INTERNATIONAL STANDARD

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Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai

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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10328 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

This first edition cancels and replaces the eight parts of the first edition (ISO 10328-1:1996 to ISO 10328-8:1996), which have been technically revised and combined into one single document.

Introduction

Throughout this International Standard, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent or deficient limb segment.

As a result of concern in the international community about the need to provide prostheses that are safe in use, and also because of an awareness that test standards would assist the development of better prostheses, a series of meetings was held under the aegis of the International Society for Prosthetics and Orthotics (ISPO). The final one was held in Philadelphia, PA, USA in 1977 at which a preliminary consensus was reached on methods of testing and the required load values. From 1979 onwards this work was continued by ISO Technical Committee 168 leading to the development of ISO 10328:1996. The test procedures may not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subjected to a series of load actions, each varying individually with time. The test methods specified in this International Standard use static and cyclic strength tests which typically produce compound loadings by the application of a single test force.

The static tests relate to the worst loads generated in any activity. The cyclic tests relate to normal walking activities where loads occur regularly with each step. This International Standard specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of lower-limb prostheses and their components requires controlled field trials in addition to the laboratory tests specified in this International Standard.

The laboratory tests and field trials should be repeated when significant design changes are made to a load-bearing part of a prosthesis.

Ideally, additional laboratory tests should be carried out to deal with function, wear and tear, new material developments, environmental influences and user activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be determined.

In order to allow continuity of testing by checking the test methods for ankle-foot devices and foot units specified in Clause 16 of ISO 22675:2006 against those specified in this International Standard, a transition period will be established, during which both test methods are valid. For practical reasons, this transition period will be adapted to the period of time after which the systematic review of this International Standard and ISO 22675:2006 is indicated. The systematic review of both standards is expected to result, among other outcomes, in the finding on whether the test methods specified in ISO 22675:2006 have demonstrated their suitability.

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of lower limb prosthetic devices/structures with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE 1). Prosthetic ankle-foot devices and foot units on the market, which have demonstrated their compliance with the strength requirements specified in 4.4 of EN 12523:1999 through submission to the relevant tests of ISO 10328:1996, need not be retested to ISO 22675:2006.

WARNING — This International Standard is *not suitable* to serve as a guide for the selection of a specific lower limb prosthetic device/structure in the prescription of an individual lower limb prosthesis! Any disregard of this warning can result in a safety risk for amputees.

This International Standard specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 2) which typically produce compound loadings by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.

The tests described in this International Standard comprise

— principal static and cyclic tests for all components;

— a separate static test in torsion for all components;

— separate static and cyclic tests on ankle-foot devices and foot units for all ankle-foot devices as single components including ankle units or ankle attachments and all foot units as single components;

— a separate static ultimate strength test in maximum knee flexion on knee joints and associated parts for all knee units or knee-shin-assemblies and adjacent components that normally provide the flexion stop on a complete prosthesis;

— separate static and cyclic tests on knee locks for all mechanisms which lock the knee joint in the extended position of the knee unit or knee-shin-assembly.

The tests described in this International Standard apply to specific types of ankle-disarticulation prostheses (see NOTE 3), to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses and to the distal (lower) part of hip-disarticulation and hemi-pelvectomy prostheses (see NOTE 4).

NOTE 1 ISO 22523 (formerly EN 12523) addresses those of the Essential Requirements listed in Annex 1 of the European Medical Device Directive 93/42/EEC that are applicable to external limb prostheses and external orthoses.

NOTE 2 The tests can be performed on complete structures, on part structures or on individual components.

NOTE 3 The tests only apply to ankle-disarticulation prostheses which include (foot) components of prosthetic ankle-foot devices taken from the normal production line.

NOTE 4 The distal part comprises the knee unit, the ankle-foot device and all parts between. Tests on hip units are described in ISO 15032.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

ISO 22523:2006, *External limb prostheses and external orthoses — Requirements and test methods*

ISO 22675:2006, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 8549-1 and the following definitions apply.

3.1
proof strength
static load representing an occasional severe event, which can be sustained by the prosthetic device/structure and still allow it to function as intended

3.2
ultimate strength
static load representing a gross single event, which can be sustained by the prosthetic device/structure but which could render it thereafter unusable

3.3
fatigue strength
cyclic load which can be sustained by the prosthetic device/structure for a given number of cycles

3.4
batch
set of test samples of a prosthetic device/structure submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this International Standard

4 Designations and symbols of test forces and moments

The designations and symbols of all relevant test forces and moments are listed in Table 1.

Table 1 — Designations and symbols of test forces and moments

Designation	Symbol
Test forces; twisting moments	F, F_1, F_2; M_u
Proof test force of end attachments	F_{pa}
Stabilizing test force	F_{stab}
Settling test force	F_{set}
Static proof test force	F_{sp}
Static proof test force on heel/forefoot	F_{1sp}, F_{2sp}
Static ultimate test force	F_{su}
Static ultimate test force on heel/forefoot	F_{1su}, F_{2su}
Minimum test force	F_{cmin}
Maximum test force	F_{cmax}
Range of pulsating test force	F_{cr}
Mean test force	F_{cmean}
Amplitude of pulsating test force	F_{ca}
Pulsating test force	$F_c(t)$
Final static test force	F_{fin}
Minimum test force on heel/forefoot	F_{1cmin}, F_{2cmin}
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}
Mean test force on heel/forefoot	F_{1cmean}, F_{2cmean}
Amplitude of pulsating test force on heel/forefoot	F_{1ca}, F_{2ca}
Pulsating test force on heel/forefoot	$F_{1c}(t)$, $F_{2c}(t)$
Final static test force on heel/forefoot	F_{1fin}, F_{2fin}
Stabilizing twisting moment	$M_{u\text{-}stab}$
Settling twisting moment	$M_{u\text{-}set}$
Maximum twisting moment	$M_{u\text{-}max}$
NOTE Further details of the test forces and moments listed are given in Table 3.	

5 Strength and related performance requirements and conditions of use

5.1 According to 4.4.1 of ISO 22523:2006, a lower limb prosthetic device/structure "*… shall have the strength to sustain the loads occurring during use by amputees […] in the manner intended by the manufacturer for that device according to his written instructions on its intended use*".

For the assessment of the conformity of lower limb prosthetic devices/structures with the above requirement (see also Scope), this International Standard provides a means of determining the three categories of strength defined in 3.1 to 3.3 and, in addition, the static strength in torsion and the security against slipping of clamped components.

All of these are listed in Table 2, together with the related performance requirements and the test methods for their verification.

5.2 In order to satisfy the general requirement in 5.1 for a specific lower limb prosthetic device/structure, the following safety concept shall apply.

The device/structure shall

a) comply with the requirements of this International Standard (see 9.1, 9.2 and 9.3) for a specific test loading level (see 7.2)

and

b) be used in accordance with the body mass limit specified by the manufacturer in consideration of the intended use of that device (see NOTE).

The conditions in a) and b) are regarded in both the classification and designation of prosthetic devices/structures according to Clause 20 and their labelling according to Clause 21.

NOTE The statement of the body mass limit not to be exceeded by amputees is part of the conditions of use to be specified, with justification, by the manufacturer in his written instructions on the intended use of a specific lower limb prosthetic device/structure, taking account of all other factors affecting the loads expected to be exerted on that lower limb prosthetic device/structure by amputees (see Clause B.1).

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

Category of strength	Related performance requirement [a]	Test method for verification
Proof strength (see 3.1)	Structure shall sustain static loading by proof test forces at prescribed values for prescribed times	Principal static proof test (16.2.1), separately applied in two test configurations, separate static proof test for ankle-foot devices and foot units (17.2.3), successively applied in heel and forefoot loading, separate static proof test for knee locks (17.4.3), applied in a single test configuration.
	Permanent deformation of structure shall not exceed prescribed values in any loading condition	Principal static proof test (16.2.1), separate static proof test for knee locks (17.4.3)
Ultimate strength (see 3.2)	Structure shall sustain static loading by ultimate test forces at prescribed values	Principal static ultimate strength test (16.2.2), separately applied in two test configurations, separate static ultimate strength test for ankle-foot devices and foot units (17.2.4), separately applied in heel and forefoot loading, separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (17.3), separate static ultimate strength test for knee locks (17.4.4), applied in a single test configuration
Fatigue strength (see 3.3)	Structure shall sustain successively 1) static loading by maximum test forces at prescribed values for prescribed times; 2) cyclic loading by pulsating test forces at prescribed values for prescribed numbers of cycles; 3) final static loading by final test forces at prescribed values for prescribed times	Principal cyclic test (16.3), separately applied in two test configurations, separate cyclic test for ankle-foot devices and foot units (17.2.5), separately applied in heel and forefoot loading, separate cyclic test for knee locks (17.4.5), applied in a single test configuration
Static strength in torsion	Structure shall sustain static loading by static test force at prescribed value for prescribed time	Separate static test in torsion (17.1), applied in two opposite directions of twisting
Security against slippage of clamped components	Relative angular movement between ends of structure shall not exceed prescribed value	

[a] The performance requirements related to a specific category of strength are specified in full length in an individual subclause following the subclause in which the test method for their verification is specified.

6 Coordinate systems and test configurations

6.1 General

6.1.1 For ease in interpretation and presentation, two test configurations are specified, one for right-sided and a mirror image for left-sided application. This measure makes it possible to apply uniform sign conventions for corresponding components of loading generated in the load-bearing structures of right and left prostheses or in asymmetrically designed prosthetic components.

6.1.2 Each test configuration shall be defined in a three-dimensional, rectangular coordinate system (see Figure 1), having an origin 0 and containing a geometric system of planes, lines and points (see Figures 2 and 3).

6.1.3 Each test configuration specifies reference parameters both for the position of the line of application of the test force and for the alignment of test samples within the coordinate system.

6.2 Axes of coordinate systems

6.2.1 The axes of each of the coordinate systems are specified in 6.2.2 to 6.2.4 in relation to a prosthesis which is standing on the ground in an upright position.

If a test sample is not in the upright position, the axes of the coordinate system shall be rotated to correspond.

6.2.2 The u-axis extends from the origin 0 of the coordinate systems (see Figure 1) and passes through the effective ankle-joint centre and the effective knee-joint centre (see 6.7.3 and 6.7.6 as well as Figure 6). Its positive direction is upwards (in the proximal direction).

6.2.3 The o-axis extends from the origin 0 perpendicular to the u-axis (see Figure 1) and parallel to the effective knee-joint centreline (see 6.7.5 and Figure 6). Its positive direction is outward (in the lateral direction), which is to the left for a left prosthesis and to the right for a right prosthesis.

6.2.4 The f-axis extends from the origin 0 perpendicular to both the o-axis and the u-axis (see Figure 1). Its positive direction is forward towards the toe (in the anterior direction).

6.3 Reference planes

6.3.1 General

The reference planes (see Figures 2 and 3) shall be parallel planes perpendicular to the u-axis. They are specified in 6.3.2 to 6.3.5.

NOTE The reference planes specified in 6.3.2 to 6.3.5 also contain reference lines which relate to Annex B.

6.3.2 Top reference plane, T

The top reference plane, T, is located at a distance $u = u_T$ from the origin. It contains the top load application point P_T (see 6.4).

6.3.3 Knee reference plane, K

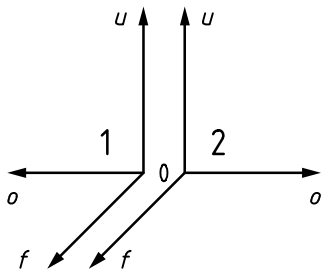
The knee reference plane, K, is located at a distance $u = u_K$ from the origin. It contains the knee load reference point P_K (see 6.4) and the effective knee-joint centre (see 6.7.6).

6.3.4 Ankle reference plane, A

The ankle reference plane, A, is located at a distance $u = u_A$ from the origin. It contains the ankle load reference point P_A (see 6.4) and the effective ankle-joint centre (see 6.7.3).

6.3.5 **Bottom reference plane**, B

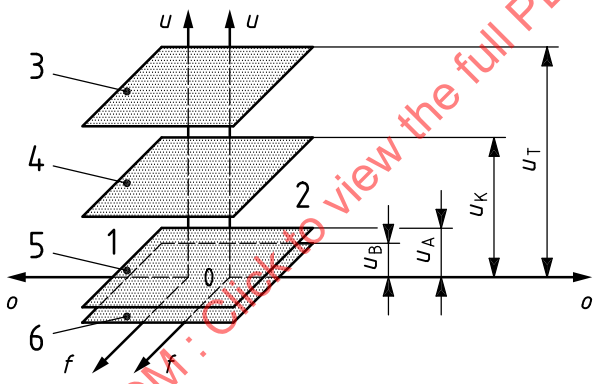
The bottom reference plane, B, is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see 6.4).



Key

1	right	*f*	forward
2	left	*o*	outward
0	origin	*u*	upward

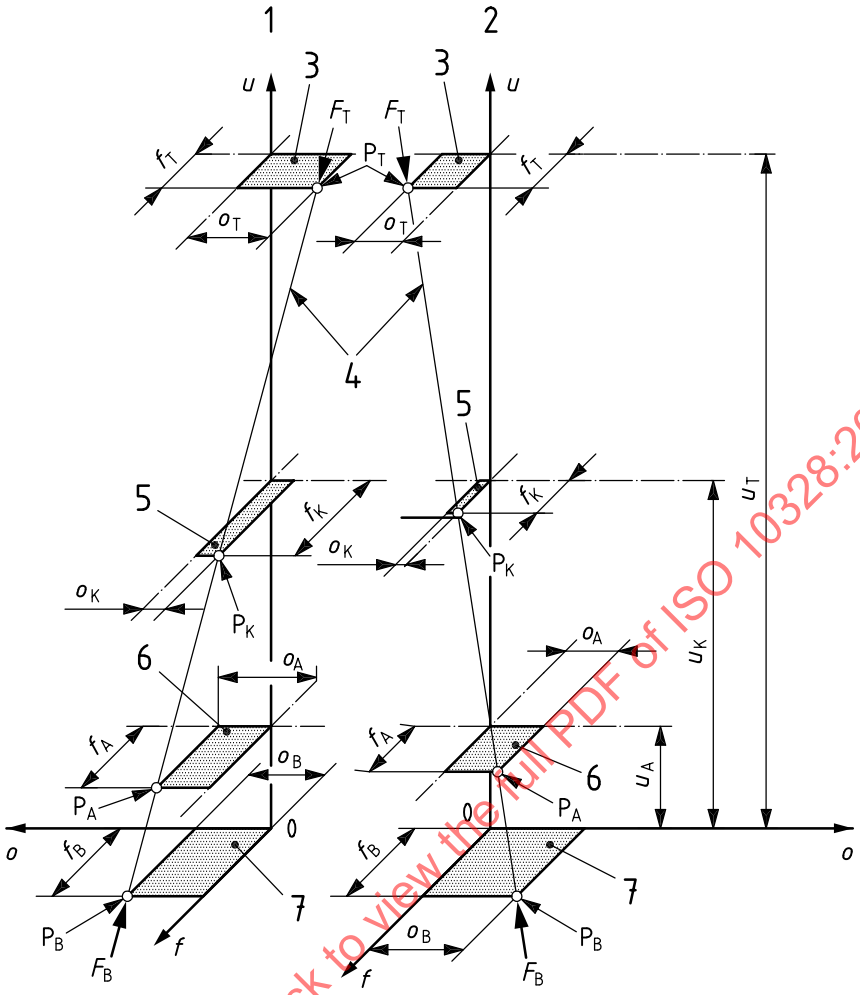
Figure 1 — Coordinate systems for right and left-sided application



Key

1	right	4	knee reference plane, K
2	left	5	ankle reference plane, A
3	top reference plane, T	6	bottom reference plane, B

Figure 2 — Coordinate systems according to Figure 1 with reference planes



Key

1	right leg	5	knee reference plane, K	P_T	top load application point
2	left leg	6	ankle reference plane, A	P_K	knee load reference point
3	top reference plane, T	7	bottom reference plane, B	P_A	ankle load reference point
4	load line			P_B	bottom load application point

NOTE This figure illustrates a typical test loading condition representative of the condition of forefoot loading during the stance phase of normal walking. It does not illustrate the test loading conditions defined in 7.1.2.

Figure 3 — Specific configuration with u_B = 0, showing coordinate systems with reference planes (see Figures 1 and 2), **reference lines, reference points and test force, F, for right and left-sided application**

6.4 Reference points

The reference points are the points of intersection of the load line (see 6.6) with the reference planes (see Figure 3). The coordinates of the reference points are as follows:

— top load application point, P_T (f_T, o_T, u_T)

— knee load reference point, P_K (f_K, o_K, u_K)

— ankle load reference point, P_A (f_A, o_A, u_A)

— bottom load application point, P_B (f_B, o_B, u_B)

IMPORTANT — In the subsequent clauses of this International Standard, the f- and o-coordinates are also referred to as OFFSETS (see also 6.8.1).

6.5 Test force

The test force, F, is a single compressive load applied to the bottom and top load application points P_B and P_T specified in 6.4.

6.6 Load line

The load line is the line of application of the test force, F. It passes through the reference points specified in 6.4.

6.7 Longitudinal axis of the foot and effective joint centres and centrelines

6.7.1 General

In order to align the test sample within the appropriate coordinate system (see 6.1 to 6.3) it is necessary to locate

a) the longitudinal axis of the foot (see 6.7.2);

b) the effective ankle-joint centre (see 6.7.3);

c) the effective ankle-joint centreline (see 6.7.4);

d) the effective knee-joint centreline (see 6.7.5);

e) the effective knee-joint centre (see 6.7.6).

If the location of the longitudinal axis of the foot or any effective joint centre or effective joint centreline is not straightforward, the manufacturer/submitter shall provide a diagram or instructions, with justification, identifying its location in relation to the test sample.

6.7.2 Longitudinal axis of the foot

Unless otherwise specified by the manufacturer/submitter, the longitudinal axis of the foot shall be taken to pass through the centre of the widest part of the forefoot and equidistant between the medial and lateral borders of the foot at a quarter of the length of the foot from the most posterior part of the foot with the foot placed as specified in 6.7.3.3 and illustrated in Figure 4.

