

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](http://www.standards.org.au)

[www.standards.govt.nz](http://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

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

- 
- Looking for additional Standards? Visit Intertek Inform Infostore
  - Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation
-