SLE 2000 HFO

Ventilator

User manual

High Frequency Oscillatory
Ventilator

CE 0120

Issue
13

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How to use the SLE2000 HFO

NOTE THE WARNINGS (PAGE 12) MUST BE READ AND UNDERSTOOD BEFORE USING THE SLE2000 HFO VENTILATOR. FAILURE TO DO SO COULD LEAD TO INJURY OR DEATH

1 PERFORM THE FUNCTIONAL TESTS : PAGE 18

(THIS SHOULD TAKE NO MORE THAN 20 MINUTES)

2 SETUP THE SLE2000 HFO IN THE CHOSEN MODE: PAGE 25

3 THE SLE2000 HFO IS READY FOR USE

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1. Introduction

The SLE2000 HFO ventilator is designed for use on neonates/infants. Its principle of operation is time cycled, pressure limited ventilation using a constant fresh gas flow.

Main features are that it has no expiratory valve but uses a reverse flow of mixed gas that is injected into the expiratory limb of the patient circuit from the exhaust manifold. This flow of gas has the effect of compressing 5 LPM humidified gas into the patient ET tube.

The advantage of this system is that there is no expiratory resistance due to valves or diaphragms, therefore no inadvertent PEEP is generated. Also the fresh gas flow does not require adjusting for various rates. Another advantage is that the driving flow in the exhaust manifold is controlled by a regulator and therefore provides constant pressure at all breathing rates.

The oscillatory feature is provided by a rotating jet, driven by a motor, situated at the rear of the exhaust block. From this jet a stream of driving gas is rotated into the exhalation manifold which provides both, an active inspiratory and active expiratory flow. It can also be combined with a conventional mode such that we can have oscillation superimposed on the inspiratory pressure plateau, or during the expiration phase, or a combination of both. Finally with the ventilator operating in the CPAP mode, the SLE2000 HFO can act as a pure oscillator where the mean airway pressure is adjusted via the CPAP control, and the differential pressure can be set by the oscillation regulator.

Another main feature of the ventilator is its patient trigger system. This functions without any transducer in the patient circuit, on the principle of monitoring the rate of change of pressure during the onset of inspiratory effort. In fact it measures inspiratory flow by this means and not a pressure plateau.

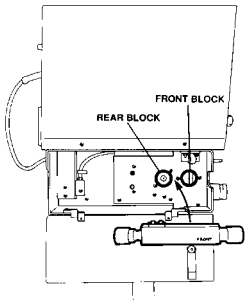
Additionally the SLE2000 HFO has a built in oxygen monitoring cell, fresh gas and leak alarms.

1.1 Principles of Operation SLE 2000 HFO

The patient circuit is supplied with a constant fixed flow of fresh gas at 5 litres per minute. This gas comes from the internally mounted Oxygen Blender and its concentration is monitored by a fuel cell and displayed on the FIO_2 digital display.

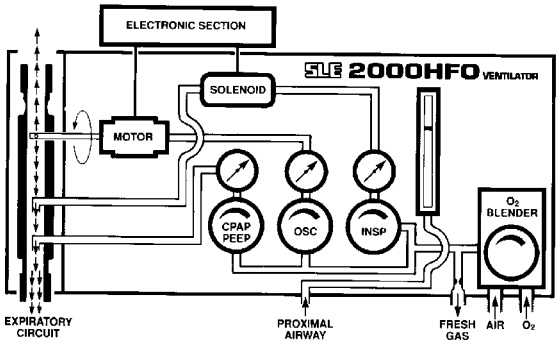
This Fresh Gas Supply is then passed through a humidifier to the Inspiratory port of the patient ET connector. Built into the ventilator are circuits to detect either a gas flow failure or a tubing blockage. This circuitry requires a restrictor fitted into the Inspiratory port of the patient circuit. Therefore, only SLE2000 approved patient circuit must be used with this equipment.

The Exhalation block mounts onto two pressure manifold blocks as shown.



The front block has two nozzles. The first is used to generate CPAP/PEEP via the CPAP/PEEP regulator, by generating an opposing flow to the fresh gas in the exhalation tube thus creating CPAP/PEEP. The second is used to generate the peak Inspiratory pressure. The Inspiratory regulator sets the pressure that is supplied to a solenoid valve which is connected to the rear nozzle.

The Electronic Section controls the rate and duration of opening of the solenoid valve.



When the valve is open the Driving Gas enters the expiratory tube in opposition to the Fresh Gas flow. This opposing flow acts as a pneumatic piston and creates a pressure plateau at the ET connector

The lung inflation pressure and hence the tidal volume are controlled by the Inspiratory regulator in conventional ventilation.

The same gas mixture from the Oxygen Blender is used to supply the patient Fresh Gas, CPAP, Inspiratory and Oscillation driving gas pressure. This avoids any possibility of dilution of the Fresh
Gas mixture.

There is a wave shape switch. This modifies the Driving Gas flow rate from the Solenoid valve through the nozzle and is used to slow down the rise time of the pressure waveform. In the taper position The rise time is approximately 250 ms.

The second or rear manifold block is the High Frequency Oscillator pressure generator. Creating a pressure by means of a spinning jet of gas thus providing an active positive and negative waveform (Sinusoidal). Pressure is controlled via the oscillator regulator and frequency via the Frequency or
Rate control.

When operating the HFO in Inspiratory or expiratory mode, gas release is controlled via a solenoid synchronised with the Inspiratory time and BPM.

2. User/Owner Responsibility.

This SLE 2000 HFO INFANT VENTILATOR and the authorised accessories for it are designed to be used in accordance with supplied manuals and instructions. This equipment must be periodically checked, recalibrated, maintained and components repaired and replaced when necessary for the equipment to operate safely and reliably.

Parts that have failed, in whole or in part, or exhibit excessive wear, or are contaminated, or are otherwise at the end of their useful life, should not be used and must be replaced immediately with parts supplied by SLE, or parts which are otherwise approved by SLE. Equipment which is not functioning correctly or is otherwise in need of repair or maintenance must not be used until all necessary repairs and/or maintenance have been completed and a factory authorised service representative has certified that the equipment is fit and ready for use. This equipment, its accessories or component parts should not be modified. The use of non-approved parts or accessories will invalidate the warranty.

The owner/user of this equipment shall have the sole responsibility and liability for any damage or injury to persons or property (including the equipment itself) resulting from operation not in accordance with the operating instructions, or from faulty maintenance not in accordance with the authorised maintenance instructions, or from repair by anyone other than the factory authorised service representative, or from unauthorised modification of the equipment or accessories, or from the use of components or accessories that have been either damaged or not authorised for use with this equipment by the manufacturer.

3. Warnings

3.1 Operational Warnings

The following warnings must be read and understood before using the SLE2000 HFO ventilator. Failure to do so could lead to injury or death.

1 The whole of this manual should be read and understood before using the SLE2000 HFO Operators must be suitably trained and clinically authorised for using the SLE2000 HFO with patients. Particular care should be taken to check the ventilator pressures prior to changing modes.

2 Oxygen - Clinical use. Oxygen is a drug and should be prescribed as such.

3 Oxygen - Fire Hazard. Oxygen vigorously supports combustion and its use requires special precaution to avoid fire hazards. Keep all sources of ignition away when oxygen is in use. Do Not use oil or grease on oxygen fittings or where oxygen is used.

4 Audible and Visual warning alarms indicate a potentially harmful condition to the patient. **However when ventilating a patient with a 3mm or smaller size endotracheal tubes, in case of patient extubation or the ET tube disconnecting from its ET connector, only the monitoring of flow (module SLE 2100), or of SpO_2, or $Pt0_2/PtCO_2$ will dependably alert the medical team to an alarm situation, not the monitoring of pressures.**

5 When the ventilator is being used on a patient, a suitably trained person must be in attendance at all times to take prompt action should an alarm or other indication of a problem occur.

6 The ventilator functional tests must be carried out each time the SLE 2000 HFO is used on patients. If any of these tests do not function as described then there is a problem and the ventilator must not be used until it is rectified.

7 The humidifier used in the patient circuit must be operated and maintained in accordance with its manufacturer’s instructions.

8 Any water trap used in the patient circuit must be drained regularly before it is full.

9 Failure to comply with the recommended service programs could lead to injury to the patient, operator or damage to the ventilator. It is the owners responsibility to ensure that the equipment is regularly maintained.

10 Functioning of this ventilator may be adversely affected by high frequency surgical (Diathermy) defibrillators, short-wave therapy or equipment producing strong magnetic fields, operating in the vicinity.

11 The Ventilator must be connected to a suitably rated and grounded electrical power source.

12 There is no special protection provided against ingress of water or liquids.

13 The equipment is not suitable for use with, or in the presence of flammable anaesthetic mixtures.

14 Use only SLE approved patient circuits. On no account should antistatic or electrically conductive tubing be used in the patient circuit.

15 No external voltage should be applied to the auxiliary socket. Any connections to this socket must be approved by SLE and screened to comply with EMC regulations. Ensure protection cap is fitted when socket is not in use.

16 The electronic module of the ventilator contains a primary battery, if the ventilator is not to be used for 3 months or more, then the battery should be removed.

17 Care should be taken when attaching other equipment as this may affect stability.

3.2 Clinical Warnings

Failure to take corrective action when the alarms are activated could result in injury or death to the patient.

There are risks inherent in the use of both conventional and high-frequency forms of mechanical ventilation in the newborn and during infancy and childhood. These may include:

1 Under- or over-ventilation (with consequent abnormalities in blood gases);

2 Incorrect humidification;

3 Intracranial haemorrhage, cerebral ischaemia;

4 Chronic lung disease (bronchopulmonary dysplasia in the newborn);

5 Damage to trachea and bronchi;

6 Over- or under-inflation of the lung;

7 Atalectasis;

8 Air leak syndrome (pneumothorax, pneumomediastinum, pneumopericardium. pulmonary interstitial emphysema);

9 circulatory abnormalities (reduced systemic or pulmonary venous return, hypotension, tachycardia, bradycardia, reduced cardiac output, excessive variability of blood pressure);

10 Mobilisation of secretions and airway blockage.

Maintenance of an adequate airway is paramount in the infant or child undergoing high-frequency oscillatory ventilation. The following points should be stressed in airway management on units employing HFOV:

1 The largest endotracheal tube should be used which is compatible with a close, but not tight, fit in the larynx;

2 Chest wall "bounce" (vibrations of chest and abdominal wall caused by HFOV) should be verified regularly as part of nursing care;

3 Transcutaneous carbon dioxide measurement or frequent arterial blood gas samples must be employed to alert the users to partial or total airway failure;

4 Avoid episodes of total disconnection during endotracheal tube toilet.

The minimum patient monitoring requirements for HFOV are:

1 ECG/heart rate;

2 Chest wall movement;

3 Blood pressure (continuous intravascular/regular, intermittent measurements);

4 Oxygen saturation;

5 Transcutaneous carbon dioxide / intravascular carbon dioxide / regular, intermittent arterial/ capillary samples;

6 Regular arterial blood gases;

7 Regular chest X-rays;

8 Regular cranial ultrasound examinations (in the newborn);

9 Standard nursing care for Intensive Care patients.

Special care should be taken when ventilating using HFOV during the administration of natural surfactant to avoid "foaming" of surfactant in the lung and subsequent deterioration.

When switching from conventional to high-frequency ventilation, or vice-verse, rapid alterations in ventilator settings and inspired oxygen concentrations may be required.

Exposing a baby to elevated concentrations of oxygen may lead to Retrolental Fibroplasia (retinopathy of prematurity).

HFOV should only be instituted by fully trained and experienced medical personnel.

4. Glossary of Abbreviations Used in This Manual

bar	Unit of Barometric Pressure	Kg	Kilogram
BPM	Breaths Per Minute	LED	Light Emitting Diode
cm	Centimetre	LF	Low Frequency
cms	Centimetres of Water	LPM	Litres per Minute
cmH_2O	Centimetres of Water	MIT	Maximum Inspiratory Time
CMV	Controlled Mechanical Ventilation	ml	Millilitres
CPAP	Continuous Positive Airway Pressure	ms	Millisecond
°C	Degrees Celsius	O_2	Oxygen
°F	Degrees Fahrenheit	PTV	Patient Triggered Ventilation
dP	Delta Pressure	PIP	Peak Inspiratory Pressure
EMC	Electromagnetic Compatibility	PEEP	Positive End Expiratory Pressure
ET	Endotracheal	psi	Pounds per Square Inch
FIO_2	Fractional Concentration of Inspired Oxygen	SaO_2	Saturated oxygen
Hz	Hertz	SIMV	Synchronised Intermittent Mandatory Ventilation
HFO	High Frequency Oscillation	$tcPCO_2$	Transcutaneous Carbon Dioxide
HFOV	High frequency oscillatory ventilation	$tcPO_2$	Transcutaneous Oxygen
I:E	Inspiratory : Expiratory Ratio	≈	Approximately equal to
Insp.	Inspiration Time		

5. Symbols

The Following Symbols are used on the Equipment

Alternating Current

Attention, consult accompanying documents.

