A NEW MICROPROCESSOR-CONTROLLED ANAESTHETIC MACHINE


Most of the anaesthetic apparatus which is in current use is simple, robust and mechanically reliable. Versatility is achieved by the use of interchangeable vaporizers, breathing systems and ventilators, but this leads to several problems. First, the add-on units may be produced by different manufacturers, so there is no guaranteed compatibility between components. Second, there may be no interaction between the different components; for example, it may be possible to switch on a ventilator when there is no flow of fresh gas into the system. Third, breathing systems have to be constructed from a number of separate components, so that misconnections may result. Thus versatility is gained at the expense of patient safety. Furthermore, the machine with many add-on components is usually ergonomically unsound. Although the mortality and morbidity attributable directly to anaesthetic apparatus is relatively low [1-5], there are undoubtedly a number of near-misses which are not reported. Many other minor faults are detected regularly by anaesthetists and remedied without risk to the patient [6].

In recent years there has been an increased use of devices which monitor machine function, but care is needed to ensure that the monitoring system can detect all possible hazard situations. This is achieved best by designing an integrated anaesthetic apparatus and monitoring system.

Many monitoring devices use microprocessor technology for control and artefact rejection. It is therefore a natural progression to utilise microprocessors to control the components of an anaesthetic machine and produce an integrated monitoring system. The present paper describes the development of a microprocessor-controlled anaesthetic machine based on these principles.

SUMMARY

This paper describes the development of a microprocessor controlled anaesthetic machine comprising an integrated anaesthetic apparatus and monitoring system. Following prolonged reliability trials in the laboratory, changes have been made to major components which were described in earlier publications.

TECHNOLOGY

We have made full use of the power of microprocessor control to simplify the mechanical components of the machine. For example, it would be uneconomical and unnecessarily complex (and, therefore, less reliable) to take an existing anaesthetic vaporizer which incorporates elaborate mechanical and pneumatic devices to compensate for the effects of flow, pressure and temperature variations on the delivered concentration, and then to drive the control knob by an electric motor under microprocessor control. However, if the microprocessor is used to control the addition of vapour to the fresh gas flow, the vaporizer may be reduced to a very simple mechanical device.

Microprocessors are composed fundamentally of on/off switches and so are interfaced more easily to digital rather than analogue devices. For example, the flowmeter control valves of the
Fig. 1. Mechanical components of fresh gas and vaporizer units.

Fig. 2. Relationships between controls (solid arrows) and monitoring of machine function (dotted arrows) on microprocessor-controlled anaesthetic machine. $V_I$ and $V_E$ = inspired and expired volumes; $f$ = frequency; $P_{aw}$ = airway pressure; $F_{io_2}$ = inspired oxygen concentration; $CO_2\%$ = carbon dioxide concentration; $O_2\%$ = oxygen concentration.
conventional machine are analogue devices which have been replaced in the new design by a digital system which generates small, fixed volumes of gas, the number of pulses of gas being adjusted to produce the desired flow. The concentrations of the gases can be controlled by the ratio of flows through two such devices [7] and, in a similar manner, vapour can be added in the form of small volume pulses of saturated vapour from a copper kettle type of vaporizer [8].

Figure 1 shows the arrangement of the mechanical components of the new machine and figure 2 shows how the integrated monitoring system checks continuously each aspect of machine function. The fresh gas supplies are connected to regulators to produce constant low-pressure sources which feed the solenoid-operated gas control valves. The pulses of gas passing through these valves in the open position are discharged through sonic chokes into a mixing chamber which is maintained at a constant pressure by a variable orifice–constant pressure valve. This acts also as a flowmeter by measuring the displacement of the float as in a Rotameter. A second constant pressure valve provides a pressure differential to control similar pulsed gas flow into the vaporizer units. The vaporizers are designed to ensure that the gas pulses passing through the vaporizer are fully saturated with vapour. As the temperature within the vaporizer is measured and the vapour pressure curve is known, it is possible to predict the flow of gas through the vaporizer which is required to produce a known concentration in the final gas mixture.

