

# CONSOLIDATED VERSION

# VERSION CONSOLIDÉE



**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**

**Appareils électromédicaux –  
Partie 1-10: Exigences générales pour la sécurité de base et les performances  
essentiels – Norme collatérale: Exigences pour le développement des  
régulateurs physiologiques en boucle fermée**



## THIS PUBLICATION IS COPYRIGHT PROTECTED

Copyright © 2013 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester.

If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de la CEI ou du Comité national de la CEI du pays du demandeur.

Si vous avez des questions sur le copyright de la CEI ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de la CEI de votre pays de résidence.

IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

#### Useful links:

IEC publications search - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

The advanced search enables you to find IEC publications by a variety of criteria (reference number, text, technical committee,...).

It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available on-line and also once a month by email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in additional languages. Also known as the International Electrotechnical Vocabulary (IEV) on-line.

Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [csc@iec.ch](mailto:csc@iec.ch).

### A propos de la CEI

La Commission Electrotechnique Internationale (CEI) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

### A propos des publications CEI

Le contenu technique des publications de la CEI est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

#### Liens utiles:

Recherche de publications CEI - [www.iec.ch/searchpub](http://www.iec.ch/searchpub)

La recherche avancée vous permet de trouver des publications CEI en utilisant différents critères (numéro de référence, texte, comité d'études,...).

Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

Just Published CEI - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Restez informé sur les nouvelles publications de la CEI. Just Published détaille les nouvelles publications parues. Disponible en ligne et aussi une fois par mois par email.

Electropedia - [www.electropedia.org](http://www.electropedia.org)

Le premier dictionnaire en ligne au monde de termes électroniques et électriques. Il contient plus de 30 000 termes et définitions en anglais et en français, ainsi que les termes équivalents dans les langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (VEI) en ligne.

Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [csc@iec.ch](mailto:csc@iec.ch).



IEC 60601-1-10

Edition 1.1 2013-11

# INTERNATIONAL STANDARD

## VERSION CONSOLIDÉE



**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**

**Appareils électromédicaux –  
Partie 1-10: Exigences générales pour la sécurité de base et les performances  
essentielle – Norme collatérale: Exigences pour le développement des  
régulateurs physiologiques en boucle fermée**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 11.040

ISBN 978-2-8322-1286-8

**Warning! Make sure that you obtained this publication from an authorized distributor.  
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**



# REDLINE VERSION

## VERSION REDLINE



**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**

**Appareils électromédicaux –**  
**Partie 1-10: Exigences générales pour la sécurité de base et les performances**  
**essentiels – Norme collatérale: Exigences pour le développement des**  
**régulateurs physiologiques en boucle fermée**

