MAGNAMED

Operations Manual

Electronic Pulmonary Ventilator

Oxymag Max 300

This operating manual includes the Oxymag Max 300 Pulmonary Ventilator developed and manufactured by Magnamed Tecnologia Médica S/A.

Revision of this Operation Manual: No. 02

ANVISA Registration No. 80659160012

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1 Safety Notes

1.1 Definitions

WARNING

- ***Informs the user of the possibility of injury, death, or other serious adverse reaction associated with the use or misuse of the equipment.***

ATTENTION

- ***It informs the user about the possibility of equipment failures associated with the use or misuse, such as: malfunction, damage to the equipment itself, damage to third party assets and indirectly, injury to the patient.***

Observations

- *Important information to observe.*

1.2 Warning

WARNING

- ***Whenever there is a  symbol, consult this manual for more information.***
- ***This manual shall be read in its entirety carefully to ensure correct and safe use of the equipment and to provide maximum safety and the best resources to the patient. Observe all "WARNING" and "ATTENTION" contained in this manual and on the labeling of the equipment.***
- ***The equipment shall be used only for the purpose specified in Intended Use (Chapter 2.1) and with appropriate monitoring.***
- ***The equipment shall be operated by trained and qualified personnel, who shall maintain vigilance during use, including in volume limited ventilation, so that in case of malfunction or failure, help is available immediately.***
- ***Explosion Hazard: This equipment is not approved for use with flammable anesthetic agents.***
- ***Equipment may be adversely affected and may be subject to interference from certain transmitting equipment, such as cellular telephones, walkie-talkie, cordless telephones, pagers, high frequency surgical equipment (diathermy), and shortwave therapy, which may interrupt the operation of the equipment. Do not use this transmission equipment near the ventilator.***
- ***This equipment shall not be used during a nuclear magnetic resonance (MTR, NMR, NMI), as it may cause interference, causing adverse effects to the patient.***
- ***Before first use or after use on each patient, clean the equipment as indicated in chapter 8.***
- ***When powering up the equipment, perform basic scanning and adjustment procedures. Follow the instructions in chapter 5.***
- ***ALARMS and WARNINGS shall be promptly serviced in order to maintain the integrity of the equipment operation and patient safety.***
- ***Do not use electrically conductive antistatic hoses or tubes in the respiratory system of the ventilator.***
- ***Always check that the equipment is correctly set before using it.***
- ***After starting the ventilation, using monitoring verify if ventilatory parameters are adequate.***
- ***Do not add any connection or accessory to the ventilator that contradicts the instructions for use of the ventilator or accessory, as the ventilator may not operate properly, leading to the risk of patient death or serious deterioration of health.***
- ***During prolonged use of the equipment with patients with excess secretion and / or using a heated humidifier, the condition of the flow sensor shall be be frequently checked, draining any fluid that may have accumulated in the respiratory circuit as necessary.***
- ***The equipment has an independent electrical power supply and has its own "backup" system (battery).***
- ***Connect the AC/DC converter source to an NBR 14136:2002 (2P+T) three-pin outlet.***
- ***Keep the equipment connected to an electrical source even when it is turned off, so that the internal***

batteries are always charged.

- ***After using the equipment or after an extended period of storage, fully recharge the batteries.***
- ***If LOW BATTERY alarm occurs, IMMEDIATELY connect the ventilator to an electrical Network. If this is not possible, provide another suitable means of ventilatory support and then DISCONNECT patient equipment.***
- ***Recharge the batteries before the next use, otherwise, any electrical power failure may interrupt the operation of the ventilator.***
- ***Always check that there are no obstructions, as it is extremely important for the correct monitoring of ventilatory parameters that the respiratory circuit is completely unobstructed.***
- ***Never obstruct the pressure connections. The pressures measured at these points are used by the patient monitoring system.***
- ***After use, reusable respiratory circuit components shall go through a high-level disinfection process before their next use.***
- ***All parts of the equipment that come in contact with fluids from the patient SHALL be discarded, disinfected, sterilized or disposed of as potentially infectious hospital waste.***
- ***All parts of the OxyMag Max ventilator that are in the gas passage way, including accessories and applied parts, are made of non-toxic material, latex-free and phthalates-free, and do not cause irritation or allergy to the patient, including pregnant women and children.***
- ***Common use non-exclusive OxyMag Max accessories, such as masks, circuits, nebulizers, humidifiers, HME filters, among others, shall be registered with ANVISA.***
- ***Do not use the equipment if a problem cannot be solved.***
- ***Have a manual ventilation device available in the case of complete discharge of the battery, lack of gases for the operation of the device or even for general failure of the ventilator. The absence of manual ventilation in these cases may result in death of the patient.***
- ***Always use officially approved oxygen cylinders and pressure reducing valves that meet local government requirements.***
- ***For proper ventilation, when adjusting the ventilator, take into consideration the dead spaces of the respiratory circuit, especially for low tidal volumes.***
- ***The ventilator shall not be covered or positioned in such a way that operation or performance is affected.***
- ***When components of the respiratory circuit or other components or subassemblies are added to the respiratory system of the ventilator, the pressure gradient across the respiratory system, measured relative to the patient's port of attachment, may increase, adversely affecting the performance of the ventilator.***
- ***Nebulization or humidification can increase the resistance of respiratory system filters. The operator shall monitor any increased resistance and filter blockage in the respiratory system.***
- ***The accuracy of the ventilator may be affected by the gas added by the use of the nebulizer.***
- ***The ventilator shall not be used in a hyperbaric chamber.***
- ***The ventilator should not be used with inlet gases, which are not specified for use (e.g., helium or mixtures with helium). Such use may cause the ventilator to malfunction, causing the patient's death***

or serious deterioration of health.

- ***The ventilator should not be used with nitric oxide. Such use may cause the ventilator to malfunction, causing the patient's death or serious deterioration of health.***
- ***The expiratory branch may become contaminated with bodily fluids or expired gases during normal use of the equipment and in the event a single fault.***
- ***HME filter, HEPA filter and airway adapter are single use. The reuse of these accessories may cause cross contamination.***
- ***OxyMag Max does not generate sub atmospheric pressure during the expiratory phase.***
- ***Use only parts, and accessories specified by MAGNAMED listed in this manual, which have been tested and approved for use in conjunction with this equipment; otherwise, it may impair the operation endangering the patient or user.***
- ***It is the responsibility of the responsible organization to ensure that the oxygen source is compatible with the rated range of pressure, flowrate and oxygen concentration as marked on the ventilator and indicated in the instructions for use as this can affect the performance of the ventilator that can consequently result in patient death or serious deterioration of health.***
- ***When using nebulizer or respiratory system filters, as well as heat and moisture exchangers, they may require more frequent replacement to prevent further resistance and blockage.***
- ***The accuracy of the ventilator may be affected by the gas added to the ventilator's breathing system by the use of a pneumatic nebulizer.***
- ***Do not cover the ventilator or place it in a position that will affect proper operation.***
- ***Make sure you have manual ventilation equipment available, in case of complete battery discharge, lack of gases for the operation of the device or any general failure of the transport ventilator. Lack of an alternative means of ventilation, such as a self-inflating, hand-fed mask resuscitator, may result in the death of the PATIENT if the VENTILATOR fails.***
- ***Do not use the ventilator in explosive environments. Such use may cause an explosion***
- ***The ventilator must be continuously serviced by an operator. Failure to provide this ventilator may contribute to patient death or serious injury.***
- ***The expiratory branch can become contaminated with exhaled body fluids or gases during use of the equipment under normal conditions and under a single fault.***
- ***The ventilator should not be used with nitric oxide. Such use may cause malfunction of the ventilator, causing the death of the patient or serious deterioration of health.***
- ***The ventilator should not be used with inlet gases that are not specified for use (e.g., helium or helium mixtures). Such use may cause malfunction of the ventilator, causing the death of the patient or serious deterioration of health.***
- ***Do not obstruct the GAS INLET PORT.***
- ***When the volume is set to 50 ml, the ventilator should be equipped with a CO2 sensor to measure the expiratory concentration of carbon dioxide before being put into service.***
- ***Selecting the patient type at startup will perform the initial transport ventilator calculations and display certain ventilation modes as options.***
- ***Do not use HEPA and HME filters at the same time. The use of two filters will increase the resistance***

of the breathing circuit. If you want to use the HME filter, remove the HEPA filter from the breathing circuit and connect the HME filter.

- *The responsible organization needs to ensure the compatibility of the equipment and all parts and accessories intended to be used to connect to the patient before use.*
- *To prevent premature deterioration of parts, use only registered and approved cleaning and disinfecting solutions as recommended by the manufacturer in chapter 8.*
- *When disposing of ventilator components, treat components that may have been contaminated as biohazardous waste.*
- *After each use by the patient or as needed, the respiratory circuit should be disassembled and discarded, and the ventilator should be cleaned and then disinfected using the specific cleaning methods and solutions indicated in chapter 10.*
- *Do not allow blood or body fluids to dry on the equipment for more than 1 hour.*
- *To avoid cross-contamination, use a HEPA filter following the specifications in chapter 10.27, with local registration.*
- *The use of the HME filter is mandatory to avoid cross-contamination. Follow the HME filter specifications described in chapter 10.26, with local registration.*
- *If there is no image on the display when switching on, avoid using the equipment, as there will be no visual indication. If during use there is no image on the display, the ventilation adjustment will be maintained, the equipment should be changed as soon as possible.*
- *Before using the equipment and accessories, carefully open the packages and remove the items from their packaging.*
- *Always have immediate access to an alternative means of ventilation, which is ready for use, in order to reduce the possibility of patient death or further deterioration of health.*
- *Do not add any attachments or accessories to the ventilator that are not listed as intended for use in combination with the ventilator in the ventilator or accessory's instructions for use, as the ventilator may not operate properly, leading to the risk of patient death or further serious deterioration of health.*
- *Fully recharge the batteries after a long period of storage.*
- *Do not reuse the single-use breathing circuit. Reuse may cause cross-contamination.*
- *If any serious incident occurs in relation to the device, the user and/or patient should inform the manufacturer and the competent authority of the Member State in which the user and/or patient is established.*
- *The single-use breathing circuit with the accessories is not recommended for use for more than 24 hours per patient.*
- *Replace the HME filter in 24 hours or less if the filter is saturated. Otherwise, moisture can reach the expiratory branch of the respiratory circuit.*
- *The Equipment is NOT intended for use in Oxygen-rich environments.*

1.3 Attention

ATTENTION

- ***This ventilator does not emit electromagnetic waves that may interfere with the operation of equipment in its vicinity.***
- ***Perform all maintenance according to the operating time specified in this manual.***
- ***All service, modification or maintenance on the ventilator can only be carried out by qualified technician, trained and duly authorized by MAGNAMED.***
- ***Only use parts, cables, sensors, filters and breathing circuits specified by MAGNAMED and compatible with the system. For purchase, please inform the codes presented in the corresponding chapter.***

1.4 Observation

Observations

- *The technical specifications of MAGNAMED products are subject to change without notice.*

2 Features

2.1 Intended Use

The Oxymag Max is a transport and emergency ventilator designed to provide invasive and non-invasive ventilatory support for neonate patients, with a tidal volume greater than 2 mL, to adults who have impaired respiratory functions and require care in emergency or transport.

Oxymag Max is intended for use in:

- Emergency Primary Medical Care and Field Rescue;
- Intra-hospital transport;
- Inter-hospital transport in road ambulances;
- During air transport (fixed-wing aircraft, helicopters);
- Intermediate care;
- Emergency rooms;

2.2 Principle of Operation

The Oxymag Max 300 delivers a mixture of ambient air and oxygen at operator-adjusted concentrations using the Precise Oxygen Concentration Flowair System. In addition, it performs control of flows and pressures in the respiratory circuit to provide control of volume, pressure, and cycled ventilation mode in a timely manner to the patient's conditions.

The Oxymag Max 300 has a proportional oxygen valve and the FlowAir system, consisting of a turbine to electronically control the airflow and obtain oxygen concentrations from 21%.

The O2 concentration is measured through a galvanic cell by indirect contact with the patient's gas, through the passage of gas through the sensor. In addition, the ventilator controls flows and pressures in the respiratory circuit to provide the appropriate ventilation modalities for the patient's condition.

Observations

- Parts *and* pieces indicated in this manual may be used in the patient’s environment.

2.3 General Features

- Integration of the entire system into a single low volume and weight electronic pneumatic module;
- Electronic flow control system for the patient, using digital technology;
- Intelligent and integrated alarm system with all safety systems required by national and international standards;

- Electrical power backup system;
- Possibility to use the parameter adjustment performed before the equipment was switched off;
- Volatile storage (while the equipment is not turned off), of all parameters, for each ventilatory mode, allowing a quick return to previously used settings (e.g. weaning);
- Fully adjustable equipment via both the touch screen and the turn-confirm button;
- Adjustable resistance compensation for both endotracheal and tracheostomy tubes;
- Volume compensation / compliance according to the respiratory circuit;
- Automatic altitude compensation;
- Automatic barometric pressure compensation.
- Leakage compensation;
- Trend charts, with memorization of the last 240 hours of ventilation;
- Inspiratory and expiratory hold with variable time, determined by the operator;
- Freeze and save up to 3 simultaneous loops (PxV and VxF);
- Complete monitoring;
- Additional monitor with data related to the respiratory mechanics of the patient;
- Breath adjustment option in controlled volume ventilatory modes;
- Alarm mute time adjustment option;
- Time adjustment and O_2 concentration for aspiration Option;
- Monitor with complete ventilation graphics:
    - Pressure x Time Curve
    - Flow x Time Curve
    - Volume x Time Curve
    - Pressure x Volume Loop
    - Volume x Stream Loop
    - Pressure x Flow Loop
- Instant pressure bar graph with numerical indicator of peak, plateau or instantaneous pressure;

ATTENTION

- ***This equipment shall be operated only by qualified personnel and properly trained for its use.***

2.4 Technical Characteristics

- 7" color liquid crystal display (TFT LCD), with a resolution of 1024 x 600 pixels, touch-sensitive;
- Screen configurable for night mode;
- Control Boards with:
    - Presentation of the data in the display;
    - Processor IMX6 SOM-IMX6;

- Hotkeys for:
    - STAND BY
    - SILENT ALARMS (2 min)
    - O2+ (oxygen flush)
    - MANUAL (manual shooting)
    - PAUSE (inspiratory or expiratory)
    - FREEZE (freezing graphics)
    - LOCK (keypad lock)
    - MODE (ventilatory modes)
    - MENU (displays more options)
    - EVENTS (displays active and historical alarms)
    - PATIENT (adjusts patient data)
    - BATTERY (displays advanced battery information)
- Pressure reading in the respiratory circuit;
- Regulated pressure reading;
- Network pressure reading;
- Auxiliary pressure reading;
- Barometric pressure reading;
- Reading of the O_2 concentration in the gas mixture administered;
- Speaker for alarms and alerts;
- High brightness LED for prompt identification of alarms with 360-degree visibility;
- GREEN LED indicator for power supply connection, turning on when the equipment is connected to a power supply and off when the equipment is being powered by the battery only;
- Universal flow sensor autoclavable for all types of patients, and can be used in the distal or proximal position.
- Built-in flow sensor for all types of patient;
- External input 100-240 VAC – 50 – 60 Hz;
- On/off switch;
- Galvanic O2 cell;
- Nebulizer or TGI;
- Volume, pressure and concentration compensation when used with a nebulizer;
- Pedestal with lockable casters on front casters 5", heated humidifier fitting;
- Oximetry or capnography sensor;
- FlowAir system consisting of high-performance high-flow turbine and anti-noise system;
- High-flow therapy (flowmeter mode);
- Software Update via USB;
- Engineering mode;
- Maintenance mode for technical assistance;
- Low O2 pressure inlet;

- Standard Ethernet Connector that enables HL7 protocol communication;
- RS-232C serial interface;
- Adult, pediatric, and neonatal respiratory circuit;

2.5 Safety Features

- Anti-asphyxia valve to protect against gas supply failure.
- 100 hPa relief valve, in compliance with the basic standard of ventilators, avoiding possible overpressure in the respiratory circuit.
- Alarm and alert system with speaker and RGB led.

3 Unpacking the Product

3.1 Initial Verifications

Observations

- *If the package is damaged, DO NOT OPEN and immediately report it to the carrier responsible and to Magnamed.*

Table 1 – Initial Verifications

Step	Procedure
1	Check that the packaging is intact, making sure there are no dents, punctures or any other form of damage.
2	Open the package carefully, following the indications on the box.
3	Check the contents of the package.

3.2 List of Components

The following items are integral parts of the equipment and are for the exclusive use of the same:

Table 2 - Components that accompany Oxymag Max

Item	Code	Description	Qty.	UMI
1	1603020	OXYMAG MAX 300 - EMERGENCY AND TRANSPORT VENTILATOR	01	PC
2	3902647	O2 DISS X2 HOSE	01	PC
3	3804865	EXHALATION VALVE WITH STABILIZING RING	01	PC

Item	Code	Description	Qty.	UMI
4	3800248	MAGNAMED EXHALATION VALVE DIAPHRAGM	01	PC
5	1703218	RESPIRATORY CIRCUIT SILICONE - ADULT 1,2M STRAIGHT Y	01	PC
6	1707410	AUTOCLAVABLE UNIVERSAL FLOW SENSOR KIT	01	PC
7	2809416	2 WAY ASSEMBLED AC NETWORK CABLE 3M 2.5MM2 - NBR 14136	01	PC
8	1603020-NE-171-RR	OPERATION MANUAL	01	PC
9	7009307	QUICK GUIDE - OXYMAG MAX 300	01	PC
10	2409751	15V POWER SUPPLY WITH 4-WAY CONNECTOR - OXYMAG MAX	01	PC

3.3 Optional Parts & Accessories

ATTENTION

- ***Always use original parts and accessories to ensure the safety and efficacy of the equipment.***
- ***The instructions for use identify the equipment required for the intended use of the humidifier***

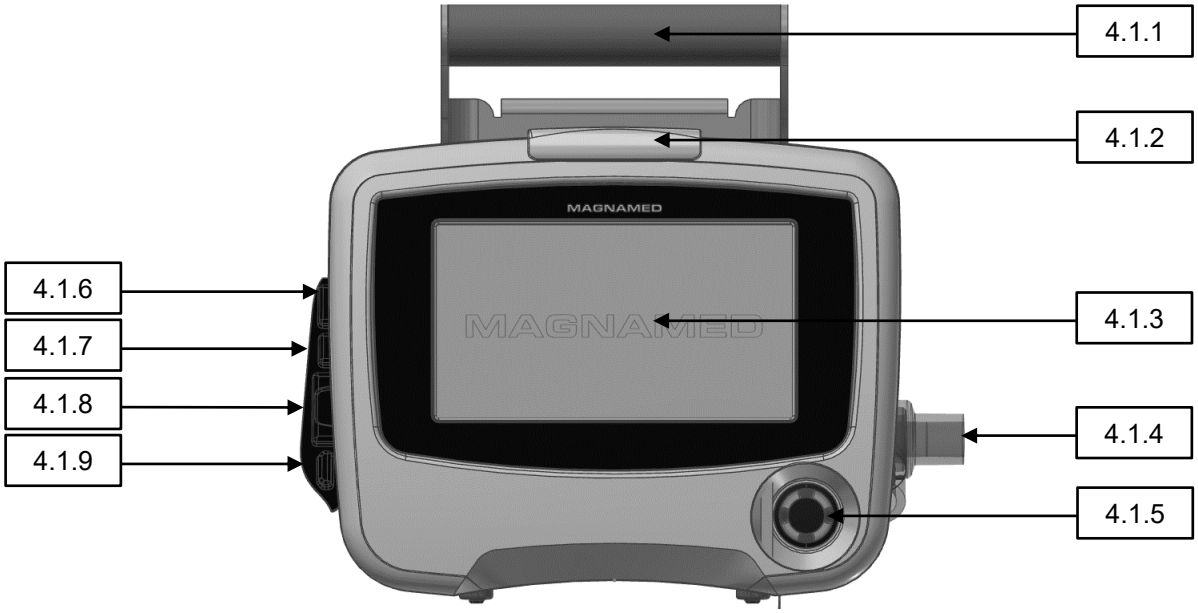
Table 3 – OPTIONAL Parts & Accessories

Item	Code	Description	Qty.	UMI
1	1702654	RESPIRATORY CIRCUIT PEDIATRIC AUTOCLAVABLE 1.2M Y90	01	PC
2	1704409	PULSE OXIMETER SPO2 MASIMO - ADAPTER CABLE AND PED-ADU SENSOR	01	PC
3	1704410	PULSE OXIMETER SPO2 MASIMO - ADAPTER CABLE AND NEONATAL SENSOR	01	PC
4	1708046	ARTICULATED ARM TO SUPPORT RESPIRATORY CIRCUITS	01	PC
5	1708533	WALL STAND FOR OXYMAG MAX	01	PC
6	1704396	CO2 MAINSTREAM SENSOR WITH INTERCONNECTION CABLE AND 5 ADULT AIRWAY ADAPTER	01	PC
7	1704395	CO2 SENSOR ADULT/ PEDIATRIC AIRWAY ADAPTER	01	PC
8	1704394	CO2 SENSOR NEONATAL AIRWAY ADAPTER	01	PC
9	1705142	HME FILTER NON STERIL WITH EXTENSION	01	PC
10	3905085	HEPA FILTER	01	PC
11	1708577	OXYMAG MAX TRANSPORT BACKPACK WITH OXYGEN CILINDER	01	PC
12	1709306	OXYMAG MAX CASE WITHOUT CYLINDER	01	PC
13	1709739	TROLLEY WITH CASTERS FOR OXYMAG MAX VENTILATOR	01	PC
14	1707816	KIT DISPOSABLE RESPIRATORY CIRCUIT ADUL / PED	01	PC
15	1710211	KIT DISPOSABLE RESPIRATORY CIRCUIT PED/NEO	01	PC
16	1707451	RESPIRATORY CIRCUIT ADULT WITH WATER TRAP STRAIGHT Y	01	PC

Item	Code	Description	Qty.	UMI
17	1707453	RESPIRATORY CIRCUIT NEONATAL WITH WATER TRAP Y 90	01	PC
18	1707452	RESPIRATORY CIRCUIT PEDIATRIC WITH WATER TRAP Y 90	01	PC
19	1704601	RESPIRATORY CIRCUIT - ADULT 1.6M STRAIGHT Y AUTOCLAVABLE	01	PC
20	1704603	RESPIRATORY CIRCUIT - PEDIATRIC 1.6M Y 90 - AUTOCLAVABLE	01	PC
21	1705498	REUSABLE CIRCUIT ADULT WITH HEATED WIRE	01	PC
22	1707750	BREATHING CIRCUIT RT202 ADU (Fischer & Paykel)	01	PC
23	1707754	BREATHING CIRCUIT RT331 NEO PED (Fischer & Paykel)	01	PC
24	1705213	ADULT HUMIDIFIER HEATING CHAMBER FISHER & PAYKEL MR370	01	PC
25	1705490	HEATED HUMIDIFIER FISHER & PAYKEL MR850 - 110VAC	01	PC
26	1708467	FILTER KIT	01	PC
27	1710311	KIT COOLER FILTER	01	PC

4 Identification of Components

4.1 Front view



4.1.1 Carrying Handle

4.1.2 Led Alarm Indicator

4.1.3 Liquid Crystal Display, Color and Touch Screen Monitor

4.1.4 Expiratory Valve

4.1.5 Knob button with power supply LED indicator

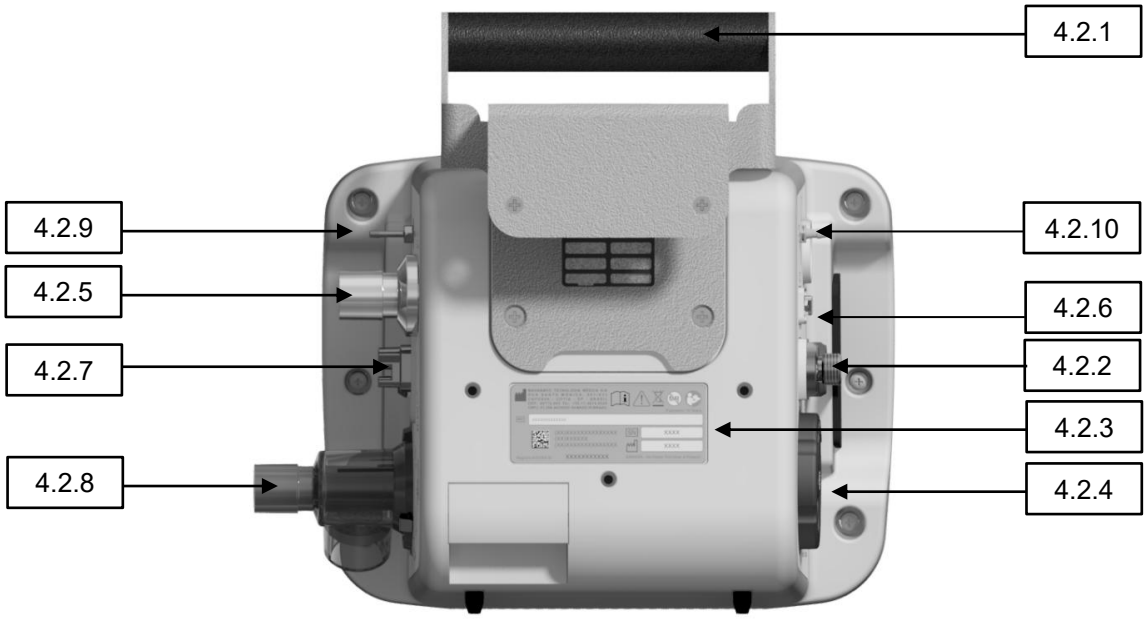
4.1.6 Standard RJ-45 Ethernet Connector

4.1.7 Standard USB Connectors

4.1.8 Standard RS-232 Connector

4.1.9 Standard HDMI Connector

4.2 Rear View



4.2.1 Carry Handle

4.2.2 Oxygen Gas Inlet

4.2.3 Labeling label

4.2.4 Air Outlet for Cooling

4.2.5 Inspiratory branch connection

4.2.6 Connection for Capnography or Oximetry Sensor

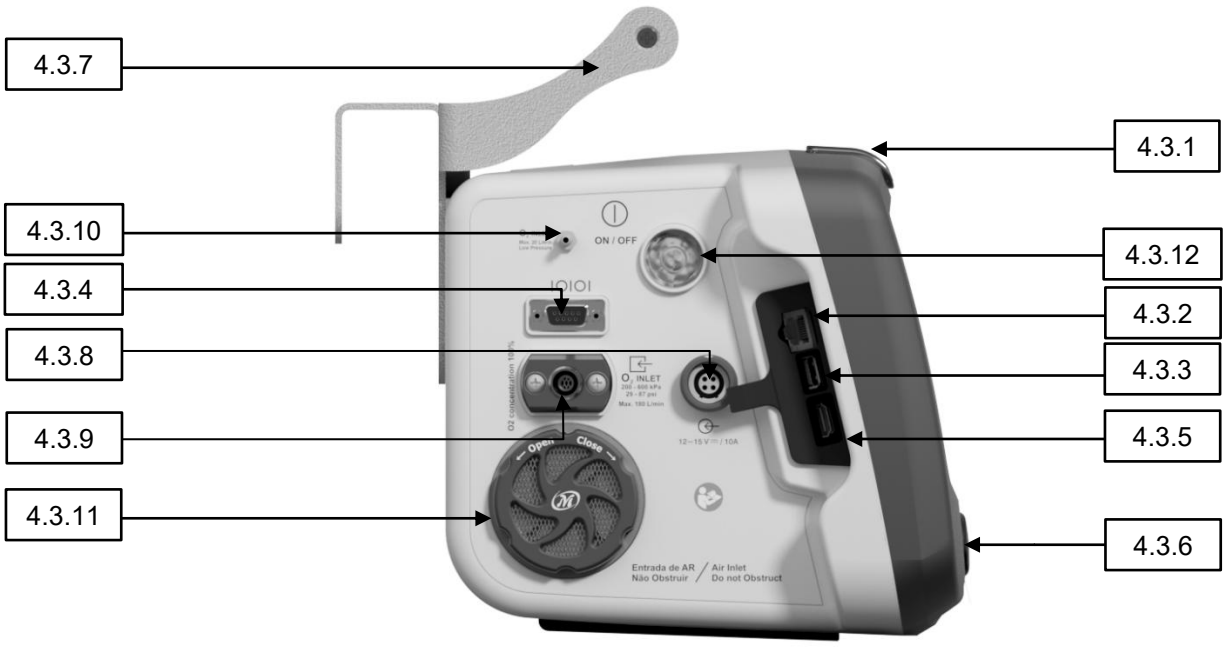
4.2.7 Flow Sensor Line Connection

4.2.8 Expiratory Valve

4.2.9 External Auxiliary Pressure Nozzle

4.2.10 Low Pressure O2 Inlet

4.3 Left side view – Oxymag Max 300



4.3.1 LED Alarm Indicator

4.3.2 Standard RJ-45 Ethernet Connector

4.3.3 Standard USB Connectors

4.3.4 Standard RS-232 Connector

4.3.5 Standard HDMI Connector

4.3.6 Knob Button

4.3.7 Carry Handle

4.3.8 Low Pressure O2 Inlet

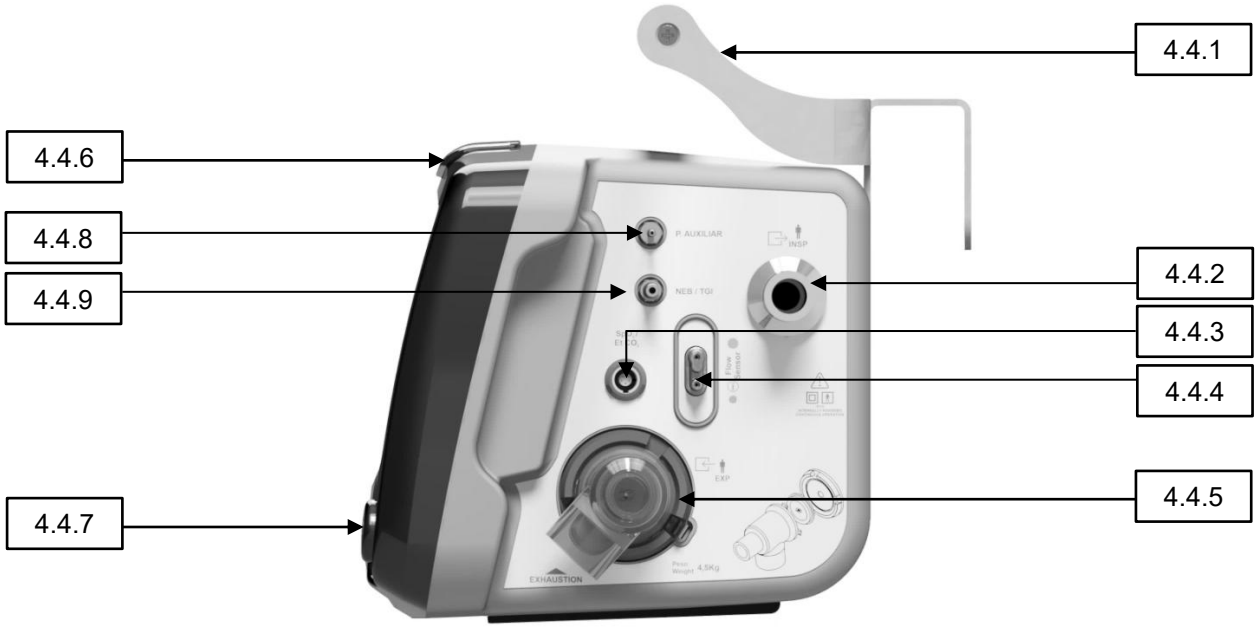
4.3.9 Oxygen Gas Inlet

4.3.10 Low Pressure O2 Inlet

4.3.11 Air Outlet for Cooling

4.3.12 On/Off button

4.4 Right side view



4.4.1 Carrying Handle

4.4.2 Inspiratory branch connection

4.4.3 Connection for Capnography or Oximetry Sensor

4.4.4 Flow Sensor Line Connection

4.4.5 Expiratory Valve

4.4.6 LED Alarm Indicator

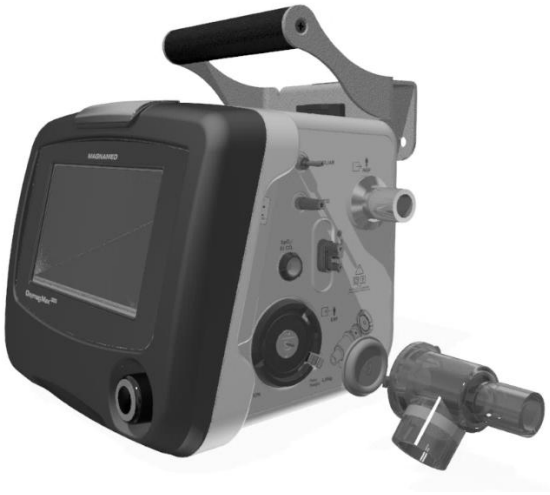
4.4.7 Knob button

4.4.8 External auxiliary pressure nozzle

4.4.9 Nebulizer or TGI connector

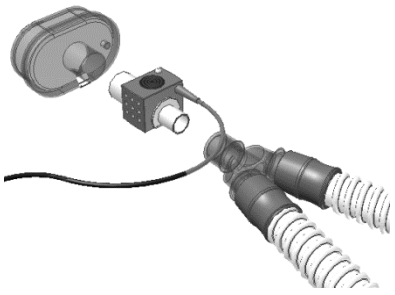
5 Preparation for Use

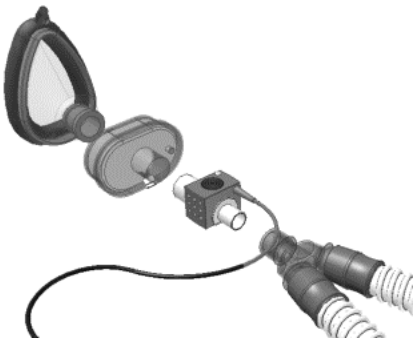
5.1 Assembly

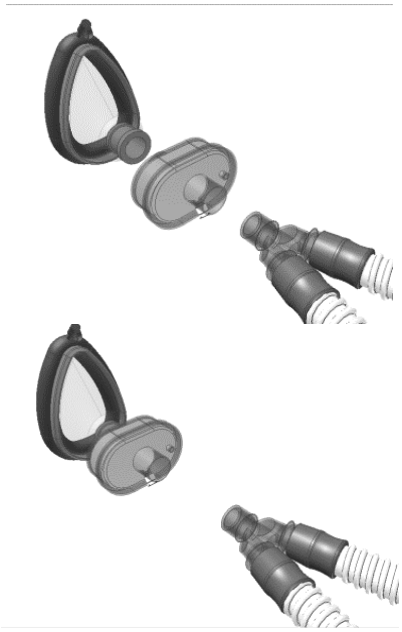
OK	Item	Assembly Sequence	Image
☐	1	Position the diaphragm on the expiratory branch of the expiratory valve in the position indicated in the figure opposite. Attach the exhalation valve to the back panel. **ATTENTION** • ***To withdraw the expiratory valve, depress the valve and turn counterclockwise.***	
☐	2	Connect the patient's circuit to the inspiratory cone of the ventilator and to the expiratory valve as shown in the image on the side.	

