Designation: F 1101 – 90 (Reapproved 1996)

Standard Specification for Ventilators Intended for Use During Anesthesia[1]

This standard is issued under the fixed designation F 1101; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification applies to all ventilators specifically introduced for sale following acceptance of this specification and intended for use during the administration of anesthesia. Definitions, performance requirements, test methods, and a rationale for all mandatory requirements are included.

1.2 The anesthesia ventilator cannot protect against malfunctions within the anesthesia machine, nor can it protect against inappropriate or inadvertent use of the oxygen flush valve, and therefore, no attempt has been made to address problems that may arise from malfunctions with these devices in this specification. (See also X3.1.)

1.3 Several definitions have been included in Section 2 and Appendix X1 that are not used in the text of this specification. This material has been included for the sake of completeness, and for any possible educational benefit that may be served. Appendix X1 also outlines various characteristics of ventilators intended for use during anesthesia and defines the main classes of breathing machines that may be used in medical practice and indicates how these may be subdivided according to their mode of action.

1.4 The following precautionary caveat pertains to the test methods portion, Section 6 of this specification. *This standard may involve hazardous materials, operations, and equipment. This standard does not purport to address all of the safety concerns associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* For an additional safety precaution, see Note 6.

2. Referenced Documents

2.1 *ASTM Standards:*

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes[2]

F 1161 Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines[2]

2.2 *ANSI Standards:*

Z-79.10 Standard for Oxygen Analyzers[3]

Z-79.11 Standard for Scavenging Systems for Excess for Anesthetic Gases[3]

2.3 *ISO Standard:*

ISO 4135 Anesthesiology Vocabulary[4]

2.4 *Other Standards:*

IEC 601-1 Safety of Medical Electrical Equipment[5]

CGA V-5, 1978 Specifications for DISS Connections[6]

3. Terminology

3.1 *Definitions*—For the purposes of this specification, the definitions in 3.1.1-3.1.51 shall apply.

3.1.1 *airway pressure (P_{aw})*—pressure at a specified point in the patient's airway. The site and conditions under which measurements are made should be given.

3.1.2 *alarm*—a means of alerting the operator that a particular condition exists.

3.1.3 *alveolar pressure (P_A)*—pressure in the alveoli. In the case of the lung model, this is represented by the pressure in the compliance chamber.

3.1.4 *apparatus internal compliance*—volume/pressure relationship, expressed in millilitres per kilopascal (or millilitres per centimetre H_2O) of those portions of the patient system that are pressurized during the inspiratory phase time (see also 5.8 and 3.1.36).

3.1.5 *continuous positive airway pressure (CPAP)—P_{aw}* maintained by the ventilator above ambient.

3.1.5.1 *Discussion*—Common usage of the term references spontaneous ventilation.

3.1.6 *control*—a means available to the operator of directly adjusting a ventilator function.

3.1.7 *cycling pressure*—that pressure which, when reached in the patient system, causes the ventilator to cycle from inspiratory to expiratory phase or from expiratory to inspiratory phase.

3.1.8 *differential inspiratory triggering pressure (ΔP_{tr})*—change in airway pressure at the patient connection port which

[1] This specification is under the jurisdiction of ASTM Committee F-29 on Anesthetic and Respiratory Equipmentand is the direct responsibility of Subcommittee F29.10on Anesthesia Workstations.

Current edition approved April 4, 1990. Published May 1990.

[2] *Annual Book of ASTM Standards*, Vol 13.01.

[3] Available from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

[4] Available from International Standards Organization, 1, Rue de Varembe, Case postale 56, CH-1211.

[5] Available from International Electrotechnical Commission, 3 rue de Varembé, 1211 Geneva 20, Switzerland.

[6] Available from Compressed Gas Association, 1235 Jefferson Davis Highway, Arlington, VA 22202.

must be generated by the patient to initiate the ventilator inspiratory phase.

3.1.8.1 *Discussion*—Pressure shall be expressed in terms of gage pressure in units of kilopascals (or centimetres H_2O) to follow the kPa units.

3.1.9 *expiratory pause time (T_{EP})*— interval from the end of expiratory flow to the start of inspiratory flow.

3.1.10 *expiratory phase time (T_E)*— interval from the start of expiratory flow to the start of inspiratory flow.

3.1.11 *expiratory positive airway pressure (EPAP)*—P_{aw} above ambient during the expiratory phase, generally approximated by P_{ps}.

3.1.12 *expiratory (sub-atmospheric) subambient pressure*—pressure lower than ambient, during the expiratory phase time.

3.1.12.1 *Discussion*—Subambient pressure may be constant throughout the expiratory phase time or it may vary through the phase time, depending upon the method by which such pressure is generated.

3.1.13 *frequency (ventilatory) (f)*—number of breathing cycles per minute.

3.1.14 *heat and moisture exchanger (HME)*—a passive device which is designed to converse some of the patient's exhaled moisture and heat, and to release heat and moisture to the patient's airway during inspiration.

3.1.15 *high priority alarm*—signal which indicates a condition requiring immediate action.

3.1.16 *inspiratory-expiratory phase time ratio (I:E ratio)*—ratio of the inspiratory phase time to the expiratory phase time.

3.1.17 *inspiratory minute volume ($\dot{V}_I$)*—volume of gas inspired per minute by the patient, measured in litres (L).

3.1.18 *inspiratory pause time (T_{IP})*— interval from the end of inspiratory flow to the start of expiratory flow.

3.1.19 *inspiratory phase time (T_I)*— interval from the start of inspiratory flow to the start of expiratory flow.

3.1.20 *inspiratory positive airway pressure (IPAP)*—P_{aw} above ambient during the inspiratory phase of CPAP, generally approximated by P_{ps}.

3.1.21 *inspiratory triggering flow ($\dot{V}_{Tr}$)*—flow which must be generated by the patient at the patient connection port to initiate the ventilator inspiratory phase.

3.1.22 *inspiratory triggering pressure (P_{tr})*—airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.

3.1.23 *inspiratory triggering response time (T_{tr})*—time delay between the satisfaction of the inspiratory triggering pressure or flow, or both, volume requirements, and the start of inspiratory flow.

3.1.24 *inspiratory triggering volume (V_{tr})*—volume, measured at the patient connection port, which must be moved by the patient to initiate the ventilator inspiratory phase.

3.1.25 *intermittent mandatory ventilation (IMV)*— a mode of operation of the ventilator that permits spontaneous breathing of a controlled inspiratory gas mixture between predetermined ventilator-delivered breaths using the same inspiratory gas mixture.

3.1.26 *low priority alarm*—signal which indicates a condition which requires operator awareness, but not necessarily action.

3.1.27 *maximum limited pressure ($P_{L\,max}$)*—highest gage pressure which can be attained in the patient system during malfunction of the ventilator but with functioning safety mechanisms.

3.1.27.1 *Discussion*—The title of this definition is different from the title given in ISO 4135. However, the text is identical to ISO 4135. The title of the ISO definition is *maximum safety pressure*.

3.1.28 *maximum working pressure ($P_{w\,max}$)*—highest gage pressure which can be attained in the patient system during the inspiratory phase when the ventilator is functioning normally.

