USER'S MANUAL

LEGENDAIR®

HOME CARE PRESSURE &

VOLUME VENTILATOR

AIROX
Parc d'Activités Pau-Pyrénées – L'Echangeur
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FRANCE

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CE 0459

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CONTENTS

GENERAL PRECAUTIONS FOR USE

⚠ It is essential to read, understand and follow these instructions before using the **LEGENDAIR®** ventilator.

The LEGENDAIR® ventilator was designed according to standards of pulmonary ventilators intended for patients at home. This ventilator is recommended for Non-Invasive Ventilation (NIV) as well as Invasive Ventilation (IV) in temporary or continual use for adult patients or for pediatrics (children over 5 kg).

For patients who are totally dependent, supplementary surveillance is recommended according to the patient's handicap, as well as a backup means of ventilation. In such case, when running the device on its internal battery, the AIROX *OPEN Pack*® external battery must be readily available.

In order to use the apparatus correctly and efficiently and in order to prevent incidents, bear the following points in mind:

- The **LEGENDAIR®** ventilator must be used only under the responsibility and on the prescription of a doctor.
- The **LEGENDAIR®** ventilator must not be used with inflammable anaesthetic substances.
- The apparatus must not be connected to anti-static tubes or conduits or electric conductors.
- The operation of the **LEGENDAIR®** ventilator may be disrupted by electro-magnetic interference. It needs to be installed and then started according to the recommendations in the installation guide. In particular the use of nearby mobile and portable communications equipment using radio frequencies such as mobile telephones or other systems exceeding the levels set in the CEI 60601-1-2 standard may affect its operation.
- The **LEGENDAIR®** must not be used near other equipment or stacked with other equipment other than those indicated in the user guide distributed by AIROX. If this type of location is necessary, the normal operation of the equipment must be verified under the final conditions of use.
- The RS232 series communications port is sensitive to electro-static discharges:. It must only be handled after the usage precautions for this type of product have been made (earth the operator with an anti-static bracelet).
- The electrical supply to which the **LEGENDAIR®** ventilator will be connected and which will provide its required power must comply with the standards in force. In the case of the use of a D.C. 24 V external power, this shall be in conformity with directive 93/42/EEC.
- All electrical cables that can be connected to the apparatus (electrical power supply, sensor signals, digital communication) shall observe recommendations on length and protection fixed in the present document.

- The use of any accessory other than those specified, with the exception of the power supplies or cables sold by AIROX when replacing internal components, may lead to an increase in electro-magnetic emissions or a decrease in the equipment's insulation against electro-magnetic emissions.
- To ensure correct performance of the **LEGENDAIR®** ventilator, the connections of the outlet towards the patient and the return to the exhalation block (if installed) must be made with tube of 1.10 m to 2.00 m length between ventilator and patient, tube must conform to standard EN 12342 and be fitted with Ø 22 mm terminals conforming to standard ISO 5356-1. Precaution must be taken to ensure that the length and the internal volume of the patient circuit are well adapted to the tidal volume: ringed tube Ø 22 mm for adults and ringed tube Ø 15 mm for pediatrics with tidal volume lower than 200 ml.
- The inspiration resistance level of circuits and accessories that may be added on (anti-bacterial filter, humidifier) must not exceed 4 mbar at 60 l/min.
- In the case where the nose or face mask is used in Non-Invasive Ventilation (NIV), this device must not have an expiration aperture (no leak).
- The piloted expiration valve must have no resistance to expiration and permit a rapid discharge of the circuit.
- For all ventilation modes using an inspiration trigger, bear in mind the possible risk of hyperventilation in the case of excessive patient trigger demand.
- In the case of oxygen supply, it must be noted that oxygen therapy for patients with respiratory failure is a well thought-out medical prescription. Too high an oxygen flow is likely to lead to serious complications such as decreased minute ventilation due to change in the peripheral and central regulation processes of ventilation, and the increase in anomalies in ventilation/perfusion ratios due to modifications of the regulation of pulmonary perfusion. Direct surveillance of the FiO_2 rate is thus recommended.
- Since the battery of the **LEGENDAIR®** ventilator contains more than 8 g equivalent lithium, it is considered by the IATA (International Air Transport Association) to be Class 9 "dangerous goods" even though the ventilator meets current safety standards. This imposes specific transport conditions. This classification varies, however, depending on the country and the airline. In addition, in the case of air transport of the **LEGENDAIR®** ventilator, whether as checked or carry-on baggage, it is recommended to check with the carrier as to which measures to take before starting your voyage.
- The **LEGENDAIR®** requires special precautions for electro-magnetic compatibility and needs to be installed then started according to the recommendations in the user's manual:

Electro-magnetic emissions

The **LEGENDAIR®** is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is being properly used in this environment.

Emission test	Conformity	Recommended electro-magnetic environment
RF emissions CISPR 11	Group 1	The **LEGENDAIR®** only uses RF energy for its internal operations. Therefore its RF emissions are very weak and cannot be assumed to interfere with nearby electronic equipment.
RF emissions CISPR 11	Class B	The **LEGENDAIR®** may be installed in any establishment including domestic establishments and those directly connected to the public networks supplying domestic buildings.
Harmonic emissions CEI 61000-3-2	Class A	
Transient emissions / Voltage fluctuation CEI 61000-3-3	Compliant	

Electro-magnetic immunity

Immunity test	Test level CEI 60601	Level of conformity	Recommended electro-magnetic environment
Electro-static discharge (ESD) CEI 61000-4-2	± 6 kV on contact ± 8 kV in the air	± 6 kV on contact ± 8 kV in the air	The floor must be wood, concrete or ceramic. If the floor is covered with a synthetic material, humidity must be at least 30%.
Transient electrical impulses in bursts CEI 61000-4-5	± 2 kV on power lines ± 1 kV on inputs / outputs	± 2 kV on power lines ± 1 kV on inputs / outputs	The quality of the power supply sector must be equivalent to a commercial or hospital environment.
Lightening CEI 61000-4-5	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	The quality of the power supply sector must equivalent to a commercial or hospital environment.
Dips, cuts and voltage variations in the electrical power supply CEI 61000-4-11 *Note: Opposite U_T is the voltage sector before applying the test level.*	< 5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	< 5% U_T (>95% dip in U_T) for 0.5 cycles 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles < 5% U_T (>95% dip in U_T) for 5 s	The quality of the power supply sector must equivalent to a commercial or hospital environment. If the **LEGENDAIR®** user requires it to continuously operate during interruptions in power supply, it is recommended that **LEGENDAIR®** is connected to a non interruptible power supply or to a battery.
Magnetic fields in the Power Supply Frequencies (50/60 Hz) CEI 61000-4-8	3 A/m	3 A/m	Magnetic fields in the Power Supply Frequencies must be at levels similar to a commercial or hospital environment.

Electro-magnetic immunity (follows)

The **LEGENDAIR®** is designed to be used in the electro-magnetic environment specified below. The equipment's customer or user must ensure that it is being properly used in this environment.

Immunity test	Test level CEI 60601	Level of conformity	Recommended electro-magnetic environment
Conducted Radio frequency	3 V rms 150 kHz to 80 MHz outside ISM [(a)] bands 10 V rms 150 kHz to 80 MHz within ISM [(a] bands	10 V 10 V	Portable RF communications equipment must not be used near the **LEGENDAIR®** or its connecting cables. The distance « d » of separation to be kept expressed in meters (m) in terms of the maximum power « P » in Watts (W) of the emitter according to the manufacturer's data and according to the frequency of the same emitter is [(b)]: **d = 0.35√P from 150 kHz to 80 MHz outside ISM bands** **d = 1.2√P from 150 kHz to 80 MHz within ISM bands** **d = 1.2√P from 80 MHz to 800 MHz** **d = 2.3√P from 800 MHz to 2.5 GHz** The power of the magnetic field emitted by a fixed RF emitter, as determined by the electro-magnetic surveillance site [(c)], must be below the level of conformity for each frequency interval. [(d)] Electro-magnetic interference may occur near to equipment with the symbol: 
Radiated Radio frequency IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	

NOTE 1: At 80 MHz and 800 MHz, the highest frequency interval is applied

NOTE 2: This guide is not applicable in every situation. The issue of electro-magnetic waves is affected by the absorption and the reflection of structures, objects and people.

[(a)] The ISM bands (Industrial, Scientific and Medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.70 MHz.

[(b)] Conformity levels in ISM frequency bands between 150 kHz and 80 MHz and between 80 MHz and 2.5 GHz are supposed to reduce the probability that mobile/portable communication equipment cause interference if they are unknowingly placed near to a patient. This is why an additional 10/3 factor is used in calculating the distance of separation for emitters with this frequency range.

[(c)] Force fields from fixed emitters, such as cordless telephone bases, mobile radios, CB radios, AM and FM radio emissions, TV emissions may not be accurately predicted in theory. In order to evaluate the electro-magnetic environment from fixed emitters, an electro-magnetic surveillance site must be considered. If the force field measured in the environment where the **LEGENDAIR®** *has to be used, exceeds the above applicable RF levels, the* **LEGENDAIR®** *must be watched to check if it is working normally. If abnormal performance is observed, extra measures have to be taken such as redirecting or moving the* **LEGENDAIR®**.

[(d)] Above the 150 kHz to 80 MHz frequency range, force fields must be less than 10 V/m.

Recommended distance between portable and mobile RF communications equipment and the LEGENDAIR®

The **LEGENDAIR®** is designed to be used in an environment where RF disturbances are controlled. The **LEGENDAIR®** customer or user may prevent electro-magnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the **LEGENDAIR®** as specified below in accordance with the maximum power of the communications equipment.

Maximum power of the emitter (W)	**Distance apart in terms of the emitter's frequency (m)**			
	150 kHz to 80 MHz outside the ISM bands $d = 0.35\sqrt{P}$	**150 kHz to 80 MHz within the ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

For checked emitters with a maximum power not listed above, the recommended separation distance « d » in meters (m) may be determined using the equation applicable to the emitter's frequency, where « P » is the maximum power of the emitter in Watts (W) according to the emitter's manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance of the highest frequency range is applied.

NOTE 2: ISM bands (Industrial, Scientific and Medical) between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz and 40.66 to 40.70 MHz.

NOTE 3: Another 10/3 factor is used in calculating the separation distance for emitters in the 150 kHz and 80 MHz ISM range as well as the frequency range between 80 MHz and 2.5 GHz in order to reduce the probability that mobile/portable communication equipment causes interference if they are unknowingly taken near the patient.

NOTE 4: This guide is not applicable in every situation. The issue of electro-magnetic waves is affected by the absorption and the reflection of structures, objects and people.

- This apparatus is relatively fragile; laying objects on it during use and storage or letting it function a long time with a direct exposure in the sun light are not recommended.
- Bearing in mind the need to protect the environment, the **LEGENDAIR®** ventilator and its constituent parts, regardless of their respective operating statuses, must not be discarded mixed into ordinary household waste, but mandatorily be subjected to appropriate selection for possible recycling in accordance with Directive 2002/96/CE governing Electrical and Electronic Equipment Waste.
- The optional exhalation block is for single use, single patient ; it must be replaced periodically and in no case be used again with a new patient.

QUALIFICATION OF PERSONNEL

AIROX cannot be held responsible for incidents caused by this apparatus unless the installation, maintenance or modifications are made by an authorised and trained person (in particular, training for the handling of products sensitive to electro-static discharges must include a section on the use of ESD protection devices and an explication of the symbol:), using original spare parts and respecting quality assurance and traceability rules approved by AIROX.

COMPLIANCE

The **LEGENDAIR®** ventilator complies with the specifications of current standards:

- NF C 74-011 / EN 60 601-1 / IEC 601-1 (1996)
  Electro-medical apparatus – General safety regulations
- IEC 60601-1-2 (2001)
  Collateral Standard: Electromagnetic compatibility – Directions and tests
- IEC 601-1-4 (1999)
  Collateral Standard: Safety regulations for programmable electronic medical systems

The compliance of the **LEGENDAIR®** ventilator to the IEC 601-1-4 standard warranties the software mastery and minimizes the risks that it could induce.

- NF S 99-211 / ISO 14971 (2003)
  Application of risk management to medical devices
- NF C 20-010 / EN 60 529 (2000)
  Degree of protection produced by envelopes (IP code)
- NF EN ISO 10651-2 (2004)
  Lung Ventilators for Medical Use - Particular Requirements for Basic Safety and Essential Performance - Part 2: Home Care Ventilators for Ventilator-Dependent Patients

  Except for art. 6.3 g) – 51.103 – 51.106 (strictly single branch version) -

The CE marking attests the apparatus' compliance with the applicable provision and essential requirements of the Medical Device Directive 93/42/EEC.

SYMBOLS USED


It is essential to read and understand the User's Manual and to comply with the instructions before using the apparatus.


BF type Apparatus (applied part)


Direct current (DC)


Alternating current (AC)


Insulation class II


Movement of cursor upwards / Incrementation of parameters


Movement of cursor downwards / Decrementation of parameters


Validations of command actions


Inhibition of alarms – Access to monitoring menu


Starting – Stop of ventilation


Air outlet towards patient


Air return from patient (double branch option)


Patient proximal pressure socket


Piloting of the expiration valve


FiO_2 sensor connection


Oxygen inlet


External alarm repeater connection


Serial link

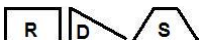
0 Switch in "Off" position

1 Switch in "On" position


Locking key


Indicator of battery presence

Pressure rise times



Flow ramps

■ ♦ Shows cursor position when not locked

\- Shows cursor position when locked

± Shows parameter setting action


Indicator of inspiratory effort detection (patient triggering)


Observe the precautions necessary when handling a device subject to the damage of electrostatic discharge


This Product must not be eliminated mixed with household waste, covered by selective collection for recycling


Single use – Single patient appliance. Not to be re-used.

COMMON ABBREVIATIONS USED

- Pressures:

IPAP : Inspiratory pressure

EPAP : Positive expiratory pressure.

Maxi P : Maximum inspiratory pressure or High pressure

Pi Mini : Minimum inspiratory pressure or Low pressure

- Volumes and Flows:

Vt : Tidal Volume delivered on each cycle

Vti : Tidal volume inspired

Vte : Tidal volume expired

Target Vt : Ventilation volume objective

- Rates:

R : Rate or Number of respiratory cycles per minute

Mini R : Rate or Number of minimum cycles per minute

Back Up R : Rate or Number of cycles to be provided in case of apnea

R SIMV : Rate or period between the SIMV volume cycles

- Time:

I/T : Ratio in % between insufflation time and the total time of one cycle

I/E : Auto-descriptive ratio of the insufflation time to the expiration time

Ti : Time or duration of insufflation

Te : Time or duration of expiration

Tt : Total time or duration of one cycle

Apnea : Apnea time or duration without patient inspiration

- Miscellaneous:

Flow Ramp : Shape of flow during inspiration.

Rise Time : Shape or duration of pressure rise at the beginning of inspiration

Trigg I : Inspiration trigger threshold – Indicates the inspiratory effort that the patient must exert to trigger a spontaneous inspiratory cycle

Trigg E : Expiration Trigger – Percentage ratio between the drop in inspiration flow and the maximal peak flow.

Sigh : Sigh volume and rate – Periodic increase of volume by modification of inspiratory time.

TECHNICAL CHARACTERISTICS

The **LEGENDAIR®** is a dual ventilator enabling ventilation with an expiration valve and can be used in a continuous way. In the case of pediatric use, make sure that the adjusted tidal volume and the patient circuit type are compatible with the needs of the child.

It enables ventilation of patients either with a nasal or face mask or on a tracheotomy canula with a circuit equipped with an expiration valve.

The ventilation modes available are:

- Pressure Support Ventilation (PSV S) or spontaneous ventilation
- Pressure Support Ventilation with Back Up Rate (PSV BUR)
- Pressure Controlled Ventilation (PCV)
- Pressure Assisted Controlled Ventilation (PACV)
- Controlled Volume (CV):
- Assisted Controlled Volume (ACV):
- Synchronous Intermittent Mandatory Ventilation (SIMV)

An additional option available in dual-pressure level modes enables ventilation with a Target tidal volume, which requires the setting of additional parameters (see paragraph on Target Volume Ventilation).

A set of surveillance systems for the patient ventilation and the ventilator itself is integrated to the apparatus. Some alarm parameters can be set by the clinician (see paragraph on Alarms and Defaults).

A software-type key prohibits access to ventilation parameter settings and ventilation mode changes in order to distinguish between "clinician" usage and "patient" usage (see paragraph on Locking key).

An oxygen supply from an external source is possible. It must be limited to 15 l/min and 50 mbar; the ventilator can do the monitoring but its regulation is independent. The extra flow created by this oxygen supply is, however, taken into account by the apparatus (see paragraph on Oxygen supply).

The ventilator can be used with a single or double branch patient circuit, associated in this case with an "exhalation block" for single use – single patient (see paragraph on Accessories and Options).

The general technical data of the apparatus are as follows:

- Insufflation Flow: from 0 to 200 L/min (or dm^3/min) in absolute(1)
  Maximum flow at 10 mbar = 190 l/min
  Maximum flow at 20 mbar = 160 l/min
  Precision of measurement: ± 10% above 15 l/min
- Tidal Volume: from 50 to 1400 ml (or cm^3) absolute(1)
  Precision of measurement: ± 20 ml up to 200 ml and ± 10% above
- Insufflation Pressure: from 5 to 55 mbar (or hPa) absolute(1)
  Precision of measurement: ± (0.8 mbar + 4% of reading)

The maximum pressure limit threshold above which the device cannot supply a flow of air (intrinsic limitation of the turbine motor) is 80 mbar instead of 60 mbar according to the article 51.103 of the norm ISO 10651-2.

ATTENTION
The insufflation pressure can be higher than the limit of 60 mbar set by the norm ISO 10651-2 only for volumetric modes when the high pressure alarm level is set above this level.

Note: The pressure data are displayed in “mbar” instead of “hPa” and “cmH2O” according to the art. 6.3.g of the norm ISO 10651-2. The conversion policy is as follows: 1 hPa = 1 mbar and 1 cmH2O = 0,980665 hPa.

- Cycling rate: from 4 to 60 bpm (or breaths/min) absolute(1)
  Precision of calculation: ± 1 bpm
- I/T cycling mode: from 25% to 50% in absolute setting
  Precision of calculation: ± 10%
- I/E cycling mode: from 1/1 to 1/3 in absolute setting
  Precision of calculation: ± 10%
- FiO_2 measurement: from 18% to 100% with COMEPA MI COM 102-1 cell (see paragraph on Accessories and options) at 1013 hPa and 25°C
  Precision of measurement: ± 3%
  Response time: < 13 s for 90% of the final value
  Stability of the precision of measurement: ± 1% past 8 h

(1) There are specific limitations for each mode – see paragraph on Parameter settings

Note: The measurement of the FiO_2 rate is influenced by pressure variations. The calibration of the FIO_2 sensor should be repeated regularly, weekly if possible, and specifically in the case of variations in altitude of ± 150 m (see paragraph on Oxygen Supply).

- Inspiratory resistance of the ventilator: 3 mbar at 60 l/min
- Exhalation resistance of the ventilator (for double branch option): 0.4 mbar at 60 l/min (without exhalation valve)
- Exhalation unit volume (for double branch option): 14 cm^3
- Level of sound pressure in accordance with standard NF EN ISO 17510-1: 30 dBA
- A/C Electrical supply:
  115/230 V ± 10% – 50/60 Hz
  Consumption: 80 VA nominal and 90 VA max.
- DC Electrical supply:
  24 V ± 1.5 V -3.3 A max
  Consumption: 80 VA nominal
- Internal battery: 25.2 V -4.4 Ah of the Lithium Ion - rapid recharge type.

The autonomy offered by the internal battery depends on the level of adjustments made, the environmental conditions (primarily in terms of temperature) as well as the physiological characteristics of the patient.

On average autonomy with a temperature of 25°C is as follows:

Ventilation parameters	Average autonomy based on maximum battery charge
Vt ≈ 200 ml IPAP ≈ 10 mbar R ≈ 20 bpm	10 h
Vt ≈ 300 ml IPAP ≈ 20 mbar R ≈ 15 bpm	8 h
Vt ≈ 500 ml IPAP ≈ 30 mbar R ≈ 15 bpm	6 h
Maximum ventilation parameters	4 h

The time taken to recharge the internal batteries is of the order of 8 hours to obtain a good level of autonomy. It is recommended to allow the apparatus to recharge for 12 h when recharging takes place during use of the apparatus (see paragraph on Battery maintenance).

Note: Recharging the internal battery may sometimes be incomplete, regardless of the charge time, if the ambient temperature is above 30°C.

- Insulation class: Class II
- Protection index of enclosure: IP 31
- Medical device class: Class II B – Type BF applied part

- Dimensions (excluding accessories): H = 154 mm, L = 235 mm, P = 315 mm
- Weight: 4.5 kg in double branch option

The following environmental conditions shall be respected:

- In storage or transport:
  Temperature: -20 to 60 °C
  Humidity: 5 to 95% RH
  Atmospheric pressure: 600 to 1100 hPa
- In use:
  Temperature: 5 to 40°C (Battery recharge exception: 30°C)
  Humidity: 10 to 95% RH
  Atmospheric pressure: 600 to 1100 hPa

Note: When the ambient temperature is above 35°C, the temperature of the air breathed out by the patient can exceed 41°C.

Note: The flow measurements and thus the volume calculations that result are influenced by atmospheric pressure variations. A calibration of the flow sensor is recommended if atmospheric pressure has changed around 100 hPa since the last calibration has been done (see § Sensor Calibration). For example, altimetry variation of 1000 m leads to a variation of flow measurement of the order of 10%.

Under extreme conditions of use beyond the recommendations above but within the limits of a temperature of 50°C or a humidity of 95% HR or an atmospheric pressure of 600 or 1100 hPa or a supply voltage of –20% compared to nominal or the combination of a temperature of 45°C and humidity of 75% HR, the ventilator does not demonstrate particular malfunction nor danger for the user. However, operating the device during hours or repeatedly under such extreme conditions could involve a premature ageing of components which will require a more frequent maintenance.

DESCRIPTION OF THE DEVICE

PRESENTATION

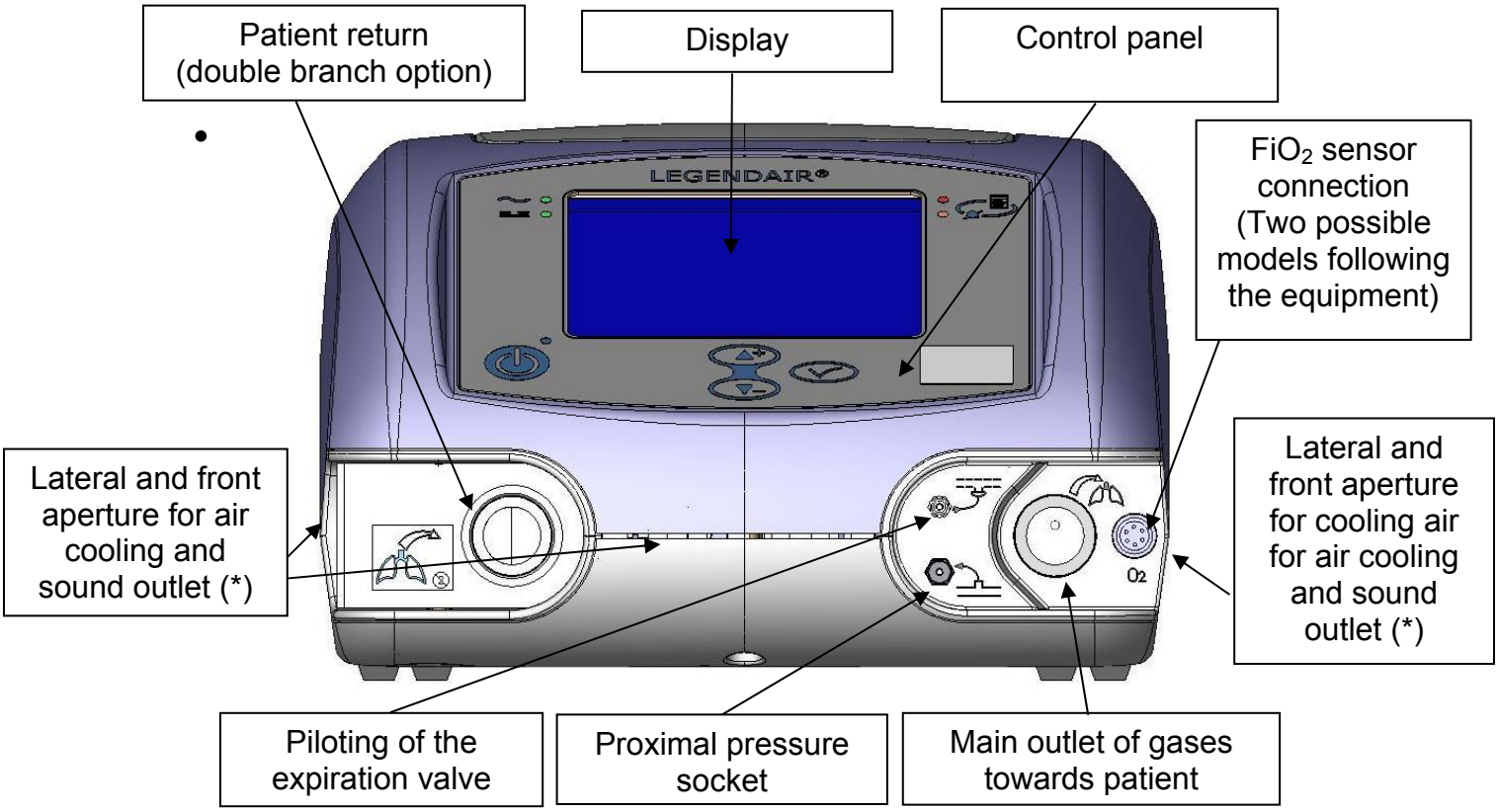
The **LEGENDAIR®** ventilator is delivered with a basic set of components, which are:

- A carrying case containing
- A mains power supply cord with a maximum length of 1.8 m
- A connector for an external oxygen source
- A single use patient circuit of 1.8 m with expiration valve and single-use proximal pressure socket
- A set of fine-particle air inlet filters
- Plus the current user's manual

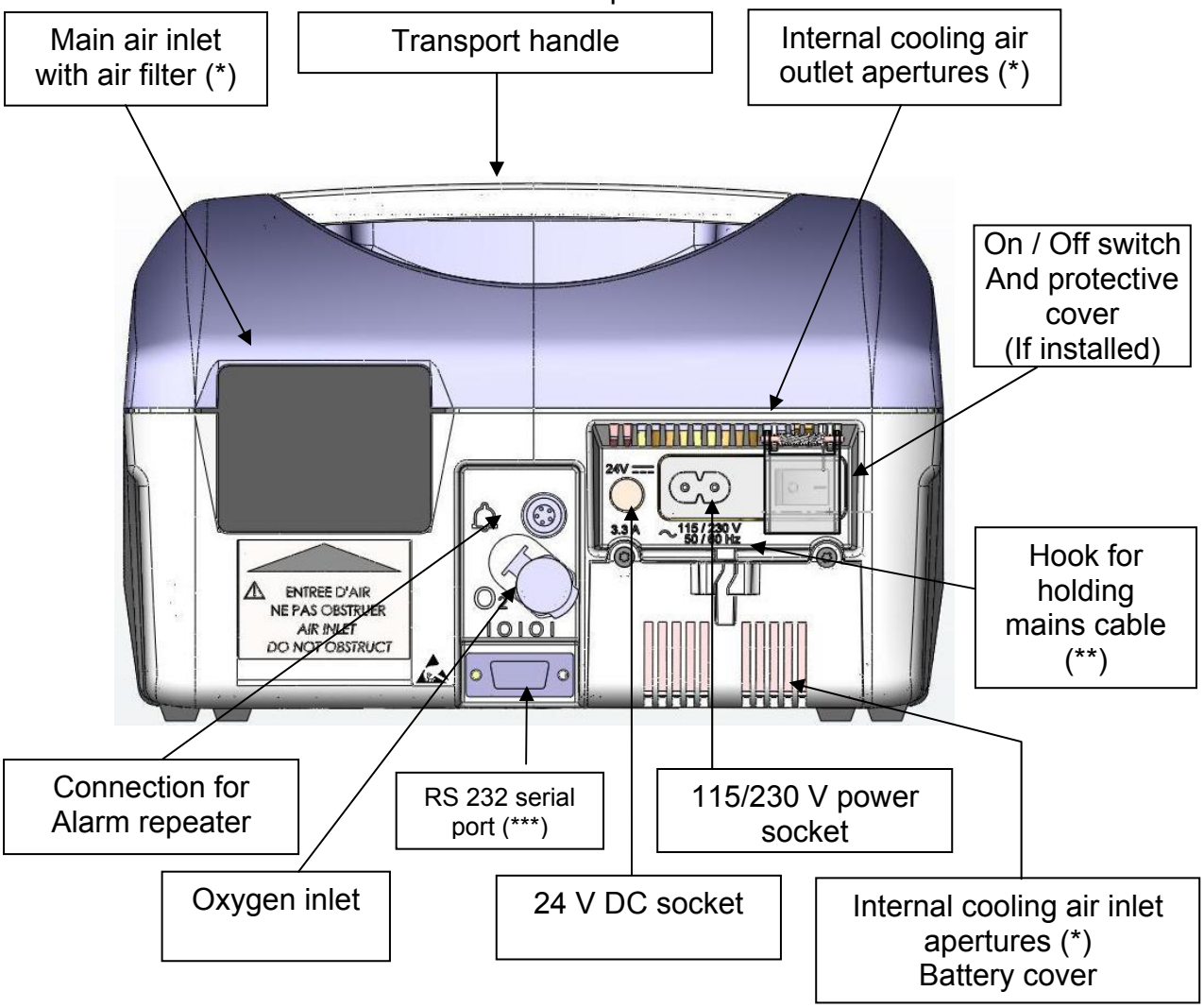
Other optional accessories are available (see paragraph on Accessories and options).

EXTERNAL INTERFACES AND FUNCTIONAL APERTURES

- Front: "Patient" interfaces and User - Machine Interface



Rear: Electrical interfaces and technical aperture



WARNING

(*) It is essential to ensure that the apparatus air inlet and outlet are never united.

