

ISO 22523:2006-10 (E)

External limb prostheses and external orthoses - Requirements and test methods

Contents		Page
Foreword		vi
Introduction		vii
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements	4
4.1	Risk management	4
4.2	Intended performance and technical documentation	5
4.3	Clinical evaluation	5
4.4	Strength and related conditions of use	5
5	Requirements for materials	6
5.1	Flammability of materials and toxicity of combustion products	6
5.2	Biocompatibility, contaminants and residues	7
5.2.1	General	7
5.2.2	Contaminants and residues	7
5.3	Infection and microbiological contamination	7
5.4	Resistance to corrosion and degradation	7
6	Noise and vibration	7
7	Electromagnetic compatibility (EMC)	8
8	Electrical safety	8
8.1	Battery-powered prosthetic and orthotic devices	8
8.1.1	Battery housings and connections	8
8.1.2	Charge level indicators	8
8.2	Circuit protection	9
8.3	Electronic programmable systems	9
8.4	Electrically heated blankets, pads and similar flexible heating appliances	9
8.5	Prosthetic and orthotic devices with skin contact electrodes	9
8.6	Prosthetic and orthotic devices with radio equipment	9
8.6.1	General	9
8.6.2	Frequency spectrum of radio equipment	9
8.6.3	Operation of radio equipment by the user	9
9	Surface temperature	10
10	Sterility	10
11	Design requirements	10
11.1	Safety of moving parts	10
11.2	Safety of connections	10
12	Mechanical requirements	10
12.1	Restrictions on use	10
12.2	Forces in soft tissues of the human body	11

12.3	Ergonomic principles	11
13	Information supplied by the manufacturer	11
13.1	General	11
13.2	Labelling	12
13.3	Intended use	12
14	Packaging	12
Annex A	(informative) Guidance on methods of determining the strength of upper-limb prosthetic devices	13
Annex B	(normative) Method of determining the mechanical properties of knee joint assemblies for lower-limb orthotic devices	28
Annex C	(informative) Guidance on methods of determining the flammability and toxicity of combustion products of lower-limb prosthetic devices	41
Annex D	(informative) Guidance on methods of establishing the force or moment required to operate the control and actuating mechanisms on prosthetic and orthotic devices	55
Annex E	(informative) Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142	80
Bibliography	82
Figure A.1	-- Test sample segment lengths	15
Figure A.2	-- Configuration of test 1	16
Figure A.3	-- Configuration of test 2 and test 4	17
Figure A.4	-- Configuration of test 3 and test 5	17
Figure A.5	-- Examples of test sample configurations	18
Figure B.1	-- Example of a test rig design suitable for the application of the four-point loading system	34
Figure B.2	-- Arrangements of the four-point loading system (continued on Figure B.3)	35
Figure B.3	-- Arrangements of the four-point loading system (continued from Figure B.2)	36
Figure B.4	-- Test orientations for joint assemblies intended to restrain motion in four directions mutually at right angles (see B.5.1)	37
Figure B.5	-- Example of a bending moment/angular deflection curve: single-stage failure (see 3.17, 3.18 and 3.19)	38
Figure B.6	-- Examples of a bending moment/angular deflection curve: two-stage failures (see 3.17, 3.18 and 3.19)	39
Figure C.1	-- Test sample dimensions trans-femoral (above-knee) -- Finished limb	48
Figure C.2	-- Test sample dimensions trans-tibial (below-knee) -- Finished limb	49
Figure C.3	-- Test sample dimensions trans-femoral (above-knee) -- Socket former	50
Figure C.4	-- Test sample dimensions trans-tibial (below-knee) -- Socket former	50
Figure C.5	-- Radiant heat source test	51

Figure C.6 -- Flaming ignition source test	52
Figure C.7 -- Sample support frame and weighing platform	53
Figure D.1 -- Bowden cable arrangement during test	69
Figure D.2 -- Test set-up according to D.6.2 for sample category D.3.1 a) Orthotic knee joints with locking mechanism	70
Figure D.3 -- Test set-up according to D.6.3 for sample category D.3.1 b) Orthotic elbow joints with locking mechanism	70
Figure D.4 -- Test set-up according to D.6.4 for sample category D.3.1 c) Prosthetic knee units with locking mechanism (continued on Figure D.5)	71
Figure D.5 -- Test set-up according to D.6.4 for sample category D.3.1 c) Prosthetic knee units with locking mechanism (continued from Figure D.4)	72
Figure D.6 -- Test set-up according to D.6.5 for sample category D.3.1 d) Prosthetic elbow units with locking mechanism	72
Figure D.7 -- Test set-up according to D.6.6 for sample category D.3.1 e) Prosthetic elbow units with user-driven articulation	73
Figure D.8 -- Test set-up according to D.6.7 for sample category D.3.1 f) Terminal devices with built-in closing function	74
Figure D.9 -- Test set-up according to D.6.8 for sample category D.3.1 g) Terminal devices with built-in opening function	75
Figure D.10 -- Test set-up according to D.6.9 for sample category D.3.1 h) Terminal devices with no built-in closing or opening function, actuated by force application	76
Figure D.11 -- Test set-up according to D.6.10 for sample category D.3.1 i) Terminal devices with no built-in closing or opening function, actuated by torque application	77
Figure D.12 -- Test set-up according to D.6.11 for sample category D.3.1 j) Terminal devices with break-open feature for emergency situations	78
Figure D.13 -- Test set-up according to D.6.12 for sample category D.3.1 k) Prosthetic devices with fail-safe release unit, illustrated for a separable prosthetic adaptor plate	79
Table A.1 -- Number of tests and test samples required	19
Table B.1 -- Example of test report	40
Table C.1 -- Worked example of calculating the TTPD	54
Table D.1 -- Parameters of the test set-up for sample category D.3.1 a)	60
Table D.2 -- Parameters of the test set-up for sample category D.3.1 c)	62
Table D.3 -- Details of the test report	67
Table D.4 -- Values of actuating/operating force (and displacement) and moment measured on different categories of test sample	68
Table E.1 -- Correspondence between this International Standard and the essential principles of ISO/TR 16142	81