ISO 80601-2-69:2014-07 (E)

Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential per formance of oxygen concentrator equipment

Contents

Page

Foreword 5
Introduction 7
201.1 Scope, object and related standards 1
201.2 Normative references 3
201.3 Terms and definitions 4
201.4 General requirements 5
201.5 General requirements for testing of ME EQUIPMENT 6
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 6
201.7 ME EQUIPMENT identification, marking and documents 6
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 12
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 12
201.10 Protection against unwanted and excessive radiation HAZARDS 13
201.11 Protection against excessive temperatures and other HAZARDS 13
201.12 Accuracy of controls and instruments and protection against hazardous outputs 16
201.13 HAZARDOUS SITUATIONS and fault conditions 20
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 20
201.15 Construction of ME EQUIPMENT 20
201.16 ME SYSTEMS 20
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 21
201.101 Outlet connector 21
201.102 Requirements for parts and ACCESSORIES 21
201.102.1 * General 21
201.102.2 Labelling 21
201.102.3 * Fire RISK reduction in ACCESSORIES 22
201.103 SIGNAL INPUT/OUTPUT PART 22
201.103.1 General 22
201.103.2 * Connection to a DISTRIBUTED ALARM SYSTEM 22
201.103.3 * Connection for remote control 23
201.104 * Indication of duration of operation 23
201.105 Integrated CONSERVING EQUIPMENT 23
202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests 23

202.6.2.1.10 Compliance criteria 23
206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability 23
208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems 24
211 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment 24
211.4.2.2 Environmental operating conditions 24
ANNEX C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 25
Annex D (informative) Symbols on marking 29
Annex AA (informative) Particular guidance and rationale 30
Annex BB (informative) Reference to the Essential Principles 37

Figures

Figure 201.101 – Standard resistance 13