This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

WORKING DRAFT - FOR COMMENT

DRAFT REVIEWER GUIDANCE FOR VENTILATORS

July 1995

Anesthesiology, Respiratory, and Defibrillator Devices Group

Division of Cardiovascular, Respiratory, and Neurological Devices

ABOUT THIS DRAFT GUIDANCE DOCUMENT

This draft Reviewer Guidance for Ventilators will be discussed at a meeting of the Anesthesiology and Respiratory Therapy Device Panel, September 8, 1995. The material consolidates, by reference, various standards (ASTM F 100-90 Standard Specification for Ventilators Intended for Use in Critical Care and ASTM F 1246-91 Standard Specification for Electrically Powered Home Care Ventilators, Part 1 - Positive-Pressure Ventilators and Ventilator Circuits) and guidance documents (including those addressing software and electromagnetic compatibility) into a single document for 510(k) submissions for common conventional positive pressure ventilators. Positive pressure ventilators constructed with a fixed or passive exhaust port are specifically addressed. Such ventilators are now commonly used for mask or tracheal tube ventilation, but have not been previously reviewed as continuous ventilators, in part because such ventilators could not directly meet the requirements of current standard. The rationale for test methods and requirements corresponding to or differing from extant standards is provided separately from the draft guidance document as an appendix. Some ventilator types are not specifically addressed, but aspects of this document may be pertinent. After review of public comments and advice of the Panel, the document will be redrafted. This paragraph is not part of the draft guidance document.

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INTRODUCTION

This document specifies material to be provided in premarket notification (510(k)) submissions for continuous ventilators (21 CFR 868.5895). Included as continuous positive pressure ventilators are devices providing gas for respiration with cyclic or intermittent variation in airway pressure, which are intended for more than several minutes continuous use in the treatment of respiratory failure, respiratory insufficiency, or sleep apnea.

Previously, only one product code (21 CFR 868.5895, 73 CBK) was provided for continuous ventilators. This product code will to be used for conventional critical care ventilators. Separate product codes have been provided for continuous ventilators which operate using a fixed or passively operated exhaust port (MNS, passive exhaust port, not critical care; MNT ventilator, passive exhaust port, critical care). Such ventilators are typically used to treat patients who require only some of the functions expected critical care ventilators classified under CBK. Included in these categories are ventilators previously reviewed as non-continuous ventilators, but for which continuous use indications are prevalent. The classification for non-continuous ventilators (21 CFR 868.5905, 73 BZD) will include those positive pressure systems intended only for the treatment of adult obstructive sleep apnea.

Hyperbaric ventilators (21 CFR 868.5895, 73 KLM), negative pressure ventilators (21 CFR 868.5935, 73 BYT), non-continuous ventilators (21 CFR 868.5905, 73 BZD), emergency ventilators (CFR 21 868.5815, 73 BTM and CFR 21 868.5825, 73 BTL), anesthesia ventilators, and high frequency ventilators (capable of rates of greater than 150 breaths per minute, class III devices) are not specifically addressed in this document. However, relevant portions of this document may be useful in preparation of submissions for such devices.

This guidance makes reference to published voluntary standards and recommendations, and to Food and Drug Administration (FDA) reviewer guidance documents. Requirements of voluntary standards are selected or modified as appropriate for the review of 510(k) submissions for ventilators. This guidance document first details the material for conventional continuous ventilator (73 CBK) submissions, much of which also applies to the new classification numbers 73 MNS and 73 MNT. The specific differences for MNS and MNT ventilator submissions are then addressed.

All FDA requirements regarding premarket notification submissions are not repeated in this document. Please refer to the Draft Reviewer Guidance for Premarket Notification Submissions (November 1993) the Draft Guidance for Format and Content for Premarket Notification 510(k), and the Premarket Notification: 510(k) Regulatory Requirements for Medical Devices (FDA 90-4158). These may be obtained from the Division of Small Manufacturers Assistance (DSMA) at 800-638-2041 or 301-443-6597.

Depending on the material construction and/or intended use of a device, not all testing described in this document may be relevant for specific devices. The manufacturer should provide justification for the omission of any testing possibly applicable to a device. Alternative test methods for individual devices may be used if the same test objective can be achieved by other means. However, an explanation as to how the alternate methods are comparable to those described in this guidance document or the referenced standards, and a rationale for the use of alternative test methods, should be provided.

All devices and portions of devices used for testing described in this document shall be samples of the finished product unless justification is provided. Prototypes of these devices may be used in the testing as long as it can be demonstrated that the prototypes were assembled in the same manner as the final product will be assembled, and that the components with reliability and performance requirements essential to the operation of the device will be the same in the finished product.

1.0 PURPOSE

The purpose of this document is to facilitate the preparation, and the review, of premarket notification submissions for common ventilators and ventilator components. The scope of this document includes submissions for continuous ventilators (21 CFR 868.5895, Classification Number 73 CBK) as well as ventilators previously reviewed as non-continuous ventilators, but for which continuous use indications are prevalent.

Detachable components or accessories, such as exhaust ports or masks containing exhaust ports, which have characteristics that are essential to the operation of the device, are also addressed.

Masks which have individually molded features for specific patients made at the request of a practitioner are not custom devices exempt from some provisions of the Food, Drug and Cosmetic act if the device is generally available to or generally used by other practitioners, or if the device is offered through labeling or advertising for commercial distribution in finished form for purchase. Such devices may be reviewed as 510(k) devices if a predicate for the device design is identified, and the range of individual configurations is equivalent to the predicate.

2.0 REFERENCES

Branson RD, Chatburn RL: Technical description and classification modes of ventilator operation. Respiratory Care 37:1026-1044, 1992. (Proceedings of consensus conference on the essentials of mechanical ventilators, Cancun, February 1992).

Slutsky, AS (chairman). American College of Chest Physicians Consensus Conference - Mechanical Ventilation. Chest 104:1833-1859; 1993.

Pierson DJ, Kacmarek RM ed. Foundations of Respiratory Care. Churchill Livingstone, New York, 1992.

Tablan O, Anderson L, Arden, NH et al: Guideline for prevention of nosocomial pneumonia. Infect Control and Hosp Epidemiol 15:587-627, 1994. (Centers for Disease Control and Prevention (CDC) Guideline).

ASTM F 1100-90 Standard Specification for Ventilators Intended for Use in Critical Care. Available from American Society for Testing and Materials, 1916 Race Street, Philadelphia, PA 19103-1187.

ASTM F 1246-91 Standard Specification for Electrically-Powered Home Care Ventilators, Part 1 - Positive-Pressure Ventilators and Ventilator Circuits. Available as above.

FDA Documents: These documents are available from the Division of Small Manufacturers Assistance (DSMA) at 800-638-2041 or 301-443-6597.

Device Labeling Guidance, March 8, 1991. Office of Device Evaluation Guidance Memorandum, G91-1.

Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance. Office of Device Evaluation March 1995 Draft. Comments to: Chief, Infection Control Devices Branch, Pilot Device Evaluation Division, Office of Device Evaluation, 9200 Corporate Blvd. Rockville, MD 20856.

Reviewer Guidance for Premarket Notification Submissions, November 1993. Anesthesiology and Respiratory Devices Branch. Division of Cardiovascular, Respiratory, and Neurological Devices.

3.0 TERMINOLOGY

3.1 The following definitions of respiratory insufficiency and respiratory failure are from Pierson and Kacmarek, Chapter 29:

Respiratory insufficiency: "Impairment in respiratory function severe enough to prohibit certain activities that the patient might normally pursue, and to interfere with daily living; occurring in association with measurements of respiratory mechanics and/or gas exchange that are markedly abnormal.

Respiratory failure: "Abnormality of one or more aspects of respiratory function of sufficient degree to threaten the life of the individual".

3.2 Terminology for modes of ventilator operation within submissions should follow the terminology recommended by Branson and Chatburn as published (1992), with respect to control, trigger, limit, and cycle, and when practical should follow their recommended classification of ventilator modes. Four of the definitions are quoted below:

Control variable: "A control variable is the variable (i.e., pressure, volume, flow or time) that the ventilator manipulates to cause inspiration. ..."

Trigger: "The trigger variable causes inspiration to begin. ....."

Limit: "The limit variable is the variable (pressure, volume, or flow) with a preset maximum value during an assisted inspiration. When the limit variable is met, inspiration is not terminated. ..." (see Cycle)

Cycle: "The cycle variable, when reached, terminates inspiration. During PSV, inspiration is flow-cycled when inspiration decays to a preset minimum flow or percentage of initial flowrate. ... "

4.0 DEVICE DESCRIPTION

A precise and detailed description of the device should be provided. This information should include a complete description of the intended use, method of operation, a discussion of the control and phase variables, modes and output waveforms, and device specifications. Specifically, this information should address: (1) the controls provided with the device, the operating range of the controls, and dependence on other controls; (2) monitored data including the parameters, sensing mechanisms and detection ranges, and associated alarming capabilities; (3) threshold levels and alarm limits for alarming capabilities; (4) modes of ventilation with characteristic waveforms; (5) back up ventilation parameters and characteristics (default values); (6) display ranges with resolution; and (7) default values for each ventilator control, limiting and alarm parameter. The device description information should include engineering drawings of the pneumatic and electrical subsystems. The above information should also be provided for any additional device accessories or components.

4.1 INTENDED USE

The 510(k) submission for a ventilator should identify the intended use of the device under review. The intended use statement should identify the purpose and function of the device, the intended patient population (i.e., adult, pediatric, infants, neonates), the intended environments of use, and all device claims. The indications should be consistent with each ventilator classification (i.e., CBK, MNS, MNT). This information, as well as, all claims should be compared to a legally marketed predicate device. If the device features new indications that may raise clinical issues, additional clinical testing information may be required.

