

ISO 17966:2016-01 (E)

Assistive products for personal hygiene that support users - Requirements and test methods

Contents		Page
Foreword		vii
Introduction		viii
1	Scope	1
2	Normative references	2
3	Terms and definitions	3
4	General requirements and test methods	6
4.1	Risk analysis	6
4.2	Intended performance	6
4.3	Clinical evaluation and investigation	6
4.4	Assistive products for personal hygiene that can be dismantled	6
4.5	Fasteners	7
4.6	Means to prevent falling out	7
4.7	User mass/load limits	7
4.8	Apparatus	7
4.9	Test conditions	17
5	Materials	18
5.1	General	18
5.2	Flammability	18
5.2.1	General	18
5.2.2	Moulded parts used as enclosures for electrical equipment	18
5.2.3	Upholstered parts and moulded parts	18
5.3	Biocompatibility and toxicity	18
5.4	Infection and microbiological contamination	19
5.4.1	Cleaning and disinfection	19
5.4.2	Resistance against temperature alternations	19
5.4.3	Animal tissue	19
5.5	Resistance to corrosion	19
6	Emitted sound and vibration	19
6.1	Noise and vibration	19
6.2	Sound pressure levels and frequencies of audible warning devices	20
7	Electromagnetic compatibility	20
7.1	General	20
7.2	Emissions	20
7.3	Immunity	20
7.4	Power frequency magnetic field immunity	20
8	Electrical safety	21
8.1	General	21
8.2	Electrical systems	21
8.3	Safe positioning	21
8.4	Single fault safety	21
8.5	Hold to run activation	21
8.6	Emergency stopping functions	21

8.7	Continuity of power supply	22
8.8	Battery powered assistive products for personal hygiene	23
8.8.1	Battery housings	23
8.8.2	Connection	23
8.8.3	Charge level indicator	23
8.9	Circuit protection	23
8.10	Electrically heated blankets, pads and similar flexible heating appliances	24
8.11	Ingress of liquids	24
9	Overflow,leakage,andingressofliquids	24
9.1	Ingress of liquids	24
9.1.1	Requirements	24
9.1.2	Test method	24
9.2	Overflow and leakage	24
9.2.1	General	24
9.2.2	Substances which may leak from an APPH in intended use and in fault conditions	25
10	Temperaturesofpartsthatcomeincontactwithhumanskin	25
11	Safety of moving and folding parts	26
11.1	Squeezing	26
11.2	Velocity of powered lifting and lowering movements	27
11.2.1	Requirements	27
11.2.2	Test method	27
11.3	Mechanical wear	27
11.4	Trapping zones for feet in relation to moving parts	27
12	Prevention of traps for parts of the human body	28
12.1	Holes and clearances	28
12.2	V-shaped openings	29
13	Folding and adjusting mechanisms	29
13.1	General	29
13.2	Locking mechanisms	29
14	Lifting and carrying means	30
14.1	General	30
14.2	Requirement	30
14.3	Test method	30
15	Portable and hand-held products for personal hygiene or hand-held parts	31
16	Staticstrength,impactanddurability	32
16.1	General	32
16.2	Formulae	32
16.2.1	Formulae for calculating forces	32
16.3	Number of test cycles for durability	33
16.4	Static strength of lying support, arm and foot supports and seat and back surfaces	33
16.4.1	Requirements	33
16.4.2	Test methods	34
16.5	Durability	40
16.5.1	Requirements	40
16.5.2	Test methods	41
16.6	Impact	46
16.6.1	Requirements	46
16.6.2	Test methods	46
17	Stability	49
17.1	Requirements for static stability	49
17.2	Test method for static stability	49

