

Continuous  
Anesthesia  
Gas  
Monitoring

*Hedley-Whyte/Thompson, EDITORS*



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# Continuous Anesthesia Gas Monitoring

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The quality of the papers in this publication reflects not only the obvious efforts of the authors and the technical editor(s), but also the work of these peer reviewers. The ASTM Committee on Publications acknowledges with appreciation their dedication and contribution of time and effort on behalf of ASTM.

# Foreword

This publication, *Continuous Anesthesia Gas Monitoring*, contains papers presented at the symposium of the same name held in London, England, on 21 February 1989. The symposium was sponsored by ASTM Committee F-29 on Anesthetic and Respiratory Equipment and ISO Committee TC-121 on Anaesthetic and Respiratory Equipment. Dr. John Hedley-Whyte, West Roxbury V.A. Medical Center, Boston, MA, and Dr. Peter W. Thompson, University Hospital of Wales, Heath Park, Cardiff, Wales, United Kingdom, presided as symposium cochairmen and were editors of this publication.

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# Overview: Technology Assessment in Medicine and Surgery and the Voluntary Consensus Standards Writing Process

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International standards activity in anesthesia and intensive care commenced in Technical Committee 121 on Anaesthetic and Respiratory Equipment of the International Organization for Standardization (ISO) in 1966 and was initially dependent on prior work by national standards writing bodies, especially those in the United Kingdom (British Standards Institution, or BSI), United States (American National Standards Institute, or ANSI) and France (Association Française de Normalisation, or AFNOR). National work has continued, but the United States committee was transferred to the American Society for Testing and Materials (ASTM) in 1983 [1].

More recently, many of the ISO standards have been written jointly by delegates from the 20 participating countries and 24 observer countries with the corresponding Committee 62D on Electromedical Equipment of the International Electrotechnical Commission (IEC), reflecting the increasing role of electronics in medical equipment. At present there are 26 published international standards under the purview of TC 121 and 10 draft international standards which are also purchasable [2].

Anesthetic mishaps frequently result in anoxic brain damage or death. The outcome of anoxic brain-damaged patients is strikingly inferior to the outcome of patients with prolonged coma after craniocerebral trauma [3]. In a recent review of 1,175 anesthetic-related closed malpractice claims in the United States, reviewers were asked if the poor outcomes would have been preventable by proper use of additional monitoring devices. In over 1000 patient records, sufficient information was available to judge whether or not the mortality or morbidity was preventable by the use of additional monitoring devices, and in almost a third of patients (31.5%) it would have been. The costs of legal judgment or settlement of mishaps judged preventable by additional monitoring were eleven times costlier ( $p < 0.01$ ) than those after mishaps not so preventable. Pulse oximetry plus capnometry were deemed to be most useful in mishap prevention, and together these two technologies were considered potentially able to prevent 93% of the preventable mishaps [4]. Continuous anesthesia vapor monitoring techniques were among other monitors deemed valuable in the remaining cases.

Medical equipment technologies evolve through three stages—development, diffusion, and established practice. ASTM Committee F-29 on Anesthetic and Respiratory Equipment and ISO Technical Committee 121 felt that continuous anesthesia vapor monitoring at the end of the 1980s was in the process of diffusion, and that experts should opine on whether a transition to the third stage was merited. Hence this volume.

If continuous anesthesia vapor monitoring becomes established practice, it would be wise to heed the advice of Dr. Henry Krakauer of the United States Health Care Financing Administration to the Technology Assessment Group of the Harvard University School of

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Public Health: "As it [technology] undergoes refinement and as new competing technologies enter into practice, information must continue to accrue to permit the continuing comparison of the relative merits of alternative procedures, and the adjustment of incentives to assure the most effective utilization of resources" [5]. For these resources are indeed limited [6].

### *Acknowledgments*

The editorial staff and publications committee of ASTM have been invaluable in the preparation of this publication. The continued help of Professor Frederick Mosteller, Director, Technology Assessment Group, Department of Health Policy and Management, Harvard University School of Public Health and Roger I. Lee Professor of Mathematical Statistics, Emeritus, and Professor Robert J. Blendon, Chairman of the Department of Health Policy and Management, Harvard University School of Public Health, is gratefully acknowledged.

