

User's Manual

VS Serena



Réf. NEAT0202079-K from version 2.04

User's manual *VS Serena*
Reference : NEAT0202079-K
From version 2.04



Manufacturer :

SAIME

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WARNINGS

- ☞ This manual should be read and understood before using this device on a patient.
- ☞ This User's Manual goes with a Service Manual NTA0208095 which should be read and understood by the technical staff in charge of the overhaul.
- ☞ Professionally trained and competent personnel working under the doctor's responsibility may carry out the settings.
- ☞ A medical doctor should decide the ventilation settings.
- ☞ This device has been classified as fit for adult and paediatric ventilation.
- ☞ This device must not be used for life support.
- ☞ This device has been approved for a continuous service.
- ☞ The device should not be restarted immediately if conditions of storage and/or transport are different than the recommended operating conditions.
- ☞ The device should not be used onto the mains without being removed from its transport bag.
- ☞ SAIME is willing to provide further information on the steps taken to guarantee the cleanliness of the respirator elements during the production and delivery phases.
- ☞ The device should be used only in its normal operating position, placed firmly on its feet.
- ☞ Use the unit's carry handle for the transport and handling. Do not use the device carry handle if a patient is being ventilated on the machine.
- ☞ Do not block up the ventilator's inlets.
- ☞ The device must not be covered or placed in such a way as to adversely affect ventilation.
- ☞ The complete patient circuit should be thoroughly checked for leaks or defects before connecting the patient.
- ☞ The pressure in the ventilator is greater than the atmospheric pressure at all times during the exhale cycle.
- ☞ The device and the turbine conception have been designed in such a way as to limit the output pressure to a maximum of 39 hPa.
- ☞ The alarms should be checked regularly, especially before the ventilator is used on the patient and when used for on-going home ventilation.
- ☞ This device should not be used with inflammable anaesthetic agents.
- ☞ The ventilator may dysfunction if used in the presence of devices that generate short wavelengths or high frequencies (defibrillators, diathermia devices, electro surgical devices, X-ray devices, cellular phones, etc...).

- ☞ Electromagnetic fields exceeding 10 V/m may adversely affect the ventilator.
- ☞ This device should not be used with patient circuits made with current conducting material.
- ☞ No device sterile, under non-watertight film wrapping.
- ☞ Do not expose the ventilator to direct sunlight.
- ☞ This device is fragile. Do not handle it roughly.
- ☞ AC mains supply must be in conformity with local regulation.
- ☞ The ventilator should be run from its external DC supply, in case of serious mains supply disturbances.
- ☞ In case of a prolonged storage without being connected onto the mains, the back-up battery naturally runs down. When starting the device, if the back-up battery alarm releases, connect the device onto the mains for several hours.
- ☞ Make sure that the total resistance of the patient circuit and ventilation accessories does not exceed 6 hPa at 60 litres/minute for adults and 6 hPa at 30 litres/minute for children.
- ☞ All faulty fuses on the supply board should be replaced with identical fuses respecting identical standards. The primary fuse on the mains socket protects the transformer from overload.
- ☞ Before every use on a new patient and when using the device for the first time, the ventilator must be cleaned and disinfected according to the procedure (see chapter “Maintenance and Disinfection”).
- ☞ The ventilator should be disinfected and decontaminated as per the manufacturer's indications and the procedure(s) set down by the hospital or the home ventilation care organisation.
- ☞ Power supply 230/100 VAC 50-60 Hz 52 VA and/or external supply 26 VDC, 3A maxi (medical CE EN 60601-1).
- ☞ The specific cable delivered with the device should supply the appliance current, using another model could be dangerous for the patient.
- ☞ The device and its user's manual have obtained the CE-marking (TÜV Rheinland). Every used accessory should be CE too.
- ☞ The re-inhalation of the carbon dioxide is limited by the leaks at the mask and the cleaning of the circuit by the constant flow circulation.
- ☞ The serial number of the device gives the product code, the manufacturing year and month, the number of the device in the month.
- ☞ In case of a technical alarm, switch off the device plug it from the mains and from O2 supply.

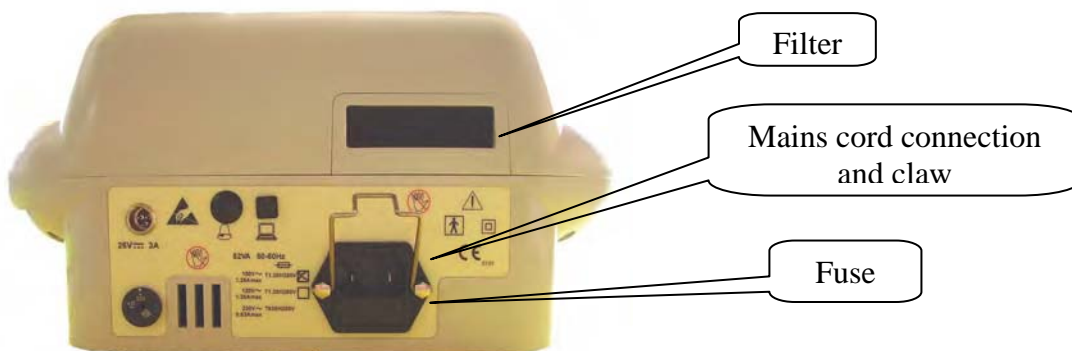
☞ This device should be disposed of separately, not as unsorted waste
To dispose of your device, you should use appropriate collection, reuse and recycling systems available in your region. The use of these collection, reuse and recycling systems is designed to reduce pressure on natural resources and prevent hazardous substances from damaging the environment This directive applies to all devices manufactured after august 2005 and with serial numbers bigger than VS0508001;

