SLOVENSKI STANDARD
SIST EN 60601-2-31:1995

01-maj-1995

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

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

Medizinische elektrische Geräte -- Teil 2-31: Besondere Festlegungen für die Sicherheit von externen Herzschrittmachern mit interner Stromversorgung

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

Ta slovenski standard je istoveten z: **EN 60601-2-31:1995**

ICS:

11.040.60	Terapevtska oprema	Therapy equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-31

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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	-	-

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Partie 2:
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Medical electrical equipment –

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

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CONTENTS

Clause Page

SECTION NINE: ABNORMAL OPERATION AND FAULT CONDITIONS; ENVIRONMENTAL TESTS

SECTION TEN: CONSTRUCTIONAL REQUIREMENTS

Figures

Appendix/Annexes

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international cooperation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.

2) The formal decisions or agreements of the IEC on technical matters, prepared by technical committees on which all the National Committees having a special interest therein are represented, express, as nearly as possible, an international consensus of opinion on the subjects dealt with.

3) They have the form of recommendations for international use published in the form of standards, technical reports or guides and they are accepted by the National Committees in that sense.

4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.

5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.

International Standard IEC 601-2-31 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this Particular Standard is based on the following documents:

DIS	Report on voting
62D(CO)78	62D(CO)81

Full information on the voting for the approval of this Particular Standard can be found in the report on voting indicated in the above table.

Annexes AA and BB are for information only.

In this Particular Standard, the following print types are used:

– Requirements, compliance with which can be tested and definitions: in roman type;

– Explanations, advice, introduction, general statements, exceptions and references: in smaller type;

– *Test specifications: in italic type;*

– TERMS USED THROUGHOUT THIS PARTICULAR STANDARD WHICH HAVE BEEN DEFINED IN CLAUSE 2 AND IN IEC 601-1, IEC 601-1-2, IEC 801-2 AND ISO 5841-1: SMALL CAPITALS.

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).