LEISTUNG

MECHANICAL VENTILATOR
LEISTUNG LUFT NEO

R 04-04 (52) REV. 01

GMP CERTIFICATE
NBR ISO 9001:2008
EN ISO 13485:2003 + AC 2009


LEISTUNG
Equipamentos Ltda.
LUFTneo
PCV
NEONATAL
MENU
MODOS OPERATIVOS
FLUXOS AUXILIARES
PAUSA INSPIRATORIA
SENSIBILIDADE EXPIRATORIA
MECANICA RESPIRATORIA
PERFIL TECH/OPERAT
MONITOR REMOTO
P Pico 17
P Media 12
P Base 5
Fluxo 4
V Tidal 18
Freq 40
T Ins 0.60
I:E 1:1.5
FIO2 0.50
Pressão
Fluxo
FIO2 0.50
R Time 5
T Ins 0.60
Freq 40
P Con 12
PEEP 5
Sens 1.0
ENERGIA ELÉTRICA
LEISTUNG
ALARMES
SELEÇÃO
VALVULA EXALATORIA
NEBULIZADOR
CIRCUITO PACIENTE

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GMP Certificate
EN ISO 13485:2003 + AC 2009
NBR ISO 9001:2008

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ANVISA registration:
Technical Name: Pressure – Volume Lung Ventilator
Commercial Name: Mechanical Ventilator Leistung LUFT NEO
ANVISA registration No.: 80203470006

CONTENTS

GUIDELINES AND DECLARATIONS OF LEISTUNG EQUIPAMENTO LTDA. ABOUT ELECTROMAGNETIC COMPATIBILITY (EMC)

Manufacturer guidelines and declarations – Electromagnetic emission		
The **LUFT-NEO** is designated for use in electromagnetic ambience as specified bellow. It is recommended that the LUFT-NEO user ensures it be utilized in such ambience.		
Emission tests	**Compliance**	**Electromagnetic ambience - guidelines**
RF emissions ABNT NBR IEC CISPR11	Group 1	**Lung ventilator LUFT-NEO** utilizes RF energy only for its internal functions. However, its RF emissions are very low and it is improbable it causes any interference with nearby equipments.
RF emissions ABNT NBR IEC CISPR11	Class A	**Lung ventilator LUFT-NEO** is appropriated for all establishments but domestic and may be used in residential establishments and those directly connected to the public low voltage power distribution that supplies edifications for domestic use, since the following warning is attended: **Warning:** This equipment is designated for use only by health area professional. It may causes radio-interference or interrupts operation of nearby equipments. It may be necessary to adopt mitigation procedure like reorientation or reallocation of the LUFT-NEO or blindage of the local.
Harmonic emissions IEC 61000-3-2	Not applicable	
Emissions due to the fluctuation of voltage flicker IEC 61000-3-3	Not applicable	

⇒ In order to avoid RF interference, the **Lung Ventilator LUFT-NEO** should not be used stacked on others equipment. If this is required, it is recommended to be observed the normal use of equipments.

Manufacturer Guidance and Declaration – Electromagnetic Immunity			
The **Lung Ventilator LUFT-NEO** is intended for use in environment electromagnetic specified below. It is recommended that the client or user of Lung Ventilator LUFT-NEO ensures that it is used in such environment.			
Emission tests	**Test Level** **ABNT NBR IEC 60601**	**Compliance Level**	**Electromagnetic Environment – Guidances**
Electrostatic Discharges (ESD) IEC 61000-4-2	± 6 kV by contact ± 8 kV by air	Complies	Floors should be wood, concrete or ceramic. If the floors are covered with synthetic material, relative humidity should be at least 30%.
Fast Transient Burst (“Burst”) IEC 61000-4-4	± 2 kV at power lines ± 1kV at I/O lines	Complies	Quality of power supply should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	Complies	Quality of power supply should be that of a typical commercial or hospital environment.
Power outage, short interruptions and voltage variations on the lines of power input IEC 61000-4-11	< 5% **U_t** (> 95% voltage drop of Ut) by 0.5 cycles. 40% U_t (60% voltage drop of Ut) by 5 cycles. 70% U_t (30% voltage drop of Ut) by 25 cycles. < 5% U_t (> 95% voltage drop of Ut) by 5 seconds.	Complies	Quality of power supply should be that of a typical commercial or hospital environment.
Magnetic fields at power line frequency	3A/m	Complies	Magnetic fields at power supply frequency should be that of a typical commercial or hospital environment.

Manufacturer Guidance and Declaration – Electromagnetic Immunity

The **Lung Ventilator LUFT-NEO** is intended for use in environment electromagnetic specified below.

It is recommended that the client or user of **Lung Ventilator LUFT-NEO** ensures that it is used in such environment.

Immunity tests	Test level ABNT NBR IEC 60601	Compliance level	Electromagnetic Environment – Guidances
RF Conducted IEC 61000-4-6	3 Vrms 150 kHz up to 80 MHz	3 Vrms	Portable and mobile RF communication equipments must not be used close to any part of the lung ventilator LUFT-NEO, including cables, Recommended separation distance (equation with respect to the transmitter frequency: $d = 1.17\ [P]^{1/2}$ $d = 1.17\ [P]^{1/2}$ 80 MHz up to 800 MHz
RF Radiated IEC 61000-4-3	3 V/m 80 MHz up to 2,5 GHz	3 V/m	$d = 2.33\ [P]^{1/2}$ 800 MHz up to 2.5 GHz Where ***P*** is the maximum nominal power output of transmitter, in watts (W), according to transmitter manufacturer, and ***d*** is the recommended separation distance, in meters (m). The field intensity established by RF transmitter, as determined by electromagnetic inspection on the local[C] should be less than compliance level in each frequency band [D]. Interference may occur around the equipment marked with this symbol: 

NOTE 1 At 80 MHz and 800 MHz applies the highest range of frequency.

NOTE 2 This guidance may be not applicable in all situations. The electromagnetic propagation is affected by absorption and reflection of structures, objects and people.

A The field intensity established by fix transmitters, like base transceiver stations, telephone (cellular and wireless), land mobile radio, amateur radio, AM and FM transmitter and TV transmitter, can´t be predicted theoretically with accuracy. To evaluate the electromagnetic environmental due to RF fix transmitters, it is recommended to consider a local electromagnetic inspection. If the local field intensity where the **Lung Ventilator LUFT-NEO** is located exceeds the above applicable RF compliance level, the **Lung Ventilator LUFT-NEO** should be observed in order to verify the normal operation. If an unusual performance is observed, additional procedure may be necessary, such as reorienting or replacement of **Lung ventilator LUFT-NEO**.

B Above the frequency range of 150kHz up to 80 MHz, the field intensity must be less than 3 V/m.

Recommended separation distances between portable and mobile RF communication equipment and the Lung Ventilator LUFT-NEO

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

Rated maximum output power of transmitter (watts) W	**Separation distance according to frequency of transmitter (meters) m**		
	150 kHz up to 80 MHz $d = 1.17 [\boldsymbol{P}]^{½}$	80 MHz up to 800 MHz $d = 1.17 [\boldsymbol{P}]^{½}$	800 MHz up to 2.5GHz $d = 2.33 [\boldsymbol{P}]^{½}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.7	11.7	23.3

For transmitters with a maximum rated output power not listed above, the recommended separation distance *d* in metes (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

CHAPTER 1 – PRESENTATION

In this User Manual, are presented the necessary information for the correct use of the **Lung Ventilator LUFT-NEO.** The indications relating to enforcement and regulations, mentioned in this manual, is a guideline, the physician should adapt, as their criterion, the needs of patients.

GENERAL	
MODEL	**LUFT NEO**
Registry ANVISA	**No: 80203470006**
MEDICAL DEVICE CLASSIFICATION	**CLASS III**
OPERATION MODE	**Continuous operation**
Classification according to type against electrical shock (insulation).	**CLASS I Internally Energized Device**
Classification according to type of protection against electrical shock (applied part).	**TYPE B**
Level of protection against water penetration	**IPX1**
⚠ **Equipment not suitable for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.**	

PHYSICAL CHARACTERISTICS	PARAMETERS	VALUES
Dimensions (Ventilator without the screen)	High	290 mm
	Width	378 mm
	Depth	315 mm
	Weight without accessories	9.200 kg
	Weight with accessories	31.380 kg

EXTERNAL POWER SOURCE	
VOLTAGE – CURRENT	90V – 264V ~ 1.5A – 0.50A
FREQUENCY	47 up to 63 Hz
POWER	130 VA
FUSE	250V ~ 2A 20mm SB (Slow)

INTERNAL POWER SOURCE		
Nominal voltage	12 V ⎓	
Nominal capacity	5.0Ah	
Type	VRLA (Sealed, does not emit gas)	
Autonomy	Complete battery charge 77ºF (25ºC)	120 minutes autonomy
Capacity affected by temperature	104ºF (40ºC) 77ºF (25ºC) 32ºF (0ºC) 5ºF (-15ºC)	102% 100% 85% 65%
Auto-discharge 68ºF (20ºC)	Capacity after 3 months Capacity after 6 months Capacity after 12 months	90% 80% 60%

Maximum Discharge Current 77ºF (25ºC)	48A (5s)	
Charge (Constant Voltage)	Floating 77ºF (25ºC)	13.6 – 13.8V / 1.25A (max).
Charging Time (Battery Discharged)	Vmin=10.5V	4 Hours
Maximum temperature	131ºF (55ºC)	
Internal fuses	4A 20mm SB	
SPECIFICATIONS INFORMED BY BATTERY MANUFACTURER.		
THE INTERNAL BATTERY AND FUSE ARE NOT REPLACEABLE BY OPERATOR.		
RISK OF ELECTRICAL SHOCK. THE CASE MUST BE REMOVED ONLY BY QUALIFIED PERSONNEL.		
THE SWITCHING FOR INTERNALLY BATTERY OCCURS AUTOMATICALLY WITHOUT THE NECESSITY OF EXTERNAL INTERVENTION, IT DOES NOT INTERFERES THE OPERATION OF THE EQUIPMENT BUT TRIGGERS AN ALARM AS EXPLAINED IN CHAPTER 9.		

ELECTRICAL OUTPUT	
VOLTAGE – CURRENT	110V ~ 0.63A
FREQUENCY	60 Hz
POWER	40 VA
FUSE	250V ~ 0.5A T 20mm SB (Slow)

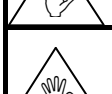
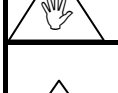
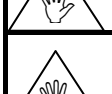
PNEUMATIC INPUTS	
OXYGEN	Input DISS 9/16” – 18
AIR	Input DISS 3/4” – 16
PRESSURE	From 2.8 up to 6 kg/cm²
FLOW	Up to 180 l/min
USE ONLY MEDICAL GRADE GAS.	

ENVIRONMENTAL SPECIFICATIONS		VALUES
Environment Temperature	Operation	+10ºC up to 35ºC
	Storage – Transport	+2ºC up to 40ºC (*)
Relative Humidity	Operation	10% up to 95% No condensable
	Storage – Transport	0% up to 95% No condensable
Atmospheric Pressure	Operation	66 – 100 kPa
	Storage – Transport	66 – 100 kPa

	The measure of volume and pressure is standardized by barometric pressure at sea level, body temperature and water vapor saturate (btps) and they are adjusted in function of altitude.
	(*) The storage of the lung ventilator for long periods at temperature greater than 27ºc, or without electrical connection for periods greater than 2 months, may affect the internally battery life.

WARNINGS, CAUTIONS AND NOTES

WARNINGS

	Constant attention of specialized personnel is required when patient is connected.
	Whenever the equipment is in use, an alternative ventilation way must be available.
	Operation problems require immediate corrective action.
	The alarms do not mean a total safety in case of the equipment be defective.
	The professional in charge of its use should, using your own criterion and knowledge, adjust the equipment according to the patient needs.
	Do not use anti-static tubes or electrical conductor in the patient circuit.
	Do not sterilize the equipment with ethylene oxide. There is a high probability to occur irreversible damage in the ventilator components.
	The equipment must be connected to AC voltage with protective earth connection.
	The equipment may be affected by High Frequency Electromagnetic Interference (such as cellular, wireless telephone, defibrillators, electro-surgical knifes, magnetic resonance, etc.). Keep these emission sources at least 3(three) meters away from the equipment.
	The use of accessories and cables other than the specified ones, except accessories and cables furnished by LEISTUNG EQUIPAMENTOS LTDA as spare parts for internal components, may result in EMISSION increasing or IMUNITY reduction of LUFT-NEO.
	Before first utilization and after utilization in each patient, it is necessary to clean the ventilator. To sterilize the accessories, follow the instructions on chapter 11.
	Electrical shock danger: NEVER disassemble the ventilator case In case of problems or difficulties, contact the authorized technical service.
	The equipment must be supplied by battery when there is doubt about the integrity of ground connector, taking care not to exceed the battery life.

PRECAUTIONS

	During the warranty period, the stay or movement of equipment should be performed with the original packaging, with its internal correspondent protection, otherwise will result in loss of warranty.
	Never sterilize the ventilator, the internal components is not compatible with sterilization techniques.
	Follow the instructions at chapter 11 for equipment cleaning and accessories sterilization.
	Never operate the equipment exposing it to direct heat or sunlight.
	Never cover or place the equipment in order to block the air entry for cooling.
	To ensure electrical protections and avoid risk of fire, never change the fuses. If the equipment does not work, contact the Authorized Technical Support.
	The improper replacement of the fuses nullifies warranty and represents a risk for the equipment operation, operator and patient safety.

NOTES

	The ventilator is a medical device that has to be operated by qualified and trained personnel, supervised by a doctor.
	The LUFT-NEO is produced with recyclable materials and should not be thrown into common landfills because it contains toxic materials to nature, for this, contact an authorized dealer.
	Electric Diagrams, Circuit Diagrams, component list, repair instructions and training can be provided by Leistung Equipamentos Ltda, by agreement between the parts.
	Leistung Equipamentos Ltda. is a company of continuous improvement in its products and technical specifications can change without previous notice.

CHAPTER 2 – INTRODUCTION

LUFT-NEO is among the most complete lung ventilators in the world market, offering a high ventilation quality adapted for each patient, with great ease of operation through an extremely intuitive panel design, which allows the operator to utilize all the parameters using few command keys, due to its intelligent graphical interface, making the work of the operator easier, allowing the operator to provide more attention to the patient.

Suitable for pediatric and neonatal patients, LUFT-NEO is able to assume the most complete and rigorous therapies, effectively, reliable and accurate.

Based on an easy operative system, it is interactive with the operator, it has fast and safe interconnection system with the patient circuit, avoiding any possibility of error. Its starts with a default configuration, which ensure a safe and accurate ventilation, giving to the operator the control of the equipment and assuring sensitivity values that avoid self-cycling, allowing a better progress of the patient without interferences. Warning messages are very easy to understand which turns possible to take decisions respecting the alarms situation and critical parameters variation.

The final result is an ICU medical ventilator with a friendly interface, where its handling is very easy and intuitive. Ventilation modes menu is focused for pediatric and neonatal patients at the same time its configuration is simple and affective, so LUFT-NEO practicability and operator competence can walk together, so that the maximum of LUFT-NEO can be obtained: perfect and natural mechanical ventilation, delivering comfort and safety for adults and neonates.

VENTILATION MODES		
PATIENT	**TYPE**	**VENTILATION**
PEDIATRIC	ASSISTED CONTROLLED	VOLUME CONTROLLED (VCV)
		PRESSURE CONTROLLED (PCV)
	SPONTANEOUS	PRESSURE SUPPORT (PSV)
		CONTINUOUS POSITIVE PRESSURE (CPAP)
		NON-INVASIVE (NIV)
	VARIABLES	SIMV (VCV / PCV) + PSV
		MANDATORY MINUTE (MMV) + PSV
		PSV + ASSURED TIDAL VOLUME
		BIPHASIC PRESSURE
NEONATOLOGY	ASSISTED CONTROLLED	PRESSURE CONTROLLED (PCV)
		CONTINUOUS FLOW
	SPONTANEOUS	PRESSURE SUPPORT (PSV)
		CPAP
		Nasal CPAP
	VARIABLES	SIMV (PCV) + PSV

SPECIFICATIONS	
Backup ventilation	PCV or VCV in pediatric and PCV in neonatology Emergency ventilation
FIO_2	21 to 100% **(electronically regulated on the panel with graphic display monitoring)**
Inspiration Time	0.1 to 25 seconds
I:E Ratio	5:1 - 1:99
Ventilator frequency	1 - 180 bpm
Tidal volume	10 up to 2500 ml
Sensibility	• By flow: 0.5 up to 10 l/min • By Pressure: -0.5 up to -15 H_2Ocm (compensated PEEP)
Pressure Control (PCV)	2 up to 70 H_2Ocm over PEEP (with adjustable “RISE TIME”)
Pressure Support (PSV)	0 up to 70 H_2Ocm over PEEP (with adjustable “RISE TIME”)
Inspiration Pressure	2 up to 120 H_2Ocm
Expiration Sensibility	Adjustable from 5% up to 80% of initial flow
PEEP / CPAP	0 up to 50 H_2Ocm
Nebulization	Synchronized in inspiratory phase
TGI	Synchronized in expiratory phase
Inspiratory flow	In VCV mode: automatic adjustment In PCV and PSV modes: up to 180 l/min Continuous flow in neonatology: 2 up to 15 l/min Inspiratory flow in neonatology: 1 up to 100 l/min
Base Flow	Off up to 50 l/min
Expiratory Flow	Up to 120 l/min
Sigh (VCV mode)	Cycles per hour, quantity, volume and maximum pressure.
Inspiratory Pause (VCV mode)	0 up to 2 seconds with plateau value
Manual trigger 100% O_2	Oxygenation for aspiration with synchronized system
Flow waveform	In VCV mode: rectangular, descendent ramp, sinusoidal and ascending ramp. In PCV and PSV: descendent ramp.
Automatic By pass of the Air-O_2 net	In case of break of one of them, the equipment continues operating normally.
Inspiratory pressure inner safety valve	Adjusted in 120 H_2Ocm
Regulating pressure valve of air and O_2 input	Internally incorporated into the equipment.
STAND BY	To maintain the configuration without cycling.
SCALES	Automatic actualization for vertical and horizontal analysis.
FREEZE	For graphics analysis.
Signal output	To external communication and software update.

