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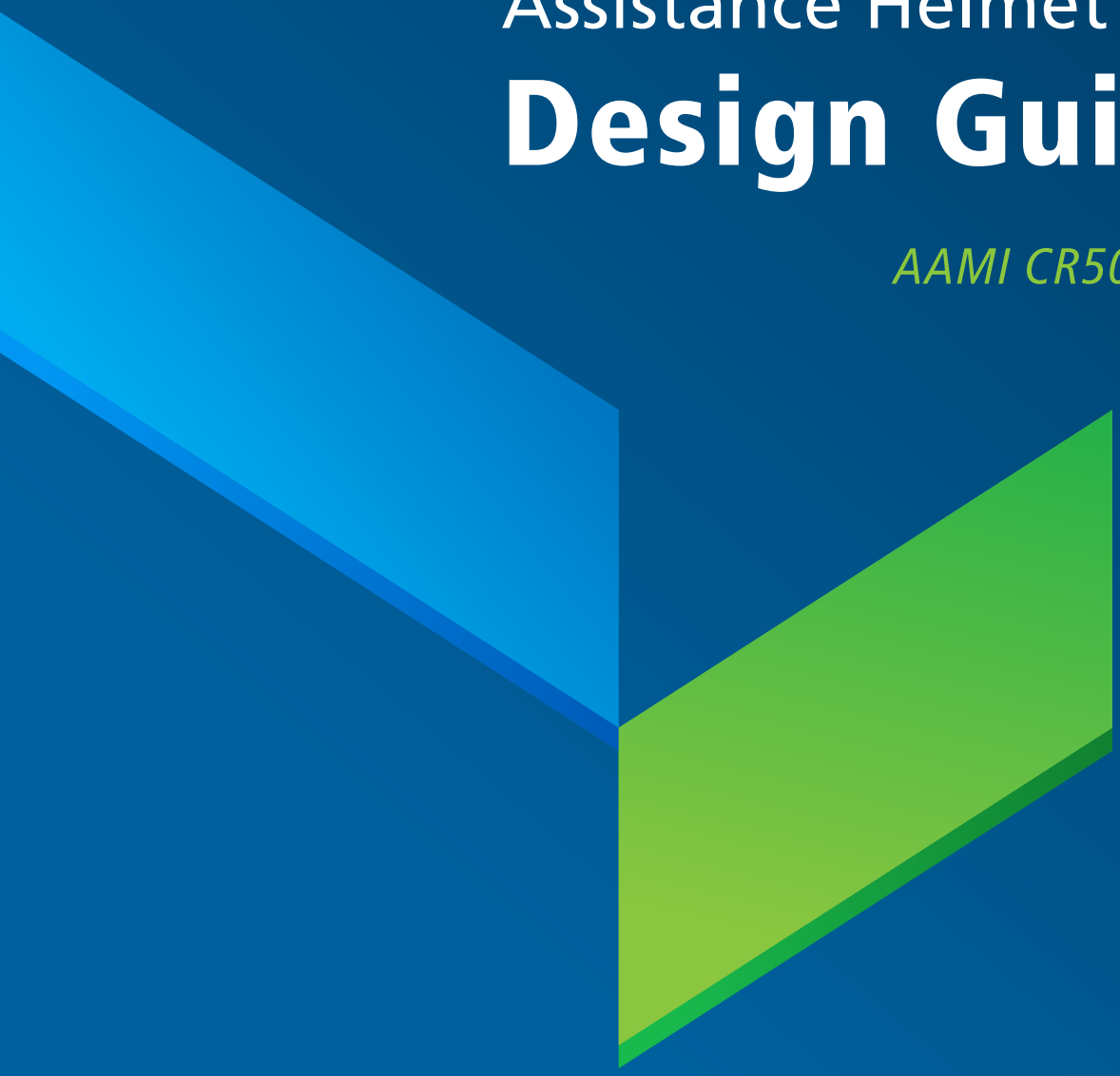
Advancing Safety in Health Technology

AAMI Consensus Report

Emergency Use Ventilatory Assistance Helmet (VAH) Design Guidance

AAMI CR508:2020/(R)2022



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AAMI CR508:2020/(R)2022
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Emergency use Ventilatory Assistance Helmet (VAH) design guidance

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Abstract: Provides targeted design constraints to enable rapid development of emergency use VAH equipment to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of an emergency use VAH by an authority having jurisdiction.

Keywords: COVID-19

AAMI Consensus Report

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Task Group representation

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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Emergency use Ventilatory Assistance Helmet (VAH) design guidance

Purpose

This document provides targeted design constraints to enable rapid development of emergency use VAH equipment to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of emergency use VAH by an authority having jurisdiction.

