

***AAMI Consensus Report***

Basic Safety of Emergency Use  
**Medical Devices**

*AAMI/CR507:2020*



# Basic safety of emergency use medical devices

Revisions are expected to be made to this document as the COVID-19 situation evolves. Please go to [https://www.aami.org/covid\\_cr](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 [celliot@ami.org](mailto:celliot@ami.org) with any comments or questions.

Approved 6 May 2020 by  
**AAMI**

**Abstract:** The purpose of this document is to provide a general overview of key safety issues to be considered when developing medical equipment under the scope of an FDA emergency use authorization (EUA) such as the FDA Emergency Use Authorization (EUA) on Ventilators, issued March 24, 2020.

**Keywords:** COVID-19

## AAMI Consensus Report

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- When existing standards or other documents require additional context/clarification

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## Task Group representation

### Association for the Advancement of Medical Instrumentation

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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.

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## 2 **Basic safety of emergency use medical devices**

### 3 **1 Purpose**

4 The purpose of this document is to provide a general overview of key safety issues to be considered when  
5 developing medical equipment under the scope of an FDA emergency use authorization (EUA) such as the  
6 FDA Emergency Use Authorization (EUA) on Ventilators, issued March 24, 2020.

7 This document is intended to be used as a supplement to recent AAMI Consensus Reports issued in  
8 response to the COVID-19 pandemic for emergency use ventilation devices. Documents published at the  
9 time of writing are listed in the References and Resources below. The list of published reports and guidance  
10 is expected to grow; the current list is available at: [https://www.aami.org/news-resources/covid-19-](https://www.aami.org/news-resources/covid-19-updates/covid_cr)  
11 [updates/covid\\_cr](https://www.aami.org/news-resources/covid-19-updates/covid_cr). The content of this document is intended to supplement, not replace, the existing AAMI  
12 consensus reports on this topic.

13 This document focuses on the general requirements for basic safety of medical electrical equipment as  
14 defined and specified in the International Electrotechnical Commission (IEC) 60601 series of standards.  
15 The AAMI guidance documents referenced above are also based on the requirements of the IEC 60601  
16 series. The requirements of these standards are widely accepted as providing a baseline of the safety of  
17 medical electrical equipment, including equipment such as ventilators and other respiratory support  
18 devices.

19 Every noncompliance with a requirement in the IEC 60601 series of standards is widely viewed as posing  
20 unacceptable risk to patients and/or operators. In an emergency, when equipment meeting established  
21 safety standards is not available, it might become prudent to consider improvising alternative solutions that  
22 do not have all the safeguards afforded by use of the standard. However, this should be done with a full  
23 understanding of the increased risk. This document should not be interpreted as conferring approval to  
24 develop or use equipment that does not meet established safety standards. That approval must come from  
25 other sources. However, recognizing that difficult times can require difficult choices, this document was  
26 prepared to provide the developers of improvised medical equipment some insight into the importance of  
27 these standards. While this document provides simplified explanations and pragmatic advice addressing  
28 some of the more important safety requirements of IEC 60601-1<sup>1</sup>, it is far from a comprehensive treatment  
29 of the subject.

### 30 **2 References and resources**

31 Free access to critical standards provided by ANSI during the public health emergency (registration  
32 required):

33 [https://www.ansi.org/news\\_publications/news\\_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-](https://www.ansi.org/news_publications/news_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-284d997323b2)  
34 [284d997323b2](https://www.ansi.org/news_publications/news_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-284d997323b2)

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<sup>1</sup> The U.S. national version is ANSI/AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. The U.S. national version contains modifications to harmonize with the U.S. National Electric Code and is recognized by the U.S. Food and Drug Administration (FDA).

35 Free access to AAMI Consensus Reports (CRs):

36 [https://www.aami.org/news-resources/covid-19-updates/covid\\_cr](https://www.aami.org/news-resources/covid-19-updates/covid_cr)

37 FDA Emergency Use Authorization (EUA): <https://www.fda.gov/media/136423/download>

38 FDA Enforcement Policy for Respiratory Devices: <https://www.fda.gov/media/136318/download>

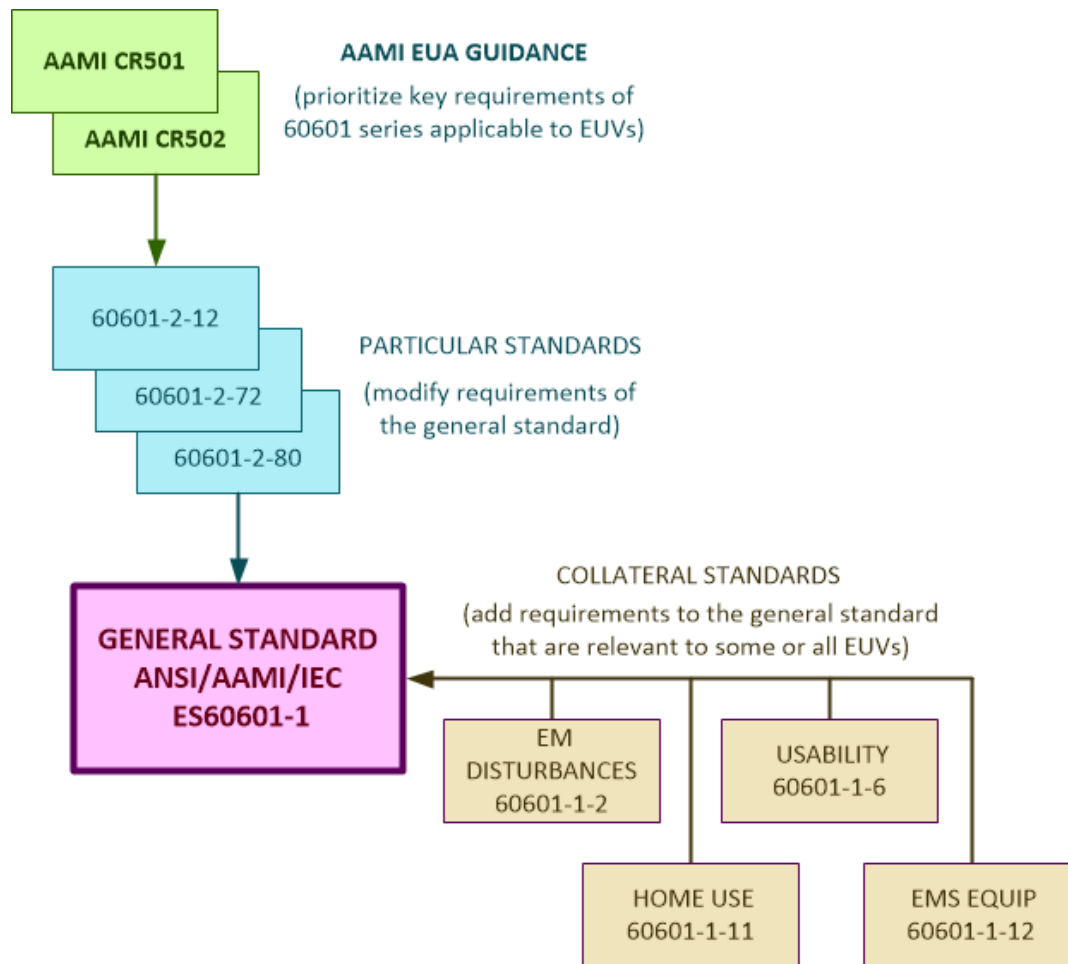
39 Additional information on available resources:

40 <https://www.aami.org/news-resources/covid-19-updates/coronavirus-resources-for-the-field>

41 Referenced Standards and Guidance:

42 IEC 60601-1:2012, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and*  
43 *Essential Performance*. U. S. National Version: ANSI/AAMI ES 60601-1

