Blease

DATUM®

L Series

Anaesthesia Vaporizer

User Manual
Datum 'L' Vaporizer

User Manual

'L' Series Datum are smaller and lighter than other Datums. The serial number, found on the back of the vaporizer, ends with the letter 'L'.

MODIFICATIONS LABEL

<table>
<thead>
<tr>
<th>ECN 1</th>
<th>ECN 2</th>
<th>ECN 3</th>
<th>ECN 4</th>
<th>ECN 5</th>
</tr>
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<tr>
<td>3573</td>
<td>3707</td>
<td>4445</td>
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</tbody>
</table>

V2.11/10/04

Part Number: 130UM000
Issue 2/December 1999
Read this Manual *before* operating the ventilator.
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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 persons with written authorisation from the manufacturer.

Datum® Service Policy

The Blease Datum® must only be serviced by qualified service personnel. The contents of this manual are not binding. If any significant difference is found between the product and this manual please contact Blease for further information.

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

In communication with Blease, quote the model and serial number of the equipment, with the approximate date of purchase. If the unit is being returned for repair, indicate the nature of the fault or the work you require to be carried out. Contact the Company to obtain a Goods Return Number (GRN) prior to returning the product. This is to ensure traceability and to speed the return following repair.

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

Responsibilities of the User

The Blease Datum® 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, it should under no circumstances be used.
Broken, worn, missing or contaminated components must be replaced immediately; contact the Blease distributor from whom the vaporizer was obtained for further service advice.

Contact:

Blease
Beech House
Chiltern Court
Asheridge Road
Chesham
Buckinghamshire HP5 2PY
England
Tel: 01494 784422
Fax: 01494 791497

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Datum 'L' Vaporizer

Foreword

This manual contains all appropriate information concerning the use, function, performance and maintenance of the Blease Datum® vaporizer.

Blease Medical 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, Anaesthetic Apparatus Terminology.

The following symbols are used in this manual in addition to those specified above:

%Vol — volumetric percentage. A method of expressing the concentration of a vapour in order to compare it with the concentration of a true gas. 100%Vol is equivalent to 100% partial pressure in a mixture.

WARNING: There is danger of personal injury to the user or the patient.

Caution: There is danger of damage to the vaporizer or other equipment.

Note: Further relevant or helpful information.
Warnings and Cautions

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

1. This device may be sold to, and used on the order of, a medically qualified practitioner only.

2. This vaporizer is designed for use with one anaesthetic agent only, which is that named on the filler.
   Incorrect dosage may result if the wrong drug is used in this vaporizer.
   National and international standards are provided for by the keyed filler version of this vaporizer.

3. The anaesthetic 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.

4. 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.

5. 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 when 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 the Blease Service Department or an authorized engineer for advice.
Datum 'L' Vaporizer

6. Anaesthetic agents are poisonous; great care must be taken 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 anaesthetic gases should be extracted from the operating theatre by an approved anaesthetic gas scavenging system.

7. 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.

8. Do not overfill the vaporizer. If it is overfilled, it must be withdrawn from use and the Blease Service Department or an authorized engineer contacted for advice.

9. While in use, check frequently that the liquid level is between the minimum and maximum marks on the level indicator.

10. The vaporizer may cease to function correctly if it is exposed to excessive temperatures as the temperature compensation device may be damaged. The vaporizer should be stored between -20°C and 50°C (-5°F and 122°F).

11. The output of the vaporizer is affected by barometric pressure, and it may be necessary to use a correction factor when analysing the output, especially at high altitudes >1500 metres (See 7.6)

The barometric pressure is not normally of clinical significance. All Blease vaporizers are calibrated at sea level.

12. Anaesthetic 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.
13. The vaporizer must never be modified or dismantled by any unauthorised person, but should be serviced at the prescribed intervals by a Blease Service engineer or Agent, or a trained technician, and no-one else.

14. The vaporizer must be connected so that the flow of gas to the patient is as indicated by the arrows on the device. The delivered concentration will be incorrect if the flow is reversed.

