Prima 465 Anaesthesia Machine

ANAESTHESIA SOLUTIONS

User Manual

Penlon

IMPORTANT

Servicing and Repairs

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

We recommend that the Prima 465 Anaesthesia Machine should be serviced on the following schedule:

1. Six monthly inspection and function testing.
2. Annual service which includes routine replacement of seals etc., as preventive maintenance.

Details of these operations are in the Prima 465 Anaesthesia Machine servicemanual, which contains servicing procedures etc. Servicing should be carried out by engineers trained by Penlon Ltd.

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

or communicate directly with:

UK and ROW, except USA

Technical Support
Penlon Limited
Abingdon Science Park
Abingdon, OX14 3NB, UK

Tel: +44 (0) 1235 547076
Fax: +44 (0) 1235 547062
E-mail:technical.support@penlon.com

USA

Penlon Inc.
11515 K-Tel Drive
Minnetonka
MN 55434
USA

Toll Free: 800-328-6216
Tel: 952-933-3940
Fax: 952-933-3375
E-mail: customer.service@penlon.com

Always give as much of the following information as possible:

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

NOTE

The Serial Number can be found on the device ID label.

Foreword

This manual has been produced to provide authorised personnel with information on the function, routine, performance and maintenance checks applicable to the Prima 465.

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

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

IMPORTANCE OF PATIENT MONITORING

WARNING

Anaesthesia 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 system 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, the user must check that it conforms to the relevant standards.

Contents

Contents

User Responsibility

This device 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 Penlon Limited or the nearest Penlon Service Centre.

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 Limited or its appointed agents.

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

The reader must 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 system.

1.1 Warnings

1. **This anaesthetic system 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 anaesthetic system must not be operated with such panels missing. Unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.**
3. **To isolate the machine from the mains power supply, disconnect the mains cable from the hospital power outlet.**
   Always use a mains power outlet socket that can be easily accessed.
4. **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.**
5. **Attaching or removing a medical gas cylinder:**
6. **Follow appropriate manual handling guidelines when lifting.**
7. **Check 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.**
8. **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.**
9. **The anaesthesia system 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.
10. **Prima 465 machines must only be used with Selectatec-compatible vaporizers installed on the Selectatec-type backbar 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 auxiliary common gas outlet (ACGO) 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 overdosage when the flush valve is operated.)
11. **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.
12. **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.**
13. **Because breathing systems require frequent cleaning they are not a permanent part of the anaesthetic machine and therefore cannot be directly under the control of the anaesthetic machine manufacturer. 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.**
14. **Always perform a pre-use check of the machine, including vaporizers, ventilator, 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.
15. **The machine must not be used if any of the alarm, monitoring or protection system devices are not functioning correctly.**
16. **Auxiliary gas outlets: Flow rates greater than 60 L/min could affect the fresh gas flow to the patient.**
17. **The gas supply failure systems within the anaesthetic machine will not necessarily operate as indicated in this manual during any procedures that are outside the scope of the indications for use of the machine:**
18. **Machine set to deliver Air only**
    If the machine is operated with an Air flow only, note that there may still be retained oxygen in the system, and that the oxygen supply visual indicator will continue to indicate green, even though oxygen is not being delivered.
19. **Machine set to deliver Oxygen only through Auxiliary Outlets. The 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).**
20. **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.**
21. **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.**

22. **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.**
23. **To avoid the risk of electric shock, this system must only be connected to a mains supply with a protective earth. 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.**
24. **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.**
25. **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.**
26. **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.
27. **Accessories must be removed before the machine is transported.**
28. **MRI compatibility - Prima 465 models are not MRI compatible.**
29. **To prevent patient injury in the event of total anaesthesia system failure, an alternative means of ventilation must be available whenever the device is in use.**
30. **Obstruction of the breathing system can restrict or stop gas flow to the patient, and can cause injury or death. Make sure that there are no obstructions in the breathing system.**
31. **Keep very small components/parts/plugs away from the breathing system.**
32. **You must only use non-conductive breathing system hoses.**
33. **Do not touch any electrical device connector at the same time as the patient.**
34. **This machine is not suitable for use in oxygen-rich environment.**
35. **This device must not be altered or modified in any way without the written permission of Penlon limited.**

1.2 Cautions

1. Open cylinder valves slowly to avoid damage to pressure reducing valves.
   Check that cylinder valves are at least one full turn open when in use.
2. Under no circumstances should anaesthetic agents be used for cleaning purposes.
3. After use, always disconnect the machine from the piped gas supply and/or close the gas cylinder valves.
4. Anti-Hypoxic Device (AHD) system - The oxygen flow control is restricted to prevent the needle valve from fully closing. This checks a minimum basal flow of oxygen.
   DO NOT attempt to close the flow to zero.
   Do not overtighten.
5. Compressed gas supplies must be clean and dry.
6. When the auxiliary gas outlets are in use on a machine using cylinder supply only (i.e. if the pipeline supply is not in use), check flow rate requirements, and check that adequate back-up cylinders are available.
7. The requirements of IEC 60601-1 apply to any device connected to the auxiliary electrical sockets. Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary power sockets
8. In the event of malfunction of any device powered by the auxiliary sockets, check if the circuit breaker has tripped.
9. Do not apply excessive pressure to the display screens.
10. Connect the external COMMS outlet only to approved devices using protocol provided by Penlon Ltd. Contact Technical Support Department for details.
11. Vaporizers: Read the instruction manual supplied with the vaporizer before clinical use.

1.3 Note

1. Refer to Appendix 4 for labelling and symbols

2. Purpose

2.1 Purpose

The Prima 465 anaesthetic machine range is for use by a professional operator in a hospital or clinical environment, and must be continually attended when in use. The device 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 device 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 machine can be used in open or closed circuit configurations.

2.2 Gas supplies

Three gases - oxygen, nitrous oxide, and air.

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

Backbar manifold for Selectatec-compatible type vaporizers.

2.3 Anti-Hypoxic Device (AHD)

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

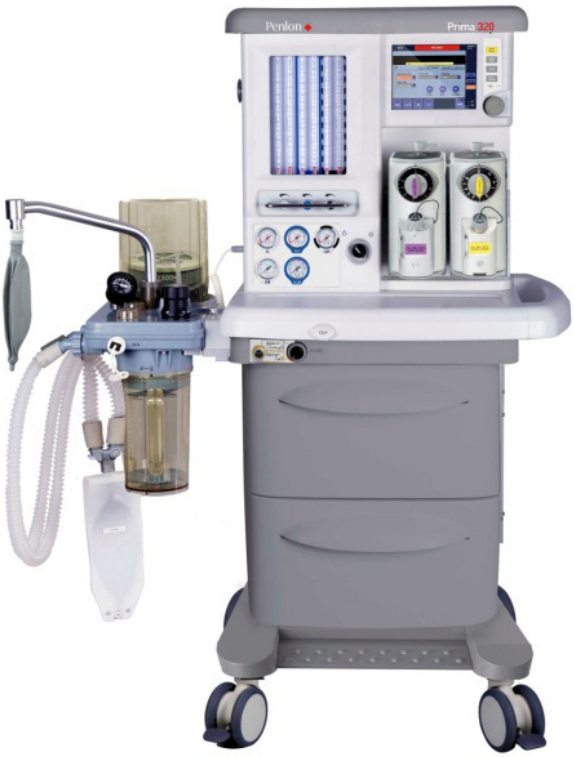
3. Description

3.1 Medical Electrical Equipment

The Prima 465 is a Medical Electrical (ME) Equipment as defined in BS EN 60601-1.

The Prima 465 has the components that are described as Applied parts:

The Prima 465 has a single connection to a mains power supply.



3.2 Frame

The machine has a metal aluminium base, extruded aluminium uprights, and aluminium and plastic mouldings.

3.3 Mobility

Four castors with a brake on each front castor.
A footrest is built into the front of the machine.

3.4 Mounting brackets

A mounting system is built into each pair of side uprights, to allow the use of mounting brackets for accessories.

3.5 Work surface

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

3.6 Gas circuit

The anesthesia machine has pipeline and cylinder gas inlets and a regulated supply of O_2, Air, and N_2O is routed to the electronic mixer at a constant pressure. The user sets the required flows and mixed gas is then supplied to the vaporizer backbar.

The ventilator is a pneumatically driven, microprocessor-controlled anesthesia delivery system. The drive gas comes from the O_2 or Air gas supply.

A full description of the gas circuit is given in Appendix 5.

A gas circuit schematic is shown on the next page.

3.7 Closed Circuit configuration

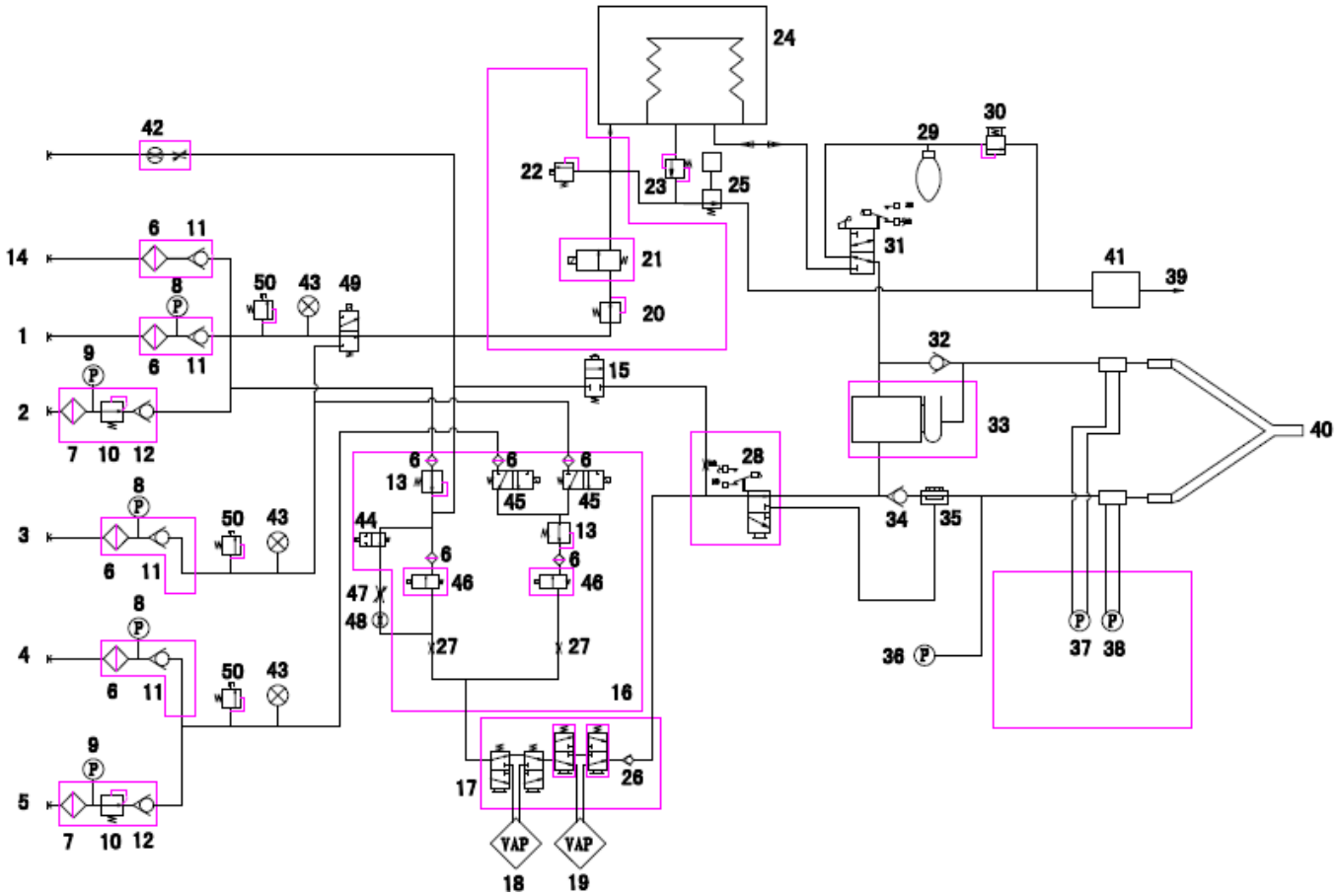
The closed circuit confguration utilises the ventilator and the absorber to recycle anaesthetic and expired gases.

3.8 Open Circuit configuration

The open circuit configuration utilises the O_2 flow from the Common Gas Outlet (CGO).

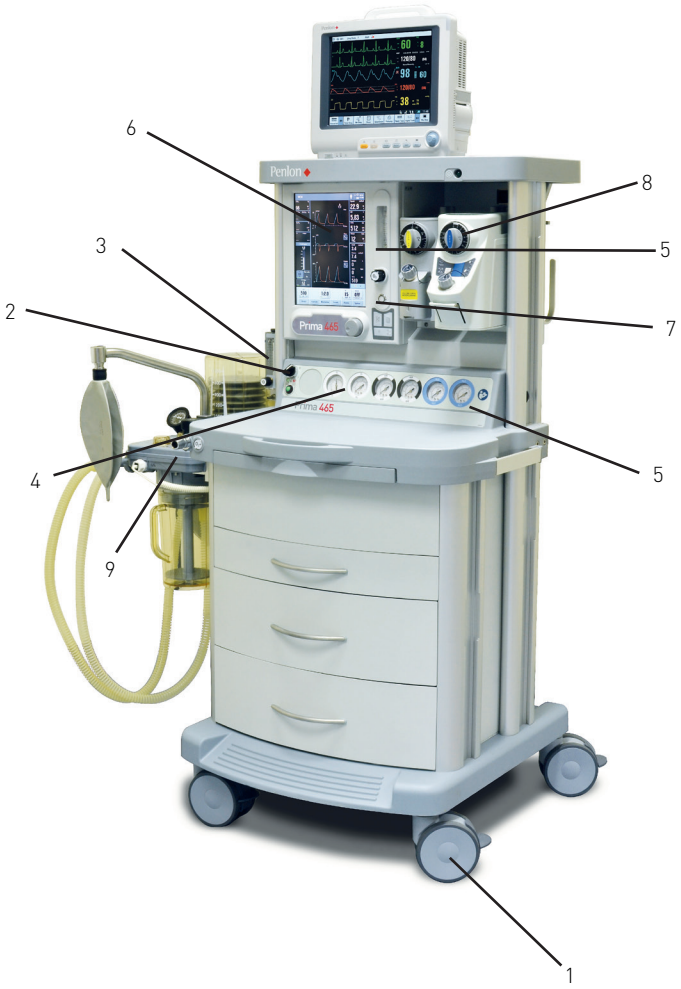
Description

3.9 Gas Circuit Schematic



1	O_2 pipeline supply connector	23	'Pop-off' valve	44	Alternate O_2 valve
2	O_2 cylinder	24	Bellows	45	N_2O/Air valve
3	Air pipeline	25	Positive end-expiratory pressure (PEEP) valve	46	Flow control
4	N_2O pipeline	26	Check valve	47	Flow regulator
5	N_2O cylinder	27	Restrictor	48	Alternate O_2 flowmeter
6	Pipeline supply filter	28	CGO control	49	Drive gas valve
7	Cylinder filter	29	Manual Bag	50	Safety valve (0.7 MPa)
8	Pressure gauge - pipeline	30	Adjustable pressure limiting (APL) valve		
9	Pressure gauge - cylinder	31	Manual/mechanical ventilation switch		
10	Regulator (400 kPa)	32	Expiratory check valve		
11	Check valve 1	33	Absorber canister		
12	Check valve 2	34	Inspiratory check valve		
13	Regulator (250 kPa)	35	Oxygen sensor		
14	O_2 pipeline	36	Airway pressure gauge		
15	O_2 flush button	37	Expiratory flow sensor		
16	Electronic mixer module	38	Inspiratory flow sensor		
17	Selectatec manifold	39	Outlet to AGSS system		
18	Vaporizer	40	Patient		
19	Vaporizer	41	Connector for anaesthetic gas scavenging system (AGSS)		
20	Regulator (250 kPa)	42	Auxiliary oxygen supply		
21	Inspiratory flow control valve	43	Pressure sensor		
22	Over-pressure valve (110 kPa)				

3.10 Front view

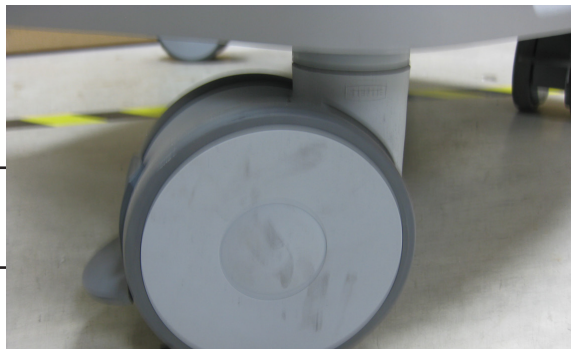


1. Castors (with front brakes)
2. Anaesthesia system switch
3. Auxiliary oxygen outlet and flowmeter.
4. Cylinder pressure gauges
5. Alternate oxygen control
6. Display screen
7. Alternate oxygen control and flowmeter
8. Vaporizer
9. Common Gas Outlet and O_2 flush button

3.10.1 Castors

The Prima 465 Anaesthetic machine has four castors (1) supporting the machine at the four corners of the base.

Each castor has a pedal (2) that is used to operate the foot brake. Each brake will brake only a single castor.



3.10.1 Anaesthesia system switch

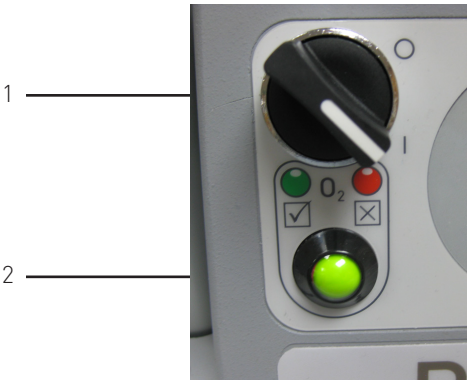
The Anaesthesia system switch control the operation of the anaesthesia machine.

The anaesthesia system switch incorporates a single dolls eye indicator. The dolls eye indicator shows the colours that follow:

a) RED when the machine is not operational (O)

b) GREEN when the machine is operational (I).

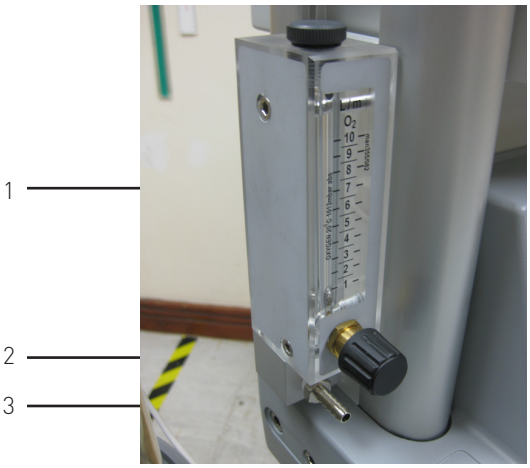
When the switch is set to the O position, the machine will provide no anaesthetic functions. When the switch is in the I position, the anasthetic machine will become functional and, once self tests and pre-use checks have been completed, will be able to deliver anaesthetic services to the patient.



3.10.2 Auxiliary Oxygen outlet and flowmeter

Auxiliary Oxygen is provided directly from the O_2 cylinder or the O_2 pipeline supply.

The Auxiliary O_2 outlet (3) privides O_2 at a pressure controlled by the control knob (2) at a pressure that is displayed on the Auxiliary O_2 Flowmeter (1).



3.10.3 Cylinder pressure gauges

The five pressure gauges on the front panel display the gasdelivery pressure that follow:

a) O_2 Pipeline delivery pressure (1)

b) O_2 Cylinder delivery pressure (2)

c) Air delivery pressure (3).

d) N_2O Pipeline delivery pressure (4)

e) N_2O Cylinder delivery pressure (5).

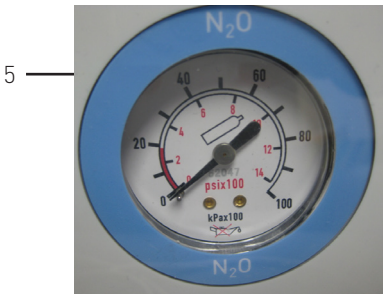
Pipeline gauges measure delivered pressures between 0 and 100 kPa (0 - 140 Psi)

Cylinder gauges measure delivered pressures as follows:

- O_2 between 0 and 30000 kPa (0-4000 psi)
- N_2O between 0 and 10000 kPa (0- 1400psi)

Cylinder gauges have a red zone that indicates a reduced delivery pressure. The red zones are shown as follows:

- O_2 between 0 and 2000 kPa (0-300 psi)
- N_2O between 0 and 2000 kPa (0-300 psi).



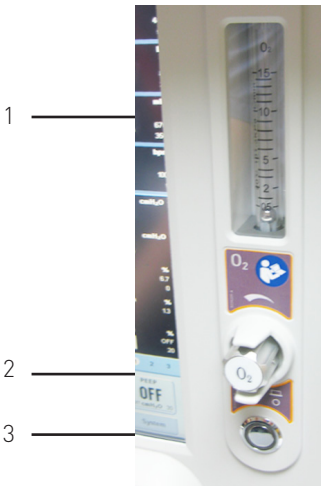
3.10.4 Alternate O_2 control and flowmeter

The Alternate O_2 control and flowmeter consists of the components that follow:

- A flowmeter (1)
- An Alternate O_2 control knob (2)
- An ON/OFF switch.

The ON/OFF switch is illuminated Green when the switch is in the ON position. In the ON position the Alternate O_2 control knob can be used to vary the amount of O_2 supplied. The Flowmeter indicates the volume of O_2 supplied.

The alternate O_2 bypasses the software controlled FG Flow control, allowing an alternate control of O_2 flow to the breathing system.



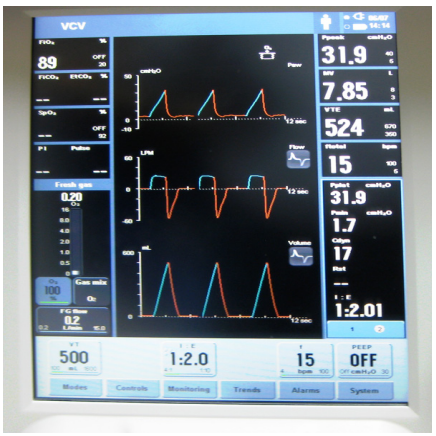
3.10.5 Display screen

The Prima 465 includes a display screen that is controlled by the onboard software and uses a touch screen and multifunction control interact with the user.

The operation of the multifunction control is explained in xxxxxx.

The touch screen allows the operator to select functions made available by the using touch.

The Functions of the software are listed in section 7.

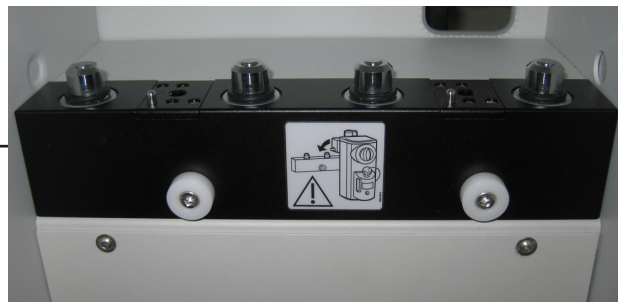


3.10.6 Vaporizer

The Prima 465 has a Selectatec-type backbar system that is capable of supporting two compatible vaporizers. The backbar (1) has an interlock system that allows the use of only one vaporizer at any time.

The backbar (1) has two locating spigots that locate into a selectatec compatible vaporizer.

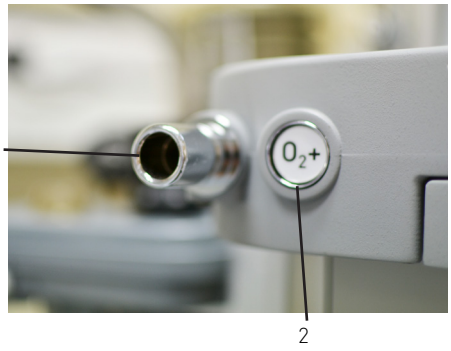
For more information on the Vaporizer, refer to the Instructions For Use (IFU) supplied with the vaporizer in use.



3.10.7 Common Gas Outlet and O_2 flush button

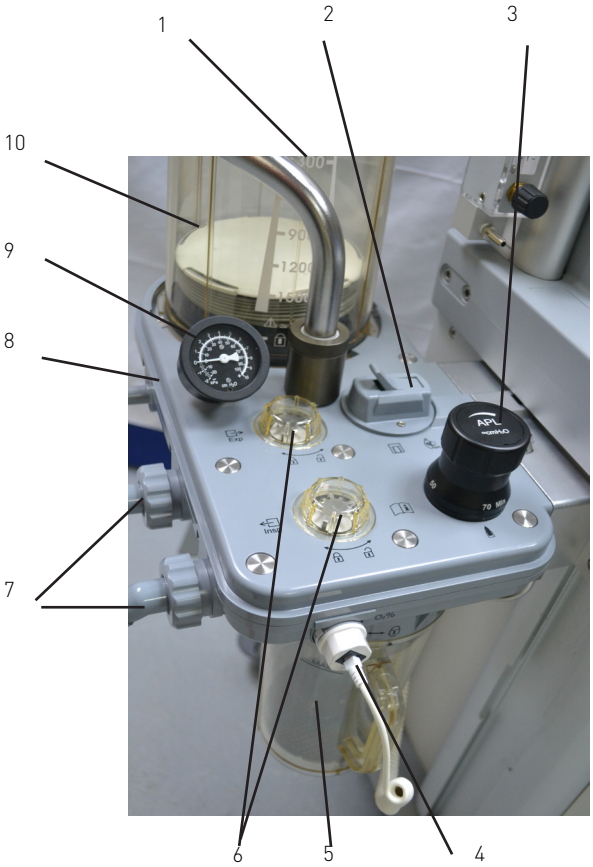
The Common Gas Outlet (CGO) allows the operator to use the Anaesthetic machine in the Open Circuit configuration.

The O_2 flush button is used to send O_2 directly to the CGO. When the CGO is in use the O_2 flush button is illuminated green.