44 IEC 60601-1-2:2014, *Medical Electrical Equipment – Part 1-2: General requirements for basic safety and*  
45 *essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*. U.  
46 S. National Version: ANSI/AAMI/IEC 60601-1-2



47

48

**Figure 1 - IEC 60601-1 Series and Current Guidance<sup>2</sup>**

49 IEC 60601-1-6:2013, *Medical electrical equipment – Part 1-6: General requirements for basic safety and*  
 50 *essential performance – Collateral standard: Usability*

51 IEC 60601-1-8:2012, *Medical Electrical Equipment – part 1-8: General requirements for basic safety and*  
 52 *essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems*  
 53 *in medical electrical equipment and medical electrical systems.* U. S. National Version: ANSI/AAMI/IEC  
 54 60601-1-8

55 IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and*  
 56 *essential performance – Collateral Standard: Requirements for medical electrical equipment and medical*  
 57 *electrical systems used in the home healthcare environment (home use ventilators)*

58 ISO 80601-2-12:2020, *Medical electrical equipment – Part 2-12: Particular requirements for the basic safety*  
 59 *and essential performance of critical care ventilators*

<sup>2</sup> This figure is provided to explain the relationship between referenced standards and reports; it does not include all necessary standards. Note, the particular standards may also make modifications to the collateral standards. See Clause 3, AAMI CR500:2019, Introduction to IEC 60601 Series.

60 ISO 80601-2-72:2015, *Medical electrical equipment – Part 2-72: Particular requirements for basic safety*  
61 *and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

62 ISO 80601-2-80:2018, *Medical electrical equipment – Part 2-80: Particular requirements for basic safety*  
63 *and essential performance of home healthcare environment ventilatory support equipment for ventilator*  
64 *insufficiency*

65 IEC 60529:2013, *Degree of protection provided by enclosures (IP Codes)*

66 IEC 62133-1:2017, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety*  
67 *requirements for portable sealed secondary cells, and for batteries made from them, for use in portable*  
68 *applications – Part 1: Nickel systems*

69 IEC 62133-2:2017, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety*  
70 *requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in*  
71 *portable applications – Part 2: Lithium systems. U. S. National Version: UL 62133-2*

72 CGA V-5, *Standard for Diameter Index Safety System (Noninterchangeable Low Pressure Connections for*  
73 *Medical Gas Applications)*

74 ISO 5359:2017, *Anesthetic and respiratory equipment — Low-pressure hose assemblies for use with*  
75 *medical gases*

76 AAMI CR500:2019, *Introduction to IEC 60601 Series*

77 AAMI CR501:2020, *Emergency Use Ventilator (EUV) Design Guidance*

78 AAMI CR502:2020, *End User Disclosures for Emergency Use Ventilators (EUVs)*

79 AAMI CR503: 2020 *Emergency Use Resuscitator Systems Design Guidance*

80 AAMI CR504:2020, *End User Disclosures for Emergency Use Resuscitator Systems*

81 AAMI CR505:2020, *Emergency Use CPAP/BiPAP Design Guidance (15 April 2020, Revision 1)*

82 AAMI CR506:2020, *End User Disclosure for CPAP/BiPAP (15 April 2020, Revision 1)*

83 A subset of report templates are available in MS Word using the link below. These reports may be useful  
84 for documenting compliance with the AAMI CR Documents when submitting an EUA Application.

85 <https://isotc.iso.org/livelink/livelink?func=ll&objId=21187586&objAction=browse&viewType=1>

86 ANSI C63.18-2014 (R 2019), *American National Standard Recommended Practice for an On-Site, Ad Hoc*  
87 *Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency*  
88 *(RF) Emissions from RF Transmitters*

89 FDA guidance - Information to Support a Claim of EMC of Electrically-Powered Medical Devices:  
90 <https://www.fda.gov/media/94758/download>

91 FDA guidance - Radio Frequency Wireless Technology in Medical Devices:  
92 <https://www.fda.gov/media/71975/download>

93 **3 Introduction to the IEC 60601-1 Series**

94 The IEC has published a series of safety standards that establish comprehensive design, construction,  
95 safety, and safety-related performance requirements for medical electrical equipment<sup>3</sup> and systems. IEC  
96 60601-1 is the principal standard in the series. It specifies requirements that are broadly applicable to most  
97 medical devices, as well as definitions and rationales that support the requirements. It is often referred to  
98 as the *general standard*. In the U. S., IEC 60601-1 has been adopted along with a set of deviations required  
99 for compatibility with U. S. building codes such as the National Electrical Code. Its formal designation is  
100 ANSI/AAMI ES60601-1 (including all existing corrections and amendments). This is the current version to  
101 use for medical electrical equipment and systems sold in the U. S.

102 In addition to the general standard, the IEC 60601 series includes what are called *collateral standards* that  
103 impose additional requirements to address specific environments, technological hazards, or types of  
104 equipment. These are considered mandatory extensions to the general standard to the extent that the risks  
105 addressed by the standards are applicable to the device in question. Collateral standards are numbered  
106 IEC 60601-1-XX.

107 A third category of standards in the IEC 60601 series are the so-called *particular standards*, which add to,  
108 subtract from, or modify the requirements of the general and collateral standards for a specific type of  
109 medical device, such as infusion pumps or ventilators. Particular standards are numbered IEC 60601-2-XX  
110 or ISO/IEC 80601-2-XX, depending on whether they were developed under IEC or International  
111 Organization for Standardization (ISO) leadership.<sup>4</sup>

112 When assessing conformity to IEC 60601, one merges all the applicable requirements from the general  
113 and collateral standards as modified by the requirements of the relevant particular standard. It should be  
114 noted that in case of conflict, particular standards take precedence.

115 Figure 1 shows how these relationships work, including guidance on applying parts of this series during the  
116 COVID-19 emergency.

117 **4 General Considerations**

118 Many of the requirements from IEC 60601-1 are discussed at a high level in the remaining sections of this  
119 document. Given enough time, an EUV being designed and manufactured under the EUA should fully  
120 comply with the appropriate standards (e.g., IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 80601-2-80),  
121 and most manufacturers choose to utilize independent testing laboratories to assess conformity. With the  
122 urgent need to combat COVID-19, it is recognized that there is not likely to be enough time to comply fully,  
123 let alone verify compliance with the applicable standards. This document intends to highlight the key items  
124 that should be considered. This document could be useful in assessing the risk associated with an EVU  
125 and provides some guidance on how these risks can be managed.

126 This document is intended to provide guidance for use only during the global pandemic associated with  
127 COVID-19 and should not be used as a basis for designing medical equipment that will be used following  
128 the pandemic.

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<sup>3</sup> These terms are defined in IEC 60601-1, definitions 3.63 and 3.64. These should not be confused with medical devices which is a broader definition

<sup>4</sup> IEC and ISO are eminent international standards development organizations (SDOs). IEC focuses on standards for electric and electronic products, systems, and services. ISO standards have a broader scope, focusing on both process and product standards meeting the needs of businesses, customers, and regulators. While the first edition of the 60601-1 general standard was developed by IEC, both organizations now jointly administer the IEC 60601 series. The formal designation of a standard in the series reflects whether its development was led by an IEC or ISO committee, and can also reflect a national adoption having minor differences from the international version of the standard.

129 The sections below represent the most applicable requirements. At this time, the American National  
130 Standards Institute (ANSI) has made the standards referenced in this document, and many others available  
131 free of charge during this crisis. Information on how to register and download free standards can be found  
132 at the website listed below:

133 [https://www.ansi.org/news\\_publications/news\\_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-  
134 284d997323b2](https://www.ansi.org/news_publications/news_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-284d997323b2)

135 To download and view these free standards, you will need to register with ANSI and have Adobe Acrobat  
136 Reader with a plugin FileOpen (this plugin enforces the documents copyright). There is no cost to any of  
137 these necessary items/steps.

