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A New Anesthesia Delivery System

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A prototype anesthesia delivery system has been developed to test the appropriateness of new technological design approaches. The objectives were to eliminate human-factors problems associated with present anesthesia apparatus and to lay a suitable technical foundation for the development of new techniques in anesthesia management. This prototype performs all the functions of a conventional anesthesia machine, as well as many monitoring and surveillance tasks. Eventual incorporation of new teaching functions, and additional monitoring and record-keeping activities, are intended. The system is fundamentally electronic with few moving parts. Reliability, safety, and clarity of operation were the primary criteria in selection and application of the specific technologies employed. The result is a promising first step in the development of a system oriented toward supporting rather than preoccupying the anesthetist. (Key words: Equipment: anesthesia machines; monitors; computers; vaporizers; safety.)

TODAY'S ANESTHESIA MACHINES are not dissimilar to those introduced in the first third of this century.[1] They are basically mechanical assemblies with some inherent operational hazards and with basic limitations that have probably been impediments to progress and innovation in anesthesia management. A system has evolved around the anesthesia machine in a haphazard and incoherent manner. It is a system that gives anesthesiologists little technological support in coping with difficult and extended surgical procedures. A complex proliferation of devices, displays, and controls often encourages rather than discourages human error. Neither the design of the present system nor the design of many of its components reflects known human-factors principles.[2] Improvements and developments have been individual and narrow, arising in response to each specific safety problem as discovered and defined.[3–5] New concepts, as they have emerged, have been added to the system in the form of new and separate boxes and gadgets that further complicate the maze of wires, cords, and objects which currently clutters the operating room and the anesthetist's visual field.

With this as background, we ask the following question: If one were to design an anesthesia system afresh, what fundamental tenets and strategies would one adopt? Clearly, the desired functions of such a system must first be defined and the implications of the operating environment must be understood. Figure 1 is an aid in considering these issues. It is a schematic representation of the interrelationships among the anesthetist, the apparatus, and the patient. Some measurements of patient status are made with the anesthetist's own senses, some with technological extensions of those senses. Decisions are made and actions carried out using the anesthesia delivery system—the machine, intravenous apparatus, ventilator, etc. One observes that the performance of this system must be monitored by the anesthetist as closely as is the status of the patient. Technological aids must be rugged, reliable, failsafe, and effective. The operating environment must be considered hostile to technical devices. The man-machine communication links are critical in the system, and they must function effectively with a minimum of attention and effort. These constraints and requirements have served as guidelines for us in the selection of technological strategies that represent a fresh approach to anesthesia system design. A prototype has now been completed and can serve as a reference point for discussions about the anesthesia system and about the role of technology in anesthesia care.

Prototype Design and Function

General Structure

It has become clear that a substantial amount of electronic technology must be involved in any apparatus built to meet the constraints just described. Organizing information, sensing gases, implementing alarms, and keeping records are all functions that require electronic technology for efficiency, flexibility, and effectiveness. However, it is unlikely that any hybrid system that one might develop would be reliable if it involved wedding new electronic technology with traditional mechanical technology. Interfaces between the two technologies would be too complex and cumbersome. For example, the attachment of servomotors to needle valves would not be the simplest and most appealing technical approach to flow control. We

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have concluded that it is necessary to develop or acquire methods of metering gas flows and liquid anesthetics that are inherently compatible with electronic apparatus in order to allow development of a reasonably simple, coherent, and reliable system. We employed that strategy in developing this prototype. The design is based entirely on the use of "on–off" devices with few moving parts. No potentiometers or servomotors are used for control functions. Flow calibrations depend on the tolerances of fixed orifices rather than on the tolerances of moving parts. Sensors are used primarily for safety checks and for monitoring and do not control critical system functions.

The general structure of the prototype is shown schematically in figure 2. The desired mixture of oxygen and nitrous oxide is generated by special valves. Liquid anesthetic is added directly into this gas mixture in pulses by an injector. All of the injected liquid vaporizes in a passive evaporator coil. The active devices are under the control of an electronic microprocessor[6] that receives instructions from the control panel and scans a number of machine sensors. The processor continuously monitors system functions and either corrects or alarms when the machine or the user acts in an unsafe or inappropriate manner. The processor itself is monitored separately to insure appropriate warning or corrective action in the event of a functional problem. A rechargeable battery provides back-up power in the event of line failure.

This prototype system performs the basic tasks of a conventional anesthesia machine, but the strategy of employing a microprocessor-based architecture allows orderly expansion and communication with other electronic devices. It will accept new sensors relatively easily and will allow development of practical, automated record-keeping techniques. In addition, this technology allows important innovations in the design of man-machine interfaces with the intent of reducing the possibilities for human error.

Operation

The prototype is shown in figure 3. The upper console is the control unit, on which all necessary information has been organized. Controls and displays for the anesthesia machine functions are grouped on the left (shown in more detail in fig. 4). The right side of the console contains a message panel for displaying alarms and warnings and a large area for future use in displaying electronically generated trend plots and anesthetic-record information.

The flows and concentrations are indicated by illuminated bar-graph columns§ (fig. 4). A color-coded,

§ Self-Scan Plasma Display, Burroughs, Inc.

