# IEC 60601-1-10

Edition 1.0 2007-11

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

**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 essentielles – Norme collatérale: Exigences pour le développement des régulateurs physiologiques en boucle fermée**



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# 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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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.

The text of this collateral standard is based on the following documents:

| FDIS | Report on voting |
|---|---|
| 62A/576/FDIS | 62A/585/RVD |

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 18 P-members out of 19 having cast a vote.

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 this publication will remain unchanged until the maintenance result 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

# 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.

# 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;

– "this collateral standard" designates IEC 60601-1-10 alone;

– "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 are indispensable for the 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*

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

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*



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



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, IEC 60601-1-6:2006, IEC 60601-1-8:2006 and the following apply.

NOTE An index of defined term used in this collateral standard is found beginning on page 38.

**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.

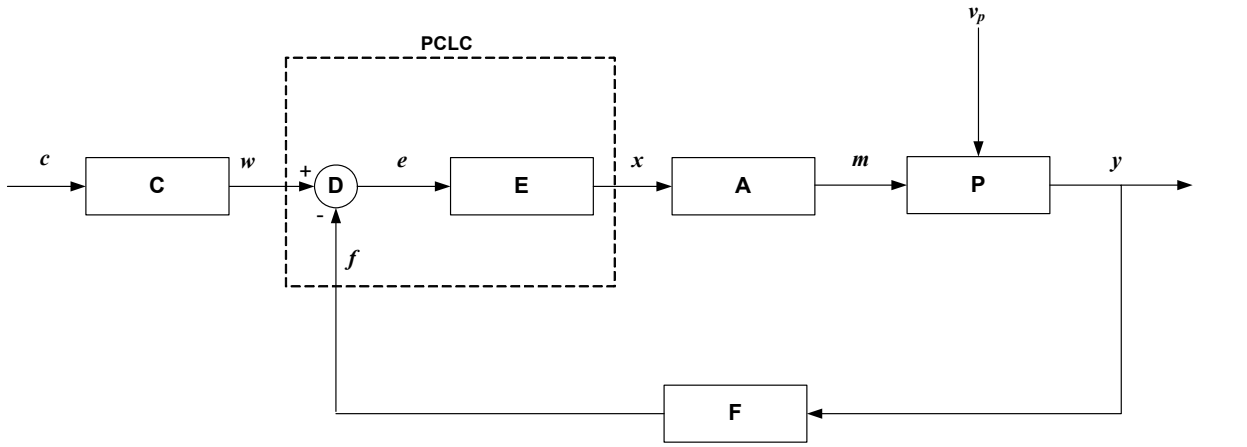
EXAMPLE 2 An infusion pump delivers a fluid or drug.

EXAMPLE 3 An anaesthetic agent vaporizer delivers a vapour concentration.

EXAMPLE 4 A ventilator delivers an inspiratory volume.

**3.2**
**COMMAND OVERSHOOT**
$y_{co}$
for a step response, the maximum positive deviation of the PHYSIOLOGIC VARIABLE ($y$), from the COMMAND VARIABLE ($c$)

NOTE See also Annex B.




| Elements | | VARIABLES | |
|---|---|---|---|
| **PCLC** | PHYSIOLOGIC CLOSED-LOOP CONTROLLER | | |
| **A** | ACTUATOR | $m$ | MANIPULATED VARIABLE |
| **C** | COMMAND TRANSFER ELEMENT | $w$ | REFERENCE VARIABLE |
| **D** | COMPARING ELEMENT | $e$ | ERROR VARIABLE |
| **E** | CONTROL TRANSFER ELEMENT | $x$ | CONTROLLER OUTPUT VARIABLE |
| **F** | MEASURING TRANSFER ELEMENT | $f$ | FEEDBACK VARIABLE |
| **P** | PATIENT TRANSFER ELEMENT | $y$ | PHYSIOLOGIC VARIABLE |
| | | $v_p$ | PATIENT DISTURBANCE VARIABLE |
| | | $c$ | COMMAND VARIABLE |

NOTE DISTURBANCE VARIABLES ($v$), not shown, can act on any element or VARIABLE.