## 138 **5 Risk Mitigation Strategies**

139 ISO 14971 is the international standard that provides the framework for identifying, evaluating and  
140 controlling risk for medical devices. This standard specifies a systematic approach that can be used to  
141 complete the tasks of risk identification, risk analysis, risk control and the steps that should be taken to  
142 continue to monitor risk after devices have been placed on the market and entered into use.

143 The principles and recommendations of this document consider both the need to control risks and the  
144 urgency of bringing equipment under the scope of this guidance to patients that need them.

145 Given enough time, risk should be controlled using the following methods, listed in order of preference  
146 (highest to lowest):

- 147 1. Design Solution (ISO 14971 “inherent safety by design”) – design the equipment to remove hazard  
148 or hazardous situation completely. Examples include removing lithium ion batteries from the design  
149 or to design controls into the equipment that will address the risk associated with use of lithium ion  
150 batteries.
- 151 2. Provide Guards (ISO 14971 “protective measures in the medical device itself or in the  
152 manufacturing process”) – put protective measures in place to prevent the risks from becoming  
153 harm to the patient or operator. Examples include providing an enclosure around moving parts to  
154 prevent body parts from becoming trapped, pinched, or crushed or including alarm signals to  
155 identify a need for intervention to prevent harm.
- 156 3. Provide Warnings (ISO 14971 “information for safety”) – provide warning about a specific risk that  
157 will communicate how to avoid being harmed. These can be provided in the instructions for use, or  
158 as specific labels on the equipment. One example would be to provide a marking on parts of the  
159 equipment that could be hot, communicating that they should not be touched.

160 It is normally assumed that the instructions for use of medical equipment are unlikely to be read by all the  
161 users of the equipment. As a result, more emphasis is placed on solutions 1 and 2 above than on solution  
162 3. For equipment under the scope of this document, this assumption is magnified in that many of these  
163 devices will be novel devices (not traditional devices) or devices used for novel treatments (not their normal  
164 intended use), and the operators will not have ample time to study the instructions and labeling prior to  
165 operating the devices.

## 166 **6 Equipment Markings and Power Consumption Recommendations**

167 The equipment should be marked with the rated supply voltage, frequency and power or current  
168 consumption during normal use.

169 When possible, the power or current draw should be measured to ensure the marking is accurate.  
170 Measurement of the current draw can be made using a commonly available digital multi-meter (DMM).

171 - Set the DMM to “Amps” or “A”; if AC or DC is available, select AC. Note: Some DMMs have  
172 limitations on the current they can measure (e.g. 10 A).

173 - Carefully place the DMM in series with the line (hot) leg of the power supply (or power supply cord).

174 - Power ON the equipment and put it into the normal operating mode; if motors are used, ensure  
175 they are running. If the speed is adjustable, test at the minimum and maximum speed.

176 - Record the maximum value seen. This should be marked on the equipment.

177 - Note that the current draw can change with increasing or decreasing mains voltage. For some  
178 equipment, such as equipment having mains-powered motors, the current draw will likely increase  
179 with increasing supply voltage. In other cases, particularly when the equipment incorporates  
180 switching power supplies, maximum current draw can occur when the supply voltage is at its lowest  
181 value.

182 If a power analyzer is available, measurements can typically be made for current or power.

183 When equipment is powered using an off-the-shelf power supply, the ratings marked on the power supply  
184 should be sufficient to cover the labeling requirement provided the ratings are not exceeded during normal  
185 use. Testing should be performed to verify that off-the-shelf power supplies are not being used above their  
186 output rating, the output draw should be measured. If this is not possible to measure the output draw it is  
187 possible to check if the power supply output is exceeded by leaving the equipment running for an extended  
188 period of time in the maximum specified ambient temperature. During this time, observe the equipment;  
189 unexpected responses (e.g., loss of function) can indicate if the equipment is drawing too much  
190 current/power from the power supply. Many power supplies have built in protection that will cause them to  
191 shut down if they overheat or if too much current is drawn. If the equipment unexpectedly shuts down when  
192 left operational for extended periods of time, it is likely that the power supply ratings are being exceeded  
193 and a power supply with a higher output rating should be used. It is also important to note that motors can  
194 have similar protective devices – if they stop operating unexpectedly when running for extended periods of  
195 time, it is likely they are overheating, and different motors should be selected for the design.

## 196 **7 Electrical Safety Recommendations**

197 The main electrical safety concern that should be considered is electric shock. Note: Concerns related to  
198 fire (generally caused by electrical parts) are covered in Thermal Safety Recommendations below. It is  
199 important to note that there is a drastically different threshold of what is acceptable for patients and  
200 operators. The main reason this is the case is that a healthy, fully conscious person (typical operator) can  
201 generally remove themselves from harm’s way if they feel the effects of a minor shock (e.g. placing your  
202 tongue across a 9V battery). A patient, especially one in need of ventilation, is not able to do the same –  
203 this makes them more vulnerable to hazards than a healthy, fully conscious person. In addition, many  
204 medical devices come into intimate contact with internal organs and body tissues, where the risk of harm  
205 due to electric shock is greatly magnified.

206 Selecting components that have already been tested/certified is one way to help ensure that appropriate  
207 levels of safety are provided. A few of the key components to consider are listed below.

208 — Power Supplies:

209 ○ A power supply that will not be accessible to the patient and is compliant with IEC  
210 60950-1 or IEC 62368 will provide the expected level of safety for the operator, but not

211 for a patient-connected device. These standards are for information technology and  
212 audio/video equipment (computers, printers, monitors).

213 ○ If the power supply is (or can be in contact with the patient, it is recommended that a  
214 low leakage (current) medical grade power supply compliant with IEC 60601-1 be  
215 selected. The power supply should provide protection identified in IEC 60601-1 as  
216 means of patient protection (MOPP). When selecting an off-the-shelf power supply,  
217 operating conditions, including temperature, humidity and altitude/pressure should  
218 match both the anticipated environment for use and the specifications of the  
219 equipment. It is recommended that the design consider a minimum altitude of 3000 m.  
220 Note that this is more applicable to terrestrial applications, as cabins in commercial  
221 aircraft are pressurized, resulting in a much lower equivalent altitude.

222 — Power Supply Cords:

223 ○ If the equipment will be connected to earth ground using a three-conductor power cord,  
224 a hospital grade power cord should be used. There are additional requirements for  
225 these cords applicable to the ground connection that are intended to ensure a low  
226 impedance and durable connection. The plug configuration on these cords is a NEMA  
227 5-15 Hospital Grade Plug, marked with “Hospital Grade”, “Hosp. Grade” or “HG”, and  
228 with a green dot next to the ground pin on the attachment plug.

229 ○ If the equipment is Class II (non-grounded), cord with a NEMA 1-15P (polarized) plug  
230 should be used.

231 ○ There might be additional considerations based on the intended environment of use.  
232 See the Safety Ground section.

233 — Electromagnetic Interference (EMI)/Electromagnetic Compatibility (EMC) Line Filters:

234 ○ If EMI/EMC filters are used in your commercial or custom-designed power supply, they  
235 should be medical grade. Medical-grade filters generally have a construction that helps  
236 limit leakage current while still providing the necessary filtering to assure  
237 electromagnetic compatibility. Some medical-grade power supplies that are compliant  
238 with IEC 60601 incorporate low-leakage EMI/EMC filtering, but others pass only with  
239 the addition of an external filter. Commercial-grade power supplies, including those  
240 compliant with IEC 60950-1 or IEC 62368, typically do not meet IEC 60601 leakage  
241 current requirements. A potential solution is to use off-the-shelf Medical-grade isolation  
242 transformers to help reduce leakage current from a non-compliant power supply to an  
243 acceptable level. If the isolation transformer is external to (separate from) the  
244 equipment, it may be less likely that they will be put into use in the field.

