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VP300 Vaporizer

User Manual

Beijing Aeonmed Co., Ltd

Statement

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Manufacturer Responsibility:

Aeonmed is responsible for the security, reliability and function of the equipments when to following conditions are adhered to:

- Installation, adjustments, mending and repairs must be performed by individuals authorized by Aeonmed;
- Necessary electrical equipment and the working environment must be in accordance with the national standards, professional standards and the requirements listed in this manual;
- Equipment must be used as instructed in the operating instructions.

CAUTION: This equipment is not for family use.

CAUTION: Malfunctioning equipment may become invalid and cause bodily injury if a set of effective and approving repairing proposals cannot be submitted by the institution which is responsible for using this equipment.

The paid theoretical framework diagram will be supplied according to customer requirements by Aeonmed, plus calibrating method and other information to help the customer, under the assistance of qualified technicians, repair the equipment parts where can be done by customer himself based on the stipulation by Aeonmed.

Warranty:

Manufacturing techniques and materials:

For a period of one year from the date of original delivery, the components and assemblies of this product is warranted to be free from defects manufacturing techniques and materials, provided that the same is properly operated under the conditions of normal use and regular maintenance. The warranty period for parts is three months, expendable parts are not included. Aeonmed's obligation under the above warranties is limited to repairing free of charge.

Free Obligations:

- Aeonmed's obligation under the above warranties does not include the freight and other fees;
- Aeonmed is not responsible for any direct, indirect or final product broken and delay which result from improper use, alteration by using the assemblies unapproved and maintenance by anyone other than Aeonmed;
- This warranty does not apply to the followings:

  Improper use;

  Machines without maintenance or machines broken;

  The label of Aeonmed original serial number or mark is removed or replaced;

  Other manufacturers' product.

Security, reliability and operating condition:

Aeonmed is not responsible for the security, reliability and operating condition of this product in case that:

- The assemblies are disassembled, extended and readjusted
- This product is not operated correctly in accordance with the manual instruction. The power supply used or operating environment does not follow the requirements in this manual.

Return

Follow the steps in case that the product needs to be returned to Aeonmed:

1. Obtain the rights of return

Contact with the customer service of Aeonmed by informing them the number and type of the product. The number is marked on the surface of the product. Return is unacceptable if the number cannot be identified. Enclose a statement of the number, type and the reason of return as well.

2. Transportation charges

Transportation and insurance charges must be prepaid by the user for transporting the product to Aeonmed for repairing. (Customers charges is added with regard to the products sold to non-Chinese mainland users)

CE 0123

Foreword

Thank you for purchasing and utilizing Aeonmed equipment.

For using the apparatus rightly and effectively, please read throughtly and carefully the User Manual before use.

Any use of the apparatus requires full understanding and strict observation of these instructions.

The apparatus is only to be used for purpose specified here.

One who is not authorized by Aeonmed shall not be allowed to open and dismantle the apparatus for maintaining, checking and repairing.

For further assistance contact Aeonmed, good service would be supplied.

Welcome to contact Aeonmed by the following address:

Manufacture:	Beijing Aeonmed Co., Ltd.
Address:	No.4, Hangfeng Road, Fengtai Science Park, Fengtai District, Beijing, China
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E-mail:	service@aeonmed.com

Contents

1 Introduction

1.1 Precautions

⚠ WARNING: **Do not fill the vaporizer with any agent other than the agent specified on the front label. The vaporizer is designed for that agent only. If any substance other than that specified is used, patient injury could occur.**

Do not attempt to use a vaporizer that has been dropped. A dropped vaporizer must be sent to the nearest Aeonmed Field Operations Unit for servicing.

Do not use malfunctioning equipment. Make all necessary repairs or have the equipment serviced by an authorized Aeonmed service center. After repair, test the equipment to ensure that it is functioning properly in accordance with the manufacturer's published specifications.

⚠ CAUTION: **European Standard EN 740 - *Anesthetic Workstations and Their Modules* requires that an appropriate gas monitor is used to monitor the concentration of anesthetic agent vapor in the inspiratory gas when the vaporizer is in operation in order to provide protection against hazardous output in the event of a device malfunction.**

Aeonmed strongly recommends the use of anesthesia gas monitoring device according to ISO 21647:2004 with this equipment Refer to local standards for mandatory monitoring.

Aeonmed strongly recommends that you keep all relevant documentation, including this manual and accompanying labels, immediately available to all users.

VP300 is intended to be used with anesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3 standard.

⚠ **WARNING: VP300 is unsuitable for use in a magnetic resonance imaging (MRI) environment.**

⚠ **WARNING: The user of VP300 must be professional and trained.**

1.2 Symbols

⚠ Warnings and ⚠ Cautions tell you about conditions that can occur if you do not follow all instructions in this manual.

⚠ **WARNING**: tells about conditions that can cause injury to operators or patients.

⚠ **CAUTION**: tells about conditions that can cause damage to the equipment.

Read and follow all warnings and cautions.

	Lock		Unlock
	CE Representative	**SN**	Serial Number
	Airflow direction		Warning or Caution, ISO 7000-0434
	Date of manufacture		Address of manufacture
	Indicator		Type B equipment
			The system, with this label under the stipulations in the user manual, complies with the requirements related from 93/42/EEC.

2 Description

This manual and its associated documentation must be studied before any attempt is made to install, operate or clean any part of the VP300 Vaporizer.

2.1 What's VP300 Vaporizer

The VP300 Vaporizer is designed for incorporation in the fresh gas supply system of continuous flow anesthetic machine, directly connected between the flowmeter and the common gas outlet of the machine.

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

Its purpose is the provision of accurate concentrations of anesthetic drugs in the fresh gas supply, in accordance with the setting of the control dial, when the fresh gas supply flow is between 0.2 and 15 liters/min. Refer to Section 7.

Each vaporizer is agent specific and is clearly labeled with the anesthetic agent that it is designed for.

The vaporizer is temperature, flow and pressure compensated so that its output remains relatively constant despite cooling due to evaporation, variations in inlet flow and fluctuating pressures as described in Section 7, Effects of Variables.

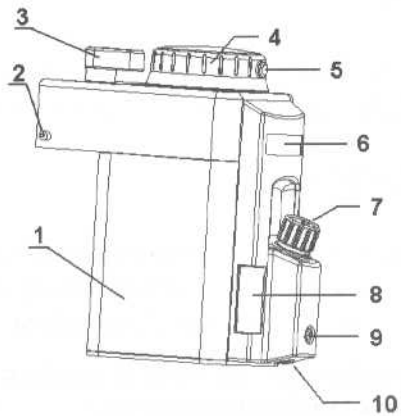

Figure 2-1 VP300 Vaporizer

Legend:

1	body	2	interlock bolt	3	lock lever
4	control dial	5	Release button	6	Anesthetic tag
7	Screw cap	8	Liquid level indicator	9	Drain valve
10	Drain hole				

⚠ **WARNING**: **Improper use may result in patient injury.**

Only operate the vaporizer with dry medical gases.

⚠ **CAUTION**: **The vaporizer is intended to be operated in its upright position. Turn the vaporizer to 'OFF' when it is not in use.**

2.2 Components

2.2.1 Control dial

Single control dial with a concentration scale calibrated in percentage of anesthetic agent vapor per total volume (VOL%) sets the desired concentration of the anesthetic agent.

A release button in the dial assembly helps prevent accidental displacement of the control dial from the 'OFF' position. To select an ON setting, squeeze the dial release and simultaneously rotate the dial counter-clockwise.

On returning the dial to OFF, the release button will automatically spring outwards into the locked OFF position.

