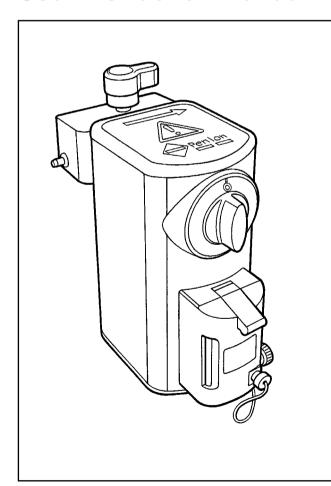


Sigma Delta Vaporizer User Instruction Manual



This manual contains calibration and service records for Sigma Delta Vaporizer, Serial No.

Keep this manual with the vaporizer at all times

Quality and Assurance in Anaesthesia

WARNING

Anaesthetic systems have the capability to deliver mixtures of gases and vapours to the patient which could cause injury or death unless controlled by a qualified anaesthetist.

There can be considerable variation in the effect of anaesthetic drugs on individual patients so that the setting and observation of control levels on the anaesthesia systems does not in itself ensure total patient safety.

Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist but are not true clinical monitors as the condition of the patient is also dependent on his respiration and the functioning of his cardio-vascular system.

IT IS ESSENTIAL THAT THESE **ELEMENTS ARE MONITORED** FREQUENTLY AND REGULARLY AND THAT ANY OBSERVATIONS ARE GIVEN **PRECEDENCE** OVER MACHINE CONTROL PARAMETERS IN JUDGING THE STATE OF Α CLINICAL PROCEDURE.

IMPORTANT

Servicing and Repairs

In order to ensure the full operational life of the Sigma Delta vaporizer, we recommend that a periodic service check should be performed by a Penlon trained engineer. This check comprises a vaporizer CALIBRATION CHECK and LEAK CHECK.

Note:

(a) The calibration check must be performed using a suitable agent analyser, e.g. a Riken refractometer or infrared analyser.
(b) The service check is part of the recommended pre-use check for your Anaesthesia System.

Should the calibration check show the unit to be outside the specified performance requirement (see section 11) then a service must be performed.

This may be done on site by:

- (a) A trained user.
- (b) An authorised Penlon agent.
- (c) A Penlon service engineer.

A calibration and service record section is provided to maintain a record of the vaporizer's performance.

For any enquiry regarding the service or repair of this vaporizer, contact the nearest accredited Penlon agent* or contact the Service Department at Penlon Limited.

*Agent's name and address:

Service and Repair Department Penlon Ltd Abingdon OX14 3PH

UK

Tel: +44 (0) 1235 547063 Fax: +44 (0) 1235 547062 E-mail: service@penlon.co.uk

Always give as much of the following information as possible:

- 1. Type of equipment
- 2. Product name
- Serial number
- 4. Approximate date of purchase
- Apparent fault

FOREWORD

This manual has been produced to provide authorised personnel with information on the function, routine performance and maintenance checks, applicable to the Penlon Sigma Delta vaporizer.

Information contained in the manual is correct at the date of publication. The policy of Penlon Limited is one of continued improvement to its products. Because of this policy Penlon Limited reserves the right to make any changes, which may affect instructions in this manual, without giving prior notice.

Personnel must make themselves familiar with the contents of this manual before using the vaporizer.

Terminology

This manual complies with ISO 4135, Anaesthetic Apparatus Terminology.

The following additional definitions should be noted:

Vol.% - shortened form of volumetric percentage.

The commonly used method of expressing vapour concentrations so that they can be compared with concentrations of true gases.

100 Vol.% is equivalent to 100% partial pressure in a mixture.

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USER RESPONSIBILITY

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

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

The user must accept responsibility for any malfunction which results from non-compliance with the servicing requirements detailed in section 8.1.

Worn, broken, d i s t o r t e d, contaminated or missing components must be replaced immediately. Should such a repair become necessary it is recommended that a request for service advice is made to the nearest Penlon service centre.

This vaporizer and any of its constituent parts must be repaired only in accordance with written instructions issued by Penlon Limited, and must not be altered or modified in any way without the written approval of Penlon Limited. The user of this equipment shall have the responsibility for any

malfunction which results from improper use, maintenance, repair, damage or alteration by anyone other than Penlon Limited or its appointed agents.

This vaporizer must only be supplied to, and used by, suitably qualified medical practitioners. In the USA and Canada: Caution: Federal Law restricts this device to sale by or on the order of a physician.

Statements in this manual preceded by the following words are of special significance.

WARNING - means there is a possibility of personal injury to yourself or others.

CAUTION - means there is a possibility of damage to the instrument or other property.

NOTE - indicates points of particular interest for more efficient and convenient operation.

The reader must take particular notice of the warnings, cautions. and notes printed throughout the manual.

The following Warnings and Cautions must be read and understood before using this vaporizer

WARNINGS General Information

- 1. The user must read and be familiar with the contents of this instruction manual before using the vaporizer
- 2. The vaporizer is designed for use only with the specific anaesthetic agent named on the filler block (and further indicated by colour coded labelling). Misdosage may occur if the vaporizer is filled with the wrong drug. Agent specific (keyed) filler devices are provided on certain models to meet national and international standards. (See section 9 for standards).
- 3. The pharmacopoeia name of the drug is used on the label according to BP, USP, or Ph EUR.

 The user is responsible for confirming that any trade name of a drug is equivalent to the registered name.

- 4 This vaporizer must not he modified or disassembled by an unauthorised person. It should be regularly serviced by a Penlonauthorised service agent. trained technician engineer and by no other person. (see section 8)
- 5. Vaporizers may malfunction if exposed to excessively high temperatures, e.g. by storage above a radiator. This may affect the

calibration.

Maximum storage temperature: 50°C (122°F)

Minimum storage temperature: -20°C (-5°F)

Operating temperature range: 15 to 35^OC (58 to 95^OF)

Before use, function test any vaporizer that has been subjected to temperatures near the upper/lower limits given above.

Filling and draining the vaporizer

- 6. The filler system must be maintained in accordance with the instructions given in the User Maintenance section.
- The vaporizer must be filled only by suitably skilled and trained personnel.
- 8. Anaesthetic drugs are poisonous and there is evidence that there is a health hazard to personnel due to prolonged inhalation of trace concentration in the atmosphere. Care must be taken to avoid spillage anaesthetic drugs when filling or draining vaporizers.
- 9. The vaporizer control must be in the 0 (zero) position during the filling or draining process. Overfilling and/or spilling may occur if the control is not in the 0 (zero) position. Provided the control is in the 0 (zero) position, gas mav continue to be

from

anaesthetic machine to

delivered

the patient during the filling procedure.

- The vaporizer must be upright during filling to minimise the risk of overfilling.
- 11. Dο not use the anaesthetic agent bottle to fill the vaporizer if the bottle is cracked or the filler connector is loose or broken. This mav result in overfilling or contaminated agent entering the vaporizer.
- 12. If a new bottle of anaesthetic agent is to be used, check that the tamper-evident shrink band is undamaged.
- 13. Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.
- 14. Do not tamper with the filling system valve. This may cause a vapour and fresh gas leak.

 Anaesthesia system monitors and patient monitors are very desirable aids for the

the

anaesthetist but are not true clinical monitors as the condition of the patient is also dependent on his respiration and the functioning of his cardiovascular system.

15. Do not overfill.

A vaporizer that has been overfilled must be withdrawn from use.

Contact the Service Department at Penlon for advice.