### **References**

- [1] Hedley-Whyte, J., *Clinical Anaesthesiology*, Vol. 2, No. 2, 1988, pp. 379–389.
- [2] Stratton, R. R., "Report of the Secretariat on Progress of Work Since the 17th Meeting Held in Helsinki in July 1988," ISO TC 121 Doc. No. N 476, British Standards Institution (BSI), 2 Park Street, London, W1A 2 BS, 22 August 1989.
- [3] Groswasser, Z., Cohen, M., and Costeff, H., *Archives of Physical Medicine and Rehabilitation*, Vol. 70, 1989, pp. 186–188.
- [4] Tinker, J. H., Dull, D. L., Caplan, R. A., Ward, R. J., and Cheney, F. W., *Anesthesiology*, Vol. 71, 1989, pp. 541–546.
- [5] Krakauer, H., "An Approach to the Systematic Assessment of Medical Technologies," report to the Registries and Datasets Subgroup, Technology Assessment Group, Department of Health Policy and Management, Harvard University, School of Public Health, F. Mosteller, Director, 677 Huntington Avenue, Boston, MA 02115, 1989.
- [6] Thorpe, K. E. and Siegel, J. E., *Journal of the American Medical Association*, Vol. 262, No. 15, 1989, pp. 2114–2118.

# Anesthesia Vapor Monitoring: Questions To Be Answered

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**REFERENCE:** Hedley-Whyte, J., "Anesthesia Vapor Monitoring: Questions To Be Answered," *Continuous Anesthesia Gas Monitoring, ASTM STP 1090*, J. Hedley-Whyte and P. W. Thompson, Eds., American Society for Testing and Materials, Philadelphia, 1990, pp. 3-6.

**ABSTRACT:** From 1985 to 1987, according to the Medical Device Reporting System of the United States Food and Drug Administration, 1554 deaths were ascribed to medical devices either wholly or in part; another 29 176 patients were seriously injured. Anesthesia machines were the subject of 1807 malfunction reports during this time and were the medical device sixth most likely to cause death. An award of 15 million dollars was made in the United States for failure to detect a change in anesthetic concentration. Cost of anesthesia vapor monitoring varies, but the costs of additional training in its use have also to be considered. If anesthesia vapor monitoring is to become universal, the versatility of the anesthesia machine and circuit can be cut down.

**KEY WORDS:** anesthesiology, assessments, design standards, government, medical equipment/medical equipment failure, performance evaluation, standardization

In the standards process one of the first questions is, "Should there be a standard?" When a standard is developed, it has policy implications for practice, cost, and safety. Although the U.S. Government has evidence that anesthesia machines still cause significant mortality (Tables 1, 2, 3, and 4) [1], it is unclear whether work should be started on a standard for continuous anesthetic vapor monitoring. So International Organization for Standardization (ISO) Technical Committee TC 121 and ASTM Committee F-29 decided that one way to resolve this question and therefore advise standards writing bodies, and thus governments, was to have a meeting of experts from academia, from manufacturing, from government, and from standards writing bodies.

The aim of this publication, based on that meeting, was to make a recommendation—either that it is wise or unwise to proceed with the standard. That recommendation will be based on answers to various questions.

The questions obviously are, first, safety: will there be increased safety from what is recommended? This includes safety to the patient, to operating room personnel, and in the widest sense, to our planetary environment. Cost is clearly important. There is cost to the patient, cost to the environment, cost in litigation, and the latter may not be trivial. An award of over 15 million dollars was recently made in the United States for failure to pick up a change in anesthetic concentration.

