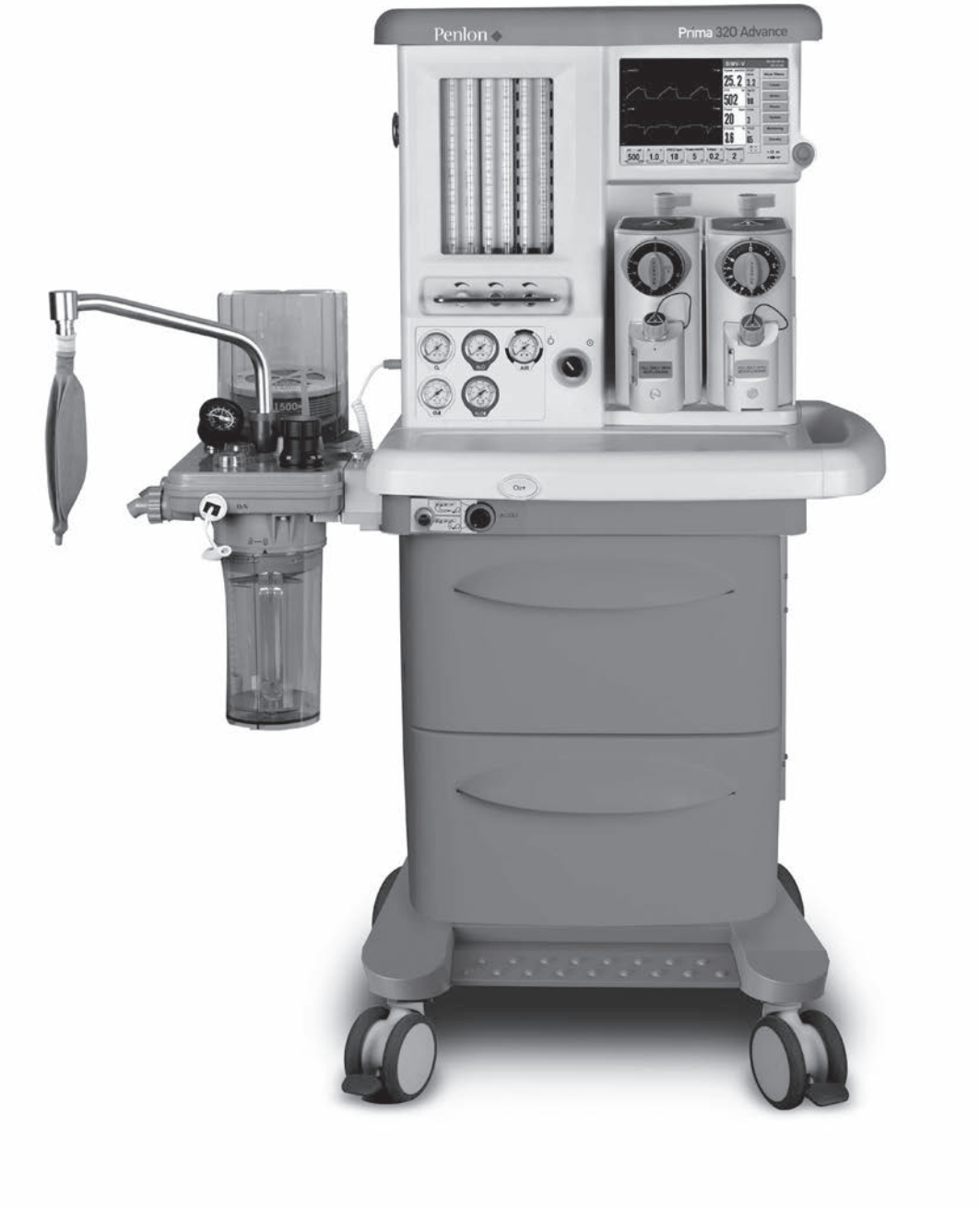
Prima 320 Advance Anaesthetic Machine

User Manual

ANAESTHESIA SOLUTIONS



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.

The machine must be serviced to the schedule detailed in section 7.1.

Details of these operations are in the Prima 320 Advance service manual, 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

Technical Support
Penlon Limited
Abingdon Science Park
Abingdon, OX14 3NB, UK
Tel: +44 (0) 1235 547060
Fax: +44 (0) 1235 547061
E-mail: tech.support@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 320 Advance anaesthetic machine.

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.

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Contents

User Responsibility

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

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

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

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

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

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

Territory information

USA and Canada

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

Saudi Arabia

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Saudi Food And Drug Authority.

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 machine.

WARNINGS

1. This anaesthetic machine 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 machine 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.
4. Always use a mains power outlet socket that can be easily accessed.
5. 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.
6. When you attach or remove a medical gas cylinder:
   a) Follow appropriate manual handling guidelines when lifting.
   b) Ensure that the machine yoke and cylinder faces are dust free and clean and that the sealing washer provided is in position between the cylinder valve and the yoke.
   c) 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.
7. The machine 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.
8. This device 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
9. 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.)
10. Ventilating Neonatal and Paediatric patients:
    a) IMPORTANT
    Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates.
    b) IMPORTANT
    Switching ventilation modes during a clinical procedure:
       i. The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.
       ii. To protect the neonatal/paediatric patient from adult ventilation settings, always switch to Standby before switching ventilation modes.
       Set appropriate neonatal/paediatric parameter values for the mode that you are about to use, before recommencing ventilation.
    c) Always set a low target pressure first and then increase to the required level.
    d) Use breathing circuits and filters specifically designed for neonatal/paediatric use.
    e) Do not ventilate pre-term babies with a birth weight below 2.4 kg.
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 anaesthesia system to the patient and disposes of expired gases is a vital part of the anaesthetic delivery system. Because breathing systems require frequent cleaning and disinfection they are not a permanent part of the anaesthesia system 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.
13. Always perform a pre-use check of the system, including vaporizers, ventilator, absorber and monitors before clinical use. Follow the pre-use checklists (see sections 5.9 to 5.14) before each clinical procedure as a minimum requirement.
    Many clinical incidents occur because of a failure to check for correct function.
14. The anaesthesia system must not be used if any of the alarm, monitoring or protection system devices are not functioning correctly.
15. The gas supply failure systems within the anaesthesia system 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:

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

16. The system must not be fitted with more than three operator accessible mains socket outlets. There is a risk of an excessive leakage current. This can result in a reduced level of safety.
17. Be aware that when equipment is connected to an auxiliary outlet, a medical electrical system is created as defined in IEC 60601-1-1. (Refer to Caution 8)
18. On machines with pipeline connections, be aware that a malfunction of the central gas supply within your facility may cause immediate cessation of gas delivery and total anaesthesia system failure.
19. 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.
    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.
20. Before using any additional electrical equipment powered by the auxiliary sockets on the machine, a trained engineer must check that the additional equipment is correctly wired and is earthed through its plug.
    In the event of malfunction of any device powered by the auxiliary sockets, a trained engineer must check the device and machine fuses.
21. 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.
22. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
23. 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.
24. Accessories must be removed before the machine is transported.
25. MRI compatibility - The Prima 320 Advance is not MRI compatible.
26. 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.
27. The Apnea alarm is a visual, onscreen alarm (no audio function), and is active only in SPONT/PSV mode.
28. **User maintenance:**
    User Maintenance is restricted to cleaning the external surfaces of the machine (see Section 7.2).
    All other maintenance and servicing and the replacement of components, including fuses and the mains electrical cable, must be carried out only by Penlon-trained engineers.

CAUTIONS

1. Flowmeter needle valves are designed to seal with light torque and may be damaged if tightened excessively.
   Do not force the control knob past either the fully open or fully closed positions.
2. Open cylinder valves slowly to avoid damage to pressure reducing valves.
   Ensure that cylinder valves are at least one full turn open when in use.
3. Do not use anaesthetic agents for cleaning purposes.
4. After use, always disconnect the machine from the piped gas supply and/or close the gas cylinder valves.
5. Anti-hypoxic device (AHD) system - The oxygen flow control is restricted to prevent the needle valve from fully closing. This ensures a minimum basal flow of oxygen.
   DO NOT attempt to close the flow to zero.
   Do not overtighten.
6. Compressed gas supplies must be clean and dry.
7. When the auxiliary gas outlets are in use on a machine using cylinder supply only (i.e. If the pipeline supply is not in use), check flow rate requirements, and ensure that adequate back-up cylinders are available.
8. The requirements of IEC 60601-1-1 apply to any device connected to the auxiliary electrical sockets. Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary power sockets
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.

NOTE

1. Refer to Appendix 3 for labelling and symbols

2. Purpose

Purpose

The Prima 320 Advance anaesthetic machine is for use by a professional operator in a professional 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, semi-open, semi-closed or closed circuit configurations.

Intended patient population

This product is intended for a patient population from neonatal (infants) to adult.

Gas supplies

Three gases - oxygen, nitrous oxide, and air.

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

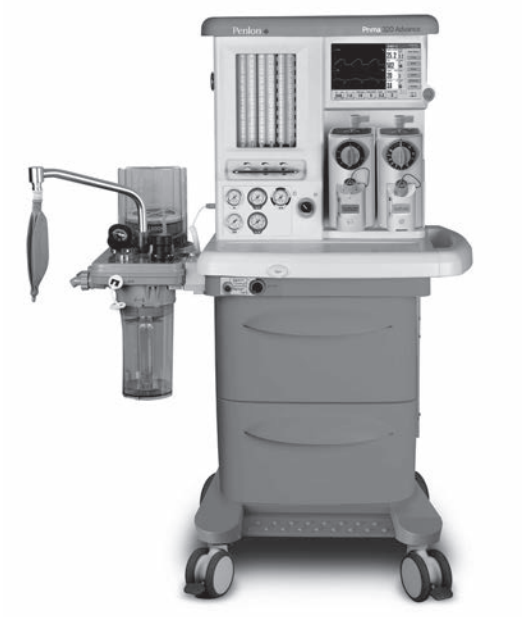
Backbar manifold for Selectatec-compatible type vaporizers.

Anti-Hypoxic Device (AHD)

The AHD system is designed to minimise the risk of a hypoxic mixture reaching the patient.

3. Description

3.1 General Construction



Frame

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

Mobility

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

Mounting Brackets

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

Work Surface and Lighting

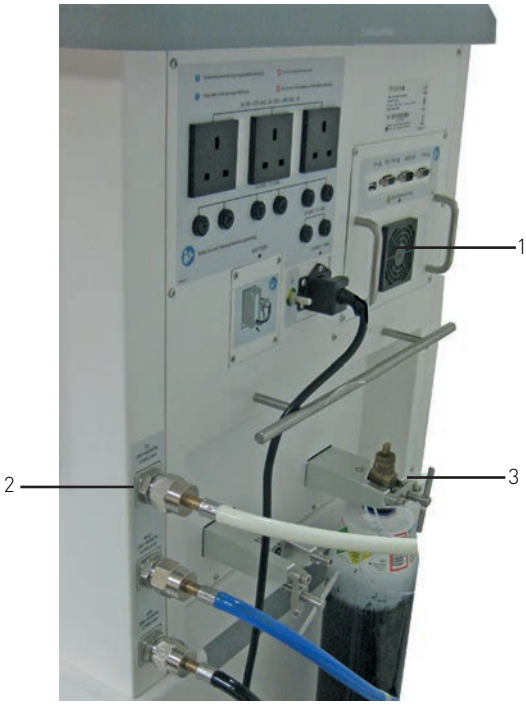
The work surface has raised edges to retain instruments, vials etc.

An LED lighting unit, provides work-area lighting. The switch is located under the top shelf, above the display screen

Extractor Fan Outlet

CAUTION

Do not obstruct the extractor fan outlet (1).



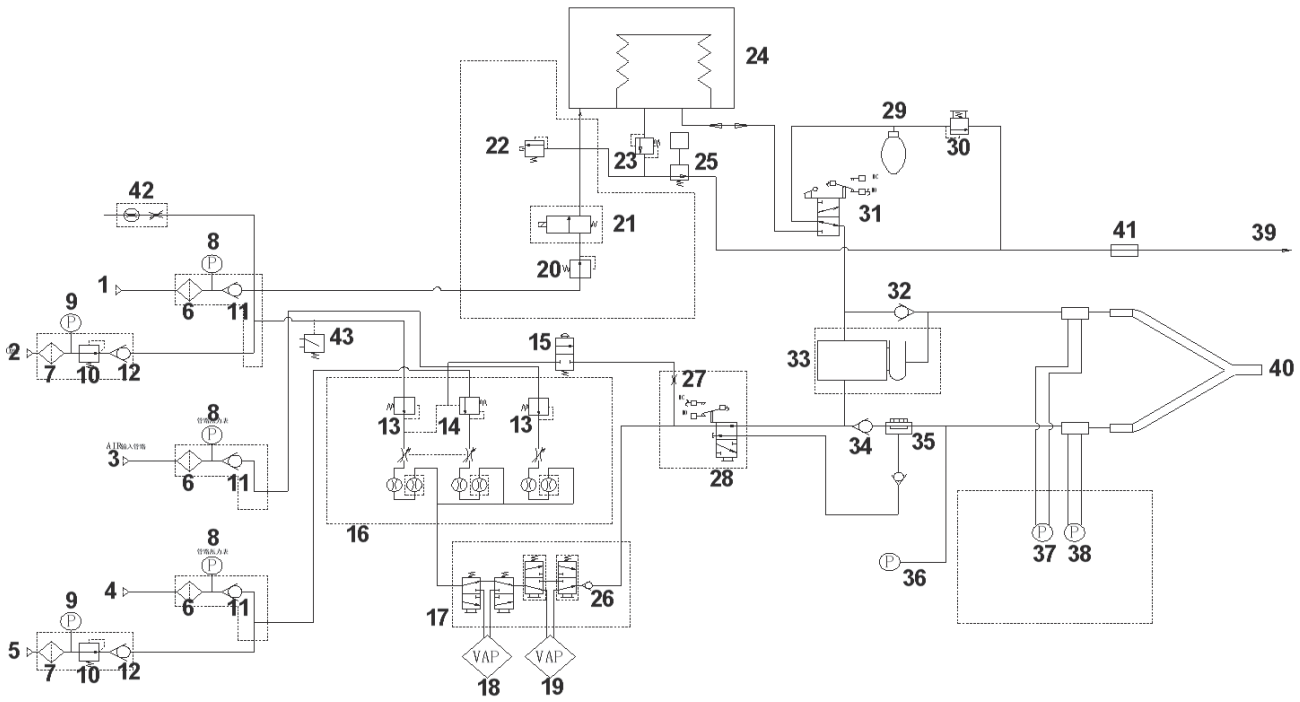
3.2 Gas Circuit

The machine has pipeline (2) and cylinder (3) gas inlets. The user sets the required flows and mixed gas is then supplied to the vaporizer backbar.

The ventilator is a pneumatically driven, microprocessor-controlled anaesthesia delivery system. The drive gas is supplied by the O_2 or Air gas supply, see section 3.12.

A gas circuit schematic is shown on the next page.

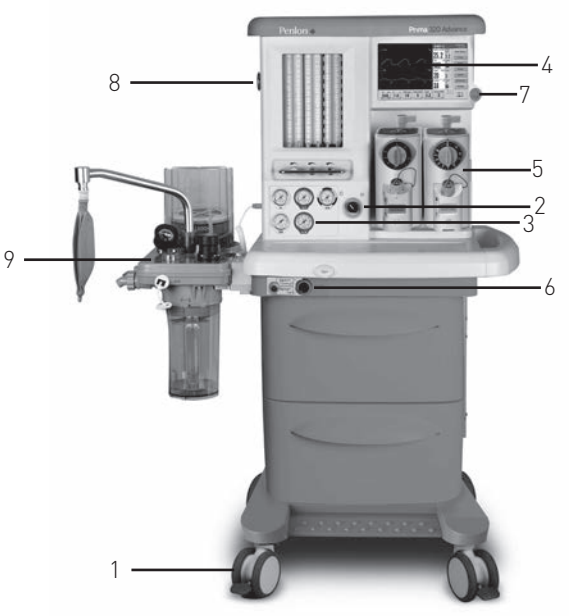
Gas Circuit Schematic



1	O_2 pipeline inlet	23	Exhalation valve - ventilator
2	O_2 cylinder inlet	24	Bellows - ventilator
3	Air pipeline inlet	25	Positive end-expiratory pressure (PEEP) valve
4	N_2O pipeline inlet	26	Non-return valve
5	N_2O cylinder inlet	27	Restrictor
6	Pipeline supply filter	28	ACGO control
7	Cylinder supply filter	29	Manual bag
8	Pressure gauge - pipeline	30	Adjustable pressure limiting (APL) valve
9	Pressure gauge - cylinder	31	Manual/mechanical ventilation switch
10	Regulator (350 – 400 kPa)	32	Expiratory non-return valve
11	Non-return valve	33	Absorber canister
12	Non-return valve - cylinder supply	34	Inspiratory non-return valve
13	Regulator (250 kPa)	35	Oxygen sensor
14	Cut-off valve	36	Airway pressure gauge
15	O_2 flush button	37	Expiratory flow sensor
16	Flowmeter assembly	38	Inspiratory flow sensor
17	Bypass valve on backbar	39	Outlet to gas scavenging system (AGSS)
18	Vaporizer	40	Patient
19	Vaporizer	41	Connector - gas scavenging system
20	Regulator (250 kPa) - ventilator	42	Auxiliary oxygen supply
21	Inspiratory flow control valve - ventilator	43	Pressure sensor
22	Over-pressure valve (100 kPa) - ventilator		

3.3 Front View

1. Castors (with brakes)
2. Anaesthesia system switch
3. Pressure gauges
4. Display screen
5. Vaporizer
6. Common Gas Outlet (ACGO) and O_2 flush button
7. Multifunction control
8. Auxiliary oxygen supply outlet
   Refer to Appendix 3 for details of a Penlon O_2 therapy flowmeter kit
9. Absorber assembly

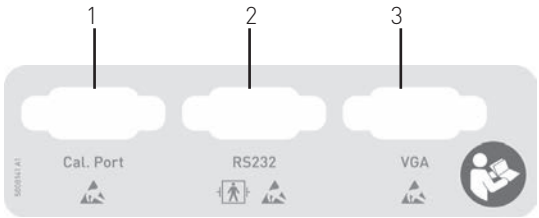


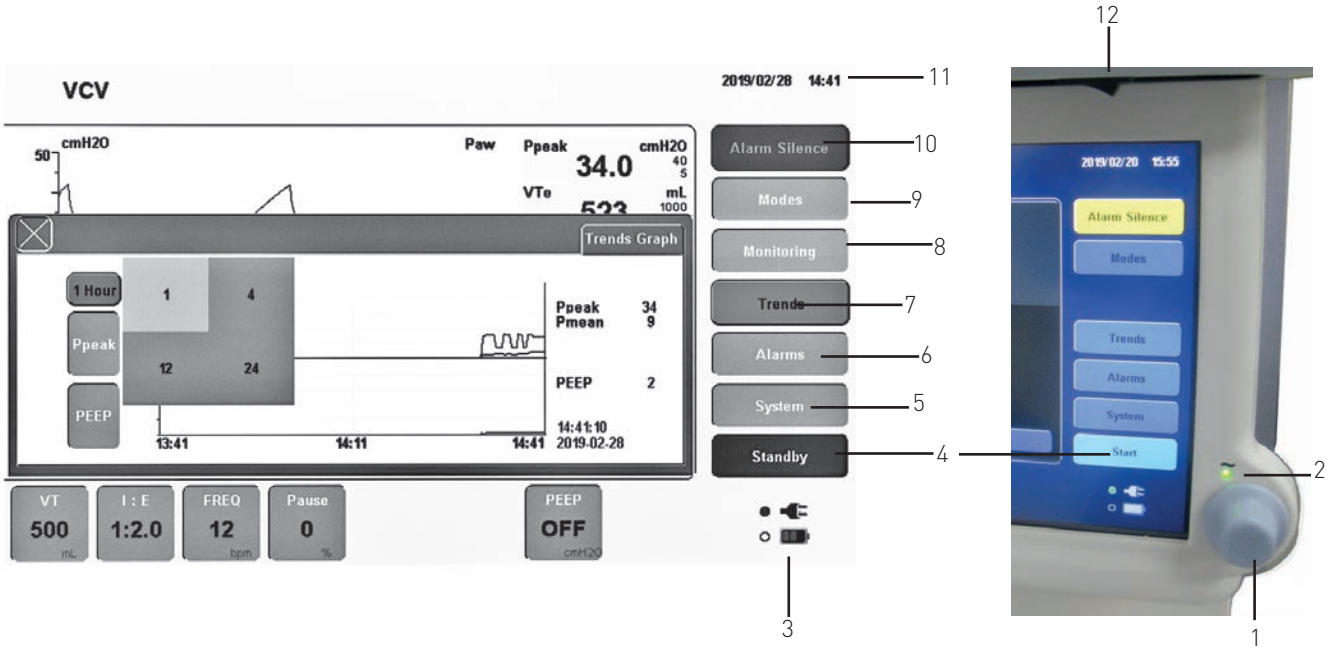
3.4 Rear View

1. Cylinder yoke
2. Multiple socket outlets
3. Mains inlet
4. Communication port (see section 3.5)
5. Battery box cover
6. Medical gas pipeline supply inlets
7. Extractor fan outlet

3.5 Communications Port

1. Calibration and software upgrade port - designed for use by trained Penlon engineers only.
2. RS232 Interface
   Connect the interface only to approved devices using protocol provided by Penlon Ltd.
   Contact Technical Support Department for details.
3. VGA port - not functional on all models





3.6 Control Panel

1. Multifunction control knob
   Push the control knob to select a menu option or confirm your setting.
   Turn the control knob clockwise or counterclockwise to scroll through the menu options, or to change a setting.
2. Mains electrical supply indicator
3. Power status fields
   Orange: The anaesthesia machine is connected to an AC power source, and the battery is being charged.
   Green: The system is operating on battery power.
4. Start/Standby
   Press the key to enter standby mode, or to exit standby mode and start ventilating the patient.
5. System
6. Alarms
7. Trends
8. Monitoring
9. Modes

   Alarm silence key:
   Press the key to set a 120-second alarm silence period. The alarm silence symbol and a 120-second countdown sequence appear to the left of the Date/time display.

Note
The O_2 Supply Failure alarm is not silenceable.

10. Date/time display
11. On/off switch - work surface lighting

3.7 Electrical Power Supply

3.7.1 Mains power supply

WARNING

Always use a mains power outlet socket that can be easily accessed.
To isolate the machine from the mains power supply, disconnect the mains cable from the power outlet socket.

Power is supplied to the machine via the mains cable (1) at the rear upper panel.

3.7.2 Auxiliary mains power supply sockets

Current leakage

CAUTION

The requirements of IEC 60601-1 apply to any device connected to the auxiliary sockets (2). Users must be aware of the risks of increased leakage currents when equipment is connected to the auxiliary mains power sockets.

NOTE

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

3.7.3 Battery

A back-up battery automatically provides power to the machine in the event of an AC mains power failure.

CAUTION

1. **Use the battery at least once every month.**
2. **Battery life depends on how often and how long the battery is used. A properly maintained and stored battery has a life expectancy of approximately 2 years. Replace the battery every 2 years.**
3. **In case of battery failure, a replacement battery must be fitted by a trained engineer. The user must not fit the replacement battery.**
4. **When the anaesthetic machine is connected to the AC power source, the battery is charged regardless of whether or not the system switch is on.**
5. **If a battery has been discharged and/or has been stored for a long time, charging may take longer than 4 hours.**

Backup Time

A fully charged battery will power the anaesthesia machine for up to 2 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 from total discharge

CAUTION

Check every month and fully charge the battery if necessary.

Battery Life

Battery life depends on frequency and period of use.
We recommend that the battery is replaced every 2 years.

3.7.4 On-screen power status and battery indicators

On-screen power status indicator

	AC power is being used. Battery icon flashing: Battery is charging Battery icon static: Battery is fully charged
	AC power is off, battery power is being used

On-screen battery status indicator

	Battery is fully charged
	Battery power is being used
	Battery power is being used - low capacity A high level alarm [BATTERY LOW] will be triggered. Ventilation will still be possible when a low battery alarm is triggered.
	Battery approaching total discharge When the icon shows empty display sectors, and the battery total discharge alarm is triggered, automatic shutdown will occur unless mains power is restored. See section 6.11.6. Connect the AC power immediately or use an alternative ventilation method.

3.7.5 Installing and replacing the battery

WARNING

Battery installation must be undertaken by a trained engineer, see section 7.11.

3.8 Vaporizers

CAUTION

Read the instruction manual supplied with the vaporizer before clinical use

3.8.1 Vaporizer mounting system

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

WARNING

1. **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.**
2. **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).**

3.8.2 Selectatec-compatible vaporizer

A maximum of two Selectatec-compatible vaporizers (1) may be installed.

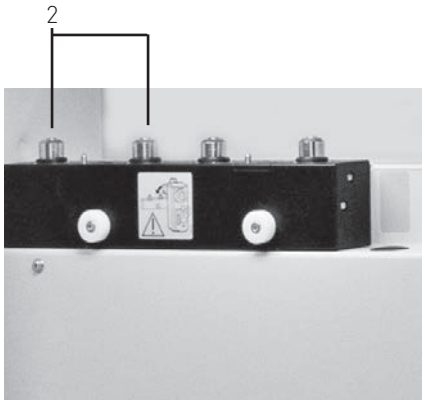
Each backbar station is fitted with two valve capsule assemblies (2) for vaporizer connector block attachment. When a vaporizer is installed on a station the valves on that station open automatically to allow gas flow into and out of the vaporizer.

Removal of the vaporizer from the station closes the valves on that station.

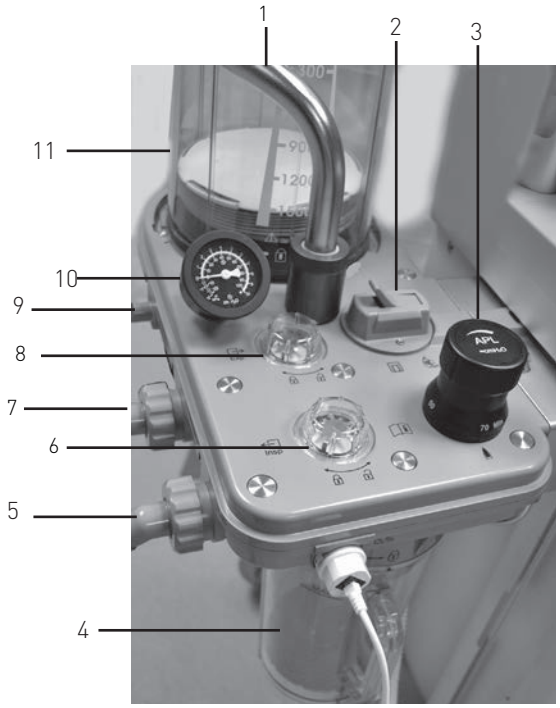
Installation: refer to Section 5.4.

