AAMI
Advancing Safety in Health Technology

AAMI Consensus Report

Emergency Use Resuscitator Systems Design Guidance

AAMI/CR503:2020

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.

Emergency use resuscitator system (EURS) design guidance

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 8 April 2020 by
AAMI

Abstract: Provides targeted design constraints to enable rapid development of an “ambu bag squeezer” as an emergency use resuscitator system (EURS) to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of an EURS by an authority having jurisdiction.

Keywords: COVID-19

AAMI Consensus Report

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Emergency use resuscitator systems (EURS) design guidance

Purpose

The goals of this document are to provide targeted design constraints to enable rapid development of an "ambu bag squeezer" as an emergency use resuscitator system (EURS) to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of an EURS by an authority having jurisdiction.

It is recognized that the surge in COVID-19 is requiring extraordinary measures to provide mechanical ventilatory support to keep pace with clinical need. This global community of clinicians, engineers, manufacturers, regulators, and others are responding to this need by designing and producing, inexpensive, and often open-source, ventilators of varying complexity and capabilities for rapid deployment. This document identifies clinical, engineering and test requirements appropriate to support safe operation. The document identifies requirements that are required for non-EURSs but might not be required for EURSs that have appropriate disclosures. Therefore, equipment complying with the requirements of this document need not provide a level of performance equivalent to that of critical care ventilators (ISO 80601-2-12[1]) or life-supporting homecare ventilators (ISO 80601-2-72[2]) or of ventilatory support equipment (ISO 80601-2-80[3]).

NOTE This document is intended to be used in conjunction with AAMI CR504:2020, *End user disclosures for emergency use resuscitator systems (EURS)*.

Introduction

The requirements outlined in this paper are modeled on the MIT E-vent[4] ventilator project, where a machine has been designed to replace a trained clinician by mechanically squeezing a user-powered resuscitator (e.g. "ambu bag") as specified in ISO 10651-4[5].

The requirements outlined in this paper are presuming usage in traditional healthcare facilities (e.g. hospitals, assisted living facilities, nursing homes) as well as spaces converted for the care of large numbers of COVID-19 patients (e.g. convention centers, university dormitories, motels). This paper presumes that the operators of the EURS are all trained professional healthcare providers and not lay

1 ISO 80601-2-12, *Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

2 ISO 80601-2-72, *Medical electrical equipment — Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

3 ISO 80601-2-80, *Medical electrical equipment — Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency*

4 https://e-vent.mit.edu

5 ISO 10651-4, *Lung ventilators — Part 4: Particular requirements for operator-powered resuscitator*

persons. Hence the requirements of IEC 60601-1[6] specifically the home healthcare environment are considered not applicable to an EURS intended for the treatment of COVID-19 patients.

Fundamentally, the EURS needs to provide ventilation at the patient-connection port as set by the operator or inform the operator via an alarm condition that ventilation is not occurring. Such alarm conditions need to include:

- Electricity supply failure.
- EURS switched off inadvertently.
- Maximum inspiratory airway pressure exceeds 40 cmH_2O.
- Low inspiratory pressure (equivalent to disconnection alarm condition).
- Continuing pressure
- Estimated tidal volume not achieved or exceeded.

  Note: This equipment is not required to be able to measure tidal volume. For equipment without the ability to measure tidal volume, it can be estimated e.g., by calibrating the volume delivered based on the displacement of the resuscitator bag.

The ventilatory support needs of a COVID-19 patient can range from simple BIPAP (bilevel positive airway pressure) for patients that are breathing spontaneously to mandatory ventilation in either a pressure-support or volume control mode. Additionally, these patients are very likely to require inspired oxygen concentrations (FiO_2) in excess of the 21% contained in room air.

To properly manage a COVID-19 patient, the EURS needs to indicate to the operator at a minimum:

- The current settings (e.g., inspiratory pressure, tidal volume estimate, frequency).
- The current delivery (e.g., inspiratory pressure, respiratory rate) at the patient-connection port).

