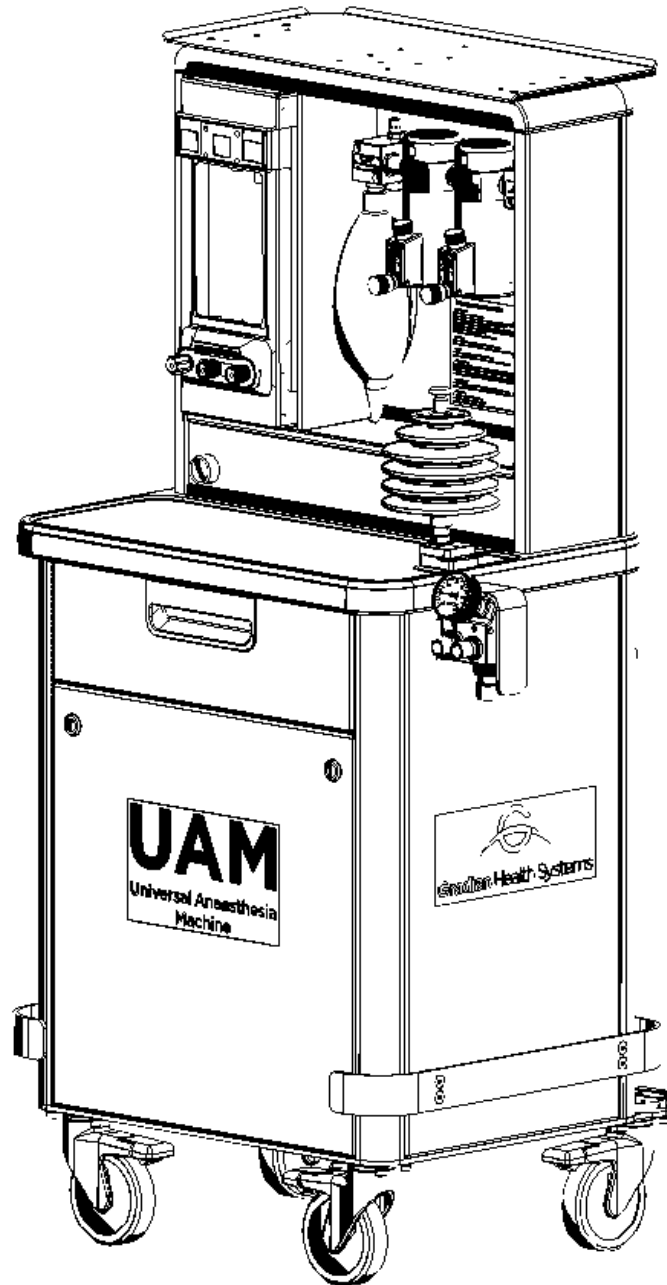


# Gradian Health Systems



## Universal Anaesthesia Machine User Manual

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Doc number 1973-510 Issue L June 2023





# Universal Anaesthetic Machine

## User Manual

Doc number 1973-510 Issue L July 2023

Modification Record					
Rev A April 2010	Rev B April 2012	Rev C June 2014	Rev D Jan 2015	Rev E Oct 2015	Rev F Sept 2018
First Issue	General update	Update to include indications for use	General update	Correction to CE mark	Updated manual for Mk 2 UAM
Rev G Jan 2020	Rev H Aug 2021	Rev F Feb 2023	Rev K Feb 2023	Rev L July 2023	
Update to CE 1639	Removal of CE mark	Updated for Mk 3 UAM	Spelling & formatting	Updated to reflect design changes	

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## **Forward**

The Universal Anaesthesia Machine is manufactured by Canon Virginia Inc. for Gradian Health who exclusively promote, sell and support the machine throughout the world.

## **Servicing, Spares and Repairs**

The Universal Anaesthesia Machine is designed for a long service life with little servicing requirements; the equipment is robust in design but must be looked after correctly.

In order to achieve the full operational life of 10 years the Universal Anaesthetic Machine the following service schedule must be adhered to:

- (a) Daily function pre-use test by the user to ensure patient safety
- (b) 6 monthly inspection and function check by a trained engineer.
- (c) 18 month service with replacement of cylinder Bodoc seals, oxygen fuel cell and any other parts required found during the inspection.
- (d) 5 year full inspection with parts replaced if required.

Service requirements are detailed in the service support package that is available to factory approved trained personnel.

Service and testing must only be undertaken in a workshop by appropriately skilled and trained personnel using approved spares. No modification of this equipment is allowed.

Training courses are offered through Gradian Health Systems.

Further servicing details are available from the manufacturer at:

The Service Department,  
Gradian Health Systems  
service@gradianhealth.org  
+254 794 764 415

Always provide the following information with any communication:

- (a) Product type and part number.
- (b) Serial number.
- (c) Date of purchase.
- (d) Full details of suspected fault.

The serial number is formed of two sections divided by a dash (-). A typical example is A2302-001, the construction of this is:

A: Anesthesia machine

23: year 2023

02: month in year

-001 is device consecutive serial number in batch.



## **Warnings and Cautions**

Throughout this manual warnings and cautions relating to various aspects of use of this anesthetic machine are given.

It is the responsibility of the user to read this manual and fully understand the functions of this anesthetic machine prior to use.

No clinical advice on the use of this anaesthesia machine is given or implied within this manual, the various technical functions are described and its use by the anesthetist must be based on best safe clinical practice using all necessary additional patient monitoring considered necessary for patient safety.

**Warning** – 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.

**Warning** – The UAM and draw over vaporizer are not for use with flammable anesthetic agents due to the risk of fire.

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

**Warning** – the UAM must be function checked and serviced in compliance with the schedule advised: under no circumstances must it be used in a malfunctioning condition or in a modified state. **If in doubt consult the local service expert or contact Gradian Health Systems 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 UAM.

**Warning** – The use of patient monitoring during the use of this anesthetic machine is recommended and considered essential for patient safety. The patients' true clinical condition must be observed for patient safety.

**Warning** – This machine 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 the performance of the oxygen monitor.

**Warning** – If the anesthetic system is not going to be used for some time, remove the oxygen concentrator alarm back up battery. See User Maintenance section.

**Warning** – An additional auxiliary set of sockets or extension cord shall not be attached to the UAM auxiliary socket panel. Only connect devices which form part of the UAM anaesthesia System. Connection of any non approved devices may increase the leakage current above recommended levels.

**Warning** – Service and testing must only be undertaken in a workshop by appropriately skilled and trained personnel using approved spares. No modification of this equipment is allowed.

**Warning** – If additional ME devices are attached to the auxiliary sockets of the UAM, it is the user's responsibility to ensure that the maximum leakage current from the UAM is within safe limits.

**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.

### **Indications for Use**

The Universal Anaesthesia Machine (UAM) is designed to provide safe, reliable continuous controlled flows of medical and anesthetic gases to patients during anesthesia in conditions lacking the reliable infrastructure found in most hospitals.

The equipment can safely be used when necessary without a mains electricity supply in manual draw over mode, which will allow the ventilator to entrain air from within the hospital theatre.

Multiple modes of oxygen supply make the machine highly flexible in virtually any condition that may be encountered. Anesthetic agent is able to be provided from the UAM draw-over vaporizer.

