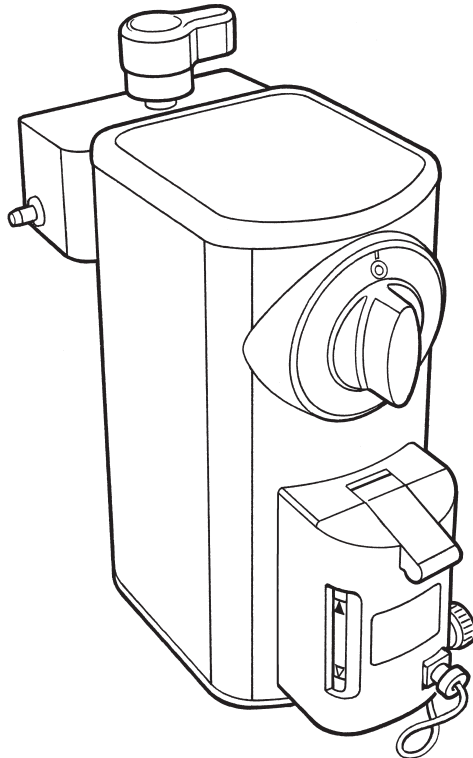


Sigma Delta Vaporizer

User Manual

ANAESTHESIA SOLUTIONS



IMPORTANT

Servicing and Repairs

To ensure the full operational life of the Sigma Delta vaporizer, periodically check vaporizer output and carry out a leak check.

Note:

(a) Check the calibration using a suitable agent analyser, e.g. a Riken refractometer or infrared analyser.

(b) The checks are part of the recommended pre-use check for your Anaesthesia System.

Service the vaporizer if the calibration check shows that vaporizer output is outside the specified performance requirement.

Output checks and servicing may be done on site by:

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

The user should 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

UK and International

Penlon Limited
Abingdon Science Park
Barton Lane
Abingdon
OX14 3NB
UK
www.penlon.com

Technical Support
Tel: 44 (0) 1235 547060
E: tech.support@penlon.com

Always give as much of the following information as possible:

1. Type of equipment
2. Product name
3. Serial number (refer to the I.D. label)
4. Approximate date of purchase
5. 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 and the product before using the vaporizer.

Terminology

This manual complies with ISO 4135, Anaesthetic and respiratory equipment - Vocabulary.

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.

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 A CLINICAL PROCEDURE.

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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 9.1.

Worn, broken, distorted, 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.

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

WARNING: indicates a possibility of personal injury to yourself or others.

CAUTION: indicates 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.

Territory information

USA and Canada

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

Saudi Arabia

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Saudi Food And Drug Authority.

1. WARNINGS AND CAUTIONS

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

WARNINGS

General Information

1. Users must make themselves familiar with the contents of this manual and the product 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 10 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 be modified or disassembled by an unauthorised person. It should be regularly serviced by a Penlon-authorized service agent, trained

technician or engineer and by no other person.
(see section 9)

5. Vaporizers may malfunction if exposed to excessively high temperatures, e.g. by storage above a radiator. This may affect calibration. Before use, function test any vaporizer that has been subjected to temperatures near the upper/lower limits given in section 4.6.

Filling and draining the vaporizer

6. Check the drug name on the vaporizer and the supply bottle before commencing the filling process.
Key (agent specific) filler models:
Ensure that the bottle is fitted with a keyed collar
7. The filler system must be maintained in accordance with the instructions given in the User Maintenance section.
8. The vaporizer must be filled only by suitably skilled and trained personnel.
9. 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 of anaesthetic drugs when filling or draining vaporizers.

WARNINGS AND CAUTIONS

10. 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 may continue to be delivered from the anaesthetic machine to the patient during the filling procedure.
 11. The vaporizer must be upright during filling to minimise the risk of overfilling.
 12. 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.
 13. If a new bottle of anaesthetic agent is to be used, check that the tamper-evident shrink band is undamaged.
 14. Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.
 15. Do not tamper with the filling system valve. This may cause a vapour and fresh gas leak.
 16. Do not overfill.
Withdraw the vaporizer from use if it has been overfilled. Contact Penlon Service Department for advice.
 17. Anaesthetic drugs must be treated as a 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 liquid as a hazardous chemical.
 18. 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
19. Do not use the vaporizer if the agent level is not visible in the sight glass, or the level is above the maximum mark or below the minimum mark.

WARNINGS AND CAUTIONS

20. If a vaporizer is 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

21. 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.

22. 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.

23. 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.

24. Before use:

a) The vaporizer must be mounted on an anaesthetic workstation or machine that complies with ISO 80601-2-13.

b) At first installation, carry out a vaporizer output check, see section 7.1

c) Test all joints for gas tightness, and perform backbar function and leak tests as detailed in the user manual supplied with the anaesthetic machine.

d) Interlock system: check that only one vaporizer at a time can be turned on.

e) Carry out the pre-use checks detailed in section 7.2.

Using the vaporizer

25. Do not set the control dial between zero (0) and the lowest graduation.

WARNINGS AND CAUTIONS

26. Check the liquid level frequently when using the vaporizer and maintain the level between the minimum and maximum marks.
The vaporizer control must be in the zero (0) position during the filling process (see warning 10).
 27. 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 8.3).
 28. 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.
 29. The vaporizer must not be used downstream of the common gas outlet.
 30. As stated in section 2, the vaporizer is of relatively high resistance and must not be incorporated within a breathing system.
 31. Always use an anaesthetic gas scavenging (AGS) system to extract expired anaesthetic vapours from the operating theatre.
The AGS system must comply with ISO 80601-2-13.
 32. Patient monitoring:
 - a) Always use an anaesthetic agent monitor that complies with ISO 80601-2-55.
 - b) Always monitor oxygen concentrations.
 - c) Always check that the monitors are functioning correctly before starting the clinical procedure.
 33. Anaesthesia system monitors and patient monitors are very desirable aids for the anaesthetist. However, they are not true clinical monitors, as the condition of the patient is also dependent on his respiration and the functioning of his cardiovascular system.
 34. An alternative means of delivering anaesthetic agent must be available whenever the vaporizer is in use.
- User Maintenance
35. Do not pour or spray water, or any cleaning solutions into the vaporizer.
 36. Users must not attempt any procedures in this manual that are designated to be carried out only by trained technicians or engineers.