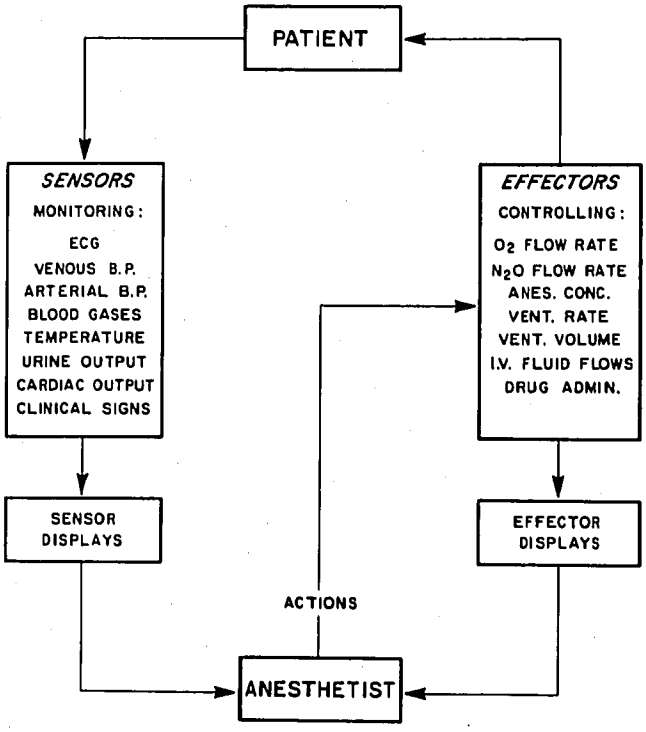

Fig. 1. A view of the anesthetist's role as a controller.

illuminated scale is alongside and an illuminated label is below each of the columns. Settings are changed by operating the color-coded "increment/decrement" switches located below each label.¶ The left-hand bar represents total gas flow, with a range of 0 to 10 l/min. The second bar from the left indicates the nitrous oxide concentration in volumes per cent. It is adjustable from 0 to 100 per cent with certain time restrictions on operation above 80 per cent, which are discussed later. The third column is automatically labelled with the name of the volatile liquid anesthetic currently in the machine. The range of adjustment is 0 to 5 per cent. The last two columns display measured values of expired-oxygen concentration and airway pressure and thus have no associated control switches.

The proportioning scheme, in which "total flow," "nitrous oxide per cent," and "volatile agent per cent" are the controlled variables, is an experimental approach to gas flow control. It provides a simpler, more physiologic basis for controlling the breathing mixture and may eliminate some of the mental errors associated with the use of individual oxygen and nitrous oxide rotameters. When desired, the system can be easily switched over to a more conventional format (*i.e.*, with individual oxygen and nitrous oxide

¶ Holding a switch lever up causes its corresponding bar to start rising at a steady rate. Releasing the switch freezes the setting, and pushing the switch down reverses the process.

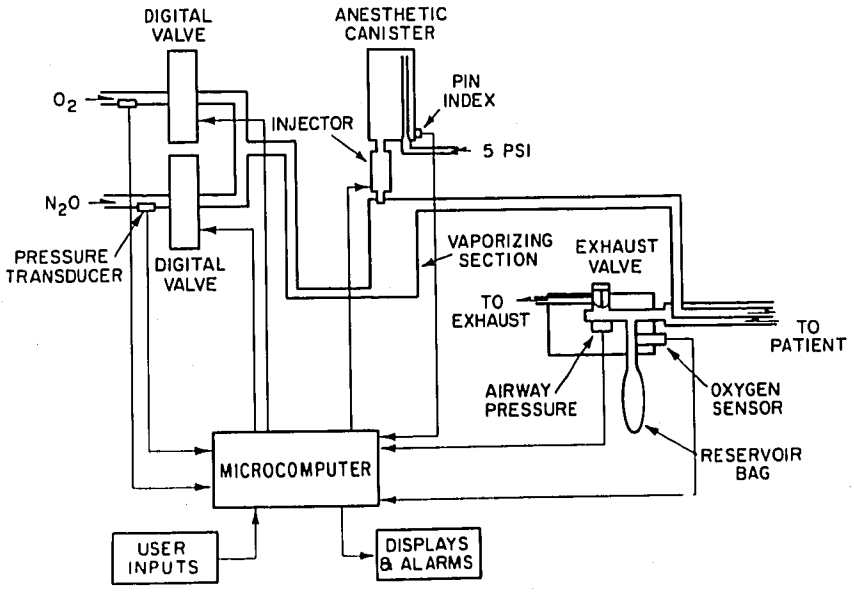

FIG. 2. A schematic representation of the prototype anesthesia machine. The term microcomputer refers to the ensemble of the microprocessor with its necessary support electronics, including input and output circuitry, power supplies, memory devices, etc.

flow controls) in just seconds, because of the flexibility of the programmed design.

The three pushbutton switches on the lower margin of the console perform special functions. The left-hand button switches all of the concentration displays from high-flow ranges to low-flow ranges to afford improved resolution for low-flow management techniques.** The round button is an anesthetic cut-off switch that, when depressed, unambiguously terminates the flow of anesthetics. The third console pushbutton activates a ventilator alarm function in which airway pressure is automatically and continuously monitored in search of a ventilation cycle at least every 30 seconds. A breathing-circuit disconnection or other failure to ventilate will result in an alarm message.

