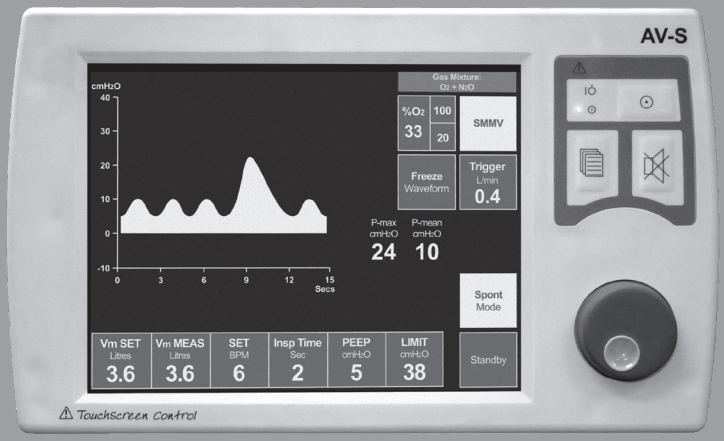
AV-S Ventilator

User Manual



This manual contains information for software upgrade v.1.87.01

DRE

USER DATASHEET

AV-S Ventilator User Manual

Software Version 1.87.01

Addendum to the User Manual

Introduction

AVS software V. 1.87.01 introduces a new user interface. However, if you are familiar with the AV-S, please note that the basic operation and calibration procedures remain as per v.1.86.

Modifications to the User Interface

Setting up the Ventilator for use

1. Introduction Screen

1.1 Start-up

At start-up, the introduction screen allows the user to select one of three default settings:

SITE DEFAULTS
ADULT DEFAULTS
PEDIATRIC DEFAULTS

NOTE
a) The user must select one of the above default groups before the ventilator will switch to standby in that default mode

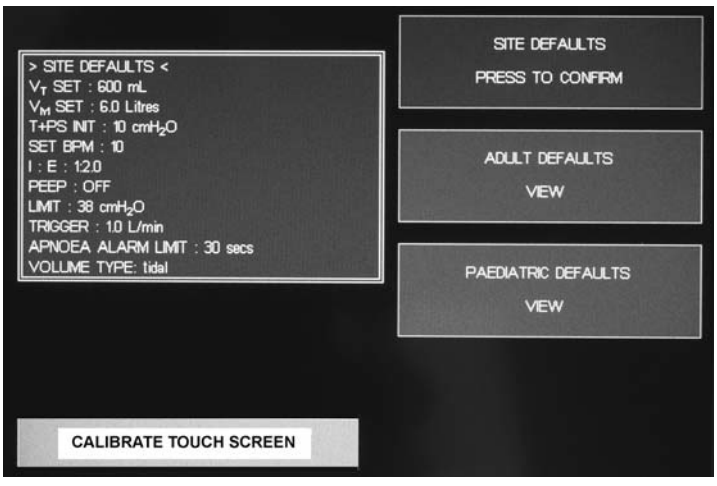
b) SITE DEFAULT is editable in standby mode (see section 1.2, below)

c) Settings can be saved via the service menu to create a new site default

1.2 Default Settings

1.2.1 Selection
The user can select ADULT, or PEDIATRIC, or SITE, and view the default parameter settings.
The options will remain, even after the ventilator is turned off.

1.2.2 Site Default Settings
Adjust the parameter values from within the Service menu (SITE DEFAULTS)
Press to confirm the new settings for site defaults.



1.3 Calibrate Touchscreen

The introduction screen allows the user to calibrate the screen

Keep this Datasheet with the User Instruction Manual for AV-S at all times

2. Parameter Display Identification

2.1 Active Parameters

Active parameters that can be set for use in the current mode are displayed as:

White Text on Blue

2.2 Inactive Parameters

Inactive parameters that can be set for any non-current mode are displayed as:

White Text on Blue Label

White values on Black

2.3 Measured Parameters

Yellow values on Black

2.4 T+PS INIT (target and pressure support initial value)

The initial pressure value can be changed so that when entering either PRESSURE or PSV modes the TARGET value or PSUPP value are pre-selected.

NOTE

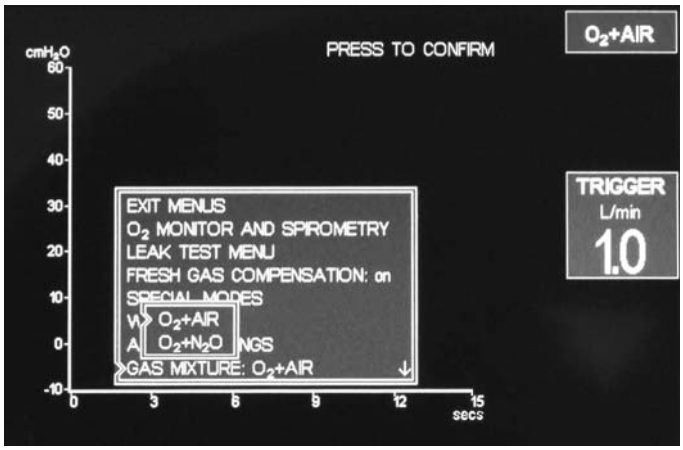
Changing either of these limits in their active modes will maintain the value when changing between PSV, PRESSURE, and STANDBY modes.

3. Gas Mixture

The Gas Mixture window is an active touch-selectable area (in any mode), with a drop down menu.

Gas Mixture is also available through the menu structure.

Selection of the required mixture is in the normal way with the scroll wheel.



Using the Ventilator - description of modes and functions

4. Modes

4.1 Access to Support Modes

Access is available in Standby mode (depending on the support mode options on the ventilator).

Support Mode

a) PSV

b) SIMV

c) SMMV

d) SIGH ENABLE

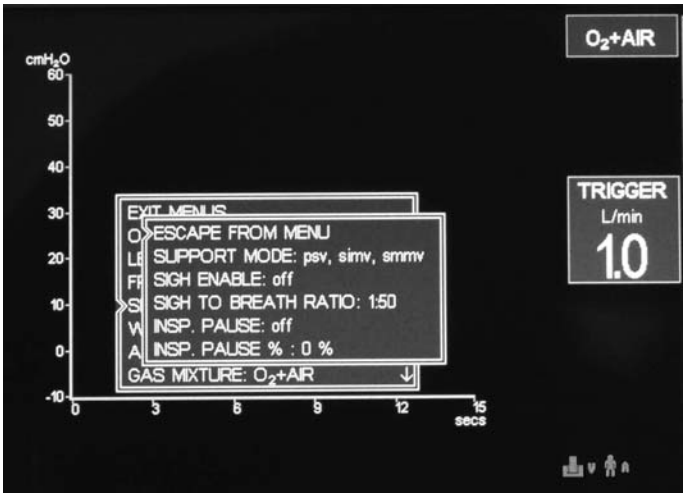
SIGH TO BREATH RATIO

e) INSP PAUSE

INSP PAUSE %

WARNING

Modes a, b, and c are only available when Spirometry is enabled.



4.2 Standby Mode

a) Standby mode at ventilator start-up:
The last used Volume mode settings will be displayed

b) Standby mode selected while the ventilator is in use:
The screen will display the previous ventilation mode, highlighted in yellow, within the relevant box. The last used parameters will also be displayed.

4.3 Spontaneous Mode

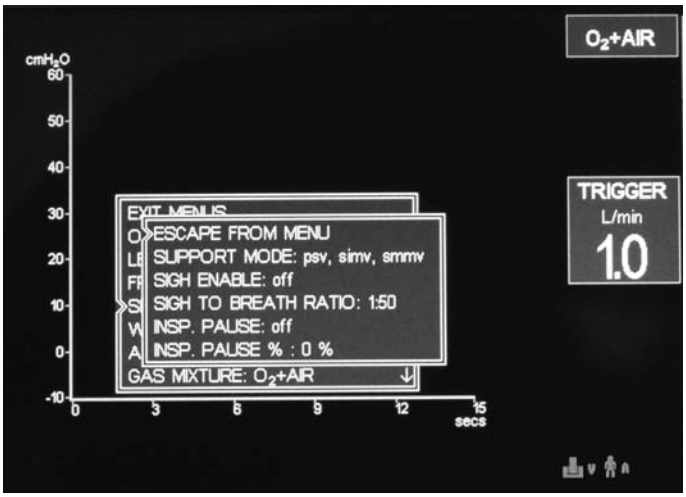
a) Spontaneous mode at ventilator start-up:
Default values will be displayed in white on a black background if the ventilator has just been powered ON.

b) Spontaneous mode selected while the ventilator is in use:
The last used ventilation mode (underlined) will be displayed, with the last used set values in white on a black background

4.4 Sigh

Sigh is settable from 1:n, where n has a range of 10 to 100.
The Sigh menu can also be accessed by touching the icon area of the screen.

NOTE
1:10 is one sigh to ten normal breaths.



4.5 Inspiratory Pause

Inspiratory pause can be varied in the menu from 0 - 60%.
The inspiratory pause menu can also be accessed by touching the icon area of the screen.

WARNING
This can affect the maximum Tidal Volume.

5. Apnoea Alarm Mute - Spontaneous mode only

NOTE
The occurrence of another alarm event will override this feature

In spontaneous mode the mute button acts both to silence an existing apnoea alarm and inhibit new apnoea alarms for a given period (provided that no other alarm events are present) .

This time period is selectable (choose from 15, 30, 60, 120, or 180 seconds) through the alarm settings menu, or accessed by touching the alarm area of the screen.

To adjust the default setting, use the SITE DEFAULT menu option.

6. Touchscreen Access to Mode Configuration Options

Touch the screen in the area containing the green icons to access mode configuration options (including INSP PAUSE, SIGH, and APNOEA ALARM mute/inhibit).

7. Waveform Pause and Print

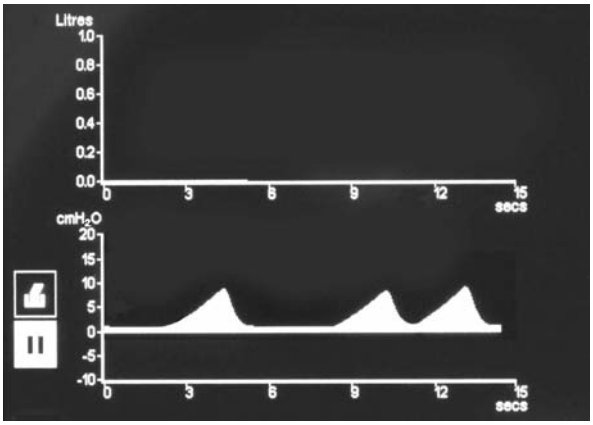
Waveform pause and print icons are located to the left hand side of the waveform displays.

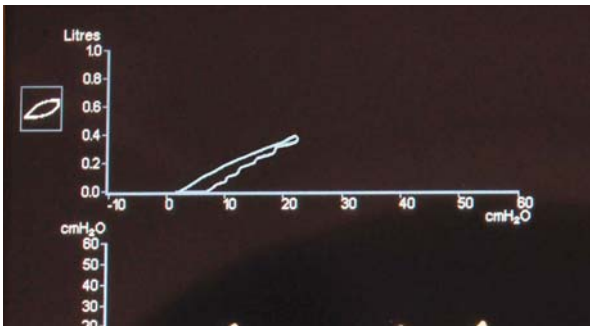
Ensure that a compatible printer is connected, and switched On (see section 5.1.8).

To print the waveform information, press the pause icon. The print icon will be displayed. Press the icon to print.
Press the pause icon to unfreeze the waveform.

8. Waveform Freeze Loop

The FREEZE LOOP icon is located at the left hand side of the top waveform.





9. Leak Test

a) Select LEAK TEST through the Menu in Standby Mode.

b) With the bag/vent switch in VENT position, this checks for a leak using an occluded breathing system

The leak test procedure is given in section 5.1.12 in the user manual.

Modifications to Operational Envelope
(sections 4.5 and 4.6 in user manual)

Flow Range:	2 – 70 Litres per min.
Volume Range:	20 ml – 1.6 Litres (tidal) 2 – 50 Litres per min (minute vol.)
Rate	4 – 100 bpm
I:E Ratio	1:0.2 – 1:8.0 (normal) 1:2.0 – 1:8.0 (effective in support modes)
Inspiratory Time	0.3 – 10 seconds (normal) 0.3 – 5 seconds (effective in support modes)
ExpiratoryTime	0.3 – 10 seconds (effective dependent on Inspiratory time)

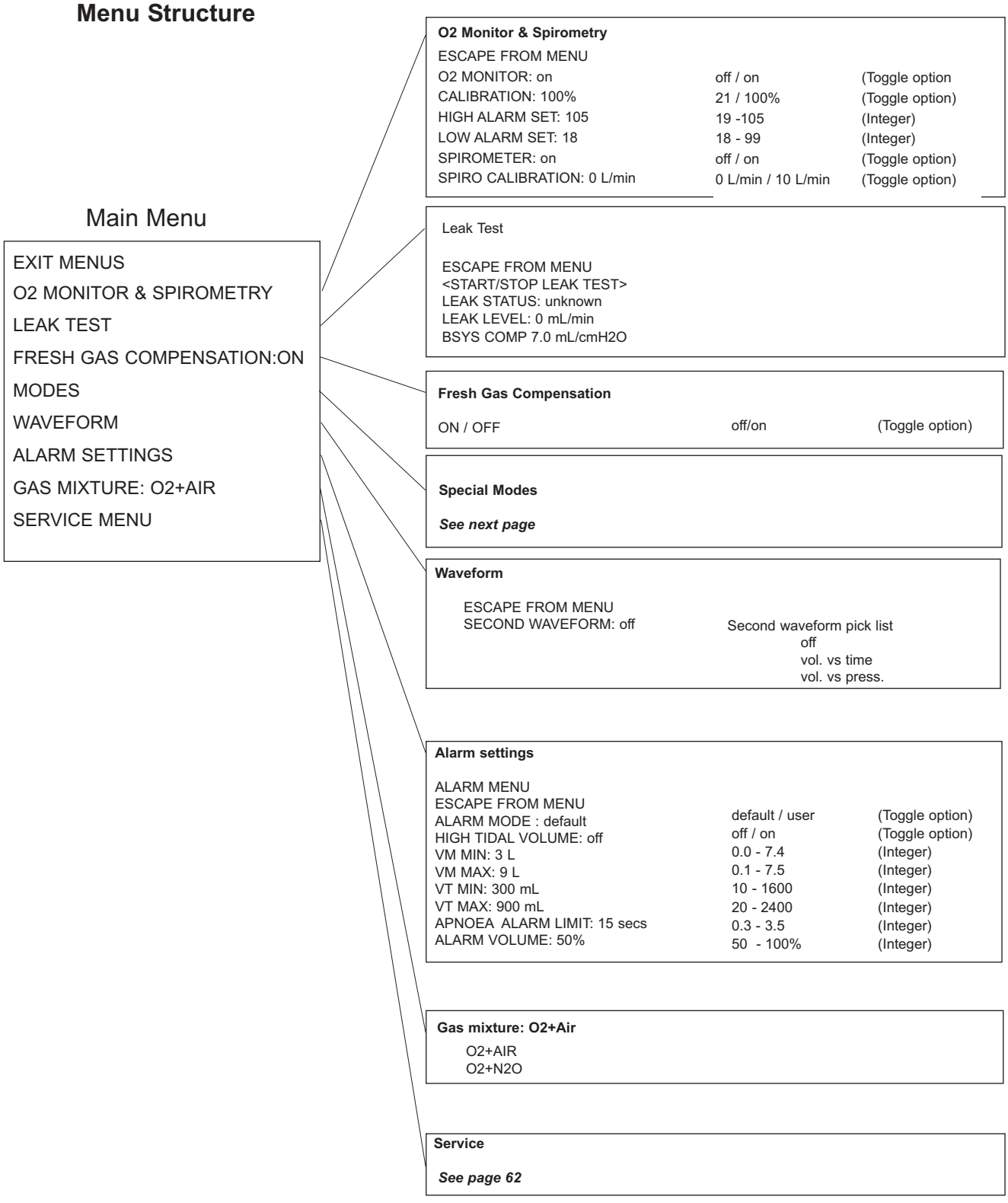
Additional information on Sigh and Inspiratory Pause
(section 3.7.2.4)

Inspiratory Pause
Inspiratory Pause has a range of 0 to 60% of the inspiratory time.

