IEC 60601-2-40

Edition 3.0 2024-12
REDLINE VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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

IEC 60601-2-40:2024-12 RLV(en)

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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

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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9) IEC draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at https://patents.iec.ch. IEC shall not be held responsible for identifying any or all such patent rights.

This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition IEC 60601-2-40:2016. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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.

IMPORTANT – The "colour inside" logo on the cover page of this document indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 ~~the latest edition of the general standard~~ 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 ~~the general standard~~[1] 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.]

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[1] ~~The general standard is IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*~~

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.

~~For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.~~

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.~~147~~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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 apply, except as follows:

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 30.

Additional terms and definitions:

201.3.201
ELECTROMYOGRAPH
ME EQUIPMENT for the detection or recording of biopotentials accompanying nerve and muscle action, either spontaneously, intentionally or evoked by electrical or other stimulation

201.3.202
EVOKED RESPONSE EQUIPMENT
ME EQUIPMENT for the detection or recording of biopotentials resulting from an evoking stimulus

Note 1 to entry: The stimulus ~~may~~ can be electrical, tactile, auditory, visual, olfactory, etc.

201.3.203
ELECTRICAL STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of electric currents via ELECTRODES in direct contact with the PATIENT, for the evoking of biopotentials

201.3.204
PULSE DURATION
duration of the electrical stimulus pulse WAVEFORM at 50 % of the peak amplitude

201.3.205
WAVEFORM
variations in magnitude of an electrical stimulus output (either voltage or current) as a function of time appearing in the APPLIED PART(S) of the ELECTRICAL STIMULATOR or the collected biopotentials by the BIOPOTENTIALS INPUT PART

201.3.206
AUDITORY STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of sound pressure from a transducer (headphone, bone conductor or free-field) to the ear(s) of the PATIENT, for the evoking of biopotentials

201.3.207
VISUAL STIMULATOR
part of ~~ELECTROMYOGRAPHS and EVOKED RESPONSE~~ ME EQUIPMENT for the application of pulsed electromagnetic radiation in the visible spectrum from a transducer to the eyes of the PATIENT, for the evoking of biopotentials

201.3.208
BIOPOTENTIAL INPUT PART
APPLIED PART(S) of ELECTROMYOGRAPHS and EVOKED RESPONSE EQUIPMENT for the collection of biopotentials

201.3.209
ELECTRODE
conductive portion that is applied to the PATIENT to detect electrical activity ~~and/~~or to apply the stimulus from the ELECTRICAL STIMULATOR to the PATIENT

201.3.210
PATIENT LEAD
cable connected between an ELECTRODE and either a PATIENT CABLE or the ME EQUIPMENT

201.3.211
PATIENT CABLE
multiwire cable used to connect PATIENT LEADS to ME EQUIPMENT

201.4 General requirements

Clause 4 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.4.2 *RISK MANAGEMENT PROCESS for ME EQUIPMENT ~~and~~ or ME SYSTEMS

Addition:

MANUFACTURERS shall include, within their RISK MANAGEMENT FILE, the RISK associated with the potential use of their STIMULATORS and accessories to deliver current exceeding 10 mA RMS or current densities for any ELECTRODE exceeding 2 mA/cm^2.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

~~NOTE~~ Because of the variety of clinical applications for ELECTROMYOGRAPHS and EVOKED RESPONSE, no additional ESSENTIAL PERFORMANCE is specified in this document. However, ESSENTIAL PERFORMANCE ~~shall be~~ is determined by the manufacturer in accordance with the requirements of 4.3 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

201.4.11 Power input

Replacement:

The power input is measured with a load resistance of the lowest value specified in the technical description (see 201.7.9.3.101 a)), and with any output controls set to result in maximum power input.

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows.

201.5.4 Other conditions

Addition:

Where values of voltage and current are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current averaged over 1 s unless stated otherwise.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.6.2 * Protection against electric shock

Amendment:

Delete TYPE B APPLIED PART.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020 applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

Safety sign ISO 7010-M002 shall be used (see Table D.2, safety sign 10 in Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.2.7 Electrical input power from the SUPPLY MAINS

Replacement:

The RATED power input of MAINS operated ME EQUIPMENT shall be the maximum power input averaged over any period of 5 s under the specified operating conditions set out by the manufacturer.

201.7.2.8 Output connectors

201.7.2.8.2 Other power sources

Addition:

See also 201.12.4.102.

201.7.2.13 * Physiological effects (SAFETY SIGNS and warning statements)

Addition:

ME EQUIPMENT capable of delivering electrical stimulus outputs into a load resistance of 1 000 Ω in excess of 10 mA RMS or 10 V RMS averaged over any period of 5 s shall be marked near the ELECTRODE connections with the safety sign ISO 7010-M002 (see safety sign 10 in Table D.2 of Annex D of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, and IEC 60601-1:2005/AMD2:2020).

201.7.4 Marking of controls and instruments

201.7.4.2 * Control devices

Replacement:

~~An output control for the ELECTRICAL STIMULATOR shall be incorporated which will control the ELECTRICAL STIMULATOR output from minimum to maximum of the range continuously, or in discrete increments of not more than 1 mA peak amplitude or 5 V peak amplitude per increment. At its minimum setting, the output shall not exceed 2 % of that available at the maximum setting of the control.~~

~~The type of stimulator output, constant voltage and/or constant current shall be described and specified in the ACCOMPANYING DOCUMENTS. *Compliance is checked by inspection and measurement, using the load impedance which is the least favourable within the range specified in the ACCOMPANYING DOCUMENTS.*~~

~~*Or, as an alternate method of compliance, the following may be chosen:*~~