DIN EN 13544-1:2007-07 (E)

Respiratory therapy equipment - Part 1: Nebulizing systems and their components

Contents

Page

Foreword 5

Introduction 6

1 R) Scope 7

2 Normative references 7

3 Terms and definitions 9

4 General requirements and general requirements for test 10
4.1 Modifications to Clause 3 of EN 60601-1:1990 10
4.2 Clause 4 of EN 60601-1:1990 10
4.3 Alternative type-test methods 11

5 Classification 11

6 Identification, marking and documents 11
6.1 Marking on the outside of equipment or equipment parts 11
6.3 Marking of controls and instruments 12
6.4 Symbols 12
6.8.2 Instructions for use 12
6.8.3 Technical description 14

7 Power input 14

8 Basic safety categories 14

9 Removable protective means 14

10 Environmental conditions 15

11 Not used 15

12 Not used 15

13 General 15

14 Requirements related to classification 15

15 Limitation of voltage and/or energy 15

16 Enclosures and protective covers 15

17 Separation 15

18 Protective earthing, functional earthing and potential equalization 15

19 Continuous leakage currents and patient auxiliary currents 15

20 Dielectric strength 16

21 Mechanical strength 16
22 Moving parts 16
23 Surfaces, corners and edges 16
24 Stability in normal use 16
25 Expelled parts 16
26 Vibration and noise 16
27 Pneumatic and hydraulic power 17
28 Suspended masses 17
29 X-radiation 17
30 Alpha, beta, gamma, neutron radiation and other particle radiation 17
31 Microwave radiation 17
32 Light radiation (including lasers) 17
33 Infra-red radiation 17
34 Ultra-violet radiation 17
35 Acoustical energy (including ultra-sonics) 17
36 Electromagnetic compatibility 18
37 R Locations and basic requirements 18
38 R Marking, accompanying documents 18
39 R Common requirements for category AP and category APG equipment 18
40 R Requirements and tests for Category AP equipment, parts and components thereof 18
41 R Requirements and tests for Category APG equipment, parts and components thereof 18
42 Excessive temperatures 18
43 R) Fire prevention 18
44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization and disinfection 19
45 Pressure vessels and parts subject to pressure 19
46 Human errors 19
47 Electrostatic charges 19
48 Biocompatibility 20
49 Interruption of the power supply 20
50 Accuracy of operating data 20
51 Protection against hazardous output 20

52 Abnormal operation and fault conditions 21

53 Environmental tests 21

54 General 21

55 Enclosures and covers 21

56 Components and general assembly 21

57 Mains parts, components and layout 23

58 Protective earthing - Terminals and connections 23

59 Construction and layout 23

Annex A A (informative) Rationale 24

Annex B B (informative) Diameters of the particles depositable fraction 27

Annex C C (normative) Test methods for the aerosol output rate, the aerosol output and for particle sizing 28

CC.1 Method of test for the aerosol output rate 28

CC.1.1 Test conditions 28

CC.1.2 R) Principle of test 28

CC.1.3 Test equipment 28

Annex D D (normative) Mass balance checks on cascade impactor tests 36

DD.1 Aerosol output rate and aerosol output tests: 36

DD.2 Particle sizing test 36

Annex E E (informative) Environmental aspects 37

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC on medical devices 39

Bibliography 41