SPACELABS Healthcare

BleaseDatum®

Anesthesia Vaporizers

User Manual

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Blease Datum® Vaporizers User Manual

Modifications Label				
ECO A PR023022	ECO B PR024135	ECO C PR024600	ECO D	ECO E
ECO F	ECO G	ECO H	ECO I	ECO J

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CE 0123

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This user manual applies to the BleaseDatum® vaporizers, which are identified by the serial number located on the back of the vaporizer.

Read this User Manual before you operate the anesthesia machine!

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Responsibilities of the Manufacturer

The manufacturer accepts responsibility for the effects on safety, reliability and performance of the equipment only if assembly operations, extensions, adjustments, modifications and repairs are carried out by personnel with written authorization from the manufacturer.

BleaseDatum® Service Policy

The BleaseDatum® vaporizers must only be serviced by qualified Global Technical Support personnel. The contents of this manual are not binding. If any significant difference is found between the product and this manual, please contact Spacelabs Healthcare.

The BleaseDatum® is designed to function reliably without the inconvenience of an expensive regular maintenance schedule.

Isoflurane, Enflurane and Sevoflurane vaporizers require full service after 10 years. Halothane vaporizers require full service after 5 years.

Replace broken, worn, missing or contaminated components immediately. Contact your Spacelabs Healthcare representative for assistance.

Responsibilities of the User

The BleaseDatum® vaporizer conforms with the specifications and operating procedures described in this manual and on any accompanying notices and labels only if it has been installed, used and maintained in accordance with the instructions. The safe function of the vaporizer can only be guaranteed if it is regularly checked and serviced at or in excess of the standards specified in this manual.

If the vaporizer is suspected of being worn, defective or otherwise unfit for use, do not use it under any circumstances.

For all communications with Spacelabs Healthcare, quote the model and serial number of the equipment, with the approximate date of purchase. If the equipment is being returned for repair, indicate the nature of the fault or the work you require to be performed.

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CE Marking

CE 0123 The product is labeled with the CE mark and notified body number.

About This Manual

This manual contains all appropriate information concerning the use, function, performance and maintenance of BleaseDatum® vaporizers.
Spacelabs Healthcare has a policy of continued product improvement and therefore reserves the right to make changes which may affect the information contained in the manual without giving prior notice.

Read this manual before operating the vaporizer.

The user must be familiar with the machine and its various functions before using it on a patient.

The terminology in this manual complies with ISO4135, Anesthetic Apparatus Terminology.

Safety Notices

The following symbols are used in this manual to alert you to potential hazards. Be sure to read all of the Warnings and Cautions listed in the Safety Summary section before using the BleaseDatum® Vaporizer with your anesthesia machine.

Warning Notices

Warning notices denote a potential hazard to the health and safety of users and/or patients. These notices clearly state the nature of the respective hazard and the means by which it can be avoided. Warning notices appear in full in the preliminary pages and are repeated at their points of application in the manual.

Caution Notices

Cautionary notices denote a potential hazard to the physical integrity of equipment/software but NOT a danger to personnel. These notices clearly state the nature of the hazard and the means by which it can be avoided.

Notes
This symbol indicates information that is relevant or helpful to the user.

Safety Summary

The following statements are made to comply with the requirements of IEC 60601-1 and ISO 8835-4.

1. Federal law restricts the sale of this device by or on the order of a licensed physician.
2. This device may be sold to and used on the order of a medically qualified practitioner only.
3. While the vaporizer is in use, an anesthetic agent monitor complying with ISO 11196 must be used.
4. Datum vaporizers are intended for use with machines equipped with an anesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3.
5. Each vaporizer is designed for use with one anesthetic agent only, which is identified on the filler.
   - Incorrect dosage may result if the wrong drug is used in the vaporizer.
   - National and international standards are provided for by the keyed filler version of this vaporizer.
6. The anesthetic agent is named on the filler according to BP, USP or Ph EUR. It is the user's responsibility to ensure that the trade name of a drug is equivalent to that used in the appropriate pharmacopoeia.
7. The vaporizer must be secured in the upright position before it is connected to a patient and a leak test performed. Excess dosage may be delivered if the vaporizer is moved suddenly during use.

8. In the interests of health and safety it is recommended that the vaporizer be drained prior to transportation.
   - The concentration control must be set to zero if the vaporizer is transported while filled. The vaporizer must be secured in the upright position for at least one hour before it is connected to a breathing system. It should then be flushed at 4 l/min for two minutes before being connected to a patient.
   - Excess dosage may be delivered if adequate time is not allowed for the liquid to return to its normal level.
   - If the vaporizer has been transported with the concentration control at any position other than zero, contact Spacelabs Healthcare Global Technical Support for assistance.
9. Anesthetic agents are poisonous. Take great care to avoid the spilling of an agent during filling or drainage to prevent the hazard of prolonged inhalation of trace concentrations from the atmosphere. Expired anesthetic gases should be extracted from the operating theatre by an approved anesthetic gas scavenging system.
10. The concentration control must be set to zero during the draining or filling process.
    - The delivered concentration will be incorrect when the filler port is open.
    - The vaporizer must be secured in the upright position during filling in order to prevent overfilling.
11. Do not overfill the vaporizer. If it is overfilled, you must remove it from use. Contact Spacelabs Healthcare Global Technical Support for advice.
12. While the vaporizer is in use, check frequently that the liquid level is between the minimum and maximum marks on the level indicator.
13. The vaporizer may not function correctly if it is exposed to excessive temperatures as the temperature compensation device may be damaged. Store the vaporizer between -20°C and 50°C (-5°F and 122°F).
14. The output of the vaporizer is affected by barometric pressure, and it may be necessary to use a correction factor when analyzing the output, especially at high altitudes [>1500 meters] (See section 7). The barometric pressure is not normally of clinical significance. All BleaseDatum® vaporizers are calibrated at sea level.

