

CASE REPORTS

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An Unexpected Penlon Sigma Elite Vaporizer Leak

Sandra E. Lewis, M.D.,* J. Jeff Andrews, M.D.,† Gary W. Long, M.D.‡

THE Penlon Sigma Elite vaporizer (Penlon Ltd., Radley Road, Abingdon, UK) has been widely distributed throughout the United States to meet the consumer demand for delivery of sevoflurane. We present a case describing a Penlon Sigma Elite Vaporizer leak that was not detected using the 1993 Food and Drug Administration (FDA) Anesthesia Apparatus Checkout Recommendations¹ for anesthesia gas delivery machines. To our knowledge, this is the first case report describing a potential problem with the Penlon Sigma Elite Vaporizer when used on an Ohmeda Modulus II anesthesia machine (Madison, WI).

Case Report

A 49-yr-old, 68-kg man with a laryngeal stenosis was scheduled for direct laryngoscopy, esophagoscopy, and biopsy with carbon dioxide laser correction. Before this case, two cases were performed that day

uneventfully using the same Ohmeda Modulus II anesthesia machine. It was equipped with three vaporizers, including a Penlon sevoflurane Sigma Elite, an Ohmeda isoflurane Tec 4, and an Ohmeda desflurane Tec 6. The vaporizers were mounted on a Selectatec manifold (Ohmeda), and a circle breathing system was used. The anesthesia machine was checked before the first case of the day by a clinical anesthesia year 1 anesthesiology resident using the FDA 1993 Anesthesia Apparatus Checkout Recommendations.¹ No leaks were detected. Between case 2 and case 3, the anesthesiology resident refilled the sevoflurane vaporizer using a keyed filler. Before induction of anesthesia for case 3, the circle system was tested for leaks using a positive-pressure leak test, with all of the vaporizers in the "off" position.

The anesthetic plan included an inhalation induction at a flow rate of 6 l/min using nitrous oxide, oxygen, and sevoflurane. At 5 min, despite incremental increases to a dial setting of 5%, the inspired concentration of sevoflurane had not increased as rapidly as expected. The Datex Ultima (Tewksbury, MA) multigas analyzer indicated an inspired sevoflurane concentration of only 0.7%, instead of the expected 3–5%.

There was no problem with bag-mask ventilation throughout the induction. However, a sevoflurane odor was detected in the ambient air. Because the patient had a heavy beard, the source of the odor was initially assumed to be a leak between the face mask and the beard. It was then observed that the clamp screw that tightens the filler plug located in the 3-o'clock position of the Penlon Sigma Elite sevoflurane vaporizer was screwed fully out counter clockwise, or in the "open" position instead of in the normal "closed" clockwise position (fig. 1, left). The filler control knob located in the 12-o'clock position was correctly screwed clockwise to the closed position. After it was discovered that the screw clamp knob was in the open position, it was screwed back into the closed position (fig. 1, right). The patient had no awareness or recall and did well.

After the case was over, the leak was reproduced, and a Datex Ultima multigas analyzer was used to quantitate the concentration of sevoflurane escaping from the leak. The vaporizer dial setting was 5% sevoflurane, and flow from the anesthesia machine was 6 l oxygen/min. The filler plug was removed entirely, and the distal end of the Datex sampling line was inserted into the square fill port. The sevoflurane concentration indicated by the Datex analyzer was 15%, and the oxygen concentration was 79%. Because the upper end of the measuring range for sevoflurane for the Datex analyzer is 15%, it was necessary to calculate the actual sevoflurane concentration. The only two gases that could escape through the leak were oxygen and sevoflurane. Because the oxygen concentration was measured to be 79%, the calculated sevoflurane concentration was 21% ($100\% - 79\% = 21\%$). This value corresponds to the saturated vapor pressure of sevoflurane at 20°C at one atmosphere ($160 \text{ mmHg} \div 760 \text{ mmHg} = 21\% \text{ sevoflurane}$).

