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

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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.
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.

4 General requirements for tests

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

Additional subclause:

4.6 Other conditions

aa) *ACCESSORIES*

OPERATING TABLES shall be fitted where they exist with at least the following ACCESSORIES:

a) anaesthetic screen;

b) arm rest.

*5 Classification

This clause of the General Standard applies.

6 Identification, marking and documents

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

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

aa) Concise instructions for use of the OPERATING TABLE in an emergency, for example failure of power supply, shall be provided on the outside of the EQUIPMENT or in a prominent position in the operating room.

6.8 ACCOMPANYING DOCUMENTS

6.8.2 Instructions for use

Addition:

aa) Instructions for use shall provide warnings referring to the manufacturers' instructions for high-frequency surgical equipment, cardiac defibrillators and cardiac defibrillator-monitors.

6.8.3 Technical description

a) General

Addition:

For PERMANENTLY INSTALLED OPERATING TABLES, the technical description shall include the following:

– information on the method of provision of an antistatic leakage path;

– if completion of this path depends upon installation on an antistatic floor, an instruction that the resistances from the APPLIED PARTS of the table to protective earth have to be measured after installation.

For MOBILE OPERATING TABLES, the technical description shall include advice that if an antistatic pathway is required, the table is to be used on an antistatic floor.

For all OPERATING TABLES, the technical description shall include a statement from the manufacturer that the anti-static properties of the table depend upon the use of the recommended mattress.

Section two – Environmental conditions

The clauses and subclauses of the General Standard apply.

Section three – Protection against electric shock hazards

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

17 Separation (Previous title: Insulation and protective impedances)

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

h) Amendment:

For OPERATING TABLES without potential equalization and with a DEFIBRILLATION-PROOF APPLIED PART hazardous electrical energies do not appear on:

- the ENCLOSURE, including the outer surfaces, of accessible leads and connectors does not apply.

18 Protective earthing, functional earthing and potential equalization

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

Item *e)*

Addition:

In countries where potential equalization is required, the APPLIED PARTS OF OPERATING TABLES with ACCESSIBLE METAL PARTS which are not PROTECTIVELY EARTHED shall be provided with a potential equalization connector.

For EQUIPMENT with potential equalization connectors the impedance between the potential equalization connector and the ACCESSIBLE METAL PARTS shall not exceed 0,2 Ohm.

Compliance is checked by using the test method of 18 f) of the General Standard.

NOTE – Figure 101 shows a possible potential equalization connection.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

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

19.3 Allowable values

Addition:

OPERATING TABLES with a B-TYPE APPLIED PART shall have an ENCLOSURE LEAKAGE CURRENT and a PATIENT LEAKAGE CURRENT not exceeding 0,01 mA in NORMAL CONDITION and 0,05 mA in SINGLE FAULT CONDITION.

20 Dielectric strength

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

20.2 Requirements for EQUIPMENT with an APPLIED PART

Amendment:

Item B-b does not apply.

Section four – Protection against mechanical hazards

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

21 Mechanical strength

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

Additional subclause:

21.101 OPERATING TABLES and TRANSPORTERS shall be designed so that failure or permanent deformation shall not occur when subjected to 2,2 times SAFE WORKING LOAD.

Figure 102 shows SAFE WORKING LOAD.

Compliance is checked by the following test:

a) In NORMAL POSITION and at maximum height the EQUIPMENT shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deformation after 5 min is recorded.

The EQUIPMENT shall not be operated or moved during this part of the test.

b) The load is removed and replaced with SAFE WORKING LOAD.

c) In NORMAL POSITION and at maximum height the EQUIPMENT shall be statically loaded with 2,2 times SAFE WORKING LOAD. The deflections are compared to the values measured under a) and shall be within ±2,5 mm of the original readings.

d) The load is removed and replaced with SAFE WORKING LOAD and the EQUIPMENT shall operate over the full range of movements.

22 Moving parts

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

22.7 *Replacement:*

If a source of electrical energy or any source of power produces mechanical movement, which could cause a SAFETY HAZARD, accessible means shall be provided for interrupting the movement of the relevant part of the EQUIPMENT in the case of any SINGLE FAULT CONDITION.

Compliance is checked by inspection and by functional test (if necessary).

NOTE – A SAFETY HAZARD for example is the unintentional movement of an OPERATING TABLE.

The interruption of the movement of the OPERATING TABLE by the USER is an accessible means to prevent a SAFETY HAZARD of an unintentional movement.