Sigh

This function must be enabled in the mode menu but is only operational in volume ventilation.
The sigh ratio is 1 to n (1:n) with n giving a range of 10 – 100 breaths between sighs.

Menu Structure



SPECIAL MODES MENU

ESCAPE FROM MENU

SUPPORT MODE: SIMV, SMMV, PSV

VOLUME TYPE: Tidal

SIGH ENABLE:

SIGH TO BREATH RATIO:

INSP. PAUSE% : 0%

APPLY: SITE DEFAULT

The SPECIAL MODES menu is context sensitive, with the contents dependent on current mode.

In STANDBY the SPECIAL MODES menu is:

ESCAPE FROM MENU
SUPPORT MODE: SIMV, SMMV, PSV (1)
VOLUME TYPE: Tidal
SIGH ENABLE: (2)
SIGH TO BREATH RATIO:
INSP. PAUSE% : 0%
APPLY: SITE DEFAULT

In SPONT mode and VOLUME mode, and SIMV/ SMMV, the SPECIAL MODES menu is:

ESCAPE FROM MENU
VOLUME TYPE: Tidal
SIGH ENABLE: (2)
SIGH TO BREATH RATIO:
INSP. PAUSE% : 0%

In PRESSURE mode and PSV modes the SPECIAL MODES menu is:

ESCAPE FROM MENU
SIGH ENABLE: (2)
SIGH TO BREATH RATIO:
INSP. PAUSE% : 0%

Notes

(1) Support mode depends on configuration options.
The SUPPORT MODE option will be missing from the SPECIAL MODE menu if:
a) Options are not enabled
b) ''SPIROMETRY: off'' is displayed.

The support mode sub menu can include:
none / PSV / SIMV / SMMV

(2) The options here are: 0 - 60%

(3) The options here are:
on - off
1:10 to 1:100

Note
1:10 indicates 1 breath with sigh, then 10 breaths without sigh

(2) The TRIGGER values are L/min with SPIROMETRY enabled, or cmH_2O when SPIROMETRY disabled.

Spirometry enabled	*Spirometry disabled*
0.7 L/min	*0.5 cmH_2O*
0.8 L/min	*0.6 cmH_2O*
0.9 L/min	*0.7 cmH_2O*
1.0 L/min	*0.8 cmH_2O*
1.5 L/min	*0.9 cmH_2O*
2.0 L/min	*1.0 cmH_2O*
2.5 L/min	*1.2 cmH_2O*
3.0 L/min	*1.5 cmH_2O*
3.5 L/min	*1.7 cmH_2O*
4.0 L/min	*2.0 cmH_2O*

SERVICE MENU

Service

ESCAPE FROM MENU
LANGUAGE: ENGLISH
PATIENT LOG MENU
SITE DEFAULTS
SERIAL MODE: none
ABSORBER SWITCH; ON
CLOCK MENU
UPGRADE MENU
AMBIENT PRESSURE: 988 mBar
DISPLAY HISTORY
*SERVICE PIN: 0
*ENGINEER MENU

PATIENT LOG MENU
ESCAPE FROM MENU
PRINT PATIENT DATA
LOGGING: off
LOG STATUS: disabled
CLEAR LOG DATA
LOGGING WINDOW: 10 min

SITE DEFAULTS

ESCAPE FROM MENU

SAVE TO SITE

VIEW: SITE DEFAULTS

VOLUME TYPE : tidal

Vt SET: 550 ml

Vm SET: 5.5 Litres

T+PS INIT: 10 cmH2O

SET BPM : 10

I : E : 1:1.0

PEEP : OFF
LIMIT : 38 cmH2O

TRIGGER : 10 L/min

APNOEA ALARM LIMIT : 15 Sec

BACK LIGHT LEVEL : 50 %

**NOTE*
Sub-menus for Service PIN and Engineer Menu are not accessible by users.

CLOCK MENU

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

UPGRADE MENU

ESCAPE FROM MENU
I/O HARDWARE: 2
I/O FIRMWARE: vx.xx [Build xx]
MAIN FIRMWARE: vx.xx [Build xx]
REGISTRATION KEY: unknown
UPGRADE FIRMWARE: unavailable
ADD NEW FEATURE: unavailable

DISPLAY HISTORY

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

Doc No. AVS 0408DS (U)
September 2008
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Fax: (502) 244-0369
Web: www.dremed.com

IMPORTANT

Servicing and Repairs

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

The ventilator must be serviced to the following schedule:

(a) Six monthly service - inspection and function testing.
(b) Annual / two year / four year service - inspection and function testing, and component replacement.

Details of these operations are given in the Service Manual for the AV-S, available only for engineers trained by the manufacturer.

For any enquiry regarding the servicing or repair of this product, contact DRE, Inc.

Technical Support
DRE, Inc.
1800 Williamson Court
Louisville, KY 40223
USA

Tel: (502) 244-4444
Fax: (502) 244-0369
Web: www.dremed.com

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 authorized personnel with information on the function, routine performance and maintenance checks applicable to the AV-S Anesthesia Ventilator.

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

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

The Importance of Patient Monitoring

WARNING
Anesthetic 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 anesthetist.

There can be considerable variation in the effect of anesthetic drugs on individual patients so that the setting and observation of control levels on the anesthesia systems does not in itself ensure total patient safety. Anesthesia system monitors and patient monitors are very desirable aids for the anesthetist 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.

Before using any monitoring system or device, the user must check that it conforms to the relevant standard, as listed in the table below.

Parameter / Device	Relevant Standard
Pressure Measuring	ISO 8835-2
Pressure Limitation Device	EN 60601-2-13:2006 - 51.101.1
Exhaled Volume Monitor	EN 60601-2-13:2006 - 51.101.4
Breathing System Integrity Alarm System	EN 60601-2-13:2006 - 51.101.5
Continuing Pressure Alarm	EN 60601-2-13:2006 - 51.101.6
Oxygen Monitor	ISO 7767
Carbon Dioxide Monitor	ISO 9918
Breathing Circuit	ISO 8835-2
Agent Monitor	ISO 11196
Gas Scavenging	ISO 8835-3

For information on installing and connection of any of these systems or devices, please refer to the relevant manufacturer's instructions.

CONTENTS

CONTENTS

USER RESPONSIBILITY

This anesthesia 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 DRE, Inc.

This device and any of its constituent parts must be repaired only in accordance with written instructions issued by the manufacturer and must not be altered or modified in any way without the written approval of the manufacturer. 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 the manufacturer.

USA and Canada:
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 AV-S ventilator is used clinically for the first time a Calibration Check and Output Check must be successfully completed.***

   Calibration and output checks must be carried out by a DRE-trained technician, following the procedure in Appendix 6 in the AV-S Service Manual.

3. ***Before the ventilator is used clinically for the first time, verify that the hospital engineering department has carried out an earth continuity test.***
   If the integrity of the protective conductor is in doubt, the ventilator must not be used.

4. ***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.

5. ***If used with a mains extension cord, the unit may be subject to electro-magnetic interference.***

6. ***The driving gas supply must be clean and dry to prevent ventilator malfunction.***

7. ***This ventilator is designed to be driven by oxygen or medical air only. The drive gas is set during manufacture and the ventilator is calibrated for that gas.***

   Before the ventilator is used clinically for the first time, the commissioning engineer must confirm that the air/oxygen selection is set correctly for the drive 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.

8. ***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.

9. ***The bellows can only support approximately 1 kPa (10 cmH_2O) 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.

10. ***Breathing System***

    The breathing system which conveys gases from the anesthetic 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 anesthetic ventilator and therefore cannot be directly under the control of the anesthetic ventilator manufacturer.
    However, we strongly recommend that only breathing systems which have been approved and authorized by the manufacturer 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.

WARNINGS AND CAUTIONS

11. *The spirometer sensors are mounted within the A200SP absorber. Do not fit a spirometer sensor to any other location.*
The device will not measure exhaled volumes in any other position.

12. *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 authorized service technician.

13. *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 Safelock fittings are used throughout the breathing circuit.

14. *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.

Using the Ventilator

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

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

17. *Anesthesia apparatus must be connected to an anesthetic 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.

18. *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.*

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

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

21. *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*

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

23. *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.

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

WARNINGS AND CAUTIONS

25. 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.

26. 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.

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

User Maintenance

28. User maintenance is restricted to cleaning the outside surfaces of the ventilator, see section 6. Other procedures detailed in this manual must be carried out by trained technicians.

Service and repair operations must only be carried out by an engineer trained by the manufacturer. The warranty for this product is void if the product is not maintained in accordance with the service schedule detailed in section 6.1, and the procedures published in the Service Manual for this product.

Control Unit

29. Opening the control unit by unauthorized 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.

30. For continued protection against fire hazards, any replacement fuses must be the identical type and rating as the original components. Replacement must be carried out by trained technician. See section 4 for fuse rating.

31. 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.

32. 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.

33. Exterior panels must not be removed by unauthorized personnel and the apparatus must not be operated with such panels missing. There is a possible electric shock hazard.

Bellows Assembly

34. The valve seat on the patient gas exhalation diaphragm valve in the base of the bellows assembly must be cleaned regularly. Note that the bellows assembly is built into the A200SP Absorber - please refer to User Manual for this product. 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 sterilize the ventilator control unit. The patient block assembly must be removed from the control unit before sterilization (see section 6.2.5). All other internal components are not compatible with sterilization techniques and damage may result.*

2. *For ventilator components which require sterilization, peak sterilization temperatures should not exceed 134^{O}C (275^{O}F) to prevent possible damage. (See section 6).*

3. *Care must be taken not to let any liquid run into the control unit; serious damage may result.*

4. *The exhalation valve located in the bellows base assembly and the pediatric bellows adaptor must be cleaned and sterilized separately. Note that the bellows assembly is built into the A200SP Absorber - please refer to User Manual for this product.*

5. *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. Note that the bellows assembly is built into the A200SP Absorber - please refer to User Manual for this product.*

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

Note that the sensor for the oxygen monitor is built into the A200SP Absorber - for additional information, please refer to the A200SP User Manual.

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.

6. ***The oxygen sensor is not suitable for sterilization.***
   If contamination is suspected, fit a new sensor (see section 6.4) and dispose of the contaminated unit according to hospital, local, state and federal regulations.

CAUTIONS

1. *Do not sterilize any oxygen monitor component.*

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 anesthetic 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 pediatric patients under general anesthesia.
In addition, in spontaneous mode, it can be used to monitor spontaneously breathing patients
It is designed for use in closed-circuit anesthesia.

Indications for use of the device:

The AV-S Ventilator is intended to provide continuous mechanical ventilatory support during anesthesia. 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 pediatric patients.
The ventilator is intended for use by health care providers, i.e. Physicians, Nurses and Technicians with patients during general anesthesia.
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 anesthesia, and is intended for adult and pediatric 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 anesthesia.

3. DESCRIPTION

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 patient support -
SIMV, SMMV, PSV, PEEP

Spontaneous Mode Patient Support
SIMV - Synchronised Intermittent Mandatory Ventilation
SMMV - Synchronised Mandatory Minute Ventilation
PSV - Pressure Supported Ventilation
PEEP - Positive End Expiratory Pressure

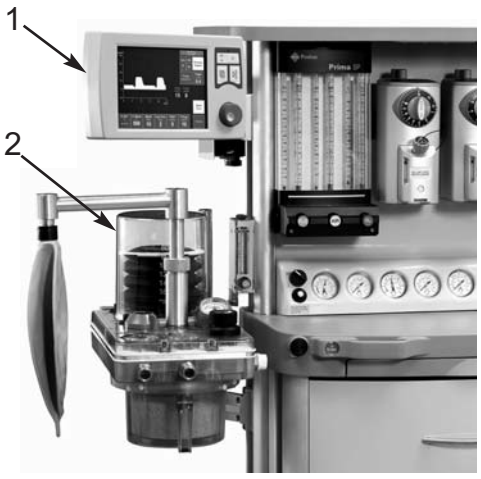
Patient Monitoring
Airway pressure, measured from the expiratory limb of the breathing circuit.

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.

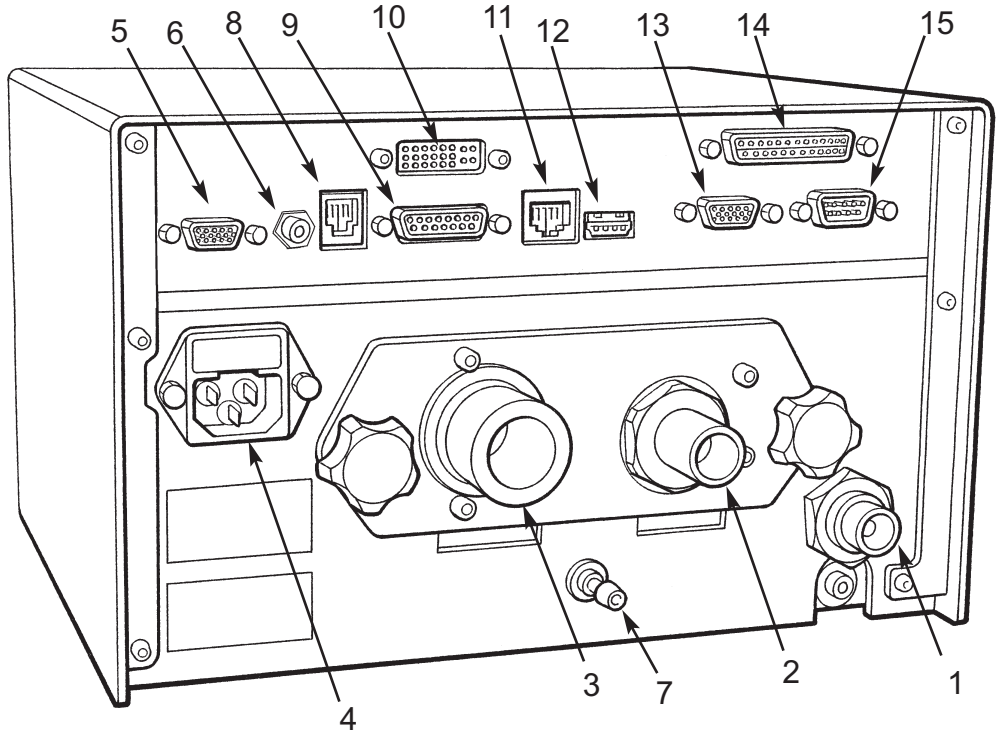
Screen
210 mm (8.4 inch) high definition, colour TFT screen, with single/dual waveform display.
Mounting:
Remote, arm-mounted as illustrated (1) or optional combined control unit / screen (see section 5.1.1).



Bellows unit
The bellows unit (2) is built into the A200SP absorber. A pediatric bellows assembly is available as an option

Drive gas supply
The drive gas supply can be oxygen or air.
The supply must be at 310 to 689 kPa (45 to 100 psi). Note that the drive gas is specified by the customer, and set during manufacture. Conversion from one drive gas to another must only be carried out by an authorized service engineer trained by the manufacturer.

DESCRIPTION



Control Unit Rear Panel

Gas Connections

1. Ventilator drive gas inlet
   - connect to anesthetic machine auxiliary gas outlet
2. Bellows Drive Gas Output
   - connect to bellows via A200SP absorber - see section 5.1.5
3. Outlet - Exhaust Valve
   - connect to scavenge system - see section 5.1.6

Electrical Connection

4. Electrical mains input and fuse unit

Interface and Parameter inputs

5. A200SP Absorber Bag/Vent switch interface, and Spirometer connector
6. Integra AV-S Interface connector - (primary on/off switch)
7. Pressure Monitor Port
8. Input socket - Oxygen monitor sensor

Data and Printer Ports

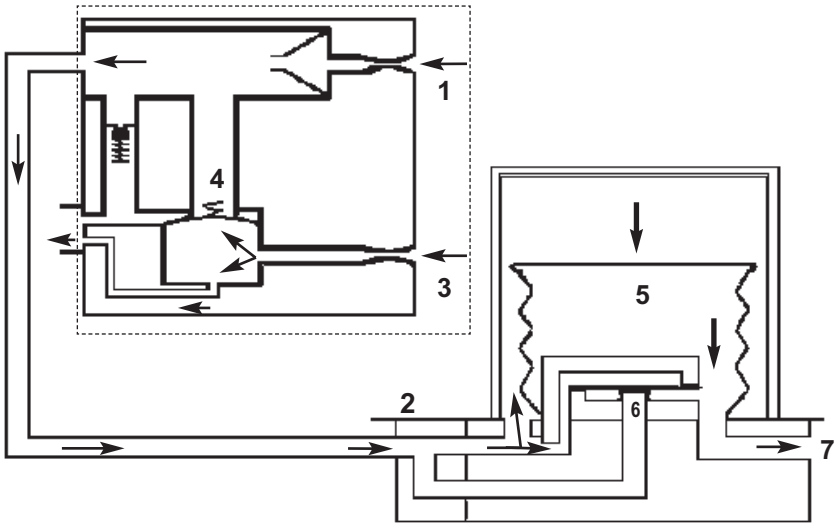
9. Data Output
10. Output to remote display
11. Ethernet
12. USB
13. VGA
14. Printer port
15. RS232 (manufacturer's use only)

NOTE
USB port is for access only by engineers trained by the manufacturer.
All other data ports are read only.
For further information, please contact your distributor's service department, or the manufacturer.