3.1.28.1 *Discussion*—This may be limited by a controllable ventilator mechanism to less than $P_{L\,max}$.

3.1.29 *medium priority alarm*—signal which indicates a condition requiring prompt action.

3.1.30 *minimum limited pressure ($P_{L\,min}$)*—highest numerical value of sub-atmospheric gage pressure which can be attained in the patient system during malfunction of the ventilator but with functioning safety mechanisms.

3.1.30.1 *Discussion*—The title of this definition is different from the title given in ISO 4135. However, the text is identical to ISO 4135. The title of the ISO definition is *minimum safety pressure*.

3.1.31 *minimum working pressure ($P_{w\,min}$)*—highest numerical value of sub-atmospheric gage pressure which can be attained in the patient system during the expiratory phase when the ventilator is functioning normally.

3.1.31.1 *Discussion*—This may be limited by a controllable ventilator mechanism to a sub-atmospheric pressure that is numerically smaller than $P_{L\,min}$.

3.1.32 *minute volume ($\dot{V}$)*—volume of gas, expressed in litres per minute, entering or leaving the patient or lung model. The physical conditions under which measuring was made should be given.

3.1.33 *monitor (indicator display)*—a means of informing the operator of the status or numerical value of ventilation or a ventilator.

3.1.34 *nebulizing humidifier*—device designed to add water to the inspired gas in the form of droplets.

3.1.35 *negative end expiratory pressure (NEEP)*— the P_{ps} at the end of expiration, below ambient.

3.1.36 *patient system*—that part of the gas system of a ventilator through which respired gas travels at appropriate respiratory pressures.

3.1.37 *patient system compliance*—volume/pressure relationship, expressed in millilitres per kilopascals (or millilitres per centimetre H_2O) of those portions of the patient system that are pressurized during the inspiratory phase time.

3.1.38 *positive end-expiratory pressure (PEEP)*—P_{ps} at the end of expiration, above ambient.

3.1.39 *pressure, patient system (P_{ps})*— pressure at a specified point in the patient system. Conditions under which measurements are made shall be given.

3.1.40 *pressure support*—a ventilator mode designed to augment the patient's ventilation synchronously with his inspiratory effort until a preset pressure is met.

3.1.41 *selector valve*—a valve that routes the breathing

mixture to the breathing bag of the anesthesia circuit or to a ventilator.

3.1.42 *sigh (ventilator)*—deliberate increase in tidal volume for one or more breaths at intervals.

3.1.43 *spirometer*—device designed to measure a volume of gas.

3.1.44 *synchronous intermittent mandatory ventilation (SIMV)*—an IMV mode which provides a mechanism for synchronizing the ventilator-delivered breaths with a patient's inspiration, as detected by the ventilator.

3.1.45 *tidal volume (V_T)*—volume of gas, expressed in millilitres (mL), entering or leaving the patient or the lung model during the inspiratory or expiratory phase time. The physical conditions under which gas volumes are measured should be given.

3.1.46 *time constant*—time in which an exponential process is 63 % complete.

3.1.47 *vaporizing humidifier*—device designed to add water to the inspired gas in the form of vapor.

3.1.48 *ventilator expiratory resistance*—for ventilators in which expiration is not assisted, the total resistance to gas flow from the patient connection port through the expiratory port of the patient system to atmosphere. This is expressed in kilopascals (or centimetres H_2O) referred to a flow of 0.5 L/s.

3.1.48.1 *Discussion*—This definition is applicable in those types of ventilators in which expiration is not assisted.

3.1.49 *ventilator-patient system*—that part of the ventilator gas system through which inspired gas travels at respiratory pressures.

3.1.50 *ventilators intended for use with anesthesia*—ventilator designed to be used with or integral to an anesthesia breathing system.

3.1.51 *ventilator pressure (P_{vent})*— pressure at a specified point in the ventilator. The site and conditions under which measurements are made should be given.

3.2 *Symbols:Symbols:*

3.2.1 *C*—indicates compliance in units of mL/kPa (or mL/cm H_2O), for example, C20 = 20 mL/kPa (20 mL/cm H_2O).

3.2.2 *R*—indicates resistance to flow in units of kPa (or cm H_2O)/L/s; for example, *R*5 = 0.5 kPa/L/s (5 cm H_2O/L/s).

3.2.2.1 *Discussion*—For the purposes of clarity, all other abbreviations have been listed in parentheses following the related term or phrase in Section 2.

4. Materials and Manufacture

4.1 *Sterilization or Decontamination or Both*:

4.1.1 All components of the ventilator that come in contact with the patient's respired gases shall be capable of being sterilized, or shall be for single use only. (See also 6.2.)

4.1.2 All external surfaces of the ventilator shall be capable of being disinfected. (See also 6.2 and X3.2.)

5. Performance Requirements

5.1 *Volume and Wave-Form*—The tests in 6.1.3 and 6.1.4 shall be carried out on one or more samples of production ventilators with the assurance that the results, which shall be made available to customers, are representative of all production ventilators of that type. These tests include one test for endurance and two tests for performance. The endurance test shall be performed first and the performance tests immediately thereafter.

5.2 *Ventilator Endurance*—Each tested ventilator (as described in 5.1) shall be tested for endurance with respect to each group of patients for which its use is recommended, that is, for adults, for children, and for infants. A separate machine may be used for each group or the period of tests may be divided equally between groups. Inspiratory/expiratory phase time ratio shall be as close to 1:2 as possible and the ventilator run for 72 h against the appropriate condition shown in Table 1. (See also X3.3.1.)

5.3 *Power Sources*:

5.3.1 *Electrical*—When tested as outlined in 6.3.1, the ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a range of ± 10 % fluctuation of the stated nominal voltage and ±1 % fluctuation of the stated frequency for electrical power sources. For all other aspects, ventilators intended for use during anesthesia shall comply with the electrical requirements of IEC 601-1. (See also X3.3.3.)

NOTE 1—The IEC is presently developing electrical safety standards specifically addressing ventilators. When approved, these will take precedence over the requirements in IEC 601-1.

5.3.2 *Pneumatic*—When tested as outlined in 6.3.1, the ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a range of supply pressures of 55 psig + 20 % and − 25 %. The device's gas connection shall be non-interchangeable. If the device has a threaded connection, it shall conform to the appropriate CGA V-5 1978 specification for DISS connections. If the ventilator is capable of being independently connected to the gas piping system, it shall have permanently attached a Body Fitting number 1240 (oxygen) if intended to be powered by oxygen, or a Body Fitting number 1160 (compressed air) if intended to be powered by air. (See also X3.3.3.)

5.4 *Accuracy of Calibrated Controls, Indicators, and Pressure Relief Devices*:

5.4.1 *Calibrated Working Pressure Control*—If provided, calibrated controls for $P_{w\,max}$ shall be accurate to 0.245 kPa (± 2.5 cm H_2O) up to 2.94 kPa (30 cm H_2O) and to 0.49 kPa (± 5 cm H_2O) above 2.94 kPa (30 cm H_2O) when tested as described in 6.4.1. (See also X3.3.4.1.)

