

Elektromedicinsk udstyr – Del 2-20: Særlige krav til grundliggende sikkerhed og væsentlige funktionsegenskaber for transportkuvøser

Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators

DANSK STANDARD
Danish Standards Association

Göteborg Plads 1
DK-2150 Nordhavn

Tel: +45 39 96 61 01
dansk.standard@ds.dk
www.ds.dk

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December 2023

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English Version

Medical electrical equipment - Part 2-20: Particular requirements
for the basic safety and essential performance of infant transport
incubators
(IEC 60601-2-20:2020/AMD1:2023)

Appareils électromédicaux - Partie 2-20: Exigences
particulières pour la sécurité de base et les performances
essentielles des incubateurs de transport pour nouveau-nés
(IEC 60601-2-20:2020/AMD1:2023)

Medizinische elektrische Geräte - Teil 2-20: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von Transportinkubatoren
(IEC 60601-2-20:2020/AMD1:2023)

This amendment A1 modifies the European Standard EN IEC 60601-2-20:2020; it was approved by CENELEC on 2023-12-14. 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

European foreword

The text of document 62D/2068/FDIS, future IEC 60601-2-20/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 60601-2-20:2020/A1:2023.

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) 2024-09-14
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2026-12-14

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 60601-2-20:2020/AMD1:2023 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 standard indicated:

IEC 60601-1-10:2007	NOTE Approved as EN 60601-1-10:2008 (not modified)
IEC 60601-1-10:2007/A1:2013	NOTE Approved as EN 60601-1-10:2008/A1:2015 (not modified)
IEC 60601-1-10:2007/A2:2020	NOTE Approved as EN 60601-1-10:2008/A2:2021 (not modified)
IEC 80601-2-49:2018	NOTE Approved as EN IEC 80601-2-49:2019 (not modified)

(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.

Replace the references to IEC 60601-1 and IEC 60601-1-2 with the following references:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
+ 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 60601-1-12	2015
+ A1	2020		+ A1	2020

Add the following references:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
-	-		+ AC	2014
-	-		+ A11	2017
+ A2	2020		+ A2	2021

This is a preview of DS/EN IEC 60601-2-20:2020/A1:2023. [Click here to purchase the full version from the ANSI store](#)

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	EN 60601-1-12	2015
+ A1	2020		+ A1	2020



INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1 AMENDEMENT 1

**Medical electrical equipment –
Part 2-20: Particular requirements for the basic safety and essential performance
of infant transport incubators**

**Appareils électromédicaux –
Partie 2-20: Exigences particulières pour la sécurité de base et les performances
essentielles des incubateurs de transport pour nouveau-nés**





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

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

**Medical electrical equipment –
Part 2-20: Particular requirements for the basic safety and essential performance
of infant transport incubators**

**Appareils électromédicaux –
Partie 2-20: Exigences particulières pour la sécurité de base et les performances
essentiels des incubateurs de transport pour nouveau-nés**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

**Part 2-20: Particular requirements for the basic safety
and essential performance of infant transport incubators**

AMENDMENT 1

FOREWORD

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Amendment 1 to IEC 60601-2-20:2020 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

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

Draft	Report on voting
62D/2068/FDIS	62D/2086/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

This is a preview of DS/EN IEC 60601-2-20:2020/A1:2023. Click here to purchase the full version from the ANSI store.

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/publications/.

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- withdrawn, or
- revised.

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1817/RR.

201.1 Scope, object and related standards

Replace the existing footnote 1 with the following text:

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

Add an asterisk () at the beginning of the subclause title.*

Replace, in the existing second paragraph, "IEC 60601-1-2:2014" with "IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020" and "IEC 60601-1-12:2014" with "IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020".

Add, after the existing second paragraph, the following new paragraph:

If a BABY CONTROLLED TRANSPORT INCUBATOR is based on a temperature measurement that is substantially influenced by the INFANT'S core or body temperature IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 apply. Examples for temperature measurements stipulating applicability of IEC 60601-1-10:2007, IEC 60601-1-10:2007/AMD1:2013 and IEC 60601-1-10:2007/AMD2:2020 are provided in Annex AA.

201.1.4 * Particular standards

Replace, in the existing third paragraph, "IEC 60601-1 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".

Add, after the existing last paragraph, the following new paragraph:

IEC 80601-2-49 [9] applies to an INFANT TRANSPORT INCUBATOR supplied with dedicated physiological monitoring. Measured parameters related to the inherent function of an INFANT TRANSPORT INCUBATOR i.e. the SKIN TEMPERATURE, are not considered to be a physiological monitoring unit as per IEC 80601-2-49 [9].

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-1-2 with the following new references:

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 60601-1-2:2014, *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

Add, under "Addition:", the following new references:

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

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