DESCRIPTION

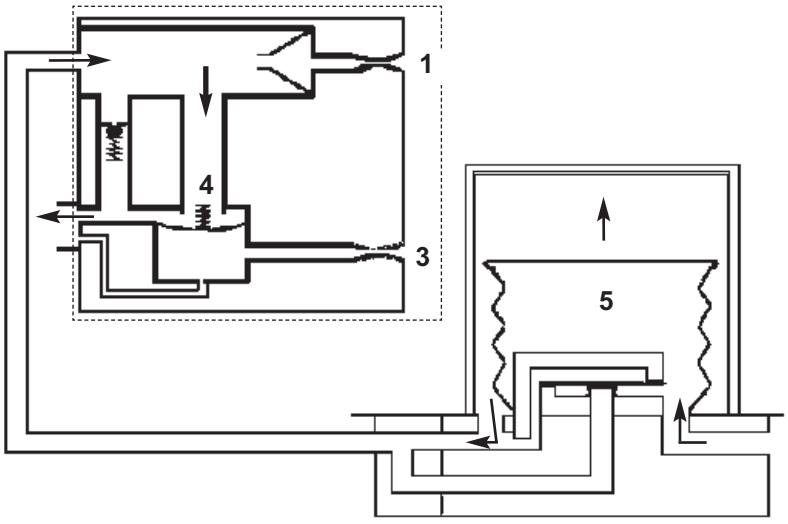
3.2 Ventilation Cycle

This section provides a simplified description of the ventilation cycle.



1. Inspiratory Phase

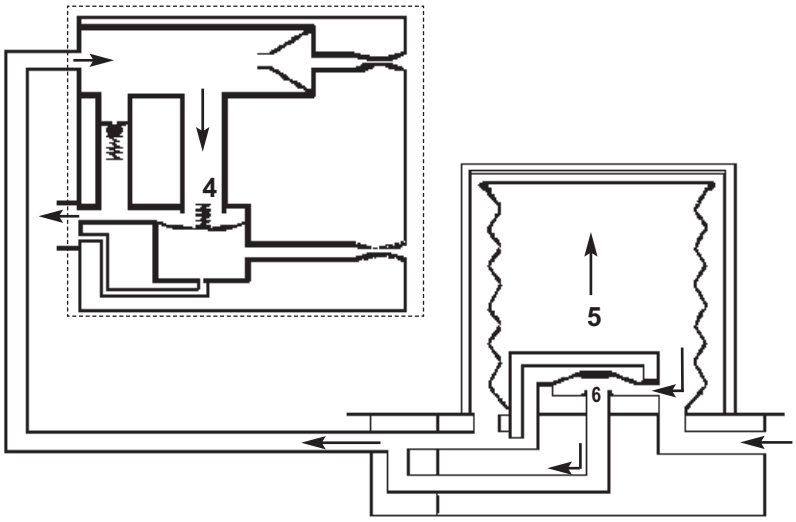
The drive gas proportional valve (1) in the control unit opens.
Drive gas is delivered to the bellows housing (2).
The patient proportional valve (3) opens, and gas flows through the bleed valve. The back pressure ensures that the exhaust valve (4) is kept closed.
Drive gas pressure builds up above the bellows (5), which starts to move down.
The diaphragm (6) in the bellows assembly base is held closed, and patient gas is forced out of the bellows base (7) into the breathing system.



2. Beginning of Expiratory Phase

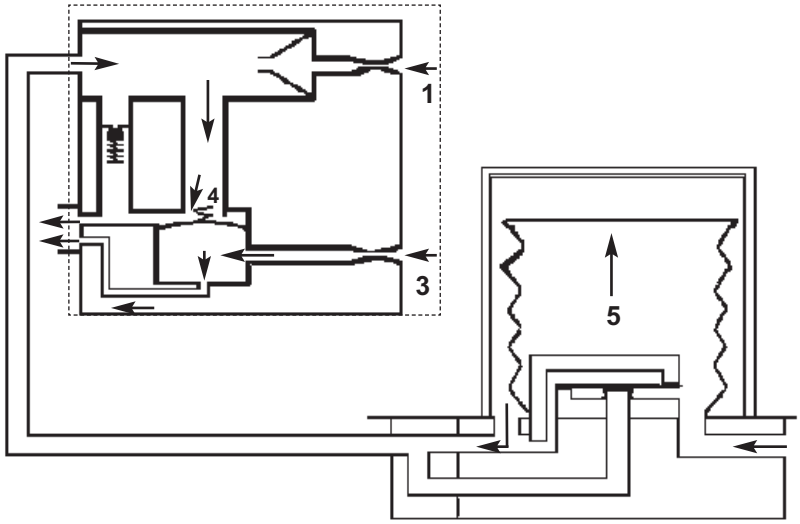
The drive gas proportional valve (1) closes.
The patient proportional valve (3) closes.
The exhaust valve (4) opens.
Patient gas returns to the bellows (5).
As the bellows rises, redundant drive gas is pushed out through the exhaust valve.

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 (6) lifts and allows gas to exit through the exhaust valve (4).

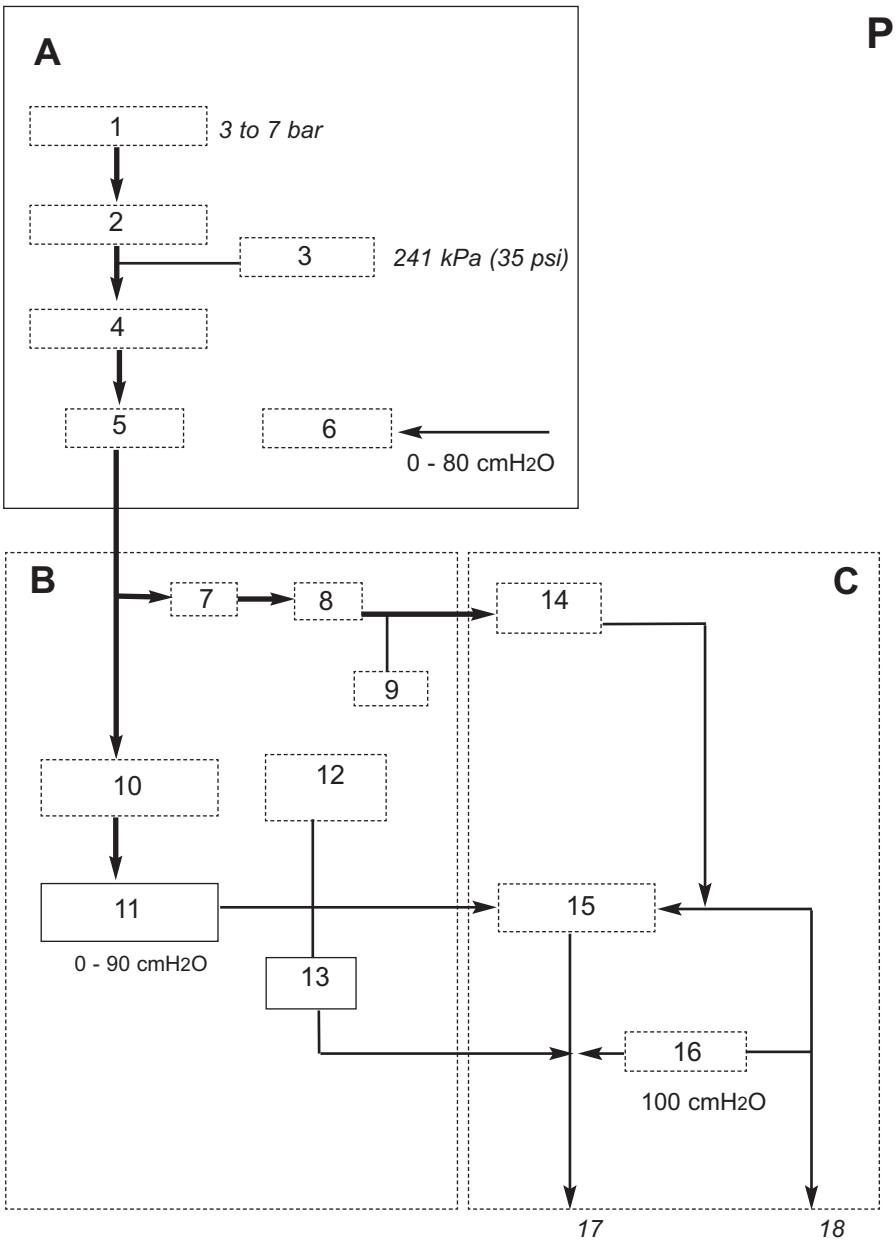


4. PEEP Positive End Expiratory Pressure (user selectable)

The patient 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 (5) will cause gas to bleed past the exhaust valve (4).
If there is a fall in pressure in the breathing circuit, the continuous flow from the drive gas proportional valve (1) helps maintain the set PEEP pressure.

DESCRIPTION

Pneumatic Flow Diagram



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. Drive Gas Proportional Valve
8. Drive Gas Flow Sensor
9. Drive Gas Pressure Sensor
10. Low Pressure Regulator
11. Patient 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_2O
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 the following mains voltage supplies:

100 to 120 VAC, 50 to 60 Hz

200 to 240 VAC, 50 to 60 Hz

Note that the ventilator adjusts automatically to the supply voltage range.

The connector is a standard IEC type.

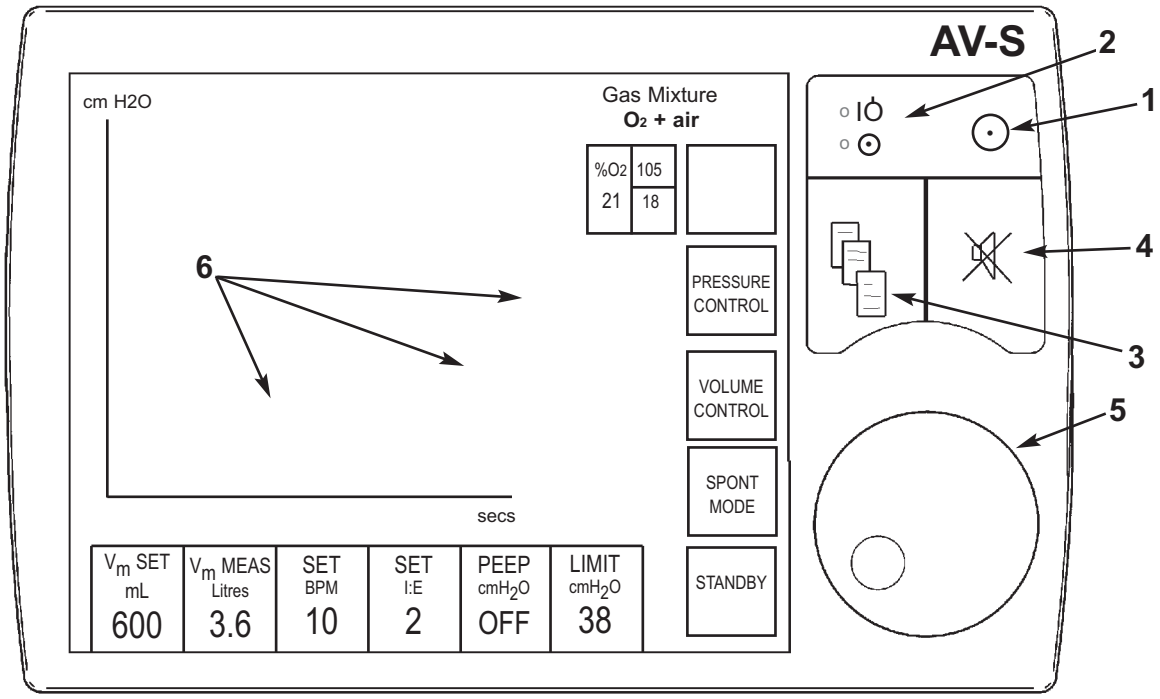
Back-up Battery
In the event of mains electrical failure, the back-up battery cuts in automatically.

Standard battery:
A fully charged battery will power the ventilator for approximately 30 minutes.

High-power battery (option):
A fully charged battery will power the ventilator for approximately one hour.

See Appendix for battery care procedures.

DESCRIPTION



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: Power down sequence with progress indicator

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, including alarm settings.

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.

6. **Active Tabs**
   Touch the screen at the appropriate tab area to activate the required function/parameter.

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.

3.5.2 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.

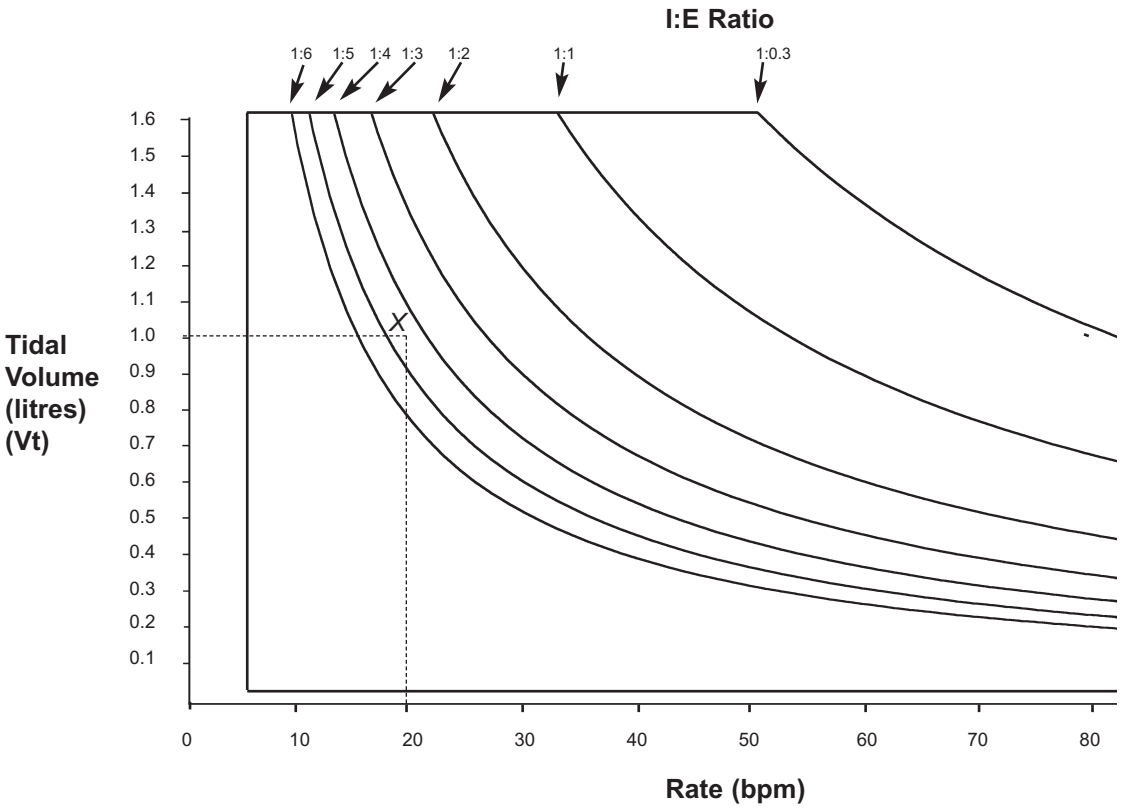
Tidal Volume Range	20-1600 ml
Rate	4-100 bpm
I:E Ratio	1:0.3 to 1:8
PEEP	4-20 cmH2O Can be set to OFF
Pressure Limit	
Volume mode:	10-80 cmH2O
Pressure mode:	10-50 cmH2O

Alarm limits (user adjustable alarms only - see 3.11)

DESCRIPTION

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, and a minimum flow of 2 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 = 1.0 L

2. Select rate = 20 bpm

In this example, the point of intersection X on the graph shows that an I:E ratio can be set from 1:0.3 to 1:4, as these curves are all above the intersection point.