The dial and release button are designed to enable an ON setting to be selected using only one hand.

2.2.2 Safety interlocks

The vaporizer incorporates an interlock mechanism. This mechanism also interfaces with the mounted manifold to help satisfy the following criteria:

- The vaporizer must be locked onto the manifold before it can be turned ON.
- Only one vaporizer at a time can be turned ON when two or more vaporizers are fitted on a mounted manifold.
- The gas flow enters only the vaporizer that is turned ON.

- Any unwanted anesthetic trace vapor is minimized after a vaporizer is turned to 'OFF'.

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

⚠ **WARNING:** **The Dräger compatible model with interlock must only be used with other Dräger-compatible interlock vaporizers, to maintain the integrity of the interlock system.**

3 Installation

⚠ **WARNING:** **Do not lift or support the vaporizer by holding the control dial. Handle the vaporizer with care at all times.**

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

Do not use a vaporizer if the liquid level decreases below the minimum level.

Before using a vaporizer allow it to attain the ambient temperature of the location in which it has to be used.

⚠ **CAUTION:** **When mounted manifold provide mounting positions for three vaporizers require that if only two vaporizers are fitted, then the center position must be occupied. If the center position is not occupied, the interlock that helps ensure that only one vaporizer at a time can be turned ON is ineffective.**

⚠ **CAUTION:** **Vaporizers with different interlock interfaces can't be installed the same anesthetic system.**

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⚠ **CAUTION:** **Vaporizers with different interlock interfaces can't be installed the same anesthetic system.**

3.1 Pre-use Check List

In addition to the pre-use warnings listed for different models in sections 3.1 to 3.3 the following check list procedure must be carried out on ALL vaporizers before use

1 Check that the vaporizer concentration control is in the 'OFF' position.

2 Check that the liquid level is between the upper and lower marks on the filter block.

3 On pour fill (screw cap filler) models, check that the filler cap is securely closed.

4 Perform a back bar manifold leak test as detailed in the relevant anesthetic machine user instruction manual.

⚠ **WARNING: Anesthetic 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 anesthetic machine allows correct installation of the vaporizer.

3.2 Selectatec Compatible with Interlock

The vaporizer is designed to be used on Selectatec Series Mounted Manifolds. The vaporizer can be installed on other Manifolds but the interlock system is designed to function on Selectatec Series Mounted Manifolds only.

Before mounting a vaporizer onto the Selectatec Series manifold, ensure that each manifold port valve O-ring is intact and that there is no foreign matter around the mating surfaces. A damaged O-ring and/or foreign matter around the mating surfaces can cause leaks.

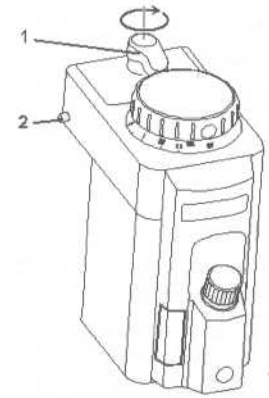
3.2.1 Mounting the vaporizer

1 Carefully offer the vaporizer up to the manifold.

2 Align the gas connection ports with the valve capsule on the manifold. (The capsule is referred to as the valve 'cartridge' in some user literature)

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

4 Lock into position by rotating the locking lever (1)clockwise through 90°.



1. Locking Lever 2. Interlock Bolts
Figure 3-1 Selectatec compatible interlock

Step 1

Set the dial to OFF.

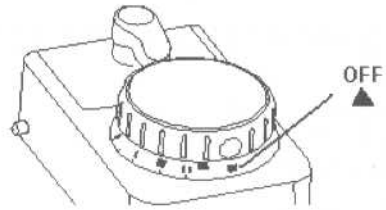


Figure 3-2 Setting the concentration dial

Step 2

Unlock the locking lever (1).

- Turn the lever counter-clockwise.
- Make sure the lever releases.

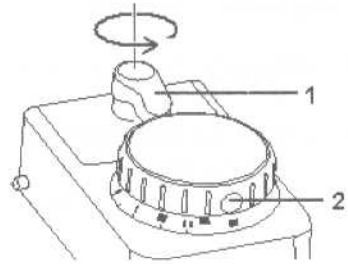


Figure 3-3 Unlocking the locking lever

Step 3

Prepare the manifold.

Remove any plugs fitted to the vaporizer interlock block ports.

Verify that each manifold port valve O-ring is intact if necessary, remove the existing O-rings and fit one new O-ring to each port valve, as described in the relevant anesthesia system User's Reference Manual.

Replacement O-rings are supplied with each vaporizer.

1. Vaporizer Interlock Block Port - ensure plugs removed
2. Replace Manifold Port Valve O-ring, if necessary

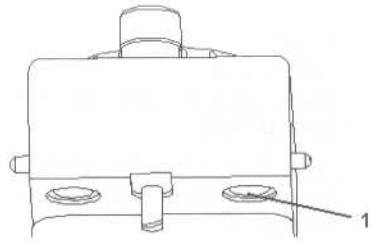


Figure 3-4 Readying the manifold

Step 4

Install the vaporizer onto the manifold.

Hold the main body of the vaporizer in an upright position with both hands.

Lower the vaporizer onto the manifold, ensuring that the vaporizer interlock block ports engage correctly with the manifold port valves.

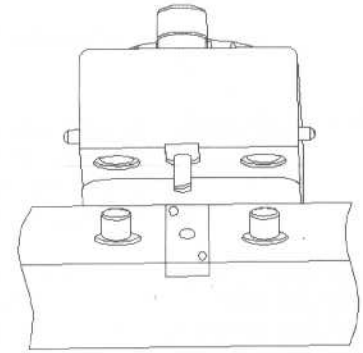


Figure 3-5 Installing the vaporizer

⚠ **CAUTION:** **Push the locking lever all the way down before turning it. The mechanism can be damaged if an attempt is made to turn the lever before it is pushed all the way down.**

Step 5

Lock the vaporizer onto the manifold.

Turn it clockwise to the locked position to lock the vaporizer onto the manifold.

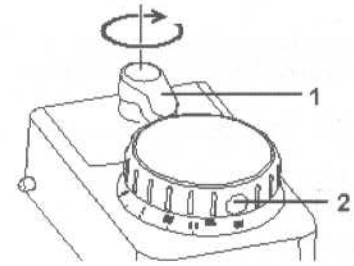


Figure 3-6 Locking the vaporizer onto a manifold

Step 6

Ensure that the vaporizer is correctly mounted.

3.2.2 Checking the vaporizer for correct mounting

⚠ **WARNING: To help ensure correct operation, do not use a vaporizer that is either visibly out of line on the manifold or that can be lifted off the manifold when the locking lever is in the locked position.**

If more than one vaporizer is fitted, visually check to make sure that the tops of the vaporizers are level. If the vaporizer is visibly out of line, perform steps 2 and 3 as described in Removing the vaporizer from a manifold and remount it correctly.

When the vaporizer appears to be level and the locking lever is in the locked position, attempt to lift the vaporizer straight up from the manifold. If the vaporizer can be lifted off the manifold, it is not correctly mounted. Remount the vaporizer (see Vaporizer mounting procedure).

Verify that the interlock rods are in alignment by making sure that only one vaporizer at a time can be turned ON.

Check the anesthesia system for leaks in accordance with the relevant User's Reference Manual with the vaporizer dial turned to OFF.

3.2.3 Removing the vaporizer from a manifold

Step 1

Set the dial to 'OFF'.

If the dial is not completely turned to the 'OFF' position the vaporizer cannot be released from the manifold.

