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**Medical electrical equipment —**

Part 2-84:

**Particular requirements for the basic  
safety and essential performance of  
ventilators for the emergency medical  
services environment**

*Appareils électromédicaux —*

*Partie 2-84: Exigences particulières relatives à la sécurité de base  
et aux performances essentielles des ventilateurs utilisés dans  
l'environnement des services médicaux d'urgence*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*.

This first edition cancels and replaces ISO 10651-3:1997, which has been technically revised. The main changes compared to the previous edition are as follows:

- extension of the scope to include the *EMS ventilator* and its *accessories*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator for the emergency medical services environment*, and thus not only the *ventilator for the emergency medical services environment* itself;
- identification of *essential performance* for *ventilator for the emergency medical services environment* and its *accessories*;
- modification of the tests for environmental conditions (via IEC 60601-1-12);
- modification of the tests for *alarm conditions* (via IEC 60601-1-8);
- modification of the tests for electromagnetic disturbances (via IEC 60601-1-2);
- addition of the following:
  - tests for ventilation performance;
  - test for instability from unwanted lateral movement;

- test for audible acoustic energy;
- tests for mechanical strength (via IEC 60601-1-12);
- tests for environmental conditions (via IEC 60601-1-12);
- tests for *alarm conditions* (via IEC 60601-1-8);
- tests for electromagnetic disturbances (via IEC 60601-1-2);
- inclusion of the *usability engineering process* (via IEC 60601-1-6);
- new symbols;
- requirements for *ventilator for the emergency medical services environment* as a component of an *ME system*;
- tests for *enclosure* integrity (water ingress via IEC 60601-1-12);
- tests for *cleaning and disinfection*;
- determination of probability of component failure during the *expected service life*;
- delivered gas maximum enthalpy requirement;
- performance test and disclosure requirements for other *inflation-types*;
- enhanced inspired oxygen *monitoring equipment* requirements;
- consideration of input gas of Oxygen 93 %;
- use of the vocabulary and semantics of ISO 19223:2019;
- consideration of contamination of the breathing gas delivered to the *patient* from the *gas pathways*.

A list of all parts in the ISO 80601 series and the IEC 80601 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).