

Prima SP2 Anaesthetic Machine Range User Manual



Partnership for Life

IMPORTANT

Servicing and Repairs

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

The machine must be serviced to the schedule detailed in section 6.4.

Details of these service operations are given in the Prima SP2 Service Manual, available only for Penlon trained engineers.

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

or communicate directly with:

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

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

Always give as much of the following information as possible:

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

FOREWORD

This manual has been produced to provide authorised personnel with information on the function, routine performance and maintenance checks applicable to the Prima SP anaesthetic machine range.

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

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

Copyright © Penlon Limited, 2008

All rights reserved.

The Importance of Patient Monitoring

WARNING

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

There can be considerable variation in the effect of anaesthetic drugs on individual patients so that the setting and observation of control levels on the anaesthesia systems does not in itself ensure total patient safety. Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist but are not true clinical monitors as the condition of the patient is also dependent on his respiration and the functioning of his cardio-vascular system.

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

Before using any monitoring system or device with the anaesthetic machine, 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
Gas Scavenging	ISO 8835-3
Vaporizers	ISO 8835-4
Ventilators	ISO 8835-5
Agent Monitor	ISO 11196

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

CONTENTS

	Page No.
USER RESPONSIBILITY	1
1. WARNINGS AND CAUTIONS	2
2. PURPOSE	4
3. DESCRIPTION	5
3.1 Framework and General Construction	5
3.2 Gas Circuit	5
Gas Circuit Schematic	6
3.3 Gas Supply Safety Devices	7
3.4 Mechanical Anti Hypoxic Device (AHD)	8
3.5 Pressure Gauges	8
3.6 Flowmeters and Controls	9
3.7 Vaporizers	10
3.8 Common Gas Outlet (CGO)	10
3.9 Electrical Power Supply	11
3.10 Auxiliary Gas Outlets	13
3.11 A200SP Absorber	13
3.12 AV-S Ventilator	13
4. SPECIFICATION	14
4.1 Physical Dimensions	14
4.2 Gas Supplies	15
4.3 Flowmeters	15
4.4 Gas Pressures	16
4.5 Auxiliary Gas Outlets	16
4.6 Oxygen Failure Warning Devices	16
4.7 Oxygen Flush	16
4.8 Mechanical AHD System	17
4.9 Environmental	17
4.10 Electrical Supply	17
4.11 Device Classification and Labelling	18
5. PRE-USE CHECKS	19
5.1 Pre-use Check List	19
5.2 Pre-use Checks - Gas Supply	21
5.2.1 Gas Pipeline Supplies	21
5.2.2 Gas Cylinder Supplies	21
5.2.3 Flowmeters	22
5.3 Vaporizers	23
5.4 Electrical Supply	24

CONTENTS

5.5	Patient Breathing System	25
5.6	Leak Rate Check - Low pressure gas System	28
5.7	Oxygen Flush	28
5.8	Anaesthetic Gas Scavenge System (AGSS)	28
5.9	Ventilator	29
5.10	Alarm System Testing	30
6.	USER MAINTENANCE	
6.1	Cleaning and Sterilisation	31
6.2	A200SP Absorber	32
6.3	Service Schedule	33
APPENDIX		
	Disposal at end of useful life: risk assessment	34
	Accessories	35

USER RESPONSIBILITY

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

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

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

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

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

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

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

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

WARNING *means there is a possibility of injury to yourself 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 anaesthetic apparatus.

WARNINGS

1. *This apparatus is designed for use only with non flammable anaesthetic agents. It must not be used with or in close proximity to flammable anaesthetic agents, due to a possible fire or explosion hazard.*

2. *Exterior panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing.*

On machines with an electrical power supply, unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.

3. *No oil, grease or other flammable lubricant or sealant must be used on any part of the machine in close proximity to medical gas distribution components. There is a risk of fire or explosion.*

4. *When attaching cylinders of medical gases ensure that the machine yoke and cylinder faces are dust free and clean and that the sealing washer provided is in position between the cylinder valve and the yoke.*

Tighten the yoke securely before opening the cylinder valve. Dust and dirt presents a fire hazard in the presence of high pressure gas.

Leakage of high pressure gas can cause serious injury.

5. *Anaesthesia apparatus must be connected to an anaesthetic gas scavenging system (AGSS) to dispose of waste gas and prevent possible health hazards to operating room staff.*

This requirement must be observed during test procedures as well as during use with a patient.

6. *Prima SP series machines must only be used with Sigma Delta vaporizers (or other vaporizers approved by Penlon Limited) installed by means of the Cagemount or Selectatec system.*

Free-standing vaporizers may be accidentally tipped, resulting in excessive and uncalibrated volumes of anaesthetic drug entering the breathing system

Do not install or connect any vaporizers of any description between the Common Gas Outlet (CGO) and the breathing system unless they are specifically designed for such use.

(If this is done, the oxygen flush flow will pass through the vaporizer and may result in gross overdose when the flush valve is operated.)

7. *The breathing system which conveys gases from the anaesthetic machine to the patient and disposes of expired gases is a vital part of the anaesthetic delivery system.*

Because breathing systems require frequent cleaning and disinfection they are not a permanent part of the anaesthetic machine and therefore cannot be directly under the control of the anaesthetic machine manufacturer.

However, we strongly recommend that only breathing systems which have been approved and authorised by Penlon for use with the Prima SP range should be employed.

This is particularly important when mechanical ventilation is employed.

8. *When mechanical ventilation is employed the patient breathing system must be connected directly to an over-pressure relief valve to prevent the possibility of barotrauma.*

9. *Always perform a pre-use check of the machine, including vaporizers, ventilator, circle absorber and monitors before clinical use. Follow the pre-use checklist (see section 5) as a minimum requirement.*

Many clinical incidents occur because of a failure to check for correct function.

10. *The machine must not be used if any of the alarm, monitoring or protection system devices are not functioning correctly.*

11. *The gas supply failure systems within the anaesthetic machine will not necessarily operate as indicated in the user manual during any procedures that are outside the scope of the indications for use of the machine:*

WARNINGS AND CAUTIONS

(A) Machine set to deliver Air only

When the machine is operated with an Air flow only, note that there may still be retained oxygen in the system, and that the visual O₂ alarm will continue to indicate green, even though oxygen is not being delivered.

(B) Machine set to deliver Oxygen only through Auxiliary Outlets

The oxygen failure alarm is designed to operate during normal use of the machine, i.e. when providing controlled concentrations and flows of gases to a patient breathing system, as described in Section 2 (Purpose).

Do not use the machine solely to provide large flows of oxygen, via the anaesthetic machine auxiliary outlets, to external devices which may not be equipped with a supply failure alarm.

12. **The machine must not be fitted with more than four operator accessible mains socket outlets. There is a risk of an excessive leakage current.**
13. **The use of antistatic or electrically conductive breathing hoses is not recommended when using high frequency electrical surgery equipment (e.g. : Diathermy). Burns may be caused.**
14. **Before any electrically powered machine is used clinically for the first time, check that the hospital engineering department has carried out an earth continuity test.**
15. **Before using any additional electrical equipment powered by the auxiliary sockets on the machine, check that the additional equipment is correctly wired and is earthed through its plug.**
A missing or defective protective earth conductor may increase earth leakage currents to the patient to values exceeding the allowable limits, resulting in ventricular fibrillation, or interference with the pumping action of the heart.
16. **Additional equipment placed on the top shelf must be securely attached.**
Take care when moving a fully loaded machine, particularly when negotiating ramps.
Check that hoses or power leads are not trailing on the floor.
17. **Prima SP2 series anaesthetic machines are not MRI compatible.**

CAUTIONS

1. Flowmeter needle valves are designed to seal with light torque and may be damaged if tightened excessively.
Do not force the control knob past either the fully open or fully closed positions.
2. Open cylinder valves slowly to avoid damage to pressure reducing valves.
Ensure that cylinder valves are at least one full turn open when in use.
3. Under no circumstances should anaesthetic agents be used for cleaning purposes.
4. After use, always disconnect the machine from the piped gas supply and/or close the gas cylinder valves.
5. Mechanical AHD system - The oxygen flow control is restricted to prevent the needle valve from fully closing. This ensures a minimum basal flow of oxygen.
DO NOT attempt to close the flow to zero.
Do not overtighten.
6. Compressed gas supplies must be clean and dry.
7. When the auxiliary gas outlets are in use on a machine with cylinder supply only, or if the pipeline supply is not in use, check flow rate requirements, and ensure that adequate back-up cylinders are available.
8. The requirements of IEC 60601-1-1 apply to any device connected to the auxiliary sockets. Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary power sockets
9. In the event of malfunction of any device powered by the auxiliary sockets, check if the circuit breaker has tripped.
10. On machines with pipeline connections, note that a malfunction of the central gas supply within your facility may cause immediate cessation of gas delivery and total anaesthesia system failure.