3.11 Absorber

1. Bag support arm
2. Bag / Vent switch
3. APL (Adjustable pressure-limiting) valve
4. Oxygen sensor
5. Absorber canister
6. Inspiratory and expiratory check valve
7. Inspiratory and expiratory ports
8. Leak test plug
9. Airway pressure gauge
10. Bellows housing



3.11.1 Bag support arm

3.11.2 Bag/Vent switch

3.11.3 Adjustable pressure-limiting (APL) valve

3.11.4 Oxygen sensor

3.11.5 Absorber canister

3.11.6 Inspiratory and expiratory ports

3.11.7 Leak test plug

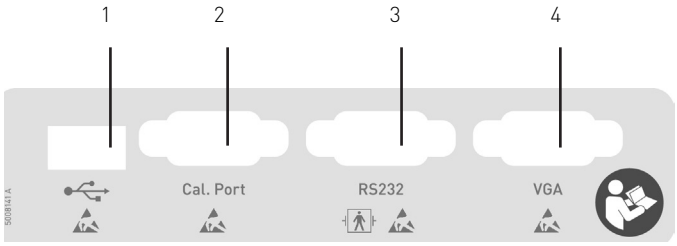
3.11.8 Airway pressure gauge

3.11.9 Bellows housing

3.12 Rear view

1. Cylinder yoke
2. Multiple socket outlets
3. Mains inlet
4. Communication port
5. SPO_2 sensor connection
6. Battery box cover

3.13 Communication port



1. USB interface
2. Calibration and software update port
3. RS232 Interface (external multi-gas detection module IRMA CO_2 or IRMA AX + only - not for other devices.
4. VGA port

3.13.1 USB interface

The USB interface is currently non-functional.

3.13.2 Calibration and software update port

The calibration and software update port is designed for use by trained penlon engineers only.

3.13.3 RS232 interface

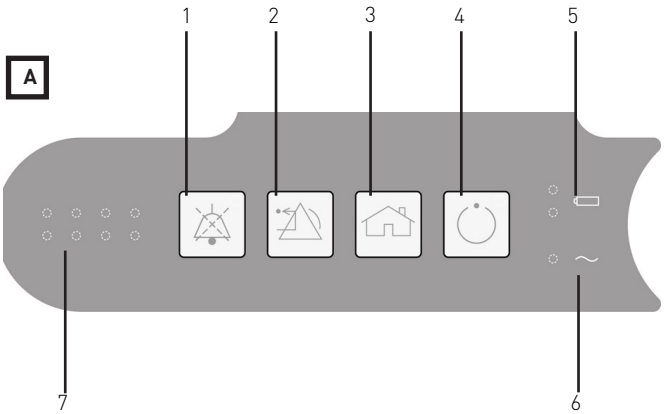
The RS232 interface is designed for use with the Masimo mainstream gas module only.

3.13.4 VGA port

The VGA port is currently non-functional.

3.14 Control Panel

1. Alarm silence key:
2. Alarm reset key
3. Home key:
4. Start / Standby
5. Battery LED
6. Mains power LED
7. Alarm indicators
8. Multifunctioncontrol knob



3.14.1 Alarm silence key
The alarm silence key is used to

3.14.2 Alarm reset key

3.14.3 Home key

3.14.4 Start/Standby key

3.14.5 Battery LED

3.14.6 Mains power LED

3.14.7 Alarm indicators

3.14.8 Multifunction control knob

3.15 Battery

If the AC power supply fails, the system automatically switches to battery supply.

Backup time: Approximately 1.5 hours

A fully charged battery will power the anesthesia workstation for up to 1.5 hours, depending on configuration and operation. For example, frequent use of monitoring modules will shorten the backup time available.

Battery recharge
The battery is charged automatically when the machine is connected to an AC power source.
Recharge time: Approximately 4 hours to charge from total discharge

3.11.1 Battery life
Battery life depends on frequency and period of use. A correctly maintained and stored Nickel-hydrogen battery, has an average life expectancy of approximately 2 years.
We recommend replacement every 2 years.

3.11.1 Battery replacement
Warning
Replacement must be carried out by trained service personnel – see Section 8.10. The user must not replace the battery.

3.11.1 Battery indicator

The battery indicator has three sectors.

Ventilation will still be possible when a low battery alarm is triggered.

When the battery indicator shows empty display sectors, and the battery total discharge alarm is triggered, automatic shutdown will occur unless mains power is restored.

Caution

1. **If a battery has been stored in a discharged state, charging may take longer than the time stated above.**
2. **Charge the batteries at least once in every two months if the machine is in storage.**

3.16 Vaporizers

CAUTION

Read the instruction manual supplied with the vaporizer before clinical use

3.16.1 Vaporizer Mounting System

Two Selectatec-compatible vaporizers for the administration of volatile anaesthetic agents can be fitted to the universal backbar manifold as follows:

WARNING

All 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.

Do not install or connect any vaporizer of any description between the auxiliary common gas outlet (ACGO) and the breathing system, unless it is specifically designed for such use. (If this is done, the oxygen flush flow will pass through the vaporizer, and severe overdosage may result).

3.16.2 Selectec-compatible vaporizer

Upto two selectatec-compatible vaporizers can be fitted to the Prima 465.

Each station is 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.

3.16.3 Vaporizer interlock system

Selectatec-compatible vaporizer interlock systems are described in the literature supplied with the vaporizer.

4. Specification

4.1 Physical Dimensions

NOTE

All data is approximate

Overall frame size	Height - 131 cm
	Width - 79 cm
	Depth - 70 cm
Work surface	Height - 86 cm
	Size - 58 x 25 cm
	Loading - 30 Kg
Writing Tablet	Size 30 x 22 cm
	Loading 10 Kg (22 Lb.) (evenly distributed)
Top Shelf	Size 71 x 35 cm
	Loading 30 Kg (66 Lb.) (evenly distributed)
Drawers	Size 12 x 54.5 x 35 cm
	Loading 10 Kg (22 Lb.) (evenly distributed)
Castors	Diameter - 12.5 cm (5 In,)
Gas scavenging fixing	Bracket on frame upright
	Loading 30 Kg (66 Lb.)
Auxiliary Common Gas Outlet	2.2 cm male taper with coaxial 1.5 cm female taper connections
Mass	125 Kg (275 Lb.)

Specification

4.2 Gas Supplies

Cylinders	Three.
	Pin-indexed cylinder connections are available
Pipeline	Three inlet pipelines are provided. Connectors are territory specific.
	UK and Europe - NIST connectors
	USA - DISS connectors
	Australia - SIS connectors
Medical gas colour codes	
Oxygen	Green or White*
Nitrous Oxide	Blue
Medical Air	Yellow or Black*
* to comply with relevant national standards	

4.3 Gas Pressures

	USA/Canada/Japan	**UK**
Pipeline supplies:		
Supply Pressure	280-600 kPa (40.6 - 87.0 psig)	280-600 kPa (40.6 - 87.0 psig)
Cylinder supplies:		
Supply pressure	19 985 kPa (2900 psig)	19 985 kPa (2900 psig)
Reduced pressure from regulator (at 5 L/min)	310 kPa + 15 kPa/-35 kPa (45 psig +2 psig/-5psig)	380 kPa + 15 kPa/-35 kPa (55 psig +2 psig/-5psig)
Regulator diaphragm bursting pressure	2800 kPa (406 psig)	2800 kPa (406 psig)
Reduced pressure from secondary regulators (at 5 L/min)		
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 cmH_2O	90 cmH_2O

4.4 Auxiliary Gas Outlets

Oxygen	
Two self-sealing connections on rear of machine	
Air (on machine with Air supply option)	
Two self-sealing connections on rear of machine	
Supply pressure	
Pipeline supply in use:	Gas is supplied at pipeline supply pressure (Section 4.4)
Cylinder supply	Gas is supplied at reduced pressure from the cylinder supply secondary regulator (Section 4.4)
Flow rate	
Flow rate for each gas:	60 L/min maximum

WARNING

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

4.5 Oxygen Failure Warning Devices

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

4.6 Oxygen flush

Button on the front edge of the worksurface

The system supplies 25-75 L/min when the button is fully depressed.

4.7 AHD System

Maximum Oxygen Concentration	30% ± 3% (of total O_2 + N_2O flow)

4.8 Environmental

Operating conditions	
Temperature	+10 to 40° (50 to 104°F)
Atmospheric pressure range	70 to 106 Kpa
Altitude	2438m (8000 ft) maximum
Humidity	10 - 85 % R.H. non-condensing
Transport and storage temperature	
Basic machine	-5 to 40°C (23 to 104°F)
Cleaning	Wipe external surfaces with dry or damp cloth. Use mild soap, or disinfectant solution if necessary (See Section 6.1)

4.9 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 switch
US/CSA specification machines:	20A
Non US/CSA specifcation:	10A
Power cable:	Permanently attached lead (3m). Stowage hooks are fitted at the rear of the machine.
Internal power distribution	
1. Ventilator/Absorber IEC sockets	5A maximum
Fuses	T5AH 250V ceramic (5 x 20 mm) high breaking capacity (On live and neutral on each outlet)
2. Workspace lighting and electronic flow displays	12 VDC, 5A maximum
Fuses	T3.15AH 250V ceramic (5 x 20 mm) high breaking capacity (On live and neutral on each outlet)
Power outlets:	
1. Total power outlets	Four
Rear Auxiliary Power Outlets	Three outlets, country specific: 5 A per outlet
US/CSA specification machines	15A (nominal): maximum current depends on internal power outage.
Non-US/CSA specification machines	10A (nominal): maximum current depends on internal power outage.
Fuses	T5AH 250V ceramic (5 x 20 mm) high breaking capacity (On live and neutral on each outlet)
2. Front power outlet	One outlet (IEC Socket)
US/CSA specification machines	5A maximum
Fuses	T5AH 250V ceramic (5 x 20 mm) high breaking capacity (On live and neutral on each outlet)
Non-US/CSA specification machines	3.15 A maximum
Fuses	T3.15AH 250V ceramic (5 x 20 mm) high breaking capacity (On live and neutral on each outlet)
Electromagnetic compatibility The Prima 465 meets the requirements of EN 60601-1-2 (electromagnetic compatibility - requirements and tests). Refer to Appendix 8.	
Replaceable battery specification	20 x GRPH-18670 8400P 12V

4.10 Device Classification and Labelling

Mode of Operation

Continuous

Type B Applied Part

Degree of protection against electric shock

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 4

Patient Class

All patient types: No residual risks from phthalates that are carcinogenic, mutagenic, or toxic to reproduction.

Oxygen compatibility

The Prima 465 anaesthetic machine is not suitable for use in an Oxygen rich environment

5. Installation and Pre-Use Checks

5.1 Absorber Assembly

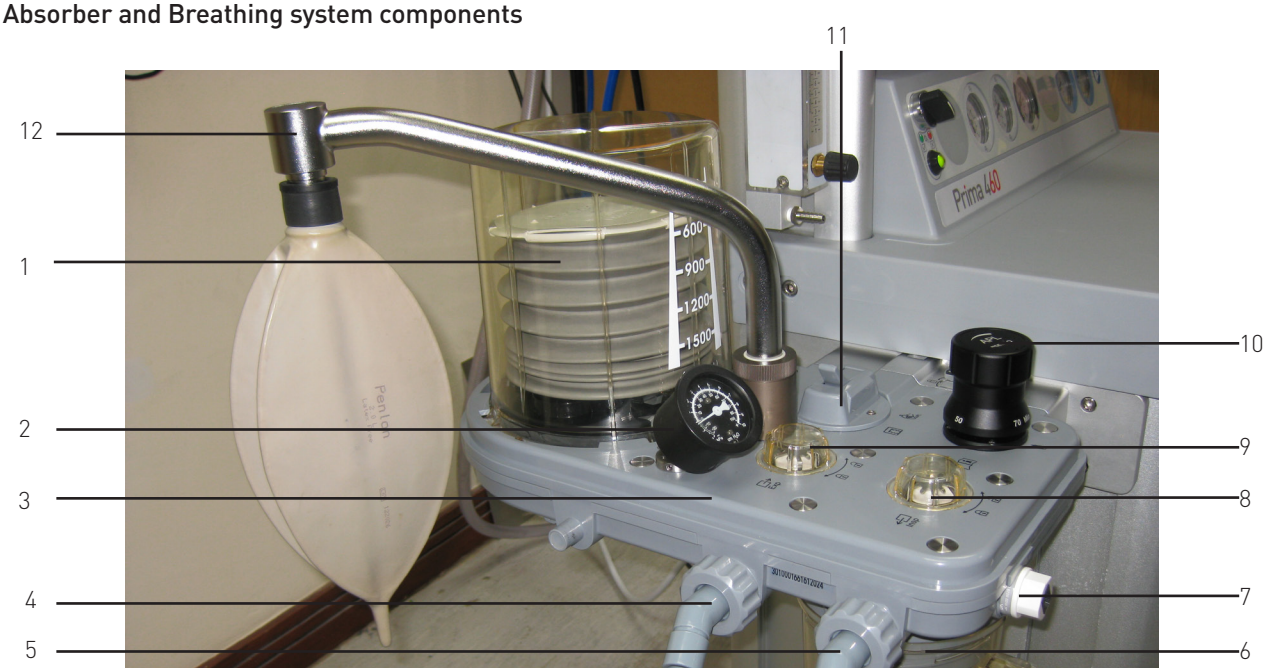
WARNING

1. **Check that pipeline gas supply hoses and breathing circuit components are not toxic, and will not cause allergic reactions in patients or react with anaesthetic vapour and gases.**
2. **Check that the soda lime in the absorber canister is not desiccated. Continuous use of desiccated soda lime may endanger patient safety. Always turn off all gases after each clinical procedure.**
3. **When using electrical surgical equipment, keep cables away from the breathing circuit, oxygen sensors, and flow sensors.**
4. **Manual ventilation devices, and monitoring and life support equipment must be available.**
5. **Do not use antistatic or conductive face masks. They can cause burns if used near high frequency electrosurgical equipment.**
6. **This equipment must be installed by a Penlon-trained engineer.**
7. **The anesthesia machine has waste gas exhaust ports. Check that residual breathing gas is scavenged.**
8. **Total mains power usage must be within the specifications listed in Section 4.9.**
9. **Remove all packing materials before installation and use.**

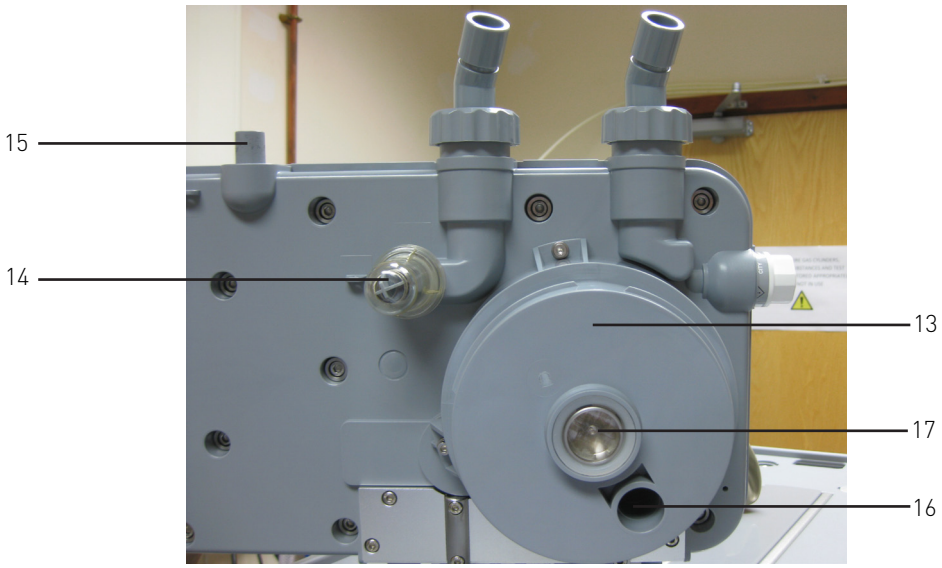
CAUTION

Check levels of soda lime in the canister and the anesthetic agent in the vaporizer after use.

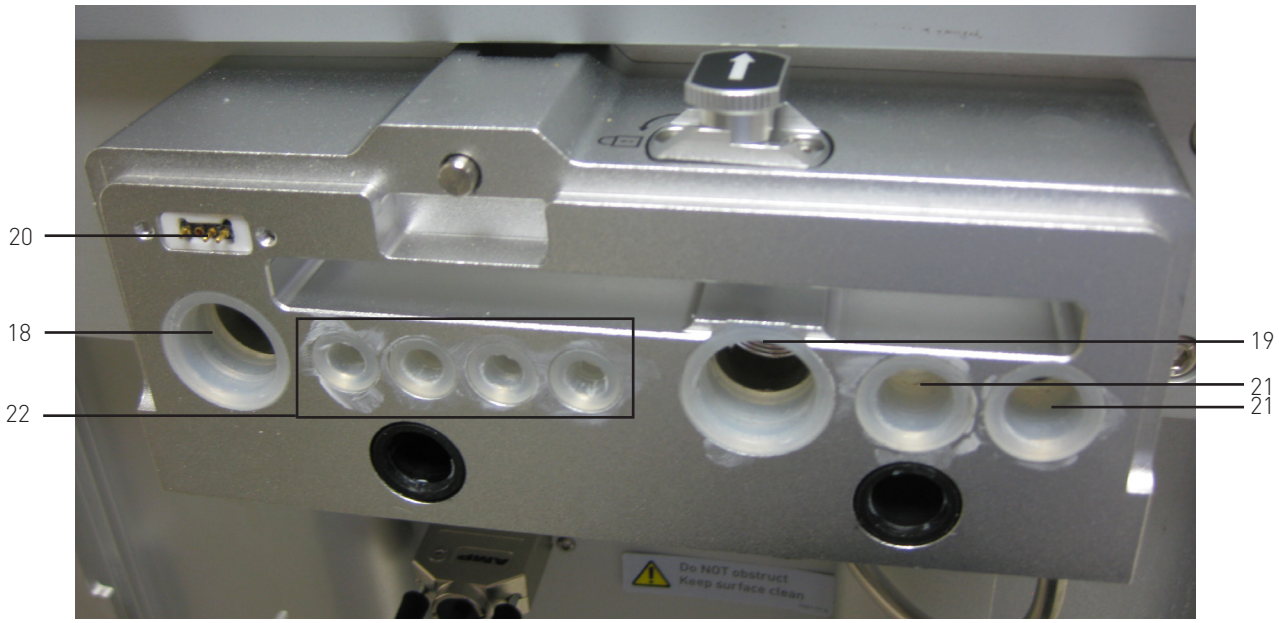
5.1.1 Absorber and Breathing system components



1. Bellows housing
2. Airway pressure gauge
3. Breathing system block
4. Expiratory port .
5. Inspiratory port
6. Absorber canister
7. Oxygen concentration sensor
8. Expiratory check valve
9. Inspiratory check valve
10. APL valve
11. Bag/vent switch
12. Bag arm



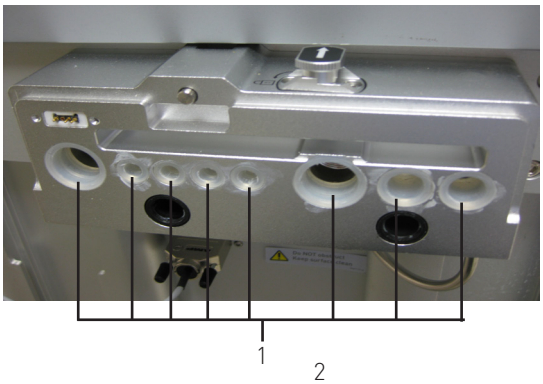
13. Absorber canister mount
14. Water container
15. Test plug
16. Absorber canister inlet
17. Absorber canister outlet



18. Inspiratory port
19. Expiratory port
20. Heater interface
21. Driving gas inlet
22. Flow sensors connectors (inspiratory/expiratory)

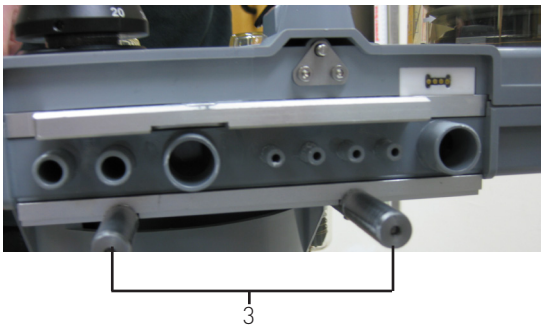
5.1.2 Installing the absorber and breathing system assembly

1. Make sure that the eight silicon inserts (1) are in place and are not damaged.
2. Use BG87 or Fomblin grease to lightly lubricate the eight silicon inserts (1).



3. Lift and turn the locking catch to the unlocked position.

4. Align the two connectors (3) on the absorber with the matching holes on the circuit adapter plate.



5. Push the absorber assembly into the circuit adapter plate with moderate force.
6. Reset the locking catch (2) to the locked position.

WARNING

Set the locking catch to the locked position after the absorber assembly is installed. To prevent a serious fresh gas leak and inaccurate tidal volume measurement, always check that the assembly is locked in position.

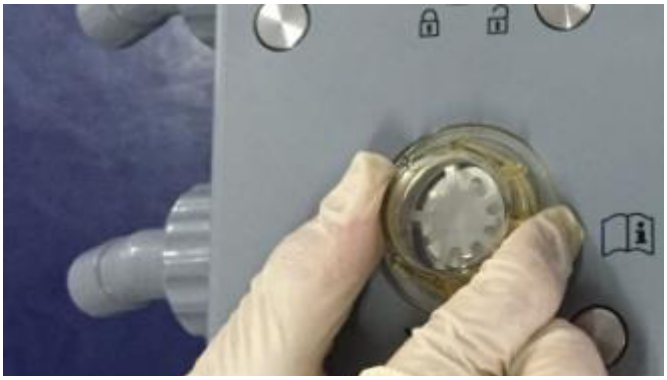
5.1.3 Install the expiratory and inspiratory check valve assemblies

NOTE

The inspiratory and expiratory caheck valves are identical, the procedure that follows can be used for either check valve.

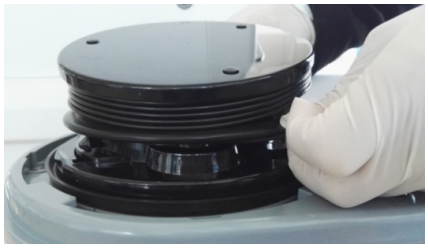
1. Install the check valve inserts.
2. Install the check valve cover.

3. Finger tighten the check valve cover.



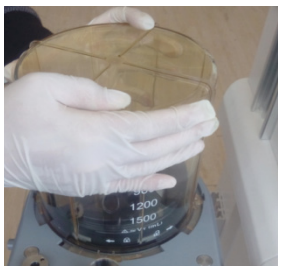
5.1.4 Install the bellows

1. Attach the bottom ring of the bellows to the bellows base
2. Make sure that the bellows are tightly connected to the base.



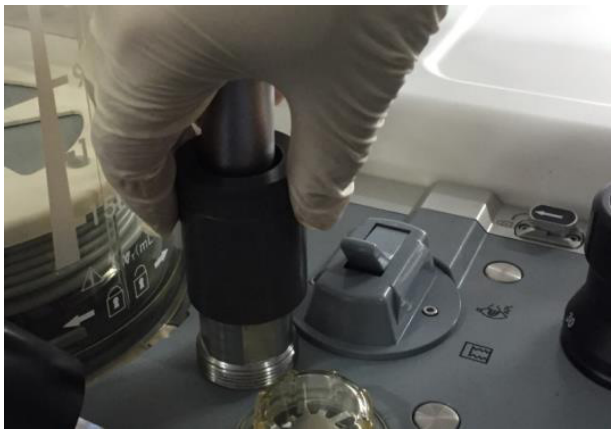
3. Align the bellows housing bayonet tabs with the slots on the breathing system.
4. Lower the bellows housing.
5. Make sure that the bellows housing sits enenly on the seal.

6. Hold the bellows housing tightly and turn it clockwise until it stops.
7. Make sure that the side of the housing marked with the scale will face the user.



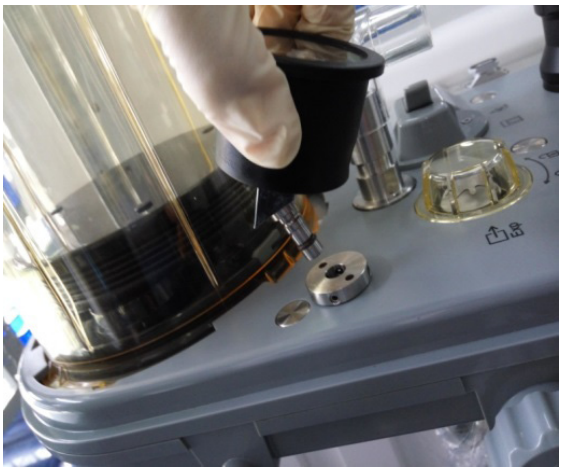
5.1.5 Install the bag support arm

1. Install the bag bag support arm to the to the port on the top of the absorber.
2. Turn the locking nut clockwise.



5.1.6 Install the Airway pressure gauge

Push-fit the airway pressure gauge to the port on the top of the absorber.

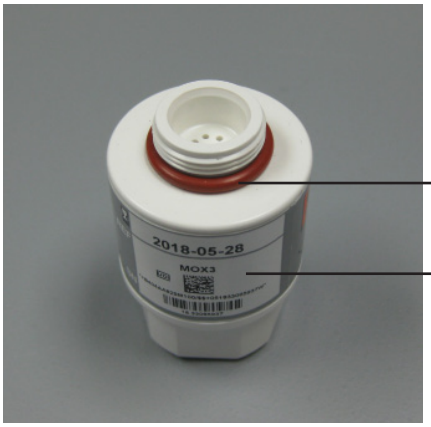


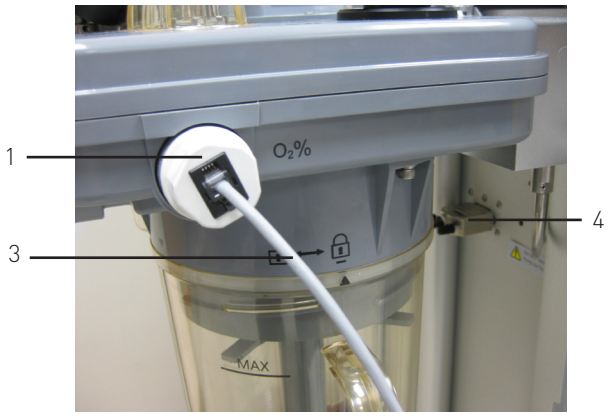
5.1.7 Install the oxygen sensor

CAUTION

1. **Before installing the O_2 sensor (2), check that the O ring (1) on the O_2 sensor (2) is in good condition. Fit a new O_2 sensor (2) if the O ring (1) is missing or damaged.**
2. **Tighten the O_2 sensor (2) manually, do not use a wrench or other tool.**

1. Align the threads of the O_2 sensor (1) with the O_2 sensor connector.
2. Turn the O_2 sensor (1) clockwise to tighten.
3. Install the O_2 sensor cable (3).
4. Connect the plug on the O_2 sensor cable (4) to the cable socket.
5. Make sure that there are no cables in front of the Canister sensor (5).

