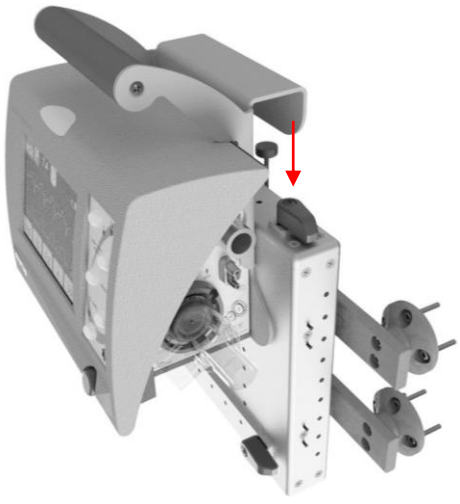
3. Replace the Oxymag handle. Unscrew the handle.



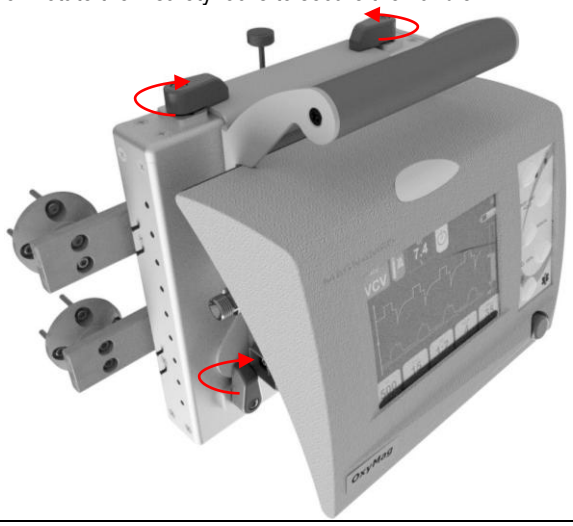
Screw the elongated handle.



4. Position the Oxymag on the support and lower it to fit.



5. Rotate the 4 safety locks to secure the handle



4.4 Inspection Before Use

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

WARNING

- ***This equipment must pass the "Basic adjustments and Inspection procedures" to ensure the effectiveness of the equipment and the safety of both the operator and patient.***

4.5 Initial procedures

This equipment must pass the "Basic adjustments and Inspection procedures" to ensure the effectiveness of the equipment and the safety of both the operator and patient, as the following sequence:

- ✓ Make sure the equipment is off.
- ✓ Perform a visual inspection of the equipment and its components, ensuring that they are of full integrity.
- ✓ Check if all equipment components are connected and correctly installed.
- ✓ Check for the presence of the ambient air inlet filter.
- ✓ Ensure that the connection of the exhalation valve is securely connected. It is important to check the presence of the diaphragm.
- ✓ Check that the breathing circuit is securely connected.
- ✓ Check for the secure connection of the oxygen hose.
- ✓ Check the pressure in the cylinder gauge, where applicable this should be according to item 12.3.2 Connecting to the Oxygen Supply.
- ✓ Check for 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 are played, 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 the equipment on standby, press the STAND-BY button:

- ✓ The equipment is ready for use immediately before been turned on.

WARNING

- ***If you do not 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.***

4.6 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 a 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 the TI_{NS} obtained.

The other parameters will have the default value:

- Maximum Pressure – 30 hPa (cmH2O)
- PEEP – 5 hPa (cmH_2O)
- Plateau Pressure – 30 % of T_{INS}
- Flow – Square

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

Table 7: Modes available for the types of patients

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

When selecting the type of patient at the startup of the equipment, the values of ideal height and weight are 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 graph area, menu, and then selecting the Settings button (in the General Tab). Setting is as shown in the 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 to the height of the patient.

Note

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

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

4.6.1 Normal Startup Sequence

1. Initial screen of Oxymag Agile – 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 patient type to be ventilated. The ventilator will be initialized in the mode indicated in *Table 7*: Modes available for the types of patients

3. Last Adjust – This button brings back the last parameters set when the equipment was switched off the last time. These settings are automatically saved (optional).

4. By choosing NEONATAL, the ventilator will start ventilation with the following parameters:

Table 10: List of parameters in the Neonatal mode

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

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

Table 11: List of parameters in the Pediatric mode

PCV	Default
P_{insp}	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 choosing ADULT, the ventilator will start ventilation with the following parameters:

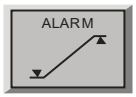
Table 12: List of the parameters in the adult mode

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

VCV	Default
P_{max}	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 graph screen of the ventilator. Audible alarms will be disabled for the first 2 minutes. Note that the white bar next to the mute alarm symbol is reducing over time. After 2 minutes the audible alarm will be reactivated.

8. Press the ventilation mode button

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

and the Alarm Settings screen will appear. Select the alarm to be set and use the knob to change the value. When the desired value is set, confirm it by pressing the knob.

    To return to the secondary menu with the selection of graphs, data, settings, and alarms press the button. To automatically adjust the alarm values, select the parameter “Automatic” and select 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 is selected, these alarms return to the alarm default values for the patient type set at startup.
    To enable the automatic adjustment, it is required that the ventilator is not in STAND-BY.

12. By pressing the CONFIG button, you can:

- Change the height of the Patient, thereby defining the ideal weight (IMC 22), which in turn recalculates the default ventilatory parameters of this patient.

- Turn on or off NIV (Non-Invasive Ventilation) mode. When NIV is activated, there will be leak compensation of approximately 40L/min, depending on the ventilator settings.
- Turn on or off the external blender compensation. In this condition, the device doesn't allow the change of FiO_2. The FiO_2 adjustment will be done directly with the blender.
- Turn on or off the sigh function. In this condition, there will be a sigh every 100 cycles in control modes.
- VCV and V-SIMV – sigh add 50% of set volume
- Select the language of the equipment.
- Press the O_2 tab to perform calibrations of the O_2 cell. Press the "Calibrate FiO_2"button to calibrate the oxygen cell. Calibration can be performed at one of two reference points: 21% (ambient air) or 100% oxygen. The system will automatically carry out the process, and the readings must be visually confirmed on the display. If any failure occurs during the procedure or if there is instability in the oxygen cell, the equipment will issue a failure message, as calibration is only considered complete when the O_2 concentration values are validated and stable at 21% (ambient air) and/or 100% (oxygen), according to the selected procedure.
- Press Ventilator tab to:
- **Set:**
    - Audio volume – to set the alarm audio volume. Use the knob 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 passed since the last maintenance.

13. Press the screen on graph area and then menu. A panel of buttons will be displayed for selection of graphs, data, settings, and alarms.

Note

- It is not necessary to discard calibration gases.

4.6.2 Test Sequence

The tests are essential to check if the equipment is operating as expected and to adjust 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 auto 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 the NO key; otherwise press YES to proceed to the next test.
3. By pressing the "NO" key, the message: "Inoperative Device" – Contact Technical assistance will appear. The equipment requires the presence of an open breathing circuit with a y-connector. Press Ok when this condition is carried out.

WARNING

- ***After any ventilation, change the patient type tested in the test sequence by restarting the equipment, select the type of patient desired and restart the equipment again, 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 13)***

5. Occlusion of the breathing circuit at the "Y" 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 values are suitable for use in the ventilator.

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

4.6.3 Failure Diagnosis

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

Note

- After performing repairs, you should restart the equipment and perform the sequence test again; if the failure 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 found in 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
Air Flow+ O_2	Ensure that the oxygen supply pressure is according to the specification found in 15.3.2 Connecting to the Oxygen Supply	Lack of flow, use not allowed
O_2 Cell	Contact Technical Assistance	No warranty for O2 cell, use not allowed
Exhalation Valve	Check the positioning of the diaphragm in the Exhalation Valve	Failure in the pressure monitoring and control, use not allowed
Pressure Sensor	Check the positioning of the diaphragm in the Exhalation Valve, check leakage in breathing system	Failure in the pressure monitoring control, use not allowed

5. Description of modes

5.1 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. The flow waveform of the can take square, descending, sine, and ascending shapes. VCV is equivalent to CMV – VC and A/C – VC of ISO 19223.

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

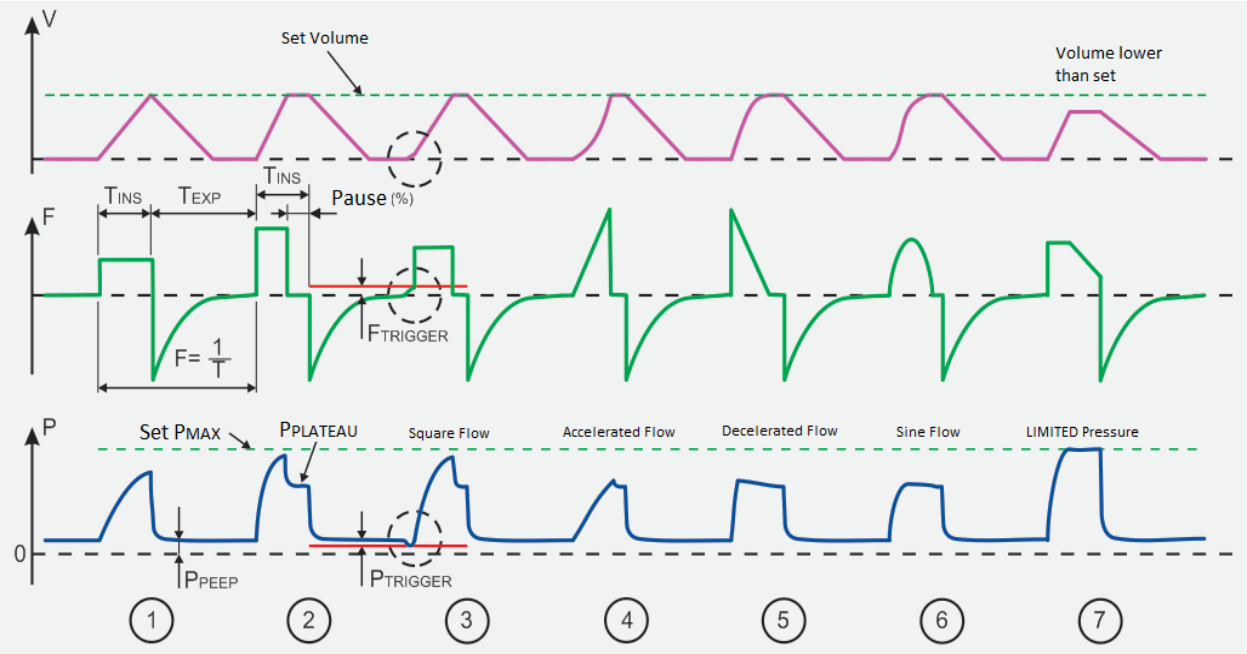


Figure 9: VCV Curves

Once all ventilation parameters are received by the ventilator, it calculates T_{INS}, T_{EXP}, T_{PAUSE}, F_{INS} based on Ratio I:E, Pause, and Frequency, thus obtaining all ventilation control times.