4.2 TECHNICAL SPECIFICATION

The technical information should identify device specifications for the subject ventilator and the predicate device to which substantial equivalence is claimed. The specification information should address all device parameters and characteristics. Performance testing information, described in sections 5 and 6 of this guidance document, should be provided to support the following specifications:

Frequency (BPM)
Tidal volume (mL)
Minute volume (L)
Inspiratory time (sec)
Expiratory time (sec)
I:E Ratio:
Maximum/peak inspiratory flow (L/min)
Inspiratory peak pressure limit (cm H2O)
Inspiratory pause/plateau time (sec)
Expiratory Resistance Pressure (cm H2O)
Expiratory pause/plateau time (sec)
Spontaneous ventilation inlet valve pressure (cm H2O)
Oxygen concentration range (%)
Oxygen concentration accuracy
Sigh frequency (BPM)
Sigh pressure (cm H2O)
Sigh volume (mL)
Inspiratory relief valve pressure (cm H2O)
Minimum and maximum safety pressure (cm H2O)
Minimum and maximum working pressure (cm H2O)
Internal compliance (L/cm H2O)
System input pressure control (psig)
CPAP/PEEP pressure range (cm H2O)
Intermittent Mandatory Ventilation (IMV) frequency (BPM)
IMV waiting time (sec)
Inspiratory trigger response time for each relevant mode of ventilation
Inspiratory trigger pressure for each relevant mode of ventilation (cm H2O)
Inspiratory trigger volume for each relevant mode of ventilation
Inspiratory trigger flow for each relevant mode of ventilation
Inspiratory delay time for each relevant mode of ventilation (sec)
Internal Safety relief valve pressure (cm H2O)
Available Modes (This information should include the, trigger, control, limits, and cycle variables associated with each mode)
Available waveforms
Flow generator type
Low flow generator type
Fail safe mechanisms
Back up ventilation parameters
Pressure monitoring
Pressure displays
Tidal volume monitoring
Tidal volume displays

Patient circuit pressures should be expressed in centimeters of water pressure (cm H2O). Supply gas pressures should be expressed as pounds per square inch pressure (psi). Use of other units such as kilopascals is optional; such optional values should be written after the cm H2O or psi units, in

parentheses. For example, "the pressure is 10 cm H2O (0.98 kPa) etc." Airway pressures should be stated relative to ambient pressure.

5.0 GENERAL REQUIREMENTS & TESTING FOR VENTILATORS

Because many of the requirements and testing discussed in ASTM F 1100-90 (Standard Specification for Ventilators Intended for Use in Critical Care) establishes minimum performance and safety requirements for critical care ventilators for infants to adults, and specifically excludes other ventilators, e.g., high frequency, jet, anesthesia, transport, and those specified for home care, critical care ventilators should be expected to conform to these requirements. A similar statement can be made for ASTM F 1246-91 (Standard Specification for Electrically Powered Home Care Ventilators, Part 1- Positive-Pressure Ventilators and Ventilator Circuits) pertaining to only electrically powered lung ventilators used in the home environment. However, intended uses and designs of ventilators are not always this specific, and many ventilator manufacturers design and market these devices for use in several environments and applications. For example, some models of ventilators are intended to be used in the hospital and home, hospital and transport applications, home and transport, or a combination of all three. Furthermore, some ventilators are intended to be used in critical care and anesthesia applications within the hospital, and it is also recognized that specific types of ventilators and ventilator modes are used on diverse patient populations from respiratory failure, respiratory insufficiency, to adult obstructive sleep apnea applications.

Due to the factors discussed in the preceding paragraph, it is difficult to classify every ventilator to a specific category or type. Because of these factors, a 510(k) submission for a ventilator shall specifically state the intended environment of use and the type of patients for which it is to be used (i.e., adult, pediatric, infant, neonate). Refer to section 4.1 of this guidance document. If a ventilator does not have an actively controlled exhalation valve and may be more limited in its use and application, then refer to section 6.0 of this guidance document for performance requirements and testing of this type of device (product codes MNS and MNT). If a critical care ventilator does not meet any part of the recommendations of the standard, the manufacturer shall provide a justification for not meeting the recommendation and a justification as to how the performance of the device is substantially equivalent to a legally marketed predicate device that meets the standard. If alternate test methods are used, an explanation as to how the alternate test methods are comparable to those specified in this guidance document and the referenced standards, and a rationale for the use of the alternate test methods should be provided.

5.1 REQUIREMENTS FOR VENTILATORS INTENDED FOR CRITICAL CARE

In general, requirements for critical care ventilators (product code CBK) are presented in ASTM F 1100-90. Critical care ventilators (except those without an actively controlled exhalation valve) should meet the performance requirements of this voluntary standard. Performance requirements should be determined with several samples of production ventilators, or prototypes that have been assembled as the production units, without reinforcements, and contain the same components vital to the ventilators operation. The manufacturer should provide information describing how the components and manufacture of the prototype will resemble and demonstrate the performance of the production device. As previously discussed, all performance and testing requirements in the standard are applicable to critical care ventilators (CBK) unless adequate justification or comparable information for alternate test methods is provided. The following paragraphs discuss general performance requirements and may not repeat all information in the standard.

The following is a listing of some of the general performance requirements for critical care ventilators as derived from section 5 of ASTM F 1100-90 (the standard) unless otherwise noted.

- The ventilator shall be subject to waveform testing for all modes of ventilation as described in section 5.1 of the standard. The data provided from these tests shall be shown to be substantially equivalent to other legally marketed predicate devices which also meet the standard.

- Ventilator's inspiratory to expiratory times shall be limited from 1:4 to 4:1 (not in standard) and should be compared to a legally marketed predicate device.

- Fluctuations of the electrical power supply should be consistent with the requirements of the draft Reviewer Guidance for Premarket Notification Submissions dated November 1993.

- For pneumatically powered ventilators, the device should continue to function within specifications for supply pressures of 55 psig +20%, -25% as described in section 5.5.2 of the standard.

- The gas connections shall not be interchangeable and should be consistent with specifications for DISS connections, Nut and Gland Fitting No. 1240 (oxygen) or Nut and Gland fitting No.1160 (air), where appropriate as discussed in section 5.5.2.1 of the standard.

- Infant ventilator working pressure controls shall be accurate to +/-2cm H2O over the entire range, while other ventilators shall be accurate to within +/- 5 cm H2O up to 30 cm H2O and +/- 10 cm H2O above. All other calibrated controls shall be accurate to within 10% of setting as described in section 5.6.1 of the standard.

- Positive pressure control devices shall restrict the airway pressure to within +/-5 cm H2O up to 30 cm H2O and to within +/- 10 cm H2O for settings above if provided in the breathing circuit as described in section 5.6.1.1 of the standard.

- All indicators shall be within 10% of the reading as described in paragraph 5.6.2 of the standard.

- The ventilator shall include limited pressure relief controls as described in paragraph 5.6.3 of the standard.

- Ventilatory frequency indicators and controllers shall be accurate to one breath per minute or 10% as described in section 5.6.4 of the standard.

- Except for continuous flow ventilators, spirometers and other devices used for the indication of ventilator function shall comply with section 5.7 of the standard. This includes provisions for connections of a spirometer if not an integral part of the device, accuracy requirements of 10% and a pressure drop of less than 2.0 cm H2O, performance at all humidity levels and temperatures of 20 - 37°C, and design provisions from becoming obstructed by patient secretions.

- Ventilators that include gas mixture controls shall be consistent with the requirements in section 5.8 of the standard.

- Expiratory resistance for adult, pediatric and infant ventilators shall comply with section 5.9 of the standard.

- Fittings connecting adult ventilator, patient, and spirometer shall comply with section 5.10 of the standard.

- Alarm systems shall provide a warning if the function of the ventilator deviates from the control settings by more than the performance requirements specified in the appropriate paragraphs of the standard as discussed in section 5.11. This includes appropriate warnings for loss of main power supply, breathing circuit integrity, high airway pressure, and alarm battery power supplies as discussed. The alarm signals shall comply with F 1463-93 (Alarm signals in medical equipment used in Anesthesia and Respiratory Care) as appropriate.

- Humidifiers shall comply with ANSI Z-79.9, 1978 as described in section 5.12 of the standard.

- Please see section 5.3 of this guidance document regarding electromagnetic interference. This supersedes section 5.13 of the standard.

- Breathing tubing shall be sufficiently rigid and designed to prevent occlusion as described in section 5.14 of the standard.

- The ventilator shall include an oxygen monitor with the ventilator or recommend a monitor for use in the labeling as described in section 5.15 of the standard. ASTM F 1462-93 is the current standard for oxygen monitors.

- The ventilator controls shall be designed so that inadvertent changes can not occur. (refer to X.5.1)

5.2 TESTING OF VENTILATORS INTENDED FOR CRITICAL CARE

This section presents only the differences from ASTM F 1100-90 regarding testing of ventilators intended for use in critical care. Those tests not mentioned shall be performed in accordance with the standard. The testing information provided should include testing procedures and protocols, test results, and an analysis of the results, which includes an explanation as to how the device complies with the standard requirements. As previously discussed, all performance and testing requirements in the standard are applicable to critical care ventilators (CBK) unless adequate justification or comparable information for alternate test methods is provided. If a critical care ventilator does not meet any part of the recommendations of the standard, the manufacturer shall provide information justifying how the performance of the device is substantially equivalent to a relevant predicate device or how other testing and methods are comparable.

