

Safety in the Use of Nitrous Oxide:

A Modification of the Standard Anesthetic Machine to Eliminate Sources of Human Error and System Failure

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PURE NITROUS OXIDE is a poison. Numerous instances of hypoxic hypoxia owing to failure of oxygen supply or human error have been reported.^{1,2} Standard anesthesia machines, however, are still capable of delivering 100 per cent nitrous oxide to a patient. It appeared desirable to develop a system which could deliver a minimum of 25 per cent oxygen in a nitrous oxide-oxygen mixture. In addition, the system should fulfill the following requirements: 1) additional oxygen should be easily added; 2) the actual percentage of oxygen in the mixture should be displayed on a single-scale; 3) total flow (including additional oxygen) should be indicated by a flowmeter; 4) total flow (of 25 per cent oxygen and 75 per cent nitrous oxide) should be easily adjustable in the range of four to 20 l/min; 5) the ratio of oxygen to nitrous oxide should be held reliably and automatically constant despite wide pressure changes in the oxygen delivery line. If the oxygen supply should fail, no other gas should be delivered to the patient. Of practical importance is that the system should be adaptable to a standard anesthesia machine and the cost of installation should be reasonable in comparison with the original cost of the machine.

Two systems have been devised to meet the above requirements. Each system has six main components:

- 1) A filter on each gas line to remove any particulate matter from the inflowing gases.
- 2) A "master-slave"³ pressure-regulating system with the "master" pressure regulator in the oxygen line, and one or two "slave" pressure-regulators in the nitrous oxide line. The "master-slave" system assures that any change in pressure in the oxygen line will be matched by a like change in the nitrous oxide line. Further, if the oxygen supply fails, the nitrous oxide supply is cut off.
- 3) Fixed pneumatic resistances (gasistors) in both nitrous oxide and oxygen lines to act as throttling devices to establish the desired minimum ratio of oxygen to nitrous oxide. The proper functioning of this ratio mixer depends upon the maintenance of identical pressures in the oxygen and nitrous oxide lines by the master-slave system.
- 4) A device for regulating total gas flow.
- 5) A flow-ratio meter⁴ for continuous indication of the actual percentage of oxygen delivered. This is achieved by means of a loosely-fitting black glass ball in a slotted, horizontal glass tube.
- 6) A total-flow meter calibrated for 25 per cent oxygen and 75 per cent nitrous oxide to replace the usual nitrous oxide flowmeter.

The major difference between the two systems is the method of regulating total gas flow. The older system (Appendix, fig. 21) was added to two Ohio Chemical Company Kinet-o-meters and has functioned without difficulty for four years. In this system five fixed flows (3, 5, 8, 15 and 20 l of the 25 per cent oxygen, 75 per cent nitrous oxide mixture) are obtained by means of combinations

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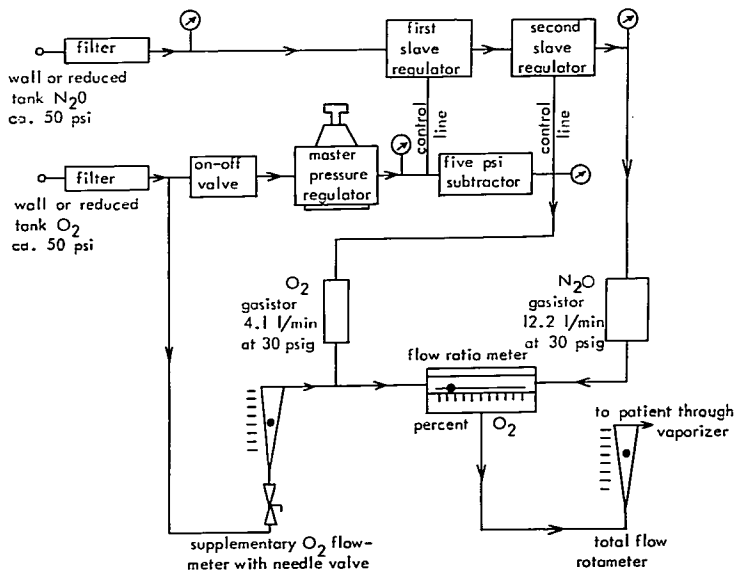


