SLE 2000

Ventilator

User manual

Infant Ventilator

CE 0120

Issue
9

Contact Information:

SLE Limited
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey CR2 6PL

Telephone: **+44 (0)20 8681 1414**

Fax: **+44 (0)20 8649 8570**

E-mail: **admin@sle.co.uk** (E-mail's should be addressed to the Service Manager)

Web site: **www.sle.co.uk**

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SLE Part Nº: **N2000/11**

Contents

Operating Instructions

Technical Information

How to use the SLE2000

NOTE THE WARNINGS (PAGE 10) MUST BE READ AND UNDERSTOOD BEFORE USING THE SLE2000 VENTILATOR. FAILURE TO DO SO COULD LEAD TO INJURY OR DEATH

1 PERFORM THE FUNCTIONAL TESTS : PAGE 19

(THIS SHOULD TAKE NO MORE THAN 20 MINUTES)

2 SETUP THE SLE2000 IN THE CHOSEN MODE: PAGE 26

3 THE SLE2000 IS READY FOR USE

FOR MORE INFORMATION SEE TECHNICAL SECTION PAGE 32

FOR TROUBLE SHOOTING SEE TROUBLESHOOTING CHART PAGE 51

1. Introduction

The SLE2000 is a constant flow, time cycle, and pressure limited neonatal ventilator with patient triggering.

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

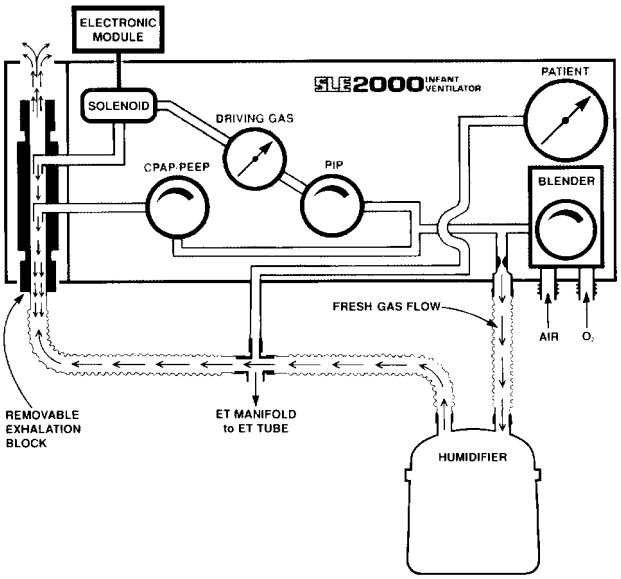
The advantage of this system is that there is no expiratory resistance due to valves or diaphragms, therefore no inadvertent PEEP is generated.

2. Principles of Operation SLE2000 Valveless System*

The patient circuit is supplied with a constant fixed flow of 5LPM fresh gas. This gas comes from the internally mounted oxygen blender and its concentration is also 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. The patient circuit requires a restrictor fitted into the inspiritory port. Therefore, only SLE approved patient circuits must be used.

The Expiratory limb of the patient circuit is connected to the Exhalation port on the ventilator. This consists of a removable block mounted on a manifold, accessed by lowering the left hand side cover. The expiratory manifold has two nozzles. The front one to generate CPAP/PEEP and is supplied via the CPAP regulator on the front panel of the Pneumatic Module. The rear one to generate peak inspiratory pressure(PIP).

To avoid the possibility of gas dilution these regulators are supplied with the same oxygen concentration as the Fresh Gas supply . The front nozzle is used to generate an opposing flow to the Fresh Gas in the exhalation block and thus create CPAP The rear nozzle is used to generate the peak inspiratory pressure in the same way, supplying constant pressures at all breathing rates.



The PIP regulator and gauge on the front panel set the pressure that is supplied to a solenoid valve which is connected to the rear nozzle.
The Electronic Module controls the rate and duration of the flow of Driving Gas into the Exhalation block in opposition to the Fresh Gas flow. This opposing flow acts as a pneumatic piston and creates a pressure wave at the ET manifold. The lung inflation pressure and hence the tidal volume are controlled by the PIP regulator.

NOTE: The ventilator should be set to a square waveform for breathing rates above 60 BPM

*** The Valveless Ventilation Principle was designed and patented by Prof. J G Whitwam and Mr. M. K. Chakrabarti of the R.P.G.M.S Hammersmith Hospital.**
This patent is exclusively licensed to SLE

THE EQUIPMENT IS HOUSED IN TWO MODULES, PNEUMATIC AND ELECTRONIC, THESE CAN BE UNCOUPLED FOR EASE OF SERVICE.

3. User/Owner Responsibility

This SLE 2000 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.

4. Warnings

4.1 Operational Warnings

The following warnings must be read and understood before using the SLE2000 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. Operators must be suitably trained and clinically authorised for using the SLE2000 with patients. Particular care should be taken to check the ventilator pressures prior to changing modes.

2 It is recommended that the back panel BPM range key switch is removed during use.

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

4 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.

5 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.**

6 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.

7 The ventilator functional tests must be carried out each time the SLE 2000 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.

8 The humidifier used in the patient circuit must be operated and maintained in accordance with its manufacturer's instructions. It is the owners responsibility to ensure that the equipment is regularly maintained. (See service programme on page 54)

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

10 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. (See service programme on page 54)

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

12 The Ventilator must be plugged into a suitably rated and grounded electrical power source.

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

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

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

16 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.

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

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

19 When using nebulizers and other delivery systems e.g. NO with the ventilator in High Alarm or gas leak condition, the patient can receive inaccurate mixtures.

20 If the SLE 2000 Infant Ventilator is adversely affected by equipment emitting electromagnetic interference then that equipment should be switched off or removed from the vicinity of the 2000. Conversely, if the 2000 is the source of such interference to neighbouring equipment then it should be switched off or taken to another location.

4.2 Clinical Warnings

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

There are risks inherent in the use 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 retum, hypotension, tachycardia, bradycardia, reduced cardiac output, excessive variability of blood pressure).

10 Mobilisation of secretions and airway blockage.

11 Exposing a baby to elevated concetrations of Oxygen may lead to Retrolental Fibroplasia. (Retinopathy of prematurity)

The minimum patient monitoring requirements for Ventilation are:

1 ECG/heart rate.

2 Chest wall movement.

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

4 Transcutaneous carbon dioxide/intravascular carbon dioxide/regular, intermittent arterial/capillary samples.

5 Regular arterial and transcutaneous blood gas monitoring.

6 Regular chest X-rays.

7 Regular cranial ultrasound examinations.

8 Standard nursing care for Intensive Care patients.

5. Glossary of Abbreviations Used in This Manual

bar	Unit of Pressure	**LED**	Light Emitting Diode
BPM	Breaths Per Minute	**LF**	Low Frequency
cm	Centimetre	**LPM**	Litres per Minute
cms	Centimetres	**MIT**	Maximum Inspiratory Time
cmH_2O	Centimetres of Water	**ml**	Millilitres
CMV	Controlled Mechanical Ventilation	**ms**	Millisecond
CPAP	Continuous Positive Airway Pressure	**O_2**	Oxygen
°C	Degrees Celsius	**PTV**	Patient Triggered Ventilation
°F	Degrees Fahrenheit	**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
I:E	Inspiratory : Expiratory Ratio	**tcPCO_2**	Transcutaneous Carbon Dioxide
Insp.	Inspiration Time	**tcPO_2**	Transcutaneous Oxygen
Kg	Kilogram	≈	Approximately equal to