It is recognized that the surge in COVID-19 is requiring extraordinary measures to provide ventilatory support to keep pace with clinical need. In the very early stage of acute respiratory failure, management of mild respiratory failure, or the weaning phase from respiratory failure, spontaneous breathing with the assistance from a CPAP, BiPAP or Respiratory High Flow device and as well be the environment of supplemental oxygen may be sufficient[1]. VAH equipment can provide the patient interface for delivery from a CPAP or as needed BiPAP device and as well be the environment of supplemental oxygen.

A global community of clinicians, engineers, manufacturers, regulators, and others are responding to this need by designing and producing, inexpensive, and often open-source, equipment of varying complexity and capabilities for rapid deployment. This document identifies clinical, engineering and test requirements appropriate to support safe operation of VAH equipment.

Introduction

Due to similarities, the requirements outlined in this paper are modeled on ISO 17510,[2] with modifications to reflect differences in VAH geometry and function (e.g., containing a large volume of gas relative to tidal volume and being of flexible materials) that are also reflected herein. We presume usage in established healthcare facilities (e.g., hospitals, assisted living facilities, nursing homes) as well as spaces converted for the care of large numbers of patients with COVID-19 (e.g., convention centers, university dormitories, motels). This document presumes that the operators of the VAH are trained professional healthcare providers.

The VAH is expected to be normally operated at pressures below 25 cm H_2O, with transient excursions above this, for example due to patient coughing. Pressure safety relief and device integrity are therefore specified to be above the expected working pressure.

Leakage can be important during treatment of COVID-19 patients for containment of pathogens, and protection of health care providers and other patients, and thus is included below. Leakage is not typically adverse for the patient being treated and is generally not of concern for non-infectious patients.

Terms and definitions

exhaust port

[1] Plant PK, Owen JL, Elliott MW. Early use of non-invasive ventilation for acute exacerbations of chronic obstructive pulmonary disease on general respiratory wards: a multicentre randomised controlled trial. Lancet. 2000;355(9219):1931-5.

[2] ISO 17510 Medical devices — Sleep apnoea breathing therapy — Masks and application accessories

port through which excess and/or waste gas(es) is (are) discharged either to atmosphere or to anesthetic gas scavenging system

[SOURCE: ISO 4135:2001,4.2.1.6]

maximum working pressure

highest pressure which can be attained at the patient connection port during the inspiratory phase with the ventilator operating normally

[SOURCE: ISO 4135:2001,3.3.5]

normal condition

condition in which all means of protection are intact

[SOURCE: IEC Guide 104:2010, 3.7]

single fault condition

condition in which there is a fault of a single protection (but not a reinforced protection) or of a single component or a device

Note 1 to entry: If a single fault condition results in one or more other fault conditions, all are considered as one single fault condition.

[SOURCE: IEC Guide 104:2010, 3.8]

Connections and ports

There shall be at least two ports:

a) There shall be at least one patient-connection port suitable for BREATHING GAS inflow.
b) There shall be at least one port that functions as an EXHAUST PORT.

VAH gas port(s) shall be a 22 mm male adapter conforming with ISO 5356-1:2015.

If provided, auxiliary ports shall be provided with a means to provide a gas-tight seal at the maximum operating pressure.

If provided, the inlet connection for fresh gas shall be the nipple of EN 13544-2:2002+AMD1:2009, Figure 1, with a maximum internal bore diameter of 2,95 mm; or a male 9/16-18 UNF-2A-RH fitting

The nipple of EN 13544-2+AMD1:2009 may be connected to this male 9/16-18 UNF-980 2A-RH fitting without the use of a tool.

The gas supply hoses shall remain positioned when pulled with a force of (40 ±5) N at any angle within a cone of 45° to the major axis of the connection.

Working pressure

The VAH shall accommodate a MAXIMUM WORKING PRESSURE of at least 25 cm H_2O.

The MAXIMUM LIMITED PRESSURE shall not exceed 35cm H_2O. Pressure release means may be part of the VAH or may be provided and/or recommended elsewhere in the circuit. If incorporated in VAH, it may be delivered in a configuration in which the health care provider may disable the pressure release means, for example to prevent leakage of pathogens in the health care environment.

Filtration

Means shall be provided to attach a viral protection device so that all exhaust gas is filtered prior to entering the room in order to prevent contamination to the environment. The filter should not be easily dislodged during normal operation and in all anticipated patient positions. The viral filter shall remain positioned when pulled with a force of (40 ±5) N at any angle within a cone of 45° to the major axis of the filter.

Access to patient for airway management

Means shall be provided for the operator to remove the VAH or components of the VAH to provide emergency access the patient's airway in less than 15 s.

All components of the VAH shall be capable of removal from the patient in less than 30 s by healthcare professionals.

Resistance to flow (pressure drop)

The resistance to flow (pressure drop) across the VAH shall be measured at flowrates of 50 l/min and 100 l/min.

ISO 17510 Annex C provides guidance for measuring the resistance to flow (pressure drop).

Inspiratory pressure drop should account for all elements of the inspiratory limb between the patient connection port and the patient (e.g., connectors, adaptors).