Example :

VS 02 07 003 ← number in the month
year ↑ ↑ month

Packing list

DESIGNATION
Kit Accessories (KIT012892)
Mains cord (COR011870)
Certificate of conformity
User's manual
Recommendation concerning safe battery
Tubes 180 cm (TUY010993)



Vs Saime Bag

Recommendations

The Vs bi-level has been made to work in an optimum way with different types of leaks masks present on the market. The characteristics of those masks have been taken into account in the algorithms of calculations. However, the use of a facial mask can slightly modify the sensibility of the triggering. In this configuration, it is recommended to use the ST mode and the AUTO Start function disactivated (NO).

With software version 2.04.

we recommend the following RESMED¹ masks when using an open circuit ventilation (i.e. leakage):

16518	KIT MASQUE MIRAGE STANDARD for PPC
16519	KIT MASQUE MIRAGE LARGE for PPC
16545	KIT MASQUE ULTRA MIRAGE PPC STANDARD
16546	KIT MASQUE ULTRA MIRAGE PPC LARGE
16578	ULTRA MIRAGE MASK SHALLOW –WIDE CE
60003	ENSEMBLE MASQUE MIRAGE VISTA STANDARD
60004	ENSEMBLE MASQUE MIRAGE VISTA PROFOND
60103	MASQUE MIRAGE ACTIVA STANDARD
60104	MASQUE MIRAGE ACTIVA LARGE
60105	MASQUE MIRAGE ACTIVA SHALLOW
60011	MASQUE MIRAGE KIDSTA SML
632003	KIT COMPLET MASK PAPILLON TAILLE 1
632004	KIT COMPLET MASK PAPILLON TAILLE 2 LARGE
60610	MASQUE FACIAL ULTRA MIRAGE PETIT STD
60611	MASQUE FACIAL ULTRA MIRAGE PETIT SHALLOW
60612	MASQUE FACIAL ULTRA MIRAGE MEDIUM STD
60613	MASQUE FACIAL ULTRA MIRAGE MEDIUM SHALLOW
60614	MASQUE FACIAL ULTRA MIRAGE LARGE STD
60615	MASQUE FACIAL ULTRA MIRAGE LARGE SHALLOW

CAUTION

KIT MASQUE MIRAGE SWIFT TAILLES S/M/L (RESMED, reference 60506) must not be used with version 2.04.

¹ or equivalent.

With software version 2.03 and former versions,

we recommend the following RESMED² masks when using an open circuit ventilation (i.e. leakage):

16518	KIT MASQUE MIRAGE STANDARD for PPC
16519	KIT MASQUE MIRAGE LARGE for PPC
16545	KIT MASQUE ULTRA MIRAGE PPC STANDARD
16546	KIT MASQUE ULTRA MIRAGE PPC LARGE
16578	ULTRA MIRAGE MASK SHALLOW –WIDE CE
60003	ENSEMBLE MASQUE MIRAGE VISTA STANDARD
60004	ENSEMBLE MASQUE MIRAGE VISTA PROFOND
60103	MASQUE MIRAGE ACTIVA STANDARD
60104	MASQUE MIRAGE ACTIVA LARGE
60105	MASQUE MIRAGE ACTIVA SHALLOW
60011	MASQUE MIRAGE KIDSTA SML
632003	KIT COMPLET MASK PAPILLON TAILLE 1
632004	KIT COMPLET MASK PAPILLON TAILLE 2 LARGE

CAUTION

The following masks must not be used with version 2.03 and former versions:

60610	MASQUE FACIAL ULTRA MIRAGE PETIT STD
60611	MASQUE FACIAL ULTRA MIRAGE PETIT SHALLOW
60612	MASQUE FACIAL ULTRA MIRAGE MEDIUM STD
60613	MASQUE FACIAL ULTRA MIRAGE MEDIUM SHALLOW
60614	MASQUE FACIAL ULTRA MIRAGE LARGE STD
60615	MASQUE FACIAL ULTRA MIRAGE LARGE SHALLOW
60506	KIT MASQUE MIRAGE SWIFT TAILLES S/M/L

² or equivalent.

The VS bi-level can also be connected with a humidifier as :

Fisher & Paykel type "HC150", or equivalent.



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1. Description and Assembling