2. PURPOSE

The Prima SP2 anaesthesia workstation range is intended to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system, from where the anaesthesia ventilator and breathing circuit will then deliver this fresh gas mixture to the patient

Use the Prima SP2 in conjunction with anaesthetic vaporizers, breathing hoses and patient connection fittings which comply with the relevant ISO standard or equivalent.

Depending upon the patient circuit selected, the machines can be used in open, semi-open, semi-closed or closed circuit configurations.

The range has been designed to give a wide choice of configurations and accessories, including:

Gas supplies

Up to four gases - oxygen, nitrous oxide, and air, with optional fourth gas (see section 4).

Pin-index cylinder yokes, and provision for up to three pipeline supply inlets.

Vaporizer mounting systems

Backbar manifold for Selectatec Compatible, or Cagemount type vaporizers.

Anti-hypoxic Device (AHD)

The mechanical AHD system is designed to minimise the risk of a hypoxic mixture reaching the patient (see section 3).

3. DESCRIPTION

3.1 General Construction

Frame

The machine has a cast aluminium base, extruded aluminium uprights, with aluminium and plastic panels.

Mobility

Four castors are fitted, with a brake on each of the front castors. The castors are five inches diameter.

A footrest is built into the front of the machine and, to aid manoeuvrability, two handles are provided.

Mounting posts and brackets

A mounting system is built into each side upright, to allow the use of pole-mount brackets, V-brackets, and ventilator mounting brackets.

The pole mount upright can be used to mount an A200SP Absorber assembly.

Work surfaces

The work surface has raised edges to retain instruments, vials etc.

A pull-out writing tablet is mounted under the work surface.

3.2 Gas Circuit

Gas Circuit Schematic

A gas circuit schematic is shown on the following page.

Gas Supplies

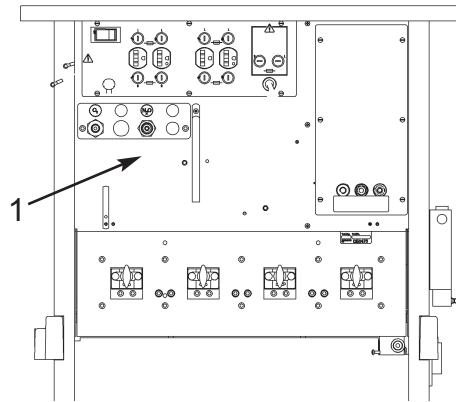
A variety of cylinder and pipeline combinations can be added to the basic specification of oxygen and nitrous oxide cylinder and pipeline supply.

For example, two extra gas cylinders (choose from one additional oxygen, one additional nitrous oxide, one air), and one extra pipeline supply - Air.

Cylinder Yokes

The yokes are rear mounted and conform with ISO standards for pin-index fitting.

To ensure that only cylinders of the appropriate gas may be installed the yokes are designed so that the retaining latch cannot be closed unless the index pins are fully engaged.



Pipeline Inlets (1)

Up to three, rear mounted pipeline gas inlets can be fitted.

Pipeline supply hoses are connected by non-interchangeable, screw threaded unions.

CAUTION

A malfunction of the central gas supply within your facility may cause immediate cessation of gas delivery and total anaesthesia system failure.

Filters

To prevent dirt entering the gas system, cylinder yokes and pipeline inlets are fitted with filters.

Gas Inlet Block

Each individual cylinder or pipeline supply, is routed through a separate gas block.

Each gas block has an integral high pressure gauge tapping for direct mounting of a pressure gauge, and a non-return valve to prevent back flow of gas.

In addition, cylinder gas blocks have a diaphragm pressure regulator to reduce the pressure of the compressed gas supply, and a pressure relief valve, factory set to 517 kPa (75 psi). This prevents pressure build up under the diaphragm should any leakage develop across the reducing valve seat.

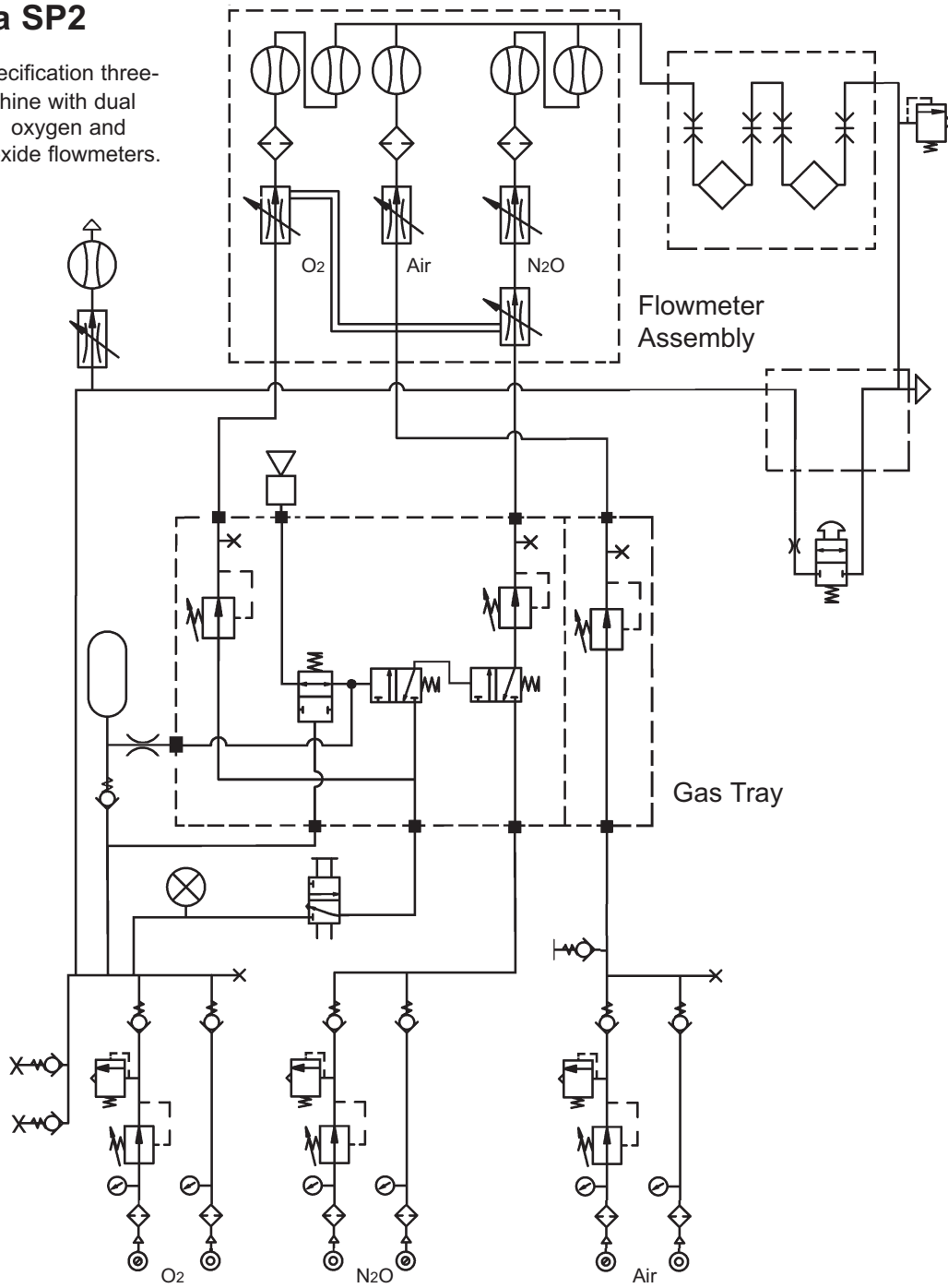
Secondary Pressure Regulator

A second stage regulator reduces the pressure supplied to each flowmeter control (see section 4).

The fitment of a secondary regulator for oxygen and nitrous oxide enhances the performance of the mechanical AHD system. Secondary regulation of the air supply aids the stabilisation of the output at the flowmeter.

Prima SP2

USA specification three-gas machine with dual cascade oxygen and nitrous oxide flowmeters.



	Pneumatic pressure source		Gas cut-off valve (normally open)		Flowmeter
	Pressure gauge		Reservoir		Vaporizer
	Pressure regulator		Pneumatic on/off switch		Oxygen flush valve
	Pressure relief valve		Flow control valve (variable)		Non-return valve
	Audible alarm		Filter		Power take-off point (or test point)
	Restrictor				Visual indicator

DESCRIPTION

3.3 Gas Supply Safety Devices

3.3.1 Gas Supply Cut-off Device

A gas cut-off device, triggered by low oxygen supply pressure, cuts the supply of nitrous oxide, and carbon dioxide or other fourth gas (if fitted).

The cut-off operates when the oxygen pressure falls to 200 ± 14 kPa (29 ± 2 psig).

Gas supplies are reinstated only when the oxygen supply pressure rises above 227 kPa (33 psig).

