



Designation: F 1100 – 90 (Reapproved 1997)

Standard Specification for Ventilators Intended for Use in Critical Care¹

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1. Scope

1.1 *General*—This specification establishes minimum performance and safety requirements for all ventilators and ventilator circuits intended for use with adult, child, or infant patients in critical care within the hospital and introduced for sale after the acceptance date of this specification, except as noted below. Definitions, performance requirements, test methods, and rationale are included. Several definitions have been included in Section 3.1 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.

1.2 *Exclusions*—This specification does not apply to body ventilators such as the tank ventilator or the chest cuirass nor does it apply to ventilators utilizing the Sanders technique or “jet” ventilation, (venturi effect type) high frequency ventilators (greater than 2.5 Hz), or anesthesia ventilators. This specification does not apply to ventilators intended for use in transport applications or home care, nor does it apply to those ventilators developed for veterinary applications. The application of critical care ventilators in the home environment is not covered by this specification nor is the hospital use of transport or home care ventilators. (See also X2.1.)

1.3 The following precautionary caveat pertains to the test methods portion only, Section 6, of this specification: *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.*

2. Referenced Documents

2.1 ASTM Standards:

F 1054 Specification for Conical Fittings of 15-mm and 22-mm Sizes²

2.2 ANSI Standards:

ANSI Z-79.9, 1978, Humidifiers and Nebulizers for Medical Use³

ANSI Z-79.10, 1979, Requirements for Oxygen Analyzers for Monitoring Patient Breathing Mixtures³

2.3 ISO Standards:

ISO 4135 Anesthesiology Vocabulary⁴

ISO 5356 Anesthetic and Respiratory Equipment Conical Connectors⁴

2.4 Other Standards:

CGA V-5 Specifications for DISS Connections⁵

MDS 201 Electromagnetic Compatibility Standard for Medical Devices⁶

3. Terminology

3.1 *Descriptions of Terms*—For the purposes of this specification the definitions in 3.1.1–3.1.49 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 8.1).

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

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

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

³ Available from the American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

⁴ Available from the International Standards Organization, 1, Rue de Varembe, Case postale 56, CH-1211 Geneve 20, Switzerland.

⁵ Available from the Compressed Gas Association, 1725 Jefferson Davis Highway, Suite 1004, Arlington, VA 22202-4102.

⁶ Available from the National Technical Information Service (NTIS), Accession #PB271635, 5285 Port Royal Rd., Springfield, VA 22161.

¹ This specification is under the jurisdiction of ASTM Committee F29 on Anesthetic and Respiratory Equipment and is the direct responsibility of Subcommittee F29.14 on Ventilators.

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² Annual Book of ASTM Standards, Vol 13.01.



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})—changes in airway pressure at the patient connection port which 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 kilopascal 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) sub-ambient pressure*—pressure lower than ambient, during the expiratory phase time.

3.1.12.1 *Discussion*—Sub-ambient 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 conserve 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 *inspiratory-expiratory phase time ratio (I:E ratio)*—ratio of the inspiratory phase time to the expiratory phase time.

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

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

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

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

3.1.20 *inspiratory relief valve*—unidirectional valve designed to admit air to the patient system when the patient inspires spontaneously and the supply of inspiratory gases from the ventilator is inadequate.

3.1.21 *inspiratory relief valve resistance*—pressure difference across the inspiratory relief valve at a constant flow of 30 L/min.

3.1.22 *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.

3.1.23 *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.

3.1.24 *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.

3.1.25 *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.

3.1.25.1 *Discussion*—In some devices there exists a complex relationship between the multiple parameters as defined in 3.1.22-3.1.25.

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

3.1.27 *maximum limited pressure* (P_{Lmax})—the 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 that in ISO 4135. The title of the ISO definition is *maximum safety pressure*.

3.1.28 *maximum working pressure* (P_{wmax})—the 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_{Lmax} .

3.1.29 *minimum limited pressure* (P_{Lmin})—the 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.

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

3.1.30 *minimum working pressure* (P_{wmin})—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.

3.1.30.1 *Discussion*—This may be limited by a controllable ventilator mechanism to a sub-atmospheric pressure that is numerically smaller than P_{Lmin} .

3.1.31 *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.

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

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

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

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



3.1.36 *patient system compliance*—volume/pressure relationship, expressed in mL/kPa (or mL/cm H₂O), of those portions of the patient system that are pressurized during the inspiratory phase time.