6.7.3 Effective ankle-joint centre

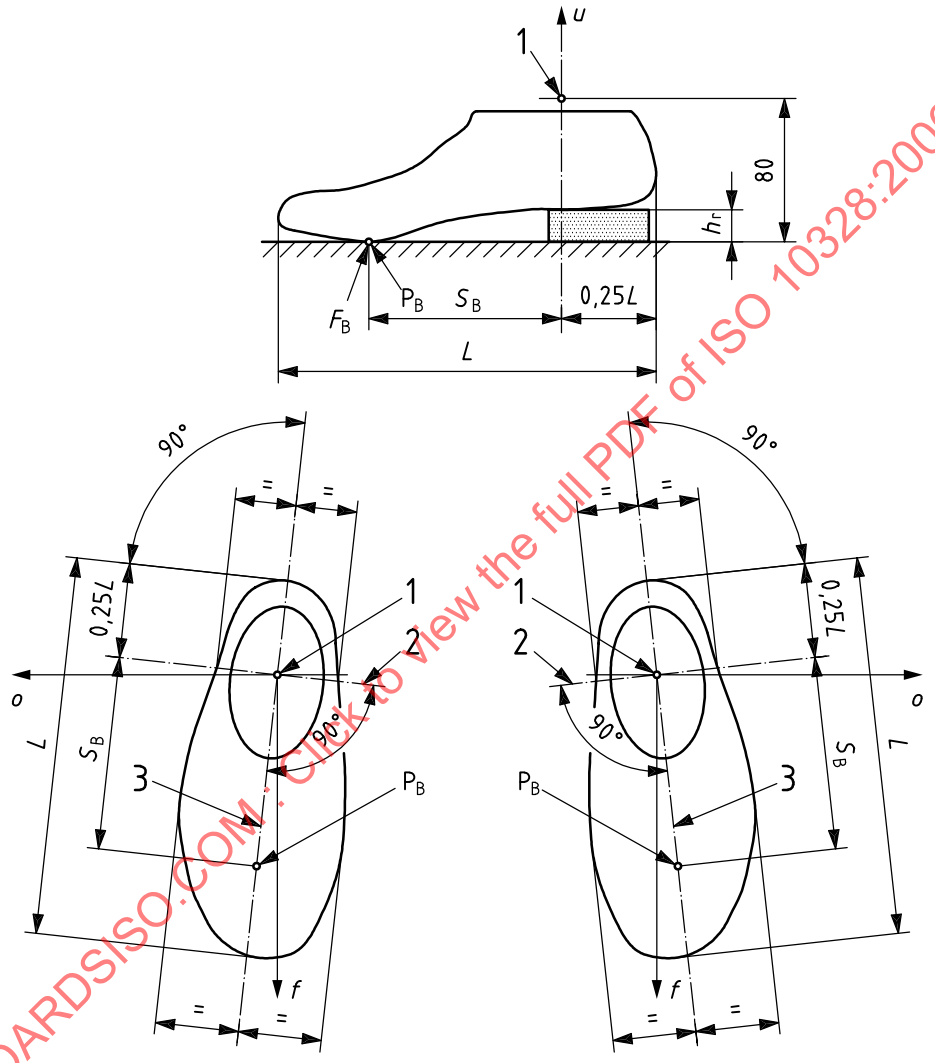
6.7.3.1 Locate the effective ankle-joint centre as described in 6.7.3.2 to 6.7.3.4.

NOTE The position of a mechanical axle for plantar- and dorsiflexion (if present) is irrelevant to the alignment of the test sample within the appropriate coordinate system.

6.7.3.2 Locate the longitudinal axis of the foot as described in 6.7.2 or in accordance with any specific instruction from the manufacturer/submitter.

6.7.3.3 Place the foot on a horizontal surface with a block of the manufacturer's/submitter's recommended heel height h_r placed under the heel of the foot (see Figure 4).

Dimensions in millimetres



Key

1 effective ankle-joint centre
2 effective ankle-joint centreline
3 longitudinal axis of foot corresponding to 6.7.2
h_r heel height
L foot length
P_B bottom load application point on forefoot (test loading condition II)
S_B combined bottom offset of bottom load application point P_B on forefoot from u-axis

NOTE The recommended heel height for the ankle-foot device or foot unit under test is taken as h_r = 20 mm unless otherwise specified by the manufacturer/submitter.

Figure 4 — Determination of longitudinal axis of foot (see 6.7.2), effective ankle-joint centre (see 6.7.3) and effective ankle-joint centreline (see 6.7.4) for test loading conditions I and II and of combined bottom offset S_B (see 6.8.2) for test loading condition II [see 7.1.2 b)]

6.7.3.4 The effective ankle-joint centre lies

a) in a vertical plane passing through the longitudinal axis of the foot;

b) in the ankle reference plane located 80 mm above the bottom reference plane, i.e. 80 mm above the horizontal line passing through P_B;

c) a quarter of the length of the foot from the most posterior part of the foot.

6.7.4 Effective ankle-joint centreline

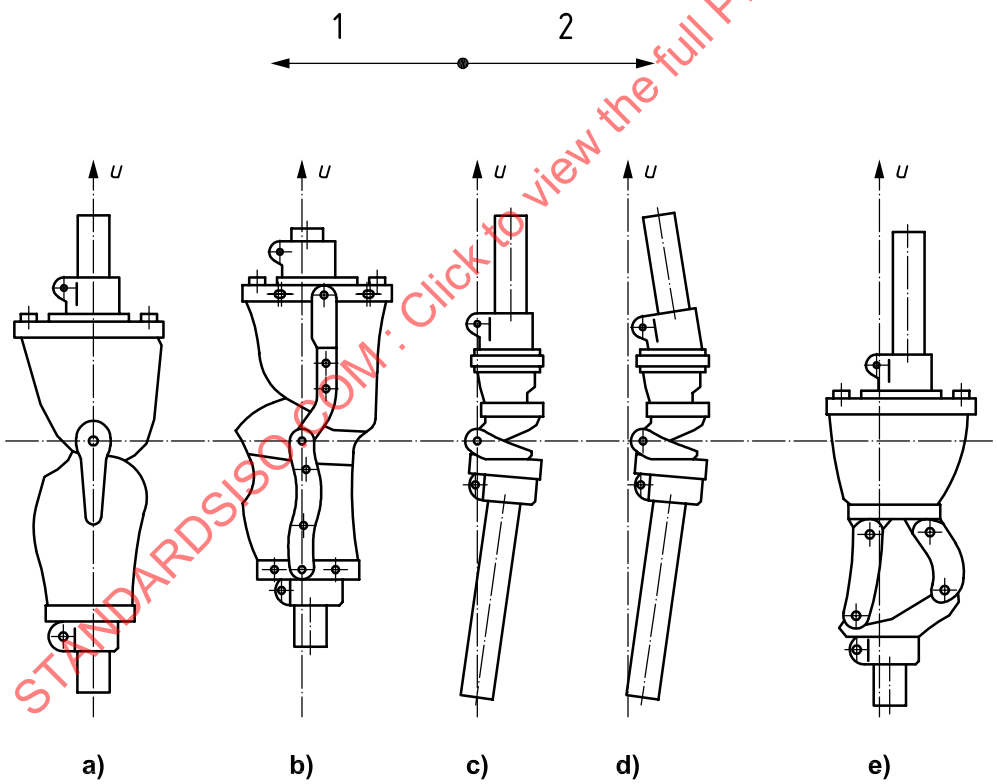
The effective ankle-joint centreline shall be the horizontal line passing through the effective ankle-joint centre (see 6.7.3) perpendicular to the longitudinal axis of the foot (see 6.7.2).

6.7.5 Effective knee-joint centreline

6.7.5.1 For a monocentric knee unit which has no knee lock or stance phase control mechanism, the effective knee-joint centreline shall coincide with the joint flexion axis [see Figure 5 a), b) and c)].

This shall also apply to a monocentric knee unit with a knee lock or a stance phase control mechanism which allows walking when these are disengaged.

6.7.5.2 For all knee units not covered by 6.7.5.1, the effective knee-joint centreline shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit [see Figure 5 d) and e)].



a), b), c) are examples with the effective knee-joint centreline as specified in 6.7.5.1.

d), e) are examples with the effective knee-joint centreline as specified in 6.7.5.2.

Key

1 orientation 1 = posterior (toward the rear)

2 orientation 2 = anterior (toward the front)

Figure 5 — Position of effective knee-joint centreline for prosthetic knee units of different types

6.7.6 Effective knee-joint centre

6.7.6.1 The effective knee-joint centre shall lie on the effective knee-joint centreline.

6.7.6.2 For symmetrical knee units, the effective knee-joint centre shall be the point on the effective knee-joint centreline equidistant from the external boundaries of the unit.

6.7.6.3 For asymmetrical or handed knee units, the position of the effective knee-joint centre shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit.

6.8 Reference distances

6.8.1 Offsets

The offsets shall be the perpendicular distances of the reference points specified in 6.4 from the o-u plane and the u-f plane of the coordinate systems specified in 6.1 and 6.2. Their values are identical with the corresponding f- and o-coordinates of these reference points.

6.8.2 Combined offsets

The combined offsets S_B, S_A, S_K and S_T shall be the perpendicular distances of the reference points P_B, P_A, P_K and P_T specified in 6.4 from the u-axis of the coordinate systems specified in 6.1 and 6.2.

NOTE S_B is also addressed in 10.1.2 and illustrated in Figures 4 and 6 for test loading condition II defined in 7.1.2 b).

6.8.3 Effective lever arms L_A and L_K

The effective lever arms are the perpendicular distances of the effective joint centres from the load line, where L_A represents the ankle effective lever arm length and L_K the knee effective lever arm length.

6.8.4 Distance L_{BT}

L_{BT} shall be the distance between the bottom load application point P_B and the top load application point P_T (see 6.4).

7 Test loading conditions and test loading levels

7.1 Test loading conditions

7.1.1 General

The complexity of the load actions to which a lower-limb prosthesis is actually subjected during use by the amputee cannot be simulated by a single test procedure. Therefore, several types of static and cyclic strength tests are specified in the two categories "Principal structural tests" (Clause 16) and "Separate structural tests" (Clause 17), each type of test applying a single or two different test loading condition(s) (see 7.1.2 and 7.1.3).

Each test loading condition is characterized by a specific test load acting along or about a specific line of load application and producing axial compression, shear forces, bending moments and/or torque as single components of loading or compound loadings.

The test loading condition(s) for each type of test are addressed in Table 16 and specified in the relevant Tables 3 to 14. Further details are given in the relevant test procedures, specified in Clauses 16 and 17.

NOTE For further information see also Annexes A and B.

7.1.2 Test loading conditions of principal structural tests

The loading of the static and cyclic principal structural tests specified in 16.2 and 16.3 shall be applied in two different test loading conditions I and II relating to the maxima occurring at different instants during the stance phase of normal walking as described in a) and b). For both test loading conditions the position of the line of load application (see 7.1.1) within the coordinate system (see 6.1 and 6.2) shall be three-dimensional (see Figures 3, 6 and 11). The specific values of offsets, combined offsets and test forces for each test loading condition and each principal structural test are specified in Tables 6, 7 and 8.

a) Test loading condition I is related to the instant of maximum loading occurring early in the stance phase of walking.

b) Test loading condition II is related to the instant of maximum loading occurring late in the stance phase of walking.

7.1.3 Test loading conditions of separate structural tests

7.1.3.1 Test loading condition of the separate static test in torsion

The loading of the separate static test in torsion specified in 17.1 shall be applied as torque about the u-axis (see 6.2.2) first in one direction and then in the other direction. The specific values of torque are specified in Table 9.

7.1.3.2 Test loading conditions of the separate tests on ankle-foot devices and foot units

The loading of the separate static and cyclic tests on ankle-foot devices and foot units specified in 17.2 shall be applied in two different test loading conditions simulating heel loading in the direction determined by the angle α and forefoot loading in the direction determined by the angle β. For both test loading conditions the position of the line of load application (see 7.1.1) within the coordinate system (see 6.1 and 6.2) shall be two-dimensional (see Figure 7). The specific values of angles and forces for each test loading condition and each test are specified in Tables 10 and 11.

7.1.3.3 Test loading condition of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts

The loading of the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts specified in 17.3 shall be applied in a single test loading condition simulating kneeling or squatting (deep knee bend). The position of the line of load application (see 7.1.1) within the coordinate system (see 6.1 and 6.2) shall be two-dimensional (see Figure 8). The specific values of length and test force are specified in Table 12.

7.1.3.4 Test loading condition of the separate tests on knee locks

The loading of the separate static and cyclic tests on knee locks specified in 17.4 shall be applied in a single test loading condition simulating a situation in which heel loading tends to flex the knee while it is locked in full extension. The position of the line of load application (see 7.1.1) within the coordinate system (see 6.1 and 6.2) shall be two-dimensional. The specific values of offsets and test forces are specified for each test in Tables 13 and 14.

7.2 Test loading levels

7.2.1 The load actions referred to in the first paragraph of 7.1.1 vary with individual physical parameters, locomotion characteristics of the amputee and other factors. For these reasons different categories of prostheses are needed and, consequently, different test loading levels are required, each being specified by individual values of dimensions and loads.

The series P test loading levels designated as given in 7.2.3 shall apply to lower limb prostheses for adults.

NOTE For further information see Annex B.

7.2.2 The specification of the test loading conditions of each of the test loading levels listed in 7.2.3 is governed by a safety concept, characterized in the following manner (see also Tables 3 and 8).

— The values of test force, F_{cr}, of the principal cyclic test according to 16.3.2 are set at a level which covers the full range of load actions disclosed by the locomotion data acquired from the group of amputees representative of the relevant test loading level (see Annex B); the values of the test forces, F_{1cr} and F_{2cr}, of the separate cyclic test for ankle-foot devices and foot units according to 17.2.5 and the test force, F_{cr}, of the separate cyclic test for knee locks according to 17.4.5 are set correspondingly.

— The corresponding values of the test forces, F_{sp} and F_{su}, of the principal static tests according to 16.2.1 and 16.2.2, the test forces, F_{1sp}/F_{2sp} and F_{1su}/F_{2su}, of the separate static tests for ankle-foot devices and foot units according to 17.2.3 and 17.2.4 and the test forces, F_{sp} and F_{su}, of the separate static tests for knee locks according to 17.4.3 and 17.4.4 are calculated by application of factors as specified in Table 3; the values of the twisting moment, M_{umax}, of the separate static test in torsion according to 17.1 and the test force, F_{su}, of the separate static ultimate strength test in maximum knee flexion according to 17.3 are set correspondingly.

— The specification of all test forces takes account of records on component failures of lower limb prostheses, taken in clinical or technical service.

7.2.3 Designation of test loading levels for adults is given below.

Test loading levels: P3, P4, P5, P6

NOTE 1 Field experience has shown that there is a need for lower limb prostheses which sustain loads above the level covered by test loading level P5. In order to allow the structural testing of such prostheses on a uniform basis, test loading level P6 has been developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units (see Annex D).

NOTE 2 The values of the dimensions and loads of test loading levels P3, P4 and P5 are specified in separate tables in Clause 8. As an interim measure, pending validation, it is suggested that the values of the dimensions and loads specified in D.3 and D.4 and Tables D.2 and D.3 are appropriate for test loading level P6. Further test loading levels will be defined, if necessary.

8 Values of test loads, dimensions and cycles

Forces and twisting moments; segmental lengths, offsets and angles; prescribed number of cycles are addressed.

Tables 3 to 13 describe and/or specify the values of

— test forces and twisting moments,

— dimensions such as segmental lengths, offsets and angles and

— cycles (prescribed number of loading cycles).

Table 3 — Test loads and relevant references

Test force [a] or moment		Reference		
		Clause	Table	Test descriptor [b]
Proof test force on end attachments	$F_{pa} = 1{,}2\ F_{su,\ upper\ level}$	13	4, D.1	A
Stabilizing test force	F_{stab}	13, 16, 17	4, 8, 14, D.2	A, 1, 2, 3, 9, 10, 11
Settling test force	$F_{set} = 0{,}8\ F_{cr}$	13, 16, 17	4, 8, 14, D.2	A, 1, 2, 3, 9, 10, 11
Static proof test force	$F_{sp} = 1{,}75\ F_{cr}$	16, 17	8, 14, D.2	1, 9
Static proof test force on heel	$F_{1sp} = 1{,}75\ F_{1cr}$	17	11, D.3	5
Static proof test force on forefoot	$F_{2sp} = 1{,}75\ F_{2cr}$	17	11, D.3	5
Static ultimate test force				
– lower level	$F_{su,\ lower\ level} = 1{,}5\ F_{sp}$	16	8, D.2	2
– upper level	$F_{su,\ upper\ level} = 2{,}0\ F_{sp}$	16	8, D.2	2
Static ultimate test force	F_{su}	17	12	8
Static ultimate test force	$F_{su} = 2{,}0\ F_{sp}$	17	14	10
Static ultimate test force on heel				
– lower level	$F_{1su,\ lower\ level} = 1{,}5\ F_{1sp}$	17	11, D.3	6
– upper level	$F_{1su,\ upper\ level} = 2{,}0\ F_{1sp}$	17	11, D.3	6
Static ultimate test force on forefoot				
– lower level	$F_{2su,\ lower\ level} = 1{,}5\ F_{2sp}$	17	11, D.3	6
– upper level	$F_{2su,\ upper\ level} = 2{,}0\ F_{2sp}$	17	11, D.3	6
Minimum test force	F_{cmin}	13, 16, 17	8, 14, D.2	3, 11
Maximum test force	F_{cmax}	13, 16, 17	8, 14, D.2	3, 11
Range of pulsating test force	F_{cr}	13, 16, 17	8, 14, D.2	3, 11
Mean test force	$F_{cmean} = 0{,}5\ (F_{cmin} + F_{cmax})$	13	8, 14, D.2	3, 11
Amplitude of pulsating test force	$F_{ca} = 0{,}5\ F_{cr}$	13	8, 14, D.2	3, 11
Pulsating test force	$F_c(t)$	13, 16, 17		3, 11
Final static test force	$F_{fin} = F_{sp}$	16, 17	8, 14, D.2	3, 11
Minimum test force on heel/forefoot	F_{1cmin}, F_{2cmin}	13, 17	11, D.3	7
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}	13, 17	11, D.3	7
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}	13, 17	11, D.3	7
Mean test force on heel/forefoot	F_{1cmean}, F_{2cmean}	13	11, D.3	7
Amplitude of pulsating test force on heel/forefoot	F_{1ca}, F_{2ca}	13	11, D.3	7
Pulsating test force on heel/forefoot	$F_{1c}(t)$, $F_{2c}(t)$	13, 17		7
Final static test force on heel/forefoot	F_{1fin}, F_{2fin}	17	11, D.3	7
Stabilizing twisting moment	$M_{u\text{-}stab}$	17	9	4
Settling twisting moment	$M_{u\text{-}set}$	17	9	4
Maximum twisting moment	$M_{u\text{-}max}$	17	9	4

NOTE To simplify application of this International Standard, all relevant test loads are listed in this table together with references to the specific clauses, tables and test procedures.

[a] The test forces F_{set}, F_{pa}, F_{sp} and F_{su} are determined using appropriate factors.

[b] Test descriptors

A: Proof test of end attachments (apparatus)
1: Principal static proof test
2: Principal static ultimate strength test
3: Principal cyclic test
4: Separate static test in torsion
5: Separate static proof test for ankle-foot devices and foot units
6: Separate static ultimate strength test for ankle-foot devices and foot units
7: Separate cyclic test for ankle-foot devices and foot units
8: Separate static ultimate strength test in maximum knee flexion
9: Separate static proof test for knee locks
10: Separate static ultimate strength test for knee locks
11: Separate cyclic test for knee locks

Table 4 — Test forces of the proof test of end attachments for test loading levels P5, P4 and P3 (see 13.2.1.2)

End attachments for			Stabilizing test force, F_{stab}	Settling test force, F_{set}	Proof test force, F_{pa}
Test procedure	**Test loading level**	**Test loading condition**	N	N	N
Principal structural tests [a]	**P5**	I	50	1 024	5 376
		II		920	4 830
	P4	I		944	4 956
		II		828	4 348
	P3	I		736	3 864
		II		638	3 348
Separate tests on knee locks	**P5, P4, P3**		50	800	4 200

NOTE For the additional test loading level P6 the test forces are specified in Table D.1.

[a] End attachments that satisfy the stiffness requirements of the proof test of end attachments for proof test forces F_{pa} = 1,2 $F_{su,\ upper\ level}$ of a specific test loading level specified in this table are suitable for all static and cyclic tests of this International Standard carried out at this specific test loading level and at all lower levels.

For sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard and/or to the specific requirements of the prosthetic device/structure submitted for test, particular conditions apply (see the option described in 13.2.1.2.1).