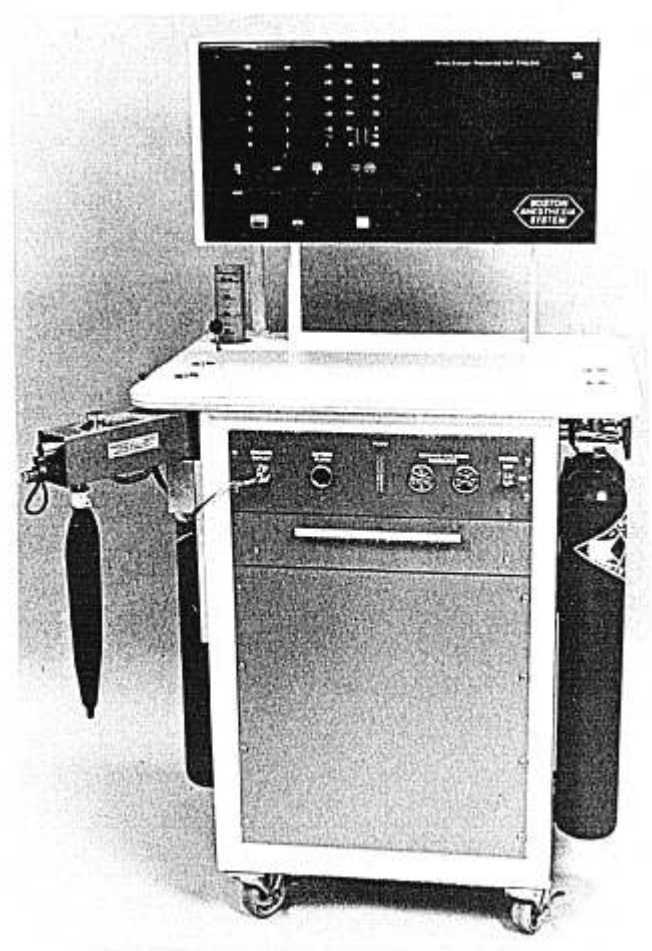

FIG. 3. The prototype anesthesia system. The control console is detachable from the base cabinet.

The compact, flat control console is actually detachable from the large base of the machine and could be installed in the location optimal for the anesthetist. Indeed, a duplicate or slave console could be used in the same room or in a different room for a variety of purposes.

A small, roughly calibrated rotameter flowmeter, located in the center of the front panel of the base cabinet (fig. 3), is provided to lend assurances to a skeptical user of proper gas flow. The power on–off switch, reserve-cylinder pressure gauges, and oxygen flush control are located on the same panel. The oxygen flush is mechanically actuated, providing a back-up for life support in the event of a major electronics failure.

Alarm Functions

The current version of the system is capable of delivering any of 16 different warning messages under

** The left-hand bars then represent oxygen flow and nitrous oxide flow separately with ranges of 0 to 1,000 ml/min, and the third bar then represents anesthetic vapor flow with a range of 0 to 100 ml/min and a resolution of 1 ml/min. The color coding and labels change automatically to reflect the changed control format.

