

AAMI Consensus Report

**Emergency Use Ventilator
(EUV) Design Guidance**

AAMI CR501:2020/(R)2022

Emergency use ventilator (EUV) design guidance

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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

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Task Group representation

Association for the Advancement of Medical Instrumentation

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2 **Emergency use ventilator (EUV) design guidance**

3 **Purpose**

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

7 It is recognized that the surge in COVID-19 is requiring extraordinary measures to provide mechanical
8 ventilatory support to keep pace with clinical need. This global community of clinicians, engineers,
9 manufacturers, regulators, and others are responding to this need by designing and producing, inexpensive,
10 and often open-source, ventilators of varying complexity and capabilities for rapid deployment. This
11 document identifies clinical, engineering and test requirements appropriate to support safe operation. The
12 document identifies requirements that are required for non-EUVs but might not be required for EUVs that
13 have appropriate disclosures. Therefore, ventilators complying with the requirements of this document need
14 not provide a level of performance equivalent to that of critical care ventilators (ISO 80601-2-12¹) or life-
15 supporting homecare ventilators (ISO 80601-2-72²).

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

18 **Introduction**

19 The requirements outlined in this paper are modeled on ISO 80601-2-80:2018³ presuming usage in
20 traditional healthcare facilities (e.g. hospitals, assisted living facilities, nursing homes) as well as spaces
21 converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university
22 dormitories, motels). This paper presumes that the operators of the EUV are all trained professional
23 healthcare providers and not lay persons. Hence the requirements of ISO 80601-2-80:2018 specifically for
24 lay operators or the home healthcare environment are considered not applicable to an EUV intended for
25 the treatment of COVID-19 patients.

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

- 29 • Gas or electricity supply failure.
- 30 • 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*

- 31 • Inspiratory airway pressure exceeded.
- 32 • Inspiratory and PEEP pressure not achieved (equivalent to disconnection alarm condition).
- 33 • Tidal volume not achieved or exceeded.

34 The ventilatory support needs of a COVID-19 patient can range from simple BIPAP (bilevel positive airway
 35 pressure) for patients that are breathing spontaneously to mandatory ventilation in either a pressure-support
 36 or volume control mode. Additionally, these patients are very likely to require inspired oxygen
 37 concentrations (FiO₂) in excess of the 21 % contained in room air.

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

- 39 • The current settings (e.g., inspiratory pressure, tidal volume, frequency, PEEP, FiO₂, ventilation
 40 mode).
- 41 • The current delivery (e.g., inspiratory pressure, tidal volume, respiratory rate, PEEP, and FiO₂ at
 42 the patient-connection port).

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

- 44 • FiO₂ over the range of 21 % (ambient) to 95 % of the source oxygen concentration input to the EUV
 45 in no more than 10 % steps

46 NOTE When oxygen is provided by an oxygen concentrator, the input concentration is not 99.5%, but can
 47 vary from 90% to 96% in which case the upper limit of FiO₂ would be 90 %.

- 48 • Set PEEP (i.e. BAP) (5 to 20) cmH₂O in no more than 5 cmH₂O steps
- 49 • I:E ratio (ratio of inspiratory to expiratory time) of 1:2 preferably adjustable from 1:1 to 1:3
- 50 • For mandatory modes, respiratory rate from (10 to 30) inflations/min preferably adjustable in steps
 51 of no more than 2 inflations/min
- 52 • Tidal volume (350 to 450) ml ±10 % in no more than steps of 50 ml, preferably a lower range of
 53 250 ml and an upper range of 600 ml or 800 ml
- 54 • Where applicable, inspiratory pressure limit (15 to 40) cmH₂O preferably adjustable in steps of no
 55 more than 5 cmH₂O

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

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

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

61 Remember that ISO 80601-2-80 is a particular standard so it is written on top of (i.e. it modifies) the GS
62 (the general standard, IEC 60601-1⁴) and the collateral standards (i.e. IEC 60601-1-2⁵ on EMC, IEC 60601-
63 1-6⁶ on usability and IEC 60601-1-8⁷ on alarms). There are additional applicable collateral standards (and
64 hence requirements) if the EUV is intended for home use, ambulance use or as part of a physiological
65 closed loop control system. These standards can be purchased from many sources including ANSI⁸ and
66 AAMI⁹.