WARNING

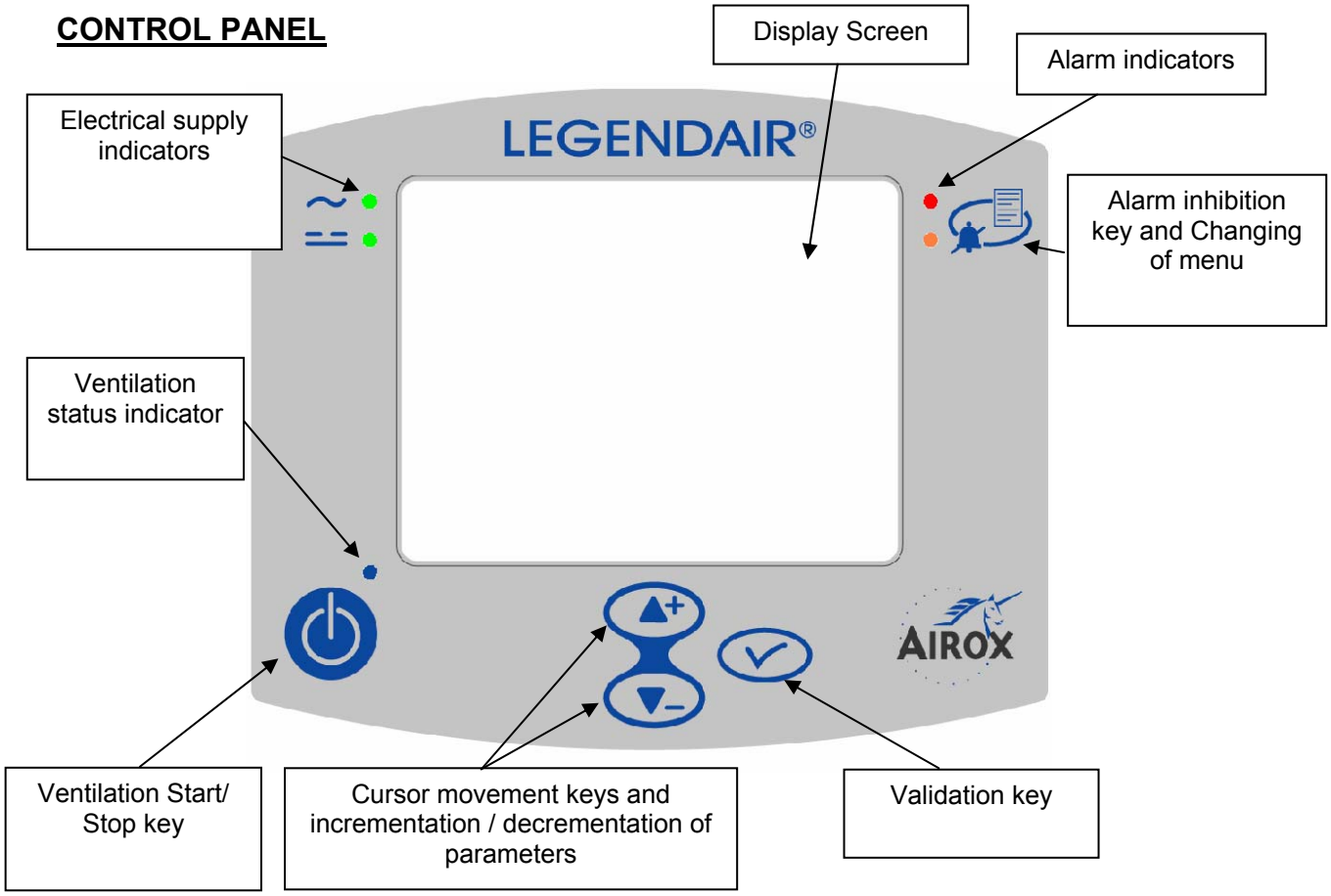
(**) For the mains power cable to be held firmly in place, it must be inserted in its holding hook built into the battery cover and located below the mains power supply socket.

To easily introduce the mains power cable into this holding system, it is necessary to present it on its section in the hook then to push it top to the bottom so that it takes by slip and natural rotation its final position.

WARNING

(***)The RS232 series communications port is sensitive to electro-static discharges and it must only be handled after the usage precautions for this type of product have been made (earth the operator with an anti-static bracelet).

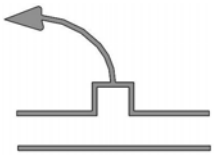
CONTROL PANEL



When the apparatus is in stand-by (not in ventilation), the display contrast can be modified by pressing the key, then by adjusting using the incrementation or decrementation keys.

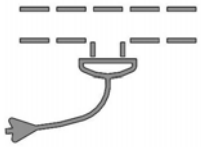
LABELS / IDENTIFICATION AND INSTRUCTION INFORMATION

Several labels or specific indications are affixed to the ventilator. They indicate the precautions to be taken for the correct use of the various elements of the apparatus and contribute to the traceability of the product.

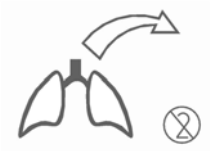


PATIENT PRESSURE CONNECTION

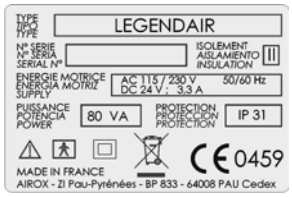
AIR OUTLET CONNECTION



EXPIRATION VALVE CONNECTION



PATIENT RETURN CONNECTION
(Double Branch Option)
Single use – single patient exhalation block



APPARATUS IDENTIFICATION LABEL

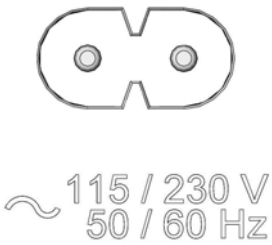
FIO_2 EXTERNAL SENSOR CONNECTION

(*): The serial number of the unit enables its date of manufacture to be identified by the letter indicating the decade (example K cover 2000 to 2009) and the final three figures, the first indicating the year within the decade and the last 2 the month in that year (example: . . . . . K . . . 409 for September 2004).

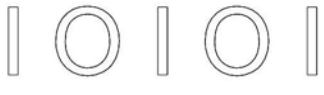
OPERATING PRINCIPLES

AIR INLET LABEL

24 V EXTERNAL POWER SUPPLY CONNECTION



MAINS POWER CONNECTION

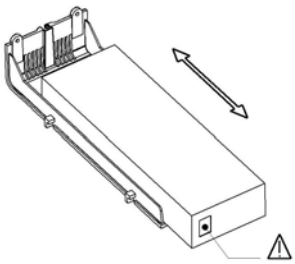


CONNECTION BY 9-PIN SERIAL PORT (RS 232)

OXYGEN INLET

EXTERNAL ALARM REPEATER CONNECTION

"PRODUCT SENSITIVE TO ELECTROSTATIC DISCHARGE" LABEL



MARKING SHOWING DIRECTION OF INSTALLATION OF THE INTERNAL BATTERY

- Functional architecture of the ventilator:

The **LEGENDAIR®** ventilator is composed on one hand of an airflow generator capable of supplying a sufficient range of flows and pressures and on the other hand of a three-way valve enabling piloting of the expiration valve. The flow generator is a low-inertia micro-turbine driven by a brushless electric motor: the valve is a proportional piezzo valve.

These two actuators are controlled according to specific piloting laws by a computer receiving information from the pressure and flow sensors built into the apparatus.

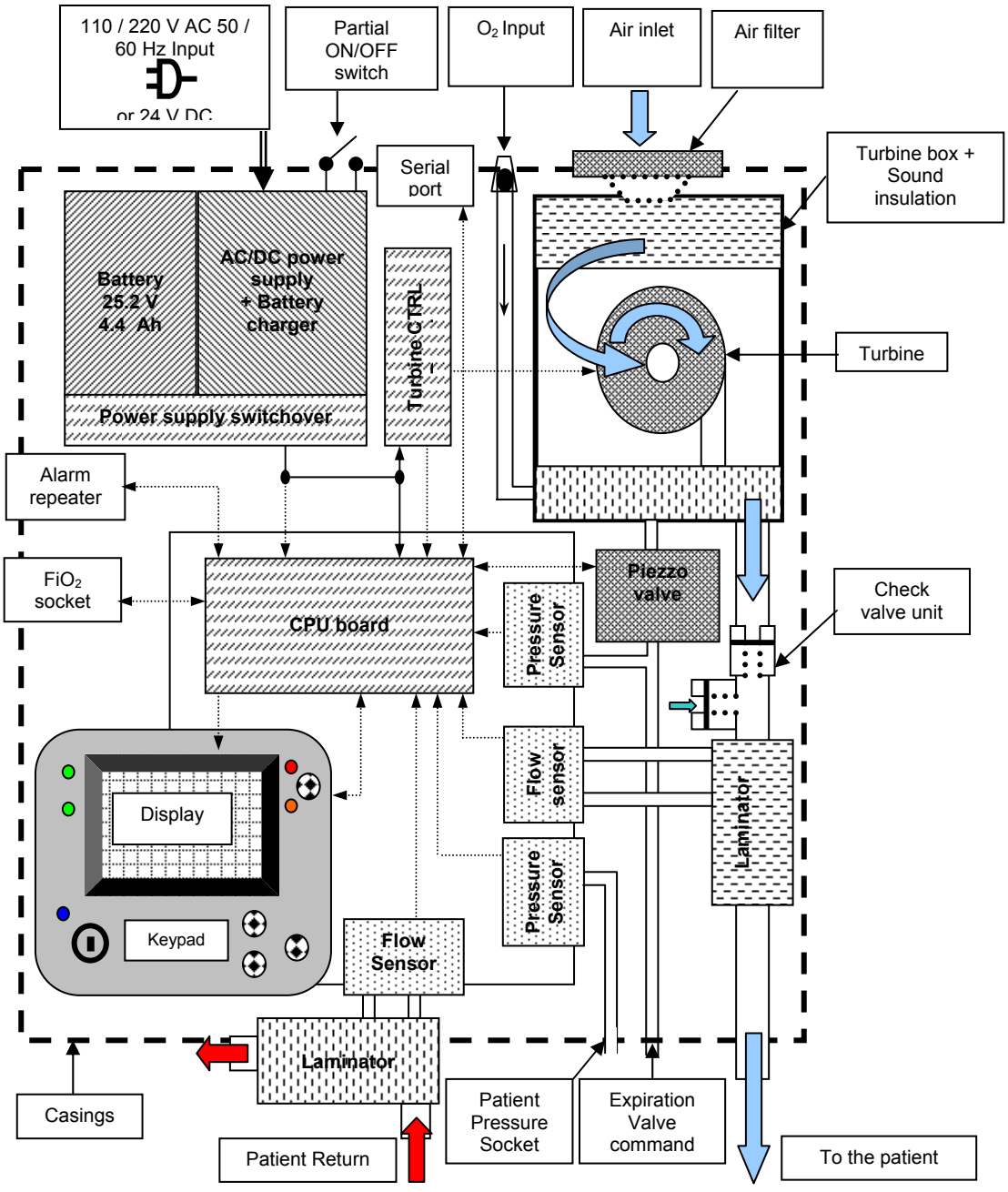
The main function units are as follows (see diagram below):

- Generator unit:
  - Turbine: 24 V / 4A – Vmax 53100 rpm – Pmax 80 mbar – Qmax 200 l/min
  - Turbine housing: Soundproofed metal-plastic box
  - Filtration of the air: Foam or combination fine-particle filter
- Power supply unit:
  - AC/DC and Charger power supply: 115-230 V at 50-60 Hz / 24-28V – 3.3 A or 24 V direct inlet – 3.3 A external
  - Battery: 25.2 V -4.4 Ah Li-Ion
  - Switching of the power supplies: between AC or DC or Battery
  - Switch: 240 VA double pole (with protective cover if installed)
- Pneumatic unit:
  - Check valve unit: check and spontaneous breathing valve.
  - Inspiration unit: laminator and outlet cone Ø22, male
  - Pressure socket and Piloting of the valve Ø 6.5 and Ø 4 pneumatic connections

- Piloting of the valve: Proportional piezzo valve
- Oxygen supply: self-blanking union
- Exhalation block (option): laminator and return cone Ø22, female

- Casing unit:
  - Top/bottom casing, Covers and Handle: in ABS
- User/machine interface unit:
  - Keypad: 5 keys and 5 displays (LEDs)
  - Display: 1/4 VGA 320 x 240 monochrome with neon
- CPU unit:
  - Piloting electronic board
  - Turbine control board.

❑ General diagram:



- Operation of the device:

The operation of the device is based on a self-adapting drive system in a closed loop of the speed of the flow generator. The speed of the flow generator (turbine) is servo-controlled to the patient pressure signal or the inspired flow signal.

The laws for piloting turbine speed are based on equations and vary according to the ventilation modes, settings and the respiratory cycle phases. Thus, fixing the pressure rise time or flow ramp has an influence on the level of turbine acceleration at the start of insufflation. The transition between the insufflation and expiration phase is itself controlled by a deceleration or braking proportional to the difference in pressure between the two phases.

The expiration valve is itself pressure-piloted during the inspiratory phase and as the main regulation part during the expiratory phase. The speed of the turbine is thus adapted to the expiratory pressure threshold during the entire expiratory phase in order to compensate for "parasite" leaks in the circuit beyond the leak regulated by the valve. This rinsing flow is as small as possible in order to limit the patient expiratory brake phenomenon without however cancelling it in order to prevent turbine overheating and expired gasses re-aspiration phenomena. A system of check and spontaneous breathing valves are used to facilitate the threshold of balance.

The measurement of the flow completes the system by enabling detection of patient inspiratory efforts and to trigger insufflation phases. The flow measurement can also be used to determine the end of the insufflation phase in certain ventilation modes. Finally, it serves to calculate the leak volumes and rates reached at each cycle, regardless of the ventilation mode in progress. This also enables the proposal of an automatic adjustment of the insufflation pressure between two determined limits in order to attain a desired volume.

The various measurement signals used in the piloting and detection are specifically filtered in order to limit risk of disturbance and malfunction.

VENTILATION PRINCIPLES

For each of the ventilation modes proposed, the process principles and the characteristic curves are as follows:

PSV S / PSV ST MODES

Two pressure levels (IPAP and EPAP) are set as well as a form of obtaining inspiration pressure on the base of pressure rise time. The insufflation time depends on the level of the expiration trigger set on the basis of a fall in flow after the maximum insufflation flow available for the patient is obtained. The insufflation time is however limited by a minimum threshold that corresponds to a pressure ramp and a maximum safety threshold that corresponds to the last elapsed inspiratory time or 3s at the most.

It is possible to set a back up rate enabling the ventilator to ventilate in the case of patient apnea. These are "controlled" cycles provided after an apnea, and not a minimum rate. The apnea time can in fact be set and enables "pauses" in the sequence of spontaneous cycles. The "controlled" cycles following a period of apnea observe the expiration trigger level and the same temporal boundaries as those of the spontaneous cycles. These controlled cycles end as soon as a new inspiration trigger is detected. Setting of a rate enables changeover from PSV S to PSV BUR.

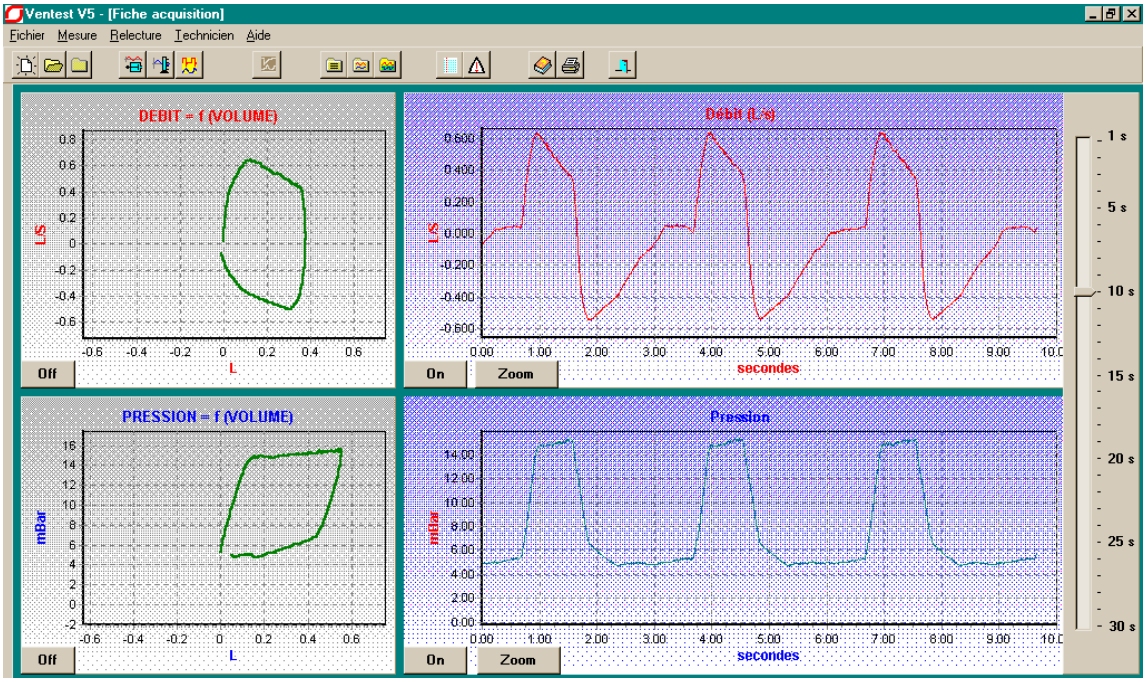
The objective of the insufflation phase is the establishment of an IPAP pressure level with a variable rise time and a hold time that depends on the behaviour of the associated flow.

The objective of the expiration phase is maintaining an EPAP pressure level until the start of the following inspiration phase but also to sufficiently "rinse" the circuit in order to evacuate the residual expired gasses.

The patient circuit is "leakproof" during the insufflation phase and the entire machine flow is distributed to the patient, less "parasite" leaks. In this case, especial care is taken to control where pressure objectives have been exceeded and, for this, the valve is pressure-piloted. If the objective is excessively exceeded, a switch is immediately made to the expiration phase.

During the expiration phase, the level of pressure is regulated by the expiration valve together with a rinsing of the gasses enabling compensation for "parasite" leaks.

Typical signals of pressure and flow of these modes have the following shape:



PCV / PACV MODES

Two pressure levels (IPAP and EPAP) are set as well as a shape of obtaining inspiration pressure on the base of pressure rise time. The insufflation time is set by a rate and a cycling ratio. This insufflation time remains fixed when the patient increases his or her inspiration rhythm in the case where an inspiration trigger threshold has been set. If there is no set or detected trigger, the ventilator continues to send cycles at the set rate. Changeover from PCV to PACV is done by adjusting the inspiration trigger.

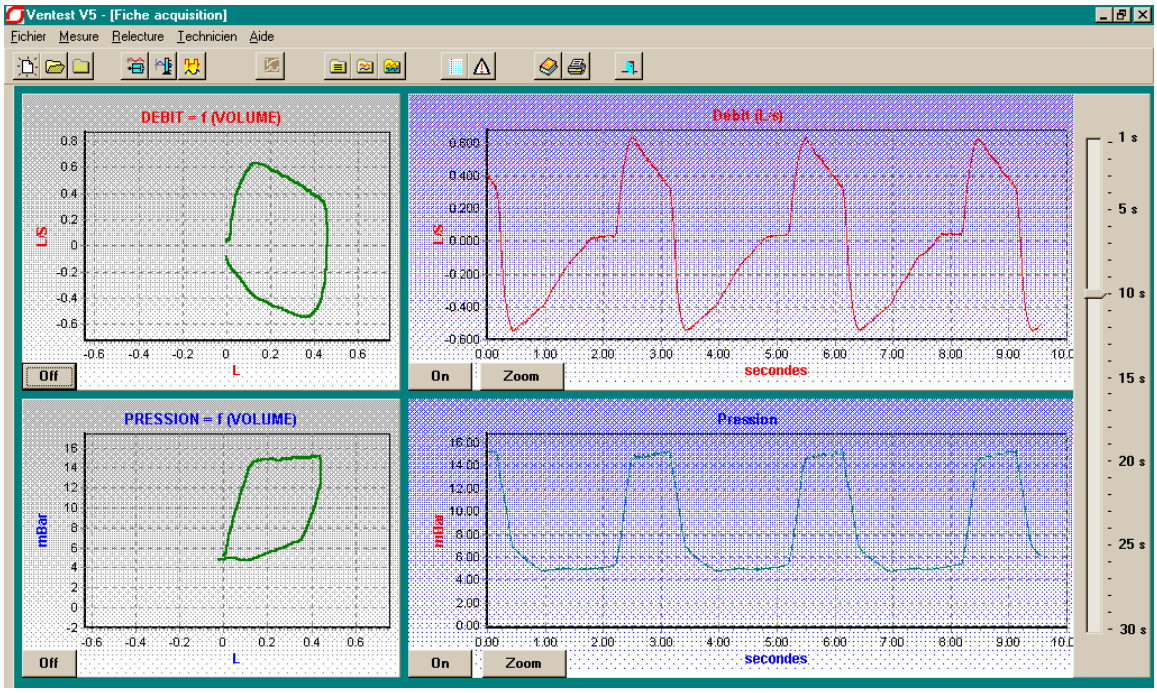
The objective of the insufflation phase is the establishment of an IPAP pressure level with a variable rise time and a hold time fixed by the rate levels and cycling ratio set.

The objective of the expiration phase is maintaining an EPAP pressure level until the start of the following inspiration phase but also to sufficiently "rinse" the circuit in order to evacuate the residual expired gasses.
The patient circuit is "leakproof" during the insufflation phase and the entire machine flow is distributed to the patient, less "parasite" leaks. In this case, especial care is

taken to control where pressure objectives have been exceeded and, for this, the valve is pressure-piloted. If the objective is excessively exceeded, a switch is immediately made to the expiration phase.

During the expiration phase, the level of pressure is regulated by the expiration valve together with a rinsing of the gasses enabling compensation for "parasite" leaks.

Typical signals of pressure and flow of these modes have the following shape:



CV / ACV MODES

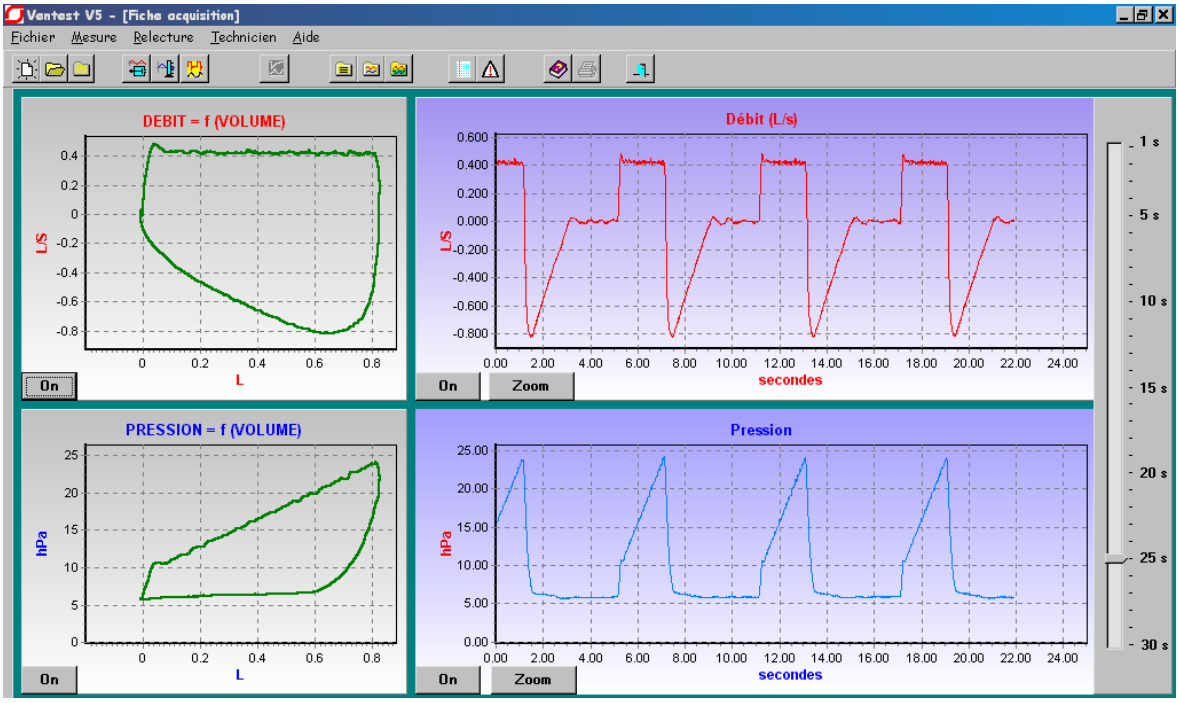
A tidal volume is set as well as a rate and a cycling ratio which will be used to define an insufflation time and thus an average insufflation flow. A flow ramp also defines the shape of the evolution of the flow during insufflation: Decelerated (Maximum flow then decreasing) or Rectangle (Constant flow) or Sinusoidal (Half sinus flow). A high pressure threshold (alarm parameter) is used to give a maximum pressure limit which is not be exceeded during the insufflation phase. The insufflation time remains fixed when the patient increases his or her inspiration rhythm in the case where an inspiration trigger threshold has been set. If there is no set or detected trigger, the ventilator continues to send cycles at the set rate. Changeover from CV to ACV is done by adjusting the inspiration trigger. An expiratory pressure level EPAP may also be set; however, it must be significantly lower than the high pressure limit authorised for the insufflation phase.

The objective of the insufflation phase is the distribution of a Vt tidal volume with a suitable flow shape and during a time fixed by the set frequency levels and cycling ratio.

Since the patient circuit is "leakproof" during the insufflation phase, the entire machine flow is distributed to the patient, less "parasite" leaks: there is a resultant rise in circuit pressure and the pulmonary system which is dependent upon patient characteristics. In this case, especial care is taken to control where maximum pressure or high pressure objectives have been exceeded; if they have been, a switch is immediately made to the expiration phase, thus interrupting the distribution of tidal volume.

The objective of the expiration phase is maintaining a pressure level EPAP until the start of the following inspiration phase but also to sufficiently "rinse" the circuit in order to evacuate the residual expired gasses as well as compensating for "parasite" leaks.

Typical signals of pressure and flow of this mode have the following shape:



SIMV MODE

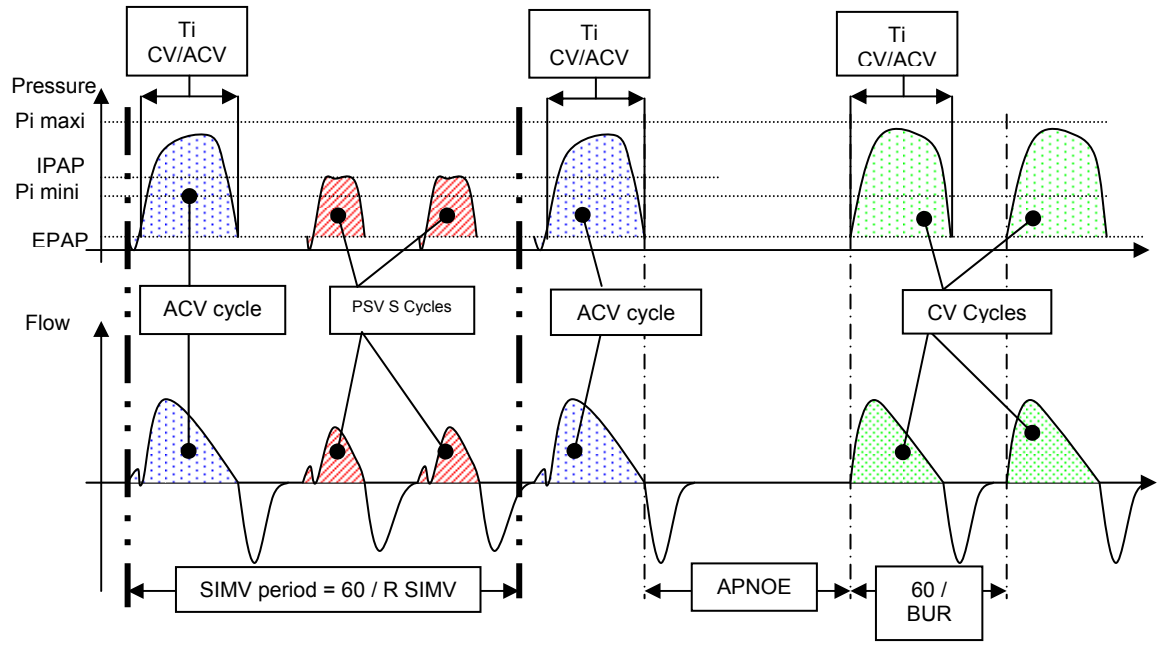
The SIMV mode is a combination of CV/ACV and PSV S modes. The alternation between them is determined by the setting of a SIMV rate or period.

A tidal volume (Vt) as well as a rate (minimum and or back up) and a cycling ratio are set for volume cycles and an insufflation pressure is set for barometric cycles. A high pressure threshold (alarm parameter) is used to give a maximum limit which is not be exceeded during the volumetric insufflation phases. An inspiratory trigger must be fixed and cannot be cancelled in this mode. A second pressure level, EPAP expiratory pressure, may be set for all barometric and volume cycles. The shape characteristics of the flow of the volume cycles, and the pressure ramp and expiration trigger of the barometric cycles, are set by default and cannot be adjusted. The insufflation time of the volume cycles thus depends upon the (back up) rate and the cycling ratio and the insufflation time of the barometric cycles depends on the expiration trigger level set. The insufflation time of the barometric cycles is, however, limited by a maximum safety threshold. The back up rate will moreover enable the ventilator to ventilate in the case of patient apnea. The "controlled" cycles following an apnea will be volume cycles. These cycles end as soon as a new inspiration trigger is detected.

Except for apnea phases, the volume and barometric cycles alternate between each other according to a SIMV fixed period or rate. All the cycles are synchronized on inspiration triggers. A SIMV period always includes a volume cycle plus as many barometric cycles as have been triggered by the patient; beyond the SIMV period the following inspiration trigger will initiate a new volume cycle and so forth.

The objectives of the insufflation and expiration phases as well as the constraints for volume and barometric cycles are alternatively and respectively the same as those described in the CV/ACV and PSV S modes above.

