User’s Manual

RUAH LUNG VENTILATOR

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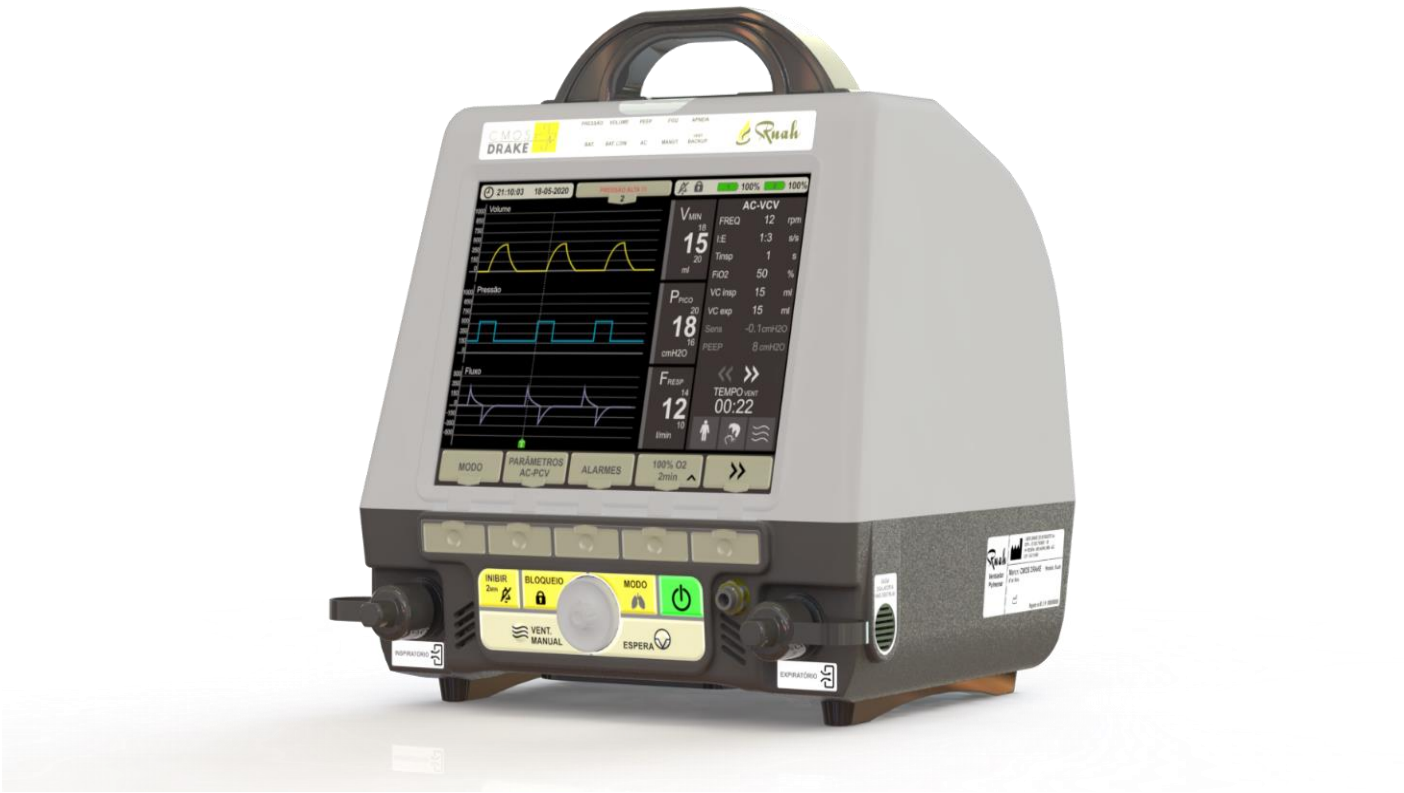

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ATTENTION!

CMOS DRAKE is exempt from any liability for personal or material damage caused by the incorrect use of the RUAH LUNG VENTILATOR and its accessories.
The following situations are considered incorrect use:

- Use outside the recommendations, information and warnings of the User's Manual.
- Application other than the intended purpose.
- Breakage of the security seal, which characterizes loss of warranty.
- Interventions, repairs or changes to the equipment outside the authorized network.
- Use of defective accessories or components, beyond the date of expiration or not supplied or specified by the Manufacturer;
- Equipment operation by unqualified person.

To guarantee the expected operation, only use parts and accessories supplied or specified by the manufacturer and its authorized personnel.

For more information on warranty or technical assistance, contact CMOS DRAKE technical support.

Congratulations for the purchase of the CMOS DRAKE Ruah Lung Ventilator.

All information necessary for the safe and correct use of the Ruah Lung Ventilator can be found in this manual, in addition to information on essential care, conservation, clarifications related to Technical Assistance and Warranty Certificate.

The complete reading of this manual must precede the use of the equipment, and it is a mandatory condition for the operation of the equipment. Always keep the manual close to the equipment for consultation, doubts and clarifications.

TABLE OF CONTENTS

1 ACRONYMS

AC-PCV	Mandatory pressure assisted/controlled ventilation
AC-VCV	Mandatory volume assisted/controlled ventilation
PSV	Pressure support ventilation
FREQ	Respiratory frequency
P_{peak}	Peak pressure
T_{insp}	Inspiration time
F_{resp}	Respiratory flow
V_{tidal}	Tidal volume
FiO_2	Fraction of inspired oxygen
I:E	Ration between the time of inspiration and expiration in a respiratory cycle
PEEP	Positive end-expiration pressure
$AUTO_{peep}$	Patient's intrinsic PEEP.
$SENS_{resp}$	Equipment sensitivity to voluntary inspiration
T_{apneia}	Apnea time
$P_{support}$	Support pressure
NIV	Noninvasive ventilation
V_M	Ventilation minute
RF	Radiofrequency

2 TERMINOLOGY

Software	A program recorded in an electronic device that determines how it functions.
Hardware	The physical part of a device that contains the interconnected electronic circuits and components.
Equipment	It refers to the Ruah Lung Ventilator.
Service	Period in which the Equipment is in operation connected to an individual.
Patient	Individual who is under the Equipment's Service.
Operator	Duly qualified person who is operating the Equipment during a Service.

3 SYMBOLS

Figure	Relevant Standard	Description
	IEC 60878 - 5036	Hazardous Electric Potential Difference (Voltage)
	IEC 60878 - 5031	Direct Current
	IEC 60878 - 5032	Alternating Current
	IEC 60878 - 5172	Class II Equipment
	IEC 60878 - 5036	Attention!
	IEC 60601-1	It refers to the instructions manual
	IEC 60878 - 5010	On/Off Key
	N/A	Button to interrupt the ongoing ventilation.
	N/A	It inhibits alarms for 2 minutes.
	N/A	It allows the ventilation mode to be defined.
	N/A	Button to increase.
	N/A	Button to decrease.
	N/A	Indicative of fully charged internal battery.

	N/A	Indicative of battery in use (below 75%)
	N/A	Indicative of battery in use (50% of use)
	N/A	Indicative of critical battery (below 20%)
	N/A	Fully discharged internal battery.
	N/A	Command to ventilate the patient.
	N/A	Inspiratory circuit connection.
	N/A	Expiratory circuit connection.
	ISO 780	This side up: indicates the correct position in which the box should be transported
	ISO 780	Fragile: indicates that the package must be transported and handled with care
	ISO 780	Keep dry: indicates that the package should be kept in a dry place
	ISO 780	Number 5: indicates the maximum stacking of five overlapping units
	IEC 60878 - 0632	Minimum and maximum temperature
	N/A	It indicates that it is a medical equipment and, therefore, it deserves special handling
	EN 980	Manufacturer
	IEC TR 60878	It indicates that it is composed of recyclable raw material
	Directive 2002/96/CE	Wastes from electric and electronic equipment - Disposal separated from other objects

4 UNITS

Type	Unit	Name	Equivalence
Time	ms	Millisecond	10^{-3} s
	s	Second	1 s
	m	Minute	60 s
	h	Hour	3600 s
Frequency	Hz	Hertz	1 Hz
	kHz	Kilohertz	10^{3} Hz
	MHz	Megahertz	10^{6} Hz
	GHz	Gigahertz	10^{9} Hz
	rpm	Respiration per Minute	1 rpm
Length	mm	Millimeter	10^{-3} m
	cm	Centimeter	10^{-2} m
	m	Meter	1 m
Area	mm^2	Square Millimeter	10^{-6} m^2
	cm^2	Square Centimeter	10^{-4} m^2
	m^2	Square Meter	1 m^2
Volume	dL	Deciliter	10^{-2} L
	L	Liter	1 L
	mm^3	Cubic Millimeter	10^{-9} m^3
	m^3	Cubic Meter	1 m^3
Speed	mm/s	Millimeter per Second	10^{-3} m/s
	m/s	Meter per Second	1 m/s
Flow	L/s	Liter per Second	1 L/s
	L/m	Liter per Minute	60 L/s
Mass	g	Gram	1 g
	kg	Kilogram	10^{3} g
Pressure	mmHg	Millimeter of Mercury	133.3 Pa
	hPa	Hectopascal	10^{2} Pa
	Pa	Pascal	1 Pa
	cmH_2O	Centimeter of water	0.98 hPa
	cmH_2O	Centimeter of water	0.98 mbar

	cmH_2O	Centimeter of water	0.01 psi
Temperature	°F	Degree Fahrenheit	(1 °C – 32) 5/9
	°C	Degree Celsius	1 °C
Resolution	px	Pixel	N/A
Impedance	Ω	Ohm	1 Ω
	MΩ	Megaohm	10^9 Ω
Electric Potential Difference / Voltage	mV	Millivolt	10^{-3} V
	V	Volt	1 V
	kV	Kilovolt	10^3 V
Current	µA	Microampere	10^{-6} A
	mA	Milliampere	10^{-3} A
	A	Ampere	1 A
Current Density	A/m	Ampere per meter	1 A/M
Electric Charge	C	Coulomb	1 C
	mAh	Milliampere-hour	3.6 C
Power	W	Watt	1 W
Energy	J	Joule	1 J
Intensity	dB	Decibel	1 dB
Digital Storage	B	Byte	1 B
	MB	Megabyte	10^6 B
	GB	Gigabyte	10^9 B

5 SAFETY

GENERAL WARNINGS

Equipment maintenance must be performed exclusively by the Manufacturer or Authorized Technical Assistance, otherwise, the technical assistance warranty is interrupted and the equipment owner becomes solely responsible for possible physical, material and other damages.

Only use the equipment on one patient at a time. Simultaneous ventilation in more than one patient is not recommended and can lead to a worsening of the clinical condition and, in extreme situations, to death.

Do not use the RUAH LUNG VENTILATOR near other equipment. If this occurs, it may affect the correct functioning of the equipment. Always check its functionality if this instruction is not followed.

Reading this manual does not in any way override the training of people who will use the equipment.

Only the CMOS DRAKE approved patient circuit can be used with the Ruah lung ventilator.

Only use properly pressurized medical grade oxygen and compressed air for proper equipment operation.

The equipment must not be covered or positioned in a way that could adversely affect its operation, for example close to curtains or barriers that block the flow of cooled air causing the equipment to overheat.

Keep the Ruah Lung Ventilator away from Magnetic Resonance Imaging equipment.

WARNINGS ON BATTERIES AND ELECTRICAL MAINS

Always disconnect the power cable from the electrical mains before starting any maintenance.

As the Li-Ion battery charges and discharges over time, its ability to hold a charge is reduced with use. This can shorten the length of time the ventilator can operate while powered solely by the internal batteries.

The removable battery must be replaced when it does not meet the user's needs. This depends on a number of factors, including settings and usage patterns.

The removable battery must be kept permanently installed in the equipment to prevent it from discharging.

When the low battery alarm sounds, only a limited amount of power is available and an alternate power source must be connected immediately.

Charge the batteries for a minimum of three hours before turning on the ventilator. This keeps them fully charged.

During storage, charge batteries for a minimum of three hours every 30 days. This keeps them charged.

Always keep the Ruah ventilator connected to an AC power source when not in use to ensure the best battery performance.

WARNINGS ABOUT OPERATION

All settings and adjustments to ventilation modes must be made in accordance with the treatment prescribed by a physician.

Always use a moisture filter or equivalent on the Airway Pressure connector to protect internal transducers from moisture and other contaminants.

Use appropriate monitors to ensure sufficient oxygenation and ventilation (such as a pulse oximeter and/or capnograph) when the equipment is in use on a patient.

When a failure in the ventilator is detected, and its life support functions are in doubt, immediately discontinue use. Use an alternate method of ventilation until the fault is corrected, and contact your supplier or Cmos Drake immediately.

In the event of equipment failure, lack of immediate access to alternative means of ventilation could result in the PATIENT'S DEATH.

