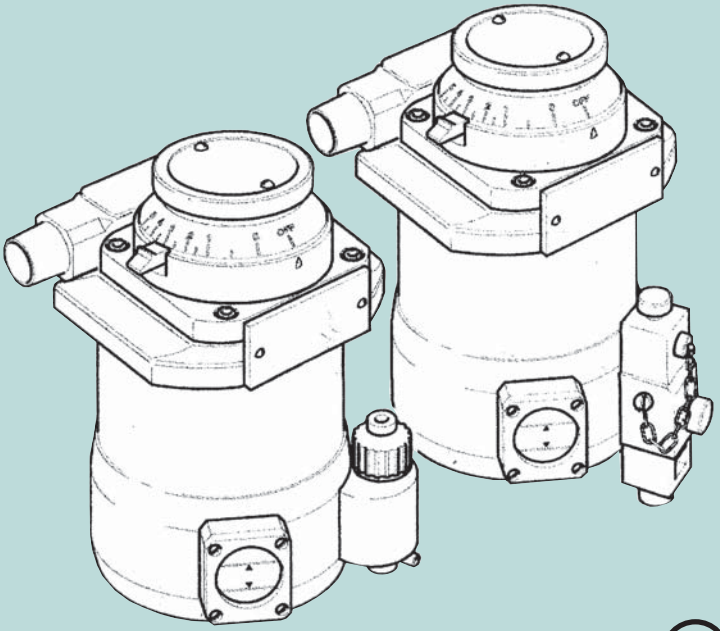
NEW CONTINUOUS FLOW VAPORISERS



CE 0086

OPERATOR MANUAL

O&M New Issue 2

CONTENTS

OPERATING INSTRUCTIONS

1. General

1.1 Warnings & Cautions

1. A number of Warnings  and Cautions  are used throughout this manual. These draw attention to possible hazards and adverse conditions which may occur if the information and instructions provided are not strictly observed. Warnings are used to draw attention to a condition which can endanger either the patient or the operator.

   Cautions are used to draw attention to a condition which can result in damage to the equipment.

   Special attention must be made to each Warning and Caution as it appears in the manual.

2. The vaporiser is designed for use with one anaesthetic agent/drug only, which is that named on the vaporiser. Incorrect dosage may result if the wrong drug is used in the vaporiser. National and International standards are provided for by the Keyed Filler version of this vaporiser.

3. During use, frequently check that the liquid level is between the minimum and maximum marks on the sight glass level indicator. Refill the vaporiser before the liquid level reaches the minimum mark (▼) in the level.

4. The vaporiser must NEVER be modified, dismantled, calibrated or serviced by unauthorised personnel. The vaporiser MUST be serviced at an approved Service Centre. (See the rear cover of this manual for your nearest approved Service Centre). Failure to comply with these instructions will invalidate the manufacturers product warranty.

5. The vaporiser MUST be connected so that the flow of gas to the patient is as indicated by the arrows on the device.

   The delivered concentration will be incorrect if the flow is reversed.

6. The vaporiser has a relatively high resistance and must not be incorporated in a breathing system downstream of the common gas outlet.

7. Before use, ALL connections must be checked for leaks and functional tests MUST be performed as described in the anaesthetic machine User Manual.

8. **This vaporiser should not be used on a anaesthesia machine that allows more than (1) vaporiser to be fitted/attached at any one time.**