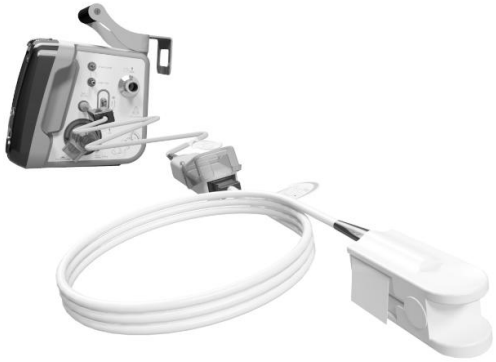
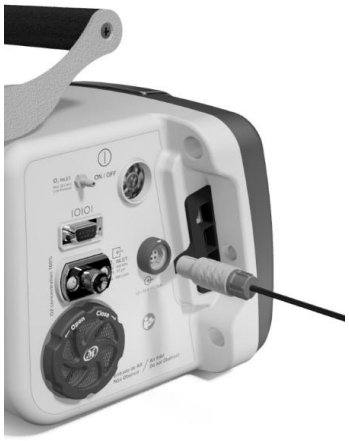
OK	Item	Assembly Sequence	Image
☐	4	Connect the flow sensor. A. Universal sensor in proximal position: Connect the universal sensor line as indicated in the figure opposite. Connect the flow sensor into the patient's breathing circuit, after the Y. Connect the other end of the universal sensor line to the flow sensor at the position indicated in the figure opposite. **ATTENTION** • ***The flow sensor connectors should face upwards to prevent condensation and secretion build-up at the measurement points.*** B. Universal sensor in distal position: Attach the universal flow sensor to the expiratory valve.	

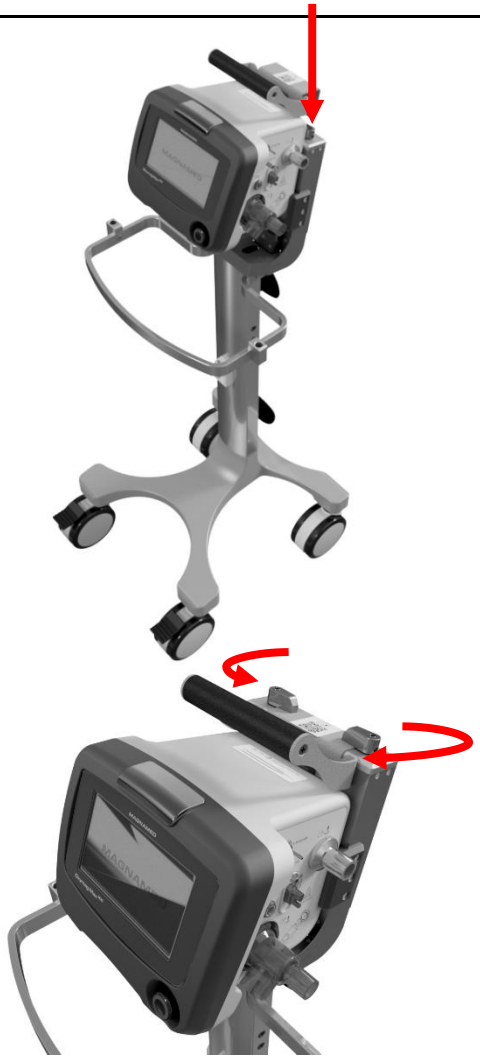
OK	Item	Assembly Sequence	Image
		Plug one end of the 0.2m line into the universal flow sensor and the other end into the equipment.	

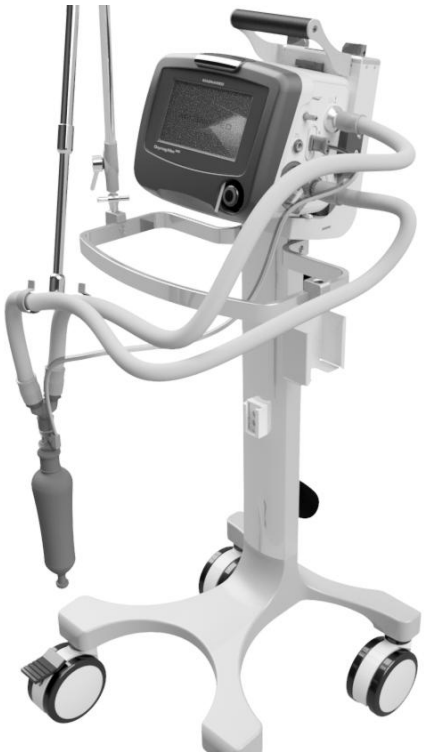
OK	Item	Assembly Sequence	Image
☐	5	If you want to use the IRMA CO2 sensor, connect the airway adapter to the IRMA CO2 sensor. Connect the IRMA CO2 sensor right after the proximal flow sensor, if you are using this sensor, or directly into the Y connector. Plug the cable into one of the external sensor connectors on the front panel.	
☐	6	If you are going to use the breathing circuit with the IRMA CO2 sensor and the HME (Heat and Moisture Exchange) filter, assemble as shown in the image on the side. **ATTENTION** • ***Use only filters specified by MAGNAMED.***	

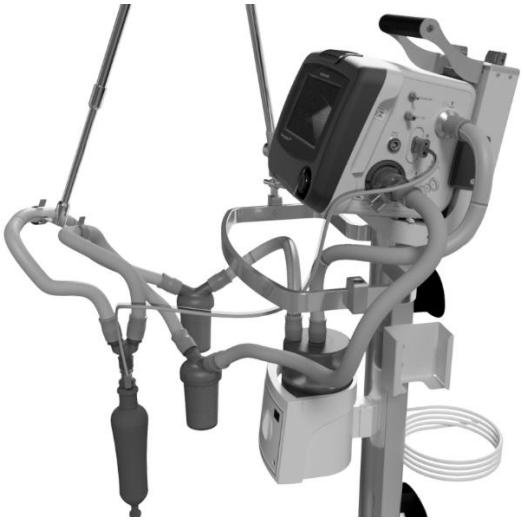
OK	Item	Assembly Sequence	Image
☐	7	If you are going to use the respiratory circuit for NON-INVASIVE VENTILATION (NV or NIV – Noninvasive Ventilation) with the use of a mask, in addition to the filter and IRMA CO2 sensor, follow the sequence in the image on the side. **ATTENTION** • ***Use only MASKS specified by MAGNAMED.*** • ***Use a mask suitable for the type of patient.***	 
☐	8	If you are going to use the respiratory circuit for NON INVASIVE VENTILATION (NIV or Non Invasive Ventilation) with the use of the mask and without the filter, mount it on the side.	 

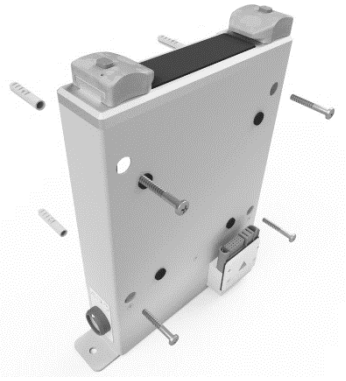
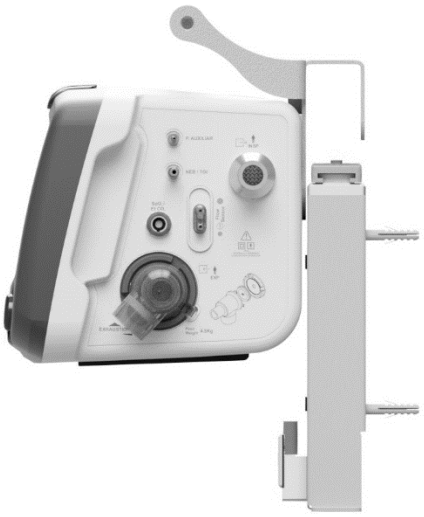
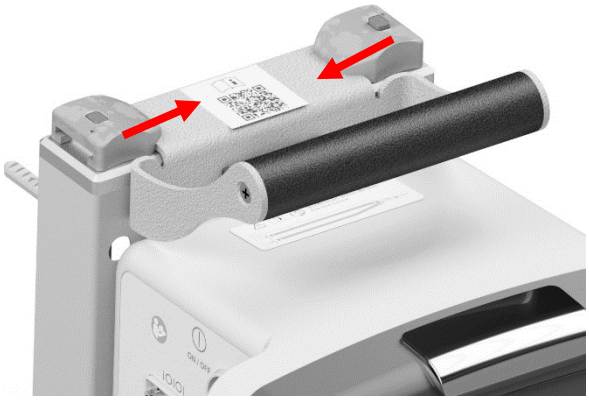
OK	Item	Assembly Sequence	Image
☐	9	If you are going to use the respiratory circuit for NON INVASIVE VENTILATION (NIV or Non Invasive Ventilation) without the filter.	
☐	10	If you are going to use the respiratory circuit for NON-INVASIVE VENTILATION (NIV) with mask and HME filter, then mount it on the side.	
☐	11	If using a HEPA filter, fit the filter between the expiratory branch of the expiratory valve and the expiratory branch of the patient's circuit.	

OK	Item	Assembly Sequence	Image
☐	12	If you want to use the oximetry sensor, plug the sensor cable into the external sensor connector on the front panel. Position the oximetry sensor on the patient's finger. The oximetry sensor must be removed and the site inspected within a minimum of 4 hours, or sooner if necessary. If circulatory condition or skin integrity suggests, it should be repositioned to a different monitoring site.	
☐	13	Connect the power cord to the equipment and the mains.	
☐	14	Connect the O2 hose as indicated. **ATTENTION** • ***Input pressures exceeding the specified***	

OK	Item	Assembly Sequence	Image
		limit can damage the equipment. • ***The hoses shall comply the requirements of ISO 5359:2014*** • ***The gas network connected to the equipment shall meet the requirements of ABNT NBR 12188:2012.***	
☐	15	Pedestal: Fit the ventilator to the location indicated in the figure opposite.	

OK	Item	Assembly Sequence	Image
		Turn the screws to secure.	
		Attach the articulating arm to the carrying handle and rotate the handle to secure. Position the patient's respiratory circuit on the articulated arm.	

OK	Item	Assembly Sequence	Image
☐	16	Circuit for O2 Therapy: Disconnect the exhalation valve from the machine. Connect the circuit and humidifier to High Flow as indicated in the figure opposite. Connect the appropriate prong for the type of patient.	 

OK	Item	Assembly Sequence	Image
☐	17	Wall Bracket: The wall bracket is an optional item and can be used on ambulances or installation walls in hospital environments. To install, fix the 4 screws to the wall with the use of wall plugs when necessary. Lean the Oxymag Max handle bracket just above the wall bracket and slide the Oxymag Max down until it fits snugly. To lock, press the blue buttons and slide the latches forward. To withdraw Oxymag Max, perform the reverse procedure.	  

5.2 Electrical Network Connection

The equipment must be connected to a grounded power supply network that complies with the local legislation.

The equipment's internal batteries shall always be charged and ready for use in the event of a power grid failure or for use in external operations. To do so, you must keep your power supply connected to the mains to charge the batteries, even if the equipment remains turned off.

After prolonged use of the equipment using only the internal battery power, it is necessary to fully recharge the equipment, preparing the equipment for the next use. During the recharge of the internal batteries, the performance of the equipment is not affected.

If the equipment remains unplugged from the electrical network for a period of more than one month, the batteries must be fully recharged.

When switching from electrical network to battery, the performance of the equipment is not affected. The "no AC power" low priority alarm is triggered, and the battery icon is displayed. If the equipment remains disconnected from the electrical network, when the battery charge is less than 50%, the "low battery" medium priority alarm will be displayed and at least 5 minutes before the battery runs out the high priority alarm "low battery".

In case of power loss, the alarm recording system will not be affected and will keep the history as well as notify that it occurred through an alarm related to this loss.

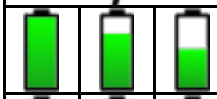
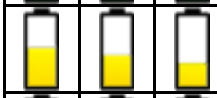
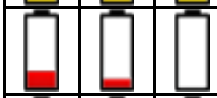
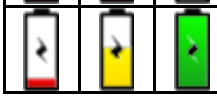
WARNING

- ***If LOW BATTERY alarm occurs, IMMEDIATELY connect the ventilator to the electrical network. If this is not possible, provide another suitable means of ventilatory support and DISCONNECT the equipment from the patient.***

Observation

- *While the equipment is in operation, the performance of the equipment will not be affected and accuracies will be maintained after the electrical network has been interrupted and reconnected, as long as there is a charge on the internal battery.*
- *After a period of long interruptions from the electrical network, connect the equipment to the electrical network, switch on the equipment and wait for 30 min. Perform calibrations and autotest.*

When switching from battery to electrical network, the performance of the equipment is not affected. Alarms related to the battery are deactivated and the battery icon is displayed.

Icon	Description	Alarm
	Equipment charged and connected to electrical network	No alarm
	Equipment operating on battery, with a load above 50%	Low priority "No AC power"
	Equipment operating on battery with charge between 50 and 20%	Medium priority "Low Battery"
	Equipment operating on battery with load below 20%	High Priority "Low Battery"
	Equipment connected to electrical network and battery charging	No alarm

5.3 Verification Before Use

The purpose of this verification is to ensure greater safety through some simple and quick procedures, that must be performed before each use or at least at the beginning of each work period.

Table 4 – Verification before use

Item	Procedure
1	Verify that the machine is turned off.
2	Perform a visual inspection of the equipment and its components, seeking to assess the integrity of the equipment.
3	Verify that all components are properly connected or inserted.
4	Verify that the integrated valve is installed correctly and is firmly seated. Also note the conditions of the diaphragm.
5	If using the sensor in the distal position, check that the flow sensor is firmly connected to the expiratory valve.
6	Verify that the breathing circuit is firmly connected and is suitable for the patient.
7	If using the sensor in the proximal position, check the tight connection of the flow sensor to the Y.
8	Verify the tight connection of the oxygen gas hose.
9	Verify that the inlet pressure is within the specified range.

Item	Procedure
	ATTENTION • ***Input pressures exceeding the specified limit can damage the equipment.*** • ***For inlet pressures less than 250 kPa, the maximum flow shall be 120 L/min.***
10	Check the power cord connection, if applicable. The ventilator can be used on battery power for up to 390 minutes continuously under usual ventilation conditions. **WARNING** • ***If LOW BATTERY alarm occurs, IMMEDIATELY connect the ventilator to the electrical network. If this is not possible, provide another suitable means of ventilatory support and then DISCONNECT the equipment from the patient.***
11	If all items are OK, then the equipment is ready for use. The equipment will be ready for use immediately after it is turned on.

WARNING

- ***Perform all verification procedures before each use.***
- ***If any problem is found, correct it BEFORE USING THE DEVICE.***
- ***If the problem cannot be resolved immediately, contact qualified technical assistance.***

5.4 Shutdown Procedure

The Oxymag Max lung ventilator is a life support device and must be compulsorily disconnected from the patient in order to be turned off. The equipment must be turned off at the on/off switch, identified in 4.3 Left side view (item 4.3.10). When the machine is turned off, a continuous audio signal will be produced indicating that the machine has been turned off. Finally, press the turn confirmation button, identified in 4.1 Front view (item 4.1.5).

6 Instructions for Use

6.1 Initial sequence

Turn on the ventilator via the on/off push button located on the side of the machine.

The initial screen will be presented with the patient options and available services.

In 12 s, a home screen will be presented, select the type of patient by tapping on the corresponding icon.

Once the patient type is identified, the flow sensor and humidifier adjustment screen will be displayed, and the operator will have the option to perform the autotest or initiate ventilation.

Select the type of humidifier or heat exchanger and the chosen flow sensor (distal or proximal).

ATTENTION

- ***The choice of humidifier or heat exchanger is important for the correct calculation of volumes according to the temperature and humidity conditions presented (STPD or BTPS).***
- ***Only one type of external, distal OR proximal flow sensor will be tested. If you made a mistake while selecting it, restart the equipment and redo the autotest.***
- ***If you choose to use the distal flow sensor, do not use suction systems at the exhaust gas outlet.***

If you wish to perform the autotest, make sure to perform the steps below:

- The ventilator must be disconnected from the patient.
- The ventilator should preferably be connected to the electrical network or, if this is not possible, shall have enough battery power.
- The ventilator should be connected to an O2 source within the recommended pressure range.
- The red LED indicating priority alarms shall remain on.
- It shall be possible to hear the alarm speaker test.
- A RESPIRATORY CIRCUIT APPROPRIATE TO THE TYPE OF PATIENT SHALL BE CONNECTED.

WARNING

- ***Never start the autotest procedure with the ventilator connected to the patient.***

If you heard the speaker test, answer YES. Otherwise, answer NO. In this case the equipment shall not be used and therefore, it will be inoperative until a new autotest is carried out, that is, until the equipment is restarted.

To start the autotest, press the confirm button or, if you want to start the ventilation immediately, press the ventilation button.

WARNING

- ***Never respond YES if you could not hear the speaker test under the risk of malfunctioning of the priority alarms during ventilation.***
- ***Always perform the autotest procedure before connecting the ventilator to a patient.***

The autotest checks all the important items for proper ventilation:

- Regulated Oxygen Pressure
- Oxygen Proportional Valve
- Flow Air System
- Flow Sensors
- Expiratory valve
- O_2 cell
- Leakage and complacency
- Resistance

At the end of the leakage test, the RESPIRATORY CIRCUIT OUTPUT SHALL BE UNOBSTRUCTED to perform the resistance test and, where appropriate, the proximal flow sensor test.

ATTENTION

- ***Do not forget to unobstruct the circuit output before the resistance test.***

ATTENTION

- ***If there is a recurring failure in one or more items of the autotest, suspend use of the equipment until the problem is resolved.***

The autotest can be canceled at any time by the operator. To perform only some of the tests, you must enter the RESTRICTED menu.

ATTENTION

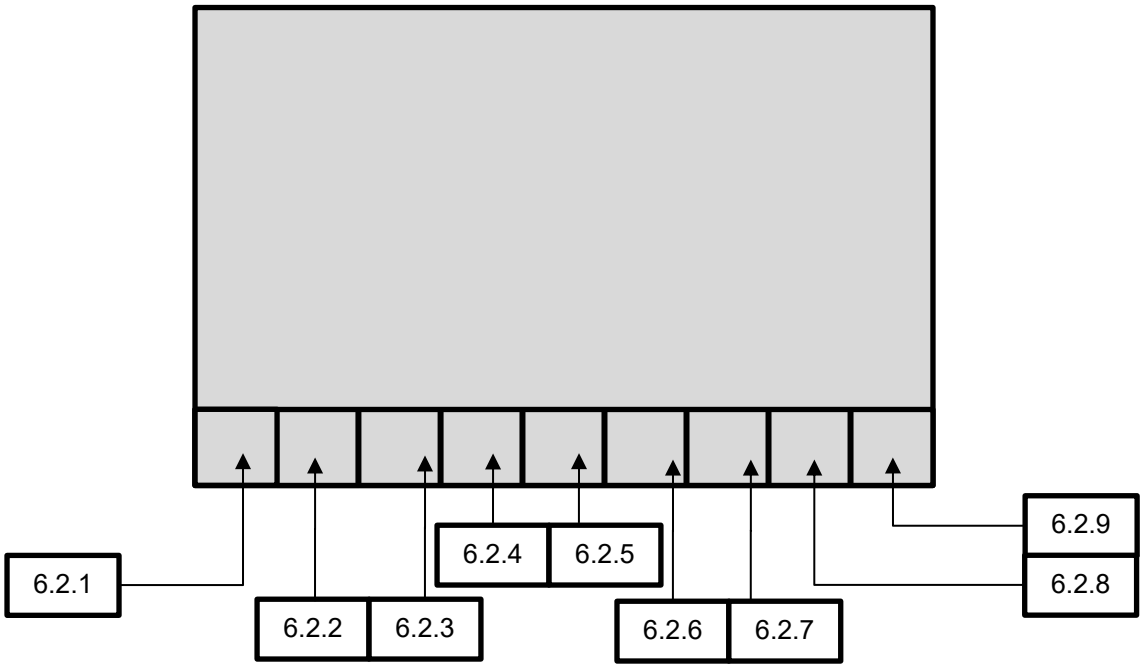
- ***The RESTRICTED menu is only accessible with a password.***

Once the autotest process is complete, press VENT to go to the vent screen.

ATTENTION

- ***Position the patient close to the Oxymag Max so that the breathing circuit is not stressed.***
- ***When using the respiratory circuit with water traps, keep them at a lower level to ensure the correct operation of the collectors.***

6.2 Restricted menu



This menu is password-only accessible and allows you to perform advanced settings, calibrations, and autotests, and allows you to view system, battery, and status information.

6.2.1 Patient

Clicking this button will return you to the patients screen.

6.2.2 Autotest – Closed TA

In this menu, it is possible to perform the closed-loop tests, cancel and view the results individually. In this menu, information on air network pressure and O2, date and time of the last test performed are also displayed.

6.2.3 Autotest – Open TA

In this menu, it is possible to perform the open circuit tests, cancel and view the results individually. In this menu, information on air network pressure and O2, date and time of the last test performed are also displayed.

6.2.4 Calibration

In this menu, it is possible to perform the calibration of the distal flow sensor, expiratory valve and oxygen cell. In this menu, information on air network pressure and O2, date and time of the last test performed are also displayed.

To perform calibrations, occlude the breathing circuit, select the items you want to calibrate, and press the calibrate button.

It is recommended to calibrate some components before use in the following situations:

6.2.4.1 Expiratory valve

- Expiratory valve replacement;
- Diaphragm replacement;
- Incorrect control of PEEP;
- Excessive leakage.

6.2.4.2 O2 cell (galvanic cell only)

- Cell replacement;
- The monitored concentration values (FiO2) do not appear to be correct;
- The lower and upper limits do not reach 21 and 100% O2, respectively;
- Change of patient.

6.2.5 Status

In this menu, information is displayed on the total time of use of the ventilator, time since the last maintenance, air and O2 network pressure, date and time, date and time of the last test performed and date and time of the last calibration performed.

6.2.6 Battery

Percentage and battery status information is displayed in this menu.

6.2.7 System

In this menu you can set the date, time, language, brightness, day or night mode and audio volume. If the ventilator is connected to the internet, its possible to retrieve the IP address through the Restricted mode, which gives access to the engineering mode through a password. Within this mode, another password gives acccess to export data, such as trends, black boxes and screenshots, to a flash drive.

ATTENTION

- ***Make sure that the volume adjusted for the audio of the alarms is compatible with the distance that the equipment will be from the clinicians.***

6.2.8 Advanced

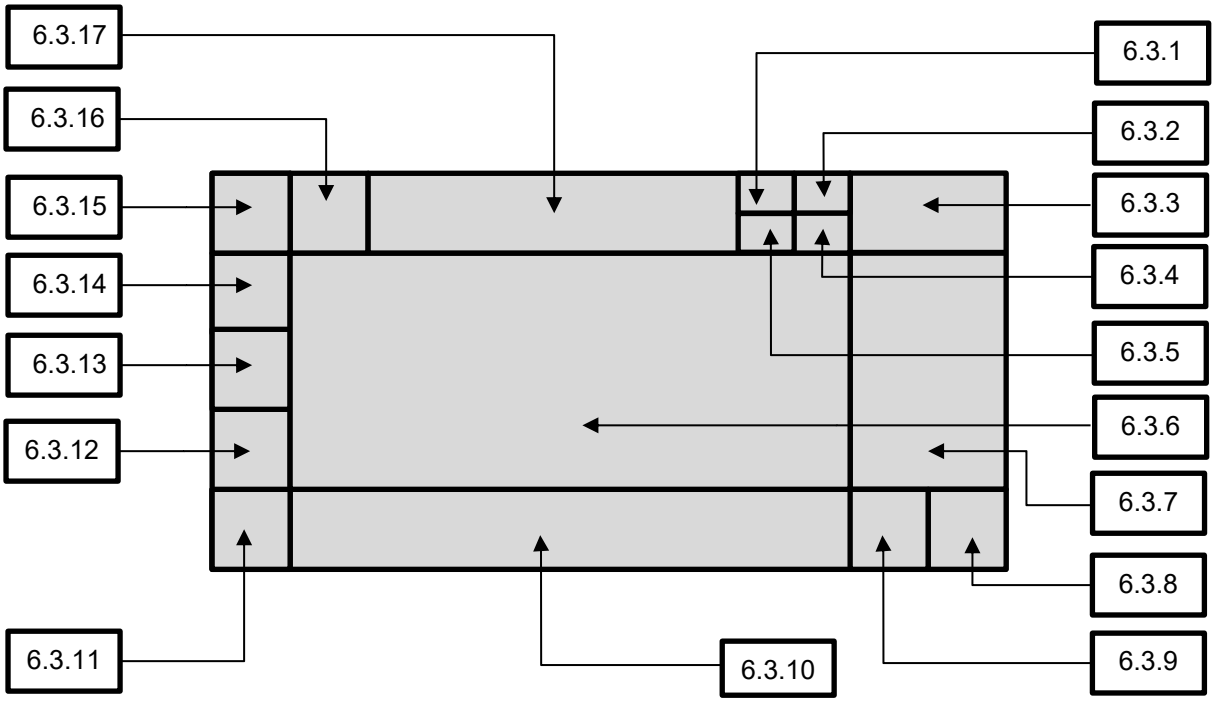
In this menu you can adjust time and O_2+ concentration, inspiratory and expiratory hold time, keypad lock time, alarm mute time, type of controlled volume adjustment, type of flow sensor, pressure unit and oximeter settings, when used.

6.2.9 Ventilation

This menu gives access to the main ventilation screen of the patient.

The ventilator will start ventilating. To enter standby mode, press and hold the Standby button for two (2) or press and confirm the message on the screen.

6.3 Main Screen



6.3.1 Patient Information Area

Patient information such as ID, name, initials, last name, sex, height, and volume / weight are set in this menu.

6.3.1.1 Volume x weight patient definition

As soon as a patient is selected, the ventilator automatically estimates an appropriate tidal volume. However, in order to obtain the best tidal volume, it is important to know the ideal weight for each patient.

It is possible to obtain the ideal weight for adult and pediatric patients (IBW) according to sex and height. To do so, simply select the patient's sex and then adjust the height value, so that the equipment calculates their ideal weight. The adjustment of the volume-by-weight (mL per kilogram) parameter complements the information necessary for the best adjustment of the tidal volume.

For neonatal patients, the ventilator calculates ventilatory parameters according to the patient's body weight. To do this, simply select the patient's sex and adjust the body weight value.

Observation

- *To reduce the risk of lung injury, the ventilator uses the ideal weight as a reference for adjusting ventilatory parameters. If you want to change the parameters set by the ventilator, simply select the parameter and change it.*

6.3.2 Battery Status Area

This menu displays battery percentage and status information.

6.3.3 Ventilation Mode Setting Area

Pressing this button displays the options of available ventilatory modes.

6.3.3.1 Ventilatory Modes Available

Table 5 - Ventilatory modes

Mode	Systematic code according to ISO 19223	Backup	Backup Mode(1)	
			Neo	Ped and Adu
VCV	CMV-VC A/C-VC	✔	–	**Auto**
PCV	CMV-PC A/C-PC	✔	**Auto**	**Auto**
PRVC	CMV-vtPC A/C-vtPC	✔	–	**Auto**
PLV	CMV-PC A/C-PC	✔	**Auto**	–
V-SIMV + PS	SIMV-VC\PS	✔	–	**Auto**
P-SIMV + PS	SIMV-PC\PS	✔	**Auto**	**Auto**
PRVC + SIMV + PS	SIMV-vtPC\PS	✔	–	**Auto**
CPAP/PS	CSV-PS CPAP	✔	**Adjustable PLV + Auto**	**VCV & PCV Adjustable + Auto**
DualPAP	SIMV-PC{S}\PS(x2)	✔	**Adjustable PLV + Auto**	**VCV & PCV Adjustable + Auto**
APRV	SIMV-PC{S}\PS(x2)	✔	**Adjustable PLV + Auto**	**VCV & PCV Adjustable + Auto**
Nasal CPAP	CSV-PS CPAP	✔	**Adjustable PLV + Auto**	–

Mode	Systematic code according to ISO 19223	Backup	Backup Mode(1)	
			Neo	Ped and Adu
NIV	CSV-PS	✔	–	**VCV & PCV Adjustable + Auto**
MMV	SIMV-VC\PS	✔	–	**VCV & PCV Adjustable + Auto**
VS	CSV-vtPS	✔	–	**Adjustable PRVC + Auto**
VG	CMV-vtPC A/C-vtPC	✔	**Auto**	–
CPR	—	X	–	–
O2 Therapy	—	X	–	–

Observations

- *For modes in which the backup (guard) is set to "Auto", whenever the set apnea time is reached, the ventilator initiates a ventilatory cycle, the configuration of which is based on the settings of the current ventilatory mode.*
- *When the equipment goes into backup mode, it is necessary for the patient to make an effort to return to the adjusted ventilatory mode.*

6.3.3.2 Adjustment ventilatory modes

To change or reconfigure a ventilatory mode, simply touch the button that indicates the active mode in the upper right corner of the screen and the ventilatory modes adjustment screen will load.

Observations

- *The available ventilatory modes will be determined according to the selected patient (see **Table 5**).*

To select a ventilatory mode, simply touch the tab with the acronym of the desired mode. Next, the main settings of the mode will be displayed. To access all the parameters available for the mode, it is necessary to confirm the chosen mode and then make the adjustments in the lower parameter adjustment bar.

Observations

- *Adjustment of the backup ventilation parameters is only available in spontaneous ventilation modes. In the others, the backup ventilation is automatic and considers the parameters set for the ventilatory mode itself.*
- *When the operator adjusts a pressure or flow sensitivity, the controlled modalities (VCV, PCV, PRVC and PLV) will become assist-controlled. In this case, this information will be displayed on the active mode button.*

After adjusting the parameters, in order for them to be activated, it is necessary to press the CONFIRM button.

To cancel the settings made and remain with the previous settings, including the ventilatory mode, simply press the CANCEL button. In this way, the ventilator will ignore the adjustments made on this screen and return to the main screen.

ATTENTION

- ***In case the new value is not confirmed, the adjustment will be cancelled after the screen lock time.***

6.3.4 Graphic freeze button

When you press this button, the graphics are frozen.

6.3.5 Screenshot

By clicking on this button, the screenshot will be taken, which can be exported via USB stick.

6.3.6 Graphics area

In this area, the adjusted graphics layout is displayed. The available charts are:

- Pressure x Time Curve
- Flow x Time Curve
- Volume x Time Curve
- Pressure x Volume Loop
- Volume vs. Flow Loop
- Pressure vs. Flow Loop

- Volume x CO_2 Loop
- Volume x FCO_2 Loop
- CO2 x Time Curve(1)
- SpO2 x Time Curve(1)
- Instant pressure bar graph with numerical peak, plateau or instantaneous pressure indicator

(1) This chart option is only available when an external sensor (oximeter or capnograph) is attached.

The option to display monitored parameters is also available, where up to 18 of the 54 monitored parameters are displayed.

6.3.7 Bargraph area and monitored parameters

According to the graph layout, the pressure bargraph or bargraph and 3 monitored parameters will be displayed.

6.3.8 Standby button

Pressing this button turns the standby mode on or off. In standby mode, alarms are interrupted, and ventilation is paused. For security reasons, to activate or deactivate the standby mode, press and hold the button for 2 seconds.

6.3.9 Screen Lock Button

Accidental change protection system. Locks or unlocks the touchscreen. When the controls on the display are locked, press this key to release them IMMEDIATELY.

To lock again, simply press this key once or wait for the time set in the general setting without touching the screen.

Auto-lock can be turned off in the advanced menu.

6.3.10 Ventilatory Mode Parameter Setting Area

In this area, all the parameters for adjusting the current ventilatory mode are displayed. To change a parameter, simply press the corresponding button, and use the increment and decrement buttons via touchscreen or turn-confirm button. To confirm a parameter, simply press the confirm button or press the knob (ENTER) button.