The ventilator will be ready to operate only when:

- **It is fully assembled.**
- **The quick self-test procedure has been concluded successfully.**

Constant attention from qualified medical personnel is recommended whenever a patient is ventilated with the equipment.

Failure to identify the cause of ventilator-generated alarms could result in patient injury.

Make sure that the compressed air and oxygen inlets are connected before using the Ruah Lung Ventilator for correct pressurization and ventilation of the patient.

Perform periodic cleaning of the compressed air inlet filter to ensure proper system pressurization.

Always make sure the green LED 

is on after connecting the Ruah Lung Ventilator to the electric mains. If the LED is not illuminated, check all power connections and resolve any issues.

To avoid the risk of cross contamination, follow the cleaning guidelines contained in this manual.

It is highly recommended to calibrate the equipment weekly and always after changing the patient circuit. This procedure is necessary to ensure the best accuracy in calculating the patient's ventilation parameters.

The use of additional accessories or other components or sub-assemblies of the respiratory system may alter the pressure gradient throughout the ventilator's breathing system and adversely affect the performance of the equipment.

The use of HEPA filters in the expiratory and inspiratory connections of the equipment is mandatory to avoid cross-contamination.

Nebulization or humidification can increase the resistance of the ventilator's respiratory system filter and the OPERATOR should frequently monitor this filter due to increase of resistance and blockages.

During use in non-invasive ventilation, the patient's exhaled volume may differ from the measured exhaled volume due to leaks in the mask.

The Ruah Lung Ventilator does not generate sub-atmospheric pressure in the patient's airways.

The internal sensing device of the Ruah Lung Ventilator is, at fixed intervals, connected to the atmosphere to prevent the propagation of degradations in measurement accuracy and the negative effects of moisture or condensation on the sampled gases. The higher the adjusted respiratory rate and/or the further the I/E ratio is from 1:1 (both direct and inverse), the smaller the interval required for connection to the atmosphere.

The Ruah Lung Ventilator has a fully mechanical internal system designed to relieve the ventilatory control/monitoring pressure when it exceeds 90 cmH_2O, so that higher pressures are not sustained.

The use of the Ruah Lung Ventilator adjacent to or on top of other equipment should be avoided as improper operation may result. If this use becomes necessary, it is convenient that this and the other equipment are observed to verify that they are operating normally.

WARNINGS ABOUT ELECTROMAGNETIC AND BIOLOGICAL COMPATIBILITY

Avoid using a cell phone or any devices that pick up radio frequency near the equipment. The high level of electromagnetic radiation emitted by these devices can result in interference, impairing the normal functioning of the ventilator, putting patient safety at risk. The recommended minimum distance is 50cm or as indicated in the table - Appendix D.

In general, the EQUIPMENT Parts and ACCESSORIES of the Ruah Lung Ventilator intended to come into contact with biological tissues, cells or body fluids are tested and analyzed in accordance with the guidelines and principles of ISO 10993-1, which deals exclusively with testing of biocompatibility of the applied parts.

On Aircrafts / Ambulances / Vehicles in General:
- Low level of radiation from electromagnetic fields.
- High immunity to transients and external electromagnetic fields.
- High mechanical resistance to vibration.

If the performance of the Lung Ventilator is degraded due to EM Disturbances, it is expected that these disturbances can cause interference in the operation of the indicative LEDs of the equipment, keeping them constantly on, or small interferences on the display, causing a sensation of reset of the equipment.

WARNINGS ABOUT MAINTENANCE

In the event of prolonged equipment downtime of more than 1 month, it is necessary to inspect, clean and calibrate the equipment again.

In case of equipment stoppage, it is necessary to close the patient circuit connections using their respective plugs to avoid the accumulation of organic residues. Before starting

to use the equipment again, perform a thorough cleaning. It helps prevent unwanted patient contamination.

Risk of electric shock if the equipment cabinet is opened. Any type of technical service or upgrades to the equipment and its parts must be carried out after uncoupling the power cable and may only be carried out by personnel duly trained and authorized by Cmos Drake.

Disposable materials must not be reused. They must be disposed of in appropriate places according to the special procedures for hospital waste.

All parts of the Ruah Ventilator that come into contact with fluids coming from the patient (e.g. breathing circuit) are potentially contaminated, before disposal (at the end of their useful lives) or sending for maintenance or repair, a disinfection process of high level or sterilization.

If any part of the equipment, battery and disposable materials need to be replaced, contact the manufacturer or the authorized network to supply the material and replace it, when necessary. If accessories from suppliers other than those indicated by Cmos Drake are used, the company is not responsible for the operation of the equipment and will have its warranty nullified.

There is a risk of polluting the environment associated with the use of accessories and consumables at the end of their useful life. Accessories and consumables must be disposed of in hospital waste in accordance with environmental law. Batteries must be delivered to appropriate locations or returned to the manufacturer or an appropriate collection center after replacement due to a defect or end of life.

No modifications to this equipment and its parts are permitted.

A Cmos Drake factory trained and authorized technician must perform all repairs and service on the Ruah Lung Ventilator.

Do not open the ventilator or service an open unit while connected to external power.

Use standard anti-static techniques when working on the internal parts of the ventilator or handling of any electronic parts

Clean all external parts of the ventilator before maintenance.

Review the Ruah Lung Ventilator User Manual before servicing the ventilator.

The Ruah Liung Ventilator is equipped with an automatic leak compensation system with fixed amplitude. In case of inadequate and/or unsuccessful maintenance, which allow leakage levels higher than the self-compensating ones, it is likely that adverse effects on the performance of the PEEP and FiO2 control systems will be present during use. Authorized Service Personnel should consult the Technical Manual for further information.

WARNINGS ABOUT AREAS OF RISK

This equipment is not designed to operate in environments containing flammable anesthetics and cleaning agents. There is a risk of explosion if used in the presence of flammable gases.

To prevent the risk of fire or undue shock, avoid operating or placing the equipment near water source or flammable products, do not leave liquid products on the cabinet and/or battery charger.

Do not use the Ruah Lung Ventilator in areas where there is a risk of explosion.

Do not use the Ruah Lung Ventilator inside x-ray and MRI rooms.

The Ruah Lung Ventilator cannot be used in hyperbaric chambers.

The Ruah Lung Ventilator cannot be used with nitric oxide.

The Ruah Lung Ventilator cannot be used with helium or with mixtures containing helium.

The precision of the Ruah Lung Ventilator may be affected by the gas added when using the nebulizer.

6 PRESENTATION

GENERAL FEATURES

This product is a microprocessor-controlled, internal electronic compressed air and oxygen mixer (Blender) ventilator with pressure support for spontaneous breathing. He is capable of performing non-invasive or invasive mechanical ventilation, with volume, pressure or flow controls.

The Ruah Lung Ventilator provides backup ventilation and allows manual inflation in addition to having an anti-asphyxia valve for emergency admission that allows the patient to breathe ambient air into the patient circuit in the event of complete loss of gas pressure supply.
The opening pressure is approximately -3 cmH_2O (-3 mbar) during emergency intake.

The Ruah Lung Ventilator can be powered by the electric mains (100-240 VAC) or by its internal rechargeable Li-Ion batteries with an autonomy of 3 hours when fully charged.

In addition to Blender, the pneumatic system is composed of electronically controlled pressure regulators, valves and solenoids.

SAFETY ITEMS

- Anti-asphyxia valve for protection against gas supply failure.
- Active overpressure valve to reduce pressure in the patient circuit in case of obstructions.
- Self-diagnostics for checking alarms, detecting faults, measuring leaks, resistances and system compliances.
- Ability to operate for up to 3 hours disconnected from the mains (power outage).
- Loudspeaker for alarms and audible alerts with volume control.
- Differentiation between inspiratory and expiratory phases, indication of trigger modes (assisted, spontaneous or manual) and window period.
- Option for proximal flow sensors (pediatric and adult).
- Real-time monitoring of battery charge.

INTENDED USE

The Ruah Lung Ventilator is intended to provide continuous or intermittent mechanical ventilation support for the care of pediatric and adult individuals with impaired respiratory function who require mechanical ventilation.
The Ruah Lung Ventilator allows for invasive (through patient intubation) or non-invasive (respiratory mask ventilation) ventilation support. Its essential performance consists in

providing ventilatory support to adult and pediatric patients, invasively or non-invasively, with the display of curves referring to ventilation parameters on the equipment screen and correct operation of its alarm system.

The Ruah Lung Ventilator is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician. It is suitable for use in hospitals, intensive and semi-intensive care units, post-operative, post-anesthesia recovery (PA) rooms as well as emergency response applications.

PRINCIPLE OF OPERATION

The Ruah Lung Ventilator is a microprocessed medical device whose operating principle is based on the integration of three main modules:

- Pneumatic module (manifold and valves)
- Electronic control module
- Electronic interface module

Two valves regulate the pressure of gases coming from the hospital network at the entrance of the pneumatic module, ensuring an adequate pressure range for the equipment. This pressure is constantly monitored so that the absence or insufficiency of gases is detected and immediately signaled through a priority alarm.
The volume and concentration of gases required in each operating mode are guaranteed by electronic proportional valves for precise regulation of the flow of gases.
After adjusting the individual flows of each gas, the gases are mixed in the manifold where the measurement of the O2 concentration is obtained, as well as the measurement of the resulting flow.

The patient's exhaled flow is measured through a proximal flow sensor, connected to the patient's “Y” intermediate output, whose measurement is based on the pressure differential between two points.
System pressures are taken through points on the pneumatic module, which are connected to transducers on the electronic control module.

All these flow and pressure measurements are converted into digital signals by the electronic control module and used to feed back the control algorithm, ensuring a gradual and safe adjustment of the ventilation process.

The input and output of information are processed by the electronic interface module that receives the information entered by the operator, via touch on the screen or via mechanical buttons and sends this translated information to the electronic control module. In this way, the Ruah Lung Ventilator establishes the parameters suitable for the ventilation mode selected for the patient.

In addition to receiving information, the control module also sends it to the interface module, which, in turn, makes it available to the user in the form of audible and visual signals on the equipment's display.

All risk situations that require operator intervention are analyzed by the control module and sent to the interface module, which then issues, according to the degree of risk, the necessary alarms or alerts.

CONTRAINDICATIONS

- This equipment cannot be used in the presence of flammable agents, such as anesthetic gases, fuels, among others;
- This equipment should not be used by laypersons without proper training in mechanical ventilation, always under the supervision of a physician.

REGULATORY REQUIREMENTS

This equipment has been designed in full compliance with all relevant Standards and Guidelines for medical electrical equipment. For more details see Appendix A.

ITEMS INCLUDED

- 2 (two) complete autoclave-sterilizable circuits (1 adult and 1 pediatric);
- 1 (one) test lung;
- Hoses for O_2 network and compressed air
- 1 Power cable.

OPTIONAL ITEMS

- 1 (one) articulated arm;
- 1 (one) sterilizable thermal jar;
- 1 (one) heated humidifier;
- 1 (one) pedestal with casters.
- 1 (one) face mask.

RECOMMENDED CONSUMPTION ITEMS

- HEPA filter;
- HMEF filter;
- Face Shield for NIV.

7 INSTRUCTIONS

PACKAGING

Upon receipt of the Ruah Lung Ventilator, inspect each box for damage to the physical integrity of the packaging or product and that all required accessories are present.

If any product accessory and/or other requested additional accessory is not present or if damage to the equipment or any accessories is verified, contact Cmos Drake within thirty (30) days after receiving the product.
After 30 (thirty) days of receipt, any claim will be evaluated by CMOS DRAKE, not guaranteeing the replacement of the product and its accessories.

If you identify damage to the physical integrity of the package, open it and record the physical state of the equipment and its accessories in the presence of the carrier. Please forward this incident immediately with knowledge of the carrier to CMOS DRAKE's customer support department for appropriate action.

PREPARING THE EQUIPMENT FOR USE

Before starting to use the equipment, it is necessary to assemble the parts and position the equipment in the place of use.
Follow the assembly sequence in the table below to carry out the preparation of the equipment:

Step	Description
1	Remove the RUAH LUNG VENTILATOR from the packaging box.
2	Check the presence of all items that came with the product.
3	Assemble the accessories
4	install the batteries
5	Position the equipment in a suitable and obstacle-free location
7	Connect the RUAH LUNG VENTILATOR (with internal rechargeable battery) to the electric mains.

The equipment must be connected to a grounded electrical supply network that complies with the standard ABNT NBR 13534:2008 – "Low voltage electrical installations – Specific requirements for installation in healthcare establishments".

The equipment's internal batteries must always be charged and ready for use in the event of a power failure or for use in external operations. Therefore, you must keep your power supply connected to the electrical network to charge the batteries, even if the equipment remains off.

