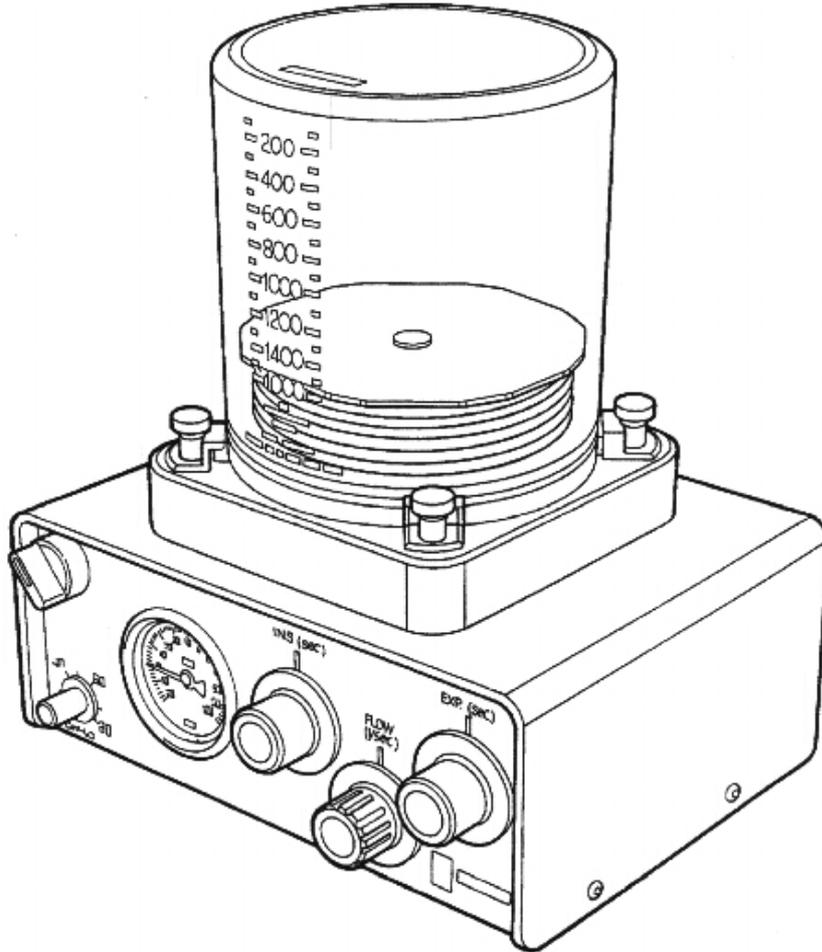


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INSTRUCTIONS FOR USE

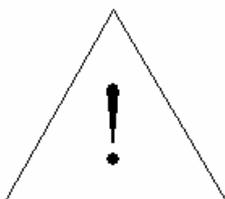
ORION PNEUMATIC VENTILATOR

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INDEX

| CONTENTS | PAGE NO |
|---|---------|
| Index | 2 |
| Service and repairs | 3 |
| User Responsibilities | 4 |
| Warnings and cautions | 4 |
| Purpose | 5 |
| Description : | |
| Front panel - description | 5 |
| Front panel - illustration | 7 |
| Rear panel - description | 8 |
| Rear panel - illustration | 10 |
| Adult bellows assembly - description | 11 |
| Adult bellows assembly - illustration | 12 |
| Ventilation cycle - description | 13 |
| Pneumatic circuit - description | 14 |
| Specification | 15 |
| Ventilator standard parts | 16 |
| Ventilator set up procedure | 17 |
| Pre-use function test | 18 |
| Clinical operation | 19 |
| Fault finding | 20 |
| User maintenance - service schedule | 21 |
| Cleaning of the control unit | 21 |
| Cleaning and sterilisation of the bellows unit | 21 |
| Ordering information | 22 |
| Disposal | 23 |

NOTE :



This symbol appears on the shortform instruction label of the ORION Ventilator.

It's intended meaning is to refer the user to this manual.

