InterMed Penlon

AV-S Ventilator

Remote Display Module and Interface

for use with A200SP Absorber

Service Manual

Partnership for Life

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.

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 / 2 Year / four year service including component replacement.

Details of these operations are given in this Manual for the AV-S, available only for Penlon trained engineers.

For any 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.   Approximate date of purchase
5.   Apparent fault

FOREWORD

This manual has been produced to provide authorised personnel with information on the function, routine performance, service and maintenance applicable to the AV-S Anaesthesia Ventilator.

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 servicing the apparatus.

CONTENTS

CONTENTS

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 non-compliance 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 cmH$_2$O) differential positive pressure, above which it may be dislodged from the mounting ring, resulting in dangerous malfunction of the ventilator.*

   Do not connect a positive end expiratory pressure (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.

9. *Breathing System*

   The breathing system which conveys gases from the anaesthetic machine to the patient, and disposes of expired gases, must conform to the requirements of ISO 8835-2.
   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 AV-S 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.   The AV-S ventilator is not intended for use in intensive care applications.

14.   This apparatus must not be used with, or in close proximity to, flammable anaesthetic agents.
There is a possible fire or explosion hazard.

15.   Anaesthesia apparatus must be connected to an anaesthetic gas scavenging system (AGSS) 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.
The scavenging transfer and receiver system must conform to ISO 8835-3.
Any problem arising from an improperly functioning scavenging system is solely the user's responsibility.
Do not use a scavenging system that restricts drive gas flow when negative pressure is exerted on it.

16.   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.

17.   In compliance with good anaesthesia practice, an alternative means of ventilation must be available whenever the ventilator is in use.

18.   It is recommended that the patient oxygen concentration should be monitored continuously.

19.   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

20.   An audible alarm indicates an anomalous condition and should never go unheeded.

21.   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,
B) a fresh gas compensation algorithm.

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

22.   Care must be taken to ensure that the flow sensors are connected correctly to the inspiratory and expiratory ports of the absorber.

23.   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, 'Ventilator Inoperative' will be displayed on the front control panel display.

WARNINGS AND CAUTIONS

24. *The High and Low Airway Pressure Alarms are important for patient care.*
It is important that the sensor is properly located in the expiratory limb of the circuit - refer to section 5.1.10.

25. *The patient must be continuously attended and monitored when Advanced Breathing Modes are in use.*

User Maintenance

Control Unit

26. *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.

27. *For continued protection against fire hazards, replace the two fuses only with the identical type and rating of fuse.*
See section 4 for fuse rating.

28. *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 Appendix for battery maintenance.
See also CAUTION No. 7.

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

29. *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.

30. *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.

31. *Check that the cable between the control unit and remote display screen unit is connected before use.*
Always use a cable type recommended by the manufacturer.

Bellows Assembly

32. *The valve seat on the patient gas exhalation diaphragm valve in the base of the bellows assembly must be cleaned regularly - see section 6.2.*
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 patient block assembly must be removed from the control unit before sterilisation (see section 6.2.4).
   All other internal components are not compatible with sterilisation techniques and damage may result.

2. For ventilator components which require sterilisation, peak sterilisation temperatures should not exceed $136^{O}C$ $(275^{O}F)$ to prevent possible damage. (See section 6).

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 section 6.

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 section 6.

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. 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. 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_2 monitor is switched OFF.

10. Circuit compliance is not activated until Fresh Gas Compensation is switched OFF.

NOTES

1. The term 'cycle' is used to designate the transition to the exhalation phase.

2. The term 'trigger' is used to indicate the transition to the inhalation phase.

WARNINGS AND CAUTIONS - Oxygen Monitor

Oxygen Monitor

WARNINGS

1. **We recommend calibration of the oxygen monitor every time the system is turned on, as a safety precaution.**

2. **Do not attempt to open the fuel cell. 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.

3. **ALWAYS check the integrity of the sensor assembly before use.**

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

5. **The sensor measures oxygen partial 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. *Only use low temperature ethylene oxide sterilisation for the oxygen sensor.*
   The sensor is not compatible with other sterilisation techniques - damage may result.
   Do not sterilise any other components.

2. *Do not autoclave or expose the sensor to high temperatures.*

3. *If the sensor shows signs of being affected by condensation, dry the sensor with soft tissue.*
   Do not use heat to dry the sensor.

NOTES

1. *The O2 SENSOR FAULT alarm indicates 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).

3. *To maintain maximum sensor life:*
   i) always switch off the anaesthetic machine after use, to ensure that the basal flow ceases.
   ii) disconnect the breathing circuit after use.

4. *The accuracy of flow and volume measurements may be reduced if the oxygen monitor is not in use.*

5. *Fresh gas mixture compensation is disabled if the oxygen monitor is switched OFF.*

2. PURPOSE

The AV-S 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 AV-S 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.

The AV-S ventilator is not intended for use in intensive care applications.

Oxygen Monitor
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 an integral part of the ventilator.

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. DESCRIPTION
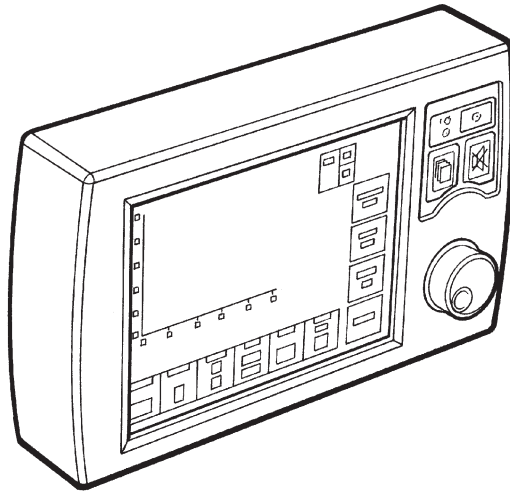
AV-S Ventilator

3.1   General Description

The AV-S Ventilator is a pneumatically driven, software controlled, multi-mode ventilator.

The ventilator is a time-cycled, volume/pressure controlled, and pressure limited.

The ventilator has compliance compensation and a user selectable option of an inspiratory pause fixed at 25% of the inspiratory time.
In addition, fresh gas compensation and user selectable gas mixture compensation is a standard feature.

Ventilation Modes
Volume Mode - continuous mandatory ventilation
Pressure Mode - pressure controlled ventilation
Spontaneous, with advanced features - SIMV, SMMV, PSV
PEEP

Patient Monitoring
Airway pressure, measured from the expiratory limb of the breathing circuit.

Tidal volume and Minute Volume measurement is provided by a dual spirometry system

An integral oxygen monitor system measures oxygen concentration in the breathing circuit inspiratory limb.

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.

Screen
210 mm (8.4 inch) high definition, colour TFT screen, with single/dual waveform display.

DESCRIPTION

Bellows unit
The bellows unit (1) is built into the A200SP absorber.
A paediatric bellows assembly is available as an option

Mounting options
The AV-S integral screen and control unit can be mounted securely on the anaesthetic machine shelf or side bracket.

Drive gas supply
The supply must be at 310 to 689 kPa (45 to 100 psi).
The ventilator drive gas supply can be oxygen or air.
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 Penlon-trained service engineer.
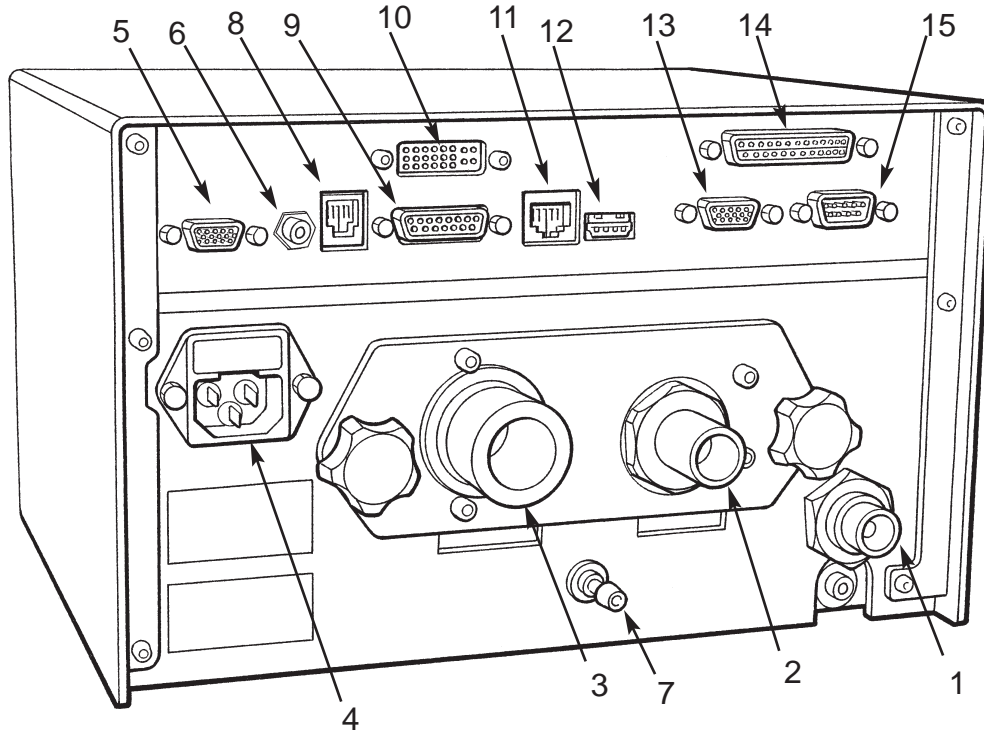
1

DESCRIPTION

Control Unit
Rear Panel

Gas Connections
1. Ventilator drive gas inlet
    - connect to anaesthetic machine auxiliary gas outlet
2. Bellows Drive Gas Output
    - connect to bellows
   (on Prima SP with A200SP absorber, connect to absorber - see section 5.1.5)
3. Outlet - Exhaust Valve

Electrical Connection
4. Electrical mains input and fuse unit

Interface and Parameter inputs
5. A200SP Absorber Bag/Vent switch interface
   Spirometer connector
6. Prima SP Interface connector
7. Pressure Monitor Port
8. Input socket - Oxygen monitor sensor

Data and Printer Ports
9. Data Output
10. Output to remote screen
11. Ethernet
12. USB
13. VGA
14. Printer port
15. RS232

NOTE
USB port is for use by Penlon-trained engineers only.
All other data ports are read only.
For further information, please contact Penlon Technical Support.

DESCRIPTION

3.2   Ventilation Cycle

This section provides a simplified description of the ventilation cycle.
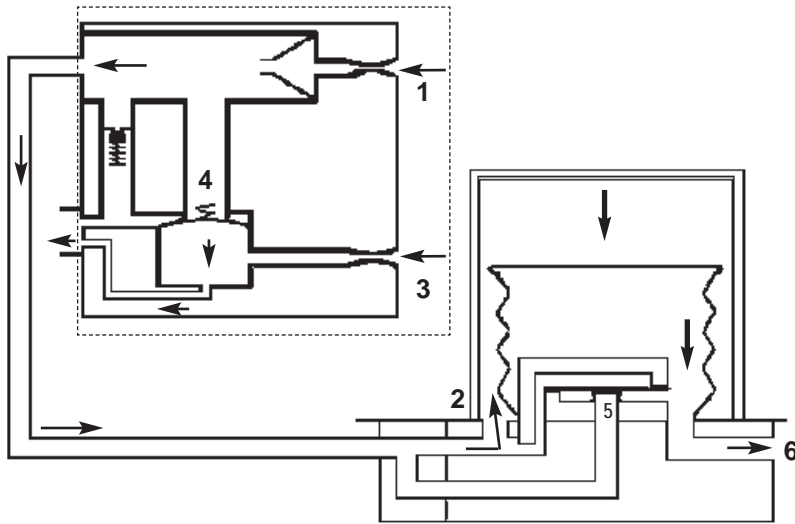
1.   Inspiratory Phase

The inspiratory proportional valve (1) in the control unit opens, and bellows drive gas is delivered to the bellows housing (2).
The expiratory proportional valve (3) opens and gas flows through the bleed valve. The back pressure ensures that the exhaust valve (4) is kept closed
Drive gas pressure builds up above the bellows, which starts to move down.
The diaphragm (5) in the bellows assembly base is held closed, and patient gas is forced out of the bellows base (6) into the breathing system.
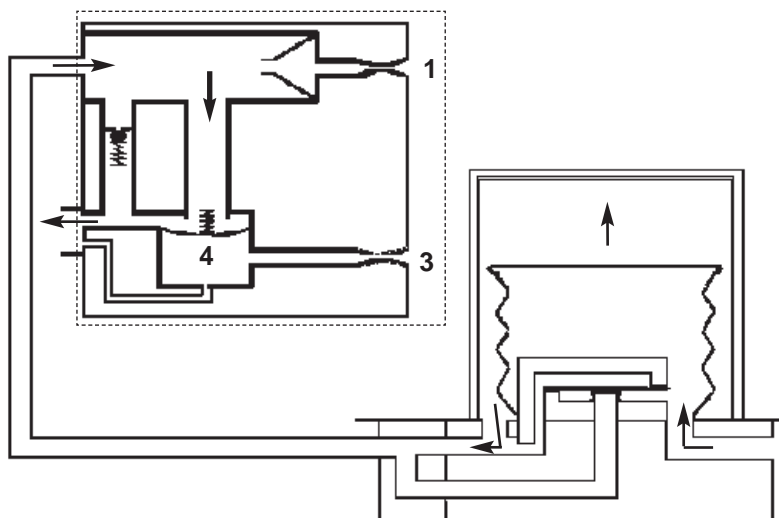
2.   Beginning of Expiratory Phase

The Inspiratory (1) and Expiratory (3) proportional valves close and the exhaust valve (4) opens. Patient gas returns to the bellows. As the bellows rises, redundant drive gas is pushed out through the exhaust valve.

DESCRIPTION
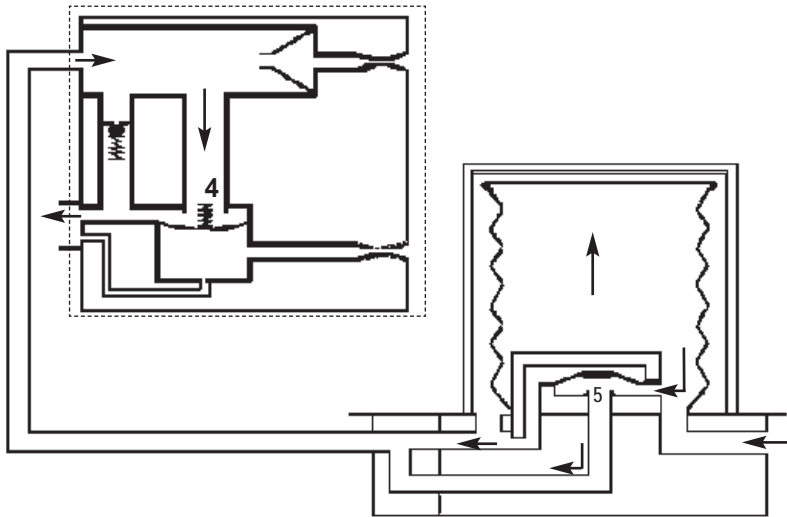
3. End of Expiratory Phase

With the bellows at the top of its housing fresh gas continues to flow. To prevent a high pressure build up the exhalation diaphragm (5) lifts and allows gas to exit through the exhaust valve (4).
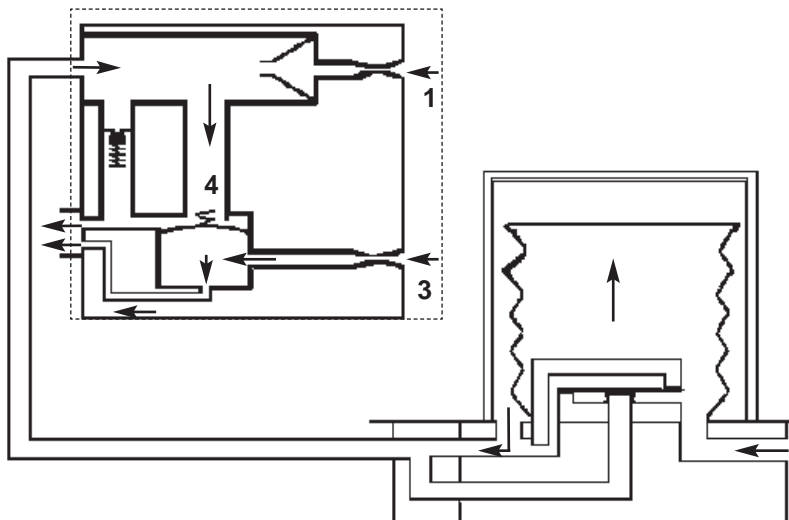
4. PEEP Positive End Expiratory Pressure (user selectable)

During PEEP the Exhalation Proportional valve (3) applies PEEP pressure plus 20 cmH2O to the exhaust valve, which remains closed at this stage.

As fresh gas flows in the patient circuit, any pressure increase above PEEP pressure in the bellows will cause gas to bleed past the exhaust valve (4).

A continuous flow from the Inspiratory proportional valve (1) ensures that any fall in pressure is compensated by driving the bellows as required.

DESCRIPTION

Pneumatic Flow Diagram

A

1	*3 to 7 bar*
2	
3	*241 kPa (35 psi)*
4	
5	
6	

0 - 80 cmH2O

B

7 → 8 → 14 **C**

9

10

12

11

0 - 90 cmH2O

13

15

16

100 cmH2O

17 18
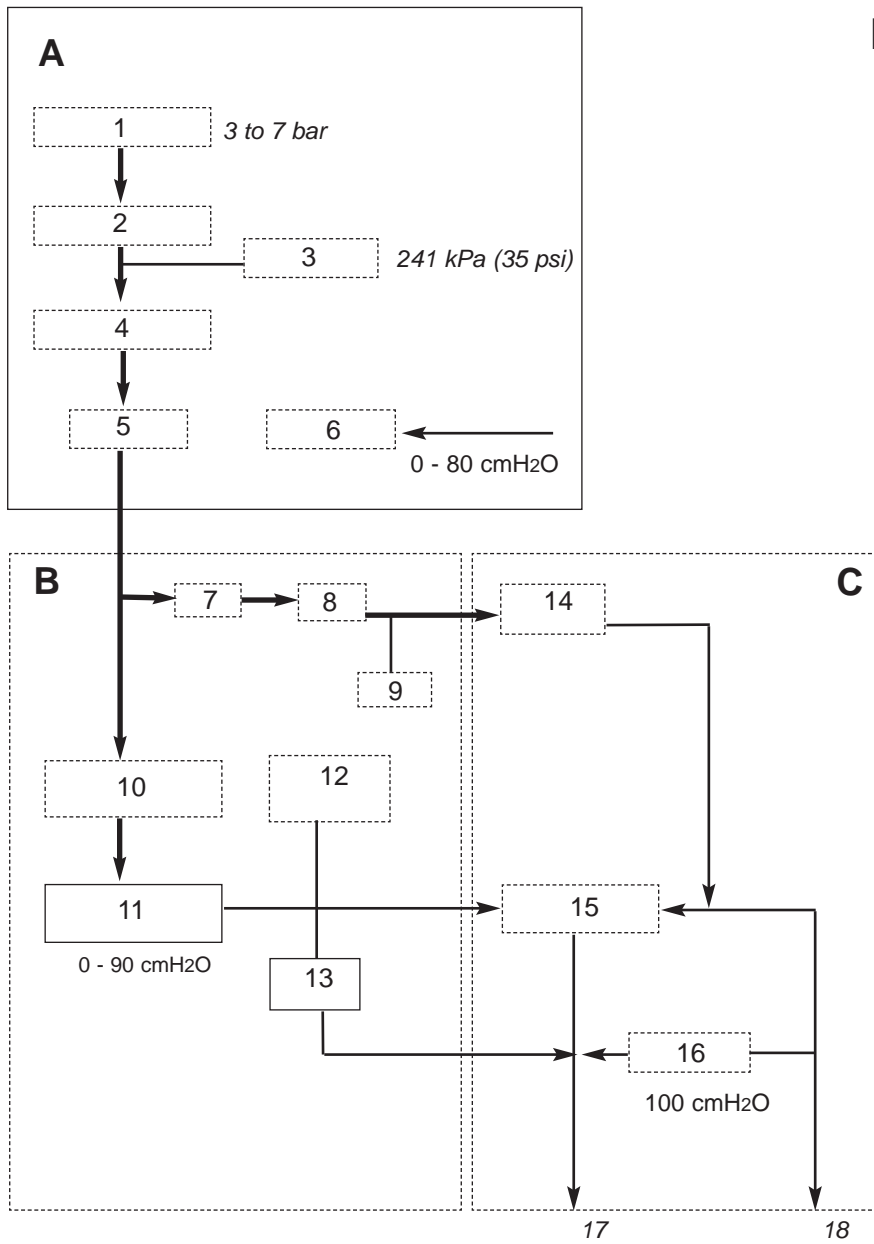
DESCRIPTION

3.3   Pneumatic System

3.3.1   System Operation

Refer to the pneumatic system diagram on the previous page.

A) Gas inlet manifold block

The AV-S Ventilator is designed to operate on a 310 - 689 kPa (45 -100 psi) drive gas supply (oxygen or air - to customer's requirement).

1.   DISS Connector
      The gas source is connected to the DRIVE GAS SUPPLY 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 310 kPa (45 psi).

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

3.   The Low Supply Pressure Detector
      The pressure switch is set at a predetermined level to detect a loss or reduction of the input gas source pressure.
      When the pressure falls below 235 kPa (35 psi ± 1 psi), the LOW SUPPLY PRESSURE indicator will be displayed and the high priority audible alarm will activate.