5.4.2 *Indicators*—The manufacturer shall disclose the accuracy of all indicators when tested as outlined in 6.4.1 unless accuracy is otherwise addressed in this draft standard. (See also X3.3.4.2.)

5.4.3 *Maximum Working Pressure Control*— A maximum working pressure control may be provided in the anesthesia

TABLE 1 Ventilator and Test Lung Settings for Endurance Test

	Compliance[A]	Resistance	Frequency	Tidal Volume, mL
Adult	*C* 20	*R*20 (R_p 20)	10/min	600
Pediatric	*C* 10	*R*50 (R_p 50)	20/min	200
Infant	*C* 3	*R*200 (R_p 200)	40/min	50

[A] *C* 20 refers to a compliance of 20 mL/0.098 kPa (1 cm H_2O), and *C* 10 to a compliance of 10 mL/0.098 kPa (1 cm H_2O), and *C* 3 refers to a compliance of 3 mL/0.098 kPa.

ventilator. If provided, these devices shall limit $P_{w\,max}$ and shall be accurate to within ±10 % of the set value (if calibrated) when tested as outlined in 6.4.2. If the ventilator derives its patient breathing mixture from a continuous flow anesthesia machine, then the manufacturer shall disclose the pressure at the breathing system connection port when a flow of 75 L/min is passed through the ventilator system with the $P_{w\,max}$ control activated. (See also X3.3.4.3.)

5.4.4 *Maximum Limited Pressure Mechanism ($P_{L\,max}$)*—A maximum limited pressure mechanism may be provided in the ventilator. If provided, these devices shall control $P_{L\,max}$) during ventilator malfunction, and may be operator adjustable. These devices shall be accurate to within 0.98 kPa (± 10 cm H_2O) of the set value at the opening pressure when tested as described in 6.4.3. (See also X3.3.4.3.)

NOTE 2—The maximum limited pressure control may not protect against malfunction in the anesthesia machine.

5.4.5 If provided, integral devices indicating ventilatory frequency shall be accurate to one breath per min or 10 % of actual (whichever is smaller) when tested as described in 6.4.4. (See also X3.3.4.3.)

5.4.5.1 Calibrated devices controlling ventilator frequency shall be accurate to within one breath per min or 10 % of actual (whichever is smaller) when tested as described in 6.4.4.

NOTE 3—This accuracy specification is not considered as an additive error in combination with the requirement of 5.4.5.

5.5 *Delivered Volume*—Delivered volume of the ventilator shall be indicated to the operator by some means and shall be accurate to ±15 % and shall be repeatable to ±5 % over a 1 h period. Test conditions shall be stated.

5.6 *Accuracy of Gas Mixture Controls*— When ventilators have incorporated as a primary control an inspiratory gas mixture control, the accuracy of the mean delivered oxygen concentration shall be within± 10 % of the set oxygen concentration or 3 % oxygen, whichever is greater, throughout the range of pressures, frequencies, and tidal volumes of which the ventilator is capable when tested as described in 6.6. At a given setting of the ventilator, the delivered oxygen concentration shall be ±3 % oxygen for at least 1 h. (See also X3.3.6.)

5.7 *Expiratory Resistance*:

5.7.1 *Adult and Child Ventilators*—When tested as described in 6.7, and in the absence of expiratory resistors or positive end expiratory pressure devices, the pressure at the breathing system connection for adult and child ventilators shall not exceed 0.49 kPa (5 cm H_2O) at a flow of 50 LPM when spirometer or breathing attachments, or both, as specified by the manufacturer, are used. If the ventilator is integral to the anesthesia machine, the manufacturer shall disclose the expiratory resistance when the flush valve is activated. The manufacturer should specify the maximum negative pressure created by the anesthesia ventilator with no fresh gas flow when the bellows does not reach the limiting stop. (See also X3.3.7.1.)

5.7.2 If the ventilator incorporates a weighted descending bellows, the manufacturer shall specify the maximum negative pressure created when tested as outlined in 6.7.2. (See also X3.3.7.2.)

5.8 *System Internal Compliance*—The manufacturer shall disclose the internal compliance of the ventilator and shall provide, upon request, the test methods used to determine the derived values. Manufacturers of ventilator tubing that recommend the use of their tubing with several ventilators, or who do not manufacture ventilators, shall provide the data on the compliance of their tubing in the labeling of their product. (See also 6.8 and X3.3.8.)

5.9 *Fittings Connecting Ventilator, Ventilator Circuit and Spirometer*:

5.9.1 The fitting for the tubing connecting the ventilator to the breathing circuit shall be a standard 22-mm male conical fitting, according to the dimensions specified in Specification F 1054. For flow direction-sensitive devices, the direction of flow shall be permanently marked on the connector, and the connector should be designed so that it cannot be installed in the reverse direction. (See also 6.9.1 and X3.3.9.1.)

5.9.2 If a 22-mm connector for a bag for manual ventilation is provided on the ventilator, it shall be marked *bag* with either the symbol or the word, and should face downward and shall be situated away from the connectors for the patient breathing tubes. No valve shall be permitted on the ventilator which will channel the patient's exhaled gas into the manual bag. The bag mount should provide a secure connection. (See also 6.9.2 and X3.3.9.2.)

5.9.3 If there is a separate outlet for the spirometer on the breathing tubes or the machine, the gas outlet leading to the spirometer should be a 30-mm male conical fitting.

5.9.4 If an ambient air inlet is fitted to the ventilator, it shall not be a 22, 15, 19, or 30-mm male cone and shall be clearly marked as *air inlet*. (See also 6.9.3 and X3.3.9.3.)

5.9.5 Outlets for anesthetic gas pollution control devices shall conform with ANSI Z-79.13. If an expired gas outlet (other than an outlet for spirometer) is fitted to the machine, it shall be designed in such a way that it cannot easily be connected to either 22 or 15-mm cones or sockets, or to 22-mm internal diameter tubing. (See also 6.9.4 and X3.3.9.3.)

5.10 *Mechanical Stability and Transportability*—Ventilators intended for use during anesthesia that are not an integral part of an anesthesia machine shall comply with Clause 24 of IEC 601-1.

5.11 *Ventilatory Monitoring and Alarms*— If provided as an integral part of the ventilator, ventilatory monitoring and alarms shall comply with the relevant sections set forth in Specification F 1161 and with the requirements of this section.

5.11.1 The alarm characteristics of monitors specified in this specification shall be grouped in three categories: (I) High Priority, (II) Medium Priority, and (III) Low Priority (see Table 2).

5.11.1.1 The audible components of these alarms should be designed to allow silencing until the anesthesia ventilator is placed in use (in other words, connected to the patient) in order

TABLE 2 Alarms

Category	Priority	Auditory	Visual	Operator Response
I	High	Not II or III	Not II or III	Immediate
II	Medium	Not I or III	Not I or III	Prompt
III	Low	Not I or II	Not I or II	Awareness

to reduce nuisance alarms.

5.11.1.2 The visual indicators for these alarms shall conform to the requirements given in the first two sentences of 5.13.

5.11.1.3 The audible component of these alarms at minimum volume should be discernible, to a person with normal hearing, above a background white noise level of 55 dB(A) at a distance of 3m from the front of the anesthesia gas machine.

