

ISO 80601-2-13:2022-04 (E)

Medical electrical equipment - Part 2-13 : Particular requirements for basic safety and essential performance of an anaesthetic workstation

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	10
201.5 General requirements for testing <i>ME equipment</i>	11
201.6 Classification of <i>ME equipment</i> or <i>ME systems</i>	12
201.7 <i>ME equipment</i> identification, marking and documents	12
201.8 Protection against electrical <i>hazards</i> from <i>ME equipment</i>	17
201.9 Protection against <i>mechanical hazards</i> of <i>ME equipment</i> and <i>ME systems</i>	18
201.10 Protection against unwanted and excessive radiation <i>hazards</i>	19
201.11 Protection against excessive temperatures and other <i>hazards</i>	19
201.12 Accuracy of controls and instruments and protection against hazardous outputs	22
201.13 <i>Hazardous situations</i> and fault conditions.....	28
201.14 <i>Programmable electrical medical systems (PEMS)</i>	28
201.15 Construction of <i>ME equipment</i>	29
201.16 <i>ME systems</i>	29
201.17 Electromagnetic compatibility of <i>ME equipment</i> and <i>ME systems</i>	31
201.101 Additional requirements for <i>anaesthetic gas delivery systems</i>	31
201.102 Additional requirements for an <i>anaesthetic breathing system</i>	37
201.103 Additional requirements for an <i>AGSS</i>	48
201.104 Additional requirements for interchangeable and non-interchangeable <i>anaesthetic vapour delivery systems</i>	53
201.105 Additional requirements for an <i>anaesthetic ventilator</i>	58
201.106 Display of pressure-volume loops	64
201.107 Clinical evaluation	64
202 Electromagnetic disturbances — Requirements and tests	65
203 General requirements for radiation protection in diagnostic X-ray equipment.....	65
206 <i>Usability</i>	65
208 General requirements, tests and guidance for <i>alarm systems</i> in <i>medical electrical equipment</i> and <i>medical electrical systems</i>	66
209 Requirements for environmentally conscious design	66

210 *Process* requirements for the development of physiologic closed-loop controllers..... 67

211 Requirements for *medical electrical equipment* and *medical electrical systems* used in the home healthcare environment 67

212 Requirements for *medical electrical equipment* and *medical electrical systems* intended for use in the *emergency medical services environment*..... 67

Annex C (informative) Guide to marking and labelling requirements for *ME equipment* and *ME systems* or their parts 68

Annex D (informative) Symbols on marking 78

Annex AA (informative) Particular guidance and rationale 80

Annex BB (normative) Test for flammability of anaesthetic agent..... 97

Annex CC (informative) Terminology — alphabetized index of defined terms..... 98

Bibliography102