15. Anesthetic agents must be treated as pharmaceutical products. Liquid must never be drained into an open container and reused in case of contamination. The liquid must always be disposed of as a hazardous chemical.
16. The vaporizer must never be modified or dismantled by any unauthorized person, but should be serviced at the prescribed intervals by a qualified Spacelabs Healthcare Global Technical Support representative only.
17. The vaporizer must be connected so that the flow of gas to the patient is oriented as indicated by the arrows on the device. The delivered concentration will be incorrect if the flow is reversed.
18. The BleaseDatum® vaporizer has a relatively high flow resistance and must not be incorporated in a breathing system downstream of the common gas outlet.
19. Before use, check all connections for leaks and perform the backbar function tests as described in the user manual for the anesthesia machine.
20. If the vaporizer is fitted with a Selectatec®, Dräger or interlocking Cagemount manifold, the interlock function is void if used with a non-interlock device.

Importance of Patient Monitoring

Anesthesia systems have the capability to deliver mixtures of gases and vapors to the patient which could cause injury or death unless controlled by a qualified anesthetist.

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

Always ensure the use of appropriate patient monitoring and agent analysis whenever posssible.

It is essential that respiration and cardiac function are monitored frequently and regularly and that any observations are given precedence over machine controls.

Symbols & Abbreviations

cmH_2O	Gauge pressure expressed in centimetres of water
O_2	Oxygen
CO_2	Carbon Dioxide
L/pm	liters per minute
ml	milliliter
psi	pounds per square inch
kPa	Kilopascals
mBar	millibars
%Vol.	Percent concentration of agent per total volume
	Date of Manufacture
	Manufacturer
	Confers approval under the European Medical Device Directive and the notified body number
	Caution
	Caution: Attention, see instructions for use
	WARNING: There is danger of personal injury to the user or patient
	Further relevant or helpful information
	Unlocked
	Locked
	Federal law restricts this device for sale by or on the order of a physician.
	Filling
	Push in to turn
	Do not tip when charged

1 - Introduction

The BleaseDatum® Vaporizer is intended for use in the fresh gas supply of a continuous flow anesthesia machine. It should be connected between the flowmeters and the common gas outlet.

Because of the high internal resistance, the vaporizer is unsuitable for use in a breathing system.

The BleaseDatum® Vaporizer provides accurate concentrations of anesthetic gases in the fresh gas supply. The concentration is specified using a dial on the front of the vaporizer. The fresh gas supply should be between 0.5 L/min and 15 L/min. Please consult the instructions for use of the specific agent for appropriate flow rate information. Certain agents are not recommended for use at flow rates below 2 L/min.

2 - Vaporizer Descriptions

Selectatec® Compatible Interlock Model Standard Version

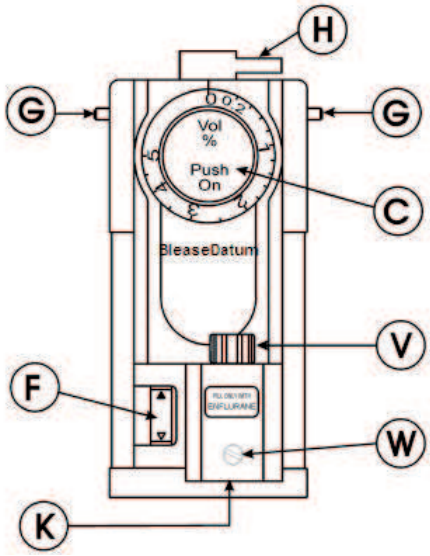

Figure 1: Selectatec Compatible Interlock Model, Standard Version

Figure 1 Key	
C	Concentration Control
F	Level Indicator
G	Interlock Pins
H	Locking Valve
K	Drain Plug
V	Filler Cap
W	Drain Screw

The sight glass markings at **F** in Figure 1 are shown as a filled triangle for the Maximum Liquid Level and an empty triangle for the Minimum Liquid Level.

Cagemount Model Key Filler Version

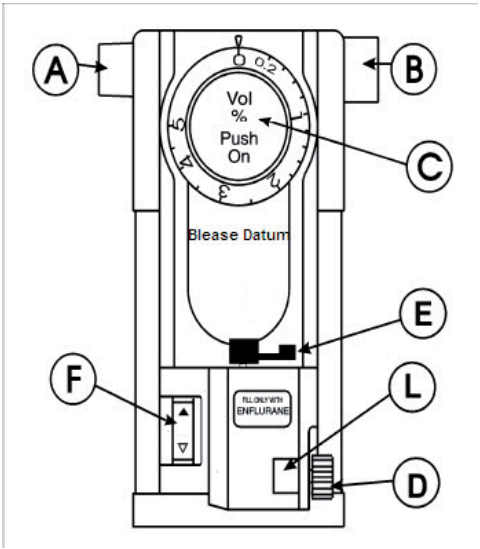

Figure 2 Key	
A	Inlet Connector
B	Outlet Connector
C	Concentration Control
D	Filler Port Clamp
E	Filler Valve Control
F	Level Indicator
L	Filler Port

Figure 2: Cagemount Model Key Filler

The sight glass markings at **F** in Figure 2 are shown as a filled triangle for the Maximum Liquid Level and an empty triangle for the Minimum Liquid Level.

Principles of Operation

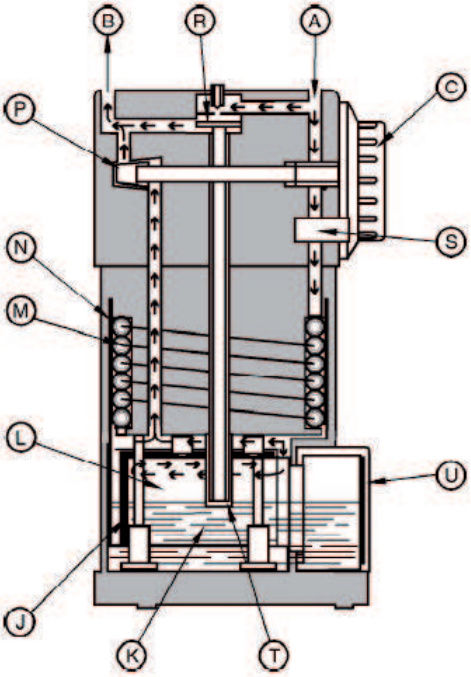

Figure 3: Vaporizer Components

Figure 3 Key	
A	Inlet Connector
B	Outlet Connector
C	Concentration Control
K	Anesthetic Drug in Liquid Form
L	Vapor Chamber
M	Wick (IPPV Coil)

The Blease Datum® Vaporizer is designed and tested for use only with the drug specified on the front panel.