Cost of anesthesia vapor monitoring equipment varies widely and can be assessed accurately, but one must not forget the cost of additional training. Each time we add equipment or modify medical practice, there is an enormous cost in extra training, which has frequently

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TABLE 1—Overall medical device regulation (MDR) reporting rates by type of report, 1985–1987.<sup>a</sup>

| Type of Report | 1985           |         | 1986           |                  | 1987           |         | All 3 years    |         |
|----------------|----------------|---------|----------------|------------------|----------------|---------|----------------|---------|
|                | No. of Reports | Percent | No. of Reports | Percent          | No. of Reports | Percent | No. of Reports | Percent |
| Death          | 561            | 3       | 513            | 3                | 480            | 3       | 1 554          | 3       |
| Serious injury | 9 044          | 50      | 11 057         | 61               | 9 075          | 54      | 29 176         | 55      |
| Malfunction    | 8 349          | 47      | 6 685          | 37               | 7 099          | 43      | 22 133         | 42      |
| Total          | 17 954         | 100     | 18 255         | 100 <sup>b</sup> | 16 654         | 100     | 52 863         | 100     |

<sup>a</sup> From the U.S. General Accounting Office, *Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation* [1].

<sup>b</sup> Percentages do not total 100 because of rounding. Source: MDR data tape provided by FDA.

TABLE 2—*The ten most frequently reported devices, 1985–1987.<sup>a</sup>*

| Device Name                      | No. of Reports | Percent         |
|----------------------------------|----------------|-----------------|
| Pacemaker                        | 14 243         | 27              |
| Pacemaker electrode              | 5 304          | 10              |
| Ventilator                       | 4 115          | 8               |
| Glucose monitor <sup>b</sup>     | 1 886          | 4               |
| Anesthesia machine               | 1 807          | 3               |
| Heart valve                      | 1 390          | 3               |
| Breast prosthesis, inflatable    | 1 356          | 3               |
| Infusion pump                    | 1 349          | 3               |
| Intravascular administration set | 972            | 2               |
| Breast prosthesis, silicone      | 636            | 1               |
| Top ten devices                  | 33 058         | 63 <sup>c</sup> |
| All other devices                | 19 805         | 37              |
| Total: all devices               | 52 863         | 100             |

<sup>a</sup> From U.S. General Accounting Office, *Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation* [1].

<sup>b</sup> Includes reports on glucose hexokinase, an in vitro diagnostic reagent used in blood glucose monitoring devices.

<sup>c</sup> Percentages do not add to 63% because of rounding. Source: MDR data tape provided by FDA.

TABLE 3—*The ten devices most frequently reported as associated with the death of patients, 1985–1987.<sup>a</sup>*

| Device                            | No. of Reports | Percent         |
|-----------------------------------|----------------|-----------------|
| Heart valve                       | 244            | 16              |
| Defibrillator                     | 240            | 15              |
| Pacemaker                         | 90             | 6               |
| Ventilator                        | 88             | 6               |
| Pacemaker electrode               | 60             | 4               |
| Anesthesia machine                | 53             | 3               |
| Intravascular diagnostic catheter | 50             | 3               |
| Infusion pump                     | 47             | 3               |
| Tampon                            | 40             | 3               |
| Intra-aortic balloon              | 24             | 2               |
| Top ten devices                   | 936            | 60 <sup>b</sup> |
| All other devices                 | 618            | 40              |
| Total: all devices                | 1554           | 100             |

<sup>a</sup> From U.S. General Accounting Office, *Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation* [1].

<sup>b</sup> Percentages do not add to 60% because of rounding. Source: MDR data type provided by FDA.

been hidden both from the government and from the general public. We have more medical and paramedical personnel per bed now than 20 years ago. A main reason is because of changes in practice that involve equipment.

If anesthetists are going to move to lower flow anesthesia, they will have to take into account problems of pregnancy, extremes of age, shock, obesity trauma, altitude, abnormal lung function such as chronic obstructive pulmonary disease and asthma, and congestive cardiac failure. All of these have to be considered in the extra training. Most anesthetists are not as familiar with low flow techniques, which tend to follow continuous anesthesia vapor monitoring.