4.   Input Pressure Regulator
      Regulates the input drive gas to 260 kPa ± 21 kPa (38 psi ± 3 psi).

5.   Cut-off Valve
      The valve isolates the the gas supply :
      a) when the ventilator is switched off
      b) when a fault condition occurs.

6.   Airway Pressure Sensor
      Connected to expiratory limb of breathing circuit.

B) Pneumatic Control Manifold Block

7.   Inspiratory Proportional Valve

8.   Flow Sensor

9.   Drive Gas pressure Sensor

10.   Low Pressure Regulator

11.   Expiratory Proportional Valve

12.   PEEP pressure sensor

13.   Restrictor
        The restrictor allows a flow of up to 2 L/min (<2 L/min bleeding)

C) Exhaust Manifold Block

14.   Check Valve

15.   Diaphragm Valve

16.   Pressure Relief valve
        Set to 100 cmH$_2$O

17.   Exhaust Port (to AGSS)

18.   Bellows drive gas outlet (to bellows assembly)

DESCRIPTION

3.4   Electrical System

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.

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 30 minutes.

See Appendix 1 for battery care procedures.

DESCRIPTION

Touchscreen control diagram labeled AV-S with callouts 1–5
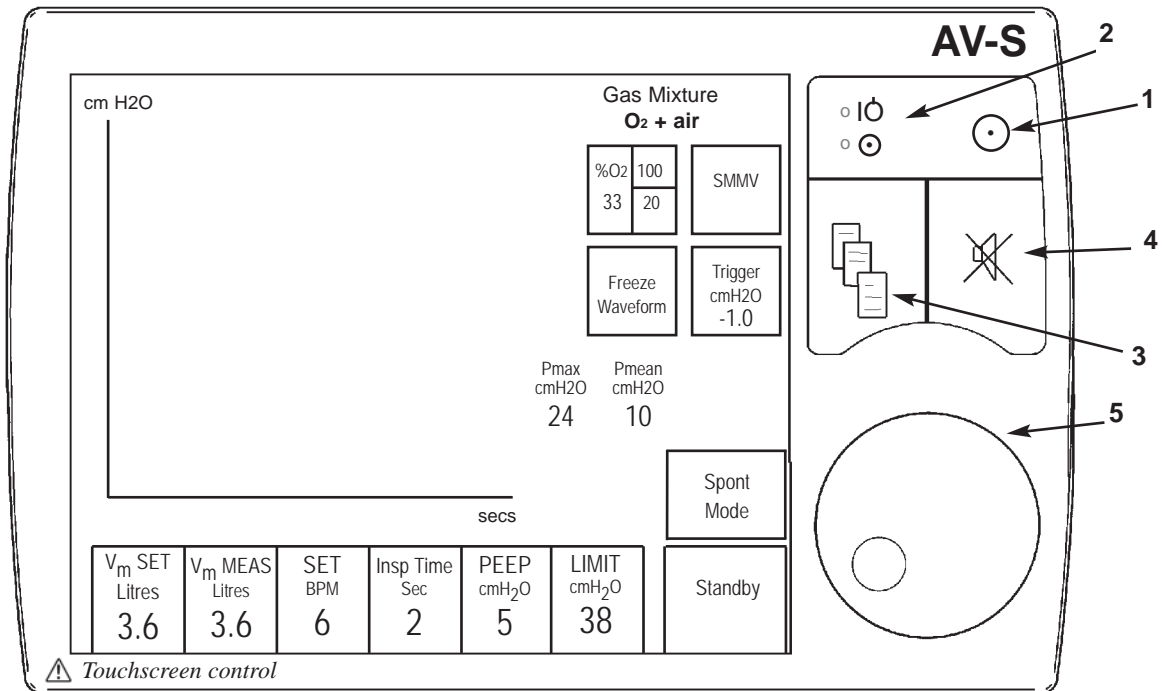
3.5 Control Panel

3.5.1 Touchscreen and Navigator Wheel / Push Button

3.5.1.1 Control Panel

1. **On/Off control**
   Switch On:
   Short internal test sequence
   Switch Off:
   5 second power down sequence with audible tones

2. **Status indicators for electrical power (mains/battery supply)**
   Yellow indicator
   - illuminated whenever power is applied to the unit and internal battery is being charged
   Green indicator
   - illuminates when the unit is switched on, .

3. **Menu switch**
   The menu function provides access to user and service pages

4. **Alarm mute switch**
   30 second or 120 second Alarm silence, depending on alarm status.
   Note also that some alarms are not mutable (see 3.11).

5. **Navigator Wheel and Press Button**
   Turn the wheel to select a function or parameter, or to alter the value of an active parameter.
   Press to confirm the setting.

3.5.1.2 Selecting Functions and Parameters
The functions/parameters shown on the screen can be activated as follows:
a) touch the screen at the appropriate tab area.
b) rotate the navigator wheel and press it when the indicator arrow is on the required parameter tab
Note that parameters default to factory-set values when the ventilator is switched on and no further user selection is made.

3.5.1.3 User Adjustable Parameters
Variable parameters can be altered by rotating the navigator wheel.
When the required value is displayed, press the active tab **or** the wheel to confirm the setting.

DESCRIPTION

3.5.2 User Adjustable Parameters

Tidal Volume Range   20 - 1600 ml

Rate   4 - 100 bpm

I:E Ratio   1:0.3 to 1:8

PEEP   4 - 30 cmH2O
                                          Can be set to OFF

Pressure Limit
       Volume mode: 10 - 80 cmH2O
       Pressure mode: 10 - 70 cmH2O

3.5.3 Operational Capability

Tidal Volume, Rate, and I:E ratio settings are all limited by a
maximum inspiratory flow of 75 L/min.
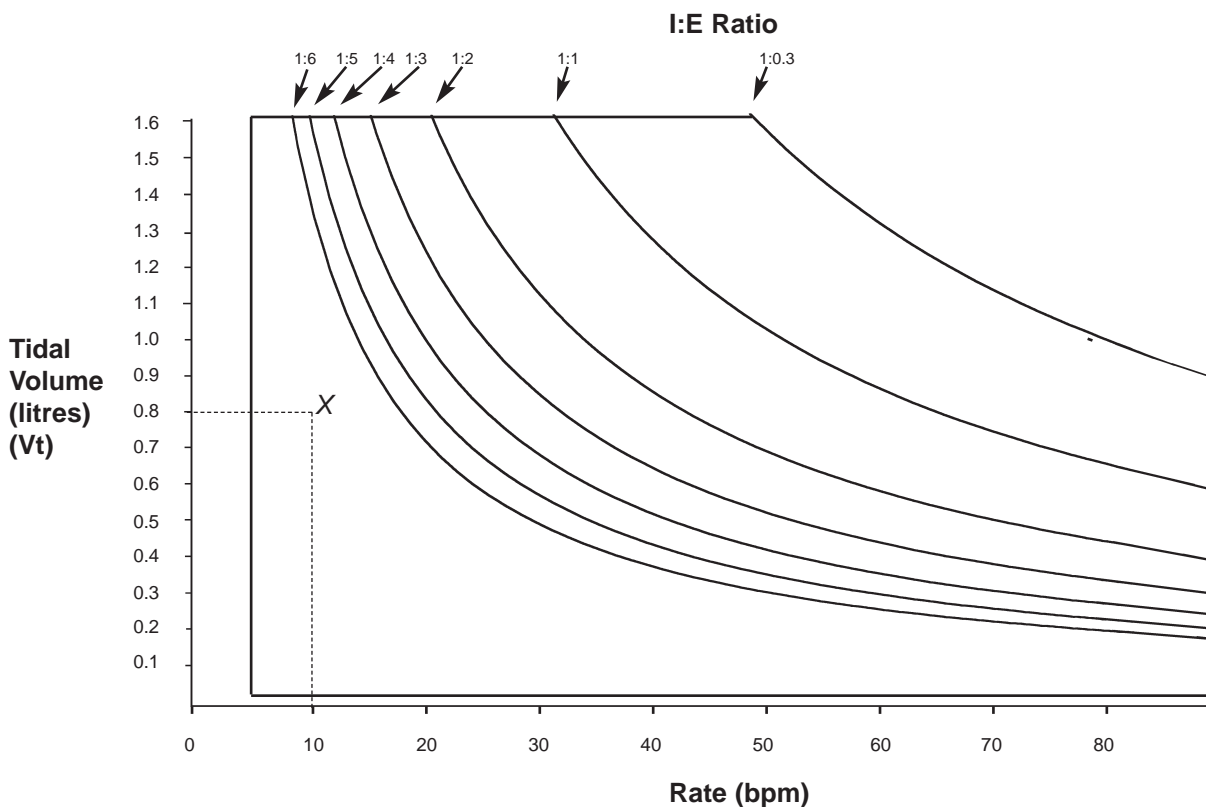
The ventilator is capable of operating at the volumes and rates below each I:E ratio curve.

Example
1.   *Select required volume (Vt) (e.g. 0.8 L)*
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.*

DESCRIPTION

3.5.4 Output Compensation Functions

WARNING
The AV-S automatically compensates for fresh gas (spirometry On), fresh gas mixture (spirometry and oxygen monitor On), and altitude.
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.
The patient must be monitored independently from the ventilator.
It is the responsibility of the user to monitor the patient for adequate ventilation.

Fresh Gas Compensation
Adjusts delivered volume up to 60%
Alarms if measured volume is 50% different than set volume
User adjustable

NOTE
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.

NOTE
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.

If the O2 monitor is switched OFF, a 40%/60% mixture of O2/N2O is assumed.

Altitude Compensation
Monitors ambient pressure
Adjusts delivered volume accordingly

DESCRIPTION

3.6 Interface to Prima SP2/3 and A200SP

The AV-S is designed to interface with the Prima SP Anaesthetic Machine and the A200SP Absorber.

3.6.1 Prima SP Interface

The interface cable links the socket (A) on the control panel to a socket on the rear panel of the anaesthetic machine.

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, as described in section 3.5.1.

c) Turn the Prima SP Gas Delivery Switch to OFF. The ventilator will power-down.
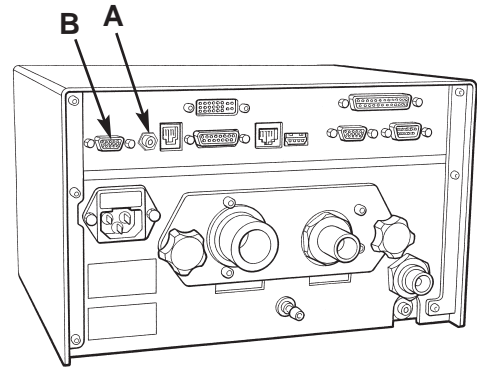
3.6.2 A200SP Absorber Interface

The interface cable links the socket (B) on the control panel to a socket (C) at the rear of the absorber.

a) The A200SP is fitted with fitted with a sensor that detects the position of the absorber bag/vent control (D).
   The sensor signal cabling is routed internally to connector (C) and a second cable runs to the the rear of the AV-S control unit.

b) Operation of the Bag/Vent control will trigger automatic Mode switching on the AV-S ventilator, as follows:
   i) If the Absorber Bag/Vent control is moved from Vent to Bag, the ventilator will change from Volume Mode, or Pressure Mode, into Spontaneous Mode.
   ii) Switching the absorber Bag/Vent control from Bag to Vent:
   The ventilator will reset from Spontaneous Mode to the previously set active mode.
   iii) If the ventilator is in any mode other than those detailed above, operation of the absorber Bag/Vent control will not affect the ventilator.
   NOTE This function can be enabled/disabled through the AV-S on-screen menus (Service Sub-menu, see appendix).
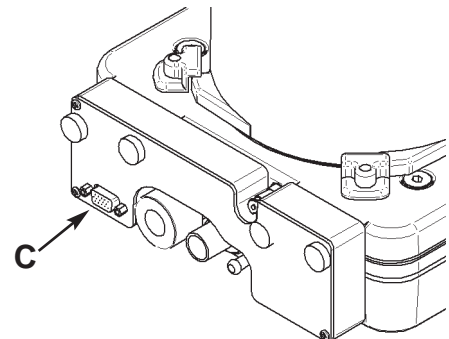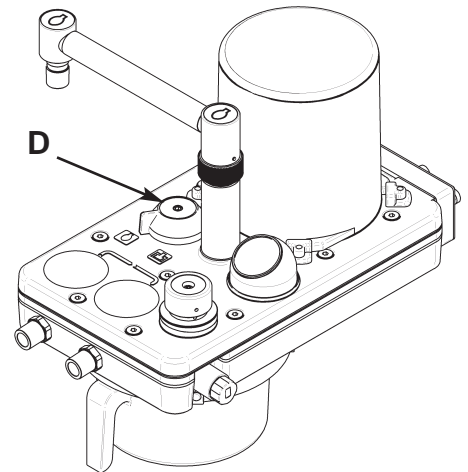
DESCRIPTION

3.7   Ventilation Modes

3.7.1 Standby Mode

Allows parameters to be set.

Some patient alarms are active:
High airway pressure (at 80 cmH2O)
High/Low O2
Negative pressure
Incorrect Rate/Ratio

DESCRIPTION

3.7.2   Volume Mode

The ventilator delivers a mandatory set volume of gas at preset, fixed breath intervals.
The Patient is making no respiratory effort.

3.7.2.1   Fresh Gas Compensation
Adjusts delivered volume up to 60%
This delivered volume will consist of the volume delivered from the ventilator bellows plus the fresh gas flow from the anaesthetic machine fresh gas supply, minus any compliance loss and minus any leak.
This gives a total actual inspired tidal volume.
An alarm is triggered if measured volume is 50% different than set volume
User adjustable

Altitude Compensation
Monitors ambient pressure
Adjusts delivered volume accordingly

3.7.2.2 Operating Functions

Inspiratory Pause function: Creates 25% plateau

Sigh function:
When the ventilator is in Volume Cycle mode the "sigh" option is available. When selected, this option provides extra volume for 1 to 4 breaths in 50 (frequency is user selectable).
The extra volume will be 50% above the tidal volume set by the user.

Volumes measured if Spirometry function selected

Auto High and Low volume alarms if measured volume different by 50% of set volume
User adjustable option

If max pressure limit achieved, ventilator cycles to expiratory phase

3.7.2.3 Volume Type Selection
Use the menu to switch between Tidal Volume and Minute Volume.
NOTE   Minute Volume is derived from a rolling average during a 30 second period.

Volume Mode Parameters	
Tidal volume	20 – 1600 mL
Rate	4 – 100 bpm
I:E ratio	1:0.3 – 1:8
PEEP 'Off' or adjustable	4 – 30 cmH2O
Inspiratory pressure limit	10 to 80 cmH2O
Inspiratory pause (does not affect I:E ratio)	25%
Sigh	1.5 x Set Vt is delivered once, twice, three times or four times every 50 breaths (user selects frequency)

DESCRIPTION

3.7.3   Pressure Mode

3.7.3.1 Parameters
The ventilator delivers a volume of gas to achieve a set pressure at fixed breath intervals.
The Patient is making no respiratory effort.
This is a common mode for the ventilation of small paediatric patients.

Inspiratory pressure   10 - 70 cmH2O
Rate   4 – 100 bpm
I:E ratio   1:0.3 – 1:8
PEEP 'Off' or adjustable: 4 – 30 cmH2O

Inspiratory decelerating flow controlled by the ventilator according to pressure setting
No Inspiratory pause function

3.7.3.2 Pressure Mode Operating Functions
Defaults to 10 cmH2O
Maximum Inspiratory Flow to achieve target pressure
Sustaining flow maintains circuit pressure
Control achieved using exhaust valve

DESCRIPTION

3.7.4 Spontaneous Mode

3.7.4.1 Parameters
The ventilator monitors the following patient parameters:

Rate
I:E ratio
Pressure
Tidal volume

Provides waveform displays

Inspiratory oxygen is measured

3.7.4.2 Spontaneous mode operating functions

No mechanical ventilation
No Inspiratory Pause function

Patient Monitoring (Bag mode and Ventilator mode):
Airway pressures
FiO2,
Vt,
Rate
I:E ratio,
Supply pressures
Ventilation conditions

Advanced Spontaneous Breathing modes are selectable from
this mode - see below, and section 3.7.5.

3.7.4.3 Advanced Spontaneous Breathing Modes

Support modes available from 'Special Modes' (select from
main menu):
SIMV
SMMV
PSV

The A200SP Absorber Bag/Vent control must be in 'Vent'
position for these modes to be selected.

Note that if the system fails to detect an absorber bag/vent
switch, a confirm message will be displayed.

DESCRIPTION

3.7.5   Advanced Spontaneous Breathing Modes

3.7.5.1 SIMV Synchronised Intermittent Mandatory Ventilation

Guarantees a minimum level of volume. SIMV allows spontaneous breaths and a set mandatory breath

SIMV - Spontaneously Breathing Patient
Inspiratory flow in the Trigger Window (generated by the patient's spontaneous breath) results in a synchronised mandatory breath at a preset volume and rate
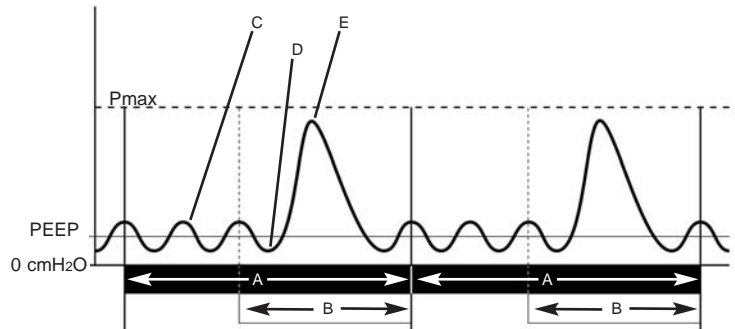
SIMV - Spontaneously Breathing Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Spontaneous Breath
D = Trigger
E = Mandatory breath at the set Vt

SIMV - No breathing effort by Patient
If the patient makes no effort to breathe during a cycle, a mandatory breath, at the end of the trigger window, will still be delivered at the preset volume and rate
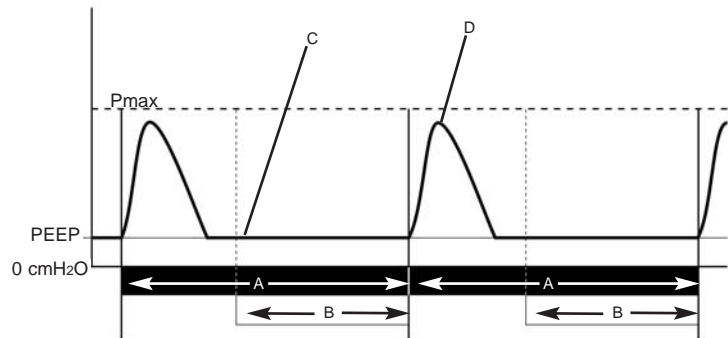
SIMV - Selection
Select Standby
Select Menu
Select Special Modes
Select SIMV

SIMV is now on the main screen in Spontaneous mode.

SIMV - No breathing effort by Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Flat Pressure Trace (no breathing effort)
D = Mandatory breath at the end of the Trigger Window at the set Vt

NOTE
1. *SIMV is triggered by flow when Spirometry is active.*
    SIMV is triggered by pressure If Spirometry is disabled.
2. *The trigger window is pre-set to 60% of the BPM cycle time.*
3. *The trigger pressure is PEEP referenced*
4. *If the pressure limit and alarm are activated the inspiratory phase is terminated*

SIMV Default Settings

The ventilator will default to the settings shown in the table, after selecting 'SIMV'. Note that Vt can be adjusted before SIMV is confirmed.

Trigger setting defaults to 0.4 L/min, and is adjustable between 0.2 and 1.0 L/min.

Default Settings - SIMV			
	Adult	**Paediatric**	**Overall range**
Vt	600 ml	200 ml	As Volume Mode
BPM	6	10	As Volume Mode
Insp. (Ti)	2	1	I:E display box
Trigger level	0.4 L/min	0.4 L/min	0.2 to 1.0 L/min

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DESCRIPTION

3.7.5.2 SMMV Synchronised Mandatory Minute Ventilation

Guarantees a set level of minute volume ventilation. SMMV allows spontaneous breaths, combined with a synchronised mandatory breath, to achieve the set minute volume

SMMV -
Spontaneously Breathing Patient
Inspiratory flow in the Trigger Window (generated by the patient's spontaneous breath) results in a synchronised mandatory breath, ensuring that the set minute volume is achieved

SMMV -
No breathing effort by Patient
If the patient makes no effort to breathe during a cycle, a mandatory breath, at the end of the trigger window, will still be delivered at the preset volume and rate

SMMV - Selection
Select Standby Mode
Select Menu
Select Special Modes
Select SMMV

SMMV is now on the main screen in Spontaneous mode.

NOTE
1. *SMMV is triggered by flow when Spirometry is active.*
   SMMV is triggered by pressure If Spirometry is disabled.
2. *The trigger window is pre-set to 60% of the BPM cycle time.*
3. *The trigger pressure is PEEP referenced*
4. *If the pressure limit and alarm are activated the inspiratory phase is terminated.*

SMMV Default Settings

The ventilator will default to the settings shown in the table, after selecting 'SMMV'.
Note that Vm can be adjusted before SMMV is confirmed.

Trigger setting defaults to 0.4 litres/min, and is adjustable between 0.2 and 1.0 litres/min.

