



SAIME

Fabricant de Matériel Médical
Medical Device Manufacturer

HELIA-S

*PRESSURE SUPPORT PULMONARY
VENTILATOR*

Service Manual

Ref. NTA0005042-b

WARNING

- ⇒ This Service Manual may be used as a complement of Helia User's Manual. It is therefore compulsory to have read and understood the User's Manual prior to the lecture and understanding of the Service Manual.

- ⇒ Helia S settings should be made by professionally trained and competent personnel working under a doctor's responsibility.

- ⇒ Helia S settings exclusively depend on a doctor's medical prescription.

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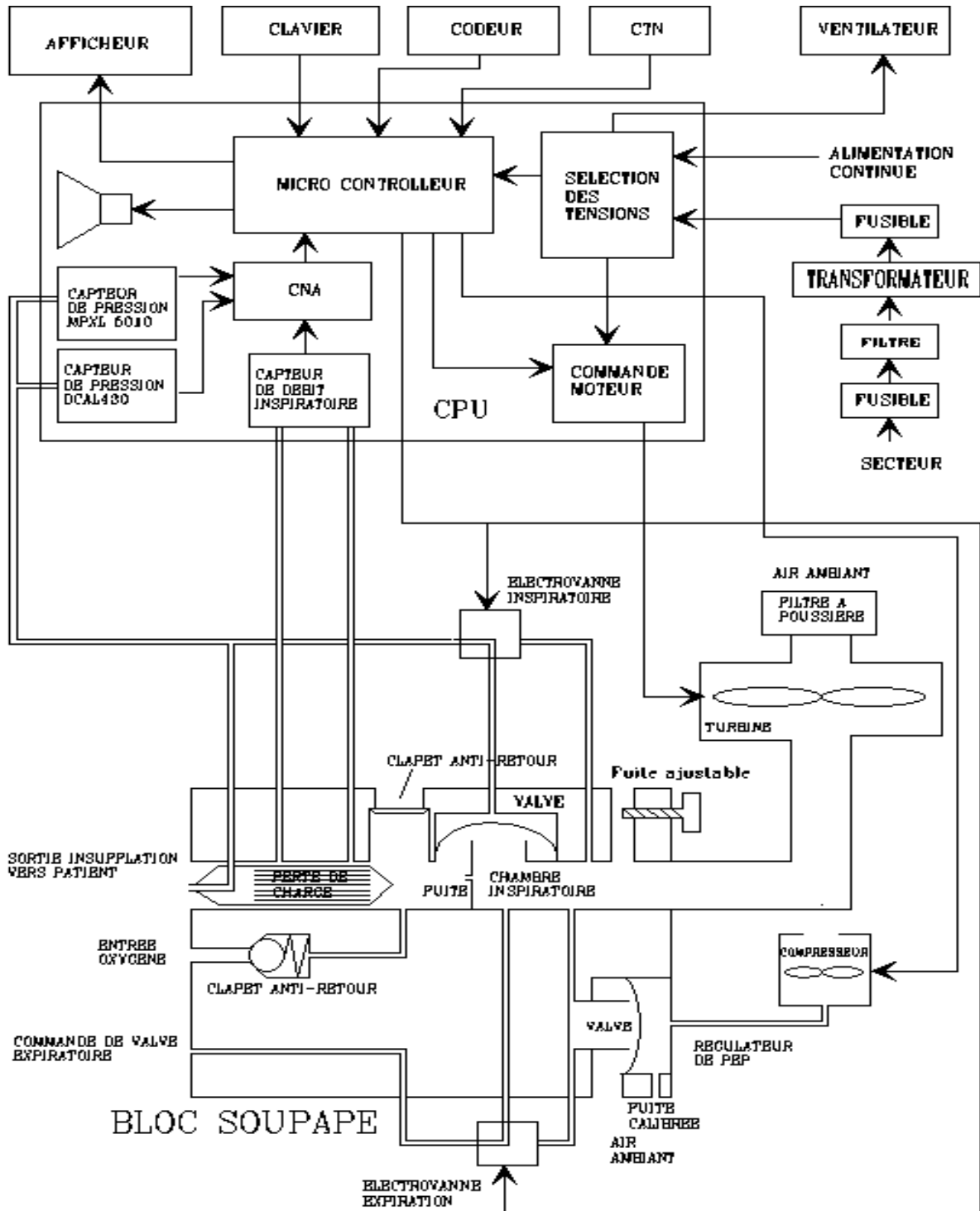
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1. FUNCTIONAL DIAGRAM

1.1 Synoptic



1.2 Synoptic translation

Afficheur	Display
Air ambiant	Ambient air
Alimentation continue	Continuous DC external supply
Alimentation extérieure	External power supply
Alimentation Secteur	Mains supply
Alimentation secteur carte	PWR card mains supply
BLOC SOUPAPE	VALVE UNIT
Capteur de débit expiratoire	Exhale rate sensor
Capteur de débit inspiratoire	Inhale rate sensor
Capteur de Pression	pressure sensor
Capteur de Pression DCAL 430	DCAL 430 pressure sensor
Capteur débit	Flow rate sensor
Capteur Oxygène	Oxygen sensor
Carte alimentation	Power supply board
Carte CPU	CPU board
Carte FDC	FDC board
Chambre expiratoire	Exhale chamber
Chambre inspiratoire	Inhale chamber
Clapet anti-retour	Non-return valve
Clavier	Keyboard
CNA	CNA
Codeur	Coder
Comande moteur	Motor control
Command de valve expiratoire	Exhale valve control
Compresseur	Compressor
CYN	CYN
Electrovanne	Electro valve
Electrovanne Dépression	Volume drop electro valve
Electrovanne Expiratoire	Exhale electro valve
Electrovanne Inspiratoire	Inhale electro valve
Entree des gas	Gas input
Entree Oxygène	Oxygen input
Expiration	Exhale circuit
Extérieur	Outside
Filtre poussière	Dust filter
Fuite ajustable	Adjustable vent
Fuite calibrée	Calibrated Vent
Fusible	Fuse
Inspiration	Inhale direction
Insufflation	Insufflation toward patient
Mesure débit expiratoire	Exhale rate measurement
Mesure débit inspiratoire	Inhale rate measurement
Mesure Oxygène	Oxygen measuring cell
Mesure Pression	pressure measurement
Moteur	Motor
Regulateur PEEP	PEEP regulator

Retour Expiration patient	Patient exhale return
Secteur	Mains
Selection des tensions	Voltage selector
Sélection pression débit	Flow rate pressure selector
Sortie des Gaz expirés	Exhaled gas output
Sortie insufflation vers patient	Insufflation output toward the patient
Transformateur	Transformer
Turbine	Supply Head
Turbine Moteur MINIMOTOR	Supply Head / Minimotor motor
Valve	Valve
Valve expiratoire	Exhale Valve
Ventilateur	Ventilator

2. OPERATING PRINCIPAL

2.1 Principle

- ✓ The pneumatic system is based on a supply head and pneumatic block.
- ✓ The supply head is driven by a brushless DC motor. The supply sucks in the surrounding air and passes it through a filter. The pneumatic block either distributes the air to the patient (the insufflation cycle) or else blocks off the gas during the expiration cycle.
- ✓ The pressure delivered by the ventilator during the inhale cycle depends on the rotation speed of the supply head.
- ✓ The Positive End Expiratory Pressure (PEEP) is determined via a compressor and a pneumatic regulator.
- ✓ Non-return safety valves ensure that the patient can breath freely through the ventilator.

2.2 Microcontroller

The microcontroller on the Central Processing Unit (CPU) manages:

- ✓ The ventilation cycles (frequencies, inspiration times..) by means of the inhale and exhale electrovalves.
- ✓ The pressure level by means of the supply head and pressure sensor readings.
- ✓ The Positive End Expiratory Pressure (PEEP) by means of the compressor.
- ✓ The inhale trigger by means of the pressure sensor.
- ✓ The exhale trigger (PSV & PSV+F modes) by means of the inhale flow rate sensor (pressure loss type sensor)
- ✓ Man/machine interface communication (keyboard, LED, display, etc.)
- ✓ The alarms (buzzer)
- ✓ Power supply source switching

2.3 Current supply possibilities

- ✓ The Helia S may be run either from:
 - the mains (230 AC – 50 Hz – 1.25 A maximum)
 - an external DC supply between 24 VDC / 2A maximum.
- ✓ The V.EXT LED indicates the presence of the external voltage.

Note: The two sources may be connected simultaneously in which case the ventilator will default to the mains supply.

Warning

The Helia S has no internal battery. It is wholly dependent on the mains and/or the external DC supply. With none of those power sources, Helia S stops working. However, an audible alarm is released in such case.