245 — Switches, Fuses, Circuit Breakers, etc.:

246 Pay attention to the safety ratings of all components connected to mains voltage. Don't  
247 overlook associated wires, terminals, connectors, and other current-carrying hardware.  
248 Employ best practices and approved tools for assembling and wiring the device. Seek  
249 expert advice if you are unfamiliar with these practices.

250 - Fuses may be rated for high or low breaking capacity, as well as speed of  
251 operation. Labeling should be provided near the fuse or fuse holder that  
252 identifies the type and ratings of the fuse. These ratings can generally be  
253 taken from the fuse packaging or manufacturers specification/datasheet. An  
254 example would be T6.3AH/250 V where T designates time delay, A (Amps), H  
255 designates High Breaking Capacity, V (Volts). The instructions for use should  
256 also specify the fuse ratings and caution against replacing the fuse with one  
257 having different ratings.



258 Separation/Isolation of parts:

259 Separation of parts refers to keeping hazardous voltages away from people and/or non-hazardous  
260 voltages. Separation is normally achieved through the combination of the following:

- 261 - adequate physical distance (creepage/clearance<sup>5</sup>) separating hazardous voltage/low  
262 voltages/patient-connected circuitry;
- 263 - selection and use of appropriate electrical insulation materials;
- 264 - the application of a dielectric strength or hi-pot<sup>6</sup> test across the points of  
265 separation/isolation.

266 This is a complicated topic that cannot easily be described in a short guidance document.

267 Typically, an isolation diagram of the equipment is created early in the design, if this is possible, it  
268 is highly recommended. This diagram is a tool that identifies the requirements for spacings and  
269 dielectric strength along with the specific points of the equipment that will require measurement  
270 and testing. The isolation diagram indicates how the patient and operator are isolated from the  
271 mains and secondary circuits of the device and provides a simple way to evaluate different isolation  
272 options that might exist.

273 A compliance evaluation should include the measurement of creepage/clearance distances and  
274 performance of dielectric strength/hi-pot tests. At a minimum, testing the dielectric strength/hi-pot  
275 should be performed to provide some assurance the adequate separation has been achieved.

276 The key separation requirements include the following:

- 277 — Between the power supply cord Line and Neutral and the patient connection(s), there should  
278 be two means of patient protection (MOPP). Assuming the equipment is supplied by 120 VAC,  
279 the dielectric strength test value (applied for 1 min) should be 3000 V.
- 280 — Between the power supply cord Line and Neutral and ground there should be one means of  
281 operator protection (MOOP). Assuming the equipment is supplied by 120 VAC, the dielectric  
282 strength test value (applied for 1 min) should be 1000 VAC.
- 283 — Between the power supply cord Line and Neutral and any communication ports (USB, Ethernet,  
284 HDMI) there should be two MOOP. Assuming the equipment is supplied by 120 VAC, the  
285 dielectric strength test value (applied for 1 min) should be 2000 VAC.
- 286 — Between secondary (low voltage) circuits, including communication ports and the patient  
287 connection(s)/applied parts there should be two MOPPs. Here an assumption is made that the  
288 secondary voltage is less than 25 VAC / 60 VDC. The dielectric strength test value (applied for  
289 1 min) should be 1000 VAC.

---

<sup>5</sup> Creepage Distance is the shortest distance along the contour of material separating two conductors. Clearance Distance is the shortest air distance between two conductors. The standard specifies minimum creepage and clearance distances at all locations where physical separation between conductors is relied upon to prevent a shock hazard.

<sup>6</sup> Hi-pot is an abbreviation for high-potential, referring to high-voltage. A hi-pot tester is a generic name for a category of test equipment that applies a large voltage (typically up to 4000 VAC / 6000 VDC) across an insulation barrier and measures the leakage current that flows. This is another item of test equipment that can be found in many hospital clinical/biomedical engineering labs. Hi-pot testing poses considerable risk to the operator, so such testing must be performed by individuals who are qualified to safely set up and conduct the testing.

- 290 — Between the enclosure (chassis) and the patient connection(s)/applied parts there should be  
291 two MOPPs. Here an assumption is made that the secondary voltage is less than 25 VAC / 60  
292 VDC. The dielectric strength test value (applied for 1 min) should be 1000 VAC.
- 293 — Between the patient connection and ground there should be one means of patient protection.  
294 Assuming the equipment is supplied by 120 VAC, the dielectric strength test value (applied for  
295 1 min) should be 1000 VAC
- 296 — When applying these tests, any non-conductive parts should be wrapped in foil or immersed in  
297 0.9% saline during the test.
- 298 — If adjustable, the trip current on the dielectric strength tester should be set to the maximum  
299 value.

### 300 Leakage Current:

301 Leakage current is unwanted current that is available to flow to a ground conductor, patient or  
302 operator. Many patient-connected medical devices impose measurable leakage current on the  
303 patient under some operating conditions. As noted above, patients can be more susceptible than  
304 the general population to injury from leakage current. The requirements of IEC 60601-1 help ensure  
305 that the leakage current will remain below the threshold of harm during normal use of the equipment  
306 as well as in certain well-specified fault scenarios.

307 IEC 60601-1 provides tests and limits for the leakage current that is accessible to the patient based  
308 on the type of equipment to which the patient is connected. One of the primary means of limiting  
309 leakage current to the patient is to only have non-conductive connections to the patient. If  
310 equipment under the scope of this guidance makes only non-conductive contact with the patient, it  
311 can be reasonably assumed that the leakage currents would be low enough to be within acceptable  
312 limits.

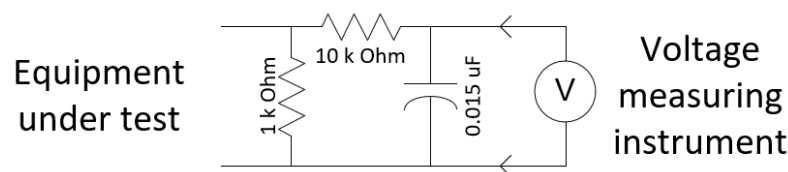
313 Where equipment makes electrical or conductive contact with the patient, the leakage current  
314 available to the patient should be measured to ensure that it is within acceptable limits. For the  
315 purpose of this guidance, it is recommended that the limits for Type BF Applied Parts as defined in  
316 IEC 60601-1, Table 3 are used to determine acceptance. A brief description of the methods for  
317 measuring leakage current is presented below<sup>7</sup>.

- 318 — Electrical safety test sets are commercially available to verify that leakage current is within  
319 prescribed limits. These test sets, and people knowledgeable in their use, are generally  
320 available in the clinical/biomedical engineering department of most hospitals.
- 321 — For the purpose of measuring leakage current without a commercially available test set,  
322 connect the equipment to the intended power supply (plug into a wall outlet at 120 VAC, 60 Hz).  
323 Typically, testing is done at 10% over the rated supply (132 V typically for the US). If 132VAC  
324 is not available, 120V can be used; however, and the allowable values should be reduced by  
325 10%.
- 326 — Leakage current can be measured with a standard DMM using the test circuit shown below in  
327 Figure 2. If the test circuit is not available, measurements can be made using only the 1000  $\Omega$   
328 resistor.
  - 329 ○ Use of the 1000  $\Omega$  resistor is only recommended if the frequency of the leakage current  
330 (source) is below 2 kHz. At frequencies above 2 kHz, use of a 1000  $\Omega$  resistor will not  
331 yield similar results as using the test circuit specified above. An oscilloscope (if

<sup>7</sup> For additional information on the Leakage Current Test, See IEC 60601-1, Clause 8.7 Figures 13 through 20 and Table 5.