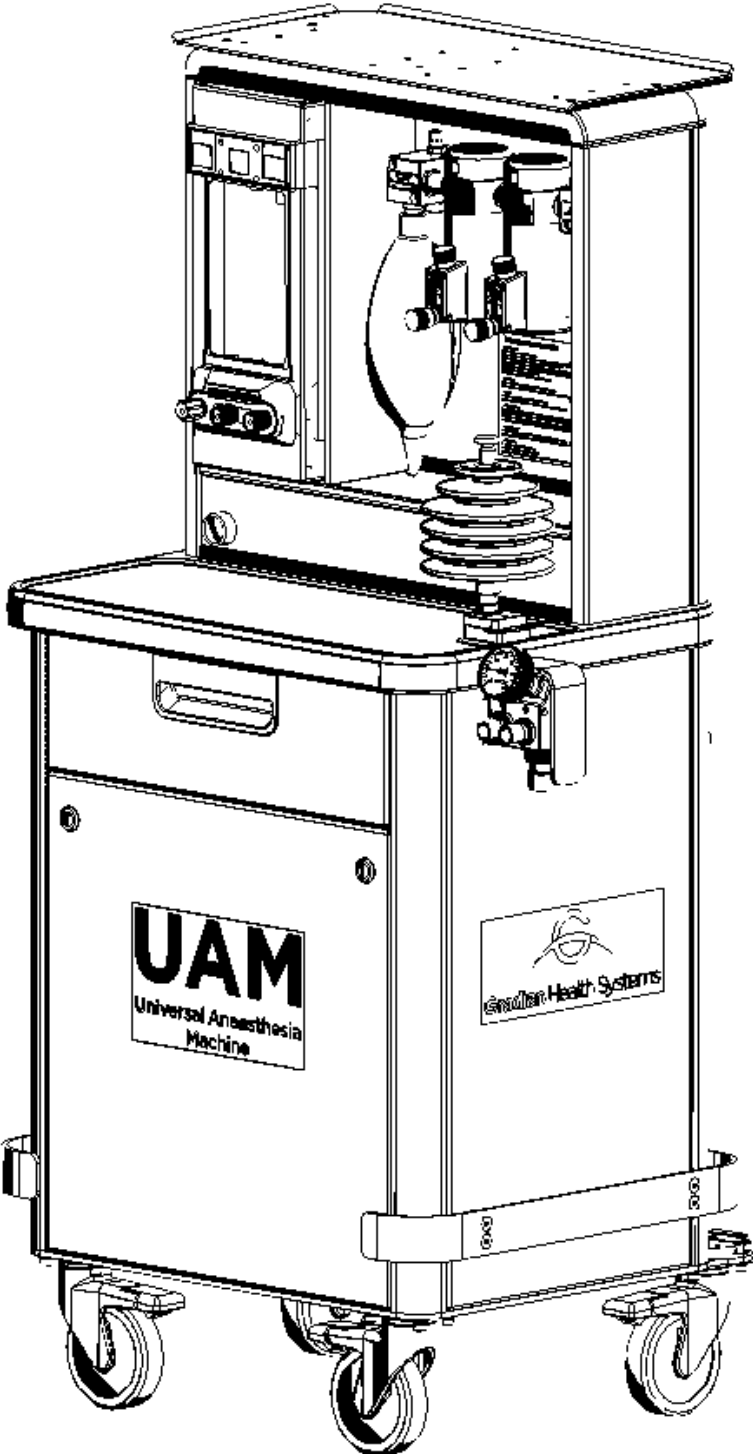
A manual bellows is provided for ventilation, even if there is no oxygen and/or if the UAM is not switched on.

### **Contraindications for Use**

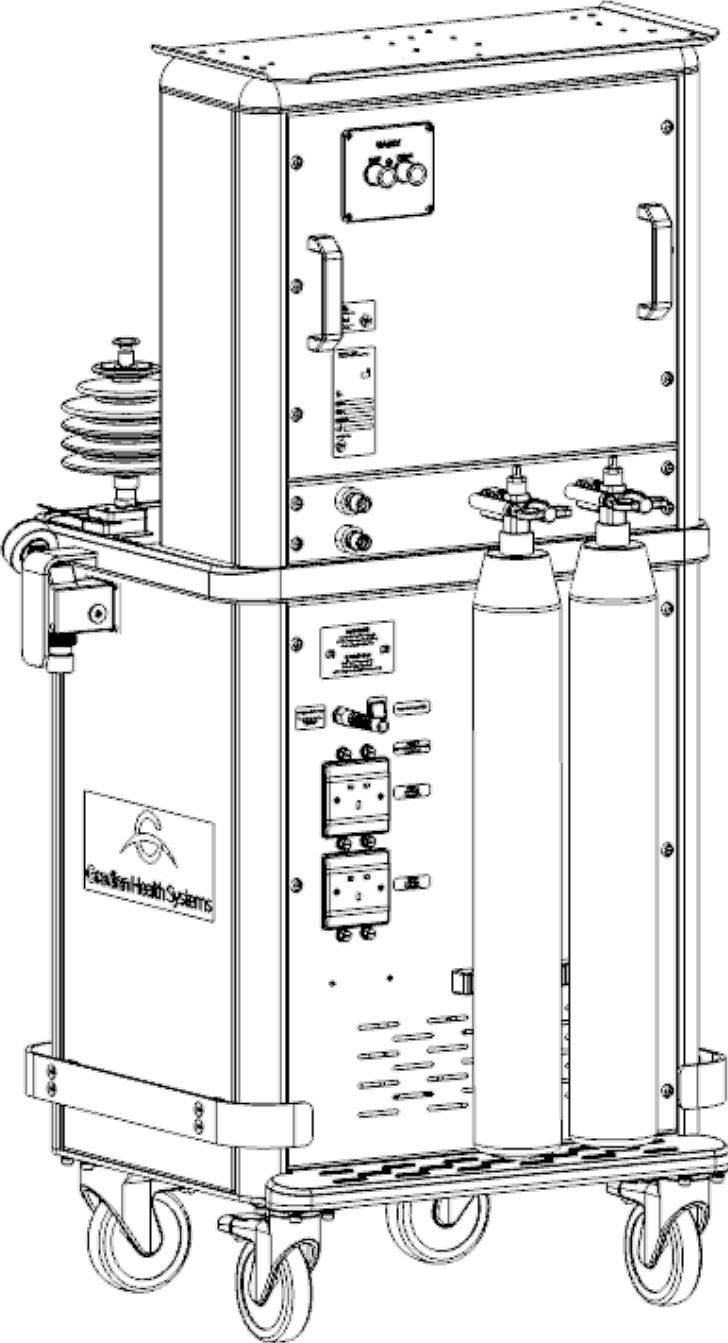
There are no contraindications for use of this device.