Inlet pressures greater than the specified limit can damage the equipment.
The gas network connected to the equipment must meet the requirements of ABNT NBR 12188:2012

CHOOSING THE INSTALLATION SITE

- Keep the RUAH LUNG VENTILATOR in a suitable and easily accessible place.
- Keep the RUAH LUNG VENTILATOR away from equipment that generates strong magnetic fields such as radiological devices, air conditioning systems and others.
- Make sure that the installation location has adequate ventilation and is within the pressure and temperature ranges indicated in this manual (Appendix B - Technical Specifications of the Equipment).

INSTALLATION

After following the directions in the previous step (choosing the installation site), proceed as detailed below:

- Fit the Compressed Air hose (yellow) to connector #5 described in the Rear Panel figure in index 8 below.
- Fit the Oxygen hose (green) to connector #4 described in the Rear Panel figure at index 8 below.
- Pressurize the Compressed Air and Oxygen lines to 40 ~ 90 psi (2.76 ~ 6.21 bar).
- Connect the AC network cable to connector #2 described in the Rear Panel figure in index 8 below. Always give preference to using the equipment connected to the commercial AC power network.
- Turn on the equipment and check the results of the self-test routine. All topics are expected to return a PASS status.

After completing the steps described above, the equipment is considered installed. For patient circuit connection, proceed as detailed below:

- Connect the standard universal size tubes (22 mm) to the equipment nozzles, indicated by the Main Panel figure in index 8 below.
- Connect the proximal tube to the inlet dedicated to it, indicated by the Main Panel figure in index 8 below.
- Connect the opposite end to the corresponding “Y” piece to subsequently access the patient.
- If the ventilation to be sustained is for a child patient, use the adapters of the 22 mm tubes for 15 mm supplied together with the equipment accessories.

GUIDELINES FOR USE

- Read without exemptions this Manual.

- Only use accessories supplied exclusively by the manufacturer.
- Follow the instructions for the equipment's texts and intuitive icons.
- The Ruah Lung Ventilator and its basic and optional accessories will promote safety if used for the correct purpose and according to the instructions described in this Manual.
- All those who need or wish to use the Ruah Lung Ventilator must be qualified through specific training in mechanical ventilation and must always be monitored / supervised by a physician.
- Reading of the user ‘s manual and compliance with the safety rules and warnings contained therein are mandatory.

GUIDELINES FOR COVID-19 PATIENTS

The guidelines below were based on the following recommendations:

- *Clinical management protocol for Covid-19 in Specialized Care [electronic resource] / Ministry of Health, Department of Specialized Healthcare, Department of Hospital, Home and Emergency Care. – 1. ed. rev. – Brasilia : Ministry of Health, 2020.*
- *TECHNICAL NOTE GVIMS/GGTES/ANVISA No. 04/2020 - GUIDELINES FOR HEALTH SERVICES: PREVENTION AND CONTROL MEASURES THAT SHOULD BE ADOPTED DURING ASSISTANCE IN SUSPECTED OR CONFIRMED CASES OF THE NEW CORONAVIRUS (SARS-CoV-2) INFECTION.*

For correct ventilation and prevention of disease transmission between patients and healthcare professionals, it is recommended:

- If you need to use a bag valve mask (or Ambu bag), use a reservoir to prevent the dispersion of aerosols, in addition to a closed suction system and a HEPA or HMEF filter.
- In patients with no indication for mechanical ventilation, administration of oxygen by nasal catheter or mask is recommended.
- Use HEPA filter on the inspiratory and expiratory branches and HMEF on the output of the patient circuit.
- Change the HMEF filters every 24 hours and the HEPA filters every 48 hours.

To reduce the incidence of ventilator-associated pneumonia:

- Prefer oral to nasal intubation and perform oral hygiene regularly.
- Keep the patient in a semi-recumbent position (headrest elevated between 30° and 45°).
- Use closed suction system; periodically drain and discard the condensate
- in piping.
- Use a new ventilation circuit for each patient; replace it whenever it is dirty or damaged, but not routinely.
- Change the humidifier when it malfunctions, when it becomes dirty or every 5-7 days, following the manufacturer's recommendations and according to the protocols defined by the CCIH of the health service.
- Reduce the time of invasive mechanical ventilation.

General guidelines for intubation:

- All materials must be prepared outside the box or cutting area.
- The intubation team should be limited to the physician and the fewest people possible.
- During intubation, a circulating staff may remain outside the isolation room to respond to requests from in-house staff.
- Before intubation: Install HEPA, HMEF or HME filter with filtration for virus in the ambu bag. Preferably, connect directly to the mechanical ventilator, avoiding the use of an ambu bag in this patient.
- The laryngoscope set used in intubation must be sent for regular cleaning and disinfection (according to the protocol of the health service).

ASPIRATION SYSTEM:

Preferably, install a closed suction system - *trach care* in all patients; in the impossibility of using this system, only perform aspiration in case of high peak pressure in mechanical ventilation, presumably due to accumulation of secretion.

GUIDELINES FOR NEBULIZATION:

- Aerosol generating nebulization devices should be avoided.
- Use bronchodilator medication in puff administered by a device that comes with *trach care* or retractable air chamber.

AMBU:

- It is recommended to use an ambu bag with a reservoir to prevent the dispersion of aerosols.
- The closed suction system and HEPA, HME or HMEF filter must come with a virus filtering specification attached.

OXYGEN THERAPY:

In patients with no indication for mechanical ventilation, administer oxygen by nasal catheter or mask (as closed as possible), as there is an increased risk of aerosol dispersion.

CHANGE OF TRACH CARE AND HME FILTERS:

The orotracheal tube (OTT) should be clamped with forceps, before disconnection for change of the system (*Trach Care* or HME filter), disconnection of the ambu bag or change from transport ventilator to the unit's ventilator.

Another technique is to use an occluder in the orotracheal tube, always with the idea of not leaving the airway open to the environment.

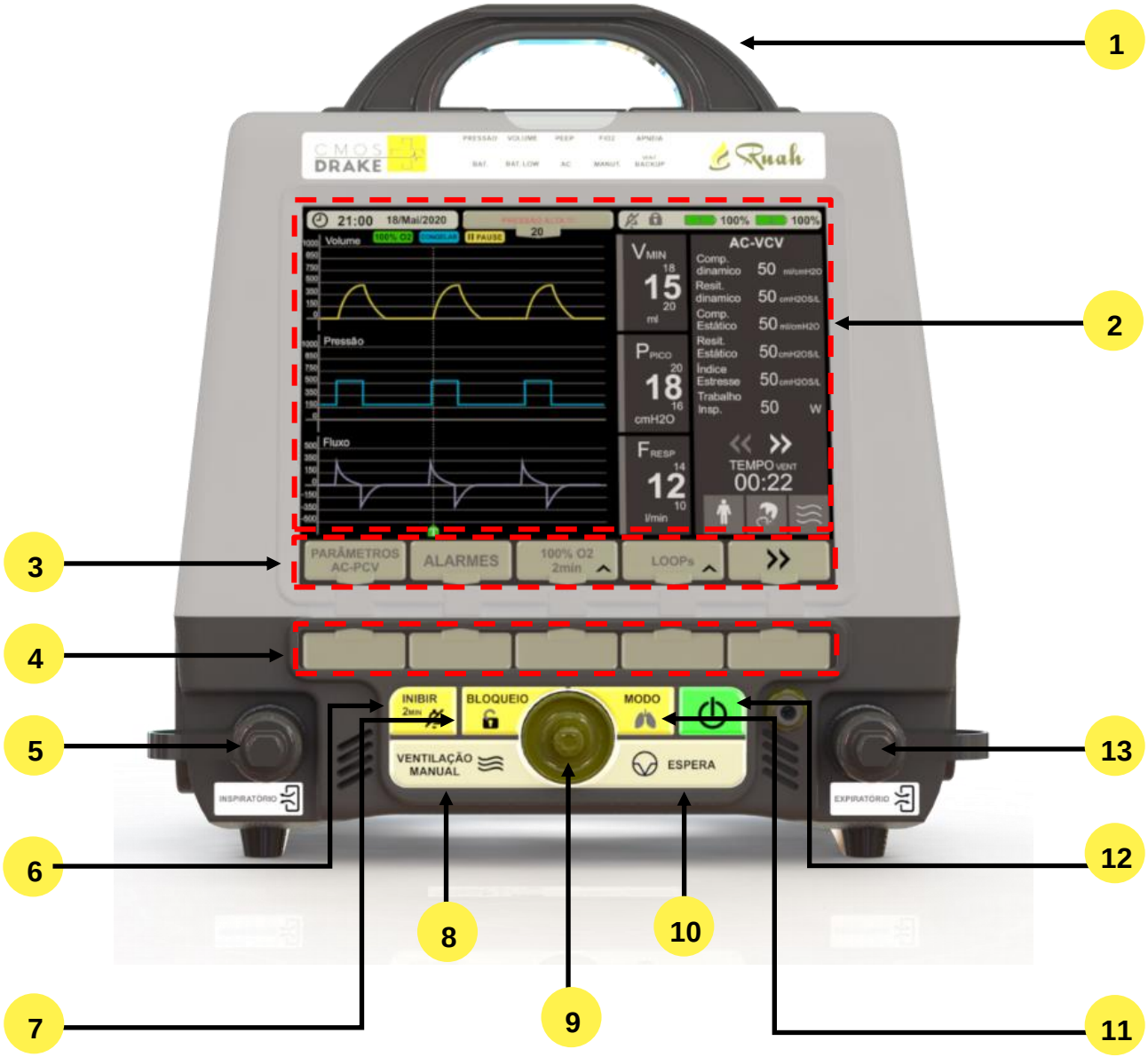
8 THE PRODUCT

GENERAL ASPECTS OF THE EQUIPMENT

1. Ability to perform invasive mechanical ventilation (VI) and non-invasive mechanical ventilation (NIV) in adult and pediatric patients;
2. Ability to print assisted-controlled (AC) and spontaneous ventilation modes;
3. Ability to start backup ventilation automatically in case of apnea and make it impossible to disable this function during invasive ventilations in spontaneous modes;
4. Face mask for non-invasive ventilation application, with automatic flow compensation.
5. 10.4” color LCD touchscreen display with simultaneous display of 3 curves: Pressure, Volume and Flow;
6. Ability to provide the necessary resources for nebulization;
7. Internal gas mixer (blender) with electronic adjustment;
8. Carrying out a self-test of the alarm system, recharging the batteries, connecting to the AC network, among others, during startup;
9. Internal rechargeable batteries with autonomy of 9 hours (sum);
10. Power supply 100~240V, 50/60Hz;
11. Internal backup system with monitoring of the main control system and guarantee of an audible alarm in case of identification of failure.

MAIN PANEL

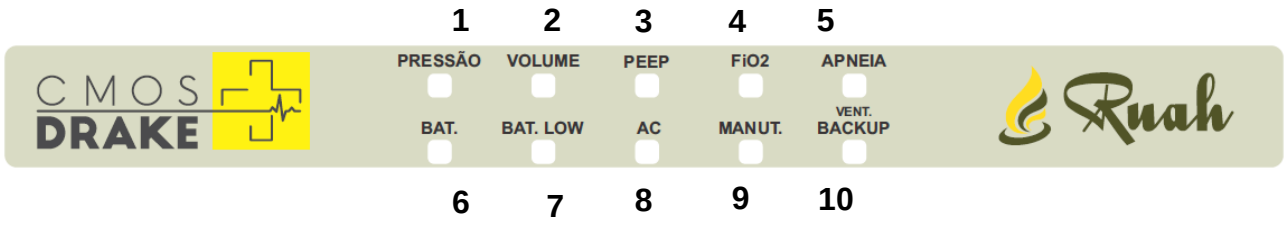
The front panel contains control buttons, visual indicators, display and patient circuit connection.



1	**Carrying handle**	2	**Display viewing area:** Allows you to view patient data in real time.
3	**Multifunctional touch screen keys:** Allow operator to modify alarms, ventilation parameters, oxygen, Key lock and menu access.	4	**Multifunctional panel keys:** Allow operator to modify alarms, ventilation parameters, oxygen, Key lock and menu access.
5	**Inspiratory circuit connector to the patient**	6	**Alarm Inhibit Button** It allows you to inhibit the alarm sound for a predetermined time.

7	**Keyboard lock button** It allows key lock and menu access.	8	**Manual Ventilation Button** It allows activation of manual ventilation.
9	**Knob:** It allows the operator to confirm changes and change parameters quickly.	10	**Hold key:** It allows the user to stop ventilation for changes to ventilation parameters.
11	**Mode Button** It allows the ventilation mode to be selected.	12	**On / Off Key** It allows you to turn on and off the equipment.
13	**Expiratory circuit connector**		

LED PANEL



1	On when pressure alarms occur or are active.	2	**On when volume alarms occur or are active.**
3	On when PEEP alarm occurs or is active.	4	**On when FiO2 alarm occurs or is active.**
5	On when apnea alarm occurs or is active.	6	**On when backup ventilation is in use.**

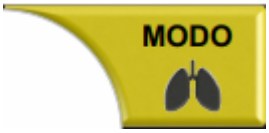
7 On when operating with the internal battery.

