Penlon Prima 451 MRI Anaesthetic Machine

ANAESTHESIA SOLUTIONS

- Approved for use with 1.5 and 3 tesla scanners, up to 1000 gauss[1]
- Electronic touch screen ventilator
- Designed specifically for use in an MRI environment
- Compact footprint, optimum manoeuvrability
- Total system compatibility
- Designed and manufactured in the UK

TESTED AND APPROVED FOR USE WITH

GE Healthcare, Philips and Siemens MRI Scanners[3]

Penlon

Penlon Prima 451 MRI Anaesthetic Machine

Feature-rich specification for your complete solution for safe, advanced anaesthesia in the MRI suite

1. Six ventilation modes, and patient support for spontaneous breathing
2. Auxiliary oxygen flowmeter (option)
3. Sigma Delta vaporizer with interlock, four agent and two filler block options
4. Large workspace
5. Enclosed body construction or new optional drawer unit[2]
6. Lockable castors - assists stability
7. GCX™ compatible aluminium uprights for secure accessory mounting
8. Integrated CO_2 absorber with ventilator interface

The Penlon Prima 451 is a compact MRI anaesthetic machine, with advanced patient support modes, and has been designed for use with 1.5 and 3 tesla scanners

Prima 451 is a sophisticated design, tested for performance stability and effect on image, and built for the special requirements of the anaesthetist working in the MRI suite.

MRI compatibility

The Prima 451 is an MR-conditional anaesthetic machine, approved for use with 1.5 and 3 tesla MRI scanners, up to 1000 gauss[1].

- Tested as a complete system[2], as illustrated
- Approved for use with GE Healthcare, Philips and Siemens MRI scanners[3]
- Distinctive colour scheme and labelling

Platform

The Prima 451 Anaesthetic Machine has a strong core specification including integrated AV-S Ventilator and A200SP Absorber.

- Two station Selectatec compatible backbar[2].
- Fully compliant to ISO 80601-2-13 standard, and to the Restrictions of Hazardous Substances (RoHS) Directive.
- GCX™ compatible, secure top mounting system for patient monitor[2]
- Enclosed body construction, now available with an optional drawer unit[2]
- Cylinder[2] and pipeline gas supply inlets

Options

- Front or rear-mounted common gas outlet
- Wide choice of territory-specific electrical power outlets

Accessories

Penlon supplies side-mounted accessories suitable for use in the MRI suite, with provision for secure mounting on the side of the machine.

- AGSS (anaesthetic gas scavenging system) receiver
- Suction controller kit
- Therapy flowmeter
- Sigma Delta
- Diamond MRI Fibrelight Laryngoscope

System components

Ultra low-flow anaesthesia, from a reliable platform, combining advanced features and value for money. The Prima 451 is easy to use and maintain, with proven performance and low life costs.

1 AV-S Ventilator
An easy to use, multifunction anaesthesia ventilator, designed for adult, paediatric and neonatal patient profiles. Standard specification includes three advanced spontaneous support modes and electronic PEEP. The AV-S has integrated oxygen monitoring and spirometry, plus seamless integration with both the absorber and anaesthetic machine.

2 A200SP Absorber
A high performance absorber with a ventilator interface as standard that provides ventilator mode switching, triggered by the bag/ventilator control. The unit has a quick-release canister, and the main components are autoclavable.

3 Sigma Delta Vaporizer with interlock
Award winning, high performance market leader, offering multi-choice agent and fill system options.

4 Flowmeter bank
Anti-hypoxic system giving enhanced patient safety. Cascade flow tubes as standard.

Maintenance and after-sales support

Penlon is committed to a successful, long term relationship with all our customers. Comprehensive warranty provides user peace of mind and after-sales support.

Additional services and warranties can be purchased to meet your particular needs.

[1] Conditions apply.

[2] Do not place any object on or in this machine unless it is specifically labelled to be used in an MRI scanning room and on the Prima 451 MRI Anaesthetic Machine.

[3] Visit www.penlon.com for further information and to download compatibility statements.

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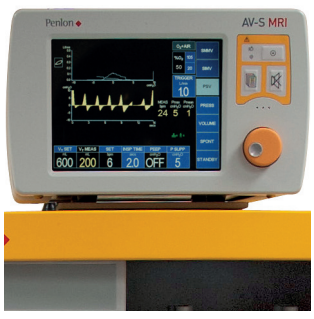


2


3

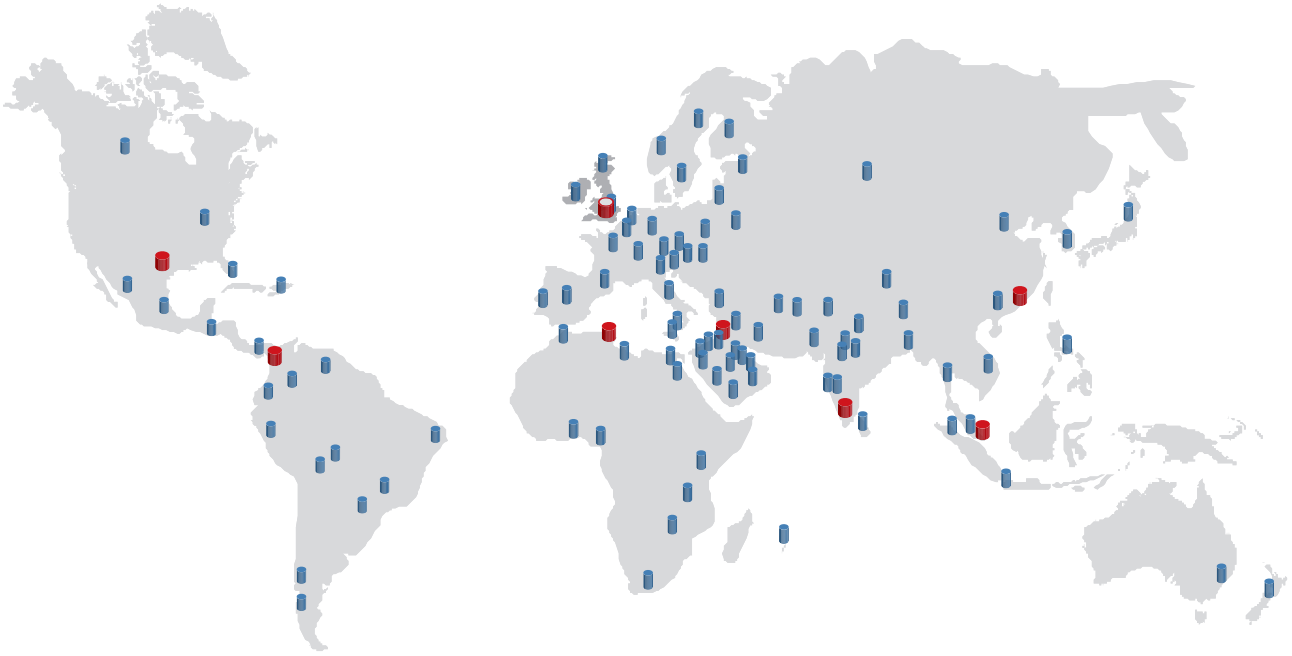

4


About Penlon

Penlon was founded in 1943 by personnel from the Department of Anaesthesia at Oxford University. One of the first products was the Macintosh Laryngoscope, then a revolutionary design, and still the most widely used today, invented by the late Sir Robert Macintosh, Professor of Anaesthetics at Oxford University.

Today Penlon continues to design, engineer and build high quality anaesthesia products at its UK headquarters. The company is proud to have over 70 years' dedicated experience, many awards for product design, and an impressive four Queen's Awards for Enterprise, one for 'Innovation' and three for 'International Trade'.

