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IEC 60601-1-10:2007+AMD1:2013 CSV (ED.1.1)

AS IEC 60601.1.10:2017

Australian STANDARD

Medical electrical equipment

Part 1.10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers

STANDARDS Australia

This Australian Standard® was prepared by Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 10 May 2017. This Standard was published on 23 June 2017.

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- Australasian College of Physical Scientists and Engineers in Medicine
- Australian and New Zealand College of Anaesthetists
- Australian Chamber of Commerce and Industry
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- College of Biomedical Engineering Engineers Australia
- Department of Defence (Australian Government)
- Engineers Australia
- Testing Interests (Australia)
- Therapeutic Goods Administration

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Australian Standard®

Medical electrical equipment

Part 1.10: General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of physiologic closed-loop controllers

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PREFACE

This Standard was prepared by the Standards Australia Committee HE-003, Medical Electrical Equipment.

The objective of this Standard is to specify requirements for the development (analysis, design, verification and validation) of a physiologic closed-loop controller (PCLC) as part of a physiologic closed-loop control system (PCLCS) in medical electrical (ME) equipment and ME systems to control a physiologic variable.

This Standard is identical with, and has been reproduced from IEC 60601-1-10:2007+AMD1:2013 CSV (ED. 1.1), *Medical electrical equipment*, Part 1-10: *General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of physiologic closed-loop controllers.*

As this Standard is reproduced from an International Standard, the following applies:

(a) In the source text 'this International Standard' should read 'this Australian Standard'.

(b) A full point substitutes for a comma when referring to a decimal marker.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

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FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This Consolidated version of IEC 60601-1-10 bears the edition number 1.1. It consists of the first edition (2007) [documents 62A/576/FDIS and 62A/585/RVD] and its amendment 1 (2013) [documents 62A/888/FDIS and 62A/896/RVD]. The technical content is identical to the base edition and its amendment.

This Final version does not show where the technical content is modified by amendment 1. A separate Redline version with all changes highlighted is available in this publication.

This publication has been prepared for user convenience.

International standard IEC 60601-1-10 has been prepared by IEC subcommittee 62A: *Common aspects of electrical equipment used in medical practice*, of IEC technical committee 62: *Electrical equipment in medical practice*, and ISO subcommittees SC1: *Breathing attachments and anaesthetic machines*, and SC3: *Lung ventilators and related devices* of ISO technical committee 121: *Anaesthetic and respiratory equipment*.

It is published as double logo standard.

This first edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

– a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or

– a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

– requirements and definitions: roman type.

– *test specifications: italic type.*

– informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the eight numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 8 includes Subclauses 8.1, 8.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 8.1, 8.2 and 8.2.1 are all subclauses of Clause 8).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

The use of PHYSIOLOGIC CLOSED-LOOP CONTROLLERS in ME EQUIPMENT and ME SYSTEMS are expected to provide a successful strategy to improve PATIENT safety and reduce healthcare costs [9][10][11][12][13] [1)]. New RISKS that are not directly addressed by previous standards are emerging in the development of this equipment. MANUFACTURERS employ a variety of methods to validate the safety and integrity of control systems with varying degrees of success. Classical methods of software VALIDATION for PHYSIOLOGIC CLOSED-LOOP CONTROLLERS can be insufficient to ensure performance with acceptable RISKS under all clinical and physiologic conditions.

1) Figures in square brackets refer to the Bibliography.

INTRODUCTION TO THE AMENDMENT

The first edition of IEC 60601-1-10 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012, to update IEC 60601-1-6:2006 to IEC 60601-1-6:2010, including its Amendment 1 and to update references to IEC 60601-1-8:2006 to include its Amendment 1:2012. This amendment also removes the normative reference to IEC 62304:2006. This collateral standard made reference to IEC 62304 because elements of the software process were not fully covered by Clause 14 of IEC 60601-1:2005. Amendment 1 to IEC 60601-1:2005 incorporates the needed software process requirement into Clause 14. Therefore, it is redundant and potentially confusing to have IEC 62304 explicitly called out in this collateral standard.

AUSTRALIAN STANDARD

Medical electrical equipment

Part 1.10: General requirements for basic safety and essential performance— Collateral Standard: Requirements for the development of physiologic closed-loop controllers

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard specifies requirements for the development (analysis, design, VERIFICATION and VALIDATION) of a PHYSIOLOGIC CLOSED-LOOP CONTROLLER (PCLC) as part of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM (PCLCS) in ME EQUIPMENT and ME SYSTEMS to control a PHYSIOLOGIC VARIABLE.

NOTE A PHYSIOLOGIC VARIABLE can be a body chemistry (e.g. electrolytes, blood glucose), a physical property (e.g. PATIENT temperature, electrophysiologic, hemodynamic), or a pharmaceutical concentration.

This collateral standard applies to various types of PCLC, e.g. linear and non-linear, adaptive, fuzzy, neural networks.

This collateral standard does not specify:

- additional mechanical requirements; or
- additional electrical requirements.

This collateral standard applies to a closed-loop controller (see Figure 1) that sets the CONTROLLER OUTPUT VARIABLE in order to adjust (i.e., change or maintain) the measured PHYSIOLOGIC VARIABLE by relating it to the REFERENCE VARIABLE.

A closed-loop controller that maintains a physical or chemical VARIABLE, using feedback that is not measured from a PATIENT, is outside the scope of this standard.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);