* Assistant Professor of Anesthesiology, Department of Anesthesiology, University of Alabama at Birmingham School of Medicine; Anesthesiology Service, Veterans Affairs Medical Center.

† Professor and Vice-chair for Clinical Development, Department of Anesthesiology, University of Alabama at Birmingham School of Medicine; Chief, Anesthesiology Service, Veterans Affairs Medical Center.

‡ Anesthesiology Resident, Department of Anesthesiology, University of Alabama at Birmingham School of Medicine.

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Address reprint requests to Dr. Lewis: Anesthesiology Service (129), Birmingham Veterans Affairs Medical Center, 700 South 19th Street, Birmingham, Alabama 35233. Address electronic mail to: JeffAndrews@ccc.uab.edu

Key words: FDA anesthesia apparatus checkout recommendations; low-pressure circuit leak test; negative-pressure leak test; patient awareness under anesthesia; unexpected vaporizer leak; variable bypass vaporizers.

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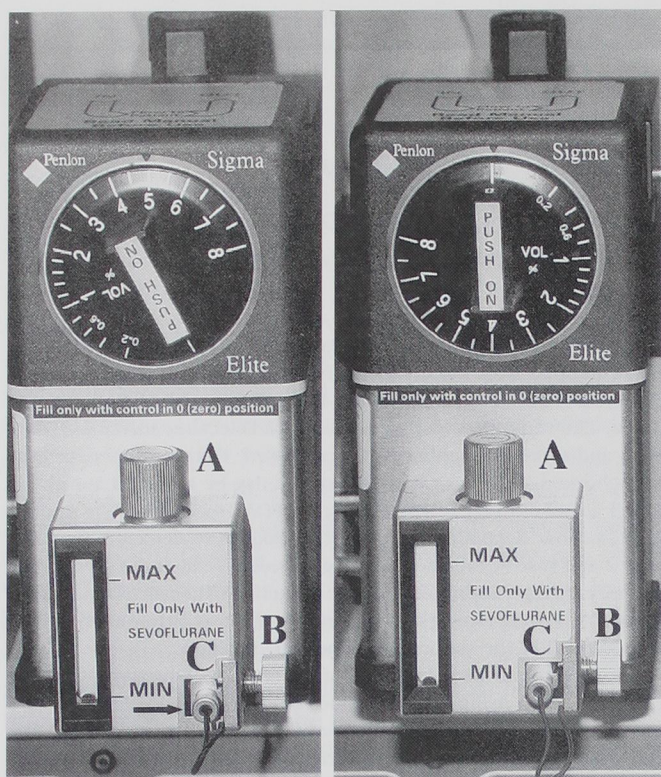


Fig. 1. Photographs of the Penlon Sigma Elite Vaporizer. A = filler control knob, B = clamp screw, C = filler plug, arrow = leak. (Right) The clamp screw, B, is fully closed, and it pushes the filler plug, C, firmly to the left, preventing a leak. (Left) The clamp screw, B, is fully open. Saturated sevoflurane (21%) vapor escapes through the leak indicated by the arrow. Unlike with Ohmeda vaporizers, anesthetic gas, rather than liquid, escapes through the leak.

Discussion

Factors that contributed to the problem encountered include: (1) unfamiliarity with the product; (2) vaporizer design; (3) anesthesia machine design; (4) use of a non-Ohmeda product on an Ohmeda machine; and (5) limitations of the 1993 FDA Anesthesia Apparatus Checkout Recommendations.