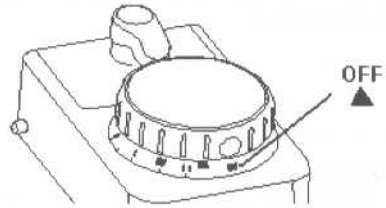


Figure 3-7 Setting the concentration dial

Step 2

Unlock the locking lever.

Turn the locking lever counter-clockwise.

Release the locking lever and check that the locking lever springs up to the unlocked position to release the vaporizer from the manifold.

1. Locking lever 2. Dial

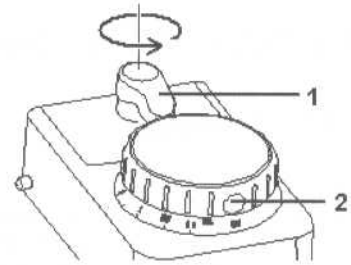


Figure 3-8 Unlocking the locking lever

Step 3

Carefully lift the vaporizer up from the manifold.

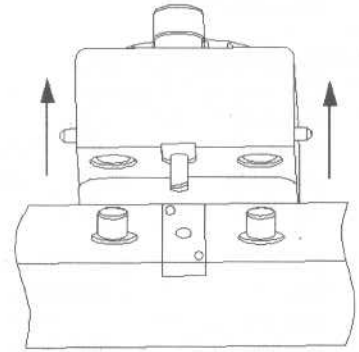


Figure 3-9 Lifting the vaporizer

3.3 Dräger 'Plug-in' Compatible (interlock)

3.3.1 Installation

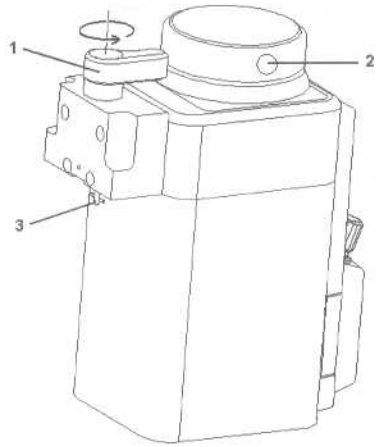
⚠ **CAUTION:** **When installing two vaporizers only on a three station manifold, the centre station must be occupied by one of the vaporizers.**

1 Carefully offer the vaporizer up to the manifold

2 Align the gas connection ports with the valve capsule on the manifold. (The capsule is referred to as the valve 'cartridge' in some user literature)

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

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



1. Locking Lever 2. Interlock Bolts 3. Back bar Manifold Locking Shaft

Figure 3-10 Dräger Plug-in compatible interlock

3.3.2 Pre-use Checks

Interlock system - check that only one vaporizer at a time can be turned on.

Observe the WARNING below and carry out the check list procedure given in section 3.4.

⚠ **WARNING:** **To prevent damage to the locking shaft, and to ensure that the gas connection ports are correctly engaged, check that the vaporizer is firmly positioned on the manifold before tightening the locking lever.**

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

3.3.3 Removing the vaporizer

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

3.4 North American Dräger compatible (interlock)

3.4.1 Installation

1 Check that each gas port (1) is fitted with the correct O seal, as supplied by the anesthetic machine manufacturer.

2 Carefully offer the vaporizer up to the manifold.

3 To secure the vaporizer to the manifold, use two M4 x 30 screws and fan-type lock washers, as supplied with the machine. From the rear of the anesthetic machine fit the two screws through the manifold block holes (2), and screw into the threaded holes in the vaporizer. Tighten the screws to a torque of 2.7 to 3.0 Nm.

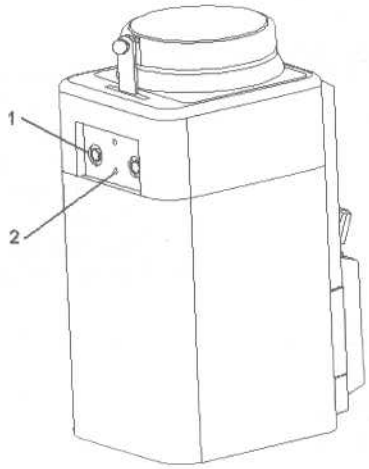


Figure 3-11 North American Dräger compatible interlock

3.4.2 Pre-use Checks

Interlock System - check that only one vaporizer at a time can be turned on.

Carry out the check list procedure given in section 3.4.

3.4.3 Removing the vaporizer

1 Support the vaporizer, and remove the securing screws.

2 Detach the vaporizer from the manifold.

3 Check that the O-seals are retained in the gas ports.

4 Operating Instructions

4.1 Setting the dial

⚠ **WARNING:** **High percent dial settings combined with low gas flows may lead to hypoxic mixtures in the breathing circuit. Aeonmed strongly recommends the use of oxygen monitoring.**

The dial release must be operated to turn the dial from the 'OFF' setting.

Do not turn the dial if the vaporizer is not property locked onto the manifold.

⚠ **CAUTION:** **The vaporizer should not be used between 'OFF' and the first graduation mark.**

Step 1

Press the dial release and turn the dial in a counter-clockwise direction from the 'OFF' setting.

Note: that it is not possible to turn on the vaporizer if an adjacent one is turned on.

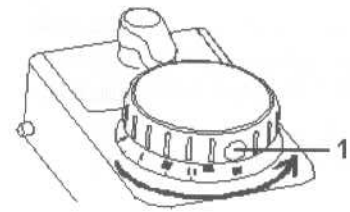


Figure 4-1 Releasing the dial

Step 2

To avoid inadvertent delivery of small concentrations, turn the control dial to 'OFF' when the vaporizer is not in use.

4.2 Filling and draining the vaporizer

⚠ WARNING: **Do not fill the vaporizer with any agent other than the agent specified on the front label. The vaporizer is designed for that agent only. If any substance other than that specified is used, patient injury could occur.**

Only fill the vaporizer when it is in an upright position. Failure to do so may result in the vaporizer being overfilled.

To avoid explosive hazards, flammable anesthetic agents such as Ether and Cyclopropane must not be used in or with this vaporizer. Only anesthetic agents that comply with the requirements for non-flammable anesthetic agents in the IEC 60601-2-13 Standard, Particular Requirements for the Safety of Anesthesia Machines, are suitable for use in the presence of this vaporizer.

The use of antistatic breathing tubes and face masks is not necessary. The use of antistatic or electrically conductive breathing tubes when using high frequency electric surgery equipment may cause bums and is therefore not recommended in any application of this vaporizer.

Do not fill the vaporizer unless the control dial is in the 'OFF' position.

Do not turn the dial ON during filling process.

Do not drain the agent into any container other than a properly marked drug container.

Ensure that the filler cap is tightened prior to use.

Anesthetic agent vapor must not be inhaled danger to health.

⚠ CAUTION: **To minimize atmospheric pollution in the operating room, fill the vaporizer in a fume cupboard or under an extractor hood.**

Observe information on use and use-by date of anesthetic agent.

Note: color-coding (according to DIN 13252 and ISO 5360 and ISO 8835-4) of anesthetic agent bottle and Vapor.

Anesthetic agent	Enflurane	Isoflurane	Sevoflurane	Halothane
Color strip	orange	purple	yellow	red

When filling the VP300 Vaporizer, observe the following:

- Periodically check the agent level. The vaporizer should be refilled at appropriate intervals. The vaporizer is designed to function according to specification as long as there is agent visible above the foot-level mark.
- The vaporizer must be filled and used in an upright position. Small deviations from the upright position do not affect either the output or the safety of the vaporizer.
- Every two weeks, preferably when the agent level is low, drain the contents of the vaporizer into an appropriately marked container and discard the agent .Less frequent intervals may be used when the anesthetic agent does not contain additives or stabilizing agents, but the procedure must be performed at least once every year.