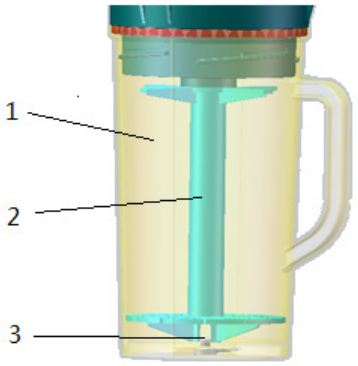




5.1.8 Install the absorber canister

Canister components

1. Absorber canister
2. Canister support
3. Water drain valve

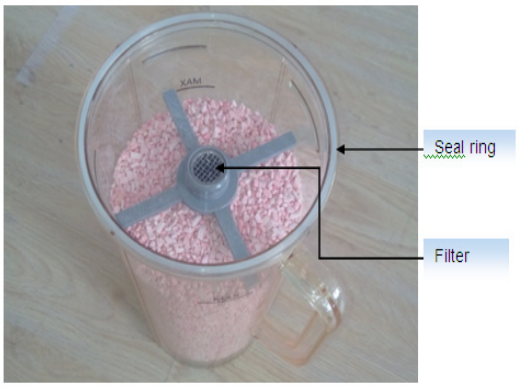


WARNING

1. **Do not allow absorbent to come into contact with skin or eyes. If this occurs, immediately flush with water and seek medical help.**
2. **Check that the canister is correctly locked in place to prevent leakage of the patient's expired CO_2.**
3. **Although the system has a 'NO ABSORBER alarm', CO_2 concentration monitoring is strongly recommended when the anesthesia machine has a BYPASS function.**
4. **Before installation, check the color of the soda lime in the canister and change if necessary.**
5. **Check the colour of the soda lime during and at the end of a clinical procedure. During non-use, soda lime may return to its original color. Check the manufacturer's instructions.**
6. **To prevent the sodalime from becoming desiccated, turn off all gases at the end of each clinical procedure. If the soda lime completely dries out, it may give off carbon monoxide (CO) when exposed to anesthesia agents. If necessary, renew the soda lime.**
7. **Clean the perimeter of the canister regularly to prevent a breathing system leak.**
8. **Before installation, inspect the rim of the canister perimeter, the canister support, and the seal for soda lime particles. Remove any build up of soda lime to prevent breathing system leakage.**

CAUTION

1. The absorber canister must only be used with air, oxygen, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane.
2. Remove the soda lime when the system is not in use, to prevent the buildup of non-metabolic gases.



5.1.9 Canister installation

WARNING

Before installation, inspect the rim of the canister perimeter, the canister support, and the seal for soda lime particles. Remove any build up of soda lime to prevent breathing system leakage.

1. Insert the canister support into the canister outlet.

2. Tighten counterclockwise until the two vertical lines on the canister and absorber mount are aligned.

CAUTION

After installation, carry out a breathing system leak test.

5.1.10 Replace absorbent

Caution

A gradual color change of the soda lime in the canister indicates approximately the level of absorption of carbon dioxide. Use carbon dioxide monitoring to determine when to change the soda lime.

Follow local regulations regarding disposal of hospital waste when the soda lime is changed. If left standing for several hours, it may regain its original color and give a misleading indication of useability.

1. Remove the absorber canister
2. Empty the canister.
3. Refill with new soda lime to the MAX line.
   Remove any soda lime that has collected on the filter.
4. Wipe the dust ring around the absorber canister support.
5. Refit the canister – see Section 5.1.7

WARNING

When refitting the absorber canister after changing the sodalime, make sure that the canister is installed correctly.

To prevent dust and particles do not enter the breathing circuit, the filter must be put in the correct position – see Section 5.1.7.

5.1.11 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.

5.1.12 CO_2 Monitoring Modules

Two types of CO_2 monitoring can be fitted - mainstream and sidestream.

Note that the two types can't be used at the same time.

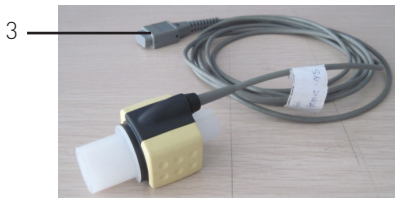
Mainstream CO_2 monitoring is provided by the anesthetic gas monitoring module.

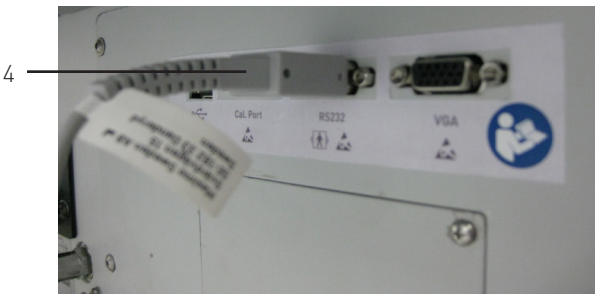
5.1.13 Connecting a mainstream CO_2 module

1. Snap the probe (1) on top of the airway adapter (2). The probe (1) will click into place when properly seated.
2. Use the connector (3) to connect the probe cable to the RS232 port (4).
3. Connect the smaller end of airway adapter (2) to the Y-piece connector in line withe face mask.

CAUTION

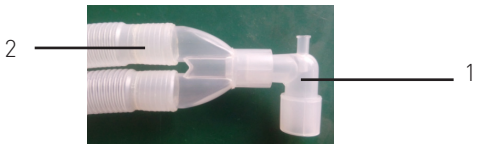
When Power is applied to the system, a green LED on the probe (1) indicates that the probe is ready for use.

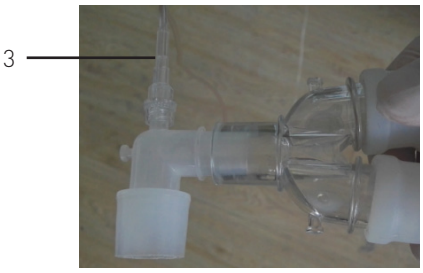




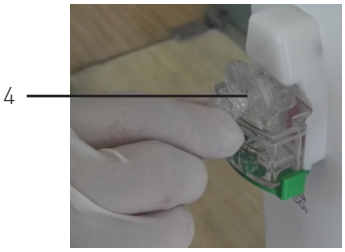
5.1.14 Connecting a sidestream CO_2 module

1. Connect the elbow (1) to the Y-piece (2)





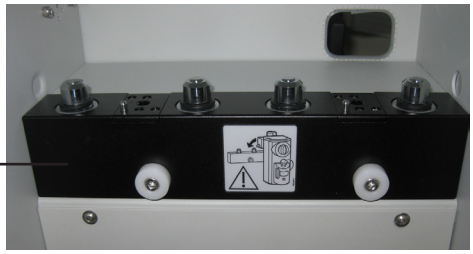
2. Connect the sampling tube (3) to the elbow (1) water trap (4).



3. Connect the elbow to the breathing mask.

5.1.15 Installing the Vaporizer

(DG: See 3.12.1 for additional instructions for vaporizer installation)

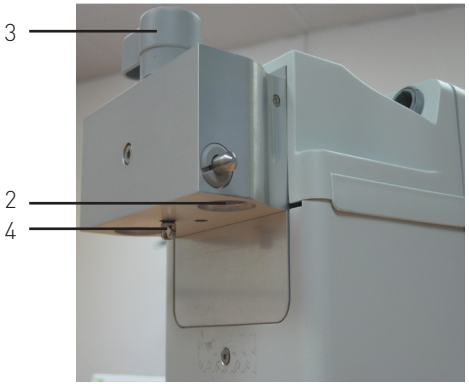


NOTE

1. Read the vaporizer instruction manual before clinical use.
2. Up to two Selectatec-compatible vaporizers may be fitted.

Install the vaporizer

1. Carefully offer the vaporizer up to the manifold (1).
2. Check that the gas connection ports (2) on the vaporizer are aligned with the valves on the manifold (1).
3. Carefully lower the vaporizer onto the manifold
4. Turn the locking lever (3) clockwise through and lock the vaporizer into position by clockwise rotation of the locking lever (3) through 90°.



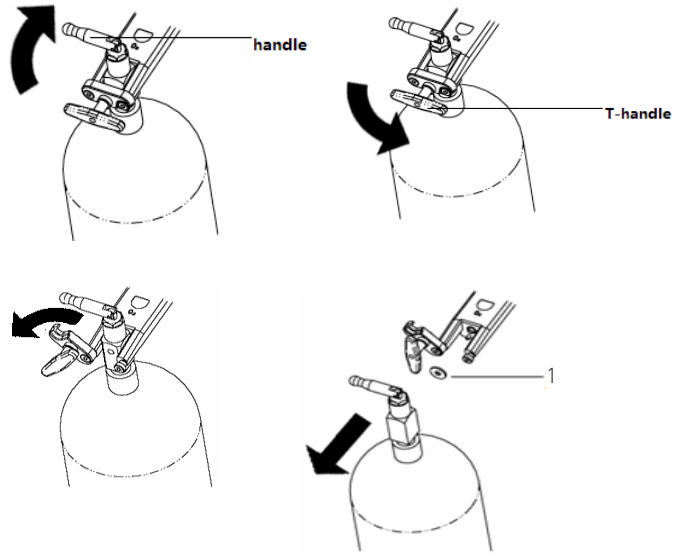
NOTE: Do not use excessive force to lock the vaporizer onto the manifold. Damage to the locking fastener will result.

CAUTION

To prevent damage to the locking shaft (4), check that the gas connection ports are aligned with the valves on the manifold (1), and are correctly engaged, before tightening the locking lever.

5.1.16 Install a Gas Cylinder

1. Turn the handle of the cylinder valve clockwise to close the valve on the cylinder to be replaced.
2. Turn the T-handle counterclockwise, to open the yoke latch.
3. Remove the cylinder.
   Position the cylinder to avoid inury or damage in the event of a release of high pressure gas.
4. Check that a serviceable seal (1) is installed.
5. Position the new cylinder in its installed position.
6. Momentarily open and close the cylinder valve to clean the cylinder outlet.
7. Align the cylinder post with the index pins.
8. Close the yoke gate and tighten the tee handle.
9. Carry out a high pressure leak test (section 6, Cylinder tests).



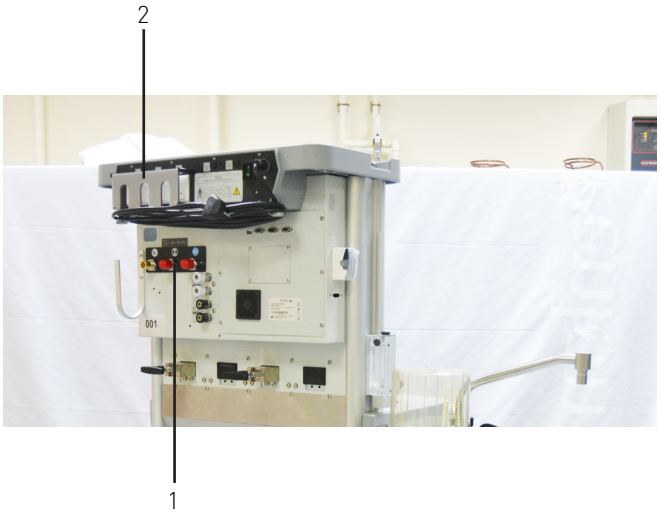
WARNING

Do not leave a gas cylinder valve open if the pipeline supply is in use. Cylinder supplies could be depleted, leaving an insufficient reserve supply in case of pipeline failure.

Gas cylinders must conform with the requirements of IEC60601-1.

5.1.17 Medical Gas Pipeline Connection

Connect the medical gas hose between the central gas supply terminal and the inlet (1) on the Anesthesia workstation.



WARNING

1. **Gas connections are not interchangeable, check the label, symbol, and color code while connecting.**
2. **Use medical grade gas supplies only. Other types of gas supplies may contain water, oil, or other contaminants.**
3. **Check that cylinders are available as a backup in case of a central gas supply failure.**

5.1.18 Power Connector

WARNING

Powering additional devices through the auxiliary power outlets can increase the total leakage current. Test for leakage current at regular intervals. To reduce the total leakage current, use devices with an isolation transformer.

5.1.19 AGSS

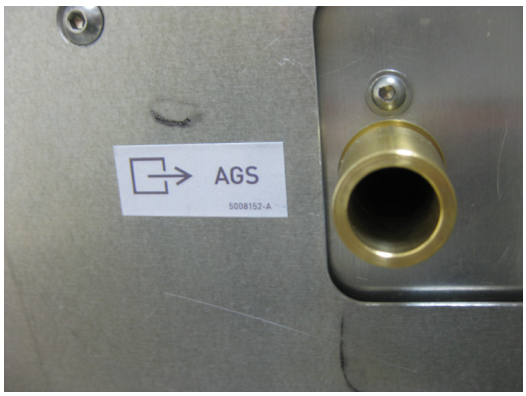
The gas scavenging outlet port is located at the right rear of the machine, as shown:

Warning

Use an anesthesia gas scavenging system that complies with ISO 80601-2-13.

Do not connect any vacuum system directly to the outlet port. A receiving system with a positive and negative pressure control function must be interposed.

5.3.1 Read the AGSS instruction manual before clinical use.



5.2 Pre-use Test before each clinical procedure

WARNING

1. Accessories must be removed before the machine is transported.
2. Additional equipment placed on the top shelf must be securely attached. Do not install additional equipment on the top shelf heavier than 30 kg or above 450 mm in height.

5.2.1 Test interval

Recommended testing schedule:

	Daily, before the first patient	Each patient, before use
Visual Inspection	5.2.2	
System check	5.2.3	
Power failure alarm	5.3.1	
Pipeline gas supplies	5.4.1	
Cylinders gas supplies	5.5.1	
Flow control system	2	
Vaporizer	5.6	
Alarms	5.7	
Breathing circuit		5.6.3
O_2 flush		5.7.7
Preparing for system operation		5.7.10

CAUTION

Before using this equipment, read this user manual, and to understand the function and operation of each component.

If the system fails a test, do not use the device. Contact a Penlon-trained engineer.

5.2.2 Visual Inspection

CAUTION

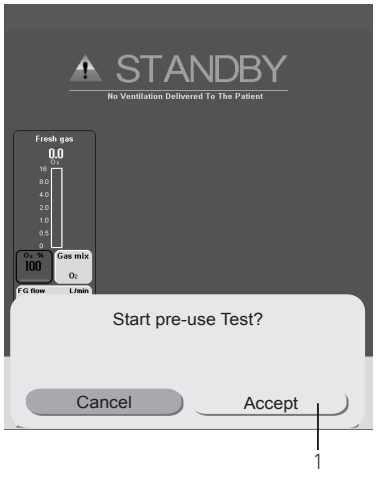
Check that the absorber and breathing system are not damaged and are correctly connected.

Checks

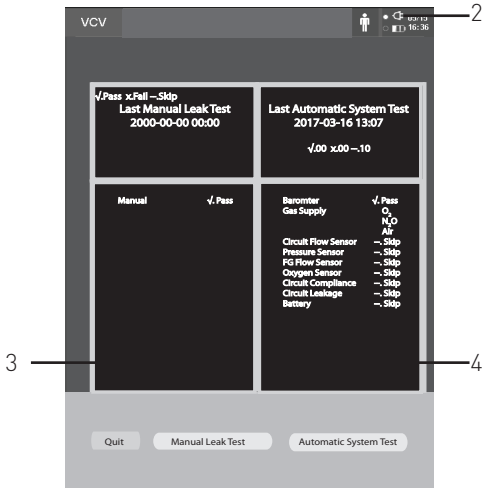
1. Make sure that the anesthesia machine is undamaged.
2. Make sure that all components are correctly attached.
3. Make sure that the breathing system is correctly connected, and that the breathing tubes are undamaged.
4. Make sure that the vaporizers are locked in position and contain sufficient agent.
5. Make sure that the gas supplies are connected and the pressures are correct.
6. Make sure that the cylinder valves are closed (on units with cylinder supplies).
7. Make sure that the necessary emergency equipment is available and in good condition.
8. Make sure that equipment for airway maintenance and tracheal intubation is available and in good condition.
9. Make sure that the applicable anesthetic and emergency drugs are available.
10. Make sure that the castors are not damaged or loose and the brakes are set and function correctly.
11. Make sure that the absorber unit is locked in position.
12. Make sure that the AC mains indicator and the battery indicator come on when the power cord is connected to an AC mains power source. Note that if the indicators are not on, the system does not have electrical power.
13. Make sure that the anesthesia machine can be switched on or off normally.

5.2.3 System Check

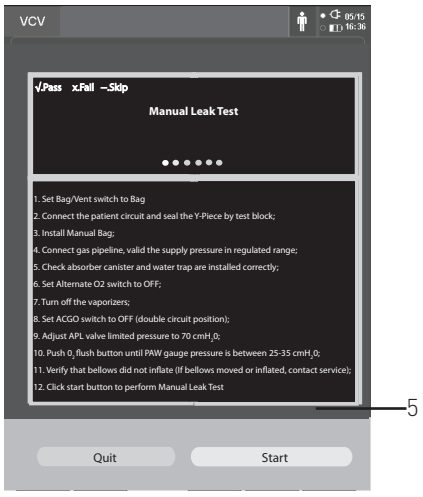
1. Connect the machine to the the mains supply
2. Set the Anaesthesia system switch to the ON position.
3. Allow the anaesthetic machine to perform its pre-use tests.
4. Push the ACCEPT button (1) when the machine is ready to carry out its pre-use tests.



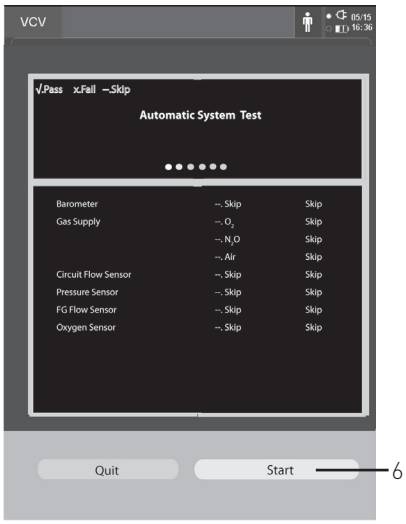
5. Select the Manual Leak Test button (3) from the pre-use test screen (2).



6. Follow the on-screen instructions before you press the Start button (5).
7. Make sure that the Last Manual Leak Test dialogue box is updated with the current date.
8. Make a note of the result of the Manual Leak Test as shown on the Last Manual Leak Test progress screen.



9. Select the Automatic System Test button (4) from the pre-use test screen (2).
10. Press the Start key (6).
11. Observe the Automatic System test progress screen, make a note of test that Fail or Skip.



12. Set the Anaesthesia system switch to the OFF position.

5.3 Alarm Test

1. Connect the machine to the the mains supply
2. Set the anaesthesia system switch to the ON position.
3. Make sure that the alarm lamp flashes yellow and red once in turn.
4. Make sure that an audible beep sound is heard.
5. Make sure that the start-up screen (1) is displayed.
6. Make sure that the standby screen is shown after approximately 15 seconds.
7. Make sure that audio and visual alarm indicators are triggered.
8. Set the anaesthesia system switch to the off position.
9. Disconnect the machine from the the mains supply.

5.3.1 Power failure alarm test

1. Connect the machine to the mains electrical supply.
2. Set the anaesthesia system switch to the ON position.
3. Disconnect the machine from the mains power supply.
4. Make sure that the mains indicator is extinguished
5. Make sure that the battery indicator light illuminates.
6. Make sure that the message MAINS FAILURE is displayed.
7. Connect the machine to the mains electrical supply.
8. Make sure that mains indicator is illuminated
9. Make sure that the battery indicator is not illuminated while the Battery is charged.
10. Set the anaesthesia system switch to the OFF position.

5.4 Pre-Use Check - Gas Supply

5.4.1 Gas pipeline supplies

CAUTION

Do not leave gas cylinder valves open if the pipeline supply is in use. Cylinder supplies could be depleted, leaving an insufficient reserve supply in case of pipeline failure.

5.4.2 O_2 Pipeline supply test

1. Set the anaesthesia system switch to the ON position.
2. Make sure that all cylinder valves are closed.
3. Connect an O_2 supply to the machine
4. Use the alternate O_2 flow control knob to adjust the flow to the middle of the measurement range.
5. Check that all pipeline pressure gauges show 280 to 600 kPa.
6. Disconnect the O_2 supply.
7. Make sure that the O_2 SUPPLY DOWN!!! alarm is triggered.
8. Make sure that the O_2 gauge shows zero kPa.
9. Use the alternate O_2 flow control knob to reduce the flow to minimum.
10. Set the anaesthesia system switch to the OFF position.

5.4.3 N_2O Pipeline supply test

1. Set the anaesthesia system switch to the ON position.
2. Make sure that all cylinder valves are closed.
3. Connect an O_2 supply to the machine

CAUTION

When testing the N_2O pipeline supply, connect the O_2 supply first to enable N_2O flow control.

Check that when the N_2O supply is disconnected and N_2O pressure decreases, that the condition that follow apply:

- No O_2 warnings are seen
- The N_2O SUPPLY DOWN !! alarm is triggered.

4. Set the anaesthesia system switch to the OFF position.

5.4.4 Air Pipeline test

1. Set the anaesthesia system switch to the ON position.
2. Make sure that all cylinder valves are closed.
3. Connect an O_2 supply to the machine
4. Set the concentration level above 0.
5. Disconnect the Air supply.
6. Make sure that the AIR SUPPLY DOWN !!! alarm is triggered.
7. Set the anaesthesia system switch to the OFF position.

5.5 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.**
2. **Make sure that the FG FLOW is off until gas supplies are required.**

5.5.1 Cylinder test - cylinder full

1. Disconnect the central gas supply pipeline.
2. Open each cylinder valve and check each cylinder pressure.
3. Replace the cylinder if necessary, refer to Section 5.1.15.
4. Close the cylinder valve.

5.5.2 O_2 cylinder high pressure leak test

1. Set the anaesthesia system switch to the OFF position
2. Disconnect the Oxygen pipeline.
3. Set the auxiliary O_2 flowmeter to the minimum flow position.
4. Open the O_2 cylinder valve.
5. Make a record of the current cylinder pressure.
6. Close the O_2 cylinder valve.
7. Make a record of the cylinder pressure after two minute.
8. If the cylinder pressure decreases more than 690 kPa (100 psi), install a new cylinder seal.
9. Repeat steps 1 through 7. If the leak continues, contact a penlon-trained engineer. Do not use the cylinder supply system.
10. Set the anaesthesia system switch to the OFF position
11. Connect the Oxygen pipeline.

5.5.3 N_2O cylinder High pressure leak test

1. Set the anaesthesia system switch to the ON position
2. Disconnect the N_2O pipeline.
3. Open the N_2O cylinder valve.
4. Make a record of the current N_2O cylinder pressure.
5. Close the N_2O cylinder valve.
6. Make a record of the N_2O cylinder pressure after one minute.
7. If the cylinder pressure decreases more than 690 kPa (100 psi), install a new cylinder seal.
8. Repeat steps 1 through 6. If the leak continues, contact a penlon-trained engineer. Do not use the cylinder supply system.
9. Set the anaesthesia system switch to the OFF position
10. Connect the N_2O pipeline

5.5.4 O_2 verification

1. Set the anaesthesia system switch to the ON position
1. Press the Standby button.
2. Make sure that the system is in Ventilation mode.
3. Set the FG FLOW display to show O_2/N_2O.
4. Set the concentration to approximately 50.
5. Set the FG Flow to 5 Lt
6. Observe the FIO_2 indication, make sure that the FIO_2 indication reduces to approximately 50.
7. Set the anaesthesia system switch to the OFF position

5.6 Vaporizer

5.6.1 Vaporizer back pressure test

WARNING

1. **Use only Selectatec series vaporizers Check that each vaporizer is securely mounted - refer to Section 5.1.14.**
2. **The machine must be connected to an anaesthetic gas scavenging system (AGSS).**

1. Connect the O_2 pipeline supply or open the O_2 cylinder valve.
2. Turn the alternate O_2 flow to 6 L/min.
3. Check that the O_2 flow stays constant.
4. Set a vaporizer concentration of 1%.

CAUTION

Do not test the vaporizer when the concentration control is between "0" and the first graduation above "0" (zero).

5. Adjust the vaporizer control over the full range of movement above the first graduation.
6. Check that the O_2 flow does not decrease more than 1 L/min through the full range.
7. If the vaporizer fails this test, install a different vaporizer and repeat operation 5. If the problem persists, the malfunction is in the anesthesia system. Do not use the system, contact trained technical personnel.
8. Test each vaporizer as above.

5.6.2 Vaporizer interlock system test

1. Make sure that two vaporizers are fitted.
2. Make sure that the interlock mechanism of each vaporizer is working correctly as follows:
   a) Make sure that only one vaporizer at a time can be turned on.
   b) Refer to the vaporizer user manual for additional pre-use checks.

5.6.3 Breathing System Test

WARNING

1. **Obstruction of the breathing system can restrict or stop gas flow to the patient, and can cause injury or death. Make sure that there are no obstructions in the breathing system.**
2. **Keep very small components/parts/plugs away from the breathing system.**

1. Set the anaesthesia system switch to the ON position
2. Check that the breathing system is not damaged and correctly installed.
3. Use the Y-piece connector to connect a test lung or manual bag to the anaesthatic machine.
4. Check that the check valves in the breathing system work correctly:
   a) The inspiratory check valve opens during inspiration and closes at the start of expiration.
   b) The expiratory check valve opens during expiration and closes at the start of inspiration.
5. Set the anaesthesia system switch to the OFF position
6. Disconnect the Y-piece connector from the test lung or manual bag.

5.6.4 Bellows test

1. Set the anaesthesia system switch to the ON position
2. Set the system to standby.
3. Set the Bag/Vent switch to the vent position.
4. Set FG Flow to minimum.
5. Use your hand to close the breathing system at the patient connection.
6. Press and hold the O_2 flush button to fill the bellows.
7. The airway pressure gauge must indicate a maximum of 15cmH_2O.
8. Release the O_2 flush button.
9. If the bellows deflates within one minute,.remove the bellows and reinstall, refer to Section 5.1.3.
10. Do the bellows test again..
11. Set the anaesthesia system switch to the OFF position

5.6.5 Breathing system leak test

1. Set the anaesthesia system switch to the ON position
2. Make sure that the breathing bag and breathing tubes are correctly connected.
3. Set the Bag/Vent switch to the bag position.
4. Use a hose to connect the inspiratory and expiratory outlets.
5. Turn the APL valve counterclockwise to the minimum position.
6. Set the FG Flow to 2 Lt/min.
7. Press the O_2 flush button until the airway pressure gauge reads 25 cmH_2O.
8. Set the FG Flow to 0.2 Lt/min when the airway pressure gauge reads 30 cmH_2O.
9. Make sure that the airway pressure gauge reading does not reduce. A pressure decrease on the airway pressure gauge indicates a leak.

CAUTION

If a leak is suspected, check the bellows, breathing tube, absorber, and connectors for correct function and security.

Retest the system. Do not use the machine if the circuit continues to leak. Contact a Penlon-trained engineer.

10. Turn the APL valve counterclockwise to the Min position.
11. Set the anaesthesia system switch to the OFF position
12. Disconnect the hose from the inspiratory and expiratory outlets.