1. Ventilation without Inspiratory Pause: After T_{INS}, 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 an exhalation pause until a complete T_{INS}, 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 established levels. The information of what type of trigger activated the inspiratory cycle is reported in the screen area of status and messages. The detection of patient's inspiratory effort for synchronization occurs at any time during exhalation.

Note

- When the patient begins to demonstrate inspiratory effort and the ventilator is with either 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. This condition is reported in the screen area of status and 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 for initial reference. Reset the ventilation parameters as needed by the patient.***
- ***Volume limited ventilators must not to be used in patients without supervision.***
- ***In this mode, the inspiratory flow values depend on the settings of V_t, Rate, and I:E. The Insp time values depend on the Rate and I:E adjustments.***

5.2 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, a 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. PCV is equivalent to CMV – PC and A/C – PC of ISO 19223.

Set Parameters:

- INSP PRESSURE
- RATE
- RATIO I:E
- PEEP
- FiO_2
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- RISE TIME

Note

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

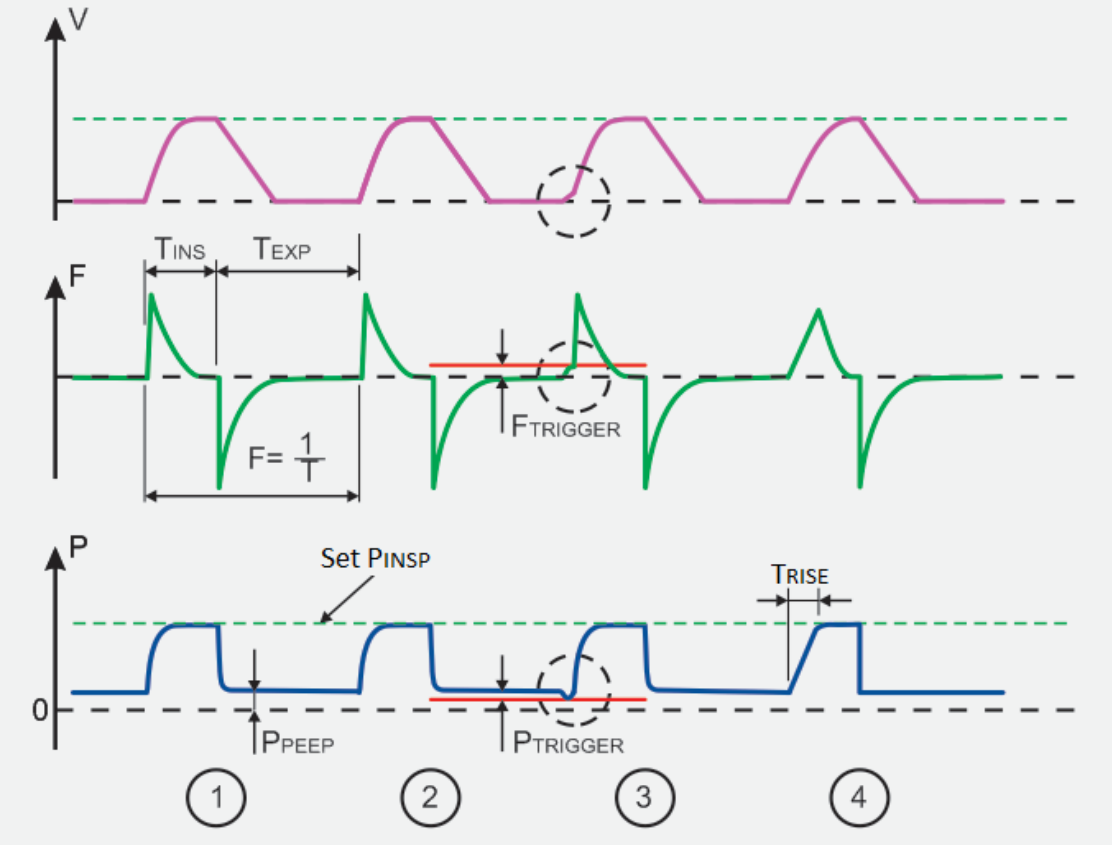


Figure 10: PCV Curves

Once all ventilation parameters are set on the ventilator, it calculates T_{INS} and T_{EXP} 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. The volume delivered to the patient is the result of resistance and compliance of their breathing circuit. The ventilator remains at the inspiratory pressure level set during T_{INS}, after which it cycles to exhalation, maintaining the PPE pressure set.

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

Note

- When the patient begins to demonstrate inspiratory effort and the ventilator is with either flow or pressure triggers 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 $T_{RISE\ TIME}$, the initial peak flow is generally smaller than that in $T_{RISE\ TIME}$=0 (depending on the resistance and compliance of the patient's breathing circuit).

WARNING

- ***Default values are only for initial reference. Reset the ventilation parameters as needed by the patient.***
- ***In this mode, the inspiratory time values depend on Rate and I:E adjustments.***

5.3 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

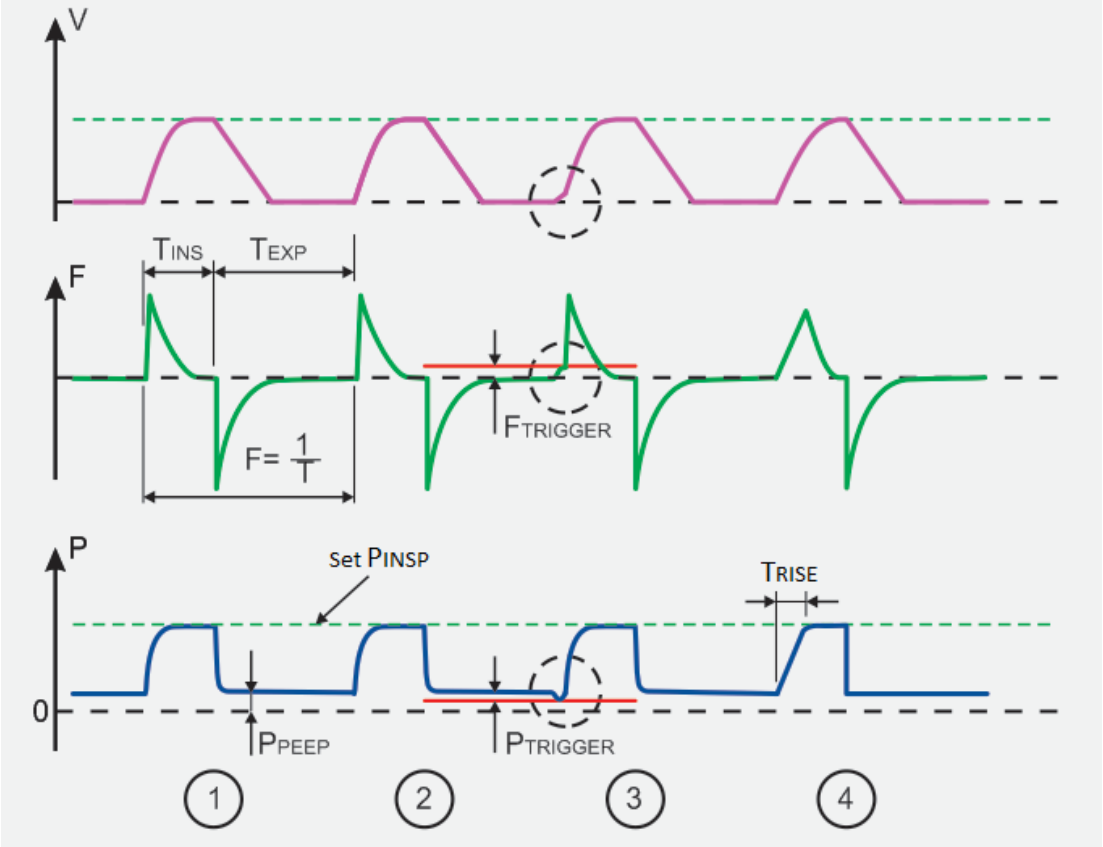


Figure 11: PLV Curves

Once all ventilation parameters are set on the ventilator, it calculates T_{EXP} based on Rate and T_{INS} and, thus, obtain all ventilation control times.

1 and **2** Pressure Limited Ventilation – The ventilator seeks to achieve the set inspiratory pressure, and this is accomplished by the 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 T_{INS}, after which cycles to exhalation, maintaining the set PEEP pressure.

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

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 either flow or pressure triggers 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 CO_2 from the respiratory circuit, in addition to reduce undesirable PEEP.
- In this mode, the I:E ratio parameters depend on the settings of Insp time and Rate.

5.4 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).
V-SIMV is equivalent to SIMV-VC\PS in ISO 19223.

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 (%)
- FiO_2
- ΔPS (Pressure support – PEEP)
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- WAVEFORM OF THE FLOW
- CYCLING BY FLOW (% FLOW)
- RISE TIME
- FLOW (- only to NEONATE);