OUTPUT PARAMETERS
AIRWAY PRESSURE: PEAK, PLATEAU, MEAN, BASE(PEEP)
INSPIRATORY TIME
I:E RATIO AND SPONTANEOUS BREATHINGS
EXHALED TIDAL VOLUME
INSPIRATORY PEAK FLOW

TOTAL FREQUENCY
GRAPHIC INDICATOR OF SPONTANEOUS AND MECHANICAL CYCLES
EXHALED MINUTE VOLUME
FIO_2 CONCENTRATION

BREATHING MECHANICS
AUTOPEEP
ALARMS
INSPIRATORY MAXIMUM / MINIMUM AIRWAY PRESSURE (DISCONNECTION OF THE PATIENT CIRCUIT)
MAXIMUM / MINIMUM EXHALED TIDAL VOLUME
APNEA WITH ADJUSTABLE TIME
MAXIMUM RESPIRATORY FREQUENCY
MAXIMUM / MINIMUM PEEP AND CONTINUOUS PRESSURE
GAS SUPPLY SOURCE (AIR-O_2)
POWER OUTAGE
LOW BATTERY CHARGE
MICROPROCESSOR
INTERRUPTED CYCLE IN PRESSURE MODES
MAXIMUM / MINIMUM FIO_2
INVERTED I:E RATIO
ALARMS ARE TRIGGERED FOLLOWING PRIORITY ORDER, WITH LIGHT OR SOUND WARNINGS AND/OR SCREEN MESSAGE.
GRAPHICS
PRESSURE – FLOW / TIME

TENDENCY CURVES (LAST 18HS)
PEAK AND BASE PRESSURE
FLOW
TIDAL VOLUME
MINUTE VOLUME
FREQUENCY
DYNAMIC COMPLIANCE

ALARMS LOG
LOG OF THE LAST 1000 EVENTS WITH DATE, HOUR AND ALARM CAUSE
OTHER MENUS
MENU OF TIME INDICATION AND EXECUTED SERVICES
ALTITUDE ADJUSTMENT FOR VOLUME COMPENSATION
LANGUAGE SELECTION

SELF-TESTS
PATIENT CIRCUIT LEAKAGE
EXPIRATORY FLOW
PEEP VALVE
PATIENT CIRCUIT COMPLIANCE

PATIENT CIRCUIT TEST (AUTOTEST) IS PERFORMED BY THE OPERATOR WHENEVER THE EQUIPMENT IS TURNED ON.
ONCE REALIZED AUTOTEST, THE EQUIPMENT MAKES THE CALIBRATION WITHOUT OPERATOR'S INTERVENTION.
WHEN NECESSARY, THE EQUIPMENT CLEANS THE FLOW SENSORS AUTOMATICALLY (EXALATORY VALVE) WITHOUT ITS OPERATION BE INTERRUPTED.

IN CASE OF LEAKAGE IN THE CIRCUIT DURING THE INITIAL TEST (AUTOTEST) THE EQUIPMENT SHOWS ON THE DISPLAY A MESSAGE INDICATING THE VALUES OF LEAKING. FOR THE CORRECT OPERATION OF THE EQUIPMENT IT IS IMPORTANT THAT THERE IS NOT ANY LEAKING IN THE PATIENT CIRCUIT.

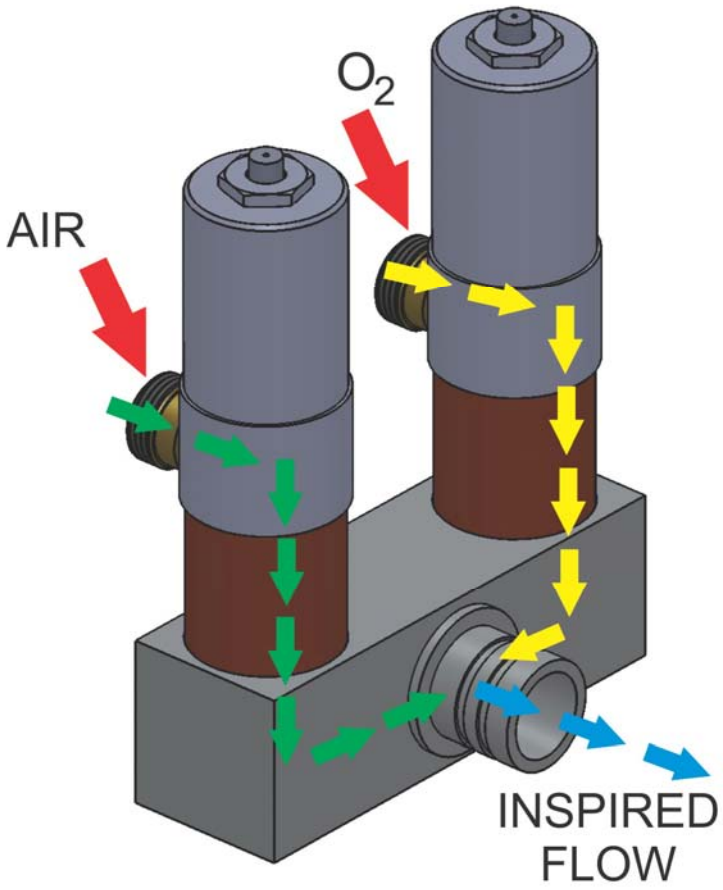
AT THE EXPIRATORY FLOW TEST THE GAS LINES (AIR AND O_2) MUST GIVE A FLOW OF AT LEAST 100 l/min, SO THAT IT DOES NOT INTERFERES WITH ITS OPERATION. IN CASE OF BAD CONNECTION, WRONG ASSEMBLY OR INVERSION OF THE SENSORS, THE EQUIPMENT WILL SHOW AT THE DISPLAY A MESSAGE INDICATING READING ERROR OF FLW AND THE OPERATOR MUST CONFIRM IF HE WILL WORK WITH OR WITHOUT THE EXPIRATORY FLOW READING.

WHEN FINISHED THE COMPLIANCE TEST OF THE CIRCUIT THE EQUIPMENT SHOWS ON THE DISPLAY THE VALUES TO BE COMPENSATED AND THE OPERATOR CAN CHOOSE ABOUT COMPENSATE OR NOT THIS VALUE. THE EQUIPMENT WILL COMPENSATE ONLY IF THE OPERATOR CHOOSE YES, OTHERWISE IT WILL NOT DO IT.

ELECTRONIC BLENDER OPERATION (AR-O_2 BLENDER)

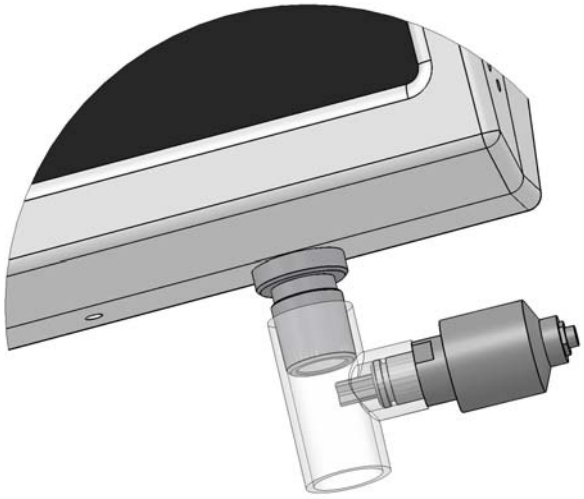
FiO_2 (fraction inspired of oxygen) indicates the quantity of oxygen in the gas inspired by the patient. In general, it may vary from 21% (79% of Nitrogen and 21% of O_2) to 100% (pure Oxygen), for example a FiO_2 of 60% means that 60% of the inspired volume by patient is oxygen and 40% are composed by nitrogen and other gases.

FiO_2 in LUFT NEO is generated by an electronic blender system, which dispenses any external device. The mixture is performed by two proportional actuators, known as proportional valve, which has this name due to its function: to control proportionally the flow of air and oxygen that passes through each one of them. Each flow is measured by its respective pneumotachograph (device used for flow measurement) which send to CPU board the current value of the generated flows by the proportional valves. The value of FiO_2 is given by the fraction of gas delivered by each proportional valve, where each one of them gets responsible only for one part of the total inspired volume. This system is very accurate, because once the physical quantities are very well known like volume, pressure and flow and the variation of concentration of oxygen in the air are very small as well as the percentage of oxygen 100% provided, is enough that the control calculates the flow value of each value will deliver to patient it is obtained, with a negligible error, the correct FiO_2.



FIO_2 MEASUREMENT

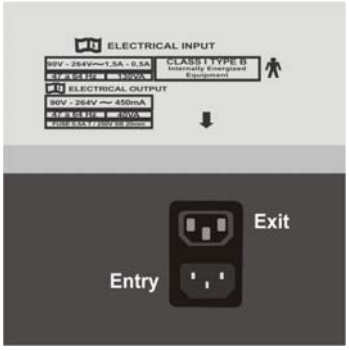
FiO_2 measurement is performed through measurement cells furnished along with the equipment. As standard the cell that is included with the equipment is the galvanic oxygen cell which uses electrochemistry reactions for O_2 percentage measurement in the inspired gas flow. Due to this characteristic, these cells has life time which starts counting from the moment it is exposed to oxygen in the air, which must be replaced after its determined time. The following figure illustrates the right place to put the cell.



As optional, Leistung Equipments Ltd. offers the paramagnetic oxygen cell, which is installed internally in the equipment. The use of paramagnetic cell dispenses the use of galvanic one and also dispenses the periodic replacement, avoiding this additional cost, thus, although it has a price higher than the galvanic one, this difference is compensated in long term.

CHAPTER 3 – ASSEMBLY AND CONNECTION

POWER SOURCE CONNECTION



The electrical connection is located in the back of the case.

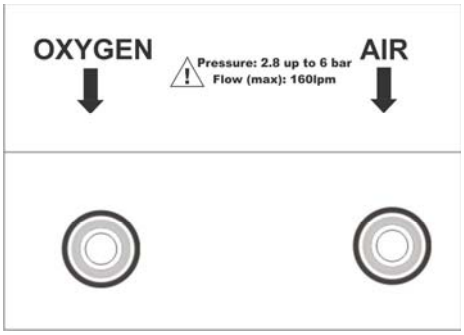
In its case there are indicated the voltage values of operation along with the current ones and nominal power of the equipment.

There is also indicated the corresponding fuse values.

	THE EQUIPMENT HAS INCLUDED FROM FACTORY FUSES OF 2A 20mm SB SLOW ABLE TO 90V UP TO 264V~
	THE ELECTRICAL CHARACTERISTICS OF THE EQUIPMENT IS FOUND IN THE CHAPTER 1 OF THIS MANUAL

	THE SUPPLY INPUT IS UNIVERSAL. THE EQUIPMENT WORKS IN WHOLE VOLTAGE RANGE (90V UP TO 264V) WITHOUT OPERATOR'S INTERVENTION EVEN WHEN THERE IS A VOLTAGE REDUCTION OF THE POWER DURING THE NORMAL OPERATION.
	CERTIFY THAT THE CONNECTION OF THE EQUIPMENT IS REALIZED WITH A GROUNDED PLUG TO ASSURE ITS CORRECT OPERATION. NEVER START THE EQUIPMENT WITHOUT GROUND CONNECTION.
	THE ELECTRICAL INSTALLATION WHERE THE EQUIPMENT WILL BE PLACED MUST BE IN COMPLIANCE WITH THE **NBR 13534** STANDARD, WHICH DETERMINES THE MINIMAL CONDITIONS OF ELECTRICAL INSTALATION IN HEALTH CARE STABLISHMENTS.

GAS SOURCE CONNECTION



The gas connection source is located at the back of the case.

In its case are indicated corresponding inputs of air and oxygen.

AIR INPUT	Male connector DISS ¾" –16
OXYGEN INPUT	Male connector DISS 9/16"-18

	AT THE PRESSURE TIP TUBES ARE UTILIZED THE FEMALE CORRESPONDING CONNECTORS.

 THE SCREWABLE CONNECTIONS USED IN THE AIR INPUTS ARE ACCORDING WITH **NBR 11906** STANDARD, WHICH DETERMINES THE MINIMAL CONDITIONS FOR THIS TYPE OF CONNECTION.
 THE AIR AND OXYGEN INPUTS OF THE EQUIPMENT ARE MADE WITH VALVES THAT PREVENT REVERSE FLOW OF GASES THROUGH THE INPUT PORTS AND THE CROSSFLOW OF GASES.

INPUT PRESSURE	
AIR	2.8 up to 6 kg/cm^2
OXYGEN	2.8 up to 6 kg/cm^2
MINIMUM FLOW SUPPLY	60 l/min.
MAXIMUM FLOW	180 l/min.

 DO NOT USE THE EQUIPMENT IN PRESENCE OF ANESTHESIC INFLAMMABLE GASES. EXPLOSION AND/OR FIRE DANGER.
 IT MUST BE USED AIR AND OXYGEN COMPRESSED, CLEAN AND DRY IN ORDER TO AVOID CONTAMINATION THAT AFFECTS THE EQUIPMENT AND MAY GENERATE A BAD OPERATION.
 IN CASE OF MISSING OF ONE OF THE GAS SUPPLY (AIR OR O_2) THE EQUIPMENT CONTINUES OPERATING NORMALLY WITH THE OTHER GAS SUPPLY
 LUFT NEO SUPPORTS INLET PRESSURE UP TO 1000 KPA (10.2 KG/CM^2), AVOIDING THE USE OF EXTERNAL PRESSURE REGULATORS UNTILL THIS VALUE.

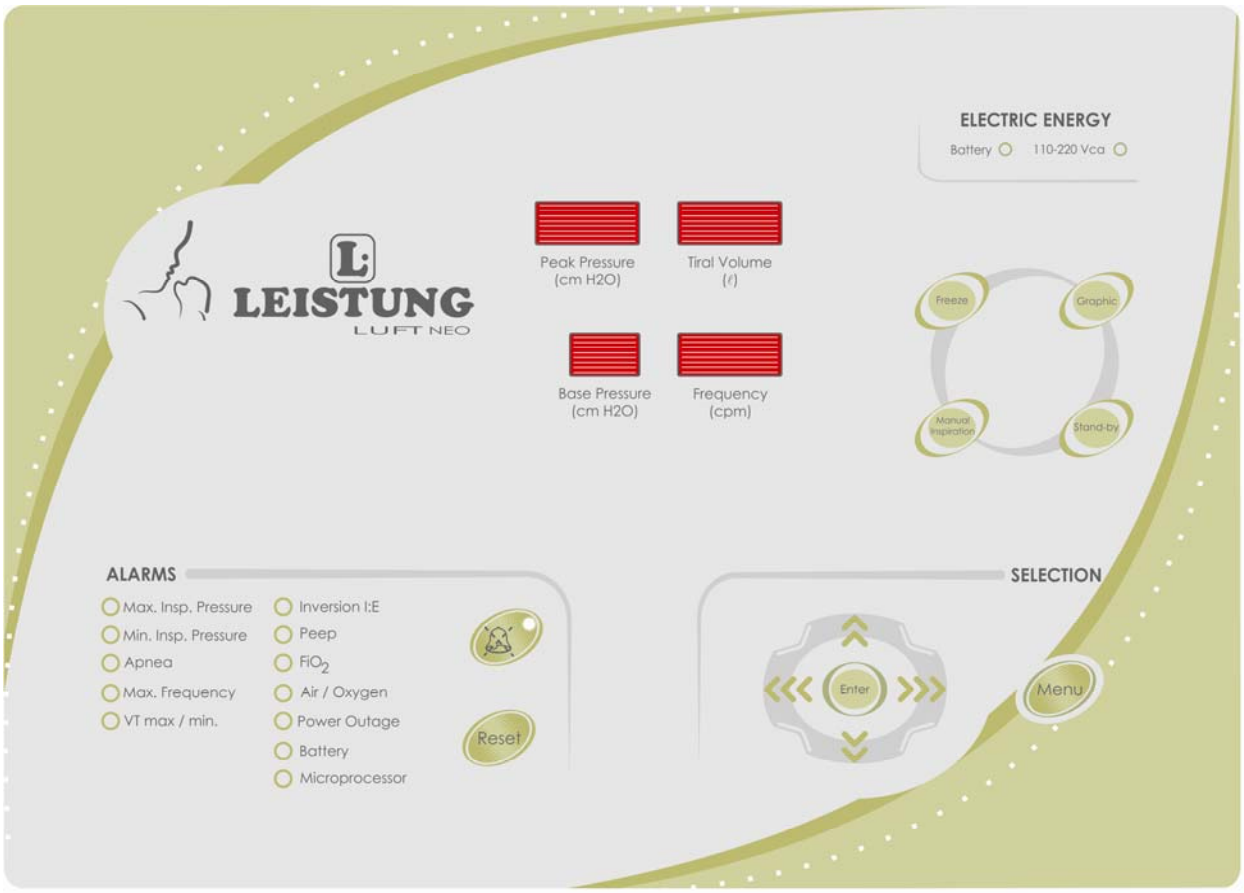
BREATHING CIRCUIT

Utilize respiratory circuit as the necessity: pediatric or neonatal. The difference is in the tubes diameter.

 IN RESPIRATORY CIRCUITS WHICH HAVE WATER DRAIN IN ITS BRANCHS (INSPIRATORY/EXPIRATORY), VERIFY THE HEMERTICITY TO AVOID VOLUME LEAKAGE IN THE CIRCUIT.
 WHEN THE CALIBRATION OF THE PATIENT CIRCUIT IS PERFORMED, THE NEBULIZER MUST NOT BE CONNECTED IN IT.
 VERIFY THE CORRECT POSITION OF THE DIAPHRAGM OF THE EXALATORY VALVE. **SEE CHAPTER 10.**
 THE CONNECTORS OF THE PATIENT CIRCUIT ARE CONICAL TYPES (22mm IN PEDIATRIC AND 15mm IN NEONATAL) AND THEY ARE ACCORDING WITH THE **ISO 5356-1(NBR13475)** STANDARD, WHICH DETERMINES THE MINIMAL EXIGIBLE CONDITIONS FOR THESE CONNECTOR TYPES.