Gas and vapour analysis in the fresh gas system is performed by an interferometer [9]. The oxygen concentration in the inspired limb of the breathing system is measured by a separate paramagnetic analyser, which is used also to measure the fresh gas oxygen concentration when oxygen/air is selected. There is a separate infrared carbon dioxide analyser which continuously analyses the gas sample from the patient Y-piece or tracheal tube. Inspired and expired gas volumes are measured by turbine flowmeters in the inspiratory and expiratory limbs of the breathing system. Airway pressure is sensed by a pressure transducer close to the inspiratory valve and also by an aneroid gauge connected directly to the breathing system.

It will be apparent that each machine function is provided with a checking device which monitors its function. However, these devices are not used to produce closed-loop control. Each function is programmed and controlled by a microprocessor according to the setting of a manual control, whilst the output of the checking device is displayed on the control panel by a separate microprocessor so that the operator can compare visually the set and measured values. In addition, the microprocessors compare continuously the set and measured values and alert the operator if a significant discrepancy occurs, or if any other hazard situation arises.

**DESIGN SPECIFICATION**

The machine consists of a base unit, a control/display panel, and a shelf for patient monitoring equipment (fig. 3). The base unit contains the gas supplies, and the gas mixing, vaporizing, gas analysis, breathing system and ventilator modules, together with space for a drawer or suction unit.
The cylinder contents and pipeline supply gauges are situated at the back of the machine above the worktop, and the mains switch and illuminated bargraphs, showing which vaporizer is in use and its state of filling, are incorporated in a small panel above the pressure gauges. The controls and displays are situated on a panel which can be moved sideways and rotated so that it lies over the breathing system module at an angle of 45° to the long axis of the base unit. This brings the displays close to the head of the patient, but does not impair the anaesthetist’s view of the operation.

The control/display panel is divided into three main sections (fig. 4). The left-hand section contains the controls for selection of fresh gas mixture, breathing system and vapour, together with the controls for oxygen concentration, fresh gas flow and vapour concentration. The measured values for fresh gas oxygen concentration, flow and vapour concentration are displayed digitally to the right of the controls. The ventilator controls are situated on the right hand section of the panel, whilst the centre panel contains the breathing system monitors and alarms. In the centre of this section there is an electro-luminescent (E-L) screen which displays information on tidal volume as a vertical bargraph, and breathing system airway pressure or carbon dioxide concentration, in analogue and digital form, together with malfunction messages in English text. The time of day and output from the stop-watch are also displayed (fig. 5). The inspired oxygen in the

**FIG. 4.** The control panel showing the fresh gas, breathing system and vapour selector controls on the left, with the controls and measured values of oxygen concentration, flow and vapour concentration immediately to the right. The ventilator controls are on the extreme right of the panel, whilst the centre panel contains the breathing system monitors and alarms. An analogue trace of airway pressure or carbon dioxide concentration may be selected for display on the electro-luminescent panel, a vertical bargraph of tidal volume always being displayed on the left of this panel. The stop-watch and digital clock displays are situated in the two lower corners.
New Anaesthetic Machine

Fig. 5. Electro-luminescent panel showing text messages (black letters on white background) with analogue displays (white on black background). The digital display of peak end-tidal carbon dioxide or airway pressure now shows the variable not chosen for analogue display, so that both variables can be monitored continuously.

Breathing system and the expired minute volume are displayed digitally above the E-L screen, and there are stop-watch controls and switches for selection of the graphics mode below the screen.

Control functions

Fresh gas supply. The machine provides mixtures of oxygen–air or oxygen–nitrous oxide in the range 25–100 % v/v oxygen at total gas flow rates varying from 2 to 20 litre min⁻¹. An oxygen–5 % v/v carbon dioxide gas mixture may also be selected. The gas mixture selected is shown by an indicator light adjacent to the selector switch and a yellow warning panel is illuminated when oxygen–5 % v/v carbon dioxide is selected. Gas flow is initiated by pressing the “Gas On” button, and terminated by pressing “Standby”. Subsequent depression of the Gas On button reactivates the set fresh gas flow and oxygen concentration, but vapour addition is not recommenced automatically. If the vapour control has not been zeroed, a “reset to zero” reminder is illuminated and must be obeyed before a selected vapour concentration is delivered.

