

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE



## AMENDMENT 1 AMENDEMENT 1

**Medical electrical equipment –  
Part 2-26: Particular requirements for the basic safety and essential performance  
of electroencephalographs**

**Appareils électromédicaux –  
Partie 2-26: Exigences particulières pour la sécurité de base et les performances  
essentiels des électroencéphalographes**

<https://standards.iteh.ai/catalog/standards/iec/399dbcbd-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>





**THIS PUBLICATION IS COPYRIGHT PROTECTED**  
**Copyright © 2024 IEC, Geneva, Switzerland**

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

IEC Secretariat  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

#### About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

#### About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

#### IEC publications search - [webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee, ...). It also gives information on projects, replaced and withdrawn publications.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

#### IEC Customer Service Centre - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: [sales@iec.ch](mailto:sales@iec.ch).

#### IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)

Discover our powerful search engine and read freely all the publications previews. With a subscription you will always have access to up to date content tailored to your needs.

#### Electropedia - [www.electropedia.org](http://www.electropedia.org)

The world's leading online dictionary on electrotechnology, containing more than 22 500 terminological entries in English and French, with equivalent terms in 25 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

#### A propos de l'IEC

La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

#### A propos des publications IEC

Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

#### Recherche de publications IEC -

[webstore.iec.ch/advsearchform](http://webstore.iec.ch/advsearchform)

La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études, ...). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

#### IEC Just Published - [webstore.iec.ch/justpublished](http://webstore.iec.ch/justpublished)

Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

#### Service Clients - [webstore.iec.ch/csc](http://webstore.iec.ch/csc)

Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: [sales@iec.ch](mailto:sales@iec.ch).

#### IEC Products & Services Portal - [products.iec.ch](http://products.iec.ch)

Découvrez notre puissant moteur de recherche et consultez gratuitement tous les aperçus des publications. Avec un abonnement, vous aurez toujours accès à un contenu à jour adapté à vos besoins.

#### Electropedia - [www.electropedia.org](http://www.electropedia.org)

Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 500 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 25 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

<https://standards.iec.ch/catalog/standards/iec/399dbcbd-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>

<https://standards.iec.ch/catalog/standards/iec/399dbcbd-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>



IEC 80601-2-26

Edition 1.0 2024-02

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE



AMENDMENT 1  
AMENDEMENT 1

**Medical electrical equipment –  
Part 2-26: Particular requirements for the basic safety and essential performance  
of electroencephalographs**

**Appareils électromédicaux –  
Partie 2-26: Exigences particulières pour la sécurité de base et les performances  
essentielles des électroencéphalographes**

INTERNATIONAL  
ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
INTERNATIONALE

ICS 11.040.01

ISBN 978-2-8322-8177-2

**Warning! Make sure that you obtained this publication from an authorized distributor.  
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.**

## INTERNATIONAL ELECTROTECHNICAL COMMISSION

---

**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-26: Particular requirements for the basic safety  
and essential performance of electroencephalographs****AMENDMENT 1****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) IEC and ISO draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC and ISO take 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 and ISO 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> and/or [www.iso.org/patents](http://www.iso.org/patents). IEC and ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to IEC 80601-2-26:2019 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO subcommittee SC3: Respiratory devices and related equipment used for patient care, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/2106/FDIS	62D/2115/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 Amendment 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](http://www.iec.ch/members_experts/refdocs). The main document types developed by IEC are described in greater detail at [www.iec.ch/standardsdev/publications/](http://www.iec.ch/standardsdev/publications/).

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](http://webstore.iec.ch) in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

[IEC 80601-2-26:2019/AMD1:2024](https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024)

<https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>

## INTRODUCTION

*Replace, in the existing first paragraph, “IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012” with “IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020”.*

*Replace the existing second paragraph with the following:*

The aim of this document is to bring this particular standard up to date with reference to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020 and IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 through technical changes.

### 201.1 Scope, object and related standards

*Replace the existing text in footnote 1 with the following:*

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

### 201.1.3 Collateral standards

Replace, in the existing second paragraph, the first sentence with the following:

IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in Clauses 202 and 206 respectively.

### 201.1.4 Particular standards

Replace, in the third paragraph, the first sentence with the following:

For brevity, IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are referred to in this particular document as the general standard.

Replace, in the eighth paragraph, "3.147" with "3.154".