Similarly, a ratio of 1:5 cannot be set, as this is below the intersection point.

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%
An alarm is triggered if the measured volume varies by 50% from the set volume.
This function is 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.

Compliance compensation

The ventilator will apply compliance compensation to account for compliance loss in the breathing system in cases where:

i) Fresh gas compensation is disabled, or

ii) Spirometry is unavailable or disabled

IMPORTANT
For correct operation the value of the breathing system compliance must be established first, by completing the ventilator leak-test as part of the Pre-operation Procedure.
Refer to section 5.1.12, noting that breathing system compliance is displayed as 'Bsys.comp'

If the leak test is not carried out, the default value will be used.

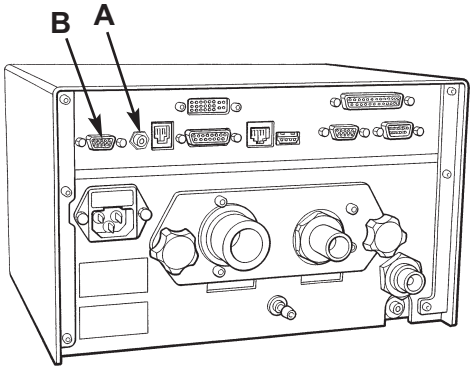
NOTE
In compliance compensation mode any fresh gas used will be in addition to the set tidal volume.

Altitude Compensation
This function monitors ambient pressure, and adjusts the delivered volume accordingly
NOTE Altitude compensation is automatically applied during calibration of the oxygen monitor - see section 5.3.2.

DESCRIPTION

3.6 Interface to Integra AV-S and A200SP Absorber

The AV-S is designed to interface with the Integra AV-S Anesthetia Machine and the A200SP Absorber.



3.6.1 Integra AV-S Interface

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

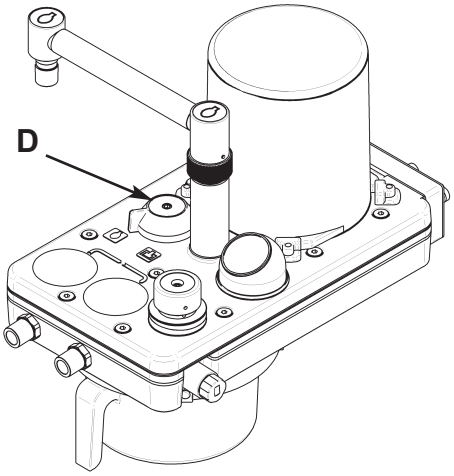
a) Turn the anesthetic machine Gas Delivery Switch to ON. The ventilator will power-up.

b) While the anesthetic machine 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 anesthetic machine 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.



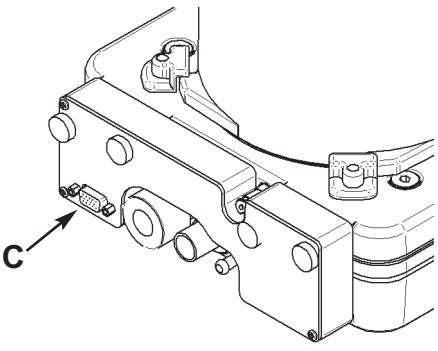
a) The A200SP is fitted with a sensor that detects the position of the absorber bag/vent control (D). The sensor signal cabling is routed internally to connector (C), and a second cable runs to the the rear of the AV-S control unit.

b) Operation of the Bag/Vent control will trigger automatic Mode switching on the AV-S ventilator, as follows:

i) Ventilator in Volume or Pressure mode

Switching the absorber Bag/Vent control from Vent to Bag

- the ventilator will change from Volume Mode, or Pressure Mode, into Spontaneous Mode.



ii) Ventilator in Spontaneous Mode

Switching the absorber Bag/Vent control from Bag to Vent

Note that the mode switching operation is dependant on the original selection process used to reach Spontaneous Mode:

A) If the ventilator was previously in Volume, or Pressure, or Special Mode, and Spontaneous Mode was automatically selected by the operation of the bag/vent control (from Vent to Bag, as described above):

- the ventilator will now revert to that previous mode.

B) If the ventilator was in Standby Mode, and Spontaneous Mode was selected on-screen:

- the ventilator will revert to Volume Mode.

NOTE

a) operation of the absorber Bag/Vent control will have no effect on the ventilator unless the above conditions are met.

b) This function can be enabled/disabled through the on-screen 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:

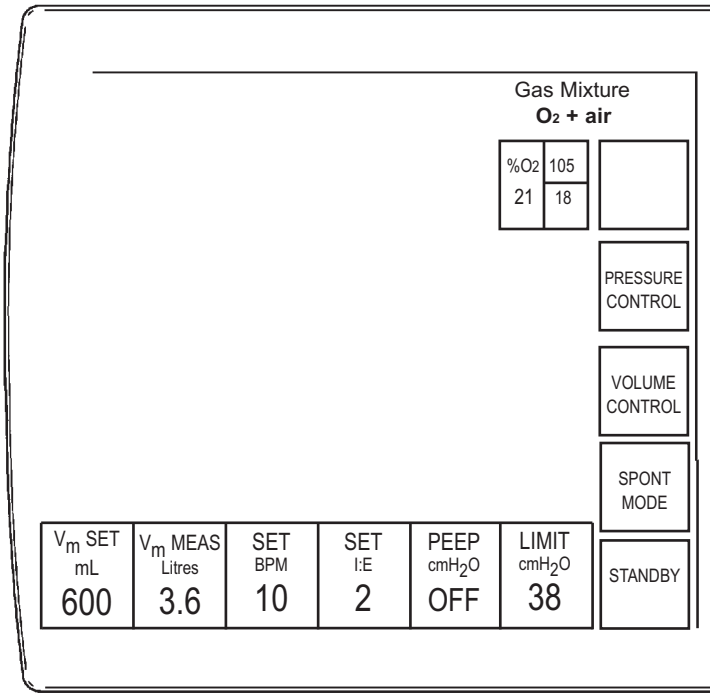
High airway pressure
(at 80 cmH_2O)

High/Low Oxygen

Negative pressure

Incorrect Rate/Ratio

Continuous high pressure



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

The delivered volume is adjusted by up to 60%.
This delivered volume will consist of the volume delivered from the ventilator bellows, plus the fresh gas flow from the anesthetic 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 the measured volume is 50% above or below the set volume.

This function is user adjustable.

Compliance Compensation
Please refer to section 3.5.4

Altitude Compensation
This function monitors ambient pressure, and adjusts the delivered volume accordingly.

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 -20 cmH_2O
Inspiratory pressure limit	10 to 100 cmH_2O
Inspiratory pause (does not affect I:E ratio)	25%
Sigh	Approximately 1.5 x Set Vt is delivered once, twice, three times or four times every 50 breaths (user selects frequency)

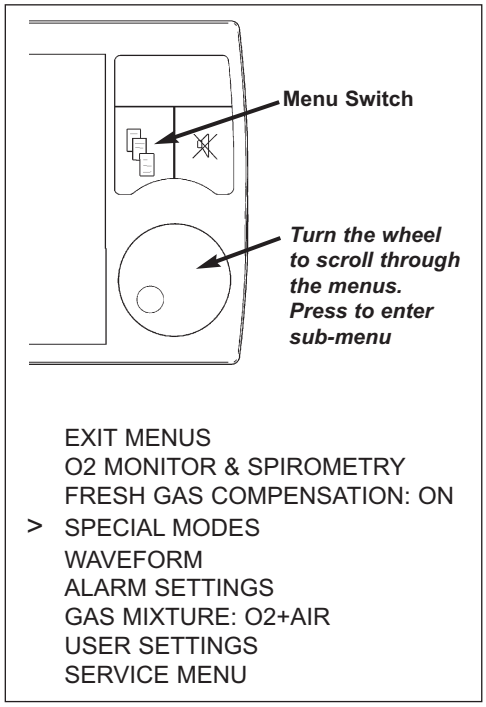
3.7.2.2 Select Volume Mode

Volume Mode selected from Standby Mode:

1. Press the screen tab: 'VOLUME CONTROL'

Volume Mode selected from Pressure Mode:

1. Press the screen tab: 'VOLUME CONTROL' The ventilator continues to ventilate in Pressure Mode.
2. The Volume Set display shows the previous setting, or default setting.
3. A new Volume value can be set if required.
   WARNING
   Set appropriate values for the clinical procedure in progress. Take note of all on-screen symbols and display messages.
4. Press to confirm change of mode and new setting.
   NOTE
   Pressure limit will default to the previous Pressure Target value + 5 cmH2O
5. At confirmation, the ventilator will switch to Volume Mode.
   NOTE
   Volume Mode will commence at the beginning of an exhalation 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.

3.7.2.4 Volume Mode Operating Functions

Inspiratory Pause function:

This function creates a plateau that equates to 25% of the inspiratory time.

Select Inspiratory Pause

Press the Menu switch
Select Special Modes
Select Insp pause on/off
Exit menus

The symbol for Inspiratory Pause will appear on the display:

Note that Inspiratory Pause function is cancelled when Standby is selected

DESCRIPTION

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 (the user can select 1, 2, 3, or 4 breaths).
The extra volume will be approximately 50% above the tidal volume set by the user.
Note that the High Volume Alarm is not triggered when 'Sigh' is selected.

Select Sigh function:

Press the Menu switch
Select Special Modes
Select Sigh Enable on/off
Select Sigh to Breath Ratio
Rotate the wheel to select required value
Press wheel to confirm
Exit menus

The legend for Sigh will appear on the display: **SIGH**

Note that sigh function is cancelled when Standby is selected

Volume measurement:
Volumes are measured if the Spirometry function is selected.

Automatic High or Low volume alarms are triggered if the measured volume is 50% above or below the set volume.

User adjustable option
If the maximum pressure limit is achieved, the ventilator cycles to the expiratory phase.

3.7.3 Pressure Mode

3.7.3.1 Parameters

In pressure mode the ventilator delivers a flow of gas to achieve a set pressure at fixed breath intervals.

The Patient is making no respiratory effort.

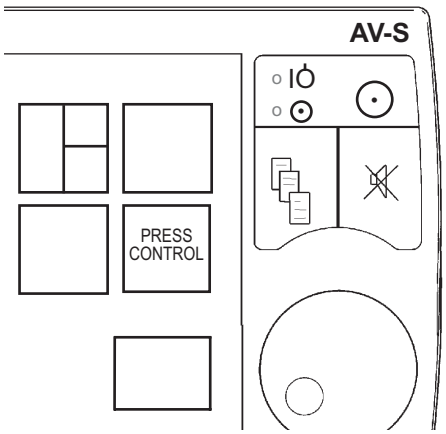
This is a common mode for the ventilation of small pediatric patients.

Inspiratory pressure	10 - 70 cmH_2O
Rate	4 - 100 bpm
I:E ratio	1:0.3 - 1:8
PEEP 'Off' or adjustable:	4 - 20 cmH_2O

Inspiratory decelerating flow is controlled by the ventilator according to the pressure setting.

There is no Inspiratory Pause function in pressure mode.

3.7.3.2 Selecting Pressure Mode



Pressure Mode selected from Standby Mode:

1. Select by touching the screen tab: 'PRESS CONTROL'.

Pressure Mode selected from Volume Mode:

1. Select by touching the screen tab: 'PRESS CONTROL'. The ventilator continues to ventilate in Volume Mode.
2. The target pressure button flashes (the display shows the previous setting of target pressure, or default setting).
3. The user can set a new Target Pressure if required.
   WARNING
   Set appropriate values for the clinical procedure in progress. Take note of all on-screen symbols and display messages.
4. Press to confirm change of mode and new target pressure.
5. At confirmation of the new mode, the ventilator will switch to Pressure Mode.
   NOTE
   Pressure Mode will commence at the beginning of an exhalation phase.

3.7.3.3 Pressure Mode Operating Functions

Pressure mode defaults to a target pressure of 10 cmH_2O at switch on.

A high Inspiratory Flow is used to achieve and maintain the target pressure.

The exhaust valve operates to prevent excess pressure.

3.7.4 Spontaneous Mode

3.7.4.1 Parameters

The ventilator monitors the following patient parameters:

Rate

I:E ratio

Pressure

Tidal volume

In spontaneous mode the waveform displays are active, and inspiratory oxygen levels are measured

3.7.4.2 Spontaneous Mode Operating Functions

Selection during Ventilation

Move the absorber Bag/vent switch to 'Bag' - the ventilator will switch from Pressure Mode or Volume Mode to Spontaneous Mode (see 3.6.2 - Absorber Interface).

Functions

No mechanical ventilation
No Inspiratory Pause function

Patient Monitoring (Bag mode and Ventilator mode):
Airway pressures
FiO2,
Tidal volume,
Rate
I:E ratio,
Supply pressures

Advanced Ventilation Modes

Patient support modes are selectable from this mode - see below, and section 3.7.5.

3.7.4.3 Patient Support Modes

The following support modes are selectable from the 'Special Modes' menu, and must be pre-selected from the main menu, whilst in Standby.

SIMV - Synchronised Intermittent Mandatory Ventilation

SMMV - Synchronised Mandatory Minute Ventilation

PSV - Pressure Supported Ventilation

CAUTION

The required patient support mode must be pre-selected in ***Standby Mode*** *(select from main menu), before it can be activated during the ventilation of a patient.*

Please refer to sections **3.7.5.1, 3.7.5.2, 3.7.5.3.**

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

3.7.5 Advanced Spontaneous Breathing Modes

3.7.5.1 SIMV Synchronised Intermittent Mandatory Ventilation

SIMV provides a minimum level of tidal volume.

SIMV allows spontaneous breaths and a set mandatory breath, synchronised with the start of a patient breath

SIMV must be pre-selected in Standby Mode
Select Standby
Select Menu
Select Special Modes
Select Support Mode
Select SIMV
Escape Menu

SIMV will be displayed on the main screen when Spontaneous mode is selected or triggered.

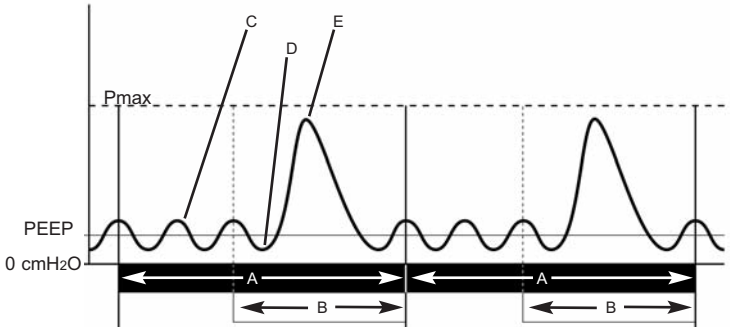
NOTE
1. *The trigger window is pre-set to 60% of the BPM cycle time.*
2. *The trigger is flow activated.*
3. *If Spirometry is disabled then SIMV is not available*
4. *If the pressure limit and alarm are activated the inspiratory phase is terminated*

Activate SIMV during Ventilation
NOTE
SIMV will not function unless already pre-selected in Standby Mode

1. Select 'Special Mode' on the display. If the absorber Bag/Vent switch is not detected, a message will appear: 'SET ABSORBER TO VENT' Press the navigator wheel / push button to confirm.
2. Move the absorber Bag/vent switch to 'Ventilator'.
3. Check that SIMV is functioning correctly.

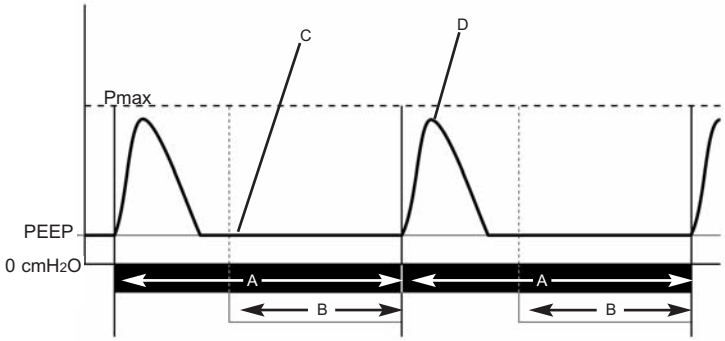
SIMV Default Settings
The ventilator will default to pre-set values for Tidal volume (Vt), Rate, Inspiratory Time and Trigger Level, after selecting 'SIMV'.