Electrical failure is becoming more common in the Western World. There are still problems with piped oxygen [2] and nitrous oxide [3] supply failure and with compressed gases [4,5]

TABLE 4—*The ten devices most frequently reported as malfunctioning.*

| Device Name                                        | No. of Reports | Percent         |
|----------------------------------------------------|----------------|-----------------|
| Ventilator                                         | 3 972          | 18              |
| Pacemaker                                          | 2 136          | 10              |
| Anesthesia machine                                 | 1 693          | 8               |
| Glucose monitor                                    | 1 672          | 8               |
| Infusion pump                                      | 980            | 4               |
| Intravascular administration set                   | 811            | 4               |
| Pacemaker electrode                                | 805            | 4               |
| Intra-aortic balloon                               | 517            | 2               |
| Respiratory gas humidifier                         | 365            | 2               |
| Peritoneal dialysis administration set, disposable | 348            | 2               |
| Top ten devices                                    | 13 299         | 60 <sup>b</sup> |
| All other devices                                  | 8 834          | 40              |
| Total: all devices                                 | 22 133         | 100             |

<sup>a</sup> From U.S. General Accounting Office, *Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation* [1].

<sup>b</sup> Percentages do not add to 60 because of rounding. Source: MDR data tape provided by FDA.

from tanks. For medicolegal reasons and reasons of patient care, charting differences frequently have to be overcome. If you do introduce anesthesia vapor monitoring, the versatility of the circuitry can be cut down, and that has pros and cons. Temperature control with low flow anesthesia may be harder, and the early detection of hyperthermia may present problems.

The logistics for remote areas have to be considered because—at least in the United States—there is now evidence that the malpractice burden is one reason for the bankruptcy of remote hospitals, and we are having a lot of bankruptcy of hospitals in the United States at the moment.

References

[1] U.S. General Accounting Office, report to the Chairman, Subcommittee on Health and the Environment, Committee on Energy and Commerce, House of Representatives, "Medical Devices: FDA's Implementation of the Medical Device Reporting Regulation," Report No. GAO/PEMD-89-10, GAO, Washington, DC, 1989.

[2] Feeley, T. W., McClelland, K. J., and Malhotra, I. V., *The Lancet*, Vol. 1, 1975, pp. 1416-1418.

[3] Feeley, T. W. and Hedley-Whyte, J., *Anesthesiology*, Vol. 44, 1976, pp. 301-305.

[4] Eichhorn, J. H., Bancroft, M. L., Laasberg, L. H., du Moulin, G. C., and Saubermann, A. J., *Anesthesiology*, Vol. 46, 1977, pp. 286-289.

[5] Feeley, T. W., Bancroft, M. L., Brooks, R. A., and Hedley-Whyte, J., *Anesthesiology*, Vol. 48, 1978, pp. 72-74.

## Volatile Agent Monitoring

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**REFERENCE:** Whitcher, C., "Volatile Agent Monitoring," *Continuous Anesthesia Gas Monitoring, ASTM STP 1090*, J. Hedley-Whyte and P. W. Thompson, Eds., American Society for Testing and Materials, Philadelphia, 1990, pp. 7-19.

**ABSTRACT:** A case for routine monitoring of volatile anesthetic agents (halocarbons) is based on presumptions of enhanced patient safety, quality patient care, and economy. The patient under anesthesia stands to benefit when halocarbon concentrations in anesthetic gas mixtures are precisely known. Although dial settings of halocarbon vaporizers may roughly approximate halocarbon concentrations present in anesthetic breathing systems, several factors contribute to discrepancies between dial-set concentrations and directly measured concentrations. These discrepancies are often clinically significant. The variables causing discrepancies are complex, being influenced by multiple factors such as the duration of anesthesia, flow rates of gases employed with halocarbons, and vaporizer accuracy. These variables are often difficult to predict and correct for. Therefore, the continuous monitoring of halocarbon concentrations in anesthetic breathing systems offers the most viable method of assessing the halocarbon concentrations present.

Halometry is likely to prove cost-effective on at least two counts, including facilitation of economical reduced flow-rate anesthetic techniques, which conserve expensive halocarbons, and decreased anesthetic mishaps due to over- and underdosage, which may reduce litigation and insurance rates.

Halometers are readily available for routine use. Clinically useful features include frequency response sufficient for breath-by-breath analysis, as end-tidal concentrations are related to anesthetic depth. Readability to two significant figures is also useful. The capability of specific agent recognition seems important primarily when vaporizers are easily misfilled with wrong agents. The overall complexity of patient monitoring need not be objectionably increased by routine halometry. The time may be appropriate for a halometry standard.

