# ELEKTRILISED MEDITSIINISEADMED. OSA 2-26: ERINÕUDED ELEKTROENTSEFALOGRAAFIDE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

# Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 80601-2-26:2019 + IEC 80601-2-26:2019/AMD1:2024)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

| | |
|---|---|
| See Eesti standard EVS-EN IEC 80601-2-26:2020 +A1:2024 sisaldab Euroopa standardi EN IEC 80601-2-26:2020 ja selle muudatuse A1:2024 ning paranduse AC:2021 ingliskeelset teksti. | This Estonian standard EVS-EN IEC 80601-2-26:2020+A1:2024 consists of the English text of the European standard EN IEC 80601-2-26:2020, its amendment A1:2024 and its corrigendum AC:2021. |
| Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.<br><br>Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.04.2020, muudatus A1 22.03.2024. | This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.<br><br>Date of Availability of the European standard is 03.04.2020, for A1 22.03.2024. |
| Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] ⟨A1⟩.<br><br>Parandusega AC lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [AC] ⟨AC⟩.<br><br>Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest. | The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1] ⟨A1⟩.<br><br>The start and finish of text introduced or altered by corrigendum AC is indicated in the text by tags [AC] ⟨AC⟩.<br><br>The standard is available from the Estonian Centre for Standardisation and Accreditation. |

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.55; 11.040.99

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN IEC 80601-2-26 + A1

April 2020, March 2024

ICS 11.040.55; 11.040.99

Supersedes EN 60601-2-26:2015 and all of its amendments and corrigenda (if any)

English Version

# Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs (IEC 80601-2-26:2019 + IEC 80601-2-26:2019/AMD1:2024)

Appareils électromédicaux - Partie 2-26: Exigences particulières pour la sécurité de base et les performances essentielles des électroencéphalographes (IEC 80601-2-26:2019 + IEC 80601-2-26:2019/AMD1:2024)

Medizinische elektrische Geräte - Teil 2-26: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Elektroenzephalographen (IEC 80601-2-26:2019 + IEC 80601-2-26:2019/AMD1:2024)

This European Standard was approved by CENELEC on 2020-01-01. Amendment A1 was approved by CENELEC on 2024-03-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard and its Amendment A1 exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

# European foreword

The text of document 62D/1666/FDIS, future edition 1 of IEC 80601-2-26, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-26:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

This document supersedes EN 60601-2-26:2015 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association.

## Endorsement notice

The text of the International Standard IEC 80601-2-26:2019 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

| | | |
|---|---|---|
| IEC 60601-1-3 | NOTE | Harmonized as EN 60601-1-3 |
| IEC 60601-1-9 | NOTE | Harmonized as EN 60601-1-9 |
| IEC 60601-1-10 | NOTE | Harmonized as EN 60601-1-10 |
| IEC 62366-1:2015 | NOTE | Harmonized as EN 62366-1:2015 (not modified) |

## A1 Amendment A1 European foreword

The text of document 62D/2106/FDIS, future IEC 80601-2-26/AMD1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-26:2020/A1:2024.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2024-12-20
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2027-03-20

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

### Endorsement notice

The text of the International Standard IEC 80601-2-26:2019/AMD1:2024 was approved by CENELEC as a European Standard without any modification. A1

# IEC 80601-2-26

Edition 1.1 2024-02
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

colour inside



**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**

IEC 80601-2-26:2019-05+AMD1:2024-02 CSV(en-fr)

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

Tel.: +41 22 919 02 11
info@iec.ch
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**
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**
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**
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

**IEC Products & Services Portal - 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**
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**
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**
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**
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

**IEC Products & Services Portal - 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**
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.

# IEC 80601-2-26

Edition 1.1 2024-02
CONSOLIDATED VERSION

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

colour inside



## 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 978-2-8322-8318-9

[Blank page]

# CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

_____

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

## 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 80601-2-26 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

This publication is published as a double logo standard.

This document cancels and replaces the third edition of IEC 60601-2-26 published in 2012. This edition constitutes a technical revision to align with Amendment 1:2012 of IEC 60601-1:2005, new versions of collateral standards and amendments thereto.

The text of this standard is based on the following documents of IEC:

| FDIS | Report on voting |
|---|---|
| 62D/1666/FDIS | 62D/1681/RVD |

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by xxx P members out of yyy having cast a vote.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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 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 80601 International Standard, 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 "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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 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 committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

The contents of the corrigendum of October 2021 have been included in this copy.

## A1 Amendment A1 FOREWORD

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. The main document types developed by IEC are described in greater detail at 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 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. A1

# INTRODUCTION

This particular standard concerns the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS. It amends and supplements ▌A1⟩ IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 ⟨A1▐, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

▌A1⟩ 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. ⟨A1▐

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 standard 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 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs



## 201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

### 201.1.1 * Scope

*Replacement:*

This part of the 80601 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ELECTROENCEPHALOGRAPHS as defined in 201.3.204, hereafter also referred to as ME EQUIPMENT or ME SYSTEM. This document is applicable to ELECTROENCEPHALOGRAPHS intended for use in professional healthcare facilities, the EMERGENCY MEDICAL SERVICES ENVIRONMENT or the HOME HEALTHCARE ENVIRONMENT.

This document does not cover requirements for other equipment used in electroencephalography such as:

– phono-photic stimulators;
– EEG data storage and retrieval;
– ME EQUIPMENT particularly intended for monitoring during electroconvulsive therapy.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title or 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 follows.

The clause or subclause applies to ME EQUIPMENT, as default. For ME EQUIPMENT with the corresponding safety measure or function not completely integrated into the ME EQUIPMENT but instead implemented in an ME SYSTEM, the ME EQUIPMENT MANUFACTURER specifies in the ACCOMPANYING DOCUMENTS which functionality and safety requirements are provided by the ME SYSTEM to comply with this document. The ME SYSTEM is verified accordingly.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document.

NOTE See also 4.2 of the general standard.

### 201.1.2 Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for ELECTROENCEPHALOGRAPHS as defined in 201.3.204.

---

1 〈A1〉 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*. 〈A1〉

### 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.

〚A1〛 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. 〚A1〛 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 the general standard and collateral standards as appropriate for the particular ME EQUIPMENT or ME SYSTEM under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard and collateral standards.

〚A1〛 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. 〚A1〛 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 document addresses the content of Clause 1 of the general standard) 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 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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 〚A1〛 3.154 〚A1〛, 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, e.g. 202 for IEC 60601-1-2, etc.

The term "this document" 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

NOTE Informative references are listed in the Bibliography.

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

*Replacement:*

〚A1〛 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 〚A1〛

*Addition:*

〚A1〛 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 〚A1〛

IEC 60601-2-2:2017, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*