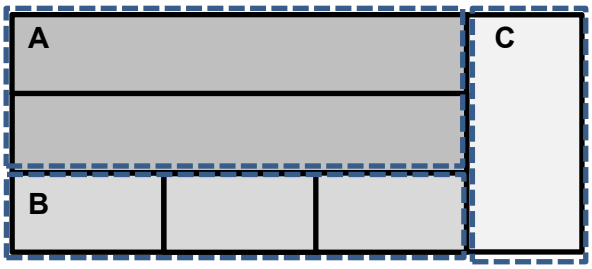
6.3.11 Menu access area

When you press this button, the following menus are displayed: Layout, Features, Trend, Advanced, System, Calibration, and Status.

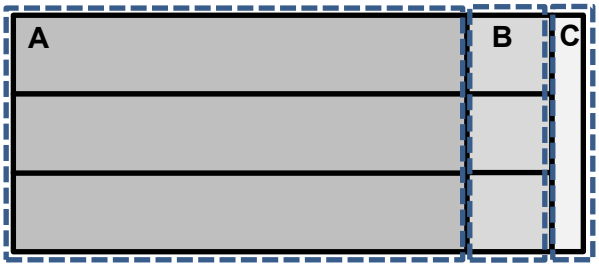
6.3.11.1 Layout

By pressing this button, the available chart layouts are displayed: 2 curves, big numbers, monitor, 3 curves, lung, and 2 loops.

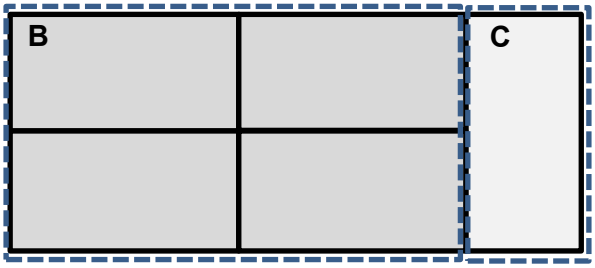
2 curves



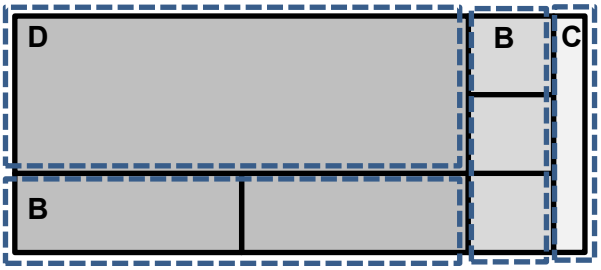
3 curves



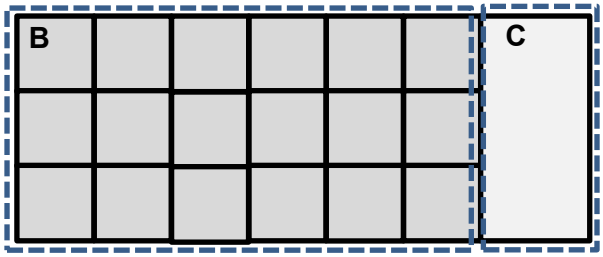
Big numbers



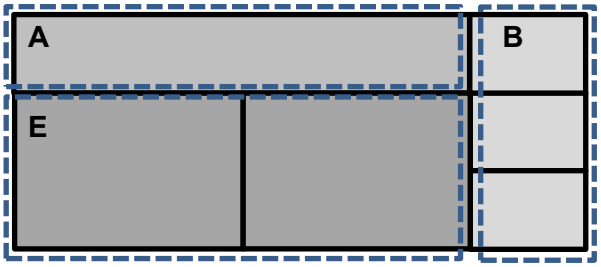
Lung



Monitor



2 loops



Legend:

A – Graphs: SpO2, CO2, CO2(%), Flow, Volume, Pressure

B – Monitored Parameters: Peak Pressure (Ppeak), Positive End-Expiratory Pressure (PEEP), Intrinsic PEEP (iPEEP), Mean Pressure (Pmed), Plateau Pressure (Pplat), Distension Pressure (Driving Pressure), Expiratory Tidal Volume (Vte), Inspiratory Tidal Volume (Vti), Spontaneous Expiratory Tidal Volume (Vte sp), Minute Volume (MV), Consumption of O_2 (O2 Consumption), O2 Concentration (O2), Respiratory Rate (Freq), Spontaneous Respiratory Rate (RR sp), I:E Ratio (I:E), Inspiratory Time (Ti), Expiratory Time (Te), Time Constant (Tc), Total Time Inspiratory Time (Ti/Ttot), Inspiratory Resistance (IR), Expiratory Resistance (RE), Dynamic Compliance (C dyn), Static Compliance (C stat), Elastance (E), Leakage by Percentage (Leakage), Leakage F, Tobin Index (RSBi), Work of Breathing Index (WOBi), Oxygen Actuation (SpO2),

Heart Rate (Pulse), Perfusion (Perf), Photoplethysmograph Variability Index (PVI), Partial Pressure of$_{CO2}$ at the end of expiration (EtCO2), Partial Pressure of CO2 at the end of inspiration (iCO2), Stress Index (Stress Index), C20/C, Inspiratory Volume/Weight (Vol/ Insp Weight), Expiratory Volume/Weight (Vol/ exp Weight), Peak Inspiratory Flow (Peak Insp Flow), Peak Expiratory Flow (Peak Exp Flow), Anatonic Dead Space Ventilation (RVaw), Anatonic Dead Space Ventilation by Expired Tidal Volume (VDaw/VTE), Alveolar Tidal Volume (Vtalv), Alveolar Minute Volume (V'alv), $CO_{Volume\ 2}$ Expired (VeCO2), Volume of Exhaled CO2 per breath (VCO2), Volume of CO2 eliminated per minute (V'CO2), Mean Alveolar Partial Pressure of CO2 (PACO2), Partial Pressure of CO2 in Exhaled Gas (PETCO2), Fraction of Expired CO2 (FECO2), Fractional Concentration of CO2 in Exhaled Gas (FetCO2), Inclination of CO2 (InclinCO2)

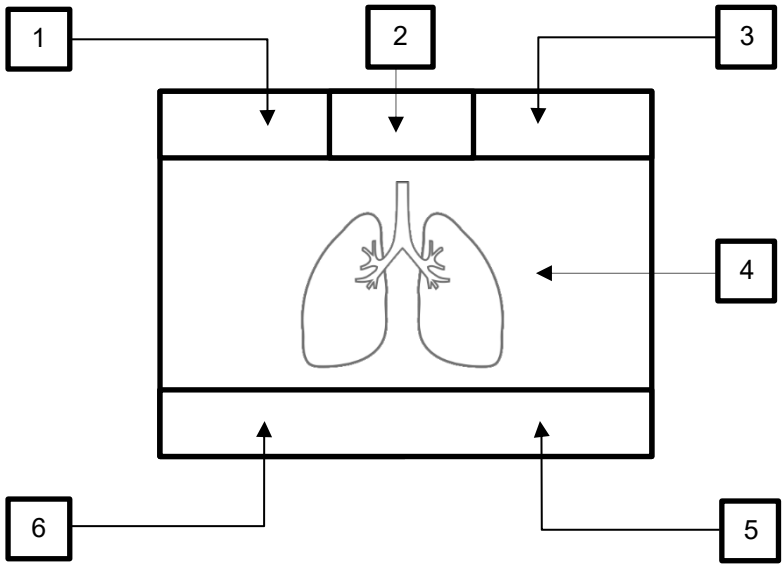
C – Bargraph

D – Lung

E – Loops: PxV, PxF, VxF, $VxCO_2$, VxFCO2

6.3.11.1.1 Lung Layout

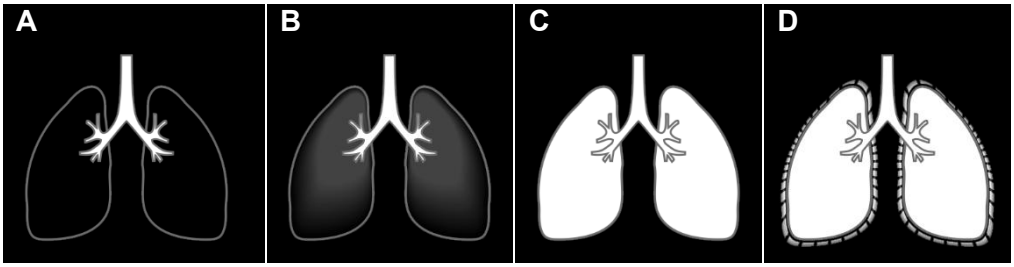
Aiming to optimize, protect and individualize pulmonary ventilation, focusing on the patient and their pathology, this layout was developed for protective monitoring, allowing the operator to have access to continuous evaluation to define the best ventilation strategy.



In this layout, the operator can define the limits for protective ventilation. For this, the operator must adjust the minimum (1) and maximum (3) volume/weight. In (1) the minimum volume calculated according to the adjusted minimum volume/weight is displayed and in (3) the maximum volume calculated in accordance with the adjusted maximum volume/weight.

(2) shows the monitored volume and the calculated volume/weight based on the patient's adjusted weight and the monitored volume.

In (4) the lung is displayed, which alternates the tonality to represent four states: empty (a), insufficient volume (b), ideal volume (c) and excessive volume (d), allowing the operator to see if the ventilation is ideal or not for the patient according to the minimum and maximum volumes calculated in (1) and (3). If the monitored volume is below the minimum volume calculated in (1), the lung will be represented in gray tone, indicating insufficient volume (b). If the monitored volume is between the minimum (1) and maximum (3) limits, the lung will be represented completely filled in white, indicating ideal volume (c). If the monitored volume exceeds the maximum volume calculated in (3), the lung will be represented as fully filled and an overflow will flash in white, indicating excessive volume (d). During expiration, the lung will be represented in black, indicating an empty state (a).



Executing an inspiratory pause, static compliance (6) and inspiratory resistance (5) are calculated, allowing the operator to visualize the evolution of the patient's clinical condition.

6.3.11.2 Resources

When you press this button, the following features are displayed: NIV, Auxiliary External Pressure, Tube Compensation, Sigh, Nebulizer-TGI, and Humidifier.

6.3.11.2.1 Non-invasive ventilation (NIV)

Noninvasive ventilation (NIV) refers to the application of ventilatory support without invasive airway methods, such as orotracheal intubation or tracheostomy. Nasal or oronasal masks are the most frequently used interfaces for the application of NIV in a hospital environment.

When applying NIV in pressure-controlled modes, the pressure value should not be set to 0 (ZERO) and pressure drop cycle triggering should be active. Flow triggering remains disabled.

In NIV, the ventilator automatically compensates for higher leakage flows and ignores high minute volume, high tidal volume, and flow sensor check alarms.

NIV is available for all ventilatory modes.

WARNING

- ***The default values are only an initial reference.***
- ***Readjust the ventilation parameters as per the patient's needs.***
- ***Use the appropriate mask for each type of patient to avoid excessive leakage.***

- ***The exhaled volume of the PATIENT may differ from the exhaled volume measured due to leaks in the mask.***
- ***In non-invasive ventilation, use means of expiratory carbon dioxide concentration measurements in accordance with ISO 80601-2-55 (See Cap 11 – IRMA CO2 sensor (optional)).***

Observation

- *Flow triggering remains disabled during non-invasive ventilation.*
- *The controlled or support pressure (ΔPS) is a value above the PEEP and can be adjusted between +5 cmH2O and PMAX.*
- *The continuous flow, which apparently 'leaks' through the expiratory valve, is normal and serves to reduce the response time of the patient's ventilation control system.*

6.3.11.2.2 Tube Compensation

The main purpose of this feature is to compensate for the work imposed on the patient by the endotracheal tube.

WARNING

- ***Wrong selection of the endotracheal tube type or gauge can cause injury to the patient.***

In the ATC tube compensation window, select the intubation mode and then adjust the endotracheal diameter and compensation percentage.

After certifying that the fit is suitable for the patient, close the setup window and enable tube compensation.

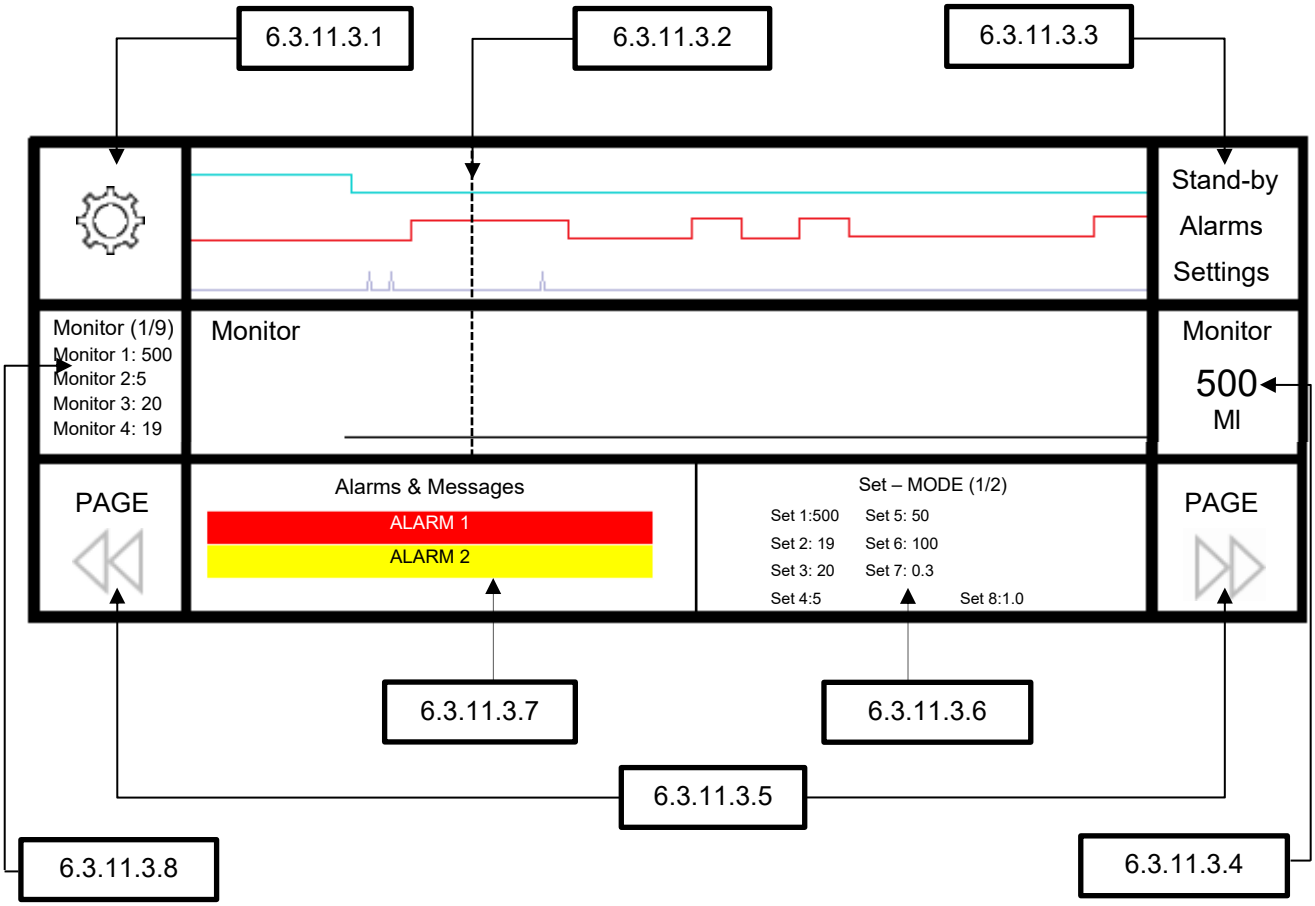
By activating this option, a new estimated patient pressure curve will be drawn, with its instantaneous values.

This pressure value is estimated based on algorithms that take into account the pipe diameter and compensation percentage.

The patient's pressure curve, read by the equipment, continues to be traced and usually tends to be higher than the estimated pressure.

6.3.11.3 Trend

By pressing this button, the records of the last hours of ventilation will be displayed. Browsing through the pages (6.3.10.3.5), you can view up to 240 hours of logs (up to 432000 events). When it reaches maximum capacity, the oldest data is overwritten. All logs are kept when the equipment is turned off and on/off events are logged, even when there is a total loss of power supply. The trend is presented in the following layout:



In this example, at the position the timeline is in, the ventilator was cycling with the settings displayed in 6.3. 10.3.6, with the occurrence of three alarms simultaneously and one message displayed in 6.3. 10.3.7, where two high-priority alarms, one medium-priority alarm and one message and the monitoring of that instant is displayed in 6.3.10.3.4 and 6.3.10.3.8.

6.3.11.3.1 Set Up Trend

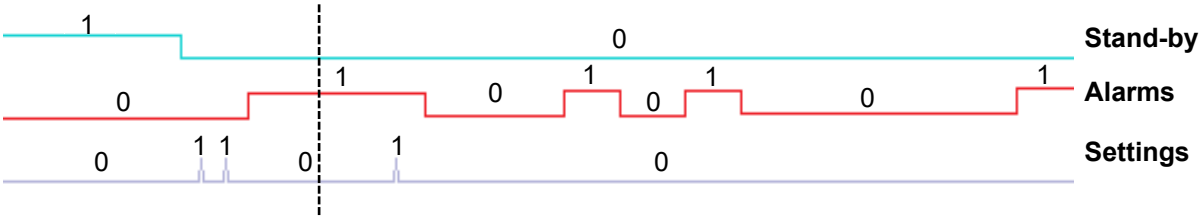
This menu allows you to configure the trend data display interval, adjustable from 2 seconds to 16 minutes.

6.3.11.3.2 Cursor

This cursor allows navigation through the timeline displayed on the current page, navigable via *touch screen* or via turn-confirm button. To navigate the trend, orient yourself by the date and time displayed at the top.

6.3.11.3.3 Events

In this area, stand-by events, alarms and timeline adjustments are displayed. The occurrence of events is represented by the change in position of the line, where line at level 0 indicates no occurrence of events and line at level 1 indicates occurrence of events, as exemplified below:



In the example above, 1 indicates occurrence of events and 0 indicates no occurrence of events. On the Stand-by line, 1 indicates that the ventilator is on stand-by and 0 indicates that it is cycling (not on stand-by). In the Alarms row, 0 indicates no occurrence and 1 indicates occurrence of alarms or messages. In the Settings line, 0 indicates no adjustments and 1 indicates that some parameter has been set.

Therefore, in the timeline (dashed), the ventilator is cycling, an alarm is occurring, and no parameters have been changed at that instant.

6.3.11.3.4 Monitor

In this menu it is possible to configure 1 monitored parameter to be displayed on the timeline. By scrolling through the timeline with the cursor, it is possible to observe the variation of the monitored parameter.

6.3.11.3.5 Page

Through these buttons, it is possible to move forward and backward in time along all the trend pages. The forward and backward orientation in time should be based on the date and time displayed at the top of the trend.

6.3.11.3.6 Set

In this area you can see the mode adjustment at the instant the timeline is positioned. Some modes have more than one settings page. In these modes, to view the other pages, click on the adjusted area to go to the next page.

6.3.11.3.7 Alarms & Messages

In this area it is possible to view the alarms and messages at the instant in which the timeline is positioned. When more than one alarm occurs at the instant the timeline is positioned, all alarms will be displayed in this area.

6.3.11.3.8 Monitor

In this area it is possible to view all the parameters monitored at the instant in which the timeline is positioned. To view all monitored parameters, click on the monitor area to go to the next page.

6.3.11.4 Advanced

When you press this button, the following settings are displayed: O2 flush, pause ins and exp, keypad lock, alarm silence, controlled volume adjustment, flow sensor, pressure unit, and Masimo preferences.

6.3.11.5 System

This menu displays the system settings are displayed: date and time, language, network, brightness adjustment, day/night mode, and audio volume. It also includes a restricted mode, accessible by password, for performing maintenance or exporting trend data, black box data, and screenshots.

6.3.11.6 Calibration

By pressing this button, the available calibrations are displayed: O2, CO2 and touch screen. To perform the calibration, put the equipment in StandBy mode and select the item you want to calibrate.

It is recommended to calibrate some components before use in the following situations:

6.3.11.6.1 O2 Cell

- Cell replacement.
- The monitored concentration values (FiO2) do not appear to be correct.
- The lower and upper limits do not reach 21 and 100% O2, respectively.
- Change of patient.

Observation

- *To access the calibration screen, press the CALIBRATION button in the MENU.*
- *It is not necessary to dispose of calibration gases.*

6.3.11.7 Status

This menu displays status information, such as total time of use of the equipment, time since the last maintenance, gas network pressure, date and time of the last test performed, date and time of the last calibration performed, and current date and time.

6.3.12 O2 flush button (O2+)

By pressing this button, an O2 flush is performed with the concentration and timing set in the ADVANCED menu. During this time, conveniently, the high FiO2 alarm will be inhibited. This feature can be used for pre- and post-aspiration procedures of airway secretion and is available in all ventilatory modes. Use with an aspiration catheter can be performed in any modality and does not require a specific adjustment.

6.3.13 Pause button (insp or exp)

By pressing this button, an inspiratory or expiratory pause is performed, according to the moment of the cycle at which the button is pressed. The pause will be performed for the time set by the operator in the ADVANCED menu. While performing this maneuver, the apnea alarm is not displayed. Only an informational message "Inspiratory pause" or "Expiratory pause" is displayed.

6.3.14 Manual cycle button

Manually triggers an inspiratory cycle, depending on the selected ventilatory mode.

6.3.15 Alarm silence button

By pressing this button, alarms are silenced for the time set in the ADVANCED menu. If a new alarm occurs while the mute button is active, the silence is disabled and the audible alarm occurs.

6.3.16 Alarm setting area

For each of the alarms directly related to the ventilation process, there are one or two thresholds (high value and low value) to be adjusted. These thresholds are set directly in the ALARM menu.

To make these adjustments, tap on the button corresponding to the alarm to be set. To adjust, use the increment and decrement buttons via touchscreen or knob button. To confirm the set value, press the confirm button via touchscreen or press the knob (ENTER) button.

In this menu, it is also possible to set the maximum allowable apnea time of the patient, which will determine the start of backup ventilation (backup).

There is also the option of automatic adjustment of the alarms, to enable it it is necessary that the ventilator is cycling, and preferably, that the ventilation is stabilized, aiming for greater patient safety.

6.3.17 Events History Area

In this menu, the history of events related to alarms, ventilation, maneuvering, settings, battery, calibration, actions and tests is displayed.

6.4 Automatic Breathing Circuit Compensation

For volumes and pressures, delivered and monitored, leaks are always considered because of circuit compliance and resistance.

In the event of failure in the compliance and resistance autotest, the efficiency of the compensations is maintained as long as the circuit used is compatible with the values defined in the Table 33 - Expiratory and inspiratory branch resistance specifications and Table *34* – Respiratory circuit compliance specifications.

7 Troubleshooting

In this topic, the main occurrences and possible solutions are presented.

Occurrence	Probable causes	Proposed solution
Low battery alarm	Depletion of internal battery charge.	*Connect the equipment to the mains or provide another means of ventilatory support.*
	Failure of the internal battery charging system, even with electrical power.	*Contact technical assistance for service.*
Disconnection Alarm	Disconnection in the respiratory circuit.	*Locate the disconnect point and firmly connect all parts of the breathing circuit.*
	Lack of inspiratory flow.	*Check for inspiratory flow and increase it if necessary.*
	Alteration of the patient's respiratory mechanics.	*Establish appropriate parameters for ventilatory support.*
	Expiratory valve diaphragm improperly placed or damaged.	*Replace or return the diaphragm to the correct position.*
	Failure of the electronic pressure control system.	*Contact technical assistance for service.*
Communication Failure Alarm	Electronic fault	*Contact technical assistance for service.*
High Pressure Alarm	Alteration of the patient's respiratory mechanics.	*Establish appropriate parameters for ventilatory support.*
	Obstruction in the expiratory branch of the respiratory tract or in the expiratory valve.	*Unclog the circuit or reposition the expiratory valve diaphragm.*
	Obstruction of the patient's airway.	*Clear or aspirate the patient's airway.*
	Monitored inspiratory pressure is higher than expected.	*Check the inspiratory (absolute) pressure setting, the value of which is the sum of the controlled (relative) pressure and PEEP.*
	Tube compensation is on.	*Turn off or reconfigure the automatic tube compensation.*
Low Pressure Alarm	Alteration of the patient's respiratory mechanics.	*Establish appropriate parameters for ventilatory support.*
	Excessive leakage in the breathing circuit.	*Locate the leak and fix it.*
Electrical network alarm	Disconnection of the power cord.	*Properly connect the power cable to the equipment or in case of intra-hospital transport, check that there is sufficient battery charge.*
	Fault in the mains supply.	*Try to re-establish the power grid.*
Inoperable alarms	Electronic failure.	*Contact technical assistance for service.*
Incorrect control of PEEP	Expiratory valve calibration.	*Restart the equipment and calibrate the expiratory valve.*

Occurrence	Probable causes	Proposed solution
Curves and/or vent loops appear with inappropriate scales or tracing speed.	Automatic adjustment of scales or graphic speed off.	*Tap on the graphic screen and select the automatic adjustment in the corresponding window.*
Curves and trend values do not appear or are incorrect.	System clock adjustment failed.	*Contact technical assistance for service.*
Equipment does not start ventilation	Equipment in standby mode (STAND BY).	*Press and hold the STAND BY button for 2 seconds to pull the ventilator out of standby mode.*
Failed proportional valve tests.	Oxygen mains pressure of the minimum limit.	*Check and readjust the mains pressure so that it reaches the specified range.*
Distal flow sensor test failed.	The outlet of the respiratory circuit was not occluded.	*Restart the ventilator and redo the autotest with the breathing circuit closed.*
Proximal flow and resistance sensor test failed.	The outlet of the breathing circuit was not released.	*Restart the ventilator and redo the autotest, remembering to open the breathing circuit when prompted.*
Expiratory valve test failure	The outlet of the respiratory circuit was not occluded.	*Restart the ventilator and redo the autotest with the breathing circuit closed.*
	The diaphragm of the expiratory valve	*Reposition the expiratory valve diaphragm, restart the equipment, and redo the autotest.*
It is not possible to activate automatic alarm setting.	Equipment in standby mode (STAND BY).	*Automatic alarm adjustment can only be calculated when the ventilator is cycling.* *Press the STAND BY button for 2 seconds to take the ventilator out of standby mode, wait for the ventilation to stabilize and only then activate the automatic adjustment.*
It is not possible to query the events that have occurred.	There isn't a loaded trend curve yet.	*Select a trend range before attempting to query the events.*
Adjusting the parameters returns to the previous value.	Adjustment has not been confirmed.	*Confirm the setting by pressing the rotate and confirm button or by tapping on the parameter that has been reset.*
Inspiratory or expiratory pauses do not end as soon as the respective button is released.	The minimum pause time set is longer than desired.	*Press the* ADVANCED MENU *button and reset the minimum pause time.*
Alarm sound is off	Alarm silence time activated.	*Turn off alarm silence.*
	Electronic failure.	*Contact technical assistance for service.*
Backup venting is not activated.	Apnea time alarm off.	*Set an interval for the apnea alarm.*

WARNING

- ***Never operate the equipment if a problem cannot be solved.***

8 Cleaning, Disinfection and Sterilization

This chapter provides information on ventilator maintenance procedures, as well as cleaning, disinfecting, and sterilization instructions. All procedures in this chapter must be performed by the operator.

WARNING

- ***Before use, perform all cleaning, sterilization, and disinfection procedures specified in this manual.***
- ***After cleaning and decontaminating the parts, be sure to perform all necessary tests as described in chapters 5 and 6.***

8.1 Equipment Cleaning

Observations

- *Make sure the machine is turned off to perform the display cleaning procedure.*
- *Care that no residue accumulates on the equipment connections.*
- *For cleaning, do not use products that are not compatible with polymers.*

The single-use breathing circuit (1707816 or 1710211) should be disassembled and discarded after each patient use or as needed.

The outer surfaces of the Oxymag Max ventilator, hose, touchscreen, power supply, and power cords should be cleaned with a clean, soft cloth moistened with enzymatic detergents (e.g., Empower), after each patient use or as needed.

To clean the equipment parts:

1. Disassemble all detachable parts:
    a. Disconnect the expiratory valve and diaphragm from the expiratory branch.
    b. Disconnect the inspiratory branch
    c. Disconnect the Flow Sensor Line
    d. Disconnect all parts of the breathing circuit
    e. Disconnect the oxygen hose
    f. Disconnect the AC/DC power supply

2. Prepare a solution with enzymatic detergent and warm water. Check the concentrations in the manufacturer's recommendations.
3. Dampen a lint-free cloth.
4. Clean the surface areas of the product and parts and remove external impurities by carefully rubbing the screw grooves, inspiratory flow connector hole, and expiratory flow connector with a soft cloth. Repeat the cleaning process if there are still visible impurities.
5. Inspect all areas and replace if damaged or if there is evidence of corrosion.
6. Continue with the disinfection procedure. Examples of acceptable cleaning products: Empower, Manufacturer: Metrex Research

WARNING

- ***The single-use breathing circuit should not be reused. Reuse may cause cross-contamination.***
- ***Do not allow blood or body fluids to dry on the equipment for more than 1 hour.***

8.2 Disinfection

The exterior surfaces of the Oxymag ventilator, hose, power supply, touchscreen, and power cords should be disinfected with a clean, soft cloth moistened with ethyl alcohol (70%) registered and approved by local government legislation or spray disinfectant, after each use on patient or as needed. The whole process can take approximately 20 minutes.

To disinfect the equipment:

1. First, run the cleaning process.
2. Do not reassemble loose parts
3. Use ethyl alcohol (70%) or spray sanitizer and moisten a lint-free cloth, or use ready-to-use disinfectant wipes.
4. Disinfect areas of equipment surfaces and parts.
5. Inspect all areas and replace if damaged/corroded.
6. Reassemble, prepare, and perform all necessary tests described in Chapters 4 and 5.

Example of acceptable disinfectant product:

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

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

ATTENTION

- ***Make sure that no residue accumulates on the equipment connections.***
- ***Do not clean/disinfect the interior of the ventilator to avoid damaging any internal components.***
- ***Be sure to clean only around the connection ports, not inside them.***
- ***For touchscreen cleaning, avoid using a gritty cloth.***
- ***DO NOT clean/disinfect the interior of the ventilator.***
- ***Make sure the machine is turned off before cleaning the display.***

WARNING

- ***Do not reuse disposable accessories. Reuse of single-use accessories can affect the properties of the product and cause injury to the patient.***
- ***To prevent premature deterioration of parts, use only cleaning and disinfecting solutions that are registered and approved by local government legislation as recommended by the manufacturer in chapter 8.***
- ***Do not use phenol (>5%), ketones, formaldehyde, hypochlorite, chlorinated hydrocarbons, aromatic hydrocarbons, inorganic acids, and quaternary ammonia compounds for cleaning or disinfection.***
- ***Never use saline solutions, especially sodium hypochlorite (bleach) and saline, disinfectants, hydrogen peroxide for cleaning or rinsing accessories and parts.***

8.3 Sterilization

After cleaning and disinfection, the accessories of the reusable breathing circuit should be sterilized in an autoclave (135°C for 5 minutes).

Table 6 – Autoclavable accessories

Description	Autoclave cycles (service life)
Reusable breathing circuit	50
Reusable Universal Flow Sensor	50
Reusable Silicone Lines	50
Exhalation valve	50
Expiratory valve diaphragm	50

8.4 Capnography Sensor (EtCO2)

To clean the capnography sensor, follow the instructions below:

1. Remove the Airway Adapter.
2. Clean the exterior surfaces until they are free of any visible residue, using one of the following solutions:
    a. A cloth dampened with 70% isopropyl alcohol
    b. A quaternary ammonium chloride solution solution (e.g., CaviWipes™)
        - Note: Pay special attention to crevices and hard-to-reach areas of the equipment.
    c. Use a soft-bristled brush to gently remove any visible residue from the crevices as needed.
1. Repeat the above cleaning step using a clean cloth or baby wipe.
2. Allow the capnography sensor to dry completely before using it again.

Capnography sensor surfaces have been tested to be chemically resistant to the following disinfectants/solutions:

- *Isopropyl alcohol 70%*
- *Ethanol 70%*
- *Quaternary Ammonium Chloride Solution*
- *Cidex Plus (3.4% glutaraldehyde)*
- *0.5% sodium hypochlorite (bleach solution 1:10)*
- *Accelerated hydrogen peroxide*

Always wipe off residues of disinfecting solutions with a damp cloth after exposure.

ATTENTION

- ***Do not immerse the capnography sensor in any liquid.***
- ***Do not apply excessive pressure to IR windows.***
- ***Never completely saturate the capnography sensor with any disinfectant solution.***

WARNING

- ***IRMA Airway Adapters should not be cleaned.***
- ***IRMA Airway Adapters are intended for single-patient use. They are disposable and should not be reused. Reuse of adapters for use in a single patient may cause cross-infection.***
- ***IRMA Airway Adapters should be disposed of in accordance with local regulations for biohazardous waste.***

8.5 Oximetry sensor (oximeter)

Masimo reusable sensors and cables come non-sterile and are not sterilizable.

To clean the oximeter sensor, follow the instructions below:

1. Remove the sensor from the patient and disconnect the equipment cable.
2. Dampen a cloth or gauze pad with a Masimo-approved cleaning solution* and wipe down all surfaces of the sensor and cable.
3. If using 70% isopropyl alcohol as a cleaning solution, allow the sensor to dry completely before placing it on a patient.
4. If using a cleaning solution other than 70% isopropyl alcohol, saturate another cloth or gauze pad with sterile or distilled water and wipe all surfaces of the sensor and cable. Then dry the sensor and cable with a clean cloth or dry gauze.