Table 5 — Total length and segmental lengths of different types of test samples for principal tests and separate tests on knee locks, for all test loading conditions and test loading levels
(see also 10.2, 10.3, 16.2, 16.3, 17.4 and Figure 2)

Dimensions in millimetres

Reference plane level	Typical combinations of segmental lengths of test samples [a,b]		
	A	**B**	**C**
u_T	—	—	—
	$(u_T - u_K)$ = 150 [b]	$(u_T - u_K)$ = 150 [b]	
u_K	—	—	$(u_T - u_A)$ = 570
	$(u_K - u_A)$ = 420		
u_A	—	$(u_K - u_B)$ = 500	—
	$(u_A - u_B)$ = 80		$(u_A - u_B)$ = 80
u_B	—	—	—
Total length $(u_T - u_B)$ [a,b]	650	650	650

NOTE The total length and the segmental lengths also apply to the additional test loading level P6 specified in Annex D [see D.3 a)].

[a] The total length of 650 mm can be achieved by different combinations of segmental lengths. Examples of the combinations of segment lengths specified in columns A, B and C, typical of the different types of test sample, are shown below.

– Complete structure: A
– Partial structure: A, B, C
– Any other structure: A, B, C

[b] For the testing of samples of prosthetic structures including knee-disarticulation or transfemoral (above-knee) sockets (see 10.3.3), the value of 150 mm specified in columns A and B for the segment length $(u_T - u_K)$ and the value of 570 mm specified in column C for the segment length $(u_T - u_A)$ are too short and need to be increased as required, by increasing the total length $(u_T - u_B)$. In this case the values of the offsets f_T and o_T, specified in Table 6, need to be replaced by new values adapted to the increased total length $(u_T - u_B)$, to be calculated using the formulae in Figure 12 (see also footnote b in Table 6).

Table 6 — Values of offsets for all principal tests
(see 16.2 and 16.3)

Dimensions in millimetres

Reference plane	Direction and location [b]	Offset [a]					
		Numerical value mm					
		Test loading condition					
		Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
Top [c]	f_T	82	55	89	51	81	51
	o_T	– 79	– 40	– 74	– 44	– 85	– 49
Knee	f_K	52	72	56	68	49	68
	o_K	– 50	– 35	– 48	– 39	– 57	– 43
Ankle	f_A	– 32	120	– 35	115	– 41	115
	o_A	30	– 22	25	– 24	24	– 26
Bottom [c]	f_B	– 48	129	– 52	124	– 58	124
	o_B	45	– 19	39	– 22	39	– 23

NOTE The offsets specified for P5 also apply to the additional test loading level P6 specified in Annex D [see D.3 b)].

[a] See 6.8.1.

[b] For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 5, the offsets f_T and o_T specified in this table need to be adapted, using the formulae in Figure 12 [see also footnote b in Table 5].

[c] Only for guidance in aligning test samples.

Table 7 — Values of combined offsets related to the values of offsets listed in Table 6
(see 10.1.2 and 13.2.1.2.3)

Dimensions in millimetres

Reference plane	Dimension and location [b]	Combined offsets $S_x = \sqrt{f_x^2 + o_x^2}$ [a]					
		Numerical value mm					
		Test loading condition					
		Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
Top	S_T	114	68	116	67	117	71
Knee	S_K	72	80	74	78	75	81
Ankle	S_A	44	122	43	118	48	118
Bottom	S_B	66	130	65	126	70	126

NOTE The combined offsets specified for P5 also apply to the additional test loading level P6 specified in Annex D.

[a] For the determination of the size of prosthetic feet and the setting of the length of load application levers, specific values of combined offsets (see 6.8.2) may be required. This table states values of combined offsets related to the values of offsets listed in Table 6.

[b] For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 5, the combined offset S_T specified in this table needs to be adapted, using the formulae in the heading [see also footnote b in Table 5].

Table 8 — Test forces of all principal tests and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3
(see 16.2 and 16.3)

Test procedure and test load			Unit	Test loading level (P_x) and test loading condition (I; II)					
				P5		P4		P3	
				I	II	I	II	I	II
Static and cyclic test procedures	Stabilizing test force	F_{stab}	N	50					
	Settling test force	F_{set}	N	1 024	920	944	828	736	638
Static test procedure	Proof test force	F_{sp}	N	2 240	2 013	2 065	1 811	1 610	1 395
	Ultimate static test force	$F_{su,\ lower\ level}$	N	3 360	3 019	3 098	2 717	2 415	2 092
		$F_{su,\ upper\ level}$	N	4 480	4 025	4 130	3 623	3 220	2 790
Cyclic test procedure	Minimum test force	F_{cmin}	N	50					
	Cyclic range	F_{cr}	N	1 280	1 150	1 180	1 035	920	797
	Maximum test force	F_{cmax} $F_{cmax} = F_{cmin} + F_{cr}$	N	1 330	1 200	1 230	1 085	970	847
	Mean test force	F_{cmean} $F_{cmean} = 0{,}5\ (F_{cmin} + F_{cmax})$	N	690	625	640	568	510	449
	Cyclic amplitude	F_{ca} $F_{ca} = 0{,}5\ F_{cr}$	N	640	575	590	518	460	399
	Final static force	F_{fin} $F_{fin} = F_{sp}$	N	2 240	2 013	2 065	1 811	1 610	1 395
	Prescribed number of cycles		1	3×10^6					

NOTE For the additional test loading level P6 the values of the test forces and the prescribed number of cycles are specified in Table D.2.

Table 9 — Twisting moments of the separate static test in torsion
(see 17.1)

Test loading level	Static test load N·m		
	Settling twisting moment, $M_{u\text{-}set}$	**Stabilizing twisting moment**, $M_{u\text{-}stab}$	**Maximum twisting moment**, $M_{u\text{-}max}$
P5, P4, P3	3	1	50
NOTE The specified test loads also apply to the additional test loading level P6 specified in Annex D.			

Table 10 — Angles of directions of loading of all separate tests on ankle-foot devices and foot units, for test loading levels P5, P4 and P3
(see 17.2 and Figure 7)

Angles	Degrees
α	15
β	20
γ	7
NOTE The specified directions of loading also apply to the additional test loading level P6 specified in Annex D.	

Table 11 — Test forces of all separate tests on ankle-foot devices and foot units and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3
(see 17.2)

Test procedure and test load			Unit	Test loading level (P_x) and test loading condition (F_{1x}; F_{2x})					
				P5		P4		P3	
				Heel loading, F_{1x}	Forefoot loading, F_{2x}	Heel loading, F_{1x}	Forefoot loading, F_{2x}	Heel loading, F_{1x}	Forefoot loading, F_{2x}
Static test procedure	Proof test force	F_{1sp}, F_{2sp}	N	2 240	2 240	2 065	2 065	1 610	1 610
	Ultimate static test force	$F_{1su,\ lower\ level}$, $F_{2su,\ lower\ level}$	N	3 360	3 360	3 098	3 098	2 415	2 415
		$F_{1su,\ upper\ level}$, $F_{2su,\ upper\ level}$	N	4 480	4 480	4 130	4 130	3 220	3 220
Cyclic test procedure	Minimum test force	F_{1cmin}, F_{2cmin}	N	50					
	Cyclic range	F_{1cr}, F_{2cr}	N	1 280	1 280	1 180	1 180	920	920
	Maximum test force	F_{1cmax}, F_{2cmax} $F_{xcmax} = F_{xcmin} + F_{xcr}$	N	1 330	1 330	1 230	1 230	970	970
	Mean test force	F_{1cmean}, F_{2cmean} $F_{xcmean} = 0{,}5\ (F_{xcmin} + F_{xcmax})$	N	690	690	640	640	510	510
	Cyclic amplitude	F_{1ca}, F_{2ca} $F_{xca} = 0{,}5\ F_{xcr}$	N	640	640	590	590	460	460
	Final static force	F_{1fin}, F_{2fin} $F_{xfin} = F_{xsp}$	N	2 240	2 240	2 065	2 065	1 610	1 610
	Prescribed number of cycles		1	2×10^6					

NOTE For the additional test loading level P6 the values of the test forces and the prescribed number of cycles are specified in Table D.3.

Table 12 — Loading parameters of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts
(see 17.3 and Figure 8)

Test loading level	Length, L_e mm	Ultimate static test force, F_{su} N
P5, P4, P3	400	1 750
NOTE The specified loading parameters also apply to the additional test loading level P6 specified in Annex D.		

Table 13 — Offsets of all separate tests on knee locks, for test loading levels P5, P4 and P3
(see 17.4)

Reference Plane	Offset [a]	
	Direction	Numerical value mm
Knee	f_K	– 50
	o_K	0
Ankle	f_A	– 50
	o_A	0
NOTE The specified offsets also apply to the additional test loading level P6 specified in Annex D.		
[a] See 6.8.1.		

Table 14 — Test forces of all separate tests on knee locks and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3
(see 17.4)

Test procedure and test load			Unit	Test loading level (P_x) P5, P4, P3
Static and cyclic test procedures	Stabilizing test force	F_{stab}	N	50
	Settling test force	F_{set}	N	800
Static test procedure	Proof test force	F_{sp}	N	1 750
	Ultimate static test force	F_{su}	N	3 500
Cyclic test procedure	Minimum test force	F_{cmin}	N	50
	Cyclic range	F_{cr}	N	1 000
	Maximum test force	F_{cmax} $F_{cmax} = F_{cmin} + F_{cr}$	N	1 050
	Mean test force	F_{cmean} $= 0,5\ (F_{cmin} + F_{cmax})$	N	550
	Cyclic amplitude	F_{ca} $F_{ca} = 0,5\ F_{cr}$	N	500
	Final static force	F_{fin} $F_{fin} = F_{sp}$	N	1 750
	Prescribed number of cycles		1	1×10^6
NOTE The specified test the forces and the prescribed number of cycles also apply to the additional test loading level P6 specified in Annex D.				

9 Compliance

9.1 General

In order to claim compliance with this International Standard for a prosthetic device/structure submitted for test, a prescribed number of test samples of this structure from the allowed batch, specified in Table 16, shall satisfy the relevant requirements of Clauses 9, 10, 16 and 17 and the relevant test loading conditions and test loading levels of Clauses 7 and 8. Any claim of compliance shall state the test loading level at which tests were conducted.

Compliance of a prosthetic device/structure submitted for test with the performance requirements of a specific test of this International Standard required (see 9.2) shall be certified by the test laboratory/facility only for the specific prosthetic assembly and alignment simulated in the set-up of the batch of test samples of the prosthetic device/structure which have been subjected to this test (see 9.4).

NOTE The manufacturer/submitter may claim compliance also for other prosthetic assemblies and/or alignments in which the prosthetic device/structure submitted for test can be used, provided it can be certified that these lie within the range of loading covered by the most adverse assembly and the worst-case alignment simulated in the test sample set-up of the prosthetic device/structure submitted for test.

9.2 Selection of tests required to claim compliance with this International Standard

The different combinations of principal and separate structural tests, required to be completed on test samples of prosthetic structures submitted for test representing complete assemblies, partial assemblies or individual components (see Clause 10) to claim their compliance with this International Standard, are indicated in Table 15.

9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this International Standard

9.3.1 General

For batches of test samples of prosthetic structures submitted for test including an ankle-foot device or foot unit, the claim of compliance with this International Standard requires that the ankle-foot device or foot unit satisfy the requirements of the separate tests on ankle-foot devices and foot units specified in 17.2, independent of other tests required to claim compliance with this International Standard, which also may involve/load the ankle-foot device or foot unit.

9.3.2 Particular arrangements concerning the ankle-foot device or foot unit

In order to claim compliance with this International Standard, for a prosthetic structure submitted for test including an ankle-foot device or foot unit that is detachable:

— samples of this ankle-foot device or foot unit from the permitted batch (see Table 16) shall be subjected only to the separate tests on ankle-foot devices and foot units specified in 17.2

while

— the samples of the remainder of the prosthetic structure shall be subjected to the principal structural tests specified in 16.2 and 16.3 with the ankle-foot device or foot unit replaced by a rigid lever arm (bottom load application lever).

9.3.3 Particular arrangements and requirements concerning the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure

9.3.3.1 In order to claim compliance with this International Standard for a prosthetic structure submitted for test including an ankle-foot device or foot unit that is detachable, batches of the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base, shall be tested in either of the ways specified in 9.3.3.2 and 9.3.3.3.

9.3.3.2 If the manufacturer/submitter intends to claim compliance with this International Standard for a specific assembly of connecting part and ankle-foot device or foot unit or for specified assemblies of the connecting part and several types of ankle-foot device or foot unit, then batches of samples of each specific assembly shall be subjected to the separate tests on ankle-foot devices and foot units specified in 17.2.

9.3.3.3 If the manufacturer/submitter intends to claim compliance with this International Standard for assemblies of the connecting part and any type of ankle-foot device or foot unit in accordance with the NOTE in 9.1, then batches of samples of this part shall be subjected to the principal structural tests specified in 16.2 and 16.3 in a test sample set-up in which the foot unit is replaced by a rigid lever arm, in order to apply the longest effective lever arm possible corresponding to the requirements of 10.3.4.

9.4 Number of tests and test samples required to claim compliance with this International Standard

The minimum number of tests required for each type of test in the prescribed loading conditions in order to claim compliance with this International Standard is shown in Table 16.

The tests shall be conducted on test samples from the batch specified in Table 16 for each type of test.

The minimum number indicates how many test samples of a prosthetic device/structure submitted for test shall complete the tests without failing.

All tests shall be conducted in the worst-case alignment position of the test samples (see 10.6) and, if these include partial structures according to 10.2.2 which can be used in various prosthetic assemblies, in the most adverse prosthetic assembly possible (see 10.3.4).

NOTE The total number of test samples actually needed for the conduct of a selection of specific types of tests relevant to the prosthetic device/structure submitted for test may differ from the total calculated by addition of the number of test samples specified in Table 16 for each of the types of tests selected, since the number of substitutes needed may vary, and since test samples that have completed a specific test without failing may be used for another test (see 9.5, 16.2.1.1.2, 16.2.2.1.2, 17.2.3.1.2, 17.2.4.1.2, 17.4.3.1.2 and 17.4.4.1.2).

9.5 Multiple use of test samples

9.5.1 General

Test samples, which have demonstrated compliance with the performance requirements of any of the tests specified in this International Standard, may be subjected to other tests of this International Standard, except as stated in 9.5.2.

Any decision on the multiple use of test samples shall be based on a corresponding indication in the test submission document (see Clause 12) and/or the agreement between the manufacturer/submitter and the test laboratory/facility.

As a general rule, any failure occurring during a test on a test sample that has previously been subjected to another test justifies the repetition of the failed test on a substitute test sample (see Table 16).

NOTE The multiple use of test samples is specifically addressed in the principal static tests (16.2.1 and 16.2.2), the separate static tests for ankle-foot devices and foot units (17.2.3 and 17.2.4) and the separate static tests for knee locks (17.4.3 and 17.4.4) – (see also references in the NOTE in 9.4).

Unless otherwise indicated in the test submission document and/or agreed between the manufacturer/submitter and the test laboratory/facility, this International Standard does not stipulate that the tests required to claim compliance for the prosthetic device/structure submitted for test be conducted in a particular order, with the exception of the restriction specified in 9.5.2.

9.5.2 Restriction

Compliance of any test sample with the performance requirements of any of the cyclic tests of this International Standard cannot be claimed if the test sample has previously been subjected to any of the static ultimate strength tests of this International Standard.

9.6 Testing at particular test loading levels not specified in this International Standard

For different reasons the intended use of a particular design of a lower limb prosthetic device/structure may require the tests of this International Standard to be applied at a particular test loading level not specified in this International Standard, derived from the next lower regular test loading level of this International Standard by increasing its test loads by x %.

In this case compliance with this International Standard cannot be claimed for that particular test loading level.

However, compliance with this International Standard can be claimed for the next lower regular test loading level of this International Standard, from which that particular test loading level has been derived.

Reference to this International Standard may also be given by stating that the prescribed batch (or batches) of test samples of a prosthetic device/structure submitted for test has (have) been tested a) following this International Standard or in a more specific manner b) by applying the tests of this International Standard at test loads set x % above test loading level P_y.

Table 15 — Tests required to claim compliance with this International Standard for prosthetic structures representing complete assemblies, partial assemblies or individual components

Examples of prosthetic structures submitted for test[a]	Principal structural tests [b]	Separate structural tests			
		Test in torsion [c]	Tests on ankle-foot devices and foot units [d]	Test in maximum knee flexion [e]	Tests on knee locks [f]
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis with foot unit	× (see 9.3)	×	× (see 9.3)	×	×
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis without foot unit	×	×		×	×
Complete structure of transtibial prosthesis with foot unit	× (see 9.3)	×	× (see 9.3)		
Complete structure of transtibial prosthesis without foot unit	×	×			
Partial structure including knee unit and ankle-foot device or foot unit	× (see 9.3)	×	× (see 9.3)	×	×
Partial structure including knee unit but not ankle-foot device or foot unit	×	×		×	×
Partial structure including ankle-foot device or foot unit but not knee unit	× (see 9.3)	×	× (see 9.3)		
Partial structure without knee unit and without ankle-foot device or foot unit	×	×			
Ankle-foot device or foot unit (e.g. of ankle-disarticulation prosthesis) only		×	× (see 9.3)		

[a] Examples of the different types of test samples of prosthetic structures submitted for test are specified in 10.2.
[b] Tests required for test samples of all prosthetic structures except samples of single ankle-foot devices or foot units.
[c] Test required for test samples of all prosthetic structures.
[d] Tests required for test samples of prosthetic structures including an ankle-foot device or foot unit, independent of other tests required to claim compliance with this International Standard, which also may involve/load the ankle-foot device or foot unit.
[e] Test required for test samples of prosthetic structures including a knee unit which, under real conditions of use as a member of a finished lower limb prosthesis, will be loaded at its physical boundaries of angular movement in the position of maximum knee flexion of that prosthesis. (This need not happen in every case, as the position of maximum knee flexion may be determined by other parts of the prosthesis which come into contact first.)
[f] Tests required for test samples of prosthetic structures including a knee unit which can be locked in the extended position.

Table 16 — Number of tests and test samples required to claim compliance with this International Standard

Type of test	Test loading condition and manner of application	Minimum [a] number of tests required	Batch [b] of test samples allowed for each type of test		
			Regular test samples	Possible substitute test samples	
				No. [c]	Reference
Principal structural tests					
Static proof test (see 16.2.1.1)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2 2	2 2	1 1	16.2.1.1.12
Static ultimate strength test (see 16.2.2.1)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2 2	2 2	1 1	16.2.2.1.9 and 16.2.2.1.10 (option)
Cyclic test [d] (see 16.3.2)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2 2	2 2	1 1	16.3.2.22
Separate test in torsion					
Static test (see 17.1.3)	Two opposite directions of loading, successively applied to each test sample (7.1.3.1)	2	2	—	—
Separate tests on ankle-foot devices and foot units					
Static proof test (see 17.2.3.1)	Direction of loading at angle α and direction of loading at angle β, successively applied to each test sample (7.1.3.2)	2	2	1	17.2.3.1.11
Static ultimate strength test (see 17.2.4.1)	Direction of loading at angle α and Direction of loading at angle β (7.1.3.2)	2 2	2 2	1 1	17.2.4.1.15 and 17.2.4.1.17 (option) 17.2.4.1.15 and/or 17.2.4.1.16 and 17.2.4.1.17 (option)
Cyclic test [d] (see 17.2.5.1)	Direction of loading at angle α and direction of loading at angle β, alternately applied to each test sample (7.1.3.2)	2	2	—	—
Separate static ultimate strength test in maximum knee flexion on knee joints and associated parts					
Static test (see 17.3.4)	Single condition (7.1.3.3)	2	2	—	—
Separate tests on knee locks					
Static proof test (see 17.4.3.1)	Single condition (7.1.3.4)	2	2	1	17.4.3.1.12
Static ultimate strength test (see 17.4.4.1)	Single condition (7.1.3.4)	2	2	1	17.4.4.1.9
Cyclic test [d] (see 17.4.5.1)	Single condition (7.1.3.4)	2	2	1	17.4.5.1.22

a The term *minimum* indicates that repetition of tests on permitted substitute test samples may be necessary to satisfy the compliance conditions.

b For the definition of *batch* see 3.4.

c The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed in the reference column applies.

d All cyclic tests are followed by final static tests, applied in the same test loading conditions (directions of loading).

