



Medical electrical equipment

Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

(ISO 80601-2-61:2017, corrected version 2018-02)

Medizinische elektrische Geräte — Teil 2-61: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Pulsoximetriegeräten

(ISO 80601-2-61:2017, korrigierte Fassung 2018-02)

Appareils électromédicaux — Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls

(ISO 80601-2-61:2017, version corrigée 2018-02)

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National Foreword

This ÖNORM EN ISO represents the national edition of EN ISO 80601-2-61:2019-01.

Standard users shall be notified that this English reference version contains several printing errors.

The following clauses should be revised:

- Subclause 201.3.214: In the key to the formula, the minus sign is not displayed correctly. “ $(SpO_{2i} \ominus SpO_{2fit,i})$ ” should actually read “ $(SpO_{2i} - SpO_{2fit,i})$ ”.
- Subclause 201.12.1.101.1, 1st paragraph: The minus sign is not displayed correctly. “+3 % of the lower value and \ominus 3 % of the upper value” should actually read “+3 % of the lower value and -3 % of the upper value”.
- Annex CC.1, 2nd paragraph, 2nd sentence: The minus sign is not displayed correctly. “(a value of $n \ominus 1$ is replaced with n)” should actually read “(a value of $n - 1$ is replaced with n)”.
- Annex CC.2.3, last paragraph: The minus sign is not displayed correctly. “ $b = 0,100 \cdot 2 \cdot x \ominus 8,67$ ” should actually read “ $b = 0,100 \cdot 2 \cdot x - 8,67$ ”.
- Annex CC.2.4: In the key to the formula, the minus sign is not displayed correctly. “ $(SpO_{2i} \ominus SpO_{2fit,i})$ ” should actually read “ $(SpO_{2i} - SpO_{2fit,i})$ ”.
- Annex HH.3: The current clause numeration “A.1 Clinical context” should correctly read “HH.3 Clinical context”.

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English Version

Medical electrical equipment -
Part 2-61: Particular requirements for basic safety and
essential performance of pulse oximeter equipment
(ISO 80601-2-61:2017, Corrected version 2018-02)

Appareils électromédicaux - Partie 2-61: Exigences
particulières pour la sécurité de base et les
performances essentielles pour les oxymètres de pouls
(ISO 80601-2-61:2017, Version corrigée 2018-02)

Medizinische elektrische Geräte -
Teil 2-61: Besondere Festlegungen für die Sicherheit
einschließlich der wesentlichen Leistungsmerkmale
von Pulsoximetriegegeräten
(ISO 80601-2-61:2017, korrigierte Fassung 2018-02)

This European Standard was approved by CEN on 13 December 2018.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 06 March 2019.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN 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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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 80601-2-61:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by January 2022.

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

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Endorsement notice

The text of ISO 80601-2-61:2017, Corrected version 2018-02 has been approved by CEN as EN ISO 80601-2-61:2019 without any modification.

ÖNORM

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2017-12

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Medical electrical equipment —

Part 2-61:

Particular requirements for basic safety and essential performance of pulse oximeter equipment

Appareils électromédicaux —

Partie 2-61: Exigences particulières pour la sécurité de base et les performances essentielles pour les oxymètres de pouls



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CP 401 • Ch. de Blandonnet 8
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Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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