IEC 60601-2-40

Edition 2.0 2016-08

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

IEC 60601-2-40:2016-08(en-fr)

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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

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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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.

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] applies, except as follows:

201.1.1 Scope

Replacement:

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

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

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 is excluded:

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 particular standard 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 particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2 applies 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.

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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*

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard 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 the general standard.

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 particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x”, where × is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.) 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 or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this standard 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, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

Clause 2 of the general standard applies, except as follows*:*

NOTE Informative references are listed in the bibliography beginning on page 29.

Addition:

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 the following apply.

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

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

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

Addition:

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 be electrical, tactile, auditory, visual, olfactory, etc.

201.3.203
ELECTRICAL STIMULATOR
part of ELECTROMYOGRAPHS and EVOKED RESPONSE 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 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 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 the general standard applies, except as follows:

201.4.2 RISK MANAGEMENT PROCESS for ME EQUIPMENT and 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 r.m.s 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 particular standard. However, ESSENTIAL PERFORMANCE shall be determined by the manufacturer in accordance with the requirements of sub-clause 4.3 of the general standard.

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 of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows.

201.5.4 Other conditions

Addition:

Where values of voltage and current are used in this document, they mean the r.m.s. 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 the general standard 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 the general standard 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 the general standard).

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)

ME EQUIPMENT capable of delivering electrical stimulus outputs into a load resistance of 1 000 Ω in excess of 10 mA r.m.s or 10 V r.m.s. averaged over any period of 5 s shall be marked near the ELECTRODE connections with the safety sign ISO 7010-M002 (see safety sign No. 10 in Table D.2 of Annex D of the general standard).

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:

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 as specified in the ACCOMPANYING DOCUMENTS or indicated on the ME EQUIPMENT (see 201.7.9.2.101).

The following shall be addressed in the RISK MANAGEMENT FILE:

Voltage range, current range, increment, accuracy.

Compliance is checked by inspection of ACCOMPANYING DOCUMENTS and the RISK MANAGEMENT FILE.

201.7.9 ACCOMPANYING DOCUMENTS

201.7.9.2 Instructions for use

Addition:

201.7.9.2.101 Additional information in instructions for use

The instructions for use shall contain additionally:

a) * Information on the output WAVEFORM(s), including any DC component, PULSE DURATIONS, pulse repetition frequencies, maximum amplitude of output voltage and/or current, and the effect of load impedance on the demanded parameters.

b) * Advice on the size of ELECTRODES to be used and the method of application for each particular type of examination for which the ELECTRICAL STIMULATOR is intended.

c) Advice on any necessary precautions to be taken when the output contains a DC component larger than 10 µA when averaged over 1 s.

d) * Advice that a PATIENT with an implanted electronic device (for example a cardiac pacemaker) should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

e) Advice to avoid trans-thoracic stimulation.

f) A warning on the following potential HAZARDS:

– Connection of a PATIENT to a high frequency (HF) surgical equipment and to an ELECTROMYOGRAPH or EVOKED RESPONSE EQUIPMENT simultaneously may result in burns at the site of the ELECTRODES and possible damage to the APPLIED PARTS;

– Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the APPLIED PARTS.

g) * For ME EQUIPMENT capable of delivering output values in excess of 10 mA r.m.s. or 10 V r.m.s. into the specified load impedance (see 201.7.9.3.101a)), averaged over 1 s, or having an energy greater than 10 mJ per pulse into the specified load impedance:

a list of recommended ELECTRODES that can be used with the ME EQUIPMENT.

h) * Advice to avoid accidental contact between connected but unapplied APPLIED PARTS and other conductive parts including those connected to protective earth.

i) * Any known susceptibilities to electromagnetic phenomena.

201.7.9.3 Technical description

Addition:

201.7.9.3.101 Additional information in the technical description

The technical description shall additionally contain the following:

a) The technical description shall specify the parameters mentioned in 201.7.9.2.101 along with the range of load impedances for which these parameters are valid.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies, except as follows:

201.8.3 * Classification of APPLIED PARTS

Replacement:

The APPLIED PARTS of ELECTRICAL STIMULATORS, VISUAL STIMULATORS, AUDITORY STIMULATORS and BIOPOTENTIAL INPUT PARTS shall be TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

201.8.5.2.3 PATIENT LEADS or PATIENT CABLES

Addition:

PATIENT LEADS of ELECTROMYOGRAPHS are usually kept short and tied together; therefore, any PATIENT LEAD which falls off will stay in the vicinity of the PATIENT and thus there are no additional requirements for the ELECTRODE.

Where the PATIENT LEADS are long or not tied together, compliance is verified by inspection of the RISK MANAGEMENT FILE.

201.8.8.3 * Dielectric strength

Addition to item a):

Where the voltage to which the relevant insulation is subjected in NORMAL USE is non-sinusoidal AC, the test may be performed using a sinusoidal 50 Hz or 60 Hz test voltage. Where this method is used, the value of test voltage shall be determined from Table 6 of the general standard using a reference voltage (U) V DC equal to the measured peak-to peak voltage divided by $2\sqrt{2}$