FIG. 1. Improved Safety Mixer with continuously adjustable total flow. Block diagram. See Appendix, fig. 20, for detailed functional diagram.

of three pairs of fixed resistances (gasistors) in the oxygen and nitrous oxide lines. A cam-operated selection system among the various gasistors gives the desired flows. This system has several disadvantages: it provides stepwise rather than continuously variable total flow rates; the system is mechanically complicated and therefore expensive; further, the complexity would seem likely to increase the danger of mechanical failure, although no failures have been experienced in four years.

Our newer, simpler system (fig. 1; also, Appendix, fig. 20) employs a pressure regulator to vary both gasistor input pressures, and thus the total flow. The pressure regulator is adjusted so that the system continuously delivers flows varying from 4 to 20 l/min. Since the minimum pressure output of the regulator will always yield at least a 4 l/min flow of the oxygen-nitrous oxide mixture, an on-off valve

has been placed in the line so that flow of the mixture can be completely stopped when nitrous oxide is not desired. This system has been in use on a Boyle's Model 10 Anesthesia Machine (fig. 2) for two years, and has functioned perfectly.

In each of the two systems a separate oxygen line is led from the usual oxygen flow-meter to the oxygen input side of the flow-ratio meter. Thus, supplementary oxygen can be added and the actual oxygen concentration delivered to the patient can be read directly from the flow-ratio meter. This meter is accurate to within ± 2 per cent of the indicated oxygen concentration by repeated tests using a Pauling oxygen analyzer.

When volatile anesthetics are employed, this system is best used with vaporizers that are relatively insensitive to changes in total gas flow (*i.e.*, Fluotec, Pentec, Fluomatic, Pento-

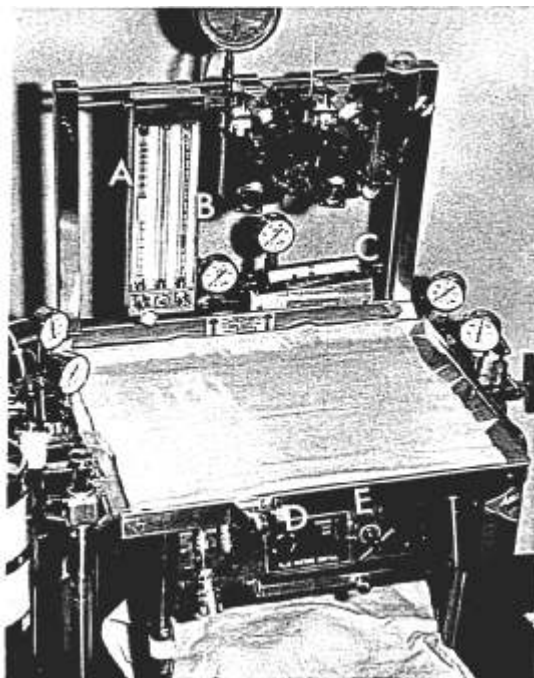
matic). Vaporizers such as the Copper Kettle or Vernitrol are sensitive to flow changes and therefore must be reset to maintain the vapor concentration if total flow rates are changed. This introduces the possibility of human error. Should the flow of nitrous oxide fail, the anesthesiologist will observe a sudden decrease in total flow of gas. In addition, the flow-ratio meter will indicate that 100 per cent oxygen is being delivered.

Two variations on these systems were tried (Appendix, fig. 23) and later abandoned. In the first a double master-slave system was employed. Both oxygen and nitrous oxide functioned as master gases. Reduction of either nitrous oxide or oxygen pressure caused identical reduction of the other gas pressure. Fail-

ure of supply pressure of either gas caused cessation of the other gas flow. Of course, the supplementary oxygen still continued to flow. This variation was mechanically more complex, requiring a third slave pressure regulator. It was abandoned largely in the interest of uniformity (to be like the other two machines).

