IEC 60601-1-10

Edition 1.0 2020-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 2
AMENDEMENT 2

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

IEC 60601-1-10:2007-11/AMD2:2020-07(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8622-7

FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

The text of this amendment is based on the following documents of IEC:

FDIS	Report on voting
62A/1394/FDIS	62A/1409/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the amendment has been approved by 17 P members out of 17 having cast a vote.

The committee has decided that the contents of this amendment and the base publication 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- withdrawn,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 users of this document 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 mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION TO AMENDMENT 2

The first edition of IEC 60601-1-10 was published in 2007 and amended in 2013. Since the publication of IEC 60601-1-10:2007+A1:2013, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the second edition of IEC 60601-1-10, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 13 items were presented to the National Committees present. All 13 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the second edition of IEC 60601-1-10.

The "short list" of issues was documented in the design specification for Amendment 2. As IEC 60601-1-10 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 5. JWG 5 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-10:2007, the style in force at the time of publication of IEC 60601-1-10 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, references to amendments take the following form: "IEC 60601-1:2005+A1:2012+A2:2020".

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

1.1 * Scope

Replace the existing second paragraph and note with the following new paragraph and example:

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) to control at least one PATIENT VARIABLE (i.e. a PHYSIOLOGIC VARIABLE) in ME EQUIPMENT and ME SYSTEMS.

EXAMPLE A PATIENT VARIABLE can be a measure of body chemistry (e.g. electrolytes or blood glucose value), a physical property (e.g. body temperature, electrophysiologic characteristic, hemodynamic quantity), or a pharmaceutical concentration.

1.3.1 IEC 60601-1

Replace, in the first two dashes of the existing second paragraph, the parentheses, added by Amendment 1, with the words ", including any amendments"*.*

2 Normative references

Replace the existing references to IEC 60601-1, IEC 60601-1-6, IEC 60601-1-8, IEC 62366 and ISO 14971, modified by Amendment 1, by the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020

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
Amendment 2:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
Amendment 1:2020

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

Add the following new normative reference:

ISO 9000:2015, *Quality management systems – Fundamentals and vocabulary*

3 Terms and definitions

Replace the existing first paragraph with the following new paragraph:

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-6:2010+A1:2013+A2:2020, IEC 60601-1-8:2006+A1:2012+A2:2020, IEC 62366-1:2015+A1:2020, ISO 9000:2015 and the following apply.

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

*Add, to the definition of symbol "y" in the existing key, the word "controlled" before "*PHYSIOLOGIC VARIABLE*".*

3.4
*** COMMAND VARIABLE**

Add the following new note:

NOTE A COMMAND VARIABLE may be a range or a function (e.g. clinical protocol).

3.20
*** PHYSIOLOGIC CLOSED-LOOP CONTROLLER**

Add the following new notes:

NOTE 1 A PCLC may utilize multiple PHYSIOLOGIC VARIABLES and COMMAND VARIABLES as well as multiple CONTROLLER OUTPUT VARIABLES.

NOTE 2 A PATIENT VARIABLE may be used as an input to adjust the parameters of the CONTROL TRANSFER ELEMENT.

3.21
PHYSIOLOGIC VARIABLE

Replace the existing definition with the following new definition:

PATIENT VARIABLE intended to be controlled

Delete the existing note.

3.23
RELATIVE OVERSHOOT

*Add, after "*PHYSIOLOGIC VARIABLE*" in the existing Note 1, the words "or* FEEDBACK VARIABLE*".*

Add the following new term and definition:

3.29
*** PATIENT VARIABLE**
PATIENT attribute, characteristic, quantity or condition that is measured

EXAMPLE A PATIENT VARIABLE can be a measure of body chemistry (e.g. electrolytes or blood glucose value), a physical property (e.g. body temperature, electrophysiologic characteristic, hemodynamic quantity), or a pharmaceutical concentration.

4 * General requirements

Add, before the word "substances" *in the existing two bullets of the first paragraph, the words* "or removed" *in two places*.

Add, after the existing dash "PATIENT TRANSFER ELEMENT, including any hysteresis" *of the first paragraph, the following new dash:*

– uncertainty of the model of the PATIENT TRANSFER ELEMENT;

5.1 * Instructions for use

Replace, in the existing second paragraph, "Table C.2" *with* "Table C.1".

5.2 Technical description

Add, before the first existing paragraph, the following new paragraph:

In addition to the requirements in 7.9.3 of the general standard, the technical description shall contain the PCLCS block diagram and theory of operation.

Replace, in the existing first paragraph, "Table C.3" *with* "Table C.2".

Add, after the existing paragraph, the following new paragraph:

Compliance is checked by inspection of the technical description.

