
Medical electrical equipment —
Part 2-12:
Particular requirements for basic
safety and essential performance of
critical care ventilators

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*

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This second edition cancels and replaces the first edition (ISO 80601-2-12:2011), which has been technically revised. It also incorporates the Technical Corrigendum ISO 80601-2-12:2011/Cor 1:2011. The main changes compared to the previous edition are as follows:

- alignment with IEC 60601-1:2005+AMD1:2012, IEC 60601-1-8:2006+AMD1:2012, IEC 60601-1-2:2014 and IEC 60601-1-6:2010+AMD1:2013.
- determination of probability of component failure during the *expected service life*;
- delivered gas maximum enthalpy requirement;
- new test protocol for *internal electrical power source* operation time;
- performance test and disclosure requirements for other *inflation-types*;
- additional protections against hazardous outputs;
- clarification of performance requirements during abnormal testing;
- consideration of input gas of Oxygen 93 %; and
- harmonization of terminology with ISO 19223, where appropriate.