Penlon devices feature intuitive user interfaces that require minimal operator training, putting clinicians in control, enabling them to focus on what is most important – patient safety and wellbeing.



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Prima 451 MRI Anaesthetic Machine

User Manual

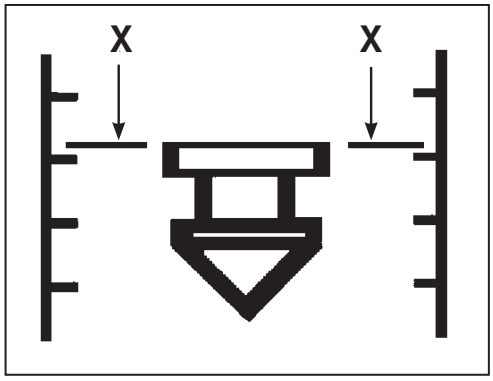
ANAESTHESIA SOLUTIONS

Penlon

3.6 Flowmeters and Controls

3.6.1 Flowmeters

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 (X), as shown above.

3.6.2 Flow Controls

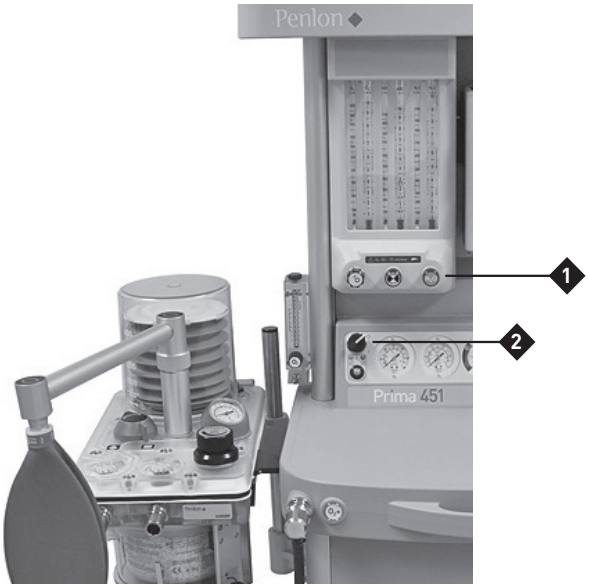
Each flow control valve is positioned directly underneath the flow tube assembly to which it corresponds, and the control knob (1) is colour-coded for the gas which it controls.

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, the air flowmeter is always installed in the inner position on the flowmeter assembly
This position is blanked out if air is not specified for 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.

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

NOTE
1. The gas delivery switch (2), positioned on the front panel controls the supply of oxygen and must be in the ON position for normal operation of the machine.
2. The switch also controls the operation of the AV-S ventilator. (see section 3.9.3).

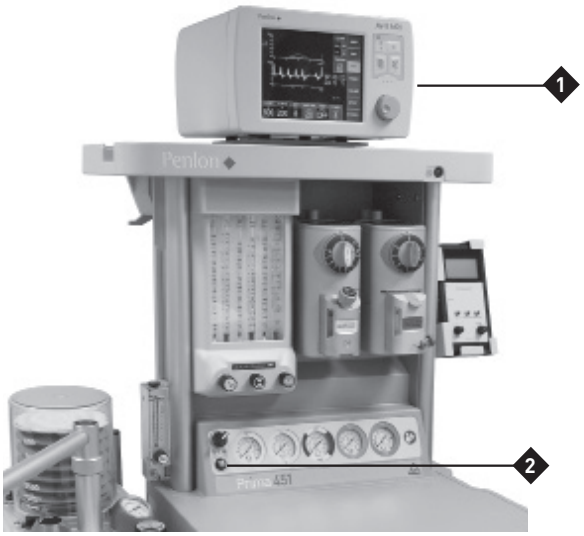
3.6.3 Dual Cascade Flow Tubes

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.

3.9.3 AV-S MRI Ventilator Power Supply

The ventilator (1) power supply unit is connected internally to the machine power supply.

Note that the Prima 451 gas delivery switch (2) must be in the 'On' position for operation of the ventilator (see section 5.4), and refer also to section 3.4 in the AV-S MRI 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 60 minutes, if the battery has been maintained in a fully charged condition.

Refer to section 3.4 in the AV-S MRI user instruction manual.

3.9.4 Monitor and other devices

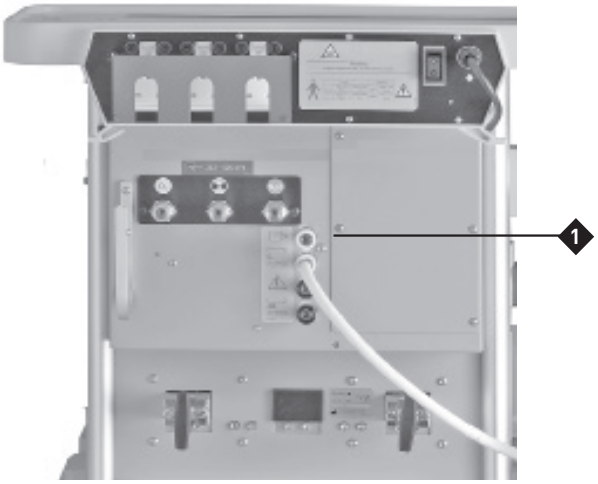
The mains lead (or adaptor) for a monitor system or other devices requiring an electrical supply can be plugged into one of the auxiliary sockets on the rear of the machine (see section 3.9.2).

Warning
The Prima 451 MRI has been designed for use in an MRI environment only as a system.
It is the user's responsibility to ensure that fitting third-party components to the anaesthesia machine, ventilator, or breathing system will not compromise the MR status of the Prima 451 MRI System.
Do not place any object on or in this machine unless it is specifically labelled to be used in an MRI scanning room and suitable for your facility.
Objects placed on or in this machine that are not designed for use with this anaesthesia system may be strongly attracted to the magnet and may cause serious injury or death when the machine is used in an MRI scanning room.

If a third-party accessory or device is mounted on the machine (e.g. AGSS receiver or patient monitoring equipment) ensure that it is MR compliant for your facility, and is securely mounted.
Installation must be carried out by trained engineering personnel.
In addition, do not assume that individual components of the Prima 451 MRI System (including any Penlon accessories), can be safely used with MRI scanners when used on any other anaesthesia system.
See also Warnings 1 and 2 in section 1).

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.



Warning
Use only non-magnetic cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.

Oxygen and Air

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

Supply pressure: See section 4.5.

4. Specification

4.1 Physical Dimensions

NOTE: All data is approximate

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.
Top shelf:	71 cm x 35 cm
Loading:	30 kg (66 lb) - evenly distributed.
Drawer (optional):	12 x 36 x 35
Loading:	30 kg (66 lb) - evenly distributed.
Castors:	Diameter: 125 mm (5 inches) All braked
Pole-mount 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
Mass (weight):	110 kg (242 lb)

4.2 Gas Supplies

Cylinders:	**Warning** **Use only non-magnetic cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.** A maximum of two cylinder fittings can be specified. All cylinder yokes are pin-indexed
Pipeline:	Maximum of three pipeline inlets(oxygen, nitrous oxide, air). Gas inlet connectors and pipeline supply hoses are territory specific, to relevant national standards: NIST connectors are for UK & Europe DISS connectors for USA specification SIS connectors for Australia
Medical gas colour codes:	*To comply with relevant national standards.
Oxygen	Green or White*
Nitrous oxide	Blue
Medical air	Yellow or Black/White*

4.3 Flowmeters

Flow ranges:		
Single flow tubes:		
Oxygen:		0 - 10 L/min
Nitrous Oxide:		0 - 10 L/min
Air		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 ± 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)
Air	240 mm (9.45 inch)
Scale length	152 mm (6 inch) minimum

4.4 Gas Pressures

	USA/Canada/Japan	UK
Pipeline supplies:		
Supply pressure:	280-600 kPa (40.6-87 psig)	280-600 kPa (40.6-87 psig)
Cylinder supplies:		
Supply pressure:	19 985 kPa (2900 psig)	19 985 kPa (2900 psig)
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 from secondary regulators (at 5 L/min flow)		
Oxygen and Nitrous Oxide	152 - 241 kPa (22 - 35 psig)	152 - 241 kPa (22 - 35 psig)
Air	207 - 283 kPa (30 - 41 psig)	207 - 283 kPa (30 - 41 psig)
Fresh gas supply pressure:		
Safety valve	90 cmH2O	90 cmH2O

4.5 Auxiliary Gas Outlets

Oxygen: Two self sealing connections on rear of machine
Air (on machines with Air supply option): Two self sealing connections (mini-Schrader) on rear of machine.