SERVICING AND REPAIRS

In order to achieve the full operational life of the ORION ANAESTHESIA VENTILATOR the following service schedule must be adhered to :-

- (a) Three monthly inspection and service check.
- (b) Six monthly bellows replacement.
- (c) Two yearly replacement of exhaust diaphragm.
- (d) Five yearly overhaul.

Service requirements are detailed in the service manual that is available to factory trained personnel.

Further details are available from :-

The Service department,
OES MEDICAL LTD
UNIT 10, AREA D,
RADLEY ROAD INDUSTRIAL ESTATE,
ABINGDON,
OXFORDSHIRE,
OX14 3RY,
ENGLAND.

Phone 01235 539618

Fax 01235 539619

Always provide the following information with any communication:-

- (a) Type of product and part number.
- (b) Product name.
- (c) Serial number.
- (d) Date of purchase.
- (e) details of suspected fault.

USER RESPONSIBILITIES

It is the responsibility of the user of the Orion Ventilator to install, use and maintain it according to the instructions in this manual. OES Medical Ltd is not liable for any consequences arising from the use of the Orion Ventilator outside the prescribed conditions, including use by under-qualified personnel.

WARNINGS AND CAUTIONS

Throughout this manual warnings and cautions relating to various aspects of use of this ventilator are given.

WARNING

A warning indicates that there is a possible hazard to the patient, user or environment. It is enclosed in a box to draw the reader's attention and *MUST BE HEEDED*.

CAUTION

A caution indicates that there may be a risk of damage to equipment. It is advisable to follow the instructions given in the caution.

NOTE

Notes may appear throughout the text of this manual to indicate useful points to the user.

It is the responsibility of the user to read this manual and fully understand the functions of this ventilator prior to use.

PURPOSE

The OES ORION VENTILATOR is a pneumatically controlled oxygen driven anaesthesia ventilator with bellows unit, designed for mechanical ventilation during anaesthesia.

It can be used in closed circuit anaesthesia and to drive a Bain circuit.

The Orion Ventilator must only be used by suitably qualified personnel, for the above purpose.

DESCRIPTION

The OES ORION VENTILATOR is a time cycled flow generator type ventilator that is oxygen driven and is provided with an ascending bellows unit which is easily detachable for cleaning.

FRONT PANEL - DESCRIPTION

- (1) On/Off switch - rotates 90 degrees clockwise to turn the ventilator on.
- (2) Manometer - calibrated between -20 to +100 cm H₂O, the gauge must be connected to the inspiratory limb of the breathing circuit via the connector on the rear panel.
- (3) Adjustable pressure relief valve - calibrated at 20 cm H₂O, at 0.5 litres per second flow. Note - the pressure relief valve will relieve at a slightly lower or higher level depending on the flow rate selected on the flow control knob.

WARNING

The pressure relief valve is not intend for use as a pressure limiter but as a pressure relief valve.

- (4) Inspiratory time control knob - calibrated between 0.25 and 3.0 seconds, accuracy the greater of $\pm 10\%$ or 0.05 seconds.

Rotation of the knurled knob clockwise increases the inspiratory time.

- (5) Expiratory time control knob - calibrated between 0.5 and 6.0 seconds, accuracy $\pm 10\%$.

Rotation of the knob in a clockwise direction increases the expiratory time.

Breaths per minute is determined in the following way :-

$$\text{B.P.M} = \frac{60}{\text{Inspiratory time} + \text{Expiratory time}}$$

The I:E ratio is determined in the following way :-

$$\text{I:E RATIO} = \frac{\text{INSPIRATORY TIME}}{\text{EXPIRATORY TIME}}$$

(6) Flow control knob - calibrated between 0.1 and 1.0 litres per second, accuracy $\pm 10\%$.