5.6.6 APL valve test

1. Set the anaesthesia system switch to the ON position
2. Set the Bag/Vent switch to bag.
3. Make sure that the breathing bag and breathing tubes are connected.
4. Turn the APL valve clockwise to 70 cmH_2O position..
5. Connect the Y-piece to the test plug.
6. Set FG Flow to 4 Lt/min.
7. Push the O_2 flush button until the airway pressure gauge rises to approximately 35 cmH_2O.
8. Set the APL valve to 30 cmH_2O.
9. Check that the reading on the airway pressure gauge is within the range 25 to 35 cmH_2O.
10. Set the APL valve to 20 cmH_2O.
11. Check that the reading on the airway pressure gauge is within the range 15 to 25 cmH_2O.
12. Set the APL valve to the minimum position.
13. Set the anaesthesia system switch to the OFF position
14. Check that the reading on the airway pressure gauge is less than 5 cmH_2O.

5.7 Preparation for the alarm test

1. Connect a test lung or manual bag to the Y-piece patient connector.
2. Set the Bag/Vent switch to Vent.
3. Set the anaesthesia system switch to the ON position.
4. Set the system to standby mode.
5. Set the ventilator control setting to the follows:
   a) Ventilation mode: VCV
   b) Tidal volume [VT]: 500 mL
   c) Respiratory rate [Rate]: 12 BPM
   d) Breathing ratio [I: E]: 1:2.0
   e) PEEP: OFF
6. Push the O_2 flush button to fill the bellows.
7. Set the FG Flow to between 0.5 and 1 L/min.
8. Use the standby key to exit standby mode.
9. Make sure that the bellows inflate and deflate normally during mechanical ventilation.
10. Make sure that the value of VT displayed at the bottom of the screen is 500 mL ± 10 %.
11. Make sure that the values of respiratory rate, and breathing ratio, displayed at the bottom of the screen are as set in step 5.
12. Set the anaesthesia system switch to the OFF position.

5.7.1 Oxygen concentration monitoring and alarm test

CAUTION

This test is not required if the O_2 sensor is not fitted.

1. Set the anaesthesia system switch to the ON position
2. *Use the standby key to enter standby mode.*
3. *Set the bag/vent switch to vent.*
4. *Do a System Oxygen Calibration as follows:*
    a) *Press the SYSTEM button*
    b) *Press the CALIBRATION tab*
    c) *Press the OXYGEN CELL CAL button*
    d) *Press the 100% button*
    e) *Follow the on-screen instructions.*
5. *Set the FiO_2 low alarm limit to 45%.*
6. *Use the standby key to exit standby mode.*
7. *Set FG Flow to 4.0 L/min.*
8. *Set O2-N2O concentration to 25%.*
9. *Make sure that after a short period of time, a LOW FiO_2 alarm is triggered.*
10. *Set the FiO_2 low alarm limit back to a value less than the measured FiO_2 value. Check that the alarm is cancelled.*
11. *Set the FiO_2 high alarm limit to 50%.*
12. *Make sure that the manual bag is connected to the manual bag port.*
13. *Use the O_2 flush button to fill the bag.*
14. *Check that the O_2 reading is greater than 80%.*
15. *Check that a high FiO_2 alarm is triggered.*
16. *Set the FiO_2 high alarm limit to 100% and check that the alarm is cancelled.*
17. Set the anaesthesia system switch to the OFF position

5.7.2 Minute volume (MV) low alarm test

1. Set the anaesthesia system switch to the ON position
2. Set the bag/Vent switch to Vent.
3. Set the MV low alarm limit to a minimum of 11 L/min.
4. Make sure that a MV LOW!!! alarm is triggered.
5. Set the MV low alarm limit to 2.0 L/min.
6. Make sure that the MV LOW!!! alarm is cancelled.
7. Set the anaesthesia system switch to the OFF position

5.7.3 High airway pressure (Paw) alarm test

1. Set the anaesthesia system switch to the ON position
2. Set the pressure high alarm limit to 30cmH_2O.
3. Check the Ppeak reading.
4. Adjust the tidal volume until the reading is higher than the pressure high alarm limit.
5. Check that a High Pressure alarm is triggered.
6. Set the anaesthesia system switch to the OFF position.

5.7.4 Apnea alarm test

7. Set the anaesthesia system switch to the ON position

1. *Make sure that the manual bag is connected to the manual bag port.*
2. *Set the Bag/Vent switch to bag.*
3. *Set the APL valve to the minimum position.*
4. *Inflate the manual bag and check that a complete breathing cycle occurs.*
5. *Stop inflating, wait for more than 20 seconds, check that the apnea alarm is triggered.*
6. *Inflate the manual bag. Check that the alarm is cancelled.*
7. Set the anaesthesia system switch to the OFF position.

5.7.5 Continuous high positive airway pressure alarm test

1. Set the anaesthesia system switch to the OFF position
2. Set the FG Flow to 0.2 L/min.
3. Set the APL valve to 30 cmH_2O.
4. Set the Bag/Vent switch to Bag.
5. Press and hold the O_2 flush button to fill bag until the reading on the airway pressure gauge is approximately 30 cmH_2O.
6. After 15 seconds, check that a continuous positive airway pressure alarm is triggered.
7. Set the anaesthesia system switch to the OFF position.

5.7.6 Airway pressure low alarm test

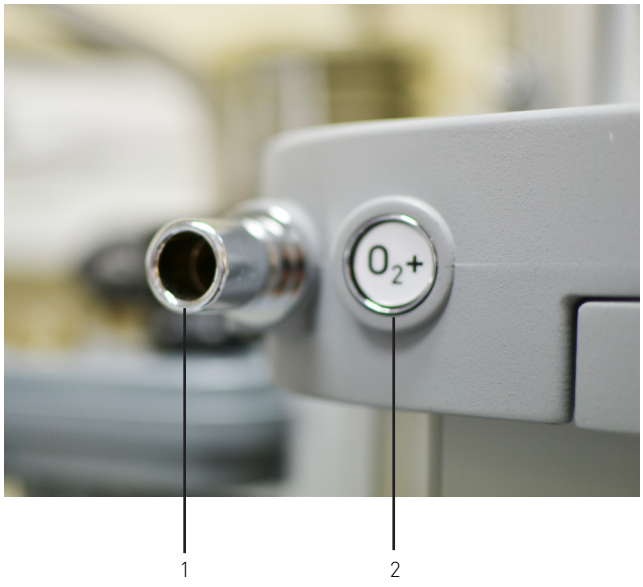
1. Set the anaesthesia system switch to the ON position.
2. Set the Bag/Vent switch to Bag.
3. Set the Paw low alarm limit to 5 cmH_2O.
4. Disconnect the test lung from the Y piece patient connection.
5. Check that a low Paw alarm is triggered.
6. Connect the test lung to the Y piece port.
7. Check that the low Paw alarm is cancelled.
8. Set the anaesthesia system switch to the OFF position.

5.7.7 Oxygen flush test

1. Set the anaesthesia system switch to the ON position
2. Connect O_2 pipeline or cylinder
3. Set the Bag/Vent switch to bag.
4. Check that the test lung and breathing tube are connected.
5. Turn the ACGO control to the O_2 flush position.
6. Press the O_2 button (2).
7. Check that the bellows fully inflate within 4 seconds.
8. Release the ACGO control.
9. Release the O_2 button (2).
10. Set the anaesthesia system switch to the OFF position.

5.7.8 Auxiliary common gas outlet test

1. Set the anaesthesia system switch to the ON position.
2. Turn the ACGO control to the ACGO position
3. Check that there is a flow of fresh gas from the ACGO (1).
4. Release the ACGO control.
5. Check that the flow of O_2 from the ACGO (1) stops.
6. Set the anaesthesia system switch to the OFF position.



5.7.9 Back-up O_2 supply test

1. Set the anaesthesia system switch to the ON position
2. Adjust FG Flow until a suitable flow output is obtained.
3. Set the Back-up O_2 switch to the On.
4. Adjust the flow control knob and check that there is a flow of gas.
5. Push the Back-up O_2 switch.
6. Adjust the flow control knob, check that the gas flow stops.
7. Set the anaesthesia system switch to the OFF position.

5.7.10 Preoperative procedure

1. Set the anaesthesia system switch to the ON position.
2. Check that the ventilator parameters and alarm limits are set to applicable clinical levels. For details, refer to Section "7. Operating the Anaesthesia System".
3. Make sure that the system is in Standby.
4. Make sure that equipment for airway maintenance, manual ventilation, racheal intubation, and applicable anesthetic and emergency drugs are available.
5. Set the Bag/Vent switch to Bag.
6. Make sure that the manual bag is connected to the bag port.
7. Turn off all vaporizers.
8. Turn the APL valve control counterclockwise to the MIN position.
9. Set FG FLOW to 0.2 L/min.
10. Make sure that the breathing system is not damaged and correctly connected.

WARNING

Before connecting a patient, flush the anesthesia machine with 5 L/min of O_2 for at least one minute. This removes unwanted gas mixtures from the system.

11. Set the anaesthesia system switch to the OFF position

6. User Maintenance

IMPORTANT

User maintenance

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.

Servicing and Repair

Prima 465 machines must only be serviced or repaired by Penlon-trained engineers, according to the schedule and procedures given in the Service Manual, which contains circuit diagrams, service kits and component lists.

WARNINGS

1. **Exterior panels**

Panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing. Ensure that all panels are secure after any work by authorised personnel.

2. **Electrical power supply**

   a) **Unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard.**

   b) **Fuse holders must be carefully tightened using an appropriate tool, e.g. flat-blade screwdriver.**

   c) **If replacement of the mains lead is necessary, this work must be carried out only by Penlon-trained engineers.**

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

6.1 Cleaning and Sterilisation

WARNING

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

2. **Care must be taken not to allow liquids to run into enclosed areas; serious damage may result.**

CAUTION

Do not use harsh abrasive cleaning agents.

Cleaning

All the surfaces of the anaesthetic machine and monitors should be cleaned on a daily basis with an appropriate disinfectant, or immediately if visibly contaminated.

The surfaces of the anaesthetic machine, especially those areas which are likely to have been touched by the gloved hand that has been in contact with blood or secretions, should be regarded as contaminated and should be cleaned at the earliest opportunity, between patients.

Appropriate disinfectants suitable for use with the anaesthetic machine are isopropyl alcohol, or alcohol wipes (e.g. azowipes)

Display screen surface

CAUTION

Do not apply excessive pressure to the display screens.

Cleaning of flowmeter screen surfaces is restricted to soap based sanitising wipes, or Milton sterilising solutions 1.8 % v/v.

After cleaning

Make sure that all cleaning agent residues are fully removed after cleaning.
Always allow the machine to dry off thoroughly before clinical use.

Sterilisation

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

An effective, new bacterial / viral breathing circuit filter should be used for every patient

7. Operating the Anaesthesia System

7.1 Ventilation modes

WARNING

If the power-up self test fails, do not use the device. Contact a Penlon-trained maintenance engineer.

Ventilator modes - Description

The ventilator is capable of operating in one of the following seven modes:

1. Volume Control Ventilation (VCV)
2. Pressure Control Ventilation (PCV)
3. PRVC
4. SIMV-V
5. SIMV-P
6. SIMV-PRVC
7. SPONT/PSV mode.

7.1.1 Volume Control Ventilation (VCV)

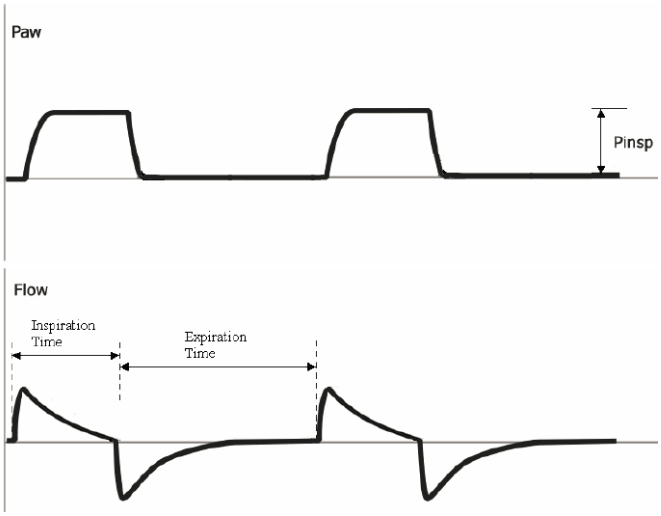
7.1.1.1 Description

Volume control ventilation (VCV) mode is a basic fully-mechanical ventilation mode. In VCV mode, each time mechanical ventilation starts, gas is delivered to the patient at a constant flow, to deliver the preset VT within the gas delivery time.
To achieve the preset VT, the resulting airway pressure (Paw) changes based on patient pulmonary compliance and airway resistance.
In VCV mode, as long as Paw is less than the pressure high limit and the gas delivery flow is kept constant, expiration starts immediately after the high pressure limit is reached.

In VCV mode, you must set the Pressure high limit to prevent high airway pressure from injuring the patient.
In this mode, you can select [Pause] to improve patient pulmonary gas distribution and [PEEP] to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

7.1.1.2 VCV mode waveforms

Paw waveform and flow waveform in VCV mode are shown.
In VCV mode, the flow waveform is at a constant flow during inspiration and the Paw waveform rises in the same period



7.1.1.3 Parameter Range and Default Value in VCV Mode

Parameter	Range	Step	Default
VT	Infant:20 to 100 ml Paediatric:50 to 360 ml Adult:300 to 1500 ml	20 to 100 ml: 5 ml 100 to 1500 ml:10 ml	510 ml
I:E	4:1 to 1:10	0.5	1:2
f	4 to 100 bpm	1bpm	15bpm
PEEP	OFF, 3 to 30 cmH2O	1 cmH2O	OFF
Pause	0% to 60%	5%	0%
SIGH	OFF, 50 to 150	25	OFF

7.1.2 Pressure Control Ventilation (PCV)

7.1.2.1 Description

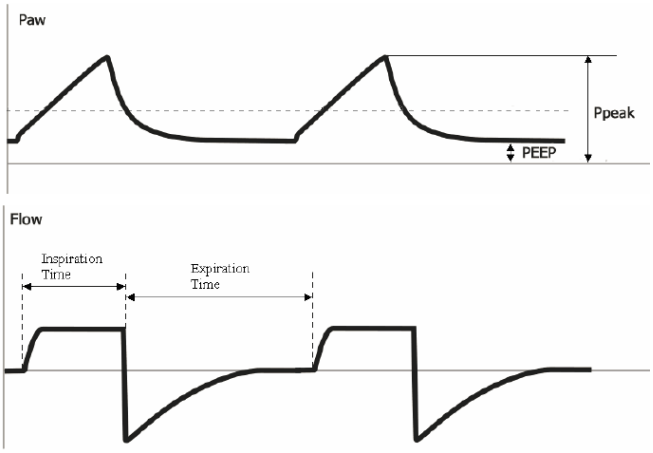
Pressure control ventilation (PCV) mode is a basic fully-mechanical ventilation mode.
In PCV mode, each time mechanical ventilation starts, Paw rises rapidly to the preset pressure control value. Then gas flow slows down through the feedback system to keep Paw constant until expiration starts at the end of inspiration.
The tidal volume delivered in PCV mode changes, based on patient pulmonary compliance and airway resistance. In PCV mode, the user can also select PEEP to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

7.1.2.2 PCV Waveforms

PCV mode waveforms for Paw and flow are shown.

Generally, in PCV mode, the Paw waveform rises sharply during inspiration and stays at the plateau for a relatively long time without peak. The flow waveform declines in the same period.

In the PCV mode, tidal volume is measured instead of the preset.



7.1.2.3 Parameter Range and Default Value in PCV Mode

Parameter	Range	Step	Default
Pinsp	5 to 70 cmH2O	1 cmH2O	15 cmH2O
I:E	4:1 to 1:10	0.5	1:2
f	4 to 100 bpm	1 bpm	15 bpm
PEEP	OFF, 3 to 30 cmH2O	1 cmH2O	OFF
Tslope	0 to 2 s	0.1 s	0.2 s

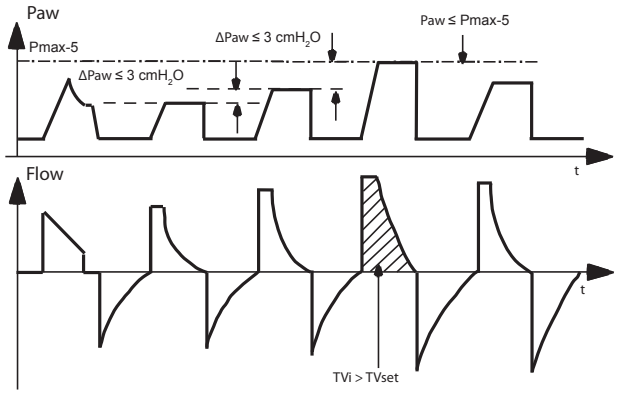
7.1.3 PRVC

7.1.3.1 Description

In PRVC a tidal volume is set and the ventilator delivers that voulume using a decelerating flow and a constant pressure. The ventilator will adjust the inspiratory pressure needed to deliver the set tidal volume breath-by-breath so that the lowest pressure is used.The pressure range that the ventilator will use is between the PEEP+2 cmH_2O level on the low end and 5 cmH_2O below pressure high limit. The inspiratory pressure change between breaths is a maximum of +/- 3 cmH_2O.

This mode will deliver breaths with the efficiency of pressure controlled ventilation, yet still compensate for changes in the patients lung characteristics. PRVC mode begins by first delivering a volume breath at the set tidal volume. The patient compliance is determined from this volume breath and the inspiratory pressure level is then established for the next breath.

7.1.3.2 PRVC Waveforms



7.1.3.3 Parameter Range and Default Value in PRVC Mode

Parameter	Range	Step	Default
VT	Infant:20 to 100 ml Paediatric:50 to 360 ml Adult:300 to 1500ml	20 to 100 ml: 5 ml 100 to 1500 ml:10ml	510 ml
I:E	4:1 to 1:10	0.5	1:2
f	4 to 100 bpm	1bpm	15 bpm
PEEP	OFF, 3 to 30 cmH2O	1 cmH2O	OFF
Tslope	0 to 2 s	0.1 s	0.2 s

7.1.4 SIMV-V

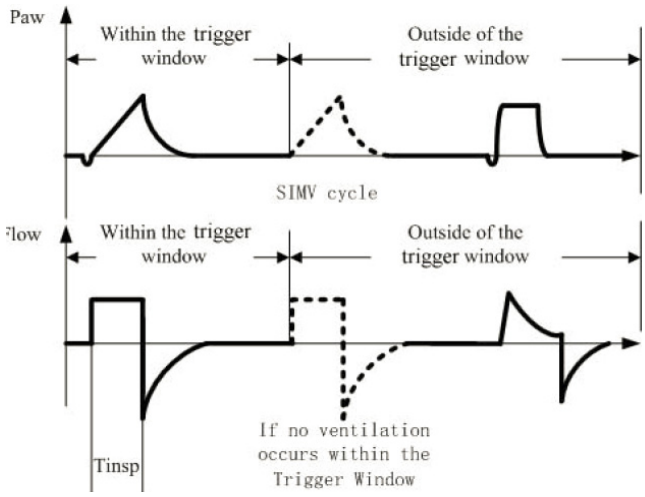
7.1.4.1 Description

SIMV-V delivers volume controlled breathing to the patient by phase at the preset intermission.
In SIMV-V mode, the ventilator waits for the patient's next inspiration based on the specified time interval.

Sensitivity is dependant on Trigger Level (optional flow and pressure).

If the Trigger Level is reached within the trigger waiting time (synchronous Trigger Window), the ventilator delivers volume controlled breathing synchronously with the preset tidal volume and inspiratory time.
If the patient does not inspire within the Trigger Window, the ventilator delivers volume controlled breathing to the patient at the end of Trigger Window.
Spontaneous breathing outside of the Trigger Window can acquire pressure support.

7.1.4.2 SIMV-V Waveforms



7.1.4.3 Setting the parameters in SIMV-P mode

Parameter	Range	Step	Default
VT	Infant:20 to 100 ml Paediatric:50 to 360 ml Adult:300 to 1500ml	20 to 100 ml: 5 ml 100 to 1500ml:10ml	510ml
Tinsp	0.1 to 10.0s	1.33	1:2
f	4 to 100 bpm	1 bpm	15 bpm
PEEP	OFF, 3 to 30 cmH2O	1 cmH2O	OFF
Psupp	0 to 70 cmH2O	1 cmH2O	15 cmH2O
Tslope	0 to 2 s	0.1 s	0.2 s
Fsens/Psens	Fsens:0.5 to 20.0 L/min Psens:0 to 20 cmH2O	Fsens:0.1 L/min Psens:1 cmH2O	Fsens:3 L/min Psens:2 cmH2O
Esens	5% to 80%	5%	25%

7.1.5 SIMV-P

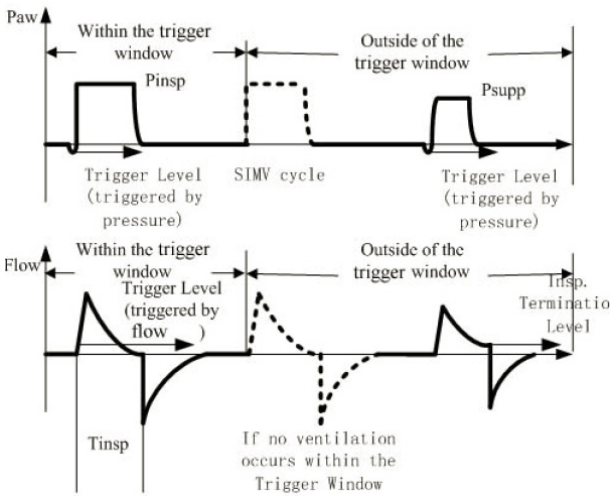
7.1.5.1 Description

SIMV-P delivers pressure controlled breathing to the patient by phase at the preset intermission.
In SIMV-P mode, the ventilator waits for the patient's next inspiration, based on the specified time interval.

Sensitivity depends on the Trigger Level (optional flow and pressure). If the Trigger Level is reached within the trigger waiting time (called synchronous Trigger Window), the ventilator delivers pressure controlled breathing synchronously with the preset tidal volume and inspiratory time.
If the patient does not inspire within the Trigger Window, the ventilator delivers pressure controlled breathing to the patient at the end of the Trigger Window.
Spontaneous breathing outside of the Trigger Window can acquire pressure support.

If the Trigger Level is reached outside of the Trigger Window, the ventilator delivers pressure-supported ventilation based on the preset [Psupp].

7.1.5.2 SIMV-P Waveforms



7.1.5.3 Setting the parameters in SIMV-P mode

In SIMV-P mode, the following parameters need to be set

Parameter	Range	Step	Default
Pinsp	5 to 70 cmH_2O	1 cmH_2O	15 cmH_2O
Tinsp	0.1 to 10.0 s	1.33	1:2
f	4 to 100 bpm	1 bpm	15 bpm
PEEP	OFF, 3 to 30 cmH_2O	1 cmH_2O	OFF
Psupp	0 to 70 cmH_2O	1 cmH_2O	15 cmH_2O
Tslope	0 to 2s	0.1s	0.2s
Fsens/Psens	Fsens: 0.5 to 20.0 L/min Psens: 0 to 20 cmH_2O	Fsens: 0.1 L/min Psens: 1 cmH_2O	Fsens: 3 L/min Psens: 2 cmH_2O
Esens	5% to 80%	5%	25%

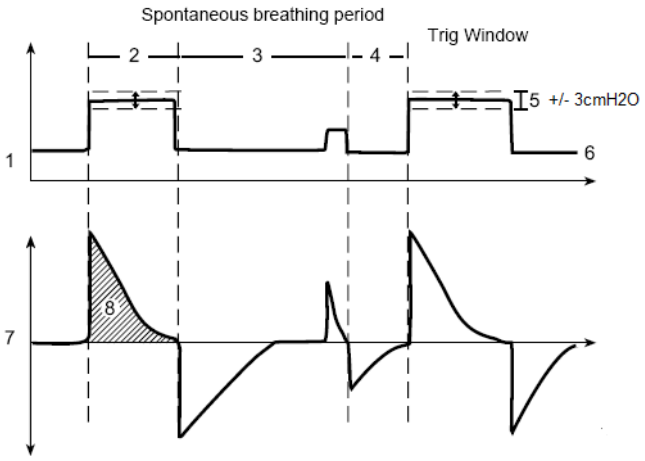
7.1.6 SIMV-PRVC

7.1.6.1 Description

SIMV-PRVC delivers pressure controlled breathing to the patient by phase at the preset intermission. In the SIMV-PRVC mode, the ventilator waits for patient's next inspiration based on the specified time interval. The sensitivity depends on [Trigger Level] (flow and pressure). If [Trigger Level] is reached within the trigger waiting time (called synchronous [Trigger Window]), the ventilator delivers pressure guaranteed ventilation - volume control breathing synchronously with the preset tidal volume and inspiratory time. If the patient does not inspire within the [Trigger Window], the ventilator delivers pressure controlled breathing to the patient at the end of [Trigger Window].Spontaneous breathing outside of [Trigger Window] can acquire pressure support.

If Trigger Level is reached outside of the Trigger Window, the ventilator delivers pressure-supported ventilation based on the preset [Psupp].

7.1.6.2 SIMV-PRVC Waveforms



7.1.6.3 Setting the parameters in SIMV-PRVC mode

Parameter	Range	Step	Default
VT	Infant: 20 to 100 ml Paediatric: 50 to 360 ml Adult: 300 to 1500 ml	20 to 100 ml: 5 ml 100 to 1500 ml: 10 ml	510 ml
Tinsp	0.1 to 10.0 s	1.33	1:2
f	4 to 100 bpm	1 bpm	15 bpm
PEEP	OFF, 3 to 30 cmH_2O	1 cmH_2O	OFF
Psupp	0 to 70 cmH_2O	1 cmH_2O	15 cmH_2O
Tslope	0 to 2s	0.1s	0.2 s
Fsens/Psens	Fsens: 0.5 to 20.0 L/min Psens: 0 to 20 cmH_2O	Fsens: 0.1 L/min Psens:1 cmH_2O	Fsens: 3 L/min Psens: 2 cmH_2O
Esens	5% to 80%	5%	25%

7.1.7 Spontaneous/Pressure Support Ventilation

7.1.7.1 Description

Spontaneous/Pressure support ventilation mode (SPONT/PSV) is an auxiliary breathing mode which needs patient's spontaneous breathing to trigger mechanical ventilation.
When the patient's spontaneous inspiration reaches the preset Trigger Level, the ventilator begins to deliver gas and Paw rises to the preset Psupp rapidly.

The ventilator then slows down the flow through the feedback system to keep Paw constant.

When the inspiration flow drops to the preset level, the ventilator stops delivering gas and the patient is allowed to expire, and the ventilator waits for the next inspiration trigger.

If inspiration is not triggered within the set time (Backup Mode Active), the system automatically switches to the backup ventilation mode (Volume or Pressure).

In SPONT/PSV mode, VT does not need to be set. VT depends on the patient's inspiratory force and pressure support level, and compliance and resistance of the patient and of the whole system.