Vapour concentration. Halothane 0–5 % v/v, 0–7 % v/v enflurane or 0–6 % v/v isoflurane may be added to the respired gases, selection of the correct vapour being confirmed by an indicator light situated by the vapour selector control, and by the illumination of the appropriate vaporizer filling indicator on the lower panel.

The breathing system module. The machine has a 22/15-mm inspiratory port or common gas outlet and a 22-mm expiratory port. Actuation of a selector switch on the control module permits a choice of one of the following breathing systems (fig. 6): (a) common gas outlet (for connection of an oxygen mask, paediatric breathing system, etc.); (b) Mapleson A (Magill/Lack) [10]; (c) Mapleson D (Bain) [11]; (d) circle with carbon dioxide absorption; (e) circle with gas bypassing the absorber. A non-rebreathing system can be provided also by small modifications to the microprocessor programme and the valve block in the breathing system module.

Positive identification of the breathing system in use is shown by an indicator light on the breathing system selection control. All breathing systems except (a) utilize two 1-m × 22-mm corrugated tubes to connect the inspiratory port and expiratory port to the patient connection port. If expired gas is detected by the expiratory flow meter when “Common Gas Outlet” is selected, a “check breathing system” warning is displayed on the E-L screen.

With Mapleson A, D or circle breathing systems, ventilation may be either spontaneous or controlled manually, the APL (adjustable pressure limiting) valve being spring-loaded as in conventional systems, but controlled remotely from a knob situated close to the bag mount. This arrangement allows the volume of gas spilt from the breathing system to be adjusted smoothly during manual ventilation, and also allows the APL valve to be used as a PEEP valve during mechanical ventilation. The ventilator is activated by a push-button control on the ventilator panel, but functions only when the Gas On button has been pressed and when the Mapleson D or circle systems have been selected. This prevents accidental use of the ventilator when there is no fresh gas flow, or when the breathing system selector control has been switched to Common Gas Outlet or Mapleson A [12].

Mechanical ventilator. This is a time-cycled flow-generator which compresses a rising bellows. The ventilator has a frequency range of 8–40 b.p.m., a tidal volume range of 200–1500 ml and a minute volume range of 3–16 litre min⁻¹. The inspiratory:expiratory time ratio is variable in
fixed steps between 1:1 and 1:3. The microprocessor alters the stroke volume of the bellows to compensate for changes in fresh gas flow, so that a constant tidal volume is maintained with different fresh gas flows or breathing systems. There is an end-inspiratory pause so that changes in dynamic compliance and airway resistance may be deduced from the analogue airway pressure display and expired volume measurement.

**Monitoring of machine function and alarms**

A Ritchie whistle provides an audible warning of a reduction in pressure in the oxygen line leading to the gas mixing unit. Fresh gas oxygen concentration, total fresh gas flow and vapour concentration are displayed by large LED digital displays close to the appropriate control (fig. 4). Deviation of the measured value of oxygen concentration, fresh gas flow rate or vapour concentration from the set value by more than the predetermined tolerance is indicated by flashing of the relevant digital display (table I). Breathing system inspired oxygen concentration (monitored by the paramagnetic analyser in the breathing system inspiratory limb) and expired minute volume are displayed at the top of the monitor panel. The former flashes when the inspired oxygen concentration is less than 21% v/v, and the latter when the minute volume differs from that set on the tidal volume and frequency controls of the ventilator by more than the predetermined tolerance (table I). The electro-luminescent panel is used to display tidal volume as a bargraph, and airway pressure or carbon dioxide concentration in analogue and digital form. The panel also displays in English text alarm situations and important aspects of machine function (fig. 5): these include the machine initial self-check programme and specific machine faults. Up to eight of the 31 possible alarm messages may be displayed at one time, the most important messages being situated at the top of the panel whilst the normal analogue display remains in the lower part of the panel.
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Table I. Warnings of departure from normal function