- 332 available) could be used to determine the frequency of any accessible leakage  
333 currents.
- 334 — When using the test circuits described above, a value on the DMM of 1 mV corresponds to  
335 1  $\mu$ A of leakage current.
- 336 — During the test, any non-conductive parts that are measured from should be wrapped in foil to  
337 provide a conductive connection to the DMM. If the equipment has non-conductive parts (e.g.,  
338 tubing) that is expected to be filled with fluid, measurements should be made with these parts  
339 filled with a representative conductive fluid (e.g., 0.9% saline).
- 340 — If the equipment is grounded, measurements should be taken with the ground wire in the  
341 equipment power supply cord both connected, and disconnected (e.g., by cutting the ground  
342 wire, using a two-prong adaptor (cheater plug) or removing the ground pin of the power supply  
343 cord). Note: Care should be taken, when testing with the ground disconnected, not to touch  
344 the equipment while it is plugged in and the disconnected ground wire at the same time.  
345 Otherwise, the tester could receive a shock.
- 346 — Measure the leakage current between the patient connection and earth ground with the  
347 equipment energized and operating normally. The limit in this case is 100  $\mu$ A. Repeat this  
348 measurement with the ground connection to the equipment disconnected. The limit in this case  
349 is 500  $\mu$ A.
- 350 ○ Repeat the measurements noted above for all parts that can be in contact with the  
351 patient. The same limits apply.
- 352 — Measure the leakage current between any accessible part of the equipment and earth ground;  
353 use foil to contact any non-conductive parts as noted above. Take this measurement from any  
354 surface that can be touched by the operator. The limit for this measurement is 100  $\mu$ A in normal  
355 condition and 500  $\mu$ A in single fault condition.
- 356 — If the equipment is grounded, measure the leakage current accessible in the ground path. This  
357 is done by placing the measuring device in series with the ground wire (if the ground wire is cut  
358 as noted above, use the measuring circuit to re-connect the ground path). The limit for this  
359 measurement is 5 mA in normal condition and 10 mA in single fault condition

360



361

362 **Figure 2 - IEC 60601-1 Measuring Device (Leakage Current)<sup>8</sup>**

363 Safety Ground:

364 One of the primary means to address electric shock hazards is to connect any accessible,  
365 conductive surfaces to ground (referred to as ground, grounded or grounding). It is reasonable to  
366 assume that these grounded parts will effectively have no voltage on them, thereby reducing the  
367 risk of electric shock to a person contacting these parts of the equipment. Medical equipment that  
368 relies on ground for safety is required to use a hospital grade power supply cord. These cords have

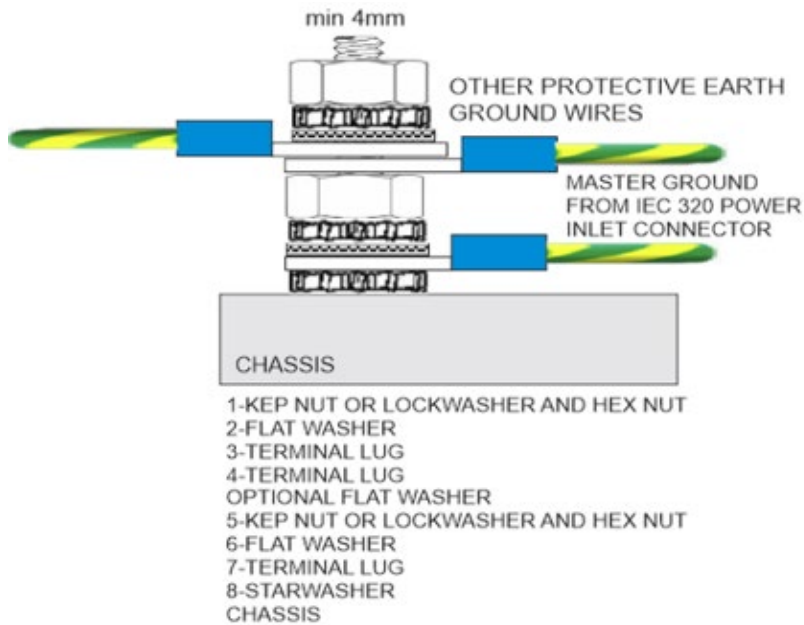
<sup>8</sup> Figure 2 is adapted from IEC 60601-1:2005, AMD1:2012 Figure 12a

369 a more durable ground connection/wiring than standard power supply cords used on other  
370 equipment. They are also tested to ensure a sufficiently low impedance ( $< 0.1 \Omega$ ). The internal  
371 impedance between grounded parts and the main ground connection in the equipment should not  
372 exceed  $0.1 \Omega$ ; this gives a total acceptable ground impedance of  $0.2 \Omega$  when measured from the  
373 ground pin on the power supply cord to the accessible, grounded part(s). However, there might be  
374 additional considerations, based on the intended environments of use. For example, in some  
375 situations, the earth connection can be unreliable, such as in tent hospitals, where the medical  
376 equipment is connected to earth ground via long extension cords. In this scenario, there can be a  
377 large voltage drop over the length of the cord safety ground conductor, creating a shock hazard. If  
378 the equipment is intended to be used in these types of environments and a reliable ground  
379 connection cannot be assured, the equipment should be designed to be Class II. Class II  
380 Equipment uses only a two-prong power supply cord without the ground connection.

381 Typically, ground impedance is measured by applying a 25 A current from a low-voltage source (6  
382 V) between these points, measuring the voltage drop, and calculating the impedance ( $R = V/I$ ,  
383 where  $V$  is the voltage drop and  $I$  is the applied current). The current should only be applied for as  
384 long as necessary to take the specified measurement; it is not recommended to apply the current  
385 for more than 10 s at a time. Clinical/Biomedical Engineering departments in hospitals will generally  
386 have the equipment necessary to perform this test. If this specialized test equipment is not  
387 available, the impedance can be measured directly; however, these measurements would typically  
388 require a more accurate (e.g., 4-Wire) DMM.

389 When making ground connections inside the equipment, it is important to ensure that any  
390 painted/coated surfaces have the coating removed to allow a good connection – this can be done  
391 by masking during the painting process, sanding to remove the paint or using a star washer that  
392 will break through the paint. It is recommended to use the same gauge wire for internal ground  
393 connections as used in the power supply cord – this will typically be 18 AWG minimum. Any crimp  
394 connectors that are used should be double crimped and ground wires should be adequately  
395 secured in place to ensure that they will not come loose (e.g., tab connections should be locking,  
396 or lock washers or lock nuts should be used). Hardware used to attach the ground wire to a  
397 conductive surface should be dedicated to that single purpose. For example, a screw used to  
398 secure an access panel to the equipment should not be used as an attachment point for a ground  
399 wire.

400 A PEM stud is highly recommended (see Figure 3 below). Crimp connections should be provided  
401 with dual crimp type lugs to ensure that insulation does not pull back and expose uninsulated wire.  
402 Using this construction can reduce the possibility of the ground connection being disconnected  
403 externally.



404

405

**Figure 3 - Recommended Grounding Construction (PEM Stud)**

406

407 Defibrillation of Patients:

408 It is expected that patients using equipment under the scope of this guidance will need to be  
 409 defibrillated. Medical equipment is either designed to be left on the patient while they are  
 410 defibrillated or required to be removed prior to the defibrillation of the patient.

411 If equipment will be left in place on the patient, the concerns are:

- 412 — energy be delivered to the patient, and not absorbed by the equipment,
- 413 — equipment survive the defibrillation pulse (up to 5000 VDC), and
- 414 — the defibrillation pulse does not become accessible on the equipment (e.g., on the  
 415 enclosure or communication ports).

