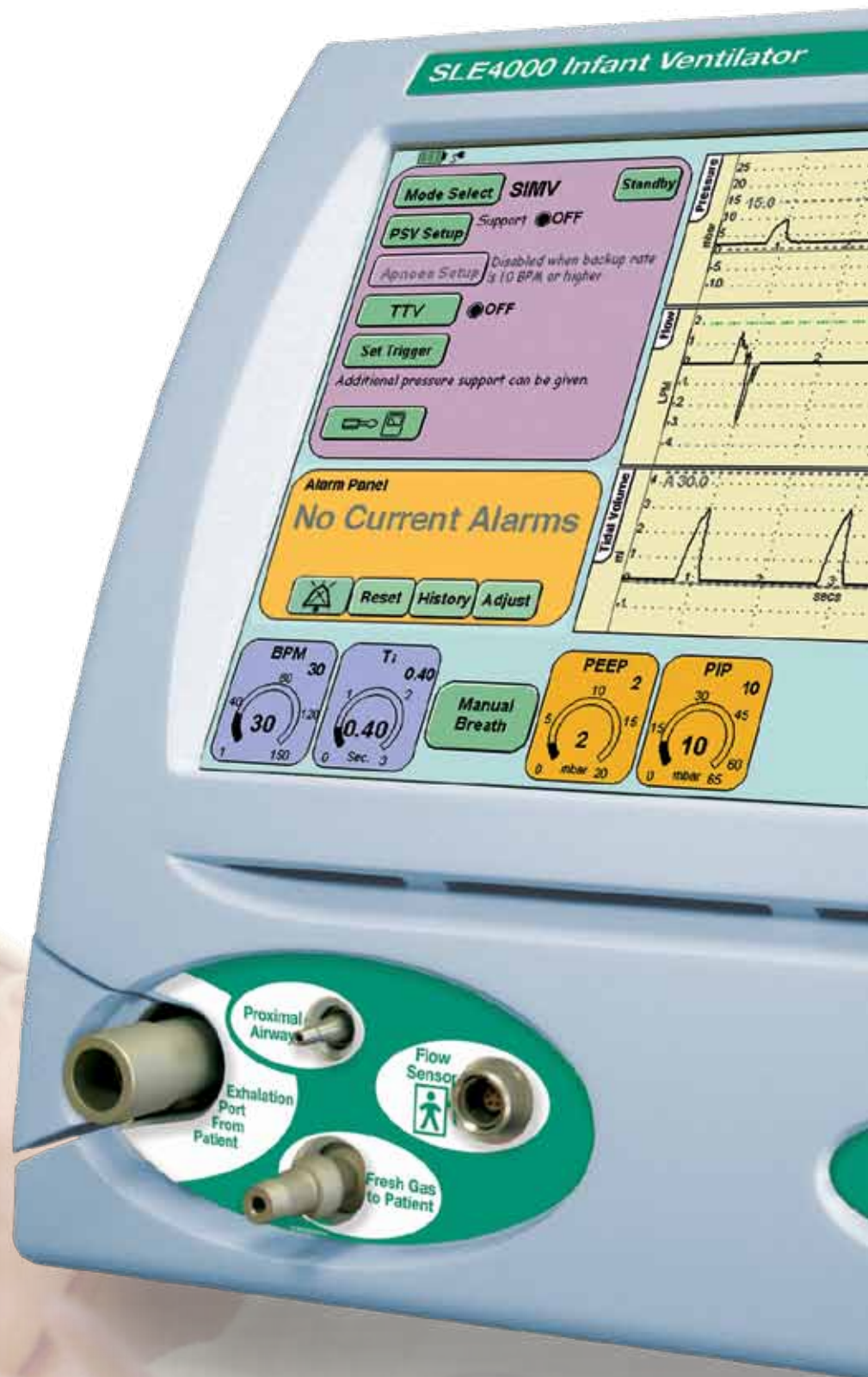


SLE4000

Infant Ventilator with
touch-screen operation



 **SLE**

When the smallest thing matters



SLE4000 - The Total Solution for Conventional Infant Ventilation

SLE is a world leader in the design and manufacture of neonatal ventilators. Years of ventilation experience have given the company an understanding of the challenges facing clinicians when caring for the tiniest and most critical babies.

