



## IMPORTANT

### Commissioning a new vaporizer

Before use on a patient:

Fill the vaporizer with desflurane.

Set a concentration setting of 18%.

Purge at 4 L/min fresh gas for a minimum of 30 seconds.

Refer to section 5.1.





# Important

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## Servicing and Repairs

In order to ensure the full operational life of this vaporizer, servicing by a Penlon-trained engineer should be undertaken periodically.

The vaporizer must be serviced to the schedule detailed in section 8:

Every 6 months: Operational check, including vaporizer output.

Every 2 years: Return to Penlon Ltd in the UK for a full service, including fitment of the vaporizer preventive maintenance kit.

Details of service operations that can be carried out by Penlon-trained engineers are given in the Sigma EVA Service Manual.

For any enquiry regarding the servicing or repair of this vaporizer, contact the nearest accredited Penlon agent:

or, communicate directly with Penlon:

## UK and Global

Technical Support

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Always give as much of the following information as possible:

1. Type of equipment
2. Product name
3. Serial number
4. Filler type (Piramal or Baxter)
5. Approximate date of purchase
6. Apparent fault

# Foreword

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

Information contained in this 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 vaporizer function before use.

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# User Responsibility

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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.

To ensure the safety of this device 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 this manual.

Additionally, the user must accept responsibility for any malfunction which may result from misuse of any kind or non-compliance with other requirements detailed in this manual.

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 be made to the nearest Penlon accredited agent.

This device 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 sole responsibility for any malfunction which results from improper use, maintenance, repair, damage or alteration by anyone other than Penlon or its appointed agents.

## **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.

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

### **WARNING**

**means there is a possibility of injury to yourself or others.**

### **CAUTION**

**means there is a possibility of damage to the apparatus or other property.**

### **NOTE**

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

Always take particular notice of the warnings, cautions and notes provided throughout this manual.

# 1. Warnings and Cautions

---

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

## WARNINGS

### Commissioning a new vaporizer

1. Before use on a patient, the vaporizer must be filled with desflurane and purged at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds. Refer to section 5.1.

### General Information

2. Users must make themselves familiar with the contents of this manual and the product before using the vaporizer.
3. The vaporizer is validated for use only with desflurane and must only be filled from a desflurane agent-specific bottle.
4. Misdosage will occur if the vaporizer is filled with the wrong drug.  
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.
5. This vaporizer must not be serviced, modified, repaired, or disassembled by an unauthorised person. Refer to section 8.
6. The vaporizer may malfunction if exposed to excessively high temperatures, e.g. by storage above a radiator. This may affect calibration.  
Storage temperature:  
-20°C to 60°C (-4 to 140°F)  
Operating temperature:  
18 to 30°C (64 to 86°F)  
Before use, function test any vaporizer that has been subjected to temperatures near the upper/lower limits given above.
7. Exterior panels must not be removed by unauthorised personnel and the vaporizer must not be operated with such panels missing.  
There are no user-serviceable parts within the vaporizer.  
Unauthorised personnel must not attempt to access fuses or other electrical components. There is a possible electric shock hazard. To isolate the vaporizer from the electrical power supply, disconnect the power cable from the socket on the top of the vaporizer.
8. To avoid the risk of electric shock, this vaporizer must only be used on an anaesthetic machine connected to a mains supply with a protective earth. Always use a mains power outlet socket that can be easily accessed. Check that a trained technician or engineer at your facility has carried out an earth continuity test.
9. Excessive electronic noise caused by poorly regulated devices, such as an electrocautery unit, may adversely interfere with the proper functioning of the vaporizer. Do not power the vaporizer from the same electrical wall outlet or adaptor strip into which an electrocautery unit is connected.
10. The EVA vaporizer is EMC-compliant with all cables, transducers and accessories supplied by Penlon Limited.
  - a) The vaporizer may cause radio interference or may disrupt the operation of nearby equipment.  
It may be necessary to take mitigation measures such as [1] reorienting or relocating the Sigma EVA vaporizer (do not remove from the anaesthetic machine backbar), or [2] shielding the location.
  - b) The use of cables, transducers and accessories other than those specified may result in increased emissions or decreased immunity of the EVA vaporizer.
11. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

# Warnings and Cautions

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12. MRI compatibility - The Sigma EVA vaporizer is not MRI compatible.

## Filling the vaporizer

13. Check the type of filler system (Piramal Fill or Baxter SAFE-FIL) before commencing the filling process.
- a) Piramal Fill: see sections 3.4.1 and 6.2  
Important:  
Read the warnings listed in section 6.2.2.
  - b) Baxter SAFE-FIL: see sections 3.4.2 and 6.3.  
Important:  
Read the warnings listed in section 6.3.1.
14. If the vaporizer is run dry, refill and then purge the system before use on a patient. See section 5.1
15. Do not refill when the back-up battery is powering the vaporizer.
16. Check the drug name on the supply bottle before commencing the filling process.
17. The vaporizer must be filled only by suitably skilled and trained personnel.
18. 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 the vaporizer.
19. The vaporizer must be upright during filling.
20. 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 contaminated agent entering the vaporizer.
21. If a new bottle of anaesthetic agent is to be used, check that the tamper-evident band is undamaged.
22. Do not tamper with the filler system. This may cause a vapour and fresh gas leak.

23. Liquid that has been spilled or drained should never be reused. Contamination is likely.  
Always dispose of this liquid as a hazardous chemical.

24. After filling:  
Remove the bottle and refit the filler cap before using the vaporizer.

## Before using the vaporizer

25. If a vaporizer is transported when filled with liquid drug the control must be in the 0% (zero) position during transport.
26. The vaporizer must be mounted on an anaesthesia workstation or machine that complies with BS EN ISO 80601-2-13
27. Mount the vaporizer on the anaesthetic machine backbar before use, see section 5.2. Do not use on mobile paramedic equipment or outside the hospital operating theatre.
28. 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. Check all anaesthetic machines with a Selectatec-compatible type backbar. 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.  
See section 5.2.1.

## Pre-use checks

29. At first installation, carry out a vaporizer leak check and output check, see section 5.5.
30. Daily pre-use checklist, see section 6.4.  
The daily pre-use checks for the vaporizer must be carried out as part of the anaesthesia system pre-use check and must include a backbar manifold leak test (refer to the anaesthesia system manufacturer's user manual).

# Warnings and Cautions

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## Using the vaporizer

31. Do not set the control dial between 0% and 1%.
32. Check the liquid level frequently when using the vaporizer, and maintain the level above minimum.
33. 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.
34. 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.
35. The vaporizer must not be used downstream of the common gas outlet.
36. The vaporizer is of relatively high resistance and must not be incorporated within a breathing system.
37. Always use an anaesthetic gas scavenging (AGS) system to extract expired anaesthetic vapours from the operating theatre. The AGS system must comply with BS EN ISO 80601-2-13.
38. Do not use the vaporizer in an oxygen-rich environment.
39. Patient monitoring:
  - a) Always use an anaesthetic agent monitor that complies with the latest relevant standard.
  - b) Always monitor oxygen concentrations.
  - c) Always check that the monitors are functioning correctly before starting the clinical procedure.
40. 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.

41. In compliance with good anaesthesia practice, an alternative means of delivering anaesthetic agent must be available whenever the vaporizer is in use.

## Powering down the vaporizer

42. Refer to section 6.7.  
During shutdown the LED indicators flash until all internal systems have powered down.  
Do not reconnect the power cable during this period.  
**NOTE:**  
If the vaporizer is running on battery power and the control (1) is set to zero, the vaporizer will automatically start the power-down sequence.

## User Maintenance

43. Refer to section 8.2.  
Do not sterilize, autoclave, or immerse in cleaning solutions or water.  
Do not pour or spray water, or any cleaning solutions into the vaporizer.
44. Users must not attempt any procedures in this manual that are designated to be carried out only by trained technicians or engineers.
45. Replacement fuses and batteries must only be fitted by trained service personnel.

# Warnings and Cautions

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## CAUTIONS

1. Anaesthetic machine and workstation standards require that an interlock system is provided on each vaporizer to ensure that gas cannot pass through more than one vaporizer chamber.
2. Penlon Sigma EVA 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 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.

## 2. Purpose

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The vaporizer is suitable for use by a professional operator in a professional healthcare facility and must be continuously attended when in use.

Its purpose is the provision of accurate concentrations of desflurane agent into 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.

The Sigma EVA vaporizer is indicated for use for inhalation anaesthesia of desflurane. The Sigma EVA is not used with any other anaesthetic agent such as enflurane, halothane, isoflurane, or sevoflurane.

### Environment

Do not use the device near HF surgical equipment, or outside the RF shielded room of a medical system for magnetic resonance imaging where the intensity of EM disturbances is high.

The vaporizer is designed to be mounted on an anaesthetic workstation that complies with BS EN ISO 80601-2-13.

## 3. Description

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### 3.1 Operating Principles

The vaporizer is uniquely designed and tested for use with desflurane anaesthetic agent (1).

The agent is contained in liquid form in a heated reservoir in the base of the vaporizer.

The anaesthetist sets the required concentration using the dial (2) and vaporized agent is mixed with the carrier gas flowing from left to right through the vaporizer.

The software-controlled operating system continuously monitors the output of the vaporizer to ensure that delivered agent in the fresh gas flow to the patient is within the specified tolerance.



### 3.2 Controls

#### 3.2.1 Automatic On/Off Control

The vaporizer switches on automatically when the power cable is connected to a mains supply outlet.

The vaporizer switches off when the concentration control dial (2) is set to 0% (zero) and the mains supply is disconnected.

#### 3.2.2 Concentration Control

The vaporizer has a single, forward facing rotary control dial (2) to regulate the vapour concentration delivered to the patient.

The dial is locked at zero when not in use.

With the vaporizer on, and in Standby mode, the user can set a concentration level by pushing the dial assembly in and rotating anti-clockwise.

Align the required concentration graduation with the top of the bezel (3).

In the zero position the anaesthetic vapour is shut-off completely from the carrier gas flowing through the vaporizer

#### **WARNING**

**Do not set the control dial between 0% (zero) and the 1% graduation.**

When turned to zero, the dial will automatically spring outwards into the locked 'off' position.

