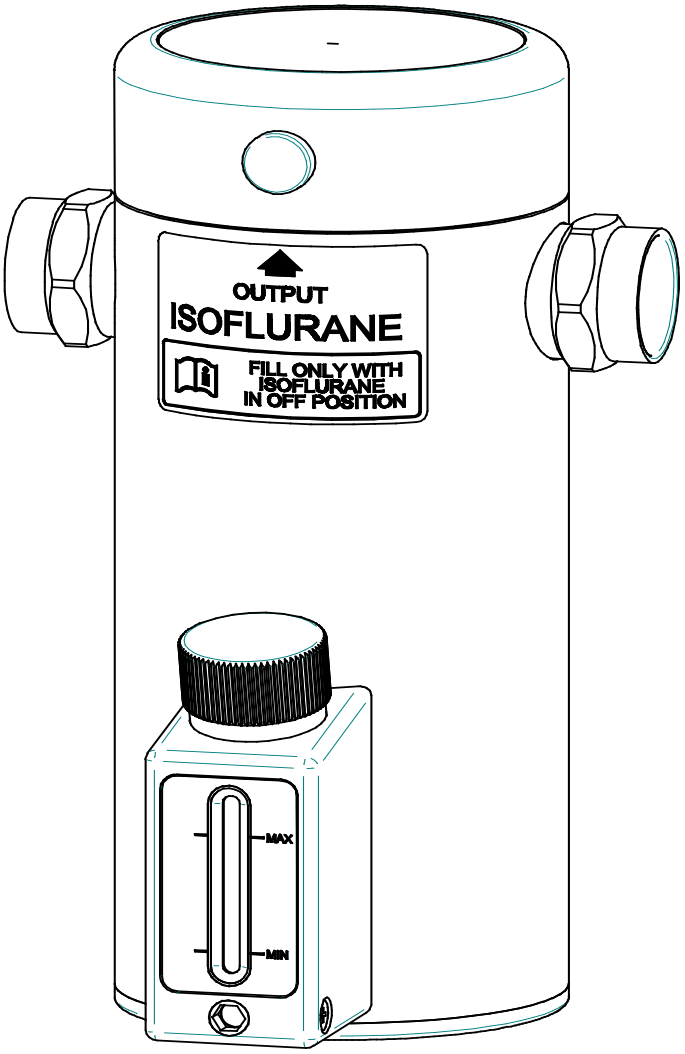
OES MEDICAL



Draw over Anaesthetic vaporizer User Manual

Doc number 1983-510 Issue D Oct 2015

CE 0120

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Rev A April 2010	Rev B Jun 2014	Rev C Jan 2015	Rev D Oct 2015	Rev E
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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

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The OES Medical Draw over vaporizer has been developed by OES Medical for use with the UAM anaesthetic machine which was developed with financial aid of the Nick Simons Foundation (NSF). The foundation is a 501(c) (3) private foundation established in July 1, 2005 to honour the memory of Nick Simons.

The foundation aims to perpetuate Nick's interest in developing countries, especially for the rural and remote populations of Nepal. The foundation is governed by a seven-member Board of Directors - all members of the Simons family.

The design of the Universal Anaesthetic Machine is a collaboration between the Nick Simons Foundation, Dr Paul Fenton – FFARCS[1] and OES Medical [2].

1 Dr Paul Fenton FFARCS, has many years of clinical experience working specifically in areas with difficult environmental conditions providing anaesthesia and training for those working and living there.

2 OES Medical are the sole manufacture of the UAM anaesthesia gas delivery system and provide medical support, technical and manufacturing expertise.

Servicing, spares and repairs

The OES Medical Draw-over anaesthetic vaporizer 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 the vaporizer the following service schedule must be adhered to: -

(a) Daily function test by the user to ensure patient safety.
(b) 6 monthly inspection and function check by a trained engineer.
(c) 2 year service with replacement of pour filler seal 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 manual that is available to factory approved trained personnel.