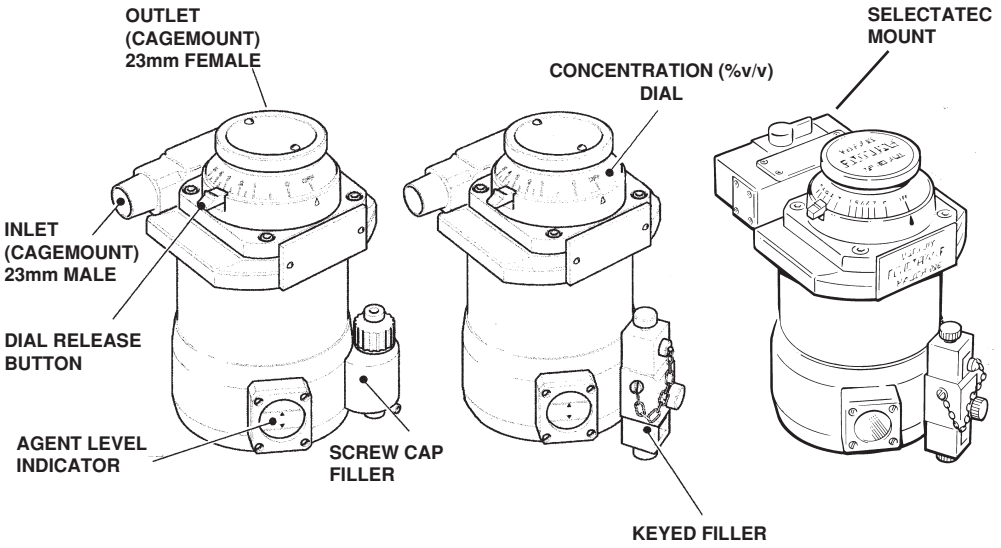
1.2 Description

WARNING: This manual and all its associated documentation must be studied thoroughly before any attempt is made to install, operate or maintain any part of the vaporiser. Failure to do so may result in patient injury.

The vaporiser is designed for “out of circuit” use in continuous flow techniques of inhalation anaesthesia.

The vaporiser is temperature and flow compensated so that its output remains relatively constant despite cooling due to vaporisation and variations in inlet flow.

Every vaporiser is labelled to show the name of the anaesthetic agent for which it is designed and calibrated.



2. Installation

WARNING: Keep the vaporiser upright at all time. Do not carry the vaporiser by holding the dial control.

WARNING: To help minimise cross - contamination of anaesthetic agents, only one vaporiser should be fitted to an anaesthetic machine at any one time.

The vaporiser must always be mounted between the gas flow (fresh gas supply) metering unit and the patient breathing circuit and upstream of any absorber or humidifier.

Check the integrity of the fittings to ensure that they are leak tight. If in doubt, seek advise from the manufacturer of the equipment to which the vaporiser is attached.

2.1 Mounting the Vaporiser

2.1.1 Cagemount

Cagemount vaporisers are equipped with 23 mm male (Inlet) and female (Outlet) tapered ports. There are two M6 threaded holes at the rear of the vaporiser which are utilised to secure the vaporiser on to the backbar of the anaesthesia machine using appropriate M6 screws. Spacers may be needed to ensure the vaporiser lines up with the fresh gas In / Out connections.

1. Lightly smear the tapers with oxygen - safe grease such as “Krytox”
2. Push the fresh gas connectors (23mm male In and 23mm female Out) onto their appropriate mating tapers. There should be no need to use force other than physical pressure to ensure a leak free connection.

WARNING: Before use, ALL connections must be checked for leaks and functional tests MUST be performed as described in the anaesthetic machine User Manual.

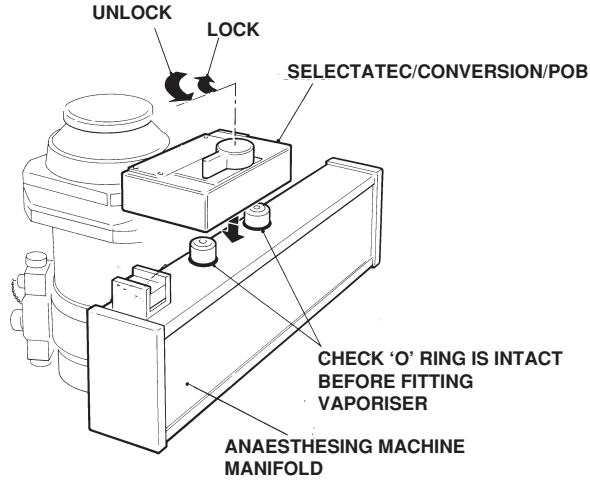
WARNING: It is recommended that only one vaporiser is mounted to the anaesthetic machine at any one time, thus assisting with the prevention of cross - contamination of anaesthetic agents.

2.1.2 Selectatec

Selectatec Systems are designed to allow the change over of Selectatec vaporisers by simply lifting off one vaporiser and replacing it with another.

WARNING: To avoid potential leaks, before mounting on the Selectatec Manifold / backbar check that the manifold port valve “O” rings are intact and that there is no foreign matter around the mating surfaces.