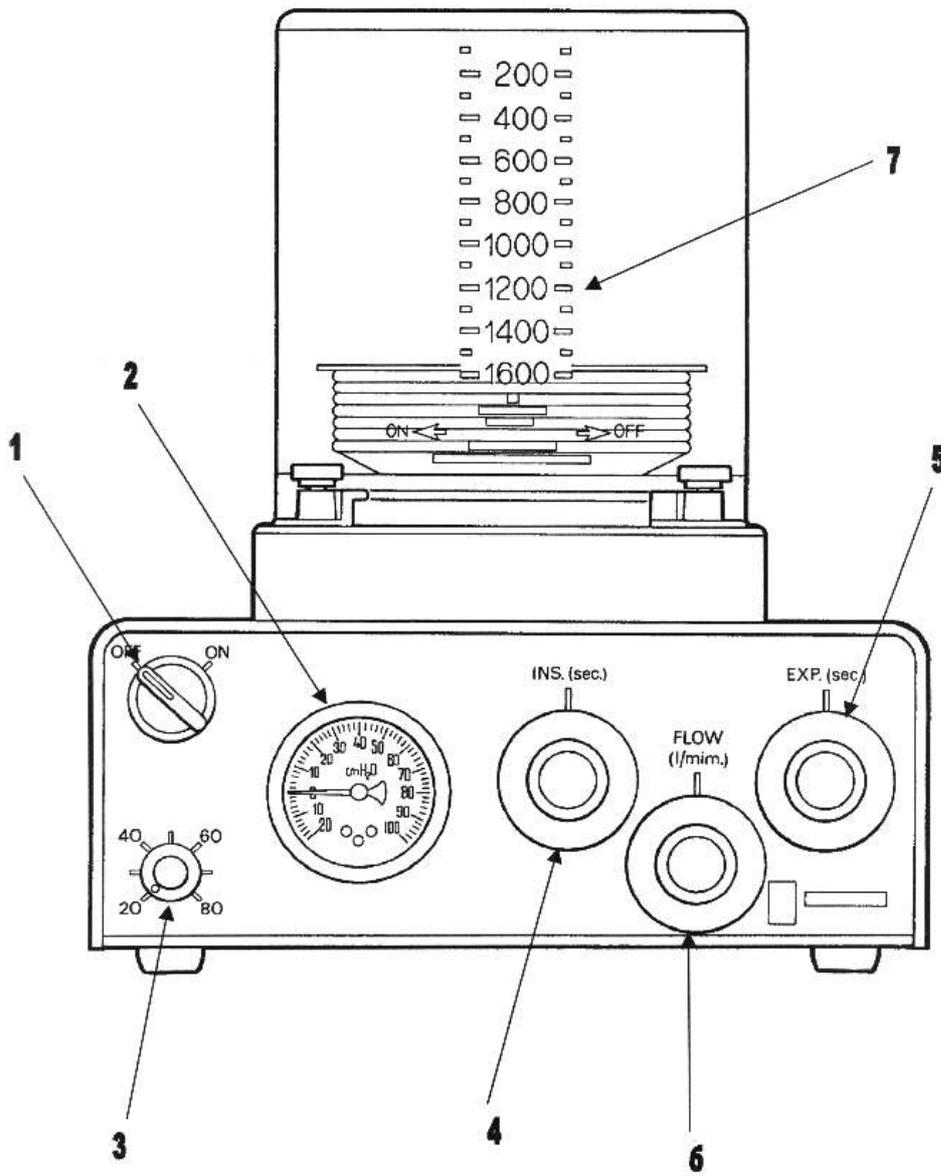
Rotation of the grooved knob in an anti clockwise direction increases the flow rate.

The tidal volume delivered to the patient is determined in the following way :-

$$\begin{array}{l} \text{Tidal volume} = \text{inspiratory time} \times \text{flow rate} \\ \text{(litres)} \qquad \qquad \text{(seconds)} \qquad \qquad \text{(litres per second)} \end{array}$$

Minimum tidal volume is 0.035 litres, maximum deliverable is 1.6 litres because of the bellows capacity.

(7) Bellows unit assembly - the bellows canister is marked with a scale which allows the tidal volume to the patient to be determined with bellows movement. Further information on the bellows unit assembly are given on page 12 and 25.



REAR PANEL- DESCRIPTION

(1) High pressure oxygen inlet connector - a 1.5 metre long high pressure hose is supplied for connection to the DISS oxygen inlet connector.

(2) Driving gas connector - a 17 mm male taper which connects to the bellows drive gas connector with a flexible corrugated tube. (shown in the illustration)

(3) Drive gas exhaust port - the exhaust port which allows the drive gas to be exhausted from within the bellows canister (the outside of the bellows) as the bellows rise during the expiratory phase.

