

ICS 11.040.10;

PN-EN ISO 80601-2-12:2011/AC

grudzień 2011

Wprowadza

EN ISO 80601-2-12:2011/AC:2011, IDT
ISO 80601-2-12:2011/AC1:2011, IDT

Dotyczy

PN-EN ISO 80601-2-12:2011

Medyczne urządzenia elektryczne -- Część 2-12: Szczegółowe wymagania dotyczące podstaw bezpieczeństwa i zasadniczego działania respiratorów stosowanych w intensywnej terapii

Na wniosek Komitetu Technicznego nr 284

ds. Sprzętu, Narzędzi i Urządzeń Medycznych Mechanicznych

Poprawka do Normy Europejskiej EN ISO 80601-2-12:2011/AC:2011 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators - Technical Corrigendum 1 (ISO 80601-2-12:2011/AC1:2011)

ma status Poprawki do Polskiej Normy

English version
Version Française
Deutsche Fassung

Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators - Technical Corrigendum 1 (ISO 80601-2-12:2011/Cor 1:2011)

Appareils électromédicaux - Partie 2-12:
Exigences particulières relatives à la
sécurité de base et aux performances
essentiels des ventilateurs pulmonaires
pour utilisation en soins intensifs -
Rectificatif technique 1 (ISO 80601-2-
12:2011/Cor 1:2011)

Medizinische elektrische Geräte - Teil 2-12:
Besondere Festlegungen für die Sicherheit
einschließlich der wesentlichen
Leistungsmerkmale von Beatmungsgeräten
für die Intensivpflege (ISO 80601-2-
12:2011/Cor 1:2011)

This corrigendum becomes effective on 15 October 2011 for incorporation in the three official language versions of the EN.

Ce corrigendum prendra effet le 15 octobre 2011 pour incorporation dans les trois versions linguistiques officielles de la EN.

Die Berichtigung tritt am 15. Oktober 2011 zur Einarbeitung in die drei offiziellen Sprachfassungen der EN in Kraft.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 80601-2-12:2011/AC:2011) 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.

Endorsement notice

The text of ISO 80601-2-12:2011/Cor 1:2011 has been approved by CEN as a EN ISO 80601-2-12:2011/AC:2011 without any modification.



INTERNATIONAL STANDARD ISO 80601-2-12:2011
TECHNICAL CORRIGENDUM 1

Published 2011-10-15

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Medical electrical equipment

Part 2-12:

Particular requirements for basic safety and essential performance of critical care ventilators

TECHNICAL CORRIGENDUM 1

Appareils électromédicaux

Partie 2-12:

Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs pulmonaires pour utilisation en soins intensifs

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO 80601-2-12:2011 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

Page iii to v, Table of contents

Between 201.1.1 and 201.108.2, some items contain extra spaces between the second period and the subsequent part of the number. Remove these superfluous spaces.

Remove all asterisks from the table of contents.

Page iv to page 57

Replace the misprint “u” with “≤” in all the following instances:

Page iv	Table of contents, item 201.12.4.103.2
Page 7	201.3.212, definition
Page 18	Table 201.102, last column
Page 19	201.9.101 b), existing item ii) 201.9.101 e), third list item
Page 23	201.12.1.101, second list, third item
Page 26	201.12.1.102, second list, third item
Page 31	Table 201.105, last column
Page 32	201.12.4.103.2, title, first sentence and second sentence
Page 34	201.12.4.107, third list item
Page 37	201.15.3.5.101.2, first, second and third list items under 4)
Page 42	201.102.7.1 c), third item 201.103, third item
Page 57	Subclause 201.5.101, last line

Page 5, 201.2

Replace the reference ISO 60529:1989 with IEC 60529:1989.

Page 13, 201.7.4.3

Move “*Amendment (add to the bottom as a new row in Table 1)*” to a new line.

Page 14, 201.7.9.2.1.101

Add “Additional subclauses:” prior to this heading.

Page 16, 201.7.9.2.14.101 b)

Replace the reference 201.4.101 with 201.4.3.101.

Page 18 to 57

Replace the misprint “w” with “≥” in all the following instances:

Page 18	Table 201.102, first and second columns
Page 19	201.9.101 b), first and second list items 201.9.101 e), first and second list items
Page 23	201.12.1.101, second list, first and second list items
Page 26	201.12.1.102, second list, first and second list items
Page 31	Table 201.105, first and second columns
Page 34	201.12.4.107, first and second list items
Page 42	201.102.7.1 c), first and second list items 201.103, first and second list items
Page 57	Subclause 201.5.101, last line

Page 19, 201.9.101 b)

Renumber the second and third list items as ii) and iii) respectively.

Page 21, 201.11.6.5.101

Add “*Additional subclause:*” prior to this heading.

Page 22, 201.11.8.101

Add “*Additional subclauses:*” prior to this heading.

Page 34, 201.12.101

Add “*Additional subclause:*” prior to this heading.

Page 38 to 45

Amend the styling of all titles from 201.101 to 201.108.2, and 202.6.2.1.10, so that they are in Arial font.

Page 42, 201.102.7.2

In the first line of the second paragraph, delete the words “and the VENTILATOR”.

Page 78, Index item PRIMARY OPERATING FUNCTION

Replace the reference IEC 62366:2006, 3.6, with IEC 62366:2007, 3.14.