CHAPTER 4 – INDICATORS, CONTROLS AND ALARMS

FRONT PANEL



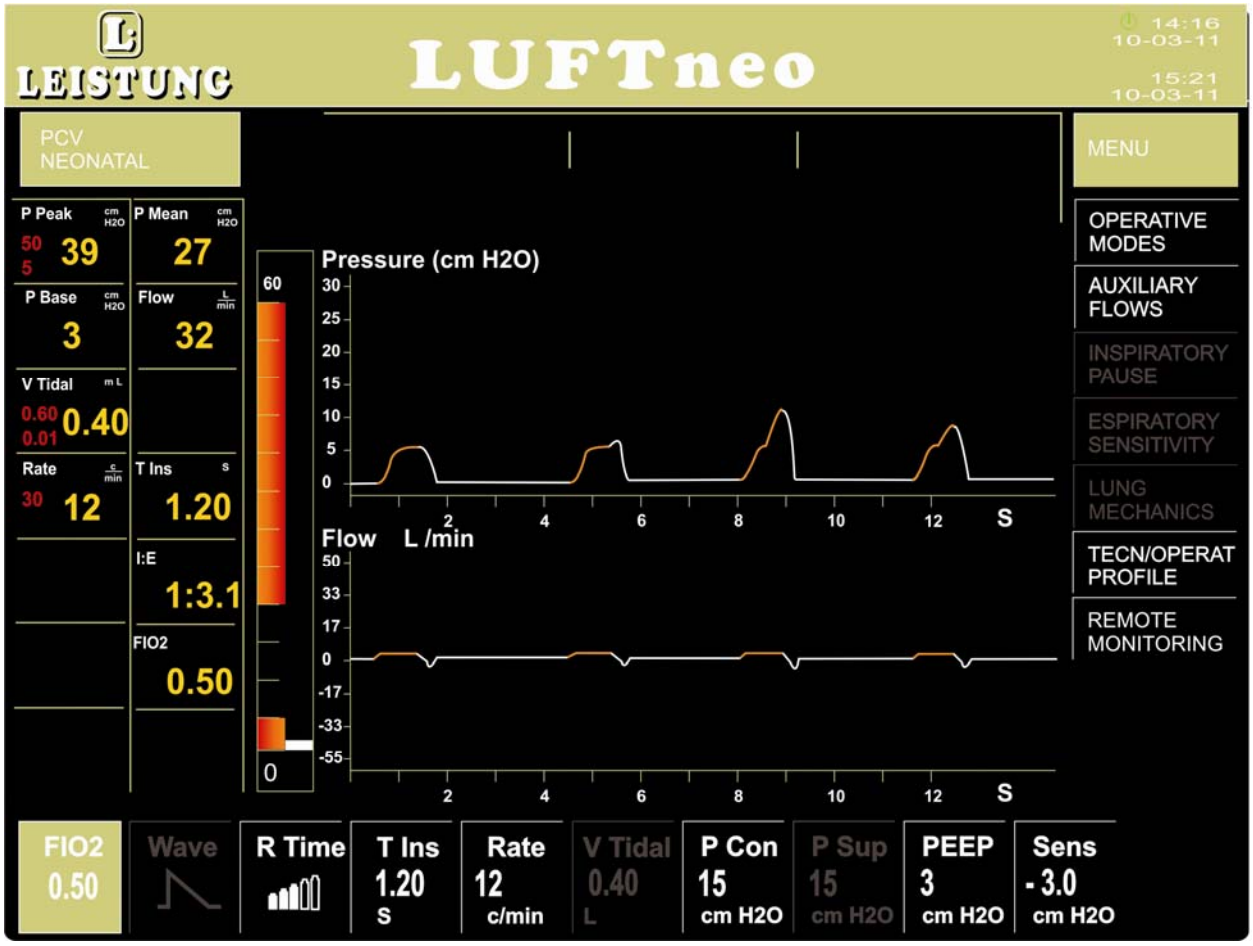
INDICATORS AREA

LEISTUNG LUFT-NEO counts with a double monitoring system with graphic and numeric indications.

LCD SCREEN

Color LCD screen shows the selected values, curves and resultant values.

The screen has an information distribution so that permits to the operator a fast localization of the data to be read, offering so a high operability.



Seeking a greater ease and speed in handling, the 17-inches LCD display is organized in areas: alarm area, monitoring area, configuration area and the graphs areas where all these information are evidenced with different colors.

All values in white color are possible to be adjusted through the operator's adjustments, the resultant values cannot be adjusted and they are in yellow. The alarm values are red colored giving to the operator a greater ease of configuration.

In alarms area there are the alarms of: maximum pressure, minimum pressure, maximum volume, minimum volume, maximum frequency, maximum minute volume and minimum minute volume as well as their resultant values.

In monitoring area it is possible to view the numeric values of peak pressure, mean pressure and base pressure as well as inspiratory peak flow, inspiratory time, I:E ratio and FIO_2.

On the bottom of the display are the parameters adjustable by the operator, such as: FIO_2, WAVEFORM, RISE TIME, INSPIRATORY TIME, FREQUENCY, TIDAL VOLUME, CONTROL PRESSURE, SUPPORT PRESSURE, PEEP and SENSIBILITY. To change the values, the operator must select the desired option, press ENTER, adjust the value and confirm it pressing ENTER again. In sensibility option, the operator may choose for work with SENSIBILITY BY FLOW (l/m) or PRESSURE (H_2Ocm); to change option go in sensibility and press ENTER then confirm the change with the side keys (right/left) changing from l/m to H_2Ocm, and the directional keys (up/down), ranging work values. Resultant values that remain in yellow and are located in monitoring area are not adjustable, they are resultant parameters of the adjustable ones, i.e. the values measured by the equipment. Ex: peak pressure, base pressure and mean

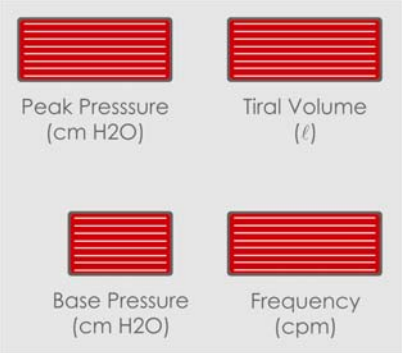
pressure in airways, exhaled tidal volume, frequency, flow peak, dynamic compliance, inspiratory time, I:E ratio and FIO_2 monitoring.

On the upper side of the screen is indicated:

1 – Upper left side – Company's name and equipment model, below there are the patient type and ventilation mode (see chapters 5 and 6).

2 – Upper right side – Date and hour the equipment was started, below there are current date and hour of the equipment.

NUMERIC DISPLAYS AND SUPPLYING INDICATORS



LEISTUNG LUFT-NEO counts with a set of numeric displays which show the values of pressures (peak and base), expired volume and frequency, for the case of failure in the graphic display or visualization at distance. The maximum sampling error is ±10%.

LEISTUNG LUFT-NEO counts with an indicator of the type of power source (external "110-220V~" or internal "Battery") which the equipment is using. Whenever the "110-220V~" indicator is turned on, the internal battery is being recharged.

ALL MEASURES USED AND SHOWN BY THE EQUIPMENT ARE EXPRESSED FOR AMBIENT TEMPERATURE AND DRY PRESSURE (ATDP).

CONTROL AREAS

In this sector there are the keys that permit to select, adjust and confirm of data, and also the access to options selection by screen menu.

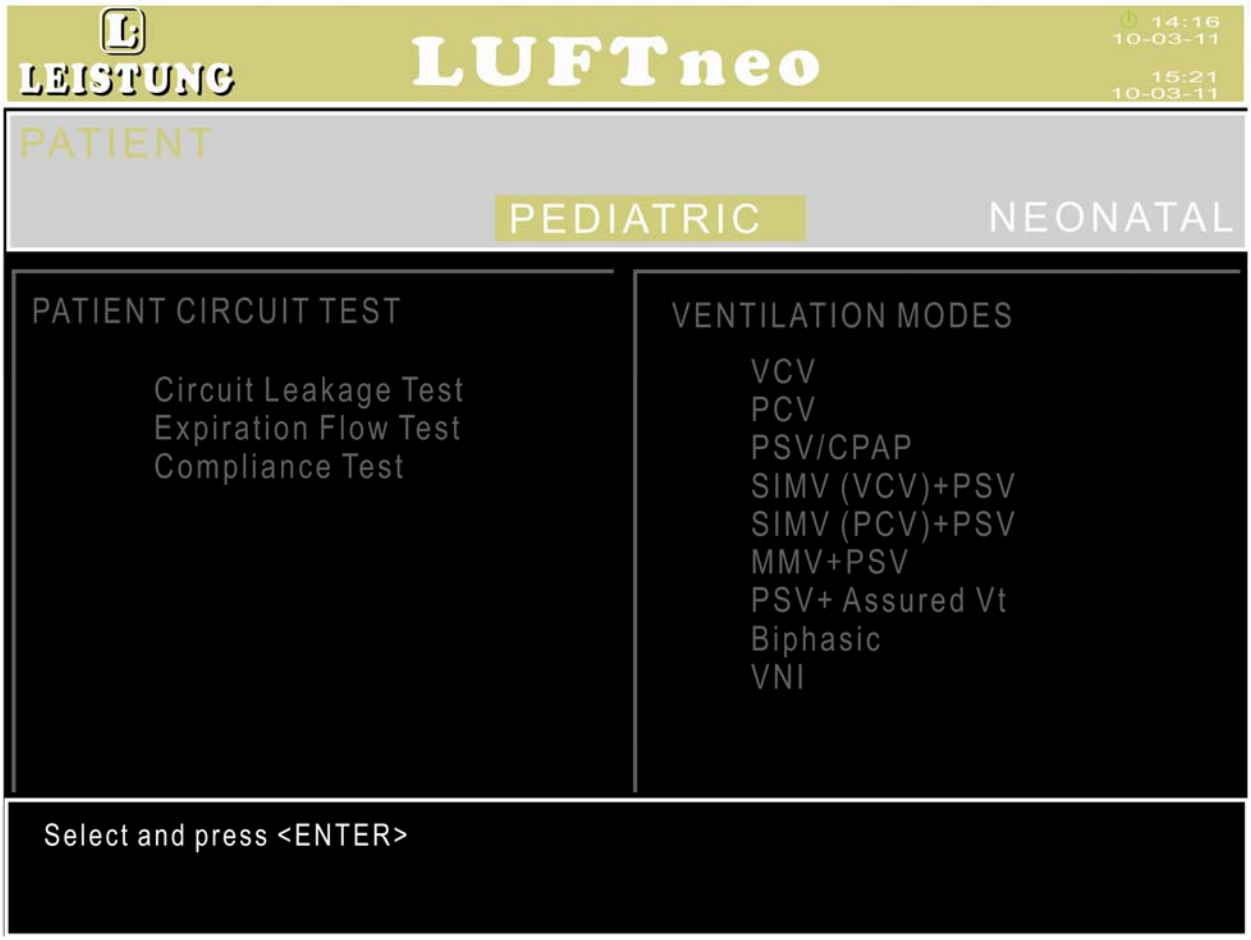
DIRECTIONAL KEYS

Directional keys permit to move the selection cursors of menus and parameters. Also is utilized for adjustment of the selected parameters.

ENTER

When the parameters are selected, activates adjustment mode and realize the values confirmation. It is also utilized to activate menu options.

CHAPTER 5 – LUFT NEO OPERATION



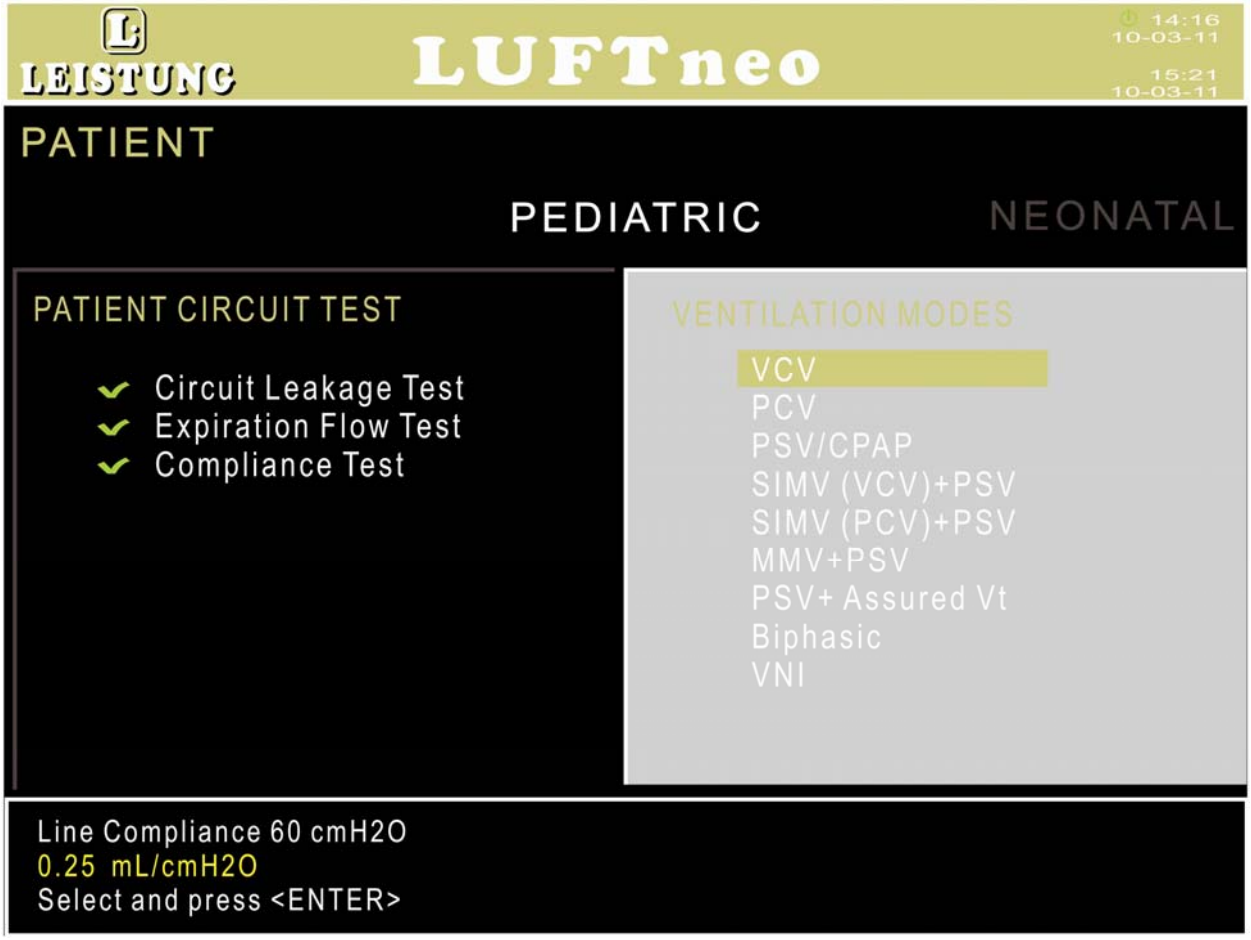
When starting the equipment, an initialization sequence is performed which includes memory test, internal battery, indicator LEDs etc.

Finished the initial sequence, the categories to be ventilated are shown to be selected according to type of patient:

- PEDIATRIC
- NEONATAL

⚠ THIS SELECTION INFLUENCES THE OPTIONS OF THE OFFERED VENTILATION MODES AND THE INITIAL PARAMETER VALUES OF OPERATION.

IS CONSIDERED:
- PEDIATRIC: PATIENTS BETWEEN 10 AND 30 KG OF WEIGHT.
- NEONATAL: PATIENTS WITH LESS THAN 10 KG OF WEIGHT.



Following is performed a test of the patient circuit. It is necessary to install the circuit and maintain blocked the Y output during the entire test.

In this test is verified if there is leakage, it measures and compensates the circuit compliance and is verified the PEEP control and exhalation valve flow.

⚠	THE INCORRECT OBSTRUCTION OF THE PATIENT OUTPUT MAY RESULT IN LEAKAGE ON THE SYSTEM.
⚠	IF THE EXHALATION VALVE IS ASSEMBLED INCORRECTLY OR WITHOUT ITS READING INTERNAL MEMBRANE (INTERNAL MAILER), THE EQUIPMENT WILL NOT BE ABLE TO READ THE EXHALATED VOLUME, WHERE THE OPERATOR MAY OPT TO WORK WITHOUT THIS READING OR RESTART THE TEST.

Finally is accessed the operative modes menu.

The mode is chosen by the selection keys (up and down).

Confirmation of the selection is done through pressing ENTER and will show on the screen the necessary parameters for its use.

SELECTION SEQUENCE, ADJUSTMENT AND DATA CONFIRMATION

Using the selection keys, the parameters to be selected can be accessed.

When selected the option, pressing ENTER the parameter has its color changed permitting its configuration by the vertical and horizontal keys.

To finish, press again ENTER to confirm, change can be canceled by pressing RESET. Change is also canceled if the parameter remains selected for more than 5 seconds or without any modification Is made in its value.

Adjustments made in parameters will not be activated until the mode configuration is finished and the ventilation is started through pressing Manual inspiration key.

ONCE CONFIRMED THE VALUES, THE ACTION CAN NOT BE UNDONE. ALWAYS CHECK THE MODIFIED VALUES BEFORE CONFIRMING.

CHAPTER 6 – MENU

MENU

Pressing MENU, it will show in the right side of the LCD screen the following options:

VENTILATION MODES

A list of operative modes according to the type of selected patient is shown when the equipment is started (pediatric or neonatal). Select the required mode using the directional keys and press ENTER, immediately it will be shown on the display the values of the new mode to be applied and confirm the change pressing MANUAL INSPIRATION. While the change is not confirmed, the equipment will keep working under the adjustments done before.

To see the operative modes which this equipment counts with, see chapter 6.

	LUFT-NEO NEVER STOPS OPERATING DURING CHANGES OF OPERATIVE MODES.
	IN CASE OF CANCELING CHANGES, JUST PRESS RESET TO DENY ALL THE CHANGING PROCESS.