For circuits incorporating electronic components the following fault conditions are considered and, if necessary, applied one at a time:

– short-circuit of any two terminals of an electronic component, other than integrated circuits. Resistors shall not be considered to become short-circuited;
– failure of an integrated circuit.

All possible output signals are considered under SINGLE FAULT CONDITIONS within the integrated circuit. If it can be shown that a particular output signal is unlikely to occur, then the relevant fault is not considered.

24 Stability in NORMAL USE

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

24.1 *Addition:*

For the overbalance test the EQUIPMENT is provided with ACCESSORIES as specified in 4.6 aa) and loaded with a weight distributed according to figure 102, which represents the SAFE WORKING LOAD.

24.3 *a) Replacement:*

a) EQUIPMENT is provided with ACCESSORIES as specified in clause 4.6 aa) and loaded with a weight distributed according to figure 102, which represents the SAFE WORKING LOAD.

24.3 *aa) Addition:*

OPERATING TABLES with transferable table tops shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental separation of the table tops when being transferred.

Specifications concerning table-top transfer operations shall indicate in the operating manual the safety elements inherent in the transfer operation.

Compliance is checked by inspection and the following tests:

Having transferred the table top to the TRANSPORTER, the stability in NORMAL USE test of 24.3 b) shall be carried out. The table top shall not disengage from the TRANSPORTER.

The test is then repeated with the table top being replaced on the base and the stabilty test is carried out on the base immediately after transfer.

Additional subclause:

24.3.101 MOBILE OPERATING TABLES and TRANSPORTERS shall have brakes fitted so that, when applied, EQUIPMENT cannot swivel or move on a 10° slope when the EQUIPMENT is in NORMAL POSITION, minimum height and loaded according to figure 102.

Compliance is checked by inspection and function test.

Section five – Protection against hazards from unwanted or excessive radiation

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

29 X-Radiation

This clause of the General Standard does not apply.

36 Electromagnetic compatibility

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

Additional subclause:

36.101 OPERATING TABLES and remote control devices for OPERATING TABLES shall not present a SAFETY HAZARD, when used together with high-frequency surgical equipment.

Compliance is checked by the following tests:

The high-frequency surgical equipment which is used for this test shall comply with IEC 60601-2-2, shall have a rated output power of 400 W, a quasi-squarewave output frequency characteristic and shall operate in the frequency range of 400 kHz to 1 MHz.

The leads of the active and neutral electrodes shall be draped along the side-rails and/or the exposed metal parts of the OPERATING TABLE top. The high-frequency surgical equipment will then be operated in a mode which generates an output power of 400 W.

a) Operation of the high-frequency surgical equipment at open circuit shall cause no movement of the OPERATING TABLE.

b) Operating the high-frequency surgical equipment while short-circuiting the active and neutral electrodes shall cause no movement of the OPERATING TABLE.

Section six – Protection against hazards of ignition or flammable anaesthetic mixtures

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

39 Common requirements for CATEGORY AP and CATEGORY APG EQUIPMENT

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

39.3 Prevention of electrostatic charges

Item b)

Addition:

Provision of electrically conductive paths from MOBILE OPERATING TABLES to a conductive floor or the protective earth system or the potential equalization system or via wheels to an antistatic floor of the medically used room shall exist, whether or not the table is connected to a SUPPLY MAINS.

NOTE – The electrical resistance responsible for the prevention of electrostatic charges does not prevent burns caused by the use of high-frequency surgical EQUIPMENT and is no protection against electric shock hazards.

Section seven – Protection against excessive temperatures and other safety hazards

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

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection

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

Additional subclause:

44.101 OPERATING TABLES shall be at least IPX4.

49 Interruption of the power supply

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

Additional subclause:

49.101 In the event of interruption of the power supply, whether or not the power supply is restored, the height and configuration of the table top shall not alter. Movement into NORMAL and Trendelenburg POSITION shall remain possible.

Compliance is checked as follows:

a) By test after interruption of the power supply with the table top in any position, other than the NORMAL POSITION, midway between its maximum and minimum heights and uniformly loaded with a load according to figure 102. Movement into and out of the NORMAL POSITION shall be obtainable using the methods described by the manufacturer.

b) By observation after restoration of the power supply.

Section eight – Accuracy of operating data and protection against hazardous output

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

50 Accuracy of operating data

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

Additional subclause:

50.101 Remote control devices of OPERATING TABLES shall be secure against activation by other EQUIPMENT, which can lead to malfunctions. The remote controls shall be clearly assigned to the individual items of EQUIPMENT.