Supply pressure

Pipeline supply: Gas is supplied at pipeline supply pressure (see above)

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

Flow rate

Flow rate for each gas: 60 L/min maximum

WARNING

Flow rates greater than 60 L/min could affect the fresh gas flow to the patient.

4.6 Oxygen Failure Warning Devices

1. Gas system whistle (see section 3.3.2)
2. Visual indicator, direct pressure operated (see section 3.3.4)

4.7 Oxygen Flush

Control button on front edge of worksurface

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

4.8 Mechanical AHD System

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

Basal Flow - Oxygen

Cascade flow tubes	50-75 ml/min
Single flow tubes	100-200 ml/min

4.9 Environmental

Operating Conditions

Temperature	+10 to 38°C (50 to 100°F)
Atmospheric Pressure range	70 to 106 kPa
Altitude	2438 m (8000 ft) maximum
Humidity	10-85% R.H. non-condensing

Transport and storage

Temperature	-5 to 40°C (23 to 104°F)
Atmospheric Pressure range	50 to 106 kPa
Humidity	10-85% R.H. non-condensing

Cleaning

Wipe external surfaces with dry or damp cloth. Use mild soap, or disinfectant solution if necessary (see section 6.1).

Do not leave cleaning materials on the machine.

4.10 Electrical Supply

Power Input:	
US/CSA specification machines:	100 - 130 VAC, 50 - 60 Hz, 2000 - 2600 VA maximum
Non-US/CSA specification machines:	200 - 240 VAC, 50 - 60 Hz, 2000 - 2400 VA maximum
Overload Protection	Thermal circuit breaker built into the On/Off
US/CSA specification machines	20 A
Non-US/CSA specification machines	10 A
Power cable:	Permanently attached lead (3 m), with stowage hooks on rear.
Internal power distribution	
Ventilator IEC socket	5 A maximum
Fuse	T5 AH 250 V ceramic (5 x 20 mm) high breaking capacity (on Live and Neutral).
Power Outlets:	
Auxiliary Power Outlets	Three outlets, country specific: 5 A per outlet
US/CSA specification machine	15 A (nominal): maximum current depends on internal power usage
Non-US/CSA specification machines	10 A (nominal): maximum current depends on internal power usage
Fuses	T5AH ceramic (5 x 20 mm) high breaking capacity (on Live and Neutral on each outlet)
Electromagnetic Compatibility	The Prima 451 meets the requirements of EN 60601-1-2 (electromagnetic compatibility - requirements and tests)

4.11 Device Classification and Labelling

Mode of operation: Continuous

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: Refer to Appendix 3

Patient Class

All patient types

No residual risks from phthalates that are carcinogenic, mutagenic, or toxic to reproduction.

Magnetic Resonance (MR) Conditional

The Prima 451 is a MRI-conditional machine and includes special components that allow it to operate in a MRI environment.

The Prima 451 poses no known hazard in a specified MR environment (see below), with specified conditions of use (see section 1) and specific configurations.

Specified MR environment

The Prima 451 is approved for use in a magnetic resonance (MR) environment up to the 1000 gauss (100 mT) line, with scanners rated at 1.5 tesla and 3 tesla.

CAUTION

Special operational conditions apply to Prima 451 systems with the AV-S MRI ventilator - see Appendix 5.

Monitors

1. Working and configured correctly. Refer to warning in section 3.9.6.
2. Alarms, limits and volumes set

Airway equipment

1. Full range required, working, with spares. Refer to warnings 1 and 3 in section 1

NOTE:
Record this check in the patient record

Summary: Don't forget:

1. Self-inflating bag. Refer to warnings 2 and 3 in section 1
2. Difficult airway equipment. Refer to warnings 2 and 3 in section 1
3. Resuscitation equipment. Refer to warnings 2 and 3 in section 1
4. Total intravenous anaesthesia (TIVA) and/or other infusion equipment. Refer to warnings 2 and 3 in section 1

PRE-USE CHECKLIST - BEFORE EACH CLINICAL CASE

Breathing system

1. Whole system unobstructed and leak free using 'two-bag' test (see below)
2. Vaporizers – fitted correctly, filled, leak free, plugged in (if necessary)
3. Alternative systems (Bain, T-piece) – checked Refer to warnings 2 and 3 in section 1

Ventilator

1. Working and configured correctly
2. Refer to Penlon ventilator user manual for pre-use check instructions

Airway equipment

Full range required, working, with spares. Refer to warnings 2 and 3 in section 1

Suction

Clean and working

NOTE:
Record this check in the patient record

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

The two-bag test

A two-bag test should be performed after the breathing system, vaporizers and ventilator have been checked individually

1. Attach the patient end of the breathing system (including angle piece and filter) to a test lung or bag. Refer to warnings 1 and 3 in section 1
2. Set the fresh gas flow to 5 L/min and ventilate manually. Check the whole breathing system is unobstructed and the non-return valves are moving. Check the function of the APL valve by squeezing both bags.
3. Turn on the ventilator to ventilate the test lung. Turn off the fresh gas flow, or reduce to a minimum. Open and close each vaporizer in turn. There should be no loss of volume in the system.

5.2 Pre-use Checks - Gas Supply

5.2.1 Gas Pipeline Supplies

CAUTION
When connecting pipeline hoses, always ensure that each supply hose is connected to the correct gas inlet, and that a gas-tight connection is achieved.

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 correct basal flow of oxygen is delivered (see section 4.8).
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 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

Warning
Use only non-magnetic cylinders with this machine. Steel cylinders can cause serious injury or death if brought into an MRI scanning room.
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) Nitrous oxide: cylinder pressure does not indicate cylinder content.

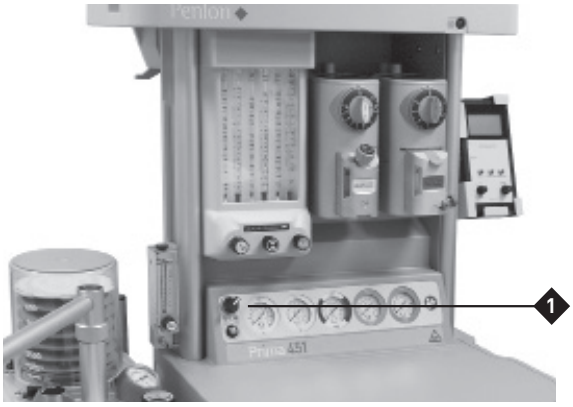
2. Ensure that all flowmeters are kept closed until gas supplies are required.