6. 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)**

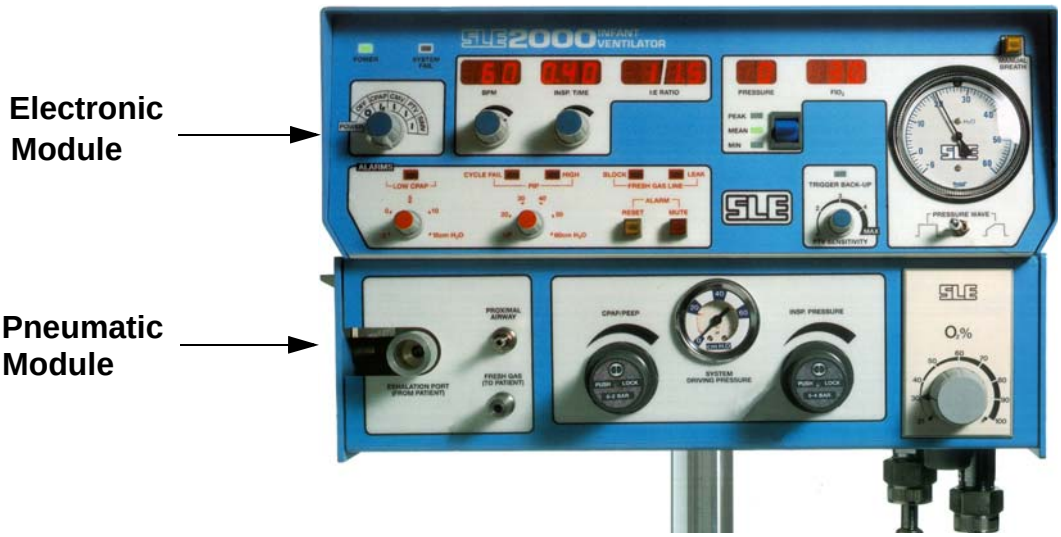
O **Off (power: disconnected from the mains)**

Rotate: clockwise to increase, anticlockwise to decrease

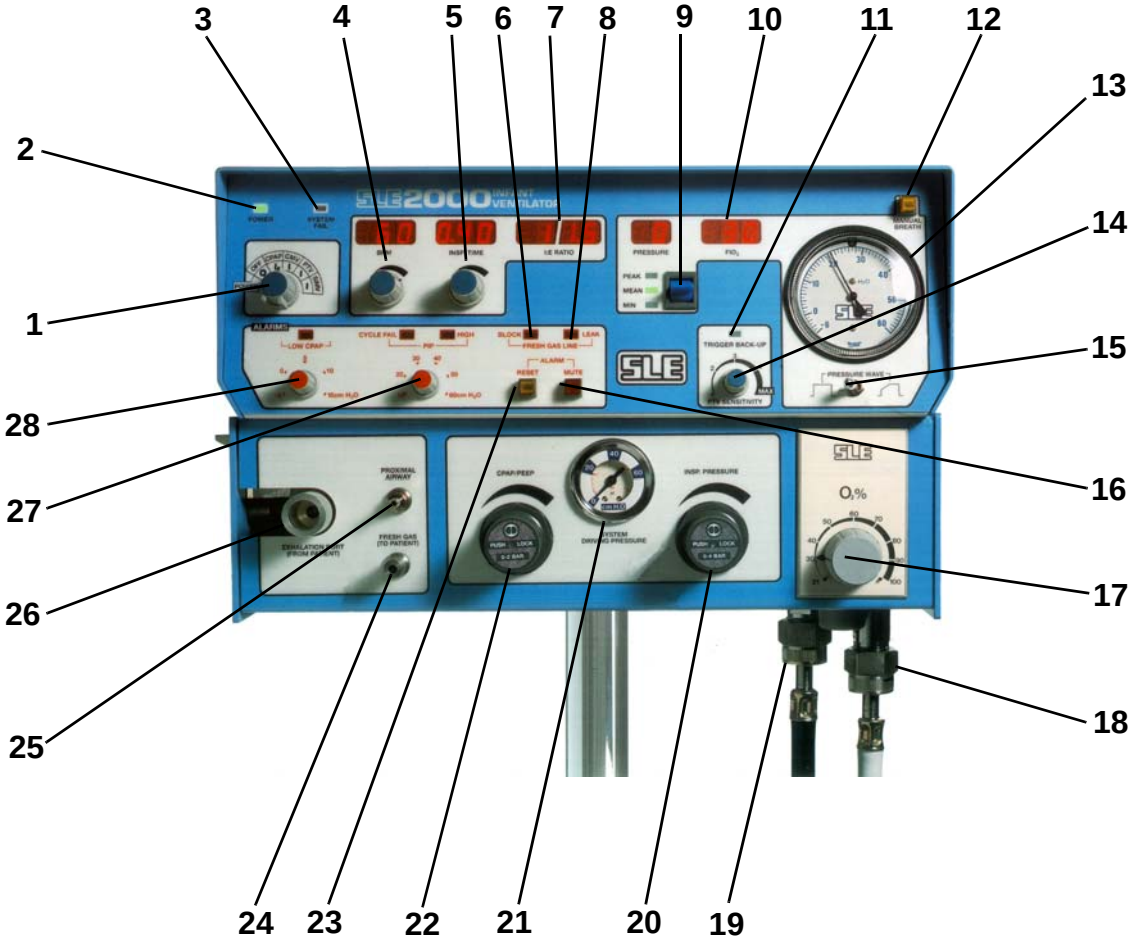
OPERATING INSTRUCTIONS

7. Ventilator Description

The SLE 2000 consists of two linked modules, Electronic and Pneumatic.



7.1 Front Panel



7.2 Function of Front Panel Controls and Indicators

Nº	Item	Description
1	POWER and OPERATIONAL MODE Switch	Selects Power OFF, ALARM TEST/CPAP, CMV, PTV, SIMV modes.
2	POWER LED	Indicates power is 'ON'.
3	SYSTEM FAIL LED	When this LED lights and the alarm sounds, it indicates failure of the main processor. If this happens, the ventilator must be removed from service.
4	BPM digital display with adjustment knob	Displays between 1-250 BPM. Available in two ranges: 1-125 BPM& 126-250 BPM, selectable by rear security key switch
5	INSP. TIME digital display with adjustment knob	Inspiratory Time Displays 0.1-3.0 seconds in 1-125 BPM range or 0.01-0.3 seconds in 126-250 BPM range.
6	FRESH GAS BLOCK audible alarm.	Indicates problems within the patient circuit line.
7	I:E RATIO digital display	Displays from 9.9:1 to 1:9.9 calculated from BPM and Insp. time
8	LEAK LED's audible alarm.	Indicates problems within the patient circuit line.
9	MAX MEAN MIN switch with digital PRESSURE display	Selects and displays Max., Mean or Min airway pressures.
10	FIO_2 digital display	Accurately displays the % O_2 as set by the Air-Oxygen Blender.
11	TRIGGER BACK-UP LED	Indicates a machine-delivered breath due to patient failure to trigger ventilate or during back-up time window.
12	MANUAL BREATH Pushbutton	Causes delivery of a single breath in CPAP, CMV and PTV modes to preset inspiration times and pressures.
13	Pressure Gauge -6 to +60 cmH_2O.	Proximal Airway Pressure. This pressure is displayed more accurately by the independent digital display.
14	PTV SENSITIVITY control	Variable patient trigger level setting. Sensitivity between 1(least sensitive to patient effort) and 5 (most sensitive to patient effort).

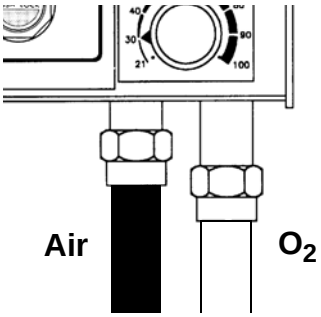
Nº	Item	Description
15	PRESSURE WAVE switch	Permits change of leading edge of pressure wave from square to taper in 1-125 BPM range only.
16	ALARM MUTE Pushbutton and LED	Mutes audible alarms for one minute.
17	AIR OXYGEN BLENDER control	Sets air/oxygen mix between 21 and 100% 0_2 ± 3% with digital indication from independent monitoring circuits.
18	O_2 inlet	O_2 hose connector.
19	Medical air inlet	Medical air hose connector.
20	Inspiratory Pressure Regulator	Adjusts driving pressure to set circuit inspiratory pressure. Range 0-60 cmH_2O.
21	SYSTEM DRIVING PRESSURE gauge	Approximate indication of the pressure above PEEP which will be delivered to the patient in CMV, PTV, SIMV or manual breath modes.
22	CPAP/PEEP regulator	Sets CPAP level in the circuit, range is 0 to 15 cmH_2O (nominal).
23	ALARM RESET Pushbutton	Resets audible and visual alarms.
24	Fresh Gas Port	5LPM blended gas supply to patient (ventilator powered up). 1LPM blended gas supply to patient (ventilator OFF)
25	Proximal airway	Proximal airway tube connector.
26	Exhalation block	Connection for expiratory limb of patient circuit.
27	PIP, CYCLE FAIL and HIGH alarm LED's with control	Sets visual and audible alarm level for inspiratory pressure between 0 and 60 cmH_2O.
28	CPAP Alarm LED and control	Sets visual and audible alarm level for CPAP pressure.

