AAMI

Advancing Safety in Health Technology

AAMI Consensus Report

End User Disclosures for CPAP/BiPAP

AAMI CR506:2020/(R)2022

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In this redline revision, a vertical line in the margin shows where the technical content is modified from the original.

Additions are in green text, deletions are in strikethrough red text.

End user disclosures for CPAP/BiPAP

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: Identifies high priority hazards and their causes to be considered in development and the information to be disclosed by emergency use CPAP and BiPAP therapy equipment (EUCP) manufacturers to the end user. These are based on the hazards identified in IEC 60601-1 and ISO 80601-2-70.

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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Comments on this document are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Rd, Suite 300, Arlington, VA 22203.

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Contents

Page

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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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End user disclosures for CPAP/BiPAP

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 CPAP and BiPAP therapy equipment (EUCP) manufacturers to the end user. These are based on the hazards identified in IEC 60601-1[1] and ISO 80601-2-70 [2]

NOTE This document is intended to be used in conjunction with AAMI CR505:2020, *Emergency use Emergency Use CPAP/BiPAP design guidance*.

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 EUCP (voltage, frequency, amperes).
- DC power input requirement, if applicable.
- Indicate the electrical classification of EUCP:
    - Class I (EUCP has a protective earth connection with a 3-wire power cord)
    - Class II (EURS 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 EUCP or a rechargeable battery external to EUCP)

        NOTE An EUCP 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:

[1] IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

[2] ISO 80601-2-70, *Medical electrical equipment —Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

Warning: This EUCP 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.

- 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 EUCP can withstand mechanical stresses from being carried or wheeled while being transported indoors or outdoors.

Disclosures:

- Identify the mobility of the EUCP:
  - Transit operable: EUCP is intended to operate while being moved.
  - Portable: EUCP is intended to be carried (but not operating) from one location to another.
  - Mobile: EUCP is intended to be wheeled (but not operating) from one location to another.

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

Disclosures:

- If the EUCP 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 EUCP can be stored and operated in its intended environment.

Disclosures:

- Indicate the temperature/humidity/altitude range over which the EUCP is intended to operate and meets its specifications.
- Indicate the intended range of conditions (temperature/humidity specifications) in which the EUCP can be stored.

4 CO_2 Rebreathing

Purpose: to reduce the risk of excessive carbon dioxide in the bloodstream.

Disclosures:

- Describe the means implemented to minimize the risk of rebreathing and to keep residual exhaled CO_2 to acceptable levels.

5 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 EUCP and the accessories.
- Description of location and specifications of required EUCP particle filters and replacement intervals.

6 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].

7 Electromagnetic Compatibility (EMC)

Purpose: to ensure that the EUCP is adequately protected from electromagnetic emissions from other electrical sources (e.g. cell phones, ESD) and to ensure that the EUCP 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 EUCP 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.

8 Alarm System

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

[3] ISO 18562, *Biocompatibility evaluation of breathing gas pathways in healthcare applications*

[4] ISO 10993, *Biological evaluation of medical devices*

[5] IEC 60601-1-2, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

Disclosures:

- Describe the functionality of the alarm system.
- List available alarm conditions, their relative priority and default alarm limits.
- 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.

9 Accuracy of controls and measurements

Purpose: to reduce the risk of hazardous output from the EUCP to the patient.

Disclosures:

- List of therapy settings and monitored values that are displayed: e.g., pressure, respiratory rate.
- Describe how the displayed monitored values are determined.
- List the accuracy of therapy parameters.

10 Accessories

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

Disclosures:

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

11 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 whether the software is protected to prevent the ventilator from digital cyberattacks.
- List any known unresolved software anomalies that can lead to the compromise of sensitive information or that can affect communication security.
- 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.

[6] IEC 62304, *Medical device software — Software life cycle processes*

12 Risk Management Process

Purpose: to ensure risks were comprehensively identified and adequately managed.

Disclosures:

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

13 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);
    - 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 EUCP enclosure: IP 22 is recommended (protection against foreign objects ≥ 12.5 mm and against dripping (15° tilted) water).
- Indicate if the EUCP 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 EUCP 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 EUCP operating at pipeline pressure).

[7] ISO 14971, *Medical devices - Application of risk management to medical devices*

[8] IEC 62133, *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] IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*