

DIN EN ISO 22675:2016-12 (E)

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2016)

Contents

	Page
European foreword.....	5
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered.....	6
Foreword.....	8
Introduction.....	9
1 Scope.....	10
2 Normative references.....	10
3 Terms and definitions.....	11
4 Designations and symbols of test forces.....	11
5 Strength and related performance requirements and conditions of use.....	12
6 Coordinate system and test configurations.....	13
6.1 General.....	13
6.2 Origin and axes of the coordinate system.....	13
6.3 Reference points.....	14
6.4 Test force F	15
6.5 Line of application of test force F	15
6.6 Lines of action of resultant reference forces F_{R1} and F_{R2}	15
6.7 Longitudinal axis of the foot and effective ankle joint centre.....	15
6.7.1 General.....	15
6.7.2 Longitudinal axis of the foot.....	15
6.7.3 Effective ankle-joint centre, C_A	16
7 Test loading conditions and test loading levels.....	17
7.1 Test loading conditions.....	17
7.2 Test loading levels.....	17
8 Values of test forces, dimensions and cycles.....	18
9 Compliance.....	25
9.1 General.....	25
9.2 Particular arrangements and requirements concerning the part required to connect an ankle-foot device or foot unit to the remainder of a prosthetic structure.....	26
9.2.1 Arrangements for testing.....	26
9.2.2 Requirements for claiming compliance.....	26
9.3 Number of tests and test samples required to claim compliance with this International Standard.....	26
9.4 Multiple use of test samples.....	27
9.4.1 General.....	27
9.4.2 Restriction.....	27
9.5 Testing at particular test loading levels not specified in this International Standard.....	27

10	Test samples	28
10.1	Selection of test samples.....	28
	10.1.1 General.....	28
	10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot.....	28
10.2	Types of test sample.....	29
	10.2.1 Complete structure.....	29
	10.2.2 Partial structure.....	29
10.3	Preparation of test samples.....	29
10.4	Identification of test samples.....	30
10.5	Alignment of test samples.....	30
10.6	Worst-case alignment position of test samples.....	30
11	Responsibility for test preparation	32
12	Test submission document	33
12.1	General requirements.....	33
12.2	Information required for test samples.....	33
12.3	Information required for tests.....	34
	12.3.1 General.....	34
	12.3.2 For all tests.....	34
	12.3.3 For the static proof test and the static ultimate strength test.....	34
	12.3.4 For the static ultimate strength test.....	34
	12.3.5 For the cyclic test.....	34
13	Equipment	35
13.1	General.....	35
13.2	End attachments.....	35
	13.2.1 General.....	35
	13.2.2 Proof test of end attachments.....	35
13.3	Jig (optional).....	36
13.4	Test equipment.....	38
	13.4.1 Test equipment to perform static heel and forefoot loading.....	38
	13.4.2 Test equipment to perform cyclic loading.....	39
14	Accuracy	46
14.1	General.....	46
14.2	Accuracy of equipment.....	46
14.3	Accuracy of procedure.....	46
15	Test principles	47
15.1	General.....	47
15.2	Static test procedure.....	48
15.3	Cyclic test procedure.....	48
16	Test procedures	48
16.1	Test loading requirements.....	48
	16.1.1 Preparation for test loading.....	48
	16.1.2 Test loading conditions.....	52
16.2	Static proof test.....	52
	16.2.1 Test method.....	52
	16.2.2 Performance requirement.....	54
	16.2.3 Compliance conditions.....	54
16.3	Static ultimate strength test.....	56
	16.3.1 Test method.....	56
	16.3.2 Performance requirements.....	59
	16.3.3 Compliance conditions.....	59
16.4	Cyclic test.....	60
	16.4.1 Test method.....	60
	16.4.2 Performance requirements.....	63
	16.4.3 Compliance conditions.....	64

17	Test laboratory/facility log	66
17.1	General requirements.....	66
17.2	Specific requirements.....	66
18	Test report	66
18.1	General requirements.....	66
18.2	Specific requirements.....	67
18.3	Options.....	67
19	Classification and designation	67
19.1	General.....	67
19.2	Examples of classification and designation.....	67
20	Labelling	68
20.1	General.....	68
20.2	Use of mark “*” and warning symbol.....	69
20.3	Examples of label layout.....	69
20.4	Label placement.....	70
Annex A (informative) Reference data for the specification of the test loading conditions and test loading levels of this International Standard		71
Annex B (informative) Guidance on the application of an alternative static ultimate strength test		79
Annex C (normative) Application of an additional test loading level P6, P7, and P8		80
Annex D (informative) Summary of the records to be entered in the test laboratory/facility log ...		82
Annex E (informative) Information on Technical Report ISO/TR 22676 [1]		88
Annex F (informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142		99
Bibliography		100