AUXILIARY FLOWS

Pressing MENU, select the AUXILIARY FLOWS option, in this menu it is possible to activate the auxiliary flows outputs, which are:

NEBULIZER: Selecting this option the operator can adjust the time of exit of FIO_2 for nebulization, synchronized with inspiration time, this time may be 5, 10, 15 or 20 minutes, according to the necessity. This output is deactivated automatically at the end of the adjusted time, or manually setting zero the time in menu.

	IN VOLUME LIMITED MODES, THE VOLUME AT THE PATIENT OUTPUT IS REDUCED TO COMPENSATE THE VOLUME AGGREGATED BY NEBULIZES FLOW.

TGI: Selecting this option the operator may activate the output flow of tracheal gas insufflations (TGI) synchronized with expiratory time. To deactivate it is necessary to access the menu manually.

OXYGEN 100%: Selecting this option is started an oxygenation as follows:

1. The operator may choose among 5, 10, 15 or 20 minutes to ventilate the patient with pure oxygen.
2. Once selected the time, the ventilator will show the value of O_2 100% over selected value of FIO_2, and a horizontal bar will appear on the upper right corner of the screen indicating the selected time and elapsed time.

3. The equipment can be disconnected from the patient as often as needed without having its operation modified, silencing for 30 seconds the alarms.

4. The equipment permits changing in ventilation parameters and base pressure (PEEP), since the initial ventilation mode used to start the process is respected. To change ventilation mode, canceling O_2 100% is required.

5. After elapsed the selected time, the equipment will resume FIO_2 value that was selected before the procedure start.

6. To exit before the end of the procedure, the operator must access manually the auxiliary flows menu and set the O_2 100% time as “0”.

OBJECTIVE: Simplify handling of the equipment during the process in airways and/or lung recruitment after a depressurization. Facilitate initial ventilation of the patient since his clinic and semiologic progress.

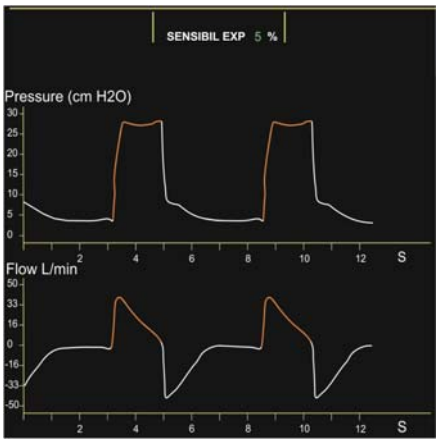
INSPIRATORY PAUSE

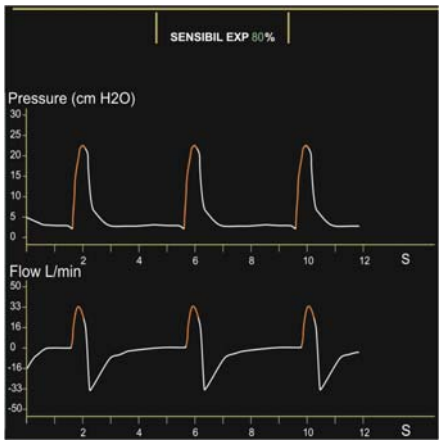
Pressing MENU key, select Inspiratory Pause option. Inspiratory pause is a brief pause (0.10 - 2.00 seconds) at the end of inspiration, during which the pressure remains constant and the flow is zero. To deactivate it, access again Inspiratory Pause and set to “0”.

EXPIRATORY SENSIBILITY (PSV)

Modes that use PSV have flow in descending ramp waveform and allow adjusting the flow value that performs the changing between inspiration phase and exhalation phase (cycle).

To change exhalation sensibility you must press “MENU” and select “Exhalation Sensibility” option. Exhalation Sensibility may be adjusted with values between 5% and 80% of inspiration flow peak.





IF THERE IS LEAKAGE IN THE PATIENT CIRCUIT, A LOW VALUE OF EXPIRATORY SENSIBILITY MAY HAMPER THE CYCLE, DUE TO THE LEAKAGE BE GREATER THAN THE SELECTED INPUT VALUE.

RESPIRATORY MECHANICS

Press MENU key and select Respiratory Mechanics option.

AUTO-PEEP

Auto-PEEP is conceptualized as the persistence of an alveolar positive pressure at the end of exhalation, non intentional, due to the presence of a final exhalation lung volume bigger than the previewed residual functional capacity. It occurs in patients submitted to mechanical ventilation, in consequence of starting an inspiratory phase with positive pressure, before the expiratory time is enough to a complete exhalation of the inspired volume previously.

Auto-PEEP is not evident, may changes drastically the alveolar dynamic and generates a considerable risk in situation that affects the flow during expiration, leading to unnecessary increasing of the respiratory system mechanical work.

To request Auto-PEEP measurement just press MENU key, select Respiratory Mechanics option and access Auto-PEEP window.

Upon selecting Auto-PEEP window, LUFT-NEO starts measuring it and shows on the screen the following message:

When measurement procedure and calculus of Auto-PEEP is concluded, LUFT-NEO shows on the upper part of the screen the value of the TOTAL PEEP, Auto-PEEP and PEEP.

TECHNICAL/OPERATIVE PROFILE

Within technical/operative profile are found the options: Maintenance, Language, Sighs, Hour/Date and PEEP alarm.

- **MAINTENANCE:** In this option are visualized the hours of use of the equipment, as well as the hours of use and date corresponding to the maintenance done described in annex 3.

- **LANGUAGE**: Enables the operator to choose among the languages: ENGLISH, PORTUGUESE and SPANISH.

IT IS IMPORTANT TO REMIND THAT TO CHANGE THE LANGUAGE, THE EQUIPMENT MUST BE RESTARTED.

- **SIGHS:** This option permits to configure:

⇒ Quantity of sighs: quantity of consecutive sighs (1 up to 3) performed in each cycle.

⇒ Cycles per hour: quantity of times (5, 10, 15, 20) the sigh cycles will be repeated per hour.

⇒ Volume: amount of additional volume (it will be added with the already set volume) which will be given by the ventilator in each sigh.

⇒ Maximum pressure: During sighs this value is taken as reference for activation of maximum alarm.

- **PEEP ALARM**: In this option is permitted the modification of PEEP alarm values. The operator can choose to work among the limits of 2, 4, 6, 8, 10 H_2Ocm.

THE ALARM WILL BE ACTIVATED ALLWAYS THE PRESSURE IS BELOW OR ABOVE THE FIXED VALUE OF PEEP, BEING ITS ACTUATION IMMEDIATE OR THROUGH PRIORITIES WITH AS MAXIMUM THE TIME OF 5 SECONDS.

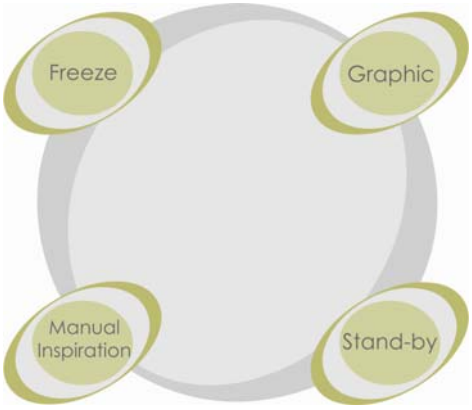
REMOTE MONITOR

Within the remote monitor option it is possible to select the following features:

- **ALARMS LOG**: Shows a list containing the events of alarms since the last time the equipment was turned on, i.e. the hour, the date and the cause of the alarm.
- **TENDENCIES**: Shows a list of available graphs. Select the graph and press ENTER. To see other graphs press again MENU key and select another graph of the list. To exit tendencies press RESET.

DIRECT ACCESS FUNCTIONS AREA

The area of direct access keys includes the keys more frequently used, allowing a fast and easy access. These keys are:



- GRAPHIC
- STAND BY
- FREEZE IMAGE
- MANUAL INSPIRATION

GRAPHIC

Permits to select the graphic type to be shown on screen: Airway Pressure, Inspired/Expired Flow, Pressure + Flow. It also enables the operator to select the reading time of the graphics on screen.

STAND BY

Permits to select *Stand by* mode, which maintains the ventilator in state of repose without alarms until it gets connected to the patient again, without losing the previous set operation parameters.

WHILE IN STAND BY, ALL THE KEYS ARE LOCKED, EXCEPT MANUAL INSPIRATION KEY

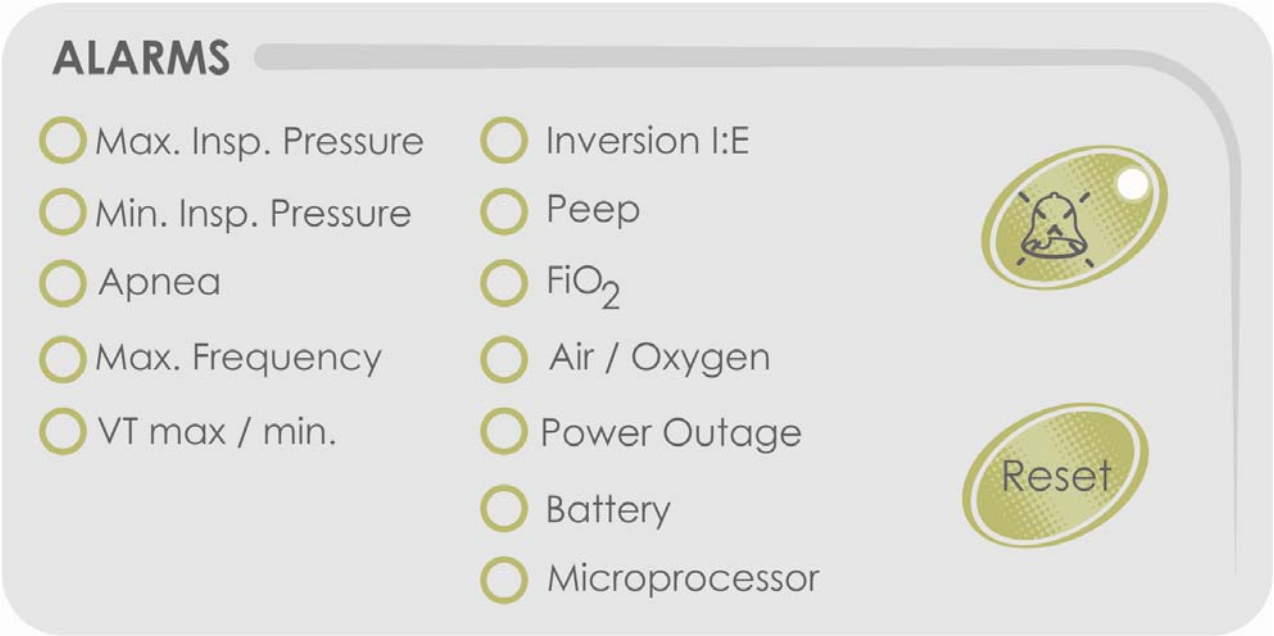
FREEZE IMAGE

Freezes the graphs currently shown on screen, maintaining active patient monitoring and updating output values and airway pressure bar.

MANUAL INSPIRATION

Each time this key is pressed, a new inspiratory cycle is started. It is only active at expiratory phase.

ALARMS AREA



In this sector are the light indicators corresponding to the alarms, which when activated are followed by an alert sound and by messages on screen.

The light indicators turns on intermittently to indicate which alarm is activated, once solved the cause of the alarm, the indicator will remain turned on permanently to indicate which alarm was triggered, until the key RESET be pressed. All the triggered alarms are registered with hour and date at the menu Alarms History (See MENU key).

SILENCE

This key is used to silence the alarm, without affect the light indicators, during a time of 1 minute. If at the end of this time the cause of the alarm was not solved, the sound will get started again.

RESET

This key is used to nullify all the light and sound alarm indicators and it is maintained until any alarm is activated.

CHAPTER 7 – VENTILATION MODES – PEDIATRIC

VENTILATION MODE SELECTION

Pressing Menu key, main menu is accessed. The first option is for ventilation modes.

Pressing ENTER, a list containing all the usual modes for the selected category is shown.

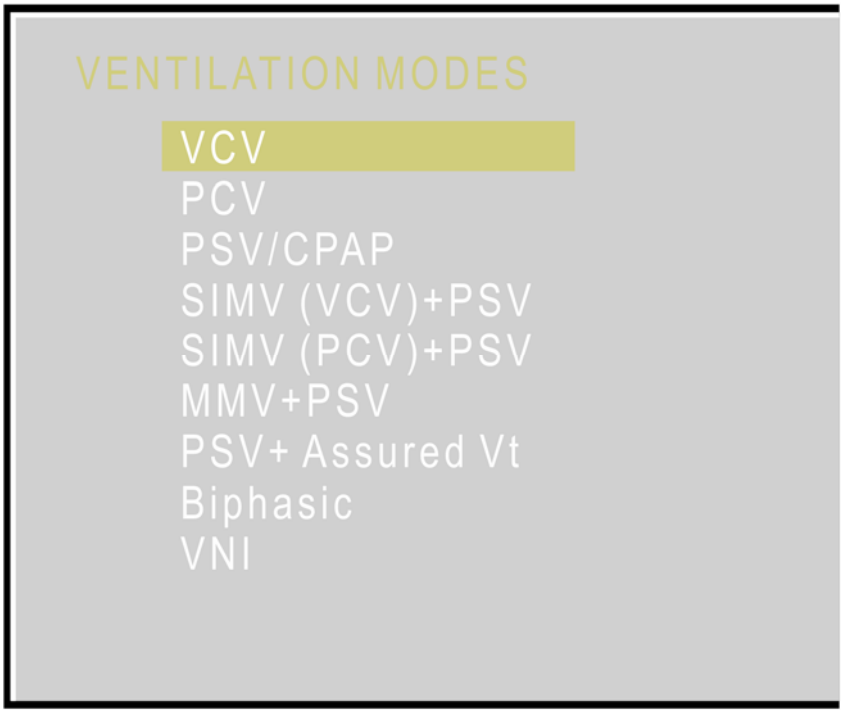
The vertical and horizontal selection keys allow selecting the desired mode.

When confirmed the mode by pressing ENTER, are shown on the screen all the parameters related with the selected mode.

If the ventilator are at this moment ventilating a patient through another mode, the changes are not concluded until manual inspiration key is pressed, which permits to finish the previous mode and start a new one.

Pressing RESET, all the changes are canceled and the previous mode is resumed.

Following there are brief descriptions of the ventilation modes.



VCV – VOLUME CONTROLLED VENTILATION

In VCV mode, LUFT-NEO integrates the air flow with inspiration time and delivers to patient the programmed current volume. Therefore, VCV is flow limited and volume cycled.

To perform flow changes the operator must change the current volume, flow waveform or inspiratory time according to necessity, i.e. the flow delivered by the equipment is the resultant of current volume, inspiratory time and flow waveform requested by the operator.

The resultant pressure is free and depends exclusively on physical and mechanical conditions of the respiratory system.

VCV is an assisted/controlled ventilation mode and its inspiratory cycles may be triggered by time, flow or pressure.

In this mode the following variables must be adjusted:

- FiO_2;
- Flow curve (Wave);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Tidal volume (VTidal);
- PEEP;
- Sensibility (Sens);

FIO_2

FiO_2 is related to the fraction of oxygen inspired by the patient. To modify FiO_2 just select its window with ENTER and adjust the fraction between 21 and 100%.

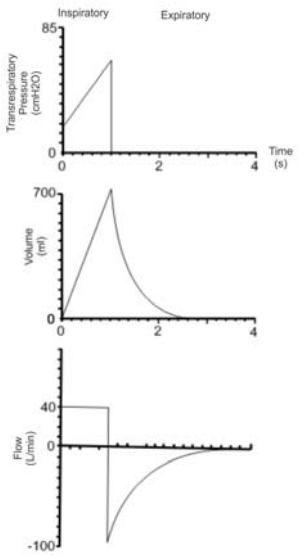
FLOW CURVES

LUFT NEO provides square and descending ramp flow waves. Flow waves may be selected in volume controlled modes.

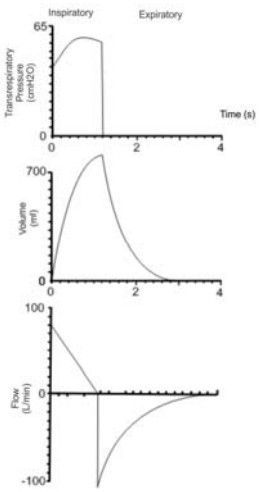
WAVEFORMS

The initial work waveform in volume modes is always square and to change it, you must access “WAVEFORM” in the bottom left corner of the screen, press ENTER, choose the requested waveform and confirm with ENTER. The waveform is changed in the first cycle. There are two common wave patterns:

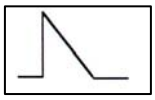
SQUARE WAVE



With this adjustment, the flow accelerates very fast and reaches a flow value which will be maintained during inspiration. This wave pattern permits an appropriate I:E ratio with a normal torrential. If the airway peak pressure of the patient is higher than the normal, the patient feels uncomfortable, the wave pattern can be inverted in order to decrease this pressure or to accommodate a more normal breathing pattern.
When the flow pattern is square, the volume has a ramp wave and the pressure is a scale followed by a ramp.

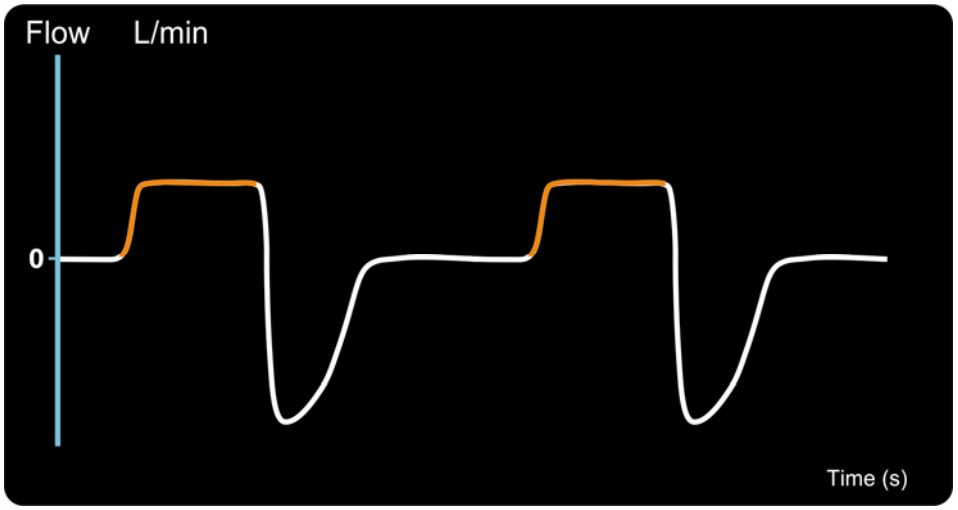


DESCENDING RAMP WAVE



This waveform uses a fast flow acceleration followed by a slow climbdown. This waveform may request very high flows to obtain an appropriate I:E ratio. This wave may be used to provide a better distribution of inspired air.