NOTE PEEP is controlled with this equipment by utilizing a PEEP valve attached to the user-powered resuscitator.

Equipment made according to this specification does not necessarily ~~measure:~~

- measure flow, ~~so~~ in which case the tidal volume is not measured. It is only an estimate and is dependent on both the patient and model of user-powered resuscitator utilized.
- measure or control FiO_2. The value of FiO_2 relies on O_2 delivery to the reservoir bag.

To properly manage a COVID-19 patient, the operator needs to be able to control the EURS at a minimum:

- I:E ratio (ratio of inspiratory to expiratory time) of 1:2 preferably adjustable from 1:1 to 1:4
- Respiratory rate from (10 to 30) inflations/min preferably adjustable in steps of no more than 2 inflations/min

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

- Tidal volume estimate (350 to 450) ml in no more than steps of 50 ml, preferably a lower range of 250 ml and an upper range of 600 ml or 800 ml

~~It is recommended that patient monitoring that includes capnography be employed and that continual monitoring of the patient be employed when utilizing an EURS.~~

To help prevent contaminating the environment (and particularly the clinicians), filters need to be placed in the expiratory pathways. Particular attention needs to be placed on the exhaust port.

Review of the requirements of IEC 60601-1 and their applicability to an EURS

NOTE 1 Adding an electromechanical squeezing accessory to a non-electrically powered resuscitator complying with ISO 10651-4 creates a system that now falls within the scope of IEC 60601-1[7].

NOTE 2 Any subclause marked with an asterisk (*) means that further guidance for this requirement is available in Annex A of the standard.

The GS (the general standard, IEC 60601-1) has required collateral standards (i.e. IEC 60601-1-2[8] on EMC, IEC 60601-1-6[9] on usability and IEC 60601-1-8[10] on alarms) that apply to an EURS. There are additional applicable collateral standards (and hence requirements) if the EURS is intended for home use, ambulance use or as part of a physiological closed loop control system. These standards can be purchased from many sources including ANSI[11] and AAMI[12].

NOTE 3 Words written in small caps are not 'normal English'. They are defined terms and have specific, defined meanings. See Clause 3 in the GS for their definitions.

Clause 3 Terminology and definitions

Additional definitions include:

AIRWAY PRESSURE
pressure at the PATIENT-CONNECTION PORT, relative to ambient pressure unless otherwise specified

Note 1 to entry: In addition to its direct reference, this term or its symbol P_{aw}, displayed in various character styles, is only used, in context or by qualification, to designate this concept as a measured quantity.

Note 2 to entry: The site(s) of actual measurement(s) may be anywhere in the breathing system, providing that the indicated value is referenced to that at the PATIENT-CONNECTION PORT.

Note 3 to entry: This is the generic term for this fundamental concept. Post-coordinated terms, for example, peak inspiratory pressure and baseline airway pressure, are used in particular contexts.

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7 IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

8 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*

9 IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*

10 IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

11 ANSI, https://webstore.ansi.org/

12 AAMI, https://my.aami.org/store/

Note 4 to entry: Although providing no explicit indication as to where along the PATIENT'S airway this pressure is measured, this term, along with its symbol, has become widely adopted as referencing the pressure at the point at which artificial-ventilation equipment is connected to the PATIENT'S airway or to an airway device. This is the final site where a common and replicable pressure can be continuously monitored, conveniently, before breathing gas enters the PATIENT.

Note 5 to entry: A pressure measured in the PATIENT'S airway at a site other than at the PATIENT-CONNECTION PORT is referred to in this document as a respiratory pressure.

BIOCOMPATIBILITY
ability to be in contact with a living system without producing an unacceptable adverse effect

Note 1 to entry: Medical devices may produce some level of adverse effect, but that level may be determined to be acceptable when considering the benefits provided by the medical device.

