SAIME

*Fabricant de Matériel Médical*
*Medical Device Manufacturer*

# EOLE 3 S

# EOLE 3 XLS

## *Volumetric Pulmonary Ventilator*

# *Service Manual*

*P/N: NTA0004036-a*

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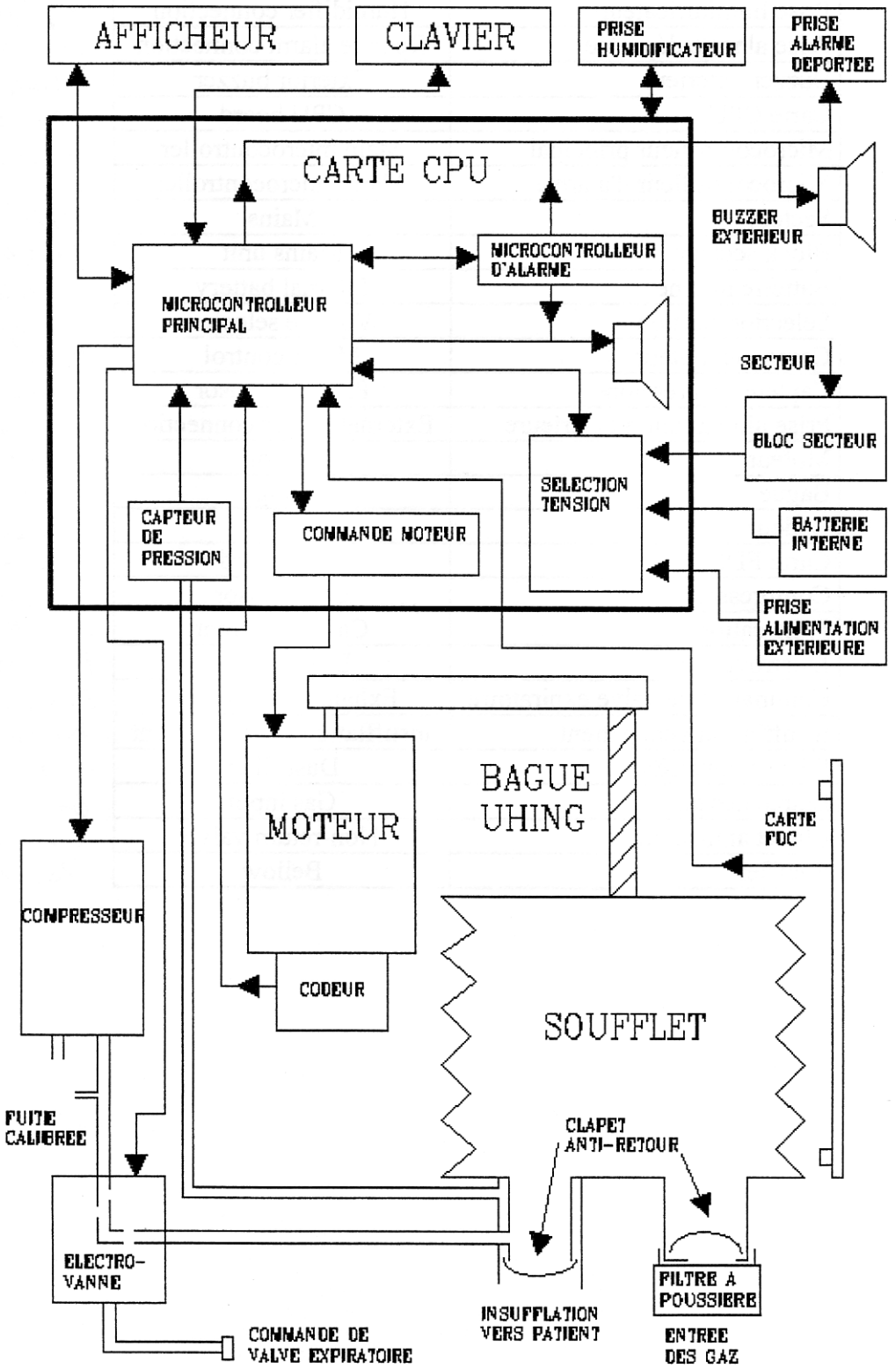
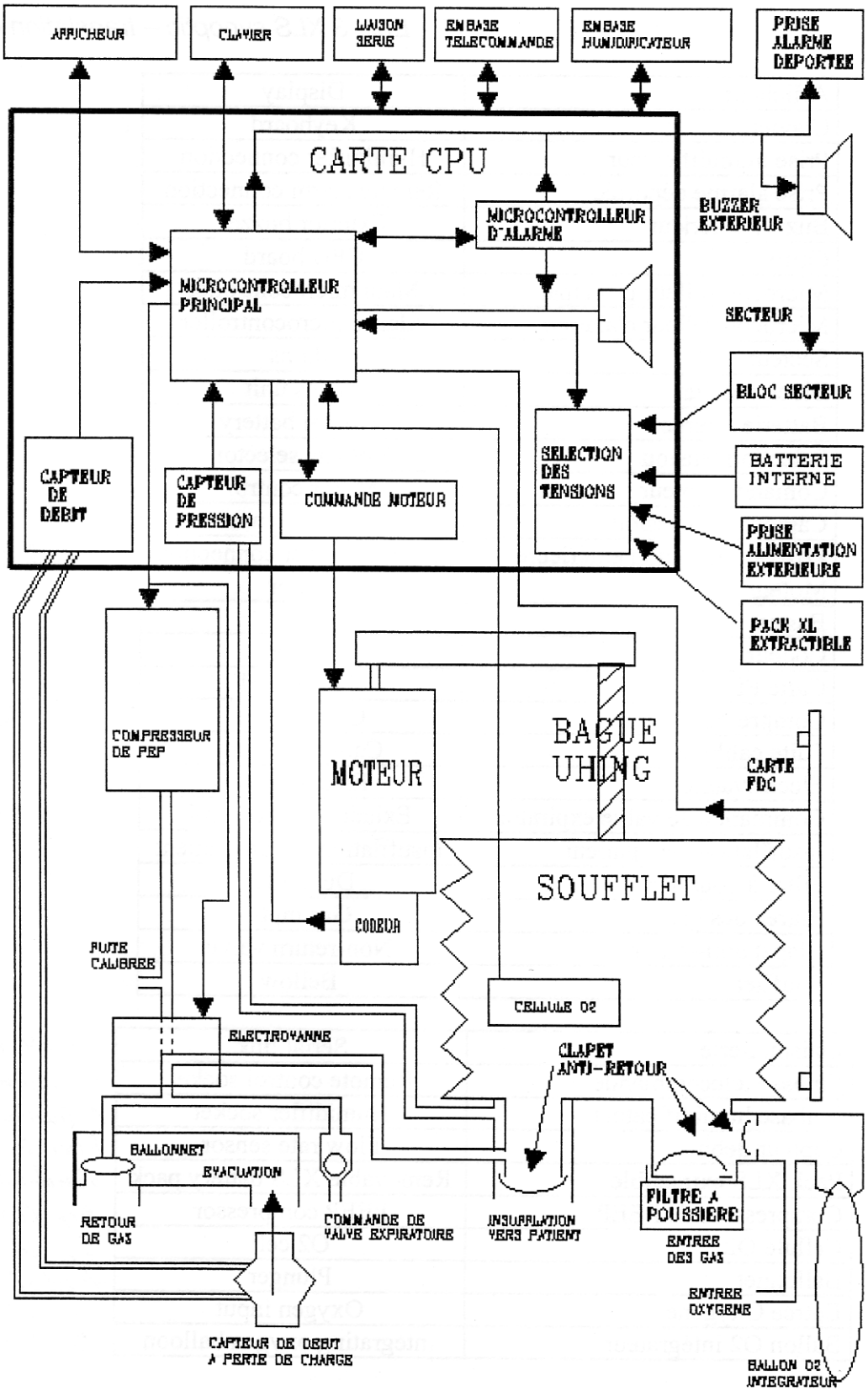


## Eole 3 S synoptic – translation chart

| | |
|---|---|
| Afficheur | Display |
| Clavier | Keyboard |
| Prise humidificateur | Humidifier connection |
| Prise alarme déportée | Remote alarm connection |
| Buzzer extérieur | Exterior buzzer |
| Carte CPU | CPU board |
| Microcontrolleur principal | Main microcontroller |
| Microcontrolleur d'alarme | Alarm microcontroller |
| Secteur | Mains |
| Block secteur | Mains unit |
| Batterie interne | Internal battery |
| Selection tension | Voltage selector |
| Comande moteur | Motor control |
| Capteur de pression | Pressure sensor |
| Prise alimentation extérieure | External power connection |
| Moteur | Motor |
| Bague | Ring |
| Codeur | Coder |
| Carte FDC | FDC board |
| Compresseur | Compressor |
| Fuite calibrée | Calibrated vent |
| Electrovanne | Electrovalve |
| Commande de valve expiratoire | Exhale valve control |
| Insufflation vers patient | Insufflation toward patient |
| Filtre à poussière | Dust filter |
| Entree des gaz | Gas input |
| Clapet anti-retour | Non-return valve |
| Soufflet | Bellow |

Anzeige
Tastatur
Befeuchter Anschluß
Externer Alarm Anschluß
Externer Summer
CPU - Karte
Haupt-Mikroprozessor
Alarm-
Netz
Netzeinheit (Netzteil)
interne Batterie
Spannungswahlschalter
Motorsteuerung
Drucksensor
Ext. Spannungsanschluß
Motor
Achse ?
Geber
FDC - Karte
Kompressor
Kalibrierte Öffnung
Elektroventil
Exspirationsventil
Patientenanschluß steuern
Staubfilter
Gas - (Luft-) einlass
Ein-Weg-Ventil
Balgen

## 1.2 Eole 3 XLS with oxygen option




➢ *Eole 3 XLS synoptic*

*Eole 3 XLS synoptic – translation chart*

| | |
|---|---|
| Afficheur | Display |
| Clavier | Keyboard |
| Prise humidificateur | Humidifier connection |
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| Entree des gaz | Gas input |
| Clapet anti-retour | Non-return valve |
| Soufflet | Bellow |

| | |
|---|---|
| Liaison Serie | Serial link |
| Embase télécommande | Remote control socket |
| Embase humidificateur | Humidifier socket |
| Capteur debit | Flow rate sensor |
| Pack XLS extractible | Removable XLS battery pack |
| Compresseur de PEEP | PEEP compressor |
| Cellule O2 | O2 cell |
| Ballonnet | Plunger |
| Entree Oxygène | Oxygen input |
| Ballon O2 intégrateur | Integrating oxygen balloon |

# 2. ELECTRICAL POWER SUPPLY

## 2.1 Introduction

The ventilator can be operated on mains, with an external 11 to 29 Volt DC supply. Alternatively, it can be run on its internal battery (14.4 V 4 AH) for 6 hours for standard cases of ventilation. The XLS model features an optional removable battery (14.4 V / 8 AH) which offers 8 additional hours off the mains (for a consumption of 1 AH) or 12 hours for standard ventilation.

The ventilator automatically selects the most available and reliable source of energy. In doing so, the respected priorities are:
1: Mains voltage
2: Voltage provided by an external source if this is sufficient
3: Internal battery (and XLS pack option)

The External Voltage LED indicates the presence of an external power supply.

The battery's recharge system automatically recharges the battery when the unit is connected to the mains or to an external source whose voltage is greater than 21 volts.

When the unit is in operation, the green LED battery check 75% and red LED battery check 25% on the front panel indicate the charge level of the internal battery (as well as the XLS pack option)

When the unit is running on its internal batteries, the charge level displays on the battery check screen (after 15 sec). The level is given in 5 of 5%.

In case of mains fallout, the internal battery will power the unit, an audible alarm goes off and the message "MAINS!" displays. Press the Alarm Off button to turn off the alarm.

In case of external DC power fallout, the internal battery will power the unit, an audible alarm goes off and the message "MAINS!" displays. Press the Alarm Off button to turn off the alarm.