CE 0120

Conformance mark and notified body registration

Type B (IEC601-1) protection against electric shock.

I **On (power: connection to the mains)**

O **Off (power: disconnected from the mains)**

Rotate: clockwise to increase, anticlockwise to decrease


OPERATING INSTRUCTIONS

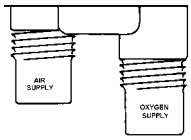
6. SLE 2000 HFO Functional Tests

The following functional tests must be carried out to ensure that this equipment is working correctly before connection to a patient.

- **NOTE: IF ANY OF THESE TESTS DO NOT FUNCTION AS DESCRIBED, THERE IS A PROBLEM AND THE UNIT SHOULD NOT BE USED UNTIL IT HAS BEEN REPAIRED. PLEASE CONTACT AN SLE APPROVED ENGINEER, OR SLE.**

With **HFO** and **Mode** switches set to **OFF**, **High** alarm set to maximum and all other variable controls set to minimum.

Step 1. Connect AIR, OXYGEN Hoses to ventilator and plug into gas supplies, at a gas pressure of about 4 bar. Connect mains cable to a suitably rated and grounded electrical power source.

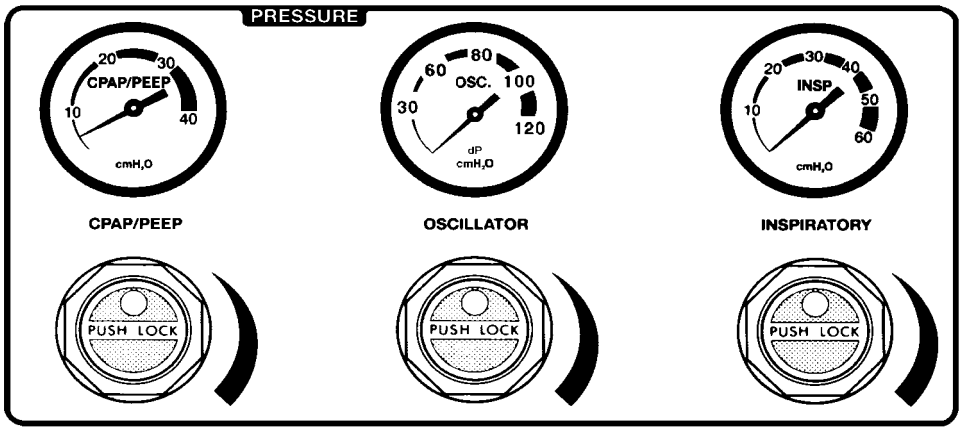


Step 2. Connect SLE approved patient circuit with test lung to the ventilator.

- For further information see page 47 or instructions supplied with patient circuit.

6.1 Pressure Regulators and Gauges

Check in turn the CPAP/PEEP, OSCILLATOR and INSPIRATORY regulators and gauges by turning the regulator controls from minimum to maximum and making sure that the gauges read between minimum and maximum. Return regulators to minimum.



Regulator Controls are lockable. Push to lock, Pull to unlock.

Note: These gauges are for indication only and not for measuring operating pressures.

6.2 Automatic Power On Test

Select ventilator mode to **CPAP**.

The ventilator will now carry out a self test as follows.

Power LED shows green and an automatic test of functions & alarms is initialised. Firstly the displays and audible alarms are turned on for approximately two seconds to demonstrate that they are operable, then for a further three seconds all the digital displays show a sequence of numbers from O to 9 before returning to their normal state.

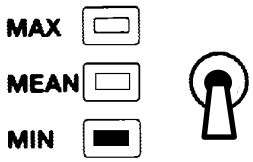
Note: HFO Fail and Block LEDs do not come on during this sequence.

6.3 Setting Alarm Limits

- Set the **High Alarm** to maximum 60 cmH_2O
- Set the **Cycle Fail Alarm** to approximately 28 cmH_2O
- Set the **Low Alarm** to minimum -60 cmH_2O

6.4 CPAP Mode

Set **CPAP/PEEP Regulator** to give 30 cmH_2O on the pressure display with the **pressure display selector** switch in the **MIN** position.



Set **Inspiratory Regulator** to 20 cmH_2O

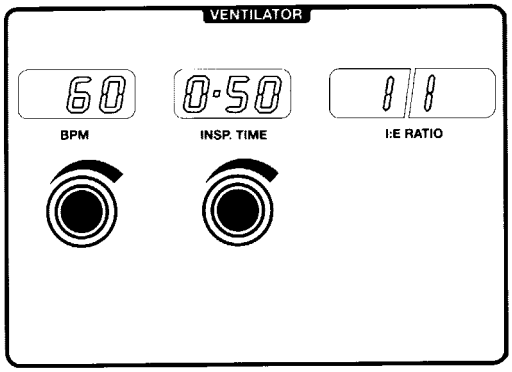
Ensure that:-

- **Bargraph** display reads 30 cmH_2O ± 2 cmH_2O
- **CPAP/PEEP** gauge reads ≈30 cmH_2O
- An Inspiratory cycle is initiated when manual breath button is pressed

Note: Alarm limits will also be shown on the bargraph display.

6.5 CMV Mode

Step 1. Set the following ventilator conditions :-



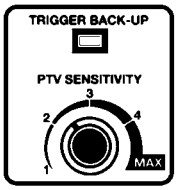
- **CPAP/PEEP** regulator to 0 cmH_2O
- **Inspiratory** regulator to ≈ 30 cmH_2O
- Mode switch to **CMV**
- **BPM** Rate to 60
- **INSP TIME** to 0.50
- **Cycle Fail Alarm** to mid waveform
- Press **Reset** to cancel all alarms

Ensure that :-

- The ventilator is cycling
- I:E Ratio display reading 1:1
- Pressure waveform is shown on graphics display
- Pressure waveform shape changes with operation of **PRESSURE WAVE SWITCH.** (Return the switch to the square wave setting.)

6.6 PTV Mode

Set **BPM** rate to 20
Set the **CPAP/PEEP** regulator to 10 cmH_2O on the gauge
Set the **PTV Sensitivity** to 3
Select **PTV** with mode switch.



Ensure that :-

- Ventilator should continue to cycle
- **BPM** display reading is initially 0
- **TRIGGER BACK-UP LED** is “ON”

Apply slight pressure to test lung and release to simulate patient inspiratory effort.

Ensure that with each operation :-

- The ventilator cycles once.
- The **TRIGGER BACK-UP LED** is “OFF”.

6.7 SIMV Mode

Select **SIMV** with mode switch.

Ensure that:-

- The ventilator continues to cycle.
- The **BPM** display shows set rate.
- The **TRIGGER BACK-UP LED** illuminates on each inspiration.

Apply a varying pressure to test lung to simulate patient breathing.

Ensure that:-

- The ventilator continues to cycle at the set rate but synchronised with the pressure from test lung.
- The **TRIGGER BACK-UP LED** is “OFF”.

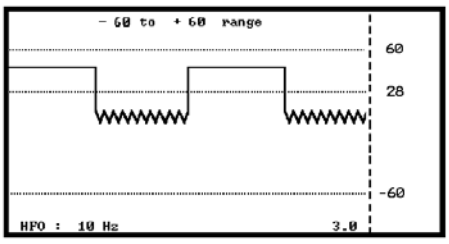
6.8 HFO Modes

Set the following conditions:-

- **CMV** Mode
- **BPM** rate to 30
- **INSP Time** to 1.00
- **Oscillator Regulator** to ≈ 30 cmH_2O
- **Inspiratory Regulator** to ≈ 20 cmH_2O
- HFO Mode to **EXP**
- HFO **Rate** to 10 Hz
- **Display Switch** to 3 seconds
- **Screen Switch** to ±60 cms
- Press **Alarm Mute** Button

Ensure that :-

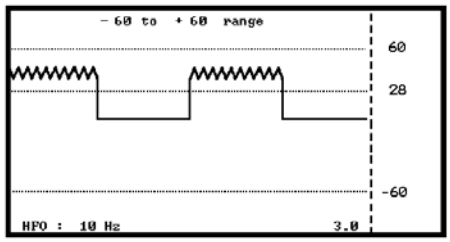
- The ventilator is cycling.
- 10 Hz oscillation shown on expiratory cycle of waveform.



Set HFO mode to **INSP**

Ensure that :-

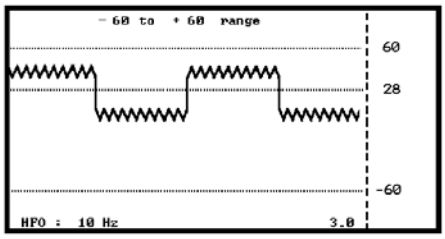
- 10 Hz oscillation shown on inspiratory cycle of waveform.



Set HFO mode to **CONT**

Ensure that :-

- 10 Hz oscillation shown on both inspiratory and expiratory cycles of waveform.

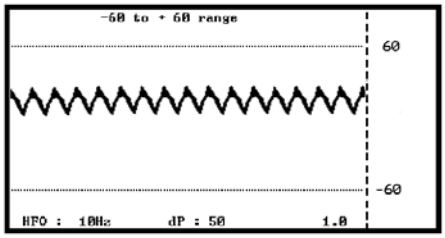


Set mode switch to **CPAP**.

Ensure that :-

- Continuous 10 Hz waveform is seen on the screen.

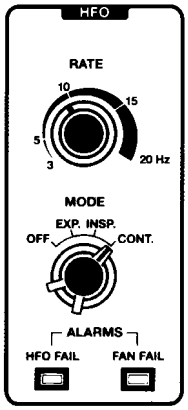
Press the reset button to autoset the alarms.



6.9 Alarm Test

6.9.1 To Verify Alarms

Set the following ventilator conditions :-



- HFO mode **OFF**.
- **CPAP/PEEP** regulator to ≈10 cmH_2O.
- **Inspiratory** regulator to ≈30 cmH_2O.
- **Oscillator Regulator** to 0 cmH_2O
- Mode switch to **CMV**
- **Rate** to 60 BPM
- **INSP. TIME** to 0.50
- Ensure ventilator is cycling and check the following alarms
- Set Cycle fail alarm to mid waveform
- Reset all alarms

6.9.2 High Alarm

Reduce high alarm setting so that alarm cursor line is below the peak pressure wave on the screen. This should initiate an audible alarm and a HIGH and LEAK visual indication. Return alarm setting to maximum position. Reset alarm by the reset button.

Note: The Fresh Gas flow is reduced from ≈ 5 LPM to ≈1 LPM in the High Alarm condition.

6.9.3 Cycle Fail Alarm

Increase the alarm setting so that alarm cursor line is above peak pressure wave on the screen. This will initiate an audible and **CYCLE FAIL** visual alarm indication. Return alarm setting to within the pressure wave, audible alarm should self cancel. Reset visual alarm by the reset button

Decrease the alarm setting so that alarm cursor line is below pressure wave on the screen. This should initiate an audible and **CYCLE FAIL** visual alarm indication. Return alarm setting to within the pressure wave, audible alarm should self cancel. Reset visual alarm by the reset button.

6.9.4 Low Alarm

Increase low alarm setting so that alarm cursor line is above the minimum pressure wave on the screen. This should initiate an audible and **LOW** visual alarm indication. Visual alarms once set can only be cancelled by pressing the reset button. Return alarm setting to required position. Reset visual alarm by the reset button.

6.9.5 Leak/block Alarm

Disconnect the fresh gas tubing from the ventilator. This should initiate an audible and **LEAK** visual alarm indication. Occlude the fresh gas outlet. This should initiate an audible and **BLOCK** visual alarm indication. Reconnect tubing, audible and visual alarms should self reset.

6.9.6 Mains Failure Alarm

DO NOT TURN MODE SWITCH TO OFF).

Disconnect mains power by switching off or removing mains plug from power socket.
This should initiate an audible alarm. Reconnect mains power supply, ventilator should carry out self test and resume previous mode of operation.

6.9.7 O_2 Blender Alarm

Set Blender to 60%. Disconnect Air supply from wall outlet, an audible alarm should be heard from Blender. Reconnect Air Supply, alarm should self cancel. Disconnect O_2 supply, an audible alarm should be heard from blender. Reconnect O_2 supply, alarm should self cancel.

6.9.8 Oxygen Concentration Alarm

Set the Oxygen concentration to 60% and press the reset button. Wait 1minute for the reading to stabilise. Increase the Oxygen concentration to 100%, the alarm should sound. Decrease the Oxygen concentration to 21%, the alarm should cancel as the Oxygen concentration crosses the alarm threshold and then sound again as the Oxygen concentration gets too low. Press Reset.

6.10 O_2 Cell

6.10.1 Condition Of O_2 Cell.

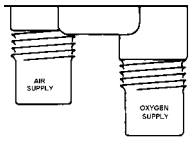
Set blender to 100% and observe that displayed FIO_2 is 100%. Set blender to 21% and observe that displayed FIO_2 is 21%. To adjust, set blender control to 100%. Remove Air Supply Hose and allow 3 minutes before adjusting control on rear panel. If unable to set 100%, O_2 Cell must be replaced. Ignore any blender alarms during this adjustment.