1. Mount the vaporiser on the manifold and lock on by turning the locking knob clockwise.
2. Check the integrity of the fittings to ensure that they are leak tight etc. If in doubt advice should be sought from the manufacturer of the equipment to which the vaporiser is being attached.



3. Operating instructions

WARNING: Keep the vaporiser upright at all times.

WARNING: Do not carry the vaporiser by the control dial.

WARNING: Handle the vaporiser with care.

3.1 Turning the Vaporiser "ON"

To turn the vaporiser "ON" , depress the control dial release button.

The "0" graduation indicates the position above which vapour is delivered, but, to avoid inadvertent delivery of small concentrations the control dial should be turned "OFF" when the vaporiser is not in use.

4. Filling and Draining

4.1 General

WARNING: Do not fill the vaporiser with any liquid or anaesthetic agent other than the one specified on the Front Label. The vaporiser is designed for that agent only. Any other agent than that specified can prove to be dangerous to a patient.

WARNING: Do not fill vaporisers unless the Control Dial is in the "OFF" position.

WARNING: Do not turn the Control Dial "ON" during filling or attempt to fill beyond the "Full" mark.

WARNING: Do not drain the agent into a container other than a properly marked container.

Periodically check the agent level. The vaporiser should be refilled at appropriate intervals. The vaporiser will function satisfactorily as long as there is agent visible in the sight glass.

The vaporiser should be filled and used in a upright position. Small deviations from the upright position will not affect the output or the safety of the vaporiser, but because the agent depth is shallow in relation to the diameter of the vaporising chamber more frequent checks of the agent levels should be carried out in order to avoid obtaining a misleading impression of the amount of agent in the vaporiser.

It is good practice when the liquid level is low, to drain the vaporiser of residual anaesthetic agent. This will help preserve agent purity by removing oxidised impurities, accumulated contaminants and stabilisers. This small amount of liquid should be carefully discarded.

At intervals, ideally not exceeding two weeks and when the agent level is low, the vaporiser should be drained into a properly marked container and the liquid discarded. Less frequent intervals can be used when the anaesthetic agent does not contain additives or stabilising agents.

4.2 Screw Cap Filler

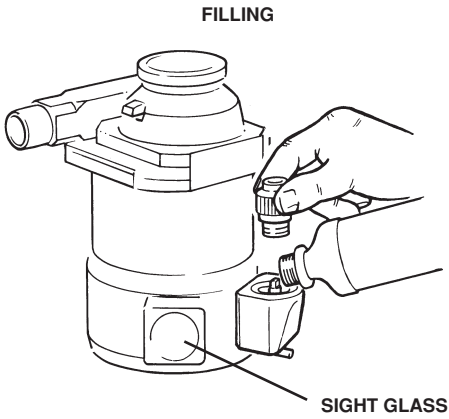
To Fill: Control Dial should be in “OFF” position. Remove filler cap by turning counter clockwise. Be sure drain plug is closed.

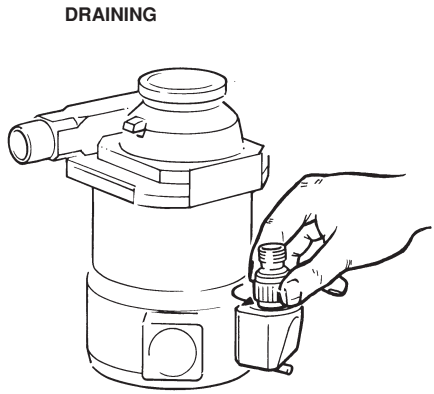
Verify liquid agent is same as specified on label at front of vaporiser. Pour agent slowly into opening. Observe proper agent level through sight glass mounted at front of vaporiser.

If the vaporiser is dry the level will fall slightly as the wicks absorb agent.

Replace cap by turning clockwise. Cap should be tight to prevent leaks.

To Drain: Control Dial should be in “OFF” position. Remove filler cap to reveal drain plug. Place a suitable container beneath the drain outlet, unscrew the drain plug, do not remove. When all liquid has been drained tighten the drain plug and replace the filler cap.