- 16. Anaesthetic drugs must treated as pharmaceutical product. Liquid should never be drained from a vaporizer into an open container and then reused. Contamination is likely. Always dispose of such drained liauid as hazardous chemical.
- 17. After filling or draining:

Pour Fill (Screw cap) filler - always refit and retighten the filler cap.

Key (agent specific) filler models - always tighten the filler control. In addition, on key filler systems, always refit the key filler plug and tighten the clamp screw before using the vaporizer. The vaporizer will leak if this is not done.

Quik-Fil models - remove the bottle and refit the filler block cap before using the vaporizer.

Delivered concentrations are inaccurate while the filler port is open.

Before using the vaporizer

- 18. Do not use the vaporizer if the agent level is not visible in the sight glass or the level is outside of the Max - Min indicator.
- 19. vaporizer transported when filled with liquid drug the control must be in the 0 (zero) position during transport and a period of at least ten minutes in a secured upright position must elapse before connection to an anaesthetic breathing system.

Movement during transport can result in over-dosage unless time is allowed for drainage of liquid to the normal

position.

If a vaporizer has been transported with the control in the open position it must be flushed at 5 L/min for ten minutes before clinical use on a patient

20. The vaporizer must not be tipped over or inverted.

If the vaporizer has been tipped over or inverted it must be set to maximum output and flushed at 5 L/min for ten minutes before clinical use on a patient.

- 21. The vaporizer must be securely fixed and in an upright position before connection to a patient. There is a danger of overdosage if sudden inadvertent movement occurs during use.
- 22. Anaesthetic machine designs are constantly evolving, and new models may differ dimensionally from existing equipment. It is the user's responsibility to ensure that the configuration of the anaesthetic machine allows correct installation of the vaporizer.

There must be sufficient clearance between the

selectatec manifold and the rear frame panelling of the machine to allow the vaporizer connector block to seal correctly on the manifold.

 Before use test all joints for gas tightness, and perform back bar function tests as detailed in the anaesthetic machine user manual.

Using the vaporizer

- 24. Check the liquid level frequently when using the vaporizer and maintain the level between the min. and max. marks.
 - The vaporizer control must be in the zero (0) position during the filling process (see warning 7).
- 25. Vaporizer outputs are sensitive to barometric pressure.

A correction factor may be necessary when assessing the output using an analyser, for example at high altitude.

Barometric pressure effects are not usually of clinical importance. (see section 7.3).

- 26. The vaporizer is a flow direction-sensitive apparatus and the direction of gas flow towards the patient must be as indicated by the arrow on the top label.

 Reversal of flow may cause inaccuracies of delivered concentration.
- 27. The vaporizer must not be used downstream of the common gas outlet.
- 28. As stated in section 2, the vaporizer is of relatively high resistance and must not be incorporated within a breathing system.
- 29. Expired anaesthetic vapours should be extracted from the theatre by an anaesthetic gas scavenging system. (see section 9 for standards.)
- 30. Do not use the vaporizer with flammable anaesthetics.

User Maintenance

31. Do not pour water, or any cleaning solutions into the vaporizer.

CAUTIONS

- Anaesthetic machine and workstation standards require that means be provided to ensure that gas cannot pass through more than one vaporizer chamber.
 - Vaporizers without interlock devices or systems must only be used on machines which only have one vaporizer mounting station.

2. PURPOSE

The Sigma Delta vaporizer is designed for incorporation in the fresh gas supply system of continuous flow anaesthetic machines, directly connected between the flowmeter unit and the common gas outlet of the machine.

The vaporizer is unsuitable for use within a breathing system 'in circuit' because of the relatively high internal resistance.

Its purpose is the provision of accurate concentrations of anaesthetic drugs in the fresh gas supply, in accordance with the setting of the control dial, when the fresh gas supply flow is between 0.2 and 15 litres/min.

Refer to section 7 (Performance Characteristics), which shows the extent of modifications to the control calibration.

3. DESCRIPTION

3.1 Operating Principles

Each model is uniquely designed and tested for use only with the drug specified on the filler block.

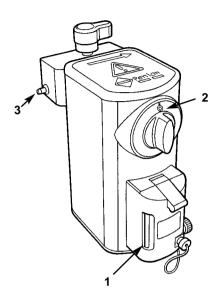
The vaporizer contains a chamber, the base of which holds the anaesthetic agent in liquid form. A wick ensures that the upper part of the chamber is filled with the saturated vapour of the agent. The wick has a patented construction.

The concentration of saturated vapour is many times higher than those used clinically and the function of the concentration control is to proportion the flow of the carrier gas through a bypass passage and through the vapour chamber so that the desired dilution is produced.

In the zero position the bypass remains open but the vaporizing chamber is shut off completely from the gas flow to the patient.

A temperature-compensating valve is situated in the bypass, arranged to operate so that as the vapour pressure varies with temperature. the dilution ratio produced by the control valve is varied to compensate. and maintain a constant output concentration.

The vaporizer has a liquid level indicator, with maximum and minimum level marks.



- 1. Liquid level indicator
- 2. Control dial 0 (zero) position
- 3. Interlock bolt

3.2 Controls

The vaporizer has a single, forward facing calibrated control to regulate the vapour concentration delivered. The dial is locked at zero when not in use. To set a concentration level, push the dial assembly in and rotate anti-clockwise.

Align the required concentration graduation with the mark at the top of the bezel.

On returning the dial to zero, the dial assembly will automatically spring outwards into the locked 'off' position.

Interlock Models

When the vaporizer is mounted on the anaesthetic machine back bar with other interlock vaporizers, initial operation of the concentration control dial activates the interlock system ensuring that only one of the vaporizers con be in use at any time

The interlock deactivates as soon as the control dial is returned to the locked out zero position.

NOTE

The Sigma Delta Selectatec Compatible Vaporizer with Interlock can be used on a Selectatec Universal Series Manifold back bar in conjunction with other types of Selectatec compatible vaporizers (i.e. from other manufacturers) fitted with the interlock function.

WARNING

The Drager compatible model with interlock must only be used with other Drager-compatible interlock vaporizers, to maintain the integrity of the interlock system.

4. SPECIFICATION

4.1 Physical Dimensions

	Width	Height	Depth
Cagemount Selectatec Compatible with Interlock	133 120	219 242	158 190
Drager 'plug in' Compatible	100	242 242	190

Dimensions given above are in millimetres

NOTE

For Screw Cap Filler models depth, subtract 11 mm from the depth dimensions given above.

4.2 Weight

Approximate weight: 4.8 kg.

4.3 Capacity

Volume at MAX mark 250 ml (nominal) Volume at MIN mark 35 ml (nominal)

NOTE

After draining, approximately 60 ± 10 ml of liquid is retained by the wick.

4.4 Filling System

Key Filler (Agent Specific)

Used with corresponding agent specific filler adaptor, see section 10, Ordering Information.

Pour Fill (Screw Top)

Quik Fil - Sevoflurane only

Use with corresponding agent specific bottle.

SPECIFICATION

4.5 Control Dial Scale

The control dial is marked as follows: From 0 to 2% vol, by intervals of 0.2% vol From 2 to maximum, by intervals of 0.5% vol

The control dial is marked '0' at zero

4.6 Patents

The Sigma Delta is protected by UK and foreign patents.

4.7 Temperature Range

Operating Temperature Range 15 to 35°C (58 to 95°F)
Storage Temperature Range -20 to 50°C (-5 to 122°F)
Storage in Transit (up to 7 days) -40 to 60°C (-40 to 149°F)

4.8 Flow Range

Operating Flow Range 0.2 to 15 litres/min.

