

ISO 80601-2-13:2011-08 (E)

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

Contents

Page

Foreword	v
Introduction	vi
201.1 Scope, object and related standards	1
201.2 Normative references	3
201.3 Terms and definitions	5
201.4 General requirements	9
201.5 General requirements for testing ME EQUIPMENT	11
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	11
201.7 ME EQUIPMENT identification, marking and documents	11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	15
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS	16
201.10 Protection against unwanted and excessive radiation HAZARDS	17
201.11 Protection against excessive temperatures and other HAZARDS	17
201.12 Accuracy of controls and instruments and protection against hazardous outputs	19
201.13 HAZARDOUS SITUATIONS and fault conditions	24
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	24
201.15 Construction of ME EQUIPMENT	25
201.16 ME SYSTEMS	25
201.17 Electromagnetic compatibility of ME EQUIPMENT AND ME SYSTEMS	26
201.101 Additional requirements for ANAESTHETIC GAS DELIVERY SYSTEMS	26
201.102 Additional requirements for an ANAESTHETIC BREATHING SYSTEM	32
201.103 Additional requirements for an ANAESTHETIC GAS SCAVENGING SYSTEM	39
201.104 Additional requirements for an ANAESTHETIC VAPOUR DELIVERY SYSTEM	43
201.105 Additional requirements for an ANAESTHETIC VENTILATOR	47
201.105.7 * Timed ventilatory pause	50
201.105.7.1	Expiratory pause 50
201.105.7.2	Inspiratory pause 50
201.106 Display loops	53
201.107 Clinical evaluation	53
202 Electromagnetic compatibility -- Requirements and tests	54
203 General requirements for radiation protection in diagnostic X-ray equipment	54
206 Usability	54
208 General requirements, tests and guidance for ALARM SYSTEMS in MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS	55
209 Requirements for environmentally conscious design	55
210 PROCESS requirements for the development of physiologic closed-loop controllers	56
211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare	56
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS or their parts	57

Annex D (informative) Symbols on marking	67
Annex AA (informative) Particular guidance and rationale	69
Annex BB (normative) Test for flammability of anaesthetic agent	84
Annex CC (informative) Environmental aspects	85
Annex DD (informative) Reference to the essential principles	87
Bibliography	94
Alphabetized index of defined terms used in this particular standard	96