

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 |