416 The design and testing for these types of equipment are highly specialized. Given this, it is  
 417 recommended that non-invasive equipment (e.g., mask-based equipment) under the scope of this  
 418 guidance not be left applied to the patient during defibrillation. The labeling provided with the  
 419 equipment should clearly indicate whether it should be disconnected from the patient if the need  
 420 for defibrillation arises. This is significantly more important for equipment with a conductive  
 421 connection to the patient. It is strongly recommended that invasive equipment (e.g., equipment  
 422 requiring intubation) be designed and tested to these requirements.

423 Current and energy limiting:

424 While shock hazards are well-recognized for electrical equipment, another major concern is the  
 425 prevention of fires originating from an electrical fault. IEC 60601-1 has several requirements  
 426 addressing this concern. Even low-voltage sources can present a significant fire risk; for example,  
 427 a 12 V battery in a transport ventilator or a low-voltage power supply in mains-operated medical

428 equipment can supply enough energy to ignite a fire if the associated wiring is not protected by a  
429 fuse or circuit breaker.

430 If the power requirements of your equipment are low enough, you might be able to employ an off-  
431 the-shelf external power supply that is energy limited. Such power supplies are designed and  
432 certified as limiting the energy delivered to the equipment to a value that is unable to support ignition  
433 under any foreseeable operating conditions.

434 In most cases, however, you will need to pay close attention to the selection of fuses, circuit  
435 breakers, or other protective components, both in the mains circuitry of your device and in the low-  
436 voltage circuitry. You need to pay attention not only to the current rating of your fuse or circuit  
437 breaker, but also to its maximum voltage rating, current interrupting capacity, and time-to-trip  
438 characteristics.

439 It is recommended to purchase certified, medical grade power supplies. These power supplies will  
440 provide adequate overcurrent protection for the output. The Line and Neutral should also be fused,  
441 not all certified power supplies will be provided with fusing in both supply leads. External fusing  
442 may be required.

443 Another key design concern is ensuring that every conductor in your equipment, whether a discrete  
444 wire, a wire in a cable bundle, or a conductor on a printed wiring board, is sized to handle the  
445 maximum current that could be imposed on it under normal and fault conditions. An undersized  
446 conductor under short-circuit conditions can quickly reach a temperature sufficient to melt insulation  
447 and/or ignite nearby flammable materials. In equipment intended for continuous use, the continuous  
448 current draw should not exceed 80% of the current rating of any wiring, including the power supply  
449 cord and all internal wiring of the equipment.

## 450 **8 Mechanical safety recommendations**

451 A primary concern for mechanical safety is the risk of injury from moving parts – especially where equipment  
452 will be used on patient who will have limited, if any, capacity to distance themselves from moving parts.  
453 Brief overviews of other mechanical safety recommendations are also discussed below.

### 454 **Moving Parts**

455 The hazards associated with moving parts generally consist of cutting, squeezing, shearing and  
456 crushing. There are several design solutions that are discussed in IEC 60601-1, Clause 9; these  
457 are summarized below

#### 458 **Safe Distance:**

459 If possible, keep the moving parts far enough away from patients and operators that they  
460 are not accessible. This solution prevents persons from being subjected to harm. This  
461 might not be possible for equipment that is used in close proximity to the patient, or where  
462 the operator needs access to the moving parts for inspection, maintenance or adjustment  
463 to help ensure proper operation.

#### 464 **Guards:**

465 Where safe distances are not possible, guards should be considered to prevent access to  
466 moving parts. Consideration should be given to the strength/rigidity of the guards as well  
467 as the need for them to be removeable. If removeable, the likelihood of replacement after  
468 removal should be considered; the frequency of removal and the complexity of  
469 de/reattachment should factor into this discussion.

470

**Table 1 – Acceptable Gaps<sup>9</sup>**

<b>Body Part</b>	<b>Adult Gap (mm)</b>	<b>Child Gap (mm)</b>
<b>Body</b>	<b>&gt;500</b>	<b>&gt;500</b>
<b>Head</b>	<b>&gt;300 or &lt;120</b>	<b>&gt;300 or &lt;60</b>
<b>Leg</b>	<b>&gt;180</b>	<b>&gt;180</b>
<b>Foot</b>	<b>&gt;120 or &lt;35</b>	<b>&gt;120 or &lt;25</b>
<b>Toe</b>	<b>&gt;50</b>	<b>&gt;50</b>
<b>Arm</b>	<b>&gt;120</b>	<b>&gt;120</b>
<b>Hand/wrist/fist</b>	<b>&gt;100</b>	<b>&gt;100</b>
<b>Finger</b>	<b>&gt;25 or &lt;8</b>	<b>&gt;25 or &lt;4</b>

471

472 Gaps:

473 If access to moving parts cannot be addressed through safe distances or guards, Table 1,  
474 taken from IEC 60601-1, Table 20, specifies the minimum gaps that should be used to  
475 prevent body parts from becoming trapped or from entering potential trapping zones. When  
476 possible, these values should be incorporated into the design of unprotected moving parts.

477 Sharp corners/edges:

478 Sharp corners and edges should be avoided where they are accessible to patients or operators.  
479 While IEC 60601-1 does not provide specific requirements on what constitutes “sharp”, here are  
480 some simple guidelines that can be applied.

481 — If a pencil eraser can be cut/sliced by running it along an edge, it should be considered  
482 sharp.

483 — Corners, especially of rigid materials, that are not rounded should be avoided or  
484 provided with “bumpers”.

485 Stability/Instability:

486 It should be assumed that equipment under the scope of this guidance will need to be easily moved  
487 and will be placed in whatever location is available near a patient in need. The equipment should  
488 be designed so that it will not tip over if set on uneven or non-level surfaces. IEC 60601-1 specifies  
489 that equipment should remain stable when placed on a 10° incline, or that it should remain stable  
490 on a 5° incline and be marked indicating it has limited stability. The stability can be easily tested by  
491 placing the equipment on a moveable surface (e.g., a piece of wood) and raising one side to create  
492 the necessary angle. It is recommended that the following text (or equivalent) be marked on

<sup>9</sup> Table 1 is adapted from IEC 60601-1:2005, Table 20 – Acceptable gaps

493 equipment that does not remain stable on a 10° incline: “This equipment could become unstable if  
494 not used on a level surface”.

495 Supply Pressure:

496 Equipment that is intended to connect to an external pressure source (hospital air/oxygen, oxygen  
497 tanks, etc.) should be clearly marked with the maximum supply pressure that can be safely  
498 connected. Consideration should be given during the design regarding the inclusion of safety  
499 features (e.g., valves, reliefs) to help ensure that the equipment remains safe if the maximum  
500 supply pressure is exceeded. It is recommended that the parts of the equipment subject to pressure  
501 be designed to withstand a minimum of 2x the marked maximum supply pressure. If possible, this  
502 should be confirmed through testing; however, this testing should be done with extreme care.

503 Mechanical Connections:

504 Another concern is for the security of mechanical connections, both electrical and mechanical (such  
505 as airway or fluid connections), to ensure that they do not become inadvertently dislodged during  
506 use.

507 Gas inlet connections shall meet CGA V5 standard DISS connectors for air and oxygen.

508 Air and Oxygen gas hoses shall meet ISO 5359:2017

## 509 **9 Thermal safety recommendations**


510 There are several hazards associated with heat (e.g., touch temperature) that are discussed in this section.  
511 Where possible, testing should be performed, at a minimum, to determine the maximum externally  
512 accessible surface temperatures. This testing can be done using InfraRed (IR) thermometers by running  
513 the equipment for an extended period (e.g., more than 4 hrs) while taking measurements 15 min apart to  
514 determine the maximum surface temperature.