For cables:

1. Remove the cable from the equipment and remove any connected sensors or adapters.
2. Follow steps 2-4 above to clean all surfaces on the cable.

Masimo-approved cleaning solutions:

- Isopropyl alcohol 70%
- Bleach/water solution 1:10 (sodium hypochlorite solution 0.5% - 0.55%)
- Wet wipes preparations containing up to 0.55% sodium hypochlorite, such as Clorox Healthcare® Bleach Germicidal Wipes
- Solution of up to 2.5% glutaraldehyde, such as Metrex MetriCide™ 28
- Solutions with up to 55% alcohol/0.5% ammonium chloride, such as Ecolab Asepti-Wipe II Germicidal Wet Wipe and PDI Super Sani-Cloth Germicidal Wet Wipe®

ATTENTION

- ***Do not use undiluted bleach (5% – 5.25% sodium hypochlorite).***
- ***Do not immerse the sensor or connectors in any liquid solution.***
- ***Do not attempt to sterilize by any method.***

WARNING

- ***Masimo has not tested cleaning solutions and wipes containing chemicals other than those listed above and cannot guarantee that other cleaning solutions containing different chemicals are safe to use on all Masimo products. Do not use other cleaning chemicals.***

8.6 Processing Methods

Component	Processing Method		
	Neutral Enzyme Detergent	Alcohol 70%	Steam autoclave 135ºC for 5 min
Ventilator surface	✓	✓	x
Touchscreen	✓	✓	x
Reusable silicone breathing circuit	✓	✓	✓
Reusable Silicone Pressure Line	✓	✓	✓
Exhalation valve	✓	✓	✓
Diaphragm	✓	✓	✓
Reusable Universal Flow Sensor	✓	✓	✓
Sensor de SpO2	x	✓	x
Sensor de EtCO2	x	✓	x
Single-use breathing circuit	x	x	x
Single-use universal flow sensor	x	x	x
Single-use pressure line	x	x	x

9 Preventive Maintenance

WARNING

- ***The symbol***  ***displayed on the ventilator screen indicates that the equipment has entered the preventive maintenance period. For ICU equipment, this period is 5,000 hours or 12 months, whichever comes first.***
- ***Failure to perform maintenance may affect the safety and performance of the ventilator.***
- ***Servicing shall be carried out as directed by the manufacturer and only by an authorized technical service. Failure to do so will result in loss of warranty and manufacturer's obligations related to the ventilator.***
- ***Schedule preventive maintenance only with the authorized Magnamed technical service.***
- ***Before sending the equipment to the technical service, STRICTLY observe the cleaning and disinfection process.***
- ***Any service, modification or maintenance on the ventilator may only be performed by a qualified technician, trained and duly authorized by MAGNAMED.***

9.1 Verifications

The following checks should be made daily and every time the equipment is used:

- Integrity of the AC/DC converter power cord;
- Operation of the alarm system, including audio;
- Air/O2 filters installed and unobstructed;
- LCD display;
- Charged batteries;
- Touchscreen;
- Knob rotates and confirms;
- Correct installation of the respiratory circuit (including the diaphragm of the expiratory valve);
- Mesh filter installed.

WARNING

- ***Daily checking should be performed with the ventilator disconnected from the patient.***
- ***The Oxymag Max, its parts and accessories should not be serviced during use.***

9.2 Preventive Maintenance Schedule

Magnamed recommends performing preventive maintenance of the ventilators with its authorized network distributed throughout the country.

Below is a spreadsheet with the schedule of maintenance and replacement of preventive parts. If you need more details, please contact MagnaService (Magnamed Technical Assistance).

Table 7 – Preventive maintenance schedule

ITEM	Period									
	5000 h or 1 year	10000 h or 2 years	15000 h or 3 years	20000 h or 4 years	25000 h or 5 years	30000 h or 6 years	35000 h or 7 years	40000 h or 8 years	45000 h or 9 years	50000 h or 10 years
Evaluation according to Magnamed procedures	x	x	x	x	x	x	x	x	x	
Evaluation of the exchange of consumable materials	x	x	x	x	x	x	x	x	x	
LI-ION Battery		x		x		x		x		
O2 Cell		x		x		x		x		
Flowair						x				
Equipment Disposal										x

9.3 Consumable Items

Table 8 – Replacement of consumable items

ITEM	Period
Reusable Silicone Line	2 years or after 50 sterilization cycles
Diaphragm	2 years or after 50 sterilization cycles
Reusable Universal Flow Sensor	2 years or after 50 sterilization cycles
Reusable breathing circuit	2 years or after 50 sterilization cycles
Mesh Filter	500 h of use
Air/O2 Inlet Filter	Replace if it is obstructed
Single-Use Silicone Line	24 hours
Single-use flow sensor	24 hours
Single-use breathing circuit	24 hours

9.4 Internal Batteries

These batteries are responsible for maintaining the operation of the equipment even in the absence of electrical power and their duration in normal operation is specified in the chapter 10.

WARNING

- ***In order for there to be sufficient battery charge during a power outage, it is important that the equipment remains WHENEVER POSSIBLE, connected to an electrical power grid.***

ATTENTION

- ***In order for the batteries in normal operation to be fully capable, they shall be replaced as indicated in the technical specification.***
- ***Replacement of internal batteries shall be performed by trained and qualified personnel.***

9.5 Mesh Filter

ATTENTION

- ***The mesh filter is used for equipment protection. To protect the patient from contamination by bacteria and viruses, use a HEPA filter as specified in chapter 10.27 HEPA Filter.***

The mesh filter is used to protect the equipment from particulate matter suspended in the environment. To perform filter replacement, consider the following instructions:

Instruction	Image
Rotate the filter to the left side to remove. Fit the new filter and turn to the right side to lock.	

9.6 O2 Concentration Cell

This ventilator is equipped with O2 monitoring media for inspiratory oxygen concentration measurements in accordance with ISO 80601-2-55. This equipment measures the concentration of oxygen through the galvanic cell, which generates an electrical signal proportional to the concentration of oxygen in the gas mixture administered to the patient and the intensity of this electrical signal is due to the chemical reaction. This measuring medium is consumable, and the service life of the cell, according to the original manufacturer's specification, is 10,000 hours at 100% O2, i.e., more than one year of continuous use. However, we recommend switching to preventative maintenance on a 24-month or 10,000-hour schedule (whichever comes first).

ATTENTION

- ***The galvanic cell for measuring oxygen concentration should be replaced as indicated in the chapter 10.19.***
- ***Replacement should be performed by trained and qualified personnel.***
- ***The galvanic O2 cell undergoes degradation of less than 1% per month in the accuracy of the measurement.***

10 Technical Specifications

10.1 Classification

10.1.1 Class II Equipment

According to NBR – IEC – 60601, internally energized, type BF for continuous operation. IP34 dust-protected and splash-proof equipment.

10.1.2 Protection class of the applied parts

Patient circuit, flow sensor, oximetry sensor and capnography sensor are BF type.

10.1.3 ANVISA – Class III

According to RDC 751/22 – Classification rule 12 – All active medical devices intended for administering into the human body or removing medicinal products, body fluids or other substances from it are classified in class II, unless this is done in a potentially hazardous manner, taking into account the nature of the substances or the part of the body involved and the manner of application, in which case they are classified in Class III.

10.2 Applicable Standards

- **IEC 60601-1:2005 / A1:2012 (EN 60601-1:2006 + A1:2013) / ABNT NBR IEC 60601-1:2010 + EM1:2016 + EM2:2022** - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- **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
- **ISO 5359:2014/Amd 1:2017** - Low-pressure hose assemblies for use with medical gases
- **ABNT NBR IEC 60601-1-2:2017 + EM1:2022 / IEC 60601-1-2(2014) / (EN IEC 60601-1-2:2015)** - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- **IEC 62304:2006 +AMD1:2015 (EN 62304:2006/2008)** - Medical device software - Software life-cycle processes
- **IEC 60601-1-8 Ed. 2.0 (2006)/A1:2012/ A2:2020 (EN 60601-1-8:2007/A11:2017) / ABNT NBR IEC 60601-1-8:2010 + EM1:2014 + EM2:2022** - Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

- **IEC 60601-1-6:2010 + AMD1:2013 + AMD2:2020 (EN 60601-1-6:2010 + AMD1:2013 + AMD2:2020) / ABNT NBR IEC 60601-1-6:2011 + EM1:2020 + EM2:2022** - Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- **IEC 62366:2007 (EN 62366:2008)** - Medical devices - Application of usability engineering to medical devices
- **EN ISO 17665-1:2006 -** Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- **EN ISO 17664:2004 -** Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
- **EN 1041:2008 -** Information supplied by the manufacturer of medical devices
- **ISO 15223-1:2021 (EN ISO 15223-1:2021) -** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- **ISO 80601-2-55:2018 (EN 80601-2-55:2018) / ABNT NBR ISO 80601-2-55:2020** - Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- **ISO 80601-2-61:2011 / ABNT NBR ISO 80601-2-61:2015:** Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- **IEC 60601-1-9:2007 + AMD1:2013 + AMD2: 2020 / ABNT NBR IEC 60601-1-9:2010 + EM1:2014 + EM2:2022 (clauses 4.1, 4.5.2 and 4.5.3) -** Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
- **IEC 60601-1-12:2014 / ABNT NBR IEC 60601-1-12:2020:** 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

10.3 Physical and Environmental Specifications

Table 9 - Physical and environmental specifications

Parameter		Specification	Tolerance	Unit
Dimensions & Weight – With Handle (Basic Unit)				
a.	Height	210	± 5	mm
b.	Width	287	± 5	mm
c.	Depth (with handle)	224	± 5	mm
d.	Weight	5,2	± 0,15	kg

Parameter		Specification	Tolerance	Unit
Operation [1]				
a.	Temperature	-18 to 50	---	°C
b.	Barometric pressure	600 to 1100	---	hPa
c.	Relative humidity (non-condensing)	15 to 95	---	%
Storage [1]				
a.	Temperature	-25 to 70	---	°C
b.	Barometric pressure	500 to 1200	---	hPa
c.	Relative humidity (non-condensing)	5 to 95	---	%
Lifetime				
Oxymag Max 300		10	---	years
Time for equipment to reach operating temperature				
Time to heat or cool equipment stored at extreme temperatures to operate at 20°C		30	---	minutes

[1] Permissible operating and storage conditions for the entire electromedical system.

WARNING

- ***Do not expose the product to extreme temperatures beyond that specified in 10.3 during use. Equipment performance may be adversely affected if the operating temperature is outside the specified limits.***

10.4 Electrical Specifications

10.4.1 Electrical network

Item	Specification	Tolerance	Unit
Electrical Network (50/60Hz)	100 to 240	± 10%	VAC
Maximum power consumed	80	± 10%	VA

Item	Specification	Tolerance	Unit
AC cable	Connector (equipment side): According to IEC 60320, type C13 Plug: According to local legislation Electrical Requirements: Compatible with the power supply specifications of each equipment (Voltage and Current). Check the marking on the machine.		

10.4.2 Batteries

Item	Specification	Tolerance	Unit
Internal Li-Ion 14.8 VDC batteries	4000	± 15%	mAh
Battery life of internal batteries (at full charge and normal use)(2)	390	± 15%	min
Average time to recharge to full load (module in operation)(1)	240	± 15%	min

(1) The battery should be charged at an ambient temperature of 5 to 35 ºC
(2) Adult patient in VCV mode and default parameters.

10.4.3 External DC power supply

Item	Specification	Tolerance
Power Supply(1)	Voltage: 12 to 15 VDC	± 10%
	Current: 11.5 A	

(1) OPTIONAL external power supply

ATTENTION

- ***It is not possible to recharge the equipment's internal batteries via the external DC power source.***
- ***The sole purpose of this input is to allow the equipment to be temporarily powered by a compatible external power source when there are no other alternatives.***
- ***In ventilation, before turning off an external power source, make sure there is enough charge in the internal batteries or connect the equipment to the electrical network.***

10.4.4 Connectors

Table 10 - Connectors

Connector	Specification
External power supply network	3 (three) pin connector, center ground pin. According to ABNT NBR 14136:2012
External power supply	External auxiliary power input from 12 to 15V. Connector housing 3.96mm – 4-pin 180º female Color - Green
External Sensor: Capnograph(1)	Redel connector – 5-pin female receptacle Color - Blue
External Sensor: Oximeter(1)	Redel connector – 5-pin female receptacle Color - Blue
Standard RS-232 connector (EIA RS-232C)	DB9 Female Type (On Top) Used for maintenance services and data transfer through ARM (Magnamed Remote Assistance), only by people authorized and trained by Magnamed.
Data Out Connector (Network)	Standard RJ-45 Ethernet connector Used to send data to an electronic health recorder Use a CAT 5E cable category conforming to ANSI/TIA/EIA-568 or higher with a maximum length of 3 meters to connect to the ventilator's network port.
Standard USB connector	Used to transfer screenshots, trends, logs, and recordings to an external USB memory storage device ("flash drive"). It can also be used to software update, only by persons trained and authorized by Magnamed. Be sure to use only known and trusted USB devices. Do not use stop purposes other than described in that paragraph.

(1) Optional

ATTENTION

- ***Connected devices shall be approved medical devices in accordance with IEC 60601-1.***
- ***Use only certified cables on the equipment connectors.***
- ***Connecting the ventilator to an IT network may result in risks to the patient, operator, or third parties, which have not been previously identified. The responsible organization must identify, analyze, assess, and control these risks.***
- ***Subsequent changes to the IT network may introduce new risks and require additional analysis by the responsible organization. Changes to the IT network include: configuration changes, connecting additional items, disconnecting items, upgrading equipment connected to the IT network, and improving equipment connected to the data communication port.***
- ***Failure to implement the communication protocol will result in the failure to send data to other equipment.***

10.4.4.1 Protocol used for data communication with external devices

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

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

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

The information is transferred in the same way: the Oxymag Max sends the data to the electronic health recorder which responds that it has received it. The electronic health recorder may perform questions or request for data to the Oxymag Max, which immediately responds or confirms the request.

ATTENTION

- ***For the communication protocol implementation guide, contact MagnaService.***
- ***This implementation should be carried out on a network with the characteristics described in 10.4.4.1 by an IT specialist.***
- ***Failures of the IT network to provide the required characteristics can cause delays in data communication or transmission of incorrect, incomplete or corrupted data, resulting in incorrect information for the user.***

10.4.5 Gas inlet connections

Table 11 – Gas inlet connections

Item	Specification
Connections	According to ABNT NBR 11906:2011
Hose & Extension	According to ISO 5359:2014/Amd 1:2017
Oxygen Inlet Pressure	200 to 600 kPa (29 to 87 psi)

Breathing Circuit	ISO 5367:2014 compliant

ATTENTION

- ***Inlet pressures exceeding the specified limit may damage the equipment.***
- ***For inlet pressures less than 250 kPa, the maximum flow rate will be 120 L/min.***

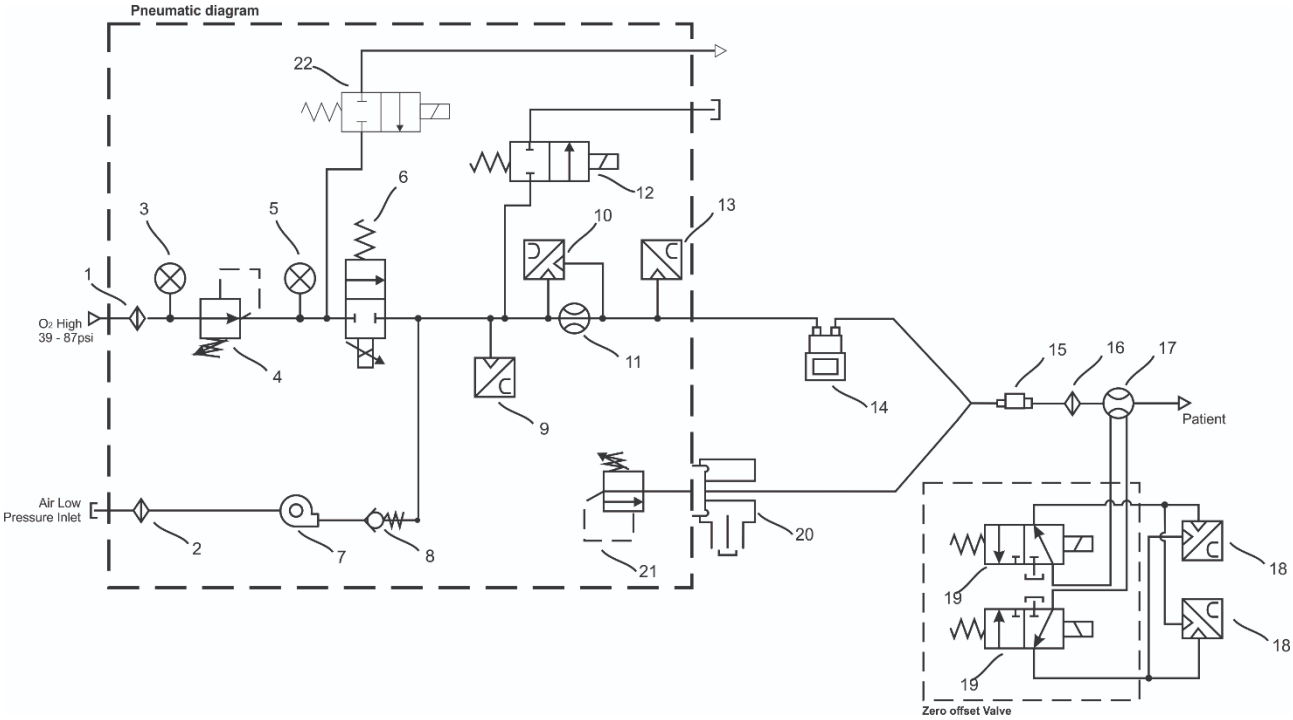
Observations

- *All the materials that make up the product are compatible with oxygen gas, ambient air and medical compressed air.*

10.5 Pneumatic Specifications

10.5.1 Pneumatic diagram

10.5.1.1 Oxymag Max 300



1	Mesh Filter	12	Overpressure valve
2	Air Intake Filter	13	Measuring point (inspiratory pressure)
3	High Pressure Sensor	14	Humidifier (optional)
4	Pressure Regulating Valve	15	Capnograph (optional)
5	High Pressure Sensor	16	HME or HEPA filter (optional)
6	30 lpm proportional valve	17	Universal Flow Sensor
7	Flow Air	18	Measuring point (proximal differential pressure)
8	Check Valve	19	X-1 Offset Zero Valve / 6 psi Solenoid Valve
9	O2 cell measuring point	20	Exhalation valve
10	Measuring Point (Internal Flow Sensor)	21	Linear actuator
11	Internal Flow Sensor	22	x-5 solenoid valve 100 psi (Neb/TGI)

10.6 Internal Flow Transducer Specifications

Table 12 – Internal Flow Transducer – General Specifications

General Specifications	
The internal flow transducer contains two sensors, one for flow and the other for measuring temperature. Each sensor has an independent non-linear voltage output. To determine the mass flow of gas passing through the transducer, the output voltage of each of the sensors is measured. A microprocessor processes the results and calculates the flow using a specific algorithm. The circuit that measures flow is typically known as a thermal sensor or hot wire anemometer. This flow transducer uses a wire sensor that is heated and kept at a temperature of 150°C. The velocity of the gas passing through the sensor determines the rate of heat transfer between the sensor and the gas. This rate of heat transfer is translated into a voltage required to maintain the temperature at 150°C. Consequently, this voltage is a function of the mass flow of gas passing through the sensor. The heat transfer rate is also influenced by the gas temperature. A thermistor circuit is used to measure the temperature of the gas and a correction is also made through a specific algorithm.	
Reading Range	Air: 0 to 300 SLPM O2: 0 to 300 SLPM
Specified Tolerance	Air: 2.0% or 0.05 SLPM (whichever is greater) O2: 2.0% or 0.05 SLPM (whichever is greater)
Resistance	< 2.5mbar
Gas Temperature Range	5 to 46°C
Humidity range	Dry gas (< 10% UR)
Operating Pressure	Atmospheric pressure
Feeding	5V ±10% sensor and 2.7V – 5.5V Eeprom
Response Time	< 2.5ms
Burst pressure	above 100 psi
Weight	21g

10.7 Universal Flow Sensor Specifications

Table 13 – Universal Flow Sensor – General Specifications

General Specifications	
Intended Use	Measure the patient's inspired and exhaled flow
Working Principle	Pressure differential
Reading Range	-180 to 180 SLPM
Tolerance	± 10%
Material	PSU

10.8 Pressure Sensor Specifications

Table 14 – Pressure Sensor – General Specifications

General Specifications	
Intended Use	Measure patient-inspired pressure
Working Principle	Pressure differential
Reading Range	-60 to 120 cmH2O
Tolerance	± 5% (0 to 85°C)
Sensitivity	90mV/kPa
Response Time	< 1ms

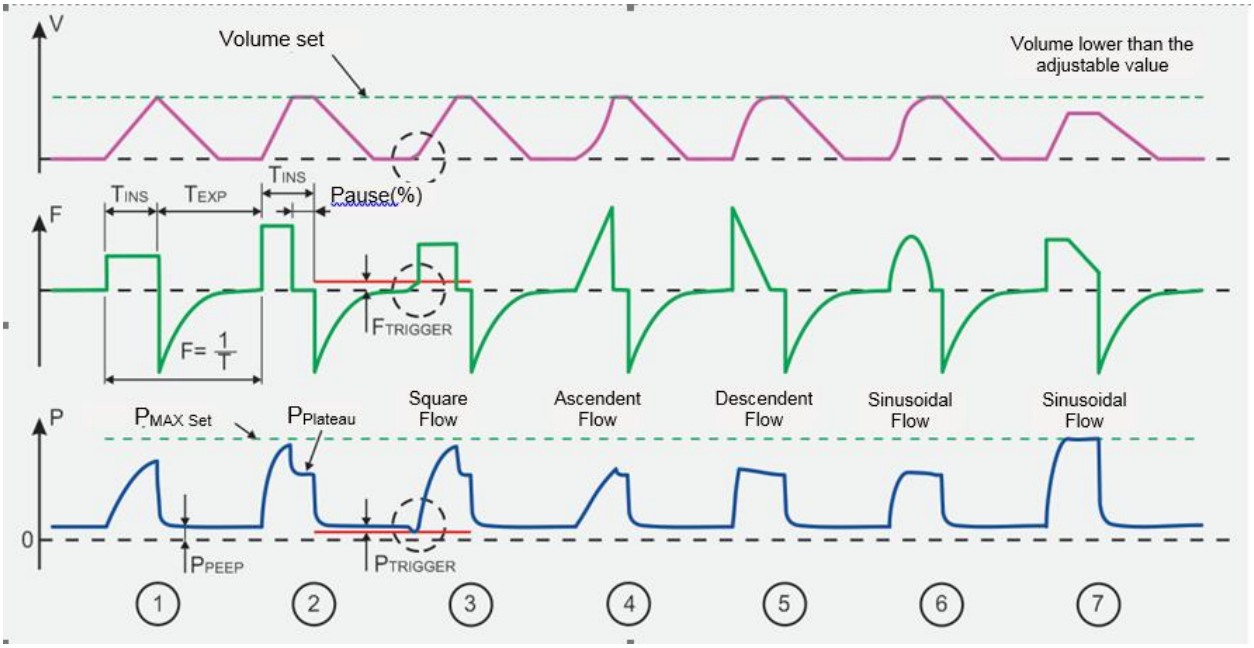
10.9 Galvanic O2 Cell Specifications

General Specifications	
Intended Use	Measure the concentration of O2 delivered from the equipment to the patient
Measuring range	0 to 100%
Output Signal	9 – 13 mV
Response Time 90%	13 sec.
Precision	± 2%
Linearity	± 2%
Recommended Flow Rate	0.1 – 10 lpm
Data Sampling Rate	7 Hz

General Specifications	
Method for Calculating Gas Level Reading	Simple Moving Average (SMA) 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 Steam Interference	
Gases or Vapor	**Gas Level**
80% NO Response	< 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%
10% CO2 response	< 5%

10.10 Ventilatory Modes Specifications

10.10.1 VCV

VCV – Mandatory volume-controlled ventilation	
Description: In this mode, the respiratory rate, tidal volume, and inspiratory flow (or inspiratory ratio or time) are set. The onset of inspiration (triggering) occurs according to the pre-established respiratory rate. triggering occurs exclusively for time, if the sensitivity setting is off. The transition between inspiration and expiration (cycling) occurs after release of the pre-set tidal volume at given velocity through the flow (or ratio or inspiratory time).	Set Parameters: • VOLUME • RESPIRATORY RATE • FLOW or RATIO I:E or INS TIME • PEEP • O2 CONCENTRATION • LIMIT PRESSURE • INSP PAUSE (% or s) • PRESSURE TRIGGER • FLOW TRIGGER • FLOW WAVEFORM Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.
	

As soon as all the ventilation parameters are received by the ventilator, it calculates the T_{INS}, T_{EXP}, T_{PAUSE} and I:E Ratio, as a function of the adjusted Flow, Pause, Wave and Frequency, thus obtaining all the ventilation control times.

1. Ventilation without Inspiratory Pause, after the T_{INS} the ventilator cycles to expiration. The inspiratory pressure reached is a consequence of the volume delivered and the resistance and compliance of the patient's respiratory circuit.
2. Ventilation with Inspiratory Pause, after delivery of the adjusted volume the ventilator maintains interrupted exhalation until completing T_{INS}, after which the ventilator cycles to expiration, the characteristic is the formation of a pressure plateau (the unevenness between the peak and the plateau depends on the resistance of the airways).
3. If the pressure or flow trigger is activated, then the ventilator tries to synchronize the beginning of the next inhale with the patient's effort, according to the established levels. The information of what type of shot was the one that activated the inspiratory cycle is informed in the status and messages area. The detection of the patient's inspiratory effort for synchronization occurs at any moment of expiratory time.

Observation

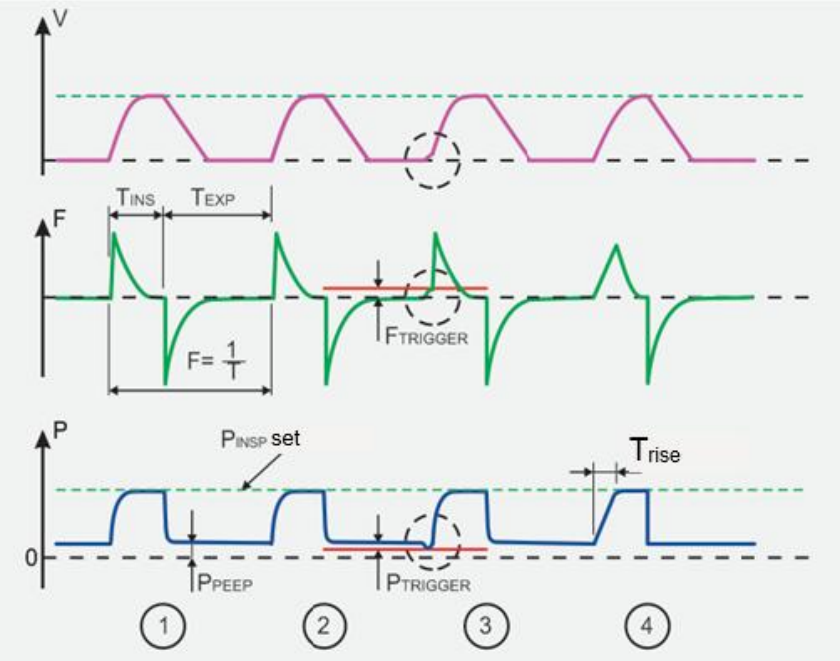
- *If the patient performs inspiratory efforts and the sensitivities are adequately adjusted, the ventilatory mode becomes assisted-controlled. In this situation, the monitored respiratory rate may be significantly higher than the adjusted one.*

4. ASCENDING (or accelerated) waveform of flow.
5. DESCENDING (or decelerated) waveform of flow.
6. SINUSOIDAL flow waveform.
7. Representation of Pressure Limiting. In this situation, the ventilator limits the pressure to the set value and as a consequence of factors such as the patient's lung compliance and the pressure limit imposed, the set volume is NOT DELIVERED and this condition is reported in the alarms area of the screen (PRESSURE LIMITED message).

WARNING

- ***Upon reaching the pressure limit set in the maximum pressure setting (PRESSURE LIMITED alarm), the set volume is NOT DELIVERED.***
- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***

10.10.2 PCV

PCV – Mandatory Pressure Controlled Ventilation	
Description: In this ventilatory mode, the respiratory rate, the inspiratory time, and the inspiratory pressure limit are set. The onset of inspiration (triggering) occurs according to the pre-established respiratory rate. The trigger, if the sensitivity adjustment is deactivated, is determined exclusively by the respiratory rate, and cycling (end of inspiration and beginning of expiration) is determined by the inspiratory time. The tidal volume depends on the preset inspiratory pressure, the respiratory system impedance conditions and the inspiratory time selected by the operator.	Set Parameters: • INSPIRATORY PRESSURE • RESPIRATORY RATE • INSP TIME • PEEP • O2 CONCENTRATION • RISE TIME • PRESSURE TRIGGER • FLOW TRIGGER • FLOW ($\dot{V}$ - NEONATAL) Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.
	

As soon as all the ventilation parameters are set on the ventilator, it calculates the period, T_{EXP} and the I:E Ratio as a function of T_{INS} and Frequency, thus obtaining all the ventilation control times.

1. Pressure Controlled Ventilation – The ventilator seeks to achieve the adjusted inspiratory pressure in the shortest possible time, and this is accomplished by controlling the inspiratory flow.
2. The volume delivered to the patient is a consequence of the resistance and compliance of his respiratory circuit. The ventilator remains at the set inspiratory pressure level during T_{INS} after which it cycles to expiration, maintaining the adjusted PEEP pressure.
3. If the pressure or flow trigger is activated, then the ventilator tries to synchronize the beginning of the next inhale with the patient's effort, according to the established levels. The information of what

type of shot it was that activated the inspiratory cycle is informed in the status and messages area of the screen. The detection of the patient's inspiratory effort for synchronization occurs at any moment of expiratory time.

Observation

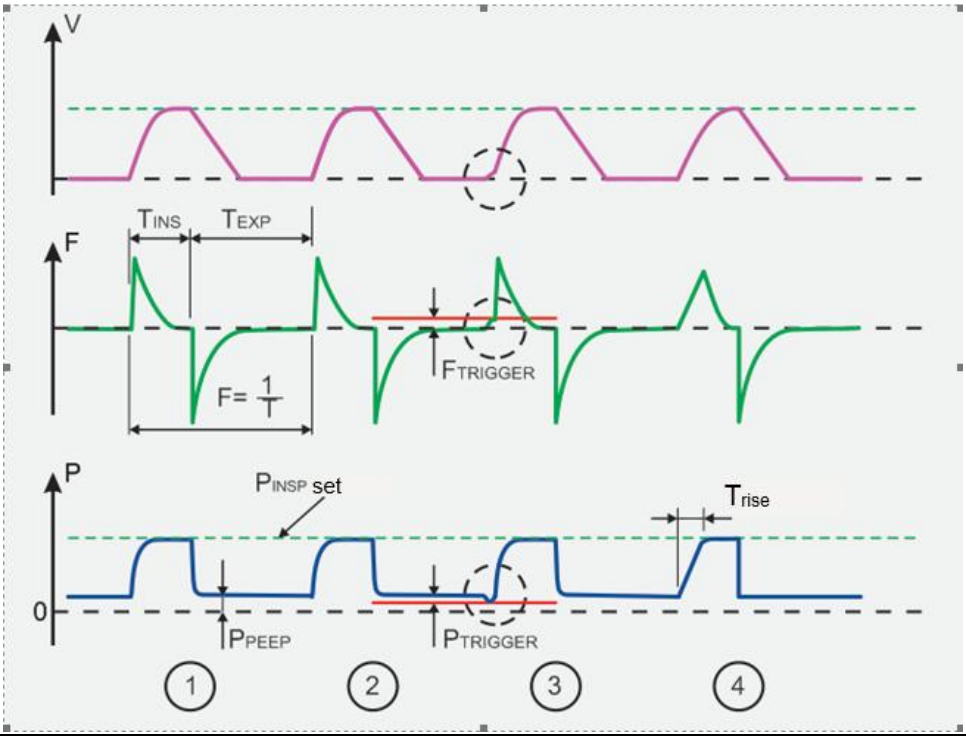
- *If the patient performs inspiratory efforts and the sensitivities are adequately adjusted, the ventilatory mode becomes assisted-controlled. In this situation, the monitored respiratory rate may be significantly higher than the adjusted one.*

4. The rise time of the pressure can be adjusted by T_{RISE} (RISE TIME), the initial peak flow is generally lower than that in which T_{RISE} = 0 (depends on the resistance and compliance of the patient's respiratory circuit).

WARNING

- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***

10.10.3 PLV

PLV – Limited Pressure Ventilation	
Description: In this bias-flow ventilatory mode, the respiratory rate, inspiratory time, and inspiratory pressure limit are set. The onset of inspiration (triggering) occurs according to the pre-established respiratory rate. The trigger, if the sensitivity adjustment is disabled, is determined exclusively by the respiratory rate, but cycling (end of inspiration and beginning of expiration) occurs according to the inspiratory time. The tidal volume depends on the preset inspiratory pressure, the respiratory system impedance conditions and the inspiratory time selected by the operator. Usually by observing the flow curve, you see a peak of flow that decreases as time goes by.	Set Parameters: • INSPIRATORY PRESSURE • RESPIRATORY RATE • INSP TIME • PEEP • O2 CONCENTRATION • FLOW($\dot{V}$) • PRESSURE TRIGGER • FLOW TRIGGER Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.
	