18	Surfaces, corners, edges and protruding parts	50
19	Small parts	50
20	Forces in soft tissues of the human body	50
21	Ergonomic principles	50
22	Mobile APPHs	51
22.1	General	51
22.2	Immobilizing means	51
22.2.1	General	51
22.2.2	Requirements for locking devices	51
22.2.3	Test methods for locking devices	52
22.2.4	Test methods for durability of brakes	52
22.2.5	Brake operated by a lever	52
22.3	Electrical safety for mobile APPHs	52
22.3.1	Power-driven mobile APPHs	52
22.4	Rough handling and movement	52
22.4.1	General	52
22.4.2	Requirements	52
22.4.3	Test method for movement over a threshold	53
22.4.4	Test method for door frame shock	53
22.5	Functional requirements for mobile APPHs	53
22.5.1	Foot supports	53
22.5.2	Position of push handles/points	53
22.5.3	Turning diameter of mobile APPHs	53
22.6	Moving forces	54
22.6.1	Requirements for moving forces	54
22.6.2	Test methods for moving forces	54
23	Fixed APPHs	55
23.1	General	55
23.2	Requirements	55
23.3	Shower seats (09 33 03)	56
23.3.1	Description	56
23.3.2	Test methods for static strength, durability and impact for shower seats	56
23.4	Bathing stretchers, shower tables and diaper changing tables (09 33 12)	57
23.4.1	Description	57
23.4.2	Test methods for static strength and durability for bathing stretchers, shower tables and diaper changing tables	57
23.5	Bath/shower chairs (without wheels), bath boards, stools, back supports and seats (09 33 03)	58
23.5.1	Description	58
23.5.2	Test method for durability	58
23.6	Raised toilet seats (09 12 18)	59
23.6.1	Description	59
23.6.2	Requirements for static strength for raised toilet seats	59
23.6.3	Test methods for static strength and durability for raised toilet seats	59
23.7	Handrails, grab bars and handgrips (18 18 03 and 18 18 06)	60
23.7.1	Description	60
23.7.2	Ergonomic principles for handrails, grab bars and handgrips	60
23.7.3	Test methods for static strength and durability for handrails, grab bars and handgrips ...	61
23.8	Removable grab rails and handgrips (18 18 10)	62
23.8.1	Description	62
23.8.2	Ergonomic principles for removable grab rails and handgrips	62
23.8.3	Test methods for static strength and durability for removable grab rails and handgrips ...	62
23.9	Hinged rails and arm supports (18 18 11)	63
23.9.1	Description	63
23.9.2	General	63
23.9.3	Test method for static strength for hinged rails and arm supports	63
23.10	Height-adjustable plinths and brackets (18 15 06)	64

23.10.1	Description	64
23.10.2	Test methods for static strength and durability for height-adjustable plinths and brackets	64
24	Static APPHs	65
24.1	General	65
24.2	Stability and strength tests for static APPHs	65
24.3	Toilet seats inserts (non fixed) (09 12 15)	65
24.3.1	Description	65
24.3.2	Impact	65
24.4	Toilet seats with built-in raising mechanism to help standing up and sitting down (non-fixed) (09 12 21)	68
24.4.1	Description	68
24.4.2	Durability	68
24.5	Bath/shower chairs (without wheels), bath boards, stools, back supports and seats (09 33 03)	68
24.5.1	Description	68
24.5.2	Materials	68
24.5.3	Stability	68
24.5.4	Stability tests for APPHs designed to be supported by the sides of a bathtub	68
24.5.5	Strength test of brackets	73
24.5.6	Friction test of bath board/seat	76
24.5.7	Static horizontal force test on handle	77
24.5.8	Static vertical force test of handle of bath and transfer boards	77
25	Requirements for information supplied by the manufacturer	78
25.1	General	78
25.2	Instructions for use	78
25.2.1	Pre-sale information	78
25.2.2	User information	79
25.2.3	Service information	80
25.3	Labelling	80
26	Packaging	80
27	Test report	81
Annex A (informative) Cognitive impairment		82
Annex B (informative) General recommendations		83
Annex C (informative) Environmental and consumer-related requirements		90
Annex D (informative) Periodic inspection		95
Bibliography		96