AAMI

Advancing Safety in Health Technology

AAMI Consensus Report

Basic Safety of Emergency Use Medical Devices

AAMI CR507:2020/(R)2022

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AAMI CR507:2020/(R)2022
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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 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.

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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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- 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

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Contents

Page

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Association for the Advancement of Medical Instrumentation

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Basic safety of emergency use medical devices

1 Purpose

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.

This document is intended to be used as a supplement to recent AAMI Consensus Reports issued in response to the COVID-19 pandemic for emergency use ventilation devices. Documents published at the time of writing are listed in the References and Resources below. The list of published reports and guidance is expected to grow; the current list is available at: 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 consensus reports on this topic.

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

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

2 References and resources

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

https://www.ansi.org/news_publications/news_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-284d997323b2

[1] 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).

Free access to AAMI Consensus Reports (CRs):

https://www.aami.org/news-resources/covid-19-updates/covid_cr

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

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

Additional information on available resources:

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

Referenced Standards and Guidance:

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

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

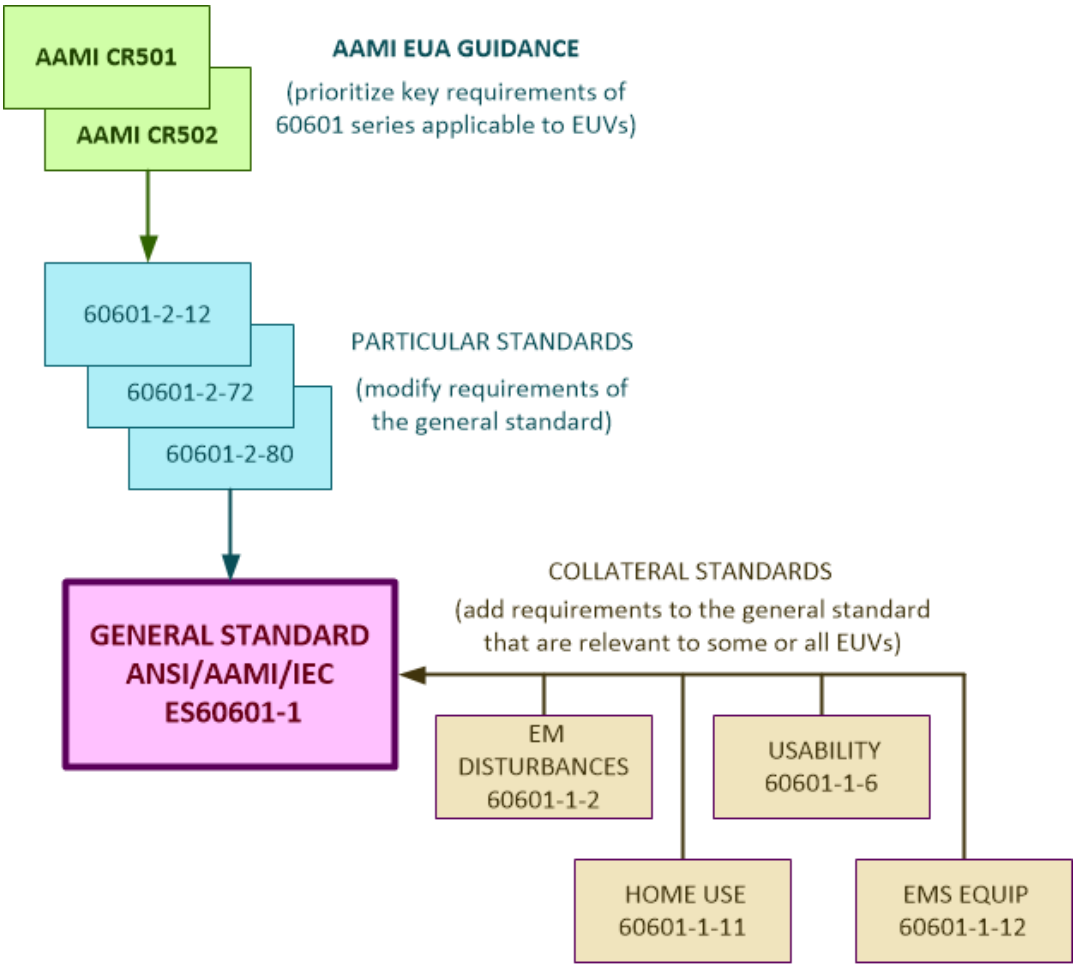

Figure 1 - IEC 60601-1 Series and Current Guidance[2]

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

IEC 60601-1-8:2012, *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*. U. S. National Version: ANSI/AAMI/IEC 60601-1-8

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

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

[2] 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Introduction to the IEC 60601-1 Series

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

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

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

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

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

4 General Considerations

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

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

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[3] 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

[4] 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.