**KEY WORDS:** agents, anesthetics, halocarbons, halometry, monitoring, anesthetic agent monitoring, halocarbon monitoring, halometry, monitoring of anesthetic depth, monitoring of halocarbons, volatile agent monitoring

The objective of this paper is to convey information of possible use in the development of a standard for devices which monitor anesthetic vapors such as isoflurane.

### Epidemiology

About 20 000 000 anesthetics are administered annually in the U.S. Estimates of anesthetic deaths range from 2000 to 10 000 per year; 33 to 90% of these deaths are considered preventable. Halocarbons and their vaporizers play a role in deaths considered preventable.

Keenan [1] has reported that 33% of cardiac arrests were caused by absolute agent overdose, defined as dosage of agent above normal clinical concentrations. An additional 33% of cardiac arrests were caused by relative agent overdose, defined as a normal clinical dose which the patient did not tolerate.

The rate of insurance claims paid relative to anesthetic mishaps is about 1.5 per 10 000

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anesthetics, or about one mishap each eight years for an average practice. Although the rate of claims paid is higher than desirable, mishaps are expected infrequently in any individual anesthetist's practice. Thus, based on individual experience, it is difficult to discern whether any given procedure or piece of equipment is either safe or unsafe [2]. For example, the anesthetist may use a copper kettle vaporizer for many years without mishap and therefore conclude, on the basis of personal experience, that this type of vaporizer is safe. On the other hand, the manufacturer bases an impression of safety on the collective experience of many anesthetists. Certain manufacturers perceive that the kettle type vaporizer is frequently implicated in mishaps [3].

Cooper's studies [4] show that 1% of 507 reported critical incidents involved difficulties with vaporizers. Of critical incidents with substantive negative outcomes, overdosage of inhalation agents was involved in 2.9%. Judgemental overdosage figured in 11% of substantive negative outcomes. These results are open to bias because of changes in vaporizer practices during studies. Kettle vaporizers were being phased out, and preventive maintenance programs were newly applied to selected vaporizers. Certain notably imprecise vaporizers were still in use [5].

Mishaps, including those related to halocarbon misdosage, may appear to occur randomly, involving even the most experienced, conscientious anesthetist and even the healthiest, lowest risk patient. Although the higher ASA physical status classes of patients are the most at risk on a per patient basis, the lower ASA physical status classes are the most frequently anesthetized. By reason of their larger numbers, and neglecting their presumably greater physiologic stability, the latter group may be the more at risk and therefore the more likely to benefit from monitoring.

Outpatients appear to be at substantially lower risk than inpatients, with the former showing anesthetic mortality rates of 1:50 000 [6] versus 1:5000 to 1:10 000, respectively. Reasons for the lower rate remain to be shown. However, outpatients are generally younger and healthier, and the types of surgical procedures performed are usually less complicated. Their apparently lower mortality could possibly be considered as an indication for a somewhat lesser level of monitoring than in the case of inpatients. However, avoidable risks must be held to a minimum, and the breath-by-breath monitoring of all ventilatory gases and vapors among all patients may be presumed to maximize patient safety.

### **Mishaps and Their Prevention: Monitoring**

Frequently recurrent mishaps, together with monitors designed to recognize them, are shown in Figure 1. Categories of mishaps shown which may involve halocarbons and vaporizers primarily include overdosage and underdosage. Insufficient halocarbon may be associated with hyperventilation, hypertension, and tachycardia, arrhythmias, and recall. Overdosage may cause hypoventilation, hypotension, and cardiac arrest.

The clinical utility of monitoring with sophisticated equipment such as the halometer is not to be minimized, but the use of such equipment represents a supplement to, not a substitute for, good clinical judgement and basic direct clinical observations. The primary protection against mishaps is the alert, attentive, well-trained clinician, continuously observing the patient and the anesthesia equipment with the unaided senses. Elaborate monitoring miscarries if it becomes a distraction.