515 Temperature Limits:

516 Patient Contact Parts:

517 Typically, parts that must be in contact with the patient (e.g., mask, hoses) are not allowed  
518 to exceed 43 °C when used at their maximum rated temperature (typically 40 °C).  
519 Additionally, where these parts exceed 41 °C, a justification is required in the instructions  
520 for use as well as a disclosure of the maximum surface temperature. It is recommended  
521 that the limit of 41 °C be applied when measuring the temperature at room ambient (~22  
522 °C).

523 Parts that could be in contact with the patient (e.g., equipment enclosures, power supply  
524 enclosures), should not exceed 48 °C on the surface. Note: external power supplies (similar  
525 to laptop supplies) could exceed these limits; if they do, they should be marked with the  
526 following symbol indicating that they could be hot:

527  <sup>10</sup>

---

<sup>10</sup> Safety Sign – ISO 7010-W017



528 The surface contact limits for patients are low, this takes into account that patients will most  
529 likely be unable to respond or feel hot surfaces, leading to a higher likelihood of burns.

530 Operator Contact Parts:

531 Parts that could be in contact with the operator should not exceed 60 °C unless marked  
532 with the symbol shown above indicating that they could be hot. Note: this symbol should  
533 not be used on parts that the operator must contact in order to operate the equipment.

534 Construction Requirements

535 It is recommended that the equipment be designed to comply with the requirements for fire  
536 enclosures found in IEC 60601-1, Clause 11.3 which are summarized below:

537 — enclosures should be constructed of metal or plastic with a flammability rating of V-2 or  
538 better;

539 — insulated wire within the enclosure should have a flame rating of V-1 or VW-1;

540 — Printed Circuit Boards and other insulating materials (e.g., plastic connectors, terminal  
541 blocks) should have a flame rating of V-2 or better;

542 — any openings in the bottom of the enclosure should be provided with baffles or screens to  
543 prevent flaming drips from escaping. These same requirements should apply to openings  
544 in the side of the enclosure where a source of fire is above the opening. (See IEC 60601-  
545 1, Figures 38 and 39). Baffles should be constructed of metal or plastic with a flame rating  
546 of V-2 or better.

## 547 **10 Safety recommendations for equipment used with Oxygen**

548 It is anticipated that equipment covered by this guidance could be designed to deliver oxygen or be used  
549 in environments where there might be an elevated concentration of oxygen. Air contains 21% oxygen. For  
550 the purpose of this section, any concentration exceeding 25% oxygen should be considered elevated and  
551 potentially hazardous.

552 Oxygen itself is not flammable; however, it feeds fire as well as increases the flammability of other materials  
553 when they are subject to an elevated concentration of oxygen. The steps outlined below can be taken to  
554 help ensure that any hazards associated with the use of or with elevated concentrations of oxygen are  
555 managed. Please note that these requirements apply both when elevated concentrations of oxygen might  
556 be present in the ambient environment in which the equipment is used, such as an ICU or patient room,  
557 and in the closed *internal* environment of the device, such as an electrically-heated tubing set used to  
558 deliver oxygen-enriched air to the patient.

559 Separation:

560 Keeping electronic components separated from elevated concentrations of oxygen is the best  
561 method to limit the risk of fire. This can be done by sealing the enclosure where electronic  
562 components are located to prevent oxygen from entering the enclosure, or by routing oxygen  
563 delivered by the equipment outside of the electronics enclosure. If the equipment delivers oxygen,  
564 the maximum supply pressure should be considered when designing and testing the seal – see  
565 Mechanical Safety Recommendations above for additional details regarding supply pressure  
566 recommendations.

567 Ventilation:

568 When equipment delivers oxygen (but is not used in an environment where elevated concentrations  
569 of oxygen exist), the electronics enclosure can be ventilated to prevent the buildup of oxygen within  
570 the equipment. If ventilation is provided (e.g., fan), consideration should be given to how the  
571 equipment will react/respond if the ventilation fails.

572 Care should be taken when determining where the ventilation openings will be – they should not  
573 be placed near sources of electricity (e.g., where the power cord connects to the equipment or near  
574 battery compartments). They should also not exhaust near any components that could spark/arc  
575 (e.g., switches, motors...).

576 Limited Power:

577 This option is difficult to achieve without significant investment in design resources. If it is not  
578 possible to separate the electronics from elevated concentrations of oxygen, or to ventilate the  
579 enclosure preventing the concentration of oxygen exceeding 25%, the power available to these  
580 electronics in normal and single fault condition should not exceed 10 VA.

581 Selection of Components:

582 For equipment that delivers elevated concentrations of oxygen or is used in environments with  
583 elevated concentrations of oxygen, care should be taken to select components that do not spark/arc  
584 unless these components can be separated from the elevated concentrations. Key components to  
585 consider include the following:

- 586 - motors;
- 587 - switches;
- 588 - relays.

589 Electrical connectors and connections:

590 For electrical connectors/connections of equipment in oxygen rich environments ( $O_2 > 25\%$ ) the  
591 connectors should be either rated explosion proof or to be gas tight to avoid a spark/arc.

## 592 **11 Safety recommendations for equipment with batteries**

593 Traditional equipment providing lifesaving or life supporting functions are generally provided with batteries  
594 to keep the equipment operational if power is lost. While this should be viewed as a positive feature, there  
595 is usually a significant investment of time and resources to properly design the battery system to help  
596 ensure safety. Given the time constraints associated with the development and use of equipment under the  
597 scope of this guidance, it is recommended that battery backup be avoided.

598 If battery backup will be included in the design, some key considerations are listed below.

- 599 — Rechargeable batteries can swell, crack and leak when exposed to repetitive charge/discharge  
600 cycles. The equipment should be designed to prevent the buildup of toxic gases that might  
601 escape from the battery.
- 602 — Rechargeable batteries will have a maximum charging voltage, charging current, discharge  
603 voltage, discharge current that can safely be used – exceeding these can be dangerous. The  
604 design must be able to control the voltage and current provided to rechargeable batteries,

605 including in fault conditions as well as manage the discharging of the battery (too quickly, too  
606 high current load). It is possible to purchase off-the-shelf batteries that have these protections  
607 built into the battery pack. It is also possible to purchase off-the-shelf battery control circuitry  
608 that can be customized for a range of voltages, currents, times and temperatures for charging  
609 and discharging.

610 — Lithium/Lithium-ion batteries have additional safety concerns as fires resulting from types of  
611 batteries are difficult to contain and require specialized equipment to extinguish. Use of  
612 lithium/lithium-ion batteries is not recommended unless these batteries have been designed  
613 and tested to IEC 62133-2. Third party certification is strongly recommended.

614 — When battery backup is provided, consideration should be given to providing the following:

- 615 ○ a means to determine the state of charge;
- 616 ○ a means to indicate that the equipment is running from the battery;
- 617 ○ a means to indicate when the battery is charging;
- 618 ○ a means to indicate when the battery is approaching a level where it will be unable to  
619 operate (the timing of this indication should be included in the instructions provided with  
620 the equipment);
- 621 ○ battery management circuitry to prevent overcharge, over discharge and fast charging  
622 beyond the battery manufacturer's limits. Note: Some of these features are available built  
623 in to off-the-shelf battery packs.

624 If battery backup is not provided, a medical grade uninterruptable power supply (UPS) could be considered  
625 to address risks associated with loss of power. It is strongly recommended that any UPS be certified to the  
626 appropriate medical standards by a third party. Note: using a UPS to power multiple devices can lead to an  
627 increase in leakage current if the UPS does not also provide isolation/separation between the outputs; care  
628 should be taken when selecting or using a UPS with multiple devices.