3.3.2 Oxygen Supply Failure Warning Whistle

WARNING: Refer to WARNING 11 (section 1).

A whistle gives an audible warning when there is a reduction of oxygen supply pressure.

Operated solely by the remaining oxygen in the machine system, the warning whistle is prolonged by an oxygen reservoir built into the gas circuit, allowing a minimum warning whistle of 7 seconds duration.

The whistle will start to sound when the pressure falls to 200 ± 21 kPa (29 ± 3 psig), and will continue to sound until the pressure falls to approximately 70 kPa (10 psig).

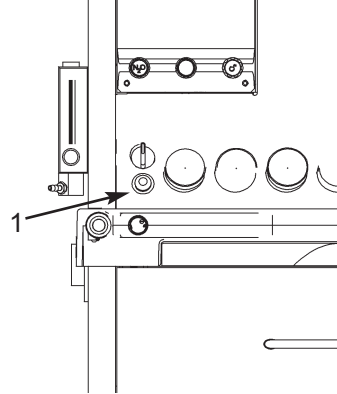
Oxygen consumption of the whistle is approximately 2 L/min when sounding and nil at other times.

3.3.3 Fresh Gas Pressure Relief Valve

A pressure relief valve is mounted between the vaporizer back bar and the common gas outlet (CGO) on the inside face of the machine right hand upright.

It is designed to prevent fresh gas being delivered to the breathing system at pressures exceeding 41 kPa (6 psi).

This valve also protects machine components against excessive pressure in the event of a total blockage of the CGO.



3.3.4 Oxygen Supply Visual Indicator

WARNING: Refer to WARNING 11 (section 1).

The indicator (1) is mounted on the front of the machine and is operated from the oxygen supply and shows GREEN when the supply is at working pressure, and RED if the pressure falls.

3.3.5 Mechanical AHD

A mechanical link between the oxygen control valve and a needle valve in the nitrous oxide flow ensures that the machine delivers a fresh gas mixture with a minimum 30% ($\pm 3\%$) oxygen, irrespective of the flow of nitrous oxide set by the anaesthetist. With the nitrous oxide control valve fully open, the oxygen and nitrous oxide flows are then both controlled by the oxygen control valve.

See section 3.4 for a full description

3.3.6 Low Pressure Gas Tubing

Diameter-indexed tubing is used for the low pressure gas system - see section 4.

DESCRIPTION

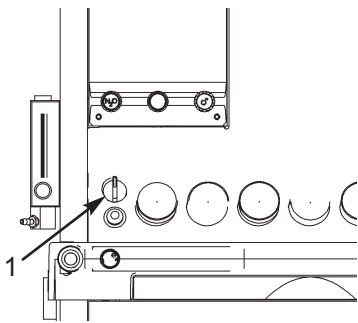
3.4 Mechanical AHD (Anti Hypoxic Device)

3.4.1 Introduction

The Mechanical AHD is housed within the flowmeter module and comprises a gear linkage between the oxygen control valve and a needle valve in the nitrous oxide flow.

The system controls the relative flow rates of oxygen and nitrous oxide.

A predetermined minimum oxygen concentration of 30% \pm 3% in the oxygen / nitrous oxide mixture is maintained over the flow range to prevent delivery of a hypoxic mixture.



3.4.2 Gas Delivery Switch (1)

The Gas Delivery Switch (1) operates on the oxygen supply and must be in the 'On' position for normal operation of the anaesthetic machine.

The switch consequently controls the supply of all gases provided with a gas cut-off triggered by a predetermined pressure level within the oxygen supply (see section 3.3.1).

A whistle (oxygen failure warning whistle) will sound briefly whenever the gas delivery switch is turned on or off. Note that the whistle functions continuously if the oxygen supply fails (see section 3.3.2).

NOTE

The switch also controls the electrical supply to the optional flowmeter lighting unit.

3.4.3 Gear Linkage and Nitrous Oxide Control Valves

A gear linkage connects the oxygen control knob on the flowmeter module and a needle valve in the nitrous oxide flow. This linkage limits the flow of nitrous oxide relative to the flow of oxygen set by the user.

Note that this needle valve acts as the primary nitrous oxide valve, and is actuated only by movement of the oxygen control.

The nitrous oxide control knob on the flowmeter module operates a secondary needle valve in the nitrous oxide flow. It is positioned downstream of the primary valve and therefore is used only to restrict the flow already set by the primary valve, which itself has been determined by the position of the oxygen control knob.

Therefore, for any oxygen flow set by the user, the mixture delivered will still contain a minimum 30% \pm 3% oxygen even with the nitrous oxide control knob fully open.

As the nitrous oxide knob is progressively closed, the oxygen content of the mixture increases to 100%.

3.4.4 Oxygen Basal Flow

To allow the system to function correctly, an oxygen basal flow is continuously supplied.

Single Flow Tubes: 100 - 200 ml/min

Dual Cascade System Flow Tubes:
50 - 75 ml/min

This basal flow can only be turned on and off by using the Gas Delivery Switch.

CAUTION

The oxygen control is restricted to prevent the needle valve from fully closing. This ensures a minimum oxygen basal flow.

DO NOT attempt to close the flow to zero. Do not overtighten the knob.

3.5 Pressure Gauges

Pressure gauges (50 mm diameter) are located on the front panel below the flowmeter bank.

The gauge for Air is positioned between oxygen and nitrous oxide. Unused gauge positions are blanked out.

All pressure gauges are colour coded and labelled for the gases whose pressures they are indicating.

Cylinder gauges are marked: CYLINDER.

Pipeline gauges are marked: PIPELINE.

The gauges are calibrated in kPa x 100.

DESCRIPTION

3.6 Flowmeters and Controls

3.6.1 All models

The flowmeters, mounted behind the perspex cover on the left hand side of the machine, are length-indexed to prevent inadvertent, incorrect installation.

All floats indicate flow rate in line with the upper surface as shown below.

Each flow control valve is positioned directly underneath the flow tube assembly to which it corresponds, and the control knob is colour-coded for the gas which it controls.

The oxygen flow control knob is made physically distinguishable from the other flow controls for identification by touch in accordance with ISO standards.

When fitted, air and carbon dioxide flowmeters are always installed in the inner positions on the flowmeter assembly. These positions are blanked out if air or carbon dioxide are not specified for the machine.

The gas delivery switch (see 3.4.2), positioned on the front panel controls the supply of oxygen and must be in the ON position for normal operation of the machine.

Flow control of each gas is achieved by a needle valve comprising a polished stainless steel needle mounted concentrically in a common manifold block. To minimise wear and material pick-up the needle seat is manufactured from silver. The flow control knob is turned counter-clockwise to increase the gas flow.

CAUTION

Needle valves are designed to seal with light torque and may be damaged if tightened excessively. DO NOT USE EXCESSIVE FORCE.

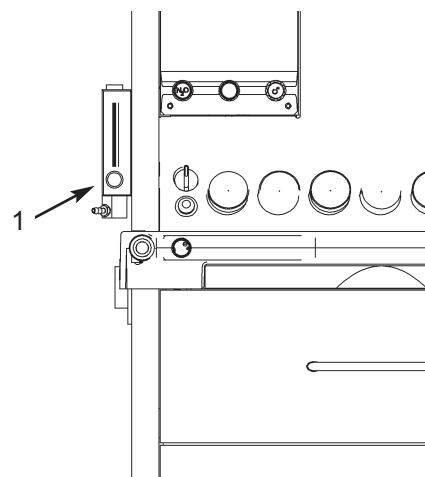
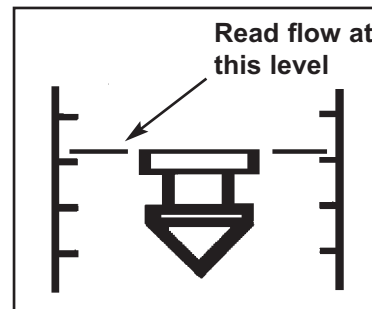
3.6.2 Dual Cascade Flow Tubes

The flow of gas through dual cascade system flow tubes always flows through the low-flow tube first. The high-flow tube should not show any flow until more than 1 L/min is set.

At flows above 1 L/min, the high-flow tube reading indicates the rate of flow for that gas.

3.6.3 Auxiliary Oxygen Flowmeter

An oxygen flowmeter (1), with outlet, is mounted to the left of the machine flowmeter bank.



DESCRIPTION

3.7 Vaporizers

CAUTION

Read the instruction manual supplied with the vaporizer before clinical use.

3.7.1 Vaporizer Mounting Systems

Vaporizers for the administration of volatile anaesthetic agents can be fitted as follows:

- (a) Penlon Delta Selectatec compatible vaporizers, mounted on a Selectatec compatible universal backbar.
- (b) Penlon Delta Cagemount vaporizers mounted on a Modura rail (check that relevant national standards for your country allow fitment of more than one cagemount type vaporizer).