GAS PATHWAY
interior surfaces, over which gases or liquids that can be inspired, in a medical device bounded by the ports through which gases or liquids enter and leave the medical device including the patient interface or the interior surfaces of enclosures that are in contact with gases or liquids that can be inspired

Note 1 to entry: PATIENT contact surfaces such as the outer surfaces of a tracheal tube or the cushion of a mask are evaluated according to the ISO 10993 series.

EXAMPLE 1 The breathing system, inlet filter, gas mixer, blower and internal piping.

EXAMPLE 2 Enclosed chamber of an incubator including the mattress or the inner surface of an oxygen hood.

EXAMPLE 3 The inner surfaces of breathing tubes, tracheal tubes or masks and mouthpieces.

MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and indicates the value of a variable to the OPERATOR

PATIENT-CONNECTION PORT
port of a breathing system intended for connection to an airway device

Note 1 to entry: The PATIENT-CONNECTION PORT is the end of the ventilator breathing system proximal to the patient.

Note 2 to entry: The PATIENT-CONNECTION port is typically in the form of a suitable for connection to an airway device such as a tracheal or tracheostomy tube, a face mask, or a supralaryngeal airway, or to a test apparatus.

Note 3 to entry: Current particular standards typically specify that the PATIENT-CONNECTION PORT is required to be in the form of a specific standardized connector(s), for example, a connector(s) conforming to ISO 5356-1.

Note 4 to entry: In ventilators designed to provide NIV (non-invasive ventilation) and where the ventilation function is dependent upon a design feature of a component that connects the ventilator to the *patient's* airway, then the PATIENT-CONNECTION PORT typically becomes the contact line of the seal to the PATIENT'S face and there is no PATIENT-CONNECTION PORT connector.

PROTECTION DEVICE
part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

Clause 5 General requirements for testing of ME EQUIPMENT

This Clause of the GS is fully required.

Clause 6 Classification of ME EQUIPMENT and ME SYSTEMS

This Clause of the GS is fully required.

An EURS may be Class I or Class II or internally powered.

Unless there are electrical connections to the PATIENT (e.g. monitoring ACCESSORIES) or heated breathing tubes or electrically powered ACCESSORIES (e.g. expiratory valves located proximal to the PATIENT), the plastic breathing tubes provide adequate floating electrical isolation.

Protection from the ingress of water: IP21 should be required and IP22 is recommended for the electrical parts. Body fluids and IV bags are an expected normal part of the environment of use.

Since the EURS compresses a resuscitator that can contain an oxygen concentration in excess of the 25 %, the considerations for an OXYGEN RICH ENVIRONMENT apply (see IEC 60601-1, 11.2.2). However, if care has been taken to ensure that any motor and the electronics are not in the oxygen rich environment, then these requirements do not apply.

Clause 7 ME EQUIPMENT identification, marking and documents

7.1 General

This subclause of the GS is recommended but not required.

Rationale: Although ensuring that the EURS can be read both over the indicated illumination level and the indicated cone of visibility is recommended, in this pandemic situation it is not considered mandatory. It is noted that operators are likely wearing PPE and will have reduced visual acuity. Consideration should be given to doubling the distance of the observer.

7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

This subclause of the GS is required.

7.3 Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts

This subclause of the GS is required.

7.4 Marking of controls and instruments

This subclause of the GS is required.

201.7.4.2 Control devices

This subclause is required.

201.7.4.3 Units of measurement

This subclause is required.

7.5 Safety signs

This subclause of the GS is required.

7.6 Symbols

This subclause of the GS is required.

7.7 Colours of the insulation of conductors

This subclause of the GS is required.

7.8 Indicator lights and controls

This subclause of the GS is required.

NOTE The pending amendment to the GS clarifies this requirement.

7.9 ACCOMPANYING DOCUMENTS

This subclause of the GS is required.

201.7.9.1 Additional general requirements

This subclause is required.

Clause 8 Protection against electrical HAZARDS from ME EQUIPMENT

This Clause of the GS is generally required.

