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**Elektrisk utrustning för medicinskt bruk –
Del 1-10: Allmänna fordringar beträffande säkerhet
och väsentlig prestanda –
Tilläggsstandard: Fordringar för utveckling av
återkopplade system för fysiologiska signaler**

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

Som svensk standard gäller europastandarden EN 60601-1-10:2008. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-10:2008.

Nationellt förord

Europastandarden EN 60601-1-10:2008

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-1-10, First edition, 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**

utarbetad inom International Electrotechnical Commission, IEC.

Denna standard utgör ett tillägg till SS-EN 60601-1, Elektrisk utrustning för medicinskt bruk – Del 1: Allmänna fordringar beträffande säkerhet och väsentliga prestanda.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

Standarder underlättar utvecklingen och höjer elsäkerheten

Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

Många standarder inom elområdet beskriver tekniska lösningar och metoder som åstadkommer den elsäkerhet som föreskrivs av svenska myndigheter och av EU.

SEK är Sveriges röst i standardiseringsarbetet inom elområdet

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SEK samordnar svenska intressenters medverkan i SEKs tekniska kommittéer och stödjer svenska experters medverkan i internationella och europeiska projekt.

Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

Standardiseringsarbetet inom SEK är organiserat i referensgrupper bestående av ett antal tekniska kommittéer som speglar hur arbetet inom IEC och CENELEC är organiserat.

Arbetet i de tekniska kommittéerna är öppet för alla svenska organisationer, företag, institutioner, myndigheter och statliga verk. Den årliga avgiften för deltagandet och intäkter från försäljning finansierar SEKs standardiseringsverksamhet och medlemsavgift till IEC och CENELEC.

Var med och påverka!

Den som deltar i SEKs tekniska kommittéarbete har möjlighet att påverka framtida standarder och får tidig tillgång till information och dokumentation om utvecklingen inom sitt teknikområde. Arbetet och kontakterna med kollegor, kunder och konkurrenter kan gynnsamt påverka enskilda företags affärsutveckling och bidrar till deltagarnas egen kompetensutveckling.

Du som vill dra nytta av dessa möjligheter är välkommen att kontakta SEKs kansli för mer information.

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**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
(IEC 60601-1-10:2007)**

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
(CEI 60601-1-10:2007)

Medizinische elektrische Geräte -
Teil 1-10: Allgemeine Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale -
Ergänzungsnorm: Anforderungen
an die Entwicklung von physiologischen
geschlossenen Regelkreisen
(IEC 60601-1-10:2007)

This European Standard was approved by CENELEC on 2008-03-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/576/FDIS, future edition 1 of IEC 60601-1-10, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, and ISO SC 1, Breathing attachments and anaesthetic machines, and SC 3, Lung ventilators and related devices, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-10 on 2008-03-01

The following dates were fixed:

- latest date by which the EN has to be implemented
at national level by publication of an identical
national standard or by endorsement (dop) 2008-12-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2011-03-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

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: in roman type;
- *test specifications: in 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: IN 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 (*).

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-10:2007 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 9000	NOTE	Harmonized as EN ISO 9000:2005 (not modified).
ISO 14001	NOTE	Harmonized as EN ISO 14001:2004 (not modified).
ISO 14021	NOTE	Harmonized as EN ISO 14021:2001 (not modified).
ISO 14040	NOTE	Harmonized as EN ISO 14040:2006 (not modified).

Annex ZA

(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
IEC 60601-1-6	2006	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability	EN 60601-1-6	2007
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	EN 60601-1-8	2007
IEC 62304	2006	Medical device software - Software life-cycle processes	EN 62304	2006
ISO 14971	- ¹⁾	Medical devices - Application of risk management to medical devices	EN ISO 14971	2007 ²⁾

¹⁾ Undated reference.

²⁾ Valid edition at date of issue.

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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*