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

69 **201.4.11.101 Additional requirements for pressurized gas input**

70 Fully required.

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

72 **Clause 5 General requirements for testing of ME EQUIPMENT**

73 This Clause of the GS is fully required.

74 **201.5.101 Additional requirements for the general requirements for testing of ME EQUIPMENT**

75 Fully required.

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

77 **Clause 6 Classification of ME EQUIPMENT and ME SYSTEMS**

78 This Clause of the GS is fully required.

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

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

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

85 Since the EUV is expected to handle gas with an oxygen concentration in excess of the ambient 25 %, the
86 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/>

87 **201.6.101 Additional requirements for classification of ME EQUIPMENT and ME SYSTEMS**

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

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

90 **Clause 7 ME EQUIPMENT identification, marking and documents**

91 **7.1 General**

92 This subclause of the GS is recommended but not required.

93 Rationale: Although ensuring that the EUV can be read both over the indicated illumination level and the
94 indicated cone of visibility is recommended, in this pandemic situation it is not considered mandatory. It is
95 noted that operators are likely wearing PPE and will have reduced visual acuity. Consideration should be
96 given to doubling the distance of the observer.

97 **7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**

98 This subclause of the GS is required.

99 **201.7.2.4.101, 201.7.2.13.101, and 201.7.2.101**

100 These subclauses are required.

101 **7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**

102 This subclause of the GS is required.

103 **7.4 Marking of controls and instruments**

104 This subclause of the GS is required.

105 **201.7.4.2 Control devices**

106 This subclause is required.

107 **201.7.4.3 Units of measurement**

108 This subclause is required.

109 **7.5 Safety signs**

110 This subclause of the GS is required.

111 **7.6 Symbols**

112 This subclause of the GS is required.

113 **7.7 Colours of the insulation of conductors**

114 This subclause of the GS is required.

115 **7.8 Indicator lights and controls**

116 This subclause of the GS is required.

117 NOTE The pending amendment to the GS clarifies this requirement.

118 **7.9 ACCOMPANYING DOCUMENTS**

119 This subclause of the GS is required.

120 **201.7.9.1 Additional general requirements**

121 This subclause is required.

122 **201.7.9.2.1.101, 201.7.9.2.1.102 and 201.7.9.2.9.101**

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

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

126 **201.7.9.2.2.101 Additional requirements for warnings and safety notices**

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

128 **201.7.9.2.8.101, 201.7.9.2.12, 201.7.9.2.13.101 and 201.7.9.2.14.101**

129 These subclauses are required.

130 **201.7.9.3.1.101 and 201.7.9.3.101**

131 These subclauses are required.

132 **Clause 8 Protection against electrical HAZARDS from ME EQUIPMENT**

133 This Clause of the GS is generally required.

134 NOTE 1 Unless there are electrical connections to the PATIENT (e.g. monitoring ACCESSORIES) or heated breathing tubes
135 or electrically powered ACCESSORIES (e.g. expiratory valves located proximal to the PATIENT), the plastic breathing tubes
136 provide adequate floating electrical isolation for PATIENT LEAKAGE CURRENT.

137 NOTE 2 Commercially available ITC (information technology communications) power supplies can be used, but
138 electrical safety criteria (e.g. ENCLOSURE TOUCH CURRENTS and dielectric withstand) are likely to exceed IEC 60601-1
139 limits. This can be mitigated in several ways such as:

- 140 • use of a low leakage SEPARATION DEVICE (isolation transformer) (see 16.5 of the GS);
- 141 • a second PERMANENTLY INSTALLED PROTECTIVE EARTH CONNECTION (see 16.6 of the GS);
- 142 • instructing the OPERATOR to not touch the EUV and the PATIENT at the same time.

