SOMNI 3

VETERINARY ANESTHETIC VAPORISER OPERATIONS MANUAL

SOMNI PRODUCT MANUAL

SOMNI
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TABLE OF CONTENTS

SOMNI SCIENTIFIC

USER RESPONSIBILITY

The SOMNI 3 is a precision medical vaporiser designed for **Veterinary Use Only.** This vaporiser was designed to mix the vapors of specified liquid anesthetic gas agents with anesthetic delivery gases. The vaporiser will continue to provide reliable performance only if the manufacturer's operating and maintenance instructions are followed. The vaporiser, as with any mechanical medical device, requires periodic preventative maintenance and calibration. Any components, which become worn, distorted, or contaminated should be replaced by a factory authorized service center. A vaporiser that requires service should not be used until it has been accurately tested and verified by a factory authorized service center. Field-testing of vaporiser output using portable test equipment, while valuable, is not a substitute for factory authorized preventative maintenance. Factory service and calibration is recommended every two years, field testing is recommended annually at minimum. The user assumes full responsibility and liability of any use of the vaporiser.

WARNINGS AND CAUTIONS

- This vaporiser is intended for **Veterinary Use Only**
- **Do not** fill the vaporiser with any agent other than the one specified on the front label. Vaporisers are specifically designed dependent on agent type. Therefore, any other agent used can prove to be dangerous to a patient.
- **Do not** use this vaporiser until it is mounted upright, vertical and out of operation for a minimum of **(1) hour** after initial filling to allow for proper initial wick absorption. Failure to allow wicking time may result with inaccurate output at the selected dial setting.
- **Do not** carry vaporiser by control dial. Handle and transport vaporiser with care by grasping the vaporiser firmly with two hands.
- **Do not** modify, tamper, or disassemble the vaporiser. There is a probable danger of damaging the vaporiser and altering the calibration accuracy.
- **Do not** put vaporiser into any liquid, including water.
- **Do not** attempt to sterilize vaporiser.
- **Do not** drain anesthetic agent into any container other than a properly marked container.
- **Do not** tilt or tip vaporiser beyond a 45-degree angle while filled with liquid agent. If unit is accidentally tipped on its side, please call the manufacturer for specific instructions.
- **Do not** have vaporiser serviced by anyone other than a SOMNI Scientific authorized service center.
- **Do not** operate vaporiser prior to leak testing the anesthetic equipment, ensuring secure connections to prevent unnecessary anesthetic exposure
- Turn the vaporiser **OFF** when not in use
- It is recommended that the vaporiser is kept upright at all times, after installation.