Refer to Figure 3 as you read this section.

The vapor chamber contains the anesthetic drug in liquid form **K**, and the wick **M** and **N** ensures that the upper part of the chamber remains filled with a saturated vapor of the drug.

As the vapor is many times more concentrated than required for clinical use, a concentration control **C** regulates the gas flow through the vapor control valve **P**, the bypass valve **R** and vapor chamber to produce the required concentration.

When the control is set to zero, the bypass remains open; however, the vapor chamber is completely isolated from the patient gas flow. When the control is set to the desired concentration, valve **S** opens allowing flow into the vapor chamber.

The temperature-compensating device **T** varies the dilution ratio provided by the concentration control and bypass passage **R**, so that the output concentration remains substantially constant irrespective of temperature.

The vaporizer may be fitted with a screw-cap filler, a Quik-Fil® filler or a keyed filler.

Concentration Control

The concentration control **C** regulates the concentration of delivered vapor. The dial automatically locks at the zero position when turned to off, and must be pushed inwards and rotated counterclockwise to set a concentration according to the graduations on the dial.

Switching On the Vaporizer

Always verify that the vaporizer is locked onto the manifold before you switch on the vaporizer.

1. Push in the dial and rotate it counterclockwise to the desired concentration, as indicated by the markings on the control knob.

2. When the vaporizer is not in use, the control should be turned to the zero position to prevent any delivery of vapor.

3 - Specifications

Physical Specifications

Vaporizer	Weight (kg)	Capacity (ml, ±25)	Height (mm)	Width (mm)	Depth (mm)
Selectatec Standard	7.5	250	225	114	200
Cagemount Standard	7.3	250	220	137	190
Drager Standard	7.5	250	225	100	175
Selectatec Key Fill	7.5	250	225	114	200
Cagemount Key Fill	7.3	250	220	137	190
Drager Key Fill	7.5	250	225	104	175
Selectatec Quik-Fil	7.5	250	225	114	210
Cagemount Quik-Fil	7.3	250	220	137	200
Drager Quik-Fil	7.5	250	225	100	185

Concentration Control

Halothane, Isoflurane and Enflurane Models

The control dial is graduated in increments of 0.2%Vol. from 0 to 2%Vol., and in increments of 0.5%Vol. from 2 to maximum 5%Vol.

8% Sevoflurane models

The control dial is graduated in increments of 0.25%Vol. from 0 to 2%Vol., and in increments of 0.5%Vol. from 2 to 8%Vol.

The control is marked 0 at the zero (off) position.

Do not use the vaporizer when the control is set between zero and the first graduation mark.

4 - Filling and Draining a Vaporizer

Follow the instructions given for the type of vaporizer you want to fill/drain:

- Standard Screw Cap Fill
- Key Fill
- Quik-Fil

WARNINGS!

1. **Secure the vaporizer in an upright position while filling and draining, either by attaching it to an anesthesia machine or standing it on a flat, level surface. Do not tip the vaporizer during filling.**

2. **Do not use the anesthetic agent bottle to fill the vaporizer if the bottle is cracked or the filler connector is loose or broken. This may result in overfilling or a contaminated agent entering the vaporizer.**

3. **If you are using a new bottle of anesthetic agent, check that the tamper-proof shrink band is undamaged.**

4. **The vaporizer must be filled only by suitably skilled and trained personnel.**

5. **Do not use the vaporizer if the agent level is not visible in the sight glass or the level is outside of the Max-indicators.**

6. **Set the concentration control to zero before filling the vaporizer.**

7. **Check that the anesthetic agent name displayed on the supply matches the name displayed on the front of the vaporizer.**

Standard Screw Cap Fill Vaporizers

This type of vaporizer is not available in all markets.

Filling the Vaporizer

Never fill the vaporizer if gases are flowing through the anesthesia machine.

1. Unscrew the filler cap and place it somewhere safe to prevent contamination.
2. Remove the cap of the supply bottle and fill the chamber slowly and carefully. Check the liquid level regularly, and stop filling when the liquid reaches the Maximum level mark.

DO NOT OVERFILL the vaporizer. If the vaporizer is overfilled, you must remove it from service.

Do not tip the vaporizer during the filling operation because you may overfill it

3. Check that the seal on the filler cap is in place and intact, then replace the cap and tighten it fully to finger-tight.

Do not use the vaporizer if the filler cap is not replaced correctly. This may cause an incorrect dose to be delivered to the patient, and result in significant pollution levels.

Draining the Vaporizer

Secure the vaporizer in an upright position with the concentration control set to zero before you drain it.

1. Unscrew the filler cap.
2. Place a suitable receptacle under the drain plug to catch the liquid.
3. Use the bar in the bottom of the cap to undo the drain screw at least two turns and allow all the liquid to drain into the receptacle.

4. Fully tighten the drain screw, then replace the filler cap.

Tighten the drain plug securely before replacing the filler cap.

Discard anesthetic agent drained from the vaporizer - do not reuse. Treat discarded agent as a hazardous chemical.

Key Fill Vaporizers

Filling the Vaporizer

1. Ensure that the filler control is turned fully counterclockwise (closed).
2. Loosen the clamp screw and remove the slipper block from the filler port.
3. Screw the filler adaptor on to the supply bottle and tighten it fully to ensure it is airtight.
4. Insert the end of the filler adaptor until it stops, into the filler port on the vaporizer. If an incorrect adaptor has been fitted to the supply bottle it will not be possible to insert it into the port.
5. Tighten the clamp screw and ensure that the adaptor is secured.
6. Raise the bottle to a level above the filler port so that any air in the bottle cannot enter the filler tube.
7. Open the filler control port by pulling the lever clockwise until it stops.
8. Fill the chamber to the required level shown on the indicator.

DO NOT OVERFILL the vaporizer. If the vaporizer is overfilled, you must remove it from service.

Do not tip the vaporizer during the filling operation because you may overfill it.

Do not loosen the filler adaptor from the drug container during filling. You may overfill the vaporizer.

9. Push the filler lever back to its original position.
10. Lower the bottle to below the level of the filler port to allow any liquid in the adaptor tube to run back into the bottle.
11. Loosen the clamp screw and remove the bottle adaptor from the filler port.

12. Replace the slipper block into the port and re-tighten the clamp screw.

It is normal for a small amount of liquid to be spilled as the adaptor is removed from the filler port.