✓ Both Power Sources fail

If both of these fail, an alarm warns the user that the ventilator has stopped working. This alarm is turned off by pressing the Alarm Off button.

✓ The DC supply fails

If the DC supply fails (but the mains keeps running) an alarm goes on and a "EXT PWR!" message is displayed. This alarm is turned off by pressing the Alarm Off button.

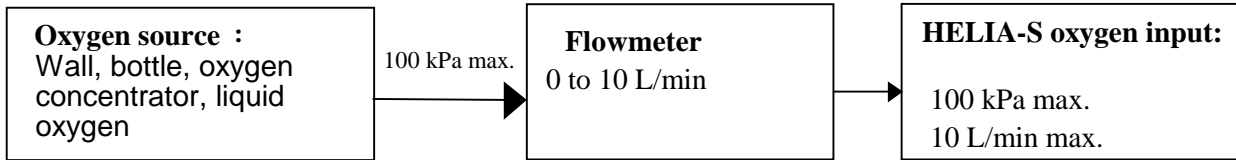
✓ The mains supply fails


If the mains supply fails (but the DC power keeps running) an alarm goes on and a "MAINS!" message is displayed. This alarm is turned off by pressing the Alarm Off button.

☞ **NOTE: The external power supply must have a runtime of at least one hour.**

3. OXYGEN SUPPLY REMINDER

Synoptic



- ✓ Oxygen source must be connected to the oxygen input identified on the front face by the symbol: 
- ✓ Oxygen source shall provide:
 - maximum pressure: 100kPa
 - maximum adjustable flow: 10 L/min
- ✓ Accessory: Grooved on-line female coupler (diameter 4mm – ref: PMC17-02 CPC coupler) ref COU006231.

Note 1: with a maximum oxygen flow of 10 L/min, Helia S can accept FiO₂ from 21 to 70%.

Note 2: Helia S does not feature any oxygen monitoring system. Oxygen concentration is regulated by an external flowmeter.

Warning: if the oxygen pressure is higher than 1 bar, a pressure reducer must be used.

4. VENTILATION SETTINGS REMINDER

4.1 Ventilation settings chart

Settings	Adjustment range	Adjustment increment	Display precision	Control precision	Ventilation modes				Notes
					PSV +F	PSV	PCV	APCV	
PS	05 to 60hPa	1 hPa	1hPa	±0,54 hPa	Yes	Yes	Yes	Yes	
PEEP	00 - 03 to 12hPa	1 hPa	1hPa	±1 hPa	Yes	Yes	Yes	Yes	
FREQ	05 to 60 cycles/min	1	1	±10 ms	Yes	No	Yes	Yes	Set to "SV" for spontaneous ventilation
TRIGGER	01 to 10	1	1	±0,54 hPa	Yes	Yes	No	Yes	Set to « CV » in PCV mode
FIN.I	05 to 90% or «AUTO»	1 %	1 %	±5 %	Yes	Yes	No	No	
Tins	0,5 to 3,5s	0,1 s	0,1 s	±20 ms	No	No	Yes	Yes	
SLOPE	00 to 02	1	1	without	Yes	Yes	Yes	Yes	

4.2 Delivered minute volume

The minute volume delivered to the patient by the ventilator depends on the ventilator settings (Pressure level, Frequency, Inspiratory time) and the physiological traits of the patient (resistance & compliance). With PS=40hPa et a measured I/E=1/2, results are:

Compliance	Minute volume delivered for a resistance calibrated Rp20 (2,0 cm H ₂ O/litre/s)	Minute volume delivered for a resistance calibrated Rp5 (0,5 cm H ₂ O/litre/s)
0,03 L/cm H ₂ O	23 litres	43 litres
0,04 L/cm H ₂ O	24 litres	44 litres
0,05 L/cm H ₂ O	24 litres	45 litres
0,06 L/cm H ₂ O	25 litres	46 litres
0,07 L/cm H ₂ O	25 litres	46 litres

4.3 Measured parameters

- ✓ 5 measured parameters are available:
 - Maximum pressure : bargraph.
 - Machine operating time: when the ventilator is turned on.
 - Frequency, I/E ratio, inspired Vt: automatically displayed when no button has been activated for 6 seconds.
- ✓ The measured parameters display automatically when the ventilator is turned on.
- ✓ If the operator displays the ventilation settings and then touches no button for 6 seconds, the measured parameters are automatically displayed again.

Measured parameter	Adjustment Range	Adjustment increment	Display precision	Notes
Pmax=xxhPa	0 to 76hPa	±0,54hPa	±1hPa	Sensor tip pressure at insufflation
Frequency=xx/min	0 to 99 cycles/min	±20 ms	±1cycle/min	
I/E = 1/x.x	1/0.1 to 1/9.9	±0.1	±0.1	
Vti = x.xxL	0.00 to 4.00 L	Full range ±5%. Error at low volumes: ± 0.05L	±0.01l	Insufflated volume control (average volume over 2 cycles)
CLOCK=xxxxHww	0 to 99999H99	±10 ms	±1 minute	Machine operating time

4.3.1 Pressure sensor characteristics

- ✓ The DCAL 430 GN sensor is a differential pressure sensor (+76 hPa), consisting of a compensated and amplified piezo-resistive bridge with a ratiometric output voltage.
- ✓ The pressure measurement precision of +/- 0.54 hPa (characteristics of the sensor and the processing chain). This precision is defined for the linear zone 0 to 76 hPa. However, the sensor gives returns pressure readings up to 85 hPa..

4.3.2 Flow Rate sensor characteristics

- ✓ The AWM3201CR sensor is a differential pressure sensor (1.25 hPa) with a 4-20mA output current.
- ✓ The flow rate precision depends on the characteristics of the pressure loss sensor used.
- ✓ The sensor gain in Litres/sec x pressure gives the precision in litres/s.

4.3.3 *Measuring the inspiratory volume control*

- ✓ The measurement is given under ATPD conditions i.e. ambient temperature and pressure conditions and dry air (no water vapour).
- ✓ The volumes can be considered acceptable down to 0.1 litre. However, at low volumes (from 0.1 litre downwards), the volume reading error is 0.05 litre i.e. 50% of 0.1 litre.

5. ALARMS

5.1 Automatic not adjustable alarms.

Sorted by decreasing priority:

- ✓ General Electrical Power Cutoff alarm
- ✓ "MAINS!" (Mains Failure alarm)
- ✓ "LOW PRESSURE!" (except in PSV mode without frequency).
- ✓ "HIGH PRESSURE!"
- ✓ "HIGH FREQUENCY"
- ✓ "TECHNICAL!" (internal technical problem)
- ✓ "EXTERNAL POWER!" (external DC power supply failure)

5.1.1 Low Pressure Alarm

- ✓ This alarm has been programmed to go on at 3 hPa below the set ventilation pressure.
- ✓ If, after 5 respiratory cycles, the pressure is insufficient, the alarm goes on.

Note: this alarm does not exist in spontaneous ventilation mode but is replaced by "APNEA" alarm.

5.1.2 High Pressure Alarm

- ✓ This alarm has been programmed to go on at 10 hPa above the set ventilation pressure.
- ✓ If, after 0.5 seconds, the pressure exceeds +10 hPa, the alarm goes on.

Note: if, after 1 second, the pressure still exceeds +10 hPa, the ventilator switches to automatic expiration.

5.2 Adjustable alarms

Adjustable setting	Adjustment range	Message displayed
Min Vt level	No: -0.1 to 2.9 L	Insufficient Vt alarm
Max Vt level	0.1 to 4.0 L – No.	Excess Vt alarm

5.3 Signalling alarms

When an alarm goes on

- ✓ The red alarm LED goes on,
- ✓ A discontinuous beep is heard,
- ✓ The alarm message blinks on the screen.

If the operator presses the Alarm Off button

- ✓ The audible alarm stops for 2 minutes (except for the MAINS alarm or the EXTERNAL POWER alarm),
- ✓ The red LED continuously goes on,
- ✓ The alarm message blinks on the screen.

If the source of the alarm disappears

- ✓ The red LED goes off,
- ✓ The sound signal goes off,
- ✓ The alarm message displays without blinking on screen (alarm stored in memory) as long as the Alarm Off button hasn't been pressed.

5.4 Alarms operation*5.4.1 Mains*

- ✓ The "MAINS!" alarms means the power supply failure.
- ✓ The audible alarm disappears if a correct tension is back. In this case, the message is memorized and displayed on screen.
- ✓ Pressing the Alarm Off button makes it disappear.

5.4.2 External supply

- ✓ The "EXT.PWR!" message means a loss of external supply. It is never release when the ventilator is turned on.
- ✓ It can be active in 2 ways:
 - Helia S not plugged onto the mains: display and fast buzzer can not be inhibited.
 - Helia S plugged onto the mains: display and normal buzzer with silence alarm function available.