The knowledge and experience gained during years of development is evident in the SLE4000 ventilator; the result of SLE's ongoing commitments to innovation, competency and care.

Modes include: CPAP, CMV+ TTV, PTV, PSV, SIMV+ TTV + PSV

- Ability to preset parameters in all modes of operation
- Full colour, total touch-screen operation
- Integral flow monitoring measuring lung mechanics and displaying of loops and waveforms
- Trending of measured parameters
- Standard patient circuit for all modes (Except with NO therapy)
- Unique, patented valveless technology
- Integral battery with up to 60 minutes operating capability
- Software based, allowing for upgrading to versions with new or improved functions

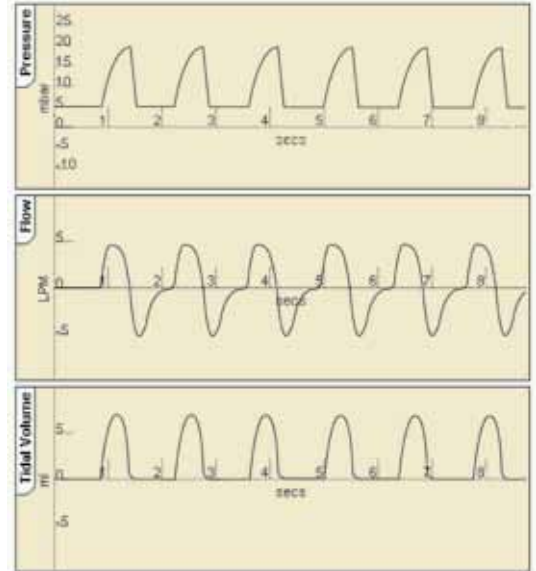
Advanced Ventilator Features

Targeted Tidal Volume *plus* (TTV^{plus})

The SLE4000 features TTV^{plus} - an entirely new way of managing the patient's tidal volume.

Lung protective ventilation strategies in neonates are now accepted as a marker for improved ventilation outcome. One such strategy is the use of a targeted tidal volume in pressure ventilation. The aim of TTV^{plus} is to deliver a stable tidal volume at the lowest possible pressure. All this has to occur in the presence of a changing lung environment, that also has a potential for a variable leak around the ET tube.

TTV^{plus} approaches this challenge by assuring a stable expired volume, with a leak adjustment capability within safe limits. TTV^{plus} can be used in all conventional ventilation modes and provides a stable tidal volume control according to your patients' requirements.

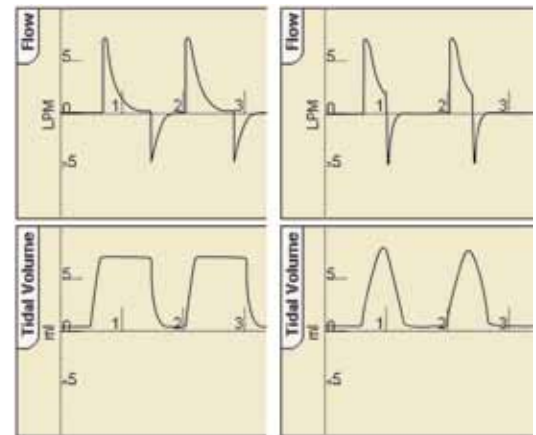


Pressure Support Ventilation (PSV)

PSV was developed on the SLE4000 as a method to decrease the work of breathing between ventilator mandated breaths by providing an elevated pressure triggered by spontaneous breathing, that supports ventilation during inspiration. In addition, SIMV might be combined with PSV so that additional breaths beyond the SIMV programmed breaths are supported.

Whilst the SIMV mandated breaths have a preset volume or peak pressure, the PSV breaths are designed to cut short when the inspiratory flow reaches a percentage of the peak inspiratory flow (e.g. 0 - 50%). It includes automatic leak compensation thereby ensuring the flow termination of inspiration even in the presence of a leak.

All of this means that breathing on the SLE4000 ventilator is even easier for the smallest of babies, allowing them to use their energy to grow.