In the second variation (Appendix, fig. 23) supplementary oxygen was not fed through the flow-ratio meter. The flow-ratio meter was used only to monitor the proper function of the gasistor system. The advantage of being able to see the exact percentage of oxygen delivered to the patient (when the basic nitrous oxide mixture was enriched with oxygen) became apparent. This was easily accomplished as described.

FIG. 2. Boyle Anesthesia Machine with added Safety Mixer system. A, oxygen flowmeter; B, total-flow meter; C, flow-ratio meter; D, on-off valve; E, flow selector.



Three anesthetic machines, modified as described, have been used to administer more than 3,400 anesthetics during the past four years. There has been one small mechanical difficulty. In each of two machines, soon after they were put into use, the indicator ball in the flow-ratio meter stuck, owing to a speck of dirt. Cleaning the tube corrected this problem. In a more recently modified machine special care was taken to clean all parts of the system before assembly, and it has functioned perfectly for two years.

Conclusions

Modifications of standard anesthetic machines to eliminate sources of human error and system failure in administering nitrous oxide-oxygen anesthesia have been described. These modifications are part of this department's attempts to improve engineering design.² Human error in mis-setting the nitrous oxide flow has been reduced by removing the nitrous oxide needle valve and flow tube and substituting a system which will deliver a minimum of 25 per cent oxygen. Further, to prevent undetected alteration of the flow-ratio system, the established ratio of oxygen to nitrous oxide can be changed only in the factory or shop. The "master-slave" pressure-regulating system automatically compensates for changes in line pressure which cause undesired changes in gas composition. This protects the patient from anoxic gas mixtures should an inadvertent decrease or complete cessation of oxygen flow not be discovered immediately by the anesthesiologist. The mechanisms employed in these systems are described in detail in the Appendix.

References

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APPENDIX

To elucidate the system and component functions, it is convenient to define the system elements and present suitable symbols.



FIG. 1. A throttling device (often called a valve)—extracts energy from a stream of gas, thus lowering its pressure while keeping its velocity rather low and its temperature relatively unchanged.

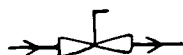


FIG. 2. A manually-operated throttling device—a needle valve is an example of this.

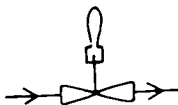


FIG. 3. An on-off valve (with toggle or other type of indicator-knob). Toggle up, valve is "on," i.e., will pass gas. Toggle down, valve shuts off gas flow.

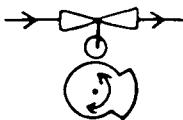


FIG. 4. A cam-operated on-off valve. This valve is spring-loaded, so that when permitted by the cam, it automatically shuts off. When the cam pushes the valve stem upward, the valve is open.



FIG. 5. A throttling device operated by a diaphragm. Force exerted by the diaphragm (caused by gas pressure above the diaphragm) downwards on the valve stem causes a lesser throttling action.

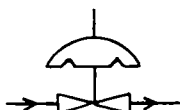


FIG. 6. A chamber above the diaphragm with a gas line leading into it. Gas pressure above the diaphragm pushes down and decreases throttling action.

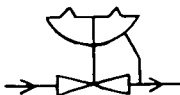


FIG. 7. A chamber below the diaphragm with a gas line leading into it. Increased pressure causes increased throttling.

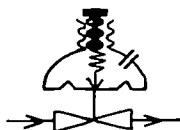


FIG. 8. A spring pushing upon the diaphragm. The amount of push varied by the adjusting knob. The spring's push downward upon the valve stem decreases throttling action. Note the chamber containing the spring has a hole open to atmosphere. Thus, only atmospheric pressure can exist above the diaphragm.

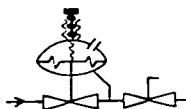


FIG. 9. A pressure regulator, sometimes misnamed a "reducing valve." Ideally, the output pressure may be set by the control knob; once set, the output pressure is independent of flow rate or input pressure changes. A needle valve is shown in the output of the pressure regulator to emphasize that the output is not freely open to the atmosphere.