Draining the Vaporizer

1. Ensure the filler control is turned fully counterclockwise (closed).
2. Loosen the clamp screw and remove the slipper block.
3. Screw the filler adaptor on to the supply bottle and tighten it fully to ensure it is airtight.
4. Insert the end of the filler adaptor into the filler port on the vaporizer. If an incorrect adaptor has been fitted to the supply bottle, it will not be possible to insert it into the port.
5. Tighten the clamp screw and ensure the adaptor is secured.
6. Keeping the bottle below the level of the filler port, open the filler port by pulling the lever clockwise until it stops.
7. Once the vaporizer is drained, the filler port must be closed by pushing the lever back to its original position.
8. Loosen the clamp screw and remove the bottle adaptor from the filler port.
9. Replace the slipper block and re-tighten the clamp screw.

Discard anesthetic agent drained from the vaporizer - do not reuse. Treat discarded agent as a hazardous chemical.

Quik-Fil Vaporizers

Do not tamper with the filling system valve. Tampering may cause a vapor and fresh gas leak.

Filling the Vaporizer

1. Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to prevent loss of liquid agent.
2. Check that the vaporizer concentration control is in the off ('0') position.
3. Remove the yellow protective cap from the anesthetic agent bottle filler, checking that the bottle and filler mechanism are not damaged.
4. Remove the vaporizer black filler cap (**1**) and insert the bottle nozzle into the filler block. Rotate the bottle to align the bottle filler nozzle keys (**2**) with the index slots (**3**) in the filler block.
5. Note the liquid level in the vaporizer sight glass and press the agent bottle fully into the vaporizer filler block. Allow the liquid to flow into the vaporizer until the maximum level mark is reached, paying continuous attention to the level in the sight glass and the air return bubbles (**4**) flowing into the bottle.
6. Release the bottle when the vaporizer is full and the continuous stream of bubbles ceases.
7. Withdraw the bottle from the vaporizer filler and replace the black filler cap (**1**), and the yellow cap on the agent bottle.

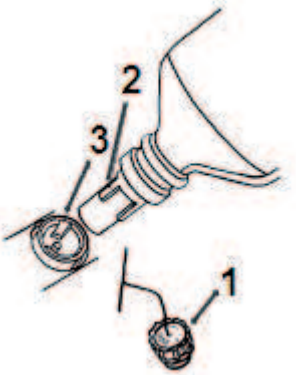

Figure 4 - Fill the Vaporizer

DO NOT OVERFILL the vaporizer. If the vaporizer is overfilled, you must remove it from service.

Do not tip the vaporizer during the filling operation because you may overfill it.

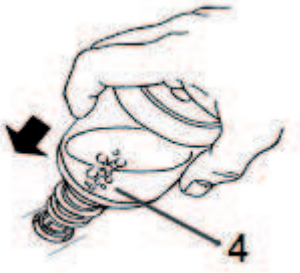

Figure 5 - Air Return Bubbles

Draining the Vaporizer

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

Reattach the black filler cap before using the vaporizer.

Discard anesthetic agent drained from the vaporizer - do not reuse. Treat discarded agent as a hazardous chemical.

1. Remove the cap (**1**) from the vaporizer filler block.

Figure 6 - Remove the Cap

2. Remove the yellow protective cap from an empty Sevoflurane bottle.
3. Insert the bottle nozzle into the drain funnel.
4. Rotate the bottle to align the index slots in the drain funnel (**2**) with the bottle filler nozzle keys (**3**) and screw the drain funnel onto the empty bottle.

Figure 7 - Align the Drain Funnel

5. Fully insert the drain funnel into the keyed drain slot (**4**) in the bottom of the vaporizer filler block.

Figure 8 - Attach the Drain Funnel

6. Remove the drain plug (**5**) with the key (**6**). Continue to drain the vaporizer until empty. Close the drain plug and tighten, and withdraw the drain funnel.

7. Remove the drain funnel from the bottle and reattach the bottle cap (**1** in Figure 6).

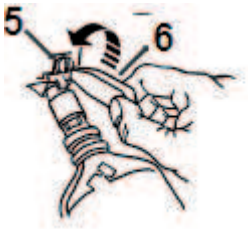

Figure 9 - Remove the Drain Plug

Reattach the black filler cap before using the vaporizer.

5 - Install the Vaporizers

Follow the instructions given for the type of vaporizer you want to install:

- Cagemount Model
- Selectatec®-Compatible Interlock Model
- Drägerwerk® AG-Compatible Model

Install the Cagemount Model Vaporizer

The Blease Datum® Cagemount vaporizer is fitted with the standard 23mm tapers, male (inlet) on the left and female (outlet) on the right, when viewed from the front. There are two M6 threaded studs at the rear of the vaporizer, each fitted with a nut and washer to retain the clamp plate and spacers. The vaporizer can thus be secured to the backbar of the anesthesia machine. You can adjust the distance between the backbar and tapers as required.

1. Secure the vaporizer to the backbar of the anesthesia machine using the studs, nuts, washers and spacers provided.
2. Lightly apply an oxygen-safe grease (such as Fomblin) on the tapers.
3. Push the gas tubing fully onto the appropriate tapers and tighten the fixing nuts.

Ensure that all connections are gas-tight before using the machine.

Perform a backbar function test before using the machine, as described in the anesthesia machine User Manual.

For non interlocking cagemount models, only one vaporizer should be connected at any time.

If the vaporizer is fitted with a Selectatec ® or interlocking Cagemount manifold, the interlock function is void if used with a non-interlock device.

Install the Selectatec®-Compatible Interlock Model Vaporizer

The BleaseDatum® Selectatec®-compatible vaporizer incorporates interlock pins to prevent use when another vaporizer is installed. This model is compatible with the Ohmeda TEC®4, TEC®5, TEC®6 and TEC®7 and the Penlon PPV® Sigma® Selectatec®interlock-compatible models ONLY.

1. Carefully position the vaporizer against the backbar. Ensure that the gas connection ports and button plates are aligned correctly.
2. Lower the vaporizer onto the backbar and ensure that it is correctly seated.
3. Lock the vaporizer into position by pushing down and turning the locking lever on the top fully clockwise to the locked position.
4. Ensure that the vaporizer is locked securely to the backbar, and that the vaporizer manifold is positioned level with and parallel to the top face of the backbar.