8 **Equipment connected to the electric power mains.**

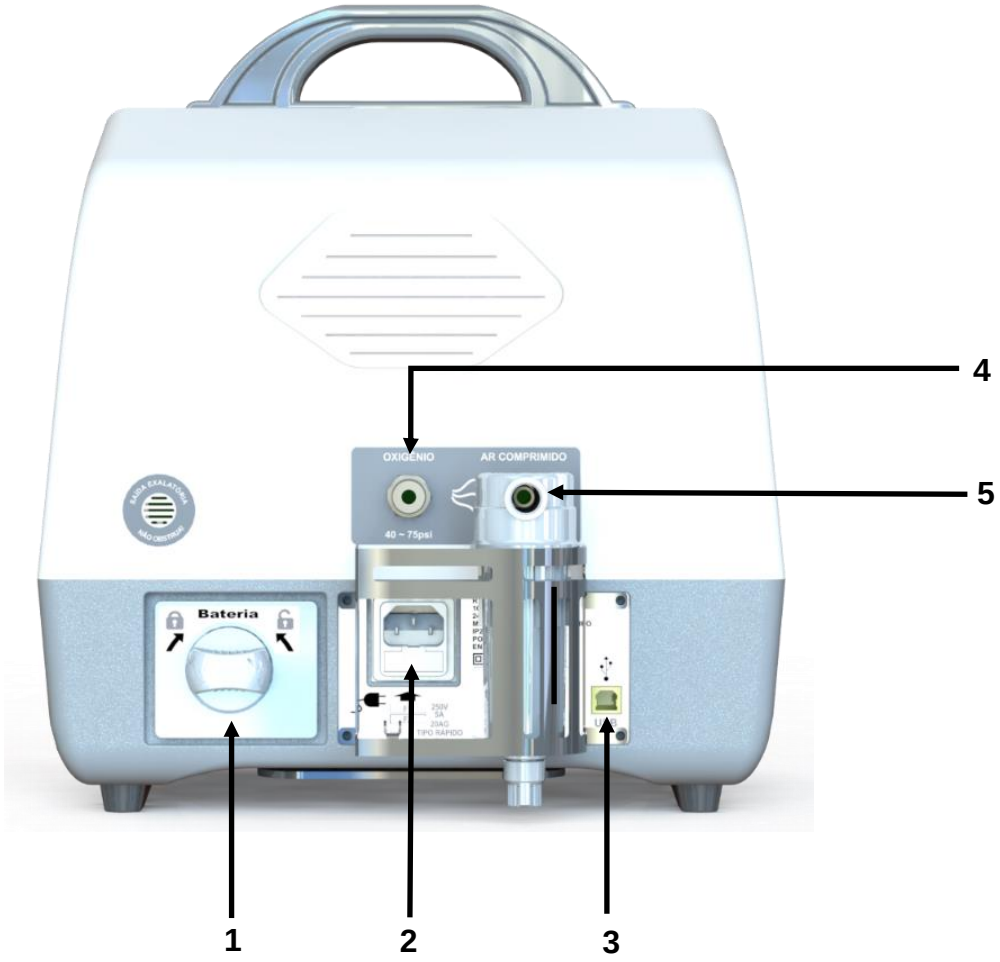
9 On when the equipment has identified a technical problem.

10 **Critical battery (below 20%).**

COMMAND PANEL

	On/Off Key
	It inhibits alarms for 2 minutes.
	It allows the activation of the keys to be blocked.
	It allows the ventilation mode to be defined.
	Ventilation key that allows activation of manual ventilation.
	Standby key that allows the user to stop ventilation for changes of ventilation parameters.
	Knob for faster selection of parameter values.

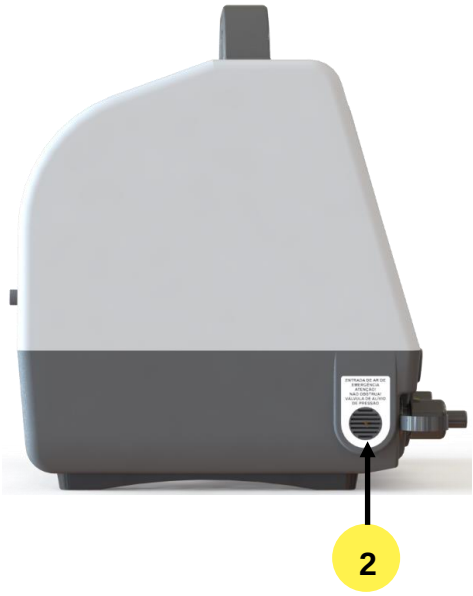
REAR PANEL



1 Access for maintenance of removable battery.	**2** AC Connector with Fuses
3 USB Port.	**4** Oxygen inlet
5 Compressed air filter.	

SIDE PANEL

Emergency air / anti-asphyxia vent



Emergency air / anti-asphyxia inlet

Keep emergency/anti-asphyxiation outlets and inlets free from obstacles.

A check for obstruction of emergency outlets must be carried out at least once a year.

The Ruah Lung Ventilator is an equipment capable of predetermining the respiratory rate through its mandatory (controlled) characteristic. The test method to determine the respiratory rate declared for spontaneous ventilation is through the excitation of pressure sensors (proximal), where positive variations indicate the expiratory phase and negative variations indicate the inspiratory phase. Once the duration of the two phases has been determined, it is possible to determine the respiratory rate.

The data sampling rate of the Ruah Lung Ventilator is on the order of 1 kHz.

Given the connection capacity of internal sensing devices to the atmosphere, at the end of a service (either pause and/or complete shutdown), the system internally expels the sampled gases, so that there are no remaining gas level readings to be calculated. When starting a new service (or resuming ventilation from the paused state) new gases are sampled.

9 INSTRUCTIONS FOR USE

INITIAL CHECKS

To ensure greater safety, it is recommended to carry out the checks below before each use or, at least, at the beginning of each working period.

Item	Description
1	Make sure the equipment is turned off.
2	Check the integrity of the equipment and its components, through a general visual inspection.
3	Check that all components are correctly connected or inserted.
4	Check that the breathing circuit is securely connected and suitable for the patient.
5	Check the tight connection of the oxygen and compressed air hoses.
6	Check that the inlet pressure is within the specified range.

TURNING ON THE VENTILATOR

The Ruah Lung Ventilator can be used either with an AC power source (mains) or by the internal batteries, however, you should prefer to use the power supply through the electrical network in order to keep the batteries always charged for use in situations that the electrical network is not functional or is not present in the installation.

When pressing the  (On/Off) button, the equipment initialization screen will be displayed and the ventilator will perform a brief self-test to ensure the equipment's operation.

During the self test, verify that all LED indicators illuminate and audible alarms sound.

In case of fault detection, a report with the self-test checks will be displayed, reporting the faults that have occurred, as shown in the figure below:

Always check and adjust alarm settings after starting ventilation or changing parameters. It will ensure efficient monitoring of the patient's ventilation condition.

To ensure the best ventilation, the equipment must be positioned on a level location so as not to compromise internal flow measurements.

PARAMETERIZING THE VENTILATOR

SELECTION OF PATIENT TYPE AND VENTILATION TYPE

After the self test, if there is no error detection, the Ventilator will enter the ventilation parameters configuration mode, presenting the first configuration screen in which the user must choose the patient type (**Adult** or **Child**) and the ventilation type (**invasive** or **non-invasive**).

When navigating between screens, it is possible that there is more than one page for parameter configuration. Select the corresponding page on the touch screen display.

Once the patient and ventilation types have been selected, a screen showing the selected options will be displayed and the user must press the CONFIRMAR (**CONFIRM**) key to proceed to the ventilation mode selection screen or the **CANCEL** key to return to the previous screen and select again. patient types and ventilation.

SELECTION OF VENTILATION MODE

In the next step, the user must select in which mode he wants to proceed with the ventilation of the patient.

The Ruah Lung Ventilator provides 10 (ten) ventilation modes, 8 (eight) for Invasive Ventilation and 2 (two) for Non-Invasive Ventilation. A description of the characteristics of each mode can be found in APPENDIX A of this manual, item “Specification of Ventilation Modes”

Modes for Invasive Ventilation

AC-VCV Mode

After pressing the AC-VCV key, a screen will be displayed for the user to choose whether to act on the control of the Inspiratory Time parameter (T_{INSP}) or on the Flow.

With Inspiratory Time Control

If the user has selected (T_{INSP}), the first parameter selection screen for this mode will be displayed and the user must adjust the values of Tidal Volume (V_{TIDAL}), Frequency $(FREQ)$ and Inspiratory Time (T_{INSP}) through the respective keys − and + on the touch screen display or using the Knob on the panel.

Then, press the key » to access the second parameterization screen for the AC-VCV mode with inspiratory time control, where the user can select the values for the parameters PEEP, Inspired Oxygen Fraction ($FiO2$) and Sensitivity $Sens$) through the respective keys − and + on the touch screen display or using the Knob on the panel.

With Flow Control

If the user has selected Flow, the screen below will be displayed and the user must adjust the values for the parameters Tidal Volume (V_{TIDAL}), Frequency $(FREQ)$ and Flow through the respective keys − and + on the touch screen display or using the Knob on the panel.

Then, press the key » to access the second parameterization screen for the AC-VCV mode with Flow control, where the user can select the values for the parameters PEEP, Inspired Oxygen Fraction ($FiO2$) and Sensitivity $Sens$) through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

AC-PCV Mode

On the ventilation mode selection screen, press the AC-PCV option and the first screen will be displayed so that the user can adjust the values for the parameters Inspiratory Pressure (P_{INSP}), Frequency $(Freq$),

Inspiratory Time (T_{INSP}) and Relation between Inspiratory Time and Expiratory Time (T_{INSP}) through the respective keys − and + on the touch screen display or using the Knob on the panel.

By pressing the key », the user will have access to the second parameterization screen for the AC-PCV ventilation mode, where he can adjust the values for the parameters PEEP, Ramp Time (T_{rampa}), Inspired Oxygen Fraction $(FiO2\ \ )$ and Sensitivity through the respective keys − and + on the touch screen display. or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

SIMV-V-VCV Mode

After pressing the SIMV-VCV key, a screen will be displayed for the user to choose whether to act on the control of the Inspiratory Time parameter (T_{INSP}) or on the Flow.

With Inspiratory Time Control

If the user has selected (T_{INSP}), the parameter screen will be displayed in which the user must adjust the values for Tidal Volume(V_{TIDAL}), Frequency $(FREQ)$ and Inspiratory Time (

$T_{INSP})$ through the corresponding keys − and − on the touch screen display or using the Knob on the panel.

Then, press the key » to access the next parameter adjustment screen of the SIMV-VCV mode, where the parameters PEEP, Inspired Oxygen Fraction $(FiO2\ \ )$ and Sensitivity $(Sens\ \ )$ through the respective keys $Sens\ \ )$ and + on the touch screen display or using the Knob of the panel.

Press the key » again to access the last parameter screen of the SIMV-VCV ventilation mode where the Support Pressure », Ramp Time (T_{ramp}) and Cycle Flow (F_{CICLO}) parameters must be adjusted through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

With Flow Control

If the user has selected Flow, the parameter screen will be displayed in which the user must adjust the values for the parameters Tidal Volume (V_{TIDAL}), Frequency $(FREQ)$ and Flow through the respective keys − and + on the touch screen display or using the Knob on the panel.

Then, press the key » to access the next parameter adjustment screen of the SIMV-VCV mode, where the parameters PEEP, Inspired Oxygen Fraction ($FiO2$) and Sensitivity ($Sens$) through the respective keys − and + on the touch screen display or using the Knob of the panel.

Press the key » again to access the last parameter screen of the SIMV-VCV ventilation mode where the Support Pressure (P_{Sup}), Ramp Time (T_{ramp}) and Cycle Flow (F_{CICLO}) parameters must be adjusted through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

SIMV-PCV Mode

After pressing the SIMV-PCV key, a screen will be displayed for the user to choose the values for the parameters Peak Pressure (P_{PICO}), Frequency ($Freq$), Inspiratory Time (T_{INSP}) and Relationship between Inspiratory Time and Expiration Time ($I:E$)
through the corresponding keys − and + on the touch screen display or using the Knob on the panel.

Then, press the key » to access the next parameter adjustment screen of the SIMV-PCV mode, where the PEEP parameters, Ramp Time (T_{rampa}), Support and Inspired Oxygen Fraction must be adjusted ($FiO2$) through the respective keys − and + on the touch screen display or using the Panel Knob.

Press the key » again to access the last screen of parameters of the SIMV-PCV ventilation mode where the Sensitivity parameter must be adjusted ($Sens$) through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

PSV Mode

After pressing the PSV key, a screen will be displayed for the user to choose the values for the parameters Support, Frequency ($Freq$), Inspiratory Time ($Freq$) and Inspired Oxygen Fraction ($FiO2$) through the respective keys − and + on the touch screen display or using the Knob on the panel.