Notes:

- ✓ *The non-inhibited alarm is released if the external supply tension is lower than 21.5V for at least 5 seconds. The inhibited alarm is released if the external supply tension is in-between 21.5 & 22.5 V, or higher than 29 V, for at least 5 seconds.*
- ✓ *This alarm system is particularly suitable for external battery packs SB Helia supplied by Saime.*

5.5 Alarms - Summary table

Means of Report	Symptom	Possible causes	Corrective actions
Continuous sound alarm No message	Complete ventilator stop	General electricity failure	<input type="checkbox"/> Check fuses F1, F2 and the mains fuse. <input type="checkbox"/> Reconnect the mains or external DC supply <input type="checkbox"/> Use an alternative means of ventilation.
MAINS Discontinuous sound alarm	Mains electricity supply failure	<input type="checkbox"/> Mains failure. <input type="checkbox"/> Mains cable has fallen out or is defective.	<input type="checkbox"/> Check fuses F and F1. <input type="checkbox"/> Check the mains cable. <input type="checkbox"/> Run the ventilator from the back-up supply unit.
EXTERNAL POWER Discontinuous sound alarm.	External DC supply failure	<input type="checkbox"/> External DC power failure. <input type="checkbox"/> External DC voltage insufficient or the batteries of the external DC source discharged. <input type="checkbox"/> Cable has fallen out or is defective. <input type="checkbox"/> External DC supply faulty	<input type="checkbox"/> Make sure the DC source is connected. <input type="checkbox"/> Check fuse F2. <input type="checkbox"/> Replace/charge the external supply. <input type="checkbox"/> Check the cable. <input type="checkbox"/> Check/replace the fuses of the external DC supply. <input type="checkbox"/> Run the ventilator from the mains
LOW PRESSURE or APNEA Discontinuous sound alarm.	Low Inspiratory pressure	<input type="checkbox"/> Patient circuit leaks <input type="checkbox"/> Patient disconnected. <input type="checkbox"/> Change of the patient's clinical state. <input type="checkbox"/> Faulty pressure sensor.	<input type="checkbox"/> Eliminate leaks. <input type="checkbox"/> Reconnect the patient. <input type="checkbox"/> Adapt the settings to the patient's new clinical condition. <input type="checkbox"/> Call maintenance if the problem persists.
HIGH PRESSURE Discontinuous sound alarm.	High Pressure	<input type="checkbox"/> Patient circuit occlusion. <input type="checkbox"/> Change of the patient's clinical state. <input type="checkbox"/> Faulty pressure sensor.	<input type="checkbox"/> Eliminate the source of the occlusion. <input type="checkbox"/> Adapt the settings to the patient's new clinical condition. <input type="checkbox"/> Call maintenance if the problem persists.
VT min Discontinuous sound alarm.	Low inspiratory tidal volume	<input type="checkbox"/> Patient circuit leaks. <input type="checkbox"/> Partial patient circuit occlusion. <input type="checkbox"/> Patient disconnected. <input type="checkbox"/> Leaks on the endotracheal sensor or the balloon has deflated. <input type="checkbox"/> Alarm level setting not correct. <input type="checkbox"/> Change of the	<input type="checkbox"/> Eliminate the source of the leaks. <input type="checkbox"/> Make sure that neither the patient circuit nor the intubation sensor do not contain any excessive resistances and the patient's air passage is not blocked. <input type="checkbox"/> Check the balloon sensor and pressure. <input type="checkbox"/> Check the level of the

		<p>patient's clinical state.</p> <ul style="list-style-type: none"> ❑ Faulty flow rate sensor. 	<p>alarm.</p> <ul style="list-style-type: none"> ❑ Adapt the settings to the patient's new clinical condition. ❑ Call maintenance if the problem persists.
<p>VT max</p> <p>Discontinuous sound alarm.</p>	<p>Excessive inspiratory tidal volume</p>	<ul style="list-style-type: none"> ❑ Patient circuit leaks. ❑ Alarm level setting not correct. ❑ Change of the patient's clinical state. ❑ Faulty flow rate sensor. 	<ul style="list-style-type: none"> ❑ Eliminate the source of the leaks. ❑ Check the level of the alarm. ❑ Adapt the settings to the patient's new clinical condition. ❑ Call maintenance if the problem persists.
<p>TECHNICAL</p> <p>Discontinuous sound alarm.</p>	<p>Technical problem with the ventilator</p>	<ul style="list-style-type: none"> ❑ Pressure sensor and/or supply head control faulty 	<ul style="list-style-type: none"> ❑ Use an alternative means of ventilation. ❑ Call maintenance if the problem persists.

6. CLEANING AND STERILISING

Warning

The ventilator should be cleaned and disinfected as described in the technical notice if the ventilator is being used for the first time or is being used on a new patient.

6.1 Maintenance frequency

The disposable ventilator elements should be cleaned or replaced in accordance with either the manufacturer's instructions or the medical policy in operation on the place of use. However, the table below gives Saime maintenance frequency for the pneumatic circuit elements.

Element Interval	New patient	Frequency given by constructor	Frequency given by medical staff
Patient circuits	Yes	Yes	Yes
Heating chamber	Yes	Yes	Yes
Bacteria filter	Yes	Yes	Yes

6.2 Patient circuit

- ✓ Reusable patient circuit elements should be disinfected and cleaned as per the manufacturer's recommendations.
- ✓ The reusable patient circuit should be regularly cleaned with soapy water, rinsed with clear water and dried before re-use.
- ✓ This basic maintenance procedure is recommended for home ventilation on one single patient.
- ✓ Only silicon tubes and valves are autoclavable.
- ✓ Cold disinfecting by immersion is also possible; use the BACTINYL® 5M solution.

6.3 Bacteria filter

- ✓ Bacteria filters used for bacterial and viral filtering should be replaced in accordance with manufacturer's instructions and whenever a new patient is connected.
- ✓ Filters used to filter dust should be changed every 500 hours.

6.4 External unit parts

- ✓ The external parts of the ventilator can be cleaned with a dry cloth or, if necessary, a slightly wet sponge.
- ✓ Do not use abrasive powders, alcohol or solvents.

6.5 Heating chamber

Note: we recommend using disposable chambers.

- ✓ Disposable heating chambers should not be put into an autoclave.
- ✓ Also, they should not be used with solutions containing phenol, ketone, formaldehyde, hypochloride, chlorinated hydrocarbons, aromatic hydrocarbons, and organic acids.
- ✓ Cold decontamination by immersion is also possible for reusable chambers; use a 2% or 4% BACTINYL® instrumentation liquid soap solution.
- ✓ Should you wish to disinfect an element after decontamination, use a 2% BACTINYL® 5M solution. Follow the same procedure as for the BACTINYL® instrumentation liquid soap.

Note: maintenance centres may use other decontamination procedures. However, they must be approved and respect current rules and regulations.

Warning: if other products are used, they must respect the conditions detailed in the French Pharmacopoeia; they must guarantee the absence of all residual products and they must not interfere with the ventilator's operation. Furthermore, they must not be in contradiction with the security measures recommended by Saime.

7. MAINTENANCE AND PREVENTIVE INSPECTIONS

Assuming the ventilator is used in normal operating conditions, the following procedure is recommended:

- ✓ The alarms should be regularly checked, especially before connecting a new patient.
- ✓ The pneumatic circuit should be checked before connecting a new patient.
- ✓ The dust filter should be regularly replaced.

The following schedule recommends time-tabled technical interventions:

At 4000 hours or 1 year *

- ✓ Check the alarms
- ✓ Check the LED light displays.
- ✓ Replace the valves, the non-return valves and the O-seals on the pneumatic block*.
- ✓ Check the internal pneumatic circuit for leaks*
- ✓ Check all connections (mechanical behaviour, insulation)*
- ✓ Calibrate the pressure and flow rate sensors*
- ✓ Check the voltages (24V, 12 V, 5V) and the DC supply*.
- ✓ Check the voltage of the CPU back-up battery (> 3.6 V)*
- ✓ Check the fuses*

At 12000 hours added to 4000 hours checking

- ✓ Fit a new supply head.
- ✓ Fit a new PEP compressor

This maintenance schedule shall be carried out following the indications provided by Saime. It is recommended to attend Saime technical trainings in order to get the maximum capability.

Note: unless otherwise mentioned, Helia S should be turned off for all internal handling. Also, the checks should be made only by correctly trained and qualified personnel.

8. CHECKING THE VENTILATOR

8.1 Checking the pneumatic circuit

8.1.1 The pneumatic block

To remove the pneumatic bloc

- ✓ Remove the back cover,
- ✓ Disconnect the electric leads and pneumatic tubes coming into the block,
- ✓ Unscrew the front panel,
- ✓ Take off the front cover,
- ✓ Unscrew the supply head,
- ✓ Disconnect the tube leaving the supply head and unscrew the screws on the front of the block.