SMMV - Spontaneously Breathing Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Spontaneous Breath
D = Trigger
E = Vt of Mandatory Breath is equal to Vm / BPM minus the volume spontaneously breathed during the cycle (maintaining the set Vm)

SMMV - No breathing effort by Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Flat Pressure Trace (no breathing effort)
D = Mandatory breath at the end of the Trigger Window at the set Vm

Default Settings - SMMV			
	Adult	**Paediatric**	**Overall range**
Vm	3.6 L	2 L	As Volume Mode
BPM	6	10	As Volume Mode
Insp. (Ti)	2	1	I:E display box
Trigger level	0.4 L/min	0.4 L/min	0.2 to 1.0 L/min

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DESCRIPTION

3.7.5.3 PSV Pressure Supported Ventilation

PSV assists each spontaneous breath to achieve
a preset pressure, thus reducing the effort required to breathe
Inspiratory flow (generated by the patient's spontaneous breath) results in synchronised
pressure support

PSV is used to support spontaneously breathing patients ONLY
If the patient makes no attempt to breathe, the ventilator will not provide support and the apnoea alarm will be activated

PSV - Selection
Select Standby Mode
Select Menu
Select Special Modes
Select PSV

PSV is now on the main screen in Spontaneous mode.

NOTE
1. *The trigger window is pre-set to 60% of the BPM cycle time.*
2. *The trigger pressure is PEEP referenced.*
3. *If the Spirometry is disabled then PSV is not available.*
4. *If the pressure limit and alarm are activated the inspiratory phase is terminated.*

PSV Default Settings

The ventilator will default to the settings shown in the table, after selecting 'PSV' from Spontaneous Mode.

Note that Support Pressure can be adjusted before PSV is confirmed.

Trigger setting defaults to 0.4 litres/min, and is adjustable between 0.2 and 1.0 litres/min.

PSV Pressure Supported Ventilation
A = Set Inspiratory Time
B = Pressure Support Level
C = Spontaneous Breath results in a synchronised pressure supported breath

Default Settings - PSV			
	Adult	**Paediatric**	**Overall range**
P. Supp	10 cmH$_2$O	10 cmH$_2$O	3-20 cmH$_2$O
Insp. (Ti)	2 sec	1 sec	I:E display box
Trigger level	0.4 L/min	0.4 L/min	0.2 to 1.0 L/min

DESCRIPTION

3.7.5.4   PEEP (Positive End Expiratory Pressure)

The AV-S ventilator includes a microprocessor-controlled, electronically integrated PEEP system, regulated using secondary pressure on exhaust diaphragm.

The ventilator controls PEEP by allowing flow from, or delivering flow into the bellows drive circuit, maintaining pressure

PEEP is electronically controlled

Variable from 4-30 cmH2O in increments of 1 cmH2O

Clear "OFF" indication when not in use

Switch off the ventilator - PEEP is switched off.

PEEP is switched off during 'Spont' mode to minimise patient's breathing effort.

Selecting PEEP
Select by touching the screen tab PEEP, or using the navigator wheel
The setting will flash.

Rotate the navigator wheel to set the required PEEP pressure.
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 A200SP Absorber Interface - Ventilator Mode Selection

1.   Ventilator is in Volume Ventilation Mode

2.   PEEP selected, pressure set to required level.
      PEEP display indicates pressure

3.   A200SP Absorber Bag/Vent control (A) 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.

4.   Bag/Vent control reset to 'Vent' position.
      Ventilator automatically switches to the mode
      previously set by the user.
      PEEP is Off.
      PEEP display indicates Off.

5.   Set ventilator to Volume Ventilation Mode.
      PEEP remains Off.
      Select PEEP if required.
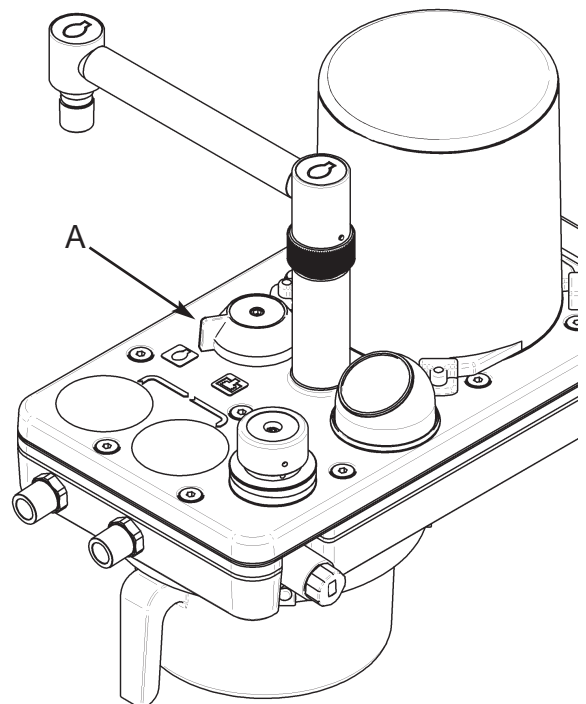
DESCRIPTION

3.8   On-Screen Menus

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

    EXIT MENUS
    O2 MONITOR & SPIROMETRY
    FRESH GAS COMPENSATION: ON
    SPECIAL MODES
    WAVEFORM
    ALARM SETTINGS
    GAS MIXTURE: O2+AIR
    USER SETTINGS
    SERVICE MENU

To Exit:
Press the menu switch on the front panel, or, select EXIT MENUS and press the wheel.

NOTE
*The menu window will **not** be displayed if:*
A)   Control parameters (V_T MEAS, BPM, I:E, PEEP, or LIMIT) are enabled but not confirmed.
B)   A display window is active

To Operate:
1.   Rotate the navigator wheel clockwise to scroll through the menu options - the cursor (>) aligns with each parameter in turn.
2.   Press the wheel to enter the required sub-menu.
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.

See Appendix 2 for a full description of the Menu system.

Menu Switch

Turn the wheel to scroll through the menus. Press to enter sub-menu
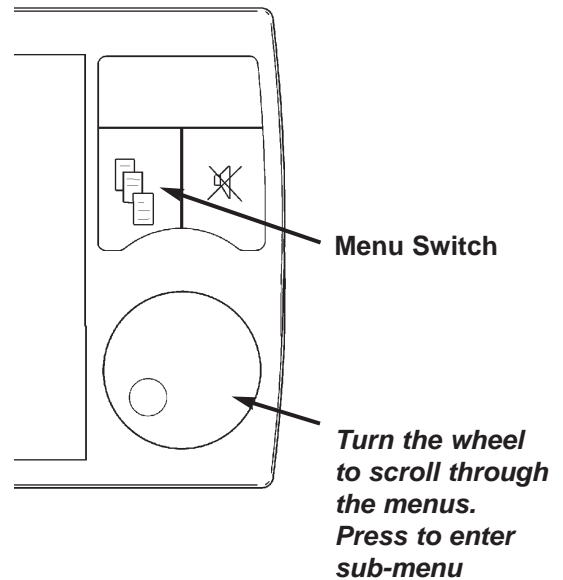
DESCRIPTION

3.9   Spirometry

Spirometry 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)   Special Modes are disabled.

See Appendix 3, for a detailed description of the spirometry system.

3.10   Display Waveforms

Default waveform is always Pressure v Time (cmH_2O *v* seconds)

Wave Freeze is available when ventilation is in progress.

Second waveform
A second waveform can be displayed by using menu control or touch waveform on screen.

The second waveform is selectable:
Volume *v* Time (litres *v* seconds)
Volume *v* Pressure (litres *v* cmH_2O)
Compliance loop waveform
 - First loop can be frozen
 - Subsequent loops overlaid

Display Functions

Automatic Scale adjustment

Y axis
a)   Scale adjusts as Plimit is changed
      (-20 to 40, 60, 80 cmH_2O)

b)   In *Vol. v Time* mode as Vt is changed
      (0 to 0.5L, 1.0 L, 2.0 L)

X axis
a)   Scale adjusts as Rate is changed
      0 to 15sec, 5 sec, 3sec

b)   In *Vol. v Pres.* mode as Plimit is changed
      (-20 to 40, 60, 80 cmH_2O)

DESCRIPTION

3.11 Alarms

Alarm	Priority	Trigger	Mute time	Set by:
Ventilator Inoperative	High	Internal failure or Battery failure	zero	Automatic
Power About to Fail	High	Ventilator is on battery, and the battery voltage is less than 10.2 v	zero	Automatic
Low Drive Gas Supply Pressure	High	Less than 235 kPa (35 psi +/-1 psi)	zero	Automatic
Low Bellows Drive Gas Pressure	High	Fails to reach target level	30 s	Automatic
High Bellows Drive Gas Pressure	High	Exceeds calculated target level	30 s	Automatic
High Continuous Airway Pressure	High	Breathing system pressure fails to return to below 30 cmH$_2$O by the start of the next inspiratory phase	120 s	Auto
High Airway Pressure	High	Pressure reaches set limit (10 to 80 cmH2O adjustable)	30 s	User / Default
Low Airway Pressure	High	Breathing system pressure fails to reach minimum level	120 s	Default
Negative Airway Pressure	High	Breathing system pressure exceeds 10 cmH2O	120 s	Automatic
Low Tidal Volume	High	a) Measured Vt less than 50% of volume set b) Spirometer disconnected	120 s	User / Default
Low Minute Volume	High	Calculated volume lower than 50% of volume set	120 s	User / Default
Apnoea	High	In Spontaneous mode, no breath detected within 15 seconds	120 s	Auto
High Tidal Volume	High	Measured value exceeds 150% of set value	120 s	User / Default
High Minute Volume	High	Calculated value exceeds 150% of set value	120 s	User / Default
High O2 Concentration	High	Measured O2 % exceeds set value	120 s	User / Default
Low O2 Concentration	High	Measured O2 % lower than set value	120 s	User / Default
O2 Sensor low output	Low	Sensor life exhausted	zero	Auto
O2 sensor fault	High	Sensor disconnected	120 s	Auto
Incorrect Rate or Ratio	Medium	Settings outside 75 L/min	120 s	Auto
Mains Failure	Low	Mains power fails 30 minutes use available (if battery is fully charged)	zero	Auto
Battery Power Fail	Medium	Battery disconnected, or missing, or totally discharged	120 s	
Low Battery	Low	Battery voltage has dropped below 11.2 v	zero	
Absorber cable fault (A100SP)	Medium	Disconnection or short circuit	120 s	Auto
Printer not available	Low	Printer disconnected, or has no power, or has no paper	zero	

Priority identification:

High Priority: 5 ascending tones - repeated   *Medium Priority: 3 ascending tones - repeated*   *Low Priority: Single Tone - repeated*

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DESCRIPTION - *O2 Monitor*

3.12   Oxygen Monitor

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.

3.12.1 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 (1) is supplied with a 2 m (6 ft) extendable cable.

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

Bacterial Filter

Use a breathing system bacterial filter in the expiratory limb of the breathing circuit to protect the oxygen sensor (see section 5 in the AV900 or AV-S user manual).

CAUTION

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

3.12.2 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 1500 000 O2 percent hours at 20°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.

O2 Sensor Location
Prima SP with A200SP Absorber
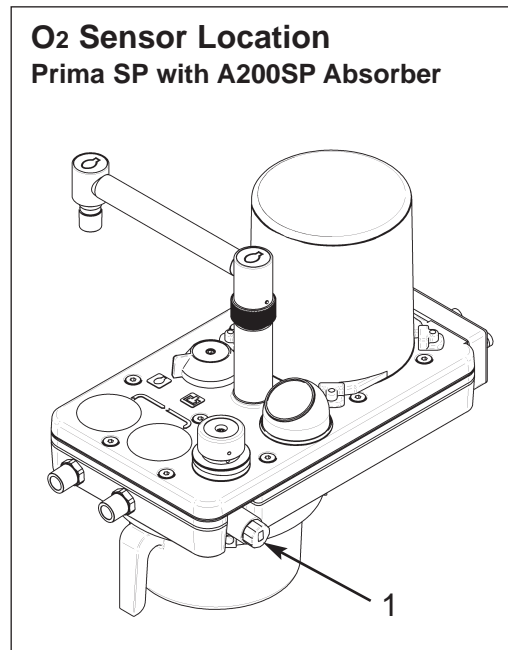
DESCRIPTION

3.12.3   O$_2$ Monitor sub-menu

ON/OFF
Turn the navigator wheel to switch between ON and OFF.
Press to confirm.
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 5.3.2 for full procedure).
To exit the menu, scroll to EXIT MENUS and press the wheel.

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 5.3.4 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.

O$_2$ Monitor sub-menu

```
 O2 Monitor & Spiro

    ESCAPE FROM MENU
 >  O2 MONITOR: on
    CALIBRATION: 100%
    HIGH ALARM SET: 105
    LOW ALARM SET: 18
    SPIROMETER: on
    SPIRO CALIBRATION: 0 L/min
```

O$_2$ Monitor sub-menu - calibration

```
 O2 Monitor & Spiro

    ESCAPE FROM MENU
    O2 MONITOR: on
 >  CALIBRATION: 100%
    HIGH ALARM SET: 105
    LOW ALARM SET: 18
    SPIROMETER: on
    SPIRO CALIBRATION: 0 L/min
```

O$_2$ Monitor sub-menu - alarms

```
 O2 Monitor & Spiro

    ESCAPE FROM MENU
    O2 MONITOR: on
    CALIBRATION: 100%
 >  HIGH ALARM SET: 105
    LOW ALARM SET: 18
    SPIROMETER: on
    SPIRO CALIBRATION: 0 L/min
```

3.12.4 Display
High-set, low-set, and oxygen concentration percentage readings are displayed on screen.
Touch the tab to activate O2 menu

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 5.3.4.

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 5.3.4.

High Alarm Set Value

%O2 100
33 20

Measured O2 concentration
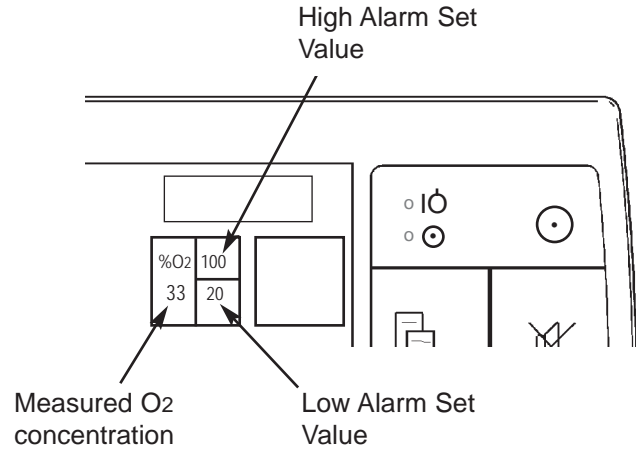
Low Alarm Set Value

3.12.5 Display

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

a) The **High O2 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:

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

ii) if the O2 concentration exceeds 110%.

a) The message **O2 SENSOR FAULT** will be displayed.

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 O2 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 6.5 for sensor replacement.

3.12.6 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%.

4. SPECIFICATION

4.1 Application   Ventilation for use in anaesthesia.

4.2 Internal Compliance
      Adult bellows   3 ml/cmH$_2$O (nominal)
      Paediatric bellows   2 ml/cmH$_2$O (nominal)

4.3 Physical
Size (mm)
      - control unit only   290 wide x 300 deep x 185 high
      - with adult bellows   290 wide x 300 deep x 385 high

Screen Size   210 mm (8.4") TFT

Weight   - control unit only   7.6 kg
      - with adult bellows   9 kg
Bellows
Adult (Latex free):   20 ml - 1600 ml
Paediatric :   20 - 350 ml
(Note - latex free paediatric available as option)

Power   90 - 264 VAC, 47 - 63 Hz
Battery Back-up: 30 minutes (assumes fully charged battery)
Drive Gas   Oxygen or Air
                                     (dry, and oil free) at 45 to 100 psi (310 to 689 kPa).

4.4 Alarms
Alarm Mute   30 or 120 seconds (see 3.11)
Low Drive Gas Pressure   Less than 235 kPa (35 psi)
High Continuous Airway Pressure   Above 30 cmH$_2$O at start of cycle
Low Pressure   4 - 14 cmH$_2$O PEEP referenced
Low Tidal Volume   50% of Volume set (Spirometry)
Incorrect Rate or Ratio
Mains Failure   30 minutes (nominal) Battery Backup
Low Battery   5 minutes Use
Ventilator Inoperative   Internal or Battery Failure

Alarms - User Set
Vt (Tidal)
      Min   0 - 1600 ml
      Max   20 - 1600 ml
Vm (Minute)
      Min   0 - 10 L
      Max   0 - 30 L

Apnoea   Adjustable Re-set Pressure (PEEP referenced)

Low and High O$_2$ Concentration   18% - 105%

High Airway Pressure   10 - 80 cmH$_2$O adjustable

SPECIFICATION

4.5 Functional

Tidal Volume

Adult bellows	20 to 1600 ml (±10%)
Paediatric bellows	20 to 350 ml (±10%)

At ambient temperature of 20°C (+/-10%) and ambient atmosphere of 101.3 kPa (+/-10%).

Minute Volume	0 to 30 L
Rate	4 - 100 bpm
I:E Ratio	1:0.3 - 1:8
Pressure Limit	10 - 80 cmH$_2$O
Fresh Gas Compensation	Automatic Tidal Volume adjustment
Modes	Off Standby Volume Cycle Pressure Controlled Spontaneous (includes advanced breathing modes)
Pressure Control	10 - 70 cmH$_2$O
Inspiratory Flow	2 - 75 L/min
Spontaneous Mode	Active Volume and Pressure Alarms, Advanced Breathing Modes selectable (see section 4.6)
Electronic PEEP	4 - 30 cmH$_2$O
Oxygen Monitor	Fuel Cell type *For full specification, see section 4.15.*
Spirometry - Resolution	±1 ml

Ventilator Performance - accuracy of delivered volumes

>300 ml	± 10%
>100 ml <300 ml	± 20%
<100 ml	± 50%.

NOTE
The ventilator is designed for use with Spirometry ON.
Accuracy of delivered volumes with Spirometry OFF may vary from the figures given above.

SPECIFICATION

4.6 Advanced Spontaneous Breathing Modes (SIMV, SMMV, PSV)

Trigger (PEEP Referenced)   0.2 to 4 L/min
Trigger Window   Set 60% of Expiratory Time
Vt and Vm   As Volume Mode
Insp Time (Ti)   0.5 to 5 secs
Support Pressure   3 to 20 cmH_2O

Default settings

Volume	Vt	BPM	I:E	Pmax
Adult	600 ml	10	1:2	38 cmH2O
Paediatric	150 ml	15	1:2	38 cmH2O

Pressure	Vt	BPM	I:E	P-target
Adult	600 ml	10	1:2	10 cmH2O
Paediatric	150 ml	15	1:2	10 cmH2O

SIMV	Vt	BPM	Insp time	Trigger
Adult	600 ml	6	2 sec	0.4 L/min
Paediatric	200 ml	10	1 sec	0.4 L/min

SMMV	Vm	BPM	Insp time	Trigger
Adult	3.6 L	6	2 sec	0.4 L/min
Paediatric	2 L	10	1 sec	0.4 L/min

PSV	Support Pressure	Insp time	
Adult	10 cmH2O		0.4 L/min
Paediatric	10 cmH2O		0.4 L/min

4.7 Disinfection and Sterilisation   Bellows base assembly, Patient Block assembly   and inside of bellows can be sterilised if necessary - section 6.

4.8 Bacterial Filter   None (see section 5.1.4, use a bacterial filter in the breathing system to protect components that are not autoclavable, e.g. oxygen sensor)

4.9 Fail Safe Mechanism   Battery back-up in case of mains electricity failure
Gas shut-off in the event of electronic failure

4.10 Reliability   MTBF: 5×10^6 to 50×10^6 cycles

4.11 Waveform Tests   Not applicable

4.12 Volume Tests   Not applicable

4.13 Mobility and Mounting

(A) Mobility   Secure mounting on anaesthesia machine shelf or side bracket required.
(B) Mounting   Mounting bracket available as optional extra. The bellows assembly is built into the A200SP Absorber.

4.14 Fuse (mains supply)   Two fuses, Type T 2AH
2 A, 250 V rating, 20 mm, anti surge, ceramic.

SPECIFICATION - *O2 Monitor*

4.15   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: Flashing, 5 audio pulses with 6 seconds repeat
time.
Medium Priority Alarm: Flashing, 3 audio pulses with 24 seconds repeat time
Low Priority Alarm: Static with single beep sound
Alarm Mute: 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

Sensor
Type: Galvanic fuel cell sensor (0-100%)
Life: 1500000 O2% hours
                            (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_2 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. PRE-OPERATION PROCEDURES

5.1 Ventilator Set-up

5.1.1 Mounting the Ventilator

Mounting
The display screen is mounted on an adjustable arm, with the control unit mounted at the rear or side of the anaesthetic machine.

Optional Mounting System
Locate the ventilator control unit 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 disconnection of the hoses.
To mount the ventilator control unit permanently on a Penlon bracket:
1. Align the four mounting feet over the mating holes in the bracket.
2. 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 the kit.

Pole-mount type mounting brackets and side frame brackets are available from Penlon Limited.

Bellows unit
The bellows unit is built into the A200SP absorber.

5.1.2 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.