<table>
<thead>
<tr>
<th>Factor</th>
<th>Alarm activation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1:</strong> Audible and visible alarm, by</td>
<td></td>
</tr>
<tr>
<td>illuminated text on panel, together with</td>
<td></td>
</tr>
<tr>
<td>message on Electroluminescent Panel (ELP).</td>
<td></td>
</tr>
<tr>
<td>Low inspired oxygen</td>
<td>&lt; 21 % oxygen</td>
</tr>
<tr>
<td>High airway pressure</td>
<td>&gt; 1.5 kPa for 3 s</td>
</tr>
<tr>
<td>Airway leak</td>
<td>&gt; 20 % of minute volume</td>
</tr>
<tr>
<td>(The above share a common two-tone audible</td>
<td></td>
</tr>
<tr>
<td>alarm)</td>
<td></td>
</tr>
<tr>
<td>Oxygen supply failed</td>
<td>&lt; 50 % of normal operating pressure</td>
</tr>
<tr>
<td>(The audible alarm is a Ritchie whistle)</td>
<td></td>
</tr>
<tr>
<td><strong>Group 2:</strong> Visible alarm only, by colour</td>
<td></td>
</tr>
<tr>
<td>light on panel and message on ELP</td>
<td></td>
</tr>
<tr>
<td>Nitrous oxide or air supply failed</td>
<td>&lt; 50 % of normal operating pressure</td>
</tr>
<tr>
<td><strong>Group 3:</strong> Visible warning only, by flashing</td>
<td></td>
</tr>
<tr>
<td>&quot;Measured&quot; LED and message on ELP</td>
<td></td>
</tr>
<tr>
<td>Incorrect fresh gas flow</td>
<td>Difference between &quot;set&quot; and &quot;measured&quot; values exceeds:</td>
</tr>
<tr>
<td>Incorrect fresh gas O₂ %</td>
<td>± 10 % of set value ± 0.3 litre min⁻¹</td>
</tr>
<tr>
<td>Incorrect vapour (%)</td>
<td>± 10 % of set value ± 5 % oxygen</td>
</tr>
<tr>
<td>Low minute volume</td>
<td>± 10 % of set value ± 0.5 % v/v</td>
</tr>
<tr>
<td></td>
<td>− 15 % of set value</td>
</tr>
<tr>
<td><strong>Group 4:</strong> Visible indication by message</td>
<td></td>
</tr>
<tr>
<td>on ELP</td>
<td></td>
</tr>
<tr>
<td>Electronic malfunctions</td>
<td>Error codes to assist diagnosis by a service</td>
</tr>
<tr>
<td></td>
<td>engineer are displayed during the SELF TEST procedure</td>
</tr>
</tbody>
</table>

The number of combined audible and visual alarms has been deliberately kept to a minimum. The visual indicators for these alarms are grouped on the alarm panel and when activated are accompanied by a common audible alarm. The audible alarms are listed in Table I. The audible alarm for airway leak can be inactivated for preset periods by repeated pressure on the mute button so that the alarm does not sound in situations when a large leak is expected (for example during an inhalation induction of anaesthesia). "System fault" in the microprocessor system is also provided with audible and visual alarms.

OTHER SAFETY FEATURES

**Fresh gas concentrations and flows**

There is a mechanically-operated oxygen flush control which is connected directly to the oxygen line and which provides a flow of 30–70 litre min⁻¹ to the common gas outlet. A text warning is displayed on the E–L panel when the oxygen flush is activated.

The machine is designed to deliver a minimum oxygen flow of 1 litre min⁻¹ and a minimum total fresh gas flow of 3 litre min⁻¹. However, when the carbon dioxide absorption system is selected, a "low flow option" is provided which permits the total fresh gas flow to be reduced to 2 litre min⁻¹. When this option is chosen, a yellow alert, "low flow selected", is illuminated.