Descriptions and Illustrations

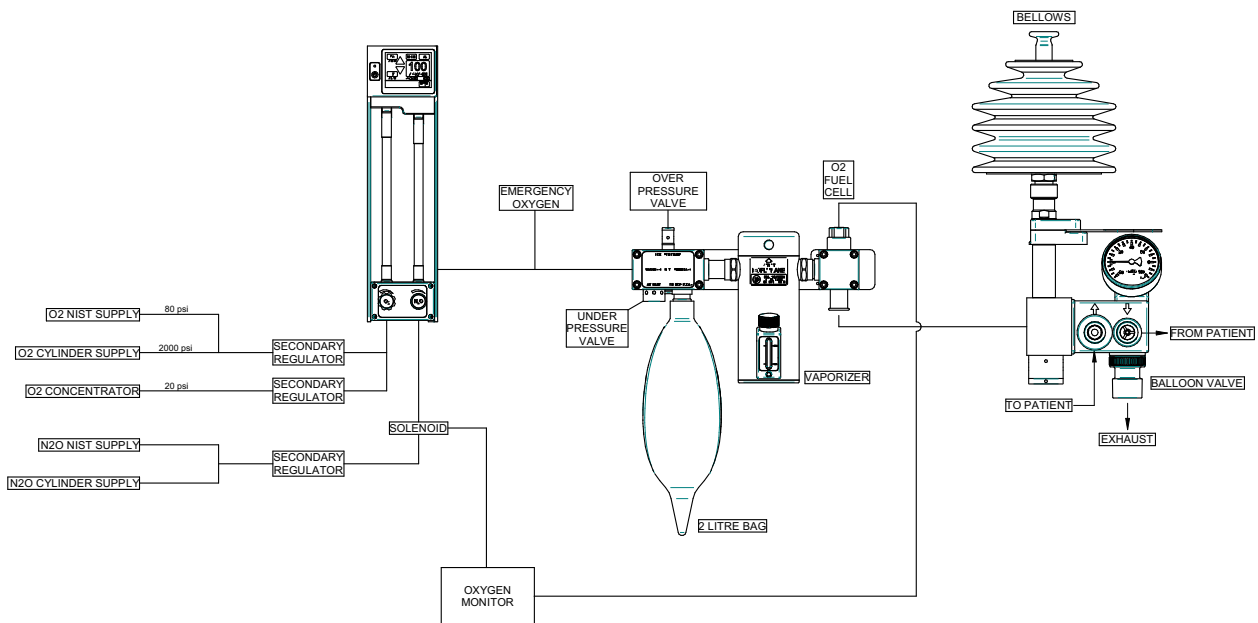
Front Illustration UAM



**Rear Illustration UAM**



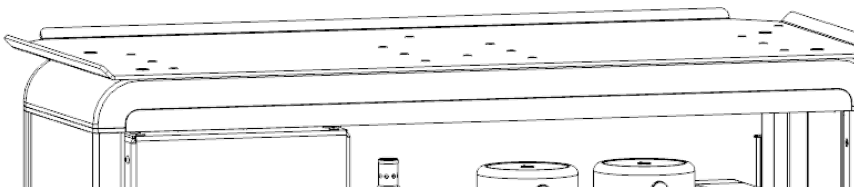
## Machine Circuit Illustration



## Machine Frame

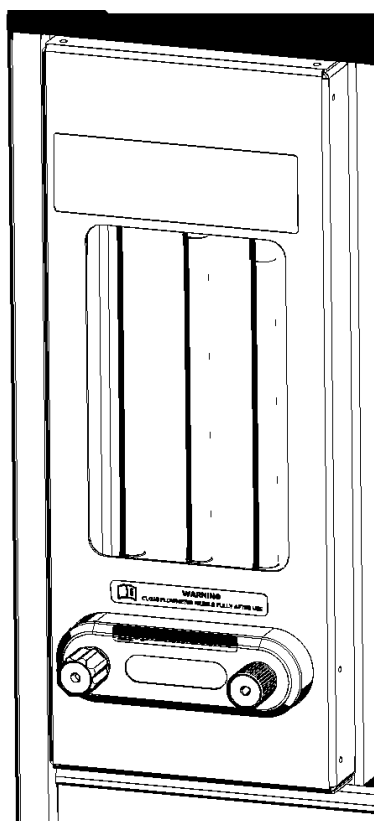
The anesthesia machine frame is constructed of an extruded aluminium upright with a sheet metal work surface / drawer front, with non-ferrous aluminium panels.

## Top Shelf



The top shelf is manufactured from pressed aluminium and is powder coated. Monitor brackets can be supplied to bolt items securely to the top of the machine.

## Flowmeter Bank



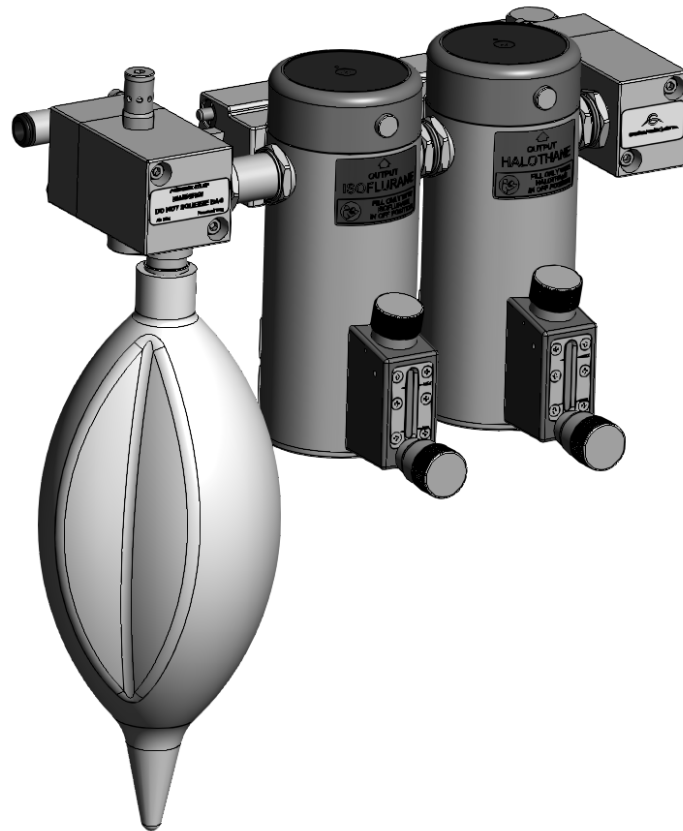
The flowmeter bank is available as a 2 gas oxygen and nitrous oxide option only.

All machines have dual taper, single flow tubes with oxygen calibrated between 0.1 and 10 liters per minute flow and nitrous oxide between 0.2 and 12 liters per minute.

The flow tubes have an antistatic coating to prevent the floats sticking with static in dry hot conditions. The floats are fluted to ensure that they rotate during use to provide an indication of correct function. The gas flows are read from the top level of the rotating float.

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

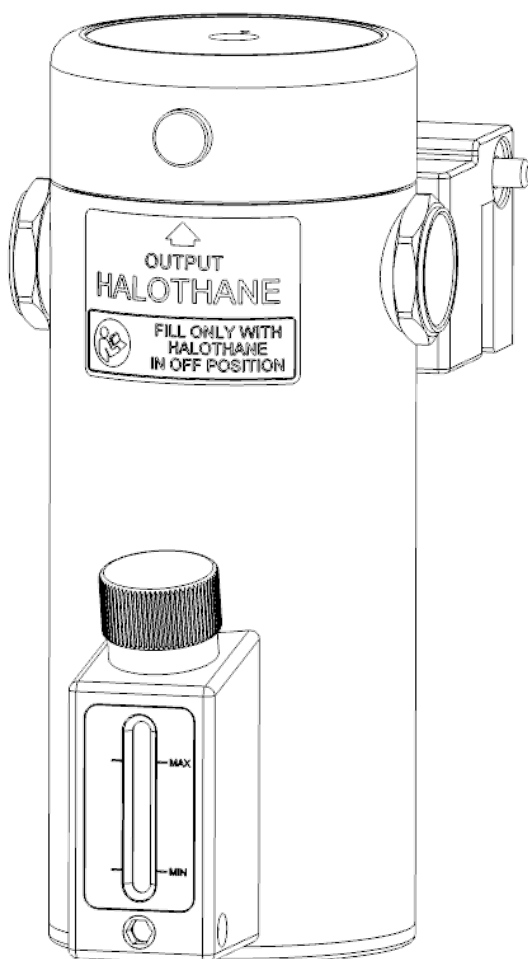
## Vaporizer Backbar



The UAM is fitted with a dual-position vaporizer backbar suitable for a drawover vaporizer. The connections between machine and vaporizer are made with parallel fittings to prevent jamming and potential damage during vaporizer removal.

