

<b>STN</b>	<b>Zdravotnícke elektrické prístroje Časť 2-26: Osobitné požiadavky na základnú bezpečnosť a nevyhnutné prevádzkové vlastnosti elektroencefalografov Zmena A1</b>	<b>STN EN IEC 80601-2-26/A1</b>  36 4800
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Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/24

STN EN IEC 80601-2-26 z augusta 2020 sa bez tejto zmeny A1 môže používať do 20. 3. 2027.

Obsahuje: EN IEC 80601-2-26:2020/A1:2024, IEC 80601-2-26:2019/AMD1:2024

**138730**

EUROPEAN STANDARD

**EN IEC 80601-2-26:2020/A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

March 2024

ICS 11.040.01

English Version

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

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

This amendment A1 modifies the European Standard EN IEC 80601-2-26:2020; it 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 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 amendment exists 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.

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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**

**EN IEC 80601-2-26:2020/A1:2024 (E)****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.

## EN IEC 80601-2-26:2020/A1:2024 (E)

## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: [www.cencenelec.eu](http://www.cencenelec.eu).

The Annex ZA of EN IEC 80601-2-26:2020 applies with the following changes:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replace the first five entries with the following, without modifying "Addition" or "Replacement":</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar. 2010	
+ A1	2012		+ A1	2013
-	-		+ A12	2014
+ A2	2020		+ A2	2021
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	EN 60601-1-2	2015
+ A1	2020		+ A1	2021
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ A1	2013		+ A1	2015
+ A2	2020		+ A2	2021
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	EN 60601-1-11	2015
+ A1	2020		+ A1	2021

**EN IEC 80601-2-26:2020/A1:2024 (E)**

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 used in the emergency medical services environment	EN 60601-1-12	2015
+ A1	2020		+ A1	2020



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  
essentiels des électroencéphalographes**

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IEC 80601-2-26

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# 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**

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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**MEDICAL ELECTRICAL EQUIPMENT –****Part 2-26: Particular requirements for the basic safety  
and essential performance of electroencephalographs****AMENDMENT 1****FOREWORD**

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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.

IEC 80601-2-26:2019/AMD1:2024

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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/).

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- withdrawn, or
- revised.

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## 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.*

**koniec náhl'adu – text ďalej pokračuje v platenej verzii STN**