ISO 22675:2024-12 (E)

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods

Contents

Page

Foreword ..... **vi**

Introduction ..... **vii**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **2**

4 Symbols **3**

5 Strength and related performance requirements and conditions of use **3**

6 Coordinate system and test configurations **4**
6.1 General 4
6.2 Origin and axes of the coordinate system 4
6.3 Reference points 5
6.4 Test force F 6
6.5 Line of application of test force F 6
6.6 Lines of action of resultant reference forces F_{R1} and F_{R2} 6
6.7 Longitudinal axis of the foot and effective ankle joint centre 6
6.7.1 General 6
6.7.2 Longitudinal axis of the foot 6
6.7.3 Effective ankle-joint centre C_A 6

7 Test loading conditions and test loading levels **8**
7.1 Test loading conditions 8
7.2 Test loading levels and Test Ranges (R) 8

8 Values of test forces, dimensions and cycles **9**

9 Compliance **17**
9.1 General 17
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 18
9.2.1 Arrangements for testing 18
9.2.2 Requirements for claiming compliance 18
9.3 Number of tests and test samples required to claim compliance with this document 18
9.4 Multiple use of test samples 18
9.4.1 General 18
9.4.2 Restriction 19
9.5 Testing at particular test loading levels not specified in this document 19

10 Test samples **20**
10.1 Selection of test samples 20
10.1.1 General 20
10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot 20
10.2 Types of test sample 21
10.2.1 Complete structure 21
10.2.2 Partial structure 21
10.3 Preparation of test samples 21
10.4 Identification of test samples 21
10.5 Alignment of test samples 22
10.6 Worst-case alignment position of test samples 22

11 Responsibility for test preparation **24**

12 Test submission document **25**
12.1 General requirements 25
12.2 Information required for test samples 25
12.3 Information required for tests 26
12.3.1 General 26
12.3.2 For all tests 26
12.3.3 For the static proof test and the static ultimate strength test 26
12.3.4 For the static ultimate strength test 26
12.3.5 For the cyclic test 26

13 Equipment **27**
13.1 General 27
13.2 End attachments 27
13.2.1 General 27
13.2.2 Proof test of end attachments 27
13.3 Jig 29
13.4 Test equipment 30
13.4.1 Test equipment to perform static heel and forefoot loading 30
13.4.2 Test equipment to perform cyclic loading 31

14 Accuracy **37**
14.1 General 37
14.2 Accuracy of equipment 38
14.3 Accuracy of procedure 38

15 Test principles **38**
15.1 General 38
15.2 Static test procedure 39
15.3 Cyclic test procedure 42

16 Test procedures **42**
16.1 Test loading requirements 42
16.1.1 Preparation for test loading 42
16.1.2 Test loading conditions 45
16.2 Static proof test 46
16.2.1 Test method 46
16.2.2 Performance requirement 48
16.2.3 Compliance conditions 48
16.3 Static ultimate strength test 50
16.3.1 Test method 50
16.3.2 Performance requirements 52
16.3.3 Compliance conditions 52
16.4 Cyclic test 53
16.4.1 Test method 53
16.4.2 Performance requirements 56
16.4.3 Compliance conditions 56
16.5 Separate static test in torsion 59
16.5.1 General 59
16.5.2 Purpose of test 59
16.5.3 Test method 59
16.5.4 Performance requirements 60
16.5.5 Compliance conditions 60

17 Test laboratory/facility log **61**
17.1 General requirements 61
17.2 Specific requirements 61

18 Test report **61**
18.1 General requirements 61
18.2 Specific requirements 62
18.3 Options 62

19 Classification and designation **62**
19.1 General 62
19.2 Example of classification and designation 62
20 Identifier **63**
20.1 General 63
20.2 Identifier layout 63
20.3 Identifier placement 63
Annex A (informative) **Reference data for the specification of the test loading conditions and test loading levels of this document** **64**
Annex B (informative) **Guidance on the application of an alternative static ultimate strength test** **73**
Annex C (informative) **Summary of the records entered in the test laboratory/facility log** **74**
Annex D (informative) **Information on ISO/TR 22676** **79**
Annex E (informative) **Background data (reduced) of the six-minute walk test for adults** **90**
Bibliography **91**