

ISO 8835-4:2004-06 (E)

Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements and general requirements for tests	2
5	Classification	2
6	Identification, marking and documents	2
7	Power input	4
8	Basic safety categories	4
9	Removable protective means	4
10	Environmental conditions	4
11	Not used	4
12	Not used	4
13	General	4
14	Requirements related to classification	4
15	Limitation of voltage and/or energy	5
16	Enclosures and protective covers	5
17	Separation	5
18	Protective earthing, functional earthing and potential equalization	5
19	Continuous leakage currents and patient auxiliary currents	5
20	Dielectric strength	5
21	Mechanical strength	5
22	Moving parts	5
23	Surfaces, corners and edges	5
24	Stability in normal use	5

25	Expelled parts	5
26	Vibration and noise	6
27	Pneumatic and hydraulic power	6
28	Suspended masses	6
29	X-radiation	6
30	Alpha, beta, gamma, neutron radiation and other particle radiation	6
31	Microwave radiation	6
32	Light radiation (including lasers)	6
33	Infra-red radiation	6
34	Ultraviolet radiation	6
35	Acoustical energy (including ultrasonics)	6
36	Electromagnetic compatibility	6
37	Locations and basic requirements	7
38	Marking and accompanying documents	7
39	Common requirements for category AP and category APG equipment	7
40	Requirements and tests for category AP equipment, parts and components thereof	7
41	Requirements and tests for category APG equipment, parts and components thereof	7
42	Excessive temperatures	7
43	Fire prevention	7
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility	8
45	Pressure vessels and parts subject to pressure	8
46	Human errors	8
47	Electrostatic charges	8
48	Biocompatibility	8
49	Interruption of the power supply	8
50	Accuracy of operating data	9
51	Protection against hazardous output	9
52	Abnormal operation and fault conditions	10
53	Environmental tests	11
54	General	11
55	Enclosures and covers	11

56	Components and general assembly	11
57	Mains parts, components and layout	11
58	Protective earthing -- Terminals and connections	11
59	Construction and layout	11
101	Additional requirements for AVDDs	11
102	Appendices of IEC 60601-1:1988	12
	Annex AA (informative) Rationale	13
	Annex BB (informative) Recommended colours for colour coding of anaesthetic vapour delivery devices	16
	Annex CC (normative) Test for flammability of anaesthetic agents	17
	Bibliography	18