Note:
1. Vt can be adjusted before SIMV is confirmed.
2. The trigger setting is adjustable between 0.7 and 4.0 L/min.



SIMV - Spontaneously Breathing Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Spontaneous Breath
D = Trigger
E = Mandatory breath at the set tidal volume (Vt)

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 - 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

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.

DESCRIPTION

3.7.5.2 SMMV Synchronised Mandatory Minute Ventilation

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

SMMV must be pre-selected in Standby Mode
Select Standby
Select Menu
Select Special Modes
Select Support Mode
Select SMMV
Escape Menu

SMMV will now be displayed on the main screen when Spontaneous mode is selected or triggered.

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

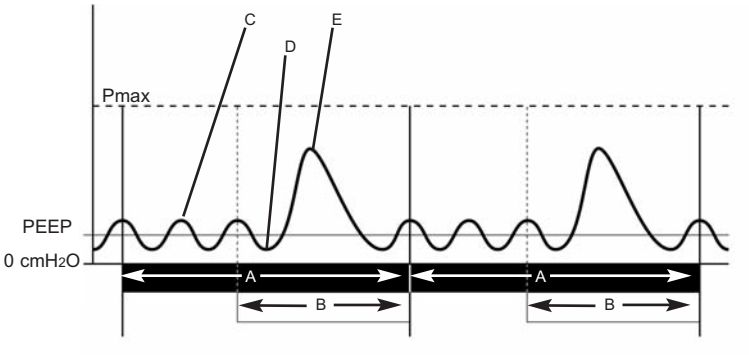
Activate SMMV during Ventilation
NOTE
SMMV will not function unless already pre-selected in Standby Mode

1. Select 'Special Mode' on the display. If the absorber Bag/Vent switch is not detected, a message will appear:
   'SET ABSORBER TO VENT'
   Press the navigator wheel / push button to confirm.
2. Move the absorber Bag/vent switch to 'Ventilator'.
3. Check that SMMV is functioning correctly.

SMMV Default Settings

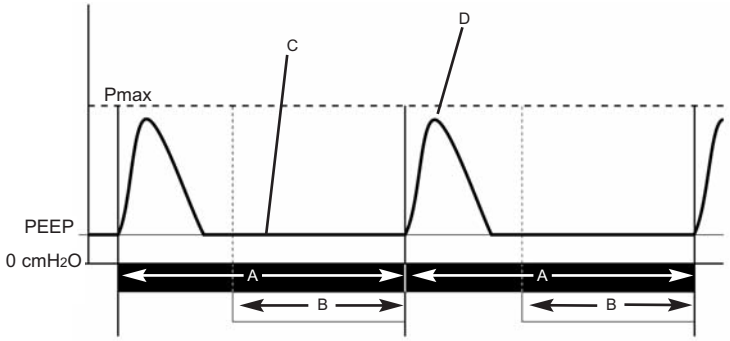
The ventilator will default to pre-set values for minute volume (Vm), Rate, Inspiratory Time and Trigger Level, after selecting 'SMMV'.

Note:
1. Vm can be adjusted before SMMV is confirmed.
2. The trigger setting is adjustable between 0.7 and 4.0 L/min.



SMMV - Spontaneously Breathing Patient
A = Cycle Time (set from BPM)
B = Trigger Window
C = Spontaneous Breath
D = Trigger
E = Mandatory Breath tidal volume.
This is equal to Vm/BPM, minus the volume spontaneously breathed during the cycle (this maintains the set Vm)

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
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)

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

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 must be pre-selected in Standby mode
Select Standby Mode
Select Menu
Select Special Modes
Select Support Mode
Select PSV
Escape Menu

PSV will be displayed on the main screen when Spontaneous mode is selected or triggered.

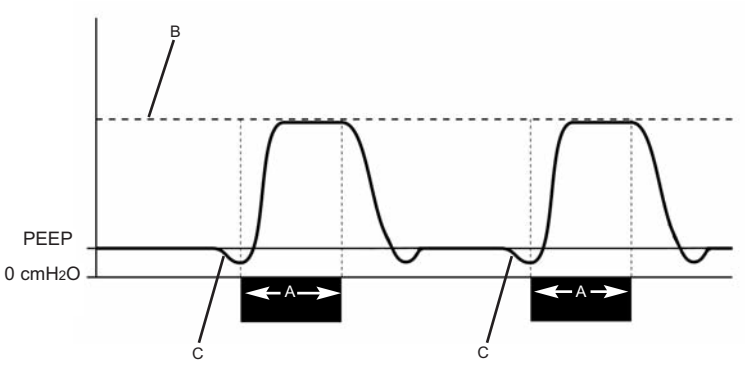
Activate PSV during Ventilation
NOTE
PSV will not function unless already pre-selected in Standby Mode

1. Select 'Special Mode' on the display.
   If the absorber Bag/Vent switch is not detected, a message will appear:
   'SET ABSORBER TO VENT'
   Press the navigator wheel / push button to confirm.
2. Move the absorber Bag/vent switch to 'Ventilator'.
3. Check that PSV is functioning correctly.

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 system 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 pre-set values for Support Pressure, Inspiratory Time, and Trigger Level after selecting 'PSV' .

Note:
1. Support Pressure can be adjusted before PSV is confirmed.
2. The trigger setting is adjustable between 0.7 and 4.0 L/min.



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

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

3.7.5.4 PEEP (Positive End Expiratory Pressure)

The AV-S ventilator includes a microprocessor-controlled, electronically integrated PEEP system, regulated by the secondary pressure on the exhaust diaphragm (see 3.2).

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

NOTE

1. *PEEP is electronically controlled*
2. *PEEP is variable from 4 - 20 cmH_2O, in increments of 1 cmH_2O*
3. *The display shows "OFF" when PEEP is not in use*
4. *PEEP is switched off when the ventilator is switched off.*
5. *PEEP is switched off during 'Spont' mode to minimise patient's breathing effort.*

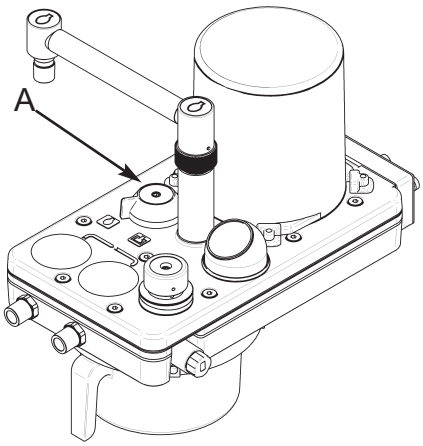
Selecting PEEP

1. Select by touching the screen tab PEEP, or using the navigator wheel
   The setting will flash.
2. Rotate the navigator wheel to set the required PEEP pressure.
   A confirm message will be displayed.
3. 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. Switch the ventilator to Volume Ventilation Mode
2. Select PEEP, and set pressure to the required level.
   The PEEP display indicates pressure.
3. Switch the A200SP Absorber Bag/Vent control (A) to the 'Bag' position.
   The ventilator automatically switches to Spontaneous Mode.
   PEEP is automatically switched off *(does not function in Spontaneous Mode)*
   PEEP display is blank.
4. Reset the Bag/Vent control 'Vent' position.
   The ventilator automatically switches to the mode previously set by the user.
   PEEP is Off.
   PEEP display indicates Off.
5. Set the ventilator to Volume Ventilation Mode.
   PEEP remains Off.
   Select PEEP if required.

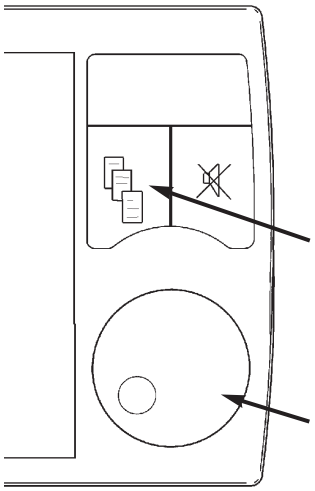


DESCRIPTION

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
LEAK TEST MENU
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 further information on the Menu system.

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

NOTE
1. The default waveform is always Pressure v Time (cmH_2O *v* seconds)
2. Wave Freeze is available when ventilation is in progress

Second waveform
The second waveform can be displayed by using the menu control or by touching the waveform on screen.
Select from:

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) The scale adjusts as Plimit is changed (-20 to 40, 60, 80 cmH_2O)

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

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

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

DESCRIPTION

3.11 Alarms

NOTE User Adjustable Alarms - use the menu system to set the required limits - press the menu switch on the front panel (see 3.8), and select ALARM SETTINGS.

Alarm	Priority	Trigger	Mute time	Set by:
Ventilator Inoperative (vent inop)	High	Internal failure or Battery failure	zero	Automatic
Outlet blocked	High	Positive pressure exceeds 120 cmH2O, due to blocked exhaust valve outlet	zero	Automatic
Power About to Fail	High	Ventilator is using the 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_2O 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 (4 to 14 cmH_2O)	120 s	Automatic
Negative Airway Pressure	High	Breathing system pressure exceeds 10 cmH_2O	120 s	Automatic
Low Tidal Volume (Vt)	High	a) Measured Vt less than 50% of volume set b) Spirometer disconnected	120 s	User / Default
Low Minute Volume (Vm)	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	Automatic
High Tidal Volume (Vt)	High	Measured value exceeds 150% of set value	120 s	User/Default
High Minute Volume (Vm)	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	Automatic
O2 sensor fault	High	Sensor disconnected	120 s	Automatic
Incorrect Rate or Ratio	Medium	Settings outside 75 L/min	120 s	Automatic
Mains Failure	Low	Mains power fails Fully charged battery gives 30 mins use (60 mins with high power battery)	zero	Automatic
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 (A200SP)	Medium	Disconnection or short circuit	120 s	Automatic
Printer not available	Low	Printer disconnected, or has no power, or has no paper	zero	

Priority identification:

High Priority: Five ascending tones - repeated Medium Priority: Three ascending tones - repeated Low Priority: Single tone - repeated

DESCRIPTION - *O_2 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

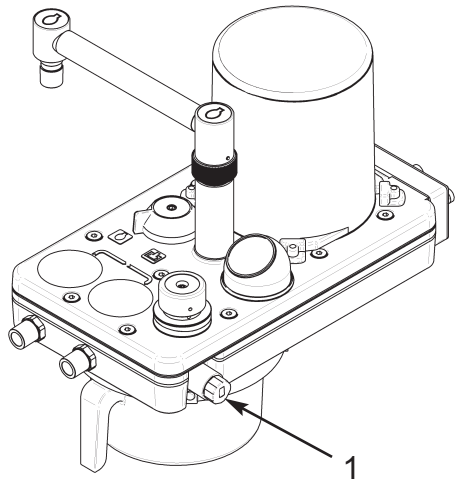
Always use a breathing system bacterial filter in the expiratory limb of the breathing circuit to protect the oxygen sensor and breathing system components from contamination (see section 5).

CAUTION

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

O_2 Sensor Location

Integra AV-S with A200SP Absorber



3.12.2 The Oxygen Sensor

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

The sensor 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 O_2% hours at 20^{o}C
(minimum one year in most normal applications).

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

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

DESCRIPTION - *O2 Monitor*

3.12.3 O2 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.

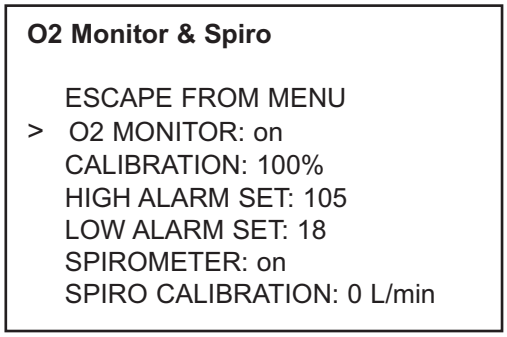
CALIBRATION
Press the navigator wheel to initiate the calibration procedure (see section 5.3.2 for full procedure).
To exit the menu, scroll to EXIT MENUS and press the wheel.

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).

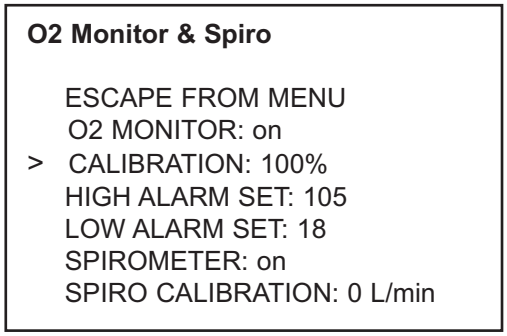
High Alarm range:	19% to 105%
Low Alarm range	18% to 99%

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

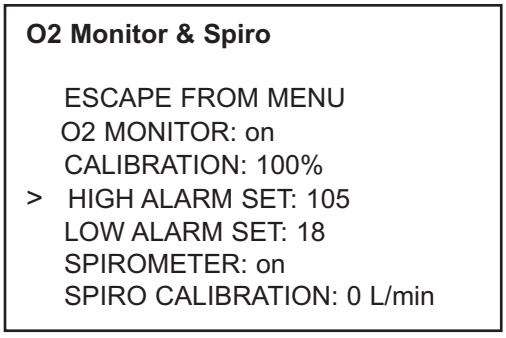
O2 Monitor sub-menu



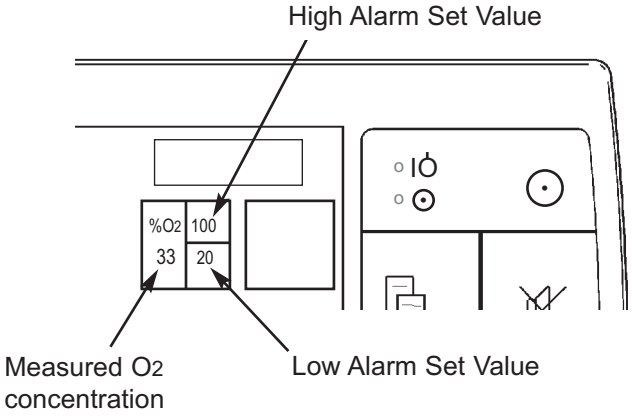
O2 Monitor sub-menu - calibration



O2 Monitor sub-menu - alarms



DESCRIPTION - *O2 Monitor*



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.

3.12.5 Oxygen Monitor Alarms

HIGH O2 ALARM

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

a) The **High 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 anesthesia.

4.2 Internal Compliance

Adult bellows	3 ml/cmH_2O (nominal)
Pediatric bellows	2 ml/cmH_2O (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
Pediatric :	20 - 350 ml

(Note - latex free pediatric available as option)

Power	100 - 120 VAC, 50 - 60 Hz, 0.6 A max. 200 - 240 VAC, 50 - 60 Hz, 0.3 A max. (automatic ranging)
Fuse (mains supply)	Two fuses, Type T 2AH 2 A, 250 V rating, 20 mm, anti surge, ceramic.
Battery Back-up:	Standard battery: 12 V, 1.2 Ah, sealed lead-acid battery Fully charged battery provides 30 minutes (nominal) backup High power battery (option): 12 V, 2 Ah, sealed lead-acid battery Fully charged battery provides one hour (nominal) backup
Fuse (battery)	3 A mini-blade type
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)
Apnoea	Flow referenced (no breath detected within 15 seconds)
Low Drive Gas Pressure	Less than 235 kPa (35 psi)
High Continuous Airway Pressure	Above 30 cmH_2O at start of cycle Volume Mode: alarms after 10 seconds Standby Mode: alarms after 30 seconds
Low Pressure	4 - 14 cmH_2O PEEP referenced
Incorrect Rate or Ratio	
Mains Failure	Fully charged standard battery provides 30 mins (nominal) backup Fully charged high-power battery (option) provides one hour (nominal) backup
Low Battery	5 minutes Use
Ventilator Inoperative	Internal or Battery Failure
Outlet Blocked	Exhaust valve outlet blocked

SPECIFICATION

Alarms - User Adjustable

Low Tidal Volume	Measured value is below 50% of volume set Range: 0 - 1600 ml
High Tidal Volume	Measured value exceeds 150% of volume set Range: 20 - 1600 ml
Low Minute Volume	Calculated value is 50% below volume set Range: 0 - 10 L
High Minute Volume	Calculated value exceeds 150% of volume set Range: 0 - 30 L
Low and High O_2 Concentration	18% - 105%
High Airway Pressure	10 - 80 cmH_2O adjustable

4.5 Functional

Tidal Volume

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

At ambient temperature of 20^{O}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 - 100 cmH_2O
Fresh Gas Compensation	Automatic Tidal Volume adjustment
Modes	Off Standby Volume Cycle Pressure Controlled Spontaneous (includes advanced breathing modes)
Pressure Control	10 - 70 cmH_2O
Inspiratory Flow	2 - 70 L/min
Spontaneous Mode	Active Volume and Pressure Alarms, Advanced Breathing Modes selectable (see section 4.6)
Electronic PEEP	4 - 20 cmH_2O
Spirometry - Resolution	±10 ml

Ventilator Performance - accuracy of delivered volumes

≤ 100 ml	± 50%.
> 100 ml	± 20%

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)	0.7 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
Pediatric	150 ml	15	1:2	38 cmH2O

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

SIMV	**Vt**	**BPM**	**Insp time**	**Trigger**
Adult	600 ml	6	2 sec	1 L/min
Pediatric	200 ml	10	1 sec	1 L/min
SMMV	**Vm**	**BPM**	**Insp time**	**Trigger**
Adult	3.6 L	6	2 sec	1 L/min
Pediatric	2 L	10	1 sec	1 L/min

PSV	**Support Pressure**	**Trigger**
Adult	10 cmH2O	1 L/min
Pediatric	10 cmH2O	1 L/min

4.7	**Disinfection and Sterilization**	Patient Block assembly can be sterilized if necessary - section 6. *NOTE : The bellows assembly, oxygen monitor sensor, and spirometer sensors are built into the A200SP Absorber - for information, please refer to the User Manual for A200SP.*
4.8	**Bacterial Filter**	None (always use a bacterial filter in the breathing system to protect the oxygen sensor - see section 5.1.4)
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**	Not applicable
4.11	**Waveform Tests**	Not applicable
4.12	**Volume Tests**	Not applicable
4.13	**Mobility and Mounting**	
	(A) Mobility (B) Mounting	Secure mounting required Control unit and remote screen are mounted on anesthetic machine . The bellows assembly is built into the A200SP Absorber.