Although a significant component of clinical anesthesia remains an art tempered by clinical judgement, anesthetic practice is becoming increasingly quantitative as rapidly improving instruments become available. It is now technically simple to measure the concentrations of each gas ventilated by the patient, breath by breath, at a level of precision which is comparable with the usual precise administration of intravenous drugs. Although the unaided senses play an important role in monitoring, the patient may be inaccessible to direct observations. Surgical draping may almost completely cover the patient, particularly in

TABLE OF MONITOR UTILITY

| MONITORS                | MISHAPS       |                 |                       |                      |                 |                     |             |              |              |              |            |                     |            |                  |
|-------------------------|---------------|-----------------|-----------------------|----------------------|-----------------|---------------------|-------------|--------------|--------------|--------------|------------|---------------------|------------|------------------|
|                         | Disconnection | Hypoventilation | Esophageal Intubation | Bronchial Intubation | Circuit Hypoxia | Halocarbon Overdose | Hypovolemia | Pneumothorax | Air Embolism | Hypertension | Aspiration | Acid Base Imbalance | Arrhythmia | IV Drug Overdose |
| Pulse Oximeter          | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Capnograph              | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Spirometer              | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Autosphyg.              | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Stethoscope             | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Halometer               | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| O <sub>2</sub> Analyzer | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| ECG                     | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |
| Thermometer             | ■             | ■               | ■                     | ■                    | ■               | ■                   | ■           | ■            | ■            | ■            | ■          | ■                   | ■          | ■                |

■ HIGH VALUE    ■ MODERATE VALUE    ■ LOW VALUE    ■ NO VALUE

FIG. 1—Matrix of monitoring equipment versus type of mishap. This matrix represents the author's estimate of the most useful monitors in mishap prevention. A nerve stimulator for assessment of neuromuscular blockade would be added to a list of most useful routine monitors. IV = intravenous; Autosphygmomanometer = automatic noninvasive sphygmomanometer; O<sub>2</sub> analyzer = breathing circuit oxygen analyzer; ECG = monitor of cardiac electrical activity. Adapted (with permission) from: Whitcher C., Ream A. K., Parsons D., et al., "Anesthetic Mishaps and the Cost of Monitoring: A Proposed Standard for Monitoring Equipment, *Journal of Clinical Monitoring*, Vol. 4, 1988, pp. 5-15.

certain plastic, eye, ear, nose and throat, and neurosurgical procedures, maximizing the need for instrumental monitoring aid. Moreover, instruments can measure physiologic functions which cannot be directly observed, e.g., end-tidal concentrations of halocarbons. A further advantage is the alarms provided by monitors, which, when well designed, can alert the anesthetist when attention must be directed away from direct patient observations. Alarms provide early warning, gaining time to muster corrective measures and indicating the success of those measures.

How may the incidence of mishaps be reduced? Continuing efforts are in order to improve resident selection and to offer enhanced training programs both during residency and continuing thereafter. The critical importance of vigilance is obvious. The development of simulators is promising. However, it seems unrealistic to expect substantial improvement in human factors such as resident selection and training, and in vigilance. On the other hand, the rapid improvements in monitoring, including halometry, could reasonably lead to a reduction of mishaps.

The author's case for routine halometry is based on presumptions of enhanced patient safety, quality of patient care, continuing education of the anesthetist, and economy. Mishaps due to unexpected concentrations of halocarbons, both high and low, may be

prevented. The quality of patient care and the continuing education of the anesthetist may both be enhanced with the anesthetist continuously informed of the precise inhaled and end-tidal concentrations of halocarbons, breath by breath. Economy may be achievable through the use of low flow-rate anesthetic techniques, facilitated by monitoring, and by mishap prevention, which leads to reductions of insurance claims paid and insurance rates.