8. 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 **Power** switch set to **OFF** carry out the following steps.

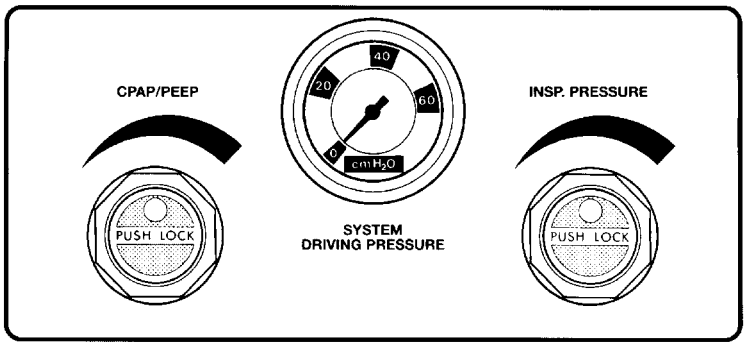


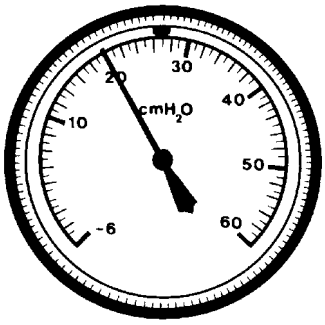
- Connect AIR, OXYGEN Hoses to ventilator and plug into gas supplies, at a gas pressure of about 4 bar.
- Connect mains cable to a suitably rated and grounded electrical power source.
- Connect SLE approved patient circuit with test lung to the ventilator. For further information see page 44 or instructions supplied with patient circuit.

8.1 Pressure Regulators and Gauges

Check the **CPAP/PEEP** regulator, by turning the control from minimum to maximum making sure the large gauge reads between 0 and greater than 15. Check the **INSPIRATORY** regulator, by turning the control from minimum to maximum and making sure that the system driving pressure gauge reads between minimum and maximum, this gauge is for indication only and not for measuring operating pressures. Return regulators to minimum.

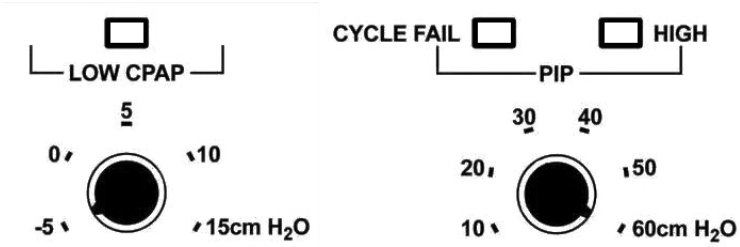
•Regulator Controls are lockable. Push to lock, Pull to unlock.





8.2 Pre-setting alarm limits

- Set the **CPAP alarm** control to **-5 cmH_2O** and the **PIP alarm** control to **60 cmH_2O**



8.3 Power On Automatic Test

- Set ventilator mode switch to **CPAP**.

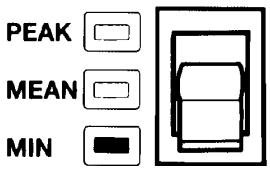
The ventilator will now carry out a self test as follows.

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: Block LED does not come on during this sequence.

8.4 Pressure Display

- Set **CPAP/PEEP** regulator to give 10 cmH_2O on the pressure display with the **pressure display selector** switch in the **MIN** position.
- Set the INSP pressure to 40 cmH_2O
- Set the INSP Time to 0.5min

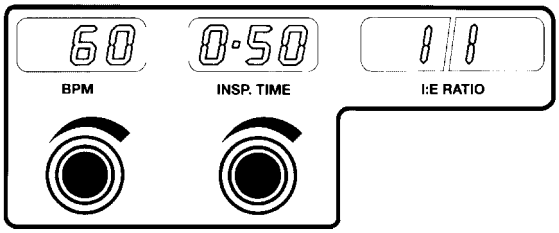


Ensure that :-

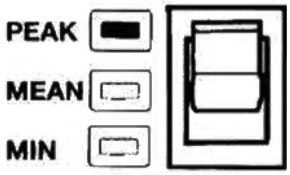
- **LED Pressure** display reads 10 cmH_2O ± 2 cmH_2O
- **CPAP/PEEP** gauge reads ≈10 cmH_2O
- Inspiratory cycle is initiated when manual breath button is pressed. (The pressure display will read 50 cmH_2O and then return to 10cmH_2O)

Press reset to cancel the cycle fail alarm.

8.5 CMV Mode



- Set the following ventilator conditions :-
- **CPAP/PEEP** regulator to 10 cmH_2O
- Re-set **Inspiratory** regulator to ≈30 cmH_2O



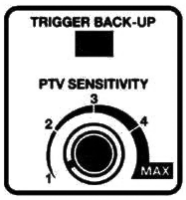
- Set the Pressure display switch to **PEAK**
- Set **PIP alarm control** to 40 cm H_2O
- Advance the mode switch to **CMV**
- Set the **BPM** Rate to 60
- Set the **INSP TIME** to 0.50

Ensure that :-

- The ventilator is cycling
- I:E Ratio display reading 1:1
- With the pressure switch check that the mean reads approximately 20 and the peak reads approximately 40 on the LED.

8.6 PTV Mode

- Set **BPM** rate to **20** in **CMV** mode
- Advance the mode switch to **PTV**
- Set the **PTV Sensitivity** control to **1**

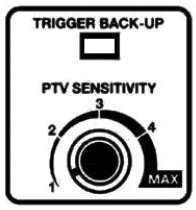


Ensure that :-

- 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”.



Note: It may be necessary to adjust the PTV sensitivity to achieve correct operation.

Note: The BPM display will show patient effort detected each minute

8.7 SIMV Mode

◆ Advance the mode switch to **SIMV**

Ensure that :-

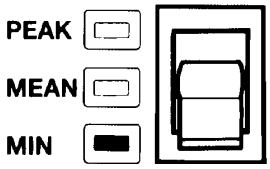
- The ventilator continues to cycle.
- The **BPM** display shows set rate.

◆ Gently squeeze and release the 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.

◆ Set **Pressure Display Selector** switch in the **Min** position.

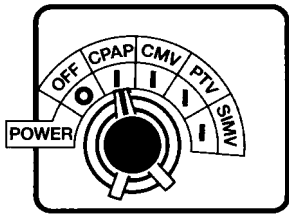


8.8 Alarm Test

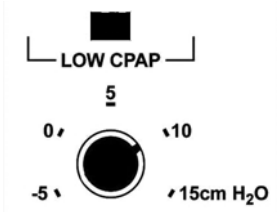
8.8.1 Low CPAP

Set the following ventilator conditions :-

- Return the mode switch to **CPAP.**
- Set the **CPAP/PEEP** regulator to ≈5 cmH_2O.

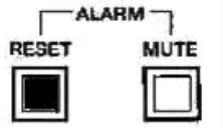


- Increase the **Low CPAP** alarm control to 10 cmH_2O. The Low CPAP alarm will sound and the LED in the alarm panel will illumuniate.



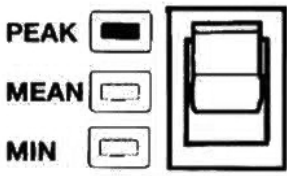
- Reset the **Low CPAP** alarm control below 5 cmH_2O. The Low CPAP audible alarm will cancel but the LED in the alarm panel will remain illumuniated.

- Press the reset button to cancel the visual alarm.



8.8.2 High and Cycle Fail Alarm

- Set the **PIP** alarm control to 30 cmH_2O.
- Set the Pressure display switch to **PEAK**
- Advance the mode switch to **CMV**

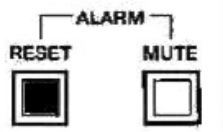


The ventilator will start to cycle

- Adjust the Inspiratory pressure regulator to give a pressure of 30 cmH_2O on the pressure LED display.

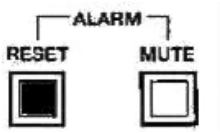
The ventilator is ready for the High and Cycle Fail Alarm tests

- Decrease the PIP alarm control to 20 cmH_2O. This will trigger the **HIGH** visual and audible alarm and the **LEAK** visual alarm
- Increase the PIP alarm control to 30 cmH_2O. The **HIGH** visual and audible alarm and the **LEAK** visual alarm will continue
- Press the reset button to cancel the alarms.