10 Test samples

10.1 Selection of test samples

10.1.1 General

The test samples of prosthetic devices/structures selected for test shall be taken from normal production. Details of the selection shall be recorded in the test submission document (see Clause 12). If the manufacturer/submitter supplies a certificate stating that the test sample has been taken from the normal production line, this certificate shall be included in the test submission document, together with details of the sampling method.

NOTE Test samples of prosthetic devices/structures may also be submitted for specific tests by any interested party.

10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot

10.1.2.1 For principal structural tests on samples of prosthetic structures including an ankle-foot device or a foot unit that forms an integral part of the structure and cannot be detached (see 9.3), the size of the foot selected shall allow the application of load in accordance with the combined bottom offset S_B specified for the test (see 6.8.2, Table 7 and Figures 4 and 6), S_B being determined by the formula

$$S_B = \sqrt{f_B^2 + o_B^2} \tag{1}$$

where f_B and o_B are the f- and o-offsets of the bottom load application point P_B.

The selection of the size of the foot and possible subsequent adaptations of the test force shall be carried out as follows:

a) select a size that gives the correct combined bottom offset, S_B;

b) if a correct size foot is not available, use the next larger size;

c) if the foot available is shorter than the correct length, then increase the applied test force F to F' where:

$$F' = F\left(\frac{S_{B\,spec}}{S_{B\,act}}\right) \tag{2}$$

and where

$S_{B\,spec}$ = specified combined bottom offset;

$S_{B\,act}$ = actual combined bottom offset.

10.1.2.2 For separate structural tests on ankle-foot devices and foot units on samples of prosthetic structures including an ankle-foot device or a foot unit that can be detached or on samples comprising an ankle-foot device or a foot unit as a single component, the size of the foot selected shall provide the worst-case loading (see note) that is possible for that type of foot when subjected to the heel and forefoot loading specified for the test (see Tables 10 and 11).

The size of foot providing the worst-case loading shall be determined by the manufacturer/submitter (see NOTE) and shall be stated, with justification, in the test submission document (see Clause 12).

NOTE The determination of the size of foot providing the worst-case loading may be based on design features, on findings of risk management and/or on the results of appropriate preliminary tests conducted on feet of different size.

An appropriate measure for the worst-case loading is the direction and magnitude of the ankle (A-P) bending moment (see Annex A), generated by the test forces applied to the heel and forefoot of the ankle-foot device or foot unit and determined by the lengths of the effective lever arms on which these test forces act.

Although there is a fundamental relationship between the lengths of the effective lever arms and the size of the foot, the worst-case loading need not necessarily be provided in each case by the largest size of foot available for the test loading level to be applied, but can also be influenced by other design parameters.

10.2 Types of test samples

10.2.1 Complete structure

10.2.1.1 For a knee-disarticulation or a transfemoral (above-knee) prosthesis, a complete structure consists of a knee unit and ankle unit or ankle attachment with all parts between. It may also contain parts above the knee unit, including the socket (see 10.2.1.4), and below the ankle unit or ankle attachment, including the foot unit.

10.2.1.2 For the distal part of a hip-disarticulation (or hemi-pelvectomy) prosthesis, a complete structure consists of a knee unit and ankle unit or ankle attachment with all parts between. It may also contain parts below the ankle unit or ankle attachment, including the foot unit.

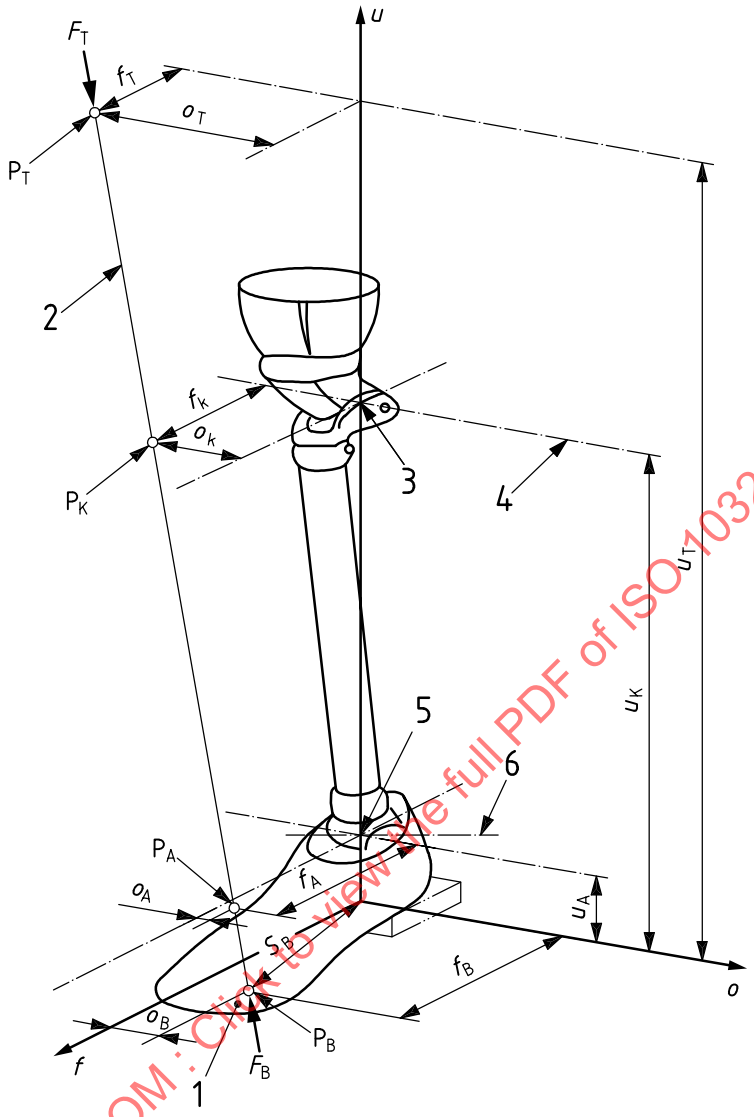
NOTE Tests of components of hip-disarticulation (or hemi-pelvectomy) prostheses which are above the level of the knee are specified in ISO 15032.

10.2.1.3 For a transtibial (below-knee) prosthesis, a complete structure consists of the ankle unit or ankle attachment and the socket attachment with all parts between. It may also contain parts above the socket attachment, including the socket (see 10.2.1.4), and below the ankle unit or ankle attachment, including the foot unit.

10.2.1.4 The mechanical connection between a transtibial (below-knee), knee-disarticulation or transfemoral (above-knee) socket and the distal shin-socket or knee-socket attachment is a critical region of a prosthetic structure.

In order to demonstrate that this connection has the strength required to sustain the loads expected to occur during use by amputees in the manner intended, manufacturers shall submit complete structures, including the socket or a socket dummy, for test in accordance with the relevant requirements of this International Standard.

10.2.1.5 An example of a complete structure of a left transfemoral (above-knee) prosthesis and its alignment within the coordinate system is shown in Figure 6.



Key

1 left foot
2 load line
3 effective knee-joint centre
4 effective knee-joint centreline
5 effective ankle-joint centre
6 effective ankle-joint centreline
P_K knee-load reference point
P_A ankle load reference point
P_B bottom load application point
P_T top load application point

NOTE This figure illustrates a typical test loading condition representative of the condition of forefoot loading during the stance phase of normal walking. It corresponds to test loading condition II defined in 7.1.2 b).

Figure 6 — Application of a specific test configuration with u_B = 0 to a left-sided sample specified in 10.2.1

10.2.2 Partial structure

For any type of prosthesis, a partial structure is less than a complete structure and may be a single component, such as a knee unit or an ankle-foot device.

A specific example of a partial structure is a test sample of a foot unit or the structural parts of a foot unit used in specific types of ankle-disarticulation prostheses.

When a partial structure is tested, the end connections shall have mechanical characteristics similar to those of the intended adjacent components, unless otherwise specified in this International Standard.

10.2.3 Any other structure

If the design of a leg structure does not allow it to be tested as a test sample in accordance with 10.2.1 or 10.2.2, then a special test set-up may be used for testing. For example, such a leg could be a one-piece flexible plastic structure that includes the foot.

If the manufacturer/submitter and the test laboratory/facility certify in writing in the test submission document (see Clause 12) and the test report (see Clause 19), that the effective geometry of the test sample and the test loading conditions comply with the requirements of Clauses 7, 8 and 16 or 17, as appropriate, then testing may be carried out and a test report issued in accordance with Clause 19, in which this compliance is specifically addressed.

If the test sample satisfies the requirements of the relevant clauses of this International Standard, then compliance with these clauses can be claimed. The claim shall clearly indicate that the test sample complies with 10.2.3 of this International Standard.

If the geometry of the test sample cannot be so certified, then compliance with these clauses cannot be claimed.

10.3 Preparation of test samples

10.3.1 The samples shall include all parts normally fitted.

10.3.2 Any cosmetic components shall be omitted from the sample, unless they contribute to the structural strength.

10.3.3 Where any test sample includes a socket or socket dummy, the preparation of the test sample shall include the measures listed in a) to c).

a) The distal portion of the socket or socket dummy, into which the distal socket attachment device extends, shall either be a void or be filled with foam or soft materials, in order to allow this portion to deform freely under load.

b) The remaining proximal portion of the socket or socket dummy shall be connected rigidly to the top end attachment, consisting of the extension piece, as required, and the top load application lever.

   The use of a mandrel as extension piece, anchored within the socket or socket dummy by means of rigid foam, has been found to be suitable.

c) For a transtibial (below-knee) socket or socket dummy, the position of the effective knee-joint centre and the direction of the effective knee-joint centreline shall be identified, based on anatomical features derived from the socket shape. This is necessary to allow the alignment of the socket as required (see 10.5 and 10.6).

   It has been found to be suitable to transfer the effective knee-joint centreline to the socket by drilling holes through the medial and lateral socket wall in the direction of the effective knee-joint centreline, the holes to serve as guide for alignment pins of a jig.

10.3.4 Where any test sample includes a partial structure according to 10.2.2 which can be used in different prosthetic assemblies, then the test sample set-up shall be prepared in accordance with a) and b) and the test submission document (see Clause 12).

a) If the partial structure is intended to be allowed for free use in any prosthetic assembly, then the test sample set-up shall be prepared to represent the most adverse prosthetic assembly possible.

b) If the partial structure is intended to be allowed for limited use in specified prosthetic assemblies, then the test sample set-up shall be prepared to represent each prosthetic assembly specified.

10.3.5 Where any test sample includes any end fittings, then it shall be assembled in accordance with Clause 11 and the test submission document.

10.3.6 For the principal structural tests (see Clause 16) and the separate structural tests on knee locks (see 17.4), all test sample types according to 10.2 shall be given a fixed total length, using end attachments consisting of extension pieces and the load application levers.

The fixed total length shall be determined by the dimension $u_T - u_B$ and shall be achieved by selecting either one of the combinations specified in Table 5 for different types of test sample (see 10.2) or any other relevant combination. The combination of segment lengths selected shall be recorded.

10.3.7 For the separate tests on ankle-foot devices and foot units, the ankle-foot device or foot unit, selected in accordance with 10.1.2, shall be submitted assembled by the manufacturer/submitter to the part connected to the remainder of the prosthesis such as an ankle unit, alignment device, pylon base, compliant structure or exoskeletal member. The type and identification of the part connected shall be recorded.

10.3.8 For the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (see 17.3.4), the test sample shall consist of the assembly of knee unit and associated parts that normally provides the knee flexion stop on a complete prosthesis, comprising

— sub-assemblies of knee units and adjacent components normally required for their attachment to the proximal and distal part of a prosthesis and/or their alignment within a prosthesis, and

— knee-shin-assemblies, including adjacent components required for their attachment to the proximal part of a prosthesis and/or their alignment within a prosthesis.

Parts outside the specific assembly may be substituted. The form of the specific assembly and any substituted parts shall be recorded.

If a specific knee unit or knee-shin-assembly can be used in conjunction with different attachment/alignment components, then the test sample set-up shall represent the assembly where the knee flexion stop point is nearest to the axis of rotation (monocentric design) or nearest to the instantaneous centre of rotation (polycentric design) of the knee unit or knee-shin-assembly at maximum knee flexion of the test sample. (This is in accordance with 10.3.4.).

10.3.9 For the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, all test samples shall have extension pieces attached above and below the knee unit, to represent wholly or in part the thigh and shin portion (for details see 10.5.3.1). The lengths of these extension pieces shall be recorded.

10.4 Identification of test samples

The test laboratory/facility shall apply to each test sample an indelible, unique and traceable identification.

10.5 Alignment of test samples

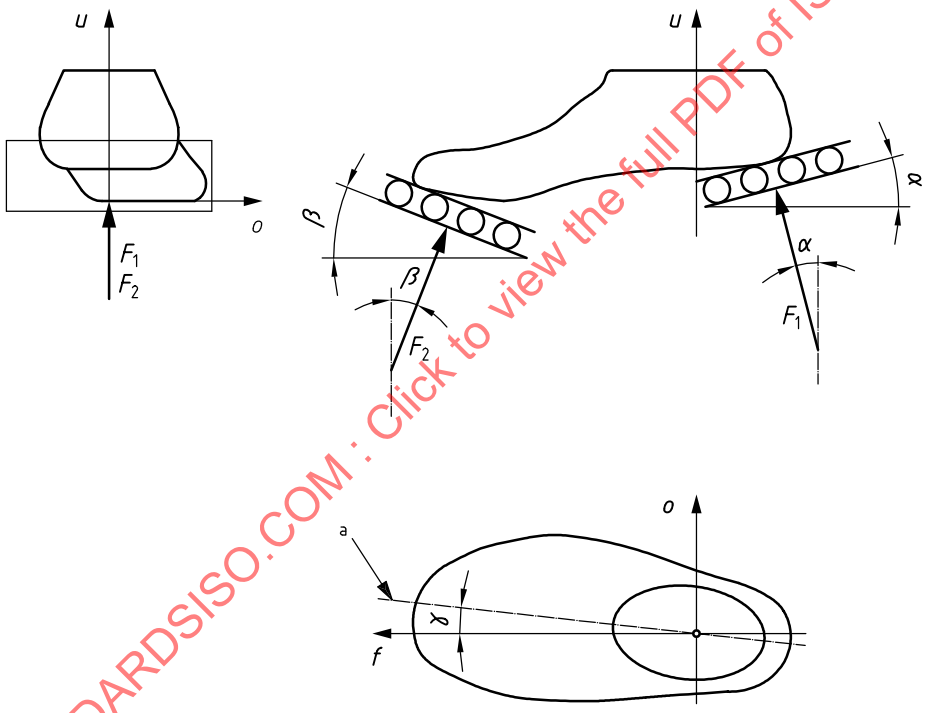
10.5.1 Test samples for principal tests and separate tests on knee locks

10.5.1.1 For the principal structural tests (see Clause 16) and the separate structural tests on knee locks (see 17.4), all test sample types specified in 10.2 shall be aligned within the appropriate coordinate system in accordance with 6.1 to 6.3, 6.7.3 to 6.7.6, 10.6, 14.3 a) to d), Tables 5 and 6 or 13 and the test submission document (see Clause 12).

10.5.2 Test samples for separate tests on ankle-foot devices and foot units

10.5.2.1 Test samples of an ankle-foot device or foot unit shall be aligned within the appropriate coordinate system in accordance with 6.1 to 6.3, 6.7.2 to 6.7.4, 14.3 a) and d), Table 10 and the test submission document (see Clause 12).

The longitudinal axis of the foot (see 6.7.2) shall be turned by γ = 7° as shown in Figure 7 and specified in Table 10 to give a “toe out” position of the ankle-foot device or foot unit.



a longitudinal axis of foot corresponding to 6.7.2.

NOTE The test mechanism used to apply F_1 and F_2, each should allow low-friction motion in both tangential directions, realized e.g. by ball bearings.

Figure 7 — Position of foot in test equipment
(see 10.5.2, 13.4 and 17.2)

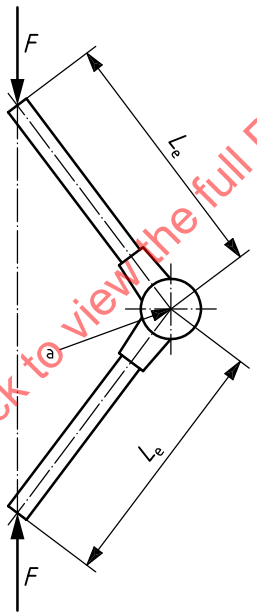
10.5.3 Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts

10.5.3.1 In the initial test sample set-up with the knee unit fully extended, the extension pieces attached above and below the knee unit to represent wholly or in part the thigh and shin portion shall be aligned on the u-axis and perpendicular to the effective knee-joint centreline and shall provide a length, L_e, of 400 mm, measured from the effective knee-joint centre, in accordance with 6.2.2, 6.7.5, 6.7.6, 10.3.9, 14.3 a) and b), Table 12 and Figure 8).

10.5.3.2 If the alignment of the test sample is adjustable, it shall be set in the worst-case alignment position in accordance with 10.6.

10.5.4 Test samples for separate tests on knee locks

If the lock position is adjustable or alignment adjustment of the test sample moves the lock in relation to the centre of rotation, then the test sample shall be set so that the lock is as close as possible to the effective knee-joint centre (see 6.7.6).



L_e length of thigh and shin portion

[a] Effective knee-joint centre.

Figure 8 — Test configuration for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts
(see 10.5.3.1, 13.5 and 17.3.4)

10.6 Worst-case alignment position of test samples

10.6.1 All tests shall be conducted in the worst-case alignment position of the test samples as defined by the criteria specified in 10.6.2 to 10.6.4.

10.6.2 The structurally worst alignment position shall, if possible, be defined by the manufacturer/ submitter in the test submission document (see Clause 12). It shall lie within the limitations of the manufacturer's written instructions for the alignment of the limb as supplied with every component of the type.

10.6.3 Where the structurally worst position cannot be defined as required in 10.6.2, then the sample shall be adjusted so that it is moved 90 % of the distance from neutral alignment to extreme alignment. The adjustment shall be directed away from the load line so as to increase the effective lever arm (see 6.8.3).

10.6.4 For samples for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts, the worst-case alignment position is when the perpendicular distance of the axis of rotation (monocentric design) or the instantaneous centre of rotation (polycentric design) of the knee unit from the load line at maximum knee flexion of the test sample assembly reaches its maximum value (but see NOTE).

In order to ensure that the test sample reaches the highest possible value of knee flexion that can occur in a normal prosthesis, the structures representing the thigh and shin portion (including the extension pieces) shall be designed and/or arranged so that their posterior contour/shape and extension keep within the "reference" contour/shape determined by the smallest dimensions that are possible in accordance with the manufacturer's instructions for the intended application(s) of the knee unit or knee-shin-assembly taking account of

— the type(s) of prosthesis (knee-disarticulation, transfemoral or hip-disarticulation prosthesis);

— the attachment of these assemblies to the proximal and distal part of the prosthesis;

— the alignment of the knee joint within the prosthesis;

— the intended use of these assemblies within a complete prosthesis by the envisaged group(s) of amputees.

NOTE In order to enlarge the free space on the posterior side of the test sample to allow the maximum value of knee flexion to be reached, it may be appropriate or necessary to start the adjustment of the alignment with the knee unit placed in a position of posterior displacement relative to the longitudinal axis of the structure representing the thigh and shin portion, which would have the opposite effect on the distance referred to in the first paragraph of 10.6.4, and then to re-adjust the alignment in a way which moves the knee unit from the position of posterior displacement in the anterior direction so as to increase this distance.