5.11.1.4 There should be a visual indication that an audible alarm has been silenced.

5.11.1.5 The set points of adjustable alarms shall be indicated continuously or on user demand.

5.11.1.6 *Testing of Alarm Function*—A means shall be provided to test the function of the audible and visual annunciation of all alarms.

5.11.2 *High Priority Alarms*:

5.11.2.1 There shall be a visual indication of the high priority alarm. It shall be different and distinguishable from the visual signals specified in 5.11.3 and 5.11.4.

5.11.2.2 There shall be a simultaneous audible indication of the high priority alarm. This audible indication shall be different and distinguishable from the audible signals specified in 5.11.3 and 5.11.4.

5.11.2.3 The audible indicators shall reset automatically when the condition causing the alarm has cleared. The maximum time an audible high priority alarm can be silenced shall be 120 s.

5.11.3 *Medium Priority Alarms*:

5.11.3.1 There shall be a visual indication of the medium priority alarm. It shall be different and distinguishable from the visual signals specified in 5.11.2 and 5.11.4.

5.11.3.2 There shall be a simultaneous audible indication of the medium priority alarm. This audible indication shall be different and distinguishable from the audible signals in 5.11.2 and 5.11.4.

5.11.3.3 The audible indicator shall reset automatically when the condition causing the alarm has cleared. The audible indicator may be silenced for not more than 120 s, or until a different medium priority alarm condition occurs.

5.11.4 *Low Priority Alarms*:

5.11.4.1 There shall be a visual indication of the low priority alarm. It shall be different and distinguishable from the visual signals in 5.11.2 and 5.11.3.

5.11.4.2 There shall be a simultaneous audible indication of the low priority alarm. This audible indication shall be different and distinguishable from the audible signals specified in 5.11.2 and 5.11.3.

5.11.4.3 The audible indicator shall reset automatically when the condition causing the alarm has cleared. The audible indicator may be silenced until a different low priority alarm condition occurs.

5.11.5 *Required Alarms*—The following alarms shall be provided in association with all ventilators or ventilator/patient systems intended for use during anesthesia:

5.11.5.1 *Loss of Main Power Supply—Alarm Category: High Priority*—A loss of main power alarm shall be provided, and shall have a duration of at least 2 min at a constant sound pressure level when tested as outlined in 6.10. A means shall be provided for silencing this alarm following disconnection from the main power supply. This means of silencing the alarm shall not be remote from the ventilator, and the alarm silencing mechanism shall automatically reset when the main power is restored (see 6.10). If alternatively an alarm is provided to indicate loss of main power with backup power functioning, it shall be assigned to the *Low Priority* category. (See also X3.3.10.)

5.11.6 *Battery Power Supplies*—If any alarm incorporates a battery power supply: (*1*) the system shall include a means whereby the user may determine that the battery needs to be replaced for disposable batteries or recharged, and (*2*) the battery should be of a type readily obtainable.

5.12 *Anesthetic Gas Pollution Controls*— If provided as a part of the ventilator, pollution control devices shall comply with the requirements of ANSI Z-79.11.

5.13 *Controls and Indicators*—The faces of all scales and gages shall be legible and all controls and indicators shall be visible at a distance of 1 m (3.3 ft) and at a light level of 215 lux (20 footcandles) to an operator with 6.5 (20-20) vision (corrected), seated or standing in front of the anesthesia machine. The markings and calibrations should be readily identified with the controls, gages, meters, or indicators with which they are associated. Flowmeters, gages, controls, and other displays that need to be read most frequently should be grouped together and should be placed as close as possible to the operator's field of vision when in the normal position of operating the anesthesia machine and observing the patient. (See Appendix X4.)

6. Test Methods

6.1 *Lung Models and Method of Testing Performance of Lung Ventilators*:

6.1.1 *Test Equipment*—The lung models illustrated in Figs. 1 and 2 do not preclude the development of different or more sophisticated lung models with the same ranges of compliance and linear or alinear resistances. If nonlinear resistances are used, their characteristics must be specified.

6.1.1.1 *Lung Models*—Lung models are designed to provide impedances to the ventilator output that simulate both normal and diseased lung states. The impedances to ventilator output are lung elastance and airflow resistance, which can be simulated in the lung models by a compliance and a resistance connected in series (see Figs. 1 and 2). The various combinations of compliances and resistances used in the test procedures are given in Table 1.

6.1.1.2 *Compliances*—The required compliances are given in Table 2. These compliances shall include the compliances of all components of the lung model system. The volume-pressure characteristics of the model compliances including connections shall be determined at ambient pressure and temperature and shall be determined as in 6.1.2 and shall be within ±5 % of the required compliance values shown in Table 1.

6.1.1.3 *Resistors*—The required resistors are given in Table 1. Values for these resistors are given in Tables 3 and 4. These values relate to measurements at NTPD (20°C, 760 mm Hg, and 0 % RH).

6.1.2 *Test Methods—General*—Make measurements of pressure, flow, and volume as shown in Fig. 1 accurate to