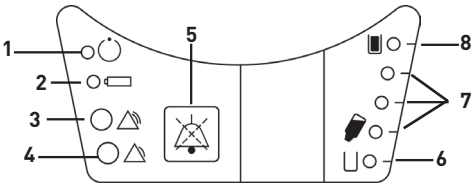
# Description

## 3.3 Alarms and Indicators

### 3.3.1 Descriptions

NOTE

To avoid erroneous alarm signals the system may delay the alarm trigger for No Output and Low Output by up to 30 seconds.



| Alarm/Indicator                                | Alarm priority / state            | Mute | Trigger, description, and visual indication                                                                                                                                                                                                            |
|------------------------------------------------|-----------------------------------|------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| System fault alarm                             | High                              | No   | No output.<br><br>The vaporizer powers down (a) when the mute control (5) is pressed, or (b) after a period of 5 minutes if no user intervention is detected.<br><br>Repeated high priority audio sequence (ten tones).<br><br>All indicators flashing |
| No output                                      | High                              | No   | System output control fault - output stopped.<br><br>Repeated high priority audio sequence (ten tones).<br><br>Indicator 3 flashing                                                                                                                    |
| Total battery discharge - automatic power down | High                              | No   | High priority audio sequence (10 tones).<br>Indicator 3 will flash immediately prior to shutdown.                                                                                                                                                      |
| Low output                                     | Medium                            | Yes  | 1. Fresh gas flow is less than 200 ml/min - output paused.<br>2. Internal condition or fault - output continues<br><br>Repeated medium priority audio sequence - three tones. Indicator 4 flashing                                                     |
| Control dial position during warm-up           | Medium                            | Yes  | Control dial not in zero position.<br><br>Repeated medium priority audio sequence - three tones. Indicator 4 flashing                                                                                                                                  |
| Battery in use                                 | No mains power                    |      | Repeated single audio tone.<br>Indicator 2 flashing                                                                                                                                                                                                    |
| Battery low                                    | Battery in use, but charge is low |      | Repeated single audio tone.<br><br>Indicator 2 flashing rate increases                                                                                                                                                                                 |

# Description

|                                        |                                             |  |                                                                                                                                                                                                                                                 |
|----------------------------------------|---------------------------------------------|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Battery charged                        | Battery power >90%                          |  | Indicator 2 switches off                                                                                                                                                                                                                        |
| Agent level low                        | Vaporizer requires a refill.                |  | Single audio tone, repeated every 60 seconds.<br>Indicator 6 flashing, Indicators 7 and 8 are off.                                                                                                                                              |
| Concentration control position         | Concentration control set at 12% or greater |  | If a concentration of 12% or above is set, a single audio indication (two tones) will sound.<br><br>At settings between 12% and 18%, a single audio indication (two tones) will sound each time the user changes the concentration by 0.5% v/v. |
| Power cable connected to mains supply. |                                             |  | All indicators illuminate, plus audio indication.                                                                                                                                                                                               |
| Warm-up in progress                    | Mains supply connected                      |  | Indicator 1 flashes during warm up                                                                                                                                                                                                              |
| Ready to use                           | Warm-up complete                            |  | Single audio tone.<br>Indicator 1 is on                                                                                                                                                                                                         |
| Powering down<br>Refer to section 6.7  | No output                                   |  | Repeated audio sequence (three tones).<br><br>Indicators 1, 2 (if battery was recharging), and 6, 7, and 8 flash until power off.<br>Indicator 1 or 8 will continue to flash until internal systems have powered down.                          |

## 3.3.2 Alarm Mute

Press the alarm mute control [1] to pause the audible alarm for 2 minutes.

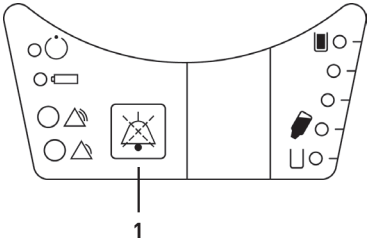
Press the control again to cancel the pause command.

The following alarms cannot be silenced:

- System fault
- No output

### NOTE

- The visual indication of the alarm condition will continue during the audio pause period.
- If a vaporizer self-test is initiated during an alarm mute period, the alarm mute will be released. See section 6.6 .



# Description

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## 3.4 Filler Systems

### 3.4.1 Piramal Fill system

#### WARNING

1. The vaporizer is validated only for use with Piramal desflurane and must only be filled from a Piramal Desflurane bottle.
2. The vaporizer filler system is compatible with the Piramal Fill system for Piramal desflurane.
3. Check the drug name on the supply bottle before commencing the filling process.
4. The vaporizer must be filled only by suitably skilled and trained personnel.

The illustration shows the filler cap (1)

For filling instructions, refer to section 6.2.



### 3.4.2 Baxter SAFE-FIL system

#### WARNING

1. The vaporizer is validated for use only with Baxter Suprane (desflurane) and must only be filled from a Baxter Suprane (desflurane) agent-specific bottle.
2. The vaporizer filler system is compatible with the Baxter SAFE-FIL system for Baxter Suprane (desflurane)
3. Check the drug name on the supply bottle before commencing the filling process.
4. The vaporizer must be filled only by suitably skilled and trained personnel.

The vaporizer filler system comprises the filler cap (1) and filler control bar (2), and is compatible with the SAFE-FIL system and Baxter Suprane (desflurane) anaesthetic agent.

For filling instructions, refer to section 6.3



# Description

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## 3.5 Interlock Systems

### 3.5.1 Selectatec-compatible Interlock System

The Sigma EVA Selectatec-compatible model can be used on a Selectatec Universal Series Manifold backbar in conjunction with other vaporizers (i.e. from other manufacturers) with a compatible interlock system.

#### Interlock activation

1. Initial operation of the concentration control dial (1) activates the interlock system.
2. The interlock bolts (2) move outwards, ensuring that only one vaporizer can be in use at any time.

**The interlock deactivates when the control dial is returned to 0% (zero).**



### 3.5.2 Drager Auto-exclusion and Drager Plug-in interlock systems

1. For correct operation, refer to the user manual for your anaesthetic machine.

#### WARNING

**Before use, always check that the interlock system is functioning correctly.**

# Description

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## 3.6 Electrical Power Supply

### 3.6.1 Mains Power Supply

#### WARNING

Excessive electronic noise caused by poorly regulated devices, such as an electrocautery unit, may affect the functioning of the vaporizer.

Do not power the vaporizer from the same electrical wall outlet or adaptor strip into which an electrocautery unit is connected.

#### WARNING

To avoid the risk of electric shock, this vaporizer must only be used on an anaesthetic machine connected to a mains supply with a protective earth.

#### NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.

#### Power adaptor

The vaporizer is supplied with a mains electrical power adaptor which is connected to the input socket (1).

To isolate the vaporizer from the mains supply, disconnect the cable from the input socket (1) or disconnect the power adaptor cable from the mains supply.

Only use the correct Penlon power adaptor (part number 5007115) with the vaporizer.

#### Anaesthetic machine On/Off control

#### NOTE

Check if the vaporizer power adaptor is connected to an auxiliary electrical mains outlet on the anaesthetic machine.

Note that if an On/Off switch is fitted on the anaesthetic machine, this will then control the electrical supply to the vaporizer.



# Description

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## 3.6.2 Back-up Battery Power Supply

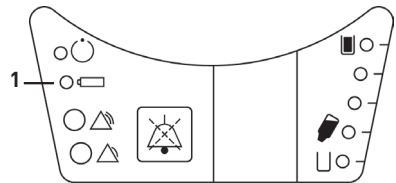
The vaporizer is fitted with an internal battery. In the event of mains supply failure the battery automatically cuts in to power the vaporizer.

A fully-charged battery provides a minimum of 5 minutes backup depending on fresh gas flow rate and concentration setting (see below - **Battery back-up period**)

### Charging the battery

The battery charge level is maintained at maximum when the vaporizer is connected to the mains electrical supply.

The indicator (1) will light continuously while the battery is being charged.



### Mains Power Supply Failure

In the event of mains power supply failure, the back-up battery supply automatically powers the vaporizer.

### WARNING

**Do not refill with agent when the back-up battery is powering the vaporizer.**

1. Changeover is instantaneous, the vaporizer remains in operating mode.
2. A single audio tone sounds, repeated periodically, and the indicator (1) will flash when the battery is in use.

### Battery back-up period

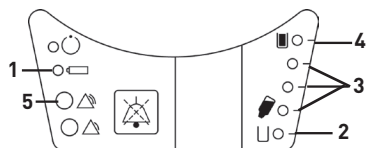
1. A fully-charged battery will power the vaporizer for a minimum of five minutes at the following concentration and flow settings:  
Concentration: 6% set  
Fresh gas flow: 4 L/min  
At higher settings the back-up period may be shortened.
2. The back-up period may extend to a maximum of 30 minutes, depending on fresh gas flow rate and concentration setting.

# Description

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## Note

- a) At approximately five minutes of back-up time remaining, indicators 2, 3, and 4 display a descending sequence, and the audio sounder gives a sequence of three tones.
- b) The audio sequence is repeated at one minute intervals until the end of the back-up period.
- c) **The vaporizer will then automatically power down.**  
**A high priority alarm (audio sequence of 10 tones) will sound and indicator 5 will flash immediately prior to shutdown, to indicate battery discharge.**



# 4. Specification

---

## 4.1 Physical Dimensions

|       |        |          |
|-------|--------|----------|
| Width | Height | Depth    |
| 120   | 256.5  | 273 (mm) |

## 4.2 Weight

Approximate weight (empty): 4.45 kg

## 4.3 Capacity

|                                        |                  |
|----------------------------------------|------------------|
| Maximum Volume                         | 315 ml (nominal) |
| Volume at 'refill required' indication | 70 ml            |

### NOTE

1. When in use the vaporizer will continue to deliver the set concentration until the agent reservoir is nominally empty.
2. When the vaporizer is switched on, a minimum volume of agent is required to complete warm-up mode; i.e. the system will not allow the user to set a concentration until the vaporizer is refilled.

## 4.4 Filler Systems

1. Anaesthetic Agent: desflurane only
2. Use with a 'Piramal Fill' or 'Baxter SAFE-FIL' desflurane agent-specific bottle (refer to section 6.2 (Piramal) or 6.3 (Baxter)).
3. Filling is allowed when the vaporizer is in use.  
Filling is not allowed when the back-up battery is powering the vaporizer
4. Fill time: Approximately one minute (vaporizer at room temperature)

## 4.5 Mounting and Mobility

### Mounting

The EVA vaporizer must be mounted on (1) a Selectatec Universal Series Manifold backbar, (2) a Drager Auto-exclusion backbar, or (3) a Drager Plug-in backbar, on an anaesthetic machine. The vaporizer must be level when in use.

### Transport

The EVA vaporizer can be transported in a filled state by trained clinical staff, e.g. moved between the hospital pharmacy and the operating theatre.

## 4.6 Concentration Control Dial Scale

Concentration output range 1% to 18%

The control dial is marked as follows:

|                     |                          |
|---------------------|--------------------------|
| From 1 to 10% vol   | by intervals of 0.5% vol |
| From 10% to maximum | by intervals of 1% vol   |

The control dial is marked 0% at zero

# Specification

---

## 4.7 Alarms and Information Signals

Note: Refer to section 3.3 for information on individual alarms.