11 Responsibility for test preparation

11.1 The manufacturer/submitter shall be responsible for the selection and assembly of the components to be tested including screw connection torque settings in accordance with the manufacturer's written instructions for the assembly of components as supplied with every component of the type.

Correct tightening torque setting is of particular importance for the bolts of clamped connections regarding security against slippage, which is tested in the separate static test in torsion (see 17.1.3.1).

11.2 The manufacturer/submitter shall be responsible for the provision with the test sample of specified parts to be replaced when the number of cycles of the principal cyclic test and the separate cyclic test for knee locks has reached a value at which such replacement is indicated [see 16.3.1.2/16.3.2.16, 17.2.5.1.2 a)/17.2.5.1.9 and 17.4.5.1.1 b)/17.4.5.1.16].

11.3 The manufacturer/submitter shall be responsible for preparing the test submission document in accordance with Clause 12.

11.4 The manufacturer/submitter or the test laboratory/facility shall be responsible for the attachment of the end attachments required for the principal structural tests and the separate tests on knee locks (see 13.2.1

and 13.6.1) and the extension pieces required for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts (see 13.5.1).

Whoever assembles them shall be responsible for their static alignment in accordance with

— 10.5.1 for the principal structural tests;

— 10.5.3 for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts;

— 10.5.1 and 10.5.4 for the separate tests on knee locks.

11.5 The test laboratory/facility shall be responsible for the verification that the test sample is assembled in accordance with Clause 10, the test submission document (see Clause 12) and the manufacturer's/submitter's written instructions supplied with every component of the type.

If the test sample assembly is not correct the test laboratory/facility shall, in consultation with the manufacturer/submitter, alter it to the specified configuration.

11.6 The test laboratory/facility shall be responsible for adjustment of the alignment to give the correct offsets and effective lever arms during test, in accordance with

— 10.5.1 for the principal structural tests (see also 16.2.1.1.2/16.2.1.1.5, 16.2.2.1.2/16.2.2.1.5 and 16.3.2.2/16.3.2.5);

— 10.5.3 for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts (see also 17.3.4.1);

— 10.5.1 and 10.5.4 for the separate tests on knee locks (see also 17.4.3.1.2/17.4.3.1.5, 17.4.4.1.2/17.4.4.1.5 and 17.4.5.1.2/17.4.5.1.5).

12 Test submission document

12.1 General requirements

12.1.1 The manufacturer/submitter shall prepare the test submission document with any associated information and shall provide at least one copy with the batch of test samples of every prosthetic device/structure submitted for test.

12.1.2 The manufacturer/submitter shall, if appropriate, state in the test submission document which of the measurements and recordings of the ankle and knee offsets f_A, f_K, o_A and o_K and/or effective lever arms L_A and L_K, indicated at various stages of the principal structural tests (see 16.2 and 16.3) and the separate structural tests on knee locks (see 17.4), shall be carried out.

NOTE Although these data may provide interesting and useful information particularly on the deformation of test samples under load, they are irrelevant to the performance requirements to be satisfied according to the compliance conditions of each of these tests. For this reason, the measurements and recordings referred to will be carried out only if requested by the manufacturer/submitter.

12.1.3 The manufacturer/submitter shall, if appropriate, state in the test submission document which of the information to be recorded in the test log in accordance with this International Standard shall be included in the test report in addition to the information required to be included according to Clause 19.

12.1.4 The manufacturer/submitter shall clearly indicate a name and address for communication purposes. If appropriate, the identity of the original equipment manufacturer shall be provided.

12.1.5 The manufacturer/submitter shall provide a unique and traceable identification for the test submission document which shall also be indelibly marked on the test sample. The manufacturer/submitter shall maintain a record of such identification.

12.1.6 The manufacturer/submitter shall clearly indicate the test laboratory/facility required to conduct the test.

12.1.7 The manufacturer/submitter shall clearly indicate the date of submission or dispatch to the test laboratory/facility.

12.2 Information required for test samples

12.2.1 All test samples

The following information, attributable to a fully traceable identification for each test sample, shall be included in the test submission document:

a) manufacturer's name and model identification and/or number or other means of identification;

b) type of sample in accordance with 10.2.1, 10.2.2 or 10.2.3;

c) any certification from the manufacturer which states that the test sample has been taken from normal production and which gives details of the method of selection in accordance with 10.1.1;

d) any special assembly instructions for the test sample and/or attachments in accordance with 10.3;

e) if not straightforward, identification of the position of effective centres (6.7.3 and 6.7.6) and/or effective centrelines (6.7.4 and 6.7.5) in accordance with 10.5;

f) identification of the worst-case alignment position in accordance with 10.6;

g) tightening torque values for connecting bolts in accordance with 11.1;

h) record of the supply of any replacement parts provided in accordance with 11.2;

i) record of any end attachments and/or extension pieces and their static alignment in accordance with 10.3, 10.5 (and 11.3).

12.2.2 Test samples for tests on ankle-foot devices and foot units

The manufacturer/submitter shall include in the test submission document

a) a record of any agreement on the identification of the longitudinal axis of the foot in accordance with 6.7.2;

b) information relating to the arrangements for tests on samples of prosthetic structures including ankle-foot devices and foot units, addressed in 9.3;

c) a statement, with justification, of the size of foot providing the worst-case loading, in accordance with 10.1.2.2.

12.2.3 Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts

The manufacturer/submitter shall include in the test submission document a specification of the location/position of the knee flexion stop on each type of prosthesis for which the knee unit or knee-shin-assembly can be used according to their intended application, together with an identification of associated parts that are involved in the provision of the knee flexion stop, in accordance with 10.3.4 and 10.3.8.

12.3 Information required for tests

12.3.1 General

The information addressed in 12.3.2 to 12.3.7 for each test sample shall be included in the test submission document.

12.3.2 For all tests

a) The particular test requested (Clauses 9 and 16 or 17) and the test loading condition(s) and test loading levels [Clauses 7 and 8 (and Annex D)];

b) particular values of dimensions and forces for the conduct of the test (Clause 8);

c) the most adverse assembly and the worst-case alignment of the test sample (10.3.4 and 10.6).

12.3.3 For static tests in torsion and on ankle-foot devices and foot units

The request to proceed with the test procedure in the second direction of loading on the occurrence of failure in the test procedure in the first direction of loading in accordance with 17.1.3.7, 17.2.3.1.5 and 17.2.4.1.6.

12.3.4 For static ultimate strength tests

a) If appropriate, request for continuation of the test until failure actually occurs in accordance with 16.2.2.1.6 and/or 17.2.4.1.5/17.2.4.1.11 and/or 17.4.4.1.6 and recording of the value of the failure load and any further instructions concerning the documentation of test results.

b) Only for principal static ultimate strength tests (16.2.2.1) and separate static ultimate strength tests for ankle-foot devices and foot units (17.2.4.1): the application of an increased rate of loading in accordance with 16.2.2.1.1 and 16.2.2.1.6 and/or 17.2.4.1.1 and 17.2.4.1.5/17.2.4.1.11, and Annex C.

12.3.5 For cyclic tests

a) The test frequency called for in accordance with 16.3.2.10 and 16.3.2.13 and/or 17.2.5.1.7 and 17.2.5.1.8 and/or 17.4.5.1.10 and 17.4.5.1.13;

b) Replacement intervals of service items in accordance with 16.3.1.2 and 16.3.2.16, 17.2.5.1.2 a) and 17.2.5.1.9 and/or 17.4.5.1.1 b) and 17.4.5.1.16;

c) If appropriate, request for visual examination with specification of magnification in accordance with 16.3.1.4 and 16.3.2.21 and/or 17.2.5.1.2 c) and 17.2.5.1.14 and/or 17.4.5.1.1 d) and 17.4.5.1.21. This request shall include instructions concerning the documentation of test results.

d) Only for principal cyclic tests and separate cyclic tests for knee locks: the request to carry out the final static test in the manner required to cover the related static proof test in accordance with 16.2.1.1, 16.3.1.3 and 16.3.2.18 and/or 17.4.3.1.1, 17.4.5.1.1 c) and 17.4.5.1.18.

e) Only for principal cyclic tests and separate cyclic tests for knee locks: if appropriate, specification of a test frequency of less than 3 Hz, to be applied to a substitute test sample in the repetition of test on the occurrence of failure at a test frequency of 3 Hz or higher in accordance with 16.3.2.22 and/or 17.4.5.1.22.

12.3.6 For tests in torsion

Identification of the mid-positions of all adjustable components in accordance with 17.1.3.2.

12.3.7 For tests on ankle-foot devices and foot units

Information related to the arrangements for tests on samples of prosthetic structures including ankle-foot devices and foot units, addressed in 9.3.

13 Equipment

13.1 General

The different types of test listed in Tables 15 and 16 and specified in Clauses 16 and 17 require different types of test equipment.

Each piece of test equipment shall provide sufficient freedom of movement for the test sample to permit and not restrict its deformation under load within the specified range.

Other pieces of equipment are

— end attachments required for specific set-ups of test samples;

— a special jig that may be used on an optional basis to facilitate the setting, adjusting and/or measuring of segment lengths and offsets of test samples;

— any devices used to measure loads and dimensions.

13.2 Equipment for the principal tests specified in 16.2 and 16.3

13.2.1 End attachments

13.2.1.1 General

For the application of test loading conditions I and II of the principal structural tests, the test sample set-up requires the use of end attachments, consisting of load application levers and non-prosthetic extension pieces.

The end attachments shall not enhance or reduce the stresses due to the specified test loads in the structure under test.

The end attachments shall satisfy the requirements of the proof test of end attachments, specified in 13.2.1.2.

13.2.1.2 Proof test of end attachments

13.2.1.2.1 The test shall be carried out on end attachments required for the application of test loading conditions I and II of the principal structural tests specified in 16.2 and 16.3.

The proof test of end attachments is, in principle, also applicable to the end attachments required for the application of the test configuration of the separate structural tests for knee locks specified in 17.4 (see 13.6.1). In this case steps 13.2.1.2.3 to 13.2.1.2.11 of the test are to be carried out accordingly.

End attachments which satisfy the stiffness requirements of the proof test of end attachments for proof test forces F_{pa} = 1,2 $F_{su,\ upper\ level}$ of a specific test loading level (see Tables 3, 8 and D.2) are suitable for all principal static and cyclic tests of this International Standard carried out at this specific test loading level and at all lower levels.

OPTION — If it is the intention to use different sets of end attachments, individually designed to the specific requirements of the test loading conditions of the principal static and cyclic tests of this International Standard (see EXAMPLE) and/or to the specific requirements of the prosthetic devices/structures submitted for test, the proof test of end attachments shall be applied to each of these sets. In this case each set shall satisfy the stiffness requirements of the proof test of end attachments at values of test force F_{pa} relating as shown in

Table 17 to the highest value of test force F_{su}, F_{sp} or F_{cmax} (see Tables 3, 8 and D.2) to be applied during the test for which this set has been designed.

EXAMPLE A particular reason for the use of a specific set of (light-weight) end attachments for the cyclic test is the reduction of inertia effects caused by the mass of (heavyweight) universal end attachments suitable for all tests.

It is not necessary to repeat the proof test of end attachments if earlier results for previously tested relevant combinations of end attachments are available and are suitable.

Table 17 — Option for end attachments of specific design

Intended use of end attachments	Test force to be applied
For the static ultimate strength test	$F_{pa} = 1{,}2\ F_{su,\ upper\ level}$
For the static proof test	$F_{pa} = 1{,}2\ F_{sp}$
For the cyclic test	$F_{pa} = 1{,}2\ F_{sp} = 2{,}1\ F_{cmax}$ [a]

[a] The value of test force to be applied to end attachments intended to be used for cyclic tests takes into account that each test sample having passed the cyclic test is subjected to a final static test without preceding re-alignment. The latter condition cannot be met if the procedure requires the exchange of end attachments, which would be the case, if the set-up of the test sample for the cyclic test contained end attachments specifically designed for cyclic tests only.

13.2.1.2.2 Carry out the proof test of end attachments, consisting of the load application levers and any non-prosthetic extension pieces used, by measuring their stiffness in the manner specified in 13.2.1.2.3 to 13.2.1.2.11.

Assemble any non-prosthetic components used in the test sample for the application of the test loading conditions for the principal structural tests. Set the bottom and the top load application lever in the same plane with the load application points pointing in the same direction.

If the non-prosthetic extension pieces used have means of adjustment, this shall be set to the worst structural condition in the meaning of 10.6, i.e. the adjustment shall be directed away from the load line so as to increase the effective lever arm.

If it is necessary to use additional non-prosthetic components to allow assembly of end attachments, the stiffness of these components shall not be less than the stiffness of the other non-prosthetic components when assembled in the test situation.

Record the details of the assembly of end attchments.

13.2.1.2.3 Within the range of adjustability required for the application of the relevant test loading condition(s) and test loading level(s), set the bottom load application point P_B on the bottom load application lever and the top load application point P_T on the top load application lever (in the same direction) to their maximum distance from a line corresponding to the u-axis of the test sample in the test situation.

If the load application levers are used for the application of several test loading conditions and/or test loading levels, the range of adjustability on each lever shall allow the load application point to be set to the maximum distance required for the application of the test loading condition and/or test loading level with the highest value of combined offset at this point (see 6.8.2 and Table 7).

If, for instance, the load application levers are used for the application of test loading conditions I and II of the principal structural tests at all test loading levels specified, the bottom load application point P_B shall be set to the maximum distance within the range of adjustability required for the application of test loading condition II at test loading level P5 and the top load application point P_T to the maximum distance within the range of adjustability required for the application of test loading condition I at test loading level P3.

Record the details of the adjustment of the bottom and top load application points P_B and P_T.

13.2.1.2.4 Mount the assembly in the test equipment or suitable device.

Record the test loading condition and test loading level to be applied, together with the corresponding values of test forces.

13.2.1.2.5 Apply to the bottom and top load application points of the assembly the settling test force F_{set} of the relevant test loading condition and test loading level, specified in Table 4 or Table D.1.

Maintain this force, F_{set}, at the prescribed value for (30 ± 3) s and then remove it.

13.2.1.2.6 Apply to the bottom and top load application points of the assembly the stabilizing test force F_{stab}, specified in Table 4 or Table D.1, and maintain it until the measurement specified below is completed.

Measure and record the distance L_{BT} (see 6.8.4) as L_1 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_1.

13.2.1.2.7 Increase the test force F smoothly at a rate of between 100 N/s and 250 N/s to the proof test force F_{pa} of the relevant test loading condition and test loading level, specified in Table 4 or Table D.1, and maintain it until the measurement specified below is completed.

Measure and record the distance L_{BT} as L_2 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_2.

13.2.1.2.8 Decrease the test force F to F_{stab} and maintain it until the measurement specified below is completed.

Measure and record the distance L_{BT} as L_3 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_3.

13.2.1.2.9 Calculate and record the deflection, D_1, at F_{pa} and the permanent deformation, D_2, at F_{stab} as follows:

$$D_1 = L_1 - L_2 \quad \text{or} \quad D_1 = \delta_2 - \delta_1 \tag{3}$$

$$D_2 = L_1 - L_3 \quad \text{or} \quad D_2 = \delta_3 - \delta_1 \tag{4}$$

13.2.1.2.10 Do not use the end attachment if the calculated values exceed the following limits:

Maximum deflection at F_{pa}: D_1 = 2 mm.

Maximum permanent deformation at F_{stab}: D_2 = 1 mm.

13.2.1.2.11 Record the results.

13.2.2 Jig (optional)

A jig may be used to facilitate the setting, adjusting and/or measuring of segment lengths and offsets of test samples for the principal structural tests and the separate structural tests on knee locks. It shall be capable of applying the stabilizing test force F_{stab} while this is carried out.

13.2.3 Test equipment

13.2.3.1 Test equipment to perform static compression loading – (Compression testing machine or other equipment)

The test equipment shall be capable of producing static test forces at a loading rate of between 100 N/s and 250 N/s (but see NOTE) up to the values specified in Table 4 or Table D.1 and Table 8 or Table D.2 for

the relevant test procedure, test loading condition and test loading level, to be applied in the configurations specified in Tables 5 and 6 and illustrated in Figures A.1 and A.2.

NOTE For the alternative static ultimate strength test according to Annex C, increased loading rates of between 1 kN/s and 5 kN/s are considered to be appropriate.

13.2.3.2 Test equipment to perform cyclic compression loading – (Compression testing machine or other equipment)

13.2.3.2.1 The test equipment shall be capable of producing cyclic test forces up to the values specified in Table 8 or Table D.2 for the relevant test loading condition and test loading level, to be applied in the configurations specified in Tables 5 and 6 and illustrated in Figures A.1 and A.2.

13.2.3.2.2 The test equipment shall generate a single pulsating test force $F_c(t)$ as illustrated in Figure 9.

13.2.3.2.3 The waveform of the pulsating test force $F_c(t)$ generated by the test equipment shall be sinusoidal (see Figure 9). If it is certified that a sinusoidal form is not possible, then the waveform of the pulsating test force $F_c(t)$ shall be smooth with no overshoot spikes, characterized by a course corresponding to the description given in 13.2.3.2.5.

13.2.3.2.4 The test force $F_c(t)$ according to 13.2.3.2.2, 13.2.3.2.3 and Figure 9 shall be described/specified by means of any appropriate selection of the following components/parameters:

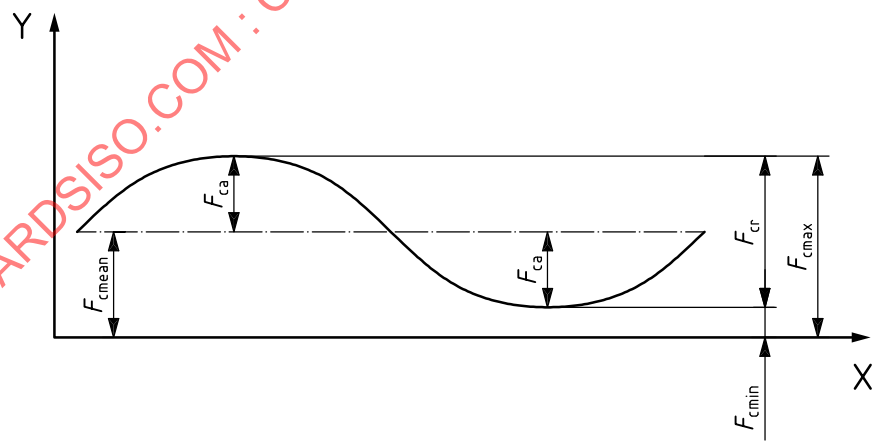
— minimum test force F_{cmin};

— range of the pulsating test force (the cyclic range), F_{cr};

— maximum test force, F_{cmax};

— mean test force F_{cmean};

— amplitude of the pulsating test force (the cyclic amplitude) F_{ca}.



Key

X	time	F_{cr}	cyclic range of test force
Y	test force	F_{ca}	cyclic amplitude of test force
F_{cmax}	maximum test force	F_{cmean}	mean test force
F_{cmin}	minimum test force		

Figure 9 — Load cycle parameters for the principal cyclic test

13.2.3.2.5 For the purposes of both designation and specification in Table 8 and several requirements in 16.3.2, the test force $F_c(t)$ shall be described as a single pulsating force, oscillating through the cyclic range F_{cr} with a minimum test force F_{cmin} to generate a maximum test force F_{cmax}, where

$$F_{cmax} = F_{cmin} + F_{cr}. \quad (5)$$

13.2.3.2.6 For the purposes of setting or programming test machines for generating the pulsating test force $F_c(t)$ as a sine wave, which normally will require the input of the values for the mean test force F_{cmean} and the cyclic amplitude F_{ca}, the test force $F_c(t)$ shall be described by the function

$$F_c(t) = F_{cmean} + F_{ca} \sin(\omega t) \text{ with } F_{cmean} = 0{,}5\,(F_{cmin} + F_{cmax}) \text{ and } F_{ca} = 0{,}5\,F_{cr}, \quad (6)$$

where $\sin(\omega t)$ describes a sine wave with the frequency $f = \omega/(2\pi)$ Hz.