Typical signals of pressure and flow of this mode have the following shape:



TARGET VOLUME VENTILATION

Target tidal volume function is available only in the case of barometric modes. This method consists of continuously adjusting the level of the insufflation pressure between the "base" insufflation pressure and a maximum pressure level in order to keep the inspired tidal volume as close as possible to the Target Volume, i.e. between Target Vt and Target Vt + 20%.

Adjustments of the insufflation pressure levels is done by increasing steps between the cycles, for both pressure increase and decrease. The minimum step is 0.5 mbar and the maximum step is 2 mbar. This approach enables an immediate reaction if an unbalance is detected without a strong reaction that would be uncomfortable to the patient. Change is gradual and oscillations around the set point are limited.

Changes in insufflation pressure levels during operation of the target volume option is shown schematically as follows:

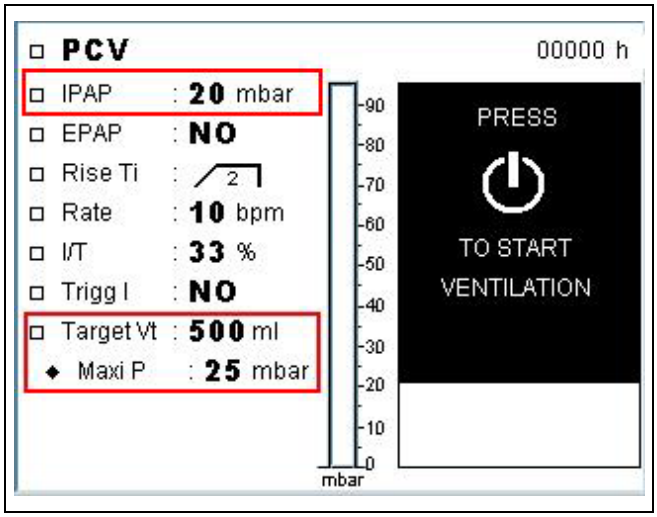
For example:

In PCV mode

IPAP = 20 mbar

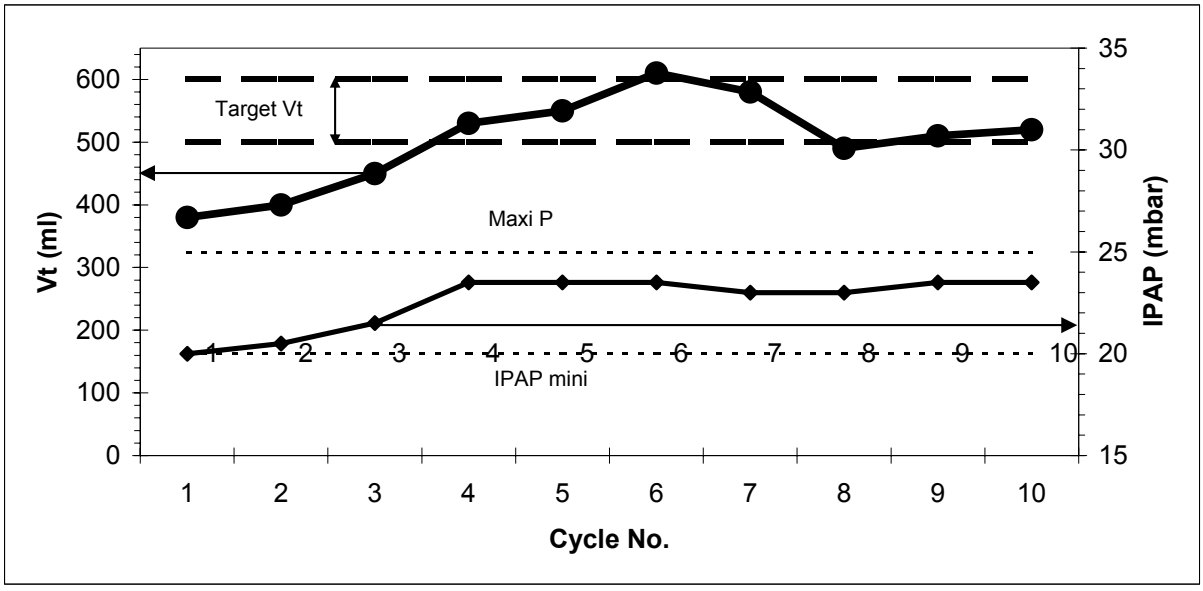
Maxi P = 25 mbar

And Target Vt = 500 ml, i.e. an objective of 500 to 600 ml (0/+20%)



During ventilation, pressure changes could be as follows:

Cycle No.	1	2	3	4	5	6	7	8	9	10
IPAP set point (mbar)	20	20 + 0.5 = 20.5	20.5 + 1 = 21.5	21.5 + 2 = 23.5	23.5	23.5	23.5 – 0.5 = 23	23	23 + 0.5 = 23.5	23.5
Measured Vti (ml)	380 ▼	400 ▼	450 ▼	530 =	550 =	610 ▲	580 =	490 ▼	510 =	520 =



Note: The implementation of this function is put on hold at start-up.

INSTALLATION

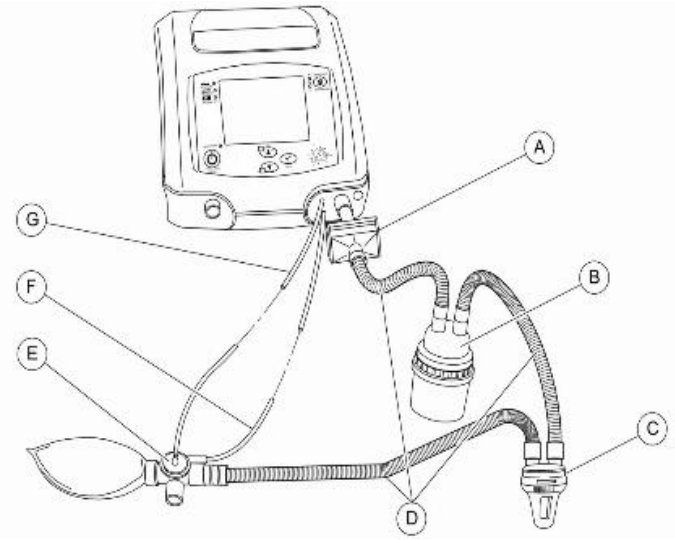
To install your **LEGENDAIR®** ventilator correctly we recommend that you proceed in the following manner:

- Choose an area where fresh air is favourable (avoid proximity of flying textile such as curtains) and without permanent and direct exposure to sun light.
- Lay the apparatus down on a flat and stable surface so that the damper stands are all in contact with the surface. However, the apparatus may also operate in all positions (being sure that the air inlet is not obstructed).
- Connect the external power supply: one of the indicators on the top left corner of the apparatus will light up (~ for 220 V mains supply and ⎓ for 24 V external direct current supply).

WARNING
For the mains power cable to be held firmly in place, it must be inserted in its holding hook built into the battery cover and located below the mains power supply socket.

- Connect the patient circuit (single-use or reusable) to the air interfaces on the front of the apparatus:

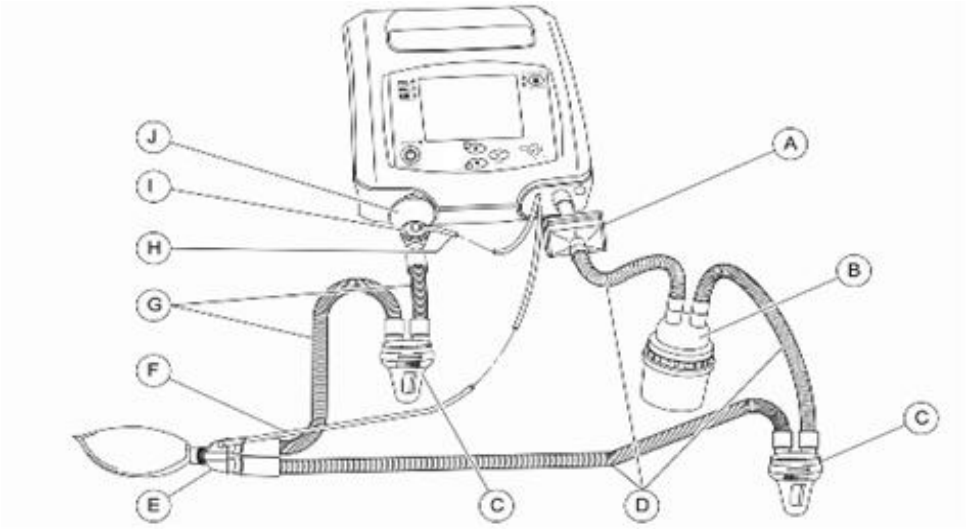
  Single-branch circuit:



1. Install the filter (A) on the Ø 22 patient outlet port.
2. Attach one end of the short circuit tubing (D) to the filter (A)
3. Attach the other end of the circuit tubing to the inlet port (B) of the humidifier.
4. Place a water trap (C) between the other port of the humidifier and the exhalation valve inlets (E).
5. The expiration valve (E) is placed at the level of the patient.
6. Connect one end of the proximal pressure tubing (F) to the proximal pressure port on the exhalation valve (E) and the other end on the ventilator patient Ø 6,5 pressure port.

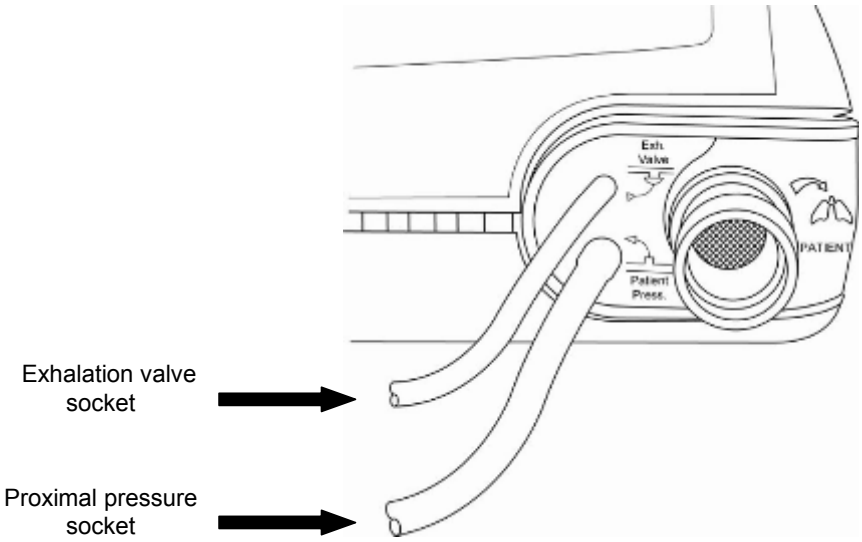
7. Connect one end of the exhalation valve tubing (G) to the exhalation valve port on the exhalation valve (E) and the other end on the ventilator Ø 4 exhalation valve port.

Double limb circuit (possible only with the exhalation block option)



1. Install the filter (A) on the Ø 22 patient outlet port.
2. Attach one end of the short circuit tubing (D) to the filter (A).
3. Attach the other end of the circuit tubing to the inlet port (B) of the humidifier.
4. Place a water trap (C) between the other port of the humidifier and the patient connection (E) on the dual limb circuit.
5. Connect one end of the proximal pressure tubing (F) as close as possible to the patient at the level of the dual limb circuit connection (E) and the other end on the ventilator Ø 6,5 patient pressure port.
6. Place a water trap on the expiratory limb of the patient circuit (G) between the dual limb circuit connection (E) and the exhalation valve (I).
7. Place the passing expiratory valve (I) (special valve on the dual limb circuit) on the end of the expiratory branch of the patient circuit (G).
8. Place the antibacterial filter (J) between the expiratory valve (I) and the Ø 22 inlet port of the ventilator exhalation block.
9. Connect one end of the exhalation valve tubing (H) to the exhalation valve port of the exhalation valve (I) and the other end on the Ø 4 ventilator exhalation valve port.

Detail of connection to the device of proximal pressure and expiratory valve sockets:



For both types of circuits above, you should connect the end of the proximal pressure tube as close as possible to the patient (at mask or canula entry if possible) so the apparatus can take into account all load losses due to the circuit and its potential accessories. If this is not the case, it is best to adapt the setting of the "DISCONNECTION" alarm triggering threshold for volume modes and to set a Vti maxi value, even if it is high, to trigger the "HIGH VTI" alarm for barometric modes. It is also possible to use the double limb configuration and to set a Vte mini value allowing therefore the triggering of the « LOW VTE» alarm whatever the mode.

Reminder: Precaution must be taken to ensure that the length and the internal volume of the patient circuit are well adapted to the tidal volume: ringed tube Ø 22 mm for adults and ringed tube Ø 15 mm for pediatrics with tidal volume lower than 200 ml, use if necessary a 22F-15M link on the outlet and a 15M-22M link on the return connector with a double branch circuit.

To use a double branch circuit, you must first install the single use - single patient exhalation block. This equipment, already mounted on the device at the factory or also deliverable as option can be installed easily or replaced, without requiring any tools. (see § Single use exhalation block).

WARNING
The exhalation block is for single use - single patient. It cannot be be disinfected nor sterilised and in no case re-used by another patient.

⚠ ***WARNING***
If a Non Invasive Ventilation (NIV) mask is used with a single branch or double branch exhalation valve circuit, it is vital that this mask has no exhalation aperture (no calibrated leakage).

WARNING
The LEGENDAIR® requires special precautions for electro-magnetic compatibility (refer to § General Precautions for use). In particular it must not be used near other equipment or stacked with other equipment other than those indicated in the user guide distributed by AIROX. **If this type of location is necessary, the normal operation of the equipment must be verified under the final conditions of use.**

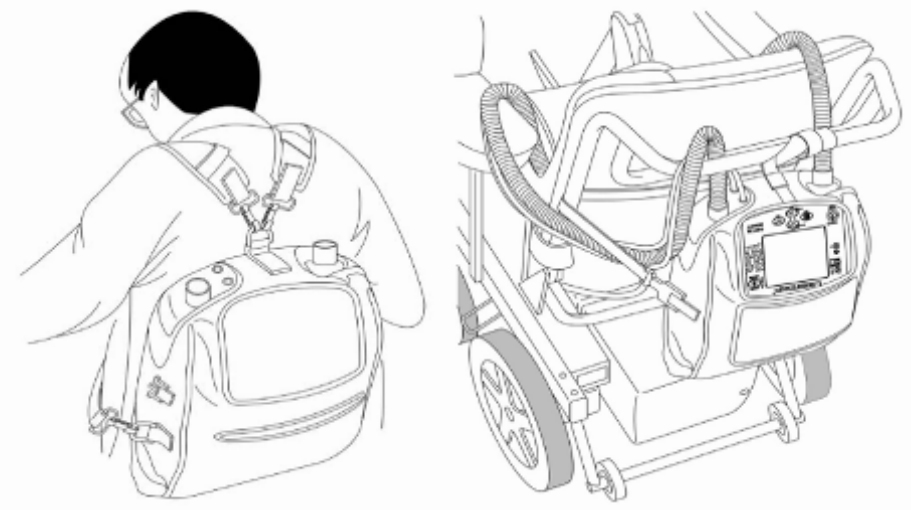
We recommend to regularly check the cleanliness of the device before its first operation (refer to § Cleaning and disinfecting).

WARNING
After storage of the apparatus at a temperature sharply differing from the one applied at the moment of the installation (typically +/- 20°C), it is necessary to allow the apparatus to stabilise in temperature for at least 15 minutes before running it.

MOUNTING THE VENTILATOR ON A WHEELCHAIR

⚠ *WARNING*
Ensure that the battery is fully charged before ventilating the patient.
Due to its limited autonomy, the ventilator should only be operated occasionally with its internal battery.
Due to typical voltage fluctuations that occur during normal power wheelchair use, the wheelchair mains battery should never be used to power the ventilator. It is recommended to use an independent external DC supply when using the ventilator on a wheelchair.
It is not recommended to operate the ventilator for a long time in a direct exposure to sunlight or near heat source.
Fluid (e.g. if it is raining) must not be allowed to seep inside the ventilator, in particular the air inlet filter or the cooling apertures located in the side, rear and bottom panels of the ventilator.
For outdoor uses we recommend to install the* LEGENDAIR® *ventilator within its dedicated carrying bag for protecting it against water and dust entrances and limiting the effect of shocks and vibrations.

The **DUAL BAG** is a carrying bag which allows to easily adapt the **LEGENDAIR®** onto a wheelchair or also to carry it as a backpack:



Refer to **DUAL BAG**'s instruction for installation of the ventilator.

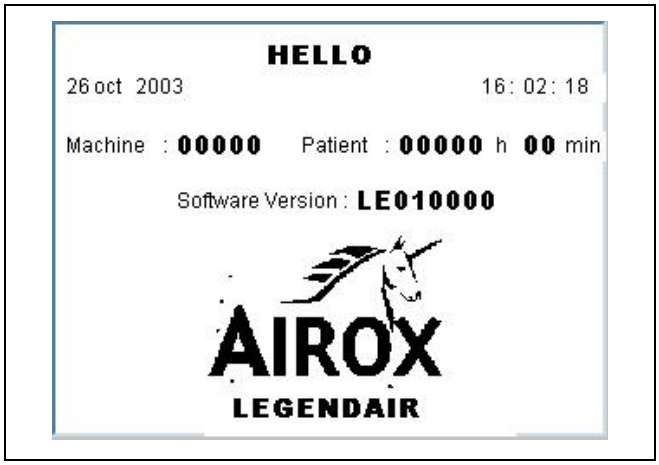
Check regularly the cleanliness of the air inlet filter located on the rear of the ventilator and particularly when the ventilator is installed on a wheelchair as environmental conditions may cause the filter to become dirty more rapidly.

RUNNING THE APPARATUS

The apparatus is turned on with the switch found at the rear and protected by a self closing cover (if installed).

Every time the machine is turned on with the switch, the ventilator systematically effects an initialisation phase before ventilation. During the phase, which lasts approximately 5 seconds, certain components of the machine are tested and initialised. Technical messages may signal malfunctions at the end of this phase (see paragraph on Alarms and Defaults.)

A welcome menu is temporarily displayed during this phase. The machine and patient hour meters (see § Timer) as well as the current software version is displayed in this welcome menu.



Note: If the ventilator had been previously stopped with the switch when ventilation was in progress, the apparatus starts directly to ventilate and does not show the welcome menu.

As soon as the welcome menu finishes, ventilation can be run at any time by the ⏻ button. It is however possible to skip this welcome menu by pressing the ⏻ button and starting ventilation immediately.

A blue LED that is located on the left of the ⏻ key indicates that the ventilation is on stand by. It lights off when the ventilation starts.

When the ventilation is on stand by, a prompt to press the ⏻ key to start the ventilation appears in the right window in each menu.

The ventilation mode recalled after the welcome menu is the last one used and the settings are those that were in force the last time it was stopped. If their memorisation is faulty, a "CHECK PARAMETER" alarm is activated, the parameters should therefore be re-saved otherwise the machine will operate on default values. This alarm is systematically activated at the first start-up that follows the downloading of a new version of the software. In this case, inhibit the alarm.

Ventilation modes can be changed and parameters can be modified at any time from the setting menus of each mode (see paragraph on Adjustment of Operating Parameters), unless the locking key has been installed (see paragraph on Locking Key).

We recommend testing the correct activation of the basic apparatus alarms before connecting and ventilating the patient. To do so, the following is recommended:

- Allow the apparatus to operate for several cycles without connecting the patient: a sound alarm and the "DISCONNECTION" message should activate within a few seconds depending on the ventilation mode and the setting of delay set in setup menu (see § Setup). Otherwise, move the proximal pressure socket so that is as close as possible to the end of the circuit on the patient side. If this installation is not possible, raise the "DISCONNECTION" alarm triggering threshold alarm by adjusting Pi mini in volume mode or set up a "HIGH VT" alarm threshold by setting a Vti maxi in barometric mode or use a double branch circuit and set up a “LOW VTE” alarm threshold by setting a Vte mini for all modes. It is thus this last alarm that may best reveal a disconnection of the patient circuit under such conditions.
- Inhibit the alarm by the button
- Disconnect the external electrical power cord: a sound alarm and the "POWER FAIL" or "DC POWER FAIL" message should activate immediately. The internal battery charge indicator will be displayed on the first line. If the battery charge is insufficient, an "EMPTY BATTERY" alarm will be activated (see paragraph on Operation with Internal Battery).
- Inhibit the alarm by the button

Note: If the main external electrical supply is of the direct current type, the alarm "POWER FAIL" will activate upon starting to show the absence of an energy source that would charge the internal batteries. However, it is recommended that you carry out the test above with the electrical power source temporarily disconnected to check switching to the internal batteries and their state.

- Reconnect the electric power supply cord to restore power.

In the case of use of a ventilator with an oxygen source associated with an FiO_2 measurement (see paragraph on Oxygen source), testing the activation of top and bottom limit alarms of the FiO_2 is recommended. To do so, we recommend that you proceed as follows:

- Hook up and calibrate the FiO_2 sensor (see paragraph on Oxygen source)
- Adjust FiO_2 mini and FiO_2 maxi thresholds if necessary.
- Run ventilation, either without introducing oxygen in the apparatus or after placing the FiO_2 sensor away from the flow for at least 15 seconds. Then, verify that the FiO_2 measurement returned by the apparatus is indeed 21%. A beep and the "LOW FIO2" message should be activated after a few cycles (unless the FiO_2 mini was set below 21%).
- Inhibit the alarm by the button and replace the sensor in the main flow of the ventilator output.
- Set a maximum flow on the oxygen source or place the sensor on a tube directly connected to an oxygen source not mixed with ambient air. Check in this case that the measurement of FiO_2 returned by the apparatus is indeed of the order of 100%. A beep and the "HIGH FIO2" message should be activated after a few cycles (unless the FiO_2 maxi was set to 100%).

- Inhibit the alarm by the button, restore the oxygen flow setting of the external source or reconnect this source to the apparatus and replace the sensor in the main flow of the ventilator output.
- Disconnect the FiO_2 sensor connection cable of the apparatus: a beep and the "FIO2 FAIL" message should activate immediately.
- Re-connect the cable to restore the situation and inhibit with the button; the user is prompted to calibrate the sensor if the cable has already been reconnected.

Once these tests have been done, you can connect the patient to the apparatus and begin ventilation safely.

SETUP

The setup menu can be accessed in two ways:

- When the apparatus is turned off: by simultaneously pressing the On/Off switch located to the rear of the machine (position "1") and keeping the key pressed until the menu appears on the screen.
- When the apparatus is running: stop ventilation (see paragraph on Stopping the apparatus) then place the cursor on the first line of the ventilation menu by pressing the or keys to make the title flash, then press on the until the menu appears. This access is possible only if the locking key has not been installed (see paragraph on Locking key)

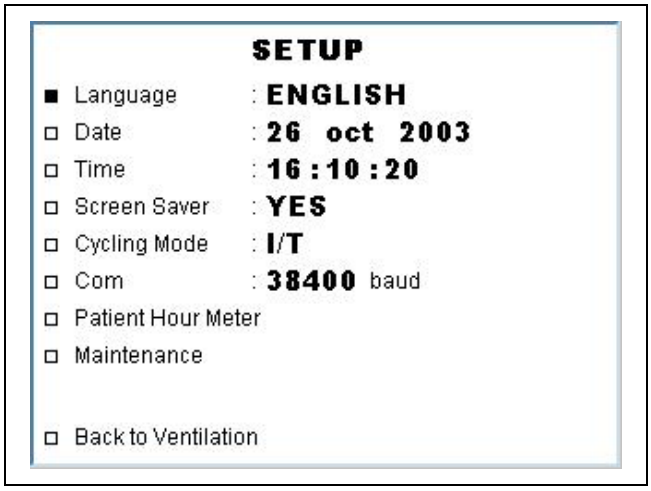
To modify the setup parameters, it is necessary to:

- Put the cursor next to the parameter to be modified using the or keys
- Validate your intention to modify the parameters by the key: the parameter flashes and the left cursor becomes
- Modify its value using the or keys.
- Validate the new value with the key. When a parameter comprises several adjustment fields (ex. Date, Time) go from field to field using the same key.

If a parameter modification is not validated after 7 seconds, the ventilator restores the previous value.

The parameters of the setup menu remain memorised until they are partially or completely modified anew.

The setup menu is as follows:



The data handled in this menu is:

■ **LANGUAGE**

FRANCAIS	ENGLISH	ESPANOL	ITALIANO	DEUTSCH

The choice of a language immediately puts all messages and denominations in the chosen language. The languages available depend on the software version.

■ **DATE** □□ □□□ □□□□

Sets time in DD MMM YYYY.

■ **TIME** □□: □□: □□

Sets the time in HH : MM : SS

■ **SCREEN SAVER** □□□

YES = Screen saver automatically activated after one minute without use of keypad.

NO = No screen saver, which remains permanently lit.

Regardless of the setup selected for the screen saver and when the apparatus is in stand-by (not in ventilation), the display contrast can be modified by pressing the key, then by adjusting contrast with the + and − keys.

■ **CYCLING MODE** □□□

The choice offered is relative to the expression rule permitting the adjustment of parameters setting the insufflation period of "controlled" modes (CV, ACV, PCV, PACV, SIMV).

There are two possibilities:

- I/E ratio: It is expressed as an non-dimensional auto-descriptive ratio with a unitary insufflation time over the Te expiration time brought to the Ti unit:

  $$I/E = 1 / (Te / Ti) = 1 / E$$

- I/T ratio (%): It is expressed as a percentage corresponding to the ratio between the duration of inspiration Ti and the total duration of the respiration cycle Tt = Ti+Te:

  $$I/T\ (\%) = [Ti / (Ti+Te)] \times 100$$

In PACV, ACV and SIMV mode, the cycling ratio can evolve during ventilation by the inspiration triggering by the patient. The insufflation time nevertheless remains set and corresponds to the rate and cycling ratio settings.

■ **DISCONNECTION** □□ s

Sets triggering delay of the “DICONNECTION” alarm. This delay can be set from 3 to 30 s by steps of 1 s and the initial default value is 15 s. This triggering delay applies for all ventilation modes except for PSV ST and SIMV modes where the delay is the maximum value between the set delay and apnoea time + 1 s.

The real triggering delay of the alarm can be shorter than the setting depending on the ventilation phase where an effective disconnection of the patient circuit or the patient occurs. Indeed when the set expiratory pressure level is lower than the alarm threshold, the disconnection timer starts from the beginning of expiratory phase even if there is no effective disconnection. In such conditions, if disconnection occurs during the expiratory phase, the triggering delay is shortened of the expiratory time already passed.

For the same reasons, it’s better to check that the set triggering delay remains higher than the allowed expiratory time which depends on rate and cycling

ratio used for ventilating. Otherwise the "DISCONNECTION" alarm could be triggered during each expiratory phase when the alarm threshold is higher than the set expiratory pressure level. A triggering delay higher than 8 s avoids such a phenomenon even for the lowest rate and cycling ratio.

- **PATIENT HOUR METER**

Gives access to the Patient Timer Menu (see paragraph on Hour Meters).

- **MAINTENANCE**

Gives access to the Maintenance Menu (see paragraph on Maintenance).

- **BACK TO VENTILATION**

Goes back to the menu of the last ventilation mode used.

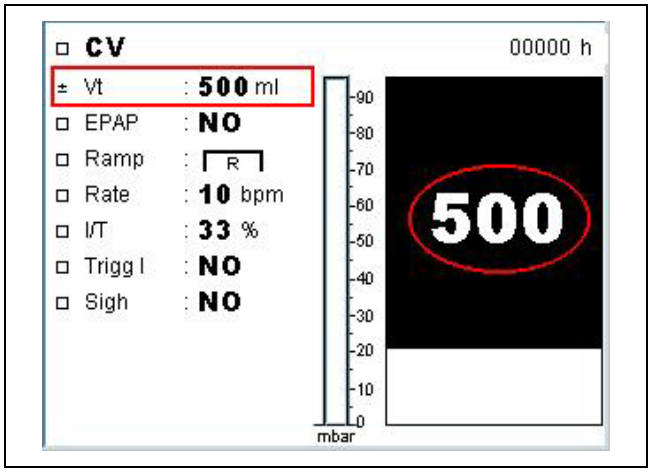
ADJUSTMENT OF OPERATING PARAMETERS

CHANGING THE PARAMETERS OF A MODE

A menu specific to each ventilation mode enables the setting of various parameters necessary to operation (if the locking key is not installed).

To modify the adjustment parameters, it is necessary to:

- Put the cursor next to the parameter to be modified using the ▲+ or ▼- keys
- Validate your intention to modify the parameters by the ✓ key: the parameter flashes, a zoom of the parameter is displayed in the right-hand window and the left cursor becomes ±
- Modify its value using the ▲+ or ▼- keys
- Validate the new value with the ✓ validation key; the zoom then disappears and the left-cursor goes back to ■



If a parameter modification is not validated after 7 seconds, the ventilator re-establishes the previous value.

The ventilation parameters stay memorised until part or whole of the parameters are modified once again.

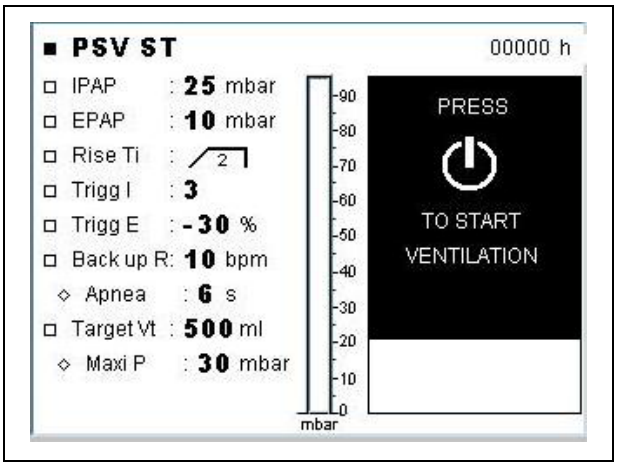
It is recommended, once the machine is in service in the patient's home, to unit access with the locking key (see paragraph on Locking key).

