AAMI

Advancing Safety in Health Technology

*AAMI Consensus Report*

End User Disclosures for Emergency Use

# Ventilatory Assistance Helmet (VAH)

*AAMI/CR509:2020*

**AAMI Consensus Report**

**AAMI CR509:2020**
**Revision 1**
**16 July 2020**

# End user disclosures for emergency use Ventilatory Assistance Helmet (VAH)

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.

Approved 16 July 2020 by
**AAMI**

**Abstract:** Identifies safety related disclosures to be provided to end users of Emergency Use VAH. These details are based on the hazards identified in IEC 60601-1 and ISO 17510.

**Keywords:** COVID-19

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

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## Contents

Page


Task Group representation ..... iv

Acknowledgments ..... v

Purpose ..... 1

1 Working Pressure ..... 1

2 Accessories ..... 1

3 Resistance to flow (pressure drop) ..... 1

4 Breathing during single fault condition ..... 2

5 $CO_2$ Rebreathing ..... 2

6 Fresh Gas Port ..... 2

7 Reuse hazards ..... 2

8 Biocompatibility ..... 2

9 Risk Management Process ..... 3

10 Acoustic noise ..... 3

11 Oxygen enriched environment ..... 3

12 Volume ..... 4

## 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.

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# End user disclosures for emergency use Ventilatory Assistance Helmet (VAH)

## Purpose

This document identifies safety related disclosures to be provided to end users of Emergency Use VAH. These details are based on the hazards identified in IEC 60601-1[1] and ISO 17510[2].

## 1 Working Pressure

Purpose: to ensure compatibility of the VAH interface with the patient and source of ventilatory assist.

Disclosures:

Indicate the rated:

- MAXIMUM WORKING PRESSURE
- minimum pressure

## 2 Accessories

Purpose: to ensure the safe use of the VAH with compatible accessories.

Disclosures:

List of recommended accessories and their replacement intervals e.g., tubing, filters, valves, monitoring systems.

List of recommended fresh gas sources e.g. ventilators, ventilatory assist equipment, gas mixers, flow meters.

## 3 Resistance to flow (pressure drop)

Purpose: to ensure the patient receives the required therapeutic pressure and to limit the inspiratory and expiratory resistance to an acceptable level.

Disclosures:

Inspiratory resistance: The resistance to inspiratory flow derived from pressure drop between the patient connection port and the patient measured at 50L/min and 100L/min.

[1] Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
[2] Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

Expiratory resistance: The resistance to expiratory flow derived from pressure drop between the interior of the VAH and ambient, measured at 50L/min and 100L/min.

## 4 Breathing during single fault condition

Purpose: to limit breathing resistance and to prevent excessive rebreathing when there is insufficient fresh gas flow from the ventilatory assist equipment during a single fault condition.

Disclosures:

If an anti-asphyxia valve is provided, the open-to-atmosphere and closed-to-atmosphere pressures shall be disclosed.

If an anti-asphyxia valve is not provided in the VAH, manufacturers shall disclose the means by which the patient shall access fresh gas in the case of a SINGLE FAULT CONDITION.

Manufacturers shall disclose the necessity of continual monitoring of the patient by the operator and/or by monitoring equipment capable of creating alarm conditions in the case of faults.

## 5 $CO_2$ Rebreathing

Purpose: to reduce the risk of excessive inspired carbon dioxide

Disclosures:

Disclose the minimum flow required to prevent unacceptable $CO_2$ rebreathing.

Describe the means implemented to minimize the risk of rebreathing exhaled $CO_2$. The means can be included in the VAH or the equipment providing gas delivery or ventilation.

## 6 Fresh Gas Port

Purpose: since the source of fresh gas is not included in the VAH, identify the pressure or supplemental oxygen delivery interface.

Disclosures:

Disclose the means of interfacing with the fresh gas delivery system or ventilatory assist device.

## 7 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 VAH and accessories.

Description of location and specifications of required VAH viral filters and replacement intervals.

## 8 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].

## 9 Risk Management Process

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

Disclosures:

Indicate whether the VAH design has been developed using a risk management process (e.g., ISO 14971[5]).

## 10 Acoustic noise

Purpose: to ensure acoustic noise inside the VAH is at an acceptable patient level.

Disclosures:

Disclose if hearing protection is necessary and provided by the VAH manufacturer. If not provided by the VAH manufacturer provide the requirements for such hearing protection.

If measured, disclose in dBA the acoustic noise level measured at the minimum required fresh gas flowrate

## 11 Oxygen enriched environment

Purpose: to reduce the risk of thermal injury resulting from ignition of the VAH or its accessories when the VAH is used with supplemental oxygen therapy.

Disclosures:

Indicate that electronic devices used inside or in the vicinity of the VAH shall be suitable for use in an oxygen enriched environment > 25 % $O_2$. Examples of electronic devices are microphones, headphones, cell phones, and electro-medical devices.

Indicate that the use of lotions, salves, dressing, makeup, or lubricants (e.g., grease for O-rings and fittings on device) in an oxygen enriched environment requires special consideration.

If alcohol or flammable cleaning or disinfection agents are used, ensure that they have completely evaporated prior to use.

Examples:

> a warning statement to the effect that "WARNING: Use only water-based lotions, salves or dressings that are oxygen-compatible before and during oxygen therapy. Never use these products to avoid the risk of fire and burns".

[3] Biocompatibility evaluation of breathing gas pathways in healthcare applications.
[4] Biological evaluation of medical devices
[5] Medical devices - Application of risk management to medical devices

a warning statement to the effect that "WARNING: Do not use lubricant for any fittings, connections, tubing, or other accessories unless certified for use in an oxygen enriched atmosphere to avoid the risk of fire and burns."

## 12 Volume

Purpose: Provide health care providers with information to better understand the device.

Disclosures:

- Approximate volume of gas with the helmet during NORMAL USE