

AS/NZS IEC 60601.2.40:2022
IEC 60601-2-40:2016



Australian/New Zealand Standard™

Medical electrical equipment

Part 2.40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment



AS/NZS IEC 60601.2.40:2022

This Joint Australian/New Zealand Standard™ was prepared by Joint Technical Committee HE-003, Medical Electrical Equipment. It was approved on behalf of the Council of Standards Australia on 8 May 2022 and by the New Zealand Standards Approval Board on 4 May 2022.

This Standard was published on 27 May 2022.

The following are represented on Committee HE-003:

- AusBiotech
- Australasian College of Physical Scientists and Engineers in Medicine
- Australian & New Zealand College of Anaesthetists
- Australian College of Perioperative Nurses
- Australian Dental Association
- Australian Industry Group
- Australian Radiation Protection and Nuclear Safety Agency
- Australian Society of Anaesthetists
- Certification Body Australia (Certification Interests Australia)
- College of Biomedical Engineering Engineers Australia
- Department of Defence (Australian Government)
- Engineers Australia
- Medical Technology Association of Australia
- Medical Technology Association of New Zealand
- MidCentral District Health Board
- National Clinical Engineering Managers Forum (for District Health Boards)
- Queensland Health
- Therapeutic Goods Administration (TGA)
- WorkSafe New Zealand

This Standard was issued in draft form for comment as DR AS/NZS IEC 60601.2.40:2022.

Keeping Standards up-to-date

Ensure you have the latest versions of our publications and keep up-to-date about Amendments, Rulings, Withdrawals, and new projects by visiting:

www.standards.org.au

www.standards.govt.nz

ISBN 978 1 76113 784 6

Australian/New Zealand Standard™

Medical electrical equipment

Part 2.40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment

Originated as AS/NZS 3200.2.40:1999.
Revised and redesignated as AS/NZS IEC 60601.2.40:2022.



© IEC Geneva Switzerland 2022 — All rights reserved
© Standards Australia Limited/the Crown in right of New Zealand, administered by the New Zealand Standards Executive 2022

All rights are reserved. No part of this work may be reproduced or copied in any form or by any means, electronic or mechanical, including photocopying, without the written permission of either the IEC or the publisher, unless otherwise permitted under the Copyright Act 1968 (Cth) or the Copyright Act 1994 (New Zealand). If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please see the contact details on the back cover or the contact us page of the website for further information.

Preface

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HE-003, Medical Electrical Equipment, to supersede AS/NZS 3200.2.40:1999, *Medical electrical equipment, Part 2.40: Particular requirements for safety—Electromyographs and evoked response equipment*.

The objective of this document is to specify requirements for the basic safety and essential performance of electromyographs and evoked response equipment, also known as ME equipment.

Myofeedback equipment, where the capturing of muscle contraction is based on electromyography, is 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 is excluded:

- (a) ME equipment intended for transcutaneous electrical nerve stimulators.
- (b) Electrical muscle stimulators (these are covered by AS 60601.2.10:2018).

The particular requirements of this document refer to IEC 60601-1, which has been adopted as AS/NZS IEC 60601.1. Reference to these general requirements is essential for the application of this document.

This document is identical with, and has been reproduced from, IEC 60601-2-40:2016 (ED.2.0), *Medical electrical equipment – Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment*.

As this document has been reproduced from an International document, the following apply:

- (i) In the source text “this particular standard” should read “this document”.
- (ii) A full point substitutes for a comma when referring to a decimal marker.

Australian or Australian/New Zealand Standards that are identical adoptions of international normative references may be used interchangeably. Refer to the online catalogue for information on specific Standards.

The terms “normative” and “informative” are used in Standards to define the application of the appendices or annexes to which they apply. A “normative” appendix or annex is an integral part of a Standard, whereas an “informative” appendix or annex is only for information and guidance.

NOTES

CONTENTS

FOREWORD.....	3
INTRODUCTION.....	6
201.1 Scope, object and related standards.....	7
201.2 Normative references	8
201.3 Terms and definitions	9
201.4 General requirements	10
201.5 General requirements for testing of ME EQUIPMENT.....	10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....	11
201.7 ME EQUIPMENT identification, marking and documents.....	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	13
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	14
201.10 Protection against unwanted and excessive radiation HAZARDS	14
201.11 Protection against excessive temperatures and other HAZARDS.....	14
201.12 Accuracy of controls and instruments and protection against hazardous outputs	14
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	16
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	16
201.15 Construction of ME EQUIPMENT	17
201.16 ME SYSTEMS	17
201.17 ELECTROMAGNETIC COMPATIBILITY of ME EQUIPMENT and ME SYSTEMS	17
202 * ELECTROMAGNETIC DISTURBANCES – Requirements and tests	17
Annexes	22
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....	22
Annex AA (informative) Particular guidance and rationale	23
Bibliography	29
Index of defined terms used in this particular standard	30
Figure AA.1 – Suggested test layout for EMISSION and IMMUNITY testing	26
Figure AA.2 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT	27
Figure AA.3 – Example of test setup for protection against the effects of HF SURGICAL ME EQUIPMENT	28
Table 202.101 – Pass/fail criteria for Table 4 of IEC 60601-1-2:2014	19
Table 202.102 – Pass/fail criteria for Table 7 of IEC 60601-1-2:2014	20
Table 202.103 – Pass/fail criteria for Table 8 of IEC 60601-1-2:2014	20
Table 201.C.101 – Marking on the outside of ELECTROMYOGRAPHES and EVOKED RESPONSE EQUIPMENT or its parts	22

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 standard¹ 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.

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