Further servicing details are available from: -

The Service department,
OES Medical Ltd,
ABC House, Cotswold Dene,
Standlake, Witney,
Oxfordshire
OX29 7QG,
Tel 01865 301711,
Fax 01865 301573

E mail richard@oes-medical.co.uk

Always provide the following information with any communication: -
(a) Product type and part number.
(b) Serial number.
(c) Date of purchase.
(d) Details of suspected fault.

Warnings and cautions

Throughout this manual warnings and cautions relating to various aspects of use of this draw-over vaporizer are given.

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

No clinical advice on the use of this draw-over vaporizer is given or implied within this manual, the various technical functions are described and it's use by the anaesthetist must be based on best safe clinical practice using all necessary additional patient monitoring considered necessary for patient safety.

Warning – The UAM and draw-over vaporizer are not for use with flammable anaesthetic agent due to the risk of fire.

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

Warning – the OES draw-over vaporizer must be function checked and serviced when required, under no circumstances must it be used in a malfunctioning condition.
If in doubt consult the local service expert or contact OES Medical direct for advice

Warning – This equipment must only be operated by a clinician who is locally approved and trained specifically in the use of the draw-over vaporizer and the anaesthesia machine to which it is attached.

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

Purpose

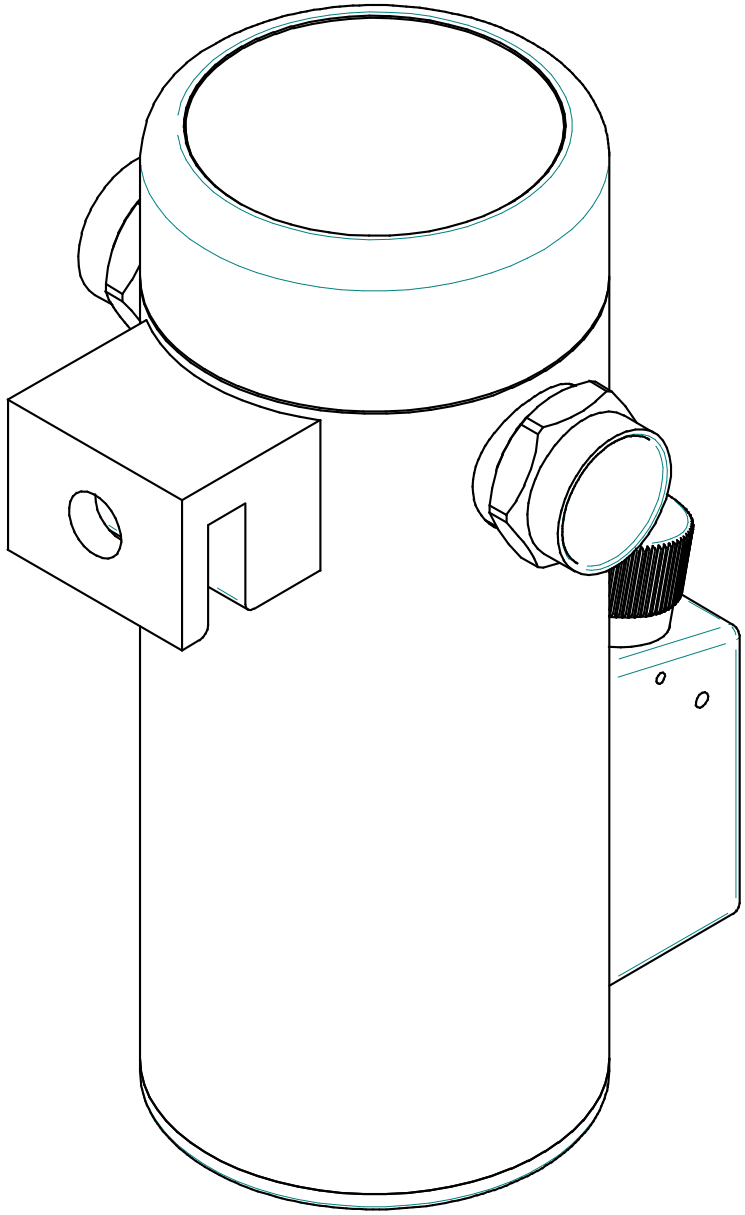
The OES draw-over anaesthetic vaporizer is designed to allow patient anaesthetic induction with only room air, no high pressure medical gases are required although supplementary oxygen is recommended to prevent low patient saturated oxygen concentrations. The vaporizer is designed so that typical patient tidal volume flows can be drawn through the vaporizer by the bellows of the draw-over anaesthesia machine.