1.1 Definition and field of application

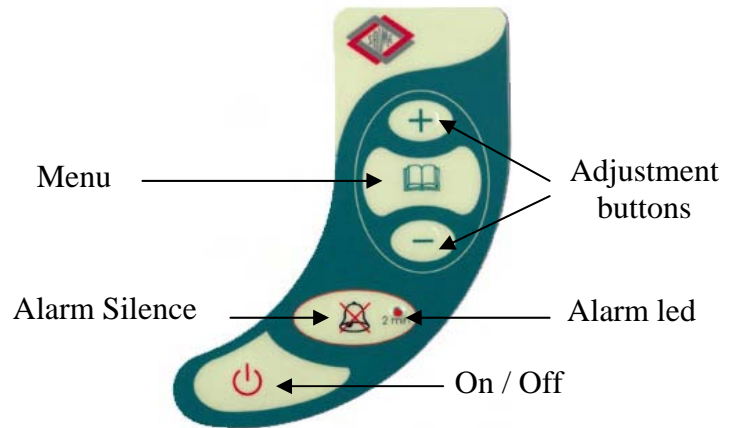
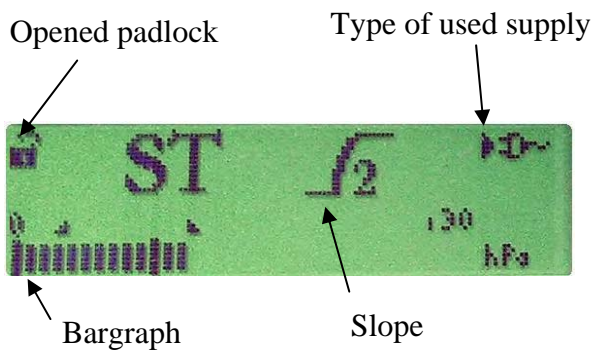
VS^{Serena} is a device used for the two pressure levels non-invasive ventilation, for adult or paediatric patients, at hospital and / or at home if the patient has enough spontaneous ventilation. This device is not designed for neonatal use.

The device should be used with a single-circuit system and a leaks mask.

The device has **four leakage modes** :

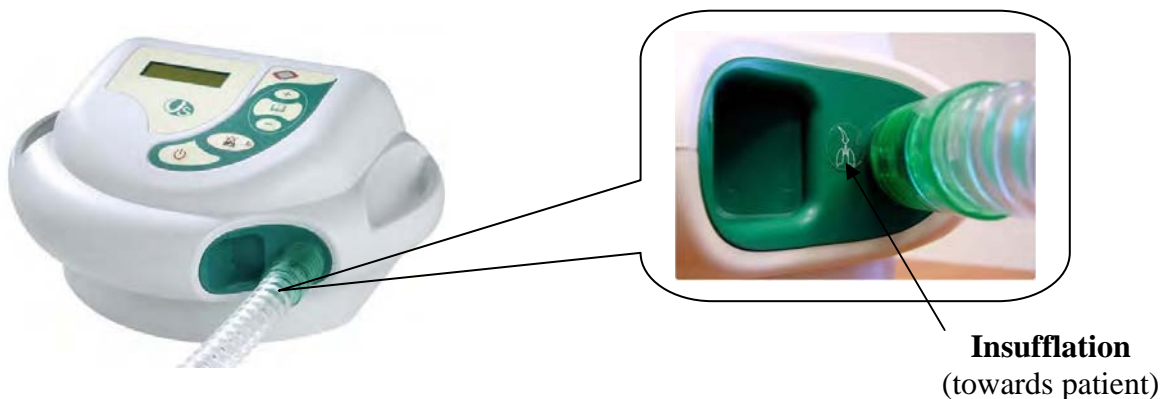
- S : Spontaneous
- ST : Spontaneous with security frequency
- CPAP : Continuous Positive Airway Pressure (when EPAP = IPAP)
- T(s) : Timed mode with frequency

1.2 Screen / Buttons



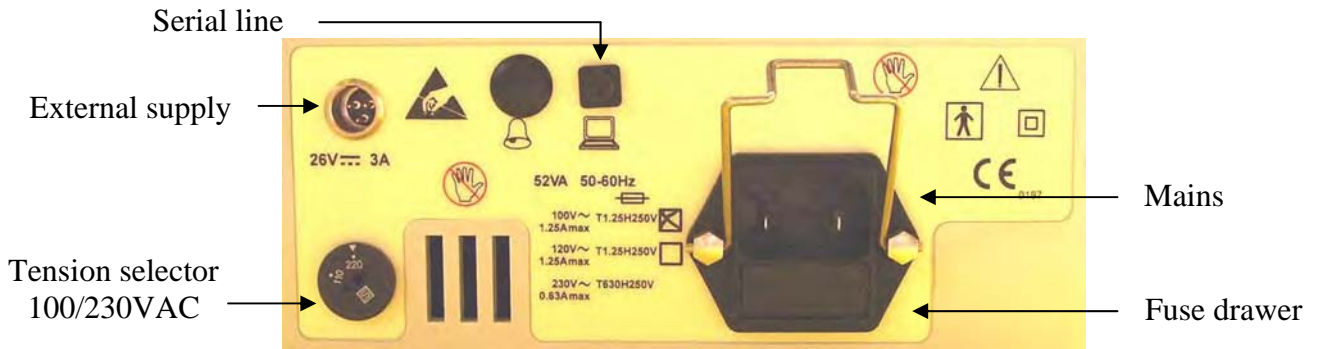
1.3 Patient circuit Connection

Before starting the Bi-level, connect the patient circuit :