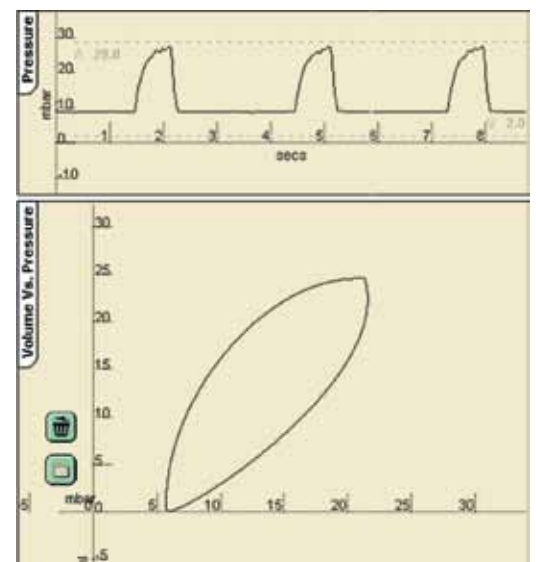
Without flow termination

With flow termination

Respiratory Mechanics Measurement

Loops and waveforms allow the clinician to monitor and adjust ventilator strategy.

- Real-time lung dynamics
- Loops can be displayed in real time or frozen
- Breath-by-breath display of resistance, compliance and C10/C values





Quality Build

The SLE4000 case is manufactured in a unique solid cast polyurethane moulding. This tough material is ideal for use in a busy neonatal unit and easily withstands the knocks and bumps of everyday life.

Integral screen

Colour-coded user touch screen. Easy-to-use, logical sequence allowing quick, smooth adjustments. The SLE4000's 12.1 inch screen means that all the data you need can be easily seen.

Real-time Data Display

Real-time lung mechanics measurements and ventilatory data. This allows for continuous feedback for making crucial clinical decisions.

Audible and Visual Alarms

The alarm panel provides an immediate audible and pictorial view of the alarm condition, thus allowing easy monitoring, plus an alarm history of the last 100 conditions.

User Interface

Brightly coloured user touch screen. Easy-to-use with a logical sequence allowing quick, smooth adjustments. Parameters can be preselected for the next mode whilst continuing to ventilate the patient in the current mode of ventilation.

Compact Unit

The SLE4000 ventilator is housed in a single compact box, making it easier to clean and use. The integrated touch screen is angled for perfect visibility and easy to read from a distance.

Patient Circuit Connections

Front panel mounted patient circuit connections with (autoclavable) exhalation block.