The differences from the ASTM F 1100-90 standard regarding testing of ventilators intended for use in critical care are as follows:

- Ventilator endurance should be determined according to section 6.3.1 of the standard; however, this is only a subset of reliability performance requirements. The manufacturer should establish the reliability on production type ventilators which include determination of the mean time between failures of those components which are essential to the device operation, as well as others subject to wear. A failure occurs when the device or component does not meet its performance specifications and should be consistent with the device's maintenance manual regarding replacement and maintenance intervals. Reliability performance should also be established on the essential components in the device, and may include accelerated performance testing intended to stress the component. Theoretical presentations and data may be supplied, but is not a substitute for actual reliability data. Because some modes of ventilation may be subject to more stress on vital components of the device (e.g. accelerating flow, higher frequency of 150 breaths per minute, etc.), the data provided should reflect stressing of these components for extreme conditions. After completion of endurance testing specified in subsection 6.3.1 of the standard, it shall be demonstrated that the ventilator meets the performance requirements of the standard. This information should be comparable to that for the predicate device.

- Flow is regulated to deliver a tidal volume in a specific time and pattern for a volume based breath. The resultant pressure is mainly based upon lung compliance and resistance. During a pressure based breath a ventilator regulates air flow to deliver a specific pressure during a specified time. The resultant tidal volume, peak flow, and flow pattern are mainly based on lung compliance and resistance. Waveform testing shall be implemented as described in paragraph 6.3.2 of the standard in all modes ventilation in order to demonstrate all characteristic waveforms. Because some ventilator modes are intended to operate in a reverse inspiratory to expiratory ratio (e.g., inverse ratio pressure control ventilation), waveform testing, as well as all other performance testing throughout the standard, should account for reverse inspiratory to expiratory modes of ventilation, as well as, all volume and pressure based modes. The test information submitted in a 510(k) should explain how these modes

have been adequately assessed for the device, and are substantially equivalent to a legally marketed predicate device that also meets the standard.

- Fluctuations of the electrical power supply should be consistent with the testing in the draft Reviewer Guidance for Premarket Notification Submissions dated November 1993.

- Ventilator testing shall include trigger sensitivity and timing regarding patient effort sensing devices. This should include waveform data and diagrams demonstrating the lag time between a sensed patient breath and the delivered breath. This shall include flow, negative pressure, or other patient effort sensing systems.

- Ventilator testing shall address all performance characteristics and specifications of the device. Refer to section 4.2 of this guidance document.

5.3 REQUIREMENTS FOR ELECTRICALLY POWERED HOME CARE VENTILATORS

In general, requirements for electrically powered home ventilators (product code CBK) are presented in ASTM F 1246-91. Home ventilators (except those without an actively controlled exhalation valve) should meet the performance requirements of this voluntary standard. Performance requirements should be determined with several samples of production ventilators, or prototypes that have been assembled as the production units, without reinforcements, and contain the same components vital to the ventilators operation. The manufacturer should provide information describing how the components and manufacture of the prototype will resemble and demonstrate the performance of the production device. As previously discussed, all performance and testing requirements in the standard are applicable to electrically powered home care ventilators (CBK) unless adequate justification or comparable information for alternate test methods is provided.

The following is a listing of some of general performance requirements for electrically powered ventilators intended for use in the home as derived from section 4 of ASTM F 1246-91 (the standard) unless otherwise noted:

- Fluctuations of the electrical power supply should be consistent with the requirements in the draft Reviewer Guidance for Premarket Notification Submissions dated November 1993.

- An integral battery power source shall be provided as described in section 4.1.2 of the standard.

- All calibrated controls and indicators shall be accurate to within 10% as described in section 4.2 of the standard.

- Pressure at the sensing site shall agree with the control setting within +/-5 cm H2O up to 30 cm H2O and +/-10 cm H2O over 30 cm H2O as described in section 4.2.2 of the standard.

- The ventilator shall contain limited pressure relief controls as described in section 4.2.3 of the standard.

- Actual minute or tidal volume delivered at the patient outlet of the device shall be within +/- 10% of the control setting for calibrated controls or indicated setting for uncelebrated controls as described in section 4.3 of the standard.

- Volume delivered by the ventilator shall not vary by more than +/-10% of the set tidal volume or stability shall not vary by more than +/-10% of the expired volume as described in section 4.3.1 of the standard.

- Ventilatory frequency controllers shall be accurate to one breath per minute or +/- 10% as described in section 4.4.1 of the standard.

- Ventilator frequency controls shall not vary by more than +/- 10% of the set value as described in section 4.4.2 of the standard.

- Accuracy of inspiratory time controls shall be accurate to within +/- 10% of the set or indicated value as described in section 4.5 of the standard.

- Inspiratory time controls, if provided, shall be accurate to within 10% of the set or indicated value as described in section 4.5.2 of the standard.

- Inspiratory flow control accuracy and stability shall be within +/- 10% of the set value over its range as specified in section 4.6 of the standard.

- Intermittent deep breath volume (sigh), if provided, shall be accurate to within +/- 10% of the set value as specified in section 4.7 of the standard.

- The markings of all controls and indicators shall be legible from a distance of 1 m by an operator with 20/20 vision and shall be provided with means to minimize the possibility of inadvertent control manipulations as described in section 4.8 of the standard.

- Fittings regarding flow direction sensitive devices, outlet ports for spirometers, ambient air inlets, expired gas outlets, and gas connections for pressurized gases shall comply with section 4.9 of the standard.

- Breathing circuits shall comply with the requirements described in section 4.10 of the standard.

- The ventilator shall be capable of being provided with supplemental oxygen as described in section 4.11 of the standard.

- Breathing circuit alarm, high airway pressure alarm, battery use event alarm, and anti-asphyxia valves shall be provided on all home care ventilators as described in section 4.12 of the standard.

- Anti-asphyxia valves and negative pressure relief valves provided separate from the spontaneous breathing inlet valve, the ventilator or breathing circuit, or both, shall provides a means for the patient to inhale ambient air in the event of a ventilator failure as described in section 4.13 of the standard.

- Electrical safety should conform to section 4.14 of the standard; however see section 5.5 of this guidance document regarding additional electromagnetic compatibility testing.

5.4 TESTING FOR ELECTRICALLY POWERED HOME CARE VENTILATORS

This section presents only the differences from ASTM F 1246-91 regarding testing of electrically powered ventilators intended for home use. Those tests not mentioned shall be performed in accordance with the standard. The testing information provided should include testing procedures and protocols, test results, and an analysis of the results, which includes an explanation as to how the device complies with the standard requirements. As previously discussed, all performance and testing requirements in the standard are applicable to electrically powered ventilators intended for use in the home unless adequate justification or comparable information for alternate test methods is provided. If a home use ventilator does not meet any part of the recommendations of the standard, the manufacturer shall provide information justifying how the performance of the device is substantially equivalent to a relevant predicate device or how other testing and methods are comparable.

The differences from the ASTM F 1246-91 standard regarding testing of electrically powered ventilators intended for use in the home are as follows:

- Ventilator endurance should be determined according to section 6.3.1 of ASTM F 1100-90; however, *this is only a subset of reliability performance requirements.* The manufacturer should establish the reliability on production type ventilators which include determination of the mean time between failures of those components which are essential to the device operation, as well as others subject to wear. A failure occurs when the device or component does not meet its performance specifications and should be consistent with the device's maintenance manual regarding replacement and maintenance intervals. Reliability performance should also be established on the essential components in the device, and may include accelerated performance testing intended to stress the component. Theoretical presentations and data may be supplied, but is not a substitute for actual reliability data. Because some modes of ventilation may be subject to more stress on vital components of the device (e.g., accelerating flow, higher frequency of 150 breaths per minute, etc.), the data provided should reflect stressing of these components for extreme conditions. After completion of endurance testing specified in subsection 6.3.1, it shall be demonstrated that the ventilator meets the performance requirements of the standard.

- Flow is regulated to deliver a tidal volume in a specific time and pattern for a volume based breath. The resultant pressure is mainly based upon lung compliance and resistance. During a pressure based breath, a ventilator regulates air flow to deliver a specific pressure during a specified time. The resultant tidal volume, peak flow, and flow pattern are mainly based on lung compliance and resistance. Waveform testing shall be implemented as described in paragraph 6.3.2 of ASTM F 1100-90 in all modes of ventilation in order to demonstrate all characteristic waveforms. Because some ventilator modes are intended to operate in a reverse inspiratory to expiratory ratio (e.g., inverse ratio pressure control ventilation), waveform testing, as well as all other performance testing throughout the standard, should account for reverse inspiratory to expiratory modes of ventilation as well as all volume and pressure based modes. The test information submitted in a 510(k) should explain how these modes have been adequately assessed for the device, and are substantially equivalent to a legally marketed device with the same intended use.

- Fluctuations of the electrical power supply should be consistent with the testing in the draft Reviewer Guidance for Premarket Notification Submissions dated November 1993.

- If an electronically controlled ventilator includes aspects of a critical care ventilator as described in ASTM F 1100-90, and substantial equivalence can be demonstrated to a legally marketed predicate device with the same intended use, the requirements and testing of ASTM F 1100-90 may apply as long as it is consistent with the safe use of a home use ventilator.

- Ventilator testing shall include trigger sensitivity and timing regarding patient effort sensing devices. This should include waveform data and diagrams demonstrating the lag time between a sensed patient breath and the delivered breath. This shall include flow, negative pressure, or other patient effort sensing systems.