The choice of a minimum fresh gas flow of 3 litre min⁻¹ was based on four considerations:

1. At fresh gas flows of 3 litre min⁻¹ and greater, the concentration of vapour in the inspiratory limb of a circle system approximates closely to the concentration delivered from a vaporizer situated in the fresh gas supply line [13]. This obviates the need for a rapid analyser in the breathing system.
2. When this fresh gas flow is used there is unlikely to be gross hypercapnia with any of the semi-closed breathing systems incorporated in the breathing system module (Sykes and colleagues, in preparation).
3. The adoption of a minimum oxygen flow of 1 litre min⁻¹ results in a fresh gas oxygen concentration of 50 % v/v when the total flow of oxygen and nitrous oxide is 2 litre min⁻¹, 33 % v/v when the flow is 3 litre min⁻¹, and 25 % v/v when the flow is 4 litre min⁻¹ and greater. These fresh gas oxygen concentrations ensure that the inspired oxygen in a circle absorption system remains
adequate despite variations in nitrous oxide uptake with time [14].

(4) Small leaks in the breathing system are less hazardous when fresh gas flow approaches the minute volume.

Gas and vapour analysis

Conventional electrochemical sensors for oxygen have a limited life and can fail in an unsafe mode [15], whilst currently available vapour analysers suitable for use in the breathing system are expensive, have a limited frequency response [16], and may be affected by water vapour. It was, therefore, decided to utilize a simple, stable and extremely reliable analyser to perform the gas and vapour analysis in the fresh gas system. By using the microprocessor to control sequential sampling from the fresh gas supply lines, the gas mixer output and the mixer output it has proved possible to use an automated interferometer to follow the gas mixing and vapour mixing process [9,17]. Samples are taken sequentially from each of these sites at frequent intervals and the panel displays are updated continuously while gas is flowing to the patient. The interferometer samples also the gas inputs to the gas mixing unit and positively identifies these during the pre-use check procedure which is initiated when the mains supply is switched on. A paramagnetic oxygen analyser samples from the inspiratory limb of the breathing system to provide measurement of inspired oxygen concentration as this may differ from the fresh gas oxygen concentration. It is this analyser which activates the alarm and safety system when the inspired oxygen concentration decreases to less than 21 % v/v.

Breathing systems

Bidirectional flow transducers are situated in the inspiratory and expiratory limbs of the breathing system. These enable inspired and expired tidal volumes to be monitored continuously for detection of breathing system leaks. These flowmeters are used also to check that the APL valve does not leak during inspiration and that there is no malfunction of the gravity operated one-way valves used in the circle systems. Selection of “Common Gas Outlet” while retaining the normal twin hose breathing system also results in an alert signal.

Microprocessor system

Separate microprocessors are used to control the gas mixing, vaporizer and ventilator modules, and a fourth is dedicated to the gas analyser. Each of these is connected to the monitor microprocessor (fig. 7). In the event of catastrophic failure of the electronics system, or a simultaneous failure of the mains supply and back-up battery, the ventilator reverts to manually controlled or spontaneous breathing and the oxygen flush control continues to function normally. A more likely mode of failure would be the loss of one of the control modules (gas mixer, vaporizer or ventilator), or one of the two surveillance modules (gas analyzer or monitor).

Recent modifications

During the course of the prolonged reliability and laboratory trials, a number of changes have been made to the major components which have been described in earlier papers [7-9].

(a) Gas mixing device. Hazard and risk analysis revealed the need to include a further solenoid valve in the nitrous oxide supply. This valve is of the “normally closed” type and is held open only when a signal from the gas analyser confirms that the oxygen concentration in the mixed gas exceeds 21 % v/v. This system protects the patient in the event of the pulsing solenoid failing open and also meets the ISO standard for a nitrous oxide cut-off device to operate in the event of oxygen supply failure.

Trials of the lung ventilator revealed that the original gas mixing system had excessive internal compliance. This resulted in the fresh gas flow being distorted by the back-pressure generated by IPPV in the breathing system, so that flow was reduced considerably during the inspiratory phase and increased during the expiratory phase. The effect on oxygen provision and carbon dioxide elimination was unpredictable, but clearly unacceptable.