7. Basic Set Up for the SLE 2000 HFO

<u>Warning</u> It is the operator's responsibility to check the ventilator pressures prior to changing modes

The ventilator must not be connected to the patient during this set up procedure.

Step 1. Connect AIR and OXYGEN hoses to ventilator and plug into gas supplies, at a gas pressure of about 4 bar. Connect mains cable to a suitably rated and grounded electrical power source.



Step 2. Connect SLE approved patient circuit to the Ventilator and Humidifier.

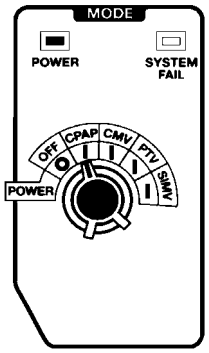
- **For further information see page 47 or instructions supplied with patient circuit.**
- **To test the system the patient manifold must be occluded or a Test Lung fitted.**
- **Only an SLE approved patient circuit should be used with this equipment**

Step 3. Set up humidifier to manufacturer's instructions

Step 4. Set the following ventilator conditions :-

- **High** alarm to maximum
- **Low** alarm to minimum
- HFO mode **OFF**
- Three pressure **regulators** to minimum

Step 5. Select mode of ventilation to CPAP



The ventilator will now carry out a self test as described on page 19. Ensure that this test is completed satisfactorily before continuing.

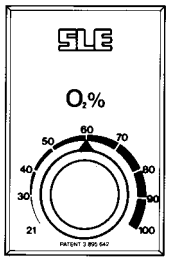
If after completion of the above self test an alarm continues, a red light might indicate either BLOCK or LEAK in the fresh gas tubing of the patient circuit. Ensure that all patient fittings are correctly made and secure.

Do not continue until alarms are cleared

- The ranges of the graphic display can be set using the display controls. A FREEZE button allows the waveform to be held. Press to freeze, press again to un-freeze.

- Do not carry out any adjustments with the display in the freeze mode.

Step 6. (a) Set required O_2 concentration by means of O_2 Blender Control. $\%O_2$ Oxygen will be monitored and displayed in FlO_2 Digital Display.



The oxygen monitor will alarm if the oxygen concentration rises or falls by more than 5% and a warning message will be displayed on the LCD.

The ventilator should now be ready to connect to a patient.

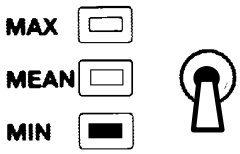
Changes will take 30 seconds to stabilise on the FlO_2 display.

Oxygen - Clinical use. Oxygen is a drug and should be prescribed as such. Exposing a baby to elevated concentrations may lead to Retrolental Fibroplasia.

Oxygen - Fire Hazard. Oxygen vigorously supports combustion and its use requires special precaution to avoid fire hazards. Keep all sources of ignition away when oxygen is in use. Do Not use oil or grease on oxygen fittings or where oxygen is used.

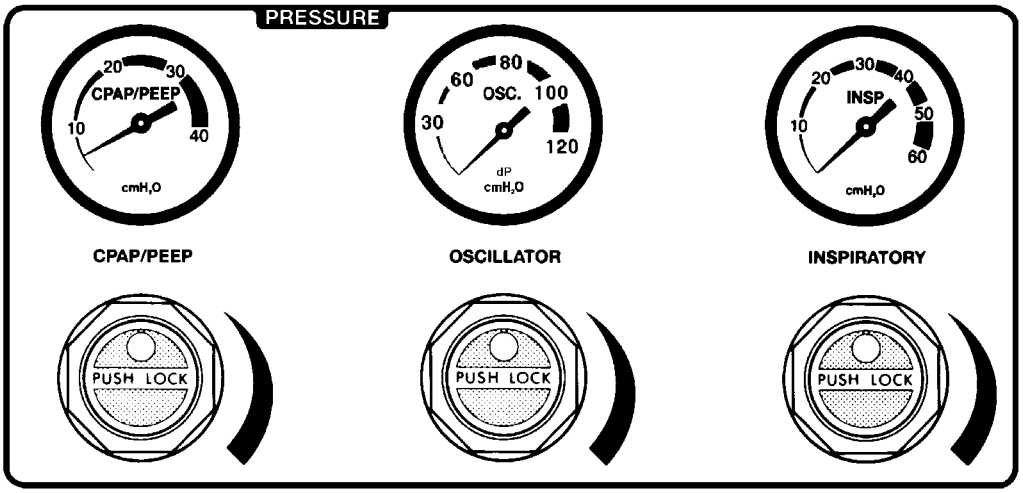
7.1 To Use the SLE 2000 HFO in CPAP Mode

As steps 1 to 6 in basic set-up



Step 7. (a) Set **pressure display switch** to minimum

(b) Increase **CPAP/PEEP** pressure to required level



These Controls are lockable. Push to lock, Pull to unlock.

Pressure will be indicated on the digital display, the graphic display and bargraph.

(c) Set Low alarm to the required level.

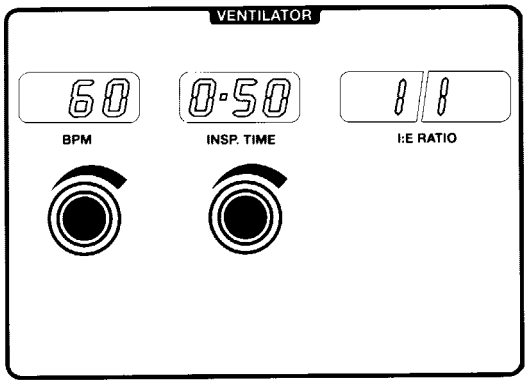
The alarm levels are digitally and pictorially displayed on the graphic display.

A manual breath can be delivered, of the set inspiratory time, by pressing the **Manual Breath Button**.

7.2 To Use the SLE 2000 HFO in CMV Mode

As steps 1 to 7 basic set-up and CPAP then:-

Step 8. (a) Set **INSP. TIME** to required rate (displayed in seconds)



(b) Select Pressure Wave Shape **SQUARE** or **TAPER**

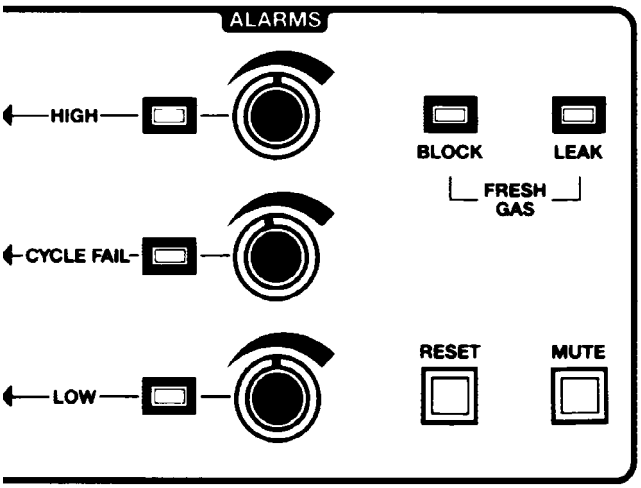
(c) Switch mode switch from **CPAP** to **CMV**

Note: Ventilator will start to cycle and the alarms will probably sound - press MUTE to silence them.

(d) Adjust the **BPM** to required rate.

(e) Set the pressure display switch to **MAX** and increase the **INSP** pressure to the desired level. This is indicated on the digital pressure display, the graphic display and the bargraph.

(f) Set the **CYCLE FAIL** and **HIGH** alarms to required levels. Press **RESET** to clear the alarms lights.



HIGH will activate if setting is exceeded and also open a pressure relief valve and activate **LEAK** alarm

CYCLE FAIL will activate if pressure wave fails to pass through threshold on inspiration and expiration

LOW is activated if pressure falls below setting

7.3 Patient Trigger Modes

7.3.1 To Use SLE 2000 In PTV or SIMV Mode

As steps 1 to 7 then:-

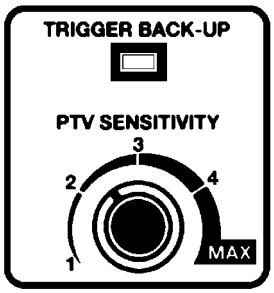
Step 9. (a) Set **PTV** sensitivity to min

(b) Set the **BPM** control to provide either:-

The desired back-up rate for **PTV**

or

The desired number of mandatory breaths per minute for **SIMV**



(c) Switch mode from **CMV** to **PTV** or **SIMV**

Once connected to a patient, increase the **PTV** sensitivity towards **Max** until patient effort triggers the ventilator. This is indicated by the **TRIGGER BACK-UP** light extinguishing.

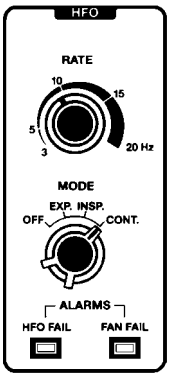
- The weaker the patient the higher the sensitivity required.

After 60 seconds with an update every 60 seconds, the **BPM** LED display will indicate the number of patient initiated breaths that were delivered in the preceding minute.

Care should be taken not to set the PTV sensitivity too high as it will self trigger.

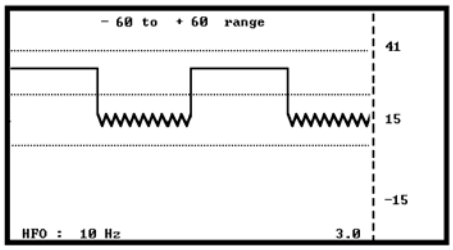
7.4 To Use the SLE 2000 HFO in the Oscillator Mode

THERE ARE 4 OSCILLATORY MODES



1 EXP.

Expiratory oscillation combined with conventional ventilation.



(a) Set ventilator mode to CMV (see page 28)

(b) Set HFO mode to EXP

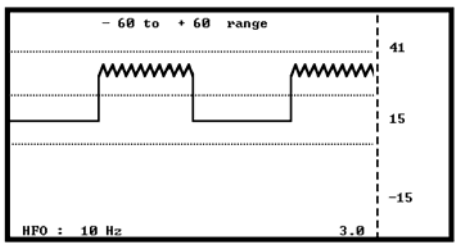
(c) Set HFO frequency using rate control.

(d) Set amplitude using oscillation pressure regulator

- Oscillation is added to the conventional pressure waveform. The frequency of oscillation will be shown on the screen.

2 INSP

Inspiratory oscillation combined with conventional ventilation.



(a) Set ventilator mode to **CMV** (see page 28).

(b) Set HFO mode to **INSP**

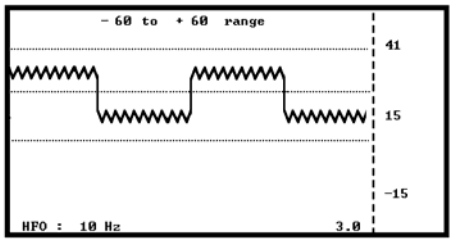
(c) Set HFO frequency using rate control.

(d) Set amplitude using **oscillation pressure regulator**

- Oscillation is added to the conventional pressure waveform. The frequency of will be shown on the screen.

3 CONT. (combined)

Insp+Exp oscillation combined with conventional ventilation.



(a) Set ventilator mode to **CMV** (see page 28)

(b) Set HFO mode to **CONT**

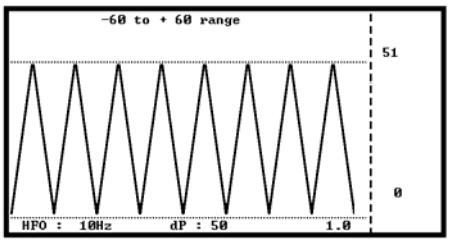
(c) Set HFO frequency using rate control

(d) Set amplitude using **oscillation pressure regulator**

- Oscillation is added to the conventional pressure waveform. The frequency of oscillation will be shown on the screen.

4 CONT. (oscillation only)

Oscillation only



(a) Set ventilator mode to **CPAP** (see page 27)

(b) Set HFO mode to **CONT**

The delta P monitoring system will be activated; see note below

(c) Set the Digital Pressure Display switch to mean

(d) Use CPAP regulator to adjust mean pressure

(e) Set HFO Frequency using rate control and amplitude using oscillation pressure regulator

(f) Reset the delta P alarm level by pressing the reset button twice

Note. The current delta P amplitude pressure (dP in centimetres of water) will be displayed on the LCD The function of this monitor is to alarm if the delta P goes too LOW or display a warning if it goes too HIGH.

The HIGH warning message is **“Delta P rise detected push reset to set new alarm level”**

The LOW alarm message is **“Delta P drop detected check patient connection”** The alarm cursors can be used as well as the pressure displays to check ventilation pressures. It is easier to use the display in the ±60 cms mode for oscillation only.

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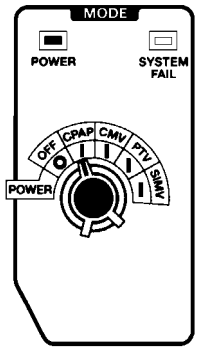
TECHNICAL INFORMATION

8. Ventilator Controls

8.1 Electronic Module



8.1.1 Mode Switch (5 positions)

OFF- CPAP- CMV- PTV- SIMV

- OFF = All electrical power off.