WARNING

Vaporizers must always be securely mounted, and never used free-standing. Unmounted vaporizers may be accidentally tipped resulting in uncalibrated and excessive volumes of liquid anaesthetic drug entering the breathing system.

Vaporizers of any description must not be installed or connected between the Common Gas Outlet (CGO) and the Breathing System, unless they are specifically designed for such use. (If this is done, the oxygen flush flow will pass through the vaporizer, and severe overdosage may result).

3.7.2 Selectatec Compatible Vaporizer

Selectatec compatible vaporizers, (e.g. the Sigma Delta with the Selectatec connector block), may be mounted on a universal backbar manifold, built onto the Prima SP range as an option.

Single and two-station manifolds are available, with each station fitted with two valve capsule assemblies for vaporizer connector block attachment.

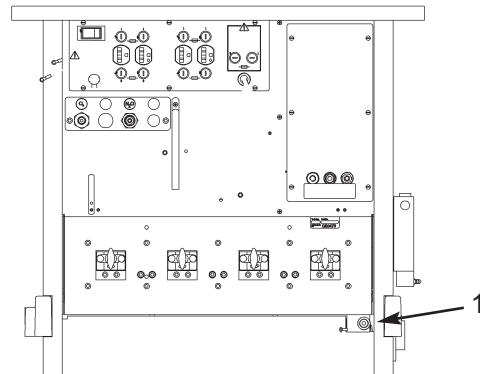
When a vaporizer is installed on a station the valves on that station open automatically to allow gas flow into and out of the vaporizer. Removal of the vaporizer from the station closes the valves on that station. Selectatec compatible vaporizer interlock systems are described in the literature supplied with the vaporizer.

3.7.3 Cagemount Vaporizer

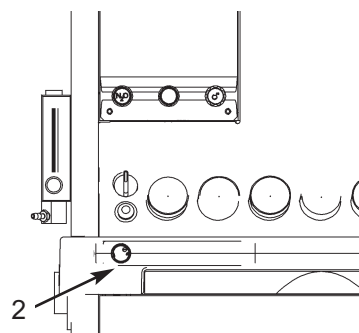
Vaporizers fitted with cagemount tapers have the male taper (inlet port) on the left, and the female taper on the right (viewing the front of the vaporizer).

It is recommended that detachable cagemount connectors are retained with a safety clip (catalogue number 52275) to prevent inadvertent disconnection.

3.8 Common Gas Outlet (CGO)



The outlet (1) can be located at the front or rear of the machine, and has a 22 mm male taper and concentric 15 mm female taper. The male taper incorporates the Penlon Safelock system designed to prevent accidental disconnection of the breathing system.



Oxygen Flush

An emergency oxygen flush valve button (2) is mounted at the front of the machine and is marked 'O₂ FLUSH'.

Depressing the button provides a delivery of between 35-75 litres/min of oxygen through the common gas outlet (1).

Releasing the button allows the spring-loaded valve to return to its normal position.

DESCRIPTION

3.9 Electrical Power Supply

3.9.1 Mains Power Supply

Power is fed to the machine via the mains lead, to power an optional auxiliary output panel, and/or lighting system.

Mains Power Indicator

The warning lamp (1) is illuminated, when mains power is connected.



Current Leakage

NOTE

a) It is the user's responsibility to ensure that the total sum of leakage currents from additional equipment plugged into the auxiliary sockets plus the leakage current from the machine does not exceed the values specified in any relevant national standards that may apply in the country where the machine is in use (see also, below)

b) Each socket is protected with a 5 A fuse in both the live and neutral wire.

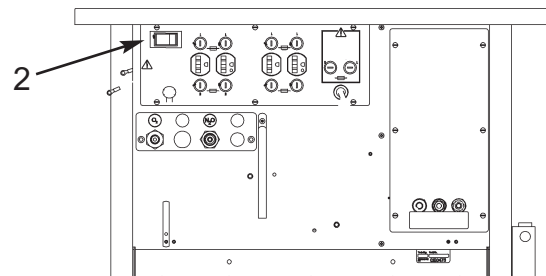
3.9.2 Auxiliary Power Supply Sockets

CAUTION

The requirements of IEC 60601-1-1 apply to any device connected to the auxiliary sockets. Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary power sockets.

The optional mains electricity outlet panel is fitted to the rear of the machine.

The supply is controlled by an ON/OFF switch (2), which also incorporates a circuit breaker.



Switch labelling: I indicates On
 0 indicates Off

CAUTION

In the event of malfunction of any device powered by the auxiliary sockets, check if the circuit breaker has tripped.

3.9.3 Flowmeter Bank Lighting

The lighting system is controlled by a three-way switch (3).

The three positions denote:

- A: Off
- B: Bright light
- C: Dim light



DESCRIPTION

3.9.4 Ventilator Power Supply

The mains lead for an AV-series ventilator can be plugged into one of the auxiliary power sockets on the rear of the machine.

AV-S with interface link to Prima SP2

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

For further information, refer to section 3.6 in the AV-S user manual.

AV-S Ventilator Back-up Battery

If the power supply to the ventilator fails, the ventilator back-up battery will power the ventilator for 30 minutes, if the battery has been maintained in a fully charged condition. Refer also to the user instruction manual supplied with the ventilator

Battery charging takes place automatically when the ventilator mains lead is connected to a 'live' mains supply.

The OFF indicator on the ventilator front control panel will show a yellow light during charging.

NOTE

The stated battery back-up period will only be available if the battery is kept fully charged. If the battery has been allowed to discharge below the LOW BATTERY condition, the ventilator will not function correctly until the voltage raises above the LOW BATTERY level. A fourteen hours recharge will be necessary to bring the battery to full charge.

3.9.5 Monitor and other Accessories

The mains lead (or adaptor) for a monitor system or other accessories requiring an electrical supply can be plugged into one of the auxiliary sockets on the rear of the machine.

DESCRIPTION

3.10 Auxiliary Gas Outlets

CAUTION

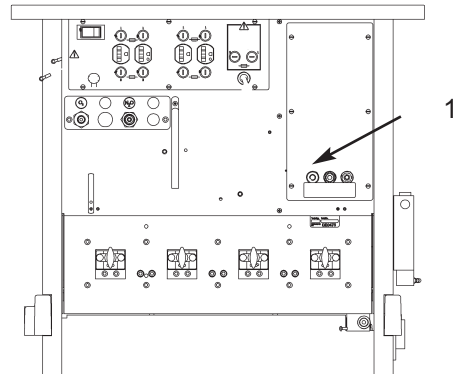
When the auxiliary gas outlets are in use on a machine with cylinder supply only, or if the pipeline supply is not in use, check flow rate requirements, and ensure that adequate back-up cylinders are available.

Oxygen and Air

Auxiliary outlets (1) are mounted on the rear of the machine.

Supply pressure

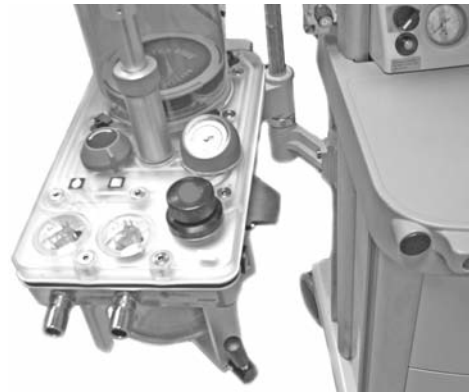
See section 4.5



3.11 A200SP Absorber

The A200SP Absorber and ventilator bellows assembly is mounted on a polemount bracket attached to the machine frame upright.

Refer to the user instruction manual for A200SP for detailed information on installation and operation.



3.12 AV-S Ventilator

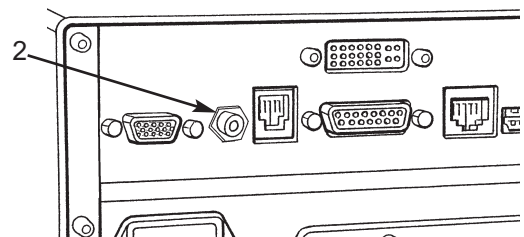
Interface to Prima SP 2

An interface cable links the gas delivery switch on the anaesthetic machine, via a socket (1) on the rear panel of the machine to the socket (2) marked 'Prima Master' on the rear of the ventilator control unit.

Ventilator ON/OFF function

- Turn the machine Gas Delivery Switch (see 3.4.2) ON.
The ventilator will power-up.
- While the Prima SP2 power is ON, the Ventilator can be turned OFF and ON, using the ventilator On/Off switch (refer to ventilator user manual).
- Turn the Gas Delivery Switch to OFF.
The ventilator will power-down.

Refer to the user instruction manual for AV-S for detailed information on installation and operation.