Ensure correct alignment and engagement of the gas connection ports and button plate before locking the vaporizer.

Ensure all joints are gas-tight before using the machine.

Perform a backbar function test before using the machine, as described in the Anesthetic Machine's User Manual.

If more than one vaporizer is installed, check that the interlock mechanism works by switching on each in turn and checking that the other will not function. If the interlock fails, the faulty vaporizer must be taken out of service.

The vaporizer dial can be activated without the locking mechanism in place. Always ensure the vaporizer is locked into position before use.

Remove the Selectatec®-Compatible Interlock Model Vaporizer

1. Unlock the vaporizer by turning the locking lever on the top fully counterclockwise to the unlocked position.
2. Carefully lift the vaporizer upwards until it is clear of the backbar.

Install the Drägerwerk® AG-Compatible Model Vaporizer

1. Carefully position the vaporizer against the backbar. Ensure the gas connection ports and button plates are aligned correctly.
2. Lower the vaporizer onto the backbar and ensure that it is correctly seated.
3. Lock the vaporizer into position by turning the locking lever on the top fully clockwise to the locked position.
4. Ensure that the vaporizer is locked securely to the backbar, and that the vaporizer manifold is positioned level with and parallel to the top face of the backbar.

Ensure all connections are gas-tight before using the machine.

Perform a backbar function test before using the machine, as described in the anesthesia machine User Manual.

6 - Routine Care

Do not attempt any adjustment or disassembly of the vaporizer outside the scope of the following instructions.

Cleaning

Clean the exterior of the vaporizer using a clean damp cloth only.

Draining Halothane

The Halothane versions of the Blease Datum® should be drained at intervals (weekly if in regular use) and the liquid disposed of as a hazardous chemical. This is because Halothane contains a stabilizing agent (0.1% thymol) which is only slightly volatile and will accumulate in the vaporizer, eventually causing the output concentration to decrease. The concentration of thymol may also have clinically deleterious effects on the patient (see Rodenburg -Alila: Anaesthesia, 1984: 38: 581-583).

Anesthetic agents may suffer from brown or yellow discoloration if exposed to light and gases for long periods. Discolored anesthetic agents must not be used and should be disposed of as a hazardous chemical.

All vaporizers should be drained of anesthetic agent, if not in regular use, and the liquid disposed of as a hazardous chemical.

Verify Output Concentration

The performance of a vaporizer in clinical use is monitored by observing patient signs and consumption of anesthetic agent. Some hospitals may have a policy of a comparison check against an anesthetic agent analyser to determine any variation from normal. This check may be carried out routinely or as part of a periodic investigation.

Spacelabs Healthcare follows highly specified test conditions and methods which are carried out as part of the production process.

If a hospital requires that calibration verification is performed, observe the following points:

1. Due consideration of the above statement should be taken into account.
2. The test method should be so designed that it follows closely the clinical conditions of use.
3. The sampling technique should be such that it truly represents the output of the unit under test.
4. If a number of units are to be tested together and a consistent error is observed, this is unlikely to be the fault of the vaporizer. The reliability and accuracy of equipment and test set-up should be considered first.
5. Full account of the effects of the carrier gas composition should be considered.
6. If results are unexpectedly different from that expected, the accuracy of test equipment, such as flow meters and analyzers, should be questioned and verified.
7. When the comparative test is done due consideration of the effects of Altitude and ambient temperature should be allowed for. The readings of test equipment and the output of the vaporizer will both vary in sympathy with the conditions. All BleaseDatum® vaporizers are calibrated at sea level.
8. If extremely low readings are recorded on Selectatec® fitting units, the possibility of a cross leak or leak to atmosphere should be considered before suspecting the vaporizer.
9. If in doubt, please contact Spacelabs Healthcare Global Technical Support.

Service Training

Spacelabs Healthcare offers a training course for engineers and technicians who are required to service BleaseDatum® vaporizers. The course includes:

- Leak testing
- Seal replacement
- Internal cleaning
- Major sub-assembly replacement
- Output regulation

The BleaseDatum® Technical Manual contains a description of all the above procedures.

Pre-Use Check

Before using the vaporizers, perform the following verifications.

1. Check that the vaporizer(s) for the required volatile agent(s) are installed correctly to the anesthesia machine, that any backbar locking mechanism is fully engaged and that the control valve(s) rotate through their full range(s). Turn off the vaporizer(s).

2. Check that the flow through each vaporizer is in the correct direction.

3. When filling each vaporizer, ensure that the correct anesthetic agent is used and that the filling port is left tightly closed.

4. For machines that are fitted with a pressure relief valve, perform the following tests. (*Do not perform these tests if the valve is not installed. There may be a dangerous increase in pressure, if these tests are performed in the absence of a pressure relief valve*.)

    a. Set a suitable test flow of oxygen (6-8 L/min), and, with the vaporizer in the “off” position, temporarily occlude the common gas outlet. There should be no leak from any of the vaporizer components, and the flowmeter bobbin will dip.

    b. Repeat this test with each vaporizer in the “on” position. There should be no leak of liquid from the filling port.

5. Turn off the vaporizer(s), and the oxygen flowmeter control valve.

7 - Performance

The Halothane Model

Variation of output with flow rate (T = 22°C) (Air carrier gas)

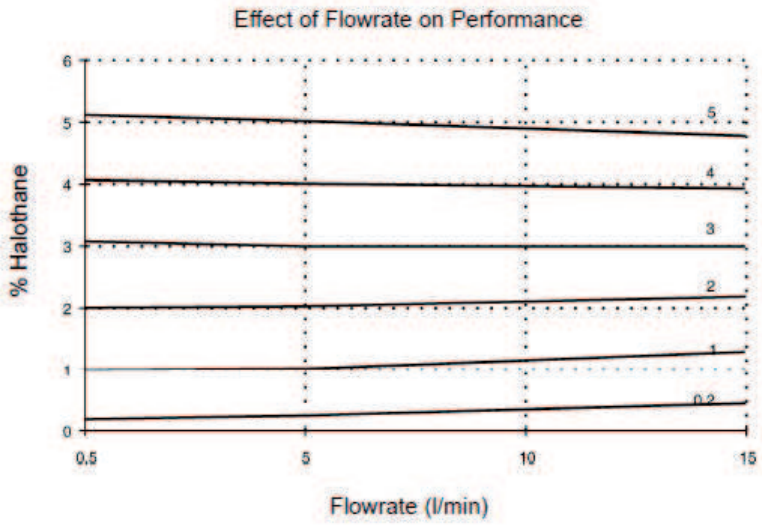

Figure 10 - Effect of Flowrate on Halothane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

