End User Disclosures for Emergency Use Ventilators

Purpose

The goal of this document is to identify high priority hazards and their causes to be considered in development and the information to be disclosed by Emergency Use Ventilator (EUV) manufacturers to the end user. These are based on the hazards identified in IEC 60601-1[1] and ISO 80601-2-80[2] .

1. Electrical Shock Hazard

Purpose: to ensure adequate patient and operator safety in terms of shock (leakage current, dielectric strength, ground continuity)

Disclosures:

List AC input power requirements of the EUV (voltage, frequency, amperes)

DC power input requirement if applicable

Indicate the electrical classification of EUV:

Class I (EUV has a protective earth connection with a 3-wire power cord)

Class II (EUV does not have a protective earth ground but is double insulated with a 2-wire power cord)

Internally powered (powered by a rechargeable battery inside the EUV or external to EUV)

Note: an EUV can have more than one classification e.g. Class II/internally powered

If the power supply connected to mains power is not medical grade (i.e., IEC 60601-1 compliant), describe the means used to reduce leakage currents to IEC 60601-1 limits (e.g. use of an isolation transformer, second permanently installed protective earth connection)

If the power supply connected to mains power is Class I, add a warning:
Warning: This ventilator relies on the integrity of the protective earth ground to reduce the risk of electrical shock. Check the integrity and verify the function of the protective earth ground of the supply mains receptacle prior to use.

[1] Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
[2] Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency

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Describe the type of patient connection: basic, basic floating, cardiac floating (type B, BF or CF) and defibrillation-proof

2. Mechanical Hazards

a) Purpose: to ensure that the EUV can withstand mechanical stresses from being carried or wheeled while being transported indoors or outdoors.

Disclosures:

Identify the mobility of the EUV

Transit operable: EUV is intended to operate while being moved

Portable: EUV is intended to be carried (but not operating) from one location to another

Mobile: EUV is intended to be wheeled (but not operating) from one location to another

b) Purpose: is to ensure that the moving parts of the EUV do not pose an unacceptable risk to the patient or operator.

Disclosures:

If the EUV has wheels, assess the stability and disclose the safe angle before tipping occurs

Identify any trapping zones (e.g. trapping fingers, hair, PPE) and how they are guarded

3. Environmental Hazards

Purpose: to ensure that the EUV can be stored and operated in its intended environment

Disclosures:

Indicate the temperature/humidity/altitude range over which the EUV is intended to operate and meets its specifications

Indicate the intended range of conditions (temperature/humidity specifications) in which the EUV can be stored

4. Reuse hazards

Purpose: to reduce the risk of cross contamination

Disclosures:

Describe the cleaning and disinfection procedures needed between uses and between patients for both the EUV and the accessories

Description of location and specifications of required EUV particle filters and replacement intervals

5. Biocompatibility

Purpose: to reduce the risk of biological reaction to foreign substances

Disclosures:

For the gas pathway, indicate if any biocompatibility evaluations were performed per ISO 18562 (series)[3]

For parts intended to touch the patient, indicate if any biocompatibility evaluations were performed per ISO 10993 (series)[4]

6. Electromagnetic compatibility (EMC)

Purpose: to ensure that the EUV is adequately protected from electromagnetic emissions from other electrical sources (e.g. cell phones, ESD) and to ensure that the EUV does not interfere with the operation of other nearby electronic medical devices

Disclosures:

Indicate if any EMC testing was performed and identify the standards (e.g. IEC 60601-1-2[5]) to which the EUV was evaluated

If EMC testing has not been performed, add a warning:
This ventilator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.

7. Alarm System

Purpose: to reduce the risk to the patient by alerting the caregiver of a hazardous situation

Disclosures:

Describe the functionality of the alarm system

List available alarm conditions, their relative priority and default alarm limits

[3] Biocompatibility evaluation of breathing gas pathways in healthcare applications.
[4] Biological evaluation of medical devices
[5] Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

Describe the default alarm settings (e.g. latched, not latched alarm signals, alarm condition disabled)

Indicate the means by which the auditory alarm signal can be inactivated and for how long

8. Accuracy of controls

Purpose: to reduce the risk of hazardous output from the EUV to the patient

Disclosures:

List of displayed parameters: e.g. pressure, tidal volume, respiratory rate

Describe how the displayed parameters are measured or determined

List the accuracy of therapy parameters

9. Accessories

Purpose: to ensure the safe use of the EUV with compatible accessories

Disclosures:

List of recommended accessories and their replacement intervals e.g. tubing, patient interface, filters, replacement batteries

10. Programmable Electrical Medical Systems

Purpose: to ensure that the software operates safely and as specified

Disclosures:

Indicate whether the software was developed under a controlled life cycle process (e.g. IEC 62304[6])

List any known unresolved software anomalies and workarounds.

Indicate: Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.

11. Risk Management Process

Purpose: to ensure risks were comprehensively identified and adequately managed

Disclosures:

[6] Medical device software — Software life cycle processes

Indicate whether the EUV design has been developed using a risk management process (e.g. ISO 14971[7])

12. Other hazards

Purpose: to reduce the risk of thermal injury or other events

Disclosures:

If applicable, indicate the battery specifications including:

the type of battery and chemistry

A description of the means to determine the status of the battery (e.g. charging, low battery indicator)

Identify conformance to applicable standards (e.g., IEC 62133[8] for rechargeable batteries or IEC 60086-4[9] for non-rechargeable batteries)

Indicate the ingress protection (IP) of the EUV enclosure: IP 22 is recommended (protection against foreign objects ≥ 12.5 mm and against dripping (15^{o} tilted) water)

Indicate if the EUV is suitable for use in an oxygen enriched environment > 25 % O_2 (are adequate protections in place to reduce risk of fire ignition)

If the EUV contains oxygen at pressures exceeding 5 bar, the protections taken to ensure that auto-ignition from adiabatic compression cannot occur e.g. parts of the EUV operating at pipeline pressure.

[7] Medical devices - Application of risk management to medical devices

[8] Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

[9] Primary batteries – Part 4: Safety of lithium batteries