Then

- ✓ Check the non-return valves.
- ✓ Disassembly the 2 pneumatic chambers and check the valves and seals.
- ✓ Make sure the nipples are tight.
- ✓ Make sure the electrovalves are tight.
- ✓ Replace faulty parts and put the unit back together again.

8.1.2 Pneumatic circuit tubes

- ✓ Check the tube between the supply head and the block.
- ✓ Check the pneumatic tubes as per the pneumatic circuit diagram 99-040-CAB-P.
- ✓ Connect the ventilator to a test lung with a resistance Rp20 and a compliance 0.05.
- ✓ Fit a pressure gauge to the pneumatic circuit.
- ✓ Make the settings: PCV, PS=40hPa, PEEP=0hPa, FREQ=16, TIns=1.2.
- ✓ Check the pressure rise in the ventilator.

8.2 Electrical Circuit Checks

8.2.1 Checking the fuses

- ✓ Turn off the ventilator.
- ✓ The fuse of the mains connector is a **T1,2AH250V** fuse (1.25A time lagged) and protects from overload.
- ✓ The fuse labelled **F2** on the PCB is a **T4AH250V** (4A time lagged). This is the secondary transformer fuse and protects from overheating.
- ✓ The fuse labelled **F1** on the PCB is a **T2AH250V** (2A time lagged). This fuse is connected to the external DC power supply and protects from overload.

Note: all defective fuses should be replaced with identical fuses respecting identical norms.

8.2.2 Checking the LED

- ✓ Connect an external source between 24 volts (minimum) and 26 volts (maximum) and make sure that the External V LED on the front panel lights up.
- ✓ Start the ventilator and check the LED for each of the ventilation modes, the Alarm LED and the trigger LED.

8.2.3 Electrical wiring

- ✓ Remove the back panel.
- ✓ Check the electrical wiring as per the wiring plan 99-040-CAB-E.
- ✓ Make sure that the ventilator is being run from the specific cable delivered with the ventilator. Using a different mains cable could be dangerous for the patient.

8.2.4 Checking the voltages on the CPU board

- ✓ The DC voltage between the pins 2 and 14 of the test connector should be $5V \pm 0.2V$
- ✓ The 12 Volts between the pins 3 and 14 of the connector test should be $12V \pm 0.02V$.
- ✓ The 5 volt reference voltage between the pins 4 and 14 of the J8 connector (buzzer side) should be $5V \pm 0.05V$.

8.3 Checking the ventilator

- ✓ Take off the ventilator's back cover.
- ✓ Start the ventilator from the mains with a pneumatic circuit connected.
- ✓ Leaving the mains connected, supply the machine with a 24 V DC supply.
- ✓ Disconnect the mains.
- ✓ The Mains alarm goes on.
- ✓ Press the Alarm Off button.
- ✓ Plug the mains back in and remove the DC supply.
- ✓ The External DC Supply alarm goes on.
- ✓ Press the Alarm Off button.
- ✓ Go to the PCV mode and set: PS = 20 hPa, FREQ= 16, Tins=1.2s
- ✓ Disconnect the pneumatic tube at the insufflation input.
- ✓ The Low Pressure alarm goes on.
- ✓ Reconnect the pneumatic tube at the insufflation input.
- ✓ Press the Alarm Off button.
- ✓ Disconnect the tube on the pressure sensor MPXL5010 at the back of the ventilator but pinch the tube closed so as to keep the ventilator working correctly. Apply a pressure of over 20hPa to the pressure sensor.

- ✓ The High Pressure alarm goes on.
- ✓ Reconnect the pneumatic tubes.
- ✓ Press the Alarm Off button
- ✓ Adjust the pneumatic test set for an inspiratory volume control of about 0.6 litre.
- ✓ Set Vt minimum on 2.5L
- ✓ The INSUFFICIENT TV alarm goes on.
- ✓ Block the minimum volume alarm.
- ✓ Press the Alarm Off button
- ✓ Set Vt maximum on 0.5L
- ✓ The EXCESS TV alarm goes on.
- ✓ Block the maximum volume alarm.
- ✓ Press the Alarm Off button
- ✓ Turn off the ventilator without pressing the Alarm Off button.
- ✓ The general power cut-off continuous sound alarm is activated.
- ✓ Press the Alarm Off button

9. ADJUSTING THE VENTILATOR SETTINGS

Warning:

The following settings may only be adjusted if the ventilator's memory containing the various settings has been unlocked. This should only be done by trained personnel with the required test material (test lung, spirometer, pressure gauge, endotest).

9.1 Technical Access

9.1.1 To access the technical menu

- ✓ Press the Alarm Off button and then, very quickly, the On/Off button. The technical menu displays on the screen and the supply head stops.
- ✓ Press the ventilation modes buttons to scroll the technical menu left or right.
- ✓ A setting has to display on the top-left of the screen before it can be adjusted.

9.1.2 To leave the technical menu

- ✓ Press the Alarm Off button and then, very quickly, the On/Off button.
- ✓ The technical menu disappears from the screen and the ventilator starts up again.

Note: if Helia S is turned off without having relocked the Technical menu, it will automatically proposes the regular menu next time it will be turned on.

9.2 Adjusting the Sensors

The ventilator should have been running for one hour before the following adjustment is made.

- ✓ Use the ventilation mode settings to display the OFD1 in the adjustment zone.
- ✓ Use the rotating button in order to get DEB1 between 0000 and 0001.
- ✓ Repeat the procedure for the settings OF-PR/PRES and OF-PR2/PRES2.

9.3 Adjusting the pressure (DIV.P)

- ✓ Hook up the ventilator to a test lung with a resistance Rp20 and a compliance 0.05.
- ✓ Fit a pressure gauge to the pneumatic circuit.
- ✓ Settings: PCV, PS= 40hPa, PEEP=0hPa, FREQ=10, Tins=2s.
- ✓ During the inspiratory phase, check that the measured pressure is 40hPa \pm 0.5 and that the bargraph contains 20 full squares. If the pressure setting is not within the range, select the P.DIV setting in order to increase or decrease the level of pressure read, then leave the technical menu and check the new setting.

9.4 Adjusting the Peep compressor

- ✓ Hook up the ventilator to a test lung with a resistance Rp20 and a compliance 0.05. Fit a pressure gauge to the pneumatic circuit.
- ✓ Adjust the following settings: PCV, PS= 20hPa, PEEP=5hPa, FREQ=16, Tins=1.2s.
- ✓ After 3 cycles, check the expiration pressure is indicated by the bargraph by 2.5 +/- 1 squares.
- ✓ Adjust the same settings but PEEP=10 hPa.
- ✓ After 3 cycles, check the expiration pressure is indicated by the bargraph by 5 +/- 1 squares.

If the expiratory pressure is out of this range, follow the instructions:

- ✓ Adjust PEEP=0
- ✓ Go to the technical menu
- ✓ Select AJ.PR setting to increase or decrease the PEEP value
- ✓ Leave the technical menu
- ✓ Follow the procedure as above indicated to check the settings at 5 and 10 hPa

9.5 Adjusting the inspiratory volume

- ✓ Hook up the ventilator to a test lung with a resistance Rp20 and a compliance 0.05.
- ✓ Connect a spirometer to the lung's entrance.
- ✓ Adjust the following settings: PCV, PS= 20hPa, PEEP=0hPa, FREQ=16, Tins=1.2s.
- ✓ Make sure that the inhale volume measured by the ventilator corresponds to the volume measured by the spirometer at ± 0.03 litre.
- ✓ If the volume setting is not within the range, enter the technical menu, select the I.VOL setting to increase or decrease the inhale volume as required, then leave the technical menu and check the setting.