5.5 TRANSPORT/CRITICAL CARE VENTILATORS

Critical care ventilators labeled for transport use should comply with applicable ASTM standards, as well as, the minimum requirements for Automatic Transport Ventilators as described in the Guidelines for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care from the American Heart Association (AHA), pages 2200 and 2201 JAMA, October 28, 1992 - Vol 268, No.16. It is recommended that transport ventilators operate under all conditions and extremes of temperature. Because of the environmental difference between home, hospital, and transport conditions, testing should demonstrate that the device can still perform in accordance with ASTM standards and AHA guidelines

when subject to extreme temperature and environmental conditions. Electrical, electromagnetic compatibility, mechanical, and environmental testing should be consistent with the intended environment of use, as well as, the test methods described in section 5.6 of this guidance document.

According to the American Heart Association, transport ventilators should function as constant inspiratory flow rate generators and should have the following minimum features:

-lightweight connector with a standard 15mm/22mm coupling for a mask, endotracheal tube, or other airway adjunct,

-a lightweight (2 to 5 kg), compact, rugged design,

-capability of operating under all common environmental conditions and extreme of temperature,

-a peak inspiratory pressure limiting valve set at 60 cm H2O with the option of an 80 cm H2O pressure that is easily accessible to the clinician,

-an audible alarm that sounds when peak inspiratory limiting pressure is generated to alert the user/rescuer that low compliance or high airway resistance is resulting in a diminished tidal volume,

-minimal gas consumption (e.g., a tidal volume of one liter and a rate of 10 breaths per minute [10 L/min ventilation], the device should run for a minimum of 45 minutes on an E cylinder),

-minimal gas compression volume in the breathing circuit,

-ability to deliver an FiO2 of 1.0,

-an inspiratory time of 2 seconds in adults and 1 second in pediatric (children) patients, and maximal inspiratory flow rates of approximately 30 L/min in adults and 15 L/min in pediatric (children) patients,

-at least two rates, 10 breaths per minute for adults and 20 breaths per minute for pediatric (children) patients,

-if a demand valve is incorporated, it should deliver a peak inspiratory flow rate on demand of at least 100 L/min at -2 cm H2O, and

-features such as pressure manometer, provisions for continuous positive airway pressure, rate and tidal volume controls, and low-pressure alarms to indicate depletion of the oxygen cylinder.

5.6 REQUIREMENTS & TESTING - EMC, ELECTRICAL, ENVIRONMENTAL, MECHANICAL

Because the ASTM standards described in sections 5.1 - 5.4 of this document do not include complete electromagnetic compatibility (EMC) requirements and testing, this section provides this information. Ventilators should be subject to the performance and testing requirements as established in the draft Reviewer Guidance for Premarket Notification Submissions, dated November 1993, for electrical and electromagnetic compatibility. The information provided in a 510(k) submission should include electrical testing as well as EMC testing. Mechanical, temperature, humidity, and fluid ingress requirements and testing for critical and home care ventilators should also be consistent with the reviewer guidance document.

5.6.1 RADIATED ELECTROMAGNETIC FIELDS TESTING

The following describes only the differences in the radiated electromagnetic fields immunity testing from that described in the Reviewer Guidance for Premarket Notification Submissions. These differences in requirements and testing pertain specifically to ventilators.

- The ventilator should be tested for immunity to EMI at 20 V/m for transport critical care ventilators, 10 V/m for critical care ventilators or ventilators used in the home for treatment of respiratory failure, and 3 V/m for ventilators indicated for treatment of respiratory insufficiency or adult obstructive sleep apnea.

- In addition to the modulation frequencies stated (passband of 0.5 Hz), the ventilator should also be tested using a modulation of 1kHz.

- Failure of this test constitutes any performance deviation from the applicable standards and device specifications.

- The dwell time at each frequency should be a minimum of 3 complete ventilator cycles (i.e., 12 breaths per minute requires a 15 second dwell time) or ten seconds, whichever is greater. The dwell time at each frequency shall not be less than the time necessary for the device to be exercised and be able to respond. Worst case performance data during dwell time should be recorded, not an average.

- A minimum of 3 of the most sensitive faces of the device should be tested.

It should be noted that ventilators which include electronic displays and monitoring but are pneumatically driven are subject to the same performance requirements. All other performance requirements should be consistent with the reviewer guidance document.

5.6.2 ENVIRONMENTAL TESTING

The following describes only the differences in the environmental testing from that described in the Reviewer Guidance for Premarket Notification Submissions. These differences in requirements and testing pertain specifically to ventilators.

- In addition to the mechanical and environmental tests of the Reviewer Guidance for Premarket Notification Submissions, MIL-STD-810E should be used for mechanical shock, vibration, and altitude testing of transport devices.

5.7 REQUIREMENTS & TESTING FOR REUSABLE VENTILATOR COMPONENTS

"In general, reusable components that directly touch a patient's mucous membranes (e.g., face mask or tracheal tube) or become readily contaminated with a patient's respiratory secretions (e.g., y-piece inspiratory and expiratory tubing and attached sensors) are cleaned and subject to high-level decontamination or sterilization between patients" (Tablan et al, 1994). The 1994 CDC recommendations (Tablan et al, 1994) section E "Contamination of Devices Used on the Respiratory Tract" may also be used as the reference for choices of decontamination levels and other matters.

The draft FDA Reviewer Guidance on Labeling Reusable Medical Devices enumerates seven issues with respect to reprocessing:

-The labeling must describe a reprocessing method.

-The method must include cleaning instructions.

- The instructions must indicate the appropriate microbicidal process for the device. The labeling should indicate either high, medium, or low level disinfection, or sterilization.

- The process must be feasible considering the intended location of reprocessing. For example, medical equipment in the home may be cleaned, surface disinfected and serviced on site.

- The instructions must be understandable.

- The instructions must be comprehensive, and following them should provide an appropriate level of decontamination. The user must be able to determine if a reusable device meets specifications before reuse.

- The instructions must include only devices and accessories that are legally marketed.

5.7.1 REQUIREMENTS FOR DISINFECTION

Disinfection and cleaning information should be provided. Face masks, exhaust ports, exhalation valves, and ventilator tubing are regarded as semi-critical items with respect to disinfection and should be subject to high-level decontamination or sterilization prior to reuse by another patient.

Unless special patient considerations apply, thorough cleaning will suffice for devices to be reused by a single patient. However, semi-critical devices labeled for single patient reuse must be demonstrated to be compatible with intermediate-level disinfection since such disinfection is commonly necessary for protection of health workers from tuberculosis or other infectious disease.

The information should be as detailed in the draft Reviewer Guidance on Labeling Reusable Medical Devices, which also states "The applicant must provide reasonable grounds for omission of reprocessing information (per 21 CFR 201.109(c)) for prescription devices. For example, an applicant may claim and provide documentation that there are "commonly understood" infection control practices for a simple device. ... If FDA accepts the omission the applicant should be informed that they must still validate and document reprocessing of the device according to the referenced practices."

The number of reprocessing cycles used in testing the device for the useful reprocessing life should be stated in the labeling.

5.7.2 BIOCOMPATIBILITY

Biocompatibility information for tubing and masks should be provided in accordance with ISO-10993 "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" for externally communicating (tissue/bone/dentin/communicating) permanent devices. When there is insufficient documented prior testing of the effects of decontamination or decontaminant residues after reprocessing for the materials and reprocessing method used, then biocompatibility testing should be performed on the device after the stated useful reprocessing life.

5.7.3 BRIEF SUMMARY OF LABELING FOR REUSE, TESTING, & BIOCOMPATIBILITY

The following summary may be helpful to interpret the preceding requirements. However, the relevant guidance documents for reuse labeling and biocompatibility apply.

Disinfection and cleaning of patient-contact accessories:

The Center for Disease Control and Prevention recommendations include high-level decontamination for masks and similar devices used between patients. "In general, reusable components that directly

touch a patient's mucous membranes (e.g., face mask or endotracheal tube) or become readily contaminated with a patient's secretions (e.g., y-piece inspiratory and expiratory tubing and attached sensors) are cleaned and subjected to high-level disinfection or sterilization between patients." (Tablan et al 1994) These may also be termed "semi-critical" items. Two classes of devices are legally marketed for high level decontamination (specific glutaraldehyde formulations, and specific hot-water pasteurization methods). Accessory masks, tubing, exhaust ports, and other similar accessory devices, which are indicated for reuse among different patients should be suitable for such decontamination (e.g., have no areas such as narrow lumens), and should be constructed of non-absorbent materials which maintain integrity and functional performance after reprocessing.

The submission should identify at least one recommended method for high level decontamination or sterilization for each semi-critical component. If a liquid disinfectant is to be used, the concentration of the active ingredients, or the brand and specific product may be stated. Results of functional testing after a specified number of high-level decontamination cycles or sterilization cycles should be provided for semi-critical items indicated for reuse. A sample size of 10 items should be adequate. If a liquid disinfectant is used, then biocompatibility testing information should be provided for the patient-contact polymer portions of the item after the specified number of cycles, to preclude the possibility of leaching of toxic residue. A sample size of 3 items should be adequate. Instructions should specify which components or accessories should be subjected to sterilization or high-level decontamination between uses by different patients, should state the recommended methods, and should state and identify the common alternative methods which (if not tested) should not be used. For example: "This device may be disinfected using a 2% Glutaraldehyde solution; this device should not be subjected to heat sterilization, hot water pasteurization, autoclaving, or ethylene oxide gas sterilization." Instructions should identify the number of cycles and include testing information for a sample of 10 items for each recommended method. Instructions should include specific inspection criteria that the user may apply to verify the functional performance of the device after high-level decontamination.

