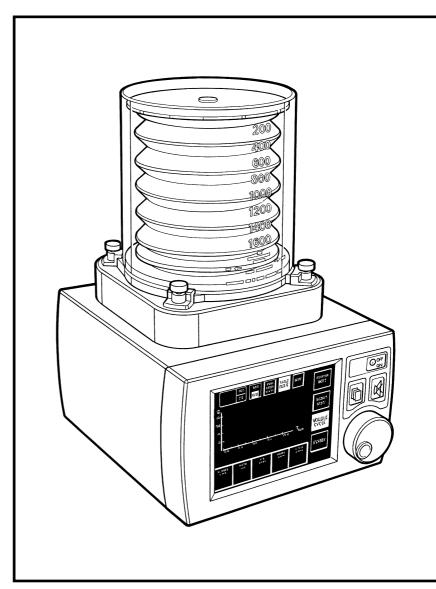


# AV900 Ventilator V.4 User Manual



AV900 Version 4 Software

Partnership for Life

## **IMPORTANT**

### **Servicing and Repairs**

In order to ensure the full operational life of this ventilator, servicing by a Penlon-trained engineer should be undertaken periodically.

The ventilator must be serviced to the following schedule:

- (a) Six monthly service inspection and function testing.
- (b) Annual service.
- (c) Five year major service including battery replacement.

Details of these operations are given in the AV900 Service Manual, available only for Penlon trained engineers.

For any technical enquiry regarding the servicing or repair of this product, contact the nearest accredited Penlon agent:

or communicate directly with:

Technical Support Penlon Limited Abingdon Science Park Barton Lane Abingdon OX14 3PH UK

Tel: 44 (0) 1235 547076 Fax: 44 (0) 1235 547062 E-mail: technicalsupport@penlon.co.uk

Always give as much of the following information as possible:

- 1. Type of equipment
- 2. Product name
- 3. Serial number
- 4. Software revision number
- 5. Approximate date of purchase
- 6. Apparent fault

## FOREWORD

This manual has been produced to provide authorised personnel with information on the function, routine performance and maintenance checks applicable to the AV900 Anaesthesia Ventilator with version 4 software.

Information contained in this manual is correct at the date of publication. The policy of Penlon Limited is one of continued improvement to its products. Because of this policy, Penlon Limited reserves the right to make any changes which may affect instructions in this manual, without giving prior notice.

Personnel must make themselves familiar with the contents of this manual and the machine's function before using the apparatus.

#### THE IMPORTANCE OF PATIENT MONITORING

#### WARNING

Anaesthetic systems have the capability to deliver mixtures of gases and vapours to the patient which could cause injury or death unless controlled by a qualified anaesthetist.

There can be considerable variation in the effect of anaesthetic drugs on individual patients so that the setting and observation of control levels on the anaesthesia systems does not in itself ensure total patient safety.

Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist but are not true clinical monitors as the condition of the patient is also dependent on his respiration and the functioning of his cardio-vascular system.

IT IS ESSENTIAL THAT THESE ELEMENTS ARE MONITORED FREQUENTLY AND REGULARLY AND THAT ANY OBSERVATIONS ARE GIVEN PRECEDENCE OVER MACHINE CONTROL PARAMETERS IN JUDGING THE STATE OF A CLINICAL PROCEDURE.

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## USER RESPONSIBILITY

This anaesthesia ventilator has been built to conform with the specification and operating procedures stated in this manual and/or accompanying labels and notices when checked, assembled, operated, maintained and serviced in accordance with these instructions.

To ensure the safety of this device it must be checked and serviced to at least the minimum standards laid out in this manual. A defective, or suspected defective, product must not under any circumstances be used.

The user must accept responsibility for any malfunction which results from noncompliance with the servicing requirements detailed in this manual.

Additionally, the user must accept responsibility for any malfunction which may result from misuse of any kind or non-compliance with other requirements detailed in this manual.

Worn, broken, distorted, contaminated or missing components must be replaced immediately. Should such a repair become necessary it is recommended that a request for service advice be made to the nearest Penlon accredited agent.

This device and any of its constituent parts must be repaired only in accordance with written instructions issued by Penlon Limited and must not be altered or modified in any way without the written approval of Penlon Limited. The user of this equipment shall have the sole responsibility for any malfunction which results from improper use, maintenance, repair, damage or alteration by anyone other than Penlon or its appointed agents.

USA and Canadian Federal Law restricts the sale and use of this device to, or on the order of, a licensed practitioner.

Statements in this manual preceded by the following words are of special significance:

WARNING	means there is a possibility of injury to the user or others.
CAUTION	means there is a possibility of damage to the apparatus or other property.
NOTE	indicates points of particular interest for more efficient and convenient operation.

Always take particular notice of the warnings, cautions and notes provided throughout this manual.

## **1. WARNINGS AND CAUTIONS**

The following WARNINGS and CAUTIONS must be read and understood before using this ventilator.

### WARNINGS

#### **General Information**

1. Personnel must make themselves familiar with the contents of this manual and the machine's function before using the ventilator.

#### **Before Using the Ventilator**

- 2. Before the ventilator is used clinically for the first time, verify that the hospital engineering department has carried out an earth continuity test.
- 3. Excessive electronic noise caused by other poorly regulated devices, such as an electrocautery unit, may adversely interfere with the proper functioning of the ventilator.

To avoid this problem, do not connect the ventilator's power cord into the same electrical wall outlet or adaptor strip into which an electrocautery unit is connected.

- 4. If used with a mains extension cord, the unit may be subject to electro-magnetic interference.
- 5. The driving gas supply must be clean and dry to prevent ventilator malfunction.
- 6. This ventilator is designed to be driven by oxygen or medical air only. It is calibrated during manufacture for use with either gas.

Before the ventilator is used clinically for the first time, the commissioning engineer must confirm that the internal Air/Oxygen switch is set correctly for the gas that is to be used.

The use of any other gas will cause inaccurate operation and may damage the ventilator, resulting in potential injury to the patient. 7. The driving gas is discharged through the opening in the back of the ventilator control unit. The discharged gas may contaminate the environment, and should therefore be extracted using a gas scavenging

system.

8. The bellows can only support approximately 1 kPa (10 cmH2O) differential positive pressure, above which it may be dislodged from the mounting ring, resulting in dangerous malfunction of the ventilator.

Do not connect a PEEP valve or other restrictive device to the exhaust port on the bellows base.

This would increase the pressure inside the bellows and the bellows could detach from the base, causing serious malfunction.

The breathing system which conveys 9. gases from the anaesthetic machine to the patient, and disposes of expired gases, is a vital part of the anaesthetic delivery system. Because breathing systems require frequent cleaning and disinfection they are not a permanent part of the anaesthetic ventilator and therefore cannot be directly under the control of the anaesthetic ventilator manufacturer. However, we strongly recommend that only breathing systems which have been approved and authorised by Penlon for use with AV900 should be employed.

Do not use conductive breathing system hoses.

When mechanical ventilation is employed the patient breathing system must be connected directly to a pressure relief valve to prevent the possibility of barotrauma.

10. Do not connect a spirometer to the exhaust port on the bellows base. The device will not measure exhaled volumes in that position.

## WARNINGS AND CAUTIONS

11. The operation of each alarm function should be verified daily.

Periodically check the alarms at clinically suitable intervals. If the audible alarm or the visual indicator of any alarm function fails to activate during any alarm condition or fails to reset after the alarm has been cleared, refer the unit to an authorised service technician.

12. Before using the ventilator check that all connections are correct, and verify that there are no leaks.

Patient circuit disconnects are a hazard to the patient. Extreme care should be taken to prevent such occurrences.

It is recommended that Penlon Safelock fittings are used throughout the breathing circuit.

### **Using the Ventilator**

- 13. This apparatus must not be used with, or in close proximity to, flammable anaesthetic agents. There is a possible fire or explosion hazard.
- 14 Anaesthesia apparatus must be connected to an anaesthetic gas scavenging system to dispose of waste gas and prevent possible health hazards to operating room staff. This requirement must be observed during test procedures as well as during use with a patient. Any problem arising from an improperly functioning scavenging system is solely the user's responsibility.
- 15. When the ventilator is connected to a patient, it is recommended that a qualified practitioner is in attendance at all times to react to an alarm or other indication of a problem.
- 16. In compliance with good anaesthesia practice, an alternative means of ventilation must be available whenever the ventilator is in use.

- 17. The basic model AV900 is not equipped with an oxygen analyser. It is recommended that the patient oxygen concentration should be monitored continuously, at or near the proximal airway with an oxygen monitor that includes high/low alarms.
- 18. If the drive gas supply pressure drops below a nominal 241 kPa (35 psi), the LOW DRIVE GAS SUPPLY alarm will activate both audibly and visually. Patient minute volume may be reduced due to lowered flow rates
- 19. An audible alarm indicates an anomalous condition and should never go unheeded.
- 20. The characteristics of the breathing circuit connected between the ventilator and the patient can modify or change patient ventilation. To assist the maintenance of the delivered patient tidal volume, the ventilator control system software includes: A) a compliance compensation algorithm, a fresh gas compensation B)

*B) a fresh gas compensation algorithm.* 

However, patient ventilation must be monitored independently from the ventilator. It is the responsibility of the user to

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

- 21. On models with spirometry, care must be taken to ensure that the flow sensors are connected correctly to the inspiratory and expiratory ports of the absorber.
- 22. The Vent Inop (ventilator inoperative) alarm indicates that one of the following conditions has occurred:A) The drive gas solenoid has failed.
  - B) The flow control valve has failed.
  - C) Internal electronic fault.
  - D) Internal electrical fault.

E) Software error.

Note that if a ventilator error is detected, an error code will be displayed on the front control panel display.

## WARNINGS AND CAUTIONS

23. The High and Low Airway Pressure Alarms are important for patient care. The ventilator is designed to be used with a distal sensing tee only. (Catalogue No. 53194, Breathing System Tee Assembly - see section 8).

> It is important that the distal sensing tee is properly located in the expiratory limb of the circuit between the patient and the expiratory one way valve. See section 5.1.4.

24. The patient must be continuously attended and monitored when Patient Support Mode is in use.

#### **User Maintenance**

#### **Control Unit**

25. Opening the control unit by unauthorised personnel automatically voids all warranties and specifications.

> Prevention of tampering with the control unit is exclusively the user's responsibility. If the control unit seal is broken, the manufacturer assumes no liability for any malfunction or failure of the ventilator.

26. For continued protection against fire hazards, replace the two fuses only with the identical type and rating of fuse.

See section 4.41 for fuse rating.

27. If the internal battery is fully discharged, the ventilator will not function in the event of mains power failure. The battery must be recharged before the ventilator is used clinically, otherwise backup cannot be guaranteed. See section 9 for battery maintenance.

See also CAUTION No. 7.

Used or defective batteries must be disposed of according to hospital, local, state, and federal regulations.

28. No oil, grease or other flammable lubricant or sealant must be used on any part of the ventilator in close proximity to medical gas distribution components. There is a risk of fire or explosion. 29. Exterior panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing. There is a possible electric shock hazard.

#### **Bellows Assembly**

30. The valve seat on the patient gas exhalation diaphragm valve in the base of the bellows assembly must be cleaned regularly - see section 7.2. Failure to keep the valve seat clean could result in the diaphragm sticking, thus preventing exhalation.

> Great care must be taken not to damage the precision surface of the valve seat on the patient gas exhalation diaphragm valve in the base of the bellows assembly.

> Never use any hard object or abrasive detergent to clean it; use only a soft cloth.

If the valve seat is damaged, the valve will leak and may cause serious ventilator malfunction.

## WARNINGS AND CAUTIONS

### CAUTIONS

- 1. Do not sterilise the ventilator control unit. The internal components are not compatible with sterilisation techniques and damage may result.
- For ventilator components which require sterilisation, peak sterilisation temperatures should not exceed 136<sup>o</sup>C (275<sup>o</sup>F) to prevent possible damage. (See sections 7.2 and 7.3).
- Those parts suitable for ethylene oxide sterilisation should, following sterilisation, be quarantined in a well ventilated area to allow dissipation of residual gas absorbed by the components. Follow the steriliser manufacturer's recommendations for any special aeration periods required.
- 4. The exhalation valve located in the bellows base assembly and the paediatric bellows adaptor must be cleaned and sterilised separately. See sections 7.2 and 7.3.
- 5. Care must be taken not to let any liquid run into the control unit; serious damage may result.
- 6. Always check for correct fitment, and carry out a full function test before clinical use, if the bellows has been removed and refitted for any reason. See sections 5.2 and 7.2.
- 7. Damage may occur to the battery if it is allowed to remain in a discharged state. Check the battery frequently if the ventilator is in storage (see Appendix 1).
- 8. On models with spirometry, fresh gas compensation is disabled if :
  a) The spirometry system is turned OFF through the menu system, or
  b) The spirometry system is not functioning correctly.
- 9. On models with spirometry, fresh gas mixture compensation is disabled if :
  a) The spirometry system is turned OFF through the menu system, or
  b) The spirometry system is not functioning correctly.
  - c) The O<sub>2</sub> monitor is switched OFF.

10. NOTE: On models with spirometry, circuit compliance is not activated until Fresh Gas Compensation is switched OFF.

## WARNINGS AND CAUTIONS - Oxygen Monitor

### **Oxygen Monitor**

#### WARNINGS

- We recommend calibration of the 1. oxygen monitor every time the system is turned on, as a safety precaution.
- Do not attempt to open the fuel cell. 2. The sensor contains small quantities of :

a) electrolyte, classified as a harmful irritant which is potentially hazardous, and

b) lead.

Used or defective cells must be disposed of according to hospital, local, state, and federal regulations.

- ALWAYS check the integrity of the 3. sensor assembly before use. See section 3.4.
- 4. Once exhausted, the sensor must be disposed of according to hospital, local, state and federal regulations.
- The sensor measures oxygen partial 5. pressure, and its output will rise and fall due to pressure change. An increase in pressure of 10% at the sensor inlet will produce a 10% increase in sensor output.

### CAUTIONS

- 1. Do not sterilise the oxygen sensor or control unit components. These components are not compatible with sterilisation techniques and damage may result.
- 2. Do not autoclave or expose the sensor to high temperatures.
- If the sensor shows signs of being affected З. by condensation, dry the sensor with soft tissue.

Do not use heat to dry the sensor.

### NOTES

- The O2 SENSOR FAULT alarm indicates 1. that one of the following conditions has occurred.
  - a) Internal electrical fault
  - b) Software/electronics fault
  - c) Oxygen sensor fault.
- 2. The concentration read-out may, in certain conditions of excess pressure, show a value above 100%. To accommodate these conditions it is possible to set the high alarm value up to 105% (see section 5.4.4).
- З. To maintain maximum sensor life, always remove the unit from the breathing circuit after use.
- The accuracy of flow and volume 4. measurements may be reduced if the oxygen monitor is not in use.
- Fresh gas mixture compensation is disabled 5. if the oxygen monitor is switched OFF.

The AV900 Ventilator is a software controlled, multi-mode ventilator, designed for mechanical ventilation of adult and paediatric patients under general anaesthesia.

In addition, in spontaneous mode, it can be used to monitor spontaneously breathing patients

It is designed for use in closed-circuit anaesthesia and also to drive a Mapleson D circuit.

### Indications for use of the device:

The AV900 Ventilator is intended to provide continuous mechanical ventilatory support during anaesthesia. The ventilator is a restricted medical device intended for use by qualified trained personnel under the direction of a physician. Specifically the ventilator is applicable for adult and paediatric patients.

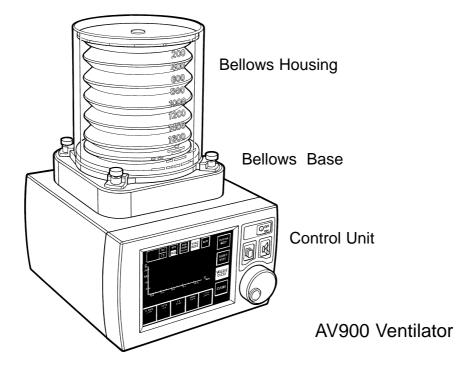
The ventilator is intended for use by health care providers, i.e. Physicians, Nurses and Technicians with patients during general anaesthesia

### Oxygen Monitor (optional)

The Oxygen Monitor is intended to continuously measure and display the concentration of oxygen in breathing gas mixtures used in anaesthesia, and is intended for adult and paediatric patients.

The oxygen monitor is a module within an anaesthesia machine, and is a mandatory module when the spirometry option for AV900 is specified.

The oxygen monitor is intended for use by health care providers, i.e. Physicians, Nurses and Technicians for use with patients during general anaesthesia.



### 3.1 General Description

The AV900 is a time-cycled, volume/pressure controlled, and pressure limited ventilator for closed circuit ventilation or for use with a Mapleson D circuit.

The ventilator is compliance compensated and has a user selectable option of an inspiratory pause fixed at 25% of the inspiratory time.

In addition, models with spirometry are fresh gas compensated and also feature user selectable gas mixture compensation.

The print function provides a permanent record of function activity for up to eight hours during a procedure, or can be used to record waveforms.

The bellows unit can be easily detached and then refitted to the bellows base assembly to facilitate cleaning.

### Drive gas supply

The ventilator drive gas supply can be oxygen or air. The supply must be at 262 to 689 kPa (38 to 100 psi). Note that the drive gas is specified by the customer prior to delivery. Conversion from one drive gas to another must be carried out by a Penlontrained service engineer.

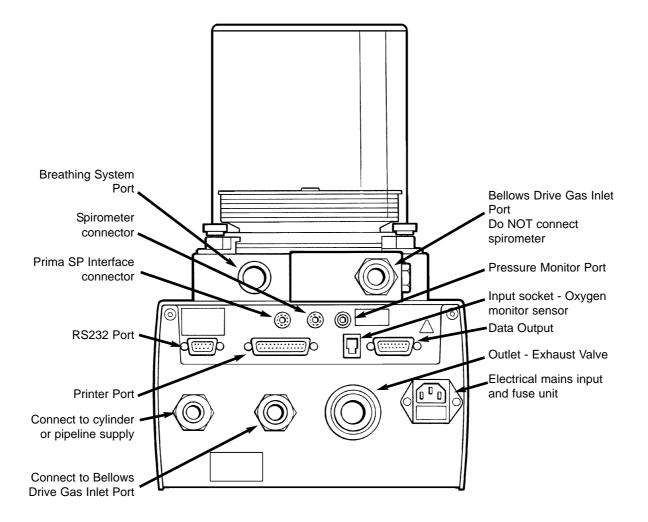
### Options

a) Spirometry, and an integral oxygen monitor to measure oxygen concentration in the breathing circuit.

Note that on models without spirometry, the patient support function is disabled.

b) Paediatric bellows assembly.