Vaporizer Interlock System

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



3.9 Absorber



1. Bag support arm
2. Bag / ventilator switch
3. APL (adjustable pressure-limiting) valve
4. Absorber canister
5. Inspiratory port
6. Inspiratory non-return valve
7. Expiratory port
8. Expiratory non-return valve
9. Leak test plug
10. Airway pressure gauge
11. Bellows housing

3.9.1 Bag/Ventilator switch

The Bag/Ventilator switch (2) facilitates switching between ventilator mode and manual bag mode.

Ventilator mode: move the switch to the right.

Bag mode: move the switch to the left.

Automatic ventilator mode switching

With the system operating in mechanical ventilation mode, moving the switch from Ventilator to Bag position will trigger an automatic ventilator mode change to Manual ventilation.

Moving the switch from Bag to Ventilator position triggers a return to the previous mode.

3.9.2 Adjustable pressure limiting valve

The APL valve (3) provides breathing system pressure control, and excess pressure relief.

Turn the dial clockwise to increase the pressure limit up to a maximum of approximately 70 cmH_2O.

3.9.3 Absorber canister

The absorber canister (4) contains 1.5 litres of carbon dioxide absorbent. Do not overfill. Do not exceed the 'MAX' line marked on the canister, refer to section 6.9.2.

WARNING

A gradual colour change of the soda lime absorbent indicates approximately the level of absorption of carbon dioxide. Check the instructions supplied with the absorbent.

Canister 'not fitted' alarm

A sensor (12) triggers an alarm when the canister is removed.

CAUTION

Do not obstruct the sensor - do not route any hoses or cables in front of the sensor.

3.9.4 Inspiratory and expiratory ports

The inspiratory (5) and expiratory (7) ports are connected to the patient breathing circuit.

A differential pressure flow sensor is located within each port. The sensors measure flow and volume within the patient circuit.

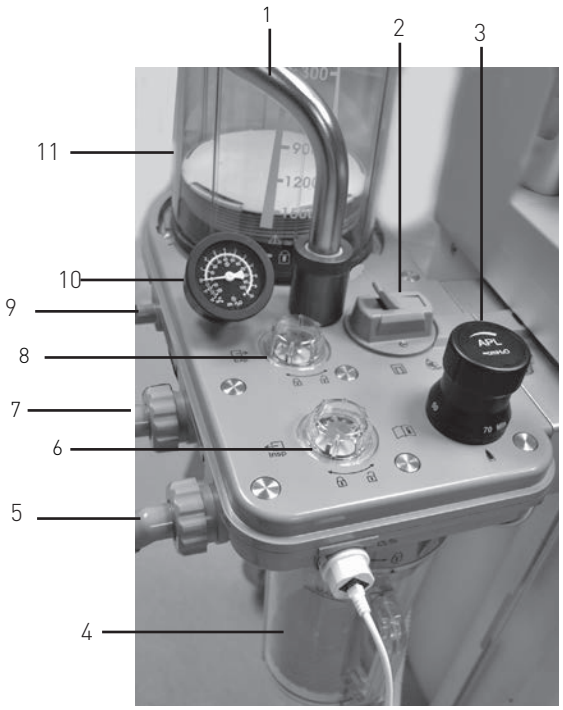
3.9.5 Inspiratory and expiratory non-return valves

The inspiratory (6) and expiratory (8) valves control the direction of the gas flow through the system.
Each valve consists of a disc located over a valve seat.

WARNING

The discs operate by gravity. The absorber must be securely mounted in an upright position.

The valve discs are visible, and the operation of each valve can be visually checked as the patient breathes in and out.



3.9.6 Airway pressure gauge

The pressure gauge (10) displays airway pressure in the inspiratory circuit.

Pressure is displayed in cmH_2O and kPa.

3.9.7 Bellows housing

The bellows housing (11) provides an airtight compartment for the breathing system bellows.

3.9.8 Breathing bag support arm

The bag arm (1) can be rotated to position the bag for ease of use when manual ventilation is applied.

3.9.9 Oxygen monitor sensor

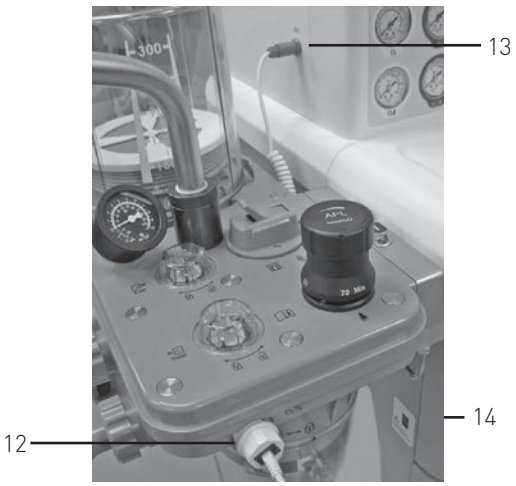
The oxygen sensor (12) measures the O_2 content of the circle system. The sensor cable connects to an input socket (13) on the side of the machine.

CAUTIONS

1. **Check the sensor calibration during the start-up tests whenever the system is switched on.**
2. **Do not route the cable in front of the canister sensor (14).**

NOTE

If a sidestream gas monitoring module is installed (with optional oxygen monitoring) the oxygen sensor shown (6) is not required and the sensor port is blanked off.



3.10 Auxiliary Common Gas Outlet (ACGO) and O_2 Flush control

The ACGO port (1) and ACGO control switch (2) are mounted on the front of the machine.

ACGO control

The AGCO control switch (2) has two positions:

1. Upper position (3) - fresh gas is directed to the patient through the breathing circuit to the expiratory port (4).
2. Lower position (5) - fresh gas is directed to the patient through the ACGO port (1).

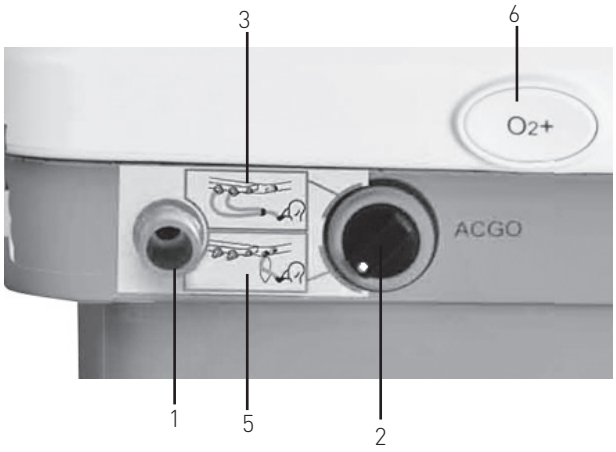
O_2 Flush control

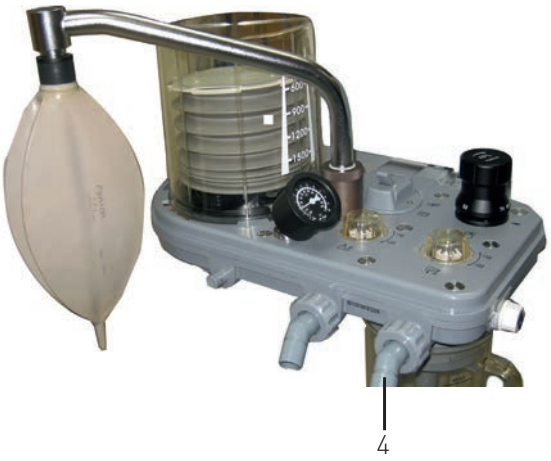
The O_2+ button (6) directs an oxygen flow of 25-75 L/min to:

(a) the ACGO port (control switch in the lower position (5))

or;

(b) into the breathing system.





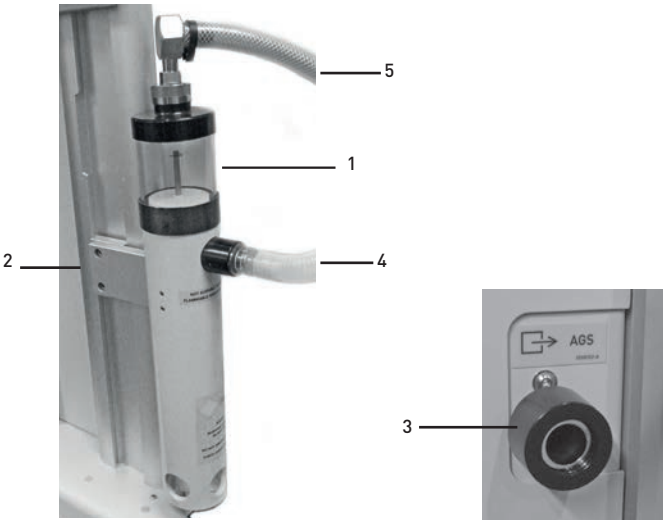
3.11 Anaesthetic Gas Scavenge System (AGSS)

The Penlon AGSS receiver (1) is mounted on the side of the machine (2), see section 5.8.

All sources of expired anaesthetic gases (e.g. directed from the absorber APL valve, and the ventilator bellows patient gas exhaust), are directed internally to the outlet (3) at the right-hand-side of the rear of the machine. A hose (4) connects the outlet to the receiver unit inlet port.
The output hose (5) connects to the hospital disposal system.

WARNING

1. **Do not connect any vacuum system directly to the outlet (3).**
2. **The receiving system (1), with a positive and negative pressure control function, must be used.**
3. **Systems must comply with ISO 80601-2-13.**



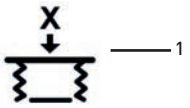
3.12 Ventilator

WARNING

Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates - see section 6.4.

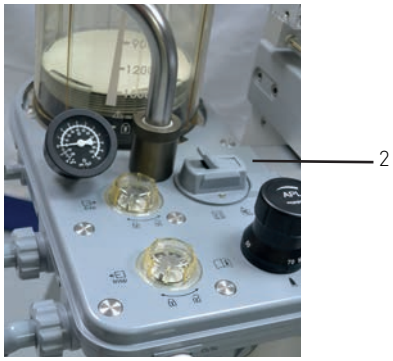
The ventilator is a pneumatically driven, microprocessor-controlled device, with manual and mechanical modes.

Drive gas: oxygen or air
The drive gas icon (1) is displayed on screen, below the Alarm message field. 'X' will be shown as the drive gas in use.
If the supply of drive gas in use fails, the system automatically switches to the other gas.



Automatic ventilator mode switching

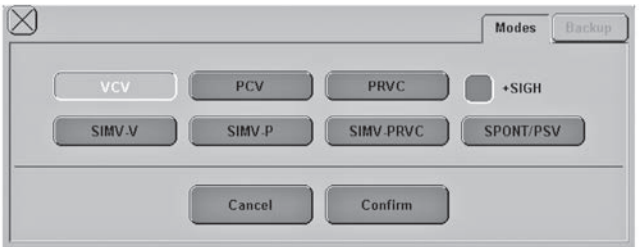
With the system operating in mechanical ventilation mode, moving the Bag/Ventilator switch (2) on the absorber from Ventilator to Bag position will trigger an automatic ventilator mode change to Manual ventilation.



Moving the switch from Bag to Ventilator position triggers a return to the previous mode.

NOTE

The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.



3.12.1 Volume control ventilation (VCV)

The ventilator delivers a mandatory set volume of gas at preset, fixed breath intervals. Sigh function is available.

The patient is making no respiratory effort

3.12.2 Pressure control ventilation (PCV)

The ventilator delivers a variable flow of gas to achieve a set pressure at fixed breath intervals. The patient is making no respiratory effort

3.12.3 Pressure-regulated volume controlled ventilation (PRVC)

In PRVC a tidal volume is set and the ventilator delivers that volume at a constant pressure. The ventilator will adjust the inspiratory pressure breath-by-breath, so that the lowest pressure is used to deliver the set tidal volume.

3.12.4 Synchronised intermittent mandatory ventilation - Volume control (SIMV-V)

The ventilator delivers volume controlled breaths which are synchronised with the patient's inspiratory efforts. The ventilator also allows spontaneous breaths with pressure support.

3.12.5 Synchronised intermittent mandatory ventilation - Pressure control (SIMV-P)

The ventilator delivers pressure controlled breaths which are synchronised with the patients inspiratory efforts. The ventilator also allows spontaneous breaths with pressure support.

3.12.6 Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)

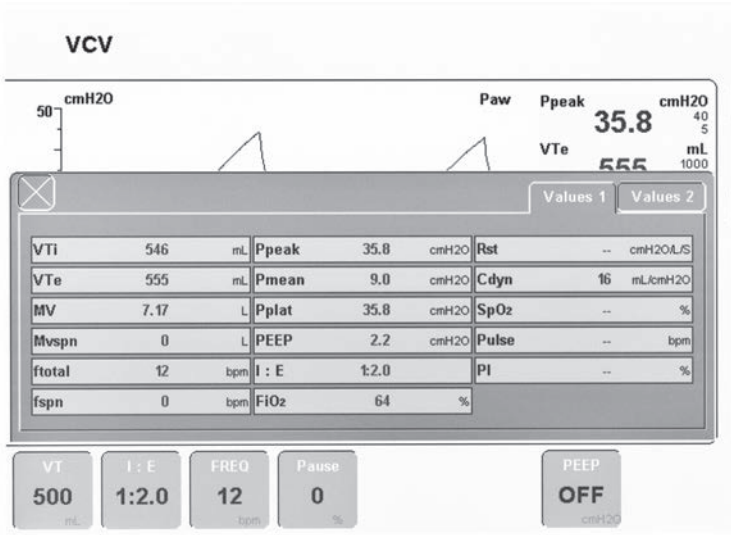
The ventilator delivers synchronised pressure controlled breaths at the lowest possible pressure in order to deliver the set tidal volume. The ventilator also allows spontaneous pressure support breaths.

3.12.7 Spontaneous / Pressure support ventilation (SPONT/PSV)

The ventilator allows spontaneous breaths and delivers pressure support at a preset trigger level. In the event of an apnea condition, the ventilator enters backup mode - either VCV or PCV, whichever the user has preselected.

3.13 Patient monitoring - Parameters

Measured parameters are grouped on-screen into two displays - Values 1 and Values 2.



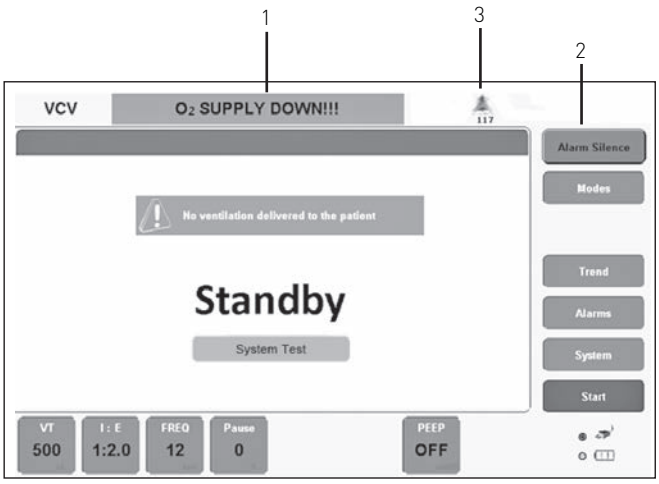
Values 1

- Inspiratory tidal volume (VTI)
- Expiratory tidal volume (VTE)
- Minute ventilation (MV)
- Spontaneous minute ventilation (MVspn)
- Respiratory rate (ftotal)
- Spontaneous breathing frequency (fspn)
- Peak airway pressure (Ppeak)
- Mean airway pressure (Pmean)
- Inspiratory plateau pressure (Pplat)
- Positive end expiratory pressure (PEEP)
- Minimum airway pressure (Pmin)
- Respiratory ratio (I:E)
- Airway resistance (Rst)
- Compliance (Cdyn)
- Fraction of inspired oxygen - FiO_2
- Peripheral oxygen saturation -SpO_2 (optional)
- Pulse rate (bpm)
- Perfusion index (PI)- (optional)

Values 2

- Fraction of inspired carbon dioxide - $FiCO_2$ (optional)
- End tidal carbon dioxide - $FiCO_2$ - (optional)

3.14 Alarm system



WARNING

1. **If the system self-test at start-up indicates an alarm system failure do not use the machine. Contact a service engineer.**
2. **When the machine is in use, the alarm message field (1) must visible to the user at all times.**

3.14.1 Alarm and message types

Alarms are triggered by a vital sign that appears abnormal, or by a technical condition within the anaesthetic machine. Alarms are indicated by visual and audible indicators.

Physiological alarms

Physiological alarms, also called patient status alarms, are triggered by

1. A monitored parameter value that violates set alarm limits
2. An abnormal patient condition

Technical alarms

Technical alarms, also called system status alarms, are triggered by

1. A device malfunction
2. Patient data.

Prompt messages

Prompt messages are not alarm messages.
Physiological, technical alarm messages, and system status messages are also displayed.
Messages are usually displayed in the prompt message area.

3.14.2 Alarm levels

Values for all technical alarms and some physiological alarms are preset at the factory and are not adjustable.

High level alarm

Indicates a life threatening situation requiring immediate action.

Medium level alarm

Indicates that the patient's vital signs appear abnormal and immediate action is required.

Low level alarm

Indicates that the patient's vital signs appear abnormal and action may be required.

3.14.3 Alarm silence

Press the alarm silence key (2) to silence the audio alarm. 'Alarm silenced' status will be set.

The alarm silence symbol (3) and a 120-seconds countdown period will be displayed.

NOTE
The O_2 Supply Failure alarm is not silenceable.

4. Specification

CAUTION
All technical specifications and ratings are subject to change without notice.

4.1 Physical

Machine	
Size	1410 × 950 × 650 mm (H × W × D)
Weight	110 kg (approximately)
Maximum load - top shelf	30 kg
Display	
Type	Colour TFT LCD (touchscreen)
Size	10.4 inches
Resolution	800 × 480 pixels
Audio sounder	Alarm tones to IEC 60601-1-8, with adjustable volume
Function controls	
Multifunction knob	Clockwise/counterclockwise rotation and press to operate
Screen button	Alarm pause, alarm reset, standby, return to main screen
Interface	
Electrical power supply	AC power inlet, three auxiliary output outlets
Monitor	VGA monitor connector, 15-pin D-sub socket
Equipotential	Equipotential ground terminal
USB	One standard USB connector
RS232 Connector	One standard RS232 connector
Mobility	
Castors	Diameter: 125 mm
Brake	Brake on each castor, plus central brake control option.
Storage and side mounting system	
Drawers	200 × 392 × 398 mm (H × W × D)
Mounting system for accessories	GCX-type mounting system built into the machine side uprights. Loading: 20 kg maximum (each section)

4.2 Gas Supplies

Cylinders	Two (oxygen and nitrous oxide), with pin-indexed cylinder yokes
Pipeline	Three pipeline inlets (oxygen, air, nitrous oxide). UK and Europe: NIST USA: DISS
N_2O cut-off	N_2O supply is cut-off when the internal O_2 supply pressure is less than 90 kPa.

4.3 Gas Supply Pressure

Pipeline	280-600 kPa (40.6-87.0 psig)
Cylinder (reduced pressure from regulator)	400 kPa max

4.4 Flowmeter Tubes

Flow range	
Air	0-15 L/min
Oxygen	0-10 L/min
Nitrous oxide	0-12 L/min
Accuracy	± 10% of full scale reading or ± 200 ml/min (whichever is greater)

4.5 Auxiliary Oxygen Supply

Supply pressure	250 kPa
Flow rate	100 L/min

Refer to Appendix 3 for details of a Penlon O_2 therapy flowmeter kit

4.6 Auxiliary Common Gas Outlet (ACGO)

Connector	22 mm male conical connector incorporating a coaxial female 15 mm conical connector.

4.7 Oxygen Flush

Flow rate	25-75 L/min

4.8 Fresh Gas Mixture

Anti-hypoxic fresh gas mixture	Minimum oxygen concentration : 25% +5%/-4% (of total O_2 + N_2O flow) - a minimum of 21% oxygen

4.9 Environmental

Operating conditions	
Temperature	10 - 40°C
Atmospheric pressure	70 - 106 kPa
Humidity	5 - 95% non-condensing
Transport and storage	
Temperature	-20 to +55°C
Atmospheric pressure	50 - 106 kPa
Humidity	10 - 95% non-condensing
Cleaning and disinfection	Refer to section 7.4

4.10 Electrical Supply

Power input:

Mains supply	100-240 VAC, 50/60 Hz, 150 VA maximum
Fuse:	T10 A /250 V
Power cable:	3 m

Power outlets

Auxiliary power outlets	Three outlets: 2 A (200-240 VAC) or 1 A (100-120 VAC) per outlet, maximum
Fuses	T215ALH 250 V (on live and neutral on each outlet)

Battery

Battery specification	NiMH, 12 V, 4.28.4 Ah.
Back-up time	Up to 2 hours (fully charged battery) Back-up time depends on the configuration of the machine, and operational requirements (see sections 3.7.3 and 3.7.4)
Recharge time	4 hours from total discharge (approximately) Note: The battery is charged automatically when the machine is connected to an AC power source.

4.11 Absorber and Breathing System

Bellows volume	1500 mL (approximately)
Absorber canister volume	1500 mL (approximately)
Connectors (ACGO, inspiratory and expiratory ports, manual bag port and AGSS)	Standard OD: 22 mm, ID: 15 mm, tapered connector Note: AGSS connector has an adaptor.
System leak limit	Not greater than 140 mL/min leakage (in any mode)
System compliance	Loss due to the system's internal compliance:<3 mL/cmH_2O
Respiratory system resistance	Inspiratory resistance: less than 0.6 kPa. Expiratory resistance: less than 0.5 kPa
APL valve range	0 to 70 cmH_2O (approximately)
Airway pressure gauge	-20 to +100 cmH_2O
Water collection container	12 mL (approximately) Can be emptied during use.

Pressure and flow data (APL valve fully open)

Flow rate (L/min)	APL pressure (cmH_2O, dry)	APL pressure (cmH_2O), moist
3	0.95	1.03
30	1.86	2.10
40	2.08	2.45
50	2.29	2.72
60	2.57	3.14
70	3.02	3.41

4.12 Ventilator

Display		10.4" TFT, with touchscreen
Waveforms		Pressure, Flow rate, Volume, P-V loop, F-V loop, Pleth (requires optional SpO_2) Support mode waveforms are displayed in colour
Drive gas		O_2 or Air, user selectable Automatic switching during operation, if there is a failure of the gas supply in use.
	Inlet pressure	280-600 kPa
	Max flow	⩽ 120 L/min
Ventilator modes		Volume control ventilation (VCV), Pressure control ventilation (PCV) Pressure-regulated volume controlled ventilation (PRVC) Synchronised intermittent mandatory ventilation - Volume control (SIMV-V) Synchronised intermittent mandatory ventilation - Pressure control (SIMV-P) Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC) Spontaneous / Pressure support ventilation (SPONT/PSV), Manual
Safety pressure		System pressure does not exceed 12.5 kPa

Parameters

Tidal volume	10 - 1500 mL 0 - 1600 ml measured in PCV Increment: 10 ~ 100 mL: 5 mL 100 ~ 1500 mL: 10 mL
Respiratory rate	1 ~ 100 bpm; increment: 1 bpm
Tinsp (inspiratory time)	0.1 ~ 10.0 s; increment: 0.1 s
I:E ratio	4:1 to 1:10; increment: 0.5
Percentage of inspiratory pause	0 to 60%; increment: 5%
PEEP	OFF, 3 ~ 30 cmH_2O; increment: 1 cmH_2O.
Pressure support	0 ~ 70 cmH_2O; increment: 1 cmH_2O
Pressure control	5 ~ 70 cmH_2O; increment: 1 cmH_2O
Flow trigger	0.5 ~ 20 L/min; increment: 0.1 L/min
Pressure trigger	0 ~ 20 cmH_2O; increment: 0.1 cmH_2O
SIMV-P inspiration termination level	5 ~ 80 %; increment: 5%

4.13 Monitored Parameters

Inspiratory tidal volume	0 ~ 2500 mL; Resolution: 1 mL
Expiratory tidal volume	0 ~ 2500 mL; Resolution: 1 mL
Minute ventilation (Mv)	0 ~ 60 L / min; Resolution: 0.1 L/min
Spontaneous minute ventilation (Mvspont)	0 ~ 60 L/min; Resolution: 0.1 L/min
Respiratory rate	0 ~ 100 bpm; Resolution: 1 bpm
Spontaneous respiratory rate	0 ~ 100 bpm; Resolution: 1 bpm
I:E	30:1 to 1:150; resolution: 0.1

Peak airway pressure	0 ~ 100 cmH_2O; Resolution: 1 cmH_2O
Mean airway pressure	0 ~ 100 cmH_2O; Resolution: 1 cmH_2O
PEEP	0 ~ 100 cmH_2O; Resolution: 1 cmH_2O
Inspiratory plateau pressure	0 ~ 100 cmH_2O; Resolution: 1 cmH_2O
FiO_2	15 to 100%; Resolution: 1%
Compliance	0 ~ 300 mL/cmH_2O; resolution: 1 mL/cmH_2O
Airway resistance	0 ~ 600 cmH_2O / (L / S); Resolution: 1 cmH_2O / (L / S)
$EtCO_2$ (optional)	0-15% (0 ~ 150 mmHg; Resolution: 1 mmHg
$FiCO_2$ (optional)	0 to 15%; Resolution: 0.1%
Waveforms	CO_2 (optional)
FiAA	Halothane, Isoflurane, Enflurane: 0 to 8%
	Sevoflurane: 0 to 10%
	Desflurane: 0 to 22%
	Resolution: 0.1%
EtAA	Halothane, Isoflurane, Enflurane: 0 to 8%
	Sevoflurane: 0 to 10%
	Desflurane: 0 to 22%
	Resolution: 0.1%
FiN_2O	Range: 0 to 100%; Resolution: 1%
EtN_2O	Range: 0 to 100%; Resolution: 1%
MAC values	Range: 0 to 10%; Resolution: 0.01%

4.14 Alarm Settings

Alarm type	Range	
Tidal volume	High	30 ~ 2000 mL, OFF
	Low	20 ~ 1500 mL
Minute ventilation	High	1 ~ 99 L
	Low	0 ~ 98 L
Respiratory rate	High	1 ~ 100 bpm
	Low	0 ~ 99 bpm
FiO_2	High	19 ~ 100%, OFF
	Low	18 ~ 99%
Airway pressure	High	10 ~ 99 cmH_2O
	Low	1~ 98 cmH_2O
$ETCO_2$ (optional)	High	0 - 15%;
	Low	0 - 14.9%
$FiCO_2$ (optional)	High	0.1 - 15%
Pulse (optional)	Upper limit	31 ~ 250 bpm
	Lower limit	30 ~ 249 bpm

Specification

Alarm type	Range
SPO_2 (optional)	Upper limit 50 ~ 99%
	Lower limit 49 ~ 99%
Continuous pressure - High	Airway pressure greater than PEEP + 15 cmH_2O. When an alarm is triggered, 15 is sustained.
Negative pressure	Airway pressure less than -10 cmH_2O
Apnea	Setting time: 10 ~ 60 s; increment: 1 s
Oxygen low pressure	Oxygen pressure less than 280 kPa
AC power failure	Mains supply failure or power cord disconnection
Low battery	More than 10 minutes remaining
Battery is exhausted	More than 5 minutes remaining
Alarm silence	≤ 120 s
FiN_2O (optional)	High: 0 ~ 100%
	Low: 0 ~ 100%
FiAA (optional)	**High**
	Halothane, Isoflurane, Enflurane: 0.1 to 7.9%, OFF
	Sevoflurane: 0.1 to 9.9%, OFF
	Desflurane: 0.1 to 19.9%, OFF
	Low
	Halothane, Isoflurane, Enflurane: 0 to 7.8%
	Sevoflurane: 0 to 9.8%
	Desflurane: 0 to 19.8%
EtAA (optional)	**High**
	Halothane, Isoflurane, Enflurane: 0.1 to 7.9%, OFF
	Sevoflurane: 0.1 to 9.9%, OFF
	Desflurane: 0.1 to 19.9%, OFF
	Low
	Halothane, Isoflurane, Enflurane: 0 to 7.8%
	Sevoflurane: 0 to 9.8%
	Desflurane: 0 to 19.8%

4.15 Device Classification and Labelling

The device is classified as Medical Electrical (ME) equipment as defined in BS EN 60601-1.

