DRAFT Emergency Use Ventilator (EUV) Design Guidance

This draft guidance is under development by the AAMI COVID-19 Response Team to provide targeted design constraints to enable rapid development of emergency use ventilators (EUV) to treat patients with COVID-19 respiratory failure. It may also be useful to guide the review of an EUV by an authority having jurisdiction.

This document reflects the work of the experts on the response team and has not undergone a consensus review process. It will be modified and updated as discussions continue and more information becomes available.

It is being made available to the public for information purposes and to seek comments. Comments and suggestions for changes should be sent to celliott@aami.org.

Emergency Use Ventilator Design Guidance

Purpose

The goals of this document are to provide targeted design constraints to enable rapid development of emergency use ventilators (EUV) to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of an EUV by an authority having jurisdiction.

It is recognized that the surge in COVID-19 is requiring extraordinary measures to provide mechanical ventilatory support to keep pace with clinical need. This global community of clinicians, engineers, manufacturers, regulators, and others are responding to this need by designing and producing, inexpensive, and often open-source, ventilators of varying complexity and capabilities for rapid deployment. This document identifies clinical, engineering and test requirements appropriate to support safe operation. The document identifies requirements that are required for non-EUVs but might not be required for EUVs that have appropriate disclosures. Therefore, ventilators complying with the requirements of this document need not provide a level of performance equivalent to that of critical care ventilators (ISO 80601-2-12[1]) or life-supporting homecare ventilators (ISO 80601-2-72[2]).

Introduction

The requirements outlined in this paper are modeled on ISO 80601-2-80:2018[3] presuming usage in traditional healthcare facilities (e.g. hospitals, assisted living facilities, nursing homes) as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, motels). This paper presumes that the operators of the EUV are all trained professional healthcare providers and not lay persons. Hence the requirements of ISO 80601-2-80:2018 specifically for lay operators or the home healthcare environment are considered not applicable to an EUV intended for the treatment of COVID-19 patients.

Fundamentally, the EUV needs to provide ventilation at the patient-connection port within the alarm limits set by the operator or inform the operator via an alarm condition that ventilation within the alarm limits is not occurring. Such alarm conditions need to include:

- Gas or electricity supply failure.
- Ventilator switched off while in mandatory ventilation mode.
- Inspiratory airway pressure exceeded.
- Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm condition).
- Tidal volume not achieved or exceeded.

[1] ISO 80601-2-12, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

[2] ISO 80601-2-72, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

[3] ISO 80601-2-80, *Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency*

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The ventilatory support needs of a COVID-19 patient can range from simple BIPAP (bilevel positive airway pressure) for patients that are breathing spontaneously to mandatory ventilation in either a pressure-support or volume control mode. Additionally, these patients are very likely to require inspired oxygen concentrations (FiO_2) in excess of the 21% contained in room air.

To properly manage a COVID-19 patient, the EUV needs to indicate to the operator at a minimum:

- The current settings (e.g., inspiratory pressure, tidal volume, frequency, PEEP, FiO_2, ventilation mode).
- The current delivery (e.g., inspiratory pressure, tidal volume, respiratory rate, PEEP, and FiO_2 at the patient-connection port).

To properly manage a COVID-19 patient, the operator needs to be able to control the EUV at a minimum:

- FiO_2 over the range of 21% (ambient) to 95% of the source oxygen concentration input to the EUV in no more than 10% steps

  Note: When oxygen is provided by an oxygen concentrator, the input concentration is not 99.5%, but can vary from 90% to 96% in which case the upper limit of FiO_2 would be 90%.

