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Medical electrical equipment—Part 1 : General requirements for safety

ICS 11.040.01

Descriptors : electrical medical equipment, electrotherapy equipment, safety measures, safety

Reference number : **JIS T 0601-1 : 1999 (E)**

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry and Minister of Health and Welfare through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

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In the event of any doubts arising as to the contents, the original JIS is to be the final authority.

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Section Five—Protection against hazards from unwanted or excessive radiation

Section Six—Protection against hazards of ignition of flammable anaesthetic mixtures

Section Seven—Protection against excessive temperatures and other safety hazards

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Medical electrical equipment— Part 1 : General requirements for safety

Introduction This Japanese Industrial Standard has been prepared based on **IEC 60601-1** *Medical electrical equipment—Part 1 : General requirements for safety* published in 1988 as the second edition, Amendment 1 (1993) and Amendment 2 (1995) without modification of their technical contents.

In this Standard, the following print types are used:

a) Terms used throughout this Standard which have been defined in Clause 2 and also given in the Index: SMALL CAPITALS.

b) Test specification: *in italic type*.

c) Other terms: in Roman type.

The mark * on the left upper side of item number means that the general guidance and rationale are stated in Appendix A (informative).

In this Standard, the portions shown by dotted underlines or sidelines on the left and right mean the matters not stated in the original International Standard.

Section One—General

*1 Scope and object

1.1 Scope

This Standard applies to the safety of MEDICAL ELECTRICAL EQUIPMENT (as defined in Sub-clause **2.2.15**).

Although this Standard is primarily concerned with safety, it contains some requirements regarding reliable operation where this is connected with safety.

SAFETY HAZARDS resulting from the intended physiological function of EQUIPMENT covered by this Standard are not considered.

Appendices in this Standard are not mandatory unless made so by an explicit statement in the main text.

1.2 Object

The object of this Standard is to specify general requirements for the safety of MEDICAL ELECTRICAL EQUIPMENT and to serve as the basis for the safety requirements of Particular Standards.

*1.3 Particular Standards

A Particular Standard takes priority over this General Standard.

1.4 Environmental conditions

See Section Two.

1.5 Collateral Standards

In the **JIS T 0601** series, Collateral Standards specify general requirements for safety applicable to:

— a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);

— a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. electromagnetic compatibility).

If a Collateral Standard applies to a Particular Standard, then the Particular Standard takes priority over the Collateral Standard.

2 Terminology and definitions

For the purpose of this Standard, the following shall apply:

— Where the terms "voltage" and "current" are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

— The auxiliary verb:

- "shall" means that compliance with a requirement or a test is mandatory for compliance with this Standard;
- "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this Standard;
- "may" is used to describe a permissible way to achieve compliance with a requirement or test.

Informative reference : The statements "not used" and "no general requirements" mean that the contents specified in the first edition of **IEC 60601-1** are not used in the second edition due to elimination or transfer to other clauses. Accordingly, those statements mean that the contents are not used in this Standard.

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

2.1.1 ACCESS COVER

Part of an ENCLOSURE or guard providing the possibility of access to EQUIPMENT parts for the purpose of adjustment, inspection, replacement or repair.

2.1.2 ACCESSIBLE METAL PART

Metal part of EQUIPMENT which can be touched without the use of a TOOL. See also Subclause **2.1.22**.

2.1.3 ACCESSORY

Optional component necessary and/or suitable to be used with EQUIPMENT in order to enable, facilitate or improve the intended use of EQUIPMENT or to integrate additional functions.

2.1.4 ACCOMPANYING DOCUMENTS

Documents accompanying EQUIPMENT or an ACCESSORY and containing all important information for the USER, OPERATOR, installer or assembler of EQUIPMENT, particularly regarding safety.