

Index des termes définis utilisés dans la présente norme collatérale

DOCUMENT D'ACCOMPAGNEMENT.....	CEI 60601-1: 2005, 3.4
ACTIONNEUR (A).....	3.1
CONDITION D'ALARME	CEI 60601-1-8:2006+A1:2012, 3.1
SIGNAL D'ALARME.....	CEI 60601-1-8:2006, 3.9
SYSTEME D'ALARME.....	CEI 60601-1-8:2006, 3.11
SECURITE DE BASE	CEI 60601-1: 2005, 3.10
DEPASSEMENT DE LA CONSIGNE.....	3.2
ELEMENT DE TRANSFERT DE LA CONSIGNE (C)	3.3
VARIABLE DE CONSIGNE (<i>c</i>)	3.4
COMPARATEUR (D).....	3.5
ELEMENT DE TRANSFERT DE LA COMMANDE (E)	3.6
VARIABLE DE SORTIE DU REGULATEUR (<i>x</i>)	3.7
SPCBF REPARTI	3.8
VARIABLE PERTURBATRICE (<i>v</i>)	3.9
VARIABLE D'ERREUR (<i>e</i>)	3.10
PERFORMANCE ESSENTIELLE	CEI 60601-1: 2005+A1:2012, 3.27
MODE REPLI AUTOMATIQUE.....	3.11
VARIABLE DE REACTION (<i>f</i>)	3.12
DANGER	CEI 60601-1:2005+A1:2012, 3.39
SIGNAL D'INFORMATION.....	CEI 60601-1-8:2006, 3.23
UTILISATION PREVUE	CEI 60601-1:2005+A1:2012, 3.44
SOURCE D'ENERGIE ELECTRIQUE INTERNE.....	CEI 60601-1:2005, 3.45
VARIABILITE INTERPATIENT	3.13
VARIABILITE INTRAPATIENT	3.14
VARIABLE REGLANTE (<i>m</i>)	3.15
FABRICANT	CEI 60601-1:2005+A1:2012, 3.55
APPAREIL EM	CEI 60601-1:2005, 3.63
SYSTEME EM.....	CEI 60601-1:2005, 3.64
ELEMENT DE TRANSFERT DE LA MESURE (F)	3.16
CONDITION NORMALE	CEI 60601-1:2005, 3.70
UTILISATION NORMALE	CEI 60601-1:2005+A1:2012, 3.71
PREUVE TANGIBLE	CEI 60601-1:2005+A1:2012, 3.72
OPERATEUR.....	CEI 60601-1:2005, 3.73
PROFIL DE L'OPERATEUR.....	CEI 60601-1-6:2006, 3.5
PATIENT	CEI 60601-1:2005+A1:2012, 3.76
ENVIRONNEMENT DU PATIENT	CEI 60601-1:2005, 3.79
VARIABLE PERTURBATRICE DU PATIENT (<i>v_p</i>).....	3.17
ELEMENT DE TRANSFERT DU PATIENT (P).....	3.18
SYSTEME PHYSIOLOGIQUE DE COMMANDE EN BOUCLE FERMEE (SPCBF)	3.19
REGULATEUR PHYSIOLOGIQUE EN BOUCLE FERMEE (RPBF)	3.20
VARIABLE PHYSIOLOGIQUE (<i>y</i>).....	3.21
PROCESSUS.....	CEI 60601-1:2005+A1:2012, 3.89

SYSTÈME ÉLECTROMÉDICAL PROGRAMMABLE (SEMP)	CEI 60601-1:2005, 3.90
SOUS-SYSTEME ELECTRONIQUE PROGRAMMABLE (SSEP)	CEI 60601-1:2005, 3.91
ENREGISTREMENT	CEI 60601-1:2005+A1:2012, 3.98
VARIABLE DE REFERENCE (w)	3.22
DEPASSEMENT RELATIF (y_{ro})	3.23
RISQUE RESIDUEL	CEI 60601-1:2005+A1:2012, 3.100
TEMPS DE REPONSE (T_r)	3.24
RISQUE	CEI 60601-1:2005+A1:2012, 3.102
ANALYSE DE RISQUE	CEI 60601-1:2005+A1:2012, 3.103
GESTION DES RISQUES	CEI 60601-1:2005+A1:2012, 3.107
DOSSIER DE GESTION DES RISQUES	CEI 60601-1:2005+A1:2012, 3.108
PERSONNEL D'ENTRETIEN	CEI 60601-1:2005, 3.113
DUREE D'ETABLISSEMENT (T_{st})	3.25
CONDITION DE PREMIER DEFAULT	CEI 60601-1:2005+A1:2012, 3.116
ECART EN REGIME PERMANENT (y_{sd})	3.26
RESEAU D'ALIMENTATION	CEI 60601-1:2005, 3.120
ERREUR DE POURSUITE (E_{tr})	3.27
FORMATION	CEI 60601-1-6:2006, 3.8
ERREUR D'UTILISATION	CEI 60601-1-6:2006, 3.9 62366:2007, 3.21
APTITUDE A L'UTILISATION	CEI 60601-1:2005, 3.136 62366:2007, 3.17
INGENIERIE DE L'APTITUDE A L'UTILISATION	CEI 60601-1-6:2006, 3.12 62366:2007, 3.18
DOSSIER D'INGENIERIE DE L'APTITUDE A L'UTILISATION	CEI 60601-1-6:2006, 3.13 62366:2007, 3.19
VALIDATION	CEI 60601-1-6:2006, 3.15 62366:2007, 3.26
VARIABLE	3.28
VERIFICATION	CEI 60601-1:2005+A1:2012, 3.138

FINAL VERSION

VERSION FINALE

**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
INTRODUCTION TO THE AMENDMENT	8
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	15
5.1 * Instructions for use	15
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	16
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	21
8.2.5 * PCLCS VALIDATION	22
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 and ME SYSTEMS.....	37
Bibliography.....	38
Index of defined terms used in this collateral standard	39
Figure 1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED- 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 VARIABLE36

Table A.1 – Examples of ME EQUIPMENT or ME SYSTEMS that incorporate a PCLCS23

Table C.2 – ACCOMPANYING DOCUMENTS, instructions for use37

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

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

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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.

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);