PSV mode is used only when the patient is breathing spontaneously.

When PSV mode is applied alone, PCV and VCV backup modes are available.

If within the preset time (Backup Mode Active), no spontaneous breathing occurs or spontaneous breathing is not strong enough to reach the Trigger Level, the backup mode is triggered automatically when the time period for Backup Mode Active ends. Mechanical ventilation then commences

If SPONT / PSV mode is used, the system is provided with a backup ventilation mode.

If an Apnea situation occurs, and there is no spontaneous breathing, or spontaneous breathing and an inspiratory trigger condition is not reached, the system in accordance with the set 'Apnea time', automatically enters backup ventilation mode.

7.1.7.2 PSV mode Waveforms

Paw and flow waveforms in SPONT/PSV mode.

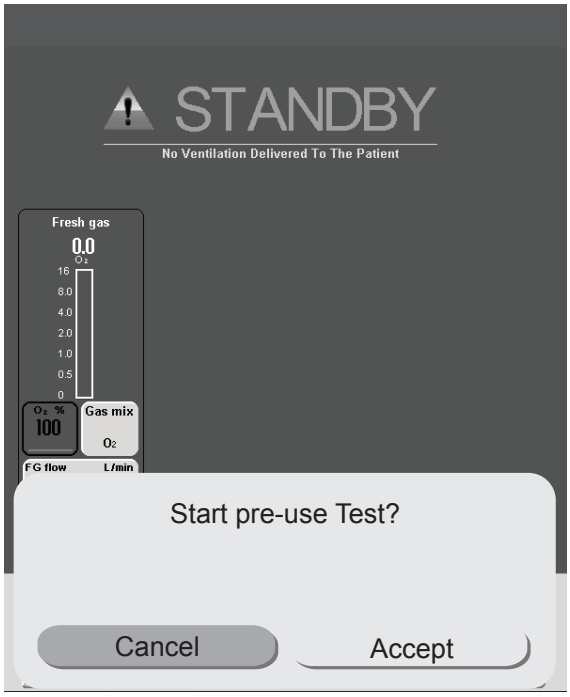
7.1.7.3 Settting the parameters in SPONT/PSV mode

SPONT/PSV mode can be used jointly with SIMV-V or SIMV-P.

Parameter	Range	Step	Default
PEEP	OFF, 3 to 30 cmH_2O	1 cmH_2O	OFF
Psupp	0 to 70 cmH_2O	1 cmH_2O	15 cmH_2O
Tslope	0 to 2 s	0.1 s	0.2 s
Fsens/Psens	Fsens:0.5 to 20.0 L/min Psens: 0 to 20 cmH_2O	Fsens:0.1 L/min Psens:1 cmH_2O	Fsens:3 L/min Psens: 2 cmH_2O
Esens	5% to 80%	5%	25%

A backup mode should be selected in advance.

7.2 Standby modes



7.2.1 Pre-Use Test

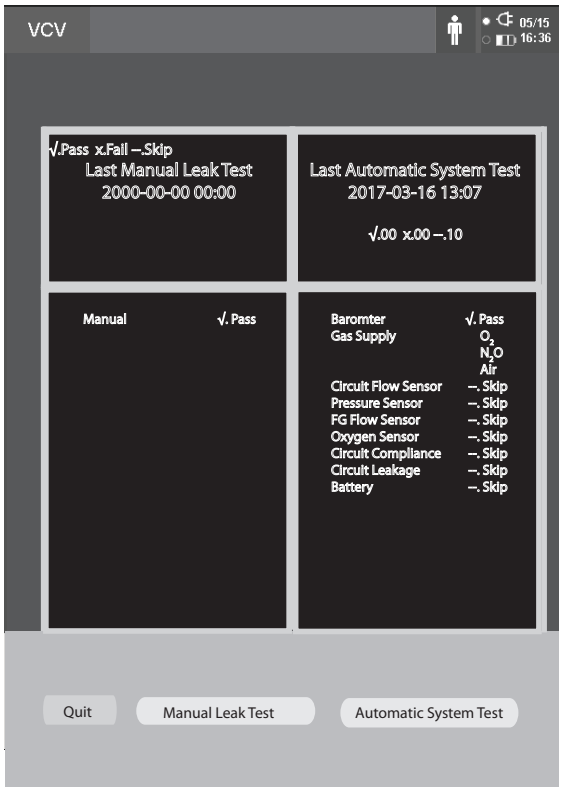
The pre-use test allows the user to run the following two tests:

- Manual Leak test
- Automatic System test.

The manual leak test and the automatic system tests must be carried out before the first clinical procedure of the day

7.2.2 Standby mode

1. Set the Anaesthesia system switch to ON.
   After the power-up self test, the system enters standby mode automatically.
2. In standby mode, press the standby key, the system enters operating mode.
3. To return to standby mode during mechanical ventilation, press the standby key, and in the pop up menu select the 'Activate Standby Mode' button.



7.2.3 Standby page

If the system is not in use, select standby to save power. The system enters standby status automatically after start-up.

Displayed monitored parameters and waveforms are not shown. Ventilation stops

Standby mode features:

- Parameters can be set and the system will operate based on those settings when standby is exited.
- Physiological alarms are cleared automatically
- Technical alarms function normally.
- The monitor module enters standby status.
- Service modes are activated.

The standby page allows the operator to select one of the following two options:

- PATIENT
- SYSTEM TEST.

System test directs the operator to the previously described self test functions.

Patient directs the operator to the patient pages.

The patient page allows the operator to select one of the following options:

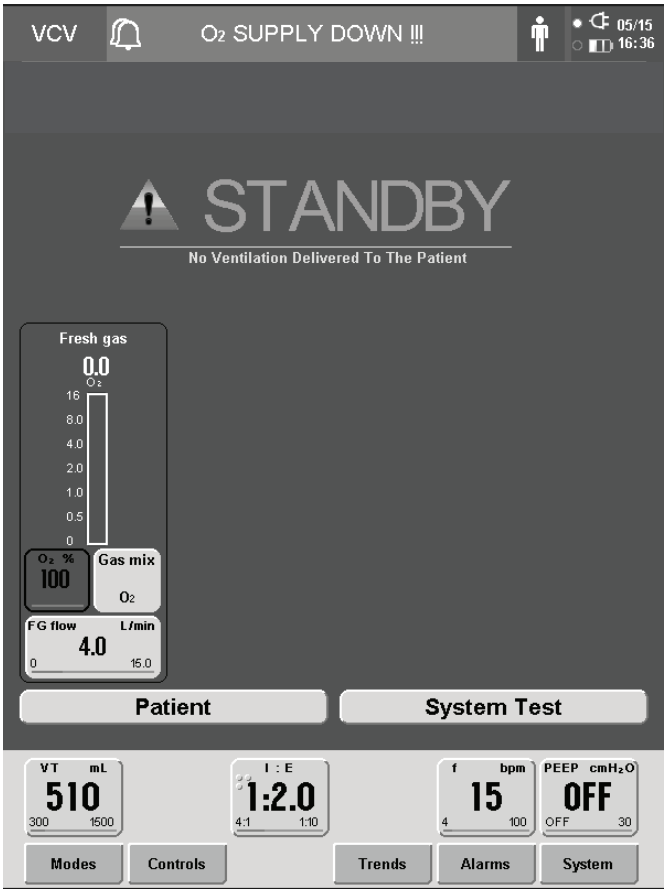
- NEW PATIENT
- PREVIOUS PATIENT.

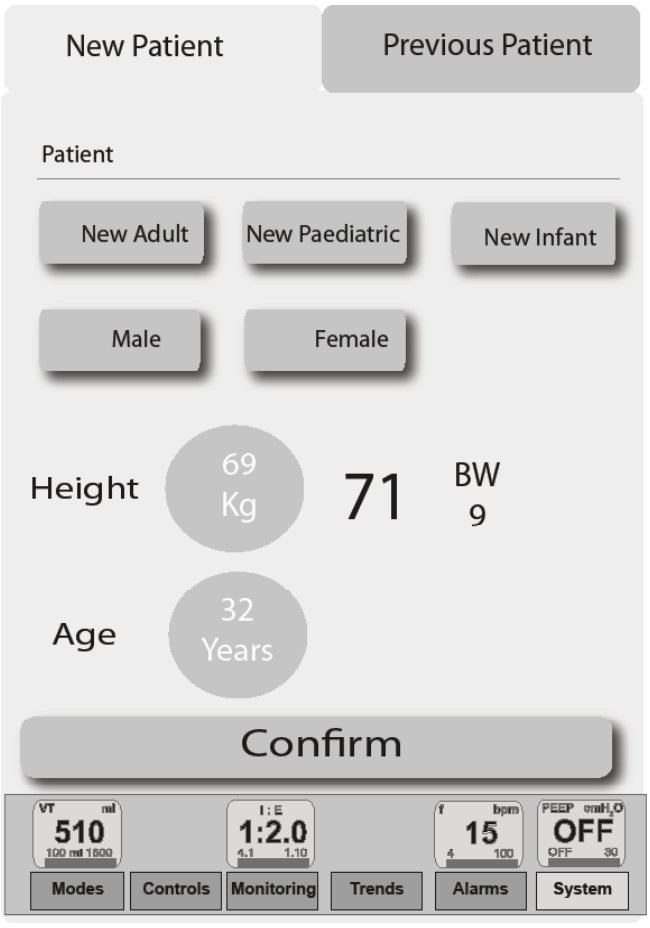
New patient data is entered on the NEW PATIENT page. The following options are avaialble to teh operator:

- Patient options -
  - New Adult
  - New Paediatric
  - New Infant
- Gender options -
  - Male
  - Female

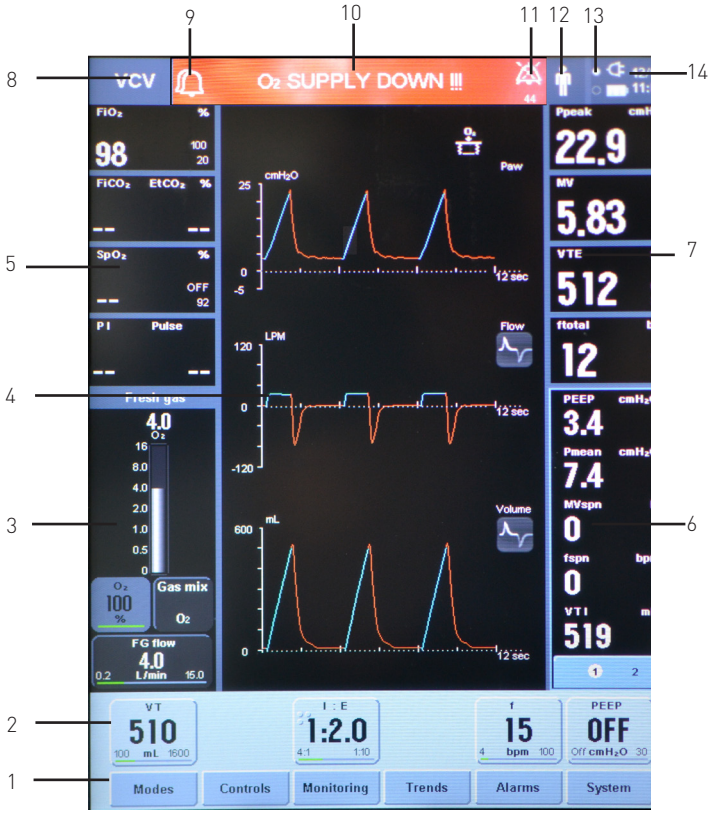
Additionally patient height and age can be entered.

The previous patient page will maintain the data from the previous patient.





7.3 Home screen



1. Function fields
   The following function fields are available:
   - Modes
   - Controls
   - Monitoring
   - Trends
   - Alarms
   - System.
2. Ventilator setting fields:
3. Fresh gas fields:
4. Waveforms fields:
5. Anesthetic agent (AG) fields (optional):
6. Measured values fields
7. Key parameter measured values fields
8. Ventilation mode:
9. Alarm silence icon:
10. Alarm message fields
11. System prompt message and icons field:
12. Patient type icon
13. Power status display fields:
14. System time field:

CAUTION

Confirm the new setting before adjusting another parameter. If confirmation is not given, the ventilator reverts to the pre-set value.

NOTE

1. The software is primarily controlled using the multifunction control. The multifunction control can be twisted to move the highlight area between dialog boxes, or to increase or decrease values within those dialog boxes. Pushing the multifunction control selects the set value.
2. A dialog box with three cirlces next to the title, indicates that that dialog box has more than one value associated with the dialog box. Pressing the multifunction control swaps between the foreground and background value.

7.4 Function Fields

The function fields give the user access to the following six menu structures:

- MODES
- CONTROLS
- MONITORING
- TRENDS
- ALARMS
- SYSTEM

7.4.1 Modes

Touch the MODE button to view the mode setting screen. Depending on the configuration, there are seven ventilation modes available.

When a mode is selected the display will show the CONTROLS screen that is associated with the selected mode.

7.4.2 Controls

The controls buttons gives the user access to the control panels for each of the seven ventilation modes.

7.4.2.1 Volume Control Ventilation (VCV)

To set the ventilation settings in VCV mode, select the desired hotkey in the ventilator settings fields. Parameters to be set are shown below.

VT Tidal volume

I:E Respiratory ratio

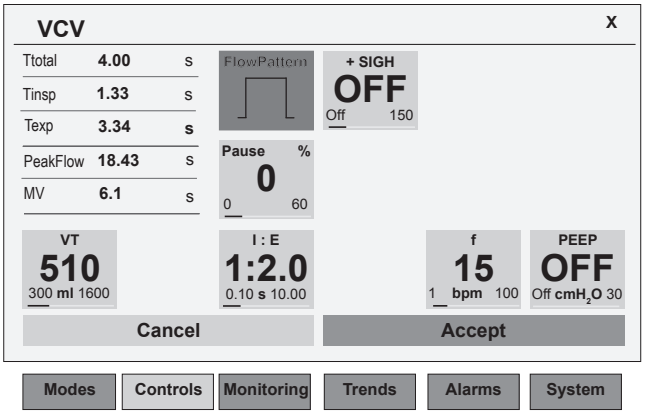
FREQ Respiratory rate

Pause Inspiratory pause .

PEEP Positive end expiratory pressure

Flow pattern: Decelerating or constant flow

+Sigh: Sigh interval



7.4.2.2 Pressure Control Ventilation (PCV)

To set the ventilation settings in PCV mode, select the desired hotkey in the ventilator settings fields. Parameters to be set are shown below.

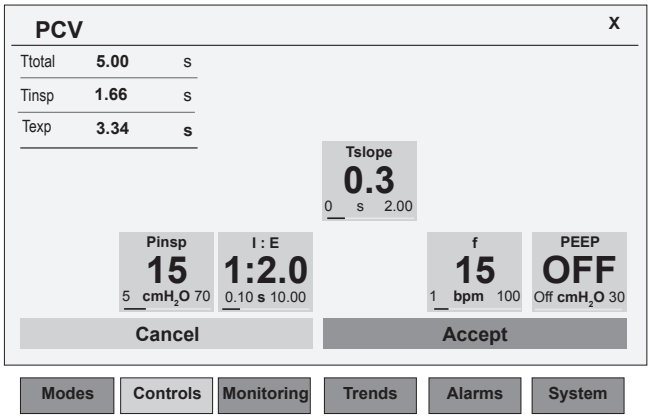
Pinsp Pressure control level

I:E Respiratory ratio

FREQ Respiratory rate

Tslope Pressure rise time

PEEP Positive end-expiratory pressure



7.4.2.3 Pressure Guaranteed - Volume Control Ventilation (PRVC)

To set the ventilation settings in PRVC mode, select the desired hotkey in the ventilator settings fields. Parameters to be set are shown below.

1. VT: Tidal volume
2. Tinsp: Inspiratory time
3. Psupp: Pressure support
4. FREQ: Respiratory rate
5. PEEP: PEEP
6. Psens/Fsens: Pressure trigger / Flow trigger
7. Tslope: Pressure rise time
8. Esens: Expiratory trigger sensitivity

7.4.2.4 Synchronized Intermittent Mandatory Ventilation - Volume Control (SIMV-V)

To set the ventilation settings in SIMV-V mode, select the desired hotkey in the ventilator settings fields.
The figure shows parameters setting.

VT: Tidal volume

TI: Inspiratory time

FREQ: Respiratory rate

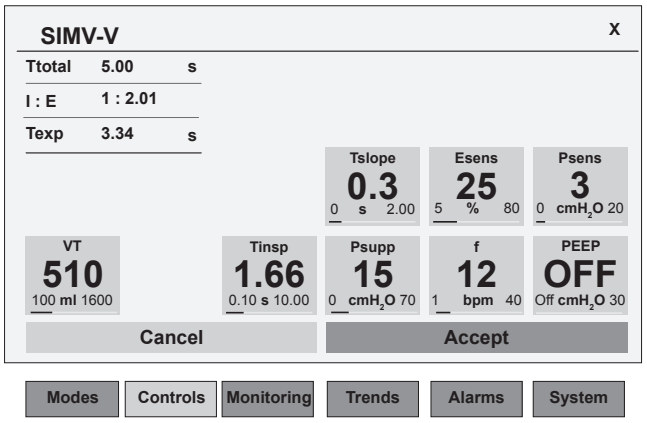
Psupp: Pressure support level

Tslope: Pressure rise time

Psens/Fsens: Pressure trigger / Flow trigger

PEEP Positive end expiratory pressure

Esens: Pressure trigger sensitivity



7.4.2.5 Synchronized Intermittent Mandatory Ventilation - Pressure Control (SIMV-P)

To set the ventilation settings, select the desired hotkey in the ventilator settings fields. The figure shows the parameter settings.

Pinsp Pressure control level

TI Inspiratory time

FREQ Respiratory rate

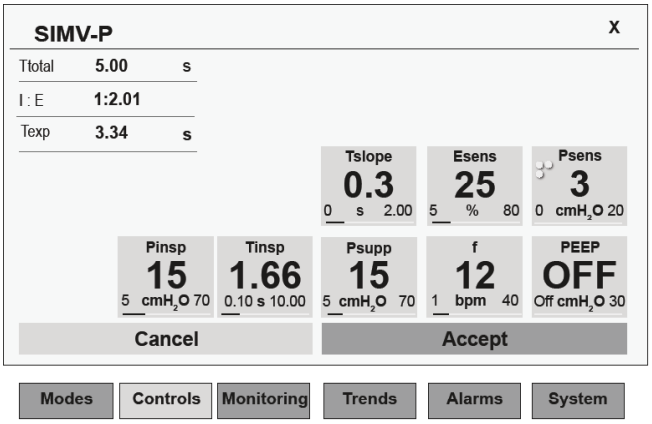
Psupp Pressure support level

Tslope Pressure rise time

Psens/Fsens Pressure trigger / Flow trigger

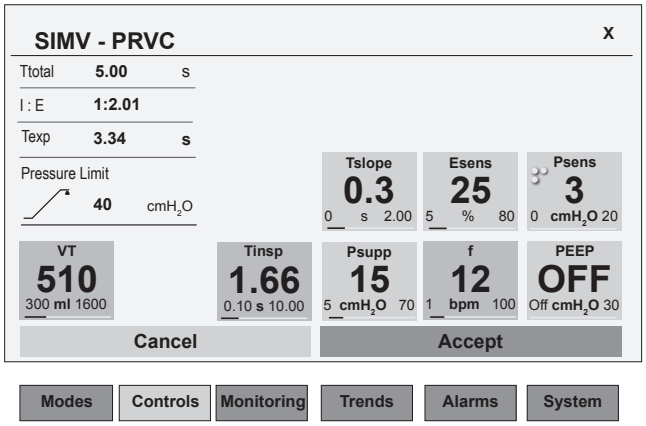
PEEP Positive end expiratory pressure

Esens: Pressure trigger sensitivity



7.4.2.6 Synchronized Intermittent Mandatory Ventilation - Pressure Guaranteed - Volume Control Ventilation (SIMV-PRVC)

To set the ventilation settings in PRVC mode, select the desired hotkey in the ventilator settings fields. Parameters to be set are shown below.



VT Tidal volume

Pinsp Pressure control level

I:E Respiratory ratio

FREQ Respiratory rate

Tslope Pressure rise time

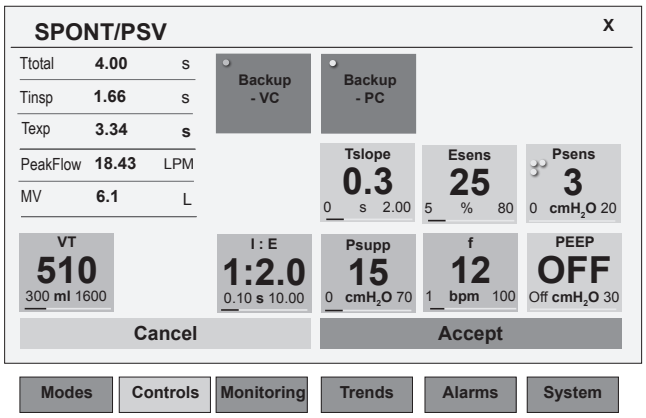
PEEP Positive end-expiratory pressure

7.4.2.7 Spontaneous/Pressure Support Ventilation (SPONT/PSV)

To set the ventilation settings in SPONT/PSV mode, select the desired hotkey in the ventilator settings fields. The figure shows the parameters setting.

Psu

In SPONT/PSV mode, the backup parameters should be set. The backup ventilation mode can be one of the volume mode and pressure mode.



Psupp Pressure support level

Psens/Fsens Pressure trigger / Flow trigger

Tslope Pressure rise time

PEEP Positive end-expiratory pressure

Esens: Pressure trigger sensitivity

To set Backup Modes:

1. Select the [Modes] shortcut key-> [Backup].
2. Touch [Volume] or [Pressure] to set desired backup mode.

Volume selected: the following parameters are available:

VT Tidal volume

I:E Respiratory ratio

FREQ Respiratory rate

Pressure selected: the following parameters are available:

Pinsp Pressure control

I:E Respiratory ratio

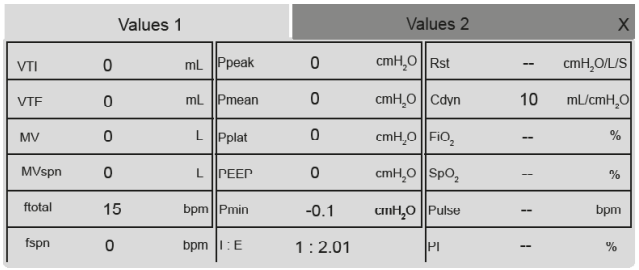
FREQ Respiratory rate

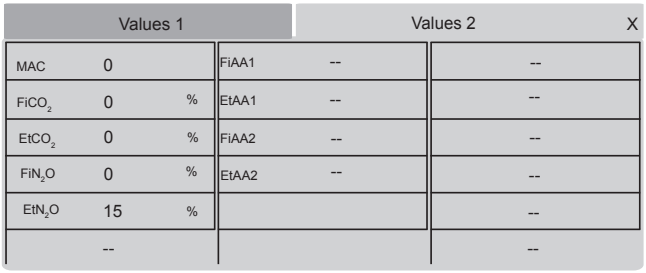
7.4.3 Monitoring

When the MONITORING function key is pressed the monitoring screen is shown. The monitoring screen has 2 pages that display 27 set parameters.

The parameters are divided between the two pages, titled Values 1 and Values 2, as follows:

- Values 1
  - VTI
  - VTE
  - MV
  - MVspn
  - ftotal
  - fspn
  - Ppeak
  - Pmean
  - Pplat
  - PEEP
  - Pmin
  - I : E
  - Rst
  - Cdyn
  - FiO_2
  - SpO_2
  - Pulse
  - PI
- Values 2
  - MAC
  - $FiCO_2$
  - $EtCO_2$
  - FiN_2O
  - EtN_2O
  - FiAA1
  - EtAA1
  - FiAA2
  - EtAA2





7.4.4 Trends

A trend graph is used to review the trend of parameter values within a specific time period. The trend is reflected through a curve. Every point on the curve corresponds to the parameter value at a specific time point. You can review VTE,VTI, MV, MVspn, ftotal, fspn, Ppeak, Pmean, PEEP, $EtCO_2$, $FiCO_2$, EtN_2O, FiN_2O, FiAA, EtAA, SpO_2, Pulse, PI, Cdyn and Rst data within a maximum of 24-hour operating time.

Select the [Trends] menu to access the display

1.Time Scale button

2.Parameter selection button

3.Trend graph

4.Cursor time

5.Cursor

6.Parameter and Parameter value

7.4.4.1 Setting trends

1. Select [Time Scale] button, push the control knob to select the desired scale from 1, 4, 12 and 24 hours.

2. Select [Parameter selection] button, push the control knob to select the desired scale from VTE,VTI, MV, MVspn, ftotal, fspn, Ppeak, Pmean,PEEP, $EtCO_2$, $FiCO_2$, EtN_2O, FiN_2O, FiAA, EtAA, SpO_2, Pulse, PI, Cdyn and Rst.

3. Rotary control button to adjust the position of the cursor to view the corresponding time point parameter values

CAUTION

1. **When the anesthesia machine is used to set the system time the trend graph is recorded again.**
2. **When the anesthesia machine is used to set the type of patient the trends can select save or recorded again.**

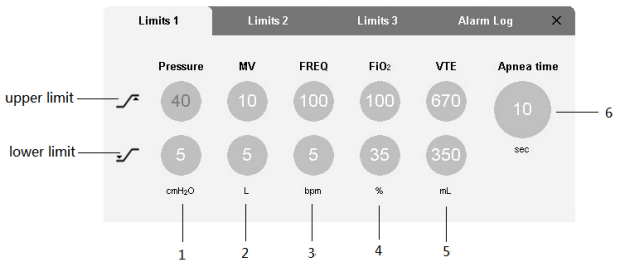
7.4.5 Alarms

Alarms, triggered by a vital sign that appears abnormal or by technical problems of the anesthesia machine. To prevent patient injury, you can set upper and lower limits for the following parameters.

When setting alarm limits, push the hotkey, turn the knob to the value that you want to set, then push the knob.

7.4.5.1 Limits 1 display

In Limits 1, alarms are generally related to mechanical ventilation.



Pressure

MV Minute ventilation

FREQ Respiratory rate

FiO_2 Fraction of inspired oxygen

VTE Expiratory tidal volume

Apnea time

In the SPONT/PSV mode, you can set the [Apnea Time] for Apnea alarm, and if the patient failed to trigger, anesthesia ventilator will automatically convert to Backup mode, [BACKUP] will be displayed in the mode display fields.