Then, press the key » to access the next parameter adjustment screen of the PSV mode, where the PEEP, Sensitivity ($Sens$) and Relation between Inspiratory Time and Expiration Time) parameters must be

adjusted ($I:E$) through the respective keys  and  on the touch screen display or using the Panel Knob.

After finishing the ventilation mode parameterization and pressing the  (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the  (**ALARMS**) key.

PRVC Mode

After pressing the PRVC key, a screen will be displayed for the user to choose the values for the parameters Volume, Peak Pressure P_{Pico}, Frequency $(Freq)$ and PEEP through the respective keys  and  on the touch screen display or using the Knob on the panel.

Then, press the key  to access the next parameter adjustment screen of the PRVC mode, where the Inspired Oxygen Fraction parameter must be adjusted ($FiO2$) through the respective keys  and  on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the  (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the  (**ALARMS**) key.

IPPV Mode

After pressing the IPPV key, a screen will be displayed for the user to choose the values for the parameters Volume, Frequency $(Freq)$ and PEEP and Inspired Oxygen Fraction ($FiO2$) through the respective keys  and  on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the  (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the  (**ALARMS**) key.

BACKUP Mode

By clicking on the BACKUP button, the user can choose to configure one of the available modes to act as a patient ventilation backup. To configure the selected mode, follow the instructions for the respective mode previously described.

Modes for Noninvasive Ventilation

APRV Mode

After pressing the APRV key, a screen will be displayed for the user to choose the values for the parameters, High Pressure P_{alta}, Low Pressure P_{baixa}, High Time T_{alto} and Low Time T_{baixo} through the respective keys  and  on the touch screen display or using the Knob on the panel.

Then, press the key » to access the next parameter adjustment screen of the APRV mode, where the Inspired Oxygen Fraction parameter must be adjusted ($FiO2$) through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

CPAP Mode

After pressing the CPAP key, a screen will be displayed for the user to choose the values for the parameters CPAP, Inspired Oxygen Fraction ($FiO2$) and Flow through the respective keys − and + on the touch screen display or using the Knob on the panel.

After finishing the ventilation mode parameterization and pressing the CONFIRMAR (**CONFIRM**) key, the equipment will show a screen with the selected parameters and will enable the MODE, PARAM, ALARMS, TIMES and SYSTEM buttons. On this screen, the user must proceed with the parameterization of the alarms using the ALARMES (**ALARMS**) key.

Setting the ventilation mode can be done at any time by pressing the [MODE] button on the touch screen display or on the control panel.

ALARM ADJUSTMENTS

After finishing the parameter adjustments of the chosen mode, it is necessary to adjust the alarm limits to be applied during the patient's ventilation.

The user must press the key ALARMES **(ALARMS)** on the screen below:

Next, the screen for setting Alarm 1 will be displayed, where the user can adjust the Lower Peak Pressure ($P_{PICO\ BAIXO}$), Lower Tidal Volume ($P_{PICO\ BAIXO}$), LOWER RESPIRATORY FREQUENCY ($F_{RESP\ BAIXO}$) and Upper Peak Pressure ($P_{PICO\ ALTO}$) fields using the − and + buttons.

After configuring the above values, the user must press the button » to access the Alarm 2 screen and adjust the Upper Tidal Volume ($V_{TIDAL\ ALTO}$), Upper Respiratory Rate ($F_{RESP\ ALTO}$), Lower Respiratory Rate ($F_{RESP\ BAIXO}$), and Lower PEEP (($PEEP_{BAIXO}$).

After setting the values for alarm 2, press the button » to access the Alarm 3 screen and adjust the Lower Inspired Oxygen Fraction ($FiO2_{BAIXO}$), Upper Frequency ($FREQ_{ALTO}$), Upper PEEP ($PEEP_{ALTO}$) and Upper Inspired Oxygen Fraction ($FiO2_{ALTO}$) fields.

Then press the button » to access the alarm 4 setting screen and configure the Apnea Time field (T_{APNEIA}).

After configuring all the alarm fields, press the **CONFIRM** button to return to the HOLD screen, as shown in the image below.

If you want to change any field of the previous alarms, just activate the ALARM and navigate through the screens using the buttons « and » until you see the screen with the field you want to change.

DESCRIPTION OF THE ALARMS

The Ruah Lung Ventilator has an alarm system with audible and visual indications, for physiological and technical alarms or alert messages, with high, medium or low priority levels.

Alarm	Type	Priority	Cause
High Flow	Physiological	High	When the inspired or expired flow exceeds the defined limit
Low Flow	Physiological	High	When the inspired or expired flow drops below the defined limit
High Pressure	Physiological	High	When the pressure in the airways is above the defined maximum limit
Low Pressure	Physiological	High	When the pressure in the airways is above the defined minimum limit
High PEEP	Physiological	High	When the Pressure at the end of expiration is above the defined maximum limit
Low PEEP	Physiological	High	When the Pressure at the end of expiration is above the defined minimum limit
High V_{tidal}	Physiological	High	When the Volume is above the defined maximum limit
Low V_{tidal}	Physiological	High	When the Volume is below the defined minimum limit
High RR	Physiological	Mean	When the Respiratory Frequency is above the defined maximum limit
Low RR	Physiological	Mean	When the Respiratory Frequency is below the defined minimum limit
Apnea	Physiological	High	When no respiratory cycle is identified after the defined Apnea Time
High FiO2	Physiological	Mean	When FiO2 is above the defined maximum limit for 3 consecutive cycles
Low FiO2	Physiological	Mean	When FiO2 is below the defined minimum limit for 3 consecutive cycles
Low Battery	Technical	Mean	When the battery load capacity is below 50%.
Critical Battery	Technical	High	When the battery load capacity is below 20%.
Unknown Battery	Technical	Mean	When the Battery is not present

Low AC Pressure	Technical	Mean	When the Compressed Air circuit pressure is below 30 psi
High AC Pressure	Technical	Mean	When the Compressed Air circuit pressure is above 85 psi
Low O2 Pressure	Technical	Mean	When the Oxygen circuit pressure is below 30 psi
High O2 Pressure	Technical	Mean	When the Oxygen circuit pressure is above 85 psi
Power Supply Failure	Technical	High	When any failure occurs in one of the following power supplies of 3.3 V, 5 V, 12 V or 24 V.
Memory Failure	Technical	Mean	When user parameters cannot be registered, data records or data is corrupted
Electric Network for Battery	Alert	Low	When the AC Mains power is disconnected and the equipment starts to consume battery power
Auto PEEP	Technical	High	When the pressure at the end of expiration is greater than 2 cmH_2O for more than 5 cycles

DETAILING THE SYSTEM FUNCTION

The SYSTEM button is available on the STANDBY screen to start ventilation, through which, after activation, the user can access the SELF TEST, CALIBRATION, BACKUP MODE SETTING and FACTORY SETTING functions.

STARTING PATIENT VENTILATION

After parameterizing the Ruah Lung Ventilator, check the alarm limits and control settings, make sure they are appropriate for the patient to be ventilated, and only then can you start ventilation.

Starting the Ruah Lung Ventilator:

1. Press the “Standby” button for 1 second to start ventilation. A "starting ventilation" message indicates that the button has been pressed.
2. Connect the patient circuit to the patient.
3. Check that the Low and High pressure alarms are at the proper levels. If not, readjust them.
4. Verify that the TRIG indicator flashes each time the patient initiates a spontaneous inspiratory effort. Readjust the sensitivity as needed.

5. Re-evaluate alarms for High V_{tidal} and LOW V_{tidal} and adjust to appropriate levels.

INTERRUPTING VENTILATION

If it is necessary to interrupt ventilation, this action can be performed by pressing “**Standby**” for 1 second when the ventilator is in patient ventilation operation.

TURNING OFF THE VENTILATOR

The Ventilator can be turned off only from ventilation mode. If the Ventilator is not ventilating, you must start ventilation and then proceed to shutdown.

To turn off the Ventilator:

1. On the Ventilator front panel, press the  (On / Off) button. The system displays a message: "Are you sure you want to turn it off?

   To turn off, press the button  for 2 seconds". The Power button LED flashes to indicate that it must be pressed again for 2 seconds.

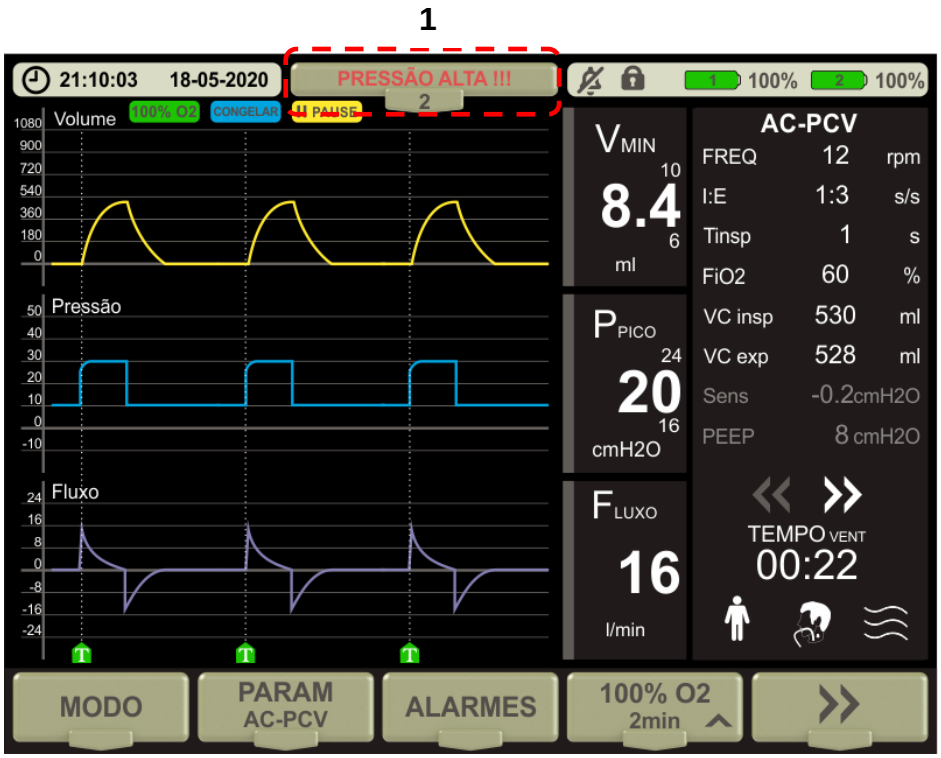
2. Press the Power button for 2 seconds, within five seconds of receiving the message.

   You can press the key 

   to inhibit the audible alarm after turning off the ventilator.

When operating on battery power only, the Ventilator turns off automatically if ventilation is not started within five minutes of power on.

OPERATION SCREEN



On this screen, the patient's real-time VOLUME, PRESSURE and FLOW data are shown in the left column. In addition, data specific to the selected ventilation mode is shown in the right column.

Region 1 highlighted in the image corresponds to the area where the short description of alerts are shown.

When pressing the area referring to region 1 on the touch screen display, the list with active and occurred alerts is displayed.

Press button | AWARE | to confirm and return to the main screen.

Alarms are based on conditions defined by the operator. To set alarm conditions, press the key 

.

Navigating between screens | ALARMS 1 |, | ALARMS 2 |, | ALARMS 3 | and | ALARMS 4 | it is possible to define the alarm trigger conditions corresponding to each monitored parameter.

DESCRIPTION OF MAIN KEYS

Access to the ventilation mode selection screen

Access to current ventilation mode parameters.

Access to the alarm configuration screen

Quickly defines 100% FiO_2 for 2 minutes.

Advance to the next screen.

10 MAINTENANCE

PRECAUTIONS AND SPECIAL CARES

- Do not lean any type of material against the equipment;
- Do not reuse disposable materials, after use they must be discarded in appropriate places according to special procedures for hospital waste;

For greater durability of the Ruah Lung Ventilator and its accessories, we recommend that preventive inspections and cleaning be carried out periodically following the table below.

Applied Verification	Frequency
Cleaning	Weekly
Preventive Inspections	Biannual
Revision in Authorized Technical Assistance	Annual
Mandatory Calibration	Annual
Display integrity	Monthly

To check the integrity of the display, observe if there is any degradation of contrast or the presence of shadows that make it difficult to see the image correctly.

Visually inspect the equipment for damage in the equipment cabinet.

It is highly recommended to calibrate the equipment weekly and always after changing the patient circuit. This procedure is necessary to ensure the best accuracy in calculating the patient's ventilation parameters.

Batteries must be replaced every 2 years to preserve the equipment's autonomy.

Check if contrast degradation, whitening, or the presence of shadows in the image make viewing difficult

In case of equipment downtime of more than 1 month, it is necessary to inspect, clean and calibrate the equipment again.