### 4.7.1 Alarms

|                        |                                                       |
|------------------------|-------------------------------------------------------|
| High priority alarms:  | Repeated high priority audio sequence - ten tones     |
| Medium priority alarms | Repeated medium priority audio sequence - three tones |
| Alarm volume           | Sound pressure level - 45-80 dB [A]                   |

### 4.7.2 Alarm mute

Mute period: 2 minutes

Note that the following alarms cannot be silenced:

- System fault
- No output

### 4.7.3 Audible Information signal

Low agent Single tone sounds every 60 seconds

### 4.7.4 Visual Information signal

Flash rate 1.4 to 2.8 Hz (High priority)  
0.4 to 0.8 Hz (Medium priority)

## 4.8 Environmental

### Operating conditions

|                                      |                              |
|--------------------------------------|------------------------------|
| Temperature range                    | 18 to 30°C [64 to 86°F]      |
| Humidity range                       | 30% to 75% RH non-condensing |
| Operating atmospheric pressure range | 70 to 110 kPa                |

### Storage / transport

|                   |                              |
|-------------------|------------------------------|
| Temperature range | -20 to 60°C [-4 to 140°F]    |
| Pressure range    | 11.5 to 110 kPa              |
| Humidity range    | 30% to 75% RH non-condensing |
| Altitude          | Up to 2900 m                 |

### Electromagnetic compatibility:

The EVA meets the requirements of IEC 60601-1-2: Medical electrical equipment; General requirements for safety; Collateral standard; Electromagnetic compatibility; Requirements and tests

### Electromagnetic environment

#### WARNING:

**This equipment is intended for use by healthcare professionals only and may cause radio interference or may disrupt the operation of nearby equipment.**

It may be necessary to take mitigation measures such as (1) reorienting or relocating the Sigma EVA vaporizer (do not remove from the anaesthetic machine backbar), or (2) shielding the location.

**MRI compatibility:** The EVA is not suitable for use in an MRI environment.

## 4.9 Tilting

Maximum tilt angle during operation 10° (any direction)

# Specification

---

## 4.10 Flow Range

Anaesthesia system operating flow range 0.2 to 15 L/min

## 4.11 Flow Resistance

Fresh gas flow resistance is less than 15 kPa with a flow of 15 L/min oxygen

## 4.12 Pressure Range

Maximum manifold pressure 38 kPa (5.5 psi)

## 4.13 Electrical Power Supply

|                                |                                                                                         |
|--------------------------------|-----------------------------------------------------------------------------------------|
| Mains supply to power adaptor  | 100-240 VAC, 2.0-1.0 A, 50-60 Hz                                                        |
| Power unit supply to vaporizer | 12.4 VDC, 5.8 A                                                                         |
| Battery backup time period     | 5 minutes nominal (vaporizer set to deliver a concentration of 6% at a flow of 4 L/min) |

Only use the correct Penlon power adaptor (part number 5007115) with the vaporizer.

### Fuses

#### WARNING

**Fuses are not user accessible. Contact Technical Support at Penlon limited if a replacement fuse is required, see section 8.3.3.**

## 4.14 Warm-up Time

Warm-up time Approximately 10 minutes

Note that warm-up time depends on:

- The temperature of the vaporizer and the temperature of the agent
- The volume of agent in the vaporizer
- The backup battery must be sufficiently charged

## 4.15 Device Classification and Labelling

**Power Supply:** Class I power supply with internal battery back-up

### Ingress Protection:

Classification according to the degree of protection against ingress of water: IPX0 (not protected)

**Mode of operation:** Continuous

**Patient Class** All patient types  
No residual risks from phthalates that are carcinogenic, mutagenic, or toxic to reproduction.

**Labelling** Refer to Appendix 4

## 5. Installation

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### 5.1 Commissioning a new vaporizer

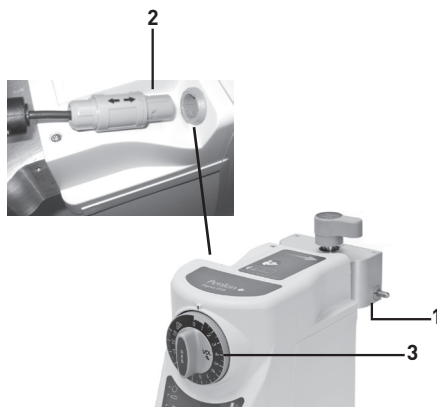
#### 5.1.1 Purge the new vaporizer before use

##### WARNING

Before use on a patient, the vaporizer must be filled with desflurane and purged at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds.

##### Procedure

1. Carefully remove the vaporizer from the packaging.  
If possible, retain the original packaging for use when the vaporizer is returned to Penlon Ltd for a service. This will prevent damage during transit. Refer to sections 8.3.1 / 8.4.
2. Remove the transit seals from the inlet and outlet ports on the connector block (1) at the rear of the vaporizer.
3. Mount the vaporizer on an anaesthetic machine, refer to section 5.2.  
The anaesthetic machine must be equipped with an anaesthetic gas scavenging (AGSS) receiver. The receiver must be connected to an AGSS disposal system terminal unit for extraction of waste anaesthetic gases from the facility.
4. Connect the vaporizer power supply cable (2), refer to section 5.3.1.  
The vaporizer powers up when the power supply is connected to a mains supply outlet.
5. Fill the vaporizer with desflurane. Refer to section 6.2/6.3.
6. The vaporizer progresses automatically through a warm-up period to Standby mode.
7. Set a fresh gas flow of 4 L/min mixture on the anaesthetic machine,
8. Set the concentration dial (3) to 18%.
9. **Important:**  
Purge the vaporizer for a minimum of 30 seconds.



# Installation

---

## 5.2 Installing the Vaporizer on the Anaesthetic Machine

### WARNINGS

1. The vaporizer is a flow direction-sensitive apparatus and the direction of gas flow towards the patient must be as indicated by the arrow (1) on the top label.
2. 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.
3. Patient monitoring:
  - a) Use an anaesthetic agent monitor that complies with the latest relevant standard.
  - b) Always monitor oxygen concentrations.
  - c) Patient monitors must be checked before starting the clinical procedure.
4. Use an anaesthetic gas scavenging (AGS) system to extract expired anaesthetic vapours from the operating theatre. The AGS system must comply with BS EN ISO 80601-2-13.



### Installation

1. Check that the vaporizer concentration control (2) is in the 0% (zero) position.
2. Follow the instructions in the next sections (5.2.1 to 5.4).
3. New vaporizer at commissioning:  
Carry out a leak test and check the vaporizer output - see section 5.5.
4. Reinstalling a vaporizer:  
Carry out the pre-use checks listed in section 6.4.

# Installation

## 5.2.1 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 manifold (1) and the rear panelling/frame (2) of the machine to allow the vaporizer connector block (3) to seal correctly on the manifold (1).

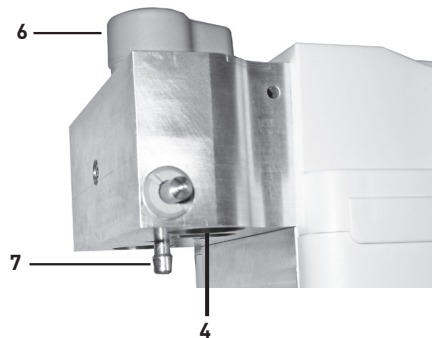
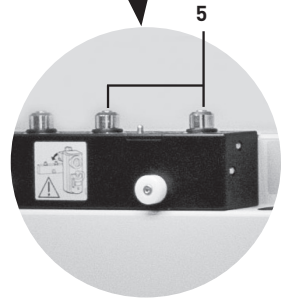


## 5.2.2 Two-station Selectatec Compatible Backbar Manifold

1. Carefully offer the vaporizer up to the manifold.
2. Align the gas connection ports (4) on the underside of the connector block with the valve capsules (5) on the manifold. (The capsules are referred to as valve 'cartridges' 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.
4. Lock into position by pushing the locking lever (6) downwards and rotating clockwise through 90°. The lever must be locked in place correctly to allow a concentration to be set by the user.

### WARNING

To prevent damage to the locking shaft (7), recheck that the gas ports (4) on the vaporizer are correctly engaged with the valve capsules (5) before tightening the locking lever.



# Installation

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## 5.2.3 Three-station Selectatec-compatible Backbar Manifold

### 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.

### Penlon three-station manifold with interlock system

3. Penlon three-station backbar manifolds on anaesthetic machines built from June 2011 are fitted with an interlock system. Please refer to section 5 in the user manual for your Penlon anaesthetic machine.

#### NOTE

- a) If two vaporizers only are installed it is not necessary to ensure that the centre station is occupied.
- b) Always check that the backbar interlock system is functioning correctly.

## 5.2.4 Drager Auto-exclusion and Drager Plug-in interlock systems

1. For correct installation and operation, refer to the user manual for your anaesthetic machine.

#### WARNING

**Before use, always check that the interlock system is functioning correctly.**

## 5.2.5 Interlock system pre-use checks

The operation of the interlock system must be checked as part of the Vaporizer pre-use check list (see section 6.4).

#### NOTE

The interlock system is activated when a concentration is set by the user, but note that the concentration control cannot be activated until the vaporizer is connected to the power supply and has progressed through the warm-up stage to Standby mode.

# Installation

## 5.3 Power Supply

### WARNING

1. Excessive electronic noise caused by poorly regulated devices, such as an electrocautery unit, may adversely interfere with the proper functioning of the vaporizer. Do not connect the power cable for the anaesthetic machine into the same electrical wall outlet or adaptor strip into which an electrocautery unit is connected.
2. The EVA vaporizer is EMC-compliant with all cables, transducers and accessories supplied by Penlon Limited.  
The vaporizer may cause radio interference or may disrupt the operation of nearby equipment - refer to Warning 9 in Section 1.  
The use of cables, transducers and accessories other than those specified may result in increased emissions or decreased immunity of the EVA vaporizer.
3. To avoid the risk of electric shock, this vaporizer must only be used on an anaesthetic machine connected to a mains supply with a protective earth.

### 5.3.1 Connecting the Power Supply

Connect the electrical power adaptor cable to the socket (1) on the vaporizer top assembly.

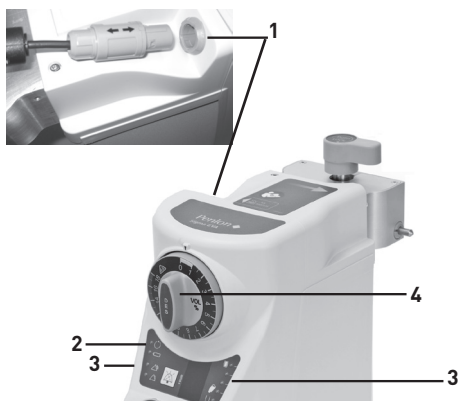
Only use the correct Penlon power adaptor (part number 5007115) with the vaporizer.

### NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.

### Automatic Power-up Cycle

1. The power supply indicator (2) flashes for approximately 5 seconds.
2. Self-validation check: All indicators (3) flash, accompanied by a repeated single audio tone.
3. Warm-up: The power supply indicator (2) flashes.



# Installation

4. The warm-up period is variable, see section 4.14.
5. During the warm-up period the concentration control (4) is locked. It will not be possible to set a concentration.
6. Automatic progression to Standby mode: The power supply indicator (2) is illuminated continuously to confirm Standby mode.



## WARNING

Carry out pre-use checks (see section 6.4) before clinical use.