The unit consumes between 0.7 to 4.0A when operating on the 12 V DC.

*Warning:*
*We recommend you use the mains cable supplied with the unit. In any case, you should use an angled plug so as to minimise the chances of pulling out the mains cable accidentally.*

## 2.2 State of Charge of the Internal Battery (and XLS pack option)

1: The Green LED battery check 75% lights up: this means the battery is charged.
2: The Green LED battery check 75% blinks: this means the battery is beginning to lose its charge.
3: The Red LED battery check 25% blinks: this means that the battery is not charged.
4: The Red LED battery check 25% remains lit up: this means that the battery has to be recharged.

*NOTE:*

- *If the battery has lost more than 75% of its charge, the display lighting turns off in order to save the battery.*
- *If the unit is running on its internal batteries, the display lighting turns off quicker.*
- *The runtime of the battery depends on the ventilation settings and cannot be given accurately.*
- *However, and considering a worst case scenario, as soon as the Red LED battery check 25% begins to blink, you can count a minimum remaining runtime of 30 minutes and as soon as the Red LED battery check 25% remains on permanently, you can count a minimum remaining runtime of 15 minutes.*
- *The BATT= xx% setting is used to determine when the battery LOW alarm should be activated.*
- *The BATT= xx% setting is used to determine when the battery OUT OF ORDER alarm should be activated.*

## 2.3 Internal Batteries

For maximum security, the state of the internal battery should be checked regularly as stipulated in the maintenance requirements. These checks should be carried out even if the unit is constantly connected to the mains.

Make sure the internal battery remains in good working condition by taking the unit off the mains and running it from the battery at least once a month, at which time the battery should be completely discharged and its runtime checked.

The internal battery should be replaced at least every 2 years.

The internal battery is a special SAIME product.

When the unit is being stored (i.e. is off the mains), the battery connector should be unplugged to avoid internal battery discharge through the charging circuit.

## 2.4 Removable Battery Pack

The EOLE3 XLS features a removable battery pack as option. A special SAIME external charger with a quick-charge facility is used to recharge it. The removable pack is likewise a SAIME product.

For maximum security, the state of the removable battery should be checked regularly as stipulated in the maintenance requirements. These checks should be carried out even if the unit is constantly connected to the mains.

At this time the battery should be completely discharged and its runtime checked.

The removable battery pack should be replaced at least every 2 years.

When the unit is being stored (i.e. is off the mains), the battery connector should be removed to prevent its discharge.

NB: the removable battery pack is not recharged by EOLE3.

## 2.5 Taking Out The Removable Battery Pack

- Pull the 2 locks behind the unit.
- Pull the block back out towards you.
- Follow the handling instructions on the pack.
- The instructions required to recharge the pack are given with the specific SAIME EOLE3 XLS charger.
- Make sure you put the pack back in the correct direction and match up the guides on the pack labels and the rear panel.

## 2.6 SAIME heating base

Saime heating base runs only when Eole 3 is plugged onto the mains.

# 3. PATIENT CIRCUIT

## 3.1 Patient circuit and volume control

Depending on the volume, SAIME recommends the following (minimum) tube characteristics:

| VOLUME | TUBE |
|---|---|
| From 50ml to 100ml | Internal diameter: 8.5mm<br>Length: 1.10 to 1.70 meters |
| | |
| From 100ml to 600ml | Internal diameter: 10mm<br>Length: 1.10 to 1.80 meters |
| | |
| From 600ml to 1300ml | Internal diameter: 15mm<br>Length: 1.50 to 2.00 meters |
| | |
| From 1300ml to 1700ml | Internal diameter: 19mm<br>Length: 1.50 to 2.00 meters |

*Note: the patient tubes should be in silicon or polyurethane.*

For optimal security, use only the patient circuits recommended by the constructor. Other circuits could reduce the unit's performance.

## 3.2 Connecting the patient circuit and its accessories

### *3.2.1 Pneumatic Circuit Elements*

Ventilator
Bacteria Filter
Humidifier
Single or double patient circuit
Flow rate sensor
Oxygen Supply

### *3.2.2 Circuit Characteristics (plus accessories)*

Average volume of complete pneumatic system: 1.4 to 2 litres
Internal compliance: 1.5 ml/hPa minimum, – 6.3 ml/hPa maximum
Patient circuit compliance: 0.7 ml/hPa

#### 3.2.2.1 Pneumatic system connections

EOLE3 S block
The Insufflation toward patient output is a standard external 22mm diameter male cone and a standard internal 15mm diameter female cone.

EOLE3 XLS block
The Insufflation toward patient output is a standard external 22mm diameter male cone and a standard internal 15mm diameter female cone.
The Exhaled Gas Return input is a standard 22mm diameter female cone
The Exhaled Gas Evacuation output is a 23mm diameter female cone

#### 3.2.2.2 Oxygen Supply

The O2 oxygen input is a nipple adaptable to a grooved on-line female coupler (diameter 4mm – ref: PMC17-02 CPC).

The input to the integrating balloon is a standard 15mm diameter female cone.

#### 3.2.2.3 Exhale valve connection

EOLE3 S
Grooved M5 nipple

EOLE3 XLS
Grooved output tailpiece SMM-02 Series SMC CPC, diameter 4

#### 3.2.2.4 Flow Rate sensor connection

Grooved M5 nipples, marked blue and white on the ventilator's front panel.

For the Pitot tube sensor, a special SAIME tapered connector (24mm male & 22mm female) is fitted to the Exhaled Gas Evacuation output.

#### 3.2.2.5 Exhale Valve

We recommend clapper valves and advise against using plunger type valves and BENNET valves.

#### 3.2.2.6 Bacteria filter input

A non-standard (SAIME product) 22mm diameter female cone can be used.

### *3.2.3 Setting up the complete pneumatic circuit*

#### 3.2.3.1 Installing the EOLE3 S

The basic pneumatic circuit only has one tube connected to the INSUFFLATION output on the front panel. In this case, an auxiliary exhale valve has to be added to the patient circuit and its pneumatic control should be connected to the EXHALE VALVE CONTROL.

**Humidification**

WARNING:

Containers and tanks should be used in accordance with manufacturers' indications.

Humidifier containers and tanks intended for hospital use should be filled with sterile liquid.

The temperature of the liquid poured into the container or the tank should not exceed 37°C.

Using non-recommended output tubes can be dangerous and reduce unit efficiency.

The fill level should be respected for optimized humidification.

Check the temperature at the gas output; this should not exceed 40°C.

#### 3.2.3.2 Installing the EOLE3 XLS

A simple pneumatic circuit can be used. Its set-up is similar to the EOLE3 S (see above).

The double pneumatic circuit contains two tubes that are connected to the INSUFFLATION output and the GAS RETURN input on the front panel. The exhaled gases are evacuated via the EVACUATION output.

The EOLE3 XLS works with a special SAIME Pitot flow rate tube sensor. The rate sensor is connected to the 2 grooved nipples on the front panel.

If a double circuit is used:

To measure the exhale volume (TV ALARM), the sensor is positioned at the output of the exhale valve at the evacuation of the exhaled gases.

**Humidifier**

A humidifier can be placed at the INSUFFLATION towards patient output.

**Bacteria filter**

A bacteria filter can be placed directly at the INSUFFLATION towards patient output. However, in this case, the unit's internal pneumatic circuit is not protected (bellows).

Fitting the bacteria filter to the GAS INPUT: unscrew and remove the foam filter cap. Replace it with the female inlet connector (22mm diameter) to which the filter is then attached.

### *3.2.4 Patient circuits resistance*

Make sure that inspiratory and expiratory circuit resistances are less than 6 hPa or mbar at 60 litres for adults and 6 hPa or mbar at 30 litres for children. The expiratory resistance and the residual expiratory pressure are determined by the quality of the expiratory valve.

#### 3.2.4.1 EOLE3 S Pneumatic block

| | |
|---|---|
| Inspiratory resistance at 60 litres/minute | 3.6 hPa or mbar (with SAIME input filter) |
| Inspiratory resistance at 60 litres/minute | 1.9 hPa or mbar (without SAIME input filter) |
| Inspiratory resistance at 30 litres/minute | 2.1 hPa or mbar (with SAIME input filter) |
| Inspiratory resistance at 30 litres/minute | 1.5 hPa or mbar (without SAIME input filter) |

#### 3.2.4.2 EOLE3 XLS Pneumatic block

| | |
|---|---|
| Inspiratory resistance at 60 litres/minute | 3.6 hPa or mbar (with SAIME input filter) |
| Inspiratory resistance at 60 litres/minute | 3.4 hPa or mbar |
| Inspiratory resistance at 30 litres/minute | 1.7 hPa or mbar (with SAIME input filter) |
| Inspiratory resistance at 30 litres/minute | 2.3 hPa or mbar |

# 4. OXYGEN SUPPLY

## 4.1 Description

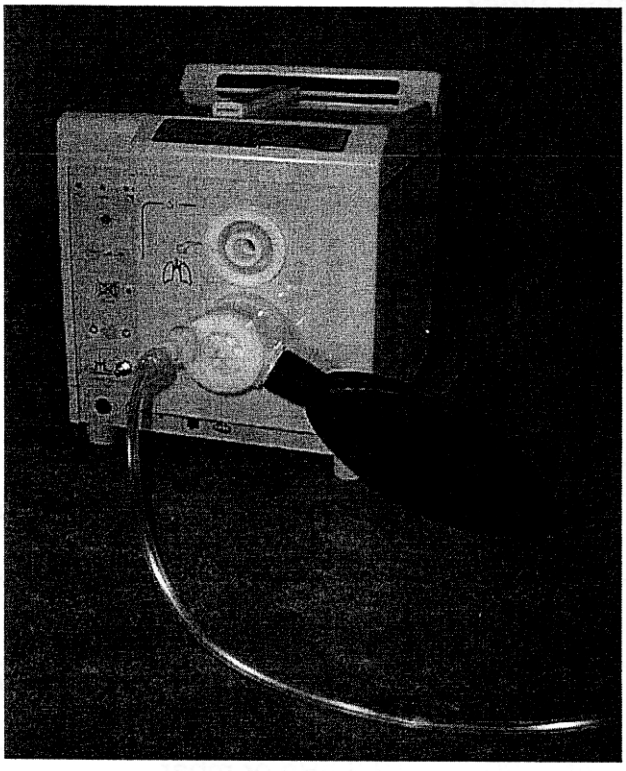
### *4.1.1 Precision*

- The enrichment level is fixed outside the unit. The oxygen flow rate is regulated via a flowmeter. The oxygen source and the flowmeter must cover the range 0 to 30 litres per minute.
- If an oxygen concentrator is used, its output flow rate must be set to a maximum.
- For hospital usage, the oxygen pressure from the wall taps (or bottles) is very high. In this case, a regulating trigger should be used to reduce the pressure.

Note: for maximum security, the oxygen pressure coming into the unit should never exceed 1 bar.

### *4.1.2 Eole 3 S*

- With Eole 3 S, oxygen concentration can be enriched with an optional oxygen kit. It allows the user to get an oxygen-input piece to plug on the ambient air input.
- To adapt this kit to Eole 3 S, the air inlet connector must be unscrewed and replaced by Eole 3 S oxygen kit. The oxygen flow is regulated by an external flowmeter.



### 4.1.3 Eole 3 XLS

The Eole 3 XLS model with Oxygen option allows the insufflated patient gases to be enriched in oxygen. This options features a cell included with the pneumatic block.
The unit uses the FiO2 = xx% setting to measure (and monitor) the oxygen concentration.

The oxygen is fed in through the O2 oxygen input on the front panel by means of a nipple adaptable to a grooved on-line female coupler (diameter 4mm – ref: PMC17-02 CPC).

An integrating balloon is connected to the pneumatic block on the top right side of the unit by means of an elbow connector.

The oxygen option is fitted with a display chart stuck onto the unit. This chart indicates the oxygen flow rate settings as a function of the volume delivered by the unit to pre-set an FIO2 level. The oxygen enrichment level is set outside the unit and the FIO2 reading is the only reliable way of checking this level.