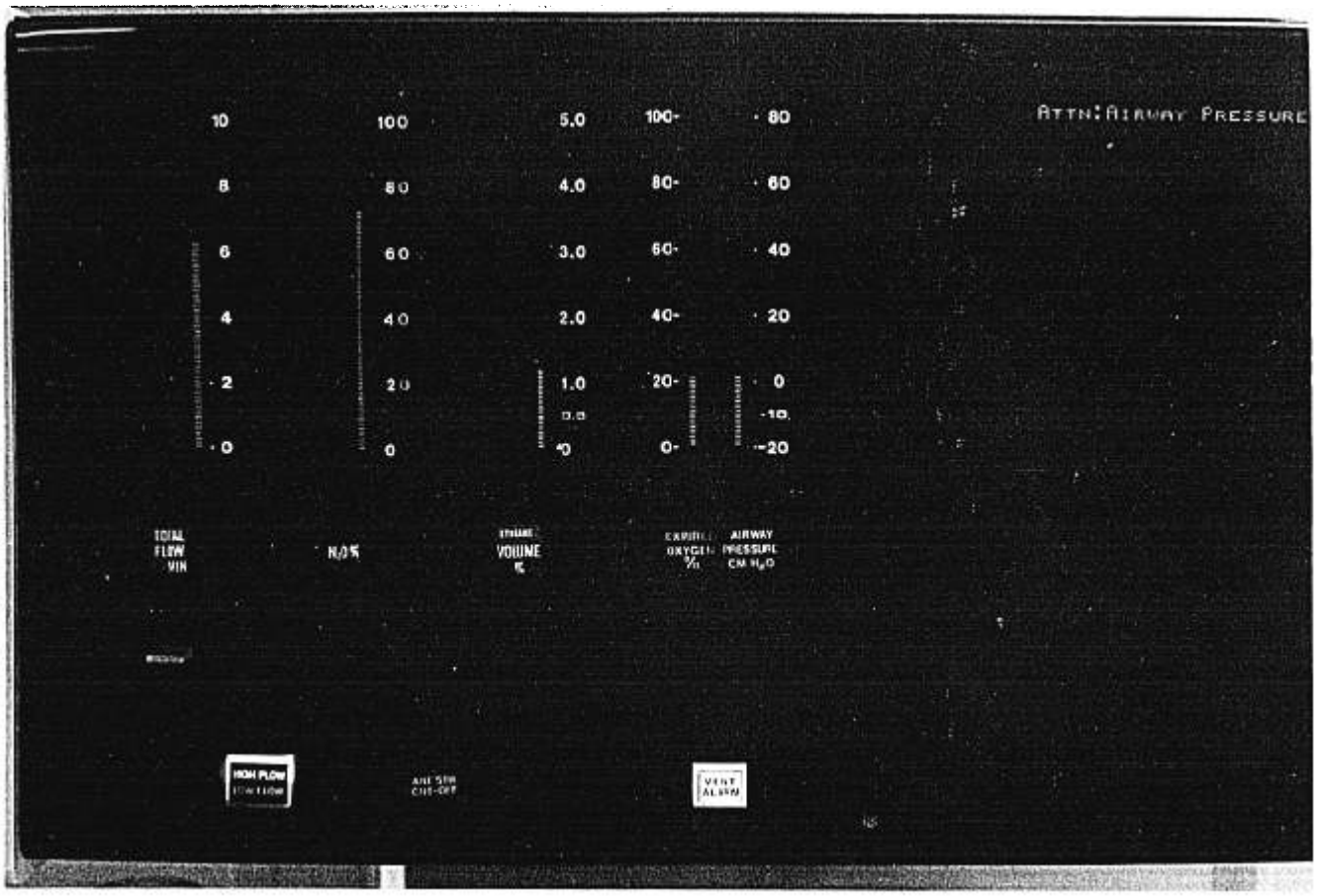

FIG. 4. A view of the bar-graph displays on the left side of the operating console. The switch levers, bar labels, and scale markings are all color-coded (total flow is white; nitrous oxide percentage is blue; anesthetic volume percentage is red). The volatile anesthetic label indicates that an enflurane canister was in use when the photograph was taken. All the labels and scales change dramatically in going from the "high-flow" mode to the "low-flow" mode, not depicted here.

various circumstances. When an unsafe condition exists or an improper action is attempted by the user, the appropriate message is displayed in the upper right section of the console. A message is accompanied by a distinctive audio alarm repeated every 5 seconds. The audio signal attracts the user's attention to the message panel for an indication of the immediate problem. When more than one problem exists at any given time, the message with the highest priority (the one requiring the most immediate action) is displayed until its associated problem is corrected by the user. Subsequent messages will appear in order until all problems are resolved (table 1). Each message becomes self-explanatory with actual use of the machine. For instance, trying to set a nitrous oxide concentration prior to choosing a non-zero value for the total gas flow is one of the conditions under which the message "Please Increase Total Gas Flow" would be displayed. An attempt to switch from the "High Flow" to "Low Flow" mode when any of the current gas flows would be off-scale in the low-flow range triggers the message "Please Reduce Flow For Low Mode." The message "Attn: Hypoxic Gas Mixture" is displayed when the delivered oxygen concentration is set below 20 per cent in any operating mode. The machine will allow such a condition to exist for as long as 45 seconds, and will then automatically readjust the flow ratio to create a 50 per cent oxygen mixture, subject to further adjustments by the user.†† A low oxygen concentration on the expiratory side of the breathing circuit will cause an additional alarm at any time.

Every 0.1 seconds, the microprocessor performs a variety of checks for proper operation of the system. Thus, mechanical difficulties are reported with appropriate alarm messages. For example, a serious decrease in oxygen supply pressure leads automatically to display of message 5. A low state of charge of the back-up battery power supply is indicated by message 13. The library of messages can be easily extended or modified by us or by any subsequent developer. Even-

†† This is a protective feature, not a substitute for good judgment. The time interval could be shortened or eliminated, if desired, in any revision of the program.

TABLE 1. Alarm and Warning Messages* (in Order of Priority)

"Please" introduces those messages that result from attempt of an illegitimate operation of the machine. They are displayed only momentarily, upon the specific switch actuation, as explanation for the machine's inability to respond to that command. Hence their high priority only momentarily interferes with display of an important message such as number 6.

"Attn:" introduces alarm messages that represent undesirable situations. Further arguments about priority are inevitable, but may be diminished when an expanded display unit is in place and permits simultaneous listing of all current alarm conditions.

1. Please Increase O_2Flow
2. Please Increase Total Gas Flow
3. Please Reduce Flow for Low Mode
4. Please Reduce Agent Flow
5. Attn: Low O_2 Supply Pressure
6. Attn: Low Expired O_2 Percent
7. Attn: High Airway Pressure
8. Please Engage Agent Canister
9. Attn: Agent Flow Set Too High
10. Attn: Airway Pressure Not Cycling
11. Attn: Low N_2O Supply Pressure
12. Attn: Hypoxic Gas Mixture
13. Attn: Battery Low: Plug In!
14. O_2 Sensor Calibrate In Progress
15. O_2 Sensor Calibration Completed
16. O_2 Sensor Calibration Aborted

* The somewhat artificial language of these messages is simply a consequence of the 32-character limit of our current display unit.

tually, those alarm messages appropriate for physiologic monitoring can be channeled through the same system. Thus, the problem of a multiplicity of nonspecific and competitive alarms in anesthesia instrumentation can be solved by this unified approach.