If the device is indicated for home use, the submission should also identify a method for effective cleaning of accessory patient-contact components for use by a single patient. An intermediate level disinfection process should be identified, and should be recommended for use when it is thought that the patient might have a communicable disease that could be transmitted by contact with the accessory.

Results of functional testing after a specified number of cleaning and intermediate-level disinfection cycles should be provided for items indicated for reuse. A sample size of 10 items should be adequate. Biocompatibility testing should be performed after the specified number of cycles, if the cleaning method or disinfection method presents the possibility of leaching of toxic residue. A sample size of 3 items should be adequate. Instructions should specify which components or accessories should be subjected to cleaning and disinfecting, should state the recommended methods, and should state and identify common alternative methods which (if not tested) should not be used. Instructions should identify the number of cycles and include testing information for a sample of 10 items for each recommended method. Instructions should include specific inspection criteria that the user may apply to verify the functional performance of the device after cleaning.

6.0 SPECIAL REQUIREMENTS & TESTING FOR VENTILATORS WITH NON-ACTIVE EXHALATION VALVE CONTROL

The devices discussed in this section are ventilators which do not have actively controlled exhalation valves or mechanisms functionally equivalent to actively controlled exhalation valves. The devices are indicated for continuous positive airway pressure (CPAP) and for positive pressure ventilation of adult patients to treat obstructive sleep apnea, respiratory insufficiency, and acute respiratory failure. The patient circuit consists of two essential parts: a large-bore tube from the ventilator to the patient and a required exhaust port. The exhaust

port is an orifice which may be part of the adaptor between the tubing and the mask, the tracheal tube or the mouthpiece. Alternatively, the exhaust port may be an orifice which is part of the patient mask. The gas exhaled by the patient leaves the system through the exhaust port as does additional gas provided by the ventilator. In current examples of these devices, positive pressure ventilation is achieved by alternating between a continuous positive airway pressure (CPAP) pressure during exhalation and a higher inspiratory pressure during inspiration. This is equivalent to pressure support ventilation for patient-triggered breaths (Branson and Chadwick, 1992). Machine-triggered breaths may also be provided.

The functions of pressure support ventilators constructed without an active exhaust valve are a subset of the functions of a general purpose intensive care ventilator. For these reasons, all positive pressure ventilators when indicated for respiratory insufficiency or respiratory failure will be reviewed as a continuous ventilator, CFR 21, 868.5895, including ventilators constructed without an active exhaust valve.

Current examples of ventilators without an active exhaust valve are constructed using a blower which continuously provides a large flow of air. The system includes a transducer to measure pressure in the patient circuit. Pressure in the patient circuit is controlled via a rapid-responding valve which vents excess flow to atmosphere. Flow in the pressure circuit is measured and the flow signal is used both for triggering and cycling the ventilator to the exhalation phase. Increasing flow after exhalation is sensed to trigger inspiration and decreasing flow during inspiration is sensed to cycle the ventilator to terminate inspiration.

The devices addressed in this section can provide pressures not exceeding 30 cm H2O and provide pressure regulation within a stated range at patient flows of at least ~40 to 100 l/min (for adults). The transition between exhalation and inhalation pressures for current devices can be triggered either by patient initiated flows or by preset times. Devices using alternative means of triggering, limiting, and cycling the ventilator may also be reviewed under this guidance.

It is recognized that the devices addressed in this section cannot perform many of the functions of an ICU ventilator. Therefore, separate product codes - MNS (ventilator, passive exhaust port, non-critical care), and MNT (ventilator, passive exhaust port, critical care) have been established for these types of ventilators. Ventilators classified under MNS may be indicated for treatment of adults with obstructive sleep apnea, and ventilatory support during chronic or acute respiratory insufficiency. However, in all cases the patients should be expected to have no more than minor and transient adverse effects if mechanical ventilation or CPAP cannot be provided during extensive periods of time (e.g., overnight).

Ventilators classified under MNT (respiratory failure) should be similar to conventional critical care ventilators, or home care ventilators, with respect to alarms, durability, and validation of performance characteristics.

For both MNS and MNT devices, ventilation of patients via a tracheostomy tube or other tracheal tube may be indicated for selected patients if specific device criteria are met. For use with either a mask or tracheal tube, indications for use in patients smaller than 30 kg (including children) will require additional testing and documentation because of the lower flows expected for triggering and cycling the ventilator. This additional testing and documentation may include clinical data.

The notable differences distinguishing MNS from MNT ventilators are as follows: certain alarms may be optional if there are adequate anti-asphyxia characteristics, battery-backup would not be required for home use, and the ability to provide oxygen would not be required for home use. Also, there would be no need to concurrently display basic settings and monitored values for MNS (see human factors, below).

Ventilator modes should be described as defined in the proceedings of the Consensus Conference on the Essentials of Mechanical Ventilators (Branson and Chatburn, 1992). This terminology should be used in preference to that of ASTM F 1100-90 when the terminology differs. This terminology should also be used in preference to proprietary terminology when the suggested terminology is adequate to describe the ventilator mode. For example, a blower ventilator mode which provides two levels of CPAP and provides timed breaths

unless a spontaneous breath supervenes should be described as SIMV (spontaneous intermittent mandatory ventilation) with pressure support. An expanded description would be as follows: (a) mandatory breaths are time-triggered, pressure-controlled and flow-cycled; and (b) spontaneous breaths are flow-triggered, pressure-controlled and flow-cycled.

Portions of ASTM F 1100-90 and ASTM F 1246-91 are relevant, as are all other sections of this guidance document. This section is written for review of these devices as adult ventilators. The following requirements are for pressure controlled, time triggered or patient-triggered (flow or pressure triggered), flow or pressure cycled operation, pressure-limited ventilation (typically pressure-support ventilation). Requirements and testing for use as a ventilator for children or infants will be similar but will require use of different test parameters corresponding to the patient populations and may require clinical data.

6.1 REQUIREMENTS FOR VENTILATORS WITH NON-ACTIVE EXHALATION VALVE CONTROL (DIFFERENCES RELATIVE TO ASTM F 1100-90)

This section is written for review of these devices as adult ventilators. The following requirements are for pressure controlled, time triggered or patient-triggered (flow or pressure triggered), flow or pressure cycled operation (typically pressure-support ventilation). Performance requirements of ASTM F 1100-90 (section 5) are generally applicable, but there are specific exceptions:

6.1.1 The maximum working pressure (F 1100-90, section 5.6.1.1) should not exceed 30 cm H2O.

6.1.2 Direct spirometry (F 1100-90, section 5.7 and 5.10.3) is not relevant to ventilators constructed without an active exhaust valve.

6.1.3 The accuracy of the gas mixture controls (F 1100-90, section 5.8 and 5.8.1) may be applicable. Although no gas mixture controls may be provided as part of the ventilator, the accessory masks or other patient circuit components may incorporate provisions for providing supplementary oxygen. If such provisions are made, testing must be done to determine the effective administered oxygen concentration under simulated operating conditions (see section 6.2.5 of this guidance document).

6.1.4 The expiratory pressure requirements should be met, as described in F 1100-90 section 5.9 "expiratory resistance". At these pressures (5 cm H2O for adults and children, 3 cm H2O for infants) the ventilator should have adequate flow to prevent rebreathing (refer to section 6.2.10 of this guidance document). The specific testing method in F 1100-90, section 5.9.1 is not relevant.

6.1.5 The alarm requirements as stated in F 1100-90, section 5.11 may be adapted.

6.1.5.1 However, the loss of main power supply alarm is required per F 1100-90, section 5.11.3.1.

6.1.5.2 With respect to breathing circuit alarms (F 1100-90, section 5.11.3.2), when the device is intended for ventilation of patients who can tolerate extended periods without ventilation (MNS), incorporates an effective anti-asphyxia function, and provides a negative pressure relief valve mechanism per F 1246-91, section 4.13, and tested per 6.2.10 of this guidance document, then the alarms per F 1100-90, section 5.11.3.2 may not be required, or the alarms may be disarmed by a user-accessible switch.

6.1.5.3 For MNT (ventilator, passive exhaust port, critical care) devices, an internal mechanism that allows the choice of enabling or disabling the audible breathing circuit integrity alarm which is not user-accessible and is set according to prescription may be included. When enabled, the user may disable the alarm by means of an external switch. If such a mechanism is provided the device should have a prominent front-panel indication automatically displaying the status "automatic audible alarm reset disabled - not for critical care use" when the alarm is disabled. The device has only indications

consistent with the MNS classification when the audible alarms are disabled (except for treatment of specific patients) and an effective anti-asphyxia mechanism must be implemented.

6.1.5.4. High airway pressure alarms are required (F 1100-90, section 5.11.3.3) as are suitable alarm battery supplies (F 1100-90, section 5.11.4).

6.1.6 The ASTM requirement F 1100-90, section 5.13 regarding electromagnetic interference is superseded by section 5.6 of this guidance document.

6.1.7 Measurement of oxygen concentration (ASTM F 1100-90, section 5.15) cannot be directly accomplished for these devices. The manufacturer shall provide or recommend equipment to monitor the flow of supplemental oxygen and the concentration of the supplemental oxygen, or provide an equivalent alternative for a MNT classified ventilator.

6.1.8 Human Factors:

The set values for mode, rate, CPAP pressure, I:E ratio, pressure support level, and tidal volume, when applicable, should be displayed either as control settings of calibrated switches or potentiometers, or as digital representations of electronically stored control values. These displayed values should be concurrent and continual. Monitored values for pressure, tidal volume, and rate, if applicable, should be displayed continually and concurrently. This paragraph applies to MNT classified ventilators.