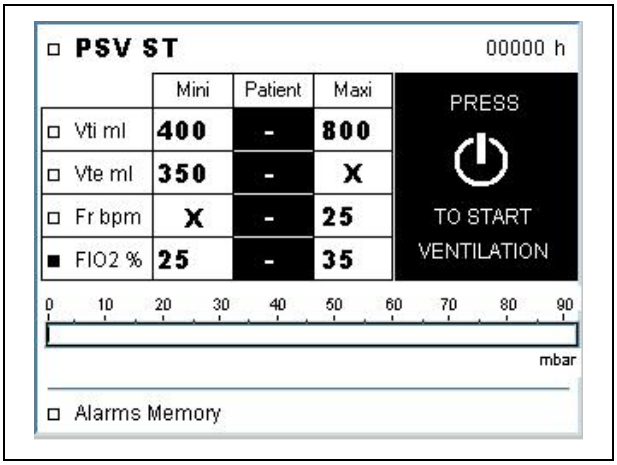
The adjustment ranges of certain parameters are limited below the announced amplitude ranges in order to stay compatible with the levels of other previously set parameters.

Ventilation is not interrupted by the adjustment of a value; it continues according to previous settings. New parameters go into force only after their validation and are synchronised in the following cycle.

CHANGE IN VENTILATION MODE

All the ventilation modes are made up of two menus: the menu of ventilation parameters and the menu of alarm parameters:





You can "loop" between these menus by moving the cursor with the ▲+ and ▼- keys or jump to a page directly with the ↺ key.

Ventilation mode can be changed at any time from these menus. The method of changing the mode differs depending on ventilation status:

- During ventilation: it is possible to view and adjust the parameters of the current mode but also those of modes not being used. There is thus a "display" step when changing mode in this case. Parameters of the new mode may be adjusted in this step before the actual change of mode is confirmed (or not). During a modification procedure, the name of the current mode is accompanied by the "**ACTIVE"** addition; other "viewable" modes are accompanied by the "**NO ACTIVE**" addition.
- When not ventilating: a change in mode is equivalent to a change in menu without a need for confirmation of the change. All the modes are potentially "ACTIVE" as long as ventilation has not been run and there is no status information with the name of these modes.

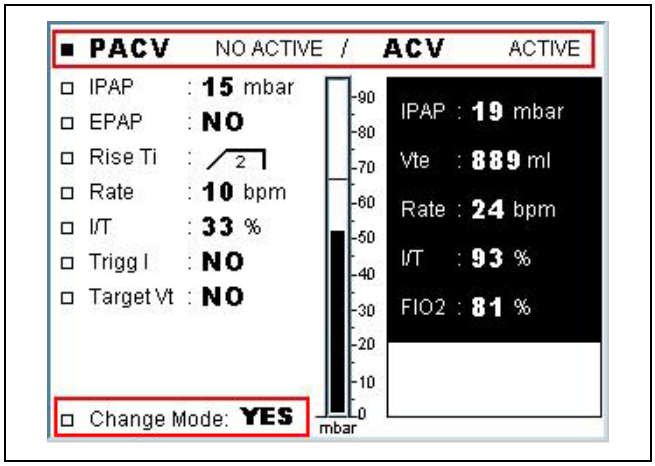
To change the ventilation mode, you must:

- Place the cursor on the first line of the menu (title line) with ▲+
- Validate your intention to modify the parameters by the ✓ key: the titles flashes and the left cursor becomes ↕
- Modify its value using the ▲+ or ▼- keys
- Validate the new mode by the ✓ validation key.
- Set the parameters if necessary

If the modification is not validated after 7 seconds, the ventilator restores the title of the previous mode.

If the adjustment is made during ventilation, the change in mode will not have yet gone into effect. Two new displays will appear on the screen:

- Information or additional status information on the modes on the title line instead of other informal displays: the name of the new mode selected is displayed on the left followed by "**NO ACTIVE**" additional status information which flashes. The name of the current mode is displayed on the right following by "**ACTIVE**" additional status information which does not flash.
- Mode change line at the bottom of the menus for setting ventilation and alarms: "□ **Change Mode: YES** ». This last field will be used to activate the last new displayed mode instead of the current mode without stopping ventilation. It is not visible when the apparatus is on stand-by or in the menu of the mode being used or active.



A change in ventilation mode can go into effect by positioning the cursor on the "■ **Change Mode: YES**" line, then by pressing the ✓ key.

Note: To access that line in the current page rapidly and from any line, keep the ▼ key pressed down. You can also access that line from the title line by pressing the ▲ key which gives access to the last line of the supplementary page of the mode.

After the "□ **Change Mode: YES**" has been validated, the additional status information of the modes and the name of the old active mode then disappear from the title line as well as the "■ Change Mode: YES" line. The mode change then goes into effect after ventilation. The new ventilation mode is applied, its parameters are synchronised on the next ventilation cycle, and the monitoring window switches to the new mode.

WARNING
When making changes to the mode in effect during ventilation, significant transitions of pressure, flow or cycling rate might occur depending on how the settings may differ between the modes. **It is best to be careful that the settings between the different modes are coherent in order to avoid harmful effects to the patient's comfort and health during this change.**

The change of mode during ventilation must not necessarily go into effect at this stage. After having called up the menu of a "NO ACTIVE" mode, all or part of the ventilation and alarm parameter settings of this mode may be modified; these modifications are memorised for this mode regardless of whether it will be used immediately afterwards or not. The settings of all or part of available modes can be "prepared" in this way while ventilation is in progress in another mode.

When the menu of a "NOT ACTIVE" mode is displayed and if there is no action on the keypad, "ACTIVE" ventilation mode is displayed again on the screen and the "□ Change Mode: YES" line disappears after 14 seconds. The menu of the "ACTIVE" mode can also be brought back without waiting for this time to elapse by restoring the name of the mode on the title line directly.

During a parameter setting procedure of a "NO ACTIVE" mode, the monitoring data displayed in the window to the right of the menu for setting ventilation parameters stays the same as those of the current ventilation mode or "ACTIVE" mode regardless of the menu for setting ventilation parameters of the new "NO ACTIVE" mode displayed on the left.

However, in the menu for adjusting alarm parameters, the centre monitoring column of the table as well as the right-hand window become those of the "NO ACTIVE" displayed mode, but the measurements displayed remain those of the "ACTIVE" mode. The monitoring data of the window are masked temporarily by the zoom only when the parameters of the new "NOT ACTIVE" mode are being adjusted.

Similarly, if alarms are activated while the "NOT ACTIVE" mode is being adjusted, its message is displayed in the window for alarm display.

A change in mode during stand-by and ventilation is possible only if the locking key has not been installed. It is recommended, once the machine is in service in the patient's home, to unit access with the locking key (see paragraph on Locking key).

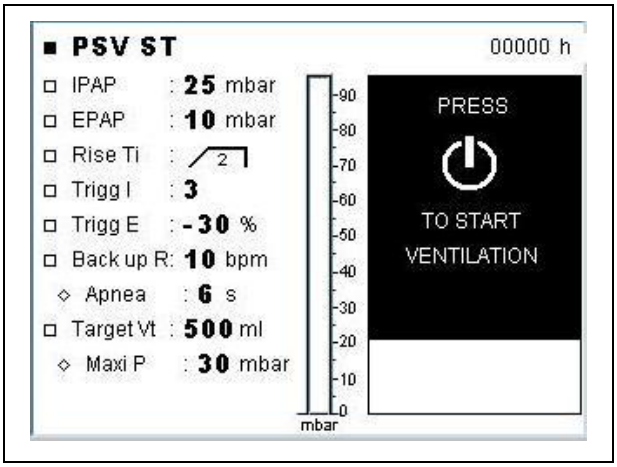
The ventilation parameters of each mode and the current mode stay memorised until part or whole of the parameters are modified again, even after the machine is stopped.

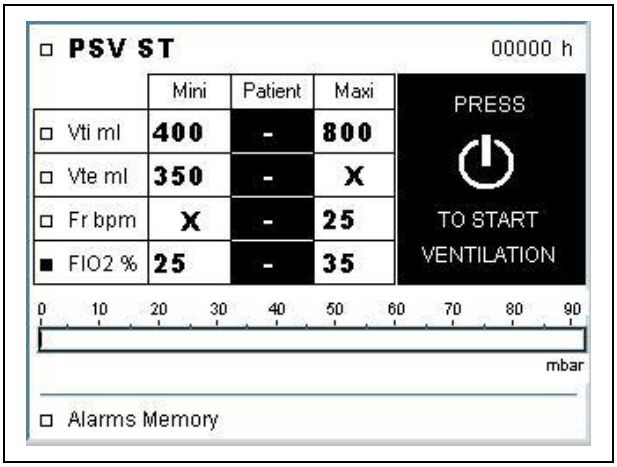
PARAMETERS OF PSV S / PSV ST MODES

PSV S = **P**RESSURE **S**UPPORT **V**ENTILATION **S**PONTANEOUS

PSV ST = **P**RESSURE **S**UPPORT **V**ENTILATION **S**PONTANEOUS **T**IMED

The menus of **PSV S** and **PSV ST** ventilation modes are:





You can "loop" between these menus by moving the cursor with the ▲+ and ▼- keys or jump to a page directly with the key.

Ventilation parameters that can be set in the menu of modes **PSV S** / **PSV ST** and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
IPAP	mbar (or hPa)	5	40	1	15	IPAP ≥ EPAP + 5 mbar
EPAP	mbar (or hPa)	0	20	1	0	EPAP ≤ IPAP – 5 mbar
Rise Time	-	1	4	1	2	-
Trigg I	-	1	5	1	2	-
Trigg E	%	-15	-75	5	AUTO = -25	-
Back Up R	bpm (or breaths/min)	4	40	1	NO	-
Apnea	s	3	30	1	AUTO = Maxi[3;60/R]	Not adjustable if BUR = NO 30/BUR ≤ Apnea ≤ 180/BUR
Target Vt	ml (or cm^3)	50	1400	10	NO	-
Maxi P	mbar (or hPa)	8	55	1	NO	Not adjustable if Target Vt = NO IPAP + 3 mbar ≤ Maxi P ≤ IPAP + 15 mbar

Changeover from **PSV S** to **PSV ST** can be done by selecting and setting a Back Up Rate. Display of the mode denomination then changes automatically.

Alarm parameters that are adjustable in the menu of modes **PSV S** / **PSV ST** and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Vti mini	ml (or cm^3)	30	1250	10	NO	Vti mini < Target Vt Vti mini ≤ Vti maxi – 50 ml
Vti maxi	ml (or cm^3)	80	3000	10	2000	Vti maxi > Target Vt Vti maxi ≥ Vti mini + 50 ml
Vte mini	ml (or cm^3)	30	1250	10	NO	Vte mini ≤ Target Vt
Fr maxi	bpm (or breaths/min)	10	120	1	NO	Fr maxi ≥ BUR + 5 bpm
FiO_2 mini	%	18	90	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %
FiO_2 maxi	%	30	100	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %

Commentary specific to each adjustable parameter:

■ IPAP – INSUFFLATION PRESSURE □□mbar

Its setting determines the level of pressure reached during the insufflation phase. Its value is displayed beside the parameter.

IPAP is an absolute value independent of the EPAP and must always be greater to the EPAP (Δ mini = 5 mbar).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the maximum value reached at each cycle is plotted on the bar graph and is repeated in the alarm parameter monitoring menu window.

As a safety measure, a low pressure alarm may be activated if the insufflation pressure level is not reached (see paragraph on Alarms and Defaults.)

Similarly, a switch to expiration will be made if the insufflation pressure level is significantly exceeded.

■ EPAP – POSITIVE EXPIRATORY PRESSURE □□mbar

Its adjustment determines the level of pressure maintained during the expiratory phase. Its value is displayed beside the parameter.

The EPAP must always be less than the IPAP (minimum Δ = 5 mbar).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the average value reached at each cycle is plotted on the bar graph and is repeated in the alarm parameter monitoring menu window.

■ RISE TIME □

This parameter permits the adjustment of the time of the increase of the IPAP during the insufflation phase, and indirectly the minimum insufflation time.

The different levels available correspond to:

- Rise time 1 = 0.2 to 0.7 s (theoretical time = 0.2 s)
- Rise time 2 = 0.4 to 1.0 s (theoretical time = 0.4 s)
- Rise time 3 = 0.6 to 1.2 s (theoretical time = 0.6 s)
- Rise time 4 = 0.8 to 1.5 s (theoretical time = 0.8 s)

These time ranges depend on the conjunction of the pressure adjustment desired, the cycling rate and the state of the patient.

The IPAP rise time is systematically built up; the end of insufflation cannot intervene until after this pressure rise time or minimum insufflation time.

■ Trigg I – INSPIRATION TRIGGER

The inspiration trigger sets the level of inspiratory effort the patient has to provide during the exhalation period to activate a machine cycle. It is mixed type, which means based on flow or pressure signals. The detection levels are adjusted by an algorithm taking into account the bias flow, the expiratory pressure and the duration of the exhalation to optimize sensitivity and to avoid potential auto triggering phenomena.

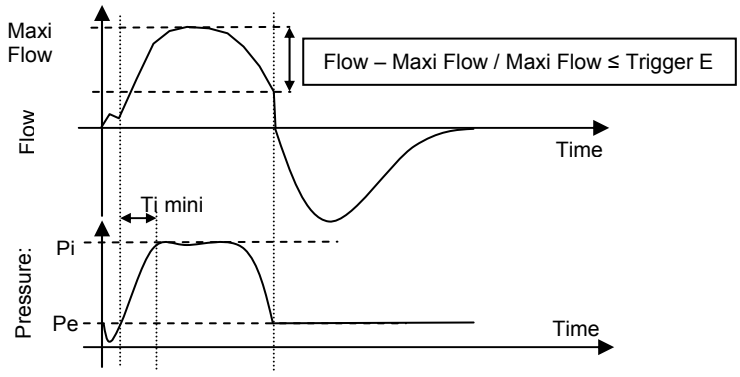
The sensitivity levels from 1 to 5 are decreasing: the higher the index is, the lower the trigger sensitivity is. Those levels correspond to flow differences compared to bias flow or to pressure differences compared to expiratory pressure. They are decreasing with the time between 0.7 to 3 s :

- Trigg I 1 = Bias Flow + 3,5 lpm or Pe – 0,3 mbar
- Trigg I 2 = Bias Flow + 4,0 lpm or Pe – 0,5 à 0,7 mbar / Time
- Trigg I 3 = Bias Flow + 4,5 lpm or Pe – 0,6 à 0,8 mbar / Time
- Trigg I 4 = Bias Flow + 4,5 lpm or Pe – 0,7 à 0,9 mbar / Time
- Trigg I 5 = Bias Flow + 4,5 lpm or Pe – 0,8 à 1,0 mbar / Time

WARNING
It is recommended to adapt carefully the trigger threshold in order to avoid a risk of machine self-activation. The level 1, the more sensitive, is convenient for paediatrics.

■ Trigg E – EXPIRATION TRIGGER – %

Adjusts the inspiratory time in a cycle; it is expressed as a percentage corresponding to the ratio between the fall of the inspiratory flow and the maximum inspiratory flow reached in the cycle.



Trigger E goes into effect, however, only after the level of insufflation pressure set or the rise time made up by a minimum insufflation time has been reached.

If the drop in the flow observed is insufficient past a given time, the end of the inspiratory phase is activated by default independently of the % of TRIGG E. This time period or maximum insufflation time is the shortest time of 3 s or the insufflation

time that would correspond to a ratio of I/T = 50% or I/E = 1/1 at the last rate measured.

The corresponding AUTO adjustment has a threshold of –25% that is retained by default if no other adjustment is made.

■ Back up R – BACK UP RATE □□bpm

Rate of ventilation cycles to be provided in the case of prolonged apnea and as long as no inspiration trigger is detected.

Associated apnea time can be set, enabling "pauses" between spontaneous cycles whose rate may be less than the back-up rate (see below). Beyond the apnea time without detection of the inspiration trigger, the ventilator ventilates at the back up rate, which is set.

The inspiratory time of cycles applied in the case of apnea always depends on the detection of Trigger E and the Trigger E safety limit applies by default.

The flow ramp of these cycles is identical to cycles triggered by the patient within the limit of compatibility with an insufflation time corresponding to the back up rate set for an I/T of 33% or an I/E of 1/2.

When ventilation cycles consecutive to an apnea are activated, the "CONTROLLED CYCLES" message appears in the alarm message window (see paragraph on Alarms and Defaults) and flashes during the application period of these cycles.

The successive controlled cycles are interrupted as soon as a new spontaneous inspiration of the patient is detected.

Setting of a Back up Rate is optional; if you choose "NO" during setting, no ventilation will be triggered in the event of apnea and mode is **PSV S** (the display switches automatically).

If the patient circuit is disconnected or if there is a significant leak, after a delay higher than the maximum value between the apnoea delay + 1 s and the setting from 3 to 30 s done in setup menu (see § Setup) a “DISCONNECTION” alarm might be activated (see § Alarms and Defaults).

■ Apnea – APNEA LIMITS □□ s

After a back up rate has been set, i.e. in PSV ST mode, an apnea time can be set.

The limits of apnea time and the default or "Auto" value proposed directly depend on the back up rate that was set: 30 / Rate ≤ Apnea Time ≤ 180 / R and Auto Apnea = 60 / R within the limit of 3 to 30 s.

■ Target Vt – TARGET TIDAL VOLUME □□□□ ml

Setting a Target Volume is optional, but if it is set, this means that a IPAP maxi must also be set (see below).

This option consists in leaving the ventilator to continuously adjust the level of the insufflation pressure between the "base" or minimum insufflation pressure and a maximum pressure threshold in order to keep the inspired tidal volume as close as possible to the target volume. The implementation of this pressure adjustment function is put on hold at start-up.

Reminder: Precaution must be taken to ensure that the patient circuit is well adapted to the tidal volume (tube Ø 22 mm for adults and Ø 15 mm for pediatrics with tidal volume lower than 200 ml).

■ Maxi P – MAXIMUM INSUFFLATION PRESSURE □□ mbar

If a Target Volume has been set, a maximum insufflation pressure is associated with it.

It is always greater than the level of "base" or minimum insufflation time (min. Δ = 3 mbar) and the maximum gradient between the minimum and maximum insufflation pressure is also limited (max. Δ = 15 mbar).

During operation, automatic adjustments of the insufflation pressure levels is done in relation with the tidal volume measured at each cycle by increasing steps between the cycles, for both pressure increase and decrease.

If the maximum pressure level is significantly exceeded, insufflation is interrupted and automatic pressure adjustment will not be active at the next cycle (see paragraph on Alarms and Defaults).

■ Vti – INSPIRED TIDAL VOLUME □□□□ ml

It is possible to set a minimum and/or maximum inspired tidal volume alarm threshold.

The setting of Vti mini is limited by the Target Vt level which must stay greater than it. If the Target Vt level were to become less than the Vt mini previously set, the Vt mini would be automatically re-adjusted with a difference of 10 ml.

The setting of Vti maxi is limited by the Target Vt level which must stay less than it. If the Target Vt level were to become greater than the Vt maxi set, the Vti mini would be automatically re-adjusted with a difference of 10 ml.

Similarly, the difference between Vti mini and Vti maxi must be at least 50 ml.

When Vti alarm thresholds are set, two types of alarms may be activated during ventilation:

- "LOW VTI" visual and sound alarm if the tidal volume measured stays less than the minimum tidal volume threshold set after three consecutive cycles.
- "HIGH VT" visual and sound alarm if the tidal volume measured stays greater than the maximum tidal volume level set after three consecutive cycles. This alarm is not activated if there is a state of low pressure. This alarm if correctly adjusted can reveal a leak in the patient circuit, even in single-branch.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic. (see paragraph on Alarms and Defaults).

The adjustment of a Vti mini and/or maxi is not mandatory (choice = "NO"); the display of the measured value however remains active.

We recommend, however, to keep the Vti maxi setting active at a threshold, even a high one, by default in the case where load would be lost on the patient circuit after the proximal pressure connection. This is due to the fact that the triggering of the "DISCONNECTION" alarm is not always ensured when the circuit is disconnected.

The Vti is calculated from the flow measured at the apparatus outlet to the patient. The value displayed on the monitoring windows is not necessarily the volume received by the patient since it does not take into account, amongst other things, possible leaks in the patient circuit. It is only in a double-branch setup with the exhalation block that these flow and volume measurements can be more precise and reveal leaks.

■ Vte – EXPIRED TIDAL VOLUME □□□□ ml

A minimum level of expired tidal volume can always be set. However, it will only be able to be used in double-branch setup when an exhalation block is installed (see paragraph on Accessories and Options). Its setting is limited by the set Target Vt level which must stay greater than it.

It can be used to activate an alarm in the event where the tidal volume expired by the patient is less than this limit. Thus, the "LOW VTE" message is displayed after 3 consecutive cycles in these conditions.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The adjustment of the Vte mini is not mandatory (choice = "NO") and the display of the measured value remains active.

■ Fr maxi – MAXI FREQUENCY □□bpm

The maximum rate threshold set permits the warning of any risk of hyperventilation or racing of the machine. If the rate measured exceeds this level for 3 consecutive cycles, a sound alarm is emitted and the alarm message displayed is "MAXI FREQUENCY".

The maximum rate threshold must always remain greater than the back up rate if one has been set (minimum Δ = 5 bpm). If the back up rate is readjusted, the maximum rate is automatically readjusted if necessary on the basis of a minimum difference of 5 bpm.

Above the maximum rate value, whether adjusted or not, a supplementary safety exists from 80 bpm (see paragraph on Alarms and Defaults).

■ FiO_2 – FRACTION OF INSPIRED OXYGEN □□%

In all the modes, FiO_2 mini and FiO_2 maxi thresholds can be set only if there is a sensor to trigger these alarms. These settings cannot be cancelled if a sensor is connected. The settings can be cancelled by the user intentionally only if no sensor is connected. Settings are automatically restored as soon as a sensor is re-connected. An information message will be sent back by the machine in this case to prompt the user to calibrate the sensor once again if necessary (see paragraph on Oxygen Source).

FiO_2 settings are the same for all these modes and there must be a minimum difference between the minimum and maximum thresholds (minimum Δ = 10%).

Alarms called FiO_2 mini and FiO_2 maxi relating to the observance of FiO_2 ranges during ventilation are triggered if:

- the minimum FiO_2 set is not reached during three consecutive cycles.
- the maximum FiO_2 set is exceeded during three consecutive cycles.

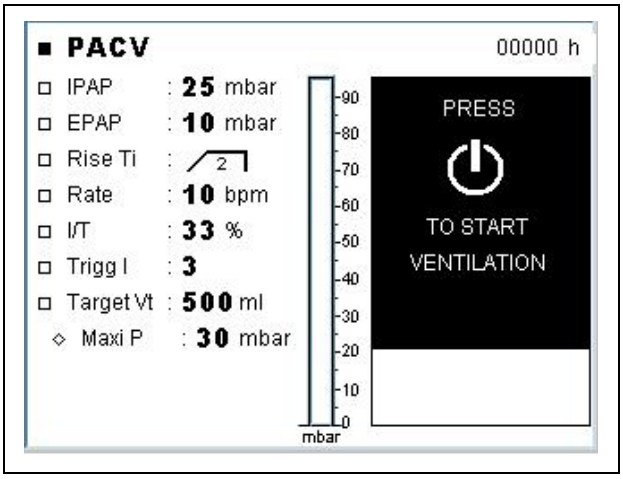
The sound of these alarms may be inhibited for two minutes but their cancellation can only be automatic.

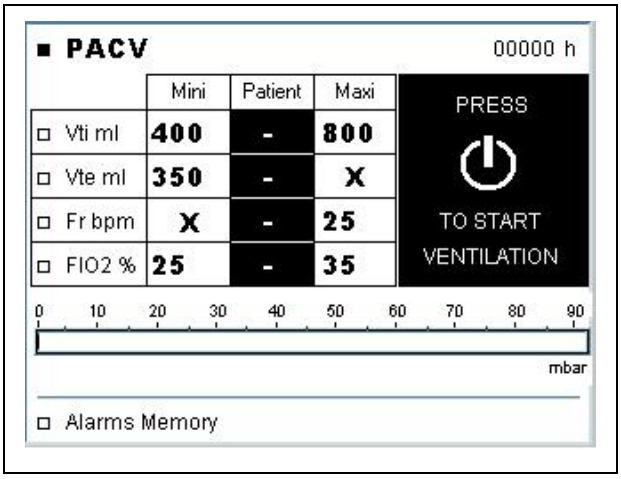
PARAMETERS OF PCV / PACV MODES

PCV = **P**ressure **C**ontrolled **V**entilation

PACV = **P**ressure **A**ssisted **C**ontrolled **V**entilation

The menus for the **PCV** and **PACV** ventilation modes are:





You can "loop" between these menus by moving the cursor with the ⊕ and ⊖ keys or jump to a page directly with the ☞ key.

Ventilation parameters that can be set in the menu of modes **PCV** / **PACV** and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
IPAP	mbar (or hPa)	5	40	1	15	IPAP ≥ EPAP + 5 mbar
EPAP	mbar (or hPa)	0	20	1	0	EPAP ≤ IPAP – 5 mbar
Rise Time	-	1	4	1	2	-
Rate	bpm (or breaths/min)	5	60	1	10	-
I/T Radio	%	50	25	1	33	-
Or **I/E Ratio**	-	1/1.0	1/3.0	0.1	1/2.0	-
Trigg I	-	1	5	1	NO	-
Target Vt	ml (or cm^3)	50	1400	10	NO	-
Maxi P	mbar (or hPa)	8	55	1	NO	Not adjustable if Target Vt = NO IPAP + 3 mbar ≤ Maxi P ≤ IPAP + 15 mbar

Changeover from **PCV** to **PACV** can be done by selecting and setting a Trigger I. Display of the mode denomination then changes automatically.

Alarm parameters that are adjustable in the menu of modes **PCV** / **PACV** and their setting limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Vti mini	ml (or cm^3)	30	1250	10	NO	Vti mini < Target Vt Vti mini ≤ Vti maxi – 50 ml
Vti maxi	ml (or cm^3)	80	3000	10	2000	Vti maxi > Target Vt Vti maxi ≥ Vti mini + 50 ml
Vte mini	ml (or cm^3)	30	1250	10	NO	Vte mini ≤ Target Vt
Fr maxi	bpm (or breaths/min)	10	120	1	NO	Fr maxi ≥ R mini + 5 bpm Keep NO for PCV
FiO_2 mini	%	18	90	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %
FiO_2 maxi	%	30	100	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %

Commentary specific to each adjustable parameter:

■ IPAP – INSUFFLATION PRESSURE □□mbar

Its setting determines the level of pressure reached during the insufflation phase. Its value is displayed beside the parameter.

IPAP is an absolute value independent of the EPAP and must always be greater to the EPAP (Δ mini = 5 mbar).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the maximum value reached at each cycle is plotted on the bar graph and is repeated in the alarm parameter monitoring menu window.

As a safety measure, a low pressure alarm may be activated if the insufflation pressure level is not reached (see paragraph on Alarms and Defaults.)

Similarly, a switch to expiration will be made if the insufflation pressure level is significantly exceeded.

■ EPAP – POSITIVE EXPIRATORY PRESSURE □□mbar

Its adjustment determines the level of pressure maintained during the expiratory phase. Its value is displayed beside the parameter.

The EPAP must always be less than the IPAP (minimum Δ = 5 mbar).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the average value reached at each cycle is plotted on the bar graph and is repeated in the alarm parameter monitoring menu window.

■ RISE TIME □

This parameter is used to adjust rise time to IPAP during the insufflation phase.

The different levels available correspond to:

- Rise time 1 = 0.2 to 0.7 s (theoretical time = 0.2 s)
- Rise time 2 = 0.4 to 1.0 s (theoretical time = 0.4 s)
- Rise time 3 = 0.6 to 1.2 s (theoretical time = 0.6 s)
- Rise time 4 = 0.8 to 1.5 s (theoretical time = 0.8 s)

These time ranges depend on the conjunction of the pressure setting desired, the cycling rate and the state of the patient.

The pressure rise time built-up at each cycle depends on the insufflation time corresponding to the combination of the rate set and the I/T or I/E cycling ratio set. The pressure rise time effected is always less than the insufflation time – 0.3 s:

- Rise Time 1 always a possibility
- Rise Time 2 built up only if Ti ≥ 0.7 s
- Rise Time 3 built up only if Ti ≥ 0.9 s
- Rise Time 4 built up only if Ti ≥ 1.1 s

■ Rate □□bpm

During ventilation in PACV mode, the rate value set is a minimum value; the patient activation of an inspiration trigger can modify this rate.

The average rate of the cycles is displayed and is updated continuously after the start of ventilation. The insufflation time nevertheless remains set.

In the absence of an inspiration trigger, the ventilation cycles are linked to the minimum rate as in PCV mode.

■ I/T or I/E Ratio – CYCLING RATIO □□% or 1/ □.□

This ratio can be used, in combination with the rate, to adjust the inspiratory time in a cycle. The cycling ratio mode is expressed in the setup menu (see paragraph on Setup):

- I/E ratio: It is expressed as an non-dimensional auto-descriptive ratio with a unitary insufflation time over the Te expiration time brought to the Ti unit:

  $$I/E = 1 / (Te / Ti) = 1 / E$$

- I/T ratio (%): It is expressed as a percentage corresponding to the ratio between the duration of inspiration Ti and the total duration of the respiration cycle Tt = Ti+Te:

  $$I/T (\%) = [Ti / (Ti+Te)] \times 100$$

In PACV mode, the cycling ratio can evolve during ventilation by the inspiration trigger demand made on the part of the patient. The insufflation time nevertheless remains set.

■ Trigg I – INSPIRATION TRIGGER □

The inspiration trigger sets the level of inspiratory effort the patient has to provide during the exhalation period to activate a machine cycle. It is mixed type, which means based on flow or pressure signals. The detection levels are adjusted by an algorithm taking into account the bias flow, the expiratory pressure and the duration

of the exhalation to optimize sensitivity and to avoid potential auto triggering phenomena.

The sensitivity levels from 1 to 5 are decreasing: the higher the index is, the lower the trigger sensitivity is. Those levels correspond to flow differences compared to bias flow or to pressure differences compared to expiratory pressure. They are decreasing with the time between 0.7 to 3 s :

- Trigg I 1 = Bias Flow + 3,5 lpm or Pe – 0,3 mbar
- Trigg I 2 = Bias Flow + 4,0 lpm or Pe – 0,5 à 0,7 mbar / Time
- Trigg I 3 = Bias Flow + 4,5 lpm or Pe – 0,6 à 0,8 mbar / Time
- Trigg I 4 = Bias Flow + 4,5 lpm or Pe – 0,7 à 0,9 mbar / Time
- Trigg I 5 = Bias Flow + 4,5 lpm or Pe – 0,8 à 1,0 mbar / Time

WARNING
It is recommended to adapt carefully the trigger threshold in order to avoid a risk of machine self-activation. The level 1, the more sensitive, is convenient for paediatrics.