As soon as all the ventilation parameters are set on the ventilator, it calculates T_{EXP} as a function of Frequency and T_{INS}, thus obtaining all ventilation control times.

1. Pressure Limited Ventilation – The ventilator seeks to achieve the adjusted inspiratory pressure, and this is accomplished by occlusing the expiratory valve. It is important to note that the pressure rise time is dependent on the adjusted continuous flow.
2. The volume delivered to the patient is a consequence of the resistance and compliance of his respiratory circuit. The ventilator remains at the set inspiratory pressure level during T_{INS} after which it cycles to expiration, maintaining the adjusted PEEP pressure.
3. If the pressure or flow trigger is activated, then the ventilator tries to synchronize the beginning of the next inhale with the patient's effort, according to the established levels. The information of what type of trigger was the one that activated the inspiratory cycle is informed in the message and status area of the screen. Detection of the patient's inspiratory effort, for synchronization, occurs at any time during expiratory time.

WARNING

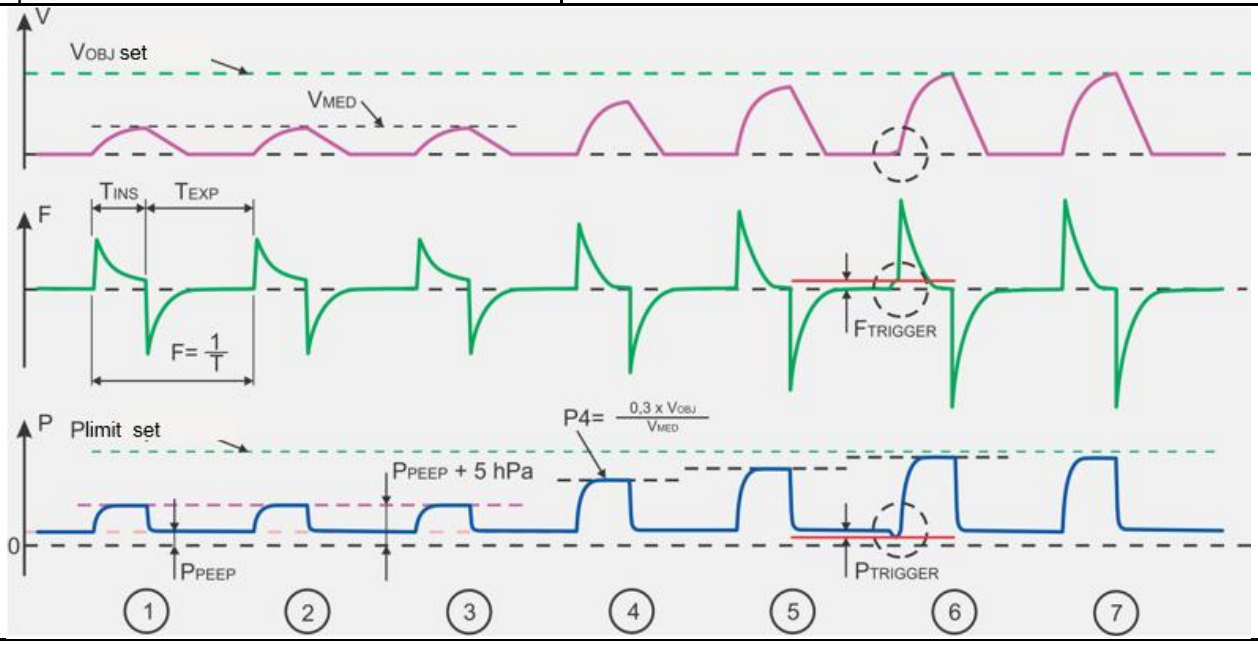
- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***
- ***The operator shall consider the inspiratory time and respiratory mechanics of the patient to define the bias flow adjusted. If the flow is not enough, the airway pressure may not reach the adjusted value.***

Observation

- *If the patient performs inspiratory efforts and the sensitivities are adequately adjusted, the ventilatory mode becomes assisted-controlled. In this situation, the monitored respiratory rate may be significantly higher than the adjusted one.*

10.10.4 PRVC

PRVC – Volume controlled with regulated pressure	
Description: Time-limited, pressure-limited cycling mode that uses tidal volume as feedback to continuously adjust the pressure limit. The first three respiratory cycles are in volume-controlled mode, allowing the ventilator to calculate respiratory mechanics. In the next cycles the ventilation is distributed with pressure limit and cycled by time to reach 60% of the adjusted volume. The onset of inspiration (triggering) occurs according to the pre-established respiratory rate. The end of the inspiration and beginning of the expiration (cycling) happens according to the adjusted inspiratory time. At each cycle the ventilator adjusts the pressure limit (5 cmH2O up) according to the tidal volume distributed in the previous cycle, until the tidal volume indicated by the operator is reached. The maximum pressure limit is 5 cmH2O below the pressure limit indicated by the operator.	Set Parameters: • VOLUME • LIMIT PRESSURE • RESPIRATORY RATE • INSP TIME • PEEP • O2 CONCENTRATION • RISE TIME • PRESSURE TRIGGER • FLOW TRIGGER Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.



As soon as all the ventilation parameters are set on the ventilator, it calculates the T_{EXP} as a function of Frequency and T_{INSP}, thus obtaining all the ventilation control times.

1,2,3. Lung compliance assessment phase. After obtaining the compliance value, the ventilator automatically adjusts a pressure value to reach 60% of the set volume, and then the ventilator automatically adjusts the pressure every three PCV cycles.

4,5. Start of automatic pressure control to reach the set volume.

6. If the pressure sensitivity and flow sensitivity are active, then the ventilator seeks to synchronize the onset of the next inspiration to the patient's effort, according to the configured sensitivity. Detection of the patient's stress "window" for synchronization begins in the last quarter of the controlled ventilation period.
7. Volume reached.

WARNING

- ***Upon reaching the pressure limit set in the maximum pressure setting (PRESSURE LIMITED alarm) the set volume is NOT DELIVERED.***
- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***

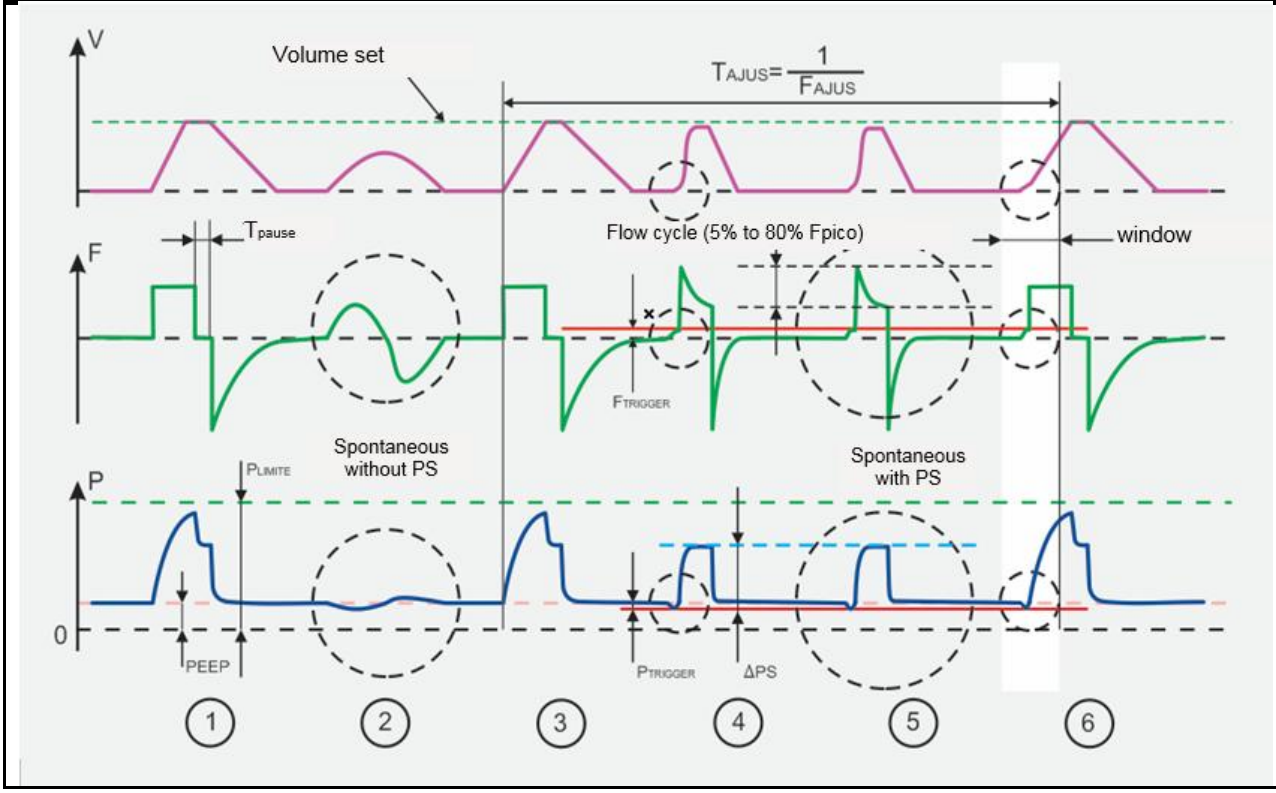
Observation

- *If the patient performs inspiratory efforts and the sensitivities are adequately adjusted, the ventilatory mode becomes assisted-controlled. In this situation, the monitored respiratory rate may be significantly higher than the adjusted one.*
- *Automatic pressure control occurs with PEEP + 5cmH2O and PLimite*

10.10.5 V-SIMV

V-SIMV - Volume controlled synchronized intermittent mandatory ventilation	
Description: In V-SIMV, the respiratory rate, tidal volume and inspiratory flow or inspiratory time or ratio are set, as well as the trigger criterion for the occurrence of ventilator triggering by the patient. This mode allows the ventilator to apply predetermined preset cycles in sync with the patient's inspiratory effort. Mandatory cycles occur in the pre-determined window of time (the onset of inspiration occurs according to the pre-established respiratory rate), but synchronized with the patient's trigger. If there is apnea, the next cycle will be triggered by time until the patient's inspiratory incursions return. The transition between inspiration and expiration in the mandatory cycles occurs after release of the pre-set tidal volume at given velocity through the flow (or ratio or inspiratory time). In spontaneous cycles, cycling (transition between inhalation and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value. In order to obtain the IMV in this mode, simply deactivate the support pressure by setting the support pressure equal to zero (ΔPS = 0) or the flow and pressure sensitivities, equal to zero.	Set Parameters: • VOLUME • RESPIRATORY RATE • FLOW or RATIO I:E or INS TIME • PEEP • O2 CONCENTRATION • FLOW WAVEFORM • PAUSE (%) • PRESSURE TRIGGER • FLOW TRIGGER • ΔPS (Pressure Bearing – PEEP) • RISE TIME • FLOW CYCLING (% FLOW) • LIMIT PRESSURE Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

V-SIMV - Volume controlled synchronized intermittent mandatory ventilation



As soon as all the ventilation parameters are set in the ventilator, it calculates the T_{INSP} and T_{EXP} as a function of the Flow, Pause, Wave and Rate, thus obtaining all the ventilation control times.

1. Represents a cycle of VCV (controlled volume) with inspiratory pause;
2. Represents a spontaneous breathing cycle WITH NO PRESSURE SUPPORT;
3. Represents a cycle of VCV (volume controlled) after the SIMV period;
4. It represents a cycle of spontaneous breathing WITH PRESSURE SUPPORT, which is cycled by flow, as soon as it falls to a certain percentage of its maximum value reached.
5. The percentage of peak flow at which cycling from the inspiratory phase to the expiratory phase occurs is programmable. The rise time (T_{RISE}) also applies to the support pressure (see PCV).
6. If the patient performs inspiratory effort, at the end of the SIMV period there is a window for the synchronism of the controlled ventilation cycle, which is 'opened' from 0.75 x TSIMV, i.e., in the last quarter of the SIMV period, a synchronism window of the mandatory ventilation cycle opens. The information of what type of trigger was the one that activated the inspiratory cycle is informed in the message and status area of the screen.

WARNING

- ***The adjusted support pressure (ΔPS) is a value above the PEEP. Therefore, inspiratory pressure support will be the sum of PEEP and ΔPS.***
- ***Default values are initial reference only.***

- ***Readjust the ventilation parameters as per the patient's needs.***

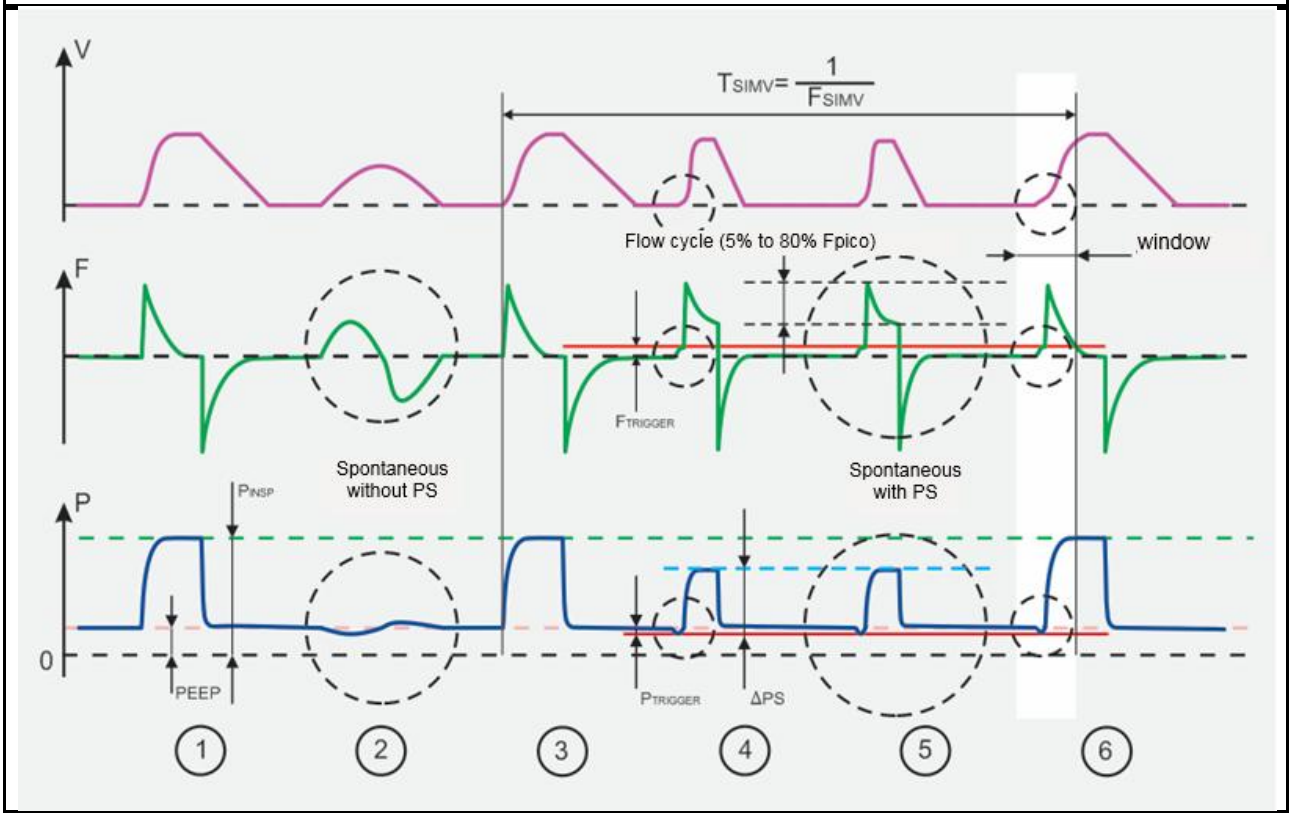
Observation

- *The monitored respiratory rate may be higher than the adjusted respiratory rate, as the patient may breathe spontaneously during mandatory ventilation cycles.*

10.10.6 P-SIMV

P-SIMV – Pressure controlled synchronized intermittent mandatory ventilation	
Description: In P-SIMV, the respiratory rate, inspiratory pressure and inspiratory time are set, as well as the sensitivity criterion for the occurrence of ventilator triggering by the patient. This mode allows the ventilator to apply predetermined preset cycles in sync with the patient's inspiratory effort. Mandatory cycles occur in the pre-determined window of time (the onset of inspiration occurs according to the pre-established respiratory rate) but synchronized with the patient's trigger. If there is an apnea, the next cycle will be triggered for time until the patient's inspiratory incursions return. The transition between inspiration and expiration in the mandatory cycles occurs after release of the pre-set tidal volume at given velocity through the flow (or ratio or inspiratory time). In spontaneous cycles, cycling (transition between inhalation and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value. In order to obtain the IMV in this mode, simply deactivate the support pressure by setting the support pressure equal to zero (ΔPS = 0) or the flow and pressure sensitivities, equal to zero.	Set Parameters: • INSPIRATORY PRESSURE • RESPIRATORY RATE • INSP TIME • PEEP • O2 CONCENTRATION • RISE TIME • ΔPS (Support Pressure – PEEP) • FLOW CYCLING (% FLOW) • PRESSURE TRIGGER • FLOW TRIGGER • FLOW ($\dot{V}$ - NEONATAL) Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

P-SIMV – Pressure controlled synchronized intermittent mandatory ventilation



As soon as all the ventilation parameters are set on the ventilator, it calculates the T_{EXP} as a function of the T_{INS} and Rate, thus obtaining all the ventilation control times.

1. Represents a pressure-controlled (PCV) cycle during TINS
2. Represents a spontaneous breathing cycle WITH NO PRESSURE SUPPORT;
3. It represents a cycle of PCV (controlled pressure) after the SIMV period;
4. It represents a cycle of spontaneous breathing WITH PRESSURE SUPPORT, which is cycled by flow, as soon as it falls to a certain percentage of its maximum value reached.
5. The percentage of peak flow at which cycling from the inspiratory phase to the expiratory phase occurs is programmable. The rise time (T_{RISE}) also applies to the support pressure (see PCV).
6. If the patient performs inspiratory effort, at the end of the SIMV period there is a window for the synchronism of the controlled ventilation cycle, which is 'opened' from 0.75 x TSIMV, i.e., in the last quarter of the SIMV period, a synchronism window of the mandatory ventilation cycle opens. The information of what type of trigger was the one that activated the inspiratory cycle is informed in the message and status area of the screen.

WARNING

- ***The adjusted support pressure (ΔPS) is a value above the PEEP. Therefore, inspiratory pressure support will be the sum of PEEP and ΔPS.***

- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***

Observation

- *The monitored respiratory rate may be higher than the adjusted respiratory rate, as the patient may breathe spontaneously during mandatory ventilation cycles.*

10.10.7 CPAP/PS

<table>
<tr><th colspan="2">CPAP/PS – Spontaneous ventilation with positive airway pressure and pressure support</th></tr>
<tr>
<td>Description:

In CPAP / PS, the ventilator allows the patient to breathe spontaneously, but provides continuous pressurization in both inspiration and expiration, and assist ventilation during inspiration by maintaining a supporting pressure until the patient's inspiratory flow is reduced to a critical (adjustable) level of inspiratory peak flow reached.

The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time.

This allows the patient to control the respiratory rate and inspiratory time, and thus the volume of inspiratory air.

Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.

If the support pressure value (ΔPS) is set to 0 (ZERO) and the means for cycle triggering are both turned off, ventilation with pure CPAP mode will be activated, which is a mode of spontaneous ventilation not assisted by the ventilator.

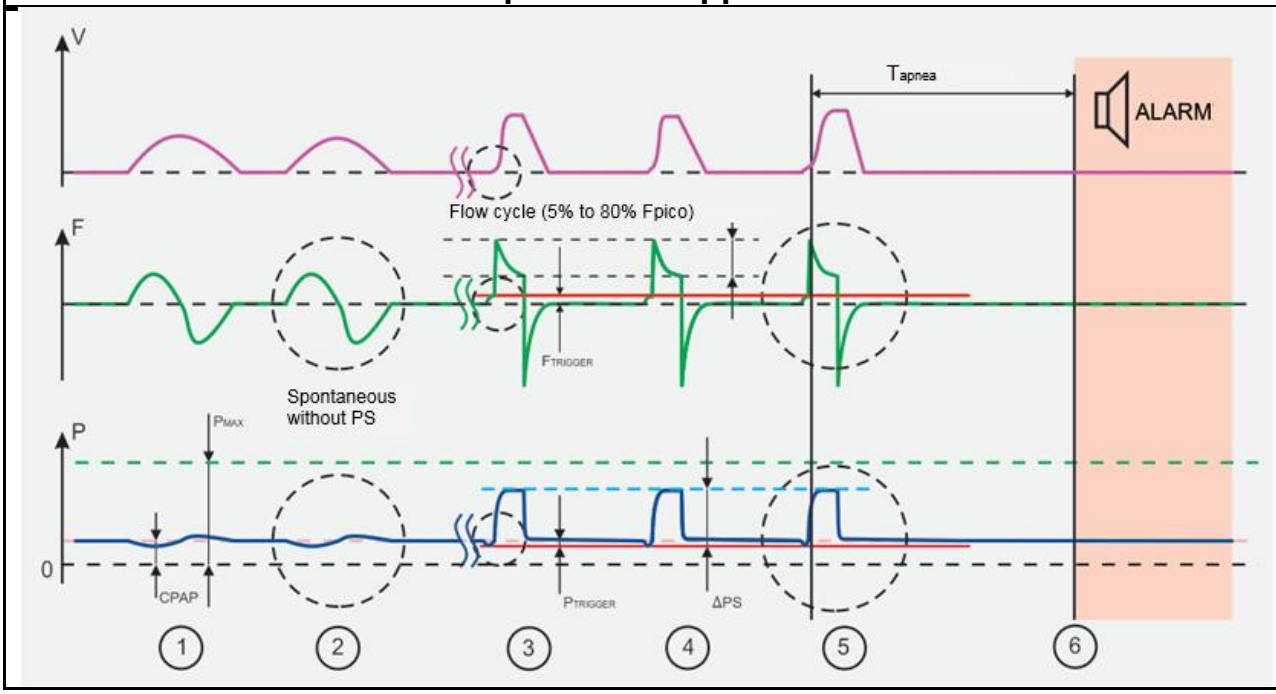
The tidal volume depends on the respiratory effort of the patient and the conditions of respiratory mechanics of the lung and chest wall.</td>
<td>Set Parameters:

• PEEP/CPAP
• O2 CONCENTRATION
• ΔPS (Support Pressure – PEEP)
• FLOW CYCLING (% FLOW)
• RISE TIME
• PRESSURE TRIGGER
• FLOW TRIGGER
• FLOW (NEONATAL)
• BACKUP

○ Backup VCV
▪ VOLUME
▪ R. RATE
▪ FLOW
▪ LIMIT PRESSURE
○ Backup PCV
▪ INSP PRESSURE
▪ R. RATE
▪ INSP TIME
▪ RISE TIME

○ Backup PLV-NEONATAL
▪ INSP PRESSURE
▪ R. RATE
▪ INSP TIME
○ Auto Backup(1)
1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.</td>
</tr>
</table>

CPAP/PS – Spontaneous ventilation with positive airway pressure and pressure support



1 and 2. They represent spontaneous cycles with the support pressure at ZERO.

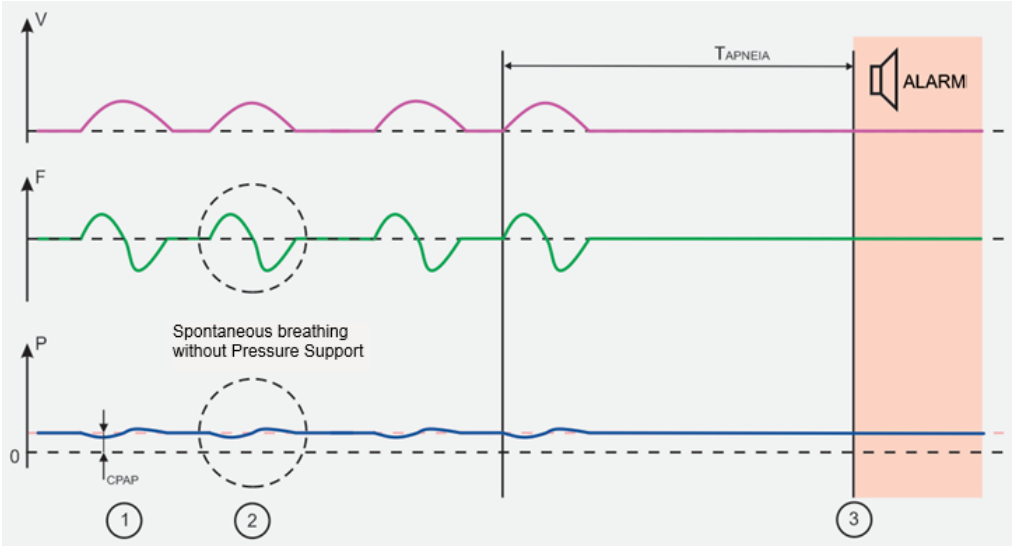
3, 4 and 5. They represent cycles of spontaneous breathing of the patient with pressure support greater than zero. T_{RISE} (Rise Time) of the support pressure can be adjusted so that the initial flow is smoothed.

Cycling occurs by flow, as soon as it drops to a certain percentage of its maximum value reached.

6. If the patient becomes apnea, after T_{APNEA}(s) the ventilator will present this condition through alarm in its message area and alarms on the screen and will start the selected backup ventilation, according to programmed settings and parameters.

WARNING

- ***The adjusted support pressure (ΔPS) is a value above the PEEP. Therefore, inspiratory pressure support will be the sum of PEEP and ΔPS.***
- ***Default values are initial reference only.***
- ***Readjust ventilation parameters as needed by the patient***



1 and 2. They represent spontaneous cycles.

1. If the patient does not breathe after the time for apnea, the ventilator goes in with the backup and activates the apnea alarm.

10.10.8 DualPAP

<table>
<tr><th colspan="2">DualPAP - Two-stage positive pressure ventilation</th></tr>
<tr>
<td>Description:

In DualPAP, the ventilator operates at two pressure levels set by the operator, Superior Pr and Inferior Pr:

The change to the lower pressure level (end of inspiration) occurs at the end of Superior T (time set for the superior pressure level). Likewise, restoring the superior pressure level (beginning of inspiration) occurs as soon as the Lower T (the time for the lower pressure level) is exhausted.

Consequently, the respiratory rate and the I: E ratio are directly related to this alternation between levels.

DualPAP allows spontaneous cycles at both pressure levels and counts with the possibility of synchronization with the patient's inspiratory effort. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.

Without spontaneous breathing, DualPAP is similar to the controlled pressure mode, differing from this by adjusting the times (Superior T and Inferior T) rather than respiratory rate.

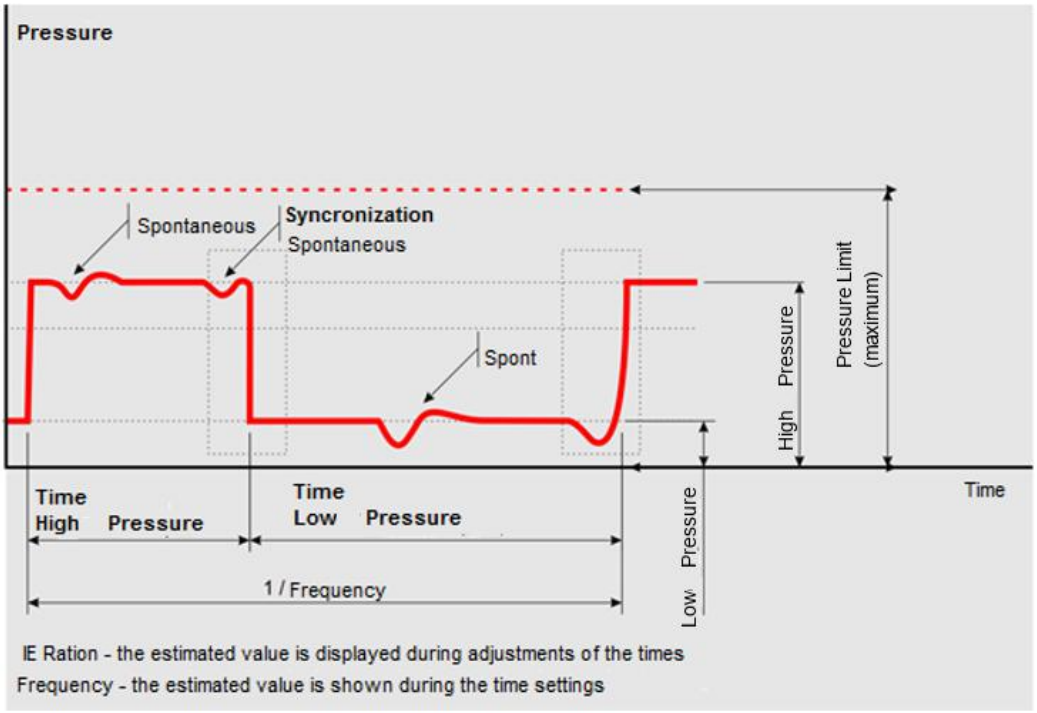
The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time.</td>
<td>Set Parameters:

• SUPERIOR PR.
• SUPERIOR T.
• INFERIOR PR.
• INFERIOR T.
• O2 CONCENTRATION
• ΔPS (Support pressure – PEEP)
• LIMIT PRESSURE
• CYCLE (% FLOW)
• PRESSURE TRIGGER
• FLOW TRIGGER
• RISE TIME
• FLOW($\dot{V}$ - NEONATAL);
• BACKUP

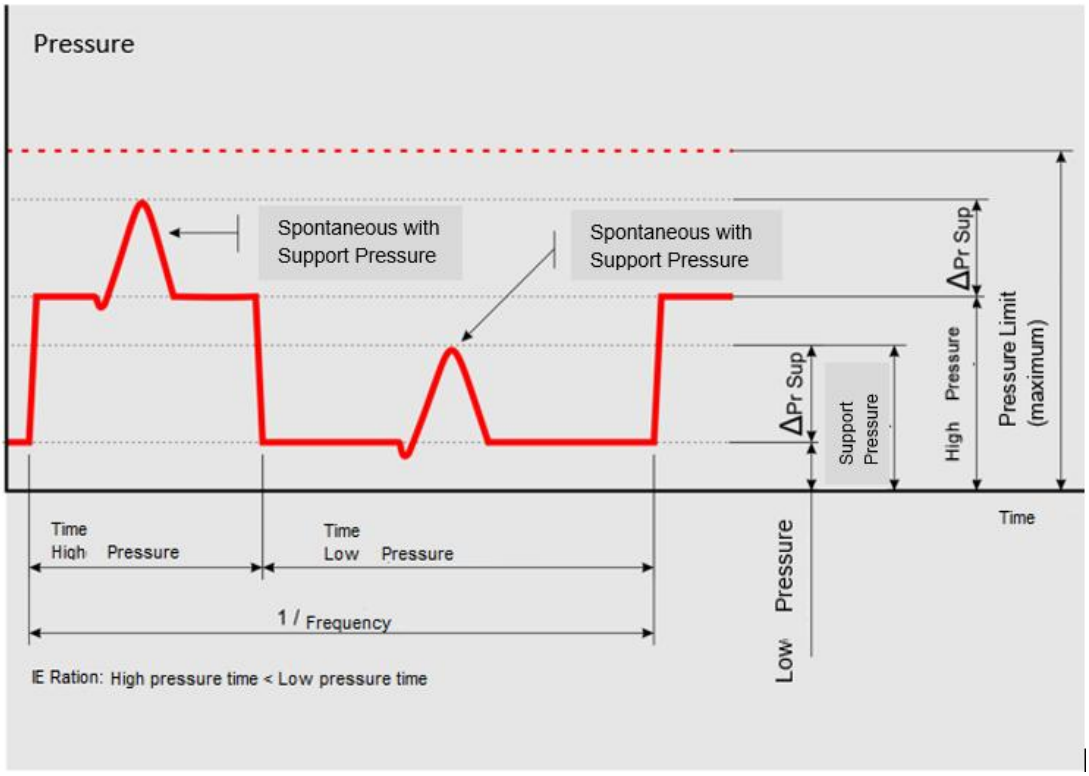
○ Backup VCV
▪ VOLUME
▪ R. RATE
▪ FLOW
▪ LIMIT PRESSURE
○ Backup PCV
▪ INSP PRESSURE
▪ R. RATE
▪ INSP TIME
▪ RISE TIME

○ Backup PLV-NEONATAL
▪ INSP PR
▪ R. RATE
▪ INSP TIME
○ Auto Backup(1)
1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.</td>
</tr>
</table>

DualPAP - Two-stage positive pressure ventilation



IE Ration - the estimated value is displayed during adjustments of the times
Frequency - the estimated value is shown during the time settings



IE Ration: High pressure time < Low pressure time

WARNING

- ***The support pressure (ΔPS) is a value above the superior or inferior pressure. Therefore, the maximum support pressure will be the sum of that reference pressure with ΔPS.***
- ***Default values are initial reference only.***
- ***Readjust ventilation parameters as required by the patient***
- ***In the absence of spontaneous cycles when in DualPAP, adjust the superior and inferior pressures so that the minute volume delivered to the patient is enough.***

