DIN EN ISO 22675:2007-04 (E)

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2006)

Contents

Page

Foreword 6

Introduction 7

1 Scope 8

2 Normative references 9

3 Terms and definitions 9

4 Designations and symbols of test forces 9

5 Strength and related performance requirements and conditions of use 10

6 Coordinate system and test configurations 11
6.1 General 11
6.2 Origin and axes of the coordinate system 11
6.3 Reference points 12
6.4 Test force F 13
6.5 Line of application of test force F 13
6.6 Lines of action of resultant reference forces FR1 and FR2 13
6.7 Longitudinal axis of the foot and effective ankle joint centre 13
6.7.1 General 13
6.7.2 Longitudinal axis of the foot 13
6.7.3 Effective ankle-joint centre, CA 14

7 Test loading conditions and test loading levels 15
7.1 Test loading conditions 15
7.2 Test loading levels 15

8 Values of test forces, dimensions and cycles 16

9 Compliance 23
9.1 General 23
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 24
9.2.1 Arrangements for testing 24
9.2.2 Requirements for claiming compliance 24
9.3 Number of tests and test samples required to claim compliance with this International Standard 24
9.4 Multiple use of test samples 25
9.4.1 General 25
9.4.2 Restriction 25
9.5 Testing at particular test loading levels not specified in this International Standard 25

10 Test samples 26
10.1 Selection of test samples 26
10.1.1 General 26
10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot 26
10.2 Types of test sample 27
10.2.1 Complete structure 27

10.2.2 Partial structure 27
10.3 Preparation of test samples 27
10.4 Identification of test samples 28
10.5 Alignment of test samples 28
10.6 Worst-case alignment position of test samples 28

11 Responsibility for test preparation 30

12 Test submission document 31
12.1 General requirements 31
12.2 Information required for test samples 31
12.3 Information required for tests 32
12.3.1 General 32
12.3.2 For all tests 32
12.3.3 For the static proof test and the static ultimate strength test 32
12.3.4 For the static ultimate strength test 32
12.3.5 For the cyclic test 32

13 Equipment 33
13.1 General 33
13.2 End attachments 33
13.2.1 General 33
13.2.2 Proof test of end attachments 33
13.3 Jig (optional) 35
13.4 Test equipment 35
13.4.1 Test equipment to perform static heel and forefoot loading 35
13.4.2 Test equipment to perform cyclic loading 37

14 Accuracy 44
14.1 General 44
14.2 Accuracy of equipment 44
14.3 Accuracy of procedure 45

15 Test principles 45
15.1 General 45
15.2 Static test procedure 46
15.3 Cyclic test procedure 46

16 Test procedures 46
16.1 Test loading requirements 46
16.1.1 Preparation for test loading 46
16.1.2 Test loading conditions 50
16.2 Static proof test 50
16.2.1 Test method 50
16.2.2 Performance requirement 52
16.2.3 Compliance conditions 52
16.3 Static ultimate strength test 54
16.3.1 Test method 54
16.3.2 Performance requirements 57
16.3.3 Compliance conditions 57
16.4 Cyclic test 59
16.4.1 Test method 59
16.4.2 Performance requirements 61
16.4.3 Compliance conditions 62

17 Test laboratory/facility log 65
17.1 General requirements 65
17.2 Specific requirements 65

18 Test report 65
18.1 General requirements 65
18.2 Specific requirements 66

18.3 Options 66

19 Classification and designation 66
19.1 General 66
19.2 Examples of classification and designation 66

20 Labelling 67
20.1 General 67
20.2 Use of mark "*)" and warning symbol 68
20.3 Examples of label layout 68
20.4 Label placement 69

Annex A (informative) Reference data for the specification of the test loading conditions and test loading levels of this International Standard 70

Annex B (informative) Guidance on the application of an alternative static ultimate strength test 78

Annex C (informative) Guidance on the application of an additional test loading level P6 79

Annex D (informative) Summary of the records to be entered in the test laboratory/facility log 81

Annex E (informative) Information on Technical Report ISO/TR 22676 [1] 87

Annex F (informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142 98

Bibliography 99

Annex ZA (informative) Clauses of this European Standard addressing essential requirements
Figure 1 -- Coordinate system with reference parameters 12