This parameter can be deleted (choice = NO) and ventilation mode becomes **PCV** (automatic commutation of the display).

■ Target Vt – TARGET TIDAL VOLUME □□□□ ml

Setting a Target Volume is optional, but if it is set, this means that an IPAP maxi must also be set (see below).

This option consists in leaving the ventilator to continually adjust the level of the insufflation pressure between the "base" or minimum insufflation pressure and a maximum pressure threshold in order to keep the inspired tidal volume as close as possible to the target volume. The implementation of this function is put on hold at start-up.

Reminder: Precaution must be taken to ensure that the patient circuit is well adapted to the tidal volume (tube Ø 22 mm for adults and Ø 15 mm for pediatrics with tidal volume lower than 200 ml).

■ Maxi P – MAXIMUM INSPIRATORY PRESSURE □□ mbar

If a Target Volume has been set, a maximum insufflation pressure is associated with it. It is always greater than the level of "base" or minimum insufflation time (minimum Δ = 3 mbar) and the maximum gradient between the minimum and maximum insufflation pressure is also limited (maximum Δ = 15 mbar).

During operation, automatic adjustments of the insufflation pressure levels are done in relation with the tidal volume measured at each cycle by increasing steps between the cycles, for both pressure increase and decrease.

If the maximum pressure level is significantly exceeded, insufflation is interrupted and automatic pressure adjustment will not be active at the next cycle (see paragraph on Alarms and Defaults).

■ Vti – INSPIRED TIDAL VOLUME □□□□ ml

It is possible to set a minimum and/or maximum inspired tidal volume alarm threshold.

The setting of Vti mini is limited by the Target Vt level which must stay greater than it. If the Target Vt level were to become less than the Vt mini previously set, the Vt mini would be automatically re-adjusted with a difference of 10 ml.

The setting of Vti maxi is limited by the Target Vt level which must stay less than it. If the Target Vt level were to become greater than the Vt maxi set, the Vti maxi would be automatically re-adjusted with a difference of 10 ml.

Similarly, the difference between Vti mini and Vti maxi must be at least 50 ml.

When Vti alarm thresholds are set, two types of alarms may be activated during ventilation:

- "LOW VTI" visual and sound alarm if the Tidal volume measured stays less than the minimum tidal volume threshold set after three consecutive cycles.
- "HIGH VT" visual and sound alarm if the Tidal volume measured stays greater than the maximum tidal volume level set after three consecutive cycles. This alarm is not activated if there is a state of low pressure. This alarm if correctly adjusted can reveal a leak in the patient circuit, even in single-branch.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic. (see paragraph on Alarms and Defaults).

The adjustment of the Vti mini and/or maxi is not mandatory (choice = "NO"); the display of the measured value however remains active.

We recommend, however, keeping the Vti maxi setting active at a threshold, even a high one, by default in the event where load would be lost on the patient circuit after the proximal pressure connection. This is due to the fact that the triggering of the "DISCONNECTION" alarm is not always ensured when the circuit is disconnected.

The Vti is calculated from the flow measured at the apparatus outlet to the patient. The value displayed on the monitoring windows is not necessarily the volume received by the patient since it does not take into account, amongst other things, possible leaks in the patient circuit. It is only in a double-branch circuit setup with the exhalation block that these flow and volume measurements can be more precise and reveal leaks.

■ Vte – EXPIRED TIDAL VOLUME □□□□ ml

A minimum level of expired tidal volume can always be set. However, it will only be able to be used in double-branch setup when an exhalation block is installed (see paragraph on Accessories and Options). Its setting is limited by the set Target Vt level which must stay greater than it.

It can be used to activate an alarm in the event where the tidal volume expired by the patient is less than this limit. Thus, the "LOW VTE" message is displayed after 3 consecutive cycles in these conditions.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The adjustment of the Vti mini is not mandatory (choice = "NO") and the display of the measured value remains active.

■ Fr maxi – MAXI FREQUENCY □□bpm

The set threshold of maximum rate permits the warning of any risk of hyperventilation or racing of the machine. If the rate measured exceeds this level for 3 consecutive cycles, a sound alarm is emitted and the alarm message displayed is "MAXI FREQUENCY".

The maximum rate threshold must always remain greater than the minimum rate (minimum Δ = 5 bpm). If the back up rate is readjusted, the maximum rate is automatically readjusted if necessary on the basis of a minimum difference of 5 bpm.

Above the maximum rate value, whether adjusted or not, a supplementary safety exists from 80 bpm (see paragraph on Alarms and Defaults).

■ FiO_2 – FRACTION OF INSPIRED OXYGEN □□%

In all the modes, FiO_2 mini and FiO_2 maxi thresholds can be set only if there is a sensor to trigger these alarms. These settings cannot be cancelled if a sensor is connected. The settings can be cancelled by the user intentionally only if no sensor is connected. Settings are automatically restored as soon as a sensor is re-connected. An information message will be sent back by the machine in this case to prompt the user to calibrate the sensor once again if necessary (see paragraph on Oxygen Source).

FiO_2 settings are the same for all these modes and there must be a minimum difference between the minimum and maximum thresholds (minimum Δ = 10%).

Alarms called FiO_2 mini and FiO_2 maxi relating to the observance of FiO_2 ranges during ventilation are triggered if:

- the minimum FiO_2 set is not reached during three consecutive cycles.
- the maximum FiO_2 set is exceeded during three consecutive cycles.

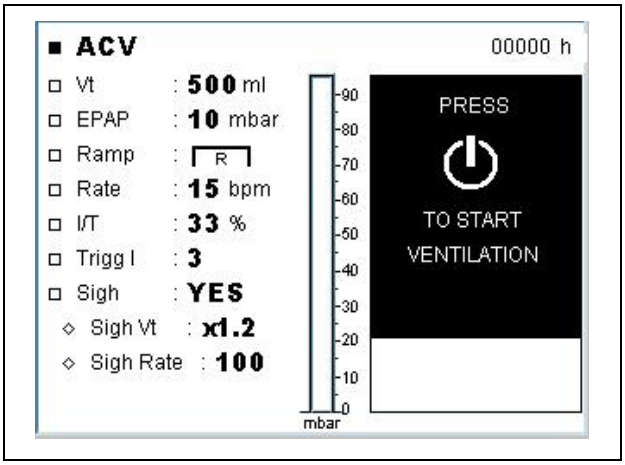
The sound of these alarms may be inhibited for two minutes but their cancellation can only be automatic.

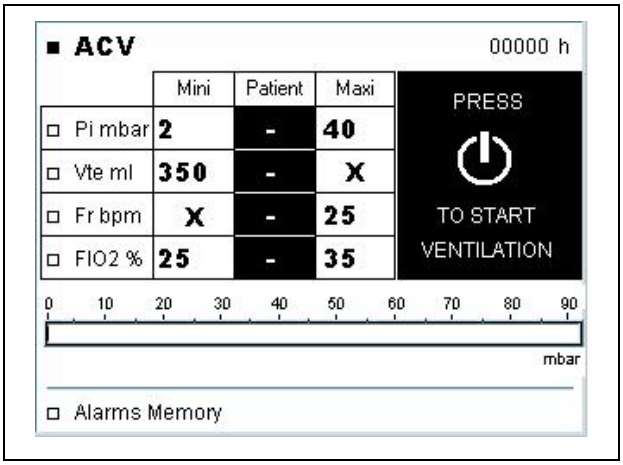
PARAMETERS OF CV / ACV MODES

CV = **C**ontrolled **V**entilation

ACV = **A**ssisted **C**ontrolled **V**entilation

The menus for the **CV** and **ACV** ventilation modes are:





You can "loop" between these menus by moving the cursor with the ▲+ and ▼- keys or jump to a page directly with the 📄 key.

Ventilation parameters that can be set in the menu of modes **CV** / **ACV** and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Vt	ml (or cm^3)	50	1400	10	500	1.5 l/min ≤ Vt x R ≤ 20 l/min
EPAP	mbar (or hPa)	0	20	1	0	-
Ramp	-	R	S	1	D	-
Rate	bpm (or breaths/min)	5	60	1	10	1.5 L/min ≤ Vt x R ≤ 20 L/min
I/T Ratio	%	50	25	1	33	-
Or **I/E Ratio**	-	1/1.0	1/3.0	0.1	1/2.0	-
Trigg I	-	1	5	1	NO	-
Vt Sigh	-	x 1.0	x 2.0	0.1	NO	Vt Sigh ≤ 1,400 ml
Sigh rate	-	50	250	50	NO	-

Changeover from **CV** to **ACV** can be done by selecting and setting a Trigger I. Display of the mode denomination then changes automatically.

Alarm parameters that are adjustable in the menu of modes **CV** / **ACV** and their setting limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Pi mini	mbar (or hPa)	2	35	1	2	Pi mini ≥ EPAP + 2 mbar Pi mini ≤ Pi maxi – 10 mbar
Pi maxi	mbar (or hPa)	15	80	1	40	Pi maxi ≥ EPAP + 15 mbar Pi maxi ≥ Pi maxi + 10 mbar
Vte mini	ml (or cm^3)	30	1250	10	NO	Vte mini ≤ Vt
Fr maxi	bpm (or breaths/min)	10	120	1	NO	Fr maxi ≥ R mini + 5 bpm Keep NO for CV
FiO_2 mini	%	18	90	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %
FiO_2 maxi	%	30	100	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %

Commentary specific to each adjustable parameter:

■ Vt – TIDAL VOLUME □□□□ml

Its setting determines the volume of air to be administered to the patient at each insufflation phase. For physiological and machine performance reasons, its setting is limited by a "Minute Volume" range which corresponds to the product of "Vt x R". However for some patients delivering the tidal volume could in specific cases not be achieved due to limitations of the machine performances. In such a case an alarm « CHECK VT » will be activated.

The volume measured during ventilation is displayed at each cycle in the alarm parameter monitoring menu window.

Reminder: Precaution must be taken to ensure that the patient circuit is well adapted to the tidal volume (tube Ø 22 mm for adults and Ø 15 mm for pediatrics with tidal volume lower than 200 ml).

■ EPAP – POSITIVE EXPIRATORY PRESSURE □□mbar

Its adjustment determines the level of pressure maintained during the expiratory phase. Its value is displayed beside the parameter.

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the average value reached at each cycle is plotted on the bar graph and is repeated in the monitoring window.

■ Ramp – SHAPE OF FLOW □

This parameter permits the adjustment of the flow distribution shape during the insufflation phase. The different shapes available correspond to:

- Ramp R : Rectangle or "constant" flow
- Ramp D : Decelerated or decreasing flow from "max" to zero
- Ramp S : Sinusoidal or half sinus flow

These shapes are executed more or less "faithfully" depending on the physiological characteristics of the patient.

■ Rate – MINIMUM RATE □□bpm

During ventilation in ACV mode, the rate value set is a minimum value. It is only by activating the inspiration trigger that the patient can modify this rate. For physiological and machine performance reasons, the setting of the rate is limited by a "Minute Volume" range which corresponds to the product of Vt x R.

The average rate of the cycles is displayed and is updated continuously after the start of ventilation. The insufflation time nevertheless remains set.

In the absence of an inspiration trigger, the ventilation cycles are linked to the minimum rate as in CV mode.

■ I/T or I/E Ratio – CYCLING RATIO □□% or 1/ □.□

This ratio can be used, in combination with the rate, to adjust the inspiratory time in a cycle. The cycling ratio mode is expressed in the setup menu (see paragraph on Setup):

- I/E ratio: It is expressed as an non-dimensional auto-descriptive ratio with a unitary insufflation time over the Te expiration time brought to the Ti unit:

  $$I/E = 1 / (Te / Ti) = 1 / E$$

- I/T ratio (%): It is expressed as a percentage corresponding to the ratio between the duration of inspiration Ti and the total duration of the respiration cycle Tt = Ti+Te:

  $$I/T (\%) = [Ti / (Ti+Te)] \times 100$$

In ACV mode, the cycling ratio can evolve during ventilation by the inspiration trigger demand made on the part of the patient. The insufflation time nevertheless remains set.

■ Trigg I – INSPIRATION TRIGGER □

The inspiration trigger sets the level of inspiratory effort the patient has to provide during the exhalation period to activate a machine cycle. It is mixed type, which means based on flow or pressure signals. The detection levels are adjusted by an algorithm taking into account the bias flow, the expiratory pressure and the duration of the exhalation to optimize sensitivity and to avoid potential auto triggering phenomena.

The sensitivity levels from 1 to 5 are decreasing: the higher the index is, the lower the trigger sensitivity is. Those levels correspond to flow differences compared to bias flow or to pressure differences compared to expiratory pressure. They are decreasing with the time between 0.7 to 3 s :

- Trigg I 1 = Bias Flow + 3,5 lpm or Pe – 0,3 mbar
- Trigg I 2 = Bias Flow + 4,0 lpm or Pe – 0,5 à 0,7 mbar / Time
- Trigg I 3 = Bias Flow + 4,5 lpm or Pe – 0,6 à 0,8 mbar / Time
- Trigg I 4 = Bias Flow + 4,5 lpm or Pe – 0,7 à 0,9 mbar / Time
- Trigg I 5 = Bias Flow + 4,5 lpm or Pe – 0,8 à 1,0 mbar / Time

WARNING
It is recommended to adapt carefully the trigger threshold in order to avoid a risk of machine self-activation. The level 1, the more sensitive, is convenient for paediatrics.

This parameter can be deleted (choice = NO) and the ventilation mode then becomes **CV** (automatic commutation of the display).

■ Sigh – SIGH VOLUME & RATE x □.□ & □□□□

The sigh function consists of increasing the tidal volume periodically according to the "normal" (base tidal volume) cycle rate. During a sigh, the set flow ramp is kept, the insufflation time is increased to maintain the set cycling ratio and minute volume (VtxF); the rate is therefore decreased on each sigh cycle.

The adjustment of the SIGH is not obligatory, if the choice is "NO" the corresponding lines of parameter adjustment disappear.

When the SIGH choice is "YES", two parameters must be adjusted:

- VOLUME: it is regulated by choosing a tidal volume multiplying factor. The resultant must however not exceed 1,400 ml.
- RATE: this adjustment corresponds to the number of "normal" cycles occurring between each sigh.

■ Pi – LIMIT INSUFFLATION PRESSURE □□ mbar

It is necessary to set a minimum or low pressure and maximum or high pressure alarm threshold.

The Pi mini or Low Pressure setting determines the level of pressure above which the insufflation's phase should occur. When the pressure drops below this level during a delay higher than the setting from 3 to 30 s done in setup menu (see § Setup) a "DISCONNECTION" alarm is activated, this enables the detection of a disconnection or a significant leak (see § Alarms and Defaults).

The Pi maxi or High Pressure setting determines the level of pressure which is not to be exceeded during the insufflation phase. As soon as this level is attained, insufflation is interrupted. An alarm "HIGH PRESSURE" is activated if the level is exceeded for 3 consecutive cycles (see paragraph on Alarms and Defaults).

WARNING
The insufflation pressure can be higher than the limit of 60 mbar set by the norm ISO 10651-2 only for volumetric modes when the high pressure alarm level is set above this level.

Pi mini and Pi maxi must keep a minimum difference between each other and the EPAP level, whose modification may lead to automatic changes to the Pi mini and/or the Pi maxi.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the maximum value reached at each cycle is plotted on the bar graph and is repeated in the monitoring window.

■ Vte – EXPIRED TIDAL VOLUME □□□□ ml

A minimum level of expired tidal volume can always be set. However, it will only be able to be used in double-branch setup when an exhalation block is installed (see paragraph on Accessories and Options). Its setting is limited by the Vt level set which must stay greater than it.

It can be used to activate an alarm in the event where the tidal volume expired by the patient is less than this limit. Thus, the "LOW VTE" message is displayed after 3 consecutive cycles in these conditions.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The adjustment of the Vti mini is not mandatory (choice = "NO") and the display of the measured value remains active.

■ Fr maxi – MAXI FREQUENCY □□bpm

The maximum rate threshold set permits the warning of any risk of hyperventilation or racing of the machine. If the rate measured exceeds this level for 3 consecutive cycles, a sound alarm is emitted and the alarm message displayed is "MAXI FREQUENCY".

The maximum rate threshold must always remain greater than the minimum rate (minimum Δ = 5 bpm). If the back up rate is readjusted, the maximum rate is automatically readjusted if necessary on the basis of a minimum difference of 5 bpm.

Above the maximum rate value, whether adjusted or not, a supplementary safety exists from 80 bpm (see paragraph on Alarms and Defaults).

■ FiO_2 – FRACTION OF INSPIRED OXYGEN □□%

In all the modes, FiO_2 mini and FiO_2 maxi thresholds can be set only if there is a sensor to trigger these alarms. These settings cannot be cancelled if a sensor is connected. The settings can be cancelled by the user intentionally only if no sensor is connected. Settings are automatically restored as soon as a sensor is re-connected. An information message will be sent back by the machine in this case to prompt the user to calibrate the sensor once again if necessary (see paragraph on Oxygen Source).

FiO_2 settings are the same for all these modes and there must be a minimum difference between the minimum and maximum thresholds (minimum Δ = 10%).

Alarms called FiO_2 mini and FiO_2 maxi relating to the observance of FiO_2 ranges during ventilation are triggered if:

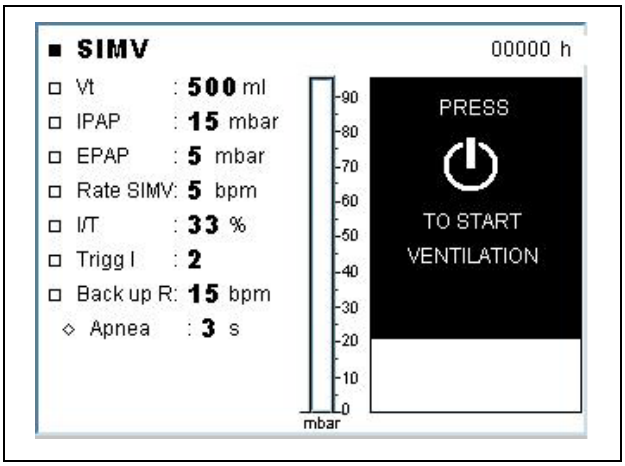
- the minimum FiO_2 set is not reached during three consecutive cycles.
- the maximum FiO_2 set is exceeded during three consecutive cycles.

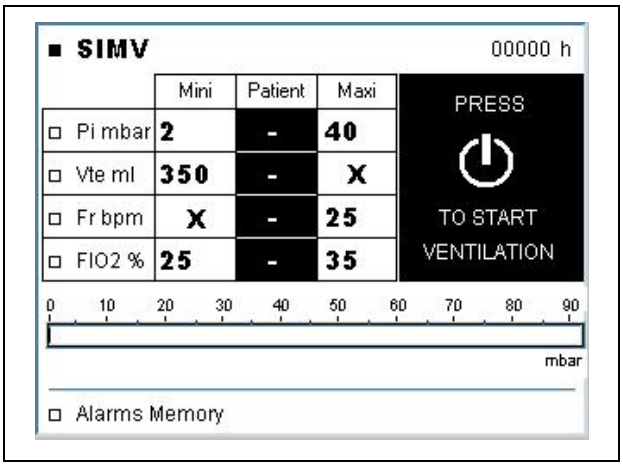
The sound of these alarms may be inhibited for two minutes but their cancellation can only be automatic.

PARAMETERS OF SIMV MODE

SIMV = **S**ynchronous **I**ntermittent **M**andatory **V**entilation

The menus for the **SIMV** ventilation mode are:





You can "loop" between these menus by moving the cursor with the ▲+ and ▼- keys or jump to a page directly with the key.

The adjustable ventilation parameters in the **SIMV** mode menu and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Vt	ml (or cm^3)	50	1400	10	500	1.5 l/min ≤ Vt x BUR ≤ 20 l/min
IPAP	mbar (or hPa)	5	40	1	15	IPAP ≥ EPAP + 5 mbar
EPAP	mbar (or hPa)	0	20	1	0	EPAP ≤ IPAP – 5 mbar
Rate SIMV	bpm (or breaths/min)	2	20	1	5	Rate SIMV ≤ BUR – 2 bpm
I/T Ratio	%	50	25	1	33	-
Or **I/E Ratio**	-	1/1.0	1/3.0	0.1	1/2.0	-
Trigg I	-	1	5	1	2	-
Back Up R	bpm (or breaths/min)	4	40	1	10	1.5 l/min ≤ Vt x BUR ≤ 20 l/min BUR ≥ Rate SIMV + 2 bpm
Apnea	s	3	30	1	AUTO = Maxi[3;60/R]	30/BUR ≤ Apnea ≤ 180/BUR.

Alarm parameters that are adjustable in the menu of mode **SIMV** and their adjustment limits are as follows:

Adjustment parameters	Unit	Min. Value	Max. Value	Pitch	Default value	Limitation of adjustment by
Pi mini	mbar (or hPa)	2	35	1	2	Pi mini ≥ EPAP + 2 mbar Pi mini ≤ IPAP Pi mini ≤ Pi maxi – 10 mbar
Pi maxi	mbar (or hPa)	15	80	1	40	Pi maxi ≥ EPAP + 15 mbar Pi maxi ≥ IPAP + 2 mbar Pi maxi ≥ Pi mini + 10 mbar
Vte mini	ml (or cm^3)	30	1250	10	NO	Vte mini ≤ Vt
Fr maxi	bpm (or breaths/min)	10	120	1	NO	Fr maxi ≥ BUR + 5 bpm
FiO_2 mini	%	18	90	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %
FiO_2 maxi	%	30	100	1	NO	FiO_2 mini ≤ FiO_2 maxi – 10 %

Commentary specific to each adjustable parameter:

■ Vt – TIDAL VOLUME □□□□ml

Its setting determines the volume of air to be administered to be patient at each insufflation phase of intermittent or successive volume cycles in the event of patient apnea. For physiological and machine performance reasons, its setting is limited by a "Minute Volume" range which corresponds to the product of "Vt x Back up R". However for some patients delivering the tidal volume could in specific cases not be achieved due to limitations of the machine performances. In such a case an alarm « CHECK VT » will be activated.

The volume measured during ventilation is displayed at each cycle in the alarm parameter monitoring menu window.

Reminder: Precaution must be taken to ensure that the patient circuit is well adapted to the tidal volume (tube Ø 22 mm for adults and Ø 15 mm for pediatrics with tidal volume lower than 200 ml).

■ IPAP – INSUFFLATION PRESSURE □□mbar

Its setting determines the level of pressure reached during insufflation phases of spontaneous barometric cycles. Its value is displayed beside the parameter. IPAP is an absolute value independent of the EPAP and must always be greater than PAP.

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the maximum value reached at each cycle is plotted on the bar graph and is repeated in the alarm parameter monitoring menu window.

As a safety measure, a “DISCONNECTION” alarm may be activated if the insufflation’s pressure level is not reached (see § Alarms and Defaults.)

■ EPAP – POSITIVE EXPIRATORY PRESSURE □□mbar

Its adjustment determines the level of pressure maintained during the expiratory phase. Its value is displayed beside the parameter. The EPAP must always be less than the IPAP (minimum Δ = 5 mbar).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the average value reached at each cycle is plotted on the bar graph and is repeated in the monitoring window.

■ Rate SIMV □□bpm

The Rate or SIMV period is used to define a duration during which, except for apnea phases, the volume and barometric cycles alternate between each other. During this period, all the cycles are synchronized on inspiration triggers. A SIMV period always includes a volume cycle plus as many barometric cycles as have been triggered by the patient; beyond the SIMV period the following inspiration trigger will initiate a new volume cycle and so forth. The SIMV rate must be less than the back up rate so that "complete" volume cycles have a duration less than the SIMV period and enables the patient to make spontaneous barometric cycles between two volume cycles.

■ I/T or I/E Ratio – CYCLING RATIO □□% or 1/ □.□

This ratio can be used, in combination with the back up rate, to adjust the inspiratory time in volume cycles. The cycling ratio mode is expressed in the setup menu (see paragraph on Setup):

- I/E ratio: It is expressed as an non-dimensional auto-descriptive ratio with a unitary insufflation time over the Te expiration time brought to the Ti unit:

$$I/E = 1 / (Te / Ti) = 1 / E$$

- I/T ratio (%): It is expressed as a percentage corresponding to the ratio between the duration of inspiration Ti and the total duration of the respiration cycle Tt = Ti+Te:

$$I/T\ (\%) = [Ti / (Ti+Te)] \times 100$$

The cycling ratio can evolve during ventilation by the patient inspiration triggering. The volume cycle insufflation time nevertheless remains set.

■ Trigg I – INSPIRATION TRIGGER □

The inspiration trigger sets the level of inspiratory effort the patient has to provide during the exhalation period to activate a machine cycle. It is mixed type, which means based on flow or pressure signals. The detection levels are adjusted by an algorithm taking into account the bias flow, the expiratory pressure and the duration of the exhalation to optimize sensitivity and to avoid potential auto triggering phenomena.

The sensitivity levels from 1 to 5 are decreasing: the higher the index is, the lower the trigger sensitivity is. Those levels correspond to flow differences compared to bias flow or to pressure differences compared to expiratory pressure. They are decreasing with the time between 0.7 to 3 s :

- Trigg I 1 = Bias Flow + 3,5 lpm or Pe – 0,3 mbar
- Trigg I 2 = Bias Flow + 4,0 lpm or Pe – 0,5 à 0,7 mbar / Time

- Trigg I 3 = Bias Flow + 4,5 lpm or Pe – 0,6 à 0,8 mbar / Time
- Trigg I 4 = Bias Flow + 4,5 lpm or Pe – 0,7 à 0,9 mbar / Time
- Trigg I 5 = Bias Flow + 4,5 lpm or Pe – 0,8 à 1,0 mbar / Time

WARNING
It is recommended to adapt carefully the trigger threshold in order to avoid a risk of machine self-activation. The level 1, the more sensitive, is convenient for paediatrics.

■ Back up R – BACK UP RATE □□bpm

The back up rate determines two elements necessary to ventilation: the insufflation time of (triggered or controlled) volume cycles and the rate of volume cycles to be provided in the case of patient apnea. The ventilator shall provide volume cycles at this rate after an apnea limit and as long as no inspiration trigger is detected. The inspiratory time of these cycles is determined by the rate and the cycling ratio. The flow ramp of these cycles is identical to those of the cycles triggered by the patient. The successive controlled cycles are interrupted as soon as a new spontaneous inspiration of the patient is detected in favour of alternating volume and barometric cycles according to the SIMV period or rate.

The adjustment of the back up rate is limited by a "Minute Volume" range that corresponds to the product of "Vt x Back up R" and by the SIMV rate so that "complete" volume cycles have a duration less than the SIMV period and enables the patient to make spontaneous barometric cycles between two volume cycles.

Associated apnea time can be set, enabling "pauses" between spontaneous cycles whose rate may be less than the back-up rate (see below).

When ventilation cycles consecutive to an apnea are activated, the "CONTROLLED CYCLES" message appears in the alarm message window (see paragraph on Alarms and Defaults) and flashes during the application period of these cycles.

■ Apnea – APNEA LIMITS □□ s

The limits of apnea time and the default or "Auto" value proposed directly depend on the back up rate that was set: 30 / Rate ≤ Apnea Time ≤ 180 / R and Auto Apnea = 60 / R within the limit of 3 to 30 s.

■ Pi – LIMIT INSUFFLATION PRESSURE □□ mbar

It is necessary to set a minimum or low pressure and maximum or high pressure alarm threshold.

The Pi mini or Low Pressure setting determines the level of pressure above which the insufflation phase should occur during the volume cycles. The pressure level that is taken into account for pressure cycle is the maximum value between the level deduced from the inspiration pressure set for the pressure cycles and the value of the Pi mini set for the volume cycles : max of Pi mini set and Pi – 20%.

When the pressure drops below this level an alarm is activated after the max value between the apnea time +1s or after 3 to 30s if set in the Set Up menu (refer to § Set Up); a “DISCONNECTION” alarm is triggered, which enables the detection of a disconnection or a significant leak (see paragraph on Alarms and Defaults).

The Pi Maxi or High Pressure setting determines the level of pressure which is not to be exceeded during insufflation phases of volume cycles. As soon as this level is attained, insufflation is interrupted. An alarm “HIGH PRESSURE” is activated if the level is exceeded for 3 consecutive cycles (see paragraph on Alarms and Defaults).

WARNING
The insufflation pressure can be higher than the limit of 60 mbar set by the norm ISO 10651-2 only for volumetric modes when the high pressure alarm level is set above this level.

Pi mini and Pi maxi must keep a minimum difference between them and the IPAP and EPAP level; modifications to them may lead to automatic changes to the Pi mini and/or the Pi maxi. If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The pressure recorded during ventilation is displayed in the form of a bar graph in each menu; the maximum value reached at each cycle is plotted on the bar graph and is repeated in the monitoring window.

■ Vte – EXPIRED TIDAL VOLUME □□□□ ml

A minimum level of expired tidal volume can always be set. However, it will only be able to be used in double-branch setup when an exhalation block is installed (see paragraph on Accessories and Options). Its setting is limited by the Vt level set which must stay greater than it.

It can be used to activate an alarm in the event where the tidal volume expired by the patient is less than this limit. Thus, the "LOW VTE" message is displayed after 3 consecutive cycles in these conditions.

If a sound warning goes into effect, it will be possible to inhibit it for two minutes but its cancellation can only be automatic (see paragraph on Alarms and Defaults).

The adjustment of the Vte mini is not mandatory (choice = "NO") and the display of the measured value remains active.

Nevertheless we recommend to use a double branch circuit and to let active the Vte mini setting when load losses should be present on the patient circuit downstream the proximal pressure link because in such a case the “DISCONNECTION” alarm triggering could not be systematically done when a circuit disconnection occurs.

■ Fr maxi – MAXI FREQUENCY □□bpm

The maximum rate threshold set permits the warning of any risk of hyperventilation or racing of the machine. If the rate measured exceeds this level for 3 consecutive cycles, a sound alarm is emitted and the alarm message displayed is "MAXI FREQUENCY".

The maximum rate threshold must remain greater than the back up rate (minimum Δ = 5 bpm). If the back up rate is readjusted, the maximum rate is automatically readjusted if necessary on the basis of a minimum difference of 5 bpm.

Above the maximum rate value, whether adjusted or not, a supplementary safety exists from 80 bpm (see paragraph on Alarms and Defaults).