Principles of operation of the SLE4000 valveless system

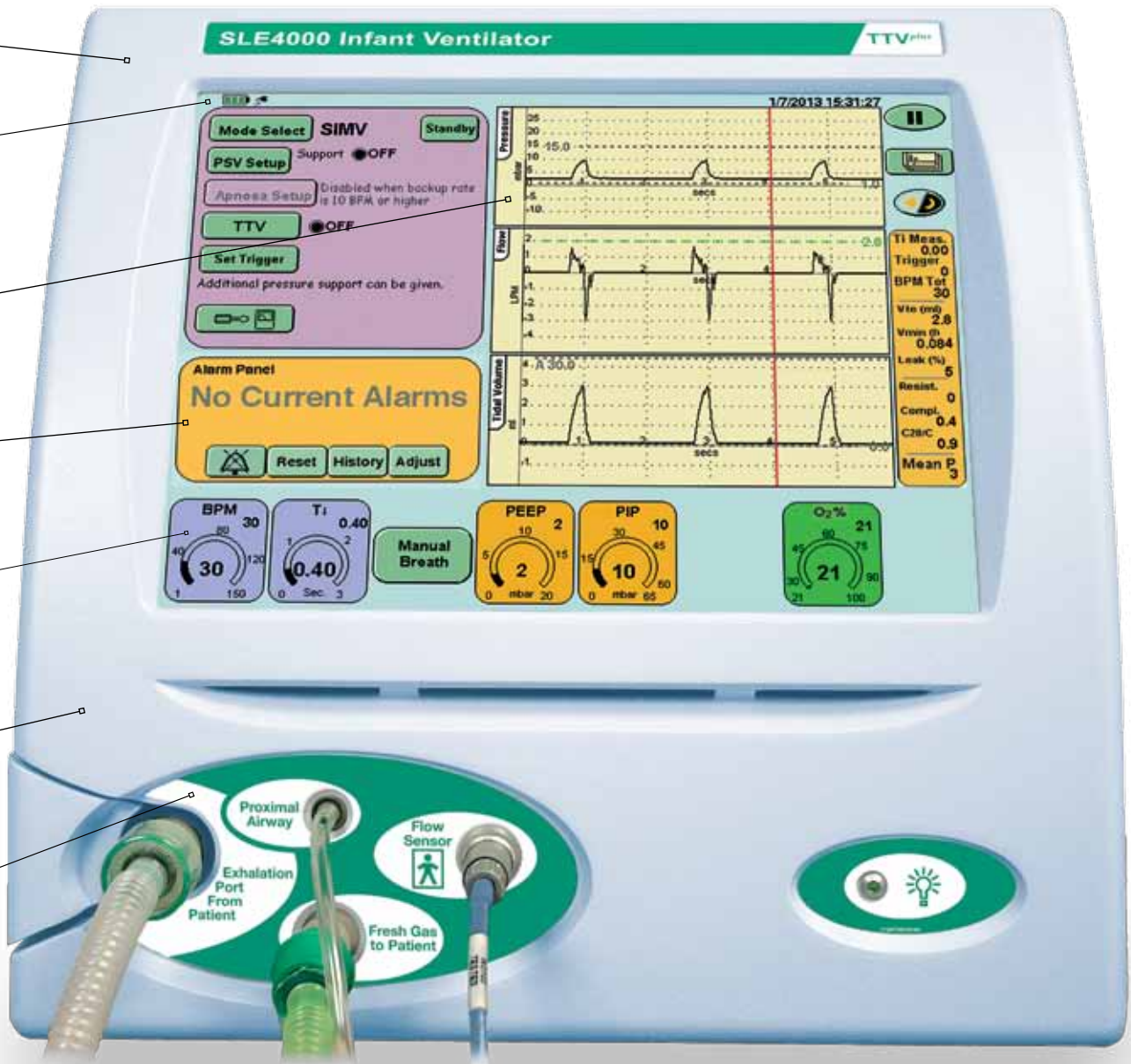
A constant flow of fresh gas is supplied to the patient circuit at 8 l/min. The expiratory manifold has three jets (❶, ❷ and ❸). The front jet (❶) is used to generate an opposing flow to the fresh gas in the exhalation manifold and thereby creates CPAP/PEEP.

The rear jet (❷) is used to generate the Peak Inspired Pressure (PIP) in the same way.

A third (reverse) jet (❸) is used to help eliminate excess circuit pressure.

To avoid gas dilution these jets are supplied with the same oxygen concentration as the fresh gas supply. Sophisticated software controls the rate and duration of the flow of driving gas into the exhalation manifold in opposition to the fresh gas flow. The opposing flow acts as a pneumatic piston and creates a pressure wave at the ET manifold.

Since the opposing flow pressure is set by pressure regulators it automatically compensates for patient and circuit compliance changes.



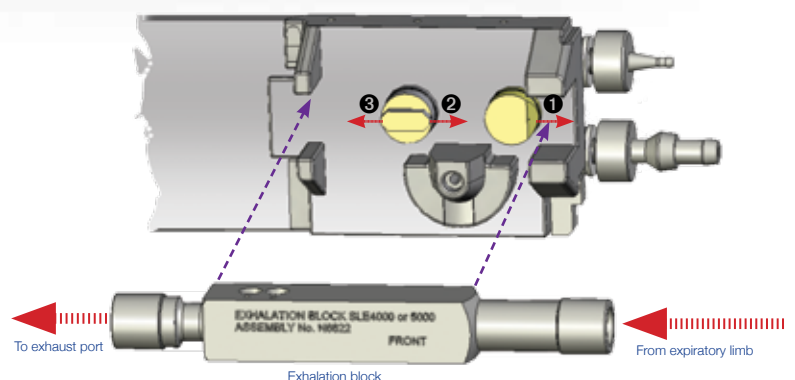
How does it work...?

The illustration shows the exhalation block removed from its mountings in the ventilator. When replaced, the jets (1 and 2) create a positive pressure on flow from the patient circuits's expiratory limb.

Jet 3 is used to create a negative pressure and helps reduce excess circuit pressure.