SUBSYSTEM DESIGNS

Gas Proportioning

Oxygen and nitrous oxide are supplied from yoke-mounted cylinders or standard pipeline connections. The cylinder gases are reduced in pressure by standard regulators and then filtered through separate line filters. Solid-state pressure transducers‡‡ (fig. 2) monitor the pressure downstream of each filter and relay that information to the microprocessor. The flow of each gas is then controlled by a separate custom-built, eight-element, digital flow controller.[7],§§ Each of these flow controllers (valves) consists of a parallel group of calibrated orifices whose flow resistances are weighted in a binary fashion. The smallest orifice, when opened, delivers 49 ml/min of gas at 345 kPa (50 psi) driving pressure. Each subsequent open orifice delivers twice the flow of the one below it in the sequence. An orifice is either opened or closed by an associated solenoid valve. The maximum available flow with all of the valve's orifices open simultaneously is 12.7 l/min at 345 kPa (50 psi) driving pressure, and 10 l/min at 255 kPa (37 psi).

Since these orifices comprise a sequence of flow devices weighted in proportions of 1, 2, 4, 8, 16, etc., they can be controlled directly by a binary "word" from the microprocessor. The assembly is thus inherently digital. It is also extremely reliable, operating only in terms of "on" and "off" commands. The flow rate does not depend on tolerances of moving parts, as with conventional valves. For a typical driving pressure the flow can be set to within about 25 ml/min of the desired flow (half of the smallest orifice's flow). This resolution could be improved easily by modulating the "on" time of the orifices or by extending the sequence. Each of these orifices is actually designed as a sonic nozzle. That is, its shape is such that sonic velocity will occur in the nozzle throat when the pressure drop across the orifice exceeds 20 per cent of the absolute upstream pressure. Under these conditions, the flow through the nozzle is essentially independent of downstream pressure fluctuations and can be accurately predicted from a knowledge of only the upstream pressure and the nozzle's fixed calibration constant. (Temperature changes in this application are small enough to be ignored.) The microprocessor is programmed to perform the computations necessary to achieve the desired flow, given the measured upstream pressure.¶¶

Volatile Anesthetic Subsystem

The flows from the two digital valves are joined to produce an oxygen and nitrous oxide mixture. Liquid anesthetic is then injected directly into that gas stream in equal volumes of approximately 5 μl each (depending on the anesthetic). The injector device is an automatic fuel injector*** modified so that its components will be resistant to deterioration from exposure to halothane or other anesthetics. It is a simple, solenoid-operated, on–off valve. The pulse time width and liquid driving pressure are maintained at constant values. Thus, the volume of liquid anesthetic injected varies only with the physical properties of the liquid. The exact calibration constant for each liquid anesthetic is permanently stored in the machine's memory for the electronic processor's use.

The necessary frequency of injector pulses is determined by the programmed processor. The frequency

‡‡ National Semiconductor LX1720A.

§§ Process Systems, Incorporated.

¶¶ The accuracy of this system is a complex function of orifice and pressure-transducer accuracies, the flow rate of the smallest orifice and the computational precision in the various modes of operation. We do not discuss it here in detail since the accuracies are well within the bounds of any physiologically realistic requirements.

*** Robert Bosch Corporation.

is a multiplicative function of the selected total gas flow rate, the desired anesthetic concentration, the calibration constant, and the known ratio of liquid volume to vapor volume at standard temperature and pressure for the particular anesthetic. The liquid is atomized into a chamber as it emerges from the injector, and complete vaporization is achieved in a copper vaporizing coil. Thus, temperature compensation is not necessary.†††

Liquid is supplied to the injector from interchangeable, prefilled, plastic canisters (fig. 5). Each canister is translucent to permit observation of liquid level and is labeled to indicate its contents. Each has a capacity of 200 ml. The canisters are fabricated from a special nylon polymer that is immune to attack from the relevant anesthetics.‡‡‡ A canister of the desired anesthetic is plugged into the machine by inserting it into a socket in the table top (fig. 3). It is then automatically pressurized with oxygen at 34.5 kPa (5 psi).§§§ A magnetically coded key on the base of the canister precludes incorrect mounting. A magnetic sensing device verifies for the microprocessor controller that a canister is in place and also indicates which anesthetic the particular canister contains. When a change is desired, the canister is released by pushing the disconnect lever and an alternate is inserted. Opportunities for mix-ups are minimized. It is envisioned that canisters would be filled or refilled only by a manufacturer or distributor. Thus, liquid anesthetics would be handled in the same controlled manner as compressed gases are at present.