The left hand block of the backbar contains a positive pressure relief to prevent the reservoir bag being over pressurised, a negative pressure relief valve to allow entrainment of air if the fresh gas flow has failed or is set too low and a 2 liter reservoir bag which fills with fresh gas from the flowmeter during the patients expiratory phase. The right hand block of the backbar transfers the gas flow to the manual bellows breathing system.

## Draw Over Vaporizer



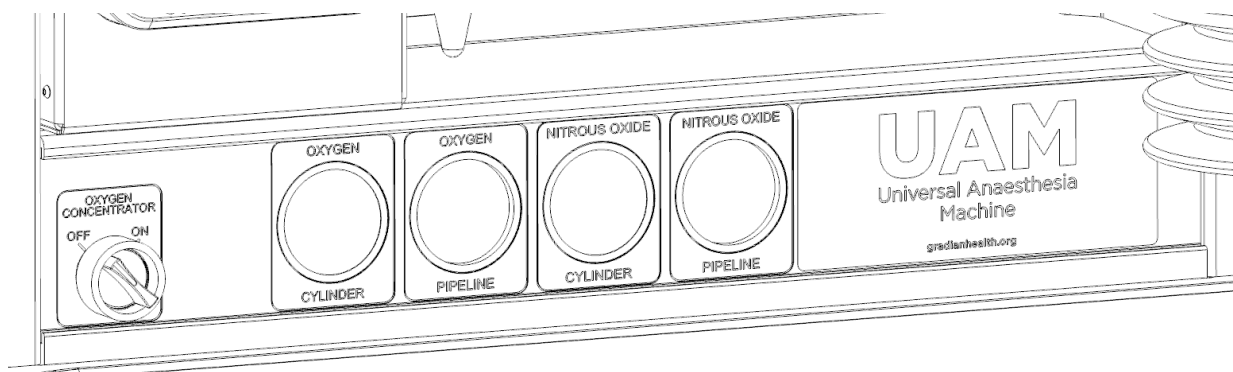
The machine is fitted with a draw over vaporizer with a pour filler. The vaporizer is available for Halothane, Isoflurane or Sevoflurane anesthetic agents. Filling level is indicated by a flat glass indicator where overflow beyond the maximum fill level is also indicated. Filling must take place only when the vaporizer is attached to the machine and when the machine is on a level surface.

Halothane vaporizers must be drained on a 3 monthly cycle to prevent thymol build up – the old anesthetic agent must be disposed of in an environmentally friendly way as a hazardous chemical.

The vaporizer agent capacity between minimum and maximum is 100 cc. The vaporizer must not be used if overfilled beyond the maximum fill line – an over filled vaporizer must be drained back to the maximum fill level, left for 2 hours, turned full on and a fresh gas flow of 10 litres per minute passed through to ensure that output is to calibrated settings.

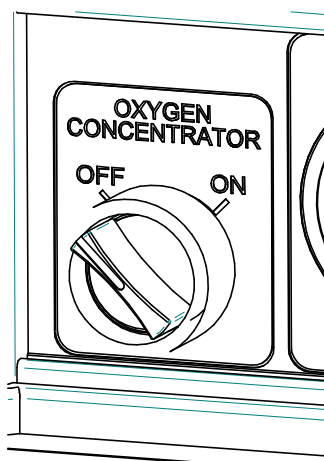


## Gauge Panel



The cylinder and pipeline contents gauges are mounted below the flowmeter bank in an 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 Pascals).

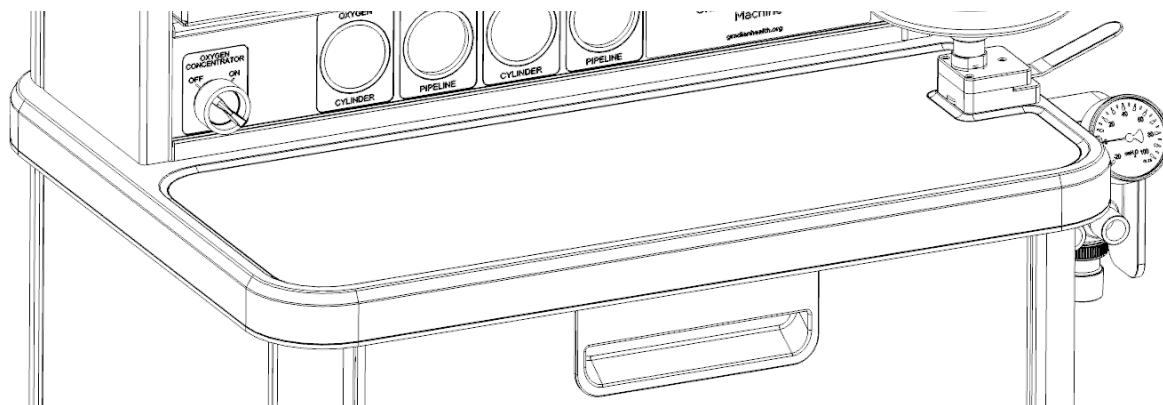
## Oxygen Concentrator On/Off Switch



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. This switch turns the oxygen concentrator on. The switch allows pneumatic power to the anesthetic machine and flowmeters.

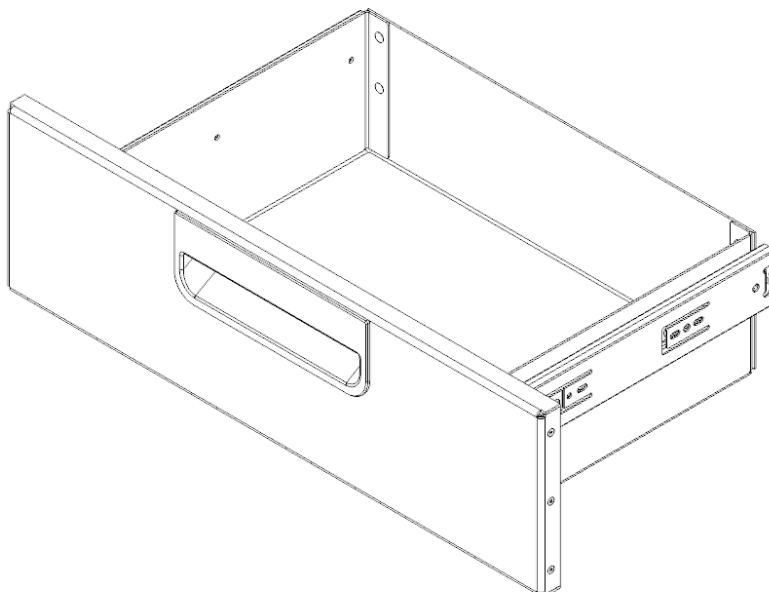
When the oxygen concentrator is required, it should be turned on prior to use to ensure oxygen concentration has reached a minimum of 90% oxygen.