Variation of output with temperature (flow rate = 5 L/min Air)

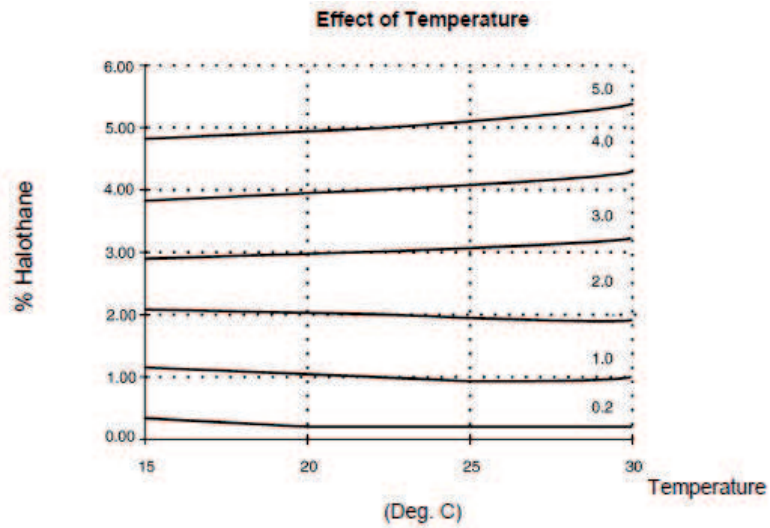

Figure 11 - Effect of Temperature on Halothane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

The Enflurane Model

Variation of output with flow rate (T = 22°C) (Air carrier gas)

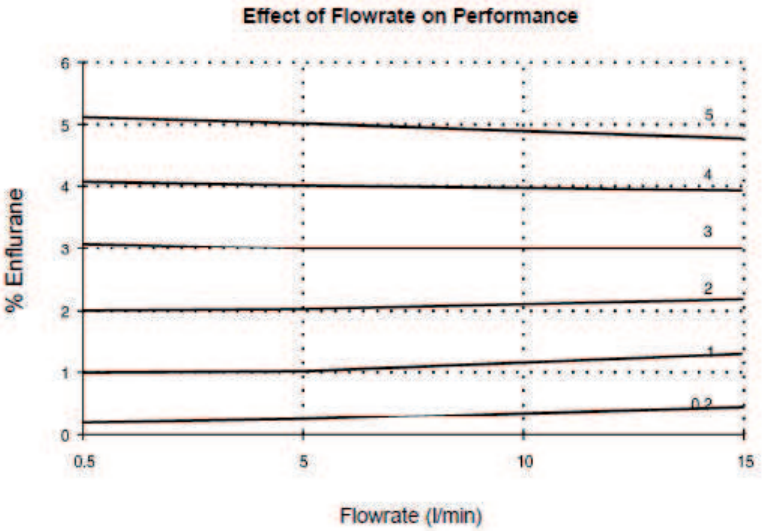

Figure 12 - Effect of Flowrate on Enflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

Variation of output with temperature (flow rate = 5 L/min Air)

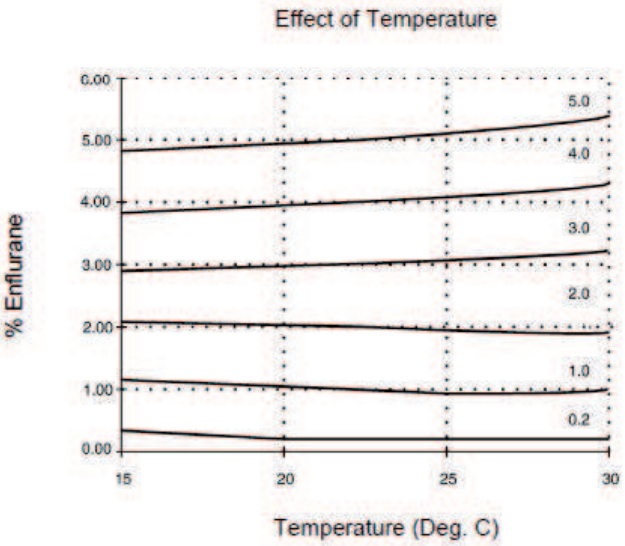

Figure 13 - Effect of Temperature on Enflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

The Isoflurane Model

Variation of output with flow rate (T = 22°C) (Air carrier gas)

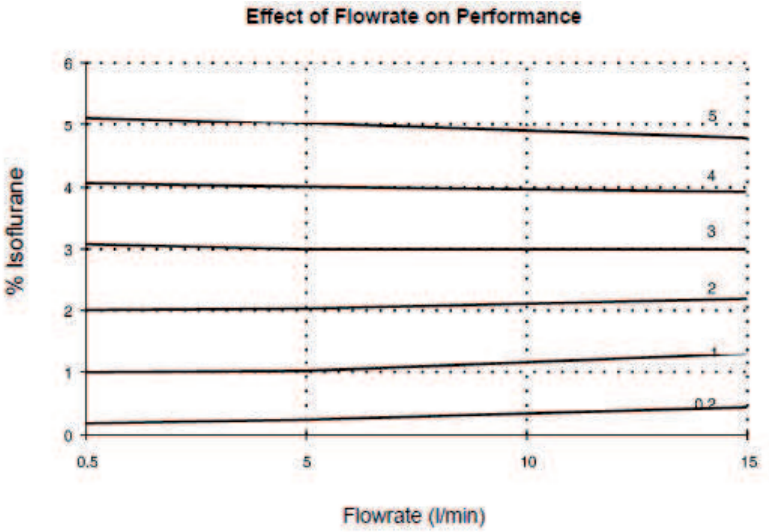

Figure 14 - Effect of Flowrate on Isoflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

Variation of output with temperature (flow rate = 5 L/min Air)