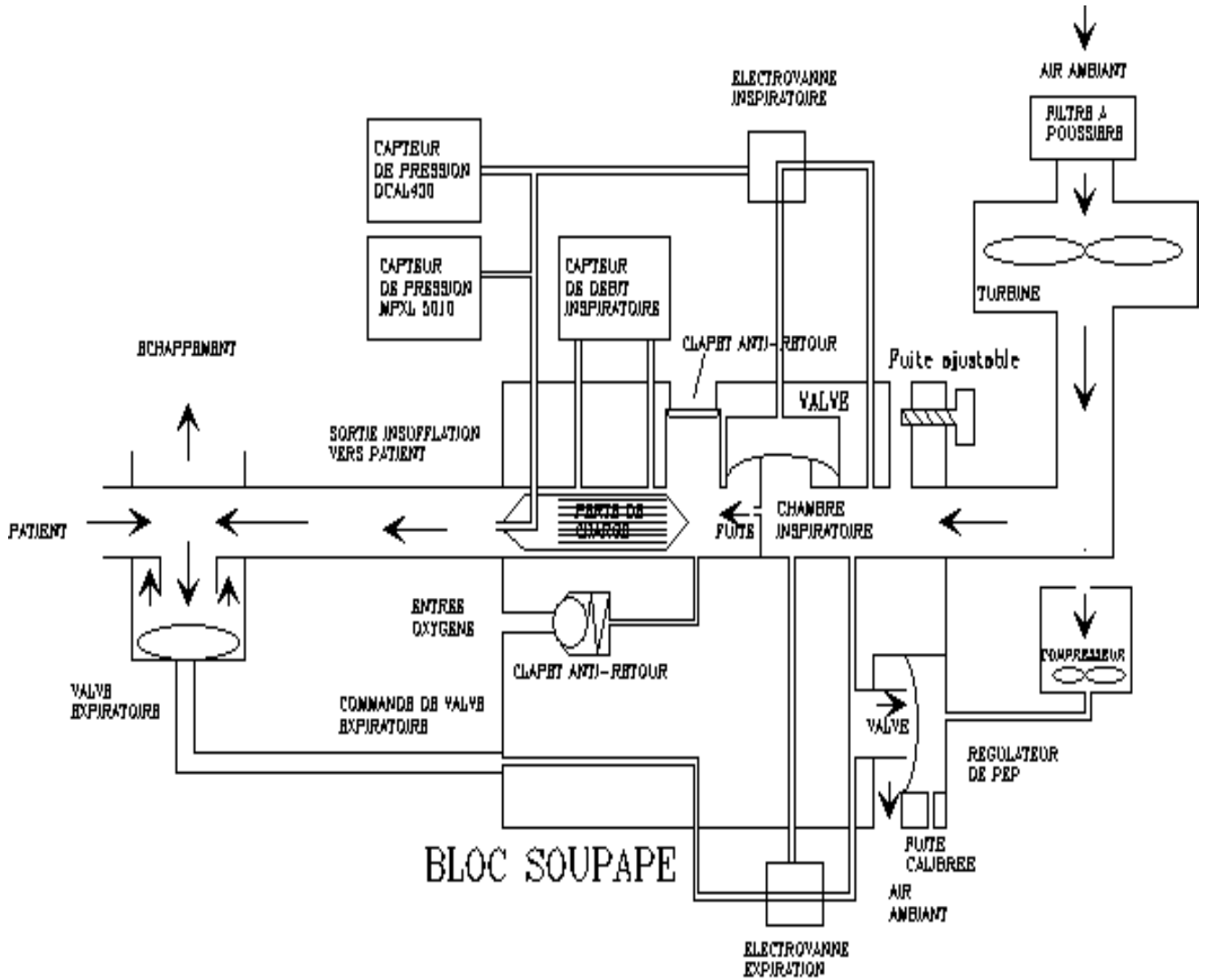
9.6 Adjusting the display contrast

- ✓ Remove the back cover from the ventilator.
- ✓ Start the ventilator and use the POT1 potentiometer on the CPU to adjust the contrast.

Inspiration cycle – Translation chart

Air ambiant	Ambient air
BLOC SOUPAPE	VALVE UNIT
Buzzer extérieur	Exterior buzzer
Capteur de débit expiratoire	Exhale rate sensor
Capteur de débit inspiratoire	Inhale rate sensor
Capteur de Pression 26 PC	26 PC pressure sensor
Capteur de Pression DCAL 430	DCAL 430 pressure sensor
Chambre inspiratoire	Inhale chamber
Clapet anti-retour	Non-return valve
Command de valve expiratoire	Exhale valve control
Compresseur	Compressor
Electrovanne Expiration	Exhale electrovalve
Electrovanne Inspiratoire	Inhale electrovalve
Entrée Oxygène	Oxygen input
Filtre poussière	Dust filter
Fuite	Leak
Fuite ajustable	Adjustable leak
Fuite calibrée	Calibrated leak
Perte de Charge	Pressure loss
Régulateur de PEP	PEEP regulator
Sortie insufflation vers patient	Insufflation output toward the patient
Turbine	Supply Head
Valve	Valve

10.2 Expiration cycle



➤ HELIA-S – expiration cycle

Expiration cycle – Translation chart

Air ambiant	Ambient air
BLOC SOUPAPE	VALVE UNIT
Buzzer extérieur	Exterior buzzer
Capteur de débit expiratoire	Exhale rate sensor
Capteur de débit inspiratoire	Inhale rate sensor
Capteur de Pression 26 PC	26 PC pressure sensor
Capteur de Pression DCAL 430	DCAL 430 pressure sensor
Chambre inspiratoire	Inhale chamber
Clapet anti-retour	Non-return valve
Command de valve expiratoire	Exhale valve control
Compresseur	Compressor
Electrovanne Expiration	Exhale electrovalve
Electrovanne Inspiratoire	Inhale electrovalve
Entrée oxygène	Oxygen input
Echappement	Release
Filtre poussières	Dust filter
Fuite	Leak
Fuite ajustable	Adjustable leak
Fuite calibrée	Calibrated leak
Perte de Charge	Pressure loss
Régulateur de PEP	PEP regulator
Sortie insufflation vers patient	Insufflation output toward the patient
Turbine	Supply Head
Valve	Valve

11. TECHNICAL SPECIFICATIONS

11.1 Ventilator specifications

Pulmonary ventilator	HELIA-S
Type	Pressure Support / Barometric
Ventilation	adult / children
Patient circuit	Single limb (with exhale valve)
Ventilation Modes	PSV / PSV+F / PCV / APCV
Weight	7 kg
Size (W x H x D)	21,0 x 34,0 x 26,5 cm

11.2 Power Supply

HELIA S is a Class II-b ventilator.

11.2.1 Mains

- ✓ 230V AC 50Hz 2A maximum / 80 VA
- ✓ Fuses T 2A H250V and T5A H250V

11.2.2 External supply

- ✓ 24V DC 2A maximum
- ✓ Fuse T2 H250V

11.3 Performances

- ✓ Maximum pressure delivered by the supply head in first-fault condition < 80 hPa.
- ✓ Maximum adjustable pressure: 60 hPa (P_{insp}+PEEP)
- ✓ Maximum pressure delivered by ventilator under normal operating conditions < 70 hPa.
- ✓ Flow rate at 40 hPa: 240 litres per minute (the flow rate is limited to 240 litres/min)
- ✓ Ventilator compliance: not measurable (depends on elasticity of air).

HELIA S has the following specifications with the filter, circuit and humidifier:

- ✓ Volume: 0,9 to 1,8L
- ✓ Compliance: 1,3 to 1,5 ml/hPa
- ✓ Inspiratory resistance: lower than 6hPa at 60L/min

Pressure losses in the pneumatic circuit:

Flow rate in litres per minute	Maximum inspiratory resistance in hPa
0	0
10	0.3
20	0.6
30	0.9
40	1.4
50	2
60	2.7
70	3.4
80	4.1
90	4.8
100	5.6
110	6.4
120	7.2

11.4 Conditions of use

- ✓ Operating temperature: +10 to +40°C
- ✓ Relative humidity: 10 to 75%
- ✓ Pressure: 600 to 1100 hPa

11.5 Ventilator operating limits

Any one of the following 5 conditions would be considered an operating limit:

- ✓ Ambient temperature from 5°C to 50°C
- ✓ Ambient relative humidity from 10% to 95%.
- ✓ Atmospheric pressure from 600 to 1100 hPa.
- ✓ Mains voltage deviating –20% to +10% from the nominal value.
- ✓ External supply tension from –20% to +10%, for an external tension lower than 24VDC-10% (21,6V), the external supply alarm is released.
- ✓ A combination of +45°C and 75% RH.

11.6 Storage conditions

11.6.1 The ventilator and its accessories **are** in original boxes

- ✓ Storage temperature: from +5° to +60°C.
- ✓ Do not store in humid conditions.
- ✓ The ventilator is fragile, it should be handled with care.
- ✓ The ventilator should be stored as it is used, i.e. in a vertical position on all legs.

11.6.2 The ventilator and its accessories **are not** in original boxes

- ✓ Storage temperature: from +5° to +60°C.
- ✓ Do not store in humid conditions.
- ✓ The ventilator is fragile, it should be handled with care.
- ✓ The ventilator should be stored as it is used, i.e. in a vertical position on all legs.

11.7 Transport conditions

- ✓ The ventilator and its accessories should be placed in their original SAIME packaging for transport.
- ✓ Transport temperature: +5°C to +60°C.

