AAMI
Advancing Safety in Health Technology

AAMI Consensus Report

End User Disclosures for Emergency Use Resuscitator Systems

AAMI CR504:2020/(R)2022

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 emergency use resuscitator systems (EURS)

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 resuscitator system (EURS) manufacturers to the end user. These are based on the hazards identified in IEC 60601-1 and ISO 10651-4.

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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Task Group representation

Association for the Advancement of Medical Instrumentation

COVID-19 Response Team Members

This AAMI Consensus Report (CR) was developed by a task group under the auspices of the AAMI COVID-19 Response Team.

The **AAMI COVID-19 Response Team** had the following members:

Cochairs:
Jennifer Danieley
David Feinstein
Julian Goldman

Members:
Simona Bancos, FDA/CDRH
Andrew Bath, ResMed Inc.
Brandon Blakely, FDA/CDRH
Brad Bonnette, ECRI Institute
Caitlin Brady, Intertek
David Busch, UT Southwestern Medical Center
Anthony Ciccarello, Philips
Steven Dain, University of Western Ontario
Rakhi Dalal, FDA/CDRH
Jennifer Danieley, FDA/CDRH
Andy Doering, Medtronic
Simon Dunham, Weill Cornell Medicine
David Feinstein, American Society of Anesthesiologists (ASA)
Bruce Friedman, GE Healthcare
Hamed Ghods, FDA/CDRH
Julian Goldman, Partners HealthCare System
Ralf Heesch, Draeger Medical Systems Inc.
Heidi Horn, Nuvolo Technologies
Fernando Isaza, Philips
Michael Jaffe, Cardiorespiratory Consulting LLC
Gardner Kimm, Medtronic Inc Campus
Robert Kopotic, Edwards Lifesciences
Hubertus Lasthaus, VitalAire Germany
Ed Madsen, Avanos Medical
Phoebe Mainland, Alfred Health
Madeleine Manousaridis, Standards Australia
Benoit Marchal, Air Liquide
Thomas Marmet, GE Healthcare
Debra Milamed, Harvard University
Cyndy Miller, Medtronic Inc Campus
Bryant Moeller, ResMed Inc.
Curtis Morgan, 3M Health Care
Akito Ohmura, Teikyo University-Mizonokuchi Hospital
David Osborn, Philips
John Stark, 3M Health Care
Robert Steurer, Steurer Consulting Group
Dongbo Wang, FDA/CDRH
Sandy Weininger, FDA/CDRH

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 emergency use resuscitator systems (EURS)

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 resuscitator system (EURS) manufacturers to the end user. These are based on the hazards identified in IEC 60601-1[1] and ISO 10651-4 [2].

NOTE This document is intended to be used in conjunction with AAMI CR503:2020, *Emergency use resuscitator systems (EURS) 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 EURS (voltage, frequency, amperes).
- DC power input requirement, if applicable.
- Indicate the electrical classification of EURS:
  - Class I (EURS 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 EURS or a rechargeable battery external to EURS)

    NOTE An EURS 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 10651-4, *Lung ventilators – Part 4: Particular requirements for operator powered resuscitators*

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.

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

Disclosures:

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

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

Disclosures:

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

Disclosures:

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

- Description of location and specifications of required EURS 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 EURS is adequately protected from electromagnetic emissions from other electrical sources (e.g. cell phones, ESD) and to ensure that the EURS 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 EURS 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 EURS to the patient.

Disclosures:

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

10 Accessories

Purpose: to ensure the safe use of the EURS 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.

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

- 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.

12 Risk Management Process

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

Disclosures:

- Indicate whether the EURS 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 EURS enclosure: IP 22 is recommended (protection against foreign objects ≥ 12.5 mm and against dripping (15° tilted) water).
- Indicate if the EURS 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 EURS 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 EURS 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*