4. SPECIFICATION

4.1 Physical Dimensions

Overall frame size:	Height x Width x Depth (cm) 139 x 71 x 70
Work surface	
Height:	86 cm
Size:	58 cm x 25 cm
Loading:	30 kg (66 lb) - evenly distributed.
Writing tablet:	30 x 22 cm
Top shelf:	71 cm x 35 cm
Loading:	30 kg (66 lb) - evenly distributed.
Drawers:	12 x 54.5 x 35 cm
Loading:	10 kg (22 lb) - evenly distributed
Castors:	Diameter: 127 mm (5 inches) Front pair braked
Ventilator bellows post	Bushed to accept 25.4 mm (1 inch) or 22 mm (7/8 inch) poles.
Loading:	30 kg (66 lb)
Gas scavenging fixing	Bracket on frame upright
Loading:	30 kg (66 lb)
Common gas outlet:	22 mm male taper with coaxial 15 mm female taper connections, Safelock fitting
Weight:	75 kg (165 lb) (approximate, depending on specification)

SPECIFICATION

4.2 Gas Supplies

Cylinders: A maximum of four cylinder fittings can be specified
All cylinder yokes are pin-indexed

Fourth Gas Options: Carbon dioxide, Helium, Xenon

Pipeline: Maximum of three (oxygen, nitrous oxide, air).
All specifications to relevant national standards.

Medical gas colour codes:

Oxygen	Green or White*
Nitrous oxide	Blue
Medical air	Yellow or Black/White*
Carbon dioxide	Grey
Helium	Brown
Xenon	Green (bright)

**To comply with relevant national standards.*

Internal pipework is diameter indexed for each gas:

Oxygen	8 mm	Carbon Dioxide	4 mm
Nitrous oxide	6 mm	Helium	4 mm
Air	5 mm	Xenon	4 mm
Mixed gas	10 mm		

4.3 Flowmeters

Flow ranges:

Single flow tubes:

Oxygen:	0 - 10 L/min
Nitrous Oxide:	0 - 10 L/min
Air	0 - 10 L/min
Helium	0 - 10 L/min

Cascade flow tubes:

Oxygen / Air / Nitrous Oxide	(1)	0 - 1000 ml/min
	(2)	0 - 10 L/min (graduated 1 - 10 L/min)

Flowmeter Accuracy

The accuracy of the flowmeter tubes is $\pm 2.5\%$ of full scale reading.

Flowmeter construction and dimensions

Tubes and floats are matched, and must not be interchanged.
Flowmeter tubes have antistatic coatings.

Tubes are length indexed:

Oxygen	260 mm (10.24 inch)
Nitrous oxide	250 mm (9.84 inch)
Other gases	240 mm (9.45 inch) (see 3.12)

Scale length 152 mm (6 inch) minimum
(all tubes except carbon dioxide)

SPECIFICATION

4.4 Gas Pressures

	USA/ Canada/Japan	UK
Pipeline supplies:	340 kPa (50 psig)	400 kPa (58 psig)
Cylinder supplies:		
Reduced pressure from regulator (at 5 L/min flow)	310 kPa +15 kPa / -35 kPa (45 psig +2 psig / -5 psig)	380 kPa +15 kPa / -35 kPa (55 psig +2 psig / -5 psig)
Regulator diaphragm bursting pressure	2800 kPa (406 psig)	2800 kPa (406 psig)
Reduced pressure system safety valve	600 kPa (87 psig)	600 kPa (87 psig)
Safety valve (protects flowmeter, vaporizer etc.)	41 kPa ±10% (6 psi ±10%)	41 kPa ±10% (6 psi ±10%)
Reduced pressure from secondary regulators (at 5 L/min flow)		
Oxygen and Nitrous Oxide	152 - 241 kPa (22 - 35 psi)	
Air	207 - 283 kPa (30 - 41 psi)	

4.5 Auxiliary Gas Outlets

Pipeline supply:	Gas is supplied at pipeline supply pressure (see above)
Cylinder supply:	Gas is supplied at reduced pressure from cylinder regulator (see above)

Oxygen

Two self sealing connections on rear of machine

Total flow rate: not less than 100 L/min to free air

80 L/min against 243 kPa (36 psig) resistance

70 L/min against 270 kPa (40 psig) resistance

50 L/min against 297 kPa (44 psig) resistance

Air (on machines with Air supply option)

One self sealing connection on rear of machine.

4.6 Oxygen Failure Warning Devices

1. Gas system whistle
2. Visual indicator, direct pressure operated

4.7 Oxygen Flush

Button on front edge of worksurface

The system supplies 35 - 75 L/min when the button is fully depressed.

SPECIFICATION

4.8 Mechanical AHD System

Minimum oxygen concentration: 30% ± 3% (of total O₂ + N₂O flow)

Basal Flow

Cascade flow tubes

Oxygen basal flow 50-75 ml/min

Single Flow tubes

Oxygen basal flow 100-200 ml/min

Reduced pressure from secondary regulators:

See section 4.4.

4.9 Environmental

Operating Conditions

Temperature

+10 to 38°C (50 to 100°F)

Atmospheric Pressure range

70 kPa to 106 kPa

Altitude

2438 m (8000 ft) maximum

Humidity

10 - 95% R.H. non-condensing.

Transport and storage temperature:

Basic machine

-5 to 40°C (23 to 112°F)

Oxygen monitor option

-5 to 50°C (23 to 122°F)

Cleaning

Wipe external surfaces with dry or damp cloth.

Use mild soap, or disinfectant solution if necessary.

Please refer to section 6.1.

4.10 Electrical Supply

Power Input

NOTE: The internal power circuit feeds the machine lighting systems only.

Option 1: Internal power / auxiliary power sockets

US/CSA specification machines: 110 - 120 VAC, 60 Hz, 1350 VA maximum

Non-US/CSA specification machines: 100 - 240 VAC, 50 - 60 Hz, 1100 - 2500 VA maximum

Option 2: Auxiliary power outlets / No internal power

US/CSA specification machines: 110 -120 VAC, 60 Hz, 1200 VA maximum

Non-US/CSA specification machines: 100 - 240 VAC, 50 - 60 Hz, 1000 - 2400 VA maximum

Option 3: Internal power / No power outlets

Non-US/CSA specification machines only: 100 - 240 VAC, 50 - 60 Hz, 100 VA maximum

Fuses (internal power): T2AH ceramic (¼ x 1¼ inch) high breaking capacity fuses

Power cable: Permanently attached lead (3 m), with stowage hooks on rear.

SPECIFICATION

Power Outlets

Auxiliary power outlets	Four outlets: 5 A per outlet 10 A maximum total
Fuses	T5AH ceramic (¼ x 1¼ inch) high breaking capacity fuse on Live and Neutral on each outlet
Overload Protection	10 A thermal circuit breaker incorporated within the power outlet On/Off switch

Electromagnetic Compatibility

The Prima SP2 meets the requirements of EN 60601-1-2 (electromagnetic compatibility - requirements and tests)

4.11 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

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



5. PRE-USE CHECKS

5.1 Pre-use Checklist

A pre-use checklist for the Prima SP2 range of machines is printed on the next page. This checklist is also supplied with the machine.

Where necessary, subsequent sections in this manual provide an explanation and procedure for setting up the machine and ancillary equipment and the various checks that must be carried out before clinical use.

WARNING

Pre-use checks must be performed before each period of clinical use.

These checks must be supplemented by periodic Function Testing, and full Service Testing by a Penlon-trained engineer to the Service Schedule given in the Prima SP2 Service Manual.

Note that these checks will not in themselves ensure the safe use of the apparatus, which remains the responsibility of the qualified practitioner in charge of it.

PRE-USE CHECKS

PRE-USE CHECKLIST

The machine must be carefully inspected and checked as follows.

An incorrectly functioning machine must be repaired by a suitably qualified person before use.

1. Check for visible damage, machine stability, and condition of gas supply hoses.
2. Check for labelling which may indicate status of machine, including faults or recent servicing.
3. Check correct connection of electrical supply.
4. Check correct connections of gas supplies.
5. Check adequate pipeline supply and back-up cylinder supply.
6. Switch on gas delivery switch, and note special operating system:
Check functioning of flowmeters.
Check function of Mechanical AHD
7. Check correct connection and functioning of the vaporizers.
8. Check functioning of oxygen flush.
9. Check leak rate of low pressure gas system.
10. Check the integrity of the patient circuit.
11. Test the alarm system.

Refer to Section 5 for further information.

Ancillary equipment

12. Check operation of the AGSS.
13. Check functioning of ventilator, including disconnect alarm.
14. Check that the oxygen analyser and other patient monitoring equipment functions correctly.

Refer to the relevant user manual for further information.