See section 7.4.1 for output accuracies at extreme conditions.

4.9 Pressure Range

Operating Pressure Range 0 to 5 kPa (0 to 0.7 psi)
Maximum Manifold Pressure 38 kPa (5.5 psi)
Maximum Test Pressure 38 kPa (5.5 psi)

5.1 Key Filler System

WARNING

The vaporizer must be either secured to the anaesthetic machine or free standing on a level table so that in either case it is upright during the filling process.

Overfilling may occur if the vaporizer is tipped during the filling process.

WARNING

The vaporizer concentration control must be in the 0 (zero) position during the filling process. Provided this is done, gas may continue to be delivered from the anaesthetic machine to a patient during the filling process.

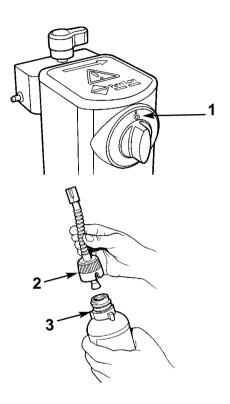
WARNING

Check that the drug name on the vaporizer and the supply bottle are the same before commencing the filling process, and ensure that the bottle is fitted with a keyed collar.

Filling the Vaporizer

This system is manufactured in compliance with ISO 5360.

- Check that the vaporizer concentration control (1) is in the 0 (zero) position as illustrated.
- 2. Attach the keyed filler adaptor (2) to the bottle (3).



NOTE

Penlon supply a complete range of agent specific filler adaptors, see section 10.

3. Tighten the adaptor to ensure an airtight joint, which must be maintained throughout the filling operation.

WARNING

Failure to observe this instruction may result in overfilling.

- 4. Loosen the clamp screw (4). Remove the plug (5).
- Insert the keyed end of the bottle adaptor (2) fully into the vaporizer receiver.

Only the correct keyed-adaptor can enter the receiver.

Tighten the clamp screw (4) to secure the adaptor.

- 6. Raise the bottle above the filler (see arrow on the illustration).
- Open the filler control (6) lift upwards.
 Allow the liquid to flow into the vaporizer until the upper mark is reached on the filler block (7).

WARNING DO NOT OVERFILL.

A vaporizer that has been overfilled must be withdrawn from use.

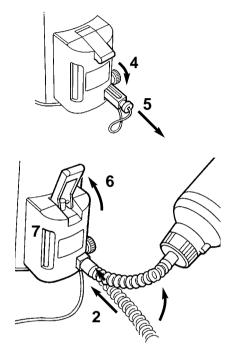
If the vaporizer has been inadvertently overfilled, excess liquid agent will spill from the drain hole in the keyed slot in the filler block. DO NOT REUSE THIS AGENT Allow all the excess liquid to drain from the vaporizer before inserting the plug (5).

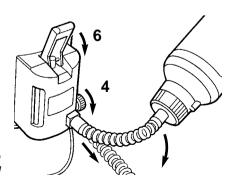
- 8. Close the filler control (6).
- Lower the bottle below the level of the filler and allow the liquid in the bottle adaptor to flow back into the bottle.

Loosen the clamp screw (4), remove the bottle adaptor from the receiver.

NOTE

A small amount of liquid is always likely to spill when the bottle adaptor is removed from the receiver.



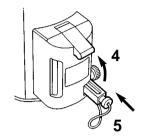


10. Insert the plug (5) and tighten the clamp screw (4).

WARNING

For the vaporizer to function correctly it is important to insert the sealing plug (5) fully, until it stops, before clamping it into position with the clamp screw (4) after filling is completed.

If this is not done, the possibility exists that agent may leak from the vaporizer or the vaporizer may not pressurise properly, giving reduced concentration output and gas flow to the patient.



Draining the Vaporizer

CAUTION

To reduce atmospheric pollution in the operating room, it is recommended that vaporizer drainage should be performed in a fume cupboard or under an extractor hood.

WARNING

The vaporizer must be either secured to the anaesthetic machine or free standing on a level table so that in either case it is upright during the draining process.

. WARNING

The vaporizer concentration control must be in the 0 (zero) position during the draining process

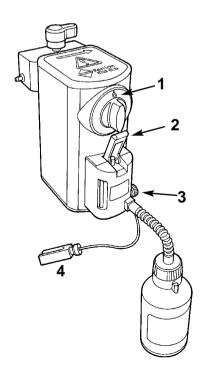
- Check that the vaporizer concentration control (1) is in the 0 (zero) position.
- Follow steps 2 to 5 of the procedure for filling the vaporizer (see above), but keep the bottle below the filler.
- Raise the the filler control

 (2) and allow the liquid to
 run into the bottle until the
 flow ceases.
- Close the filler control (2), loosen the clamp screw (3), and reinsert the plug (4). Tighten the clamp screw (3).

WARNING

Anaesthetic drugs must be treated as a pharmaceutical product. Liquid should never be drained from a vaporizer into an open container and reused.

Contamination is likely. Always dispose of such drained liquid as a hazardous chemical.



5.2 Screw Cap Filling System (Pour Fill)

CAUTION

To minimise atmospheric pollution in the operating room, fill the vaporizer in a fume cupboard or under an extractor hood.

WARNING

The vaporizer must be either secured to the anaesthetic machine or free standing on a level table so that in either case it is upright during the filling process.

Overfilling may occur if the vaporizer is tipped during the filling process.

WARNING

The vaporizer control must be in the 0 (zero) position during the filling process.

Provided this is done, gas may continue to be delivered from the anaesthetic machine during the filling process.

WARNING

Check the drug name on the vaporizer and the supply bottle before commencing the filling process.

Filling the Vaporizer

If the vaporizer is empty, check that the control screw (1) is fully tightened before filling

- Check that the vaporizer concentration control (2) is in the 0 (zero) position as illustrated.
- 2. Unscrew the filler cap (3).

 Remove the bottle cap and fill the vaporizer slowly and carefully, stopping to check the liquid level occasionally. Stop filling when the upper mark is reached on the filler block

WARNING

DO NOT OVERFILL.

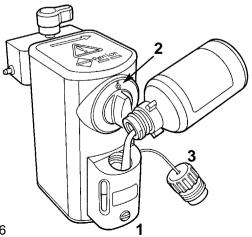
A vaporizer that has been overfilled must be withdrawn from use.

 Replace the filler cap after a visual check that the seal is in position on the cap.
 Tighten finger tight only. DO NOT use a wrench.

WARNING

Do not operate the vaporizer if the filler cap is not secured in position.

Incorrect concentration may be delivered to the patient and pollution may result.



Draining the Vaporizer

CAUTION

To minimise atmospheric pollution in the operating room, perform vaporizer drainage in a fume cupboard or under an extractor hood.

WARNING

The vaporizer must be either secured to the anaesthetic machine or free standing on a level table, so that in either case it is upright during the draining process.

WARNING

The vaporizer concentration control must be in the 0 (zero) position during the draining process.

- Check that the vaporizer concentration control (1) is in the 0 (zero) position, as illustrated.
- Unscrew the filler cap (2).
- Place a bottle marked with the drug name on the vaporizer under the drain tube in the base of the filler block and undo the drain screw (3) at least three full turns.