INSPIRATORY TIME



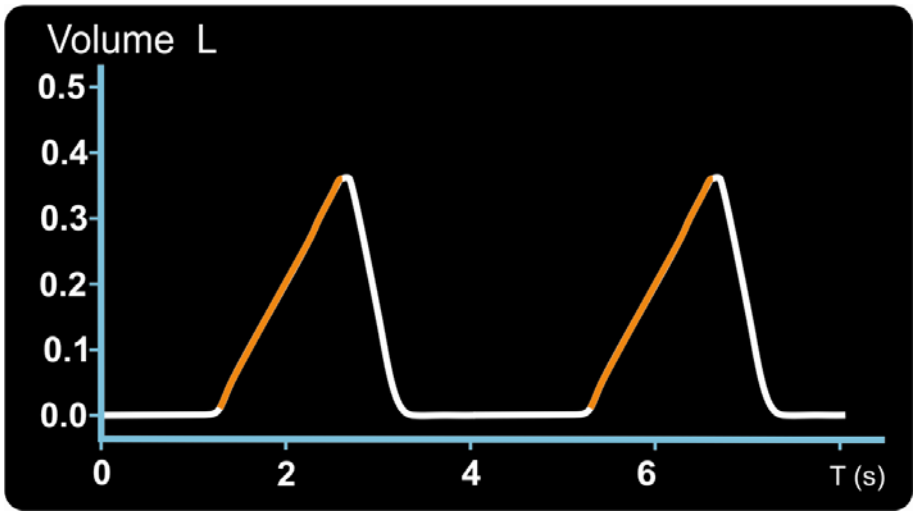
The inspiratory time correspond to the orange color on the graph above.

Integrated to current volume, the inspiratory time works as a flow controller, volume cycled, furthermore, to perform changes in the velocity of the inspiratory flow the operator must change the variables: inspiratory time and tidal volume.

RESPIRATORY FREQUENCY

Refers to ventilation cycles quantity given by LUFT-NEO to patient within the period of one minute.

TIDAL VOLUME



Tidal volume (V Tidal) represents the volume in liters delivered to patient in each ventilation cycle.

PEEP

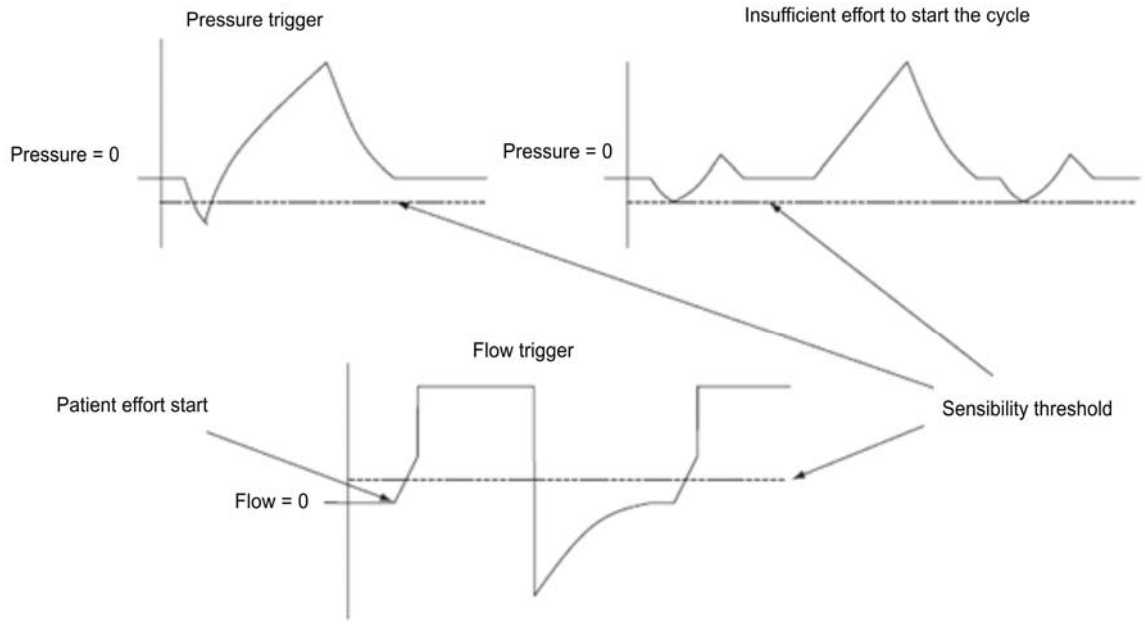
PEEP (Positive End-Expiratory Pressure) is a tool used to recruit and maintain the alveoli open, besides optimizing gases exchanges and to combat lung shunts.

	SOME PATHOLOGIES REQUIRE SPECIFIC PEEP VALUES TO RECRUIT THE ALVEOLI WITHOUT DAMAGING THEM.
	THE USE OF PEEP GENERATES HEMODYNAMIC REPERCUSSIONS THAT MUST BE KNOWN BY THE OPERATOR.

SENSIBILITY

During artificial ventilation, a pre determined trigger variable must be reached to initiate the inspiration. In VCV the ventilation may be controlled by time, i.e by respiratory frequency, or controlled by the patient himself who triggers the cycles as his necessity.

In LUFT NEO the sensibility trigger is by pressure or flow. The ventilator detects a drop in pressure or flow threshold, which is produced by the patient effort in his airway. The inspiration may be triggered if performed effort exceeds the pressure of flow threshold selected to sensibility.



The pressure or flow threshold is determined by the operator in the ventilator, which always indicates the negative pressure under PEEP or the displaced flow in the circuit necessary to trigger the ventilator. When the sensibility limit is reached the inspiratory valve is open and a new cycle starts.

To choose the numeric value of the sensibility just select its window and move the cursor on the vertical direction. When the presented is with negative signal and unit of measure cmH2O it means the sensibility is adjusted by pressure and when it is with unit of measure L/min it means it is adjusted by flow. To change this configuration just access its window and move the cursor on horizontal direction.

PCV – PRESSURE CONTROLLED VENTILATION

In PCV the LUFT NEO delivers to patient the adjusted pressure, the inspiratory flow is automatically adjusted to maintain the pressure constant during the adjusted inspiratory time. Therefore, PCV is pressure limited and time cycled.

	IN PRESSURE MODES THE FLOW WAVEFORM CAN NOT BE CHANGED, WHICH WILL BE ALWAYS DESCENDING RAMP.

The resultant volume is free and depends only on physical and mechanical conditions of the respiratory system.

PCV is an assisted/controlled ventilation mode and the inspiratory cycles may be triggered by time, flow or pressure.

In this ventilation mode the following variables must be adjusted:

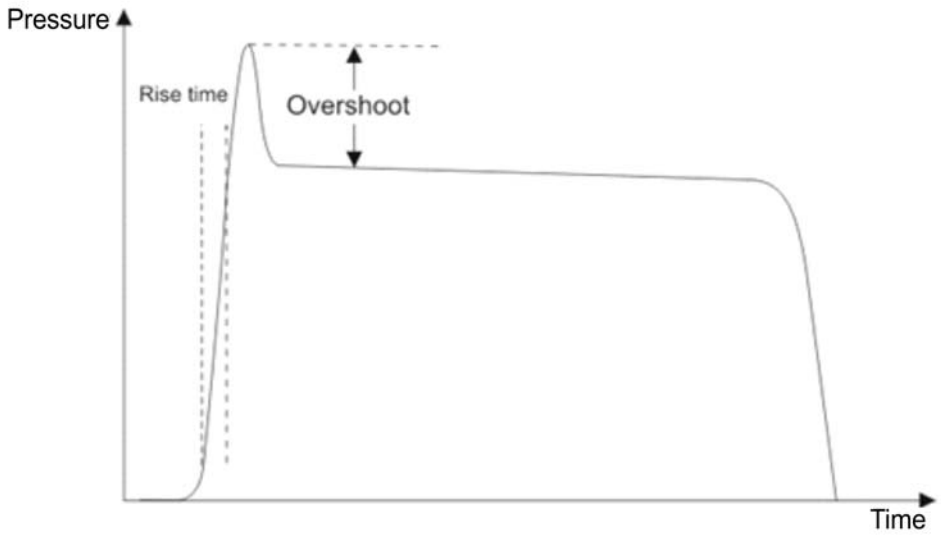
- FiO_2
- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Controlled pressure (P Con);
- PEEP;
- Sensibility (Sens).

RISE TIME

Rise Time is the time the ventilator requires reaching the selected pressure. Increase or decrease this time may assist in the comfort of the patient.

In LUFT NEO the Rise Time is modulated by flow, i.e the higher the rise time, the shorter the time to reach the adjusted pressure and the shorter the rise time, the longer the time to reach the selected pressure.

For an appropriate ventilation, the rise time must be adjusted in order to provide the smallest overshoot possible.



	IF DURING A MANDATORY OR SPONTANEOUS CYCLE THE EQUIPMENT DETECTS ANY VARIATION OF FLOW GENERATING A PRESSURE VALUE HIGHER THAN THE DETERMINED THE ALARM OF INTERRUPTED CYCLE IS ACTIVATED AND LIMITS THE PEAK PRESSURE VALUE. THE CAUSE OF THIS ALARM MAY BE CORRECTED THROUGH SENSIBILITY OR RISE TIME ADJUSTMENT.

CONTROLLED PRESSURE

In PCV, the airway pressure level is the main parameter to be adjusted, because it will have a direct influence over the tidal volume available for the patient.

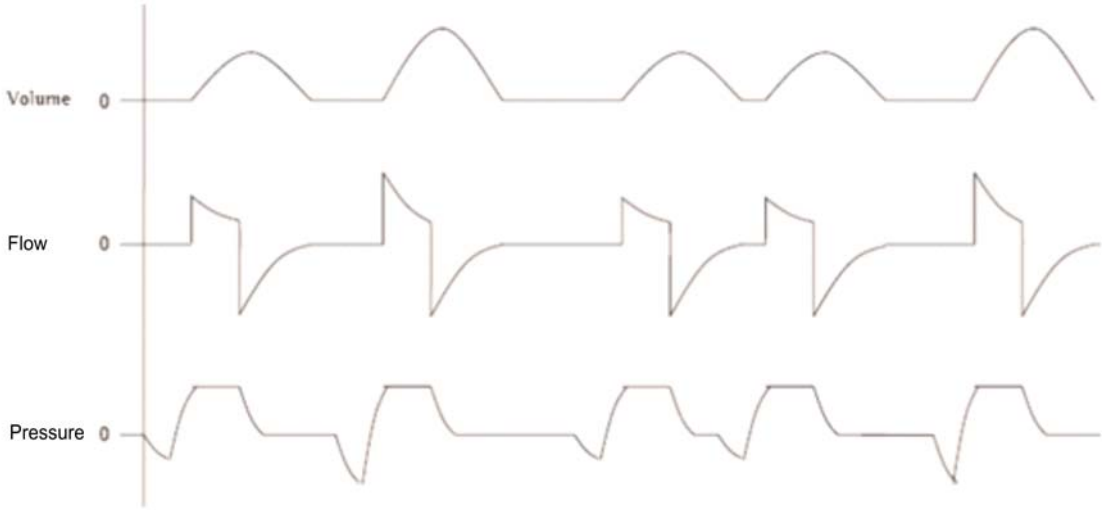
To adjust the controlled pressure you must remind that “P.Con” adjustment refers to pressure value over established value for PEEP.

PSV/CPAP – PRESSURE SUPPORT VENTILATION OR CONTINUOUS POSITIVE PRESSURE

Spontaneous ventilation mode triggered by flow or pressure through patient effort. In this mode the ventilator supports the patient through maintaining a positive pressure adjusted in “P Sup” window. This maintains free to patient to control the respiratory frequency, inspiratory time and inspired air volume. Therefore, the tidal volume depends on inspiratory effort, pre established support pressure and the mechanics of the respiratory system.

To perform this function, the ventilator, upon starting, increases the pressure in the circuit to a defined pressure support level.

The end of the inspiration occurs when the inspiratory flow, upon reduction, reaches a pre determined value called expiratory sensibility. Expiratory sensibility is adjusted in MENU “Expiratory Sensibility”, and its variation may be adjusted with values between 5 and 80% of the inspiratory peak flow.



The control variable in this mode is P Sup (support pressure). The volume variation depends on physical conditions and it will be proportional to inspiratory effort of the patient and the adjusted support pressure.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Maximum inspiratory time (TI max);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens);

MAXIMUM INSPIRATORY TIME

As safety procedure, LUFT NEO goes to expiratory phase if the maximum inspiratory time is reached.

SUPPORT PRESSURE

In PSV, airway pressure level is the main parameter to be adjusted, because it will have direct influence about the tidal volume received by the patient.

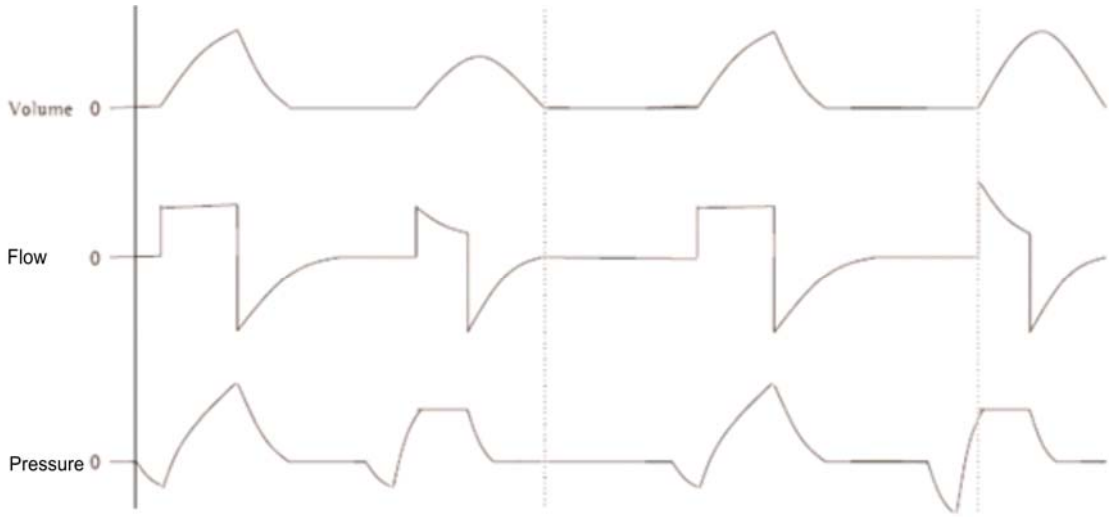
To adjust support pressure you must remind that the adjust “P Sup” refers to support pressure value over the established for PEEP.

	CPAP MODE IS ACTIVATED WHEN THE SUPPORT PRESSURE OFFERED IS REDUCED AT ITS MAXIMUM.

SIMV (VCV) + PSV - SYNCHRONIZED INTERMITENT MANDATORY VENTILATION BY PRESSURE WITH PRESSURE SUPPORT

Permits the patient to synchronize spontaneous breathings (PSV) with mandatory breathings (VCV), ensuring to patient a minimum threshold of ventilation and oxygenation. This is an alternative to start mechanical ventilation weaning process.

This mode has the function of decreasing the quantity of mandatory ventilations and permits the patient to perform spontaneous ventilations between each pre established VCV cycle.



In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Tidal volume (VTidal);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens).

SIMV (PCV) + PSV - SYNCHRONIZED INTERMITENT MANDATORY VENTILATION BY PRESSURE WITH PRESSURE SUPPORT

Permits the patient to synchronize spontaneous breathings (PSV) with mandatory breathings (PCV), ensuring to patient a minimum threshold of ventilation and oxygenation. This is an alternative to start mechanical ventilation weaning process.

This mode has the function of decreasing the quantity of mandatory ventilations and permits to patient to perform spontaneous ventilations between each pre established PCV cycle.

	THE PRESSURE SUPPORT CYCLE IS DIFFERENT FROM PRESSURE CONTROLLED AS IT FINISHES WHEN THE MINIMUM DEMAND FLOW OF THE PATIENT IS REACHED (ADJUSTABLE THROUGH EXPIRATORY SENSIBILITY), WHILE PRESSURE CONTROLLED CYCLE IS LIMITED BY THE ADJUSTED INSPIRATORY TIME.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Controlled pressure (P Con);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens).

MMV + PSV – MINUTE MANDATORY VENTILATION WITH PRESSURE SUPPORT

This mode works associating PSV mode with a minute volume value determined by the operator.

The ventilator evaluates periodically the minute volume delivered to patient. In case of a minute volume smaller than determined, LUFT NEO increase support pressure in order to increase the ventilation and reach the required value.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Minute volume (V Min);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens).

MINUTE VOLUME

Minute Volume refers to the volume delivered to patient within a period of one minute.

PSV + VT – PRESSURE SUPPORT VENTILATION WITH ASSURED TIDAL VOLUME

Spontaneous mode which allows the operator to select a minimum tidal volume for each ventilation cycle the patient requests.

In this mode, upon starting inspiratory cycle, the ventilator will control the pressure through flow assistance (P Sup). If upon ending of previewed inspiratory period the volume delivered to patient is smaller than the determined, the ventilator extend the delivery time maintaining the flow constant to complete the missing volume.

If the volume is bigger than expected, no volume is added in such cycle. The objective of this mode is to ensure delivered time bigger or equal to established.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Tidal volume (V Tidal);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens).

BIPHASIC - BIPHASIC PRESSURE VENTILATION

In Biphasic mode, the ventilator works in two pressure levels. In pre determined times occurs transitory relief from the high pressure to low pressure and after that, after a pre determined time, the higher pressure is reestablished. For patients who do not perform spontaneous efforts, Biphasic mode is similar to controlled pressure mode with relation TI/TE which may be or not be inverted, with the only difference of allowing the patient to trigger the spontaneous cycles in two pressure levels.