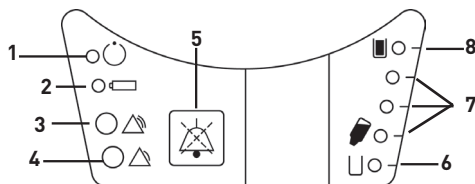
### 5.4 Front Label: Status Indicators and Alarm Mute Control

1. Power indicator
2. Battery indicator
3. Alarm - no output
4. Alarm - low output
5. Alarm mute control

#### NOTE

This control is also used to start a user-initiated self-test function. See section 6.6 .

6. Agent level low (<20%) - refill required. The indicator flashes, accompanied by an audio signal.



## WARNING

If the vaporizer is run dry, refill and then purge the system before use on a patient. Refill with desflurane (refer to section 6.2/6.3).

Purge at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds. Refer to section 5.1

7. Agent level: Graduated indication
8. Agent level >80%

For further information, see section 3.3

# Installation

## 5.5 Leak Check and Output Check: New vaporizers

### WARNING

Before the leak check and output check, and use on a patient, the vaporizer must be filled with desflurane and purged at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds.

See section 5.1.

### NOTE

1. The anaesthetic machine must be equipped with an anaesthetic gas scavenging (AGSS) receiver. The receiver must be connected to an AGSS disposal system terminal unit for extraction of waste anaesthetic gases from the facility.
2. The vaporizer leak check must be preceded by an anaesthetic machine leak check, see section 5.5.2.
3. The output concentration test should be carried out only by trained technicians or a Penlon-trained engineer, using a calibrated, industry standard, agent analyser.

### 5.5.1 Preparation

#### WARNING

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

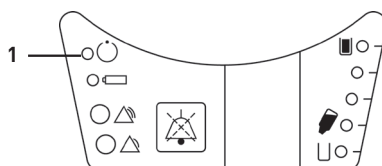
Please refer to the anaesthesia system manufacturer's user manual, but note that some anaesthesia machine manufacturers may not list specific vaporizer checks.

#### WARNING

Keep the vaporizer upright at all times.

Power up the vaporizer; refer to section 5.3.1. The vaporizer must remain in Standby mode for 30 minutes before starting the leak check and output check. The indicator (1) illuminates continuously to confirm Standby mode.

Fill the vaporizer if necessary - follow the instructions in section 6.2/6.3.



# Installation

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## 5.5.2 Anaesthetic Machine Leak Test

Ensure the leak tightness of the anaesthetic machine by performing a backbar manifold leak test as detailed in the anaesthetic machine user instruction manual.

## 5.5.3 Vaporizer Leak Test

### NOTE

Mount the vaporizer on the anaesthetic machine.

The test procedure varies, depending on the compliance of the anaesthetic machine to BS EN ISO 80601-2-13.

Mount the vaporizer on an anaesthetic machine, refer to section 5.2.

The anaesthetic machine must be equipped with an anaesthetic gas scavenging (AGSS) receiver

The receiver must be connected to an AGSS disposal system terminal unit for extraction of waste anaesthetic gases from the facility.

### 5.5.3.1 Leak test for a vaporizer fitted to an anaesthetic machine that complies with BS EN ISO 80601-2-13:

#### NOTE

These machines are fitted with a safety valve with a maximum pressure of 125 cmH<sub>2</sub>O (approximately 92 mmHg).

1. Connect a 0-400 cmH<sub>2</sub>O (0-300 mmHg) gauge to the common gas outlet of the anaesthetic machine.  
Note: If a tee-piece is used to mount the gauge, occlude the tee outlet.
2. Before fitting the vaporizer, use the flowmeter to set a flow of 60 to 80 ml/min, and watch the pressure gauge rise to a steady state.
3. The pressure reading must be greater than or equal to 30 cmH<sub>2</sub>O (approximately 22 mmHg). Record the value.
4. Reset the flowmeter to zero.
5. Fit the vaporizer to the anaesthetic machine - see section 5.2

# Installation

---

6. Connect the electrical power adaptor cable to the socket (1) on the vaporizer top assembly.

## NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.

7. The vaporizer will automatically power-up and progress through self-validation checks and a warm-up cycle to Standby mode. Check that the power supply indicator (2) flashes during warm-up and then illuminates continuously to confirm Standby mode.
8. Set the concentration dial (3) to 9%.
9. Set a flow of 60 to 80 mL/min, and watch the pressure gauge rise to a steady state.

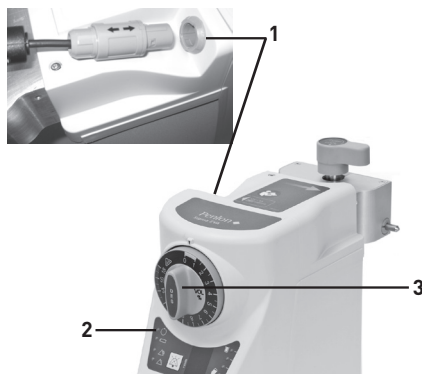
## NOTE

The vaporizer low output alarm will be triggered at this low flow setting - refer to the table shown in section 3.3. The alarm condition will not affect the leak test results.

10. Compare the pressure gauge reading with the value recorded for the anaesthetic machine in operation 3, above. Confirm that the values do not vary.
11. Turn the concentration dial to 0% (zero) and the flow to minimum.
12. Remove the pressure gauge from the common gas outlet.
13. Proceed to section 5.5.4 (Output concentration (calibration) check).

### 5.5.3.2 Leak test for a vaporizer fitted to an anaesthetic machine built before the introduction of BS EN ISO 80601-2-13:

1. Connect a 0-400 cmH<sub>2</sub>O (0-300 mmHg) gauge to the common gas outlet. Note: If a tee-piece is used to mount the gauge, occlude the tee outlet.
2. Fit the vaporizer to the anaesthetic machine - see section 5.2.



# Installation

---

3. Connect the electrical power adaptor cable to the socket (1) on the vaporizer top assembly.

## NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.

4. The vaporizer will automatically power-up and progress through self-validation checks and a warm-up cycle to Standby mode. Check that the power supply indicator (2) flashes during warm-up and then illuminates continuously to confirm Standby mode.
5. Set the concentration dial (3) to 9%.
6. Set a flow to increase system pressure to 200 cmH<sub>2</sub>O (150 mmHg).
7. Check that a flow of less than 200 ml/min is needed to maintain this pressure.

## NOTE:

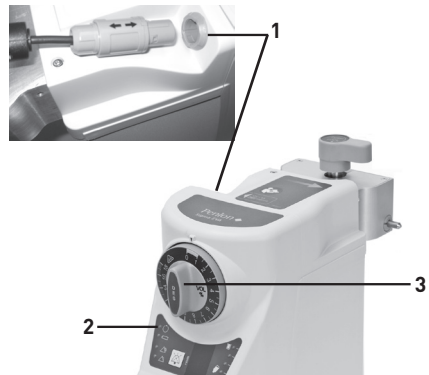
If the anaesthetic machine basal flow is greater than 200 ml/min, check that system pressure is maintained at that basal flow value.

## NOTE:

The vaporizer low output alarm will be triggered at this low flow setting - refer to the table shown in section 3.3.

The alarm condition will not affect the leak test results.

8. Turn the concentration dial to 0% (zero) and the flow to minimum.
9. Remove the pressure gauge from the common gas outlet.
10. Proceed to section 5.5.4, below



# Installation

---

## 5.5.4 Output Concentration Check (calibration)

### Note

**This test is suitable for all machines**

1. Connect an anaesthetic agent analyser to the common gas outlet of the anaesthetic machine.
2. Set an oxygen flow of 4 L/min.  
Set a concentration of 5% or greater.  
Check that the measured output concentration is within  $\pm 20\%$  of the set value.
3. Turn the concentration dial to 0% (zero) and the flow to minimum.  
Note that at zero output the concentration should not exceed 0.1% vol., when tested in accordance with BS EN ISO 80601-2-13.
4. Please contact Penlon Technical Support or your local Penlon-trained engineer if you have any questions or issues regarding the installation and test procedures.

## 6. Operating the Vaporizer

### 6.1 Powering up the vaporizer

1. Check that the vaporizer is fitted correctly to the anaesthetic machine. The backbar locking shaft (1) must be fully engaged.
2. Connect the electrical power adaptor cable to the socket (2) on the vaporizer top assembly.

#### NOTE

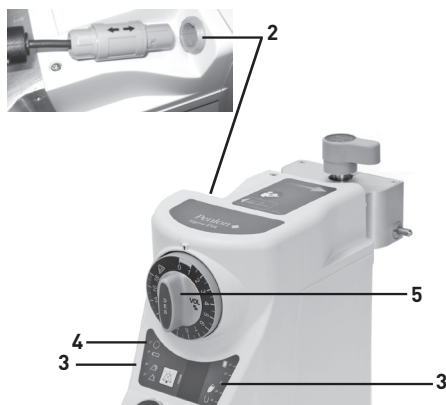
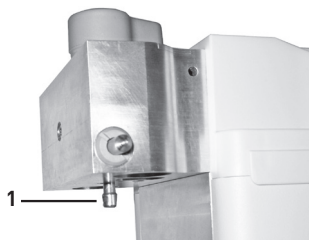
The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.

#### Automatic Power-up Cycle

3. Self-validation check:  
All indicators (3) flash, accompanied by a repeated single audio tone.
  4. Warm-up cycle:  
The power supply indicator (4) flashes.
- NOTE
- a) The warm-up period is variable, depending on the temperature of the agent in the vaporizer.
  - b) During the warm-up period the concentration control (5) is locked. It will not be possible to set a concentration.
5. Automatic progression to Standby mode:  
The power supply indicator (5) is illuminated continuously to confirm Standby mode.

#### WARNING

**Do not use the vaporizer if there is any malfunction. The vaporizer must be checked by a trained engineer.**



# Operating the Vaporizer

---

## 6.2 Filling the Vaporizer - Piramal Fill System

### 6.2.1 Filler System

#### WARNING

If the vaporizer is run dry, refill and then purge the system before use on a patient.

The vaporizer must be filled with desflurane and purged at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds. Refer to section 5.1

#### NOTE

1. Residual agent in the reservoir:  
When the vaporizer is in use the set concentration will be delivered until the reservoir is empty.
2. Filling is allowed when the vaporizer is in use. Check that the agent bottle is at room temperature.
3. The vaporizer filler system is compatible with the Piramal Fill filler system. A Piramal Desflurane bottle must be used. Refer to Warning 2, below.

### 6.2.2 General Warnings

It is important to understand the care required during the filling process.

The Piramal Desflurane bottle is used in a unique manner compared to other agent-specific bottles.

Do not use excessive force during the filling procedure. Rotate the bottle slowly during connection and removal, as described in section 6.2.3.

In addition, read the following warnings before filling the vaporizer:

1. Do not refill when the back-up battery is powering the vaporizer.
2. Check the drug name and drug manufacture's name on the agent bottle before commencing the filling process.  
The vaporizer is designed for use only with Piramal desflurane and must only be filled from a Piramal Desflurane bottle.
3. The vaporizer must be filled only by suitably skilled and trained personnel.