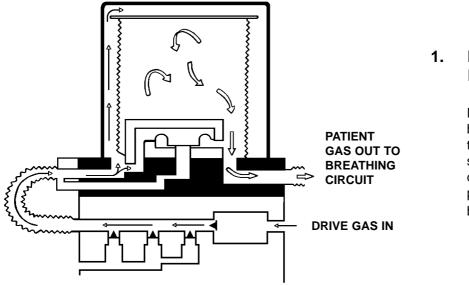
c) Mounting options - the AV900 can be mounted on the anaesthetic machine as a single, complete unit, or the bellows unit and the control unit can be mounted separately.



### **Rear Panel and Gas Ports**

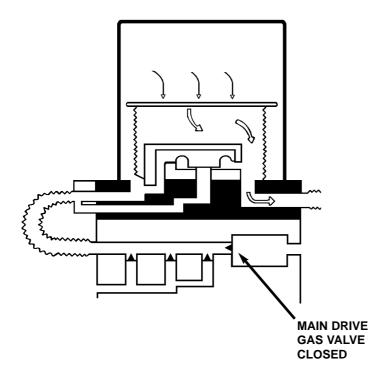
### 3.2 Ventilation Cycle

This section provides a simplified description of the ventilation cycle.



# . Inspiratory Phase

Drive gas pressure builds up above the bellows, which starts to move down, forcing patient gas into the breathing system.



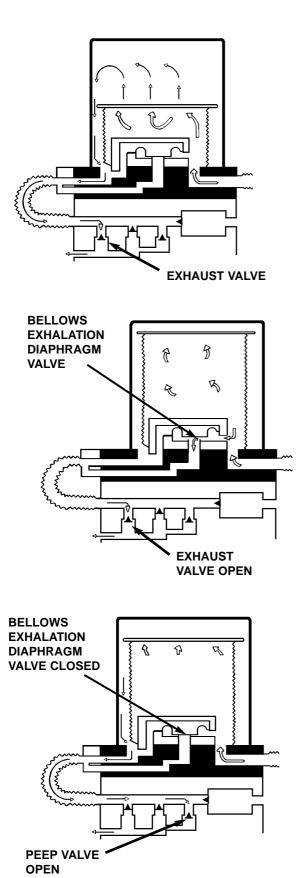
### 2. End of Inspiratory Phase

The main drive gas valve closes and the bellows stops moving.

### NOTE

Inspiratory Pause (Volume Mode only, user selectable) Inspiratory pause holds the inspiratory phase at the end of inspiration, for a period of 25% of the inspiratory time before reverting to expiratory phase.

See section 3.3.3.



### 3. Beginning of Expiratory Phase

The exhaust valve opens, allowing the drive gas above the bellows to escape to atmosphere.

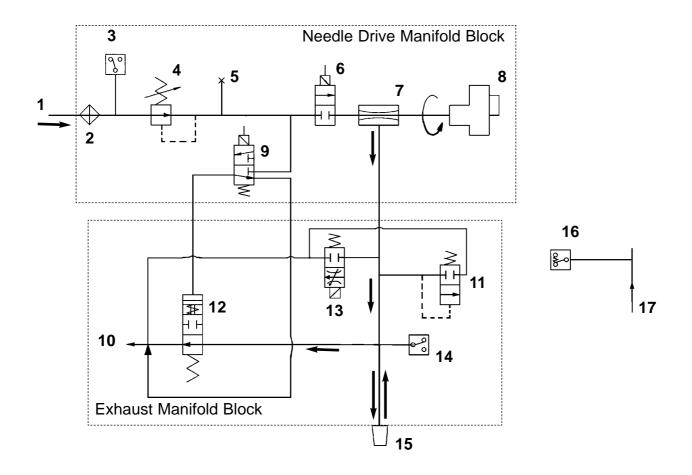
The bellows starts to rise and exhaled gas enters the bellows.

### 4. End of Expiratory Phase

The bellows exhalation diaphragm valve in the base of the bellows assembly opens when the bellows reaches the top of the chamber. Patient circuit gas exits through the bellows assembly exhaust port, and then through the ventilator exhaust valve.

5. PEEP - Positive End Expiratory Pressure (user selectable)

> During PEEP, the bellows exhalation diaphragm valve is closed. Fresh gas flows in the patient circuit. Pressure in the bellows increases. The PEEP proportioning valve will maintain the pressure with a controlled bleed flow.



### PNEUMATIC SYSTEM DIAGRAM

- 1. Gas supply
- 2. Input gas filter
- 3. Low supply pressure detector
- 4. Input pressure regulator
- 5. Test point
- 6. Inspiratory valve
- 7. Drive gas flow metering valve
- 8. Stepper motor and feedback potentiometer (for 7)
- 9. Expiratory valve

- 10. Exhaust outlets
- 11. Pressure relief valve
- 12. Exhaust valve
- 13. Proportional valve
- 14. Drive gas over-pressure switch
- 15. Outlet to bellows assembly
- 16. Pressure transducer
- 17. Inlet from breathing circuit

### 3.3 Pneumatic System

### 3.3.1 System Operation

Refer to the pneumatic system diagram on the previous page.

The AV900 Ventilator is designed to operate on a 262 - 689 kPa (38 -100 psi) drive gas supply (oxygen or air - to customer's requirement). The gas source is connected to the DRIVE GAS SUPPLY DISS fitting on the rear of the ventilator control unit.

The gas supply should be capable of a flow rate of 80 L/min while maintaining a minimum pressure in excess of 262 kPa (38 psi).

The drive gas is filtered with a 40-micron Input Gas Filter which protects the pneumatic components from incoming particulate matter.

The Low Supply Pressure Detector is a pressure switch set at a predetermined level to detect a loss or reduction of the input gas source pressure.

When the pressure falls below 243 kPa (35 psi), the LOW SUPPLY PRESSURE indicator will be displayed and the high priority audible alarm will activate.

The Input Pressure Regulator conditions the input drive gas to 221 kPa  $\pm$  21 kPa (32 psi  $\pm$  3 psi) which will operate the internal pneumatic system.

The Inspiratory Valve is an electropneumatically-driven valve with a large orifice. The valve supplies the drive gas to the Drive Gas Flow Metering Valve .

The Expiratory Valve operates as a pilot valve for the exhaust valve.

The Drive Gas Flow Metering Valve is a variable-orifice needle valve which determines the drive gas flow rate to the bellows during inspiration.

The Valve Position Feedback Potentiometer and the Flow Control Motor function together to set a flow rate as required by the front panel controls.

The flow from the Drive Gas Flow Metering Valve goes to the Bellows Assembly, via the drive connector.

The flow then closes the exhalation diaphragm valve and pushes the bellows downward.

As the bellows moves downwards, the gas

inside the bellows is forced into the Breathing System.

At the end of inspiration the exhaust valve opens and allows the drive gas in the top of the bellows housing to exhaust out through the Exhaust Outlet.

As the pressure in the top of the bellows housing is reduced to zero, the patient exhales into the breathing system and the bellows rises.

### 3.3.2 Compliance Compensation and Fresh Gas / Fresh Gas Mixture Compensation

#### WARNING

The AV900 has circuit compliance compensation (and fresh gas compensation on models fitted with spirometry). However, the actual tidal volume delivered to the patient may be different to the ventilation parameters set by the user, due to:

- A) an extreme compliance condition,
- B) a substantial system leak,
- C) patient circuit pressure effects, or
- D) extreme fresh gas flows

In addition, high fresh gas flows will lead to an increased Vt being delivered to the patient.

Note that on models fitted with spirometry, the actual tidal volume exhaled will be displayed.

The patient <u>must</u> be monitored independently from the ventilator.

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

#### **Circuit Compliance Compensation**

A compliance compensation algorithm is built into the control software which monitors the volume of gas delivered and the rate of pressure rise.

It calculates an additional volume to deliver into the breathing system to compensate for the reduced volume delivered to the patient as a result of the increased breathing system pressure.

As a safety feature, this additional volume is restricted to a maximum of 15% of the set tidal volume irrespective of the maximum pressure rise.

NOTE: On models with spirometry, circuit compliance compensation is not activated until Fresh Gas Compensation is switched OFF.

## Fresh Gas Compensation - models with Spirometry

A fresh gas compensation algorithm is built into the control software.

Delivered volume will be altered by up to 45% to allow compensation for fresh gas.

Fresh gas compensation is disabled if :

a) The spirometry system is turned OFF through the menu system, or

b) The spirometry system is not functioning correctly.

### Fresh Gas Mixture Compensation - models with Spirometry

The spirometry system compensates for fresh gas mixture - the user must access the menu system and select the gas mixture that will be used for each clinical procedure.

Fresh gas mixture compensation is disabled if : a) The spirometry system is turned OFF through the menu system, or

b) The spirometry system is not functioning correctly.

c) The O<sub>2</sub> monitor is switched OFF.

### 3.3.3 User Selectable Inspiratory Pause

A user selectable inspiratory pause is provided which, when activated, holds the inspiratory phase at the end of inspiration, for a period of 25% of the inspiratory time before reverting to the expiratory phase.

### NOTE

Inspiratory Pause function is not available in PRESSURE mode and SPONTANEOUS mode.

### 3.3.4 Automatic Altitude Compensation

Ambient pressure is monitored and the ventilator automatically compensates the delivered volume according to the local atmospheric pressure.

#### 3.3.5 Patient Gas Pressure Transducer

The Patient Gas Pressure Transducer is connected to the patient breathing system via the rear panel.

In VOLUME CYCLE mode whenever this pressure exceeds the maximum working pressure as set on the front panel, an alarm is activated and the following occurs:

1. The HIGH AIRWAY PRESSURE visual

indicator is illuminated (high priority alarm).

- 2. The audible alarm is activated (high priority alarm).
- The Inspiratory Valve is closed, the exhaust valve is opened, and the inspiration cycle is ended. Note:

The rate of breaths per minute will be affected in this condition as the ventilator will cease to deliver flow above the maximum working pressure.

#### WARNING

## If this alarm is ignored, the patient may receive an insufficient minute volume.

In PRESSURE controlled mode, when the set pressure is reached the following occurs:

- 1. The Inspiratory valve is closed.
- 2. The ventilator maintains the set pressure until the end of the inspiration cycle.

### 3.3.6 High Pressure Protection

High pressure in the ventilator is limited by three independent protective systems.

- 1. The Pressure Transducer has already been described.
- 2. The Driving Gas Over-pressure Switch is set at 80 cmH2O and will shut off drive gas flow at this value.
- The Pressure Relief Valve is a mechanical over-pressure relief which will open at 80 cmH2O, diverting the driving gas to atmosphere through the exhaust port.

The Exhaust Outlet on the back of the control unit accepts the drive gas exhaust from all internal pneumatic components.

### 3.3.7 Spirometry System

Spirometry (if fitted) can be enabled, or disabled via the on-screen menu system.

NOTE

*If the spirometry system is turned OFF:* 

a) Fresh gas / fresh gas mixture compensation is disabled.

b) Patient support function is disabled.

## **DESCRIPTION** - O2 Monitor

# 3.4 Oxygen Monitor (Optional)

The oxygen monitor continuously measures and indicates the concentration of oxygen in the breathing system, and triggers an alarm when the concentration varies from the set levels.

### 3.4.1 System Description

The Oxygen Monitor uses a fast-responding, oxygen-specific, self powered sensor that achieves 90% of final value in less than 10 seconds.

An external probe is supplied with a 2 m (6 ft) extendable cable and diverter fitting. The probe has a safety lock.

The system has user-adjustable high-level and low-level alarms with visual and audible indication of alarm conditions.

### 3.4.2 The MOX-3 Oxygen Sensor

The MOX-3 oxygen sensor offers quick response, linear output over the entire 0-100% oxygen range, and long service life.

The MOX-3 is a self-powered galvanic cell that generates a current proportional to oxygen concentration.

The cell has a highly stable output over its operating life. Significant output loss is only shown at the very end of its life.

Typical sensor drift rates are less than 1% per month when the sensor is exposed to gas in typical applications.

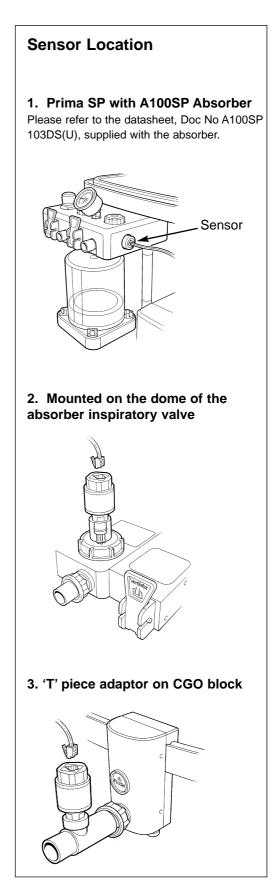
#### Sensor life:

approximately 1 500 000 O2 percent hours at 20<sup>o</sup>C (minimum one year in most normal

applications).

Sensor lifetime is governed by the mass of lead available to react with the oxygen and its rate of consumption. High oxygen partial pressure and high temperature will increase the sensor output current, thus shortening the operation life.

At the point where all lead has been consumed, the output will fall very quickly to zero over a period of two to three weeks.



## **DESCRIPTION** - O2 Monitor

### 3.4.3 Display

High-set, low-set, and oxygen concentration percentage readings are displayed on screen.

### **Oxygen Concentration**

The display provides a direct readout of measured oxygen concentrations in the range 0-100%.

#### Low Alarm Set - limited within 18-99%

The oxygen percentage, set by the user, at which the low alarm will be activated.

To set the low oxygen alarm, see section 5.4.4

#### High Alarm Set - limited within 19-105%

The oxygen percentage, set by the user, which the high alarm will be activated.

Note that in certain conditions of excess pressure, the readout may show a value above 100%.

To set the high alarm, see section 5.4.4.

### 3.4.4 Oxygen Monitor Alarms

### **HIGH O2 ALARM**

The high O2 alarm is triggered when the oxygen concentration is 1% above the set value.

a) The High O<sub>2</sub> Alarm visual indicator will illuminate.

b) A high priority audible alarm will sound.

To cancel this alarm, the high alarm setting must be equal to, or above the oxygen concentration. The alarm can be muted for 120 seconds.

LOW O2 ALARM The low alarm is triggered when the oxygen concentration is 1% below the set value.

a) The Low O2 Alarm visual indicator will illuminate.

b) A high priority audible alarm will sound.

To cancel this alarm, the low alarm setting must be equal to, or below the oxygen concentration. The alarm can be muted for 120 seconds.

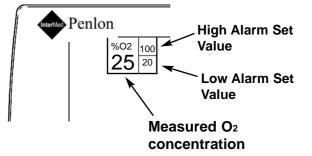
### **O2 SENSOR FAULT**

The alarm is triggered:

when either the oxygen sensor is i) disconnected or approaching the end of its life.

ii) if the O<sub>2</sub> concentration exceeds 110%.

a) The legend O2 SENSOR FAULT will illuminate.



### **Oxygen Monitor Display**

b) A high priority audible alarm will sound.

To cancel this alarm, check the sensor connection or replace the sensor. The alarm can be muted for 120 seconds.

### **O2 SENSOR LOW**

This alarm indicates the sensor has approached the end of its life.

The legend O<sub>2</sub> SENSOR LOW will be displayed, and a low priority alarm (single note) will sound.

The sensor must be replaced as the output will fall very quickly to zero within two to three weeks of normal usage.

See section 7.5 for sensor replacement.

### 3.4.5 Oxygen Monitor Alarm Mute

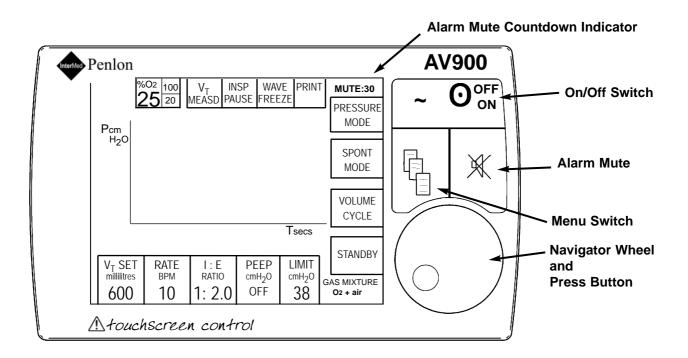
In an alarm condition, pressing the ALARM MUTE button will deactivate the audible alarm but the alarm message display will remain on screen.

The switch will illuminate, and a single note will sound.

The alarm mute can not be operated:

a) Until the mute time is over, or the alarm condition has been rectified.

b) When O2 concentration drops below 18%.



### 3.5 Control Unit

### 3.5.1 System Controls and Parameters

### Ventilator parameters:

VENTILATION MODE RATE AIRWAY PRESSURE CONTROL MENU FUNCTION INSPIRATORY PAUSE (volume cycle mode only) TIDAL VOLUME I:E RATIO ELECTRONIC PEEP WAVEFORM DISPLAY

The parameters default to factory-set values when the ventilator is switched on (see 3.5.2). The parameters can be activated and new values assigned by using the touchscreen and navigator wheel (see 3.5.3).

Based on the control settings, the system:

- 1. Calculates INSPIRATORY FLOW, and the INSPIRATORY and EXPIRATORY times (see section 3.7).
- 2. Controls the flow metering valve.
- 3. Displays values for tidal volume or minute volume, rate, and I:E Ratio on the front panel.
- 4. Generates the appropriate messages and alarms.

### **Oxygen Monitor parameters**

- O2 High Alarm
- O2 Low Alarm

The parameters are set via the menu system (see 3.5.4)

### 3.5.2 Power Switch

### OFF

### **Electrical Circuit Condition**

Mains power disconnected

- all functions are unpowered.

Mains power connected

- the backup battery recharge circuit is live
- the yellow LED is illuminated.

Switch to OFF after use To switch off, hold down the switch for at least one

second.

Screen display shows:

POWERING DOWN 5...4...3...2...1....

### ON

The ventilator automatically initiates a three second internal test sequence.

During this period,

- the 'boot up' screen is displayed, and

- the audible alarms will activate.

After the test sequence, the ventilator switches to STANDBY mode and the following parameters default to the values shown:

TIDAL VOLUME	600 ml
RATE	10 bpm
I:E RATIO	1:2
AIRWAY PRESSURE LIMIT	38 cmH2O
PEEP	Off

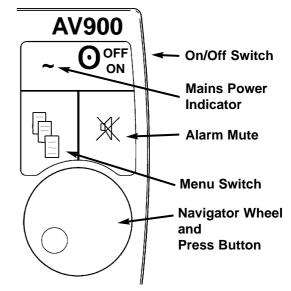
### **Interface to Prima SP**

The AV900V4 can be interfaced to the Prima SP Anaesthetic Machine and A100SP Absorber through a connection (A) at the rear of the ventilator control unit.

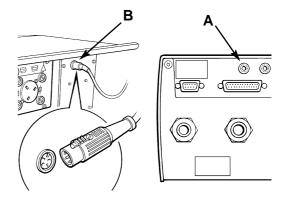
The interface cable is plugged into the socket (B) on the rear panel of the anaesthetic machine.