Note: There is a limited fresh gas supply with mode switch in the OFF position, if ventilator is used with Head boxes etc. switch to CPAP.

Switching to CPAP. CMV. PTV or SIMV (power on),

Power LED shows green and an automatic test of functions & alarms is initiated. Firstly the displays and audible alarms are turned on for approximately two seconds to demonstrate that they are operable, then for a further three seconds all the digital displays show a sequence of numbers from O to 9 before returning to their normal state.

Note: HFO Fail, Fan Fail and Block LEDs do not come on during this sequence.

8.1.2 System Fail LED

Lights if main microprocessor system or other electronic circuitry fails (See “Alarms” on page 42.)

8.1.3 CPAP Mode

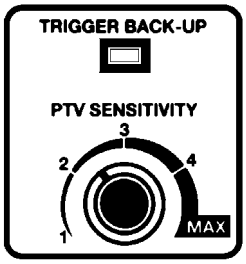
Activates INSP. Time control (for Manual Breath) and digital display, FIO_2, mean and min airway pressure digital displays. Also activated is the Manual Breath push button and associated with it the 'High', 'Low', 'Failure to Cycle' and 'Fresh Gas' alarms. The mean airway pressure in CPAP will show an average of airway pressures.

8.1.4 CMV Mode

Additionally enables the BPM control and INSP. TIME controls to set and display the rate and MIT of the ventilator cycles, and from these settings calculates and displays the I:E ratio.

- If these controls are set outside valid safety limits their respective displays will flash. The position of last control adjusted should be decreased to bring the adjustment to valid safety settings and stop the display from flashing.

8.1.5 PTV Mode



BPM control no longer functions in this mode. The last **BPM** setting in **CMV**, prior to switching to **PTV** will be the back-up rate. (Setting a time window for Apnea). Additionally the **PTV** sensitivity control is activated, all inspiratory efforts at chosen sensitivity should trigger the ventilator.

However, if the sensitivity is set too low, or the patient fails to make an inspiratory effort during the back-up time window, the ventilator will deliver a back-up breath and indicate this by the **TRIGGER BACK UP** LED. If the sensitivity is set too high the ventilator could self trigger at a high rate.

After 60 seconds with an update every 60 seconds, the **BPM** LED display will indicate the number of patient initiated breaths that were delivered in the preceding minute.

In this mode inspiratory times of less than 0.5 seconds are recommended.

- In **PTV** mode the **BPM** display will show only patient initiated breaths. To check back up rate it is necessary to change the mode switch temporarily to **CMV**.

- To enable an audible back-up bleep, hold the **Reset** button in during the automatic test mode on power up**.**

Note: PTV has a default of 12 breaths per minute, if the mode switch is turned straight to PTV mode with out stopping on CMV mode to set the back up breath rate.
This is also the case if there is an interruption to the power supply, the ventilator will also default to this setting. It will be necessary to change the mode switch temporarily to CMV to reset the required BPM.

8.1.6 SIMV Mode.

This mode enables **BPM** control to select and display the maximum number of breaths, triggered or untriggered, to be delivered by the ventilator.

If the patient fails to trigger the ventilator during the first half of the **SIMV** time window, the ventilator will immediately deliver a mandatory breath indicate this with an audible bleep. Any additional spontaneous breaths by the patient will be unsupported by the ventilator.

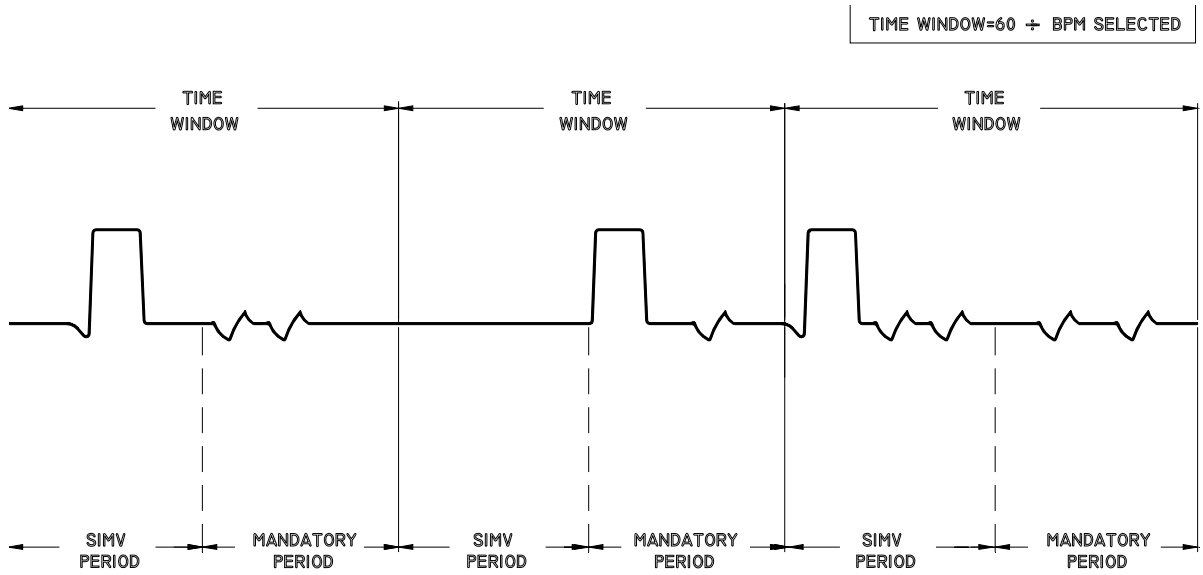
- To enable an audible back-up bleep, hold the **Reset** button in during the automatic test mode on power up.

The SIMV mode of the SLE 2000HFO functions in the following manner:

The BPM control setting will determine the number of breaths that will be supplied in each minute. In the period between each of these breaths a time window is opened. During the first half of this time window, should the patient attempt to make an inspiratory effort the ventilator will deliver a single synchronised mandatory breath. If, however, after the first half of this time window has elapsed the patient has made no detected effort to breathe the ventilator will then supply a single unsynchronised mandatory breath and make a short audible bleep.

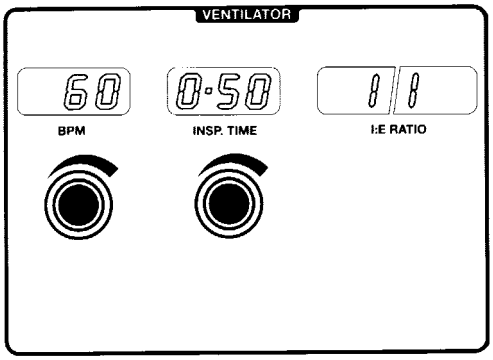
It is possible to disable the audible bleep made on each mandatory breath in the SIMV mode. Whilst switching the ventilator mode switch from the OFF position to SIMV, and during the initial ventilator system check, when the digital displays run the their numerical check, the RESET button is held in. This will disable the audible bleep, until the ventilator is switched OFF again.

The ventilator will only supply one breath during each time period set by the BPM rate. So the total number of breaths delivered either synchronised or mandatory will be only that shown in the BPM display.



If an inspiratory effort is detected during SIMV period, ventilator will deliver a synchronised breath. All further spontaneous breaths during this time window are not assisted.	If patient fails to make an effort during SIMV period, ventilator will deliver a mandatory breath at start of mandatory period, any further efforts during time window are ignored.	Patient triggers breath at start of time window and ventilator will ignore all breaths until this time window has elapsed.

8.1.7 BPM



Ten-turn control with LED digital indication to set the breath rate per minute.

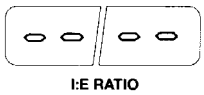
8.1.8 Inspiration Time

Set by ten-turn control with indication on 3 digit LED display showing the set value in seconds.

Invalid settings of the BPM. and INSP. TIME controls are indicated by these two displays flashing. The ventilator will not allow the expiration time to be set to less than 0.25 seconds.

8.1.9 I:E Ratio

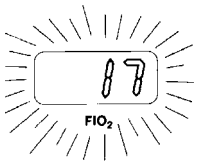
This appears on a four digit LED display and is calculated from the settings of the **BPM** and the **INSP. TIME** controls.



- If the **BPM** and the **INSP TIMES** are set so that the **I:E ratio** exceeds 9.9:1 or 1:9.9, the display will show four dashes. This will also occur in the **PTV Mode.**

8.1.10 Oxygen (FIO_2)

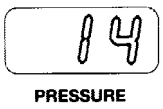
Indication of the oxygen concentration of the Fresh Gas supply to the patient appears on a 3 digit LED display. Should the indication fall below 18% the display will flash. The oxygen monitor will alarm if the oxygen concentration rises or falls by more than 5% and a warning message will be displayed on the LCD.



- Recalibration at 100% O_2 is effected by rear panel screwdriver adjustment. See section 11. on page 46

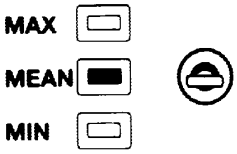
8.1.11 Pressure Display.

Digital LED indication ±65 cm/H_20



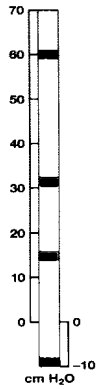
8.1.12 Three Position Switch.

For selecting display of **MAX** (maximum), **MEAN**, or **MIN** (Minimum) airway pressures.



8.1.13 Pressure Display Bargraph.

Shows pressure and selected alarm settings -10 to +70 cms



8.1.14 Pressure Wave Switch

This switch alters the pressure waveform from **SQUARE** to **TAPERED** as indicated.

- This is an Automatic Locking Toggle Switch. Pull toggle lever to release.
- The ventilator should be set to a **square waveform** for breathing rates above 60 **BPM.**

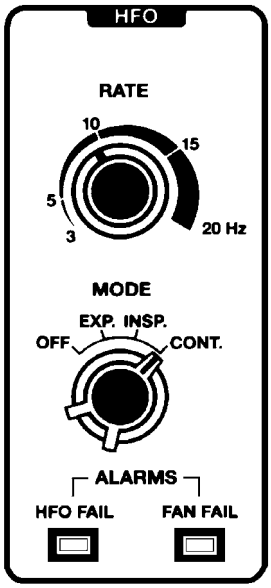
8.1.15 Manual Breath

The manual breath push button functions in the **CPAP**, **CMV** and **PTV** modes, with the **High** pressure and **Failure to Cycle** alarms operative. Manual breath button is inoperative in any **HFO** mode.

Manual Breath

- Manual breath duration = **INSP. TIME** setting

8.1.16 HFO Controls



Mode. Four positions.

OFF - EXP- INSP - CONT

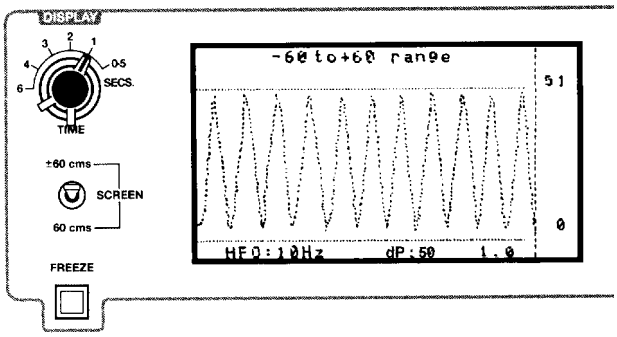
Oscillation is provided on the expiratory, inspiratory and expiratory/inspiratory parts of the pressure wave. Continuous oscillation can also be provided by selecting CONT on the HFO mode control and CPAP on the MODE control.

Rate

Controls the frequency of HFO oscillation in Hertz. Oscillation rate is displayed on the screen.

8.1.17 Time Control Switch

Choice of the time for one complete sweep across the screen. Selectable between 0.5 to 6 seconds in six setting.



Note: In HFO mode, positions 4 to 6 do not have any effect. The display will remain set at 3.

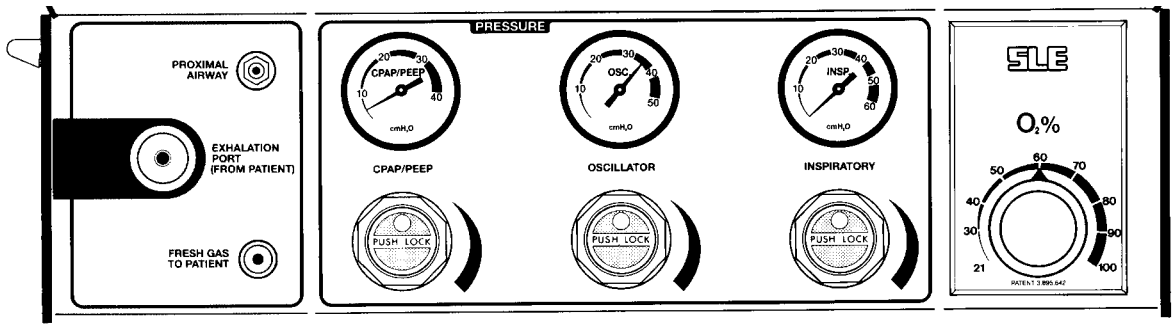
8.1.18 Screen Switch

Controls the range of the screen display between -5 to 60 cms and ± 60 cms.
Use -5 to 60 cms for ventilation or ventilation/oscillation modes.
Use ± 60 cms for oscillation mode only.