SPECIFICATION

4.14 Environmental

Operating:

Temperature	15 to 30^{O}C (59 to 86^{O}F)
Humidity	10 - 95% RH (relative humidity), non-condensing
Altitude	Up to 2775 m (9000 feet)
Air Pressure	70 - 110 kPa

Storage and Transport:

Temperature	-5 to 40^{O}C (23 to 104^{O}F) *Note: For battery care during storage, refer to Appendix 1.*
Humidity	10 - 95% RH (relative humidity), non-condensing
Air Pressure	11.5 - 110 kPa

Electro-magnetic compatibility:

The AV-S meets the requirements of EN60601-1-2 (Electromagnetic compatibility - requirements and tests).

MRI compatibility: The AV-S is not suitable for use in an MRI environment

4.15 Device Classification and Labelling

Type B Applied Part
Degree of protection against electric shock

This symbol denotes: Type B equipment: 

Class 1 Classification
Type of protection against electric shock
Class 1 with internal electrical power source (battery backup)

IPX0 Ingress protection
Classification according to the degree of protection against ingress of water
IPX0 (not protected)

Labelling

This symbol denotes: Refer to the User Manual 

4.16 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 approximately 10 seconds (air to 100% O_2)
Operating Temperature:	15 to 30^{O}C (59 to 86^{O}F)
Storage Temperature:	-5 to 40^{O}C (23 to 104^{O}F)
Relative Humidity Range:	10 - 95% (non-condensing)

SPECIFICATION

Oxygen monitor, continued

Battery Back-up:	As per ventilator
High Priority Alarm:	Flashing, 2x5 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 O_2% hours (One year minimum in typical applications)

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

Interference	***Volume % Dry***	***Interference in O_2%***
Nitrous Oxide	*80%*	*<1%*
Carbon Dioxide	*5%*	*<1%*
Halothane	*5%*	*<1%*
Enflurane	*5%*	*<1%*
Isoflurane	*5%*	*<1%*
Sevoflurane	*5%*	*<1%*

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.

NOTE

Altitude compensation is automatically applied during calibration.

5. PRE-OPERATION PROCEDURES

5.1 Ventilator Set-up

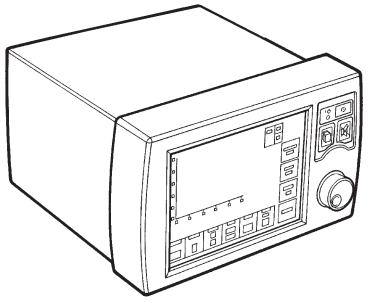
WARNING
Before the AV-S ventilator is used clinically for the first time a Calibration Check and Output Check must be successfully completed.

Calibration and output checks must be carried out by a DRE-trained technician, following the procedure in Appendix 6 in the AV-S Service Manual.

5.1.1 Mounting the Ventilator

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

Location for optional control unit / screen
Preferably, mount the unit permanently on the shelf of the anesthesia machine or on a strong bracket.
This will protect the unit from accidental fall and disconnection of hoses and cables.



To fit the unit permanently on a mounting 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 the manufacturer.

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.

PRE-OPERATION PROCEDURES

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) Anesthetic machine O_2 auxiliary gas outlet,
   c) O_2 pipeline supply from a wall outlet.

   AIR SUPPLY:
   a) Air cylinder,
   b) Anesthetic 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 anesthetic machine or supply line.

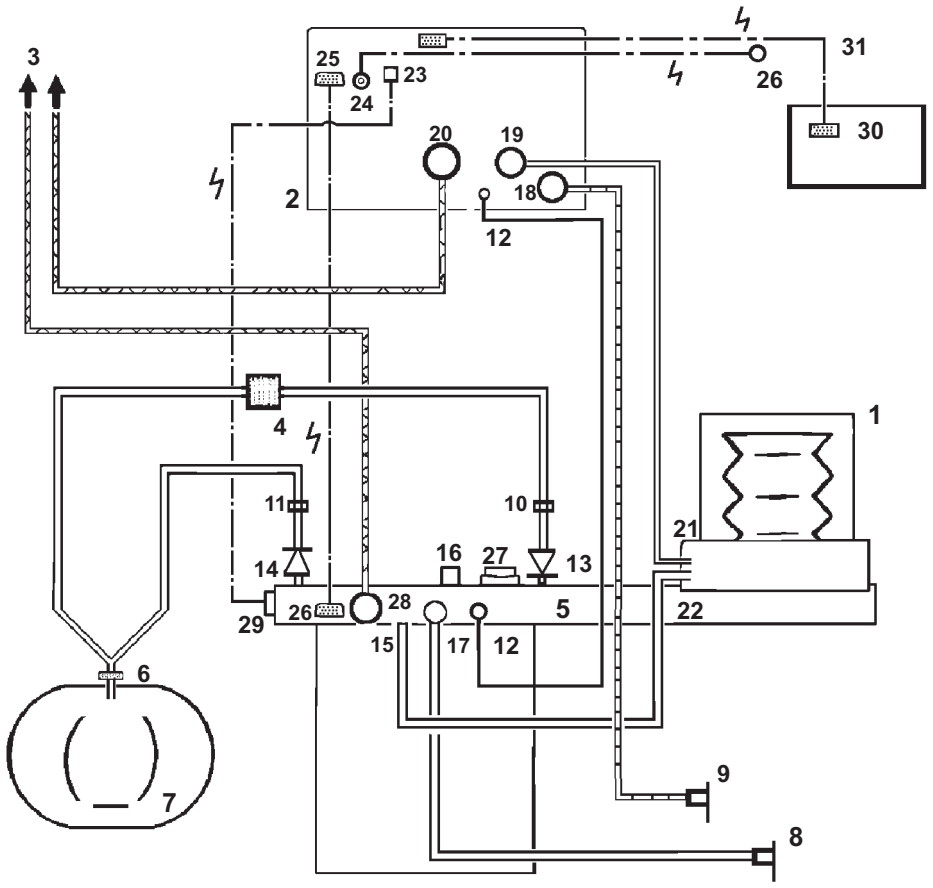
   NOTE: It is possible to reconfigure the ventilator for use with a different drive gas to the gas originally specified.
   This work must be carried out by an engineer trained by the manufacturer.

5.1.4 Breathing System Schematic

The next page contains a schematic showing the cables and tubing for an AV-S ventilator mounted on a Integra SP I/SP II anesthesia machine with an integral A200SP Absorber.

PRE-OPERATION PROCEDURES

Hoses and Cables Schematic
AV-S (with remote screen) and
A200SP Absorber



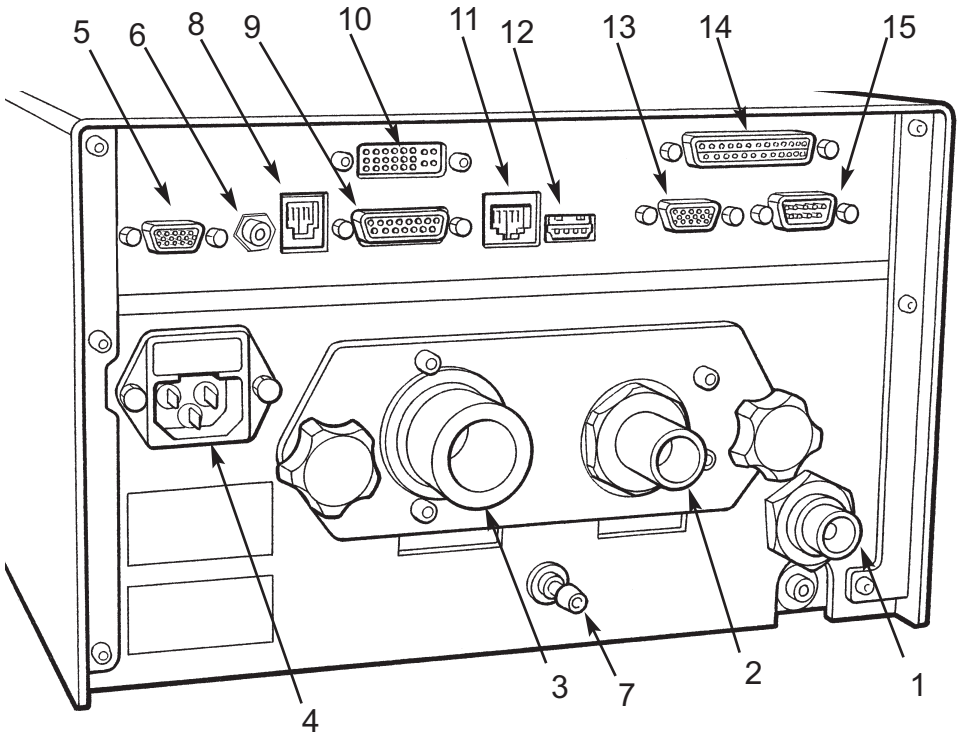
Note

1. AV-S has spirometry and oxygen monitor.
2. Interface cabling is shown for connection to Integra AV-S On/Off switch and A200SP Bag/Vent switch.

PRE-OPERATION PROCEDURES

1. Bellows
2. Ventilator Control Unit
3. Outlets to Anesthetic Gas Scavenging System (AGSS)
4. Bacterial Filter
5. Absorber valve block
6. Heat and moisture exchanger (a combined unit with a bacterial filter can be used - see 5.1.9)
7. Patient
8. CGO Block on anesthetic machine (Fresh Gas Supply)
9. Auxiliary Outlet on anesthetic 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 - Integra AV-S interface
    (SP on/off switch)
25. Input socket:
    (i) A200SP Absorber Bag/Vent control position
    (ii) Spirometer sensor signal
26. Interface connections on Integra AV-S and A200SP
27. APL Valve
28. Outlet from APL Valve to AGSS
29. Oxygen sensor
30. Remote screen unit
31. Cable - control unit to screen

PRE-OPERATION PROCEDURES



Control Unit Rear Panel

Gas Connections

1. Ventilator drive gas inlet
   - connect to anesthetic machine auxiliary gas outlet
2. Bellows Drive Gas Output
   - connect to bellows
   (on Integra AV-S with A200SP absorber
   - connect to absorber - see section 5.1.5)
3. Outlet - Exhaust Valve
   - connect to scavenge system

Electrical Connection

4. Electrical mains input and fuse unit

Interface and Parameter inputs

5. A200SP Absorber Bag/Vent switch interface, and Spirometer connector
6. Integra SP I/SP II Interface connector - (primary on/off switch)
7. Pressure Monitor Port
8. Input socket - Oxygen monitor sensor

Data and Printer Ports

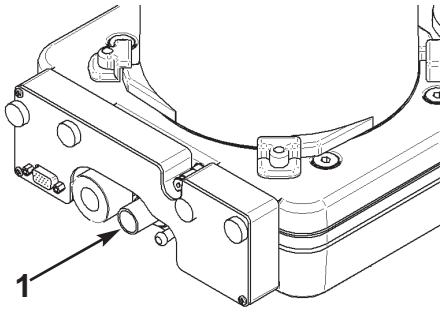
9. Data Output
10. Output to remote screen
11. Ethernet
12. USB
13. VGA
14. Printer port
15. RS232 (manufacturer's use only)

NOTE
USB port is for access only by engineers trained by the manufacturer.
All other data ports are read only.
For further information, please contact your distributor's service department, or the manufacturer.

PRE-OPERATION PROCEDURES

5.1.5 Bellows drive gas hose

1. Integra AV-S 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 Anesthetic Gas Scavenging System

1. Connect the EXHAUST valve port on the control unit to a properly functioning scavenging system.
   Use a 19 mm hose.
2. Fit a 10 cmH_2O 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.

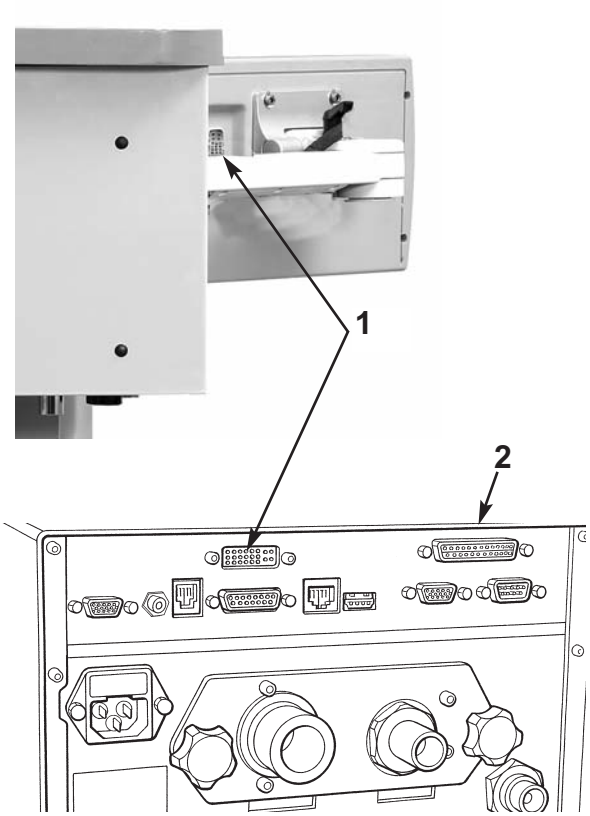
5.1.7 Remote Screen

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.

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.
   (a combined HME / bacterial filter can also be used, but note that the expiratory limb bacterial filter is still required)

   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 anesthetic machine APL valve.

PRE-OPERATION PROCEDURES

5.1.10 Spirometer

5.1.10.1 Flow sensors fitted to an A200SP Absorber mounted on a Integra AV-S

1. Use a breathing system bacterial filter - see section 5.1.9, 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.

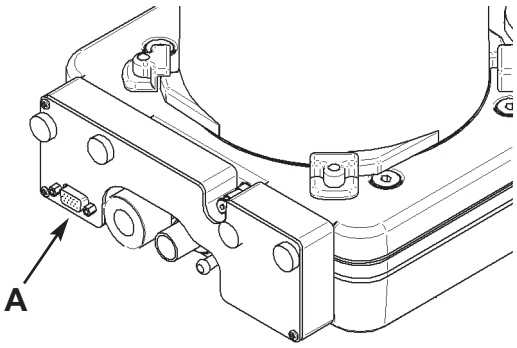
3. Connect the cable assembly between the connector at the rear of the A200SP Absorber (A) and the the socket (B) at the rear of the Ventilator control unit.
4. Check that the cable connections are secure.