■ FiO_2 – FRACTION OF INSPIRED OXYGEN □□%

In all the modes, FiO_2 mini and FiO_2 maxi thresholds can be set only if there is a sensor to trigger these alarms. These settings cannot be cancelled if a sensor is connected. The settings can be cancelled by the user intentionally only if no sensor is connected. Settings are automatically restored as soon as a sensor is re-connected. An information message will be sent back by the machine in this case to prompt the user to calibrate the sensor once again if necessary (see paragraph on Oxygen Source).

FiO_2 settings are the same for all these modes and there must be a minimum difference between the minimum and maximum thresholds (minimum Δ = 10%).

Alarms called FiO_2 mini and FiO_2 maxi relating to the observance of FiO_2 ranges during ventilation are triggered if:

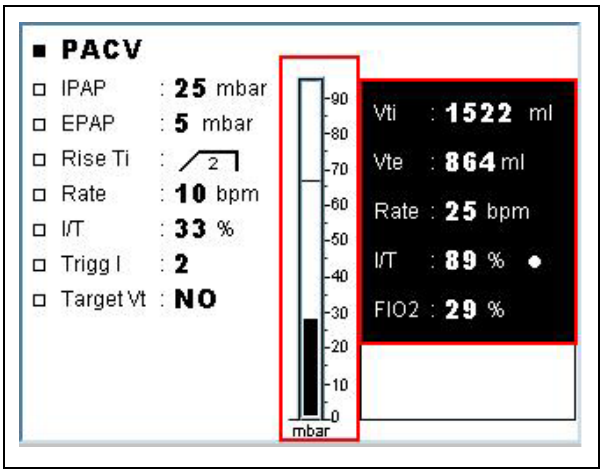
- the minimum FiO_2 set is not reached during three consecutive cycles.
- the maximum FiO_2 set is exceeded during three consecutive cycles.

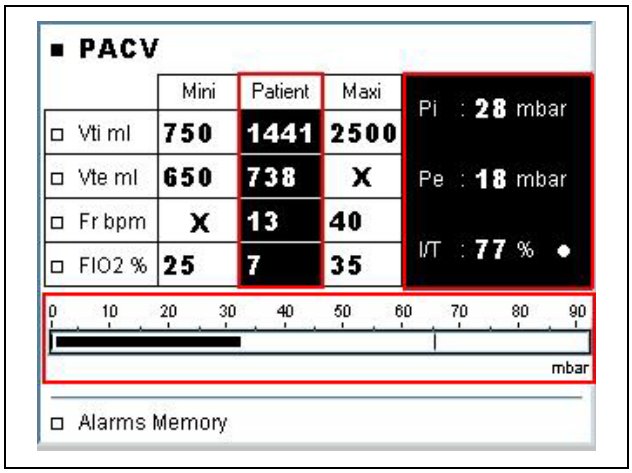
The sound of these alarms may be inhibited for two minutes but their cancellation can only be automatic.

MEASUREMENT VISUALISATION

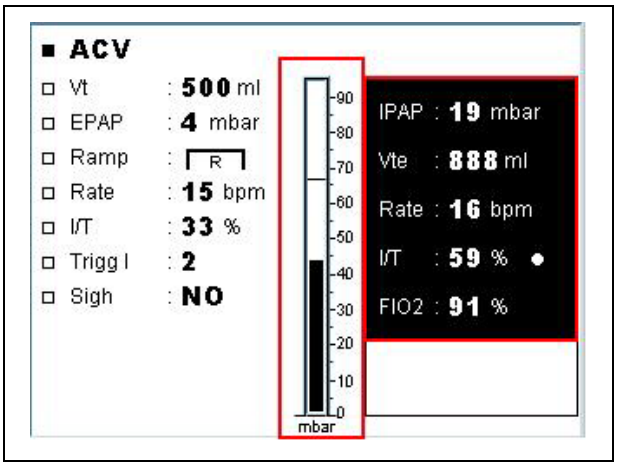
When ventilation is in progress, the main parameters, measured or calculated, pertaining to the ventilation in progress, may be viewed in each menu.

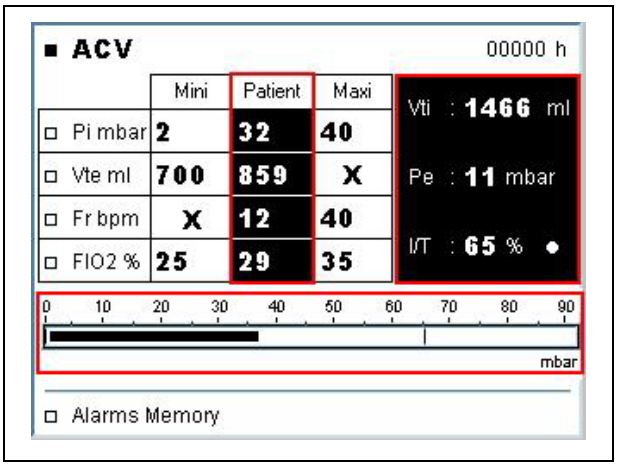
These "monitorings" are all displayed in reverse video, supplementing the ventilation or alarm parameters that differ depending on the modes classified as barometric type (PSV S, PSV ST, PCV, PACV:)





and volume type (CV, ACV, SIMV):





The different types of monitoring are defined as follows:

■ Volumes – Vti & Vte □□□□ml

Tidal volume inspired – Vti: this is the tidal volume sent by the ventilator at each cycle. It is calculated on the basis of measurements of flow leaving the apparatus during the insufflation phase; it does not take circuit leaks into account.

Tidal volume expired – Vte: this is the tidal volume returned by the patient at each cycle. However, it will only be able to be used in double-branch setup when an exhalation block is installed (see paragraph on Accessories and Options). It is calculated on the basis of measurements of flow entering the apparatus minus the outgoing rinsing flows during the expiration phase.

The precision of calculation of volumes is ± 20% below 150 ml and ± 10% above. The Vti and Vte results are rounded off to the nearest ± 5 ml.

Note: The flow measurements and thus the volume calculations that result are influenced by variations in atmospheric pressure. A calibration of the sensors is recommended if there is a significant difference from 1000 hPa atmospheric pressure (see paragraph on Sensor Calibration). For example, altimetric variation of 1000 m leads to a variation of flow measurement of the order of 10%.

■ **Pressures – IPAP & EPAP** □□mbar

The pressure levels reached during each ventilation cycle are returned both in the form of a bar graph where values reached are plotted and in the form of numeric values in the monitoring windows.

Numeric values are refreshed at each cycle and correspond to the maximum pressure level reached during the inspiration phase and the average pressure level reached during the expiration phase respectively.

The precision of pressure measurement is ± (0.8 mbar + 4% of reading). The results are rounded off to ± 1 mbar.

■ **R – RATE** □□bpm

The actual cycling rate is returned at the end of each complete ventilation cycle.

The precision of calculation of the rate is ± 1 bpm.

■ **I/T or I/E Ratio – CYCLING RATIO** □□% or 1/ □.□

The actual cycling ratio is returned at the end of each complete ventilation cycle.

The cycling ratio mode is expressed in the setup menu (see paragraph on Setup):

- I/E ratio: It is expressed as an non-dimensional auto-descriptive ratio with a unitary insufflation time over the Te expiration time brought to the Ti unit:

  $$I/E = 1 / (Te / Ti) = 1 / E$$

- I/T ratio (%): It is expressed as a percentage corresponding to the ratio between the duration of inspiration Ti and the total duration of the respiration cycle Tt = Ti+Te:

  $$I/T\ (\%) = [Ti / (Ti+Te)] \times 100$$

The precision of calculation of the cycling ratio is ± 10%.

■ **Inspiration Trigger** (●)

During each insufflation phase triggered by an inspiratory effort on the part of the patient (upon each detection of an inspiration trigger), the "●" symbol is displayed to the right of the actual cycling ratio.

■ **FiO_2 – FRACTION OF INSPIRED OXYGEN** □□%

If an oxygen sensor is connected to the ventilator, the FiO_2 reached during each insufflation phase is displayed, rounded to ± 1% at each end of insufflation. This is an average of measurements taken during the insufflation phase.

ALARMS AND DEFAULTS

The alarms or defaults managed by your **LEGENDAIR®** ventilator are classified in two categories: ventilation or utilisation alarms, and technical defaults addressed only to maintenance technicians.

VENTILATION – UTILISATION ALARMS

Some of the alarms managed by your **LEGENDAIR®** ventilator can or must be adjusted depending on ventilation modes (see paragraph on Adjustment of Operating Parameters). Other alarms that cannot be parametered by the user are used to ensure a permanent level of apparatus safety for the patient.

Those that are signalled directly by text messages and/or sounds handle events likely to affect the ventilation in progress in the short term and necessitate rapid interventions (see paragraph on Resolution of Incidents). These may be accompanied by the illumination of reminders on the front face of the apparatus. Certain alarms that are more secondary are signalled only by visual messages.

The general convention for criticality and signalling of alarms is as follows:

- **Very High Priority (VHP): Immediate critical situation; ventilation is impossible:** Continuous Sound Signalling / With or Without Continuous Red LED Illumination / With or Without Message / With or Without Display Lighting
- **High Priority (HP): Critical situation in the short term; ventilation is potentially compromised:** High Frequency Sound Signalling / Flashing Red LED Illumination / With Message / With Display Lighting
- **Medium Priority (MP): Critical situation in the long term; ventilation is not affected in the short term.** Medium Frequency Sound Signalling / Flashing Orange LED Illumination / With Message / With Display Lighting
- **Low Priority (LP): Signalling to be judged by the user.** No Sound Signal / Continuous Orange LED Illumination / With Message / No Display Lighting
- **Very Low Priority (VLP): Information for the user.** With or Without Sound Signalling / Without LED Illumination / With Direct or Indirect Message / Without Display Lighting
- **No Priority (NP): Inconsequential** No Signalling / Automatic recovery action.

In the event where several alarms are activated at the same time, the sound and light signals in force are those of the highest priority alarm but the visual messages are all displayed in turn (see paragraph on Visualisation and inhibition of alarms).

Alarms relative to the ventilation or use available on your **LEGENDAIR®** ventilator are the following:

Alarm Parameters	Associated Message	Activation modalities	Type	Sound inhibition (2 min)
Low pressure	DISCONNECTION	Patient pressure less than Pi mini (in CV/ACV and CV/CAV cycles for SIMV) or IPAP – 20% (in PSV/PCV/PACV) or maxi between Pi mini and IPAP – 20% (PSV cycles for SIMV) for more than the triggering delay set (see § Setup) or maxi time between the set triggering delay and Apnoea Time + 1 s for PSV ST and SIMV	High Priority	YES
High Pressure	HIGH PRESSURE	Inspiratory pressure greater than Pi maxi (CV/ACV/SIMV) or greater than IPAP +20% (PSV/PCV/PACV) Immediate passage on exhalation for all ventilation modes. Alarm signal after three consecutive cycles (CV/ACV/SIMV)	High Priority	YES
		Inspiratory and expiratory pressure greater than Pi maxi or IPAP + 20% for three consecutive cycles	High Priority	YES
Apnea	CONTROLLED CYCLES	This message appears only in PSV ST and SIMV in the event where no inspiration trigger is detected by the ventilator past a set apnea time.	Very Low Priority	Not applicable
Volume inspired	LOW VTI	Inspired tidal volume less than the minimum tidal volume threshold set for three consecutive cycles (PSV/PCV/PACV)	Medium Priority	YES
	HIGH VT	Inspired tidal volume greater than the maximum tidal volume threshold set for three consecutive cycles Unless DISCONNECTION is in progress (PSV/PCV/PACV)	High Priority	YES
	CHECK VT	Inspired tidal volume 10% higher or lower than the tidal volume set for at least six consecutive cycles after the inter cycle volume automatic adjustment (CV/ACV/SIMV)	High Priority	YES
Volume expired	LOW VTE	Expired tidal volume less than the minimum tidal volume threshold set for three consecutive cycles	Medium Priority	YES
Rate	MAXI FREQUENCY	Measured rate greater than the maximum rate threshold set for three consecutive cycles	Medium Priority	YES
	HIGH RATE	Measured rate greater than 80 bpm for 30 consecutive cycles	High Priority	YES
FiO_2	LOW FIO2	Measured FiO_2 less than the minimum FiO_2 threshold set for 15 s	Medium Priority	YES
	HIGH FIO2	Measured FiO_2 greater than the maximum FiO_2 threshold set for 15 s	Medium Priority	YES
	FIO2 FAIL	Disconnection or absence of the FiO_2 sensor when the alarm thresholds are set	High Priority	YES
	CALIBRATE FIO2	Detection of the FiO_2 sensor when no alarm threshold has been set Automatic recall of previous alarm thresholds	Low Priority	YES Permanent
	CALIBRATION FAILURE	Calibration of the FiO_2 sensor outside tolerance ranges Recall of previous calibration or by default	Low Priority	YES Permanent

Alarm Parameters	Associated Message	Activation modalities	Type	Sound inhibition (2 min)
Electrical power supply interruption	POWER FAIL	Interruption of the AC mains electrical power supply Switchover to the external DC battery power supply or internal battery.	Medium Priority	YES Permanent
	DC POWER FAIL	Interruption of the DC external power supply Switchover to the internal battery.	Medium Priority	YES Permanent
Internal Battery	EMPTY BATTERY	Charge level of the internal battery < 5% Or supply level < 23.8 V if internal battery under default	High Priority	YES
	END OF BATTERY	Charge level of the internal battery = 0% Or supply level < 21.8 V if internal battery under default Ventilation stops immediately	Very High Priority	NO
	CHECK BATTERY	Charging of the internal battery impossible Monitoring problem of the power supply voltages For more than 1 min 30 s	Medium Priority	YES
Pressure measure-ment	CHECK PRESSURE	Abnormal pressure: Constant or negative pressure for more than 45 s (except if DISCONNECTION active)	Medium Priority	YES
		Abnormal pressure: Constant or negative pressure for more than 2 min (except if DISCONNECTION active)	High Priority	YES
Expiration valve	CHECK VALVE	Abnormal valve internal pressure for 15 s or measured EPAP > EPAP + 10 hPa for 45 s	Medium Priority	YES
		Abnormal valve internal pressure or measured EPAP > EPAP + 10 hPa for 2 min	High Priority	YES
	VALVE LEAKAGE	Expired flow abnormally high during the inspiration phase (in double-branch version)	Medium Priority	YES
Internal memory	CHECK PARAMETERS	Loss of memorised parameters This alarm is systematic after downloading of new software.	Medium Priority	YES Permanent
Keyboard	CHECK KEYS	Key of the keyboard not released for 20 s (*)	High Priority	NO
Involuntary Stop	-	Electrical power supply to the machine is interrupted with the switch when ventilation is in progress	Very High Priority	NO

Note: If electrical power supply to the machine is interrupted with the switch when ventilation is in progress, the apparatus re-starts directly in ventilation when the power supply is restored.

WARNING
(*) When the keys ⊕ or ⊖ are united, the effective activation of all alarms is temporized for 20 seconds.

TECHNICAL DEFAULTS

The user is not directly alerted of technical defaults that do not directly affect machine operation or will not affect it in the short-term. Technical anomalies may be consulted via the Maintenance menu (see § Maintenance.)

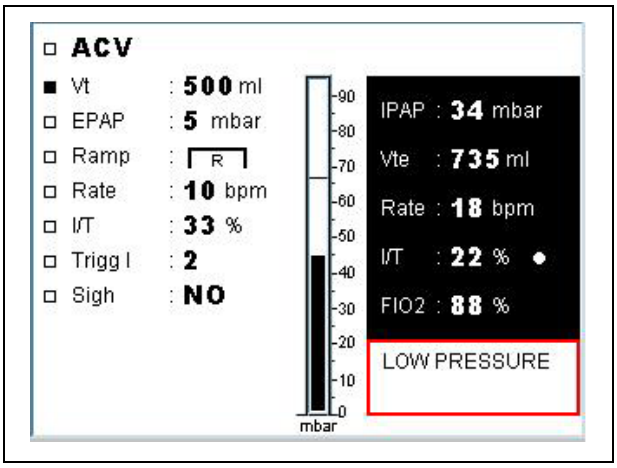
A number corresponds to each type of default. This information can be taken into account by authorised and trained technicians during periodic visits.

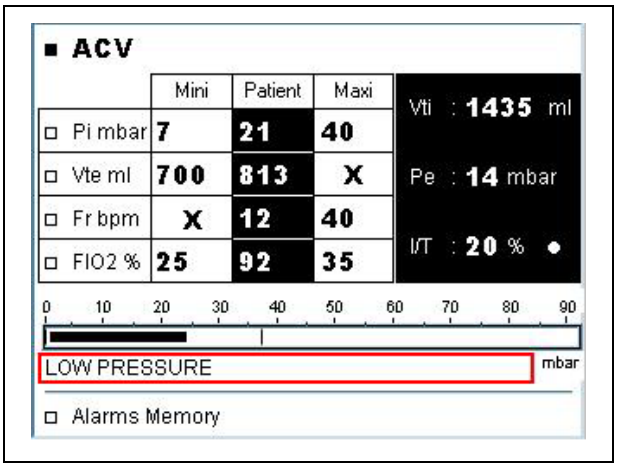
Possible technical defaults are as follows:

Default parameters	Associated Message	Technical cause	Type
Inspired flow measure-ment	No. 1	Flow constant for one minute (except if DISCONNECTION active)	Very Low Priority
	No. 2	Sensor calibration not performed or faulty	Low Priority
Expired flow measure-ment	No. 3	Sensor calibration not performed or faulty	Low Priority
Valve pressure measure-ment	No. 4	Sensor calibration not performed or faulty	Low Priority
Patient pressure measure-ment	No. 5	Sensor calibration not performed or faulty	Low Priority
Turbine speed measure-ment	No. 6	Abnormal turbine speed measurement	Very Low Priority
Clock	No. 7	Loss of clock parameters	Very Low Priority
Buzzer	No. 8	Buzzer electrical supply insufficient	Very Low Priority

VISUALISATION AND INHIBITION OF ALARMS

During operation, when an alarm is activated, one of the red or orange keypad indicators to the left of the button lights up, either continuously or flashing (depending on the alarm priority), a sound signal may be activated (according to alarm priority) and finally the message about the current alarm appears and flashes at the bottom of the menu for as long as the causes have not disappeared:



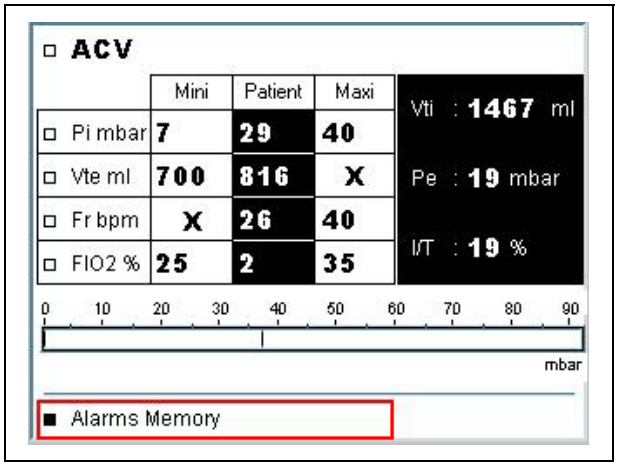


In the event where several alarms are activated at the same time, the sound and light signals in force are those of the highest priority alarm but the visual messages are all displayed, in turn.

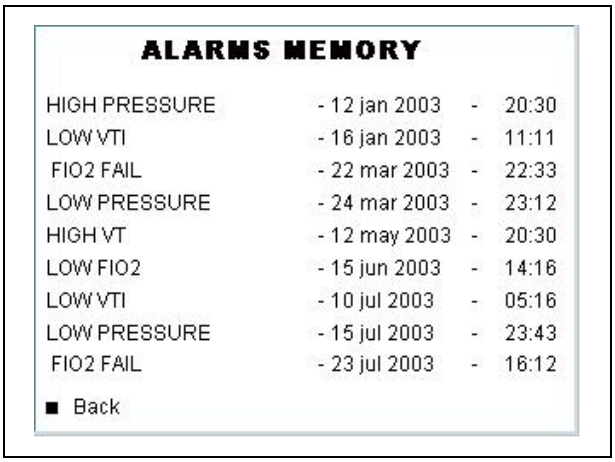
It is possible to inhibit a sound alarm for a short time (for two minutes) by pressing the key (except for Very High Priority alarms) in whichever menu you are. Inhibited alarms are automatically reactivated after two minutes if the causes persist (unless exception).

All alarms are recorded in the internal memory of the ventilator at the time they are activated. In this way, you can view the last 9 alarm messages saved at any time (ventilation in progress or on stand-by).

To do so, access the alarm parameter menu of the mode in progress, place the cursor on the "Alarms Memory" line located at the bottom of the page with the key if necessary; then press the key:



The following menu is accessed:



This menu is displayed for 15 s. You can intentionally quit the menu by pressing ✓.

These accesses are possible regardless of the software lock status.

Note: The alarm memory list displayed by the apparatus can sometimes show a message "???", it's only a reading error of alarm code in the memory without any consequences on the device operating.

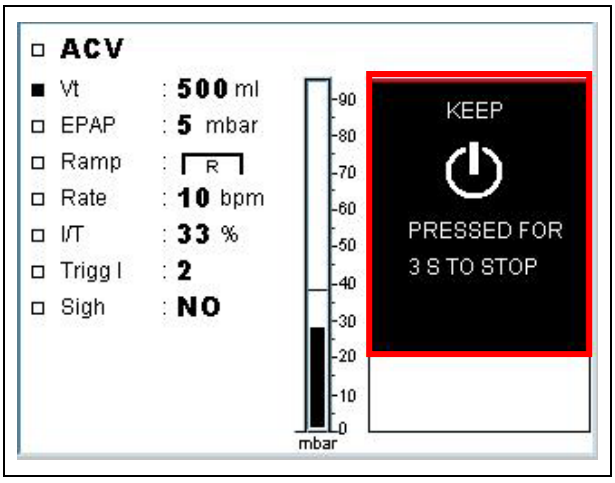
Note: It is also possible to consult all the alarms as well as events recorded by the ventilator with a PC equipped with **AIROX COMMUNICATION** software (see paragraph on Accessoires and Options). The alarm « CHECK KEYS » will be displayed as default n°9 in **AIROX COMMUNICATION** for versions before V3.5.1.

STOPPING THE APPARATUS

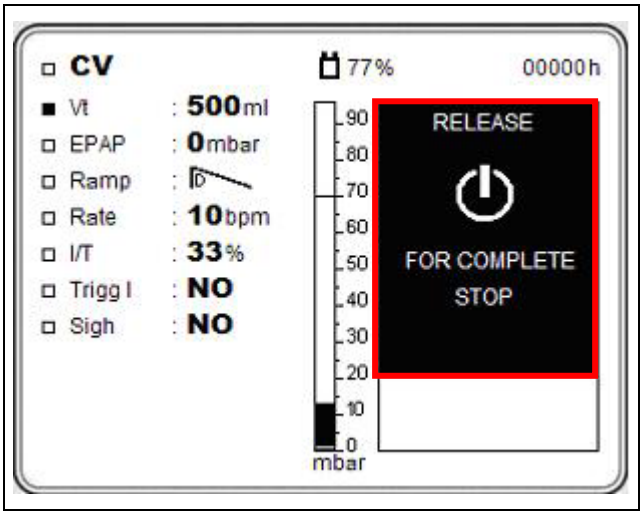
Stopping your **LEGENDAIR®** ventilator is possible from any menu. When the ventilation is in progress the device must be stopped through two steps:

- **Step n°1** : Stopping the ventilation

By keeping the ⏻ button pressed for 3 seconds, the ventilation in progress will then stop and the software is put in stand-by mode. A message prompting the user to keep the button pressed appears on the monitoring window:



Once the above mentionned time has passed keeping the⏻ button pressed, a new message will inform the user to release the key for ventilation to effectively stop:



The effective stop of the ventilation will be obtained only after releasing the ⏻ button. The blue LED located at the left of the ⏻ button lights up to show apparatus stand-by status and the message for a new start of the ventilation is displayed.

- **Step n°2** : Switching off the device

This can be done by using the switch located at the back of the equipment and protected by a self closing cover (if present). Mains power source is then cut.

Only this step is required when the ventilator is out of ventilation whatever the displayed menu is.

WARNING
When ventilation is in progress if the ventilator is stopped by direct interruption from the switch without previously stopping the ventilation, a continuous and non inhibable alarm is activated during some minutes. **Then when the apparatus is switched back on, it will directly start ventilating without having to press the ⏻ button.**

Note: When the apparatus is completely stopped but mains is still connected (green led ~ active), the charge of internal battery is still assured.

LOCKING KEY

When the machine is in service at a patient's home, it is advised to unit the possibilities of adjustment by the installation of the locking key.

The locking key of your **LEGENDAIR®** ventilator is a software program. It enables the prohibiting of access to the ventilation parameter settings and changes of ventilation mode in order to distinguish between "clinician" use or "patient" use.

To lock the access to the settings as well as access to the changes in ventilation modes you must press on the ▲+ and ▼- keys simultaneously for 6 seconds. The locking key symbol 🔑 will appear in the top left corner of the screen.

Once the locking key is in place, only the inter-menu navigation, apparatus on/off and ventilation functions are available.

To take off the locking key, you must repeat the previous operations above. The locking key symbol disappears and all adjustments and changes are again possible.

HOUR METERS

Your **LEGENDAIR®** ventilator has two types of hour meters:

MACHINE HOUR METER

The machine hour meter indicates the full number of hours of operation of the ventilator from the first time it was run. It is displayed in the welcome menu when the apparatus is started and can also be consulted in the maintenance menu.

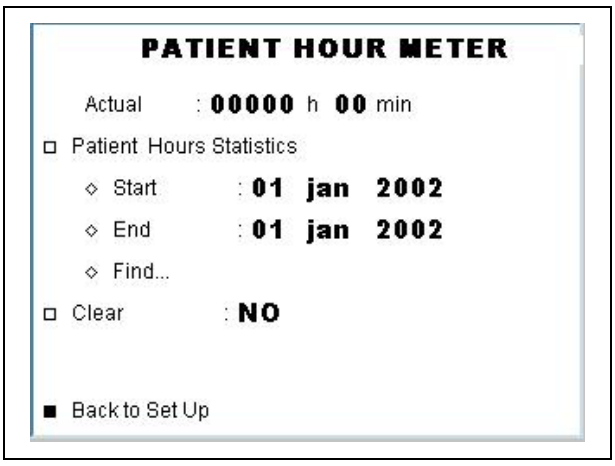
Note: the machine hour meter is reset if the motherboard is changed.

PATIENT HOUR METER

The patient hour meter indicates the number of hours and minutes of effective ventilation starting from the last time the timer was reset.

It is displayed in the welcome menu when the apparatus is started and is recalled at the top right-hand corner of each menu when the apparatus is on stand-by and for one minute after ventilation has been started. It can also be consulted in a menu specific to hour meter management that can be accessed from the setup menu (see paragraph on Setup).

The patient hour meter management menu accessible from the setup menu has the following presentation:



Operations that can be done from this menu are:

- Consultation of patient hour meter in progress
- Access to a "statistic" search on the machine utilisation rate by the patient.
- Clearing the current hour meter in order to start the hour meter at the time of installation of a new patient

Statistical search of the patient timer

The "statistic" search on the machine utilisation by the patient can be used to find out real utilisation time (time of effective ventilation) between two dates set. This search is done by placing the cursor on the "Patient Hours Statistics" line then by pressing the ✓ key. The cursor then goes automatically to the "Start" line. The start and end dates can be adjusted in the same way as the other parameters with the following limitations:

- Start date = no earlier, and by default, the date the last time the last hour meter was cleared
- End date = no later, and by default, the current date.

No statistical search on the hour meter can be done until the hour meter has first been cleared.

After adjusting (or not) these two dates, the search can be launched. To launch the search, place the cursor on the "Search" line and launch the operation with the ✓ button. After calculation, the total time is returned in the form "Total: 00020h05min".

The counting of the daily ventilation durations is based on the total of the times between 12:00 (the day before the start date) and 12:00 (of the end date).

Clearing the patient hour meter

The hour meter can be cleared using the same procedure as for parameter modification: placement of the cursor on the "Clear" line, press on ✓, press on ▲ or ▼ to go to YES then press on ✓ again to validate your choice.

The hour meter immediately changes to 00000h00min.

The patient hour meter stays at zero until the machine has not been cleared a first time.

To quit this menu, you can either place the cursor on the "Back to Set Up" line then press the ✓ key, or stop the machine with the main switch.

OPERATION WITH INTERNAL BATTERY

⚠ *WARNING*
Ensure that the battery is fully charged before ventilating the patient. **Charge the battery after unpacking the device.** **Due to its limited autonomy, the ventilator should only be operated occasionally with its internal battery.** **A back up external power supply should be available when operating the ventilator solely with its internal battery.**

When no other external source of supply is available, the ventilator switches automatically to its internal battery. The change to internal battery is systematically accompanied by an alarm which can be inhibited (see paragraph on Alarms and Defaults).

⚠ *WARNING*
When running the device solely on its internal battery, a backup source of ventilation must be available.

When the machine is operating on the internal battery, a battery symbol "🔋" is displayed in each of the menus on the title line. This symbol is accompanied by a rate of residual charge expressed in % of which the calculation depending on the voltage measurement is based on the typical behaviour of discharging batteries.

When a charge level of the order of 5% is attained, an alarm is activated and the message "EMPTY BATTERY" is displayed. Even though this alarm can be inhibited for 2 minutes, it cannot be cancelled.

⚠ *WARNING*
When the "EMPTY BATTERY" alarm is triggered, the device must be reconnected to an external power source as quickly as possible.

From the time that an "EMPTY BATTERY" alarm is activated, if no action is taken to remedy the situation, other technical alarms indicative of the insufficiency of the batteries might be activated before the apparatus comes to a complete stop.

In the ultimate phase of discharge towards a 0% level, the alarm will become continuous, the ventilation will be interrupted and the message "END OF BATTERY" will be displayed.

⚠ *WARNING*
When the "END OF BATTERY" alarm is triggered, the device must be immediately reconnected to an external power source.

Note: the "END OF BATTERY" alarm may disappear a few seconds before the complete stop of the device but a final continuous alarm is always triggered.

