AAMI

Advancing Safety in Health Technology

AAMI Consensus Report

Emergency Use CPAP/BiPAP Design Guidance

AAMI/CR505:2020

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AAMI CR505:2020
Revision 1
15 April 2020

Emergency use CPAP/BiPAP design guidance

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Approved 15 April 2020 by
AAMI

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

Keywords: COVID-19

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Association for the Advancement of Medical Instrumentation

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Emergency use CPAP/BiPAP design guidance

Purpose

The goals of this document are to provide targeted design constraints to enable rapid development of emergency use CPAP and BiPAP therapy equipment (EUCP) to treat patients with COVID-19 respiratory failure. This document is also intended to guide the review of an EUCP 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, equipment 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-EUCPs but might not be required for EUCPs that have appropriate disclosures. Therefore, CPAP and BiPAP therapy 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]), life-supporting homecare ventilators (ISO 80601-2-72[2]), ventilatory support equipment (ISO 80601-2-80[3]) or sleep apnea therapy equipment (ISO 80601-2-70[4]).

NOTE This document is intended to be used in conjunction with AAMI CR506:2020, *End User Disclosures for CPAP/BiPAP*.

Introduction

The requirements outlined in this paper are modeled on ISO 80601-2-70:2015 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 EUCP are trained professional healthcare providers and not lay persons. Hence the requirements of ISO 80601-2-70:2015 specifically for lay operators or the home healthcare environment are considered not applicable to an EUCP intended for the treatment of COVID-19 patients.

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

- Gas or electricity supply failure.

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

- Ventilator switched off while in mandatory ventilation mode.
- Inspiratory airway pressure exceeded.
- In BiPAP mode, expiratory airway pressure exceeded.
- Inspiratory pressure not achieved (equivalent to disconnection alarm condition).
- In a mandatory BiPAP mode, failure to cycle.

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

To properly manage a COVID-19 patient, ideally the EUCP needs to indicate to the operator:

- The current settings (e.g., expiratory pressure, FiO_2 (if possible), ventilation mode, and in BiPAP mode, inspiratory pressure).
- The current delivery (e.g., expiratory pressure and in BiPAP mode, inspiratory pressure).

To properly manage a COVID-19 patient, ideally the operator needs to be able to control the EUCP:

- FiO_2 over the range of 21 % (ambient) to 85 % of the source oxygen concentration input to the EUCP in no more than 10 % steps.

  NOTE 1 When oxygen is provided by an oxygen concentrator, the input concentration is not 99.5 %, but can vary from 90% to 96% in which case the upper limit of FiO_2 would be 76 %.

  NOTE 2 When oxygen is provided by a standalone, single patient oxygen concentrator where the oxygen is entrained into the breathing system, the upper limit of FiO_2 is much lower as those concentrators can generally only provide 6 l/min to 10 l/min.

- Set CPAP or expiratory pressure (5 to 15) cmH_2O in no more than 5 cmH_2O steps.
- In BiPAP mode, inspiratory pressure (10 to 40) cmH_2O in no more than 5 cmH_2O steps.
- For mandatory modes, respiratory rate from (10 to 30) inflations/min preferably adjustable in steps of no more than 2 inflations/min.

To help prevent contaminating the environment (and particularly the clinicians), viral filters need to be placed in the expiratory pathways. Particular attention needs to be placed on the exhaust port. As a result, **conventional CPAP masks and nasal pillows cannot be used for treating COVID 19 patients** because they are vented to the room. Non-vented ventilation masks must be used and the exhaust port needs to be moved down from the mask and be able to be fitted with a bacterial/viral filter so that all exhaust gas is filtered prior to entering the room.

For devices with a room air intake port, an intake viral filter.

Review of the requirements of IEC 80601-2-70 and their applicability to an EUCP

NOTE 1 Any subclause marked with an asterisk (*) means that further guidance for this requirement is available in Annex A of the standard.

Remember that ISO 80601-2-70 is a particular standard so it is written on top of (i.e. it modifies) the GS (the general standard, IEC 60601-1[5]) and the collateral standards (i.e. IEC 60601-1-2[6] on EMC and IEC 60601-1-6[7] on usability). Unlike sleep apnea therapy equipment, a EUCP needs to have an alarm system so parts of IEC 60601-1-8[8] on alarm systems apply. There are additional applicable collateral standards (and hence requirements) if the EUCP 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[9], AAMI[10], IEC[11] and ISO[12] and may be available for free.