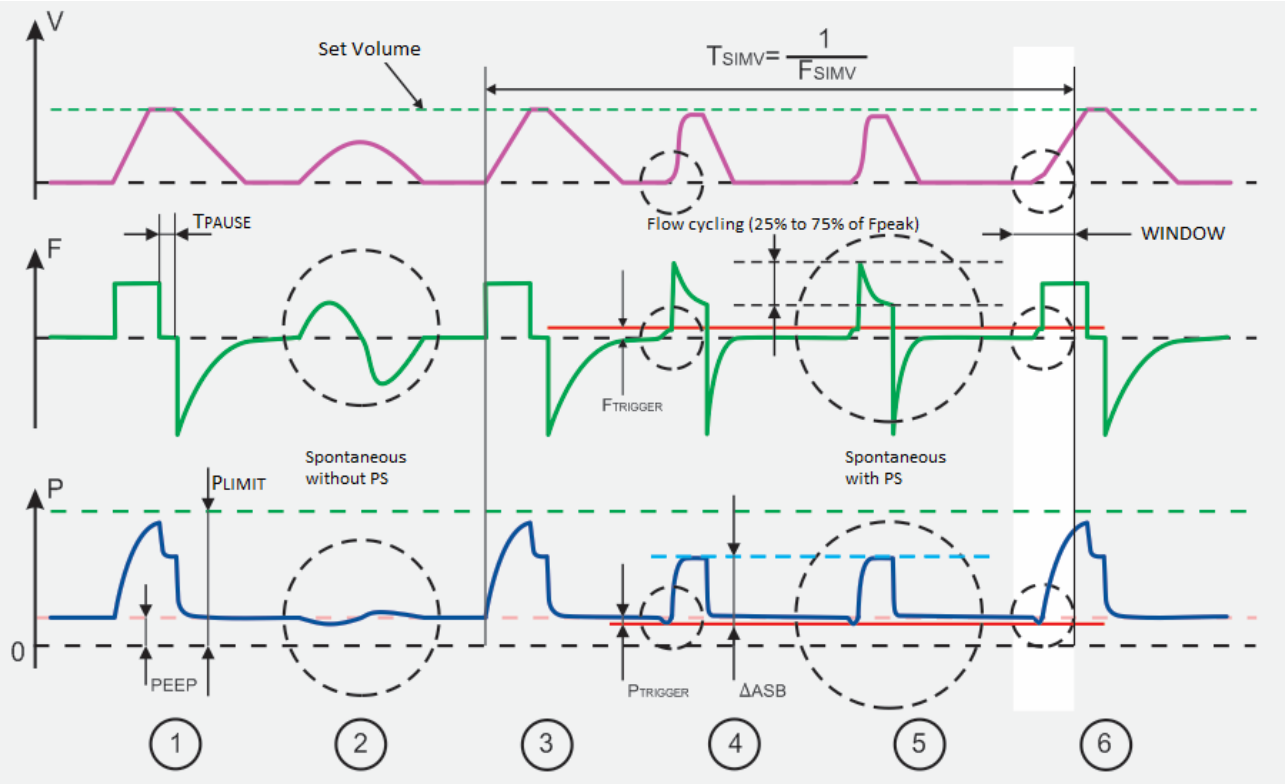


Figure 12: V-SIMV curves

Once all ventilation parameters are set on the ventilator, it calculates T_{EXP} and F_{INS} 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 a 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 ($T_{RISE\ TIME}$) also applies to pressure support (see PCV).

6 If the patient performs inspiratory effort, at the end of the SIMV period (T_{SIMV}), there is a window to the timing of controlled ventilation cycle, which is 'open' from 0.75 x T_{SIMV}, 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 screen area of status and messages.

Note

- The monitored respiratory rate 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.***

5.5 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).
P-SIMV is equivalent to SIMV-PC\PS in ISO 19223.

Set Parameters:

- INSP PRESSURE
- RATE
- INSPIRATORY TIME
- PEEP
- FiO_2
- ΔPS (Pressure Support – PEEP)
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- CYCLING BY FLOW (% FLOW)
- RISE TIME
- FLOW (- only to NEONATE);

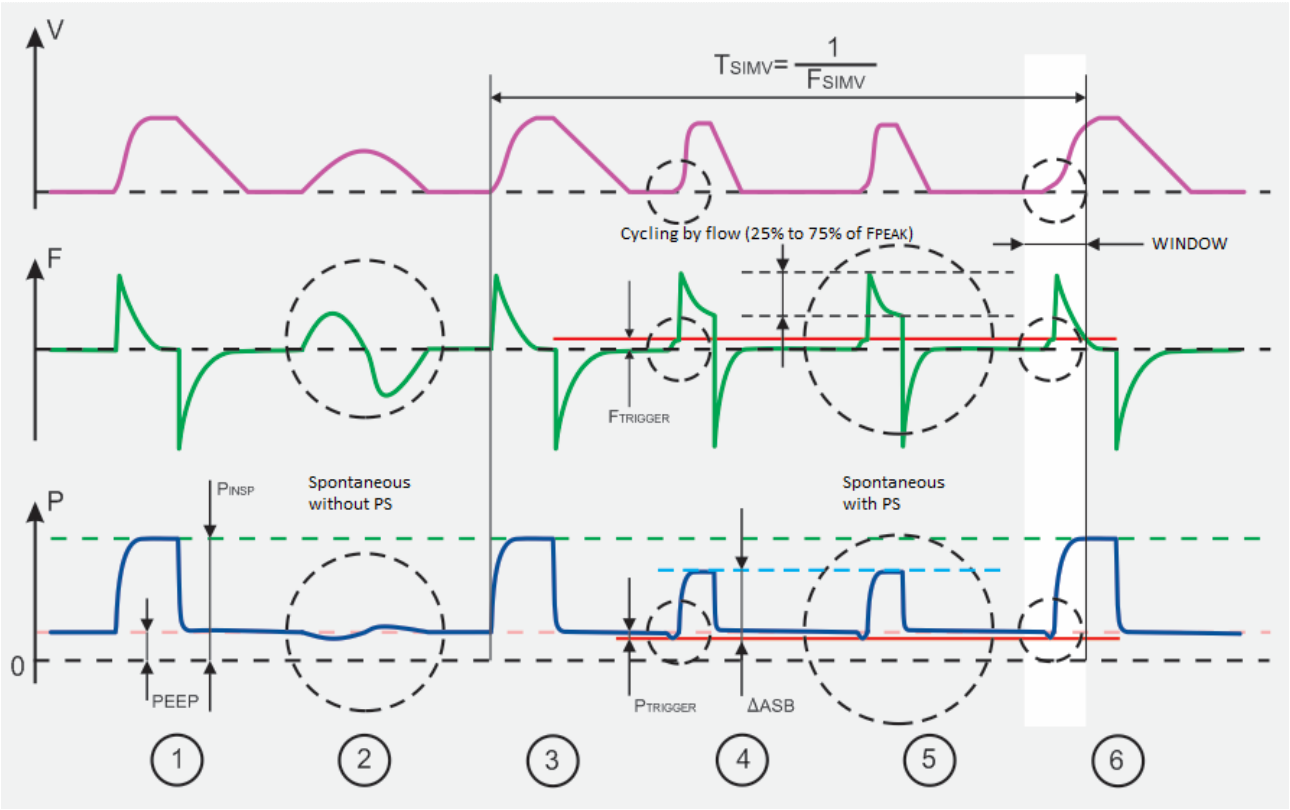


Figure 13 - P-SIMV Curves

Once all ventilation parameters are set on the ventilator, it calculates T_{EXP} based on T_{INS} and Rate, thus obtaining all ventilation control times.

1 Represents a PCV (pressure controlled) cycle during $T_{INS.}$

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. The percentage of peak flow in which cycling occurs from inspiratory phase to expiratory phase is programmable. Rise time ($T_{RISE\ TIME}$) also applies to pressure support (see PCV).

6 If patient performs inspiratory effort, in the end of SIMV period (T_{SIMV}), there is a timing window of the controlled ventilation cycle, which is 'open' from 0.75 x T_{SIMV}, 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 screen area of status and messages.

WARNING

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

Note

- The monitored respiratory rate 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.

5.6 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 and 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 methods (pressure or flow) are disabled, pure CPAP mode will be activated, i.e., without pressure support. In this condition, the PEEP parameter will be displayed as CPAP.
CPAP is equivalent to CPAP and CSV-PS in ISO 19223.

Set Parameters:

- PEEP or CPAP
- ΔPS (Pressure Support – PEEP)
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- FiO_2
- CYCLING BY FLOW (% FLOW)
- RISE TIME
- BACK-UP MODE (VCV, PCV, 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)

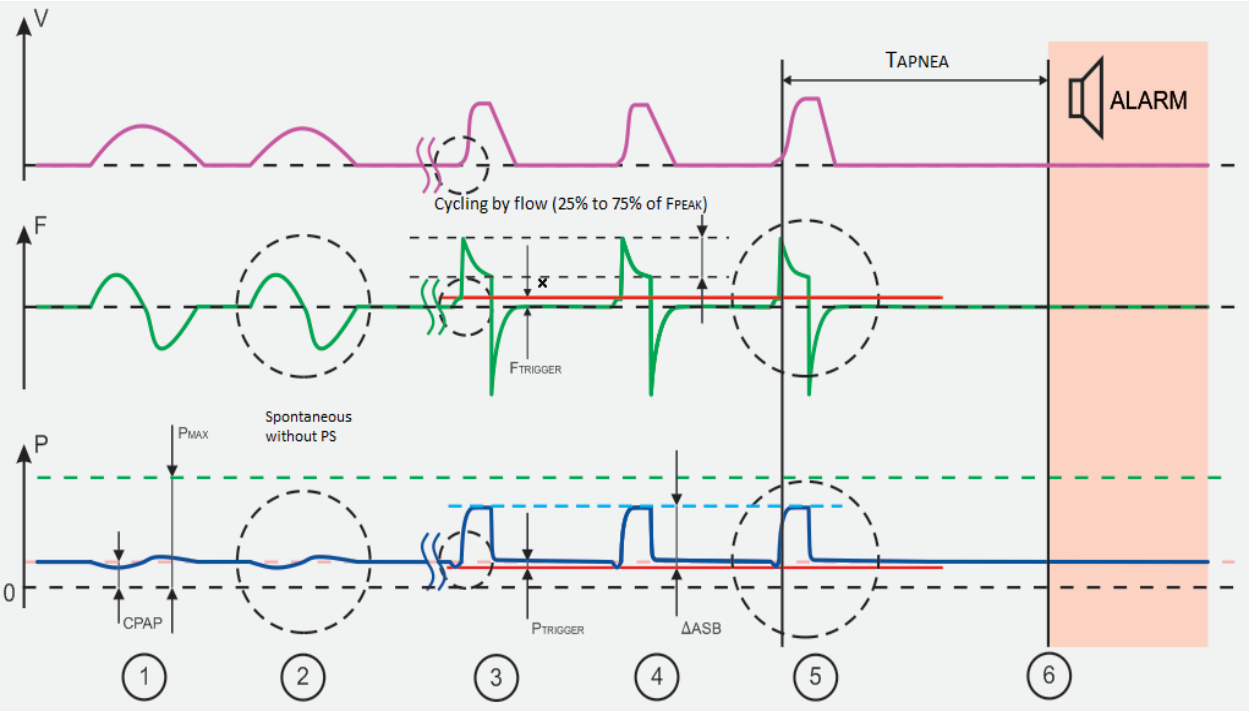


Figure 14: PSV (CPAP + ΔASB) Curves

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. $T_{RISE\ TIME}$ of pressure support may be adjusted so that initial flow is smoothed.

6 If the patient enters in apnea, after T_{APNEA} (s), the ventilator will show this condition with alarm in its screen area of status and messages and will initiate the ventilation backup that was selected according to the programed settings and parameters.

WARNING

- ***Apnea alarm should be set to a safe value for the patient. However, apnea alarms can be RESET. In this condition, there will be no information or alarm for apnea conditions and no backup ventilation in action. The equipment operator must be aware of the DEACTIVATED Apnea Alarm condition (OFF INDICATED ON DISPLAY).***
- ***If backup ventilation selected is NO BACK-UP, the equipment operator must be aware of this situation (INDICATED 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.