6.1 * USABILITY

Replace the three existing dashes after "the current value of:" *with the following new dashes:*

– COMMAND VARIABLE or REFERENCE VARIABLE;
– CONTROLLER OUTPUT VARIABLE or MANIPULATED VARIABLE;
– PHYSIOLOGIC VARIABLE or FEEDBACK VARIABLE; and
– any PATIENT VARIABLE that is used by the PCLC;

6.3 * PCLCS VARIABLE logging

Replace the existing first paragraph with the following new paragraphs:

ME EQUIPMENT or ME SYSTEMS that incorporate a PCLC shall provide a means to log the values of at least

– the COMMAND VARIABLE or REFERENCE VARIABLE;
– the CONTROLLER OUTPUT VARIABLE or MANIPULATED VARIABLE;
– the PHYSIOLOGIC VARIABLE or FEEDBACK VARIABLE; and
– any PATIENT VARIABLE that is used by the PCLC.

The log is necessary to analyze the performance of the PCLCS. The resolution and duration of the log shall be based on HAZARDS identified in Clause 4. The log should be capable of storing the information for a reasonable period of time.

8.2.1 RECORDS and PROCESS scaling

Replace, in the existing first paragraph, "IEC 62304:2006" *with* "Clause 14 of the general standard".

8.2.2.1 * Application specification

Replace the existing subclause, including its title, with the following new subclause and title:

8.2.2.1 * USE SPECIFICATION

The MANUFACTURER shall prepare the USE SPECIFICATION, as required in IEC 62366-1, of the ME EQUIPMENT or ME SYSTEM that incorporates a PCLC.

A summary of the USE SPECIFICATION shall be included in the instructions for use.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE and the instructions for use.

8.2.2.2 * State VARIABLES

Replace the existing subclause, including its title, with the following new subclause and title:

8.2.2.2 * PCLCS attributes

The MANUFACTURER shall characterize attributes of the following:

– the COMMAND VARIABLE or REFERENCE VARIABLE;

– the CONTROLLER OUTPUT VARIABLE or MANIPULATED VARIABLE;

– the PHYSIOLOGIC VARIABLE or FEEDBACK VARIABLE; and

– the PATIENT VARIABLE that is used by the PCLC.

The MANUFACTURER shall characterize the limitations and ranges of the PATIENT TRANSFER ELEMENT, including INTERPATIENT VARIABILITY and INTRAPATIENT VARIABILITY.

If practicable, the MANUFACTURER shall develop and use a mathematical model to characterize the PATIENT TRANSFER ELEMENT. If using a MATHEMATICAL MODEL, the MANUFACTURER shall provide a justification to support that the model represents the relevant PATIENT responses. The justification shall consider INTERPATIENT VARIABILITY and INTRAPATIENT VARIABILITY and identify the limitations of that model, including a characterization of the uncertainty of that mathematical model, such as by using a credibility assessment framework.

NOTE See reference [14] for additional information.

If developing a mathematical model of the PATIENT TRANSFER ELEMENT is not practicable, the MANUFACTURER shall provide a justification for any assumptions made regarding the PATIENT TRANSFER ELEMENT.

The MANUFACTURER shall describe the PCLC modes of operation.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

8.2.5.1 * VALIDATION plan

Replace, in the existing first paragraph, the fourth and fifth dashes with the following new dashes:

– monitoring of the PHYSIOLOGIC VARIABLES or FEEDBACK VARIABLES;

– PATIENT TRANSFER ELEMENT, including INTERPATIENT VARIABILITY and INTRAPATIENT VARIABILITY; and

Replace, in the existing note, the word "NOTE" with "NOTE 1".

Add, after the existing note, the following new paragraph and note:

When a mathematical model of the PATIENT TRANSFER ELEMENT is used as part of PCLCS VALIDATION, the MANUFACTURER shall provide a rationale to support that the model is sufficiently credible for its role in PCLCS VALIDATION. A credibility assessment framework may be used to generate a rationale to support that a mathematical model is sufficiently credible for a proposed context of use.

NOTE 2 See reference [14] for additional information.

A.1 General guidance

Add, after "delivery" in the existing first paragraph, the words "or removal".

Replace, in the existing note following the third paragraph, the word "NOTE" with "NOTE 1".

Replace the existing Example 1 with the following new example:

EXAMPLE 1 ME EQUIPMENT providing a safety interlock that stops (and does not titrate or restart) energy or substance delivery based on physiologic limits is not a PCLCS because the PATIENT VARIABLE is not controlled (i.e. it is not a PHYSIOLOGIC VARIABLE). For example, ME EQUIPMENT that stops, or decreases by a pre-determined rate, the infusion of a sedative-hypnotic or opioid intravenous infusion when blood oxygen saturation (SpO_2) or respiratory rate decreases below threshold values is not a PCLCS. On the other hand it would be a PCLCS, if the ME EQUIPMENT interrupts and restarts the infusion or increases the infusion based on a PHYSIOLOGIC VARIABLE rising above a threshold or falling below a threshold.

Replace the existing Example 3 with the following new example:

EXAMPLE 3 A pressure-controlled (or pressure-regulated volume-controlled) ventilator that uses airway pressure (or pressure and volume) for feedback to control breathing system pressure. The ventilator is a closed-loop control system, but not a PCLCS, because while the breathing system pressure (or pressure and volume) is both the 'MANIPULATED VARIABLE' and 'FEEDBACK VARIABLE', it is not a quantity or condition measured from the PATIENT.

Replace, in the existing note following Example 3, the word "NOTE" with "NOTE 2".

