EESTI STANDARD EVS-EN 60601-2-46:2002

Elektrilised meditsiiniseadmed. Osa 2-46: Erinõuded operatsioonilaudade ohutusele

Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables

EESTI STANDARDIKESKUS

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-2-46:2002 sisaldab Euroopa standardi EN 60601-2-46:1998 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-46:2002 consists of the English text of the European standard EN 60601-2-46:1998.
Käesolev dokument on jõustatud 18.12.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.	This document is endorsed on 18.12.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.140

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-46

August 1998

ICS 11.140

Descriptors: Medical electrical equipment, operating tables, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-46: Particular requirements for the safety of operating tables
(IEC 60601-2-46:1998)

Appareils électromédicaux
Partie 2-46: Règles particulières de sécurité pour les tables d'opération
(CEI 60601-2-46:1998)

Medizinische elektrische Geräte
Teil 2-46: Besondere Festlegungen für die Sicherheit von Operationstischen
(IEC 60601-2-46:1998)

This European Standard was approved by CENELEC on 1998-08-01. 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 60601-2-46:1998 E

Foreword

The text of document 62D/276/FDIS, future edition 1 of IEC 60601-2-46, 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 60601-2-46 on 1998-08-01.

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) 1999-05-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-05-01

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 annex AA is informative.
Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-46:1998 was approved by CENELEC as a European Standard without any modification.

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 60601-2-2	1991	Medical electrical equipment Part 2: Particular requirements for the safety of high frequency surgical equipment	EN 60601-2-2	1993

INTERNATIONAL STANDARD

IEC 60601-2-46

First edition
1998-06

Medical electrical equipment –

Part 2-46: Particular requirements for the safety of operating tables

Appareils électromédicaux –

Partie 2-46:
Règles particulières de sécurité
pour les tables d'opération

Reference number
IEC 60601-2-46:1998(E)

Numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series.

Consolidated publications

Consolidated versions of some IEC publications including amendments are available. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Validity of this publication

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology.

Information relating to the date of the reconfirmation of the publication is available in the IEC catalogue.

Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is to be found at the following IEC sources:

- **IEC web site***
- **Catalogue of IEC publications**
  Published yearly with regular updates
  (On-line catalogue)*
- **IEC Bulletin**
  Available both at the IEC web site* and as a printed periodical

Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

INTERNATIONAL STANDARD

IEC 60601-2-46

First edition
1998-06

Medical electrical equipment –

Part 2-46: Particular requirements for the safety of operating tables

Appareils électromédicaux –

Partie 2-46: Règles particulières de sécurité pour les tables d'opération

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http: //www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE R

For price, see current catalogue

CONTENTS

Clause Page

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

MEDICAL ELECTRICAL EQUIPMENT –
Part 2-46: Particular requirements for the safety of operating tables

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 co-operation 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 express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are 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.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-46 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and CENELEC.

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

FDIS	Report on voting
62D/276/FDIS	62D/290/RVD

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

Annex AA is 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;
– notes, explanations, advice, introductions, 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 60601-1: SMALL CAPITALS.

A bilingual version of this standard may be issued at a later date.

INTRODUCTION

This Particular Standard amends and supplements IEC 60601-1 (second edition, 1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard (see 1.3).

This Particular Standard is necessary because of the special attention which has to be given to features of OPERATING TABLES which are used together with OTHER MEDICAL ELECTRICAL EQUIPMENT.

Additional requirements for safety, beyond those stated in the General Standard, are specified.

An asterisk (*) beside a clause or subclause number indicates that some explanatory notes are given in annex AA at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –
Part 2-46: Particular requirements for the safety of operating tables

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 safety requirements for OPERATING TABLES, as defined in 2.12.101, whether or not having electrical parts, including TRANSPORTERS, as defined in 2.12.104, used for the transportation of the table top to or from the base or pedestal of an OPERATING TABLE with detachable table top.

This Particular Standard does not apply to

– dental patient chairs;
– examination chairs and couches;
– patient-supporting systems of diagnostic and therapeutic devices;
– operating table heating blankets;
– patient transfer equipment;
– delivery tables and beds;
– hospital beds;
– field tables.

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 amendments 1 (1991) and 2 (1995).

For brevity, part 1 is referred to in this Particular Standard either as the "General Standard" or as the "General Requirements(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.

The requirements of this Particular Standard take priority over those of the General Standard.

An asterisk (*) beside 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.

2 Terminology and definitions

This clause of the General Standard applies, except as follows:

Additional definitions:

2.12.101
OPERATING TABLE (hereinafter also referred to as EQUIPMENT)
A PATIENT-supporting table for general, surgical/medical procedures

2.12.102
MOBILE OPERATING TABLE
An OPERATING TABLE intended to be moved from one location to another

2.12.103
NORMAL POSITION
The position of the OPERATING TABLE top with all sections set in the horizontal position

2.12.104
TRANSPORTER
A device intended for the transportation of the table top, with or without a PATIENT in place, to or from the base or pedestal of an OPERATING TABLE, or the transportation of the table top complete with the base, again with or without the PATIENT in place

NOTE – This does not include devices intended to simply transport the PATIENT from one location to another without the transfer of parts associated with an OPERATING TABLE.