13.2.3.2.7 The test equipment shall switch off if the pulsating test force $F_c(t)$ exceeds the tolerances specified in 14.3 f) and g), with the exception specified in 13.2.3.2.8.

13.2.3.2.8 If the test equipment control mechanism used to generate the pulsating test force $F_c(t)$ requires a number of cycles to achieve the waveform according to 13.2.3.2.3, during this settling in period the waveform of the test force shall be smooth with no overshoot spikes, and the highest force applied shall not exceed the maximum test force F_{cmax} by more than 10 %.

NOTE Experience has shown that the repeated loading at values exceeding the maximum test force F_{cmax} by more than 10 % can cause an early deterioration of the test sample.

13.2.3.2.9 The test equipment shall switch off if, when it is running at the prescribed load with the prescribed waveform, the distance L_{BT} (6.8.4) between the bottom and top load application points P_B and P_T at F_{cmax} or the displacement δ of the moving load application point from its reference position in the test equipment at F_{cmax} changes by more than 5 mm from its value at F_{cmax}, measured and recorded at the initial or previous occasion of start up (16.3.2.10/16.3.2.12).

13.3 Equipment for the separate static test in torsion specified in 17.1

13.3.1 Test equipment

13.3.1.1 Test equipment to perform static torsional loading

The test equipment shall be capable of applying torque in a forward and reverse direction up to the values specified in Table 9 at a loading rate not exceeding 4 N·m/s.

13.3.1.2 Measuring device

The device shall be capable of measuring the angular positions of identified parts relative to twisting about the axis of torque application.

13.4 Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2

13.4.1 Test equipment

13.4.1.1 Test equipment to perform static heel and forefoot loading

13.4.1.1.1 The test equipment shall be capable of producing static test forces at a loading rate of between 100 N/s and 250 N/s (but see NOTE) up to the values specified in Table 11 or Table D.3 for the relevant test procedure, test loading condition and test loading level, to be applied in the directions of loading determined by the angles α and β specified in Table 10, as illustrated in Figure 7.

NOTE For the alternative static ultimate strength test according to Annex C, increased loading rates of between 1 kN/s and 5 kN/s are considered to be appropriate.

13.4.1.1.2 The static test forces shall be transmitted to the heel and forefoot portion by a loading platform (loading platforms), which can be adjusted perpendicular to the direction of loading determined by angle α for heel loading and perpendicular to the direction of loading determined by angle β for forefoot loading.

The loading platform(s) shall incorporate appropriate means that minimize the transmission of transverse forces (see Figure 7).

13.4.1.1.3 The loading platform(s) of the test equipment shall have sufficient length to allow simultaneous heel and forefoot contact on one and the same platform.

13.4.1.1.4 Test equipment with a twin actuator set-up shall allow the arrangement

a) of the heel loading platform so that it supports the forefoot if heel loading deforms the test sample to such an extent that forefoot support is necessary to avoid unrealistic conditions of loading and

b) of the forefoot loading platform so that it supports the heel if forefoot loading deforms the test sample to such an extent that heel support is necessary to avoid unrealistic conditions of loading.

13.4.1.1.5 As a consequence of 13.4.1.1.4, test equipment with a twin actuator set-up shall ensure that

a) during a test in heel loading the forefoot cannot contact the forefoot loading platform and

b) during a test in forefoot loading the heel cannot contact the heel loading platform.

13.4.1.2 Test equipment to perform cyclic heel and forefoot loading

13.4.1.2.1 The test equipment shall be capable of producing cyclic test forces up to the values specified in Table 11 or Table D.3 for the relevant test loading condition and test loading level, to be applied in the directions of loading determined by the angles α and β specified in Table 10, as illustrated in Figure 7.

13.4.1.2.2 The cyclic test forces shall be transmitted to the heel and forefoot portion by a loading platform (loading platforms), which can be adjusted perpendicular to the direction of loading determined by angle α for heel loading and perpendicular to the direction of loading determined by angle β for forefoot loading.

The loading platform(s) shall incorporate appropriate means that minimize the transmission of transverse forces (see Figure 7).

13.4.1.2.3 The test equipment shall generate two pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ as illustrated in Figure 10.

13.4.1.2.4 The waveform of the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ generated by the test equipment shall be sinusoidal [see Figure 10 a), b) and c)]. If it is certified that a sinusoidal form is not possible, then the waveform of the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ shall be smooth with no overshoot spikes, characterized by a course corresponding to the description given in 13.4.1.2.6.

13.4.1.2.5 The test forces $F_{1c}(t)$ and $F_{2c}(t)$ according to 13.4.1.2.3, 13.4.1.2.4 and Figure 10 a), b) and c) shall be described/specified by means of any appropriate selection of the following components/parameters:

— minimum test forces, F_{1cmin}, F_{2cmin};

— ranges of the pulsating test forces (the cyclic ranges), F_{1cr}, F_{2cr};

— maximum test forces F_{1cmax}, F_{2cmax};

— mean test forces, F_{1cmean}, F_{2cmean};

— amplitudes of the pulsating test forces (the cyclic amplitudes) F_{1ca}, F_{2ca}.

13.4.1.2.6 For the purposes of both designation and specification in Table 11 and several requirements in 17.2.5.1, the test forces $F_{1c}(t)$ and $F_{2c}(t)$ shall be described as single pulsating forces, oscillating through the cyclic ranges F_{1cr} and F_{2cr} with the minimum test forces F_{1cmin} and F_{2cmin} to generate the maximum test forces F_{1cmax} and F_{2cmax}, where

$$F_{1cmax} = F_{1cmin} + F_{1cr} \quad (7a)$$

$$F_{2cmax} = F_{2cmin} + F_{2cr} \quad (7b)$$

13.4.1.2.7 For the purposes of setting or programming test machines for generating the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ as sine waves or portions of them, which normally will require the input of the values for the mean test forces F_{1cmean} and F_{2cmean} and the cyclic amplitudes F_{1ca} and F_{2ca}, the test forces $F_{1c}(t)$ and $F_{2c}(t)$ shall be described by the functions:

$$F_{1c}(t) = F_{1cmean} + F_{1ca} \sin(\omega t) \text{ with } F_{1cmean} = 0{,}5\,(F_{1cmin} + F_{1cmax}) \text{ and } F_{1ca} = 0{,}5\,F_{1cr} \quad (8a)$$

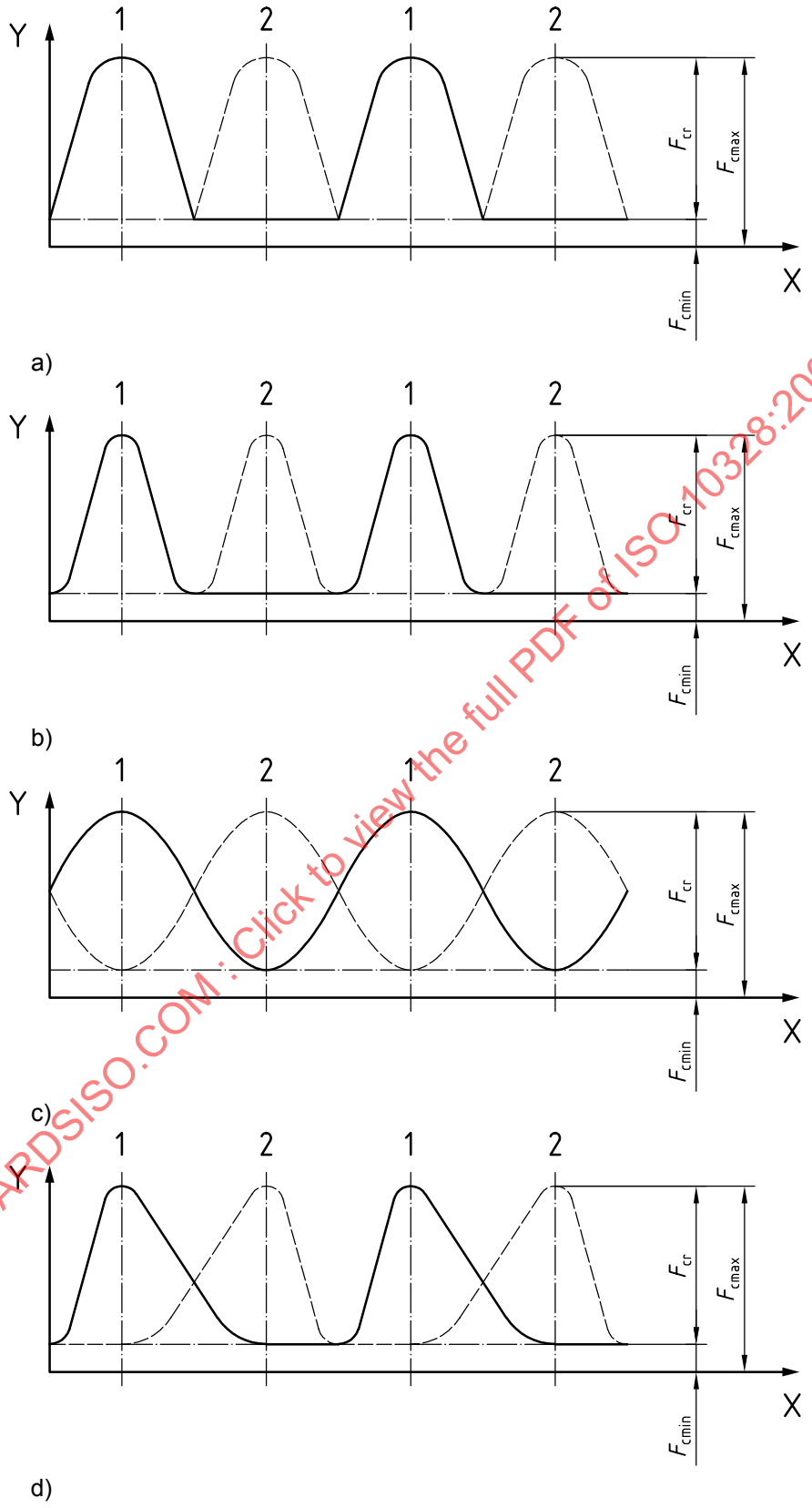
$$F_{2c}(t) = F_{2cmean} + F_{2ca} \sin(\omega t - n\pi) \text{ with } F_{2cmean} = 0{,}5\,(F_{2cmin} + F_{2cmax}) \text{ and } F_{2ca} = 0{,}5\,F_{2cr} \quad (8b)$$

where $\sin(\omega t)$ describes a sine wave with the frequency $f = \omega/(2\pi)$ Hz, and $(\omega t - n\pi)$ indicates that $F_{2c}(t)$ is generated with a phase shift, which corresponds to a half period of the sine wave for $n = 1$ [Figures 10 a) and c)] and a full period of the sine wave for $n = 2$ [Figure 10 b)].

13.4.1.2.8 The test equipment shall switch off if the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ exceed the tolerances specified in 14.3 f) and g), with the exception specified in 13.4.1.2.9.

13.4.1.2.9 If the test equipment control mechanism used to generate the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ requires a number of cycles to achieve the waveform according to 13.4.1.2.4, during this settling in period the waveform shall be smooth with no overshoot spikes, and the highest force applied to the heel or forefoot portion shall not exceed the maximum test force F_{1cmax} or F_{2cmax} by more than 10 %.

NOTE Experience has shown that the repeated loading at values exceeding the maximum test force F_{1cmax} or F_{2cmax} by more than 10% can cause an early deterioration of the test sample.



NOTE Background information on the different loading profiles illustrated in a) to d) is given in Annex F.

Key

X	time	1	heel load
Y	test force	2	forefoot load

Figure 10 — Load cycle parameters for the separate cyclic test for ankle-foot devices and foot units

13.5 Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3

13.5.1 Extension pieces

For the application of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, all test samples shall have extension pieces attached above and below the knee unit, to represent wholly or in part the thigh and shin portion.

The posterior shape of the extension pieces shall be of the smallest dimensions possible in accordance with the manufacturer's instructions, so that the test sample reaches the highest possible value of knee flexion occurring in a normal prosthesis (see 10.6.4).

The stiffness of the extension pieces shall not be less than the stiffness of the thigh and shin portion of a normal prosthesis which they represent wholly or in part.

13.5.2 Test equipment to perform static compression loading – (Compression testing machine or other equipment)

The test equipment shall be capable of producing static test forces at a loading rate of between 100 N/s and 250 N/s up to the value specified in Table 12, to be applied in the configuration specified in Table 12 and illustrated in Figure 8.

13.6 Equipment for the separate tests on knee locks specified in 17.4

13.6.1 End attachments

For the application of the test loading condition for the separate structural tests on knee locks, the test sample set-up requires the use of end attachments, consisting of load application levers and non-prosthetic extension pieces.

The end attachments shall not enhance or reduce the stresses due to the specified test loads in the structure under test.

The end attachments shall satisfy the requirements of the proof test of end attachments specified in 13.2.1.2.

13.6.2 Jig (optional)

See 13.2.2.

13.6.3 Test equipment

13.6.3.1 Test equipment to perform static compression loading – (Compression testing machine or other equipment)

The test equipment shall be capable of producing static test forces at a loading rate of between 100 N/s and 250 N/s up to the values specified in Tables 4 and 14 for the relevant test procedure, to be applied in the configuration specified in Tables 5 and 13.

13.6.3.2 Test equipment to perform cyclic compression loading – (Compression testing machine or other equipment)

13.6.3.2.1 The test equipment shall be capable of producing cyclic test forces up to the values specified in Table 14, to be applied in the configuration specified in Tables 5 and 13.

13.6.3.2.2 The cyclic test forces shall satisfy the requirements of 13.2.3.2.2 to 13.2.3.2.9 with the following exceptions:

a) the description of the test force $F_{c(t)}$ given in 13.2.3.2.5 for the purposes of both designation and specification shall apply to Table 14 and several requirements in 17.4.5.1.

b) the limit of change in the distance L_{BT} (6.8.4) between the bottom and top load application points P_B and P_T at F_{cmax} or the displacement δ of the moving load application point from its reference position in the test equipment at F_{cmax}, referred to in the switch-off requirement of 13.2.3.2.9, shall be measured and recorded at the initial or previous occasion of start-up according to 17.4.5.1.11/17.4.5.1.13.

14 Accuracy

14.1 General

Details of methods used to measure accuracy shall be recorded.

The test equipment, any jig used for alignment and/or measurement and any devices used to measure loads and dimensions shall be calibrated at least annually and whenever any part is replaced. Records of the calibration shall be maintained.

14.2 Accuracy of equipment

In order to meet the accuracy of procedure specified in 14.3, the test equipment, any jig used for the setting-up of test samples and any measuring devices should be capable of measuring a) to d) to the accuracy specified:

a) linear dimensions to an accuracy of ± 0,2 mm,

b) angular dimensions to an accuracy of ± 0,2°,

c) test forces and moments to an accuracy of ± 1 % of the highest value required in the test, and

d) the frequency of cyclic tests to an accuracy of ± 1 % of the test frequency used.

14.3 Accuracy of procedure

a) Linear dimensions, except segment lengths, shall be initially set and finally adjusted with a tolerance of ± 1 mm.

b) Segment lengths shall be set with a tolerance of ± 2 mm.

c) Angular dimensions, except the angular “toe-out” position of prosthetic feet, shall be set with a tolerance of ± 1°.

d) The angular “toe-out” position of prosthetic feet shall be set with a tolerance of ± 3°.

e) Static test forces and moments shall be applied with a tolerance of ± 2 % of the highest value prescribed for the test.

NOTE It has been found suitable and sufficiently accurate to use the weight of a mass of 5 kg to develop the stabilizing test force F_{stab} in any jig used for the adjustment and/or measurement of offsets at F_{stab} in the upright position of the test sample.

f) Pulsating test forces $F_c(t)$ shall be applied at the instant of F_{cmin} with a tolerance of ± 25 N and at the instant of F_{cmax} with a tolerance of ± 3 % of the value prescribed for F_{cmax}.

g) The frequency of cyclic tests shall be controlled with a tolerance of ± 10 % of the test frequency used.

h) The distance L_{BT} between the load application points or the displacement δ of the moving load application point shall be controlled with a tolerance of ± 1 mm.

15 Test principles

15.1 General

The test methods specified in this International Standard use static and cyclic strength tests which typically produce compound loadings by the application of a single test force.

The static tests relate to the worst loads generated in any activity. The cyclic tests relate to normal walking activities where loads occur regularly with each step.

15.2 Static test procedure

The static test procedure (e.g. 16.2) consists of a proof test (16.2.1) and an ultimate strength test (16.2.2). This test procedure is carried out to determine the performance of the load-bearing structures under typical severe loading conditions that can occur during use by users as occasional single events.

15.3 Cyclic test procedure

The cyclic test procedure (e.g. 16.3) consists of repeated applications of a prescribed load to a test sample with loading conditions typical of normal walking, followed by a final static test (16.3.1.3) for which the loading and unloading procedures of the relevant static proof test (16.2.1) apply.

16 Test procedures – Principal structural tests

16.1 Test loading requirements

16.1.1 Preparation for test loading

The preparation for loading shall proceed as follows.

a) The test sample shall be assembled to a fixed length using end attachments consisting of extension pieces as required and the load application levers (see 10.2, 10.3 and Table 5).

b) In order to establish the position of the line of application of the test force as described in 7.1.2, the test sample shall be set up in the test equipment with the bottom and top load application levers having a combination of forward/backward and outward/inward offsets (see 10.5 and Table 6). Figure 11 shows the geometry for a left leg and Figure 12 gives all the formulae for the calculation of theoretical offsets.

NOTE 1 The preparation for test loading described in a) and b) applies, in principle, also to the separate tests for knee locks (see 17.4).

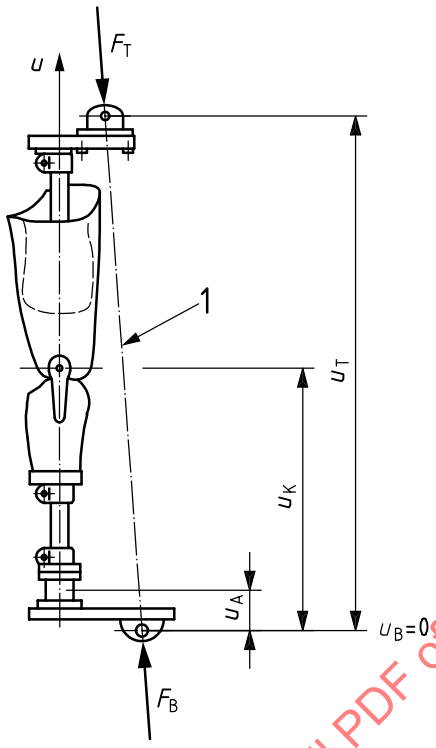
NOTE 2 For some prosthetic designs it may not be possible to set up a test sample in accordance with these requirements. Special test set-ups may then be used in certain cases (see also 10.2.3).

16.1.2 Application of test loading

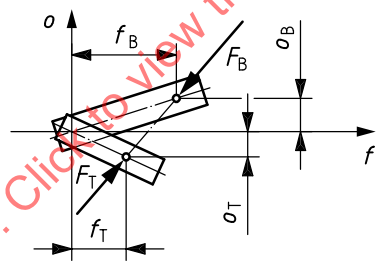
The loading shall be applied in the two test loading conditions I and II described in 7.1.2 and specified in Tables 6, 7 and 8 and illustrated in Figures A.1 and A.2.