Your **LEGENDAIR®** ventilator continuously and automatically checks the state of the internal batteries, even if these are not used as the main source of energy. The "CHECK BATTERY" alarm will reveal any problem of the batteries or the charger at any time. However this alarm can be set to 1 min 30 s to avoid excessive triggering when recharging a completely empty battery.

It is recommended, however, to periodically disconnect the apparatus from the external supply source in order to ensure that the state of the internal connections linking the batteries to other components is in good order (see paragraph on Battery maintenance).

OXYGEN SOURCE

INSTALLATION

A connector for an external oxygen source is available at the rear of the ventilator. It is essential to use the coupler supplied with the apparatus to attach the external oxygen source in order not to damage the connector that is fitted with a non-return airtight valve system.

WARNING
The coupler must not be kept hooked up to an external oxygen source at the connector unless it is hooked up to a leak-proof external gas source or when an oxygen supply is not being used; otherwise, an air leak may compromise performance of the apparatus.

The flow of oxygen introduced into the machine by this route is integrated into the global volume delivered to the patient when ventilation is in progress.

WARNING
To avoid any dysfunction of the ventilator's sensors, it's necessary to remove any humidification system of the oxygen's source which would be placed upstream ventilator and to replace it by an humidifier installed downstream from the ventilator.

Your **LEGENDAIR®** ventilator has been validated to function with FIO_2 up to 50%; however, it is advised never to exceed oxygen flows by more than 15 l/min.

Whatever the adjustments made, it is desirable to never exceed an oxygen supply pressure to the machine of more than 50 mbar under 15 l/min.

Moreover, the source of oxygen supply must be shut off when ventilation is interrupted. We advise leaving the apparatus to continue for a few cycles without oxygen introduction when ventilation is started and when it is stopped. In the event of an oxygen leak, shut down the supply of oxygen from the source, keep away from any incandescent source and air the room.

The external source must also have an independent means of flow adjustment independent from the **LEGENDAIR®**.

AREA OF USE

An oxygen supply can be used whatever the ventilation mode but in all cases, the use of the FIO_2 sensor placed in series on the patient circuit is indispensable to ensure a correct level of adjustment and adequate surveillance (see paragraph on FiO_2 Measurement below).

WARNING
Oxygen therapy for patients with respiratory failure is a well thought-out medical prescription. Too high an oxygen flow is likely to lead to serious complications such as a decrease of minute volume due to a change in the peripheral and central regulation of ventilation, and the increase in anomalies in ventilation/perfusion ratios due to a change of the regulation of pulmonary perfusion.

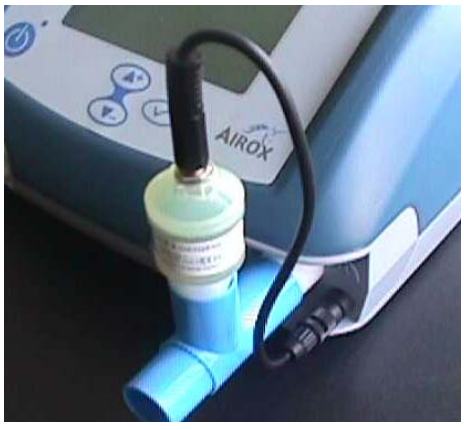
Moreover, any change of ventilation parameters influencing the insufflation or expiration flow (Rate, I/T, IPAP, EPAP) will change the FIO_2 rate.

No monotone variation law enables the FiO_2 rate to be predicted, as a function of the oxygen flow introduced into the apparatus. The expiration rinsings are in fact proportional to the level of expiration pressure but are dependent on the difference in pressure between inspiration and expiration, but also on expiration valve behaviour.

It is thus recommended to adjust the oxygen flow setting for a patient and given settings in relation to a direct FIO_2 measurement taken at the machine outlet.

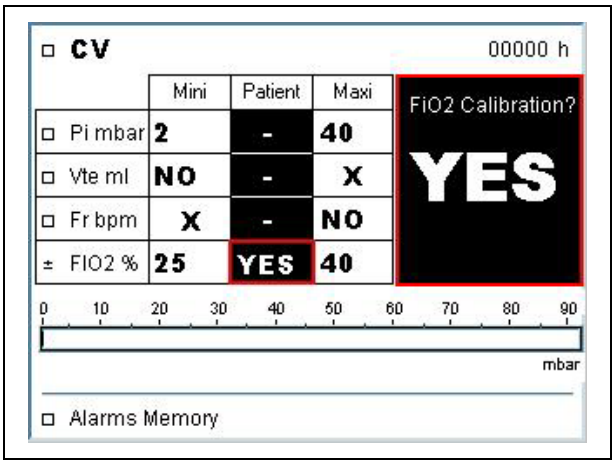
FiO_2 MEASUREMENT

It is possible and recommended when administering oxygen to use a sensor that can be placed at the apparatus outlet on the Ø 22 mm connector. The sensor available as an option (COMEPA MI COM 102-1 cell (see paragraph on Accessories and options) is fitted on a "T" union adapted to the ventilator and fitted with a cable that is directly connected to the contact located at the lower right of the main outlet:



When the sensor is hooked up to the apparatus, calibration of the measuring chain (sensor + ventilator) is recommended. When the apparatus detects a sensor after a period without a sensor and without alarm thresholds (cancelled thresholds), the previously memorized alarm thresholds are automatically restored by the apparatus. A specific information message in the form of a cancellable alarm is then triggered to prompt the user to calibrate the sensor.

The sensor may be then calibrated in the alarm parameter menus by placing the cursor on the line for adjusting of the FiO_2 mini and FiO_2 maxi alarm thresholds whose previously-saved values are automatically recalled when the sensor is positioned. You may then start a modification sequence by the ✓ key. After the FiO_2 min. threshold is validated, a message shows that calibration is then possible. To calibrate, the sensor first needs to be vented (outside of a flow that may be oxygen-enriched) for a period of 15 to 30 seconds. Then, press on either the ▲+ or ▼- key to display the "YES" message. Lastly, validate with ✓. Calibration is confirmed by a beep and the FiO_2 maxi threshold can be adjusted if necessary:



If the calibration performed is outside tolerances set out a "CALIBRATION FAILURE" alarm is triggered. This alarm must be inhibited, thus leading to its cancellation in order to continue the sequence of setting FiO_2 markers. It is necessary to repeat the complete adjustment procedure in order to calibrate the sensor anew. However, the default calibration of the apparatus is kept if the operation is not repeated, but the precision of measurement will be affected.

The calibration operation should be repeated regularly, weekly if possible. Since the FIO_2 measurement is influenced by pressure variations, the calibration operation must also be repeated if there is a variation in altitude of ± 150 m.

Note: When using a new sensor for the first time, it must be allowed to balance out for approximately 20 minutes in ambient air before it is calibrated and used with the ventilator.

Moreover, it is recommended that correct FIO_2 measurement and triggering of associated alarms be verified before ventilating a patient with a monitored oxygen supply (see paragraph on Running The Apparatus).

When FiO_2 mini and maxi thresholds are set, but no FiO_2 monitoring is possible due to a missing sensor or an accidentally disconnected sensor, a "FIO2 FAIL" alarm is triggered after a complete ventilation cycle (no triggering in ventilation stand-by). This alarm may be inhibited for two minutes but its cancellation will be automatic only if the sensor is connected or the FiO_2 alarm thresholds are cancelled (NO setting).

MAINTENANCE

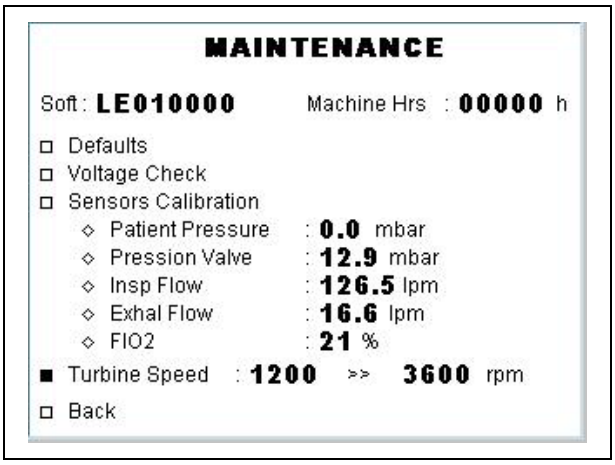
The general maintenance of the apparatus must be carried by trained and qualified personnel only. The methods presented below only cover the basic operations, and to go beyond this, it is necessary to refer to the "Maintenance Manual" which is supplied during the training for the qualification for technical interventions on this apparatus.

MAINTENANCE MENU

The maintenance menu can be accessed only from the setup menu (see paragraph on Setup). This menu can be used to perform a certain number of adjustments and checks without any dismantling of the apparatus.

These operations should be done periodically (at least once a year) and every time there is doubt as to the correctness of ventilation results.

The maintenance menu has the following appearance:



Other than the information directly displayed (software version, machine hour meter status, measurements of various sensors), the checking and calibration operations can be done through this menu.

The operations, which are to be carried out by qualified personnel with the necessary professional equipment, are the following (for information only):

Technical defaults alarms memory

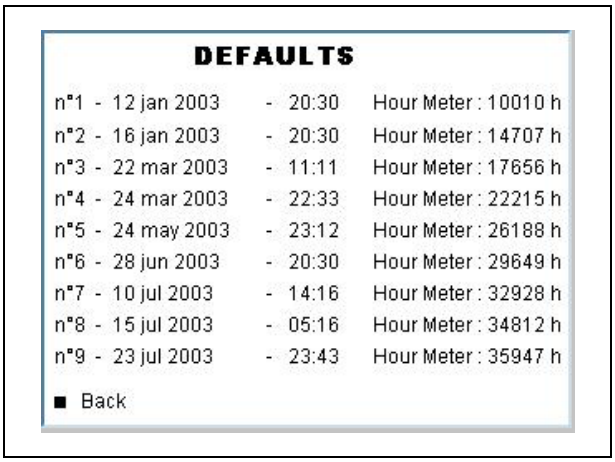
In order to consult the list of technical defaults saved by the apparatus, place the cursor on the corresponding line, then press the ✓ button.

You then access a menu where the numbers of the last 9 defaults saved are displayed in reverse chronological order as well as the date and time of their respective occurrences.

Note: It is also possible to consult all the alarms as well as events recorded by the ventilator with a PC equipped with **AIROX COMMUNICATION** software (see paragraph on Accessories and Options). The alarm « CHECK KEYS » will be displayed as default n°9 in **AIROX COMMUNICATION** for versions before V3.5.1.

Default numbers and their technical cause are given in detail in the paragraph on Technical Defaults.

This screen has the following display:

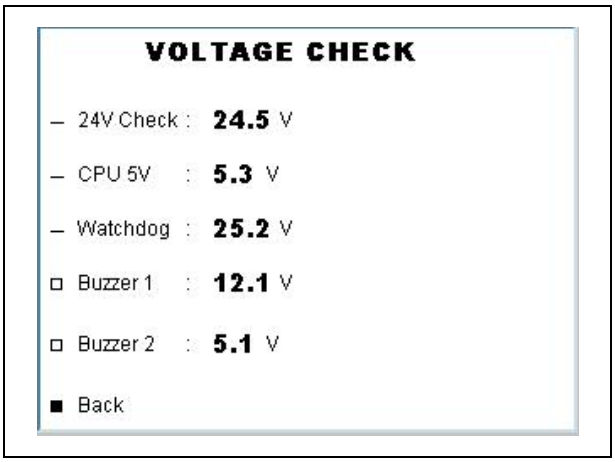


You can quit the menu by pressing the ✓ key to go back to the maintenance menu.

Verification of internal electrical supplies

In order to consult the internal voltage check menu, place the cursor on the corresponding line, then press the ✓ button.

You then access the following menu:



The information contained is as follows:

- **General electrical supply: 20.5 V to 29.4 V**

This is the voltage supplied by the electrical power supply source connected to the machine. It can come directly from the AC/DC converter, an external DC source or from the internal battery. There is a battery symbol « » to the right of the voltage displayed if the voltage measured comes from the internal battery.

It must be above 20.5 V.

- **CPU logic voltage: 5.1 V ± 250 mV**

The CPU logic voltage must be within the tolerances above, otherwise the function of the board and the measurements of flow or pressure will be affected.

- **Watchdog voltage: 21 to 30 V +/- 5%**

The Watchdog voltage enables the confirmation of the correct condition of the power supply loss detection circuits.

- **Activation of buzzers:**

By placing the cursor on the line of each one of the sound warnings and by pressing on the ✓ validation key, you can activate those buzzers and ensure that they operate correctly and are correctly supplied.

You can quit the menu by placing the cursor on the "Back" line and by pressing the ✓ key to go back to the maintenance menu.

Calibrating the sensors

- **Pressure sensors:**

The pressure sensors built into the machine have been factory calibrated. This calibration must be carried out again if the electronic board or sensors have been changed. It is advised to check the validity of the sensor calibration periodically.

In order to calibrate the sensors, first place the cursor on the "Sensor Calibration" line and press on the ✓ key in order to access the lines of each sensor.

➢ Patient Pressure Sensor:

To calibrate the patient pressure sensor, you must use a manometer that can measure pressure of at least 0 to 40 mbar. The manometer must be connected to a union fitted with a leak aperture of the order of 4 mm (maximum) placed on the Ø 22 main male outlet cone of the ventilator and connected to the Ø 6.5 mm connector of the proximal pressure socket.

Place the cursor on the "Patient Pressure" line. You can start a calibration sequence by pressing the ✓ key. You will hear a beep and the first "00" calibration objective will be displayed on the "Patient Pressure" line. After making sure that the external manometer does show a pressure of 0 mbar, the point is validated by pressing the ✓ key; this validation will be confirmed by a beep. The second "40" calibration objective will then be displayed and the machine regulates the speed of the turbine in order to reach the point to adjust.

You must therefore adjust, if necessary, the point of operation of the ventilator with the ▲ or ▼ the buttons so that the pressure read on the external manometer will read 40 mbar ± 0.2 mbar. The corresponding turbine speed set point is indicated permanently in the lower part of the screen.

When the value measured on the manometer is correct, validate the configuration of the ventilator by pressing the ✓ button until a beep confirms the updating of the point.

Every calibration procedure undertaken must be carried out to its end, i.e. the validation of the 2 points of the pressure curve.

➢ Valve pressure sensor:

Place the cursor on the "Valve Pressure" line and repeat the same operations as above. For this sensor, a single "00" calibration objective needs to be validated and the use of an external manometer is not necessary.

In the event that the sensors are not calibrated or have calibration errors, the apparatus sends several beeps when the point is validated. A technical default will be activated by the apparatus (see paragraph on Technical Defaults) if this error is not corrected.

- **Flow sensors:**

The flow sensor or sensors integrated into the machine have been factory calibrated. This calibration must be carried out again if the electronic board or sensors have been changed.

As far as the expired flow sensor is concerned, it must be calibrated when an exhalation block is set up or each time it is removed (see paragraph on Accessories and options).

As a last point, we recommend that you periodically check sensor calibration validity.

Note: The measurements of the flows and therefore the calculations of volume that result are influenced by variations in atmospheric pressure. A calibration of the flow sensor is recommended if atmospheric pressure differs significantly from 1000 hPa. For example, altimetric variation of 1000 m leads to a variation of flow measurement of the order of 10%.

In order to calibrate the sensors, first place the cursor on the "Sensor Calibration" line and press on the ✓ key in order to access the lines of each sensor.

➢ Inspired flow sensor:

To calibrate the inspired flow sensor, you will need an external reference point for the measurement of the flow, the characteristics of which must permit the obtaining of a flow ranging from 0 to 200 l/min with as little loss of charge as possible. This system must be connected directly to the main male outlet cone Ø 22 mm of the ventilator via a tube of sufficient length and section. No part should be placed in series between the ventilator and the means of measuring the external reference flow during the operation so as not to introduce either leak or loss of supplementary charge.

Place the cursor on the "Inspired flow" line. You can start a calibration sequence by pressing the ✓ key.

The flow objectives to be calibrated are displayed in succession facing "Insp Flow." There are 8 of them: 0, 5, 12, 37, 60, 90, 135 and 160 l/min.

On each calibration point the machine automatically adjusts the speed of the generator to reach the point to adjust.

You must therefore adjust the point of operation of the ventilator with the ▲ or ▼ the buttons so that the flow read on the external measuring instrument will be ± 0.2 l/min from the point to calibrate. The corresponding turbine set point is indicated permanently in the lower part of the screen.

When the value measured on the external means is correct you validate the configuration of the ventilator by pressing the ✓ button until a beep confirms that the point has been updated. The level of the next flow objective is shown, and so forth.

Every calibration procedure undertaken must be carried out to its end, i.e. the validation of the 7 points of the flow curve.

➢ Expired flow sensor:

As far as the expired flow sensor is concerned, calibration is necessary only when the apparatus is fitted with an exhalation block (see paragraph on Accessories and options). To calibrate it, no external means of measurement is necessary; you need only connect a Ø 22 mm tube between the male outlet cone and the female patient return cone. Then place the cursor on the "Insp Flow" line. You can start a calibration sequence by pressing the ✓ key. The sensor shall then be automatically calibrated with reference to the values measured by the previously calibrated inspired flow sensor.

In the event that the sensors are not calibrated or have calibration errors, the apparatus sends several beeps. A technical default will then be activated by the apparatus (see paragraph on Technical Defaults).

- **FiO_2 sensor:**

You can connect a FiO_2 sensor to the apparatus (see paragraph on Oxygen Supply) and this sensor must be calibrated before use. There is no factory ventilator - sensor calibration and only a default setting has been set up. The sensor can be calibrated either by the ventilation menu (see paragraph on Oxygen source) or maintenance menu.

The calibration operation should be repeated regularly, weekly if possible. Since the FIO_2 measurement is influenced by pressure variations, the sensor must be re-calibrated if there is a variation in altitude of ± 150 m.

Note: When using a new sensor for the first time, its exposure to ambient air must be allowed for approximately 20 minutes until it is balanced and before it is calibrated and used with the ventilator.

In order to calibrate a sensor, first connect the FiO_2 sensor to the apparatus, then, in the maintenance menu, place the cursor on the "Sensor Calibration" line and press on the ✓ key in order to access the lines for each sensor.

Then, place the cursor on the "FiO_2" line. The calibration sequence can be started by pressing on the ✓ key. A beep is emitted and the "21%" calibration objective is then displayed on the "FiO_2" line. After making sure that the sensor is exposed to ambient air (not in an oxygen-enriched flow) for a period of 15 to 30 seconds, the first calibration point must be validated by pressing on the ✓ key; this validation is confirmed by a beep.

For this sensor, a single "21%" calibration objective needs to be validated and the use of an external instrument is not necessary. The exactitude of the measurement can however be checked by comparing the value displayed by the apparatus with an external reference oxygen analyser.

In the event the sensor is not calibrated or if the process undergoes calibration failures, the apparatus emits several beeps at the stage of the concerned validation point. An alarm is recorded by the apparatus (see paragraph on Ventilation – Utilisation alarms) if this error is not corrected.

Test of the turbine

By placing the cursor on the "Turbine Speed" line it is possible to directly control the turbine command motor by pressing first on the ✓ key then by pressing keypad buttons ▲ and ▼. The speed set point value that you can adjust has a range of 0 to 50000 and it is displayed next to "Turbine Speed". The real speed of the turbine is

displayed to the right of the set point; it can vary from one machine to another at constant set point and according to the thermal state and wear of the apparatus.

On acting on the speed of the turbine it is not only possible to check the level of air tightness inside the machine, the exactitude of the flow (± 2%) and pressure (± 1 mbar to 30 mbar) sensors but also the state of fouling or wear on the system (for more information refer to the "Maintenance Manual").

To quit the turbine command, simply press the button again. Abort is automatic after 7 seconds without pressing the or keys of the keypad. To stop the turbine, you need only quit the "Turbine Speed" line.
If you wish to check the maximum performance levels of the turbine, a maximum speed (Set point of 50000) can be obtained automatically by pressing the key when the cursor is on the "Turbine speed" line.

WARNING
To avoid excessive overheating of and possible damage to the components, the operation of the turbine with no outlet flow should be limited to a few minutes.

PREVENTIVE MAINTENANCE

Consumables and change frequencies

In the case of normal use of the ventilator, i.e., in a non dusty atmosphere, and independently of specific damage to parts (shocks, cracks, significant dirt...), the frequencies of change of consumable elements are as follows:

Element concerned	Code	Recommended change frequency
Inlet Air Filter (Foam + Fine Particle)	2963399 (x6)	Once a month or more often depending on the state of fouling
Patients circuits	5092800 5093000	15 days Single Use
FiO_2 Cell	2964200	14 to18 months or in case of persistent calibration failure
Exhalation block	3823099	4 months Single use - single patient

Note (*) : The exhalation block change frequency may be 2 months for the most critical patients or under extreme environmental conditions of use (in particular when humidity rate > 75%) or if significant amount of mucus is produced by the patient. On the other hand the change frequency may be extended to 6 months for the least critical patients.

The non-observation of these recommendations can result in the loss of performance, excessive overheating, even the loss of certain functions and in the long term compromise the potential durability of the apparatus.

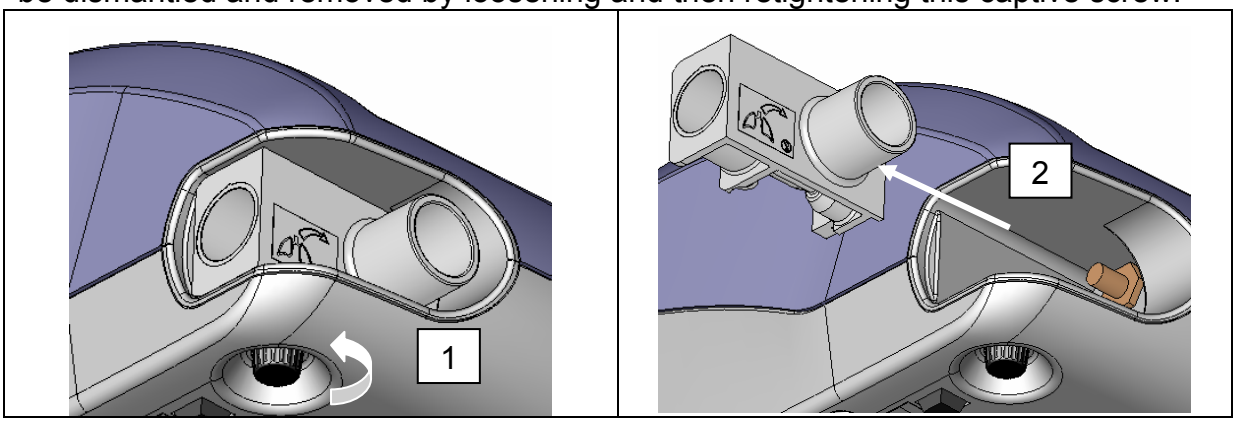
Note : For all the additional accessories not necessarily considered as consumable (see § Accessories and options), consult the recommendations of the maker

Servicing the exhalation block

Under extreme environmental conditions of use (in particular when humidity rate > 75%), or if significant amount of mucus is produced by the patient, the exhalation block can be cleaned (refer to § Cleaning and disinfecting) in order to avoid excessive triggering of the mini tidal volume alarm that would be linked to the block congestion. However the periodical cleaning of the exhalation block is not obligatory, and under less extreme conditions, it can be left until the next change occurs.

Make sure that the exhalation block has been correctly dried after it has been possibly cleaned, so that fluids cannot disturb the sensors that are linked to it.

It can be easily removed from the device. No special tools are needed to do so. It held in place by a captive screw accessible through the bottom of the device. It can be dismantled and removed by loosening and then retightening this captive screw.



After installing a new exhalation block on the machine, it is indispensable that the expiration flow sensor be recalibrated before the exhalation block is used. This calibration does not require any specific testing equipment (see § Calibration of sensors).

Note : The recommendation of the calibration of the exhalation block sensor after it has been possibly cleaned or changed aims the precision of the displayed measures for the exhaled tidal volume be maintained, that is so say ± 20 ml until 200 ml and ± 10% above. This flow measure however only affects the monitoring of the exhaled tidal volume and the triggering of the associated exhaled Vt mini alarm. On the other hand it doesn't directly affect the ventilation provided by the device. Therefore when the measure of the exhaled flow is not used for a very precise supervision of the exhalation whereas a ± 20 à 30% error on the exhaled volume can be tolerated, the calibration of the exhalation flow sensor cannot be carried out systematically after intervention.

Internal Battery Maintenance

The internal battery does not need to be taken out to check correct operation. For replacement, refer to the "Maintenance Manual."

- **Periodic test of the internal battery:**

Your **LEGENDAIR®** ventilator continuously and automatically controls the state of the internal battery, even if this is not used as the main source of energy. It is

nevertheless recommended to check their charge status every month either via the maintenance menu (see paragraph on Maintenance) or by unplugging the apparatus from external electricity supplies. Such a test is imperative after an opening of the apparatus or after a prolonged lack of use of more than one month in order to ensure the correct working of internal connections linking the battery to other components.

- **Charging the batteries:**

In the case where the battery charge level is considered insufficient, either via the battery unit display of the potential (potential ≤ 75%) or via a check of the charge in the maintenance menu (charge < 25.2 V) a recharge is necessary. In general, it is recommended to leave the apparatus charge when not used and to systematically recharge it after storage and before using it again.

To do so, connect the apparatus to the mains. The illumination of the AC light on the front panel then confirms that the apparatus is switched on and that the battery is charging. It is not necessary to start the apparatus to charge the battery, but should this be the case, the charge is still assured.

For a maximum level of autonomy, it is necessary to leave the apparatus on charge for 8 hours and if possible for 12 hours when recharging takes place when the apparatus is being used.

WARNING
Recharging the internal battery may sometimes be incomplete regardless of charge time, if the ambient temperature is above 30°C because of the battery's internal heat safety device.

Note: The use of the apparatus on an external 24 V DC does not allow the charging of the internal battery.

- **Periodic maintenance of the internal battery:**

No specific maintenance is necessary even if there are complete discharges within the limit of 300 cycles or, inversely, there is no discharge in 12 months (see the storage conditions below if necessary). Only a periodic check of battery potential is desirable (see above).

- **Periodicity of changing the internal battery:**

After 300 complete cycles of charge and discharge or every three years. A drop in potential of approximately 20% can however be detected close from 300 complete cycles of battery charge and discharge.

Internal Battery Changing:

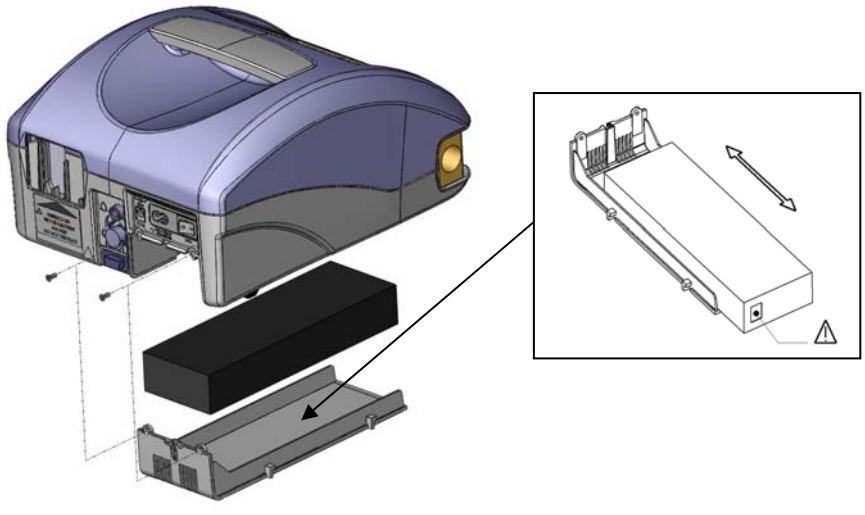
WARNING
The apparatus must be disconnected from all external power supplies and be turned off during this operation.

Procedure:

- Place the apparatus on a work table.
- Take out the screws securing the battery cover located behind the apparatus using a "Torx" T15 screwdriver.
- Slide the cover off by pulling it towards the back of the apparatus.
- Take the old battery out of the cover

WARNING
 **Faulty batteries should be disposed of according to environmental legislation in your country.** **Never expose the batteries to direct flame.**

- Take the new battery out of its package and install it into the cover with the battery contacts in line with those of the apparatus according to the drawing on the label on the back of the cover:



- Put the cover with the battery back on its slide rails
- Put back the screws securing the cover and tighten them with the screwdriver.

WARNING
Push on the cover from the rear towards the right to take pressure off the cover's mounting brackets, which could otherwise break when the screws are tightened.

- **Conditions of storage for batteries:**

If the apparatus is to be stored for an extended period of time, removing the battery is not necessary.

It is best however for it to be stored in a temperate (≈ 21°C), dry (< 80% RH) and well-ventilated atmosphere.

If the battery is stored more than a month at a temperature greater than 21°C or for more than one or two weeks at a temperature greater than 45°C, the capacities of the battery may be affected. It would then be necessary to recharge the battery before using it again.

The batteries should not be stored for more than two years, whatever the conditions.

Cleaning and disinfecting

Your **LEGENDAIR®** ventilator can be cleaned with a cloth or a sponge lightly moistened with a bactericide or germicide solution.

It is recommended to clean and disinfect the apparatus before any maintenance operation or before storage.

WARNING
Fluid must not be allowed to seep inside the apparatus, in particular the air inlet filter or the cooling apertures located in the side, rear and bottom panels of the apparatus.

For total decontamination of the entire internal air circuit of the machine the use of a vaporiser is possible; however it is necessary to ensure the compatibility of the product with the materials used:

- Air inlet filter in polyurethane-polyester
- Seals and deck in silicone, SEBS and SANTOPRENE
- Soundproofing in polyester foam or polymethacrylic imide
- Turbine in ABS, ULTEM (polyetherimide) or PEEK and Stainless steel
- Tubes and Unions in Polyethylene, Silicone, Nylon, acetyl Delrin and polypropylene
- Box and Casings in anodised aluminium, polysulfone and ABS
- Methacrylate and/or epoxy bonding
- Laminator, valve holder and valve unit in stainless steel
- Valve membranes in silicone
- Outlet cone and exhalation block in ABS

We recommend the use of products such as ANIOSPRAY 29 or 41 or AMPHOSPRAY 41.

The optional exhalation block (see paragraph on Accessories and options) is for single use - single patient: it can be the subject of cleaning with soapy water but can neither be disinfected nor sterilized. The single use exhalation block will have to be changed periodically and in no case be re-used with a new patient.