Spontaneous cycles performed by patient will be support pressure cycles with independent adjustment.

The tidal volume delivered in each cycle is free and depends on the respiratory mechanics, pressure releasing time and patient effort.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Superior time (T Spr);
- Superior pressure (P Spr);
- Inferior time (T Inf);
- Inferior pressure (P Inf);
- Support pressure (P Sup);
- Sensibility (Sens).

SUPERIOR TIME

Superior time refers to the interval of time in which the superior pressure remains constant.

SUPERIOR PRESSURE

Superior pressure refers to high pressure reached in each cycle. The superior pressure may be compared to the sum of PEEP with controlled pressure. This pressure remains constant during the selected superior time.

INFERIOR TIME

Inferior time refers to the interval of time in which the pressure remains in the level of base pressure.

INFERIOR PRESSURE

Inferior pressure is the base pressure, which remains in this level during inferior time. Inferior pressure may be compared to PEEP.

NIV – NON INVASIVE VENTILATION

NIV mode is a way to ventilate the patient without invading his airway. NIV is offered through use of adapted masks.

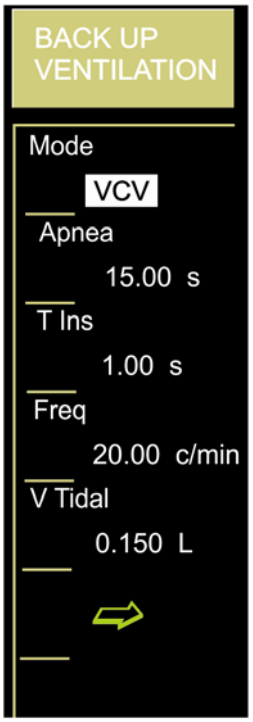
NIV is similar to PSV, with the difference that eventual leakage by mask-patient face adaptation can be compensated.

LUFT NEO in NIV allows the operator to establish the variable of inspiratory pressure limit and has the capacity to compensate leakages until 50 l/min, without generating auto-trigger.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Maximum inspiratory time (TI max);
- Suport Pressure (P Sup);
- PEEP;
- Sensibility (Sens);

	IN NIV THE SENSIBILITY IS MODULATED ONLY BY PRESSURE.



BACK UP VENTILATION

Back up ventilation is available in all ventilation modes which have a spontaneous parameter.

In LUFT NEO the back up is obligatory in modes: PSV, CPAP, MMV + PSV, PSV + Vt Assured and NIV. In modes SIMV (VCV) + PSV, SIMV (PCV) + PSV and Biphasic, back up ventilation is available and the operator can let it activated or deactivated.

At the moment that SIMV (VCV) + PSV, SIMV (PCV) + PSV or Biphasic is selected the operator can select the option YES to activate back up ventilation or NO to deactivate it.

When the selected mode is PSV, CPAP, MMV + PSV, PSV + Vt Assured or NIV the ventilator provides directly the back up ventilation configuration screen.

To set back up ventilation the following parameters must be adjusted:

- Ventilation mode;
- Apnea;
- Inspiratory time;
- Respiratory frequency;
- Tidal volume or Controlled pressure.

To initiate the operation in spontaneous mode the operator must accept all back up configuration by pressing ENTER key over the green arrow on configuration screen. In case of not accepting or pressing RESET the ventilator resumes to its previous mode.

Back up ventilation output is automatic if the patient retakes spontaneous breathing, or manual if the operator select any assisted/controlled ventilation mode.

VENTILATION MODE

Refers to the selected mode for cycling during back up ventilation period. VCV or PCV can be chosen.

To change back up mode you must press ENTER over the ventilation mode on back up ventilation screen and move the vertical cursor, selecting the requested mode with ENTER key.

APNEA TIME

Apnea is the period without spontaneous breathing, the maximum period of time in which the ventilator waits before triggering audio and visual alarm and starting back up ventilation.

Apnea time may be adjusted from 5 to 60 seconds.

CYCLING VARIABLES

To set back up ventilation the following variables must be adjusted: Inspiratory time, Respiratory frequency, Tidal volume (V Tidal) or Controlled pressure (P con).

	TIDAL VOLUME ADJUSTMENT WILL BE AVAILABLE SELECTING VCV MODE AND P CON WILL BE AVAILABLE WHEN SELECTING PCV MODE.

PEEP

PEEP level during back up ventilation will be the same of the programmed in spontaneous mode.

	WHEN ASSISTED MODE IS SELECTED THE CONFIGURATION OF BACK UP VENTILATION IS NEEDED, BECAUSE IF THE PATIENT DOES NOT MAKE ANY INSPIRATORY EFFORT THE EQUIPMENT WILL RESPECT THE SELECTED APNEA TIME TO DELIVER BACK UP VENTILATION ACCORDING TO THE CONFIGURATION PERFORMED.
	APNEA TIME IS NOT ACTIVE IN VCV AND PCV MODES.
	IN ALL MODES WHICH WORK WITH CONTROL PRESSURE AND SUPPORT PRESSURE, THE CHANGES ARE DONE INDEPENDENTLY AND DIRECTLY BY THE OPERATOR.
	IN ALL VENTILATION MODES OF LUFT NEO (PEDIATRIC - NEONATAL) THERE IS A DEFAULT CONFIGURATION. DEFAULT CONFIGURATION IS NONSPECIFIC AND IT MUST BE ADJUSTED BY THE OPERATOR ACCORDING TO THE PATIENT NEEDS.
	LUFT NEO NEVER STOPS WORKING DURING CHANGING FROM A VENTILATION MODE TO ANOTHER ONE.
	IN CASE TO CANCEL VENTILATION MODE CHANGE, YOU MUST PRESS RESET KEY.

CHAPTER 8 – VENTILATION MODES – NEONATALOGY

VENTILATION MODE SELECTION

Pressing MENU key, main menu is accessed. The first option is for ventilation modes.

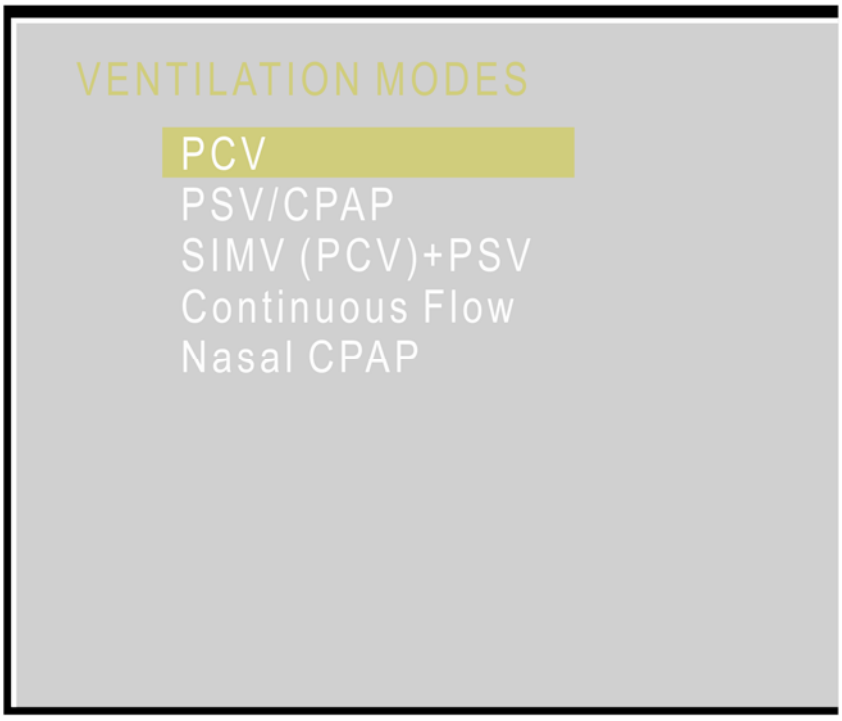
Pressing ENTER key, is shown a list of all the modes available for the select category.

The vertical and horizontal selection keys allow selecting the requested command.
When confirmed with ENTER key, all the related parameters with the selected mode are shown.

If the ventilator is operating while the operator is configuring another ventilation mode, changing will not be done until MANUAL INSPIRATION is pressed, which allows finishing previous mode and initializing the new one.

Pressing RESET, all changes are canceled and the previous mode is resumed.

Following is a brief description of the ventilation modes.



PCV – PRESSURE CONTROLLED VENTILATION

In PCV the LUFT NEO delivers to patient the adjusted pressure, the inspiratory flow is automatically adjusted to maintain the pressure constant during the adjusted inspiratory time. Therefore, PCV is pressure limited and time cycled.

	IN PRESSURE MODES THE FLOW WAVEFORM CAN NOT BE CHANGED, WHICH WILL BE ALWAYS DESCENDING RAMP.

The resultant volume is free and depends only on physical and mechanical conditions of the respiratory system.

PCV is an assisted / controlled ventilation mode and the inspiratory cycles may be triggered by time, flow or pressure.

In PCV, airway pressure level is the main parameter to be adjust, as it will have direct influence about the tidal volume available to patient.

To adjust controlled pressure you must have in mind that “P Con” refers to the pressure value above the established value for PEEP.

In this ventilation mode the following variables must be adjusted:

- FiO_2
- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Controlled pressure (P Con);
- PEEP;
- Sensibility (Sens).

Rise Time is the time the ventilator requires reaching the selected pressure. Increasing or decreasing this time may assist in the comfort of the patient.

In LUFT NEO the Rise Time is modulated by flow, i.e. the higher the rise time, the shorter the time to reach the adjusted pressure and the shorter the rise time, the longer the time to reach the selected pressure.

For an appropriate ventilation, the rise time must be adjusted in order to provide the smallest overshoot possible.

IF DURING A MANDATORY OR SPONTANEOUS CYCLE THE EQUIPMENT DETECTS ANY VARIATION OF FLOW GENERATING A PRESSURE VALUE HIGHER THAN THE DETERMINED THE ALARM OF INTERRUPTED CYCLE IS ACTIVATED AND LIMITS THE PEAK PRESSURE VALUE. THE CAUSE OF THIS ALARM MAY BE CORRECTED THROUGH SENSIBILITY OR RISE TIME ADJUSTMENT.

PSV/CPAP – PRESSURE SUPPORT VENTILATION OR CONTINUOUS POSITIVE PRESSURE

Spontaneous ventilation mode triggered by flow or pressure through patient effort. In this mode the ventilator supports the patient through maintaining a positive pressure adjusted in “P Sup” window. This maintains free to patient to control the respiratory frequency, inspiratory time and inspired air volume. Therefore, the tidal volume depends on inspiratory effort, pre established support pressure and the mechanics of the respiratory system.

To perform this function, the ventilator, upon starting, increases the pressure in the circuit to a defined pressure support level.

The control variable in this mode is P Sup (support pressure). The volume variation depends on physical conditions and it will be proportional to inspiratory effort of the patient and the adjusted support pressure.
To adjust controlled pressure you must have in mind that “P Sup” refers to the pressure value above the established value for PEEP.

As safety procedure, LUFT NEO goes to expiratory phase if the maximum inspiratory time is reached.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Maximum inspiratory time (TI max);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens);

CPAP MODE IS ACTIVATED WHEN THE SUPPORT PRESSURE OFFERED IS REDUCED AT ITS MAXIMUM.

SIMV (PCV) + PSV - SYNCHRONIZED INTERMITENT MANDATORY VENTILATION BY PRESSURE WITH PRESSURE SUPPORT

Permits the patient to synchronize spontaneous breathings (PSV) with mandatory breathings (PCV), ensuring to patient a minimum threshold of ventilation and oxygenation. This is an alternative to start mechanical ventilation weaning process.

This mode has the function of decreasing the quantity of mandatory ventilations and permits to patient to perform spontaneous ventilations between each pre established PCV cycle.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Rise Time (R. Time);
- Inspiratory time (T. Ins);
- Respiratory frequency (Freq);
- Controlled pressure (P Con);
- Support pressure (P Sup);
- PEEP;
- Sensibility (Sens).

CONTINUOUS FLOW

It is a ventilation mode with continuous flow, time cycled and pressure limited.

In this mode the mandatory cycles are provided to patient, however, between each mandatory cycle the patient can breaths spontaneously due to the presence of continuous flow.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Inspiratory time (T Ins);
- Respiratory frequency (Freq);
- Continuous flow (Flow);
- Controlled pressure (P Con);
- PEEP;
- Sensibility (Sens).

NASAL CPAP – CONTINUOUS POSITIVE PRESSURE VENTILATION

Nasal CPAP is a spontaneous ventilation mode which permits the operator to establish pressure and continuous and constant flow in the breathing circuit.

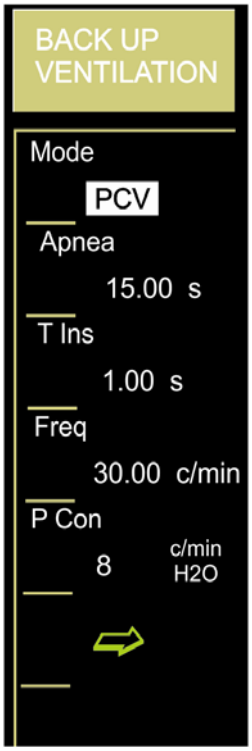
This mode is applied in Neonatology and may be offered to patient through cannulas or nasal prongs.

In this ventilation mode the following variables must be adjusted:

- FiO_2;
- Continuous flow (Flow);
- PEEP;

BACK UP VENTILATION

Back up ventilation is available in all ventilation modes which have a spontaneous parameter.
In LUFT NEO the back up is obligatory in PSV/CPAP mode. When the selected mode is PSV/CPAP the ventilator provides directly the back up ventilation configuration screen.



In SIMV (PCV) + PSV back up ventilation is available and the operator can let it activated or deactivated. At the moment that SIMV (PCV) + PSV is selected the operator can select the option YES to activate back up ventilation or NO to deactivate it.

To set back up ventilation the following parameters must be adjusted:

- Apnea;
- Inspiratory time;
- Respiratory frequency;
- Controlled pressure.

To initiate the operation in spontaneous mode the operator must accept all back up configuration by pressing ENTER key over the green arrow on configuration screen. In case of not accepting or pressing RESET the ventilator resumes to its previous mode.

Back up ventilation output is automatic if the patient retakes spontaneous breathing or manual if the operator selects any assisted / controlled ventilation mode.

APNEA TIME

Apnea is the period without spontaneous breathing, the maximum period of time in which the ventilator waits before triggering audio and visual alarm and starting back up ventilation.

Apnea time may be adjusted from 5 to 60 seconds.

CYCLING VARIABLES

To set back up ventilation the following variables must be adjusted: Inspiratory time, Respiratory frequency and Controlled pressure (P con).

PEEP

PEEP level during back up ventilation will be the same of the programmed in spontaneous mode.

	WHEN PSV/CPAP IS SELECTED THE CONFIGURATION OF BACK UP VENTILATION IS NEEDED, BECAUSE IF THE PATIENT DO NOT MAKE ANY INSPIRATORY EFFORT THE EQUIPMENT WILL RESPECT THE SELECTED APNEA TIME TO DELIVER BACK UP VENTILATION ACCORDING TO THE CONFIGURATION PERFORMED.
	IN ALL MODES WHICH WORK WITH CONTROL PRESSURE AND SUPPORT PRESSURE, THE CHANGES ARE DONE INDEPENDENTLY AND DIRECTLY BY THE OPERATOR.
	IN ALL VENTILATION MODES OF LUFT NEO (PEDIATRICO - NEONATAL) THERE IS A DEFAULT CONFIGURATION. DEFAULT CONFIGURATION IS NOT SPECIFIC AND IT MUST BE ADJUSTED BY THE OPERATOR ACCORDING TO THE PATIENT NEEDS.
	LUFT NEO NEVER STOPS WORKING DURING CHANGING FROM A VENTILATION MODE TO ANOTHER ONE.
	IN CASE TO CANCEL VENTILATION MODE CHANGE, YOU MUST PRESS RESET KEY.
	AFTER LINE TEST, THE EQUIPMENT COMPENSATES LEAKAGES IN THE CIRCUIT UNTIL 10 L/MIN.
	THE EQUIPMENT COMPENSATES THE PATIENT CIRCUIT COMPLIANCE.

CHAPTER 9 – ALARMS

COLORS AND MEANINGS OF GRAPHIC INDICATORS

These signals were developed according to current standards in order to be immediately known by the operator. An alarm indication like Caution or Danger to patient is a criterion used by Leistung Equipamentos Ltda. and serves only as orientation, the operator must adapt them to patient needs according to his own criterion.

COLOR	MEANING
RED	Danger! An immediate action of the operator is needed.
YELLOW	Caution! An action of the operator is necessary.

ALARMS PRIORITY SEQUENCE

Alarms are triggered according to the following sequence, from the highest to the lowest:

Sequence	Alarm	Priority
15	Low gas pressure	**High Priority**
14	Low battery	
13	High inspiratory pressure	
12	Interrupted cycle	
11	Low inspiratory pressure	
10	Low FiO_2	
09	High FiO_2	
08	Apnea	
07	Minimum tidal exhaled volume	**Low Priority**
06	Maximum frequency	
05	Maximum tidal exhaled volume	
04	I:E inversion	
03	PEEP	
02	Minimum minute volume	
01	Maximum minute volume	
00	Power source	

ALARMS DESCRIPTION

HIGH INSPIRATORY PRESSURE

This alarm is activated if the airways pressure overpasses the fixed value at the maximum pressure limit control. The sound is activated and the light corresponding to high inspiratory pressure. Resolving the cause that activated the alarm, the intermittent sound is turned off after 10 seconds, but the light remains turned on continually until it is turned off manually through RESET key.

ALWAYS THERE IS A PARTIAL OR CONTINUOUS OBSTRUCTION OF THE PATIENT CIRCUIT, THIS ALARM IS ACTIVATED.

LOW INSPIRATORY PRESSURE

This alarm is activated if upon ending respiratory cycle, the pressure did not reach the fixed values at low inspiratory pressure. The sound and light are activated light corresponding to low inspiratory pressure. Resolving the cause that activated the alarm, the intermittent sound is turned off after 10 seconds, but the light remains turned on continually until it is turned off manually through RESET key. This alarm also indicates if there was an accidental disconnection or if the circuit was taken off from the patient.