15. The Blease Datum® vaporizer has a relatively high flow resistance and must not be incorporated in a breathing system downstream of the common gas outlet.

16. Before use, all joints must be checked for leaks and the backbar function tests must be performed as described in the anaesthetic machine User Manual.

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

Importance of Patient Monitoring

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

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

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

**WARNING:** It is essential that these elements are monitored frequently and regularly and that any observations are given precedence over machine control parameters in judging the state of a clinical procedure.
Symbols and abbreviations used on Blease Equipment

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>bpm</td>
<td>Breaths per minute</td>
</tr>
<tr>
<td>cmH₂O</td>
<td>Gauge pressure expressed in centimetres of water</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous positive airway pressure</td>
</tr>
<tr>
<td>PEEP</td>
<td>Positive end expiratory pressure</td>
</tr>
<tr>
<td>I:E Ratio</td>
<td>A ratio of inspiratory to expiratory time</td>
</tr>
<tr>
<td>!</td>
<td>IEC symbol to consult the instructions for use</td>
</tr>
<tr>
<td>⚠</td>
<td>IEC symbol denoting type of equipment (B)</td>
</tr>
<tr>
<td>⚠️</td>
<td>WARNING: There is danger of personal injury to the user or patient</td>
</tr>
<tr>
<td>📝</td>
<td>Further relevant or helpful information</td>
</tr>
<tr>
<td>🕒</td>
<td>Shows that by turning the control in the direction of the thickening line, an increase in that parameter is produced</td>
</tr>
<tr>
<td>⚪️</td>
<td>Power off or closed</td>
</tr>
<tr>
<td>⚫️</td>
<td>Power on or open</td>
</tr>
<tr>
<td>⚡️</td>
<td>Dangerous voltage</td>
</tr>
<tr>
<td>l/min</td>
<td>Litres per minute</td>
</tr>
<tr>
<td>ml</td>
<td>Millilitres</td>
</tr>
<tr>
<td>O₂</td>
<td>Oxygen</td>
</tr>
<tr>
<td>psi</td>
<td>Pounds per square inch</td>
</tr>
<tr>
<td>psig</td>
<td>Pounds per square inch gauge</td>
</tr>
<tr>
<td>l</td>
<td>Litres</td>
</tr>
<tr>
<td>⚢️</td>
<td>IEC symbol for alternating current</td>
</tr>
<tr>
<td>☑️</td>
<td>Confers approval under the European Medical Device Directive</td>
</tr>
<tr>
<td>🔔</td>
<td>Push in to turn</td>
</tr>
<tr>
<td>📜</td>
<td>Filling</td>
</tr>
<tr>
<td>📜</td>
<td>Do not tip when charged</td>
</tr>
<tr>
<td>🕒</td>
<td>Locked</td>
</tr>
<tr>
<td>🕒</td>
<td>Unlocked</td>
</tr>
</tbody>
</table>
Datum 'L' Vaporizer

1 Introduction

The Blease Datum® Vaporizer is intended for use in the fresh gas supply of a continuous flow anaesthetic 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 Blease Datum® Vaporizer provides accurate concentrations of anaesthetic 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 and 15 l/m.
2 Description

Cagemount Model Key Filler Version

Key
A  Inlet connector
B  Outlet connector
C  Concentration control
D  Filler port clamp
E  Filler valve control knob
F  Level indicator
L  Filler port

The sight glass markings at F on this diagram are shown as a filled triangle for the Maximum Liquid Level and an empty triangle for the Minimum Liquid Level.
Selectatec® compatible Interlock Model Standard Version

Key
- C Concentration control
- F Level indicator
- G Interlock pins (Selectatec® only)
- H Locking knob
- K Drain plug
- V Filler cap
- W Drain screw

The sight glass markings at F on this diagram are shown as a filled triangle for the Maximum Liquid Level and an empty triangle for the Minimum Liquid Level.
2.1 Principles

Key
A  Inlet connector
B  Outlet connector
C  Concentration control
K  Anaesthetic drug in liquid form
L  Vapour chamber
M  Wick (IPPV coil)
Datum 'L' Vaporizer

**WARNING:** The Blease Datum\textsuperscript{®} Vaporizer is designed and tested for use only with the drug specified on the front panel.