NOTE 1 Unless there are electrical connections to the PATIENT (e.g. monitoring ACCESSORIES) or heated breathing tubes or electrically powered ACCESSORIES (e.g. expiratory valves located proximal to the patient), the plastic breathing tubes provide adequate floating electrical isolation for PATIENT LEAKAGE CURRENT.

NOTE 2 Commercially available ITC (information technology communications) power supplies can be used, but electrical safety criteria (e.g. ENCLOSURE TOUCH CURRENTS and dielectric withstand) are likely to exceed IEC 60601-1 limits. This can be mitigated in several ways such as:

- Use of a low leakage SEPARATION DEVICE (isolation transformer) (see 16.5 of the GS);
- A second PERMANENTLY INSTALLED PROTECTIVE EARTH CONNECTION (see 16.6 of the GS);
- Instructing the OPERATOR to not touch the EURS and the PATIENT at the same time.

Clause 9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

This Clause of the GS is recommended but not required, except for 9.2 and 9.3 that are required.

Clause 10 Protection against unwanted and excessive radiation HAZARDS

This Clause of the GS is required.

Clause 11 Protection against excessive temperatures and other HAZARDS

This Clause of the GS is required, except as indicated below.

11.7 BIOCOMPATIBILITY of ME EQUIPMENT and ME SYSTEMS

The GAS PATHWAYS should be evaluated for BIOCOMPATIBILITY according to ISO 18562-1:2017.

The chosen materials for the GAS PATHWAYS need to be reasonably pure and simple in nature (minimize the use of additives where possible). Avoid Polyvinyl chloride (PVC) in the GAS PATHWAYS. 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 foreign material (e.g. oil, particles, volatile organic compounds, mold release agents should be avoided in the GAS PATHWAYS). 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. The ACCOMPANYING DOCUMENTS should include cautionary statement for any BIOCOMPATIBILITY identified RISK.

Rationale: The tests of ISO 18562 (series)[13] are very expensive, time consuming to perform and require very specialized test equipment. Requiring these tests for an EURS would so delay their availability such that new designs would not be available when needed. The preponderance of the gas pathways (i.e. the user-powered resuscitator and tubing) are existing legally marketed medical devices.

11.8 Interruption of the power supply/supply mains to ME EQUIPMENT

This subclause is required with the following additions:

a) An EURS shall be equipped with an INTERNAL ELECTRICAL POWER SOURCE.

b) An EURS shall be equipped with an automatic switchover to the internal electrical power source when the supply mains falls outside the values necessary to maintain normal operation.

c) A fully charged INTERNAL ELECTRICAL POWER SOURCE shall be capable of powering the EURS for at least 30 min.

d) A means shall be provided for determining the state of this INTERNAL ELECTRICAL POWER SOURCE.

e) A means shall be provided to indicate that the EURS is powered from the INTERNAL ELECTRICAL POWER SOURCE.

f) The EURS shall either:

   1) be equipped with an ALARM SYSTEM that:

      i) detects an ALARM CONDITION of at least a LOW PRIORITY to indicate the switchover to the INTERNAL ELECTRICAL POWER SOURCE;

      ii) detects an ALARM CONDITION of at least a MEDIUM PRIORITY to indicate that the INTERNAL ELECTRICAL POWER SOURCE is nearing depletion at least 15 min prior to the loss of ventilation;

   2) or be equipped with an INTELLIGENT ALARM SYSTEM, based on additional information, determines that the impending INTERNAL ELECTRICAL POWER SOURCE failure ALARM CONDITION is suppressed or its priority is changed.

NOTE The OPERATOR needs sufficient time “prior to the loss of all power” to take action to ensure that alternative arrangements can be made to continue the function of the EURS.

g) The instructions for use shall disclose:

[13] ISO 18562 (series), *Biocompatibility evaluation of breathing gas pathways in healthcare applications*

1) the operational time of the EURS when powered from each power source under the following conditions a fully charged power source and the conditions of Table 201.102;

2) the behavior of the EURS after a switch-over to:

   i) the INTERNAL ELECTRICAL POWER SOURCE, or

   ii) an alternative SUPPLY MAINS.