The design of the Penlon Sigma Elite Vaporizer is different from Ohmeda vaporizers, and unfamiliarity with design differences can become a contributory factor in the occurrence of critical incidents. According to reports by Cooper *et al.*,^{2,3} equipment design and insufficient familiarity with equipment were indictable in many categories of human error. This case shows the continued need for evaluation and training in the proper use of new equipment, and it reveals some of the potential shortcomings in equipment designs when different manufacturers' products are paired. The anesthesia care

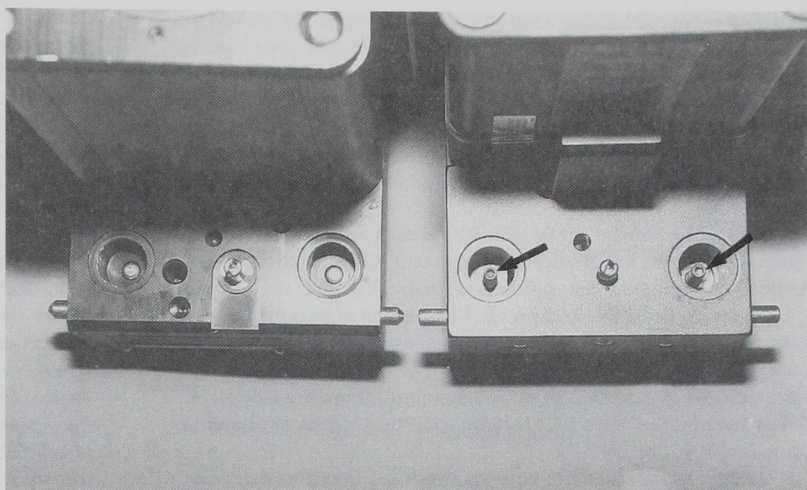
providers delivering anesthesia during this case were unfamiliar with the Penlon Sigma Elite Vaporizer. The anesthesia attending had not been adequately trained in its use, and the CA-1 resident was new to the service. In academic and private practice settings, anesthesia care providers occasionally encounter equipment with which they are not familiar. To avoid problems such as this one, it is of paramount importance to have ongoing in-service education of new equipment, particularly if coverage is provided by a large number of anesthesia care providers on a rotational basis.

The design of the Penlon Sigma Elite Vaporizer is different from Ohmeda vaporizers. The major difference is that liquid anesthetic does not leak from the Penlon vaporizer, even when the filler plug is completely removed. On keyed, filled Ohmeda vaporizers, if the handle (which is equivalent in function to the Penlon agent-specific filler plug clamp screw) is moved to the open position, liquid inhaled anesthetic leaks out the keyed filler port. Thus, on Ohmeda vaporizers, the leak is obvious, but it is not so apparent on the Penlon vaporizer. Only one revolution of the Penlon clamp screw located in the 3-o'clock position (fig. 1, B) differentiates fully open *versus* fully closed. This subtle difference is very difficult to appreciate without very careful and close observation.

Design features of the Ohmeda Modulus II anesthesia machine also contributed to the problem. This vaporizer leak is particularly inconspicuous, especially when the Penlon Sigma Elite Vaporizer is mounted on a Modulus II machine, which has a check valve at the common gas outlet. In this case, a positive-pressure leak test failed to detect the vaporizer leak entirely because the low pressure circuit is isolated from the breathing circuit by the check valve.^{4,5} The negative-pressure leak check recommended by Ohmeda (or by the FDA) would have detected the leak, however. In 1993, Meister and Becker⁶ reported a case of a fresh gas flow leak through a Dräger Vapor 19.1 vaporizer (North American Dräger, Telford, PA) with a key-index fill port. They recommended a positive-pressure leak test with each vaporizer turned to the on position. Because North American Dräger machines do not have a check valve in the low-pressure circuit, this recommendation would detect a large (but not necessarily a small) low-pressure system leak caused by an open fill port. However, in our case, a positive-pressure leak test would not have detected the internal vaporizer leak *even if the vaporizer was turned on* because the Ohmeda check valve divorces the breath-

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Fig. 2. Bottom view of two variable-bypass vaporizers. The vaporizer on the left is an Ohmeda Tec 4, and the one on the right is a Penlon Sigma Elite. Both vaporizers are turned off. Notice how the Penlon vaporizer on the right has two centrally located permanent pins (arrows) that automatically open the inlet and outlet port valves of the vaporizer manifold when the vaporizer is mounted to the manifold. Therefore, fresh gas flows through the head of the Penlon vaporizer even when it is turned off.



ing circuit from the low-pressure circuit.^{4,5} The negative-pressure leak check recommended by Ohmeda or by the FDA would have detected the leak only if the vaporizer was turned on.