Expiratory resistance should account for all elements of the expiratory limb (e.g., PEEP valve, filters and any other expiratory elements).

Breathing during SINGLE FAULT CONDITION

If an anti-asphyxia valve is provided, the open-to-atmosphere pressure shall be less than the minimum rated pressure of the VAH.

Means shall be provided to limit inspiratory and expiratory resistance in SINGLE FAULT CONDITION.

The following test methods in ISO 17510 provide guidance on evaluating an anti-asphyxia valve:

a) Annex D: ANTI-ASPHYXIA VALVE pressure testing
b) Annex E: Determination of the inspiratory and expiratory resistance under SINGLE FAULT CONDITION

Protection against rebreathing

Means shall be implemented to minimize the risk of rebreathing and to keep residual exhaled CO_2 to acceptable levels. This may be integral to the VAH or provided by other means. This requirement may be fulfilled by continual monitoring by a CO_2 monitor with alarm capability. If provided, the CO2 monitor shall be ISO 80601-2-55 compliant.

The manufacturer shall disclose the minimum fresh gas flowrate required to minimize rebreathing. This requirement may be fulfilled by a gas flow monitor with alarm capability.

The following test methods are based on ISO 17510: The following parts of ISO 17510 provide guidance on evaluating protection against rebreathing:

a) Clause 5.3: Protection against rebreathing

b) Annex F: Carbon Dioxide Rebreathing

7.1 Rebreathing in normal condition protection

Under normal condition, the relative CO_2 increase shall not exceed 20 % when tested at recommended flow rates.

7.2 Rebreathing in single fault condition protection

VAH shall be designed to minimize rebreathing during SINGLE FAULT CONDITION.

Under SINGLE FAULT CONDITION, the relative CO_2 increase shall not exceed 60 % when tested with blockage of an exhaust port.

Constructional requirements

VAH shall be constructed to maintain integrity up to the maximum rated working pressure for at least 72 hours at room temperature. Maintaining integrity includes no separation of seals or parts, and no unintentional leaks from unused ports.

VAH neck seal should be constructed to prevent significant leakage up to the maximum rated working pressure.

VAH shall include means for securing the VAH in place at pressures up to the maximum rated working pressure, for example under-arm straps and/or anchor locations on a bed. If underarm straps are provided, care should be taken to maintain skin integrity. Straps will be compatible with skin contact where in contact with the patient, and provide padding and/or means for ensuring padding remains in place during therapy.

Biocompatibility

9.1 General

When possible, efforts should be taken to use materials which have a long history of safe use in currently marketed medical devices. Care is needed to ensure that gas pathways are free of residual foreign material before use (e.g., oil, particles, volatile organic compounds, mold release agents). Care is needed to ensure that gas pathways do not contain toxic compounds (e.g., formaldehyde), and do not release noxious gases (e.g., ozone, carbon monoxide) and fumes.

9.2 Gas Pathways

Test methods for evaluating biocompatibility of gas pathways are found in ISO 18562 (series)[3].

9.3 VAH components that are likely to contact the patient's skin

Test methods to evaluate biocompatibility of parts in patient contact are found in ISO 10993 (series)[4].

Reprocessing VAH

Instructions shall identify portions of the VAH or its components that are intended for cleaning, disinfecting and/or reprocessing. Adequate instructions shall be provided to the healthcare professionals on the

[3] ISO 18562 (series) Biocompatibility evaluation of breathing gas pathways in healthcare applications
[4] ISO 10993 (series) Biological evaluation of medical devices

disassembly and/or re-assembly for the purpose of cleaning, disinfecting and/or reprocessing the device. Indicate the care needed to ensure that the functionality of the VAH is maintained.

Consider the number of times that the VAH can be re-used.

Noise

Manufactures should disclose in dBA the acoustic noise level measured at the minimum required fresh gas flowrate and if necessary, the means of hearing protection. A recommended test method may be found in Annex G of ISO 17510. For VAH, the test method can be modified to move the positions of the microphones to inside the VAH.

Oxygen enriched environment

11.1 Electronic devices

All electronic devices operated within the VAH shall be compatible for use in an oxygen enriched environment in order to reduce the risk of ignition in the event of a SINGLE FAULT CONDITION.

NFPA 99[5] clause 14.2.9.3.17.4 provides the requirements for patient use devices.

> **Note**: NFPA 99 is available for free download at NFPA 99 by registering on the NFPA website: https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=99

IEC 60601-1[6] clause 11.2.2 provides requirements for the design of medical devices used in an oxygen enriched environment

11.2 Lubricants

Any lotions, salves, dressings, lubricants and cleaning agents used in an oxygen enriched environment shall not be petroleum or oil based. These include patient use and those used to lubricate fittings. If alcohol or flammable cleaning or disinfection agents are used, ensure that they have completely evaporated prior to use.

[5] NFPA 99 Health Care Facilities Code
[6] IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance