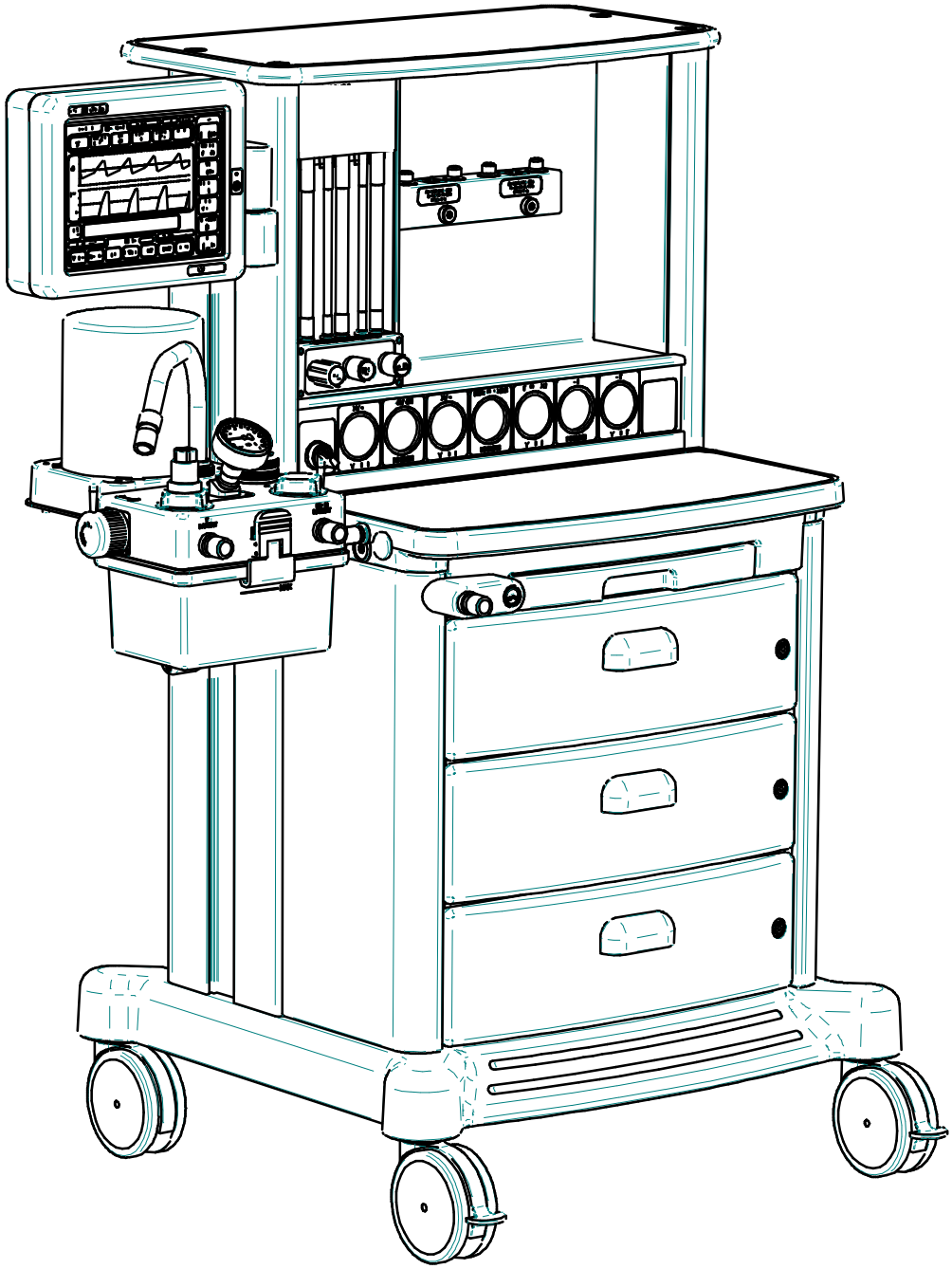
Gradian Health Systems®

Gradian C-AM
User Manual

Gradian C-AM



Gradian Classic Anaesthesia Machine with Integrated Ventilator and Airway Gas Monitor User Manual

Doc number 1973-512 Issue A Nov 2020

CE 1639

HOW TO GET HELP

EMAIL: service@gradianhealth.org
WEB: www.gradianhealth.org
WHATSAPP: +254 794 764 415
ADDRESS: Gradian Health Systems
40 W 25th St., 6th Floor
New York, NY 10010, USA

GENERAL DESCRIPTION OF THE GRADIAN C-AM

The Gradian Classic Anaesthesia Machine (C-AM) is a fully featured high-end anaesthesia workstation for the modern operating room. It combines all the benefits of an integrated system with the flexibility and ease of use of a modular design. The Gradian C-AM incorporates a proven and well-tested conventional flow control system with a mechanical anti-hypoxic system ensuring maximum patient safety. A multifunction anaesthesia ventilator is fully integrated into the machine and is designed for adult and paediatric use, with full integration with both the absorber and anaesthetic machine. The ventilator also features several advanced ventilation modes, including volume-control and pressure-control. The Gradian C-AM is CE marked.

GENERAL DESCRIPTION OF GRADIAN HEALTH SYSTEMS

Gradian Health Systems is a nonprofit medical technology company that works to transform the impact of medical equipment in resource-constrained hospitals around the world. We develop, distribute, and sustain medical devices and provide local, hands-on training and customer support. Gradian products, including the Gradian UAM (Universal Anaesthesia Machine), the Gradian C-AM (Classic Anaesthesia Machine), and the Gradian CCV (Comprehensive Care Ventilator), are in health facilities across more than 30 countries across Africa, Asia, and Central America.

IMPORTANT NOTE

All references to “Astra 3i” or “Astra,” “C-AM,” “C-AM ventilator,” “C-AM anaesthesia ventilator,” or “Integrated C-AM Ventilator” in this manual are to be interpreted as references to the Gradian C-AM (Gradian Classic Anaesthesia Machine).

The Gradian C-AM is manufactured by OES Medical Ltd., but is distributed by Gradian Health Systems. All inquiries regarding the Gradian C-AM should be directed to Gradian Health Systems by emailing service@gradianhealth.org or calling or messaging +254 794 764 415 on Whatsapp.

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Modification Record				
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First Issue				

OES Medical Ltd
ABC House,
Cotswold Dene
Standlake,
Witney,
Oxfordshire,
England.
OX29 7QG

Phone 0044 (0) 1865 301711
Fax 0044 (0) 1865 301573
E mail sales@oes-medical.co.uk
www.oes-medical.co.uk

This manual applies from the following software versions or later:

Software version	1.5.1
Hardware version	1.40.1
Mechanical version	1.0.0

See section 3.2 (Operating the Ventilator) for information on which software version is currently installed

CE
1639

This CE mark demonstrates that the device is compliant with the relevant Medical Device Directive and reviewed by the notified body allocated this registration number.

This user Manual is constructed in 5 sections

Section 1 Notices and important information
Section 2 Gradian Classic Anaesthesia Machine (C-AM)
Section 3 C-AM Anaesthetic Ventilator
Section 4 Airway Gas Monitor
Section 5 Hydra Absorber

Table of Contents

Section 1

Notices and important information

Section 1 Notices and Important Information

1 Forward

This user instruction manual has been produced to provide authorised personnel with information on the function, performance and regular maintenance checks applicable to the Gradian Classic Anaesthesia Machine (C-AM) with integrated Anaesthesia Ventilator. Users must make themselves familiar with the contents of this manual and the machine with ventilator's (anaesthesia system) function before use.

2 The Importance of Patient Monitoring

WARNING: Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist, however it is essential that the condition of the patient respiration and cardio-vascular system are monitored frequently and regularly and that any patient observations are given precedence over machine control parameters in judging the state of a clinical procedure. There can be considerable variation in the effect of anaesthetic drugs on individual patients so that the setting and observation of control levels on the anaesthesia systems does not in itself ensure total patient safety.

It is essential that these elements are monitored frequently and regularly and that any observations are given precedence over machine control parameters in judging the state of a clinical procedure.

Before using any monitoring system or device with the anaesthetic system, the user must check that it conforms to the latest revision of the relevant standard.

3 User Responsibility

General

This anaesthetic system has been built to conform with the specifications 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.

The user must ensure the safety of the anaesthetic system before each use. It must be pre-use checked and serviced to at least the minimum standards laid out in this manual and a defective, or suspected defective ventilator must not under any circumstances be used.

The user accepts responsibility for any malfunction that results from non-compliance with the pre-use checks, service or maintenance requirements detailed in this manual. Additionally, the user must accept responsibility for any malfunction that may result from misuse of any kind or non- compliance with other requirements detailed in this manual.

Should any repair become necessary it is recommended that a request for service advice be made to OES Medical or its agents.

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

To reduce the probability of cross infection from one patient to another it is recommended that good clinical practice is maintained and that the machine side of any breathing system is protected with a new breathing circuit filter for each patient.

It is the responsibility of the user to read this manual and fully understand the functions of this anaesthetic system prior to use.
No clinical advice on the use of this anaesthesia system is given or implied within this manual, the various technical functions are described and it’s use by the anaesthetist must be based on safe best clinical practice using all necessary additional patient monitoring considered necessary for patient safety.

It is the responsibility of the person installing and configuring this ventilator for use as an anaesthesia system to ensure that sufficient user instructions and check lists are provided to ensure its safe use.

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 a more efficient and convenient operation

Always take particular notice of warnings, cautions and notes provided throughout this manual.

Electrostatic Sensitive Device

The ventilator uses semiconductors which are susceptible to damage by electrostatic discharge.

During normal use the ventilator must be provided with a ground to earth.

Always transport the ventilator in a conductive bag or container.

Never place the ventilator on ungrounded surface – avoid synthetic (non-conductive) carpeting and cellophane wrappers etc.

In addition to ESD, Lethal voltages are present within the ventilator when it is connected to the mains electrical supply. Do not remove any ventilator covers

Indications for Use

The C-AM is designed to provide controlled concentrations and flows of anaesthetic gases and vapours into the patient breathing system.

The C-AM can be used with both open, semi open and closed and semi closed patient circuits.

The C-AM ventilator is designed “To provide controlled volumes and pressures of anaesthesia breathing gases into a patient breathing system, monitor ventilation parameters and inspiratory oxygen levels"

Device Configuration

The C-AM with ventilator is classified as an anaesthesia system and shall be configured for use with the following relevant modules to ensure adequate patient safety during use:

- Pressure measuring	IEC 80601-2-13 51.101.1
- Pressure limitation device	IEC 80601-2-13 51.101.1
- Exhaled volume monitor	IEC 80601-2-13 51.101.4
- Breathing system integrity alarm system	IEC 80601-2-13 51.101.5
- Continuing pressure alarm	IEC 80601-2-13 51.101.6
- Anaesthetic agent delivery	IEC 80601-2-13 51.101.7
- Breathing systems	IEC 80601-2-13 51.101.8
- Transfer and receiving system	IEC 80601-2-13 51.101.5
- O2 monitor	BS EN ISO 80601-2-55
- Agent monitor	BS EN ISO 80601-2-55
- CO2 monitor	BS EN ISO 80601-2-55

Warnings and cautions

Warning – the Gradian Classic Anaesthesia Machine (C-AM) must be function checked and serviced in compliance with the schedule advised: Under no circumstances must it be used in a malfunctioning condition.
If in doubt consult the local service expert or contact Gradian Health directly at the listed contact point for advice

Warning - This equipment must only be used and operated by a clinician who is suitably approved and trained in the use of the Gradian Classic Anaesthesia Machine (C-AM).

Warning - The use of patient monitoring during the use of this anaesthetic system is essential for patient safety.

Warning - Use no oil or grease in the presence of medical equipment – explosive hazard with oxygen.

Warning - This anaesthesia system is NOT suitable for use with flammable anaesthetic agents.

Warning - An incorrectly functioning anaesthetic system must be removed from service and labelled **"NOT FOR CLINICAL USE UNTIL REPAIRED"** and must be properly repaired by a trained service engineer.

Warning – Always use a breathing circuit filter at the patient end of a breathing system to protect the anaesthesia system from contamination and cross contamination to a patient from a previous patient.

Warning – The use of patient monitoring during the use of this anaesthesia system is recommended and considered essential for patient safety. The patient's true clinical condition must be observed for patient safety.

Warning – This anaesthesia system has been tested to, and complies with the requirements of IEC 60601-1-2 medical electrical equipment electromagnetic compatibility - requirements and tests. Notwithstanding these requirements note that use of this equipment in areas with higher power electromagnetic fields may adversely affect its performance.

Warning – The ventilator has a backup battery for use in the event of loss of mains power. The specified back up time is only available if the battery is fully charged and in a serviceable condition.

Warning – If the anaesthetic ventilator is not going to be used for some time remove the backup battery. See User Maintenance section.

Warning – Operating rooms are critical work areas with many hoses, power cables and patient connected leads. It is important that all work areas are kept as clean and tidy as possible to prevent trip or fall hazards and ensure that patient connections do not become crossed, misconnected or disconnected.

Warning – In the case of Anaesthetic workstation failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury.

Warning – If not already equipped with halogenated anaesthetic agent monitoring equipment the anaesthetic workstation must be equipped with Monitoring equipment complying with ISO 80601-2-55 before the system is put into service.

Warning – Anaesthetic gas Scavenging Systems (AGSS) complying with ISO 80601-2-13 must be used with this system.

4 Servicing and Repairs

In order to achieve the full operational life and safety of the Gradian Classic Anaesthesia Machine (C-AM) the following service schedule must be adhered to: -

(a) Daily and pre use check by user. As a minimum requirement the ventilator and the associated anaesthesia system must be checked in compliance with the relevant professional bodies or hospital authority recommendations.
See “Pre Use” Check section as a guide.
(b) Weekly calibration of oxygen sensor and patient flow sensor.
(c) Six monthly inspection and function check - See Six Monthly Inspection.
(d) Five yearly overhaul- See Five Year Inspection.

Service requirements are detailed in the service documentation that is available only to factory-trained personnel working for Gradian / OES dealers.

Further details are available from Gradian Health Systems: -

Gradian Health Systems
40 W 25th St., 6th Floor
New York, NY 10010, USA

Phone +254 794 764 415
Email service@gradianhealth.org

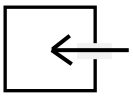
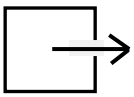
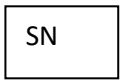
Always provide as much of the following information as possible with any communication: -
(a) Type of product and part number.
(b) Product name.
(c) Serial number.
(d) Software, Hardware and mechanical revision.
(e) Date of purchase.
(f) Details of suspected fault.

Serial number and year of manufacture code

The serial number is formed of two sections divided by a dash (-). A typical example is 21503-037, the construction of this is:
2: year 2000
15: 15th year in 2000, i.e. 2015
03: month in year
-037 is device consecutive serial number in batch.

5 Symbols used

Labelling

	Operating instructions (this user manual)		On
	Refer to manual		Fuse symbol and specification, plus orientation of Neutral and live fuses
	Manufacturer		Date of Manufacturer
	Gas inlet (pipeline or cylinder)		Gas outlet
	IEC Symbol denoting type B applied part		Electrostatic Device
	Serial number YYYMM-XXX		Do not dispose of in land fill, Follow your hospital, local, state and federal regulations

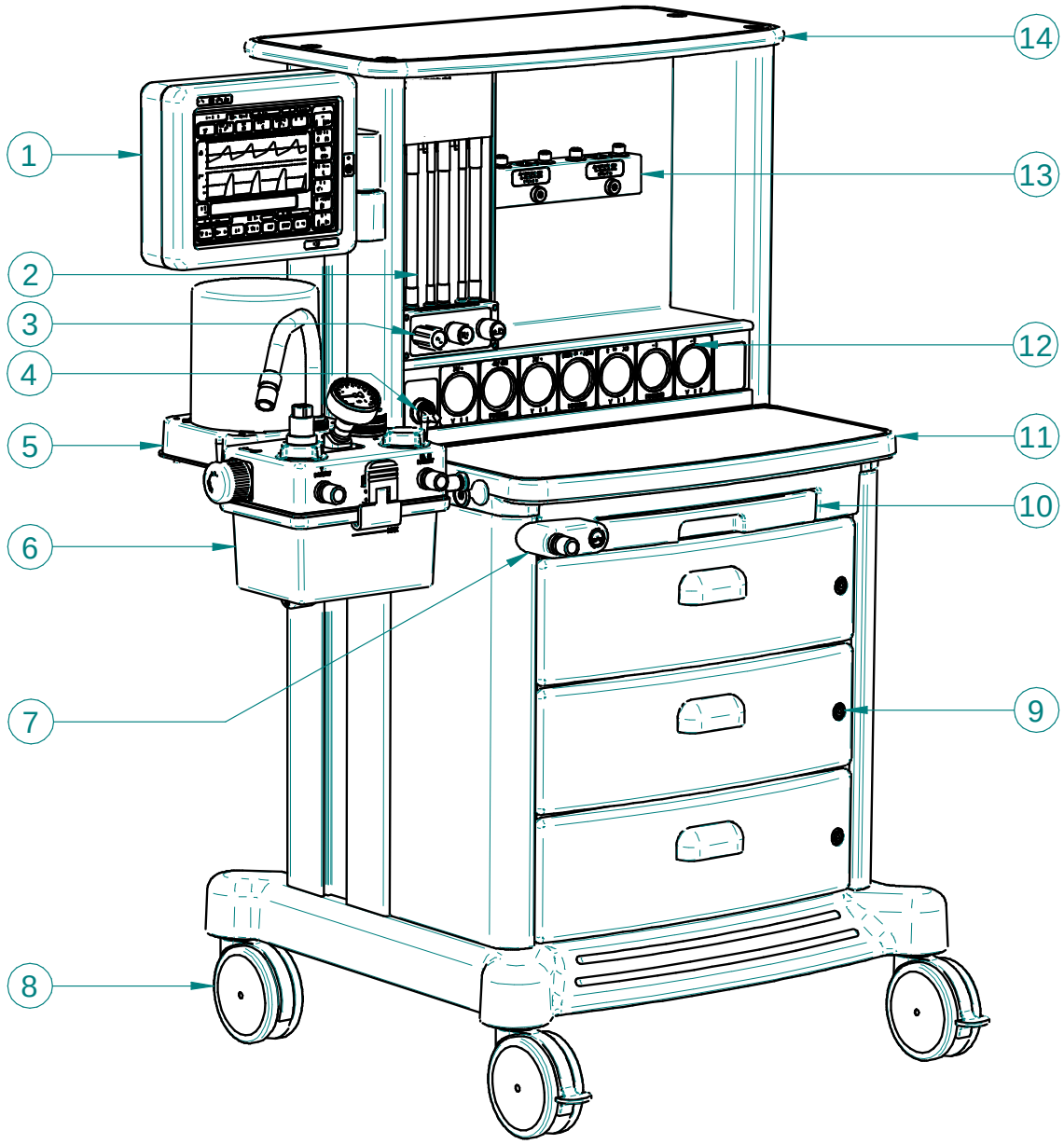
Section 2

Gradian Classic Anaesthesia Machine (C-AM)

Section 2 Gradian Classic Anaesthesia Machine (C-AM)

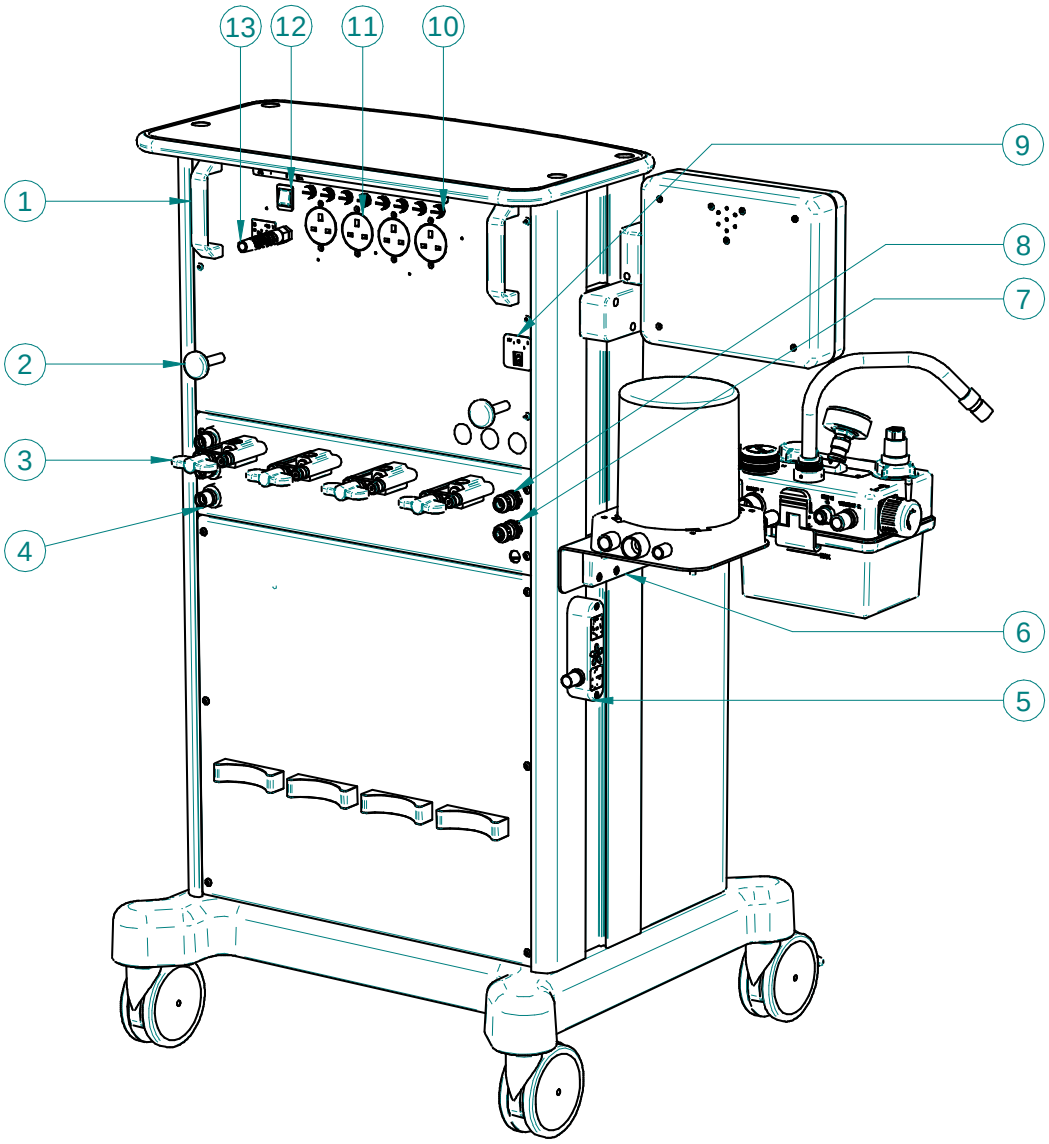
2.1 General Description

Classic Anaesthesia Machine (C-AM)– Front illustration



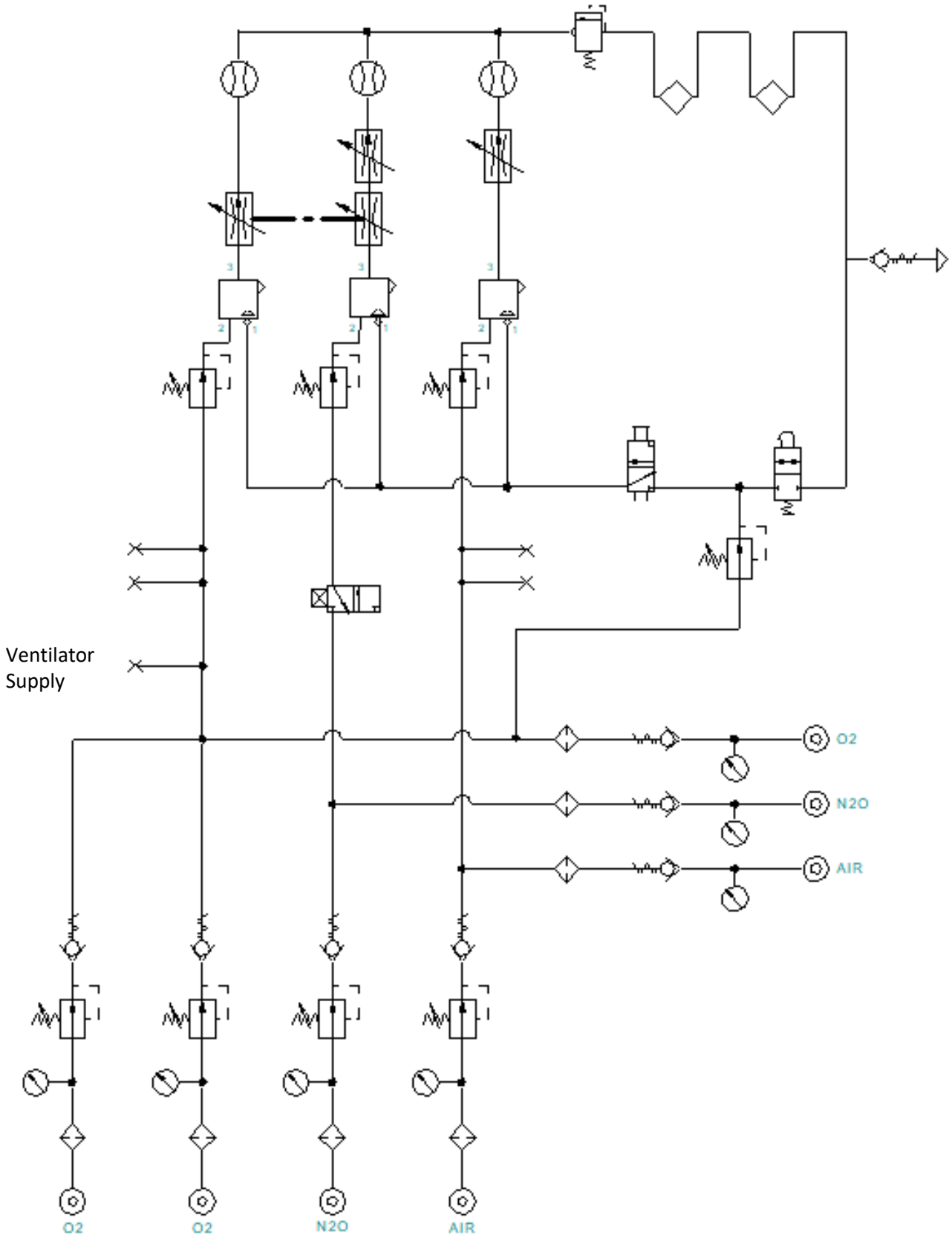
1	C-AM ventilator display	8	Castors
2	Flowmeter	9	Drawer units
3	Flowmeter controls	10	Writing Table
4	On/Off Switch	11	Work Surface
5	C-AM ventilator Bellows	12	Gauge Panel
6	Hydra Absorber	13	Vaporizer Backbar
7	CGO / Oxygen Flush Button	14	Top Shelf

Classic Anaesthesia Machine (C-AM) – Rear illustration

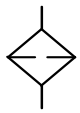


1	Handle	8	Auxiliary gas power outlet
2	Cord wrap	9	Oxygen sensor connector
3	Cylinder yokes	10	Power outlet Fuses
4	Pipeline inlets	11	Power outlet
5	ventilator connections	12	System Master On/Off Switch
6	Absorber /bellows mounting bracket	13	Power cord inlet
7	Auxiliary gas power outlet		

Classic Anaesthesia Machine (C-AM) – Pneumatic Circuits
with electronic O2 failure and N2O cut-off

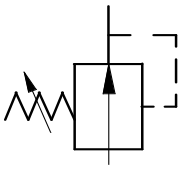


Pneumatic pressure source

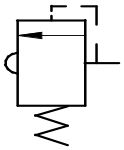


Filter

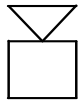
Pressure gauge



Pressure regulator

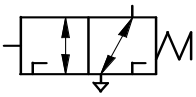


Pressure relief valve

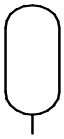


Audible alarm

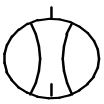
Restrictor



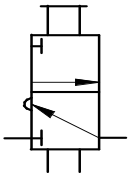
Gas cut-off valve (normally open)



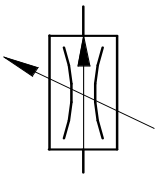
Reservoir



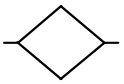
Flowmeter



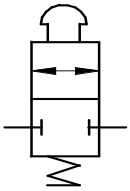
Pneumatic on/off switch



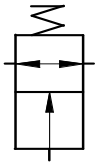
Flow control valve (variable)



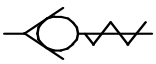
Vaporizer



Oxygen flush valve

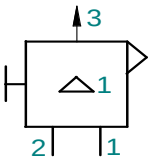


Whistle cut-in valve

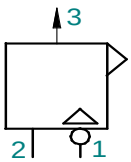


Non-return valve

Power take-off point (or test point)



Logic element - Yes



Logic element - No

Top shelf
The top shelf is manufactured from a fire resistant plastic moulding and is painted with anaesthetic resistant textured paint.
Mounting brackets that attach to the top shelf fixing screws include slots for attaching a nylon strap to prevent equipment moving when placed on the top shelf.

Auxiliary Electrical Outlet Sockets
4 off Hospital mains style sockets each twin fused 5 amp anti surge are fitted to the top rear of the machine with an independent isolator switch which is not connected through the machine on/off switch.

Warning: Equipment connected to auxiliary mains socket outlets must comply with IEC 601-1-12 and the total sum of the system leakage current shall not exceed 300 Micro amps. It is the USER'S responsibility to ensure compliance with the above standard and that the leakage current limits are not exceeded.

Machine on/off switch
The machine on/off switch is mounted on the left hand side of the gauge panel and is protected by a shroud to prevent inadvertent turning off. Turning the switch clockwise will turn on the gas to the flowmeter valves and at the same time provide electrical power to the C-AM and flowmeter electroluminescent panel.

Loss of Mains electrical power
In the event of loss of mains electrical power the auxiliary power outlet sockets will fail to deliver electrical power and any connected devices will not be supplied with electrical power. The electroluminescent flowmeter back light will extinguish (if fitted).
There will be no change to the function of the gas delivery system including oxygen safety devices.

Mains Lead
The Gradian Classic Anaesthesia Machine (C-AM) has a 4 metre mains lead is supplied for connection into a hospital mains electrical power outlet.

Warning: The connection of equipment to the auxiliary mains socket outlet(s) may increase the leakage currents to values exceeding the allowable limits in the event of a defective protective earth conductor. If multiple pieces of equipment are connected together, and one power cord supplies power, the leakage current of the whole assembled system should be measured.

Machine frame
The anaesthesia machine frame uprights are constructed of anodised extruded aluminium with moulded drawer fronts, side panels. Rear covers are aluminium Epoxy powder coated with anaesthetic resistant textured paint.

GCX Mounting System
The machine frame is designed with a GCX standard accessory mounting system form within the frame uprights. For mounting equipment such as, drip stands, suction controllers and jars etc.

2.2 Flowmeter bank
The flowmeter bank is available as a three-gas unit - oxygen and nitrous oxide and air being fitted as standard on the C-AM. Two gas options are available.

Flow tubes
All machines have cascade flow tubes on oxygen, nitrous oxide and Air providing accurate low flow indication, with the tubes calibrated between 100 and 1000 cc (low flow tube) and 1 and 10 litres (high flow tube) or 1-12 l/min Air. The flow tubes are diameter indexed and colour coded to prevent incorrect assembly and have an antistatic coating to prevent bobbin stiction.
The flow reading is made at the top horizontal surface or the flowmeter bobbin.

Flow meter back lighting
The flowmeter rear panel can be illuminated by an electro-luminescent back lighting panel as an option.

Oxygen basal flow
The oxygen flow is set to provide a minimum flow rate of 200 cc +/- 50 cc when the machine on/off switch is turned on.

Diameter indexed oxygen flowmeter knob
The oxygen flow knob is longer, larger and grooved to provide touch identification, and all knobs have a colour-coded label identifying the gas which it controls.

Flow needle stops
All flow control needles have stops provided to prevent inadvertent damage if rotated with excessive torque when fully open or closed.

Mechanical anti hypoxic device
The flowmeter is fitted with a gear driven mechanical anti hypoxic device to ensure that oxygen concentrations of less than 25 % are not delivered to the patient. With the nitrous oxide knob fully open the flow is controlled by the oxygen knob, which is connected to the primary nitrous oxide control needle.

Warning – The use of this equipment is not recommended without suitable patient monitoring.
The patient true clinical condition must be observed for patient safety.

2.3 Gas supplies
The following gas supply pressures are nominal and are required for normal operation. The anaesthesia gas delivery device will function safely at gas supply pressure tolerance extremes (+/- 10%) specified in national standards.
Gas supply inlets are protected with 40µm sintered filters.

Pipeline supply pressures:
USA/ Canada/Japan - 340 kPa (50 psig)
UK - 400 kPa (58 psig)

Cylinder supplies: 13700 kPa (2000 psig)
ANESTHESIA VENTILATOR shall not exceed 60 L/min at a pressure of 50 +0/–5 psig measured at the gas inlet connector.

Low oxygen audible alarm
The oxygen supply is fitted with an Audible and visual alarm which is indicated on the ventilator display when the oxygen pressure drops to an unsafe level.

Pressure to drive the alarm is supplied from the ventilator supply tubing on the main pressure sensor board; it continues even with complete oxygen failure.

The low oxygen alarm automatically resets when the oxygen supply is reinstated.

Nitrous oxide cut off
With oxygen failure the nitrous oxide flow is cut to prevent a hypoxic concentration of gas being supplied to the patient. The nitrous oxide cut off automatically resets when the oxygen supply is reinstated.

Air supply
With complete oxygen failure the air remains on with the on/off switch no longer working as the system is powered by the machine oxygen supply.

2.4 Vaporizer backbar

The anaesthesia machine can be fitted with a single or two station vaporizer backbar suitable for a Selectatec style vaporizer. A pressure relief valve is fitted into the rear upstream end of the backbar for machine protection.

Gauge panel

The cylinder and pipeline contents gauges are mounted below the flowmeter bank in a epoxy powder coated aluminium extrusion with a Perspex cover set into the extrusion.
The gauges are 50 mm diameter and have a rectangular colour coded label identifying the gas type and cylinder or pipeline supply.
The supply pressure is marked in kPa x 100 (kilo Pascal's)

Machine on/off switch

The machine on/off switch is mounted on the left hand side of the gauge panel and is protected by a shroud to prevent inadvertent turning off.

Nitrous Oxide / Air switch

The Nitrous Oxide / Air switch is mounted on the right hand side of the
Gauge panel – fitted as an option on the three gas model only.

Oxygen flush button

The oxygen flush button is mounted on the front left hand side of the machine front just below the work surface.
The button is protected by its shroud to prevent inadvertent use.
The flow rate is restricted to between 35 and 70 litres flow rate.

Work surface

The machine has a full width plastic moulded work surface with a replaceable plastic insert. The front edge of the work surface has a handle moulded under the front edge for ease of manoeuvring.

Writing Tablet

The writing tablet is integrated into the bottom of the work surface and is pulled out by an integrated handle in the moulding.
Warning – The writing tablet is not designed for sitting!

2.5 Gas tray

The cylinder yoke/regulator assemblies, pipeline inlets, auxiliary outlets and piping manifold are all mounted on the gas tray, which is bolted to the rear of the machine.
This gas tray can be completely removed for ease of servicing.

Gas cylinder yokes

The C-AM can be fitted with a maximum of 4 yokes. Each yoke is indexed to prevent connection of the wrong cylinder and has a colour coded gas identification label.
The yokes are connected directly to high-pressure regulators and incorporate a filter to prevent contamination.
The pressure regulators maintain a constant supply pressure to the anaesthesia machine gas control circuits over the range of cylinder pressures from full to empty.
Each cylinder includes a cylinder contents gauge.

Pipeline inlets

The pipeline inlets are mounted on the rear left hand side of the machine and are marked for gas identification. Each inlet includes a non-return valve and contents gauge connection, with a filter in the manifold block to prevent system contamination.

Pipeline hose assemblies
Pipeline hose assemblies are made of 4 metres of colour coded antistatic hose with a gas specific probes and connections for connecting between the wall or pendant terminal and connection to the machine.
Note – The pipeline hose assemblies do not contain phthalates.
Note – some markets may require differing hose lengths, colours or connections to comply with local market requirements.

Auxiliary gas power outlets
The auxiliary outlets for supplying gas to additional equipment are mounted on the rear of the machine to the right hand side of the cylinder yokes.
A maximum of 3 oxygen quick release connectors are available for the C-AM. These connections are Oxygen and Air and are Mini -Schrader.

Note – some markets may require different connections to comply with local market requirements.
Total flow rate not less than:
100 L/min to free air
80 L/min against 243 kPa (36 psig) resistance
70 L/min against 270 kPa (40 psig) resistance
50 L/min against 297 kPa (44 psig) resistance

Machine internal piping
The machine internal piping is colour and / or diameter indexed nylon tube with quick release connections for ease of maintenance.

Common gas outlet
The common gas outlet is mounted on the left hand side front of the work surface plastic moulding.
The patient connection is a 22 mm male/15 mm female taper and includes
a non-return valve to prevent machine contamination.

Drawer units
Three drawer units are mounted under the work surface each with a key for security.
Drawer fronts are Moulded fire resistant plastic, painted with anaesthetic resistant paint, the drawer box is Brushed finish stainless steel.
Full length drawer slides allow the drawer to fully open and they can be removed for ease of cleaning or machine servicing.
Drawers can be locked open or closed.

Castors
The machine is fitted with 125 mm diameter castors with the front two castors having brakes to prevent machine movement during use.

2.6 Machine specification

Overall Dimensions	
Height	130.0cm
Width	72.7 cm
Depth	66.7cm
Average weight	110kg

Top shelf Dimensions	
Height	60.5 cm
Width	35 cm
Maximum load	35kg even distribution

Work surface Dimensions	
Height	60.5 cm
Depth	35 cm
Height from ground	81.5 cm

Writing Tablet Dimensions	
Width	35.3 cm
Depth	30 cm
Maximum Load	10kg even distribution

Drawer unit Dimensions	
Width (internal)	48.2 cm
Depth (internal)	31.8 cm
Average weight	35kg even distribution

Vertical Tee Slot mounting system (GCX)	
Height Max	127.5 cm
Height Min	22.5 cm
Maximum Load	30kg

Machine Fuses

The auxiliary power sockets are fitted with 5 Amp anti surge fuses, one each for live and neutral and a separate on/off switch containing a thermal cut out to protect all socket outlets.

Fuse size is 5 mm x 20 mm, type T5AH250.

2.7 Environmental conditions

Condition		
Temperature	Operation	15ºC to 35ºC
	Storage	-5º to 50ºC
Humidity	Operation	0 to 95% non-condensing
	Storage	10 to 95% non-condensing
Air pressure	Operation	80 to 110 kPa
	Storage	11.5 to 110 kPa

MRI compatibility.	The standard Gradian C-AM is not approved for use in an MRI environment however there is a specific version available, and identified as suitable, for use within an MRI environment – refer to manufacturer

2.8 Flowmeter specification

Gas Specific colour specifications

Gas	Colour (ISO Countries)	Colour (ANSI Countries)
Oxygen	White	Green
Nitrous Oxide	Blue	Blue
Medical Air	Black/white	Yellow

Flow tube ranges

Gas	Range	
Oxygen	Low Flow	100 ml /min to 1000 ml/min
	High Flow	1 l/min to10 l/min
Nitrous Oxide	Low Flow	100 ml /min to 1000 ml/min
	High Flow	1 l/min to10 l/min
Air	Low Flow	100 ml /min to 1000 ml/min
	High Flow	1 l/min to10 l/min

Single tube, twin taper, flow meters are available on request

Flow tube accuracy
2.5 % of full-scale reading

Flowmeter controls
The positions of the flowmeter controls are determined by regional requirements

Flowmeter controls	ISO Countries				ANSI Countries		
2 Gas version (O_2 and N_2O)	O_2		N_2O		N_2O		O_2
2 Gas version (O_2 and Air)	O_2		Air		Air		O_2
3 Gas version	O_2	N_2O	Air		Air	N_2O	O_2

The oxygen flow knob is longer, larger and grooved to provide touch identification, and all knobs have a colour-coded label identifying the gas, which it controls. Flow is increased by turning the knob counter-clockwise.

2.9 Mechanical anti hypoxic device

Gear driven device to limit nitrous oxide flow to provide a minimum oxygen concentration of 25 %
A primary needle limits the flow of nitrous oxide in proportion to the oxygen needle position/flow rate; any reduction in nitrous oxide which is required is achieved by the main flow knob.
Minimum oxygen flow rate (basal flow) – 150 to 250 cc
Flowmeter secondary regulator pressure – less than 170 kPa (25 psi)

Low oxygen alarm

Alarm sounds when the oxygen pressure drops to below 240 kPa (35 psi)
Alarm reinstates automatically on restoration of pressure.

Nitrous oxide cut off

Nitrous oxide cuts off when oxygen pressure drops below 205 kPa (30 psi)
Air supply continues with complete oxygen failure.
The nitrous oxide flow restarts when the oxygen is reinstated.

Gas supplies

The following gas supply pressures are nominal and are required for normal operation. The anaesthesia gas delivery device will function safely at gas supply pressures between the Minimum and Maximum values shown below.
Gas supply inlets are protected with 40µm sintered filters.

Gradian C-AM	Max Number of gases	Max number of cylinders	Max number of pipeline inputs	Max number of outlets
				O_2 or Air any combination
2 Gas version	2	4	2	3
3 Gas version	3	4	3	3

Pipeline supply pressures:

	Nominal	Min	Max
UK	400 kPa (58 psig)	300 kPa (43.5 psig)	450 kPa (65 psig)
USA/ Canada/Japan	340 kPa (50 psig)	300 kPa (43.5 psig)	450 kPa (65 psig)

Cylinder supplies:

	Nominal	Min	Max
Cylinder pressure	13700 kPa (2000 psig)		
After Regulator UK	380 kPa (55 psig)	340 kPa (50 psig)	400 kPa (58 psig)
After Regulator USA	310 kPa (45 psig)	280 kPa (40 psig)	325 kPa (47 psig)

ANESTHESIA VENTILATOR shall not exceed a time weighted average demand of 60 L/min at a pressure of 50 +0/–5 psig measured at the gas inlet connector.

Auxiliary outlets
Total flow rate not less than:
100 L/min to free air
80 L/min against 243 kPa (36 psig) resistance
70 L/min against 270 kPa (40 psig) resistance
50 L/min against 297 kPa (44 psig) resistance

Vaporizer connection

The Gradian C-AM is fitted with either a single or two station Selectatec style backbar
Note: Selectatec is a GE / Datex Ohmeda trademark.
Both backbars are fitted with a pin to prevent non interlock vaporizers being attached.

2.19 Pre-use checks

Prior to use the anaesthetic machine must be inspected and checked as part of the anaesthesia system to ensure correct and safe function.

An incorrectly functioning anaesthetic machine must be removed from service and labelled **"NOT FOR CLINICAL USE UNTIL REPAIRED"** and must be properly repaired by a trained service engineer.

Pre-use check list

(1) Check the machine for labelling to indicate if the machine has any faults or has just been serviced.
(2) Check for visible signs of damage.
(3) Check gas pipeline connections are correctly secured and in good condition.
(4) Check gas pipeline supply is at correct operating pressure.
(5) Check cylinder supplies are full or adequate.
(6) Switch on the flow meter delivery switch and check for correct operation of the anti-hypoxic mechanism using an oxygen analyser.
(7) Check operation of the low oxygen alarm and the nitrous oxide cut out.
(8) Check operation of the oxygen flush.
(9) Check that the vaporizers are correctly mounted on the backbar - refer to the vaporizer manufacturers user instructions.
(10) Check the correct connection of the patient circuit and any auxiliary equipment such as oxygen analyser, patient monitoring equipment, carbon dioxide absorber etc.
(11) Check that the theatre scavenging system is connected and that the system is not creating a vacuum in the patient circuit.
(12) Perform a system overall leak check.

Service fault

Check the machine for labelling which will indicate if the machine is unserviceable or has just been serviced.

Warning – additional care must be taken during the pre-use check after any equipment has been serviced.

Warning – do not use any equipment that has a fault until it has been fully repaired by a suitably qualified service engineer.

Machine damage

Check the machine for signs of damage. Checks should include looking for loose casters, caster brakes that do not work, loose panels and monitor tray,

Pre-use checks

Pipeline supplies

(1) Check pipeline hoses for damage along their length and where they are crimped to the probe ends.
(2) Ensure that the hoses are not kinked and are routed to ensure that they will be clear of the casters when the machine is moved.
(3) Ensure that the fitting on the machine hose ends are secure and that the hose probe is secure when in its terminal unit.
(4) Connect each hose in turn and check that the pipeline contents gauge registers the correct gas and pressure and recheck that the gauge returns to zero when disconnected.

Cylinder supplies

(1) Check that the correct cylinders are attached to the yokes and that the index pins are present and not loose.

(2) Check cylinder contents level by turning cylinders on slowly one at a time; confirm that the cylinders are full and that the correct gauge is indicating the pressure.
(3) Remove the cylinder and confirm that the gauge returns to zero.

Warning – the cylinder yokes are pin indexed to prevent the wrong cylinders being attached to the machine – check that both pins are in each yoke and are secure.

Flowmeter bank

(1) Turn the flowmeter on and ensure that the oxygen is giving a minimum flow of 150 to 250 cc in the fully closed position.
(2) Check that the other gases are off with the knobs fully closed.
(3) Turn each gas to maximum and ensure that the flow tube bobbins spin freely and reach or just exceed the maximum calibrated level.
(4) Turn each flow knob on, turn the machine off and ensure that all gas flows stop.

Mechanical anti hypoxic device

(1) Connect an oxygen analyser to the machine common gas outlet of the anaesthetic machine.
(2) Turn the nitrous oxide control knob fully on.
(3) Turn on the machine and check the oxygen concentration with minimum oxygen flow rate and up the scale to maximum flow. The oxygen concentration must not be below 25 %.

Note – that this test can be performed with the integrated Oxygen monitor if fitted.

Note – the oxygen concentration will increase at high oxygen flow rates, as the nitrous oxide flow is restricted to the flow tube maximum calibrated level.

Low oxygen alarm and nitrous oxide cut off

(1) Turn each gas turned on to 5 litres per minute.
(2) Close the oxygen cylinder and or remove the oxygen pipeline supply.
(3) Check the oxygen whistle sounds followed by the nitrous oxide cut off at a pressure 240 and 205 kPa.
(4) The whistle will sound for approximately 10 seconds.

Note – the air on the three gas machine must continue with complete oxygen failure.

Oxygen flush

Press the oxygen flush button and ensure that oxygen flows from the common gas outlet. Ensure that the flow stops instantly that the button is released.

Note – with the oxygen analyser attached to the common gas outlet or with the integrated Oxygen monitor confirmation can be made that the flush gas is oxygen.

Vaporizer mounting

(1) Lower the vaporizer directly onto the backbar ports.
(2) Ensure that the vaporizer is sat fully down.
(3) Lock the vaporizer in place with the clamp lever by rotating 90 degrees clockwise – do not force the lever as damage may occur.

Note – locking the vaporizer in position may require the knob to be pushed down prior to rotation – refer to manufacturers instruction manual.

Warning – when a vaporizer has been removed from a backbar ensure that the o seal on each port is retained on the valve and has not become stuck on the backbar valve.

Warning – a leak check must be performed whenever a vaporizer is placed on an anaesthetic machine.

Warning – the vaporizer manufacturer pre use instructions must be complied with – refer to the vaporizer user manual.

Note – only Selectatec interlock compatible vaporizers are recommended for use with the C-AM range of anaesthetic machines. Use of early non-interlock vaporizers is not possible due to an index pin fitted to the vaporizer backbar.

Warning – removal of the index pin in the Selectatec backbar is forbidden.

Vaporizer pre use leak check

With the vaporizers mounted in position: -

(1) Connect a sphygmomanometer to the common gas outlet.
(2) Turn the oxygen flowmeter on with the minimum flow rate of 200 cc
(3) Check that the system pressure reaches 150 mm hg.
(4) Repeat with the vaporizers turned on at 2 % output.

Warning – do not over pressurize the system.

Patient circuit and auxiliary equipment

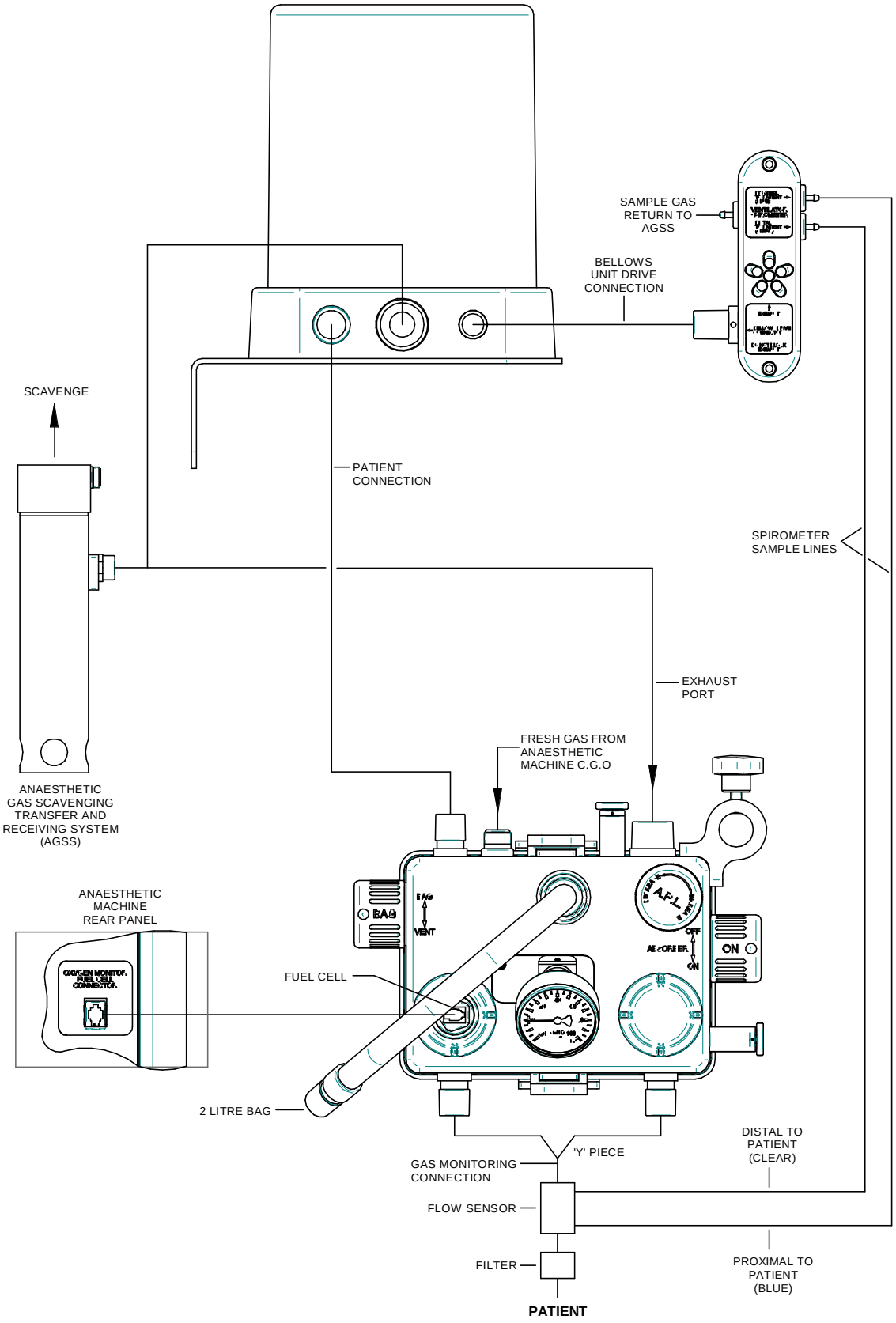
(1) Ensure that equipment such as ventilators, monitors, circle absorbers and other auxiliary equipment is securely attached the anaesthetic machine.
(2) Ensure that all cabling and sample lines are correctly attached – refer to individual manufacturer's user manuals.
(3) Connect patient circuit to the anaesthesia machine common gas outlet.

This will include connections for the following equipment: -

(a) Ventilator and bellows unit.
(b) Carbon dioxide absorber.
(c) Theatre scavenging system.
(d) Sample lines.

Warning – In the case of Anaesthetic workstation failure, the lack of immediate access to appropriate alternative means of ventilation can result in PATIENT injury

2.11 Breathing system hose illustration



Patient circuit leak check
With the patient circuit connected to the anaesthesia machine and ancillary equipment a low-pressure patient circuit check leak check can be performed.

(1) Fully close the adjustable pressure relief valve on the patient circuit.
(2) Ensure that the absorber is in bag mode.
(3) Block the breathing circuit patient connection with your thumb.
(4) Fill the reservoir bag with the oxygen flush.
(5) Turn on the flowmeter with minimum flow rate.
(6) The circuit pressure must exceed 50 cm H20 at 150 – 200 cc flow rate.

Warning – check the circuit for free flow after the pressure test by increasing the oxygen flow to 6 litres per minute and ensuring that gas flows freely from the patient connection.
Open the adjustable pressure relief valve fully and block the patient connection and ensure that the circuit pressure is not greater than 5 cm H20.

AAGBI Check List

The attached (see Appendix 2) **Checklist for Anaesthetic Equipment 2012** has been published by the AAGBI as a basic check list for pre use checking of anaesthesia systems.
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2.12 Machine cleaning
The external surfaces of the machine can be wiped with a damp cloth followed by drying off prior to clinical use.

Note – mild antiseptic solutions may be used to clean the anaesthetic machine but must be rinsed thoroughly with water prior to drying.

Warning – care must be taken to prevent water entering the machine during cleaning.

For cleaning of ancillary items such as absorbers, ventilator bellows and patient circuits refer to the manufacturer's user instructions.

2.13 User maintenance
User maintenance is restricted to: -
(1) Overall machine leak check.
(2) Removal and replacement of vaporizers.
(3) Replacement of seals on the selectatec backbar ports.
(4) Replacement of Bodok seals on the high-pressure cylinder yokes.
(5) Cleaning of the anaesthetic machine surfaces.

2.14 Ordering information
Refer to your agent for anaesthesia machine ordering information.

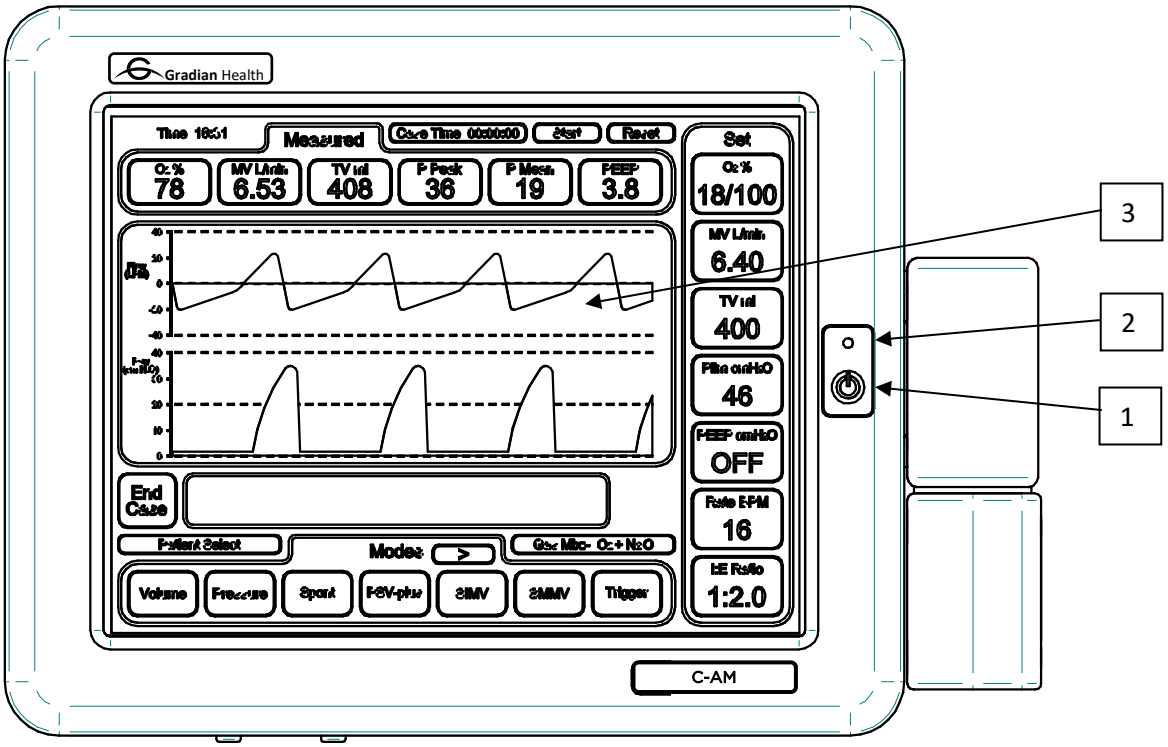
Section 3

C-AM anaesthesia Ventilator

Section 3 C-AM anaesthesia Ventilator

3.1 General Description

C-AM Ventilator - Display illustration



1 On/off push button.
2 Mains Indicator - yellow mains applied and green ventilator on.
3 Colour touch screen display.

Ventilator Description

General

The C-AM ventilator is designed to comply with the following standards:-

BS EN ISO 80601-2-13
BS EN 60601-1
BS EN ISO 60601-1-2
BS EN 60601-1-6
IEC 60601-1-8
IEC60601-1-9
IEC 62304

All gas volume. Flow and leakage specifications are expressed as STPD (Standard Temperature and pressure, Dry) where temperature is 20°C and pressure 101.3kPa

Ventilator Function

The C-AM ventilator is a pneumatically driven and software controlled flow and pressure generator type ventilator for automatic ventilation of infant, children and adult patients during anaesthesia.
An ascending bellows unit which is easily detachable for cleaning is utilised to drive the patient fresh gas to the patient circuit isolating the ventilator drive gas from the patient respired gases.

Numerous controls are provided for pressure, volume and spontaneous breathing support at user settable values. The user set and measured values are shown clearly on the ventilator front panel display.

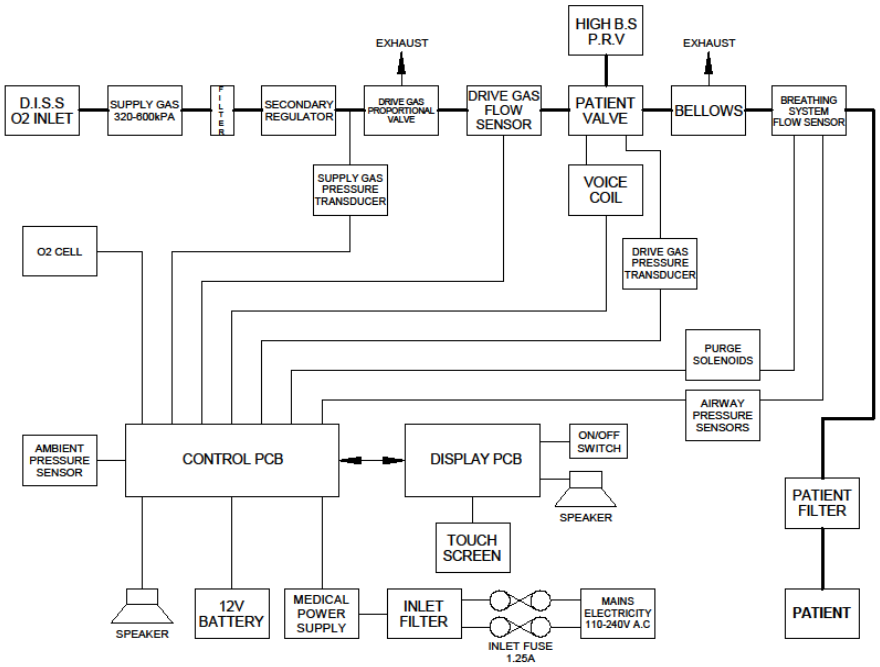
In the event of a ventilator measured parameter being outside a pre-set limit the ventilator will annunciate that anomalous condition and display the erroneous function in the Alarm area of the ventilator display.

The user operates the ventilator by selecting the required ventilation parameters, either manually or from a series of pre-set or user set saved value values and after connecting to the patient breathing system the user pressing the “Start Case” button on the display and then confirming the ventilation parameters and the ventilator will begin now to ventilate at the set values.

Ventilator Pneumatic Circuit

1. Clean and dry medical oxygen from the hospital pipeline, cylinder supply or from the anaesthetic machine auxiliary supply connectors is fed into the ventilator connection through a DISS oxygen connection.
2. The oxygen supply passes through a filter and the pressure is then regulated to 3 bar.
3. Gas flow to drive the bellows is controlled by an electronically controlled proportional flow valve.
4. The drive gas flow is controlled electronically and monitored independently by a drive gas flow sensor.
5. Fresh Gas from the bellows is driven through the patient silicone diaphragm valve that is controlled with a digitally controlled voice coil. Excess drive gas (oxygen) is exhausted through the exhaust port to the atmosphere.
6. Additional safety is provided with the addition of a preset pressure relief valve calibrated to 80 cm H_2O at 60 l/min.
7. Gas delivered through the patient valve drives the bellows down.
8. Gas from the inside of the bellows containing the anaesthetic gas mixture is driven through the patient breathing circuit and the variable orifice flow sensor, through a patient filter and to the patient.
9. In the event of excess fresh gas being delivered by the anaesthetic machine surplus gas is exhausted from the exhaust port on the bellows to a user attached scavenge system.

Ventilator Block Diagram



Gradian C-AM Ventilator Drive Gas Supply

The C-AM ventilator is designed to operate on a 300 - 600kPa drive gas supply and the ventilator is calibrated during manufacture on oxygen.

Gas Control Manifold Block

To keep the pneumatic connections and internal pipe work to a minimum the internal pneumatic controls are all contained within a special manifold assembly ensuring that pneumatic system remains as simple as possible minimising connections and the possibilities of leaks.

DISS Inlet Connector

The mains gas source is connected to the oxygen DISS drive gas supply fitting on the rear of the ventilator control unit. The gas supply should be capable of a minimum flow rate of 80 L/min while maintaining a minimum pressure in excess of 310 kPa (45 psi).

Inlet Drive Gas Filter

The drive gas is filtered with a 40-micron inlet gas filter which protects the pneumatic components from incoming particulate matter. The flat form of the large diameter filter presents a very large surface area to the gas flow ensuring that the filter has a long service life.

Inlet Pressure Regulator

The inlet pressure regulator maintains the input drive gas pressure in the ventilator at the manufactured set value allowing the use of variable pressure drive gas supplies whilst maintaining consistent ventilator performance over the recommended supply pressure range.

Low Drive Gas Supply Pressure transducer
The pressure transducer is set at a predetermined level to detect a loss or reduction of the input gas source pressure. When the pressure falls below 275 kPa, the LOW SUPPLY PRESSURE indicator will be displayed and the high priority audible alarm will activate.

Proportional Drive Gas Valve
The proportional drive gas valve is controlled by the central processor unit (CPU) and is adjusted in real time to ensure that the required ventilator parameters of flow, volume and pressure are maintained on a breath by breath basis.

Drive Gas Flow Sensor
The drive gas flow sensor monitors the instantaneous flow from the proportional drive gas valve allowing the CPU to calculate the real time setting of the valve to maintain the correct ventilator performance in conjunction with the breathing system flow sensors allowing the ventilator to compensate for variable fresh gas flows. Its proximity to the drive gas valve provides very rapid feedback of flow minimising the time delay between valve operation and breathing system flow change.

Drive Gas Pressure Sensor
The drive gas pressure sensor monitors the pressure of the drive gas allowing the CPU to calculate the real time pressure and maintain the correct ventilator performance. Its proximity to the drive gas valve provides very rapid feedback of drive gas pressure minimising the time delay between valve operation and breathing system pressure change and the potential for excess pressure in the breathing system.

High Breathing System Pressure Relief Valve
The patient valve is designed with a maximum breathing system pressure relief automatically ensuring that in the event of excess breathing system pressure over 80hPa (80 cm H2O) excess pressure will be relieved to the exhaust.

Patient Valve
The patient valve is a fast acting electronically controlled magnetic valve which the CPU adjusts in real time to maintain the correct breathing system pressure and value of PEEP irrespective of the fresh gas flow. The valve maintains breathing system pressure and opens at the end of the inspiratory phase allowing the patient to exhale.

Airway Pressure Sensor
Connected at the patient Y piece of the breathing circuit utilising the flow sensor connection tubes.

Breathing System Flow Sensor (Spirometer)
A bidirectional variable orifice flow sensor mounted at the patient Y piece and prior to the patient filter is included to measure the actual flow to and from the patient. Calibration of the flow sensor (spirometer) is required before first use. The blue sample line is connected to the flow sensor port (A) proximal to the patient and the clear sample line is connected port (B) distal to the patient on the flow sensor. The ventilator end connections are clearly marked with connection requirements.

Purge valves
Two oxygen purge valves are built into the manifold block to maintain the spirometer tubes clear of moisture which may build up causing spirometry errors.

Ambient Pressure Sensor
The ambient pressure sensor monitors the barometric pressure and adjusts the delivered tidal volume to compensate for altitude or changes in barometric pressures to maintain accuracy of ventilator volumes.

Electrical and Electronic Ventilator Control System

Note that flow and pressure sensors are mounted directly on the control PCB and are connected into the pneumatic circuit by local sample lines within the ventilator control unit.
The ventilator is controlled and its functions are continuously monitored by the software systems which read the clinicians set control values and the ventilator control system then sets the control valves to deliver the calculated gas flows to the patient, at rates which will ensure that the set values are achieved.
During both the delivery and expiratory phases the ventilator monitoring systems monitor the measured parameters and if the control systems detect that small adjustments are needed to achieve the final target values the control systems will feedback small adjustments to the control valves trimming the delivered values to take account of for example, fresh gas flows and small leaks.

Main Control PCB

There are two elements to the ventilator software systems in the C-AM ventilator and they are designed to work separately but in harmony with each other.
Firstly the ventilator control system and secondly the ventilator monitor system.
The main control PCB houses the main processor unit and the "watch dog monitoring" to ensure that the ventilator is working correctly.

Display and Display Control PCB

The display PCB is the main driver for the display unit which reads and processes the users set values. The PCB additionally controls the information shown on the display unit

Display and Touch Screen

The colour display has a LED back light and uses a touch screen layer over the display which allows the user to select relevant ventilator functions and parameters by simply touching the relevant touch sensitive areas highlighted on the display.

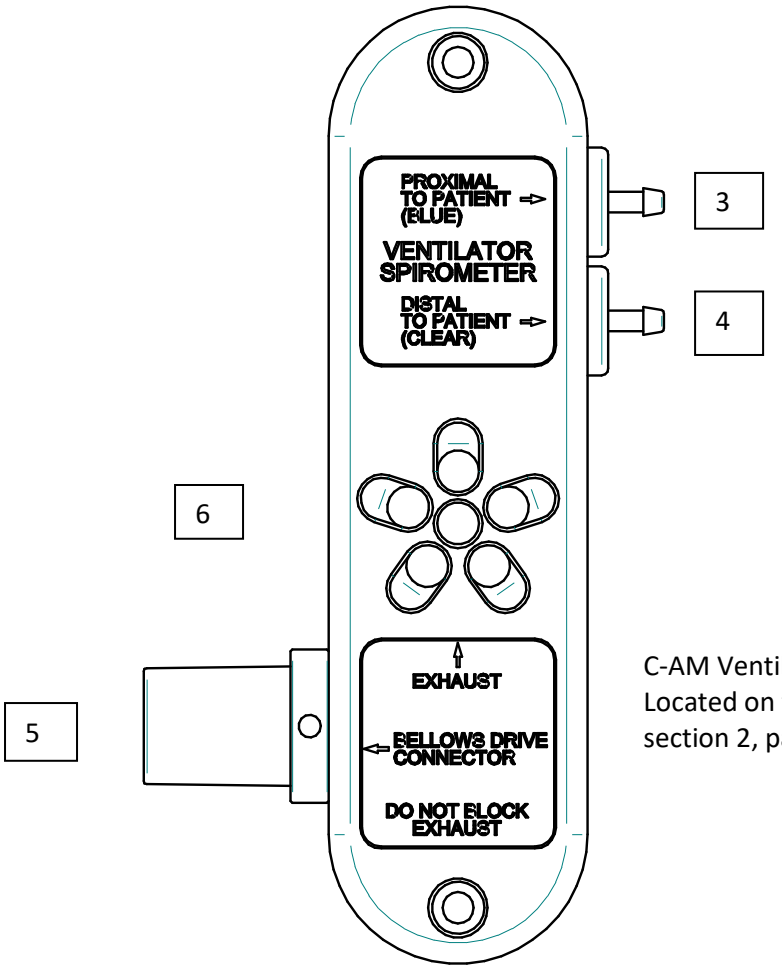
Mains Power Supply

The mains supply inlet is designed for connection to standard mains voltage supplies worldwide:
110 VAC to 220 VAC and 50 to 60 Hz
Note that the ventilator adjusts automatically to the supply voltage range and no further adjustment is required.
The connector into the ventilator is a standard IEC type cable and twin fusing at 1.25 amps is provided.

Power Supply Unit

The power supply unit consists of a switch mode power supply providing low voltage electrical power to drive the ventilator controls and maintain the backup battery in a fully charged state whilst connected to the mains electricity supply.
Mains voltage supply failure gives an alarm.
Battery backup is up to 4 hours depending on battery condition and ventilator settings. The battery condition indicator indicates a low charge condition followed by a 10 minute warning that the ventilator will turn off to prevent the battery from damage.

Ventilator Connections



C-AM Ventilator connections.
Located on the left side of the C-AM (see section 2, page 25, item 5)

3 Flow sensor connection - proximal to patient - blue tube.
The patient inspired and expired gas is measured with a variable orifice flow sensor. The blue tube is connected closest to the patient.
Note that a breathing circuit filter must be used to prevent contamination.

4 Flow sensor connection - distal to patient - clear tube.
The patient inspired and expired gas is measured with a variable orifice flow sensor. The clear tube is connected furthest from the patient.
Note that a breathing circuit filter must be used to prevent contamination.

5 Ventilator bellows driving gas connecter – 17 mm taper.
A black rubber corrugated tube is connected from the ventilator 17 mm taper to the 17 mm taper on the bellows assembly. The gas drives the bellows down during the inspiratory phase.

6 Drive gas exhaust port.
During the expiratory phase the drive gas is exhausted from around the bellows to the exhaust port and allows the bellows to return to the top position. Note there are no connections to be made as the gas go to atmosphere and the port must not be blocked.

Bellows 30 mm scavenging connection.
During use the anaesthesia machine delivers fresh gas to the breathing circuit to replenish gases and anaesthesia agent. Excess gas is exhausted from this port and is connected to a AGSS (anaesthetic gas scavenging system).

Bellows 22 mm Patient connection.
This connection is connected to the ventilator drive port on the rear right hand side of the absorber. Connection is made with a 600 mm length of disposable tubing provided with each patient circuit.

Ventilator on/off Switch
The ventilator on/off membrane switch is mounted on the right hand side of the display panel and requires actuating for 1 second to turn on. Shorter actuation prevents the ventilator turning on.
To turn the ventilator off the button must be pressed for 2 seconds, then the user must confirm that the ventilator is required to be shut down before a shutdown sequence will be initiated. If the user does not confirm the requirement to shut down the ventilator will not enter the shutdown sequence.

The C-AM ventilator is provided with medical gas and mains power from within the C-AM. Separate mains inlet fuses are fitted internally 2x T1,25AH250

Inspired oxygen fuel cell connection.
A cable is connected to the rear right hand side of the C-AM anaesthesia machine (see section 2 page 16 item 9) to the oxygen fuel cell mounted in the top of the inspiratory non return valve cover. **Note** that the fuel cell is supplied in a sealed pack and must be removed and screwed into the cover before the cable is connected.

Loss of mains electrical power
In the event of loss of mains electrical power the backup battery will continue to provide uninterrupted ventilator function for up to 4 hours.
There will be no change to the function of any of the ventilator operating or monitoring devices.
An alarm message will be displayed to indicate AC Power Loss –running on Battery.
When mains electrical power is re-established the ventilator will continue to operate with no input needed from the operator and the alarm message will be removed.
Fresh gas supply is unaffected by electrical power loss.

Ventilator Modes

The following ventilation modes are available for patient ventilation:

(a) Volume ventilation
(b) Pressure ventilation
(c) Spontaneous monitoring
(d) Intermittent support mode pressure target – PSV Plus
(e) Pressure with VG (Volume Guarantee)
(f) Intermittent support mode V_t target – SIMV
(g) Cardiac Bypass
(h) Intermittent support mode V_m target – SMMV

In addition the following additional settings are available to compliment the ventilation modes:

(a) Adjustable trigger function for supported spontaneous breathing
(b) Adjustable inspiratory pause
(c) Adjustable Sigh
(d) Adjustable Positive End Expiratory Pressure PEEP

Breathing mode definition

a) Volume Controlled Ventilation (VCV) - delivery of the set tidal or minute volume at a flow determined by the set inspiration time. If the set volume is reached early or the set pressure limit is exceeded then the inspiration phase will end at that time. Pressure ventilation - a preset target Pressure is delivered to the patient during each inspiratory phase.
b) Pressure Controlled Ventilation (PCV) - set target pressure achieved as quickly as possible during inspiration. The set target pressure is maintained for the remaining inspiration time.
c) Spontaneous - patient breathes with no assistance from the ventilator. The ventilator provides measurement of volume, peak, and mean airway pressure. An apnoea alarm is given if the patient stops breathing.
d) PSV- plus - this is a Pressure support mode that enables the patient's breath to be assisted to achieve a target pressure. The mode changes to SIMV if the patient fails to breath and reverts back to PSV - Plus when the patient resumes breathing.
e) Pressure with VG is a pressure controlled mode to deliver a set volume with the lowest pressure. The initial two breaths will appear to be volume breaths, the next breath will more closely resemble a pressure breath.
f) SIMV - Synchronised Intermittent Mandatory Volume - same as VCV except that gas delivery is triggered by the patient's own breathing. The number of assisted breaths is determined by the set BPM, which may vary +/-25% to synchronise with spontaneous breaths. The volume delivered is the set tidal volume.
g) Cardiac Bypass mode suspends all alarms allowing a constant positive pressure to be applied to enable alveolar support during Cardio-pulmonary bypass procedures.
h) SMMV - Synchronised Mandatory Minute Volume - similar to SIMV except that the volume delivered during an assisted breath is determined by the difference between set minute volume and measured minute volume. The measured minute volume is based on breaths monitored over one minute. If the spontaneous minute volume is projected to be less than 80% of the set minute volume than an assisted breath will be given at a volume equal to the set minute volume divided by the set BPM.

Additional settings - description

(1) Adjustable trigger function for spontaneous breathing - the patient spontaneous breath flow rate is used as a trigger in some modes - the trigger rates are 0.7 / 1 / 2 / 3 / 4 and 6 litres.
(2) Adjustable inspiratory pause - the inspiratory phase is increased by a user defined percentage the values are 0 / 10 / 20 / 30 / 40 and 50 %
(3) Adjustable Sigh - the inspired volume is increased by 50% every 50 / 100 or 150 breaths.
(4) Adjustable Positive End Expiratory Pressure PEEP - the patient circuit pressure is maintained at a user defined level - zero to 15 cm H2O

Breathing System Monitoring

The ventilator continuously monitors and displays a number of breathing system parameters on the ventilator front screen. In the event of these monitored parameters varying outside the set alarm limit condition, the ventilator will highlight the parameter which has fallen outside the specified limit by a flashing the set and measured function boxes with an intermittent red background and a textural warning of the error. An audible alarm will also be sounded when the alarm is of a high priority.

Within the tolerances of ventilator capability the ventilator actively adjusts either pressure or volume delivery to maintain a breath by breath accurate delivery of set volume or pressure and compensating for changes due to fresh gas delivery or minor leaks and as required, compliance compensation.

Breathing system displayed measured parameters

a) Oxygen Inspired concentration
b) Minute volume delivered - expired volume
c) Tidal volume delivered - expired volume
d) Peak Pressure delivered
e) Mean pressure delivered
f) PEEP - positive end expiratory pressure.

Compliance Compensation

During volume ventilation compliance compensation is added to each breath. This increased volume is calculated during the Leak and compliance test, by measuring the volume of drive flow needed to raise the system pressure to 30cmH2O (30hPa)

The increase in volume is given by:-
n = [sVt x (C_S / C_L)]

- where:
sVt = the set tidal volume defined by the user
C_S = system compliance determined by the Leak and Compliance test.
C_L = default lung compliance = 20 mL/cmH2O (hPa)

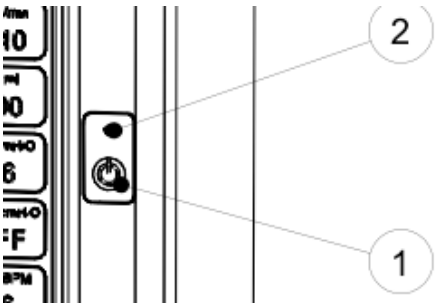
Example
C_S is calculated by the system to be 9mL/cmH2O 9hPa)
C_L = 20mL/cmH2O (hPa)
sVt = 400
then
n=[400 x (9/20)]= 180
Therefore the ventilator will deliver (at its output) 580mL to ensure that 400mLis delivered to the patient

During the leak and compliance test when the 30cmH2O (30hPa) is reached the pressure will be held for 10secondes to check for leaks

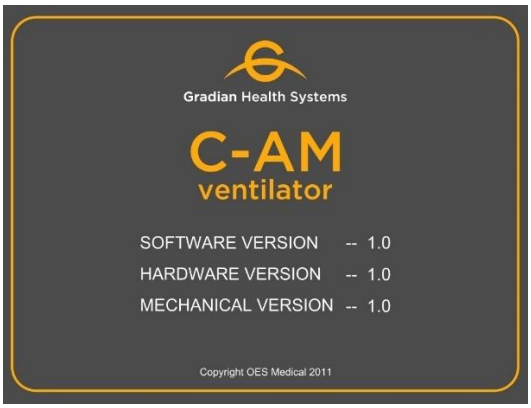
After compliance compensation there is a cycle-by-cycle adjustment made to compensate for fresh-gas and leaks.

3.2 Operating the Ventilator

Turning the ventilator on



1 On/off push button.
2 Mains Indicator. Yellow mains applied and green ventilator on.



Pressing the "on/off" button mounted on the right hand side of the bezel for one second turns on the ventilator. During ventilator start up, the display will remain blank for up to 40 seconds following which the screen will display a welcome screen showing the software version, hardware version, mechanical version and the serial number. If the ventilator has a fault this information must be provided when reporting the fault.

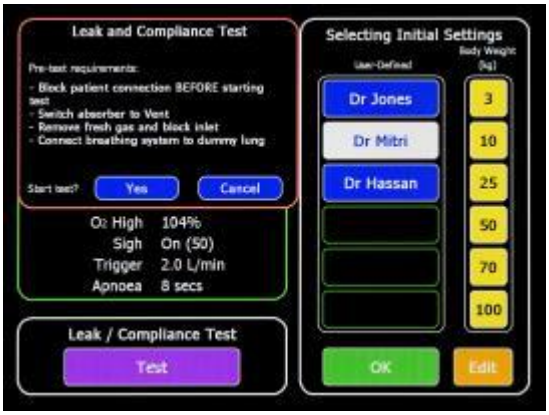
Welcome screen displaying software version, hardware version, Mechanical version and serial number.

Patient select screen

The patient select screen allows the user to perform a leak and compliance check or choose patient ventilator settings by weight - 3kg, 10kg, 25kg, 50kg, 70kg and 100kg or by selecting one of 6 user defined settings
Patient select screen with User Defined setting Dr Jones selected - note that Dr Jones selected key is now white and that the ventilator settings are displayed on the left hand side.

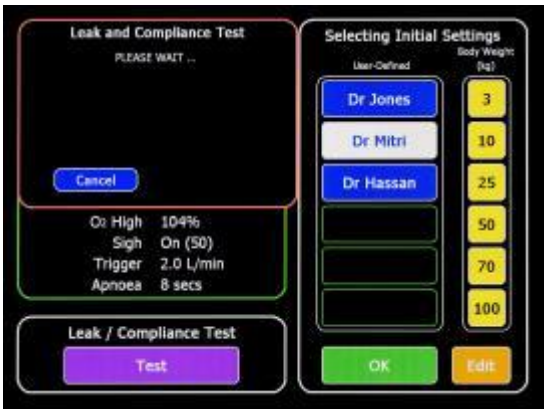
Patient select screen with Dr Jones selected.

Leak and Compliance test



Selecting the Leak and compliance test will bring up a Leak and Compliance check screen; press "Yes" to perform the check.
(a) Block the patient connection.
(b) Turn fresh gas flow off.
(c) Turn the absorber to "on" and select "ventilator" mode.

Leak and compliance test screen



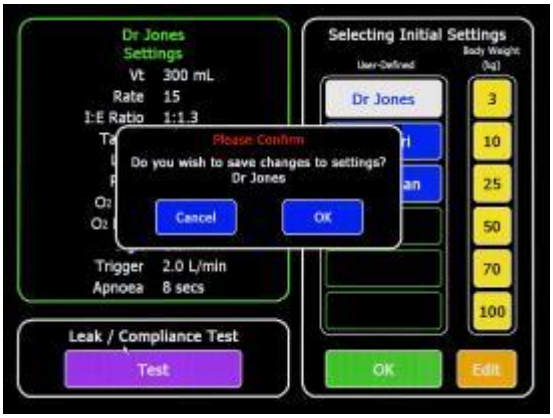
When the Leak and Compliance Test has been selected a dialogue box will indicate test in progress.

The screen indicating that the Leak and Compliance test is in progress - "PLEASE WAIT"

When the Leak and compliance Check is complete the test results will be displayed

Screen displaying the compliance and leak rate

Saving user defined settings



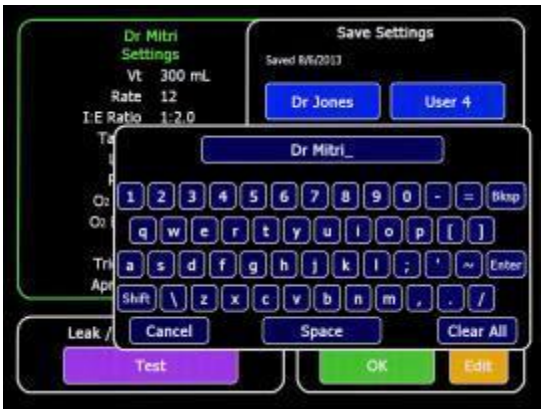
If the user wishes to save the settings that have been used, press the "Patient Select" button and the following screen will be displayed. Cancel will allow a new user or weight defined patient to be selected or OK will bring up the "Save Settings" dialogue box.
Pressing OK in the "Save Settings" dialogue box will show the following screen. Saving the new settings to an unused User Defined setting will allow the settings to be saved and the description to be changed. If a previously used User defined setting is chosen the description can be changed or the settings deleted.

Save changes to settings dialogue box

Pressing OK in the Save Settings dialogue box on the screen above will show the following screen. Saving the new settings to an unused User Defined setting will allow the settings to be saved and the description to be changed. If a ready used User defined setting is chosen the description can be changed or the settings deleted.

Save Settings dialogue box

Key Pad for changing User Defined patient settings



The description of the user defined setting can be changed by pressing the "Change Description" button, and this will bring up a key pad for adjusting the settings.
Press "Clear All" or "Backspace" (Bksp), type the required description, press enter then press "Save" on the "Save Settings" dialogue box. Failure to press the Save key will delete the new name and revert to the old.

Key Pad to alter the User Defined description.

User Confirmation of Initial Settings

After the user has selected the correct settings, a "Confirm Initial Setting" Dialogue box will be displayed asking the user to press "OK" or return to settings so the user can choose another preset user or weight defined value.

Confirm screen for Initial settings

Starting the ventilator

Once the user has chosen the initial settings the actual settings can be adjusted as required prior to starting to ventilate. If the settings are to the users satisfaction, the ventilator can be started by pressing the green "Start Case" button shown on the lower left hand side of the display. Note that NO ALARMS are indicated in the alarms dialogue box - this indicates that there are no system errors, including mains power, battery and drive gas failures. The alarms are disabled until the ventilator is switched to the "start" screen allowing the ventilator to be turned on without nuisance alarms.
Ventilator start screen

Stopping the Ventilator

At the end of a procedure pressing the white/red “End Case” button shown in on the lower left hand side stops the ventilator. This must be confirmed by pressing the “OK” button on the “End Case” dialogue box.

Ventilator cycling showing the End Case button in red

Stop watch

The ventilator is provided with a stop watch to time case length or for drug administration.
To use the stop watch press “start” on the top right of the screen.

Screen with stopwatch

To stop the stop watch press the “Stop” button. To zero the time press the “reset”.
The time can be restarted without zeroing the time.

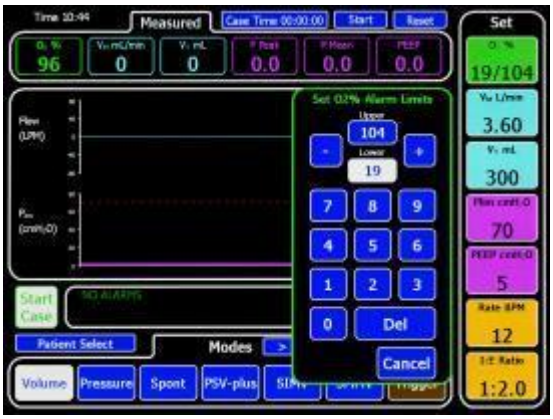
Stop watch stopped and ready for start or reset.

Adjusting Patient Settings

Patient settings are displayed in the “SET” column on the right hand side vertical column. These settings can be adjusted before or during a case.ALL functions require “OK” to be pressed to confirm the setting change. If the setting change is made and the OK button is not pressed he screen will time out and stay at the original setting.
The breathing system parameters which can be set for any one patient are limited such that the combination of settings provides for a minimum drive gas flow of 0.5 l/min and a maximum of 100 l/min. Settings outside these limits are not settable and the ventilator prevents the parameters being set.

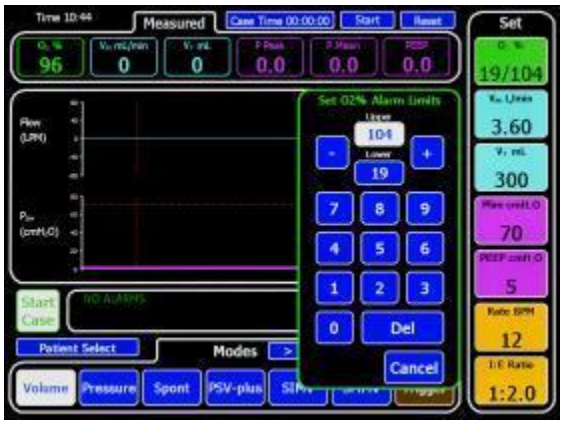
High and Low Oxygen alarms

The ventilator low and high alarms are adjustable from 18% to 50% for the low alarm and 30% to 104% for the high alarm. Note that the alarm being adjusted will retain a 5% differential if settings are set too close to each other.



Press the “O2%” key to call out the key pad.
The key pad automatically has the low Oxygen alarm level activated - the colour indicates the active alarm - the colours are inverted - white background with blue text. Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm followed by “EXIT” or wait for the key pad to time out. Note the cancel key can be used to return the setting to its original value.

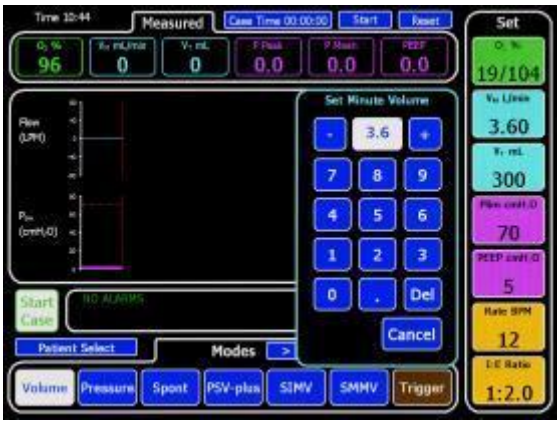
Low O2% alarm setting adjustment key pad.



Press the upper level display. The key pad changes to the “High Oxygen” alarm level - the colour indicates the active alarm - the colours are inverted - white background with blue text. Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm and then “EXIT” or wait for the key pad to time out. Note the cancel key can be used to return the setting to its original value.

High O2% alarm setting adjustment key pad.

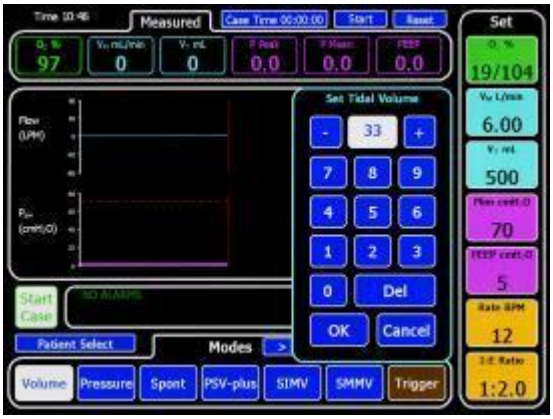
Minute Volume



Minute volume is adjustable between 0.4 and 6 litres per minute.
Press the Vm l/min key to call out the key pad.
Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Minute Volume adjustment key pad

Tidal Volume.

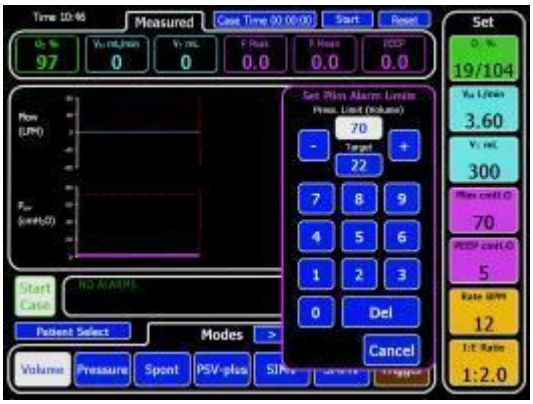


Tidal volume is adjustable between 20 and 1600 Ml.
Press the V_T ml key to call out the key pad.
Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Tidal Volume adjustment key pad

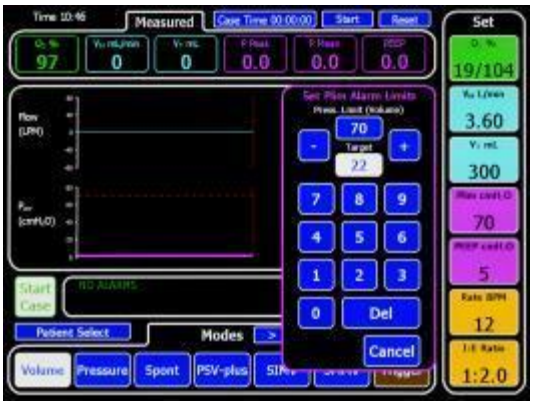
Pressure Limit

Pressure Limit is adjustable between 10 and 70 cmH_20
Target Pressure is adjustable between 10 and 50 cmH_20
Both “Limit” and “Target” pressures are adjustable, the displayed key in the Set column is dependent on whether the ventilator is in Volume or Pressure mode. The call out keypad defaults to the relevant alarm level type for the mode that has been selected.
The Target pressure alarm is relevant only to pressure modes and the Pressure Limit only to Volume modes.
Note that the Pressure limit is automatically adjusted to 10 Cm H2O above peak pressure during ventilation to maintain patient safety.



Press the P_{lim} cmH_20 or the P_{targ} cmH_2O key to call out the key pad. Press the Pressure limit for adjustment.
Either toggle the set value up or down with the + or - keys or type in the new value then press OK to confirm and then EXIT or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value

Pressure Limit key pad

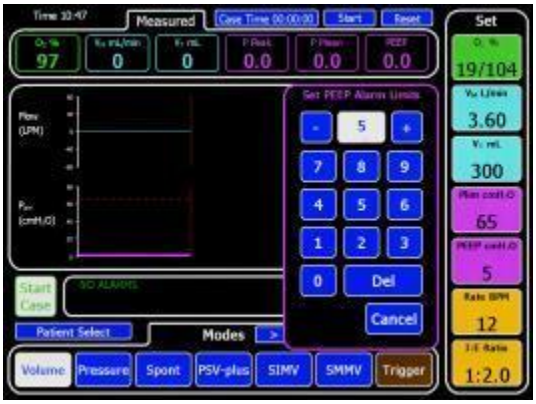


Press the P_{lim} cmH_20 or the P_{target} cmH_2O key to call out the key pad. Press the Target pressure limit for adjustment. Either toggle the set value up or down with the + or - keys or type in the new value then press OK to confirm and then EXIT or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value

Target Pressure Limit key pad

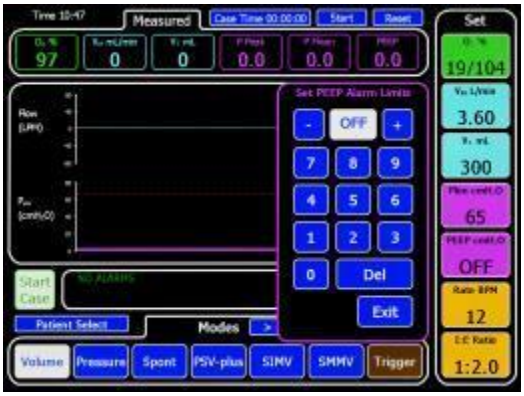
PEEP setting

Positive End Expiratory Pressure is adjustable from 5 to 20 cmH_2O



Press the PEEPcmH2O key to call out the key pad.
Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

PEEP Key pad showing 5 cmH_2O

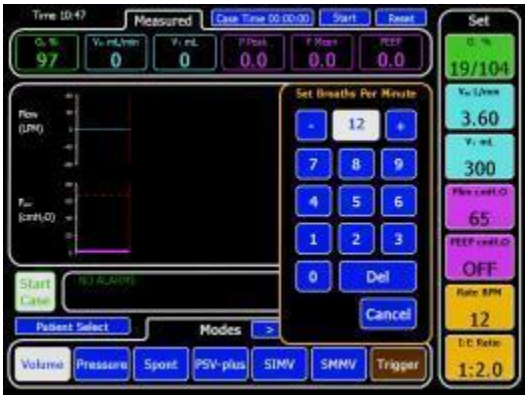


Any value selected below 5 cmH_2O will default PEEP to off.

PEEP Key pad showing PEEP OFF

BPM

The Breaths per minute can be adjusted between 4 and 100 Breaths per minute.

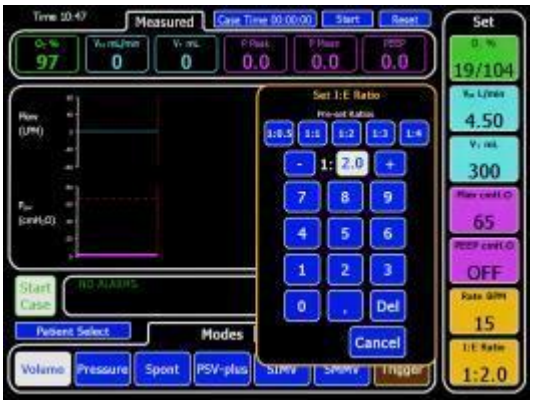


Press the “Rate BPM” key to call out the key pad.
Either toggle the set value up or down with the (+) or (-) keys or type in the new value then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Rate BPM Key pad

I:E Ratio

The I:E ratio can be adjusted between 1:05 to 1:4 and any value in between.



Press the “I:E Ratio” key to call out the key pad.
Either toggle the set value up or down with the (+) or (-) keys, type in the new value or choose a preset value displayed on the top row, then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

I:E Ratio Key Pad

Selecting Ventilator modes

The C-AM ventilator can be used in various ventilator modes, see “Ventilator Modes” section for a description of each mode. These modes are accessed through the horizontal line of select buttons at the bottom of the screen.

Volume Mode

Press the “Volume” mode key to select volume mode.

Volume Mode Key

Pressure Mode

Press the “Pressure” mode key to select volume mode.

Pressure mode Key

Spontaneous mode

Press the “Spont” mode key to select Spontaneous mode.

Spontaneous Key

PSV-Plus mode

Press the “PSV-Plus” mode key to select PSV-Plus mode.

PSV-Plus Key

SIMV mode

Press the “SIMV” mode key to select SIMV

SIMV Key

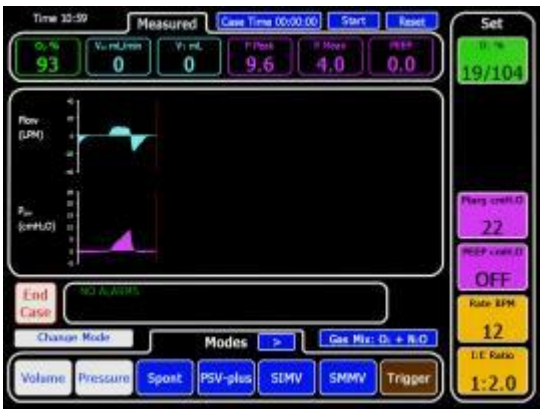
SMMV mode

Press the “SMMV” mode key to select SMMV.

SMMV Key

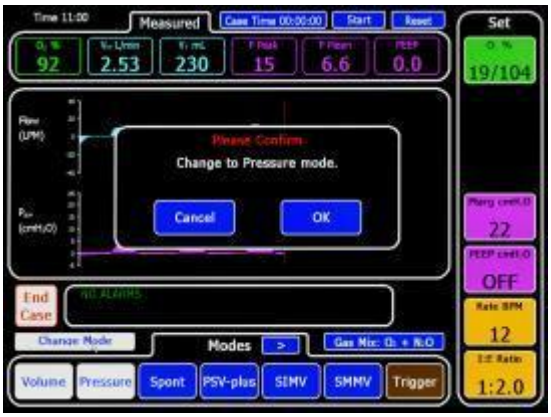
Changing Ventilation mode when ventilator is cycling

The change of mode must always be confirmed to change mode to prevent accidental mode change.



The ventilation mode in use can be changed while the patient is being ventilated without stopping ventilation. Press the key for the new mode required, the new mode and the Patient Select key will flash together, press the “Patient Select” key

Screen showing flashing keys as mode is changed



Press “OK” to change over to pressure mode.

Change to Pressure mode confirm button

Additional Patient settings

Adjusting Patient trigger flow

The patient trigger flows for spontaneous breathing patients can be adjusted to the following flow rates
0.7 / 1 / 2 / 3 / 4 and 6 litres and any settings in between.
To adjust the “Trigger” press the trigger key and select from the pre sets or adjust using the (+) and (-) toggle keys.
Then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Trigger Flow Key

Additional Modes and Settings

Additional modes and settings are available on the next Line of Modes at the bottom of the screen
Press the right hand arrow at the bottom of the screen next to the “Modes” to view the second row of additional modes and setting options.

Additional modes and settings

Additional mode options along bottom of screen

Adjusting the Inspiratory Pause

Inspiratory pause is adjustable by 0 / 10 / 20 / 30 / 40 and 50 %
To adjust the Inspiratory Pause press the “Insp Pause” key and select from the pre set values available.
Then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Inspiratory Pause Key

Adjusting the Sigh

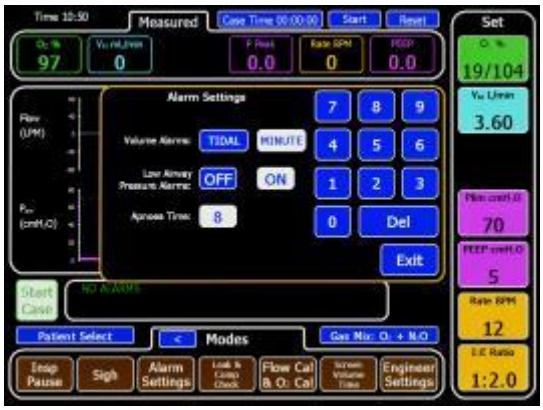
Sigh is adjustable for every 50 / 100 or 150 breaths. The volume delivered is increased by 50%
To adjust the Sigh press the “Sigh” key and select from the pre set values available.
Then press “OK” to confirm and then “EXIT” or wait for the key pad to time out.
Note the cancel key can be used to return the setting to its original value.

Sigh Key

Minute Volume or Tidal Volume Alarm

The **volume** alarm can be set so that the alarm is indicated as either Minute volume or Tidal volume.
Select the desired alarm format and press “EXIT” or wait for the key pad to time out.
The **airway pressure** alarm can be either turned on or off.
The **apnoea** time can be adjusted between 1 and 20 seconds by using the key pad.
Then press OK to confirm and then EXIT or wait for the key pad to time out.

Tidal Volume alarm selected, Low airway pressure alarm off and apnoea alarm set to 8 seconds. Key pad goes white.



Minute Volume Selected - key pad goes white

Calibrating Oxygen Fuel Cell and Patient Flow Sensor

Calibration on room Air and Oxygen

The oxygen fuel cell requires calibrating at 21% oxygen (air) and at 100% oxygen to provide accurate oxygen measurement throughout the sensor range.
First purge all anaesthesia gases from the breathing circuit with Air until the Oxygen monitor display stabilises - note that if the Anaesthesia machine does not have Medical Air, remove the fuel cell from the Inspiratory limb of the absorber and leave it in room air to stabilize. - note that this can take up to 10 minutes

Press the “Flow Cal & O2Cal” button.
Then press “Calibrate on 21% Oxygen”.

Oxygen Fuel Cell and Flow senor calibration Key Pad

Press the “Yes” button to start calibration of oxygen at 21% Calibrating On 21% Oxygen screen - note this will take 30 seconds.

Start Calibrating On 21% Oxygen key Pad

Calibration in Progress. On completion press “exit”.
Calibration can fail if the Oxygen fuel cell is exhausted.
The screen will display a sensor exhausted alarm.

Calibrating at 21% Oxygen screen

Press the “Flow Cal & O2 Cal” button.
Then press Calibrate on 100% Oxygen.

Oxygen Fuel Cell and Flow senor calibration Key Pad

Press the “Yes” button to start calibration of oxygen at 100%
Calibrating On 100% Oxygen screen - note this will take 30 seconds.

Start Calibrating On 100% Oxygen key Pad

Calibration in Progress. On completion press “exit”.
Calibration can fail if the Oxygen fuel cell is exhausted.
The screen will display a sensor exhausted alarm.

Calibrating at 100% Oxygen screen

Calibrating Patient Flow Sensor

The patient flow sensor requires calibrating when new and periodically until it is replaced. The sensor is connected onto the patient "Y" piece before the breathing system filter so that the patient does not contaminate it.

Procedure for Calibration

Disconnect the corrugated black rubber drive tube from the ventilator and attach the red plastic adaptor to the 17mm bellows drive taper on the rear of the ventilator. Connect the patient flow sensor with the flow in the patient direction and calibrate in the forward direction. When prompted by the screen turn the sensor around and calibrate in the opposite direction to calibrate for inspiratory and expiratory directions.

Press the "Flow Cal & O2 Cal" button.
Then press "Calibrate Patient Flow".

Oxygen Fuel Cell and Flow senor calibration Key Pad

Press "yes" to start Calibration of the inspired flow. When prompted, turn the flow sensor around to calibrate the expired flow and press the "continue" button. After calibration, reconnect the flow sensor to the patient circuit Y piece in the correct orientation and place a clean breathing circuit filter ready for the next case. Reconnect the black corrugated rubber tube between the bellows 17 mm taper and the ventilator 17 mm taper.

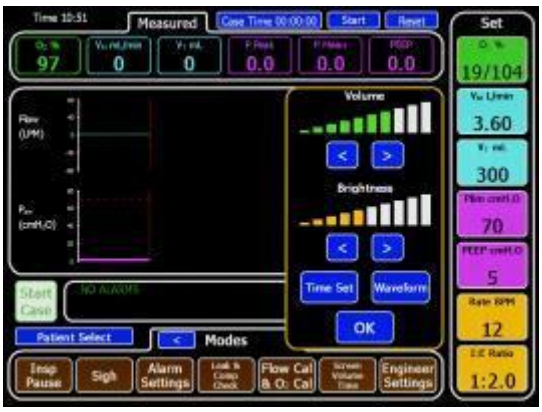
Breathing sensor Calibration screen

When prompted turn the flow sensor around to calibrate the expired flow and press the continue button.
When complete press exit.
Note that the ventilator will prompt the user to put the sensor the correct way round if connected incorrectly.
After calibration reconnect the flow sensor to the patient circuit Y piece and put on a clean patient filter ready for the next case. Reconnect the black corrugated rubber tube between the bellows 17 mm taper and the ventilator 17 mm taper.

Breathing sensor Calibration in Progress

Screen, Volume, Time and Waveform adjustment

Setting the Time and screen brightness.



Press the "Screen Volume Time" button. The volume and brightness can be adjusted by toggling the arrows to the left to reduce the volume or Brightness or to the right to increase the volume or brightness.

Volume, Brightness and Time set screen

Setting the time

Press the "Screen Volume Time" key.
The time is adjusted by activating each window and typing in the correct time for hours minutes and seconds. The date is adjusted by activating each window in turn and typing in the correct date for day month and year. The format button converts the date from Day / month / year to Month / Day / Year to Year month Day.

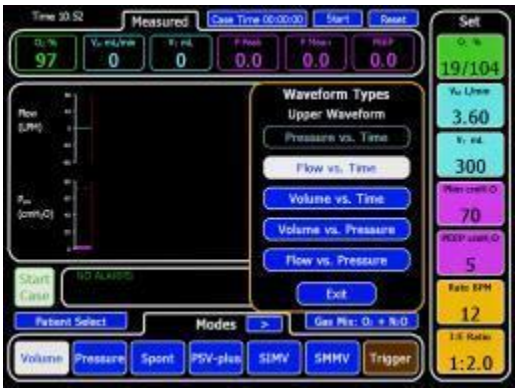
Time set screen

Setting the Screen Waveforms

The lower wave form is always Pressure vs Time. The top screen wave form can be changed to:

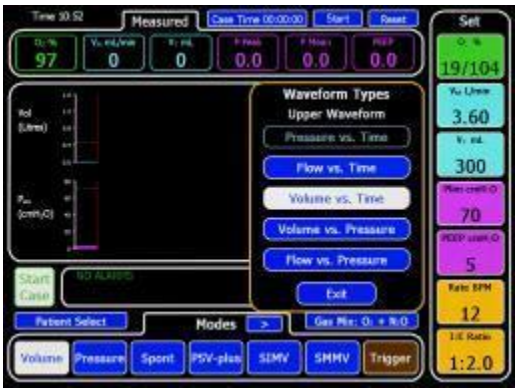
a) Flow verses Time
b) Volume verses Time
c) Volume verses Pressure
d) Flow verse Pressure

Press the Waveform key followed by the waveform key you wish to use as the top waveform.



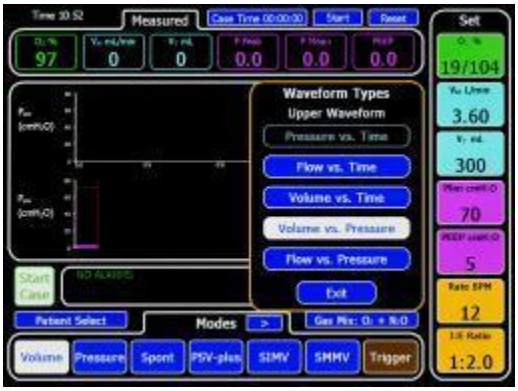
Flow verses Time screen

Flow verses time button selected



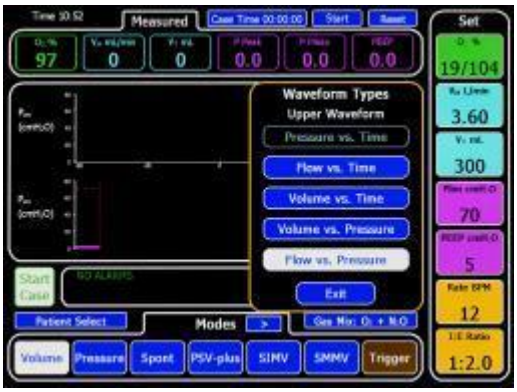
Volume verses Time screen

Volume verses time button selected



Volume verses Pressure Screen

Volume verses Pressure button selected



Flow verses Pressure Screen

Flow verses Pressure button selected

Screen Calibration

The touch screen positioning is calibrated at the factory however should the calibration drift then a calibration is included in the Engineering menu to ensure accuracy during use.

Engineer settings

Certain engineer's settings are available to the user to enable information to be obtained for fault analysis. The settings available are the voltages in Diagnosis and Service records. Information within these engineer settings is required for effective fault finding and this information should be provided when contacting the OES Medical service department.

Press the "Engineer Settings" button

Engineer Settings key pad

Press the "Diagnosis" button to display the voltages key pad

Diagnosis screen

Diagnosis key pad showing "Voltages" key Pad
Press the Voltages key to display voltage diagnostic information. This information will be required by the service department to help resolve technical issues.
When providing information take a photo and send it along with a description of the fault.

Voltage Display Screen

Service Record Information

Press the "Service record" key to obtain Serial number, Software version, Hardware version, Mechanical Version, Manufactured date, Last serviced date and Ventilator cycles since last service and since new.

Engineer settings key pad

Service record screen

Software Update

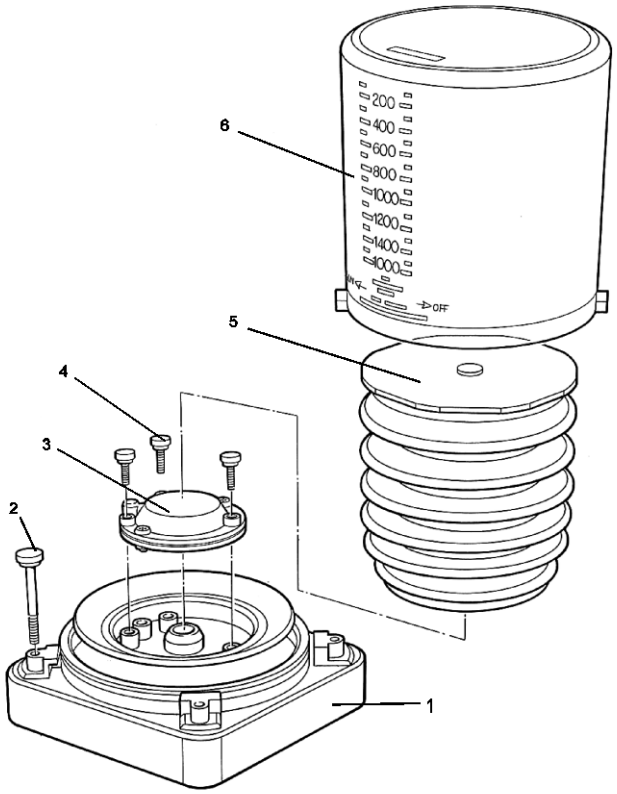
Software Update - to update software, remove the stainless steel plate on the underside of the ventilator towards the front edge to obtain access to the USB port.
Plug the memory stick with the updated software on into the USB port underneath the ventilator the Upgrade Now button will go blue then press Upgrade Now. The ventilator will indicate when the upgrade is complete.
Warning - the software is encrypted and user access is not possible, ensure that the memory stick is left in the ventilator until the update is complete.

Software Update screen

Ventilator Construction

The ventilator case is constructed of anodised aluminium with moulded front display panel and Painted cover, the paint is an Anaesthetic resistant polyester powder coat.
The internal parts are made from plated brass, stainless steel, plastic and anodised aluminium.

Bellows Unit and Bellows Base Assembly



1 Bellows base.
2 Bellows base screw.
3 Exhaust diaphragm assembly.
4 Exhaust diaphragm assembly screws.
5 Bellows.
6 Bellows housing.

Bellows Base

The bellows base unit retains the exhaust diaphragm assembly, bellows and provides a secure mounting for the bellows housing.

An expiratory exhaust valve seat which allows the escape of exhaust gas to the bellows exhaust port on the rear of the assembly is situated in the centre of the assembly.

The bellows base assembly is attached to the top of the ventilator case and incorporates an "O" seal for the bellows housing to seal against and an "O" seal to seal between the bellows base and the exhaust gas diaphragm assembly

WARNING - care must be taken not to damage the precision exhaust valve seat.

Bellows Base screws

Thumb screws, which hold the bellows base to the top of the ventilator case. (4 off)

Exhaust Diaphragm assembly

This assembly contains a diaphragm and a sealing disc which seals on the exhaust valve seat in the bellows base during the expiratory phase.

Exhaust Diaphragm assembly screws

Thumb screws which hold the diaphragm assembly onto the bellows base assembly. (3 off)

Adult Bellows

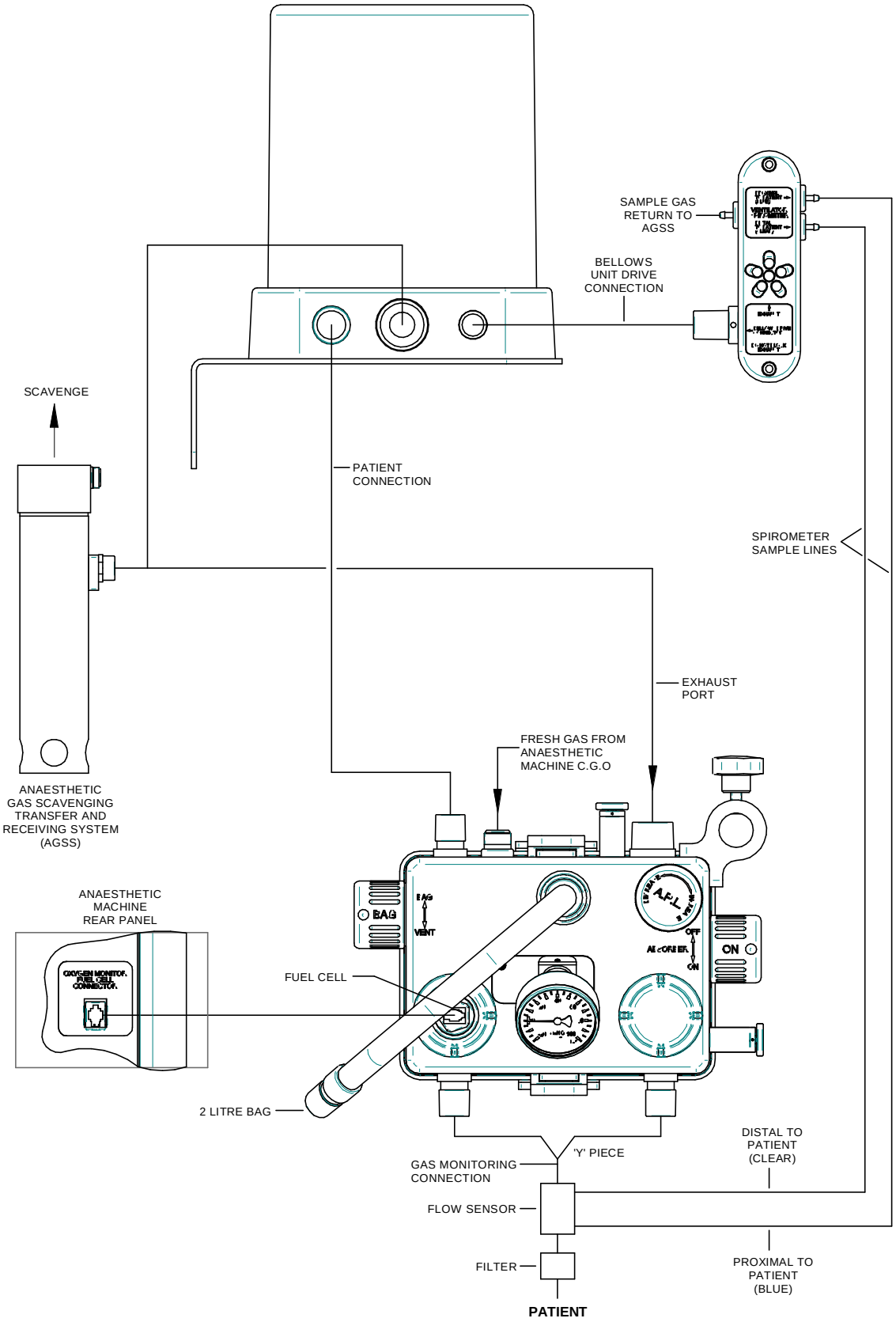
The bellows are attached to the bellows base assembly by the lower convolution on the shoulder of the bellows base assembly.

Warning – care must be taken to ensure that the bellows is attached by it's bottom convolution onto the bellows base shoulder, Failure to attach the bellows properly may result in the bellows drive gas diluting the patient circuit gas.

Adult bellows housing

The adult bellows housing is located on the bellows base assembly by the location ring on the bellows base assembly it is then locked in position by twisting clockwise until the lugs are located in the bellows base assembly.

3.3 Drive gas and breathing circuit gas connections



Bellows unit driving gas connector

A 17 mm taper which connects to the ventilator bellows drive gas connector via a flexible corrugated tube.

Patient Connection

A 22 mm male taper connection, which connects to the ventilator port on the absorber circuit via 0.8 metre length of disposable corrugated tubing.

Bellows Unit Exhaust port

A 30 mm taper to which the anaesthetic gas scavenge system must be connected.

WARNING - the anaesthetic gas scavenging system must not generate more than 0.5 cm H20 of negative or positive pressure. Failure to comply with this requirement may result in positive or negative pressure within the breathing circuit.

Breathing System Flow Sensor (Spirometer)

Connect the two Spirometer sample lines between the flow sensor unit and the two connectors on the rear of the ventilator. The blue sample line is connected to the flow sensor proximal to the patient and the clear sample line is connected distal to the patient on the flow sensor. The ventilator end connections are clearly marked with the blue connector above the clear connector point.

Gas supplies

The following gas supply pressures are nominal and are required for normal operation.
Gas supply inlets are protected with 40µm sintered filters.

Pipeline supply pressures:
USA/ Canada/Japan - 340 kPa (50 psig)
UK - 400 kPa (58 psig)

Cylinder supplies: 13700 kPa (2000 psig)

The Anaesthesia Ventilator gas continuous demand shall not exceed 60 L/min at a pressure of 50 +0/–5 psig measured at the gas inlet connector.

3.4 Cleaning

Note - Cleaning the oxygen cell with alcohol solutions may damage the cell and providing unreliable oxygen reading for a period of time and giving rise to falsely high oxygen concentration readings.
Cleaning must only be undertaken with clean distilled or de ionized water and allowed to fully dry before reuse.

The ventilator components may only be cleaned with the following approved methods:

Ventilator Component	Disposable	ETO	Autoclave 136 Deg C	Clinell Universal Sanitising Wipes:	Clinell Detergent wipes	Clinell Sanitising wipes:
Control Unit	×		×	✓	✓	✓
Bellows base assembly	×	✓	✓	✓	✓	✓
Exhaust valve assembly	×	✓	✓	✓	✓	✓
Bellows	×	✓	×	✓	✓	✓
Bellows housing	×	✓	✓	✓	✓	✓
Spirometer sensor and tubes	×	×	×	✓	✓	✓

Warning – care must be taken to prevent water entering the machine during cleaning.

Warning - Do not autoclave the oxygen sensor. It will damage the sensor

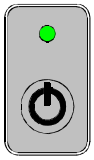
Warning – Always use a breathing circuit filter at the patient end of a breathing system to protect the ventilator from contamination and cross contamination to a patient from a previous patient.

Caution - DO NOT apply excessive pressure to the display screen, cleaning is restricted to soap-based sanitising wipes.

3.5 Specification

Model	C-AM with Integrated C-AM anaesthesia ventilator
Function	For ventilation use during anaesthesia in combination with an anaesthetic workstation
Internal Compliance	With breathing system: approximately 7 ml/cm H2O Without breathing system: approximately 3 ml/cm H2O
Drive Gas	Oxygen 3 - 7 bar at 100 l/min Air may be used if ordered separately.
Drive Gas filter	40 micron.
Mains Electricity	Universal Input voltage 100Vac to 240Vac, 50-60Hz Maximum current at 100 - 110v, 1.2 A Maximum current at 220 - 240v, 0.4 A Socket output voltage is equal to supply voltage
Power supply indicator	Mains applied (standby): Yellow Mains applied ventilator ON: Green Mains Failure: 'AC Power loss' alarm
Fuses	Mains;T1.25AH250 Battery; T10AL50 minimum voltage rating.
Battery type	Yuasa 12 volt 1.6 Amp hour
Battery Backup	With a fully charged battery, uninterrupted ventilator function will be maintained for up to 4 hours, depending on ventilator settings. 10 minutes advance warning of exhausted battery before final shut down. Battery level indicator provided.
Alarm mute	120 seconds
Function selection	Touch screen with confirmation of function selected.
Breathing gas selection	Gas mixture selection for Oxygen and Nitrous Oxide or Oxygen and Air
Ventilation Modes	
Volume	Volume control
Pressure	Pressure control
Spont	Spontaneous mode
PSV – Plus	Pressure support ventilation with intelligent switching to SIMV to assist patient in event of insufficient patient effort.
Pressure with VG	Pressure control with Volume Guarantee
SIMV	Synchronised intermittent mandatory volume
Cardiac Bypass	Cardiac Bypass
SMMV	Synchronised mandatory minute volume
Ventilation parameters	
Tidal volume	20 to 1500 ml
Target pressure	10 to 50 cm H_2O
Breathing rate	4 to 100 BPM
I:E Ratio	1:05 to 1:6
PEEP	5 to 20 cm H_2O
Support pressure	3 to 20 cm H_2O PEEP referenced.
Minute volume	1 to 20 litres per minute
Pressure limit	20 to 70 cm H_2O
Inspiratory pause	0 to 50% of inspired time
Trigger setting	0.7 to 6 LPM flow
Sigh	1.5 x V_t at 1 – 5 times per 200 breaths (Vol vent only)
Inspiratory time	0.6 – 15 secs
CAPA	4 to 20 cmH_2O

<table>
<tr><td>Ventilation Accuracy</td><td></td></tr>
<tr><td>Delivered volume
Monitored volume
Delivered pressure
Monitored pressure
PEEP</td><td>±10% or 10ml whichever is greater
±10% or 10ml whichever is greater
±10% or 2cmH_2O whichever is greater
±10% or 2cmH_2O whichever is greater
± 2cmH_2O</td></tr>
<tr><td>Alarms</td><td></td></tr>
<tr><td>Automatic Alarms</td><td><table>
<tr><td>Vent inoperative</td><td>Low supply gas pressure.</td></tr>
<tr><td>High airway pressure.</td><td>Negative airway pressure.</td></tr>
<tr><td>Patient disconnect.</td><td>High cont. Positive Airway pressure.</td></tr>
<tr><td>High oxygen.</td><td>Low oxygen.</td></tr>
<tr><td>High airway flow</td><td>High tidal volume.</td></tr>
<tr><td>Low tidal volume.</td><td>High minute volume.</td></tr>
<tr><td>Low minute volume.</td><td>Apnoea.</td></tr>
<tr><td>Power about to fail.</td><td>O2 sensor disconnected.</td></tr>
<tr><td>Low airway pressure.</td><td>High drive pressure.</td></tr>
<tr><td>Battery missing</td><td>Very low battery.</td></tr>
<tr><td>O2 sensor exhausted.</td><td>Drive valve leaking.</td></tr>
</table></td></tr>
<tr><td>User Set Alarms</td><td>High airway pressure
Low oxygen concentration
High oxygen concentration</td></tr>
<tr><td>Alarm mute</td><td>120 seconds</td></tr>
<tr><td>Alarm accuracies</td><td></td></tr>
<tr><td>Volume measurement
Pressure measurement</td><td>better than +/- 20%
better than +/- 2 cm H_2O</td></tr>
<tr><td>Default patient settings</td><td>6 Standard default settings for 3, 10, 25, 50, 70, and 100 Kg patient weights
6 User defined default settings saved by name</td></tr>
<tr><td>Oxygen Monitor</td><td></td></tr>
<tr><td>Oxygen sensor</td><td>Fuel cell type - MOX 3</td></tr>
<tr><td>Oxygen fuel cell usable life</td><td>Approximately 18 month’s general use. Note: life is dependent on the number of oxygen % hours seen by the cell.</td></tr>
<tr><td>Oxygen fuel cell stabilisation</td><td>Approximately 15 minutes</td></tr>
<tr><td>Oxygen fuel cell response time</td><td>Air to 100% oxygen T90 less than 15 seconds</td></tr>
<tr><td>Oxygen Monitor Accuracy</td><td>Oxygen reading better than +/- 2%</td></tr>
<tr><td>Oxygen cell interference</td><td>Interference Gases and Vapours (in 30% Oxygen, 70% Nitrous Oxide)
Interference at 5% concentrations
Carbon Dioxide, Halothane, Enflurane, Isoflurane, Sevoflurane: less than 1%
Nitrous Oxide at 80% in oxygen, less than 1%
Humidity: unaffected.
Temperature: unaffected.
Pressure: Directly proportional to barometric pressure change.</td></tr>
<tr><td>Oxygen fuel cell calibration interval</td><td>Weekly calibration required with daily check</td></tr>
<tr><td></td><td></td></tr>
</table>

Degree of protection against electric shock	 Type B
Classification with internal electric power source	Class 1
Classification according to the degree of protection against ingress of dust and water.	IPX0
On/off switch	
Environmental Conditions	
Temperature:	Operating 15 – 35°C Storage -5 – 50°C
Humidity	Operating 0 – 95% non condensing. Storage 10 – 95% non condensing.
Air pressure	Operating 80 – 110 kPa Storage and transport 11.5 – 110 kPa
MRI compatibility.	The standard C-AM ventilator is not approved for use in an MRI environment.

Disposal	
Disposal of used batteries.	Do not dispose in landfill; refer to an approved recycling facility. Follow your hospital, local state and federal regulations
Disposal at the end of useful life.	Do not dispose of this anaesthesia system or components in landfill. Follow your hospital, local state and federal regulations
Disposal of device packaging.	The device packing may be returned to OES Medical at customers expense for disposal or re-use
Disposal of used breathing circuit components	Follow advice above.
EC Territories.	Follow the requirements of Directive 2002/96/EC. Alternatively the device may be returned to OES Medical at, customer's expense, for disposal. 

3.6 Pre-use checks

Prior to use the anaesthetic ventilator must be inspected and checked as part of the anaesthesia system to ensure correct and safe function.

Pre-use check list

(1) Check the ventilator for labelling to indicate if the machine has any faults or has just been serviced.
(2) Check for visible signs of damage.
(3) Check gas supply connection is correctly secured and in good condition.
(4) Check the correct connection of the patient circuit and any auxiliary equipment such as oxygen analyser, patient monitoring equipment, carbon dioxide absorber, gas scavenge etc.
(5) Perform a system overall leak check.

Service fault

Check the ventilator for labelling which will indicate if the device is unserviceable or has just been serviced.

Warning – additional care must be taken during the pre-use check after any equipment has been serviced.

Warning – do not use any equipment that has a fault until it has been fully repaired by a suitably qualified service engineer.

Ventilator damage

Check the ventilator for signs of damage. Checks should include looking for blocked gas pathways, or other cause of potential gas flow restrictions or damage to any leads or mains wiring.

Patient circuit and auxiliary equipment

a) Ensure that equipment such as ventilators, monitors, circle absorbers and other auxiliary equipment is securely attached the anaesthetic machine.
b) Ensure that all cabling and sample lines are correctly attached – refer to individual manufacturer's user manuals.
c) Connect patient circuit to the anaesthesia machine common gas outlet.
   This will include connections for the following equipment: -
   a. Ventilator and bellows unit.
   b. Carbon dioxide absorber.
   c. Theatre scavenging system.
   d. Sample lines.

Patient circuit leak check

With the patient circuit connected to the anaesthesia machine and ancillary equipment a low-pressure patient circuit check leak check can be performed.

(7) Fully close the adjustable pressure relief valve on the absorber.
(8) Ensure that the absorber is in bag mode.
(9) Block the breathing circuit patient connection with your thumb.
(10) Fill the reservoir bag with the oxygen flush.
(11) Turn on the flowmeter with minimum flow rate.
(12) The circuit pressure must exceed 50 cm H20 at 150 – 200 cc flow rate.

Warning – check the circuit for free flow after the pressure test by increasing the oxygen flow to 6 litres per minute and ensuring that gas flows freely from the patient connection.
Open the adjustable pressure relief valve fully and block the patient connection and ensure that the circuit pressure is not greater than
5 cm H20.

AAGBI Check List

The attached (SEE Appendix 2) **Checklist for Anaesthetic Equipment 2012** has been published by the AAGBI as a basic check list for pre use checking of anaesthesia systems of which the C-AM may form part of. It is reproduced here for information only and is copyright of the AAGBI

Alarm Messages and Settings

HIGH PRIORITY GROUP Audio signal repeating every 1 Second, Message displayed in RED		
Priority	**Message Text**	**Set Condition**
1	VENT INOP	Software detects a non-recoverable system error
2	LOW SUPPLY GAS	Regulated supply gas outside the range 2.0 to 5.0 Bar.
3	HIGH AIRWAY PRESSURE	End Case: airway pressure > 80 cmH2O (80hPa) PCV: airway pressure > (target + 2 cmH2O(2hPa)) PSV- plus: airway pressure > (support + 2 cmH2O (2hPa)) Other modes: airway pressure > set limit
4	NEGATIVE AIRWAY PRESSURE	Spont: Average airway pressure < -10 cmH2O (-10hPa)for 1 seconds Other modes: Average airway pressure < -5 cmH2O(-5hPa) for 1 seconds
5	PATIENT DISCONNECT	Breathing system fails to detect flow and pressure in BS
6	HIGH CON. POS. AIRWAY P.	Average airway pressure > 25 cmH2O (25hPa) for 5 seconds
7	HIGH OXYGEN	Measured oxygen above upper set limit.
8	LOW OXYGEN	Measured oxygen below lower set limit.
9	HIGH AIRWAY FLOW	Cumulative tidal volume exceeds set volume by more than 50% at any point during inhalation.
10	HIGH TIDAL VOLUE	Tidal volume has exceeded set tidal volume by more than 50%.This alarm is ignored in the first cycle.
11	LOW TIDAL VOLUME	Tidal volume has undershot set tidal volume by more than 50%. This alarm is ignored in the first cycle.
12	HIGH MINUTE VOLUME	Minute volume has exceeded set minute volume by more than 50%. This alarm is ignored in the first cycle.
13	LOW MINUTE VOLUME	Minute volume has undershot set minute volume by more than 50%. This alarm is ignored in the first cycle.
14	APNOEA	No inhalation detected in the period set by the user.
15	POWER ABOUT TO FAIL	Ventilator running on battery power and voltage dropped below 10.7
16	O2 SENSOR DISCONNECTED	O2 sensor removed.
17	LOW AIRWAY PRESSURE	Airway pressure fails to reach expected pressure at the end of inhalation. Switchable on/off via “Modes > Alarm Setting”
18	HIGH DRIVE PRESSURE	PCV, PSV-plus: average drive pressure > 60 cmH2O (60hPa) Other modes: average drive pressure > set limit + 2 cmH2O (2hPa)
MEDIUM PRIORITY GROUP Audio signal repeating every 8 Seconds, Message displayed in YELLOW		
	BATTERY MISSING	No battery detected
	VERY LOW BATTERY	Ventilator running on battery power and voltage dropped below 11.0
	O2 SENSOR EXHAUSTED	O2 Sensor output has dropped sufficiently to prevent calibration being performed.
	DRIVE VALVE LEAKING	Flow detected in drive gas circuit during standby
LOW PRIORITY GROUP Audio signal single bleep on detection, Message displayed in YELLOW		
	AC POWER LOSS - RUNNING ON BATTERY	No power from medical PSU.
	LOW BATTERY	During battery discharge: voltage drops below 11.5V

3.6 User maintenance

Daily Ventilator cleaning and sterilization

See also section 8 for approved cleaning wipes.
The external surfaces of the ventilator can be wiped with a damp cloth followed by drying off prior to clinical use.

Note – mild antiseptic solutions may be used to clean the anaesthetic machine but must be wiped thoroughly with a damp cloth prior to drying.

Warning – care must be taken to prevent water entering the machine during cleaning.

For cleaning of ancillary items such as absorbers, ventilator bellows and patient circuits refer to the manufacturer's user instructions.

Daily and Weekly

(6) Overall machine leak test.
(7) Cleaning of the anaesthetic system surfaces.
(8) Function test.

(a) Daily and pre use check by user. As a minimum requirement the ventilator and the associated anaesthesia system must be checked in compliance with the relevant professional bodies (e.g. Association of Anaesthetists of Great Britain and Ireland) or hospital authority recommendations.
See section 11 "Pre Use" Check section as a guide.

(b) Weekly calibration of Oxygen sensor and patient flow sensor. Back up battery confirm fully charged.

6 monthly inspection

The 6 monthly inspections are a formal repeat of the weekly function test and including an additional inspection of the ventilator bellows and to be carried out by the hospital trained service technician and the checks formally recorded.

5 Year Service

This will consist of the 6 monthly inspection and replacement of the following components as a precaution to prevent potential device failure.

Component	Part number
Battery	1419-213
Gas supply inlet filter	1350-030
O ring	1215-023 x 3
O ring	1215-027 x 1
O ring	1215-005 x1
O ring	1215-019 x 1
Regulator	1510-023
Bellows - if required	9070-003
Drive gas hose - if required	9060-010

Service requirements are detailed in the service documentation that is available only to factory-trained personnel who are currently employed by agents of Gradian Health or OES Medical.

If the ventilator is to be placed into storage for a lengthy period of time disconnect and remove the backup battery. Battery storage time without recharge is dependent on environmental conditions.

Ordering information

Refer to your agent for anaesthesia equipment ordering information.

Electromagnetic Declaration
The C-AM ventilator meets the requirements of EN60601-1-2 (Electromagnetic compatibility - requirements and tests). See Appendix 1

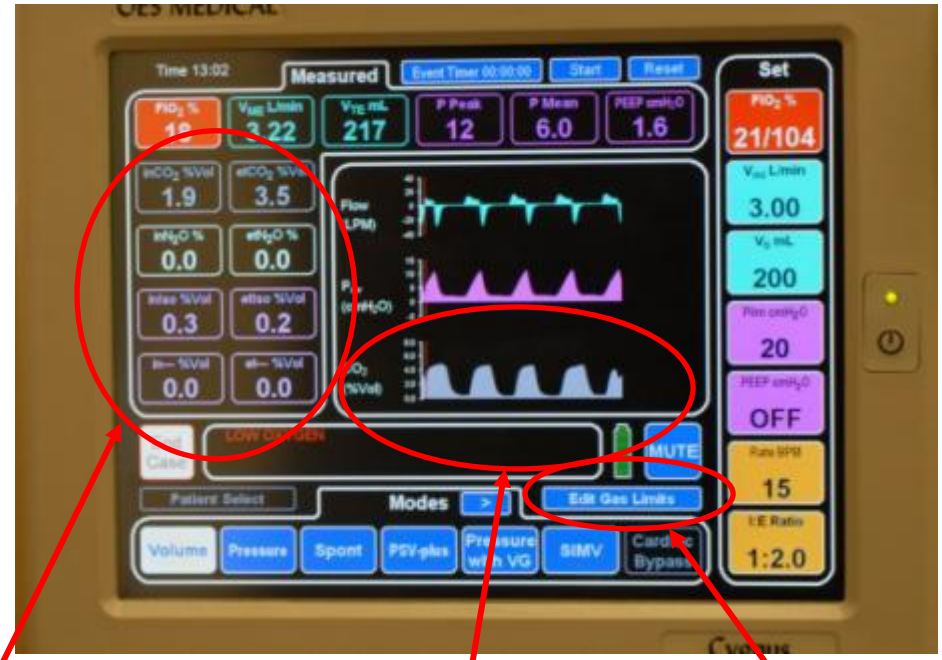
Section 4

Patient Airway Gas Monitor

Section 4 Patient Airway Gas Monitor

4.1 Patient Airway Gas monitor Description

The C-AM ventilator display screen layout is reconfigured when the Patient Airway Gas Monitor is included with the C-AM. All ventilator parameters and controls remain as for the C-AM ventilator.



The Patient Airway Gas Monitor numerical values are added in this area

The Patient Airway Gas Monitor alarm limits area changed with this button

The Patient Airway Gas Monitor has a third waveform for CO_2 added in this area

Patient Airway Gas monitor Description

General

The Patient Airway Gas Monitor is designed to comply with the following standards:-

BS EN ISO 80601-2-55
BS EN 60601-1
BS EN ISO 60601-1-2
BS EN 60601-1-6
IEC 60601-1-8
IEC60601-1-9
IEC 62304

All gas volume, flow and leakage specifications are expressed as STPD (Standard Temperature and pressure, Dry) where temperature is 20°C and pressure 101.3kPa

Gas Monitor Function

The Gas Monitor is a side stream measurement device, using Infrared measurement for CO_2, N_2O, and automatic agent identification of Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane. The Gas monitor is available with or without Paramagnetic Oxygen measurement.

A water trap is provided, consisting of two hydrophobic membranes serving to contain condensed water in order to protect the measurement module of the gas measurement. To further enhance the safety of the gas measurement, two self-sealing filter elements that close and turn blue upon contact with water are positioned in the gas stream.

Alarm limits for all measurements can be set. In the event of a Gas monitor measured parameter being outside a pre-set limit the ventilator will annunciate that anomalous condition and display the erroneous function in the Alarm area of the ventilator display.

The Gas Monitor is integrated into the C-AM ventilator and will monitor during all modes of operation of the ventilator.

Provision is provided to return the sample gas to the scavenging system.

WARNING – Any use of the medical device requires full understanding and strict observation of all parts of these instructions for use. The medical device may only be used for the purpose indicated under “Intended use”. Strictly observe all WARNINGS and CAUTION statements throughout these instructions for use and all statements on the medical device labels. Non-compliance with these WARNING and CAUTION statements constitutes a use of the medical device which is not in accordance with its intended use.

CAUTION – Risk of injury due to gas measurement failure and device failure. After an extended period of use, the eater trap membrane can become permeable, and water and bacteria can enter the measuring system. Contamination negatively affects the gas measurement and may lead to gas measurement failure. The water trap must be replaced after a service life of 4 weeks at the latest.

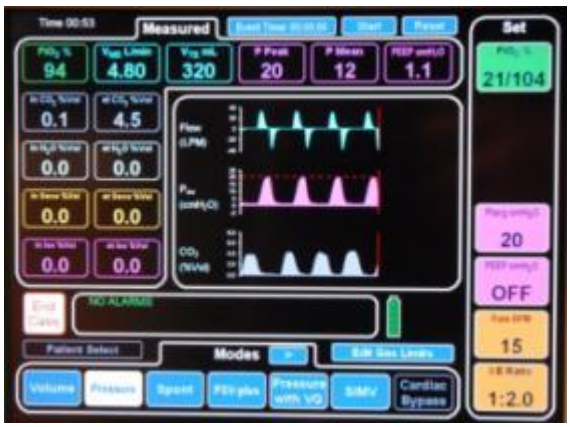
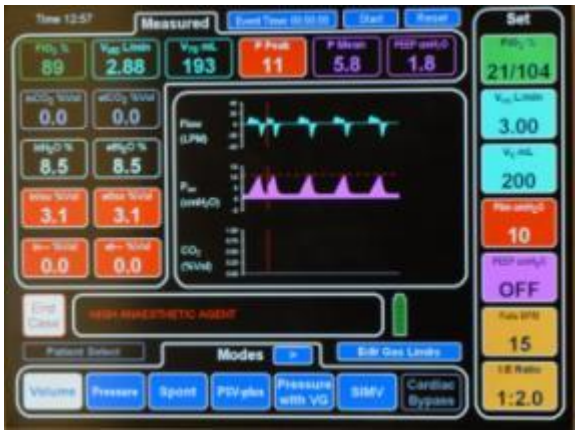
CAUTION – Risk of injury due to gas measurement failure and device failure. Alcohol or cleaning agents / disinfectants that enter the water trap may damage the membrane and the measuring system.
Do not use these substances. Do not wash, rinse or sterilize the water trap.

CAUTION – Risk of injury due to distorted measurement results. Aerosols may damage the membrane and the measuring system. Avoid the use of aerosols in the breathing system.
Do not use the water trap in conjunction with medication nebulizer.

CAUTION – Risk of injury due to distorted measurement results. Silicone may enter the measuring device and distort the gas measurement.
Do not spray the O rings of the water trap with silicone spray.

CAUTION – Risk of injury due to contamination. Particles from the ambient air may enter the device.
Do not use the device without the water trap.

4.2 Operating the Gas Monitor

Normal Run Screen	
	This is the ventilator screen in it run mode with the gas monitoring information shown to the right of the screen and the additional et CO_2 waveform. The gas monitor automatically starts when the start case button is pressed.
Adjusting Alarm Limits	
	Pressing the Edit Gas Limits button or pressing the parameter that needs to be change the dialogue box opens and allows changes to be made to alarm limits and units of measure. Press the item to change the box will turn to white, use the key pad to key in the new value. If any MIN value is set to zero the value returned in the parameter box will be OFF If the units need to be changed pressing the button will toggle through the available options. When complete press the EXIT button to return to the main screen
Alarm messages	
	Similar to all other alarm messages for the ventilator the gas monitor alarm messages will be displayed in the message box below the waveforms and the appropriate parameter will turn red.

Gas Monitor Maintenance	
	If the alarm message WATER TRAP PROBLEM is displayed check:- The water trap is fitted correctly The water trap is not full of water The water stop filters have not been activated (turned Blue) See maintenance section Replace the water trap
	If the alarm message GAS SAMPLE LINE OCCLUSION is displayed check:- The sample line does not have water in it The sample line is not folded/kinked The sample line is not trapped
Gas Monitor Calibration	
	The alarm message GAS MONITOR CALIBRATION NEEDED will be displayed when the zeros need to be calibrated. This message will only be displayed during standby mode. The method of calibration is slightly different depending on if the system has the paramagnetic oxygen measurement or the fuel cell measurement system

With Paramagnetic Oxygen measurement calibration

Press the Cal/Screen/Clock button in the second modes area.

Choose Cal. Gas Monitor (air).
A second screen will open with further instructions for pre test conditions. Follow these instructions then press YES.

Calibration will take approximately 1 min.

NOTE: When calibrating at 21% with the sample line removed from the water trap it is essential that no contamination such as spilt anaesthetic agent is present as the calibration will be incorrect.

NOTE: Calibrating at 100% O_2 is not used.

With Fuel Cell Oxygen measurement

Choose to calibrate on O_2 at 21% (AIR) or on O_2 at 100%.

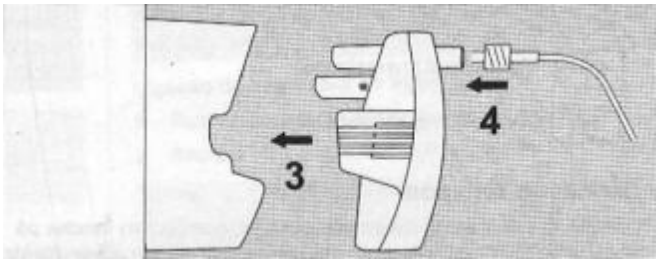
Calibration will take approximately 1 min.

NOTE: If calibrating at 21% with the sample line removed from the water trap it is essential that no contamination such as spilt anaesthetic agent is present as the calibration will be incorrect.

4.3 Gas Monitor Connections

Water trap and sample line connection

Connecting the water trap
1 Remove the new water trap from the packaging.
2 Write the current date on the front of the water trap



3 Holding the water trap by the fluted grips, insert it into the holder until it clicks audibly into place.
4 Connect the sample line to the Luer Lock connector of the water trap.
5 Connect the other end of the sample line to the patient filter.

Patient flow sensor and Sample line connections

4.4 Technical Specification

Gas Measurement	
Method	Sidestream gas measurement, Infrared measurement:CO_2, N_2O, anaesthetic agents, Paramagnetic measurement O_2
Barometric pressure compensation	Automated compensation
Gas Sample rate	200mL/min ±20ml/min
Drift compensation (zeroing)	Automated cyclical zeroing. Once per day (in error-free operation)
Zeroing duration	< 20 sec.
Cross sensitivity	None concerning alcohol (<3000 ppm blood conc.) acetone (<1000 ppm), methane, water vapour, NO, and CO
O_2	
Range	0 to 100 Vol%
Accuracy	± (2.5 Vol% + 2.5 % rel.)
Rise Time (t10....90)	< 500 ms
Time to specified accuracy	< 450 sec.
CO_2	
Range	0 to 13.6 Vol%
Accuracy	± (0.43 Vol% + 8 % rel.)
Rise Time (t10....90)	< 350 ms
Time to specified accuracy	<450 sec.
Time to availability	< 60 sec.
N_2O	
Range	0 to 100 Vol%
Accuracy	± (2 Vol% + 8% Rel.)
Rise Time (t10....90)	<350 ms
Time to specified accuracy	<450 sec.
Anaesthetic gases	
Range	
Halothane	0 to 8.5 Vol%
Isoflurane	0 to 8.5 Vol%
Enflurane	0 to 10 Vol%
Sevoflurane	0 to 10 Vol%
Desflurane	0 to 20 Vol%
Accuracy	± (0.2 Vol% + 15% Rel.)
Rise Time (t10....90)	<450 ms
Time to specified accuracy	<450 sec.
Automatic detection	
Primary gas	At the latest at 0.3 Vol%
Secondary gas	At the latest at 0.4 Vol% With Desflurane concentration greater than 4 Vol% mixture detection occurs at the latest when the concentration of the second anaesthetic gas rises above 10 % of the Desflurane concentration
Respiratory rate	
Range	0 to 100 / min
Accuracy	0 to 60 /min ± 1/min, >60 /min not specified
Resolution	1 /min
Ambient conditions	
During Operation	
Temperature	10 to 50° C (50 to 122° F)
Atmospheric pressure	620 to 1100 hPa (9.0 to 15.9 psi)
Relative humidity	5 to 95% without condensation
During storage and shipment	
Temperature	-20 to + 75°C (-4 to 158°F)
Atmospheric pressure	620 to 1100 hPa (9.0 to 15.9 psi)
Relative humidity	5 to 95% without condensation

4.5 Alarm Messages and settings

High Priority group	**Audio signal repeating every 1 Second, Message displayed in RED**
Message text	**Set condition**
Low Agent	Measured Agent below lower set limit
High Agent	Measured Agent above upper set limit
Low expired CO_2	Measured CO_2 below lower set limit
Low inspired CO_2	Measured CO_2 above upper set limit
Gas Sample Line Occlusion	Sample gas not flowing to monitor
Water trap Problem	Water trap full or not fitted correctly
Gas Monitor Inoperative	Software detects a non-recoverable system error
Medium Priority Group	**Audio signal repeating every 8 Seconds, Message displayed in YELLOW**
Gas Monitor Calibration Needed	Zeroing of monitor needed

4.6 User maintenance

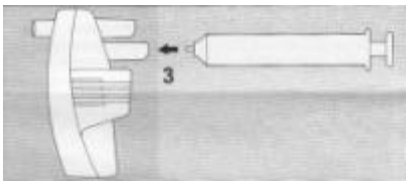
Replacing the water trap

The gas monitor is integrated into the C-AM ventilator therefore the only additional user maintenance is to check and replace the water trap:-

When the maximum service life of 4 weeks is reached
If there is an error message on the C-AM ventilator screen
If emptying does not rectify the error message
If it is severely soiled
If the swelling seals in the connection turn blue

Emptying the water trap

1 Remove the sample line from the water trap.
2 Press the fluted grips of the water trap and pull outwards



3 Insert an empty syringe without canula, at least 20mL, into the blue connector.
4 Extract water, remove syringe and dispose of full syringe as infectious hospital waste.
5 Push the water trap into the holder again until it audibly clicks into place and connect the sample line

The gas monitor will notify when the zeros need to be calibrated

Disposal

Water traps which have been taken out of service should be disposed of as infectious hospital waste. Observe local waste disposal regulations.