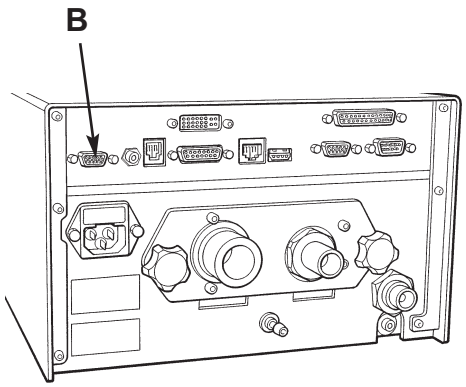
NOTE

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.



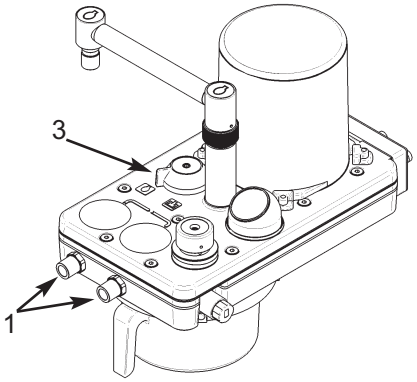


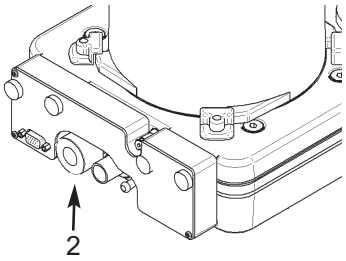
PRE-OPERATION PROCEDURES

5.1.10.2 Spirometer Zero Calibration
Flow sensors fitted to an A200SP
Absorber mounted on a Integra AV-S

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

The individual spirometers must be matched to the specific AVS ventilator by a qualified service engineer as part of commissioning or a subsequent service visit.
The following procedure defines the zero calibration which should be performed by the user as part of the daily check procedure.





1. Turn the anesthetic machine 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 Integra AV-S Gas Delivery switch).
   or,
   Disconnect the fresh gas hose from the CGO block on the anesthetic 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.

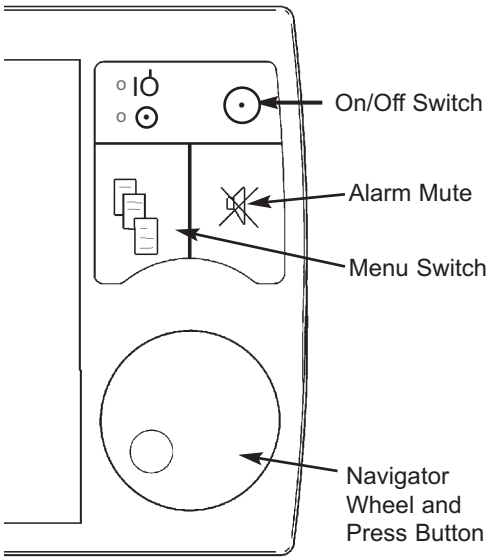
9. Select SPIRO CALIBRATION.

10. Press the wheel to initiate calibration.

11. Calibration is completed.

12. Scroll to ESCAPE FROM MENUS.

13. Press the wheel to confirm.

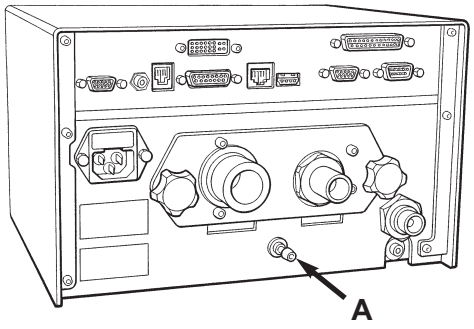


O2 Monitor & Spiro

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

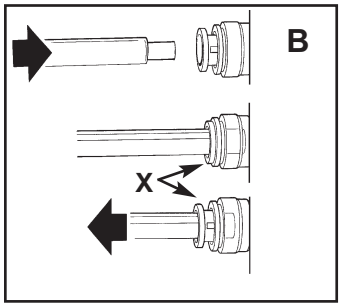
PRE-OPERATION PROCEDURES

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 tubing assembly supplied by the manufacturer to connect to the expiratory limb of the breathing system, close to the circle system expiratory valve.

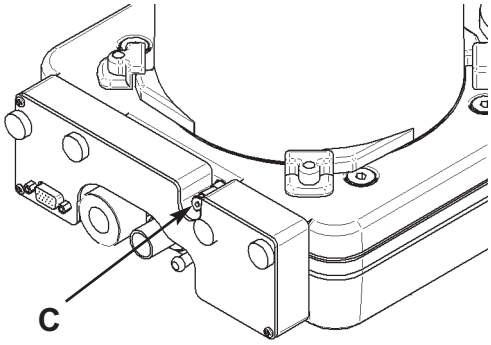


2. Push-fit, self sealing connectors (B)
   Push in the tube as far as possible
   Do not use excessive force.

   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.



NOTE

Disconnection of airway pressure tubing, or pressure sensor malfunction

Message displayed:

‘’Check pressure sensing”

Action by user:

Check the condition of the tubing, and the connection at the ventilator (A) and the rear of absorber (C).

If the tubing is undamaged and the connections are secure, the operation of the sensors must be checked by a service engineer

CAUTION

The ventilator will continue to function, although the target pressure may be exceeded by up to 10 cmH_2O.

PRE-OPERATION PROCEDURES

5.1.12 Leak Test / Compliance Value Calculation

This procedure checks the breathing system for pressure leakage, and calculates and displays **Leak Status, Leak Level,** and **Breathing System Compliance.**

1. Occlude the breathing circuit at the patient Y piece

2. Ensure that the absorber is switched to vent mode and the bellows are fully inflated.

3. Either (a) disconnect the fresh gas hose from the CGO and connect it to the end of the bag arm,
   or
   (b) Turn the anesthetic machine gas flow off at the gas delivery on/off switch (1).
   This will stop all gas flows (including oxygen basal flow) and will also turn the AVS off.
   Then switch the AV-S on (2) at the ventilator (Do not use the anesthetic machine gas delivery switch.

4. Press the menu switch (3).
   Select LEAK TEST from the main menu.
   Select <START/STOP LEAK TEST> to start the leak test.

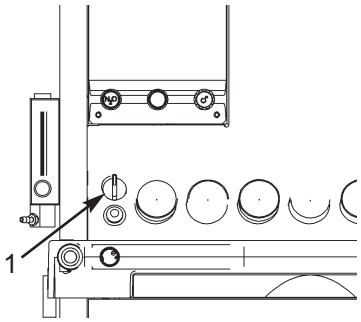
   The ventilator will now drive gas into the absorber until a pressure of 30 cmH_2O is obtained, and then hold that pressure for approximately 25 seconds before releasing the pressure and completing the test.

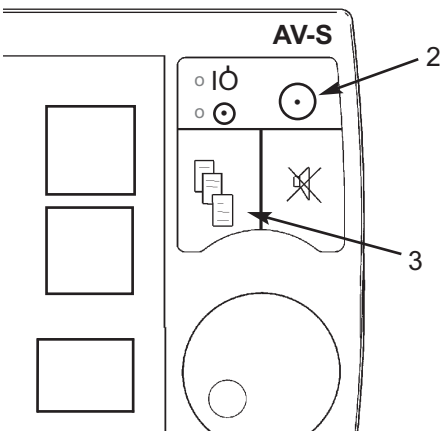
5. The menu will display the leak test results :

   (i) **Leak Status**

Excellent:	under 50 ml/min
Good:	between 50 and 149 ml/min
Poor:	between 150 and 349 ml/min
Bad:	350 ml/min or more

   NOTE
   The ventilator will still operate, irrespective of the displayed Leak Status.





Leak Test

ESCAPE FROM MENU
<START/STOP LEAK TEST>
LEAK STATUS: unknown
LEAK LEVEL: 0 mL/min
BSYS COMP 7.0 mL/cmH_2O

(ii) **Leak Level**

Indication of leak rate is displayed

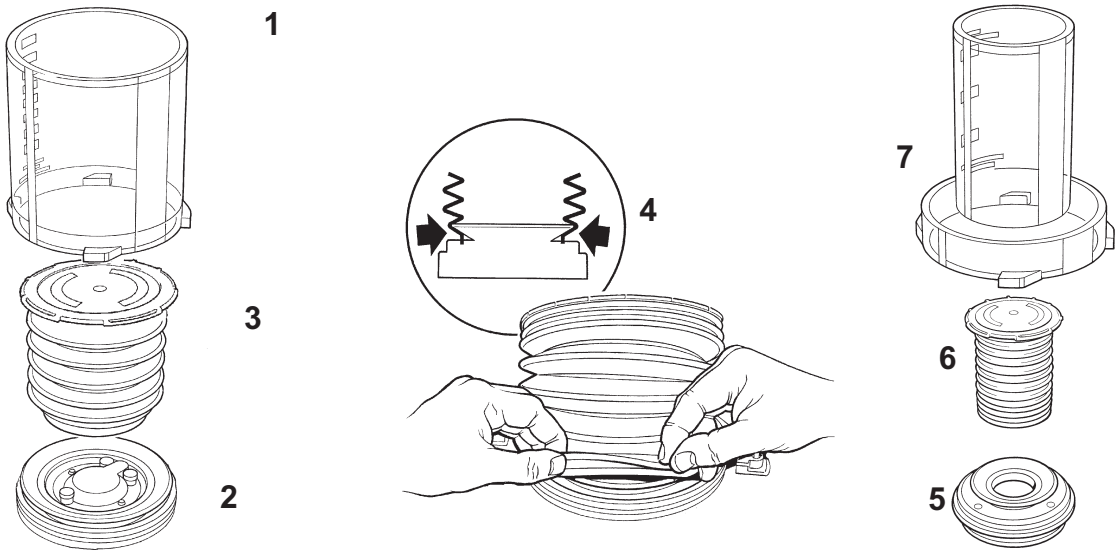
NOTE
During the test, any pressure drop discovered once the 30 cmH_2O level is reached will be displayed as a possible leak by the ventilator self-test. This includes pressure drop due to the relaxation of any elastic components in the breathing system (e.g a breathing bag)

(iii) **BSys Comp**

BSys Comp is the compliance of the breathing system and is the value that will be used in providing the default compliance compensation for volume delivery.

NOTE
This value has an upper limit of 18 cmH_2O (sufficient for normal breathing system capacities).

PRE-OPERATION PROCEDURES



5.1.13 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 an engineer trained by the manufacturer.

Note that the bellows assembly is built into the A200SP Absorber.
For additional information, please refer to the user manual for that product.

Pediatric 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 pediatric adaptor (5) - press the adaptor into the ventilator bellows assembly base (2).
3. Fit the pediatric bellows (6) to the adaptor. Check for correct assembly, as illustrated (4).
4. Fit the pediatric 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:

5.2.1.1 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 authorized service technician.

5.2.1.2 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 Integra AV-S (see section 3.5.2).

a) Turn the anesthetic machine Gas Delivery Switch to ON - the ventilator will power-up.
While machine power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch.

Test Display
Two small boxes (A and B) appear on the left hand side of the screen, showing either:

Top box BLACK, lower box GREEN

Indicates the initial system self-test has been completed successfully.

The boxes will be removed from the screen as soon as the ventilator is taken out of standby mode.

Top box RED, lower box BLACK

Indicates that the initial system self test has detected that a service calibration is required.

A full system calibration must be carried out by qualified service personnel.

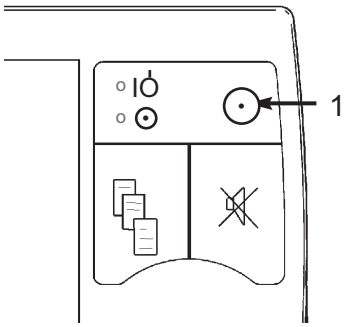
The boxes will remain visible until calibration is completed.

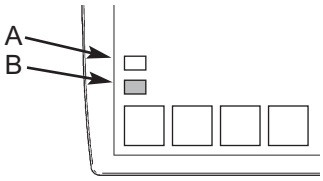
The ventilator may still be used, but with reduced accuracy.

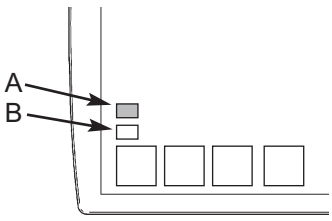
Back-up Battery
WARNING
If the internal battery is fully discharged, the ventilator will not function.

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).







5.2.1.3 Function Test

1. Set the AIRWAY PRESSURE LIMIT to 50 cmH_2O.

2. PRESSURE TRANSDUCER connection
   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 anesthetic 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 an engineer trained by the manufacturer.

8. Set a basal flow only on the anesthetic 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 an engineer trained by the manufacturer.

5.2.2 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 an engineer trained by the manufacturer.

Bellows

Check the condition of the bellows and exhalation diaphragm valve.

Note that the bellows assembly is built into the A200SP Absorber - please refer to the user manual for this product.

PRE-OPERATION PROCEDURES - *O_2 Monitor*

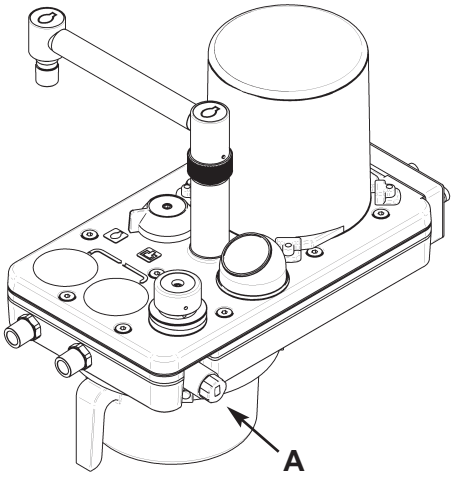
5.3 O_2 Monitor System Set-up

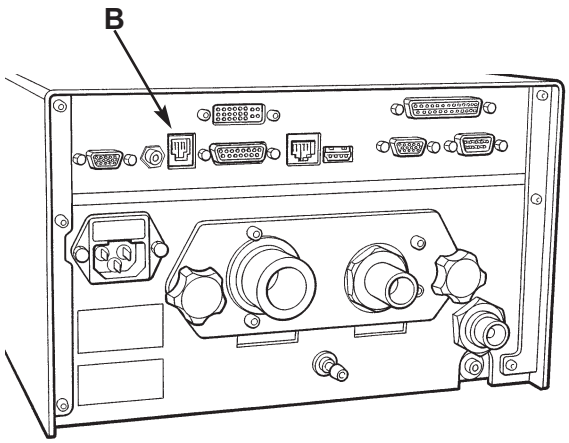
5.3.1 Installation

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 anesthetic 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 anesthetic 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 5.1.9).
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).
NOTE
Altitude compensation is automatically applied during calibration.

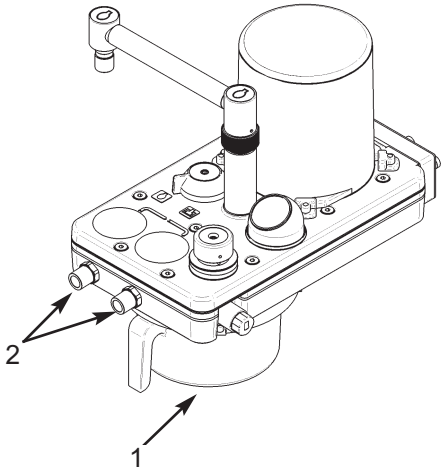
We recommend calibration with a 100% oxygen standard source, at a pressure and flow similar to your application.

PRE-OPERATION PROCEDURES - *O_2 Monitor*

5.3.2.1 Calibration - Using 100% Oxygen

AV-S ventilator mounted on a Integra AV-S anesthesia machine fitted with a A200SP absorber

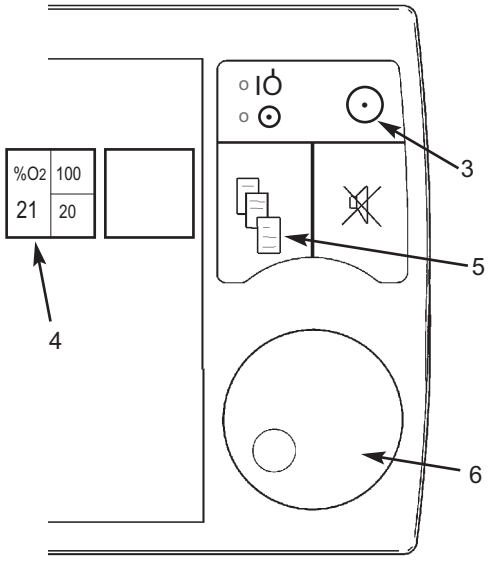
Calibrate with the sensor in position within the absorber.