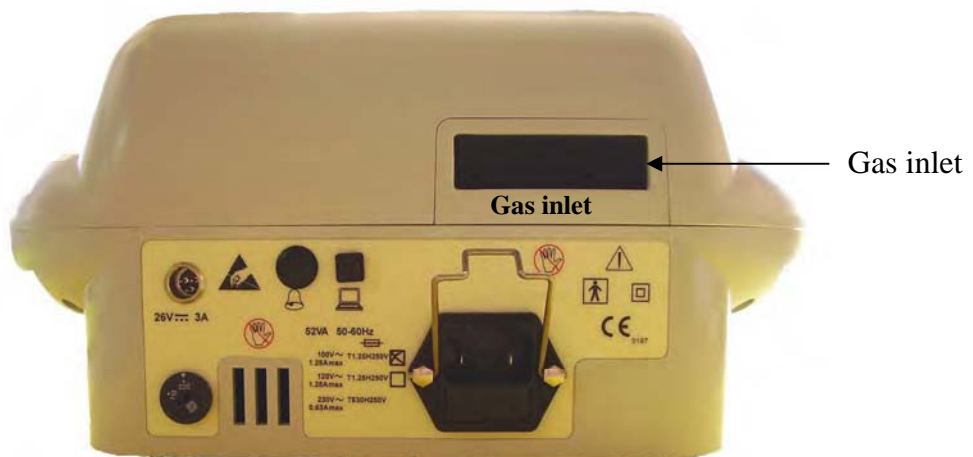


Note : Check the settings and alarms adjustment before connecting on the patient.
The insufflation connector has a standard size (22 mm).

1.4 Rear lay-out



Note : the safety hook near the mains connection protects the device against the accidental disconnection of the mains. It should be put on the mains cord after the connection (see picture below).



Caution: connectors of the rear panel are not protected against electrostatic discharges.

Note: make sure that the ventilator's inlets are not blocked up.

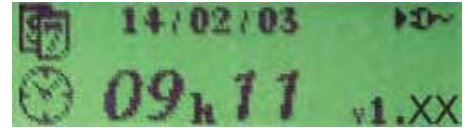
Note: when the switch is commutated on 220, the device can function on 230 VAC. When the switch is in position 100, the device can function on 100V or 120V, according to the checked box.

2. Start / Stop


2.1 Start

- Mains cord connection : the device is in stand by mode.



The following screen appears with mains symbol, date, hour, version :



- Date and hour settings : In stand by mode, press the Menu button until the date flashing. Adjust date and hour with + and - buttons, then confirm by pressing the Menu button until the date and hour stop flashing.


- Starting : Press on the  button, a buzzer rings out, the device starts on.



Note : when the device is turned on, two counters of hours are displayed and also the country of use :

- Patient :  00000 h
- Device :  00000 h

- To reset the patient counter : press simultaneously  and  while it appears. Warning : this resets the trends memory.

While the above counters are displayed, press one second on the Menu button in order to display the Meca parameter (turbine overhaul) instead of the Device counter :

- Meca :  00000 (refer to the Service Manual NTA0208095)

- To set the device with the manufacturing parameters : while the Meca counter displays, after the device turns on, press simultaneously  and  . Warning : this resets the trends memory and the Patient counter.


2.2 Control of the functioning and conditioning for a new patient



Before every use on a new patient and when using the device for the first time, the ventilator must be cleaned and disinfected according to the procedure (see chapter “Maintenance and Disinfection”).



To check the functioning of the device :


- Assembly the patient circuit with a balloon (a SIEMENS® for example) and then start the device
- Check the pressure on the bargraph, the measures and the alarms triggering (see “Procedure of alarms checking” chapter 8).
- Check also the similarity between the settings and the measures made by the device (see “Units and accuracy” chapter 7).

Pressing one second on the button  and check the display of the measured frequency and the delivered tidal volume. The screens disappear after 10 s.



2.3 Stop

- Stop : press two seconds on the  button, the ventilation stops and the device is in stand by mode.
- Disconnection of the mains cord : a continuous buzzer rings out, to confirm press on the  button.

Note : the patient can automatically starts the device, when the **Auto**  function is activated (Yes). In the S and CPAP modes, the Bi-level is automatically in stand by mode if the patient stops ventilation himself (putting out the mask).

To connect onto the mains does not inhibit the continuous alarm, you have to deactivate it by pressing the Silence Alarm button

3. Supplies

3.1 Types

" ▶ " symbol displays behind the **used** supply :



AC Mains



External supply

Note : only the connected supplies are shown at the top right of the screen.

CAUTION

This device includes a safe battery. We strongly recommend before any use to connect the device to the mains power for 24h in order to ensure the optimum charge of the batteries.


In a general way, for an optimum use, a minimum time of charge of 24h is necessary after storage for more than 4 weeks

3.2 Priority

The mains has always priority over the other supplies.

4. Access without unlocking

4.1 The measures

- The pressure is indicated on the bargraph (1 block = 1 hPa)
- Two measures display on the screen by pressing on the  button, they disappear after 10s.

During this display, press on the  and  buttons to accede to the IPAP, EPAP and f min parameters.

The measures are :

- **Tv** = estimated patient tidal volume
- **f** = patient frequency



Note : The measures are also accessible when the device is unlocked.

4.2 The slope

It is the rising time between the expiratory and inspiratory pressure.

To select this parameter, press on the  button until the slope symbol appears.

Adjust with the  and  buttons.


The adjustment values are:



0	minimal	f_0
1	400 ms	f_1
2	600 ms	f_2
3	800 ms	f_3


5. Setting access

5.1 Unlocking


It allows to accede to the following parameters :



- The ventilation mode (if $f_{\min} \geq 5$ c/min, the ST mode is activated, if $f_{\min} < 5$ c/min the S mode is activated)
- The inspiratory and expiratory pressure (IPAP / EPAP)
- The inspiratory time Ti_{\min} / Ti_{\max} (not in CPAP mode)
- The minimum frequency (f_{\min})
- The trigger (Trig.)
- Automatic starting **Auto** 
- The measures
- The slope
- The ramp (only in CPAP mode)

To accede to this menu, press on the  button until the audible bip. The  symbol appears on the screen. The device is unlocked.