NOTE 2 Words written in small caps are not 'normal English'. They are defined terms and have specific, defined meanings. See Clause 3 in the GS and 201.3 in ISO 80601-2-70 for their definitions.

4.3 ESSENTIAL PERFORMANCE

4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101— Distributed essential performance requirements

Requirement	Subclause
Providing static and dynamic pressure at the PATIENT-CONNECTION PORT of more than twice the AIRWAY PRESSURE ACCURACY limit disclosed in the instructions for use or	
generation of an *alarm condition*	
Low *airway pressure*	12.4.101.2
Continuing pressure	12.4.102
INTERNAL ELECTRICAL POWER SOURCE nears depletion	11.8
Power supply failure	11.8

4.6 * ME EQUIPMENT or parts that contact the PATIENT

aa) The breathing system or its parts or accessories that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS.

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

6 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*

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

8 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*

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

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

11 IEC, https://webstore.iec.ch/

12 ISO, https://www.iso.org/store.html

4.11.101 Additional requirements for pressurized gas input

These are the requirements for an EUCP intended to connect to either an air or oxygen pipeline.

4.11.101.1 Overpressure requirement

a) If the EUCP is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then it

   1) shall operate and meet the requirements of this part of ISO 80601 throughout its RATED range of input pressure, and

   2) shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION of 1 000 kPa.

NOTE 1 Internal pressure regulators can be needed to accommodate the SINGLE FAULT CONDITION of maximum input pressure, as well as the RATED range of input pressure.

NOTE 2 Under the SINGLE FAULT CONDITION of overpressure, it is desirable for gas to continue to flow to the breathing system. Under this condition, the flowrate from the EUCP is likely to be outside of its specification.

b) If the EUCP has a maximum RATED input pressure in excess of 600 kPa, the EUCP shall not cause an unacceptable risk under the SINGLE FAULT CONDITION of twice the maximum rated input pressure.

Check compliance by functional testing in NORMAL USE and under NORMAL CONDITION with the most adverse operating settings, by functional testing in SINGLE FAULT CONDITION and inspection of the RISK MANAGEMENT FILE.

4.11.101.2 Compatibility requirement

If the EUCP is intended to be connected to a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1, then

a) the RATED range of input pressure shall cover the range specified in ISO 7396-1, and

b) under NORMAL CONDITION,

   1) the maximum 10 s average input flowrate required by the EUCP for each gas shall not exceed 60 l/min at a pressure of 280 kPa, measured at the gas input port, and

   2) the transient input flowrate shall not exceed 200 l/min averaged for 3 s, or

   3) the ACCOMPANYING DOCUMENTS shall disclose the following:

      i) the maximum 10 s average input flowrate required by the EUCP for each gas at a pressure of 280 kPa, measured at the gas input port;

      ii) the maximum transient input flowrate averaged for 3 s required by the EUCP for each gas at a pressure of 280 kPa, measured at the gas input port;

      iii) a warning to the effect that this EUCP is a high-flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flowrate at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flowrate, thereby minimizing the risk that the EUCP interferes with the operation of adjacent equipment.

Check compliance by functional testing in NORMAL USE *and under* NORMAL CONDITION *with the most adverse operating settings and by inspection of the* ACCOMPANYING DOCUMENTS.

EXAMPLE The highest driving gas consumption, the highest fresh gas delivery, and, if provided, the highest rated gas consumption at any gas power supply output can be the most adverse conditions.

Clause 5 General requirements for testing of ME EQUIPMENT

This Clause of the GS is fully required.

201.5.101 Additional requirements for the general requirements for testing of ME EQUIPMENT

This subclause is required.

This Clause explains how to interpret and perform tests as well as how to indicate specifications.

Clause 6 Classification of ME EQUIPMENT and ME SYSTEMS

This Clause of the GS is fully required.

An EUCP 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 is required and IP22 is recommended. Body fluids and IV bags are an expected normal part of the environment of use.

Since the EUCP is expected to handle gas with an oxygen concentration in excess of 21 %, the considerations for an OXYGEN RICH ENVIRONMENT (see IEC 60601-1, 11.2.2) are fully applicable.

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 EUCP 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.

201.7.2.4.101, 201.2.13.101, and 201.7.2.101

These subclauses are 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.

201.7.4.3 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.