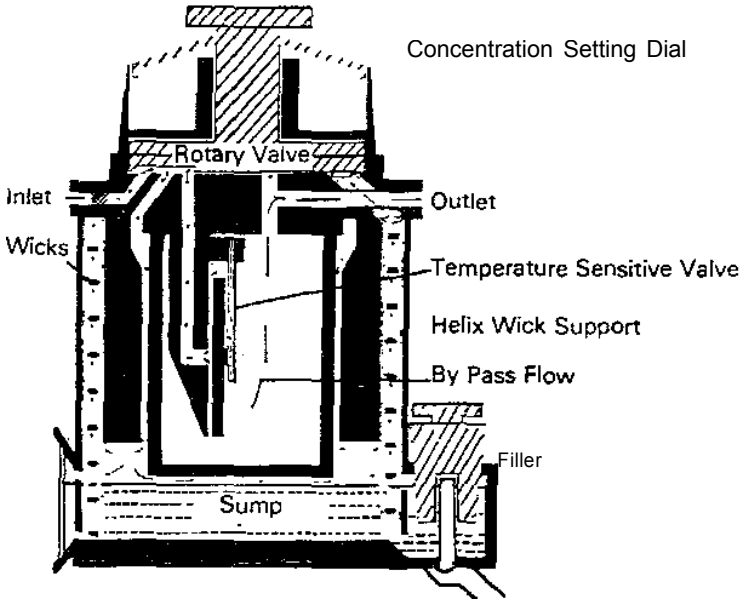
PRINCIPLES OF OPERATION

VAPORISER SUMP AND VALVE ASSEMBLY

This anesthetic vaporiser is comprised of a vaporizing chamber and duct system (located within the sump cover), rotary valve and concentration dial. The concentration dial is connected to the rotary valve underneath. The rotary valve contains ducts and a vapor control channel. With the concentration dial in the off position, the rotary valve links the inlet and outlet of the vaporiser, allowing carrier gas to pass through. When the concentration dial is turned on, the carrier gas is split in, a stream and a stream flowing into the vaporizing chamber.

The vaporizing chamber contains two concentric wicks that are in contact with the liquid anesthetic agent. The wicks ensure the vapor is maintained at saturation of concentration in the gas that leaves the vaporizing chamber. The flow through the vaporizing chamber is controlled by the concentration dial.

Temperature compensation occurs automatically utilizing a bi-metallic strip to keep the output of the vaporiser constant during conditions of changing temperature.



EXAMINATION AND PREPARATION FOR USE

1. Examine shipping carton for signs of external damage.
2. Remove contents from carton and inspect for visible damage such as dents or missing parts.
3. If damage or missing parts are discovered or suspected, notify customer service immediately at 1-877-637-3625.
4. Check that control dial operates freely.
5. Confirm the drain valve is completely closed .
6. Remove the mounting hardware (vaporiser spacer and 3-6mm bolts with washers) and drain tube (*not shown) from package.

INSTALLATION

The standard mounting system requires bolting of the vaporiser directly to a rigid back bar of an anesthetic gas machine. The vaporiser should always be mounted between the gas flow-metering unit and the breathing circuit-always upstream of any absorber or humidifier. Ensure that emergency oxygen supplies or oxygen flush enter the gas circuits downstream of the vaporiser.

A. The SOMNI 3 is supplied with mounting hardware consisting of a spacer and 3-6mm bolts. While supporting the weight of the vaporiser, install the spacer between the vaporiser and the mounting surface and secure the vaporiser using the mounting bolts provided. Ensure the bolts are tightly secured, but be sure not to over-tighten.

B. Connect the 23mm inlet and outlet adapters to the corresponding outlets on the cagemount. Twist and firmly push on for a secure, leak-free connection. It may be necessary to connect the 23mm adapters prior to mounting the vaporiser.

C. Complete a 10 second pressure test to confirm a leak free installation. **Instructions on Page 10.**

INSTALLATION

IMPORTANT!

- The direction of gas flow must be from “inlet to outlet” (i.e. from left to right) when viewing the vaporiser from the front.
- Ensure the liquid (which may accumulate in the breathing circuit or the CO2 absorber) can not enter the vaporiser while:

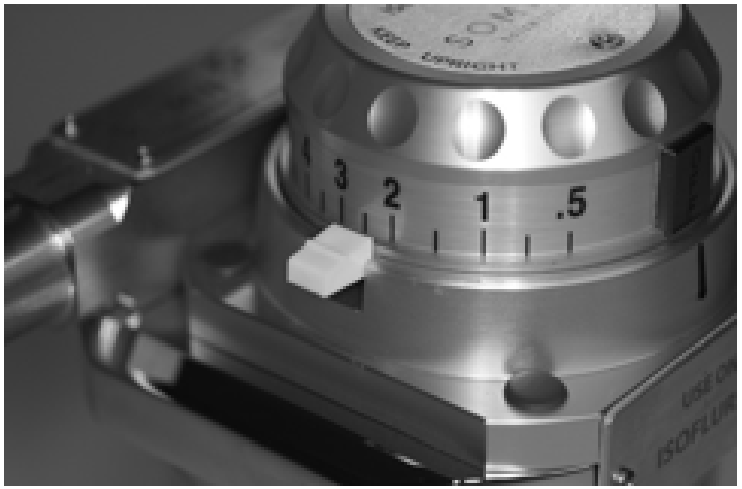
  -in use
  -during disassembly of the circuit
  -when the machine is not in use

The vaporiser is fitted with standard 23 mm inlet and outlet taper connections.