5.1.3 Ventilator Gas Supply

1. Verify the drive gas specified for the ventilator (oxygen or air).
   Always use the correct drive gas.

2. Connect the drive gas inlet port on the rear of the control unit to a dry, oil free supply.

   Supply pressure range:
   45 to 100 psi
   (3.1-6.9 bar, 310-689 kPa)

   OXYGEN SUPPLY:
   a) O_2 cylinder,
   b) Anaesthetic machine O_2 auxiliary gas outlet,
   c) O_2 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 Breathing System Schematic

The following page contains a schematic diagram showing the cables and tubing for an AV-S ventilator mounted on a Prima SP anaesthetic machine with an integral A200SP Absorber.

PRE-OPERATION PROCEDURES

Hoses and Cables Schematic
AV-S and A200SP Absorber
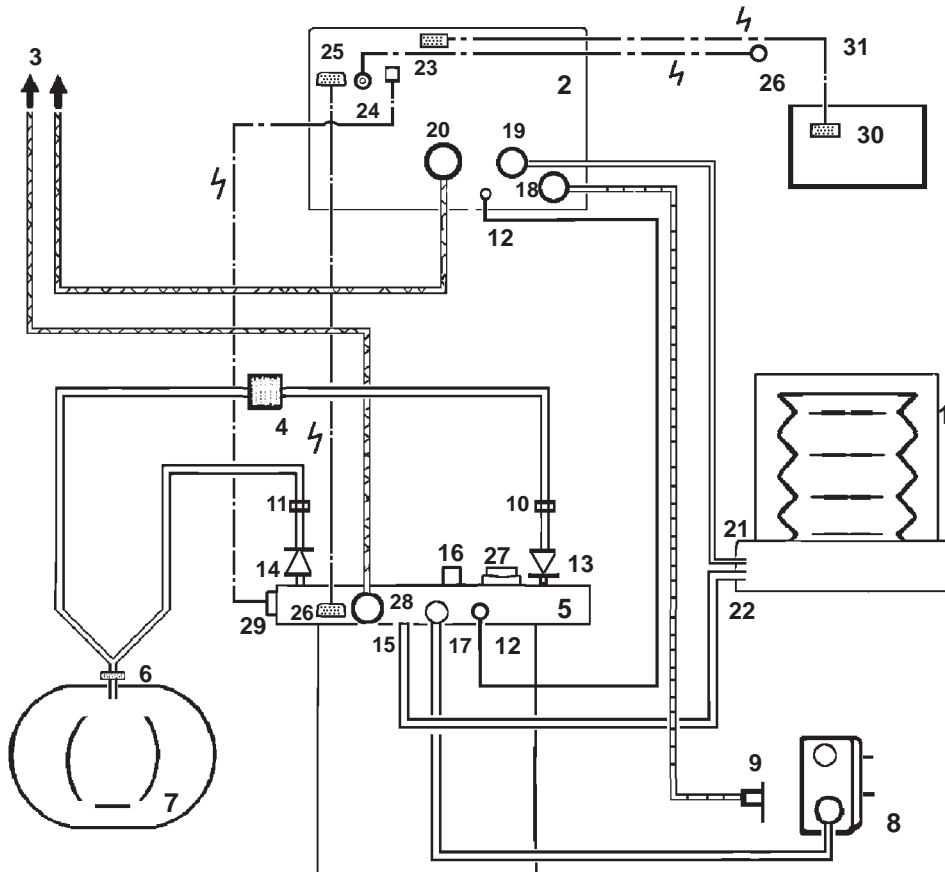
Note
1. AV-S has spirometry and oxygen monitor.
2. Interface cabling is shown for Prima SP2 On/Off switch and A200SP Bag/Vent switch.

PRE-OPERATION PROCEDURES

1. Bellows
2. Ventilator Control Unit
3. Outlets to Anaesthetic Gas Scavenging System (AGSS)
4. Bacterial Filter
5. Absorber valve block
6. Heat and moisture exchanger
7. Patient
8. CGO Block on anaesthetic machine (Fresh Gas Supply)
9. Auxiliary Outlet on anaesthetic machine (Drive Gas Supply)
10. Flow sensor - expiratory
11. Flow sensor - inspiratory
12 Connectors - sensor - pressure monitor
13. Expiratory Valve - Absorber
14. Inspiratory Valve - Absorber
15. Inlet - from Ventilator Bellows
16. Connector - Reservoir Bag
17. Inlet - Absorber - Fresh Gas Supply
18. Drive Gas Inlet - Ventilator
19. Drive gas Outlet - ventilator control unit to bellows
20. Outlet - Exhaust Valve
21. Inlet - Bellows Drive Gas
22. Outlet - to breathing system
23. Input socket - Oxygen monitor sensor
24. Input socket - Prima SP interface
    (SP on/off switch)
25. Input socket:
    (i) A200SP Absorber Bag/Vent control position
    (ii) Spirometer sensor signal
26. Interface connections on Prima SP2 and A200SP
27. APL Valve
28. Outlet from APL Valve to AGSS
29. Oxygen sensor
30. Ventilator remote screen
31. Cable - control unit to screen

PRE-OPERATION PROCEDURES
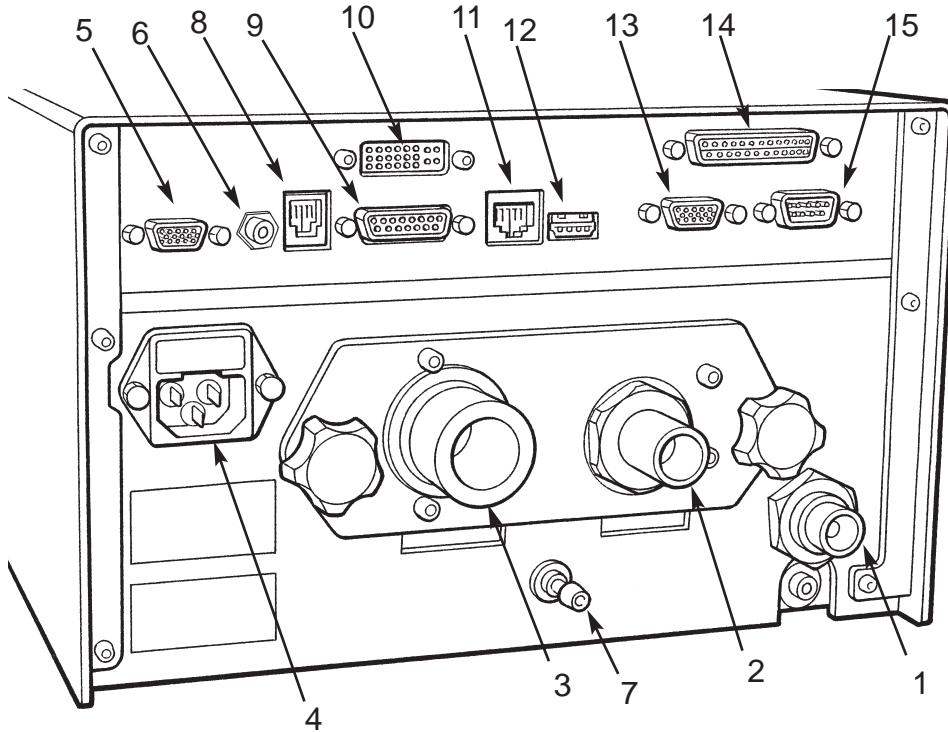
Control Unit
Rear Panel

Gas Connections
1. Ventilator drive gas inlet
    - connect to anaesthetic machine auxiliary gas outlet
2. Bellows Drive Gas Output
    - connect to bellows
    (on Prima SP2 with A200SP absorber, connect to absorber - see section 5.1.5)
3. Outlet - Exhaust Valve

Electrical Connection
4. Electrical mains input and fuse unit

Interface and Parameter inputs
5. A200SP Absorber Bag/Vent switch interface
    Spirometer connector
6. Prima SP Interface connector
7. Pressure Monitor Port
8. Input socket - Oxygen monitor sensor

Data and Printer Ports
9. Data Output
10. Output toremote display
11. Ethernet
12. USB
13. VGA
14. Printer port
15. RS232

NOTE
USB port is for use by Penlon-trained engineers only.
All other data ports are read only.
For further information, please contact Penlon Technical Support.

PRE-OPERATION PROCEDURES

5.1.5   Bellows drive gas hose

1. Prima SP2 with A200SP absorber: Connect a 16 mm diameter corrugated hose between the ventilator control unit drive gas outlet (labelled: DRIVE GAS) and the outlet (1) at the rear of the A200SP absorber.
2. All other AV-S configurations:
    Connect a 16 mm diameter corrugated hose between the control unit drive gas outlet (labelled: DRIVE GAS) and the bellows base DRIVE GAS inlet port.
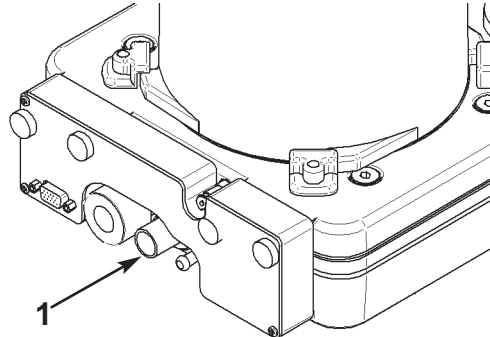
5.1.6   Anaesthetic Gas Scavenging System

1. Connect the EXHAUST valve port on the control unit to a properly functioning scavenging system
    Use a 19 mm hose (30 mm in non-USA).
2. Fit a 10 cmH$_2$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
Do not use a scavenging system that restricts drive gas flow when negative pressure is exerted on it.
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.

5.1.7   Remote Screen

Attach the DVI cable supplied with the screen between the interface connectors (1) on the rear of the control unit and screen.
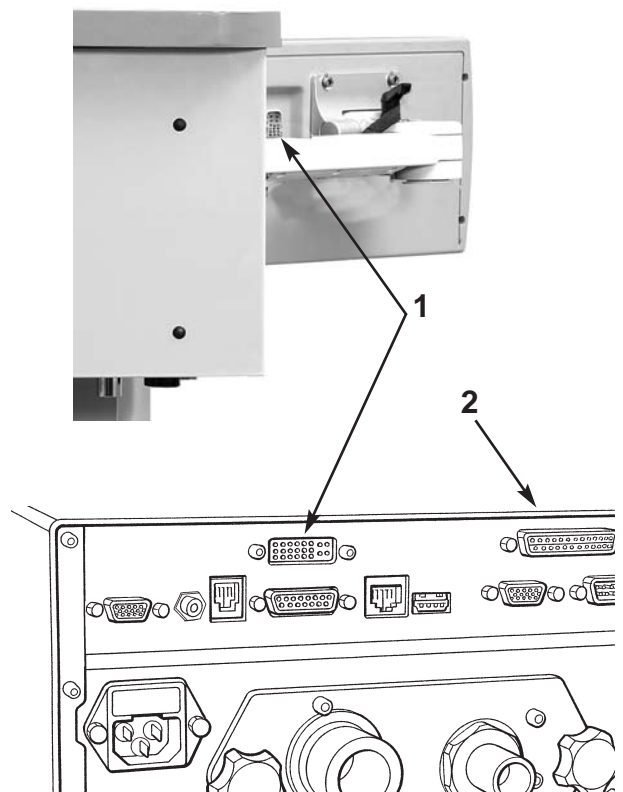
WARNING
Check that the cable between the control unit and remote display screen unit is securely connected before use.
Always use a cable type recommended by the manufacturer.

5.1.8   Printer

Attach a printer to the printer port (2) if a printed output of the ventilator function is required.

PRE-OPERATION PROCEDURES

5.1.9   Breathing System

1. Connect the ventilator bellows base BREATHING SYSTEM port to the breathing system.
2. 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.
   Fit new components at the recommended interval.

3. Connect a 2-litre breathing bag to the patient connection as a test lung.
4. Close the anaesthetic machine APL.

5.1.10   Spirometer

5.1.10.1   Flow sensors fitted to an A200SP Absorber mounted on a PrimaSP2

1. Use a breathing system bacterial filter - see section 5.1.8, operation 2.
   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 A200SP Absorber in the inspiratory and expiratory airways.
3. Connect the cable assembly between the connector at the rear of the A200SP Absorber (A) and the the 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.*

A

B
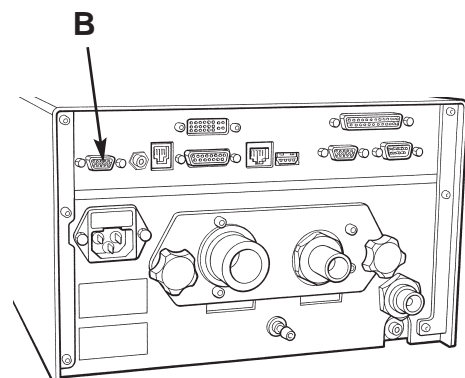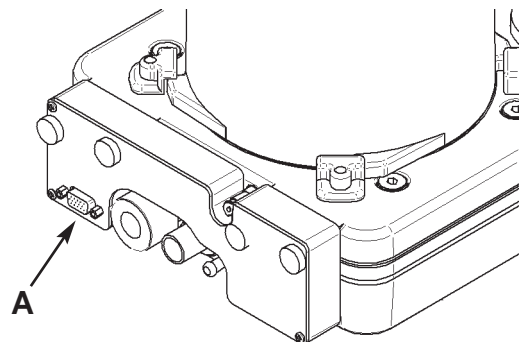
PRE-OPERATION PROCEDURES

5.1.10.2   Spirometer Calibration

Flow sensors fitted to an A200SP Absorber mounted on a Prima SP

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

1.   Turn the Prima SP gas flow off at the Gas Delivery on/off switch. This will stop all gas flows (including the AHD basal flow).
This will also turn the AV-S off.

2.   Turn the AV-S on at the ventilator (Do not use the Prima SP Gas Delivery switch).
or,
Disconnect the fresh gas hose from the CGO block on the anaesthetic machine.

3.   Remove the breathing circuit hoses from the inspiratory and expiratory connectors (1) on the absorber.

4.   Disconnect the hose that connects the APL valve outlet (2) at the rear of the manifold block to the AGSS receiver (or disconnect at receiver).

5.   a)   Remove the bag, and set the Bag/Vent control (3) to Bag position.
or,
b)   Ensure that the ventilator bellows is empty,

6.   Calibrate the spirometer via the ventilator menu procedure.

7.   Press the menu switch on the front panel.

8.   Scroll down the main menu and select O2 MONITOR & SPIROMETRY.

9.   Select SPIRO CALIBRATION.

10. Press the wheel to initiate calibration.

11. Calibration is completed.

12. Scroll to ESCAPE FROM MENUS.

13. Press the wheel to confirm.
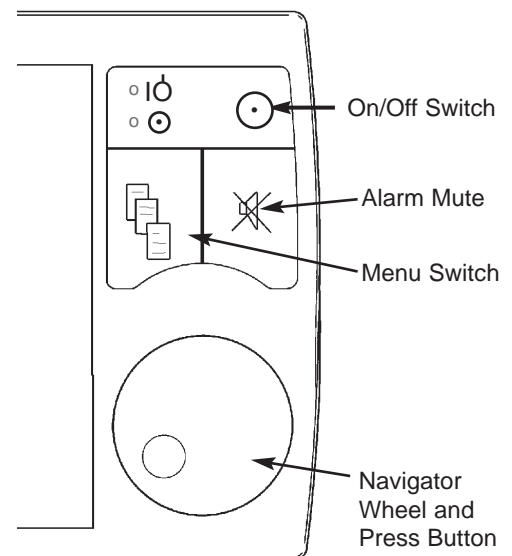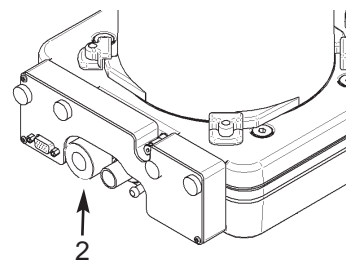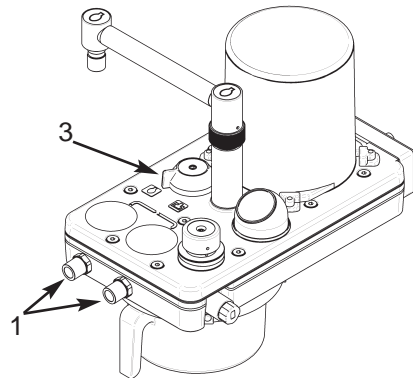
On/Off Switch

Alarm Mute

Menu Switch

Navigator Wheel and Press Button

```
O2 Monitor & Spiro

  ESCAPE FROM MENU
  O2 MONITOR: on
  CALIBRATION: 100%
  HIGH ALARM SET: 105
  LOW ALARM SET: 18
  SPIROMETER: on
> SPIRO CALIBRATION: 0 L/min
```

PRE-OPERATION PROCEDURES

5.1.11 Pressure Monitor Connections

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.

1. PATIENT PRESSURE port (**A**) on the rear panel of the control unit:
    Use the appropriate Penlon tubing assembly to connect to the expiratory limb of the breathing system, close to the circle system expiratory valve.

2. Push-fit, self sealing connectors (B)
    Push in the tube as far as possible
    Do not use excessive force.

    The connector end piece 'X' will also move inwards.

    Pull the tube carefully outwards.
    The end piece 'X' will be pulled outwards to the 'locked' position.

3. Connect the tubing (with adaptor, Part No 053049) to the push-fit, self-sealing connector (**C**) at the rear of the A200SP Absorber.
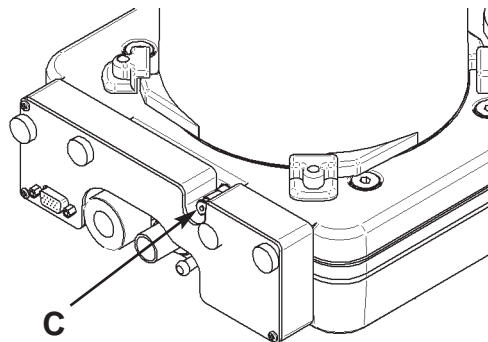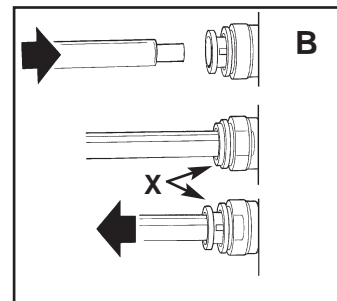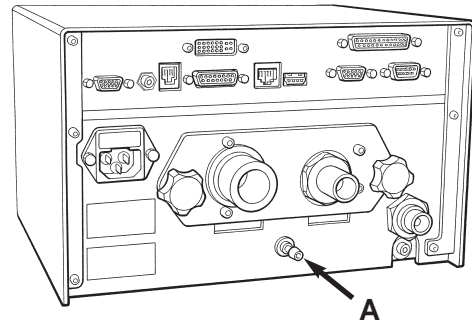
PRE-OPERATION PROCEDURES
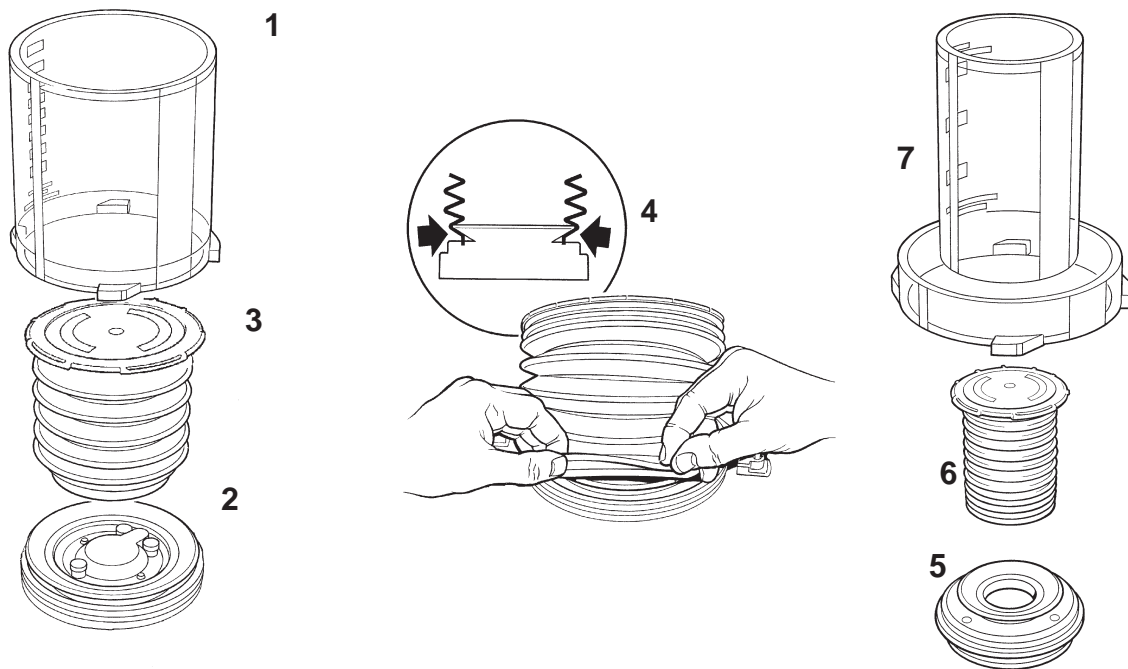
5.1.12 Bellows Assemblies

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 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

1. Remove the adult bellows housing (1) - 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).
3. 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.

PRE-OPERATION PROCEDURES

5.2 Pre-use Checklist

5.2.1 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 30 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 (1).
A three-second internal test is initiated:
1.   The 'power -up' screen is displayed.
2.   The audible alarm sounds.
3.   The ventilator reverts to STANDBY mode if no selection is made.