Note: the oxygen sensor is automatically calibrated on unit start-up. Thus, the ventilator should not receive any oxygen during the first few seconds of operation.

The FIMIN and FIMAX alarm levels must be correctly set.

# 5. VENTILATION PARAMETERS REMINDER

## 5.1 Ventilation parameters table

| MODE= | CV | ACV | SIMV | IPPB | Range and display |
|---|---|---|---|---|---|
| PARAMETERS / TYPE: **EOLE 3** | **S / XLS** | **S / XLS** | **XLS** | **S / XLS** | |
| Air volume control (litre) | TV | TV | TV | - | 0,05 → 1,55 |
| Frequency (cycles/minute) | F | F | F | F | 05 → 90 |
| Inspiratory-expiratory time ratio (1/x) | I/E | I/E | - | - | 1/1,0 → 3,5 |
| Inhale pressure (millibar or hPa) | - | - | - | PRES | 10 → 65 |
| Inhale flow rate (litre/second) | - | - | FL. | FL. | 0,4 → 1,5 |
| Positive expiratory pressure (millibar or hPa) | PEEP (option) | PEEP (option) | PEEP (option) | PEEP (option) | 3 → 12 |
| Pressure trigger (millibar or hPa) | - | TG | TG | TG | -0,3 → -2,0 |
| Counter of sigh | C.SIGH | C.SIGH | C.SIGH | - | 002 → 250 |
| Volume of sigh (litre) | V.SIGH | V.SIGH | V.SIGH | - | 1,0 → 3,0 |
| Inspiratory slope (0-1-2-3) | SLOPE | SLOPE | SLOPE | - | 0 → 3 |
| Humidifier heating (when connected: NO-1-2-3-4-5-6) | HUMID | HUMID | HUMID | HUMID | NO - 1 → 6 |
| Setting key (NO-YES) | KEY | KEY | KEY | KEY | NO - YES |
| High pressure security level (millibar or hPa) | HPSEC | HPSEC | HPSEC | - | 10 → 76 |
| Low pressure security level (millibar or hPa) | LPSEC | LPSEC | LPSEC | LPSEC | 02 → 40 |
| Visual display #1 of measured data | VIS1 | VIS1 | VIS1 | VIS1 | MODE-F-I/E PEEP-eVT-MiV FiO2 |
| Visual display #2 of measured data | VIS2 | VIS2 | VIS2 | VIS2 | MODE-F-I/E PEEP-eVT-MiV FiO2-HCNT |
| PARAMETERS / TYPE: **EOLE 3** | **XLS** | **XLS** | **XLS** | **XLS** | |
| Ventilation programs (1-2-3-4-5-6) | PROGRAM | PROGRAM | PROGRAM | PROGRAM | 1 → 6 |
| Minute expiration volume security level (when alarm set: %) | expVt | expVt | - | - | 10 → 95 |
| Minute expiration volume alarm setting (when alarm set: litre) | - | - | Vsec | Vsec | 00,5 → 25,0 |
| Flow trigger (cm cube/second) | - | TG2 | TG2 | TG2 | -15 → -98 NON |
| Upper FiO2 security level (%) - option | FiMIN | FiMIN | FiMIN | FiMIN | 18 → 98 |
| Lower FiO2 security level (%) - option | FiMAX | FiMAX | FiMAX | FiMAX | 25 → 99 |

## 5.2 Adjustment parameters list

- Ventilation mode (MODE)

- Key selection (KEY)

- Tidal volume (Vt)
  Unit: litre
  Control precision +/-0,005L
  Display precision +/- 0,01L

- Frequency (F)
  Unit: cycles / minute
  Control precision +/-1/20 ms
  Display precision +/- 1 cycle

- Inspiration/Expiration ratio (I/E)
  No Unit
  Control precision +/- 0,1
  Display precision +/- 0,1

- Inspiration level (Pinsp)
  Unit: millibar or hectoPascal
  Control precision +/-0,54 hPa
  Display precision +/- 1 hPa

- Inspiration flow (D.I)
  Unit: litre / second
  Control precision +/-0,005L/s
  Display precision +/-0,1L/s

- Sigh counter (C.SOUP)
  No Unit

- Sigh value (V.SOUP)
  Unit: litre
  Control precision +/-0,005L
  Display precision +/- 0,1 L

- PEEP pressure
  Unit: millibar or hectoPascal
  Control precision +/-1 hPa
  Display precision +/- 1 hPa

- Pressure trigger (TG1).
  Unit: millibar or hectoPascal
  Control precision +/-0,054 hPa
  Display precision +/- 0,1 hPa

- Inspiratory slope (SLOPE)
  No unit
  Control precision +/-1/4
  Display precision +/- 1

- Heating base (HEAT)
  No unit
  Control precision +/-1/6
  Display precision +/- 1

**Alarms:**

- Low pressure alarm (LP)
  Unit: millibar or hectoPascal
  Control precision +/-0,54 hPa
  Display precision +/- 1 hPa

- High pressure alarm (HP)
  Unit: millibar or hectoPascal
  Control precision +/-0,54 hPa
  Display precision +/- 1 hPa

**XLS version:**

- Minute expiration volume security level (VOLexp)
  Unit: percentage
  Control precision +/-0,0019 x pressure loss
  (L/s x mbar) x expiratory time.
  Display precision +/- 1 %.

- Minute expiration volume alarm setting (Vsec)
  Unit: litre
  Control precision +/-0,0019 x pressure loss
  (L/s x mbar) x expiratory time.
  Display precision +/- 1 %.

- Pressure trigger
  Unit: cm cube/ second
  Control precision +/-0,0019 x pressure loss
  (L/s x mbar) x expiratory time.
  Display precision +/- 1 %.

- Ventilation program (PROGRAM)

**Oxygen option:**

☞ FiO2 security high level (FIMAX)
Unit: percentage
Control precision +/- 0,5 %.
Display precision +/- 1 %

☞ FiO2 security low level (FIMIN)
Unit: percentage
Control precision +/- 0,5 %.
Display precision +/- 1 %

## 5.3 Measured parameters list

☞ Frequency (F)
Unit: cycles per minute
Measure precision +/-1/20ms
Display precision +/- 1 cycle
Maximum value: 99 cycles

☞ Inspiration/Expiration ratio (I/E)
No unit
Measure precision +/-0,1
Display precision +/- 0,1
Maximum value: 1/9,9

☞ PEEP pressure
Unit: millibar or hectoPascal
Measure precision +/-0,45 hPa
Display precision +/- 1 hPa
Maximum value: 99 hPa

☞ Counter of hours (CHOR) VIS 2 exclusively.
Unit: hours and minutes
Measure precision +/-10 ms
Display precision +/- 1 min
Maximum value: 99999 H 59 min

**XLS version:**

☞ Exhaled volume (Vte).
Unit: litre (ATPD)
Control precision +/-0,0019 x pressure loss (L/s x mbar) x expiratory time.
Display precision +/- 1 %.

☞ Exhaled volume per minute (VMi).
Unit: litre (ATPD)
Control precision +/-0,0019 x pressure loss (L/s x mbar) x expiratory time.
Display precision +/- 1 %.

**Oxygen option:**

☞ Oxygen concentration (FiO2).
Unit: percentage
Measure precision +/-0,5%
Display precision +/- 1 %
Maximum value: 99%

**NOTE:**
*The display is actualised each cycle. The average of the 6 previous cycles is done during each cycle.*
*The volume measure is displayed in ATPD conditions, e.g. at ambient temperature & when the ambient air is dry.*

### 5.4 Pressure display

Bargraph indicates the pressure during the cycle. Each rectangle represents a 2 millibar pressure level.

➢ **Bargraph**
Unit: millibar or hectoPascal
Display precision +/- 2hPa
Maximum value displayed: 80hPa

At the end of the inspiration phase, the peak of pressure is numerically displayed. The Peep pressure is displayed at the beginning of each cycle.

➢ **Maximum pressure**
Unit: millibar or hectoPascal
Display precision +/- 1hPa
Maximum value displayed: 99hPa

# 6. ALARMS RELEASING PROCEDURES

The alarms that go off during unit operation can be divided into four groups.

## 6.1 Power supply alarm

When this alarm goes off, we hear a warning signal and a warning message is posted. This alarm goes off when the unit is started off the mains or when the mains supply falls out. This alarm can be definitively turned off by pressing the Alarm Off button or by plugging in the mains.

## 6.2 Temporarily stoppable alarms requiring rapid reaction

☞ These alarms monitor the patient ventilation setting. The alarm release message from the last alarm remains on the screen as long as the Alarm Off button hasn't been pressed. This is used to save the most recent alarm even after it has been turned off.

☞ Pressing the Alarm Off button will turn the alarm off only for 2 minutes for as long as the source of the problem hasn't been dealt with. On re-start, the display lights up again and the message remains displayed. Once the alarm source has been dealt with, the alarm silence counter resets at zero.

- LOW PRESSURE ALARM
- HIGH PRESSURE ALARM
- LOW BATTERY ALARM
- MINUTE VOLUME ALARM, XLS model
- APNEA ALARM, XLS model in SIMV mode
- HIGH OXYGEN CONCENTRATION ALARM, Oxygen option
- LOW OXYGEN CONCENTRATION ALARM, Oxygen option

## 6.3 Unstoppable and potentially fatal alarms requiring immediate action

☞ These alarms are indicated by rapid tones and by warning messages returning the nature of the problem. The Alarm Off button does not work on these kinds of alarm and they will remain active until the source of the problem has been dealt with, at which point they disappear automatically.

☞ The screen will continue to display the source of the most recent alarm until the Alarm Off button is pressed. This is used to save the most recent alarm even after it has been turned off.

- BATTERY FAILURE ALARM
- TECHNICAL ALARM

- MOTOR ALARM
- HUMIDIFIER ALARM
- ALARM2: Alarm microcontroller alarm.
- O2 SENSOR ALARM, Oxygen option.

### 6.4 Unstoppable and potentially fatal microcontroller alarm requiring immediate action

These alarms are indicated by rapid tones and can be caused by two sources:

1: Board power supply failure (5V)
or
2: The main microcontroller is no longer communicating with the alarm microcontroller.

The Alarm Off button can work on these kinds of alarm whereas they will remain active until the source of the problem has been dealt with, at which point they can be turned off with the Alarm Off button.