Note : to lock the device, press again on the  button until the padlock disappears. If no button is activated for two minutes, the device is automatically locked.

5.2 Selecting

To select a parameter, scroll with the  button until the requested parameter appears.

If you press the  button while you maintain pressed the  button, you could go back in the Menu.

5.3 Adjusting

Once the selected parameter, adjust the value with the  button to increase, the  button to decrease.

6. Ventilation Modes

6.1 *The S mode : spontaneous mode (f min = NO)*

This mode is a two pressure levels ventilation. The frequency and the inspiratory time are entirely patient triggered.

The adjustable parameters are :

- The inspiratory pressure (IPAP)
- The expiratory pressure (EPAP)
- The minimum frequency (f min No)
- The minimum inspiratory time (Ti min)
- The maximum inspiratory time (Ti max)
- Automatic starting
- The slope

Note : in the case IPAP=EPAP, the CPAP mode appears, the "slope" symbol and "f min" disappear. Then you can adjust the ramp.

6.2 *The ST mode : spontaneous mode with minimum frequency (f min ≥ 5 c/min)*

In addition to the S mode characteristics, this mode allows to adjust a security frequency (f min).

The adjustable parameters are :

- The inspiratory pressure (IPAP)
- The expiratory pressure (EPAP)
- The minimum frequency (f min)
- The minimum inspiratory time (Ti min)
- The maximum inspiratory time (Ti max)
- The trigger (Trig. Yes)
- Automatic starting
- The slope

6.3 *The T(s) mode : timed mode with frequency*

The adjustable parameters are :

- The inspiratory pressure (IPAP)
- The expiratory pressure (EPAP)
- The frequency (f)
- The minimum inspiratory time (Ti min)
- The maximum inspiratory time (Ti max)
- The trigger (Trig. No)
- Automatic starting
- The slope

7. The parameters

7.1 Definition

IPAP (*Inspiratory Positive Airway Pressure*) : inspiratory pressure delivered by the device. It cannot be less than the expiratory pressure + 2 hPa (except in CPAP and S modes).

EPAP (*Expiratory Positive Airway Pressure*) : expiratory pressure delivered by the device.

The frequency (f) : minimal number of cycles per minute delivered by the device to the patient in ST mode.

- If $f_{min} < 5$ c/min , $f_{min} = \text{No} \rightarrow \text{S mode}$

- In T(s) mode, f_{min} is replaced by f.

The inspiratory time (Ti) : inspiratory phase of each cycle.


It can be adjusted as : - a minimum : **Ti min** (this parameter has always priority over Ti max)

- a maximum : **Ti max**

Note : $Ti_{max} \geq Ti_{min} + 0,3 s$

The trigger : allows the patient to release himself inspiration cycles.


This function is adjusted : from the ST mode (Trig. Yes) to the T(s) mode (Trig. No).

The automatic starting  : This function can be activated or not (Yes/No).

It allows the patient to be able to start the device when he wants by breathing through the mask.

Note : moreover it allows the device to be automatically in stand by mode after 30 s if the patient put out his mask (only in S and CPAP modes and when the device is locked).

7.2 Parameters chart depending on the ventilation modes

Ventilation Modes Parameters	S	CPAP	ST	T(s)	Padlock
IPAP (hPa)	5→30	4→20	6→30	6→30	
EPAP (hPa)	4→20	4→20	4→20	4→20	
f min (cycles/min)	No	No	5→50	(f) 5→50	
Ti min² (seconds)	0,3→2,5	--	0,3→2,5	0,3→2,5	
Ti max² (seconds)	1→3	--	1→3	1→3	
Trigger (Trig.)	AUTO ¹	AUTO ¹	Yes	No	
Slope	0 / 1 / 2 / 3	--	0 / 1 / 2 / 3	0 / 1 / 2 / 3	
Ramp (min)	--	No / 5-45	--		
Automatic starting	Yes/No	Yes/No	Yes/No	Yes/No	

¹ : in CPAP and S mode, the "Trig." parameter does not appear, the trigger is automatic.

² : Ti min and Ti max depend on the frequency adjusted.

Note : The IPAPmax pressure is limited to 30 hPa

The IPAPmin is limited to : - in S mode $\rightarrow IPAP \geq EPAP + 1 \text{ hPa}$

- in ST mode $\rightarrow IPAP \geq EPAP + 2 \text{ hPa}$

7.3 Units and accuracy

Adjustable Parameters

- *Inspiration (IPAP)*
 Unit : hectopascal (hPa)
 Readings accuracy : +/- 1 hPa
 Setting accuracy : +/- 2 hPa**
- *Expiration (EPAP)*
 Unit : hectopascal (hPa)
 Readings accuracy : +/- 1 hPa
 Setting accuracy : +/- 2 hPa**
- *Minimum Frequency (f min)*
 Unit : cycles/minute (c/min)
 Readings accuracy : +/- 1 c/min
 Setting accuracy : period 10 ms
- *Minimum inspiratory time (Ti min)*
 Unit : seconds (s)
 Readings accuracy : +/- 0,1 s
 Setting accuracy : +/- 10 ms
- *Maximum inspiratory time (Ti max)*
 Unit : seconds (s)
 Readings accuracy : +/- 0,1 s
 Setting accuracy : +/- 10 ms