Vaporiser Spacer Placement

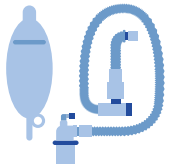
OPERATING INSTRUCTIONS

1. Observe all instructions and warnings on the vaporiser
2. Fill only with agent indicated with vaporiser in OFF position
3. Perform a leak test prior to first use (See instructions below- “10 Second Test”)
4. Depress locking button to turn dial from OFF position
5. Turn dial counterclockwise to desired concentration
6. Then turn control dial counter clockwise to desired concentration
7. Turn vaporiser to “OFF” position when not in use



10 SECOND PRESSURE TEST

Before each use, "leak test" the anaesthesia system and ensure the waste gases have a patent way through the evacuation system.

1		Close the pop-off valve and create a tight seal of the patient circuit with your hand.
2		Push the oxygen flush button, or turn on oxygen flow meter, until the bag is fully distended and/or manometer reads 30-40 cm of H20 pressure.
3		Release the oxygen flush button and/or ensure the oxygen flowmeter is off; float is at the bottom of the tube. Observe the manometer (or the bag if your machine does not have a manometer). The manometer needle should remain steady. If the manometer needle drops, the bag deflates, or if you hear a hissing sound, you have a leak.
4		Check hoses, bag, vaporizer inlet and outlet, any fittings or seals at the top and/or bottom of your CO2 absorbent container for leaks (a soapy water solution can be used for leak test). When the pressure remains constant, with the oxygen turned off, your machine can be considered leak-free on the low-pressure side.
5		Re-open the pop-off to your standard setting.
6		Squeeze the bag (with your hand still over the patient circuit) to ensure the gases have a clear way out through your scavenging system.

FILLING INSTRUCTIONS-FUNNEL FILL

WARNING:

1. Verify that vaporiser dial and delivery gas flowmeter(s) are in the “OFF” position.

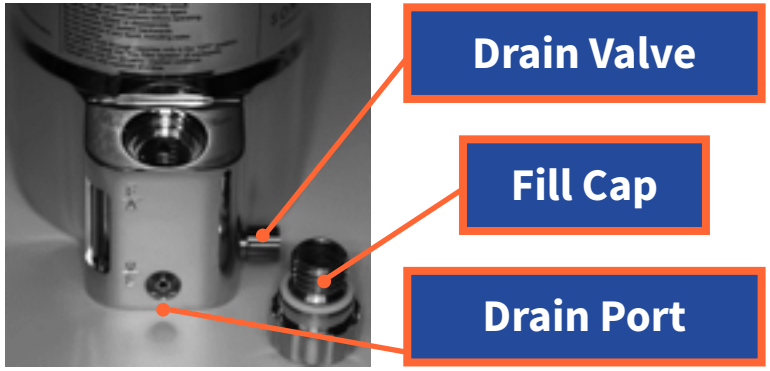
2. Verify that anesthetic agent is the same as labeled on front of vaporiser.

   DO NOT fill vaporiser with any agent other than the one specified on the front label. The vaporiser is designed for that agent only. Any agent other than specified could prove to be dangerous to a patient.

3. Verify that the drain valve on the right side of the fill assembly is closed by turning clockwise until finger tight.

4. Remove the funnel cap and pour agent slowly into opening. Simultaneously, observe the agent level through the sight glass. Note: If the vaporiser is dry, the level will fall slightly as the wick absorbs the agent.

5. Replace cap by turning cap clockwise. Cap should be tight to prevent leaks.



DRAINING INSTRUCTIONS-FUNNEL FILL

WARNING:

Liquid **MUST** be drained from the vaporiser into a properly labeled container.