3) the behavior of the EURS while the recharging of:

   i) the INTERNAL ELECTRICAL POWER SOURCE, or

   ii) an alternative SUPPLY MAINS.

4) the minimum time between complete loss of INTERNAL ELECTRICAL POWER SOURCE, and

   i) the start of the LOW PRIORITY impending INTERNAL ELECTRICAL POWER SOURCE failure ALARM CONDITION, and

   ii) the MEDIUM PRIORITY impending INTERNAL ELECTRICAL POWER SOURCE failure alarm condition.

Check conformance by functional testing and inspection of the instructions for use.

An external UPS (uninterruptable power supply) may be used to fulfill this requirement.

Rationale: The power back up and appropriate notification of power loss is what is important. It need not be integrated into the EURS.

Clause 12 Accuracy of controls and instruments and protection against hazardous outputs

This Clause of the GS is required, except as indicated below.

12~~1~~.2 Usability of ME EQUIPMENT

Conformance with IEC 60601-1-6 is recommended, but not required.

Rationale: USABILITY as described in IEC 60601-1-6 ensures safety by proscribing a design PROCESS. A proper USABILITY evaluation is extremely time consuming and requires subject matter experts. A hard to use EURS can be better than no EURS.

12~~1~~.3 ALARM SYSTEMS

Conformance with IEC 60601-1-8 is recommended, but not required.

Rationale: Full conformance with IEC 60601-1-8 would be helpful to the OPERATORS as they would more readily understand the operation of the EURS ALARM SYSTEM. Care needs to be taken with auditory ALARM SIGNALS to ensure that they are not too obtrusive, appropriately priority encoded (so that more urgent problems are more highlighted) and there must be a means to inactivate any auditory ALARM SIGNAL. The ALARM SYSTEM, ALARM LIMITS, and ALARM CONDITION priorities are complex areas to optimize for USABILITY. Annex A of IEC 60601-1-8 provides a great deal of guidance.

12.4 Protection against hazardous output

Additional requirements:

12.4.101 Measurement of AIRWAY PRESSURE

12.4.101.1 General

a) The EURS shall be equipped with MONITORING EQUIPMENT to indicate the AIRWAY PRESSURE.

b) The site of actual measurement may be anywhere in the breathing system, but the indicated value shall be referenced to the PATIENT-CONNECTION PORT.

c) Under steady-state conditions, the indicated AIRWAY PRESSURE shall be accurate to within ± (2 + 4 % of the actual reading) hPa (cmH_2O).

d) The EURS should indicate the plateau pressure at end inspiration, if measured.

NOTE This is measured by holding the user-powered resuscitator bag compressed at the end of inspiration for approximately 200 ms allowing the plateau pressure to be measured.

Check conformance by functional testing.

12.4.101.2 LOW AIRWAY PRESSURE ALARM CONDITION

a) The AIRWAY PRESSURE MONITORING EQUIPMENT shall be equipped with an ALARM SYSTEM that detects an ALARM CONDITION to indicate when the low AIRWAY PRESSURE ALARM LIMIT is reached.

b) The low AIRWAY PRESSURE ALARM CONDITION:

1) shall be at least a MEDIUM PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that:

i) the low AIRWAY PRESSURE ALARM CONDITION is suppressed, or

ii) its priority is changed, or

3) may start at LOW PRIORITY, and

4) if this state continues, escalate to medium priority.

c) The low AIRWAY PRESSURE ALARM SIGNAL may be inactivated with ALARM OFF.

d) ALARM OFF may be activated by the EURS.

e) The low AIRWAY PRESSURE ALARM LIMIT may be:

1) pre-adjusted,

2) RESPONSIBLE ORGANIZATION-adjustable,

3) OPERATOR-adjustable,

4) EURS-adjustable, or

5) a combination of operator-adjustable and EURS-adjustable.

f) If the airway pressure alarm limit is adjustable by the EURS, a summary description of the algorithm that determines the alarm limit value shall be disclosed in the instructions for use.