11.8 Materials used

The materials used in the ventilator are:

	In contact with the inspired air	In contact with breathed oxygen
AutoText		
Rubber		
Polyester		
Aluminium	✓	✓
Stainless steel	✓	✓
Brass	✓	✓
Delrin	✓	✓
Silicon	✓	✓
Foam: PPI 80 polyester	✓	

11.9 Fire prevention

For a ventilator in first-fault condition and an oxygen input set at 10 litres per minute the oxygen concentration inside the ventilator is:

- ✓ Less than 24% \pm 1%, for a stopped ventilator
- ✓ Less than 22% \pm 1%, for a working ventilator

For a ventilator in first-fault condition, the inflammable materials cannot reach their ignition temperatures without setting off a high temperature alarm fixed at 50°C.

11.10 Applied Standards

The ventilator meets with the following standards:

- ✓ EN 60 601-1 for electromedical devices (safety rules)
- ✓ IEC 601-1-4 for electromedical devices (programmable systems)
- ✓ EN 794-2 for pulmonary ventilators for use in the home.
- ✓ EN 55 011 - Class B
- ✓ EN 61 000-4-2
- ✓ EN 61 000-4-4
- ✓ EN 61 000-4-5
- ✓ IEC 801-3
- ✓ EC 0197 93/42 EC
- ✓ GM

12. TECHNICAL SPECIFICATIONS FOR THE VENTILATOR ACCESSORIES

12.1 Pneumatic circuits

- ✓ They must have the EC label
- ✓ Maximum internal volume of the circuit: 800 cm³ for a single circuit
- ✓ The average compliance of the circuits must be less than 1ml/hPa.
- ✓ Maximum resistance: 0.3 to 1 l/s
- ✓ Resistances may not be higher than 6hPa at 60 litres for the adult and 6 hPa at 30 litres for children.

Note: to use a paediatric patient circuit, a standard male/male connector 22mm/15mm may be used.

12.2 Gas input filter

This filter is supplied by SAIME.

The dust filter is a PPI 80 foam pad (Polyester foam with an 80 micron grid)

12.3 Bacteria filter

- ✓ Recommended bacteria filter: FILTA GUARD from INTERSURGICAL, code 1944.
- ✓ Viral / Bacteria filter
- ✓ Bacteria and viral retention greater than 99,999%
- ✓ Resistance at 60 litres/minute: 2.3 cm H₂O
- ✓ Compliance: non measurable (air elasticity)
- ✓ Compressible volume: 66ml
- ✓ Connector: 22mm diameter male cone / 15mm diameter female cone and 22mm diameter female cone

Note: the filter usage life is 24 hours if used as a viral/bacteria filter.

12.4 Oxygen supply

- ✓ Accessory: Grooved on-line female coupler (diameter 4mm – ref: PMC17-02 CPC coupler).
- ✓ Oxygen supplied from both bottles and wall taps should be limited to 4 bars. If this is not the case, use a pressure reducer.
- ✓ The oxygen flow rate should be adjustable up to 10 litres per minute and the oxygen pressure (as measured at the flowmeter's nozzle) should be less than 100 kPa.

12.5 Heating chambers

- ✓ Recommended types: MR 250
- ✓ Maximum volume: 0.5 litre.
- ✓ Flow rate: 180 litres/minute
- ✓ Liquid flow rate: from 10 to 25 mg/litre
- ✓ Maximum service pressure: > 80 hPa.
- ✓ Pressure drop at 180 litres/minute: < 3 hPa
- ✓ Pressure drop under conditions of natural breathing: < 3 hPa
- ✓ Gas Loss At Maximum Pressure: < 20 ml/minute
- ✓ Average compliance: 0.3 to 0.5 ml/hPa
- ✓ All equipment must have the EC label.

Complete circuit characteristics (including humidifier)

- ✓ Complete pneumatic system:
 - Average volume: 1.4 litre
 - Average compliance: 1 ml/hPa
- ✓ Circuit:
 - Average volume: 1.4 litre
 - Average compliance: 1 ml/hPa

12.6 External DC Power Supply

- ✓ The material used must have the EC label
- ✓ The external power supply must be capable of supplying a 24 DC voltage, with a maximum current of 5A and for a duration of over 1 hour non-stop.

12.7 Technical properties of BACTINYL® 5M

- ✓ BACTINYL®5M is a concentrated disinfectant: SPORICIDE, FUNGICIDE, BACTERICIDE and VIRUCIDE.
- ✓ BACTINYL®5M is used with clean materials, which has been decontaminated beforehand with soapy water.

12.7.1 Instructions for use

- ✓ Prepare an immersion bath (at 2% for products not ready to be used) in cold or lukewarm water.
- ✓ Completely immerse the equipment to be disinfected (both the patient circuit and the removable unit).
- ✓ Leave it in the water for 15 minutes.
- ✓ Rinse with sterile water (or water with low bacteria count) and let dry.

12.7.2 Caution

- ✓ Do not use with other products.
- ✓ Do not swallow.

- ✓ Rinse with clear water if the product is in contact with skin or eyes.

Information: for surface disinfecting, Saime recommends BACTINYL® (FUNGICIDE, BACTERICIDE, and VIRUCIDE).

The F. GARCIN pharmaceutical laboratories manufacture BACTINYL®: 63000 CLERMONT-FERRAND, FRANCE.

Appendix 1 : Applicable Diagrams

- Electrical wiring diagram
99-040-CAB-E
- CPU electrical layout diagram
99-040-CPU-E
- Wiring diagram for pneumatic circuit
99-040-CAB-P

Appendix 2: Symbols



Type B device



Please read the supplied documentation



AC voltage



DC voltage



Class II



Complies with EC standards



Fragile



Store and transport this side up



Keep away from water



Alarm off button

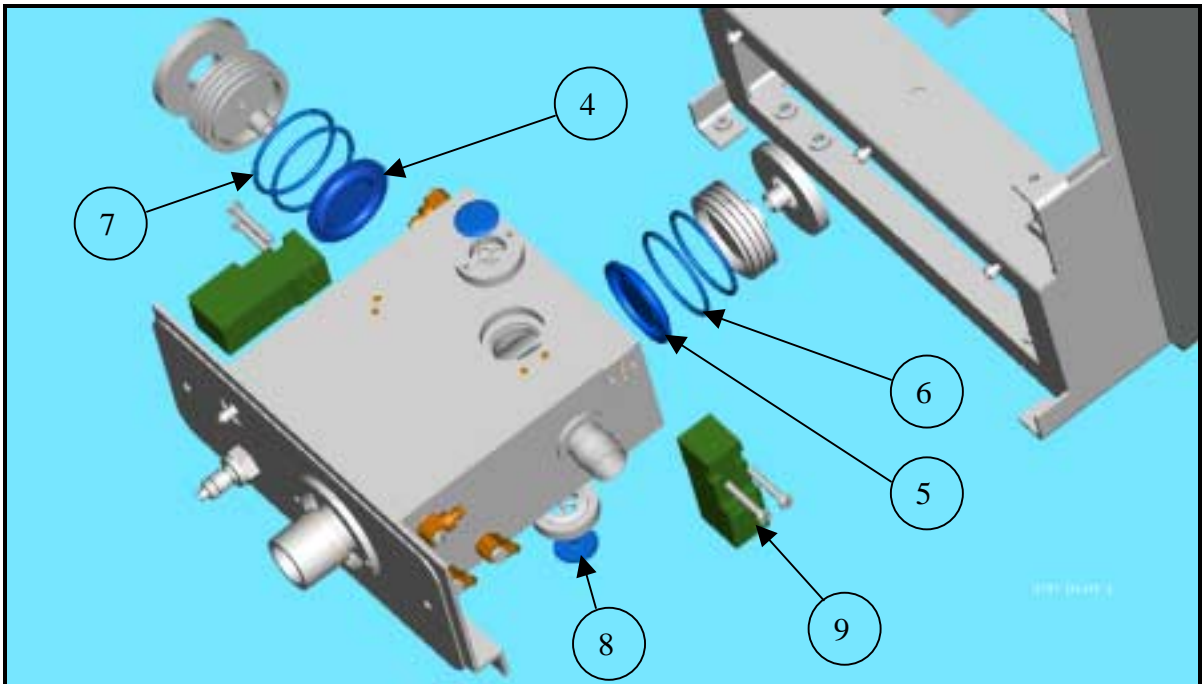
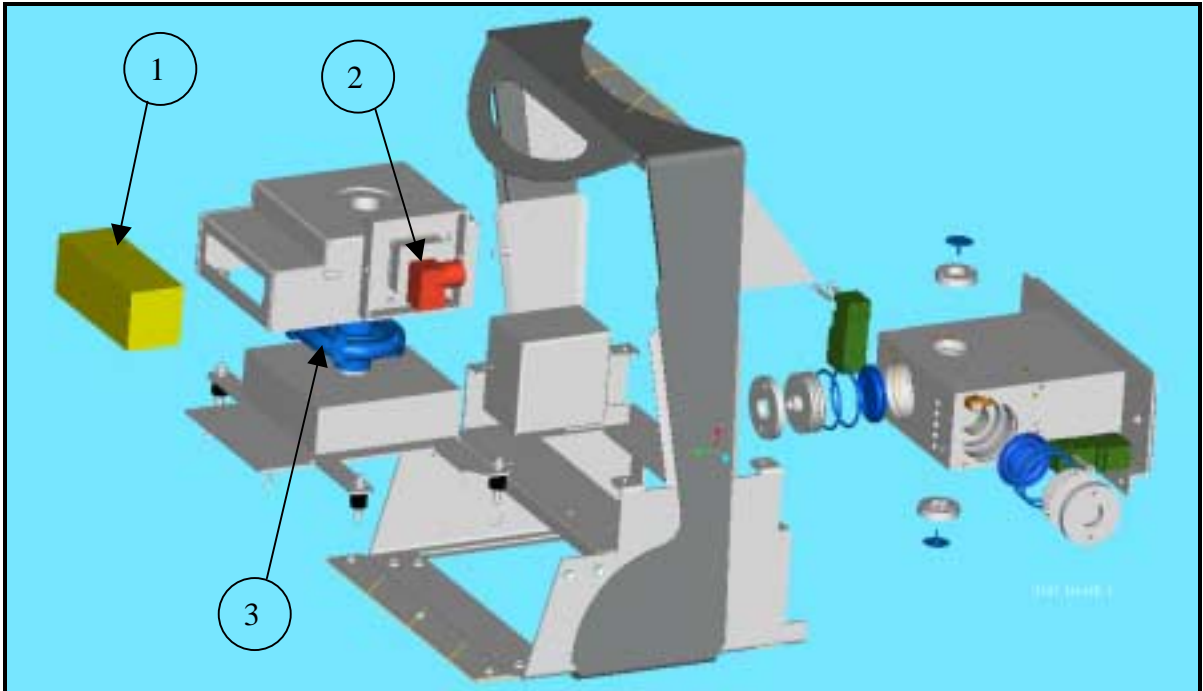