Since there are no valves or other blockages in the system, there is minimal resistance to the patient.

Fewer moving parts means there is less to clean and less risk in terms of wrong assembly or infection.

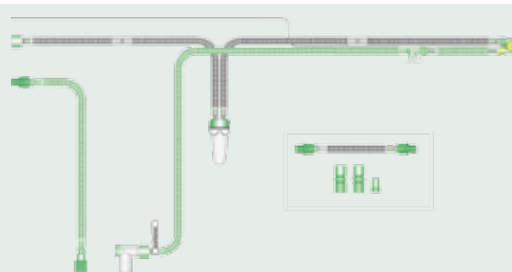


SLE4000 Patient Circuits

BC5188/100/15

Single use breathing circuit for use with SLE4000 (and SLE5000) infant ventilators. Temperature port 100 mm from ET manifold (single use). Circuit comes complete with filter connection kit and adaptors.

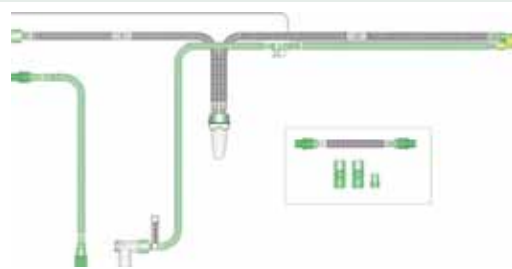
Sold in box quantity of 15



BC5188/400/15

Single use breathing circuit for use with SLE4000 (and SLE5000) infant ventilators. Temperature port 400 mm from ET manifold (single use). Circuit comes complete with filter connection kit and adaptors.

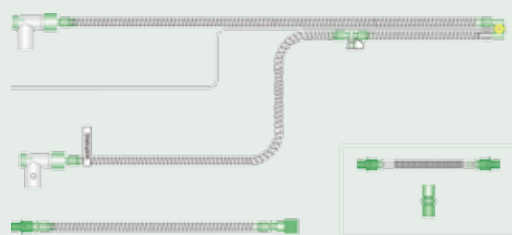
Sold in box quantity of 15



BC5488/DHW/15

Dual heated wire smooth bore breathing circuit for use with SLE4000 (and SLE5000) infant ventilators. Temperature port 170 mm from ET manifold (single use). Circuit comes complete with filter connection kit and adaptors.

Sold in box quantity of 15



BC6216

Nitric Oxide delivery kit, set of connectors.

BC2508

Nebuliser kit.

BC4110/KIT

Nitric Oxide adaptor kit for BC5188/100 and BC5188/400 breathing circuits (SLE4000 (and SLE5000) infant ventilators).

Sold in box quantity of 5

BC4110/ASY

Nitric Oxide dual hose scavenging filter assembly for SLE4000 (and SLE5000) infant ventilators.

Sold in box quantity of 1

Technical Specification

Ventilation Modes

CPAP / PTV / PSV

| | |
|-----------------------|----------------|
| Inspiratory Time: | 0.1 to 3.0 sec |
| CPAP Pressure: | 0 to 20 mbar |
| Inspiratory Pressure: | 0 to 65 mbar |
| Volume Targeting: | 2 to 200 ml |
| Oxygen: | 21% to 100% |

CMV / SIMV

| | |
|-----------------------|-------------------|
| BPM: | 1 to 150 |
| I:E Ratio: | (11.2:1 to 1:600) |
| Inspiratory Time: | 0.1 to 3.0 sec |
| PEEP Pressure: | 0 to 20 mbar |
| Inspiratory Pressure: | 0 to 65 mbar |
| Volume Targeting: | 2 to 200 ml |
| Oxygen: | 21% to 100% |

Monitoring Parameters

Measurement of Flow and Volume

| | |
|---------------------------|---|
| Flow Sensor Type: | 10 mm dual-hot-wire anemometer (autoclavable or single use) |
| Flow Rate: | 0.2 to 32 l/min (Accuracy 8%) |
| Expiratory Tidal Volume: | 0 to 999 ml |
| Expiratory Minute Volume: | 0 to 18 litres |
| Deadspace: | 1 ml |
| Weight: | 10 g |