7.4.5.2 Limits 2 display

In Limits 2, alarms are related to anesthesia gas and CO_2 monitoring

1. End-tidal carbon dioxide
2. Fraction of inspired carbon dioxide
3. Fraction of inspired nitrous oxide
4. End-tidal anesthetic agent
5. Fraction of inspired anesthetic agent

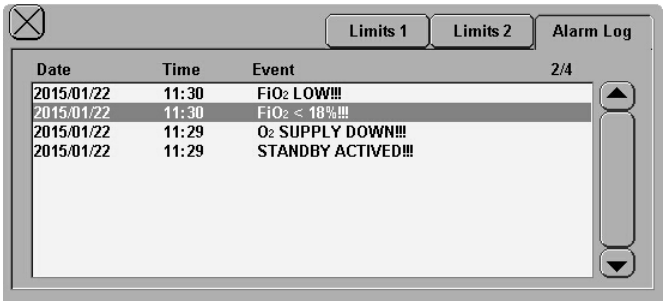
7.4.5.3 Limits 3 display

In Limits 3, alarms are related to SpO_2 monitoring (if fitted)

1. Pulse rate
2. Pulse oximeter oxygen saturation
3. Perfusion Index

7.4.5.4 Alarm Log

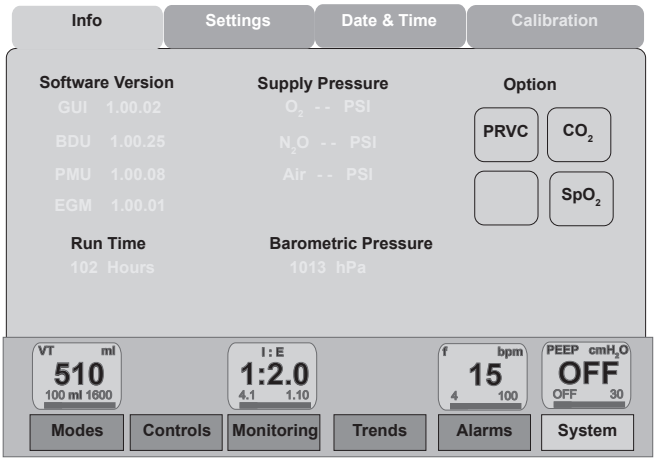
The alarm log, the system displays up to 100 events, stored in chronological order. When a new event occurs after 100 events are already stored, the new event overwrites the current earliest event.



7.4.6 System

When the SYSTEM function key is pressed the SYSTEM pages are shown. The following Four System pages are provided:

- Info
- Settings
- Date & Time
- Calibration.



7.4.6.1 Info page

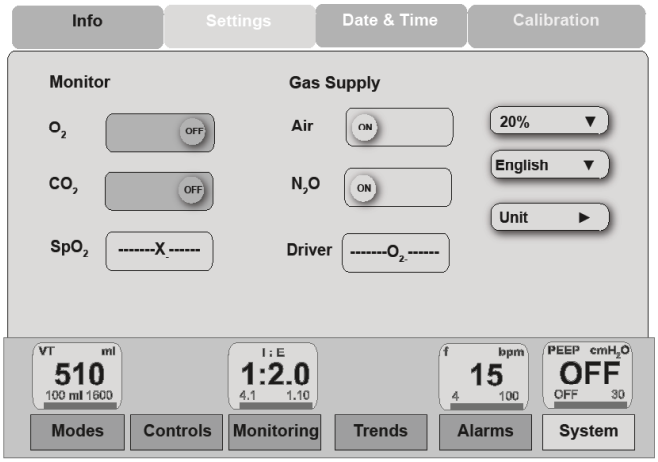
The Info page provides the following information:

- Software version
- Supply Pressure
- Run Time
- Barometric Pressure.

7.4.6.2 Settings page

CAUTION

When MONITOR switches are set to the OFF position, pressure alarms related to those gases will be non-functional.



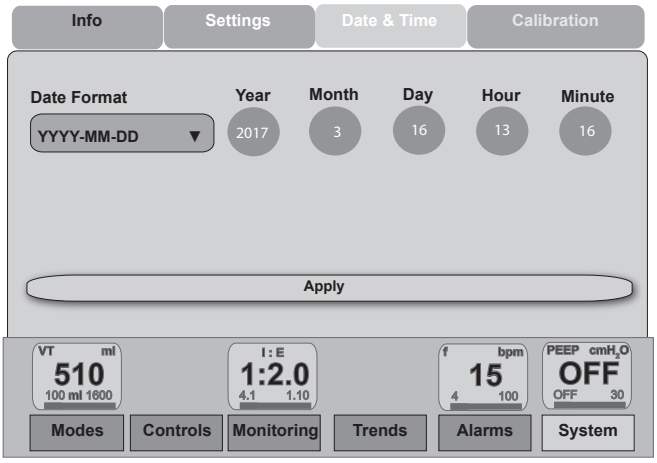
The SETTINGS page provides controls for the following parameters

- MONITOR
  - ON/OFF control for the O_2 Monitor
  - ON/OFF control for the CO_2 Monitor
  - ON/OFF control for the SpO_2 Monitor
- GAS SUPPLY
  - ON/OFF control for the Air supply
  - ON/OFF control for the N_2O supply
- Alarm volume, Language and Units
  - Alarm volume control
    - » The Alarm volume can be set to 20% (minimum); 40%; 60%; 80% or100% (maximum).
  - Language selection controls
  - Units of measure selection controls.
    - » CO_2 can be measured in %, mmHg or Kpa
    - » Airway pressure can be measured in cmH_2O or mbar
    - » Height can be entered as Cm or Inches
    - » Barometric pressure can be entered as mmHg or hPa
    - » Gas supply can be entered as kPa or PSI
    - » Weight can be entered as Kg or Lb.

7.4.6.3 Date & Time page

The DATE & TIME page provides a facility to set the system time and date.

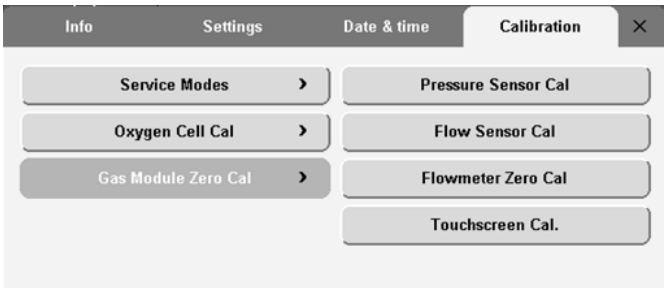
Date can be set using the UK or the US date display systems.



7.4.6.4 Calibration page

The Calibration function key allows the operator to access the following function:

- Service Modes
- Oxygen Cell Cal
  - The Oxygen Cell calibration button will show a new screen that gives instructions for the calibration procedure.
- Gas Module Cell
  - The Gas Module Cell allows the following related calibrations to be carried out:
    - » Pressure Sensor Cal
    - » Flow Sensor Cal
  - Additionally the following can be carried out from this menu:
    - » Flowmeter Zero Cal
    - » Touchscreen Cal.



7.5 Ventilator Setting fields

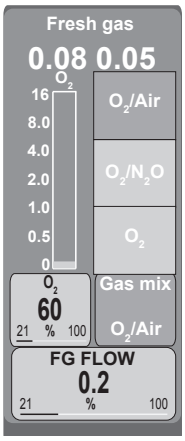
Ventilator setting fields allow the user to quickly access ventilator settings.

Ventilator setting fields are avaialble in both standby and ventilation modes. Values can be adjusted using the touch screen or the multifunction control.

The following values are available:

- Tidal Volume (VT)
- Inspiration Pressure (Pinsp)
- Respiratory ratio (I : E)
- Breathing frequency (f)
- PEEP

7.6 Fresh gas fields



The Fresh Gas (FG) fields show the current flow of fresh gases and the oxygen concentration of the fresh gas.

The FG fields has a single Gas mix buttons that is used to control the display. The Gas mix button allows the display of a single O_2 display or a dual O_2/Air or O_2/N_2O display.

The two additional buttons show Fresh Gas flow and the O_2 concentration of the fresh gas.

7.7 Waveform fields

Waveform fields are displayed in the ventilation mode only and can be appropriately configured to display data.

Select the required waveform from the display of available waveforms. Greyed out waveforms are not available due to the sensor being switched off or the monitoring module not being installed.

The following waveforms are the default waveforms.

1. Airway Pressure (Paw)
2. Flow
3. Volume.

The following waveforms are available after pressing the waveform icon.

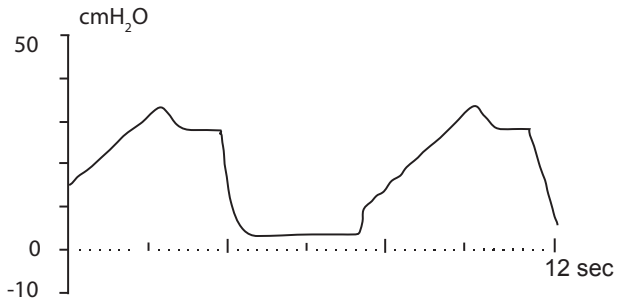
1. Paw: Airway pressure
2. Flow: Flow rate
3. Volume: Tidal Volume
4. P-V Loop: Pressure - volume loop
5. V-F Loop: Volume-flow loop
6. P-F Loop: Pressure -flow loop
7. CO_2: Carbon Dioxide
8. N_2O: Nitrous oxide
9. AA1: Anesthetic agent in use
10. Pleth: Pleth.

NOTE

The measured range corresponding to the waveform scales can be adjusted automatically.
The sweep time is fixed.

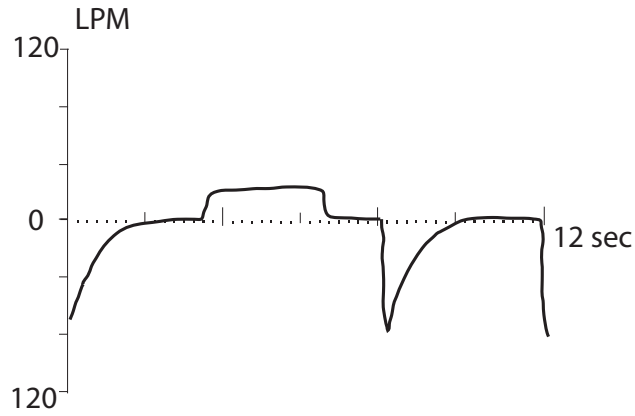
7.7.1 Airway pressure waveform

The airway pressure waveform shows the airway pressure, measured in cmH_2O, in the breathing circuit.



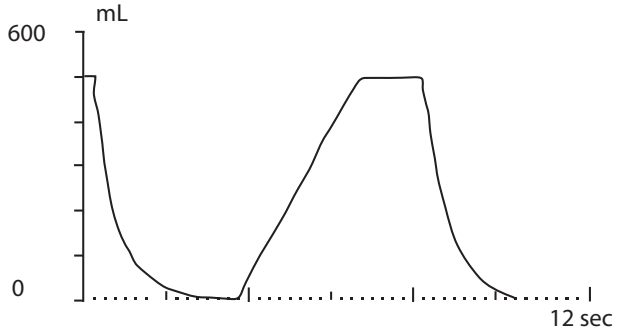
7.7.2 Flow waveform

The flow waveform shows the flow of gases in the breathing circuit.



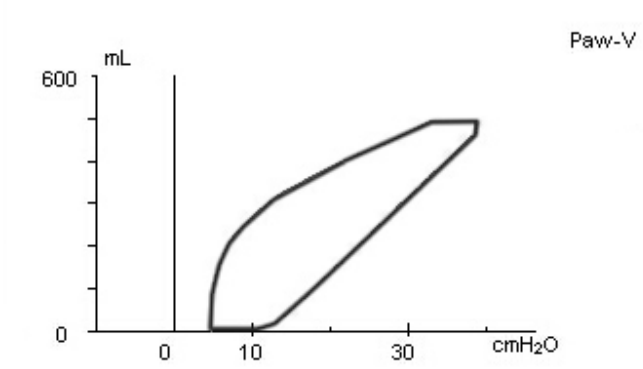
7.7.3 Volume waveform

The volume waveform shows the volume of gas in the breathing circuit.

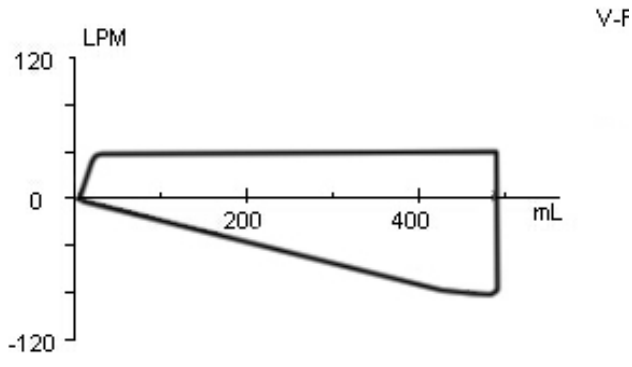


7.7.4 Pressure-Volume Loop

Select [Monitoring] -> [Graphics]
A Pressure-Volume Loop and Volume-Flow loop will displayed as shown.

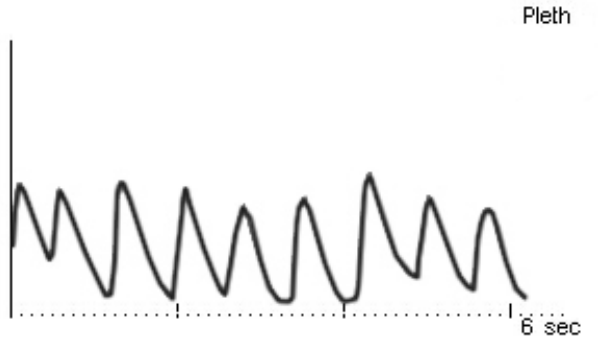


7.7.5 Volume-Flow Loop



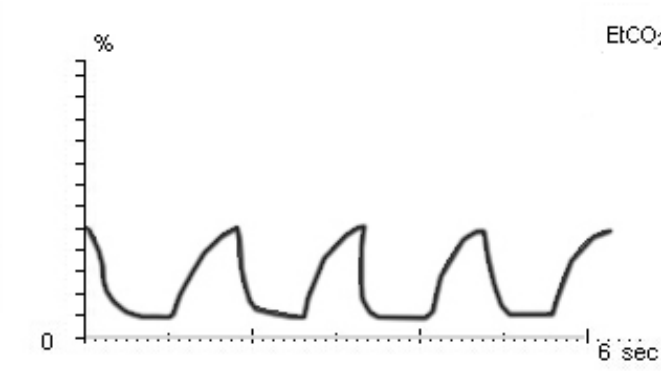
7.7.6 Pleth waveform

On machines with an SpO_2 module, a Pleth waveform is displayed as shown.



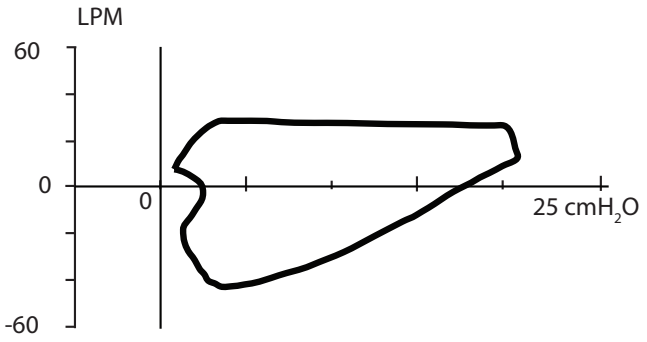
7.7.7 $EtCO_2$ waveform

On machines with CO_2, a CO_2 waveform is displayed as shown.



7.7.8 Pressure-Flow Loop

An example of a Pressure-Flow (P-F) loop is shown opposite.

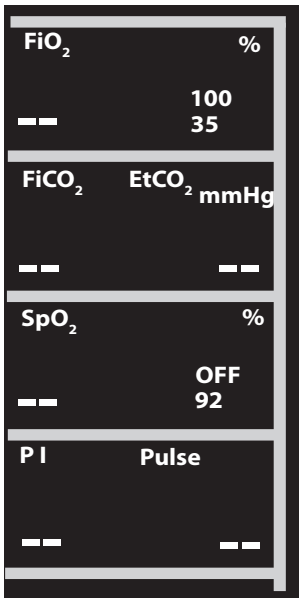


7.8 Anaesthetic Gas fields

NOTE

If your anesthesia machine is configured with AG module, you can monitor FiAA and EtAA. For details, refer to "Appendix 7 Anaesthetic Gas (AG) monitoring (optional)".

The Anaesthetic Gas (AG) fields are displayed in the upper LH display column. The fields are automatically configured to reflect the Anaesthetic in use and the ventilation mode of the machine.



When an anaesthatic gas module is not installed, the anaesthetic fields display the following values:

- FiO_2: Fraction of inspired oxygen
- $FiCO_2$: Fraction of inspired anaesthetic agent
- $EtCO_2$: End-tidal carbon dioxide
- SpO_2: Fraction of inspired nitrous oxide
- PI: Perfusion index
- Pulse: Pulse rate

When an anaesthatic gas module is installed, the anaesthetic fields display the following values:

- MAC: Minimum alveolar concentration
- FiAA: Fraction of inspired anesthetic agent
- EtAA: End-tidal anesthetic agent
- FiN_2O: Fraction of inspired nitrous oxide
- EtN_2O: End-tidal nitrous oxide.

7.9 Measurement values fields

The measured values fields are shown at the bottom of the RH column.Measured value fields are divided into two groups that are shown on two interchangeable pages. The page number that is currently active is shown in a highlighted circle below the displayed values.

7.9.1 Measured value field - Page 1

Page 1 shows the values that follow:

- PEEP: Positive end-expiratory pressure
- Pmean: Average pressure
- MVspn: Spontaneous minute volume
- fspn: Spontaneous respiratory rate
- VTI: Tidal volume

If an AG module is installed, Page 1 will show the values that follow:

- PEEP: Positive end-expiratory pressure
- Pmean: Average pressure
- $EtCO_2$: End-tidal carbon dioxide
- $FiCO_2$: Fraction of inspired carbon dioxide

- FiO_2: Fraction of inspired oxygen

7.9.2 Measured value field - Page 2

Page 2 shows the values that follow:

- Pplat: Plateau pressure
- Pmin: Minimum pressure
- Cdyn: Dynamic compliance
- I:E: Respiratory ratio

If an AG module is installed, page 2 will show the values that follow:

- Pplat: Plateau pressure
- Pmin: Minimum pressure
- MVspn: Spontaneous minute volume
- fspn: Spontaneous respiratory rate
- VTI: Inspiratory tidal volume

7.9.3 Measured value field - Page 3

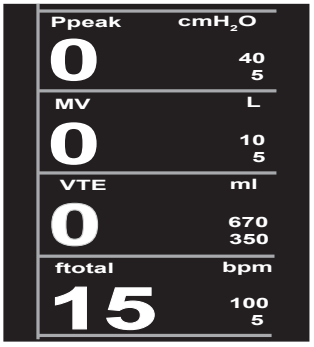
If an AG module is installed the measured field values will allow the selection of a third page, not illustrated, which will show the values that follow:

- Cdyn: Dynamic compliance
- Rst: Static resistance
- I:E: Respiratory ratio
- Pulse: Pulse rate
- SpO_2: Inhalation of anesthetic agent

7.10 Key parameter measured values fields

Key parameters are displayed at the top of the RH column at all times. The four values are as follows:

- Ppeak: Peak airway pressure
- MV: Minute ventilation
- VTE: Expiratory tidal volume
- ftotal: Total respiratory rate



7.11 Ventilation mode

The selected ventilation mode is displayed in the top LH corner of the display. All seven ventilation modes have a unique nmemonic that is displayed.

If the Bag/Vent switch is set ot Bag, the field displays the title MANUAL.

7.12 Alarm Silence Icon

Press the 120-seconds alarm silence key. 'Alarm silenced' status will be set. The audio alarm will be disabled.
The alarm silence symbol and the 120-seconds countdown time will be displayed in the upper right-hand corner of the screen.

In alarm silenced status, if an alarm occurs, the current silenced status is cancelled automatically and audible alarm tones are restored.

When the countdown time period ends, the audible alarm is restored. The alarm message will be displayed continually until the Alarm Reset key is pushed.

In the alarm silence period, press the alarm silence key again if the system does not respond.

7.13 Alarm Message field

Alarms are triggered by a vital sign that appears abnormal, or by a technical condition within the anesthesia machine

Alarms are indicated to the user by visual and audible alarm indicators.

WARNINGS

1. **Do not rely exclusively on the audible alarm system.**
2. **Decreasing the alarm volume to a low level may result in a hazard to the patient.**

CAUTION

3. When the anesthesia machine is started, the system self-test checks if the alarm lamp and audible alarm tones function normally.
4. If the self-test confirms normal function, the alarm system triggers an audible beep and the alarm lamp flashes yellow and red once in turn.
5. If a failure is detected, do not use the equipment. Contact a Penlon-trained engineer.
6. When multiple alarms of different levels occur simultaneously, the system will select the highest priority alarm and give visual and audible alarm indications accordingly.
7. Values for for all technical alarms and some physiological alarms are preset at the factory and can not be changed.

7.13.1 Alarm indicators

Alarms trigger visual or audible indicators:

Alarm lamp
Alarm message
Flashing numeric
Audible alarm tones

7.13.2 Visual indicator - Alarm lamp

If an alarm occurs, the alarm lamp will flash.
Color and frequency match the alarm level as follows:

High level alarms	The red lamp flashes quickly.
Medium level alarms	The yellow lamp flashes slowly.
Low level alarms	The yellow lamp is lit, without flashing

7.13.3 Audible indicator

Different alarm tone patterns are used to match the alarm level:

High priority: 10-note sequence, repeated every 10 seconds

Medium priority: 3-note sequence, repeated every 2 seconds

Low priority: 2-note sequence, does not repeat.

7.13.4 Alarm message

When an alarm occurs, an alarm message will appear in the alarm area.
The alarm message uses a different background color to match the alarm level:

High level alarms: red

Medium level alarms: yellow

Low level alarms: yellow

For physiological alarms, the exclamation symbol **(!)** identifies the alarm level as follows:

High level alarm: !!!

Medium level alarm: !!

Low level alarm: !

7.13.5 Clinical alarms

Message	Priority	Cause	Action
APNEA!!!	High	Breathing or ventilation has stopped.	Check patient's spontaneous breathing ability. Check for blockages in the breathing circuit
Continuous Pressure High!!!	High	Airway pressure greater than (PEEP +15) cmH_2O for 15 seconds.	Check for blockages in the breathing circuit.
PRESSURE HIGH!!!	High	Ppeak is higher than the Paw high alarm limit setting.	Decrease tidal volume setting or increase Paw high alarm limit setting. Check for blockages in the patient circuit
FiO2 < 18%!!!	High	FiO2 is lower than 18%.	Recalibrate the O_2 cell.

FiHAL HIGH!!!	High	FiAA is greater than alarm limit.	Set the alarm limits appropriately. Check agent setting.
FiENF HIGH!!!	High		
FiISO HIGH!!!	High		
FiSEV HIGH!!!	High		
FiDES HIGH!!!	High		
EtHAL HIGH!!!	High	EtAA is greater than alarm limit.	Set the alarm limits appropriately. Check agent setting
EtENF HIGH!!!	High		
EtISO HIGH!!!	High		
EtSEV HIGH!!!	High		
EtDES HIGH!!!	High		
MV LOW!!!	High	MV is lower than the low alarm limit setting.	Increase settings for tidal volume or breath rate, or decrease low alarm limit.
MV HIGH!!!	High	MV is higher than the high alarm limit setting.	Decrease settings for tidal volume or breath rate,or increase high alarm limit.
PRESSURE < -10cmH_2O!!!	High	Paw is less than -10 cmH2O	Check for blockages in the breathing circuit. Increase fresh gas flow. Check that there is high flow gas flowing through the AGSS. If yes, check the negative pressure relief valve on the receiver.
RATE LOW!!	High	Rate is less than low alarm limit.	Set the alarm limits appropriately or adjust the Rate setting
FiO_2 HIGH!!!	High	FiO_2 is greater than high alarm limit.	Set the alarm limits appropriately. Check the O_2 setting. Recalibrate theO_2 cell
FiO_2 LOW!!!	High	FiO_2 is less than low alarm limit.	Set the alarm limits appropriately. Check the O_2 setting. Check for leaks or blockages in the patient circuit. Recalibrate theO_2 cell
$EtCO_2$ HIGH!!!	High	$EtCO_2$ is greater than high alarm limit.	Check the patient settings. Set the alarm limits appropriately. Check if absorbent needs to be changed.
$FiCO_2$ HIGH!!!	High	$FiCO_2$ is greater than alarm limit.	Set the alarm limits appropriately. Check if absorbent needs to be changed.

FiN_2O HIGH!!!	High	FiN_2O is greater than alarm limit.	Set the alarm limits appropriately. Check the N_2O setting.
PRESSURE LOW!!!	High	Ppeak is lower than the Paw low alarm limit setting.	Increase tidal volume setting or decrease Paw low alarm limit setting.
SpO_2 LOW!!!	High	SpO_2 is lower than the low alarm limit setting.	Check patient's condition! Set the alarm limits appropriately.
PULSE RATE LOW!!!	High	Pulse rate is lower than the low alarm limit setting.	Check patient's condition! Set the alarm limits appropriately.
VTE HIGH!!!	High	VTE is higher than the high alarm limit setting.	Decrease tidal volume setting or increase high alarm limit.
VTE LOW!!	Medium	VTE is lower than the low alarm limit setting.	Increase tidal volume setting or decrease low alarm limit.
RATE HIGH!!	Medium	Rate is greater than high alarm limit.	Set the alarm limits appropriately or adjust the Rate setting.
PULSE RATE HIGH!!	Medium	Pulse rate is greater than high alarm limit.	Check patient's condition! Set the alarm limits appropriately.
SPO2 HIGH!!	Medium	SpO2 is greater than high alarm limit.	Check patient's condition! Set the alarm limits appropriately.
EtCO2 LOW!!	Medium	EtCO2 is less than alarm limit.	Check that patient is properly intubated. Check for leaks or blockages in the patient circuit. Set alarm limit appropriately.
FiHAL LOW!!	Medium	FiAA is less than alarm limit.	Check the fill level of the vaporizers. Set alarm limit appropriately. Check agent setting.
FiENF LOW!!	Medium		
FiISO LOW!!	Medium		
FiSEV LOW!!	Medium		
FiDES LOW!!	Medium		
EtHAL LOW!!	Medium	EtAA is less than alarm limit.	Check the fill level of the vaporizers. Set alarm limit appropriately. Check agent setting.
EtENF LOW!!	Medium		
EtISO LOW!!	Medium		
EtSEV LOW!!	Medium		
EtDES LOW!!	Medium		
FiN2O LOW!!	Medium	FiN2O is less than alarm limit.	Set the required alarm limits. Check the N2O setting

7.13.6 Technical alarms

Message	Priority	Cause	Action
O_2 SUPPLY DOWN!!!	High	O_2 pipeline pressure is less than 280kPa.	Check the O_2 pipeline and cylinder are properly connected.
BATTERY DISCHARGED!!!	High	Remaining battery power is between five and fifteen minutes.	Plug in the power cable. Check that the system circuit breaker is on.
EGM FAILURE !!!	High	Electronic mix Hardware Error	Switch to alternate O_2 control. Restart anesthetic workstation. Contact your service personnel.
Gas Module Software Error!!!	High	Gas Module Software Error!!!	Contact your service personnel.
Gas Module Hardware Error!!!	High	Gas Module Hardware Error!!!	Contact your service personnel.
Gas Module Motor Overspeed!!!	High	Gas Module Motor Overspeed!!!	Contact your service personnel.
Gas Module Factory calib lost!!!	High	Gas Module Factory calib lost!!!	Contact your service personnel.
Gas Module Replace Adapter!!!	High	Gas Module Replace Adapter!!!	Contact your service personnel.
Gas Module No Adapter!!!	High	Gas Module No Adapter!!!	Contact your service personnel.
CO_2 Unspecified Accuracy!!!	High	CO_2 Unspecified Accuracy!!!	Contact your service personnel.
N_2O Unspecified Accuracy!!!	High	N_2O Unspecified Accuracy!!!	Contact your service personnel.
AA Unspecified Accuracy!!!	High	AA Unspecified Accuracy!!!	Contact your service personnel.
Gas Module Temp Out Of Range!!!	High	Gas Module Temp Out Of Range!!!	Contact your service personnel.
Pressure Out Of Range!!!	High	Pressure Out Of Range!!!	Contact your service personnel.
AA ID Unreliable!!!	High	AA ID Unreliable!!!	Contact your service personnel.
STANDBY ACTIVED!!!	High	Switching from manual ventilation to mechanical ventilation	Press the "Alarm Reset"
BATTERY LOW!!!	High	Remaining battery power is between ten and thirty minutes.	Plug in the power cable. Check that the system circuit breaker is on
AIR SUPPLY DOWN!!	Medium	AIR pipeline pressure is less than 280kPa.	Check that the air pipeline is properly connected.
N_2O SUPPLY DOWN!!	Medium	N_2O pipeline pressure is less than 280kPa.	Check the N_2O pipeline. Check that the cylinder is properly connected.