8.1.19 Freeze

Will freeze screen for up to 1 minute. Can be reset at any time by pressing the freeze switch again.

8.2 Pneumatic Module



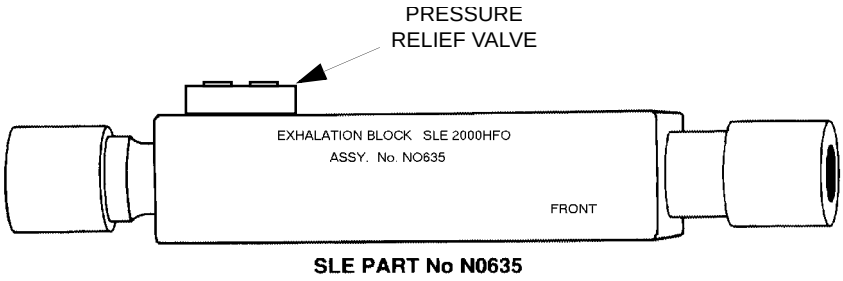
8.2.1 Proximal Airway

Input from patient ET connector to pressure display bargraph and internal pressure transducers.

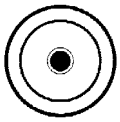
8.2.2 Removable Exhalation Block

Can be removed easily for cleaning by lowering side panel.

.

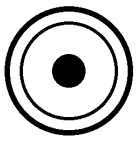


SLE PART No N0635



8.2.3 Fresh Gas Port

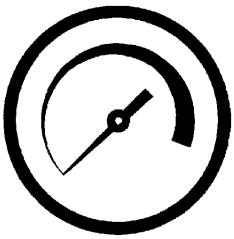
The Fresh Gas port supplies 5 LPM of the blended gas via the humidifier to the patient inspiratory port on the ET connector.



8.2.4 Regulator and Pressure Gauges

8.2.4.1 CPAP

This regulator controls the base pressure in the circuit. In HFO mode this control will be used to set the mean pressure.

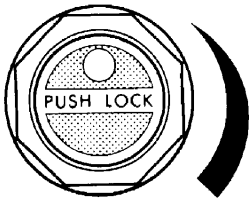


8.2.4.2 Oscillator

This regulator controls the amplitude of the oscillatory pressure.

8.2.4.3 Inspiratory

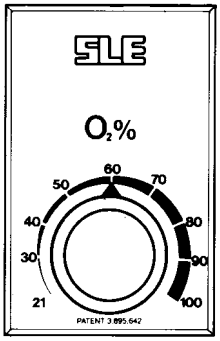
This regulator controls the peak inspiratory pressure (PIP).



These 3 pressure regulator controls have push/pull locking caps.

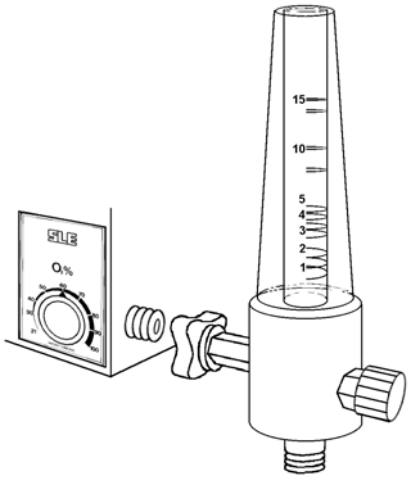
8.2.5 O_2 Blender (% FlO_2)

The oxygen blender controls the amount of oxygen available in the fresh gas supply. The blender is monitored separately by an internal analyser and displayed on the FlO_2 digital display.



There is an option (Option 3) for a blended gas output connected on the side of the unit.

Note: This output provides up to 15 LPM Blended gas controlled by the O_2% control



9. Alarms

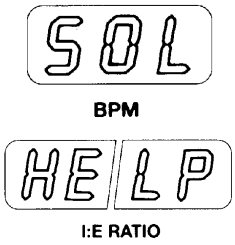
Warning Audible and Visual warning alarms indicate a potentially harmful condition to the patient. Failure to take corrective action could result in injury or death to the patient.

9.0.1 Microprocessor

The microprocessor system failure and other electronic circuitry failures are alarmed as follows.

The microprocessor carries out a self check every 20 mS, and should a failure be detected the **'SYSTEM FAIL'** LED will start to flash and the processor will attempt to reset itself. There is a secondary watchdog alarm independent of the above system which is reset by the main processor every 20 mS. Should the processor fail to reset this watchdog within 3 seconds then a HIGH FREQUENCY alarm will pulse at 2 Hz. This alarm can only be cancelled by switching the ventilator off.

Other hardware system checks are incorporated such as the monitoring of the solenoid driver circuitry. If the solenoid driver fails to operate when the processor has initiated a solenoid valve closure or opening, 'SOL' will appear in the **BPM** display window. All the front panel potentiometers are frequently checked for continuity. If a defect is found then, '**HELP**' appears in the I:E ratio display window and the solenoid is de-energised.



Further checks are made on the processor associated hardware, and again if any fault is detected the solenoid is de-energised and **'HELP'** is displayed in the I:E ratio display window.

9.0.2 Mains Failure Audible Alarm

Active when the mode switch is in any position except **OFF** and will alarm if mains voltage supply fails.

9.0.3 Gas Supply Failure Alarm

The Air and Oxygen audible alarms are an integral part of the blender, and function when AIR or O_2 pressures differ by more than 30 PSI.

9.0.4 Fresh Gas Fail Alarm (Block & Leak)

This fresh gas failure system will detect either a blockage or a leak in the Fresh Gas supply line.To achieve this there is a small restrictor fitted in the inspiratory limb of the patient circuit, creating a pressure in the alarm circuitry to the Electronics Module. Should the Fresh Gas supply to the patient fail, visual and audible alarms will activate. The Fresh Gas **LEAK** LED will illuminate and the audible alarms will operate. This alarm will reset when the gas flow is restored. Similarly the Fresh Gas **BLOCK** LED will illuminate and the alarm will sound, should there be a blockage in the patient gas supply, and a high pressure relief valve will be activated.

9.0.5 HFO Fail

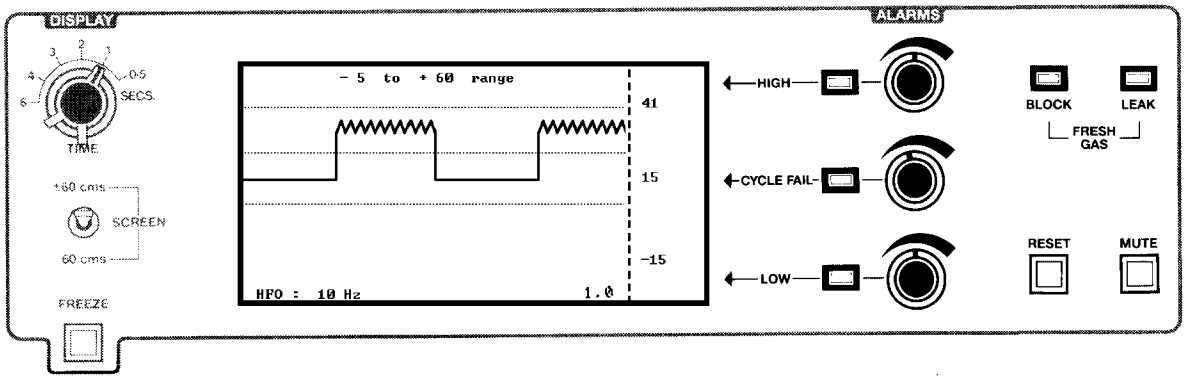
Audible and visual alarm indicating that the oscillator motor has failed therefore cutting off oscillation.

9.0.6 Fan Fail

Audible and visual alarm indicating that there has been a fan failure.

9.0.7 Adjustable Alarm

Three controls on the front panel control the settings for **HIGH, CYCLE FAIL** and **LOW** alarms. Settings are indicated by numeric displays and cursor lines on the screen. They are also shown on the Bargraph Display.



9.0.8 High Alarm

Should the airway pressure exceed the **HIGH** alarm setting, audible and visual alarms will be activated, a system leak will be introduced to vent excessive pressure and the fresh gas supply will be cut off. **HIGH** pressure alarms can only be cleared and fresh gas returned by reducing airway pressure then pressing the **reset** button.

9.0.9 Cycle Fail Alarm

This alarm will be activated should the pressure wave fail to pass through the **CYCLE FAIL** alarm setting on either inspiration or expiration, indicating a drop in airway pressure, a leak or circuit blockage. The audible alarm will reset automatically on correct pressure being restored but the visual alarm must be **RESET** by pressing the reset button.

9.0.10 Low Alarm

Should the circuit pressure fall below the **LOW** alarm setting then an audible and visual alarm will be activated. The audible alarm will reset automatically on correct pressure being restored but the visual alarm must be reset by pressing the **RESET** button.

9.0.11 Delta P Alarm

This alarm will only become operative when the ventilator is in “Oscillation only” mode (see page 31). The alarm is reset when the **RESET** button is pressed twice. It will alarm if the **DELTA P** pressure rises by more than 10% above the level it was when the alarm was set. A warning will be displayed on the LCD if the DELTA P pressure drops by more than 10% below the set level.

9.0.12 O_2 BLender Alarm

This is a mechanical alarm and will sound when the pressure difference between the supply gasses is greater than 30psi, indicating a possible gas supply failure.

9.0.13 Oxygen Alarm

This alarm will sound if the oxygen level changes by 5 percentage points from the level it was 60 seconds after reset was last pressed. A message is displayed on the LCD indicating whether the oxygen level is high or low.

9.0.14 Alarm Mute

This button will mute the audible alarms of **PATIENT GAS FAILURES, CYCLE FAIL, LOW**, and **HIGH PRESSURE** for a period of 60 seconds, but can be reset by the **RESET** push button, providing no alarm condition exists.

9.0.15 Alarm Volume

The main high frequency alarm volume is factory pre set. It is not user adjustable.

9.0.16 Alarm Verification

For the procedure for verifying the alarms (See “Alarm Test” on page 23.)

10. Auxiliary Output

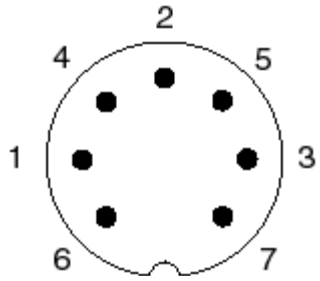
<u>Warning</u> No external voltage should be applied to the auxiliary socket. Any connections to this socket must be approved by SLE and screened to comply with EMC regulations. Ensure protection cap is fitted when socket is not in use.

Analogue signal outputs are available at the rear of the electronics module, on the 7 pin DIN connector Auxiliary O/P.

Buffered airway pressure.	Pin 1	0.42 - 6.42 volts and corresponds to ± 60 cmH_2O
FIO_2	Pin 2	0 - 4.5 volts and corresponds to 0 to 100%
Common ground.	Pin 3	
INOSYS Shut off connection	Pin 4	5V= No Alarm 0V = High alarm condition

