
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*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Foreword	vi
Introduction	viii
201.1 Scope, object and related standards	1
201.1.1 * Scope	1
201.1.2 Object	2
201.1.3 Collateral standards	2
201.1.4 Particular standards	3
201.2 Normative references	4
201.3 Terms and definitions	6
201.4 General requirements	6
201.4.3 <i>Essential performance</i>	6
201.4.3.101 * Additional requirements for <i>essential performance</i>	6
201.4.4 Additional requirements for <i>expected service life</i>	7
201.4.6 * <i>ME equipment</i> or <i>ME system</i> parts that contact the <i>patient</i>	7
201.4.11.101 * Additional requirements for pressurized gas input	7
201.4.11.101.1 Overpressure requirement	7
201.4.11.101.2 Compatibility requirement for <i>medical gas pipeline systems</i>	8
201.4.11.101.3 Compatibility requirements for pressure regulators	8
201.5 General requirements for testing of <i>ME equipment</i>	9
201.5.101 * Additional requirements for general requirements for testing of <i>ME equipment</i>	9
201.5.101.1 <i>EMS ventilator</i> test conditions	9
201.5.101.2 * Gas flowrate and leakage specifications	9
201.5.101.3 * <i>EMS ventilator</i> testing errors	9
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	9
201.7 <i>ME equipment</i> identification, marking and documents	9
201.7.2.3 * Consult <i>accompanying documents</i>	9
201.7.2.4.101 Additional requirements for <i>accessories</i>	10
201.7.2.13.101 Additional requirements for physiological effects	10
201.7.2.17.101 Additional requirements for protective packaging	10
201.7.2.18 External gas source	10
201.7.2.101 * Additional requirements for marking on the outside of <i>ME equipment</i> or <i>ME equipment</i> parts	11
201.7.4.2 * Control devices	12
201.7.4.3 * Units of measurement	12
201.7.4.101 Labelling of units of measurement	12
201.7.9.1 Additional general requirements	12
201.7.9.2.1.101 Additional general requirements	12
201.7.9.2.2.101 * Additional requirements for warnings and safety notices	13
201.7.9.2.8.101 * Additional requirements for start-up <i>procedure</i>	13
201.7.9.2.9.101 * Additional requirements for operating instructions	14
201.7.9.2.12 <i>Cleaning, disinfection, and sterilization</i>	15
201.7.9.2.14.101 * Additional requirements for <i>accessories</i> , supplementary equipment, used material	15
201.7.9.3.1.101 * Additional general requirements	15
201.7.9.3.101 Additional requirements for the technical description	16
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	16