Message	Priority	Cause	Action
NO ABSORBER ? !!	Medium	No connected Absorber canister	Installation Absorber canister
$ETCO_2$ LINE OCCLUSION!!	Medium	An error or occlusion occurred to the sampling line.	Check the CO_2 sampling line.
Mixed Agent and MAC > =3!!	Medium	Two different agents are detected and the MAC calculation is greater than or equal to3.	Make sure only one agent is on. Wait approximately two minutes for the first agent to wash out of the system.
Gas Module Inaccurate Gas Zeroing!!	Medium	Gas Module Inaccurate Gas Zeroing!!	Calibrate the Gas Module Zero. Contact your service personnel.
Mixed Agent and MAC < 3!	Low	Two different agents are detected and the MAC calculation is less than 3.	Make sure only one agent is on. Wait approximately two minutes for the first agent to wash out of the system
MAINS FAILURE!	Low	AC power disconnected or failure	Plug in the power cable. Check that the system circuit breaker is on.
SPO_2 SENSOR DISCONNECT?!	Low	SPO_2 sensor is not connected	Connect the SpO_2 sensor.
$EtCO_2$ OFF!	Low	CO_2 switch is turned off	Press the "Alarm Reset" To monitor CO_2 concentration, open the CO_2 switch
AA OFF!	Low	AA switch is turned off	Press the "Alarm Reset" To monitor Anesthetic agent concentration, open the AA switch.
SPO_2 OFF!	Low	SpO_2 switch is turned off	Press the "Alarm Reset" To monitor SpO_2, set the SpO_2 switch to on.
O_2 OFF!	Low	O_2 switch is turned off	Press the "Alarm Reset" To monitor O_2concentration, set the O_2 switch to on.

7.14 System prompt message and icons field

Prompt messages are not alarm messages.
Clinical and technical alarm messages and system status messages are also displayed. Messages of this kind are included in the prompt message category and are displayed in the prompt message area.

7.15 Patient type icon

Patient type icon displays an icon appropriate to the selected patient type.

7.16 Power status display field

The power status display indicates the Battery power available and the status of mains power connected to the machine.

7.17 System time field.

The system time field displays system time.

7.18 Start up and shut down procedures

7.18.1 Turn the system off

1. When a clinical procedure is completed:
   a) Check that the vaporizer is in the OFF position, and all gas flow controls are set to off.
   b) Turn the Anaesthesia system switch to the OFF position.

7.18.2 Turn on the System

1. Plug the power cord into an AC mains power outlet.
   The mains indicator is lit when the AC power is connected.
   The battery will be charged (if it is not already fully charged).
2. Check that the breathing system is properly connected.
3. Turn the Anaesthesia system switch to the ON position.
4. The self test will start and the indicator lights will be illuminated.
   The self-test screen will be displayed and the self test will start.
5. The self-test will continue for about 10 seconds. The device will prompt the user to perform a pre-use test. Pressing the ACCEPT button shows the pre-use test screen.

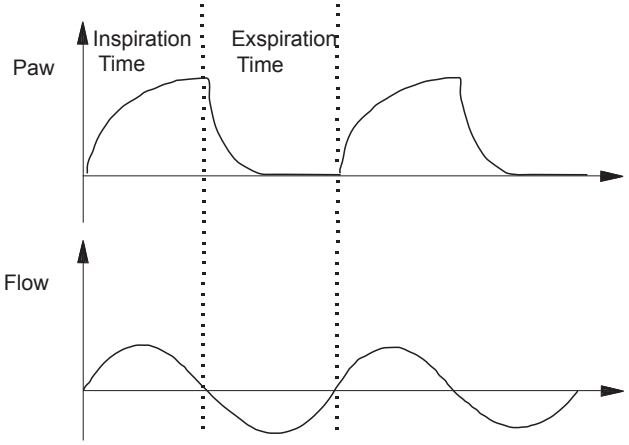
7.19 Ventilation Mode

WARNING

Before clinical use, check that all connections are secure and that the pre-operation tests are completed.
If any tests failed, do not use the system. Refer the workstation to a Penlon-trained service engineer for repair.

7.19.1 Bag Ventilation Mode

1. Turn the APL valve control to adjust the pressure in the breathing system within the appropriate range.
2. Set the bag/mechanical ventilation switch to the Bag position. The ventilation mode prompt area displays the icon for manual ventilation mode.
3. Press the O_2 flush button to inflate the bag if necessary. In manual ventilation mode, you can use the APL valve to adjust the breathing system pressure limit and gas volume in the manual bag.
   When the pressure in the breathing system reaches the pressure limit set for the APL valve, the valve opens to release excess gas.
4. The figures show the Paw waveform and flow waveform in the manual ventilation mode.



7.19.2 Select settings before starting Mechanical Ventilation Mode

1. Check that the system is in Standby mode.
2. Set the appropriate pressure high alarm value in the parameter setup.
3. Set the bag/mechanical ventilation switch to the Ventilator position.
4. If necessary, press the O_2 flush button to inflate the bellows.

7.19.3 Starting Mechanical Ventilation

CAUTION

Check the parameters are set to appropriate values before starting ventilation.

To exit Standby mode and start mechanical ventilation, press the Standby key.

7.20 Monitoring Parameters

7.20.1 FiO_2 monitoring

If the system is configured with an O_2 module or an oxygen sensor, FiO_2 values are displayed.

CAUTION

If an oxygen sensor is used, oxygen concentration monitoring may be inaccurate. Calibrate the oxygen sensor if the inaccuracies are large.

7.20.2 CO_2 monitoring

If the system is fitted with a CO_2 module, you can monitor $FiCO_2$ and $EtCO_2$ by setting the CO_2 module for open state.

7.20.3 Pressure monitoring

Pressure related parameters are measured as shown below.

PEEP

Ppeak

Pplat

Pmean

7.21 Tidal Volume Monitoring

CAUTION

The tidal volume values on the bellows housing give an approximate indication, and may be inconsistent with the actual measured volumes. This is a normal phenomenon.

International standards require that the user must monitor tidal volume during a clinical procedure.
Volume related parameters are measured as shown below.

VTI
VTE
MV
MVspn

Breath rate related parameters are measured as shown below.

ftotal
fspn

7.22 Pulmonary function

The system displays dynamic compliance monitoring, static resistance, and spirometry loops to reflect the patient's pulmonary function.

The system provides two spirometry loops: Paw-V (Paw-volume) loop and V- Flow(volume-flow) loop.
The scales of volume flow and Paw are adjusted automatically.

Paw-V loop and V- Flow loop are shown in sections 7.2.3.6 and 7.2.3.7

7.22.1 Absorber canister bypass mode

Use the canister bypass mode for continued ventilation of the patient while changing the absorber canister.

NOTE

Bypass mode seals the breathing circuit when the canister is removed.
While the absorber canister is out of the breathing circuit, the patient re-breaths exhaled gases. For safety, an infrared sensor monitors if bypass mode is activated. A technical alarm is triggered to warn the user.

7.22.2 Using canister bypass mode

1. Rotate the absorber canister release to activate the canister bypass mode.
   'No absorber!?' is shown in the alarm message area.
2. Reinstall the canister with fresh absorbent into the absorber mount.
3. Rotate the absorber canister to the required installation position.
   Check that the alarm message is cancelled.

7.23 Auxiliary Common Gas Outlet (ACGO)

The common gas outlet is mounted on the front of the machine.

7.24 Drive gas

The electronic drive gas switch controls the gas type of drive gas automatically. The default drive gas is O_2 when the air pipeline is connected. If O_2 gas source fails, the drive gas type can be switched to air.

1. Check the anesthesia machine in standby mode

2. Select the [System] -> [Settings] -> [Drive gas].

3. Select [drive gas] to desired gas type.

8. Maintenance

8.1 Cleaning and Disinfection

WARNING

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

Care must be taken not to allow liquids to run into enclosed areas; serious damage may result.

CAUTION

Do not use harsh abrasive cleaning agents.

Check the manufacturer's data sheet for each cleaning agent to be used.

Cleaning

All the surfaces of the anaesthetic worksation and monitors should be cleaned on a daily basis with an appropriate disinfectant, or immediately if visibly contaminated.

The surfaces of the anaesthetic machine, especially those areas which are likely to have been touched by the gloved hand that has been in contact with blood or secretions, should be regarded as contaminated and should be cleaned at the earliest opportunity, between patients.

Appropriate disinfectants suitable for use with the anaesthetic machine are isopropyl alcohol, or alcohol wipes (e.g. azowipes)

Flowmeter / display screen surface

CAUTION

Do not apply excessive pressure to the display screens.

Cleaning of display screen surfaces is restricted to soap based sanitising wipes, or Milton sterilising solutions 1.8 % v/v.

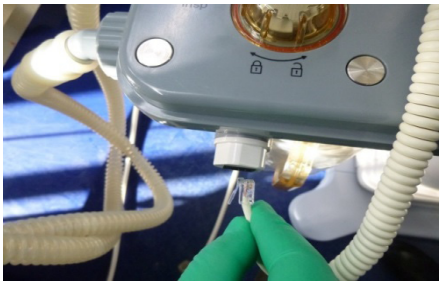
After cleaning

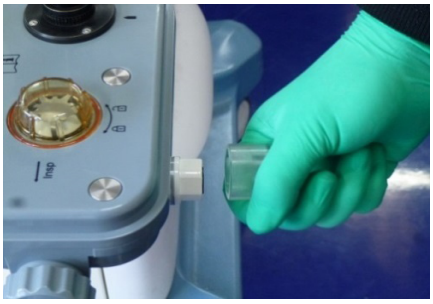
Make sure that all cleaning agent residues are fully removed after cleaning.
Allow the machine to dry thoroughly before clinical use.

Sterilisation

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

An effective, new bacterial / viral breathing circuit filter should be used for every patient.





8.2 Absorber and breathing system

CAUTION

The absorber assembly weighs approximately 15 kg (when empty). Removal and refitting must only be carried out by qualified service personnel.

When the absorber is lifted or carried by hand, always support the weight of the unit under the base.
Do not lift the absorber by gripping any of the components attached to the manifold block.

CAUTION

The canister may contain condensate. Before removing the absorber from the anaesthetic machine drain the canister and dispose of the absorbent.

1. **Set the brakes on the anaesthetic machine castors.**
2. **Disconnect all cable connectors and hoses.**
3. **Lift the absorber assembly from the pole-mount.**

Remove the following components before cleaning the system:

1. Oxygen sensor
2. Flow sensors
3. Breathing tubes
4. Bag
5. Bellows
6. Check valve assembly
7. Canister
8. Condensation drain valve
9. Water container.

8.3.1 Remove the oxygen sensor

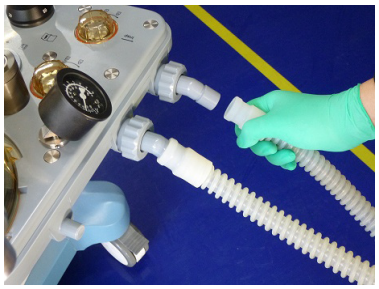
10. Unplug the oxygen sensor cable from the sensor at the port marked O_2% and unplug the other end of the cable from the machine.
11. Turn the oxygen sensor counterclockwise to remove

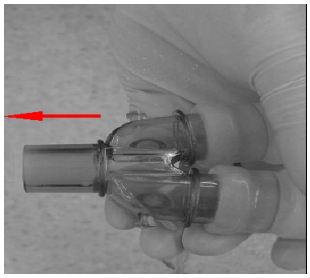
8.3.2 Remove the flow sensors

Unscrew the inspiratory and expiratory connectors and then pull the adaptor out.

8.3.3 Remove the breathing tubes

1. Pull off the inspiratory and expiratory hoses from the circuit.
2. Separate the Y-piece from the two breathing.





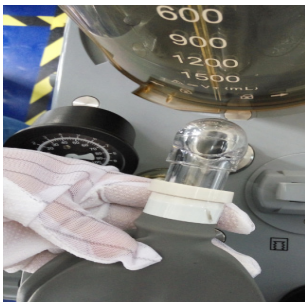
CAUTION

When disassembling the breathing tube, hold the tube connectors at both ends of the tube to prevent damage to the tube.

Do not reuse the filter. Follow local regulations regarding disposal of hospital waste when the filter is discarded.

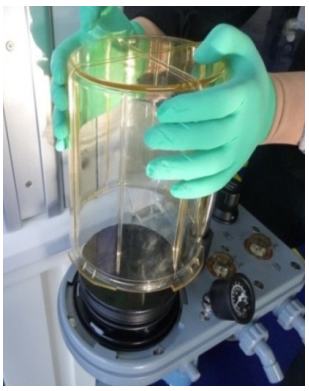
8.3.4 Remove the bag

Remove the bag from the breathing circuit manual breathing bag port.



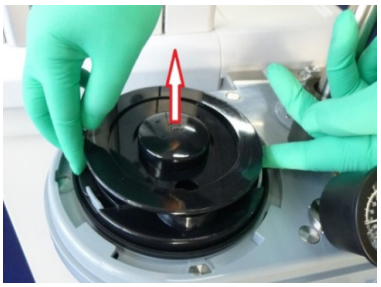
8.3.5 Remove the bellows assembly

1. Turn the bellows housing counterclockwise, and lift from the base

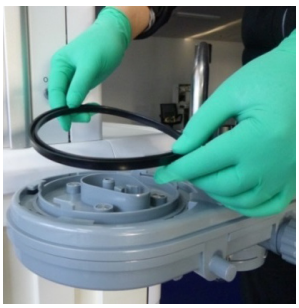


2. Remove the bellows from the base.

3. Remove the bellows base

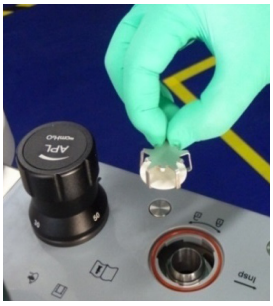


4. Remove the locking tabs and ring from the bellows base.



8.3.6 Remove the check valve assembly

1. Turn the check valve cover counterclockwise to remove.
2. Remove the check valve assembly.



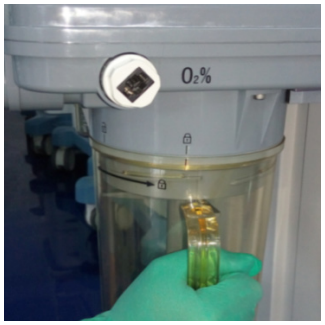
8.3.7 Remove the absorber canister

1. Hold the canister handle, rotate the canister clockwise and remove.

WARNING

Soda lime is a caustic substance and is a strong irritant to eyes, skin and respiratory system. Affected parts should be flushed with water. If irritation continues after flushing with water, seek medical assistance immediately.

Replace the canister as soon as possible.



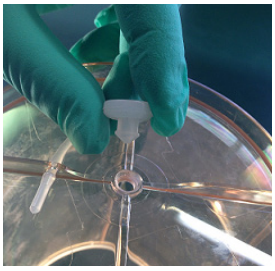
8.3.8 Remove the condensation drain valve

The drain valve allows condensation drainage without the need to remove the soda lime.

1. Pull out the water drain valve.

WARNING

After draining the water, reinstall the water drain valve immediately to prevent gas leakage



8.3.9 Remove the Water Container

1. Grip the water collection container and turn clockwise to remove

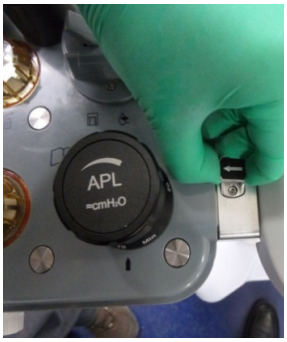
WARNING

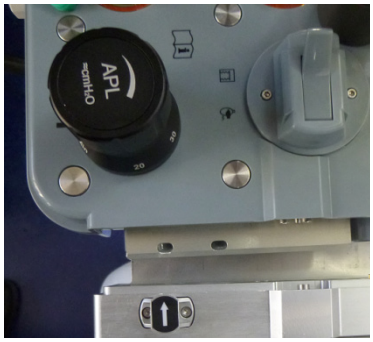
Removing the water collection container will not cause gas leakage, but always reinstall as soon as possible.

8.3.10 Remove the Absorber Assembly

Pull the locking catches on the adaptor plate up, rotate 90 degrees and pull off.

Remove the absorber assembly from the circuit adapter with both hands.





8.3.11 Absorber assembly system - Cleaning and disinfection

Cleaning

Rinse and dry all parts of the breathing system (except the O_2 sensor). Use a mild detergent (pH ranging from 7.0 to 10.5).

Autoclave

Autoclavable parts are marked. Metal and glass parts can be steam autoclaved at a maximum temperature of 134ºC.

WARNING

1. **To avoid patient injury, do not use talc, zinc stearate, calcium carbonate, corn starch or equivalent materials.**
2. **Do not autoclave the breathing system and the O_2 sensor.**
3. **Inspect all parts for deterioration and replace if necessary.**

All parts of the breathing system must be cleaned and disinfected. See below, and select the appropriate method based on the actual condition of each component, to avoid cross-contamination.

Recommended disinfection method

Patient breathing hoses and Y piece (reusable)

Rinse with water, then soak it in solution of water and detergent for 30 minutes, at a temperature of 30-41°C. Rinse with clean water. Dry and wipe, using 70% medical-use alcohol. Alternatively, autoclave at a maximum temperature of 134°C.

Flow sensor

Flush with water, then soak in a solution of water and detergent for 30 minutes, at a temperature of 30-41°C. Rinse with clean water. Dry and wipe, using 70% medical-use alcohol.

Bellows assembly

Flush with water, then soak it in a solution of water and detergent for 30 minutes at a temperature of 30-41°C. Rinse with clean water, and wipe with 70% medical-use alcohol.

Check valve assemblies

Flush with water, then soak in a solution of water and detergent for 30 minutes at a temperature of 30-41°C. Rinse with clean water, and wipe with 70% medical-use alcohol. Alternatively, autoclave at a maximum temperature of 134°C.

Oxygen sensor

Clean with a damp cloth soaked in mild detergent. Wipe off the remaining detergent with a dry lint free cloth.

Absorber canister assembly

Flush with water, then soak it in solution mixed by water and detergent for 30 minutes at a temperature of 30-41°C.
Rinse with clean water, and wipe with 70% medical-use alcohol.
Alternatively, autoclave at a maximum temperature of 134°C.

Reusable manual bag:

Flush with water, then soak it in solution mixed by water and detergent for 30 minutes at a temperature of 30-41°C. Rinse with clean water, and wipe with 70% medical-use alcohol.
Alternatively, autoclave at a maximum temperature of 134°C.

Anaesthetic gas scavenging system

Clean with a damp cloth soaked in mild detergent. Wipe off the remaining detergent with a dry lint free cloth.

Breathing system:

Flush with water, then soak it in solution mixed by water and detergent for 30 minutes at a temperature of 30-41°C. Rinse with clean water, and wipe with 70% medical-use alcohol.
Alternatively, autoclave at a maximum temperature of 134°C.

Bag Arm

Flush with water, and soak in a solution of water and detergent for 30 minutes at a temperature of 30-41°C. Rinse with clean water, finally wipe by using 70% medical-use alcohol.
Alternatively, autoclave under maximum temperature 134°C.

Water collection container

Flush with water, then soak it in solution mixed by water and detergent 30 minutes, at a temperature of 30-41°C. Rinse with clean water, then wipe by using 70% medical use alcohol.
Alternatively, autoclave at a maximum temperature of 134°C.

Flow sensor - cleaning and disinfection

Soak the flow sensor in detergent for 30 minutes to clean.
Flush with water and dry.

8.3.12 Reinstall the absorber assembly and breathing system

Make sure that all components fully dry before installation

8.3 Maintenance policy

WARNING

1. **Only use lubricants approved for anesthesia or O_2 equipment.**
   Do not use lubricants containing oil or grease that may burn or explode in high O_2 concentrations.
2. **Follow infection control and safety procedures to prevent cross-infection.**
   After clinical procedures, equipment may be contaminated with blood and body fluids.
3. **Movable parts and removable components may present a hazard. Use care when moving or replacing system assemblies and components.**
4. **Check correct operation of the system after servicing and repair.**
5. **All maintenance, repairs, cleaning, disinfection and sterilization must only be carried out when the unit is non-operational.**
6. **Devices connected to the auxiliary outlets may increase leakage currents. Check the total leakage current every six months.**
7. **All repairs and servicing, and the replacement of components must be undertaken by a competent, Penlon-trained engineer.**
8. **After repair, carry out a pre-use test - see section 5.2.**
   Do not use a malfunctioning anesthesia machine.

CAUTION

All repairs must be undertaken by a competent, Penlon-trained engineer.

Replace damaged parts with components supplied by Penlon Limited.
Test the unit to check that it complies with the manufacturer's specification.

Contact Penlon Technical Support department for further information.

8.4 Maintenance Schedule

CAUTION

4. **This schedule is based on a maximum total annual usage time of 2000 hours per year. If the actual annual usage exceeds 2000 hours, maintenance must be increased accordingly.**
5. **All repairs and servicing, and the replacement of components must be undertaken by a Penlon-trained engineer.**

Daily

1. Clean external surfaces.
2. Check for damaged components - repair or replace as necessary.
3. Check and action as necessary:
    a) Check the gas cylinder port seal.
    b) Empty the water collection container.
    c) Check for colour change of the absorbent soda lime. Replace if necessary.
    d) Replace the O_2 sensor if inaccurate measured values occur and the problem persists after multiple calibrations.
    e) Replace the flow sensor if the seal is damaged, or if the flow sensor, or the membrane inside the flow sensor, is cracked or distorted.
    f) Replace the transfer tube if it is damaged.

Monthly

Oxygen sensor calibration

Every year

1. Replace the components listed in the Service Manual for this product.
2. Calibrate the CO_2 module (if installed).
3. Clean the fan filter

Every two years

1. Replace the components listed in the Service Manual for this product.

8.5 Breathing System Maintenance

Replace any parts that are visibly damaged or worn. Refer to Section "5. Installation and Pre-Use Checks" and section "8. Maintenance".

8.6.1 Pressure sensor zeroing

CAUTION

1. **Do not perform calibration while the unit is connected to a patient.**
2. **During calibration, do not operate the pneumatic system. Do not move or compress the breathing tubes.**

Procedure

1. Stop manual or mechanical ventilation. If a breathing tube is connected, open the breathing tube patient connection to air.
   Check that the bellows falls to the bottom.
2. Turn the flowmeter to minimum.
3. In standby mode, touch the [System] hotkey -> [Calibration] hotkey ->[Pressure Sensor Cal].
   Pressure sensor zero calibration will start automatically.
   Do not touch the breathing system tubing during calibration.

CAUTION

If zeroing fails, contact a Penlon-trained engineer.

8.6.2 Flow Sensor Zeroing

1. Stop manual or mechanical ventilation. If a breathing tube is connected to the breathing system, then open the breathing tube patient connection to air.
   Check that the bellows falls to the bottom.
2. Turn off the flowmeter.
3. In standby mode, touch the [System] hotkeys -> [Calibration] hotkey ->[Flow Sensor Cal].
   Flow sensor zero calibration will start automatically. Do not touch the breathing tubes during calibration.

8.6 Oxygen concentration calibration

CAUTION

Calibrate the O_2 sensor at the same ambient pressure in which it will be used to monitor oxygen delivery in the breathing system.

1. Disassemble the O_2 sensor for calibration.
2. Check for water build-up in the sensor and its installation, dry if necessary, then refit.
3. Check that the oxygen sensor cables are connected correctly.

8.7.1 O_2 calibration at 21%

CAUTION

1. **Calibrate when the measured value of O_2 concentration is outside specification range, or when the O_2 sensor is replaced.**
2. **If calibration fails, check for a technical alarm and then check the troubleshoot section. Repeat the calibration.**
3. **In case of repeated calibration failures, replace the O_2 sensor and repeat the calibration. If it still fails, contact a Penlon-trained service engineer.**
4. **Follow your hospital biohazard disposal procedure for the discarded O_2 sensor. Do not incinerate.**

Calibration procedure for 21% O_2

1. Return to standby mode.
2. Turn off all of gas flow from flowmeter.
3. Touch the [System] hotkeys -> [Calibration] -> [Oxygen Cell Cal]->[21%].
4. Check that the patient or test lung is disconnected from the system.
5. Follow the prompts.
   Before O_2 21% calibration, flush with 10 L/min of air, or expose in air for 2 minutes minimum.
6. Remove the O_2 sensor from the breathing system and expose to room air for three minutes. Disassemble the flow sensor - see section 9.2.1.
7. Push the [Enter] hotkey to start calibration.
8. After a successful calibration, the screen shows [Calibration Completed!].
   If the message [Calibration Failure!] is displayed, repeat the calibration.