6.2 TESTING OF VENTILATORS WITH NON-ACTIVE EXHALATION VALVE CONTROL (DIFFERENCES RELATIVE TO F 1100-90)

6.2.1 For testing conditions, F 1100-90, sections 6.1 through 6.6 generally are applicable. However, the following conditions are suggested for adult ventilation, in consideration of the special characteristics of ventilators constructed without an active exhaust valve:

For mandatory ventilation, simulating no patient work (controlled ventilation):

- Rate 20, I:E 1:2
- Expiratory pressure setting: 5 cm H2O
- Inspiratory pressure setting: test at 15, 20, and 30 cm H2O
- Compliance and Resistance settings matrix: C50 and R5; C50 and R20; C20 and R5
- Inadvertent leak settings: test using above matrix at zero leak and at a simulated leak of 20 l/min. Set the simulated leak to 20 l/min using a sustained pressure of 15 cm H2O.
- There are 3 pressure settings, 3 combinations of compliance and resistance, and 2 leak states, for a total of 18 conditions.
- Airway pressure, as well as flows and volume (F 1100-90, sections 6.3.2.1.a,c,d) should be measured at the simulated patient connection (on the test lung side of the exhalation port). Flows (using a recording pneumotachometer) should also be recorded at the site between the exhalation port and the ventilator connection tubing.
- Testing should be performed using a typical exhalation port configuration. If leak for each manufacturer-specified combination of accessories is similar (as demonstrated in separate testing), then the ventilator flow testing may be performed with one configuration. If flows for different exhaust port configurations differ by more than 5 l/min at 20 cm H2O, then separate testing should be performed for the port configuration with the maximum flow and the minimum flow among the possible accessory configurations. Similarly, if leak flows at 20 cm H2O differ by more than 5 l/min for specific swivel connectors or other parts, then ventilator testing at the extremes of leak configurations (including both the port component and the connector component) should be performed.
- Documentation may consist of two complete respiratory cycles at each setting of this matrix. Test lung configuration similar to F 1100-90 FIG. 3 may be acceptable, but with the use of recording pneumotachography for flows and volumes. For mandatory ventilation, the spontaneous breath

generator limb should be free-moving.
- In addition specify the maximum total flow rate at which the highest pressure setting for the device can be maintained within 10% (e.g., 20 minus 2 cm H2O or 30 minus 3 cm H2O). This specification should be included in the table of specifications.

For patient-triggered ventilation:
- The spontaneous breath generator should be set to 500 ml/sec, inspiratory time of 1 sec, rate 20/min. The same matrix as for mandatory ventilation may be tested (18 conditions unless various port or connector configurations have different exhaust flows).
- Additional recordings should be made of flow and pressure waveforms at the inlet to the test lung during a step transition from a leak rate of 5 l/min to 20 l/min, and for the step transition from 20 l/min to 5 l/min, using test lung settings of C50 and R5, and with the most typical port and connector configuration . Separate recordings should be made with the transitions at mid-exhalation and with the transition at mid-inspiration. Recordings should be continued for ten cycles after a stable (within 10%) VT is established. There are a total of four test conditions.

6.2.3 The pressure relief function which operates when the pressure control function setting fails should be tested. The main pressure control valve which operates to control the pressure by dumping excess gas during cyclic respiration or CPAP should be disabled in the position closed to atmosphere and full open to the patient. The ventilator should then be operated with the patient connection occluded, and the results obtained. An alternative test method may be used if appropriate to the device mechanism and if adequate explanation is provided.

6.2.4 To test the accuracy of the volume estimation, an alternative testing method to F 1100-90, section 6.7.1 should be used. The "estimated exhaled tidal volume" and "estimated inadvertent leak" readings, if provided by the ventilator, should be recorded concurrently with test conditions for patient triggered breaths. Data should be provided only for the test matrix (18 conditions) using the most typical port and connector configuration, and the step leak transitions (4 conditions). Manual logging will be adequate for the 18-condition test matrix. Recordings of the output signals, appropriately scaled and labeled should be provided for the "estimated exhaled tidal volume" and "estimated inadvertent leak" during the 4-condition step change in simulated leak.

6.2.5 Testing of the characteristics of the delivered gas should be done using the following alternative method to F 1100-90, section 6.8.

- The most typical exhalation port, mask, and connector configuration should be used. At a minimum, the FIO2 (collected during the first half of the inspiratory phase) should be measured during in-vitro waveform testing during the 18 conditions for controlled ventilation (6.2.1 of this guidance document). Continuous real-time oxygen monitoring recorded from the test lung during performance of the test matrix may be used as an alternative to timed sample collection. This should be done with 6 l/min O2 flow. Each additional mask or other oxygen port configuration should be tested only at C20 R5, CPAP 5, inspiratory pressure 20, and at simulated inadvertent leaks of 0 and 20 l/min.

- The maximum recommended supplementary oxygen flow should be stated. The test sequence for patient-triggered ventilation should be repeated using the maximum recommended supplementary oxygen flow.

6.2.6 Testing of expiratory resistance may be performed using a protocol modified from F 1100-90, section 6.9.1.1. Testing may be performed with a CPAP setting of 5 cm H2O. Pressure should not exceed 5 cm H2O above the CPAP level at 50 l/min flow. If supplementary oxygen is an option, then the oxygen flow should be set to the maximum recommended flow rate. Testing should be performed with the most typical port and connector configuration. If port flows for different exhaust port configurations differ by more than 5 l/min at 20 cm H2O then separate testing should be performed for

the port configuration with the maximum flow and the minimum flow among the possible accessory configurations. Similarly, if leak flows at 20 cm H2O differ by more than 5 l/min for specific swivel connectors or other parts, then ventilator testing at the extremes of leak configurations (as the sum of both the port component and the connector component) should be performed.

6.2.7 For testing of fittings connecting the adult ventilator and patients F 1100-90, sections 6.10-7.2 should be followed, except that the absence of a spirometer outlet is expected.

6.2.8 Testing for internal compliance should not be performed.

6.2.9 The Operation and Maintenance manual should correspond to F 1100-90, sections 8.2 - 8.4.1.

- In addition, the labeling should include a tabulation of the observed mean oxygen concentration with 6 l/min oxygen flow during the first half of the inspiratory phase with simulated machine-triggered ventilation with the following characteristics: rate of 20, I:E 1:2, C20, R5, CPAP 5, inspiratory pressure 20 cm H2O, and at simulated inadvertent leaks of 0 and 20 l/min, for each configuration of oxygen mask or port. The observed tidal volume should be documented with these parameters. Labeling should include the specification for maximum oxygen supply flow consistent with proper operation of the ventilator under all conditions, including expiratory pressure considerations (6.2.6 of this guidance document).

- The mask and exhaust port configuration in part defines the characteristics of ventilators constructed without an active exhaust valve. Identify each configuration or accessory, show a simplified drawing, list indications, and provide summary test data for each configuration. Listing of the flow rate of the of the exhalation port at 5, 20, and 30 cm H2O, and separate listing of the sum of the swivel and other connector leaks at these pressures should be provided. The anti-rebreathing provision should be stated. This material should be provided as one page for each configuration. This information should be included in the operator's manual.

6.2.10 Additional testing and labeling:

- Testing of the anti-asphyxia and negative-pressure relief mechanisms should be performed. Provide test data for each configuration of accessory mask or accessory port, with the power to the ventilator off, and using the minimum leak connector configuration, with no simulated inadvertent leak. An active test lung with a 200 cc/min CO2 source, a 200 ml physical dead space, an 800 ml tidal volume, a rate of 20 bpm, and an inspiration time 1 second may be used. A means to continually mix the gas within the test lung should be provided. Pressure at the patient connection, continuous capnography at the patient connection, and pneumotachograph flows and volumes should be shown for 10 representative cycles in the first and 15th minute of continuous breathing through the test apparatus. A negative pressure of no more 10 cm H2O should be present at the beginning of inspiration and calculated resistance based on instantaneous flow and pressure should demonstrate a resistance of no more than 10 cm H2O/l/sec during inspiration (at the patient connection). The observed pCO2 during all inspiratory times should remain at ambient atmospheric concentration throughout the duration of the test, after the first 50 ml of inhaled volume.

- Testing for rebreathing should also be performed as in the preceding paragraph but with the ventilator on, for each port configuration, using the connector configuration with the least leak, using no simulated inadvertent leak, passive test lung, simulated dead space 200 ml, VT 800 ml, rate of 20 bpm, inspiration time of 1 second, and C50 R5.

Infrared transmission "mainstream" capnography or an other method providing real time CO2 recordings on the same time axis as the pneumotachograph volume recording will be required. Also required will be a fixture simulating patient facial contours, suitable for connection to the test lung via

the fixture's simulated nostrils, for use in testing the entire apparatus, including masks.

6.3 REQUIREMENTS FOR MNS & MNT ELECTRICALLY POWERED HOME CARE VENTILATORS

The ASTM F 1100-90 requirements and testing provisions as modified in sections 6.1 and 6.2 of this guidance document are appropriate. Portions of F 1246-91 (ASTM Standard Specification for Electrically-Powered Home Care Ventilators, Part 1) should be used only for relevant additional requirements and testing. In addition the following modified requirements should be included:

6.3.1. Battery powered operation (F 1246-91, section 4.1.2) and related alarms (F 1246-91, section 4.12.3) would not be required for MNS classified ventilators (ventilator, passive exhaust port, non-critical care) if an effective anti-asphyxia method is provided. Battery operation is required for MNT classified ventilators (ventilator, passive exhaust, critical care) when used as a home care ventilator.