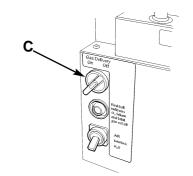
### Prima SP Interface Function:

- a) Turn the Prima Sp Gas Delivery Switch (C) to ON. The ventilator will power-up.
- b) While the Prima SP power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch, as described above.
- c) Turn the Prima SP Gas Delivery Switch to OFF. The ventilator will power-down.



### **Front Panel Controls**



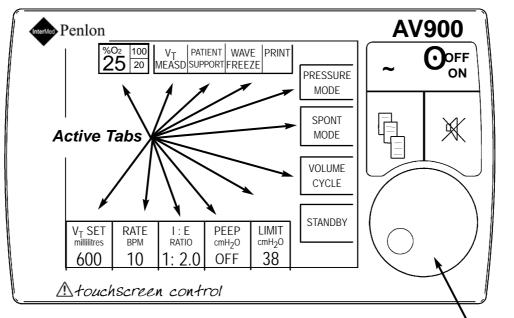


**STANDBY** The parameters listed above (ON) are active in STANDBY mode, to allow system set-up.

The following alarms are functional in STANDBY mode:

LOW SUPPLY PRESSURE MAINS FAILURE VENT INOP

LOW BATTERY HIGH AIRWAY PRESSURE Note: In STANDBY mode, this alarm is triggered at 80 cmH2O NEGATIVE AIRWAY PRESSURE **INCORRECT RATE/RATIO** O2 High Alarm (O2 Monitor option) O2 Low Alarm (O2 Monitor option) Sensor Fault (O2 Monitor option)



### **Touchscreen Active Tabs**

### 3.5.3 Touchscreen Operation and Navigator Wheel / Push Button

The functions/parameters shown on the screen above can be activated by touching the screen at the appropriate tab area. *NOTE* 

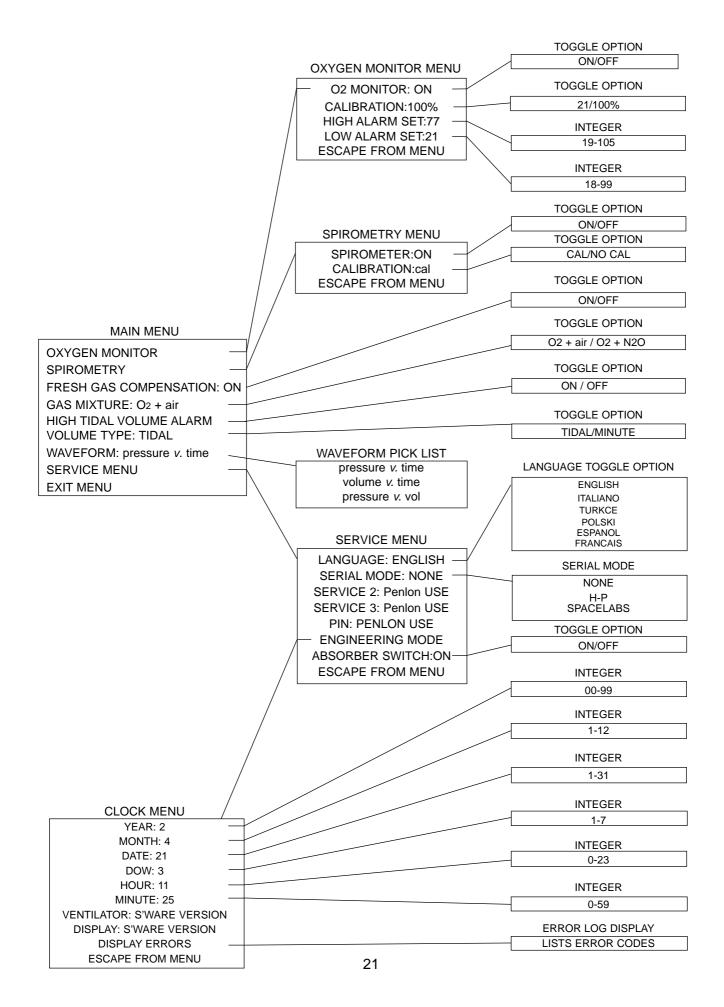
PATIENT SUPPORT is available in Spotaneous mode only.

Variable parameters can then be altered by rotating the navigator wheel.

When the required value is displayed, press the active tab <u>or</u> the wheel to confirm the setting.

<u>Turn the wheel</u> to alter the value of the active parameter. <u>Press</u> to confirm the setting

### AV 900 V.4 Menu Functions



### 3.5.4 On-Screen Menus

### To Access:

Press the menu switch on the front panel to access the following functions and parameters via drop-down menus:

OXYGEN MONITOR SPIROMETRY FRESH GAS COMPENSATION: ON GAS MIXTURE HIGH TIDAL VOLUME ALARM VOLUME TYPE: TIDAL WAVEFORM: pressure v. time SERVICE MENU EXIT MENU

#### To Exit:

Press the menu switch on the front panel, or, select EXIT MENU and press the wheel.

### NOTE

The menu window will not be displayed if:

- A) Control parameters (VT MEAS, BPM, I:E, PEEP, or LIMIT) are enabled but not confirmed.
- B) A display window is active

### To Operate:

- Rotate the navigator wheel clockwise to scroll through the menu options - the cursor ( > ) aligns with each parameter in turn.
- Press the wheel to enter the required submenu.
- 3. Rotate the navigator wheel to change any displayed values, and press to confirm.
- 4. To exit the menu display:

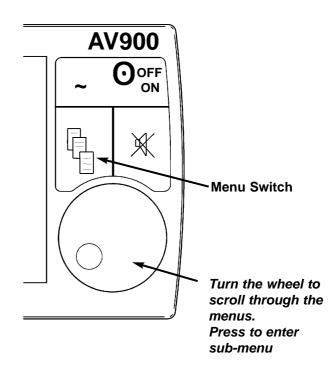
A) Press the menu switch on the front panel .

B) Scroll to EXIT MENUS

and press the navigator wheel.

#### NOTE

- A) If confirmation does not take place within 8 seconds, the parameter reverts to its previous value.
- B) If another parameter is selected using the touchscreen, the menu is de-selected.
- C) While any menu is selected:
  - the alarms are active,
  - the ventilator can be switched off.



### Default menu

 > O2 MONITOR SPIROMETRY FRESH GAS COMPENSATION GAS MIXTURE HIGH TIDAL VOLUME ALARM VOLUME TYPE WAVEFORM SERVICE EXIT MENUS

NOTE

The ventilator must be in Standby mode to access SERVICE option

### O<sub>2</sub> Monitor sub-menu

(if O2 monitor fitted)

### **ON/OFF**

Press the navigator wheel to switch between ON and OFF. Scroll to EXIT MENUS and press the wheel to exit.

### NOTE

The oxygen monitor automatically switches ON and defaults to the previous values for high and low alarm settings when the ventilator is switched on.

Fresh gas mixture compensation is disabled if the O2 monitor is switched OFF.

### CALIBRATION

Press the navigator wheel to initiate the calibration procedure (see section 5.4.2 for full procedure).

To exit the menu, scroll to EXIT MENUS and press the wheel.

### O<sub>2</sub> Monitor sub-menu

> O2 MONITOR : ON CALIBRATION HIGH ALARM SET LOW ALARM SET EXIT MENUS

### O2 Monitor sub-menu - calibration

- O2 MONITOR : ON
- CALIBRATION HIGH ALARM SET LOW ALARM SET EXIT MENUS

### HIGH ALARM SET LOW ALARM SET

Scroll to the required parameter and press the navigator wheel to activate. Rotate the navigator wheel again to change the displayed value.

(see section 5.4.4 for full procedure).

High Alarm range:	19% to 105%
Low Alarm range	18% to 99%

The displayed figure will flash on and off. Press to confirm. Scroll to EXIT MENUS and press the wheel to exit.

### O2 Monitor sub-menu - alarms

O2 MONITOR : ON CALIBRATION > HIGH ALARM SET LOW ALARM SET EXIT MENUS

### Spirometry ON/OFF

Press the navigator wheel to switch between ON and OFF. Scroll to EXIT MENUS and press the wheel to exit.

If spirometry is switched ON, a Measured Volume tab will appear on the screen.

### NOTE

If the spirometer is switched OFF:

- a) Fresh gas compensation is disabled
- b) Fresh gas mixture compensation is disabled
- c) Patient support function is disabled.

# Fresh Gas Compensation ON/OFF

Press the navigator wheel to switch between ON and OFF. Scroll to EXIT MENUS and press the wheel to exit.

### NOTE

Fresh Gas Compensation can be switched on and off, but is disabled when the spirometer is switched OFF.

### **Gas Mixture**

Press the navigator wheel to switch between O2+air and O2+N2O. Scroll to EXIT MENUS and press the wheel to exit.

### NOTE

Selection of the incorrect gas mixture can affect the accuracy of the Spirometry system. If the spirometer is switched OFF, fresh gas mixture compensation is disabled.

### **High Tidal Volume Alarm**

Rotate the navigator wheel to scroll down to HIGH TIDAL VOL. ALARM

Press the navigator wheel to switch between ON and OFF.

Scroll to EXIT MENUS and press the wheel to exit.

### Spirometry sub-menu

> SPIROMETRY : ON CALIBRATION : no cal EXIT MENUS

### **Fresh Gas Compensation**

O2 MONITOR SPIROMETRY > FRESH GAS COMPENSATION : ON GAS MIXTURE HIGH TIDAL VOLUME ALARM VOLUME TYPE WAVEFORM SERVICE EXIT MENUS

### **Gas Mixture**

O2 MONITOR SPIROMETRY FRESH GAS COMPENSATION > GAS MIXTURE O2+air HIGH TIDAL VOLUME ALARM

VOLUME TYPE WAVEFORM SERVICE EXIT MENUS

### **High Tidal Volume Alarm**

SERVICE EXIT MENUS

O2 MONITOR SPIROMETRY FRESH GAS COMPENSATION GAS MIXTURE O2+air > HIGH TIDAL VOLUME ALARM VOLUME TYPE WAVEFORM

### **Volume Type**

Press the navigator wheel to switch between Tidal Volume or Minute Volume.

NOTE:

The Set and Measured Volume change depends on the Volume Type setting.

### Waveform

Select the required waveform and press the wheel to confirm.

Scroll to EXIT MENUS and press the wheel to exit.

### **Volume Type**

- O2 MONITOR SPIROMETRY FRESH GAS COMPENSATION GAS MIXTURE HIGH TIDAL VOLUME ALARM > VOLUME TYPE WAVEFORM
  - SERVICE
  - EXIT MENUS

### Waveform sub-menu

> PRESSURE vs. TIME VOLUME vs. TIME PRESSURE vs. VOLUME EXIT MENUS

### Service

Select Standby mode Select the required parameter and press the wheel to confirm.

### NOTE

a) language - Select the required language and press the wheel to confirm

b) Use SERIAL MODE to select HP or Spacelabs monitor types for connection to the COMMS PORT (Analogue/Alarm) outlet on the rear panel (3.6.10).

c) SERVICE 2 and 3 have no user accessible functions.

d) Access to the PIN menu is restricted to Penlontrained service technicians.

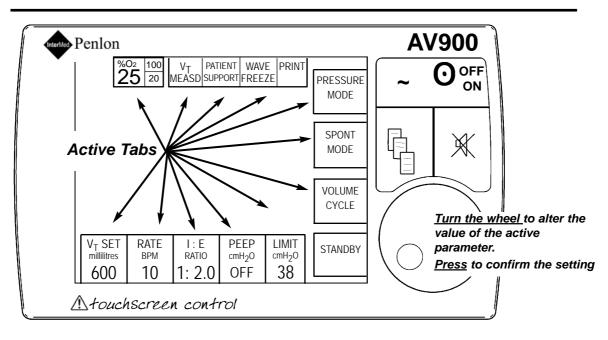
e) Use ENGINEERING MODE to access Date/Time configuration, Display Errors, and ventilator software version.

f) Use ABSORBER SWITCH to disable the function that detects the position of the Absorber Switch.(e.g. in the event of a cable fault or other related condition which persistently gives rise to an alarm).

Scroll to EXIT MENUS and press the wheel to exit.

### Service sub-menu

> LANGUAGE
 SERIAL MODE
 SERVICE 2
 SERVICE 3
 PIN
 ENGINEERING MODE
 ABSORBER SWITCH
 EXIT MENUS



### 3.5.5 Mode Selection

3.5.5.1 SPONT (spontaneous)

Select by touching the screen tab. The screen tab will flash.

A confirm message will be displayed.

Press the screen tab, or wheel to confirm. The tab background will change to orange. The ventilator will monitor/display the functions listed below.

> VENT INOP HIGH AIRWAY PRESSURE LOW SUPPLY PRESSURE NEGATIVE AIRWAY PRESSURE LOW BATTERY MAINS FAILURE O<sub>2</sub> HIGH / LOW / SENSOR FAULT LOW TIDAL VOLUME (Spirometer ON - simulates Apnoea alarm) LOW AIRWAY PRESSURE (Apnoea) (Spirometry OFF, or not fitted)

### Models with Spirometry:

Spirometry ON - the ventilator will also display values for : Tidal Volume Rate I:E ratio Maximum Pressure (Pmax)

### 3.5.5.2 PATIENT SUPPORT MODE

### WARNING

The patient must be continuously attended and monitored when Patient Support Mode is in use.

### **Patient Support Mode Function:**

- 1. The patient breathes spontaneously.
- The user has the option of setting a 'target' value for tidal volume. If this option is not taken, the ventilator will default to a target of 25% of the volume set prior to the selection of Patient Support Mode.
- 3. If the patient fails to achieve the target volume, the Low Tidal Volume alarm will trigger, and the ventilator will automatically revert to Volume Cycle mode.

Patient Support Mode must then be manually reinstated, if required.

### NOTE

a) Patient Support Mode will not function i) if Spirometry is OFF

*ii) if Spirometry is not fitted b) When selecting Patient Support Mode, ensure the Absorber BAG/VENT Switch is set to Vent Position.* 

### Selecting Patient Support Mode:

Select by touching the Screen Tab.

- a) The VT SET tab will flash, and display 25% of the previously set tidal volume.
- b) On anaesthetic machines <u>not</u> fitted with a sensor that detects the position of the absorber bag/vent lever, the ventilator will display:

"Absorber in Vent Mode?".

- c) A confirm message will be displayed. The user has 8 seconds to:
  (i) confirm that Patient Support Mode is required.
  - (ii) Set a target value for tidal volume.

Press the screen tab, or wheel to confirm. The tab background will turn to orange.

In Patient Support Mode the user can reset:

Set Tidal Volume Rate I:E Ratio Pressure Limit

### **Patient Support Function**

If the measured volume is less than the set 'target' tidal volume (averaged over a period of 15 seconds):

a) The Low Tidal Volume Alarm will sound for three seconds

b) The ventilator will then switch to Volume Cycle Mode.

To reinstate Patient Support Mode, the user must repeat the procedure given above (see **Selecting Patient Support Mode**).

### 3.5.5.3 VOLUME CYCLE MODE

Select by touching the screen tab. The screen tab will flash.

A confirm message will be displayed.

Press the screen tab, or wheel to confirm. The tab background will change to orange. Ventilator cycling will commence and all

the alarms will be activated.

The inspiratory pause function is available in this mode.

Maximum breathing system pressure will be monitored.

If maximum breathing system pressure is reached:

a) The alarm HIGH AIRWAY PRESSURE alarm will be triggered.

b) The ventilator will immediately revert to the expiratory phase, (inspiratory pause function will be overidden).

### 3.5.5.4 PRESSURE CONTROL MODE

Select by touching the screen tab. The screen tab will flash. The TARGET pressure display will flash and show the default setting (10 cmH2O). Rotate the navigator wheel to set the required target pressure.

A confirm message will be displayed.

Press the screen tab, or wheel to confirm. The tab background will change to orange. Ventilator cycling will commence and all the alarms will be activated, except high airway pressure.

NOTE

In Pressure Control Mode the flow is automatically set by the ventilator to the optimum value. The ventilator will then achieve the target inspiratory pressure as quickly as possible.

The ventilator will continue to deliver gas until the pressure target is reached.

At this point the ventilator will stop delivering gas and pause in this condition until the calculated end of inspiration time has been reached.

The ventilator will then return to the exhalation phase.

The inspiratory pause function does not operate in this mode.

### NOTE

If a high fresh gas flow has been set, a small increase above the target pressure may be observed during the inspiratory phase.

Note also that the ventilator will not compensate for any increase in pressure during the pause phase while the exhaust valve is closed.

### NOTE

a) If PEEP is selected, it must be set at least 10 cmH<sub>2</sub>O below the target pressure set value.
b) If the target pressure is subsequently reduced, the ventilator will automatically reduce PEEP to maintain the 10 cmH<sub>2</sub>O pressure gap.

### 3.5.5.5 STANDBY MODE

Allows values for Tidal Volume, Rate, I:E Ratio, and Pressure Limit to be set by the user. See also, section 3.5.2.

### 3.5.6 Tidal Volume Control

Select, by touching the screen tab VT/SET. The setting display will flash.

Rotate the navigator wheel to set the required volume.

A confirm message will be displayed. Press the screen tab, or wheel to confirm.

Real-time adjustment is only possible when the ventilator is in volume set mode.

### **Displayed values**

NOTE When the ventilator is switched from standby to the required operating mode, the spirometer will take 1 - 2 minutes before stabilising.

If the set parameters are within normal limits, the system will deliver the set volume indicated.

If during adjustment the required flow rate is less than 2 L/min or exceeds 75 L/min, the set tidal volume will be limited accordingly.

### WARNING

The AV900 has compliance compensation (and fresh gas compensation on models with spirometry) but the actual tidal volume delivered to the patient may be different to the ventilation parameters set by the user.

This may be due to:

- a) an extreme compliance condition,
- b) a substantial system leak, or
- c) patient circuit pressure effects.
- d) extreme fresh gas flow.

In addition, high fresh gas flows will lead to an increased Vt being delivered to the patient. Note that on models fitted with spirometry, the actual tidal volume exhaled will be displayed.

The patient <u>must</u> be monitored independently from the ventilator.

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

### 3.5.7 Ventilation Rate Control

### RATE BPM.

Select, by touching the screen tab RATE BPM.

The setting display will flash.

Rotate the navigator wheel to set the required rate.

A confirm message will be displayed.

Press the screen tab, or wheel to confirm.

The system will accept the setting as long as the value is within normal limits The display indicates the requested RATE. If during adjustment the required flow rate is less than 2 L/min or exceeds 75 L/min, the set rate will be limited accordingly.

### 3.5.8 Ventilator I:E Ratio

### WARNING

The ventilator settings can allow for an inverse I:E ratio up to 1:0.3. The clinician must always ensure that sufficient time is allowed for the patient to adequately exhale.

Select, by touching the screen tab I:E RATIO.

The setting display will flash.

Rotate the navigator wheel to set the required ratio.