The problem was overcome by reducing the scale of the flow-surge damper chambers and eliminating the spring-loaded diaphragms. However, in order to restore an acceptable level of flow-surge absorption, it was necessary to reduce the pulse size at low flows. The final system changes the pulse/frequency programme at three stages as flow is increased from the 2-litre min"1 minimum to 20-litre min"1 maximum.

(b) Vaporizer system. Possibly the most serious hazard associated with an anaesthetic apparatus is the ingress of liquid anaesthetic agents into the breathing system. Because of this risk, we decided
that our otherwise attractive system of gravity feed to the vaporizers from the original drug bottles was suspect. When we found in practice that these bottles, which are of ordinary commercial quality, could not be relied upon to seal satisfactorily to the filling connections, we decided that the system had to be abandoned. In its place, we now use conventional reservoirs, level with the vaporizers and connected to them by small-bore pipes to prevent the solution of nitrous oxide in the liquid [18]. Conventional or keyed fillers can be provided, and the liquid level is displayed by glass tube indicators close to the filling orifices and by electronic level indicators below the main control panel.

(c) Interferometer. The successful development of the automated interferometer proved to be technically demanding, and involved many disciplines. As a result, the interference image has been improved greatly and it is now possible to operate the unit with 40 pixels separating each peak, in place of the original 20, thus doubling the basic sensitivity. Reliable recognition of the principal peaks, even in the presence of optical and electronic distortions, was achieved by the use of an algorithm developed by Jeavons [19].

DISCUSSION

Cooper and colleagues [20] were the first to describe a radically new approach to a nitrous oxide–oxygen–anaesthetic vapour delivery system. Their prototype utilized a microcomputer to drive digital gas mixing valves and a liquid anaesthetic injector system for delivery of anaesthetic vapours. Gas delivery to the patient was via a Mapleson D system and alarm and warning messages were displayed to guide the operator in use. Wallroth [21] has described another approach which is based on the use of the circle carbon dioxide absorption system. The present machine is based on similar design concepts, but utilizes different technology to achieve greater versatility and improved monitoring of the machine functions. A special emphasis has also been given to ergonomic considerations [22].

The charge might be made that the increased complexity of the technology utilized in the present machine would add the hazard of increa-
sed unreliability, when compared with conventional mechanical counterparts. For this reason, extreme care has been taken in the design and testing of the components. For example, the solenoid valves are designed to undertake $10^8$ operations without failure, and a number of batches have been tested for much longer periods. This number of operations represents 5 years of running 8 h a day for 6 days a week, but it is planned to replace these valves at the yearly service to ensure an even greater margin of safety.

Faults in the microprocessors can also be a problem. These may be caused by external interference from diathermy or other electromagnetic sources, by latent software errors or by internal malfunction. To overcome these problems, all the five microprocessors controlling the gas mixing, gas analysis, ventilator and monitor functions have been linked through opto-isolator circuits and are under the surveillance of a software system which checks continuously on their performance (fig. 7). The most likely problem is a transient caused by high levels of electromagnetic interference from diathermy, x-ray machines and similar sources. Transient disturbances, although causing no permanent damage, can disrupt the flow of the programme in a microprocessor, causing a total loss of function. To detect such a fault, the programme regularly passes through a sequence of check points: failure to reach a checkpoint within 0.1 s activates a reset circuit and invokes an automatic software recovery procedure. In tests with simulated transient errors, normal operation was restored within a fraction of a second in 98.7% of cases [23]. It is worth recording that the man–hours expended in building and testing the additional reliability and safety factors, following a formal Reliability Engineering procedure [24], far exceeded those taken to produce the initial prototype.

One final advantage of microprocessor control is that electrical outputs for all monitored functions are available and can be used to provide the basis for a comprehensive anaesthetic record system.

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Note added in proof: Although clinical trials have validated the concepts incorporated in this apparatus, Penlon Ltd have recently decided, on commercial grounds, not to proceed with production of the machine.

REFERENCES