PRE-USE CHECKS

5.2 Pre-use Checks - Gas Supply

5.2.1 Gas Pipeline Supplies

Oxygen supply:

1. Connect the oxygen pipeline hose **only**.
Check that the correct pressure gauge reading is obtained.
2. Turn on the Gas Delivery switch (1).
Check that the warning whistle sounds briefly, and that the correct basal flow of oxygen is delivered (see section 3.8).
3. Open both oxygen and nitrous oxide flowmeter valves.
Check that flow is only shown in the oxygen flowmeter.
4. Close both valves.
Turn off the Gas Delivery switch.
Check that the warning whistle sounds briefly, and that the oxygen basal flow is stopped.

Nitrous Oxide supply:

5. Connect the Nitrous Oxide pipeline hose.
Check the gauge reading.
Turn on the Gas Delivery switch (1).
Check for a flow of nitrous oxide when the flowmeter needle valve is operated.

NOTE: cylinder supply can be used if necessary for this test.

Air supply:

6. Connect the Air pipeline hose.
Check the gauge reading.
Check for a flow of air when the flowmeter needle valve is operated.

5.2.2 Gas Cylinder Supplies

CAUTION

Open the cylinder valves slowly to avoid damage to the pressure reducing valve and pressure gauges. Ensure that valves are at least one full turn open when in use.

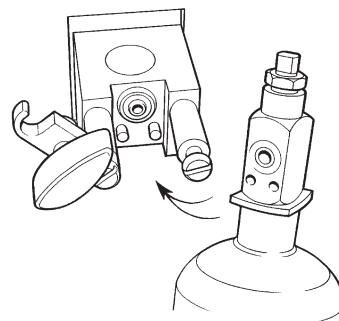
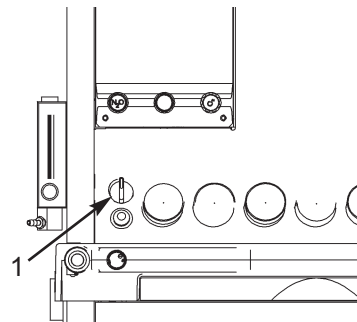
1. Fit the gas cylinders to their respective yokes, open the cylinder valves one at a time and check the pressure on each gauge.

NOTE

- a) *When two cylinders are provided for a single gas, test each separately, clearing pressure after each test by opening the flowmeter valve.*
 - b) *Turn off the reserve cylinders during normal use.*
 - c) *N₂O: cylinder pressure does not indicate cylinder content.*
2. Ensure that all flowmeters are kept closed until gas supplies are required.

CAUTION

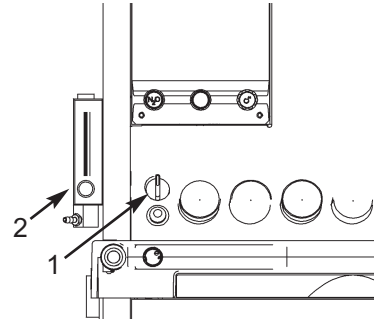
The mechanical AHD system requires that the oxygen flowmeter control is restricted to prevent the needle valve from fully closing. This ensures a minimum oxygen basal flow. DO NOT attempt to close the flow to zero. Do not overtighten the knob.



PRE-USE CHECKS

5.2.3 Flowmeters

1. Turn on the Gas Delivery switch (1) and check that the warning whistle sounds briefly briefly, and that the correct basal flow of oxygen is delivered (see section 4).
2. Open the nitrous oxide flowmeter needle valve and check that there is no nitrous oxide flow.
3. Operate the oxygen flowmeter needle valve.
Check that full scale of flow of oxygen and nitrous oxide can be achieved, and that the floats in both tubes move freely and rotate when at a steady flow.
4. Check that the nitrous oxide flow can be turned off by gentle rotation of the oxygen knob.
Check also that the nitrous oxide float reseats on the bottom stop, and that the oxygen basal flow continues to flow.
5. Operate the other flowmeter control knobs in turn to check:
the full scale of flow can be obtained;
the floats move freely and rotate at a steady flow;
the flow can be turned off by gentle rotation of the knob; and that
the floats reseal on the bottom stop.
6. Dual cascade flow tubes:
Check that gas flow is through the low flow tube initially until full flow is achieved, then through the high flow tube.
7. Auxiliary flowmeter (2)
Rotate the flowmeter control and check that a gas flow can be obtained.



PRE-USE CHECKS

5.3 Vaporizers

5.3.1 Pre-use Checks

On ALL vaporizers, before use:

1. Check all joints for gas tightness.
2. Check vaporizer agent level.
3. Check for correct agent delivery concentrations - use an agent analyser.

Always follow the procedures and checklist given in the instruction manual supplied with the vaporizer, particularly when filling the vaporizer with anaesthetic agent.

5.3.2 General Information

WARNING

Vaporizers must always be mounted, never used free-standing.

Free standing vaporizers may be accidentally tipped resulting in excessive and uncalibrated volumes of anaesthetic drug entering the breathing system.

Do not install or connect any vaporizer of any description between the CGO and the breathing system, unless it is specifically designed for such use. (This allows the oxygen flush flow to pass through the vaporizer, and severe overdose may result).

5.3.3 Selectatec Mounting System

Up to two Selectatec compatible vaporizers may be fitted (up to three on SP3 models).

To install the vaporizer:

- a) Carefully offer the vaporizer up to the manifold.
- b) Check that the gas connection ports on the vaporizer are aligned with the valves on the manifold.
- c) Carefully lower the vaporizer onto the manifold and lock the vaporizer into position by clockwise rotation of the locking lever through 90°.

NOTE Do not use excessive force to lock the vaporizer onto the manifold. Damage to the locking fastener will result.

CAUTION

To prevent damage to the locking shaft, ensure that the gas connection ports are aligned with the valves on the manifold, and are correctly engaged, before tightening the locking lever.

5.3.4 Selectatec Compatible Vaporizers with Interlock

WARNING

Only vaporizers with the Selectatec compatible interlock function will interlock if installed on a two station or three station manifold.

The installation of non-interlock vaporizers allows the possible operation of more than one vaporizer at the same time.

If two vaporizers only are mounted on a three station manifold, they must be installed on adjacent stations (i.e. the middle station must be occupied).

Check that the interlock mechanisms of all the vaporizers on the manifold are working correctly, i.e. check that only one vaporizer at a time can be turned on.

5.3.5 Cagemount Vaporizer

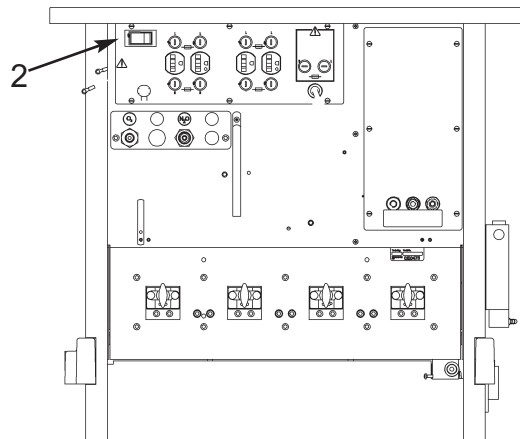
Some international standards demand that this type of vaporizer should only be used on machines with a single mounting station.

In addition, use safety clip (Cat. No. 52275) to retain the cagemount taper cones in position on the vaporizer.

PRE-USE CHECKS

5.4 Electrical Supply

1. Connect the machine power lead to a suitable mains supply socket.
Check that the mains indicator light is on.
2. Set the auxiliary power supply switch (2) to ON.
Check for correct function of each auxiliary power outlet
3. Check all electrical equipment, including devices powered by the auxiliary power outlets on the rear of the machine.
4. Machines with optional flowmeter lighting:
Check for correct operation (section 3.9.3).



PRE-USE CHECKS - All models

5.5 Patient Breathing System

5.5.1 Hose Connections

Check that all hoses are secure.

5.5.2 Breathing System Hose, Reservoir Bag, Ventilator

Connectors for the Inspiratory hose and Expiratory hose, and the reservoir bag connector are 22 mm male.

All connectors comply with ISO 5356/1.

The ventilator connection point is also 22 mm male.

Hose and bag connections are fitted with Penlon Safelock high security fittings.

Check all connections for gas tightness.

5.5.3 Fresh Gas Supply

The fresh gas hose assembly supplied with the machine has a Penlon connector at the absorber inlet and a 22 mm Safelock taper at the other end.

This should be connected to the common gas outlet of the anaesthetic machine.

Check all connections for gas tightness.