WARNINGS AND CAUTIONS

CAUTIONS

1. 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. Penlon Sigma Delta vaporizers distributed by a drug company should only be filled with drug from that drug company, to ensure materials compatibility.
3. Users must not attempt to overcome the seals or safety devices fitted to the drug bottles to use a drug from a different drug company.
4. The user of anaesthetic agent that is not supplied by Abbvie, Baxter, or Piramal must check with the supplying drug company to ensure materials compatibility before using the agent with any vaporizers supplied by Penlon, its distributors, or agents.
5. The symbol shown below denotes:
'Consult instructions for use'



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 8 (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 control dial knob (1).

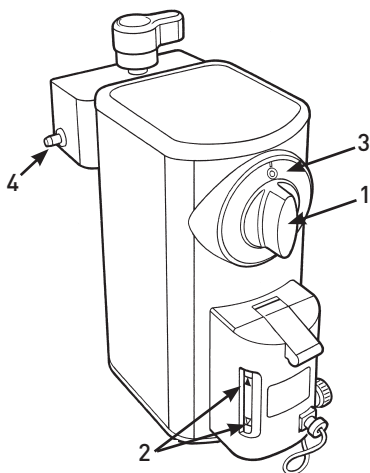
The vaporizer contains a chamber, the base of which holds the anaesthetic agent in liquid form. A wick ensures that the upper part of the chamber is filled with the saturated vapour of the agent.

The 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. Control dial knob
2. Liquid level indicator marks
3. Control dial zero (0) position
4. 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.

DESCRIPTION

Interlock Systems

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

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

Selectatec Compatible Models

NOTE

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

Drager Compatible Models

WARNING

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

NOTE

The Drager Auto Exclusion compatible model is not for sale in the USA.

4. SPECIFICATION

4.1 Physical Dimensions

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

Dimensions given above are in millimetres

NOTE For depth of Screw Cap Filler models, 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 11, Ordering Information.

Pour Fill (Screw Top)

Quik Fil - Sevoflurane only

Use with corresponding agent specific bottle.

4.5 Concentration 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.

SPECIFICATION

4.6 Environmental

Operating conditions

Temperature Range	
Sevoflurane models	15 to 40°C (58 to 104°F)
Halothane/Isoflurane models	15 to 35°C (58 to 95°F)
Storage Temperature Range	-5 to 40°C (23 to 104°F)
Transport Temperature Range	-5 to 40°C (23 to 104°F)
Humidity Range	10% to 95%
Atmospheric pressure range	11.5 to 110 kPa
MRI compatibility	The Sigma Delta is not suitable for use in a MRI environment. Contact Penlon Ltd Sales Department for details of the Sigma Delta MRI model.

4.7 Flow Range

Operating Flow Range	0.2 to 15 litres/min
----------------------	----------------------

4.8 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)

4.9 Device Classification

Mode of operation:	Continuous
Patient Class	All patient types The device does not contain phthalates. There are no residual risks from phthalates that are carcinogenic, mutagenic, or toxic to reproduction.

5. FILLING AND DRAINING

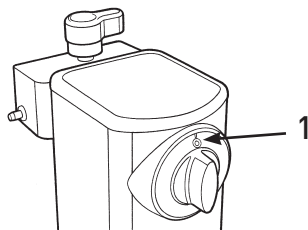
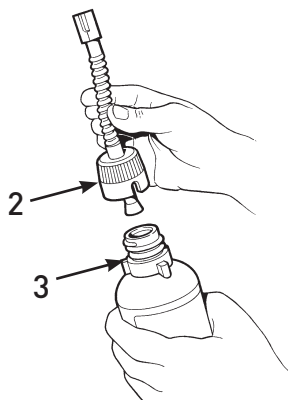
5.1 Key Filler System

WARNINGS

1. 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.
2. The concentration control (1) 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.
3. 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.

CAUTIONS

1. Penlon Sigma Delta vaporizers distributed by a drug company should only be filled with drug from that drug company, to ensure materials compatibility.
2. Users should not attempt to overcome the seals or safety devices fitted to the drug bottles to use a drug from a different drug company.
3. The user of a vaporizer that is not supplied by a drug company, or is not labelled as being supplied by a drug company, must check with the drug company to ensure materials compatibility before using any vaporizers supplied by Penlon, its distributors, or agents.



Filling the Vaporizer

This system is manufactured in compliance with ISO 5360.

1. 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

A range of agent specific filler adaptors are available, see section 11.

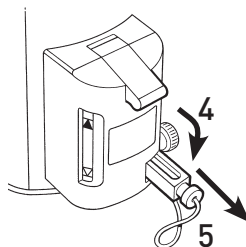
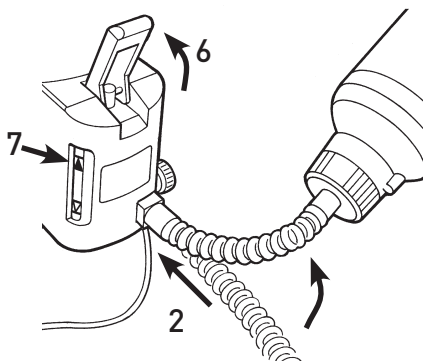
FILLING AND DRAINING

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).
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).
7. 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).



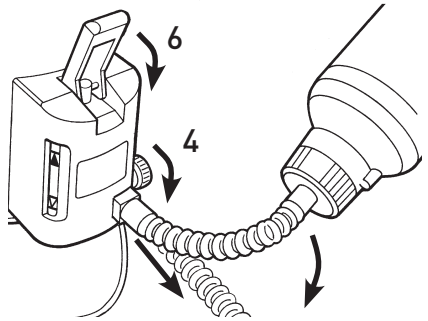
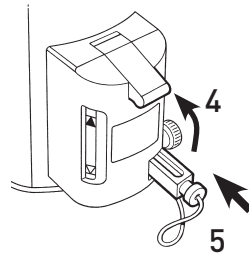
WARNING - DO NOT OVERFILL.

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).

FILLING AND DRAINING

8. Close the filler control (6).
9. 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.

FILLING AND DRAINING

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

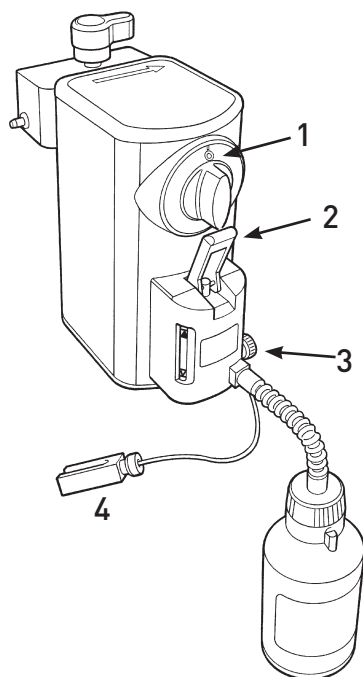
1. Check that the vaporizer concentration control (1) is in the 0 (zero) position.
 2. Follow steps 2 to 5 of the procedure for filling the vaporizer (see above), but keep the bottle below the filler.
 3. Raise the filler control (2) and allow the liquid to run into the bottle until the flow ceases.
 4. 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.