CLEANING OF EQUIPMENT AND ACCESSORIES

The Ruah Lung Ventilator and associated patient circuits are shipped in a clean, but not sterile condition. Patient circuits must be sterilized by autoclave before reuse on a patient.

Use the information in this section in conjunction with the hospital's policy and physician's prescription for cleaning the ventilator and its accessories.

All accessories must be thoroughly cleaned, washed and air dried (naturally) prior to disinfection. Check the integrity of all accessories in case of damage discard and replace the accessories.

CLEANING OF THE VENTILATOR

Clean the Ruah Lung Ventilator with each patient change, and once a week during use.

To Clean the Ventilator:

1. Clean the exterior (except the display) of the Ventilator and all parts that do not come into direct contact with patients, using a cloth dampened with a medical detergent or alcohol-based cleaning solution.
2. Clean the display using a cloth dampened with LCD cleaning solution.
3. Let it dry naturally.

Do not apply cleaning solution directly to the display.

On the Ventilator's display or cabinet, do not use agents that contain acetone, toluene, halogenated hydrocarbons or strong alkalines.

Never sterilize or use a disinfection device on the ventilator and its parts. These processes damage the equipment and its accessories, rendering them unusable. Use antimicrobial disinfectant for proper cleaning.

CLEANING OF THE REUSABLE PATIENT CIRCUITS

Patient circuit includes breathing tube with ID (internal diameter) of 22 millimeters, flow sensing kit (flow orifice, quick connector and triple tubes with ID f 2.75 millimeters).

CMOS DRAKE patient circuits are provided non-sterile.

Clean and disinfect patient circuits once a week while in use. Always use a clean and disinfected exhalation valve when the patient circuit is reassembled for patient use.

Examine the patient circuit for damage or excessive wear. Discard and replace if necessary, to avoid degradation of reusable patient circuit components, do not exceed 20 cleaning cycles or half a year of use (whichever comes first).

To disassemble the patient circuit:

1. Remove the entire circuit from the Ventilator.
2. Remove the exhalation valve and flow detection kit.
3. Disassemble the circuit to expose all surfaces for cleaning.

The CMOS DRAKE patient circuit is made from a high temperature polyester elastomer material and incorporates a silicone rubber cuff. To avoid circuit damage, connect and disconnect the circuit by handling only the silicone cuffs. Do not pull or twist the circuit.

If you are using a CMOS DRAKE patient circuit, please observe instructions below for cleaning and disinfection. If you are using another manufacturer's patient circuits approved by CMOS DRAKE, consult the manufacturer's instructions for cleaning.

To clean the patient circuit:

1. Use a running stream of water or air tubing to clean tubes and sections of clear organic matter.
2. Bathe for a minimum of 10 minutes, using liquid detergent.
3. Wash all patient circuit components with a soft brush.
4. Rinse thoroughly with sterile distilled water, removing all traces of detergent.
5. Place all parts on a clean towel to dry naturally. (Do not heat or dry with a hairdryer)

To disinfect patient circuit components:

1. Soak plastic and metal parts in any of the following solutions:
    a. One part 5% acetic acid (white vinegar) and two parts sterile distilled water for two hours (home use only).
    b. Glutaraldehyde solution (Cidex [2%]) for two hours
2. Rinse with sterile distilled water, removing all traces of detergent.
3. Dry naturally.

Patient circuit components should not come into contact with the following solutions, as they may cause the tube to disintegrate: Hypochlorite, Phenol (> 5%), inorganic acids Hydrocarbons, ketone formaldehyde, chlorinated and aromatic hydrocarbons.

Patient circuits should be inspected after disinfection to check for deterioration. If the circuit is damaged or has excessive wear, replace it with a new circuit.

CLEANING OF THE REUSABLE PATIENT CIRCUITS (AUTOCLAVE)

The provided patient circuits are not sterile.

Visually inspect the circuit component kit for damage or excessive wear. Discard if there is any sign of damage or if you fail the "Circuit Test".

To clean the patient circuit:

1. Use a running stream of water or air tubing to clean tubes and sections of clear organic matter.
2. Soak circuit components in a mild detergent for at least 10 minutes.
3. Gently wipe the entire exterior surface of the accessory with a soft cloth dampened with a detergent solution to remove any visible residue.
4. Rinse circuit components thoroughly with distilled water for at least 30 seconds to remove all traces of detergent.
5. Remove excess water, and place all parts on a clean towel to air dry.
6. Sterilize using a valid autoclave procedure at 134°C (273°F) for 4 minutes.
7. Dry circuit components by shaking excess water, and place all parts on a clean towel to air dry.

Replace components after 40 autoclave cycles at 134°C (273°F).

TROUBLESHOOTING

Problem	Potential cause	How to Identify	Recommended Action
Apnea alarm	Patient does not trigger a breath after the pre-set apnea interval.	Visual alarm. Audible alarm. Backup ventilation is enabled.	Re-evaluate patient and Ventilator settings and provide greater ventilatory support as needed.
	Patient efforts are not detected	Visual alarm. Audible alarm. Backup ventilation is enabled.	Use the sensitivity adjustment to adjust the trigger level closest to baseline pressure (0 cmH_2O) so that patient efforts are detected (indicated by the trigger indication displayed on the curve).

Low battery alarm	Removable battery voltage below 50% threshold.	Visual alarm. Audible alarm.	Immediately connect the Ruah Ventilator to the mains power supply. Check if the equipment identifies the presence of the network and the batteries start charging cycle. Check the presence of the removable battery in the equipment.
Critical battery alarm	Battery voltage below 20% threshold.	Visual alarm. Audible alarm.	Immediately connect the Ruah Ventilator to the mains power supply. Check if the equipment identifies the presence of the network and the batteries start charging cycle. Check the presence of the removable battery in the equipment.
Disconnected electric mains alarm	External power cable is unplugged	Visual alarm. Audible alarm.	Reconnect the power cable to the electric mains.
	Internal power supply failure	Visual alarm. Audible alarm. Operator confirmation.	Contact technical support

High pressure alarm	Rapid decrease in PEEP value	Visual alarm. Audible alarm.	Decrease PEEP gradually.
	Airway pressure remains above the high pressure alarm setting.	Visual alarm. Audible alarm.	Check the patient's ventilation parameters. Check for occlusion and unlock it. Check for blockage in the proximal sensor duct.
	Increase of resistance of the patient circuit.	Visual alarm. Audible alarm.	Check for obstructions (bent pipes, water in the pipeline, clogged filters, etc.).
	Control/alarm parameters have changed.	Visual alarm. Audible alarm.	Reassess the settings
High flow (insp/exp)	On inspiration or expiration the flow exceeds the set limit.	Visual alarm. Audible alarm.	

Low flow	On inspiration or expiration the flow drops below the set limit.	Visual alarm. Audible alarm.	
High PEEP		Visual alarm. Audible alarm.	
Low PEEP		Visual alarm. Audible alarm.	
High V_{Minu}		Visual alarm. Audible alarm.	
Low V_{tidal}		Visual alarm. Audible alarm. Operator confirmation.	

High FREQ	When the respiratory rate is above the set limit after 5 breath cycles	Visual alarm; Audible alarm; Operator confirmation.	
Low RATE	When the respiratory rate is below the set limit after 5 breath cycles	Visual alarm; Audible alarm; Operator confirmation.	
High FiO_2	When the FiO_2 is above the set limit after 3 breath cycles	Visual alarm; Audible alarm; Operator confirmation.	
Low FiO_2	When the FiO_2 is below the set limit after 3 breath cycles	Visual alarm; Audible alarm; Operator confirmation.	
High compressed air pressure	When it is above 85 psig	Visual alarm; Audible alarm; Operator confirmation.	

Low compressed air pressure	When it is below 30 psig	Visual alarm; Audible alarm; Operator confirmation.	
High oxygen pressure	When it is above 85 psig	Visual alarm; Audible alarm; Operator confirmation.	
Low oxygen pressure	When it is below 30 psig	Visual alarm; Audible alarm; Operator confirmation.	
Auto PEEP	When the pressure at the end of expiration is above 2 cmH_2O for at least 5 respiratory cycles.	Visual alarm; Audible alarm; Operator confirmation.	
Maintenance alarm	When it is not possible to save operator's parameters, incorrect data or problems at the source.	Visual alarm; Audible alarm; Operator confirmation.	Contact technical support.

OBSERVATION: *If the recommended actions are not sufficient to correct the problem, contact Cmos Drake Authorized Technical Support.*

ADVERSE EFFECTS

CMOS DRAKE, as a manufacturer of medical and hospital equipment, requests users to report possible defects or the occurrence of any undesirable event, in order to guarantee the quality of the equipment and accessories. Therefore, any failure or malfunction, please contact the nearest authorized technical assistance or directly with the sales consultant at the telephone or website indicated below on the last page of this manual.

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APPENDIX A

EQUIPMENT TECHNICAL SPECIFICATIONS

COMPLIANCE WITH STANDARDS AND CERTIFICATIONS

ABNT NBR IEC 60601-1+ Amendment NBR IEC:2016	Electromedical equipment - Part 1: General requirements for basic security and essential performance
ABNT NBR IEC 60601-1-2:2017	Electromedical equipment - Part 1-2: General requirements for basic security and essential performance - Collateral standard: Electromagnetic Compatibility - Requirements and testing
ABNT NBR IEC 60601-1-6:2011	Electromedical equipment - Part 1-6: General requirements for basic security and essential performance - Collateral standard: Usability
ABNT NBR IEC 60601-1-8:2014	Corrected Version:2015 - General requirements for basic security and essential performance - Collateral standard: General requirements, tests and guidelines for alarm systems in electromedical equipment and electromedical systems
ABNT NBR IEC 60601-1-9:2014	Electromedical equipment - Part 1-9: General prescriptions for basic security and essential performance - Collateral standard: Prescriptions for an eco-responsible project
ABNT NBR IEC 60601-1-10:2010 + Amendment 2017	Electromedical equipment - Part 1-10: General requirements for basic security and essential performance - Collateral standard: Requirements for the development of closed loop physiological controllers
IEC 60601-1-12:2014	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

ABNT NBR ISO 80601-2-12:2014	Particular requirements for the basic safety and essential performance of ventilators for critical cares
IEC 62304:2015/AMD1	Medical device software - Life cycle processes software
ABNT NBR IEC 62366:2016	Healthcare products — Application of usability engineering to healthcare products
ISO 10993	Biological evaluation of healthcare products

ELECTRICAL SPECIFICATIONS (AC)

Input Voltage	100 - 240 Vac
Frequency	50 – 60 Hz
Current consumption	1.25 A MAX

FIXED BATTERY SPECIFICATIONS

Battery Type	Li-Ion rechargeable
Rated voltage	16.8 Vdc
Nominal capacity	5000 mAh
Full Charge Time	22 h

REMOVABLE BATTERY SPECIFICATIONS

Battery Type	Li-Ion rechargeable
Rated voltage	16.8 Vdc
Nominal capacity	7000 mAh
Full Charge Time	40 h

VOLUMETRIC AND MASS SPECIFICATIONS

Dimensions	310 mm (W) x 280 mm (L) x 350 mm (H)
Weight	6 kg

OPERATION SPECIFICATIONS

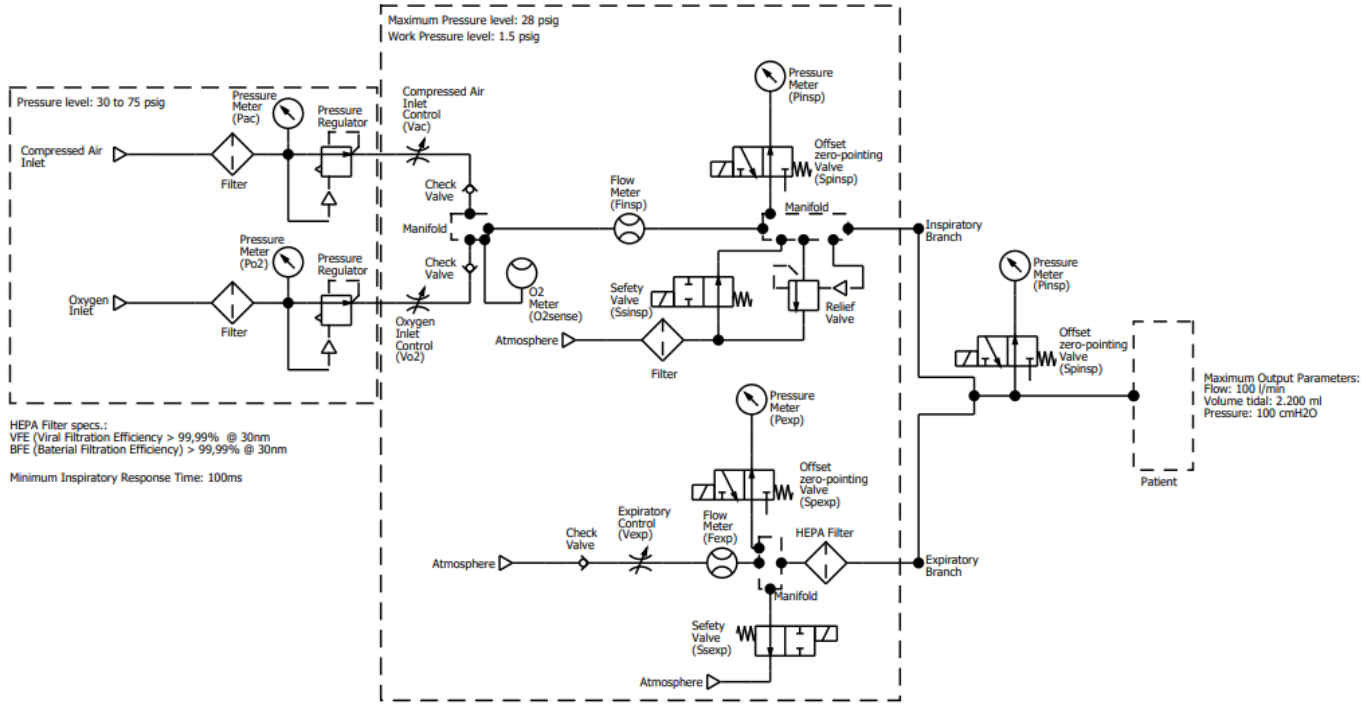
Operating Temperature	0 °C to 50 °C
Operating Humidity	15% to 95%, without condensation
Operating Atmospheric Pressure	700 hPa to 1060 hPa
Operation Mode	Continuous operation mode

