

Medical electrical equipment —

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

The European Standard EN 60601-2-26:2003 has the status of a
British Standard

ICS 11.040.55; 11.040.99

National foreword

This British Standard is the official English language version of EN 60601-2-26:2003. It is identical with IEC 60601-2-26:2002. It supersedes BS EN 60601-2-26:1995 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electromedical equipment in medical practice, to Subcommittee CH/62/4, Electromedical equipment, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

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Medical electrical equipment
Part 2-26: Particular requirements for the safety
of electroencephalographs
(IEC 60601-2-26:2002)

Appareils électromédicaux
Partie 2-26: Règles particulières
de sécurité pour
les électroencéphalographes
(CEI 60601-2-26:2002)

Medizinische elektrische Geräte
Teil 2-26: Besondere Festlegungen
für die Sicherheit von
Elektroenzephalographen
(IEC 60601-2-26:2002)

This European Standard was approved by CENELEC on 2003-03-01. 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.

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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

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Foreword

The text of document 62D/463/FDIS, future edition 2 of IEC 60601-2-26, 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 60601-2-26 on 2003-03-01.

This European Standard supersedes EN 60601-2-26:1994.

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) 2004-02-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2006-03-01

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.

In this particular standard, the following print types are used:

- requirements, compliance with which can be tested, and definitions: 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 IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-26:2002 was approved by CENELEC as a European Standard without any modification.

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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.