# Operating the Vaporizer

---

4. Do not tamper with the filler system. This may cause a vapour leak.
  - a) The vaporizer filler valve is opened automatically as the bottle is screwed into the vaporizer filler port
  - b) The bottle valve opens automatically when the bottle is screwed further into the vaporizer.
  - c) Do not attempt to open either the bottle valve or the vaporizer filler system valve with a tool or other object.
5. When inserting the bottle, ensure that the threads on the bottle nozzle are correctly engaged before slowly screwing the nozzle in fully.

If the threads are crossed, agent may spray from the bottle if the valve in the bottle nozzle opens, but the vaporizer filler valve is still closed.
6. 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 the vaporizer.
7. The vaporizer must be upright during filling.
8. Do not refill the vaporizer if the agent bottle is cracked or if the filler connector is loose or broken. This may result in contaminated agent entering the vaporizer.
9. If a new bottle of anaesthetic agent is to be used, check that the tamper-evident band is undamaged.
10. Liquid that has been spilled should never be used. Contamination is likely.

Always dispose of this liquid as a hazardous chemical.
11. After filling:

Remove the bottle slowly.  
Refit the bottle cap and vaporizer filler cap.



# Operating the Vaporizer

## 6.2.3 Filling Procedure - Piramal Fill system

### NOTE

1. Fill time: Approximately one minute with the vaporizer at room temperature.  
Filling time is longer if the vaporizer has been in use and the reservoir is in a heated state.
2. The level indicator status may change during warm-up.  
Agent level indication is most accurate when the vaporizer is in Standby mode.
3. Read the Warnings given in section 6.2.2.
4. The vaporizer must be in Standby or operating mode.  
Check that the power supply indicator (1) is illuminated to confirm Standby mode - refer to section 5.3.1.
5. Check the agent level indicators (A, B, C)  
Agent level indication is most accurate when the vaporizer is in Standby mode.
6. If indicator A flashes, or if indicators B are illuminated, refill the vaporizer until indicator C is illuminated.  
The agent reservoir is full.
7. Filling the vaporizer during a clinical procedure.

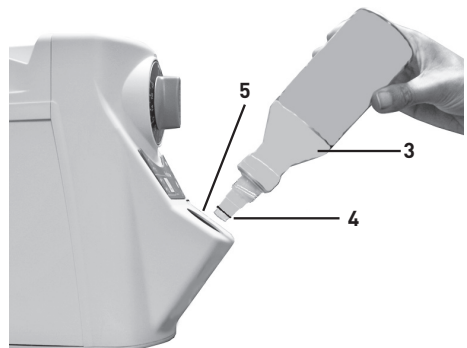
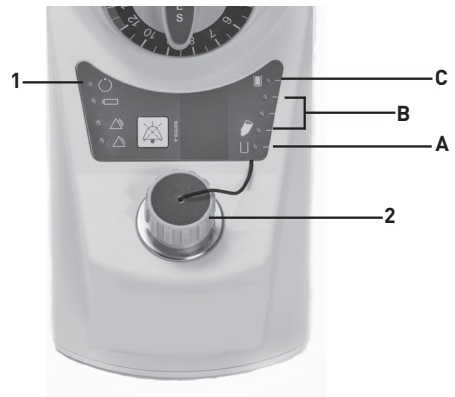
### CAUTION

**a) Check that the agent bottle is at room temperature.**

**b) Do not refill if mains power has failed and the backup battery is in use (refer to section 6.5.4).**

### Start the filling procedure

1. Remove the vaporizer filler cap (2).
2. Check the agent name and expiry date on the bottle (3).  
The vaporizer must only be filled from a Piramal Desflurane bottle.
3. Remove the bottle cap and check that the O-ring (4) is in good condition.
4. Carefully insert the bottle nozzle into the filler port (5) and rotate the bottle slowly clockwise.



# Operating the Vaporizer

## WARNING

Do not use excessive force.

Normal resistance should be felt as you rotate the bottle.

5. Check that the threads on the bottle nozzle have engaged with the threads inside the vaporizer filler port (5) without cross-threading.

## WARNING

Cross-threading may cause the valve in the bottle neck to open prematurely. Desflurane may spray from the bottle.

6. Slowly rotate the bottle (3) until resistance is felt due to the spring in the bottle nozzle.

## WARNING

Do not tilt the bottle.

7. Slowly rotate the bottle and continue until a strong resistance is felt, to fully open the bottle valve.

## WARNING

Do not apply downward force to the bottle during rotation (6).  
Do not tilt the bottle.

8. The bottle filler valve and the vaporizer filler valve are now fully open.

## WARNING

Do not rotate the bottle any further.

9. Hold the bottle firmly in place. Liquid will flow into the vaporizer. The level indicators (B) will illuminate as the level rises in the agent reservoir.

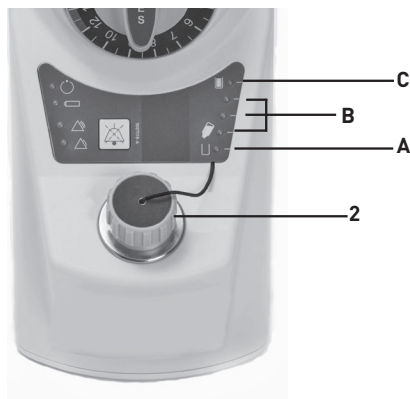
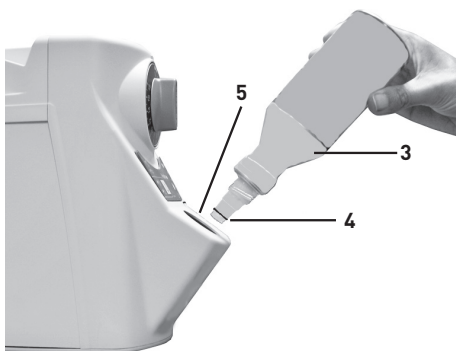
## Ending the filling procedure

10. When the 'agent reservoir full' indicator (C) illuminates, slowly turn the anaesthetic agent bottle counter-clockwise. Do not tilt the bottle.

## WARNING

Do not use excessive force. Rotate the bottle slowly during removal.

11. The spring in the filling adapter helps the valve in the bottle to close. The filling procedure is completed.



## Operating the Vaporizer

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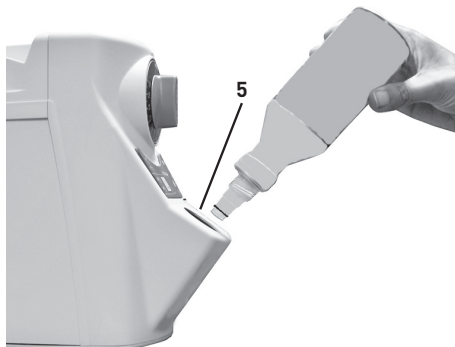
12. Continue to slowly unscrew the bottle and withdraw it from the vaporizer filler port (5). A few drops of desflurane will remain in the filler port. This is normal.

**WARNING**

**Liquid that has been spilled should never be used. Contamination is likely.**

**Always dispose of this liquid as a hazardous chemical.**

13. Refit the bottle cap.
14. Refit the vaporizer filler cap (2). Do not overtighten.



# Operating the Vaporizer

---

## 6.3 Filling the Vaporizer - Baxter SAFE-FIL system

### WARNING

If the vaporizer is run dry, refill and then purge the system before use on a patient. The vaporizer must be filled with desflurane and purged at 4 L/min fresh gas with a concentration setting of 18%. Purge for a minimum of 30 seconds. Refer to section 5.1

### NOTE

1. Residual agent in the reservoir:  
When the vaporizer is in use the set concentration will be delivered until the reservoir is empty.
2. The filling system is compatible with the SAFE-FIL system.
3. Filling is allowed when the vaporizer is in use.

### CAUTION

Check that the new agent bottle is at room temperature.

### 6.3.1 General Warnings

#### WARNING

1. Do not refill when the back-up battery is powering the vaporizer.
2. The vaporizer is designed for use only with Baxter Suprane (desflurane) and must only be filled from a Baxter Suprane (desflurane) agent-specific bottle.  
Check the drug name on the agent bottle before commencing the filling process.
3. The vaporizer must be filled only by suitably skilled and trained personnel.
4. 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.
5. The vaporizer must be upright during filling.



# Operating the Vaporizer

6. Do not refill the vaporizer if the agent bottle is cracked or if the filler connector is loose or broken.

This may result in contaminated agent entering the vaporizer.

7. If a new bottle of anaesthetic agent is to be used, check that the tamper-evident shrink band is undamaged.

8. Do not tamper with the filling system. This may cause a vapour leak.

9. Liquid that has been spilled should never be used. Contamination is likely.  
Always dispose of this liquid as a hazardous chemical.

10. After filling:

Remove the bottle.

Refit the vaporizer filler cap.

Refit the bottle cap.



## 6.3.2 Filling Procedure: Baxter SAFE-FILL

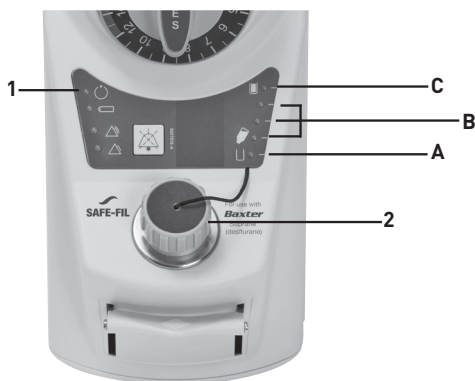
### NOTE

1. Fill time: Approximately one minute with the vaporizer at room temperature.  
Filling time is longer if the vaporizer has been in use and the reservoir is in a heated state.
  2. The level indicator status may change during warm-up.  
Agent level indication is most accurate when the vaporizer is in Standby mode.
1. Read the Warnings given in section 6.2.2.
  2. The vaporizer must be in Standby or operating mode.  
Check that the power supply indicator (1) is illuminated to confirm Standby mode - see section 5.3.1.
  3. Check the agent level indicators (A, B, C):

### NOTE

Agent level indication is most accurate when the vaporizer is in Standby mode.

- a) If indicator A flashes, a full 240-ml bottle of Suprane (desflurane) can be used to refill the vaporizer.



# Operating the Vaporizer

- b) If indicators B are illuminated:  
Refill until indicator C is illuminated.  
The agent reservoir is full.
4. Filling the vaporizer during a clinical procedure:
  - a) Check that the agent bottle is at room temperature.
  - b) Do not refill if mains power has failed and the backup battery is in use [see 6.5.4].
5. Remove the vaporizer filler cap [2].
6. Check the agent name and expiry date on the bottle [3].
7. Remove the cap and insert the bottle nozzle into the filler port [4].
8. Push the filler valve control bar [5] down, and hold in place [6].
9. The bottle will be drawn into the filler port, and held in position while the control bar is held down [6].