# 7. TROUBLESHOOTING ALARMS

## 7.1 POWER SUPPLY ALARM

**MAINS!** Mains Power Supply Alarm

| | |
|---|---|
| CAUSES | 1: Mains power fallout<br>2: Mains cable accidentally fell out.<br>3: Unit started on internal battery<br>4: Unit started on external DC power supply |
| SOLUTIONS | 1: Press the Alarm Off button<br>2: Connect the unit to the mains |

**EXT PWR!** External Power Supply Alarm

| | |
|---|---|
| CAUSES | 1: External power fallout<br>2: External power cable accidentally fell out. |
| SOLUTIONS | 1: Press the Alarm Off button<br>2: Connect the unit to the mains |

## 7.2 TEMPORARILY STOPPABLE ALARMS

**HP ALARM** High Pressure Alarm

| | |
|---|---|
| CAUSE | Pressure in the circuit exceeds the HPA setting |
| SOLUTIONS | 1: Check the pneumatic circuit<br>2: Check if the patient's breathing is blocked up.<br>3: Check the HPA setting with respect to the maximum level of the patient's inspiratory cycle.<br>4: Check the pneumatic circuit of the expiratory valve control (pinched tube)<br>5: If the problem persists, call maintenance. |

**LP ALARM** Low Pressure Alarm

| | |
|---|---|
| CAUSE | Pressure in the circuit insufficient |
| SOLUTIONS | 1: Make sure there are no gas leaks in the circuit.<br>2: Check if the patient's has become disconnected from the unit.<br>3: Check the LPA setting.<br>4: Make sure the expiratory valve control is working correctly. |

**LOW BAT!** Battery Discharge Alarm

| | |
|---|---|
| CAUSE | The battery charge level has become dangerously low. |
| SOLUTION | Connect the unit to the mains to recharge the batteries |

**VT ALARM** Volume Control Alarm (XLS model)

| | |
|---|---|
| CAUSE | The exhale volume is insufficient (XVol) |
| SOLUTIONS | 1: Check the pneumatic circuit for leaks<br>2: Check the XVol setting with respect to the set volume control (VolC)<br>3: Make sure the exhale valve is working correctly<br>4: Make sure the flow rate sensor is working correctly. |

**APNEA** Alarms indicating an absence of natural breathing in IACV (XLS model)

| | |
|---|---|
| CAUSE | The patient did not trigger the natural breathing cycle. |
| SOLUTION | Make sure the trigger is working correctly and check the level. |

**LOW.FiO2** Low Oxygen concentration level (Oxygen option)

| | |
|---|---|
| CAUSE | Oxygen concentration has fallen below the FIMIN level. |
| SOLUTIONS | 1: Check the oxygen supply circuit.<br>2: Check the FIMIN setting.<br>3: Have the oxygen sensor setting and the auxiliary distribution system checked.<br>4: Check the O2 concentration regulation system. |

**HIGH.FiO2** High Oxygen concentration level (Oxygen option)

| | |
|---|---|
| CAUSE | Oxygen concentration has exceeded the FIMAX level. |
| SOLUTIONS | 1: Check the oxygen supply circuit.<br>2: Check the FIMAX setting.<br>3: Have the oxygen sensor setting and the auxiliary distribution system checked.<br>4: Check the O2 concentration regulation system. |

## 7.3 UNSTOPPABLE ALARMS

**MOTOR!** Motor overheating alarm

| | |
|---|---|
| CAUSE | 1: Mechanical problem preventing the motor from operating correctly.<br>2: The computer detected an excessive motor current<br>3: The unit is no longer capable of correctly ventilating the patient. |
| SOLUTION | Call maintenance. |

**TECHNICAL** The unit has a serious technical problem.

| | |
|---|---|
| CAUSE | The unit is no longer capable of correctly ventilating and the motor has been stopped. |
| SOLUTION | Call maintenance. |

**ALARM 2** The unit has a serious technical problem.

| | |
|---|---|
| CAUSE | No more communication between the microcontrollers. |
| SOLUTION | Call maintenance. |

**BAT.OUT** The internal battery has a problem.

| | |
|---|---|
| CAUSE | Internal battery has failed, is disconnected or is discharged. The unit will soon stop. |
| SOLUTION | 1: Charge up the battery by connecting it to the mains.<br>2: If the problem persists, call maintenance and have the connections checked or else replace the battery. |

**H.TEMP** The humidifier has overheated.

| | |
|---|---|
| CAUSE | 1: Humidifier temperature too high.<br>2: Temperature setting system broken. |
| SOLUTION | 1: Unplug the humidifier and check it.<br>2: If the problem persists, call maintenance |

**O2.SENS** Problem with the oxygen sensor (Oxygen option).

| | |
|---|---|
| CAUSE | The oxygen sensor is either faulty, disconnected or is measuring incorrectly. |
| SOLUTION | Check the oxygen sensor. |

## 7.4 UNSTOPPABLE MICROCONTROLLER ALARM

**BUZZER** The unit has a serious technical problem.

| | |
|---|---|
| CAUSE | 1: Board power supply failure<br>2: The microcontrollers are no longer communicating with each other. |
| SOLUTION | 1: Call maintenance |

# 8. DISINFECTING

## 8.1 Maintenance Frequency

The 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.

| | New patient | Constructor frequency | Medical staff Frequency |
|---|---|---|---|
| Patient circuit | Yes | Yes | Yes |
| Heating chamber | Yes | Yes | Yes |
| Bacteria filter | Yes | Yes | Yes |
| Pneumatic block | Yes | - | Yes |

☞ If the bacteria filter is used for viral and bacterial protection, the filter replacement period given by the manufacturer should be respected.

☞ However, if the bacteria filter is only used to filter dust and particles, then it need only be changed once a week.

## 8.2 Decontamination and disinfecting procedures

### *8.2.1 Patient circuit*

Read the manufacturer's notice before removing the patient circuit.

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.

However, the silicon tubes should be disinfected in the autoclave. Neither the exhale valve nor its control tube should be placed in the autoclave.

Cold decontamination by immersion is also possible; use the BACTINYL® instrumentation liquid soap solution at 2% or 4%. This solution is a fungicide, virucide, and bactericide.

- Remove the patient circuit elements to be decontaminated from the ventilator unit.
- Prepare an immersion bath of BACTINYL® instrumentation liquid soap.
- Completely immerse the equipment to be decontaminated making sure the liquid gets to all parts of the circuit
- Leave the parts in the water for 15 minutes
- Rinse with sterile water (or water with low bacteria count)
- Leave the parts to dry (or dry, if necessary)

The decontamination is now complete. If you now wish to disinfect the element, use a 2% BACTINYL® 5M solution. Follow the same procedure as above.
This solution is a fungicide, virucide, bactericide and sporicide.

The F. GARCIN pharmaceutical laboratories manufacture BACTINYL® 5M: 63000 CLERMONT-FERRAND, FRANCE.

*Note 1: Saime advises the above protocol based onto BACTINYL ® chemical. Of course, any equivalent product can be used instead of the one recommended.*
*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.*

*Note 2: maintenance centres may use other decontamination procedures. However, they must be approved and respect current rules and regulations. Furthermore, they must not be in contradiction with the security measures recommended by SAIME.*

### *8.2.2 Removable pneumatic block*

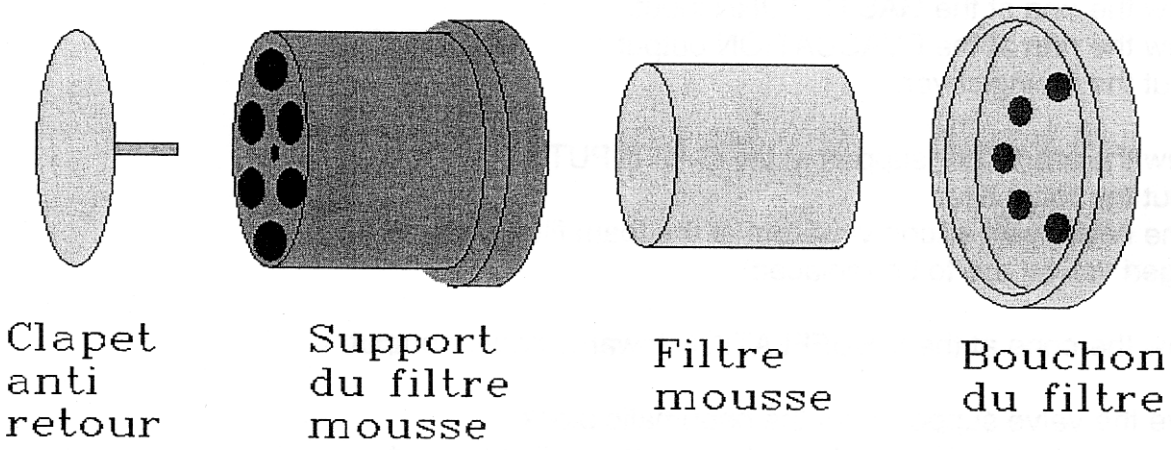
- Dismantle the extractable pneumatic block

Take out the ventilator's removable pneumatic block:
Unscrew the 4 ¼ turn screws used to close the cover.
Remove the cover by sliding it upwards.
Unscrew the knurled screw at the back of the bellows.
Disconnect the ¼ turn screws for the pneumatic circuit or the tubes.
Disconnect the electric cable on the oxygen cell (Oxygen option)
Remove the pneumatic block by sliding it upwards.

#### 8.2.2.1 EOLE3 S block

Unscrew the foam filter cap at the GAS INPUT.
Unscrew the ring at the INSUFFLATION towards patient output.
Take out the facing cover.
Unscrew the foam filter support at the GAS INPUT.

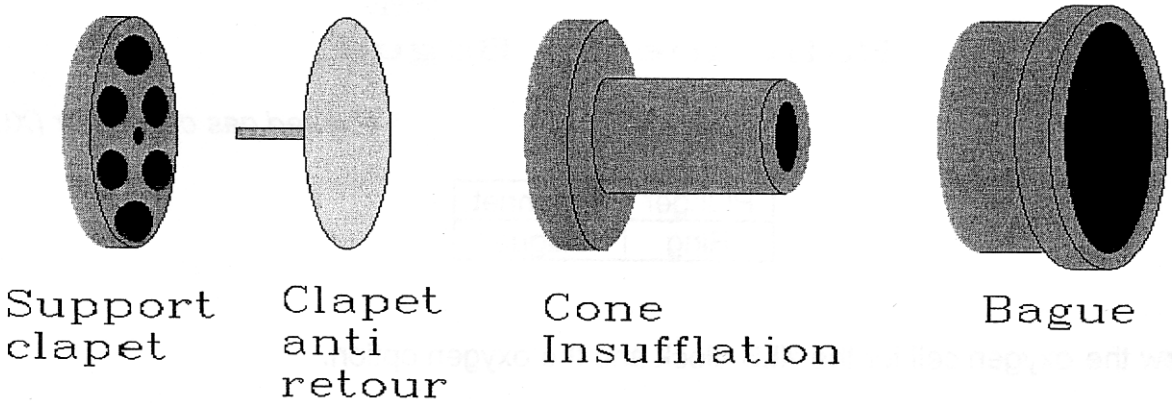
Take out the foam filter.
Take the non-return silicon valve out of the foam filter support.
(Damaged valves are to be replaced)




➢ Air input connection

| | |
|---|---|
| Non-return valve | Clapet anti-retour |
| Foam filter support | Support du filtre mousse |
| Foam filter | Filtre mousse |
| Filter cap | Bouchon du filtre |

Unscrew the INSUFFLATION toward patient output cone.
Remove the valve support from the pneumatic block.
Take the non-return silicon valve out of the foam filter support.
(Damaged valves are to be replaced)




➢ Insufflation connexion – patient circuit

| | |
|---|---|
| Valve support | Support clapet |
| Non-return valve | Clapet anti-retour |
| Insufflation cone | Cône insufflation |
| Ring | Bague |

### 8.2.2.2 EOLE3 XLS block

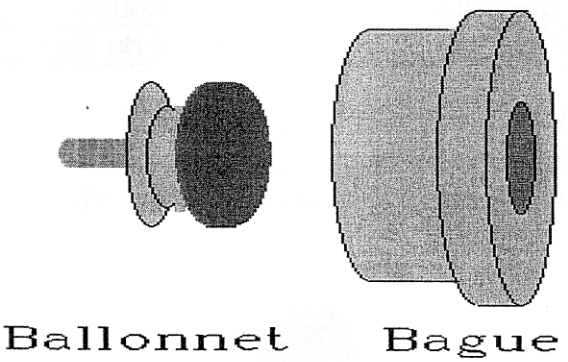
Unscrew the foam filter cap at the AIR INPUT.
Unscrew the ring at the INSUFFLATION towards patient output.
Unscrew the ring at the GAS RETURN input.
Unscrew the ring at the EVACUATION output.
Take out the facing cover.

Unscrew the foam filter support at the GAS INPUT.
Take out the foam filter.
Take the non-return silicon valve out of the foam filter support.
(damaged valves are to be replaced)

Unscrew the cone at the INSUFFLATION towards patient output.

Remove the valve support from the pneumatic block.
Take the non-return silicon valve out of the foam filter support.
(Damaged valves are to be replaced)

Unscrew the plunger at the GAS RETURN input.
(Damaged plungers should be replaced)




*Expired gas connector (XLS)*

| | |
|---|---|
| Plunger | Ballonnet |
| Ring | Bague |

Unscrew the oxygen cell for the XLS block and the oxygen option.

Disassemble the non-return valve in the air-input chamber for the XLS block and oxygen option, pushing it towards the entrance of the integrating balloon.