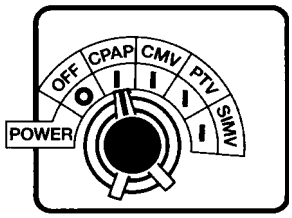


Note: The Fresh Gas flow is reduced from ≈5LPM to ≈1LPM in the High Alarm condition.

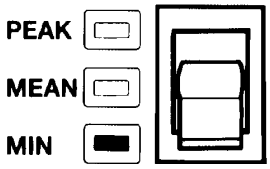
- Increase the **PIP** alarm control to 40 cmH_2O. The **Cycle Fail** visual and audible alarms will be initiated.
- Decrease the **PIP** alarm control to 30 cmH_2O. The **Cycle Fail** audible alarm will cancel but the visual alarm will continue.
- Press the reset button to cancel the visual alarm.



- Return the mode switch to **CPAP.**



- Set **Pressure Display Selector** switch in the **Min** position.



Set the **CPAP/PEEP** regulator to 10 cmH_2O.

8.8.3 Leak and Block Alarms

◆ Remove the hose from the **FRESH GAS (TO PATIENT)** port.

- The **LEAK** visual and audible alarm will be initiated.

◆ Place a finger over the **FRESH GAS (TO PATIENT)** port.

- The **BLOCK** visual and audible alarm will be initiated.

- Replace the hose to cancel the alarms

8.8.4 Mains failure alarm

(Do not turn the 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, the ventilator should carry out self test and resume previous mode of operation.

8.8.5 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.

8.9 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%.

If the reading does not reach 100% then the cell requires adjustment.

To adjust the O_2 cell reading , set blender control to 100%.

Disconnect air supply hose from the wall socket and allow 3 minutes before adjusting control on rear panel. See “Rear Panel” on page 43. for position of control).

If unable to set 100%, O_2 Cell must be replaced.

Ignore any blender alarms during this adjustment.

8.10 Completing Functional Testing

- Return all the pressure regulators to minimum.
- Set the Pressure display switch to **MIN.**
- Set the **CPAP alarm** control to **-5 cm_2O** and the **PIP alarm** control to **60 cmH_2O.**
- Turn the mode switch to OFF

Functional testing is now complete.

8.11 Basic Set Up

Warning: It is the operator's responsibility to check the ventilator pressures prior to changing modes.

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

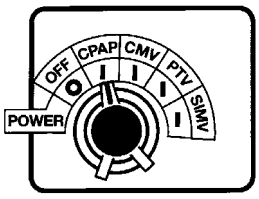
Warning: Remove the key switch from the rear of the unit when in use to avoid accidental change of modes.

Step 1. Connect SLE approved patient circuit to the Ventilator and Humidifier.

- **For further information see page 44 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 2. Set up the humidifier to manufacturer's instructions

Step 3. Set the following ventilator conditions :-



- Set the mode switch to OFF
- Set all the pressure regulators to minimum.
- Set the Pressure display switch to **MIN.**
- Set the **CPAP alarm** control to **-5 cmH_2O** and the **PIP alarm** control to **60 cmH_2O.**

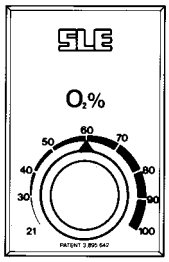
Step 4. Select mode of ventilation to **CPAP**

The ventilator will now carry out a self test as described on page 20. 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

Step 5. (a) Set required O_2 concentration by means of O_2 Blender Control. $\%O_2$ Oxygen will be monitored and displayed in FIO_2 Digital Display. The unit should now be ready to connect to a patient.



- **Changes will take 30 seconds to stabilise on the FIO_2 display.**

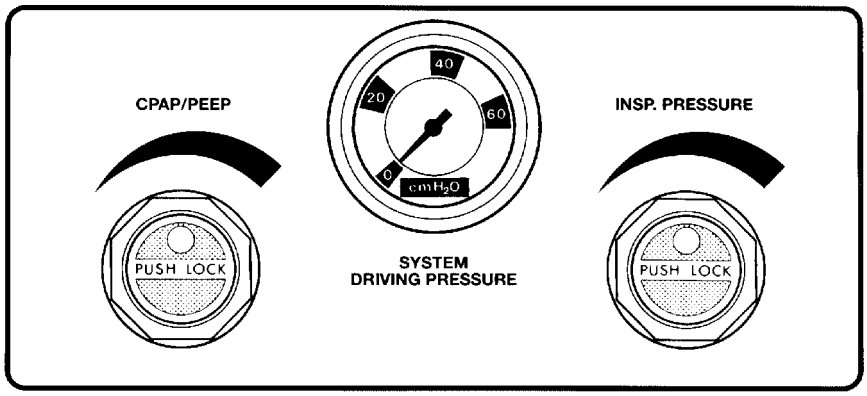
Oxygen - Clinical use. Oxygen is a drug and should be prescribed as such. Exposing a baby to elevated concentrations may lead to Retrolental Fibroplasia.

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.

8.12 To Use the SLE2000 in CPAP Mode

As in steps 1 to 5 plus:

(a) 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.

(b) Set the **CPAP** alarm to the required level.

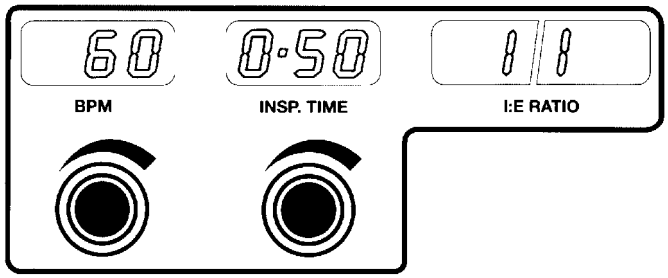
8.12.1 Manual breaths in CPAP mode.
Note: Exclusive to CPAP mode.

To set the parameters for the manual breath advance the mode switch to CMV. Set the Pressure Display switch to Peak. Set the required Inspiratory time. Increase the INSP. PRESSURE regulator to required pressure. Check by pushing the manual breath button. Return the Pressure Display switch to Min. Return the mode switch to CPAP.

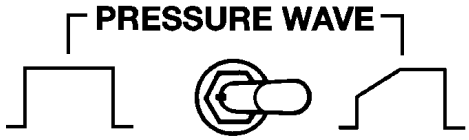
8.13 To Use the SLE2000 in CMV Mode

As in steps 1 to 5 and CPAP setup.

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



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



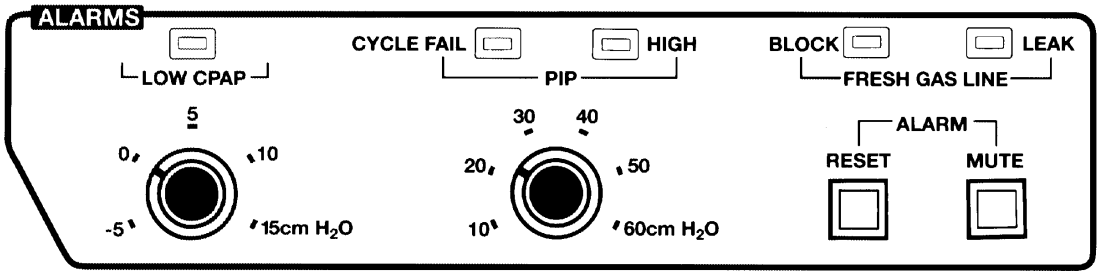
(c) Switch mode switch from **CPAP** to **CMV**

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 **PEAK** and increase the **INSP. PRESSURE** regulator to the desired level. This is indicated on the digital pressure display.

(f) Set the **PIP** alarm to required level. Press **RESET** to clear the alarms.



LOW CPAP is activated if pressure falls below setting	**HIGH** will activate if **PIP** setting is exceeded by more than 4 cms. It will also open a pressure relief valve and activate **LEAK** alarm	**CYCLE FAIL** will activate if pressure wave fails to pass through a threshold which is automatically set at 4 cms below the **PIP** setting

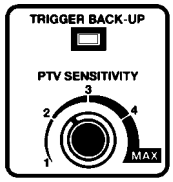
8.14 Patient Triggered Modes

8.14.1 To use SLE 2000 in PTV and SIMV mode

As in steps 1 to 5 and CPAP setup

(a) Advance the mode switch to **CMV**

(b) Set **PTV** sensitivity to 1



(c) 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**

(d) Advance the mode switch 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 could self trigger.