- Set PEEP (i.e. BAP) (5 to 20) cmH_2O in no more than 5 cmH_2O steps
- I:E ratio (ratio of inspiratory to expiratory time) of 1:2 preferably adjustable from 1:1 to 1:3
- For mandatory modes, respiratory rate from (10 to 30) inflations/min preferably adjustable in steps of no more than 2 inflations/min
- Tidal volume (350 to 450) ml ±10 % in no more than steps of 50 ml, preferably a lower range of 250 ml and an upper range of 600 ml or 800 ml
- Where applicable, inspiratory pressure limit (15 to 40) cmH_2O preferably adjustable in steps of no more than 5 cmH_2O

To help prevent contaminating the environment (and particularly the clinicians), filters need to be placed in the expiratory pathways. Particular attention needs to be placed on the exhaust port.

Review of the requirements of ISO 80601-2-80 and their applicability to an EUV

NOTE: Any subclause marked with an asterisk (*) means that further guidance for this requirement is available in Annex A of the standard.

Remember that ISO 80601-2-80 is a particular standard so it is written on top of (i.e. it modifies) the GS (the general standard, IEC 60601-1[4]) and the collateral standards (i.e. IEC 60601-1-2[5] on EMC, IEC 60601-1-6[6] on usability and IEC 60601-1-8[7] on alarms). There are additional applicable collateral standards (and hence requirements) if the EUV is intended for home use, ambulance

[4] IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[5] IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

[6] IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

[7] IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

use or as part of a physiological closed loop control system. These standards can be purchased from many sources including ANSI[8] and AAMI[9].

NOTE: Words written in SMALL CAPS are not 'normal English'. They are defined terms and have specific, defined meanings. See Clause 3 in the GS and 201.3 in ISO 80601-2-80 for their definitions.

201.4.11.101 Additional requirements for pressurized gas input

Fully required.

These are the requirements for an EUV intended to connect to either an air or oxygen pipeline.

Clause 5 General requirements for testing of ME EQUIPMENT

This Clause of the GS is fully required.

201.5.101 Additional requirements for the general requirements for testing of ME EQUIPMENT

Fully required.

This Clause explains how to interpret and perform tests as well as how to indicate specifications.

Clause 6 Classification of ME EQUIPMENT and ME SYSTEMS

This Clause of the GS is fully required.

An EUV may be Class I or Class II or internally powered.

Unless there are electrical connections to the PATIENT (e.g. monitoring ACCESSORIES) or heated breathing tubes or electrically powered ACCESSORIES (e.g. expiratory valves located proximal to the PATIENT), the plastic breathing tubes provide adequate floating electrical isolation.

Protection from the ingress of water: IP21 is required and IP22 is recommended. Body fluids and IV bags are an expected normal part of the environment of use.

Since the EUV is expected to handle gas with an oxygen concentration in excess of the ambient 25 %, the considerations for an OXYGEN RICH ENVIRONMENT (see 60601-1, 11.2.2) are fully applicable.

201.6.101 Additional requirements for classification of ME EQUIPMENT and ME SYSTEMS

This subclause is recommended but not required. An EUV need not be TRANSIT-OPERABLE.

Rationale: For pandemic treatment, a tabletop (i.e. somewhat large) EUV is acceptable.

Clause 7 ME EQUIPMENT identification, marking and documents

7.1 General

This subclause of the GS is recommended but not required.

Rationale: Although ensuring that the EUV can be read both over the indicated illumination level and the indicated cone of visibility is recommended, in this pandemic situation it is not considered

[8] ANSI, https://webstore.ansi.org/
[9] AAMI, https://my.aami.org/store/

mandatory. It is noted that operators are likely wearing PPE and will have reduced visual acuity. Consideration should be given to doubling the distance of the observer.

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

This subclause of the GS is required.

201.7.2.4.101, 201.2.13.101, 201.7.2.101 and 201.7.2.101

These subclauses are required.

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

This subclause of the GS is required.

7.4 Marking of controls and instruments

This subclause of the GS is required.

201.7.4.2 Control devices

This subclause is required.

201.7.4.3 Units of measurement

This subclause is required.

7.5 Safety signs

This subclause of the GS is required.

7.6 Symbols

This subclause of the GS is required.