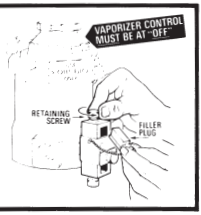
“Screw Cap Filler”

4.3 Keyed Filler

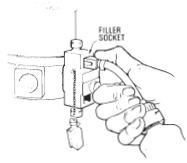
TO FILL

1 Remove cap and seal from anaesthetic bottle: Check anaesthetic bottle neck is not chipped or damaged. Match Keyed Bottle Adaptor To Keyed Bottle Collar, and screw together until airtight. The bottle is then ready for filling Vaporizer.

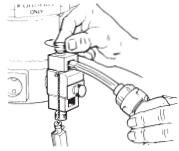
2 Ensure that the vaporizer control is set in the 'OFF' position. Turn top retaining screw on Vaporizer Filler unit counter-clockwise and withdraw Filler Plug.
Note: Turn screw slowly if vaporizer is pressurised.



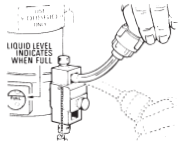
3 Grasp the Keyed Bottle Adaptor, and bottle, by the plastic tubing with the thumb on top of Adaptor at the keyway — with the two holes DOWNWARDS for filling. Fit into the Filler Socket normally sealed by the Filler Plug.
ONLY the correct Adaptor will fit into this matching Filler Socket. Take care to bend tube slightly, so bottle is below inlet level to prevent spillage.



4 After insertion, turn the retaining screw clockwise and tighten to seal Filler Adaptor in the Filler Socket.



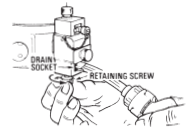
5 Raise bottle above level of Filler Socket, but avoid kinking tube. A steady stream of air bubbles should emerge from the inner tube within 2 seconds. If this does not occur perform procedures for clearing air locks.



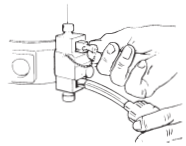
6 When vaporizer is filled to the 'full' level, lower the bottle. Remove Bottle Adaptor. If any excess liquid drains from the Filler Socket, allow this to escape completely before inserting and tightening Filler Plug. (BE SURE to replace and tighten plug or gas will escape through Filler). The Vaporizer is then ready for use.

TO DRAIN

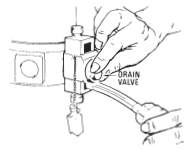
1 Insert the Bottle Adaptor in Drain (lower) Socket, with the two holes UP, and tighten retaining screw.
ONLY the correct Adaptor will fit into the matching Drain Socket.



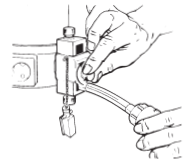
2 To let air vent from bottle and draining to occur, remove Filler Plug. Hold bottle slightly downward without kinking tube.



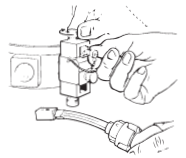
3 Open Drain Valve on front counter-clockwise and Vaporizer will drain.



4 At completion of draining close Drain Valve (clockwise). If draining process stops see 'Procedures for clearing air locks'.



5 Remove the bottle and replace the Filler Plug in the Filler Socket. Tighten retaining screw (clockwise).



PROCEDURE FOR CLEARING AIR LOCKS

Filling:

(a) Wait until air bubbles clear and slightly lower bottle (but keeping liquid level above filler socket or

(b) Gently lower and raise bottle several times or

(c) Lower and remove bottle adaptor and repeat from step 3 or

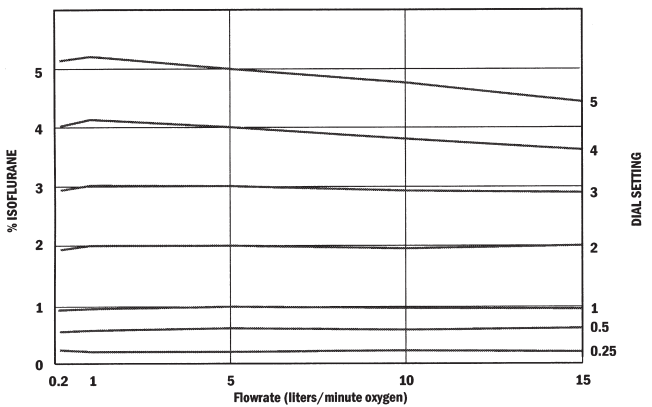
(d) Slide conical liquid deflector on inner tube away from cap to cover slide hole and repeat from step 3. Deflector must be repositioned correctly between cap and side hole immediately above side hole for draining.