A confirm message will be displayed. Press the screen tab, or wheel to confirm.

If during adjustment the required flow rate is less than 2 L/min or exceeds 75 L/min, the set I:E ratio will be limited accordingly.

## 3.5.9 Airway Pressure Limit (cmH2O)

Select, by touching the screen tab LIMIT (cmH<sub>2</sub>O).

The setting display will flash.

Rotate the navigator wheel to set the required pressure.

A confirm message will be displayed. Press the screen tab, or wheel to confirm.

This control sets a maximum breathing system pressure as sensed by the pressure transducer in the patient breathing circuit.

### In Volume Cycle mode:

The inspiratory cycle is terminated whenever this set pressure is achieved. The ventilator then reverts to the exhalation phase.

### In Pressure Control mode:

a) The inspiration valve is closed when the set pressure is achieved.

The ventilator holds the set pressure until

the end of the calculated inspiratory time, before reverting to the exhalation phase.

b) The variable pressure LIMIT control tab is replaced by the TARGET tab (see 3.5.5, PRESSURE CONTROL MODE).

c) If the user sets a target pressure in Pressure Mode, the set value will be retained if an alternative mode is selected.

Measured airway pressure is displayed on screen.

### 3.5.10 Electronic PEEP

Select by touching the screen tab PEEP cmH<sub>2</sub>O.

The setting will flash.

Rotate the navigator wheel to set the required PEEP pressure. NOTE In Pressure Control Mode: a) PEEP must be set at least 10 cmH2O below the target pressure set value. b) If the target pressure is subsequently reduced, the ventilator will automatically reduce PEEP to maintain the 10 cmH2O pressure gap.

A confirm message will be displayed. Press the Screen Tab, or Wheel to confirm.

Note that Electronic PEEP does not function in Spontaneous Mode.

### **PEEP on/off sequence**

### Using the A100SP Absorber Interface -Ventilator Mode Selection

- 1. Ventilator is in Volume Ventilation Mode
- PEEP selected, pressure set to required level.
   PEEP display indicates pressure
- A100SP Absorber Bag/Vent lever is moved to 'Bag' position. Ventilator automatically switches to Spontaneous Mode. PEEP is automatically switched off (does not function in Spontaneous Mode) PEEP display is blank.

Ventilator automatically switches to Standby Mode. PEEP is Off. PEEP display indicates Off.

 Set ventilator to Volume Ventilation Mode.
 PEEP remains Off.

Select PEEP if required.

### 3.5.11 Alarm Mute

When the alarm mute push button is depressed during an alarm condition the audible alarm will be muted as follows:

## All <u>mutable</u> alarms (except High Airway Pressure):

The mute button will silence the audible alarm for up to 120 seconds.

**High Airway Pressure Alarm: High Drive Gas Pressure Alarm:** The mute button will silence the audible alarm for up to 30 seconds.

A mute period countdown sequence (in seconds) is displayed on-screen. Mutable alarms will be immediately reinstated upon fresh alarm conditions.

Note that the alarms for Vent Inop (ventilator inoperable) and Low Supply Pressure are <u>not</u> mutable.

### 3.5.12 Inspiratory Pause

In volume ventilation mode depressing the INSP PAUSE button will allow a 25% inspiratory pause to be included at the end of the inspiratory phase.

The I:E ratio will be maintained.

To compensate for the reduced inspiratory flow time period, the inspiratory flow rate is increased (up to a maximum flow rate of 75 litres per minute).

The inspiratory pause does not function in Pressure Ventilation mode.

4. Bag/Vent lever reset to 'Vent' position. 29

### 3.5.13 Print

A printed copy of the ventilator conditions for up to eight hours of the procedure can be provided.

In addition, captured waveforms can also be printed. (first select WAVE FREEZE on the screen).

Connect a HPL 2 (or greater) format printer to the printer output port on the rear of the ventilator.

At the end of the clinical procedure switch the ventilator to standby, and press the PRINT tab once.

To cancel, press the PRINT tab again.

Turn the ventilator to OFF, and switch the ventilator back on again to clear the stored print information.

The printer port must only be connected to devices that comply to EN 60950.

For examples, see Appendix, section 9.

### 3.5.14 A100 SP Absorber with Bag/Vent Detection Switch

Automatic ventilator mode selection is enabled if the interface socket is connected to an A100 SP Absorber fitted with a sensor that detects the position of the absorber bag/vent lever:

a) If the Absorber Bag/Vent Lever is moved from Vent to Bag, the ventilator will change from Volume Mode, or Pressure Mode, into Spontaneous Mode.

b) Switching the absorber Bag/Vent lever from Bag to Vent will reset the ventilator from Spontaneous Mode to Standby Mode.

If the ventilator is in any mode other than those detailed above, operation of the absorber Bag/Vent lever will not affect the ventilator.

### NOTE

This function can be enabled/disabled through the on-screen menus (Service Sub-menu, see section 3.5.4).

#### 3.5.15 Waveform Displays

Real-time waveforms can be selected via the menu system as follows:

#### Pressure (cmH2O) v. Time (sec)

The pressure scale (y-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for airway pressure limit (LIMIT cmH2O).

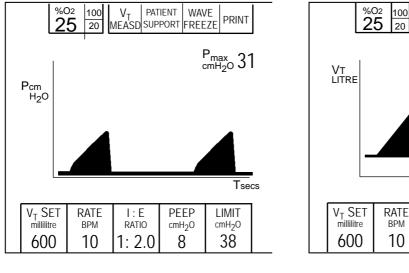
Pressure LIMIT set value 10 to 40 cmH<sub>2</sub>O 41 to 60 cmH<sub>2</sub>O 60 to 80 cmH<sub>2</sub>O Pressure scale (y-axis) range -10 to 40 cmH<sub>2</sub>O -10 to 60 cmH<sub>2</sub>O -10 to 80 cmH<sub>2</sub>O

The time scale (x-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for rate (RATE BPM).

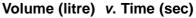
RATE BPM set value range

4 to 20
21to 40
41 to 100

Time scale (x-axis) range 0 to 15 seconds 0 to 5 seconds 0 to 3 seconds



Pressure (cmH2O) v. Time (sec)



1 : E

RATIO

1:2.0

 $V_{T}$ 

PATIENT WAVE

PEEP

cmH<sub>2</sub>O

8

MEASD SUPPORT FREEZE

PRINT

Tsecs

LIMIT

cmH<sub>2</sub>O

38

 $P_{max}$  31

#### Volume (litre) v. Time (sec)

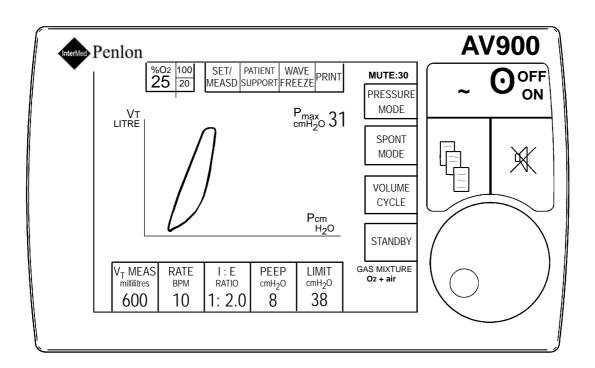
The volume scale (y-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for tidal volume (VT MEAS).

Tidal Volume set value		
20 ml to 500 ml		
550 ml to 1.0 L		
1.05 to 1.6 L		

Tidal volume scale (y-axis) range 0 to 500 ml 0 to 1.0 L 0 to 2.0 L

The time scale (x-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for rate (RATE BPM).

RATE BPM set value	Time scale (x-axis) range
4 to 20	0 to 15 seconds
21to 40	0 to 5 seconds
41 to 100	0 to 3 seconds



#### Volume (litre) v. Pressure (cmH2O) (compliance loop waveform)

The pressure scale (x-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for airway pressure limit (LIMIT cmH2O).

Pressure LIMIT set value 10 to 40 cmH<sub>2</sub>O 41 to 60 cmH<sub>2</sub>O 60 to 80 cmH<sub>2</sub>O Pressure scale (x-axis) range -10 to 40 cmH<sub>2</sub>O -10 to 60 cmH<sub>2</sub>O -10 to 80 cmH<sub>2</sub>O

NOTE In Spontaneous Mode, the x-axis defaults to -10 to 10 cmH2O

The volume scale (y-axis) has three ranges, and the correct range is displayed automatically when the user sets a value for tidal volume (V $\tau$  MEAS).

Tidal Volume set value 20 to 500 mL 550 ml to 1.0 L 1.05 to 1.6 L Tidal volume scale (y-axis) range 0 to 500 ml 0 to 1.0 L 0 to 2.0 L

### 3.6 Rear Panel

### 3.6.1 Labelling Terminology

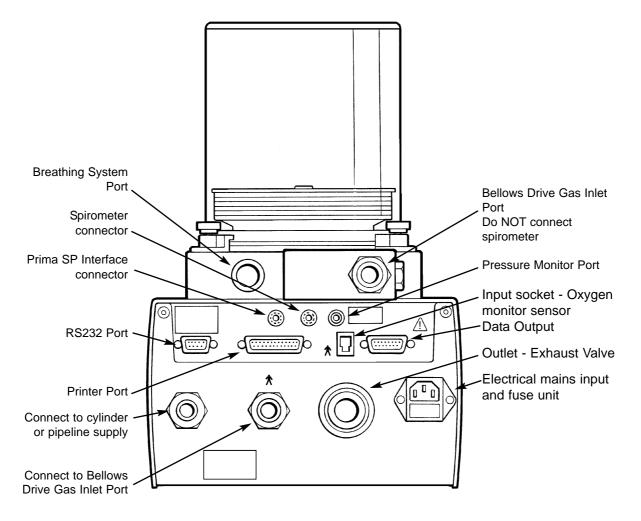
The term is defined in IEC 601-1 (the standard for electrical medical equipment).

Class 1 equipment has additional protection such that metal parts of the unit that are accessible to the user (e.g. the metal casing of the AV900 control unit) cannot become live in the event of failure of the basic insulation of the electrical components within the unit.

*This symbol denotes: Type B equipment* Type B equipment calls for a particular degree of protection against electric shock.



This symbol denotes: Refer to the User Manual



### 3.6.2 Electrical Mains Supply

The mains supply inlet is designed for connection to any mains voltage from 100 to 240 VAC and a frequency of 50 to 60 Hz, without any adjustment.

The connector is a standard IEC type.

### 3.6.3 Oxygen/Air (inlet)

Ventilator driving gas is attached to this connector at a pressure of 38 - 100 psi (262 to 689 kPa) and capable of supplying gas at a flow rate of not less than 80 L/min at the minimum pressure.

Air or Oxygen must be used as the drive gas and the supply must be clean and dry. Note that the drive gas is specified by the original customer. To change the drive gas, refer to a Penlon-trained service engineer.

### 3.6.4 Drive Gas (outlet to bellows)

The drive gas outlet is a special 17 mm diameter taper connector and delivers the drive gas from the control unit to the ventilator bellows assembly.

The drive gas over pressure relief valve is set at a non-adjustable 80 cmH2O.

### 3.6.5 Exhaust Valve

Gas from the bellows assembly, (drive gas - either air or oxygen), is exhausted through this outlet.

The port must not be blocked.

### 3.6.6 Pressure Transducer

Connected to a pressure transducer in the breathing system.

### 3.6.7 RS 232 Port

Configuration details for this port are available by special order from Penlon Limited.

The port must only be connected to devices that comply to EN 60950.

### 3.6.8 Printer Port

This standard Centronics 36 way parallel port is configured to output to any HPL 2 or equivalent compatible parallel printer.

The port must only be connected to devices that comply to EN 60950.

### 3.6.9 Spirometer Connection

An electrical DIN connector is provided for the cable carrying the signals from the Inspiration and Expiration flow sensors.

Each sensor is identified with INSP or EXP, and the direction of flow.

Care must be taken to ensure that each sensor is connected correctly to the Absorber components, to ensure that breathing cycle flow and direction is detected.

#### 3.6.10 Prima SP Interface

The connector is provided for connection to a Prima SP with an interface socket that links to the SP Master ON/OFF switch, and A100 SP Absorber BAG/VENT lever.

### 3.6.11 Data Outputs

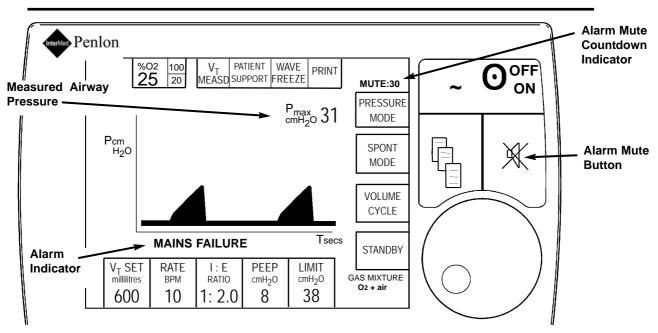
This port can be configured to interface with HP Monitors to special order.

Detailed configuration information can be accessed from "H-P Vuelink Open Interface Manual".

The port must only be connected to devices that comply to EN60950.

### 3.6.12 Oxygen Monitor Sensor

Connected to the oxygen sensor mounted in the breathing system (see section 5.4.1).



### 3.7 Alarms and Message Displays

### 3.7.1 Alarm Mute

All mutable alarms (except High Airway Pressure and High Drive Gas Pressure): The mute button will silence the audible alarm for up to 120 seconds.

#### High Airway Pressure Alarm: High Drive Gas Pressure:

The mute button will silence the audible alarm for up to 30 seconds.

A mute period countdown sequence (in seconds) is displayed on-screen.

### 3.7.2 Alarm Indicators

Visual indicators are displayed on-screen beneath the waveform display.

All alarms are self-cancelling (with a minimum activation period of 2 seconds), except VENT INOP (ventilator inoperative). Alarms comply with EN475.

#### NOTE

- a) Visual alarms can not be defeated.
- b) Alarms are priority configured.

c) The highest priority alarm will always take precedence.

Normal conditions must be restored or the unit turned off in order to cancel the alarms.

#### LOW DRIVE GAS SUPPLY (High priority)

A visual and audible alarm which activate if the input drive gas pressure has dropped below 35 psi.

This alarm is not silenceable.

Supply pressure should be monitored by a separate means, e.g. pressure gauge on anaesthetic machine or supply line.

## HIGH DRIVE GAS PRESSURE (High priority)

A visual and audible alarm which activate when the drive gas supply overpressure switch operates at the maximum pressure limit (80 cmH<sub>2</sub>O).

This alarm can be muted for 30 seconds.

Note that the High Airway Pressure Alarm (see below) does <u>not</u> activate when the overpressure switch operates.

# HIGH AIRWAY PRESSURE (High priority)

## Standby, Spontaneous, and Volume Cycle Mode

A visual and audible alarm which activate when the pressure sensed at the patient tee exceeds the setting of the AIRWAY PRESSURE LIMIT control.

This alarm will remain on until the pressure falls below the control setting for a minimum of 1 second.

This alarm can be muted for 30 seconds.

## HIGH CONT (Continuing) PRESSURE (High priority)

A visual and audible alarm which activate when the pressure sensed at the patient tee exceeds 30 cmH2O just prior to the next inspiratory cycle.

Once activated, this alarm remains on until the pressure falls below the required baseline at the beginning of a breath.

The alarm can be muted for 120 seconds.

## LOW AIRWAY PRESSURE (High priority)

(Disconnect Alarm)

A visual and audible alarm which activate if the pressure sensed at the patient tee-piece in the expiratory limb of the breathing circuit does not increase by at least 4-14 cmH2O during a ventilator inspiratory cycle, depending on tidal volume setting.

This alarm remains on until the required pressure differential is reached.

The alarm can be muted for 120 seconds.

NOTE: Spirometry fitted, and switched ON - the Low Airway Pressure Alarm does <u>not</u> function in Spontaneous Mode.

## NEGATIVE AIRWAY PRESSURE (High priority)

(Disconnect Alarm)

A visual and audible alarm which activate if the pressure sensed at the patient tee-piece in the expiratory limb of the breathing circuit falls below -20 cmH2O during a ventilator inspiratory cycle, depending on tidal volume setting.

This alarm remains on until the pressure rises above -20 cmH2O.

The alarm can be muted for 120 seconds.

## LOW TIDAL / HIGH TIDAL VOLUME (High priority)

The AV900 can be fitted with an optional external volume spirometer which provides signals to the volume display.

#### LOW TIDAL VOLUME

A visual indicator and an audible alarm are activated if the apparent tidal volume (as measured by the spirometer) falls below 50% of the set tidal volume.

The alarm can be muted for 120 seconds.

NOTE: In Spontaneous and Patient Support modes, the Low Tidal Volume Alarm acts as an Apnoea alarm.

The alarm will activate if the measured tidal volume falls below the set value (minimum value is 20 ml).

#### **HIGH TIDAL VOLUME**

The High Tidal Volume Alarm can be switched ON or OFF in Volume Mode, Pressure Mode and Spontaneous mode, using the Menu display (see section 3.5.4).

NOTE

- The alarm will reset to ON if:
- a) Standby mode is selected,

b) The ventilator is switched OFF.

NOTE: In Pressure Mode, the High Tidal Volume Alarm is activated when the measured volume rises above 150% of the tidal volume achieved by the ventilator (see 3.5.5.4).

The alarm can be muted for 120 seconds.

#### **Spirometer Disconnect**

Disconnection of a spirometer cable is indicated by

a) activation of the Low Tidal Volume Alarm, and

b) a change to the VT MEASD display.

Check the VT MEASD display:



Indicates disconnection at the back of the control unit, or,

disconnection at the back of the A100SP absorber

or, at the inspiratory spirometer sensor



A low value, decreasing to approximately 20 ml, indicates disconnection at the expiratory spiro sensor.

#### Interface Cable Disconnect (Prima SP and A100 SP Absorber Cable) (Low Priority)

If an interface cable is fitted, and is disconnected during use, a visual indicator and audible alarm are activated.

#### INCORRECT RATE OR RATIO (Low priority)

A visual indicator and audible alarm which indicates that the required inspiratory flow rate:

a) is below 2 L/min, or

b) has reached the upper limit of 75 L/min as determined by the settings for TIDAL VOLUME, RATE, I:E RATIO, and INSP PAUSE.

This alarm can be muted for 120 seconds.

#### MAINS FAILURE (Low priority)

A visual and audible alarm (low priority) which activates when mains electrical power is disconnected when the ventilator is operating. (Note that the battery must be in a charged state for this alarm to operate).

#### LOW BATTERY

#### (Low priority / Medium priority)

A visual and audible alarm which activates if the internal battery is low. In this condition the 60 minute backup period is significantly reduced.

A low battery alarm does not indicate that the ventilator is faulty.

When mains is connected the alarm is merely an indication that the battery is not fully charged and is being charged by the ventilator.

#### WARNING

Do not leave the Ventilator on if the device is not connected to the mains, this will severely drain the battery.