201.7.9.2.1.101 and 201.7.9.2.9.101

These subclauses are required.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

This subclause is required.

201.7.9.2.8.101, 201.7.9.2.12, 201.7.9.2.13.101 and 201.7.9.2.14.101

These subclauses are required.

201.7.9.3.1.101

These subclauses are 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 EUCP 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 9.3 that is required.

201.9.6.2.1.101 Additional requirements for audible acoustic energy

This subclause is not required.

Rationale: This test is hard to perform and takes expensive equipment to perform. It only provides information for disclosure that is not crucial for use during a pandemic.

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.

201.11.1.2.2 Applied parts not intended to supply heat to a PATIENT

This subclause is only applicable if a heated humidifier is utilized. See ISO 80601-2-74.

201.11.6.6 Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM

This subclause is required.

201.11.6.4 Leakage

This subclause is recommended but not required.

The chosen materials for the gas pathways need to be reasonably pure and simple in nature (e.g., 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 EUCP would so delay their availability such that new designs would not be available when needed.

201.11.8 Additional requirements for interruption of the power supply/supply mains to me equipment

This subclause is not required. See 11.8 following.

Additional requirement

11.8 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT ALARM CONDITION

This subclause is required with the following additions:

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

b) An EUCP 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 EUCP 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 EUCP is powered from the INTERNAL ELECTRICAL POWER SOURCE.

f) The EUCP 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 EUCP.

g) The instructions for use shall disclose:

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

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

2) the behavior of the EUCP after a switch-over to

i) the INTERNAL ELECTRICAL POWER SOURCE, or

ii) an alternative SUPPLY MAINS.

3) the behavior of the EUCP 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

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

i) the MEDIUM PRIORITY impending INTERNAL ELECTRICAL POWER SOURCE failure ALARM CONDITION.

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

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

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

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

This Clause of the GS is required.

201.12.1 Accuracy of controls and instruments

This subclause is not required.

Rationale: Although ensuring that the EUCP 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.

201.12.1.101 (CPAP mode)

This subclause is required.

201.12.1.102 (BiPAP mode)

If equipped with a bilevel mode, this subclause is required.

201.12.1.103

This subclause is required.

201.12.2.101 Usability of ME EQUIPMENT

This subclause is required except for d) that is not applicable.

Rationale: Requirement d) is related to home use by LAY OPERATORS.

201.12.4 Protection against hazardous output

All subclauses of 201.12.4 are required except for 201.12.4.101 that is replaced with the following.

Modify 201.12.4.101 to make the AIRWAY PRESSURE MONITORING EQUIPMENT required.

12.4.101 Measurement of AIRWAY PRESSURE

12.4.101.1 General

a) The EUCP 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 EUCP 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 compliance 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

4) may start at LOW PRIORITY, and

5) 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 EUCP.

e) The low AIRWAY PRESSURE ALARM LIMIT may be

1) pre-adjusted,

2) RESPONSIBLE ORGANIZATION-adjustable,

3) OPERATOR-adjustable,

4) EUCP-adjustable, or

5) a combination of OPERATOR-adjustable and EUCP-adjustable.

f) If the AIRWAY PRESSURE ALARM LIMIT is adjustable by the EUCP, 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 compliance by functional testing.

Additional requirement:

12.4.102 Continuing pressure ALARM CONDITION

a) When in a mandatory BiPAP mode, the EUCP 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.

201.12.101 Protection against accidental adjustments

This subclause is required.

Clause 13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

This Clause of the GS is required with the 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 compliance 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.

Clause 16 ME SYSTEMS

This Clause of the GS is required.

Clause 17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

See Clause 202.

201.101 BREATHING GAS PATHWAY connectors

This subclause is required.

201.102 Requirements for the BREATHING GAS PATHWAY and ACCESSORIES

This subclause is required.

NOTE ISO 80601-2-74 has replaced ISO 8185.

201.103 FUNCTIONAL CONNECTION

This subclause is required.

201.104 Training

This subclause is required.

202 Electromagnetic disturbances — Requirements and tests

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 EUCP 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.

206 Usability

This Clause 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 EUCP can be better than no EUCP.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

This Clause is recommended but not required.

Rationale: Full compliance with IEC 60601-1-8 would be helpful to the OPERATORS as they would more readily understand the operation of the EUCP 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.

211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

This Clause is not required.

Rationale: These requirements relate to home use.