Service parts

Component	**Part number**
Water Trap x 12	1300-145
Sample Line	1300-147

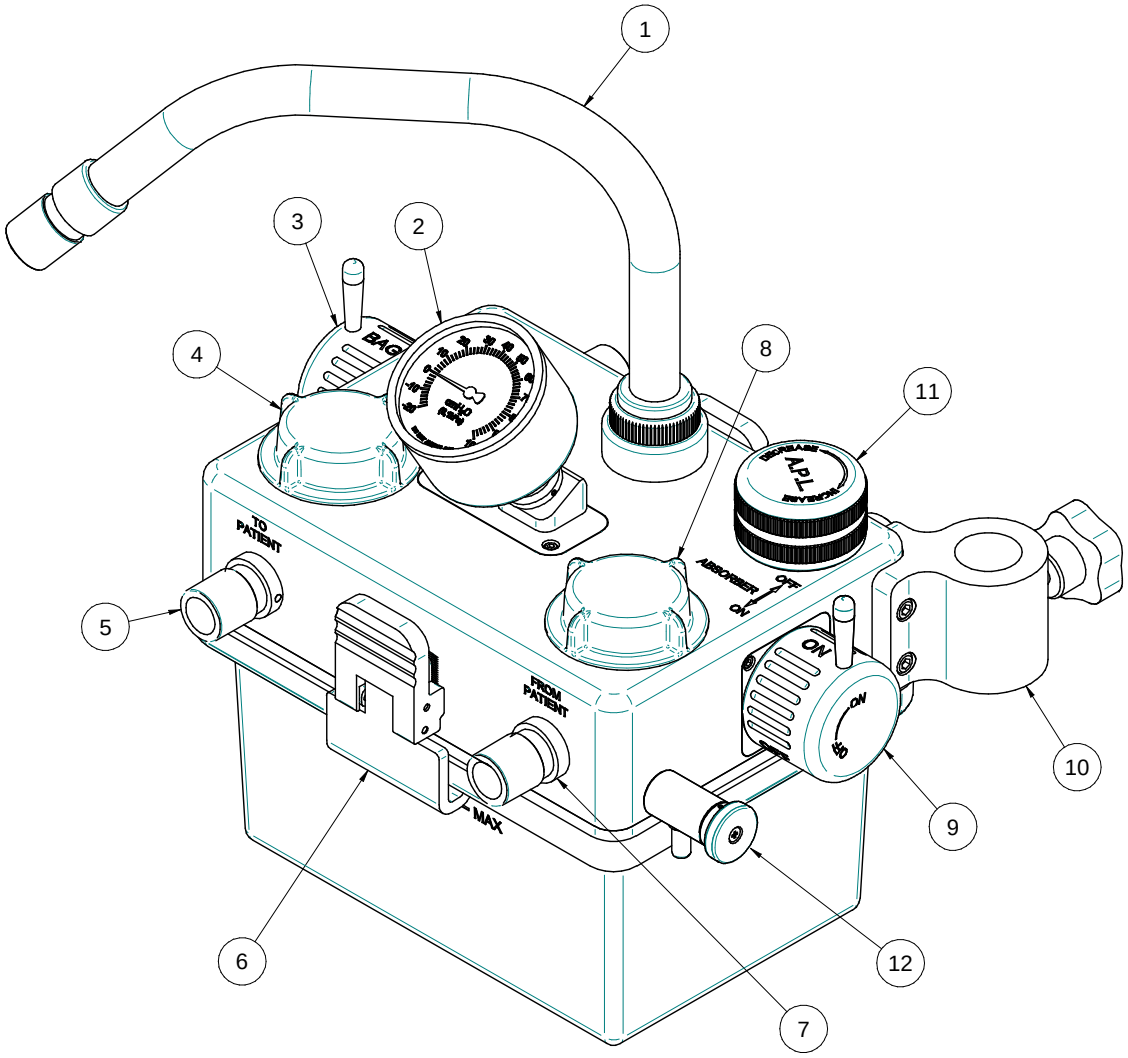
Section 5

Hydra Absorber

Section 5 Hydra Circle Absorber

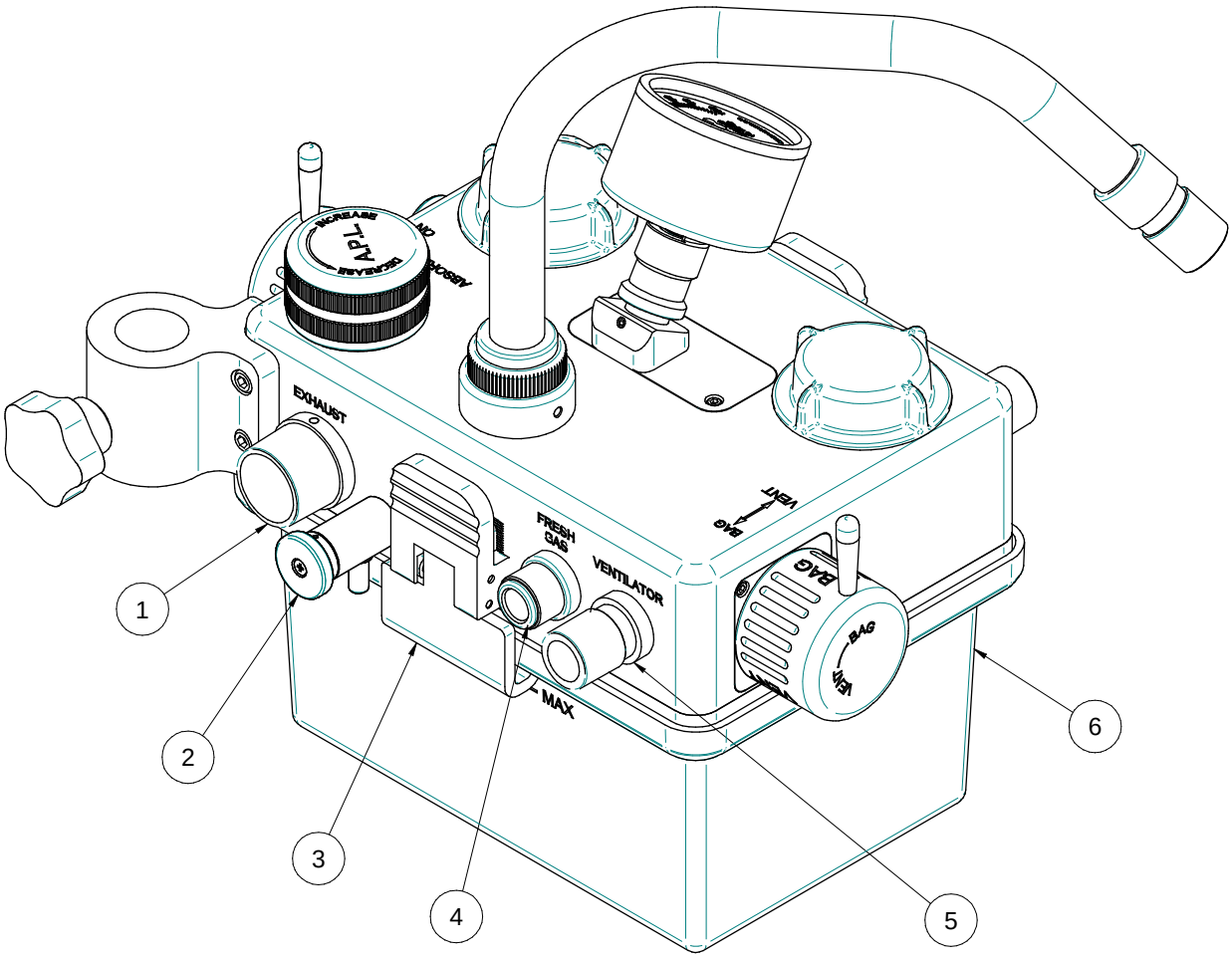
5.1 General Description

Hydra Circle Absorber Front Illustration



(1) Bag connection.
(2) Manometer.
(3) Bag / vent switch.
(4) Inspiratory non-return valve cover.
(5) Inspiratory patient connection.
(6) Canister clamp.
(7) Expiratory patient connection.
(8) Expiratory non-return valve cover.
(9) Absorber on/off switch.
(10) Pole mount block.
(11) Adjustable pressure relief valve control knob.
(12) Manual drain valve.

Hydra Circle Absorber Rear Illustration



(1) Exhaust gas scavenging connection.
(2) Manual drain valve.
(3) Canister clamp.
(4) Fresh gas inlet connection.
(5) Ventilator connection.
(6) Canister.

Front 1) Bag connector Assembly
The bag connection is designed to swivel allowing the anaesthetist to use it in a position which is most convenient, the connection for the reservoir bag is 22 mm male taper with a 15 mm female.
The complete assembly can be removed for cleaning by unscrewing the knurled nut anti clockwise.

Note – the bag connection is isolated from the circuit in ventilator mode.

Note – do not carry the absorber by the bag connection arm.

Front 2) Manometer
The manometer is mounted on the top of the manifold and incorporates a quick release connector for ease of removal.

Note - The manometer is not suitable for autoclaving.

Warning - the use of this absorber without the manometer is not recommended.

Front 3) Bag / ventilator Switch
The Bag / vent selector knob is mounted on the left hand side of the absorber. To change from one mode to the other the knob is rotated through 120 degrees.
The bag / vent engraving on the top of the absorber indicates the direction that the knob needs to be turned to change mode.

Note - When the knob is rotated into ventilator mode it is held in position by a detent, failure to turn the knob fully into the detent will allow the knob to turn back into bag mode as it is spring biased.

Front 4 & 8) Inspiratory and expiratory non-return valves
A pair of non-return valves are mounted under domed covers on the top of the manifold block in line with the patient connectors.
These valves control the direction of gas flow through the absorber to the patient.
The lifting of the discs indicate the flow of gas in and out of the patient during normal use.

Front 9) Absorber on / off Switch
The absorber on / off selector knob is mounted on the right hand side of the absorber. To change from one mode to the other the knob is rotated through 120 degrees.
The on / off engraving on the top of the absorber indicates the direction that the knob needs to be turned to change mode.

The function of the on / off selector knob is to allow the soda lime in the canister to be bypassed allowing the carbon dioxide in the circuit to build up.
When the absorber is in this mode the canister can be removed and refilled without losing circuit pressure.

Note - When the knob is rotated into absorber off mode it is held in position by a detent, failure to turn the knob fully into the detent will allow the knob to turn back into absorber on mode as it is spring biased.

Warning – when in absorber off mode the level of carbon dioxide in the circuit will build up quickly.
Carbon dioxide monitoring is essential for patient safety during the use of this and any circle system.

Front 5&7) Patient connections
A pair of 22 mm male / 15 mm female connectors are mounted on the front of the manifold block for connection of the patient circuit.

Canister
The canister is mounted on the bottom of the absorber. It has an integral central plate which directs the flow of gas from the patient to the bottom of the canister where it flows back up through the soda lime. Sufficient gap has been left at the bottom of the canister for collection of the condensation.

Warning – when the canister contains liquid in the bottom care must be taken not to spill the liquid as it is caustic due to the soda lime.

Note – dispose of the spent soda lime and liquid as recommended by the absorbent manufacturer or as dictated by local regulations.

Front 6) Canister connection
The canister is attached by two clamps on the front and rear of the manifold. It seals on two silicone seals mounted in the underside of the absorber.

Front 11) Adjustable pressure limiter (A.P.L.) valve
The adjustable pressure limiter is mounted on the top rear right hand side of the absorber and gives 270 degrees of rotation between fully open and closed.
The maximum pressure of 60 cm H_20 is achieved by rotating the knob clockwise. There is a linear increase in pressure with clockwise rotation of the control knob.

Warning - that the adjustable pressure limiter is isolated from the circuit when the absorber is in ventilator mode.

Front 10) Pole mounting block
The absorber is attached to the anaesthetic machine by the pole mount block attached to the rear right hand side of the manifold.

Rear 5) Ventilator inlet connection
The ventilator connection is on the rear left of the manifold. The taper is a 22 mm male with 15 mm female.

Rear 4) Fresh gas supply connection
The Fresh gas supply connection is on the rear of the manifold.

Rear 1) Scavenging connection
The exhaust gas connection is a 30 mm male taper which is connected to the scavenging system to remove the waste gases from the absorber when in bag mode.

Note – this connection is only used when in bag mode as during ventilation it is isolated.

Warning - Ensure that the exhaust connection on both the absorber and the anaesthesia ventilator bellows are connected to prevent contamination of the theatre.

Fresh Gas hose assembly

The fresh gas hose assembly consists of a special connector with a knurled nut to attach to the fresh gas inlet on the absorber, a 1 metre length of antistatic rubber hose and a 22 mm female connection with an o seal to prevent leakage past the taper is attached at the other end, this connects to the CGO.

Warning – the hose used on this assembly must be routed to prevent kinking as loss of fresh gas flow will interfere with patient safety.

5.2 Hydra Absorber Function

General
The Hydra circle absorber is designed to comply with the following standards:-

BS EN ISO 80601-2-13
BS EN 60601-1
BS EN ISO 60601-1-2
BS EN 60601-1-6
BS EN ISO 5356-1

All gas volume. Flow and leakage specifications are expressed as STPD (Standard Temperature and pressure, Dry) where temperature is 20°C and pressure 101.3kPa

Hydra Absorber Purpose

The Hydra absorber has been designed for use in a closed circuit breathing system for the removal of carbon dioxide during anaesthesia.

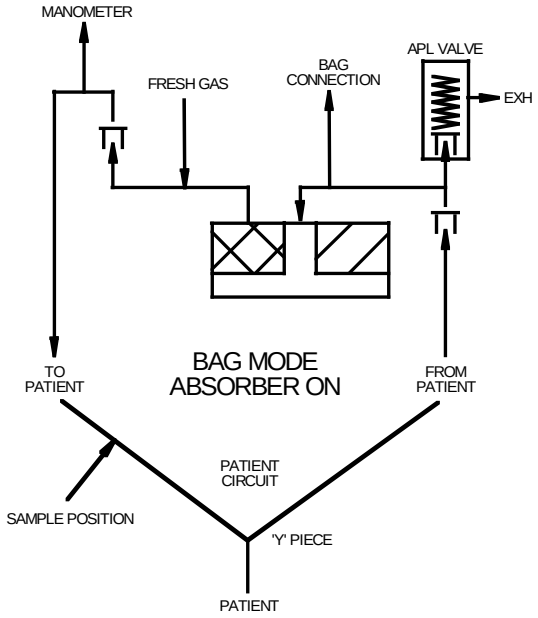
Fresh gas flows from the anaesthetic machine can be reduced as the exhaled carbon dioxide is removed from the patient circuit by the soda lime allowing the patient to breathe recycled gas containing a proportion of fresh gas.

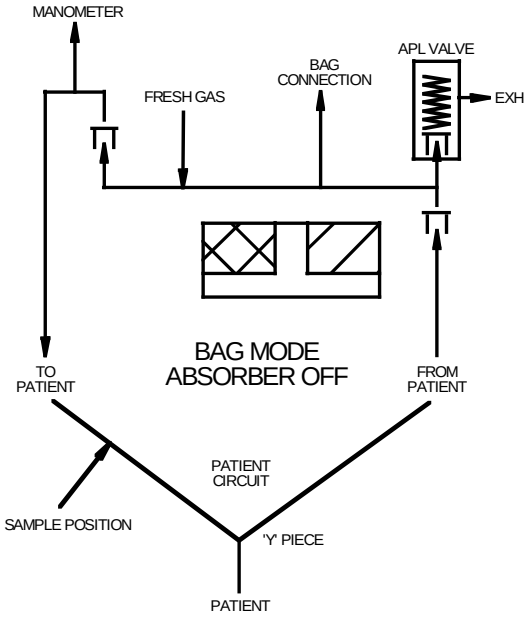
The purpose of an absorber is to reduce fresh gas flows allowing lower usage of gases from the anaesthetic machine and anaesthetic agent from the vaporizer.

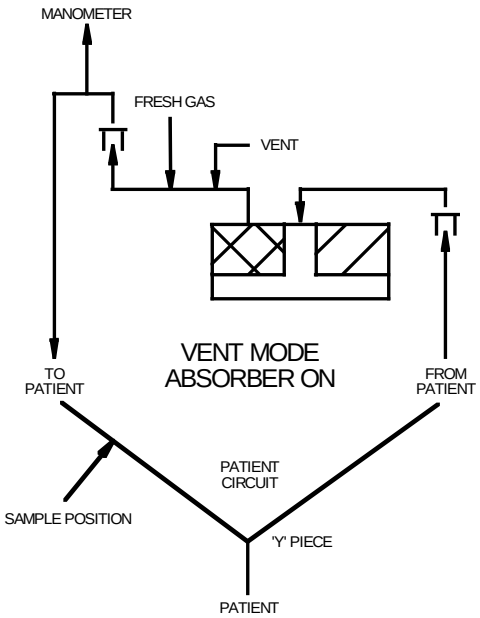
The system incorporates a Bag / Ventilator switch to enable either:-
Spontaneous breathing or manually assisted ventilation in “BAG” mode or,
Use with an anaesthesia ventilator when in “VENT” mode.

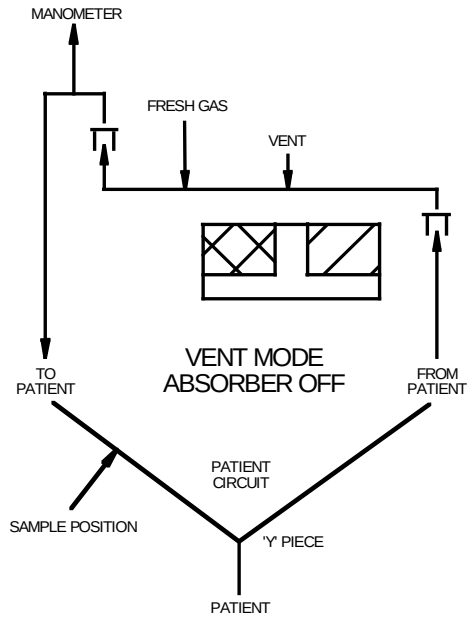
The Hydra absorber system is compatible with the anaesthetic gases O_2, CO_2, N_2O and Air, and with the anaesthetic agents Halothane, Isoflurane, Enflurane, Sevoflurane and Desflurane.

5.3 Hydra Absorber schematics









5.4 Specification

Overall Dimensions	
Height	345 mm
Width	303 mm
Depth	270 mm
Average weight	9.1 kg

Mounting system
25.4 mm (1 inch) diameter hole with clamp screw.

Absorber leak rate
With the patient circuit attached to the absorber, the adjustable pressure relief set to maximum and the patient connection blocked the leak rate must be less than 150ml/min fresh gas flow at 30hPa (30 cmH_2O)

Note – the absorber leak rate applies in bag, vent, absorber on / off mode and with the canister removed when in absorber off mode.

Canister capacity and resistance
The capacity of the canister is 1.4 kg (1600 ml) of soda lime when filled to the maximum line.

The resistance of the soda lime when freshly filled to the maximum line is 1hPa (1 cmH_2O) at 60 litres per minute.

Note – these values may vary with absorbent from different manufacturers.

Inspiratory resistance	
Bag mode and absorber on	3hPa (3 cmH_2O)
Bag mode and absorber off	2hPa (2 cmH_2O)
Vent mode and absorber on	3hPa (3 cmH_2O)
Vent mode and absorber off	2hPa (2 cmH_2O)

Condition – With the patient circuit and filter attached to the absorber and gas flow at 60 litres per minute oxygen

Expiratory resistance	
Bag mode and absorber on	3hPa (3 cmH_2O)
Bag mode and absorber off	2hPa (2 cmH_2O)
Vent mode and absorber on	3hPa (3 cmH_2O)
Vent mode and absorber off	2hPa (2 cmH_2O)

Condition – With the patient circuit and filter attached to the absorber and expired gas flow at 60 litres per minute oxygen

Absorber Internal Compliance	
Bag mode and absorber on	43 ml
Bag mode and absorber off	26 ml
Vent mode and absorber on	41 ml
Vent mode and absorber off	24 ml

Condition - With the breathing circuit attached complete with filters and the canister filled with absorbent the volume of gas required to raise the pressure in the circuit to 30hPa (30 cmH_2O)

Manometer

Manometer	
Manometer scale	-10 to +100 cmH_2O
Manometer accuracy	±5%

Environmental conditions

Condition		
Temperature	Operation	15ºC to 35ºC
	Storage	-5º to 50ºC
Humidity	Operation	0 to 95% non-condensing
	Storage	10 to 95% non-condensing
Air pressure	Operation	80 to 110 kPa
	Storage	11.5 to 110 kPa

Device classification and labelling

Protection against ingress of water and dust, IPX0, not protected.

Labelling

This symbol  denotes refer to manual.

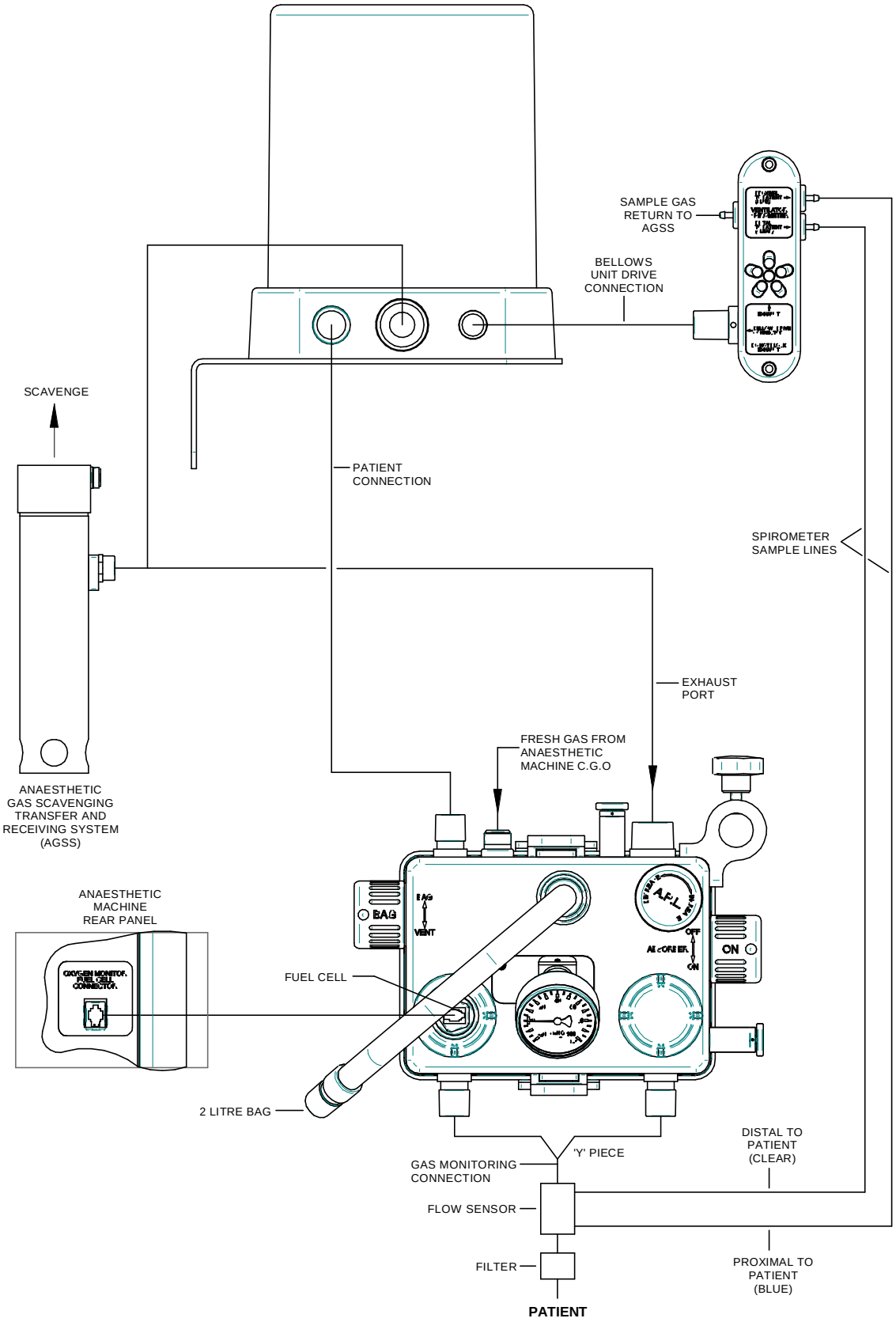
The Hydra absorber has been reviewed for compliance to the MDD requirements of 2007/47/EC and deemed to be compliant.