8.7.2 100% O_2 calibration

CAUTION

1. **If the calibration fails, check for a technical alarm and then check the troubleshoot section. Repeat the calibration.**
2. **In case of repeated calibration failures, replace the O_2 sensor and repeat the 21% O_2 calibration.**
3. **Calibrate at 100% O_2 after a 21% O_2 calibration is completed. If it still fails, contact a Penlon trained engineer.**

Calibration at 100% O_2:

1. Check that the 21% O_2 calibration is completed successfully and that the O_2 Supply Failure alarm is not triggered.
2. The system must be in Standby. Press and select [OK] from the menu to enter standby mode.
3. Turn off all of gas flow from flowmeter.
4. Touch [System] hotkeys -> [Calibration] -> [Oxygen Cell Calibration]->[100%].
5. Check that the patient or test lung is disconnected from the system.
6. Follow the prompts [e.g. before O_2 100% calibration set a supply of 10 L/min of O_2].
7. Turn the bag/vent switch to the bag position
8. Connect the bag to the bag arm.
   Set the APL to the 30 cmH_2O position.
9. Push and hold the O_2 flush button for 20 seconds.
10. Connect the Y piece with a test plug on the breathing system and set the O_2 flow to 10 L/min.
11. Push the [Enter] hotkey to start calibration.
12. After a successful calibration, the screen shows [Calibration Completed!]. Repeat the procedure if the message [Calibration Failure!] is displayed.

8.7.3 Prevention of Water Build-up

Water is formed by the condensation of exhaled gas and a chemical reaction between CO_2 and the sodalime in the absorber canister.
Lower fresh gas flows produce more condensation due to higher levels of CO_2 in the canister. In addition moist, exhaled gas remains in the breathing system and the absorber canister.

Check the flow sensors when abnormal flow waveforms or unstable tidal volume fluctuation occurs. Check for moisture and dry, before use.

To prevent water build-up

1. Use a filter between the flow sensor and the patient.
2. Check the water container and absorber canister before use. Dispose of any water build-up.

8.7 Flow Sensor Calibration

This check must be carried out by a Penlon-trained engineer in Engineering Mode.

8.8 Fault Diagnosis and Troubleshooting

Fault	Cause	Action
Ventilation system leak	APL is not closed during manual mode	Turn the APL valve to the appropriate position
	Absorber canister is not installed correctly	Reinstall
	Damaged or loose breathing tube connector	Refit or renew the breathing tube
	A loose check valve	Reinstall
	Bag/vent switch failure	Contact a Penlon-trained engineer
Bellows does not inflate completely	The respiratory rate is set to fast and expiratory time is too short.	Set respiratory rate to a reasonable value
	The breathing system leaks	Carry out a system leak test
	Flowmeter is closed	Reset the flowmeter
During the inspiratory phase, the bellows is not compressed	Bag/vent switch is still in the manual position.	Turn the switch to mechanical ventilation
	Flow control valve has failed; no drive gas is delivered.	Contact a Penlon-trained engineer
	Bellows housing is damaged	Replace the bellows housing
	During inhalation, the PEEP valve can not be closed.	Contact a Penlon-trained engineer
Manual breathing airway pressure is too high	APL valve is set too high	Reset the APL valve.
Power indicator is not lit	Power cord is not connected	Connect the power cord.
	System and ventilator switch is not turned on	Turn the switch to On
	Power cord is damaged	Replace the power cord.
	Mains power outlet is faulty	Switch to another power outlet.
	Fuse has blown	Contact a Penlon-trained engineer
No power at auxiliary outlet	Fuse has blown	Contact a Penlon-trained engineer Replace the fuse
No airway pressure waveform	There is a disconnect between the pressure sensor and the sample tube, or	Reconnect.
	Gas source is exhausted	Check the gas supply

8.9 Battery Replacement

Installing or replacing batteries must be undertaken by a competent, trained engineer.

The workstation must be switched off and disconnected from the mains supply.

Undo the screws and remove the battery cover (1) at the rear of the machine.

Fit the batteries into the holder.
Check the polarity.

Refit the cover and tighten the four screws.

6. Appendix

Appendix 1 References

The Prima 465 and its Anaesthetic Breathing System complies with the requirements of ISO 80601-2-13.

Appendix 2 Disposal at end of useful life: Risk assessment

Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.

EC territories: follow the requirements of Directive 2002/96/EC

Disposal of used batteries

Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.

NOTE

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

Appendix 3 Optional extras and approved accessories

WARNING

Only use accessories approved by Penlon Ltd.

Please contact the International Sales Department at Penlon Ltd (see below), or your local Penlon Distributor.

Tel: +44 1235 547001
E-mail: international.sales@penlon.com

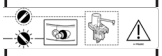
Appendix

Appendix 4 Labelling

	Operating instructions (this user manual)
	Refer to user manual
	Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state and federal regulations.
	1. General Warning (yellow background) 2. Caution (plain background)
	Emergency oxygen flush valve button
	Gas inlet pressure (pipeline or cylinder supply)
	Do not push against the machine at a height greater than 1.1. metres
	Do not sit
	Rotation (controls output)
	Backbar leak check
	Bag
	Ventilator
	Mute (alarm)

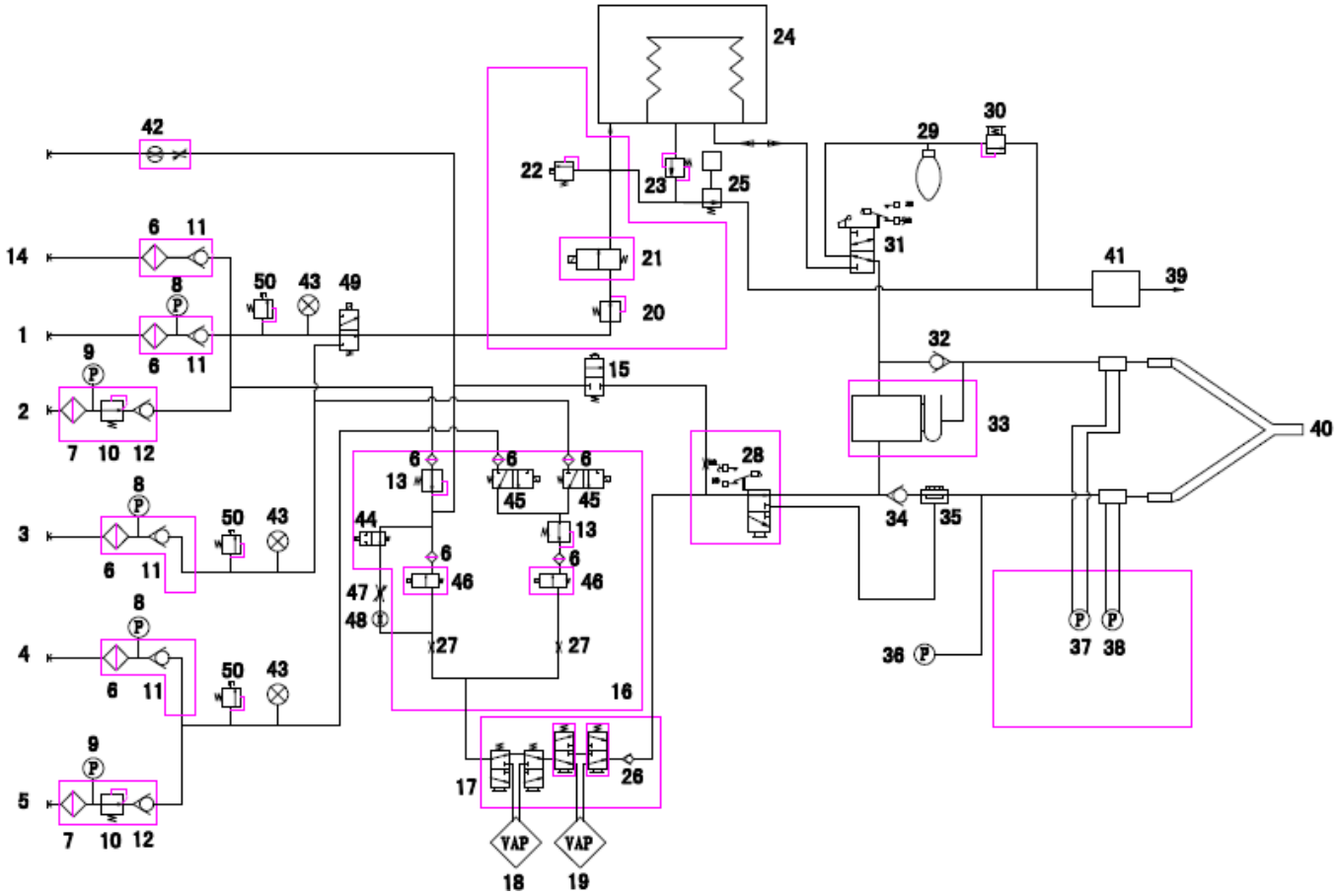
	Fuse symbol and specification, plus orientation of Neutral and Live fuses
	Protective earth
	On
	Off (mains supply connected)
	Off (disconnected from mains supply)
L	Connection for live conductor
N	Connection for neutral conductor
	Transportation: Remove accessories.
	
	1. General warning (yellow background) 2. Caution (plain background)
	
	

Appendix

	Electrostatic device
	Serial Number
	Lock
	Unlock
	USB connector
	Common Gas Outlet
	Anaesthesia system switch

Appendix

Appendix 5 Gas Circuit Description



1. Gas supplies

The anesthesia machine has pipeline and cylinder gas supplies available.
Pipeline gas supplies, O_2, N_2O and Air, go into the system through pipeline connectors 1, 3 and 4 respectively. The pipeline pressure ranges between 280 and 600 kPa.
Cylinder gas supplies, O_2 and N_2O, go into the system through cylinder connectors 2 and 5 respectively. The O_2 and N_2O cylinder pressures are 6.9 to 15 MPa and 4.2 to 6 MPa respectively, which is decreased to 400 kPa through regulator 10.
Each connector is clearly marked to prevent erroneous gas connection. All connectors have filters and check valves. Color coded gauges show the pipeline and cylinder pressures.

2. Fresh gas

When gas supplies connect, electronic mixer16 is connected to the gas supplies. Regulator 13 decreases the gas pressure to 250 kPa to check constant pressure supplied for the electronic mixer.
The mixed gas of O_2, Air and N_2O goes from the gas mixer outlet through the vaporizer 18 or 19 that is ON, and adds anesthetic agent to form the fresh gas supply.

3. Anesthesia ventilator

This anesthetic ventilator is a pneumatically driven, microprocessor-controlled anesthesia delivery system. The drive gas comes from O_2/Air gas supply.

Filter 6 filters the drive gas again. Regulator 20 helps keep the drive gas pressure to stay within a fixed pressure range. Pressure sensor 43 monitors the drive gas pressure. If the drive gas pressure is lower than the preset pressure limit, an alarm appears on the ventilator display. Inspiratory flow control valve 21 controls the inspiratory flow. The exhalation valve 25 controls and produces PEEP as well. During inspiration, the microprocessor-controlled valve 21 creates the preset inspiratory flow and exhalation valve 25 closes. The drive gas goes into the bellows 24 and depresses the bag inside the bellows to move downward. This forces the gas inside the bag to go through the absorber canister 33 to enter the patient lung until the end of inspiration. During expiration, valve 21 closes and exhalation valve 25 opens. The patient expires freely. The exhaled gas, mixed with the fresh gas, goes into the bag to lift up the bag inside the bellows. The drive gas outside of the bag is scavenged to the AGSS until the end of expiration.

During the ventilation, the ventilator performs real-time monitoring of airway pressure (paw) and tidal volume (VT). If the paw or VT is outside of the user-preset alarm limits, an audible and visual alarm occurs. When paw is higher than the limit value, the ventilator enters expiratory state automatically to avoid causing injury to the patient. In addition, the ventilator has a built-in overpressure valve 22 which opens when the inspiratory pressure exceeds approximately 110 cmH_2O to avoid sustained airway pressure.

Appendix 6 CO_2 Module

WARNINGS

1. **The CO_2 module, components and packaging must be handled in accordance with local regulations concerning disposal.**
2. **Read the instructions supplied by the manufacturer before using the module in a clinical procedure.**
3. **This module is a non-mobile device, do not use for transport applications.**

1. Product Description and Applications

The end-tidal CO_2 module can monitor exhaled concentration of CO_2, end-tidal CO_2 concentration, inhaled CO_2 concentration and respiratory rate, inspiratory time and expiratory time. The module can be used for intubated patients (via a three-way sampling system) and bedside patients (via a nasal sampling tube).

The CO_2 module can be used for newborns, children, and adults.

The module can detect and report pipeline blockages and other state data to the host. Do not reverse the airflow in the sampling tube.

The module is factory calibrated and has an automatic zero calibration function. If the user finds a significant deviation from standard performance, return the unit for factory recalibration.

2. Performance indication

Power requirements	5 .0 V ± 0.2 V DC
Power	80 mA in general use; 300 mA in extreme circumstances
Operating temperature	5 ~ 50 °C
Storage temperature	-20 ~ +70 °C
Relative humidity	0-85% (non-condensing)
Size	77 × 50 × 30 mm
CO_2 measurement range	0 - 20% by volume (0 - 150 mmHg @ BTPS)
CO_2 measurement accuracy	<5.0% CO_2 (ATPS) time: ± 2 mmHg > 5.0% CO_2 (ATPS) time: <5% of reading
Respiratory rate	2 ~ 150 BPM
Respiratory rate measurement accuracy	1% @ ± 1 BPM
Warm-up time	10 s.
Response time	Detector 28 ms, system response time depends on the implementation, flow settings and dehydration technology
Automatic offset calibration	Automatically, according to the time and temperature, or under instruction

Interfering gases and agents: effect on CO_2 measurement accuracy		
Gases or anesthetic agents	Gas concentration (volume percentage)	CO_2
Nitrous oxide	60%	1)
Halothane	4%	1)
Enflurane	5%	+10% of reading
Isoflurane	5%	+10% of reading
Sevoflurane	5%	+10% of reading
Desflurane	15%	+14% of reading
1) The module allows normal operating conditions, the interference can be ignored.		

3. Safety Guide

WARNING

This module provides data for exhaled CO_2 and respiration rate only. The data should only play a supporting role in a diagnosis. Clinical signs and symptoms must be checked before final diagnosis.

Do not reuse disposable sampling pipes.

CAUTION

This module is to be used by trained professionals. Read the manual before using the module.

Single-use water bottles (water control) must not be reused. To maintain accuracy and prevent damage to the module. The bottle must not be shared between patients to prevent cross-infection.

Dispose of components in accordance with hospital regulations and in an environmentally safe manner.

To prevent damage and maintain accuracy always empty the collection bottle when it is nearly full. Check the level once a week at least.

The sampling tubes must not be bent to prevent pump overload and maintain accuracy of measurement.

Repairs must be made only by Penlon-trained engineers, or by the manufacturer.

The manufacturer will not be held responsible if the operator uses the unit incorrectly. The module must only be used as stated in the manufacturer's instructions.

Do not use the module for the measurement of exhaled gases. Exhaled moisture may cause measurement errors, and moisture accumulation may reduce module life.

Changes in temperature may affect measured data. Always use in stable temperature environments.

Any obstruction to the flow of the sample gas (e.g. tubing severely bent, contaminants blocking the sampling tube, bottle filters blocked) may cause inaccurate measurements and damage. An obstruction lasting more than 20 seconds will trigger a pump shut down.

System risk detection conforms to EN1441: 1997 and EN62366 2008.

A pipeline leak will seriously affect the accuracy of measurement data and waveform shape.

Excess humidity can affect measurement accuracy.

4. Connection

Follow the instructions supplied by the manufacturer.

Installation – water trap

Note that the CO_2 module is installed inside the machine. The water trap mounting is on the side of the machine.

Attach the water trap to the mounting and then connect the CO_2 components as illustrated. Connect the sample tube to the water trap sample port.

Appendix 7 Anaesthetic Gas (AG) monitoring (optional)

WARNING

1. **The IRMA probe must not be used with flammable anesthesia agents.**
2. **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
3. **Used airway adapters shall be disposed of in accordance with local regulations for medical waste.**
4. **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
5. **Do not use the IRMA airway adapter with metered dose inhalers or nebulizer medications as this may affect the light transmission of the airway adapter windows.**
6. **Replace the adapter if rainout/condensation occurs inside the airway adapter.**

CAUTION

1. Do not apply tension to the probe cable.
2. Do not operate the IRMA probe outside the specified operating temperature environment.

1. Introduction

The anaesthetic gas (AG) module measures the patient's anesthetic and respiratory gases, and incorporates the features of the CO_2 module as well. The AG (anesthesia gas) module determines the concentrations of certain gases using the infrared (IR) light absorption measurement.

The gases that can be measured by the AG module absorb IR light. Each gas has its own absorption characteristic. The gas is transported into a sample cell, and an optical IR filter selects a specific band of IR light to pass through the gas. For multiple gas measurement, there are multiple IR filters. This means that higher concentration of IR absorbing gas causes a lower transmission of IR light. The amount of IR light transmitted after it has been passed though an IR absorbing gas is measured. From the amount of IR light measured, the concentration of gas present can be calculated.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. It can display of real time and derived monitoring data of CO_2, N_2O, O_2, and the Anesthesia agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be used by trained and authorized health care professionals only.

2. Specifications

a) General Specification

Description:	Compact infrared mainstream multi-gas probe with integrated ultra-fast galvanic oxygen sensor. Available in various parameter configurations.
Dimensions (WxDxH):	38 x 37 x 34 mm
Cable length	2.50 m ±0.02 m
Weight	< 25 g (cable excluded)
Operating temperature	10–40°C
Storage / transportation temperature	-20–75°C
Operating humidity	10–95% RH, non-condensing
Storage / transportation humidity	5–100% RH, non-condensing
Operating atmospheric pressure	525–1200 hPa
Storage / transportation pressure	500 to 1200 hPa
Power supply	4.5-5.5 VDC, max 1.4 W (power on surge @ 5 V: less than 350 mA over 200 ms)
Surface temperature	50°C maximum (at ambient temperature of 23°C)
Interface	RS-232
Airway adapters	
Disposable adult/pediatric:	Adds less than 6 ml dead space Pressure drop less than 0.3 cm H2O @ 30 LPM
Disposable infant:	Adds less than 1 ml dead space
	Pressure drop less than 1.3 cm H2O @ 10 LPM

3. Data output

Breath detection	Adaptive threshold, minimum 1 vol% change in CO_2 concentration
Respiration rate	0–150 bpm. Respiration rate is displayed after three breaths. Average value is updated every breath
Fi and ET	Fi and ET are displayed after one breath A continually updated breath average is given.
Automatic agent identification	Primary and secondary agent.
Waveforms	Up to five simultaneous gas concentration waveforms.
Diagnostic parameters	Atmospheric pressure, software and hardware revision, serial number.
Flags	Breath detected, apnea, replace oxygen sensor, check adapter. Unspecified accuracy and sensor error.

4. Gas analyser

Probe	2-9 channel NDIR type gas analyzer measuring at 4–10 µm. Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing the airway adapter. No span calibration required for the IR bench. Automatic oxygen sensor calibration in room air, when changing airway adapter (<5 seconds)
Warm-up time	Concentrations are reported and the automatic agent identification is running within 10s. Full accuracy within 10 s. IRMA: 20 s
Rise time (@ 10 l/min)	CO_2: ⩽ 90 ms O_2: ⩽ 300 ms N_2O: ⩽ 300 ms HAL, ISO, ENF, SEV, DES: ⩽ 300 ms
Primary agent threshold	0.15 vol%. When an agent is identified, concentrations will be measured even below 0.15 vol% as long as apnea is not detected.
Secondary agent threshold	0.2 vol% + 10% of total agent concentration
Agent identification time	< 20 seconds. (typically < 10s).
Total system response time	< 1 second

5. Accuracy – during standard conditions

CO_2

0 – 10 ±(0.2 vol% + 2% of reading)

10 – 15 ±(0.3 vol% + 2% of reading)

15 – 25 Unspecified

N_2O

0 – 100 ±(0.2 vol% + 2% of reading)

HAL, ISO, ENF

0 – 8 ±(0.15 vol% + 5% of reading)

8 – 25 Unspecified

SEV

0 – 10 ±(0.15 vol% + 5% of reading)

10 – 25 Unspecified

DES

0 – 22 ±(0.15 vol% + 5% of reading)

22 – 25 Unspecified

O_2

0 – 100 ±(1 vol% + 2% of reading)

CAUTION

1. **After storage in a condensing atmosphere, the unit must be stored for a minimum of 24 hours in an environment equivalent to the operating humidity.**
2. **The humidity range 50% to 100% is valid within the temperature range: -40 to 40°C only.**

6. Accuracy: All conditions

CO_2 ±(0.3 vol% + 4% of reading)

N_2O ±(2 vol% + 5% of reading)

Agents ±(0.2 vol% + 10% of reading)

O_2 ±(2 vol% + 2% of reading)

Accuracy values are valid for the operating temperature and humidity conditions specified.

7. System assembly - setup

a) Plug the AG module connector into the input of the anesthesia machine and switch the power on.

b) Snap the AG module probe on top of the airway adapter. It will click into place when properly seated.

c) A green LED indicates that the AG module probe is ready for use.

d) Connect airway adapter 15 mm male connector to the breathing circuit Y-piece.

e) Connect airway adapter 15 mm female connector to the patient's endotracheal tube.

f) Unless the IRMA probe is protected with an HME always position the probe with the status LED pointing upwards. See below.

g) Alternatively, connect an HME (heat and moisture exchanger) between the patient's endotracheal tube and the IRMA probe.

h) Placing an HME in front of the probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It also allows free positioning of the probe.

8. Placement of IRMA Probe

WARNING

1. **The IRMA probe is not intended to be in patient contact.**
2. **Do not place the IRMA airway adapter between the endotrachealed tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**
3. **To keep secretions and moisture from pooling on the windows or oxygen sensor port, always position the IRMA probe in a vertical position with the LED pointing upwards.**

When connecting IRMA probe to an infant patient circuit it is important to avoid direct contact between the probe and the infant's body.

If, for whatever the reason, the probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the probe and the body.

9. Pre-use check

a) Always verify gas readings and waveforms on the monitor before connecting the airway adapter to the patient circuit.

b) Check the tightness check of the patient circuit with the IRMA probe snapped on the IRMA airway adapter.

10. Zeroing Procedure

Warning

Incorrect probe zeroing will result in false gas readings.

a) In order to secure high precision of the IRMA probe measurements the following zeroing recommendations should be followed.

b) Zeroing is performed by snapping a new IRMA airway adapter onto the IRMA probe, without connecting the airway adapter to the patient circuit, and then using the host instrument to transmit a Zero reference command to the IRMA probe.

c) Do not breathe near the airway adapter before or during the zeroing procedure. The presence of ambient air (21% O_2 and 0% CO_2) in the IRMA airway adapter is of crucial importance for successful zeroing. If a "ZERO_REQ" alarm should appear directly after a Zeroing procedure, the procedure has to be repeated.

d) Always perform a pre-use check after zeroing the probe.

e) Zeroing should be performed every time the IRMA airway adapter is replaced, or whenever an offset in gas values or an unspecified gas accuracy message is displayed.

f) Allow 30 seconds for warm up of the IRMA after power on and after changing the IRMA airway adapter before proceeding with the zeroing procedure. The green LED on the probe will be blinking for approximately 5 seconds while zeroing is in progress.

11. Alarms

Status LED on the IRMA probe:

Steady green light	System OK
Blinking green light	Zeroing in progress
Steady blue light	Anesthesia agent present
Steady red light	Sensor error
Blinking red light	Check adapter

12. Cleaning

CAUTION

1. **The IRMA oxygen sensor cell and IRMA airway adapters are non-sterile devices. Do not autoclave.**
2. **Do not sterilize or immerse the IRMA probe in liquid.**

The IRMA probe can be cleaned using a cloth moistened with maximum 70% ethanol or maximum 70% isopropyl alcohol.

Remove the disposable IRMA Airway Adapter prior to cleaning the IRMA probe.

Appendix 8 Electromagnetic compatibility (EMC)

The Prima 465 anaesthetic machine is suitable for use in the specified electromagnetic environment.
The user of the Prima 465 anaesthetic machine should assume that it is used in an electromagnetic environment as described below.

Changes or modifications to this anaesthetic machine system, not expressly approved by Penlon Limited, could result in EMC issues with this anaesthetic machine. Contact Penlon Limited for more information.

The use of phones or RF emitting equipment near this anaesthetic machine may cause interference.

Always monitor anaesthetic machine operation before and during use on a patient.

The essential performance of the Prima 465 anaesthetic machine is to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system.

Cables, Transducers, and Accessories

WARNING

The Prima 465 anaesthetic machine is EMC-compliant with all cables, transducers and accessories supplied by Penlon Limited.

The use of cables, transducers and accessories other than those specified may result in increased emissions or decreased immunity of the Prima 465 anaesthetic machine.

The use of cables, transducers and accessories supplied by Penlon Limited on non-Penlon equipment may also result in increased emissions or decreased immunity of that equipment.

Table 1. Guidance and manufacturer's declaration – electromagnetic emissions

The Prima 465 series anaesthetic machine is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

<table>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions: CISPR 11</td><td>Group 1</td><td>The Prima 465 anaesthetic machine uses RF energy only for internal functions. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions: CISPR 11</td><td>Class A</td><td rowspan="3">The Prima 465 anaesthetic machine is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded

WARNING
This equipment is intended for use by healthcare professionals only and may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures such as reorienting or relocating the Prima 465 series anaesthetic machine or shielding the location.</td></tr>
<tr><td>Harmonic emissions: IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations / flicker emissions: IEC 61000-3-3</td><td>Complies</td></tr>
</table>

WARNING:

The Prima 465 anaesthetic machine should not be used adjacent to or stacked with other manufacturers equipment. If adjacent or stacked use is necessary, the Prima 465 anaesthetic machine should be observed to verify normal operation in the configuration in which it will be used.

Table 2. Guidance and manufacturer's declaration – electromagnetic immunity

The Prima 465 anaesthetic machine is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV lines to earth	±1 kV line(s) to line(s) ±2 kV lines to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle. 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Prima 465 anaesthetic machine requires continued operation during power mains interruptions, it is recommended that the Prima 465 anaesthetic machine be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Note:

U_T is the a.c. mains voltage before application of the test level

Table 3. Guidance and manufacturer's declaration - electromagnetic immunity

The Prima 465 anaesthetic machine is intended for use in the electromagnetic environment specified below. The customer or user of the Prima 465 anaesthetic machine should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance:
			Portable and mobile RF communications equipment should be used no closer to any part of the anaesthesia system including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	N/A 10 V	d = 1.2√P
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	d = 1.2√P (80 - 800 MHz) d = 2.3√P (800 MHz - 2.5 GHz) Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and d is the recommended separation distance in metres (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b]The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Prima 465 anaesthetic machine is used exceeds the applicable RF compliance level above, the Prima 465 anaesthetic machine should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Prima 465 anaesthetic machine.

[d]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the Prima 465 anaesthetic machine

The Prima 465 anaesthetic machine is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Prima 465 anaesthetic machine, as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (watts)	Separation distance 'd' (in metres) according to frequency of transmitter		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

Note. An additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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