1. Attach small drain tube to the hole in the front of the vaporiser fill assembly.

2. Hold an empty, properly labeled container under the tube.

3. Open the drain valve located on the right side of the fill assembly. After all liquid is drained, close the valve finger tight to seal.

4. Discard used anesthetic agent per proper protocol.

ASSURING PERFORMANCE OF YOUR VAPORISER

To assure the continued performance of your vaporiser, the manufacturer recommends **full factory preventative maintenance** be performed every 2 years. Accurate and efficient anesthetic gas delivery is a primary consideration in patient care. Anesthetic agent vapors are extremely potent, and a very small error in concentration could be hazardous.

Preventative Maintenance Includes:

- Disassembly of the vaporiser
- Cleaning and inspection of all components
- Replacement of internal wick and seals
- Testing of thermostat and adjusting or replacing if needed
- Reassembly and leak test
- Calibration using industry standard laser refractometer

Preventative Maintenance Ensures:

- Worn components are replaced when necessary and calibration is verified.
- Wicks are replaced to prevent the accumulation of contaminants which can hinder anesthetic vaporization and interfere with efficient anesthetic gas delivery.
- Inspection and service can reveal accidental damage that could alter performance and allows correction
- Correction of vaporiser leaks and prevents the vaporiser from contributing to unnecessary personnel exposure to waste anesthetic gas pollution.

SPECIFICATIONS

Calibration

Vaporisers are calibrated at 21° C. The variation in output with temperature, flow rate and duration of use is small, and the variation in output when used with Intermittent Positive Pressure Respiration is negligible.

Resistance to Gas Flow

5cm.wg at the “OFF” setting at 5 liter/min 02 at 22° C

Duration of Use

The rate of consumption of anesthetic agent depends primarily on flow rate and vapor output concentration. As an approximate working figure, 1.0 ml of liquid anesthetic is required to provide 200 ml of vapor.

The rate of evaporation of anesthetic agent may be used (with caution) as an approximate method of checking that the delivered output is not grossly in error. It may also be used as a means of estimating how often the vaporiser is likely to need refilling.

The approximate hourly consumption of anesthetic agents can be expressed as follows:

3 x % x F

Where % represents the setting of the vaporiser output percentage, F represents the input flow rate in liter/min.

Example: If a vaporiser is set to deliver 2% at 6 liter /min total input gas flow rate.

Approximate rate of agent consumption = 3 x 2 x 6 = 36 ml/hour.

The above figures are approximate and intended for clinical guidance only. Figures will vary depending on flow meter type (and other varying factors). Results will be grossly in error if the vaporiser drain port is not fully closed.

Liquid Capacity

Amount of anesthetic agent to fully charge the vaporiser =250 ml.

Amount retained by Wick System =75 ml.

Weight and Dimensions

Weight 15.5 lb. / 7kg
Height 7.58 in / 195 mm
Depth 5.5 in / 140 mm
Width 5.25 in / 135 mm
Capacity 250 ml
Wicking Capacity 75 ml

Some ventilators may impose higher, steady back pressures (around 100 mm HG), producing more significant depression of the v/v percentage. Increased patient uptake of agent, along with improved ventilation can often mitigate these effects, eliminating the need to compensate for increased back pressure at the vaporiser.

High Back Pressures;

Pressures in excess of 400mm Hg could conceivably occur during procedures similar to bronchoscopy or because of occlusion of downstream tubing and piping or for other reasons. These effects on v/v percentage cannot be precisely predicted but the most likely effects will be reductions in concentration (or small increases).

SPECIFICATIONS

Back Pressure Fluctuating
Fluctuating backpressures may be imposed on the vaporiser by downstream components and assisted or controlled ventilation to the patient. This can affect the vaporiser and increase the concentration by intermittently altering the pressures, therefore altering flow distribution within the vaporiser. The greatest effects are observed in combinations of very low flow rates and low dial settings, with large and rapid pressure fluctuations. These effects become progressively less notable as the dial setting and flow rates increase, causing the magnitude and rate of cycling pressure fluctuations to decrease.