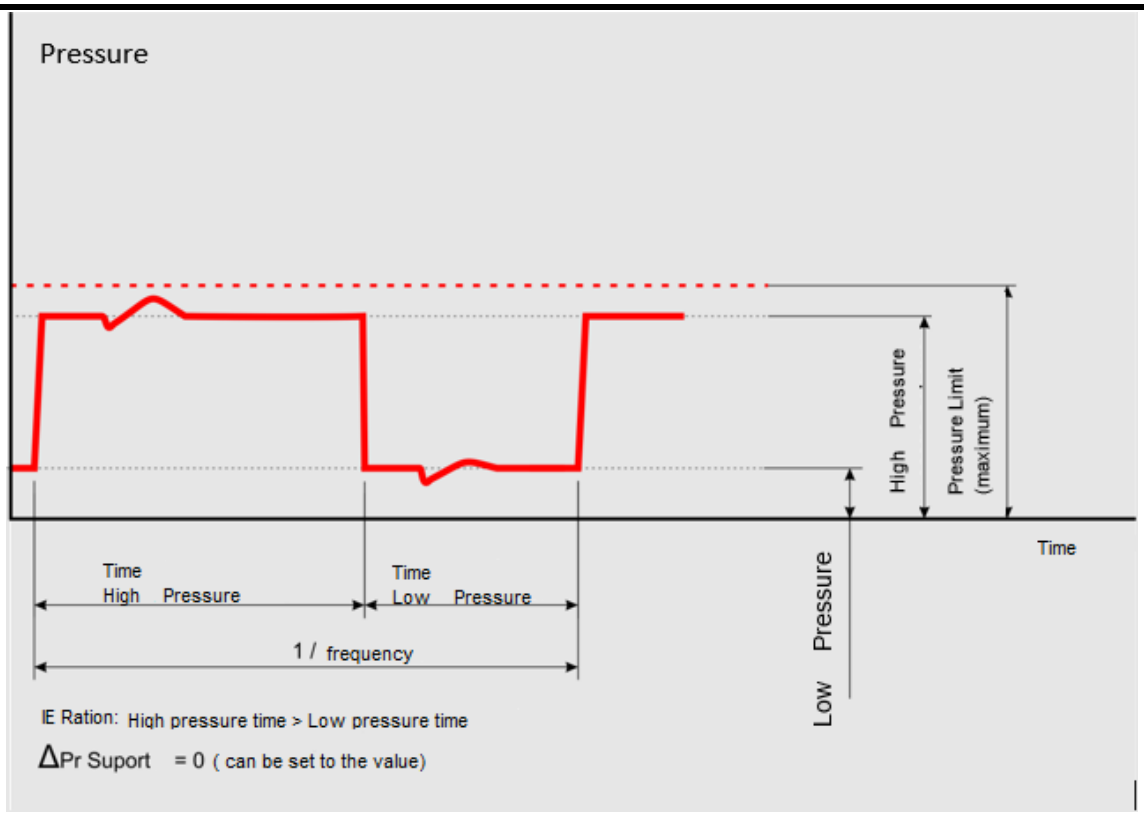
Observation

- *Changes in pressure levels are synchronized.*

10.10.9 APRV

APRV – Continuous Positive Pressure Ventilation and Airway Pressure Relief	
Description: In APRV, the ventilator operates at two pressure levels set by the operator, Superior Pr and Inferior Pr. The transient relief for the lower pressure level (end of inspiration) occurs at the end of the superior T (time set for the superior pressure level). Likewise, restoring the superior pressure level (beginning of inspiration) occurs as soon as the inferior T (pressure relief time) is exhausted. Consequently, the respiratory rate and the resulting I: E ratio are directly related to this alternation between levels. APRV has the characteristic of inversion of the I: E ratio, where the time of the inferior pressure level is usually less than that of the superior pressure level, functioning only as a temporary relief. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value. Without spontaneous breathing, APRV is similar to the controlled pressure mode, differing from this by adjusting the times (superior and inferior) rather than the respiratory rate. The onset of inspiration occurs when the patient exerts an effort that is recognized by the ventilator according to the adjusted sensitivity. If backup is active and the patient goes into apnea, the onset of inspiration will occur according to the adjusted apnea time.	Set Parameters: • SUPERIOR PR. • SUPERIOR T. • INFERIOR PR. • INFERIOR T. • O2 CONCENTRATION • ΔPS (Support Pressure – PEEP) • LIMIT PRESSURE • CYCLE (% FLOW) • PRESSURE TRIGGER • FLOW TRIGGER • RISE TIME • FLOW ($\dot{V}$ NEONATAL) • BACKUP ○ Backup VCV ▪ VOLUME ▪ R. RATE ▪ FLOW ▪ LIMIT PRESSURE ○ Backup PCV ▪ INSP PRESSURE ▪ R. RATE ▪ INS TIME ▪ RISE TIME ○ Backup PLV-NEONATAL ▪ INSP PRESSURE ▪ R. RATE ▪ INSP TIME ○ Auto Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

APRV – Continuous Positive Pressure Ventilation and Airway Pressure Relief



WARNING

- ***The support pressure (ΔPS) is a value above the superior or inferior pressure. Therefore, the maximum support pressure will be the sum of that reference pressure and ΔPS.***
- ***Default values are initial reference only.***
- ***Readjust the ventilation parameters as per the patient's needs.***

10.10.10 MMV

MMV – Spontaneous ventilation with mandatory minute volume	
Description: In this mode, semi automatic mode, initially, the ventilator allows spontaneous test cycles with a support pressure of 5 or 10 cmH2O above the adjusted PEEP. Then the minute volume is measured, and approximate compliance is calculated. For each subsequent cycle, the ventilator recalculates the compliance of the previous cycle and adjusts the pressure level to the next cycles, reaching the adjusted minute volume. The increase in pressure between the cycles never exceeds 3 cmH_2O and the maximum level reached does not exceed the value of the set limit pressure. If this value is reached, and the adjusted minute volume is not reached, the limited pressure alarm will be displayed. On the other hand, if the set apnea time is reached, the backup ventilation will be activated. The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.	Set Parameters*:* • MINUTE VOLUME • PEEP • CYCLE (% FLOW) • PRESSURE TRIGGER • FLOW TRIGGER • O2 CONCENTRATION • RISE TIME • LIMIT PRESSURE • BACKUP ○ Backup VCV ▪ VOLUME ▪ R. RATE ▪ FLOW ▪ LIMIT PRESSURE ○ Backup PCV ▪ INSP PRESSURE ▪ R. RATE ▪ INSP TIME ▪ RISE TIME ○ Auto Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

10.10.11 VS

VS – Spontaneous ventilation with assured volume	
Description: In this mode, semi automatic mode, initially, the ventilator allows spontaneous test cycles with a support pressure of 5 or 10 cmH2O above the adjusted PEEP. Then the delivered volume is measured, and the approximate compliance is calculated. For each subsequent cycle, the ventilator recalculates the compliance of the previous cycle and adjusts the pressure level for the next cycles, reaching the adjusted volume. The increase in pressure between the cycles never exceeds 3 cmH2O and the maximum level reached does not exceed the value of the set limit pressure. If this value is reached, without the adjusted volume being reached, the limited pressure alarm will be displayed. On the other hand, if the set apnea time is reached, the backup ventilation will be activated. The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.	Set Parameters: • VOLUME • PEEP • CYCLE (% FLOW) • PRESSURE TRIGGER • FLOW TRIGGER • O2 CONCENTRATION • RISE TIME • LIMIT PRESSURE • BACKUP ○ Backup PRVC ▪ R. RATE ▪ TIME ○ Auto Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

WARNING

- ***The apnea time alarm can be turned off. In this condition, BACKUP VENTING WILL NEVER BE ACTIVATED.***
- ***If backup ventilation is turned off, the operator must be sure that this adjustment is necessary and aware of the clinical implications involved.***

10.10.12 Nasal CPAP

Nasal CPAP - Spontaneous ventilation with positive nasal airway pressure	
Description: As in CPAP mode, in Nasal CPAP the ventilator allows the patient to breathe spontaneously, with the difference that the ventilator compensates for leaks automatically and ignores high minute volume, high current tidal and flow sensor verification. This mode is only available for neonatal patients and requires a compatible nasal interface. The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.	Set Parameters: • PEEP/CPAP • O2 CONCENTRATION • ΔPS (Support Pressure– PEEP) • CYCLE (% FLOW) • RISE TIME • PRESSURE TRIGGER • FLOW • BACKUP o Backup PLV-NEONATAL ▪ INSP PRESSURE ▪ R. RATE ▪ INSP TIME o Auto Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

10.10.13 NIV

<table>
<tr><th colspan="2">NIV – Non-Invasive Ventilation</th></tr>
<tr>
<td>Description:

As in CPAP mode, in NIV the ventilator allows the patient to breathe spontaneously, with the difference that the ventilator compensates for leaks automatically and ignores the high minute volume, high current tidal and flow sensor verification.

This mode is available to all patients.

The onset of inspiration occurs when the patient makes an effort that is recognized by the ventilator according to the adjusted trigger. If the backup is active and the patient goes into apnea, the onset of inspiration will occur according to the set apnea time. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.</td>
<td>Set Parameters:

• PEEP/CPAP
• O2 CONCENTRATION
• ΔPS (Pressure Bearing – PEEP)
• CYCLE (% FLOW)
• RISE TIME
• PRESSURE TRIGGER
• BACKUP

○ Backup VCV
▪ VOLUME
▪ R. RATE
▪ FLOW
▪ LIMIT PRESSURE
○ Backup PCV
▪ INSP PRESSURE
▪ R. RATE
▪ INSP TIME
▪ RISE TIME

○ Auto Backup(1)
1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.</td>
</tr>
</table>

10.10.14 VG

VG – Ventilation with Guaranteed Volume	
Description: Available only for neonatal patient, this ventilatory mode is similar to the PLV, except that a tidal volume value can be set to be delivered by the ventilator. The onset of inspiration (triggering) occurs according to the pre-established respiratory rate. Cycle (transition between inspiration and expiration) occurs by flow as it falls to a certain percentage of its maximum reached value.	Set Parameters: • INSPIRATORY PRESSURE • RESPIRATORY RATE • INSPIRATORY TIME • PEEP • O2 CONCENTRATION • FLOW ($\dot{V}$) • PRESSURE TRIGGER • FLOW TRIGGER • VOLUME Note: Automatic Backup(1) 1 – Whenever the set apnea time is reached, the ventilator triggers a ventilatory cycle, the configuration of which is based on the current mode settings.

WARNING

- ***This mode is only available for neonatal patient with proximal flow sensor.***
- ***It is mandatory to perform the autotest to enable this mode.***

10.10.15 O2 Therapy

O2 THERAPY	
Description Available for all patient types, this special mode offers continuous O_2 flush according the O_2 concentration and flow set. This mode requires a compatible interface. To use this mode, connect the appropriate breathing circuit and humidifier for the therapy following the circuit manufacturer's recommendations, place the Fleximag Max in stand-by mode, select the O2 Therapy mode, perform the O2 concentration and flow adjustments and take Fleximag Max out of stand-by mode to start therapy.	Adjustable parameters • FLOW • O2 CONCENTRATION

WARNING

- ***Connect the HIGH FLOW O2 THERAPY BREATHING CIRCUIT with the HIGH FLOW NASAL CANNULA to the VENTILATOR FLOW OUTLET.***
- ***Do not lubricate joints, fittings, piping, or other equipment accessories to avoid risk of fire and burns.***
- ***Do not use sealed patient interfaces with this equipment, to avoid the risk of suffocation or barotrauma.***
- ***Ensure sufficient intended leakage between the respiratory system and the patient to allow the patient to exhale.***
- ***Do not allow open flames within 2 m of equipment or any accessories carrying oxygen. Open flames during oxygen therapy are dangerous and can result in fire or death.***
- ***Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula or mask on bedspreads or chair cushions, if the equipment is turned on but not in use; Oxygen will make materials more flammable. Turn off equipment when not in use to avoid oxygen enrichment.***
- ***Smoking during oxygen therapy is dangerous and can result in facial burns or death. Do not allow smoking or open flames in the same room as equipment or any accessory that carries oxygen. If the patient intends to smoke, always turn off the equipment, remove the cannula and leave the room where the equipment is located. If you are unable to leave the room, wait 10 minutes after turning off the equipment.***
- ***The therapy provided to the patient may be adversely affected by the added gas by the use of a pneumatic nebulizer.***

- ***There is a fire hazard associated with oxygen enrichment during oxygen therapy. Do not use the equipment or accessories near open sparks or flames.***
- ***This equipment is only suitable for spontaneously breathing patients.***
- ***Do not connect the equipment to the battery of a battery-powered wheelchair, this may affect the performance of the equipment and consequently result in the degradation of the patient's health.***
- ***Do not use the equipment outside a temperature of 50°C. Using the equipment outside this temperature range may compromise the performance of the equipment and consequently may result in the degradation of the patient's health.***
- ***To avoid disconnection of the tubing or piping system during use, especially during ambulatory use, use only tubing with holding force in accordance with ISO 5367 or ISO 80601-2-74.***
- ***To reduce the likelihood of disconnection and avoid adverse equipment performance, use only accessories that are compatible with the equipment. Compatibility is determined by reviewing the instructions for use of the equipment or accessories.***
- ***Use only replacement parts recommended by the manufacturer to ensure proper operation and avoid the risk of fire and burns.***
- ***Only water-based lotions or ointments that are compatible with oxygen before and during oxygen therapy. Never use petroleum-based or oil-based lotions or ointments to avoid the risk of fire and burns.***
- ***Do not add to the equipment any attachments or attachments that contradict the instructions for use of the equipment or attachment, as the equipment may not function properly leading to the risk of degradation of the patient's health.***
- ***The humidifier should not be used with nitric oxide. Such use can cause the humidifier to not work properly, causing serious deterioration in health.***
- ***Covering the breathing tubes with a blanket or warming them in an incubator or with an overhead heater may affect the quality of therapy or injure the patient.***

10.10.16 PRVC-SIMV

Volume controlled with regulated pressure + Mandatory intermittent ventilation synchronized with controlled volume + Support Pressure	
Description Available for adult and pediatric patients, in this mode the ventilator fixes the respiratory rate and is limited to the pressure that uses the tidal volume as feedback to continuously adjust the pressure limit, in addition to the sensitivity criterion for the occurrence of the ventilator trip by the patient. This mode allows the ventilator to apply predetermined mandatory cycles in sync with the patient's inspiratory effort. The mandatory cycles occur in the predetermined time window (the beginning of inspiration occurs according to the pre-established respiratory rate), but synchronized with the patient's triggering. If there is an apnea, the next cycle will be triggered for time until the patient's inspiratory incursions return. In mandatory cycles, cycling (end of inhalation and beginning of exhalation) happens according to inspiratory time. In spontaneous cycles, cycling (end of inhalation and beginning of expiration) occurs by flow, as soon as it falls to a certain percentage of its maximum value reached. To obtain the IMV in this mode, simply deactivate the support pressure by setting the support pressure to zero (ΔPS=0) or the flow and pressure sensitivities to zero. The transition between inspiration and expiration in the mandatory cycles occurs after the release of the pre-established tidal volume at a determined speed through the flow (or inspiratory ratio or time). In spontaneous cycles, cycling (transition between inspiration and expiration) occurs by flow, as soon as it drops to a certain percentage of its maximum value reached.	Adjustable parameters • VOLUME • R. RATE • INSPIRATORY TIME • PEEP • LIMIT PRESSURE • O2 CONCENTRATION • RISE TIME • PRESSURE TRIGGER • FLOW TRIGGER • ΔPS • CYCLE (% FLOW)

10.10.17 CPR

CARDIOPULMONARY RESUSCITATION	
Description The CPR mode allows the performance of cardiac compression maneuvers for the recovery of cardiac functions. In this mode, the ventilator provides a CPAP level of 5 cmH2O and signals the operator when to perform the compression through the red light on the top of the ventilator and also through the monitor screen. During the cardiopulmonary resuscitation process, a stopwatch is presented showing the time elapsed after the beginning of the procedure, the frequency of compressions, the differential pulmonary pressure during compressions, and if there is a capnograph connected, the EtCO2 measured in respiration is presented.	Adjustable parameters • PEEP • O2 CONCENTRATION • ΔPS • CYCLE (% FLOW) • RISE TIME

10.11 Oxygen Adjustment Response Time

The table below indicates the time required for the oxygen concentration in the delivered volume to change from a fraction of 21% to 90% of the maximum adjustable oxygen concentration using the maximum internal volume respiratory system configuration.

Volume delivered (mL)	Maximum response time(s)
500	98
150	83
30	360

10.12 Accuracy of settings

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

Item	Parameter	Accuracy [1, 2]
1	Tidal volume (All range) [1]	± (4 mL + 15% of adjusted volume) [3]
2	Inspiratory pressure	± (2 cmH2O + 4% of set pressure) [3]
3	PEEP	± (2 cmH2O + 4% of adjusted PEEP)
4	FiO2	± (5% + 2.5% adjusted FiO2)

1 Volume and pressure accuracy is preserved for circuits with resistance up to 1.9 cmH_{2O} with 15 LPM flow and compliance up to 5 mL/cmH_{2O}.

2 Performance accuracies were determined with the worst-case configuration, with a respiratory circuit with a water trap, a heated humidifier, a proximal flow sensor, a CO_2 sensor, and a HEPA filter, because they have greater compliance and a greater number of potential leak points.

3 The accuracy specification is valid for any condition in the O_2 input concentration range.

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

Item	Parameter	Uncertainty
1	Tidal volume	± 2.5%
2	Inspiratory pressure	± 2.0%
3	PEEP	± 2.0%
4	FiO_2	± 2.0%

10.13 Adjustable Parameter Specifications

Table 15 - Adjustable parameters

Item	Parameter	Specification	Resolution		Unit
1	Tidal volume	2.0 to 3000	Neonatal(1)	2.0 to 10.0: 0.1	mL
				10 to 99:1	
			Pediatric	10 to 100: 5	
				100 to 300: 10	
			Adult	100 to 1000: 10	
				1000 to 3000: 50	
2	Respiratory Rate(2) (3)	0 to 200(9)	Neonatal	0 to 200: 1	rpm
			Pediatric	0 to 200: 1	
			Adult	0 to 100:1	
3	Rise time	0 to 2.0	0.1		s
4	Pause (plateau)	0 to 70	10		%
		0 to 2	0.1		s
5	Inspiratory and limit pressure	0(10) to 120	1		cmH2O
6	ΔPS	0 to 120	1		cmH2O
7	PEEP	0 to 50	1		cmH2O
8	Pressure trigger	0.0 to -20	0.0 to -2.0:-0.2		cmH2O
			-2 to -10: -1		
9	Flow Trigger	0.0 to 30	0.0 to 1.0: 0.1		L/min
			1.0 to 30.0: 0.5		

Item	Parameter	Specification	Resolution	Unit
10	Cycle (Flow Drop)	5 to 80 (maximum 3 sec.)	5	%
11	O2 concentration	21 to 100	1	% vol
12	Inspiratory time	0.05 to 30	0.05 to 0.70: 0.01	s
			0.70 to 1.00: 0.05	
			1.0 to 30.0: 0.1	
13	Flow Waveform	Square Descending or Slowed Down, Ascending or Accelerated, Sinusoidal or Sinusoidal	---	---
14	CPAP	0 to 50	1	cmH2O
15	Superior Pressure (DualPAP/APRV)	5 to 90	1	cmH2O
16	Inferior Pressure (DualPAP/APRV)	0 to 45	1	cmH2O
17	Superior Time (DualPAP/APRV)	0.10 to 59.8	0.20 to 0.70: 0.01	s
			0.70 to 1.00: 0.05	
			1.00 to 59.80: 0.10	
18	Inferior Time (DualPAP/APRV)	0.20 to 59.9	0.20 to 0.70: 0.01	s
			0.70 to 1.00: 0.05	
			1.00 to 59.90: 0.10	
19	Ratio I: E	1:599 to 299:1[3]	1:0.1	---
20	Backup[4]	OFF, PLV, PCV, VCV and PRVC	---	---
21	Inspiratory flow	1 to 180	1	L/min
22	Patient's height	64 to 132 (pediatric) [8]	1	cm
		133 to 250 (adult) [8]		
23	Patient's weight	0.1 to 5.9 (neonatal)	0.1	kg
24	Nebulizer Flow – 100% Oxygen[5]	5 to 8 (no direct adjustment)	---	L/min
	Nebulizer time	1 to 50	1	min

Item	Parameter	Specification	Resolution	Unit
25	TGI (Tracheal Gas Insufflation) Flow – 100% Oxygen(5)	5 to 8 (no direct adjustment)	---	L/min
26	Sigh(6)	1 to 3	1	sigh
27	Volume of the sigh(6)	10 to 100	10	%Vt
28	Rate of the sigh(6)	20 to 100	10	Cycles
29	Tube Compensation	Endotracheal Tracheostomy	---	---
30	Tube diameter	2.5 to 12.0	2.5 to 10 : 0.5 10 to 12 : 1	mm
31	% Tube Compensation	10 to 100	10	%
32	Minimal inspiratory hold(7) Minimal expiratory hold	0.1 to 30	0.1 to 1 : 0.1 1 to 30 : 1	s
33	Alarm muting time	OFF, 10 to 120	10	s
34	Screen Lock Time	OFF, 1 to 30	1 to 5:1 10 to 30: 5	min
35	Flow (only in O_2 Therapy mode)	0 to 60	0 to 60: 1	L/min
36	Minute Volume (MMV)	1.0 to 50.0	0,1	L
37	Flow (neonatal)	1 to 40	1	L/min
38	FiO_2 (O_2+ Flush)	50 to 100	1	%
39	Time (O_2+ Flush)	10 to 120	1	s
40	Alarm silence	10 to 120	1	s

(1) Volume for neonatal patient only with proximal flow sensor and in VG mode.

(2) Respiratory rate 0 (zero) will only be achieved in spontaneous modes, with sensitivities and apnea time alarm turned off.

(3) The minimum and maximum values of frequency and I:E ratio depend on the ventilatory mode set.

(4) Adjustable backup options for spontaneous modes, for the other modes, the backup is automatic.

(5) Nebulizer and TGI flows cannot be activated simultaneously.

(6) Sigh adjustment only available in VCV and V-SIMV modes

(7) Pause time when pressing and releasing the button immediately.

(8) The adult and pediatric patient weight considered by the equipment for parameter adjustment is the ideal weight (IBW), calculated according to the patient's height.

(9) The adjustment above 180 rpm is indirectly obtained by adjusting upper and lower time in DualPAP neonatal patient.

(10) Inspiratory pressure adjustment of 0 can be achieved in spontaneous mode (CPAP with backup off, DeltaPS 0 and PEEP 0).

Inspiratory pressure adjustment from 5 to 120 cmH2O is achieved in controlled modes.

ATTENTION

- ***The Oxymag Max ventilator serves any patient, from premature to morbidly obese, however, the patient height adjustment used to calculate the ideal weight is limited.***
- ***For patients exceeding this limit, the parameters can be adjusted directly by the operator.***

10.14 Monitored Parameter Specifications

The monitored parameters are calculated using the simple moving average (SMA) technique, which averages the most recent values in a data series. Thus, for each value included in the averaging, the oldest value is excluded.

Table 16 - Monitored ventilatory parameters

Parameter	Range	Resolution	Measurement Accuracy(1)
Instantaneous pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Peak Pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Mean Pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Plateau Pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
PEEP	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Intrinsic PEEP (iPEEP)	0 to 99.9 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Measured Flow (4) (5)	-180 to 180 L/min	1	± (50mL/min + 10 % of actual value)
Tidal volume in guaranteed volume (2) (3) (4) (5)	0.0 to 10.0 mL	0,1	±(4.0 mL + 15% of the actual value)
	10 to 100 mL	1	
Tidal volume (3) (4) (5)	0 to 999 mL	1	±(4.0 mL + 15% of the actual value)
	1.00 to 3.00 L	0.01	
Minute volume total (4) (5) (MV)	0.001 to 0.999 L	0.001	±(4.0 mL + 15 of actual value)
	1.00 to 9.99 L	0.01	
	10.0 to 99.9 L	0.1	
Inspiratory time	0.05 to 9.99 s	0.01	± (0.10s + 10% of the actual value)
	10.0 to 60.0 s	0.1	± (0.10s + 10% of the actual value)
Expiratory time	0.05 to 9.99 s	0.01	± (0.10s + 10% of the actual value)
	10.0 to 60.0 s	0.1	± (0.10s + 10% of the actual value)
I:E Ratio	1:599 to 599:1	1:0.1	± (0.1 + 10 % of the actual value)
Total respiratory rate	0 to 200 bpm	1	± (1bpm + 10% of actual value)
Spontaneous respiratory rate	0 to 200 bpm	1	± (1bpm + 10% of actual value)

Parameter	Range	Resolution	Measurement Accuracy(1)
O2 Concentration (FiO2)	12.0 to 99.9 %	0.1	± (2.5% + 2.5% of the actual value)
	100 to 110 %	1	
Airway resistance(3) (Ri and Re)	0 to 99.9 cmH2O/L/s	0.1	± (5cmH2O/L/s +20% of actual value)
	100 to 200 cmH2O/L/s	1	
Dynamic compliance	0 to 99.9 mL/cmH2O	0.1	± (1mL/cmH2O + 10% of the actual value)
	100 to 200 mL/cmH2O	1	
Static compliance	0 to 99.9 mL/cmH2O	0.1	± (1mL/cmH2O + 10% of the actual value)
	100 to 200 mL/cmH2O	1	
External Auxiliary Pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Estimated tracheal pressure	0 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Elastance	0 to 100 cmH2O/L	1	± (1cmH2O/L + 10% of actual value)
Leakage Flow (4)	0.0 to 19.9 L/min	0.1	± (50mL/min + 10% of actual value)
	20 to 180 L/min	1	
Percentage leakage (4)	0 to 100 L/min	1	± (10% + 10% of actual value)
Time Constant (5) (TC)	Calculated(s)	0.1	± (0.1s + 10% of the actual value)
Ti / Ttotal	Calculated(s)	0.1	± (0.1s + 10% of the actual value)
RSBi – Surface Respiration Index (IRRS, Tobin Index)	Calculated (cycles/min/L)	1	± (1 cycles/min/L + 10% of actual value)
WOBi (Imposed Respiratory Work)	Calculated (J/min)	0.01	± (0.1 J/min + 10% of actual value)
WOBi (Imposed Respiratory Work)	Calculated (J/L)	0.01	± (0.1 J/L + 10% of actual value)
Pi Max	-60 to 120 cmH2O	1	± (2 cmH2O + 4% of the actual value)
Driving Pressure	Calculated (Pplato – PEEP)	1	± (2 cmH2O + 4% of the actual value)
O_2 Consumption	0 to 180 L/min	0.1	± (50mL/min + 10% of actual value)
Maximal Inspiratory Flow	0.0 to 9.9 L/min	0.1	± (0.01 L/min + 10% of actual value)
	10 to 180 L/min	1	± (50mL/min + 10 % of actual value)

Parameter	Range	Resolution	Measurement Accuracy(1)
Maximal Expiratory Flow	-9.9 to 0 L/min	0.1	± (50mL/min + 10 % of actual value)
Stress Index	0.00 to 2.00	0.01	± (0.01 + 10% of the actual value)
C20/C	0.00 to 5.00	0.01	± (0.2 + 10% of the actual value)
Inspiratory Volume/Weight	0 to 99.9 L/min	0.1	±(4.0 mL + 15% of the actual value)
Expiratory Volume/Weight	0 to 99.9 L/min	0.1	±(4.0 mL + 15% of the actual value)
Anatomical Dead Space Ventilation (RVaw)	0 to 999 mL	1	Calculated
	1 to 3 L	0.01	
Anatomical expiratory tidal volume dead space ventilation (RVaw/VTE)	0 to 110%	1	Calculated
Alveolar Tidal Volume (VTalv)	0 to 999 mL	1	Calculated
	1 to 3 L	0.01	
Alveolar minute volume (V'alv)	0.001 to 0.999 mL	0.001	Calculated
	1 to 9.9 L	0.01	
	10 to 99.9 L	0.1	
Expired CO2 Volume (VeCO2)	0 to 999 mL	1	± (4.0 mL + 15% of reading)
	1 to 3 L	0.01	
Volume of CO2 expelled / Respiration (VCO2)	0 to 999 mL	1	± (4.0 mL + 15% of reading)
	1 to 3 L	0.01	
Volume of CO2 eliminated / minute (V'CO2)	0.001 to 0.999 mL	0.001	Calculated
	1 to 9.9 L	0.01	
	10 to 99.9 L	0.1	
Mean alveolar partial pressure of CO2 (PACO2)	0 to 189 mmHg	1	Calculated
Partial pressure of CO2 in exhaled gas (PETCO2)	0 to 189 mmHg	1	± (2.25 mmHg + 4% of reading)
Inspired Volume of CO2 (ViCO2)	0 to 999 mL	1	± (4.0 mL + 15% of reading)
	0.01 to 1.00 L	0.01	
Fractional concentration of CO2 in exhaled gas (FetCO2)	0 to 110%	1	Calculated
CO2 slope	0.00 to 9,99 % CO2/L	0.01	Calculated

(1) When two tolerances are indicated, consider the one with the highest value. Volume and pressure accuracy is preserved for circuits with resistance up to 1.9 cmH2O with a flow rate of 15 LPM and compliance of up to 5 mL/cmH2O.
(2) Only with Volume Guaranteed (VG) enabled.
(3) For airway resistances greater than 150 cmH2O/L/s, the expired volume will have its tolerance outside the declared range. In this condition, the measured inspired volume does not change.
(4) Volumes, flows, and leakage specifications associated with the ventilator's respiratory system are expressed in BTPS.
(5) Monitored, inhaled and exhaled.

WARNING

- ***Ventilation with cyclic pressure up to 100 cmH2O can add tolerance error of up to 2%.***
- ***The accuracy of the parameters may be affected under the following conditions:***
  - ***Reuse of single-use accessories;***
  - ***Use of incorrect sensor for the type of patient;***
  - ***In-circuit secretion and flow sensor;***
  - ***Leakage in the circuit;***
  - ***Oxygen cell and flow sensor not calibrated;***
  - ***Condensation in the circuit, flow sensor and gas inlet;***
  - ***Use of a nebulizer with the capnography sensor;***
  - ***Proximal flow sensor with tubes facing down.***
- ***To maintain ventilator accuracy, keep the flow sensor, breathing circuit, and gas inlet dry, clean, and non-condensing.***

Observation

- *In practice, the units of pressure measurement are equivalent, and it can be assumed that 1 mbar = 1 hPa ≈ 1 cmH2O.*
- *Oxygen monitoring is achieved accurately within 20 seconds of start-up.*

10.15 Safety System Specifications

- Anti-asphyxia valve to protect against gas supply failures.
- 100 cmH2O safety relief valve, according to basic ventilator standards in order to avoid overpressure in the respiratory circuit.

- Active overpressure valve that, when it detects obstructions, is activated to reduce the pressure in the respiratory circuit.
- The high-pressure relief valve is activated when the mains pressure is above 800 kPa (8.0 kg/cm2) sending the excess gas into the atmosphere. This will limit the ventilator supply pressure.

10.16 Alarm System Specification

Alarm priority is determined by the equipment's risk management process.

Table 17 - Alarm priority

Potential result of failure to respond to alarm cause	**Beginning of Potential Damage(1)**		
	Immediate(2)	*Promptly (3)*	*Late(4)*
Death or irreparable injury	*HIGH PRIORITY*	*HIGH PRIORITY*	*MEDIUM PRIORITY*
Repairable injury	*HIGH PRIORITY*	*MEDIUM PRIORITY*	-
Minor injury or discomfort	*MEDIUM PRIORITY*	-	-

(1) Onset of potential harm refers to the occurrence of the injury and not to its manifestation

(2) There is potential for the event to develop in a period of time that is usually not sufficient for manual corrective action.

(3) There is potential for the event to develop in a period of time usually sufficient for manual corrective action.

(4) There is potential for the event to develop over an unspecified period longer than that provided in the prompt.

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

- High-priority alarm messages will be displayed alternately.
- In the absence of high-priority alarms, medium-priority alarm messages will be displayed alternately

Alarm messages are displayed as soon as the alarm condition is detected, so there is no delay in displaying messages.

Table 18 - Characteristics of alarms

Alarm	Characteristic	High Priority	Medium Priority	Low Priority
Visual	Colour	Red	Yellow	Cyan
	Intermittent frequency	2.08 Hz	0.47 Hz	Constant
Sound	Number of pulses per burst	10 pulses	3 pulses	2 pulses
	Interburst interva	5.9 s	6.0 s	30.7 s
	Sound Pressure Range	76.83 dBA	75.71 dBA	73.44 dBA
	Pulse frequency	301 Hz	301 Hz	301 Hz

Observation

- *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.*
- *It is recommended that the operator respect the maximum distance of 1 m for the correct visualization and identification of visual alarms, however, alarm signals are perceptible up to a distance of 4 m from the equipment.*
- *Sound pressure levels of auditory alarm signals that are lower than ambient levels may prevent operator recognition of alarm conditions.*

10.16.1 Specifications of Adjustable Alarms

Table 19 – Adjustable alarms

Alarm	Adjustment	Limit	Default Values(1)			Unit
			Neonatal	Pediatric	Adult	
Peak Pressure(4)	5 to 120 mm	High	30	30	40	cmH2O
	OFF, 0 to 119	Low	OFF	OFF	OFF	
PEEP	OFF, 1 to 80	High	10	15	20	cmH2O
	OFF, 1 to 79	Low	OFF	OFF	OFF	
Total volume	OFF, 10 to 3000	High	50 mL	500 mL	1.0 L	L or mL
	OFF, 0 to 2950	Low	OFF	OFF	OFF	
Minute volume	OFF, 0.1 to 99.0	High	1.0	10	20	L

Alarm	Adjustment	Limit	Default Values(1)			Unit
			Neonatal	Pediatric	Adult	
	OFF, 0.0 to 98.9	Low	0.5	2	3.6	
Respiratory rate	OFF, 1 to 200	High	80	60	60	rpm
	OFF, 0 to 199	Low	5	5	5	
FiO_2	OFF, 19 to 100	High	80	80	80	%
	OFF, 18 to 99	Low	OFF	OFF	OFF	
$EtCO_2$(2)	OFF, 1 to 80	High	45	45	45	mmhg
	OFF, 0 to 79	Low	OFF	OFF	OFF	
CO_2Ins(2)	OFF, 0 to 80	High	3	3	3	mmhg
Heart Rate(2)	OFF, 1 to 240	High	150	120	100	bpm
	OFF, 0 to 239	Low	OFF	OFF	OFF	
SpO_2(2)	OFF, 0 to 100	Low	85	85	85	%
Apnea time	OFF, 1 to 60		15	15	15	s
Automatic Adjustment(3)	OFF, 10, 20 and 30		OFF			%
Driving Pressure	OFF, 1 to 120	High	OFF	OFF	OFF	cmH2O
	OFF, 1 to 119	Low	OFF	OFF	OFF	cmH2O
Disconnection Sensitivity	OFF, 5 to 95		OFF			%
Apnea Sensitivity	0.2 to 10.0		0,5			cmH2O

(1) Every time the equipment is started up or there is a change in the type of patient or the battery goes out without the ventilator being connected to the mains, the alarms will assume default values.