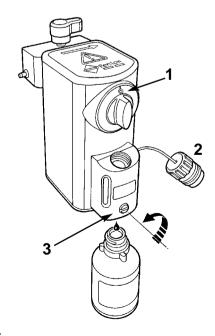
WARNING

Anaesthetic drugs must be treated as a pharmaceutical product. Liquid should never be drained from a vaporizer into an open container and reused.
Contamination is likely. Always
dispose of such drained liquid
as a hazardous chemical.

 Allow the liquid to run into the bottle until the flow ceases
 Close the drain screw (3).

CAUTION

Always close the drain screw firmly before replacing the filler cap on the vaporizer.



5.3 Quik-Fil System

WARNINGS

- Do not use the anaesthetic agent bottle to fill the vaporizer if the bottle is cracked or the filler connector is loose or broken. This may result in overfilling or contaminated agent entering the vaporizer.
- If a new bottle of anaesthetic agent is to be used, check that the tamper-evident shrink band is undamaged.
- 3. Firmly secure the vaporizer in a vertical position before filling.
- Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.
- Do not tamper with the filling system valve. This may cause a vapour and fresh gas leak.
- 6. The filler system must be maintained in accordance with the instructions given

in the User Maintenance section.

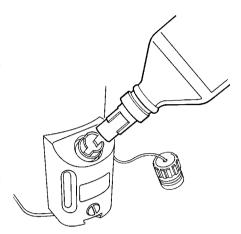
- 7. The vaporizer must be filled only by suitably skilled and trained personnel.
- After filling, remove the bottle and refit the filler block cap before using the vaporizer.
- Do not use the vaporizer if the agent level is not visible in the sight glass or the level is outside of the Max - Min indicators.

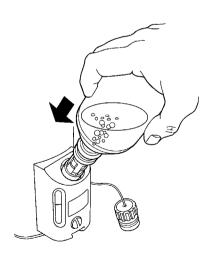
Quik-Fil System - Filling the Vaporizer

- Check that the vaporizer concentration control is in the off ('0') position.
- Remove the yellow protective cap from the anaesthetic agent bottle filler, checking that the bottle and filler mechanism are not damaged.
- Remove the vaporizer filler block cap and insert the bottle nozzle into the filler block, Rotate the bottle to align the bottle filler keys with the slots in the filler block.
- Note the liquid level in the vaporizer sight glass and press the agent bottle firmly into the vaporizer filler against the spring valve assembly.
 - Allow the liquid to flow into the vaporizer until the maximum level mark is reached, paying continuous attention to the level in the sight glass and the air return bubbles flowing into the bottle.
- Release the bottle when the vaporizer is full and the continuous stream of bubbles ceases.
- Withdraw the bottle from the vaporizer filler and replace the vaporizer filler block cap and the yellow cap on the agent bottle.

WARNING

The filler cap must be refitted before using the vaporizer.





Quik-Fil System - Draining the vaporizer

WARNING

To avoid spillage, check that the bottle to be used for draining has sufficient capacity for the volume of liquid to be drained.

- Remove the yellow protective cap from an empty sevoflurane bottle. Insert the bottle nozzle into the drain funnel. Rotate the bottle to align the bottle filler keys with the index
 - bottle filler keys with the index slots in the drain funnel, and screw the drain funnel onto the empty bottle.
- 2. Remove the vaporizer filler block cap.
- Fully insert the drain funnel into the keyed drain slot, and unscrew the drain plug. Continue to drain the vaporizer until empty.
 - Close the drain plug and tighten, and withdraw the drain funnel.
- Unscrew the drain funnel from the bottle and refit the bottle cap and the vaporizer filler block cap.

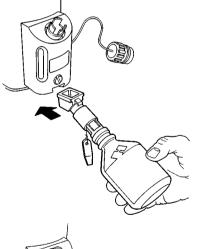
WARNING

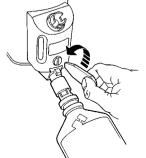
The filler cap must be refitted before using the vaporizer.

WARNING

Do not reuse the agent drained from the vaporizer. Treat as a hazardous chemical.







6.1 Gas Port Transit Seals

All vaporizers

Inlet and outlet ports are sealed for delivery transit. Ensure that these seals are removed from the vaporizer before installation on an anaesthetic machine.

6.2 Selectatec Compatible Models - with Interlock

These vaporizers are designed for installation on a Selectatec Universal Series type manifold back bar and can also be used on the Type 3 Manifold.

NOTE

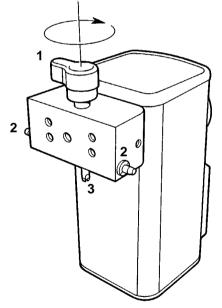
When installing two vaporizers only on a three station manifold, the centre station **must** be occupied by one of the vaporizers.

WARNING

Anaesthetic machine designs are constantly evolving, and new models may differ dimensionally from existing equipment

It is the user's responsibility to ensure that the configuration of the anaesthetic machine allows correct installation of the vaporizer.

There must be sufficient clearance between the Selectatec manifold



- Locking Lever
- 2. Interlock Bolts
 - B. Back Bar Manifold Locking Shaft

and the rear panelling/frame of the machine to allow the vaporizer connector block to seal correctly on the manifold.

Installation

- 1. Carefully offer the vaporizer up to the manifold.
- Align the gas connection ports with the valve capsule on the manifold. (The capsule is referred to as the valve 'cartridge' in some user literature)
- Carefully lower the vaporizer onto the manifold, and recheck that the gas ports are correctly engaged with the valve capsule cartridges on the manifold.
- Lock into position by pushing the locking lever downwards and rotating clockwise through 90°.

CAUTION

To prevent damage to the locking shaft, recheck that the gas ports are correctly engaged with the valve capsule cartridges on the vaporizer before tightening the locking lever.

Pre-use Checks

Observe the WARNING below and carry out the check list procedure given in section 6.7.

WARNING

Test all joints for gas tightness before using the anaesthetic machine.

The locking lever MUST be in the locked position before the vaporizer is operated.

Removal

NOTE

The concentration control dials of all the vaporizers linked by the interlock system must be turned to zero before removing the vaporizer from the manifold.

To remove the vaporizer, rotate the locking lever 90⁰ anti-clockwise and carefully lift the unit vertically until clear of the back bar.

6.3 Cagemount (23 mm) Taper Models

CAUTION

It is recommended that this type of vaporizer should only be used on machines with a single vaporizer mounting station.

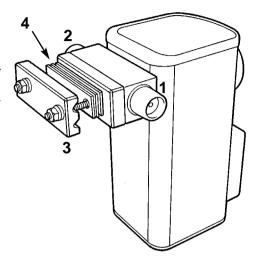
Vaporizers fitted with cagemount tapers have the male taper (1) (Inlet port) on the left and the female taper (2) on the right (viewing the front of the vaporizer).

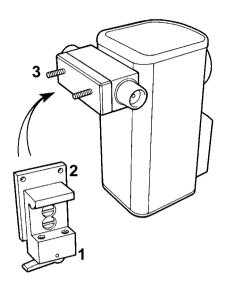
Two M6 studs with nuts, washers and a clamp plate (3) are provided to fix the vaporizer to the back of the anaesthetic machine, or Modura claw assembly.

Taper Connectors

It is essential that the taper cone joints should be engaged axially and not sideways loaded.

- Adjust the distance from the back bar to the taper joint by adding or removing the shims (4).
- The cone joints should be lightly smeared with an oxygen compatible lubricant such as Fomblin.
- 3. Engage the taper joints by applying axial pressure.
- 4. Tighten the fixing nuts (3).