Labelling

Refer to Appendix 4

Equipment classification

Protection against electric shock	Class 1, with internal power supply
Ingress protection	IP21
Environment	Oxygen compatibility: Not suitable for use in an Oxygen rich environment Anaesthetic agent: 1. Use only non-flammable anaesthetic agents. 2. Do not use in close proximity to flammable anaesthetic agents.
Mode of operation	Continuous
Patient type	All patient types No residual risks from phthalates that are carcinogenic, mutagenic, or toxic to reproduction.

Applied parts (if fitted)

Patient hoses/masks, SpO_2 sensor (optional), sidestream multigas sensor, sidestream CO_2 sensor	Type B
Masimo IRMA module	Defibrillator-proof BF

Accessories

Refer to Appendix 3

5. Installation and Pre-Use Checks

5.1 Installation and commissioning before first clinical use

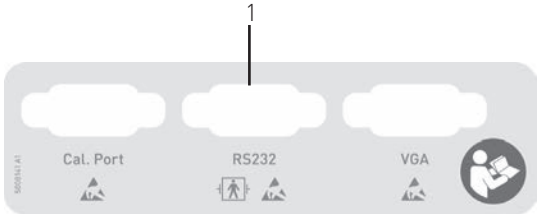
5.1.1 Warnings and cautions

WARNING

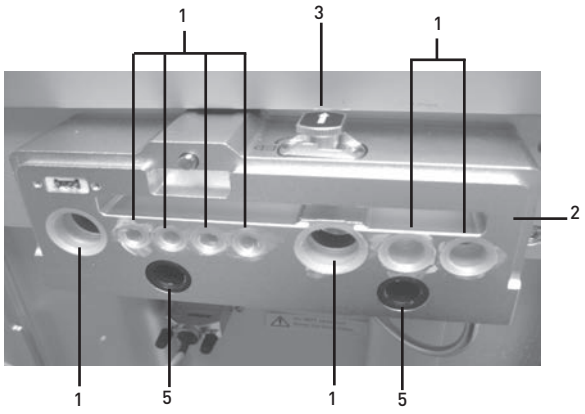
1. **Check that pipeline gas supply hoses and breathing circuit components are not toxic, and will not cause allergic reactions in patients or react with anaesthetic vapour and gases.**
2. **Check that the soda lime in the absorber canister is not desiccated. Continuous use of desiccated soda lime may 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 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. **Remove all packing materials before installation and use.**

CAUTION

1. Connect the external RS232 outlet (1) only to approved devices using protocol provided by Penlon Ltd. Contact Technical Support Department for details.



5.2 Absorber Assembly

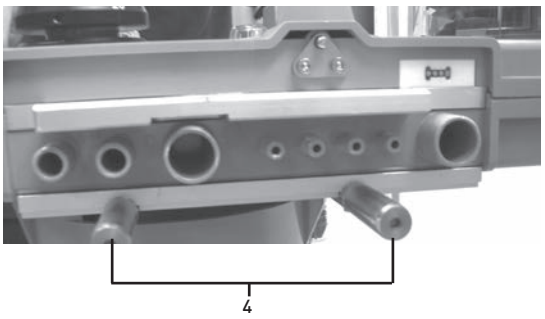


5.2.1 Absorber assembly Installation

WARNING

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.

1. Remove all packing materials before installation.
2. Make sure that the eight silicon inserts (1) on the breathing circuit adapter plate (2) are in place and are not damaged.
3. Use BG87 or Fomblin grease to lightly lubricate the eight silicon inserts (1).
4. Lift and turn the locking catch (3) to the unlocked position.
5. Align the two connector pins (4) on the absorber with the matching holes (5) on the circuit adapter plate.
6. Push the absorber assembly into the circuit adapter plate with moderate force.
7. Reset the locking catch (3) to the locked position.



WARNING

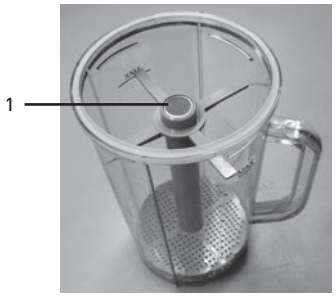
Always set the locking catch to the locked position after the absorber assembly is installed.
Before use, to prevent a serious fresh gas leak and inaccurate tidal volume measurement, always check that the assembly is locked in position.

5.2.2 Absorbent canister filling and installation

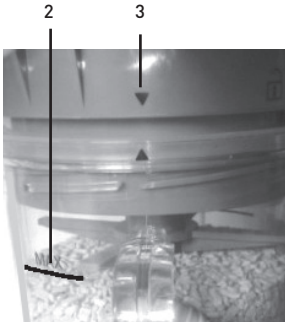
WARNING

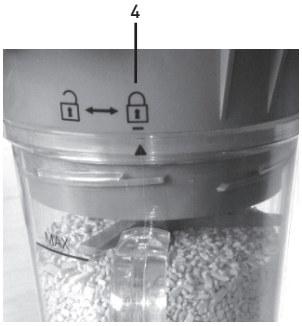
To prevent dust and particles from entering the breathing circuit, the filter (1) must be fitted in the correct position as illustrated.

Before installation, clean the rim of the canister perimeter, the canister support, and the seal to prevent breathing system leakage.



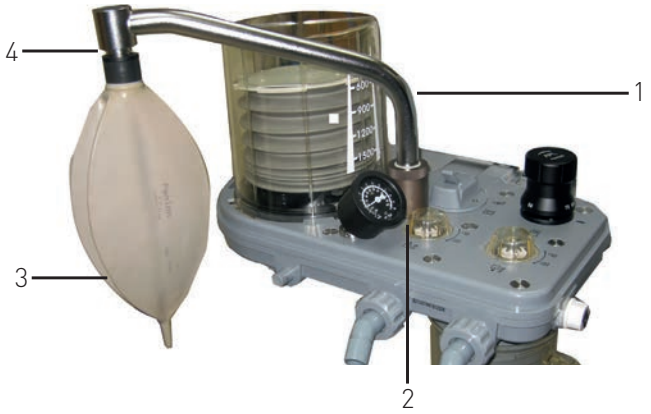
1. Fill with new soda lime to the MAX line (2).
   Remove any soda lime that has collected on the filter (1).
2. Wipe the dust from the absorber canister support.
3. Position the canister, ensuring that the threads are engaged.
   Make sure that the triangular marks (3) are aligned.
4. Tighten counterclockwise until the 'locked' symbol (4) and the triangular mark on the canister are aligned.





5.2.3 Bag arm and bag installation

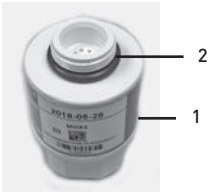
1. Fit the bag support arm (1) to the port (2) on the top face of the absorber.
2. Turn the locking nut clockwise to secure.
3. Check that the bag arm can be rotated.
4. Fit the bag (3) to the bag arm outlet (4).



5.2.4 Oxygen sensor installation

CAUTION

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

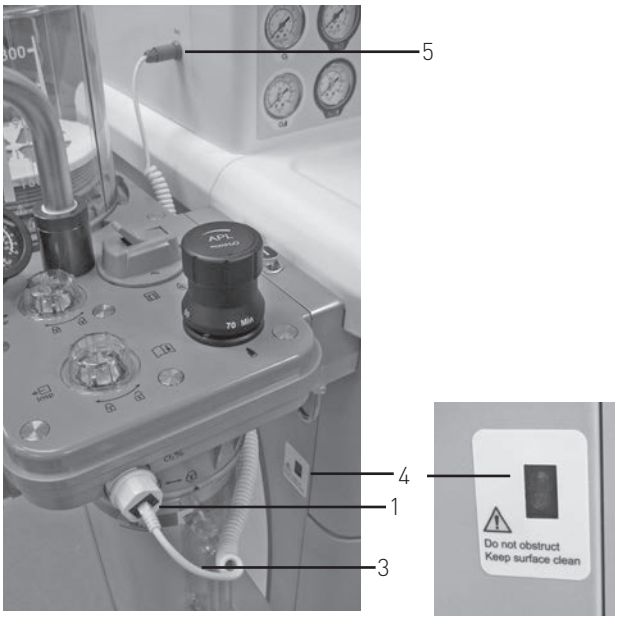


1. Align the oxygen sensor (1) with the port on the side of the absorber.
2. Fit the sensor and turn clockwise to tighten.
3. Fit the cable (3) to the sensor.

WARNING

Make sure that the absorber canister position sensor (4) is unobstructed by cables or tubing etc, at all times.
Do not route the oxygen sensor cable in front of the canister sensor

4. Connect the cable (3) to the socket (5) on the side of the anaesthetic machine.



5.2.5 Install the breathing hose and Y-piece connector

CAUTION

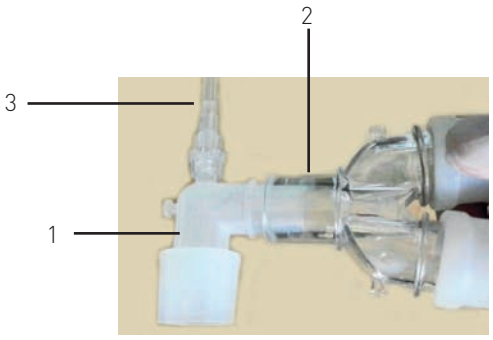
1. **When installing the breathing hoses, hold the tube connector at both ends of the tube to prevent damage to the tube.**

1. The two breathing hoses are connected to the expiratory and inspiratory connectors.
2. Connect the breathing hoses to the Y-piece.

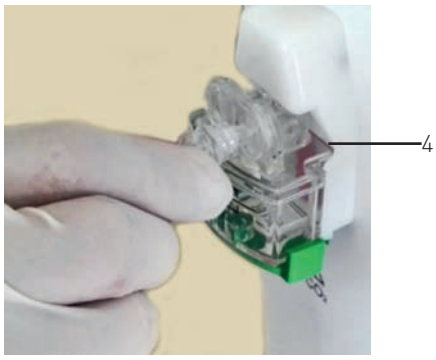
5.3 Connecting Gas Monitoring Modules

5.3 1 Connecting a NMed sidestream CO_2 module

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



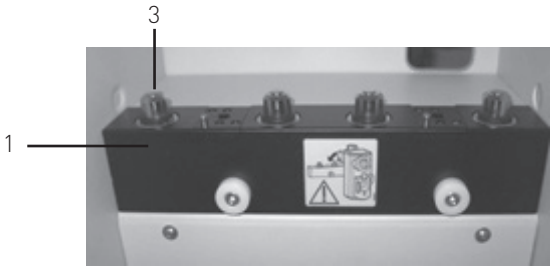
2. Connect the sampling tube (3) to the water trap (4).
3. Connect the other end of the sampling tube to the elbow.
4. Connect the other end of the elbow to the breathing bag, or to the patient breathing circuit



5.3.2 Connecting a NMed SpO_2 sensor cable

Insert the sensor cable into the connector socket labelled 'SpO_2' on the machine frame rear panel.

5.4 Installing the Vaporizer

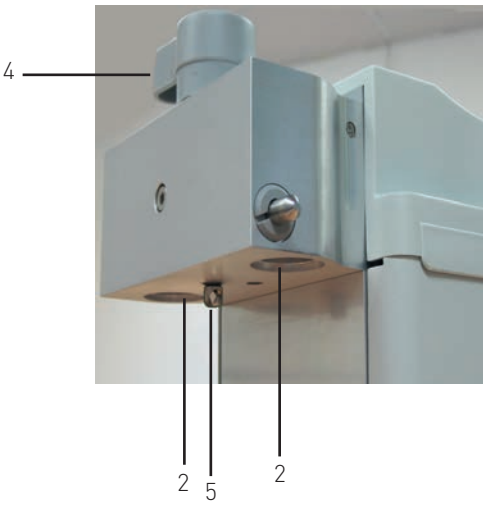


NOTE

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 (3) on the manifold (1).
3. Carefully lower the vaporizer onto the manifold
4. Turn the locking lever (4) 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.

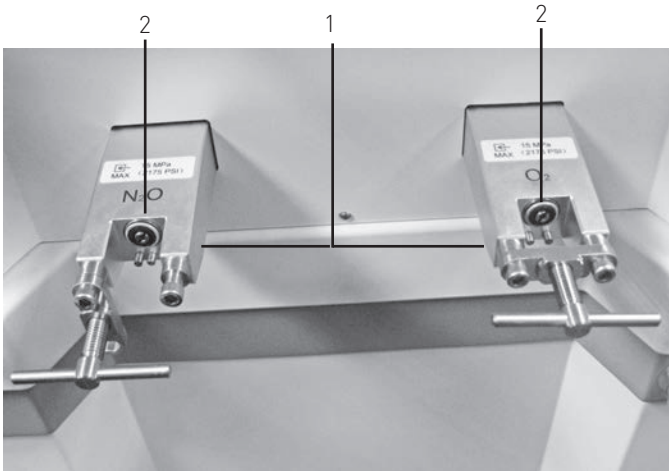
CAUTION

To prevent damage to the locking shaft (5), check that the gas connection ports are aligned with the valves on the manifold (1), and are correctly engaged, before tightening the locking lever.

5.5 Gas cylinder installation

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 (1):
2. Follow appropriate manual handling guidelines when lifting.
3. Check that the machine yoke and cylinder faces are dust free and clean.
   The sealing washer (2) must be in position between the cylinder valve and the yoke.
4. Tighten the yoke securely before opening the cylinder valve. Dust and dirt presents a fire hazard in the presence of high pressure gas. Leakage of high pressure gas can cause serious injury.
5. Open the cylinder valves one at a time and check the pressure on each gauge.

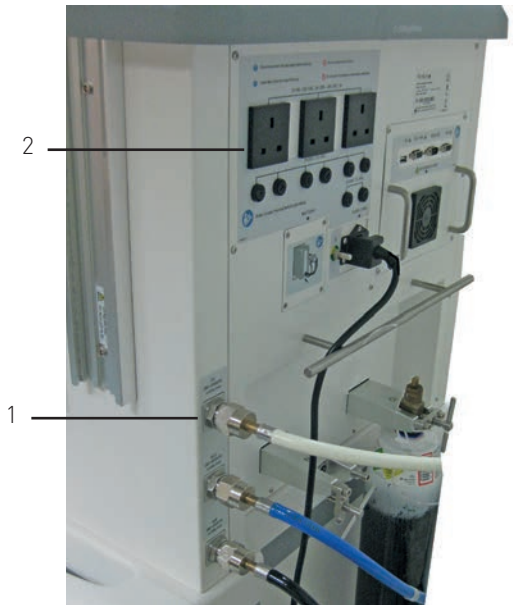
WARNING

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 IEC 60601-1.

5.6 Medical Gas Pipeline Connection

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



WARNING

1. **Gas connections are not interchangeable, check the label, symbol, and colour code before 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.**

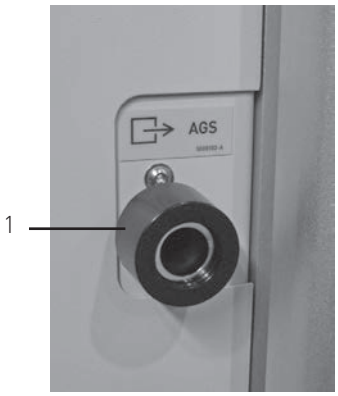
5.7 Auxiliary Power Outlets

WARNING

Powering additional devices through the auxiliary power outlets (2) 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.

5.8 Anaesthetic Gas Scavenging System (AGSS)

The gas scavenging outlet port (1)is located at the right rear of the machine, as shown:



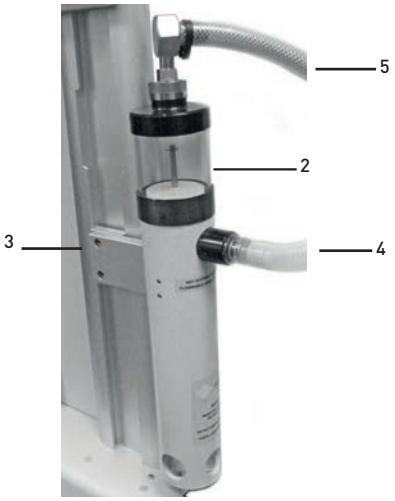
WARNING

1. **On new machines, remove the blanking plug from the port before connection to the receiver unit.**
2. **Use an anaesthesia gas scavenging system that complies with ISO 80601-2-13.**
3. **Do not connect any vacuum system directly to the outlet port. An AGSS receiving system with a positive and negative pressure control function must be interposed.**
4. **Read the AGSS receiver instruction manual before clinical use.**

The AGSS receiver (2) is mounted on the side of the machine (3).

All sources of expired anaesthetic gases (e.g. directed from the absorber APL valve, and the ventilator bellows patient gas exhaust), are directed internally to the outlet (1) at the right-hand-side of the rear of the machine. A hose (4) connects the outlet to the receiver unit inlet port.

The output hose (5) connects to the hospital disposal system.



5.9 Pre-use Test Before a Clinical Procedure

WARNING

1. **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.**
2. **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.**
   Keep very small items/components/plugs away from the breathing system.

5.9.1 Recommended test schedule:

	Daily, before the first patient	Each patient, before use
Visual Inspection	Section 5.9.2	--
System check	Section 5.9.3	--
Power failure alarm	Section 5.9.4	--
Pipeline gas supplies	Section 5.9.5	--
Cylinders gas supplies	Section 5.9.6	--
Vaporizer	Section 5.10	--
Alarms	Section 5.11	--
Breathing circuit	--	Section 5.12
O_2 flush	--	Section 5.13
Preparing for system operation	--	Section 5.14

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.

5.9.2 Visual inspection

CAUTION

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

Checks

1. Make sure that the machine is not damaged.
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 not damaged.
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.

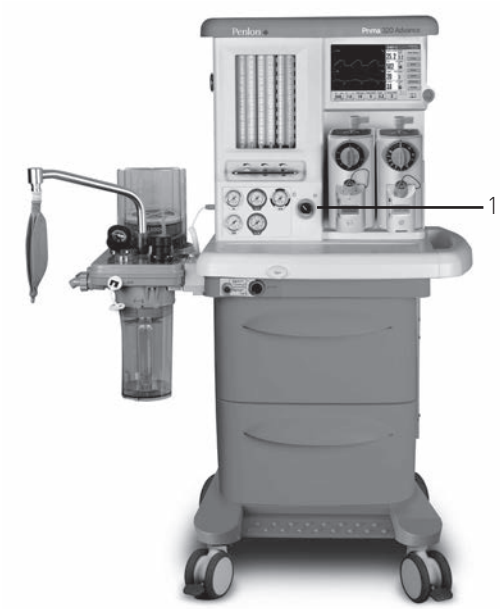
6. Check that the cylinder valves are closed.
7. Make sure that the necessary emergency equipment is available and in good condition.
8. Make sure that equipment for airway maintenance and tracheal intubation is available and in good condition.
9. Make sure that the applicable anaesthetic and emergency 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

    If the AC mains indicator and the battery indicator are not illuminated, the system does not have electrical power.
13. Make sure that the machine can be switched on or off normally.

5.9.3 System check

1. Set the anaesthesia system switch (1) to the ON position.
2. Make sure that the yellow and red alarm lamps illuminate
3. Make sure that an audible beep sound is heard.
4. Make sure that the start-up screen is displayed.
5. Wait for the countdown on the Pre-use Test screen to complete.
6. Make sure that the standby screen is shown after the Pre-use Test screen.
7. Press the blue SYSTEM TEST button to start the pre-use test
8. Select the Manual Leak Test button from the pre-use test screen.
9. Follow the on-screen instructions before you press the Start button.
10. When the manual and automatic tests are complete press the FINISH button.
11. Press the QUIT button.
12. Set the APL valve to MIN.
13. Make sure that all gas flowmeter controls are turned fully clockwise.



5.9.4 Power failure alarm test

1. Disconnect the machine from the mains power supply.
   a) Make sure that the mains indicator is extinguished
   b) Make sure that the battery indicator light illuminates.

c) Make sure that the message MAINS FAILURE is displayed.

2. Connect the machine to the mains electrical supply.

a) Make sure that mains indicator is illuminated

NOTE

The battery indicator will not be illuminated if the battery is charged.

5.9.5 Gas pipeline supplies

CAUTION

Close the gas cylinder valves when the pipeline supply is in use to ensure a reserve supply in case of pipeline failure.

O_2 pipeline supply test

1. Make sure that all cylinder valves are closed.
2. Disconnect the air and N_2O pipeline supplies from the machine
3. Use the O_2 flowmeter control knob to set a flow of 2 L/min.
4. Check that the O_2 pipeline pressure gauges shows 300 to 600 kPa.
5. Disconnect the O_2 supply.
6. Make sure that the O_2 SUPPLY DOWN!!! alarm is triggered.
7. Make sure that the O_2 gauge shows zero kPa.
8. Turn the O_2 flowmeter control knob fully clockwise.
9. Connect an O_2 supply to the machine
10. Press the Alarm Reset button.
11. Make sure that no alarms are shown on the screen.

N_2O pipeline supply test

12. Check that the O_2 pipeline pressure gauges shows 300 to 600 kPa
13. Connect an N_2O supply to the machine
14. Check that the N_2O pipeline pressure gauges shows 300 to 600 kPa
15. Use the O_2 flowmeter control knob to set a flow of 2 L/min
16. Use the N_2O flowmeter control knob to set a flow of 2 L/min
17. Disconnect the N_2O pipeline.
18. Check that no O_2 warnings are displayed when the N_2O supply pressure decreases.
19. Connect the Air pipeline.
20. Press the Alarm Reset button.
21. Make sure that no alarms are shown on the screen.

Air pipeline test

22. Use the O_2 flowmeter control to set a flow of 0.4 L/min.
23. Check that the Air pipeline pressure gauges shows 300 to 600 kPa
24. Disconnect the Air pipeline supply.

5.9.6 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 flowmeter controls are turned fully clockwise until gas supplies are required.**

5.9.6.1 Cylinder test - cylinder pressure

1. Disconnect all gas pipeline supplies.
2. Open each cylinder valve and check each cylinder pressure.
3. Replace the cylinder if necessary, refer to section 5.5.
4. Close the cylinder valve.

O_2 cylinder high pressure leak test

5. Set the anaesthesia system switch to the OFF position
6. Open the O_2 cylinder valve.
7. Make a record of the current cylinder pressure.
8. Close the O_2 cylinder valve.
9. Make a record of the cylinder pressure after two minute.
10. If the cylinder pressure decreases more than 700 kPa (100 psi), install a new cylinder seal.
11. Repeat steps Section 5.5 through Section 5.9. If the leak continues, contact a Penlon-trained engineer. Do not use the O_2 cylinder supply.
12. Reconnect the Oxygen pipeline.

N_2O cylinder High pressure leak test

13. Open the N_2O cylinder valve, and repeat the leak test sequence given above (O_2 cylinder high pressure leak test, operations 7 to 12).
14. Reconnect the N_2O gas pipeline.

O_2 verification

15. Set the anaesthesia system switch to the ON position.
16. Connect the Y-piece to the test lung
17. Press the Standby button.
18. Make sure that the system is in operational mode.
19. Use the O_2 Flow control to set an O_2 flow of 5 L/min.

20. Use the N_2O Flow control to set an N_2O flow of 5 L/min.
21. Check the FiO_2 reading, make sure that the FiO_2 level reduces to approximately 50%.

5.10 Vaporizer Tests

5.10.1 Vaporizer back pressure test

WARNING

1. **Use only Selectatec series vaporizers**
   Check that each vaporizer is securely mounted - refer to section 5.4.
2. **The machine must be connected to an anaesthetic gas scavenging system (AGSS).**

1. Turn the O_2 flowmeter control to 6 L/min.
2. Set a vaporizer concentration of 1%.

CAUTION

Do not test the vaporizer when the concentration control is between "0" (1) and the first graduation above "0" (2).

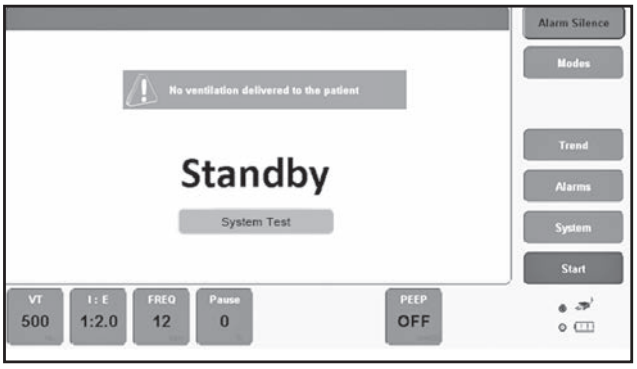
3. Adjust the vaporizer control over the full range of movement above the first graduation.
4. Check that the O_2 flow does not decrease more than 1 L/min through the full range.
5. If the vaporizer fails this test, install a different vaporizer and repeat operation 4.
   If the problem persists, the malfunction is in the anaesthesia system. Do not use the system, contact trained technical personnel.
6. Test each vaporizer as above.