#### **Medium Priority Status**

When approximately ten minutes of battery backup time remains, the alarm will change from low to medium priority.

To prevent damage to the battery, the ventilator will shut down before the battery is fully discharged.

#### **VENT INOP (High priority)**

The VENT INOP (ventilator inoperative) alarm indicates that one of the following conditions has occurred:

- a) A solenoid has failed,
- b) The flow control valve has failed,
- c) Internal electrical fault,
- d) Internal Communications error,
- e) Battery disconnected,
- f) Software error

This alarm is not silenceable.

In the event of a ventilator error being detected a 'ventilator inoperative' message will be displayed beneath the waveform display area.

In addition, code will be stored in a nonvolatile memory which can be accessed by the service engineer to assist with fault finding.

#### WARNING

To reset a VENT INOP alarm:

Turn the ventilator OFF for a minimum of one second, and then turn the ventilator back ON. If the VENT INOP alarm occurs again, do not use the ventilator and refer the unit to an authorised service technician.

#### **Oxygen Monitor Alarms**

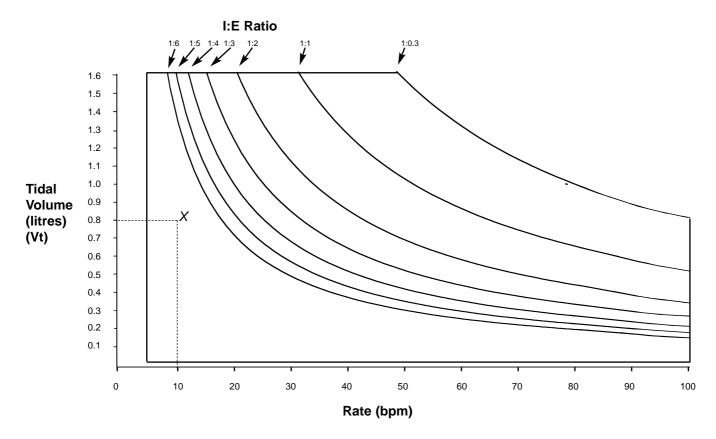
See section 3.4.4.

### 3.8 Back-up Battery

In the event of mains electrical failure, the back-up battery cuts in automatically. A fully charged battery will power the ventilator for approximately 60 minutes.

See Appendix 1 for battery care procedures.

### 3.9 Operational Capability



The ventilator is capable of operating at the volumes and rates below each I:E ratio curve.

Note a) The minimum tidal volume setting is 20 ml. b) The minimum rate setting is 4 bpm.

#### Example

- 1. Select required volume (Vt) (e.g. 0.8 litres)
- 2. Select rate (e.g. 10 bpm).
- 3. Select I:E ratio of 1:2.

The point X on the graph lies beneath the 1:2 ratio curve, and is therefore within the ventilator's capability.

## 4. SPECIFICATION

4.1	Application	Ventilation for use in anaesthesia.
4.2	Internal Compliance Adult bellows Paediatric bellows	3 ml/cmH2O (nominal) 2 ml/cmH2O (nominal)
4.3	Minute Volume Range	N/A - this parameter cannot be set.
4.4	Tidal Volume Range Adult bellows Paediatric bellows At ambient temperature of 20 <sup>o</sup> C (+/-10%) and ambient atmosphere of 101.3 kPa (+/-10%).	20 to 1600 ml (±10%) 20 to 350 ml (±10%)
4.5	Frequency (Rate) Range	4 to 100 bpm, limited by tidal volume setting
4.6	Inspiratory Phase Time Range	0.07 to 11.54 seconds (100 bpm, I:E 1:8)
4.7	Expiratory Phase Time Range	0.14 to 13.33 seconds (100 bpm, I:E 1:0.3 and 4 bpm, I:E 1:8)
4.8	Inspiratory/Expiratory Phase Time Ratio Range (I:E ratio)	1: 0.3 to 1: 8.0 - limited by tidal volume and rate settings
4.9	Pressure Control Range (pressure ventilation mode)	10 to 70 cmH2O (±10%)
4.10	Inspiratory Flow Range	2 to 75 L/ min
4.11	Airway Pressure Limit (volume ventilation mode)	10 to 80 cmH2O (±10%)
4.12	Inspiratory Triggering	N/A
4.13	Inspiratory Triggering - Response Time	N/A
4.14	Maximum Safety Pressure	80 cmH2O
4.15	Maximum Working Pressure	80 cm H2O
4.16	Minimum Safety Pressure	-10 cm H2O
4.17	Minimum Working Pressure	Atmospheric
4.18	Sub-atmospheric Pressure Range	None
4.19	Expiratory Resistance (30 L/min)	3 cmH2O
4.20	Sigh Characteristics	None
4.21	Inspiratory Mixture	No mixture controls

4.22	Flowmeters	None
4.23	Manual Changeover	None
4.24	Inspiratory Relief Valve	Fixed, 80 cmH2O
4.25	Humidifiers and Monitors	No humidifier. Volume monitor optional (spirometer) Pressure monitor built in
4.26	System Pressure Gauge	None
4.27	Airway Pressure Gauge	Airway pressure value is displayed on screen
4.28	Spirometer Accuracy	Optional +/- 20% (volume range: 20 to 300 ml) +/- 10% (volume range: 300 to 1600 ml) Note a) The Oxygen Monitor must be switched ON b) Accuracy is affected by variations in gas composition
	Range Resolution Maximum Inspiratory Pressure	20 to 1600 ml 1 ml 0 to 100 cmH₂O
4.29	Alarms (in priority order)	See section 3 for detailed descriptions.
		Vent. inop. (ventilator inoperative) - not mutable High airway pressure High drive gas pressure High cont. (continuing) airway pressure (PEEP) Low supply pressure - not mutable Low airway pressure Negative airway pressure Low tidal volume High tidal volume Incorrect rate or ratio Low battery Mains failure Interface cable fault
4.30	Power Source Electrical	100 VAC - 240 VAC 50/60 Hz, universal input. 0.30 A - 0.18 A
	Input Drive Gas	Oxygen or air (dry, and oil free) at 38 to 100 psi (262 to 689 kPa).
4.31	Power Consumption Electrical Gas	37 watts maximum 75 L/min intermittent maximum inspiratory flow.

## **SPECIFICATION**

4.32	Dimensions Height Height of control unit only Width Depth	385 mm 150 mm 240 mm 300 mm
4.33	Weight Weight with adult bellows Weight with paediatric bellows Weight of control unit only	9.0 kg 8.7 kg 7.6 kg
4.34	Method of Disinfection or Sterilisation	Bellows base assembly and inside of bellows require sterilisation - section 7.3
4.35	Bacterial Filter	None (see section 5.1.4 for recommendations for breathing system)
4.36	Fail Safe Mechanism	Battery back-up in case of mains electricity failure
4.37	Reliability	MTBF: 5x10 <sup>6</sup> to 50x10 <sup>6</sup> cycles
4.38	Waveform Tests	Not applicable
4.39	Volume Tests	Not applicable
4.40	(A) Mobility	Secure mounting on anaesthesia machine required.
	(B) Mounting	Mounting bracket available as optional extra. The bellows assembly can be separated from the control unit for remote mounting.
4.41	Fuse (mains supply)	Two fuses, Type T 2AH 2 A, 250 V rating, 20 mm, anti surge, ceramic.
4.42	Environmental	
	Ambient Temperature	
	Storage:	-5 to 50 <sup>o</sup> C (23 to 122 <sup>o</sup> F). Refer to Appendix 1 for battery care during storage.
	Operating:	10 to 38 <sup>0</sup> C (50 to 100 <sup>0</sup> F)
	Humidity	10-95% RH (relative humidity), non- condensing
	Altitude	Up to 2775 m (9000 feet)
	Ingress protection	Conforms to EN 794-1 Clause 44 (spillage test)

## **SPECIFICATION** - O2 Monitor

### 4.43 Oxygen Monitor

Measurement Range:	0-l00%
Resolution:	±1%
Accuracy and Linearity:	±2% of full scale (at constant temperature and pressure)
Response Time:	90% of final value in approx. 10 seconds (air to 100% O2)
Operating Temperature:	50°F to 100°F (10°C to 38°C)
Storage Temperature:	23°F to 122°F (-5°C to 50°C)
Relative Humidity Range:	5%-95% (non-condensing)
Battery Back-up:	As per ventilator
Sensor Type:	MOX-3 galvanic fuel cell
High Priority Alarm: Medium Priority Alarm: Low Priority Alarm: Alarm Mute:	Flashing, 5 audio pulses with 6 seconds repeat time. Flashing, 3 audio pulses with 24 seconds repeat time Static with single beep sound 30 seconds for high priority alarm 120 seconds for medium priority alarm
Low Alarm Set Range:	18%-99% (+/- 1%)
High Alarm Set Range:	19%-105% (+/- 1%)
Cable length:	2 m (6 ft), fully extended
<b>Sensor</b>	Galvanic fuel cell sensor (0-100%)
Type:	1500000 O2% hours
Life:	(One year minimum in typical applications)

Interference Gases and Vapours (in 30% Oxygen, 70% Nitrous Oxide)

Interference	Volume % Dry	Interference in O2%
Nitrous Oxide	80%	<1%
Carbon Dioxide	5%	<1%
Halothane	5%	<1%
Enflurane	5%	<1%
Isoflurane	5%	<1%
Sevoflurane	5%	<1%

### **SPECIFICATION** - O2 Monitor

#### **Oxygen Monitor - continued**

#### **Humidity Effects**

Sensor output is relatively unaffected by prolonged operation in either high or very low relative humidity.

If the sensor shows signs of being affected by condensation, dry the sensor with soft tissue.

**CAUTION** DO NOT use heat to dry the sensor.

#### **Temperature Effects**

The sensor has a built-in temperature compensation circuit, and is relatively unaffected by temperature changes within the operating temperature range given above.

#### **Pressure Effects**

The sensor measures O<sub>2</sub> partial pressure, and its output will rise and fall due to pressure change (e.g. changes in barometric pressure, or breathing system pressure). An increase in pressure of 10% at the sensor inlet will produce a 10% increase in sensor output.

### 5.1 Ventilator Set-up

## 5.1.1 Components supplied with the ventilator

The ventilator is supplied with various additional components, depending on specification and configuration:

- (a) A 210 mm long, 16 mm diameter, corrugated hose to connect the control unit to the bellows assembly
- (b) Drive gas hose (to customer specification)
- (c) Electrical mains supply cable (to customer specification).
- (d) Pressure sampling line and T-piece.
- (e) Spirometer sensors and leads (spirometer option only)
- (f) Oxygen sensor system (oxygen monitor option only)

#### 5.1.2 Mounting the ventilator

The AV900 can be mounted on the anaesthetic machine as a single, complete unit, or the bellows unit and the control unit can be mounted separately.

#### Locate the ventilator in a safe place.

Preferably, mount it permanently on the shelf of the anaesthesia machine or on a strong bracket. This will protect the ventilator from accidental fall and accidental disconnection of the hoses.

To mount the ventilator permanently on a Penlon bracket:

- 1. Align the four mounting feet over the mating holes in the bracket.
- Use the four M4 screws supplied with the mounting bracket kit, inserted through the bracket and rubber feet and screwed into the threaded inserts in the base of the ventilator.
   Only use the screws supplied with

Pole-mount type mounting brackets and side frame brackets are available, see section 8.

the kit.

#### 5.1.3 Electrical power connection

Before connecting the ventilator to the mains supply, check that the power supply is within the correct rating as stated on the label on the rear of the control unit.

#### WARNING

Excessive electronic noise caused by other, poorly regulated devices, such as electrocautery, may adversely interfere with the proper functioning of the ventilator.

To avoid this problem, do not connect the ventilator power cord into the same electrical wall outlet or strip into which an electrocautery unit is connected.

#### 5.1.4 Ventilator gas supply, breathing system connections, and start-up

Before the ventilator can be used, the following preparation must be made:

#### 5.1.4.1 Gas Supply

- 1. Verify the drive gas specified for the ventilator (oxygen or air).
- 2. Connect the drive gas inlet port on the rear of the control unit to a dry, oil free supply.

Supply pressure range: 38 to 100 psi (2.6-6.9 bar, 262-689 kPa)

#### The drive gas inlet port is labelled: OXYGEN / AIR 38 - 100 PSI

OXYGEN SUPPLY:

a) O2 cylinder,b) Anaesthetic machine O2 auxiliary gas outlet,

c) O2 pipeline supply from a wall outlet.

AIR SUPPLY:

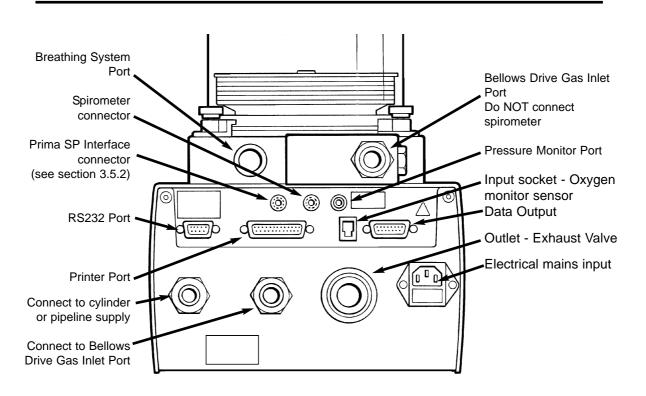
a) Air cylinder,

b) Anaesthetic machine Air auxiliary gas outlet

c) Air pipeline supply from a wall outlet.

#### Supply pressure should be monitored by a separate means, e.g. pressure gauge on anaesthetic machine or supply line.

NOTE: It is possible to reconfigure the ventilator for use with a different drive gas to the gas originally specified. This work must be carried out by a Penlon-trained engineer at your hospital, or a Penlon distributor.



## 5.1.4.2 Breathing System and Cable Connections

- 1. Connect the 16 mm diameter corrugated hose (provided), between the control unit drive gas outlet (labelled: DRIVE GAS) and the bellows base DRIVE GAS inlet port.
- 2. Connect the EXHAUST valve port on the control unit to a properly functioning scavenging system - use a 30 mm hose.

Fit a 10 cmH<sub>2</sub>O pressure relief valve between the exhaust valve port and the inlet port of the AGSS receiver. Note that the diaphragm valve under the bellows is connected internally to the EXHAUST port to facilitate the discharge of excess breathing gas at the end the expiratory phase.

#### WARNING

Applying negative or positive pressure to the bellows exhaust port results in positive pressure in the patient breathing system.

Therefore, the scavenging system must not generate more than 0.5 cmH2O positive or negative pressure when connected to the ventilator.

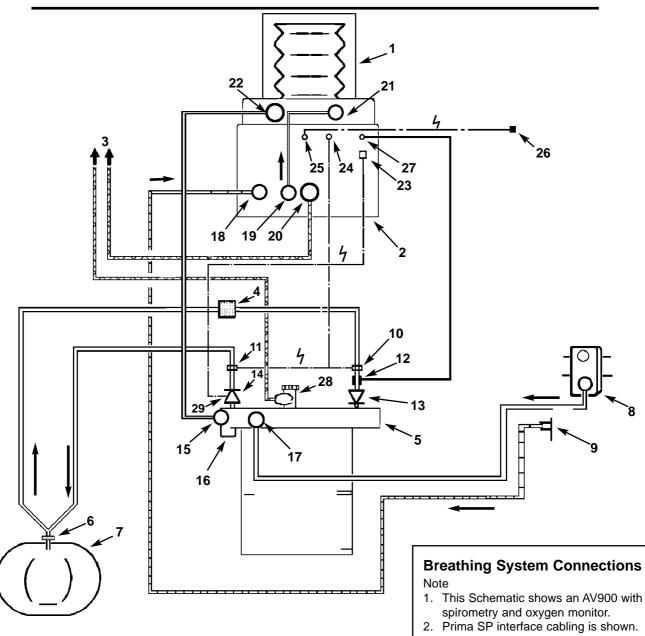
Any problem arising from an improperly functioning scavenging system is solely the user's responsibility.

- 3. Connect the spirometer sensors (if spirometry option is fitted) see Section 5.1.5.
- 4. Attach a printer to the printer port if a printed output of the ventilator function is required (see 3.5.12).
- Connect the ventilator bellows base BREATHING SYSTEM port to the breathing system.
- 6. a) Use a breathing system bacterial filter in the expiratory limb of the breathing circuit to protect the oxygen sensor
  b) Use a heat and moisture exchanger (HME) at the patient Y piece.

#### CAUTION

Replacement/Disposal - always follow the instructions supplied with the filter or HME. Always renew components at the recommended interval.

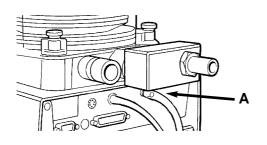
- 7. Connect a 2-litre breathing bag to the patient connection as a test lung.
- 8. Close the anaesthetic machine APL or PRV valve in the breathing system.



- Bellows 1
- **Control Unit** 2.
- Outlets to Anaesthetic Gas 3. Scavenging System (AGSS)
- **Bacterial Filter** 4.
- Absorber valve block 5.
- Heat and moisture exchanger 6.
- 7. Patient
- CGO Block on anaesthetic 8. machine (Fresh Gas Supply)
- Auxiliary Outlet on anaesthetic 9. machine (Drive Gas Supply)
- 10. Flow sensor - expiratory

- 11. Flow sensor - inspiratory
- Sensor pressure monitor 12
- Expiratory Valve Absorber 13.
- Inspiratory Valve Absorber 14.
- Inlet from Ventilator 15.
- 16. Connector - Reservoir Bag
- Inlet Absorber Fresh Gas 17. Supply
- 18. Drive Gas Inlet - Ventilator
- Drive gas Outlet control unit to 19. bellows
- 20. **Outlet - Exhaust Valve**
- 21. Inlet - Bellows Drive Gas

- The absorber is fitted with a Bag/Vent 3. switch.
  - 22. Outlet - to breathing system
  - Input socket Oxygen monitor 23. sensor
  - 24. Input socket - spirometer
  - Input socket Prima SP interface 25. (SP on/off switch, and A100SP Absorber Bag/Vent lever position)
  - 26. Interface connection on Prima SP (if fitted). See section 3.5.2.
  - Connector pressure monitor 27.
  - 28. APL Valve
  - 29. Oxygen sensor (for alternative locations, see section 3.4)



9. PRESSURE TRANSDUCER port (A) on the rear panel of the control unit: Use tubing 57523 to connect to the expiratory limb of the breathing system, close to the circle system expiratory valve.

> PrimaSP with inboard A100 Absorber: Connect the tubing (with adaptor, Part No 053049) to the self-sealing connector at **B**.

> PrimaSP with inboard A100SP Absorber: Connect the tubing (with adaptor, Part No 053049) to the self-sealing connector (**C**).

Pole mounted absorber:

Connect the tubing to the distal sensing tee at **D**.