- The following steps should be taken for Halothane vaporizers:
  - — Drain the vaporizer every two weeks.
  - — If Halothane is used infrequently the vaporizer should be drained after use.
  - — The decomposition of halothane causes the release of halides, which may corrode metal components particularly in the presence of moisture. Also a preservative added to halothane by its manufacturers to impede decomposition can leave a residue, which may cause vaporizer components to stick. If the vaporizer is not upright, check the agent level more frequently to avoid a misleading impression of the amount of agent in the vaporizer.

4.2.1 Filling procedure with funnel filler

⚠ **WARNING: Before filling a vaporizer equipped with a funnel filler, turn the cap slowly to allow any pressure to gradually vent.**

Ensure that the drain plug screw, located on the lower front of the vaporizer, is correctly tightened to help prevent loss of liquid agent.

Step 1

Remove the filler cap by turning it counter-clockwise. Ensure that the drain plug is closed by tightening it with the tool end of the filler cap.

Step 2

Verify that the anesthetic agent is the same as that specified on the vaporizer front label.

Observe the agent level through the sight glass indicator on the side of the filler body.

Pour the agent slowly into the filling port, as illustrated on Figure 4-2, until the level reaches the head-level mark.

The level may decrease slightly as the wicks absorb the agent to prevent overfill; ensure the agent level is at or below the fill line.

Step 3

Replace and tighten the filler cap to minimize leaks.

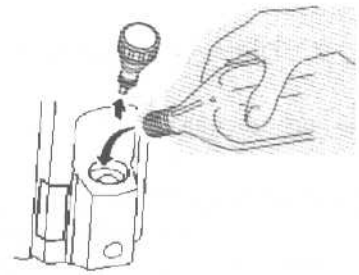


Figure 4-2 Filling a vaporizer that incorporates a funnel filler

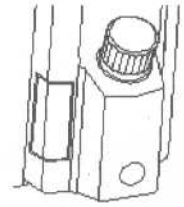


Figure 4-3 Replacing the filler cap

4.2.2 Draining procedure with funnel filler

The vaporizer must only be drained into a properly marked container.

⚠ CAUTION: Do not allow the container to become completely full during draining procedures.

Step 1

Remove the filler cap. Insert the tool end of the cap into the drain plug below the filling port on the filler body as illustrated in Figure 4-4.

Step 2

Position a properly marked container under the drain spout.

Step 3

Unscrew, but do not remove, the drain plug to allow the vaporizer contents to pour from the drain spout into the container.

Step 4

After draining is complete, tighten the drain plug to help minimize leaks.

Step 5

Replace and tighten the filler cap to help minimize leaks.

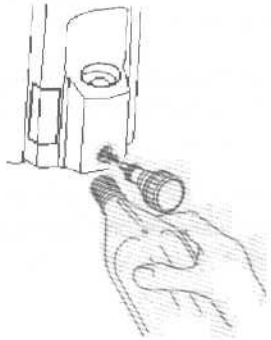


Figure 4-4 Draining a vaporizer with a funnel filler

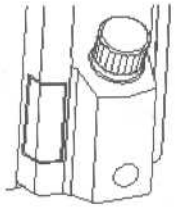


Figure 4-5 Replacing the filler cap

5 Maintenance

⚠ WARNING: To avoid fire:

- **Use the specific anesthetic agent.**
- **Never oil or grease any anesthesia or O_2 equipment. In general, oils and greases oxidize readily, and – the presence of O_2 – are highly flammable.**
- **All the covers or housings for the system use must be made of static proof material, as static material may cause fire.**

⚠ WARNING: Follow sterilizing control and security stipulations.

⚠ WARNING: Movable components and detachable parts can cause injury. Use caution when system components and parts are being moved or replaced.

⚠ WARNING: Disposal of waste or invalidated apparatus must be in accordance with the relevant policies in local government.

5.1 Service Policy

Do not use malfunctioning equipment. Make all necessary repairs, or have the equipment serviced by an authorized Aeonmed Service Representative. After repair, test the equipment to ensure that it is functioning properly, in accordance with the manufacturer's published specifications.

⚠ **CAUTION: No repair should ever be undertaken or attempted by anyone without authorization by Aeonmed.**

It is recommended that you replace damaged parts with components manufactured or sold by Aeonmed. After any repair work, test the unit to ensure it complies with the manufacturer's published specifications.

Contact the nearest Aeonmed Service Center for service assistance. In all cases, other than where Aeonmed's warranty is applicable, repairs will be made at Aeonmed's current list price for the replacement part(s) plus a reasonable labor charge.

5.1.1 Internal contamination

If the vaporizer is filled or partly filled with an incorrect volatile agent or other contaminant (such as water), proceed as follows:

1 Remove the vaporizer from service immediately and label the vaporizer stating that it is contaminated. Discard all liquid.

2 Return the vaporizer to Aeonmed Authorized Service Center stating that the vaporizer is contaminated and, if possible, the type of contaminant in the vaporizer.

5.1.2 Clearing

Anesthetic agent which retained by the wick need to remove after draining, follow this:

- Set the dial to 5% and purge the vaporizer with the carrier gas at 5 L/min for 5 hours or at 15 L/min for one hour.
- Make sure the gas via vaporizer flow into the pipeline of scavenging system.

5.1.3 Discarding

Draining fully, clearing, clearing and sterilizing must have been finished before you want to discard the vaporizer.

5.1.4 Returning the vaporizer for service or repair

The vaporizer must be drained and allowed to dry out before packing.

Always use the original packaging, to prevent damage during transit.

5.1.5 Packing for transfer

Drain vapor completely, clean and disinfect.

Each vapor must be packed individually with care. Use original packing, when possible.

If original packing is not available use strong packing, with at least 5 cm impact-resistant material.

Fasten package securely.

5.2 Maintaining Outline and Schedule

⚠ **WARNING: Do not modify, tamper with, or disassemble the vaporizer. Doing so can damage the unit and alter the graduation accuracy.**

Maintenance intervals:	Clean and disinfect Vapor before each service and also when returning for repair.
Every two weeks:	When the agent is low, drain the contents of the vaporizer into an appropriately marked container and discard the agent. For Halothane vaporizers, check the output of anesthetic agent periodically with an agent monitor.
Three years from purchase date And every six months thereafter	Planned safety inspections together with the anesthesia system by qualified personnel. Inspect and perform output concentration check. Refer to section 5.3.

⚠ **CAUTION: The decomposition of Halothane causes the release of halides, which may corrode metal components particularly in the presence of moisture. Also a preservative added to Halothane by its manufacturers to impede decomposition can leave a residue, which may cause vaporizer components to stick. If Halothane is used infrequently the vaporizer should be drained after use.**

⚠ **WARNING: Do not put water or any other solvent into a vaporizer. A vaporizer should be filled with the specified anesthetic agent only.**

5.3 Output concentration check

Carry out inspection weekly when continuous monitoring can't be performed.

Ready

Fill the vaporizer and make sure the liquid volume not less than half between upper mark and lower mark of liquid level indicator.

Make the temperature of the vaporizer filled be 20°C to 24°C.

The waiting time of that the temperature is stabilized as followings:

ΔT (rise or descent)	±2℃	±6℃	±10℃	±20℃
hours	1	3	4	5

- Check the anesthetic gas monitor (ULT-1 of Datex-Ohmeda is recommended), and carry out zero calibration with O_2.
- Connect anesthetic gas monitor to fresh gas outlet (see figure5-1), ensure that no leakage occurs.
- Connect gas scavenging system well and then startup it.