*Note:*

- *Neither the block nor the pneumatic parts nor the silicon valves nor the plunger should be placed in the autoclave.*

- *Do not expose the silicon valves to strong light. Disinfecting products can alter the valves' properties. It is recommended that they be replaced in case of mechanical deterioration.*
- *Both the pneumatic block and its constituent parts can be disinfected with formaldehyde vapours neutralised with ammonia. The disinfecting will clear away any residual products inside the circuits without altering ventilator operation.*
- *Cold decontamination by immersion is also possible; 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.*
- *Maintenance centres may use other decontamination procedures. However, they must be approved and respect current rules and regulations. Furthermore, they must not be in contradiction with the security measures recommended by SAIME.*
- *The block must be left to dry before reassemble and it is important that the tubes passing through the removable block be free from all traces of humidity before putting back the block.*

### *8.2.3 Humidifier chamber*

We recommend using disposable chambers.

*Note: disposable heating chambers should not be put into an autoclave.*
*Also, they should not be used with solutions containing phenol, ketone, formaldehyde, hypochlorite, 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. Furthermore, they must not be in contradiction with the security measures recommended by SAIME.*
*If other products are used, they must respect the conditions listed in the French Pharmacopoeia and guarantee the absence of residual products.*

### *8.2.4 Bacteria filter*

Bacteria filters should be replaced in accordance with manufacturer instructions. Otherwise, filters should be changed every 500 hours or whenever a new patient is connected.

### *8.2.5 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.

# 9. MAINTENANCE AND PREVENTIVE INSPECTIONS

WARNING:
- Prior to maintenance on Eole 3 S/XLS, technicians must have been trained by SAIME.
- Only technicians with appropriate certificates (level 2) delivered by SAIME can maintain Eole 3 S/XLS.

- The alarms should be checked before connecting a new patient or, at the least, once a week.
- The pneumatic circuit should be checked before connecting a new patient or, at the least, once a week. It should also be checked every time the bloc has been taken out for decontamination.
- The electrical system should be checked before connecting a new patient or, at the least, once a month.
- The pressure sensor should be checked before connecting a new patient.
- The unit should be checked once a year at the least by the maintenance service.
- The air filter should be changed regularly.
- The oxygen cell (optional) shall be regularly checked.

## 9.1 Pneumatic circuit checks

Before placing the valve unit in its compartment, make sure that the attachment screws for the bellow's plate and the nipples have been correctly tightened.
Check the unit for leaks.
Insert the valve block and firmly close the knurled attachment screw at the back of the bellows.

### *9.1.1 EOLE3 S*

- Check the control tube of the exhale valve between the electrovalve and the socket (condition, position).
- Check the valves block tube connected to the electrovalve, i.e. the tube on the top right of the valve block as seen from the front.
- Check the pressure tube connected to the lower pressure sensor nipple, i.e. the tube on the top left of the valve block as seen from the front.
- Check the non-return valve situated at the gas input: unscrew the parts that support it.
- Check the non-return valve situated at the insufflation output: unscrew the parts that support it.
- Check the female nipple on the exhale valve control (condition, position).
- Check the tube between the electrovalve and the PEEP compressor (option).

### 9.1.2 EOLE3 XLS

- Check the tube between the white nipple and the bottom nipple of the CPU's flow rate sensor.
- Check the tube between the blue nipple and the top nipple of the CPU's flow rate sensor.
- Check the control tube of the exhale valves, i.e. the tube coming from the electrovalve and located bottom right of the valve block as seen from the front.
- Check the pressure tube coming from the electrovalve and located top left of the valve block as seen from the front.
- Check the pressure tube connected to the lower nipple of the pressure sensor, i.e. the tube on the bottom left of the valve block as seen from the front.
- Check the non-return valve situated at the gas input: unscrew the parts that support it.
- Check the non-return valve situated at the insufflation output: unscrew the parts that support it.
- Check the state of the plunger at the gas return input: by unscrewing the front ring. Make sure the plunger and the ring are correctly tightened when reassembling the parts.
- Check the female nipple on the exhale valve control – ¼ turn screw (condition, position).
- Check the position of the oxygen sensor and the cap.
- Check the tube between the electrovalve and the PEEP compressor (option).

## 9.2 Electrical circuit checks

### 9.2.1 Checking the LEDs and power source switching

- Turn on the unit, connected to the mains.
- Check the green LED on the front panel.
- Take the unit off the mains and make sure it switches over to the battery (message BAT = xx%)
- Connect an external source between 12 volts (minimum) and 29 volts (maximum) on the "11 – 29 DC V" input and make sure that the external voltage LED on the front panel has lit up and that the EXT.PWR message displays.
- Disconnect the external source and make that the EXT.PWR to BAT switchover takes place.
- Connect the mains again and make sure the Green light battery check 75% on the front panel is working correctly.
- Disconnect the internal battery and make sure the red light battery check 25% on the front panel is working correctly.
- Reconnect the internal battery.

### 9.2.2 Checking the fuses

- Turn off the unit.
- Take off the cover to access the board's fuses.

- The fuse of the mains connector is a T1000L250V (1A time lagged)
- The fuse labeled F6 on the PCB is a T4000L250V (4A time lagged)
- The fuse on the first microcontroller protects the transformer from overload. The fuse F6 on the second microcontroller protects the transformer from overheating.
- The fuse labeled F4 on the PCB is a T5000L250V (5A time lagged). This fuse is connected to the internal battery and protects from overload.
- The fuse labeled F5 on the PCB is a T5000L250V (5A time lagged). This fuse is connected to the external DC power supply and protects from overload.

*Note: all defective fuses on the power supply module or the PCB should be replaced with identical fuses respecting identical standards.*

Replacing fuses
- Turn off the unit.
- Remove the cover from the mains connector to access the fuse.
- Take out the fuse.
- Remove the unit's cover to access the fuses on the PCB, i.e. F4, F5, F6.
- Remove the J5 connector (mains, battery, DC external)
- Remove the fuses.

### 9.2.3 Checking the internal batteries

- Turn off the unit
- Open the unit's cover to access the batteries.
- Check the voltage at the battery terminals between the fuse F4 and the earth P3 GND.
- Well-charged batteries should read 17.3V.
- Discharged batteries should read 12V.
- Make sure the batteries aren't leaking.

Replacing the internal batteries
- Turn off the unit
- Open the unit's cover to access the batteries.
- Disconnect the battery ends.
- Unscrew the holding strap (2 screws under the unit).
- Pull the batteries upwards.
- Follow the instructions on the label.

**WARNING**

- WHEN HANDLING, THE POSITIVE (RED) AND NEGATIVE (BLACK) TERMINALS MUST NOT BE SHORT-CIRCUITED.
- THE BATTERIES SHOULD BE PLACED IN THEIR COMPARTMENT AND BE CORRECTLY CONNECTED.

*Note: The batteries are a specific SAIME product (NiMH technology 14.4V 4 Ah). It is strongly recommended that only SAIME batteries be used. Other batteries could impair unit operation, notably its runtime.*

**Recommendations**

- Incorrectly connected internal batteries could damage the unit.
- The internal battery should be checked regularly, even if the unit is constantly connected to the mains.
- The unit should be taken off the mains and run on its internal battery at least once a month.
- At this point, the battery should be completely discharged and its runtime checked.
- For maximum security, the internal battery should be replaced every 2 years (500 compete charge/discharge cycles).
- The battery is perfectly sealed and should not leak. However, if the unit is going into storage for periods exceeding 3 months, the battery should be removed to completely eliminate any possibility of chemical leakage.
- An industrial waste treatment company should recycle the old batteries.

### *9.2.4 Checking the electrical accessories*

Remote alarm

Set off an alarm and connect a circuit to the remote alarm connector to make sure the remote alarm is working correctly.

Humidifier

Plug in the SAIME heating base to the connector on the unit's front panel. Set the HEAT setting to 6 and check the temperature rise of the heating plate.

Remote Control

Connect the remote control. Stop and start the unit.

### *9.2.5 The oxygen cell (optional)*

Checking the oxygen cell

- Turn off the unit.
- Open the unit's cover to access the O2 cell.
- Check the voltage of the connector J4 (pin 1 and 4) of the CPU; this should be over 10mV.

Replacing the oxygen cell

It is recommended that the cell be replaced once a year.

- Turn off the unit.
- Open the unit's cover to access the O2 cell on the top of the pneumatic block.
- Disconnect the J4 connector of the CPU and screw off the cell.

## 9.3 Checking alarms

Recommended procedure

- Apply a load to the patient output.
- Start the unit from the mains.
- Adjust the following assisted controlled ventilation settings (ACV):

| | | | |
|---|---|---|---|
| FREQ = 016 | tv = 0.80 l | i/E = ½.0 | TG = -1.0 mb |
| sigh.c = 100 | sigh.v = 1.0 | hpa = 76 mb | lpa = 04 mb |
| dis1 = freq | | | |

- Take the unit off the mains to make sure the mains alarm is working (MAINS!), and turn off the alarm.
- Supply the unit from an external DC supply. Take the unit off the external supply to make sure the EXT.PWR! alarm is working, then turn off the alarm.
- Put the unit back on the mains.
- Check the low pressure alarm by removing the load from the patient output.
- Reapply the load to the patient output.
- Check the high pressure alarm by blocking the patient output.

At the warehouse

- Turn off the internal battery and make sure the BAT.OUT alarm is working.
- Put the unit back on the battery.
- Disconnect the motor and make sure the TECHNICAL unit breakdown alarm is working.
- Re-connect the motor.
- Disconnect the pressure tube from the SENS1 sensor.
- Block the end of the disconnected pressure tube.
- Block the patient output and check the motor alarm (TECHNICAL)

XLS Model

- Set: XVol=NO
- Put the XVol setting on 50% and check the TV ALARM (volume control).

Oxygen cell (option)

- set FIMIN= 18%, FIMAX=40%
- Set FIMIN at 30% without feeding in any oxygen and check if the LowFiO2 alarm goes off (low oxygen concentration).
- Set FIMIN on 18%.
- Saturate the sensor with oxygen and check if the HIGHFi alarm goes off (high oxygen concentration).

### 9.4 Checking the batteries autonomy

- Set the following parameters → Mode : CV; Vt=0,8L; F=16; I/E=1/2; Pmax=20mb.
- Check that the runtime is at least 6 hours, 5 hours without batteries alarm is released.

*Note 1: to be correctly measured, external power packs may not be taken into account to measure the batteries autonomy. Measure first the internal batteries autonomy without the external power packs. Then, measure the autonomy of internal and external batteries together:* *4 A external battery = 6 hours*
*8 A external battery = 12 hours*
*Note 2: After 500 charge and discharge cycles, batteries still have 80% of their capacity.*

# 10. TECHNICAL INSPECTIONS AND SETTINGS

Remove the pneumatic block

1. Unscrew the 4 cover nuts.
2. Remove the cover by sliding it upwards.
3. Unscrew the knurled screw at the back of the bellows.
4. Disconnect the tubes on the pneumatic block.
5. Slide the block upwards.

## 10.1 Checking the run-ends

- Make sure that the board with the run-end sensors is correctly in place.
- Make sure that the magnet on the mobile part (with respect to the Hall effect sensors) is correctly in place.

## 10.2 Checking the mechanical system

### *10.2.1 Checking the drive belt*

- Check the drive belt condition.
- Check the tension in the drive belt: this should not be oversight and should have sag of about 2 to 3mm when a force is applied between the two pulleys.

### *10.2.2 Checking the motor brushes*

- Dismount the mechanical system.
- Dismount the 2 motor brushes.
- Vacuum clean inside the guides, then use a Q-tip to clean them.
- Check the brushes for wearing and re-assembly the unit (change the carbon contacts if less than 7mm)

### 10.3 Checking the voltages

- Start the unit.
- Check the 5V supply voltage between the P3 earth point on the main board and P1. This should be between 4.8V and 5.2V.
- Check the 6V voltage between the P3 earth point on the main board and P2. This should be between 5.8V and 7.2V.
- Check the +5V REF voltage between the P3 earth point on the main board and P4. This should be between 4.95V and 5.05V.
- Turn off the unit.
- Check the voltage at the terminals of the back-up battery on the CPU. After a few minutes of charge build-up, this should be at least 4.8V.