## Work Surface



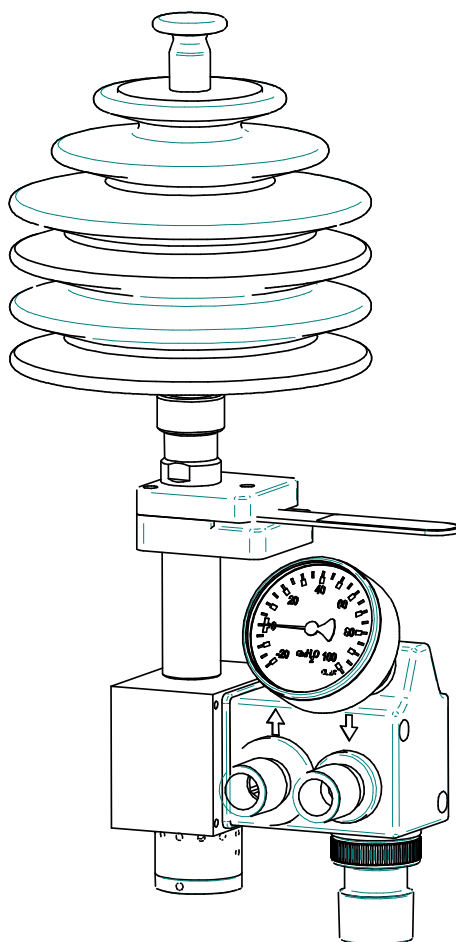
The machine has a brush finished stainless steel work surface which can be removed from the moulded work surface for cleaning.

## Drawer Unit



A metal drawer unit is mounted under the work surface. The drawer is removable for cleaning by fully opening and then pressing the toggle lever on the end of each slide to remove the drawer.

## Manual Bellows Breathing System



The patient is ventilated by anaesthetist manually operating the specially contoured silicone bellows assembly. At the same time the pressure in the breathing system operates the unique exhaust valve, closing the expiratory port. The exhaust valve is a long life silicone balloon assembly. Both the bellows and balloon assemblies can be readily removed with hand nuts for easy cleaning and disinfecting.

Non return valves are provided by silicone one way valves mounted within the patient valve assembly.

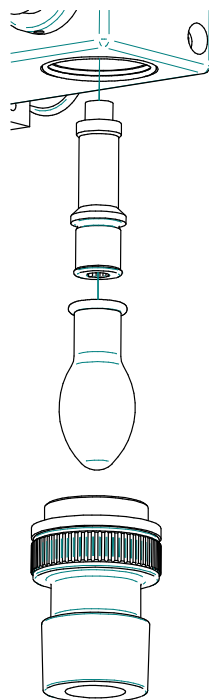
A 55 cmH<sub>2</sub>O pressure relief valve is mounted in the inspiratory limb for patient protection.

A pressure gauge is connected to the inspiratory limb to indicate the patient circuit pressure; the gauge has a quick release connection operated by pushing the collar back while holding the gauge.

An inspiratory and expiratory taper are provided for patient connections with 22 mm male / 15 mm female tapers allowing the use of conventional breathing circuits.

**Warning – A bacterial filter must be used at the patient connection port to prevent circuit contamination.**

## Fenton Balloon

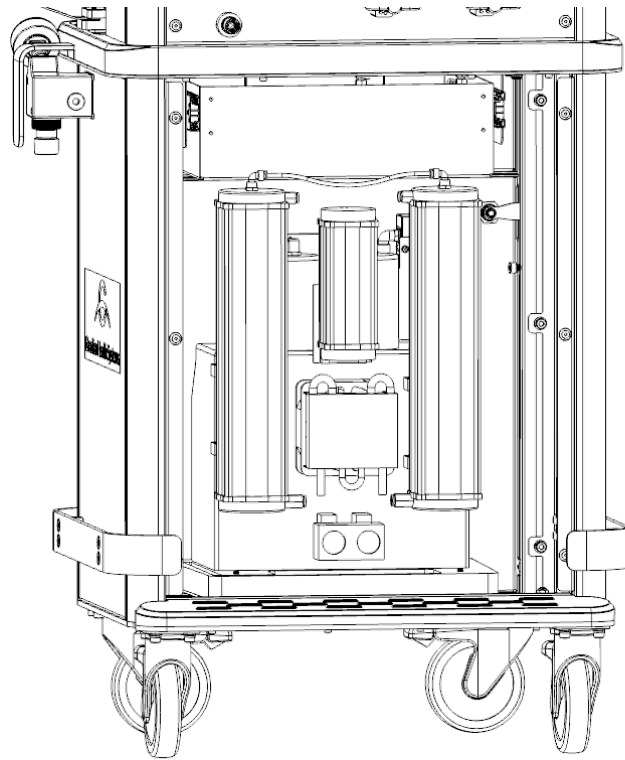


The right hand side of the machine/ breathing system block houses the “Fenton balloon” that controls the expiratory flow of gas. The balloon is moulded in silicone for long life and is housed in a metal housing complete with a 30 mm exhaust taper and non-return valve and a threaded connector to connect to the breathing system. Both connectors are permanently attached to either end.

The balloon is slid onto the shoulder of the connector and care must be taken to ensure that it is pushed fully to the shoulder. Replacement of the balloon housing is best achieved by cycling the bellows as it is screwed home to ensure that the balloon does not twist.

**Warning** – Function test bellows after reassembly – refer to the pre-use check list.

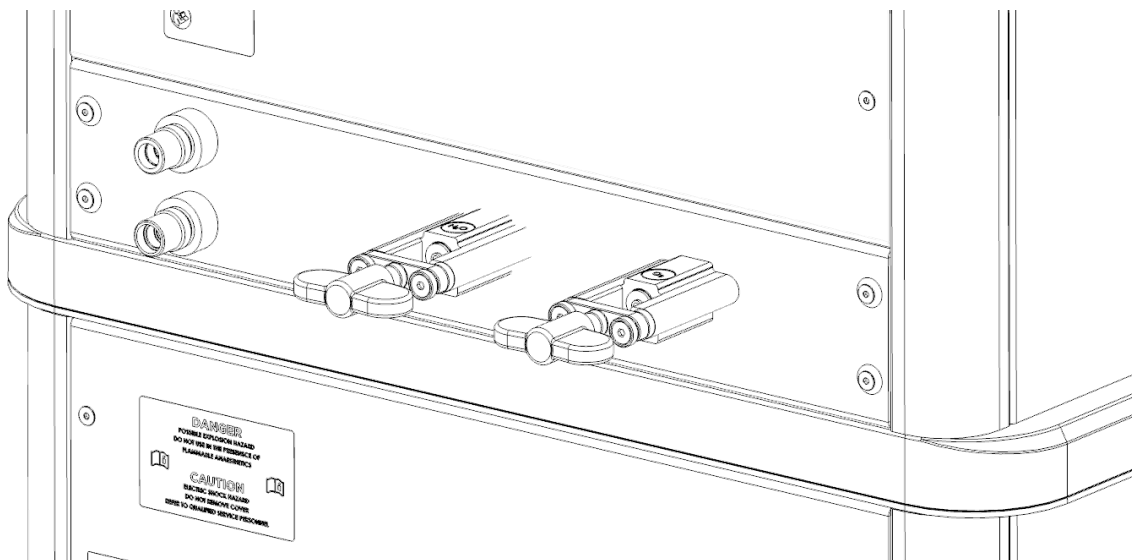
## Oxygen Concentrator



The oxygen concentrator is mounted onto the base of the UAM and is accessed through the rear cover or front panel. The concentrator is designed for easy removal for servicing with connectors for gas, electricity and the circuit boards being quick release. Four nuts underneath the base hold the concentrator in position.

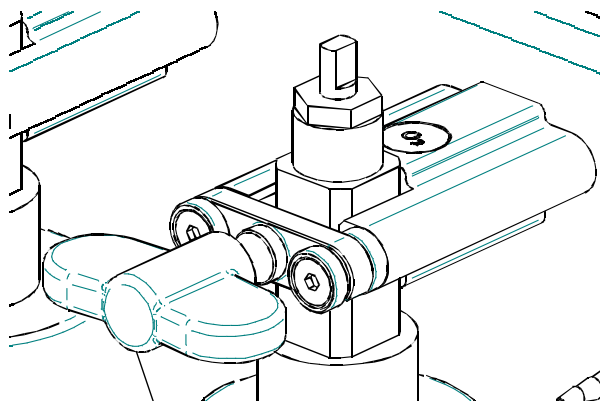
The air inlet to the concentrator is connected to a primary filter to ensure that no dust contamination of the compressor pump, control equipment or zeolite. The filter is mounted on the inside of the rear lower panel.