Measures

- *Estimated Tidal Volume (Tv)*
 Unit : litre (L)
 Readings accuracy : +/- 0,01 L
 Measure accuracy : estimation*
- *Frequency (f)*
 Unit : cycles/minute (c/min)
 Readings accuracy : +/- 1 c/min
 Measure accuracy : +/- 1 c/min
- *Pressure*
 Unit : hectopascal (hPa)
 Readings accuracy : 1 █ = 1 hPa
 Measure accuracy (bargraph) : +/- 2 hPa**

* : The precision depends on the used mask.
 The tidal volume measures correspond to ATPD conditions (no humidity in the air).

** : Accuracy : +/- 2% of the full scale + 4% of the readings (EN 17510)



8. The Alarms



8.1 Definitions

When an alarm is activated, a message flashes on the screen and a buzzer rings out.

8.1.1 The automatic alarms

Continuous Buzzer Alarm : No supply connected. The device stops.

  **Mains !** : No more mains supply with at least an other supply connected.
Check the mains supply connection.



  **Disconnection** : High flow and pressure almost zero. Check the patient circuit.

Note : In S mode, this alarm is inactive if the automatic starting is selected (Yes).

8.1.2 The technical alarms

  Global technical alarm

  Stopped turbine


  Low tension of the back-up battery.
Connect onto the mains. Check date and hour.

➤ Procedure of alarms checking

Mains ! : No more mains supply. Disconnect the mains cord with an other external alimentation connected

Disconnection : disconnect the patient circuit.

8.2 Alarms Priorities

The alarms priorities are represented by the flashing red led on the  button and by a buzzer.

8.2.1 High Priority

This priority is represented by : a quick flashing led
and a buzzer ringing out every 8 seconds (••• ••)
or a continuous buzzer ringing out in case of defect stop of the device

8.2.2 Medium Priority

This priority is represented by : - a moderate flashing led
- a buzzer ringing every 20 seconds (• • •)

8.2.3 Low Priority

This priority is represented by : - a continuous led
- a discontinuous buzzer every 5 seconds (• •)

For any further persistent alarm, or in case of any doubt, please contact your technician.

9. Maintenance and disinfection

9.1 Fuses replacement

Time lagged fuse, cutting high power :
 - T 630mA H 250V for a use on to the 230 VAC mains
 - T 1.25A H 250V for a use on to the 100 VAC mains

9.2 Dust Filter replacement

Before every use on a new patient, check the dust filter which is on the rear face.

Note : we recommend to replace this filter for each use on a new patient.

9.3 Replacement of the internal filter

The air filter placed into the turbine compartment has to be replaced by a qualified technician.

Note : we recommend to replace the internal filter yearly.

9.4 Check the calibration

Check the calibration of the pressure measurement between each patient or/and yearly (cf. the procedure in the service manual NTA0208095).

9.5 Cleaning / Sterilising

9.5.1 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. For any new patient, the process is as indicated :

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

9.5.2 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. Cold disinfecting by immersion is also possible. Use the BACTINYL[®] 5M solution or equivalent.

9.5.3 Bacteria filter

Bacteria filters situated in the inspiratory circuit and used for bacterial and viral filtering should be replaced in accordance with manufacturer's instructions and for each new patient.

9.5.4 External units 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.

9.5.5 Heating chamber (humidifier)

We recommend the use of disposable chambers.

Disposable heating chambers should not be put into an autoclave.

They should not be used with solutions containing phenol, ketene, formaldehyde, hypochloride, chlorinated hydrocarbons, aromatic hydrocarbons, and organic acids.

For reusable chambers, cold decontamination by immersion is also possible. Use a 2% or 4% of BACTINYL[®] instrumentation liquid soap solution or equivalent.

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.

9.5.6 Technical properties of BACTYNIL[®] 5M

BACTINYL[®]5M is a concentrated disinfectant : SPORICIDE, FUNGICIDE, BACTERICIDE & VIRUCIDE.

BACTINYL[®]5M is used with clean materials, which has been decontaminated beforehand with soapy water.

- **Use**

1. Prepare an immersion bath (at 2% for products not ready to be used) in cold or lukewarm water.
2. Completely immerse the equipment to be disinfected (both the patient circuit and the removable parts).
3. Leave it in the water for 15 minutes.
4. Rinse with sterile water (or water with low bacteria count).
5. Let 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.

- **Information**

For surface disinfecting, SAIME recommends BACTINYL[®] (FUNGICIDE, BACTERICIDE, and VIRUCIDE). The F. GARCIN pharmaceutical laboratories manufacture BACTINYL[®] : 63000 CLERMONT-FERRAND, FRANCE. Any equivalent chemical can be used.

