References

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

2. Cooper JB, Newbower RS, Long CD, McPeek B: Preventable anesthesia mishaps: A study of human factors. ANESTHESIOLOGY 1978; 49:399–406

3. Cooper JB, Newbower RS, Kitz RJ: An analysis of major errors and equipment failures in anesthesia management: Considerations for prevention and detection. ANESTHESIOLOGY 1984; 60:34–42

4. Myers JA, Good ML, Andrews JJ: Comparison of tests for detecting leaks in the low-pressure system of anesthesia gas machines. Anesth Analg 1997; 84:179–84

5. Andrews JJ: Anesthesia delivery systems, Clinical Anesthesia. Edited by Barash PG, Cullen BF, Stoelting RK. Philadelphia, JB Lippincott Company, 1997, pp 535–72

6. Meister GC, Becker KE: Potential fresh gas flow through Dräger Vapor 19.1 vaporizer with key-index fill port. ANESTHESIOLOGY 1993; 78:211–2

7. Tec 5 Continuous Flow Vaporizer: Operation and Maintenance Manual. Steeton, UK, The BOC Group, June, 1996

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 Recommendations[1]": 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.

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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

authors, these procedures include a leak test that would have detected the alleged leak. However, Datex-Ohmeda believes that, if available, the specific anesthesia system preoperative checkout procedures should be used instead of the generic 1993 FDA Anesthesia Apparatus Checkout Recommendations.[1] This is supported by the FDA, as the introduction of FDA Recommendations states, "This is a guideline in which users are encouraged to modify to accommodate differences in equipment design and variations in local clinical practice. Such local modifications should have appropriate peer review. Users should refer to the operator's manual for the manufacturer's specific procedures and precautions, especially the manufacturer's low pressure leak test (step #5)."[1]

Datex-Ohmeda does not believe that the design features of the Modulus II anesthesia system contributed to the problem. The Modulus II and its specific preoperative checkout procedures performed as intended. Datex-Ohmeda has no control over the design of these other manufacturers vaporizers that are being marketed as compatible with the Selectatec Vaporizer Mounting System. As previously stated, the Selectatec was designed only to accept Datex-Ohmeda Tec 4, Tec 5, and Tec 6 vaporizers.

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Reference

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