Figure 2 -- Determination of longitudinal axis of foot (see 6.7.2) and effective ankle-joint centre CA (see 6.7.3) 14

Figure 3 -- Illustration of reference points for the establishment of thresholds listed in Table 10 for specification of the loading profile of the cyclic test 21

Figure 4 -- Illustration of specific set-up of left-sided test sample with top load application point PT 30

Figure 5 -- Diagrammatic view of test equipment according to 13.4.1 and 13.4.2 with test sample 42

Figure 6 -- Profiles of test force Fc(t) and tilting angle (t) as synchronized functions of time, determining the loading condition of the cyclic test of this International Standard 43

Figure 7 -- Test force Fc() of test loading level P5 as function of tilting angle (t) of foot platform 44

Figure 8 -- Preparation for test loading of static test procedure [see 16.1.1 a)] 49

Figure 9 -- Flowchart for the static proof test specified in 16.2.1 53

Figure 10 -- Flowchart for the static ultimate strength test specified in 16.3.1 58

Figure 11 -- Flowchart for the cyclic test specified in 16.4.1 Continued on Figure 12 63

Figure 12 -- Flowchart for the cyclic test specified in 16.4.1 Continued from Figure 11 64

Figure 13 -- General concept for the label layout 67

Figure 14 -- Models for the label layout 68

Figure A.1 -- Illustration of different components of loading 76

Figure A.2 -- Illustration of the dependence of the position of the top load application point PT on the foot length L -- (see A.2.2.3) 77

Figure E.1 -- Effect of f-position of tilting axis TA of foot platform on the elevation E of the foot at the instants of heel contact and toe-off 90

Figure E.2 -- Effect of u-position of tilting axis TA of foot platform on the A/P displacement f of the foot at the instant of toe-off 91

Figure E.3 -- Illustration of the effect of A-P displacement f on the angular movement of the test sample about the top load application point PT 92

Figure E.4 -- Illustration of possibilities of transposing the top load application point PT for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L 95

Figure E.5 -- Illustration of the effect of a fixed compromise offset uTA, C of the tilting axis TA of the foot platform on the A-P displacement f at the foot [see E.3.4.2 c) 2)] 96

Table 1 -- Designations and symbols of test forces 9

Table 2 -- Categories of strength addressed in this International Standard, together with the related performance requirements and test methods for their verification 10

Table 3 -- Test forces and relevant references 16

Table 4 -- Values of bottom offsets fB1, L (heel) and fB2, L (forefoot) for given values of foot length L, relevant to the design and/or adjustment of the rigid foot dummy required to simulate or other provisions of EU Directives 100

the effective lever arms of an ankle-foot device or foot unit in the proof test of end attachments (see 13.2.2) 17

Table 5 -- Test forces of the proof test of end attachments for test loading levels P5, P4 and P3 (see 13.2.1) 17

Table 6 -- Total length of test samples and segmental lengths of end attachments 18

Table 7 -- Coordinates of top load application point PT and tilting axis TA of foot platform based on given values of foot length L, for all test loading levels 19

Table 8 -- Angles of toe-out position of foot and specific tilting positions of foot platform, for all test loading levels 19

Table 9 -- Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading levels P5, P4 and P3 (see 16.2, 16.3 and 16.4) 20

Table 10 -- Thresholds according to Figure 3 for specification of the application of the loading profile of the cyclic test 22

Table 11 -- Data specifying the values of tilting angle (t) and test force Fc(t) illustrated in Figure 6 in 30 ms time increments for guidance on their application 23

Table 12 -- Number of tests and test samples required to claim compliance with this International Standard 26

Table 13 -- Option for end attachments of specific design 33

Table A.1 -- Magnitudes of resultant reference forces FR1x and FR2x 73

Table C.1 -- Test forces of the proof test of end attachments for test loading level P6 (see 13.2.2.1) 79

Table C.2 -- Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading level P6 (see 16.2, 16.3 and 16.4) 80

Table E.1 -- Contents of ISO/TR 22676 and list of corresponding clauses/subclauses of this International Standard, in which selected items are dealt with 88

Table E.2 -- Possibilities of transposing the top load application point PT for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L 97

Table F.1 -- Correspondence between this International Standard and the essential principles of ISO/TR 16142 98