Descriptions and illustrations

Front illustration Vaporizer

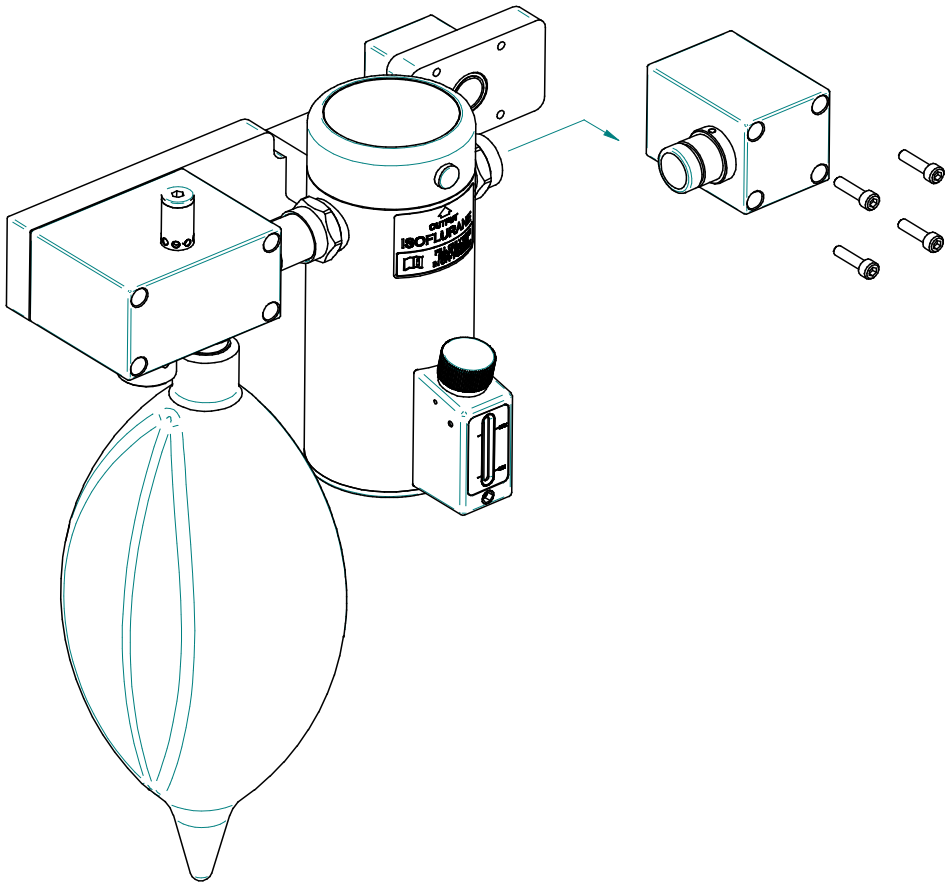
The vaporizer is available for Halothane or Isoflurane anaesthetic agents.
The draw-over vaporizer chamber is constructed from stainless steel to prevent contamination of anaesthetic agent by corrosion.
Internal parts are nickel plated brass and the control knob is anodised aluminium with an individually calibrated and laser engraved dial.
The filler assembly and the control knob button are satin chrome plated brass.
All internal seals are Viton and PTFE for long life.
Flow through the vaporizer is from left to right.