Use of a non-Ohmeda product on an Ohmeda machine can defeat safety features intended by the manufacturer. The Ohmeda vaporizer is designed for specific use with the Ohmeda Selectatec manifold. When an Ohmeda vaporizer is mounted on the Ohmeda manifold, the vaporizers are totally out of circuit when turned to the off position.⁷ Thus, when the Ohmeda vaporizers are turned to the off position, no gas flows through the bypass chamber of the vaporizer because the vaporizer is isolated from the manifold. This design offers two theoretical safety advantages. First the chance of cross-contamination between vaporizers is minimized. This safety feature helps minimize trace gas exposure during a malignant hyperpyrexia case. Second, internal vaporizer leaks of unused vaporizers do not influence normal operation of the vaporizer in use. The Penlon Sigma Elite, however, has two permanent pins centrally located in the inlet and the outlet of the vaporizer (fig. 2). These pins automatically open the vaporizer port valves when the vaporizer is mounted to the manifold. Thus, when the operator attaches the Penlon Sigma Elite to the Ohmeda manifold, flow is automatically routed through the head of the vaporizer, even when the vaporizer is in the off position. Thus, this Penlon design defeats Ohmeda's safety features described previously.

When using the Penlon Sigma Elite Vaporizer, clinicians are encouraged to make certain that both the filler control knob and the clamp screw are screwed in firmly

to the closed position using a clockwise motion. This case also shows the importance of measuring inspired and exhaled concentrations of inhaled anesthetics. Had we administered this anesthetic with only capnography, the patient would have been at risk for light anesthesia and awareness. Even though the dial setting for sevoflurane was set at 3–5%, the inspired concentration shown by the anesthetic agent analyzer was only 0.7% sevoflurane.

Strict adherence to 1993 FDA Anesthesia Apparatus Checkout Recommendations¹ may have contributed to the problem. We followed the guidelines very specifically. That is, we did a thorough machine checkout before case 1 in the morning, and the anesthesia machine and vaporizers were leak free. For cases 2 and 3, we followed the FDA guidelines as well. When one scrutinizes the FDA guidelines, section 5 states, "perform leak check of machine low pressure system." Number 5 has by it an asterisk, and the asterisk states, "If an anesthetic provider uses the same machine in successive cases, these steps need not be repeated, or they can be abbreviated after the initial checkout." Therefore, before case 3, we simply checked the breathing circuit for leaks, and we did not check the low-pressure circuit for leaks. When it is practical, anesthesia care providers should check the low-pressure system for leaks using a negative-pressure leak test after vaporizers are refilled. Also, when practical, the low-pressure system should be checked for leaks after vaporizers are switched out.

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In Reply:—Penlon vaporizers are truly compatible with the Ohmeda Selectatec (Madison, WI) back bar. If this was not true, the Food and Drug Administration (FDA) would not have licensed the Penlon vaporizer for use in the United States. Ohmeda admits that the use of a non-Ohmeda vaporizer on an Ohmeda Anaesthetic machine does not affect the machines warranty.

Selectatec back bars of Ohmeda and other manufacture from other companies are used around the world with vaporizers of Ohmeda manufacture and with vaporizers of other manufacturers, including Penlon and Draeger. This is an accepted fact and serves customers well in avoiding a monopoly of supply.