Installation on Modura Rail WARNING

The vaporizer must not be tipped or inverted during installation. If the vaporizer has been tipped or inverted, it must be set to maximum and flushed at 5 L/min for ten minutes. Check for stable output before clinical use.

- Remove the M6 nuts and washers, the clamp plate and the shims from the vaporizer.
- Fit the Modura claw (1) to the backplate (2), using the two M6 screws.
- Fit the Modura claw backplate assembly to the studs (3) on the rear of the vaporizer, and secure with the M6 nuts and washers.

4. Attach the vaporizer to the Modura rail on the anaesthetic machine and secure in place by moving the lever into its 'locked on' position.

Pre-use Check

Observe the WARNING below and carry out the check list procedure given in section 6.7.

WARNING

Test the joints for gas tightness before using the machine.

6.4 Penion Off-line Mounting System

A vaporizer with cagemount tapers may be fitted with a Penlon clip, Part No. 58090, in place of the back bar clamp. The vaporizer may then be fitted to a Penlon off-line block, (use Penlon Part No. 52280 for the Mk.2 and Part No, 52270 for the Mk.3 system).

The flexible hoses attached to the block are connected to the inlet and outlet of the vaporizer.

It is recommended that detachable cagemount connectors are retained with Safety Clip (Part Number 52275), to prevent inadvertent disconnection,

WARNING

Test the joints for gas tightness before using the machine.

6.5 Drager 'Plug-in' Compatible (interlock)

Installation

NOTE

When installing two vaporizers only on a three station manifold, the centre station **must** be occupied by one of the vaporizers.

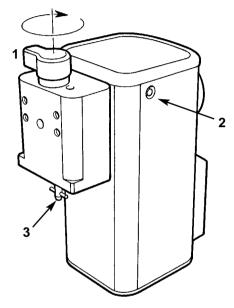
- 1. Carefully offer the vaporizer up to the manifold.
- 2. Align the gas connection ports with the valve capsule on the manifold. (The capsule is referred to as the valve 'cartridge' in some user literature)
- Carefully lower the vaporizer onto the manifold, and recheck that the gas ports are correctly engaged with the valve capsule cartridges on the manifold.
- 4. Lock into position by pushing the locking lever (1) downwards and rotating clockwise through approximately 1000.

Pre-use Checks

Observe the WARNINGS below and carry out the check list procedure given in section 6.7.

WARNING

To prevent damage to the locking shaft (3), and to ensure that the gas connection ports are correctly engaged, check



- 1. Locking Lever
- 2. Interlock Bolts
- B. Back Bar Manifold Locking Shaft

that the vaporizer is firmly positioned on the manifold before tightening the locking lever.

The locking lever MUST be in the locked position before the vaporizer is used.

Removing the Vaporizer

Rotate the locking lever fully anticlockwise and carefully lift the vaporizer from the manifold.

6.6 North American Drager Compatible (Interlock)

Installation

- Check that each gas port (1) is fitted with the correct O seal, as supplied by the anaesthetic machine manufacturer (Drager part No. M21929).
- Carefully offer the vaporizer up to the manifold.
- To secure the vaporizer to the manifold, use two M4 x 30 screws (DIN 912 Property Class 8.8) and fan-type lock washers, as supplied with the machine.

From the rear of the anaesthetic machine fit the two screws through the manifold block holes (2), and screw into the threaded holes in the vaporizer.

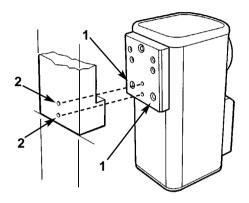
Tighten the screws to a torque of 2.7 to 3.0 Nm.

Pre-use Checks

Carry out the check list procedure given in section 6.7.

Removing the Vaporizer

- Support the vaporizer, and remove the securing screws.
- Detach the vaporizer from the manifold.
- 3. Check that the O-seals are retained in the gas ports (1).



6.7 Pre-Use Check List

In addition to the pre-use warnings listed for different models in sections 6.2 to 6.6 the following check list procedure must be carried out on ALL vaporizers before use.

- Check that the vaporizer concentration control is in the 0 (zero) position.
- Check that the liquid level is between the upper and lower marks on the filler block.
- On key fill (agent specific filler) models, check that the filler plug is fully inserted and that the clamp screw is fully tightened.
- On pour fill (screw cap filler) models, check that the filler cap is securely closed.
- 5. Perform a back bar manifold leak test as detailed in the relevant anaesthetic machine user instruction manual.

WARNING

Anaesthetic machine designs are constantly evolving and new models may differ dimensionally from existing equipment.

It is the user's responsibility to ensure that the configuration of the anaesthetic machine allows correct installation of the vaporizer.

7. PERFORMANCE CHARACTERISTICS

NOTE

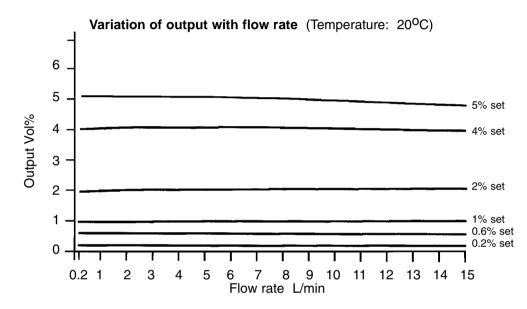
Concentration output figures quoted and shown graphically in this section were compiled from average test results from a number of vaporizers.

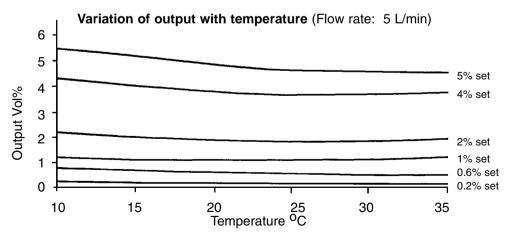
The output from individual units may vary from these average figures.