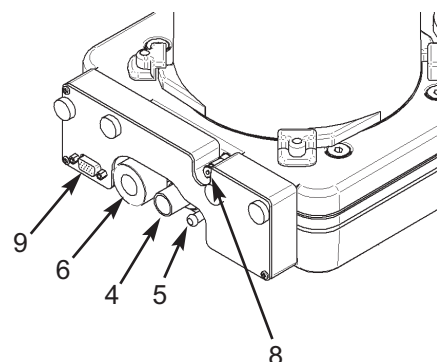
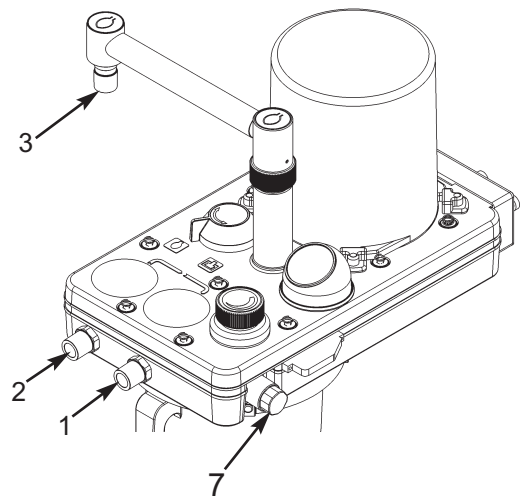
5.5.4 A200SP Absorber

Always follow the pre-use check procedures given in the instruction manual supplied with the absorber.

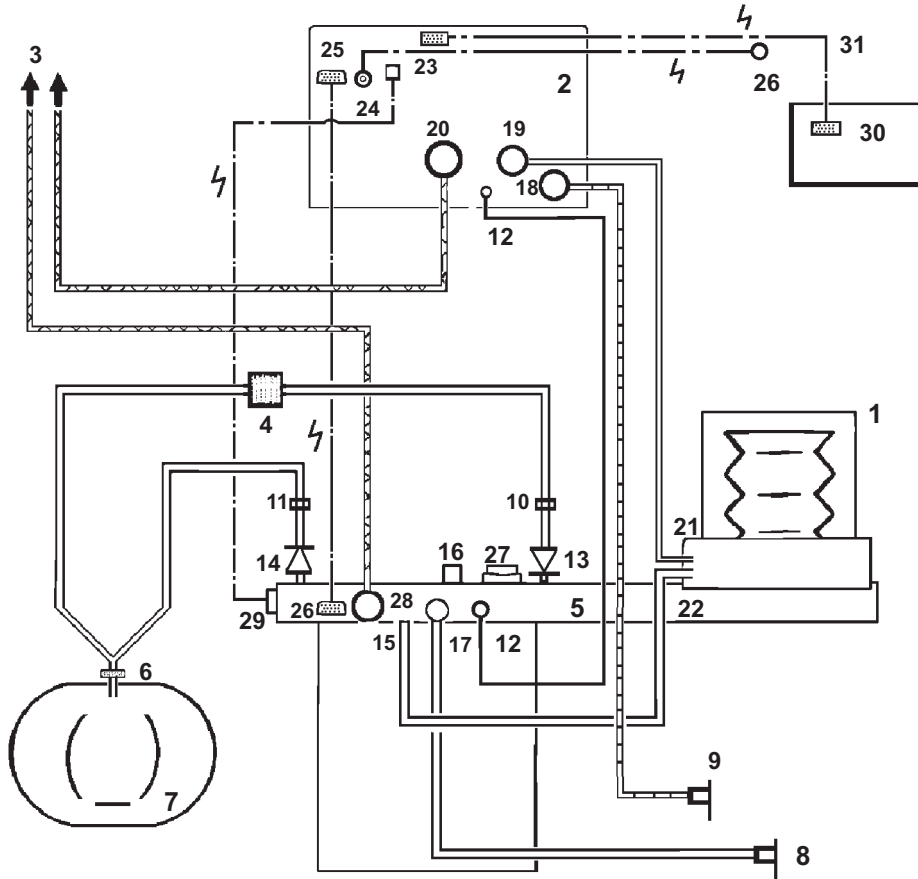
The use of an oxygen monitor (and a carbon dioxide analyser) is highly recommended when using any partial rebreathing anaesthetic system.

A200SP Connections

1. Inspiratory connector
2. Expiratory connector
3. Bag connector
4. Inlet - from DRIVE GAS outlet on ventilator control unit.
5. Inlet - fresh gas hose from Common Gas Outlet
6. Exhaust outlet from APL Valve - connect to Anaesthetic Gas Scavenge System
7. Oxygen monitor sensor
8. Outlet - sample line to Pressure Monitor Port on ventilator
9. Interface cable - Bag/Vent switch and spirometer (connects internally to Prima SP On/Off Switch interface, then to connector on ventilator control unit rear panel).



PRE-USE CHECKS



Note

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

- | | |
|--|--|
| <ol style="list-style-type: none"> 1. Bellows 2. Ventilator Control Unit 3. Outlets to Anaesthetic Gas Scavenging System (AGSS) 4. Bacterial Filter 5. Absorber valve block 6. Heat and moisture exchanger 7. Patient 8. CGO Block on anaesthetic machine (Fresh Gas Supply) 9. Auxiliary Outlet on anaesthetic machine (Drive Gas Supply) 10. Flow sensor - expiratory 11. Flow sensor - inspiratory 12. Connectors - sensor - pressure monitor 13. Expiratory Valve - Absorber 14. Inspiratory Valve - Absorber 15. Inlet - from Ventilator Bellows 16. Connector - Reservoir Bag 17. Inlet - Absorber - Fresh Gas Supply | <ol style="list-style-type: none"> 18. Drive Gas Inlet - Ventilator 19. Drive gas Outlet - ventilator control unit to bellows 20. Outlet - Exhaust Valve 21. Inlet - Bellows Drive Gas 22. Outlet - to breathing system 23. Input socket - Oxygen monitor sensor 24. Input socket - Prima SP interface (SP on/off switch) 25. Input socket: <ol style="list-style-type: none"> (i) A200SP Absorber Bag/Vent control position (ii) Spirometer sensor signal 26. Interface connections on Prima SP and A200SP 27. APL Valve 28. Outlet from APL Valve to AGSS 29. Oxygen sensor 30. AV-S remote screen 31. Cable (AV-S control unit to remote screen) |
|--|--|

PRE-USE CHECKS

5.5.5 Breathing Circuit Schematic

NOTE

1. To protect the expiratory limb of the breathing circuit, and the spirometer, use a breathing circuit bacterial filter (4), and a heat and moisture exchanger (6) at the patient Y-piece.

CAUTION

Replacement/Disposal - always follow the instructions supplied with the filter or heat and moisture exchanger.
Always renew components at the recommended interval.

2. Follow the instructions in the relevant user manual for connection to analysers and monitors.
3. Ventilator connections shown are for AV-S with spirometry and oxygen monitor.
4. For A200SP, refer also to the user documentation supplied with the absorber.

5.5.6 System Low Pressure Leak Test

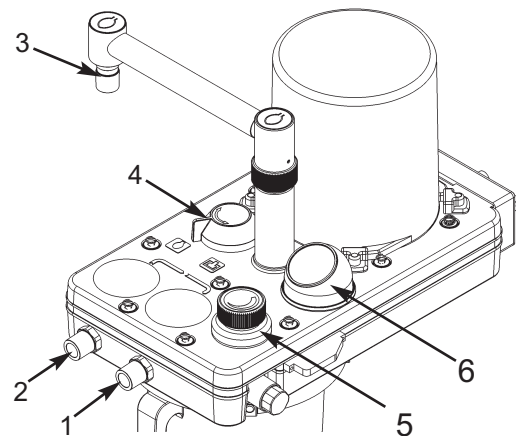
Connect the CGO outlet on the machine to the fresh gas inlet of the A200SP absorber.

NOTE

This machine must be fitted with a breathing system complying with approved design parameters, at the selection of the qualified practitioner.

The breathing system components do not constitute part of the machine but connections between the machine and breathing system should be verified as follows:

1. Fit a patient circuit to the inspiratory connector (1) and expiratory connector (2) on the absorber, and a breathing bag to the bag arm connector (3).
2. Set the bag/ventilator switch (4) on the absorber to 'Bag'
3. Close the adjustable pressure limiting (APL) valve (5), and occlude the patient connection port on the patient circuit. Press the oxygen flush valve button on the front of the machine briefly. Check that the reservoir bag inflates and the manometer (6) indicates approximately 40 cmH₂O.



4. Release the oxygen flush valve. Check that the pressure is maintained in the system with less than 200 ml/min fresh gas delivered into the breathing system, showing that no leaks are present.
5. If this test fails, check the low pressure system on the machine (section 5.6). If the low pressure test on the machine is successful, check the ventilator and absorber, referring to the relevant user instruction manual.

PRE-USE CHECKS

5.6 Machine Low Pressure Leak Test

NOTE

This test is necessary if the system fails the low pressure test 5.5.6.

1. Attach a side branch connector to the CGO outlet. Connect the side branch tube to a sphygmomanometer.
2. Turn on a flow of 150 ml/min of oxygen. Block the open port of the connector with a finger. The pressure in the low pressure gas system will rise and be displayed on the sphygmomanometer.
3. Check that the pressure rises to at least 100 mmHg. Release the finger seal immediately the pressure is reached.