### 10.4 Checking the charge voltage

- Disconnect the mains cable (230V & 50Hz).
- Disconnect the battery and connect a voltmeter to the terminals.
- Connect the 230V mains cable.
- Adjust the potentiometer POT5 on the CPU to get a reading of 17.3V (+0V/-0.1V).
- Disconnect the mains cable.
- Connect the battery.

### 10.5 Setting the display contrast

- Start up the unit.
- Adjust the potentiometer POT3 on the CPU to get the contrast required (without causing rectangles to appear in the background).

### 10.6 Accessing the technical menu

Nicht Eole 3s !!

*Note: the following settings may only be adjusted if the unit's memory containing the various settings has been unlocked. Trained personnel should only do this.*

- Use the On/Off button to stop the unit.
- Connect the unit to the mains (230 V & 50Hz)
- With the Menu Scrolling Button and the Alarm Off button pressed down, start the unit by pressing the On/Off button. => Eole 3S : "+" Taste gedrückt halten
- Keep the Menu Scrolling Button and the Alarm Off button pressed down until the unit is operating normally (display).
- Use the Menu Scrolling Button to get to the KEY setting in the menu.
- Choose the KEY=TECH position

*Note: the KEY=TECH setting will only be possible if the steps described above have been carried out beforehand. In the technical mode ("TECH"), the sound alarms are off. Under no circumstances, should a patient be ventilated during the above procedure.*

### 10.7 Peep option

Assuming the unit has been fitted with a PEP option in the factory, this can be activated by setting PEP=YES for both models. However, a specific procedure shall be followed for Eole 3 XLS.

**XLS Model**

ADJUSTMENT OF FLOW RATE SENSOR (AJUSTD SETTING)

- Set the following ventilation parameters:

| | | | |
|---|---|---|---|
| MODE = CV | FREQ = 16 | TV = 0.8 L | I/E = 1/2.0 |
| SLOPE = 0 | HPA = 80 | LPA = 02 | DIS1 = XVol |

- Fit a Pitot tube sensor to the Evacuation exit
- Connect a double circuit which is connected to a test lung (IPPB 20 and compliance 0.02)
- Press ADJUSTD successively leaving a minimum of 8 cycles between each step until XVol = 0.8 +/-3%. The average value of ADJUSTD is 100.

SETTING THE TV ALARM & THE XVOL SETTING

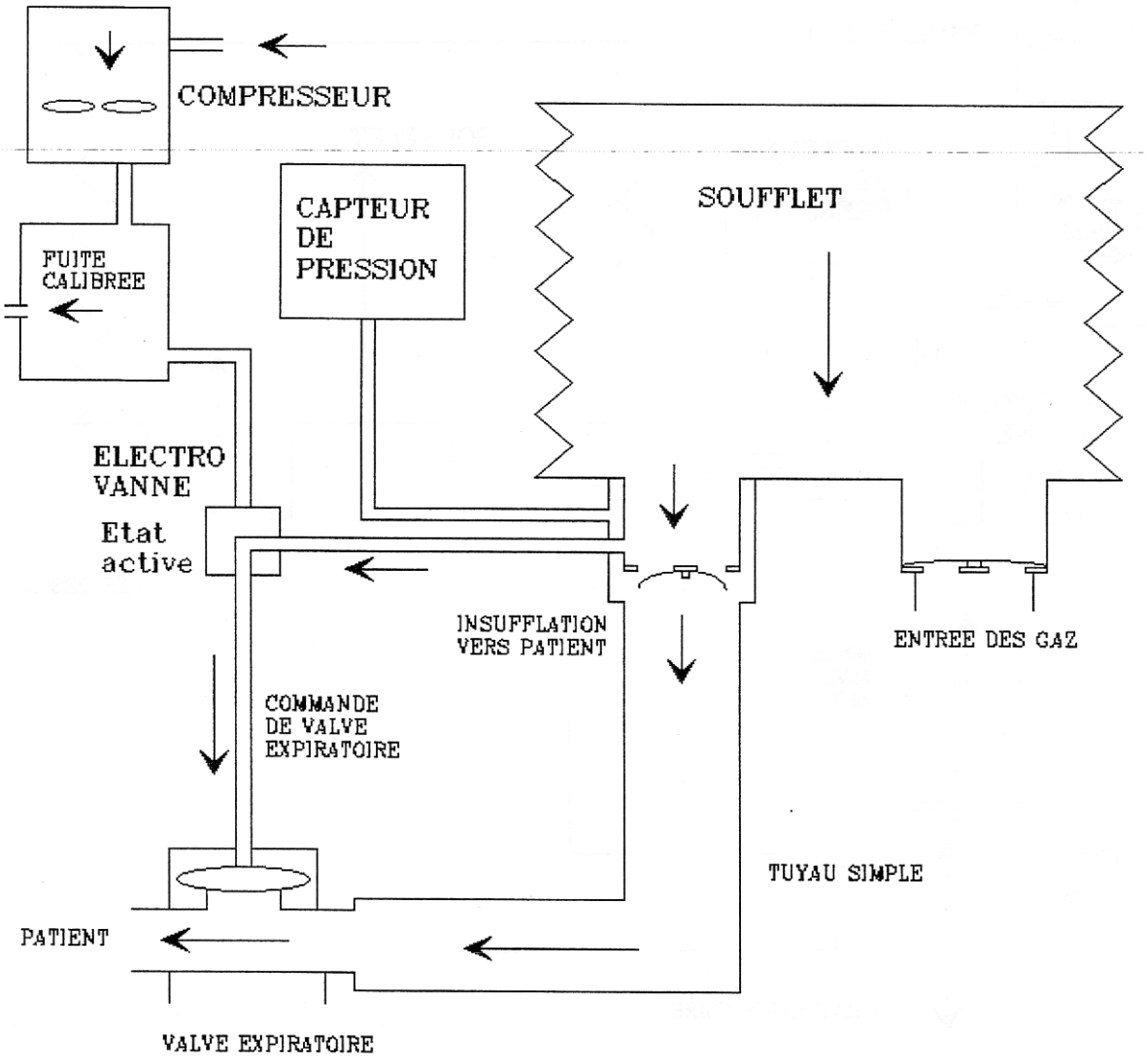
The TV alarm can be disabled by putting XVOL on NO.
In this case, either the MVol or the XVolAl setting will be absent from the main menu.

The TV alarm can be activated by putting XVOL on YES.
In this case, either the MVol or the XVolAl setting will be present in the main menu.

SETTING THE NUMBER OF PROGRAMS WITH THE NPROG SETTING

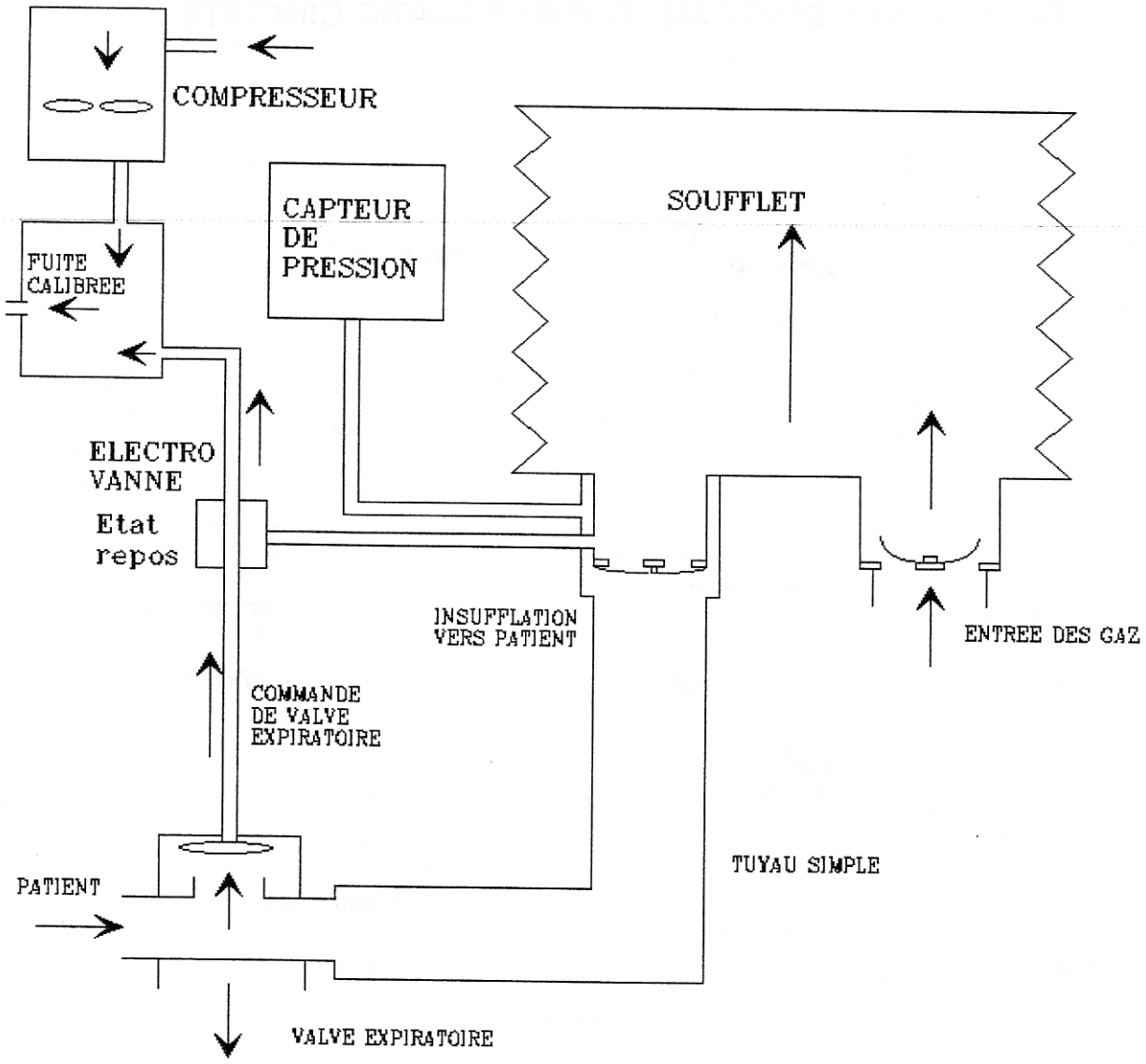
The NPROG setting is used to determine the number of unit ventilation programs. This can vary from 1 to 6 programs.