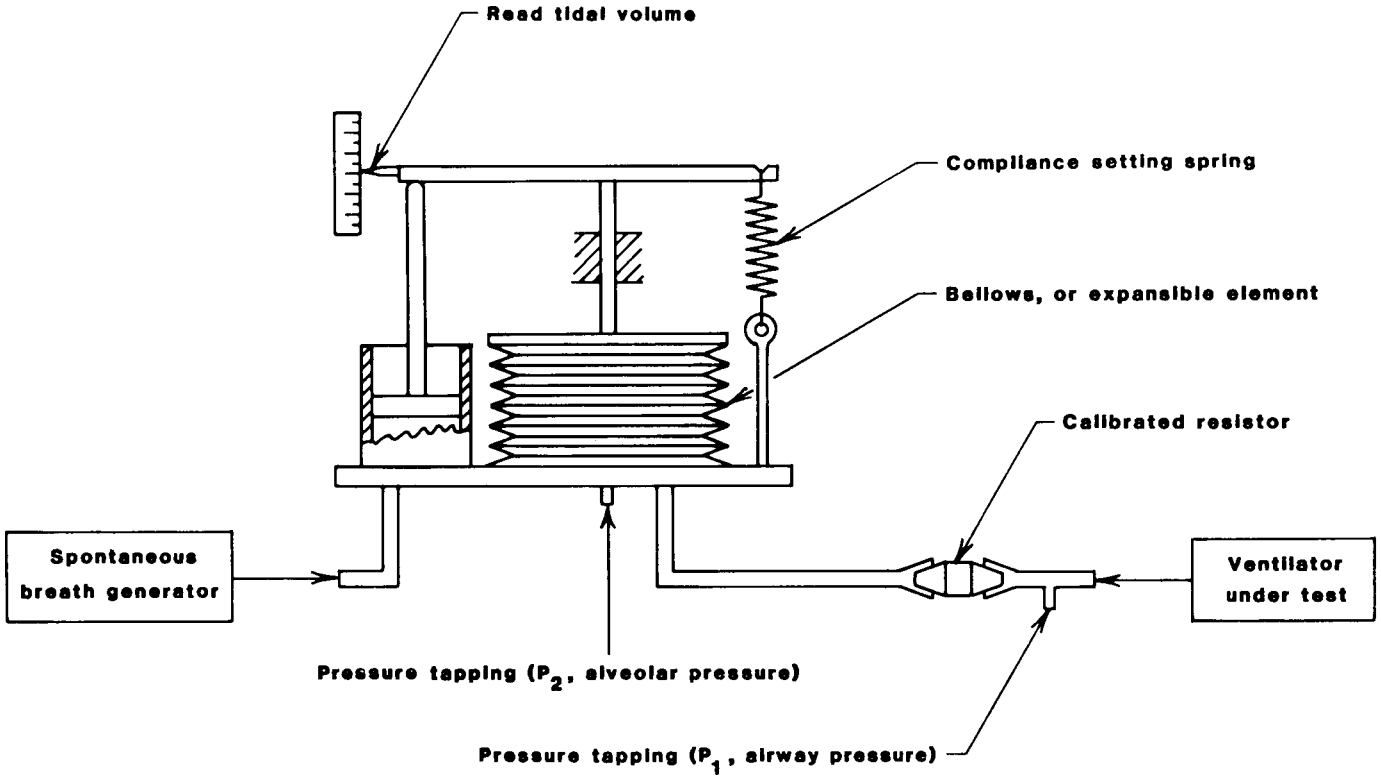

FIG. 1 Representative Active Lung Model

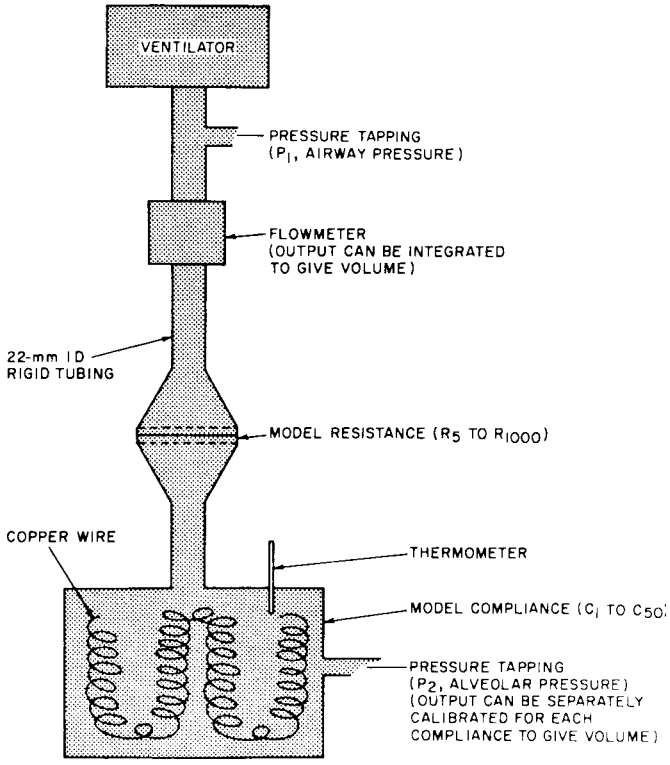

FIG. 2 Representative Passive Lung Model

TABLE 3 Linear Resistances

Resistance	Value in Flow Range		Range of Airflow
	±20 % kPa/L/s	(cmH_2O/L/s)	(L/s)
*R*20	1.96	(20)	0 to 1.0
*R*50	4.90	(50)	0 to 0.5
*R*200	19.60	(200)	0 to 0.1

TABLE 4 Parabolic Resistances[A]

$\Delta P = K V^2$ cm H_2O (where V = L/s)					
Resistances	K ± 10 %	P ± 10 % kPa	(cm H_2O)	@	V, L/s
R_p20	17.60	0.43	(4.40)	@	0.5
		1.73	(17.60)	@	1.0
R_p50	108.70	0.67	(6.79)	@	0.25
		2.67	(27.20)	@	0.5
R_p200	2440.00	0.60	(6.10)	@	0.05
		2.39	(24.40)	@	0.1

[A] Linear and parabolic resistances may be used interchangeably. Representative test lungs and the appropriate parabolic resistances are available from Michigan Instruments, Inc., 6300 28th Street, SE, Grand Rapids, MI 49506; BioTek Instruments, Highland Park, Winooski, VT 05404, or Hyco-Aulas Gauthier S.A., Bureau a Paris, 13, rue Guyton-de-Morveau, 75013 Paris, France or their equivalents have been found satisfactory for this purpose. Resistances will have different performance values, depending on the manufacturer and individual resistor configuration. The ventilator manufacturer shall supply data on the resistors used during testing upon request.

within ±2.5 % of the reading. Allow an additional tolerance of ±2.5 % of the full scale reading. Make measurements of power and work accurate to within ±5 % of the reading. Allow an additional tolerance of ±5 % of the peak reading. Maintain the reading accuracy of the recording device at frequencies up to 10 Hz. Record ambient conditions, and report all results at NTPD even though other conditions might exist during actual testing. Dry air, unless otherwise specified in an individual requirement, is the test gas.

6.1.3 *Wave-form Performance Test*—Connect the ventilator to the compliance and resistance combinations appropriate to

its intended use (that is, for adults, for children, or for infants). At the beginning of the test adjust the ventilator controls to obtain the desired frequency and tidal volume at an inspiratory/expiratory ratio that is as close to 1:2 as possible. Record the ventilator settings required to obtain these settings. If it is necessary to reset the ventilator controls to match the ventilator to the new set of conditions, note this in the results. In such an event, obtain records before and after resetting the ventilator controls. Always reset the ventilator to the standard conditions appropriate to a given tidal volume (as indicated in Table 1) before each subsequent test. Perform all tests without a subambient phase unless this is an integral feature of the ventilator mechanism.

6.1.3.1 Record the following traces during the tests and display in the order shown:

(*a*) Pressure at the patient end of the ventilator tubes, P_1(see Fig. 1),

(*b*) Pressure in the chamber (equals alveolar pressure P_2) (see Fig. 1),

(*c*) Flow at ventilator output, and

(*d*) Volume.

If desired, append additional recordings to illustrate special characteristics of the ventilator.

6.1.3.2 Reproduce the scale and clarity of the records such that a change of ±2.5 % of the peak reading can be detected easily. Inscribe all records with the appropriate scales, time base, and details of the test. Include the following:

(*a*) Ambient temperature and pressure, together with the temperature, composition, and humidity of the inspired gas.

(*b*) The nature and dimensions of the breathing tubes connecting the ventilator to the test lung and whether other apparatus (for example, humidifier, spirometer, or water traps) were included in the part of the circuit which is pressurized during inspiration. If such apparatus is included, specify the type and position. If a humidifier is included, fill it to the *full* water level with a relatively non-compressible substance. If this is not practicable, replace the humidifier with an equivalent compliance and resistance.

(*c*) A listing of all settings of controls, if possible.

(*d*) Any other relevant information (for example, source and pressure of driving gas, use of special ventilator circuits, or type of humidifier).

