IEC 60601-1-11:2015-01 (E/F)

Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Appareils électroméd icaux - Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile

Contents

Page

FOREWORD 5
INTRODUCTION 8
1 Scope, object and related standards 9
1.1 * Scope 9
1.2 Object 9
1.3 Related standards 9
1.3.1 IEC 60601-1 9
1.3.2 Particular standards 10
2 Normative references 10
3 Terms and definitions 11
4 General requirements 12
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS 12
4.2 * Environmental conditions for ME EQUIPMENT 12
4.2.1 General 12
4.2.2 * Environmental conditions of transport and storage between uses 13
4.2.3 * Environmental operating conditions 14
5 * General requirements for testing ME EQUIPMENT 16
6 * Classification of ME EQUIPMENT and ME SYSTEMS 17
7 ME EQUIPMENT identification, marking and documents 17
7.1 * USABILITY of the ACCOMPANYING DOCUMENTS 17
7.2 * Additional requirements for marking of IP classification 18
7.3 ACCOMPANYING DOCUMENTS 18
7.3.1 Contact information 18
7.3.2 LAY OPERATOR briefing information 18
7.4 Instructions for use 19
7.4.1 Additional requirements for warning and safety notices 19
7.4.2 * Additional requirements for an electrical power source 19
7.4.3 Additional requirements for ME EQUIPMENT description 20
7.4.4 Additional requirements for ME EQUIPMENT start-up PROCEDURE 20
7.4.5 Additional requirements for operating instructions 20
7.4.6 Additional requirements for ME EQUIPMENT messages 21
7.4.7 * Additional requirements for cleaning, disinfection and sterilization 21
7.4.8 Additional requirements for maintenance 21
7.4.9 Additional requirements for environmental protection 21
7.4.10 Additional requirements for ME EQUIPMENT and ME SYSTEMS 22
7.5 Technical description 22
7.5.1 PERMANENTLY INSTALLED CLASS I ME EQUIPMENT 22
7.5.2 Additional requirements for professional hygienic maintenance 22

8 Protection against excessive temperatures and other HAZARDS 22
8.1 * Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS 22
8.2 * Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS 23
8.3 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS 23
8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT 23
8.3.2 * Ingress of water or particulate matter into ME SYSTEMS 23
8.4 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM 23
8.5 Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE 24
8.5.1 * Indication of state 24
8.5.2 Accessibility of small INTERNAL ELECTRICAL POWER SOURCES 25
Accuracy of controls and instruments and protection against hazardous outputs 25
Construction of ME EQUIPMENT 25
10.1 * Additional requirements for mechanical strength 25
10.1.1 General requirements for mechanical strength 25
10.1.2 * Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT 27
10.1.3 * Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT 28
10.2 Additional requirements for actuating parts of controls of ME EQUIPMENT 29
* Protection against strangulation or asphyxiation 30
Additional requirements for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS 30
Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS 30
13.1 * Additional requirement for generation of ALARM SIGNALS 30
13.2 * Additional requirement for ALARM SIGNAL volume 30
Annex A (informative) General guidance and rationale 31
A.1 General guidance 31
A.2 Rationale for particular clauses and subclauses 32
Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 51
B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 51
B.2 ACCOMPANYING DOCUMENTS, general 51
B.3 ACCOMPANYING DOCUMENTS, instructions for use 51
B.4 ACCOMPANYING DOCUMENTS, technical description 53
Annex C (informative) Symbols on marking 54
Bibliography 56
Index of defined terms used in this collateral standard 58

Figure 1 – Small finger probe Ø 5,6 17
Figure A.1 – Saturation water vapour pressure as function of temperature 36

Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE 26
Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE 27
Table A.1 – Saturation water vapour pressure as function of temperature 37
Table A.2 – Summary by use of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT ENCLOSURE ingress of water and particulate matter requirements 46
Table A.3 – Qualitative assessment of HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT subjected to shock and vibration 47

Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 51
Table B.2 – ACCOMPANYING DOCUMENTS, general 51
Table B.3 – ACCOMPANYING DOCUMENTS, instructions for use 52
Table B.4 – ACCOMPANYING DOCUMENTS, technical description 53
Table C.1 – General symbols 54