7.7 Colours of the insulation of conductors

This subclause of the GS is required.

7.8 Indicator lights and controls

This subclause of the GS is required.

NOTE The pending amendment to the GS clarifies this requirement.

7.9 ACCOMPANYING DOCUMENTS

This subclause of the GS is required.

201.7.9.1 Additional general requirements

This subclause is required.

201.7.9.2.1.101, 201.7.9.2.1.102 and 201.7.9.2.9.101

These subclauses are required except for the portions of these subclauses relating to LAY OPERATORS are not required.

Rationale: OPERATORS of an EUV are trained professional healthcare providers.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

Elements e) and g) are not required as they are not relevant in this situation.

201.7.9.2.8.101, 201.7.9.2.12, 201.7.9.2.13.101 and 201.7.9.2.14.101

These subclauses are required.

201.7.9.3.1.101 and 201.7.9.3.101

These subclauses are required.

Clause 8 Protection against electrical HAZARDS from ME EQUIPMENT

This Clause of the GS is generally required.

NOTE: Unless there are electrical connections to the PATIENT (e.g. monitoring ACCESSORIES) or heated breathing tubes or electrically powered ACCESSORIES (e.g. expiratory valves located proximal to the PATIENT), the plastic breathing tubes provide adequate floating electrical isolation for PATIENT LEAKAGE CURRENT.

NOTE: Commercially available ITC (information technology communications) power supplies can be used, but electrical safety criteria (e.g. ENCLOSURE TOUCH CURRENTS and dielectric withstand) are likely to exceed 60601-1 limits. This can be mitigated in several ways such as:

- Use of a low leakage SEPARATION DEVICE (isolation transformer) (see 16.5 of the GS)
- A second PERMANENTLY INSTALLED PROTECTIVE EARTH CONNECTION (see 16.6 of the GS)
- Instructing the OPERATOR to not touch the EUV and the PATIENT at the same time

Clause 9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

This Clause of the GS is required.

201.9.4.3.101 Additional requirements for instability from unwanted lateral movement

This subclause is not required.

Rationale: This requirement is for equipment intended to be used while moving in e.g. a car.

201.9.4.4 Grips and other handling devices

This subclause is recommended but not required.

Rationale: This requirement is intended to make it easy to move the equipment around between uses. That is not crucial for use during a pandemic.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

This subclause is not required.

Rationale: This test is hard to perform and takes expensive equipment to perform. It only provides information for disclosure that is not crucial for use during a pandemic.

Clause 10 Protection against unwanted and excessive radiation HAZARDS

This Clause of the GS is required.

Clause 11 Protection against excessive temperatures and other HAZARDS

This Clause of the GS is required.

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

This subclause is only applicable if a heated humidifier is utilized. See ISO 80601-2-74.

201.11.6.6 CLEANING and DISINFECTION of ME EQUIPMENT or ME SYSTEM

This subclause is required.

201.11.7 BIOCOMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

This subclause is recommended but not required.

The chosen materials for the GAS PATHWAYS need to be reasonably pure and simple in nature (minimize the use of additives where possible). Avoid Polyvinyl chloride (PVC) in the GAS PATHWAYS. When possible, efforts should be taken to use materials which have a long history of safe use in currently marketed medical devices. Care is needed to ensure that gas pathways are free of foreign material (e.g. oil, particles, volatile organic compounds, mold release agents should be avoided in the GAS PATHWAYS). Care is needed to ensure that gas pathways do not contain toxic compounds (e.g., formaldehyde), and do not release noxious gases (e.g., ozone, carbon monoxide) and fumes. The ACCOMPANYING DOCUMENTS should include cautionary statement for any BIOCOMPATIBILITY identified RISK.

Rationale: The tests of ISO 18562 (series)[10] are very expensive, time consuming to perform and require very specialized test equipment. Requiring these tests for an EUV would so delay their availability such that new designs would not be available when needed.

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT ALARM CONDITION

This subclause is required.