Gas output toward patient



Exhale valve control

HELIA S Maintenance

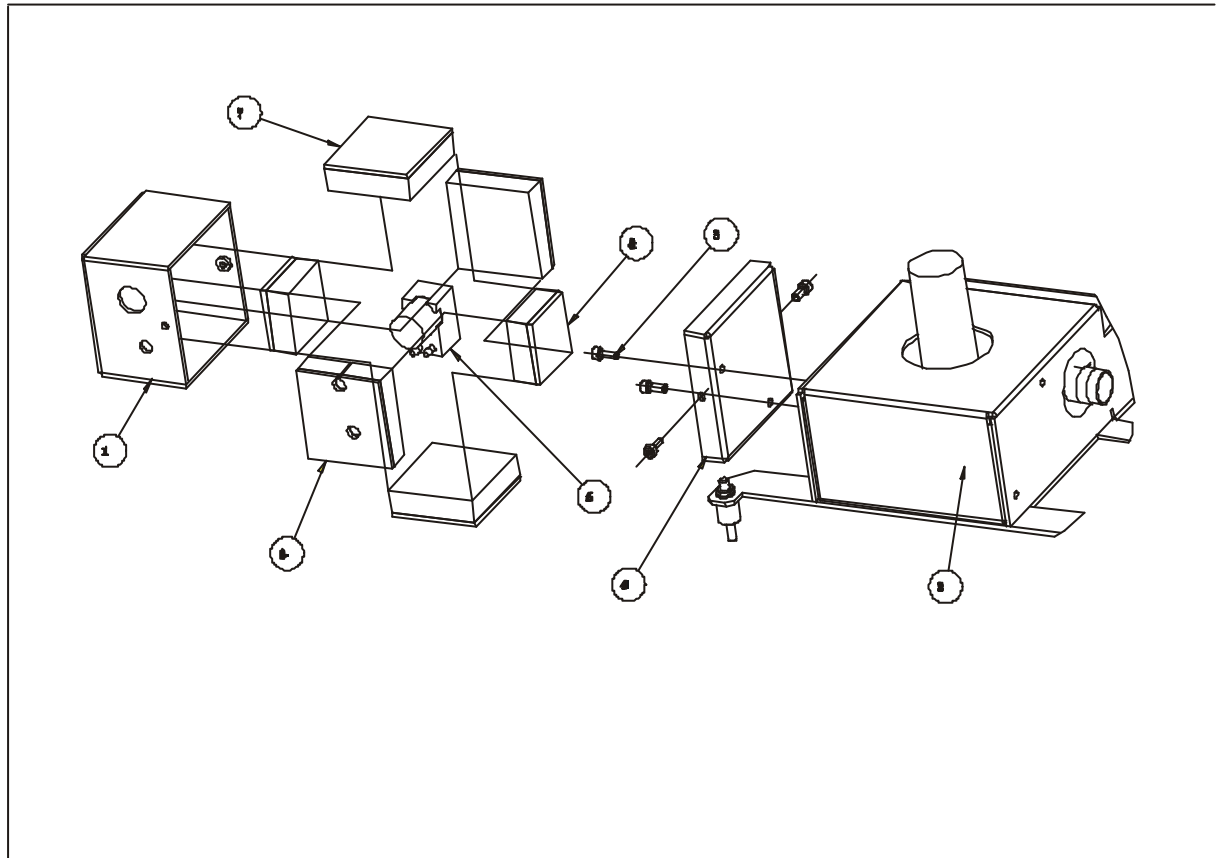


	<i>Rep.</i>	<i>Qty.</i>	<i>designation</i>	<i>reference</i>
4000 H	1	1	Air filter	FIL009663
8000 H	2	1	Micropump	S/E009683
	3	1	Turbine 120 Mbar	ELE008886
	4	1	Expiratory valve	CLA007829
	5	1	Inspiratory valve	CLA007235
12000 H			PNEUMATIC BLOC O RINGS :	KIT010152
	6	2	O ring 32x2	JOI007256
	7	2	O ring 33x2	JOI009333
	8	2	Silicon valve	SOU009078

24000 H	9	2	Electrovalves	S/E009345
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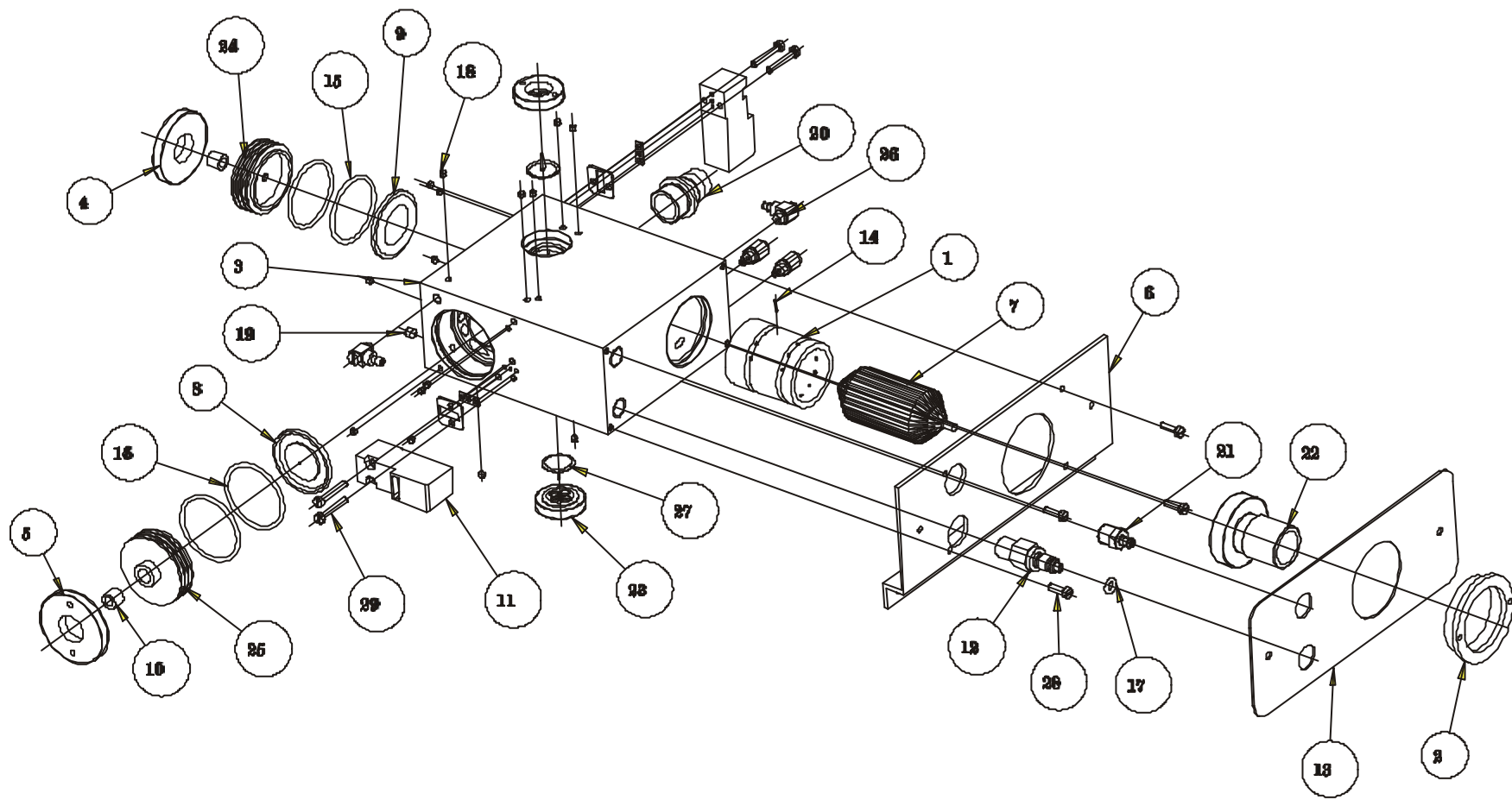
HELIA S PEEP Micropump