## 201.2 Normative references

Replace the first five entries with the following, without modifying "Addition" or "Replacement":

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 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-6:2010/AMD2:2020

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 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60601-1-11:2015/AMD1:2020

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 60601-1-12:2014/AMD1:2020

### 201.3 Terms and definitions

*Replace the existing first sentence with the following:*

For the purpose of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014, IEC 60601-1-12:2014/AMD1:2020, IEC 60601-2-2:2017 and the following apply.

#### 201.12.1.104 Input noise

*Replace the existing second paragraph of this subclause with the following:*

*Compliance is checked using the test circuit of Figure 201.105. Set any adjustable filters of the ELECTROENCEPHALOGRAPH, if provided, such that the frequency response specified in 201.12.1.105 is obtained. Turn on the mains frequency notch filter of the ELECTROENCEPHALOGRAPH, if provided.*

#### 201.12.1.105 Frequency response

*Replace the existing second paragraph of this subclause with the following:*

*Compliance is checked by inspection of the filter frequency response characteristic documentation of the ELECTROENCEPHALOGRAPH and using the test circuit of Figure 201.104. The mains frequency notch filter and any other filter of the ELECTROENCEPHALOGRAPH, if provided, shall be switched off for this test.*

#### 201.12.1.106 \* Common mode rejection

*Replace the existing second paragraph of this subclause with the following:*

*Compliance is checked using the test circuit of Figure 201.105 with any mains frequency notch filter of the ELECTROENCEPHALOGRAPH, if provided, turned off.*

**Figure 201.105 – Test circuit for noise and common mode rejection** (see 201.12.1.104 and 201.12.1.106)

*Replace, in the NOTE to figure, “PATIENT cable” with “PATIENT CABLE”.*

## 202 Electromagnetic disturbances – Requirements and tests

*Replace the existing first sentence with the following:*

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply, except as follows:

#### 202.4.3.1 Configurations

*Replace, in the existing third paragraph, “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”.*

**Figure 202.101 – Test layout for radiated and conducted EMISSION test and radiated IMMUNITY test**

*Replace, in the existing note, “IEC 60601-1-2:2014” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020”.*

**202.8.1 \* General**

*Replace the existing text in brackets in the first paragraph with the following:*

(i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and proximity magnetic fields)

*Add, before the existing last two paragraphs, the following new paragraph:*

Requirements for voltage interruptions, see 201.11.8.

*Replace, in the existing last-but-one paragraph, “IEC 60601-1-2:2014, Table 4 through 9” with “IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Table 4 to 9 and Table 11”.*

**202.8.101 \* Disturbances from HF SURGICAL EQUIPMENT**

*Replace in the existing third paragraph of this subclause, “of 300 kHz to 600 kHz” with “between 300 kHz and 600 kHz”.*

**206 USABILITY**

*Replace the existing first sentence with the following:*

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply, except as follows: [IEC 80601-2-26:2019/AMD1:2024](https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024)



## **Annex AA** (informative)

### **Particular guidance and rationale**

#### **Subclause 201.8.5.5.1 – Defibrillation protection**

*Replace the existing second sentence with the following:*

Thus this document does not require defibrillator protection, but it remains as an option.

#### **Subclause 201.12.1.106 – Common mode rejection**

*Replace, in the existing third paragraph, “PATIENT cable” with “PATIENT CABLE”.*

#### **Subclause 201.12.4.101 – Indication of invalid data**

*Replace, in the last existing sentence of the first paragraph, “safety (ESSENTIAL PERFORMANCE)” with “ESSENTIAL PERFORMANCE”.*

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[IEC 80601-2-26:2019/AMD1:2024](https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024)

<https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>

### Index of defined terms used in this particular standard

*Replace the following entries:*

HAZARD .....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.39
HAZARDOUS SITUATION .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.40
INTENDED USE (INTENDED PURPOSE).....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.44
MANUFACTURER.....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.55
RISK .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.102
RISK ANALYSIS .....	IEC 60601-1:2005 and IEC 60601-1:2005/AMD2:2020, 3.103
RISK MANAGEMENT FILE .....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 3.108
USABILITY.....	IEC 60601-1:2005/AMD2:2020, 3.136

---

**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[IEC 80601-2-26:2019/AMD1:2024](https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024)

<https://standards.iteh.ai/catalog/standards/iec/399dbcdb-f68d-4823-9d09-8479919f55b8/iec-80601-2-26-2019-amd1-2024>