5.10.2 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.

5.11 Alarm System Tests

5.11.1 Alarm system self-test at start-up



Check that the system carries out an automatic self-test at start-up.

1. The alarm lamp flashes yellow and red once in turn and an audible beep sounds.
2. The start-up screen is displayed, followed by the standby screen after approximately 15 seconds.
3. Audio and visual alarm indicators are triggered.

5.11.2 Alarm test preparation

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 system switch to ON.
4. Set the system to standby mode.
5. Set the ventilator control setting to the follows:

Ventilation Mode	Select ventilation mode [VCV].
Tidal volume [VT]	500 mL.
Respiratory rate [FREQ]	15 BPM.
Breathing ratio [I:E]	1:2
PEEP	OFF

6. Push the O2 flush button to fill the bellows.
7. Set the flowmeter to 0.5-1 L/min.
8. Press the standby key to exit to standby mode.
9. Check that the ventilator displays the correct data, and that the bellows inflates and deflates normally during mechanical ventilation.

5.11.3 Minute volume (MV) low alarm test

1. Set the MV low alarm limit to 10.0 L.
2. Check that a MV low alarm is triggered.
3. Set the MV low alarm limit to 2.0 L/min and check that the alarm is cancelled.

5.11.4 High pressure alarm test

1. Set the pressure high alarm limit to 30 cmH_2O.
2. Check the Ppeak reading. Adjust the tidal volume until the reading is higher than the pressure high alarm limit.
3. Check that a high pressure alarm triggered.

5.11.5 Continuous high pressure alarm test

1. Connect the manual bag.
2. Set the flowmeter to minimum.
3. Set the APL valve to 30 cmH_2O position.
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 high pressure alarm is triggered.

5.11.6 Low pressure alarm test

1. Set the bag/Vent switch to vent.
2. Set the Paw low alarm limit to 5 cmH_2O.
3. Disconnect the test lung from the Y-piece patient connection.
4. Check that a low pressure alarm triggered.
5. Connect the test lung to the Y-piece port.
6. Make sure the low Paw alarm is cancelled.

5.11.7 Oxygen concentration monitoring and alarm test

CAUTION

This test is required if the O_2 sensor (1) is fitted to the absorber.

1. Use the standby key to enter standby mode.
2. Calibrate the O_2 cell as follows:
   a) Press the SYSTEM button
   b) Press the CALIBRATION tab
   c) Press the O_2 CELL CALIBRATION button
   d) Press the 100% button
   e) Follow the on-screen instructions.
3. Set the FiO_2 low alarm limit to 45%.
4. Use the standby key to enter operational mode.
5. Set O_2 Flowmeter control to 2.0 L/min.
6. Set N_2O flowmeter control to 5 L/Min
7. Make sure that after a short period of time, a FiO_2 LOW alarm is triggered.
8. Set the FiO_2 low alarm limit 18%. Check that the alarm is cancelled.
9. Set the FiO_2 high alarm limit to 25%.
10. Check that a FiO_2 HIGH alarm is triggered.
11. Set the FiO_2 high alarm limit to OFF and check that the alarm is cancelled.

5.11.8 Minute volume (MV) low alarm test

1. Set the MV low alarm limit to a minimum of 11 L/min.
2. Press the HOME key (2).
3. Make sure that after a short time the MV LOW!!! alarm is triggered.
4. Set the MV low alarm limit to 2.0 L/min.
5. Make sure that after a short time the MV LOW!!! alarm is cancelled.
6. Press the Alarm reset key (1).

5.11.9 High airway pressure (Paw) alarm test

1. Set the pressure high alarm limit to 25 cmH_2O.
2. Press the HOME key (2)
3. Adjust the tidal volume (VT) until the Ppeak reading is higher than the pressure high alarm limit.
4. Make sure that an Airway Pressure High!!! alarm is triggered.
5. Set the pressure high alarm limit to 40 cmH_2O.
6. Set VT to 500.

5.11.10 Apnea alarm test

1. Use the standby button to start standby mode.
2. Set the ventilation mode to SPONT/PSV.
3. Press the CONFIRM button.
4. Use the standby button to start operational mode.
5. Make sure that a visual APNEA warning is shown.
6. Make sure that ventilation begins.
7. Set the ventilation mode to VCV.
8. Press the confirm button.
9. Press the alarm reset button.

5.11.11 Continuous high positive airway pressure alarm test

1. Use the O_2 flowmeter to set a minimum flow.
2. Set the APL valve to 30 cmH_2O.
3. Set the Bag/Vent switch to Bag.
4. Press the O_2 flush button until the reading on the airway pressure gauge is approximately 30 cmH_2O.
5. After 15 seconds, check that a continuous pressure high alarm is triggered.
6. Set the APL valve to Min.

5.11.12 Airway pressure low alarm test

1. Set the bag/vent switch to the vent position.
2. Set the Pressure low alarm limit to 5 cmH_2O.
3. Disconnect the test lung from the Y-piece patient connection.

4. Check that a low pressure alarm is triggered.
5. Connect the Y-piece to the test lung.
6. Check that the low pressure alarm is cancelled.

5.12 Breathing System Test

1. Check that the non-return valves in the breathing system work correctly:
   a) The inspiratory non-return valve opens during inspiration and closes at the start of expiration.
   b) The expiratory non-return opens during expiration and closes at the start of inspiration.

Bellows test

2. Set the system to standby mode.
3. Disconnect the Y-piece.
4. Set all gas flowmeter controls fully clockwise
5. Deflate the bellows.
6. Connect the Y-piece to the absorber test block.
7. Press and hold the O_2 flush button to fill the bellows.
8. The airway pressure gauge must indicates less than 15 cmH_2O.
9. Release the O_2 flush button.
10. If the bellows deflates within one minute,.
    a) Remove the bellows and reinstall, refer to Section 7.3.7.
    b) Repeat the bellows test.

Breathing system leak test

11. Set the Bag/Vent switch to the bag position.
12. Turn the APL valve to 50 cmH_2O
13. Press the O_2 flush button until the airway pressure gauge reads 25 cmH_2O.
14. Release the O_2 flush button.
15. Make sure that the airway pressure gauge reading does not reduce.

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.

APL valve test

16. Turn the APL valve to 70 cmH_2O position..
17. Connect the Y-piece to the test plug.
18. Push the O_2 flush button until the airway pressure gauge rises to approximately 35 cmH_2O.

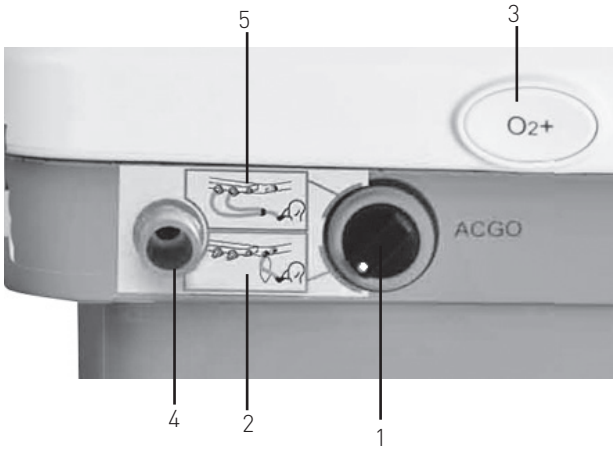
19. Release the O_2 flush button.
20. Set the APL valve to 30 cmH_2O.
21. Check that the reading on the airway pressure gauge is within the range 25 to 35 cmH_2O.
22. Set the APL valve to 20 cmH_2O.
23. Check that the reading on the airway pressure gauge is within the range 15 to 25 cmH_2O.
24. Set the APL valve to the MIN position.
25. Set the anaesthesia system switch to the OFF position.
26. Check that the reading on the airway pressure gauge is less than 5 cmH_2O.

5.13 Oxygen Flush Test

1. Set the anaesthesia system switch to the ON position.
2. Wait until the system enters standby mode.
3. Set the bag/vent switch to the vent position.
4. Disconnect the Y-piece.
5. Make sure that the bellows are deflated.
6. Connect the Y-piece to the absorber test block.
7. Turn the ACGO control to the closed circuit position.
8. Press the O_2+ button, and hold in position.
9. Check that the bellows fully inflate within 4 seconds.
10. Release the O_2+ button.

Auxiliary common gas outlet (ACGO) test

11. Turn the auxiliary common gas outlet (ACGO) control (1) to the open circuit position (2).
12. Make sure that AGCO is shown at the top of the screen.
13. Press the O_2+ flush button (3), and hold in position.
14. Check that there is a flow of fresh gas from the ACGO (4) .
15. Turn the ACGO control to the closed circuit position (5).
16. Check that the flow of O_2 from the ACGO stops.
17. Release the O_2+ flush button.



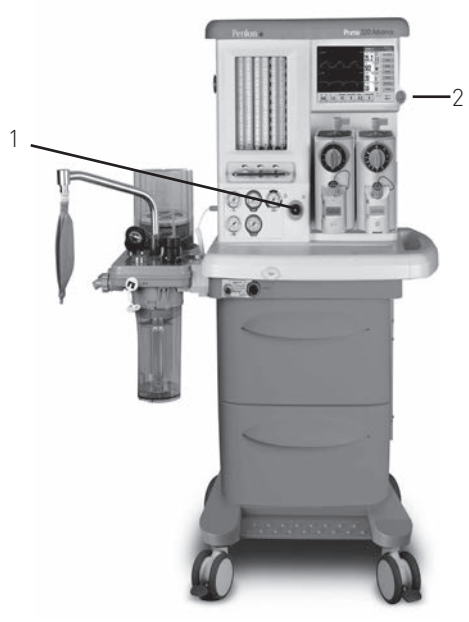
5.14 Pre-use Procedure

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. If necessary, refer to Section 6.
3. Make sure that the system is in Standby.
4. Make sure that equipment for airway maintenance, manual ventilation, tracheal intubation, and applicable anaesthetic 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 all gas flows to a minimum.
10. Make sure that the breathing system is not damaged and correctly connected.
11. Before connecting a patient, flush the machine with 5 L/min of O_2 for at least one minute. This removes unwanted gas mixtures from the system.
12. Set the anaesthesia system switch to the OFF position.

6. Operating the Anaesthesia System

6.1 Basic Operations and Settings



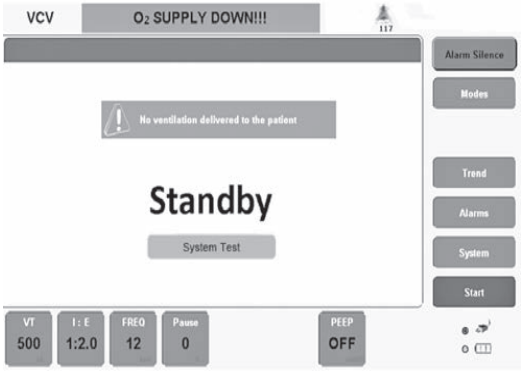
6.1.1 Turn on the system

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 system switch (1) to the ON position.
4. The self-test will start and the indicator lights will be illuminated. The self-test screen will be displayed .
5. The self-test will continue for about 10 seconds. The device will prompt the user to perform a pre-use test.
6. This test must be carried out before the first clinical procedure of the day.

WARNING

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

6.1.2 Standby mode and operating mode



1. Set the system switch (1) to ON.
2. After the power-up self test, the system enters standby mode automatically.
3. To enter operating mode, press the standby key.

6.1.3 Turn the system off

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

6.1.4 Using the touchscreen

This system uses touchscreen technology and a multifunction control knob (2) to access system functions, menus, and settings.
Touch only one touch point at a time to ensure the correct selection is made.

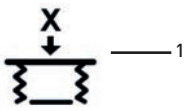
CAUTION

Do not apply excessive pressure to the display screen.

6.1.5 System settings

1. Alarm volume
   a) Select [System] -> [Settings] -> Alarm volume.
   b) Select Alarm volume:
   20%, 40%, 60%, 80%, 100%

2. System Time
   a) Select [System] -> [Date & Time].
   b) Set [Time] and [Date].
   c) Select [Apply].
3. Sigh breath internal
   a) Select the [System] -> [Settings] -> [Sigh Breath Every].
   b) In the [Sigh Breath Every] menu, set 50-150 breaths.
4. Language
   a) Select [System] -> [Settings] -> [Language].
   b) In the [Language] menu, select the required language
5. Oxygen monitoring: On or Off - systems configured with an oxygen sensor in the absorber
   If the O_2 sensor is depleted, or not fitted in the absorber, the oxygen monitor can be set to OFF to prevent the occurrence of an O_2 sensor alarm.
   a) Select [System] -> [Settings] -> [O_2].
   b) Set the oxygen monitor to [ON] or [OFF].
6. CO_2 / AA monitoring
   If a CO_2 / AG module is fitted, set the on/off switch.
   a) Select: [System] -> [Settings] -> [CO_2] / [AA].
   b) Set [ON] or [OFF].
7. SpO_2 monitoring
   If a SpO_2 module is fitted, set the ON/OFF switch.
   a) Select [System] -> [Settings] -> [SpO_2].
   b) Set [ON] or [OFF]
8. Set patient trigger type
   In [SIMV-V], [SIMV-P] and [PSV] mode, a patient trigger is permitted. Trigger sensitivity can be set in flow triggering (Fsens) or pressure triggering (Psens). Normally, flow triggering is preferable as this enables the patient to breathe with less effort.
   a) Select [System] -> [Settings] -> [Trigger Type].
   b) Select the desired trigger type.
9. Set driver gas type (O_2 or Air))
   a) Select standby mode.
   b) Select [System] -> [Settings] -> [Driver].
   c) Select the desired driver gas type: O_2 or Air.
   d) The drive gas icon (1) is displayed on screen, below the Alarm message field. 'X' will be shown as the drive gas in use.



10. Set the Air alarm switch (optional)
    a) Select [System] -> [Settings] -> [Air].
    b) Set [ON]/ [OFF].

CAUTION

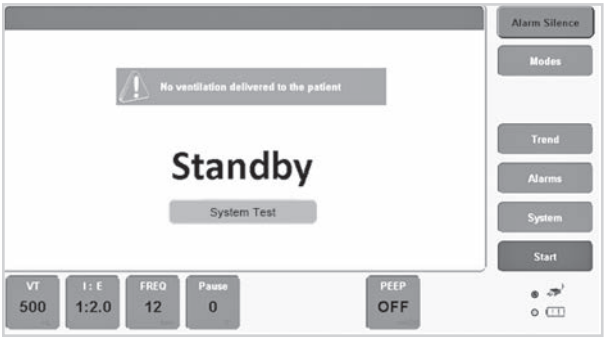
When the Air alarm switch is set to OFF, the Air supply pressure alarm is off.
Note that air supply pressure monitoring is active.

11. Set CO_2 unit
    a) Select [System] -> [Settings] -> [EtCO_2 Unit].
    b) Select: % / mmHg / kPa.

6.2 Display Controls

6.2.1 Standby screen

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



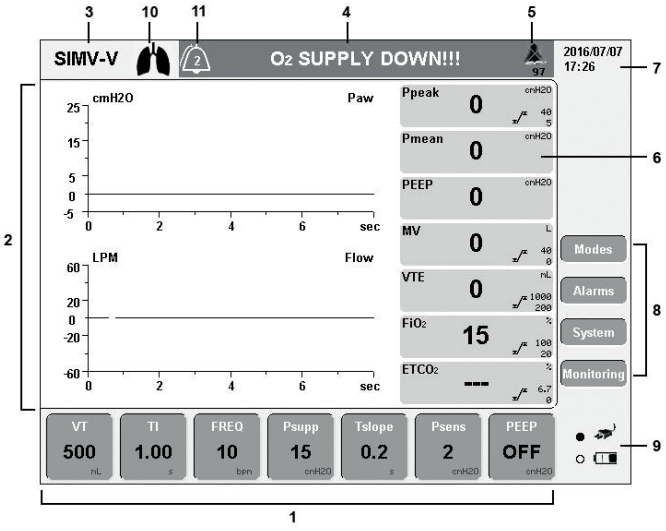
Standby mode features:

1. Displayed monitored parameters and waveforms are disabled, and ventilation stops.
2. Parameters can be set and the system will operate based on those settings when standby is exited.
3. Physiological alarms are cleared automatically
4. Technical alarms function normally.
5. The monitor module enters standby status.
6. Service modes are activated.

6.2.2 Working screen

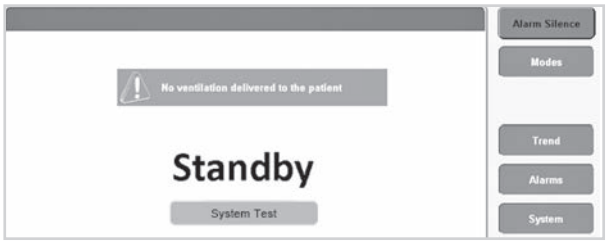
1. Ventilator setting fields:
   Parameters related to the selected ventilation mode.
2. Waveforms fields:
   Measured value waveforms are displayed.
   Waveform content can be set by the user.
3. Ventilation mode display:
   For manual ventilation, 'Manual' is displayed.
   If 'Ventilator' is selected by using the bag/vent switch, the currently selected ventilator mode is displayed.
4. Alarm message field: Active alarms are displayed.
5. Alarm silence icon:
   The icon is displayed if the alarm silence key is pressed.
   A 120-seconds countdown is triggered.

   NOTE
   The O_2 Supply Failure alarm is not silenceable.
6. Measured values fields.
   Values of standard parameters are displayed.
7. System time fields.
8. Function keys fields:
   Modes, Alarm, System, and Monitoring.
9. Power status display fields:
   Displays power supply in use.
   If the battery is in use, battery charge level is displayed.
10. Trigger Icons fields:
    The trigger icon is displayed when the patient's spontaneous inspiration reaches the preset Trigger Level.
11. Multiple Alarm Icon:
    The icon is displayed if two or more alarms are active. The highest priority alarm is displayed in the alarm message field. The number of active alarms is shown.



6.2.3 Manual ventilation

Set the bag/vent switch to the bag position.
The mode display shows the icon for manual ventilation.



6.2.4 Mechanical ventilation mode selection

1. Touch the Modes button to view the mode selection screen.
2. Touch the hotkey for the required mode.

The parameters for each mode are shown below:

6.2.4.1 Volume control ventilation (VCV) mode

VT	Tidal volume
I:E	Respiratory ratio
FREQ	Respiratory rate
Pause	Inspiratory pause
PEEP	Positive end expiratory pressure

6.2.4.2 Pressure control ventilation (PCV) mode

Pinsp	Pressure control level
I:E	Respiratory ratio
FREQ	Respiratory rate
Tslope	Pressure rise time
PEEP	Positive end-expiratory pressure

6.2.4.3 Synchronized Intermittent mandatory ventilation - Volume control (SIMV-V) mode

VT:	Tidal volume
TI:	Inspiratory time
FREQ:	Respiratory rate
Psupp:	Pressure support level
Tslope:	Pressure rise time
Psens/Fsens:	Pressure/Flow trigger sensitivity
PEEP	Positive end expiratory pressure

6.2.4.4 Synchronized Intermittent mandatory ventilation – Pressure control (SIMV-P) mode

Pinsp	Pressure control level
TI	Inspiratory time
FREQ	Respiratory rate
Psupp	Pressure support level
Tslope	Pressure rise time
Psens/Fsens	Pressure/Flow trigger sensitivity
PEEP	Positive end expiratory pressure

6.2.4.5 Spontaneous/ Pressure support ventilation (SPONT / PSV) mode

In SPONT/PSV mode, the backup mode (VCV or PVC mode) must be preselected. The parameters for the selected backup mode must also be preset.

Backup Modes:

1. Select the [Modes] shortcut key-> [Backup].
2. Touch [Volume] or [Pressure].

Volume mode parameters:

VT	Tidal volume
I:E	Respiratory ratio
FREQ	Respiratory rate

Pressure mode parameters:

Pinsp	Pressure control
I:E	Respiratory ratio
FREQ	Respiratory rate

6.2.4.6 Pressure-regulated volume control (PRVC)

VT	Tidal volume
I:E	Respiratory ratio
FREQ	Respiratory rate
PEEP	Positive end expiratory pressure
Tslope:	Pressure rise time

6.2.4.7 Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)

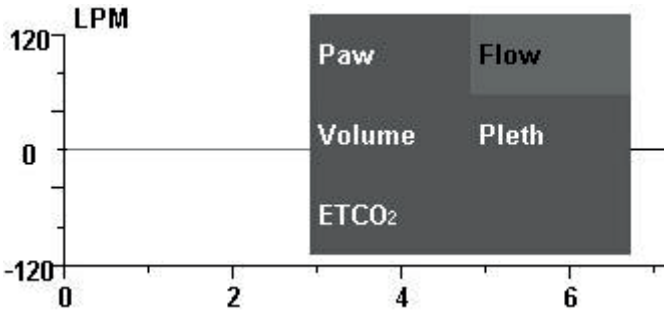
VT:	Tidal volume
TI:	Inspiratory time
FREQ:	Respiratory rate
PEEP	Positive end expiratory pressure
Psupp:	Pressure support level
Tslope:	Pressure rise time
Psens/Fsens:	Pressure/Flow trigger sensitivity

6.2.5 Waveform

To display a waveform configuration screen, touch anywhere within the field for that waveform.
Select the required waveform.

Note that if a hotkey is not available, that function has not been configured.

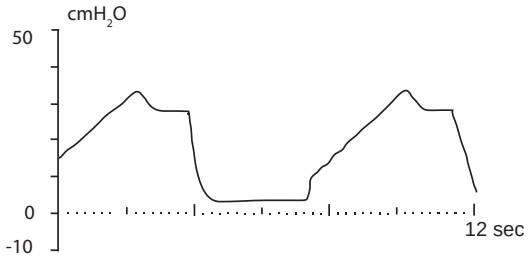
Paw	Airway pressure
Flow	Flow rate
Volume	Tidal Volume
Pleth	Plethysmograph
$EtCO_2$	End-tidal carbon dioxide



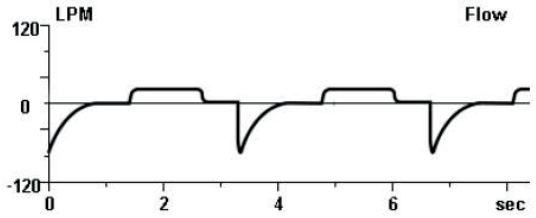
Note that the measured range corresponding to the waveform scales can be adjusted automatically. The sweep time is fixed.

6.2.5.1 Airway pressure waveform

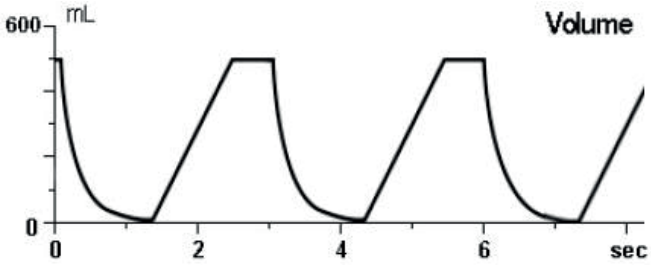
The airway pressure waveform field can be changed.



6.2.5.2 Flow waveform

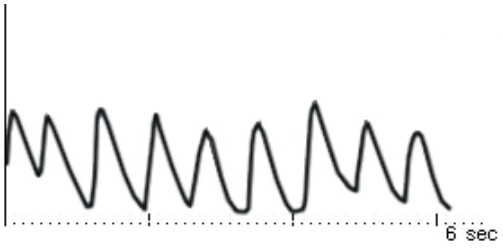


6.2.5.3 Volume waveform



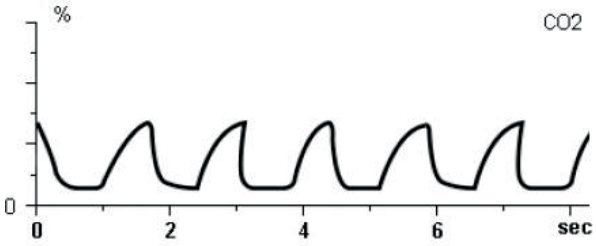
6.2.5.4 Pleth waveform

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



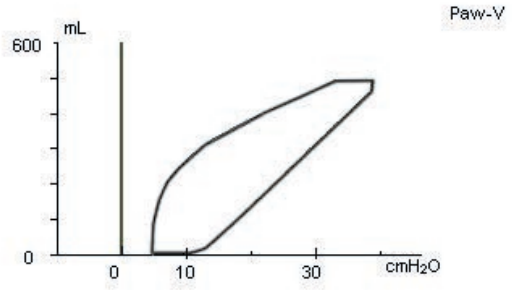
6.2.5.5 $EtCO_2$ waveform

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

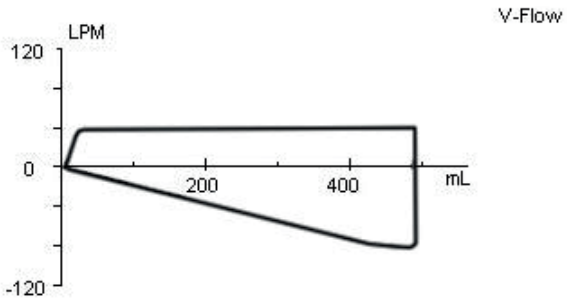


6.2.5.6 Pressure-Volume loop

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



6.2.5.7 Volume-Flow loop



6.2.6 Rapid measurement values fields

Important measured values fields are displayed.
The position of these parameters cannot be changed.

Ppeak:	Peak airway pressure
Pmean:	Average pressure
PEEP:	Positive end expiratory pressure
MV:	Minute ventilation
VTE:	Expiratory tidal volume
FiO_2:	Fraction of inspired oxygen
$EtCO_2$:	End-tidal carbon dioxide

6.2.7 Parameter monitoring

To monitor more measured values, push the required monitoring hotkey in the function keys fields.

6.2.8 Alarms

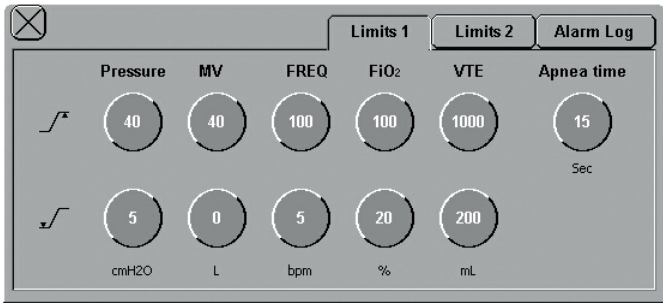
Alarms, triggered by a vital sign that appears abnormal or by technical problems within the machine. To prevent patient injury, set upper and lower limits for the following parameters.

When setting alarm limits, push the hotkey, turn the knob to the required, then push to confirm.

6.2.8.1 Limits 1 display

In Limits 1, alarms are related to mechanical ventilation.