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.*
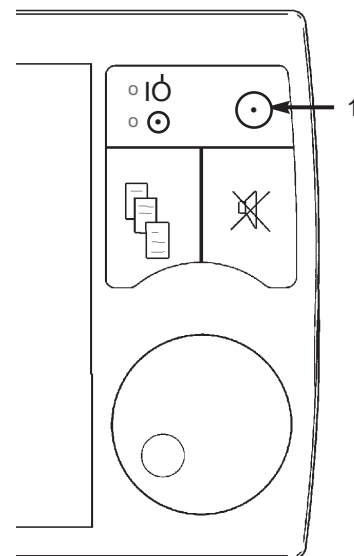
Calibrate the Spirometer - 5.1.9.2

Calibrate the O2 Monitor - 5.3.2

PRE-OPERATION PROCEDURES

5.2.2 Function Test

1. Set the AIRWAY PRESSURE LIMIT to 50 cmH$_2$O.

2. Connection for PRESSURE TRANSDUCER:
    Check that the port on the rear of the control unit is correctly connected to the port on the rear of the absorber assembly (see section 5.1.10).

3. Connect a 2-litre breathing bag to the patient connection as a test lung.

4. Adult bellows only:
    Set the tidal VOLUME to 600 ml; RATE to 10 bpm, and I:E RATIO to 1:2.0.

5. Use the O2 flush button on the anaesthetic machine to fill the bellows.

6. Select VOLUME CYCLE mode.

7. The delivered tidal volume indicated on the scale printed on the bellows housing should be approximately 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.

8. Set a basal flow only on the anaesthetic machine.
    Check the bellows after 10 breaths - the bellows should return to the top of the housing.
    Failure to return to the top of the housing indicates a leak in the breathing circuit.
    Rectify the leak before clinical use.

9. 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.

10. Open the patient 'Y' -piece to ambient pressure.
    At the second cycle, the LOW AIRWAY PRESSURE alarm should be activated.

11. 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.

PRE-OPERATION PROCEDURES

5.2.3   Weekly Checklist

At least every week, in addition to the daily function test, the following checks must be carried out:

Alarms
1.   Select STANDBY MODE.

2.   Unplug the mains power cable from the AC outlet.
       The MAINS FAILURE alarm should activate.

3.   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.

Bellows
Check the condition of the bellows and exhalation diaphragm valve - see section 6.2.2.

PRE-OPERATION PROCEDURES - *O2 Monitor*

5.3   O2 Monitor System Set-up

5.3.1   Installation

Fit the probe (A) to the A200SP absorber. Connect the cable to the input socket (B) on the back of the AV-S 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:
i) always disconnect the breathing circuit after use.
ii) Switch off the anaesthetic machine to cut-off the basal flow through the system.

Bacterial Filter
Use a breathing system bacterial filter in the expiratory limb of the breathing circuit to protect the oxygen sensor (see section 5.1.8).
CAUTION
Replacement/Disposal - always follow the instructions supplied with the filter, and always replace at the recommended interval.

5.3.2   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.
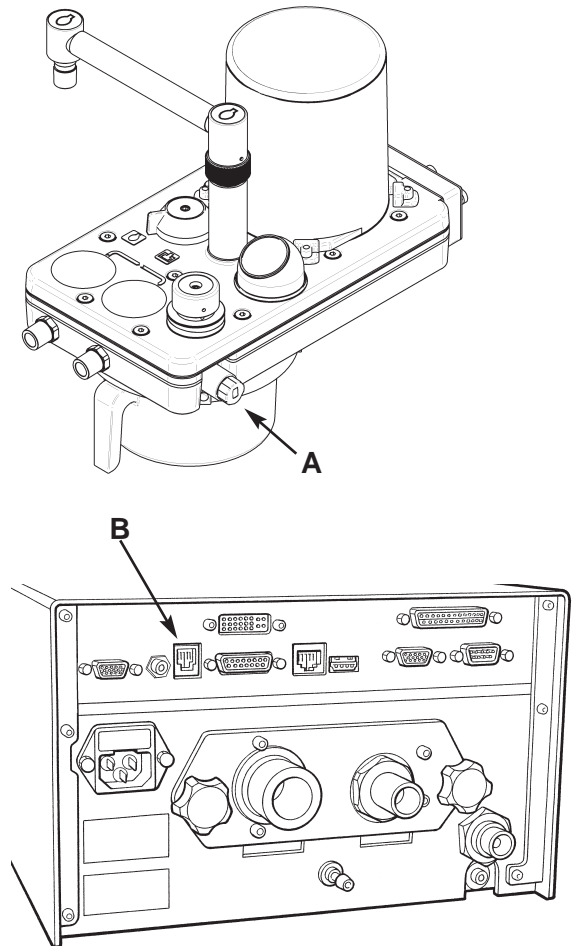
PRE-OPERATION PROCEDURES - *O2 Monitor*

5.3.2.1   Calibration - Using 100% Oxygen

AV-S ventilator mounted on a Prima SP anaesthetic machine fitted with a A200SP absorber

Calibrate with the sensor in position within the absorber.

1.   Detach the absorbent canister (1).

2.   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 (3) and the anaesthetic machine gas delivery switch.
     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 (4) stabilises.

6.   Calibrate the sensor, using the AV-S ventilator menu procedure, as follows.

7.   Press the menu switch (5) and select the O2 monitor sub-menu.

8.   Scroll to CALIBRATION.
     If the menu shows 21% (which indicates calibration using air), press the navigator wheel / button (6) to switch to 100% (calibration using oxygen).

9.   A message will flash on the screen:
               O2 AT 100% ?
     Press the button (5) 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. Scroll to ESCAPE FROM MENUS and press the button (6) to exit.

11. Turn off the flow of oxygen.

12. Refit the canister.
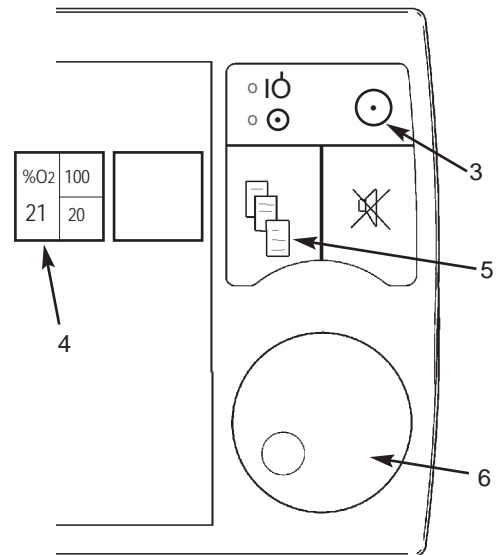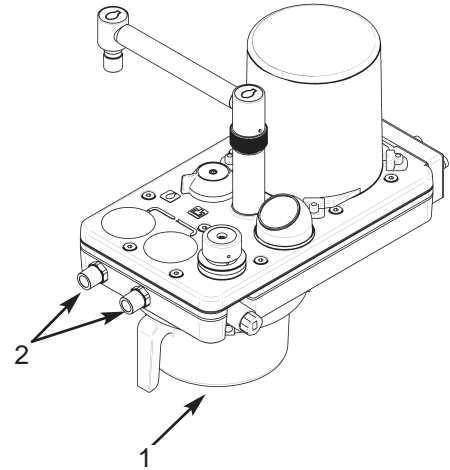

```
O2 Monitor & Spiro

   ESCAPE FROM MENU
   O2 MONITOR: on
>  CALIBRATION: 100%
   HIGH ALARM SET: 105
   LOW ALARM SET: 18
   SPIROMETER: on
   SPIRO CALIBRATION: 0 L/min
```

PRE-OPERATION PROCEDURES - *O₂ Monitor*

5.3.3 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 6.5.

```
┌─────────────────────────────────────┐
│  O2 Monitor & Spiro                  │
│                                      │
│    ESCAPE FROM MENU                  │
│   O2 MONITOR: on                     │
│   CALIBRATION: 100%                  │
│ >  HIGH ALARM SET: 105               │
│   LOW ALARM SET: 18                  │
│   SPIROMETER: on                     │
│   SPIRO CALIBRATION: 0 L/min         │
└─────────────────────────────────────┘
```
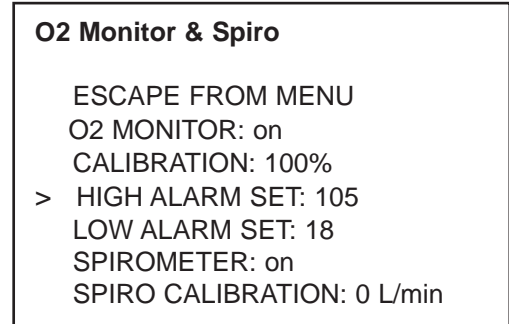
5.3.4 Setting the O₂ Alarms

5.3.4.1 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. Touch the O2 concentration display, or Press the menu switch on the ventilator front panel and select the O₂ 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.

5.3.4.2 Set Low Alarm
The low alarm value cannot be set lower than 18%, or above 99%.
1. Touch the O2 concentration display, or Press the menu switch on the ventilator front panel and 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.

High Alarm Set Value

Low Alarm Set Value

On/Off Switch

Alarm Mute

Menu Switch

Navigator Wheel and Press Button
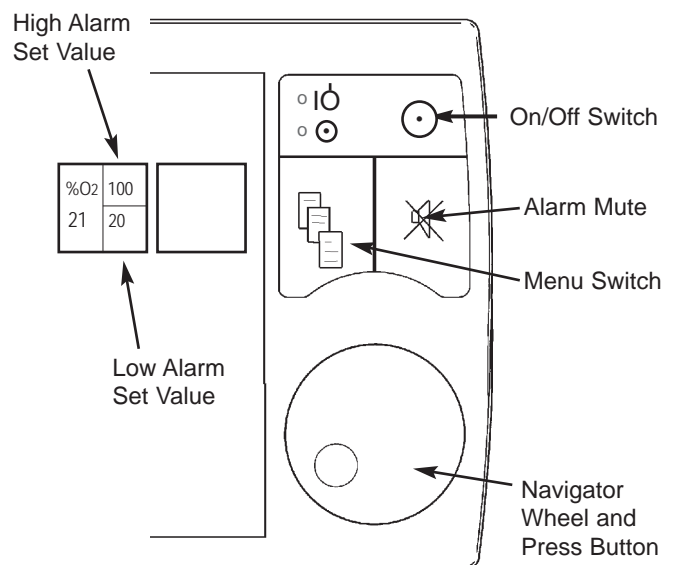
6. SERVICE PROCEDURES

6.1 Service Intervals

At 6 months, 12 months, 2 years and 4 years, the ventilator must be serviced by a Penlon-trained engineer, following the schedule given below, and the procedures given in section 7 in this 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

Every 6 months:
Inspection and Function Check.
Remove patient block assembly and clean.
Check condition of bellows.

Every 12 months:
Repeat six month procedure, plus:
Replace components, including O-seals, drive gas inlet filter, exhaust diaphragm, one way valve.
Preventive maintenance kit available.

Every 2 years:
Repeat 12 month service, plus:
Replace battery.

Every 2 years:
Repeat 12 month service, plus:
Replace PCB battery and bellows diaphragm valve.

Details of these service operations are given in this manual.

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

SERVICE PROCEDURES

6.2 Control Unit Patient Block Assembly - Removal

On a regular basis (in line with hospital procedures for infection control), the patient block (1) must be removed, cleaned and sterilised.

1. Detach the hoses from the outlets (2).
   Note different diameters for correct refitment.

2. Undo the securing knobs (3).

3. Carefully detach the assembly (1) from the control unit.
   Note that resistance will be felt until the metal tubes (4) disengage.

4. Wash thoroughly, then sterilise, as recommended in section 6.3.
   Do not disassemble.

Refitting

5. Position the patient block and push fully into the control unit, ensuring that the metal tubes (4) are engaged in their unions.

6. Fit the securing knobs (3).

7. Function test the ventilator.
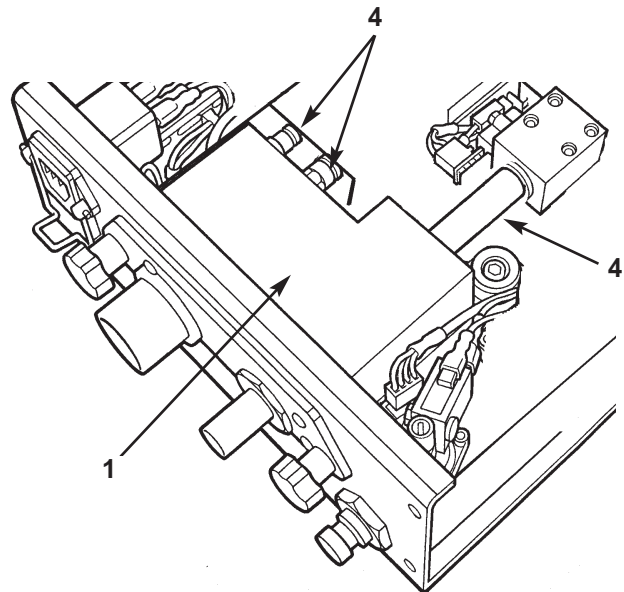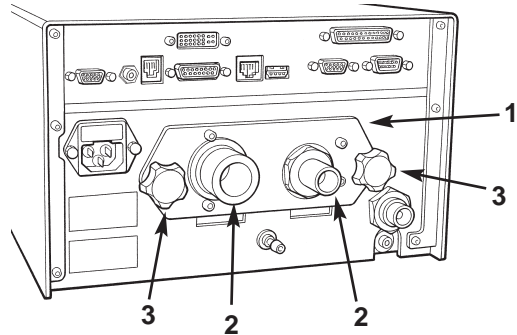
7.   SERVICE SCHEDULE

1   **Initial Checks** *(every six months)*

1.1   Check serial number to determine service required.
1.2   Check general condition of ventilator.
1.3   Check configuration of attachments, tubing, cables and connectors.
         Note, or replace as necessary.

2   **Power On and Display Checks** *(every six months)*

2.1   Check mains indicator illuminates amber when unit is switched off and connected to
         the mains.
2.2   Turn ventilator to 'Standby'.

2.3   Check audible alarm activates

2.4   Default selection screen appears and automatically defaults to adult mode after
         approximately eight seconds.
2.5   Mains indicator illuminates green

2.6   Check screen is undamaged, display is clear and that the touch sensitive screen
         functions are operating correctly.

2.7   Check operation of on-screen indicator control using navigator wheel

3   **Menu Selection Tests** *(every six months)*

3.1   Press 'Menu' button.
         Check menu screen appears.

3.2   Rotate Navigator wheel and check menu scrolls.
         Check sub-menus can be selected by pressing the Navigator wheel.
         Note some menu selections will time out after approximately 8 seconds of inactivity.

3.3   Restore any changed settings during above tests.

4   **Engineers Mode (Available in Standby only)** *(every six months)*

4.1   Press Menu button and select 'Service Menu'

4.2   Select 'Clock Menu' check date and time are correct.
                  Year = 2005 - 2099
                  Month = 1-12 (Jan - Dec)
                  Date = 1- 31
                  DOW = 1-7 =(Day of week, Mon - Sun)
                  Hour = 1-23
                  Minute = 1-59

4.3   Select 'Upgrade Menu' check software revisions
         I/O Firmware for the main board
         Main Firmware for CPU core
         Select 'Ambient Pressure'
         Check reading is correct adjust as necessary by selecting
          'Engineer Menu' - 'Penlon Options Menu' - 'Cal Pressure'
         Adjust to correct value.

SERVICE SCHEDULE

5   **Engineer Error Codes** *(every six months)*

5.1   Select 'Service Menu' - 'Engineer Menu' - 'Diagnosis Menu'- 'Display Error Log'

5.2   Check and investigate errors. Up to 30 Error Codes can be stored. Format is:
             Date - Time - Fault
             Example: 08/05/01 - 09:12:40 - On/Off Valve

5.3   Reset Error log.

6   **Bellows Assembly** *(every six months)*

6.1   Remove and clean canister.

6.2   Remove bellows from base and inspect bellows.

6.3   Discard old bellows and replace with new.   *(every 12 months)*

6.4   Remove diaphragm valve (3 x thumbscrew)

6.5   Inspect valve seat for damage

6.6   Check valve disc hangs level.

6.7   Replace diaphragm valve
         If necessary clean valve seat and valve disc using alcohol wipe.
         Do not attempt to dismantle diaphragm assembly.

6.8   Replace large orange o-ring from bellows canister (not absorbent canister)
         (every 12 months)
         Replace small o-ring from diaphragm valve.   *(every 12 months)*
         Apply oxygen approved grease

6.9   Refit diaphragm valve and secure. (3 x thumb screws)

6.10   Refit bellows and canister.

6.11   With hand occlude the Inspiratory connector of the absorber and inflate bellows
         assembly using flush button until bellows is at top of housing.
         With no flow from anaesthesia machine bellows should not drop.

6.12   Move hand from Inspiratory connector and occlude drive gas hose at rear of absorber.
         Bellows will fall momentarily but then should stop falling.

         Failure of either 6.11 or 6.12 indicates a bellows leak, diaphragm valve leak, drive gas
         hose leak or canister leak.

7   **Pneumatic System Tests (every six months)**

7.1   With unit switched off, disconnect mains supply.
         Unscrew thumbscrews at rear of unit and withdraw Patient Valve Block.

7.2   Remove Diaphragm valve, spring and spring cap.
         Remove the Non-Return Valve.
         Clean and examine for damage or discolouration.
         Replace as necessary.
         Refit the Non-Return Valve.
         With the spring, spring cap, and the diaphragm still removed, occlude the spring orifice.

SERVICE SCHEDULE

Use an inflation bulb to apply pressure to the drive gas connector.
Pressure should relieve at 100 cmH2O ± 10%

7.3   Replace diaphragm valve and Non-return valve *(every 12 months)*

7.4   Replace 5 mm, 7 mm, and 12 mm probe O-rings   *(every 12 months)*

7.5   Remove the 5mm hexagonal fitting at the rear of the control unit.
        Replace Gas Supply Filter. (every 12 months)

7.6   Leak test gas inlet to unit On/Off -valve.
        Ensure less than 7 kPa/min

7.7   With patient valve still removed, connect ventilator to power supply.
        Reconnect gas supply.
        Switch on the unit.
        In 'Standby Mode', set inspiratory flow of 5l/min using front panel settings: 500, 5, 1:1,
        OFF, 38.
        Switch ventilator to 'Volume Mode'

7.8   Connect test gauge to primary regulator test point.
        Check regulator set to 262kPa +/- 21 kPa (38 psi +/- 3 psi) during inspiratory phase.
        If adjustment is necessary unit cover will need to be removed.

7.9   Connect manometer to output of patient proportional valve (small probe) .
        Check for 90 cmH2O +/- 10% during the inspiratory phase and zero during the
        expiratory phase.
        Adjust secondary regulator as necessary

7.10   During expiratory phase ensure that there is no gas flow from the Drive Gas connector.
        If necessary carry out Drive Gas Valve Offset calibration.

8   Control Unit *(every 6 months)*

8.1   From 'Diagnosis Menu' check supply voltages and battery current as follows, with the
        mains lead connected:

          'V IN' = 1096 mV±10% (mV x 13 = input voltage)

          'V SUPP' = 1060 mV±10% (mV x 13 = input voltage)

          'I BATT' 0 - 450 mV (mV x 1.333 = mA)

8.2   Check all electrical connections and components for security. *(every 12 months)*

8.3   Replace back up battery. *(every 2 years)*

8.4   Replace Real Time battery.   *(every 4 years)*

9   Set Up *(every 6 months)*

9.1   Select drive hose 02 or Air.
        Attach to the 'Driving Gas Input' connection to the rear panel.
9.2   Connect the long corrugated hose to the 'Drive Gas Output' connector of vent and the
        vent drive gas connector at rear of absorber.

SERVICE SCHEDULE

9.3   Connect the pressure tube to 'Patient Pressure' connection on the rear panel of the control module to the Pressure Sensing port on the rear of the absorber.

9.4   Connect the cable from the 'Interface' connector on the rear panel of the control module and to the Spirometer connection on the rear of the absorber and the rear of the Prima SP anaesthesia.

9.5   Attach the 'Fresh Gas Supply' hose from the absorber to the CGO of the PrimaSP

9.6   Connect a patient breathing circuit to the CO2 absorber and attach the patient connector to a test lung.

9.7   Connect the Gas Scavenging System to the "Exhaust' connector on the rear of the vent. (If no scavenge system is attached to the rear of the ventilator, a continuous bleed during the inspiratory phase will be audible)

10   Standby *(every 6 months)*

10.1   Power On the Anaesthesia machine. Ventilator should switch 'ON'

10.2   Power Off the Anaesthesia machine. Ventilator should switch 'OFF'

10.3   Press the Power button on the ventilator.

10.4   Default selection screen appears and automatically defaults to adult mode after approximately eight seconds

10.5   Note: standby mode is highlighted white in the bottom right of screen.

10.6   Set incorrect rate, i.e. increase Vt, and/or Rate controls.
Check 'Incorrect Rate Or Ratio' displayed on screen and 3 alarm tones sound. Do not confirm settings, wait for default values to return.

11   Oxygen Analyser Function and Calibration Tests *(every 6 months)*

11.1   Connect a calibrated O2 Analyser into inspiratory connector.

11.2   Check Vent O2 sensor is inserted into the absorber O2 sampling point.

11.3   Remove canister.
Attach a short hose to inspiratory limb.
Use O2 flush for 20 seconds the set a 5 l/min flow of oxygen and allow reading to stabilise.
Ensure 100% indicated on test device and ventilator display is stable.