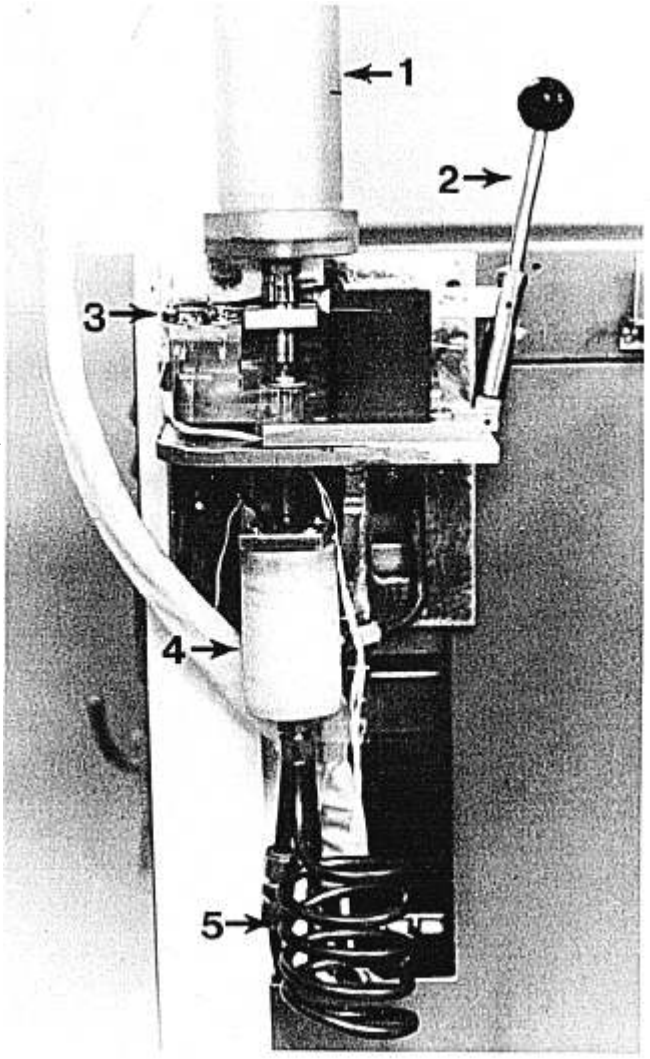

FIG. 5. The volatile-anesthetic injector subsystem with the cabinet cover removed. 1, canister reservoir; 2, release lever; 3, magnetic index switches; 4, injector housing; 5, vaporization coil.

Microprocessor Controller

The displays, digital valves, and injector are all operated by an electronic controller based on an Intel 8080 microprocessor. A discussion of its architecture and design has been presented elsewhere,¶¶¶ and only a summary of its functions is given here. The controller is a compact, dedicated computer that is permanently programmed to perform the tasks of this anesthesia system. It is in the form of 12 circuit boards, most of which are in the base cabinet. They include a central processing unit, memory (8,000 bytes), an analog-to-digital converter (16 channels), a sequencing clock, special circuits for the input and output of information (24 I/O ports), and a number of special-purpose circuits (*e.g.*, for amplifying sensor currents, driving valves). The major tasks that the controller performs are divided into communication functions and control functions.

The communication functions include:

1. Interpreting commands from console switches (*e.g.*, changes in flows or concentrations, actuation of pushbuttons).
2. Displaying current measured values and control settings.
3. Displaying alarms of unsafe or inappropriate

††† Injectors are inherently rugged devices that are required, in automotive use, to pulse in excess of 100,000,000 times under hostile conditions without failure. An equivalent lifetime in this anesthesia application would amount to delivery of several thousand 250-ml bottles of halothane. Nevertheless, ultimate failure is a concern. We are considering implementation of a thermal measurement method to detect and alarm on deviations from proper operation, and are continuing evaluation of other metering devices.

‡‡‡ Trogamid T, Thermoplastic Processes, Inc.

§§§ Regulated by a precision regulator (Brooks Instruments).

¶¶¶ Trautman ED, Cooper JB, Newbower RS: A new anesthesia delivery system using microprocessors. Proceedings of the IEEE Electro 76 Conference, Boston, 1976.