Pressure	
MV	Minute ventilation
FREQ	Respiratory rate
FiO_2	Fraction of inspired oxygen
VTE	Expiratory tidal volume
Apnea time	



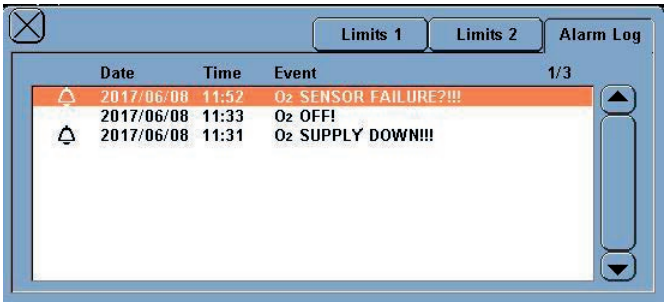
6.2.8.2 Limits 2 display

In Limits 2, alarms are related to optional SpO_2 and CO_2 monitoring.

$ETCO_2$	End-tidal carbon dioxide
$FiCO_2$	Fraction of inspired carbon dioxide
Pulse	Pulse rate
SpO_2	Pulse oximeter oxygen saturation

6.2.8.3 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.



6.2.9 System settings

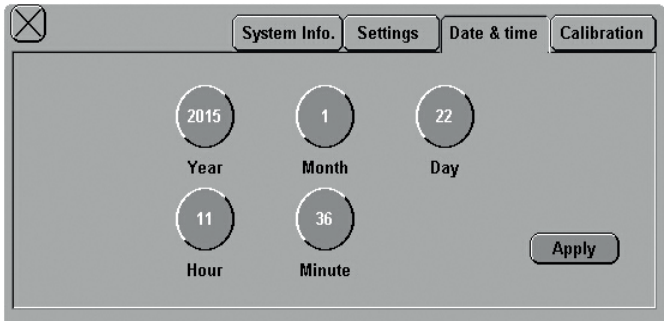
This function is used to change the settings for:

- Language
- $ETCO_2$ unit
- Trigger type
- Masimo IRMA AX+ Module - O_2 Compensation
- System time
- Loudness
- Calibration procedures.

Some hotkeys may not be available. This indicates that these functions have not been configured.
Note that if the related switch is set to OFF, the function cannot be used.

6.2.10 System time settings

These settings will be saved and effective until an update is applied.



6.2.11 System information

In this screen, the device displays software versions, running time, and maintenance information.

6.2.12 Calibration

The Gas Module Zero Calibrationbutton refers to the zero calibration of Masimo IRMA AX+ module.

Calibration options are shown.

6.3 Fresh Gas Settings

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 machine to a Penlon-trained service engineer for repair.

6.3.1 N_2O, O_2, and air supply settings

1. Check each gas supply connection and pressure.
2. Gas flow values are shown on the respective flowmeter.
3. The O_2 and N_2O flow controls are linked:
   a) Increase the N_2O flow.
   The O_2 control will increase the O_2 flow, to maintain an O_2 concentration greater than 21% in the mixed gas.
   b) Decrease the O_2 flow.
   The N_2O flow will decrease, to maintain an O_2 concentration greater than 21% in the mixed gas.

6.4 Ventilation Mode

WARNING

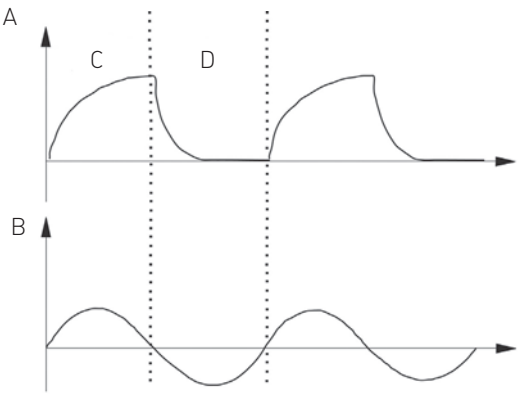
Ventilating Neonatal and Paediatric patients:

1. Use ONLY Volume Control or Pressure Control ventilation for mandatory ventilation of neonates.
2. Switching ventilation modes during a clinical procedure:
   a) The ventilator will automatically revert to the settings that were last used in the mode that you are about to use.
   b) To protect the neonatal/paediatric patient from adult ventilation settings, always switch to Standby before switching ventilation modes.
   Set appropriate neonatal/paediatric parameter values for the mode that you are about to use, before recommencing ventilation.
3. Always set a low target pressure first and then increase to the required level.
4. Use breathing circuits and filters specifically designed for neonatal/paediatric use.
5. Do not ventilate pre-term babies with a birth weight below 2.4 kg.

6.4.1 Manual ventilation mode

1. Turn the APL valve control to adjust the pressure in the breathing system within the appropriate range.
2. Set the bag/vent 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.
   The APL valve is generally set at between 20-30 cmH_2O.

Key
A: Airway pressure
B: Flow
C: Time: inspiration
D: Time: Expiration



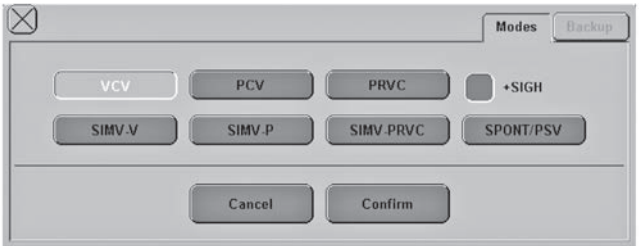
6.4.2 Mechanical ventilation mode

Select settings before starting Mechanical Ventilation

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/vent switch to the vent position.
4. If necessary, push the O_2 flush button to inflate the bellows.

Select mechanical ventilation mode

1. Mode selection
   a) Select the [Mode] hotkey to open the [mode] screen.
   b) Click the hotkey for the required ventilation mode, and then click [confirm].
   c) The ventilation mode selected will be displayed in the mode display field.



NOTE

If SPONT/PSV mode is selected, PCV or VCV backup mode must be preselected - see section 6.4.9.

6.4.3 VCV mode

Principles of volume control ventilation

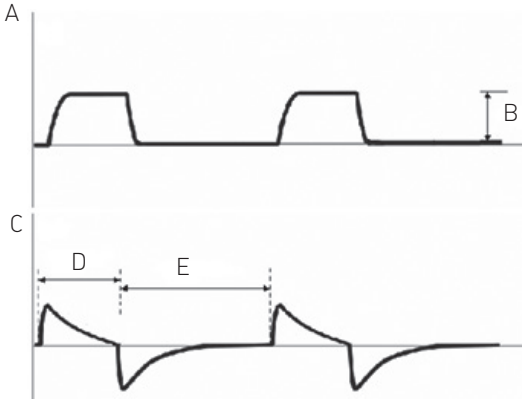
In Volume control ventilation (VCV) gas is delivered to the patient at a constant flow, to deliver the preset VT within the gas delivery time.
To achieve the preset VT, the resulting airway pressure (Paw) changes based on patient pulmonary compliance and airway resistance.
As long as Paw is less than 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 patient injury caused by high airway pressure.
Select [Pause] to improve patient pulmonary gas distribution and [PEEP] to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

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

Key
A: Airway pressure
B: Inspiratory pressure
C: Flow
D: Time: inspiration
E: Time: expiration



Setting the parameters in VCV mode

Parameter	Range	Step
VT	10-1500 mL	10 - 100 mL: 5 mL 100 - 1500 mL: 10 mL
I:E	4:1 - 10:1	0.5
FREQ	4 -100 bpm	1 bpm
PEEP	Off, 3 - 30 cmH_2O	1 cmH_2O
Pause	0% - 60%	5%
Sigh	Off, 50 - 150	25

6.4.4 PCV mode

Principles of pressure control ventilation

In PCV mode, 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. Actual tidal volume is measured.

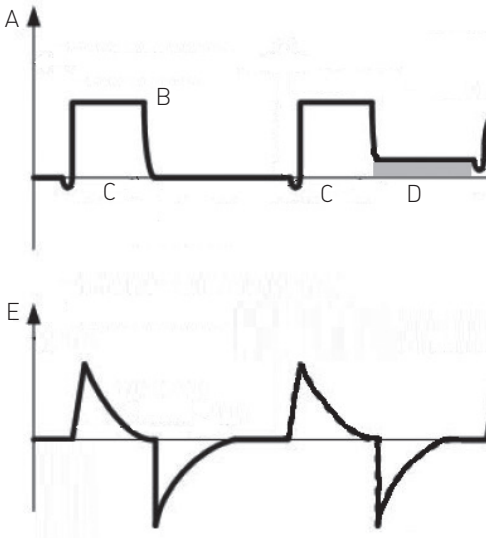
In PCV mode, select PEEP to improve expiration of end-tidal carbon dioxide and to increase oxygenation.

PCV mode 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.

Tidal volume is measured, instead of preset by the user.



Key
A: Airway pressure
B: Pmax
C: SIMV breath
D: PEEP
E: Flow

Setting the parameters in PCV mode

Parameter	Range	Step
Pinsp	5-70 cmH_2O	1 cmH_2O
I:E	4:1 - 10:1	0.5
FREQ	4 -100 bpm	1 bpm
PEEP	Off, 3 - 30 cmH_2O	1 cmH_2O
Tslope	0 - 1 s	0.1 s

6.4.5 Pressure-regulated volume control (PRVC)

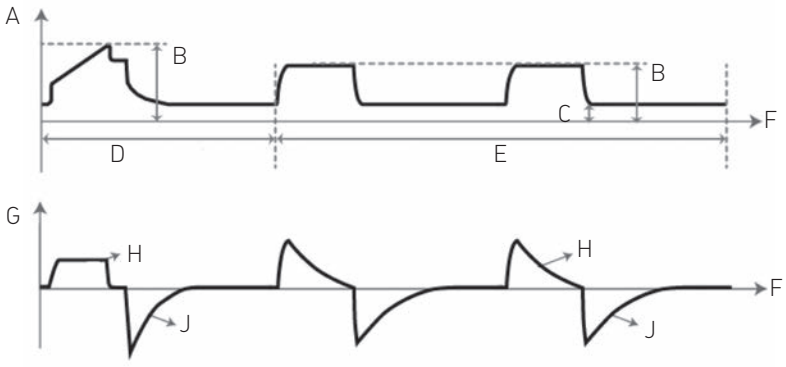
In PRVC a tidal volume is set and the ventilator adjusts the inspiratory pressure needed to deliver the set tidal volume so that the lowest pressure is used.
The pressure range is between the PEEP +2 cmH_2O level and 5 cmH_2O below pressure high limit.
The inspiratory pressure change between breaths is a maximum of +/- 3 cmH_2O.

This mode delivers breaths with the efficiency of pressure controlled ventilation, yet still compensates for changes in the patient's lung characteristics.

PRVC mode initially delivers a VCV breath. Patient compliance is determined from this volume breath.
The inspiratory pressure level is then set for the next breath.

PRVC Waveforms

Key
A: Airway pressure
B: Peak pressure
C: PEEP
D: First ventilation
E: PRVC cycle
F: Time (s)
G: Flow
H: Inspiratory volume
J: Expiratory volume



Setting the parameters in PRVC mode

Parameter	Range	Step	Default
VT	Infant: 10 to 100 ml Paediatric: 50 to 360 ml Adult: 100 to 1600 ml	10 - 100 ml: 5 ml 100 - 1500 ml: 10 ml	35 ml 120 ml 510 ml
I:E	4:1 to 1:10	0.5	1:2
FREQ	1 to 100 bpm	1 bpm	15 bpm
PEEP	OFF, 3 to 30 cmH_2O	1 cmH_2O	OFF
Tslope	0 to 1 s	0.1 s	0.2 s

6.4.6 Synchronized intermittent mandatory ventilation - Volume control (SIMV-V)

SIMV-V

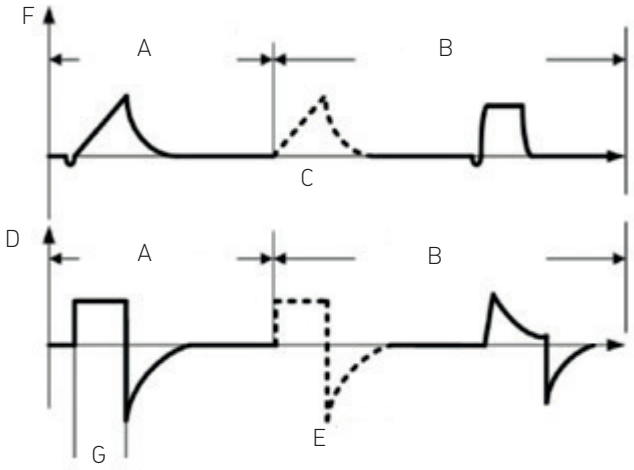
SIMV-V delivers volume controlled breathing to the patient by phase at the preset intermission.
In SIMV-V mode, the ventilator waits for the patient's next inspiration based on the specified time interval.
Sensitivity is dependent on Trigger level (Fsens = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity).

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.

SIMV-V Waveforms

Paw waveform and flow waveform in SIMV-V mode.

Key
A: Within the trigger window
B: Outside the trigger window
C: SIMV cycle
D: Flow
E: VCV applied (no ventilation within the trigger window)
F: Airway pressure
G: Inspiratory time



Parameter range and default values in SIMV-V mode

Parameter	Range	Step	Default
VT	Infant: 10 to 100 ml Paediatric: 50 to 360 ml Adult: 100 to 1600 ml	20 to 100 ml: 5 ml 100 to 1500 ml: 10 ml	35 ml 120 ml 510 ml
Tinsp	0.1 to 10.0 s	0.1 s	1:2
FREQ	1 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 1 s	0.1 s	0.2 s
Fsens	1 to 20.0 L/min	0.1 L/min	3 L/min
Psens	1 to 20 cmH_2O	1 cmH_2O	2 cmH_2O
Esens	5% to 80%	5%	25%

6.4.7 Synchronized intermittent mandatory ventilation - Pressure control (SIMV-P)

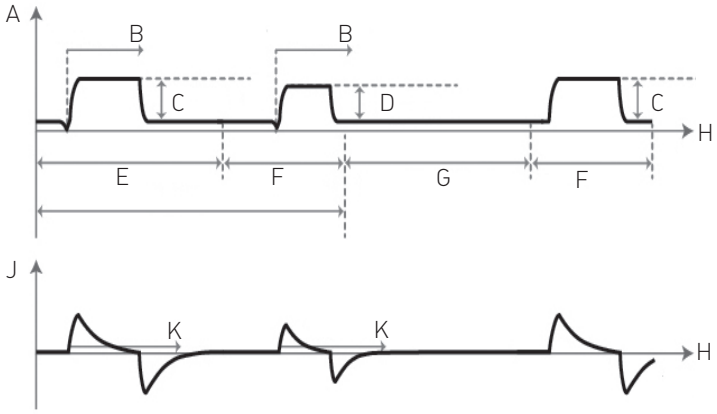
SIMV-P delivers pressure controlled breathing to the patient by phase at the preset intermission.
In SIMV-P mode, the ventilator waits for the patient's next inspiration, based on the specified time interval.

Sensitivity depends on the Trigger Level (Fsens = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity). 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].

Paw and flow waveforms in SIMV-P mode.

Key	
A: Paw	F: Outside trigger window
B: Pressure trigger	G: If no ventilation occurs within the trigger window
C: Pressure control level	H: Time
D: Pressure	J: Flow
E: Within trigger window	K: Flow trigger



Parameter range and default values in SIMV-P mode

Parameter	Range	Step	Default
Pinsp	5 to 70 cmH_2O	1 cmH_2O	15 cmH_2O
Tinsp	0.1 to 10.0 s	0.1 s	1:2
FREQ	1 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 1 s	0.1 s	0.2 s
Fsens	1.0 to 20.0 L/min	0.1 L/min	3 L/min
Psens	1.0 to 20 cmH_2O	1 cmH_2O	2 cmH_2O
Esens	5% to 80%	5%	25%

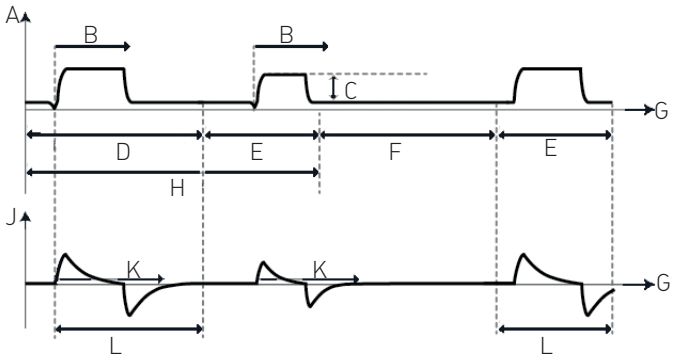
6.4.8 Synchronised intermittent mandatory ventilation - Pressure-regulated volume controlled (SIMV-PRVC)

SIMV-PRVC delivers pressure controlled breathing to the patient and the ventilator waits for patient's next inspiration based on the specified time interval.

Sensitivity depends on trigger level (F = Flow trigger sensitivity; Psens = Pressure trigger sensitivity; Esens = Expiratory trigger sensitivity).

If the 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 the 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].



SIMV-PRVC waveforms (Paw and flow)

Key	F: If no ventilation occurs within the trigger window
A: Paw	G: Time (s)
B: Trigger window	H: SIMV cycle
C: Pressure support level	J: Flow
D: Within the trigger window	K: Flow trigger
E: Outside the trigger window	L: PRVC ventilation

Parameter range and default values in SIMV-PRVC mode

Parameter	Range	Step	Default
VT	Infant: 10 to 100 ml Paediatric: 50 to 360 ml Adult: 100 to 1600 ml	20 to 100 ml: 5 ml 100 to 1500 ml: 10 ml	35 ml 120 ml 510 ml
Tinsp	0.1 to 10.0 s	0.1 s	1:2
FREQ	1 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 1 s	0.1 s	0.2 s
Fsens	1.0 to 20.0 L/min	0.1 L/min	3 L/min
Psens	1.0 to 20 cmH_2O	1 cmH_2O	2 cmH_2O
Esens	5% to 80%	5%	25%

6.4.9 SPONT/PSV mode

Spontaneous/pressure support ventilation mode (SPONT/PSV) is an auxiliary breathing mode.

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. Flow is reduced 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 pre-selected backup ventilation mode (Volume or Pressure).

CAUTION

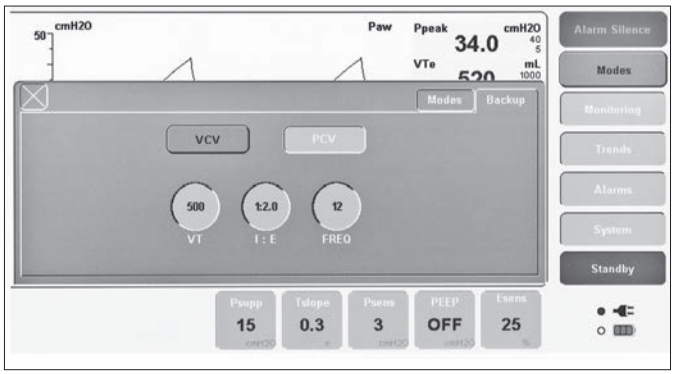
The backup mode must be selected in advance.
Parameter values for the backup mode must be appropriate.

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

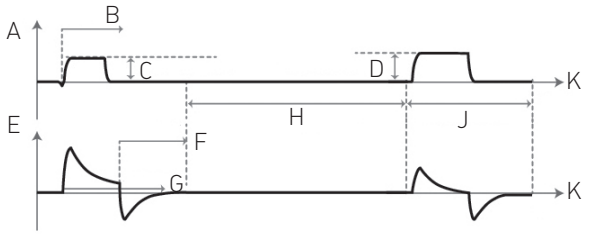
PSV mode is used only when the patient is breathing spontaneously.

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 is not strong enough to reach the Trigger Level, backup mode ventilation is triggered automatically when the time period for Backup Mode Active ends.

Apnea
If there is (1) no spontaneous breathing or (2) spontaneous breathing and an inspiratory trigger condition is not reached, the system automatically enters the preselected backup ventilation mode, in accordance with the preset 'Apnea time' see 6.4.10.



PSV mode waveforms
Airway pressure (Paw) and flow waveforms in PSV mode.



Key	
A: Airway pressure (Paw)	F: Expiratory trigger
B: Pressure trigger	G: Flow trigger
C: Pressure support level	H: Backup mode: active period
D: Pressure control level	J: Backup mode: applied period
E: Flow	K: Time (s)

Parameter range and default values 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 1 s	0.1 s	0.2 s
Fsens	1.0 to 20.0 L/min	0.1 L/min	3 L/min
Psens	1.0 to 20 cmH_2O	1 cmH_2O	2 cmH_2O
Esens	5% to 80%	5%	25%

6.4.10 Ventilator settings

CAUTION

Confirm each new setting before adjusting another parameter.
If confirmation is not given, the ventilator reverts to the preset value.

Set tidal volume

1. Select [VT] hotkey.
2. Press the control knob; and turn to set the required value.
3. Press the control knob to confirm and activate.

Set respiratory rate

1. Set Select the [FREQ] hotkey.
2. Press the control knob, and turn to set the required value.
3. Press the control knob to confirm and activate.

Set inspiratory time

1. Select the [TI] hotkey.
2. Press the control knob; turn the knob to set to set the required value.
3. Press the control knob to confirm and activate.

Set inspiratory and expiratory ratio

1. Select [I: E] hotkey.
2. Press the control knob, and turn to set the required value.
3. Press the control knob to confirm and activate.

Set pressure limit alarm levels

1. Select [Alarms] ->[Limit 1].
2. Press the control knob, and turn the knob to set the upper and lower limits [pressure] to the required values.
3. Press the control knob to confirm and activate.

Set PEEP

1. Select the [PEEP] hotkey.
2. Press the control knob, turn the knob to set the required value.
3. Press the control knob to activate and confirm the change.

Set pressure control level

1. Select the [Pinsp] hotkey.
2. Press the control knob; and turn to set the required value.
3. Press the control knob to confirm and activate the change.

Set pressure support level

1. Select [Psupp] hotkey.
2. Press the control knob and turn to set the required value.
3. Press the control knob to confirm and activate.

Set inspiratory trigger

In SIMV-V, SIMV-P, and PSV modes, patient-initiated triggering is permitted. Trigger sensitivity can be set in flow triggering (Fsens) or pressure (Psens) triggering.

Normally, flow triggering is preferable as this enables the patient to breathe with less effort.

To set trigger type, see sections 6.4.6 to 6.4.9.

1. Select the [Psens] or [Fsens] hotkey.
2. Set Psens or Fsens to the required value.
3. Push the control knob or touch button to confirm and activate the change.

Sensitivity is set as high as possible without self-triggering. This ensures that triggering is patient-initiated and avoids auto-cycling by the ventilator.

Set Apnea time

If SPONT / PSV mode is used, a backup ventilation mode can be selected.

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 the pre-selected backup ventilation mode.

1. Select [Alarm] -> [Apnea time].
2. Turn the control knob to set the required value.
3. Press the button to confirm and activate the change. To cancel the setting, close the window or return to the main screen.

Set inspiratory pause

1. In VCV mode, select the [Pause] hotkey.
2. Set the pause at the required value: 0 to 60% in 5% increments.
3. Press the control knob to confirm and activate the change.

Set rise time

In pressure mode, rise time is available.

1. Select [Tslope] hotkey.
2. Set the [Tslope] at the desired value, namely 0-1 s, (0.1 s increments).
3. Press the control knob again to activate the change.

6.4.11 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 Start/Standby key (1) .

6.5 Monitoring Parameters

6.5.1 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 O_2 sensor is used, calibrate the sensor when the measured value of O_2 concentration is outside specification range, or when a new sensor is fitted. Refer to section 7.8.

6.5.2 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.

6.5.3 Pressure monitoring

Pressure related parameters are listed below.

PEEP
Ppeak
Pplat
Pmean

6.5.4 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

6.5.5 Breath rate monitoring

Breath rate related parameters are measured as shown below.

ftotal (total respiratory rate)
fspn (spontaneous respiratory rate)

6.6 Pulmonary Function

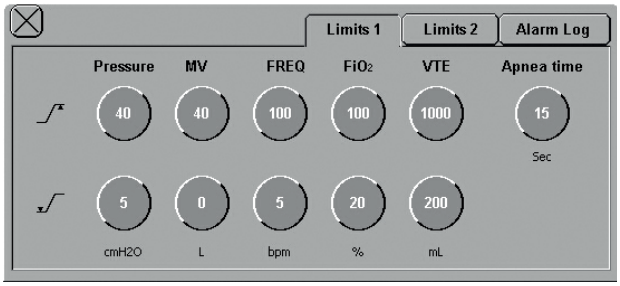
The system displays dynamic compliance monitoring, static resistance, and spirometry loops to reflect the patient's pulmonary function.

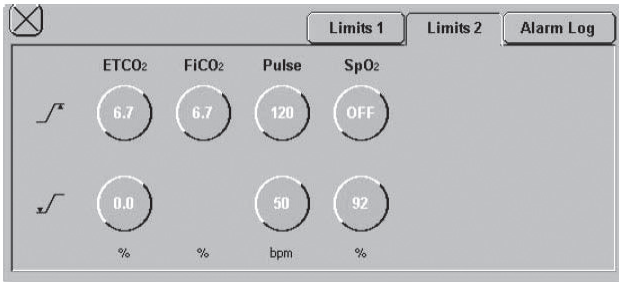
The system provides two spirometry loops: Paw-V (Paw-volume) loop and V-Flow (volume-flow) loop.
The scales of volume flow and Paw are adjusted automatically.

Paw-V loop and V-Flow loop are shown in section 6.2.5.

6.7 Alarm Setup

Use the Alarm setup menu to set and adjust alarm limits and to view alarm history. See section 6.11.6 for alarm messages.





6.7.1 Set Ventilator alarm limits

1. Select the [Alarms] hotkey and select the Limits 1 screen.
2. Set upper and lower limits respectively for each parameter, and exit the menu.

6.7.2 Set CO_2 alarm limits

If a CO_2 module (optional) is fitted, select System: >Settings.

1. Set 'CO_2 alarms' to On.
2. Select the [Alarms] hotkey and select the Limits 2 display.
3. Set upper and lower limits respectively, and exit the menu.