Rear illustration Vaporizer



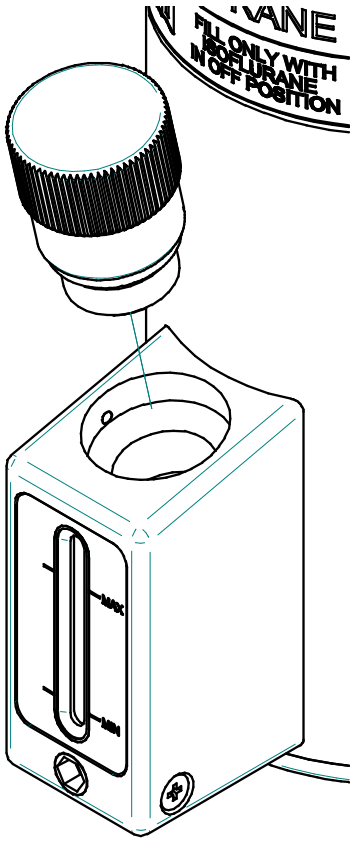
The rear of the vaporizer has a unique backbar connection bracket for fitment to the Universal Anaesthesia machine. The backbar bracket allows the vaporizer to be removed if replacement is required.
The inlet and outlet connections are parallel connections which seal on viton ‘O’ rings – this design of connection prevents the common problem of jamming associated with tapers. Each vaporizer is labelled with a part number and is individually serial numbered. A second label indicates the CE mark and manufactures details.

Vaporizer backbar



The UAM is fitted with a single position vaporizer backbar suitable for a draw-over OES Medical 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 litre reservoir bag which fills with fresh gas from the flowmeter during the patient's expiratory phase.
The right hand block of the backbar transfers the gas flow to the manual bellows breathing system.
The right hand block is also removable for the replacement of the vaporizer, this is achieved by removing the 4 off M5 screws from the front face of the block, sliding the block to the right while holding the vaporizer in position then sliding the vaporizer to the right and lifting off the backbar.
Caution – care must be taken to ensure that 'O' rings are not lost or damaged during vaporizer replacement.

Vaporizer Filler Knob



The vaporizer is filled with anaesthetic agent via the filler mounted on the front of the vaporizer can. The knurled knob is unscrewed anticlockwise for removal, the liquid anaesthetic agent is poured in until the maximum fill line is reached. Care must be taken to ensure the filler knob is screwed back in after filling and is tightened to prevent loss of vaporizer output during use.

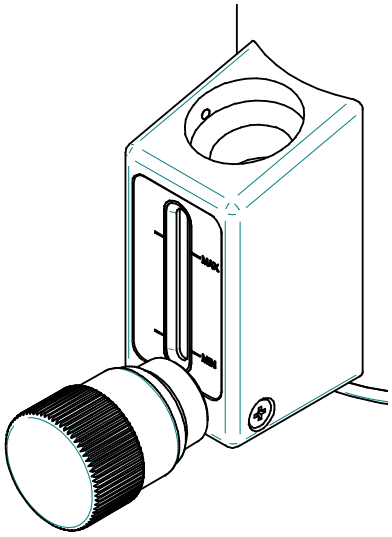
Warning – Any attempt to fill beyond this point will cause liquid spillage due to the air return port being blocked by liquid.

Warning – DO NOT FILL ABOVE THE MAXIMUM LEVEL

Warning – Do not operate the vaporizer if filled beyond the maximum fill level The vaporizer must be drained back to the maximum fill level and a fresh gas flow of 10 Litres per minute passed through for at least two hours – the output concentration must be checked to ensure that normal clinical output is obtained.

Warning – the vaporizer must be filled while on the machine and with the machine on a level surface with the control knob in the off position and the flowmeter turned off.

Vaporizer Filler Drain Screw



The vaporizer is fitted with a pour filler. Filling level is indicated by a flat glass indicator where overfill 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 anaesthetic agent must be disposed of in an environmentally friendly way.
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 clinically acceptable / calibrated settings.

To drain the vaporizer remove the filler cap and locate hexagonal end in the drain screw, loosen the drain screw anti clockwise and catch the old anaesthetic agent in an agent bottle and dispose of as required by local health and safety procedures.

Warning – do not reuse old anaesthetic agent

Warning – the vaporizer must only be filled by trained personnel.

Warning – Overfilling can cause liquid anaesthetic to flow out of the vaporizer into the breathing circuit giving grossly high percentages of concentration.
Any overfilling must be dealt with in accordance with this manual.