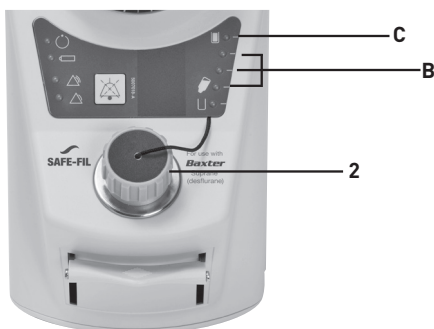
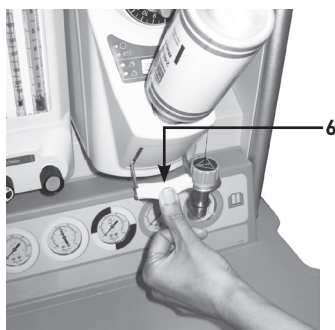
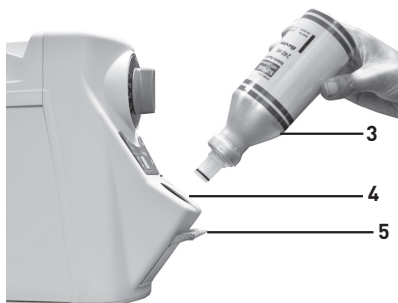
## CAUTION

**Do not release the control bar [5].**

10. Liquid will flow into the vaporizer.  
The level indicators (B) will illuminate as the level rises in the agent reservoir.
11. When the 'agent reservoir full' indicator (C) illuminates, or when the bottle is empty, hold the bottle and raise the filler valve control bar [5].
12. The bottle will disengage as the control bar is raised.
13. Remove the bottle, refit the bottle cap.
14. Refit the vaporizer filler cap [2].  
Do not overtighten.

## WARNING

**Liquid that has been spilled should never be used. Contamination is likely.  
Always dispose of this liquid as a hazardous chemical.**



# Operating the Vaporizer

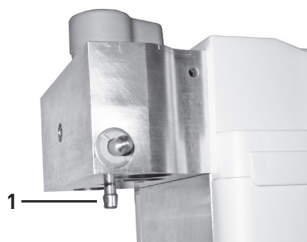
## 6.4 Daily Pre-use Check List

### WARNING

1. The daily pre-use checks for the vaporizer must be carried out as part of the anaesthesia system check.
2. The check must include a backbar manifold leak test. Refer to the anaesthesia system manufacturer's user manual.
3. Do not use the vaporizer if there is any malfunction. The vaporizer must be checked by a trained engineer

### Checklist

1. Check that the vaporizer is fitted correctly to the anaesthetic machine . The backbar locking shaft (1) must be fully engaged.



2. Connect the electrical power adaptor cable to the socket (2) on the vaporizer top assembly.

### NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied when the power cable is connected to a mains supply outlet.



3. The vaporizer will automatically power-up. Check that all the indicators illuminate and the audio sounder operates.
4. The vaporizer will progress through self-validation checks and a warm-up cycle to Standby mode.  
Check that the power supply indicator (3) flashes during warm-up and then illuminates continuously to confirm Standby mode.



### NOTE

- a) The warm-up period is variable, depending on the temperature of the agent in the vaporizer.
- b) During the warm-up period the concentration control is locked. It will not be possible to set a concentration.

# Operating the Vaporizer

---

## 5. Self-test

- a) If the vaporizer has been powered up previously and is already in Standby mode, a self-test can be initiated by the user, as follows.
  - b) Press and hold the mute control (4) for five seconds.
  - c) The test will run.  
Check that each indicator illuminates and the audio sounder operates.  
The vaporizer will return to Standby mode.
6. Check the agent level (5).  
Refill if necessary, see section 6.2/6.3.
7. Check that the filler port cap (6) is secure.
8. Set an oxygen flow of 4 L/min.  
To operate the vaporizer push in the dial assembly (7) and rotate anti-clockwise.  
Set a concentration of 5%.
9. Check for correct agent delivery concentration – use an agent analyser.  
Check that the measured output concentration is within  $\pm 20\%$  of the set value.
10. Function test the interlock system.
- a) Mount another Selectatec-compatible interlock vaporizer on the machine backbar, adjacent to the Sigma EVA.
  - b) Push in the concentration control dial assembly (7) and rotate anti-clockwise
  - c) Check that the interlock bolt (8) moves outwards so that only one vaporizer at a time can be turned on.
  - d) Check that the interlock deactivates when the control dial is returned to the locked-out zero position.



# Operating the Vaporizer

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## 6.5 Operating Mode

### 6.5.1 Vaporizer Delivering Agent

1. Check that the power supply indicator (1) is continuously illuminated.
2. Set the required fresh gas flow on the anaesthetic machine (within the range 0.2 to 15 litres/min).
3. Push in the dial assembly (2) and rotate anti-clockwise to set the required agent concentration (must be greater than 1%).
4. The vaporizer will commence delivery of agent into the fresh gas flow.  
Refer to section 7.1 for variation of concentration output with flow rate.

#### NOTE

- a) If a concentration of 12% or above is set, a single audio indication (two tones) will sound.
- b) At settings between 12% and 18%, a single audio indication (two tones) will sound each time the user changes the concentration by 0.5% v/v.

### 6.5.2 Alarm Mute Control

1. Press the audible alarm mute control (3).  
The audible alarm will be silenced for 2 minutes.
2. Press the control again to cancel the silence command.

#### NOTE

The following system fault condition alarms cannot be silenced:

1. System fault.
2. No output



# Operating the Vaporizer

## 6.5.3 Refilling the Vaporizer

The vaporizer can be filled when in use.

Piramal FILL system: refer to sections 6.2.

Baxter SAFE-FIL system: refer to section 6.3.

Read the warnings and follow the procedure given in those sections before filling.

**Do not refill with agent when the back-up battery is powering the vaporizer.**

## 6.5.4 Vaporizer Operating on Back-up Battery Power

### WARNING

**Do not refill with agent when the back-up battery is powering the vaporizer.**

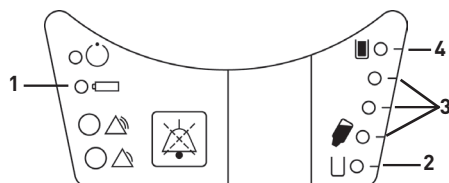
1. If the battery is in a charged state, changeover is instantaneous if the mains power supply fails. The vaporizer remains in operating mode.
2. A single audio tone sounds, repeated periodically, and the indicator (1) will flash when the battery is in use.

### Battery back-up period

1. A fully-charged battery will power the vaporizer for a minimum of five minutes at the following concentration and flow settings:  
Concentration: 6% set  
Fresh gas flow: 4 L/min  
At higher settings the back-up period may be shortened.
2. The back-up period may extend to a maximum of 30 minutes, depending on fresh gas flow rate and concentration setting.

### Note

- a) When approximately five minutes of back-up power remains, indicators 2, 3, and 4 display a descending sequence, and the audio sounder gives a sequence of three tones.
- b) The audio sequence is repeated at one minute intervals until the end of the back-up period.



# Operating the Vaporizer

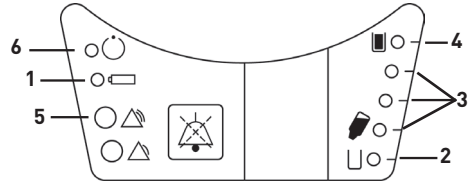
The vaporizer will then automatically power down.

A high priority alarm (audio sequence of 10 tones) will sound and indicator 5 will flash immediately prior to shutdown, to indicate battery discharge.

## Recharging the battery

The battery will be recharged automatically when the mains electrical supply is restored.

1. The power status indicator (6) will flash until battery charge is at a safe level to provide at least five minutes of battery back-up.
2. The back-up battery indicator (1) will light continuously until the battery is fully charged.

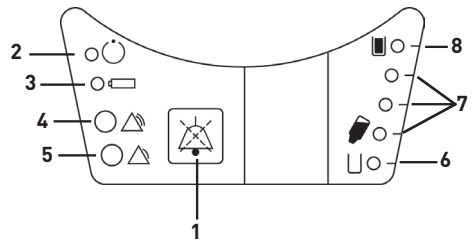


## 6.6 Vaporizer Self-test: User Initiated

With the vaporizer in Standby mode, the user can initiate a brief self-test sequence.

This may be required between clinical procedures.

1. Press the mute control (1) (and hold for five seconds) to initiate a vaporizer self-test.
2. Check that all indicators (2 to 8) flash and the audio sounder operates during the test sequence.  
The vaporizer will return to Standby mode.
3. Do not use the vaporizer if there is any malfunction.  
The unit must be checked by a trained engineer.



## 6.7 Powering down the Vaporizer

1. Set the vaporizer concentration control (1) to the 0% (zero) position.  
The vaporizer will revert to Standby mode.
2. Disconnect the power supply cable (2).  
The vaporizer will automatically exit operating mode and power down.



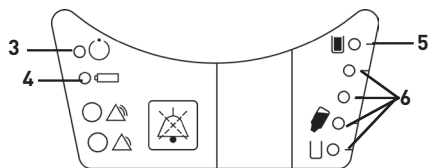
# Operating the Vaporizer

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3. Indicators 3, 4 (if the battery was recharging) and 5 and 6 will flash, accompanied by a repeated sequence of three tones.
4. Indicator 3 or indicator 5 will continue to flash until all internal systems have powered down.

## WARNING

1. Do not reconnect the power cable during this period.
2. If the vaporizer is running on battery power and the control (1) is set to zero, the vaporizer will automatically start the power-down sequence.



## 6.8 Removing the Vaporizer

1. Power the vaporizer down - see section 6.7.
2. Rotate the locking lever 90° anti-clockwise (1) and carefully lift the unit vertically until clear of the backbar.

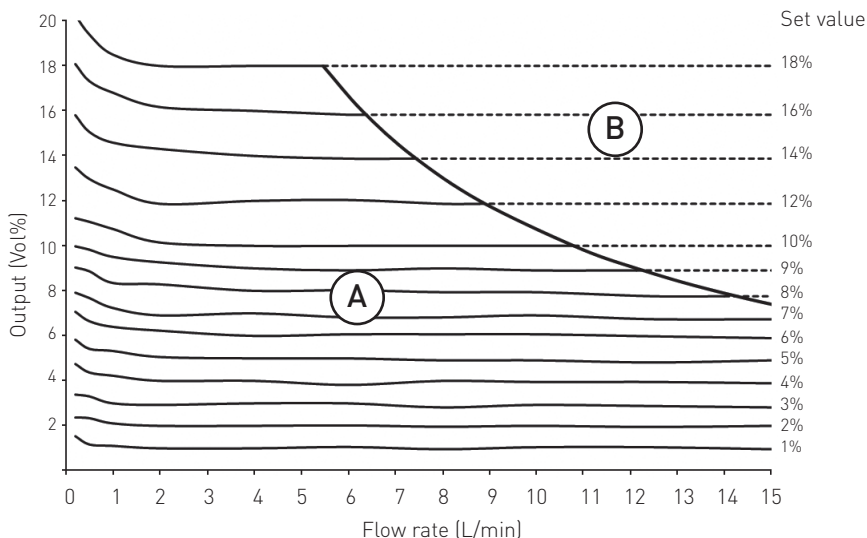


## 6.9 Storing the Vaporizer

1. Check environmental conditions - see section 4.8.
2. For a period of prolonged storage, check the expiry date of the residual agent in the vaporizer reservoir.
3. When the vaporizer is brought out of storage, carry out the pre-use checks detailed in section 5.5

## 7. Performance Characteristics

### 7.1 Output Performance Graph



Variation of concentration output with flow rates is shown.