Compliance is checked by inspection.

Section nine – Abnormal operation and fault conditions; environmental tests

The clauses and subclauses of this section of the General Standard apply.

Section ten – Constructional requirements

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

56 Components and general assembly

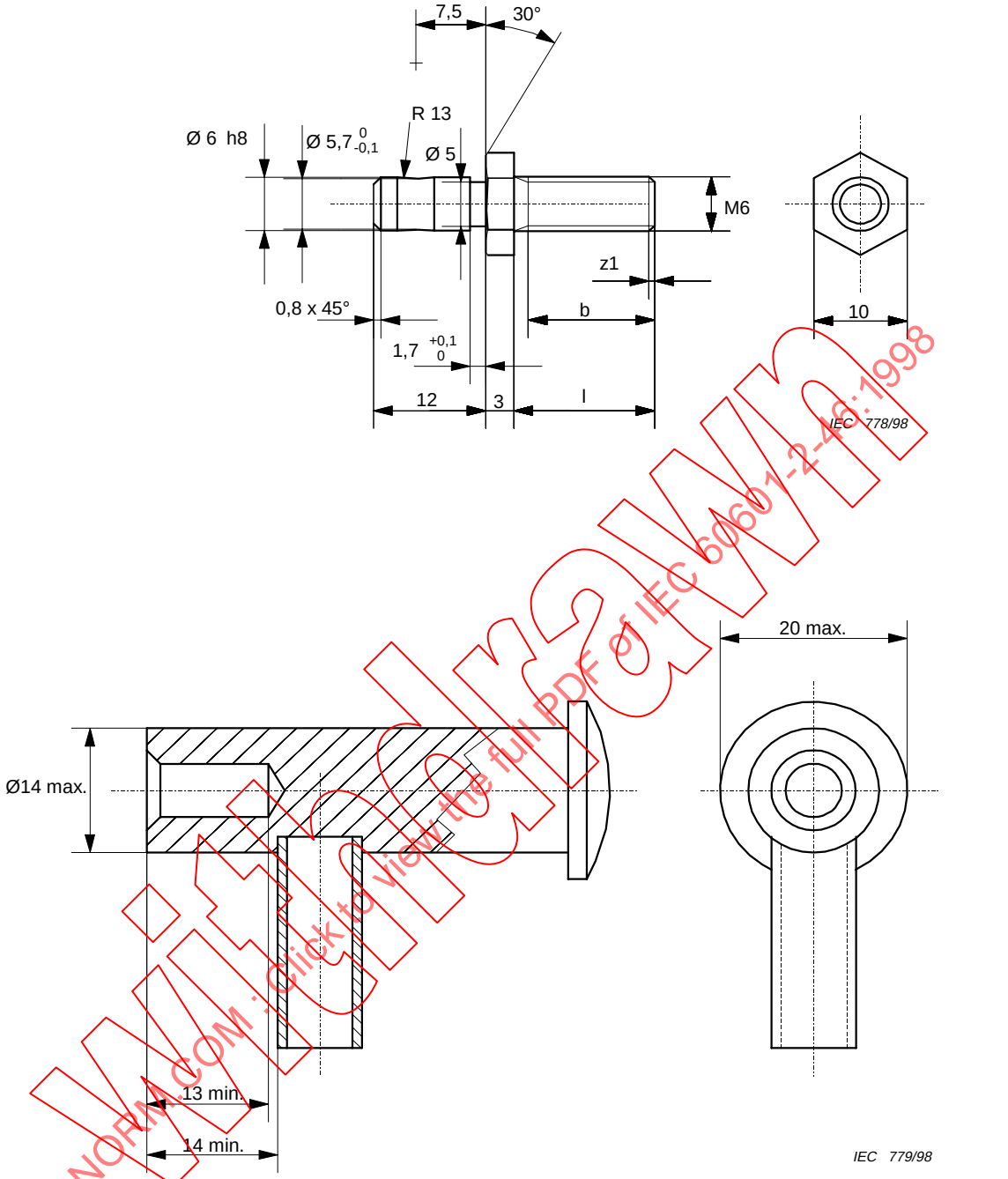
56.11 *Cord-connected hand-held and foot-operated control devices*

c) Inadvertent operation

Replacement:

The actuating force for foot-operated control devices shall not be smaller than 10 N.

Compliance is checked by inspection.



Dimensions in millimetres

Figure 101 – Connection for potential equalization