Note on the set-up for PTV
If currently ventilating a patient in CMV mode and the decision is made to change to PTV, the BPM must be reduced to approx. 10 BPM. This is done to enable the patient to trigger the ventilator. Once this has been achieved the BPM can be increased to approximately 20 BPM below the patients measured respiratory rate.

This becomes the backup BPM rate.

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TECHNICAL INFORMATION

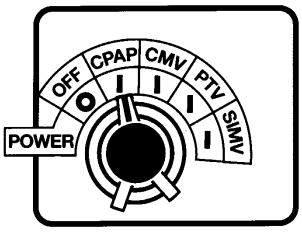
9. Ventilator Controls

9.1 Electronic module

9.1.1 Power Switch (5 positions)

OFF- CPAP- CMV- PTV- SIMV

- OFF = All electrical power off.



Note: There is a limited fresh gas supply with power switch in the OFF position, if ventilator is used with Headboxes 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: Block LEDs do not come on during this sequence.

9.1.2 System Fail LED

Lights if main microprocessor system or other electronic circuitry fails (See section on alarms page 39)

9.1.3 CPAP Mode

FIO_2, **mean** and **min** airway pressure digital displays. The **Manual Breath** pushbutton and associated with it the **'High', 'Low', 'Failure to Cycle'** and **'Fresh Gas'** alarms. Also activated is the **INSP. Time** control for maual breath. The time of this breath and pressure must be preset by the user. The mean airway pressure in **CPAP** will show an average of airway pressures.

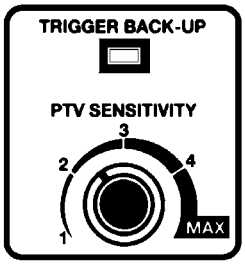
9.1.4 CMV Mode

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.

9.1.5 PTV Mode

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.



The **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 Apnoea). 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 auto 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 0.4 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.

9.1.6 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 and indicate this with an audible bleep. Any additional spontaneous breaths by the patient will be unsupported by the ventilator.

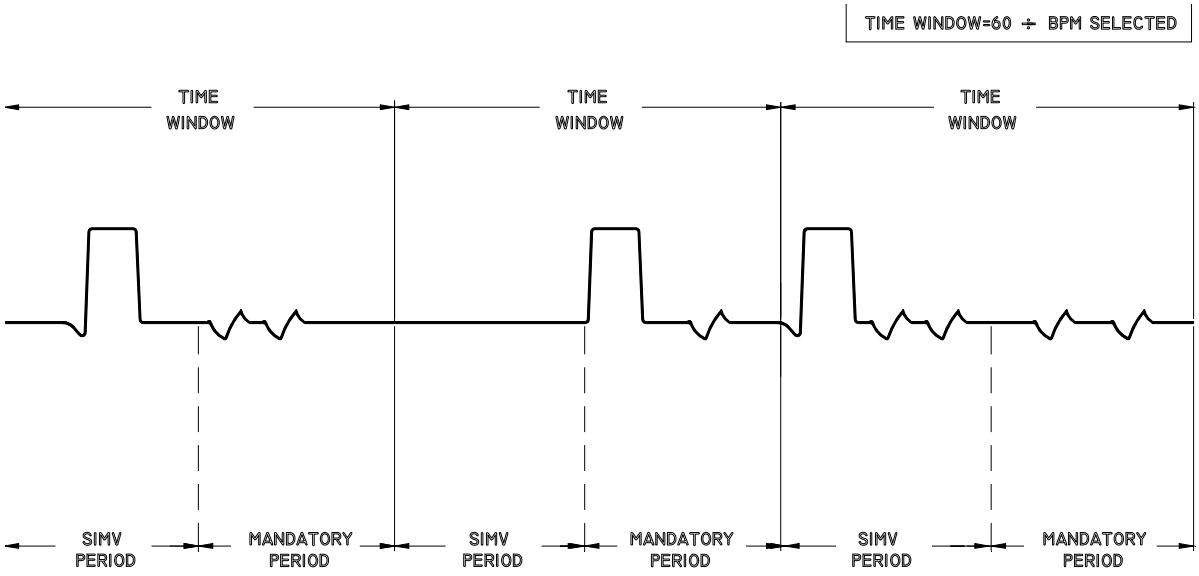
- To enable an audible back-up bleep, hold the **Reset** button in during the automatic test mode on power up.

This SIMV feature of the SLE 2000 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 enable 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 enable the audible bleep, until the ventilator is switched OFF again.

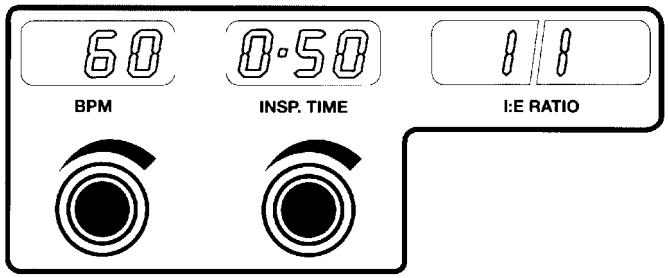
The ventilator will only supply one breath during each time period set by the BPM rate. So the total number of breaths delivered either synchronised or mandatory will be only that shown in the BPM display.



If an inspirating 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.

9.1.7 BPM

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



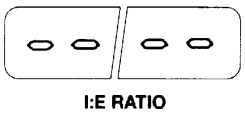
9.1.8 Inspiration Time

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.
Two ranges controlled by the rear BPM range switch
0.1-3.0 secs (1-125 BPM range) setting resolution 0.02 secs
0.01-0.3 secs (126-250 BPM range) setting resolution 0.01 secs

9.1.9 I:E Ratio

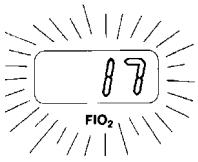
This appears on a four digit LED display and is calculated from the settings of the **BPM** and the **INSP.TIME** controls.



- 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.**

9.1.10 Oxygen (FIO_2)

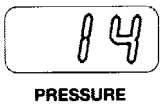
Indication of the oxygen concentration of the Fresh Gas supply to the patient appears on a 3 digit LED display. Should the indication fall below 18% the display will flash.



Recalibration at 100% O_2 is effected by rear panel screwdriver adjustment. See page 43

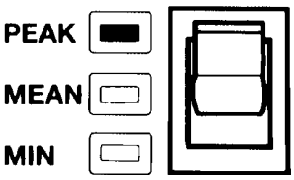
9.1.11 Pressure Display

Digital LED indication ±65 cm/H_20



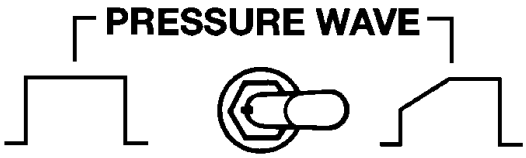
9.1.12 Three position switch.

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



9.1.13 Pressure Wave Switch

This switch alters the pressure waveform from **square** to **tapered** as indicated.



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

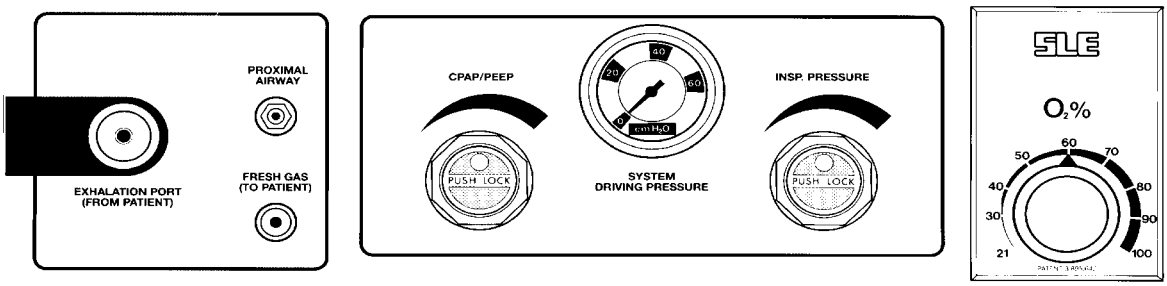
9.1.14 Manual Breath

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

- The duration of the Manual Breath is controlled by the **INSP. TIME** setting.

9.2 Pneumatic Module

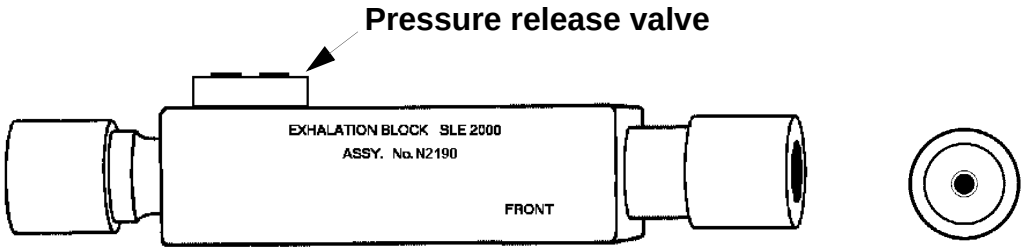


9.2.1 Proximal Airway

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

9.2.2 Removable Exhalation Block N2190

Can be removed easily for cleaning by lowering side panel.



9.2.3 Fresh Gas Port

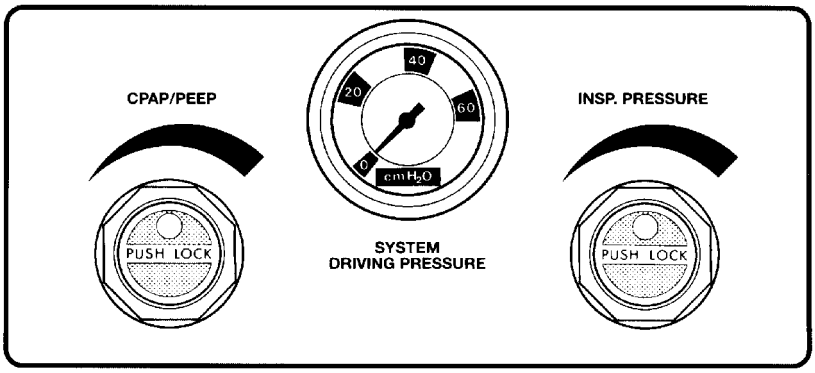
The Fresh Gas port supplies 5 LPM of the blended gas via the humidifier to the patient inspiratory port on the ET connector when the ventilator is switched on.

9.2.4 Regulator and Pressure Gauges.

- These 2 pressure regulator controls have push/pull locking caps.

CPAP/PEEP

This regulator controls the base pressure in the circuit.



INSP. PRESSURE

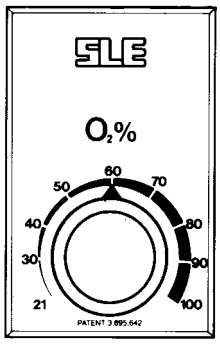
This regulator controls the peak inspiratory pressure (PIP).

SYSTEM DRIVING PRESSURE

This guage shows the pressure above CPAP/PEEP.

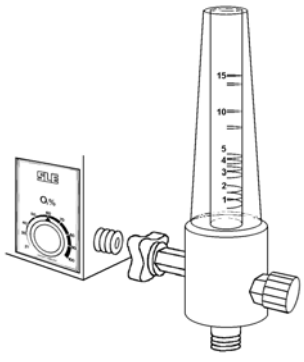
9.2.5 O_2 Blender (% FIO_2)

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 FIO_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



10. Alarms

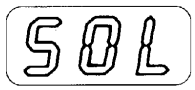
Warning Audible and Visual warning alarms indicate a potentially harmful condition to the patient . Failure to take corrective action could result in injury or death to the patient.

10.0.1 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.



BPM

I:E RATIO

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.

10.0.2 Mains Failure Audible Alarm

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

10.0.3 Gas Supply Failure Alarm

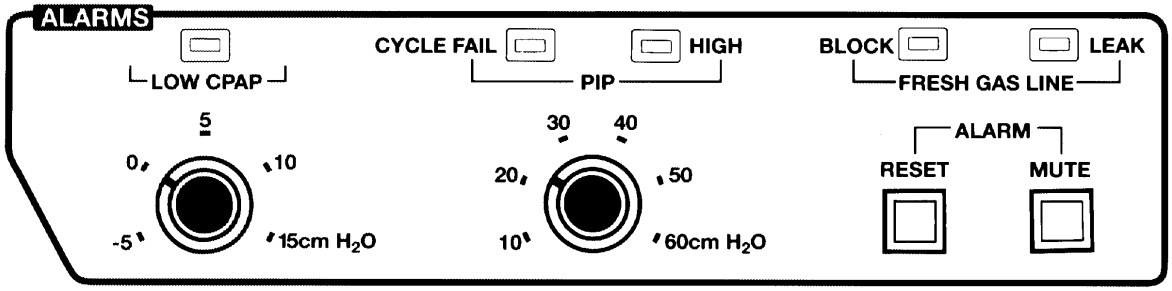
The Air and Oxygen audible alarms are an integral part of the blender, and function when AIR or O_2 pressures differ by more than 30 PSI and if either gas is disconnected.

10.0.4 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 Port 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.

10.0.5 Adjustable Alarm

Two controls on the front panel control the settings for **HIGH/CYCLE FAIL** and **LOW** alarms.



10.0.6 High Alarm

Should the airway pressure exceed the **PIP** alarm setting by more than 4 cms, 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.

10.0.7 CYCLE FAIL ALARM

This alarm will be activated should the pressure wave fail to pass through a threshold 4 cms below the **PIP** 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.

10.0.8 Low CPAP Alarm

Should the circuit pressure fall below the **LOW CPAP** 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.

10.0.9 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.

10.0.10 Alarm Mute

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

10.0.11 Alarm Volume

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

10.0.12 Alarm Verification

For the procedure for verifying the alarms see page 23.

11. 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.

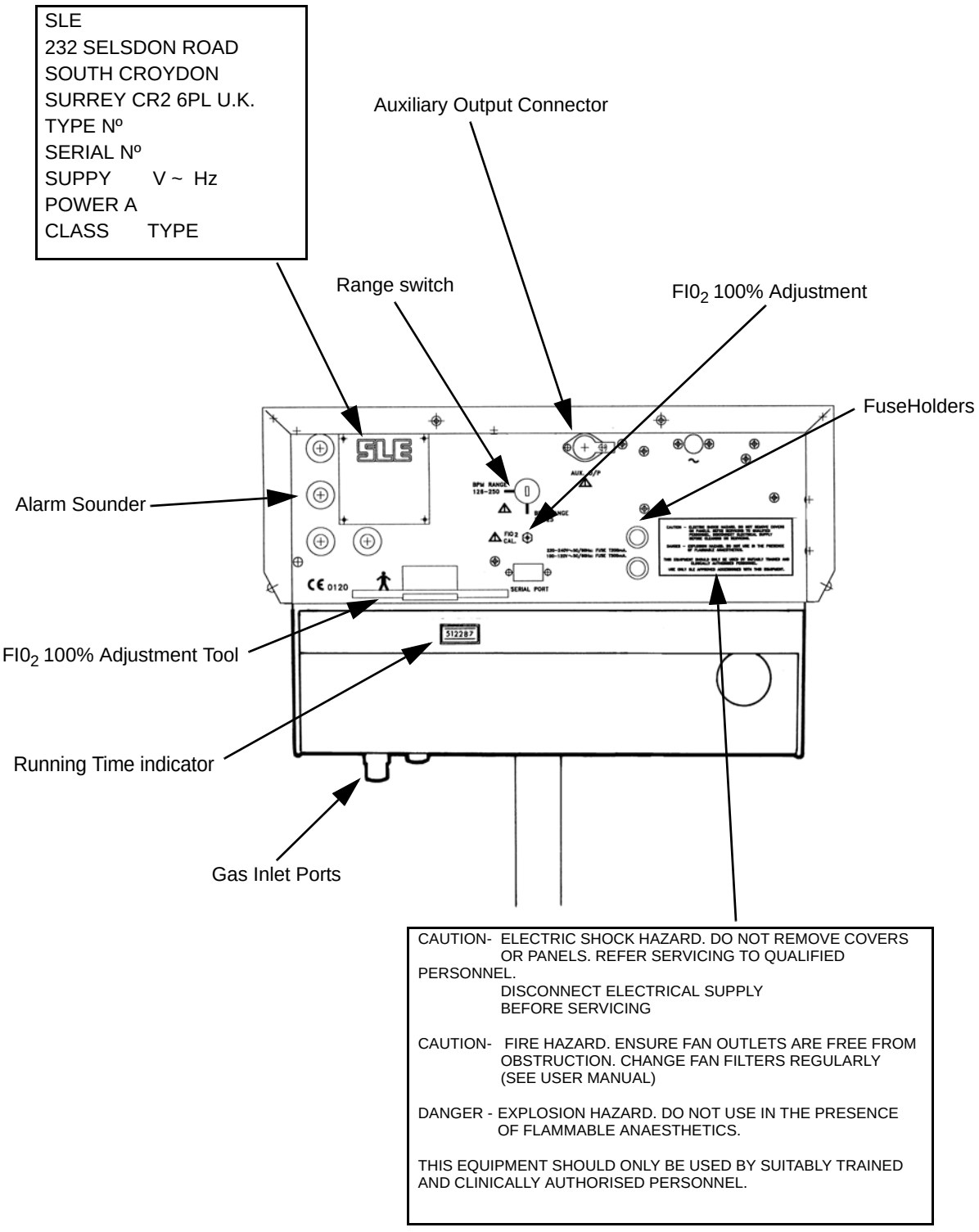
Analogue signal outputs are available at the rear of the electronics module, on the 7 pin DIN connector Auxiliary O/P.