NOTE Depending on the type of ventilation mode being utilized, there can be more than one active ALARM LIMIT.

Check conformance by functional testing.

12.4.101.3 High-pressure ALARM CONDITION and PROTECTION DEVICE

a) The EURS shall be equipped with an ALARM SYSTEM that detects a high AIRWAY PRESSURE ALARM CONDITION to indicate when the high AIRWAY PRESSURE ALARM LIMIT is reached.

b) The high AIRWAY PRESSURE ALARM CONDITION:

1) shall be HIGH PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that

i) the high AIRWAY PRESSURE ALARM CONDITION is suppressed, or

ii) its priority is changed.

c) The high AIRWAY PRESSURE ALARM LIMIT may be:

1) independently adjustable,

2) connected to an adjustable pressure limitation, or

3) related to the set pressure of the EURS.

d) If the high AIRWAY PRESSURE ALARM LIMIT is independently adjustable, it shall not be possible to set the ALARM LIMIT to a value greater than 6~~40 hPa (4~~0 cmH_2O~~)~~.

~~d)~~e) Means shall be provided to require the OPERATOR to perform a deliberate sequence of actions to confirm the setting of the ~~adjustable~~ high ~~–~~AIRWAY PRESSURE ALARM LIMIT to values exceeding 40 cmH_2O.

~~e)~~f) PATIENT-generated transient pressure increases should not cause the high AIRWAY PRESSURE ALARM CONDITION.

EXAMPLE Transient pressure increase caused by the patient coughing.

~~f)~~g) The high AIRWAY PRESSURE ALARM CONDITION DELAY shall not exceed 200 ms and the EURS shall arrest the pressure rise.

Check conformance by functional testing.

12.4.102 Continuing pressure ALARM CONDITION

a) The EURS shall be equipped with an ALARM SYSTEM that detects a continuing positive pressure of less than 10 cmH_2O variation longer than 15 s.

b) The continuing positive pressure ALARM CONDITION:

1) shall be HIGH PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that

i) the continuing positive pressure ALARM CONDITION is suppressed, or

ii) its priority is changed.

Check conformance ~~compliance~~ by functional testing.

12.4.103 Estimated tidal volume ALARM CONDITIONS

Note: If the EURS is equipped with flow measurement, tidal volume can be measured and used instead of an estimated value for this subclause.

a) The EURS shall be equipped with an ALARM SYSTEM that detects a deviation in estimated tidal volume of more than 20 %.

b) The low estimated tidal volume ALARM CONDITION:

1) shall be MEDIUM PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that:

i) the low estimated tidal volume ALARM CONDITION is suppressed, or

ii) its priority is changed.

c) The high estimated tidal volume ALARM CONDITION:

1) shall be MEDIUM PRIORITY, unless

2) an INTELLIGENT ALARM SYSTEM, based on additional information, determines that

i) the high estimated tidal volume ALARM CONDITION is suppressed, or

ii) its priority is changed.

12.4.104 Protection against inadvertent setting of high AIRWAY PRESSURE

Means shall be provided to require the *operator* to perform a deliberate sequence of actions to confirm any *airway pressure* settings exceeding 40 cmH_2O.

Check conformance ~~compliance~~ by functional testing.

Clause 13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

This Clause of the GS is required with following addition:

Independence of ventilation control function and related RISK CONTROL measures

a) A SINGLE FAULT CONDITION shall not cause the simultaneous failure of:

1) the ventilation-control function; and

2) the corresponding PROTECTION DEVICE.

b) A SINGLE FAULT CONDITION shall not cause failure in such a way that a failure of:

1) the ventilation-control function and the corresponding MONITORING EQUIPMENT is not detected, or

2) the ventilation-control function and the corresponding ALARM SYSTEM is not detected.