This function is controlled by a silicone diaphragm which is inflated during the inspiratory phase and deflates to allow gas flow during the expiratory phase.

WARNING

Do not attempt to block the drive gas exhaust port.

(4) Pressure relief valve exhaust port - this exhaust port allows the drive gas to exhaust to atmosphere when the set pressure at the adjustable pressure relief valve has been reached.

WARNING

Do not attempt to block the pressure relief exhaust port.

(5) Manometer connection - this connects to the 2.5 metres of silicone tube and the 22 mm taper male / female sensing tee which must be placed in the inspiratory limb of the patient breathing circuit.

(6) Bellows driving gas connector - a 17 mm taper which connects to the ventilator bellows drive gas connector via a flexible corrugated tube.

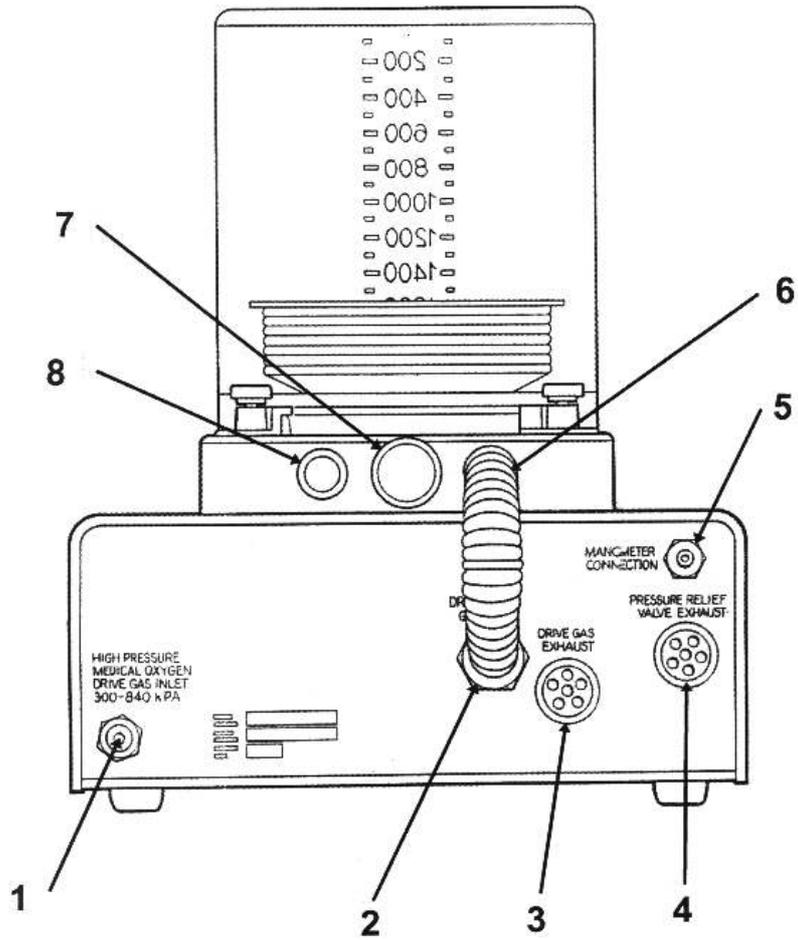
(7) Bellows unit exhaust port - a 30 mm taper to which the anaesthetic gas scavenge system must be connected.

WARNING

The anaesthetic gas scavenging system must not generate more than 0.5 cm H₂O negative or positive pressure.

Failure to comply with this requirement will result in positive or negative pressure within the breathing circuit.

(8) Bellows unit patient connection - a 22 mm male taper connection which connects to the patient circuit via 1.8 metre length of disposable corrugated tubing.



ADULT BELLOWS ASSEMBLY - DESCRIPTION

(1) Bellows base assembly - the bellows base assembly is attached to the top of the ventilator case and incorporates an 'O' seal for the bellows housing to seal against and an 'O' seal to seal between the bellows base and the exhaust gas diaphragm assembly.