6.3.2 Human factors: In addition to F 1246-91, section 4.8, it should be noted that settings must be displayed in some manner. Ventilators not intended for critical care use (MNS) may be constructed with limited facilities to continually display set values, particularly if intended for home use. If such a device is constructed without the facilities to continually display current set values, provision should be made for the current settings to be written on a card which is relatively inaccessible to unauthorized change, but which can be easily read; however, this provision may not be appropriate for all applications.

6.3.3 Provision of supplemental oxygen (F 1246-91, section 4.11) is optional for MNS classified ventilators (ventilator, passive exhaust port, non-critical care), but MNT classified ventilators (ventilator, passive exhaust, critical care) must provide a means to supply supplemental oxygen, possibly via an optional accessory. However, a MNT classified ventilator may be distributed without the accessory which would be used to provide supplemental oxygen, though this issue should be addressed in the labeling.

6.3.4 The breathing circuit alarm should perform as indicated in (F 1246-91, section 4.12.1). However, there may be an option to not provide this alarm (MNS) or to switch the alarm off for an indefinite period (see sections 6.1.5.2 and 6.1.5.3 of this guidance document).

6.3.5 The anti-asphyxia valve requirements and the negative pressure relief valve requirement F 1246-91, section 4.13 should be supplemented with testing of the anti-asphyxia characteristics as described in conjunction with 6.2.10 of this guidance document.

6.3.6 The labeling for the expected effective inspired oxygen concentration (F 1246-91, section 5.1.21) requirement should amended per 6.2.9 of this guidance document.

6.4 TESTING OF MNS & MNT ELECTRICALLY POWERED HOME CARE VENTILATORS (DIFFERENCES FROM F 1246-91)

Testing should generally correspond to section 6.2 of this guidance document and ASTM F 1100-90. ASTM F 1246-91 testing should be used for any testing not superseded by section 6.2 of other portions of this guidance document and ASTM F 1100-90. Section 6.2.10 of this guidance document, regarding testing for anti-asphyxia valves and rebreathing, are particularly important.

7.0 SOFTWARE DOCUMENTATION REQUIREMENTS FOR VENTILATORS

The information submitted for software (or firmware) documentation and performance should be consistent with the Reviewer Guidance for Computer Controlled Medical Device. This information should include software development/environment, software/system requirements, software and system hazards analysis, and software verification and validation information.

Because ventilators are life supporting/life sustaining devices, these devices are considered high risk devices and should be designed and tested as such. Use of commercial off-the-shelf software that cannot be evaluated or tested properly, be subjected to code walk throughs and inspections, or be modified if a bug or anomaly occurs, should be avoided. System level tests can be performed on commercial software, however, it is well known that most software errors are found and corrected during coding, debugging, and unit testing phases. Software development engineering is a key major factor for assuring that software is reasonably reliable since complete testing for every conceivable condition cannot be assured during testing and evaluation. The way in which the software is developed should account for safety, requirements, architecture, design, implementation, testing, analysis, quality assurance, and documentation of the software and system, which is all essential in assuring software safety and reliability. Likewise, the system hardware requirements and configuration should be designed and developed using well known architectural designs that allow for partitioning of the system and reduction in software complexity.

Information provided in the 510(k) submission should include system and software requirements, such as the safety requirements and redundant controls which assures patient safety, feedback mechanisms, limitations imposed by software on the device, self diagnostic tests etc. The safety considerations addressed in the system and software architecture and design should also be discussed. Verification and validation information should address timing and interrupt functions, stress testing, alarm testing, error and fault condition testing, range and error checking on device or user related inputs, software fault-tree and FMECA failure analyses (for the system and for the software component), and hazards analysis testing.

The following defines the information which should be included in the 510(k) submission for a ventilator:

Hazard Analysis

A device hazard analysis should be provided that takes into account all device hazards associated with the intended use, labeling, hardware, software, operator, patient, etc. A software hazard analysis should also be provided in order to demonstrate that software hazards are being considered during the software development process. Each hazard analysis should include the following for each hazard:

- -The hazardous event,
- -The method of control,
- -Corrective measures taken, including aspects of the device design/requirements, that eliminate, reduce, or warn of a hazardous event, including a discussion of its appropriateness, and
- -Testing demonstrating the implementation of the safety feature.

Software Development Lifecycle

- -Discussion of lifecycle model, including actual software development policies,
- -Discussion of activities associated with each phase of the software lifecycle model, as well as, the following for the device under review:
  - -Performance of preliminary and on-going hazard analysis,
  - -Error logging and tracking,
  - -Quality assurance activities and methods of device under review (e.g., design reviews, code walk throughs, fault tree analysis, FMECA, independent verification and validation, etc.),
  - -Coding standards,

-Documentation generated during each phase of the lifecycle of device under review,
-Verification and validation activities of device under review, and
-Software audits performed on the device under review.

-Discussion of development environment of device under review,
-Discussion of configuration management and change control, and
-Discussion of software maintenance activities, including error logging and tracking.

Software and System Requirements

-Hardware requirements, including system, microprocessor, memory, etc.,
-Programming language and program size(s),
-Performance and functional software requirements, as well as the following:
-Algorithms for therapy, diagnosis, monitoring, and interpretation (with full text references),
-Device limitations due to software,
-Internal software tests and checks,
-Error and interrupt handling,
-Timing and memory requirements, and
-Communication protocols.

-Software modularization criteria and discussion of software modules,
-Software and system safety requirements,
-Software safety requirements cross-check with software modules, units, or modularization criteria,
-Revision history,
-System block diagrams, and
-Identification of commercial off-the-shelf software (if appropriate).

Verification and validation

-System level test protocol with pass/fail criteria, data, and an analysis of the results,
-Software test report discussing how all phases and methods of testing (module, integration, performance, functional, stress, structure, hazard, and system) demonstrate that requirements are met. This should include a discussion of testing results and analysis of the following (when appropriate):
- Fault, alarm, and hazard testing,
- Error and range checking, and boundary value testing,
- Timing analysis and testing,
- Special algorithms and interpretation testing and analysis,
- Path analysis and branch testing,
- Stress testing,
- Device options, accessories, and configurations testing,
- Communications testing,
- Memory utilization testing,
- Qualification of commercial off-the-shelf software (when use is appropriate),
- Acceptance and beta site testing,
- Regression testing, and
- Test completion criteria.

-Fault tree analysis/failure mode affects criticality analysis of the software and how results were employed in the software/system requirements, design, and testing, and
-Identify all versions and revisions of software.
-Include the errors and bugs identified during development and explain how they have been corrected or were determined to not impact safety or effectiveness, including operator usage and human factors engineering aspects of the device, and how these are communicated to the user in the device labeling.

Testing should provide traceability to software and system requirements, and the test report provided should explain how the desired level of test coverage necessary for the device was achieved.

Labeling (software related)

The labeling of a medical device should be consistent with the labeling requirements discussed in the Blue Book memo Device Labeling Guidance #G91-1 dated March 8, 1991. Besides the labeling requirements discussed in this referenced memo, the following should be considered for a computer-controlled medical device:

-Consistency between intended use and software and system requirements,
-Adequate warnings and precautions,

-Operator and training manuals,
-Instruction and qualification checklist for installation,
-Trouble shooting guide, including faults/hazards to the patient, device configurations, operator instructions, and error message information,
-Listing of known anomalies and bugs (non-hazardous to patient or operator usage),
-Hazardous operating procedures identified and proscribed in warnings, and
-Adequate instructions for use.

The labeling should be appropriate for the device to ensure safe and proper installation and usage. Refer to section 8 of this guidance document for the labeling requirements for the device.

8.0 LABELING

The labeling for a ventilator should be consistent with the labeling requirements discussed in the Office of Device Evaluation Memorandum, Device Labeling Guidance #G91-1, dated March 8, 1991. Besides the labeling requirements discussed in this guidance, ASTM F 1100-90 and F 1246-91 include labeling requirements that should also be utilized. All labeling submitted should be demonstrated to conform to these guidances and standards.

The intended use of the ventilators (refer to section 4.1 of this guidance document) should also be included in the labeling. For the MNS and MNT classified ventilators, the limitations of the intended use (refer to section 6 of this guidance document) should be included in the labeling and clearly displayed on the device.

9.0 510(k) DOCUMENTATION REQUIREMENTS

This section provides general information regarding information and documentation that should be provided in 510(k) submissions for ventilators.

The premarket notification submission information (Numbers in parentheses reference the Reviewer Guidance for Premarket Submissions, November 1993 draft, section e) should address the following:

(1) 1. Premarket notification submissions shall consist of an executive summary which serves as a general description of the device and its indications. The summary should indicate if the device is new, or a modified version of a legally marketed device, whether it be modifications in hardware, software, features, accessories, components, labeling or intended use. The summary should identify all configurations of the device.

(2) 2. Premarket notification submissions shall consist of the intended uses of the device, including patient population, clinical indications, and environments of use.

(3) 3. Premarket notification submissions shall consist of a complete description of the basic principle of

operation, a discussion of the control and phase variables, modes and output waveforms, and device specifications (as presented in section 4 of this guidance document). This discussion shall include engineering drawings of the pneumatic and electrical subsystems of the device. This information should also address device accessories.

(4,5)4. Premarket notification submissions shall consist of a comparative analysis (tabular comparison and discussion) of how the intended use, performance characteristics, and specifications of the new device are similar to other legally marketed predicate ventilators. Differences should be discussed with supporting rationale and/or data demonstrating that the differences raise no new issues of safety and effectiveness. This information should also address all device accessories.