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

3.1.38 *pressure, patient system* (P_{ps})—pressure at a specified point in the patient system.

3.1.38.1 *Discussion*—Conditions under which measurements are made shall be given.

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

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

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

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

3.1.43 *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.

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

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

3.1.46 *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 kPa (or cm H₂O) referred to a flow of 0.5 L/s.

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

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

3.1.49 *volumetric displacement*—that volume, under specific conditions and expressed in millilitres, passed per cycle during the inspiratory phase through the patient connection port when the pressure at the intake to the ventilator and the outlet from the patient's connection port is equal to the atmospheric pressure.

3.2 Symbols:

3.2.1 *C*—compliance in units of mL/kPa (or mL/cm H₂O), for example, C20 = 2.0 mL/kPa (20 mL/cm H₂O).

3.2.2 *R*—resistance to flow in units of kPa/L/s (or cm H₂O/L/s), for example, R5 = 0.5 kPa/L/s (5 cm H₂O/L/s).

3.2.2.1 *Discussion*—In the interest of brevity and clarity, all other abbreviations have been provided in parentheses following the related term in Section 3.

4. Materials and Manufacture

4.1 Components of a spirometer that come in direct contact with the patient's exhaled gas shall be capable of being sterilized or disinfected or shall be labelled for single use only, or isolated in some manner from the respired gas in the patient breathing circuit. (See also X2.2.)

5. Performance Requirements

5.1 *Determination of Ventilator Endurance, Wave-form, and Volume Characteristics—General*—Compliance with the requirements given in 5.2-5.4 shall be determined with 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.

NOTE 1—The requirements given in 5.2-5.4 and the tests described in 6.3 delineate first article or design qualification tests and are not intended to be lot sampling tests. The disclosure of information referred to in 6.3 is intended to include periodic maintenance necessary during the endurance test and the results of work performed.

5.2 *Ventilator Endurance*—Each ventilator (as described in 5.1) shall be tested for endurance as described in 6.3.1 with respect to each group of patients for which its use is recommended, that is, for adults, for children, and for infants. The ventilator shall run for 2000 h against the appropriate conditions as shown in Table 1. A separate machine may be used for each group or the period of tests may be divided equally between groups. If the ventilator is provided with an assist mechanism, the mechanism shall be part of the test. If IMV or SIMV is provided, that mechanism shall be a part of the test. Data resulting from these tests shall be available on request from the manufacturer.

5.3 *Wave-form Performance*—The ventilator shall be tested as described in 6.3.2 with each of the compliance and resistance combinations appropriate to its intended use (that is, for adults, for children, or for infants), in the order shown in Table 2.

5.4 *Volume Performance*—The ventilator shall be tested against the combinations of compliance (C) and resistance (R) appropriate to its sphere of use, as shown in Table 3. 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. All results shall be expressed in the form of a table or a diagram similar to Fig. 1. The conditions under which the tests are carried out shall be stated (see 6.3.2 and 6.3.2.1).

5.5 Power Sources:

TABLE 1 Endurance Test

Group	Minute Volume V_E , L	Ventilatory Frequency, f, breaths/min ^A	Compliance	Resistance
Adult	10	20	C50	R20 or R_p20
Child	4.5	30	C20	R50 or R_p50
Infant	0.8	60	C3	R200 or R_p200

^A Or nearest possible.





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TABLE 2 Procedure for Performance Test—Waveform^A

Test Number ^B	Compliance	Resistance		Tidal Volume $V_T \pm 5\%$, mL	Ventilation Frequency $f \pm 5\%$ (breaths/min)	Sample Time Constant, s	Ventilation Pressure Limit, cm H ₂ O ^C
		Linear	Parabolic				
Adult							
[1]	C50	R5	R_p5	500	20	0.25	12.5
2	C50	R20	R_p20	500	20	1.0	20.0
3	C20	R5	R_p5	500	20	0.1	27.5
4	C20	R20	R_p20	500	20	0.4	35.0
Children							
[1]	C20	R20	R_p20	300	20	0.4	21.0
2	C20	R50	R_p50	300	20	1.0	30.0
3	C10	R20	R_p20	300	20	0.2	36.0
4	C10	R50	R_p50	300	20	0.5	45.0
[5]	C3	R20	R_p20	50	30	0.06	18.5
6	C3	R50	R_p50	50	30	0.15	20.8
7	C3	R200	R_p200	50	30	0.6	32.0
Infant							
[1]	C3	R50	R_p50	30	30	0.15	12.3
2	C3	R200	R_p200	30	30	0.6	19.0
3	C1	R50	R_p50	30	30	0.05	32.3
4	C1	R200	R_p200	30	30	0.2	39.0
[5]	C1	R200	R_p200	15	60	0.2	24.0

^A Inspiratory/expiratory phase time ratio as close to 1:2 as possible; see 6.3.2.