An exhaust valve seat which allows the escape of exhaust gas to the bellows exhaust port on the rear of the assembly at the end of the expiratory phase is situated in the centre of the assembly.

WARNING

Care must be taken not to damage the exhaust valve seat.

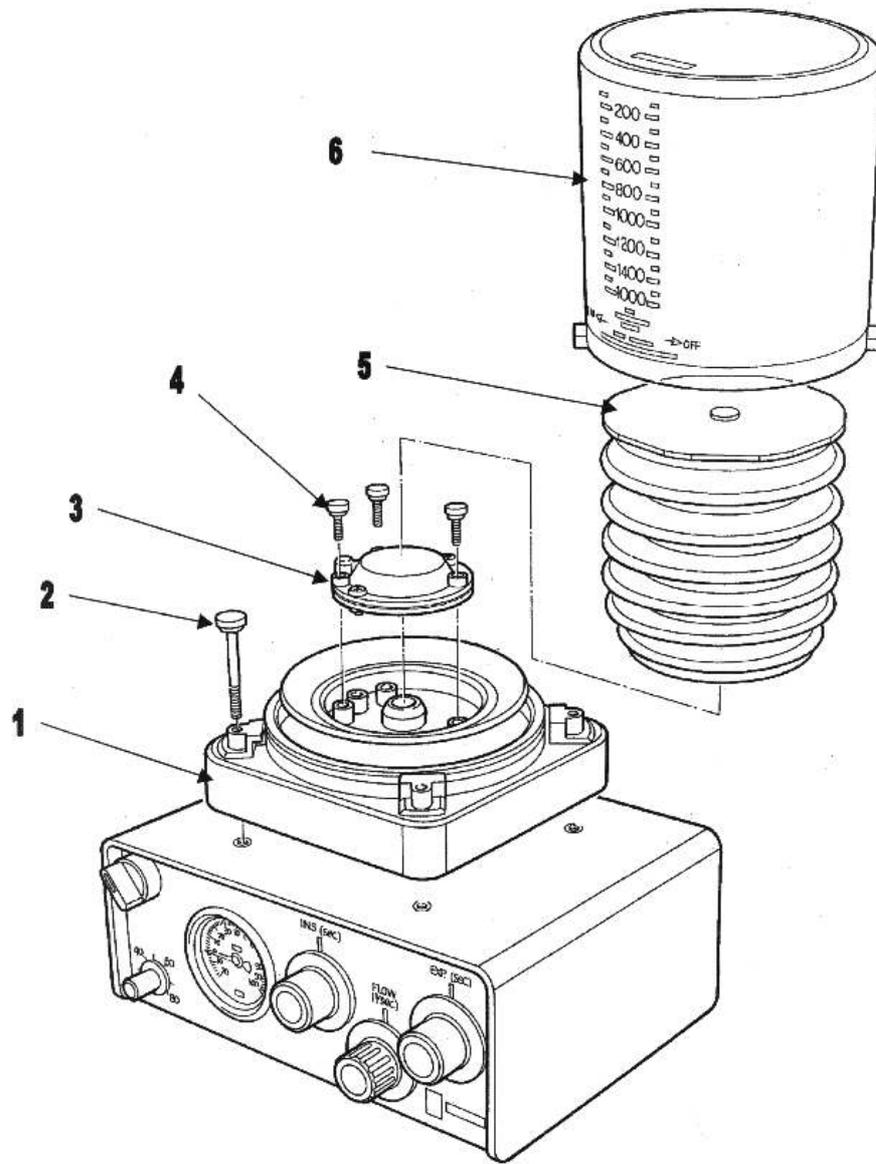
(2) Bellows base screws - thumb screws which hold the bellows base to the top of the ventilator case. (4 off)

(3) Exhaust diaphragm assembly - this assembly contains a diaphragm and a sealing disc which seals on the exhaust valve seat in the bellows base during the expiratory phase.

(4) Exhaust diaphragm assembly screws - thumb screws which hold the diaphragm assembly onto the bellows base assembly. (3 off)

(5) Adult bellows - the bellows are attached to the bellows base assembly by the lower convolution on the shoulder of the bellows base assembly.