Add, after the words "baby incubator uses" in the existing Example 4, the article "the" and add, after "baby's temperature", the parenthetical "(e.g. skin or core)".

Add, after the existing Example 8, the following new example:

EXAMPLE 9 Sleep apnoea breathing therapy equipment (including auto CPAP or auto continuous positive airway pressure equipment) uses air flow and pressure from inside the equipment for feedback control to control the delivered pressure. CPAP equipment is a closed-loop control system, but not a PCLCS, because while the breathing system pressure is both the MANIPULATED VARIABLE and FEEDBACK VARIABLE, it is not a quantity or condition measured from the PATIENT.

A.2 Rationale for particular clauses and subclauses

Definition 3.8 – DISTRIBUTED PCLCS

Replace, in the existing first paragraph, the second sentence with the following new sentence:

A typical example would be a stand-alone anaesthesia workstation controlling the effect of the anaesthetic (for example, blood pressure or EEG measurement).

Definition 3.20 – PHYSIOLOGIC CLOSED-LOOP CONTROLLER

Replace the existing text with the following new text:

A PHYSIOLOGIC CLOSED-LOOP CONTROLLER uses feedback from a PATIENT VARIABLE (i.e. a PHYSIOLOGIC VARIABLE) to adjust that variable to the COMMAND VARIABLE. Such a controlled PATIENT VARIABLE is called a PHYSIOLOGIC VARIABLE. Many such controllers are therapeutic controllers because they are being used to control the flow of energy or substances to a PATIENT for therapeutic purposes. The committee chose to not use "therapeutic" in the defined term because these controllers could also be used to control the delivery of non-therapeutic substances such as anaesthetic agents.

A PCLCS by design can incorporate multiple PCLCS, multiple PHYSIOLOGIC VARIABLES or multiple COMMAND VARIABLES. A PATIENT VARIABLE that is not controlled can be measured from the PATIENT and used to influence output of the CONTROL TRANSFER ELEMENT by adjusting algorithm parameters.

EXAMPLE 1 Neonatal PATIENT oxygenation based on controlled SpO_2 can measure pulse rate to adjust the gain in the PCLC. The PATIENT VARIABLE, pulse rate, is not being controlled but is a variable directly affecting the output of the PCLC.

EXAMPLE 2 Hemodynamic control of mean arterial blood pressure (MAP) and cardiac output (CO) by fluid resuscitation and vasopressor therapy. In this example, two PHYSIOLOGIC VARIABLES are being controlled (CO and MAP) by infusion of fluid and vasopressors. The MANIPULATED VARIABLES are the rate of fluid and vasopressor infusion and the COMMAND VARIABLES are the desired CO and MAP. This is an example of a multiple-input multiple-output PCLC.

Add, after the existing rationale to 3.22, the following new rationale:

Definition 3.29 – PATIENT VARIABLE

The term PATIENT VARIABLE distinguishes between a controlled PATIENT VARIABLE (i.e. PHYSIOLOGIC VARIABLE) and a PATIENT VARIABLE that is not directly controlled. A PATIENT VARIABLE can be used to affect different elements of the PCLCS (e.g. is used to adjust a parameter in the PCLC or FEEDBACK ELEMENT).

While environmental factors like ambient temperature, ambient light, etc. can also be recorded and used for adjustments of the controller output variable, a measured PATIENT VARIABLE reflects attribute, characteristic, quantity or condition of the PATIENT that is not just a reflection of those environmental conditions.

Subclause 5.1 – Instructions for use

Replace, in the existing first paragraph, modified by Amendment 1, the reference "IEC 62366" *with* "IEC 62366-1".

Replace, in the existing first sentence of the third paragraph, the words "end-tidal PATIENT anaesthetic agent concentration" *with* "anaesthetic agent effect on the PATIENT".

Subclause 8.2.2.1 – Application specification

Replace the existing rationale, including the title, by the following new rationale and title:

Subclause 8.2.2.1 – USE SPECIFICATION

The ME EQUIPMENT or ME SYSTEM USE SPECIFICATION describes the important attributes that are fundamental to their function. The ME EQUIPMENT or ME SYSTEM USE SPECIFICATION is the foundation for defining the PCLCS.

Subclause 8.2.2.2 – State VARIABLES

Replace the existing title with the following new title:

Subclause 8.2.2.2 – PCLCS attributes

Replace the existing penultimate dash "Limits of the range of the PATIENT TRANSFER ELEMENT", including the rationale, *with the following new dash:*

– *Model of the PATIENT TRANSFER ELEMENT*

It might not be practicable to capture the full spectrum of human variation in a model of sufficient fidelity of the PATIENT TRANSFER ELEMENT for either development or validation due to (for example) ethical or experimental constraints. Establishing the limits of the model is fundamental to the safe operation of a PCLCS as it impacts the approach taken to validate the PCLCS. Understanding the limits of variation, including the INTERPATIENT VARIABILITY and INTRAPATIENT VARIABILITY, of transfer function that is embodied by the model of the PATIENT TRANSFER ELEMENT is necessary for the design of a safe and effective PCLCS.