PERFORMANCE CHARACTERISTICS

7.1 Performance Graphs

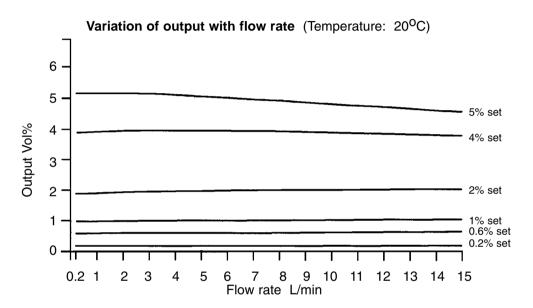
7.1.1 Halothane

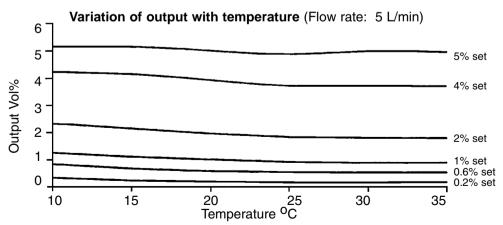




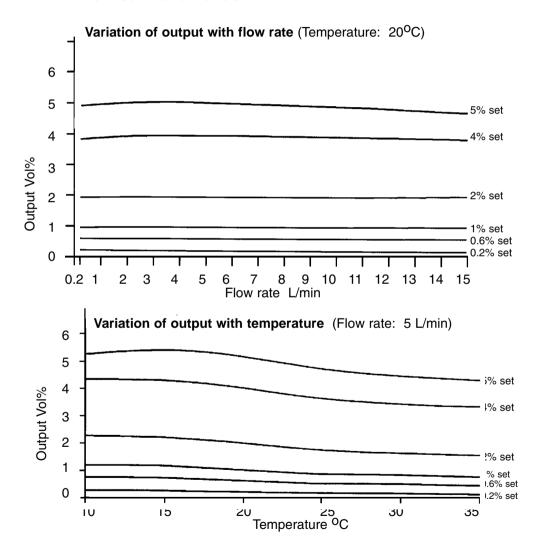
PERFORMANCE CHARACTERISTICS

7.1.2 Enflurane Models

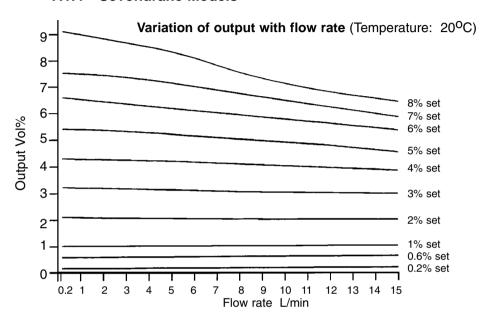


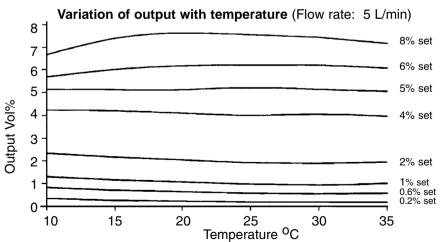


7.1.3 Isoflurane Models



7.1.4 Sevoflurane Models





7.2 Temperature Compensation

Temperature compensation is provided by the operation of a variable resistance valve in the bypass passage. The design provides compensation for the full range of user temperatures. If the vaporizer is used in extreme temperatures, (outside those shown in section 4.7) outputs may be lower or higher than indicated by the concentration control.

NOTE

The temperature compensator reacts relatively slowly to room temperature changes.

If the temperature around the vaporizer is suddenly changed (e.g. by wheeling an anaesthetic machine from a cool store into theatre), 1 to 2 hours minimum should be allowed for it to equalise with the ambient temperature before use.

7.3 Pressure Effects7.3.1 Ambient Pressure

Ambient pressure effects are not normally of clinical significance but the following rules apply:

The control is graduated in units of vol% at 101.3 kPa (14.7 psi). At any other pressure the true output will be modified according to the equation:

$$C = S\% \times 101.3$$

P is absolute pressure in kPa.

C is delivered concentration vol%, S% is the set value.

Changes in barometric pressure can be ignored clinically because they affect the vaporization in the vaporizer and the absorption of vapour through the lungs in the some way. They must be corrected for when checking outputs with an analyser.

NOTE

Some analysers include automatic barometric pressure correction. Check the instructions provided with the analyser.

7.3.2 Back Pressure

Back pressures imposed on the vaporizer by ventilators or other parts of the anaesthetic apparatus are usually relatively small, but certain ventilators can impose steady back pressures of 10 to 15 kPa (100 to 150 cmH2O) which will produce a reduction of the output concentration.

7.3.3 Intermittent Back Pressure

Intermittent back pressure imposed on the vaporizer by a ventilator may result in some change in output. The effect is greatest at low settings of the control and low flow rates, and the Sigma Delta vaporizer is designed to comply with the tests laid down in various Standards in this respect (see section 9).

7.4 Summary of Performance Specifications

7.4.1 Factors Affecting Output Accuracy

The following conditions may affect the accuracy of the vaporizer.

Column A in the table shown below lists the design limits for normal use.

Column B lists extreme conditions, and, if necessary, indicates when the vaporizer may be used reliably only after reference to the sections of the manual indicated.

Under the conditions listed in column A, the maximum deviation from the set concentration is $\pm 20\%$ of scale reading or $\pm 5\%$ of the maximum graduation, whichever is greater.

	A (Normal Use)	B (Extreme Conditions)		
Gas composition	O2, Air + N2O mixture	Helium mixture, section 7.6		
Liquid level	Liquid visible between MIN and MAX marks	See section 1, WARNING 18		
Temperature	15 to 35 ^o C	10 to 15 ⁰ C and 35 to 40 ⁰ C, section 7.2		
Flow Rate	0.5 to 10 L/min	0.2 to 0.5 and 10 to 15 L/min Accuracy not affected.		
Altitude	Sea level to 2440 m (8000 ft)	Very high altitudes* or hyperbaric conditions*		
Intermittent back pressure Movement	As Standards listed in section 9 (a) Do not agitate during use	See section 1, WARNING 21		
Inversion or tipping	Do not tip or invert	Flush for 10 minutes at 5 L/min before use. See section 1, WARNING 20		

^{*}The combination of high altitude and high temperature may lead to loss of accuracy.

7.4.2. Resistance to Gas

Resistance to gas flow, measured at:

22^oC (72^oF) 101.3 kPa (1013 mbar, or 14.7 psi), Control position 0 (zero)

Flow Rate	Resistance
using Air	(cmH2O)
(L/min)	
1	1.8
2	3.4
4	8.0
8	20.3

Resistance varies from these nominal values at other control positions, with changes with temperature, and for each agent (e.g. the nominal value for Sevoflurane at 4 L/min (air) is 12 cmH₂O).

7.5 Effect of IPPV on Output

For 2 kPa IPPV at a flow rate of 2 L/min, output concentration will vary by up to 20%,

For 5 kPa IPPV at a flow rate of 8 L/min, output concentration will vary by up to 10%.

7.6 Effect of Gas Composition on Output

The vaporizer is calibrated with pure oxygen and the scale is therefore most accurate with this gas. The effect of other gases normally used in anaesthesia is as follows:

Nitrous oxide

Nitrous oxide, added to oxygen, will produce a decrease in output below the scale value. At a concentration of 70% nitrous oxide output may decrease by up to 15%.

Carbon dioxide

Carbon dioxide is not usually added in high concentrations and is usually limited to 5%. At this concentration the effect on vaporizer output is negligible.

Air

Air will reduce the output of the vaporizer below the scale values by a maximum of 5%.

Helium

Vaporizers will give low results on helium-enriched mixtures, and the use of an analyser is recommended if accurate concentrations are required when using this gas.

7.7 Output when Control is at 0 (zero)

Output vapour concentration when the control is at 0 (zero) is less than 0.03% vol., when tested in accordance with ASTM 1161-88.

7.8 Effect of Flush Valve Operation

Operating the flush valve on the anaesthetic machine will affect output concentration by less than ±20%.

Note that the vaporizer was tested to ISO 8835.1 / IEC 60601-2-13.

8. USER MAINTENANCE

CAUTION

Do not attempt to dismantle the vaporizer or make any adjustment to it which is outside the scope of the following instructions.

8.1 Servicing

NOTE

A label is fixed across the vaporizer body and top cover, bearing the words:

GENUINE PART. LABEL TAMPERING VOIDS WARRANTY.

When the bottom cover of the vaporizer is removed this label will be damaged beyond repair as permanent evidence of unauthorised servicing, repair or modification. If this label (or other labels) is missing, do not use the vaporizer until it has been serviced (see below).

The Sigma Delta must only be serviced at an authorised service centre or by Penlon-trained technicians in accordance with the following procedure.

 (a) The calibration should be checked periodically under controlled conditions (section 8.4) and leak tests performed.

Record the measured values in section 11.

