

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 |