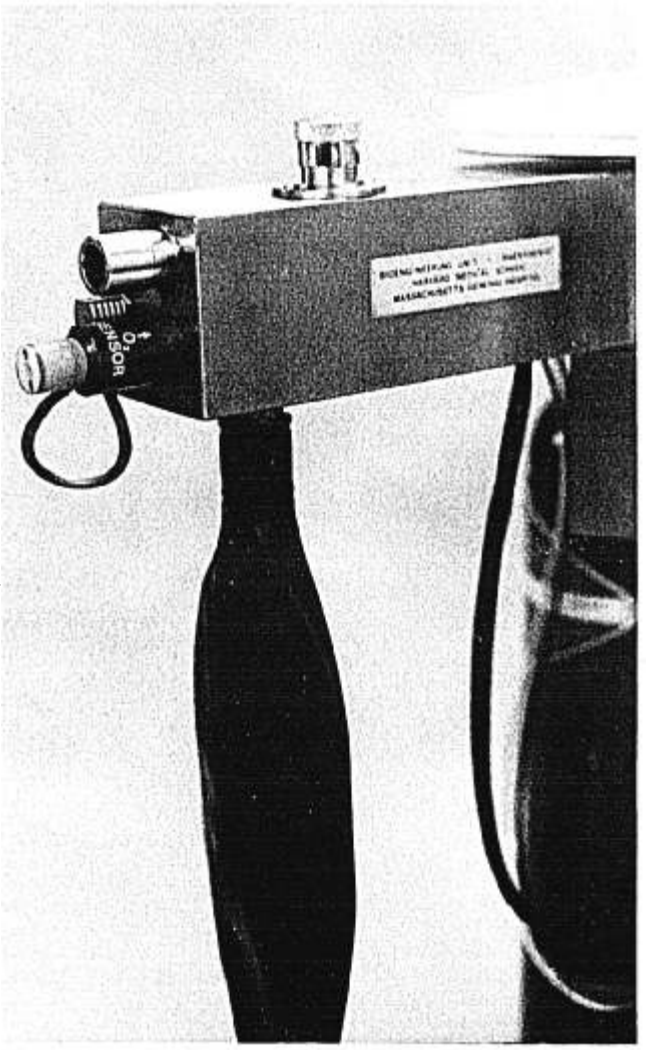

FIG. 6. The breathing-circuit adaptor intended for high-flow techniques.

conditions resulting from operator error or system dysfunction (*e.g.*, breathing circuit disconnection, oxygen supply loss).

The control functions include:

1. Reading sensors (*e.g.*, gas supply pressures, airway pressure, battery voltage).
2. Computing effector settings from operator commands and sensor readings.
3. Setting effectors (*e.g.*, digital valves, injector).

Each specific task is described by a programmed sequence of steps (a subroutine) that is contained in the permanent portion of the microcomputer memory. The entire program is executed every second. During one program cycle, one subroutine may be repeated several times. For instance, the subroutine that reads the console switches is repeated 10 times/sec. The user has no specific perception that this repetitive computing is going on. The machine responds quickly ($\leq$0.1 sec) to any command.

The processor is programmed to operate in a fail-safe manner. For example, when oxygen supply pressure decreases to below the normal range, the processor resets the valve to continue to deliver the same gas flow, while displaying an alarm message. When the oxygen pressure becomes totally inadequate, less than 138 kPa (20 psi), all flows are terminated and an additional loud alarm is sounded to indicate the event. Inadvertent hypoxic mixtures are avoided.

Even major changes in the method of operation of the entire prototype system can usually be completed quickly, since a fundamental characteristic of a programmed controller such as this one is flexibility. Most changes necessitate only rewriting the program (software) and loading the modified program into the memory devices, programmable read-only memories (PROMS), used for permanent storage in the prototype machine. Similarly, a manufactured version of this system could easily be modified by the manufacturer for special needs or updated by supplying replacement PROMS. However, the ease of modification of software can be a snare. Each change must be carefully evaluated to ensure that it does not compromise the overall safety or accuracy of the system. Minor changes can have profound effects in a programmed system and should thus be made only with the greatest caution in or beyond the clinical-trial stage. For these reasons, we have delayed trials with human subjects until all significant modifications have been defined and completed with continual laboratory testing and extensive use in animal studies.

Breathing Circuit

The overall system is designed to allow for the use of low-flow as well as high-flow anesthetic techniques. The accuracies of the metering devices, as well as the resolution of the controls and displays, were determined with that in mind. However, for our initial trials and demonstrations, we chose to design and construct a simpler breathing circuit, without CO_2 absorption, for use only with high-flow techniques (fig. 6). The front, upper port accepts the expiratory outlet of a disposable Bain circuit.**** The lower port is fitted with an oxygen sensor, while an airway pressure sensor is installed internally. The adjustable exhaust (pop-off) valve vents spilled gas through internal piping to a 5-l reservoir chamber in the base cabinet. This reservoir is continuously scavenged by connection to a standard suction line.

The oxygen sensor employed is a standard, commercially available, disposable, polarographic sensor†††† mounted in a modified probe housing. The

**** Respiratory Care, Inc.

†††† IBC/Berkley Division of Critikon, Inc.

probe is installed with its membrane in a vertical plane to minimize collection of condensed water vapor on its surface. The sensor monitors oxygen concentration at the outlet of the expiratory tube as an independent measurement helping to verify the composition of the breathing mixture. The measured value (displayed on the console) is not used for gas flow control. A low oxygen value (≤17 per cent) activates an alarm message. Failure of this electrochemical sensor does not compromise any other aspect of machine performance.

Available oxygen sensors have limitations in both their stabilities and their lifetimes. Calibration is needed periodically, as with commercial oxygen analyzers. To ease the burden of this on the anesthetist, we have incorporated a semiautomatic calibration scheme. Removing the oxygen sensor from its port initiates the cycle (via a magnetic switch). A plastic plug seals the port. The active end of the probe is assumed to be in room air and the sensor is allowed 30 sec to reach a steady state. The steady-state electrical current, when within normal limits, is memorized as corresponding to a 21 per cent oxygen concentration. The message panel signals completion of the calibration and continues to alarm until the sensor is reinserted in the breathing circuit. When calibration has been successfully completed, the appropriate bar graph and scale light up on the console. When the sensor is faulty, it can be easily removed from use without disturbing any of the other more vital functions of the system. We expect soon to implement a more sophisticated calibration algorithm in which true stability and proper sensor response will be sought, and with which a faulty sensor will be rejected. This approach to oxygen sensing is a simple example of the manner in which the limitations of available sensors can be offset by the sophisticated capabilities of the electronic system.