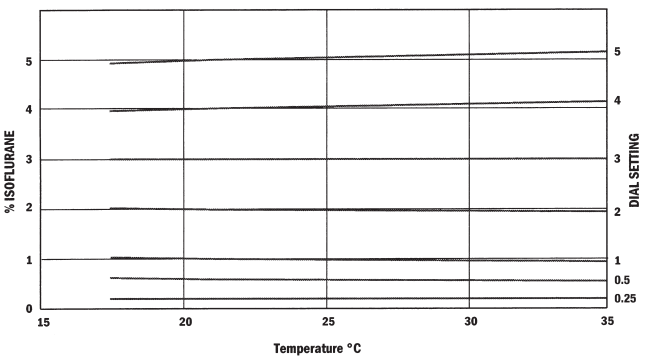
Draining:

Check conical liquid deflector is correctly positioned and reposition if necessary.

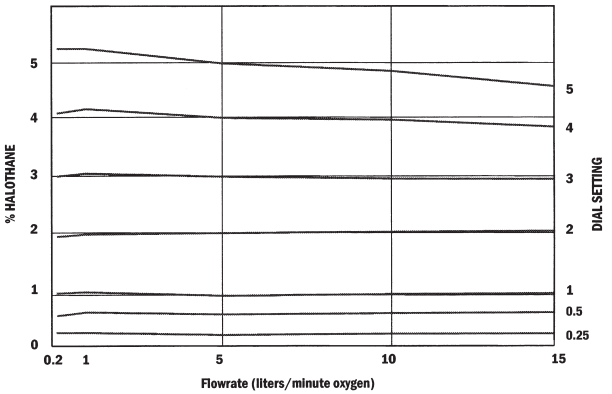
Performance Curves

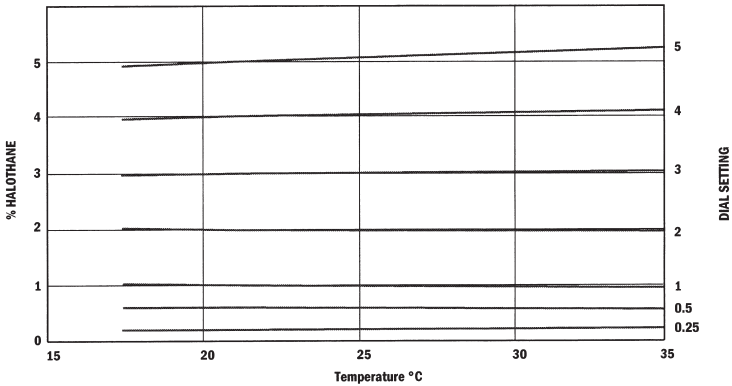
Isoflurane





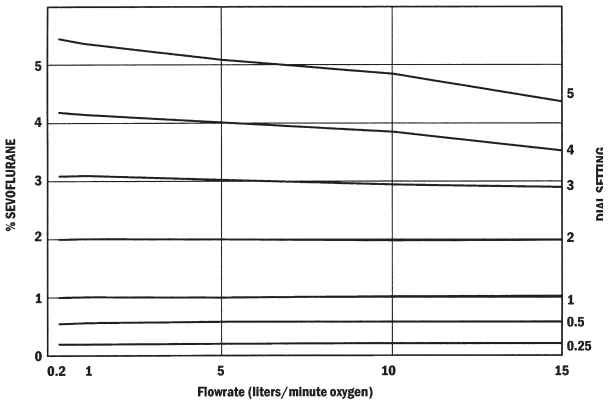
Halothane



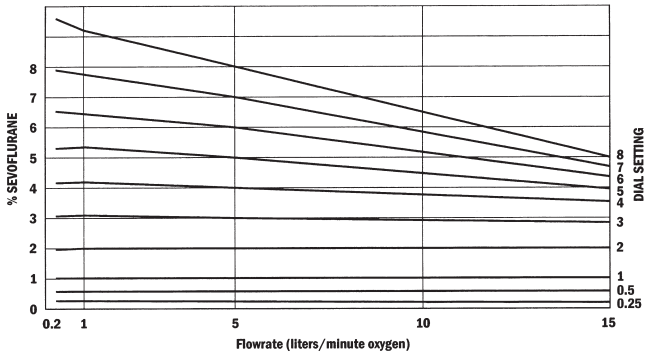


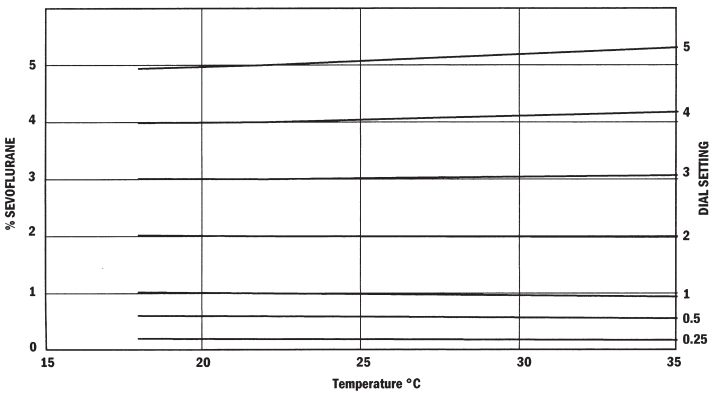
Performance Curves

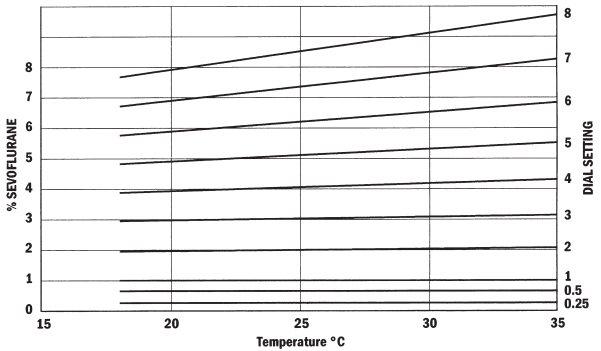
Sevoflurane 5%



Sevoflurane 8%







GENERAL PERFORMANCE

PRESSURE

Effects on Vaporiser

Vaporisers are graduated in v/v percentage at 760 mmHg. If the ambient pressure changes the v/v % will change so that at an ambient pressure P mmHg the delivered percentage (v/v) :-

$$D = \% \times \frac{760}{P}$$ where % is the nominal setting of the vaporiser.

Clinical Interpretation

It is generally accepted that the depth of anaesthesia depends on the inspired partial pressure of agent not the concentration by volume of the agent.

To obtain a consistent depth of anaesthesia when gross changes of barometric pressure occur it is necessary to change the v / v concentration in inverse proportion to the barometric pressure.

The vaporiser automatically does this and for practical clinical purposes the effects of the barometric pressure can be ignored.

BACK PRESSURE STEADY

Effects on Vaporiser

Low and Moderate pressures:

The vaporiser cannot distinguish between pressures at the outlet due to barometric pressure and pressures in excess of barometric due to steady back pressures applied by downstream components. Equation 1 therefore applies with term P now being absolute at the outlet (i.e. barometric pressure plus back pressure) Steady back pressure reduces the v / v percentage.

High pressures:

Pressures in excess of approximately 400mm Hg should not be imposed on the vaporiser since these may overcome the loads imposed by internal thrust springs.

Clinical Interpretation

low and moderate pressures:

Currently it is unlikely that the steady back pressure imposed by commonly used downstream components (other than some ventilators) will exceed 30 mm Hg at commonly used flowrates. Back pressure as high as this would reduce the delivered v / v percentage (at 760 mm Hg barometric pressure) to -

Equation 2 $\frac{760}{790}$ (= 0.96)

of what otherwise would be expected. Under normal clinical circumstances effects of this magnitude can be ignored.

Some ventilators impose higher steady back pressures of perhaps 100 mm Hg producing more significant depression of the v / v concentration. The increased patient uptake of agent with improved ventilation can often mitigate these effects so as to obviate the need to compensate for the increased back pressure at the vaporiser.

High Back Pressure:

Pressure in excess of 400 mm Hg could conceivably occur during procedures similar to bronchoscopy or because of occlusion of downstream tubing or piping or for other reasons. These effects on v / v percentage cannot be precisely predicated but the most likely effected will be reductions in concentration (or small increases).