CAUTION

Do not maintain closure of the open port longer than necessary to perform the test.

This test should be performed:

- (a) *With all vaporizers 'off' and isolated.*
- (b) *With each vaporizer in turn set to 1%.*

NOTE

This test is equivalent to (and in some cases exceeds) the requirements for system leakage rates quoted in national standards worldwide.

5.7 Oxygen Flush

Check for a high flow of oxygen through the CGO outlet when the flush valve button is pressed and that the flow ceases when the button is released.

This test is most conveniently done after the breathing system has been attached, using the reservoir bag as an indicator of gas flow.

5.8 Anaesthetic Gas Scavenge System (AGSS)

By inspection, check that all sources of expired anaesthetic gases, e.g. the absorber APL valve, and the ventilator bellows patient gas exhaust port, are connected to an approved collection system leading to an AGSS.

WARNING

Vacuum systems must not be connected directly to the APL valve on the absorber. A receiving system with a positive and negative pressure control function must be interposed.

Systems must comply with standard ISO 8835 part 2.

PRE-USE CHECKS

5.9 Ventilator

Always follow the pre-use check procedures given in the ventilator instruction manual.

Check all hose and tubing connections for gas tightness.

Check all wiring connections for correct fitment and security.

AV-S Ventilator Interface

Check the Interface Cable

Check for correct fitment of the interface cable at the socket (1) on the rear panel of the Prima SP2, and the connection on the AV-S control unit, marked 'Prima master'.

Check the interface system function

- a) Turn the Gas Delivery Switch ON.
The ventilator will power-up.
- b) While the Prima SP2 power is ON, the ventilator can be turned off and on, using the ventilator On/Off switch.
- c) Turn the Gas Delivery Switch to OFF.
The ventilator will power-down.



PRE-USE CHECKS

5.10 Alarm System Test

WARNING

The anaesthetic machine must not be used if any alarm is not functioning correctly.

Primary Oxygen Failure Alarm

The machine is fitted with a warning whistle and a visual indicator (1).

These components act as oxygen supply failure devices and constitute the primary alarm system, powered only by the residual oxygen supply, as described in section 3.

The system can be checked whenever the low pressure oxygen system is first pressurised by turning on a cylinder or connecting a pipeline.

- a) The whistle will sound briefly as pressure increases, and,
- b) The visual indicator will turn from red to green.

Whistle, Visual Indicator, and Gas Cut-off Device Test

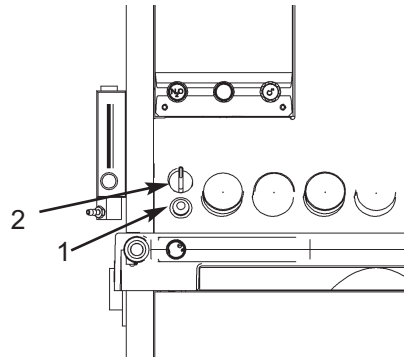
A formal test (including the action of the internal gas cut-off device) is performed as follows:

1. Connect oxygen, nitrous oxide and air supplies.
2. Set the Gas Delivery switch (2) to ON, and check that the warning whistle sounds briefly.
3. Set a flow of 2 L/min on both flowmeters.
4. Disconnect the oxygen supply at the wall socket or close the oxygen cylinder valve and check:
 - a) that as the oxygen flow slows down, the whistle starts to sound and continues for at least 7 seconds.
 - b) that the flow of nitrous oxide is cut off completely before the oxygen flowmeter shows zero flow.
 - c) that the visual indicator (1) turns red before the oxygen flow is entirely stopped.
 - d) air continues to flow.

NOTE.

All gases must be included in the pre-use check.

5. Reinststate the oxygen supply. Check that the flow of nitrous oxide is reinstated, and that the visual indicator turns green again.



6. USER MAINTENANCE

IMPORTANT

User Maintenance is restricted to cleaning the external surfaces of the machine (see section 6.1).

All other maintenance and servicing must be carried out only by Penlon-trained engineers.

The Prima SP2 must be only be serviced according to the schedule and procedures given in the Service Manual.

WARNING

Exterior panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing.

On machines with an electrical power supply, unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.

Ensure that all panels are secure after any work by authorised personnel. Fuseholders must be carefully tightened using an appropriate tool, e.g. flat-blade screwdriver.

Ancillary Equipment

Follow the instructions given in the relevant user manual for detailed information on maintenance and service requirements for the ancillary equipment used with the anaesthetic machine:

- Vaporizers
- Ventilator
- Absorber
- AGSS
- Monitoring

6.1 Cleaning and Sterilisation

CAUTION

- a) *Check that the unit is disconnected from the electrical supply before cleaning.*
- b) *Care must be taken not to allow liquids to run into enclosed areas; serious damage may result.*
- c) *Do not use harsh abrasive cleaning agents.*

To clean outside surfaces, 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.

Always allow the machine to dry off thoroughly before clinical use.

Breathing system hoses and other components must be sterilised to the manufacturer's recommended methods.

USER MAINTENANCE

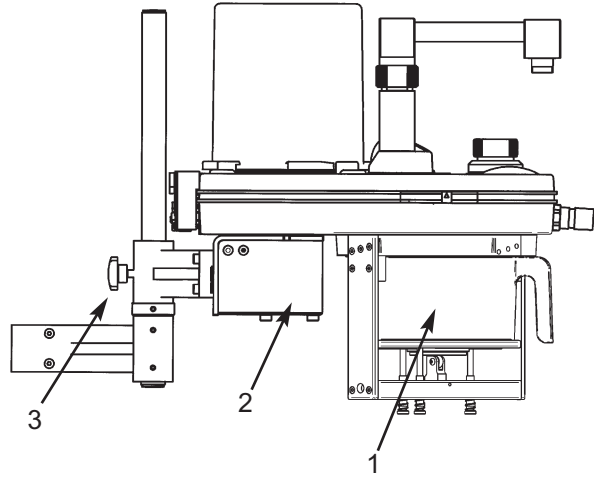
6.2 A200SP Absorber

6.2.1 Removing the Absorber Assembly

CAUTION

The canister (1) may contain condensate. Before removing the absorber from the pole-mount assembly, refer to the A200SP user manual for instructions on draining the canister and disposing of absorbent.

1. Set the brakes on the anaesthetic machine front castors.
2. Refer to the A200SP user manual and disconnect all cable connectors and hoses, including the mains lead from the heater unit (2) (if fitted).
3. Slacken the knob (3), and lift the absorber assembly from the pole-mount.



USER MAINTENANCE

6.3 Service Schedules

6.3.1 Prima SP2

The anaesthetic machine must be serviced to the following service schedule:

6 months	Inspection and Function Check
12 months	Annual service which includes routine replacement of seals, etc. as preventive maintenance
2 and 4 years	Additional tests and component replacement

Details of these service operations are given in the Service Manual, available only to engineers trained by the manufacturer.

6.3.2 Delta Vaporizer

Follow the instructions given in section 8 of the vaporizer user instruction manual.

Servicing includes a periodic leak test and calibration test, and a major overhaul at 10 years (5 years for Halothane models).

On vaporizers with interlock, the system must be tested during the vaporizer calibration test.

6.3.3 Monitoring Systems

Follow the service recommendations detailed in the monitor user instruction manual.

6.3.4 AV-S Ventilator

If the anaesthetic machine was supplied with an AV- series ventilator, refer to section 7 of the ventilator user instruction manual, for servicing requirements.

These include:

6 months	Inspection and Function Check
12 months	Replace bellows Replace O seals and drive gas inlet filter, etc.
24 and 48 months	Additional component replacement

6.3.5 A200 Absorber

6 months	Inspection and Function Check
12 months	Component replacement.

6.3.6 Anaesthetic Gas Scavenging System

Follow the service recommendations detailed in the AGSS user instruction manual.

APPENDIX

APPENDIX 1

Disposal at end of useful life: risk assessment

There are no risks associated with disposal of this product.

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

Follow your hospital, local, state and federal regulations.



APPENDIX

APPENDIX 2

Approved Accessories

WARNING

Only use accessories approved by Penlon Ltd.

UK Sales

Tel: 01235 547036

Fax: 01235 547023

E-mail: uksales@penlon.co.uk

International Sales

Tel: +44 1235 547001

Fax: +44 1235 547021

E-mail: export@penlon.co.uk

CE 0473

Cat. No. 53007
Doc. No. PRSP2 0108
July 2008

© Penlon Ltd 2008 All rights reserved.

Penlon Limited
Abingdon Science Park
Barton Lane
Abingdon
OX14 3PH
UK.

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

UK Sales
Tel: 01235 547036
Fax: 01235 547023
E-mail: uksales@penlon.co.uk

International Sales
Tel: 44 (0) 1235 547001
Fax: 44 (0) 1235 547021
E-mail: export@penlon.co.uk