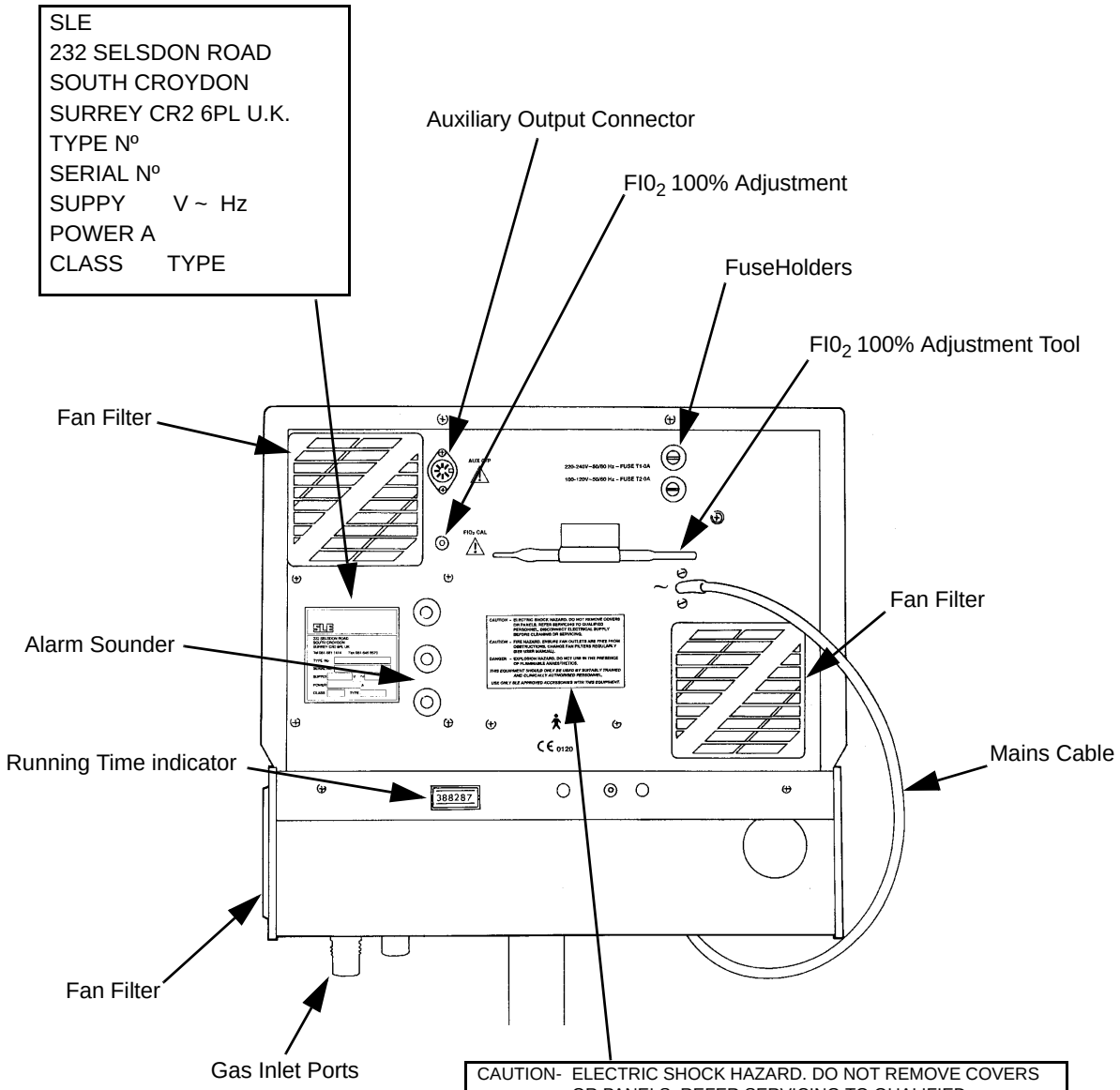
All other pins must be left unconnected.

- Only SLE approved equipment may be connected to this auxiliary output socket.



Pin numbering as viewed from the outside of the Ventilator

11. Rear Panel



CAUTION- ELECTRIC SHOCK HAZARD. DO NOT REMOVE COVERS OR PANELS. REFER SERVICING TO QUALIFIED PERSONNEL.
DISCONNECT ELECTRICAL SUPPLY BEFORE SERVICING

CAUTION- FIRE HAZARD. ENSURE FAN OUTLETS ARE FREE FROM OBSTRUCTION. CHANGE FAN FILTERS REGULARLY (SEE USER MANUAL)

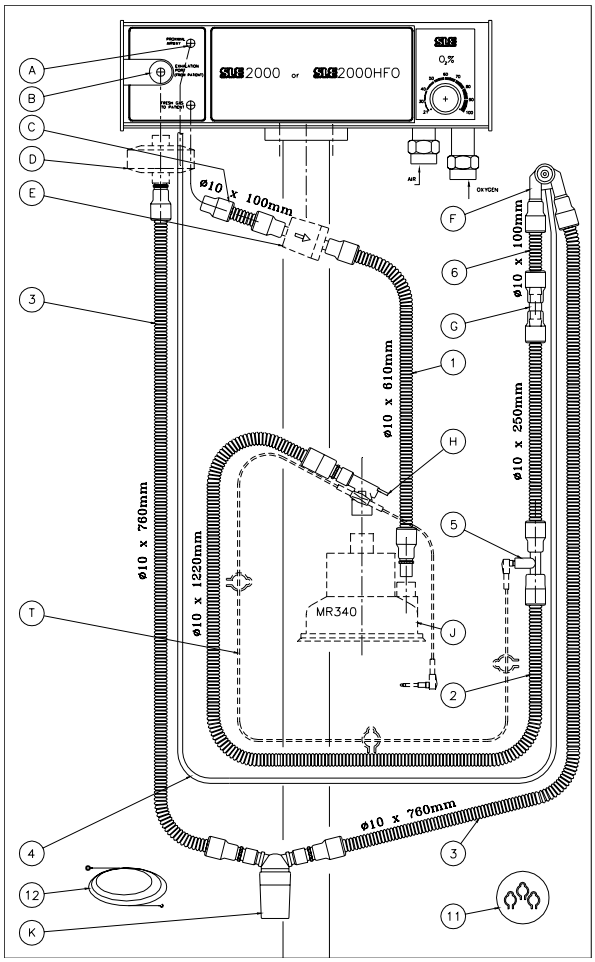
DANGER - EXPLOSION HAZARD. DO NOT USE IN THE PRESENCE OF FLAMMABLE ANAESTHETICS.

THIS EQUIPMENT SHOULD ONLY BE USED BY SUITABLY TRAINED AND CLINICALLY AUTHORISED PERSONNEL.

12. Patient Circuit Connection

RE-USABLE PATIENT CIRCUIT (SLE Part Nº N2391)

This circuit must be clean and sterilised before use. It is designed to be used with an SLE 2000 or SLE2000HFO Infant Ventilator in combination with a Servo controlled humidifier- typically a Fisher and Paykel or equivalent.

Directions For Use	Cautions
Clean and sterilise before and after subsequent use of 7 days maximum. It is recommended that a high quality bacteria filter *(SLE part no. N2029)* is fitted at the fresh gas connection to the humidifier inlet, however the circuit may be used without. Connect the patient circuit as shown in the diagram and described below. Drain water trap regularly by removing the bottom cup. (Circuit pressure is not lost when cup is removed). **1) HUMIDIFIER SUPPLY LINE** If a bacteria filter is being used, fit the short piece of tube ITEM C to the ventilator outlet marked 'Fresh Gas to Patient'. Fit the bacteria filter into this tube. Take the loose length of tube ITEM 1 and connect the free end of this to the bacteria filter and the adaptor end to the humidifier inlet. If a bacteria filter is not being used, connect the loose length of tube ITEM 1 directly between the 'Fresh Gas to Patient' ventilator outlet and the humidifier inlet. **2) INSPIRATORY SUPPLY LINE** Take the main patient circuit and fit the tube with the large connector to the humidifier outlet. Plug the humidifier heated wire supply onto electrical connector ITEM H **3) EXPIRATORY SUPPLY LINE** Take the tube with the connector and fit to the exhalation port of the ventilator. Position water trap in an upright position at the lowest point in the circuit limb. **4) PROXIMAL AIRWAY PRESSURE LINE** Connect the small diameter clear tube from the patient circuit to the proximal airway port on the ventilator. **5) TEMPERATURE MONITORING** Two ports are provided for dual temperature probes, one in the connector on the humidifier outlet (next to the heated wire inlet) and a second port in the tube tee ITEM 5. **STERILISING (Maximum Temperature 134°C)** Dismantle circuit parts and water container for cleaning. Steam autoclave only, at a recommended temperature of 121°C for 20 minutes. Allow 15 minutes dry time and return to ambient temperature before assembly and use. **DIAGRAM INDEX** A Proximal Airway Inlet B Exhalation Port (From Patient) C Ø10 x 100 Tube Assembly Pt Nº.N2998/04 D Single Use Bacteria Filter - Optional Pt Nº.N2187 or N2587 E Autoclavable Bacteria Filter - Optional Pt Nº.N2029 F ET ManifoldPt Nº.N3145 G Red Metal Restrictor Pt Nº.N2266 H Heater Connection - Dual Servo Hose AssyPt Nº.N3510 J Humidifier Chamber - Reference only K Water Trap Pt Nº.N3139 (See Separate Instructions) T Temperature Probe - Reference only 1 Humidifier Supply Line - Ø10 x 610 Tube Assy Pt Nº.N2998/24 2 Inspiratory Supply Line - Ø10 x 250 Pt Nº.N2998/10 & Ø10 x 1220 Pt Nº.N2998/48 3 Expiratory Supply Line - Ø10 x 760 Pt Nº.N2998/30 (x2) + Adaptor No.N3148 (x5) 4 Proximal Airway Pressure Line - i/Ø 1/8" x o/Ø 1/4" x 1830... Pt Nº.N2030 5 Temperature Monitoring - Probe Housing Unit Pt Nº.N3146 6 Inspiratory Supply Line - Ø10 x 100Tube assemblyPt Nº.N2998/04 11 Hose Clips - Secure Temperature Probe Lead Pt Nº. N3049 12 Draw Wire - Tool for Assembly of Heater Wire Pt Nº.N3071	• Make sure that all connections are made properly and are tight before use. • For circuit heating, follow the directions provided with the humidifier • Do not use in applications where gas temperature at outlet of humidifier exceeds 55°C. • Do not cover the circuit with anything which may cause the tube to overheat. • Do not autclave water trap if medications containing chlorinated or aromatic hydrocarbons are used. • Avoid resting the patient circuit against patient skin • Keep water trap upright with cup at bottom. Empty container before water reaches MAX Level Line. • Make sure the drain cup is secure. 

Technical Information

SINGLE USE PATIENT CIRCUIT(SLE Part Nº N2188)

This non-sterile circuit is for single patient use only. It is designed to be used with an SLE2000 or SLE2000HFO Infant Ventilator in combination with a Servo controlled humidifier - typically SLE3000, Fisher and Paykel or equivalent.

DIRECTIONS FOR USE

It is recommended that a high quality bacteria filter (SLE part No. N2029) is fitted at the fresh gas connection to the humidifier inlet, however the circuit may be used without. Connect the patient circuit as shown in the diagram and described below. Drain water trap regularly by removing the bottom cup.
(Circuit pressure is not lost when cup is removed).

1.HUMIDIFIER SUPPLY LINE

If a bacteria filter is being used, fit the very short piece of transparent tube to the ventilator outlet marked “Fresh Gas to Patient”. Fit the bacteria filter into this tube. Take the loose length of blue pipe and connect the small end of this to the bacteria filter and the larger end to the humidifier inlet. If a bacteria filter is not being used, connect the loose length of blue tube directly between the “Fresh Gas to Patient” ventilator outlet and the humidifier inlet.

2. INSPIRATORY SUPPLY LINE

Take the main patient circuit and fit the blue tube with the large connector to the humidifier outlet. Plug the electrical connector into the humidifier heated wire supply.

3. EXPIRATORY SUPPLY LINE

Take the clear tube with the large connector and fit to the exhalation port of the ventilator. Position water trap in an upright position at the lowest point in the circuit limb.

4. PROXIMAL AIRWAY PRESSURE LINE

Connect the small diameter clear tube from the patient circuit to the proximal airway port on the ventilator.

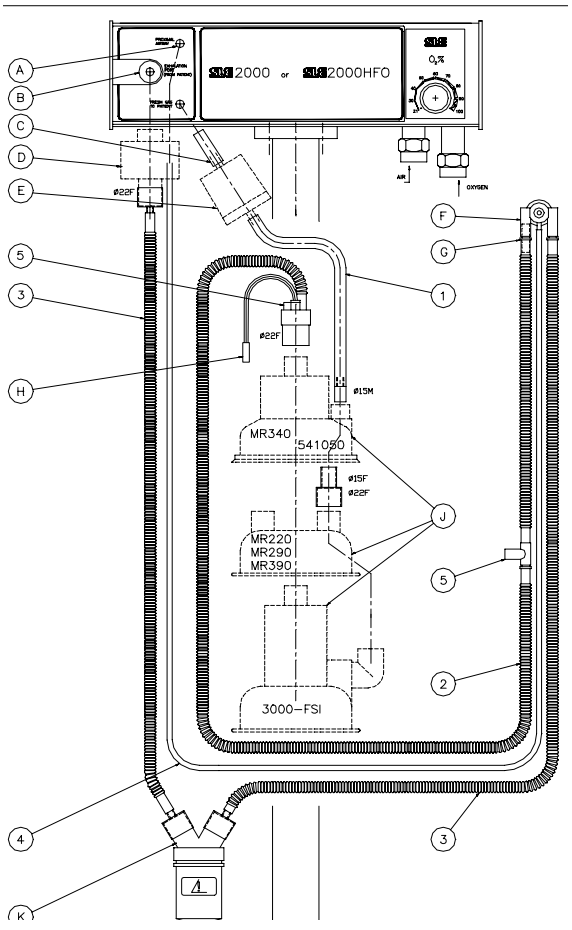
5. TEMPERATURE MONITORING

Two ports are provided for dual temperature probes, one in the connector on the humidifier outlet (next to the heated wire inlet) and a second port in the blue tube close to the ET connector.