## 11. FUNCTIONAL DIAGRAM: THE PNEUMATIC CIRCUITS



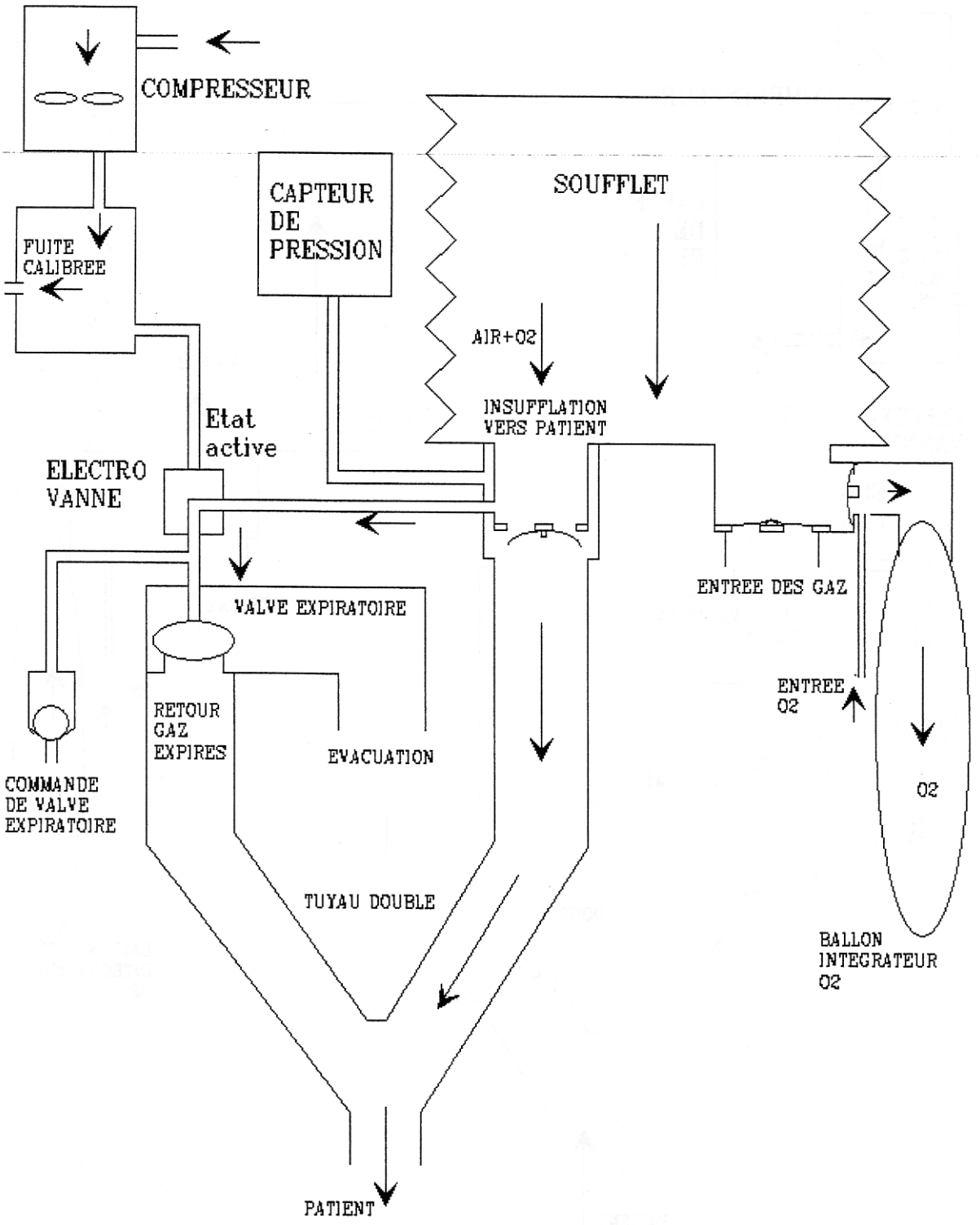

➢ *EOLE 3 S – Inspiration phase*

| | |
|---|---|
| Compresseur | Compressor |
| Fuite calibrée | Calibrated vent |
| Capteur de pression | Pressure sensor |
| Electrovanne | Electrovalve |
| Etat active | Active state |
| Soufflet | Bellow |
| Insufflation vers patient | Insufflation toward patient |
| Entrée des gaz | Gas input |
| Tuyau simple | Single tube |
| Commande de valve expiratoire | Exhale valve control |
| Patient | Patient |
| Valve expiratoire | Exhale valve |

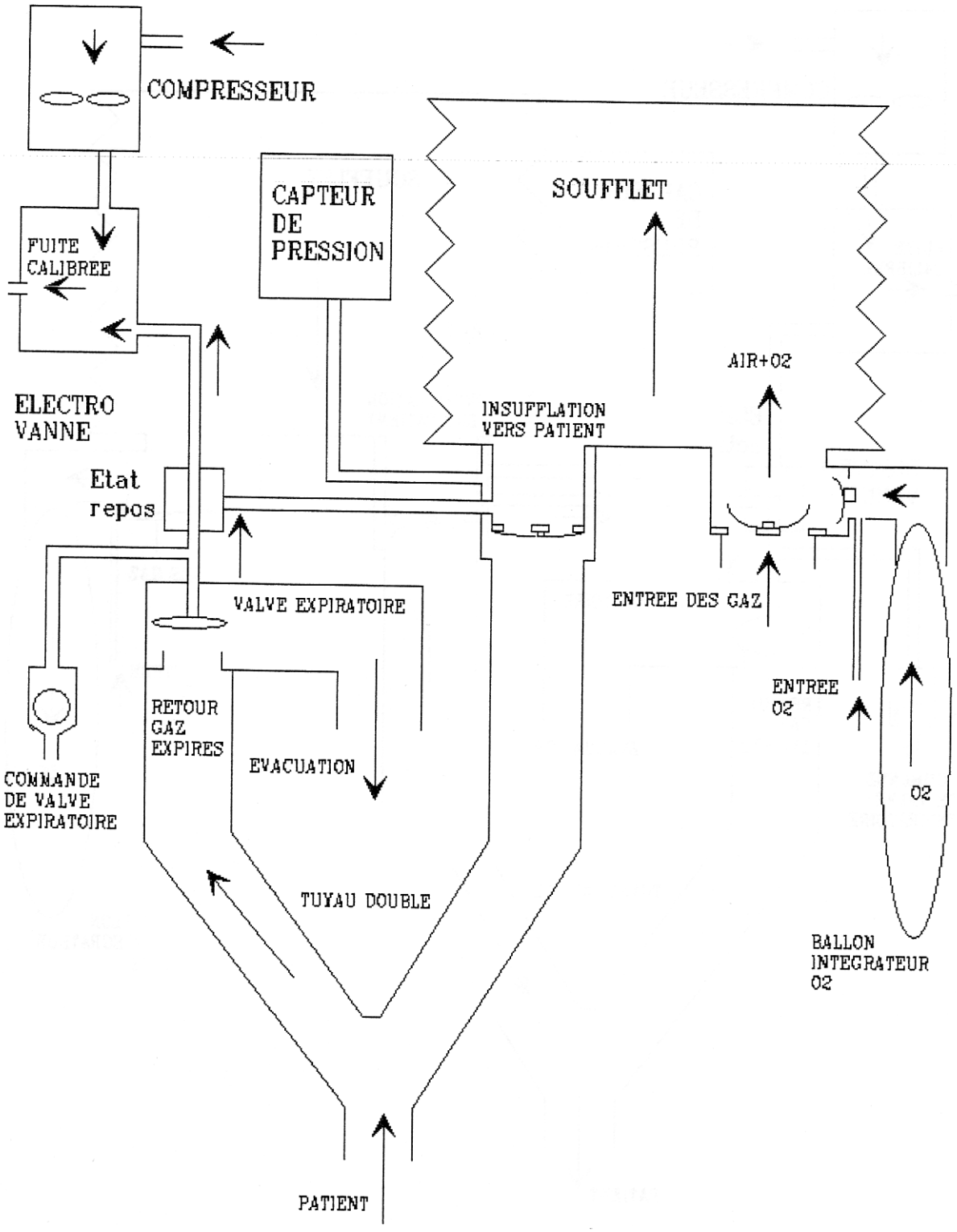



➢ *EOLE 3 S – expiration phase*

| ❑ Compresseur | Compressor |
|---|---|
| Fuite calibrée | Calibrated vent |
| Capteur de pression | Pressure sensor |
| Electrovanne | Electrovalve |
| Etat repos | Inactive state |
| Soufflet | Bellow |
| Insufflation vers patient | Insufflation toward patient |
| Entrée des gaz | Gas input |
| Tuyau simple | Single tube |
| Commande de valve expiratoire | Exhale valve control |
| Patient | Patient |
| Valve expiratoire | Exhale valve |




➢ *EOLE 3 XLS – inspiration phase with oxygen option*




➢ *EOLE 3 XLS – expiration phase with oxygen option*

***Eole 3 XLS pneumatic circuit translation chart***

| | |
|---|---|
| Compresseur | Compressor |
| Fuite calibrée | Calibrated vent |
| Capteur de pression | Pressure sensor |
| Electrovanne | Electrovalve |
| Etat active | Active state |
| Soufflet | Bellows |
| Insufflation vers patient | Insufflation toward patient |
| Entrée des gaz | Gas input |
| Tuyau simple | Single tube |
| Commande de valve expiratoire | Exhale valve control |
| Patient | Patient |
| Valve expiratoire | Exhale valve |
| Retour gaz expirés | Exhaled gas return. |
| Tuyau double | Double tube |
| Ballon intégrateur O2 | Integrating oxygen balloon |

# 12. TECHNICAL SPECIFICATIONS: VENTILATOR

## 12.1 Power supply

*Mains*

- 230V AC 50Hz 1A maximum
- 11 to 29 V DC 5A maximum
- Battery 14.4 V 4 AH (NiMH technology)
- Power consumption: 70 VA max

*Internal batteries*

- 14,4 Volts maximum (NiMH technology)
- Consummation: 70 VA maximum
- Fuse T5L250V

*External supply*

- Batteries pack: 14,4 Volts, 9 Ah (NiMH technology)
- Other external supply: 12-24 VDC/4 A maximum
- Fuse: T5L250V

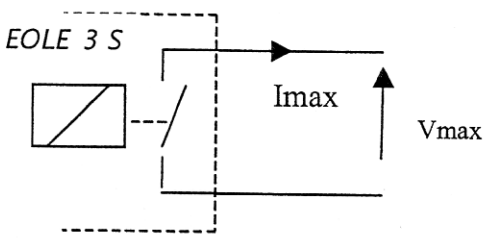
## 12.2 Battery runtime

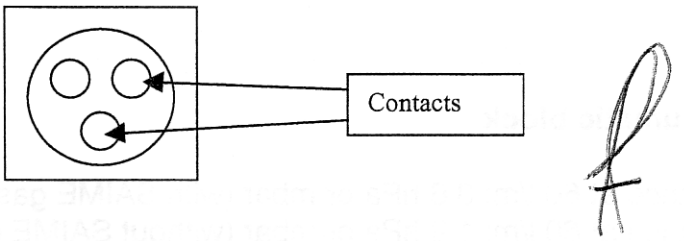
- Between 4 and 6 hours depending on the settings and how the ventilation mode.
- The internal battery requires a total re-charge time of 6 hours.
- The removable XLS battery pack offers 6 to 12 additional hours of battery operation.

## 12.3 Electrical interfaces

REMOTE ALARM

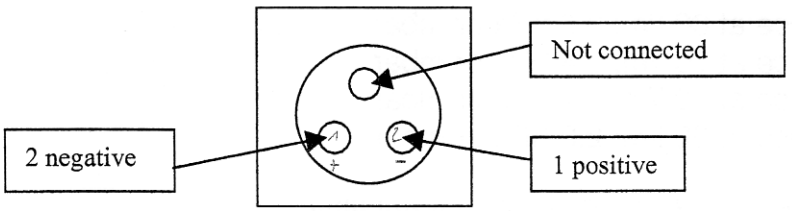
- Dry contact normally open
- Imax: 0,5 A
- Vmax: 24 V DC with respect to the unit's earth
- Binder socket: 3 point – male
- Interrupting capacity: 10VA
- Imax: 0.5A






The alarm circuit is not electrically biased

EXTERNAL DC POWER SUPPLY
UTP socket: 3 point – male




12 to 24 V DC 4A maximum

SERIAL LINK
- Binder socket: 4 point – female
- The Serial link should only be used by SAIME approved personnel for checking the unit in the factory.

REMOTE CONTROL
- Binder socket: 3 point – female
- Specific SAIME lead used to connect the remote control.

HUMIDIFIER
- Binder socket: 5 point – female
- Specific SAIME lead used to connect the humidifier.