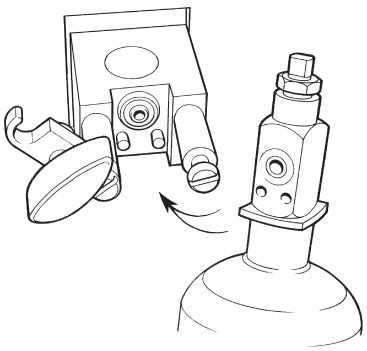
CAUTION
The mechanical AHD system requires that the oxygen flowmeter control is restricted to prevent the needle valve from fully closing.

This ensures a minimum oxygen basal flow.

DO NOT attempt to close the flow to zero.

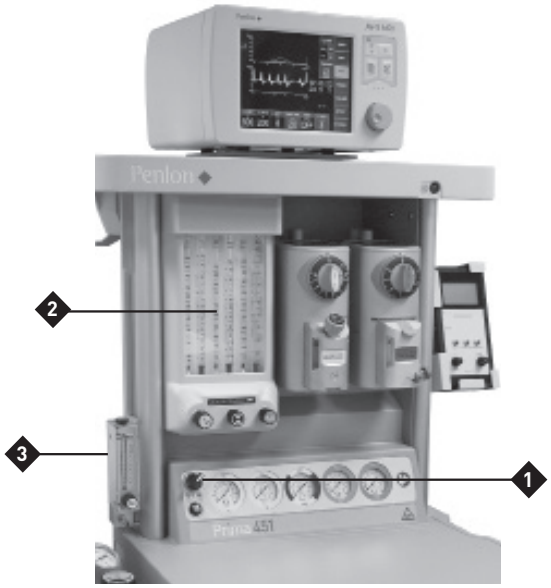
Do not overtighten the knob.





5.2.3 Flowmeters

5.2.3.1 Flow Control – Conventional flow tubes



1. Turn on the Gas Delivery switch (1).
   Check that the correct basal flow of oxygen is displayed (see section 4.8).
2. Open the nitrous oxide flowmeter needle valve and check that the flow of oxygen increases.
3. Operate the oxygen flowmeter needle valve.
   Check that full scale of flow of oxygen can be achieved.
4. Check that the floats in both tubes move freely when flows are adjusted, and rotate when at a steady flow.
5. Operate the flowmeter control knobs in turn to check:
   (a) the full scale of flow can be obtained;
   (b) the flow can be turned off by gentle rotation of the knob.
6. Check that:
   (a) the floats move freely when flows are adjusted, and rotate at a steady flow;
   (b) the floats reseat on the bottom stop.
7. Dual cascade conventional flow tubes (2):
   Check that gas flow is through the low flow tube initially until full flow is achieved, then through the high flow tube.
8. Auxiliary conventional flowmeter (optional) (3):
   Rotate the flowmeter control and check that a gas flow can be obtained.

5.2.4 Machine Low Pressure Leak Test

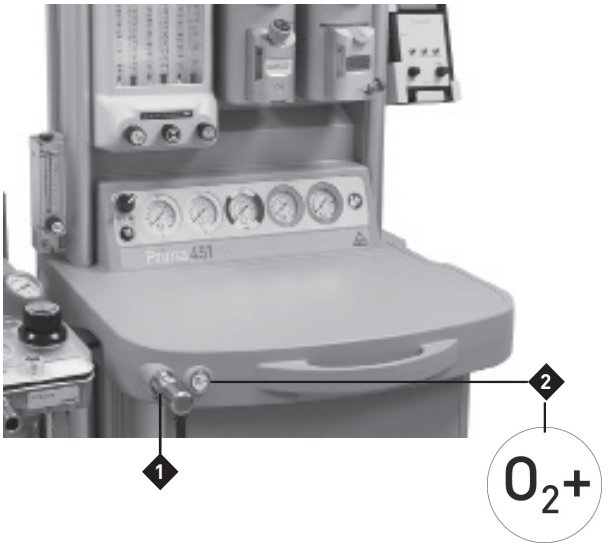
NOTE

1. Attach a side branch connector to the CGO outlet (1).
   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 75 cmH_2O.
   Release the finger seal immediately the pressure is reached.

This test should be performed:

a) With all vaporizers 'off' and isolated.

b) With each vaporizer in turn set to 1%.



5.2.5 Oxygen Flush

Check for a high flow of oxygen through the CGO outlet (1) when the flush valve button (2) 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.

5.3 Vaporizers

Penlon Sigma Delta MRI vaporizers can be supplied as part of the Prima 451 MRI system (see Appendix 2).

5.3.1 Pre-use Checks - Vaporizers

On ALL vaporizers, before use:

1. Check all joints for gas tightness.
2. Check vaporizer agent level.
   CAUTION
   See section 3.7.4 for additional information for refilling a key-fill vaporizer in the MR facility.
3. Check for correct agent delivery concentrations - use an agent analyser.

Vaporizer leak check

NOTE
The machine low pressure test (section 5.2.4) incorporates a vaporizer leak test.

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 overdosage may result).

5.3.3 Selectatec Mounting System

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 (1) 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 (2), ensure that the gas connection ports are aligned with the valves on the manifold, and are correctly engaged, before tightening the locking lever.

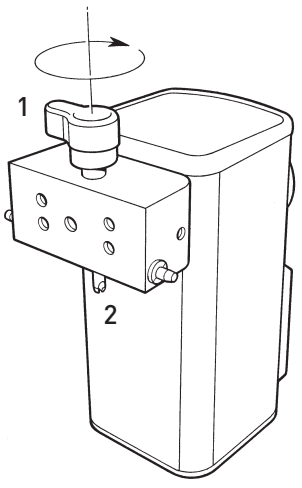
5.3.4 Selectatec Compatible MRI Vaporizers with Interlock

WARNING
Only MRI vaporizers with the Selectatec compatible interlock function will interlock if installed on a two station backbar manifold.

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

5.3.4.1 Pre-use Check - Interlock System

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 when the vaporizers are adjacent to each other.

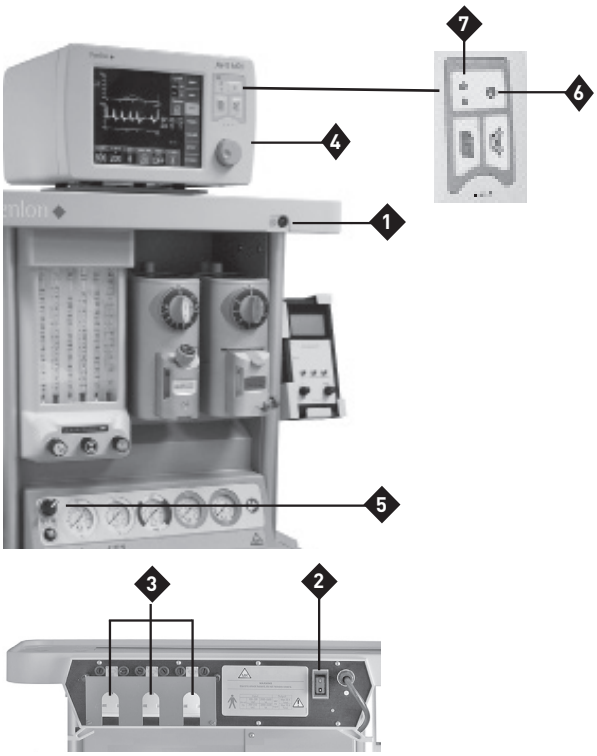


5.4 Electrical Supply

1. Connect the machine power lead to a suitable mains supply socket. Check that the mains indicator light (1) is on.
2. Set the auxiliary power supply switch (2) to ON.
   Check for correct function of each auxiliary power outlet (3)
3. Check all electrical equipment, including devices powered by the power outlets on the rear of the machine.
4. AV-S Ventilator (4).
   Check the power supply to the ventilator:

   a) Turn the Prima 451 gas delivery switch (5) to On.