NOTE Use a Penlon distal sensing tee (Cat. No. 53194, Breathing System Tee )

#### WARNING

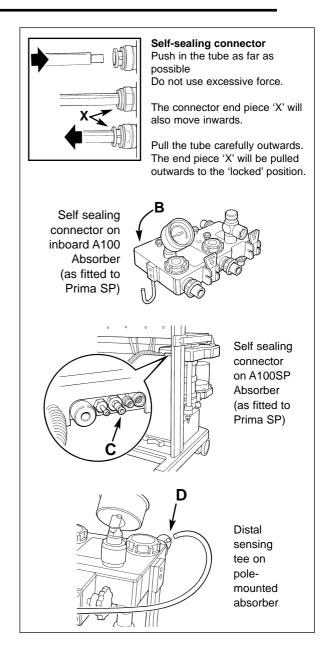
The High and Low Airway Pressure Alarms are important for patient care. The connection point must be properly located in the expiratory limb of the breathing system.

#### 5.1.4.3 Start the Ventilator

1. Press the ventilator ON/OFF switch. After a test sequence, the ventilator will revert to STANDBY mode.

NOTE special operating system on ventilators interfaced with Prima SP (see section 3.5.2).

- a) Turn the Prima Sp Gas Delivery Switch to ON - the ventilator will power-up.
- b) While the Prima SP power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch.
- c) Turn the Prima SP Gas Delivery Switch to OFF. The ventilator will power-down.
- Set the AIRWAY PRESSURE LIMIT to 50 cmH2O.



- Set TIDAL VOLUME to 600 ml, Set RATE to 10 bpm, Set I:E RATIO to 1:2.0.
- 4. Use the O2 flush button on the anaesthetic machine to fill the bellows.
- 5. Select VOLUME CYCLE.
- 6. The delivered tidal volume indicated by the scale on the side of the bellows housing should be 600 ml.
- 7. Before using the ventilator clinically:
  - a) Check all connections and verify that there are no leaks.
  - b) Spirometry check calibration (5.1.6).
  - c) Carry out a function test (see 5.3.1).

#### 5.1.5 Spirometer Connections

## Flow sensors fitted to A100 Absorber (for A100SP - see next page)

1. Use a breathing system bacterial filter - see section 5.1.4, operation 7. *CAUTION* 

Replacement/Disposal - always follow the instructions supplied with the filter. Always renew components at the recommended interval.

 Connect the two spirometry flow sensors. The recommended placement of the flow sensors is between the inspiratory and expiratory connectors on the circle absorber (A) and the patient's breathing circuit tubing.

#### CAUTION

Attach the sensors with due regard to the flow direction markings (B), and cable labelling (C). The sensors are marked for attachment to the Inspiratory or Expiratory ports of the absorber.

#### CAUTION

The electrical connectors on the flow sensors **must face upwards (D)**. This will prevent moisture entering the internal components of the sensors.

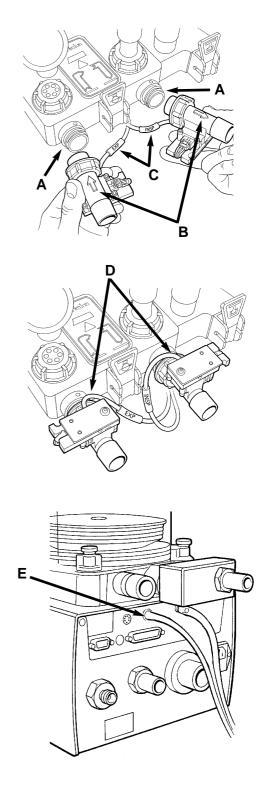
- Connect the sensor cable assembly to the 'Spiro' socket (E) at the rear of the Ventilator control unit.
- 4. Check that each sensor assembly is correctly connected between the absorber and the breathing circuit tubing. Check that the cable connections are secure.

#### NOTE

- A) If the connections are incorrectly made, the ventilator will alarm LOW TIDAL VOLUME or HIGH TIDAL VOLUME.
- B) To allow the ventilator to be used in the event of damage, or non-functioning of the spirometer heads, turn off the spirometry function see MENU function, section 3.5.

If the spirometer is switched OFF:

- a) Fresh gas compensation is disabled
- b) Fresh gas mixture compensation is disabled.
- c) Patient support function is disabled.
- C) Connection of the spirometer between the patient circuit and the absorber also provides an indication of breathing system disconnect.



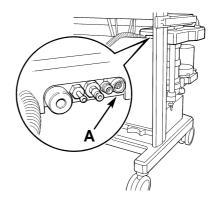
#### **Spirometer Connections**

#### Flow sensors fitted to an A100SP Absorber mounted on a Prima SP

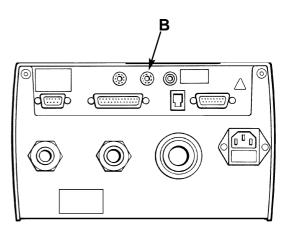
- 1. Use a breathing system bacterial filter see section 5.1.4, operation 7. *CAUTION Replacement/Disposal - always follow the instructions supplied with the filter. Always renew components at the recommended interval.*
- 2. The two spirometry flow sensors are mounted within the A100SP Absorber in the inspiratory and expiratory airways.
- Connect the sensor cable assembly between the connector at the rear of the A100SP Absorber (A) and the the 'Spiro' socket (B) at the rear of the Ventilator control unit.
- 4. Check that the cable connections are secure.

#### NOTE

- A) If the connections are incorrectly made, the ventilator will alarm LOW TIDAL VOLUME or HIGH TIDAL VOLUME.
- B) To allow the ventilator to be used in the event of damage, or non-functioning of the spirometer heads, turn off the spirometry function see MENU function, section 3.5.
  - If the spirometer is switched OFF:
  - a) Fresh gas compensation is disabled
  - b) Fresh gas mixture compensation is disabled.
  - c) Patient support function is disabled.



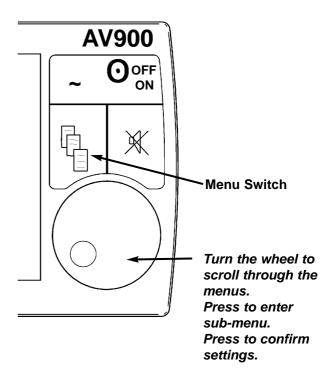
Rear view of A100SP Absorber (as fitted to Prima SP)



### 5.1.6 Spirometer Calibration

#### Spirometer system with flow sensors fitted to A100 Absorber (for A100SP - see next page)

- 1. Remove the spirometer sensors from the breathing system.
- 2. Press the menu switch on the front panel.
- 3. Scroll down the main menu and select SPIROMETRY.
- 4. Scroll down the sub-menu and select CALIBRATION.
- 5. Turn the wheel to switch display to CALIBRATION: cal
- 6. A message will appear: Remove the spirometer head.
- 7. Press the wheel to initiate calibration.
- 8. Calibration is completed.
- 9. Scroll to ESCAPE FROM MENUS.
- 10. Press the wheel to confirm.
- 11. Refit the spirometer sensors (see section 5.1.5).



### Main menu

O2 MONITOR > SPIROMETRY FRESH GAS COMPENSATION : ON GAS MIXTURE VOLUME TYPE WAVEFORM SERVICE ESCAPE FROM MENUS

#### Spirometry sub-menu

- SPIROMETRY : ON
- CALIBRATION : cal ESCAPE FROM MENUS

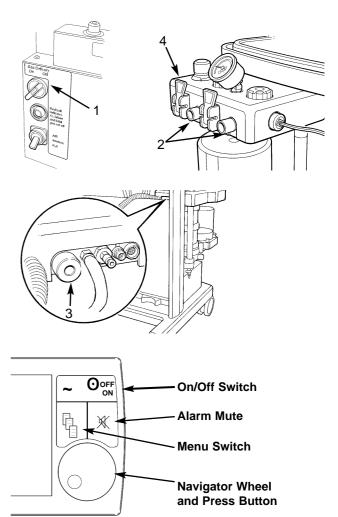
## Spirometer Calibration - system fitted to an A100SP Absorber mounted on a Prima SP

The Spirometry heads must be calibrated with zero flow going through them.

- Turn the Prima SP gas flow off at the Gas Delivery switch (1). This will stop all gas flows (including the AHD basal flow). This will also turn the AV900 off.
- 2. Turn the AV900 on at the ventilator (Do not use the Prima SP Gas Delivery switch).
- 3. Remove the breathing circuit hoses from the inspiratory and expiratory connectors (2) on the absorber.
- 4. Disconnect the fresh gas hose from the CGO block on the anaesthetic machine.
- Disconnect the hose from the APL valve outlet
   (3) at the rear of the manifold block
- 6. a) Ensure that the ventilator bellows is empty, or,

b) Remove the bag, and set the Bag/Vent lever(4) to Bag position.

- 7. Calibrate the spirometer via the ventilator menu procedure. NOTE Do NOT remove the spirometer heads.
- 8. Press the menu switch on the front panel.
- 9. Main menu select SPIROMETRY.
- 10. Sub-menu select CALIBRATION.
- 11. Turn the wheel to switch display to CALIBRATION: cal
- 12. A message will appear: "Remove the spirometer head" Do NOT remove the spirometer heads
- 13. Press the wheel to initiate calibration.
- 14. Repeat operations 8 to 12, twice more.
- 15. Calibration is completed.
- 16. Scroll to ESCAPE FROM MENUS.
- 17. Press the wheel to confirm.

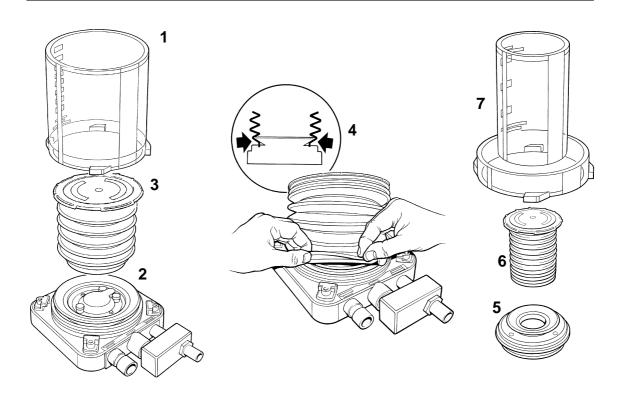


#### Main menu

O2 MONITOR > SPIROMETRY FRESH GAS COMPENSATION : ON GAS MIXTURE VOLUME TYPE WAVEFORM SERVICE ESCAPE FROM MENUS

#### Spirometry sub-menu

- SPIROMETRY : ON
- > CALIBRATION : cal ESCAPE FROM MENUS



### 5.2 Bellows Assemblies

#### CAUTION

Always ensure correct fitment of bellows (see illustration above), and carry out a full function test before clinical use, if a bellows is removed and refitted.

- 1. Remove the bellows housing (1). Twist carefully counterclockwise until the bayonet tabs become free, then lift up from the base (2).
- 2. Remove the bellows (3).
- 3. Refit the bellows and check for correct assembly, as illustrated (4).
- 4. Fit the bellows housing to the base by pushing down, then twisting clockwise until the bayonet tabs completely engage.
- 5. Function test the ventilator section 5.3.1.

#### NOTE

If there is any malfunction, the ventilator must NOT be used.

If the problem cannot be rectified, the ventilator must be checked by a Penlon trained engineer.

### **Paediatric Bellows Assembly**

- Remove the adult bellows housing

   twist carefully counterclockwise
   until the bayonet tabs become free,
   then lift up from the base (2).
   Remove the bellows (3).
- 2. Fit the paediatric adaptor (5) press the adaptor into the ventilator bellows assembly base (2).
- Fit the paediatric bellows (6) to the adaptor.
   Check for correct assembly, as illustrated (4).
- 4. Fit the paediatric bellows housing (7) to the base by pushing down, then twisting clockwise until the bayonet tabs completely engage.
- 5. Function test the ventilator section 5.3.1.

### 5.3 Pre-use Checklist

#### 5.3.1 Daily Checklist

The following tests must be carried out at the beginning of every working day:

#### Alarm System

#### WARNING

The operation of each alarm function should be verified daily.

If the audible alarm or the visual display for any alarm function fails to activate during any alarm condition or fails to reset after the alarm has been cleared, refer the unit to an authorised service technician.

#### **Back-up Battery**

#### WARNING

If the internal battery is fully discharged, the ventilator will not function.

Recharge the battery before the ventilator is used clinically.

Charging the battery for 14 hours from a discharged state will allow a minimum of 60 minutes of continuous operation.

Connect the ventilator to a mains power supply. The mains power indicator will illuminate to show that the battery is being charged (it is not necessary to turn on the ventilator).

### Ventilator internal test

Press the ON/OFF switch.

A three-second internal test is initiated:

- 1. The 'power -up' screen is displayed.
- 2. The audible alarm sounds one high tone, one low tone.
- 3. The ventilator reverts to STANDBY mode.

NOTE special operating system on ventilators interfaced with Prima SP (see section 3.5.2).

- a) Turn the Prima Sp Gas Delivery Switch to ON - the ventilator will power-up.
- b) While the Prima SP power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch.
- c) Turn the Prima SP Gas Delivery Switch to OFF. The ventilator will power-down.

#### **Function Test**

- 1. Set the AIRWAY PRESSURE LIMIT to 50 cmH<sub>2</sub>O.
- 2. Check that the PRESSURE TRANSDUCER port on the rear of the control unit is correctly connected to the expiratory limb of the breathing circuit, close to the circle system expiratory valve (see operation 10 section 5.1.4).
- Connect the ventilator bellows base BREATHING SYSTEM port to the breathing system.
- 4. Connect a 2-litre breathing bag to the patient connection as a test lung.
- 5. Close the anaesthetic machine APL or PRV valve in the breathing system,
- Adult bellows only: Set the tidal VOLUME to 600 ml; RATE to 10 bpm, and I:E RATIO to 1:2.0.
- 7. Use the O2 flush button on the anaesthetic machine to fill the bellows.
- 8. Select VOLUME CYCLE mode.
- 9. The delivered tidal volume indicated on the scale printed on the bellows housing should be 600 ml.

If the delivered tidal volume is less than 500 ml or greater than 700 ml, refer the ventilator to a Penlon-trained engineer.

- Occlude the patient 'Y' -piece. The HIGH AIRWAY PRESSURE alarm should be activated. The peak pressure read on the breathing system pressure gauge is the maximum working airway pressure limit and should agree with the setting.
- Open the patient 'Y' -piece to ambient pressure.
   At the second cycle, the LOW AIRWAY PRESSURE alarm should be activated.

12. Select STANDBY mode Before using the ventilator clinically, check that all connections are correct, and verify that there are no leaks.

NOTE

If there is any malfunction, the ventilator must NOT be used.

If the problem cannot be rectified, the ventilator must be checked by a Penlon trained engineer.

#### 5.3.2 Weekly Checklist

At least every week, in addition to the daily function test:

- 1. Select STANDBY MODE.
- Unplug the mains power cable from the AC outlet. The MAINS FAILURE alarm should activate.
- Reconnect the mains power cable to the AC outlet. The alarm should turn off.
- 4. Disconnect the drive gas supply hose. The LOW SUPPLY PRESSURE alarm should activate.

NOTE

If there is any malfunction, the ventilator must NOT be used.

If the problem cannot be rectified, the ventilator must be checked by a Penlon trained engineer.

### 5.4 Oxygen Monitor System Set-up (if fitted)

#### 5.4.1 Installation

Fit the probe as illustrated, depending on the system installed on your anaesthetic machine

- 1. Prima SP with A100SP Absorber
- 2. Mounted on the dome of the absorber inspiratory valve
- 3. 'T' piece adaptor on CGO block

Connect the cable to the input socket (A) on the back of the AV900 ventilator control unit

NOTE The anaesthetic machine gas control switch must be in the ON position for gas delivery.

#### WARNING

The sensor contains a small quantity of electrolyte, classified as a harmful irritant which is potentially hazardous.

Do not attempt to open a cell.

ALWAYS check the integrity of the sensor assembly before use.

Once exhausted, the sensor must be disposed of according to hospital, local, state and federal regulations.

NOTE To maintain maximum sensor life, always remove from breathing circuit after use.

#### **Bacterial Filter**

Use a breathing system bacterial filter in the expiratory limb of the breathing circuit to protect the oxygen sensor (see section 5.1.4.2).

#### CAUTION

Replacement/Disposal - always follow the instructions supplied with the filter, and always replace at the recommended interval.

### 5.4.2 Calibration

The new unit must be calibrated before clinical use. Thereafter, as a safety precaution, we recommend calibration of the unit every time the system is switched on.

Calibration must also be performed:

- A) when the sensor is replaced
- B) when point-of-use elevation changes by more than 160 m (500 ft).

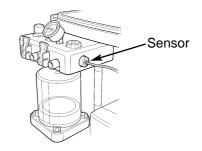
We recommend calibration with a 100% oxygen standard source, at a pressure and flow similar to your application.

Calibration at 21% (i.e. using air) is possible, but less desirable.

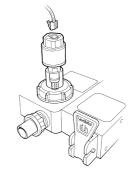
# Sensor Location and Cable Connections

1. Prima SP with A100SP Absorber

Please refer to the user instructions supplied with the absorber.



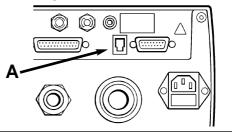
## 2. Mounted on the dome of the absorber inspiratory valve



#### 3. 'T' piece adaptor on CGO block



Cable connection on AV900 control unit rear panel



#### 5.4.2.1 Calibration - Using 100% Oxygen

#### NOTE

If the AV900 ventilator is used on a Prima SP anaesthetic machine fitted with a A100SP absorber, please refer to the User Instructions supplied with the A100SP.

1. Switch on the ventilator and the anaesthetic machine gas control switch. The oxygen monitor automatically

switches ON when the ventilator is switched on.

- 2. Ensure that all vaporizers are OFF.
- 3. Flush 100% oxygen through the CGO and maintain the flow through the total breathing circuit for approximately 20 seconds.
- 4. Allow the oxygen sensor to stabilise (30 seconds.)
- 5. Press the menu switch and select the O<sub>2</sub> monitor sub-menu.
- Scroll to CALIBRATION and press the navigator wheel to switch to 100% (calibration using oxygen) if the menu shows 21% (calibration using air).
- 7. A message will flash on the screen: O2 AT 100% ?

Press the button to confirm *NOTE* 

The message:

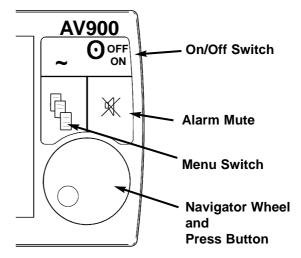
OXYGEN SENSOR LOW OUTPUT will appear on screen if the user attempts to calibrate at 21% in 100% oxygen

- 8. Scroll to ESCAPE FROM MENUS and press the wheel to exit.
- 9. Check the monitor with the sensor in Air:

Detach the sensor from the anaesthetic machine, and gently move it through the air to allow room air to circulate for 20 seconds.