MAXIMUM EXPIRED TIDAL VOLUME

It establishes a maximum expired tidal volume acceptable value. If the resultant value remains high during three cycles or for a period of time longer than 10 seconds, the alarm is activated with light and sound indicators and message on the screen.

MINIMUM EXPIRED TIDAL VOLUME

It establishes a minimum expired tidal volume acceptable value. If the resultant value remains high during three cycles or for a period of time longer than 10 seconds, the alarm is activated with light and sound indicators and message on the screen.

MAXIMUM FREQUENCY

It is activated if the resultant frequency is higher than the fixed value in alarm. When there are leakages or disconnection of the circuit, it may cause a “self cycle” that will activate the alarm.

APNEA ALARM

This alarm is activated if the time between two consecutive inspiratory efforts to start the ventilator is longer than the established period of apnea. The ventilator switches automatically the ventilation modes from backup to controlled pressure until the patient demand is restored or another ventilation mode be selected. A sound is activated and an intermittent light warning which indicates apnea. It can be silenced by the silence key. If the cause of the alarm disappears, it will be silenced automatically and the light will remain turned on in continuous form. The light can be turned off pressing RESET key.

PEEP ALARM

This alarm is activated when the PEEP value overpasses the limit established by the user. To activate this alarm, it is necessary to access MENU > PEEP ALARM and select the limit value for PEEP in H_2Ocm.

LOW GAS PRESSURE

This alarm is activated if the pressure of any one of gases inputs is less than 2 bar. This alarm is turned off automatically when restoring the input pressures. It cannot be restore manually, but can be silenced during 60 seconds pressing SILENCE key.

POWER OUTAGE

This alarm is activated if a power outage occurs while the ventilator is operating. This alarm is turned off when the power is restored. It cannot be silenced manually.

LOW BATTERY

This alarm is activated when the equipment is operating without external power and the internal battery reaches a charge of 75% of the nominal voltage (see chapter 1). This alarm is turned off automatically when the power is restored. It cannot be silenced manually. If the power is not restored, when the battery charge runs out the equipment is turned off, all the gas supply valves get closed and the anti-suffocation valve is enable, which permits the air inlet of the ambient to the patient circuit. When the power reestablished the equipment is turned on again.

MICROPROCESSOR

This alarm is activated if occurs a failure which prevent the microprocessor to maintain the control of the equipment. A light warning and a continuous sound are activated. Simultaneously, all the gas supply valves get closed and the anti-suffocation valve is enable, which permits the air inlet of the ambient to the patient circuit.

DEFAULT ALARMS SETTING		
PEDIATRICS	VCV, PCV, SIMV, CPAP+PSV, ASSURED TIDAL VOLUME+PSV, BIPHASIC PRESSURE, MMV + PSV	P max = 30 cmH_2O; P min = 05 cmH_2O; Vol max = 0.400 L; Vol min = 0.050 L; Freq. Max = 35 cpm; PEEP = 04 cmH_2O; APNEA = 15 seconds;
	NIV	P max= 30 cmH_2O; P min= 05 cmH_2O; Vol max = 0.400 L; Vol min = 0.050 L; Freq. Max = 35 cpm;
NEONATALOGY	PCV, SIMV, CPAP+PSV	P max = 20 cmH_2O; P min = 03 cmH_2O; Freq. Max = 45 cpm; PEEP = 04 cmH_2O; APNEA= 10 seconds;
	CONTINUOUS FLOW	P max = 20 cmH_2O; P min = 3 cmH_2O; Freq. Max = 45 cpm;

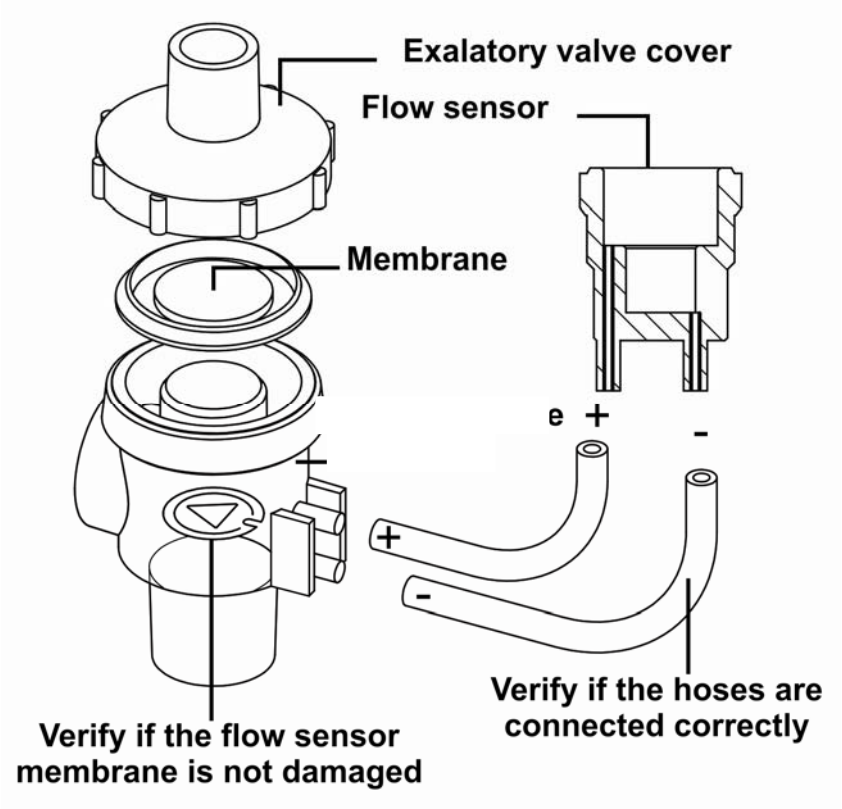
- THE DEFAULT SETTING OF ALARMS IS ADJUSTED DURING THE INITIALIZATION OF THE EQUIPMENT AND CORRESPONDS TO A MEAN VALUE OF ADJUSTMENT SCALES.
- THE PARAMETERS ADJUSTMENT MUST BE DONE BY THE OPERATOR, CONSIDERING INDIVIDUALLY EACH CLINIC CASE.

- IT IS RECOMMENDABLE TO BE VERIFIED BY THE OPERATOR **ALARMS VALUES VERIFICATION LIST**, ESPECIALLY IN EVENTUAL OPERATOR SWITCH.

ALARMS VALUES VERIFICATION LIST		
PATIENT	**OPERATION MODE**	**CHECK**
PEDIATRIC	VCV, PCV, SIMV, CPAP+PSV, ASSURED TIDAL VOLUME+PSV, BIPHASIC PRESSURE, MMV + PSV;	P max P min VT max VT min Freq. Max PEEP APNEA
	NIV	P max P min VT max VT min Freq. Max
NEONATOLOGY	PCV, SIMV, CPAP+PSV,	P max P min VT max VT min Freq. Max PEEP APNEA
	CONTINUOUS FLOW	P max P min Freq. Max

CHAPTER 10 – EXHALATION VALVE AND PATIENT CIRCUIT

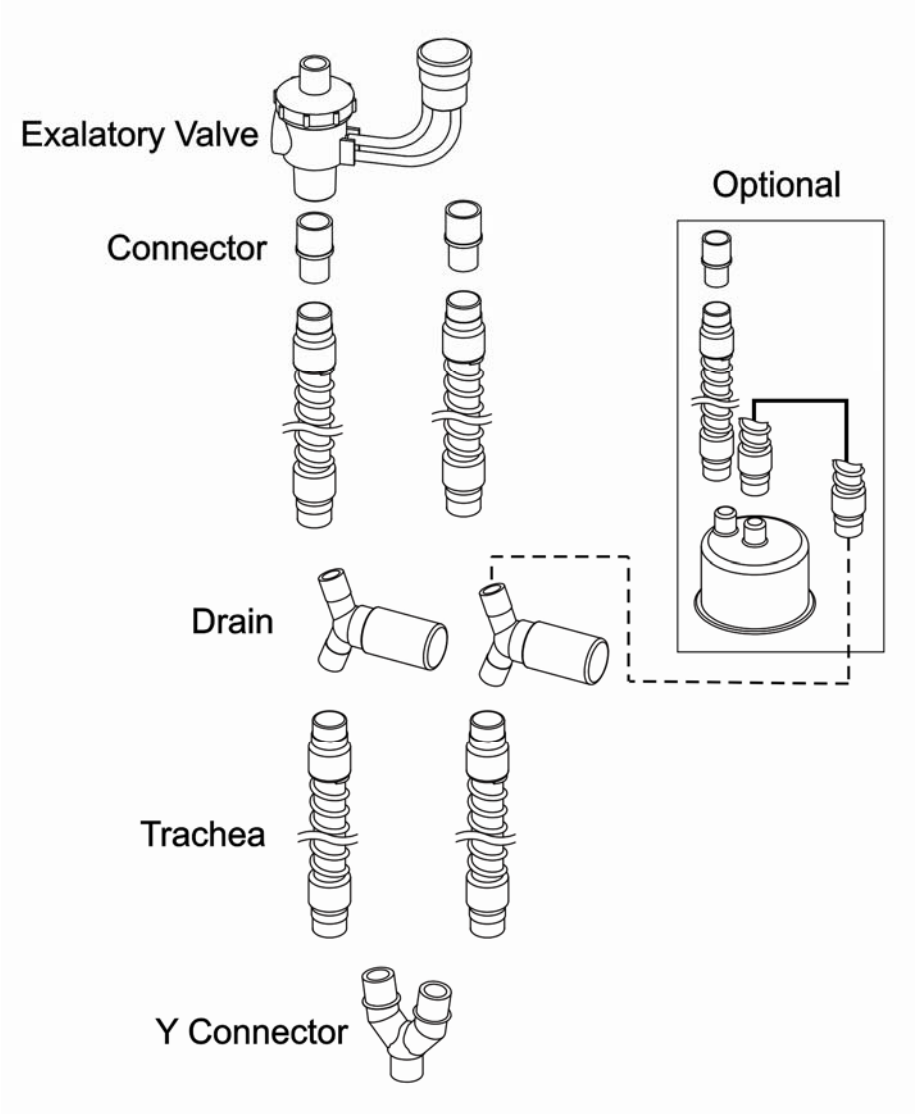
The figure below shows the exhalation valve assembly.



	UPON ASSEMBLING THE EXALATORY VALVE, PUT THE DIAPHRAGM AS INDICATED IN THE FIGURE, WITH THE SALIENCE DOWNWARD.

	THE LONGER HOSE MUST BE AT EXTERNAL SIDE OF THE EXALATORY VALVE, IN THE TERMINALS MARKED WITH PROTRUDING POINT.
	DO NOT DRY OR CLEAN THE EXALATORY VALVE WITH COMPRESSED AIR
	DO NOT INSERT IN THE BODY OF THE EXALATORY VALVE PIERCING OR CUTTING MATERIALS.

The figure below shows the patient circuit assembly.



⚠	WHEN ADDED COMPONENTS OF THE RESPIRATORY CIRCUIT OR OTHER COMPONENTS OR SUBSETS FOR THE RESPIRATORY SYSTEM, THE PRESSURE GRADIENT, MEASURED AT THE PORT OF CONNECTION OF THE PATIENT, MAY INCREASE. **UPON REMAKING THE CIRCUIT TEST, THIS GRADIENT IS AUTOMATICALLY CORRECTED BY THE EQUIPMENT.**
⚠	A BAD CLOSURE OF THE DIAPHRAGM MAY AFFECT ON THE PARAMETERS READING, GENERATING WRONG RESULTS.
⚠	THE DIAPHRAGM MUST LEAN ON THE COVER ACCOMODATION, FOR WHICH IS CONVENIENT TO FIRST PUT IT IN THE COVER AND ASSURE THAT IT IS WELL LEANED, TO THEN THREAD IT ON THE BODY.
⚠	AT THE END OF THREADING, DO NOT MAKE STRONG ADJUSTMENTS.

	VERIFY IF THE TWO PLASTIC TUBES ARE COMPLETELY WITHOUT HUMIDITY, SO IT IS POSSIBLE TO MEASURE CORRECTLY THE PRESSURE DIFFERENCE.
	WHEN STERILIZING THE VALVE, DO NOT DISCONNECT THE PLASTIC TUBES BECAUSE THEY HAVE DEFINED POSITIONS AND TO NOT DEFORM THE INTERNAL MEBRANE (TRANSPARENT) BECAUSE IT IS ENCHARGED OF ESTABLISH THE PRESSURE DIFFERENCE, WHICH THE EQUIPMENT MEASURES TO FIX THE OUTPUT PARAMETERS OF THE PATIENT, IF THE MEMBRANE IS FOLDED OR DAMAGED, THE MEASURE WILL NOT BE CORRECT.
	THE PATIENT CIRCUIT TYPE B IS MADE BY MATERIAL CERTIFIED BY FDA (FOOD AND DRUGS ADMINISTRATION) WHICH ENSURES THE BIOCOMPATIBILITY OF THIS MATERIAL. THE COPY OF THIS CERTIFICATE CAN BE ACQUIRED FROM THE MANUFACTURERFABRICANTE.

	IT MUST BE OBSERVED THAT DURING THE USE OF THE EQUIPMENT, AFTER A DETERMINED TIME THE MEASURED PARAMETERS AT INITIAL TEST OF THE PATIENT CIRCUIT AND PERIPHERALS TEND TO VARY BY TEMPERATURE, HUMIDITY, LOCATION ETC. THE VARIATIONS IN THE CIRCUIT MAY BE MORE SIGNIFICANT DURING THE FIRST HOURS OF OPERATION STABILIZING AFTER THAT.

CHAPTER 11 – CLEANING, DESINFECTION AND STERILIZATION

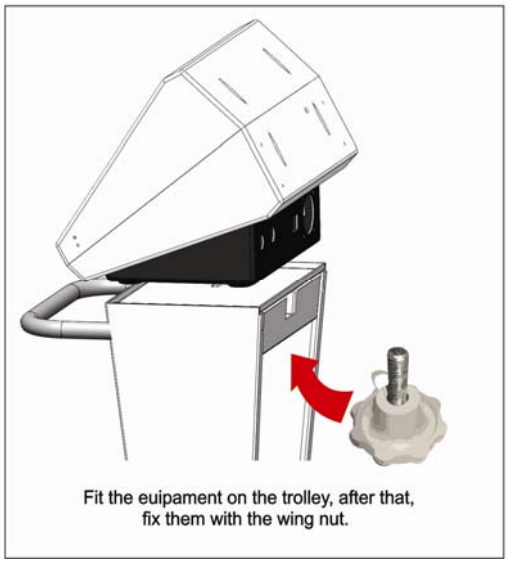
The parts in contact with the patient may be completely sterilized. The protocols which define the methods and the frequency must be adapted to the procedure of decontamination and cleaning, here indicated as a guide.
Upon removing the patient circuit of the package or always it is removed from the equipment in use, it must have its parts (exhalation valve, tracheas, drain and Y connector) cleaned and sterilized. Such methods are:

- Ethylene oxide – 55%
- Autoclave – 121°C (249,8ºF) – 15 p.s.c.g. – 15 minutes.
- Glutaraldehyde (Until two hours of disinfection. Until eight hours of sterilization).
- Peracetic acid.
- Enzymatic detergents (cleaning).

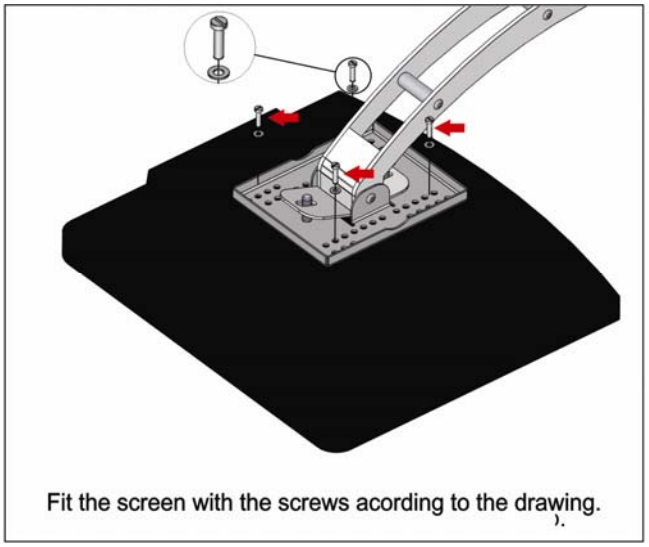
	THE STERILIZATION METHODS DESCRIBED ABOVE ARE RECOMMENDED FOR PATIENT CIRCUITS PROVIDED BY **LEISTUNG EQUIPAMENTOS LTDA.**
	THE USE OF DESINFECTANT SOLUTIONS MUST BE DONE FOLLOWING MANUFACTURER RECOMMENDATIONS AND BY STERILIZATION PROTOCOLS.
	ETHYLENE OXIDE IS TOXIC. ALL THE COMPONENTS MUST BE DRY BEFORE BEING STERILIZED.
	THE EXHALATION VALVE ACCEPTS ANY OF THE ABOVE METHODS.
	FOR ANOTHER CIRCUIT, CONSULT MANUFACTURER'S RECOMENDATIONS.
	AVOID THE USE OF PURE ALCOHOL, CLEANSING SOLUTIONS WHICH CONTAIN SOLVENTS, ACETONE, CHLORINATED SUBSTANCES OR CHLOROFORM FOR CLEANING OF THE RESPIRATORY TUBES AND PLASTIC PARTS.
	GLUTARALDEHYDE IS TOXIC FOR THE AMBIENT AND USERS, IT MUST BE MANIPULATED USING EQUIPMENTS OF INDIVIDUAL PROTECTION AND MUST BE ELIMINATED FOLLOWING THE STANDARD AND PROTOCOLS OF THE HOSPITAL.
	ETHYLENE OXIDE USE MAY ACCELERATE THE APPEARANCE OF GUM AND ITS DERIVATIVES SUCH AS MODIFY THE PLASTIC PARTS.
	THE VENTILATOR (ITS CASE) MUST NEITHER BE CLEANED WITH ETHYLENE OXIDE NOR IN AUTOCLAVE.