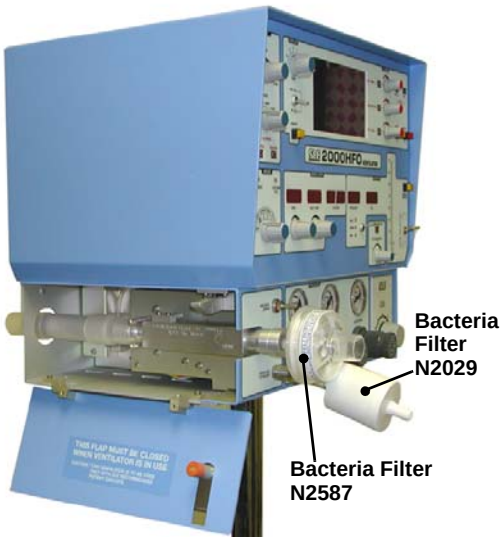
A Proximal Airway
B Exhalation Port (from patient)
C Short Tube
D Single Use Bacteria Filter SLE Part No. N2587 or N2187
E Autoclavable Bacteria Filter SLE Part No. N2029
F ET Manifold
G Red Restrictor
H To Heater Wire Adaptor
J Humidification Chamber
K Water Trap

CAUTIONS

- Make sure that all connections are made properly and are tight before use.
- For circuit heating, follow the directions provided with the
- humidifier
- Do not use in applications where gas temperature at outlet of humidifier exceeds 55oC.
- Do not cover the patient circuit with anything which may cause the tube to overheat.
- Avoid resting the patient circuit against patient skin
- Keep water trap upright with cup at bottom. Make sure the drain cup is secure.



13. Filter Systems



It is recommended that bacteria filters are fitted in the fresh gas supply and on the patient side of the exhalation block.

The filters reduce the possibility of infection to the patient and contamination of the ventilator from secretions or fluids in the breathing circuits that could accidentally enter the ventilators gas ports.

It is recommended that a silencer be fitted on the exhaust side of the exhalation block, this helps to reduce the noise level of the system.

The SLE2000 HFO can be used without bacterial filters in place, but the user must take extra care in not allowing secretions or fluids to enter the ventilators gas ports.

13.1 Bacterial filter, SLE Part Nº:N2029 (Autoclavable)

This autoclavable bacterial filter is fitted into the humidifier supply line and has to be fitted in accordance with the indicator arrow embossed on the surface of the filter.

Do not immerse the filter in any liquid.

Autoclave with pure dry saturated steam at:
134ºC (277ºF) (Allowable variation of temperature of +3ºC) at 220kPa (32psi) with a minimum holding time of 3 minutes

or

121ºC (248ºF) (Allowable variation of temperature of +3ºC) at 96kPa (14.1psi) with a minimum holding time of 15 minutes.

The filter can be autocalved a maximum of 25 times within its anticipated service life of 12 months. For other makes of bacterial filter please refer to manufacturers instructions.

13.2 Bacterial filter, SLE Part Nº:N2587 (Single use)

This single use bacterial filter is fitted onto the exhalation block outlet. This filter should be disposed of in accordance with local hospital authority guidelines. A new filter should be used for every new patient.

13.2.1 Precautions when using bacterial filter N2587

The user should be aware that any occlusion of the filter increases the resistance to airflow, resulting in increased or erratic airway pressures. Airway pressures should be monitored during use and the filter changed if found to be contaminated in any way. When using humidification the filter should be checked regularly for signs of water build up which could cause occlusion.

14. Cleaning, Disinfection and Sterilization

All cleaning, disinfection and sterilizing should be carried out under the direction of the appropriate hospital authority.

DO NOT allow moisture to enter the electronic module or its electrical sockets. Electronic malfunction may result.

DO NOT steam autoclave the SLE 2000 HFO or otherwise subject it to temperatures above 62°C.

DO NOT immerse any part of the SLE 2000 HFO in any liquid, with the exception of the expiratory exhalation block (SLE part No N0635).

14.1 Preparation of a new ventilator

Remove all transit packaging. Inspect the fresh gas port and proximal airway port for any packing material. (Retain packaging for future use as the ventilator must be returned in its original box).

Remove the protective film from the LCD screen.

Clean, disinfect and sterilize in accordance with the instructions in section 14.2 .

Remove the inlet air and O_2 gas port caps. (Retain for future use).

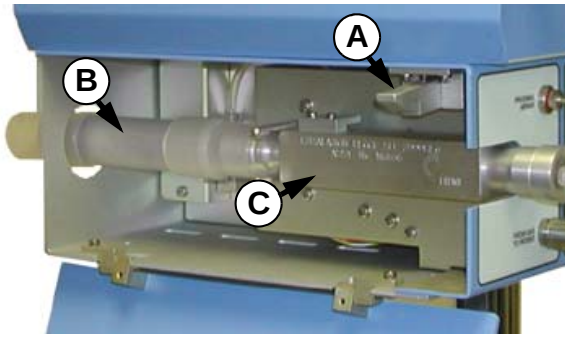
14.2 Cleaning and disinfection of an in-service ventilator

The table 1 outlines the areas of the ventilator which can be uniquely cleaned, disinfected and sterilized.

Before cleaning or disinfecting the exterior of the ventilator the following tasks should be performed:

- The mains cable should be disconnected from the mains supply.
- Remove the patient circuit and bacterial filters. Discard any single use items as per appropriate hospital authority guidelines. Reusable items should be processed as per appropriate hospital authority guidelines and the manufacturers instructions.
- Disconnect the gas supplies from the wall outlets.
- Disconnect the Oxygen and Air hoses from the ventilator and cap the inlet ports.

- Lift up lever (A) on side of ventilator and lower side flap.
- Remove the silencer (B) by pulling it through the hole at the rear.
- Remove the exhalation block (C) by firstly taking hold of the block and then pulling it out towards you without the need for undue force.



Refitting the silencer and exhalation block is the reversal of removal. **Do not force the exhalation block into place.**

14.2.1 Cleaning, Disinfection & Sterilization chart

Item	Clean	Disinfect	Sterilize
Ventilator	**Yes**	**Yes**	
Silencer			**Yes**
Exhalation block	**Yes**	**Yes**	**Yes**

Table 1

Warnings (General): Do not insert any object (such as a needle) in to the gas ports. This action will result in damage to the port. If the user believes there is a foreign object in a gas port, please refer the ventilator to qualified service personnel for inspection and repair.

Note: The silencer should be autoclaved only. If the silencer is found to have visual contamination internally, discard and replace with a new silencer.

14.3 Cleaning method

Note: Cleaning is an essential prerequisite to disinfection and sterilization.

Ventilator. For cleaning use three clean, disposable, absorbent, non-shedding cloths. Wipe clean with the first cloth using a hand hot water/mild general purpose detergent solution (as prescribed by the appropriate hospital authority). Do not overload the cloth with liquid. Remove the water/mild general purpose detergent solution with the second cloth using water only. Do not overload the cloth with liquid. Wipe dry with the remaining cloth. Care should be taken to ensure that the ventilator gas jets in the ports are not blocked by any debris.

Exhalation block. The exhalation block can be immersed and agitated in the detergent solution. Do not insert any objects into the exhalation block. Rinse the exhalation block in clean water, it must be allowed to dry thoroughly before sterilization.

Warning: Ensure that the detergent solution or water does not enter the unit or the exhalation block gas ports on the side of the machine.

14.4 Disinfection method

Note: Alcohols such as 70% isopropanol have a good activity against bacteria and viruses. They should only be used after all visible surface dirt has been removed from the area to be disinfected.

Ventilator. For disinfection use two clean, disposable, absorbent, non-shedding cloths. Wipe clean with the first cloth using Alcohol (70% isopropanol). Wipe dry with the remaining cloth.

Exhalation block. The exhalation block can be immersed in Alcohol (70% isopropanol). The exhalation block must be allowed to dry thoroughly before sterilization.

14.5 Sterilization method

The silencer SLE part Nº N2186 and exhalation block SLE part Nº N0635 must be sterilized between use on patients. The ventilator cannot be sterilized.

The exhalation block must be cleaned as an essential prerequisite to sterilization.

Autoclave with pure dry saturated steam at:

134ºC (277ºF) (Allowable variation of temperature of +3ºC) at 220kPa (32psi) with a minimum holding time of 3 minutes

or

121ºC (248ºF) (Allowable variation of temperature of +3ºC) at 96kPa (14.1psi) with a minimum holding time of 15 minutes.

There is no limit on number of autoclave cycles for the exhalation block.

The silencer can be autoclaved up to 20 times. The body of the silencer should be marked after each autoclave cycle with a high temperature, water proof, permanent maker to indicate number of sterilization cycles completed.

15. Service and Maintenance Programmes

Service or calibration of this ventilator should only be carried out by an SLE trained hospital engineer or an SLE service engineer.

15.1 Maintenance

6 Month Preventative Maintenance

Preventative maintenance should be performed at 6 monthly intervals. This maintenance is intended to be carried out in the hospital.

A service manual is available for use by qualified engineers who have been trained by SLE on this product. Contact SLE or your distributor for further information.

15.2 Overhaul at 10,000 and 20,000 hours

10,000 Hrs. (24 Months) & 20,000 Hrs. (48 Months)

These overhauls must be performed by a SLE trained hospital engineer or a SLE service engineer.

A overhaul and repair manual is available for use by qualified engineers who have been trained by SLE on this product. Contact SLE or your distributor for further information.

16. User Operational Checks

1. **Functional test** as described in section 6. on page 18, should be carried out every time the patient circuit is changed.

2. **Fan Filters** Change all three fan filters every 2000 hours use, or every 6 months. The filters are accessed by pulling the fan covers off.

- Two on the back panel and one on the side panel
- SLE part no M0701/04

3. **Check** the running time meter on the rear of the ventilator to see if preventative maintenance or overhaul is due. Arrange if necessary.

4. It is the users responsibility to ensure that the ventilator is maintained in accordance with the service programme;

Preventative maintenance:- 6 monthly
Overhaul:- 10,000 hours or 24 monthly.

17. SLE 2000 HFO Trouble Shooting Chart

Symptom	Possible Cause	Remedy
Leak Alarm - audible & visual	Incorrect circuit fitted.	Replace with correct circuit P/No. N2188 or variant.
	Damaged circuit fitted.	Replace with new circuit.
	Humidifier chamber.	Replace chamber.
	High alarm condition.	High alarm LED illuminated Reset Insp. pressure and/or adjust High alarm parameter
	Fresh gas supply has decreased.	Consult Service Manual.
	Leak alarm drift	Consult Service Manual.
Block Alarm - audible & visual	Fresh gas filter blocked.	Replace filter.
	Fresh gas restrictor blocked.	Replace circuit.
Blender Alarm - audible when both gases connected.	Alarm shuttle sticking.	Remove both gases from supply and re-connect O_2 first. If this does not work, disconnect and then connect the Air first. Consult SLE trained Engineer if alarm persists.
	Either Air or O_2 gas has failed	Repair gas supply
	Air/O_2 differential pressure exceeded.	Check that the difference in pressure between the two gasses is less then 30 PSI.
	Compressor	Check that performance gauge is within limits. Consult manufacture's User Manual.
High Alarm - audible & visual	Incorrect alarm setting.	Reset alarm parameter or pressure setting.
Cycle Fail Alarm - audible & visual.	Incorrect alarm setting.	Adjust to centre of waveform.
	Proximal Airway line disconnected.	Reconnect tubing.
	Solenoid failure.	Consult Service Manual or SLE trained Engineer.

Symptom	Possible Cause	Remedy
HFO Fail Alarm- audible & visual.	Component failure	Refer to qualified SLE trained Engineer
Fan Fail Alarm - audible & visual.	Component failure	As above.
System Fail - audible & visual.	Component failure	As above.
CPAP Unable to set desired pressure.	Faulty patient circuit. Incorrectly assembled patient circuit. Exhalation block - located incorrectly. Regulator cap is in LOCKED position. Jammed regulator. CPAP nozzle blocked.	Replace circuit. Reassemble as per drawing supplied with circuit. Relocate the block assembly. Pull regulator cap out to release from locked status. Consult SLE trained Engineer. Consult SLE trained Engineer.
PEAK INSP. PRESSURE Unable to set desired pressure.	Faulty patient circuit. Incorrectly assembled patient circuit. Exhalation block - located incorrectly. Regulator cap is in LOCKED position. Jammed regulator. Insp. nozzle blocked. High alarm condition. Water in proximal airway pressure tubing	Replace circuit. Reassemble as per drawing supplied with circuit. Relocate the block assembly. Pull regulator cap out to release from locked status. Consult Service Manual. Consult SLE trained Engineer. Consult SLE trained Engineer. Reset alarm setting. Drain tube

Symptom	Possible Cause	Remedy
OSCILLATION PRESSURE Unable to set desired pressure.	Faulty patient circuit.	Replace circuit.
	Incorrectly assembled patient circuit.	Reassemble as per drawing supplied with circuit.
	Exhalation block - located incorrectly.	Relocate the block assembly.
	Regulator cap is in LOCKED position.	Pull regulator cap out to release from locked status.
	Jammed regulator.	Consult SLE trained Engineer.
	Jet nozzle blocked.	Consult SLE trained Engineer.
	High alarm condition.	Reset alarm setting.
OSCILLATION No Oscillation when expected	HFO Mode Switch off.	Turn to EXP. or CONT.
	HFO Mode Switch in INSP. Mode while Main Mode Switch is in CPAP Mode.	Turn to Mode Switch to correct Mode of ventilation.
NO OSCILLATION WITH ALARMS.		
HFO and CYCLE fail alarms	Motor fail.	Consult SLE trained Engineer.
CYCLE fail alarm	Solenoid failure.	Consult SLE trained Engineer.
HELP message. Displayed in I:E window	System failure	Consult SLE trained Engineer.
SOL message displayed in BPM window.	System failure	Consult SLE trained Engineer.
Waveform has a slow rise time.	Water in proximal airway line.	Replace patient circuit. Consult SLE trained Engineer.