Vaporizer specification

Overall Dimensions – height x width x depth	189.5 mm x 110 mm x 134 mm
Vaporizer weight – (kg)	3.5kg
Vaporizer connection	The standard UAM is fitted with a single vaporizer with a unique custom designed parallel connection – this design prevents jamming and leaking of tapers.
Vaporizer Type	Draw over flow type, calibrated between 0 and 4 % output.
Filler type -	Pour filler.
Agent capacity	100 cc between minimum and max and a total capacity of 120 cc with a further 10cc absorbed by the wick. The vaporizer capacity is 100 ml between minimum and maximum marks and a total capacity of 180 ml including a further 10ml absorbed by the wick.
Available for Halothane or Isoflurane anaesthetic agent.	

Warning – The UAM vaporizer is designed for draw over use and the performance during use in IPPV cannot be assured.

Calibrated settings
The dial calibrated settings are – 0.5%, 1.0%, 2.0%, 3.0% and 4 % for flow rates of between 3 and 8 litres per minute flow.

Calibration Procedure
The vaporizer is calibrated at 22 degrees centigrade at 6 Litres oxygen flow rate using a laser refractometer with the anaesthetic agent level at ¾ full.
The vaporizer is turned on to maximum output (4%) for 20 seconds prior to each calibrated setting being marked for laser engraving.

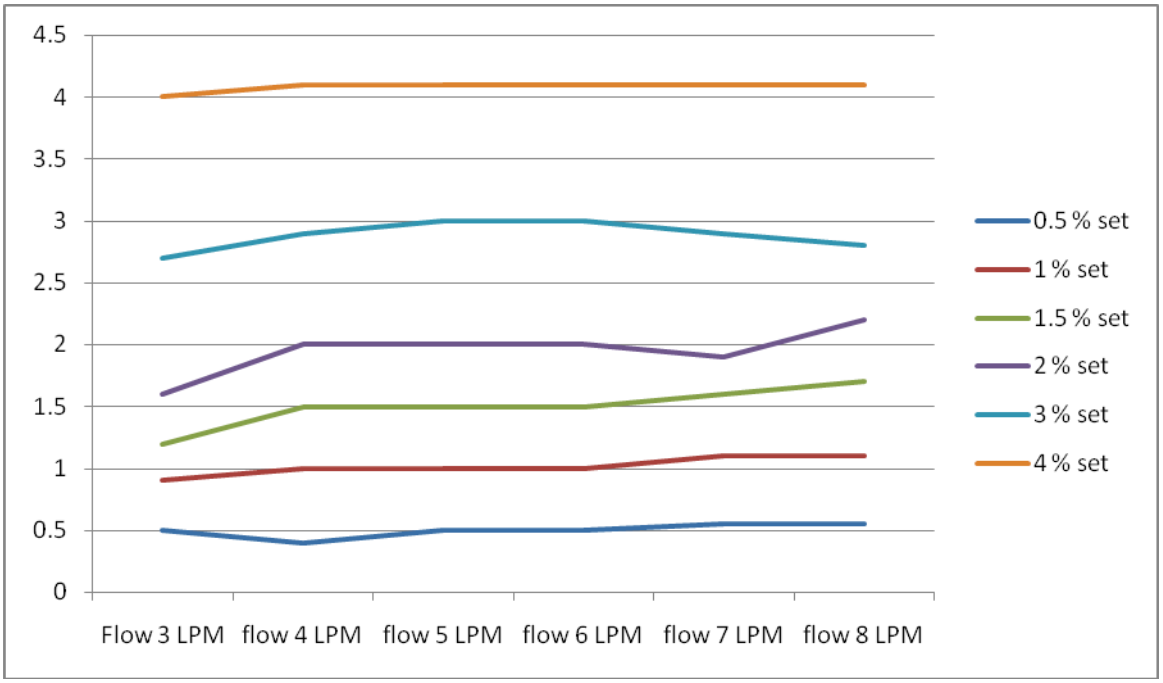
The output must drop to 4 % after 20 seconds; each further dial setting is then recorded for laser engraving in descending order. The dial is then engraved and the dial checked for accuracy.

Vaporizer Accuracy
The vaporizer complies with the requirements of ISO TS 18835:2004.