An external UPS (uninterruptable power supply) may be used to fulfill this requirement.

Rationale: The power back up and appropriate notification of power loss is what is important. It need not be integrated into the EUV.

201.11.8.101.2 Alternative power supply/SUPPLY MAINS

This subclause is only required if the EUV is TRANSIT-OPERABLE.

Rationale: For pandemic treatment, an EUV is not required to be TRANSIT-OPERABLE.

Clause 12 Accuracy of controls and instruments and protection against hazardous outputs

This Clause of the GS is required.

[10] ISO 18562 (series), *Biocompatibility evaluation of breathing gas pathways in healthcare applications*

201.12.1 Accuracy of controls and instruments

This subclause is not required.

Rationale: These requirements are intended for home use by LAY OPERATORS.

201.12.1.101, 201.12.1.102 and 201.12.1.103 (breath types)

These subclauses are required.

201.12.2.101 USABILITY of ME EQUIPMENT

This subclause is required except for d) that is not applicable.

Rationale: Requirement d) is related to home use by LAY OPERATORS.

201.12.4 Protection against hazardous output

All subclauses of 201.12.4 are required.

201.12.101 Protection against accidental adjustments

This subclause is required.

Clause 13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

This Clause of the GS is required.

201.13.2.101 * Additional specific SINGLE FAULT CONDITIONS

This subclause is required.

201.13.2.102 * Independence of ventilation control function and related RISK CONTROL measures

This subclause is required.

Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

This Clause of the GS is required.

Clause 15 Construction of ME EQUIPMENT

This Clause of the GS is required.

201.15.102 Pre-use check

This subclause does not apply.

Rationale: These requirements are directed to the needs of a LAY OPERATOR.

Clause 16 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

This Clause of the GS is required.

201.16.1.101 Additional general requirements for ME SYSTEMS

This subclause is required.

Clause 17 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

See Clause 202.

201.101 Gas connections

This subclause is required.

201.102 Requirements for the VBS and ACCESSORIES

This subclause is required.

201.103 Spontaneous breathing during loss of power supply

This subclause is required.

201.104 Training

This subclause is required.

201.105 Indication of duration of operation

This subclause is recommended but not required.

Rationale: These early warning maintenance-related requirements are not absolutely necessary in a pandemic situation.

201.106 FUNCTIONAL CONNECTION

This subclause is required.

201.107 Display loops

This subclause is required.

201.108 POWER SUPPLY CORDS

This subclause is required.

201.109 VENTILATORY SUPPORT EQUIPMENT security

This subclause is not required.

Rationale: These requirements are needed when there are LAY OPERATORS.

202 Electromagnetic disturbances — Requirements and tests

This Clause is recommended but not required.

Rationale: The tests of IEC 60601-1-2 are time consuming and expensive set of tests that take very specialized equipment. Requiring these tests for an EUV would delay availability such that new designs might not be available when needed. Disclosure that these tests have not been performed and that other equipment must be kept at a distance should be considered sufficient.

206 Usability

This Clause is recommended but not required.

Rationale: USABILITY as described in IEC 60601-1-6 ensures safety by proscribing a design PROCESS. A proper USABILITY evaluation is extremely time consuming and requires subject matter experts. A hard to use EUV can be better than no EUV.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

This Clause is recommended but not required.

Rationale: Full compliance with IEC 60601-1-8 would be helpful to the OPERATORS as they would more readily understand the operation of the EUV ALARM SYSTEM. Care needs to be taken with auditory ALARM SIGNALS to ensure that they are not too obtrusive, appropriately priority encoded (so that more urgent problems are more highlighted) and there must be a means to inactivate any auditory ALARM SIGNAL. The ALARM SYSTEM, ALARM LIMITS, and ALARM CONDITION priorities are complex areas to optimize for USABILITY. Annex A of IEC 60601-1-8 provides a great deal of guidance.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

This Clause is not required.

Rationale: These requirements relate to home use.