**Figure 1 – Functional diagram indicating typical components of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM (PCLCS) utilizing a PCLC**



**3.3**
*** COMMAND TRANSFER ELEMENT**
**C**
part of a PCLCS that provides an output having a deterministic relationship to the COMMAND VARIABLE ($c$) (see, for example, Figure 1, C)

**3.4**
*** COMMAND VARIABLE**
*c*
VARIABLE which, after signal conversion or other processing by the COMMAND TRANSFER ELEMENT (C), gives the REFERENCE VARIABLE ($w$) (see, for example, Figure 1, $c$)

**3.5**
*** COMPARING ELEMENT**
**D**
element with two inputs and one output, the output VARIABLE being the difference between the input VARIABLES (see, for example, Figure 1, D)

[IEC 60050-351, definition 351-28-03, modified]

NOTE The difference can be simple subtraction, classification within a value range, or a complex relationship such as results from a neural network calculation.

**3.6**
**CONTROL TRANSFER ELEMENT**
**E**
part of a PCLC that provides an output having a deterministic relationship to the FEEDBACK VARIABLE ($f$) (see, for example, Figure 1, E)

**3.7**
**CONTROLLER OUTPUT VARIABLE**
***x***
VARIABLE of the CONTROL TRANSFER ELEMENT (E), which is also an input VARIABLE of the ACTUATOR (A) (see, for example, Figure 1, $x$)

**3.8**
*** DISTRIBUTED PCLCS**
PCLCS that involves more than one item of equipment of a ME SYSTEM

NOTE The parts of a DISTRIBUTED PCLCS can be widely separated in distance.

**3.9**
*** DISTURBANCE VARIABLE**
***v***
VARIABLE acting on a PCLCS that is independent of the other VARIABLES of the PCLCS (see, for example, Figure 1, $v$ and $v_p$)

NOTE 1 DISTURBANCE VARIABLES are undesired, independent, and most frequently unpredictable from the perspective of the PCLC. The MANUFACTURER or OPERATOR can be aware of DISTURBANCE VARIABLES.

NOTE 2 The MANUFACTURER needs to identify the DISTURBANCE VARIABLES that are relevant to the PCLC, but their values are usually unpredictable.

**3.10**
**ERROR VARIABLE**
***e***

difference between the REFERENCE VARIABLE ($w$) and the FEEDBACK VARIABLE ($f$) (see, for example, Figure 1, $e$)


[IEC 60050-351, definition 351-27-04]



**3.11**
*** FALLBACK MODE**
mode of operation (or state) into which the PCLCS transitions when the PCLC stops operating due to detection of a fault

**3.12**
**FEEDBACK VARIABLE**
***f***
output of the MEASURING TRANSFER ELEMENT (F) (see, for example, Figure 1, $f$)

[IEC 60050-351, definition 351-27-03, modified]

**3.13**
**INTERPATIENT VARIABILITY**
variability of the PATIENT TRANSFER ELEMENT between PATIENTS

EXAMPLE The reaction of PATIENTS to the same amount of a certain drug can vary widely.

**3.14**
**INTRAPATIENT VARIABILITY**
variability of the PATIENT TRANSFER ELEMENT within the same PATIENT over time

EXAMPLE The reaction of a PATIENT to a dose of a drug that varies widely during the day.