   Press the ventilator on/off switch (6).
   Check that the green indicator light (7) is illuminated.
   Note that the gas delivery switch (5) must be in the 'On' position.



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. 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 taper at the other end for connection to the common gas outlet of the anaesthetic machine. Check all connections for gas tightness.

5.5.4 A200SP MRI Absorber

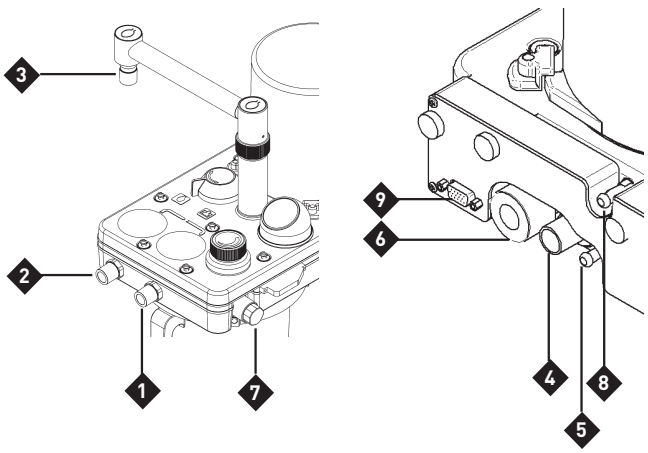
WARNING

Do not use the system in the MR facility if the absorber has a heater fitted.

Always follow the pre-use check procedures in the user manual supplied with the absorber. Use an oxygen monitor (and a CO_2 analyser) when using any rebreathing anaesthetic system.

A200SP MRI 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 ventilator Pressure Monitor port.
9. Interface cable - Bag/Vent switch and spirometer (connects internally to the AV-S MRI ventilator).



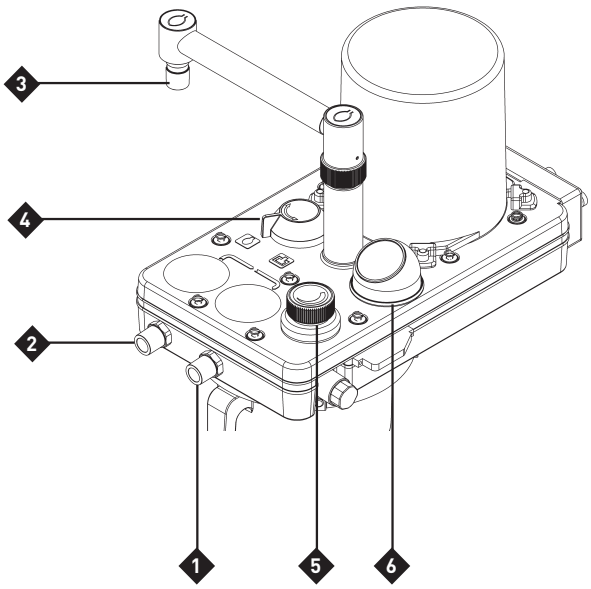
5.5.5 System Low Pressure Leak Test

Connect the CGO outlet on the machine to the fresh gas inlet of the A200SP MRI 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, recheck the low pressure system on the machine (section 5.2.4).
   If the low pressure test on the machine is successful, check the ventilator and absorber, referring to the relevant user instruction manual.



5.5.6 Breathing Circuit Schematic: AV-S MRI Ventilator

Heat and moisture exchanger

NOTE
To protect the expiratory limb of the breathing circuit, and the spirometer, use a breathing circuit bacterial filter (see schematic on following page, item 4), and a heat and moisture exchanger (see schematic, item 6) at the patient Y-piece.

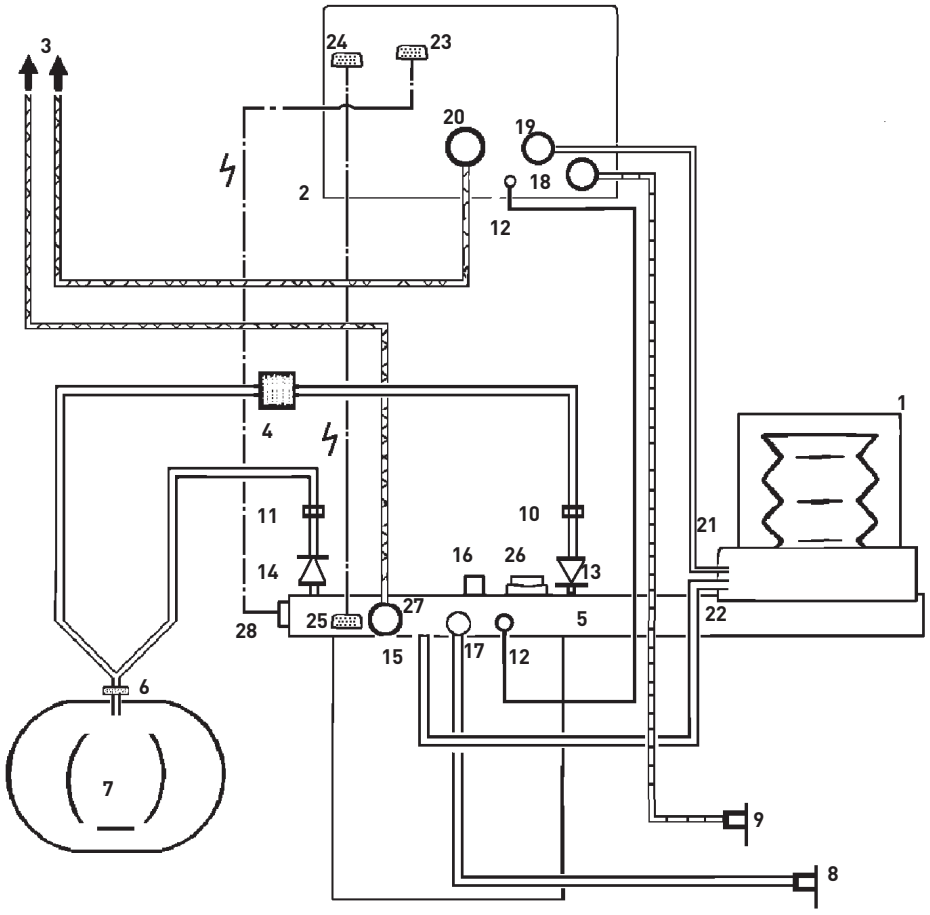
CAUTION
Replacement/Disposal - always follow the instructions supplied with the filter or heat and moisture exchanger. Always renew components at the recommended interval.

Connection to analysers and monitors

Follow the instructions in the relevant user manual for connection to analysers and monitors.

Interface cabling is shown for Prima 451 On/Off switch and A200SP Bag/Vent switch and spirometer.

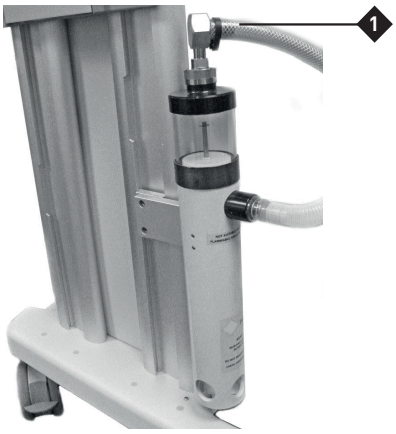
Ventilator connections shown are for AV-S MRI ventilator with spirometry and oxygen monitor.
For A200SP MRI and Nuffield 200 MRI ventilator, refer also to the user manuals supplied with those products.



