

ISO 20342-1:2022-07 (E)

Assistive products for tissue integrity when lying down - Part 1: General requirements

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	2
3	Terms and definitions	3
4	General requirements and safety	7
4.1	General requirements	7
4.2	Intended use	8
4.2.1	General requirements	8
4.2.2	Consideration regarding intended use	8
4.2.3	Intended use statement	8
4.3	APTI risk management	9
4.4	APTI usability	9
4.4.1	General	9
4.4.2	Design requirements in relation to persons with cognitive impairment	9
4.5	Design controls	9
4.6	Clinical evaluation	9
4.7	Foreseeable misuse	9
4.8	Test conditions	10
4.9	Lifting and carrying means	10
5	Safety requirements	10
5.1	Requirements for information supplied by the manufacturer	10
5.1.1	General	10
5.1.2	APTI traceability	11
5.1.3	Education and training	11
5.1.4	Pre-sale information	11
5.1.5	User information	12
5.1.6	Service information and inspection	13
5.1.7	Labelling	13
5.1.8	Marking of user weight and maximum load	13
5.1.9	Packaging	14
5.2	APTI that can be dismantled	14
5.2.1	General requirements	14
5.2.2	Small parts	14
5.2.3	Fasteners and connections	14
5.3	Resistance to corrosion	14
5.4	Noise and vibration	14
5.5	Sound audible acoustic energy	15
5.6	Default indicators	15
5.7	Feedback	16
6	Flammability	16
6.1	General	16
6.2	Flammability	17
6.3	Moulded parts used as enclosures for electrical equipment	17

7	Mechanical safety	17
7.1	Prevention of traps for the human body	17
7.2	Safety of moving and folding parts	18
7.3	V-shaped openings	19
7.4	Surfaces, corners, edges and protruding parts	19
7.5	Folding and adjusting mechanisms	19
7.6	Instability hazard	20
7.7	Temperature of parts that come into contact with human skin	20
7.8	Ergonomic principles	21
7.9	Additional consideration	21
8	Safety of electrical equipment	21
8.1	General electrical requirements	21
8.2	Electromagnetic compatibility	22
8.2.1	General	22
8.2.2	Emissions	22
8.2.3	Immunity	22
8.2.4	Power frequency magnetic field immunity	22
8.3	Liquid ingress	22
8.4	Interruption of power supply/supply mains to an APTI	23
8.5	Hold to run activation	23
8.6	Emergency stop functions	23
9	Biocompatibility	24
9.1	Biocompatibility and toxicity	24
9.2	Animal tissue	24
10	Contamination	24
10.1	Liquid ingress	24
10.2	Cleaning and disinfection	24
10.3	Cross infection and microbial contamination	25
Annex A (informative)	General information	26
Annex B (informative)	Environmental and consumer related guidance	30
Annex C (informative)	Periodic inspection	34
Bibliography		35