SLOVENSKI STANDARD
SIST EN 60601-2-40:2019

01-marec-2019

Nadomešča:
SIST EN 60601-2-40:1998

Medicinska električna oprema - 2-40. del: Posebne zahteve za osnovno varnost in bistvene lastnosti za elektromiografe in opremo za izzvane odzive (IEC 60601-2-40:2016)

Medical Electrical Equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment - Proposed Horizontal Standard (IEC 60601-2-40:2016)

Medizinische elektrische Geräte - Teil 2-40: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektromyographen und Geräten für evozierte Potentiale (IEC 60601-2-40:2016)

Appareils électromédicaux - Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué - Proposition de norme horizontale (IEC 60601-2-40:2016)

Ta slovenski standard je istoveten z: **EN 60601-2-40:2019**

ICS:

11.040.50	Radiografska oprema	Radiographic equipment

SIST EN 60601-2-40:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-40

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English Version

Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment (IEC 60601-2-40:2016)

Appareils électromédicaux - Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué
(IEC 60601-2-40:2016)

Medizinische elektrische Geräte - Teil 2-40: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektromyographen und Geräten für evozierte Potentiale
(IEC 60601-2-40:2016)

This European Standard was approved by CENELEC on 2016-09-22. 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.

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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

The text of document 62D/1366/FDIS, future edition 2 of IEC 60601-2-40, prepared by IEC/TC 62 "Electrical equipment in medical practice"" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-40:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2019-07-11
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-01-11

This document supersedes EN 60601-2-40:1998.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-2-40:2016 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1-8	NOTE	Harmonized as EN 60601-1-8.
IEC 60601-2-10	NOTE	Harmonized as EN 60601-2-10.
IEC 62368-1	NOTE	Harmonized as EN 62368-1.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition to Annex ZA of EN 60601-1:2006:				
IEC 60318	series	Electroacoustics - Simulators of human head and ear	EN 60318	series
ISO 15004-2	-	Ophthalmic instruments - Fundamental requirements and test methods - Part 2: Light hazard protection	EN ISO 15004-2	-

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Appareils électromédicaux –
Partie 2-40: Exigences particulières pour la sécurité de base et les performances essentielles des électromyographes et des appareils à potentiel évoqué

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

FOREWORD

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International Standard IEC 60601-2-40 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition of IEC 60601-2-40 published in 1998. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) no special test phantom used for EMC testing;

b) test method for continuous masking sound pressure level;

c) test method for visual stimulators;

d) allows use of equipment not intended for continuous operation;

e) clarification that audible and visible indicators are not to be considered ALARM SYSTEMS as per IEC 60601-1-8.

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

FDIS	Report on voting
62D/1366/FDIS	62D/1394/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.

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, the term

– "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– "subclause" means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title, or at the beginning of a paragraph or table title, indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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

INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT. It amends and supplements IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012), hereinafter referred to as the general standard.

The aim of this second edition is to bring this particular standard up to date with reference to the latest edition of the general standard.

The requirements of this particular standard take priority over those of the general standard.

A “General guidance and rationale” for the more important requirements of this particular standard is included in Annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the document 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 document.