No readjustments shall be made to the load application levers if the deflection of the test sample alters the values of the offsets at knee or ankle under these test loading conditions.

NOTE The second requirement also applies, in principle, to the extension pieces of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (see 17.3) and to the load application levers of the separate tests for knee locks (see 17.4).



a) side view

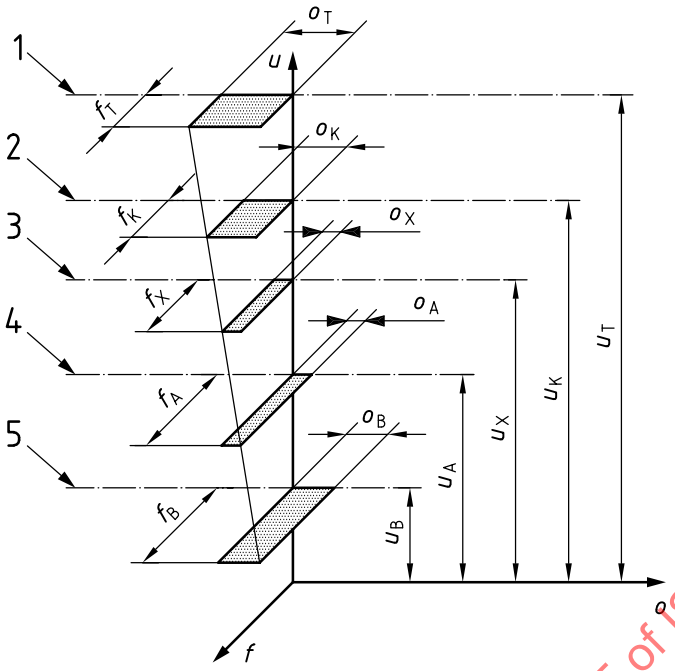


b) top view

Key

1 load line

Figure 11 — Illustration of test loading principle applied to a knee unit with attachments, aligned to simulate a left-sided test sample (see 16.1.1)



Key

1 top reference plane, T
2 knee reference plane, K
3 plane at any height $u = u_X$
4 ankle reference plane, A
5 bottom reference plane, B

$$f_X = f_K + \left\{ \frac{(f_K - f_A)(u_X - u_K)}{(u_K - u_A)} \right\} \quad \text{or} \quad f_X = f_A + \left\{ \frac{(f_K - f_A)(u_X - u_A)}{(u_K - u_A)} \right\} \tag{9}$$

$$o_X = o_K + \left\{ \frac{(o_K - o_A)(u_X - u_K)}{(u_K - u_A)} \right\} \quad \text{or} \quad o_X = o_A + \left\{ \frac{(o_K - o_A)(u_X - u_A)}{(u_K - u_A)} \right\} \tag{10}$$

Figure 12 — Method of calculating offsets at any height $u = u_X$
(see 16.1.1)

16.2 Principal static test procedure

16.2.1 Principal static proof test

16.2.1.1 Test method

16.2.1.1.1 Subject to request in the test submission document [see 12.3.5 d)] or agreement between the manufacturer/submitter and the test laboratory/facility, the principal static proof test may be covered by the final static test to be applied to a test sample which has completed the principal cyclic test without failing (see 16.3.1.3 and 16.3.2.17). This requires the application of the final static test in the manner specified in 16.2.1.1.6 to 16.2.1.1.9.

The principal static proof test may also be carried out as part of the alternative static ultimate strength test specified in Annex C [see also 16.2.2.1, Clause C.1 and C.2 c)].

The setting, adjustment and/or measurement of segment lengths and/or offsets [see 16.2.1.1.2, 16.2.1.1.5 and 16.2.1.1.8 b)] shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing force F_{stab} (see 13.2.2).

NOTE A flowchart for this test is shown in Figure 13.

16.2.1.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6.

If a test sample which has completed the principal cyclic test procedure (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6 (see also 16.2.1.1.12). Record the re-use of the test sample.

Record the test loading condition and the test loading level to be applied, together with the corresponding values of offsets and test forces. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K) (see 6.8.1) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 16.2.1.1.3.

Record whether a special jig is used.

16.2.1.1.3 Apply to the test sample the settling test force F_{set} of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2.

Maintain the force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period of not less than 10 min and not more than 20 min before proceeding with 16.2.1.1.4. Record the time at rest.

16.2.1.1.4 Apply to the test sample and maintain during the adjustments of 16.2.1.1.5 and the measurements and recording of 16.2.1.1.6 the stabilizing test force F_{stab}, specified in Table 8 or Table D.2.

If the adjustments of 16.2.1.1.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig upon transfer of the test sample from the test equipment to the jig after having completed 16.2.1.1.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 16.2.1.1.6.

Record whether a special jig is used.

16.2.1.1.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6, at the stabilizing test force, F_{stab}.

Record the final values of offsets set.

16.2.1.1.6 Carry out the following.

a) Measure and record the distance L_{BT} (see 6.8.4) as L_4 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_4.

b) If requested by the manufacturer/submitter, measure and record the effective lever arms L_A and L_K (see 6.8.3).

Take into account that the data to be acquired are irrelevant to the performance requirements of 16.2.1.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 16.2.1.1.8 b) particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated.

16.2.1.1.7 Increase the test force, F smoothly at a rate of between 100 N/s and 250 N/s to the proof test force F_{sp} of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2.

Maintain this force, F_{sp}, at the prescribed value for (30 ± 3) s.

Decrease the test force F to F_{stab}.

If the test sample sustains the static loading at F_{sp} for the prescribed time, record this and proceed with 16.2.1.1.8.

If the test sample fails to sustain the static loading at F_{sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force F_{sp} has been maintained and terminate the test (but see 16.2.1.1.12).

16.2.1.1.8 Maintain (or, if a special jig is used, apply and maintain) the stabilizing test force F_{stab} until the measurements and records of a) [and b)] specified below are completed.

a) Measure and record the distance L_{BT} as L_5 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_5. Complete the measurement within 5 min (see NOTE).

b) If requested by the manufacturer/submitter, measure and record the offsets f_A, f_K, o_A and o_K, and/or the effective lever arms L_A and L_K. Complete the measurements within 15 min (see NOTE).

Take into account that the data to be acquired are irrelevant to the performance requirements of 16.2.1.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 16.2.1.1.6 b) particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated.

If the measurements of b) are carried out with the test sample placed in a special jig, remove the stabilizing test force F_{stab} and re-apply it by the jig upon transfer of the test sample from the test equipment to the jig after having completed a).

Note and record the interval of time after decreasing the test force F to F_{stab} (16.2.1.1.7), at which each of the measurements of a) and b) is taken.

Record whether a special jig is used.

NOTE The time limits are set in order to limit the effect of recovery on the permanent deformation (16.2.1.1.9) and on the ankle and knee offsets and effective lever arms. The different values of time limit specified for the measurements of a) and b) take account of the different time required for the measurement and recording.

16.2.1.1.9 Calculate and record the permanent deformation, D_3, between the bottom and top load application points:

$$D_3 = L_4 - L_5 \quad \text{or} \quad D_3 = \delta_5 - \delta_4. \tag{11}$$

16.2.1.1.10 Decide and record whether the test sample has passed or failed the test procedure specified in 16.2.1.1.2 to 16.2.1.1.9, checking the results of steps 16.2.1.1.7 and 16.2.1.1.9 against the performance requirements of 16.2.1.2.

16.2.1.1.11 If the test sample fails to satisfy either of the performance requirements of 16.2.1.2, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.2.1.1.12 If a test sample, which has already completed the principal cyclic test procedure without failing (see 16.2.1.1.2), fails to satisfy either of the performance requirements of 16.2.1.2, repeat the test on a substitute test sample and record the failure and the repetition, including all specific records called for.

16.2.1.2 Performance requirements

In order to pass the principal static proof test, a test sample shall satisfy the following performance requirements.

a) The test sample shall sustain static loading by the proof test force F_{sp} at the prescribed value for (30 ± 3) s.

b) The value of permanent deformation D_3 of the test sample shall not exceed

- 5 mm for a total sample length $(u_T - u_B)_{specified}$ = 650 mm or
- 5 mm multiplied by the ratio $[(u_T - u_B)_{actual}/(u_T - u_B)_{specified}]$ for values of total sample length exceeding 650 mm (see Footnote b of Table 5).

If any individual prosthetic component fails to satisfy either of the requirements specified in a) and b), this constitutes a failure only in the prosthetic assembly and alignment simulated in the test sample set-up.

16.2.1.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the principal static proof test of this International Standard according to 16.2.1.2 at a specific test loading level, tests of this type shall be passed (in the meaning of 16.2.1.2) in each of the test loading conditions I and II by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 16.2.1.1.12 (see 9.4 and Table 16).

Compliance with the performance requirements of the principal static proof test can also be claimed, if the final static test (16.3.1.3/16.3.2.17) as part of the principal cyclic test procedure (16.3) is applied in the manner specified in 16.2.1.1.6 to 16.2.1.1.9 (see also 16.3.3 and 16.3.4).

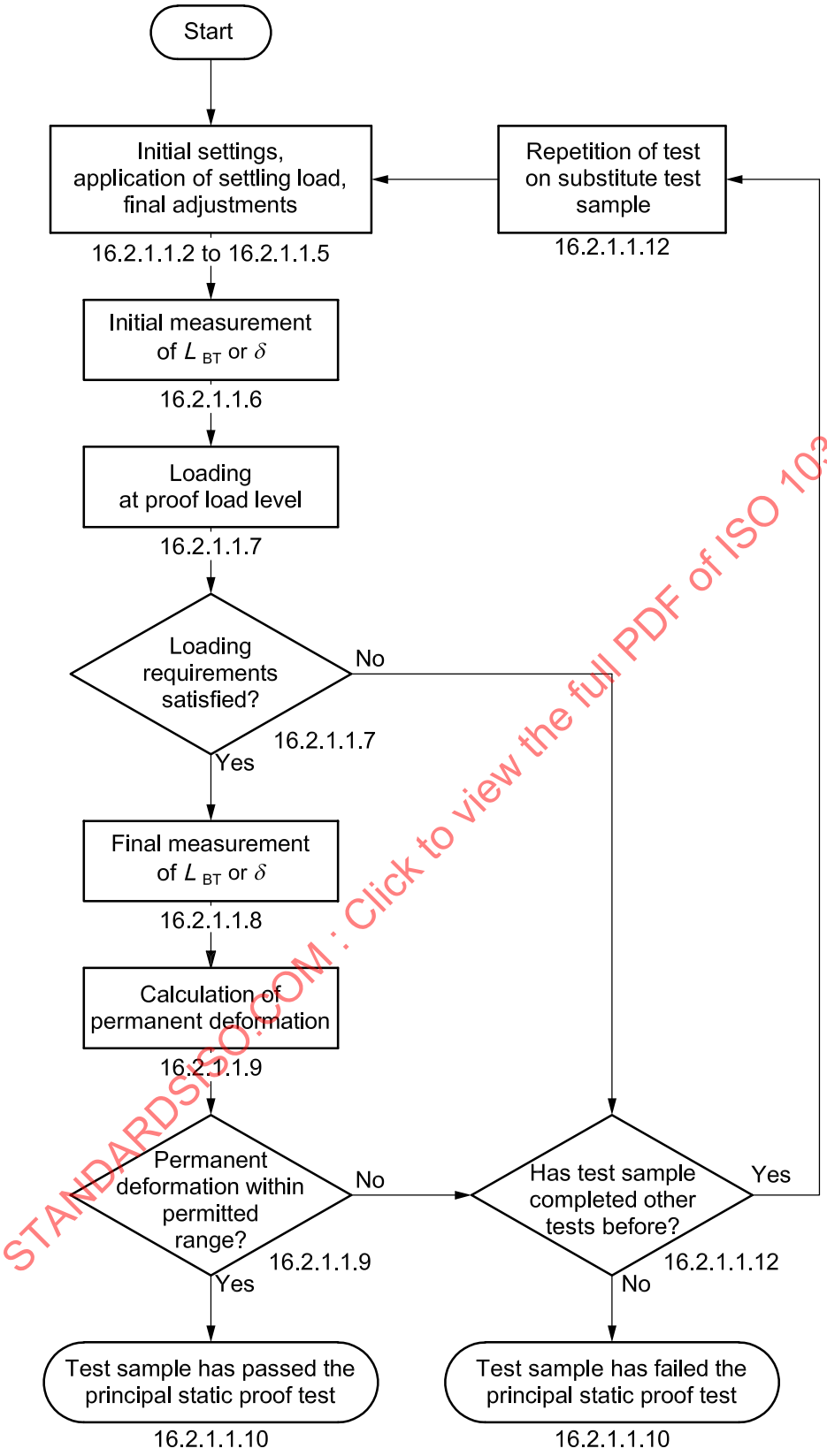


Figure 13 — Flowchart for the principal static proof test, specified in 16.2.1.1

16.2.2 Principal static ultimate strength test

16.2.2.1 Test method

16.2.2.1.1 The setting and/or adjustment of segment lengths and/or offsets (see 16.2.2.1.2 and 16.2.2.1.5) shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing test force F_{stab} (see 13.2.2).

For test samples of lower limb prostheses with material properties and/or construction features which render them unable to sustain the required ultimate test force at a rate of loading of between 100 N/s and 250 N/s, specified in 16.2.2.1.6, Annex C offers guidance on the application of an alternative static ultimate strength test, in which a higher rate of loading is applied to the sample.

The higher rate of loading shall either be specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed between the manufacturer/submitter and the test laboratory/facility (see also 16.2.2.1.6) and may be applied to the initial test sample or to a substitute test sample, if the initial test sample has failed at a rate of loading of between 100 N/s and 250 N/s (see 16.2.2.1.10).

NOTE A flowchart for this test is shown in Figure 14.

16.2.2.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6.

If a test sample which has completed the principal static proof test without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6 (see also 16.2.2.1.9). Record the re-use of the test sample.

If a test sample which has completed the principal cyclic test procedure (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6 (see also 16.2.2.1.9). Record the re-use of the test sample.

Record the test loading condition and test loading level to be applied, together with the corresponding values of offsets and test forces. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K) (see 6.8.1) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 16.2.2.1.3.

Record whether a special jig is used.

16.2.2.1.3 Apply to the test sample the settling test force F_{set} of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2.

Maintain this force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period not less than 10 min and not more than 20 min before proceeding with 16.2.2.1.4. Record the time at rest.

16.2.2.1.4 Apply to the test sample and maintain during the adjustments of 16.2.2.1.5 the stabilizing test force F_{stab}, specified in Table 8 or Table D.2.

If the adjustments of 16.2.2.1.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig upon transfer of the test sample from the test equipment to the jig after having completed 16.2.2.1.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 16.2.2.1.6.

Record whether a special jig is used.

16.2.2.1.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6, at the stabilizing test force F_{stab}.

Record the final values of offsets set.

16.2.2.1.6 Increase the test force F smoothly at a rate of between 100 N/s and 250 N/s until the test sample fails, or the test force F attains the value of the ultimate test force $F_{su,\ upper\ level}$ of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2, without failure of the test sample.

If appropriate, apply the test force F at a higher rate of loading, specified by or agreed with the manufacturer/submitter in accordance with Annex C (see 16.2.2.1.1).

Record the highest value of the test force F reached during the test and whether failure has occurred. Make specific reference if the test force F is to be applied at a higher rate of loading.

If expressly requested by the manufacturer/submitter, or if requested in the test submission document [see 12.3.4 a)], continue the principal static ultimate strength test after the test sample has withstood the ultimate test force $F_{su,\ upper\ level}$ until failure actually occurs and record the value of the load at failure.

Take into account that in this case the end attachments used need a higher value of stiffness and ensure that the values of their deflection and permanent deformation keep within the limits specified in 13.2.1.2.10 at a higher proof load than is specified in Table 4 or Table D.1 for the test loading level to be applied.

16.2.2.1.7 Decide and record whether the test sample has passed or failed the test procedure specified in 16.2.2.1.2 to 16.2.2.1.6, checking the results of step 16.2.2.1.6 against the performance requirements of 16.2.2.2.

Take into account that, according to C.2 c), a test sample that has passed the test procedure specified in 16.2.2.1.21 to 16.2.2.1.6 with step 16.2.2.1.6 applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex C (see also 16.2.2.1.1), subsequently shall pass the principal static proof test specified in 16.2.1.1 in the relevant test loading condition and at the relevant test loading level, in order to satisfy the requirements of the alternative static ultimate strength test (see also 16.2.2.3).

16.2.2.1.8 If the test sample fails to satisfy any of the performance requirements of 16.2.2.2, inspect it to detect the nature and, if possible the location of any damage and record the results.

16.2.2.1.9 If a test sample, which has already completed the principal static proof test and/or the principal cyclic test procedure without failing (see 16.2.2.1.2), fails to satisfy either of the performance requirements of 16.2.2.2, repeat the test on a substitute test sample and record the failure and the repetition, including all specific records called for.

16.2.2.1.10 OPTION — If a test sample fails this test at a rate of loading of between 100 N/s and 250 N/s, specified in 16.2.2.1.6, the test may be repeated on a substitute test sample at an increased rate of loading in accordance with Annex C, specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed between the manufacturer/submitter and the test laboratory/facility. The failure and the repetition shall be recorded, including all specific records called for.

16.2.2.2 Performance requirements

In order to pass the principal static ultimate strength test, a test sample shall satisfy one of the following performance requirements:

a) the test sample shall sustain static loading by the ultimate test force F_{su} at the value prescribed for $F_{su,\ upper\ level}$ without failing or

b) if the mechanical characteristics of the test sample prevent the requirement of a) to be satisfied, the maximum value of the ultimate test force F_{su} sustained by the test sample without loss of its structural integrity shall be equal to or greater than the value prescribed for $F_{su,\ lower\ level}$.

If any individual prosthetic component fails to satisfy either of the requirements specified in a) and b), this constitutes a failure only in the prosthetic assembly and alignment simulated in the test sample set-up.

16.2.2.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the principal static ultimate strength test of this International Standard according to 16.2.2.2 at a specific test loading level, the following shall apply.

a) If the test force F has been applied at a rate of between 100 N/s and 250 N/s, tests of this type shall be passed (in the meaning of 16.2.2.2) in each of the test loading conditions I and II by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 16.2.2.1.9 (and also by 16.2.2.1.10 as an option) (see 9.4 and Table 16).

b) If the test force F has been applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex C (see 16.2.2.1.1 and 16.2.2.1.6), the compliance condition of a) shall apply provided that the same test samples also pass (in the meaning of 16.2.1.2) the principal static proof test of this International Standard in the relevant test loading condition and at the relevant test loading level (see 16.2.2.1.7 and Annex C).