Conventional Ventilation and combined modes only:

| | |
|----------------------|---|
| Tube Leakage: | 0 to 99% (Resolution: 1%, averaged over 10 breaths) |
| Breath Rate (total): | 0 to 250 BPM |
| Dynamic Compliance: | 0 to 100 ml/mbar (Resolution: 1 ml/mbar) |
| C20/C: | Resolution 0.1 |
| Sampling Time: | 2 ms |
| Resistance: | 0 to 1000 mbar.second/l |
| Triggering: | Inspiratory flow (0.2 to 10 l/min) |

Above values are measured under ATPD (Ambient Temperature and Pressure, Dry) conditions

Oxygen Concentration

| | |
|--------|----------------------------|
| Range: | 21 to 100% (Resolution 1%) |
|--------|----------------------------|

Pressure

| | |
|---------------------------------|--------------------------------------|
| Real-time Pressure measurement: | Resolution 1 mbar |
| Sampling time: | 2 ms |
| Peak Pressure: | 0 to 175 mbar (Resolution 1 mbar) |
| PEEP Pressure: | 0 to 175 mbar (Resolution 1 mbar) |
| Mean Pressure: | -175 to 175 mbar (Resolution 1 mbar) |

User Settable alarms

High Pressure

| | |
|---|----------------|
| Autoset when patient pressure controls are adjusted or can be manually adjustable | |
| Range: | 10 to 110 mbar |
| Resolution: | 0.5 mbar |

Cycle Fail

| |
|---|
| Autoset when patient pressure controls are adjusted or may be manually adjusted |
|---|

Low Pressure

| | |
|---|----------------------------------|
| Autoset when patient pressure controls are adjusted or can be manually adjustable | |
| Range: | -10 mbar (Conventional) -70 mbar |

Low Tidal Volume

| | |
|-------------|-------------|
| Range: | 0 to 200 ml |
| Resolution: | 0.2 ml |

Low Minute Volume

| | |
|-------------|---|
| Range: | 0 to 0.02 litres below High Minute Volume threshold |
| Resolution: | 0.1 litre |

High Minute Volume

| | |
|-------------|-------------------|
| Range: | 0.02 to 18 litres |
| Resolution: | 0.1 litre |

Apnoea time

| | |
|--|-------------|
| Settable only in CPAP or when Backup rate less than 10 BPM | |
| Range: | 5 to 60 sec |
| Resolution: | 1 second |

Power, Dimensions, Standards etc.

Power Requirements

| | |
|-------------------|--|
| Voltage : | 100-250 V 50-60 Hz |
| Power : | 115 VA |
| Battery back up: | 45-60 minutes dependant on mode of operation |
| Battery Charging: | Full charge 24 hours, 80% charge after 8 hours |

Outputs

RS-232C

Air and O₂ input

| | |
|-----------------|-------------|
| Pressures: | 2.8 - 6 bar |
| Fresh Gas Flow: | 8 l/min |

Maximum gas flow: 60 l/min

Operating Environment

| | |
|-----------|------------------------|
| Temp: | 10-40 °C |
| Humidity: | 0-90% (non-condensing) |

Dimensions

| | |
|------------------------|-----------------------------|
| Size, ventilator only: | 330mm W x 330mm H x 470mm D |
|------------------------|-----------------------------|

Height on trolley: 131 cm

Weight, ventilator only: 22.1 kg

Constructed to conform to:

| |
|---------------------------------------|
| BS EN 60601-1:1990 |
| BS EN 60101-1-2:2001 |
| BS EN 60601-1-4: 1996 |
| BS EN 60601-2-12:2006 |
| Medical Devices Directive (93/42/EEC) |

European conformity mark: CE 0120

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: 500 hPa to 1060 hPa

SLE is a world leader in the design and manufacture of neonatal ventilators.

Years of ventilation experience have given the company an understanding of the challenges facing nurses and clinicians when caring for the tiniest and most critical babies.

From being the pioneers of neonatal Patient Triggered Ventilation (PTV) in the 1980's, to the introduction of combined HFO (High Frequency Oscillation) in the 1990's, SLE has maintained a position of strength in neonatal ventilation.

The company's guiding principle is to support clinical and nursing staff in their everyday work.

The knowledge and experience gained during years of development is evident in the SLE4000 ventilator: the result of SLE's ongoing commitments to innovation, competency and care.



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