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

144 This Clause of the GS is recommended but not required, expect for 9.3 that is required.

145 **201.9.4.3.101 Additional requirements for instability from unwanted lateral movement**

146 This subclause is not required.

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

148 **201.9.4.4 Grips and other handling devices**

149 This subclause is recommended but not required.

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

152 **201.9.6.2.1.101 Additional requirements for audible acoustic energy**

153 This subclause is not required.

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

156 **Clause 10 Protection against unwanted and excessive radiation HAZARDS**

157 This Clause of the GS is required.

158 **Clause 11 Protection against excessive temperatures and other HAZARDS**

159 This Clause of the GS is required.

160 **201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT**

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

162 **201.11.6.6 CLEANING and DISINFECTION of ME EQUIPMENT or ME SYSTEM**

163 This subclause is required.

164 **201.11.7 BIOCOMPATIBILITY of ME EQUIPMENT and ME SYSTEMS**

165 This subclause is recommended but not required.

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

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

177 **201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME**
178 **EQUIPMENT ALARM CONDITION**

179 This subclause is required.

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

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

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

183 **201.11.8.101.2 Alternative power supply/SUPPLY MAINS**

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

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

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

187 This Clause of the GS is required.

188 **201.12.1 Accuracy of controls and instruments**

189 This subclause is not required.

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

191 **201.12.1.101, 201.12.1.102 and 201.12.1.103 (breath types)**

192 These subclauses are required.

193 **201.12.2.101 USABILITY of ME EQUIPMENT**

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

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

196 **201.12.4 Protection against hazardous output**

197 All subclauses of 201.12.4 are required.

198 **201.12.101 Protection against accidental adjustments**

199 This subclause is required.

200 **Clause 13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT**

201 This Clause of the GS is required.

202 **201.13.2.101 * Additional specific SINGLE FAULT CONDITIONS**

203 This subclause is required.

204 **201.13.2.102 * Independence of ventilation control function and related RISK CONTROL measures**

205 This subclause is required.

206 **Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**

207 This Clause of the GS is recommended but not required.

208 **Clause 15 Construction of ME EQUIPMENT**

209 This Clause of the GS is required.

210 **201.15.102 Pre-use check**

211 This subclause does not apply.

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

213 **Clause 16 ME SYSTEMS**

214 This Clause of the GS is required.

215 **201.16.1.101 Additional general requirements for ME SYSTEMS**

216 This subclause is required.

217 **Clause 17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS**

218 See Clause 202.

219 **201.101 Gas connections**

220 This subclause is required.

221 **201.102 Requirements for the VBS and ACCESSORIES**

222 This subclause is required.

223 **201.103 Spontaneous breathing during loss of power supply**

224 This subclause is required.

225 **201.104 Training**

226 This subclause is required.

227 **201.105 Indication of duration of operation**

228 This subclause is recommended but not required.

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

231 **201.106 Functional connection**

232 This subclause is required.

233 **201.107 Display loops**

234 This subclause is required.

235 **201.108 Power supply cords**

236 This subclause is required.

237 **201.109 VENTILATORY SUPPORT EQUIPMENT security**

238 This subclause is not required.

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

240 **202 Electromagnetic disturbances — Requirements and tests**

241 This Clause is recommended but not required.

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

246 **206 USABILITY**

247 This Clause is recommended but not required.

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

251 **208 General requirements, tests and guidance for alarm systems in medical electrical equipment
252 and medical electrical systems**

253 This Clause is recommended but not required.

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

260 **211 Requirements for medical electrical equipment and medical electrical systems used in the
261 home healthcare environment**

262 This Clause is not required.

263 Rationale: These requirements relate to home use.