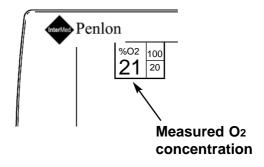
Allow the oxygen sensor to stabilise (30 seconds.)

Check that the measured O2 concentration display shows 21% (±1%).



### O2 Monitor sub-menu - calibration

O2 MONITOR : ON > CALIBRATION: 100% HIGH ALARM SET LOW ALARM SET ESCAPE FROM MENUS



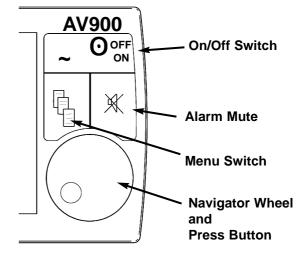
#### 5.4.2.2 Calibration - Using Room Air

#### NOTE

If the AV900 ventilator is used on a Prima SP anaesthetic machine fitted with a A100SP absorber, please see page 58.

NOTE Calibration in room air may not provide as great an accuracy as calibration carried out in 100% oxygen.

- Switch on the ventilator and the 1. anaesthetic machine gas control switch. The oxygen monitor automatically switches ON when the ventilator is switched on.
- Ensure that all vaporizers are OFF. 2.
- Detach the sensor from the anaesthetic 3 machine, and gently move it through the air to allow room air to circulate for 20 seconds.
- Allow the oxygen sensor to stabilise (30 4. seconds.)
- 5. Press the menu switch and select the O2 monitor sub-menu.
- 6. Scroll to CALIBRATION and press the navigator wheel to switch to 21% (calibration using air) if the menu shows 100% (calibration using oxygen).
- A message will flash on the screen: 7. O2 AT 21% ? Press the button to confirm Note that the message: OXYGEN SENSOR LOW OUTPUT will appear on screen if the user attempts to calibrate at 21% in 100% oxygen
- Scroll to ESCAPE FROM MENUS and 8. press the wheel to exit.
- Refit the oxygen sensor and check the 9. monitor with the sensor in oxygen: Flush 100% oxygen through the CGO and maintain the flow through the total breathing circuit for approximately 20 seconds. Allow the oxygen sensor to stabilise (30 seconds.) that the measured O2 Check concentration display shows 100%
  - (±1%).

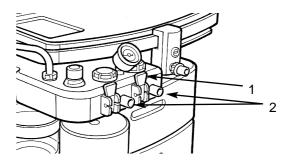


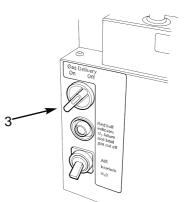
#### Calibration - Using 100% Oxygen

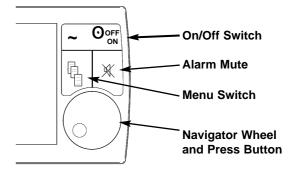
AV900 ventilator system mounted on a Prima SP anaesthetic machine fitted with a A100SP absorber,

Calibrate with the sensor in position within the absorber.

- Pull the Absorber On / Off lever (1) down to its OFF position. The flow will bypass the absorbent.
- Remove the breathing circuit hoses from the inspiratory and expiratory connectors (2) on the absorber.
   This will give a free flow of oxygen through the sensor.
- 3. Switch on the ventilator and the anaesthetic machine gas delivery switch (3). *The oxygen monitor automatically switches ON when the ventilator is switched on.* Ensure that all vaporizers are OFF.
- 4. Apply 100% oxygen only, at 5 L/min, from the anaesthetic machine flowmeter.
- 5. Allow the oxygen to flow until the oxygen monitor readout stabilises.
- 6. Calibrate the sensor, using the AV900 ventilator menu procedure, as follows.
- 7. Press the menu switch and select the O<sub>2</sub> monitor sub-menu.
- Scroll to CALIBRATION. If the menu shows 21% (calibration using air), press the navigator wheel to switch to 100% (calibration using oxygen).
- 9. A message will flash on the screen: O2 AT 100% ?
  Press the button to confirm NOTE The message: OXYGEN SENSOR LOW OUTPUT will appear on screen if the user attempts to calibrate at 21% in 100% oxygen.
- 10. Repeat operations 8 and 9 twice more.
- 11. Scroll to ESCAPE FROM MENUS and press the wheel to exit.







#### O2 Monitor sub-menu - calibration

O2 MONITOR : ON > CALIBRATION: 100% HIGH ALARM SET LOW ALARM SET ESCAPE FROM MENUS

12. Turn off the flow of oxygen.

#### 5.4.3 Sensor Low Indication

The unit automatically detects when sensor life is low. The message:

OXYGEN SENSOR LOW OUTPUT will appear on screen to indicate that the sensor must be replaced.

The sensor output will fall very quickly to zero over a period of two to three weeks from the first time that the alarm is activated.

Sensor replacement - see section 7.5.

### 5.4.4 Setting the O<sub>2</sub> Alarms

#### 5.4.4.1 Set High Alarm

The high alarm value cannot be set below 19% or above 105% (Note that in certain conditions of excess pressure, the readout may show a value above 100%.).

- 1. Press the menu switch on the ventilator front panel select the O<sub>2</sub> monitor sub-menu.
- 2. Scroll to HIGH ALARM SET and press the navigator wheel.
- 3. Rotate the wheel to change the displayed alarm figure to the desired value.
- 4. Press the wheel to confirm.
- 5. Scroll to ESCAPE FROM MENUS and press the wheel to exit.

#### 5.4.4.2 Set Low Alarm

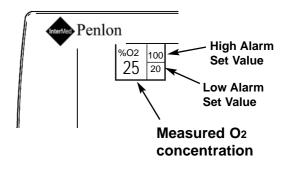
The low alarm value cannot be set lower than 18%, or above 99%.

- 1. Press the menu switch on the ventilator front panel select the O2 monitor sub-menu.
- 2. Scroll to LOW ALARM SET and press the navigator wheel.
- 3. Rotate the wheel to change the displayed alarm figure to the desired value.
- 4. Press the wheel to confirm.
- 5. Scroll to ESCAPE FROM MENUS and press the wheel to exit.

#### O2 Monitor sub-menu - calibration

O2 MONITOR : ON CALIBRATION: 100% > HIGH ALARM SET

LOW ALARM SET ESCAPE FROM MENUS



## 6. CLINICAL OPERATION

### 6.1 Before Using the Ventilator

- 1. Prior to use with a patient, check that all connections are correct and verify that there are no leaks.
- 2. Perform the daily checklist detailed in section 5.3.1.

#### WARNING

An alternative means of ventilation must be available whenever the ventilator is in use (e.g. manual resuscitation).

NOTE special operating system on ventilators interfaced with Prima SP (see section 3.5.2).

- a) Turn the Prima Sp Gas Delivery Switch to ON - the ventilator will power-up.
- b) While the Prima SP power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch.
- c) Turn the Prima SP Gas Delivery Switch to OFF. The ventilator will power-down.

### 6.2 Setting the Parameters

Select STANDBY mode, and set the appropriate parameters for the patient:

- 1. Set the TIDAL VOLUME
- 2. Set the RATE
- 3. Set the I:E ratio
- If the parameter being adjusted will not increase, and the INCORRECT RATE or RATIO alarm is activated, the flow demanded has reached the allowable maximum of 75 L/min or, minimum of 2 L/min. Adjust the other two parameters to allow a further increase or decrease of the desired parameter.
- Set the maximum airway pressure. Note that all displayed parameters are always delivered, unless the LOW DRIVE GAS SUPPLY alarm is on.

#### CAUTION

The specifications and displayed values apply only to the ventilator and may have no direct relationship to the ventilation of the patient. The characteristics of the breathing system connected between the patient and the ventilator can change or modify patient ventilation.

#### **Compliance Compensation**

#### WARNING

The ventilator has circuit compliance compensation and fresh gas / gas mixture compensation.

However, the actual tidal volume delivered to the patient may be different to the ventilation parameters set by the user, due to:

- A) an extreme compliance condition,
- B) a substantial system leak,
- C) patient circuit pressure effects, or
- D) extreme fresh gas flows

In addition, high fresh gas flows will lead to an increased Vt being delivered to the patient.

Note that on models fitted with spirometry, the actual tidal volume exhaled will be displayed.

### The patient <u>must</u> be monitored independently from the ventilator

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

#### **Circuit compliance**

NOTE: On models with spirometry, circuit compliance is not activated until Fresh Gas Compensation is switched OFF.

### Fresh Gas Compensation - models with Spirometry

Fresh gas compensation is disabled if :

a) The spirometry system is turned OFF through the menu system, or

b) The spirometry system is not functioning correctly.

#### Fresh Gas Mixture Compensation - models with Spirometry

Fresh gas mixture compensation is disabled if :

a) The spirometry system is turned OFF through the menu system, or

b) The spirometry system is not functioning correctly.

c) The O<sub>2</sub> monitor is switched OFF.

#### Ventilating the Patient

To start ventilating the patient:

- 1. Switch the breathing system from the breathing bag to the ventilator.
- 2. Select VOLUME CYCLE or PRESSURE mode on the ventilator.
- 3. Select gas mixture (see section 3.5.4).

## **CLINICAL OPERATION**

### 6.3 Positive End Expiratory Pressure (PEEP)

Select PEEP on the touchscreen display (3.5.10).

Pressure can be set between 4 and 30 cmH<sub>2</sub>O.

The only pressurised part of the breathing system should be the patient and the connecting hoses between the inspiratory and expiratory valves.

Note that the use of PEEP alters the compliance of the breathing system.

### 6.4 Bellows Pressure

#### WARNING

The bellows can support only 10 cmH2O differential pressure.

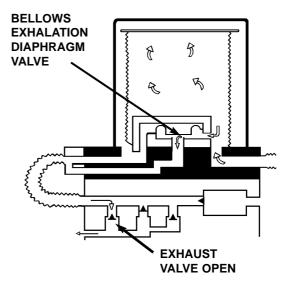
Normally the pressure on the inside and outside of the bellows are approximately the same.

During the expiratory phase the exhalation diaphragm valve under the bellows is deenergised so that the inside of the bellows is connected to the ambient through the drive gas circuit to the ventilator exhaust.

The bellows can support only 10 cmH2O across it. Above this pressure it may be dislodged from the mounting ring, resulting in a dangerous malfunction of the ventilator. The exhalation diaphragm valve has 1.5 cmH2O opening pressure to keep the bellows from collapsing.

The outside of the bellows (the space between the bellows and the bellows housing) is also connected to the ambient through the de-energised discharge valve in the control unit.

Therefore, the only pressure gradient across the bellows is the opening pressure of the exhalation diaphragm valve.



### 7.1 Service Schedule

At 6 months, 12 months, and 5 years, the ventilator must be serviced by a Penlontrained engineer, following the schedule given below, and the procedures given in the AV900 Service Manual.

#### Every day:

Pre-use function check

#### Every week:

Check the condition of the diaphragm valve, and clean as required.

Test the Mains Failure Alarm and the Low Supply Pressure Alarm - see section 5.3.2

If the ventilator is used in conjunction with an A100 or A100SP Absorber, check that the condensate is drained from the absorber, as specified in absorber User Manual.

#### Every 6 months:

Inspection and Function Check. Remove covers, internal inspection and clean. Check condition of bellows and spirometer sample lines.

#### Every 12 months:

Repeat six month procedure, plus: Replace O-seals and drive gas inlet filter. Preventive maintenance kit available.

#### Every 5 years:

Major Service Replace battery. Fit service exchange pneumatic assembly Replace the spirometer sensor and sample lines

Details of these service operations are given in the Service Manual.

Always ensure that a record is kept of any service or repair work.

### 7.2 Cleaning

## Outside surfaces and bellows housing

#### CAUTION

Care must be taken not to allow liquids to run into the control unit; serious damage may result.

Check that the unit is disconnected from the electrical supply before cleaning.

Do not use cleaning solutions containing alcohol; the bellows housing may be damaged.

To clean the outside surface of the ventilator, use a damp cloth.

If necessary use a warm, mild detergent solution to remove resistant grime. Make sure that all detergent residues are fully removed after cleaning.

Never use any harsh abrasive cleaning agent. The transparent acrylic bellows housing and, in general, the surfaces of the control unit are not scratch resistant.

The inside of the bellows housing, under normal conditions, is not in contact with the breathing gas and therefore only needs cleaning as described above.

Remove the bellows housing (A) by slightly twisting it counter-clockwise until the tabs at the bottom clear the bayonet locks, then lift it straight up from the base.

#### Touchscreen

Use a soft cloth only. Never use any harsh abrasive cleaning agent.

## Bellows and exhalation diaphragm valve

Each time the bellows assemblies are opened for cleaning, all visible components must be carefully inspected and damaged parts must be replaced.

#### **Bellows**

As with all elastomers, the bellows material deteriorates with aging and should be inspected at least every six months or after 1200 hours of use, whichever comes first. The bellows must be replaced if it shows signs of aging.

The bellows (B) can be removed by carefully pulling it off the base.

If a paediatric bellows is fitted, the bellows adaptor (C) must also be removed.

Do not dismantle the bellows.

#### **Exhalation Diaphragm Valve**

The exhalation diaphragm valve is under the bellows and can be removed by loosening the three thumbscrews.

The valve seat is now visible.

#### WARNING

Great care must be taken. Do not damage the precision surface of the valve seat (D). Never use any hard object or abrasive agent

to clean it; use only a soft cloth. If the valve seat is damaged, the diaphragm

valve will leak and may cause serious malfunction.

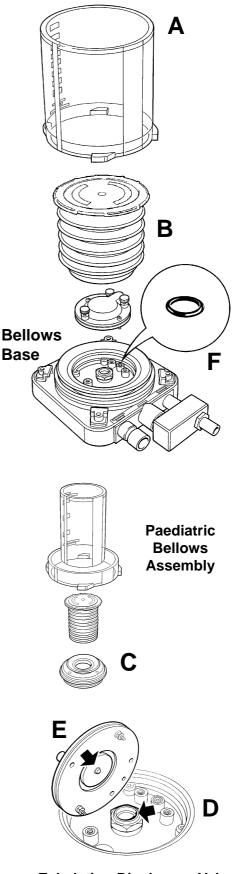
Clean the seat, and the metal disk (E) attached to the base of the diaphragm valve, thoroughly and remove all contamination from the surfaces of both components.

#### NOTE

If excessive contamination is discovered, check that a bacterial filter is used in the expiratory limb of the breathing circuit (or an HME at the patient tee-piece). See section 5.1.4.

After cleaning, check that the small O-ring (F) located in the bellows base under the diaphragm valve is in place. The ventilator will not function if the O-ring is missing.

See section 7.3 for information on sterilisation procedures.



#### Exhalation Diaphragm Valve Assembly

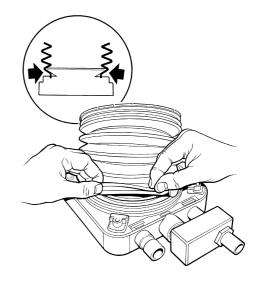
#### Refitting

Refit the diaphragm valve assembly to the bellows base and reassemble the bellows assembly (see section 5.2).

If a paediatric bellows is fitted, press the adaptor (C) into the ventilator bellows assembly base, then fit the bellows.

#### CAUTION

Always check for correct fitment of the bellows (see illustration), and function test the ventilator before clinical use.



# 7.3 Spirometer Sensors (as fitted to A100 Absorber only)

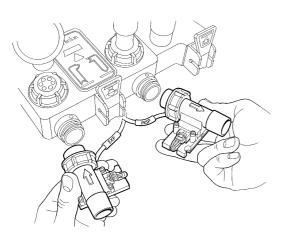
For information on the sensors fitted to the A100SP Absorber, please refer to the user instructions supplied with the A100SP.

On a regular basis (in line with hospital procedures for infection control), the spirometer sensors must be removed and sterilised.

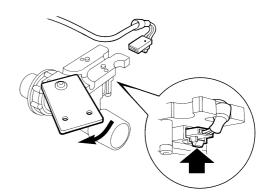
Follow the illustrated remove and refit sequence on the following page.

- a) Detach each spirometer sensor from the breathing system.
- b) Carefully disconnect the cable from each sensor.
- c) Sterilisation see section 7. Do **not** sterilise the cables.
- d) When the components are dry: Reconnect the cables - check the label on each cable and the flow direction arrow on the sensor. Route the cable as shown in illustration 3, before rotating the cover plate to its closed position.
- e) Refit the sensors to the breathing system (see also section 5.1.5).

### Spirometer Sensors - A100 Absorber

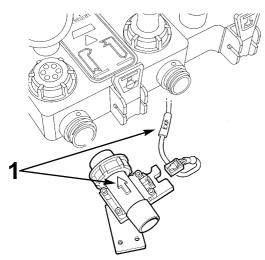


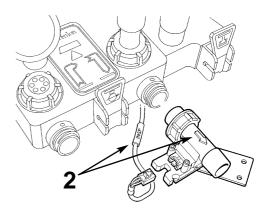
Detach each spirometer sensor from the breathing system.

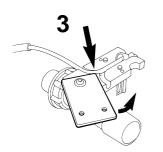


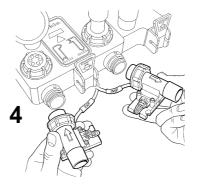
Carefully disconnect the cable from each sensor.

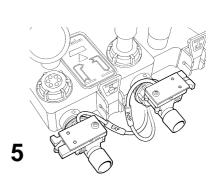
### Reassembly











### 7.4 Sterilisation

Recommended guidelines for sterilisation

#### CAUTION

To prevent possible damage to components, peak sterilisation temperatures must not exceed :

54°C (130°F) for gas (ethylene oxide) or,

 $134^{\circ}C$  (275°F) for steam autoclave.

Do not sterilise the ventilator control unit. The internal components are not compatible with sterilisation techniques and may be damaged.

Following sterilisation with ethylene oxide, components must be quarantined in a well ventilated area to allow dissipation of any residual gases.

Follow the recommendations given by the steriliser manufacturer for aeration periods required.

ITEM	METHOD
Bellows	Gas, liquid, autoclave (20 cycles max.)
Hoses	Gas, liquid, autoclave
O rings	Gas, liquid, autoclave
Bellows base	Gas, liquid, autoclave
Exhalation valve assembly	Gas, liquid, pasteurise, low temperature autoclave
Control unit	Do not sterilise - see section 7.2.
Bellows canister	Liquid, autoclave
Spirometer sensor	Autoclave

Oxygen monitor - see section 7.4

NOTE Examples of suitable liquid agents are: Nu-Cidex, Sporicidin, and Sonacide. The exhalation diaphragm valve must be removed, cleaned and sterilised separately.

# **USER MAINTENANCE**

## 7.5 Oxygen Monitor Sensor - Cleaning and Disinfection

#### CAUTION

If you use ethylene oxide for sterilisation, use only a **low** temperature ethylene oxide method. Do **not** immerse the sensor in any cleaning solution.

Do not autoclave or expose the sensor to high temperatures.