^B The ventilator controls shall be reset to suit the chosen standard conditions (bracketed) before undertaking each subsequent test. Thus, the order of recordings obtained on adults would be Test [1]; Test 2 (controls unchanged); Test 2 (controls adjusted if necessary); controls reset to satisfy Test [1] conditions; Test 3 (controls unchanged); Test [3] (controls readjusted if necessary), etc.

^C Ventilation Pressure Limit = Calculated pressure applied by constant-flow generators at the machine side of the airway resistance to achieve the required tidal volume during the set inspiratory time. These pressures will be in excess of the corresponding lung pressure that will be developed by the end of the inspiratory phase.

TABLE 3 Volume Performance Test

Type of Ventilator	Compliance	Resistance		Ventilatory Frequencies
		Linear	Parabolic	
Adult	C20	R20	R_p20	10, 15, 20, 30
Child	C10	R50	R_p50	15, 20, 30, 40
	C3	R200	R_p200	15, 20, 30, 40
Infant	C1	R200	R_p200	20, 30, 40, 60

Tidal Volume, V_T (mL)	Ventilatory Frequency, f (bpm)			
	10	15	20	30
Max	—	—	—	—
Min	—	—	—	—

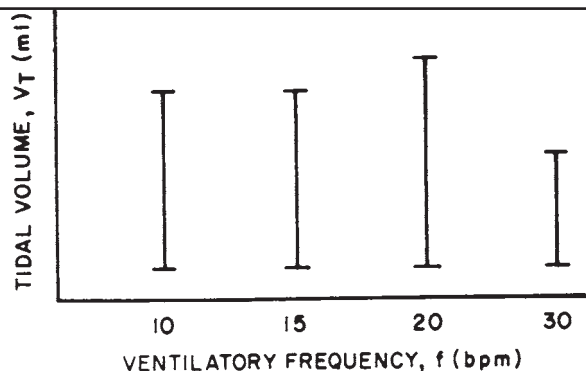


FIG. 1 Suggested Format for Volume Performance Test Report Form

5.5.1 *Electrical*—The ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a range of $\pm 10\%$ fluctuation of the stated nominal voltage and $\pm 1\%$ fluctuation of the stated frequency for electrical power sources.

5.5.2 *Pneumatic*—When tested according to the methods outlined in 6.5, the ventilator shall continue to function within the manufacturer's specifications at any control setting throughout a range of supply pressures of 379 kPa (55 psig) $\pm 20\%$, -25% . (See also Appendix X3.3.2.)

5.5.2.1 The ventilator's gas connection(s) 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 Nut and Gland Fitting No. 1240 (oxygen), if intended to be powered by oxygen, or a Nut and Gland Fitting No. 1160 (air), if intended to be powered by air, or both fittings if both gases are used. (See also Appendix X3.3.2.1.)

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

5.6.1 *Calibrated Controls*—When tested according to the methods outlined in 6.6.1, controls for $P_{w\max}$ on infant ventilators shall be accurate to within ± 0.196 kPa (± 2 cm H₂O) over the entire range. Controls for $P_{w\max}$ in all other ventilators shall be accurate to within ± 0.49 kPa (± 5 cm H₂O) up to 2.94 kPa (30 cm H₂O) and ± 0.98 kPa (± 10 cm H₂O) for settings above 30 cm H₂O. All other calibrated controls, when working at nominal power inputs, should be accurate to within $\pm 10\%$ of the setting. (See also X2.3.3.1.)

5.6.1.1 *Maximum Working Pressure*—If provided in the patient breathing circuit, positive pressure control devices shall restrict the airway pressure to within ± 0.49 kPa (± 5 cm H₂O) up to a point of 2.94 kPa (30 cm H₂O) and to within ± 0.98 kPa (± 10 cm H₂O) for settings above 30 cm H₂O, when tested by the methods described in 6.6.2. (See also X2.3.3.2.)