### 12.4 Performances

COMPLIANCE
Internal compliance: minimum: 1.5 ml/hPa & maximum: 6.3 ml/hPa
Compliance of single patient circuit: 0.7 ml/hPa

PRESSURE
Maximum pressure: 76 hPa or mbar
Safety pressure adjustable from 10 to 76 hPa or mbar.
Maximum pressure when in perfect condition: 91 hPa or mbar

RESISTANCE

- **EOLE3 S pneumatic block**

Inspiratory resistance at 60 l/m: 3.6 hPa or mbar (with SAIME gas input filter)
Inspiratory resistance at 60 l/m: 1.9 hPa or mbar (without SAIME gas input filter)
Inspiratory resistance at 30 l/m: 2.1 hPa or mbar (with SAIME gas input filter)
Inspiratory resistance at 30 l/m: 1.5 hPa or mbar (without SAIME gas input filter)

- **EOLE3 XLS pneumatic block**

Inspiratory resistance at 60 l/m: 3.6 hPa or mbar
Inspiratory resistance at 60 l/m: 3.4 hPa or mbar
Inspiratory resistance at 30 l/m: 1.7 hPa or mbar
Inspiratory resistance at 30 l/m: 2.3 hPa or mbar

Note: resistance measured with SAIME air input filter

### 12.5 Conditions of use

- *Normal use*

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

- *Unit operation limits*

Any one of the following 5 conditions would be considered an operation 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.
- A combination of +45°C and 75% RH.

### 12.6 Storage conditions

Case 1. The ventilator and its accessories **are in original boxes**
- Storage temperature: from +5° to +60°C (+35°C for the internal batteries)
- 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.

Case 2. The ventilator, its accessories and batteries **are not in original boxes**

- Storage temperature: from +5° to +60°C (+35°C for the internal batteries)
- 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.

## 12.7 Transport conditions

The respirator and its accessories should be placed in their original SAIME packaging for transport.

Note:

- Do not transport in humid conditions
- The ventilator is fragile, it should be handled with care
- The ventilator should be transported in a vertical position on all legs.
- Transport temperature: 5 to 60°C

## 12.8 Materials used

### *12.8.1 Materials in contact with the inspired air*

- Aluminum
- Stainless steel
- Brass
- Delrin
- Silicon
- Foam: PPI 80

### *12.8.2 Materials in contact with the oxygen*

- Aluminum
- Stainless steel
- Brass
- Delrin
- Silicon

## 12.9 Settings, Measures and Alarms ranges

### *12.9.1 Settings*

| | |
|---|---|
| TIDAL VOLUME | 0.05 to 1.65 litres |
| FREQUENCY | 5 to 90 cycles per minute |
| I/E | 1/1 to 1/3.5 |
| INSPIRATORY FLOW RATE | 0.4 to 1.5 litres per second |
| MAXIMUM PRESSURE IN IPPB MODE | 10 to 65 hPa |
| PRESSURE TRIGGER | 0.3 to 2 hPa or mbar |
| FLOW TRIGGER | -15 to -98 cc/s |
| SIGH COUNTER | 2 to 250 |
| SIGH VALUE | 1 to 3 |
| INSPIRATORY SLOPE | 0 to 3 |
| HEATING BASE TEMPERATURE | No / 1 to 6 |
| MAXIMUM MINUTE VOLUME | 25 litres |
| MINIMUM MINUTE VOLUME | 0.25 litres |

### *12.9.2 Alarms*

| | |
|---|---|
| HIGH PRESSURE | 10 to 76 hPa or mbar |
| LOW PRESSURE | 2 to 20 hPa or mbar |
| MAINS FALLOUT | |
| EXTERNAL DC POWER FALLOUT | |
| INTERNAL BATTERIES DISCHARGED | |
| HUMIDIFIER OVERHEATING | Fixed at 60°C |
| MOTOR OVERLOAD | |
| TECHNICAL ALARM | |
| APNEA IN SIMV MODE | XLS model |
| EXHALED TIDAL VOLUME PERCENTAGE | 21 to 98% of the insufflated minute volume (XLS model) |
| EXHALED VOLUME | 1.6 to 25 litres per minute (XLS model) |
| MINIMUM OXYGEN CONCENTRATION | 18 to 40% (oxygen option) |
| MAXIMUM OXYGEN CONCENTRATION | 21 to 99% (oxygen option) |

### *12.9.3 Measurements*

- PATIENT FREQUENCY
- PATIENT I/E RATIO
- PRESSURE AT END OF EXPIRATION CYCLE
- UNIT CLOCK

- EXHALED VOLUME (XLS model, ATPD measurement)
- EXHALED MINUTE VOLUME (XLS model, ATPD measurement)
- OXYGEN CONCENTRATION (Oxygen option)

### 12.10 Humidification

- SAIME HUMIDIFIER controlled and regulated by the unit (option)
- FISCHER AND PAYKEL HUMIDIFIER (option)

### 12.11 Fire prevention

If the machine is in first fault condition, the inflammable materials have an ignition temperature above the minimum fixed by the standards.

### 12.12 Applied standards

The ventilator meets with the following standards:

- EN 60 601-1 for electromedical devices
- EN 60 601-1-4 for programmable electromedical devices
- EN 794-2 for pulmonary ventilators
- 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

# 13. TECHNICAL SPECIFICATIONS FOR THE ACCESSORIES AND THE MAINTENANCE PRODUCTS

## 13.1 Pneumatic circuits

- They must have the EC label
- Maximum internal volume of the circuit: 800 cm3 for a single circuit
- Maximum internal volume of the circuit: 2 x 800 cm3 for a double circuit
- The average compliance of the circuits must be less than 1ml/hPa.
- Maximum resistance. 0.3 to 1 l/s per meter

Specifications for the exhale valve for the single circuit

- Maximum volume of the chamber at patient pressure: 16 cm3
- Maximum resistance. 2 hPa at 60 litres/minute
- Valve surface at patient pressure: 2 $cm^2$ < S < 3 $cm^2$
- Counter pressure surface controlled by the exhale valve. 7 $cm^2$ < S < 9$cm^2$.

## 13.2 Humidifier

Saime heating base

- Supply voltage: 15 to 25 Volts
- Can be operated only from the mains
- Power Consumption: 25 VA maximum
- Temperature range: from 30 to 55°C in 6 increments.
- Heating time: about 20 minutes to go from 21 to 55°C
- Can be used for adult and child ventilation
- Usable containers: All types of reusable or disposable chambers with volumes between 100 and 1000ml.
- Temperature at output: <28°C
- Alarm: temperature alarm if temperature goes beyond 60°C.

Heating chambers

- Types: MR 210 250
- Maximum service pressure: > 80 hPa or mbar.
- Maximum flow rate: 180 litres/minute
- Pressure drop at 180 litres/minute: < 3 hPa or mbar.
- Pressure drop under conditions of natural breathing: < 3 hPa or mbar.
- Gas loss at maximum pressure: < 20 ml/minute
- Average compliance: 0.3 to 0.5 ml/hPa
- Liquid flow rate: from 10 to 25 mg/liter

*Note: disposable heating chambers should not be put into an autoclave. Also, they should not be used with solutions containing: phenol, ketone, formaldehyde, hypochlorite, chlorinated hydrocarbons, aromatic hydrocarbons, organic acids.*

WARNING

- Containers and tanks should be used in accordance with manufacturers' indications.
- Humidifier containers and tanks intended for hospital use should be filled with sterile liquid.
- The temperature of the liquid poured into the container or the tank should not exceed 37°C.
- Using non-recommended output tubes can be dangerous and reduce unit efficiency.
- The fill level should be respected for optimized humidification.
- The heating base should not be put in an autoclave or in any liquid of any nature.
- Check the temperature at the gas output; this should not exceed 40°C.

### 13.3 Bacteria filter

- The recommended bacteria filter is FILTA GUARD from INTERSURGICAL, available under the code 1944.
- Viral/Bacteria filter
- Connectors: 22 female and 22 male/15 female.
- Bacteria and viral retention greater than 99,999%
- Resistance at 60 litres/minute: 2.3 cm H2O
- Compressible volume: 66ml
- Internal volume: 200ml
- Filter usage life: 24 hours (manufacturer recommendation).
- The material used must have the EC label

### 13.4 Gas input filter

Saime supplies this filter.

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

### 13.5 Remote alarm box

The remote alarm unit is a SAIME product.

Note: Saime can accept no responsibility for ventilator dysfunction caused by the connection of a remote alarm not respecting the specifications given in TECHNICAL SPECIFICATIONS.

### 13.6 Remote control

The remote control is a SAIME product.

Note: Saime can accept no responsibility for ventilator dysfunction caused by the connection of a remote control not respecting the specifications given in TECHNICAL SPECIFICATIONS.

### 13.7 Removable XLS battery pack

The removable battery pack is a SAIME product. NiMH technology: 14.4V & 2 x 4 AH

Note: Saime can accept no responsibility for unit dysfunction caused by incorrectly connecting the pack.

### 13.8 External DC power supply

The material used must have the EC label
It is recommended that the SAIME back-up block be used.
The external power supply must be capable of supplying a DC voltage between 11 and 29 volts, with a maximum current of 5A and for a duration of over 1 hour non-stop.

Note: Saime can accept no responsibility for ventilator malfunctions caused by failure to respect any of the above specifications.

### 13.9 Flow sensor: Pitot tubes

*Specifications of both SAIME Pitot tube sensors*

- Pressure loss: 1.18 hPa or mbar at 60 litres/minute
  0.30 hPa or mbar at 30 litres/minute.
- Measurement range: 0 to 180 litres/minute
- Volume: 12 cc
- Compliance: not measurable
- SAIME product

*22 mm diameter*

- Connector: Male 22mm cone/standard male 22mm cone.
- Bi-directional sensor

*24 mm diameter*

- Connector: male 24 mm
- uni-directional sensor

## 13.10 Integrating oxygen balloon

*Specifications of the integrating balloon*
- RUSH balloon: 1 litre capacity
- SAIME product

*Specifications for the elbow*
- Tapered male elbow diameter 15/male diameter 22
- SAIME product

## 13.11 Oxygen sensor

*Sensor*
- Type. Electrochemical
- Reference. OXYGEN MEDICEL MOX-1

*Constructor references*
- Output voltage. 10 to 13 mv for an oxygen concentration at 21%
- Response time. 10 seconds
- Operational life. 1,500,000 hours/% at 20°C,
- 800,000 hours/% at 40°C
- Measuring range: 0 to 100% concentration (0 to 75 mv)
- Precision: ± 1%

*SAIME Caution*
- Do not expose the sensor to a temperature less than -10°C and greater than 40°C (50°C low exposure).
- Make sure the cathode doesn't dry up by storing the sensor in a vertical position with the input pointing downwards.
- Keep the measuring part of the sensor away from condensation
- Do not expose the sensor to rough handling or vibrations.
- It is recommended that the cell be changed at least once a year.
- Do not open up the sensor
- When the sensor no longer returns an exact reading at a concentration level of 21%, it should be replaced to avoid electrolyte spillage.

## 13.12 Technical properties of BACTINYL®

### *13.12.1 Instrumentation liquid soap*

- BACTINYL® is a fungicide, bactericide, and virucide
- BACTINYL® instrumentation liquid soap solution at 2 or 4% can be used on all surfaces (rubber, plastic, stainless steel, etc.) with no risk of degradation or corrosion.

*Instructions for use*

- Prepare an immersion bath of BACTINYL® instrumentation liquid soap.
- Completely immerse the equipment to be decontaminated making sure the liquid gets to all parts of the circuit
- Leave the parts in the water for 15 minutes
- Rinse with sterile water (or water with low bacteria count)
- Leave the parts to dry (or dry, if necessary).

### *13.12.2 **Disinfecting BACTINYL® 5M***

- BACTINYL® 5M is a concentrated disinfectant: sporicide, fungicide, bactericide and virucide.
- BACTINYL® 5M is used with clean materials that have been decontaminated beforehand with soapy water.

*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 dry

**CAUTION**

- Do not use with other products
- Do not swallow
- Rinse with clear water if the product is in contact with skin or eyes.

NOTE:

- If other products are used, they must respect the conditions listed in the French Pharmacopoeia and guarantee the absence of residual products.
- For surface disinfecting, Saime recommends BACTINYL®.

BACTINYL® is manufactured by: F. GARCIN pharmaceutical laboratories, 63000 CLERMONT-FERRAND, FRANCE