WARNING :

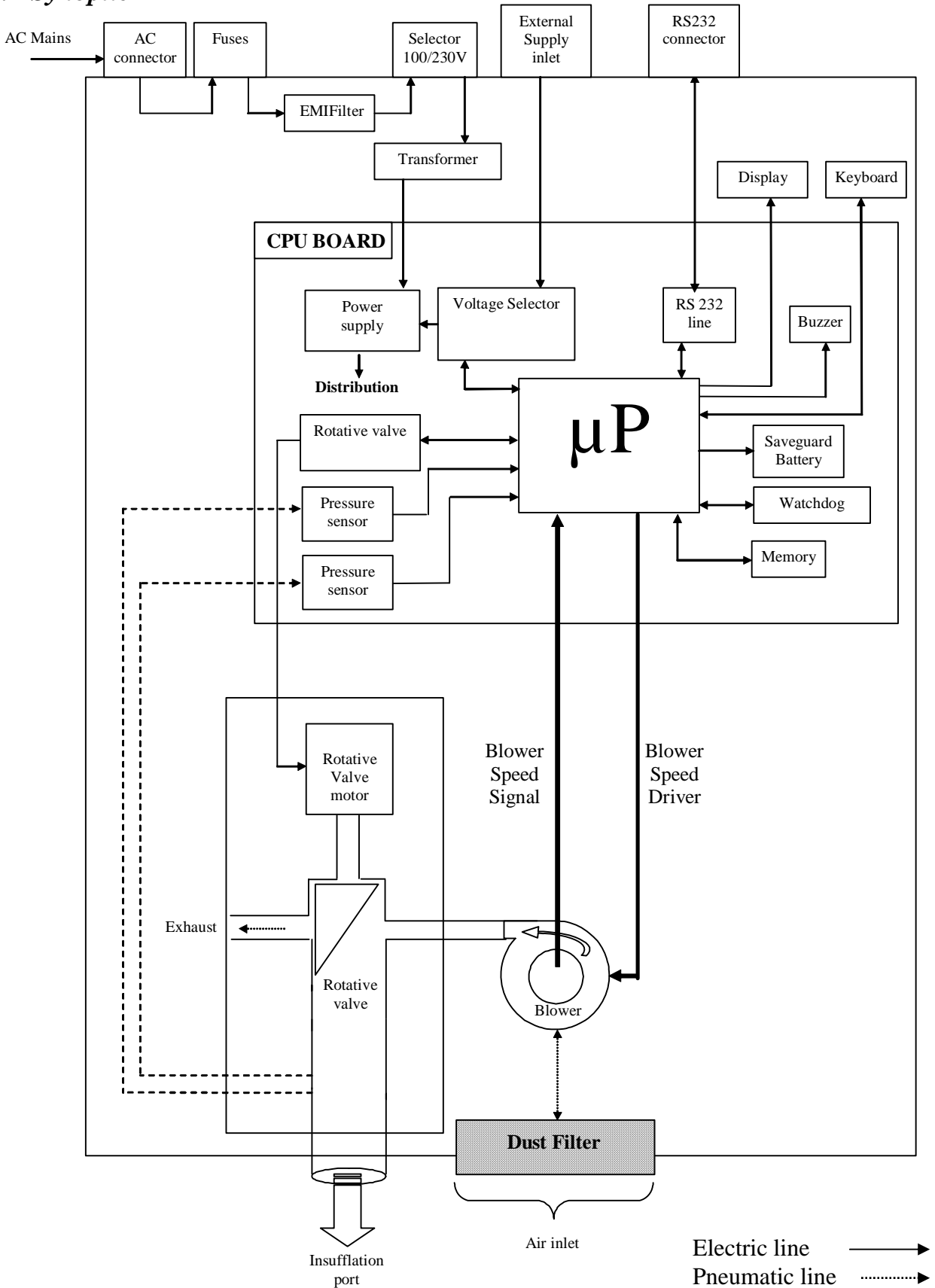
Maintenance centres may use other decontamination procedures. However, they must be approved and respect current rules and regulations. If other products are used, they must respect the conditions detailed in the French Pharmacopoeia. They must guarantee the absence of all residual products and they must not interfere with the ventilator's operation. Furthermore, they must not be in contradiction with the security measures recommended by SAIME.

Note : due to the device conception, in leakage ventilation, the contamination by the expired gas of the patient is highly limited to the pneumatic circuit. Indeed at the time of the active expiration of the patient when the cycle begins, there is a column of clean air between the device and the patient (volume of the patient circuit). During the passive phase of the expiratory cycle, a constant flow allows the expired gas to be evacuated by the leaks of the mask (cleaning). Nevertheless, using a bacteria filter is the only precaution which assures an optimal protection (particularly in hospital).

So we recommend the change of the patient circuit for each new patient. The pneumatic elements and the internal foams are not submitted to the same conditions.

10. Technical Characteristics

10.1 Synoptic



10.2 Functioning

The gas source is driven by an internal blower (the external air is inhaled through a dust filter). The positive inspiratory and expiratory pressures are driven at the settings with a pneumatic distributor. During the insufflation, a rotating valve drives the air of the blower towards the patient. At the expiration, it drives the expired gas through the exhalation outlet. Thus it reduces the concentration of re-inhaled CO₂ during the next cycle.

Inspiratory and Expiratory triggers are based on inspiratory Pressure signal analysis, pressure settings and closed loop blower signal.