- (b) Successive sets of figures should be compared to determine if performance is deteriorating. Should deterioration be detected, a service should be carried out to restore normal operation.
- (c) A major overhaul must be performed every ten years (Halothane models - 5 years) to maintain performance within the specification.
- (d) The Selectatec compatible vaporizer locking system should be inspected during the vaporizer calibration test, and if damage to the locking shaft is suspected, the device must be referred to a Penlon certified engineer,
- Interlock system vaporizers function test the interlock system during the vaporizer calibration test.
- (d) Quik-Fil system at regular intervals (3 monthly minimum, 6 monthly maximum), filling and draining must be checked under controlled conditions

NOTE

The user must accept responsibility for any malfunction which results from non-compliance with the above requirements.

USER MAINTENANCE

8.2 Cleaning and Sterilisation

WARNING

Do not pour water, or any cleaning solutions into the vaporizer.

The process of filling and emptying will clean the internal passageways of the vaporizer filler block satisfactorily.

The exterior of the vaporizer should be kept clean and dust free with a dry cloth, or, if necessary use proprietary cold sterilised wipes. Do not use water or other liquids.

8.3 Draining - Halothane Models

Because halothane contains a stabilising agent which is only slightly volatile (0.1% thymol), the

volatile (0.1% thymol), the vaporizer chamber should be drained

periodically of all liquid and the liquid disposed of as a hazardous chemical. If the vaporizer is not drained periodically, the stabilising agent will accumulate in the vaporizer and eventually cause low output.

There is some evidence that high levels of accumulated thymol can have clinically undesirable effects on the patient. (Ref. Rosenburg - Alila: Anaesthesia, 1984:38:581-583).

If the vaporizer is in regular use this draining operation should be performed weekly.

WARNING

Prolonged exposure of anaesthetic agents to light and gases may lead to a brown or yellow colouration.

Discoloured liquid and/or liquid drained from a vaporizer must not be used and should be disposed of as a hazardous chemical.

8.4 Checking Vaporizer Output

The output of the vaporizer should be checked periodically, either:

- (i) as part of the Penlon Service Contract (UK only)
- (ii) by a Penlon certified engineer
- (ill) by a suitably qualified hospital technician if agent analysis apparatus is available.

To be comparable with the master calibration, such tests must conform to the following.

- (a) The carrier gas should be oxygen.
- (b) The vaporizer must be filled, and fixed upright and stationary, at a temperature between 18 and 22°C (64 and 72°F) for at least 2 hours.

USER MAINTENANCE

- (c) A mixing chamber must be attached to the outlet of the vaporizer to ensure that a homogenous mixture is sampled.
 - This is particularly necessary at low gas flow rates.
- (d) The sampling system must be of non-absorbent material such as nylon. (Rubber, etc., absorbs vapour to a substantial extent.)
- (e) Flow rates, etc., must lie within the range covered by the master calibration charts.
- (f) The analysis apparatus must be of an approved type, e.g. а Riken refractometer. However, if the calibration check is undertaken by a hospital technician, it is permissible to use а commercially available agent analyser, but only if:
 - i) the analyser is calibrated to the manufacturer's specification and schedule
 - ii) output failures are confirmed by a Penlon certified engineer using a refractometer,
- g) Output values should be recorded in section 11.

 The vaporizer serial number and any comments must be written at the foot of each page.

8.5 Training Courses

A training course is available to engineers and hospital staff who wish to carry out routine maintenance on vaporizers.

The course covers:

- leak testing
- replacement of seals
- internal maintenance
- replacement of major subassemblies
- regulation of output

A manual describing this work is available to personnel who have undergone this course.

8.6 Returning the Vaporizer for Service or Repair

The vaporizer must be drained and allowed to dry out before packing. Always use the original packaging, to prevent damage during transit.

On key fill (agent specific filler) vaporizers, loosen the clamp screw and withdraw the plug (see section 5.1). This will prevent possible damage to the filler block seal.

9. REFERENCES

Standards

The Sigma Delta vaporizer has been designed in accordance with the following Standards.

(a) General

BS 4272, Part 3 1989, Sections 13, 14 ISO 5358, 1992, Sections 12/13/14 IEC 60601 - 2.13 ASTM F1 161, 1988, Section 12 CSA CAN3 Z168.3 M84, Section 12 DIN 13252, Sections 4.9 - 4.13, and 5.9 - 5.13

(b) Agent Specific (Keyed) Filling System

CSA CAN3Z 168.4 M83 DIN 13252, Sections 4.11 and 5.11 ISO 5360, 1993

Trademarks

Selectatec is a Datex Ohmeda trademark.

Modura is an S&W trademark.

10 ORDERING INFORMATION

A wide range of Halothane, Enflurane Isoflurane and Sevoflurane vaporizers are available

Various combinations of agent, concentration output, and connector block type. are available with either agent specific filler, screw cap, and Quik-Fil filler systems

For further information:

Contact your distributor, or Customer Service at Penlon Ltd.

UK:

Tel: 01235 547036 Fax: 01235 547023

E-mail: uksales@penlon.co.uk

International

Export: Tel: +44 1235 547001

Fax: + 44 1235 547021

E-mail: export@penlon.co.uk

Accessories

52275	Safety clip for cagemount tapers (Off-line system only)
53450	Agent Specific (Keyed) filler adaptor for halothane bottles (ICI, May and Baker, and Hoechst)
53451	Agent Specific (Keyed) filler adaptor for halothane bottles (Ohio, and Ayers)
53452	Agent Specific (Keyed) filler adaptor for enflurane bottles
53453	Agent Specific (Keyed) filler adaptor for isoflurane bottles
53454	Agent Specific (Keyed) filler adaptor for sevoflurane bottles

11.1 Service Policy

The Sigma Delta Vaporizer must be serviced according to the following system:

 The calibration should be checked periodically under controlled conditions and leak tests performed.

For further information, Penlon-trained engineers should refer to the relevant section in the the service manual.

The measured figures should be recorded in section 11.4 of this book.

At the completion of each Ten Year Overhaul (five year overhaul for Halothane models), a copy of the completed calibration records in section 11.4 must be faxed to Penlon Limited (Fax No: 44 1235 547062).

- By comparing several sets of successive figures, a trend in performance can be established and a service performed before the standard tolerance is exceeded.
- c) If the calibration check shows a departure from the standard performance or a trend towards predicted failure, the vaporizer must be serviced as described in the service manual.
- d) All vaporizers must be overhauled every ten years (Halothane models every five years) and certain items replaced even if the performance appears satisfactory.

This is a preventive maintenance requirement.

 e) Record repair and servicing work carried out on the vaporizer, in section 11.3 of this book.

11.2 Calibration Procedure using the Riken Analyser

The Riken Model 1F-18 is normally calibrated by the manufacturer for measuring up to 8% vol. Halothane, or up to 9% Sevoflurane, either in air or in oxygen.

Service checks on the vaporizer must be performed with oxygen if the vaporizer is checked on an anaesthetic machine.

Use air or oxygen if the vaporizer is checked in a test laboratory.

CAUTION

- A) It is essential that the gas used during service checks is recorded.
- B) The reference cell of the Riken must be purged with the appropriate gas before measurements are made.

Agents

The Riken gas analyser measures the refractive index of the gases and vapours and, although normally calibrated for measuring halothane, the instrument can also measure other vapours if an appropriate correction factor is applied.

To obtain the true concentration of gases other than halothane multiply the reading shown on the Riken analyser by the correction factors given below.

Carrier Gas

The refractive index of oxygen is higher than that of air so that,

- (a) the unit must be re-zeroed if the carrier gas is changed, and
- (b) the scale must be adjusted by a correction factor, applied by multiplying the Riken scale reading to obtain the true concentration.