Check conformance by inspection and functional testing.

Clause 14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

This Clause of the GS is recommended but not required.

Clause 15 Construction of ME EQUIPMENT

This Clause of the GS is required.

Additional requirements:

15.3.101 Mechanical strength

The EURS shall be tested with each user-powered resuscitator indicated in the instructions for use at the maximum tidal volume and breath rate setting for a minimum of 24 h.

Check conformance by functional testing and inspection of the user-powered resuscitator to confirm that the user-powered resuscitator has not been damaged, that the breathing system remains connected and that the user-powered resuscitator remains in place.

Additional requirement:

15.3.102 Mechanical strength

The user-powered resuscitator shall remain positioned in the EURS when oxygen tubing (connected to the oxygen tube nipple) is pulled with a force of (40 ±5) N at any angle within a cone of 45° to the major axis of the user-powered resuscitator.

Check conformance with the following test:

Attach oxygen tubing connector to the oxygen tube nipple using axial hand pressure and a twisting motion. Position the user-powered resuscitator in the EURS according to the instructions for use. Smoothly pull the oxygen tubing away from the user-powered resuscitator with a force of (40 ±5) N at any angle within a cone of 45° to the major axis of the user-powered resuscitator.

Confirm that the user-powered resuscitator remains in place and is ready to use. Disconnection of the oxygen tubing connector from the oxygen tube nipple is not considered a failure.

Clause 16 ME SYSTEMS

This Clause of the GS is required.

Clause 17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

This Clause is recommended but not required.

Rationale: The tests of IEC 60601-1-2 are time consuming and expensive set of tests that take very specialized equipment. Requiring these tests for an EURS would delay availability such that new designs might not be available when needed. Disclosure that these tests have not been performed and that other equipment must be kept at a distance should be considered sufficient.

Additional requirements for an EURS:

Spontaneous breathing during loss of power supply

a) A PROTECTION DEVICE shall be provided to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.

b) The PROTECTION DEVICE may be provided by a MASK or ACCESSORY.

c) Under these conditions, the inspiratory and expiratory pressure drop measured at the PATIENT-CONNECTION PORT with all recommended ACCESSORIES in place shall not exceed 6,0 hPa (6,0 cmH_2O) at a flowrate of:

1) 30 l/min for EURS intended to provide a DELIVERED VOLUME, $V_{del} \geq 300$ ml;

2) 15 l/min for EURS intended to provide a DELIVERED VOLUME, $V_{del} \leq 300$ ml;

NOTE This requirement is intended to allow the patient to breathe spontaneously under compromised conditions.

Check conformance by functional testing and measurement of flowrate, pressure, and resistance at the patient-connection port with that combination of accessories indicated in the instructions for use which produces the greatest pressure drop.

Training

In the application of the requirements of IEC 62366-1:2015[14], 5.6, 5.7.1 b), 5.7.3 d) and 5.8 training shall be considered necessary for both the OPERATOR and the designee of the RESPONSIBLE ORGANIZATION.

NOTE Requirements for training are found in IEC 62366-1:2015, 5.8.

Check conformance by inspection of the ACCOMPANYING DOCUMENT and the USABILITY ENGINEERING FILE.

POWER SUPPLY CORDS

Any DETACHABLE POWER SUPPLY CORD or detachable d.c. power cord of an electrically powered EURS shall be protected against accidental disconnection from the EURS under a force of 30 N.

Check conformance by inspection and, for EURS when provided with an APPLIANCE COUPLER or detachable d.c. power cord, by the following test.

a) Subject the DETACHABLE POWER SUPPLY CORD for 1 min to an axial pull of force of 30 N.

b) During the test, the MAINS CONNECTOR becoming disconnected from the APPLIANCE INLET or the detachable d.c. power cord becoming disconnected from the d.c. input connector of the EURS is considered a failure.

[14] IEC 62366-1:2015, *Medical devices - Part 1: Application of usability engineering to medical devices*