5.7 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}
- FiO_2
- ΔPS (Pressure Support – PEEP)
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- CYCLING BY FLOW (% FLOW)
- RISE TIME
- MAXIMUM PRESSURE
- FLOW ($\dot{V}$ - 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)

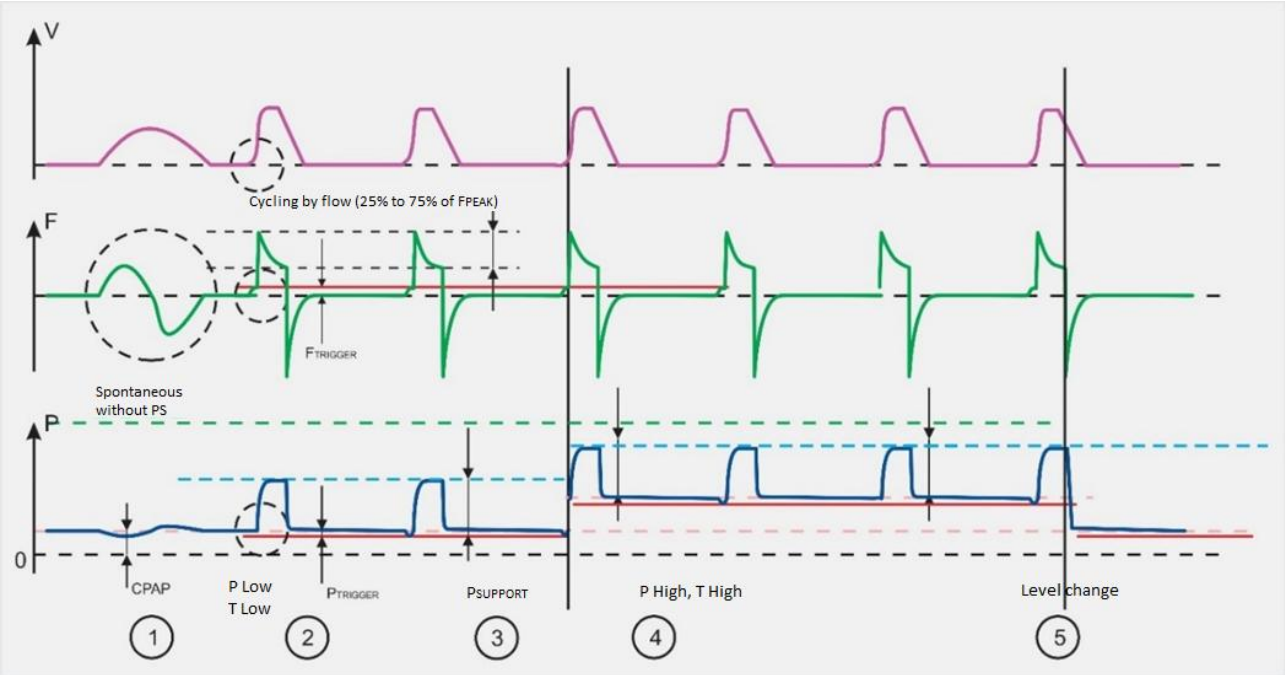


Figure 15 – DualPAP Curves

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 and **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 screen area of status and messages.

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.

5.8 APRV –Airway Pressure Release Ventilation (mode obtained 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}
- FiO_2
- ΔPS (Pressure Support – PEEP)
- TRIGGER BY FLOW
- TRIGGER BY PRESSURE
- CYCLING BY FLOW (% FLOW)
- RISE TIME
- MAXIMUM PRESSURE
- FLOW ($\dot{V}$ - 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)

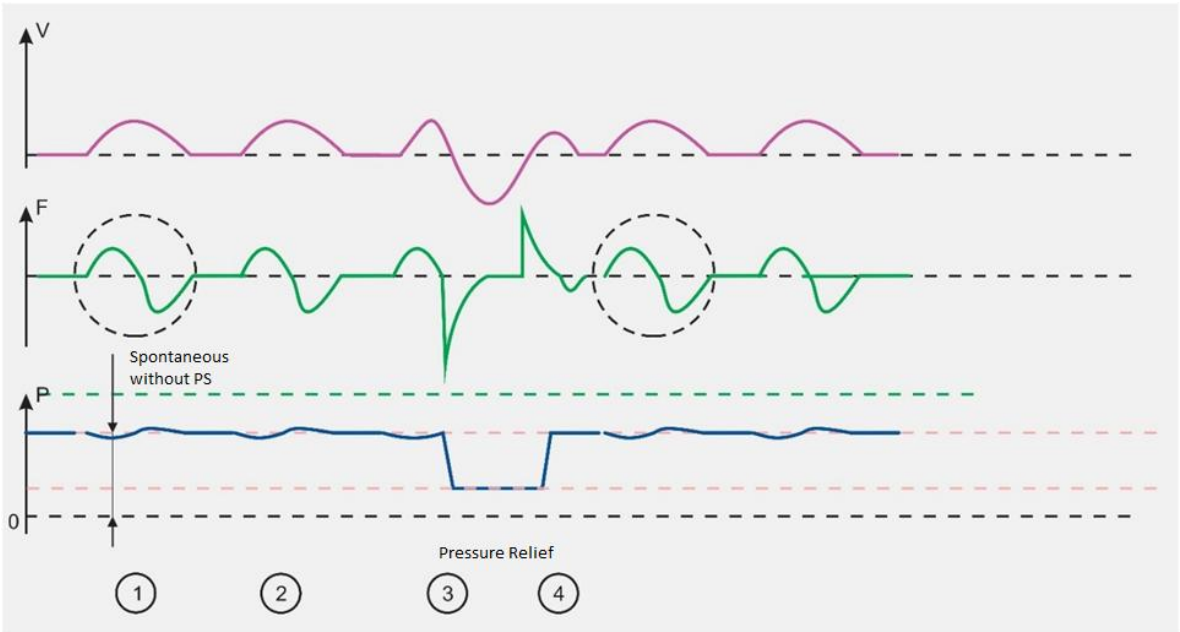


Figure 16: APRV Curves

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 screen area of status and messages.

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

- The monitored respiratory rate is the result of spontaneous breathing of the patient.
- Pressure support (ΔPS) is a value above P_{HIGH} or P_{LOW} and can be adjusted between P_{MAX} - P_{HIGH} + 5 cmH2O and P_{MAX} - P_{HIGH}.
- Changes in pressure levels are synchronized.

6. Available Alarms

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

WARNING

- ***Alarms and alerts should be treated promptly in order to maintain the operation integrity of the equipment and patient safety.***
- ***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 the situation that led the user to pause the audible alarm has been controlled, user should re-enable it for patient safety.***

6.1 Description of alarm control

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

Table 14: Classification of alarms according to its priority level

HIGH PRIORITY	Delay Time	Description
Low Battery	< 1 second	It is triggered when the internal battery is with low charge. 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 exhalation 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
FiO2 below 18%	< 3 cycles	It is triggered when the measured FiO_2 is lower than 18%

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
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.
High FiO_2	< 3 cycles	It is triggered when the measured FiO_2 has exceeded the alarm value set as the upper limit of FiO_2

MEDIUM PRIORITY	Delay Time	Description
Low FiO_2	< 3 cycles	It is triggered when the measured FiO_2 has exceeded the alarm value set as the lower limit of FiO_2

LOW PRIORITY	Delay Time	Description
AC input fail	< 1 second	It is triggered when the equipment is disconnected from the electric mains and the power is switched to internal power supply.

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

Note

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

b) Disconnection alarm

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

c) Obstruction alarm

The obstruction alarm is triggered when there is some form of obstruction in the breathing circuit preventing full exhalation of the patient. 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 15: 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
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. 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 16: 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 securely reconnect;
	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. Adjust the diaphragm to the correct position or replace diaphragm with a new one;
	5. Failure in the electronic system of pressure control;	5. Contact Technical Assistance / Magnamed
	6. Circuit integrity	6. Check circuit integrity and replace circuit if necessary

Problem	Possible Causes	Solutions
Low Pressure Alarm	1. Change in Patient's Respiratory Mechanics; 2. Excessive leakage in the breathing circuit;	1. Set new parameters for ventilatory support; 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. Low charge on the internal battery after prolonged use disconnected from the mains;	1. Immediately restore the connection of the equipment to a main 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;
AC input fail alarm	1. Disconnection to the power cord;	1. Restore connection of the equipment to a main or use the equipment with internal battery for transportation;
	2. Failure in the electrical grid;	2. Restore power grid;
Apnea alarm	1. Spontaneous breathing of the patient was interrupted 2. Adjusted apnea time is greater than the patient's respiratory rate.	1. Change the ventilation mode from spontaneous to assisted-controlled. 2. Increase the adjusted apnea time or decrease the patient's respiratory rate.
Low O_2 Pressure alarm	1. Pressure of the O2 supply is low 2. O2 hose is not connected to the equipment 3. O2 Pressure Sensor Failure	1. Increase the O2 supply pressure or change the O2 cylinder. 2. Connect the O2 hose to the device. 3. Contact Magnamed Technical Assistance.
Obstruction alarm	1. Inspiratory or expiratory branch obstructed 2. Patient's airway obstruction	1. Clear it. 2. Clear or aspirate the patient's airway.
Low Maximum Pressure alarm	1. Leak in patient circuit 2. Inspiratory pressure lower than set alarm limit	1. Locate the leak and correct. 2. Increase the lower limit of the pressure alarm or increase the set inspiratory pressure.

Problem	Possible Causes	Solutions
High Volume alarm	1. Expired volume is greater than the set alarm limit.	1. Change the parameters set in ventilation mode or set the upper limit of the volume alarm.
Low Volume alarm	1. Expired volume is less than the set alarm limit.	1. Change the parameters set in ventilation mode or adjust the lower limit of the volume alarm.
High FiO_2 alarm	1. FiO2 adjust is above alarm limit 2. O2 cell is out of calibration 3. Damaged O2 cell.	1. Change the set FiO2 or upper alarm limit 2. Calibrate O2 cell 3. Contact Magnamed Technical Assistance.
Low FiO_2 alarm	1. FiO2 adjust is below alarm limit 2. O2 cell is out of calibration 3. Damaged O2 cell.	1. Change the set FiO2 or lower alarm limit 2. Calibrate O2 cell 3. Contact Magnamed Technical Assistance.
FiO2 below 18% alarm	1. O2 concentration delivered to the inner patient is at 18%. 2. Unbalanced O2 cell. 3. Damaged O2 cell.	1. Check the O2 net or cylinder. 2. Calibrate O2 cell. 3. Contact Magnamed Technical Assistance.
High Minute volume alarm	1. Volume delivered and delivered respiratory rate are above alarm limit.	1. Change the adjusted parameters of the ventilation mode or set the upper limit of the minute volume alarm.
Low Minute volume alarm	1. The delivered volume ratio and respiratory rate are below the alarm limit.	1. Change the adjusted parameters of the ventilation mode or adjust the lower limit of the minute volume alarm.
High-Rate alarm	1. Patient's respiratory rate is above alarm limit. 2. Adjusted sensitivity is causing self-triggering.	1. Change the set respiratory rate or change the upper alarm limit. 2. Change the trigger setting.
Low-Rate alarm	1. Patient respiratory rate is below alarm limit. 2. Adjusted trigger is too high, and the ventilator does not recognize patient effort.	1. Change the adjusted respiratory rate or change the lower alarm limit. 2. Change the trigger setting.
High PEEP alarm	1. Monitored PEEP is above alarm limit. 2. Obstruction in the patient's breathing circuit.	1. Change the adjusted PEEP or change the upper alarm limit. 2. Clear it.
Low PEEP alarm	1. Monitored PEEP is below alarm limit. 2. Leak in patient circuit.	1. Change the adjusted PEEP or change the lower alarm limit. 2. Locate the leak and correct.