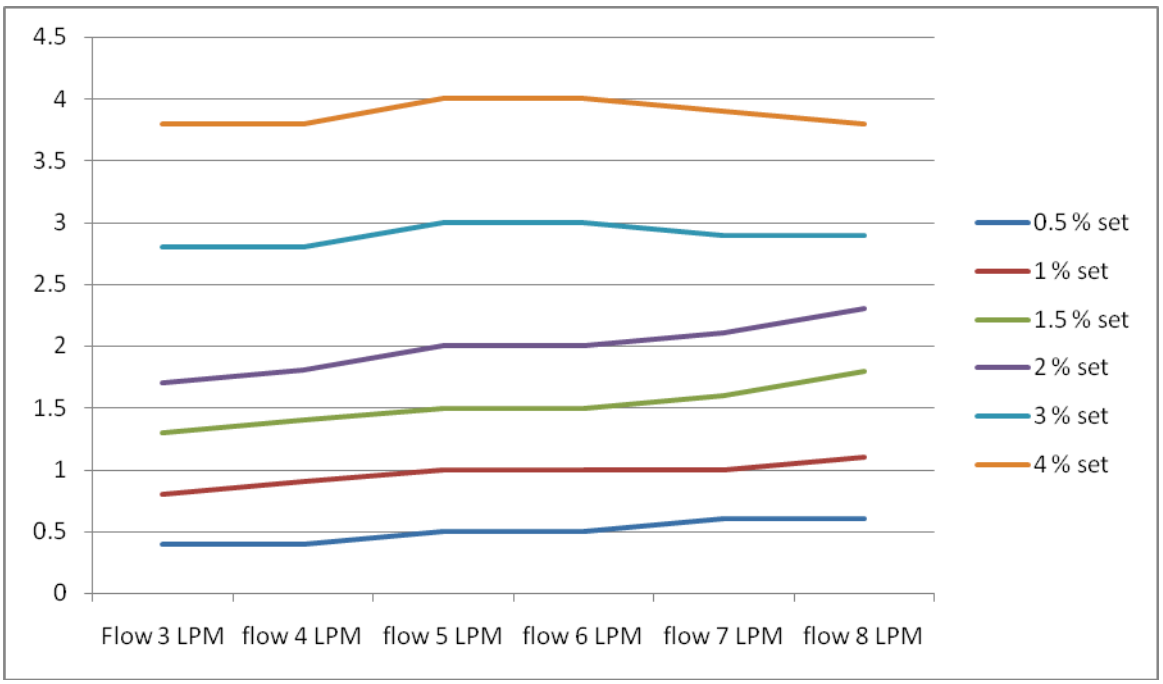
Vaporizer performance

The clinical performance of the OES draw-over vaporizer is affected by the following conditions:-
(1) Flow rate – the higher the flow rate the lower the output will become.
(2) Time – vaporizer output will drop with time.
(3) Temperature – the output will increase and decrease with temperature increase and decrease from the calibrated temperature.
(4) Anaesthetic agent level – high outputs will be reduced with low agent level.