#### NOTE

1. Concentration output figures shown graphically were compiled from average test results from a number of vaporizers.
2. The output from individual units may vary slightly from the performance curve shown.  
An anaesthetic agent monitor should be used during clinical procedures.

#### Output at high flows and set concentrations

Within area A, the vaporizer delivers output concentrations within the tolerance specified in BS EN ISO 80601-2-13.

#### WARNING

Within area B, at high flow rates and high agent concentration levels (indicated by the blue line (1) on the dial), vaporizer output will be lower than the set concentration.

#### NOTE

A low-output alarm may be triggered (see section 3.3.1).



# Performance Characteristics

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## 7.2 Summary of Performance Specifications

### 7.2.1 Output Accuracy

The vaporizer delivers output concentrations within the tolerance specified in BS EN ISO 80601-2-13 when set concentrations and flow rates are within area A on the graph shown in section 7.1.

### 7.2.2 Calibration Conditions

Temperature: 20°C ±3°C

Ambient pressure 101.3 kPa

Flow rate: 4 L/min O<sub>2</sub>

At the calibration conditions listed above, the output will not deviate from the set concentration by more than ±15% from the concentration setting, or by more than ±0.9% v/v of the maximum setting, whichever is greater.

## 7.3 Ambient Temperature Effects

Changes in ambient temperature have a minimal effect on vaporizer output. The temperature of the liquid desflurane in the reservoir is controlled electronically through temperature sensors and a heating element.

Within the specified operating temperature range the vaporizer delivers output concentrations within the tolerance specified in BS EN ISO 80601-2-13.

## 7.4 Carrier Gas Composition

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 will not affect output concentrations within the tolerance specified in BS EN ISO 80601-2-13.

## 7.5 Control Dial in 'Off' Position

The output vapour concentration when the control is in the 'Off' position (i.e. set at 0%) will not exceed 0.1% vol (tested in accordance with BS EN ISO 80601-2-13).

# Performance Characteristics

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## 7.6 Effect of Flush Valve Operation

When tested in accordance with BS EN ISO 80601-2-13 the operation of the flush valve on the anaesthetic machine will not affect the concentration tolerances for anaesthetic agent output specified in that standard.

## 7.7 Ambient Pressure and Altitude Dependency

The vaporizer is calibrated in %vol and the calibration is not affected by ambient pressure changes.

The partial pressure of the delivered output at any particular dial setting varies directly with the changes in ambient air pressure.

The required dial setting can be calculated using the following formula:

$$\text{Required setting} = \text{Normal dial setting} \times \frac{1013 \text{ mbar}}{\text{Ambient pressure (mbar)}}$$

## 7.8 Effect of Back Pressure and Sub-atmospheric Pressure

Fluctuating back pressure and sub-atmospheric pressure, when tested in accordance with BS EN ISO 80601-2-13 do not affect the output concentration within the tolerances specified in that standard.

Steady back pressure or sub-atmospheric pressure do not affect the agent delivered in %vol but do change the partial pressure of the agent as described in section 7.7 above.

## 7.9 Effect of Tilting

Within the specified tilting angle range during operation, the vaporizer delivers output concentrations within the tolerance specified in BS EN ISO 80601-2-13.

Refer to section 4.9.

## 8. User Maintenance

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### 8.1 User Maintenance

User maintenance by non-technical staff is restricted to cleaning the external surfaces of the vaporizer (refer to section 8.2).

All other maintenance and regular output checks must be carried out only by Penlon-trained engineers (refer to section 8.3).

#### WARNINGS

1. Exterior panels:

**Panels must not be removed by unauthorised personnel and the apparatus must not be operated with such panels missing. There is a possible electric shock hazard. Ensure that all panels are secure after any work by authorised personnel.**

2. Electrical power supply:

**Unauthorised personnel must not attempt to access power supply components, refer to section 8.3.3.**

### 8.2 Cleaning and Disinfection

#### WARNING

1. Disconnect the unit from the electrical supply before cleaning.

2. Do not sterilize, autoclave, or immerse in cleaning solutions or water.

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

3. Do not allow liquid to run into enclosed areas – the filler port, the area behind the concentration control dial, the fresh gas inlet and outlet ports, and the mains electrical socket.

4. Do not clean with solvents or harsh abrasive cleaning agents

#### 8.2.1 Cleaning external surfaces

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

#### 8.2.2 Disinfection

Use proprietary surface disinfectants.

Check active components: Alcohol, aldehydes, and quaternary ammonium compounds are suitable.

Follow the instructions for use issued by the manufacturer.

#### CAUTION

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

# User Maintenance

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## 8.2.3 After cleaning

Make sure that all cleaning agent residues are fully removed after cleaning.

Always allow the vaporizer to dry off thoroughly before reconnection to the electrical supply and clinical use.

## 8.3 Service and Repair

### 8.3.1 Service schedule

Every 6 months:      Operational checks,  
                                 including vaporizer output

Every 2 years:        Return to Penlon Ltd in the  
                                 UK for a full service,  
                                 including fitment of the  
                                 vaporizer preventive  
                                 maintenance kit.

### 8.3.2 Technical Support Contacts

For any enquiry regarding servicing or repair of the vaporizer, contact your Penlon Distributor, or communicate directly with:

#### **UK and International**

Penlon Limited, Abingdon Science Park  
Abingdon, OX14 3NB, UK

Tel:            +44 (0) 1235 547060

Fax:            +44 (0) 1235 547061

E-mail: [tech.support@penlon.com](mailto:tech.support@penlon.com)

Always provide the following information:

1. Type of equipment
2. Product name
3. Filler type (Piramal or Baxter)
4. Serial number
5. Approximate date of purchase
6. Apparent fault

# User Maintenance

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## 8.3.3 Unauthorized Service or Repair

### WARNING

**This vaporizer must not be serviced, modified, repaired, or disassembled by an unauthorised person.**

**Refer to section 8.3.1.**

### Exterior panels

Exterior panels must not be removed by unauthorised personnel

### NOTE

A label is fixed across the vaporizer rear panel, bearing the words:

GENUINE PART.

LABEL TAMPERING VOIDS WARRANTY.

When the outer body panels of the vaporizer are removed this label will be damaged beyond repair. This will be 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 and checked by Penlon Limited.

### Electrical Power Supply

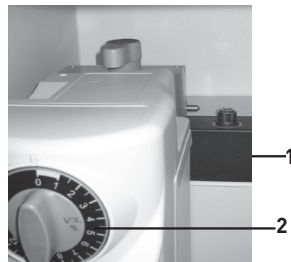
Unauthorised personnel must not attempt to access or replace:

- the power supply adaptor and mains cable
- the back-up battery
- fuses

Repair work must be carried out only by Penlon-trained engineers.

## 8.3.4 Service Checks

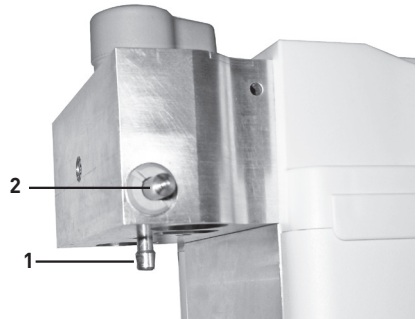
1. The output of the vaporizer must be checked every 6 months, either:
  - a) as part of a Penlon Service Contract (UK only).
  - b) by a Penlon-trained engineer.
  - c) by a suitably qualified hospital technician if calibrated agent analysis equipment is available.
  - d) The measured figures must be recorded.
2. The vaporizer must be mounted on a backbar (1) to allow the concentration control (2) to be turned on.
3. The measured figures must be analysed to determine if performance is deteriorating.  
The vaporizer must be serviced to restore normal operation.  
Contact Technical Support at Penlon Ltd.



# User Maintenance

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4. The Selectatec-compatible vaporizer locking system should be inspected during the vaporizer calibration test.  
If damage to the locking shaft (1) is suspected, the device must be referred to a Penlon-trained engineer.
5. Interlock system - Selectatec compatible:  
Function test the interlock system during the vaporizer calibration test.  
Mount another Selectatec-compatible interlock vaporizer on the machine backbar, adjacent to the Sigma EVA.  
When a concentration is set, check that the interlock bolt (2) moves outwards so that only one vaporizer at a time can be turned on.
6. Interlock system - Dräger Auto-exclusion and Plug-in compatible models:  
For correct operation, refer to the user manual for your anaesthetic machine.



## NOTE

Before using the vaporizer, the user must ensure that the above checks have been carried out, and that any necessary corrective actions have been completed.

## 8.4 Returning the Vaporizer for Service or Repair

### Returning the vaporizer to Penlon Ltd

Contact Technical Support at Penlon Ltd (tech.support@penlon.com) for instructions before returning the vaporizer.

## NOTE

1. Do not return a vaporizer until you have received confirmation from Penlon Technical Support.
2. Follow your Hospital decontamination protocol before returning the vaporizer.
3. If possible, always use the original packaging, to prevent damage during transit.

## 9. Appendix

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### Appendix 1. Disposal at end of useful life: Risk assessment

Do not dispose of in landfill, refer to an approved recycling facility.

Follow your hospital, local, state and federal regulations.

EC territories: follow the requirements of Directive 2002/96/EC



### Appendix 2. Optional extras and approved accessories

#### WARNING

**Only use accessories approved by Penlon Ltd.**

Please contact Penlon Ltd. (see below), or your local Penlon Distributor.

#### UK Sales

Tel: 01235 547036

E-mail: [uk.sales@penlon.com](mailto:uk.sales@penlon.com)

#### International Sales

Tel: +44 1235 547001

E-mail: [international.sales@penlon.com](mailto:international.sales@penlon.com)

# Appendix

## Appendix 3. Vaporizer system modes

### 1. Power-up mode

The user must connect the vaporizer to a mains power supply.

#### NOTE

The vaporizer is not equipped with an On/Off switch. Power is supplied to the vaporizer when the power cable is connected to a mains supply outlet.

#### WARNING

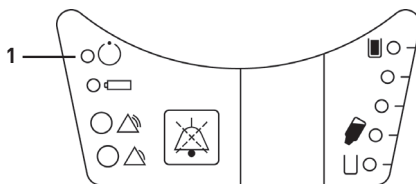
**The vaporizer will not progress to Standby mode if a mains supply is not connected.**

#### Power-up sequence

1. System self-diagnostic tests and automatic progression to Warm-up mode

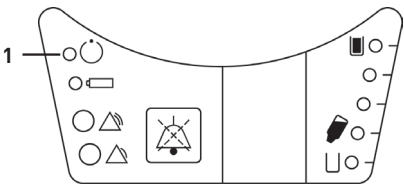
### 2. Warm-up mode

1. The power indicator (1) will flash.
2. Warm-up time depends on the temperature of (a) the vaporizer, and (b) the temperature and volume of the agent.
3. The user will not be able to set a concentration level during warm-up
4. Warm-up sequence
  - a) System self-tests, including:
  - b) Check that the control dial (2) is in the '0%' position
  - c) Agent temperature check, and activation of the agent heater system if necessary.
  - d) Agent level displayed.
  - e) Note, warm-up will not be completed if:
    - i. A system fault is detected
    - ii. The system detects that the battery does not have enough power for safe shutdown (in the event of a mains electrical supply failure).
    - iii. Mains power fails during warm-up.
    - iv. The concentration control (2) is not in the 0% (zero) position.