## Gas Tray



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

## Gas Cylinder Yokes

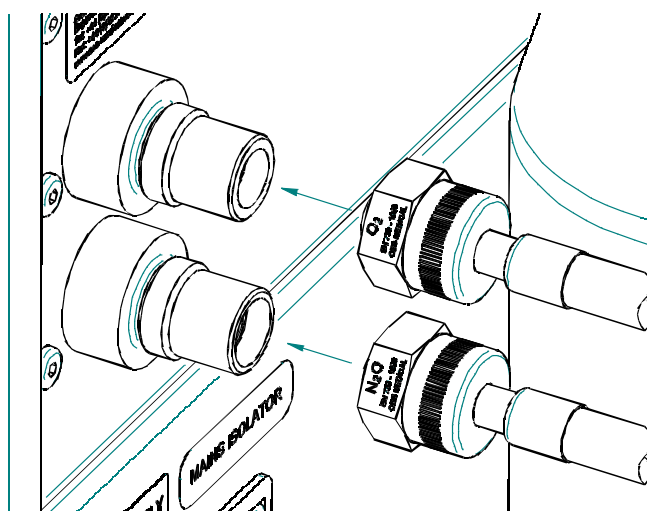


The UAM can be fitted with a maximum of 2 yokes – 1 oxygen and 1 nitrous oxide. Each yoke is pin indexed to prevent connection of the wrong cylinder and has a colour coded gas identification label.

The yokes are connected directly to high-pressure regulators and incorporate a filter to prevent dust contamination.

Each cylinder yoke and regulator includes a cylinder contents gauge, which is visible through the gauge panel at the front of the machine; each gauge has a colour-coded label.

## Pipeline Inlets



The NIST 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 with dust.

## **Pipeline Hose Assemblies**

Pipeline hose assemblies are made of 4 metres of colour coded antistatic hose with a BS 5682 probe for connection into the wall or pendant terminal and a NIST assembly to EN739 for connection to the machine.

The hose assemblies are screwed directly to the machine and must be tightened to prevent the hose becoming disconnected.

**Note** – Some markets may require differing hose lengths, colours or connections to comply with local requirements. Ask for any market specific requirement.

## **Machine Internal Piping**

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

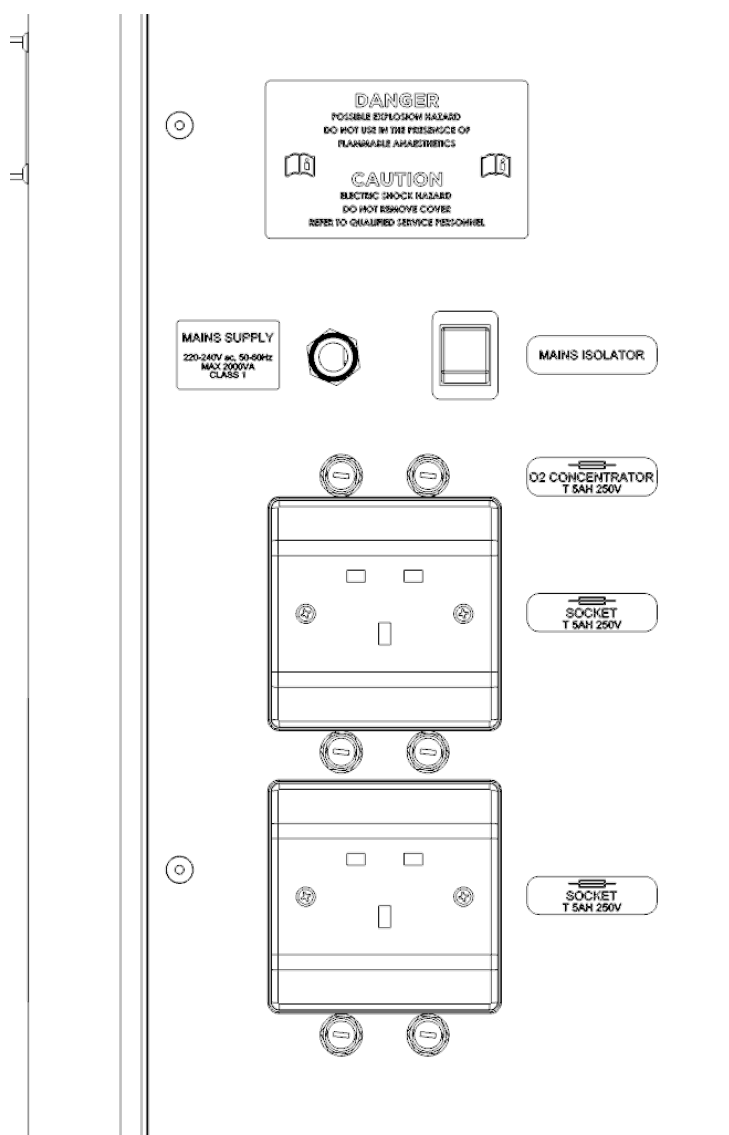
## **Machine Base**

The machine base is aluminium for stability, the oxygen concentrator hangs through the base allowing the concentrator to exhaust oxygen depleted air and for cooling of the compressor.

## **Casters**

The machine is fitted with 125 mm diameter casters with brakes to prevent machine movement during use.

## Mains Power Supply



Mains power supply is 220 - 240 volts 50 – 60 Hz the power lead is service personnel replaceable and is 1.25 mm - 13 Amp, 4 metres long and is fitted with a UK style 3-pin plug fused for 13 amps. An isolator switch is fitted which is illuminated when on and isolates incoming power to the oxygen concentrator and the two auxiliary power sockets.

## Auxiliary Power Sockets

The UAM is provided with two 5 amp fused 3 pin UK style sockets for connection of patient monitoring.



## **UAM Specification**

### **Overall Dimensions**

Width x depth x height 74.7 x 64.2 x 135.0 cm

### **Machine Weight**

Approx 130 kg

### **Top Shelf Dimensions**

Width x depth 60.0 x 28.6 cm  
Maximum top shelf loading. 35 kg with even distribution of load.

### **Work Surface Dimensions**

Width x depth x height 63.5 x 24.5 cm x 91 cm  
Maximum work surface loading. 35 kg with even distribution of load.

### **Drawer Unit Dimensions (Internal)**

Width x depth x height 37.7 x 26.2 x 11.8 cm  
Maximum drawer loading 35 kg

### **Flowmeter Specifications**

Flow tube ranges

Single tube, dual taper, anti static oxygen or nitrous oxide

Oxygen tube 100 cc to 10 liters per minute.

Nitrous Oxide tube 200 cc to 12 liters per minute.

Flow tube accuracy 2.5 % of full-scale reading

Tubes are length indexed to prevent incorrect assembly.

Tubes have an antistatic coating.

***Note that the oxygen flow tube is calibrated on medical oxygen at 100% and that the concentrator gives an output around 90% oxygen concentration, therefore the actual flow rate will be slightly higher than that indicated by the flow tube.***

## **Flowmeter Controls**

The oxygen flow control knob is shape coded to provide touch identification, and all knobs have a colour-coded label identifying the gas, which they control. Stops are provided at each end of the knob travel to prevent damage caused by excessive rotation.