11.4   Calibrate Vent in 100% Oxygen.

11.5   From menu select 'Oxygen Monitor & Spirometry'-'Calibration'.
Adjust until 100% is indicated then press navigator wheel to confirm.

11.6   Exit menu and set fresh gas flow to minimum
11.7   Expose both sensors to air and check reading is 21% +/- 2

11.8   On ventilator, adjust high and low O2 alarms and check alarms trigger when values

SERVICE SCHEDULE

lower or higher than reading on ventilator O2 display respectively.
Return alarm levels to original settings.

11.9   Restore ventilator O2 sensor to correct location.
Remove test O2 analyser.
Refit canister.

12   Spirometer Calibration *(every 6 months)*

12.1   Check condition of external Spirometer cables and connections.

12.2   Disconnect fresh gas hose from anaesthesia machine Common Gas Outlet. Switch
Bag/Vent switch to 'Bag' and remove bag from bag arm.
Remove test lung from patient connector if fitted, or remove patient circuit. Ensure
scavenging circuit is not connected.

12.3   Check Spirometer is enabled in menu.

12.4   From menu select 'Oxygen Monitor & Spirometry'- 'Spiro Calibration'.

12.5   Rotate dial until '0 L/min' is displayed.

12.6   Press Navigator wheel to calibrate Spiro.

12.7   Display will flash 'Calibrating Zero'

12.8   If successful 'Calibration complete' will be displayed.

12.14   Reconnect fresh gas hose, patient circuit and manual bag and re-set bag/vent switch
to 'Vent' position.

13   Spontaneous Mode *(every 6 months)*

13.1   Select 'Spont Mode' on touch screen.

13.2   Check absorber is in vent mode.

13.3   Operate Test Lung (by hand)
Check 'Vt meas.', 'BPM' and 'I:E' readings at bottom of the display .
Observe waveform displayed.

13.4   Stop operation of test lung.
Ensure pressure reading falls to zero and after 15 sec delay check 'Apnoea' alarm
triggered and 'Vt meas.' shows '= = ='.

13.5   Press 'Mute' verify audible alarm is muted for 120 seconds.
(Note, alarm mute countdown is displayed at bottom right of touch screen.)

13.6   Switch absorber to bag mode, close APL valve. Inflate bag with O2 flush and repeat
tests 3 - 5 above using re-breathing bag.

13.7   Switch absorber to vent mode.
From the 'Special Modes' menu select SIMV.

SERVICE SCHEDULE

Re-select 'Spont Mode' and select 'SIMV'
NB: If absorber switch is not enabled in service menu, message will read 'Absorber in vent mode?' Press 'SIMV' once again.

13.8   Operate Test Lung very gently (by hand)
          Check that occasional ventilator assistance is given.

13.9   Stop operation of test lung.
          Ensure test lung is ventilated at the default settings. 600 ml; 6 bpm; 2 sec Ti

13.10   Switch ventilator to 'Standby'
          From the 'Special Modes' menu select SMMV.
          Re-select 'Spont Mode' and select 'SMMV'

          NB: If absorber switch is not enabled in service menu message will read 'Absorber in vent mode?' Press 'SMMV' once again.

13.11   Operate Test Lung very gently (by hand)
          Check that occasional ventilator assistance is given.
          Check that the measured Minute Volume is 3.6 litres

13.12   Stop operation of test lung
          Ensure test lung is ventilated at the default settings. 3.6 litres; 6 bpm; 2 sec Ti

13.13   Switch ventilator to 'Standby'
          From the 'Special Modes' menu select Pressure.
          Re-select 'Spont Mode' and select 'PSV'

          NB: If absorber switch is not enabled in service menu message will read 'Absorber in vent mode?'
          Press 'PSV' once again.

13.14   Operate Test Lung (by hand) and check that occasional ventilator assistance is given with a pressure of 10 cmH2O.

13.15   Stop operation of test lung and ensure pressure reading falls to zero and after 30 sec delay check 'Low Tidal Volume' alarm triggered and 'Vt meas.' shows '= = ='.

14   Volume Cycle & Flow Compensation Tests _(every 6 months)_

14.1   Switch Ventilator to 'Volume ' Mode

14.2   Set 'Vt' to 600 ml, 'BPM' to 10, 'I:E' to 1:2 and 'Pressure Limit' to 80.

14.3   Verify approximately 600 ml is delivered as indicated on bellows canister.

14.4   Press 'Insp Pause' check 25% pause during the inspiratory phase.

14.5   Check measured display indicates 600 ml +/- 50ml on 'Vt Meas'

14.6   From Menu select Fresh Gas compensation OFF.

14.7   The bellows still delivers 600 ml +/- 50 ml but the measured volume will reduce to approximately 500 ml with a standard test lung

SERVICE SCHEDULE

14.8   Apply a flow of Oxygen from Anaesthetic Machine of 8 L/min.
          Check displayed 'Vt Meas' Rises.

14.9   From Menus select Fresh Gas compensation ON.
          Allow 2 minutes for reading to stabilise.
          Check displayed 'Vt Meas.' = 600 ml +/- 50 ml.
          Observe that the bellows delivers less gas than before

14.10   Press 'Wave Freeze'
          Check waveform freezes on display.
          Press again to clear.

14.11   Set PEEP to 10cm H2O
          Check waveform to see that it displays 10cm H2O of PEEP. (Straight line is good.
          Decline of line indicates leak.)
          Turn off PEEP.

14.12   Adjust Airway Pressure
          Observe changing scale on waveform.
          Reset to max.

14.13   Touch waveform screen
          Check the following second waveforms are selectable and waveform is displayed.
                    1. Volume v Time.
                    2. Pressure v Volume (Compliance Loop).
          Reset back to 'None'.

14.14   Check the ventilator is operating smoothly, test lung is inflating, and system pressure is
          displayed on both vent and absorber manometer.

15   Airway alarm Tests *(every 6 months)*

15.1   Set ventilator to default settings and ventilate test lung in 'Volume' mode.

15.2   Disconnect test lung and occlude patient connector.
          Ensure 'High Airway Pressure' occurs.
          Re-connect test lung and ensure alarm clears.

15.3   Disconnect test lung and open patient connector.
          Ensure 'Low Airway Pressure' occurs.
          Re-connect test lung
          Re-fill bellows and ensure alarm clears.

15.4   Volume cycle vent, adjust Vt Set to achieve a peak airway pressure of greater than 30
          cm H2O of water.

15.5   At peak pressure clamp pressure sensing tube.
          Displayed waveform should show pressure greater than 30 cm H2O continuously.
          Check that 'High Continuous Pressure' alarm is activated.
          Unclamp pressure-sensing tube and allow the vent to cycle.
          Reset ventilator to default settings.

15.6   Disconnect power supply.
          Verify ventilator continues to operate on battery.

SERVICE SCHEDULE

Check that the 'AC Power Fail' alarm is displayed.
Reconnect Mains lead to ventilator.

15.7 Remove drive gas line from gas supply pressure.
Check 'Low Supply Pressure' alarm activates.

15.8 Re-connect drive gas line and ensure alarm clears.

16 **Pressure Ventilation** *(every 6 months)*

16.1 Switch Ventilator to 'Pressure'

16.2 Vent will automatically Set 'Airway Pressure Limit' to 10 cm H2O.
Verify pressure is held at this setting.

16.3 Carry out leak test.
Set 'Rate' to 5 BPM, I:E 1:1, and 'Pressure Target' to 50 cm H2O.
Ensure flowmeter on anaesthesia machine is set to minimum.
Fill bellows using O2 flush.
Allow bellows to cycle and verify bellows remain full.
 If necessary adjust flow from anaesthesia machine to maintain full bellows.
Max permissible flow (leak) 200ml.

16.4 Check waveform holds the airway pressure values. (Level display)
A falling display indicates a leak either in the driving circuit, the patient circuit or the absorber system.

17 **Electrical Safety Checks (i.a.w. MDA DB 9801 supp. 1)** *(every 6 months)*

17.1 Earth Continuity (Max 0.2 ohms) at 1 Amp or less

17.2 Insulation Resistance (not less than 20 Meg Ohms) at 340-500Vdc

17.3 Earth Leakage (Max 500 micro amps)

17.4 Enclosure Leakage (Max 100 micro amps)

18 **Paperwork** *(every 6 months)*

18.1 Fill out appropriate service report.

8. PARTS LIST

Preventive Maintenance Kits

One year Kit	**Part No 57298**
Exhaust diaphragm	300580
One-way valve	300581
O-rings (x 5)	5 mm - 041204
	7 mm - 041245
	12 mm - 041222
Inlet filter	300560
Bellows	57550

2 year Kit	**Part No 57299**
As One year kit, plus:	
12v battery	103996

4 year Kit	**Part No 57300**
As 2 year kit, plus:	
3v PCB battery	104019
Bellows diaphragm valve	406020

PARTS LIST

5000492
Arm Assembly
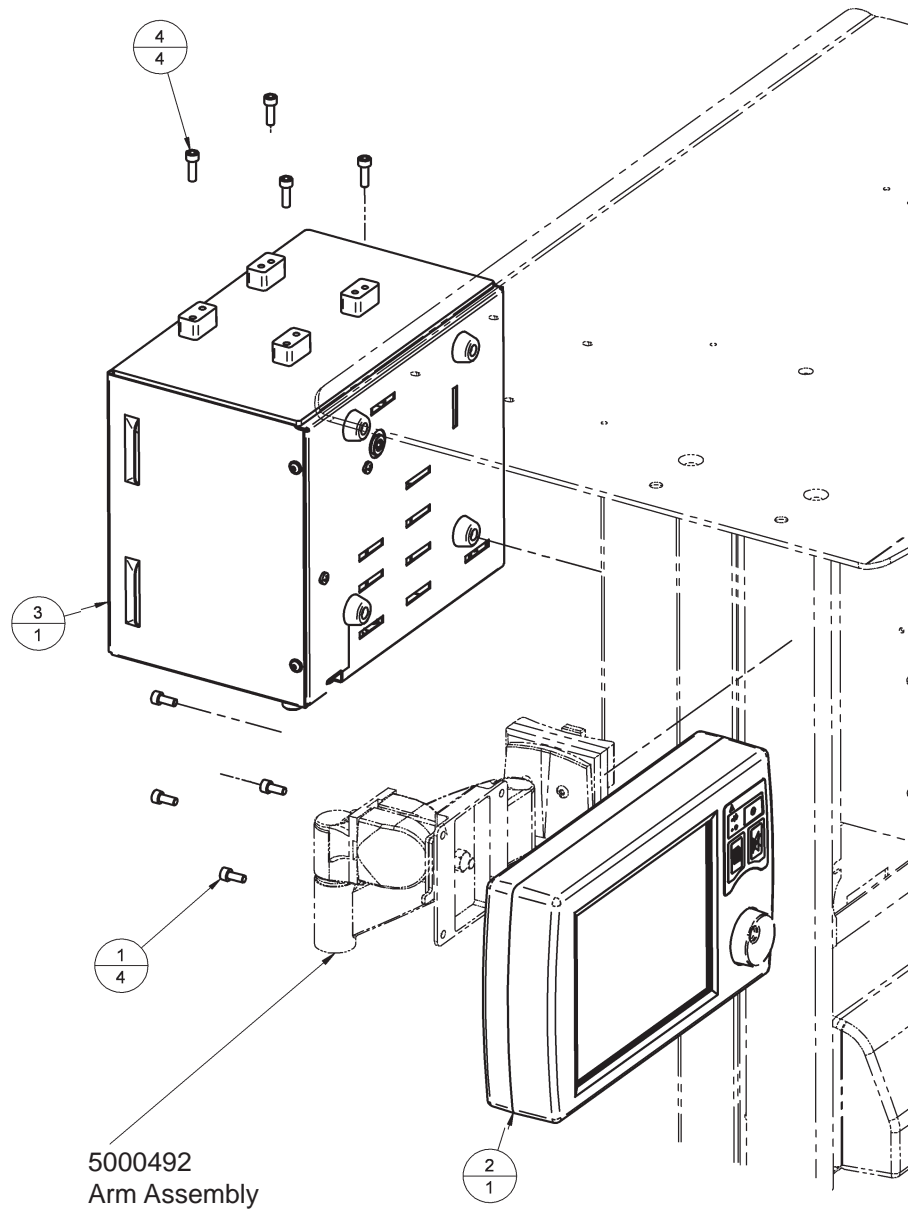
Control Unit and Remote Display Screen Assemblies

Item	Part No.	Description	Quantity
1	01056	M5 x 12 SKT HD Cap Screw	4
2	300529	Screen Display Assembly (Remote)	1
3	5000543	Chassis Assembly (Remote)	1
4	01130	M5 X 16 SKT Cap Head Screw ST STL	4
5	300549	Interface Cable - screen to control unit (not shown)	1

PARTS LIST
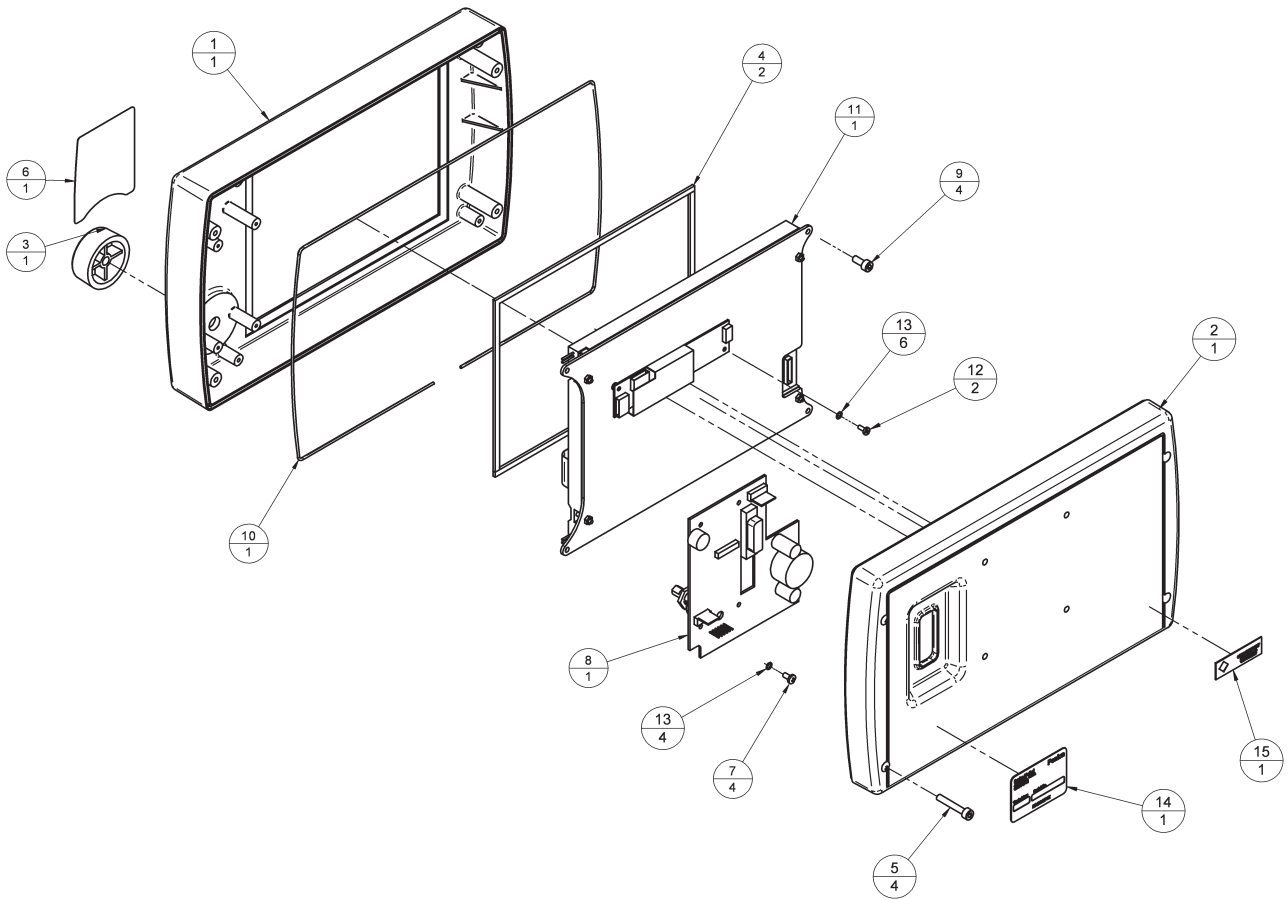
Display Screen Assembly

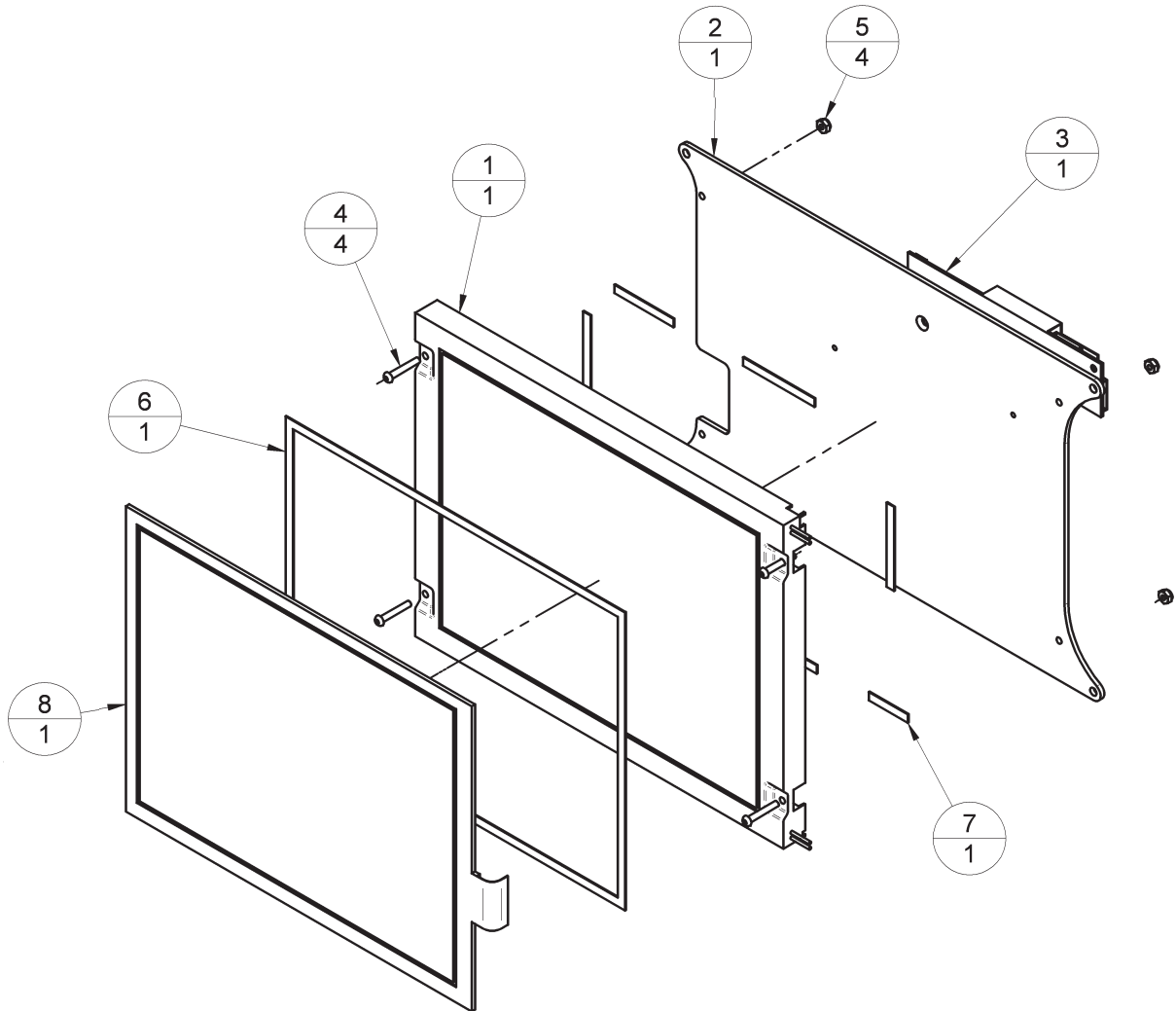| Item	Part No.	Description	Quantity
1*	300540	Front Moulding	1
2*	300541	Rear Cover	1
3	300575	Spinner Ø38 mm	1
4	300573	Gasket	2
5*	01253	M4 X 25 SKT HD Cap	4
6	300550	Membrane Switch + LED's	1
7	019122	M3 X 6 LG Button HD	4
8	300516	LVDS Encoder Assembly	1
9	01013	M4 X 10 SKT HD Cap	4
10	300547	'O' Ring Cord	1
11	300524	TFT Sub Assembly	1
12	01059	M2.5 X 6 CH HD	2
13	025606	M3 Fibre Washer	6
14	15056	Product Label	1
15	15446	Warranty Label	1

PARTS LIST

Screen Assembly (300524)

Item	Part No.	Description	Quantity
1	300565	8.4" TFT Screen (NEC)	1
2	300531	TFT Mounting Plate	1
3	300567	Inverter 5V	1
4	300599	M2.5 X 16 Butt HD SS	4
5	5000544	M2.5 Nyloc Nut ST STL	4
6	300536	Tape (Touch Screen To TFT)	1
7	300537	Tape (TFT To Plate)	1
8	300566	8.4" Touch Screen	1

PARTS LIST

Control Unit Assembly (5000453)