Breathing Circuit Schematic - AV-S Ventilator

1. Bellows
2. AV-S 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. Common gas outlet (CGO) block on anaesthetic machine (fresh gas supply)
9. Auxiliary outlet on anaesthetic machine (drive gas supply)
10. Flow sensor - expiratory (located within the absorber)
11. Flow sensor - inspiratory (located within the absorber)
12. Connectors (AV-S) - 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 - AV-S 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:
    (i) A200SP Absorber bag/ventilator control position
    (ii) Spirometer sensor signal
25. Interface connection on A200SP
26. Adjustable pressure limiting (APL) valve
27. Outlet from APL valve to AGSS
28. Oxygen sensor

5.6 Anaesthetic Gas Scavenge System (AGSS)



Receiver

A Penlon AGSS Receiver MRI is supplied as part of the Prima 451 MRI system.

WARNING

Always use the outlet hose (1) supplied with the receiver (Penlon part number 5006832) in the MRI facility.

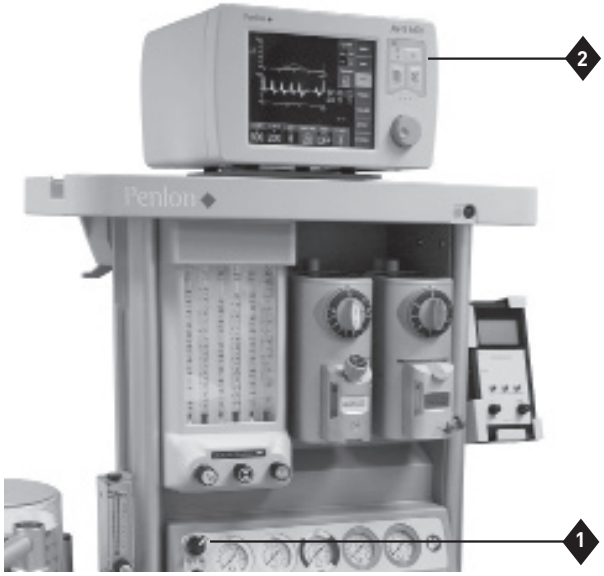
Pre-use Checks

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 the receiver.

WARNING

Do not connect any vacuum system directly to the APL valve on the absorber. Use a Penlon AGSS Receiver MRI system, complying with ISO 80601-2-13, with a positive and negative pressure control function.

5.7 AV-S MRI Ventilator



For installation and pre-use checks, refer to section 5 in the user manual supplied with the AV-S MRI ventilator.

Check all hose and tubing connections for gas tightness.
Check all wiring connections for correct fitment and security.
Check the operation of the built in oxygen monitor system.

Power up and power down

1. Turn the gas delivery switch (1) to On.
   Note that the switch must be in the 'On' position for operation of the ventilator
2. Ventilator On/Off control (2)
   Switch On: Short internal test sequence.
   Switch Off: Power down sequence with progress indicator.
3. Turn the on/off control to OFF. The ventilator will power-down. A power-down sequence is initiated and the ventilator displays the count down in seconds on the screen.
   If shutdown was started in error, the user has the opportunity to halt the power down sequence and recommence ventilation.
4. Turn the on/off control (2) to ON. The ventilator will power up and revert to Standby mode.

5.8 Nuffield 200 Ventilator

For installation, refer to section 4.1 in the user manual supplied with the Nuffield 200 ventilator.
The ventilator can be mounted on either side of the Prima 451.

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

5.9 SC760 MRI Suction Controller

For installation, refer to section 4 in the SC760 user leaflet.
Always use a non-ferrous receiver jar assembly with the SC760 suction controller in the MRI facility.

5.10 Alarm System Test

WARNING
Do not use the anaesthetic machine if any alarm, monitoring, or protection system devices are not functioning correctly.

Primary Oxygen Failure Alarm

A warning whistle and a visual indicator (1) act as oxygen supply failure devices, and constitute the primary alarm system, powered only by the residual oxygen supply, see section 3.3

Check the system when the low pressure oxygen system is first pressurised by turning on a cylinder or connecting a pipeline.

The whistle will sound briefly as pressure increases, and the visual indicator (1) 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. Set a flow of 2 L/min on both flowmeters.
3. 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) That air, if fitted, continues to flow.

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

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

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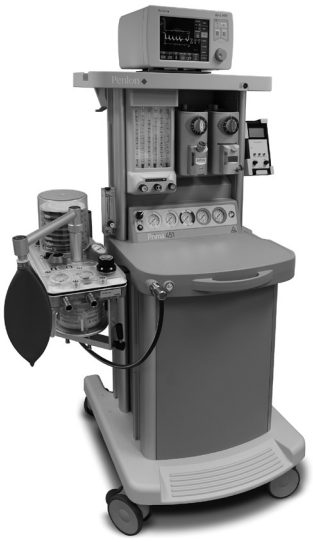
Penlon Prima 451 Anaesthesia System Technical Specifications

ANAESTHESIA SOLUTIONS



- Approved for use with 1.5 and 3 tesla scanners, up to 1000 gauss*
- Designed specifically for use in an MRI environment
- Electronic touchscreen ventilator
- Six ventilation modes, and support for spontaneous breathing patients
- Total system compatibility
- Compact footprint, optimum manoeuvrability
- Lockable castors - assists stability
- Enclosed construction - no hidden storage areas
- Illuminated workspace
- Designed and manufactured in the UK

Physical Specifications

Dimensions	
Size (H × W × D)	1390 x 790 x 700 mm
Weight	110 kg (242 lb)

Work Surface	
Height	860 mm
Size (W × D)	580 × 250 mm
Loading	30 kg - evenly distributed

Top Shelf	
Size (W × D)	710 × 350 mm
Loading	30 kg - evenly distributed

Castors	
Diameter	125 mm
Brakes	Individually braked

Vaporizer Mounting	
Vaporizers	Sigma Delta – (Sev and Iso)
Number of Positions	Two
Type	Selectatec® compatible backbar

Gas Supply

Connections		
Cylinder Connections	Two	
Connection Type	Pin-indexed	
Pipeline Connection	Three inlets	
Territory Specific Pipeline Connections	UK/Europe:	NIST
	USA:	DISS
	Australia:	SIS

Gas Scavenging Fixing	
Location	Bracket on GCX™ compatible frame upright
Loading	30 kg

Environmental

Operating Conditions	
Temperature	+10 to 38°C (50 to 100°F)
Atmospheric Pressure	70 to 106 kPa
Altitude	2438 m (8000 feet) maximum
Humidity	10 to 85% R.H. non-condensing

Transport and Storage Conditions	
Temperature	-5 to 40°C (23 to 104°F)
Atmospheric Pressure	50 to 106 kPa
Humidity	10 to 85% R.H. non-condensing

AV-S Ventilator Specification

Physical	
Size (Control Panel Only)	185 x 290 x 300 mm (H x W x D)
Screen	8.4" Colour TFT touchscreen
Weight (Control Panel Only)	15 kg
Power	100 - 240 VAC, 50 - 60 Hz
Back	60 minutes approximately
Drive Gas	Oxygen or Air

Functional	
Tidal Volume (Vt)	20 - 1600 ml (Adult), 20 - 350 ml (Paediatric)
Rate (BPM)	4 to 100 bpm
I:E Ratio	1:0.2 - 1:8
Pressure Limit (Volume Control Mode)	10 to 80 cmH_2O
Fresh Gas Compensation	Automatic Tidal Volume Adjustment
Ventilation Modes	Off, Standby, Volume, Pressure Controlled, Spontaneous, SIMV, SMMV, and PSV
Pressure Range (Pressure Control Mode)	5 to 70 cmH_2O
Electronic PEEP	4 to 20 cmH_2O (or 4 to 30 cmH_2O optional)
Oxygen Monitor	Fuel Cell type