18. Service Programmes

Service or calibration of this ventilator should only be carried out by an SLE trained hospital engineer or an SLE service engineer.

To assist in checking operational use and service periods, the ventilator is fitted with a time elapsed meter. Times should be noted when any service or major component replacement is carried out on individual units.

6 MONTHLY PREVENTATIVE MAINTENANCE

Preventative maintenance should be performed at 6 monthly intervals. This maintenance is intended to be carried out in the hospital. Preventative Maintenance will include:-

- Visual inspection of and cleaning of all exterior surfaces, controls, attachments and accessories.

- Removing the covers and cleaning all dust from interior of the unit.

- Visual inspection of all tubing, electrical wiring, connectors, crimps, screws, nuts, hardware and checking the general condition of all other internal components and assemblies.

- Inspection of the mains failure battery holder for corrosion and replacement of the battery.

- Pneumatic and Electronic testing and where necessary calibration of ventilator.

- A maintenance agreement is available. Contact your distributor for further details.

10,000 Hrs (24 MONTHLY) OVERHAUL

Overhaul should be carried out at a maximum of 10,000 hours operation or every two years of service. This overhaul must be performed by an SLE trained hospital engineer or an SLE service engineer.

In addition to the checks and items performed during the preventative maintenance, an overhaul will include replacement of:-

- Oxygen monitor cell
- Oxygen blender
- Main solenoid SV1
- Oscillator, Inspiratory and CPAP regulators

Checking operation and general condition and replacing where necessary the following components:

- Solenoid valves SV2, SV3, SV4 and SV5
- Tubing and connectors.
- Battery holder.
- Alarm sounders.
- Mode, wave shape, frequency range and pressure range switches.
- Pressure relief valves.
- Oscillator motor & Tacho system.
- Rotating jet

A service manual including circuit diagrams descriptions of operations, parts lists etc., is available for use by qualified engineers who have been trained by SLE on this product. Contact your distributor for further information.

- SLE can offer an exchange service for the complete pneumatic module.

19. Pressure Unit Conversion Constants

	PSI[a]	k Pascal	bar	cmH_2O[b]	mmHg[c]
PSI	1.000	6.8947	6.8947×10^{-2}	70.308	51.715
k Pascal	0.14504	1.000	10.000×10^{-3}	10.1973	7.5006
bar	14.5	100	1.000	1019.73	750.06
cmH_2O	1.42237×10^{-2}	0.09806	9.806×10^{-4}	1.000	0.7355
mmHg	1.9337×10^{-2}	0.13332	1.3332×10^{-3}	1.3595	1.000

For example: To convert PSI to cmH_2O multiply by 70.308

Notes:

a. PSI - pound per square inch
b. at 4 ^oC
c. at 0 ^oC

20. Technical Specification

20.1 Conventional Ventilation

Modes:	CPAP,CMV,PTV,SIMV
BPM Range:	1-150 breaths per minute (1BPM STEPS)
Inspiratory Time:	0.1-3.0 seconds (0.02 SECOND STEPS)
I:E Range :	9.9:1 - 1:9.9 calculated from BPM and Inspiratory time settings.
CPAPPressure:	0 cmH_2O to 35 cmH_2O minimum.
Inspiratory Pressure:	0 cmH_2O to 60 cmH_2O switched fast or slow rise waveforms.

20.2 HFO Ventilation

Modes:	EXP, INSP, CONT (COMBINED), CONT (OSCILLATION)
Frequency Range:	3-20 Hz. (1 Hz resolution.)
Differential Pressure Range:	0 - 90 cmH_2O peak to peak
Mean Airway Range:	0 - 35 cmH_2O.

20.3 Displays

240 × 128 pixel backlit LCD display.	
Selectable pressure range:	-5 to +60 cmH_2O or -60 to +60 cmH_2O
Selectable timebase frame:	6,4,3,2,1,0.5 seconds, showing pressure waveform, LOW, CYCLE FAIL, HIGH alarm settings and HFO rate. Freeze facility.
40 Segment bargraph display:	showing pressure waveform, LOW, CYCLE FAIL, HIGH alarm settings in the range -10 to +70 cmH_2O. (± 2 cmH_2O)
Seven segment LEDs:	showing BPM, INSP. TIME, I:E RATIO, FIO_2 and PRESSURE (max., mean or min ±1cm H_2O).
Indicator LEDs:	MAX., MEAN, MIN. pressures, MUTE, POWER, TRIGGER BACKUP.
Driving Pressure Gauges: (Scaled for resultant airway pressures)	CPAP/PEEP : 0-40 cmH_2O Oscillator : 0-50 cmH_2O Inspiratory : 0-60 cmH_2O

20.4 Controls

Conventional ventilation mode switch:	OFF, ALARM TEST/CPAP, CMV, PTV, SIMV
BPM Control (ten turn):	1 to 150 BPM
INSP. TIME Control (ten turn):	0.10 to 3.00 seconds (min exp time: 0.25 seconds)
Pressure Display Switch:	MAX., MEAN, MIN.
Pressure Display Switch LCD:	-5 to +60 cmH_2O or -60 to +60 cmH_2O
Pressure Wave Switch:	Slow or Fast rise
Manual Breath Pushbutton	
Alarm Mute Pushbutton	Mute active for 60 seconds (approximately)
Reset Pushbutton:	
Display Freeze pushbutton:	Active for 60 seconds (approximately)
Trigger Sensitivity Control:	Range: 2ml / 0.5 sec max. To 10ml / 0.5 sec min. when using SLE N2188 patient circuit.
HIGH, CYCLE FAIL, LOW pressure alarm setting controls:	Resolution : 1 cmH_2O on LCD , 2 cmH_2O on bargraph
Display Timebase selector switch:	6,4,3,2,1,0.5 seconds/frame NOTE: In HFO mode, settings 4 and 6 do not work. The display will remain set at 3.
Inspiratory Pressure and CPAP pressure controls:	
HFO Mode Switch:	OFF, EXP. INSP. and CONT
RATE Control:	3 to 20 Hz
HFO Pressure Control:	0 cmH_2O to ±45 cmH_2O
CPAP Pressure control:	0 to 35 cmH_2O
Air/Oxygen Blender Control	21-100% ± 3%

20.5 Alarms

Audible only:

Loss of mains supply:	Battery powered alarm
Loss of Air or O_2 supply:	Blender alarm.

Audible and Visual:

High Circuit Pressure
Cycle Fail
Low Circuit Pressure
Fresh Gas Block
Fresh Gas Leak Or Total Gas Supply
System Fail
Hfo Fail
Fan Fail.
Oxygen Concentration Alarm

20.6 Air and Oxygen Supplies

The SLE2000 HFO infant ventilator is designed to be use with medical grade compressed air and oxygen.

20.6.1 Oxygen supply

The SLE2000 HFO requires a supply of pure oxygen between 3 to 5 bar.

20.6.2 Air supply

The SLE2000 HFO requires a supply of medical grade compressed air to ISO8573.1 Class 1.4.1 (minimum level of filtration) between 3 to 5 bar. Recommended level of filtration is class 1.1.1.

Description of Class 1.4.1
1= particle size of 0.1 microns. 4 = Pressure dewpoint of +3ºC . 1= oil content 0.01Mg/m3

Description of Class 1.1.1
1= particle size of 0.1 microns. 1 = Pressure dewpoint of -70ºC . 1= oil content 0.01Mg/m3

20.7 Power , Dimensions etc.

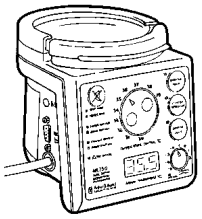
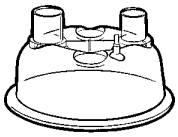
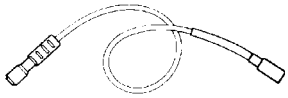
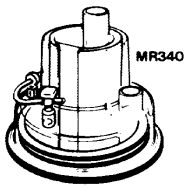
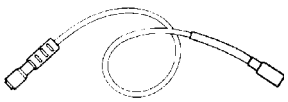
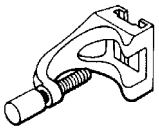
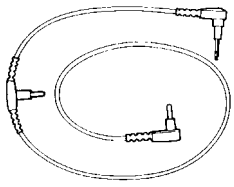
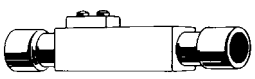
Voltage :	100-250V/ 50-60 Hz
Power :	120 VA
Fuses :	220-250V~50-60 Hz : Fuse T 1.0A 100-120V~50-60 Hz : Fuse T 2.0A
Operating Environment:	Temp: 10-40°C Humidity: 0-90% (non condensing)
Size, Ventilator only :	37 cms W × 39 cms H × 32 cms D
Height on pole:	141 cms
Weight Ventilator Only:	16 Kgs
Complies with:	IEC 601-1 and 601-2-12 1988 BS 5724 Part 1 and section 2.12.1990
Patient Circuit Required:	Model : N2188 Single use Model : N2200 Re-usable

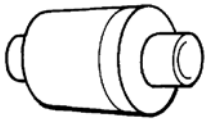
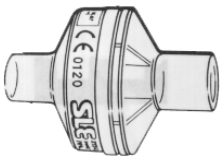
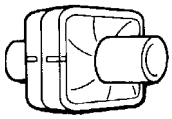
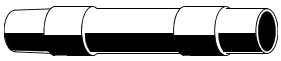
20.8 Environmental Storage Conditions

When packed for transport or storage;

Ambient Temperature :	-40°C to +70°C
Relative Humidity :	10% to 90% non condensing
Atmospheric Pressure :	500hPa to 1060hPa

21. Consumables and Accessories for SLE 2000 HFO

MR700 Heater Base usable with all appropriate items listed below N3700/01 (230V) N3700/02 (100V) N3700/03 (115V)	
N3220 -MR220 **Single use chamber** (Box of 50) for use with above	
N2188 - Standard Single use Patient Circuits for use with above (Box of 30) Other configurations available	
N3557 MR557 Heater Adapter for use with above **single use** patient circuits & chambers	
N3340 -MR340 **Re-usable chamber** for use with above	
N2391 - Re-Usable Patient Circuit for use with above	
N3558 MR558 Heater Adapter for use with above **re-usable** patient circuits & chambers	
N3170 MR170 Pole Clamp for MR700 heater base	
N3560 MR560 Dual Temperature Probe	
N0635 Spare exhalation Block	

N2029 Bacteria filter (autoclavable)	
N2587 Bacteria filter (single use) Inlet :22mm (male) Outlet 22mm (female)	
N2187 Bacteria filter (single use) Inlet:15mm (female) or 22mm (male) Outlet: 22mm (female) Tapered Connections	
N2035 O_2 (complete) 4 metres length	
N2199 Air hose, 4 bar (complete) 4 metres length	
N2186 Silencer (fitted to rear of exhalation block)	
N2006/00 User Manual for SLE 2000 HFO	
N2005/00 Service Manual for SLE 2000 HFO	
N2004/01 User Manual for SLE 2000 HFO on CD-ROM	
N2004 Service Manual for SLE 2000 HFO on CD-ROM	

22. Ordering Information for the SLE2000 HFO

SLE 2000 HFO Z2540* *(without humidifier)*	(3 single use Patient Circuits included for user start up).
SLE 2000 HFO Z2541* *(with humidifier)*	Stand mounted Ventilator, Air and Oxygen hoses & manual.
SLE 2000 HFO Z2542* *(without humidifier)*	
SLE 2000 HFO Z2543* *(with humidifier)*	As above but for shelf mounting.

*State voltage required.

22.0.1 Options**

Option 1 ref. N2200	Reusable circuit start-up kit (Part No. N2200).
Option 3 ref. Z0003	Auxiliary 0-15 LPM Blended Output.

**State operation required.

22.0.2 Air Compressors

AD 3600, ref. L0035	Suitable for 1 Ventilator
AD 2000, ref. L0030	Suitable for 2 Ventilators

23. Technical Bulletins

Listed below are all the technical bulletins that are relevant to the SLE2000 HFO infant ventilator.

TB 990603:	Removal of hour counter from electrical chassis.
TB 000201:	New versions of control software.
TB 000601:	New versions of control software (V1.12).
TB 010201:	New operational warnings.
TB 040401:	V0226 potentiometer design change

Any of the above technical bulletins can be obtained by contacting the SLE Service Department.

SLE reserves the right to make changes without prior notice in equipment, publications and prices as may be deemed necessary or desirable.

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