FILLING AND DRAINING

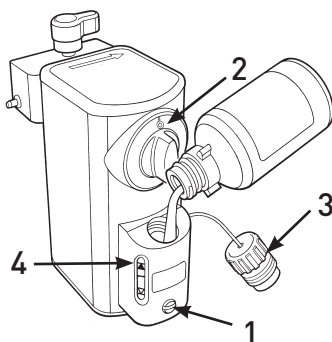
5.2 Screw Cap Filling System (Pour Fill)

WARNINGS

1. 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.
2. 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.
3. Check the drug name on the vaporizer and the supply bottle before filling.

CAUTIONS

1. To minimise atmospheric pollution in the operating room, fill the vaporizer in a fume cupboard or under an extractor hood.
2. Penlon Sigma Delta vaporizers distributed by a drug company should only be filled with drug from that drug company, to ensure materials compatibility.
3. Users should not attempt to overcome the seals or safety devices fitted to the drug bottles to use a drug from a different drug company.
4. The user of a vaporizer that is not supplied by a drug company, or is not labelled as being supplied by a drug company, must check with the drug company to ensure materials compatibility before using any vaporizers supplied by Penlon, its distributors, or agents.



Filling the Vaporizer

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

1. The concentration control (2) must be in the 0 (zero) position, as illustrated.
2. Unscrew the filler cap (3).
3. Remove the bottle cap. Fill the vaporizer slowly and carefully, stopping to check the liquid level occasionally. Stop filling when the upper mark (4) is reached on the filler block.

WARNING

DO NOT OVERFILL.

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

4. Check that the seal in the filler cap (3) is clean, and positioned correctly. Replace the filler 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.

FILLING AND DRAINING

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.

1. Check that the vaporizer concentration control (1) is in the 0 (zero) position, as illustrated.
2. Unscrew the filler cap (2).
3. 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.

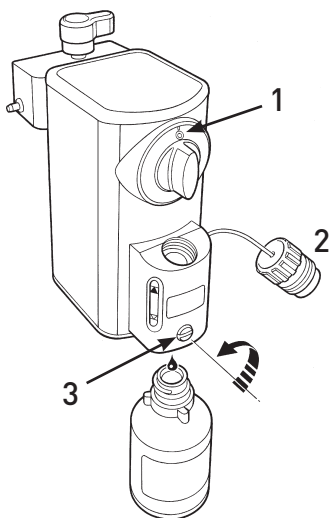
WARNING

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.

4. 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.

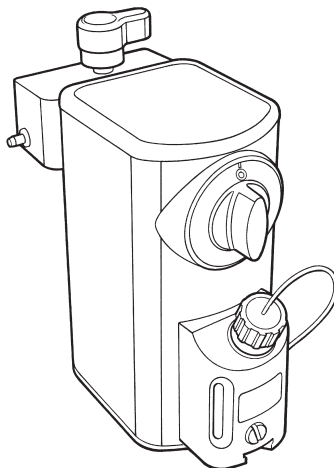
5. Check that the seal in the filler block cap (2) is clean and positioned correctly. Refit the cap - do not overtighten.

FILLING AND DRAINING

5.3 Quik-Fil System

WARNINGS

1. 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.
2. 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.
4. Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.
5. 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.
8. After filling, remove the bottle and refit the filler block cap before using the vaporizer. Check that the seal in the cap is clean.
Do not overtighten the cap.
9. Do not use the vaporizer if the agent level is not visible in the sight glass or the level is above the maximum mark or below the minimum mark.



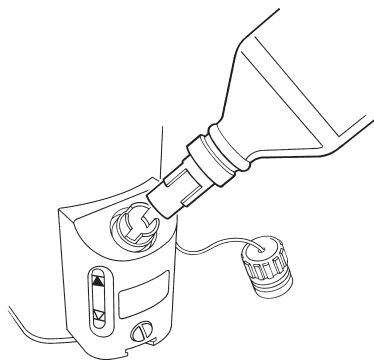
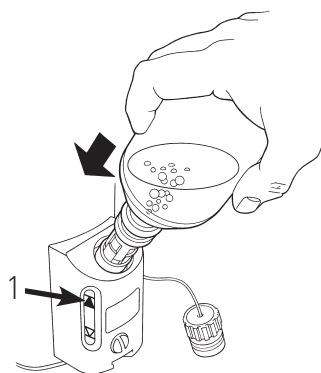
CAUTIONS

1. Penlon Sigma Delta vaporizers distributed by a drug company should only be filled with drug from that drug company, to ensure materials compatibility.
2. Users should not attempt to overcome the seals or safety devices fitted to the drug bottles to use a drug from a different drug company.
3. The user of a vaporizer that is not supplied by a drug company, or is not labelled as being supplied by a drug company, must check with the drug company to ensure materials compatibility before using any vaporizers supplied by Penlon, its distributors, or agents.

FILLING AND DRAINING

Quik-Fil System - Filling the Vaporizer

1. Check that the vaporizer concentration control is in the off ('0') position.
2. Remove the yellow protective cap from the anaesthetic agent bottle filler, checking that the bottle and filler mechanism are not damaged.
3. 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.
4. 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 (1) is reached, paying continuous attention to the level in the sight glass and the air return bubbles flowing into the bottle.
5. Release the bottle when the vaporizer is full and the continuous stream of bubbles ceases.
6. Withdraw the bottle from the vaporizer filler and replace the yellow cap on the agent bottle.
7. Check that the seal in the vaporizer filler block cap is clean. Refit the cap - do not overtighten.



WARNING

The filler cap must be refitted before using the vaporizer.

Do not overtighten.

