



Designation: F 1101 – 90 (Reapproved 1996)

Standard Specification for Ventilators Intended for Use During Anesthesia¹

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 Sizes²

F 1161 Specification for Minimum Performance and Safety Requirements for Components and Systems of Anesthesia Gas Machines²

2.2 ANSI Standards:

Z-79.10 Standard for Oxygen Analyzers³

Z-79.11 Standard for Scavenging Systems for Excess for Anesthetic Gases³

2.3 ISO Standard:

ISO 4135 Anesthesiology Vocabulary⁴

2.4 Other Standards:

IEC 601-1 Safety of Medical Electrical Equipment⁵

CGA V-5, 1978 Specifications for DISS Connections⁶

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 H₂O) 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 Equipment and is the direct responsibility of Subcommittee F29.10 on 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 Varembe, 1211 Geneva 20, Switzerland.

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

F 1101

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 H₂O) 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 H₂O) 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

ASTM F 1101

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, $C_{20} = 20$ 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.



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F 1101

ventilator. If provided, these devices shall limit $P_{w\max}$ and shall be accurate to within $\pm 10\%$ 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 H₂O) 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 $\pm 15\%$ and shall be repeatable to $\pm 5\%$ 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 $\pm 10\%$ 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 $\pm 3\%$ 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 H₂O) 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



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