Problem	Possible Causes	Solutions
Hight Temperature alarm	1. The ambient temperature is above 50 ° C.	1. Operate the ventilator under environmental conditions stated in the technical specification.
Low Temperature alarm	1. The ambient temperature is below -18 ° C.	1. Operate the ventilator under environmental conditions stated in the technical specification.

6.2 Setting Alarms

To enter the alarm setting screen, press the ALARM button

on the secondary menu screen.

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

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

6.3 Manual Patient Ventilation

To perform manual ventilation of a patient with an external device (Ambu), the ventilator must be on stand-by. In this situation, if it is connected to the patient's breathing circuit, ventilation monitoring will be fully operational, including its alarm system.

WARNING

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

6.4 Alarm test

6.4.1 Adjustable alarm test

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

Caution

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

6.4.1.1 Pressure alarm

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

6.4.1.2 PEEP alarm

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

6.4.1.3 Minute volume alarm (MV)

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

6.4.1.4 Respiratory Rate alarm

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

6.4.1.5 Volume alarm

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

6.4.1.6 Apnea alarm

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

6.4.1.7 FiO2 alarm

To test the high O2 concentration alarm, adjust the maximum concentration in the alarms below the setting in the mode. To test the low O2 concentration alarm, set a minimum concentration in the alarms above the setting in the mode.

6.4.2 Critical alarm test

6.4.2.1 Disconnection

To test the disconnection alarm, select the patient and set the desired modality. Start ventilation and disconnect somewhere in the patient circuit: inspiratory limb, expiratory limb, or Y-connector. The high priority disconnection alarm should occur.

6.4.2.2 No AC power

To test the alarm without mains power, put the ventilator in normal operation and disconnect the device from the grid. Low priority mains off alarm shall occur.

6.4.2.3 Low battery

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

6.4.2.4 Obstruction

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

6.4.2.5 Low O2 supply

To test the low O2 pressure alarm, place the ventilator in normal operation, disconnect the oxygen source from the ventilator and observe the activation of the high priority alarm.

6.5 Manual Ventilation of the Patient

To perform manual ventilation of a patient with an external device (Ambu), the ventilator must be on stand-by. In this situation, if it is connected to the patient's breathing circuit, ventilation monitoring 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***
- ***Test Sequence must be performed with the patient disconnected***
- ***In case of failure, check the Alarm Control Description***
- ***Do not use the equipment if the test fails.***

Note

- Use the recommended pressure in the gas inlet.

7. Cleaning and Sterilization

7.1 Equipment cleaning

7.1.1 External ventilator surfaces

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

Caution

- Ensure that there is no residue build up in the equipment's connections.
- For cleaning, do not use any non-compliant products to polymer
- For cleaning the touch screen, avoid:
  - Using substances other than glass cleaner and do not use any vinegar-based solutions.
  - Using clean wipes 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. Autoclavable respiratory circuit, and exhalation valve

The components that come in direct contact with respiratory gases shall be periodically disassembled in components, as accessory list, for cleaning, disinfection, or sterilization.

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

7.1.1.1 Wash

a) Always use potable water for this procedure.

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

c) Immerse the entire body of the exhalation valve 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.

7.1.1.2 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.

7.1.1.3 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.

7.2 Disinfection

7.2.1 External Parts

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

7.2.2 Autoclavable respiratory circuit, and exhalation valve

After cleaning, the items should be disinfected with 70% alcohol. External parts should be disinfected using a clean cloth moistened with 70% alcohol and internal parts 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.

7.3 Sterilization

The components that get in touch with the respiratory gases shall be disassembled in components, as accessory list, 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 Agile in any liquid.

WARNING

- ***When sending the Oxymag Agile 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 Agile undergoing repeated operations of sterilization and cleaning may be degraded and should be replaced with new ones.

7.4 Processing methods

Component	Processing methods		
	Steam sterilization 135°C for 5 min	Antimicrobial disinfectant	70% Alcohol
Ventilator surface	x	✓	x
Touch screen display	x	✓	✓
Silicone respiratory circuit	✓	✓	✓
Exhalation valve	✓	✓	✓
Diaphragm	✓	✓	x
Disposable respiratory circuit	x	x	x

Caution

- Do not reuse single use parts and pieces. The reuse of single use accessories may affect the properties of the device and harm the patient.

8. Preventive Maintenance

Caution

- Oxymag Agile should only have their maintenance performed by a qualified technician, trained, and authorized by MAGNAMED. Failure to comply will void the manufacturer's warranty and obligations regarding the ventilator.
- Failure to perform maintenance could affect the safety and performance of the ventilator.
- All maintenance shall be done with the patient disconnected from the equipment.

8.1 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.

8.2 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 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.***

8.3 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 12.3.1 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.

8.4 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 galvanic O2 cell undergoes less than 1% per month degradation in measurement accuracy.
- The oxygen concentration measuring cell should be replaced as indicated in the Technical Specification (chapter 12).
- Replacement of the oxygen concentration measuring cell should be performed only by a qualified technician, trained, and authorized by MAGNAMED.

8.5 Replacing the Ambient Air Filter

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

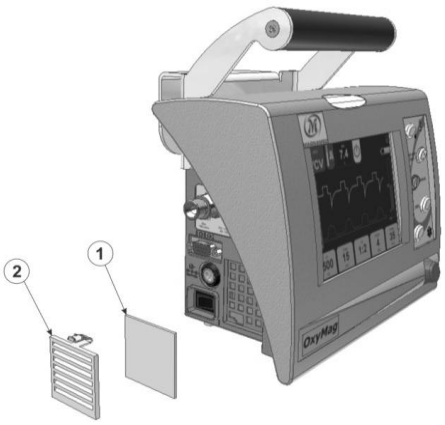


Figure 17: Example for replacing the air filter

(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.

8.6 Forwarding the Product to Repair Service

Products before being sent for repair service should be cleaned and disinfected as directed in this manual Cleaning and (chapter 8). 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 Agile for maintenance or repair services: check and closely follow the disinfection process.***
- ***Equipment visibly infected by patient fluids will be returned without carrying out maintenance or repair service.***

9. Disposal

Oxymag Agile ventilator shall be disposed of as electrical and electronic equipment. Accessories and consumables shall be disposed of as described in their instruction for use. Follow local government recommendations for proper disposal.

Caution

- When the need to discard parts of the ventilator that may be potentially contaminated indicate it as potentially infected hospital waste.
- Disposal of batteries shall comply with local regulations.
- Disposal of galvanic cells shall comply with local regulations.
- Airway adapters shall be disposed of in accordance with local regulations for medical disposal.

10. Turning off the Equipment

The lung ventilator Oxymag AGILE is a life support equipment and MUST be disconnected from the patient to be turned off. The equipment should be turned off using the on/off switch, identified in **Erro! Fonte de referência não encontrada.**

11. Technical Specification

11.1 Classification

- NBR – IEC – 60601

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

- RDC 751/22 – Classification rule 12

Class III - All active medical devices intended to administer to or remove from the human body medicines, bodily fluids or other substances are classified in class II, unless this is carried out in a potentially hazardous manner, taking into account the nature of the substances or of the part of the body involved and the method of application, in which case they are classified in class III.

11.2 Standards

- **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
- **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 (2014) (EN 60601-1-2:2015) -** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- **IEC 62304:2006 +AMD1:2015 (EN 62304:2006/2008)** - Medical device software - Software life cycle processes
- **IEC 60601-1-8:2006+AMD1:2012+AMD2:2020 (EN IEC 60601-1-8:2006+AMD1:2012+AMD2:2020) -** 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+A1:2013+A2:2020 (EN 60601-1-6:2010+A1:2013+A2:2020) -** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 60601-1-9:2007+AMD1:2013+AMD2:2020** (EN 60601-1-9:2007+AMD1:2013) - Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
- **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 80601-2-55:2018 (EN 80601-2-55: 2018)** - Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- **IEC 60601-1-12:2014+A1:2020 -** Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment
- **ISO 80601-2-84:2020** – Medical electrical equipment – Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment
- **RTCA DO-160G:2010** - Environmental Conditions and Test Procedures for Airborne Equipment(1)

(1) Tests of the following items of RTCA DO-160G:

Section	Description	Category
8	Vibration in fixed-wing aircraft	S
	Vibration in helicopters	U
16.6	Voltage fluctuations, voltage ripple	A
17	Voltage spikes	A
18.3.1	Audio frequency susceptibility, DC power input	B
20	Susceptibility to radiofrequency (irradiated and conducted)	R
21	Emission of radio frequency energy	M
25	Electrostatic Discharge (ESD)	A

11.3 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)
  - 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
- Autoclavable adult breathing Circuit
- Autoclavable pediatric and neonatal breathing circuit, optional
- Disposable breathing circuit adult/ pediatric/ neonatal, optional
- 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.
- PEEP valve integrated in the equipment.
- Automatic barometric pressure compensation
- Protection fuses for fixation support and pedestal: Voltage 250V; Current 3A; Operating speed: Medium; Breaking Capacity 100 A, Size: 5mm x 20mm, Quantity: 2.

11.3.1 Electrical Characteristics

Table 17: 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	40	± 10%	W
3	Output 12V_{DC} – 4 -way	12	± 10%	V_{DC}
4	Current	3.34	---	A
5	AC Cable	Equipment side connector: As per IEC 60320 type C13 Plug: As per local legislation. Electrical requirements: Compatible with the electrical supply specifications of each device (Voltage and Current). Confirm the marking of the equipment.		