BACK PRESSURE FLUCTUATING

Effects on Vaporiser

Fluctuating back pressures may be imposed on the vaporiser by downstream components, and assisted or controlled ventilation to the patient. These can affect the vaporiser and increase the concentration by intermittently altering the pressures and hence the flow distribution within the vaporisers. The greatest effects are observed at combinations of very low flowrate and low dial setting with large and rapid pressure fluctuations and become progressively less important as the dial setting and flowrate increase and the magnitude and rate of cycling of the pressure fluctuations decrease.

The vaporiser is designed to comply with specifications laid-down in current anaesthetic machine standards such as A.N.S.I. standard Z -79.8 - 1979.

Clinical Interpretation

In clinical use the vaporisers are considered unaffected by the fluctuating back pressures which would occur under all normal clinically encountered conditions appertaining to human anaesthesia.

CARRIER GAS COMPOSITION

Small effects can occur when the carrier gas composition is changed from oxygen to air or nitrous oxide/oxygen mixtures. As a general rule variation of output with carrier gas composition can be considered of negligible clinical significance since the effects, if any, are normally less than 10% of setting. Where changes occur the usual effect is that the output is slightly depressed when nitrous oxide is employed compared to the output when Oxygen is the carrier gas.

The presence of nitrous oxide reduces the required inspired concentration of volatile agent and this mitigates this small depression in output from the vaporiser

OTHER VARIABLES

Ambient temperature, input flowrate and duration of use can effect delivered concentration, particularly when the vaporisers are used at extremes of the usual clinical range.

The valve design and temperature compensation systems of the vaporisers reduces the effect to levels when under most clinical conditions their effect on vaporiser performance is clinically insignificant. The nominal performance data sheet should be consulted for further details.

CHECKING CALIBRATION

The clinical adequacy and reliability of the vaporisers have been demonstrated by the most stringent proof of all - that of continued widespread satisfactory use throughout the world over many years involving hundreds of millions of successful administrations.

The performance of most continuous Flow Vaporisers which are in clinical use is monitored by observing patient signs and consumption of anaesthetic agents. Some users may, however wish to employ analysers to determine whether any abnormalities of performance have developed either as a routine procedure or as part of an investigation.

In order to achieve the reliability and consistency standards of the Vaporiser the manufacturer use closely specified test conditions, test methods and detailed protocol in conjunction with training, experience and quality auditing systems. Because of this the full program necessary to ensure that a vaporiser complies with the manufacturers standards cannot be practicably carried out in a field situation.

The point below should be considered when any measurements are being carried out on vaporisers to determine whether any abnormalities of performance have developed.

1) In order to predict the concentration the vaporiser can be expected to deliver the detailed nominal performance data, and the preceding comments should be taken into account.
2) The method of test should not be such that it bears little relation to normal conditions of clinical use.
3) Any sampling techniques should be such as to ensure:
    a) The sample is fully representative of the vaporiser output which may not be a homogeneous mixture at the vaporiser outlet.
    b) Absorption of agent by any connecting tubing is negligible.
4) If a number of vaporisers are being examined at the same time the probability of them all being consistently in error is so remote as to be negligible and the cause of any apparent error will lie in the test method employed.
5) Consistent and reproducible analytical techniques should be used.
6) If unexpected results are obtained it is a wise precaution to repeat the observations since the vaporiser may be more reliable than the techniques used to observe its performance.
7) If unexpected results occur it is also worthwhile checking for other sources of error (e.g. flowmeter, leaks, absorption by adjacent components etc.).
8) Full account should be taken of any extraneous effects on the analyser which may arise from changes in carrier gas composition.

ANALYTICAL TECHNIQUES

For field checking of the state of calibration many techniques are available ranging from observing patient response to simple gravimetric or volumetric techniques to sophisticated analysers. The manufacturer would not currently recommend any one technique in preference to others. but account must be taken of errors of use and calibration of analysers and their reliability must be realistically considered.

The calibration method given below can be used where specialist equipment is not available and where a secondary check on analysers is desired. The characteristics of the vaporiser are such that if the vaporiser is satisfactory at one dial setting it should be satisfactory at all graduation settings.

1) Check that the vaporiser has been filled and has been at an ambient temperature of 22° C for at least three hours.
2) With the vaporiser securely mounted open drain until no more liquid will run out and close drain.