STORAGE AND TRANSPORT SPECIFICATIONS

Storage Temperature	-10 °C to 50 °C
Storage Humidity	10% to 95%, without condensation
Storage Atmospheric Pressure	700 hPa to 1060 hPa

Maximum Stacking	5 boxes
Box for Transport	Transport in original box of the equipment. CMOS DRAKE does not guarantee and is not responsible for any damage that occurs to equipment that is transported or stored in other packaging.

PNEUMATIC DIAGRAM



INTERNAL OXYGEN MIXER SPECIFICATIONS

Type of connector	DISS
Oxygen receptor pressure	40-70 psig / 275-480 kPa
FiO_2	21% to 100%
Precision	+- 8%
FiO_2 response time from 21% to 90%	Up to 15 seconds

GENERAL TECHNICAL SPECIFICATIONS

Classification of Applied Parts	BF Type

Safety Degree of Use in Presence of Flammable Anesthetic Mixture	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANESTHETIC MIXTURE WITH OXIDANTS.
Degree of Protection Against Electric Shock	Class II
EMC	Group I, Class A
Degree of Protection against Particle and Liquid Penetration	IP21 *

***OBSERVATION:** The **IP degree of protection** refers to an international standard used to classify and evaluate the degree of protection of electronic products against intrusion (body parts such as hands and fingers), dust, accidental contact and water. The Ruah Lung Ventilator has an IP21 rating, with the first digit (2) indicating the degree of protection against solid objects and the second digit (1) indicating the degree of protection against liquids. As it is classified as IP21, the equipment is designed to prevent the entry of solid objects with a diameter greater than 12 mm and against vertical falls of water.

SPECIFICATION OF VENTILATORY MODES

AC-VCV, AC-PCV, V-SIMV, P-SIMV, PSV, CPAP, PRVC, APRV, IPPV	See Appendix C for operation of modes.

SPECIFICATION OF CONTROL PARAMETERS

Parameter	Range	Resolution
Volume Minute	1 to 100 l/min	1 l/min
Tidal Volume	10 to 2200 ml	10 ml
Inspired pressure on PEEP	1 to 80 cmH_2O	1 cmH_2O
PEEP	0 to 50 cmH_2O	1 cmH_2O
Support Pressure on PEEP	1 to 60 cmH_2O	1 cmH_2O
Respiratory Rate	1 to 99 rpm	1 rpm
Inspiratory Time	0.1 to 30 s	0.1 s
I:E Ratio	1:99 to 3:1	1:0.1
Sensitivity to pressure	-9.9 to -0.1 cmH_2O	0.1 cmH_2O
Sensitivity to flow	1 to 10 l/min	1 l/min

PACKAGING

Closed packaging of the product, Ruah Lung Ventilator

Closed packaging of the accessories.

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SPECIFICATION OF PARTS AND ACCESSORIES

Item	Specification
Articulated arm	• Trachea support • Fast fit on rail • Weight of 0.8 kg
Thermal jar	• 250 ml water capacity • 180 l/min maximum flow • Sterilizable in autoclave
Humidifier	• 5 selectable temperature control levels • high temperature and inoperative visual alarms and indicators • Power supply: 100 – 240 V @ 50/60Hz • Dimensions: H x W x L 100 mm x 135 mm x 140 mm • Weight: 1.1Kg
Pedestal	• Caster with locks • Humidifier support • Fitting for articulated arm
Oxygen and compressed air hoses	• 250 PSI Working Pressure • Minimum Burst Pressure of 750 PSI • Working Temperature from 5°C to 55°C • Length 3m
Patient circuit	• Sterilizable in autoclave • 1.5 m long • Y with proximal pressure tapping point
Face mask	• Application of Non-Invasive Ventilation • Automatic flow compensation
AC Power Cable	

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APPLIED TECHNOLOGY

AC-VCV - ASSIST-CONTROLLED VOLUME CONTROLLED VENTILATION

When Ruah is configured in AC-VCV ventilation mode, the controlled variable is volume, the control variable is flow or time, and the cycling variable is volume.
The following settings are possible in AC-VCV ventilation mode:

- Tidal Volume (Vt) - limits: 10 ml to 2,200 ml
- Frequency (Freq) - limits: 4 rpm to 99 rpm
- Inspiratory time (ti) - limits: 0.1 s to 11.25 s [1]
- I:E Ratio - limits: 1:99 to 3:1
- Flow (V') - limits: 1 l/min to 100 l/min [1]
- PEEP - limits: 0 cmH_2O to 50 cmH_2O
- Oxygen concentration (FiO2) - limits: 21% to 100%
- Pressure sensitivity [2] - limits: -9.9 cmH_2O to -0.1 cmH_2O
- Flow sensitivity[2] - limits: 1 l/min to 10 l/m

[1] - simultaneous adjustment impossible (possible adjustments: inspiratory time or flow).
[2] - simultaneous adjustment impossible (possible adjustments: sensitivity by pressure or by flow).

In simplified terms, if the user has configured an inspiratory time, Ruah will control the flow necessary so that the configured volume can be reached within the referred inspiratory time in a controlled manner.

If the user has configured the I:E ratio, Ruah will calculate the inspiratory time and will control the flow necessary so that the configured volume can be reached within the referred inspiratory time in a controlled manner.
Finally, if the user has configured the inspiratory flow, Ruah will control the inspiratory time so that the configured volume can be reached from that flow in a controlled manner.

It should be noted that in this ventilation mode, airway pressures may vary according to the patient's characteristic impedance and the adjusted settings. In this context, if the pressure reaches the configured high pressure alarm limit, Ruah will cycle and the limited pressure alarm will be displayed. In this case, the adjusted volume may not be reached.

When the patient has the physiological ability to initiate the breathing cycle and the Ruah sensitivity is properly adjusted (by pressure or by flow), assisted ventilation takes effect and

the Ruah provides a breathing cycle for the patient. In this situation, the respiratory rate may be higher than the adjusted one.

AC-PCV - ASSIST-CONTROLLED PRESSURE CONTROLLED VENTILATION

When Ruah is configured in AC-PCV mode the controlled variable is pressure, the control variable is flow and the cycling variable is time.
The following settings are possible in AC-PCV mode:

- Peak pressure - limits; 1 cmH_2O to 80 cmH_2O [1]
- Frequency (Freq) - limits: 4 rpm to 99 rpm
- Inspiratory time (ti) - limits: 0.1 s to 11.25 s
- I:E Ratio - limits: 1:99 to 3:1
- PEEP - limits: 0 cmH_2O to 50 cmH_2O
- Rise time (tr) - limits: 0 s to 2 s
- Oxygen concentration (FiO2) - limits: 21% to 100%
- Pressure sensitivity [2] - limits: -9.9 cmH_2O to -0.1 cmH_2O
- Flow sensitivity [2] - limits: 1 l/min to 10 l/m

[1] - pressure gradient added to PEEP (as the pressure limit is 80 cmH_2O and the peak pressure is referenced to PEEP, if the PEEP adjustment is, for example, at 10 cmH_2O the upper limit of the peak pressure will be 70 cmH_2O.
[2] - simultaneous adjustment impossible (possible adjustments: sensitivity by pressure or by flow).

In pressure-controlled ventilation, the Ruah will control the pressure gradient in the patient's airway and allow the flow and volume to vary during the inspiratory time.

If the user adjusts the inspiratory time, Ruah will automatically calculate the I:E ratio that guarantees the configured frequency. If the user adjusts the I:E ratio, Ruah will automatically calculate the inspiratory time that guarantees compliance with the I:E ratio.
When the patient has the physiological ability to initiate the breathing cycle and the Ruah sensitivity is properly adjusted (by pressure or by flow), assisted ventilation takes effect and the Ruah provides a breathing cycle for the patient. In this situation, the respiratory rate may be higher than the adjusted one.

PSV - PRESSURE SUPPORT VENTILATION

When Ruah is configured in PSV mode the controlled variable is pressure, the control variable is flow and the cycling variable is time.
The following settings are possible in PSV mode:

- Support pressure (Psup) - limits; 1 cmH_2O to 80 cmH_2O [1]
- Frequency (Freq) - limits: 4 rpm to 99 rpm
- PEEP - limits: 0 cmH_2O to 50 cmH_2O
- Oxygen concentration (FiO2) - limits: 21% to 100%
- Pressure sensitivity [2] - limits: -9.9 cmH_2O to -0.1 cmH_2O
- Flow sensitivity [2] - limits: 1 l/min to 10 l/m
- Apnea time - limits: 0 s to 60 s

[1] - pressure gradient added to PEEP (as the pressure limit is 80 cmH_2O and the peak pressure is referenced to PEEP, if the PEEP adjustment is, for example, at 10 cmH_2O the upper limit of the peak pressure will be 70 cmH_2O.
[2] - simultaneous adjustment impossible (possible adjustments: sensitivity by pressure or by flow).

In pressure support ventilatory mode, Ruah works in an exclusively assisted manner, the triggers are carried out through the patient's stimuli (flow or pressure). When detecting the beginning of the patient's inspiratory effort, Ruah identifies and applies the value of the support pressure in the patient's airways in order to help his inspiration and checks the peak value of the inspiratory flow. When identifying that the inspiratory flow has reduced to 25% of its maximum value, Ruah performs the cycling, reducing the pressure in the airways to the configured PEEP level.

If the patient does not take a spontaneous inspiration and the configured apnea time is reached, the Ruah will automatically enter the backup ventilation mode according to the factory preset parameters for backup ventilation or according to the backup parameters implemented by the user in case he changes them.

V-SIMV - VOLUME CONTROLLED SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION

In the V-SIMV, the respiratory rate, tidal volume and inspiratory flow or the inspiratory ratio or time are fixed, in addition to the sensitivity criterion for the occurrence of the ventilator triggering by the patient.
This mode allows the ventilator to apply predetermined mandatory cycles in sync with the patient's inspiratory effort.
Mandatory cycles occur in the predetermined time window (according to the adjusted respiratory rate), but synchronized with the patient's trigger.
If there is apnea, the next cycle will be time-triggered until the patient's inspiratory incursions return.

P-SIMV - PRESSURE CONTROLLED SYNCHRONIZED INTERMITTENT MANDATORY VENTILATION

In the P-SIMV, the respiratory rate, the inspiratory pressure and the inspiratory time are fixed, in addition to the sensitivity criterion for the occurrence of the ventilator triggering by the patient.
This mode allows the ventilator to apply predetermined mandatory cycles in sync with the patient's inspiratory effort.
Mandatory cycles occur in the predetermined time window (according to the adjusted respiratory rate), but synchronized with the patient's trigger.
If there is an apnea, the next cycle will be time-triggered until the patient's inspiratory incursions return.

CPAP - CONTINUOUS POSITIVE AIRWAY PRESSURE

In CPAP, the ventilator allows the patient to breathe spontaneously, but provides continuous pressurization on both inspiration and expiration, in addition to assisting ventilation during

inspiration by maintaining pressure support until the patient's inspiratory flow is reduced. if at a critical (adjustable) level of peak inspiratory flow achieved.
This allows the patient to control the respiratory rate and inspiratory time and thus the volume of inspired air.
If the pressure support value (ΔPS) is set to 0 (ZERO) and the cycle triggering means are both turned off, ventilation with pure CPAP mode will be characterized, which is a mode of spontaneous ventilation not assisted by the ventilator.
Tidal volume depends on the patient's inspiratory effort and on the conditions of the respiratory mechanics of the lung and thoracic wall.