## CONTENTS

|  |          |
|--|----------|
| FOREWORD.....  | 4        |
| INTRODUCTION.....  | 7        |
| <b>INTRODUCTION TO THE AMENDMENT .....</b>   | <b>8</b> |
| <br>   |          |
| 1 Scope, object and related standards.....   | 9        |
| 1.1 * Scope .....  | 9        |
| 1.2 Object .....   | 9        |
| 1.3 Related standards .....  | 9        |
| 1.3.1 IEC 60601-1 .....  | 9        |
| 1.3.2 Particular standards .....   | 10       |
| 2 Normative references .....   | 10       |
| 3 Terms and definitions .....  | 10       |
| 4 * General requirements .....   | 15       |
| 5 ME EQUIPMENT identification, marking and documents .....   | 16       |
| 5.1 * Instructions for use .....   | 16       |
| 5.2 Technical description.....   | 16       |
| 6 Accuracy of controls and instruments and protection against hazardous outputs .....  | 16       |
| 6.1 * USABILITY .....  | 16       |
| 6.2 ALARM SYSTEMS .....  | 16       |
| 6.3 * PCLCS VARIABLE logging .....   | 17       |
| 6.4 * DISTRIBUTED PCLCS .....  | 17       |
| 7 * PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) .....   | 17       |
| 8 Requirements for PHYSIOLOGIC CLOSED-LOOP CONTROLLER (PCLC) development.....  | 17       |
| 8.1 * General.....   | 17       |
| 8.2 Attributes/activities of the PCLC development PROCESS .....  | 18       |
| 8.2.1 RECORDS and PROCESS scaling .....  | 18       |
| 8.2.2 Equipment specifications .....   | 18       |
| 8.2.3 * Disturbance management.....  | 21       |
| 8.2.4 * PCLC VERIFICATION .....  | 22       |
| 8.2.5 * PCLCS VALIDATION .....   | 22       |
| <br>   |          |
| Annex A (informative) General guidance and rationale.....  | 23       |
| Annex B (informative) Description of dynamic performance of a PCLCS .....  | 33       |
| Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT<br>and ME SYSTEMS.....                                  | 37       |
| <br>   |          |
| Bibliography.....  | 38       |
| <br>   |          |
| Index of defined terms used in this collateral standard .....  | 39       |
| <br>   |          |
| Figure 1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED-<br>LOOP CONTROL SYSTEM (PCLCS) utilizing a PCLC ..... | 11       |
| Figure B.1 – Example of PCLCS dynamic performance with no STEADY-STATE DEVIATION.....  | 34       |
| Figure B.2 – Example of PCLCS dynamic performance with STEADY-STATE DEVIATION.....   | 35       |

Figure B.3 – Example of PCLCS dynamic performance transient COMMAND VARIABLE .....36

Table A.1 – Examples of ME EQUIPMENT or ME SYSTEMS that incorporate a PCLCS .....23

Table C.2 – ACCOMPANYING DOCUMENTS, instructions for use .....37

Table C.3 – ACCOMPANYING DOCUMENTS, technical description.....37

**iTeh Standards**  
**(<https://standards.itih.ai>)**  
**Document Preview**

[IEC 60601-1-10:2007](https://standards.itih.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007)

<https://standards.itih.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007>

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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**

## 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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 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.**

**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted 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.

**IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.**

iTeh Standards  
(<https://standards.iteh.ai>)  
Document Preview

[IEC 60601-1-10:2007](https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007)

<https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007>

## 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] <sup>1)</sup>. 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.

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[IEC 60601-1-10:2007](https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007)

<https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007>

---

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.

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[IEC 60601-1-10:2007](https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007)

<https://standards.iteh.ai/catalog/standards/iec/fa2a9d46-e0ad-4bd5-96bd-87ec84fb1cfc/iec-60601-1-10-2007>

**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);

- "this collateral standard" designates IEC 60601-1-10 alone (~~IEC 60601-1-10:2007+A1:2013~~);
- "this standard" designates the combination of the general standard and this collateral standard.

### 1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

## 2 Normative references

The following ~~referenced~~ documents, in whole or in part, are normatively referenced in this document and are indispensable for ~~the its application of this document~~. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

~~Amendment 1:2012~~

IEC 60601-1-6:~~2006~~2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability*

~~Amendment 1:2013~~

IEC 60601-1-8:2006, *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*

~~Amendment 1:2012~~

~~IEC 62304:2006, *Medical device software – Software life cycle processes*~~

~~IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*~~

ISO 14971, *Medical devices – Application of risk management to medical devices*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012, IEC 60601-1-6:~~2006~~2010+A1:2013, IEC 60601-1-8:2006+A1:2012, IEC 62366:2007 and the following apply.

NOTE An index of defined term used in this collateral standard is found beginning on page 39.

### 3.1

#### ACTUATOR

##### A

part of a PCLCS that performs a specified output function (see, for example, Figure 1, A)

EXAMPLE 1 A heater delivers thermal energy.

EXAMPLE 2 An infusion pump delivers a fluid or drug.

EXAMPLE 3 An anaesthetic agent vaporizer delivers a vapour concentration.

EXAMPLE 4 A ventilator delivers an inspiratory volume.