With specific reference to the issues raised

1. "Unfamiliarity with the product": The report states that, "The anesthesia attending had not been adequately trained in use." Such training would have great value and would be brief, because the filling system works in exactly the same way as that on the widely used Draeger Vapor and Ohmeda Tec 3 and Tec 4 vaporizers.
2. "Vaporizers design": The overfill port would have leaked at a very obvious rate had the vaporizer been effectively leak checked. It is true that, in common with other manufacturers vaporizers, the leak would have been discovered only if the vaporizer was turned on.
3. "Anesthesia machine design": The inclusion of a check valve in the machine originates in the requirements for such features to prevent reverse flow through "Boyles bottle"-type vaporizers. This is, in my opinion, a redundant feature that contributes to the difficulties mentioned in leak checking the Ohmeda Anaesthetic machine.
4. "Use of non-Ohmeda product on an Ohmeda machine": It is a commercial imperative that Ohmeda, through such devices as a "Medical Device Advisory Notice," discourages the use of non-Ohmeda vaporizers on Ohmeda machines. It is true that Ohmeda vaporizers are designed to be used on Ohmeda Anaesthetic machine back bars, but they are also sold by Ohmeda for use on other machine manufacturers' Selectatec back bars. It is also true that

Penlon, Draeger, and many other manufacturers supply vaporizers that can be specified as Selectatec Back Bar compatible. The dimensions of the Selectatec system are in the public domain, therefore this is not a valid point for consideration.

The issue relating to the statement, "defeat safety features intended by the manufacturer," is one I have heard directly from Ohmeda before. Contrary to the opinion expressed, the agent is isolated from the back bar when the Penlon vaporizer is not in use. The vaporizer uses a different method than the Ohmeda unit but is equally effective. Indeed, the Penlon method of interfacing the vaporizer to the back bar allows all the interfaces to be checked during the system leak check. The Tec 5 requires the clinician to turn on each individual vaporizer one by one.

5. "Limitations of the 1993 FDA Anesthesia Apparatus Checkout Recommendations¹": The limitations of the checklist are highlighted by the Ohmeda machine design. However, as acknowledged, the check recommendations instructed in the machine and the vaporizer user manuals were not applied. The results speak for themselves.

Penlon has 50 years of experience manufacturing anesthesia systems and vaporizers, and we sell our products in every major country, including the United States. Penlon's reputation is for excellence of design, superior quality, and outstanding reliability. With the current Penlon vaporizer, the Sigma Elite, Penlon succeeds in delivering state-of-the-art performance.

The problems illustrated by the report are the product of lack of training and lack of the use of recommended procedures clearly contained within product user manuals.

Craig Thompson

Marketing Manager-Anaesthesia
Penlon Ltd.
Abingdon, OX14 3PH England

Reference

1. United States Food and Drug Administration: Anesthesia Apparatus Checkout Recommendations. Rockville, MD, Food and Drug Administration, 1993

In Reply:—Datex-Ohmeda agrees with many of the points raised in the authors' discussion, however, additional information may be helpful.

Datex-Ohmeda anesthesia systems that incorporate the Selectatec Vaporizer Mounting System, such as the Modulus II identified in the article, were not designed to accommodate vaporizers from other manufacturers. The labeling, including the respective Operation and Maintenance manuals for both the Datex-Ohmeda vaporizers and the anesthesia systems, advises users to mount only Datex-Ohmeda Tec 4, Tec 5, and Tec 6 vaporizers on the Selectatec manifold. This point was further reinforced through a Medical Device Advisory Notice, dated January 20, 1998, mailed to healthcare facilities in the United States by Datex-Ohmeda, advising clinicians against the use of other manufacturers vaporizers with the Datex-Ohmeda Selectatec Vaporizer Mounting System.

The use of a preoperative checkout procedure is clearly supported by Datex-Ohmeda. In fact, the Operation and Maintenance manual for the Modulus II, similar to other Datex-Ohmeda anesthesia systems, includes specific preoperative checkout procedures. As stated by the