FILLING AND DRAINING

Quik-Fil System - Draining the Vaporizer

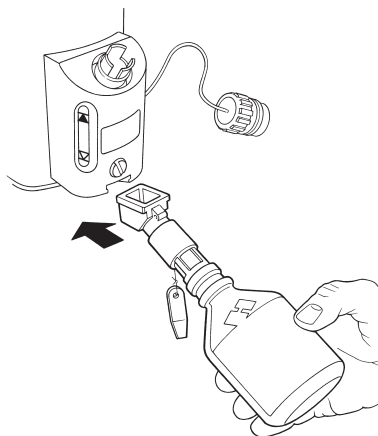
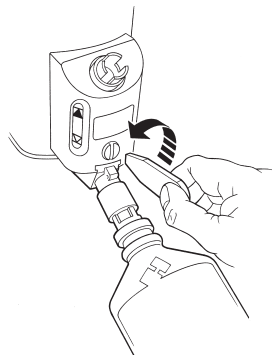
WARNING

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

1. 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 slots in the drain funnel, and screw the drain funnel onto the empty bottle.
2. Remove the vaporizer filler block cap.
3. 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.
4. Unscrew the drain funnel from the bottle and refit the bottle cap.
5. Check that the seal in the vaporizer filler block cap is clean. Refit the cap - do not overtighten.

WARNINGS

1. The filler cap must be refitted before using the vaporizer.
2. Do not reuse the agent drained from the vaporizer. Treat as a hazardous chemical.



6. INSTALLATION

6.1 Gas Port Transit Seals

All new vaporizers

CAUTION

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 Installing the Vaporizer on the Anaesthetic Machine

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.

6.2.1 All Models

1. Check that the vaporizer concentration control is in the 0 (zero) position.
2. Follow the instructions in sections 6.2.2 to 6.2.6, depending on the vaporizer model.
3. **New vaporizer at commissioning:**
Check the vaporizer output - see section 7.1.
4. **Reinstalling a vaporizer:**
Carry out the pre-use checks listed in section 7.2.

INSTALLATION

6.2.2 Selectatec Compatible Models - with Interlock

These vaporizers are designed for installation on a Selectatec type manifold backbar.

Three-station backbar manifold

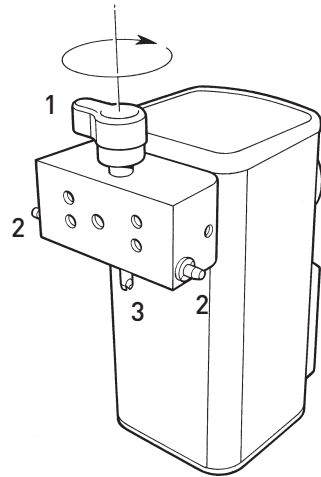
NOTE

Non-interlock type manifold

1. When installing two vaporizers only, the centre station **must** be occupied by one of the vaporizers.
2. If three vaporizers are installed, and the centre vaporizer is removed, reposition one of the remaining vaporizers to the centre station.

Manifold with interlock system

1. Penlon three station backbar manifolds on anaesthetic machines built from June 2011 are fitted with an interlock system.
2. If two vaporizers only are installed it is not necessary to ensure that the centre station is occupied.
3. **Always** check that the backbar interlock system is functioning correctly.



1. Locking Lever
2. Interlock Bolts
3. Backbar Manifold Locking Shaft

INSTALLATION

Anaesthetic machine layout

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 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.
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.)
3. Carefully lower the vaporizer onto the manifold, and recheck that the gas ports are correctly engaged with the valve capsule on the manifold.
4. Lock into position by pushing the locking lever downwards and rotating clockwise through 90°.

WARNING

To prevent damage to the locking shaft, recheck that the gas ports on

the vaporizer are correctly engaged with the valve capsule before tightening the locking lever.

Pre-use Checks

1. Interlock System - check that only one vaporizer at a time can be turned on.
2. Observe the WARNINGS below and carry out pre-use checks:
(a) Section 7.1 (installing a new vaporizer)
(b) Section 7.2 (reinstalling a vaporizer).

WARNING

1. **Test all joints for gas tightness before using the anaesthetic machine.**
2. **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 90° anti-clockwise and carefully lift the unit vertically until clear of the backbar.

INSTALLATION

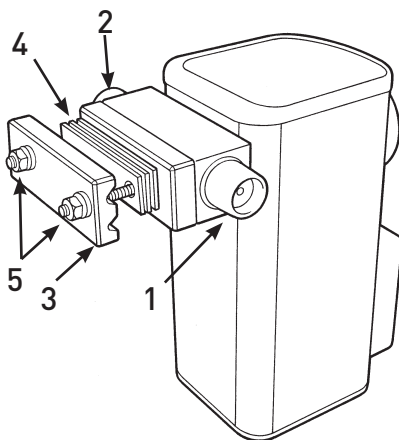
6.2.3 Cagemount (23 mm) Taper Models

CAUTION

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

Vaporizers fitted with conical 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). The conical connectors are designed in accordance with ISO 5356-1.

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



Taper Connectors

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

1. Adjust the distance from the backbar to the taper joint by adding or removing the shims (4) .
2. 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 (5).

INSTALLATION

6.2.4 Drager 'Plug-in' Compatible (interlock)

Installation

NOTE

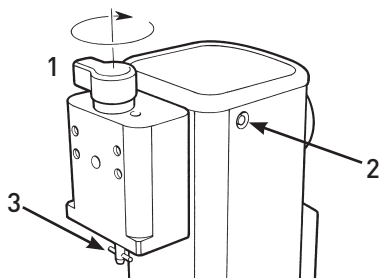
1. Not compatible with the Drager auto exclusion system.

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).
3. Carefully lower the vaporizer onto the manifold, and recheck that the gas ports are correctly engaged with the valve capsules on the manifold.

WARNING

Check that the vaporizer is firmly positioned on the manifold before tightening the locking lever. This will prevent damage to the locking shaft (3), and ensure that the gas connection ports are correctly engaged.

4. Lock into position by pushing the locking lever (1) downwards and rotating clockwise through approximately 100°.



1. Locking lever
2. Interlock bolts
3. Backbar manifold locking shaft

Pre-use Checks

1. Interlock System - check that only one vaporizer at a time can be turned on.
2. Observe the WARNINGS below and carry out pre-use checks:
(a) Section 7.1 (installing a new vaporizer)
(b) Section 7.2 (reinstalling a vaporizer).

WARNING

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

WARNING

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

Removing the Vaporizer

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

INSTALLATION

6.2.5 North American Drager Compatible (Interlock)

WARNING

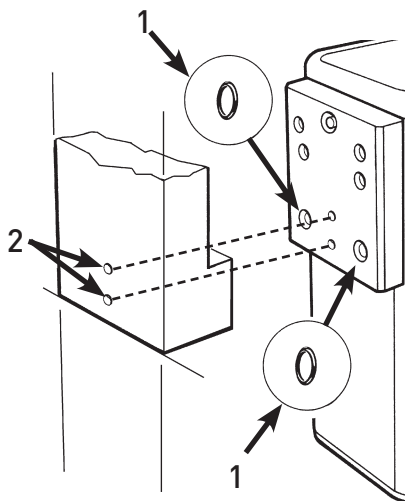
The anaesthesia workstation interlock system may require periodic adjustment as a result of normal use, to maintain system integrity.¹

In addition, adjustment may be necessary when installing a new vaporizer.