6.7.3 Set SpO_2 alarm limits

If a SpO_2 module (optional) is fitted, select System: >Settings

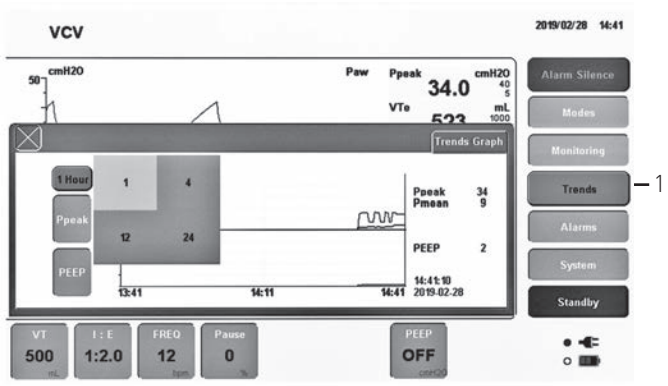
1. Select SpO_2 alarm to On.
2. Select the [Alarms] hotkey and select the Limits 2 display.
3. Set upper and lower limits respectively, and exit the menu.

6.8 Trends

A trend graph is used to review 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 parameter data within a maximum of a 24-hour operating period.

Select the [Trends] menu (1) to access the display



a) Time Scale button

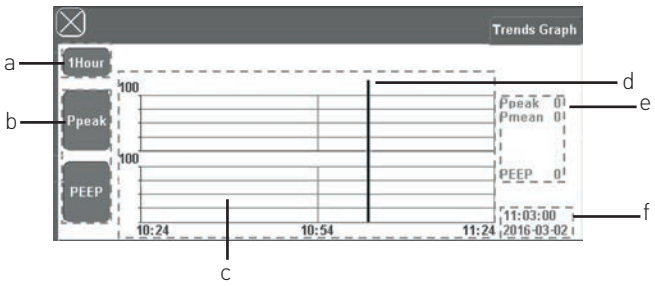
b) Parameter selection button

c) Trend graph

d) Cursor

e) Parameter value

f) Cursor position time



Setting

1. Use the Time Scale button (a) to select the desired time scale (1, 4, 12 or 24 hours).
2. Use the Parameter selection button (b) to select the desired parameter.
3. Use the multifunction control to reposition the cursor (d), to view the parameter values at the required time point.

CAUTION

1. **If system time is set, the trend graph is recorded again.**
2. **If 'Patient type' is reset, select save or record again.**

6.9 Replace Absorbent

CAUTION

A gradual colour 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 replaced.
If left standing for several hours, it may regain its original colour and give a misleading indication of usability.

6.9.1 Using 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-breathes exhaled gases. Use carbon dioxide monitoring .

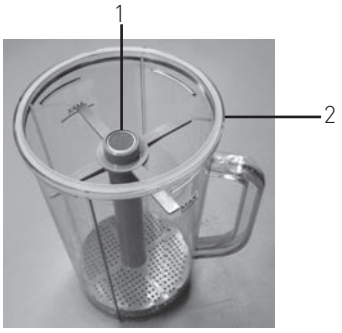
For safety, an infrared sensor monitors if bypass mode is activated. A technical alarm is triggered to warn the user.

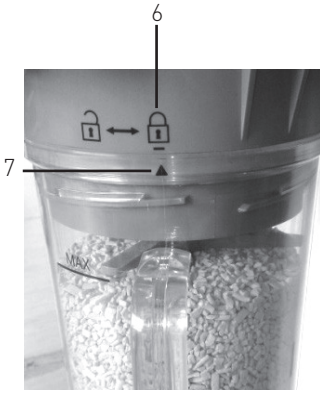
6.9.2 Absorbent change procedure

WARNING

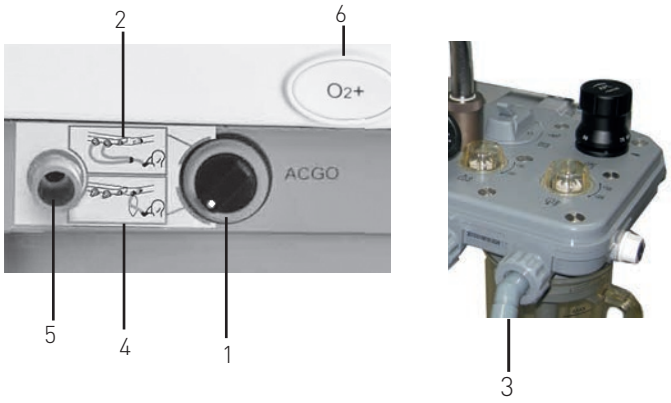
To prevent dust and particles from entering the breathing circuit, the filter (1) must be fitted securely, as illustrated. Before installation, clean all the canister components, including the seal (2).

1. Rotate the absorber canister clockwise until the triangular marks (3) are aligned.
2. Detach the canister from the absorber.
   Canister bypass mode is activated.
   'No absorber!?' is shown in the alarm message area.
3. Empty the canister
4. Fill with new soda lime to the MAX line (4).
   Remove any soda lime that has collected on the filter (1).
5. Wipe the dust from the absorber canister support (5).
6. Position the canister, ensuring that the threads are engaged.
   Make sure that the triangular marks (3) are aligned.
7. Tighten counter-clockwise until the 'locked' symbol (6) and the triangular mark (7) on the canister are aligned.
8. Check that the alarm message is cancelled.





6.10 Auxiliary Common Gas Outlet (ACGO)



ACGO control (1)

1. Upper position (2) - fresh gas is directed to the patient through the breathing circuit to the expiratory port (3).
2. Lower position (4) - fresh gas is directed to the patient through the ACGO port (5).

O_2 Flush control

The O_2+ button (6) directs an oxygen flow of 25-75 L/min to:

(a) the ACGO port (switch in the lower position 4).

or;

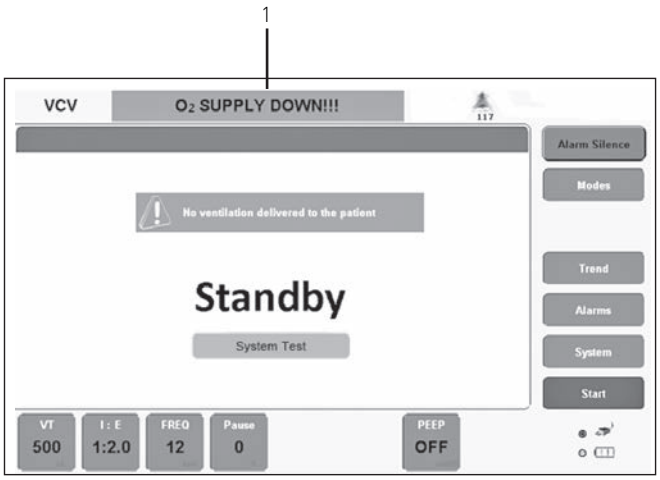
(b) the breathing circuit (switch in the upper position (2).

6.11 Alarms

6.11.1 WARNING

1. **If the system self-test at start-up indicates an alarm system failure, do not use the machine. Contact a service engineer.**
2. **When the machine is in use, the alarm message field (1) must visible to the user at all times.**

Visual and/or audible alarms are triggered by (a) A vital sign that appears abnormal, or (b) A technical condition within the anaesthesia machine



NOTE

1. On start-up, the system self-test checks if the alarm lamp and audible alarm tones function normally.
2. Normal function triggers an audible beep, and the alarm lamp flashes yellow and red once in turn.
3. If a failure is detected, do not use the equipment. Contact a Penlon-trained engineer.

6.11.2 Alarm levels

Values for all technical alarms and some physiological alarms are preset at the factory and are not adjustable.

Alarms fall into three categories: high level alarms, medium level alarms and low level alarms.

When multiple alarms of different levels occur simultaneously, the system will select the highest priority alarm and give visual and audible alarm indications accordingly.

High level alarm

Indicates a life threatening situation requiring immediate action.

Medium level alarm

Indicates that the patient's vital signs appear abnormal and immediate action is required.

Low level alarm

Indicates that the patient's vital signs appear abnormal; action may be required.

6.11.3 Alarm indicators

Alarms trigger visual or audible indicators:

Alarm lamp
Alarm message
Flashing numeric
Audible alarm tones

6.11.3.1 Visual indicator - Alarm Lamp

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

Alarm Level	Colour and Frequency
High	The red lamp flashes quickly
Medium	The yellow lamp flashes slowly
Low	The yellow lamp is lit, without flashing

6.11.3.2 Audible indicator

Alarm tone patterns are varied, to match the alarm level:

Priority	Tone Pattern
High	10-note sequence, repeated every 10 seconds
Medium	3-note sequence, repeated every 2 seconds
Low	2-note sequence, does not repeat

6.11.3.3 Alarm message

When an alarm occurs, a message appears in the alarm area.
The alarm area background colour matches the alarm level:

Alarm Level	Background Colour
High	Red
Medium	Yellow
Low	Yellow

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

Alarm Level	Symbol
High	!!!
Medium	!!
Low	!

6.11.3.4 Alarm status symbols

The alarm status icon appears on the screen to show different alarm status conditions, including Alarm Silence.

NOTE
The O_2 Supply Failure alarm is not silenceable.

6.11.4 Set alarm volume

Select [System] hotkeys ->[Settings] ->[Loudness] volume
Loudness range: 20% minimum to 100% maximum.
The settings will be saved and will not be cancelled when the machine is turned off.

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.**

6.11.5 Alarm limits

CAUTION

An alarm is triggered when the parameter value is higher than the High Limit or lower than the Low Limit.

Check that the alarm limits of a specific parameter are set to appropriate values.

6.11.6 Alarm messages

Physiological alarms message

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.
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 cmH_2O.	Check for blockages in the breathing circuit. Increase fresh gas flow. Check if 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	Pluse rate is greater than high alarm limit.	Check patient's condition! Set the alarm limits appropriately.
SPO_2HIGH!!	Medium	SpO_2 is greater than high alarm limit.	Check patient's condition! Set the alarm limits appropriately.
$EtCO_2$ LOW!!	Medium	$EtCO_2$ is less than alarm limit.	Ensure 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		
FiN_2O LOW!!	Medium	FiN_2O is less than alarm limit.	Set the alarm limits appropriately. Check the N_2O setting.

Technical alarms message

Message	Priority	Cause	Action
O_2 SUPPLY DOWN!!!	High	O_2 pipeline pressure is less than 280kPa.	Ensure 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.
STANDBY ACTIVED!!!	High	Switching from manualventilation to mechanical ventilation	Press the "Alarm Reset" Elimination of this alarm.
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.
O_2 SENSOR FAILURE!!!	High	Oxygen sensor not connected or oxygen sensor failure.	Check oxygen sensor cable. Recalibrate the O_2 cell. Change O_2 cell.
Gas Module Software Error!!	Medium	Gas Module Software Error!!!	Contact your service personnel.
Gas Module Hardware Error!!	Medium	Gas Module Hardware Error!!!	Contact your service personnel.
Gas Module Motor Overspeed!!	Medium	Gas Module Motor Overspeed!!!	Contact your service personnel.
Gas Module Factory calib lost!!	Medium	Gas Module Factory calib lost!!!	Contact your service personnel.
Gas Module Replace Adapter!!	Medium	Gas Module Replace Adapter!!!	Contact your service personnel.
Gas Module No Adapter!!	Medium	Gas Module No Adapter!!!	Contact your service personnel.
CO_2 Unspecified Accuracy!!	Medium	CO_2 Unspecified Accuracy!!!	Contact your service personnel.
N_2O Unspecified Accuracy!!	Medium	N_2O Unspecified Accuracy!!!	Contact your service personnel.
AA Unspecified Accuracy!!	Medium	AA Unspecified Accuracy!!!	Contact your service personnel.
Gas Module Temp Out Of Range!!	Medium	Gas Module Temp Out Of Range!!!	Contact your service personnel.
Pressure Out Of Range!!	Medium	Pressure Out Of Range!!!	Contact your service personnel.
AA ID Unreliable!!	Medium	AA ID Unreliable!!!	Contact your service personnel.
Gas Module Sampline Line clog!!	Medium	Gas Module Sampline Line clog!!	Check sampling ling
Gas Module NO Sampline Line!!	Medium	Gas Module NO Sampline Line!!	Check sampling ling
NO ABSORBER ? !!	Medium	No connected Absorber canister	Install Absorber canister
$ETCO_2$ LINE OCCLUSION!!	Medium	An error or occlusion occurred to the sampling line.	Check the CO_2 sampling line.
Mixed anesthetic 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 anesthetic 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" Elimination of this alarm. If you need to monitor CO_2 concentration, open the CO_2 switch
AA OFF!	Low	AA switch is turned off	Press the "Alarm Reset" Elimination of this alarm. If you need to monitor anaesthetic agent concentration, open the AA switch.
SPO_2 OFF!	Low	SpO_2 switch is turned off	Press the "Alarm Reset" Elimination of this alarm. If you need to monitor SpO_2, open the SpO_2 switch.
O_2 OFF!	Low	O_2 switch is turned off	Press the "Alarm Reset" Elimination of this alarm. If you need to monitor O_2concentration, open the O_2 switch.

7. Maintenance

7.1 User Maintenance

IMPORTANT

User maintenance

User Maintenance is restricted to cleaning the external surfaces of the machine (see Section 7.2).

All other maintenance and servicing and the replacement of components, must be carried out only by Penlon-trained engineers.

Servicing and Repair

The Prima 320 Advance must be 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

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

Check that all panels are secure after any work by authorised personnel.

Electrical power supply

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

If a replacement fuse mains lead or battery is required, this work must be carried out only by trained engineers.

If a replacement mains lead is required, 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 user maintenance and service requirements for the ancillary equipment used with the anaesthetic machine (vaporizers, anaesthetic gas scavenging system, patient monitoring).

Service Schedule

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

6 months	Inspection and functional check
12 months	Inspection and function check. Calibrate the CO_2 module (if installed) Clean the fan filter Replace seals etc., as required
2 years	Fit components supplied in the preventive maintenance kit. Inspection and function check.

Further information is given in the Prima 320 series service manual, available only to engineers trained by the manufacturer.

7.2 Cleaning and Disinfection

WARNING

1. **Disconnect the system from the mains power supply before maintenance, repairs, cleaning, disinfection and sterilization.**
2. **Read the safety information for each cleaning agent, and the user manual for the disinfection equipment.**
3. **Wear gloves and safety glasses.**
   Take care when removing the O_2 sensor (1). A damaged sensor can leak and cause burns (the sensor contains potassium hydroxide).
4. **Reuse of a non-disinfected breathing system or reusable accessories may cause cross-contamination.**
   Follow infection control and safety procedures to prevent cross-infection from components contaminated with blood and body fluids.
5. **To prevent breathing system leaks, avoid damaging the components when disassembling and reassembling.**
   Ensure correct installation, especially seals.
   Always follow the correct cleaning and disinfection methods and reassembly procedures, as described in this manual.
6. **Pre-use tests (see sections 5.9 to 5.14) must be performed before patient use if the anaesthetic machine has been disassembled for cleaning and disinfection, or servicing.**

CAUTION

1. Clean and disinfect the equipment as required before it is put into use for the first time.
2. Do not use organic, halogenated, or petroleum based solvents, anaesthetic agents, glass cleaners, acetone, or other harsh cleaning agents.
3. Do not use abrasive cleaning agents (such as steel wool, silver polish or cleaner).
4. Keep all liquids away from electronic parts.
5. Do not allow liquid to enter the equipment housings.
6. Limit the soak time for the synthetic rubber cover for the pressure relief valve in the base of the bellows to 15 minutes. This applies to all synthetic rubber components. Swelling or faster aging can occur.
   This warning applies to the silicon rubber case for the pressure relief valve in the base of the bellows (see section 7.3.1).
7. Cleaning solutions must have a pH of 7.0 to 10.5.

7.2.1 Cleaning

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.**

7.2.1.1 External surfaces

Disconnect the machine from the mains electrical supply.

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)

7.2.1.2 Flowmeter / 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.

7.2.1.3 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

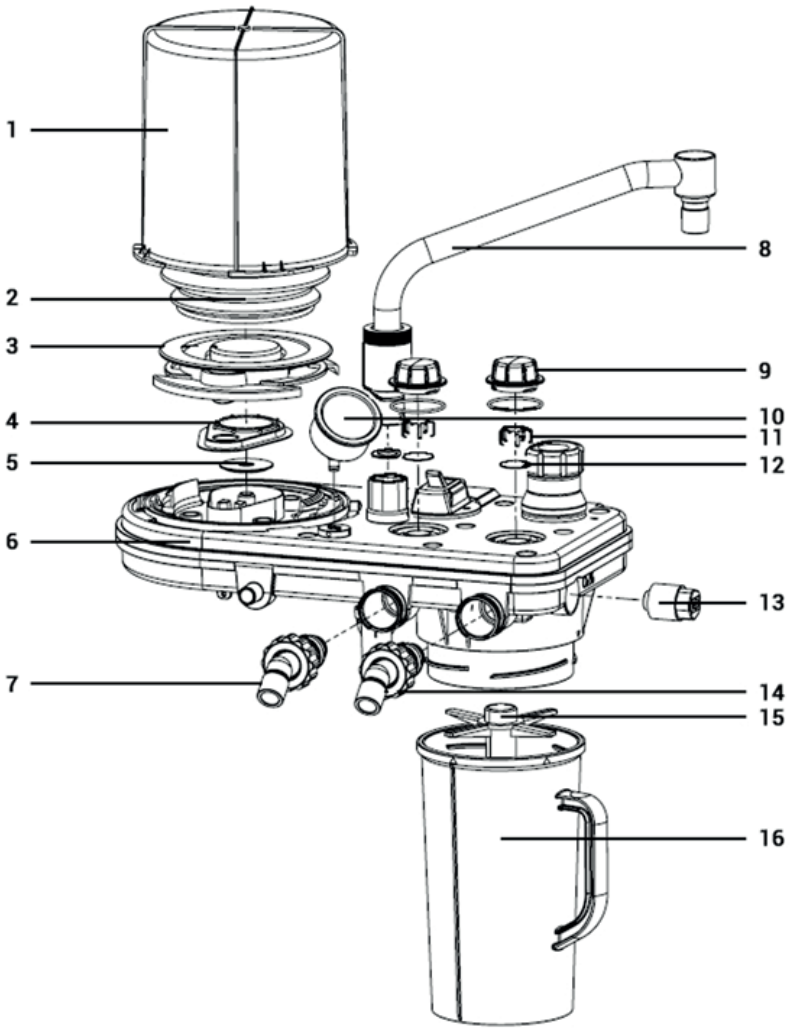
Breathing system hoses and other components must be sterilised to the manufacturer's recommended methods.

7.3 Absorber and Breathing System Components

7.3.1 Disassembly

Disassemble each part of the system that can be cleaned and sterilised:

1. Bellows housing
2. Bellows
3. Bellows base
4. Pressure relief valve silicon rubber cover
5. Pressure relief valve
6. Absorber body
7. Expiration connector assembly
8. Bag support arm
9. Non-return valve cover
10. Airway pressure gauge
11. Non-return valve guide
12. Non-return valve disc
13. Oxygen sensor
14. Inspiration connector assembly
15. Canister support
16. Absorber canister



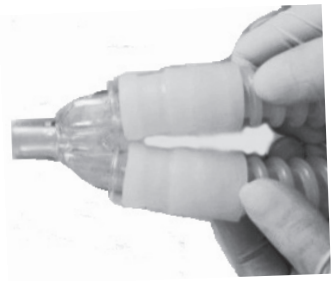
7.3.2 Remove the breathing hoses

CAUTION

1. **When separating the Y-piece, hold both hose connectors to prevent damage.**
2. **If a filter is fitted, do not reuse the filter. Follow local regulations regarding disposal of hospital waste when the filter is discarded.**

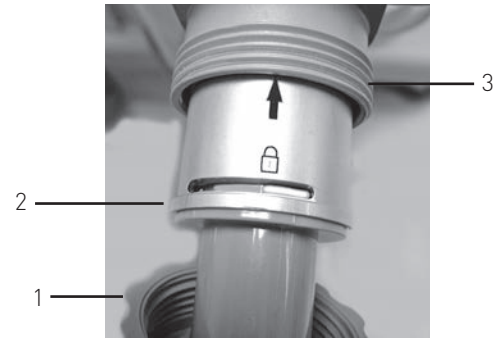
1. Remove the inspiratory and expiratory hoses from the absorber outlets.

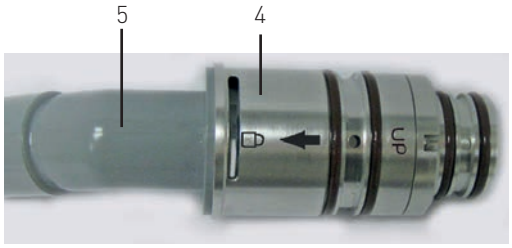
2. Separate the Y-piece from the two breathing hoses.



7.3.3 Remove the flow sensors

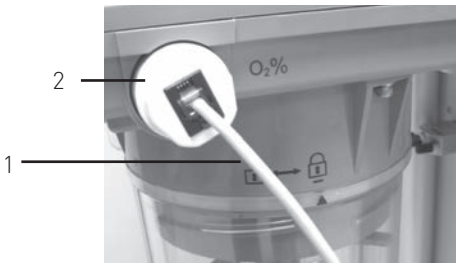
1. Unscrew the inspiratory and expiratory connectors (1), and disconnect the breathing hoses.
2. Withdraw each differential pressure flow sensor and tube assembly (2) from the absorber outlet (3).
3. Detach each flow sensor (4) from the tube (5).





7.3.4 Remove the oxygen sensor

1. Unplug the oxygen sensor cable (1) from the sensor (2).



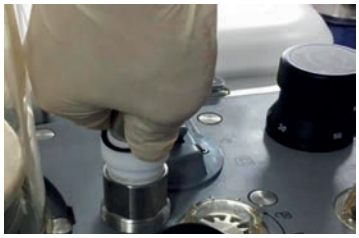
2. Remove the other end of the cable from the machine.
3. Turn the oxygen sensor counterclockwise to remove.

7.3.5 Remove the airway pressure gauge

1. Pull out the pressure gauge from the breathing system.

7.3.6 Remove the bag support arm

1. Loosen the locking nut counterclockwise.
2. Remove the bag arm from the breathing system.

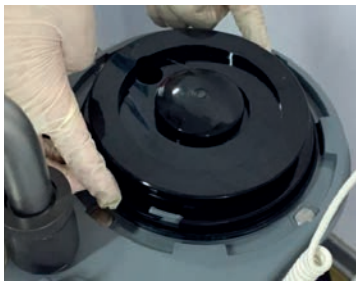


7.3.7 Remove the bellows assembly components

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 pressure relief valve assembly from absorber.

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

7.3.8 Remove a check valveassembly

1. Turn the check valve cover counterclockwise to remove.

2. Remove the check valve assembly.

7.3.9 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.

Drain the condensation from the canister

WARNING

If the water is drained during a clinical procedure, reinstall the drain plug immediately to prevent gas leakage

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

1. Wear protective gloves
2. Hold the canister over a drain or collection bowl.
3. Carefully pull out the water drain plug.
4. Dilute the drained condensate before disposal.
5. Refit the plug.
6. Empty the canister.
   Dispose of the absorbent in line with local regulations.

7.3.10 Remove the water container

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

CAUTION

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

7.3.11 Remove the absorber assembly

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

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

7.4 Cleaning and Disinfection Methods

WARNING

1. **Before cleaning this device, disconnect the mains power supply.**
   While cleaning, do not let cleaning fluids flow into the machine.
   After cleaning, ensure all components are completely dry before use.
2. **O_2 sensor: Do not autoclave, or immerse in cleaning liquid.**
3. **Reusable consumables (breathing system hoses, Y-piece, bag): check the manufacturer's instructions.**

CAUTION

1. Water quality will affect the cleaning process.
   Water quality should not be lower than the quality of drinking water.
   Deionized water is recommended.
2. Clean the components thoroughly in water (<35°C).
   Remove organic matter, such as blood and other residues.
   Cleaning in water at temperatures above 35°C may cause solidification of organic matter.
3. Recommended cleaning and disinfection methods for the various components are detailed in the table below.

Cleaning and disinfection methods

A. Use disinfection equipment.

B. Use a mild detergent with a pH of less than 10. For example: soak for a minimum of 45 minutes with 2% glutaraldehyde solution). Rinse with water

C. Autoclave (maximum temperature: 134°C, see 7.4.3))

D. Wipe with a damp cloth soaked in a soft detergent solution (70% ethylene glycol or isopropyl alcohol).

Component	Cleaning and disinfection method			
	A	B	C	D
Anaesthetic machine interface				√
Breathing tubes and Y-piece	√	√	√	
Bag	√	√		
Flow sensors		√		√
Check valve cover and base	√	√	√	√
Check valve discs		√		√
Oxygen sensor				√
Airway pressure gauge				√
Bag support arm	√	√	√	
Bellows assembly	√	√		
Absorber canister	√	√	√	
Water container	√	√	√	
Absorber body	√	√	√	

7.4.1 Using disinfection equipment

CAUTION

1. To minimize the impact on the environment, use only water when disinfecting. The maximum temperature during disinfection is within the range 90°C to 95°C.
2. Clean or rinse with clean water.
3. Use disinfected equipment for disinfection.
   If detergent is used with cleaning and sterilizing, use a detergent with a pH of <10.
4. Dry the components, assemble and/or store.

7.4.2 Using detergent

CAUTION

1. Use a detergent with a pH of <10.
2. Limit the soak time for the synthetic rubber cover (1) for the pressure relief valve in the base of the bellows to 15 minutes.
3. Clean or rinse with clean water.
4. Use a mild detergent with a pH of less than 10, for 2% glutaraldehyde solution).
5. Use clean water to rinse off the residual disinfectant
6. Dry the components, assemble and/or store.

7.4.3 Autoclave

CAUTION

1. Steam autoclave will shorten the service life of the component.
2. Use a certified process, typically at temperatures of:
   a) 121°C (250°F) for 15 minutes, or
   b) 134°C (275°F) for 4 minutes.
3. Components can also be autoclaved at a temperature of 134°C (275°F) for 18 minutes.
4. Procedure
   a) Clean or rinse with clean water.
   b) Dry the components.
   c) Use steam autoclave.
   d) Dry the components, assemble and/or store.

7.4.4 Display screen

CAUTION

The display screen must not be cleaned with liquid.

1. Wipe with a cotton cloth soaked in soft detergent solution.
2. Wipe off the residual detergent solution with a dry, soft, lint-free cloth.

