INTERNATIONAL STANDARD

IEC 60601-2-46

First edition
1998-0

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

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PRICE CODE R

For price, see current catalogue

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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 –
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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.