Installation

Installation and adjustment must be carried out by suitably trained technicians only.

1. Check that each gas port is fitted with the correct O seal (1) (Penlon Part No. 041126).
2. Carefully offer the vaporizer up to the manifold.
3. To secure the vaporizer to the manifold, use two M4 x 30 screws (Penlon Part No. 01267) and fan-type lock washers. From the rear of the anaesthetic machine fit the two screws through the holes (2) in the manifold block, and screw into the threaded holes in the vaporizer.
4. Tighten the screws to a torque of 3.0 Nm.



Pre-use Checks

1. Interlock System - check that only one vaporizer at a time can be turned on. If the vaporizer fails this check, carry out the adjustment procedure detailed on the next page.
2. Observe the WARNING below and carry out pre-use checks:
 - (a) Section 7.1 (installing a new vaporizer)
 - (b) Section 7.2 (reinstalling a vaporizer).

WARNING

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

Removing the Vaporizer

1. Support the vaporizer, and remove the securing screws (2).
2. Detach the vaporizer from the manifold.
3. Check that the O-seals are retained in the gas ports (1).

¹Anesthesiology, V104, No 4, Apr 2006, p.891.

INSTALLATION

Interlock Function Check and Adjustment

Check that only one vaporizer at a time can be turned on.

If necessary, adjust the position of the interlock screw (3) on the vaporizer to ensure that the system functions correctly (see 1 and 2, below):

Adjustment to be carried out by suitably trained technicians only.

1. If the Delta vaporizer, or any vaporizer on the machine, is difficult to turn on (or can not be turned on at all):

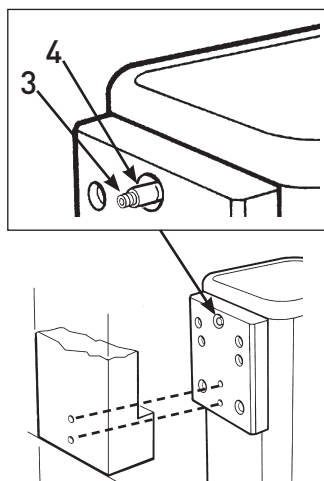
- i) Remove the vaporizer from the machine to enable adjustment (refer to the sub-section 'Removing the Vaporizer' on previous page).
- ii) Carefully pull the interlock screw (3) and sleeve (4) outwards, and hold the sleeve.
- iii) Use a 2.5 mm Allen Key to adjust the position of the screw (3) inwards.
- iv) Refit the vaporizer and recheck the interlock system.

WARNING

The anaesthesia workstation interlock system may also require adjustment to maintain system integrity.

2. If the vaporizer is on, and another vaporizer can also be turned on:

- i) Turn the vaporizer off.



- ii) Remove the vaporizer from the machine to enable adjustment (refer to the sub-section 'Removing the Vaporizer' on previous page).
- iii) Carefully pull the interlock screw (3) and sleeve (4) outwards, and hold the sleeve.
- iv) Use a 2.5 mm Allen Key to adjust the position of the screw (3) outwards.
- v) Refit the vaporizer and recheck the interlock system

WARNING

The anaesthesia workstation interlock system may also require adjustment to maintain system integrity.

INSTALLATION

6.2.6 Drager Auto Exclusion Compatible (Interlock)

Installation

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).
3. Carefully lower the vaporizer onto the manifold, and recheck that the gas ports are correctly engaged with the valve capsules on the manifold.

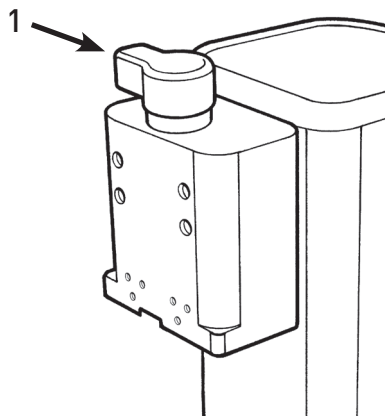
WARNING

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

4. Secure in position by rotating the lever [1] clockwise until locked.

Pre-use Checks

1. Interlock System - check that only one vaporizer at a time can be turned on.
2. Observe the WARNINGS below and carry out pre-use checks:
(a) Section 7.1 (installing a new vaporizer)
(b) Section 7.2 (reinstalling a vaporizer).



WARNING

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

WARNING

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

Removing the Vaporizer

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

7. PRE-USE CHECKS

7.1 Output Check - Commissioning a New Vaporizer

Initial checks to be carried out at first installation.

To verify the performance of the vaporizer the following checks should be carried out.

Note

Output concentration tests should be carried out only by trained persons or a Penlon-trained engineer, using a suitable purpose-made calibrated agent analyser, e.g. a Riken refractometer.

WARNING

The pre-use checks at first installation must be carried out as part of the anaesthesia system check.

Please refer to the anaesthesia system manufacturer's user manual, but note that some anaesthesia machine manufacturers may not list specific vaporizer checks.

WARNING

Keep the vaporizer upright at all times; tilting a vaporizer can result in delivery of dangerously high concentrations of vapour.

All vaporizers

1. Ensure that the vaporizer has been filled and kept at room temperature ($20^{\circ}\text{C} \pm 3^{\circ}\text{C}$) for at least 3 hours.
2. Ensure leak tightness of the anaesthetic machine by performing a backbar manifold leak test as detailed in the relevant anaesthetic machine user instruction manual.

3. Set the vaporizer concentration dial to half scale and set the flow to minimum.

Connect a 0-400 cmH₂O (0-300 mmHg) gauge to the common gas outlet. Note: If a tee-piece is used to mount the gauge, occlude the tee outlet.

4. Carry out a leak test:

(a) Machines built before the introduction of ISO 80601-2- 13 (includes Prima 101/102, Ecoflow, and Prima SP2):

With the vaporizer fitted, use the flowmeter to increase system pressure to 200 cmH₂O (150 mmHg).

Check that a flow of less than 200 ml/min is needed to maintain it. Note: If the anaesthetic machine basal flow is greater than 200 ml/min, check that system pressure is maintained at the basal flow value.