10.3 Power supply

Class II, type BF device

Mains : 230/100 VAC 50-60 Hz 52 VA I_{max} = 630 mA

External supply : 26 VDC +/- 10 % 3A maximum (CE medical EN60601-1)

10.4 Specifications

Sound level : 29 dBA (measured under ISO3744 & EN17510 standard)

Weight : 2,5 kg

Dimensions : 135 mm x 285 mm x 204 mm

Compliance : no measurable

Maximum adjusted pressure : 30 hPa

Maximum pressure in 1st fault condition : 39 hPa

Flow at 10, 20, 30 hPa : 204 L/min, 180 L/min, 168 L/min

Deliverable maximum minute volume :

In the optimal adjustment conditions, IPAP=30, EPAP=4, various frequency, and for the following physiological characteristics :

R _p = 20	C=0,05	\dot{V} =20 L/min
R _p = 5	C=0,05	\dot{V} =35 L/min

Inspiratory resistance :

Flow = 60L/min R = 4,7 hPa (+ tube resistance)

Expiratory resistance :

Flow = 60L/min R = 4,3 hPa (+ tube resistance)

Used materials in direct contact with patient gaz : ABS, Aluminium, Silicon, Stainless steel, Polyester, Brass, Chrome.

10.5 Use, storage and transport conditions

→ Current use

Operating temperature from -5°C to +40°C
 Relative humidity from 30 % to 75 %
 Pressure from 700 to 1060 hPa

→ Storage

Device with its accessories in original boxes :

Storage temperature from -10°C to +50°C
 Relative humidity from 10% to 90%
 Do not store in humid conditions. The device is fragile, it should be stored as it is used.

Device with its accessories not in original boxes :

Storage temperature from -10°C +50°C
 Relative humidity from 10% to 90%
 Do not store in humid conditions. The device is fragile, it should be stored as it is used.

→ Transport

Transport temperature from -10°C +50°C
 Relative humidity from 10% to 90%
 The ventilator and its accessories should be placed in their original SAIME packaging for transport.

Warnings : - Fragile device, sensible to humidity, respect the transport position
 - Transport temperature : from -10°C to +60°C

Note : in case of default of one of those following variations, the device works :

- Temperature : from -5° to + 40°C
- Relative humidity : from +10% to + 95% RH
- Atmospheric pressure : from 700 mb to 1060 mb
- Mains tension : from -15 % to +10% nominal.
- External supply : from 26 V -15% to +25%

10.6 Applied standards

The device meets with the following standards :

- EN 60 601-1 For electromedical devices (safety rules).
- IEC 601-1-4 For electromedical devices (programmable systems).
- EN 60 601-1-2 : Compatibilité électromagnétique pour les appareils électromédicaux.
 - EN 55 011-classe B
 - EN 61 000-4-2
 - EN 61 000-4-3
 - EN 61 000-4-4
 - EN 61 000-4-5
 - EN 61 000-4-6
 - EN 61 000-4-8
 - EN 61 000-4-11
 - CEI 801-3
 - EN 61000-3-2
 - EN 61000-3-3

- EN 17510
- EN 1441
- EN 1281-1
- EN 980
- UTC C74-003
- EN 739
- EC 0197 93/42 EEC
- WEEE 2002/96/EC European Directive concerning the proper disposal of electrical and electronic equipment.
- CE 0197 : directive 93/42 CE ; notified body TÜV Rheinland

10.7 Accessories technical specifications

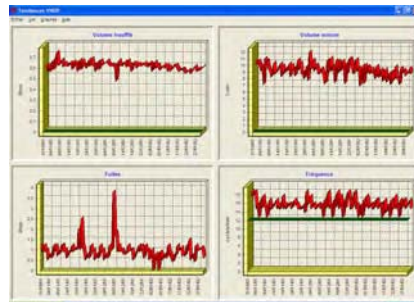
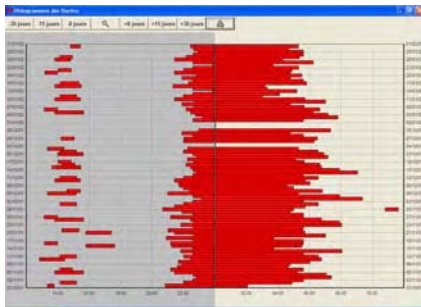
Tendances[®] is a software dedicated to the recording of the principal ventilatory parameters. This trend analysis software allows analysing the data of both patient and device stored in the Bi-level ventilator during several months of using. It gives access to the following parameters and graphics :

☞ Parameters :

- **Tv** : estimated tidal volume delivered by the device
- **F** : frequency of respiratory cycles measured by the device
- **Leaks** : estimated leaks in comparison with the leaks of the mask
- **Vol minute** : calculated volume minute (on the basis of the estimated Tv and the measured frequency)

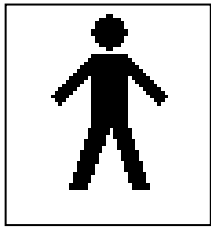
☞ Graphic analysis :

- **4 graphic trends** with dating of beginning and end of a session, length of session
- **Ventilation log (histogram of lengths)** : it includes the whole sessions of ventilation stored as histograms, day by day.

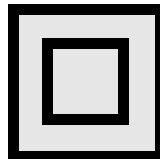


Note : in case of sudden stop of the device further to a mains cut, the last quarter of an hour of the ventilation trends is not saved and cannot be recovered.

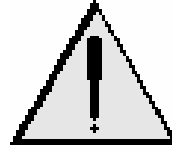
11. Symbols



Type BF device



Classe II device



Please read the supplied documentation



DC voltage



AC voltage



CE label



Store and transport this side up



Fragile



Keep away from humidity



On / Off button



Insufflation
(towards patient)



Recycling



Beware of Electrostatic discharges