### **Halocarbon Vaporizers and Monitoring**

Halocarbon vaporizers may be considered as sensitive halocarbon metering devices serving life-supporting anesthetic breathing systems. A noticeable, often clinically significant, discrepancy nearly always prevails between concentrations of halocarbons in breathing systems predicted from dial settings of vaporizers, compared with directly measured concentrations. Multiple, complex factors are involved, such as the accuracy of vaporizers, flow rates of gases employed with halocarbons, time-varying uptake rates of halocarbons, cardiac output, and variations in pulmonary ventilation. Vaporizers occasionally run dry. Depending on the law of mass action or the relative concentrations of halocarbon in the patient and in the breathing circuit, the patient may absorb agent from, or elute agent into, the breathing circuit. During anesthetic induction, when agent absorption is rapid, both inhaled and end-tidal agent concentrations in breathing circuits are usually considerably below the dial-set concentration of the vaporizer. During recovery, when the vaporizer is turned off, the inhaled concentrations of agent rapidly approaches zero, while agent eluting from the patient reduces much more slowly with time. Continuous monitoring offers the most viable method of coping with the multiple, complex causes of divergencies between vaporizer settings and concentrations actually present.

Vaporizers are rarely in perfect calibration. A 1985 study of vaporizer accuracy [7] shows that measured concentrations of halocarbons may be at least twice, to less than half, of dial set concentrations. A vaporizer known to be accurate, defined as delivering plus or minus 10% of dial-set concentrations, sent out for routine maintenance and calibration, was returned delivering isoflurane 2.7% at a dial setting of isoflurane 1.0%. Kettle-type vaporizers performed no better than agent-specific calibrated vaporizers, probably because of flow meter inaccuracy. Modern vaporizers were usually more accurate than older units, within plus or minus 20% of dial settings. Many obsolescent, inaccurate vaporizers remain in regular clinical use.

Other factors which may result in unexpected halocarbon concentrations are found in obsolescent anesthetic equipment. A vaporizer on-off switch may be inconspicuous and mistakenly either on or off. A missing vaporizer filler plug or stopper key may vent vaporized halocarbon and gases, including oxygen, to room air. A movable vaporizer may have been recently tipped, yielding very high halocarbon concentrations.

A human variable involving obsolescent equipment is the vintage of the anesthetist's training. The more recent the training, the less the familiarity with features and hazards of obsolescent equipment. Kettle-type vaporizers easily deliver lethal concentrations of halocarbons. A resident may never use a kettle during training, yet in practice a kettle alone may be available. Again, halometry offers protection; alarms give early warning.

### **Halometers**

Criteria of an ideal monitor for use in anesthesia are: It must be informative of patient condition, highly reliable and easy to use, free of misleading artifacts, and economical. Several categories of monitors which meet these criteria are readily available for the clinical measurement of halocarbons. Long-established methods depend on the principles of mass and infrared spectroscopies. Raman effect and piezoelectric monitors are also available. A photoacoustic monitor has recently become available.

### *Stand Alone Versus Time-Shared Halometers*

Mass spectrometer systems which have been available since about 1979 are intended for time-shared use. A single mass spectrometer unit is implemented with a computer-controlled valve for receiving samples from each room in sequence. A long sampling line from each room receives sample gases from each breathing circuit. Results of analysis are reported on a display device in each room. Disadvantages of this type of system are widespread loss of comprehensive monitoring in case of system breakdown, and delay in reporting. By sampling each room for 20 s, a 16-bed operating room would expect updated data about every 5 min. It has been recommended that a single mass spectrometer should serve no more than eight rooms. The impact of loss of monitoring in case of system breakdown may be attenuated by supplemental equipment. The two U.S. sources of central mass spectrometer systems offer a supplemental infrared capnometer which continuously displays the carbon dioxide wave form on the cathode ray tube, independent of the mass spectrometer and computer. An advantage of a central system is centralized calibration. A further possible advantage is economy, in that comprehensive gas analysis may be provided at lower cost than in the case of certain stand-alone monitors.

A recently developed stand-alone mass spectrometer (Ohmeda) may be commended for its compact size, easy mobility, low sampling flow rate (30 mL/min), and well-designed display and alarms. A recently developed Raman analyzer (Albion) is promising. Both units specifically analyze all gases and vapors usually associated with anesthesia.

### *Agent Specificity*

Most of the infrared halometers available at writing must be manually programmed for the specific halocarbon in use. A single wave length of infrared light is used for analysis. However, by using multiple wavelengths of infrared light, specific halocarbons can be recognized. A generation of monitors with this capability is expected in the near future.