Correction Factors:

Halothane in Air Riken

	Factor (using air)	Factor (using oxygen)
Halothane	1	1.06
Enflurane	1.05	1.11
Isoflurane	1.06	1.12
Sevoflurane	1.05	1.10

Halothane in Oxygen Riken

	Factor (using air)	Factor (using oxygen)
Halothane	0.95	1
Enflurane	0.99	1.05
Isoflurane	1	1.06
Sevoflurane	0.99	1.05

Temperature and Barometric Pressure

Calibration checks must be performed at a temperature between 19 and 21°C.

The correction factor is \pm 1.5% of readings, which is negligible in view of the accuracy of the instrument.

Temperature correction is therefore not required, but the temperature should be measured and recorded to ensure that the test is carried out within the specified range.

Changes of barometric pressure due to weather are not normally of significance and can be ignored.

Altitude can, however, have significant effects and the following correction factors should be applied when appropriate.

The Riken reading multiplied by the stated correction factor gives the true concentration corrected to Standard Temperature and Pressure (STP).

Altitude	Factor	Barometric Pressure (for reference) 910 mb		
		(for reference)		
600 m (2000 ft)	0.9	910 mb		
1200 m (4000 ft)	0.85	850 mb		
1800 m (6000 ft)	0.8	813 mb		

Method of reading the Riken Analyser

- Readings may be taken from a tee-piece connected to the common gas outlet of the anaesthetic machine.
 An AGS system must be connected.
- The sampling tube must be nylon or PTFE (which do not absorb vapours).

Rubber sleeves may be used to make end connections but there must be minimal length of rubber exposed to the gases being sampled.

- 3. Sample by 2 or 3 squeezes of the hand bulb. Wait for fringe movement to cease before taking the reading.
- After each resetting of the vapour control, time must be allowed for the output to stabilise.

Suggested timescale: at

2 L/min flow - wait 4 minutes

4 L/min flow - wait 2 minutes

8 L/min flow - wait 1 minute

- 5. As stated in the Service Manual:
 - a) The vaporizer must be half full, and rigidly supported in its correct operating position
 - b) Temperatures must be stabilised for approximately 4 hours before checking
 - c) The temperature must be in the range 19 to 21°C.

11.3 Servicing and Repair Details

Give details of any servicing, component replacements, etc., carried out on the vaporizer.

Signatura

Comments (including any additional work)

 Comments (melading any additional work)	Oignature

Date	Comments (including any additional work)	Signature

Date	Comments (including any additional work)	Signature

Date	Comments (including any additional work)	Signature

Year One

Test Period		1	2	3	4
Vaporizer serial number:					
Date:					
Signature:					
Print name:					
Carrier Gas					
Leak Test (at 200 Pressure must not	mmHg for minimum 60 secs) drop below 180 mm Hg				
Set	Tolerance				
0.0	0 - 0.1				
0.2	0.14 - 0.26				
0.6	0.45 - 0.75				
1.0	0.8 - 1.2				
3.0	2.4 - 3.6				
*4.0	3.2 - 4.8				
5.0	4.0 - 6.0				
**7.0	5.6 - 8.4				
**8.0	6.4 - 9.6				
**7.0	5.6 - 8.4				
5.0	4.0 - 6.0				
3.0	2.4 - 3.6				
1.0	0.8 - 1.2				
0.6	0.45 - 0.75				
0.2	0.14 - 0.26				
0.0	0 - 0.1				
* 4% Halothane vapo ** 7% and 8% vaporiz	orizer only zers only				
Bypass resistanc	e at 4 L/min				

Year Two

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				

Year Three

Test Period		1	2	3	4
Vaporizer serial number:					
Date:					
Signature:					
Print name:					
Carrier Gas					
	mmHg for minimum 60 secs) drop below 180 mm Hg				
Set	Tolerance				
0.0	0 - 0.1				
0.2	0.14 - 0.26				
0.6	0.45 - 0.75				
1.0	0.8 - 1.2				
3.0	2.4 - 3.6				
*4.0	3.2 - 4.8				
5.0	4.0 - 6.0				
**7.0	5.6 - 8.4				
**8.0	6.4 - 9.6				
**7.0	5.6 - 8.4				
5.0	4.0 - 6.0				
3.0	2.4 - 3.6				
1.0	0.8 - 1.2				
0.6	0.45 - 0.75				
0.2	0.14 - 0.26				
0.0	0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only					
Bypass resistance	e at 4 L/min				

Year Four

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				

Year Five

Test Period		1	2	3	4
Vaporizer serial number:		_			
Date:					
Signature:					
Print name:					
Carrier Gas					
Leak Test (at 200 Pressure must not	mmHg for minimum 60 secs) drop below 180 mm Hg				
Set	Tolerance				
0.0	0 - 0.1				
0.2	0.14 - 0.26				
0.6	0.45 - 0.75				
1.0	0.8 - 1.2				
3.0	2.4 - 3.6				
*4.0	3.2 - 4.8				
5.0	4.0 - 6.0				
**7.0	5.6 - 8.4				
**8.0	6.4 - 9.6				
**7.0	5.6 - 8.4				
5.0	4.0 - 6.0				
3.0	2.4 - 3.6				
1.0	0.8 - 1.2				
0.6	0.45 - 0.75				
0.2	0.14 - 0.26				
0.0	0 - 0.1				
* 4% Halothane vapori: ** 7% and 8% vapori:	zers only				
Bypass resistance	e at 4 L/min				

Year Six

Test Period		1	2	3	4
Vaporizer serial number:		_			
Date:					
Signature:					
Print name:					
Carrier Gas					
Leak Test (at 200 Pressure must not	mmHg for minimum 60 secs) drop below 180 mm Hg				
Set	Tolerance				
0.0	0 - 0.1				
0.2	0.14 - 0.26				
0.6	0.45 - 0.75				
1.0	0.8 - 1.2				
3.0	2.4 - 3.6				
*4.0	3.2 - 4.8				
5.0	4.0 - 6.0				
**7.0	5.6 - 8.4				
**8.0	6.4 - 9.6				
**7.0	5.6 - 8.4				
5.0	4.0 - 6.0				
3.0	2.4 - 3.6				
1.0	0.8 - 1.2				
0.6	0.45 - 0.75				
0.2	0.14 - 0.26				
0.0	0 - 0.1				
* 4% Halothane vapo ** 7% and 8% vaporiz	zers only				
Bypass resistanc	e at 4 L/min				

Year Seven

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				

Year Eight

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				

Year Nine

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				

Year Ten

Test Period	1	2	3	4
Vaporizer serial number:				
Date:				
Signature:				
Print name:				
Carrier Gas				
Leak Test (at 200 mmHg for minimum 60 secs) Pressure must not drop below 180 mm Hg				
Set Tolerance				
0.0 0 - 0.1				
0.2 0.14 - 0.26				
0.6 0.45 - 0.75				
1.0 0.8 - 1.2				
3.0 2.4 - 3.6				
*4.0 3.2 - 4.8				
5.0 4.0 - 6.0				
**7.0 5.6 - 8.4				
**8.0 6.4 - 9.6				
**7.0 5.6 - 8.4				
5.0 4.0 - 6.0				
3.0 2.4 - 3.6				
1.0 0.8 - 1.2				
0.6 0.45 - 0.75				
0.2 0.14 - 0.26				
0.0 0 - 0.1				
* 4% Halothane vaporizer only ** 7% and 8% vaporizers only				
Bypass resistance at 4 L/min				



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