## 629 **12 Safety with regard to electromagnetic disturbances**

630 IEC 60601-1-2 specifies requirements for basic safety and essential performance of medical electrical  
631 equipment and systems with regard to electromagnetic disturbances (EM safety). There are similar  
632 emissions and immunity requirements for automotive applications, published by the Society of Automotive  
633 Engineers (SAE), and for information technology equipment, specified in International Special Committee  
634 for Radio Protection (CISPR) 22 (emissions) and CISPR 24 (immunity).

635 Electromagnetic immunity is important for life supporting equipment such as ventilators because they are  
636 significant risk devices and EMI can cause unexpected degradation of performance which can lead to  
637 significant harm to the patient, including loss of life. Immunity to electromagnetic disturbances/interference  
638 from the many sources found in healthcare environments is a key safety and effectiveness consideration,  
639 as is minimizing spurious emissions to prevent EMI in other medical devices.

640 The preferred method to assure adequate electromagnetic compatibility is laboratory testing for  
641 electromagnetic emissions and immunity per IEC 60601-1-2. While not as thorough as EMC laboratory  
642 testing, RF ad hoc immunity testing such as specified by C63.18 can be performed using available  
643 transmitters. A portable AM radio tuned between stations might be used to help locate a source of low-  
644 frequency spurious RF emissions.

645 There are design techniques that can help assure electromagnetic compatibility. In addition to the EMI/EMC  
646 filters discussed in the Electrical Safety Recommendations section, techniques include shielding of

647 enclosures and cables, twisting of parallel conductors, proper grounding within and between subsystems  
648 of equipment, and minimization of circuit loop areas.

649 We recommend EMC testing related to patient safety, with scientific justification for how the selected tests  
650 demonstrate the device is safe and does not interfere with other medical or non-medical equipment.

651 Other appropriate EM safety mitigations can be used to support a favorable benefit/risk determination. If  
652 immunity testing has not been performed with recognized consensus standards for the equipment, you  
653 should provide a description of alternative mitigations, such as ad hoc testing according to ANSI C63.18  
654 and a list of labeling mitigations (e.g., continuous oversight from medical professionals, procedures to  
655 prevent harm to operators, electrostatic discharge (ESD) mitigation precautions) along with an explanation  
656 of how the mitigations protect the safety of patients and operators. Immunity considerations should also  
657 include evaluation for proximity to other medical systems that are commonly used in healthcare facilities  
658 and can cause EMI to the EUV, such as computed tomography (CT), magnetic resonance imaging (MRI),  
659 and diathermy equipment and RF identification (RFID) readers. If emissions testing has not been performed  
660 for the equipment per recognized consensus standards, then you should provide a description of potential  
661 risks to patients and providers in case the subject medical device introduces excessive emissions that might  
662 interfere with other medical or non-medical equipment. This should include justification about how each risk  
663 will be mitigated.

664 For equipment that use wireless technology, e.g., for communication, remote control, or monitoring, the  
665 issues presented in the FDA guidance Radio Frequency Wireless Technology in Medical Devices should  
666 be addressed. This includes summary information about the wireless technology, wireless security  
667 measures, wireless coexistence, EMC, and labeling for the user to understand, use, and troubleshoot the  
668 wireless functions.

### 669 **13 Information regarding potential faults that could occur during use**

670 The design of the equipment should take into consideration some of the following faults that are likely to  
671 occur.

- 672 — Loss and restoration of power. When the power is restored, how does the equipment react?
- 673 — Reverse polarity of the supply voltage (line and neutral reversed). Does the equipment operate  
674 normally? Do leakage currents remain within the acceptable (normal condition) limits?
- 675 — Loss of ground. Are there any safety hazards that become unacceptable if ground is lost? See  
676 Leakage Current above in Electrical Safety Recommendations. When possible, it is  
677 recommended that equipment be designed without relying on ground for safety (Class II  
678 devices with a 2-prong, NEMA 1-15P Plug). Note: This restricts some options discussed in  
679 other sections of this documents (e.g., Electrical Safety Recommendations/Safety Ground and  
680 Safety with regard to Electromagnetic Disturbances/Shielding)
- 681 — Buildup or spillage of liquid – is the equipment designed to protect against the buildup of liquid  
682 in the patient tubing? Is the enclosure designed to prevent spilled fluids from contacting  
683 electrical parts? IEC 60529 specifies test requirements for equipment designed to prevent the  
684 ingress of liquid or particulate matter. It is recommended that equipment be designed and  
685 tested to IP21 (protection against foreign objects larger than 12.5 mm and, protection against  
686 vertical dripping water) at a minimum.
- 687 — Use of equipment with extension cords. The resistance/impedance of a power supply cord  
688 increases with length; this includes any extension cords that are used. This increased length  
689 reduces the effectiveness of grounding as a means of protection from electric shock.  
690 Additionally, the increased impedance associated with an extension cord can increase the  
691 current required for equipment to operate, this can lead to tripping of overcurrent protective  
692 devices (fuses, circuit breakers) that are either part of the equipment or included as part of the

693 building/facility wiring. As these risks can only effectively be controlled at the point of use (by  
694 not using extension cords), it is recommended that the instructions for use indicate that  
695 extension cords not be used.

696 — Use of equipment with power strips. Similar to extension cords, power strips have the ability  
697 to reduce the effectiveness of grounding for the same reason(s). Additionally, if not properly  
698 designed for medical use, a power strip can cause the leakage current for multiple devices to  
699 be added together – increasing the possibility of electric shock to the patient or operator. It is  
700 recommended to avoid use of power strips; where they must be used, it is strongly  
701 recommended that they be medical grade and include an isolating transformer to help address  
702 the risk of additive leakage currents.

## 703 **14 Function/performance recommendations**

704 For additional information, it is highly recommended to refer to the AAMI Consensus Reports (CR) listed in  
705 the references section of this document. At the time of publication, the following CRs have been published:

706 — AAMI CR501:2020, *Emergency Use Ventilator (EUV) Design Guidance*,

707 — AAMI CR503:2020, *Emergency Use Resuscitator Systems Design Guidance*, and

708 — AAMI CR505:2020, *Emergency Use CPAP/BiPAP Design Guidance*<sup>11</sup>.

709 When possible, these design guides should be used during the design and development of emergency use  
710 equipment.

711 At a minimum, testing should be performed to document the pressure and volume of delivered air (or gas).

712 Consideration should be given to the risks associated with the following:

713 — equipment failing to provide any output;

714 — equipment providing an output that is less than expected/indicated;

715 — equipment response to loss of power, including the restoration of power;

716 — equipment use for extended periods of time, potentially while unattended;

717 — failure of safety or performance critical electronic components (e.g., motors, valves, relays):

718 ○ For equipment with motors, it is recommended to stall/lock the motor during use to evaluate  
719 how the equipment responds.

720 ○ During this test, externally accessible surface temperatures should be monitored; where  
721 they exceed 80 °C the hot surface marking referenced in this document should be applied

722 ○ If the equipment releases smoke or becomes inoperable following the test, consideration  
723 should be given to selecting a different motor. Motors with built-in thermal protection are  
724 strongly recommended.

725 Recommendations that could help offset the risks noted above are listed below.

726 — Selection of reliable (e.g., tested/certified) components.

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<sup>11</sup> This list is expected to grow, for a full list of published CRs, refer to the AAMI Website: [https://www.aami.org/news-resources/covid-19-updates/covid\\_cr](https://www.aami.org/news-resources/covid-19-updates/covid_cr)

- 727 — Incorporation of alarms to indicate when performance is lost or reduced. Note: Alarms may be
- 728 visual (e.g., flashing red LED) or audible (e.g., beeping). Consideration should be given to
- 729 which type of alarm is used. IEC 60601-1-8 prioritizes visual alarms.
  
- 730 — Recommended safety/performance checks, including their frequency.
  
- 731