Buffered airway pressure.	Pin 1	1 - 7 volts corresponding to 0 to 60 cmH_2O
FIO_2.	Pin 2	0 - 4 volts corresponding to 0 to 100%
Common ground.	Pin 3	

All other pins must be left unconnected. SLE reserve the right to use these pins for other uses.

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

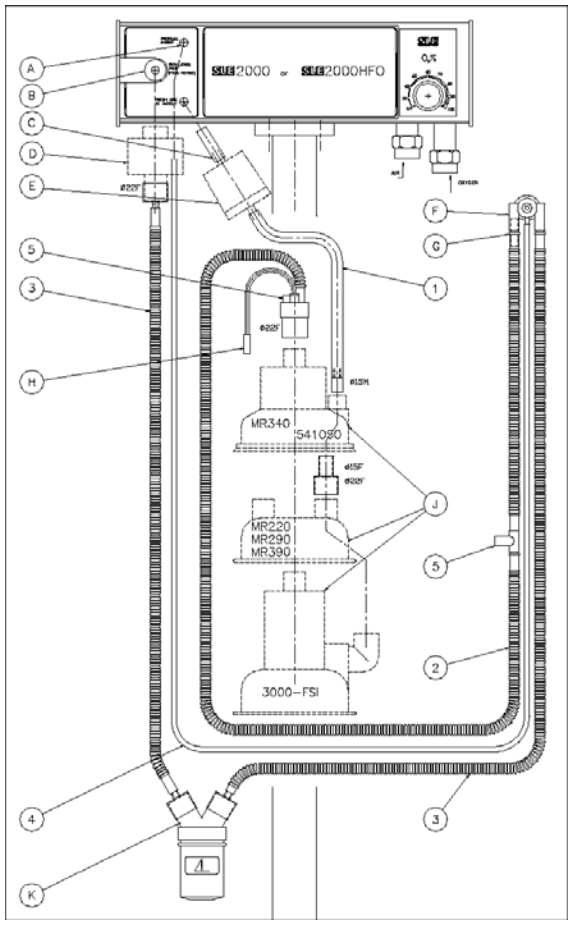
12. Rear Panel



13. Patient Circuit Connection

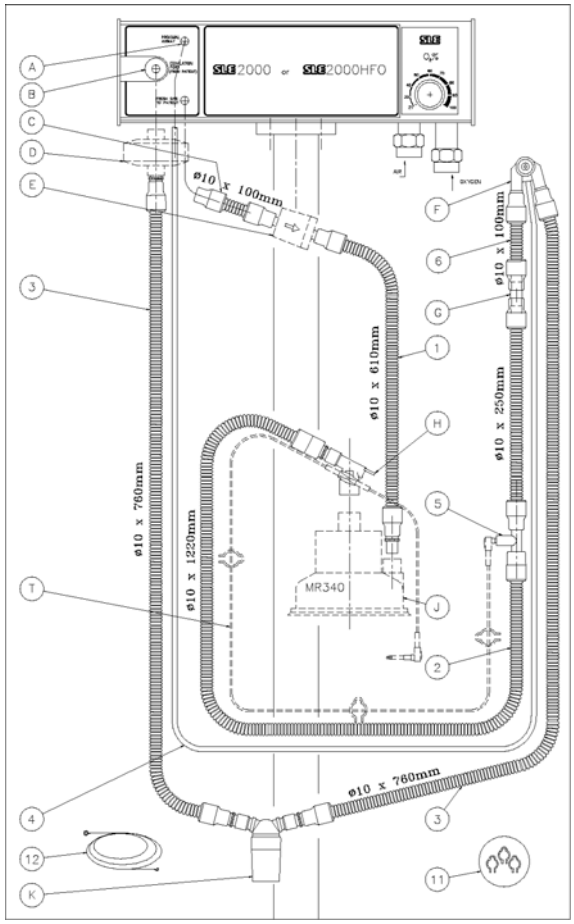
SINGLE USE HEATED PATIENT CIRCUIT (SLE Part Nº N2188)

Temperature port 450mm from ET Manifold.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	CAUTIONS
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. DIAGRAM INDEX 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 NºN2029 F. ET Manifold G. Red Restrictor H. To Heater Wire Adaptor J. Humidification Chamber K. Water Trap	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. 

REUSABLE 10mm HEATED 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 ET Manifold 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) CØ10x100Tube Assembly Part Nº N2998/04 D Single Use Bacteria Filter - Optional Part Nº N2187 or N2587 E Autoclavable Bacteria Filter - Optional Part NºN2029 F ET Manifold Part NºN3145 G Red Metal Restrictor Part NºN2266 H Heater Connection - Dual Servo Hose Assy Part NºN3510 J Humidifier Chamber - Reference only K Water Trap Part Nº N3139 T Temperature Probe - Reference only 1 Humidifier Supply Line - Ø10x610 Part NºN2998/24 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 Part Nº.N2030	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 temp. at outlet of humidifier exceeds 55ºC. Do not cover the patient circuit with anything which may cause the tube to overheat. Do not autoclave water trap if medications containing chlorinated or aromatic hydrocarbons are used or with the water container fitted. 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.  5 Temperature Monitoring - Probe Port Housing Tee Part Nº N3146 6 Inspiratory Supply Line - Ø10 x 100 Tube Assembly Part Nº N2998/04 11 Hose Clips - Secure Temperature Probe Lead Part Nº N3049 12 Draw Wire - Tool for Assembly of Heater Wire. Part Nº N3071

14. Filter Systems

IIt 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 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.

14.1 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.

14.2 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.

14.2.1 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.

15. 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 or otherwise subject it to temperatures above 62°C.

DO NOT immerse any part of the SLE 2000 in any liquid, with the exception of the expiratory exhalation block (SLE part No N2190).

15.1 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 15.2 .

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

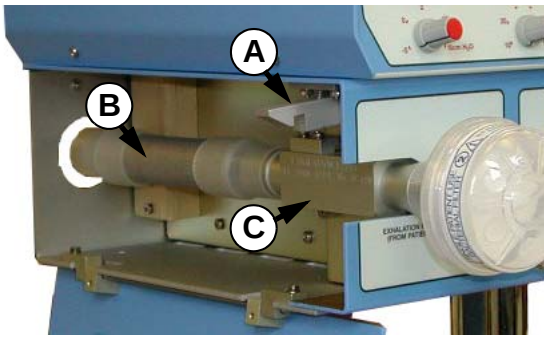
15.2 Cleaning and disinfection of an in-service ventilator

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.**

15.2.1 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.

15.3 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.

15.4 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.

15.5 Sterilization method

The silencer SLE part Nº N2186 and exhalation block SLE part Nº N2190 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.

16. User Operational Checks

1. **Functional test** as described on page 19 should be carried out every time the patient circuit is changed.

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

3. 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. SLE2000 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.
High Alarm - audible & visual	Incorrect PIP alarm setting.	Readjust alarm to INSP PRESSURE or readjust INSP Pressure regulator.