The absorber carries the CE mark. CE 1639

Warning - This anaesthesia carbon dioxide circle absorber system is NOT suitable for use with flammable anaesthetic agents.

Warning – If not already equipped with halogenated anaesthetic agent monitoring equipment the anaesthetic workstation must be equipped with Monitoring equipment complying with ISO 80601-2-55 before the system is put into service.

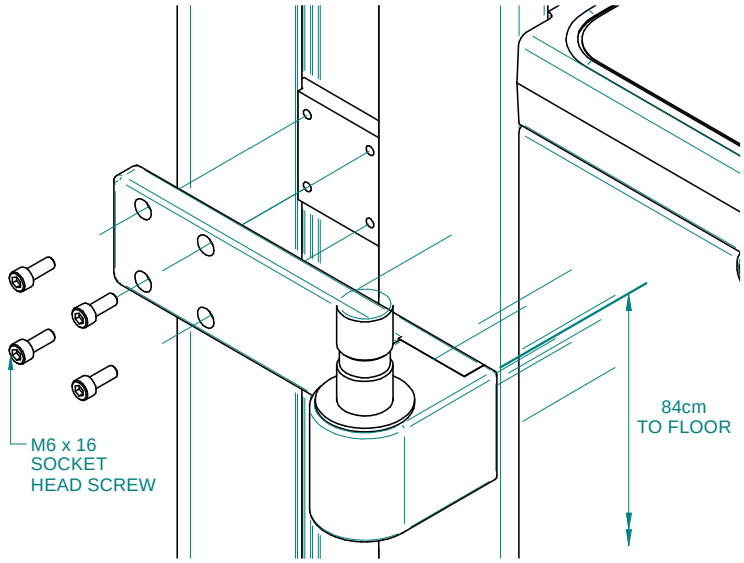
Breathing system hose illustration



Installation instructions

Attaching the absorber and ventilator brackets to the C-AM

Unpack and attach the absorber arm to the lower of the tee slot plate using the 4 off M6 screws. Set the top edge of the absorber arm to 84 cm above the ground. Tighten screws securely. - **See drawing below.**



Unpack the absorber and attach the bag arm to the top of the absorber.

Mount the absorber on to the bracket
Connect the fresh gas inlet to the common gas outlet of the anaesthetic machine.
Connect the reservoir bag to its 22 mm taper.
Attach the ventilator hose from the bellows to the 22 mm taper.
Connect the anaesthetic gas scavenging system to the 30 mm male taper.
Ensure that the bellows drive hose is connected between the bellows and the ventilator.
Attach the breathing circuit to the absorber, connect the patient flow sensor (Blue end Proximal to patient) and then the filter.
Connect the patient airway gas monitor sample line to either the port on the filter (recommended) or the port on the "Y" piece of the breathing circuit.

Filling the absorber.

Remove the canister from the absorber by undoing the toggle clamps.
Fill the absorber canister with absorbent to the maximum fill line and ensure that the absorbent is level.
Place the canister under the absorber and do up the toggle clamps.

Warning – do not fill above the maximum line.

Warning – insufficient filling with absorbent can lead to high levels of carbon dioxide.

Warning – due to the caustic nature of absorbent it is recommended that gloves be warn when changing or filling.

Warning –Condensation, which may collect in the bottom of the absorber canister, is caustic and care must be taken not to spill it on the skin when draining.

Changing the absorbent.

Remove the canister from the absorber.
Tip out the spent absorbent – note that the bottom of the canister contains water from the condensation which will be caustic.
Wash and dry the container if necessary.
Refill and replace the canister.

Note – to prevent a leak ensure that the shoulder of the canister is clean and also the seals on the underside of the absorber.

Warning – a leak check must be carried our each time the canister is removed

Hazard Notices

SODA LIME
Soda Lime is caustic. Observe the manufacturer's instructions for correct handling and storage. When handling, always wear suitable eye, face and hand protection as crushed soda lime can degrade to a fine dust which may be harmful by inhalation. To minimize the levels of soda lime dust, ensure that the soda lime is not crushed and that regular cleaning of the absorbers and breathing circuits is carried out. To prevent injury to the patient, always protect the patient's face with a face mask.

CAUSTIC CONDENSATE
The condensate in the bottom of the canister is caustic. Always wear suitable eye, face and hand protection when handling the outer canister. Drain the outer canister periodically. Rinse accidental splashes immediately with water.

5.5 Pre-use checks

Prior to use the anaesthetic machine must be inspected and checked to ensure correct and safe function.
An incorrectly functioning anaesthetic machine must be removed from service and labelled **"NOT FOR CLINICAL USE UNTIL REPAIRED"** and must be properly repaired by a trained service engineer.

Pre-use check list
Check the absorber for labelling to indicate if the equipment has any faults or has just been serviced.
Check for visible signs of damage.
Check hoses for correct connection.
Replace absorbent if necessary.
Leak check the absorber, complete with the whole breathing system and associated equipment.
Check the bag / vent switch.
Check the absorber on / off switch.
Check the pressure relief valve.
Check the non return valves for function.
Repeat the overall leak check.

Service fault

Check the machine for labelling which will indicate if the machine is unserviceable or has just been serviced.

Warning – additional care must be taken during the pre-use check after any equipment has been serviced.

Warning – do not use any equipment that has a fault until it has been fully repaired by a suitably qualified service engineer.

Absorber damage
Check the absorber for signs of damage.
Checks should include looking for: -
Cracked canister.
Cracked non return valve covers.
Dented or loose tapers.
Damaged manometer.
Jammed Bag / vent knob.
Jammed Absorber on / off knob.
Jammed Adjustable pressure relief.
Jammed Valve.
Loose pole mount bracket.

Patient circuit
Replace the basic patient circuit if it has been on the absorber for one week. Note this includes the patient inspiratory and expiratory limbs, the ventilator to absorber limb and the reservoir bag.
Replace the two filters with each new patient. Ensure that the heat and moister exchange filter is placed at the patient y piece and the hydro guard filter at the patient expiratory port.
Ensure that all connection are tight and the hoses connected correctly. Care must be taken to ensure that there are no occlusions in any hoses.

Absorbent
Replace the absorbent if it is exhausted.

Warning – care must be taken to ensure that the colour change of the make and type of soda lime being used is known to ensure that you will be familiar with the colour change that will take place as the soda lime becomes exhausted.

Leak check

Overall leak check – absorber on and in bag mode.
Ensure that the complete patient circuit is attached including the reservoir bag and the ventilator drive hose.
Select bag mode.
Select absorber on mode.
Block the patient connection port.
Fully close the adjustable pressure relief valve.
Pressurise the system to 30 cm H2O by turning on the anaesthetic machine flowmeter.
Turn off the flowmeter and check that the pressure does not drop to zero in less than one minute.

Overall leak check – absorber on and in vent mode.
Select vent mode.
Select absorber off mode.
Remove the canister.
Block the patient connection port.
Block the ventilator connection with thumb.
Pressurise the system to 30 cm H2O by turning on the anaesthetic machine flowmeter.
Turn off the flowmeter and check that the pressure does not drop to zero in less than one minute.

Warning – care must be taken to ensure that the absorber is not over pressurized while being leak tested in vent mode when the ventilator patient hose is blocked.

Overall leak check – absorber off and in vent mode.
Select vent mode.
Select absorber off mode.
Remove the canister.
Block the patient connection port.
Block the ventilator connection with thumb.
Pressurise the system to 30 cm H2O by turning on the anaesthetic machine flowmeter.
Turn off the flowmeter and check that the pressure does not drop to zero in less than one minute.

Warning – care must be taken to ensure that the absorber is not over pressurized while being leak tested in vent mode when the ventilator patient hose is blocked.

Function tests

Bag / vent knob function test

Select bag mode.
Block the patient connection.
Remove the ventilator connection hose.
Pressurise the system to 30 cm H2O by turning on the anaesthetic machine flowmeter.
Turn off flowmeter.
Turn the absorber to vent mode. Ensure that the circuit pressure is released through the ventilator connection and the reservoir bag remains inflated.
Reconnect the ventilator hose. Disconnect the bag.
Select vent mode.
Pressurise the system to 30 cm H2O by using the anaesthetic machine flowmeter and ensure that the bellows rise.
Turn off the flowmeter.
The bellows must remain inflated
Select bag mode and ensure that the circuit pressure is released through the bag connection.

Absorber on / off knob function test

Select absorber on mode.
Select bag mode.
Block the patient connection.
Pressurise the system to 30 cm H2O by using the anaesthetic machine flowmeter.
Turn the flowmeter off.
Un-clamp the canister. This should result in loss of system pressure.
Leave the canister off.
Select absorber off mode.
Pressurise the system to 30 cm H2O by using the anaesthetic machine flowmeter.
Turn the flowmeter off.
System pressure must be maintained.

Adjustable pressure relief Valve

Select bag mode.
Open the adjustable pressure relief valve fully.
Block the patient connection.
Press the oxygen flush.
The maximum pressure must be less than 5 cm H2O.
Fully close the adjustable pressure relief valve.
Block the bag connection.
Turn on the flowmeter to 200 cc minimum flow.
The circuit pressure should raise to 30 cm H2O minimum pressure.

Inspiratory and Expiratory Non Return Valves (NRV)

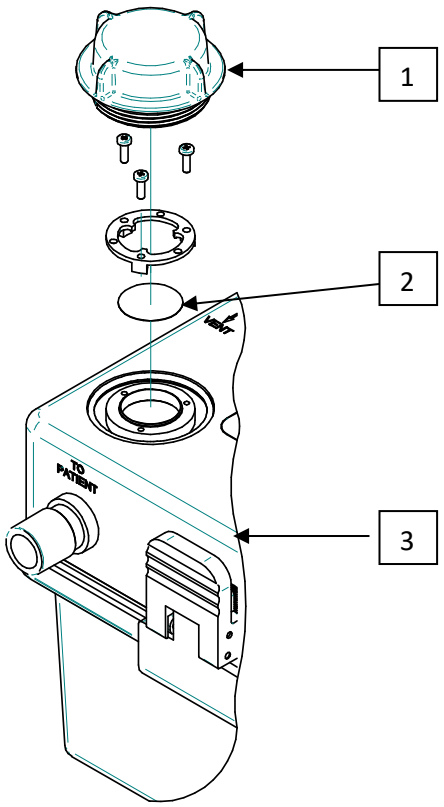
Attach the patient end of the breathing system to a bag.
Select bag mode.
Set fresh gas flow to 5lpm.
Squeeze the manual ventilation bag, the inspiratory NRV must lift.
Squeeze the patient end bag, the expiratory NRV must lift.

5.6 User maintenance

The user maintenance on the absorber is limited to the following tasks:-

Inspiratory and expiratory non-return valves
The stainless steel valve discs can be removed for cleaning.
Un-screw the cover from each valve and check the condition of the o-ring and replace if necessary.
Remove the non-return valve disc by removing the three screws holding the support ring in place.
Wash the non return valves in warm soapy water and dry thoroughly with a lint free cloth.
Wipe the top of the non-return valve seal supports with a damp cloth.
Replace the non-return valve disc on the valve seat ensure that the disc is not trapped between the seat and support ring and the valve disc lays flat without any distortion.
Replace the covers and tighten fully.

Non-return valve illustration.



(1) Non return valve cover
(2) Non return valve
(3) Absorber

Canister seals
The canister seals onto the underside of the absorber with two blue silicon seals, one around the outside edge of the canister and the second seals the expiratory flow into the centre of the canister.
The seal faces must be cleaned with a damp cloth to remove all traces of soda lime.

Warning – the seals must be kept clean to ensure that the canister seals correctly. Failure to do so may result in a leak.

Cleaning

The complete absorber can be autoclaved - excluding the manometer which must first be removed.
The absorber can be autoclaved at 137 degrees centigrade.

Cleaning procedure – autoclaving

Remove and dispose of the patient hoses and filters from the absorber.

Remove the canister and dispose of the absorbent and wash in warm water with a mild detergent and then rinse thoroughly.
Remove the manometer.
Remove the inspiratory and expiratory non-return valves and covers and wash in warm water with a mild detergent and then rinse thoroughly.
Autoclave parts.
Reassemble the absorber.
Perform a complete pre-use check on the absorber when placing the absorber back on the anaesthetic machine.

Note - When placing the parts in the autoclave ensure the parts are placed flat to prevent distortion.

Disinfectant procedure

All components excluding the manometer can be disinfected using mild disinfectants commonly used in hospital cleaning procedures.
Care must be taken to ensure that all parts are thoroughly rinsed in warm water and then dried in air prior to assembly.

Warning – follow the manufacturer's instructions on use of the disinfectant.

Spare part information

Absorber Spare part information	
Absorber complete	9075-001
Absorber arm assembly	9075-004
Manometer assembly	8075-009
Fresh gas hose assembly	9075-003
Non-return valve	6675-003
Non-return valve cover	6675-004
Non-return valve cover "O" seal	1230-342
Canister assembly	8075-003

Disposable spare part information	
Complete disposable basic breathing system	1300-039
Patient filter	1300-040
Absorber filter	1300-041

Disposable patient circuit specification

It is recommended that the absorber is used with a disposable patient breathing system and filters to prevent cross contamination.

The recommended circuit is available from Gradian Health or direct from the manufacturer: -

Intersurgical Ltd.
Crane house
Molly Millars lane
Wokingham
Berkshire
RG41 2RZ

Tel +44(0) 118 9656 300
Fax +44(0) 118 9656 356

http://www.intersurgical.co.uk

The recommend circuit and filters for the absorber are: -

1.6 metre Basic circle system with 2 litre bag elbow and 0.8 metre limb
OES part number 1300-039 Intersurgical part number 2010

Patient filter – Clear-Therm heat and moisture exchange filter
OES part number 1300-040 Intersurgical part number 1841

Absorber filter – Hydro-Guard filter
OES part number 1300-041 Intersurgical part number 1844

Reservoir Bag 2L – complying with ISO5362
OES part number 1300-070 Intersurgical part number 2820

Disposable patient circuit and filter replacement

The recommended replacement period for the disposable patient circuit and filters is as specified by the specific component manufacturers instructions however at the minimum replacements must be made as follows: -

Basic circle system – replace weekly

Patient filter and absorber filter – replace with each new patient.

Warning – to prevent cross contamination the required replacement period must be strictly adhered to.

Recommended absorbent (Soda Lime)

The recommended absorbent for use with the OES absorber is available from: -

Intersurgical
Crane house
Molly Millars lane
Wokingham
Berkshire
RG41 2RZ

Tel +44(0) 118 9656 300
Fax +44(0) 118 9656 356

http://www.intersurgical.co.uk

Two common grades are available, one turns from pink to white and the other white to violet when the absorbent is exhausted.

Spherasorb soda lime colour change pink to white
10 off 1 kg bags Intersurgical part number 2172

Spherasorb soda lime colour change pink to white
2 off 5 kg jericans Intersurgical part number 2174

Spherasorb soda lime colour change white to violet
10 off 1 kg bags Intersurgical part number 2173

Spherasorb soda lime colour change white to violet
2 off 5 kg jericans Intersurgical part number 2175

Note – absorbents from other manufacturers may be used, ensure that the granule size is 4 to 8 mesh and that there is a colour indicator to show when the absorbent is exhausted.

Appendix 1

1 Electromagnetic Emissions from the Ventilator

Declaration - Electromagnetic Emissions		
The Astra anaesthesia system is intended for use in the electromagnetic environment specified below. The user should assure that it is used in such an environments		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The Astra anaesthesia system does not use RF energy for any specific application but it is a by-product of the use of microprocessors and their required clock timers. As such the RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Astra anaesthesia system is suitable for use in all operating room environments including those connected directly to the mains electricity supply. In the event of mains electricity supplies falling outside of those required for correct operation emissions may be indeterminate.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

2 Electromagnetic immunity of the Ventilator (other than RF)

Declaration – Electromagnetic immunity

Declaration – Electromagnetic immunity

The Astra anaesthesia system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity Test	**IRC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz t 80 MHz	3 Vrms	Portable or mobile RF communications equipment should be used no closer to the Astra anaesthesia system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. d = 1,2 √P d = 1,2 √P 80 MHz to 800 mHz d = 2,3 √P 800 MHz to 2,5 GHz P = max power output rating in watts (W) according to the transmitter manufacturer and d = recommended separation distance in metres (m)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol. 

The Astra anaesthesia system is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity Test	**IRC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electroststic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete ceramic time or similar. If floors are covered with a synthetic material, the RH should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines	Mains power should be that of a typical hospital environment.

	+/- 1 kV for input/output lines	+/- 1 kV for input/output lines	
Surge IEC 61000-4-5	=/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	=/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle. 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) For 5 s	<5 % Ut (>95 % dip in Ut) for 0.5 cycle. 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) For 5 s	Mains power should be that of a typical hospital environment.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 Am	0,3 Am	Mains power should be that of a typical hospital environment. The power frequency magnetic field should be measured in the intended installation position to ensure that it is sufficiently low.
Note: Ut is the ac mains voltage prior to application of the test level.			

Appendix 2

Checklist for Anaesthetic Equipment 2012

AAGBI Safety Guideline

Checks at the start of every operating session
Do not use this equipment unless you have been trained

Check self-inflating bag available	
Perform manufacturer's (automatic) machine check	
Power supply	• Plugged in • Switched on • Back-up battery charged
Gas supplies and suction	• Gas and vacuum pipelines – 'tug test' • Cylinders filled and turned off • Flowmeters working (if applicable) • Hypoxic guard working • Oxygen flush working • Suction clean and working
Breathing system	• Whole system patent and leak free using 'two-bag' test • Vaporisers – fitted correctly, filled, leak free, plugged in (if necessary) • Soda lime - colour checked • Alternative systems (Bain, T-piece) – checked • Correct gas outlet selected
Ventilator	• Working and configured correctly
Scavenging	• Working and configured correctly
Monitors	• Working and configured correctly • Alarms limits and volumes set
Airway equipment	• Full range required, working, with spares
RECORD THIS CHECK IN THE PATIENT RECORD	
Don't Forget!	• Self-inflating bag • Common gas outlet • Difficult airway equipment • Resuscitation equipment • TIVA and/or other infusion equipment

CHECKS BEFORE EACH CASE

Breathing system	Whole system patent and leak free using 'two-bag' test Vaporisers – fitted correctly, filled, leak free, plugged in (if necessary) Alternative systems (Bain, T-piece) – checked Correct gas outlet selected
Ventilator	Working and configured correctly
Airway equipment	Full range required, working, with spares
Suction	Clean and working

THE TWO-BAG TEST

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

i. Attach the patient end of the breathing system (including angle piece and filter) to a test lung or bag.

ii. Set the fresh gas flow to 5 $l.min^{-1}$ and ventilate manually. Check the whole breathing system is patent and the unidirectional valves are moving. Check the function of the APL valve by squeezing both bags.

iii. Turn on the ventilator to ventilate the test lung. Turn off the fresh gas flow, or reduce to a minimum. Open and close each vaporiser in turn. There should be no loss of volume in the system.

This checklist is an abbreviated version of the publication by the Association of Anaesthetists of Great Britain and Ireland 'Checking Anaesthesia Equipment 2012'. It was originally published in *Anaesthesia*.
(Endorsed by the Chief Medical Officers)

If you wish to refer to this guideline, please use the following reference: Checklist for anaesthetic equipment 2012. *Anaesthesia* 2012; **66:** pages 662–63. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2044.2012.07163.x/abstract

Additional Engineer Settings

Additional Engineer Settings

Further Engineer settings are available if the service Pin is entered into the ventilator. The Service Pin is a computer generate code that is unique to each ventilator produced. The Service Pin is available to factory trained service engineers only.

Press the Service Pin Key Pad

Engineer Settings key pad

Enter the 6 digit Service code provided by the OES Medical Service department. Then press OK.

Service Pin key pad

Engineer settings - Service Engineer only

After the Service Pin has been entered the Engineer Settings Screen shows a number of additional keys that can be accessed.

Engineer settings - after service code entered

The Diagnosis key pad gives a number of options that were not available before the Service Pin was entered.

Diagnosis key pad

The Error Log displays any errors that have occurred

Error log screen

Voltages Screen - this screen provides information to allow the service engineer to diagnose any fault

Voltage screen

Valve Control - allows the service engineer to turn off Gas Supply alarm, adjust Drive, Patient and auxiliary valves. Note that changes are not required to any items on this screen.

Valve control screen

Debug Off or On - this is a developer function used only by design engineers during product development.
Do not change the setting.

Debug screen

Development Statistics - this indicates the memory loading of the ventilator on board computer. This is a developer function used only by design engineers during product development.

Development statistics screen

Service record Information - provides serial number, software version, hardware version, mechanical version, manufactured date, last serviced date with reset button, ventilator cycles since last service and ventilator cycles total.

Service record information

<u>Factory Calibration</u>

Factory calibration is carried out during manufacture and may be performed by a factory trained service engineer during upgrade or maintenance.
Note that the Zero Offsets and Touch Panel calibration are all that would normally require calibrating in the field.

Factory calibration screen

Zero Pressure offsets - this zeros all pressure transducers to ensure accuracy of readings. Press Yes to zero pressure transducers after the Oxygen supply pressure and patient circuit and bellows have been emptied to ensure there is no circuit pressure.

Calibrating Pressure Offset screen

Calibrating drive valve - the proportional valve provides the gas flow to drive the bellows during the inspiratory phase. The valve is calibrated by removing the black corrugated hose from the 17 mm taper on the rear of the ventilator and leaving it open to atmosphere without any obstructions. Press Yes and the ventilator will automatically calibrate the drive valve.

Calibrate drive flow screen

Calibrating Patient Valve - the Patient valve controls the inspiratory and expiratory times and maintains patient circuit pressure as required. The valve is calibrated by removing the black corrugated hose from the rear of the ventilator then blocking the 17mm taper on the rear of the ventilator. Press Yes and the ventilator will automatically calibrate the patient valve.

Calibrate Patient valve

Calibrating Drive flow at 20 LPM Oxygen - the flow rate of the drive valve is calibrated at 20 litres flow to achieve an accurate drive differential pressure. This improves the flow accuracy throughout the range.

Calibrate drive flow - 20 Litres

Calibrating Drive pressure at 30 cm H2O - the pressure is calibrated at 30 cm H2O to achieve an accurate pressure. This improves the pressure accuracy throughout the range.

Calibrate drive Pressure - 30 cm H2O

Repeat the Drive valve calibration - the proportional valve must be recalibrated after the flow and pressure has been calibrated to improve accuracy.

Repeat the Calibration of Drive Valve

The ventilator pressure relief must be adjusted during initial manufacturers calibration. This will not require adjustment unless the pressure relief is serviced.

Calibration of Pressure Relief

The touch screen may require calibration.
Press Touch Panel then hold a plastic pointer at each curser position shown on the screen.
When complete touch the screen and the ventilator will restart.

Calibration of Touch screen

For service issues, please contact Gradian:

EMAIL:	service@gradianhealth.org
WEB:	www.gradianhealth.org
WHATSAPP:	+254 794 764 415
ADDRESS:	Gradian Health Systems 40 W 25th St., 6th Floor New York, NY 10010, USA