An ideal halometer would be capable of quantitating any specific halocarbon in any volatile anesthetic mixture. Whether the extra instrumental complexity involved is worthwhile may depend on the filling systems of halocarbon vaporizers available in a given suite of operating rooms. Simple pour-filled vaporizers are easily misfilled with wrong agents. On the other hand, a high level of protection against unexpected liquid agent mixtures is provided by keyed vaporizer-filling systems, readily available with modern vaporizers. Such systems key each specific halocarbon bottle to each halocarbon-specific vaporizer. The author is aware of no reports of substantive patient injury due to unrecognized mixtures of halocarbons.

### *Frequency Response*

The issue of instrument frequency response is clinically relevant and important to consider in any standards writing. Halothane is a notably weak absorber of infrared light at wavelengths usually employed in halometers. Therefore, this agent is the most difficult to measure, relative to other halocarbons, and must therefore govern critical design features which provide for adequate frequency response. The frequency response of many capnometers approaches a range of 100 to 200 ms, while that of certain infrared halometers approaches a range of 600 to 800 ms. The author's limited studies [7] suggest that a 600-ms response is clinically useful, particularly under near-equilibrium conditions when the breath-by-breath changes of halocarbon concentrations amount to only a few tenths of 1%. When concentrations are changing markedly and rapidly, some rounding of waveform angles is likely to occur. If instrumental standards are to be written, requirements of frequency response should be carefully investigated.



*Significant Figures*

Readability to two significant figures is a clinically useful feature of halometers, particularly in the 0 to 1% range. This feature is not available in most modern instruments. Manufacturers indicate that two-decimal-place accuracy is difficult to achieve in such a range, particularly in the case of halothane. This granted, the clinician is more concerned with slight changes of concentrations than with absolute accuracy, as detailed later under clinical notes.

*Halometry and Complexity of Monitoring*

It may be argued that halometry, if added to the list of required monitors, could unduly contribute to the complexity of monitoring and saddle the anesthetist with one more ill-affordable distraction. Obviously, each additional monitor can only add some measure of complexity. If a new monitor is to be adopted, the additional burden imposed should be more than compensated by the usefulness of the data provided.

Capnometry, an evolving standard, is increasingly available. Given a capnometer which obtains samples via catheter, the most prevalent type, the addition of a halometer imposes only a minimal additional burden for the following reasons:

1. *Components of the two monitors may be shared.* Obvious components which may be shared include the airway adapter, sampling catheter, sampling pump, and sample disposal line [7]. The two monitors are best combined in a single case.

2. *The halographic waveform need not necessarily be displayed.* With the capnographic waveform displayed (an essential component of capnometry, in the opinion of many), the halographic data may be displayed in numeric format alone. Given a properly designed halometer with adequate frequency response, the capnogram alone may be sufficient to verify appropriate sampling.

3. *Interpretation of the halogram is simple, relative to the capnogram.* The capnogram is influenced by breathing circuit, ventilatory, cardiovascular, and metabolic considerations. Accordingly, interpretation is complex. Although multiple factors also influence the halogram, the displayed values are usually used primarily for the precise measurement of inhaled and end-tidal concentrations, and as a guide to supplement the clinician's judgement in the setting of flow meters and vaporizer to sustain the desired depth of anesthesia.

*Artifacts*

Any monitor is potentially capable of presenting artifacts and inaccurate, misleading information. Instrument maintenance and calibration must be appropriate. The anesthetist must be familiar with the features of the monitor and its requirements for proper use. Limitations, always present, must be understood.

**Sampling Techniques**

In the case of halometry, as in capnometry, the sampling technique is critical in obtaining interpretable results. Assuming that the capnogram alone is displayed, the quality of the capnogram may be taken to indicate the quality of the halogram. The capnogram must show sharply defined end-tidal plateaus and returns to baseline. Samples must be obtained sufficiently close to a point of to-and-fro rebreathing within the patient's airway in order to avoid sample dilution by fresh gases from the breathing circuit or room air. Sampling becomes increasingly difficult as tidal volumes reduce and ventilatory rates increase. Suboptimal sampling is unacceptable when misleading information is obtained. The expected sharp