Table 18: Internal Li-Ion Battery

Item	Parameter		Specification	Tolerance	Unit
1	Internal Li-Ion Battery 11.8V_{DC}		5200	± 15%	mAh
2	Autonomy of Internal Battery (with full load and normal use) (2)		480	± 15%	Min
3	Time to recharge to full load (module in standby)1)		5,0	± 15%	H
4	Dimensions	Height	37,8	---	mm
		Width	72,4	---	mm
		Length	56	---	mm
5	Number of charge cycles		500		cycles

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

(2) Operating condition:

Adult patient: Volume 500 mL, Rate 10 min^{-1}, I:E 1:2, PEEP 10 cmH_2O, Resistance 5 $hps \cdot (L/s)^{-1}$, Compliance 50 $mL \cdot hPa^{-1}$, O_2 60%

Pediatric patient: Volume 150 mL, Rate 20 min^{-1}, I:E 1:2, PEEP 10 cmH_2O, Resistance 20 $hps \cdot (L/s)^{-1}$, Compliance 20 $mL \cdot hPa^{-1}$, O_2 60%

Neonatal patient: Volume 50 mL, Rate 30 min^{-1}, I:E 1:2, PEEP 10 cmH_2O, Resistance 50 $hps \cdot (L/s)^{-1}$, Compliance 1 $mL \cdot hPa^{-1}$, O_2 60%

- Electromagnetic Compatibility:
  - Immunity: IEC 60601-1-2
  - Emission: CISPR11
  - Approvals: OS/IEC 60601-1
- Protection Class of Breathing Accessories (Disposable or Reusable): BF type (Body Floating).

11.3.2 Connecting to the Oxygen Supply

(1) Oxygen Inlet –DISS male thread 9/16" 18 wires, as per ISO 5359

- OPTIONAL –NIST Thread

- Gas pressure: 39 - 87 psi (270 - 600 kPa) (1)
- Hoses and Extensions: As per EN ISO 5359
- 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.

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

Note

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

11.3.3 Physical and Environmental Specifications

Table 19: 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		2,70	± 0,1	kg
3	Operation	Temperature	-18 - 50	---	°C
		Barometric Pressure	600 - 1100	---	hPa
		Relative Humidity (w/o condensation)	15 - 95	---	%
4	Storage/ Transport	Temperature	-25 - 75	---	°C
		Barometric Pressure	500 - 1200	---	hPa
		Relative Humidity (w/o condensation)	5 - 95	---	%
5	Oxygen consumption in the conditions: • Tidal Volume = 500 mL • R. Rate = 12 min^{-1} • FiO_2 = 40%		92	± 10%	$min/L_{O2-CYLINDER}$
6	Lifetime (useful life)		10	---	years
7	Time to heat or cool equipment stored at extreme temperatures to operate at 20 ° C		30	---	minutes

11.3.4 Internal volume of respiratory circuit components

INTERNAL VOLUME	
SILICONE RESPIRATORY TUBE 22M+22M X 1,20M AUTOCLAVABLE	407,8 mL
Y ADULT 22MM AUTOCLAVABLE WITH THERMOMETER	18,7 mL

INTERNAL VOLUME	
SILICONE RESPIRATORY TUBE 15MM X 1,20 M AUTOCLAVABLE 15F+22F	179,5 mL
INTERMEDIARY 15M+15M FOR PEDIATRIC BREATHING CIRCUIT AUTOCLAVABLE	3,6 mL
Y PEDIATRIC 15MM AUTOCLAVABLE WITHOUT THERMOMETER 90	16,9 mL

11.3.5 Extreme conditions

WARNING

- ***Do not store the ventilator in environments outside the temperature, humidity and pressure specified in 11.3.3 Physical and Environmental Specifications. Accuracy of equipment readings may be affected.***
- ***AC mains power supply with voltage values below 25% may result in switching power to the internal battery.***
- ***Power above 15% of the rated value may result in equipment AC / DC power failure, but the equipment will continue to operate normally due to switching to the internal battery.***
- ***AC mains supply with frequency values 5% below or 5% above nominal may result in switching to the internal battery, but the equipment will maintain its normal operation.***

Caution

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

11.3.6 Ventilation Modes

Table 20: Ventilation modes

Modes[1][2][3]	Description	Mode in Apnea (BACKUP)[4]
VCV	Volume-Controlled Ventilation	AUTO
PCV	Pressure-Controlled Ventilation	AUTO

Modes[1][2][3]	Description	Mode in Apnea (BACKUP)[4]
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
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 starts 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.

11.3.7 Setting Specifications of the Ventilation Parameters

Table 21: 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

Item	Parameter	Specification	Resolution	Unit
10	Automatic Inspiratory Flow (3)	0 to 150	1	L.min^{-1}
11	Inspiratory Flow (Neonatal)	4 to 20	1	L.min^{-1}
12	Cycling by Flow at Pressure Support	5 to 80	5	%
13	O_2 Concentration	35 to 100	1	%
		21 to 100 (with blender)	1	%
14	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	
15	Inspiratory Flow Waveform	Square, Decelerated, Accelerated, Sine	---	---
16	CPAP(4)	1 to 40	1	cmH_2O
17	High Pressure	5 to 55	1	cmH_2O
18	Low Pressure	0 to 40	1	cmH_2O
19	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	
20	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	
21	Ratio	1:4 to 4:1(5)	1:0,1	-
22	Backup	OFF; PLV; PCV; VCV (6)	---	-
23	Time for Apnea Alarm	OFF; 5 to 60	1	s
24	Flow (flow meter)	0 to 15	1	L.min^{-1}
25	Leak Flow Compensation(7)(8)	Neonatal: 12 L·min^{-1} Pediatric/Adult: 100 L·min^{-1}	1	L.min^{-1}

Item	Parameter	Specification	Resolution	Unit
26	Height [9]	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. By setting the CPAP/PEEP and DeltaPS parameters in CPAP/PSV mode, pressure control from 1 to 60 cmH2O can be obtained.

[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] For invasive and non-invasive modes.

[9] 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 22: Ratio Mode x type of patient

Patient Type	Initial Mode	Ideal Weight (IBW)	Height [m]
NEONATAL	PLV	2,8Kg	*0,36*
PEDIATRIC	PCV	19,8Kg	*0,95*
ADULT	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 23: Calculation of ideal weight x patient height

Patient Type	Height Adjustment [m]		Ideal Weight P [Kg]
	Min.	Max.	
NEONATAL	0,16	0,52	≤ 6,0
PEDIATRIC	0,53	1,08	6,0 < P ≤ 25
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.
- For the calculation of ventilation parameters, the patient ideal weight obtained according to height is used. Therefore, there is no indication of specific body mass for the use of the product.

11.3.8 Specifications of the Monitoring Ventilation Parameters

Table 24: *Ventilation parameters*

Item	Parameter	Range	Resolution	Accuracy	Unit
1	Instant Pressure Measured	-20 to 100	1	± (2 cmH2O + 4% of reading)	cmH_2O(2)
2	Maximum Inspiratory Pressure	0 to 90	1	± (2 cmH2O + 4% of reading)	cmH_2O
3	Measured Pressure	0 to 90	1	± (2 cmH2O + 4% of reading l)	cmH_2O
4	Plateau Pressure	0 to 90	1	± (2 cmH2O + 4% of reading)	cmH_2O
5	PEEP - Pressure at the end of expiration(6)	-20 to 90	1	± (2 cmH2O + 4% of reading)	cmH_2O

Item	Parameter	Range	Resolution	Accuracy	Unit
6	Tidal Volume Inspired (3)	0 to 3000	0 to 1000: 1 1000 to 3000:10	± (4,0 mL + 15% of reading)	mL
7	Inspiratory Time	0,05 to 60,0	0,01	± (0,10 s + 10% of reading)	s
8	Expiratory Time	0,05 to 60,0	0,01	± (0,10 s + 10% of reading)	s
9	Ratio I:E	1:100,0 to 100,0:1	1:0,1	± (0,1 + 10 % do of reading)	---
10	Respiratory Rate	0 to 200	1	± (1bpm + 10% of reading)	min^{-1}
11	FiO_2 (Oxygen Concentration)	12 to 110	0,1	± (2,5% + 2,5% of reading)	$\%O_2$
12	Flow (flowmeter)	0 to 60	0,1	± (0,5mL.min-1 + 10% of reading)	$L.min^{-1}$
13	Regulated Pressure	0 to 150	1	± (3,75 psi + 10% of reading)	psi

(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) All monitoring data are considered at ATPD (Ambient, Temperature and Pressure Dry).
(5) The Ventilator does not generate negative pressure during expiratory phase.
(6) The total PEEP is displayed on the bar graph during the expiratory pause, obtained by adding PEEP + iPEEP.

WARNING

- ***Ventilation with cyclic pressure up to 100 cmH2O can add up to 2% tolerance error.***
- ***Parameter accuracy may be affected under the following conditions:***
  - ***Reuse of single use accessories***
  - ***Leakage in the breathing circuit***
  - ***Uncalibrated oxygen cell***

11.3.9 Control accuracy

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

Table 25 – Parameters accuracy

Item	Parameter	Accuracy (1)
1	Volume delivered (all range)	± (4 mL + 15% of adjusted volume)
2	Inspiratory pressure	± (2 cmH2O + 4% of adjusted pressure)
3	PEEP	± (2 cmH2O + 4% of adjusted PEEP)

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

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

Table 26 – Parameter Uncertainty

Item	Parameter	Uncertainty
1	Volume delivered	± 2,5%
2	Inspiratory pressure	± 2,0%
3	PEEP	± 2,0%

11.3.10 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 29 according to the type of patient. It is not possible to change the default alarm settings permanently.***
- ***Default values of the alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***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 29) 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 27: .