(2) Alarms available only with the use of optional external sensors.

(3) The alarm thresholds will be adjusted according to the monitored values. Valid only for basic ventilation alarms (maximum pressure, PEEP, volume, minute volume, frequency and FiO_2).

(4) The maximum high pressure alarm setting is limited by the pressure setting (threshold pressure, upper pressure, controlled pressure, and inspiratory pressure) of the prevailing ventilatory mode. To set the alarm to values lower than the permissible limit, it is necessary to adjust the ventilatory mode pressures.

WARNING

- ***Alarms will default whenever the equipment is restarted or the patient changes.***
- ***The apnea time can be turned off and in this condition there will be no protective ventilation.***
- ***THE OPERATOR SHALL BE AWARE OF THE RISKS OF KEEPING THE APNEA ALARM OFF.***
- ***The automatic adjustment of the alarms is based on the monitored values, so it can only be used when the ventilator is NOT in standby mode (STAND BY) and preferably, when the parameters are stable.***
- ***Be careful when setting alarm thresholds. Extreme values can cause alarms not to be triggered, rendering the alarm system useless.***

- ***Alarm settings will not change when power is lost for 30 seconds or less. In this case, the equipment will be powered by an internal non-interchangeable battery.***

10.16.2 Ventilator Alarm Messages

In the event of one or more ventilator related alarms, the following messages may be displayed, according to their respective priorities:

Table 20 - High priority alarms

High Priority Alarm	Delay	Description
INOPERATIVE EQUIPMENT	< 1 second	Indicates that there has been a technical failure of the equipment that must be replaced.
LOW BATTERY	< 1 second	When the internal battery is charged at the end. Adequate means of ventilatory support should be provided for the patient.
APNEA	< 1 second	It means that the time elapsed since the last inhalation is greater than the alarm value set as the maximum apnea time.
LOW O2 SUPPLY PRESSURE	< 1 second	The pressure of the oxygen network is below the specified range. This alarm will not be triggered if the O2% parameter is set to 21% (air) and the air network is operating within the required specifications.
COMMUNICATION FAILURE	< 1 second	Indicates that there has been a technical failure of the equipment that must be replaced.
OBSTRUCTION	< 2 cycles	There is some obstruction in the respiratory circuit that prevents the patient from exhaling completely or properly.
DISCONNECTION	< 5 cycles	There was disconnection of the respiratory circuit or flow sensor lines (if any), which prevents adequate ventilation of the patient.
HIGH PRESSURE	< 2 cycles	The pressure reached exceeded the alarm value set as the upper pressure limit.
LOW PRESSURE	< 2 cycles	The pressure has not reached the alarm value set as the lower pressure limit.
CHECK INTERNAL SENSOR	< 1 second	Indicates that there has been a technical failure of the equipment that must be replaced.
CHECK BATTERY	< 1 second	Indicates that the battery may be having problems.
HIGH VOLUME	< 3 cycles	The patient's expired volume exceeded the alarm value set as its upper limit.
LOW VOLUME	< 3 cycles	The patient's expired volume is below the alarm value set as its lower limit.
FLOWAIR: VERY HIGH TEMPERATURE	< 1 second	Indicates that the temperature of the FlowAir system is too high.
FLOWAIR: FAILURE	< 1 second	Indicates that there has been a failure in the FlowAir system
FIO2 BELOW 18%	< 3 cycles	The fraction of inspired O2 is less than 18%.
SYSTEM RECOVERY	< 21 seconds	Indicates that the control software was restarted and ventilation control returned as set.

Table 21 - Medium priority alarms

Medium Priority Alarm	Delay	Description
LIMITED PRESSURE	< 1 second	When the monitored pressure reaches the set maximum pressure. In this case, the volume delivered by the ventilator module does not reach the set volume due to pressure limitation.
CHECK FLOW SENSOR	< 3 cycles	Indicates that the flow sensor is disconnected. Under these conditions all monitoring that depends on this sensor (VT, MV, Frequency, Vins, Tinsp, I:E, T exp, Cest, Cdin, Res, τ , iT, Volume Leakage, VxTime Graph) will NOT be displayed. In volume-controlled ventilatory modes, the delivered volumes of the equipment will vary by up to ±10%.
HIGH PEEP	< 3 cycles	The positive pressure at the end of expiration (PEEP) exceeded the alarm value set as its upper limit.
LOW PEEP	< 3 cycles	Positive end-expiratory pressure (PEEP) did not reach the alarm value set as its lower limit.
HIGH MINUTE VOLUME	< 3 cycles	The minute volume delivered to the patient exceeded the alarm value set as its upper limit.
LOW MINUTE VOLUME	< 3 cycles	The minute volume delivered to the patient is below the alarm value set as its lower limit.
HIGH RATE	< 3 cycles	The patient's respiratory rate exceeded the alarm value set as its upper limit.
LOW RATE	< 3 cycles	The patient's respiratory rate did not reach the alarm value set as its lower limit.
HIGH LEAKAGE	< 2 cycles	The measured leakage flow exceeded the maximum compensation limit.
HIGH O2 SUPPLY PRESSURE	< 1 second	Indicates that the mains pressure is higher than specified.
HIGH DRIVING PRESSURE	< 2 cycles	The driving pressure has exceeded the alarm value set as the upper limit of the driving pressure.
LOW DRIVING PRESSURE	< 2 cycles	The expired driving pressure is below the alarm value set as the lower limit of the driving pressure.
HIGH FIO2	< 3 cycles	The inspired fraction of O2 exceeded the alarm value set as its upper limit.
LOW FIO2	< 3 cycles	The inspired fraction of O2 did not reach the alarm value set as its lower limit.
LOW BATTERY	< 1 second	The battery is less than half of its full capacity.
FLOWAIR: HIGH TEMPERATURE	< 1 second	Indicates that the temperature of the FlowAir system is increasing.
HIGH TEMPERATURE	< 1 second	It is activated when the environment temperature ir above 50 ° C.
O2 CELL FAILURE	< 1 second	It is activated when the O2 cell voltage is below 8mV

Table 22 - Low-priority alarms

Low Priority Alarm	Delay	Description
APNEA WITH BACKUP VENTILATION	< 1 second	When apnea happens and trigger a backup vent because there is one available and enabled.
NO AC POWER	< 1 second	Indicates that it is disconnected from the mains and that the power has been switched to internal power supply.
SYSTEM RECOVERY	< 21 seconds	Indicates that the IHM software was restarted and ventilation parameters were not affected.

WARNING

- ***When you receive alarm information, provide prompt assistance to solve the problem.***
- ***Once the situation that requires the total silence of the audible alarm is terminated, the alarms shall be reactivated for patient safety.***

ATTENTION

- ***To silence the audible alarm, press the MUTE quick access button. Audible alarms will be disabled for the set period of time or until a new alarm occurs.***
- ***There may be a danger if different alarm presets are used for the same equipment or for similar equipment in the same area, such as an intensive care unit or a cardiac operating room.***
- ***The equipment will always start with the audio volume set to the maximum level (6), regardless of the level set when it was turned off.***
- ***If the audio volume is set to a value lower than the maximum level (6), if an alarm occurs, as long as there is no answer for it to cease, the audio volume will be gradually increased every 15 seconds until it reaches its maximum limit.***

10.16.3 Ventilator Alert Messages

On the occurrence of one or more ventilator related alerts, the following messages may be displayed:

Table 23 - Alert messages

Message	Delay	Description
ASSIST TRIGGER: FLOW	< 1 second	Indicates the occurrence of an assisted shot, generated by the increase in inspiratory flow.
ASSIST TRIGGER: PRESSURE	< 1 second	Indicates the occurrence of an assisted trip, generated by a pressure drop.
ASSIST. TRIGGER MANUAL	< 1 second	Indicates the occurrence of an assisted shot, manually generated by the operator.
SPONT TRIGGER: FLOW	< 1 second	It indicates the occurrence of a spontaneous trigger, generated by the increase in inspiratory flow.

Message	Delay	Description
SPONT TRIGGER: PRESSURE	< 1 second	Indicates the occurrence of a spontaneous trigger, generated by a pressure drop.
SPONT TRIGGER: MANUAL	< 1 second	Indicates the occurrence of a spontaneous trigger, manually generated by the operator.
TO VENTILATE, PRESS START	< 1 second	Indicates that the appliance is in standby mode and the button must be used to resume ventilation.
ASSURED VOLUME NOT REACHED	< 1 second	The set volume could not be reached.
INSP PAUSE	< 1 second	Indicates that the inspiratory pause were activated
EXP PAUSE	< 1 second	Indicates that the expiratory pause were activated

10.16.4 IRMA CO2 Sensor Alarm Messages

In the event of one or more alarms related to the IRMA CO2 sensor, the following messages may be displayed, according to their respective priorities:

Table 24 - High priority alarms

High Priority Alarm	Delay	Description
HIGH $EtCO_2$	< 3 seconds	The rate of expired CO2 exceeded the alarm value set as the upper limit of EtCO2.
LOW $EtCO_2$	< 3 seconds	The expired CO2 rate is below the alarm value set as the lower limit of EtCO2.
HIGH ICO_2	< 3 seconds	The inspired CO2 rate exceeded the alarm value set as the upper limit of CO2i.
CO2: APNEA	< 2 cycles	Gas exchange is not identified.

Table 25 - Medium priority alarms

Medium Priority Alarm	Delay	Description
CO2: ZERO REQUIRED	< 3 seconds	Indicates the need to reset the IRMA CO2 sensor.
CO2: OUT OF RANGE	< 3 seconds	Indicates that the CO2 reading is incorrect or inaccurate.
CO2: PARAM OUT OF RANGE	< 3 seconds	It indicates that a parameter is outside the specified range and prevents the correct CO2 reading.

Medium Priority Alarm	Delay	Description
CO2: SPEED ERROR	< 3 seconds	Problem with the CO2 engine sent by Phase In.
CO2: CALIBRATION LOST	< 3 seconds	Problem with the factory calibration of the CO2 sent by Phase In.

Table 26 - Low-priority alarms

Low Priority Alarm	Delay	Description
CO2: DISCONNECTED	< 3 seconds	CO2 monitoring was discontinued during use.
CO2: REBOOT IRMA	< 3 seconds	Indicates that the IRMA CO2 sensor should be disconnected and reconnected.
CO2: HARDWARE ERROR	< 3 seconds	Indicates that the CO2 sensor should be replaced.
CO2: REPLACE ADAPTOR	< 3 seconds	Indicates that the IRMA CO2 sensor should be replaced.
CO2: NO ADAPTOR	< 3 seconds	Indicates that the airway adapter must be properly connected.

Table 27 - Messages

Message	Delay	Description
CO2: CONNECTED	< 1 second	CO2 monitoring is active.

WARNING

- ***When you receive alarm information, provide prompt assistance to solve the problem.***
- ***As soon as the situation that required the total silence of the audible alarm is over, it shall be reactivated for the safety of the patient.***

ATTENTION

- ***There may be a danger if different alarm presets are used for the same equipment or for similar equipment in the same area, such as an intensive care unit or a cardiac operating room.***

10.16.5 Oximeter Alarm Messages

In the event of one or more oximeter-related alarms, the following messages may be displayed, according to their respective priorities:

Table 28 - High priority alarms

High Priority Alarm	Delay	Description
HIGH PULSE	< 3 seconds	The patient's heart rate exceeded the alarm value set as its upper limit.
LOW PULSE	< 3 seconds	The patient's heart rate is below the alarm value set as its lower limit.
LOW SpO_2	< 3 seconds	The O2 saturation rate is below the alarm value set as the lower limit of SpO2.
SPO2: CABLE LIFE EXPIRED	< 3 seconds	The patient cable is not working or the cable life has expired.
SPO2: INCOMPATIBLE CABLE	< 3 seconds	The connected cable is not a suitable cable
SPO2: UNRECOGNIZED CABLE	< 3 seconds	The currently connected cable is not being recognized
SPO2: DEFECTIVE CABLE	< 3 seconds	The currently connected cable is faulty and cannot be used.
SPO2: CABLE LIFE NEAR EXPIRATION	< 3 seconds	The patient cable has less than 10% of the remaining active monitoring life.
SPO2: SENSOR LIFE EXPIRED	< 3 seconds	The sensor used all available monitoring time.
SPO2: INCOMPATIBLE SENSOR	< 3 seconds	There is no proper Masimo sensor or sensor connected to a device without an appropriate parameter installed.
SPO2: DEFECTIVE SENSOR	< 3 seconds	The currently connected sensor is faulty and cannot be used.
SPO2: CHECK CABLE AND SENSOR FAULT	< 3 seconds	The cable and/or sensor connection is faulty
SPO2: SENSOR LIFE NEAR EXPIRATION	< 3 seconds	The sensor has less than 10% active monitoring life remaining
SPO2: ADHESIVE SENSOR LIFE EXPIRED	< 3 seconds	When a single-patient wearable sensor is used, the adhesive part of the sensor does not work or the life of the adhesive part of the sensor has expired.
SPO2: INCOMPATIBLE ADHESIVE SENSOR	< 3 seconds	There is no suitable Masimo disposable sensor or a disposable sensor connected to a device without an appropriate parameter installed.
SPO2: UNRECOGNIZED ADHESIVE SENSOR	< 3 seconds	Currently Connected Disposable Sensor Is Not Being Recognized
SPO2: DEFECTIVE ADHESIVE SENSOR	< 3 seconds	The currently connected sensor is faulty and cannot be used.
SPO2: ADHESIVE LIFE NEAR EXPIRATION	< 3 seconds	The adhesive is nearing the end of its life and must be replaced.
SPO2: CHECK SENSOR	< 3 seconds	The technology board is unable to collect pulsation through the acoustic sensor
SPO2: ONLY MODE	< 3 seconds	Occurs during an unsuccessful pulse search/sensor initialization routine or during monitoring.

Table 29 - Medium priority alarms

Medium Priority Alarm	Delay	Description
SPO2: FAILURE	< 3 seconds	Problem with the SpO2 sensor sent by Masimo.
SPO2: SENSOR OFF PATIENT	< 3 seconds	Indicates that the sensor is not on the patient's finger.
SPO2: NO SENSOR	< 3 seconds	Indicates that the sensor is not connected.
SPO2: LOW PERFUSION	< 3 seconds	Indicates very low signal quality.
SPO2: NO PULSE	< 3 seconds	Indicates that it is not detecting the beat in the signal.
SPO2: UNKNOWN SENSOR	< 3 seconds	Indicates that the connected sensor is not responding as expected.
SPO2: INTERF. DETECTED	< 3 seconds	Indicates that there is light interference disturbing the reading.
SPO2: EXCEEDED LIGHT	< 3 seconds	Indicates that it is not possible to measure because there is too much light passing through the patient.
SPO2: NO ADHESIVE SENSOR	< 3 seconds	Indicates that the adhesive sensor is not attached.
SPO2: LOW SIGNAL QUALITY	< 3 seconds	It indicates that the signal quality is not good enough for monitoring.
SPO2: SENSOR INITIALIZING	< 3 seconds	The device is verifying the proper functioning of the sensor and performance.
SPO2: NO CABLE	< 3 seconds	Cable not connected or not fully inserted into the connector.

Table 30 - Low priority alarms

Low Priority Alarm	Delay	Description
SPO2: DISCONNECTED	< 3 seconds	Indicates that SpO2 was disconnected during monitoring.
SPO2: BOARD FAILURE	< 3 seconds	Indicates that the SpO2 plate has stopped working.

Table 31 -Messages

Message	Delay	Description
SPO2: DEMO	< 3 seconds	Indicates that SpO2 is in demo mode.
SPO2: CONNECTED	< 3 seconds	Indicates that the sensor is connected.
SPO2: DETECTING PULSE	< 3 seconds	Indicates that SpO2 is initiating calculations.

WARNING

- ***When you receive alarm information, provide prompt assistance to solve the problem.***
- ***Once the situation that requires the mute of the audible alarm is terminated, the alarms***

shall be reactivated for patient safety.

ATTENTION

- ***There may be a danger if different alarm presets are used for the same equipment or for similar equipment in the same area, such as an intensive care unit or a cardiac operating room.***

10.16.6 Alarm Testing

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

ATTENTION

- ***Never perform the alarm test with the patient connected to the equipment.***

10.16.6.1 O2 inspiratory fraction alarm

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

10.16.6.2 Airway Pressure Alarm

To test the high pressure alarm, enter PCV mode, set PEEP at zero, Control Pr at 5, and set the upper limit of Ppeak alarm at 5. Assemble the complete circuit, place the equipment to vent and press the test balloon so that the monitored pressure is greater than the set pressure. To test the low pressure alarm, set the lower limit of the Ppeak alarm so that it is higher than the pressure monitored on the device.

10.16.6.3 Volume Expired Alarm

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

10.16.6.4 Power Failure Alarm

Remove the power supply.

10.16.6.5 Low battery alarm

Leave the equipment switched on disconnected from the mains and cycling for 3 hours.

10.16.6.6 Gas Supply Failure Alarm

Disconnect the O2 mains.

10.16.6.7 PEEP Alarm

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

10.16.6.8 Disconnection Alarm

Disconnect the simulator balloon from the respiratory circuit and leave the equipment cycling.

10.16.6.9 Obstruction Alarm

The obstruction alarm is triggered when some form of obstruction occurs in the respiratory circuit that prevents the patient from completely exhaling. In **the PEDIATRIC** and **ADULT** modes, the criterion for triggering this alarm is based on the relationship between mean values obtained from PEEP and the limit pressure (P_{max}). When the pressure value is above the average of the reference parameters (PEEP and P_{max}), the alarm is triggered.

In **NEONATAL** mode, the obstruction alarm is activated when the airway pressure is above the SET PRESSURE + 5cmH2O. When an occlusion occurs in the respiratory circuit, the ventilator activates a system of overpressure valves that relieve the pressure in the circuit in order to preserve the integrity of the patient's lungs.

To test the operation of the obstruction alarm, put the ventilator into normal operation and press the expiratory branches of the patient's circuit in such a way as to simulate the obstruction and observe the activation of the alarm.

10.16.6.10 Minute Volume Alarm

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

10.16.6.11 Respiratory rate alarm

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

10.16.6.12 Apnea alarm

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

10.16.6.13 EtCO2 Alarm

To test the EtCO2 alarm, it is necessary that a capnograph is connected to the ventilator. Assemble the complete circuit for use with a capnograph and blow on the airway adapter for the ventilator to monitor the capnography parameters. To test the high EtCO2 alarm, set the upper limit of the EtCO2 alarm so that it is lower than the EtCO2 monitored on the device. To test the low EtCO2 alarm, set the lower limit of the EtCO2 alarm so that it is higher than the EtCO2 monitored on the device.

WARNING

- ***Airway adapters are single-use. Reuse may cause cross-contamination.***

10.16.6.14 Inspired CO2 Alarm

To test the inspired CO2 alarm, it is necessary that a capnograph is connected to the ventilator. Assemble the complete circuit for use with a capnograph and blow on the airway adapter for the ventilator to monitor the capnography parameters. Set the inspired CO2 alarm so that it is less than the inspired CO2 monitored on the device.

WARNING

- ***Airway adapters are single-use. Reuse may cause cross-contamination.***

10.16.6.15 Heart rate alarm

To test the heart rate alarm, a pulse oximeter is required to be connected to the ventilator. Assemble the circuit and attach the oximeter to your finger so that the ventilator monitors the oximetry parameters. To test the high heart rate alarm, adjust the upper limit of the heart rate alarm so that it is lower than the heart rate monitored on the device. To test the low heart rate alarm, adjust the lower limit of the heart rate alarm so that it is higher than the heart rate monitored on the device.

10.16.6.16 SpO2 Alarm

To test the SpO2 alarm, it is necessary that a pulse oximeter is connected to the ventilator. Assemble the circuit and attach the oximeter to your finger so that the ventilator monitors the oximetry parameters. Set the SpO2 alarm so that it is lower than the SpO2 monitored on the device.

10.16.7 Battery Test

To check the battery status, enter the Battery menu, where the battery voltage and status information will be displayed. To test the operation of the battery, disconnect the equipment from the power supply and verify that the percentage of battery power remaining is displayed. Wait a few minutes, reconnect the equipment to the power supply, and check if the battery is recharged.

10.17 Performance Specifications

Table 32 - Performance specifications

Parameter	Specification		Unit	Tolerance
Valve Response Time $T_{0.90}$	10		ms	± 20%
Maximum Flow in Supporting Pressure and Spontaneous Breathing	Adult	180	L/min	± 10%
	Neonatal	60	L/min	± 10%
Maximum Leakage Flow Compensated – Invasive Modalities [1]	Neonatal	20	L/min	± 10%
	Pediatric	35	L/min	± 10%
	Adult	120	L/min	± 10%
Maximum Leak Flow Compensated – Non-Invasive Modalities [2]	Neonatal	30	L/min	± 10%
	Pediatric	35	L/min	± 10%
	Adult	120	L/min	± 10%

[1] Pressure control modes
[2] All modes

Observation

- *Pressure-controlled ventilation is recommended for leak flows greater than the limit specified above.*
- *In this case, the maximum compensated flow may be greater than 100 L/min.*

10.18 Respiratory Circuit Specifications

Table 33 - Expiratory and inspiratory branch resistance specifications

Respiratory Circuit	Flow (L/min)	Resistance (cmH2O/L/s)[1]			
		Circuit	Circuit + Flow Sensor	Circuit + Flow Sensor + HME Filter	Circuit + Flow Sensor + CO2 Sensor + HME Filter
Neonatal	2.5	0.3	0.85(1)		
Pediatric	15.0	0.2	1.7	1.8	1.9(1)
Adult	30.0	0.4	0.7	1.55	1.75(1)

1 Maximum strength for which accuracy is maintained.

Table 34 – Respiratory circuit compliance specifications

Respiratory Circuit	Pressure (cmH2O)	Default Compliance(1) (mL/cmH2O)	Maximum Compliance(2) (mL/cmH2O)
Neonatal	60 ± 3	0.5	1.5
Pediatric	60 ± 3	1	4
Adult	60 ± 3	2	5

1 Default compliance will be used if the autotest is not performed or the autotest fails.

2 Maximum compliance for which accuracies are maintained.

Table 35 – Operation Specifications

Description	Specification	Tolerance
Recommended Maximum Operating Temperature	37 °C	± 3 °C
Recommended Maximum Operating Pressure	120 cmH2O	± 2 cmH2O

10.19 Maintenance and Calibration Specifications

Table 36 - Maintenance and calibration specifications

Description	Specification	Tolerance
Expiratory valve diaphragm overhaul and replacement	Under inspection or 5,000 hours or 12 months (whichever comes first)	± 500 h / ± 1 month
Inspection and replacement of the O_2 galvanic cell	Recommended replacement in case of calibration problems or 10,000 hours or 24 months (whichever comes first)	
Overhaul and replacement of internal batteries	10,000 hours or 24 months (whichever comes first)	
Equipment overhaul	5,000 hours or 12 months (whichever comes first)	
Equipment Calibration	5,000 hours or 12 months (whichever comes first)	
FlowAir System	30,000 hours or 72 months (whichever comes first)	
Shelf life	10 years	---

10.20 IRMA CO2 Sensor Specifications

Table 37 - IRMA CO2 Sensor – General Specifications

General Specifications	
Description	Mainstream monitoring sensor with infrared technology.
Dimensions (L x P x A)	38 x 37 x 34mm (1.49" x 1.45" x 1.34")
Cable Length	2.50m (± 0.02m)
Weight	< 25g (without cable) | < 38g (with cable)
Atmospheric Operating Pressure	525 to 1200cmH2O (525cmH2O corresponds to an altitude of 4572m or 15000ft).
Storage and Transport Atmospheric Pressure	500 to 1200cmH2O.
Mechanical Strength	Withstands repeated drops of 1m on a hard surface.
Electrical Power Supply	4.5 to 5.5 VDC, Max 1.0W (power measured with 5V and less than 350mA for 200ms).
Surface Temperature (23°C Ambient Temperature)	Max: 41°C / 106°F.
Airway Adapter	Adult/Pediatric (Disposable): Adds less than 6ml of dead space; Pressure loss less than 0.3cmH20 at 30L/min. Neonatal (Disposable): Adds less than 1ml of dead space; Losso f pressure less than 1.3cmH20 at 10L/min.

Table 38 - IRMA CO2 Sensor – Outputs

Outputs	
Breath Detection	Adaptive threshold, minimum 1% of the volume change in CO2 concentration.
Respiratory Rate	0 to 150bpm. The Respiratory Rate is shown every 3 breaths and the average value is updated with each breath.
Fi & ET	Fi and ET are shown after one breath and their averages are continuously updated.
Wave forms	CO2.
Diagnostic Parameters	Atmospheric pressure, software and hardware review, serial number.
Information	Rebreath Detection, Apnea, Adapter Check, Unspecified Accuracy, and Sensor Error.
Method for Calculating Gas Level Reading	The highest concentration of CO2 during a respiratory cycle with a weight function applied to favor values closer to the end of the cycle

Table 39 - IRMA CO2 Sensor – Gas Analyzer

CO2 Gas Analyzer	
Sensor	Gas analyzer with 2 to 9 NDIR (Non-Dispersive Infrared) channels that measures in the range of 4 to 10µm. Corrects pressure, temperature, and interference over the entire spectral range.
Data Acquisition Rate	10 kHz
Data Sampling Rate	20 Hz
Calibration	Zero recommended with each Airway Adapter change. No need for specific IR calibration.
Warm-up Time	Concentration information is analyzed and sent every 10 seconds. Total measurement accuracy: 1 minute.
Rise time (at 10 L/min)	CO2 ≤ 90ms.
Total System Response Time	< 1s.

Observation

- *CO2 monitoring is achieved exactly 1 minute after start-up.*

Table 40 - IRMA CO2 Sensor – Accuracy/Accuracy I

Exactitude / Accuracy of measurements (under standard conditions)		
Gas Type	Range (AX+)	Accuracy/Accuracy
CO2	0 to 15 15 to 25 months	±(0.2 vol% + 2% of reading) Not specified
Note: Gas concentration expressed in units of percentage volume.		

Table 41 - IRMA CO2 Sensor – Accuracy/Accuracy II

Exactitude / Accuracy of measurements (under all conditions)	
Gas Type	Accuracy
CO2	±(0.3 vol% + 4% of reading)
Note: The accuracy specification is valid for any specified environmental condition, except in the cases expressed in the table below with "Effects of Gas and Vapor Interference".	

Table 42 - IRMA CO2 sensor – Effects of gas and steam interference

Effects of Gas and Steam Interference		
Gases or Vapor	Gas Level	CO2
N2O	60 vol%	--- (1 and 2)
HAL	4 vol%	--- (1)
ENF, ISO, SEV	5 vol%	+8% of the measure read. (3)
DES	15 vol%	+12% of the measure read. (3)
Xe (Xenon)	80 vol%	-10% of the measure read. (3)
He (Helium)	50 vol%	-6% of the measure read. (3)
Metered dose inhaler propellant	It is not designed for use with metered dose inhaler propellant.	
C2H5OH (Ethanol)	0,3 vol%	--- (1)
C3H7OH (Isopropanol)	0.5 vol%	--- (1)
CH3COCH3 (Acetone)	1 vol%	--- (1)
CH4 (Methane)	3 vol%	--- (1)
CO (Carbon Monoxide)	1 vol%	--- (1)
NO (Nitrogen Monoxide)	0.02 vol%	--- (1)
O2	100 vol%	--- (1 and 2)

(1) Negligible interference. Interference effects do not alter the values in the "Accuracy of Measurements (Under All Conditions)" Table above.

(2) For sensors that are not measuring N2O and/or O2, concentrations must be manually entered by the user.

(3) Interference with the indicated gas level. For example, 50 vol% of Helium typically decreases the values read in CO2 by 6%. This means that if the mixture contains 5.0 vol% $_{CO2}$ and 50 vol% helium, the measurement of the CO2 concentration will normally be calculated as follows:
(1 - 0.06) * 5.0 vol% = 4.7 vol% CO_2.

According to ISO 80601-2-55.

Table 43 – Quantitative effects of humidity and condensation

Temp [C]	RH [%]	P [hPa]	H2O part.pres [hpa]	Errrel [%]	Errrel ATPD [%]	Errrel [%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0 (ATPD)	0	0	+6.2
25	23	1013	7,3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63 (BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

10.21 Oximeter Specifications

Table 44 – Performance specifications

Specification Criterion	Functional SpO2 (%)	Heart rate (bpm)	Perfusion Index (%)	PVI (%)
Display range	0.0 - 100.0 %	25 – 240 bpm	0.02 – 20.0 %	0 – 100 %
Calibration Range	70 – 100 %	25 – 240 bpm	0.10 – 20.0 %	-
Calibration Standard	Invasive co-oximetry	ECG & Patient Simulator	Patient Simulator	-
No motion accuracy (ms)	≤ 2.0 %	≤ 3.0 bpm	-	-
Motion Accuracy (rms)	≤ 3.0 %	≤ 5.0 bpm	-	-
Resolution	≤ 0.1 %	≤ 1 bpm	≤ 0.01 %	≤ 1 %
Time to display	≤ 8, ≤ 12 s	≤ 8 ≤ 12 s	≤ 8, ≤ 12 s	-
Asystole detection time	≤ 8 s	≤ 8 s	≤ 8 s	-
Delay	≤ 10 s	≤ 10 s	≤ 10 s	-
Response Time	≤ 20 s	≤ 20 s	≤ 20 s	-
Display Update Frequency	≥ 1 Hz	≥ 1 Hz	≥ 1 Hz	≥ 1 Hz
Average time(s)	2-4, 4-6, 8, 10, 12, 14, 16	-	-	-

For each specified range, the SpO2 ACCURACY of the PULSE OXIMETRY EQUIPMENT is determined in terms of the difference in mean square value (vqm) between the measured values ($SpO2i$) and the reference value (SRi), as given by Equation:

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^{n} (SpO_{2i} - S_{Ri})^2}{n}}$$

Pulse rate ACCURACY is defined over the full range delineated, as the difference in mean square value (vqm) between paired pulse rate data, recorded with the PULSE OXIMETRY EQUIPMENT and a reference method. The reference method used was a Biotek Index 2 ™ electronic pulse simulator.

Table 45 – Environmental specifications

Characteristic	Specification
Operating Conditions	
Incandescent light intensity	100 k Lux (Sunlight)
Fluorescent light intensity	10 k Lux
Fluorescent Light Frequency	50, 60 Hz ± 1.0 Hz
Temperature	5 to 40 °C
Humidity	15 to 95 %, non-condensing
Pressure	500 to 1060 mbar
Maximum Optical Output Power	15 mW
Storage conditions	
Temperature	-40 to 70 °C
Humidity	15 to 95 %, non-condensing

Note: This information may be useful to physicians specifically.

10.22 Electromagnetic Compatibility

Changes or modifications made to this equipment other than with the express approval of MAGNAMED could cause EMC problems with this equipment or another. Contact MAGNAMED for technical assistance.

This equipment has been designed and tested to comply with applicable EMC standards as described below:

- Immunity: IEC 60601-1-2
- Emission: CISPR11 (Group 1 - Class A)
- Approvals: IEC 60601-1

This equipment has been designed and tested to meet the following essential requirements: deliver volume within alarm limits or generate alarm condition; FiO2 monitoring; generate PEEP alarm conditions when PEEP is above or below the alarm threshold; monitor expired volume; alarm condition to indicate when the electrical voltage has fallen below what is necessary to maintain normal operation; alarm condition to indicate when the battery charge is close to completion; technical condition of alarm to indicate failure in the air and oxygen network; limit the reverse flow between gas ports to values below 100 mL/h; ensure the accuracy of the oxygen level within the specified range.

WARNING

- ***The use of mobile phones or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse results. Monitor operation if there are sources of radio frequency emission in the vicinity.***

- ***The use of other electrical equipment in or near the system may cause interference. Before use on the patient, you should check that the equipment operates normally in the defined configuration.***
- ***Use of this equipment adjacent to or on top of other equipment should be avoided as it may result in improper operation. If this use is necessary, it is advisable to observe this and other equipment to verify that they are operating normally.***
- ***The use of accessories, transducers, and cables other than those specified or supplied by Magnamed may result in elevated 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 the Oxymag Max, including cables specified by Magnamed. Failure to do so may result in degradation of the performance of this equipment.***
- ***If essential performance is requested or degraded due to electromagnetic disturbances, the ventilator may stop ventilating. In this case, the operator must provide means of manual ventilation.***

10.22.1 Guidelines and Manufacturer's Declaration - Electromagnetic Emissions

The **Oxymag Max** is intended for use in the electromagnetic environment specified below. The purchaser or user of **Oxymag Max** should ensure that it is used in such an environment.