## **Anti-Hypoxic Device**

The flowmeter is fitted with an electronic valve on the nitrous oxide supply, driven by the UAM Ventilator, that cuts the flow of nitrous oxide if the FiO<sub>2</sub> falls below 25%. Additionally, the flow control knobs are linked such that when nitrous oxide flow is open, oxygen flow is opened as well to maintain an oxygen concentration of at least 25% to be delivered to the patient.

## **Vaporizer Connection**

The UAM is fitted with a single or double vaporizer with a unique custom designed parallel connection – this design prevents jamming and leaking of tapers.

## **Vaporizer**

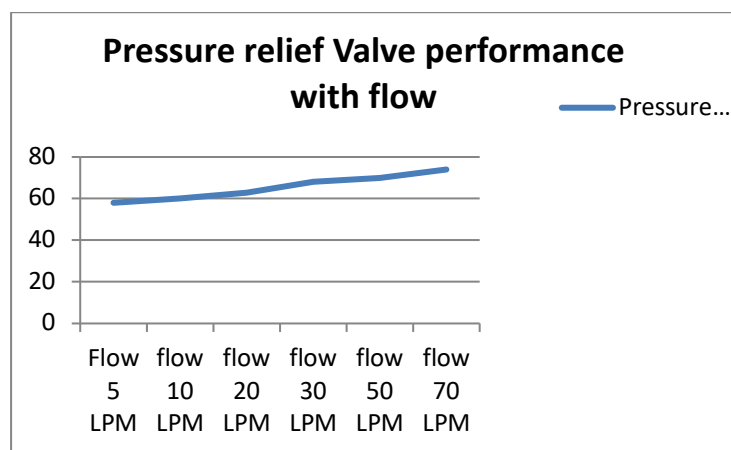
Vaporizer type.	Draw over.
Calibration range	0 to 4% v/v output.
Filler type.	Pour filler
Anesthetic agents.	Halothane, Sevoflurane, or Isoflurane.
Agent capacity.	100 ml between min and max. Total capacity of 120ml with a further 10ml absorbed by the wick.

The vaporizer design is specific to the UAM machine and can only be used correctly connected to the UAM anesthetic machine.

## **Manual Bellows Breathing System**

Inspiratory resistance	< 2 cm H <sub>2</sub> O @ 30 l/min <sup>#</sup>
Expiratory resistance	< 2 cm H <sub>2</sub> O @ 30 l/min <sup>#</sup>
	<sup>#</sup> note: testing performed without patient bacterial filter.
Circuit compliance:	approximately 3 ml/cmH <sub>2</sub> O, (excluding breathing system hoses).
Maximum bellows capacity	1600 cc.
Non return flap valve material	Silicone.
Quick release pressure gauge	(-)20 cmH <sub>2</sub> O to (+)100 cmH <sub>2</sub> O.
Exhaust balloon material	Silicone.

Pressure relief valve set at 55 cmH<sub>2</sub>O – flow characteristics shown on graph below.



## **Oxygen Concentrator On/Off Switch**

Twin pole switch mounted on the left hand side of the gauge panel, complete with a shroud to prevent inadvertent switching off.

## **Oxygen Concentrator**

Self contained twin chamber design unit with primary and secondary inlet air filters, water trap, heat exchanger and fan.

Oxygen output flow.	Up to 10 l/minute.
Oxygen concentration.	87% to 95%.
Power requirement.	220-240 volt, 50-60 Hz, 500 watt
Audible alarms.	Power failure, driven by 9 volt battery.

## **Gas Cylinder Yokes**

Gas cylinder yokes are designed for fitting “E” size cylinder with compatible high pressure pin index cylinder yokes. The oxygen inlets are rated for oxygen 137 bar (1980 psi) and nitrous oxide 44 bar (640 psi).

## **Pipeline Inlets**

The UAM is fitted with NIST pipeline gas supply inlets mounted on the rear left of the machine marked for identification. The inlets are rated for 4 bar (60 psi) and also have an integrated non-return valve.

## **Pipeline hose assemblies**

4 meters colour coded antistatic hose with a BS 5682 probe and an EN739 connection.

## **Power Supply**

220 - 240 volt, 50 to 60 Hz.

## **Fuses**

5 mm diameter by 20 mm long anti surge type "T" fuses with 1500 A breaking capacity (ceramic).

Oxygen concentrator.	2x 5 Amp anti-surge
Auxiliary outlets.	2x 5 Amp anti-surge

The mains cord is not operator replaceable.

## **Auxiliary Sockets**

2 off 13 amp UK style sockets each twin fused 5 amp anti surge type T.

## **Leakage Current**

**Warning** – Connection of additional equipment to the auxiliary sockets may increase the level of leakage current to an unacceptable level. It is the user's responsibility to test the fully configured machine for compliance with the leakage current limits before use. IEC 60601-1 clause 8.7.3 (c) 100µA in normal condition and 500 µA in SFC.

## Machine Internal Piping

Flexible nylon.  
Diameter and colour indexed.  
Labelled where required.

## Casters

150 mm diameter single wheel casters, braked.

## Device Classification and Labelling

Classification with  
internal electric  
power source.

Class 1

Operating instructions  
(this user manual)



Classification  
according to the  
degree  
of protection against  
ingress of dust  
and water.

IPX0

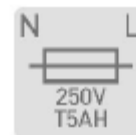
Refer to instruction  
manual



IEC Symbol denoting  
type B applied part



Fuse symbol and  
specification, plus  
orientation of Neutral  
and live fuses



Manufacturer



Date of Manufacture



## Storage

Should the UAM require to be stored for an extended period of time ensure that the following precautions are undertaken.

- Drain and dry the vaporizer.
- Remove all rubber and single use components and dispose.
- Remove O2 monitor back up battery.
- Remove the mains failure warning battery from the Oxygen concentration.

Place note on machine indicating status of machine and warning future users of the need to carry out full pre use checks before returning to service.

## **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

EC Territories: Follow the requirements of Directive 2002/96/EC.



## **Disposal of Used Breathing Circuit Components**

Follow the advice above.

## **Disposal of Used Batteries**

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

## **Environmental Conditions**

Temperature.	Operating, 15 – 35deg C Storage, -5 – 50 deg 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 UAM is not suitable for use within an MRI Environment

## **Use Outside of Specified Environmental Conditions:**

It is the responsibility for the user to perform pre-use testing before use in environments outside the above operating conditions.

## **Phthalates**



Labelling of devices or parts of devices containing particular phthalates is required because some have been classified as CMR 1 & 2, i.e. they could exhibit carcinogenic, mutagenic or reprotoxic/developmental effects. Not all the reproductive and developmental toxicity of phthalates to the human body have been confirmed. However, it has recently been suggested that precautions be taken to limit the exposure of humans particularly that of high risk patient groups such as male neonates, male foetuses and prepubertal males.

There are no components within the UAM containing phthalates.

## **Pre-Use Checks**

Prior to use the UAM must be inspected and checked to ensure correct and safe function.

An incorrectly functioning anesthetic machine must be removed from service and labelled "**NOT FOR CLINICAL USE UNTIL REPAIRED**" and must be properly repaired by a factory approved trained service engineer using spares only obtained from Gradian Health.

**Warning** - No responsibility will be taken for unapproved servicing or spares.

## **Pre-Use Checklist**

The UAM is fitted with a pre-use check list below the vaporizer and is repeated here.