The chamber contains the anaesthetic drug in liquid form \textit{K}, and the wick \textit{M} and \textit{N} ensures that the upper part of the chamber remains filled with a saturated vapour of the drug.

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

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

The temperature-compensating device \textit{T} varies the dilution ratio provided by the concentration control and bypass passage \textit{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\textsuperscript{®} filler, or a keyed filler.
2.2 Concentration Control

The concentration control \( C \) regulates the concentration of delivered vapour.

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.

2.3 Switching the Vaporizer On

**WARNING:** Never attempt to switch on the vaporizer without checking that it is fully locked on to the manifold.

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 vapour.
3 Specifications

3.1 Physical

<table>
<thead>
<tr>
<th></th>
<th>Weight kg</th>
<th>Capacity ml +/- 25</th>
<th>Height mm</th>
<th>Width mm</th>
<th>Depth mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selectatec Standard</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>114</td>
<td>200</td>
</tr>
<tr>
<td>Cagemount Standard</td>
<td>7.3</td>
<td>250</td>
<td>220</td>
<td>137</td>
<td>190</td>
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<tr>
<td>Drager Standard</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>100</td>
<td>175</td>
</tr>
<tr>
<td>Selectatec Key Fill</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>114</td>
<td>200</td>
</tr>
<tr>
<td>Cagemount Key Fill</td>
<td>7.3</td>
<td>250</td>
<td>220</td>
<td>137</td>
<td>190</td>
</tr>
<tr>
<td>Drager Key Fill</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>104</td>
<td>175</td>
</tr>
<tr>
<td>Selectatec Quik-Fil</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>114</td>
<td>210</td>
</tr>
<tr>
<td>Cagemount Quik Fil</td>
<td>7.3</td>
<td>250</td>
<td>220</td>
<td>137</td>
<td>200</td>
</tr>
<tr>
<td>Drager Quik-Fil</td>
<td>7.5</td>
<td>250</td>
<td>225</td>
<td>100</td>
<td>185</td>
</tr>
</tbody>
</table>

3.2 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 % 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.

**WARNING:** The vaporizer must not be used when the control is set between zero and the first graduation mark.
4 Filling and Draining

WARNING: The vaporizer must be secured in an upright position while filling and draining, either by fixing it to an anaesthetic machine or standing it on a flat, level surface. The vaporizer must not be tipped during filling.

WARNING: Do not use the anaesthetic agent bottle to fill the vaporizer if the bottle is cracked or the filler connector is loose or broken. This may result in overfilling or contaminated agent entering the vaporizer.

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

WARNING: The vaporizer must be filled only by suitably skilled and trained personnel.

WARNING: 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.

WARNING: Set the concentration control to zero before filling the vaporizer.

WARNING: Check that the anaesthetic agent name on the supply matches that on the front of the vaporizer.
4.1 Standard Screw Cap Filler

4.1.1 Filling

WARNING: The vaporizer should not be filled if the anaesthetic machine has gases flowing through it.

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.

WARNING: DO NOT OVERFILL. If the vaporizer is overfilled it must be withdrawn from service.

WARNING: Do not tip the vaporizer during the filling operation as overfilling may occur.

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.

WARNING: The vaporizer must not be used 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.

4.1.2 Draining

The vaporizer must be secured in an upright position with the concentration control set to zero.

1. Unscrew the filler cap.
2. Place a suitable receptacle under the drain plug into which to drain 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. Tighten the drain screw fully and replace the filler cap.
WARNING: Tighten the drain plug securely before replacing the filler cap.

WARNING: Anaesthetic agent drained from the vaporizer must be discarded and not reused. Treat as a hazardous chemical.