Table 27: *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) *The beginning of the potential injury refers to the occurrence of the injury and not to its manifestation.*
(2) *There is potential for the event to be developed over a period of time not usually sufficient for manual corrective action.*
(3) *There is potential for the event to be developed over a period of time usually sufficient for manual corrective action.*
(4) *There is potential for the event to be developed in a non-specified period not greater than that provided in "prompt".*

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

- Alarm messages of high priority will be displayed alternately, following the priority described in
-
- Table 29.
- 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 28: *Alarm features*

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

Note

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

Table 29: *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	
8	Automatic limit setting [2]	OFF, 10, 20 and 30	High	OFF			%

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

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

WARNING

- ***Default values of the alarms are only for initial reference. Reset the alarm limits as needed by the patient.***
- ***There may be danger if different default alarm values are used for the same or similar equipment in the same area.***
- ***Setting the alarm limit to its extreme value may make the alarm system inadequate. Adjust the limits as needed by the patient.***
- ***Alarm settings will not change when power is lost for 30 seconds or less. In this case, the equipment will be powered by a non-interchangeable internal battery.***
- ***Oxygen monitoring is achieved accurately within 20 seconds of initialization.***

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

11.3.11 Concentration x Pressure in the breathing circuit curve

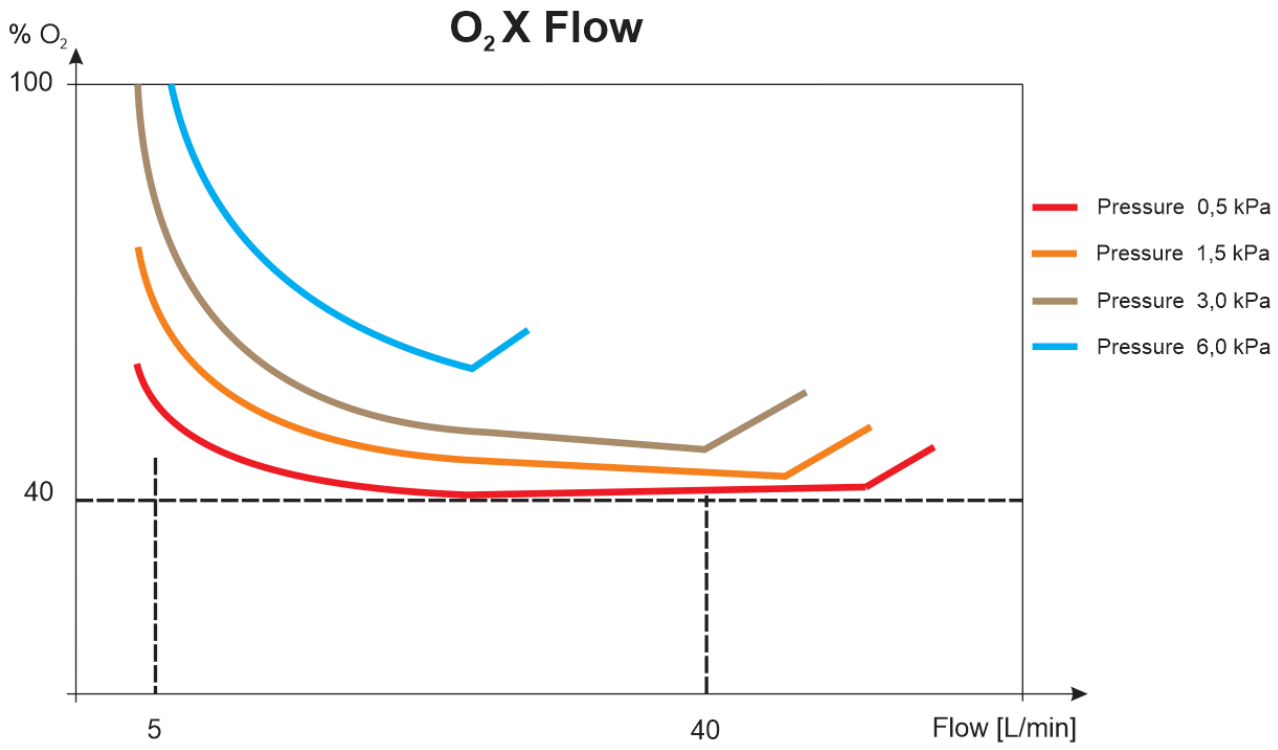


Figure 18: Concentration curve in function of pressure in the breathing circuit

11.3.12 Performance Specifications

Table 30: *Performance specification*

Item	Parameter	Specification	Tolerance	Unit
1	Maximum Flow in Pressure Support or in cycles of controlled pressure	150	± 10%	$L.min^{-1}$
2	Control Principle	Cycled by Time, Constant Volume and	---	---

		Pressure Controlled		
3	MTBF (Mean Time Between Failure)	5.000	---	hours (On) (POH)

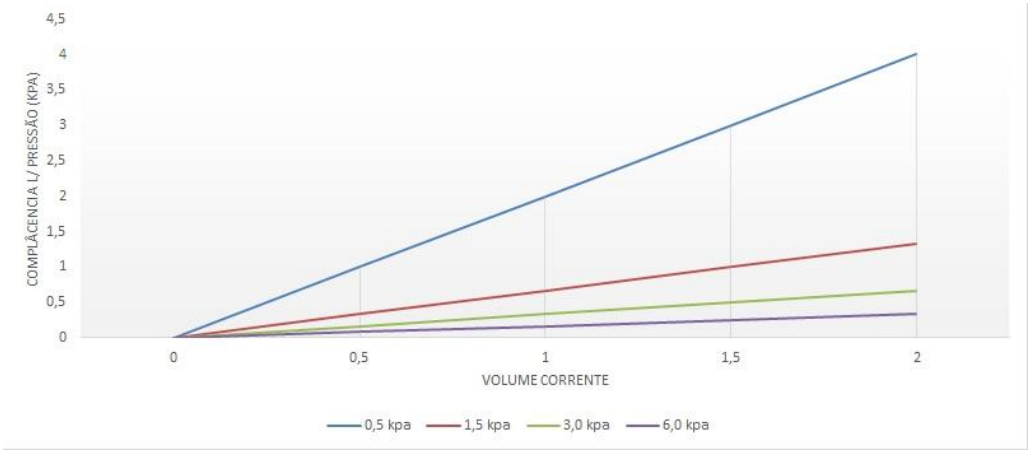


Figure 19: Influence of airway pressure on tidal volume (1)

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

11.3.13 Specifications for Maintenance and Calibration

Caution

- Processing time is after stabilizing at specified temperature and pressure.
- Check sterilization efficiency through chemical or biological indicators.

Table 31: Specification for maintenance and calibration

Item	Description	Specification	Tolerance	Unit
1	Review and replace of diaphragm (3800248)	50 cycles of steam autoclave	---	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

Item	Description	Specification	Tolerance	Unit
4	Exhalation valve (3200251)	50 cycles of steam autoclave	---	cycles
5	Breathing circuit - Adult (1703218), Pediatric (1702654)			
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

11.3.14 Mask for Non-Invasive Ventilation

Specification	
Adult/ Pediatric connection	22 mm
Neonatal connection	15 mm

11.3.15 Breathing Circuit

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

11.3.16 HME Filter

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

11.3.17 Specifications for Resistance of the Expiratory Limb

Table 32: Expiratory Resistance in Function of Breathing Circuit and Accessories Aggregates

Patient	Breathing circuit	Flow L x min^{-1}	Expiratory Resistance (hPa or cmH2O)[1]	
			Circuit	Circuit + HME Filter
Neonatal	Ped / Neo	5,0	0,8	
Pediatric	Ped / Neo	30,0	3,1	6,5
Adult	Adult	60,0	1,2	6.2

[1] The operator shall ensure that the inspiratory and expiratory resistance values are not exceeded when adding accessories or other components or subsets of the respiratory system

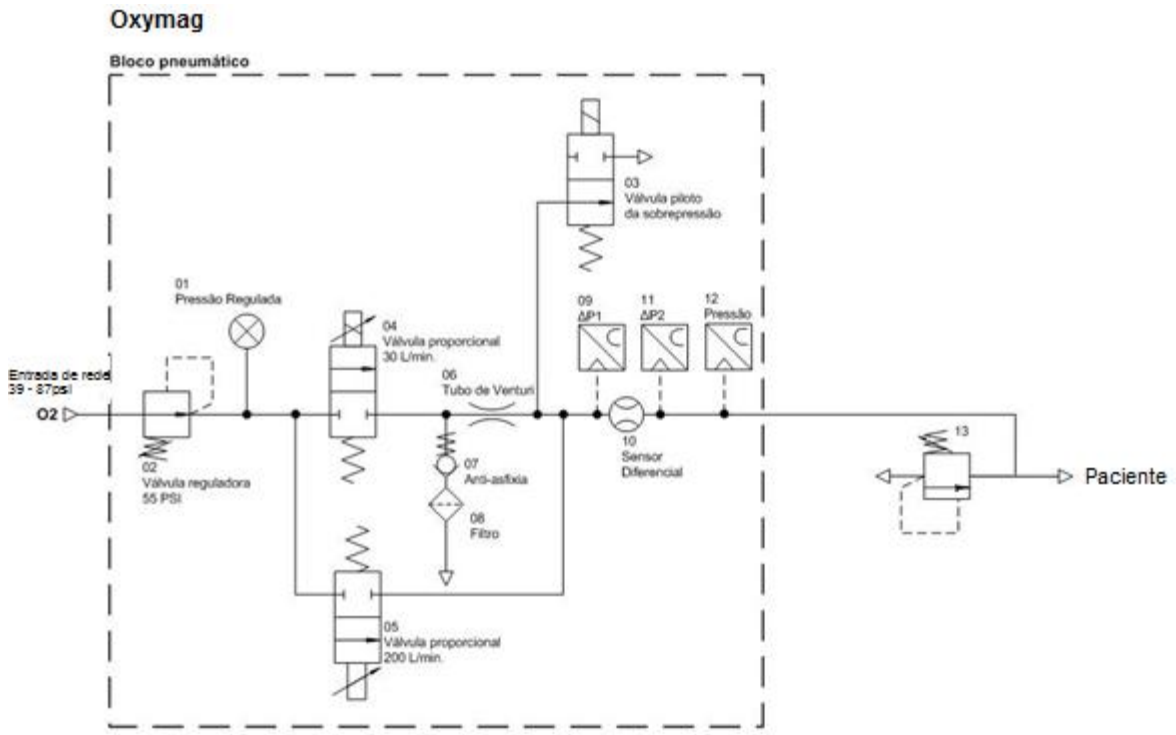
Table 33: Compliance specification of the breathing circuit

Breathing Circuit	Pressure (cmH2O)	Default Compliance [1] (mL/cmH2O)	Maximum Compliance [2] (mL/cmH2O)
Pediatric/ Neo	60 ± 3	1	4
Adult	60 ± 3	2	5

1 Default compliance will be used if the self-test is not performed, or the self-test fails.

2 Maximum compliance for which accuracy is maintained.

11.3.18 Pneumatic diagram



1 Regulated Pressure measure (Pressure sensor)
2 Pressure regulating valve
3 Valve 2/2 ways - Overpressure valve On/Off
4 Proportional valve 2/2 ways - 30 LPM
5 Proportional valve 2/2 ways - 200 LPM
6 Venturi system
7 One-way valve (anti-asphyxiation)
8 Filter
9 Inlet pressure of differential sensor
10 Differential pressure sensor
11 Pressure on the differential sensor outlet
12 Absolute pressure on outlet
13 Exhalation control - PEEP

