

ISO 80601-2-69:2026-04 (E)

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

Contents	Page
Foreword.....	v
Introduction.....	vii
201.1 Scope, object and related standards.....	1
201.2 Normative references.....	3
201.3 Terms and definitions.....	4
201.4 General requirements.....	16
201.5 General requirements for testing of <i>ME equipment</i>	18
201.6 Classification of <i>ME equipment</i> and <i>ME systems</i>	19
201.7 <i>ME equipment</i> identification, <i>marking</i> and documents.....	19
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	26
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	26
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	28
201.11 Protection against excessive temperatures and other <i>hazards</i>	28
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	32
201.13 <i>Hazardous situations</i> and fault conditions for <i>ME equipment</i>	38
201.14 <i>Programmable electrical medical systems (PEMS)</i>	38
201.15 Construction of <i>ME equipment</i>	39
201.16 <i>ME systems</i>	39
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	39
201.101 Outlet connector.....	39
201.102 Requirements for parts and accessories.....	40
201.103 Functional connection.....	42
201.104 Indication of duration of operation.....	42
201.105 Integrated conserving equipment function.....	42
202 Electromagnetic disturbances – Requirements and tests.....	43
202.4.3.1 Configurations.....	43
206 Usability.....	43
211 Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.....	44
Annex C (informative) Guide to <i>marking</i> and labelling requirements for <i>ME equipment</i> and <i>ME systems</i>	45
Annex D (informative) <i>Symbols on marking</i>	50
Annex AA (informative) Particular guidance and rationale.....	52

Annex BB (informative) Reference to the IMDRF <i>essential principles</i> and labelling guidances	60
Annex CC (informative) Terminology — alphabetized index of defined terms	64
Bibliography.....	68