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Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	2000-06-30	2	1 (1+46)	SEK Översikt 62
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Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-30: Särskilda fordringar på utrustning för automatisk repetitiv icke-invasiv blodtrycksövervakning

Medical electrical equipment –
Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

Som svensk standard gäller europastandarden EN 60601-2-30:2000. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-30:2000.

Nationellt förord

Europastandarden EN 60601-2-30:2000

består av:

– **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC
– **IEC 60601-2-30, Second edition, 1999 - Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna ändringar och tillägg.

Till SS-EN 60601-1 utges en serie tilläggsstandarder som anger allmänna fordringar på säkerhet som är tillämpliga på

– en grupp av elektrisk utrustning för medicinskt bruk, t ex radiologisk utrustning
– särskilda egenskaper hos all elektrisk utrustning för medicinskt bruk, ej särskilt behandlade i SS-EN 60601-1, t ex elektromagnetisk kompatibilitet.

Utgåva 2 är föranledd av ny utgåva av EN 60601-2-30.

SS-EN 60601-2-30, utgåva 1, 1996, gäller ej fr o m 2003-02-01.

ICS 11.040.01

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EUROPEAN STANDARD **EN 60601-2-30**

NORME EUROPÉENNE

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English version

Medical electrical equipment
Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
(IEC 60601-2-30:1999)

Appareils électromédicaux
Partie 2-30: Règles particulières de sécurité et performances essentielles des appareils de surveillance de la pression sanguine prélevée indirectement, automatiquement et périodiquement
(CEI 60601-2-30:1999)

Medizinische elektrische Geräte
Teil 2-30: Besondere Festlegungen für die Sicherheit, einschließlich der wesentlichen Leistungsfähigkeit von automatischen, zyklischen, nicht-invasiven Blutdrucküberwachungsgeräten
(IEC 60601-2-30:1999)

This European Standard was approved by CENELEC on 2000-02-01. 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and 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

Ref. No. EN 60601-2-30:2000 E

Foreword

The text of document 62D/339/FDIS, future edition 2 of IEC 60601-2-30, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-30 on 2000-02-01.

This European Standard supersedes EN 60601-2-30:1995.

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) 2000-11-01

– latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2003-02-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA, BB and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-30:1999 was approved by CENELEC as a European Standard without any modification.

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Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-1-4	1996	Medical electrical equipment Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems	EN 60601-1-4	1996
IEC 60601-2-2	1982	Part 2: Particular requirements for the safety of high frequency surgical equipment	HD 395.2.2 S1[1)]	1985
IEC 61000-4-3 (mod)	1995	Electromagnetic compatibility (EMC) Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test	EN 61000-4-3	1996
IEC 61000-4-6	1996	Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields	EN 61000-4-6	1996
IEC 61000-4-8	1993	Part 4-8: Testing and measurement techniques - Power frequency magnetic field immunity test	EN 61000-4-8	1993
CISPR 11 (mod)	1990	Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment	EN 55011[2)]	1991
ISO 1000	1992	SI units and recommendations for the use of their multiples and of certain other units	-	-

1) HD 395.2.2 is superseded by EN 60601-2-2:1993, which is based on IEC 60601-2-2:1991.

2) EN 55011 is superseded by EN 55011:1998, which is based on CISPR 11:1997, mod.

Annex ZB (informative)

Other international publications mentioned in this standard with the references of the relevant european publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2 + corr. June	1995 1995		A2 A13	1995 1996
IEC 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

*1.1 Scope

Addition:

This Particular Standard specifies requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT as defined in 2.102, hereinafter referred to as EQUIPMENT. The EQUIPMENT may be attended or unattended.

This Particular Standard does not apply to blood pressure measuring equipment which uses finger transducers or to semi-automatic blood pressure measuring equipment, typically in which each determination needs to be initiated manually.

1.2 Object

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety, including essential performance, of AUTOMATIC CYCLING NON-INVASIVE BLOOD PRESSURE MONITORING EQUIPMENT, with special attention being paid to the avoidance of hazards due to the inflation process.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1: 1988, Medical electrical equipment – Part 1: General requirements for safety, as amended by its amendment 1 (1991) and amendment 2 (1995). The General Standard also takes into account IEC 60601-1-2: 1993, Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral Standard: Electromagnetic compatibility – Requirements and tests, and IEC 60601-1-4:1996, Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems.

For brevity, IEC 60601 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”.

The term “this Standard” is used to make reference to the General Standard and this Particular Standard taken together.