Item	Part No.	Description	Quantity
1	01056	M5 x 12 SKT HD Cap Screw	4
2	300534	SP Mounting Plate	1
3	019171	M4 x 10 But Flanged HD	10
4	300564	Short Form Instructions	1
5	019049	M3 X 10 LG Pan HD	3
7	5000489	Chassis Assembly	1
8	5000499	Tray Assembly (Remote)	1
9	15446	Warranty Label	1
10	15056	Product Label	1
11	034072	M5 Cover Plug	4
12	5000460	Cover - AVS	1

PARTS LIST
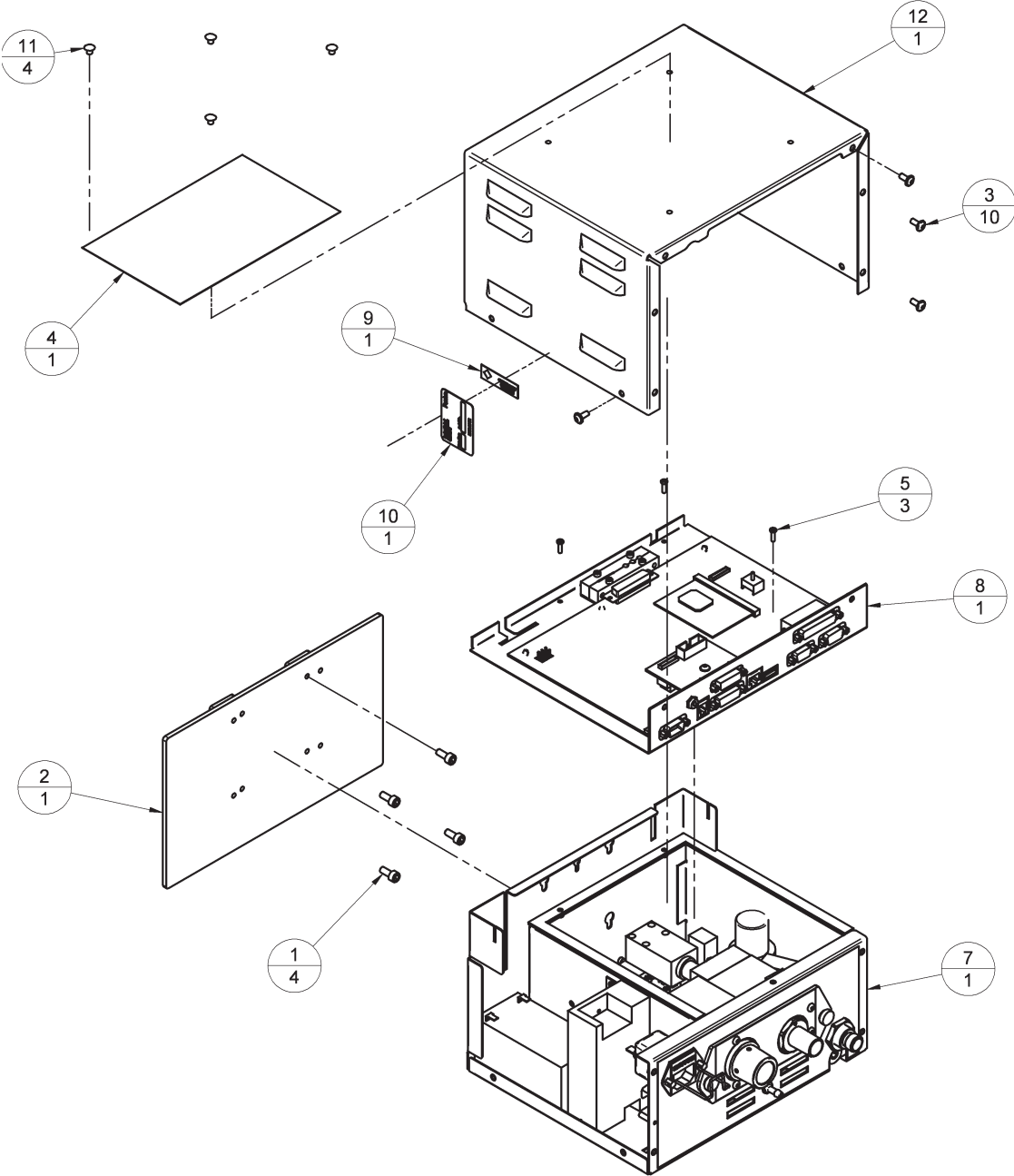
PARTS LIST

Control Unit Chassis Assembly (5000489)

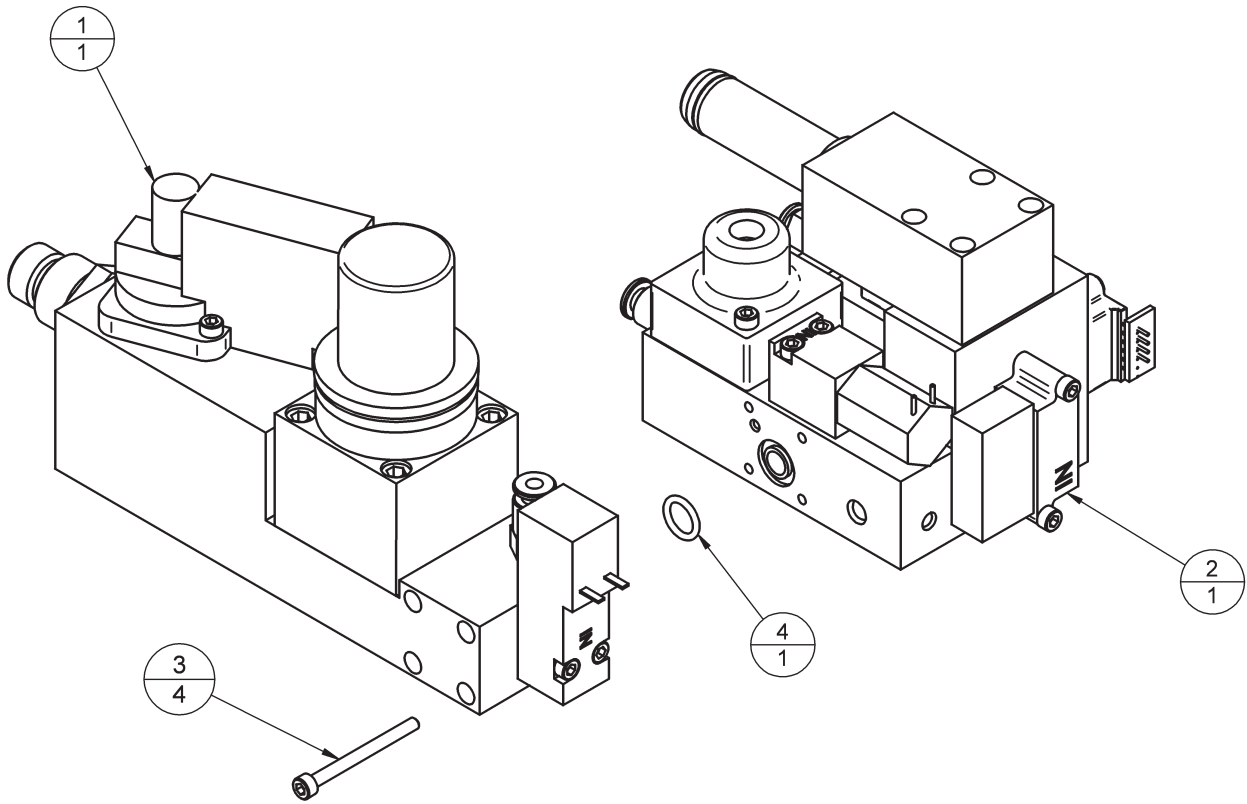| Item	Part No.	Description	Quantity
1	5000459	Chassis - AVS	1
2	5000156	Regulator & Control Assembly	1
4	300595	DISS Con' Nut	1
5	011240	Rubber Foot	4
6	01235	M8 Internal Star	1
7	01149	M8 Locknut	1
8	103996	Battery	1
9	104715	LEC Mains Connector / Filter	1
10	2220-099	LEC Mains Plug Retainer Assembly	1
11	5000449	Patient Valve Block Assembly	1
12	35150	Hose - Hose Panel Connector	1
13	019122	M3 X 6 LG Button HD	4
14	5000505	External Circlip Ø10 mm Shaft	2
15	5000498	Power Supply Bracket	1
16	5000504	External Circlip Ø8 mm Shaft	2
17	5000472	Chassis Label - AVS	1
18	300569	Power Supply	1
19	300634	Straight Connector 5 O/D Tube - M5	1
20*	5000540	Bostik Silicone Sealant	A/R
21	5000488	Pressure Connector	1
22	041204	5.1 I/D X 1.6 CSØ Viton	1
23	500506	Tray Gasket	1
24	5000487	Bleed Adaptor	1
26	054541	Tube Conn'	1
27	041245	O Seal Ø7.0 X 1.5	1
29	300609	Sensor Assembly	1
30	019067	M4 X 12 SKT HD Cap	2
31	011241	D/S Tape 3M's X 105 mm Long	2
32	019087	M3 X 16 Cap HD Screw	2
33*	057002	Loctite 222	A/R
34	011169	M4 Skiffy Cap	2
36	019121	M4 X 8 Button HD	1
37*	300638	Tube Ø4.0 O/D	A/R
38*	300637	Tube Ø5.0 O/D	A/R
39*	011092	Silicon Tube O/D 6 mm X I/D 3 mm	A/R
40	104038	Fuse, 2 Amp T HRC - 20 mm, UL	2
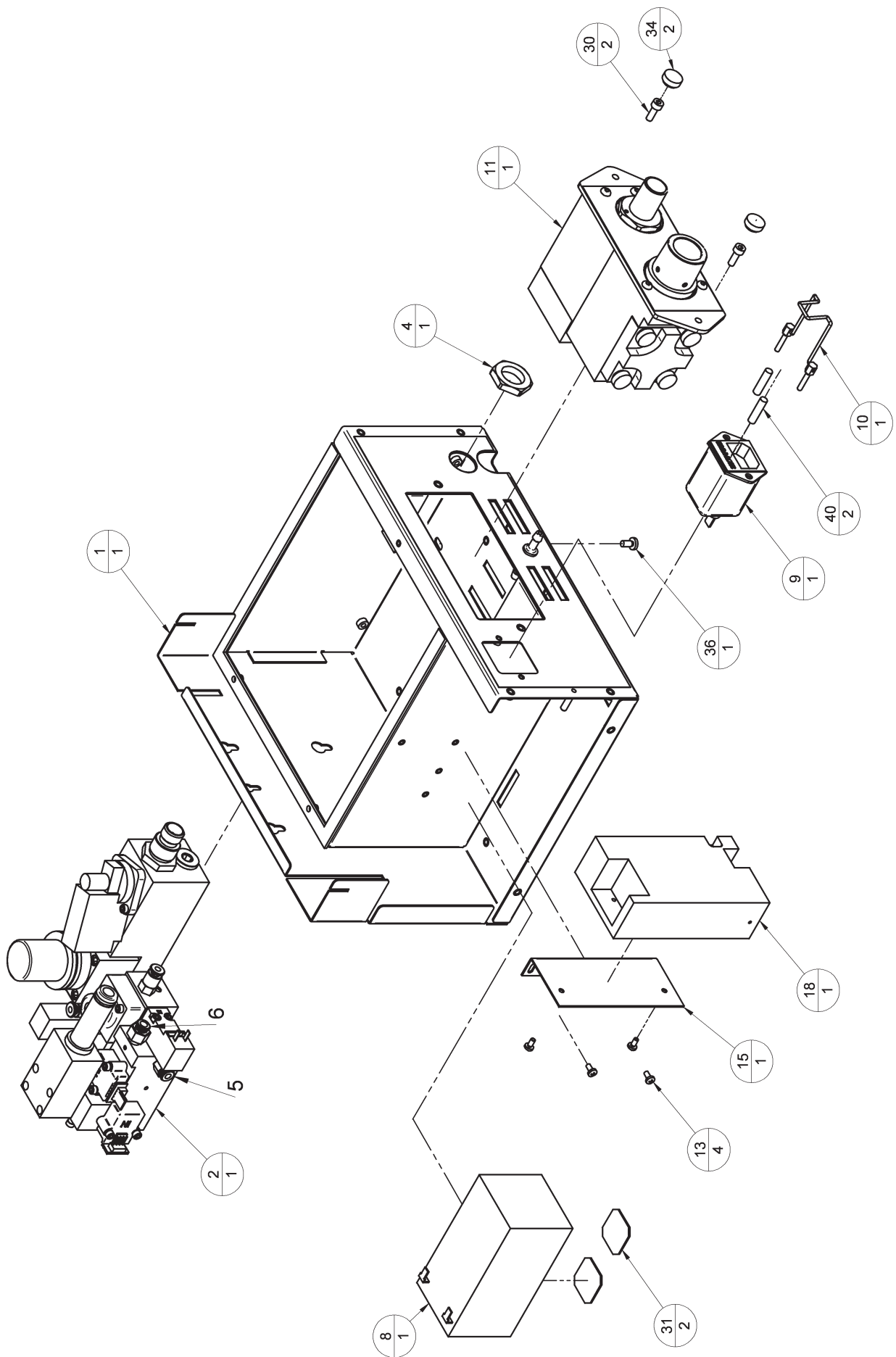
PARTS LIST

PNEUMATIC CONNECTIONS:-

CONNECT PORT 3 TO PORT 4 USING
SILICON TUBE 011092.
CONNECT PORT 1 TO PORT 5 USING
4mm O/D TUBE 300638.
CONNECT PORT 2 TO PORT 6 USING
5mm O/D TUBE 300637.
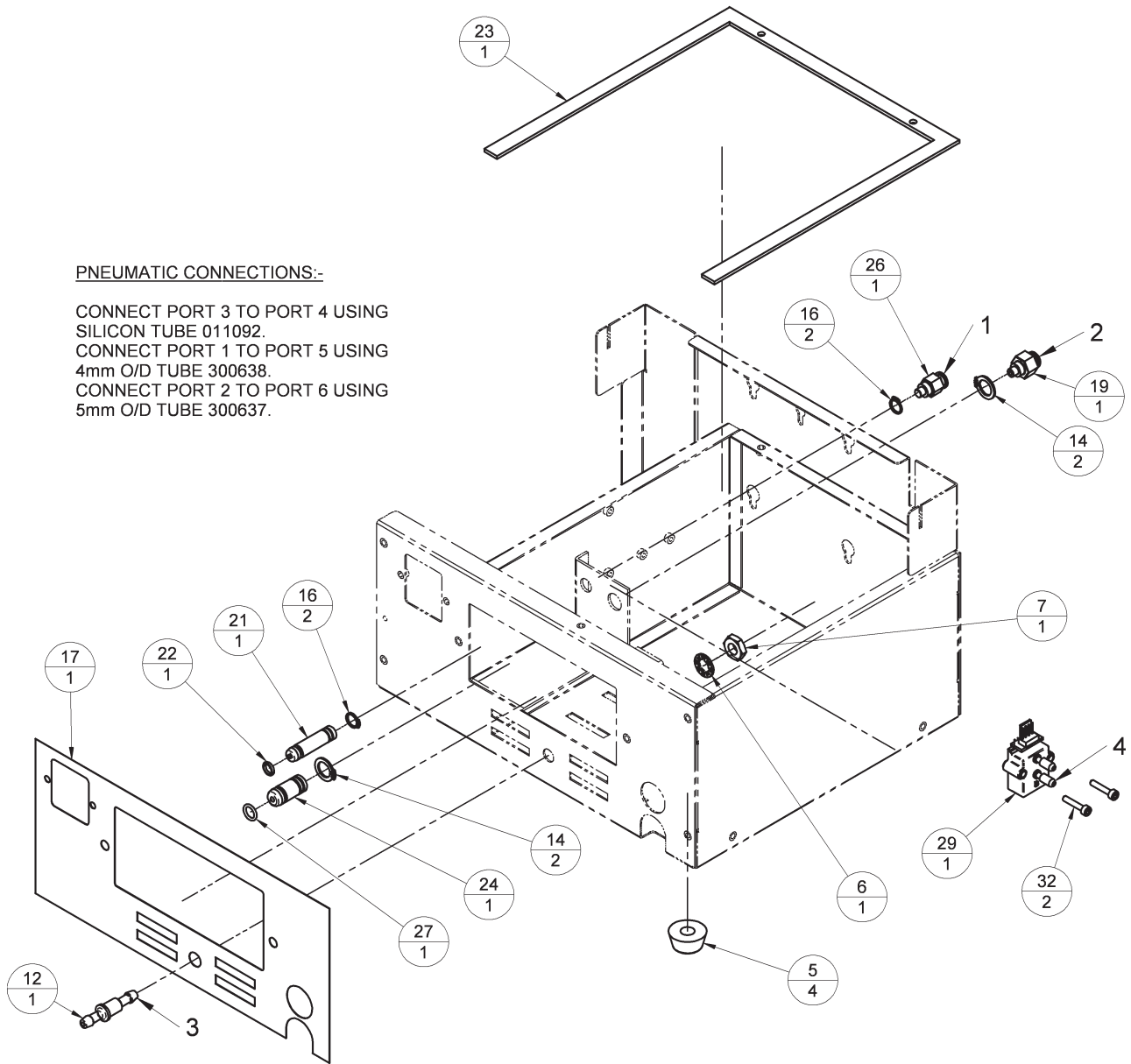
PARTS LIST

Regulator Assembly and Control Block Assembly

Item	Part No.	Description	Quantity
1	300526	Regulator Assembly	1
2	5000482	Control Block Assembly	1
3	019037	M3 X 35 Cap HD	4
4	041221	'O' Ring Ø8.1 X Ø1.6	1

PARTS LIST

Patient Block Assembly

Item	Part No.	Description	Quantity
1	300580	Diaphragm	1
2	300581	One-way valve	1
3	300583	Inline Relief Valve	1
4	5000478	Check Valve Cap	1
5	300593	Taper Adaptor	1
6	300594	Tapered Conn	1
7	5000448	Spring Guide	1
8	5000450	Valve Body	1
9	5000451	Seat Insert	1
10	5000452	Drive Gas Block	1
11	5000453	Valve Base	1
12	0501	'O' Ring	1
13	01014	M4 X 16 SKT HD Cap Screw Ss	4
14	011169	M4 Skiffy Cap	4
15	019028	M3 X 6 Grub Ss Cup	1
16	019087	M3 X 16 Cap HD Screw	4
17	019128	M4 X 8 Butt HD CHEM BLK	4
18	019153	M4 X 50 Cap Head SS	4
19	041214	'O' Ring RM 0221-16 Viton	1
20	041217	'O' Ring	1
21	041250	'O' Ring Ø27.6 X 2.4	1
22	300561	Compression Spring	1
23	5000444	M4 Tappex Trisert	8
24	5000445	M3 Tappex Trisert	4
25	5000475	Mounting Plate	1
26	5000476	Mounting Plate Label	1

PARTS LIST
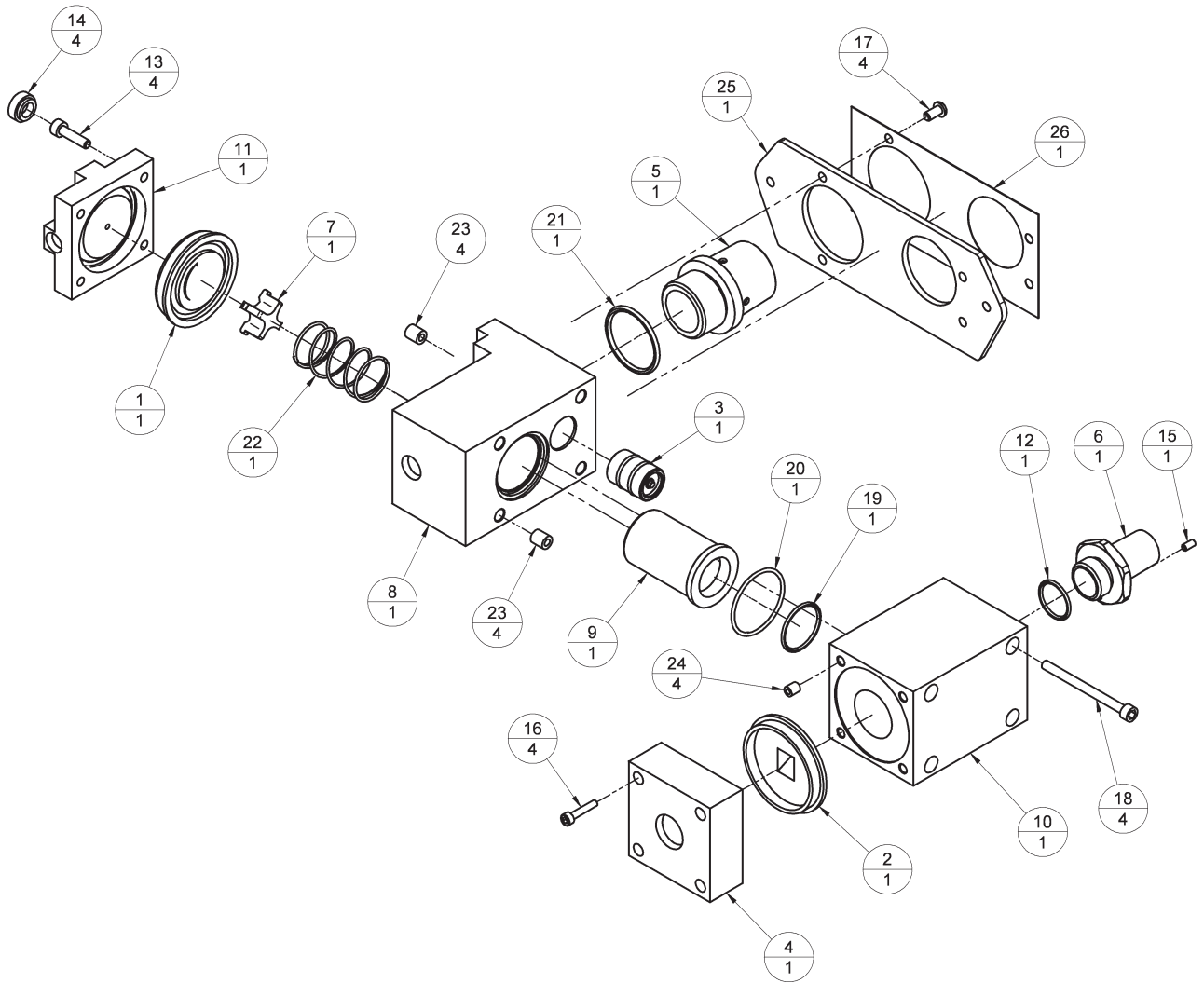
7. APPENDIX

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 recharging 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^OC (120^OF).