4.2 Keyed Filler

4.2.1 Filling

1. Ensure 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 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.

WARNING: DO NOT OVERFILL. If the vaporizer is overfilled it must be withdrawn from service.

WARNING: DO NOT LOOSEN THE FILLER ADAPTOR FROM THE DRUG BOTTLE DURING FILLING AS OVERFILLING MAY OCCUR.

WARNING: Do not tip the vaporizer during the filling operation as overfilling may occur.
Datum 'L' 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 spilt as the adaptor is removed from the filler port.

4.2.2 Draining

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.

WARNING: Anaesthetic agent drained from the vaporizer must be discarded and not reused. Treat as a hazardous chemical.
4.3 Quik-Fil Filler

**WARNING:** Do not tamper with the filling system valve. This may cause a vapour and fresh gas leak.

4.3.1 Filling

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 anaesthetic agent bottle filler, checking that the bottle and filler mechanism are not damaged.

4. Remove the vaporizer black filler cap 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.

**WARNING:** DO NOT OVERFILL THE CHAMBER. If the vaporizer is overfilled it must be withdrawn from service.

**WARNING:** Do not tip the Vaporizer during the filling operation as overfilling may occur.
4.3.2 Draining

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

**WARNING:** The black filler cap must be refitted before using the vaporizer.

**WARNING:** Anaesthetic agent drained from the vaporizer must be discarded and not reused. Treat as a hazardous chemical.

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

2. Remove the yellow protective cap from an empty Sevoflurane bottle.

   Insert the bottle nozzle into the drain funnel.

   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.

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

4. Unscrew 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.

5. Unscrew the drain funnel from the bottle and refit the bottle cap (1).

**WARNING:** The black filler cap must be refitted before using the vaporizer.

**WARNING:** Anaesthetic agent drained from the vaporizer must be discarded and not reused. Treat as a hazardous chemical.±NZ
5 Installation

5.1 Cagemount Model

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 anaesthetic machine and the distance between the backbar and tapers be adjusted as required.

1. Secure the vaporizer to the backbar of the anaesthetic machine using the studs, nuts, washers and spacers provided.

2. Lightly smear the tapers with an oxygen-safe grease (such as Fomblin).

3. Push the gas tubing fully on to the appropriate tapers and tighten the fixing nuts.

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

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

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

WARNING: If the vaporizer is fitted with a Selectatec® or interlocking Cagemount manifold, the interlock function is void if used with a non-interlock device.
5.2 Selectatec®-Compatible Interlock Model

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

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 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.

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

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

WARNING: 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.
5.2.1 Removal

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.

5.3 Drägerwerk® AG-Compatible Model

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.

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

WARNING: Perform a backbar function test before using the machine, as described in the anaesthetic machine User Manual.
6 Routine Maintenance

Any adjustment or disassembly of the vaporizer outside the scope of the following instructions must not be attempted.

6.1 Cleaning

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

6.2 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).

WARNING: Anaesthetic agents may suffer from brown or yellow discolouration if exposed to light and gases for long periods. Discoloured anaesthetic agents must not be used and should be disposed of as a hazardous chemical.

WARNING: All vaporizers should be drained of anaesthetic agent if not in regular use, and the liquid disposed of as a hazardous chemical.
6.3 Checking Output Concentration

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

Blease has very closely specified test conditions and methods which are carried out as part of the production process. At Blease we have an internal system of quality control and auditing of procedures, coupled with regular staff training and equipment calibration verification. These stringent requirements could not easily be replicated in a field situation.

If a hospital requires that calibration verification is carried out the following points must be observed.

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 analysers 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 Blease 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 doubting the vaporizer.

9. If in doubt please contact Blease Technical support.

6.4 Training

A Blease training course is available to engineers and technicians who are required to service Blease vaporizers. The course includes:

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

The Blease Datum® Service Manual contains a description of all these procedures.
6.5 Pre-Use Check

Before use carry out the following.

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

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

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

4. Where the anaesthetic machine is fitted with a pressure relief valve the following tests should be performed. (There may be a dangerous increase in pressure if these tests are performed in the absence of such a valve.)