Settings

- Switch off anesthetic ventilator or set it to make sure the pressure inside breathing tube less than 5mbar.
- Setup anesthetic gas monitor to the anesthetic agent selected and continuous measurement.
- Set the oxygen output between 1L/min and 5L/min.

Measure

- Check "OFF" mark as well as three scale from 1VOL% to 4VOL% at least.
- Setup the dial.
- Note the reading measured when stabilized.

Correction

Anesthetic gas monitor shows that as following:

%partial pressure: No correction

Vol.%: Switch to partial pressure

$$\text{Concentration (\% partial pressure)} = \frac{\text{Measured value (Vol.\%)} \times \text{atmospheric pressure (hPa)}}{1013\ \text{hPa}}$$

Acceptable range

- Acceptable range of delivered concentration: According to ISO8835-4: 2004 R51.101 sub-clause: The output concentration at all scales other than "OFF" position shall not deviate by more than +30% or -20% from the concentration setting or by more than +7.5% or -5% of the maximum setting, whichever is greater. See the following table:

Dial setting	0.2	0.5	1	2	3	4	5
Max. VOL%	0.45	0.75	1.25	2.4	3.6	4.8	6
Min. VOL%	0	0.25	0.75	1.6	2.4	3.2	4

- Confirm the acceptable tolerance of anesthetic gas monitor.
- The summation of two group data presents the acceptable range of delivered concentration

For example:

- Test sevoflurane vaporizer when the concentration setting is 3%, the measured value is 3.4%.
- Anesthetic gas monitor shows as partial pressure, so there's no correction required;
- The acceptable range of 3% (partial pressure) is 2.4~3.9%;
- And the accuracy of anesthetic gas monitor is ±5%, i.e. the tolerance of measured value (3.4%) is ±0.17 partial pressure.
- So, the acceptable range should extend to 2.23~4.07% partial pressure; The measured value (3.4%) corrected shall be within acceptable range.

Test result

If the measured value corrected is within the acceptable range of output concentration, the vaporizer can be in operation.

If not, do not use this vaporizer, or else the patients may be injured. If continue to use it, this vaporizer must be checked or repaired by authorized personnel, after finishing repair and test procedure, the vaporizer can be used contiuously.

After test

- Switch off Vaporizer: rotate the control dial to "OFF" position.
- Switch off O_2 flow.

Figure:

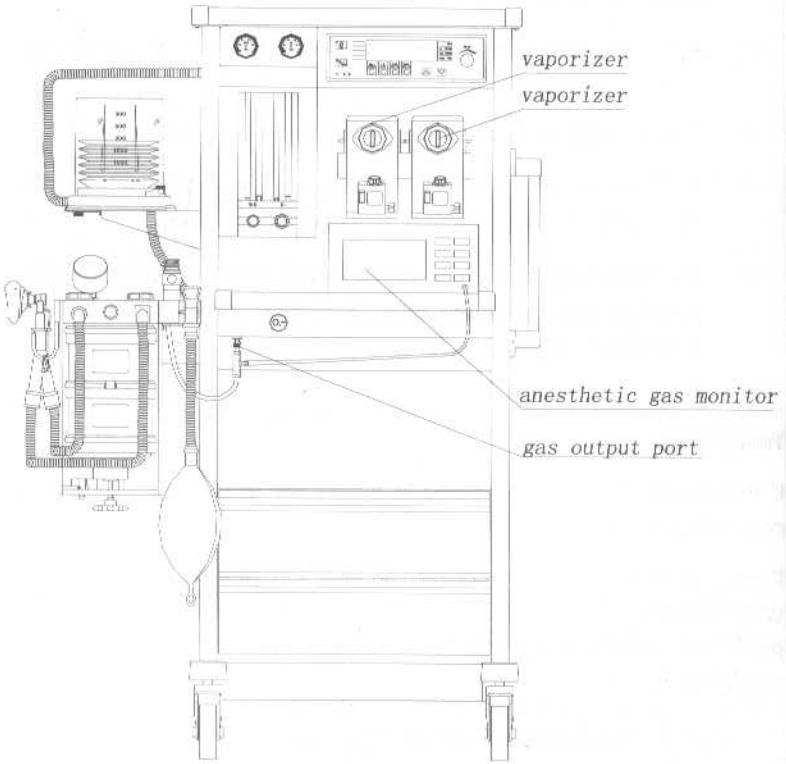


Figure 5-1 Output concentration testing

5.4 Checking the calibration

The performance of most vaporizers that are in clinical use can be confirmed by observing patient signs and consumption of anesthetic agents. Some users may, however, wish to employ analyzers either as a routine procedure or as part of an investigation to determine whether any abnormalities of performance have developed.

To help to achieve the reliability and consistency of performance of the VP300 Vaporizer, Aeonmed uses closely specified test conditions, test methods and detailed protocol in conjunction with training, experience and quality auditing systems. For these reasons, the full program necessary to help to ensure that a vaporizer complies with Aeonmed specifications cannot practicably be carried out in a field situation.

The following points must be considered when any measurements are being carried out on vaporizers to assist in determining whether any abnormalities of performance have developed.

1 To predict the concentration that the vaporizer can be expected to deliver, the detailed nominal performance data and the preceding comments must be taken into account.

2 The method of test used must not be such that it bears little relation to normal conditions of clinical use.

3 Any sampling techniques used must be such as to ensure the following:

a. The sample is fully representative of the vaporizer output, which may not be a homogeneous mixture at the vaporizer outlet.

b. The absorption of agent by any connecting tubing is negligible.

4 If a number of vaporizers are being examined at the same time the probability of all of them being consistently in error is so remote as to be negligible and the cause of any apparent error probably lies in the test method employed.

Consistent and reproducible analytical techniques must be used.

If unexpected results are obtained, it is a wise precaution to repeat the observation because the vaporizer may be more reliable than the techniques used to observe its performance.

If unexpected results occur, it is also worthwhile checking for sources of error such as the flowmeter, leaks or absorption by adjacent components.

Full account must be taken of any extraneous effects on the analyzer that may arise from changes in the carrier gas composition.

If the anesthetic machine on which the vaporizer is fitted is left for a period of time with no gases flowing, sensitive analyzers may detect small concentrations of agent for a short time at the machine outlet after the gas flow is turned ON with the vaporizer turned to 'OFF'. This is a normal machine characteristic caused by residual vapor left in the machine from previous use.

0 When the vaporizer is turned from a certain concentration to 'OFF' or above after a period out of use, an increased concentration may occur that rapidly stabilizes to the set concentration within approximately 10 seconds at 5 liters/minute flow.

1 At the 'OFF' setting it is normal for small steady concentrations to be observable on sensitive analyzers.

5.5 Analytical techniques

For field checking of the state of calibration, many techniques and analyzers are available. Aeonmed would not recommend any one technique or analyzer in preference to another, but the calibration and reliability of analyzers must be realistically considered and account must be taken of errors of use.

The following method of checking can be used where special equipment is not available or where a secondary check of analyzers is desired. The characteristics of the vaporizer are such that, if the vaporizer is satisfactory atone dial setting, it should be satisfactory at all other graduations.

1 Ensure that the vaporizer is at least half full and has been at an ambient temperature of 21 ± 2° C for at least three hours.

2 With the vaporizer securely mounted, drain the vaporizer as detailed in Section 4.2 and, after draining, ensure that the drain plug and the filler cap are both securely tightened.

3 Check that the control dial is turned to 'OFF' and then carefully and quickly pour a measured 50 milliliters of agent into the vaporizer without spilling.

4 Leave the vaporizer at a nominal temperature of 21± 2° C for one hour to help to ensure that the temperature has stabilized.