REP	Nb	Designation	Saime code
1	1	MICROPUMP BOX	BOI009598
2	1	TURBINE BOX	BOI009750
3	4	CHC_M3X8	VIS003428
4	1	MICROPUMP BOX TOP	COU009597
5	1	MICROPUM SP 250 EC	S/E009683
6	1	MICROPUMP FOAM	MOU009877
7	3	SINGLE MICROPUMP FOAM	MOU009645
8	2	MICROPUMP FOAM COVER	MOU009646



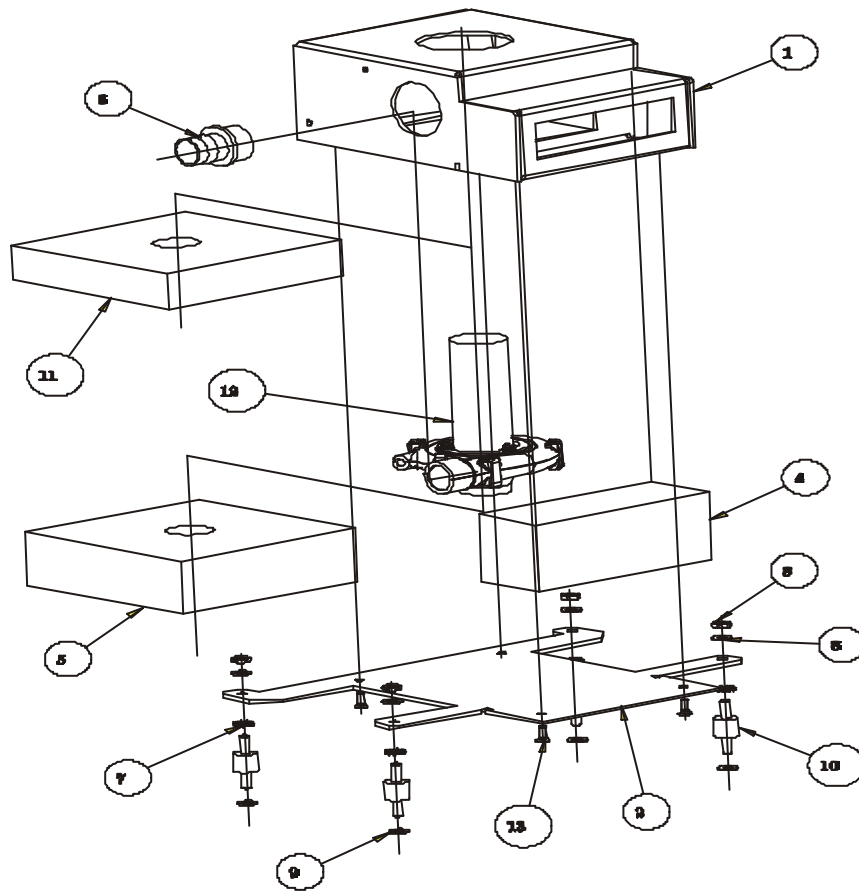
HELIA S Pneumatic block

REP	Nb	Designation	Saime code
1	1	INSPIRATORY SENSOR RING	BAG009522
2	1	HELIA S INSPIRATORY RING	BAG008545
3	1	HELIA S VALVE UNIT	COR009518
4	1	VALVE STOPPER	BOU007507
5	1	HELIA S VALVE STOPPER	BOU008835
6	1	VALVE UNIT BRIDLE	BRI008940
7	1	MERCIGNAC SENSOR	CAP007749
8	1	EXPIRATORY VALVE	CLA007829
9	1	INSPIRATORY VALVE	CLA007235
10	2	M5 SELF SCREW DEVICE	DOU007552
11	2	ELE WITHOUT HEAD	ELE007761
12	1	MALE NOZZLE WITH VALVE	EMB008798
13	1	FRONT FACE	FAC008927
14	1	08 PIN	GOU007512
15	2	32X2 O RING	JOI007256
16	2	32X2 O RING	JOI009333
17	1	O2 NOZZLE O RING	JOI006432
18	15	PIECE	PIO004917
19	1	6-10 LEAKS PIECE	PIO009716
20	1	FOAM HELIA S BLOCK CONNECTION	RAC009371
21	1	1-8 SMC FLUTED CONNECTION	RAC009380
22	1	HELIA S INSPIRATORY CONNECTION	CON008542
23	2	SUCTION CUP SEAT	BOU009525
24	1	VALVE SUPPORT	SUP007508
25	1	HELIA S VALVE SUPPORT	SUP008834
26	4	SMC BEND TEATH	rac005741
27	2	SUCTION CUP	SOU009078
28	4	VR_M3X10_A	VIS009403
29	4	VR_M3X20_A	VIS008358



HELIA S Turbine

REP	Nb	Designation	Saime code
1	1	TURBINE BOX	BOI009750
2	1	TURBINE BOX SUPPORT	SOC009751
3	4	NUT HM4	ECR005403
4	1	AIR FILTER	FIL009663
5	1	FOAM	MOU009381
6	1	EXIT CONNECTOR	RAC009370
7	4	RANGE WASHER	RON005399
8	4	M4 STEEL WASHER	RON005400
9	4	M4 NYLON WASHER	RON006947
10	4	10 BLOC SILENT	sil005839
11	1	SUPERIOR	MOU009382
12	1	TURBINE	ELE008886
13	4	M3X6 CRUCIFORM SCREW	VIS006678





INFORMATION PRODUCTS MODIFICATIONS HELIA 2 - S

➤ HELIA 2

- *Modifications*

Version of program	Applied to Serial number	Subject
V 2.5	HEL0206088	Improvement of automatic detection of simple/double circuit (uncertain release of low pressure alarm). Update of the V2.4 CPU version <i>This modification doesn't require the update of the previous versions.</i>
V2.6	Available	Improvement of automatic detection of simple/double circuit (uncertain release of low pressure alarm). Update of CPU version poorer or equal to V2.3. <i>This modification doesn't require the update of the previous versions.</i>
V2.51	HEL0301016	Improvement of useful life of O ₂ cell (measure bracket) <i>This modification doesn't require the update of the previous versions.</i>
V2.61	Available	Improvement of useful life of O ₂ cell (measure bracket) Update of CPU version poorer or equal to V2.3. <i>This modification doesn't require the update of the previous versions.</i>

Modification of connection between CPU and display by flat cable

Improvement of the connection's resistance to vibrations.

Application from ventilator HEL0107034.

This modification doesn't require the update of the previous versions.

Modification of the fixed pneumatic bloc on Helia (2 electro-valves instead of 3)

Optimization of expiratory resistance with a single electro valve.

Application from ventilator HEL0204025.

This modification doesn't require the update of the previous versions.

Modification of mains supply:

New mains bloc. Optimization of EMC, more manual settings.

Application from ventilator HEL0207033.

This modification doesn't require the update of the previous versions.

➤ **HELIA S**

- *Modifications*

Version of program	Applied to Serial number	Subject
V 1.07	HLS0207003	Modification of time counter writing (uncertain release of pressure alarm). Update of V1.06 CPU version. <i>This modification doesn't require the update of the previous versions</i>
V 1.08	Available	Modification of time counter writing (untimely release of pressure alarm). Update of CPU version poorer or equal to V 1.05 <i>This modification doesn't require the update of the previous versions</i>

Modification of connection between CPU and display by flat cable

Improvement of the connection's resistance to vibrations.

Application from ventilator HLS0108015.

This modification doesn't require the update of the previous versions.