7.5 Absorber and breathing system

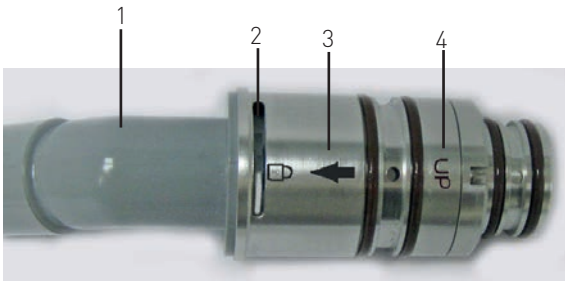
CAUTION

1. **Before assembly, check that all components are dry.**
2. **When installing, make sure that the components and seals are in good condition.**
3. **Only use lubricants approved for anaesthesia or O_2 equipment. Do not use lubricants containing oil or grease that may burn or explode in high O_2 concentrations.**

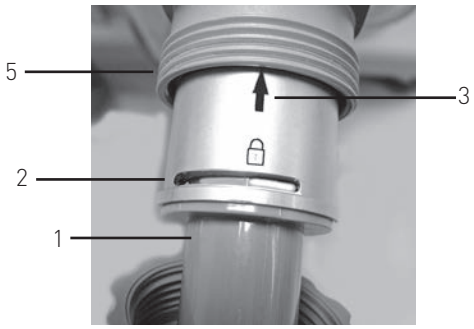
7.5.1 Reassemble the absorber and breathing system

1. All components must be fully dried before assembly and installation.
2. Replace any parts that are visibly damaged or worn.
3. Reverse the dismantling procedures given in sections 7.3.1 to 7.3.10.
   Pressure flow sensors - see section 7.5.2.

7.5.2 Refit the pressure flow sensors



1. Align the lugs on the tube (1) with the slots (2) in the flow sensor.
2. Push the tube into the sensor until the lugs engage the slots.
3. Turn the tubing clockwise until the lugs are fully engaged in the slots (2).
4. Align the flow sensor and tube assembly with the absorber.



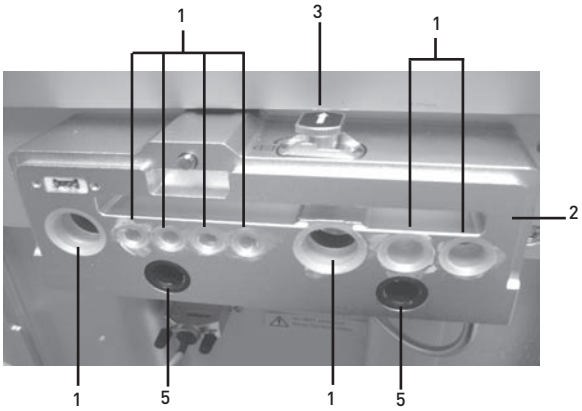
CAUTION

a) **Make sure that the arrow (3) and the word 'UP' (4) are aligned uppermost as shown in the top illustration .**

b) **The direction of the arrow (3) indicates expiratory sensor (lower illustration) and inspiratory sensor (top illustration) on the sensor.**

5. Push the flow sensor and tube assembly into the absorber assembly (5).

7.5.3 Reinstall the absorber and breathing system

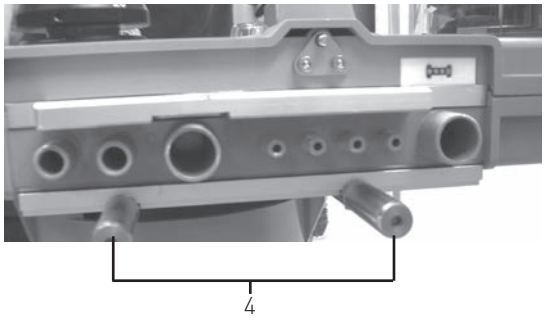


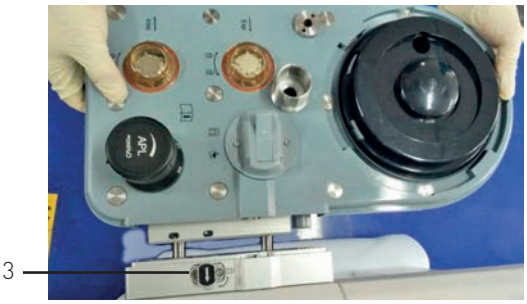
1. All components must be fully dried before assembly and installation.
2. Check that the eight silicon inserts (1) on the breathing circuit adapter plate (2) are in place and are not damaged.
3. Use BG87 or Fomblin grease to lightly lubricate the eight silicon inserts (1).
4. Lift and turn the locking catch (3) to the unlocked position.
5. Align the two connectors (4) on the absorber with the matching holes (5) on the circuit adapter plate.

6. Carefully push the absorber assembly into the circuit adapter plate with moderate force.
7. Reset the locking catch (3) to the locked position.

WARNING

Set the locking catch to the locked position after the absorber assembly is installed. Always check that the assembly is locked in position.





7.5.4 System test

CAUTION

Perform a complete system test, refer to sections 5.9 to 5.14.

7.6 Pressure Sensor Zeroing

CAUTION

1. **Do not calibrate 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.**
3. **If zeroing fails, contact a Penlon-trained engineer.**

Procedure

1. Stop manual or mechanical ventilation. If a breathing tube is connected, open the breathing tube patient connection to air.
2. Check that the bellows falls to the bottom.
3. Turn the flowmeter to minimum.
4. 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.

7.7 Flow Sensor Zeroing

1. Stop manual or mechanical ventilation.
   If a breathing tube is connected to the breathing system, 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.

7.8 Oxygen Concentration Calibration

CAUTION

1. **Calibrate the O_2 sensor (1) at the same ambient pressure in which it will be used.**
2. **Follow your hospital biohazard disposal procedure for the discarded O_2 sensor. Do not incinerate.**

1. Remove the O_2 sensor.
   Check that there is no water build-up on the O_2 sensor or within the port (2) on the side of the absorber.
2. Reinstall the O_2 sensor and check that the cable (3) is connected correctly.

7.8.1 O_2 calibration at 21%

CAUTION

1. **Calibrate when the measured value of O_2 concentration is outside specification range, or when a new sensor is fitted.**
2. **If calibration fails:**
   a) **Check for a technical alarm and then check the troubleshoot section. Repeat the calibration.**
   b) **In case of repeated calibration failures, fit a new sensor and repeat the calibration. If it still fails, contact a Penlon-trained service engineer.**

Calibration procedure at 21% O_2

1. Select standby mode.
2. Press the hotkeys -> [Calibration] -> [Oxygen Cell Cal]
3. Select [21%] and press confirm to start calibration.
4. Follow the on-screen instructions.
5. After a successful calibration, the screen shows [Calibration success!].
6. If the message [Calibration Failure!] is displayed, repeat the calibration.

7.8.2 100% O_2 calibration

CAUTION

1. **If the calibration fails, check for a technical alarm. 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. Select standby mode.

3. Touch the [System] hotkeys -> [Calibration] -> [Oxygen Cell Cal]
4. Selected [100%] and press confirm to start calibration.
5. Follow the on-screen instructions.
6. After a successful calibration, the screen shows [Calibration success!].
   Repeat the procedure if [Calibration Failure!] is displayed.

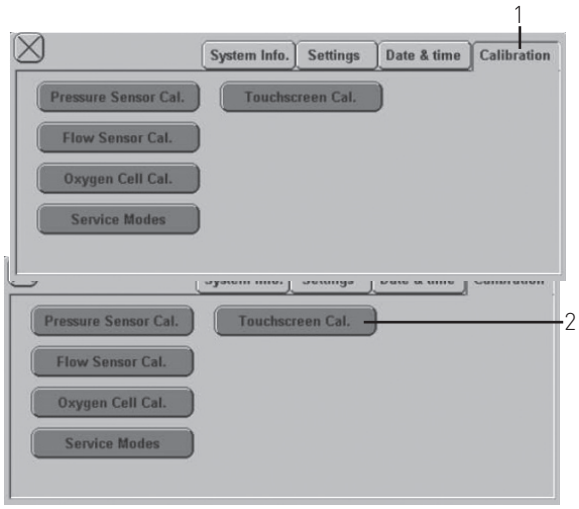
7.9 Touchscreen Calibration

CAUTION

Calibrate the touchscreen if the display is out of focus.

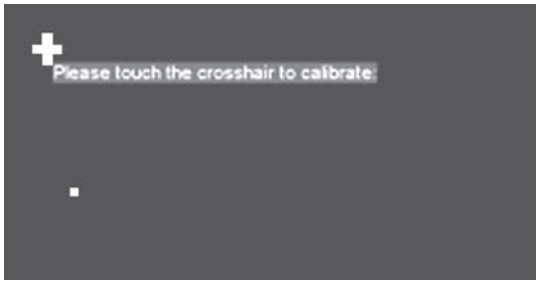
Procedure

1. Select Standby mode.
2. Press the System key.
3. Select the Calibration tab (1).
4. Select the Touchscreen Cal. option (2).
   A crosshair appears on screen.
5. Follow the on screen instructions.



NOTE

1. Touch the centre of the crosshair when it appears on screen – take care to carry this out accurately.
2. The crosshairs appear in a total of nine positions (four calibration points and five verification tests).



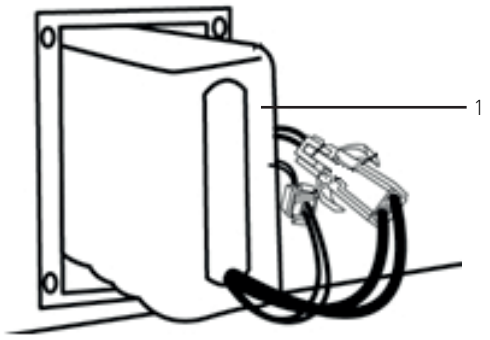
7.10 Prevention of Water Build-up

1. Water is formed by the condensation of exhaled gas and a chemical reaction between CO_2 and the soda lime in the absorber canister.
2. 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.
3. 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

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

7.11 Battery Replacement



WARNING

Battery installation must be undertaken by a competent, trained engineer.

1. Disconnect the machine mains power cable.
2. Remove the battery cover (illustrated in section 3.4), detach the battery (1) and disconnect the wiring.
3. Install a new battery and reconnect the wiring.
4. Refit the cover and tighten the four screws.

7.12 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
	Check valve is not installed correctly	Reinstall
	Manual / mechanical ventilation switch failure	Contact a Penlon-trained engineer
Bellows does not inflate completely	The respiratory rate is set too 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	Manual / mechanical ventilation 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 cannot 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. Contact a trained engineer
	Mains power outlet is faulty	Switch to another power outlet. Contact a trained engineer
	Fuse has blown	Contact a trained engineer. Diagnose the fault and fit a new fuse.
No power at auxiliary outlet	Fuse has blown	Contact a trained engineer. Diagnose the fault and fit a new fuse.
No airway pressure waveform	There is a disconnect between the pressure sensor and the sample tube, or: Gas source is exhausted	Reconnect. Check the gas supply

8. Appendix

Appendix 1 References

The Prima 320 Advance 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 the battery must only be undertaken by a trained engineer.

Appendix 3.

Appendix 3 Optional extras and approved accessories

WARNING

Only use accessories approved by Penlon Ltd.

Please contact Penlon Ltd (see below), or your local Penlon Distributor.

UK Sales

Tel: 01235 547036
E-mail: uk.sales@penlon.com

International Sales

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

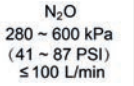
Accessories	
Hose - Air / O_2 / N_2O	Contact Sales Department
Exhalation diaphragm valve	5008688
Bellows - Latex free	5006441
O_2 sensor (MOX-4)	5008390
a) Adult adapter	5008685
b) Infant adapter	5008686
a) Sample tube (single use)	5008679
b) Water trap	5008678
Back-up battery	Contact Sales Department
SpO_2 monitor (optional)	Contact Sales Department
SpO_2 probe	5008690
CO_2 monitor (optional)	Contact Sales Department
Adult face mask	50244
Paediatric face mask	50240
Manual bag 3 L	2830000
Bacterial filter	1541197
Breathing circuit - silicon	2000000
Breathing circuit - paediatric - silicon	2142000
O_2 therapy flowmeter and tubing nipple with right angle, direct probe	5009161
Suction controller kit: High suction, with remote connector and V-plate, plus vacuum hose (4 m) and BS probe	5008959

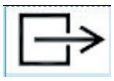
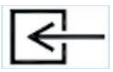
Masimo IRMA AX+ mainstream module

IRMA AX+ probes	107000086
IRMA airway adapter: Adult/ Pediatric	107000002
IRMA airway adapter: Infant	107000004

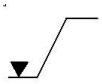
Appendix 4.

Appendix 4 Labelling

	Alternating current
	Dangerous Voltage
	Type BF equipment
	Battery
	AC power supply (Indicates a connection to mains)
	Power On
	Lighting
	Inspiratory flow
	Bag/manual ventilation
	Lock
	Flow control
	Oxygen sensor connector
	Cylinder
	N_2O supply connector

	Fuse
	General warning
	Type B equipment
	Defibrillator proof type BF equipment
	Gas Outlet
	Gas Inlet
	Equipotential
	Power Off
	USB Interface
	Expiratory flow
	Mechanical ventilation
	Unlock
	O_2 Flush button
	Bi-directional rotation

Appendix

O_2 280 ~ 600 kPa (41 ~ 87 PSI) ≤ 100 L/min	O_2 supply connector
AIR 280 ~ 600 kPa (41 ~ 87 PSI) ≤ 100 L/min	Air supply connector
AGSS	AGSS connector
	Multiple activated alarms ("x" indicates the number of active alarms)
	Audio pause
	Adjust the lower limit alarm parameters
	Caution
	Do not reuse
	Refer to instruction manual
	Handle with care
SN	Serial number
LOT	Batch code
CE XXX	CE marking and notified body number (XXX)
LATEX	Contains, or presence of, natural rubber Latex
	Temperature range limits

	Standby button
	Drive gas identification ("x" will be marked as O_2 or Air)
	Apnea alarm label - Spont mode only
	Alarm parameter adjustment cap
	Do not touch
	Identifies that the user needs to perform the operation
	Operating instructions
	Manufacturer and date of manufacture
	Recycle
REF	Part number
IP21	Protected against solid foreign objects of Φ12.5 mm and greater. 1: Protection against vertically falling water drops
	Keep dry
	Do not roll
	Upward direction

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

Appendix

	Hazardous waste (infectious) Components that must be disposed of as hazardous waste
	SpO_2 inlet connector
	Disconnect mains plug
	Disconnect gas
	Startup screen
	Alarm reset
	Standby
	Calibration port adjustment
	Do not obstruct
	Serial interface

Appendix 5.

Appendix 5 Sidestream CO_2 Module (optional)

Appendix 5.1 NMed 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.**

1. Description

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. Specification

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 anaesthetic 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

1. **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.**
2. **Do not reuse disposable sampling pipes.**

CAUTION

1. This module is to be used by trained professionals. Read the manual before using the module.
2. A single-use water trap must not be reused, to maintain accuracy and prevent damage to the module. The unit must not be shared between patients to prevent cross-infection.
3. Dispose of components in accordance with hospital regulations and in an environmentally safe manner.
4. To prevent damage and maintain accuracy always empty the water trap when it is nearly full. Check the level once a week at least.
5. The sampling tubes must not be bent. This will prevent pump overload and maintain accuracy of measurement.
6. Repairs must be made only by Penlon-trained engineers, or by the manufacturer.
7. 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.
8. Do not use the module for the measurement of exhaled gases. Exhaled moisture may cause measurement errors, and moisture accumulation may reduce module life.
9. Changes in temperature may affect measured data. Always use in stable temperature environments.
10. Any obstruction to the flow of the sample gas (e.g. tubing severely bent, contaminants blocking the sampling tube, filters blocked) may cause inaccurate measurements and damage. An obstruction lasting more than 20 seconds will trigger a pump shut down.
11. System risk detection conforms to EN1441: 1997 and EN62366 2008.
12. A pipeline leak will seriously affect the accuracy of measurement data and waveform shape.
13. 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 sampling components as illustrated.
Connect the sample tube to the water trap sample port.

Appendix 5.2 Masimo Nomoline ISA Sidestream CO_2 / AX+ / OR Module (optional)

CAUTION

The NomoLine ISA CO2/AX+/OR+ module is to be operated by, or under the supervision of, qualified personnel only.
Read this Appendix,the directions for use supplied with accessories, all precautionary information and specifications before use.
Refer to the other sections in this manual for additional safety information, warnings, and cautions.

1. Safety Warnings and Cautions

WARNINGS

1. Do not use this module if it appears or is suspected to be damaged. Damage to the device can result in exposed electrical circuits that may cause patient harm.
2. Do not adjust, repair, open, disassemble, or modify this module. Damage to the device may result in degraded performance and/or patient injury.
3. Do not start or operate this module unless the setup was verified to be correct. Improper set-up of this device may result in degraded performance and/or patient injury.
4. Do not place this module, or accessories in any position that might cause it to fall on the patient.
5. Only use Masimo authorized devices with this module. Using unauthorized devices with this module may result in damage to the device and/or patient injury.
6. Carefully route the sampling line to reduce the risk of patient entanglement or strangulation.
7. Do not lift the module by the NomoLine capnography sampling line. It might disconnect from the module, causing the module to fall on the patient.
8. Do not use the device during magnetic resonance imaging (MRI) or in an MRI environment.
9. Only use sample lines intended for anesthetic agents if N_2O and/or anesthetic agents are being used.
10. Do not re-use disposable single-patient-use NomoLine Family sampling lines, due to the risk of cross contamination.
11. Do not use the NomoLine Infant/Neonatal Airway Adapter Sets for adults/ pediatrics as they may cause excessive flow resistance (0,7 ml dead space).
12. Do not use the NomoLine Adult/Pediatric Airway Adapter Sets for infants/ neonates as the airway adapter adds 6 ml dead space.
13. Do not apply negative pressure to remove condensed water from the NomoLine Family sampling line.
14. Successful zeroing requires the presence of ambient air (21% O_2 and 0% CO_2). Therefore, ensure that the NomoLine ISA CO_2/AX+/OR+ is placed in a well ventilated place. Avoid breathing near the module before or during the zeroing procedure.
15. Exhaust gases should be returned to the patient circuit or to a scavenging system.
16. Due to the risk of patient cross-infection, always use a bacteria filter on the exhaust port side if sampled gas is intended to be re-breathed.

NOTE

1. Disconnect the device from AC mains by removing the device cable connection from the host device.
2. Use and store the NomoLine ISA CO_2/AX+/OR+ in accordance with specifications. See the Specifications section in this manual.

2. Performance Warnings and Cautions

WARNINGS

1. **NomoLine ISA CO_2/AX+/OR+ should not be used as the sole basis for** medical decisions. It must be used in conjunction with clinical signs and symptoms.
2. Use of high-frequency electrosurgical equipment in the vicinity of NomoLine ISA CO_2/AX+/OR+ may produce interference and cause incorrect measurements.
3. Do not use the NomoLine ISA CO_2/AX+/OR+ with metered-dose inhalers or nebulized medications as this may clog the bacteria filter.
4. Properly apply sampling lines according to the sampling lines directions for use. Misapplied sampling lines that become partially dislodged may cause no or incorrect readings.
5. Replace the sampling line if the sampling line input connector starts flashing red, or host device displays a check sampling line type of message.
6. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating properly.
7. Portable and mobile RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NomoLine ISA CO_2/AX+/OR+ including the cable. Otherwise, degradation of performance could result.
8. Excessive positive or negative pressure in the patient circuit might affect the sample flow.
9. Strong scavenging suction pressure might affect the sample flow.

CAUTIONS

1. Do not operate NomoLine ISA AX+ outside of the specified operating environment.
2. To avoid damage, the module should be mounted securely.

3. Cleaning and Service Warnings and Cautions

WARNINGS

1. To avoid electric shock, always physically disconnect the module and all patient connections before cleaning.
2. Do not attempt to remanufacture, recondition or recycle the module as these processes may damage the electrical components, potentially leading to patient harm.

CAUTIONS

1. Do not sterilize or immerse NomoLine Family sampling lines in liquid.

2. To avoid permanent damage to the module, do not use undiluted bleach (5% - 5.25% sodium hypochlorite) or any other cleaning solution not recommended by the manufacturer.
3. Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the module. These substances affect the device's materials and device failure can result.
4. Do not submerge the module in any cleaning solution, or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device.
5. To prevent damage, do not soak or immerse the module in any liquid solution.

4. Compliance Warnings and Cautions

WARNINGS

1. Any changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.
2. Use of accessories and cables other than those specified or provided could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
3. Make sure that the NomoLine ISA AX+ is used in the electromagnetic environment specified in this manual.
4. Dispose NomoLine Family sampling lines in accordance with local regulations for biohazardous waste.

CAUTIONS

1. Disposal of Product: Comply with local laws in the disposal of the device and/or its accessories.
2. For FCC compliance information, refer to this Operator's Manual.

NOTE

1. Use the NomoLine ISA CO_2/AX+/OR+ in accordance with the Environmental Specifications section in this Operator's Manual.

5. Intended Use

This sidestream gas analyzer and accessories (including NomoLine sampling lines) is intended to be connected to other medical backboard devices for monitoring of breath rate and the following breathing gases:

1. NomoLine ISA CO_2: CO_2
2. NomoLine ISA AX+: CO_2/N_2O/ Halothane/ Isoflurane/ Enflurane/ Sevoflurane/ Desflurane
3. NomoLine ISA OR+: CO_2/N_2O/ Halothane/ Isoflurane/ Enflurane/ Sevoflurane/ Desflurane/O_2
4. NomoLine ISA CO_2/AX+/OR+ is intended to be connected to a patient breathing circuit for monitoring of inspired/expired gases during anesthesia, recovery and respiratory care. The intended environment is the operating suite, intensive care unit and patient room. The intended patient population is adult, pediatric, infant and neonatal patients.

6. Specifications

General specifications	
Operating temperature	NomoLine ISA CO2: 0 to 50 °C (32 to 122 °F) NomoLine ISA OR+/AX+: 5 to 50 °C (41 to 122 °F)
Storage temperature	NomoLine ISA OR+: –30 to 70 °C (–22 to 158 °F) All other NomoLine ISA: –40 to 70 °C (–40 to 158 °F)
Operating humidity	10% to 95% RH (non-condensing) (Not requiring partial pressure greater than 50 hPa.)
Storage humidity	10% to 95% RH (non-condensing at ambient temperature) (Not requiring partial pressure greater than 50 hPa.)
Operating atmospheric pressure	525 mbar to 1,200 mbar (52.5 kPa to 120 kPa)
Storage atmospheric pressure	200 mbar to 1,200 mbar (20 kPa to 120 kPa)
Ambient CO2	≤800 ppm (0.08 vol%)
Power supply	4.5 to 5.5 VDC, NomoLine ISA CO2: ≤ 0.9 W (normal operation @ 5V) < 4.0 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up) NomoLine ISA AX+: ≤ 1.6 W (normal operation @ 5V) < 2.0 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up) NomoLine ISA OR+: ≤ 2.0 W (normal operation @ 5V) < 2.4 W (power surge @ 5V can last up to 500 ms when entering measurement mode from sleep mode or during start-up)
Recovery time after defibrillatortest	Unaffected
Drift of measurement accuracy	No drift
Water handling	NomoLine Family sampling lines with proprietary water removal tubing.
Sampling flow rate2	50 ± 10 sml/min
Data output	
Breath detection	Adaptive threshold, minimum 1 vol% change in CO2 concentration.
Respiration rate Measured at I/E ratio 1:1, using a breath simulator according to EN ISO 80601-2-55 fig.201.101.	0 to 150 ± 1 breaths/min

Fi and ET Measured according to EN ISO 80601-2-55	Fi and ET are displayed after one breath and have a continuously updated breath average. The following methods are used to calculate end-tidal (ET) values: **CO2:** The highest concentration of CO2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. **O2:** The highest/lowest concentration of O2 during the expiratory phase (depending on whether EtO2 is higher orlower than FiO2) **N2O and anesthetic agents:** The momentary gas concentration at the time point where EtCO2 is detected. ET will typically decrease below nominal value (ETnom) when respiration rate (RR) exceeds the RR threshold (RRth) according to the following formulas: **NomoLine ISA CO2:** CO2: ET = ETnom x √(95/RR) for RRth >95 **NomoLine ISA OR+/AX+** CO2: ET = ETnom x √(70/RR) for RRth 70 N2O, O2, DES, ENF, ISO, SEV: ET=ET nom x √(50/RR) for RRth 50 HAL ET = ETnom x √(35/RR) for RRth 35
Automatic agent identification	ISA OR+/AX+: Primary and secondary agent.
Flags	Breath detected No breaths detected Replace O2sensor Check sampling line Unspecified accuracy Sensor error
Gas Analyser	
Sensor head	**NomoLine ISA AX+/OR+:** Nine channel NDIR type gas analyzer measuring at 4 to 10 µm. Nine channel NDIR type gas analyzer measuring at 3.5 to 4.5 µm. **NomoLine ISA CO2:**Nine channel NDIR type gas analyzer measuring at 3.5 to 4.5 µm. Data acquisition rate 10 kHz (sample rate 20 Hz / channel).
Compensations	**NomoLine ISA CO2:** Automatic compensation for pressure and temperature. Manual compensation for broadening effects on CO2 **NomoLine ISA OR+/AX+:** Automatic compensation for pressure, temperature and broadening effects on CO2
Calibration	No span calibration is required. An automatic zeroing is performed 1 to 3 times per day

Warm-up time	**NomoLine ISA CO2:** < 10 seconds (concentrations reported and full accuracy) **NomoLine ISA OR+/AX+:** < 20 seconds (concentrations reported,automatic agent identification enabled and full accuracy)
Rise time at 50 ml/min sample flow	**NomoLine ISA CO2:** CO2 ⩽200 ms **NomoLine ISA OR+/AX+:** CO2 ⩽300 ms N2O, O2, ENF, ISO, SEV, DES⩽400 ms HAL⩽500 ms
Primary agent threshold (ISA OR+/AX+)	0.15 vol%. When an agent is identified, concentrations will be reported even below 0.15 vol%
Secondary agent threshold (ISA OR+/AX+)	0.2 vol% + 10% of total agent concentration
Agent identification time (ISA OR+/AX+)	< 20 seconds (typically < 10 seconds)
Analyzer system response time	ISA CO2 < 3 seconds ISA OR+/AX+ < 4 seconds (with 2m NomoLine HH Adult/Pediatric Airway Adapter Set)

Accuracy - standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa:

Gas	Range[1]	Accuracy
CO2	0 to 15 vol%	±(0.2 vol% + 2% of reading)
	15 to 25 vol%	Unspecified
N2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ENF, ISO	0 to 8 vol%	±(0.15 vol% + 5% of reading)
	8 to 25 vol%	Unspecified
SEV	0 to 10 vol%	±(0.15 vol% + 5% of reading)
	10 to 25 vol%	Unspecified
DES	0 to 22 vol%	±(0.15 vol% + 5% of reading)
	22 to 25 vol%	Unspecified
O2	0 to 100 vol%	±(1 vol% + 2% of reading)

Note: [1]All gas concentrations are reported in units of volume percent and may be translated into mmHg or kPa by using the reported atmospheric pressure.