6.1.4 *Volume Performance Test*—Test the adult ventilator against a compliance of *C* 20, and a resistance of *R* 20 (R_p20), at tidal volumes ranging from 300 to 1200 mL, and a range of frequencies from 6 to 20 breaths per min. Test pediatric ventilators at three representative volumes, that is, min, mean, and max, within the range of 50 to 300 mL tidal volume against a compliance of *C* 10 and a resistance of *R* 50 (R_p50) at a frequency of 20 breaths/min. Test the infant ventilator against a compliance of *C* 3, and a resistance of *R* 200 (R_p200), at a tidal volume range of 30 to 200 mL and a ventilatory frequency of 40 breaths per min.

6.1.5 The manufacturer shall determine the range of tidal volumes that the ventilator is capable of delivering to the lung at the specified frequencies with an inspiratory/expiratory phase time ratio as close to 1:2 as possible. Further measurements at different frequencies and with different compliance and resistance combinations may be included if desired. State the conditions under which the tests are carried out (see 5.1 and 6.1.3.1).

6.2 *Materials Requirements*—Review the operation and maintenance manual for recommended methods.

6.3 *Performance Requirements*:

6.3.1 *Power Sources*—Vary the supply pressure and voltage independently and perform the tests in 6.1.3 and 6.1.4 under the worst possible conditions, that is, Test No. 4 for adults and children, respectively. These tests are to be conducted at both the upper and lower extremes as indicated in 5.3.1 and 5.3.2.

6.4 *Accuracy of Calibrated Controls, Indicators, and Pressure Relief Devices*:

6.4.1 Connect the controls to a calibrated device (generally one five times more accurate), and test the accuracy of the controls.

6.4.2 Using the same apparatus as outlined in 6.4.1, activate the ventilator and determine the accuracy of the $P_{w\,max}$ control. Review the operation and maintenance manual for pressure data.

6.4.3 Repeat the tests as outlined in 6.4.2, however, use a flow of 150 L/min.

6.4.4 Measure the time for at least 100 breaths after a steady state is reached.

6.5 *Delivered Volume*—Measure the volume gas over a period of 5 min unless the manufacturer can show an equivalent accuracy with a lesser collection time, when measured at the outlet of the ventilator, with compensation for fresh gas flow.

6.6 *Accuracy of Gas Mixture Controls*— Measure delivered oxygen concentrations at the allowable extremes of pipeline pressures, that is, at 284 kPa and 455 kPa (41.2 psig and 66 psig). Also measure concentrations at the extremes of resistance and compliance, before and after all ventilator changes during the Endurance and Wave Form Performance tests, and under worst case combinations. Collect gases from ten breaths and the reading recorded when the analyzer has reached a steady state.

6.7 *Expiratory Resistance*:

6.7.1 Deliver a flow of 50 L/min into the patient connection port of the ventilator. Measure the pressure generated at that point.

6.7.2 Shut off the fresh gas flow, and obstruct the patient connecting port of the delivery system just after a tidal volume is delivered, then shut off the ventilator and read the pressure gage of the breathing system.

NOTE 4—The test lung has rigid walls; negative pressure *cannot* collapse the lung as it would do in actual patient application.

6.8 *System Internal Compliance*—Review the operation and maintenance manual provided with the ventilator.

6.9 *Fittings Connecting Ventilator and Spirometer*:

6.9.1 Visually inspect the connector and attempt to change connector direction.

6.9.2 Inspect the ventilator for appropriate marking and connector position, and review the ventilator circuit diagram.

6.9.3 Attempt to fit a 15, 19, or 22-mm or 30-mm fitting.

6.9.4 Repeat the test as outlined in 6.9.3 for 15 and 22-mm connectors.

6.10 *Alarms*—Connect the power supply to the ventilator, run according to the manufacturer's instructions, then disconnect the ventilator from the main power supply and determine that the alarm sounds, and maintains a constant sound pressure level ±3 dB for at least 2 min. Repeat the test as outlined above, and silence the loss of main power supply alarm. Reconnect the ventilator main power immediately after silencing the alarm, and then disconnect the ventilator from the main power supply again and determine that the alarm silencing mechanism has reset.

7. Warnings and Markings

7.1 *Marking*:

7.1.1 All breathing circuit components in which the direction of gas flow is critical shall be permanently marked in such a way that the intended direction of gas flow is immediately apparent to the operator.

7.1.2 For the purposes of this specification, all ventilator system components that contain a valve or valves, the purpose of which is to establish the direction of gas flow, are considered to be flow critical and shall be so marked. Examples include inhalation check valves, exhalation check valves, and non-rebreathing valves.

7.1.3 Where markings are applied to breathing system components in order to indicate the direction of gas flow, the minimum acceptable marking shall consist of at least one headed arrow permanently affixed to the component. Where a component contains more than one check valve, the minimum acceptable marking shall consist of at least one headed arrow indicating the direction of flow through each check valve.

7.1.4 All markings applied to breathing system components for the purpose of indicating direction of gas flow should be located, if possible, so that they will fall in the operator's normal field of view when equipment is in use.

7.1.5 Breathing system components in which the direction of gas flow is not critical need not be marked to indicate specific flow direction.

7.1.6 If possible, ventilators should be clearly marked with the following:

7.1.6.1 Adequate instructions for lubrication and routine maintenance,

7.1.6.2 Operating instructions, if a means of hand operation is provided,

7.1.6.3 Required operating gas pressure for equipment operated by gas,

7.1.6.4 Relief pressure of non-adjustable safety valves and maximum relief pressure of adjustable safety valves,

7.1.6.5 The maximum volumetric displacement, if less than 1400 mL,

7.1.6.6 The manufacturer's name or trademark and the country of manufacture,

7.1.6.7 Inlets and outlets of the machine, and

7.1.6.8 Voltage and current requirements.

NOTE 5—If it is not possible to mark this information on the ventilator, an instruction to refer to the instruction manual shall be marked on the ventilator.

7.1.7 All connectors for electrical and gas supply shall be marked with identification labels.

NOTE 6—**Precaution:** In addition to other precautions, if electrical components are included in the ventilator, the device should be marked with the phrase **Not For Use in the Presence of Flammable Anesthetic Agents**.

7.1.8 If multiple connection ports are provided, their intended use shall be marked.

7.1.9 *Alarm Operating Instructions*—The manufacturer shall provide instructions for testing and setting of the alarm. These instructions shall be either permanently marked on or attached to the ventilator or ventilator alarm.