# Appendix

- f) When warm-up self-tests are completed:
  - i. The vaporizer will release the concentration control dial lock, and progress to Standby mode  
The mains power status indicator (1) will be illuminated continuously, and a single audio tone will sound.
  - ii. The vaporizer will release the concentration control dial lock.



### 3. Standby mode

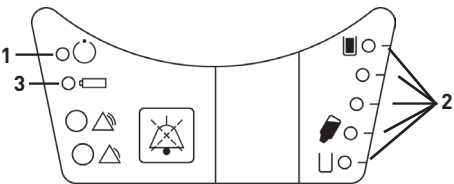
- 1. The vaporizer is held in Standby mode until the user rotates the control dial (2) anti-clockwise and sets a concentration greater than 1%.  
The vaporizer will then automatically progress to Operating mode.
- 2. Note that when the vaporizer is in use, the system will return to Standby mode if the control dial is reset to the zero position.

### 4. Operating mode

- 1. The vaporizer will automatically check for fresh gas flow and commence delivery of agent vapour.
- 2. The vaporizer will exit Operating mode:
  - a) When the user resets the concentration control to 0%.
  - b) During automatic power-down, triggered by:
    - i. Battery power is too low (during mains electrical supply failure)
    - ii. System fault.

### 5. Power-down mode

Power down is indicated by a repeated audio sequence (three tones), and the power status (1) and filler system indicators (2) will flash. Indicator 3 will flash if the battery was recharging. Refer to the instructions and Warnings in section 6.7



# Appendix

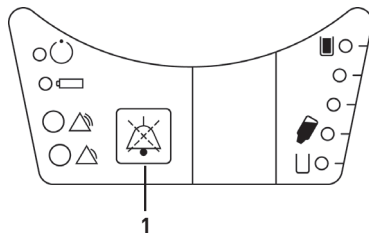
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## 6. Service mode

Service mode is for the use of Penlon-trained service personnel only, and cannot be accessed by the user. Data indicating the software version for the vaporizer can be accessed in this mode.

## 7. System fault mode

1. Visual and audible alarms are triggered. Note that the audible alarm cannot be muted.
2. Delivery of vapour is stopped.
3. The heater unit is switched off.
4. The vaporizer powers down.



### NOTE

- a) The user can start the vaporizer power down sequence in System Fault mode, by touching the alarm mute control (1). Single touch only, do not press the control continuously.
  - b) If no user intervention is detected the vaporizer will power down after a period of 5 minutes.
5. After power-down, wait for 30 seconds.
  6. Disconnect the power cable.
  7. Reconnect the power cable and restart the vaporizer.
  8. If the vaporizer is still in system fault mode, repeat operations 6 and 7.
  9. If the vaporizer is still in system fault mode after three disconnect/reconnect sequences, contact Technical Support at Penlon Limited.

### WARNING

**This vaporizer must not be serviced, modified, repaired, or disassembled by an unauthorised person.**

If necessary, return the vaporizer to Penlon Limited. Refer to section 8.4.

# Appendix

## Appendix 4. Symbols

|                                                                                     |                                                                                                                                     |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
|     | Operating instructions (this user manual)                                                                                           |
|    | Refer to 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)<br>2. Caution (plain background)                                                             |
|    | Power status                                                                                                                        |
|    | Mass                                                                                                                                |
|  | Manufacturer                                                                                                                        |
|  | Desflurane                                                                                                                          |
|  | Mandatory action                                                                                                                    |
|  | Piramal Fill system                                                                                                                 |

|                                                                                     |                                                                                 |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|
|    | Battery status                                                                  |
|    | Alarm - Medium priority                                                         |
|    | Alarm - High priority                                                           |
|    | Alarm mute                                                                      |
|    | Agent reservoir empty                                                           |
|    | Agent level                                                                     |
|  | Agent reservoir full                                                            |
|  | Possible EMC interference in the vicinity of equipment marked with this symbol: |
|  | Action prohibited                                                               |

# Appendix

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## Appendix 5. References

### Standards

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

#### **BS EN ISO 80601-2-13**

Medical electrical equipment. Particular requirements for basic safety and essential performance of an anaesthetic workstation.

#### **IEC 60601-1**

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

#### **IEC 60601-1-2**

Medical electrical equipment - Part 1-2: Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

#### **IEC 62304**

Medical devices software: Software life cycle processes

### Trademarks

Penlon and InterMed and Sigma EVA are trademarks of Penlon Limited.

All other trademarks are the property of their respective owners.

# Appendix

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## Appendix 6. Electromagnetic compatibility (EMC)

### Electromagnetic environment

The EVA vaporizer is suitable for use in the specified electromagnetic environment. The user of the EVA vaporizer should assure that it is used in an electromagnetic environment as described below.

Changes or modifications to this vaporizer, not expressly approved by Penlon Limited, could result in EMC issues with this vaporizer. Contact Penlon Limited for more information.

The use of phones or RF emitting equipment near this vaporizer may cause interference. Always monitor vaporizer operation before and during use on a patient.

The essential performance of the EVA vaporizer is to provide accurate concentrations of anaesthetic drug in the fresh gas supply of anaesthesia gases into a patient breathing system.

### WARNING

The EVA vaporizer should not be used adjacent to or stacked with other manufacturer’s equipment. If adjacent or stacked use is necessary, the vaporizer should be observed to verify normal operation in the configuration in which it will be used.

### Cables, Transducers, and Accessories

#### WARNING

The EVA vaporizer is EMC-compliant with all cables, transducers and accessories supplied by Penlon Limited.

The use of cables, transducers and accessories other than those specified may result in increased emissions or decreased immunity of the vaporizer.

The use of cables, transducers and accessories supplied by Penlon Limited on non-Penlon equipment may also result in increased emissions or decreased immunity of that equipment.

### Cables supplied by Penlon Limited

| Category                        | Function                                                                | Length (m) |
|---------------------------------|-------------------------------------------------------------------------|------------|
| AC link - EVA vaporizer         | Connects the EVA power supply unit to the input socket on the vaporizer | 0.8        |
| AC link - EVA power supply unit | Connects the EVA power supply unit to the mains electrical supply       | 1.0        |

# Appendix

## Guidance and manufacturer’s declaration – electromagnetic emissions

The EVA vaporizer is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

| Required test                                               | Compliance         | Comments                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------|--------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| RF emissions<br>CISPR 11                                    | Group 1<br>Class A | Class A equipment is suitable for use in all locations other than those allocated in residential environments and those directly connected to a low voltage power supply network which supplies buildings used for domestic purposes, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes provided the following warning is heeded |
| Harmonic emissions<br>IEC 61000-3-2                         | Complies           |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies           |                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                                                             |                    | NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.                       |

# Appendix

## Guidance and manufacturer's declaration - electromagnetic immunity

The EVA vaporizer is intended for use in the electromagnetic environment specified below. The customer or user should assure that it is used in such an environment.

| Required test                                                     | 60601 test levels for equipment used in a professional healthcare facility environment only                                                                                                                                                                                                                                           | Compliance level                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2                    | ± 8 kV contact<br>± 2, 4, 8, 15 kV air                                                                                                                                                                                                                                                                                                | ± 8 kV contact<br>± 2, 4, 8, 15 kV air                                                                                                                                                                                                                                                                                                |
| Radiated RF EM Fields<br>IEC 61000-4-3                            | 3 V/m<br>80 MHz to 2.7 GHz                                                                                                                                                                                                                                                                                                            | 10 V/m<br>80 MHz to 2.7 GHz                                                                                                                                                                                                                                                                                                           |
| Proximity fields from RF wireless communications<br>IEC 61000-4-3 | Frequency - Test level<br>385 MHz - 27 V/m<br>450 MHz - 28 V/m<br>710 MHz - 9 V/m<br>745 MHz - 9 V/m<br>780 MHz - 9 V/m<br>810 MHz - 28 V/m<br>870 MHz - 28 V/m<br>930 MHz - 28 V/m<br>1.72 GHz - 28 V/m<br>1.845 GHz - 28 V/m<br>1.97 GHz - 28 V/m<br>2.45 GHz - 28 V/m<br>5.24 GHz - 9 V/m<br>5.50 GHz - 9 V/m<br>5.875 GHz - 9 V/m | Frequency - Test level<br>385 MHz - 27 V/m<br>450 MHz - 28 V/m<br>710 MHz - 9 V/m<br>745 MHz - 9 V/m<br>780 MHz - 9 V/m<br>810 MHz - 28 V/m<br>870 MHz - 28 V/m<br>930 MHz - 28 V/m<br>1.72 GHz - 28 V/m<br>1.845 GHz - 28 V/m<br>1.97 GHz - 28 V/m<br>2.45 GHz - 28 V/m<br>5.24 GHz - 9 V/m<br>5.50 GHz - 9 V/m<br>5.875 GHz - 9 V/m |
| Electrical fast transient / burst<br>IEC 61000-4-4                | ± 2 kV for power supply lines<br>± 1 kV for input / output lines                                                                                                                                                                                                                                                                      | ± 2 kV for power supply lines                                                                                                                                                                                                                                                                                                         |
| Surge<br>IEC 61000-4-5                                            | ± 0.5, 1, 2 kV line(s) to earth<br>± 0.5, 1 kV line(s) to line(s) for power supply lines<br>± 2 kV line(s) to earth for input / output lines                                                                                                                                                                                          | ± 0.5, 1, 2 kV line(s) to earth,<br>± 0.5, 1 kV line(s) to line(s) for power supply lines                                                                                                                                                                                                                                             |

# Appendix

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|                                                            |                                                                                                                                                                     |                                                                                                                                                                    |
|------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Conducted RF<br>IEC 61000-4-6                              | 3 V - 150 kHz to 80 MHz<br>6 V - ISM bands between 150 kHz to 80 MHz                                                                                                | 3 V - 150 kHz to 80 MHz<br>6 V - ISM bands between 150 kHz to 80 MHz                                                                                               |
| Voltage dips and interruptions<br>IEC 61000-4-11           | 0% UT (100% dip in UT) for 0.5 cycle<br>0% UT (100% dip in UT) for 1 cycle<br>70 % UT (30% dip in UT) for 25/30 cycles<br>0% UT (100% dip in UT) for 250/300 cycles | 0% UT (100% dip in UT) for 0.5 cycle<br>0% UT (100% dip in UT) for 1 cycle<br>70% UT (30% dip in UT) for 25/30 cycles<br>0% UT (100% dip in UT) for 250/300 cycles |
| Power frequency (50 Hz)<br>Magnetic field<br>IEC 61000-4-8 | 30 A/m                                                                                                                                                              | 30 A/m                                                                                                                                                             |





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