SIMV, SMMV, PSV	
Trigger (PEEP Referenced)	0.7 to 4 L/min
Trigger Window	60% of Expiratory Time
Tidal Volume (Vt)	As Volume Mode
Inspiratory Time (Ti)	0.3 to 5 Seconds
Support Pressure (PSV only)	4 to 70 cmH_2O

Technical Specification

Default Settings	Adult	Paediatric
VOLUME		
• Tidal Volume (Vt)	600 ml	150 ml
• Rate (BPM)	10	15
• I:E Ratio	1:2	1:2
• Pmax	38 cmH_2O	38 cmH_2O
PRESSURE		
• Tidal Volume (Vt)	600 ml	150 ml
• Rate (BPM)	10	15
• I:E Ratio	1:2	1:2
• P-Target	10 cmH_2O	10 cmH_2O
SIMV		
• Tidal Volume (Vt)	600 ml	150 ml
• Rate (BPM)	6	15
• Inspiratory Time	2 Seconds	1.3 Seconds
• Trigger	1 L/min	1 L/min
SMMV		
• Minute Volume (Vm)	3.6 L	2.2 L
• Rate (BPM)	6	15
• Inspiratory Time	2 Seconds	1.3 Seconds
• Trigger	1 L/min	1 L/min
PSV		
• Support Pressure	10 cmH_2O	10 cmH_2O
• Inspiratory Time	2 Seconds	1.3 Seconds
• Trigger	1 L/min	1 L/min

Penlon Prima 451 Anaesthesia System Technical Specifications

ANAESTHESIA SOLUTIONS

A200SP Absorber Specification

Physical	
Size	360 x 186 x 244mm (H x W x D)
Weight	5.7kg
Absorbent	1.3 kg / 150ml absorbent
	Recommended absorbent - soda lime with colour indicator, 4-8 mesh
Mounting system	Polemount assembly

Resistance of Breathing System		
Expiratory resistance	Absorber fitted with 1060mm breathing hose complying with ISO 5367 and SafelockY piece	>0.6 kPa (6 cmH_2O)
	Absorber only	>0.6 kPa (6 cmH_2O)
Inspiratory resistance	Absorber fitted with 1060mm breathing hose complying with ISO 5367 and SafelockY piece	>0.6 kPa (6 cmH_2O)
	Absorber only	>0.6 kPa (6 cmH_2O)

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Doc. No. F00119TS / January 2019.

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Penlon Sigma Delta MRI Vaporizer

ANAESTHESIA SOLUTIONS

- Approved for use with 1.5 and 3 tesla scanners, up to 1000 gauss[1]
- Multiple agent and filler block options
- Superb performance, particularly at low flow
- Service Free[2]
- Low body weight

TESTED AND APPROVED FOR USE WITH

GE Healthcare, Philips and Siemens MRI Scanners[3]

Penlon

Penlon Sigma Delta MRI Vaporizer

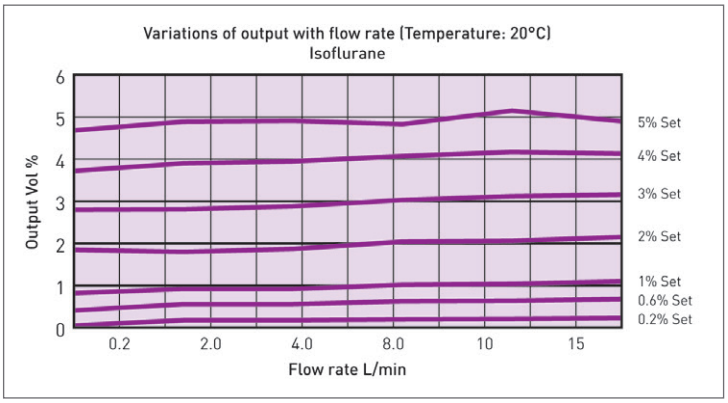
ANAESTHESIA SOLUTIONS

The Sigma Delta MRI vaporizer delivers accurate concentrations under varying conditions of flow rate and temperature, particularly at low flow

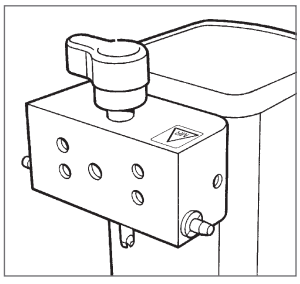
Vaporizer Type	Sevoflurane 8% Filler Type			Isoflurane 5% Filler Type		Halothane 5% Filler Type
	Pour fill	Key fill	Quik-Fil	Pour fill	Key fill	Key fill
Selectatec Compatible with Interlock	✓	✓	✓	✓	✓	✓
Cagemount Taper 23 mm	✓	✓	✓	✓	✓	✗
Dräger Auto-Exclusion® Compatible[4]	✓	✓	✓	✓	✓	✗

- Key fill, Quik Fil®, or Pour fill
- Sevoflurane, Isoflurane and Halothane
- Selectatec®, Cagemount and Dräger Auto-Exclusion®[4]
- Internationally recognised, award-winning design
- Clearly labelled as MR Conditional

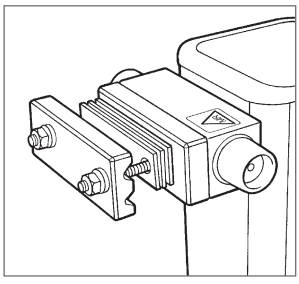
Typical performance graph



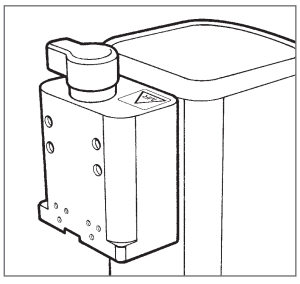
Backbar mounting systems



Selectatec Compatible with Interlock



Cagemount Taper 23 mm



Dräger Auto-Exclusion Compatible[4]

CE 1639 UK CA 0120

PenlonGlobal company/penlon-ltd PenlonGlobal PenlonGlobal

Doc. No. DM0123SL / November 2023. [1] Conditions apply. [2] Presumes ten year product life requiring no preventive maintenance service. It is recommended that a service is carried out at ten years. Halothane vaporizers require a five year service. [3] Visit www.penlon.com for further information and to download compatibility statements. [4] Auto-Exclusion not available in the US.

Rx only

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SIEMENS Healthineers

Test Certificate

concerning the test of influences on MRI systems caused by non-Siemens products

1. Test certificate, product designation and manufacturer

This is to certify that the following product

Prima 451 MRI Anaesthesia System,
tested with AVS ventilator with serial number AVM0717-001,
Nuffield Ventilator with serial numberPE0004,
Sigma Delta Vaporizer with serial number D0312-0082,
Suction Controler with serial number PE0001,
A200SP Absorber with serial number PE0005,
Anaesthetic Gas Scavenge System (AGSS) US with serial number PE0002,
Anaesthetic Gas Scavenge System (AGSS) UK with serial number PE0003
and Gaussmeter with serial number 201

of the manufacturer:

Penlon Ltd
Abingdon Science Park, Barton Lane
Abingdon, OX14 3NB

does not impair the functioning of the MRI systems of Siemens Healthcare GmbH, Magnetic Resonance Systems, specified in section 2:

Potential functional restrictions of the MRI systems are indicated in section 4.

Possible adverse effects of the MRI systems on the product indicated above are expressly not subject of the test on which this certificate is based. Therefore, this certificate does not imply non-interference of the above-mentioned product through the MRI system.