   (i) Set a suitable test flow of oxygen (6-8 litre/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 fitments, and the flowmeter bobbin will dip.

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

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

The above is an abstract from:

“CHECKLIST FOR ANAESTHETIC MACHINES
A recommended procedure based on the use of an oxygen analyzer”
(July 1990)
Published by:
The Association of Anaesthetists of Great Britain and Ireland
9 Bedford Square
London
WC1B 3RA
7 Performance

7.1 Halothane Model

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

Effect of Flowrate on Performance

NOTE: Individual vaporizers may vary slightly from these performance curves.
Variation of output with temperature (flow rate = 5 l/min Air)

Effect of Temperature

NOTE: Individual vaporizers may vary slightly from these performance curves.
7.2 Enflurane Model

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

Effect of Flowrate on Performance

NOTE: Individual vaporizers may vary slightly from these performance curves.
Variation of output with temperature (flow rate = 5 l/min Air)

Effect of Temperature

% Enflurane

Temperature (Deg. C)

NOTE: Individual vaporizers may vary slightly from these performance curves.
7.3 Isoflurane Model

Variation of output with flow rate \((T = 22^\circ C)\) (Air carrier gas)

Effect of Flowrate on Performance

NOTE: Individual vaporizers may vary slightly from these performance curves.
Datum 'L’ Vaporizer

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

Effect of Temperature

% Isoflurane

NOTE: Individual vaporizers may vary slightly from these performance curves.
7.4 Sevoflurane Model

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

Effect of Flowrate on Performance

NOTE: Individual vaporizers may vary slightly from these 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)

Effect of Temperature

NOTE: Individual vaporizers may vary slightly from these performance curves.

NOTE: The performance of the 8% model can be extrapolated from this graph.
7.5 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) a stabilising period of two hours should be allowed before the vaporizer is used.

7.6 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 %Vol. 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 H$_2$O), 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.

The Blease Datum Vaporizer is calibrated at Sea Level (760 mmHg, 1013 mbar)
7.7 Composition of the Gas

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

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

WARNING: 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.

7.8 Summary

7.8.1 Accuracy of Output

The delivered concentration of anaesthetic 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.

7.8.2 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.

<table>
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<tr>
<th>Flow rate (l/min)</th>
<th>Resistance (cm H₂O)</th>
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<td>1 - 3</td>
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<td>2</td>
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<td>4</td>
<td>10 - 18</td>
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<td>25 - 35</td>
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</tbody>
</table>
7.9 Effects of Back-Pressures on Output

7.9.1 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
- \( P \) = \( P_{\text{atmospheric}} \) + \( P_{\text{back-pressure}} \)

Therefore, in the case of 4kPa:

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

This effect can usually be ignored under normal clinical circumstances.

**WARNING:** Pressures in excess of 50kPa must not be imposed on the device without consultation with the Technical Department of Blease, as the integrity of the seals may be compromised.
7.9.2 Effect of IPPV on Output

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

7.10 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 anaesthesia.

WARNING: This device must not be used with anything other than Dry Medical Gases.

7.10.1 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.

7.10.2 Nitrous Oxide

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

7.10.3 Carbon Dioxide

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

7.10.4 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 anaesthetic agent are required.
8 References

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

8.1 General

EN 740, 1998, Section 105
BS 4272, Part 3 1989, Sections 13, 14
ISO 5358, 3 1992, Section 13
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

8.2 Keyed Filler Interlock System

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

8.3 Trademarks and Acknowledgements

Abbott Laboratories is the Trademark of Abbott Laboratories.

Quik-Fil® is a registered trademark of Abbott Laboratories.

Datum® is a registered trademark of Blease Medical Limited.

Selectatec®, TEC® and Ohmeda® are registered trademarks of BOC/Ohmeda UK Ltd.

Dräger® is a Trademark of Drägerwerk AG.

PPV® and Sigma® are registered trademarks of Penlon Ltd.
9 Order Information

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