5 Set the flowrate to 5 liters/minute oxygen.

6 Turn the control dial to 2%, note the time and check that the flowrate is still 5 liters/minute. Readjust the flowrate as necessary.

7 Leave the vaporizer at this setting for 30 minutes. Periodically check and adjust the flowrate as necessary. Turn the vaporizer to 'OFF' and turn the oxygen OFF.

Drain the vaporizer as detailed previously in Instruction of section 4.2 and measure the amount of liquid drained off. The amount of liquid consumed should be as follows:

Enflurane	15.5 milliliters
Halothane	13.5 milliliters
Isoflurane	15.5 milliliters
Sevoflurane	16.6 milliliters

Appropriate action must be taken to handle the exhaust gases and spillage.

⚠ **CAUTION:** **This method is designed to be a quick and easy check of vaporizer operation and, therefore, it is somewhat imprecise. However, it is unusual for the measured liquid consumption to vary by more than 25% of the values listed above.**

5.6 Troubleshooting

Malfunction	Cause	Operator Action
No concentration transferred, or the concentration is too high/ low.	Vaporizer is empty or not full.	Filling the vaporizer with specific agent.
	The dial is at 'OFF'	Set the dial to more than 0.2%.
	No vaporizer	Installing a vaporizer
	Vaporizer is filled with improper anesthetic agent or mixture.	Draining the vaporizer, and blow it clear.
	The direction that gas flow via vaporizer is wrong.	Check the installation and connection of vaporizer.
	Leakage, e.g. the vaporizer is not in horizontal level.	Disconnect and remove the vaporizer, then reinstall it and test for leakage.
	The connector generates leakage.	Please contact eligible service representative.
	The environment is beyond operating range, e.g. the agent filled is cool; flowrate and concentration keep the high level for long time.	Make the vaporizer to the operating temperature. And refill the agent in the room temperature.
	Vaporizer generates malfunction.	Firstly use another vaporizer to replace the original for testing. If vaporizer is failure, please contact eligible service representative.

Dial can't be set.	The dial release is not pressed.	Press the dial release and turn the dial.
	The linkage is not switched; the linkage is blocked or another vaporizer is still opening.	Close another vaporizer and switch the linkage.
Dial can be set without pressing the dial release.	The dial release failure.	Please contact eligible service representative
Liquid level in the indicator can't be seen.	The vaporizer is empty; The vaporizer is overfilled; The indicator failure.	Refill the vaporizer; Drain the anesthetic agent; make the liquid level lower than the head-level mark; Please contact eligible service representative.

Filling and draining:

Leakage generates at drain port.	Drain valve is not close fully.	Close drain valve fully.
Anesthetic agent filled in unspecific vaporizer.	----	Drain the agent fully and blow it clean, and please contact eligible service representative.
Leakage generates from filling system.	Locking lever is not locked rightly.	Turn the lock lever to specific position.
	Locking lever failure.	Please contact eligible service representative.
	Hermetization system failure.	Please contact eligible service representative.
Leakage generates owing to overfilled.	Filling the anesthetic agent beyond the head-level mark.	Drain the anesthetic agent; make the liquid level lower than the head-level mark; and check output concentration.

6 Cleaning and disinfecting

⚠ **WARNING:** **Use a cleaning and sterilizing schedule that conforms to your institution's sterilization and risk-management policies.**

- **Refer to the material safety data policy of each agent.**
- **Refer to the operating and maintaining manual of all the sterilizing equipments.**
- **Do not inhale anesthesia gas.**

⚠ **CAUTION:** **To prevent damage:**

- **Refer to the data supplied by the manufacturer if there are any questions about the agent.**
- **Never use any organic, halogenate or oil base solvent, glass agent, acetone or other irritant agents.**
- **Never use any abrasive agent to clean any of the components (i.e. Steel wool, silver polish or agent).**

⚠ **WARNING:** **Do not pour water, or any cleaning solutions into the vaporizer.**

Do not immerse the vaporizer in water or any other liquid.

Do not autoclave the vaporizer.

Cleaning and sterilization of pre-use first:

1 Cleaning

To clean external surfaces, use a moist cloth and neutral detergent (pH 7 to 10.5).

⚠ **CAUTION:** **Never allow cleaning agents to accumulate either in the filler, the gas inlet and outlet ports or around the control dial.**

2 Sterilizing

Use surface sterilizing agent for sterilization. For reasons of material compatibility use sterilizing agent based on:

- aldehydes,
- alconhols,
- Quaternary ammonium compound

General cleaning and sterilizing should be performed as the above.

7 Specifications

⚠ **CAUTION** **All specifications are nominal and subject to change without notice.**

7.1 Principle of Operation

1 Vaporizing Chamber

The fresh gas flow through the vaporizing chamber, as shown on Figure 7-1, flows from flowmeter across the sump cover where it is diverted through the central cavity of the rotary valve and back through the Intermittent Positive Pressure Ventilation (IPPV) compensating assembly.

Gas now flows from the IPPV assembly down through the tubular wick assembly where it picks up anesthetic vapor and then flows across the base of the vaporizing chamber above the liquid agent.

From the base of the vaporizing chamber the gas/agent mixture flows through the sump cover to the proportional radial drug control groove of the rotary valve and then back into the sump cover where it combines with the fresh gas from the bypass circuit.

The combined total flow then flows out from the vaporizer to the anesthesia gas delivery system.

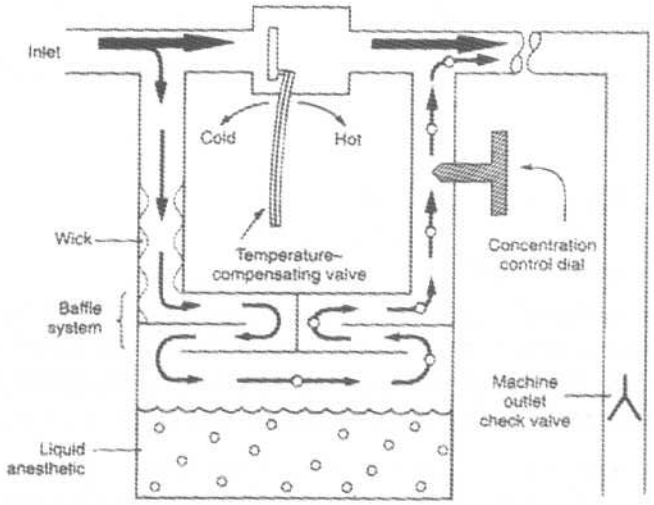


Figure 7-1 Vaporizer schematic

7.2 Performance

7.2.1 Accuracy of delivery concentration

- Recommended settings of ventilator to test output concentration:

  Flow: 2 L/min; respiratory frequency: 15 times per minute; I: E: 1:2.

- accuracy of anesthetic vapor delivery modules without applied back pressure:

  a) When the anesthetic vapor delivery module control is in the 'off' position, the delivered concentration shall not exceed 0.03 %.

  b) The delivered concentration at all graduations other than 'off', shall not deviate from the indicated value by more than +/- 20 % of the concentration setting or +/- 5 % of the maximum setting, whichever is the greater.

- accuracy of anesthetic vapor delivery modules with applied back pressure:

  The delivered concentration from the anesthetic vapor delivery module shall not vary by more than +30 %/-20 % from the concentration setting or + 7,5 %/- 5 % of the maximum setting, whichever is the greater。

7.2.2 Liquid capacity

Volume from minimum to maximum mark: 250 ml;

Volume retained by wick system: 40 ml.

7.2.3 Flow resistance (without connector)

Flow resistance at 5 liters/minute of O_2 at 21±2°C: 10 to 15 cmH_2O with Vaporizer setting OFF.

