National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 60601-2-40:1999

ICS 11.040.50

National Standards
Authority of Ireland
Dublin 9
Ireland

Tel: (01) 807 3800
Tel: (01) 807 3838

MEDICAL ELECTRICAL EQUIPMENT.

PART 2-40: PARTICULAR REQUIREMENTS FOR THE SAFETY OF ELECTROMYOGRAPHS AND EVOKED RESPONSE EQUIPMENT

(IEC 60601-2-40:1998)

This Irish Standard was published under the authority of the National Standards Authority of Ireland and comes into effect on: May 14, 1999

Price Code K

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-40

April 1998

ICS 11.040.50

Descriptors: Medical electrical equipment, electromyographs, evoked response equipment, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment
Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
(IEC 60601-2-40:1998)

Appareils électromédicaux
Partie 2-40: Règles particulières de sécurité pour les électromyographes et les appareils à potentiel évoqué
(CEI 60601-2-40:1998)

Medizinische elektrische Geräte
Teil 2-40: Besondere Festlegungen für die Sicherheit von Elektromyographen und Geräten für evozierte Potentiale
(IEC 60601-2-40:1998)

This European Standard was approved by CENELEC on 1998-04-01. 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.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Ref. No. EN 60601-2-40:1998 E

Foreword

The text of document 62D/255/FDIS, future edition 1 of IEC 60601-2-40, 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 60601-2-40 on 1998-04-01.

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) 1999-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2001-01-01

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 annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-40:1998 was approved by CENELEC as a European Standard without any modification.

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE: When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
Addition to annex ZA of EN 60601-1:1990/A2:1995:				
IEC 60601-1	1988	Medical electrical equipment Part 1: General requirements for safety	EN 60601-1 + corr. July	1990 1994
A1	1991		A1 + corr. July	1993 1994
A2	1995		A2[1)] A13	1995 1996
IEC 60601-1-1	1992	1. Collateral standard: Safety requirements for medical electrical systems	EN 60601-1-1	1993
A1	1995		A1	1996
IEC 60601-1-2	1993	2. Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	1993
IEC 60825-1	1993	Safety of laser products Part 1: Equipment classification, requirements and user's guide	EN 60825-1 + corr. February + A11 + corr. July	1994 1995 1996 1997

1) A2 includes corrigendum June 1995 to IEC 60601-1:1988/A2.

Annex ZB (informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
Addition to annex ZB of EN 60601-1:1990/A2:1995:				
IEC 60645-3	1994	Audiometers Part 3: Auditory test signals of short duration for audiometric and neuro-otological purposes	EN 60645-3	1995