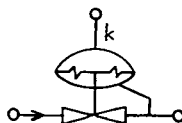


FIG. 10. This element has two names: A) A slave-pressure regulator. k is the control pressure. The output pressure equals k (providing the input pressure is high enough; B) A low-pressure selector. The output pressure is equal to the lower of the two pressures, "input" and k .



FIG. 11. A tension spring pulling upward upon the diaphragm. A closed chamber above the diaphragm with a gas line leading into it.

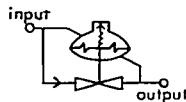


FIG. 12. A pressure subtractor. The output pressure is always a constant amount lower than the input, as determined by the ratio of the spring force to the diaphragm's effective area.



FIG. 13. A gasistor. A fixed throttling device of exceptionally stable characteristics with a flow through it almost linear with the applied pressure, has a negative temperature coefficient of about 0.2 per cent per degree C (not corrected to normal temperature).

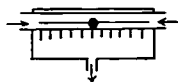


FIG. 14. A flow-ratio meter indicates per cent oxygen directly by the position of a loosely-fitting black glass ball in a horizontal cylindrical glass tube. The tube has a narrow (0.006 inch wide) slit along its active length. The position of the ball is independent of the outlet pressure.

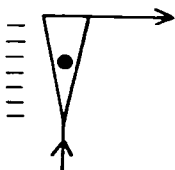


FIG. 15. A variable area flowmeter, such as a rotameter.

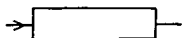


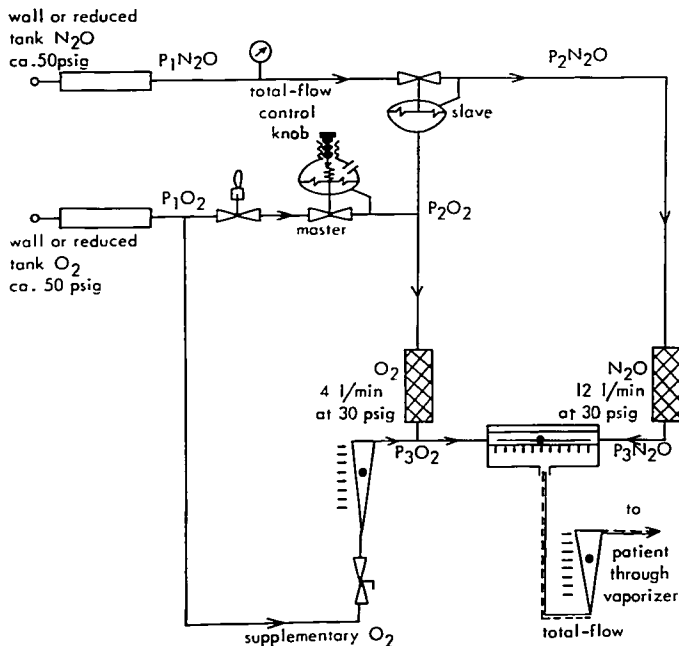
FIG. 16. A sintered metal gas filter, to remove all particles larger than 10 microns.



FIG. 17. A pressure gage—graded zero to 60 psig (pounds per square inch, gage; i.e., above atmosphere).



FIG. 18. A check valve. Often called a "one way" or "unidirectional" valve, this device allows flow in only one direction. However, there is often considerable resistance to flow (or at least some minimum pressure drop) in the allowed direction. There is usually some leakage in the forbidden direction. A check valve is said to be "patent" when the flow in the allowed direction is sufficiently unimpeded for the desired use. It is said to be "competent" when the leakage in the forbidden direction is negligible for its intended use.



(FIG. 19. See legend on next page.)

FIG. 19 (bottom of preceding page). A rudimentary form of Safety Mixer with continuously adjustable total flow. P_2O_2 is set and controlled by the master regulator (providing P_2O_2 is high enough). If P_1O_2 should become lower than the desired setting of the master, P_2O_2 obviously cannot be higher than P_1O_2 .