(b) Machines built after the introduction of ISO 80601-2-13.

These machines are fitted with a safety valve with a maximum pressure of 125 cmH₂O (approximately 92 mmHg).

This group of machines includes **Prima 400 Series:**

Before fitting the vaporizer, use the flowmeter to set a flow of 60 to 80 ml/min, watch the pressure gauge rise to a steady state.

The pressure reading must be greater than or equal to 30 cmH₂O (approximately 22 mmHg).

PRE-USE CHECKS

Repeat this test with the vaporizer fitted and locked in place, and the concentration dial set to half scale.

Compare the pressure gauge readings from each test to confirm that they do not vary.

5. Carry out a vaporizer output calibration test:

Connect the agent analyser to the common gas outlet.

Set an Oxygen flow of 4 L/min and check that the measured output concentration is within $\pm 20\%$ for set values of 1% and over (at zero output the concentration should be less than 0.03%).

Turn the concentration dial to off and the flow to minimum.

6. Please contact Penlon Technical Service or your local Penlon-trained engineer if you have any questions or issues regarding the installation and test procedures.

7.2 Daily Pre-use Check List

WARNING

The daily pre-use checks for the vaporizer must be carried out as part of the anaesthesia system check and must include a backbar manifold leak test. Refer to the anaesthesia system manufacturer's user manual.

WARNING

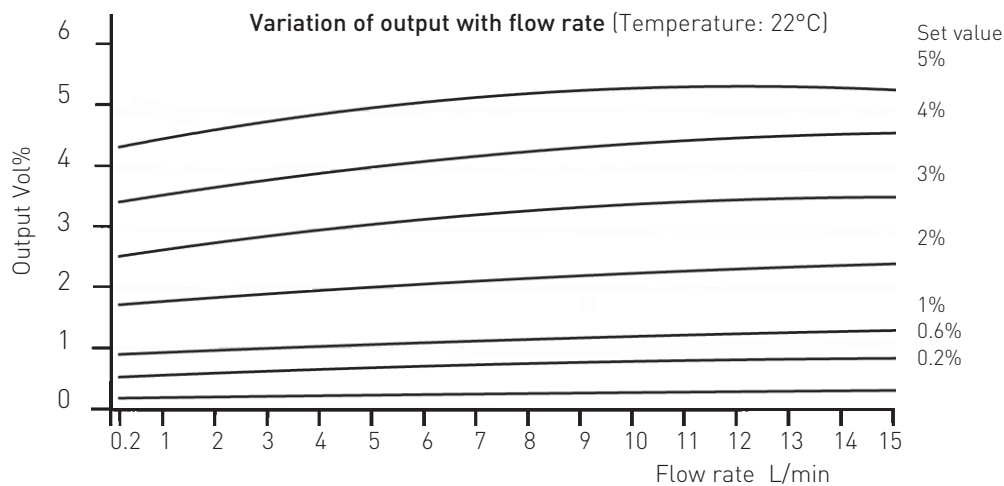
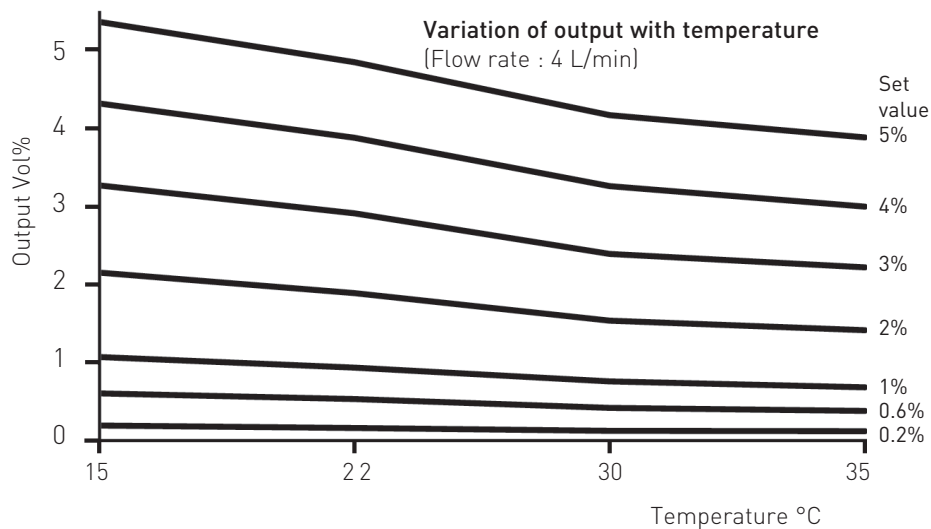
Keep the vaporizer upright at all times; tilting a vaporizer can result in delivery of dangerously high concentrations of vapour.

1. Check that the vaporizer is fitted correctly to the anaesthetic machine and that the backbar locking mechanism is fully engaged. On Cagemount models check that the taper connections are secure.
2. Check that the liquid agent level is between the upper and lower marks on the agent level sight glass.
3. Check that the filling port cap is securely closed. On key fill models, check that the filler plug is fully inserted and that the clamp screw is fully tightened.
4. Check for correct agent delivery concentrations – use an agent analyser.

