

DIN EN ISO 10328:2016-12 (E)

Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2016)

Contents

Page

European foreword 3	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC 4	4
21	21 9.5.1 General	32
9.5.2	Restriction	32
9.6	Testing at particular test loading levels not specified in this International Standard	33
10	Test samples	35
10.1	Selection of test samples	35
10.1.1	General	35
10.1.2	Selection of ankle-foot devices and foot units of appropriate size of foot	36
10.2	Types of test samples	37
10.2.1	Complete structure	37
10.2.2	Partial structure	39
10.2.3	Any other structure	39
10.3	Preparation of test samples	39
10.4	Identification of test samples	40
10.5	Alignment of test samples	41
10.5.1	Test samples for principal tests and separate tests on knee locks	41
10.5.2	Test samples for separate tests on ankle-foot devices and foot units	41
10.5.3	Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts	41
10.5.4	Test samples for separate tests on knee locks	42
10.6	Worst-case alignment position of test samples	42
11	Responsibility for test preparation	43
12	Test submission document	44
12.1	General requirements	44
12.2	Information required for test samples	45
12.2.1	All test samples	45
12.2.2	Test samples for tests on ankle-foot devices and foot units	45
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts	45
12.3	Information required for tests	45
12.3.1	General	45
12.3.2	For all tests	45
12.3.3	For static tests in torsion and on ankle-foot devices and foot units	46
12.3.4	For static ultimate strength tests	46
12.3.5	For cyclic tests	46
12.3.6	For tests in torsion	46
12.3.7	For tests on ankle-foot devices and foot units	46
13	Equipment	47
13.1	General	47
13.2	Equipment for the principal tests specified in 16.2 and 16.3	47
13.2.1	End attachments	47
13.2.2	Jig (optional)	49

13.2.3	Test equipment	50
13.3	Equipment for the separate static test in torsion specified in 17.1	52
13.3.1	Test equipment	52
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2 ...	52
13.4.1	Test equipment	52
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3	56
13.5.1	Extension pieces	56
13.5.2	Test equipment to perform static compression loading - (Compression testing machine or other equipment)	56
13.6	Equipment for the separate tests on knee locks specified in 17.4	56
13.6.1	End attachments	56
9.5	Multiple use of test samples	32
9.4	Number of tests and test samples required to claim compliance with this International Standard	32
14.1	General	57
14.2	Accuracy of equipment	57
14.3	Accuracy of procedure	57
15	Test principles	58
15.1	General	58
15.2	Static test procedure	58
15.3	Cyclic test procedure	58
16	Test procedures - Principal structural tests	58
16.1	Test loading requirements	58
16.1.1	Preparation for test loading	58
16.1.2	Application of test loading	58
16.2	Principal static test procedure	60
16.2.1	Principal static proof test	60
16.2.2	Principal static ultimate strength test	65
16.3	Principal cyclic test procedure	69
16.3.1	General requirements	69
16.3.2	Test method	69
16.3.3	Performance requirements	73
16.3.4	Compliance conditions	74
17	Test procedures -- Separate structural tests	78
17.1	Separate static test in torsion	78
17.1.1	General	78
17.1.2	Purpose of test	78
17.1.3	Test method	78
17.1.4	Performance requirements	80
17.1.5	Compliance conditions	80
17.2	Separate tests on ankle-foot devices and foot units	82
17.2.1	General	82
17.2.2	Purpose of tests	82
17.2.3	Separate static proof test for ankle-foot devices and foot units	82
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units	86
17.2.5	Separate cyclic test for ankle-foot devices and foot units	91
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts	96
17.3.1	General	96
17.3.2	Purpose of test	96
17.3.3	Applicability of the test to specific test samples	96
17.3.4	Test method	97
17.3.5	Performance requirement	98
17.3.6	Compliance conditions	98
17.4	Separate tests on knee locks	99
17.4.1	General	99

17.4.2	Purpose of tests	100
17.4.3	Separate static proof test for knee locks	100
17.4.4	Separate static ultimate strength test for knee locks	104
17.4.5	Separate cyclic test for knee locks	106
18	Test laboratory/facility log	115
18.1	General requirements	115
18.2	Specific requirements	115
19	Test report	115
19.1	General requirements	115
19.2	Specific requirements	116
19.3	Options	116
14	Accuracy	57
13.6.2	Jig (optional)	56
13.6.3	Test equipment	56
20.2	Examples of classification and designation	116
21	Labelling	117
21.1	General	117
21.2	Use of mark "*" and warning symbol	118
21.3	Examples of label layout	118
21.4	Label placement	118
Annex A (informative) Description of internal loads and their effects		120
Annex B (informative) Referenced data for the specification of test loading conditions and test loading levels of principal cyclic tests		124
Annex C (informative) Guidance on the application of an alternative static ultimate strength test ...		128
Annex D (normative) Guidance on the application of an additional test loading levels P6, P7 and P8		129
Annex E (informative) Summary of the records to be entered in the test laboratory/facility log		132
Annex F (informative) Background information on the loading profiles generated by test equipment according to 13.4.1.2 for separate cyclic tests for ankle-foot devices and foot units according to 17.2.5.1		147
Annex G (informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142		149
Bibliography		150
20	Classification and designation	116
20.1	General	116