

STN	Zdravotnícke elektrické prístroje Časť 2-40: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti elektromyografov a vyhodnocovačov evokovaných potenciálov	STN EN IEC 60601-2-40 36 4800
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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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/25

Obsahuje: EN IEC 60601-2-40:2025, IEC 60601-2-40:2024

Oznámením tejto normy sa od 29.02.2028 ruší
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EUROPEAN STANDARD

EN IEC 60601-2-40

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2025

ICS 11.040.20; 11.040.55; 11.040.99

Supersedes EN 60601-2-40:2019

English Version

**Medical electrical equipment - Part 2-40: Particular requirements
for the basic safety and essential performance of
electromyographs and evoked response equipment
(IEC 60601-2-40:2024)**

Appareils électromédicaux - Partie 2-40: Exigences
particulières pour la sécurité de base et les performances
essentiels des électromyographes et des appareils à
potentiel évoqué
(IEC 60601-2-40:2024)

Medizinische elektrische Geräte - Teil 2-40: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Elektromyographen
und Geräten für evozierte Potentiale
(IEC 60601-2-40:2024)

This European Standard was approved by CENELEC on 2025-01-24. 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

EN IEC 60601-2-40:2025 (E)**European foreword**

The text of document 62D/2168/FDIS, future edition 3 of IEC 60601-2-40, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 60601-2-40:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2026-02-28 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2028-02-29 document have to be withdrawn

This document supersedes EN 60601-2-40:2019 and all of its amendments and corrigenda (if any).

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Endorsement notice

The text of the International Standard IEC 60601-2-40:2024 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 standard indicated:

IEC 60601-1-3	NOTE	Approved as EN 60601-1-3
IEC 60601-1-8	NOTE	Approved as EN 60601-1-8
IEC 60601-1-10	NOTE	Approved as EN 60601-1-10
IEC 60601-2-2	NOTE	Approved as EN IEC 60601-2-2
IEC 60601-2-10	NOTE	Approved as EN 60601-2-10
IEC 60645-3	NOTE	Approved as EN IEC 60645-3
IEC 62368-1	NOTE	Approved as EN IEC 62368-1

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where 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.cencenelec.eu.

Annex ZA of EN 60601-1:2006¹, applies, except as follows:

Add:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ AC	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
-	-		+ AC	2022
-	-		+ A13	2024
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
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	-

¹ As impacted by EN 60601-1:2006/AC:2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014, EN 60601-1:2006/A12:2014, EN 60601-1:2006/A2:2021, EN 60601-1:2006/AC:2022-12 and EN 60601-1:2006/A13:2024.



IEC 60601-2-40

Edition 3.0 2024-12

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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IEC 60601-2-40

Edition 3.0 2024-12

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
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INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment**

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of 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, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). 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. 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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IEC 60601-2-40 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is an International Standard.

This third edition cancels and replaces the second edition published in 2016. This edition constitutes a technical revision.

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

- a) added requirements for constant voltage stimulators;
- b) clarified requirements for VISUAL STIMULATORS.

The text of this International Standard is based on the following documents:

Draft	Report on voting
62D/2168/FDIS	62D/2191/RVD

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

The language used for the development of this International Standard is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT 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 document 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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

This document 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, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

The aim of this revision is to bring this document up to date with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020.

The requirements of this document take priority over those of IEC 60601-1.

A "General guidance and rationale" for the more important requirements of this document 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.

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.1.1 Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT, hereafter referred to as ME EQUIPMENT.

NOTE 1 Myofeedback equipment, where the capturing of muscle contraction is based on electromyography, is within the scope of this document.

NOTE 2 ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT is intended for diagnostic and monitoring applications.

NOTE 3 If the ME EQUIPMENT supports both ELECTROMYOGRAPHY and EVOKED RESPONSE STIMULATION, clauses for electrical, auditory, and visual stimulators are applicable. In case the equipment supports ELECTROMYOGRAPHY, but not EVOKED RESPONSE STIMULATION, clauses concerning solely requirements for stimulators are NOT within the scope of this document.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

The following ME EQUIPMENT are excluded:

- ME EQUIPMENT intended for therapeutic application;
- ME EQUIPMENT intended for transcutaneous electrical nerve stimulators and electrical muscle stimulators (ME EQUIPMENT covered by IEC 60601-2-10).

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT [as defined in 201.3.201 and 201.3.202.]

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply as modified in Clause 202. IEC 60601-1-3, IEC 60601-1-8 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this document corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"Replacement" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"Amendment" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, for example 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, any applicable collateral standards and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

NOTE Informative references are listed in the bibliography.

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-2:2014/AMD1:2020

IEC 60318 (all parts), *Electroacoustics – Simulators of human head and ear*

ISO 15004-2, *Ophthalmic instruments – Fundamental requirements and test methods – Part 2: Light hazard protection*

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