Emissions Testing	Compliance	Electromagnetic Environment - Guidelines
RF Emissions CISPR 11	Group 1	The **Oxymag Max** utilizes RF energy only for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause any interference to nearby electronic equipment.
RF Emissions CISPR 11	Class A	Oxymag **Max** is suitable for use in all establishments other than households and can be used in households and other buildings directly connected to the public low-voltage power supply network that supplies the buildings used as households, provided that the following warning is respected: **Warning:** This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of equipment in the vicinity. It may be necessary to take action to mitigation, such as reorienting or relocating the **Oxymag Max** or shielding the site.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / Flicker emissions IEC 61000-3-3	Complies	

10.22.2 Guidelines and Manufacturer's Declaration - Electromagnetic Immunity

Oxymag **Max** is intended for use in the electromagnetic environment specified below. The purchaser or user of **Oxymag Max** should ensure that it is used in such an environment.

Immunity Test	Test level of IEC-60601	Compliance Level	Electromagnetic Environment - Guidelines
IEC 61000-4-2 - Electrostatic discharge (ESD)	± 8 kV per contact ± 15 kV by air	± 8 kV per contact ± 15 kV by air	Floors should be wooden, concrete, or ceramic. If the floors are covered with synthetic material, the relative humidity should be at least 30%
IEC 61000-4-4 – Fast/Salvo Electrical Transients	± 2 kV on AC power input interface ± 2 kV on DC power input interface ±1 kV at signal input/output parts	± 2 kV on AC power input interface ± 2 kV on DC power input interface ±1 kV at signal input/output parts	Power supply quality should be that of a typical hospital or commercial environment.
IEC 61000-4-5 - Surges	± 1 kV line(s) to line(s) ±2 kV Line(s) to Ground	± 1 kV line(s) to line(s) ±2 kV Line(s) to Ground	Power supply quality should be that of a typical hospital or commercial environment.
IEC 61000-4-11 – Voltage Drops	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°)	Power supply quality should be that of a typical hospital or commercial environment.
IEC 61000-4-11 – Voltage Interruptions	0 % UT; 250/300 cycles	0 % UT; 250/300 cycles	Power supply quality should be that of a typical hospital or commercial environment.
IEC 61000-4-8 – Magnetic field of the power frequency (50/60 Hz)	30 A/m	30 A/m	Magnetic fields in the frequency of the feeding should be at levels characteristic of a typical location in a typical hospital or commercial environment

NOTE: UT is the AC supply voltage prior to the application of the test level.

Oxymag **Max** is intended for use in the electromagnetic environment specified below. The purchaser or user of **Oxymag Max** should ensure that it is used in such an environment.

Immunity Test	Test level of IEC-60601	Compliance Level	Electromagnetic Environment - Guidelines
			Mobile or portable RF communication equipment should not be used at shorter distances than any part of the

			Oxymag Max, including cables, than the recommended separation distance, calculated by the equation applicable to the transmitter frequency. **Recommended Separation Distance**
Conducted disturbances field-induced RF([a]) IEC 61000-4-6	3 Vrms 0.15 MHz to 80 MHz outside ISM bands	3 V	d = 1.2√P
	6 Vrms 0.15 MHz to 80 MHz in ISM bands	6 V	d = 1.2√P
RF EM Fields Radiated IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.7 GHz where *P* is the maximum stated 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 of RF transmitters, as determined by an electromagnetic survey of the field,c should be determined by an electromagnetic survey of the field,c is less than the compliance level for each frequency band.[d] Interference may occur in the vicinity of the Equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the highest frequency range is applicable.

NOTE 2 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.

[a] The ISM (industrial, scientific, and medical) 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. The 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 5.4 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 frequency range from 80 MHz to 2.7 GHz are defined with the goal of reducing the possibility of mobile/portable RF communications equipment causing interference if it is inadvertently brought into the areas intended for patients. Therefore, an additional factor of 10/3 was incorporated into the formulas used to calculate the recommended separation distance for transmitters in these frequency bands.

[c] Field strength from fixed transmitters, such as radio base stations for telephones (cellular or wireless) and mobile ground radios, amateur radio, AM and FM radio broadcasts, and TV broadcasts, cannot be theoretically accurately predicted. In order to evaluate the electromagnetic environment generated by fixed RF transmitters, an electromagnetic survey of the field should be considered. If the field strength measured at the location where the **Oxymag Max** will be used exceeds the applicable RF COMPLIANCE LEVEL defined above, the **Oxymag Max** should be observed to verify that it is operating normally. If abnormal performance is detected, additional measures may be required, such as reorientation or relocation of the **Oxymag Max.**

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

Recommended Separation Distances Between Mobile or Portable RF Communication Equipment and the Oxymag Max

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

Recommended separation distance according to transmitter frequency (m)

Maximum declared transmitter output power level (W)	150 kHz to 80 MHz outside of ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in the ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.3\sqrt{P}$
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 maximum declared level of output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the transmitter frequency. Where *P* is the maximum stated output power of the transmitter in watts (W), according to the transmitter manufacturer

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the largest frequency range is applicable.

NOTE 2 The ISM (industrial, scientific, and medical) 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. The 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 5.4 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 in calculating the recommended separation distance for transmitters in the ISM frequency bands between 0.15 MHz and 80 MHz and in the frequency range from 80 MHz to 2.7 GHz, with the aim of reducing the possibility of mobile/portable RF communications equipment causing interference if it is inadvertently brought into the areas intended for patients.

NOTE 4 These guidelines may not be applicable in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects, and people.

Fields in the vicinity of RF wireless communication equipment

The Oxymag Max enclosure interface has been tested as specified in the table below using the test methods specified in IEC 61000-4-3

Band [MHz]	Freq. test [MHz]	Modulation	Testing level [V/m]
380 to 390	385	Pulse, 18 Hz	27
430 to 470	450	FM, 1 kHz, 5kHz ± Bypass	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

Magnetic fields in the vicinity

The Oxymag Max enclosure interface has been tested as specified in the table below using the test methods specified in IEC 61000-4-39

Test Frequency	Modulation	Testing level [A/m]
30 kHz	CW	8
134.2 kHz	Pulse, 2.1 kHz	65
13.56 MHz	Pulse, 50 kHz	7,5

Observation

- ***The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (ABNT NBR IEC/CISPR 11 class A). If used in a residential environment (for which ABNT NBR IEC/CISPR 11 class B is normally required), this equipment may not provide adequate protection for radio frequency communication services. The user may need to take mitigation measures, such as relocating or reorienting the equipment.***

10.22.3 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 IEC 60601-1 may not be placed within 1.5 m of the patient.***
- ***Do not connect non-medical electrical equipment directly to the AC socket in the wall. Use AC power supply with its own transformer. Otherwise, the current leakage will increase above the levels accepted by IEC 60601-1 under normal conditions and single-fault conditions. This may cause a dangerous electric shock to the patient or operator.***
- ***After connecting any equipment into these outlets, subject the system to a full leakage current test (in accordance with IEC 60601-1).***
- ***The operator of the electromedical system shall not touch non-medical electrical equipment and the patient at the same time. This may cause a dangerous electric shock to the patient or operator.***
- ***Do not connect a multi-socket outlet or extension cord to the electromedical system.***

10.23 Audible acoustic energy

Configuration	Sound Pressure Level	Sound Power Level
Volume ≥ 300 mL	43.5 dB ± 2 dB	57.5 dB ± 2 dB

Measured according to ISO 4871:1996 and ISO 3744:2010 using grade 2 engineering method.

10.24 Mask for non-invasive ventilation

Specification	
Adult/Pediatric Connection	22 mm
Neonatal Connection	15 mm

WARNING

- ***Wear only masks specified by Magnamed with ANVISA.***
- ***Wear a mask appropriate for the type of patient to avoid excessive leakage.***

10.25 Respiratory circuit

Specification	
Adult/Pediatric Connection	22 mm
Neonatal Connection	15 mm
Resistance	≤ 0.3 mbar/L.s-1

10.26 HME Filter

ATTENTION

- ***If an HME filter is used with the ventilator, it is recommended that you follow the specifications below.***

Specification		
Compliance	ISO 23328-1, ISO 23328-2; and ISO 9360-1 or ISO 9360-2	
Connection	22 mm	
Bacterial and viral filtration efficiency	99.99%	
Resistance	30 L/min	2.02 cmH2O
	60 L/min	5.19 cmH2O
	90 L/min	9.37 cmH2O

10.27 HEPA Filter

ATTENTION

- ***If a HEPA filter is used with the ventilator, it is recommended that you follow the specifications below.***

Specification		
Compliance	ISO 23328-1 and ISO 23328-2	
Connection	22 mm	
Bacterial and viral filtration efficiency	99.99%	
Resistance	30 L/min	1 cmH2O

10.28 Internal Volume of Respiratory Circuit Components

Table 46 – Internal volume of the components of the respiratory circuit

Internal volume	
Breathing tube 22mm x 1.20 m autoclavable 22f+22f	407.8 mL
Adult Y 22mm Autoclavable with Straight Thermometer	18.7 mL
Breathing tube 15mm x 1.20 m autoclavable 15f+22f	179.5 mL
Intermediary 15m+15m for autoclavable infant breathing circuit	3.6 mL
Children's Y 15mm Autoclavable Without Thermometer 90	16.9 mL
Airway Adapter	9.0 mL
Universal Flow Sensor	8.4 mL

11 IRMA CO2 sensor (optional)

11.1 Intended Use

The "mainstream" IRMA™ CO_2 sensor was developed to monitor respiratory gases in adult, pediatric and neonate patients, in care units, operating theatres and emergency departments.

It consists of a set consisting of a single-track sensor with technology of up to 9 channels of non-dispersive infrared rays ("NDIR") for gas identification, a barometric pressure sensor, an electrical voltage regulator and a microprocessor. The unit weighs less than 25g.

Carbon dioxide (CO2) concentrations are monitored along with other parameters such as respiratory rate (or respiratory rhythm – "RR"), the waveform of the gases and the concentration of each gas during inhalation and exhalation.

The airway adapter fits perfectly to the CO2 sensor. This device uses XTP™ window technology. The airway adapter should be positioned between the endotracheal tube and the breathing circuit, allowing XTP windows positioned on the sides of the sensor to measure gas concentrations.

Operating at a standard low-intensity continuous electrical voltage, the sensor is designed to meet portability and low power requirements, typically below 1 Watt. It is designed to be extremely easy to integrate with any monitoring device, allowing the visualization of gas information in real time.

11.2 Instructions for Use

The IRMA CO2 sensor is designed to be used connected to Magnamed ventilators and any other compatible monitoring device. Its function is to monitor the signal and the concentration value of the gas in real time.

It should not be used as the sole means of patient monitoring. It should always be used in conjunction with other vital signs monitoring equipment and this process should be accompanied by a specialist capable of analyzing the patient's conditions.

The IRMA CO2 sensor is designed to be used only by trained and authorized healthcare professionals.

WARNING

- ***The sensor should not have direct contact with the patient during use.***
- ***Perform the leak test on the patient circuit with the airway adapter plugged into the patient circuit.***
- ***Always check the gas and waveform reading on the ventilator before plugging the airway adapter into the patient's circuit.***
- ***Cyclic pressure up to 100 cmH2O has no interference in the gas reading.***

11.2.1 Zeroing Procedure

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

WARNING

- ***Incorrect zeroing of the sensor will result in the incorrect reading of the measured values.***

Observation

- *The sensor zeroing option will be available in the CALIBRATION window once the sensor has been identified and ready for use.*
- *It may take a few seconds before the sensor is ready for the zeroing process.*

Zeroing should be done by connecting an airway adapter to the sensor, without connecting them to the respiratory circuit. When the gas monitoring signals are stable, press the button to start zeroing.

Special care should be taken to prevent any breathing near the sensor before or during zeroing. The presence of ambient air (21% O2 and 0% CO2) in the airway adapter is of crucial importance for successful zeroing. If the calibration error message appears immediately after the end of the zeroing procedure, the calibration procedure must be repeated.

Zeroing should be performed each time the airway adapter is replaced. It should also be performed whenever there is an offset from the baseline in any of the gas measurements or when any of the alarm

messages are displayed: "IRMA PARAMETER OUTSIDE OF SPECIFIED", "IRMA CO2 OUTSIDE SPECIFIED" or even "IRMA ZERO SENSOR".

After turning on the sensor or changing the airway adapter, wait at least one minute before starting the zeroing procedure to allow the sensor to warm up.

The green LED on the sensor will blink for 5 seconds while the zeroing process is in progress.

11.2.2 Status LED Information

Table 47 - IRMA status LED CO2

Color (state)	Meaning
Green (lit constantly)	System OK
Green (flashing)	Zeroing in progress
Blue (lit constantly)	Anesthetic agent present
Red (lit constantly)	Sensor error
Red (flashing)	Check the adapter

11.3 Preventive Maintenance

Gas calibration should be checked at regular intervals by reference instrument.

11.4 Important Notices

WARNING

- ***The IRMA CO2 sensor must be operated exclusively by trained and authorized medical personnel.***
- ***The sensor should not be used with flammable anesthetic agents.***
- ***Airway adapters should not be reused.***
- ***Reusing a disposable adapter may cause a cross-infection.***
- ***Do not use the adult/pediatric airway adapter in neonate patients as the adapter adds a 6mL dead space in the patient's breathing circuit.***
- ***Do not use the Neonatal Airway Adapter in adult patients as this adapter may add excessive resistance.***
- ***The measures may be affected by radio-frequency communication equipment or by mobile devices.***
- ***The user must make sure that the sensor will be used in environments as per the electromagnetic environment specifications expressed in this manual.***
- ***Do not use the airway adapter with metered dose inhalers or with nebulized medications, as they may affect the transmission of light inside the sensor windows.***
- ***The IRMA CO2 sensor is designed to be an adjunct device in patient monitoring, so its***

information must be analyzed along with other measurements and symptoms.

- ***Incorrect zeroing can result in erroneous measurements.***
- ***Change the airway adapter if there is condensation inside the adapter.***
- ***Use only Masimo-made airway adapters.***
- ***The sensor should not come into direct contact with the patient during use.***
- ***Do not connect the airway adapter between the endotracheal tube and the elbow of the breathing circuit, as this may cause the patient's secretions to block the adapter windows, causing incorrect sensor operation.***

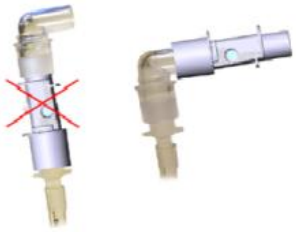


Figure 1 – Incorrect and correct positioning of the airway adapter

ATTENTION

- ***Do not apply electrical voltage to the sensor cable.***
- ***Do not use the sensor in environments where specifications are outside the limits set out in its technical specification.***

12 Pulse Oximeter (optional)

12.1 Intended Use

The Masimo MS-2040 pulse oximeter is a self-contained solution that enables reliable measurement of SpO2, heart rate, perfusion rate, and PVI, even on the move or at low perfusion. This oximeter is compatible with all Masimo LNCS sensors®. It is intended for use with neonatal, pediatric and adductal patients. In adults and pediatrics, the sensor is worn on the finger, while in neonatal patients, the sensor is multisite and can be used on the hand, foot or fingers and toes.

12.2 Principle of Operation

The Masimo SET Pulse Oximeter MS Board is based on three principles:

1. Differential absorption of oxyhemoglobin and deoxyhemoglobin from red and infrared light (spectrophotometry).
2. The volume of arterial blood in the tissue and the light absorbed in the blood changes (plethysmography).
3. Arteriovenous shunt is highly variable and its absorbance fluctuation by venous blood is the major component of noise during pulse.

The MS plate of the Masimo SET pulse oximeter, like traditional pulse dosimetry, determines SpO2 by passing red and infrared light through a capillary bed and changes the measurement during the pulsatile cycle. Red and infrared light-emitting diodes (LEDs) in oximetry sensors serve as a light source, the photodiode serves as a photodetector.

Traditionally, pulse oximetry assumes that all pulsations in the light-absorbing signal are caused by oscillations in arterial blood volume. Assuming that the blood flow in the sensor region passes entirely through the capillary bed rather than through some arteriovenous shunt. Traditional pulse oximetry calculates the ratio of pulsatile absorption (AC) to average absorption (DC) at each of the two wavelengths, 660nm and 905nm:

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

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

The oximeter then calculates the relationship between these two signals of pulse arterial absorption:

R = S(660) / S(905)

This value of R is used to find the saturation (SpO2) in a check table made by the oximeter software. The values in this table were obtained based on studies on human blood, carried out with healthy adult volunteers, in a situation of induced hypoxia.

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

S(660) = S1+N1

S(905) = S2+N2

R = S1 / S2

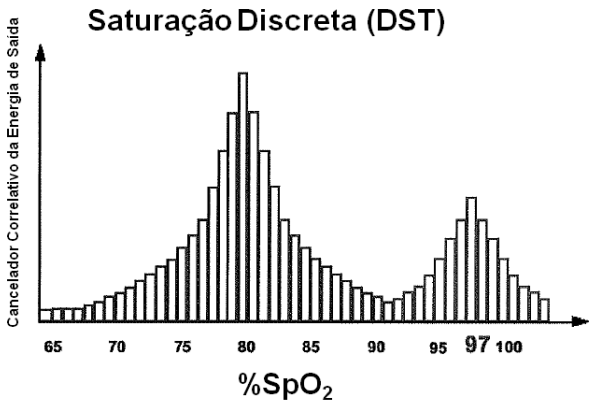
Again, R is the ratio between two pulsed arterial absorption signals, and its value is used to find SpO2 saturation in an empirically derived equation in the oximeter software. The values in the empirically derived equation were obtained based on studies on human blood, carried out with healthy adult volunteers, in a situation of induced hypoxia.

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

N' = S(660) - S(950) x R

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

The equation for the reference noise is based on the value of R, the value sought to determine SpO2. The MS board software scans all possible R values that correspond to SpO2 values between 1% and 100% and generates an N' value for each of these R values. The S(660) and S(905) signals are processed for each possible reference N' noise, for an adaptive cancellation (ACC) correlation that yields a power output versus possible SpO2 value as shown in the following figure where R corresponds to SpO2 = 97%:



The DST curve has two peaks: a peak corresponding to the highest saturation is selected as the SpO2 value. The entire sequence is repeated every two seconds for the most recent four seconds of the received

die. Concluding the SpO2 of the MS plate, corresponds to the running evaluation of arterial hemoglobin saturation updated every two seconds.

12.3 Important Notices

WARNING

- ***Explosion Hazard. A Do not use the MS pulse oximeter in the presence of flammable anesthetics or other flammable substances in contamination such as air, oxygen-enriched environments, or nitrous oxide.***
- ***The pulse oximeter shall not be used as an apnea sensor.***
- ***The heart rate is based on the optical detection of peripheral pulse flow and thus may not detect certain arrhythmias. Therefore, the pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis***
- ***A pulse oximeter can be considered an early warning device. As an indicator of the patient's deoxygenation trend, blood samples can be analyzed by co-oximetry laboratory to complete the understanding of the patient's condition.***
- ***The MS plate of the pulse oximeter should only be operated by a qualified person.***
- ***The manual, instructions for use, and all precautions and specifications information should be read before use.***
- ***There is a danger of electric shock. Do not remove the monitor cover except for battery replacement.***
- ***The operator may perform the maintenance procedures described in the producto manual.***
- ***Contact Magnamed Service for oximeter repairs.***
- ***As with all medical equipment, position the cable on the patient in order to reduce the possibility of entanglement or strangulation.***
- ***Interfering substances:***
    - ***Carboxyhemoglogin may erroneously increase readings. The level of increase is approximately equal to the amount of carboxyhemoglobin present.***
    - ***Dyes or any dye-containing substance that alter the artery's usual pigmentation may cause reading errors.***
- ***Do not use the sensor during the magnetic resonance imaging (MRI) scan:***
    - ***The induced current can potentially cause burns.***
    - ***The oximeter can affect the MRI image, and the MRI unit can affect the oximetry measurements.***
- ***If the fidelity of any measurement does not seem reasonable, first check the patient's vital signs by alternative measures and verify that the oximeter is functioning properly.***
- ***Before use, carefully read the instructions for use of the LNOP/LNCS sensors.***
- ***Use only Masimo oximetry sensors for SpO2 measurement.***
- ***Tissue damage can be caused by incorrect application or use of LNOP/LNCS sensors.***

- ***Inspect the sensor site as directed in the product's instructions for use in order to ensure skin integrity and correct sensor positioning and adhesion.***
- ***Do not use damaged LNOP/LNCS sensors.***
- ***Do not use LNOP/LNCS sensors with the optical components exposed.***
- ***Do not immerse the sensor in water, solvents, or cleaning solution (sensors and connectors are not waterproof).***
- ***Do not sterilize by irradiation, steam, or sterilization by oxides.***
- ***See cleaning instructions in the instructions for use for Masimo LNOP/LNCS reusable sensors.***
- ***Do not use damaged cables.***
- ***Do not immerse the patient cord in water, solvents, or cleaning solution (patient cord is not waterproof).***
- ***Do not sterilize by irradiation, steam or sterilization by oxides.***
- ***See cleaning instructions in the instructions for use for Masimo LNOP/LNCS Reusable Patient Cables.***
- ***Do not use the adult / pediatric sensor in a neonatal patient. This can cause incorrect reading of physiological parameters.***
- ***Do not use the neonatal sensor in an adult/pediatric patient. This can cause incorrect reading of physiological parameters.***
- ***Inaccurate measurements can be caused by:***
    - ***Incorrect application or use of the sensor.***
    - ***Elevated COHb or MetHb levels: Elevated COHb or MetHb levels may occur with an apparently normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.***
    - ***Elevated levels of bilirubin***
    - ***Elevated levels of dyshemoglobin***
    - ***Vasospastic disease, such as Raynaud's disease and peripheral vascular disease***
    - ***Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell anemia, etc.***
    - ***Hypocapnic or hypercapnic conditions***
    - ***Severe anemia***
    - ***Very low arterial perfusion***
    - ***Extreme Motion Artifact***
    - ***Abnormal venous pulsation or venous constriction***
    - ***Severe vasoconstriction or hypothermia***
    - ***Arterial catheters and intra-aortic balloon***
    - ***Intravascular dyes, such as indocyanine green or methylene blue***
    - ***Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.***

- ***Birthmark(s), tattoos, skin discoloration, moisture in the skin, deformed or abnormal fingers. and so on.***
- ***Skin color disorders***

- ***Do not place the pulse oximeter or accessories in any position that may cause it to fall on the patient.***
- ***Do not start or operate the pulse oximeter unless the setting has been verified to be correct.***
- ***To ensure safety, avoid stacking multiple devices or putting anything on the device during operation.***
- ***To protect yourself from electric shock, always remove the sensor and completely disconnect the pulse oximeter before bathing the patient.***
- ***Do not adjust, repair, open, disassemble, or modify the pulse oximeter or accessories. Personal injury or equipment damage may result. Return the pulse oximeter for service if necessary.***
- ***Do not place the pulse oximeter where the controls can be changed by the patient.***
- ***Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.***
- ***When patients are on photodynamic therapy, they may be sensitive to light sources. Pulse oximetry can be used only under close clinical supervision for short periods of time to minimize interference with photodynamic therapy.***
- ***If the Low Perfusion message is displayed frequently, find a better perfusion monitoring site. In the meantime, evaluate the patient and, if indicated, check the oxygenation status by other means.***
- ***Change the application site or replace the sensor and/or patient cable when a "Replace Sensor" and/or "Replace Patient Cable" message or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that the patient monitoring time is out on the patient's cable or sensor.***
- ***To ensure that the alarm limits are appropriate for the patiant being monitored, check the limits each time the pulse oximeter is used.***
- ***The variation in measurements can be profound and may be affected by the sampling technique as well as the physiological conditions of the patient. Any results that are inconsistent with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision-making to fully understand the patient's condition.***
- ***Replace the cable or sensor when a replacement sensor or when a low SIQ message is consistently displayed during monitoring of consecutive patients after completing the troubleshooting steps listed in this manual.***
- ***A functional tester cannot be used to evaluate the accuracy of the pulse oximeter.***
- ***When using the Maximum Sensitivity setting, the performance of the "Sensor Off" detection may be compromised. If the device is in this configuration and the sensor is dislodged from the patient, false readings may occur due to environmental "noise" such as light, vibration,***

and excessive air movement.

- ***Do not loop the patient cabling into a tight coil or wrap Around the device, as this can damage the patient cabling.***
- ***Additional information specific to Masimo sensors compatible with the pulse oximeter, including information on parameter/measurement performance during motion and low perfusion, can be found in the Instructions for Use (DFU).***
- ***Cables and sensors are supplied with X-Cal™ technology to minimize the risk of inaccurate readings and unforeseen loss of patient monitoring. Refer to the DFU of the cable or sensor for the specified duration of patient monitoring time.***
- ***The pulse oximeter should not be used as the sole basis for medical decisions. It should be used in conjunction with clinical signs and symptoms.***
- ***The pulse oximeter will not be affected when there is a loss of electrical supply for 30 seconds or less. In this case, the equipment will be powered by an internal non-interchangeable battery and the pulse oximeter will continue to operate normally.***
- ***The LNCS DC-I and LNCS YI oximetry sensors have been tested and validated together with the MASIMO SET USpO2 OXIMETRY CABLE AND OXYMAG equipment, to comply with the ABNT NBR ISO 80601-2-61 standard.***

13 Technical Service

WARNING

- ***Oxymag Max is a life support equipment and therefore, if any repair or maintenance is required on this equipment, seek only the authorized Magnamed technical service.***
- ***Failure to perform preventive maintenance may affect the safety and performance of the ventilator.***
- ***DO NOT USE the equipment if it is not operating in accordance with the specifications contained in this operating manual.***
- ***Before sending the equipment to the service technician, observe the cleaning and disinfection process RIGOROUSLY.***
- ***Magnamed will make available upon request the circuit diagrams, component list, descriptions, calibration instructions and other information necessary for the performance of authorized technical service.***

14 Discard

The Oxymag Max ventilator shall be discarded as electrical and electronic equipment. Accessories and consumables must be disposed of as described in the instruction manual. Follow local government recommendations for proper disposal.

WARNING

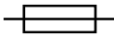
- ***Dispose of removed parts of equipment according to your institution's parts and pieces disposal protocol.***
- ***Follow local government recommendations regarding environmental protection, especially in cases of disposal of e-waste or electronic parts.***
- ***All parts of Magnamed ventilators that come into contact with patient fluids (e.g., respiratory circuit) are potentially contaminated, are called semi-critical and must undergo a high-level disinfection or sterilization process before disposal (at the end of their useful lives) or shipment for maintenance or repair service.***
- ***In the case of disposal of parts of Magnamed ventilators that have contact with fluids coming from a patient, indicate as potentially infected medical waste.***
- ***Disposal of batteries shall be in accordance with local regulations.***
- ***Disposal of the galvanic cells shall follow local regulations.***
- ***Airway adapters should be disposed of in accordance with local regulations for medical disposal.***
- ***Do not disassemble the equipment. All service or maintenance on the ventilator can only be carried out by qualified technician, trained and duly authorized by MAGNAMED.***

15 Symbology

15.1 Symbols used on equipment

Table 48 – Symbols used on the equipment

Symbol	Description
	Preventive maintenance period
	Patient
	Equipment with applied part type B
	Equipment with applied part type BF
IP34	Degree of protection IP31 for protection against solid objects 2.5 mm in diameter or more and protected against falling drops
 XXXX	EC Conformity: Indicates that the equipmet complies with the European Council directive 93/42/EEC for medical equipment
	Authorized Representative in the European Community
	Attention! Consult accompanying documents
	See operating instructions
	Separate collection of electrical / electronic equipment (do not dispose as ordinary waste)
	Manufacture date
	Manufacturer's identification
	Gas inlet (AR / O_2)
	On/Off
	Power Connection
	Serial Connection

Symbol	Description
	USB Connection
	Network connection
	Alternating current
	Direct current
	DC Input – External Power Supply
	Fuse
	Identify or advise cleaning or filter change
	US federal law restricts this device to sale by or on the order of a physician.
	Consult documentation that came with the product.

15.2 Symbols used on packaging and labelling

Table 49 – Symbols used on packaging and labelling

Symbol	Description
	Fragile
	Direction of the top face of the package
	Keep protected from sunlight
	Keep protected from moisture
	Maximum Stacking Quantity
	Temperature Limits
	EC Conformity: Indicates that the system complies with the European Council Directive 93/42/EEC for medical equipment
	INMETRO

Symbol	Description
	Single-use part or accessory. Discard after use. Reprocessing is prohibited.
	Sterile part or attachment not supplied.
	Expiration date
	Do not use if packaging is damaged
	Manufacturer's catalogue number
	Manufacturer's serial number
	Manufacturer's Lot Code
	Consult documentation that came with the product.

16 Abbreviations and Terms Used

Table 50 - Abbreviations and terms used

Abbreviation	Meaning
∆PS	Pressure Supporting Delta (pressure above PEEP)
O2	O2 concentration
PEEP	Positive end-expiratory pressure
Control Pr	Controlled pressure (pressure above PEEP)
Inferior Pr	Lower Level Pressure in APRV/DualPAP
Insp Pr	Inspiratory pressure (absolute pressure in neonatal mode)
Limit Pr	Limit pressure
Superior Pr	Pressure at the top level in APRV/DualPAP
Sensib Fl	Flow sensitivity (for triggering)
Sensib Pr	Pressure sensitivity (for triggering)
T Inferior	Time at Lower Level in APRV/DualPAP
T Rise	Ascent time (ramp or rise time)
T Superior	Time at the Higher Level in APRV/DualPAP
Ins Time	Inspiratory time
Minute Vol	Minute volume
Vol/Weight	Volume by Patient Weight
NIV or VNI	Noninvasive Ventilation
O2 +	Concentration of 50 to 100% O2 for a certain time
O2 100%	100% O_2 concentration for a given time
MANUAL CYCLE or INSP MANUAL	Manual Cycle Trigger
INSP HOLD	Inspiratory hold
EXP HOLD	Expiratory hold
Leakage	Percentage or leakage flow
Cdyn	Dynamic compliance
Cstat	Static compliance
E	Elastance
R Rate or f	Respiratory rate
Rate sp or fspont	Spontaneous respiratory rate
I:E	I:E Ratio
Pmean	Pressure Mean
Ppeak	Pressure Peak
Pplat	Plateau Pressure
RE	Expiratory resistance
RI	Inspiratory resistance
RSBi	Rapid Shallow Breathing Index (IRRS, Tobin Index)
TC	Expiratory Time Constant
Te	Expiratory time
Ti	Inspiratory time
Ti/Ttot	Reason for total inspiratory time
Vte or VTE	Total expired volume
Vte sp or VTE spont	Spontaneous total expired volume
Vti or VTI	Total Inspired Volume
MV or VM	Minute volume
MV sp or VM spont	Spontaneous minute volume
WOBi	Imposed Work Of Breathing

WARNING

- ***Pressure controlled adjustment (Pr Control) in pediatric or adult patients refers to a relative pressure, I.E, pressure value is set ABOVE PEEP.***
- ***The resulting inspiratory pressure will be the sum of the pressure controlled with PEEP.***

17 Biocompatibility Statement

We declare under our sole responsibility that all materials used in parts applied to Oxymag Max, such as silicone and polysulfone, have been widely used in the medical field over time, with no effects related to toxicity or tissue effects, ensuring their biocompatibility.

WARNING

- ***Common accessories purchased from third parties SHALL be registered with ANVISA.***

18 Warranty

The products manufactured and marketed by **MAGNAMED TECNOLOGIA MÉDICA S/A** are warranted against defects in material and manufacturing, throughout the Brazilian territory, according to the provisions below.

The warranty period of the equipment is 12 months. For batteries and accessories, the period of 3 months, as long as their original characteristics are maintained, and these periods are counted from the date of acquisition by the first buyer of the product, included in the Invoice of Sale of **MAGNAMED TECNOLOGIA MÉDICA S/A**.

Warranty liability is limited to exchange, repair and labor, for parts that are defective or do not meet the specifications contained in the product's Operating Manual.

The warranty is limited to the product that is used under normal conditions and for the purposes for which it is intended and whose preventive maintenance and replacement of parts and repairs are carried out in accordance with the instructions contained in the product's Operating Manual, by personnel authorized by the manufacturer.

The warranty does not cover defects caused by improper use or installation, accidents, improper sterilization, service, installation, operation, or alteration performed by personnel not authorized by the manufacturer.

Breakage or absence of seals or warranty seals by unauthorized personnel results in the loss of product's warranty.

Parts subject to wear or deterioration by normal use, adverse conditions of use, misuse or accidents are not covered under warranty.

Any expenses and risks with the transportation of the product are not covered by the guarantee.

For equipment sold with an extended warranty, it will only be valid if the preventive maintenance suggested by Magnamed is carried out, according to the chapter 9 of this manual.

There are no express or implied warranties other than those set forth above.

19 Training

To request training, please contact Magnamed's product specialist team who will refer you to the authorized representative closest to you. The training is carried out in person and has an average duration of 1 hour.

This product is only intended for use in pulmonary ventilation and shall be operated only by qualified professionals.

MAGNAMED

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