Accuracy - all conditions

The following accuracy specifications are valid for all specified environmental conditions except for interference specified in section 2.6 (effects from water vapor partial pressure on gas readings) and section 2.7 (interfering gas effects)

Gas	Accuracy
Gas	Accuracy
CO2	±(0.3 kPa + 4% of reading)

N2O	±(2 kPa + 5% of reading)
Agents2	±(0.2 kPa + 10% of reading)
O2	±(2 kPa + 2% of reading)

Effects from water vapor partial pressure on gas readings

When the breathing gas flows through the sampling line, the gas temperature will adapt to the ambient temperature before reaching the gas analyzer. The measurement of all gases will always show the actual partial pressure at the current humidity level in the gas sample.

As the NOMO section removes all condensed water, no water will reach the NomoLine Capnography gas analyzer. However at an ambient temperature of 37°C and a breathing gas with a relative humidity of 95% the gas reading will typically be 6% lower than corresponding partial pressure after removal of all water.

Interfering Gas and Vapor Effect

Gas or Vapor	Gas Level	CO2		Agents	N2O
		ISA CO2	ISA AX+/OR+		
N2O[4]	60 vol%	– 2	–1	–1	–1
HAL[4]	4 vol%	–1	–1	–1	–1
ENF, ISO, SEV[4]	5 vol%	+8% of reading [3]	–1	–1	–1
DES[4]	15 vol%	+12% of reading [3]	–1	–1	–1
Xe (Xenon) [4]	80 vol%	-10% of reading [3]			
He (Helium) [4]	50 vol%	+6% of reading [3]			
Metered dose inhaler propellants[4]	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol) [4]	0.3 vol%	–1	–1	–1	–1
C3H7OH (Isopropanol) [4]	0.5 vol%	–1	–1	–1	–1
CH3COCH3 (Acetone) [4]	1 vol%	–1	–1	–1	–1
CH4 (Methane) [4]	3 vol%	–1	–1	–1	–1
CO (Carbon monoxide) [5]	1 vol%	–1	–1	–1	–1
NO (Nitrogen monoxide) [5]	0.02 vol%	–1	–1	–1	–1
O2 [5]	100 vol%	–2	–2	–2	–1

Note 1: Negligible interference, effect included in the specification "Accuracy, all conditions" above.

Note 2: Negligible interference with N2O / O2 concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.

Note 3: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% CO2 and 50 vol% Helium, the actual measured CO2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO2.

Note 4: According to the EN ISO 80601-2-55:2011 standard.

Note 5: In addition to the EN ISO 80601-2-55:2011 standard.

Troubleshooting Nomoline ISA AX+ / OR+ / CO2		
Symptom	**Possible Cause**	**Correction**
NomoLine ISA AX+/OR+/CO2 values are not displayed on host device	• NomoLine ISA AX+/OR+/CO2 requires a power cycle • Host device is not configured correctly or is incompatible with NomoLine ISA AX+/OR+/CO2	• Disconnect and reconnect the NomoLine ISA AX+/OR+/CO2 connector at the host device. • Verify that the host device is correctly configured and compatible
LEGI indicator is dark (indicator is off)	• NomoLine ISA AX+/OR+/CO2 is not plugged in to the host device connector • Sampling line not plugged in to NomoLine ISA AX+/OR+/CO2 completely • Internal error	• Verify NomoLine ISA AX+/OR+/CO2 connection to the host device. • Disconnect and reconnect the sampling line to NomoLine ISA AX+/OR+/CO2. • The NomoLine ISA AX+/OR+/CO2 requires service.
LEGI indicator blinking red	• Sampling line obstructed (occlusion)	• Inspect sampling line for occlusion (blockage, kink in line). • Replace sampling line. See Sampling Line Replacement on 5.2.
LEGI indicator steady red	• NomoLine ISA AX+/OR+/CO2 requires a power cycle • Internal error	• Disconnect and reconnect the NomoLine ISA AX+/OR+/CO2 connector at the host device. • If persistent, the NomoLine ISA AX+/OR+/CO2 requires service.
Gas readings are questionable	• Incorrect sampling line used • Sampling line attached incorrectly • Sampling line leaking • Internal error	• Use the correct sampling line with NomoLine ISA AX+/OR+/CO2. • Disconnect and reconnect the sampling line to NomoLine ISA AX+/OR+/CO2. • Follow the Directions for Use to properly connect the sampling line. • Inspect sampling line for leaks. • Replace sampling line. See Sampling Line Replacement on 5.2. • Perform an Operational Check. • If persistent, the NomoLine ISA AX+/OR+/CO2 requires service.

Operation

LEGI Indicator

The Light Emitting Gas Inlet (LEGI) Indicator provides visual indications of measurement status. The LEGI Indicator (1) is located around the input connector on the front of the device.

The LEGI indicator illuminates in different colors depending on the state of the device as described in the table:

LEGI Indicator	Status
Steady green light	Capnography monitoring in operation and OK
Blinking green light	Zeroing in progress. See Zeroing on page 34.
Steady blue light	Anesthetic agent present
Steady red light	Sensor error
Blinking red light	Check the sampling line (possible occlusion)

Description

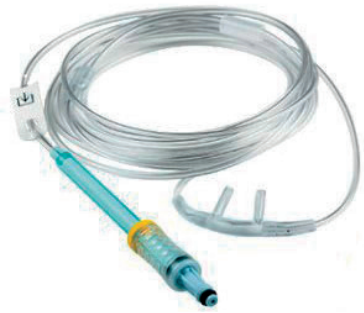
Nomoline Sampling Lines

NomoLine ISA AX+/OR+/CO2 samples gas from the respiratory circuit through the NomoLine Family sampling line at a rate of 50 sml/min, making measurements of CO2, O2, N2O, and anesthetic agents possible for adult, pediatric, infant and neonatal patients. The NomoLine Family of sampling lines are designed for optimal performance and measurement fidelity when used with the NomoLine ISA AX+/OR+/CO2 gas analyzers.

NomoLine sampling lines include nasal and nasal/oral cannulas for non-intubated patients with and without supplementary oxygen delivery and airway adapter sets for intubated patients.

As long as no sampling line is connected, the NomoLine ISA AX+/OR+/CO2 gas analyzer remains in a low-power sleep mode. Once the sampling line is connected, the NomoLine ISA AX+/OR+/CO2 gas analyzer switches to measuring mode and starts delivering measurement data.

Sampling Line Replacement



NomoLine sampling lines should be replaced between each patient or when the sampling line becomes occluded.

Occlusion occurs when water, secretions etc. are aspirated from the respiratory circuit to such an extent that NomoLine ISA AX+/OR+/CO2 cannot maintain the normal 50 ml/min sample flow.

This is indicated by a red flashing LEGI indicator and an alarm message; replace the sampling line and wait until the LEGI indicator switches to green, indicating that the NomoLine ISA AX+/OR+/CO2 gas analyzer is again ready for use.

Appendix

Set O_2 range compensation

Range:

0 - 30 vol%	Low
30 - 70 vol%	Medium
70 - 100 vol%	High

Set N_2O compensation range compensation

Range:

0 - 30 vol%	Off
30 - 70 vol%	On
70 - 100 vol%	High

Ti set compensation for O_2 and N_2O

Refer to section 6.2.9

Appendix 6.

Appendix 6 Masimo IRMA AX+ Mainstream module (optional)

WARNING

1. **The IRMA probe is intended for use by qualified medical personnel only.**
2. **The IRMA probe is intended only as an adjunct in patient assessment. It must be used in conjunction with other assessments of clinical signs and symptoms.**
3. **Disposable IRMA airway adapters shall not be reused. Reuse of the single use adapter can cause cross infection.**
4. **Used airway adapters shall be disposed of in accordance with local regulations for biohazardous waste.**
5. **Do not use the IRMA Adult/Pediatric airway adapter with infants as the adapter adds 6 ml dead space to the patient circuit.**
6. **Do not use the IRMA Infant airway adapter with adults as this may cause excessive flow resistance.**
7. **Measurements can be affected by mobile and RF communications equipment. It should be assured that the IRMA probe is used in the electromagnetic environment specified in this manual.**
8. **Use of high frequency electrosurgical equipment in the vicinity of IRMA may produce interference and cause incorrect measurements.**
9. **The IRMA probe is not designed for MRI-environments.**
10. **Do not place the IRMA airway adapter between the endotracheal tube and an elbow as this may allow patient secretions to block the adapter windows and result in incorrect operation.**
11. **To keep secretions and moisture from pooling on the windows, always position the IRMA probe in a vertical position with the LED pointing upwards.**
12. **Do not use the IRMA airway adapter with metered dose inhalers or nebulized medications as this may affect the light transmission of the airway adapter windows.**
13. **Incorrect probe zeroing will result in false gas readings.**
14. **Replace the airway adapter if rainout/condensation occurs inside the airway adapter.**
15. **Use only Masimo manufactured IRMA airway adapters.**
16. **The IRMA probe is not intended to be in patient contact.**
17. **If, for whatever the reason, the IRMA probe is in direct contact with any parts of the infant's body an insulation material shall be placed between the IRMA probe and the body.**
18. **No modification of this equipment is allowed.**

CAUTION

1. Never sterilize or immerse the IRMA probe in liquid.
2. The IRMA airway adapters are non-sterile devices. Do not autoclave - this will damage them.

3. **Do not apply tension to the probe cable.**
4. **Do not operate the IRMA probe outside the specified operating temperature environment.**
5. **(U.S. only) Caution: Federal law restricts this device to sale by or on the order of a physician. For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.**

Intended use

The IRMA mainstream gas analyzer is intended to be connected to other medical devices for monitoring of breath rate and the breathing gases CO_2, N_2O and the anesthetic agents Halothane, Enflurane, Isoflurane, Sevoflurane and Desflurane.

It is intended to be connected to a patient breathing circuit for monitoring of inspired/ expired gases during anesthesia, recovery and respiratory care. It may be used in the operating suite, intensive care unit and patient room for adult, pediatric and infant patients. IRMA CO_2 may also be used jn the emergency medical services environment and road ambulances.

NOTE:

The IRMA mainstream gas analyzer shall only be connected to medical backboard devices approved by Masimo Sweden AB.

TechnicalSpecifications

General specifications

Description	Extremely compact infrared mainstream multigas probe available in two parameter configurations.
Dimensions (W×D×H)	38 x 37 x 34 mm (1.49" × 1.45" × 1.34")
Cable length	2.5 m ±0.1 m
Weight	< 25 g (cable excluded)
Operating temperature	IRMA AX+: 10–40°C , 50–104°F
Storage temperature	-40–70°C, -40–158°F
Operating humidity	< 50 hPa H2O (non-condensing) (68 %RH at 40 °C)
Storage humidity	10–95% RH (95 %RH at 40 °C)
Operating atmospheric pressure	525–1200 hPa (525 hPa corresponding to an altitude of 5211 m / 17 100 feet)
Storage atmospheric pressure	500 to 1200 hPa (500 hPa corresponding to an altitude of 5572 m / 18 280 feet)
Mechanical strength	Withstands repeated 1.8 m drops on a hard surface. Complies with requirements for (a) shock and vibration for professional transportation according to EN ISO 80601-2-55:2011, and (b) for road ambulances according to to EN ISO 80601-2-55:2018 and EN 60601-1-12:2015.
Power supply	IRMA AX+: 4.5-5.5 VDC, max 1.4 W (power on surge @ 5 V less than 350 mA during 200 ms)
Recovery time after defibrillator test	Unaffected
Drift of measurement accuracy	No drift
Surface temperature (at ambient temp: 23°C)	IRMA AX+: Max 46°C / 115°F
Interface	Modified RS-232 serial interface operating at 9600 bps.

Airway adapters	Disposable adult/pediatric: - Adds less than 6 ml deadspace. - Pressure drop less than 0.3 cm H2O @ 30 LPM. Disposable infant: - Adds less than 1 ml deadspace. -Pressure drop less than 1.3 cm H2O @ 10 LPM. Note: Infant airway adapter is recommended for tracheal tube ID size ≤4 mm.

Data output

Breath detection	Adaptive threshold, minimum 1 vol % change in CO_2 concentration.
Respiration rate[2]	0–150 ±1 bpm. The respiration rate is displayed after three breaths and the average value is updated every breath.
Fi and ET2	IRMA AX+: CO_2, N_2O, primary and secondary agents (HAL, ISO, ENF, SEV, DES). Fi and ET are displayed after one breath and have a continually updated breath average. The following methods are used to calculate end-tidal (ET) values: CO_2: The highest concentration of CO_2 during one breathing cycle with a weight function applied to favor values closer to the end of the cycle. N_2O and anaesthetic agents: The momentary gas concentration at the time point where $ETCO_2$ is detected. ET-values for anaesthetic agents and N_2O (IRMA AX+) will typically decrease below nominal value when respiration rate exceeds 80 bpm. The maximum decrease is described by the formula ET = 80*ETnom/RR. $ETCO_2$ will be within specification for all respiration rates up to 150 bpm
Automatic agent identification	IRMA AX+:Primary and secondary agent.

Gas analyzer

Probe	2-9channel ND IR type gas analyzer measuring at 4–10µm. Data acquisition rate 10 kHz (sample rate 20 Hz/channel). Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+) No span calibration required for the IR bench.
Warm-up time	IRMA AX+: <20 s. (agent identification enabled and full accuracy)
Rise time (@ 10 l/min)	CO_2≤ 90ms 2O≤ 300ms HAL,ISO,ENF,SEV,DES≤ 300ms
Primary agent threshold	0.15 vol %. When an agent is identified, concentrations will be reported 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 < 10 seconds)
Total system response time	< 1 second
Probe	2-9 channel ND IR type gas analyzer measuring at 4–10µm. Data acquisition rate 10 kHz (sample rate 20 Hz/channel). Pressure, temperature and full spectral interference correction.
Calibration	Zeroing recommended when changing Airway adapter (IRMA AX+). No span calibration required for the IR bench.

Appendix

Accuracy-standard conditions

The following accuracy specifications are valid for dry single gases at 22 ± 5 °C and 1013 ± 40 hPa.

Gas	Range	Accuracy
CO_2	0 to 15 vol%	±(0.2 vol% + 2% of reading)
N_2O	0 to 100 vol%	±(2 vol% + 2% of reading)
HAL, ISO, ENF	0 to 8 vol%	±(0.15 vol% + 5% of reading)
SEV	0 to 10 vol%	±(0.15 vol% + 5% of reading)
DES	0 to 22 vol%	±(0.15 vol% + 5% of reading)

Accuracy-all conditions

The following accuracy specifications are valid for all specified environmental conditions - except for interference specified in "Effects from water vapor partial pressure on gas readings" and "Interfering gas effects" (see below.

Gas	Accuracy
CO_2	±(0.3 kPa + 4% of reading)
N_2O	±(2 kPa + 5% of reading)
Agents	±(0.2 kPa + 10% of reading)

Effects from water vapor partial pressure on gas readings

The effects of water vapor are illustrated by the examples in the following table. The two columns to the right show the relative error in displayed concentrations when adding or removing water vapor from the gas mixture, and referencing the measurement to dry gas conditions at actual temperature and pressure (ATPD) or saturated conditions at body temperature (BTPS).

Temp [C]	RH[%]	P [hPa]	H2O part.pres. [hPa]	errrel [%]	errrel ATPD [%]	errrel [%] BTPS
10	20	1013	2	0	-0.2	+6.0
20	20	1013	5	0	-0.5	+5.7
25	0	1013	0(ATPD)	0	0	+6.2
25	23	1013	7.3	0	-0.7	+5.5
25	50	1013	16	0	-1.6	+4.6
30	80	1013	42	0	-4.1	+2.0
37	100	1013	63(BTPS)	0	-6.2	0
37	100	700	63	0	-9.0	-2.8

The table illustrates that the gas concentrations in the alveoli, where the breathing gas is saturated with water vapor at body temperature (BTPS), are 6.2% lower than the corresponding concentrations in the same gas mixture after removal of all water vapor (ATPD).

Interfering gas effects

Gas or vapor	Gas level	CO_2		Agents	N_2O
		ISA CO_2	ISA AX+ ISA OR+		
N_2O [4]	60 vol%	–[2]	–[1]	–[1]	–[1]
HAL[4]	4 vol%	–[1]	–[1]	–[1]	–[1]
ENF, ISO, SEV[4]	5 vol%	+8% of reading[3]	–[1]	–[1]	–[1]
DES[4]	15 vol%	+12% of reading[3]	–[1]	–[1]	–[1]

Xe (Xenon)[4]	80 vol%	–10% of reading[3]	–[1]	–[1]	
He (Helium)[4]	50 vol%	–6% of reading[3]	–[1]	–[1]	
Metered dose inhaler propellants[4]	Not for use with metered dose inhaler propellants				
C2H5OH (Ethanol)[4]	0.3 vol%	–[1]	–[1]	–[1]	–[1]
C3H7OH (Isopropanol)[4]	0.5 vol%	–[1]	–[1]	–[1]	–[1]
CH3COCH3 (Acetone)[4]	1 vol%	–[1]	–[1]	–[1]	–[1]
CH4 (Methane)[4]	3 vol%	–[1]	–[1]	–[1]	–[1]
CO (Carbon monoxide)[5]	1 vol%	–[1]	–[1]	–[1]	–[1]
NO (Nitrogen monoxide)[5]	0.02 vol%	–[1]	–[1]	–[1]	–[1]
O_2 [5]	100 vol%	–[2]	–[2]	–[1]	–[1]

[1]: Negligible interference, effect included in the specification "Accuracy, all conditions" above.
[2]: Negligible interference with N_2O / O_2concentrations correctly set, effect included in the specification "Accuracy, all conditions" above.
[3]: Interference at indicated gas level. For example, 50 vol% Helium typically decreases the CO_2 readings by 6%. This means that if measuring on a mixture containing 5.0 vol% $CO_2$and 50 vol% Helium, the actual measured CO_2 concentration will typically be (1-0.06) * 5.0 vol% = 4.7 vol% CO_2.
[4]: According to EN ISO 80601-2-55:2011.
[5]: In addition to EN ISO 80601-2-55:2011.

Symbols used

Symbol	Title	Notes
REF	Catalog number	200601 = IRMA AX+ (CO_2, N_2O, 5 AA, AA ID) 200604 = IRMA AX+ (CO_2, N_2O, 5 AA, AA ID) 200607 = IRMA AX+ LEMO (CO_2, N_2O, 5 AA, AA ID)
	Pressure limitation	
	Humidity limitation	
	Waste Electrical and Electronic Equipment (WEEE)	Electrical and electric equipment shall be collected and recycled in accordance with (Directive 2002/96/EC)
IP44	IP classification indicating degree of protection against ingress of solid foreign objects and water	IPX4 = "splash-proof"
Rx ONLY	Rx only	Caution (U.S.): Federal law restricts this device to sale by or on the order of a physician
	Zero-point adjustment	IRMA Airway Adapterbox indicating recommendation to perform zeroing of IRMA AX+ when changing airway adapter.
	Time delay before adjustment of zero-point	IRMA Airway Adapter indicating time delay before zeroing the of IRMA AX+ when changing airway adapter.

System set-up

1. Plug the AG module connector into the input of the Anaesthetic machine and switch the power on.

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

3. Depending on IRMA model, perform the following

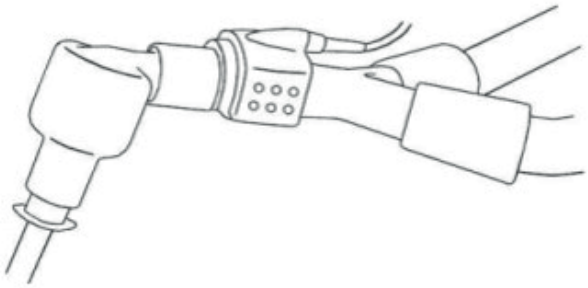
IRMA AX+
• Wait minimum 30 seconds • Perform zeroing

4. A green LED indicates that the IRMA probe is ready for use.

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

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

Alternatively; connect a HME (Heat Moisture Exchanger) between the patient's endotracheal tube and the IRMA probe. Placing a HME in front of the IRMA probe protects the airway adapter from secretions and effects of water vapor and eliminates the need of changing the adapter. It allows free positioning of the IRMA probe as well.



7. Unless the IRMA probe is protected with a HME always position the IRMA probe with the status LED pointing upwards.

Placement of IRMA Probe

When connecting the IRMA probe to an infant patient circuit it is important to avoid a direct contact between the IRMA probe and the infant's body due to the elevated surface temperature of the IRMA Probe.

WARNING

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

CAUTION

The IRMA probe is not intended to be in patient contact.

Pre-use check

Always verify gas readings and waveforms on the medical backboard device before connecting the IRMA airway adapter to the patient circuit.

Perform the tightness check of the patient circuit according to the User Manual for the medical backboard device with the IRMA probe snapped on the IRMA airway adapter.

Zeroing

WARNING

Incorrect probe Zeroing will result in false gas readings.

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

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 medical backboard device to transmit a Zero reference command to the IRMA probe.

Special care should be taken to avoid breathing near the airway adapter before or during the Zeroing procedure. The presence of ambient air in the IRMA airway adapter is of crucial importance for a successful Zeroing. If a "AA ID Unreliable!!" alarm should appear directly after a Zeroing procedure, the procedure must be repeated.

Always perform a pre-use check after Zeroing the probe.

For the IRMA AX+ module zero calibration button "Gas Module Zero Calibration" please refer to the chapter "6.2.12 Calibration"

IRMA AX+ probes:

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.

Allow 30 seconds for warm up of the IRMA AX+ probes 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.

Alarms

See Section 6.11.6 for a complete description of the alarm handling related to the IRMA mainstream gas analyzer.

Status LED on the IRMA probe:

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

Cleaning

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

CAUTION

1. **The IRMA airway adapters are non-sterile devices. Do not autoclave the devices as this will damage them.**
2. **Never sterilize or immerse the IRMA probe in liquid.**

Gas span check

Gas readings should be verified at regular intervals with a reference instrument or with calibration gas. The suggested interval for gas span check is once every year.

MAC (Minimum Alveolar Concentration) calculation

Minimum alveolar concentration (MAC) is a standard for comparing the potency of inhalation anesthetics. 1 MAC represents the end-tidal concentration of an agent (at sea level) that, in 50 percent of a testedpopulation, prevents gross muscular movement in response to a painful, standardized stimulus.

If a mechanism to determine MAC values is implemented in the host device, the algorithms used for this calculation must be adequately documented.

The MAC value may be calculated and displayed by using end-tidal (Et) gas concentrations according to the following formula:

$$MAC = \frac{\%Et(AA1)}{X(AA1)} + \frac{\%Et(AA2)}{X(AA2)} + \frac{\%Et(N2O)}{100}$$

X(AA): HAL=0.75%, ENF=1.7%, ISO=1.15%, SEV=2.05%, DES=6.0%

Note: Altitude, patient age and other individual factors are not considered in the formula above.

Spectral broadening

The presence of oxygen and nitrous oxide can cause some interference in the CO_2 measurement. This is known as spectral broadening, and must be compensated.

To ensure that the carbon dioxide measurement is accurate enough, the oxygen concentration is divided into three ranges: "high", "medium" and "low" compensation buttons. By using the above compensation button and the corresponding O_2 range value in the table below to set the relevant compensation, the maximum relative error of carbon dioxide will be limited to 1.2%.

Set O_2 range - compensation

Range:

0 - 30 vol%	Low
30 - 70 vol%	Medium
70 - 100 vol%	High

Appendix 7. Electromagnetic compatibility (EMC)

Electromagnetic environment

The Prima 320 Advance is suitable for use in the specified electromagnetic environment. The user should assure that it is used in an electromagnetic environment as described below.

Changes or modifications to this device, not expressly approved by Penlon Limited, could result in EMC issues with this device. 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 this device is to provide controlled concentrations and flows of anaesthesia gases into a patient breathing system.

WARNING

The device should not be used adjacent to or stacked with other manufacturer's equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

Cables, transducers, and accessories

WARNING

The device 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 this device.

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.

Cables supplied by Penlon Limited

Category	Function	Length (m)
AC mains supply input/output ports	Hospital mains supply to the input port (cable is fixed to the Prima 320 Advance.	⩽3.9
Oxygen sensor cable (Prima 320 Advance with an oxygen sensor on the absorber).	Connects the oxygen sensor on the absorber to the Prima 320 Advance	0.6

Guidance and manufacturer's declaration – electromagnetic emissions

This device is intended for use in the electromagnetic environment specified below.
The customer or user should assure that it is used in such an environment.

Required test	Compliance	Comments
RF emissions CISPR 11	Group 1 Class A	Class A equipment is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes, 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 NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity

This device is intended for use in the electromagnetic environment specified below. The customer or user of the device should assure that it is used in such an environment.

Required test	60601 test levels for equipment used in a professional healthcare facility environment only	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	± 8 kV contact ± 2, 4, 8, 15 kV air
Radiated RF EM Fields IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz
Proximity fields from RF wireless communications IEC 61000-4-3	Frequency - Test level 385 MHz - 27 V/m 450 MHz - 28 V/m 710 MHz – 9 V/m 745 MHz – 9 V/m 780 MHz – 9 V/m 810 MHz - 28 V/m 870 MHz - 28 V/m 930 MHz - 28 V/m 1.72 GHz - 28 V/m 1.845 GHz - 28 V/m 1.97 GHz - 28 V/m 2.45 GHz - 28 V/m 5.24 GHz – 9 V/m 5.50 GHz – 9 V/m 5.875 GHz – 9 V/m	Frequency - Test level 385 MHz - 27 V/m 450 MHz - 28 V/m 710 MHz – 9 V/m 745 MHz – 9 V/m 780 MHz – 9 V/m 810 MHz - 28 V/m 870 MHz - 28 V/m 930 MHz - 28 V/m 1.72 GHz - 28 V/m 1.845 GHz - 28 V/m 1.97 GHz - 28 V/m 2.45 GHz - 28 V/m 5.24 GHz – 9 V/m 5.50 GHz – 9 V/m 5.875 GHz – 9 V/m
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
Surge IEC 61000-4-5	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines ± 2 kV line(s) to earth for input / output lines	± 0.5, 1, 2 kV line(s) to earth, ± 0.5, 1 kV line(s) to line(s) for power supply lines
Conducted RF IEC 61000-4-6	3 V - 150 kHz to 80 MHz 6 V - ISM bands between 150 kHz to 80 MHz	3 V - 150 kHz to 80 MHz 6 V - ISM bands between 150 kHz to 80 MHz
Voltage dips and interruptions IEC 61000-4-11	0% UT (100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250/300 cycles	0% UT (100% dip in UT) for 0.5 cycle 0% UT (100% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles 0% UT (100% dip in UT) for 250/300 cycles
Power frequency (50 Hz) Magnetic field IEC 61000-4-8	30 A/m	30 A/m

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