8. Supplementary Requirements

8.1 *Information to be Included by the Manufacturer*—The following information shall be included in the information provided by the manufacturer:

8.1.1 Recommended means of sterilization or decontamination, or both, of the ventilator, and

8.1.2 Recommended power supply.

APPENDIXES

(Nonmandatory Information)

X1. CHARACTERISTICS OF VENTILATORS INTENDED FOR USE DURING ANESTHESIA

X1.1 *Volume Control:*

X1.1.1 Pressure Preset
X1.1.2 Volume Preset
X1.1.2.1 Tidal
X1.1.2.2 Minute
X1.1.3 Combined

X1.2 *Cycling Control:*

X1.2.1 Inspiration to Expiration
X1.2.1.1 Volume
X1.2.1.2 Pressure
X1.2.1.3 Time
X1.2.1.4 Flow
X1.2.1.5 Combined
X1.2.1.6 Manual override
X1.2.1.7 Other
X1.2.2 *Expiration to Inspiration*:
X1.2.2.1 Pressure
X1.2.2.2 Time
X1.2.2.3 Flow
X1.2.2.4 Combined
X1.2.2.5 Patient

X1.2.2.6 Manual override
X1.2.2.7 Other

X1.3 *Types of Safety Limits:*

X1.3.1 Volume
X1.3.2 Pressure
X1.3.3 Time
X1.3.4 Other

X1.4 *Types of Pressure Patterns:*

X1.4.1 Positive-ambient
X1.4.2 Positive-subambient
X1.4.3 Positive-positive

X1.5 *Source of Power:*

X1.5.1 Pneumatic
X1.5.2 Electric
X1.5.3 Other

X1.6 *Power Transmission:*

X1.6.1 Direct
X1.6.2 Indirect

X1.7 *Source of Inspired Gas:*

X1.7.1 Driving gas
X1.7.2 Fresh gas
X1.7.3 Mixed

X1.8 *Type of Control:*

X1.8.1 Pneumatic
X1.8.2 Electronic
X1.8.3 Mechanical
X1.8.4 Combined

X1.9 *Classification and Definitions of Types of Breathing Machines:*

X1.9.1 *Lung Ventilator*— An automatic device that is connected to the patient's airway and is designed to augment or provide for the patient's ventilation.

X1.9.2 *There are four types of lung ventilators*:

X1.9.2.1 *Controller*— A device, or mode of operation of a device, that inflates the patient's lungs independently of the patient's inspiratory effort.

X1.9.2.2 *Assister*—A device or mode of operation designed to augment the patient's breathing synchronously with his inspiratory effort.

X1.9.2.3 *Assister/Controller*—An apparatus or mode of operation that is designed to function either as an assister or a controller, and that may, in default of the patient's inspiratory effort, automatically function as a controller.

X1.9.2.4 *Assister/Controller—Spontaneous Breathing*—Those devices that incorporate various modes of operation which allow the patient to breath spontaneously (1) at or above ambient pressure levels, or (2) with or without supplemental mandatory positive pressure breaths.

X1.9.3 *High Frequency Ventilation*—Those ventilators that employ a frequency of greater than 2.5 Hz.

X2. DEFINITIONS OF ALARM CATEGORIES AND ASSOCIATED VISUAL INDICATORS

X2.1 *Category I*—A sound or indication of potential danger meaning that urgent action is required. Visual indicator—flashing indicator, colored red if indicator lights are used.

X2.2 *Category II*—A sound meaning that increased vigilance or prompt action is required. Visual indicator—flashing indicator, colored yellow if indicator lights are used.

X2.3 *Category III*—A sound meaning that alertness to a particular condition is required. Visual indicator—continuous indicator, colored yellow if indicator lights are used.

X3. RATIONALE

X3.1 *Scope:*

X3.1.1 This specification defines minimum performance and safety requirements for all types of anesthesia ventilators. The Subcommittee preparing this draft was of the opinion that the major problems with these devices would be addressed by the requirements that have been included, but was well aware that not all types of failures (double-fault, triple-fault, etc.) can be allowed for, and that it is not possible to design a totally safe or a totally effective ventilator.

X3.2 *Materials Requirements:*

X3.2.1 Although ideally all components of the ventilator should be sterilizable, certain components may not be able to be sterilized with currently available methods without causing damage to the device. These components should be capable of being disinfected with a high level disinfectant[7] or should be isolated from other portions of the patient breathing circuit.

X3.3 *Performance Requirements:*

X3.3.1 *Volume Performance*—The tests used to demonstrate compliance with these requirements were designed to demonstrate that the ventilator can provide adequate ventilation under relatively severe circumstances, that is, low compliance and high resistance. However, the values given in 6.1.4 are not considered the worst case. These values are instead considered to be median values.

[7] Garner, J. S. et al, "CDC Guidelines for the Prevention and Control of Nosocomial Infections–Guideline for Handwashing and Hospital Environmental Control, 1985" *American Journal of Infection Control*, 14:110–129, 1986, Section 2, pp. 116–129.

X3.3.2 *Wave-Form and Endurance*—The Subcommittee felt that 72 h was a reasonable length of time for an anesthesia ventilator to be able to meet the requirements of the standard without requiring readjustment or recalibration. The clinicians on the Subcommittee felt that it was quite possible that an anesthesia ventilator would be required to be used for this length of time without any possibility for recalibration.

X3.3.3 *Power Sources*— Fluctuations within the ranges specified in 5.3 are known to occur in both electrical and pneumatic power supply systems in hospitals. The causes for such variation may be outside the control of the ventilator user. For example, a decrease in the power supplied by the local electric utility, or the variation that may result from demand for power caused by such equipment as elevator motors and air-handling apparatus within the hospital will cause these types of fluctuations. The periodic testing of emergency generators may also create this type of variation. Pneumatic power sources may show transient variations as well. The filling of liquid oxygen bulk reservoirs, changes in pressure switch settings on compressed air reservoirs, and the temperature effects on regulator components in nitrous oxide systems are examples of functional variations that could cause the supply pressure to change.

X3.3.4 *Accuracy of Calibration Controls, Indicators, and Pressure Relief Devices*:

X3.3.4.1 The Subcommittee felt that this was the level of accuracy that was available with current technology.

X3.3.4.2 Accurate limiting of $P_{w\,max}$ may be desirable in certain conditions, for example, ventilation of small premature infants. The disclosure of the $P_{w\,max}$ at 75 L/min provides clinically useful information as it describes the maximum potential pressure generated in the patient system if the flush valve on the continuous flow anesthesia machine is activated during the inspiratory phase of anesthetic ventilation.

X3.3.4.3 Limits specified in requirements in 5.4.5 and 5.4.5.1 encompass the range of accuracy that the members of the Subcommittee felt were necessary and appropriate for clinical performance and that were achievable within current technology.

X3.3.5 *Delivered Volume*—The removal of carbon dioxide depends upon ventilation and the accurate measurement of the minute or tidal volumes is helpful to facilitate the control of carbon dioxide levels.

X3.3.6 *Accuracy of Gas Mixture Controls*—Maintaining the accuracy of delivered oxygen concentrations throughout the range of ventilator performance is important in order to allow for the rapid and often frequent adjustment of the ventilator without significant variation in the oxygen concentration. ANSI Z-79.10 specifies± 3 % oxygen as the range of accuracy for oxygen analyzers. Limiting the fluctuation to this level at any given ventilator setting is technologically possible, and will minimize the time spent making control adjustments. This should enhance operator confidence in the accuracy of control settings provided on the gas mixing device. With the exception of some critical care ventilators intended for use during anesthesia, the gas mixing device is often the anesthesia machine itself and not the anesthesia ventilator.

X3.3.7 *Expiratory Resistance*:

X3.3.7.1 The Subcommittee felt that it was important to test ventilators by the methods described in 6.7 to assure that *ventilator inherent PEEP* greater than 0.49 kPa (5 cm H_2O) was not generated during exhalation in the breathing system of the ventilator.