2. MAGNETOM systems involved

Seq. no.	MR System or option (type designation)
1	Sola (1.5 Tesla)
2	Sempra (1.5 Tesla)
3	Amira (1.5 Tesla)
4	Aera (1.5 Tesla)
5	Espree (1.5 Tesla)
6	Avanto (1.5 Tesla)
7	Avanto a Tim+Dot System (1.5 Tesla)

Test number: 10232
Doc.Ident.No. 10792721 ASD FR1 02

8	Avanto Dot Upgrade (1.5 Tesla)
9	Avanto fit (1.5 Tesla)
10	Avanto fit Upgrade (1.5 Tesla)
11	ESSENZA (1.5 Tesla)
12	ESSENZA a Tim+Dot System (1.5 Tesla)
13	ESSENZA Dot Upgrade (1.5 Tesla)
14	Symphony (1.5 Tesla)
15	Symphony a Tim System (1.5 Tesla)

3. Applications

The Penlon Prima 451 MRI Anaesthesia System is intended for use for the following purpose in connection with magnetic resonance application; the test certificate refers to this purpose:

- MRI Anesthetic Workplace

4. Limitations

During the use of this product the following limitations of functionality and/or applications of the MRI systems, options and accessories apply:

- n.a.

5. Warnings

The following safety precautions must be observed when using this product in connection with the MRI systems listed in section 2:

- The Prima 451 MRI Anaesthesia System includes ferromagnetic components and may therefore be operated at a minimum distance corresponding to 100 mT only. For safety reasons, a relevant warning note must be included in the operating instructions and affixed on the Prima 451 MRI Anaesthesia System.

6. Validity

This test certificate shall be valid until revoked by Siemens Healthcare GmbH.

Erlangen, 2018-06-25

Siemens Healthcare GmbH

i.V. Lochner

i.V. Steiner

SIEMENS Healthineers

Test Certificate

concerning the test of influences on MRI systems caused by non-Siemens products

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Sigma Delta Vaporizer with serial number D0312-0082,
Suction Controler with serial number PE0001,
A200SP Absorber with serial number PE0005,
Anaesthetic Gas Scavenge System (AGSS) US with serial number PE0002,
Anaesthetic Gas Scavenge System (AGSS) UK with serial number PE0003
and Gaussmeter with serial number 201

of the manufacturer:

Penlon Ltd
Abingdon Science Park, Barton Lane
Abingdon, OX14 3NB

does not impair the functioning of the MRI systems of Siemens Healthcare GmbH, Magnetic Resonance Systems, specified in section 2:

Potential functional restrictions of the MRI systems are indicated in section 4.

Possible adverse effects of the MRI systems on the product indicated above are expressly not subject of the test on which this certificate is based. Therefore, this certificate does not imply non-interference of the above-mentioned product through the MRI system.

2. MAGNETOM systems involved

Seq. no.	MR System or option (type designation)
1	Vida (3 Tesla)
2	Prisma (3 Tesla)
3	Prisma fit Upgrade (3 Tesla)
4	Spectra (3 Tesla)
5	Skyra (3 Tesla)
6	Skyra fit Upgrade (3 Tesla)
7	Verio (3 Tesla)

Test number: 10232
Doc.Ident.No. 10792721 ASD FR2 02

8	Verio Dot Upgrade (3 Tesla)
9	Verio a Tim+Dot System (3 Tesla)
10	Trio a Tim System (3 Tesla)
11	Trio (3 Tesla)
12	Biograph mMR (3 Tesla)

3. Applications

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i.V. Steiner

5. Conclusion

Based on the above analysis it can be concluded that "PENLON Prima 451 Anesthesia Machine" will not create any image issues when used with our 1.5T and 3.0T systems and proved that there were no issues related to magnetic forces pulling the cart or any equipment on it when pushed closer to the magnet beyond the 1000 Gauss line to which the Penlon system is rated, hence "PENLON Prima 451 Anesthesia Machine" is compatible to be used with our GE 1.5T and 3.0T systems. Refer all the supporting documents attached part of this document.

6. Approval

This standalone document will be approved by the following function(s) in MyWorkshop indicating that the subject qualification for compatibility is approved.

Function	Name
Sr Engineering Manager - Systems Engineering	Perelman, Benjamin
Program Manager- Accessories Compatibility Engineering	M.Ravichandran

7. Revision History

Rev	Date	Author	Comments
1	02nd May 2022	M.Ravichandran	Initial Release

PHILIPS

Philips Medical Systems Nederland B.V.

Veenpluis 6, 5684 PC Best, The Netherlands

Compatibility Statement

Penlon Limited, Abingdon Science Park, Barton Lane, Abingdon, OX14 3NB, UK markets the devices listed below (hereinafter referred to as “Product”).

Philips Medical Systems Nederland B.V. has performed compatibility tests utilizing a limited number of samples of Product on 22nd March 2022. The scope of this compatibility statement is strictly limited to the below listed Philips MRI systems (hereinafter “MRI System”) and Product.

Philips Part			**Penlon Product**	
Philips MRI system	**6NC MDD**	**6NC MDR**	**Part**	**Description**
Achieva 1.5T	781343	n.a.	Prima 451 “MI5” MRI	Anaesthesia machine
Achieva 1.5T dStream	781262	n.a.	AV-S MRI “AVSPM” MRI	Ventilator
Ingenia 1.5T CX	781262	782104	Delta “MR”	Iso, Sevo and Hal vaporizers
Smartpath to dStream 1.5T	781260	782112	SC760 MRI	Suction controller
Ingenia 1.5T	781341	782101	AGSS MRI	Scavenging receiver
Ingenia 1.5T S	781347	782102		
Ingenia Ambition 1.5T S	781359	782108		
Ingenia Ambition 1.5T X	781356	782109		
Ingenia 1.5T (Evolution)	781315	782115		
MR5300 1.5T	781315	782110		
Evolution upgrade 1.5T (transf)	n.a.	782116		
Achieva 3.0T	781278	n.a.		
Achieva 3.0T Tx	781345	n.a.		
Achieva 3T dStream	781271	n.a.,		
Ingenia 3.0T CX	781271	782105		
Smartpath to dStream for XR and 3T	781270	782113		
Ingenia Omega HP 3.0T	781342	782103		
Ingenia 3.0T	781342	n.a.		
Ingenia Elition 3.0T S	781357	782106		
Ingenia Elition 3.0T X	781358	782107		
MR7700 3.0T	n.a.	782120		
Evolution upgrade 3T (transf)	n.a.	782117		

PHILIPS

Philips Part			Penlon Product	
Philips MRI system	**6NC MDD**	**6NC MDR**		
Smartpath to Ingenia Elition X	n.a.	782118		
Prodiva 1.5T CS	781069	n.a.		
Prodiva 1.5T CX	781070	n.a.		
Multiva 1.5T	781072 781073	n.a.		

Through the basic compatibility testing with the Product, Philips found the MRI System performed as intended and specified, with no detrimental degradation of MRI System efficacy or safety when used per the conditions as stated in their Instructions for Use. This testing indicates compatibility of the Product with MRI System.

Safety and efficacy of the Product is the sole responsibility of Penlon Limited. All issues related to the use of Product shall be referred to Penlon Limited. This compatibility statement does not guarantee assurance that compatibility will be maintained with future changes to Product, including incorporated software releases, modifications, and upgrades.

Compatibility testing reference file: D001057330 Rev.A

Philips Medical Systems Nederland B.V

David Hanly
(signature)

Name: David Hanly
Title: Head of Q&R, MR Systems Best
Date: 24 MAY 2022

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AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_2
I.2. Declarația de conformitate CE	Declaratie de conformitate CE_1
I.3. Certificatul CE	Certificat CE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
DM000528570										
DM000528570	MAȘINĂ DE ANESTEZIE		PRIMA 451 MRI		Marea Britanie	PENLON LIMITED	ANCOTEC-SISTEM S.R.L.	Rg04-000136	12-06-2023	

Содержит([Code], 'DM000528570')

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