STANDARDISERINGEN I SVERIGE
SWEDISH STANDARDS INSTITUTION

SVENSK STANDARD SS-EN 60 601-2-31

SVENSKA ELEKTROTEKNISKA NORMER, SEN

Handläggande organ	Fastställd	Utgåva	Sida	Ingår i
Svenska Elektriska Kommissionen, SEK	1995-03-24	1	1 (1+4+30)	SEK Översikt 62

Registrering
Reg 486 03 51

Elektrisk utrustning för medicinskt bruk - Säkerhet - Del 2: Särskilda fordringar på externa hjärtstimulatorer med intern energikälla

Medical electrical equipment - Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source

Som svensk standard gäller europastandarden EN 60 601-2-31: 1995. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60 601-2-31: 1995.

Nationellt förord

Europastandarden EN 60 601-2-31: 1995

består av:

- **europastandardens ikraftsättningsdokument,** utarbetat inom CENELEC

- **IEC 601-2-31, First edition, 1994 - Medical electrical equipment - Part 2: Particular requirements for the safety of cardiac pacemakers with internal power source**

  utarbetad inom International Electrotechnical Commission, IEC.

Standarden skall användas tillsammans med SS-EN 60 601-1, Elektromedicinsk utrustning - Säkerhet - Del 1: Allmänna fordringar, och dess separat utgivna tillägg SS-EN 60 601-1 T1 och T2.

Till SS-EN 60 601-1 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 60 601-1, t ex elektromagnetisk kompatibilitet.

ICS 11.040.40

Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.
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Telefon: 08 - 613 52 00. *Telefax*: 08 - 411 70 35

Upplysningar om **sakinnehållet** i standarden lämnas av SEK.
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Prisgrupp R

Tryckt i juni 1995

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-31

January 1995

ICS 11.040.40

Descriptors: Electromedical equipment, external cardiac pacemaker, safety requirements, equipment specifications, test

English version

Medical electrical equipment
Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source
(IEC 601-2-31:1994)

Appareils électromédicaux
Partie 2: Règles particulières de sécurité des stimulateurs cardiaques externes à source d'énergie interne
(CEI 601-2-31:1994)

Medizinische elektrische Geräte
Teil 2: Besondere Festlegungen für die Sicherheit von externen Herzschrittmachern mit interner Stromversorgung
(IEC 601-2-31:1994)

This European Standard was approved by CENELEC on 1994-12-06. 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, 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

Foreword

The text of document 62D(CO)78, future edition 1 of IEC 601-2-31, 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 60601-2-31 on 1994-12-06.

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) 1995-12-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1995-12-01

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.

Endorsement notice

The text of the International Standard IEC 601-2-31:1994 was approved by CENELEC as a European Standard without any modification.

ANNEX ZA (normative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT 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.

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

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZA of EN 60601-1:1980/A11:1993:				
601-1	1988	Medical electrical equipment	EN 60601-1	1990
+ A1	1991	Part 1: General requirements for safety	+ A1	1993
			+ A11	1993
			+ A12	1993
			+ corr. July	1994
601-1-2	1993	2. Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
801-2	1991	Electromagnetic compatibility for industrial-process measurement and control equipment Part 2: Electrostatic discharge requirements	EN 60801-2	1993

Other publication:

ISO 5841-1:1989 - Cardiac pacemakers - Part 1: Implantable pacemakers

ANNEX ZB (informative)

OTHER INTERNATIONAL PUBLICATIONS QUOTED IN THIS STANDARD WITH THE REFERENCES OF THE RELEVANT EUROPEAN PUBLICATIONS

IEC Publication	Date	Title	EN/HD	Date
Addition to annex ZB of EN 60601-1:1980/A11:1993:				
86-1	1993	Primary batteries - Part 1: General (corrigendum December 1993)	-	-
86-2	1993	Part 2: Specification sheets	-	-

CONTENTS

Clause Page

INTRODUCTION

This Particular Standard concerns the safety of PACEMAKERS. The requirements of this Particular Standard take priority over those of the General Standard, entitled *Medical electrical equipment – Part 1: General requirements for safety.*

Basically, PACEMAKERS treat cardiac arrhythmias. Such arrhythmias reduce cardiac output and may lead to confusion, dizziness, loss of consciousness and death. The objective of pacing is to restore cardiac rhythm and output appropriate to the PATIENT's physiological needs.

There are two distinct families of CARDIAC PACEMAKERS, IMPLANTABLE PACEMAKERS and EXTERNAL PACEMAKERS. EXTERNAL PACEMAKERS are used to pace PATIENTS temporarily prior to implanting an IMPLANTABLE PACEMAKER as well as for temporary pacing related to other medical procedures, e.g. open heart surgery.

PACEMAKERS differ in the various ways in which they maintain and monitor cardiac activity in different circumstances. The simplest model stimulates the ventricle independently of the cardiac activity; others detect ventricular activity and stimulate the ventricle as and when this is necessary; others, more complex, detect the spontaneous heart activity and stimulate appropriately the atrium and/or the ventricle. Certain PACEMAKERS work on preset frequency values, amplitudes and impulse durations. Others can have several values for parameters.

Standards for EXTERNAL PACEMAKERS require attention to information which will aid in selecting and applying these devices. It is through these aspects of standardization that the central role of clinical experience should be, or has been, acknowledged. The ability to predict how a pacemaker will perform in a specific patient based on testing of a device to a set of technical criteria is limited.

Some tests and requirements are still under consideration, pending the resolution of technical issues.

An inventory of the PATIENT's *safety posed by* EXTERNAL PACEMAKERS and a rationale for the safety requirements contained in this Particular Standard are given in annex AA. It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practices or as a result of developments in technology. An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in the General guidance and rationale section at the end of this Particular Standard (see annex AA).

Documents used as resources in preparing this standard are listed in annex BB.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2: Particular requirements for the safety of external cardiac pacemakers with internal power source

SECTION ONE: GENERAL

The clauses and subclauses of this section of 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 International Standard specifies the particular safety requirements for EXTERNAL PACEMAKERS as defined in 2.1.101, hereinafter referred to as EQUIPMENT, powered by an INTERNAL ELECTRICAL POWER SOURCE.

This Standard applies to PATIENT CABLES as defined in 2.1.104.

This Standard does not apply to EQUIPMENT which can be directly or indirectly connected to a SUPPLY MAINS.

This Standard does not apply to pacing LEADS, or other equipment for cardiac stimulation which either:

1) forms an integral part of equipment with other functions; or
2) applies the stimulus across the thorax externally or in the oesophagus; or
3) provides antitachycardia therapy beyond high rate burst pacing; or
4) provides pacing system analysis functions.

Each of the two channels of DUAL CHAMBER EQUIPMENT is subject to the requirements of this Standard.

1.2 *Object*

Replacement:

The object of this Particular Standard is to establish particular requirements for the safety of EXTERNAL PACEMAKERS as defined in 2.1.101.

1.3 *Particular Standards*

Addition:

This Particular Standard refers to IEC 601-1.

For brevity Part 1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. The changes to the text of the General Standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

"Addition" means that the text of this Particular Standard is additional to the requirements of the General Standard.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items *aa)*, *bb)*, etc.

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

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.