Storage temperature	Recharge period
38 to 50^OC (100 to 122^OF)	1 month
21 to 38^OC (70 to 100^OC)	3 months
7 to 21^OF (45 to 70^OF)	6 months
0 to 7^OC (32 to 45^OF)	9 months
-5 to 0^OC (23 to 32^OF)	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 the unit to indicate date of the last charge.

C. Disposal of used batteries

Follow all hospital, local, state and federal regulations.

Note
Removal/replacement of battery must only be undertaken by a trained technician

APPENDIX

APPENDIX 2

On-screen Menus

NOTE:

1. All selection or changes in the menu are followed by a "CONFIRM" message prompt on the screen, and accompanied by a "BEEP" (user volume set)

2. The selected text or option will invert in colour

3. User settings menus only activate in Standby mode.

4. Clock menu, Upgrade menu, Diagnostic menu only activate in Standby mode.

5. Special Modes on-screen tab only activates in Spontaneous mode

6. Adult default settings
    VT=600 mL
    RATE=10 bpm
    IE RATIO=1:2
    Plimit=38 cmH2O
    Ptarget=10 cmH2O

7. Paediatric default settings
    VT=150 ml
    RATE=15 BPM
    IE RATIO=1:2
    Plimit=38 cmH2O
    Ptarget=10 cmH2O

Menu Structure

Main Menu

```
EXIT MENUS
O2 MONITOR & SPIROMETRY
FRESH GAS COMPENSATION: ON
SPECIAL MODES
WAVEFORM
ALARM SETTINGS
GAS MIXTURE: O2+AIR
USER SETTINGS

SERVICE MENU
```

O2 Monitor & Spirometry

ESCAPE FROM MENU		
O2 MONITOR: on	off / on	(Toggle option
CALIBRATION: 100%	21 / 100%	(Toggle option)
HIGH ALARM SET: 105	19 -105	(Integer)
LOW ALARM SET: 18	18 - 99	(Integer)
SPIROMETER: on	off / on	(Toggle option)
SPIRO CALIBRATION: 0 L/min	0 L/min / 10 L/min	(Toggle option)

Fresh Gas Compensation

ON / OFF	off/on	(Toggle option)

Special Modes

Support Mode pick list
none
pressure
simv
smmv

ESCAPE FROM MENU	
SUPPORT MODE: none	
TRIGGER: 5 L/min	
SIGH TO BREATH RATIO: 1:50	

Trigger pick list
0.2 L/min
0.3 L/min
0.4 L/min
0.5 L/min
1.0 L/min
1.5 L/min
2.0 L/min
2.5 L/min
3.0 L/min
4.0 L/min

Sigh to Breath
Ratio pick list
1:50
2:50
3:50
4:50

Waveform

ESCAPE FROM MENU
SECOND WAVEFORM: off

Second waveform pick list
off
vol. vs time
vol. vs press.

Alarm settings

ALARM MENU		
ESCAPE FROM MENU		
ALARM MODE : default	default / user	(Toggle option)
HIGH TIDAL VOLUME: off	off / on	(Toggle option)
VM MIN: 0.3 L	0.0 - 7.4	(Integer)
VM MAX: 0.9 L	0.1 - 7.5	(Integer)
VT MIN: 300 mL	10 - 1600	(Integer)
VT MAX: 900 mL	20 - 2400	(Integer)
APNOEA ALARM LIMIT: 0.3 cmH2O	0.3 - 3.5	(Integer)
ALARM VOLUME: 50%	50 - 100%	(Integer)

Gas mixture: O2+Air

O2+AIR
O2+N2O
O2+Xe
O2+He

User Settings

ESCAPE FROM MENU
SELECT SETTINGS
SAVE SETTINGS
BACK LIGHT LEVEL: 50%
VOLUME TYPE: tidal

Select settings
ESCAPE FROM MENU
USER1: CCT1
USER2: CCT2
USER3: CCT3
USER4: CCT4
USER5: CCT5
ADULT DEFAULT
PAEDIATRIC DEFAULT

Save settings
ESCAPE FROM MENU
USER1: CCT1 CONFIRM: CCT1
USER2: CCT2 CONFIRM: CCT2
USER3: CCT3 CONFIRM: CCT3
USER4: CCT4 CONFIRM: CCT4
USER5: CCT5 CONFIRM: CCT5

Backlight level
0 - 100%   (integer)

Volume type
tidal/minute   (toggle)

Service

See next page

Service

ESCAPE FROM MENU
LANGUAGE: ENGLISH
PRINT PATIENT DATA
SERIAL MODE: none
CLOCK MENU
UPGRADE MENU
AMBIENT PRESSURE: 988 mBar
DISPLAY HISTORY
*SERVICE PIN: 0
*ENGINEER MENU

Language pick list
    ENGLISH
    ITALIANO
    TURKCE
    POLSKI
    ESPANOL

Serial mode pick list
    NONE
    Philips
    SPACELABS

Clock

ESCAPE FROM MENU	Clock pick list	(integer)
YEAR: 2005	2005 - 2099	(integer)
MONTH: 3	1 - 12	(integer)
DATE: 16	1 -31	(integer)
DOW: 3	1 - 7 (1 = Monday)	(integer)
HOUR: 9	0 - 23	(integer)
MINUTE: 57	0 - 59	(integer)
UPDATE CLOCK		
DAYLIGHT SAVING: off	off / on	(toggle option)

Upgrade
    ESCAPE FROM MENU
    I/O HARDWARE: 2
    I/O FIRMWARE: v0.47 [Build 68]
    MAIN FIRMWARE: v0.92 [Build 32]
    REGISTRATION KEY: unknown
    UPGRADE FIRMWARE: unavailable
    ADD NEW FEATURE: unavailable

History Display
    ESCAPE FROM MENU
    MANUFACTURER DATE : 03/03/05
    TOTAL HOURS RUN: 100
    LAST SERVICE DATE: 13/08/04
    HOURS SINCE SERVICE : 100
    DRIVE VALVE CYCLES: 1253
    PATIENT VALVE CYCLES: 822
    CUTOFF VALVE CYCLES: 72

*NOTE
Service PIN
Engineer Menu

Sub-menus are not accessible by users.

APPENDIX

APPENDIX 3
AV-S Ventilator Spirometry System

Ventilator Spirometry Measurement
The AV-S ventilator drive gas and spirometry system uses a total of three mass flow gas sensors to monitor and then independently measure the gas flows within the ventilator and breathing system.
This ensures that correct volumes are delivered to the patient.
These monitors are measuring firstly in the ventilator delivery control system, and secondly in the patient breathing system.

During use of the ventilator the user will set a required tidal volume and at the first breath the ventilator will use its pre-calibrated delivery flow rate valve settings to set the proportional delivery valve position to deliver the requested tidal volume.
To confirm that the correct flow rate (tidal volume) is being delivered by the ventilator delivery system an internal flow sensor (a Honeywell AWM43300V mass flow sensor), monitors the delivered flow rate and makes adjustments every 30 ms using proportional regulation.
As this sensor is always measuring the known drive gas rather than breathing system gas the volumes measured will always be independent of breathing system gas composition. This system ensures accurate delivery volume from the ventilator control unit.

To monitor for correct delivery volumes in the breathing system there are two breathing system mass flow sensors (Honeywell AWM 720P1 spirometers).
One sensor is located in the inspiratory limb, and one in the expiratory limb.
Measurements are taken from these sensors to determine the actual delivered and exhaled gas volumes in the breathing system. This enable measurements to be made to compensate for fresh gas flow, compliance losses and possible breathing system leaks.
During the inspiratory cycle the inspiratory flow sensor measures the gas volume delivered to the patient.

The flow sensor output is read at least every 2 msec and then five sets of readings are averaged and the averaged value is sent every 10 ms to the processor for calculation of the volume delivered to the patient.
This delivered volume will consist of the volume delivered from the ventilator bellows plus the fresh gas flow from the anaesthetic machine fresh gas supply, minus any compliance loss and minus any leak.
This gives a total actual inspired tidal volume.

A similar measurement method is used for the exhaled volume. During the exhalation period the measured exhaled volume is subtracted from the inspired volume, and at the end of exhalation.
A negative (more gas coming out) volume indicates that fresh gas has increased the delivered volume.
A positive volume (less gas coming out) indicates a leak in the circuit.
The ventilator control system will then adjust the next delivered tidal volume, up to a maximum of 100 ml. This will bring the delivered volume to exactly as set.
If the variation between set and delivered is greater than the maximum rate of change allowed, the adjustment will occur gradually over several breaths.
The displayed volume is the average of the inspiratory and expiratory volumes. If this value is less or more than 50% of set volume, a low or high volume alarm is given.

Breathing System Gas Composition
Gas flow measurements are affected by the breathing system gas composition. To compensate for these effects the ventilator has
a) a gas composition setting whereby the user is able to select the gasses being delivered, i.e. oxygen/air, oxygen/nitrous oxide etc,
b) an oxygen monitor;

Thus the ventilator knows the overall oxygen concentration and the majority of the remaining gas composition.

APPENDIX

Altitude Effects

Gas flow measurements are also affected by atmospheric pressure, in a linear relationship.

To compensate for altitude effects an ambient pressure sensor is available. When the spirometers are calibrated for zero flow the ambient pressure is recorded so that the measured volume may be adjusted. The measured volume is multiplied by the ratio of Pamb to Pcal; where Pamb is the latest ambient pressure and Pcal is the ambient pressure recorded when the spirometers were calibrated at zero flow.

Carrier Gas Effects

The effect of air as the dilutent gas is different to that of nitrous oxide and as the ventilator includes only an oxygen monitor, the additional information of gas being ventilated is included to increase available accuracy. In the event of the wrong gas selection being made by the user, the error in delivered volume could reach up to approximately 7%. This possible variation is of no known clinical disadvantage.

Anaesthetic Agent Effects

The addition of anaesthetic agent is known also to increase the spirometry readings depending on the agent and its concentration by up to approximately 2%. Again this minor volume measurement variation is of no known clinical disadvantage and is therefore not compensated for other than that due to oxygen variation due to the percentage change.

Water Vapour Effects

Water vapour volumes in the breathing gas are not detectable in normal breathing system dynamics.

Additional Features

Additional spirometry features available for selection by the user are the ability to turn off the automatic compliance and fresh gas compensation and also the feedback provided by the oxygen monitor.
In this event, the ventilator relies on the basic delivery look up table and the internal flow sensor to confirm delivery volumes as

near as possible, under the circumstances. Accuracies for spirometry measurement are

>300 ml	± 10%
>100 ml <300 ml	± 20%
<100 ml	± 50%.

Flow sensor description

The microbridge mass airflow sensor operates on the theory of heat transfer. Mass airflow is directed across the surface of the sensing elements.
Output voltage varies in proportion to the mass air or other gas flow through the inlet and outlet ports of the package.

The specially designed housing precisely directs and controls the airflow across the microstructure sense element.
The microbridge mass airflow sensor has a unique silicon chip based on advanced microstructure technology. It consists of a thin-film, thermally isolated bridge structure containing heater and temperature sensing elements. The bridge structure provides a sensitive and fast response to the flow of air or other gas over the chip.

Dual sensing elements positioned on both sides of a central heating element indicate flow direction as well as flow rate.
Laser trimmed thick film and thin film resistors provide consistent interchangeability from one device to the next.

The microbridge mass airflow sensor uses temperature-sensitive resistors deposited within a thin film of silicon nitride. They are suspended in the form of two +bridges over an etched cavity in the silicon.
The chip is located in a precisely dimensioned airflow channel to provide a repeatable flow response.

Highly effective thermal isolation for the heater and sensing resistors is attained by etching the cavity space beneath the flow sensor bridges. The small size and thermal isolation of the microbridge mass airflow sensor are responsible for the extremely fast response and high sensitivity to flows.
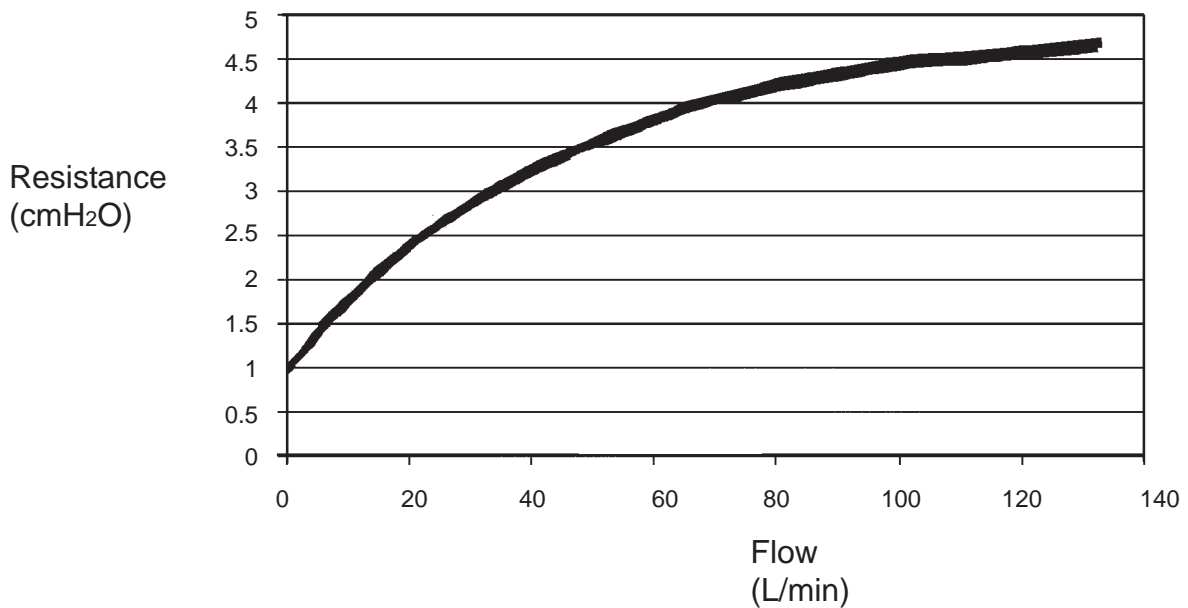
APPENDIX

Dual Wheatstone bridges control airflow measurement - one provides closed loop heater control, the other contains the dual sensing elements.

The heater circuit minimizes shift due to ambient temperature changes by providing an output proportional to mass flow. The circuit keeps the heater temperature at a constant differential (160°C) above ambient air temperature which is sensed by a heat-sunk resistor on the chip.

The ratiometric voltage output of the device corresponds to the differential voltage across the Wheatstone bridge circuit.

Sensor flow characteristics
The graph shown below is a typical flow versus resistance graph for the Honeywell spirometer head units for the flow range showing typical hysteresis between up and down flow measurements (and repeatability).

Resistance (cmH$_2$O)

Flow (L/min)

APPENDIX

APPENDIX 4
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.
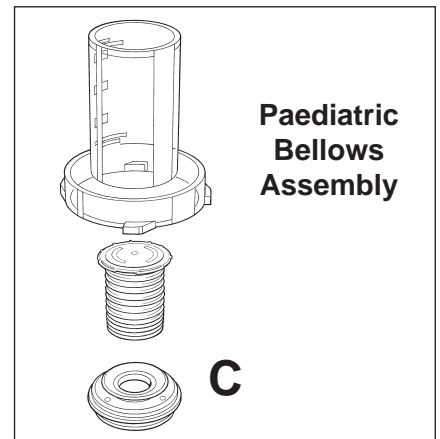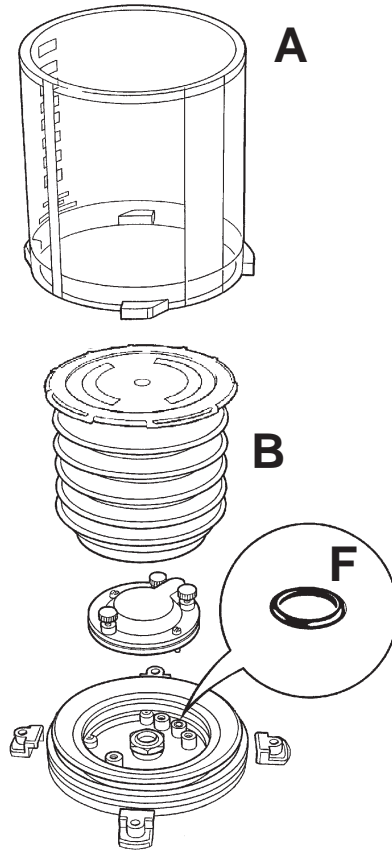
Bellows
As with all elastomers, the bellows material deteriorates with aging and should be inspected at least every six months or after 1200 hours of use, whichever comes first. The bellows must be replaced if it shows signs of aging.

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.

A

B

F

Paediatric Bellows Assembly

C

APPENDIX

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).

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 next page for information on sterilisation procedures.

Exhalation Diaphragm Valve Assembly

Refitting

Refit the diaphragm valve assembly to the bellows base and reassemble the bellows assembly
If a paediatric bellows is fitted, press the adaptor (C) into the ventilator bellows assembly base, then fit the bellows.
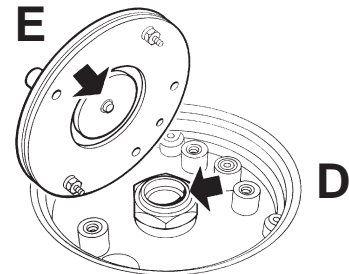
CAUTION
Always check for correct fitment of the bellows (see illustration), and function test the ventilator before clinical use.
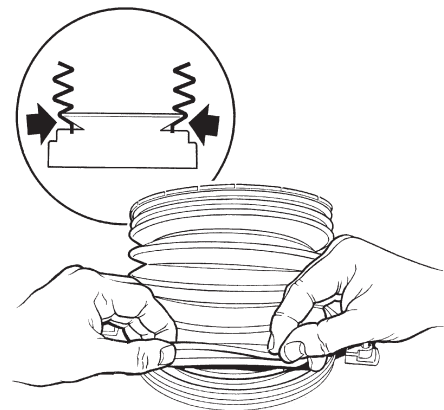
Spirometer Sensors

The sensors are built into the A200SP absorber, and cleaning and sterilisation can only be carried out when the absorber assembly is removed for cleaning.
For further information please refer to the user instructions supplied with the A200SP.

APPENDIX

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°C (275°F) for steam autoclave.

Low temperature autoclave is 121°C

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 - remove patient block
Patient Block	Autoclave
Bellows canister	Liquid, autoclave

Oxygen monitor (including sensor) - see section 6.4

NOTE
1.   Liquid method indicates the use of a high level disinfectant.
2.   Examples of suitable high level disinfection liquid agents are: Nu-Cidex, Sporicidin, and Sonacide.
3.   The exhalation diaphragm valve must be removed, cleaned and sterilised separately.

APPENDIX

Oxygen Monitor Sensor
- Cleaning / Disinfection / Sterilisation

In case of contamination the sensor may be cleaned with distilled water and allowed to dry naturally.

CAUTION
The sensor is not suitable for sterilisation by steam or exposure to chemicals such as ethylene oxide or hydrogen peroxide.
*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 (see section 5.1.8).
CAUTION
Replacement/Disposal - always follow the instructions supplied with the filter, and always replace at the recommended interval.
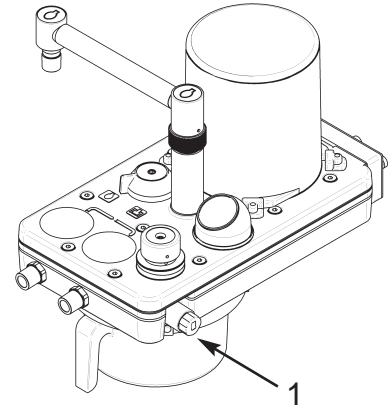
Oxygen Sensor Replacement

WARNING
The sensor (1) 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.

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.

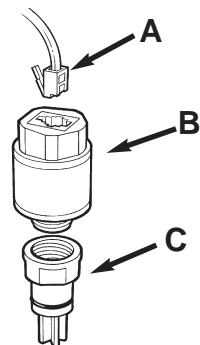| YR	0	1	2	3	4	5	X	7	8	9
MTH	J	F	M	A	M	J	J	A	S	O	N	X

Sensor Unit - Remove and Refit

Replacement parts

      102714   Sensor (includes flow diverter and O rings)

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.
7. Calibrate the new sensor, see section 5.
8. Dispose of the used components according to hospital regulations and relevant national legislation.

InterMed Penlon

$C\epsilon$