In clinical use, vaporisers are considered unaffected by fluctuating back pressures which occur frequently in most typical, clinically encountered conditions appertaining to human anaesthesia.

Carrier Gas Composition
Small effects can occur when the carrier gas composition is changed (i.e., from Oxygen to air, or in a Nitrous Oxide and Oxygen mixture). As a general rule, variation of output with carrier gas compilation should be considered of low clinical signfigance, since the side effects (if any) are typically less than 10% of the setting.

In an instance where significant changes do occur, the usual effect is a slightly depressed output once nitrous oxide is employed (compared to the output when oxygen is the carrier gas).

Other Variables
Ambient temperature, input flow rate and duration can often affect delivered concentrations, particularly when vaporisers are used at the clinical extremes of such variables.

The valve design and temperature compensation system of the Somni 3 vaporisers work to reduce the effects to levels considered not significant by clinical standards.

SPECIFICATIONS

Effects of Variables

Temperature

Temperature variation effects are typically negligible at common dial setting and ambient temperature combinations.

The vaporiser responds very slowly to change in ambient temperate to prevent the valve from closing completely. As an additional safety feature, the temperature sensitive valve does not respond to temperatures below the approximate range of 12-15° C.

Should the vaporiser temperature be lower than this, then the output can be expected to be lower than that indicated on the dial.

At temperatures above the range shown on the performance curves, the vaporiser output may be unpredictably high-particularly if the temperature approaches the boiling point of the anesthetic agent.

To avoid any inaccuracies due to extreme temperatures, the vaporiser should be allowed to reach a temperature within the suggested range (of the performance curves) prior to use.

Pressure

Vaporisers are graduated in v/v percentage at 760 mm Hg. If the ambient pressure changes the v/v % will change so that at an ambient pressure P mm Hg the delivered percentage (D % v/v)-

Equation 1 $$D = \frac{\% \times 760}{P}$$

Where % is the nominal setting of the vaporiser.

It is generally accepted that the depth of anaesthesia depends on the inspired partial pressure of agent and not the concentration by volume of agent.

To obtain a consistent depth of anaesthesia when gross changes of barometric pressure occur, it is necessary to change the v/v percentage in inverse proportion to the barometric pressure. The vaporiser automatically performs this action. For practical and clinical purposes, the effects of barometric pressure can be ignored.

The vaporiser automatically does this and for practical clinical purposes the effects of the barometric pressure can be ignored.

WARRANTY AND SERVICE

Limited Warranty

SOMNI Scientific (SOMNI) warrants to the original purchaser that the products, not including accessories, shall be free from defects in materials and workmanship under normal use, if maintained in accordance with SOMNI's guidelines and used according to its labeling, for the period specified in the manual.

Warranty period is Lifetime contingent upon a 2 year service cycle from the invoiced date of purchase.

THIS LIMITED WARRANTY, IS IN LIEU OF AND EXCLUDES ALL OTHER WARRANTIES WHETHER EXPRESSED OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

This warranty is void if the product has been altered, misused, damaged by neglect or accident, tampered with, not properly maintained, not installed in strict compliance with applicable codes and ordinances, or repaired by persons not authorized by SOMNI. This warranty does not cover normal wear and tear and maintenance items and specifically excludes accessory items and any other equipment used with the product.

Limitation of Remedies

SOMNI Scientific's only obligation under this limited warranty is the repair or replacement of the product. THIS IS THE EXCLUSIVE REMEDY. SOMNI shall not be liable for and hereby disclaims any direct, incidental, consequential or special damages or delays, including but not limited to loss of use, downtime, lost business, revenues and profits.

Warranty Procedure

To obtain warranty service, contact SOMNI Scientific **877-637-3625** or **info@somniscientific.com**.

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