(6) Adult bellows housing - the adult bellows housing is located on the bellows base assembly by the location ring on the bellows base assembly; it is then locked in position by twisting clockwise until the lugs are located in the bellows base assembly.



VENTILATION CYCLE - DESCRIPTION

(1) The bellows prior to the start of the inspiratory phase is fully inflated and retains this position due to the weight of the exhaust diaphragm valve giving a slight back pressure within the bellows with the fresh gas flow entering the breathing circuit.

(2) At the start of the inspiratory phase drive gas from the ventilator enters the inside of the bellows housing and forces the bellows down driving the patient gas within the bellows into the breathing circuit.

During the inspiratory phase the ventilator exhaust diaphragm inflates blocking the exhaust port and the bellows exhaust diaphragm is held shut by the pressure of the drive gas flow from the ventilator.

(3) At the start of the expiratory phase the flow of drive gas from the ventilator ceases and the ventilator exhaust diaphragm deflates allowing the drive gas within the bellows housing to exhaust through the ventilator drive gas exhaust port as the bellows rise as the exhaled gas enters the bellows.

Excess exhaled gas exhausts through the bellows exhaust port into the scavenging system.

PNEUMATIC CIRCUIT - DESCRIPTION

The pneumatic circuit consists of two pneumatic timers which control a spool valve supplying high pressure oxygen to the flow control valve.

The oxygen inlet pressure is regulated down by a regulator which incorporates a sintered metal filter.

As the ventilator enters the inspiratory phase the pressure at the flow control needle activates a logic valve and causes the expiratory valve diaphragm to inflate, blocking the ventilator drive gas exhaust port.

At the expiratory phase the diaphragm deflates as it exhausts through the logic valve, allowing the drive gas to exhaust to atmosphere.

The pressure at the diaphragm is controlled by a low-pressure secondary regulator.

The breathing circuit block, which is attached to the rear panel, incorporates the exhaust diaphragm, and also an adjustable pressure relief valve which relieves if the circuit pressure reaches the pre-set level during the inspiratory phase.

The relief valve consists of a spring loaded plunger which seals on a seat with a silicone seal.

The relief pressure is adjusted by changing the spring loading via the knob on the front panel.

There is no provision for sub-ambient pressure relief, as it is unlikely that the patient would be breathing spontaneously during ventilation under anaesthesia.

SPECIFICATION

- (1) Application - adult and paediatric ventilation during anaesthesia.
- (2) Gas supply - oxygen at 275 to 840 kPa, recommended 400 kPa
- (3) Gas supply hose - 1.5 metres of white anti-static hose fitted with a DISS fitting.
- (4) Hose end - as requested by the end user - oxygen probe to BS 5682, mini schrader, or open (supplied as standard)
- (5) Patient airway pressure gauge - 63 mm diameter aneroid pressure gauge with -20 to +100 cm H₂O, \pm (2% + 2 cm H₂O), zero adjustable
- (6) Ventilator to bellows connection - 17 mm taper, NOT to any published standard to avoid mis-connection
- (7) Bellows to patient taper –
22 mm taper to BS EN 1281-1:1997
- (8) Bellows exhaust gas taper –
30 mm taper to BS EN 1281-1:1997
- (9) Inspiratory time range - 0.25 to 3.0 \pm (10% or 0.05) seconds
- (10) Expiratory time range - 0.5 to 6.0 \pm (10% or 0.05) seconds
- (11) Frequency range - 7.5 to 70 breaths per minute (derived from inspiratory and expiratory times).
- (12) Inspiratory gas flow rate - 0.1 to 1.0 \pm (10% or 0.02) litre per second of oxygen; at supply pressures below 350 kPa, flow is reduced to no less than 75% of setting at 275 kPa (pro-rata)
- (13) Tidal volume range - 0.036 to 2.025 litres per breath (derived from inspiratory time and inspiratory flow rate).

NOTE

The maximum tidal volume which can be achieved is 1.6 litres due to the capacity of the bellows. If it is desired to set a tidal volume, this should be done by referring to the movement of the bellows. Small tidal volumes (less than 300 ml) should be achieved using the paediatric bellows assembly.

