Emergency use ventilator (EUV) design guidance

Revisions are expected to be made to this document as the COVID-19 situation evolves. Please go to https://www.aami.org/covid_cr to find the most current version as well as past versions. This document is freely available and may be shared with all interested stakeholders. Contact celliott@aami.org with any comments or questions.

Approved 8 April 2020 and reaffirmed 6 October 2022 by AAMI

Abstract: Provides targeted design constraints to enable rapid development of emergency use ventilators (EUV) to treat patients with COVID-19 respiratory failure. Also intended to guide the review of an EUV by an authority having jurisdiction.

Keywords: COVID-19
AAMI Consensus Report

A Consensus Report (CR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) developed to provide concise, prompt and practical guidance on narrowly focused topics of high importance to the health technology community. A Consensus Report is intended to provide initial consensus guidance in response to an urgent/immediate need for guidance in the following instances:

- While more robust data/information develops on emergent areas
- When variation in the development, implementation or use of a product or process exists
- When existing standards or other documents require additional context/clarification

A Consensus Report is not subject to the same formal process as a standard and while similar in nature to a technical information report (TIR), a CR is based on the collective knowledge and experience of a selected group of stakeholders and has not undergone the wider reviews of a TIR or standard and offers an even greater response time.

CAUTION NOTICE: This AAMI CR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, technical information reports, consensus reports and other types of technical documents developed by AAMI are voluntary, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Rd, Suite 300, Arlington, VA 22203-1633.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task Group representation</td>
<td>iv</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>v</td>
</tr>
<tr>
<td>Purpose</td>
<td>1</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>Review of the requirements of ISO 80601-2-80 and their applicability to an EUV</td>
<td>2</td>
</tr>
</tbody>
</table>
Task Group representation

Association for the Advancement of Medical Instrumentation

COVID-19 Response Team Members

This AAMI Consensus Report (CR) was developed by a task group under the auspices of the AAMI COVID-19 Response Team.

The AAMI COVID-19 Response Team had the following members:

**Cochairs:**
- Jennifer Danieley
- David Feinstein
- Julian Goldman

**Members:**
- Simona Bancos, FDA/CDRH
- Andrew Bath, ResMed Inc.
- Brandon Blakely, FDA/CDRH
- Brad Bonnette, ECRI Institute
- Caitlin Brady, Intertek
- David Busch, UT Southwestern Medical Center
- Anthony Ciccarello, Philips
- Steven Dain, University of Western Ontario
- Rakhi Dalal, FDA/CDRH
- Jennifer Danieley, FDA/CDRH
- Andy Doering, Medtronic
- Simon Dunham, Weill Cornell Medicine
- David Feinstein, American Society of Anesthesiologists (ASA)
- Bruce Friedman, GE Healthcare
- Hamed Ghods, FDA/CDRH
- Julian Goldman, Partners HealthCare System
- Ralf Heesch, Draeger Medical Systems Inc.
- Heidi Horn, Nuvolo Technologies
- Fernando Isaza, Philips
- Michael Jaffe, Cardiorespiratory Consulting LLC
- Gardner Kimm, Medtronic Inc Campus
- Robert Kopotic, Edwards Lifesciences
- Hubertus Lasthaus, VitalAire Germany
- Ed Madsen, Avanos Medical
- Phoebe Mainland, Alfred Health
- Madeleine Manousaridis, Standards Australia
- Benoit Marchal, Air Liquide
- Thomas Marmet, GE Healthcare
- Debra Milamed, Harvard University
- Cyndy Miller, Medtronic Inc Campus
- Bryant Moeller, ResMed Inc.
- Curtis Morgan, 3M Health Care
- Akito Ohmura, Teikyo University-Mizonokuchi Hospital
- David Osborn, Philips
- John Stark, 3M Health Care
- Robert Steurer, Steurer Consulting Group
- Dongbo Wang, FDA/CDRH
- Sandy Weininger, FDA/CDRH

NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.
Acknowledgments

AAMI gratefully acknowledges the writing team members, Julian Goldman, Dave Osborn, Anthony Ciccarello and Sandy Weininger for their outstanding and expeditious work in preparing these drafts for committee review and approval.
Emergency use ventilator (EUV) 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) or life-supporting homecare ventilators (ISO 80601-2-72).

NOTE This document is intended to be used in conjunction with AAMI CR502:2020, End user disclosures for emergency use ventilators (EUVs).

Introduction

The requirements outlined in this paper are modeled on ISO 80601-2-80:2018 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.

---

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
• Inspiratory airway pressure exceeded.

• Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm condition).

• Tidal volume not achieved or exceeded.

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 (FiO₂) 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, FiO₂, ventilation mode).

• The current delivery (e.g., inspiratory pressure, tidal volume, respiratory rate, PEEP, and FiO₂ 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:

• FiO₂ 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 FiO₂ would be 90%.

• Set PEEP (i.e. BAP) (5 to 20) cmH₂O in no more than 5 cmH₂O 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) cmH₂O preferably adjustable in steps of no more than 5 cmH₂O

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 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 IEC 60601-1, 11.2.2) are fully applicable.

\(^4\) 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*

\(^8\) ANSI, https://webstore.ansi.org/

\(^9\) AAMI, https://my.aami.org/store/
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 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, 201.7.2.13.101, 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 that 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 1 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 2 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 IEC 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 recommended but not required, except for 9.3 that 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)\(^\text{10}\) 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.

\(^{10}\) ISO 18562 (series), Biocompatibility evaluation of breathing gas pathways in healthcare applications
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.

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 recommended but not 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  ME SYSTEMS

This Clause of the GS is required.

201.16.1.101  Additional general requirements for ME SYSTEMS

This subclause is required.

Clause 17  Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS


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.
VENTILATORY SUPPORT EQUIPMENT security

This subclause is not required.

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

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.

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.

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.

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.