APRV - AIRWAY PRESSURE RELEASE VENTILATION

In APRV, the ventilator works at two pressure levels set by the operator, Upper Pr and Lower Pr.
Transient relief to the lower pressure level occurs at the end of Upper T (time determined for the upper pressure level). Likewise, the restoration of the upper pressure level takes place as soon as the Lower T (pressure relief time) is exhausted.
Consequently, the resulting respiratory rate and I:E ratio are directly related to this alternation between levels.
APRV is characterized by the inversion of the I:E ratio, where the time of the lower pressure level is usually shorter than that of the upper pressure level, functioning only as a temporary relief.
Without spontaneous breathing, APRV is similar to the pressure-controlled mode, differing from it in that it adjusts the times (upper and lower) rather than the respiratory rate.

PRVC - PRESSURE REGULATED VOLUME CONTROL

PRVC is a mode primarily indicated for patients with high airway resistance. In this way, the aim is to guarantee the tidal volume, consequently, the minute volume to the patient with the lowest positive inspiratory pressure (PIP), automatically adjusting the inspiratory time and flow in order to maintain constant pressure and flow control. descending during the time of inspiration.

IPPV - INTERMITTENT POSITIVE PRESSURE VENTILATION

It is an advanced mode in which there is a double control (pressure and volume), the user configures a tidal volume and a peak pressure and other parameters similar to AC-VCV and AC-PCV; the system will try to reach the configured volume; for this volume to be reached, the pressure would exceed the adjusted peak, the system will limit the pressure, automatically limiting the volume, until the inspiratory time ends and cycling occurs. User information describing that the pressure has been limited will be provided.

PRECISION AND TOLERANCE

VOLUME CONTROLLED VENTILATORY MODES

Volume-controlled ventilation modes have the following tolerances for the maximum acceptable error, in relation to the values configured for each of the following parameters in the equipment:

PARAMETER	MAXIMUM ACCEPTABLE ERROR
Volume released	+/- (Fixed error of 4.0 ml + 15% of adjusted value)
PEEP	+/- (Fixed error of 2 cmH_2O + 4% of adjusted value)
FiO2	+/- (Fixed error of 2.5% + 2.5% of adjusted value)

PRESSURE CONTROLLED VENTILATORY MODES

Pressure-controlled ventilation modes have the following tolerances for the maximum acceptable error, in relation to the values configured for each of the following parameters in the equipment:

PARAMETER	MAXIMUM ACCEPTABLE ERROR
Pressure in the airways at the end of inspiration	+/- (Fixed error of 2 cmH_2O + 4% of adjusted value)
PEEP	+/- (Fixed error of 2 cmH_2O + 4% of adjusted value)
FiO2	+/- (Fixed error of 2.5% + 2.5% of adjusted value)

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APPENDIX D

ELECTROMAGNETIC EMISSIONS
CLASSIFICIATION AND COMPLIANCE WITH REGULATORY REQUIREMENTS

OBSERVATION: *The Ruah Lung Ventilator is designed to operate in any environment shown below. The owner or operator of this Equipment must use it in one of these environments.*		
TEST	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
RF Emissions CISPR 11	Group 1	The Lung Ventilator – Ruah uses RF energy exclusively for its internal functions. Thus, its RF emission is very low and is not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class A	The Ruah Lung Ventilator is suitable for use in all establishments that are not residential and are not directly connected to a low voltage electrical network that supplies buildings used for residential purposes. If used in a home environment, this equipment may not provide adequate protection for radio frequency communication services.
Harmonics Emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / scintillation emission IEC 61000-3-3	Not Applicable	

Interference Resistance Test			
TEST	**APPLIED LEVEL**	**COMPLIANCE**	**ELECTROMAGNETIC ENVIRONMENT - GUIDANCE**
Electrical discharge (lightning) Static (ESD) according to IEC 61000-4-2	±8kV per contact ± 15 kV by air	Conform	Floors must be made of wood or cement, and must have ceramic tiles. If the floor is made of synthetic material,

			relative humidity must be at least 30%
Fast transient electrical disturbances / discharges according to IEC 61000-4-4	±2 kV on power supply lines ±1 kV on input/output lines	Conform	Power supply quality should match the voltage supplied in a typical hospital or commercial environment.
Overvoltages according to IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	Conform	
Voltage drops, Brief interruptions and Voltage fluctuations Provided in accordance with IEC 61000-4-11	< 5% Ut (>95% voltage drop in Ut) for 0.5 cycle. 40% Ut (60% voltage drop in Ut) for 5 cycles. 70% Ut (30% voltage drop in Ut) for 25 cycles. < 5% Ut (> 95% voltage drop in Ut) for 5 seconds.	Conform	The quality of the supplied voltage must correspond to the voltage provided in a typical hospital or commercial environment. If the user of the RUAH LUNG VENTILATOR requires continuous operation even when there are interruptions in the energy supply, the RUAH LUNG VENTILATOR must be powered without interruptions or with a battery.
Magnetic field at supply frequency (50/60 Hz) according to IEC 61000-4-8	3 A/m	Conform	Magnetic fields at the power frequency should be at levels characteristic of a typical location in a typical commercial or hospital environment.

RF Conducted **IEC 61000-4-6** **RF Radiated** **IEC 61000-4-3**	6 V_{RMS} 150 kHz up to 80 MHz 3 V/m 80 MHz up to 2.5 GHz	[V1] V Conform [E1] V/m Conform	Portable and mobile RF communication equipment should not be used near any part of the RUAH LUNG VENTILATOR, including cables, with a separation distance less than the recommended one, this safe distance will be calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance: d = [3.5 / V1] √P d = [3.5 / E1] √P 80 MHz to 800Mhz d = [7/E1] √P 800 MHz up to 2.5 Ghz where P is the rated maximum output power of the transmitter in Watts (W), according to the transmitter manufacturer, and d is the recommended separation distance in meters (m) It is recommended that the field strength established by the RF transmitter, as determined through an electromagnetic on-site inspection a, be less than the compliance level in each frequency range. Interference may occur around equipment marked with the following symbol: 

Note 1 Test levels defined according to ABNT NBR IEC 60601 guidelines.
Note 2 Ut is the AC supply voltage before the test level is applied
Note 3 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] *Field intensities established by fixed transmitters, such as base stations, wireless (cellular) telephone and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with precision. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is recommended. If the field strength measurement at the location where the RUAH LUNG VENTILATOR is used exceeds the compliance level used above, the RUAH LUNG VENTILATOR should be observed to verify normal operation. If abnormal performance is observed, additional procedures may be necessary, such as reorienting or relocating the RUAH LUNG VENTILATOR.*

[b] *Over the frequency range 150 kHz to 80 MHz, the field intensity should be less than [V1] V/m.*

15 APPENDIX E

TECHNICAL ASSISTANCE

Mr./Mrs. Proprietor,

Cmos Drake do Nordeste has a large list of representatives and technical assistance throughout the Brazilian territory.
So that we can provide you with a personalized service, we ask that you send us the registration form on the next page, for updates on our database and better guidance of authorized technical assistance services for each region of Brazil, training and others.
Within Brazil, for additional information about the product or for any need to use the network of authorized workshops, complaints, doubts, suggestions, and technical assistance, contact our Customer Service below:

Site	www.cmosdrake.com.br
Telephone	(0XX31) 3547-3969
E-mail	sac@cmosdrake.com.br
Address	Av. Regent 600, Sala 205
District	Alphaville, Lagoa dos Ingleses
City / State	Nova Lima, MG
Zip Code	34.018-000
Office Hours	Monday to Friday, 08:00 AM - 06:00 PM

In special cases that are necessary, CMOS DRAKE makes available, by agreement, all technical material such as circuit diagrams, list of materials, technical information, component lists, instructions for calibration and gauging or whatever is necessary to that user-qualified technical personnel can carry out repairs on the parts designated repairable by the manufacturer. Authorization for maintenance must be formally expressed by CMOS DRAKE.

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APPENDIX F

TRAINING

To request training, contact the CMOS Drake Product Specialist team for information on the specialized training center nearest you.

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APPENDIX G

REGISTRATION FORM

Mr./Mrs. Proprietor,

Please fill in the fields below with your updated data and send it to us so that we can register you in our system. This is necessary in order to provide the best service to our customers, keeping all contacts up to date for inquiries and technical assistance.

EQUIPMENT	SERIAL NUMBER
RUAH LUNG VENTILATOR	

CUSTOMER NAME	
ADDRESS	
CITY	**STATE**
TELEPHONE	**FAX**

18 APPENDIX H

MAINTENANCE CHECKLIST

Equipment	
Serial Number	
Location	

Start Date	/ /
End Date	/ /

Instruction	Result	
	OK	Failure
Visual Inspection Verification (integrity and accessories)		
Self-test verification at startup (audible alarm and visual indicators)		
Electric mains operation indicator		
Battery operation alert		
High Pressure Alarm		
Low Pressure Alarm		
Verification of Monitored Parameters		
High PEEP		

Low PEEP		
High Tidal Volume Alarm		
Low Tidal Volume Alarm		
High respiratory flow alarm		
Low respiratory flow alarm		
Apnea alarm		
Occlusion alarm		

The Ventilator will be ready for operation when all tests have been successfully completed.

RECOMMENDATION

It is recommended that this device be inspected and tested daily according to checklist.

WARNING

Possibility of damage to the Equipment:
Do not clean any part of this Equipment or its Accessories with bleach, bleach dilution or phenol-based chemical compounds.
Do not use abrasive or flammable cleaning agents. Do not attempt to sterilize this Equipment or any of its Accessories.

19 APPENDIX I

CERTIFICATE OF WARRANTY

CMOS DRAKE DO NORDESTE S.A guarantees Legal Warranty against any manufacturing defect for a period of 12 (twelve) months from the date of issuance of the sales invoice referring to the equipment purchased by the consumer with mandatory identification of the model, serial number and equipment characteristics. CMOS DRAKE do NORDESTE S.A does not grant any form or type of warranty for equipment unaccompanied by the sales invoice to the consumer.

Scope of Warranty

- Any defect diagnosed during the installation and (or) use of the product, the consumer must immediately contact CMOS DRAKE DO NORDESTE S.A. The same will activate the Authorized representatives to provide the necessary services.
- The Manufacturer will be responsible for replacing parts and components that present anomalies found to be manufacturing defects, in addition to the labor involved in this process.
- Oximetry sensors and patient cables are warranted for ninety (90) days, except for misuse, physical damage and/or breakage.
- Consumable materials subject to natural wear and tear, such as batteries, disposable electrodes, among others, are excluded from this warranty.
- This guarantee does not include any compensation for loss of profit, personal accidents and third parties and other goods.
- This warranty term is valid only for products sold and installed in Brazilian territory.

Warranty Cancellation Conditions

- If the recommendations contained in this manual regarding installation, operation, care, recommendations and warnings are not followed.
- If there is a breakage and/or violation of the security seal.
- If there is removal or alteration of the serial number of the equipment purchased by the consumer.
- If the Equipment is used with cables, sensors, accessories or consumables that are not original CMOS DRAKE or outside the normal conditions of use, such as expiration date or period or use.
- If the Equipment is tampered with, calibrated, adjusted, repaired or tampered with by professionals not Authorized by the Manufacturer.
- If the Equipment is used in a manner different from that described in the USER'S MANUAL.

- If the Equipment is damaged by accidents such as falling, knocking, misuse, neglect or natural phenomena.

Disclaimer

The Manufacturer is not responsible for expenses with installations, products or accessories damaged due to transport accidents, handling, scratches, dents, non-functioning or failures resulting from problems in the electricity supply. In locations where there is no authorized technical assistance from CMOS DRAKE, the costs of transporting the device to the factory or the authorized technician to the place where the equipment is located will be borne by the Consumer requesting the service according to a previously approved budget. The Manufacturer is not responsible for improper use and/or use by unqualified persons.

Serial Number:

CMOS DRAKE DO NORDESTE S.A
AV. REGENT 600, SALA 205; TÉRREO E 1º ANDAR
B. ALPHAVILLE, LAGOA DOS INGLESES
NOVA LIMA – MG – CEP: 34,018-000 – (0XX31) 3547-3969
TECHNICAL HEAD: BÁRBARA HELEN SOUZA MAIA
CREA/MG: 224055-D
LEGAL REPRESENTATIVE: MARCO AURÉLIO MARQUES FÉLIX

This manual was prepared by the Engineering and Quality departments of CMOS DRAKE, and approved by the Inmetro Certification Body.

CMOS DRAKE reserves the right to make any changes it deems necessary to the manual or product without any prior notice to the consumer. Any and all alterations/modifications are communicated to Inmetro and Anvisa.

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