(14) Minute volume range - derived from tidal volume and frequency. At I:E ratio of 1:1, minute volumes of more than 22.5 l/m can be achieved.

(15) Inspiratory relief pressure - variable between 20 and 80 cm H₂O, calibrated at 20 cm H₂O and 0.5 l/sec. Maximum relief pressure is 100 cm H₂O at maximum flow rate.

(17) I:E ratio - variable between 1:18 and 4.9:1

(18) Weight - 7.7 Kg

| | | |
|-------------------|-------------------------------|----------|
| (19) Dimensions - | height of complete ventilator | - 325 mm |
| | height of control unit | - 110 mm |
| | width | - 260 mm |
| | depth | - 260 mm |

(20) Sterilisation - for details on bellows assembly sterilisation see appropriate section.

(22) Alarms - none - an airway pressure alarm is available as an optional extra.

VENTILATOR STANDARD PARTS

The ventilator is supplied with the following standard parts :-

(1) High pressure drive hose. (Specification as per order)

(2) Ventilator to bellows drive hose.

(3) Manometer tube.

(4) Pressure sensing tee piece. (22 mm male/female taper)

(5) Patient breathing system drive hose with male and female 22 mm taper connectors - 1.8 metre long.

(6) User manual.

VENTILATOR SET- UP PROCEDURE

(1) Mounting the ventilator - the ventilator can be mounted either on the anaesthetic machine shelf or on to a pole mount bracket plate (to suit diameter 25.0 / 25.4 mm poles).

The bracket plate is attached by removing the feet from the ventilator and attaching the bracket in its place.

This plate is an optional extra - see the spares section for details.

(2) High pressure hose assembly - attach the hose to the ventilator, care must be taken to attain a leak free seal without over tightening the fitting. Attach the other end of the hose assembly to the high pressure oxygen supply.

NOTE

The high pressure hose assembly, when not otherwise specified, has a free end which must be terminated with the correct connector for the machine to which it will be attached.

(3) Ventilator to bellows drive hose - attach the corrugated hose to both the ventilator drive gas taper and the bellows drive gas taper.

(4) Manometer tube - attach the silicone tube to the manometer connection on the rear panel, place the pressure sensing tee piece in the inspiratory limb of the patient breathing circuit.

(5) Patient breathing system drive hose - connect the 22 mm female taper to the bellows breathing system taper, connect the other end to the patient circuit.

(6) Scavenging system - connect the exhaust port on the bellows unit to a scavenging system.

WARNING

The anaesthetic gas scavenging system must not generate more than 0.5 cm H₂O of negative or positive pressure.

Failure to comply with this requirement will result in positive or negative pressure within the breathing circuit.

PRE - USE FUNCTION TEST

- (1) Ensure that the ventilator is correctly connected - refer to the ventilator set up procedure.
- (2) Set the adjustable pressure relief valve to the required setting.
- (3) Set the desired inspiratory time.
- (4) Set the desired expiratory time.
- (5) Set the desired flow rate.
- (6) Attach a 2 litre breathing bag to the patient connection as a breathing bag.
- (7) Fill the bellows by using the anaesthetic machine oxygen flush.
- (8) Turn the ventilator on and ensure that the ventilator delivers the correct tidal volume - this can be checked by the scale on the adult bellows housing or by using a flow sensor.
- (9) Remove the breathing bag and occlude the end of the patient connector.
- (10) Refill the bellows with the oxygen flush.
- (11) Turn the ventilator back on and check that the patient circuit relieves at the set level.

WARNING

The pressure relief valve is not intended for use as a pressure limiter but as a pressure relief valve.

The pressure at which the circuit relieves is effected by the flow rate set at the ventilator.

CLINICAL OPERATION

- (1) Prior to use with a patient check that all connections are correct and that there are no leaks.
- (2) Perform the pre-use function test.
- (3) Set the desired ventilator parameters.

WARNING

The actual ventilation of the patient may vary from the set ventilator parameters due to compliance and circuit leaks.

The patient ventilation must be monitored independently from the ventilator.

It is the responsibility of the user to monitor patient ventilation.

NOTE

The use of this ventilator is not recommended without the use of an electronic breathing circuit pressure monitor with appropriate alarms.