P_2O_2 , acting upon the slave diaphragm, causes P_1N_2O to be reduced to $P_2N_2O = P_2O_2$ (again providing P_1N_2O is higher than P_2O_2). $P_2O_2 = P_2N_2O$ at practically atmospheric pressure (ca. 1 psig).

A slave regulator must be able to cause some energy loss in the gas passing through it if it is to operate with great accuracy. In addition, the less-than-infinite "amplification" of the automatic regulating system of the slave (the practical, non-zero ratio of throttling valve area to diaphragm area as well as throttling valve "stickiness") allows some variation of output pressure with changing input pressure. Thus, this system permits a certain undesirable variation of the ratio with changing N_2O input pressure.

In a fully-developed system it is desirable to constrain the range of variation of the input pressure to the final slave regulator. This is done (fig. 20 and fig. 23) by using a 5-psi subtractor ahead of the final slave.

An additional consideration in behalf of a second slave is the increase in reliability afforded by the redundancy.

A third gas may be added to the system by providing a slave regulator and a gasistor which would feed into either the N_2O inlet of the flow-ratio meter or the outlet.

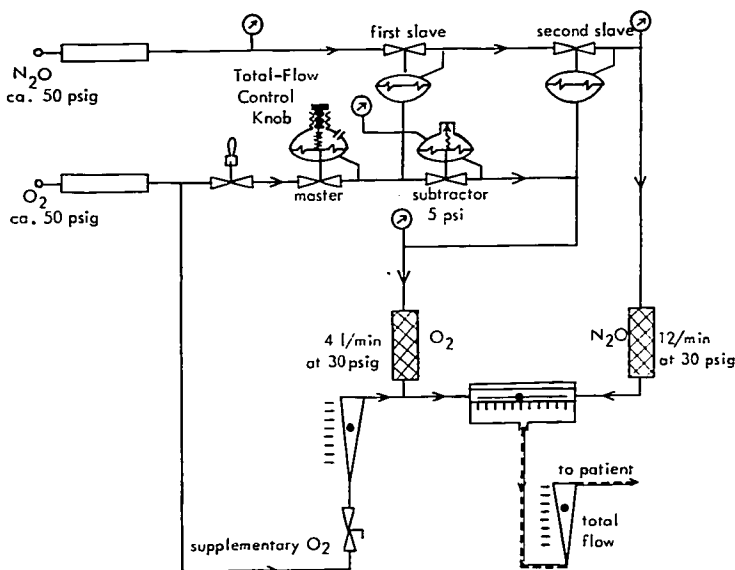


FIG. 20. Improved Safety Mixer with continuously adjustable total flow. This is the system of figures 1 and 2 in the text. This is identical to figure 19, except that a 5-psi subtractor and a second slave have been added. Thus, P_2O_2 is applied to the subtractor, the O_2 pressure being thereby lowered by 5 psi, before feeding the O_2 gasistor. P_2N_2O is applied to the second slave, which constrains the N_2O gasistor pressure to follow the O_2 gasistor input pressure exactly.