Discussion

The development of an inherently electronic anesthesia system opens interesting new avenues. A framework for integrating anesthesia monitoring and control has been created. Some previously impractical physiologic monitoring techniques and record-keeping concepts can be re-examined. Automated record keeping becomes more plausible, innovative clinical teaching methods suggest themselves, and studies of the anesthesia control loop may be facilitated.

This system does not yet monitor or display patient variables other than airway pressure and expired oxygen concentration. However, we will soon integrate some additional functions into the console for evaluation purposes. A flat display screen (plasma) will be mounted in the right portion of the console and will be used to demonstrate and evaluate trend recording and vital-sign display techniques (*e.g.*, histograms, trend plots). Initially, the patient variables to be processed and displayed will be those available from a standard portable monitor interfaced with the system, that is, electrocardiogram, arterial blood pressure, and temperature. We may later incorporate interfaces to accommodate additional physiologic variables appropriate for anesthesia. The digested data from both patient and machine will be recorded on a magnetic tape cassette in the base cabinet. We are presently evaluating methods for simultaneously generating a compressed paper record in a reasonably reliable and convenient way. For the first time, both patient data and machine data will be available in the same medium and can be recorded automatically with precise time markers, even during periods of crisis or work overload.

Although the modifications required to implement physiologic monitoring and record-keeping may appear extensive, the task has been greatly simplified by the fundamentally electronic, microprocessor-based design strategy. The basic electronics hardware (a/d converters, input/output ports, general-purpose displays, memory, and power supplies) is already provided. The required special peripheral devices (*e.g.*, ECG preamplifier and preprocessor, CO_2 or anesthetic sensor) can be interfaced to existing circuitry with relatively little difficulty. Corresponding modifications to the operating programs (software) would complete the expansion. Almost every aspect of the prototype is open to modification, given further experience or the appearance of new technologies. Feedback (servo) control of concentrations based on sensor signals was not used here because of the limited reliability and accuracy and the relatively high cost of available sensors. Yet, feedback schemes for the control of inspired or even end-expired levels of gas concentrations could be adopted when the technology of gas sensing improves.

This prototype system invites some questions about flammability hazards, susceptibility to radiofrequency interference, and user acceptance. The prototype system is not intended for use with flammable anesthetics. This decision was based on the decline in the use of flammable anesthetics in this country over the last 15 years. The technology employed here does not preclude design for safe use with flammable anesthetics, but it would be very difficult to comply with certain technical requirements of the current standards that must be met when flammable anesthetics are used.

The system was carefully designed to minimize susceptibility to interference from electrosurgical devices. These design efforts have been successful to the extent

that even older spark-gap devices will not cause changes in settings or interruptions in performance. Even if sources of interference were capable of penetrating the present levels of filtering and protection and disturbing the system's operation momentarily, the processor would be automatically reset within one second to restore normal function without changes in flow settings. Operating values of variables such as flows are stored in a carefully protected and redundantly coded form in the processor's memory. Redundant coding is also used for verifying legitimate operation of the flow rate and concentration controls. No unintended changes in flow settings have been experienced to date in the use of this prototype.

We are acutely aware that replacement of the traditional anesthesia machine with an electronic system will introduce risks and unknowns. User acceptance will ultimately depend on positive experiences—on a history of clinical reliability and on the attainment of certain standards of safety and performance. That process can only begin when production-engineered versions of such a system are available. The technologies in this prototype anesthesia system were chosen with reliability as the major criterion. Many self-checking routines are incorporated in the design and more are planned. The machine is designed to give overt indication of any difficulty and to revert to a safe mode in the event of any failure. Though only a prototype, this system has proven extremely reliable despite significant abuse encountered during shipment around the country.‡‡‡‡

The current technical revolution in electronics is critical to the success of this whole concept. To achieve reliability it is essential to be able to decrease to a small value the number of individual electronic components and the number of interconnections in a design. It has only recently been possible to develop a system with such sophisticated performance with a modest number of components. The number required will continue to decrease rapidly over the next few years as advances in electronic technology continue and higher levels of integration are achieved. Furthermore, the reliability of this technology is being proven in other demanding applications. The limitations that remain are primarily in electromechanical components (switches, electrical connectors, etc.) and mechanical components (pipe fittings, hose connectors, etc.).

The cost of the development work on which this single existing prototype is based was substantial (approximately $150,000). The total cost of duplicating this prototype would also be substantial (approximately $15,000). However, the specific technologies chosen were selected with low ultimate cost as a criterion. In particular, the cost of the electronic technology is decreasing rapidly. Thus, a production-engineered, manufactured version of this prototype need not be exorbitantly expensive; we anticipate that the final cost to the user should be competitive with that for a complete ensemble of conventional apparatus.

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‡‡‡‡ Only one minor failure has occurred since construction. A short circuit in the oxygen sensor cable connector prevented calibration and use of that sensor, but had no other effect on the system's performance and was quickly remedied by replacement of the cable.