7.2.4 Flow range

0.2 to 15 L/min; 0.2 to 10 L/min (the concentration is more than 5%).

7.2.5 Gas requirements

- Clean, medically pure mixtures of O_2 and Air, O_2 and N_2O.
- O_2 and Air: dew point <5°C (below 0.5MPa)
- N_2O: water content not more than 2 mg/L

7.2.6 Tilted angle

Not more than 10°.

7.2.7 Classification

According to 93/42/EEC EC, VP300 belongs to the following classifications:

- Class II equipment
- Type B equipment

7.2.8 Calibration

Check the calibration certificate that is included with your VP300 Vaporizer.

Vaporizers are calibrated at 21°C using an oxygen carrier gas at a flow of 2 liters/ minute and they are temperature, flow and pressure compensated within the specified operating range.

⚠ **WARNING: The VP300 Vaporizer can only be calibrated at Aeonmed Authorized Service Centers.**

7.2.9 Pressure range of outlet

-1 to 8kPa (-10 to 80 mbar).

7.3 Environment requirements

Temperature	Operation:	15 to 35 ℃ (35°C is not recommended)
	Transport / Storage:	-40 to 65 ℃
Relative Humidity	Operation:	0 to 95%, non-condensing
	Transport / Storage:	0 to 95%, non-condensing
Atmospheric pressure	Operation:	70 to 106kPa
	Transport / Storage:	70 to 106kPa

⚠ **WARNING: If a vaporizer is transported when filled with liquid drug the control must be in the OFF position during transport and a period of at least ten minutes in a secured upright position must elapse before connection to an anesthetic breathing system.**

7.4 Weight and dimensions

Weight 6.2 kg			
Dimensions:	Height	Width	Depth
Selectatec compatible with Interlock	230 mm	120 mm	210 mm
Dräger 'Plug-in' compatible interlock	235 mm	104 mm	195 mm
North American Dräger compatible interlock	235 mm	104 mm	161.5 mm