8. PERFORMANCE CHARACTERISTICS

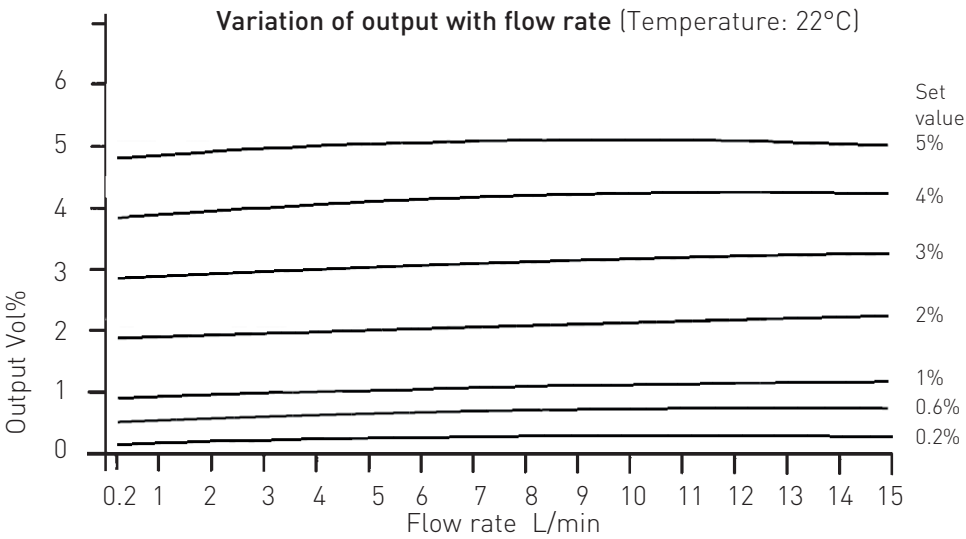
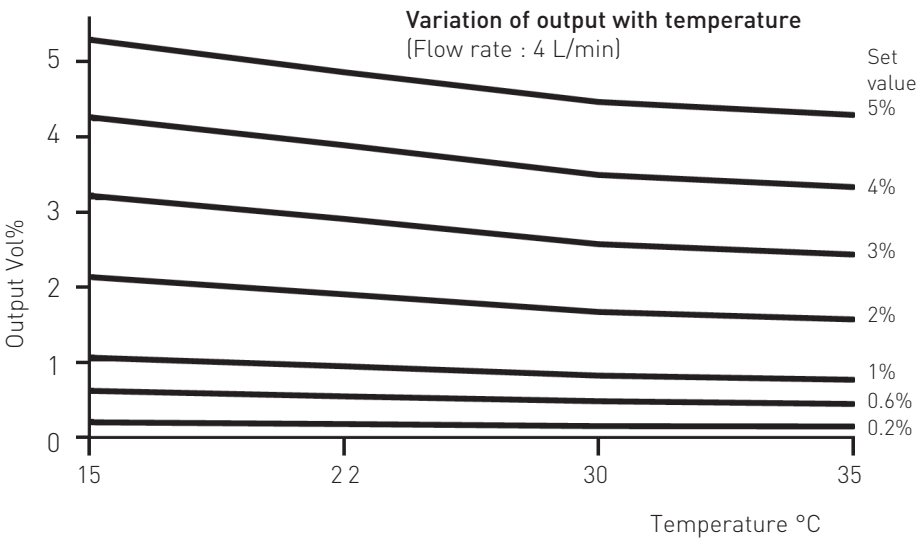
8.1 Performance Graphs

8.1.1 Halothane Models



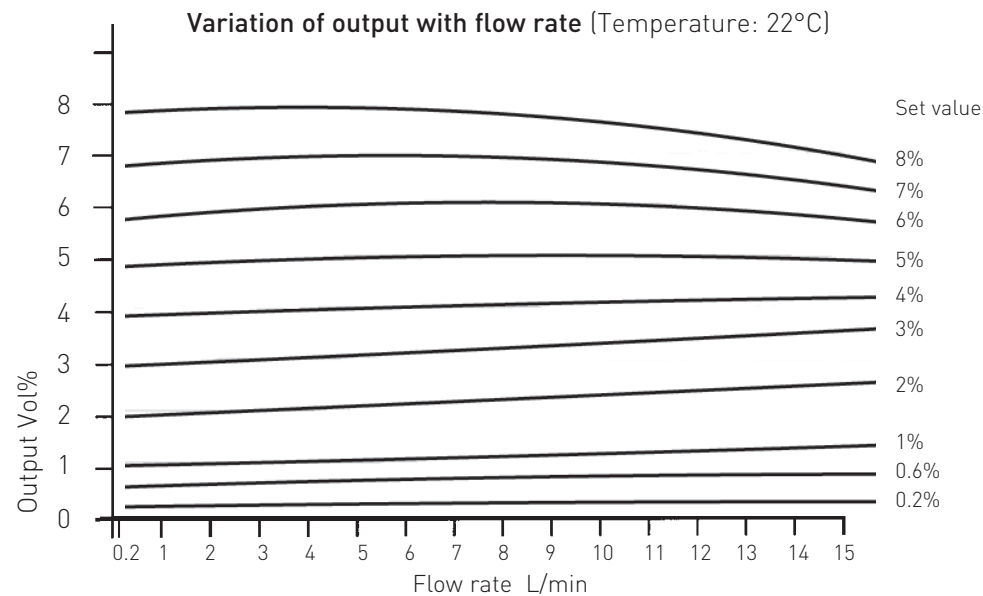
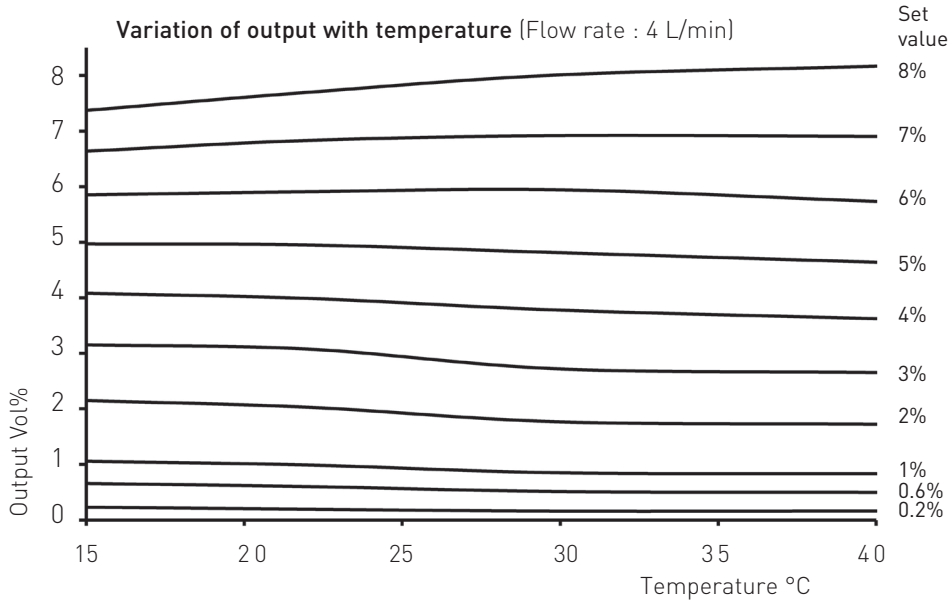
PERFORMANCE CHARACTERISTICS

8.1.2 Isoflurane Models



PERFORMANCE CHARACTERISTICS

8.1.3 Sevoflurane Models



PERFORMANCE CHARACTERISTICS

8.2 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 4.6) 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.

8.3 Pressure Effects

8.3.1 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:

$$C = \frac{S\% \times 101.3}{P}$$

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 same way. However, 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.

8.3.2 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.