Symptom	Possible Cause	Remedy
Cycle Fail Alarm - audible & visual.	Incorrect PIP alarm setting.	Readjuct PIP alarm to INSp pressure. Check sent vent pressure.
	Proximal Airway line disconnected.	Reconnect tubing.
	Proximal Airway blocked with water.	Clear blockage.
	Solenoid failure.	Consult Service Manual or SLE trained Engineer.
System Fail - audible & visual.	Component failure	As above.
CPAP 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.
	Seized regulator control.	Consult SLE trained Engineer.
	CPAP nozzle blocked.	Consult SLE trained Engineer.

Symptom	Possible Cause	Remedy
PEAK INSP. 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.
	Seized regulator control.	Consult SLE trained Engineer.
	Insp. nozzle blocked.	Consult SLE trained Engineer.
	High alarm condition.	Reset alarm setting.
	Water in proximal airway pressure tubing	Drain tube
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.
Varying pressures	Check for blocked or water logged filters.	Replace filters
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 completed at a maximum of every 6 monthls. 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 and replacement where necessary, 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
- PIP and CPAP regulators

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

- Solenoid valves SV2, SV3, and SV4
- Tubing and connectors.
- Battery holder.
- Alarm sounders.
- Mode, wave shape, frequency range and pressure range switches.
- Pressure relief valves.

- **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 ^{o}C
c. at 0 ^{o}C

20. Technical Specification

20.1 Conventional Ventilation

Modes:	CPAP,CMV,PTV,SIMV
BPM Ranges:	1-125 or 126 - 250 breaths per minute (1BPM STEPS) selected via rear security key switch
Inspiratory Time:	0.1-3.0 or 0.01-0.3 seconds
I:E Range :	9.9:1 - 1:9.9 calculated from BPM and INSP. TIME settings.
CPAP Pressure:	0 cmH_2O to 15 cmH_2O minimum.
Inspiratory Pressure:	0 cmH_2O to 60 cmH_2O switched fast or slow rise waveforms.

20.2 Displays

Proximal Airway Pressure Gauge	Gauge range -6 to +60 cmH_2O
Seven segment LED's:	showing BPM, INSP. TIME, I:E RATIO, FIO_2 and PRESSURE (max., mean or min.).
Indicator LEDs:	POWER: green LED indicates power on. SYSTEM FAIL: Indicates main processor system fail. TRIGGER BACK-UP: Indicates a machine delivered breath if patient fails to trigger ventilator during back-up time window. MAX., MEAN, MIN.: indicates which value is being displayed on the 7 segment pressure display. MUTE: Indicates that the mute function is active.
Alarm LED's	LOW CPAP : warning of the pressure dropping below the LOW CPAP alarm limit CYCLE FAIL: warning that no breath has been detected. Ventilator breath is below alarm threshold. HIGH: warning of the PIP alarm limit being exceeded BLOCK: warning of a block in the fresh gas supply limb of patient circuit. LEAK : warning of a leak in the fresh gas supply limb of the patient circuit.
Driving Pressure Gauge: (Scaled for resultant inspiratory pressures above **PEEP**)	Gauge range :0-60 cmH_2O plus PEEP level

20.3 Controls

Ventilation mode switch:	OFF, ALARM TEST/CPAP, CMV, PTV, SIMV
BPM Control (ten turn):	either 1-125BPM or 126-250BPM
INSP. TIME Control (ten turn):	either 0.10-3.00 seconds (min exp time: 0.25 seconds) or 0.01-0.3 seconds (min exp time: 0.12)
Pressure Display Switch:	MAX., MEAN, MIN.
Pressure Wave Switch:	Slow or Fast rise
Manual Breath Pushbutton	
Alarm Mute and Reset Pushbuttons:	Mute active for 60 seconds (approx.)
Trigger Sensitivity Control:	Range: 2ml/0.5 sec max. To 10ml/0.5sec min. Using SLE N2188 patient circuit.
Pressure alarm setting controls:	LOW CPAP: -5 to 15cmH_2O PIP :10 to 60 cmH_2O
Pressure controls:	INSPIRATORY CPAP/PEEP
Air/Oxygen Blender Control	21-100% ± 3%

20.4 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 FAIL SYSTEM FAIL: FAIL.

20.5 Air and Oxygen Supplies

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

20.5.1 Oxygen supply

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

20.5.2 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.

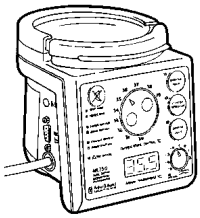
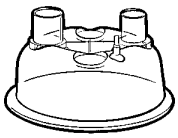
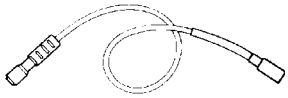
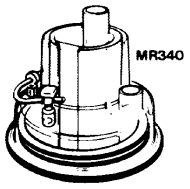
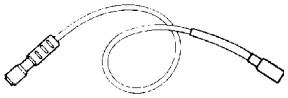
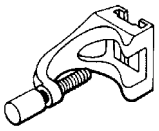
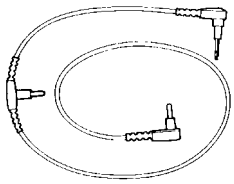
Description of Class 1.4.1
1= particle size of 0.1 microns. 4 = Pressure dewpoint of +3ºC . 1= oil content 0.01Mg/m3

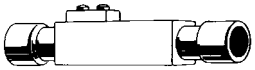
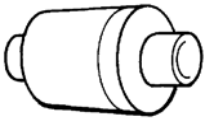
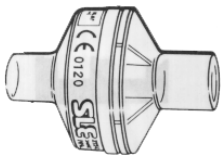
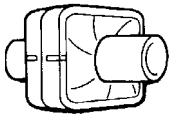
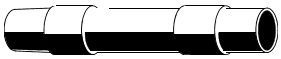
Description of Class 1.1.1
1= particle size of 0.1 microns. 1 = Pressure dewpoint of -70ºC . 1= oil content 0.01Mg/m3

20.6 Power , Dimensions etc.

Voltage :	100-120V/ 50-60 Hz 220-250V/ 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 × 31 cms H × 32 cms D
Height on pole:	137 cms
Weight Ventilator Only:	10 Kgs
Complies with:	CE DECLARATION OF CONFORMITY IEC 601-1 and 601-2-12 1988 BS 5724 Part 1 and section 2.12.1990 EMC Medical device 601-1-2
Patient Circuit Required:	Model : N2188 Single use. or variant Model : N2200 Re-usable. or variant
Transport and storage conditions	Temperature -20 to 50“C for not longer than 2.5 months Humidity 15 to 90% (non condensing) for not longer than 2.5 months Atmospheric pressure 500 to 1060hPa for not longer than 2.5 months
Protection	Class 1 Type B Protection against electric Shock
Mode of operation	Continuous

21. Consumables and Accessories for SLE 2000

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	
N2200 - Re-Usable Patient Circuit Accessory Kit	
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	

N2190 Spare exhalation Block	
N2029 Bacteria filter (autoclavable)	
N2587 Bacteria filter (single use) Inlet :22mm (male) Outlet 22mm (female)	
N2187 Bacteria filter (single use) Inlet & Outlet:15mm (female) or 22mm (male) Tapered Connections	
N2186 Silencer (fitted to rear of exhalation block)	
N2035 O_2 (complete) 4 metres length	
N2199 Air hose, 4 bar (complete) 4 metres length	
N2006/11 User Manual for SLE2000	
N2000/00 Service Manual for SLE2000	
N2002/01 User Manual for SLE2000 on CD-ROM	
N2002 Service Manual for SLE2000 on CD-ROM	

22. Ordering Information

SLE 2000* Z2002	Stand mounted Ventilator (without humidifier), Hoses, Manual and Single Use Circuits (Qty 3)
SLE 2000* Z2102	As above but for Shelf mounted Ventilator (without humidifier)
SLE 2000* Z2202	As above but for Rail mounted Ventilator (without humidifier)

*State voltage required

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

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 infant ventilator.

TB 990603:	Removal of hour counter from electrical chassis.
TB 000201:	New versions of control software
TB 000801:	Ventilator firmware revision list
TB 040301:	CPU Boards for serial Nº: E0108 & Y0963 to Y0975
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.

SLE Limited
Twin Bridges Business Park
232 Selsdon Road
South Croydon
Surrey CR2 6PL UK

+44(0)20 8681 1414 sales@sle.co.uk
+44(0)20 8649 8570 www.sle.co.uk