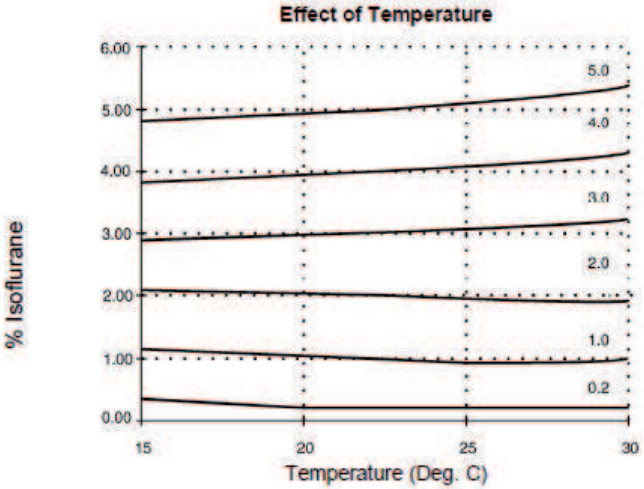

Figure 15 - Effect of Temperature on Isoflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

The Sevoflurane Model

Variation of output with flow rate (T = 22°C) (Air carrier gas)

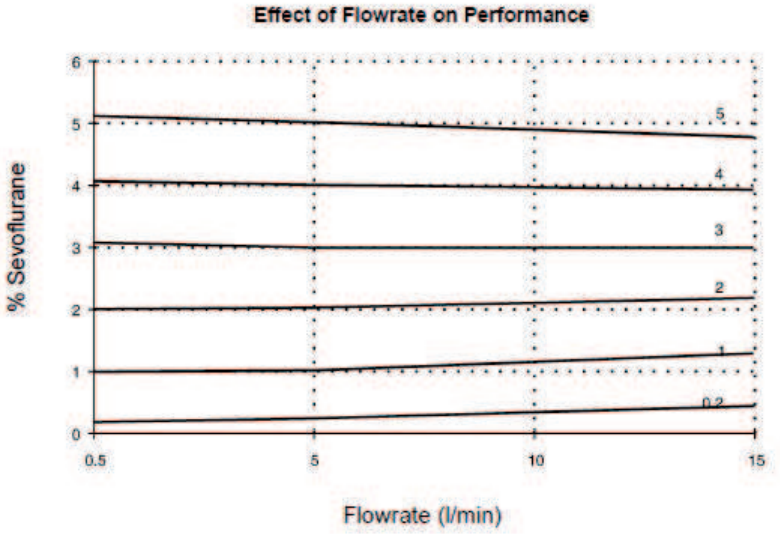

Figure 16 - Effect of Flowrate on Sevoflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

Note: **The performance of the 8% model can be extrapolated from this graph.**

Variation of output with temperature (flow rate = 5 L/min Air)

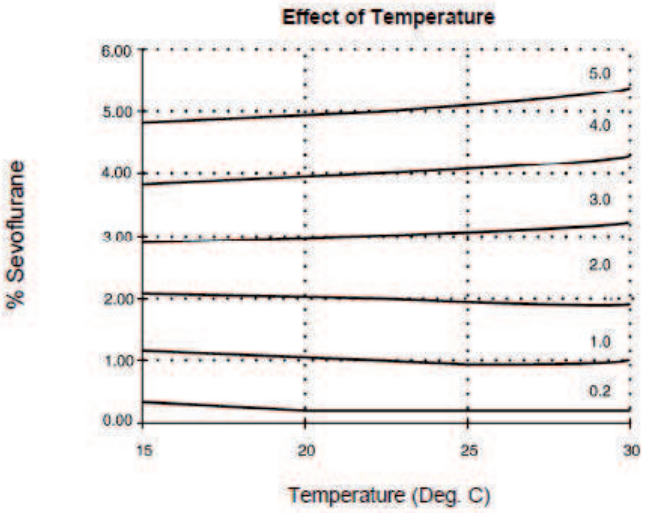

Figure 17 - Effect of Temperature on Sevoflurane Output

Note: **Individual vaporizers may vary slightly from the above performance curves.**

Note: **The performance of the 8% model can be extrapolated from this graph.**

Temperature Compensation

Variations in temperature are compensated for by a variable-resistance disc valve in the bypass passage. This provides compensation while the vaporizer is used in temperatures between 15°C and 30°C (58°F and 86°F). Use in temperatures outside this range may cause the concentration to vary from that indicated by the concentration control.

Temperature compensation is not immediate, so if a sudden temperature change is applied to the vaporizer (for instance by moving it from a cold storage room to an operating theatre), allow a stabilizing period of two hours before using the vaporizer.

Barometric Pressure

Changes in barometric pressure are not normally clinically significant. However, the following formulae and rules should be noted:

The concentration control is graduated in units of %Volume at an assumed barometric pressure of 101.3kPa (14.7psi). When the pressure varies, the true output will vary according to the formula:

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

where:

V = concentration delivered expressed as %Vol.
P = atmospheric pressure in kPa. S% = concentration set by concentration control.

It should also be noted that various makes of monitor can be affected in different ways by changes in altitude.

Normal variations in barometric pressure can usually be ignored in a clinical situation because the vaporization in the vaporizer and the patient's absorption through the lungs is affected in the same way.

However, variations must be compensated for when a non-compensated analyser is used to check the output. Also, some ventilators can impose a constant back-pressure of anything up to 15kPa (150cm H2O), which may significantly reduce the output concentration.

A small increase in output concentration can be produced by intermittent back-pressure from a ventilator, most noticeably at a low concentration with a low flow rate. However, the Blease Datum®is designed to comply with the tests specified in the various appropriate Standards with regard to this effect.