PERFORMANCE CHARACTERISTICS

8.4 Summary of Performance Specifications

8.4.1 Output Accuracy

Under calibration conditions (temperature at 22°C ±1°C, ambient pressure 101.3 kPa, flow rate of 4 L/min O₂) the output will not deviate from the set concentration by more than ±20% of scale reading, or 5% of maximum setting (whichever is greater).

8.4.2. Resistance to Gas Flow

Resistance measured at:

22°C (72°F)

101.3 kPa (1013 mbar; 14.7 psi)

Control position 0 (zero)

Flow rate using Air (L/min)	Resistance (cmH ₂ O)
1	1.8
2	3.4
4	8.0
8	20.3

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

8.5 Effect of IPPV on Output

IPPV: Intermittent positive pressure ventilation.

When tested in accordance with ISO 80601-2-13*, output will not deviate from the set concentration by more than +30% / -20%.

*Tested at:

- a) 2 kPa IPPV / flow rate of 2 L/min
- b) 5 kPa IPPV / flow rate of 8 L/min

8.6 Effect of Gas Composition on Output

The vaporizer is calibrated with pure oxygen. 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%.

PERFORMANCE CHARACTERISTICS

8.7 Output when Control is in the 'Off' (0) position

Output vapour concentration when the control is in the 'Off' position (i.e. set at 0) will not exceed 0.05% vol., when tested in accordance with ISO 80601-2-13.

8.8 Effect of Flush Valve Operation

When tested in accordance with ISO 80601-2-13 the operation of the flush valve on the anaesthetic machine will not affect anaesthetic agent output concentration by more than 20%.

8.9 Effect of Sub-atmospheric Pressure

When tested in accordance with ISO 80601-2-13 sub-atmospheric pressure will not affect anaesthetic agent output concentration by more than 20%.

8.10 Effect of variables

Delivered concentration can be affected by fresh gas flowrate, ambient flowrate and duration of use, especially if the vaporizer is used at the extremes of any usual clinical ranges.

Also, using the vaporizer at high fresh gas flowrates at high concentration settings for long periods of time may affect the concentration output.

9. USER MAINTENANCE

User maintenance

User Maintenance by non-technical staff is restricted to cleaning the external surfaces of the vaporizer (see section 9.2).

All other maintenance and servicing must be carried out only by Penlon-trained engineers.

CAUTION

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

9.1 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.

The Sigma Delta must only be serviced at an authorised service centre or by Penlon-trained engineers, as follows:

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

(i) as part of a Penlon Service Contract (UK only).

(ii) by a Penlon-trained engineer.

(iii) by a suitably qualified hospital technician if agent analysis apparatus is available. Check the output under controlled conditions and carry out a leak test.

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

The measured figures must be recorded.

- (b) Successive sets of figures should be compared to determine if performance is deteriorating. Service the vaporizer to restore normal operation.
- (c) A major overhaul must be performed every ten years (Halothane models - 5 years) to maintain performance within the specification. This is a preventive maintenance requirement.
- (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-trained engineer.
- (e) Interlock system vaporizers - function test the interlock system during the vaporizer calibration test.

USER MAINTENANCE

- (f) Quik-Fil system - at regular intervals (three-monthly minimum, six-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.

9.2 Cleaning and Disinfection

WARNING

1. Do not autoclave.
2. Do not immerse in cleaning solutions or water.
3. Do not allow liquid to run into enclosed areas – the filler and drain ports, the area behind the concentration control dial, and the fresh gas inlet and outlet ports.
4. Do not clean with solvents or harsh abrasive cleaning agents.

9.2.1 Cleaning external surfaces

Use a disposable cloth dampened with a mild detergent solution. Clean all surfaces thoroughly, particularly those areas likely to have been touched during clinical procedures.

9.2.2 Disinfection

Use proprietary surface disinfectants - isopropyl alcohol or alcohol wipes (e.g. Azowipes).

Follow the instructions for use issued by the manufacturer.

CAUTION

Do not use strong organic acids, or compounds that release oxygen or halogen.

9.2.3 Before clinical use

Check that all cleaning agent residues are fully removed after cleaning.

Always allow the vaporizer to dry off thoroughly before clinical use.

9.3 Draining - Halothane Models

Because halothane contains a stabilising agent which is only slightly 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.

High levels of accumulated thymol can have clinically undesirable effects on the patient. (Ref. Rosenberg - Alila: Anaesthesia, 1984:38:581-583).

If the vaporizer is in regular use, drain 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

USER MAINTENANCE

be used and should be disposed of as a hazardous chemical.

9.4 Training Course

A training course is available to engineers and hospital staff who wish to service the vaporizer.

The course covers:

- leak testing
- replacement of seals
- internal maintenance
- replacement of major sub-assemblies
- regulation of output

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

9.5 Returning the Vaporizer for Service or Repair

Returning the vaporizer to Penlon Ltd

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.

10. REFERENCES

References

Standards

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

(a) General

ISO 80601-2-13

Particular requirements for basic safety and essential performance of an anaesthetic workstation

ISO 5356-1

Anaesthetic and respiratory equipment - conical connectors - Part 1: Cones and sockets

(b) Agent Specific (Keyed) Filling System

ISO 5360

Anaesthetic vaporizers - agent specific filling systems

Trademarks

Penlon, Delta, and Sigma Delta are trademarks of Penlon Limited.

Selectatec and Quik-Fil are GE trademarks.

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11. ORDERING INFORMATION

A wide range of Halothane, 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

E: uk.sales@penlon.com

International:

Tel: +44 1235 547001

E: international.sales@penlon.com

Optional Extras and Approved Accessories

WARNING

Only use accessories approved by Penlon Ltd.

52275 Safety clip for cagemount tapers (off-line system only)

58090 Mounting clip for cagemount tapers (off-line system only)

53450 Agent Specific (Keyed) filler adaptor for halothane bottles
(ICI, May and Baker, and Hoechst)

53453 Agent Specific (Keyed) filler adaptor for isoflurane bottles

53454 Agent Specific (Keyed) filler adaptor for sevoflurane bottles

12. LABELLING

	Refer to the operating instructions (this user manual)
	Do not dispose of in landfill, refer to an approved recycling facility. Follow your hospital, local, state, and federal regulations.
	1. General Warning (yellow background) 2. Caution (plain background)
	Catalogue number (model number)
	Serial number
	Authorized representative in the European community
	Manufacturer
	Date of manufacture
	Keep packaging dry
	Storage temperature range
	Storage humidity range
	Storage pressure range

	Fragile
	Mass
	Maximum stacking weight
	Stacking limit by number of boxes
 Direction of flow	

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