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

https://www.ansi.org/news_publications/news_story?menuid=7&articleid=634008b9-af6c-4547-b2f9-284d997323b2

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

5 Risk Mitigation Strategies

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

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

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

1. Design Solution (ISO 14971 “inherent safety by design”) – design the equipment to remove hazard or hazardous situation completely. Examples include removing lithium ion batteries from the design or to design controls into the equipment that will address the risk associated with use of lithium ion batteries.

2. Provide Guards (ISO 14971 “protective measures in the medical device itself or in the manufacturing process”) – put protective measures in place to prevent the risks from becoming harm to the patient or operator. Examples include providing an enclosure around moving parts to prevent body parts from becoming trapped, pinched, or crushed or including alarm signals to identify a need for intervention to prevent harm.

3. Provide Warnings (ISO 14971 “information for safety”) – provide warning about a specific risk that will communicate how to avoid being harmed. These can be provided in the instructions for use, or as specific labels on the equipment. One example would be to provide a marking on parts of the equipment that could be hot, communicating that they should not be touched.

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

6 Equipment Markings and Power Consumption Recommendations

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

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

- Set the DMM to “Amps” or “A”; if AC or DC is available, select AC. Note: Some DMMs have limitations on the current they can measure (e.g. 10 A).
- Carefully place the DMM in series with the line (hot) leg of the power supply (or power supply cord).
- Power ON the equipment and put it into the normal operating mode; if motors are used, ensure they are running. If the speed is adjustable, test at the minimum and maximum speed.
- Record the maximum value seen. This should be marked on the equipment.
- Note that the current draw can change with increasing or decreasing mains voltage. For some equipment, such as equipment having mains-powered motors, the current draw will likely increase with increasing supply voltage. In other cases, particularly when the equipment incorporates switching power supplies, maximum current draw can occur when the supply voltage is at its lowest value.

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

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

7 Electrical Safety Recommendations

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

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

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

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

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

— Power Supply Cords:

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

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

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

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

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

— Switches, Fuses, Circuit Breakers, etc.:

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

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

Separation/Isolation of parts:

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

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

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

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

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

The key separation requirements include the following:

— Between the power supply cord Line and Neutral and the patient connection(s), there should be two means of patient protection (MOPP). Assuming the equipment is supplied by 120 VAC, the dielectric strength test value (applied for 1 min) should be 3000 V.
— Between the power supply cord Line and Neutral and ground there should be one means of operator protection (MOOP). Assuming the equipment is supplied by 120 VAC, the dielectric strength test value (applied for 1 min) should be 1000 VAC.

— Between the power supply cord Line and Neutral and any communication ports (USB, Ethernet, HDMI) there should be two MOOP. Assuming the equipment is supplied by 120 VAC, the dielectric strength test value (applied for 1 min) should be 2000 VAC.

— Between secondary (low voltage) circuits, including communication ports and the patient connection(s)/applied parts there should be two MOPPs. Here an assumption is made that the secondary voltage is less than 25 VAC / 60 VDC. The dielectric strength test value (applied for 1 min) should be 1000 VAC.

[5] 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.

[6] 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.

- Between the enclosure (chassis) and the patient connection(s)/applied parts there should be two MOPPs. Here an assumption is made that the secondary voltage is less than 25 VAC / 60 VDC. The dielectric strength test value (applied for 1 min) should be 1000 VAC.

- Between the patient connection and ground there should be one means of patient protection. Assuming the equipment is supplied by 120 VAC, the dielectric strength test value (applied for 1 min) should be 1000 VAC

- When applying these tests, any non-conductive parts should be wrapped in foil or immersed in 0.9% saline during the test.

- If adjustable, the trip current on the dielectric strength tester should be set to the maximum value.