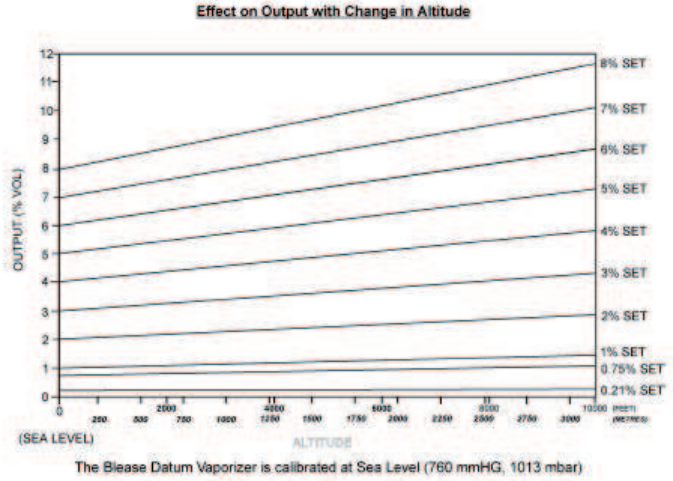

Figure 18 - Effect of Altitude on Output

Composition of the Gas

The output of the vaporizer can be affected by the composition of the gas being flowing through it.

The variation is unlikely to be more than 10% of the set concentration.

When the liquid level is low, the output may fall. Ensure the level in the vaporizer is maintained between the Minimum and Maximum levels to prevent it operating below the Minimum level.

Summary

Accuracy of Output

The delivered concentration of anesthetic agent is accurate to ± 20% of the set concentration or ± 5% of the maximum graduation, whichever is the greater, at sea level at 22°C ± 3°C.

Gas Flow Resistance

These resistances are measured at a set concentration of zero and ambient air at 22°C (72°F) and 1013mBar (14.7psi). These are nominal values which will vary when the temperature, pressure and concentration control settings are varied.

Flow Rate (L/min)	Resistance (cmH2O)
1	1 - 3
2	5 - 7
4	10 - 18
8	25 - 35

Effects of Back-Pressures on Output

Steady Back-Pressure

The use of some downstream components can introduce steady back-pressure, not usually exceeding 4kPa with the exception of some ventilators.

A back-pressure of 4kPa would cause a reduction in delivered % Vol as follows:

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

where:

V = concentration delivered expressed as %Vol. S% = set concentration
P = Patmospheric + Pback-pressure

Therefore, in the case of 4kPa:

$$V = \frac{S\% \times 101.3}{105.3} = 0.96\ S\%$$

This effect can usually be ignored under normal clinical circumstances.

Do not impose pressures in excess of 50kPa on the device without consulting the Spacelabs Healthcare Global Technical Support. The integrity of the seals may be compromised.

Effect of IPPV on Output

The greatest effects of IPPV (Intermittent Positive Pressure Ventilation) are at low concentration settings and low flow rates. The Blease Datum® has been designed to comply with the conditions specified in BS4272:Part 3:1989

Gas Composition

The Blease Datum® vaporizer is calibrated using air at 5 L/min. Therefore, the concentration control is at its most accurate when air is used. The output may vary when the gas composition is changed due to differences in density and viscosity affecting the bypass splitting ratio. Air was chosen as the calibration gas because the concentration delivered is then in the middle of the range available for anesthesia.

Do not use a BleaseDatum vaporizer with anything other than Dry Medical Gases.

Oxygen

The use of oxygen will produce a slight rise in output which is unlikely to exceed 15 % of the set value or 0.3 volume percentage. The effect is greater at high flows, with a smaller change occurring at lower flows.

Nitrous Oxide

The use of nitrous oxide will produce a slight fall in output, which is unlikely to exceed 15% in normal conditions.

Carbon Dioxide

At or below the maximum normal concentration of 5%, the effect of CO_2 is negligible.

Helium

Helium-enriched mixtures are likely to reduce the output concentration of the vaporizer, so it is recommended that an analyser be used if accurate concentrations of anesthetic agent are required.

8 - References

The Blease Datum® vaporizer is designed in accordance with the following Standards:

General

- EN 740, 1998, Section 105
- BS 4272, Part 3 1989, Sections 13, 14
- ISO 5358, 3 1992, Section 13
- ISO 8835-4
- ASTM F 1161-88 Section 12
- CSA Z168.3 1984, Sections 12, 15
- DIN 13252, Sections 4.9 to 4.13, 5.9 to 5.13

Keyed Filler Interlock System

- CSA Z168.4 M82
- DIN 13252, Sections 4.11, 5.11

Trademarks and Acknowledgements

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Dräger® is a Trademark of Drägerwerk AG.

PPV® and Sigma® are registered trademarks of Penlon Ltd.

9 - Part Numbers

Description	Part Number
Isoflurane 5% Keyed filler, Cagemount	13011118
Isoflurane 5% Keyed filler, Selectatec® Interlock-compatible	13012118
Isoflurane 5% Keyed filler, Drägerwerk® AG-compatible	13013118
Isoflurane 5% Standard filler, Cagemount	13011218
Isoflurane 5% Standard filler, Selectatec® Interlock-compatible	13012218
Isoflurane 5% Standard filler, Drägerwerk® AG-compatible	13013218
Halothane 5% Keyed filler, Cagemount	13021118
Halothane 5% Keyed filler, Selectatec® Interlock-compatible	13022118
Halothane 5% Keyed filler, Drägerwerk®AG-compatible	13023118
Halothane 5% Standard filler, Cagemount	13021218
Halothane 5% Standard filler, Selectatec® Interlock-compatible	13022218
Halothane 5% Standard filler, Drägerwerk® AG-compatible	13023218
Halothane 4% model also available	
Enflurane 5% Keyed filler, Cagemount	13031118
Enflurane 5% Keyed filler, Selectatec® Interlock-compatible	13032118
Enflurane 5% Keyed filler, Drägerwerk® AG-compatible	13033118
Enflurane 5% Standard filler, Cagemount	13031218
Enflurane 5% Standard filler, Selectatec® Interlock-compatible	13032218
Enflurane 5% Standard filler, Drägerwerk® AG-compatible	13033218
Sevoflurane 8% Keyed filler, Cagemount	13061118
Sevoflurane 8% Keyed filler, Selectatec® Interlock-compatible	13062118
Sevoflurane 8% Keyed filler, Drägerwerk® AG-compatible	13063118
Sevoflurane 8% Standard filler, Cagemount	13061218
Sevoflurane 8% Standard filler, Selectatec® Interlock-compatible	13062218
Sevoflurane 8% Standard filler, Drägerwerk® AG-compatible	13063218

Description	Part Number
Isoflurane key filler bottle adaptor	10010001
Halothane key filler bottle adaptor	10020001
Enflurane key filler bottle adaptor	10030001
Sevoflurane key filler bottle adaptor	10040001

Notes

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