The optional FiO_2 sensor (see paragraph on Accessories and options) cannot, however, be immerged in a cleaning or disinfecting solution nor can be sterilised. If it becomes contaminated, it must be changed.

The patient circuits that we distribute for this apparatus are for single use and cannot be disinfected. They must be replaced regularly.

If a re-usable patient circuit is used, follow the recommendations of the manufacturer for cleaning and disinfecting.

RESOLUTION OF INCIDENTS

Whatever the form under which the alarms are analysed (simultaneously, via the screen event memory, or by external event retrieval) the most likely resolution guide of incidents is as follows:

Message or Symptom	Probable cause of incident	Potential corrective action
DISCONNECTION *High Priority*	Low Pressure level set too high (CV/ACV/SIMV modes)	Take off the lock and re-adjust the low pressure setting
	Patient circuit disconnected, unsuited or faulty	Re-establish or change the patient circuit
	Proximal pressure check circuit disconnected or deteriorated	Re-establish the pressure check circuit or change the tube
	Internal machine circuits or pressure sensor faulty	Change the apparatus and call your service provider
HIGH PRESSURE *High Priority*	High Pressure level set too low (CV/ACV/SIMV modes)	Take off the lock and re-adjust the high pressure setting
	Patient circuit obstructed or outlet filter united	Remove the obstruction or change the patient filter or the patient circuit
	Proximal pressure check circuit obstructed	Clean the pressure check circuit or change the tube
	Patient cough	Inhibit the alarm if necessary
	Internal machine circuits or pressure sensor faulty	Change the apparatus and call your service provider
LOW VTI *Medium Priority*	Vti mini level set too high (PSV S/PSV BUR/PCV/PACV modes)	Take off the lock and modify the Vti mini level
	Pressure level is insufficient for reaching desired volume (PSV S/PSV BUR/PCV/PACV modes)	Take off the lock and modify the base and or maximum pressure level
	Patient circuit obstructed or unsuited	Clean or change the patient circuit
	Flow sensor faulty or internal machine leak	Change the apparatus and call your service provider
HIGH VT *High Priority*	Vti maxi level set too low (PSV S/PSV BUR/PCV/PACV modes)	Take off the lock and modify the Vti maxi level
	Pressure level is too high in terms of desired volume (PSV S/PSV BUR/PCV/PACV modes)	Take off the lock and modify the level of pressure
	Leak on patient circuit, unsuitability or disconnection of patient circuit	Re-establish or change the patient circuit
	Flow sensor faulty or internal machine leak	Change the apparatus and call your service provider

Message or Symptom	Probable cause of incident	Potential corrective action
LOW VTE *Medium Priority*	Vte mini level set too high	Take off the lock and modify the Vte mini level
	Leak on patient circuit, unsuitability or disconnection of patient circuit	Re-establish or change the patient circuit
	No exhalation block or exhalation block disconnected	Re-establish the exhalation block or cancel the Vte mini setting (if single-branch circuit)
	Expired flow sensor badly calibrated or faulty	Clean or change the exhalation block Otherwise change the apparatus and call your service provider if the situation persists
CONTROLLED CYCLES *Very Low Priority*	Trigger I level set too high	Take off the lock and re-adjust the Trigger I setting
	Patient apnea	None
	Defective sensors	Change the apparatus and call your service provider
MAXI FREQUENCY *Medium Priority*	Maxi frequency alarm level set too low	Take off the lock and re-adjust the Maxi Frequency setting
	Trigger I level set too low	Take off the lock and re-adjust the Trigger I setting
	Patient hyperventilation	Inhibit the alarm and call a medical team if symptoms persist.
	Inspired flow sensor faulty	Change the apparatus and call your service provider
HIGH RATE *High Priority*	Trigger I level set too low	Take off the lock and re-adjust the Trigger I setting
	Patient hyperventilation	Inhibit the alarm and call a medical team if symptoms persist.
	Inspired flow sensor faulty	Change the apparatus and call your service provider
LOW FIO2 *Medium Priority*	FiO_2 mini level set too high	Take off the lock and re-adjust the FiO_2 mini setting
	Flow setting of the external oxygen source insufficient	Increase the flow of the external oxygen source
	Connection of the external oxygen source incorrect	Correct the connection of the external oxygen source to the apparatus
	External oxygen source too low	Change the oxygen source
	FiO_2 sensor faulty	Change and calibrate the FiO_2 sensor

Message or Symptom	Probable cause of incident	Potential corrective action
HIGH FIO2 *Medium Priority*	FiO_2 maxi level set too low	Take off the lock and re-adjust the FiO_2 maxi setting
	Flow setting of the external oxygen source too high	Decrease the flow of the external oxygen source
	FiO_2 sensor faulty	Change and calibrate the FiO_2 sensor
FIO2 FAIL *High Priority*	FiO_2 sensor disconnected although the alarm thresholds are set	Reconnect and calibrate if necessary the FiO_2 sensor or take off the lock and cancel the FiO_2 alarm thresholds
CALIBRATE FIO2 *Low Priority*	FiO_2 sensor detected (automatic recall of FiO_2 alarm thresholds)	Confirm the FiO_2 alarm settings and calibrate the sensor
CALIBRATION FAILURE *Low Priority*	Base rate 21% abnormal when calibrating the FiO_2 sensor	Vent the FiO_2 sensor for 15 to 20 seconds (20 minutes after unpacking) before calibrating it or change the sensor
POWER FAIL *Medium Priority* *Operation with internal battery except if DC indicator lit (24 V DC supply active in this case)*	Mains power supply interruption	Cancel the alarm then check the power supply cables and/or the effective availability of voltage on the mains socket.
	Start-up under external 24 V DC power supply (no internal battery charge possible)	Cancel the alarm
	Protective fuse of the apparatus blown	Change the ventilator and call the maintenance technician
DC POWER FAIL *Medium Priority* *Operation with internal battery*	Interruption of the external 24 V DC source in the absence of mains power supply	Cancel the alarm then check the power supply cables and/or the effective availability of voltage on the external source.
	Protective fuse of the apparatus blown	Change the ventilator and call the maintenance technician
EMPTY BATTERY *High Priority*	Charge battery < 5% following too long operation on battery Or supply level < 23.8 V if internal battery under default	Reconnect the apparatus to the electrical supply or to an external 24V DC source rapidly Reminder: recharging the internal battery is possible only with the mains power supply.
END OF BATTERY *Very High Priority*	Charge battery = 0% following too long operation on battery Or supply level < 21.8 V if internal battery under default	Reconnect the apparatus to the electrical supply or to an external 24V DC source immediately. Reminder: recharging the internal battery is possible only with the mains power supply.
CHECK BATTERY *Medium Priority*	Battery not chargeable	Change the battery and/or the ventilator and call your service provider
CHECK PRESSURE *Medium / High Priority*	Abnormal pressure: Constant or negative pressure (except if DISCONNECTION active)	Clean the pressure check circuit or change the tube. Otherwise, change the apparatus and call your service provider if the situation persists.
CHECK VALVE *Medium / High Priority*	Abnormal obstruction or damage of the expiration valve	Clean or change the expiration valve and/or its demand tube. Otherwise, change the apparatus and call your service provider if the situation persists.
	Connection or demand tube of the expiration valve faulty	Restore or change the expiration valve and/or its demand tube

Message or Symptom	Probable cause of incident	Potential corrective action
VALVE LEAKAGE *Medium Priority*	Significant leak detected on the return branch of a double-branch circuit during the inspiration phase.	Clean or change the expiration valve and/or its demand tube. Otherwise, change the apparatus and call your service provider if the situation persists.
	Expired flow sensor contaminated or faulty	Clean or change the exhalation block. Otherwise, change the apparatus and call your service provider if the situation persists.
CHECK VT *High Priority*	Tidal Volume and/or Rate levels set too high (CV/ACV/SIMV). Limit of machine performances	Take off the lock and re-adjust the Vt and/or Rate settings
	Inspired flow sensor faulty or internal machine leak	Change the apparatus and call your service provider
CHECK PARAMETERS *Medium Priority*	Loss of memorised parameters	Check and re-adjust the prescribed parameters if necessary
	Downloading of a software package containing new parameters	
CHECK KEYS *High Priority*	Key pressed for at least 20 s	Release key
	Blocked key	Try each key of the keyboard Otherwise change the apparatus and call your service provider if not solved.
No message (screen black) *Very High Priority*	Electrical power supply to the machine is interrupted with the switch when ventilation is in progress	Restore normal electrical supply to the machine in order to start ventilation in progress back up again
No. 1 *Very Low Priority*	Flow measure incoherent	Maintenance operation: Calibrate the flow sensor or change it
No. 2 *Low Priority*	Calibration of the inspired flow sensor not in conformance	Maintenance operation: Calibrate the inspired flow sensor
No. 3 *Low Priority*	Calibration of the expired flow sensor not in conformance	Maintenance operation: Calibrate the expired flow sensor
No. 4 *Low Priority*	Calibration of the valve pressure sensor not in conformance	Maintenance operation: Calibrate the valve pressure sensor
No. 5 *Low Priority*	Calibration of the patient pressure sensor not in conformance	Maintenance operation: Calibrate the patient pressure sensor
No. 6 *Very Low Priority*	Turbine speed abnormal	Maintenance operation: Change the turbine or the CPU board
No. 7 *Very Low Priority*	Loss of clock parameters	Update the date and time or change the battery on the CPU board or the CPU board itself
No. 8 *Very Low Priority*	Buzzer electrical supply insufficient	Maintenance operation: Change the CPU board
Whistling noise or vibrations	Filter and/or Turbine silencer deteriorated	Maintenance operation: Change the turbine box
	Valve membranes damaged	Maintenance operation: Change the valve membranes
Excessive heat given off	Obstruction of main or secondary air inlets of the casings	Remove the obstructions from all the apparatus air inlets and outlets.

ACCESSORIES AND OPTIONS

WARNING
The use of any accessory other than those specified, with the exception of the power supplies or cables sold by AIROX when replacing internal components, may lead to an increase in electro-magnetic emissions or a decrease in the equipment's insulation against electro-magnetic emissions.

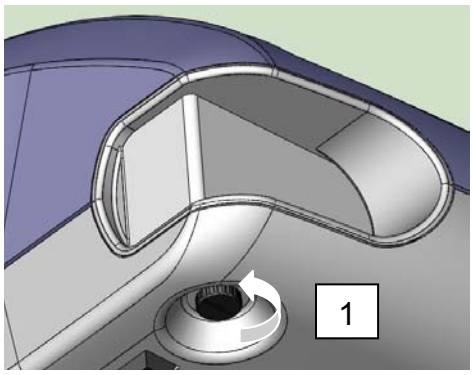
SINGLE USE EXHALATION BLOCK – Code 3823099

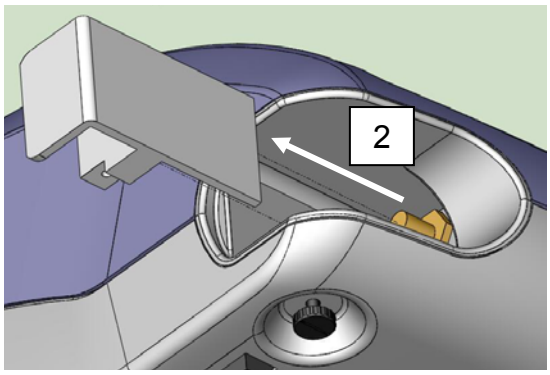
The exhalation block enables the expiration flow rate to be measured by the patient enabling the "Vte" expired flow rate to be calculated and any leaks to be effectively detected. To operate, it must be connected to a patient circuit of the "double branch" type.

ATTENTION
The exhalation block is for single use – single patient. It cannot be disinfected nor sterilized and must under no circumstances be re-used by another patient.

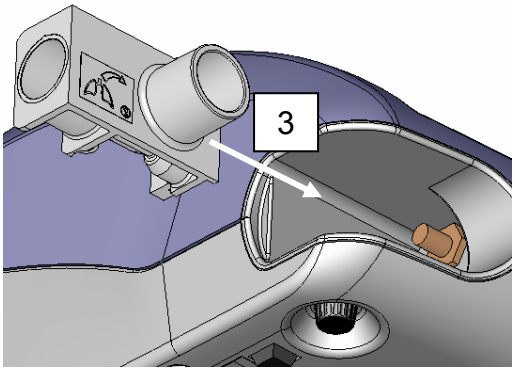
This equipment, already-mounted on the machine in the factory or alternatively available for delivery as an option (disposable) is composed of a single patient – single use exhalation block. It can be easily installed or removed from the device without requiring any tools.

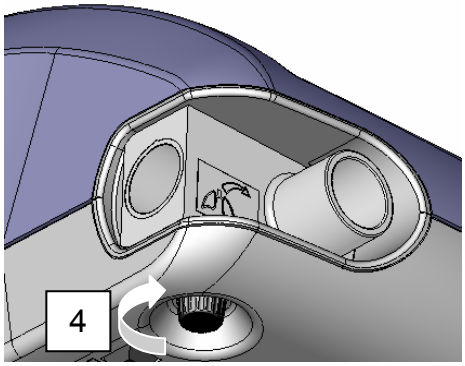
To install the exhalation block, first take the protective cover off the connections located at the bottom left-hand corner of the front face. This cover is retained by a cap knob that can be accessed from underneath the apparatus:





After taking off the protective cover, installing the exhalation block is as easy as placing it in the housing and blocking it by tightening the cap knob back:





After installing a new exhalation block on a device, it is indispensable that the expired flow sensor be recalibrated before the exhalation block is used. This calibration does not require any specific testing equipment (see § Calibration of sensors).

Note : The recommendation of the calibration of the exhalation block sensor after it has been possibly cleaned or changed aims the precision of the displayed measures for the exhaled tidal volume be maintained, that is so say ± 20 ml until 200 ml and ± 10% above. This flow measure however only affects the monitoring of the exhaled tidal volume and the triggering of the associated exhaled Vt mini alarm. On the other hand it doesn't directly affect the ventilation provided by the device. Therefore when the measure of the exhaled flow is not used for a very precise supervision of the exhalation whereas a ± 20 à 30% error on the exhaled volume can be tolerated, the calibration of the exhalation flow sensor cannot be carried out systematically after intervention.

After the unit has been installed and calibrated, your ventilator can be used in double-branch setup with or without alarm. Independently of alarms that can be adjusted by the user when an exhalation block is used with a double-branch circuit, built-in alarms will enable the detection of any possible malfunctions or deterioration of the device (see paragraph on Alarms and Defaults).

The double-branch patient circuit must be fitted with an expiration valve with a "connectable outlet" that can be connected either at the inlet or outlet of the exhalation block using 22M - 22M elbows or unions if necessary. If the user does no have a « connectable outlet » expiration valve, but a « free » outlet, he can install one down-circuit from the exhalation block by adding an obturator so as to leave open only the side outlet of the valve (see § Installation).

FIO_2 MEASUREMENT KIT– Code 3814100

This kit contains:

- O_2 COMEPA MI COM 102-1 measurement cell (code 2964200)
- Adaptation deflector of the cell on a "T" union, Ø 15 mm
- "T" union, (standard 22 M –22 F – Ø 15 mm)
- 200 mm maximum connection tube from the O_2 cell to the equipment (two models are supplied to match the different connectors according to the generation of the equipment: See below)

Allows direct connection to the measuring cell on the front of the equipment.

Version with ¼ turn connector

Version with clip connector

To install it, you must:

- Take the cell out of its airtight packaging
- Screw the cell on the deflector
- Press-fit the assembly onto the Ø 15 mm of the "T" union
- Put the "T" directly onto the Ø 22 outlet of the ventilator; if this is not possible, it must be below any patient circuit humidifying system.
- Connect and screw in or click in (according top model) the electricity cable connectors to the recorder and to the ventilator
- Fit the patient circuit after the "T" union

Note: When using a new sensor for the first time, its exposure to ambient air must be allowed for approximately 20 minutes until it is balanced and before it is calibrated and used with the ventilator

The COMEPA MI COM 102-1 cell is a partial-pressure galvanic sensor which is temperature-compensated. It is comprised of two electrodes, one gel electrolyte and one oxygen-permeable membrane. Oxygen in contact with these electrodes causes electrochemical oxidation inducing voltage between these electrodes.

WARNING
The oxygen sensor is a sealed device containing a low-acid electrolyte and lead (Pb)-based components. **Faulty or contaminated sensors should be disposed of according to environmental legislation in your country.** **The oxygen sensor cannot be immerged in a cleaning or disinfecting solution nor be sterilised.** **If it becomes contaminated, it must be changed.**

Technical characteristics of the COMEPA MI COM 102-1 cell are as follows (under standard conditions of 1013 hPa and 25°C)

- Precision of measurement: ± 3%
- Response time: < 13 s for 90% of the final value
- Stability of the precision of measurement: ± 1% past 8 h

- Service life: 10^6 h $\%O_2$ (i.e. approximately 14 to 18 months under normal conditions of use)
- Chemical interferences < 0.5% with:
  CO_2: 10% of dry volume
  N_2O: 80% of dry volume
  Halothane: 7.5% of dry volume
  Isoflurane: 7.5% of dry volume
  Enflurane: 7.5% of dry volume
  Sevoflurane: 9% of dry volume
  Desflurane: 20% of dry volume
- Influence of humidity: – 0.03% relative per % RH

Note: FiO_2 measurement is influenced by pressure variations. The calibration of the FIO_2 sensor should be repeated regularly, weekly if possible, and specifically in the case of variations in altitude of ± 150 m (see paragraph on Oxygen Supply).

We recommend that you calibrate the sensor before each time you use the measurement cell. The apparatus prompts the user to calibrate the sensor as soon as a sensor is connected. This operation is also systematically proposed by the apparatus during an adjustment sequence of the corresponding alarm thresholds. Since calibration consists in identifying oxygen content in the atmosphere, it is best to vent the sensor outside the patient circuit for 15 to 20 seconds during this operations (see paragraph on Oxygen Source)

It is also recommended that correct FIO_2 measurement and triggering of associated alarms be verified before ventilating a patient with a monitored oxygen supply (see paragraph on Running The Apparatus).

ALARM REPEATER – Code 4096000

The alarm repeater can re-transmit the sound alarms of your ventilator over a distance of 5 metres (longer lengths can be considered upon request after study). Its operation is based on the "normally closed" principle.

This unit possesses its own autonomy of more than one year or 150 hours of continuous alarms via its 9 V battery. This battery allows the warning of surveillance personnel in the case of a disconnection of a ventilator.

When a sound alarm is activated, you must identify the cause on the ventilator.

Technical characteristics of the alarm repeater:

- Dimensions: 114 x 72 x 72 mm
- Weight: 150 g
- Consumption: 0.1 mA on standby and 3 mA in alarm
- Autonomy: 150 hrs continuous alarm or over 1 year
- Power supply: 6F22 9 V alkaline battery

CARRYING BAG – Code 3809000

This functional and discreet blue carrying case has two separate compartments with zip closures and an adjustable shoulder strap enabling it to be carried as a backpack.

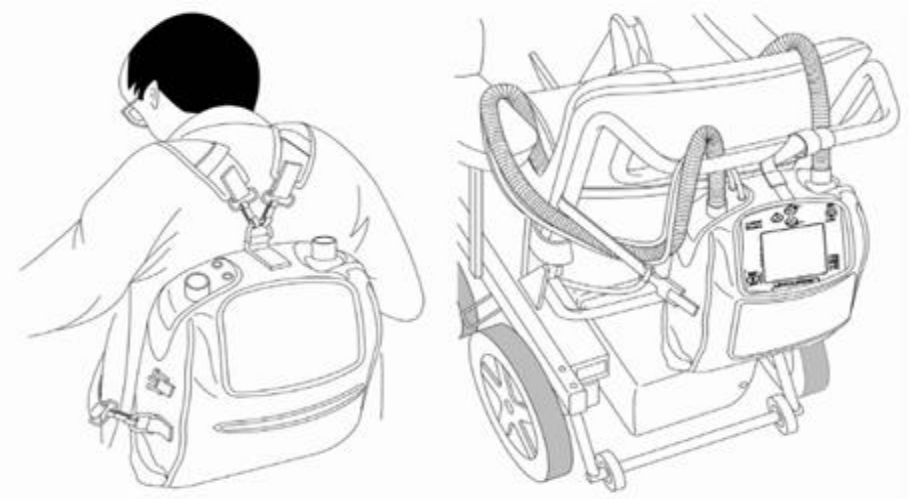
The upper compartment has cushioned sides and will protect the ventilator from shocks, whereas a complete patient circuit and small accessories will fit in the lower compartment.

DUAL BAG – Code 2967200

This bag is designed to accommodate a **LEGENDAIR®** appliance and keep it partly protected against impacts, dust and view. The various functional interfaces of the ventilator remain accessible, hence enabling the equipment to be used when the patient in being moved. Particular care has been given to the design of the bag for two different conditions of transport:

- that in which the ventilator has to be adapted and secured to a wheelchair. To this, the bag is fitted with a hanger strap and belt holder strap.
- that in which the ventilator is to be carried like a back-pack. The bag is also delivered with detachable and adjustable padded shoulder suspenders equipped with patient circuit holding rings.

In addition, the bag is fitted with rings and clips for hooking belts and an access window to the screen and keypad of the unit, protected by a closing visor.



BATTERY PACK *OPEN Pack®* – Code 4096300

The ***OPEN Pack®*** system is a “smart” battery pack which allows to supply **AIROX** ventilators with 24 V DC power.

It is delivered as a basic version with one battery (fixed) and the following set of elements:

- A cable for connecting the system to the mains Code 2967400 with a maximum length of 2.5 m.
- A 115/230 VAC mains relay cable Code 2968100 with a maximum length of 30 cm for connecting Class II ventilators to the mains (without grounding socket).
- A carrying bag Code 3818900 for protecting and carrying the ***OPEN Pack®*** and attaching it to the **LEGENDAIR®** ventilator when it is used in the **LEGENDAIR® DUAL BAG** Code 2967200.
- Two different 24V cables to supply the **LEGENDAIR®** ventilators. The 24V cable Code 3817300, with a maximum length of 26cm is intended for apparatus previous to October 2005 and the 24V cable Code 3818300 with a maximum length of 20cm is intended for apparatus prior to October 2005.

The ***OPEN Pack®*** system can contain up to two built-in batteries, one is integrated and fixed, and the other one which is removable enables the overall autonomy to be increased as desired without interrupting the power supply to the ventilator to which the apparatus is connected.

The autonomy offered by the internal battery(ies) of the ***OPEN Pack®*** system depends on the ventilator to which it is connected, the level of adjustments made, the environmental conditions (primarily in terms of temperature) as well as the physiological characteristics of the patient using the ventilator.

On average the autonomy at a temperature of 25°C when the ***OPEN Pack®*** system is connected to the ventilator is as follows:

Ventilation Parameters **LEGENDAIR®**	Average autonomy based on maximum battery charge
Vt ≈ 200 ml IPAP ≈ 10 mbar R ≈ 20 bpm	10 h with 1 battery and 20 h with 2 batteries + internal autonomy of the ventilator
Vt ≈ 300 ml IPAP ≈ 20 mbar R ≈ 15 bpm	8 h with 1 battery and 16 h with 2 batteries + internal autonomy of the ventilator
Vt ≈ 500 ml IPAP ≈ 30 mbar R ≈ 15 bpm	6 h with 1 battery and 12 h with 2 batteries + internal autonomy of the ventilator
Maximum ventilation parameters	4 h with 1 battery and 8 h with 2 batteries + internal autonomy of the ventilator

The time needed to completely recharge a battery is about 3h30 to 4 hours and hence 7 to 8 hours when the system is equipped with two batteries.

The general technical data of the apparatus are as follows:

- AC Electrical supply:
  90 to 260 VAC (115/230 V nominal) – 50/60 Hz
  Consumption: 100 VA
  Power: 100 to 300 VA depending on mains relay installation
- DC power output:
  22 to 29 VDC – 3.3 A maximum
- AC power output (mains relay):
  90 to 260 VAC (115/230 V nominal) – 50/60 Hz
  Power: 200 VA maximum
- Internal batteries: 25,2 V – 4,4 Ah Lithium Ion type - rapid recharge type.
- Electrical Insulation class: Class II
- Protection index of enclosure: IP 21
- Dimensions (excluding accessories): H = 45 mm, L = 235 mm, P = 220 mm
- Weight: 1.8 kg with 1 battery and 2.6 kg with 2 batteries (excluding cables).

24V ELECTRICAL SUPPLY CORD – Code 3810800

This cord, with a length up to 2 m, can be used for supply from an external 24 V direct current source, connecting directly to the direct current inlet located on the back of the apparatus.

Depending on the specific generation of the unit, two types of connectors are available, equipped with the following types of lead:

- Concentric contacts connector : Code **3810800**
- « push-pull » lock-on connector: Code **3818100**

SINGLE USE, SINGLE CONNECTION PATIENT CIRCUIT – Code 5092800

This 1.8m **single use** patient circuit has all the necessary parts to rapidly connect the ventilator:

- 1.8 m PVC Ø 22 mm patient tube
- Exhalation valve and its command tube directly attached to the Ø 4 ventilator nozzle
- Monitoring connection and its tube directly attached to the Ø 6.5 ventilator nozzle
- Total internal volume: 500 cm^3 – 800 cm^3 maximum
- Average circuit compliance: 1.4 ml/mbar – 1.85 ml/mbar maximum

SINGLE USE, DOUBLE CONNECTION PATIENT CIRCUIT – Code 5093000

This 2 x 1,8 m **single use** patient circuit has all the necessary parts to rapidly connect the ventilator:

- Outgoing 1.8 m PVC Ø 22 mm patient tube and 1.8 m return with water trap and 22 M – 22 M elbow and connected by a «Y»
- Exhalation valve and its command tube directly attached to the Ø 4 ventilator nozzle. The valve is directly on the exhalation unit
- Monitoring union and its tube that can be directly connected to the Ø 6.5 connector of the ventilator.
- Total internal volume: 1100 cm^3 – 1600 cm^3 maximum
- Average compliance of the circuit: 1.4 ml/mbar – 1.85 ml/mbar maximum
- Internal volume of the water trap: 100 cm^3 maximum

AIROX COMMUNICATION SOFTWARE – Code 2962000

This software delivered on a CD enables the installation of the **AIROX COMMUNICATION V3.5.1** application on a PC computer.

The minimum level required in terms of hardware performance of the PC is:

- Screen resolution: 1024 x 768 pixels
- RAM: 16 MB minimum
- Processor: 100 MHz minimum

With this software, operating under the Windows 98, 2000, Millennium and XP operating systems, you can:

- Download new software to the **LEGENDAIR®**
- Retrieve the data stored by the apparatus (list of events: on / off / alarms / defaults) and edit them in the form of a report.
- View the signals of pressure and flow or combinations of these signals (loops) in real time during ventilation.
- Display the alarms triggered on the apparatus in real time

- Save the real ventilation parameters during a period ranging from a few minutes to several hours and edit them in the form of a report.

The **AIROX COMMUNICATION V3.5.1** application is compatible with ***SMARTAIR® Plus***, ***SMARTAIR® ST***, ***SUPPORTAIR®*** and ***TWINAIR®*** ventilators in their most recent software versions however their functions are restricted with regard to those available with **LEGENDAIR®**.

Note: For using **AIROX COMMUNICATION** with a **LEGENDAIR®**, the communication speed of your PC serial port must be set to 38400 baud.

COMMUNICATION CORD – Code 2961900

This cord, with a length of up to 2 m, can be used to connect the **LEGENDAIR®** to a PC computer via their respective serial ports to run **AIROX COMMUNICATION** software.

WARNING
(***)The RS232 series communications port of the LEGENDAIR® is sensitive to electro-static discharge and it must only be handled after the usage precautions for this type of product have been made (earth the operator with an anti-static bracelet).

AFTER SALES SERVICE

The after sales service details are as follows:

AIROX

Parc d'Activités Pau-Pyrénées
L'Echangeur – BP 833
64008 PAU Cedex – France

TEL.: (+33) 5 59 14 02 02
FAX After-sales Service: (+33) 5 59 14 02 30

Other technical information, such as diagrams, intervention methods not described in the current document are presented in the "Maintenance Manual" which is supplied during the training that enables the establishment of a certification for technical intervention on this apparatus.

Any intervention on this apparatus must be undertaken by certified and qualified personnel only.

All safety precautions must be taken before intervening on the apparatus. In particular, the apparatus must be turned off and disconnected from the external power supply before being opened.

Because this apparatus carries the CE mark, no modification may be made to the apparatus without the prior approval in writing from AIROX.

WARRANTY CONDITIONS

All our equipment is warranted for one year (1) parts and labour from the date of it despatch (2) and for any default in manufacture.

The implementation of the warranty is governed by the communication to AIROX of the BL/Type numbers and serial number of the apparatus concerned.

No maintenance work for which the equipment needs to be opened is necessary within the first twelve months of operation.

A tamper proof label under the equipment states that the equipment is under "Warranty" for the first year.

The contractual warranty provided by AIROX will be null and void if this label is damaged in any way by opening the equipment during the first twelve months (unless AIROX gave written permission before the equipment was opened).

The repair or the replacement of the part or parts recognised as faulty according to our diagnosis is carried out on site for the non transportable equipment, or in our workshops (or certified After Sales Centres) for all transportable equipment. The warranty covers the cost of despatch after repair; sending the equipment to our premises is at the expense of the client.

Any part replaced under this warranty becomes the property of AIROX and must be returned upon request within the month that follows the exchange. Its non return will result in its being invoiced to the client (3).

Materials, accessories or spare parts distributed by AIROX but not of AIROX manufacture are covered by the warranty granted by their manufacturer.

The warranty does not cover the methods of normal maintenance foreseen for each piece of equipment.

The warranty does not apply in the case of abnormal use of equipment and in particular in the case of faults in electrical supply over and above the limits foreseen.

The warranty ceases rightfully in the case of intervention on the apparatus without the permission in writing of AIROX or its representative and outside the rules of quality assurance and traceability put in place by AIROX.

Specific conditions concerning equipment outside the French mainland or exported:

(1) One year and three months
(2) Date of invoicing
(3) All replacements for parts under warranty are subject to prior return of the faulty part to our factory.

Parc d'Activités Pau-Pyrénées
L'Echangeur – BP 833
64008 PAU Cedex – FRANCE

TEL.: (+33) 5 59 14 02 02
FAX: (+33) 5 59 14 02 00