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Medical electrical equipment –

Part 2-26: Particular requirements for the safety of electroencephalographs

Appareils électromédicaux –

Partie 2-26:
Règles particulières de sécurité pour les électroencéphalographes

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-26: Particular requirements for the safety of electroencephalographs

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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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 60601-2-26 has been prepared by sub-committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 1994 and constitutes a technical revision.

The text of this standard is based on the following documents:

FDIS	Report on Voting
62D/463/FDIS	62D/466/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives Part 2.

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: smaller roman type;
– *test specifications: italic type;*
– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2006. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

INTRODUCTION

This Particular Standard concerns the safety of electroencephalographs. It amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety*, including its Amendment 1 (1991) and Amendment 2 (1995), hereinafter referred to as the General Standard.

A "General guidance and rationale" for the requirements of this Particular Standard is included 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 practice or as a result of developments in technology. However, Annex AA does not form part of the requirements of this standard.

An asterisk (*) by a clause or subclause number indicates that explanatory notes are given in Annex AA of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-26: Particular requirements for the safety of electroencephalographs

SECTION ONE – GENERAL

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

1 Scope and object

*1.1 Scope

Addition:

This Particular Standard specifies the particular safety requirements for ELECTRO-ENCEPHALOGRAPHS as defined in 2.2.103 and also referred to as EQUIPMENT.

The special requirements for other equipment also used in electroencephalography are not covered by this standard, for example:

- cerebral function monitors;
- phono-photic stimulators;
- electroencephalographic telemetry;
- EEG data storage and retrieval;
- EQUIPMENT particularly intended for monitoring during electro-convulsive therapy;
- ambulatory electroencephalographic recorders.

1.2 Object

Replacement:

The object of this Particular Standard is to specify particular requirements for the safety of ELECTROENCEPHALOGRAPHS.

1.3 Particular Standards

Addition:

This Particular Standard amends and supplements IEC 60601-1 (1988*): Medical electrical equipment – Part 1: General requirements for safety* as amended by its Amendment 1 (1991) and Amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 60601-1-2 and IEC 60601-1-4 as the “Collateral Standards”.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with 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 and Collateral Standards mentioned above.

1.7 Collateral Standards

IEC 60601-1-2:2001, *Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*