Leakage Current:

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

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

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

- Electrical safety test sets are commercially available to verify that leakage current is within prescribed limits. These test sets, and people knowledgeable in their use, are generally available in the clinical/biomedical engineering department of most hospitals.
- For the purpose of measuring leakage current without a commercially available test set, connect the equipment to the intended power supply (plug into a wall outlet at 120 VAC, 60 Hz). Typically, testing is done at 10% over the rated supply (132 V typically for the US). If 132VAC is not available, 120V can be used; however, and the allowable values should be reduced by 10%.

- Leakage current can be measured with a standard DMM using the test circuit shown below in Figure 2. If the test circuit is not available, measurements can be made using only the 1000 Ω resistor.

    - Use of the 1000 Ω resistor is only recommended if the frequency of the leakage current (source) is below 2 kHz. At frequencies above 2 kHz, use of a 1000 Ω resistor will not yield similar results as using the test circuit specified above. An oscilloscope (if

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

available) could be used to determine the frequency of any accessible leakage currents.

- When using the test circuits described above, a value on the DMM of 1 mV corresponds to 1 µA of leakage current.
- During the test, any non-conductive parts that are measured from should be wrapped in foil to provide a conductive connection to the DMM. If the equipment has non-conductive parts (e.g., tubing) that is expected to be filled with fluid, measurements should be made with these parts filled with a representative conductive fluid (e.g., 0.9% saline).
- If the equipment is grounded, measurements should be taken with the ground wire in the equipment power supply cord both connected, and disconnected (e.g., by cutting the ground wire, using a two-prong adaptor (cheater plug) or removing the ground pin of the power supply cord). Note: Care should be taken, when testing with the ground disconnected, not to touch the equipment while it is plugged in and the disconnected ground wire at the same time. Otherwise, the tester could receive a shock.
- Measure the leakage current between the patient connection and earth ground with the equipment energized and operating normally. The limit in this case is 100 µA. Repeat this measurement with the ground connection to the equipment disconnected. The limit in this case is 500 µA.
    - Repeat the measurements noted above for all parts that can be in contact with the patient. The same limits apply.
- Measure the leakage current between any accessible part of the equipment and earth ground; use foil to contact any non-conductive parts as noted above. Take this measurement from any surface that can be touched by the operator. The limit for this measurement is 100 µA in normal condition and 500 µA in single fault condition.
- If the equipment is grounded, measure the leakage current accessible in the ground path. This is done by placing the measuring device in series with the ground wire (if the ground wire is cut as noted above, use the measuring circuit to re-connect the ground path). The limit for this measurement is 5 mA in normal condition and 10 mA in single fault condition

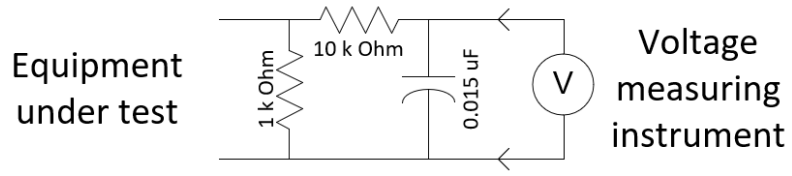

Figure 2 - IEC 60601-1 Measuring Device (Leakage Current) [8]

Safety Ground:

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

[8] Figure 2 is adapted from IEC 60601-1:2005, AMD1:2012 Figure 12a

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

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

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

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

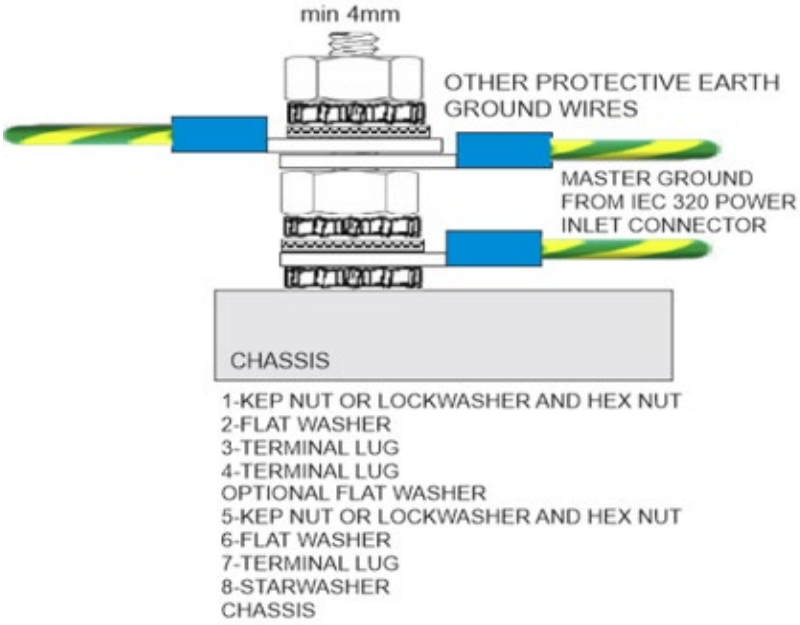

Figure 3 - Recommended Grounding Construction (PEM Stud)

Defibrillation of Patients:

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

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

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

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

Current and energy limiting:

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

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

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

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

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

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

8 Mechanical safety recommendations

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

Moving Parts

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

Safe Distance:

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

Guards:

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

Table 1 – Acceptable Gaps[9]

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

Gaps:

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

Sharp corners/edges:

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

- If a pencil eraser can be cut/sliced by running it along an edge, it should be considered sharp.
- Corners, especially of rigid materials, that are not rounded should be avoided or provided with “bumpers”.

Stability/Instability:

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

[9] Table 1 is adapted from IEC 60601-1:2005, Table 20 – Acceptable gaps

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

Supply Pressure:

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

Mechanical Connections:

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

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

Air and Oxygen gas hoses shall meet ISO 5359:2017

9 Thermal safety recommendations

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

Temperature Limits:

Patient Contact Parts:

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

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

 [10]

[10] Safety Sign – ISO 7010-W017

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

Operator Contact Parts:

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

Construction Requirements

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

- enclosures should be constructed of metal or plastic with a flammability rating of V-2 or better;
- insulated wire within the enclosure should have a flame rating of V-1 or VW-1;
- Printed Circuit Boards and other insulating materials (e.g., plastic connectors, terminal blocks) should have a flame rating of V-2 or better;
- any openings in the bottom of the enclosure should be provided with baffles or screens to prevent flaming drips from escaping. These same requirements should apply to openings in the side of the enclosure where a source of fire is above the opening. (See IEC 60601-1, Figures 38 and 39). Baffles should be constructed of metal or plastic with a flame rating of V-2 or better.

10 Safety recommendations for equipment used with Oxygen

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

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

Separation:

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

Ventilation:

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

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

Limited Power:

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

Selection of Components:

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

- motors;
- switches;
- relays.

Electrical connectors and connections:

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

11 Safety recommendations for equipment with batteries

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

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

— Rechargeable batteries can swell, crack and leak when exposed to repetitive charge/discharge cycles. The equipment should be designed to prevent the buildup of toxic gases that might escape from the battery.

— Rechargeable batteries will have a maximum charging voltage, charging current, discharge voltage, discharge current that can safely be used – exceeding these can be dangerous. The design must be able to control the voltage and current provided to rechargeable batteries,

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

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

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

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

12 Safety with regard to electromagnetic disturbances

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

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

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

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

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

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

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

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

13 Information regarding potential faults that could occur during use

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

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

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

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

14 Function/performance recommendations

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

- AAMI CR501:2020, *Emergency Use Ventilator (EUV) Design Guidance,*
- AAMI CR503:2020, *Emergency Use Resuscitator Systems Design Guidance*, and
- AAMI CR505:2020, *Emergency Use CPAP/BiPAP Design Guidance*[11].

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

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

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

- equipment failing to provide any output;
- equipment providing an output that is less than expected/indicated;
- equipment response to loss of power, including the restoration of power;
- equipment use for extended periods of time, potentially while unattended;
- failure of safety or performance critical electronic components (e.g., motors, valves, relays):
    - For equipment with motors, it is recommended to stall/lock the motor during use to evaluate how the equipment responds.
    - During this test, externally accessible surface temperatures should be monitored; where they exceed 80 °C the hot surface marking referenced in this document should be applied
    - If the equipment releases smoke or becomes inoperable following the test, consideration should be given to selecting a different motor. Motors with built-in thermal protection are strongly recommended.

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

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

[11] 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

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