Figure 20: Pneumatic Scheme of the transport ventilator

11.3.19 Block Diagram of Control Electronics

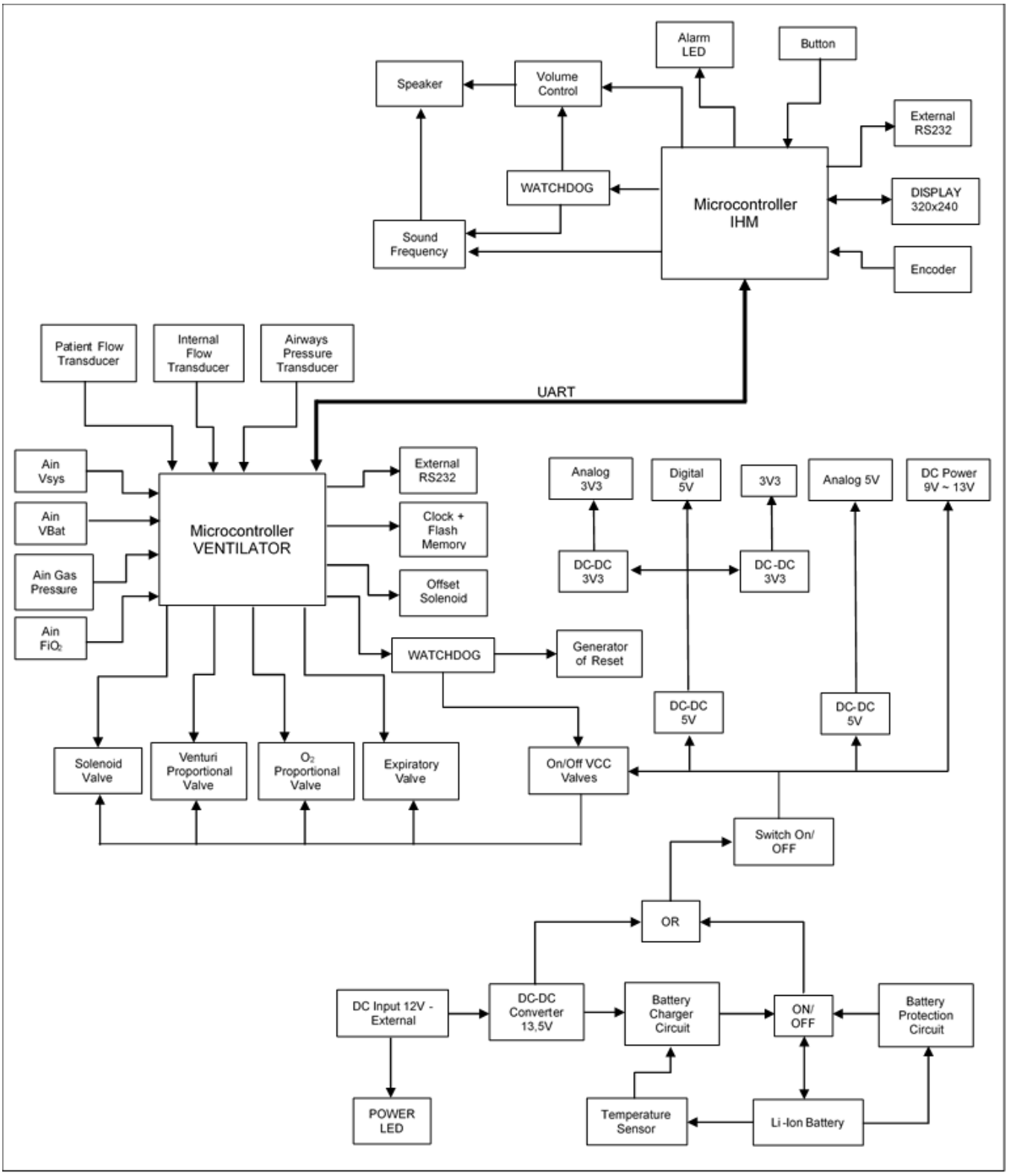


Figure 21: Block Diagram of Electronics

11.3.20 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 Agile, 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 34: Specification of electromagnetic environment of use

Emission Test	Compatibility	Directive for Electromagnetic Environment
RF Emissions IEC CISPR 11	Group 1	The system uses RF energy only for its internal functions. However, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF Emissions IEC CISPR 11	Class B	The 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

Oxymag Agile is intended for use in the electromagnetic environment specified below. The buyer or user of **Oxymag Agile** shall ensure that it is used in such an environment.

Table 35: 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	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.
IEC 61000-4-11 – Voltage interruption	0 % UT; 250/300 cycles	0 % UT; 250/300 cycles	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 36: *Radiated Immunity*

Oxymag Agile is intended for use in the electromagnetic environment specified below. The buyer or user of **Oxymag Agile** shall ensure that it is used in such an environment.

Immunity Test	Test Level IEC 60601	Compliance	Electromagnetic environment – Guidelines
---	---	---	It is not advisable to use mobile or portable RF communication equipment at shorter distances from any part of **Oxymag Agile**, including cables, than the recommended separation distance, calculated by the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted disorders induced by RF fields [(a)] IEC 61000-4-6	3 Vrms 0,15 MHz to 80 MHz outside the ISM bands [(a)]	3 V	$d = 1,2\sqrt{P}$
---	10 Vrms 0,15 MHz to 80 MHz outside the ISM bands [(a)]	10 V	$d = 1,2\sqrt{P}$
EM fields of Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,7 GHz	10 V/m	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz
---	---	---	$d = 2,3\sqrt{P}$ 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, determined by an electromagnetic field survey, [c] should be less than the level of compliance 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.

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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 Agile will be used exceeds the applicable RF CONFORMITY LEVEL set above, Oxymag Agile 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 Agile.
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

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

Table 37: 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 Agile cabinet interface has been tested as specified in the table below using the test methods specified in IEC 61000-4-3			
Band	**Freq. test**	**Modulation**	**Trial level**
[MHz]	**[MHz]**		**[V/m]**
380 to 390	385	Pulse, 18 Hz	27
430 to 470	450	FM, 1 kHz, Deviation from ± 5kHz	28
704 to 787	710 745 780	Pulse, 217 Hz	9
800 to 960	810 870 930	Pulse, 18 Hz	28
1.700 to 1.990	1.720 1.845 1.970	Pulse, 217 Hz	28
2.400 to 2.570	2.450	Pulse, 217 Hz	28
5.100 to 5.800	5.240 5.500 5.785	Pulse, 217 Hz	9

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.***

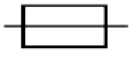
11.4 O2 galvanic cell specification

General specification	
Intended use	Measure the O_2 concentration delivered from the equipment to the patient
Measuring range	0 to 100%
Output sign	9 – 13 mV
Response time 90%	13 s
Accuracy	± 2%
Linearity	± 2%
Recommended flow rate	0.1 – 10 lpm
Data sampling rate	7 Hz
Method for calculating the gas level reading	Simple moving average (MMS) of 64 positions acquired every 140ms
Respiratory rate	The Respiratory Rate is shown every 3 breaths and the average value is updated with each breath.
Effects of gas and vapor interference	
Gases or Steam	**Gas Level**
Response to 80% NO	< 5%
Response to 7,5% Halothane	< 5%
Response to 7,5% Isoflurane	< 5%
Response to 7,5% Enflurane	< 5%
Response to 9% Sevoflurane	< 5%
Response to 20% Desflurane	< 5%
Response to 10% CO_2	< 5%

12. 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
IP34	PROTEGIDO CONTRA RESPINGOS DE ÁGUA E ENTRADA DE PARTES SÓLIDAS MAIOR OU IGUAL A 2,5MM	PROTEGIDO CONTRA SALPICADURAS DE AGUA Y ENTRADA DE PARTES SÓLIDAS MAYOR O IGUAL A 2,5MM	PROTECTED AGAINST WATER SPRAYS AND THE INGRESS OF SOLIID PARTS OF 2,5MM 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	ATENCIÓN! 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
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
	FUSÍVEL	FUSIBLE	FUSE

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
CE XXXX	CONFORMIDADE CE: INDICA QUE O SISTEMA ESTÁ EM CONFORMIDADE COM O REGULAMENTO (EU) 2017/745	CONFORMIDAD CE: INDICA QUE EL SISTEMA ESTÁ EN CONFORMIDAD CON EL REGLAMENTO (UE) 2017/745	CONFORMITY CE: INDICATES THAT THE SYSTEM IS IN ACCORDANCE WITH REGULATION (EU) 2017/745
INMETRO	INMETRO	INMETRO	INMETRO
Rx ONLY	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
NON STERILE	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
REF	NÚMERO DO CATÁLOGO DO FABRICANTE	NÚMERO DE CATÁLOGO DEL FABRICANTE	MANUFACTURER'S CATALOGUE NUMBER
SN	NÚMERO DE SÉRIE DO FABRICANTE	NÚMERO DE SERIE DEL FABRICANTE	MANUFACTURER'S SERIAL NUMBER
LOT	CÓDIGO DE LOTE DO FABRICANTE	CÓDIGO DE LOTE DEL FABRICANTE	MANUFACTURER'S MATCH OR LOT CODE
	USO ÚNICO	USO ÚNICO	SINGLE USE
	SAÍDA DE GÁS	SALIDA DE GAS	GAS OUTPUT
	ENTRADA DE GÁS MOTRIZ	ENTRADA DE GAS CONDUCTOR	DRIVING GAS INPUT
	EXAUSTÃO	ESCAPE	EXAUSTION

SYMBOLS / UNIFIED TEXTS	PORTUGUÊS	ESPAÑOL	ENGLISH
	AFERIÇÃO DA PRESSÃO Essa aferição é uma técnica de leitura de fluxo e volume. A leitura de pressão nas vias aéreas é realizada internamente.	MEDICIÓN DE PRESIÓN Esta medición es una técnica de lectura de flujo y volumen. La lectura de la presión de la vía aérea se realiza internamente.	PRESSURE GAUGE This measurement is a flow and volume reading technique. Airway pressure reading is performed internally.
	LIMITAÇÃO DE PRESSÃO ATMOSFÉRICA Indica a faixa de pressão atmosférica à qual o equipamento pode ser exposto com segurança.	LIMITACIÓN DE PRESIÓN ATMOSFÉRICA Indica el rango de presión atmosférica a la que el dispositivo médico puede exponerse de manera segura.	HUMIDITY LIMITATION Indicates the range of humidity to which the medical device can be safely exposed.
	LIMITAÇÃO DA UMIDADE Indica a faixa de umidade à qual o equipamento pode ser exposto com segurança.	LIMITACIÓN DE HUMEDAD Indica el rango de humedad a la que el dispositivo médico puede exponerse de manera segura.	ATMOSPHERIC PRESSURE LIMITATION Indicates the range of atmospheric pressure to which the medical device can be safely exposed.

13. Terms and Abbreviations

Table 38: 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	Synchronized 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

14. Statement of Biocompatibility

We declare under our sole responsibility that all materials used in applied parts (as defined by the NBR IEC 60601-1 standard) in Oxymag Agile have been widely used in the medical field over time, without effects related to toxicity or effects on tissue, thus ensuring its biocompatibility.

And according to 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 a device without direct or indirect contact with the patient's 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.***

15. Warranty

The manufactured Products and marketed by MAGNAMED TECNOLOGIA MÉDICA S/A are warranted against material and manufacture defects 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 mis installation, 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.

16. Technical Assistance

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

17. Training

To request training, please contact the 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