3) Check dial is turned off and carefully and quickly refill with a measured amount of agent without spilling (Use about 70 ml. Close drain securely)

4) Leave vaporiser at normally 22° C for about 1 hour to ensure temperature has stabilised.

5) Set flowrate to 5 litres/min 02.

6) Turn dial to 2%.

   Note time and check that flowrate is still 5 litres/min - readjust as appropriate.

7) Leave vaporiser at this setting for 30 minutes periodically checking flowrate. Turn vaporiser 'OFF' and turn 'off' oxygen.

8) Drain as in (2) and measure amount of liquid drained off.

The amount of liquid consumed in ml. should be in accordance with the table below.

Fluotec	13 1/2 ml
Enfluratec	15 1/2 ml
Isotec	15 1/2 ml

Appropriate measures to handle exhaust gases and spillage should be carried out.

It should be appreciated that the above check method is designed to be quick and easy under ordinary hospital conditions and that the method is somewhat imprecise. Nevertheless, it would be unusual for measured liquid consumption to vary from that given above by more than about 25 %

MAINTENANCE

WARNING

DO NOT MODIFY, TAMPER WITH OR DISASSEMBLE THE VAPORISER BECAUSE OF THE DANGER OF DAMAGING THE UNIT AND ALTERING THE ACCURACY OF GRADUATION.

Observation of the instructions given earlier, regular servicing, and normal professional vigilance is normally all that is required to maintain the vaporiser in a safe working condition.

SCHEDULE

Every two weeks: The vaporiser should be drained into an appropriately marked container when the agent level is low and agent discarded. less frequent intervals may be used when the anaesthetic agent does not contain additives or stabilising agent.

SERVICING

Annually: **Halothane**

Every three years: **Isoflurane / Sevoflurane**

This service includes:

1) Complete disassembly of components

2) Thorough cleaning

3) Inspection for damage and wear

4) Renewal of wicks, seals and damage, worn (or outdated) items.

5) Lubrication where necessary

6) Checks of the delivered vapour concentrations under closely defined conditions at different temperatures, and regraduation or adjustment where necessary

Cleaning

 **WARNING**

DO NOT PUT WATER OR ANY OTHER SOLVENT IN A VAPORISER. A VAPORISER SHOULD BE FILLED WITH THE SPECIFIED ANAESTHETIC AGENT ONLY.

The exterior of the vaporiser can be kept clean with a damp cloth. Never allow cleaning agents to accumulate in the filler, the gas inlet and outlet ports or around the control dial.

Contamination

If a wrong volatile agent is put into the vaporiser.

1) Drain and discard all liquid.
2) Set the dial to 'Max' and scavenge the vaporiser with 5 litres/min O2 until no trace of the contamination can be detected.
3) Allow two hours for the vaporiser temperature to stabilise before proceeding with CAUTION.

If in doubt check with the manufacturer.

If the contamination is not volatile (e.g. water), drain and return to approved Service Centre.

REPAIR

Repairs should only be carried out by the manufacturer's service representatives or agents.

WARRANTY

Such warranties are extended only with respect to the purchase of this product direct from the authorised dealers as new merchandise and are extended to the first buyer thereof, other than for the purpose of resale.

For a period of three (3) years (one (1) year for Halothane) from the date of original delivery to the first buyer or to buyer's order, this product is warranted against functional defects in materials and workmanship and to conform to the description of the product contained in the operation and Maintenance Manual and accompanying labels and inserts, provided that the same is operated under conditions of normal use, that regular periodic maintenance is performed and that replacements and repairs are made in accordance with the instructions provided.

The foregoing warranties shall not apply if the product has been repaired or serviced other than by the manufacturers authorised service facilities, or if the product has been subject to abuse, misuse, negligence or accident.

The manufacturer 's sole and exclusive obligation and the buyer's sole and exclusive remedy under the above warranties are limited to repairing or replacing, free of charge, at the manufacturer's option, a product which is confirmed as being defective by the manufacturer following the buyer's notification to the manufacturer in accordance with the instructions contained in the Servicing Section of the Operation and Maintenance Manual, not later than seven (7) days after the expiration date of the applicable warranty. The manufacture shall not be otherwise liable for any damages including but not limited to incidental damages, consequential damages or special damages.

There is no express or implied warranties which extend beyond the warranties herein above set forth. The manufacturer makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

DISTRIBUTOR