X3.3.7.2 Anesthesia ventilators utilizing weighted descending bellows generate negative pressure when the bellows are not seating on the stop. This condition may occur during anesthesia if the fresh gas flow is low and there is a slight leak in the breathing circuit, or during closed-circuit anesthesia.

X3.3.8 *System Internal Compliance*—Increasing internal compliance will (*1*) decrease the actual volume delivered to the patient from a *set* volume, and (*2*) increase measured volume above the patient's actual minute volume.

X3.3.9 *Fittings Connecting Ventilator and Spirometer*:

X3.3.9.1 Flow-direction-sensitive devices such as one-way valves or humidifiers may be caused to malfunction by inadvertent connection in the reverse manner, and it is also possible for injury to the patient to occur if flows of gas are misdirected or humidifier contents are emptied into the breathing circuit as a result of such a misconnection.

X3.3.9.2 The positioning of the connector for a bag mount, if provided, is important so that it is not mistaken for a connector to a patient breathing tube. The marking of the connector is important for the same reason. If selector valves that provide for channeling of the patient's exhaled volume into the manual bag are allowed on anesthesia ventilators, it is possible to then have two selector valves, one on the anesthesia machine and one on the anesthesia ventilator, creating a potentially serious device complication if both selector valves are set so that no flow goes into the patient.

X3.3.9.3 These requirements are intended to minimize the possibility of inappropriate connection of the ventilator breathing circuit components to the spirometer outlet, ambient air inlets or anesthetic gas scavenging connections.

X3.3.10 *Alarms*:

X3.3.10.1 The Subcommittee felt that a loss of main power supply alarm with a duration of 2 min was adequate to allow personnel to reach the ventilator and determine the cause of the alarm. The Subcommittee also felt that a means for silencing this alarm when main power was disconnected was important in order to minimize the number of spurious alarm signals in the operating room environment. If such a means for silencing an alarm was not provided, every time the ventilator was disconnected to be moved from the patient area the loss of main power alarm would sound for 2 min, distracting personnel. However, the Subcommittee also felt that the means of silencing the loss of main power alarm should not be remote from the ventilator proper, and that when the alarm sounded the operator should be forced to walk to the ventilator to determine the cause of the alarm and correct the situation.

X4. HUMAN FACTORS CONSIDERATIONS

TABLE X4.1 Applications of Various Types of Mechanical Displays

USE	SCALES		COUNTERS	PRINTERS	FLAGS
	Moving Pointer	Fixed Pointer			
QUANTITATIVE INFORMATION	FAIR May be difficult to read while pointer is in motion.	FAIR May be difficult to read while scale is in motion.	GOOD Minimum time and error for exact numerical value.	GOOD Minimum time and error for exact numerical value. Provides reference records.	N/A
QUALITATIVE INFORMATION	GOOD Location of pointer easy. Numbers and scale need not be read. Position change easily detected.	POOR Difficult to judge direction and magnitude of deviation without reading numbers and scale.	POOR Numbers must be read. Position changes not easily detected.	POOR Numbers must be read. Position changes not easily detected.	GOOD Easily detected. Economical of space.
SETTING	GOOD Simple and direct relation of motion of pointer to motion of setting knob. Position change aids monitoring.	FAIR Relation to motion of setting knob may be ambiguous. No pointer position change to aid monitoring. Not readable during rapid setting.	GOOD Most accurate monitoring of numerical setting. Relation to motion of setting knob less direct than for moving pointer. Not readable during rapid setting.	N/A	N/A
TRACKING	GOOD Pointer position readily controlled and monitored. Simplest relation to manual control motion.	FAIR No position changes to aid monitoring. Relation to control motion somewhat ambiguous.	POOR No gross position changes to aid monitoring.	N/A	N/A
GENERAL	Requires largest exposed and illuminated area on panel. Scale length limited unless multiple pointers used.	Saves panel space. Only small section of scale need be exposed and illuminated. Use of tape allows long scale.	Most economical of space and illumination. Scale length limited only by number of counter drums.	Limited application.	Limited application.

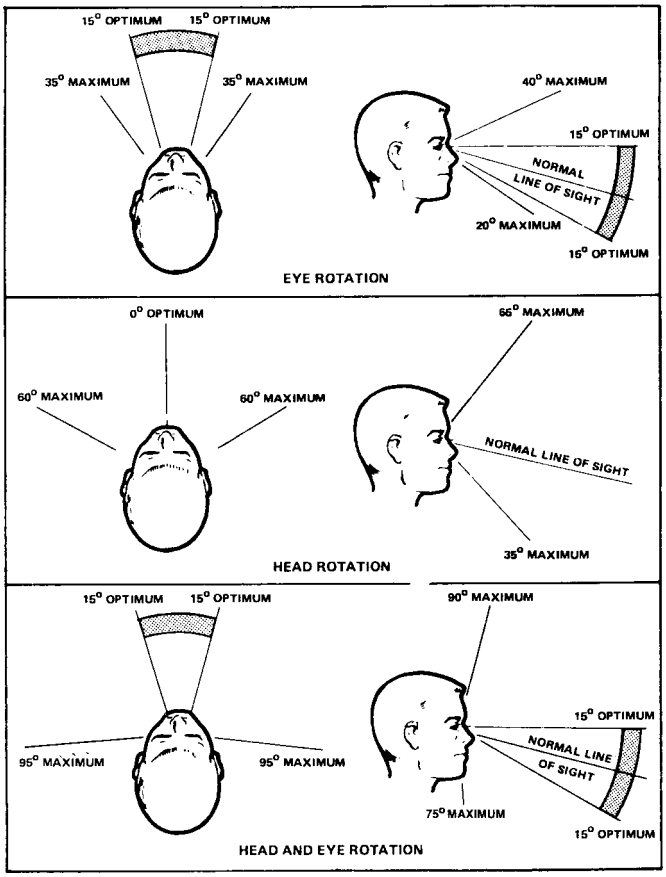

FIG. X4.1 Vertical and Horizontal Visual Field

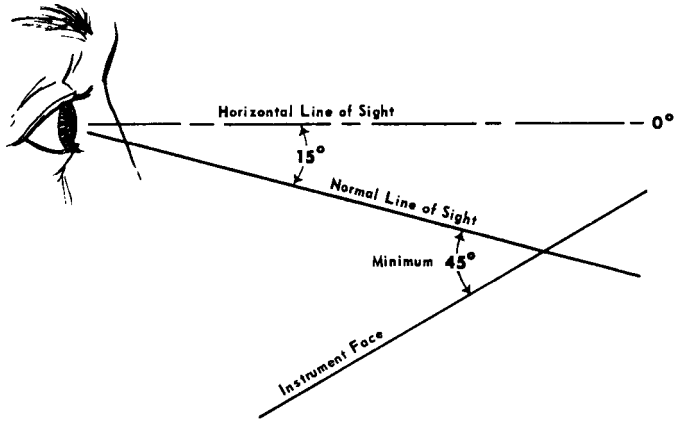

FIG. X4.2 Lines of Sight