#### **Bacterial Filter**

Use a breathing system bacterial filter in the expiratory limb of the breathing circuit (to protect the oxygen sensor - section 5.1.4.2). *CAUTION* 

Replacement/Disposal - always follow the instructions supplied with the filter, and always replace at the recommended interval.

# 7.6 Oxygen Sensor Replacement

## WARNING

The sensor contains:

A) A small quantity of electrolyte, classified as a harmful irritant which is potentially hazardous.

B) Lead

Do not attempt to open a cell.

ALWAYS check the integrity of the sensor assembly before use.

Once exhausted, the sensor must be disposed of according to hospital, local, state and federal regulations.

## 7.6.1 Sensor Expiry Date

The approximate expiry date is marked on the sensor label, using two boxes which represent the year and month.

Thus, on a sensor marked as below the approximate expiry date is the end of December 2006.

YR 0 1 2 3 4 5 X 7 8 9 MTH J F M A M J J A S O N X

## 7.6.2 Sensor Unit - Remove and Refit

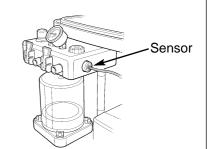
Replacement parts

102714Sensor (includes flow diverter and O rings)58779Tee adaptor

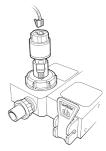
- 1. Detach the cable connector (A) from the sensor (B).
- 2. Unscrew the sensor from its location.
- 3. Discard the expired sensor and flow diverter (C).
- 4. Insert the cable connector into the new sensor (B).
- 5. Screw the new flow diverter (C) onto the new sensor, and fit new O rings.
- 6. Fit the assembly into the absorber or Tee adaptor.
- 7. Calibrate the new sensor, see section 5.4.
- 8. Dispose of the used components according to hospital regulations and relevant national legislation.

## Oxygen Sensor Location

1. Prima SP with A100SP Absorber

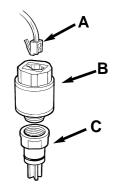


# 2. Mounted on the dome of the absorber inspiratory valve



3. 'T' piece adaptor on CGO block





# 8. ORDERING INFORMATION

#### Spares

Contact your distributor, or the Service Department at Penlon Limited for spare parts.

 Service
 Department

 Tel:
 +44
 1235
 547060

 Fax:
 +44
 1235
 547061

 E-mail:
 service@penlon.co.uk

57653 Preventive Maintenance Kit (must be fitted by a Penlon-trained engineer)

57654 Overhaul kit - Five year (must be fitted by a Penlon-trained engineer)

#### Accessories

Contact your distributor, or the sales office at Penlon Limited, for full details of the range of accessories for the AV900 ventilator.

UK:	Sales Office Tel: 01235 547036 Fax: 01235 547023 Tel: +44 1235 547041 Fax: +44 1235 5		uksales@penlon.co.uk E-mail: export@penlon.co.uk		
Mains e 57513 57493 57590	electrical power cables 1.5 m 240 V AC IEC plug. 1.5 m 120 V AC CSA plug. 3.0 m 240/220 V AC IEC wiring code, no pl	57514 57494 ug	3.0 m 240 V AC 3 pin UK plug. 3.0 m 120 V AC CSA		
<b>Drive h</b> 57510 57529 56048	oses 1.4 m DISS to mini Schraeder (O2) 1.4 m DISS to reverse DISS (O2) CSA 5.0 m DISS to DISS (O2)	57515 57528	1.4 m DISS to DISS (O2) (green) 1.0 m DISS to DISS (O2) (white)		
Options57546Paediatric bellows, canister and base57638Air hose kit, 1.5 m hose, adaptor (kit must be fitted by a Penlon-trained engineer) (also available - 574961.2 m hose - DISS to quick release - Air)					
Mounting Systems58381Mounting bracket (pole mount)57591Mounting Kit (use to mount bellows/base assembly onto an anaesthetic machine)58581Mounting bracket (Prima side mount)58585Mounting bracket (Prima pole mount)58470Mounting Kit (use to mount a bellows/base assembly onto an absorber)					
<b>Miscella</b> 57523 57655	aneous Pressure sensor tube Pressure sensor tee	053049	Tubing adaptor		
57653 57654					
57545 57548	Bellows and Canister Base assembly	57550 57547	Bellows Base assembly and AGSS adaptor.		
57554 57552	Base adaptor - Paediatric bellows Paediatric bellows	57546 57553	Paediatric: canister and bellows Paediatric canister		
57549 51537	AGSS adaptor. 19 mm female to 30 mm mal Drive gas hose. 16 mm diameter x 210 mm lo				
Oxygen Monitor					

102714 Sensor (includes flow diverter and O rings) 58779 Tee adaptor

# 9. APPENDIX

## **APPENDIX 1**

## **Care of Back-up Battery**

CAUTION Damage may occur if the battery is allowed to remain in a discharged state. Never discharge the battery to below 10.2 volts.

## A. Battery installed in ventilator

The battery must be charged before the machine is released for use with an 14 hour charge from the ventilator's internal power supply (ventilator connected to the mains supply, but not running).

Note that the mains power indicator on the front panel will show a yellow light during charging.

Subsequently the recharge periods for a battery on a ventilator in store are similar to those in B, below.

Batteries in machines in normal use will be kept charged by the internal power supply.

Note that the Low Battery Alarm indicator may be displayed if automatic rechargong is taking place as the ventilator is in use.

#### B. Battery care/storage requirements.

During storage batteries will require a periodic recharge, the frequency of which is determined by the storage temperature, which must not exceed  $50^{\circ}C$  ( $120^{\circ}F$ ).

Storage temperature	Recharge period
38 to 50 <sup>0</sup> C (100 to 122 <sup>0</sup> F)	1 month
21 to 38 <sup>o</sup> C (70 to 100 <sup>o</sup> C)	3 months
7 to 21 <sup>0</sup> F (45 to 70 <sup>0</sup> F)	6 months
0 to 7 <sup>o</sup> C (32 to 45 <sup>o</sup> F)	9 months
-5 to 0 <sup>0</sup> C (23 to 32 <sup>0</sup> F)	12 months

Duration - recharge until the charge current is less than 25 mA (typically overnight).

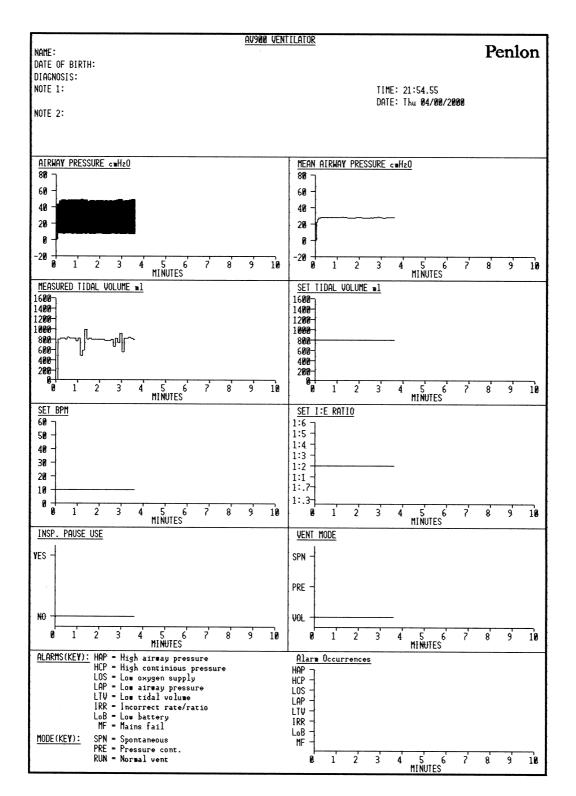
It is recommended that at each charge an updated label is affixed to each battery to indicate date of the last charge.

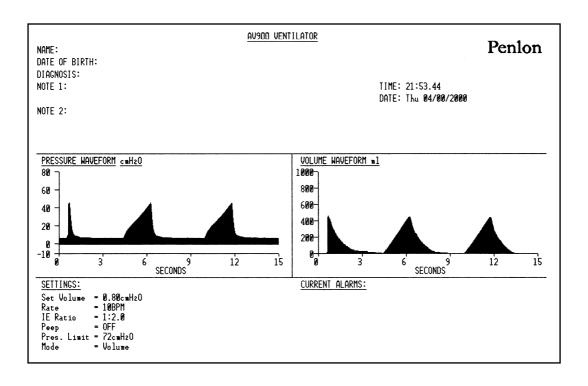
## C. Disposal of used batteries

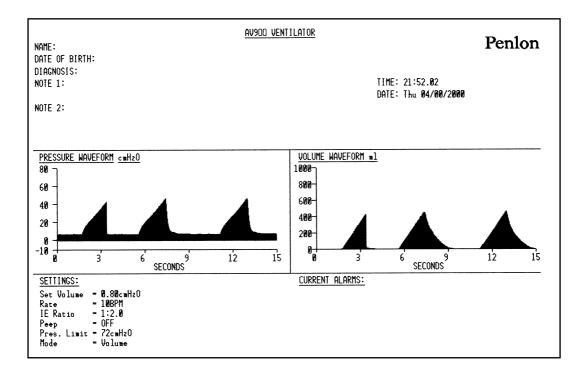
Used batteries must be disposed of according to hospital, local, state and federal regulations.

## **APPENDIX 2**

## Examples of print-out capability







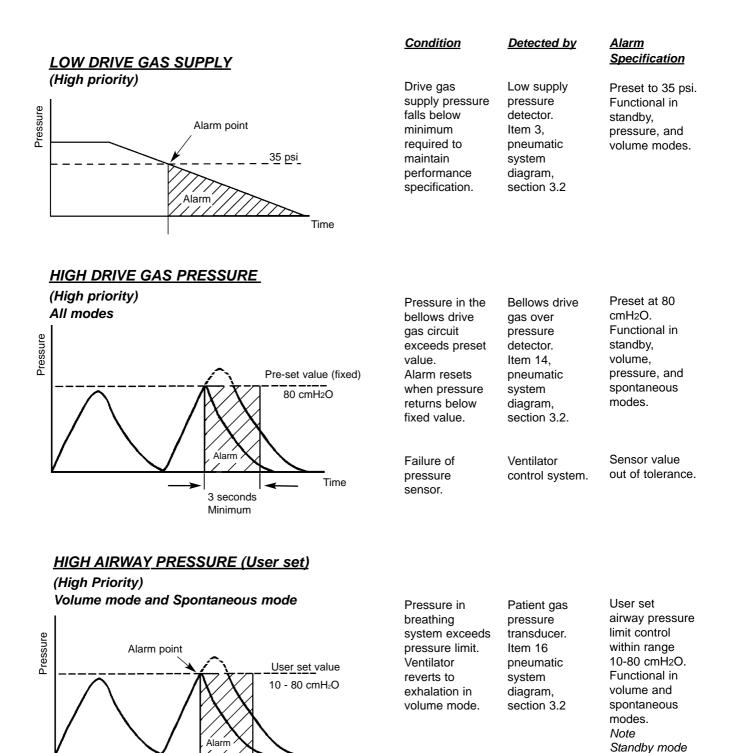
# AV900 V4

Main Board Version 4.19 onwards Front Panel Version 4.25 onwards

# Ventilator Alarms - Theory of Operation

The following pages provide information on the function and operation of the alarms fitted to the AV900 V4 Ventilator.

## APPENDIX 2 Ventilator Alarms - Theory of Operation



73

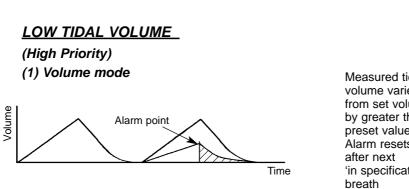
Time

3 seconds

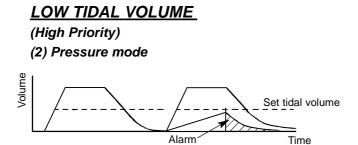
Minimum

- alarm is triggered at 80

cmH<sub>2</sub>O

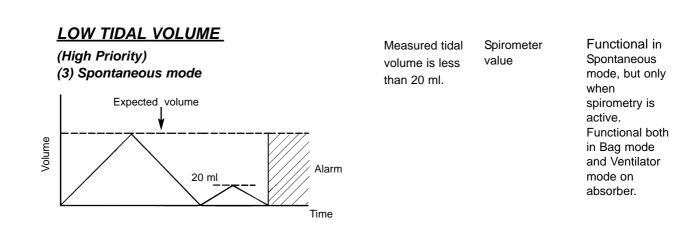


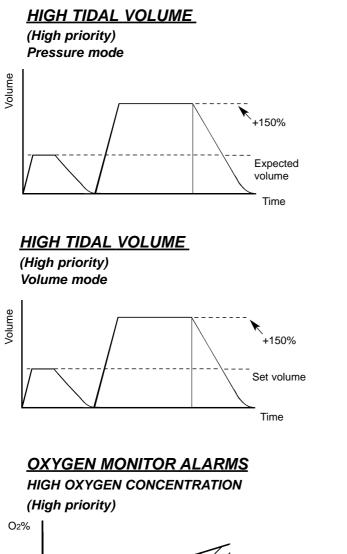
<u>Condition</u>	ndition <u>Detected by</u>	
Measured tidal volume varies from set volume by greater than preset value. Alarm resets after next 'in specification' breath	Spirometer and set value variance	Variance greater than 50% of set. Functional in volume mode



Measured tidal	Spirometer
volume fails to	Value
reach the preset	value
minimum	
volume.	

If variance is greater than 50% of set tidal volume. Functional in Pressure mode

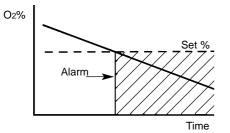




Alarm Time

## **OXYGEN MONITOR ALARMS**

LOW OXYGEN CONCENTRATION (High priority)



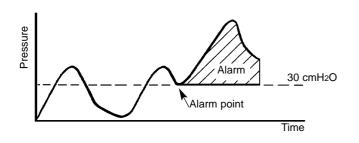
<u>Condition</u>	Detected by	<u>Alarm</u> <u>Specification</u>
Measured tidal volume exceeds expected tidal volume	Spirometer value	If variance is greater than 150% of expected volume. Functional in Pressure mode. User can select Alarm Off in Menu. The alarm will reset to ON if: a) The user selects Standby mode. b) The ventilator is switched OFF.
Measured tidal volume exceeds set tidal volume	Spirometer value	If variance is greater than 50% of set volume. Functional in Volume mode User can select Alarm Off in Menu. The alarm will reset to ON if: a) The user selects Standby mode. b) The ventilator is switched OFF.
Oxygen concentration exceeds set value	Oxygen sensor	If oxygen concentration is above High O2 Alarm set value. Range: 19 - 105% Functional in all modes.

Oxygen concentration falls below set value Oxygen sensor

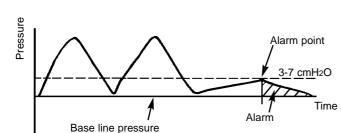
If oxygen concentration is below Low O2 Alarm set value. Range: 18 -99% Functional in all modes.

## **HIGH CONTINUOUS PRESSURE**

(High priority)



LOW AIRWAY	PRESSURE	(APNOEA)
(High priority)		



Breathing
system
pressure fails to
reach
predetermined
level. Alarm
resets at next
'in tolerance'
breath

**Condition** 

Pressure in the

breathing circuit

fails to return to

pressure during

Alarm resets at

base line

exhalation.

next 'in

tolerance' breath

> Patient gas pressure transducer. Item 16, pneumatic system diagram, section 3.2

Detected by

Patient gas

transducer.

pneumatic

pressure

Item 16,

system

diagram,

section 3.2

3-7 cmH2O above base line pressure during inspiratory period. Note: Base line pressure is not necessarily zero. Tidal volume dependant. Functional in pressure and volume mode (and Spont mode if Spirometry is disabled).

<u>Alarm</u>

**Specification** 

30 cmH<sub>2</sub>O

dependant)

pressure,

modes

Functional in

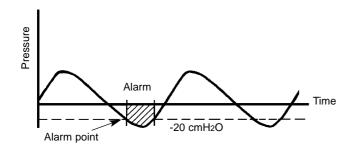
volume and

spontaeneous

(Tidal volume

# NEGATIVE AIRWAY PRESSURE

(High priority)



Breathing system pressure reaches preset negative pressure.

Patient gas pressure transducer. Item 16, pneumatic system diagram, section 3.2.

20 cmH2O (-ve). Functional in standby, pressure, volume and spontaneous modes

<u>Condition</u>

Detected by

<u>Alarm</u> Specification

## **OXYGEN SENSOR FAULT**

(High priority) Functional in all modes when Oxygen monitor functional				
Sensor disconnected Alarm = OXYGEN SENSOR FAULT	Oxygen monitor receiving an out of tolerance value	Oxygen monitor system	Oxygen cell disconnected	
Oxygen concentration greater than 110% Alarm = HIGH OXYGEN %	Oxygen monitor receiving an out of tolerance value	Oxygen monitor system	Oxygen cell fault or over- pressurised.	
Oxygen sensor Low Alarm = OXYGEN SENSOR LOW OUTPUT	Oxygen monitor receiving a low oxygen cell voltage	Oxygen monitor system	Oxygen cell returning a low voltage for specified concentration	
SPIROMETER DISCONNECT Alarm = Spirometer disconnect (HIGH TIDAL VOLUME ALARM)	Spirometer has become disconnected or broken	Ventilator monitoring system	Spirometer connections read open circuit. Functional in all modes	

## **INTERFACE CABLE DISCONNECT**

Alarm = Interface cable disconnect (ABSORBER INTERFACE CABLE FAULT) Signal cable between ventilator and absorber has become disconnected Ventilator monitoring system Interface connections read open circuit. Functional in all modes

	<u>Condition</u>	<u>Detected by</u>	<u>Alarm</u> Specification
<u>INCORRECT RATE OR RATIO</u> (Low priority)	Flow rate set is greater than, or less than predetermined values. Ventilator automatically resets flow rate.	Tidal volume, rate and I:E ratio controls	Rate less than 2 L/min or greater than 75 L/min. Functional in volume mode.
<u>MAINS FAILURE</u> (Low priority)	Mains supply voltage is less than predetermined value	Power supply	Functional in all modes.
<u>LOW BATTERY</u> (Low priority)	Battery voltage approaching minimum safe operating value.	Power supply	Battery voltage less than 11.3 volts (see Ventilator Inoperative). Functional in all modes.
<u>BATTERY POWER FAIL</u> (Medium priority)	Battery voltage below minimum safe operating value	Power supply	Less than 10.8 volts, or battery disconnected
<u>VENTILATOR SHUTDOWN</u> FROM LOW BATTERY	Battery voltage too low to maintain function	Power Supply	Less than 10.5 volts
<u>VENTILATOR INOPERATIVE</u> (High priority)	Various internal functions are monitored, and if determined to be outside specification, will trigger ventilator inoperative condition.		





Cat No 52863 Doc No AV9 (v.4) 0205UI July 2005

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