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 anesthetic 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 anesthetic 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 O_2 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 absorbent canister (1).

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 - *O_2 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

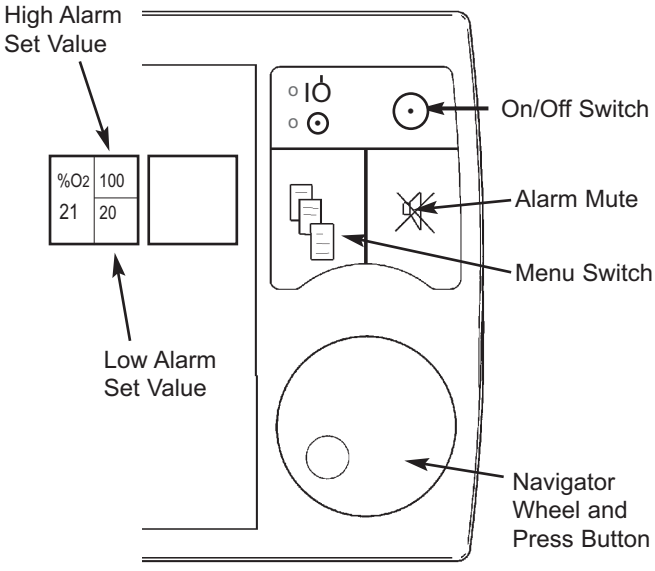
ESCAPE FROM MENU
O2 MONITOR: on
CALIBRATION: 100%
> HIGH ALARM SET: 105
LOW ALARM SET: 18
SPIROMETER: on
SPIRO CALIBRATION: 0 L/min

5.3.4 Setting the O_2 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 O_2 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 O_2 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.

6. MAINTENANCE

WARNING

1. ***User maintenance is restricted to cleaning the outside surfaces of the device, as detailed in this section.***
2. ***Other procedures detailed in this section must be carried out by trained technicians only.***
3. ***Service and repair operations must only be carried out by an engineer trained by the manufacturer.***
   The warranty for this product is void if the product is not maintained in accordance with the service schedule detailed below, and the procedures published in the Service Manual for this product.

6.1 Service Schedule

At 6 months, 12 months, 2 years and 4 years, the ventilator must be serviced by an engineer trained by the manufacturer, following the schedule given below, and the procedures given in the AV-S Service Manual.

Every day:
Pre-use function check

Every week:
Check the condition of the bellows assembly 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 O-seals and drive gas inlet filter.
Replace exhaust diaphragm valve
Preventive maintenance kit available.

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

Every 4 years:
Repeat 2 year service, plus:
Replace PCB battery.
Replace bellows diaphragm valve

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

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

MAINTENANCE

6.2 Cleaning

6.2.1 Outside surfaces

CAUTION

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

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

c) Do not use harsh abrasive cleaning agents.

To clean the outside surface of the ventilator, use a damp cloth that has been immersed in a cleaning solution and thoroughly wrung out.

Use cleaning agents as recommended by your hospital infection control department:

Use a warm, mild detergent solution to remove resistant grime.

To remove blood etc, clean as above then use an antiseptic solution, or anti-microbial wipes.

Make sure that all cleaning agent residues are fully removed after cleaning.

Touchscreen

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

6.2.2 Bellows Assembly

The bellows assembly is built into the A200SP absorber. For further information please refer to the user instructions supplied with the A200SP.

6.2.3 Spirometer Sensors

The sensors are built into the A200SP absorber, and cleaning and sterilization 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.

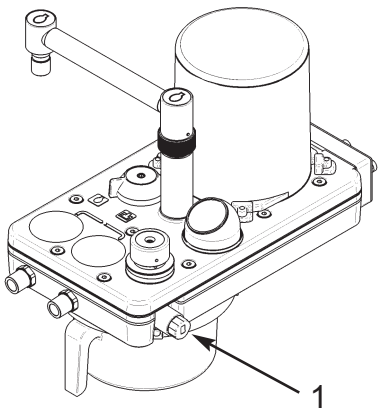
6.2.4 Oxygen Monitor Sensor

The sensor (1) is built into the A200SP absorber.
For further information please refer to the user instructions supplied with the A200SP.

WARNING

The sensor is not suitable for sterilization. If contamination is suspected, fit a new sensor (see section 6.4).

Dispose of the contaminated unit according to hospital, local, state and federal regulations.



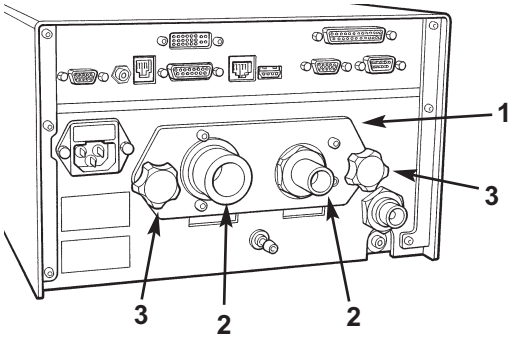
MAINTENANCE

6.2.5 Control Unit Patient Block Assembly

These operations must be carried out by suitably trained technicians only.

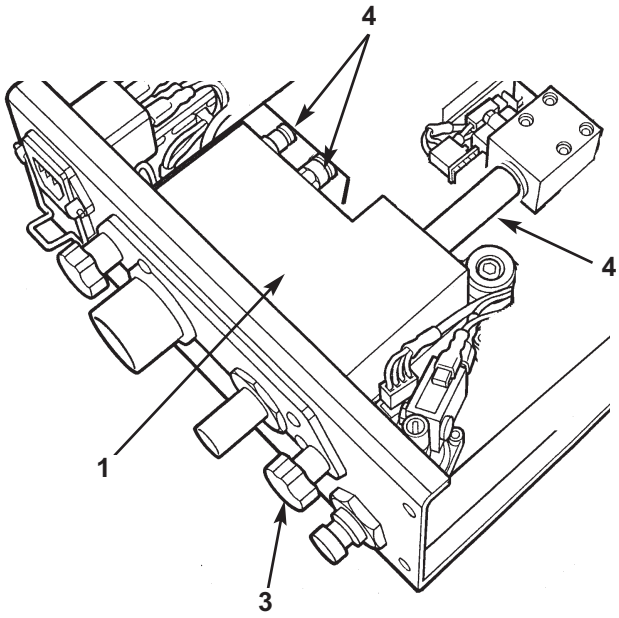
6.2.5.1 Inspection: frequency and indications

On a regular basis (in line with hospital procedures for infection control), and at least every six months, the patient block (1) must be removed, cleaned and sterilized.



6.2.5.2 Disassembly

1. Detach the hoses from the outlets (2).
   Note the 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.
   Do not disassemble the patient block before cleaning and sterilization.



6.2.5.3 Cleaning

1. Pre-cleaning - submerge the patient block in an enzymatic solution within an ultrasonic tank for a period of 20 minutes.
2. Clean the patient block in a washer/disinfector unit that incorporates an initial cold rinse, a detergent wash, a decontamination stage at 92^{O}C, followed by a final drying stage.

6.2.5.4 Sterilization

1. Sterilize, as recommended in section 6.3. Do not disassemble.

6.2.5.5 Reassembly

1. Position the patient block and push fully into the control unit, ensuring that the metal tubes (4) are engaged in their unions.
2. Fit the securing knobs (3).

6.2.5.6 Pre-use Checks

1. Function test the ventilator before clinical use - see section 5.2.1.

MAINTENANCE

6.3 Sterilization

These operations must be carried out by suitably trained technicians only.

CAUTION
To prevent possible damage to components, peak sterilization temperatures must not exceed 134^{O}C (275^{O}F) for steam autoclave.

Do not sterilize the ventilator control unit. Apart from the patient block assembly the internal components are not compatible with sterilization techniques and may be damaged.

6.3.1 Recommended Sterilization Parameters

6.3.1.1 Control Unit Patient Block Assembly

1. Clean, as described in section 6.2.5.3

2. Autoclave at 134^{O}C, for a holding time of 3.5 minutes, using packaging and equipment as listed below:

   Packaging

   Pack the control unit with material which is permeable to air and steam but has an effective maximum pore size which is small enough to exclude microbial contamination.
   All wrapping materials must comply with EN 868: Packaging Materials for Sterilization of Wrapped Goods.

   Processing Equipment

   The sterilizer must comply with the stated performance class BS 3970 and HTM 2010 and with additional requirements stated in Section D.

   If a porous-load sterilizer is used it must conform to the specifications in EN 285 and the safety specifications in EN 61010: Part 2-041.

   Sterilization must be achieved by direct contact with good quality saturated steam .

   Post-processing

   Following reprocessing the patient block must be kept in a sterile plastic pouch to avoid being re-contaminated prior to being fitted to the ventilator.

   Refit in accordance with section 6.2.5.5. Function test the ventilator before clinical use - see section 5.2.1.

MAINTENANCE

6.4 Oxygen Sensor Replacement

These operations must be carried out by suitably trained technicians only.

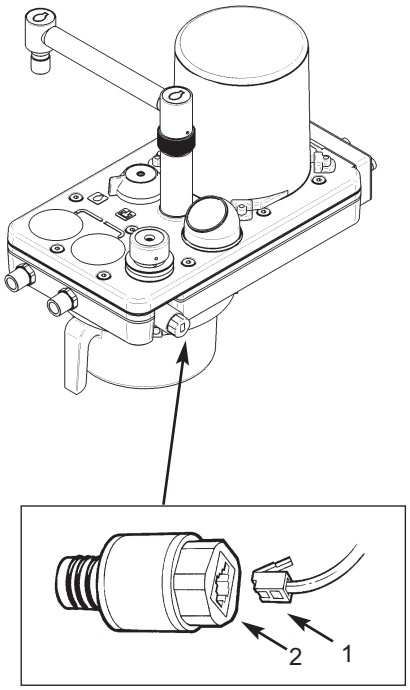
WARNING
The sensor contains:
A) A small quantity of electrolyte, classified as a harmful irritant which is potentially hazardous.
B) Lead

Do not attempt to open a cell.
ALWAYS check the integrity of the sensor assembly before use.
Once exhausted, the sensor must be disposed of according to hospital, local, state and federal regulations.

6.4.1 Sensor Unit - Remove and Refit

Replacement parts
102714 Sensor

1. Detach the cable connector (1) from the sensor (2).
2. Unscrew the sensor from the A200SP Absorber, and discard.
3. Discard the expired sensor.
4. Screw the new sensor (2) into the absorber.
5. Attach the cable connector (1).
6. Fit the assembly into the absorber.
7. Calibrate the new sensor - see section 5.2.1.
8. Dispose of the used components according to hospital, local, state and federal regulations.



7. APPENDIX

APPENDIX 1

Care of Back-up Battery

CAUTION
Damage may occur if the battery is allowed to remain in a discharged state.

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^{o}C (120^{o}F).

Storage temperature	***Recharge period***
38 to 50^{o}C (100 to 122^{o}F)	1 month
21 to 38^{o}C (70 to 100^{o}F)	3 months
7 to 21^{o}C (45 to 70^{o}F)	6 months
0 to 7^{o}C (32 to 45^{o}F)	9 months
-5 to 0^{o}C (23 to 32^{o}F)	12 months

Recharge duration - a charging cycle of at least 12 hours, to ensure that the battery is kept at full capacity.
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

Do not dispose of in landfill, refer to an approved recycling facility.

Follow your 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. Pediatric 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
- LEAK TEST
- 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)

Leak Test

ESCAPE FROM MENU
<START/STOP LEAK TEST>
LEAK STATUS: unknown
LEAK LEVEL: 0 mL/min
BSYS COMP 7.0 mL/cmH2O

Fresh Gas Compensation

ON / OFF	off/on	(Toggle option)

Special Modes

See next page

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
- PEDIATRIC 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 page 62

SPECIAL MODES MENU

NOTE
The SPECIAL MODES menu is context sensitive, with the contents dependent on current mode.

In STANDBY the SPECIAL MODES menu is:

ESCAPE FROM MENU	
SUPPORT MODE:	none (1)
TRIGGER:	1.0 L/min (2)
SIGH ENABLE:	off (3)
SIGH TO BREATH RATIO:	1:50 (4)
INSP. PAUSE:	off (3)

In SPONT mode the SPECIAL MODES menu is:

ESCAPE FROM MENU	
TRIGGER:	1.0 L/min (2)

In VOLUME Control the SPECIAL MODES menu is:

ESCAPE FROM MENU	
SIGH ENABLE:	off (3)
SIGH TO BREATH RATIO:	1:50 (4)
INSP. PAUSE:	off (3)

In PRESSURE, SIMV, SMMV, or PSV modes:
The SPECIAL MODES menu is unavailable.

Notes

(1) Support mode depends on configuration options.
The SUPPORT MODE option will be missing from the SPECIAL MODE menu if:
a) Options are not enabled
b) ''SPIROMETRY: off" is displayed.

The support mode sub menu can include:
- *none*
- *PSV*
- *SIMV*
- *SMMV*

(2) The TRIGGER values are L/min with SPIROMETRY enabled, or cmH_2O when SPIROMETRY disabled.

Spirometry enabled	*Spirometry disabled*
0.7 L/min	*0.5 cmH_2O*
0.8 L/min	*0.6 cmH_2O*
0.9 L/min	*0.7 cmH_2O*
1.0 L/min	*0.8 cmH_2O*
1.5 L/min	*0.9 cmH_2O*
2.0 L/min	*1.0 cmH_2O*
2.5 L/min	*1.2 cmH_2O*
3.0 L/min	*1.5 cmH_2O*
3.5 L/min	*1.7 cmH_2O*
4.0 L/min	*2.0 cmH_2O*

(3) The options here are: on or off.

(4) The options here are:
- *1:50*
- *2:50*
- *3:50*
- *4:50*

SERVICE MENU

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 system and spirometry system uses a total of three mass flow gas sensors. The sensors monitor, and then independently measure the gas flows within the ventilator and breathing system.
This ensures that correct volumes are delivered to the patient.
The sensors 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 method 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. 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 anesthetic 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 again 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 composition of the breathing system gas. To compensate for these effects the ventilator has
a) a gas composition setting whereby the user is able to select the gases 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.

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 used. 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.

APPENDIX

Anesthetic Agent Effects

The addition of anesthetic agent is known also to increase the spirometry readings (by up to approximately 2%) depending on the agent and its concentration. 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

≤100 ml	± 50%.
>100 ml	± 20%

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 airflow (or other gas flow) through the inlet and outlet ports of the unit.

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 a 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.

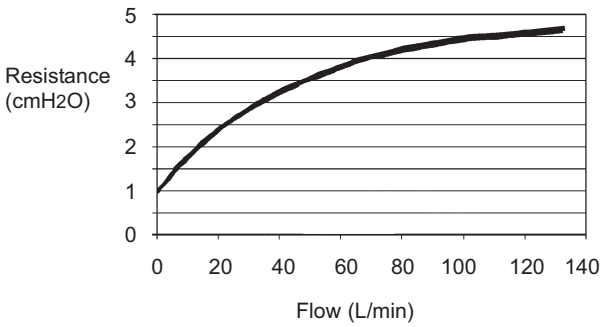
The microbridge mass airflow sensor uses temperature-sensitive resistors deposited within a thin film of silicon nitride. They are suspended in the form of two +bridges over an etched cavity in the silicon.
The chip is located in a precisely dimensioned airflow channel to provide a repeatable flow response.

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.

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).



APPENDIX

APPENDIX 4

Disposal at end of useful life - risk assessment

Do not dispose of in landfill, refer to an approved recycling facility.

Follow your hospital, local, state and federal regulations.

EC territories: Follow the requirements of Directive 2002/96/EC.

Note *Disposal of used batteries - see Appendix 1.*

APPENDIX 5

Approved Accessories

WARNING
Only use accessories approved by DRE, Inc.

57655	Compact Pressure Tee
57523	Pressure sensing tube
57545	Adult Bellows and base canister
57551	Adult Canister
57550	Adult Bellows
57548	Bellows Base
57656	Bellows base manifold block
	Additional to bellows base, use on stand-alone unit
57553	Pediatric Canister
57552	Pediatric Bellows
57554	Pediatric Bellows Adaptor

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Doc No AV-S (A2) 0208UI
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