ISO 80601-2-67:2026-04 (E)

Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment

Contents

Page

Foreword iv

Introduction vi

201.1 Scope, object and related standards 1

201.2 Normative references 3

201.3 Terms and definitions 4

201.4 General requirements 13

201.5 General requirements for testing of *ME equipment* 15

201.6 Classification of *ME equipment* and *ME systems* 16

201.7 *ME equipment* identification, *marking* and documents 17

201.8 Protection against electrical *hazards* from *ME equipment* 23

201.9 Protection against *mechanical hazards* of *ME equipment* and *ME systems* 23

201.10 Protection against unwanted and excessive radiation *hazards* 23

201.11 Protection against excessive temperatures and other *hazards* 24

201.12 Accuracy of controls and instruments and protection against hazardous outputs 26

201.13 *Hazardous situations* and fault conditions 29

201.14 *Programmable electrical medical systems* (*PEMS*) 29

201.15 Construction of *ME equipment* 30

201.16 *ME systems* 30

201.17 Electromagnetic compatibility of *ME equipment* and *ME systems* 31

201.101 Gas connections 31

201.102 Requirements for parts and *accessories* 32

201.103 Oxygen pressure regulators 33

202 Electromagnetic disturbances – Requirements and tests 34

206 Usability 34

Annex C (informative) Guide to *marking* and labelling requirements for *ME equipment* and *ME systems* 36

Annex D (informative) *Symbol*s on *marking* 41

Annex AA (informative) Particular guidance and rationale 42

Annex BB (informative) Reference to the IMDRF *essential principles* and labelling guidances 51

Annex CC (informative) Terminology — Alphabetized index of defined terms 55

Bibliography 58