7.5 Flow characteristics

7.5.1 Isoflurane

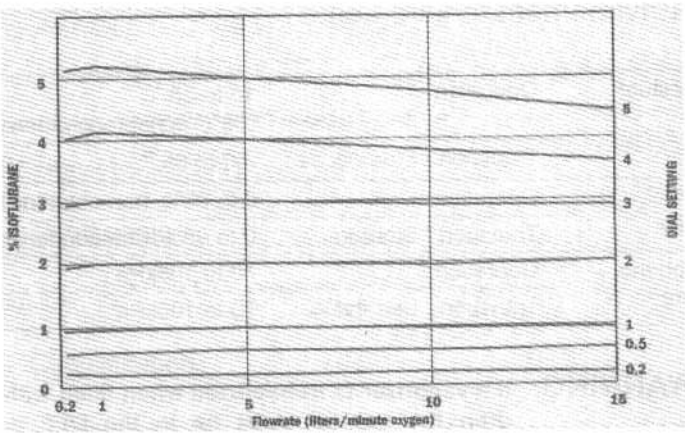


Figure 7-2 Effect of flowrate at 21±2°C with oxygen flowing

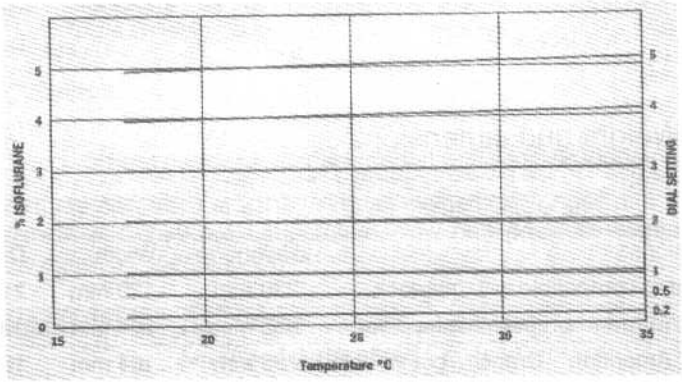


Figure 7-3 Effect of temperature at 5L/min with oxygen flow

7.5.2 Halothane

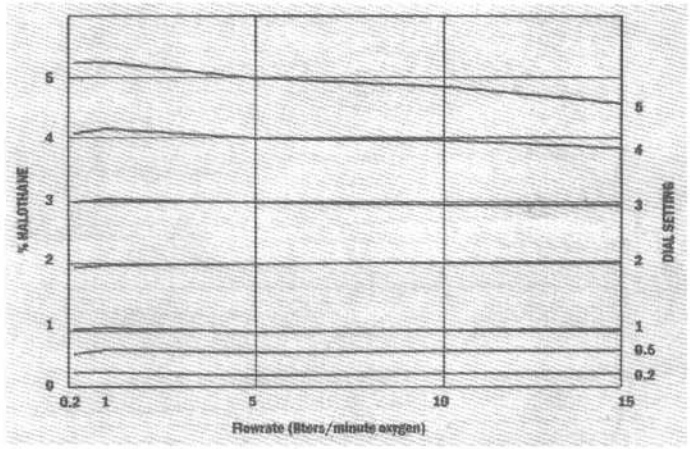


Figure 7-4 Effect of flowrate at 21±2°C with oxygen flowing

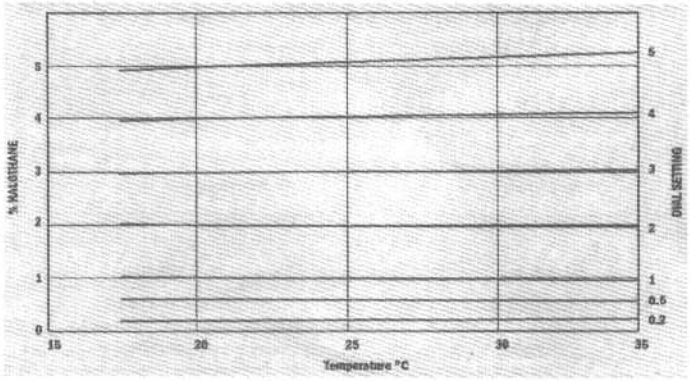


Figure 7-5 Effect of temperature at 5L/min with oxygen flow

7.5.3 Enflurane

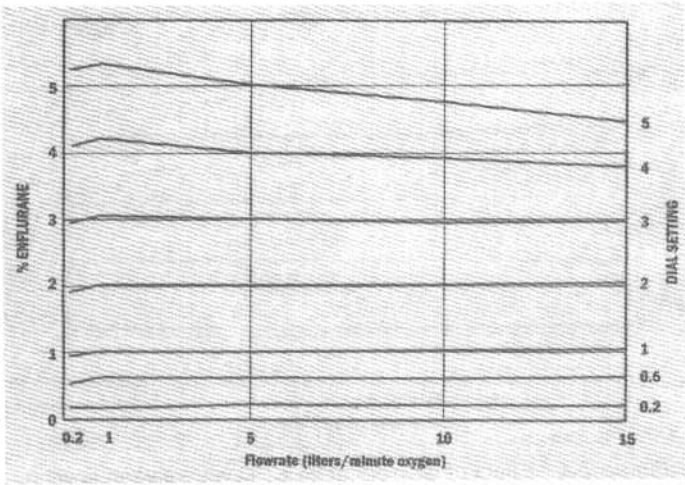


Figure 7-6 Effect of flowrate at 21±2°C with oxygen flowing

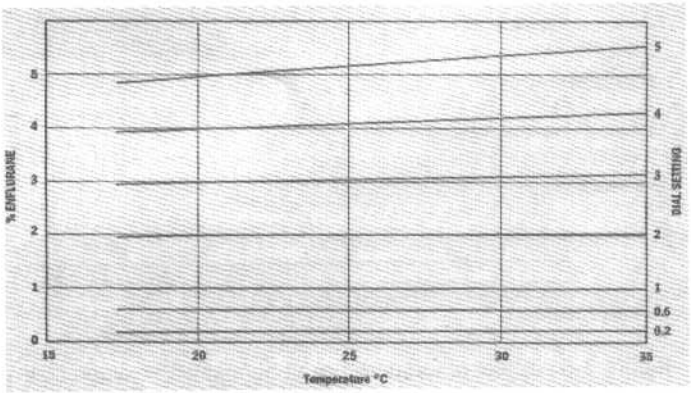


Figure 7-7 Effect of temperature at 5L/min with oxygen flow

7.5.4 Sevoflurane

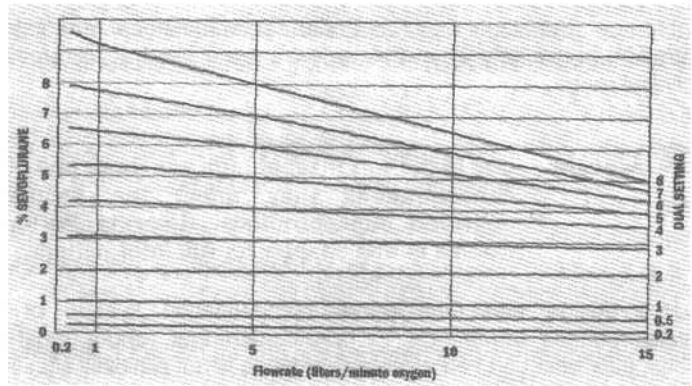


Figure 7-8 Effect of flowrate at 21±2°C with oxygen flowing

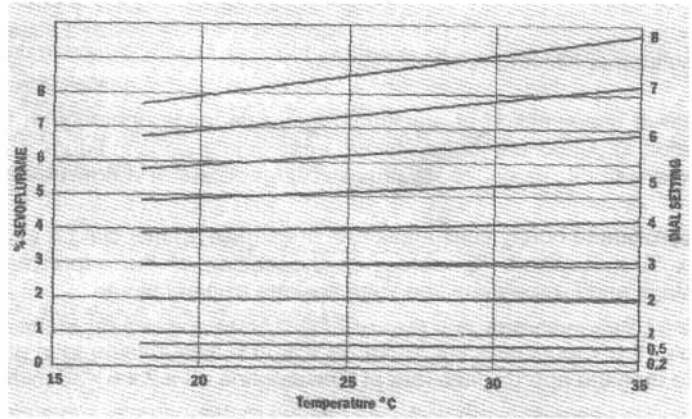


Figure 7-9 Effect of temperature at 5L/min with oxygen flow

7.6 Effects of variables

Ambient temperature, input flow rate and duration of use can affect delivered concentration, particularly when the vaporizers are used at extremes of the usual clinical range.

⚠ **CAUTION: Use of the vaporizer at high gas flows and high dial concentrations may affect the accuracy of delivered concentrations. Refer to Performance Curves in this chapter for full information.**

The valve design and temperature compensation system of VP300 Vaporizers reduces the effects to levels such that, under most clinical conditions, their effect on vaporizer performance is not clinically significant.

7.6.1 Anesthetic agent consumption

- Isoflurane, Halothane and Enflurane

The rate of consumption of anesthetic agent depends primarily on flowrate and vapor output concentration. As an approximate working figure, 1 milliliter of liquid anesthetic is required to provide 200 milliliters of vapor.

The approximate hourly consumption of anesthetic agents can be expressed as 3 x % x F, where % represents the setting of the vaporizer output percentage and F represents the input flowrate in liters/minute.

Example: If a vaporizer is set to deliver 2% at 6 liters/minute total gas input flowrate then the approximate rate of consumption =3 x 2 x 6= 36 ml/hour.

The figures are approximate and are intended for general guidance only.

- Sevoflurane

The rate of consumption of anesthetic agent depends primarily on flow rate and vapor output concentration. As an approximate working figure, 1 milliliter of liquid anesthetic is required to provide 200 milliliters of vapor.

The approximate hourly consumption of anesthetic agents can be expressed as 3.3 x % x F, where % represents the setting of the vaporizer output percentage and F represents the input flow rate in liters/minute.

Example: If a vaporizer is set to deliver 2% at 6 liters/minute total gas input flow rate then the approximate rate of consumption = 3.3 x 2 x 6 = 39.6 ml/hour.

The figures are approximate and are intended for general guidance only.

7.6.2 Ambient pressure

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

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

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

P is absolute pressure in kPa. C is delivered concentration vol%, S% is the set value.

To obtain a consistent depth of anesthesia when gross changes of barometric pressure occur, the Vol% must be changed in inverse proportion to the barometric pressure.

The vaporizer automatically makes this Vol% change and for practical clinical purposes the effects of barometric pressure can be ignored.

7.6.3 Ambient temperature

The effects of variation in temperature are normally negligible at commonly used combinations of dial setting and ambient temperature.

If the vaporizer temperature is above the range shown on the performance curves, the vaporizer output may be unpredictably high, particularly if the temperature of the agent approaches the agent boiling point specified by the agent manufacturer.

If the vaporizer temperature is below the range shown on the performance curves, the vaporizer output may be lower than expected.

To help avoid inaccuracies due to extreme temperatures, before using the vaporizer it must be allowed to attain a temperature within the range shown on the performance curves.

7.6.4 Back pressure

⚠ **WARNING: Pressures in excess of 400 mmHg may overcome the internal pressure balance and cause a variation in output.**

- Steady back pressure

The vaporizer cannot distinguish between pressures at the outlet due to barometric pressure and pressures in excess of barometric due to steady back pressures applied by downstream components. The equation given in the section Barometric Pressure therefore applies with the term P now being the absolute pressure at the outlet, that is, barometric pressure plus back pressure. Steady back pressure reduces the Vol%.

Currently, it is unlikely that the steady back pressure imposed by commonly used downstream components, other than some ventilators, exceeds 30 mmHg at commonly used flowrates. Back pressures as high as 30 mmHg would reduce the delivered Vol%, at 760 mmHg barometric pressure, to the following:

$$\frac{760}{/\,yV} = 0.96 \text{ of what would otherwise be expected.}$$

- Fluctuating back pressure

Under normal clinical circumstances effects of this magnitude can be ignored.

Fluctuating back pressure may be imposed on the vaporizer by downstream components and/or assisted or controlled ventilation to the patient. These fluctuating back pressures can affect the vaporizer and increase the concentration by intermittently altering the pressures, and consequently the flow distribution, within the vaporizer.

The greatest effects are observed at combinations of very low flowrates and low dial setting with large and rapid pressure fluctuations. The effects become progressively less important as the dial setting and flowrate increase and the magnitude and rate of cycling of the pressure fluctuations decrease.

7.6.5 Carrier gas composition

Small output decreases can occur when the carrier gas composition is changed from 100% oxygen.

When either air or nitrous oxide is employed as the carrier gas, the output is lowered compared to the output when oxygen is the carrier gas. This effect is the greatest (up to 20% of setting) at low flows when nitrous oxide is employed, but using nitrous oxide reduces the required inspired concentrations of volatile agent that can, depending upon the proportion, mitigate the decreases in output from the vaporizer.

⚠ **WARNING: Only operate the vaporizer with dry medical gases.**

VP300 Vaporizer User Manual

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Beijing Aeonmed Co., Ltd.