5. Premarket notification submissions shall consist of a critical element fault-tree analysis (or FMECA) documenting all potential failure modes of the device and the potential outcome (hardware/software). This information should describe how failures of the device have redundant controls, provide sufficient warning to the user, and have been appropriately documented in a trouble shooting guide in the Operator's Manual. This should include device accessories as well (if appropriate).

(6,7,11)6. Premarket notification submissions shall consist of a description of the test protocols and procedures, data, and analysis of results associated with all testing described in sections 5 and 6 of this document. This includes:

-Device performance and functional testing (including accessories),
-Reliability testing, data, and analysis,
-EMC/electrical, and
-Environmental testing (Mechanical, temperature, humidity, and fluid ingress).

(8) 7. If clinical data is needed to address a new characteristic or indication of the ventilator, then the information described in the Reviewer Guidance for Premarket Notification Submissions, paragraph 8 of section (e) shall be provided. The information should include the hypothesis to be tested, protocol, entry/exit criteria, and data analysis, including the clinical and statistical justifications of the study and results. Since ventilators are significant risk devices, an approved investigational device exemption (IDE) is required prior to initiating the clinical trials.

(9) 8. Premarket notification submissions shall include software documentation and system testing as discussed in Section 7 of this document:

-Hazards Analysis,
-Software development engineering,
-Software and system requirements,
-Software verification and validation, and
-Labeling associated with software issues.

(10)9. Premarket notification submissions shall include biocompatibility information if the device includes any component that is intended to contact the patient, unless the device is a legally marketed device or is made of known biocompatible materials (including the manufacturing compounds used to make other medical devices).

(12)10. Premarket notification submissions shall include information regarding disassembly, cleaning, and sterilizing components of the ventilator and patient circuit which prevent cross-contamination between patients (via device/patient circuit). This information should be included in the device labeling. Section 5.7 includes a discussion of disinfection issues and data consistent with this information should be provided.

(13,14)11. Premarket notification submissions shall include labeling (promotional literature, operator's manual, and maintenance manual) as discussed in section 8 of this document. All device accessories should be included in the labeling as well.

(16)12. Premarket notification submissions shall include a 510(k) statement or summary, as well as a truth and accuracy statement.

General information required in a premarket notification submission is discussed in the Reviewer Guidance for Premarket Notification Submissions (November 1993), the Draft Guidance for Format and Content for Premarket Notification (510(k)), and the Premarket Notification: 510(k) Regulatory Requirements for Medical Devices (FDA 90-4158).

APPENDIX: STATEMENT OF RATIONALE

X.3.0 While perhaps desirable, there is no expectation that new descriptors for ventilator modes will replace older terminology on ventilator controls and in other labeling. However, the various modes can be more clearly stated using a simplified terminology, and this will facilitate consistent review. It is also recognized that the use of the suggested terminology cannot assure an unambiguous description of all ventilator modes.

X5.1 Ideally it should not be possible to operate a control unless the control is relevant to the mode of ventilation in use at the time (not in standard).

X5.2 & X5.4 Reliability is not addressed in the ASTM standards, except for durability testing. All modes of ventilation, waveform testing, and patient triggered events are also not specifically addressed.

X5.5 The field strength near ambulances can exceed 10 V/m during radio transmission (Boyd S, Boivin W, Coletta J, Neunaber L: Characterization of the Ambulance Electromagnetic Environment. AAMI Meeting, Anaheim Proceedings, 5/24/95) and thus, testing to 20 V/m is appropriate for transport ventilators. Hand held transmitters (e.g., cell phones, etc.) can produce fields exceeding 3 V/m within 1-2 meters of the transmitter (Bassen et al). Testing of life support devices will be to 10 V/m, but non-life support device may be tested at 3 V/m.

X.5.6 The 1994 CDC decontamination recommendations for various types of respiratory devices are similar. The statement for anesthesia equipment is most concise, and therefore and is quoted, but is understood to be generally applicable.

The draft reviewer guidance on labeling reusable medical devices is open for comment as of the date this draft (July 1995). Some changes are likely, and may affect the draft ventilator guidance.

X.5.6.2 The devices may be used for either acute or chronic treatment, and so should be tested for chronic use.

X.5.6.3 High-level disinfection has been recommended for such material since 1985 (AAMI TIR No. 12 - 1994).

X.6 Despite the limitations, there is an important purpose for ventilators which can provide a subset of ICU ventilator functions. Blower-operated ventilators are capable of providing alternating higher and lower pressures which could ventilate a patient, without the need for a separate source of compressed air. If pressure-support or other pressure-limited ventilation modes are adequate, and if other functions of a typical critical care ventilator are not needed, then the type of ventilator under consideration may have advantages, in simplicity of operation, and in functionality for mask ventilation. It is appropriate to provide a clear regulatory path for the marketing of such devices.

It should also be noted that pressure support ventilation administered via mask or other methods was developed using conventional ventilators, and the use of a conventional continuous ventilator for noninvasive pressure

support ventilation is entirely practical (see for example Wysocki M, Laurent T, Wolff MA, Millet H, Herman B: Noninvasive Pressure Support Ventilation in Patients With Acute Respiratory Failure A Randomized Comparison With Conventional Therapy: Chest 107:761-768; 1995).

Limitation of current examples of ventilators addressed in this section are related to the patient circuit design. The devices cannot directly measure inhaled or exhaled volumes, although tidal volumes may be estimated if the leak around the mask as well as respiratory rate and volumes are reasonably constant for a period of time. Although phasic metering of oxygen could improve the efficiency of oxygen delivery, in current versions the delivery of oxygen is inefficient and the delivered concentration is not constant, because of the open patient circuit with large and variable airflows.

Alarms based on volume measurements are impractical to implement on these devices, and thus the breathing circuit integrity alarms may be limited to the detection of cyclic pressure fluctuations within selected limits. For some clinical uses, it may be appropriate to not use breathing circuit integrity alarms.

However, the ventilator should not be allowed via a single failure to put the patient at risk of suffocation if alarms are not implemented. Thus the anti-asphyxia mechanism must be permit the patient to breath ambient air in the event of ventilator failure where there is reduced or absent provision of fresh gas.

The device must also provide a means to detect and prevent application of sustained high pressure in the event of ventilator failure which otherwise results in sustained high pressure. This should be done in addition to alarms since sustained high airway pressure exposes the patient to immediate risk of reduced blood pressure and cardiac output, in addition to preventing respiration. The pressure-support ventilators addressed in this section should have infrequent false positive overpressure alarm conditions, so the inclusion of overpressure alarms and overpressure dump functions should not render the devices impractical for routine use.

X6.1.2 Ventilators constructed without an active exhaust valve are also in a sense continuous flow ventilators. However the infant continuous flow ventilators are substantially different and rely on the function of an exhalation valve to control respiration.

X6.1.4 Expiratory pressure is inherent in the design of these ventilators, since an outflow from the ventilator during the exhalation phase is necessary to displace exhaled gas from the patient circuit, in order to prevent rebreathing of exhaled gas. The nature and location of the exhalation port will be an important variable in determining the minimum CPAP pressure required to clear the circuit of exhaled gas.

X6.1.5.1 Loss of main power supply alarms are simple, inexpensive, and create no false alarms.

X6.1.5.1 & X6.1.5.3 It may be necessary to be able to switch the breathing circuit integrity alarm "off" for sustained periods of time during treatment of specific patients using MNS or MNT devices. For example, during daytime ventilation via mouthpiece of alert ventilator dependent patients, sustained muting of the breathing circuit integrity alarm may be essential to permit other patient activities (Bach JR, Saporito RL: Indications and criteria for decannulation and transition from invasive to non-invasive long-term ventilatory support. Respiratory Care 39:515-531, 1994).

X6.1.6 Because of the increased use both of transmitters such as cellular telephones and of digital computers incorporated into medical devices, it is important for medical devices to be adequately resistant to electromagnetic interference. Similarly, medical devices should not emit electromagnetic radiation which will affect other nearby medical devices.

X6.1.8 This constitutes a requirement which corresponds to common practice, but which should now be explicitly stated because of the potential for evanescent display of control settings possible using keypad or "softswitch" input to microprocessor-controlled devices, and the evanescent display of analog variables as digital data.

X6.1.10 The anti-asphyxia characteristics of the device are of particular relevance for patients receiving home care without continuous professional attendance (Draft international Standard ISO/DIS 10651-2.2. 7.8b, also ASTM F 1246-91, section 4.13), or when the device permits use without alarms enabled (section 6.1.5.3 of this guidance document). Because the actual use of the device may not correspond with the label indications the anti-asphyxia testing should be done for all MNS or MNT ventilators, to establish the likely consequence of continued breathing through the ventilator circuit after complete failure of the ventilator.

The rebreathing characteristics (with the ventilator operating) are generally relevant for devices with no active exhaust valve (Ferguson GT, Gilmartin M: CO_2 Rebreathing During BiPAP Ventilatory Assistance. Am. J. Resp Crit Care Med 151; 1126-1135, 1995). A greater minute volume requirement is reasonable for patients with lung disease; Slutsky, 1993, page 1840).

X6.2.5 Retesting of patient triggering characteristics is appropriate since the additional oxygen flows may interact with the triggering mechanism.

X6.3.2 This requirement is intended to allow any provider to read the settings of the device and to verify that the device operation corresponds to the desired settings. This is analogous to the practice of listing the drug, dose and route of administration on dispensed prescription drug containers.