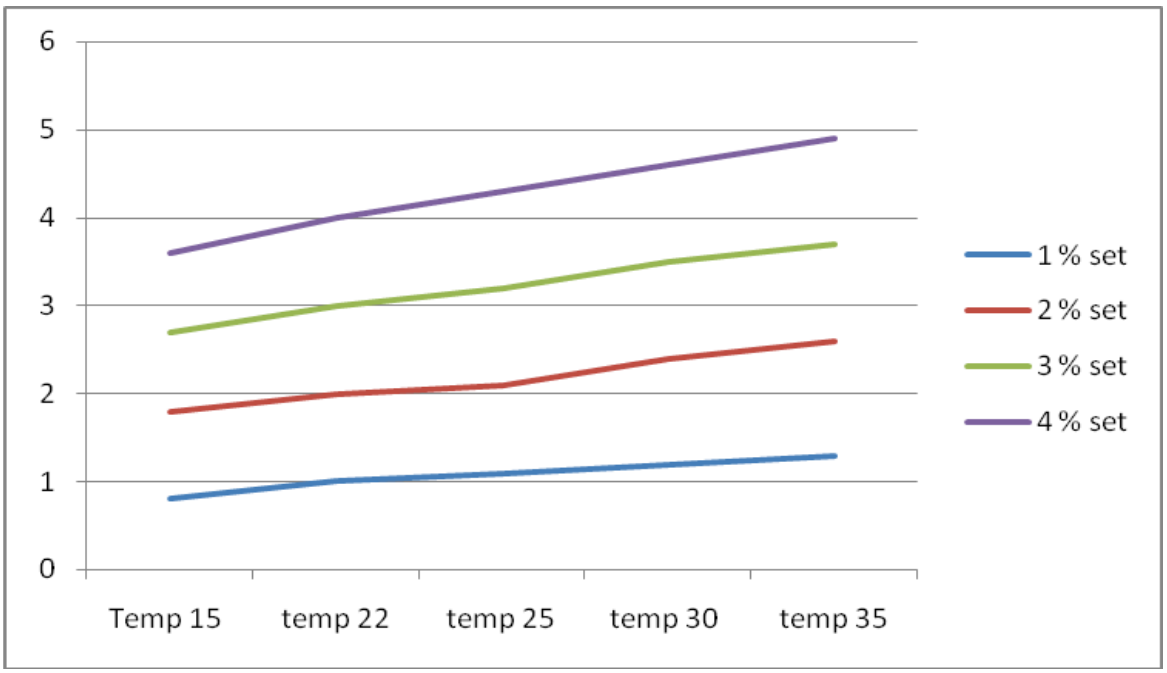
Vaporizer Performance graphs



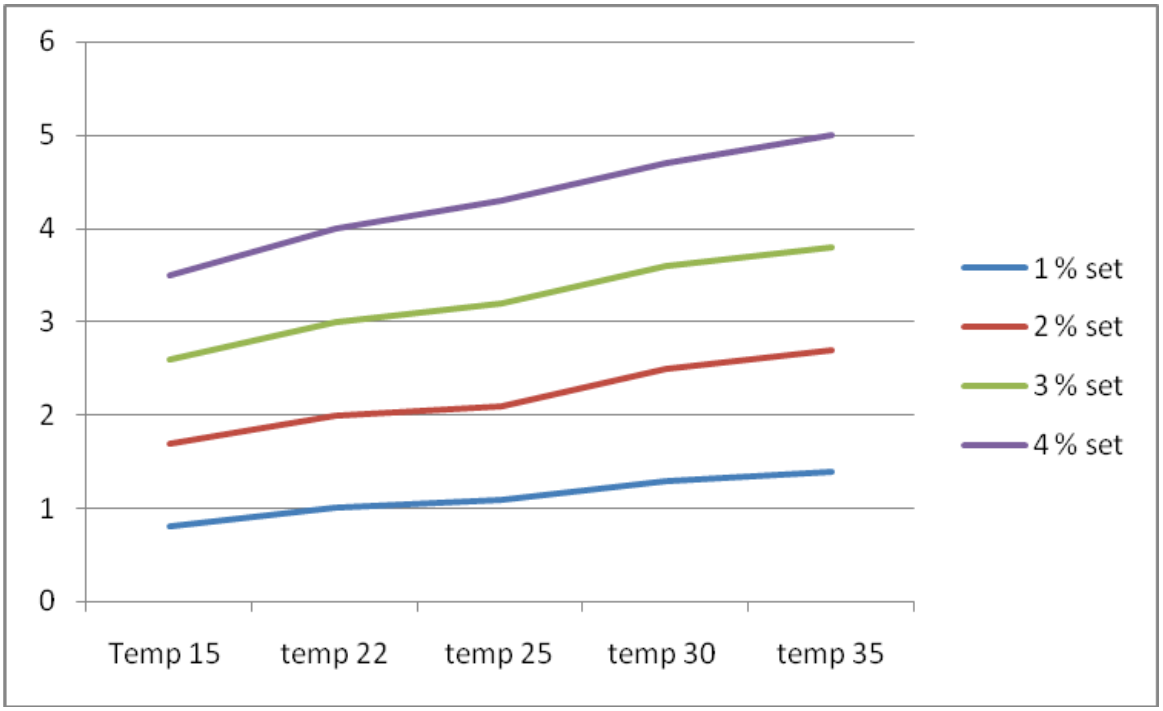
Vaporizer performance against flow rate for Isoflurane draw over vaporizer



Vaporizer performance against flow rate for Halothane draw over vaporizer



Typical Isoflurane Vaporizer performance against temperature



Typical Halothane Vaporizer performance against temperature

Pre-use checks

The vaporizer is an integral part of the UAM and requires pre-use checks in conjunction with the anaesthesia machine.