CHAPTER 12 – MOUNTING THE EQUIPMENT ON THE TROLLEY

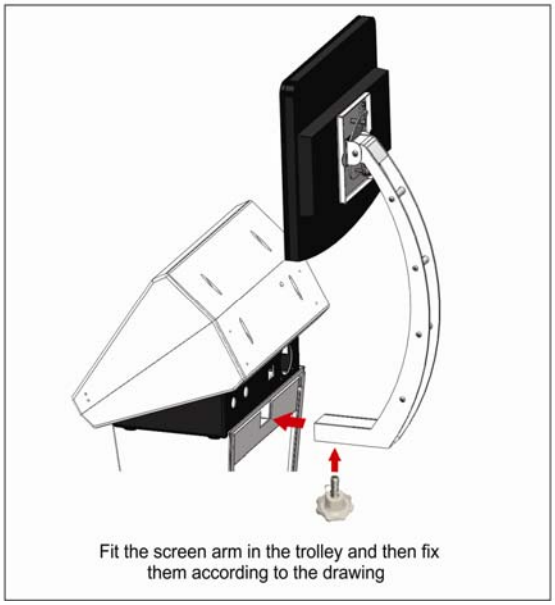
The figures sequence shows how to fix the equipment on the trolley and how to fix the display in the support arm.



Fit the euipament on the trolley, after that, fix them with the wing nut.



Fit the screen with the screws acording to the drawing.



Fit the screen arm in the trolley and then fix them according to the drawing

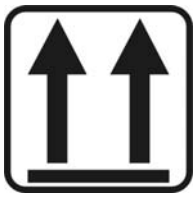
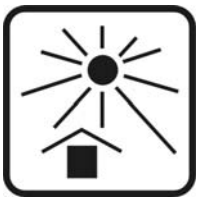
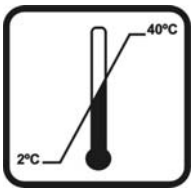
⚠	THE ASSEMBLED EQUIPMENT HAS A LIMITATION ABOUT RISK OF FALLING, MAY BE INCLINED AT A MAXIMUM OF FIVE DEGREES DURING OPERATION.
⚠	WHEN MOVING THE EQUIPMENT ON THE TROLLEY, IT IS NECESSARY TO BE CAREFULL IN ORDER TO AVOID IT TO FALL DOWN.
⚠	THE TRANSPORT OF THE EQUIPMENT MUST BE DONE IN ITS ORIGINAL PACKAGE, WITH THE TROLLEY AND THE LCD DISPLAY DISASSEMBLED.

ANNEX 1 – SIMBOLOGY

1 - Meaning of the standardized symbols, printed on the equipment, internal and external.

Symbol	Standard	Description
	IEC 60601-1:1994 Symbol No.417-5032	Alternating current
	IEC 60601-1:1994 Symbol No.417-5031	Direct current
	IEC 60601-1:1994 Symbol No.417-5017	Functional ground terminal
	IEC 60601-1:1994 Symbol No.417-5019	Protection ground terminal
	IEC 60601-1:1994 Symbol No.348	Attention! Consult the documents.
	IEC 60601-1:1994 Symbol No.417-5007	Connected (Connection to power source, internal or external)
	IEC 60601-1:1994 Symbol No.417-5008	Disconnected (Disconnection from the power source, internal or external)
	IEC 60601-1:1994 Symbol No.878-02-02	Equipment Type B
	IEC 60601-1:1994 Symbol No.878-03-01	Risk of electrical shock
	IEC 417 Symbol No.5016	Fuse
	ISO 15223:2000 Symbol No.3.3	Consult Instructions of use

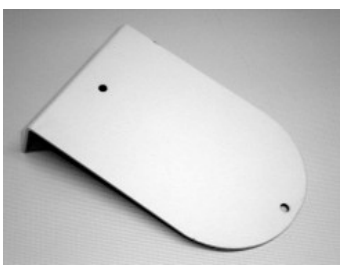
2 – Meaning of the standardized symbols, printed on the equipment package:

Symbol	Standard	Description
	ISO 780:1997 (E) No. 1	FRAGILE Handle carefully
	ISO 780:1997 (E) No. 3	THIS SIDE UP Indicates the up side of the package
	ISO 780:1997 (E) No. 4	PROTECT AGAINST SUNLIGHT The package must be kept out of direct sunlight
	ISO 780:1997 (E) No. 6	PROTECT AGAINST RAIN The package must be kept out of rain.
	ISO 780:1997 (E) No. 14	MAXIMUM STACKING UP Indicates the maximum number of packages can be stacked up for transport and storage.
	ISO 780:1997 (E) No. 17	TEMPERATURE LIMIT Indicates the limit temperature for storage and manipulation of the package.

3 – Meaning of symbols, printed in this user manual:

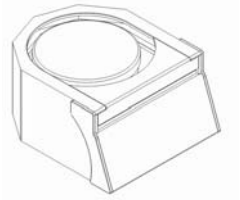
Symbol	Standard	Description
	----------	**WARNING!** Condition before which there is the possibility to cause damage to operator or others
	IEC 60601-1:1994 Symbol No.348	**ATTENTION** Condition before which there is the possibility to cause damage the equipment, its accessories or others
	----------	**NOTE** Specifies important observations which need to be considered for a correct use of the equipment
	AN 980	**MANUFACTURER**

ANNEX 2 – LUFT NEO ACCESSORIES

DESCRIPTION	FUNCTION
PATIENT CIRCUIT WITH EXHALATION VALVE  	**PATIENT-EQUIPMENT INTERFACE** **NOTE:** **1 – ONLY THE MODEL INCLUDED WITH THE EQUIPMENT MUST BE USED** **2 – THE PATIENT CIRCUIT IS MADE ACCORDING THE STANDARD ISO 5367 AND REGISTERED AT THE HEALTH MINISTRY BY THE MANUFACTURER.**
HIGH PRESSURE HOSE (AIR AND OXYGEN) 	**GAS SUPPLY**
TROLLEY 	**SUPPORT DESK FOR THE EQUIPMENT, WHITH ANTI-CORROSION TREATMENT, APPROVED IN SALT SPRAY TEST. (NBR8094/5770)**
HUMIDIFIER SUPPORT 	**SUPPORT FOR HUMIDIFIER FIXING**

ARTICULATED ARM 	**ARTICULATED SUPPORT FOR PATIENT CIRCUIT**
POWER CABLE 	**ELECTRIC POWER SUPPLY** **NOTE: IT MUST BE USED ONLY THE CABLE INCLUDED WITH THE EQUIPMENT**
LOCKNUT 	**TO FIX THE EQUIPMENT WITH THE TROLLEY**
USER MANUAL	**INFORMATION ABOUT FUNCTIONS, REQUIREMENTS AND OPERATION OF THE EQUIPMENT.**
TEST RESISTANCE 	**SIMULATES RESISTANCE TO VERIFY THE CYCLES OF THE EQUIPMENT.**

Illustrative photos only

OPTIONAL	
TOUCHSCREEN MONITOR 	**PERMITS TO CONTROL THE EQUIPMENT BY TOUCHING DIRECTLY THE SCREEN**
HUMIDIFIER 	**HUMIDIFICATION AND HEATING OF GAS: IT MUST BE USED THE MODEL AVAILABLE AT MARKET**
PATIENT CIRCUIT WITH EXHALATION VALVE AND NEBULIZER (PEDIATRIC / NEONATAL)	**PATIENT-EQUIPMENT INTERFACE** **NOTE: IT MUST BE USED ONLY THE APPROPRIATE MODEL FOR LUFT-NEO**
TEST LUNG (PEDIATRIC) 	**VERIFICATION OF OPERATION AND CYCLING OF THE EQUIPMENT**
TEST LUNG (NEONATAL) 	**VERIFICATION OF OPERATION AND CYCLING OF THE EQUIPMENT**
LUFT NEO SOFTWARE	**SOFTWARE WHICH PERMITS THE CONNECTION OF THE EQUIPMENT WITH A COMPUTER**
O_2 CELL 	**FIO_2 ANALYSIS**
O_2 CELL CONNECTOR 	**FOR O_2 CELL CONNECTION IN PATIENT CIRCUIT**

Illustrative photos only

The utilization of accessories and cables which are not specified by LEISTUNG EQUIPMENTS LTDA. may result in electromagnetic emission increasing or immunity reduction of the equipment.

ANNEX 3 – PREVENTIVE MAINTENANCE

It is mandatory to be performed a preventive maintenance respecting the following chronogram

Maintenance	Hours of use
1st	1500
2nd	3000
3rd	5000
4th	7000
5th	9000

Such preventive maintenance must be performed by a qualified professional and respecting the corresponding protocols.

At main menu the last item of the second level indicates the operation time and the registry of maintenance.

	LUFT-NEO PERFORMS AN SELFTEST OF THE BATTERY CONDITION EVERY FIVE MINUTES, HOWEVER, IT IS RECOMMENDED TO DISCONNECT FROM THE POWER AT LEAST ONCE A MONTH. LETING THE EQUIPMENT UNDER BATTERY SUPPLY IN ORDER TO TEST ITS CONDITIONS.
	IT IS RECOMMENDED TO CHANGE THE INTERNAL BATTERY EVERY FOUR YEARS.
	THE MANUFACTURER IS NOT RESPONSIBLE FOR NORMAL OR SPECIAL DAMAGE.

ALARMS SYSTEM INTEGRITY TEST

1 – With the test balloon connected to the equipment, choose VCV, at alarm board, configure Pmax with a value lower than the peak value shown at the screen. The Maximum Pressure alarm must be triggered.

2 – Adjust the Pmax value with a value higher than the peak value shown at the screen and disconnect the test balloon. It must trigger Minimum pressure alarm.

3 – Adjust the value Fmax with a value lower than the shown one at the screen, after 10 cycles it must trigger the Maximum Frequency alarm.

4 – Adjust the minimum volume value with a value higher than shown in Tidal Volume. It must trigger the minimum VT alarm.

5 – Adjust the maximum volume value with a value higher lower than shown in tidal volume. It must trigger the maximum VT alarm.

6 – Disconnect the **Pneumotachograph** from exalatory valve. It must triggers PEEP alarm. Connect it again.

7 – Access one of spontaneous ventilation modes (PSV), after elapse apnea time, it must trigger the apnea alarm.

8 – Disconnect the air high pressure hose from the gas input. It must trigger the air/oxygen alarm. Connect the air hose and repeat this procedure for the oxygen high pressure hose to check the same alarm.

9 – Disconnect the power cable from plug. It must trigger power outage alarm.

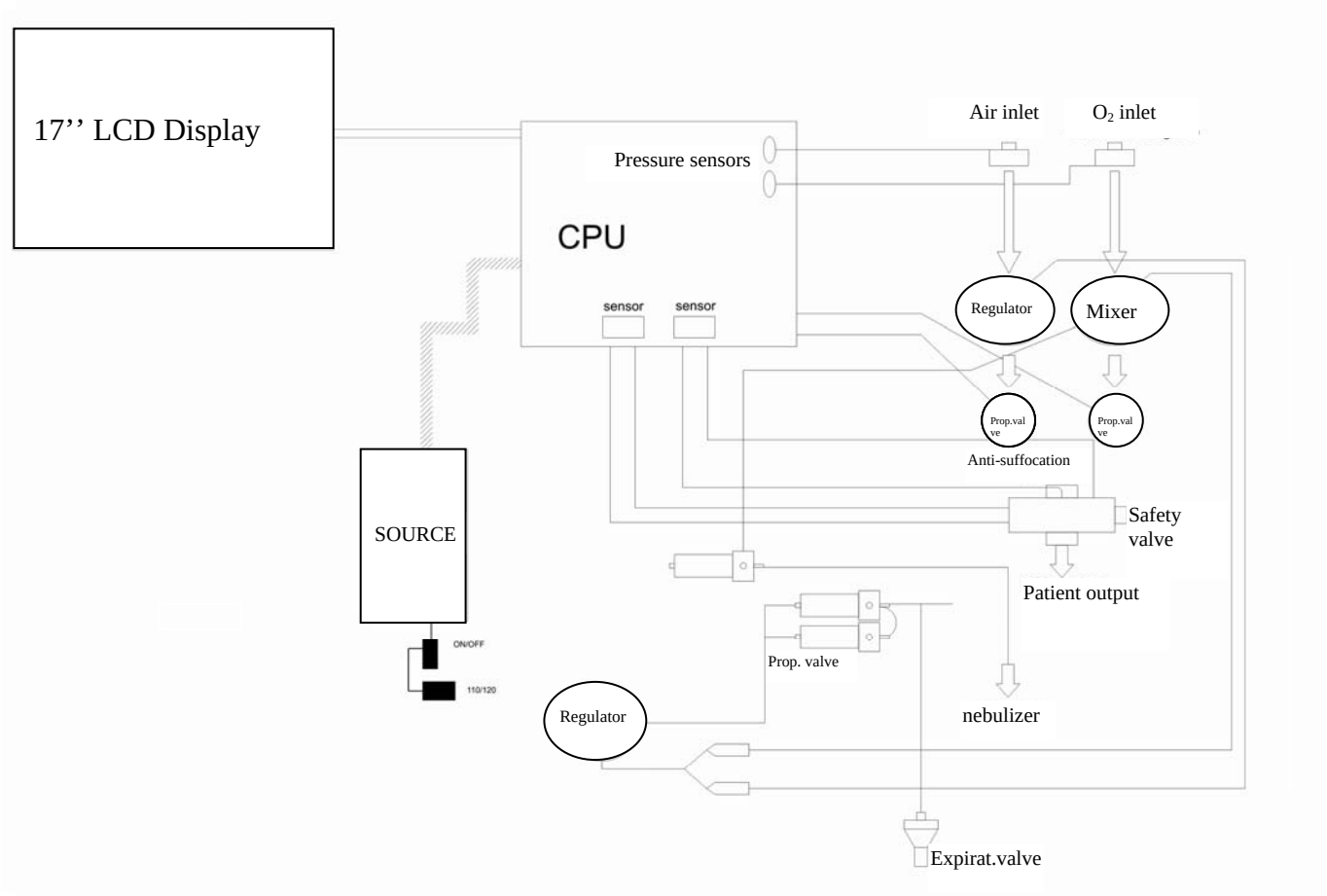
10 – Let the equipment without electric supply for approximately 75% of battery life. It must trigger battery alarm.

- EACH TEST IS INDEPENDENT, SO IT IS POSSIBLE TO CHECK THE ALARMS IN ANY ORDER.
- THE TIME BETWEEN THE PARAMETER ADJUSTMENT AND ALARM TRIGGERING MAY VARY IN EACH TEST.

- IT IS RECOMMENDED FOR THIS TEST TO BE DONE ALONG WITH PREVENTIVE MAINTENANCE, DESCRIBED AT THE BEGINNING OF THIS CHAPTER.

ANNEX 4 – BLOCK DIAGRAM

The following figure represents the pneumatic diagram of LUFT NEO



ANNEX 5 – WARRANTY

LEISTUNG brand LUFT-NEO model

Series No..... **ANVISA Registry No 80203470006**

Acquired by:.....

Purchase date:.....

Chit No.....

This equipment is guaranteed for 12 (twelve) months after purchase date, where the factory is responsible for any defect or manufacturing failure.

This warranty must be stamped and signed by LEISTUNG EQUIPAMENTOS LTDA.and accompanied of purchase chit.

The conditions for use, installation and maintenance necessary for this equipment must be followed, respecting technical specifications and installation according to user manual.

This warranty is annulled when:

a) The equipment identification label was modified or removed;

b) The installation of the equipment was not performed according to instruction manual;

c) If is discovered that the damages were caused by bad electrical installation, floating or voltage differences which the equipment works with.

d) Damages due to hit or accidents of any type after purchase.

e) If is discovered intervention of any other person but technical service of LEISTUNG EQUIPAMENTOS LTDA.

The installation of the equipment is responsibility of the buyer.

LEISTUNG EQUIPAMENTOS LTDA. is not responsible for bad installation and use of the equipment.

ANNEX 6 – GLOSSARY

ALARM: It is a light or audio signal or both ones that occurs when an unexpected event happens in the equipment.

AUTOPEEP: The lung pressure at the end of expiration.

CYCLE: The period of a mechanical supported inspiration.

COMPLIANCE: It is the relation between volume and pressure.

STATIC COMPLIANCE: It is the relation between volume and pressure at locations without gas flow.

WEANING: Gradual reduction of ventilation support.

ASSISTED EXPIRATION: It is the expiratory flow generated by negative switch at trans-respiratory pressure due to an external agent (like a respiratory pressure drop generating a value lower than the reference value).

EXPIRATORY PHASE (EXPIRATION): The part of the ventilation cycle that includes since the beginning of expiratory flow until the beginning of inspiratory flow.

INSPIRATORY PHASE (INSPIRATION): The part of the ventilation cycle that includes since the beginning of inspiratory flow until the beginning of expiratory flow. At this phase any inspiratory pause is included.

FLOW: Traffic gas rate that gets in and out of the lung.

ASSISTED INSPIRATION: It is the inspiratory flow generated by positive switch at trans-respiratory pressure due to an external agent (like an increment in respiratory pressure generating a value higher than the reference value).

NEBULIZER: An aerosol generator which requires a gas source to nebulizer liquid medicaments.

PEEP: Positive End-Expiratory Pressure.

TRANS-RESPIRATORY PRESSURE: The difference of pressure between airway and the surface of the body.

I:E RATIO: It is the relation between inspiration time and expiratory time.

SPONTANEOUS BREATHING: The breathing started and finished by the patient.

SENSIBILITY: It is the measurement of the patient effort to start a cycle.

SIGHS: It is a number of additional respirations performed during a defined time intervals.

EXPIRATORY TIME: Duration of expiratory phase, in seconds.

INSPIRATORY TIME: Duration of inspiratory phase, in seconds. As the inspiratory time increases, the mean respiratory pressure increases and the I:E ratio too.

TGI: Tracheal Gas Insufflations during expiration.

ASSISTED VENTILATION: It is the process to provide a respiration with positive pressure as reaction of an inspiratory effort of the patient.

NON INVASIVE VENTILATION: Ventilation performed through facial mask.

VOLUME: Space occupied by material measured in cubic millimeters or liters.