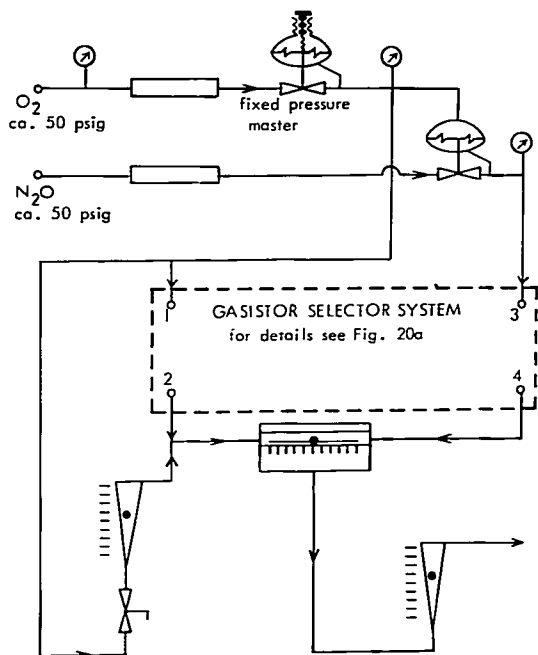
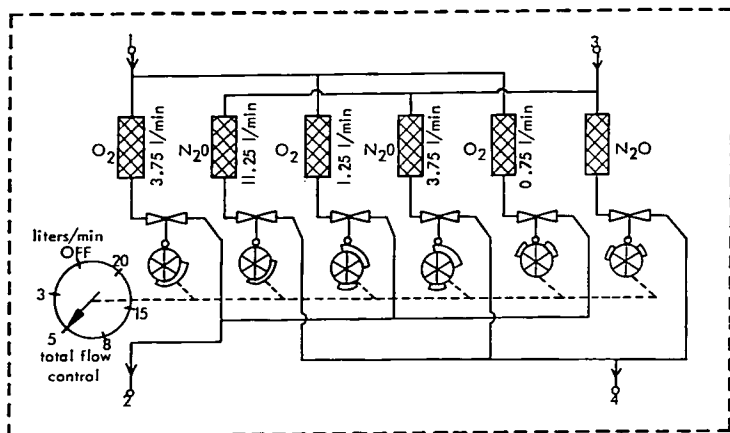


FIG. 21. Safety Mixer with cam-operated gas-selector selective valves (for total-flow control). This system is deemed excessively mechanically complicated.



(FIG. 22. See legend on next page.)

FIG. 22 (bottom of preceding page). Cam drawing (insert into Appendix, fig. 21). Note that the "total-flow control" selects combinations of the three pairs of gasistors by selectively operating the three pairs of cam-operated on-off valves. If the O_2 pressure should fall below the preset value, the N_2O pressure will follow; the ratio of O_2 to N_2O will not vary, although the total flow will fall proportionately.

In the 5-l/min position of the total-flow control only the middle pair of gasistors are "on." In the next counterclockwise position (8 l/min) both the middle pair and the right-hand pair of gasistors are "on."

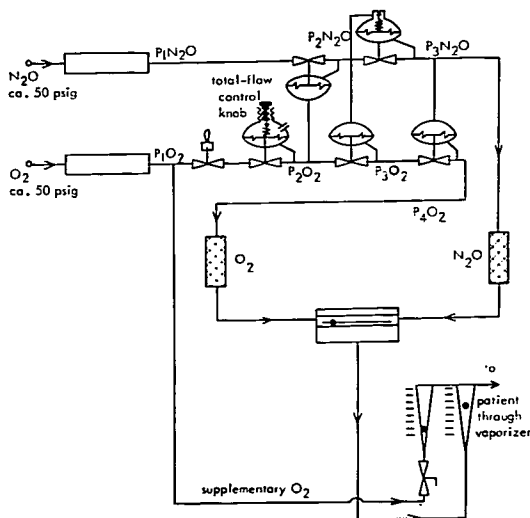


FIG. 23. "Double-master" Safety Mixer with flow-ratio meter monitoring gasistor-controlled 25 per cent ratio only.

P_2O_2 is controlled and set by the *master regulator*. Of course, if P_1O_2 falls below the setting, P_2O_2 will equal P_1O_2 . The *low-pressure selector* chooses the lower pressure of P_2N_2O and P_1N_2O . Thus, P_2N_2O is equal to the lower of P_1N_2O and P_2O_2 . The *first slave* reduces the O_2 pressure to P_2N_2O . The *subtractor* yields a pressure 5 psi lower than its input. Thus, P_3N_2O is 5 psi lower than P_2N_2O . The *second slave* reduces the O_2 pressure to P_3N_2O . $P_4O_2 = P_3N_2O$.

The flow through the gasistors is almost linear with respect to pressure. In any case, the curves of flow vs. pressure for the two gases are sufficiently alike so that the ratio of the flows is acceptably constant (± 2 per cent in ratio).

P_4O_2 and P_4N_2O are practically atmospheric (1 psig maximum).

The double-master principle was abandoned (the system modified to be that of Fig. 20) so that all three of our machines would be functionally similar as well as slightly less complicated.