### **Inspect and Test**

- (1) Check stability of machine and functionality of casters and brakes
- (2) Cycle bellows and confirm free movement and absence of leaks
- (3) Attach test lung, check action of exhalation balloon by inflating with bellows while observing balloon
- (4) Check PRV by pushing bellows with patient Y-piece blocked, confirm max. pressure 55 cmH<sub>2</sub>O
- (5) Check that gas scavenging is configured correctly

### **Vaporizer**

- (1) Check the volatile agent level in the vaporizer and fill as necessary
- (2) Check the vaporizer selector wheel to ensure smooth operation (press silver button to unlock)

### **Power**

- (1) Confirm that the UAM is connected to mains power
- (2) Switch on green mains isolator switch on the UAM back and confirm that it lights up

### **Oxygen Supply**

- (1) Confirm that oxygen monitoring is available and properly calibrated
- (2) Turn on the oxygen concentrator by using the switch on the front of the machine
- (3) Set oxygen flow to 8 L/minute, wait 1-3 minutes. Oxygen % should be greater than 90%

### **Nitrous Oxide**

- (1) Confirm that electronic anti-hypoxic device (AHD) is present
- (2) Fully open the nitrous flow, and confirm that the oxygen flow rises to 10 L/minute or greater
- (3) Shut off the concentrator, confirm that the AHD cuts off nitrous flow at the appropriate FiO<sub>2</sub> limit

## **Pre-Use Checks – In Depth Description**

Prior to use the UAM must be fully inspected for faults or damage sustained since it was last used.

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, the equipment settings may have been left outside those considered clinically acceptable and therefore will require adjustment.

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

**Warning** - No responsibility will be taken for unapproved servicing or spares.

## **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, flowmeter knobs should be checked for smooth movement and maximum gas flow.

## **Electrical Power**

Check that the machine electrical power systems are functioning correctly and that the battery is fully charged.

(1) Connect the machine into a mains power outlet and from the rear of the machine switch green mains isolator green switch “on”. Turn on the oxygen concentrator switch on the front of the machine. Check that the oxygen concentrator begins to run.

## **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 fittings 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.
- (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 relevant cylinder pressure.



(3) Remove the cylinder turn on the flow valve 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 oxygen flowmeter fully on and ensure that it is giving a maximum flow of 10 litres per minute in the fully open position.
- (2) Close the flowmeter and ensure that the flow stops.

**Note** - The bobbins on each gas must spin freely with flow

### **Anti-Hypoxic Device**

Nitrous oxide flow is controlled by an electronic valve system built into the flowmeter.

- (1) Turn on the UAM Ventilator and the oxygen flow
- (2) Increase the nitrous oxide flow, and confirm that the oxygen flow opens to maintain an FiO<sub>2</sub> of at least 25%.
- (3) Shut off all oxygen sources, and confirm that the nitrous oxide flow is automatically cut.

**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.

### **Vaporizer Mounting**

The vaporizer is mounted on a custom designed back bar.

The vaporizer is taken off by removing the left and right hand block on the backbar, this is achieved by unscrewing two screws each with an Allen key. The blocks then slides off the vaporizer, the vaporizer then can be lifted off.

To assemble, slide the vaporizer down onto the backbar, slide on the right and left hand blocks and secure with the 2 screws.

**Warning** – Ensure that the 'O' ring in the rear face of the right hand block is in position during reassembly.

**Note** – The UAM has been designed for use with only the Gradian Draw Over Vaporizer. No other vaporizer will fit as the fitting system is unique to the UAM.

## **Testing the Negative Pressure Relief Valve**

The left hand block on the vaporizer contains the positive and negative pressure relief valves.

To test the negative pressure relief valve cycle the bellows until the reservoir bag is empty, the valve should then allow room air to be sucked into the backbar.

**Note** – Induction of air into the backbar is indicated by pulsing of the reservoir bag during filling of the bellows.

## **Testing the Positive Pressure Relief Valve**

The positive pressure relief valve is designed to prevent the reservoir bag overfilling with fresh gas.

To test the positive pressure relief valve, block the patient connection and increase the fresh gas flow, the reservoir bag fills then the valve opens so that the bag does not become pressurized.

## **Patient Circuit**

Two options are available for the patient circuit.

The first is a conventional silicone twin tube and Y piece, which connects to the inspiratory and expiratory connections of the UAM, this circuit is autoclavable and reusable.

The second is a coaxial circuit consisting of an inner and outer tube which is connected to the inspiratory connector with a side connector being connected to the expiratory, this circuit is disposable.

**Warning** – Ensure that the connections are pushed fully onto the UAM patient tapers and that the hoses are routed to prevent tangling and the possibility of disconnection due to them being caught on other equipment.

**Note** – The patient circuit must be used in conjunction with a patient anti bacterial filter to protect the breathing circuit and UAM.

## **Patient Circuit Function and Leak Check**

With the patient circuit connected to the UAM, block the patient connection port and cycle the bellows and ensure that patient pressure can be achieved.

**Note** - The bellows should not require excessive movement to maintain pressure.

When the bellows is released the pressure must exhaust through the balloon.

### **Machine Cleaning and Disinfection**

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 UAM but must be rinsed thoroughly with water prior to drying.

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

The breathing system may be dismantled and cleaned with clean mild soap solution or antiseptic solution but must be rinsed thoroughly. The bellows, one way valves and the Fenton balloon can be autoclaved at 136 °C after cleaning.

The twin tube with Y piece breathing system may be autoclaved at 136 °C after cleaning.

**Warning** – Do not autoclave the coaxial breathing circuit as it is disposable.

**Warning** – Do not autoclave the oxygen sensor. It will damage the sensor.

## User Maintenance

The following items are maintainable by the user or suitably skilled technician.

**Warning** - After any maintenance procedures are undertaken, a full function test must be undertaken and the machine must be identified as having been maintained on return to the operating room to ensure the first user is aware that the machine has been the subject of maintenance.

- (1) Replacement of patient circuits.
- (2) Cleaning and replacement of the balloon.
- (3) Replacement of Bodok seals on the high-pressure cylinder yokes. Bodok seals are retained on the cylinder yoke by the tightness of fit. To replace the seal lever the old seal from the yoke and press the new seal full home.
- (4) Cleaning of the anesthetic machine surfaces. See previous section.
- (5) Replacement of the oxygen concentrator power failure alarm back up 9 volt battery. Disconnect from mains electricity supply. Remove the rear panel cover, disconnect the battery from its holder and replace with a new one.
- (6) Cleaning and replacement of the concentrator filter. Disconnect from mains electricity supply. Remove the rear panel, remove the old filter by unscrewing the M5 nut and taking off the cover plate and replace.

## Disposal of Packaging

The packaging for the UAM is produced from fully recyclable timber.

## 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

EC Territories: Follow the requirements of Directive 2002/96/EC.



Disposal of used breathing circuit components. Follow the advice above.

**Note** - Removal/replacement of battery must only be undertaken by trained technicians.

## Ordering Information

Refer to Gradian Health for ordering information on the UAM.

The following detachable parts and accessories are commonly replaceable:

Recommended breathing circuits and spares

Silicone breathing circuit with Y piece (autoclavable)	1300-082
Coaxial breathing circuit (non reusable)	1300-085
Viral filter and elbowed catheter	1300-107
Bodok seals	1190-005
Oxygen fuel cell	1300-075
Ventilator bellows	6650-022
Fenton balloon	6650-015
PP3 battery. 9 volt	1419-102
Concentrator filter	1300-069

# Electromagnetic Immunity

## 1 Electromagnetic Emissions

Declaration - Electromagnetic Emissions		
The UAM 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 UAM 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 UAM 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	

## Device Configuration

The UAM is classified as an anesthetic gas delivery in compliance with ISO 8835-7 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
- 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

## User Notes