The use of this ventilator is recommended with agent and oxygen analysers.

FAULT FINDING

| FAULT CONDITION | POSSIBLE CAUSE |
|---|---|
| When the ventilator is turned on it does not cycle. | <ol style="list-style-type: none">(1) The oxygen high pressure hose is not connected.(2) The oxygen supply is not turned on. |
| Bellows will not fill, or it collapses. | <ol style="list-style-type: none">(1) No fresh gas flow(2) Breathing system hose disconnected.(3) Detached or damaged bellows.(4) Damaged exhaust diaphragm assembly.(5) Missing or damaged 'O' seals.(6) Damaged bellows base assembly. |
| Bellows collapses progressively during use, with normal fresh gas flow. | <ol style="list-style-type: none">(1) Anaesthesia machine APL valve may be open.(2) Breathing system leak.(3) Damaged exhaust diaphragm assembly.(4) Missing or damaged 'O' seal at exhaust diaphragm assembly. |
| Tidal volume is incorrect | <ol style="list-style-type: none">(1) Missing or damaged 'O' seals.(2) Damaged exhaust diaphragm assembly.(3) Partially detached bellows.(4) High compliance.(5) low oxygen inlet pressure. |

USER MAINTENANCE

Service schedule

The ventilator must be serviced by a factory trained engineer to the following schedule: -

- (a) 3 monthly inspection and function check.
- (b) 6 monthly bellows replacement.
- (c) 2 yearly replacement of exhaust diaphragm.
- (d) 5 yearly major service.

Cleaning of the ventilator control unit

The ventilator control unit must only be cleaned with a damp cloth and if necessary with warm mild detergent to remove persistent grime.

WARNING

Do not allow the cleaning liquid to enter the control unit.

CAUTION

Do not use harsh or abrasive cleaning agents on any parts of the ventilator.

Cleaning and sterilisation of the bellows unit

To disassemble the bellows assembly for cleaning and sterilisation :-

(1) Twist the bellows housing anticlockwise until the location lugs clear the bellows base, then lift it off by pushing gently at the front.

WARNING

Ensure that the cover is not levered off on one of the location lugs on the bellows housing.

(2) Pull the bellows gently off the bellows base.

(3) Unscrew the exhaust diaphragm from the bellows base.

WARNING

Do not lose the 'O' seal which seals between the bellows base and the expiratory diaphragm.

WARNING

Do not damage the exhaust seat or the seat on the exhaust diaphragm.

| ITEM | STERILISATION METHOD |
|----------------------------|---|
| Bellows housing | Warm mild detergent solution.(no abrasive cleaner or alcohol) |
| Bellows | Gas or liquid (such as cidex, Sporicidin and Sonacide.) |
| Exhaust diaphragm assembly | Gas or liquid. |
| Bellows base assembly | Gas, liquid or low temperature autoclave |

ORDERING INFORMATION

- 9050-014 OES ORION anaesthesia ventilator.
- 9060-001 1.5 metre oxygen drive hose - DISS to open end.
- 9060-010 Corrugated drive gas hose - 265 mm
- 9060-011 Corrugated drive gas hose - 1500 mm
(for remote mounting of the bellows)
- 9060-012 Patient breathing system drive hose -1800 mm
- 9060-020 Breathing system pressure tee - piece - 22 mm
male / female taper
- 9060-015 Pressure sensing tube - silicone 2.5 metres.
- 9070-001 Adult bellows assembly.
- 9070-002 Adult bellows housing.
- 9070-003 Adult bellows.
- 9070-004 Exhaust diaphragm assembly.
- 9070-005 Exhaust diaphragm assembly screws - 3 off.
- 9070-006 Bellows base assembly.
- 9070-007 Bellows base thumbscrews - 4 off.
- 9050-005 Pole mount bracket
- 9050-001 Breathing circuit pressure monitor.

DISPOSAL

The ORION Ventilator contains metal and plastic parts, which must be disposed of appropriately at the end of the lifetime of the product. Re-cycling may be possible. Refer to your local authorities.

OES Medical Ltd will accept returned product for disposal, if it is returned at your own expense.