Refer to the UAM Manual for pre-use check information.

Prior to use the draw-over vaporizer and the anaesthesia machine to which it is attached must be inspected and checked to ensure correct and safe function. An incorrectly functioning vaporizer / anaesthetic 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 OES Medical Ltd.

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

Pre- use checks – Draw-over Vaporizer

Attention should be paid to the following:-

(1) Inspect for signs of physical damage.
(2) Ensure that the control knob turns smoothly.
(3) Fill to the maximum level with the correct anaesthetic agent.
(4) Check that the filler knob and drain screw are tight.
(5) Check vaporizer output – note that an approximate check can be achieved by looking at the oxygen monitor drop in output when the vaporizer is turned on.

Machine cleaning and sterilization

The external surfaces of the draw-over vaporizer 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 vaporizer but must be rinsed thoroughly with water prior to drying.

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

Transportation

Drain the vaporizer of anaesthetic agent and dry with a 10 litre flow of air for 2 hours prior to shipment or complete UAM transportation.

User maintenance

User maintenance is restricted to: -

(1) Checking the vaporizer output concentration –this is achieved by turning on the oxygen flow to 6 litres per minute, waiting for the Oxygen analyser to stabilise, then turning on the vaporizer to 4 % - the oxygen concentration should reduce by the vaporizer set value – in this case 4 % Additional checks can be performed at the other dial settings. Alternatively a Riken agent analyser can be connected to the UAM and the output check more accurately.

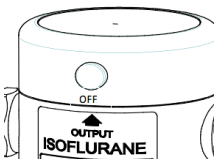
(2) Emptying Halothane vaporizers on a regular basis to prevent Thymol build up – this must be performed every 3 months or sooner if the Halothane becomes discoloured.

(3) Loosening the control knob if it becomes stiff due to thymol – over time the Thymol can coat moving parts making the control knob hard to Rotate. To clean the vaporizer :-

- (a) It must be removed from the UAM
- (b) Drained of the old Halothane.
- (c) Refilled with fresh halothane.
- (d) Block the outlets with rubber bungs.
- (e) Turn the vaporizer upside down.
- (f) Turn the vaporizer on and off until the knob is no longer stiff
- (g) Turn the vaporizer the right way up and allow most of the agent to drain back into the chamber.
- (h) Remove the rubber bungs – preferably in a fume cupboard - do not do in a confined space.
- (i) Drain the Halothane.
- (j) Purge the vaporizer with 6 litres of Oxygen for 2 hours.
- (k) Reconnect to the UAM.
- (l) Refill with anaesthetic agent.
- (m) Check vaporizer calibration as shown in (1)

(4) Cleaning of the vaporizer surfaces with a damp cloth using mild detergents and mild antiseptics only.

Device classification and labelling

IEC Symbol denoting type B applied part		On/off switch	
Refer to instruction manual		Operating instructions (this user manual)	
Classification according to the degree of protection against ingress of dust and water.	IPX0	Date of Manufacture	
		Manufacturer	

Environmental conditions:

Temperature:	Operating, 15 – 35 deg 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 Draw over vaporizer is not suitable for use within an MRI environment
CE 0120	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.

Disposal at the end of useful life	Do not dispose of this vaporizer or components in landfill. Follow your hospital, local state and federal regulations. The vaporizer may be returned, at the customers expense, to OES Medical for safe disposal. EC Territories: Follow the requirements of Directive 2002/96/EC.
Disposal of used breathing circuit components.	Follow advice above.
Disposal of Packaging	The packaging for the OES draw over vaporizer can be recycled or may be returned to OES for disposal

Ordering information

Refer to Gradian Health for ordering information on the draw-over vaporizer on the UAM.

User notes