**3.15**
**MANIPULATED VARIABLE**
***m***
output of the ACTUATOR (A), which is also an input VARIABLE of the PATIENT TRANSFER ELEMENT (see, for example, Figure 1, $m$)

[IEC 60050-351, definition 351-27-07, modified]

**3.16**
**MEASURING TRANSFER ELEMENT**
F
part of a PCLCS that provides an output having a determined relationship to the PHYSIOLOGIC VARIABLE ($y$) (see, for example, Figure 1, F)

EXAMPLE 1 thermocouple

EXAMPLE 2 current transformer

EXAMPLE 3 strain gauge

EXAMPLE 4 pH electrode

EXAMPLE 5 pulse oximeter

EXAMPLE 6 respiratory gas monitor

EXAMPLE 7 heart rate monitor

EXAMPLE 8 blood pressure monitor

EXAMPLE 9 EEG monitor

EXAMPLE 10 EMG monitor

EXAMPLE 11 cardiac output monitor



**3.17**
*** PATIENT DISTURBANCE VARIABLE**
***v*p**
DISTURBANCE VARIABLE, independent of the MANIPULATED VARIABLE ($m$), which changes the PATIENT TRANSFER ELEMENT ($P$) (see, for example, Figure 1, $v_p$)

**3.18**
**PATIENT TRANSFER ELEMENT**
**P**
relationship of the change of the PHYSIOLOGIC VARIABLE ($y$) in response to a change in the MANIPULATED VARIABLE ($m$) (see, for example, Figure 1, P)

**3.19**
**PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM**
**PCLCS**
part of ME EQUIPMENT or ME SYSTEM used to adjust a PHYSIOLOGIC VARIABLE ($y$) relative to a COMMAND VARIABLE ($c$) using a FEEDBACK VARIABLE ($f$) (see, for example, Figure 1)

**3.20**
*** PHYSIOLOGIC CLOSED-LOOP CONTROLLER**
**PCLC**
element of a PHYSIOLOGIC CLOSED-LOOP CONTROL SYSTEM in which a FEEDBACK VARIABLE ($f$) is compared with a REFERENCE VARIABLE ($w$), and their difference is transformed to set the CONTROLLER OUTPUT VARIABLE ($x$) (see, for example, Figure 1, PCLC)

**3.21**
**PHYSIOLOGIC VARIABLE**
***y***
quantity or condition from a PATIENT whose value is subject to change and can usually be measured

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.

**3.22**
*** REFERENCE VARIABLE**
***w***
input VARIABLE to a COMPARING ELEMENT (D) in a PCLC that sets the desired value of the PHYSIOLOGIC VARIABLE ($y$) (see, for example, Figure 1, $w$)

[IEC 60050-351, definition 351-27-02, modified]

**3.23**
**RELATIVE OVERSHOOT**
$y_{ro}$
for a step response, the maximum transient deviation from the final steady-state value of the PHYSIOLOGIC VARIABLE ($y$), expressed as the difference between the final and the initial steady-state values

NOTE 1 The initial steady-state value is the value of the PHYSIOLOGIC VARIABLE prior to applying the step.

NOTE 2 See also Annex B.

[IEC 60050-351, definition 351-24-30, modified]



**3.24**
**RESPONSE TIME**
$T_r$

time required for the step response of the PHYSIOLOGIC VARIABLE ($y$) to move from its initial value to a specified percentage of the final steady-state value

NOTE 1 The time is measured from the point in time that the step is applied.

NOTE 2 The conventional value for the percentage is 90 %.

NOTE 3 See also Annex B.

**3.25**
**SETTLING TIME**
$T_{st}$
duration of the time interval between the instant of a step change in one of the input VARIABLES and the instant when the PHYSIOLOGIC VARIABLE ($y$) does not deviate by more than a specified tolerance from the difference between its final and initial steady-state values

NOTE 1 The conventional value for the tolerance is 5 %.

NOTE 2 See also Annex B.

[IEC 60050-351, definition 351-24-29, modified]

**3.26**
**STEADY-STATE DEVIATION**
$y_{sd}$
deviation between PHYSIOLOGIC VARIABLE ($y$) and COMMAND VARIABLE ($c$) when transient effects have subsided and the COMMAND VARIABLE is maintained constant

NOTE See also Annex B.