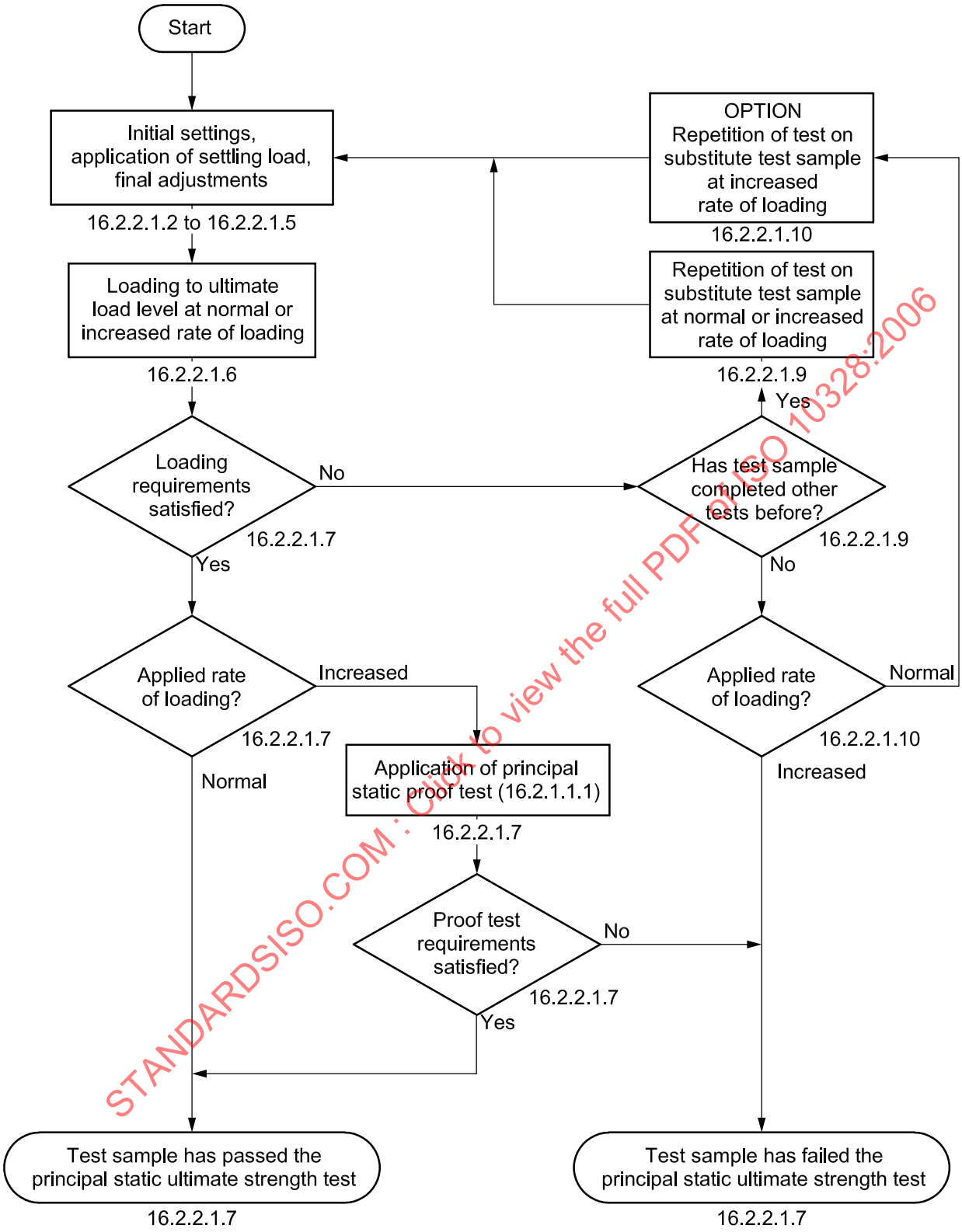


Figure 14 — Flowchart for the principal static ultimate strength test, specified in 16.2.2.1

16.3 Principal cyclic test procedure

16.3.1 General requirements

16.3.1.1 If the test frequency selected is higher than 1 Hz, then the maximum frequency shall be below the level at which dynamic mass effects or specific material characteristics (e.g. creep at increased temperatures or relaxation) begin to affect the maximum load value or the waveform.

16.3.1.2 During the course of the cyclic test, specified parts shall be replaced when the number of cycles has reached a value at which such replacement is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b)]. All such replacements shall be recorded.

16.3.1.3 A test sample that completes the cyclic test without failing shall be subjected to final static loading by the test force F_{fin}, applied at a rate of between 100 N/s and 250 N/s and maintained for (30 ± 3) s.

Subject to request in the test submission document [see 12.3.5 d)] or agreement between the manufacturer/submitter and the test laboratory/facility, the final static test may also cover the principal static proof test, if applied without re-alignment of the test sample in the manner specified in 16.2.1.1.6 to 16.2.1.1.9.

16.3.1.4 A test sample that fails and/or a test sample that completes the cyclic test without failing shall, at the request of the manufacturer/submitter, be visually examined at the magnification specified in the test submission document [see 12.3.5 c)], and the presence, location and nature of any fractures and/or cracks be recorded, together with the magnification used.

16.3.2 Test method

16.3.2.1 The setting, adjustment and/or measurement of segment lengths and/or offsets [see 16.3.2.2, 16.3.2.5, (16.3.2.16 and 16.3.2.17)] shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing test force F_{stab} (see 13.2.2).

NOTE A flowchart for this test is shown in Figures 15 to 17.

16.3.2.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 16.1.1 and Tables 5 and 6.

Record the test loading condition and the test loading level to be applied, together with the corresponding values of offsets, test forces and prescribed number of cycles. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K) (see 6.8.1) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 16.3.2.3.

Record whether a special jig is used.

16.3.2.3 Apply to the test sample the settling test force F_{set} of the relevant test loading condition and test loading level specified in Table 8 or Table D.2.

Maintain this force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period not less than 10 min and not more than 20 min before proceeding with 16.3.2.4. Record the time at rest.

16.3.2.4 Apply to the test sample and maintain during the adjustments of 16.3.2.5 and the measurements and recording of 16.3.2.6 the stabilizing test force F_{stab}, specified in Table 8 or Table D.2.

If the adjustments of 16.3.2.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig upon transfer of the test sample from the test equipment to the jig after having completed 16.3.2.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 16.3.2.6.

Record whether a special jig is used.

16.3.2.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values for the relevant test loading condition and test loading level, specified in Table 6, at the stabilizing test force F_{stab}.

Record the final values of offsets set.

16.3.2.6 Carry out the following.

a) Measure and record the distance L_{BT} (see 6.8.4) as L_6 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_6.

b) If requested by the manufacturer/submitter, measure and record the effective lever arms L_A and L_K (see 6.8.3).

   Take into account that the data to be acquired are irrelevant to the performance requirements of 16.3.3, although they may provide interesting and useful information in conjunction with the data to be acquired according to 16.3.2.8 b), 16.3.2.16 and 16.3.2.17 particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/ submitter, as indicated.

16.3.2.7 Apply to the test sample the maximum test force F_{cmax} of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2.

Maintain this force, F_{cmax}, until step 16.3.2.8 is completed.

16.3.2.8 Carry out the following.

a) Measure and record the distance L_{BT} as L_7 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_7.

b) If requested by the manufacturer/submitter, measure and record the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K.

   Take into account that the data to be acquired are irrelevant to the performance requirements of 16.3.3, although they may provide interesting and useful information in conjunction with the data to be acquired according to 16.3.2.6 b), 16.3.2.16 and 16.3.2.17 particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated.

16.3.2.9 Decrease the test force F to the minimum test force F_{cmin} specified in Table 8 or Table D.2.

If the test sample sustains the static loading at F_{cmax} until step 16.3.2.8 is completed, proceed with 16.3.2.10.

If the test sample fails to sustain the static loading at F_{cmax} until step 16.3.2.8 is completed, record this together with the highest value of test force reached or the time for which the prescribed value of the maximum test force F_{cmax} has been maintained and terminate the test.

16.3.2.10 Apply to the test sample the pulsating test force $F_c(t)$ in accordance with the requirements of 13.2.3.2 and 16.3.1.1 and the values for the relevant test loading condition and test loading level, specified in Table 6, at the frequency called for in the test submission document [see 12.3.5 a)] for a series of cycles, to allow the test sample and the test equipment to "settle down" (see NOTE 1).

NOTE 1 The number of cycles required for the test to settle down will depend on the nature of the test sample and the test equipment control mechanism.

Take care that during this settling in period the highest force applied to the test sample does not exceed the maximum test force F_{cmax} by more than 10 % (see 13.2.3.2.8 and NOTE 2).

NOTE 2 Experience has shown that the repeated loading at values exceeding the maximum test force F_{cmax} by more than 10 % can cause an early deterioration of the test sample.

Do not proceed with 16.3.2.11 until the test sample and the test equipment have settled down, and the pulsating test force $F_c(t)$ has achieved the waveform specified in 13.2.3.2.3 and keeps within the tolerances specified in 14.3 f) and g).

Stop the test equipment and record the frequency called for together with the number of cycles required to settle down and whether the pulsating test force $F_c(t)$ is applied in accordance with 13.2.3.2.3 and 14.3 f) and g).

If the frequency called for cannot be achieved or does not allow the pulsating test force $F_c(t)$ to be applied as specified, repeat the preceding steps of 16.3.2.10 at a different frequency, to be agreed upon between the test laboratory/facility and the manufacturer/submitter.

Record any agreement on a frequency differing from the value called for.

If the pulsating test force $F_c(t)$ cannot be applied at any frequency agreed between the test laboratory/facility and the manufacturer/submitter, record this and terminate the test.

16.3.2.11 Apply to the test sample the maximum test force F_{cmax}.

Measure and record the initial value of the distance L_{BT} as L_8 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_8.

16.3.2.12 Decrease the test force F to the minimum test force F_{cmin}.

16.3.2.13 Apply to the test sample the pulsating test force $F_c(t)$ in accordance with the requirements of 13.2.3.2 and 16.3.1.1 and the values for the relevant test loading condition and test loading level, specified in Table 8, at the frequency called for in the test submission document [see 12.3.5 a)] or at a different frequency agreed between the test laboratory/facility and the manufacturer/submitter (see 16.3.2.10) for the prescribed number of cycles specified in Table 8 or Table D.2.

Inspect the waveform of the applied pulsating test force $F_c(t)$. Terminate the test if the waveform does not comply with 13.2.3.2.3.

Record the frequency applied, together with the results of the inspection of the waveform and the decision on the continuation of the test.

Set the test equipment displacement trip to 5 mm below the value of the initial distance L_8 at F_{cmax} or 5 mm above the value of the initial displacement δ_8 at F_{cmax}, determined in 16.3.2.11.

16.3.2.14 Record the durations and reasons for all occurrences of switch-off, together with the number of cycles of load applied up to that time.

16.3.2.15 Examine the test sample for damage if the test equipment has switched off due to excessive displacement and proceed as follows.

a) If there is no sign of failure, restart the test from 16.3.2.10 and apply the prescribed number of cycles reduced by the number of cycles completed before the test equipment tripped. Record the restart.

b) If the test sample has failed, record this together with the number of cycles at switch-off and terminate the test (but see 16.3.2.22).

16.3.2.16 During the course of the cyclic test, replace any parts which would be replaced in normal service. Proceed as follows.

Stop the test equipment when the number of cycles of load has reached a value at which the exchange/replacement of these parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b) and 16.3.1.2]. Record the number of cycles at shutdown.

Measure and record the distance L_{BT} or the displacement δ and, if requested by the manufacturer/submitter [note the additional instructions of 16.3.2.6 b) and 16.3.2.8 b)], the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K with the test force F_{cmin} applied and subsequently with the test force F_{cmax} applied.

Exchange/replace the specified parts in accordance with the manufacturer's/submitter's service instructions and/or the test submission document.

Restart the test from 16.3.2.2, 16.3.2.3 or 16.3.2.10, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

Record the details of the exchange/replacement and the resulting conditions of the restart, together with the number of the corresponding clause.

16.3.2.17 Continue the test until failure occurs or the prescribed number of cycles specified in Table 8 or Table D.2 has been completed.

If failure occurs, record this together with the number of cycles at switch-off of the test equipment and terminate the test (but see 16.3.2.22).

If the prescribed number of cycles has been completed, stop the test equipment and measure and record the distance L_{BT} or the displacement δ and, if requested by the manufacturer/submitter [note the additional instructions of 16.3.2.6 b) and 16.3.2.8 b)], the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K with the test force F_{cmin} applied and subsequently with the test force F_{cmax} applied. Record the number of cycles at shutdown.

16.3.2.18 Subject a test sample that completes the cyclic test without failing to the final static test force F_{fin} of the relevant test loading condition and test loading level, specified in Table 8 or Table D.2, applied at a rate of between 100 N/s and 250 N/s and maintained for (30 ± 3) s (see 16.3.1.3) and record the results.

If the test sample fails to sustain the final static loading at F_{fin} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the final static test force F_{fin} has been maintained.

If the final static test is intended also to cover the principal static proof test specified in 16.2.1.1.1 (see 16.3.1.3), follow the instructions given in 16.2.1.1.6 to 16.2.1.1.9.

16.3.2.19 Decide and record whether the test sample has passed or failed the test procedure specified in 16.3.2.2 to 16.3.2.18, checking the results of steps 16.3.2.9, 16.3.2.15, 16.3.2.17 and 16.3.2.18 against the performance requirements of 16.3.3.

16.3.2.20 If the test sample fails to satisfy any of the performance requirements of 16.3.3, inspect it to detect the nature and, if possible the location, of any damage and record the results.

16.3.2.21 At the request of the manufacturer/submitter, visually examine a test sample that fails and/or a test sample that completes the principal cyclic test and the final static test without failing, in order to detect the presence, location and nature of any fractures and/or cracks (see 16.3.1.4).

Carry out the examination at the magnification specified in the test submission document [see 12.3.5 c)] or decided according to circumstances in agreement with the manufacturer/submitter.

Record the magnification used and the information obtained, taking account of the manufacturer's/submitter's instructions concerning the documentation of test results [see 12.3.5 c)].

16.3.2.22 If a test sample being tested at a frequency of 3 Hz or higher fails to satisfy any of the performance requirements of 16.3.3, repeat the test on a substitute test sample at a frequency less than 3 Hz, specified in the test submission document [see 12.3.5 e)] or agreed between the test laboratory/facility and the manufacturer/submitter. Record the failure and the repetition, including all specific records called for.

16.3.3 Performance requirements

16.3.3.1 In order to pass the principal cyclic test procedure, a test sample shall satisfy the following performance requirements.

a) The test sample shall sustain static loading by the maximum test force F_{cmax} at the prescribed value for the time required for the measurements and records of 16.3.2.8.

b) The test sample shall sustain cyclic loading by the pulsating test force $F_c(t)$ at the prescribed level and range for the prescribed number of cycles.

c) The test sample shall sustain static loading by the final static test force F_{fin} at the prescribed value for (30 ± 3) s.

16.3.3.2 In order to also pass the principal static proof test specified in 16.2.1.1.1 when being subjected to the final static test applied in the manner specified in 16.2.1.1.6 to 16.2.1.1.9 for the principal static proof test (see 16.3.1.3 and 16.3.2.18), the test sample shall satisfy 16.3.3.1 c) [which is identical to 16.2.1.2 a)], together with the following performance requirement [which is identical to 16.2.1.2 b)].

The value of permanent deformation D_3 of the test sample shall not exceed

— 5 mm for a total sample length $(u_T - u_B)_{specified}$ = 650 mm or

— 5 mm multiplied by the ratio $[(u_T - u_B)_{actual}/(u_T - u_B)_{specified}]$ for values of total sample length exceeding 650 mm (see Footnote b of Table 5).

If the test sample satisfies the performance requirement of 16.3.3.1 c) but fails to satisfy the performance requirement of 16.3.3.2, the principal static proof test shall be carried out as specified in 16.2.1.1.1.

16.3.3.3 If any individual prosthetic component fails to satisfy any of the requirements specified in 16.3.3.1 and 16.3.3.2, this constitutes a failure only in the prosthetic assembly and alignment simulated in the test sample set-up.

16.3.4 Compliance conditions

16.3.4.1 In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the principal cyclic test of this International Standard according to 16.3.3.1 at a specific test loading level, tests of this type shall be passed (in the meaning of 16.3.3.1) in each of the test loading conditions I and II by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 16.3.2.22 (see 9.4 and Table 16).

16.3.4.2 In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 also satisfies the compliance conditions of the principal static proof test of this International Standard according to 16.2.1.3, 16.3.4.1 shall apply provided that the test samples also comply with the performance requirement according to 16.3.3.2.

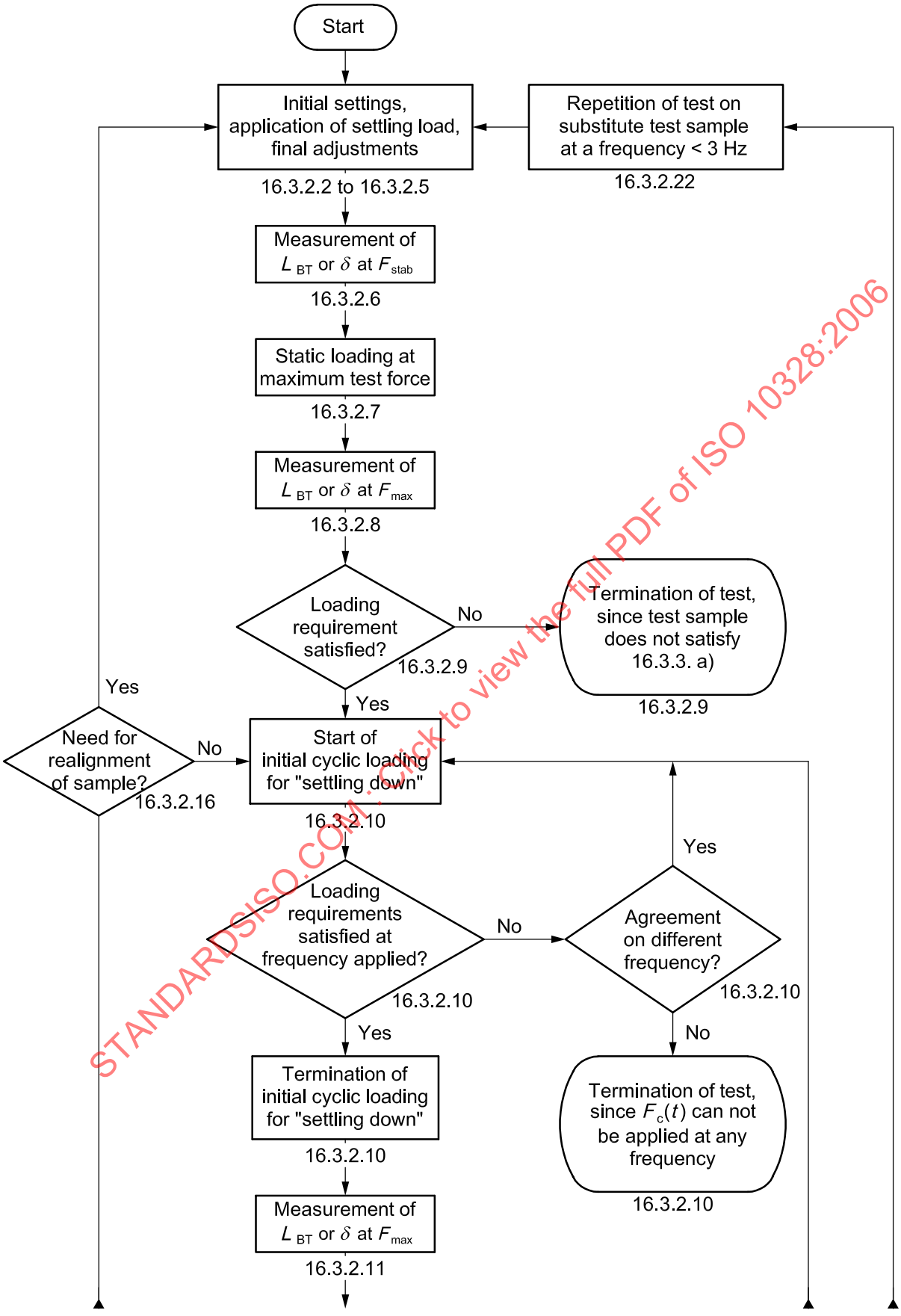


Figure 15 — Flowchart for the principal cyclic test, specified in 16.3.2
Continued on Figures 16 and 17

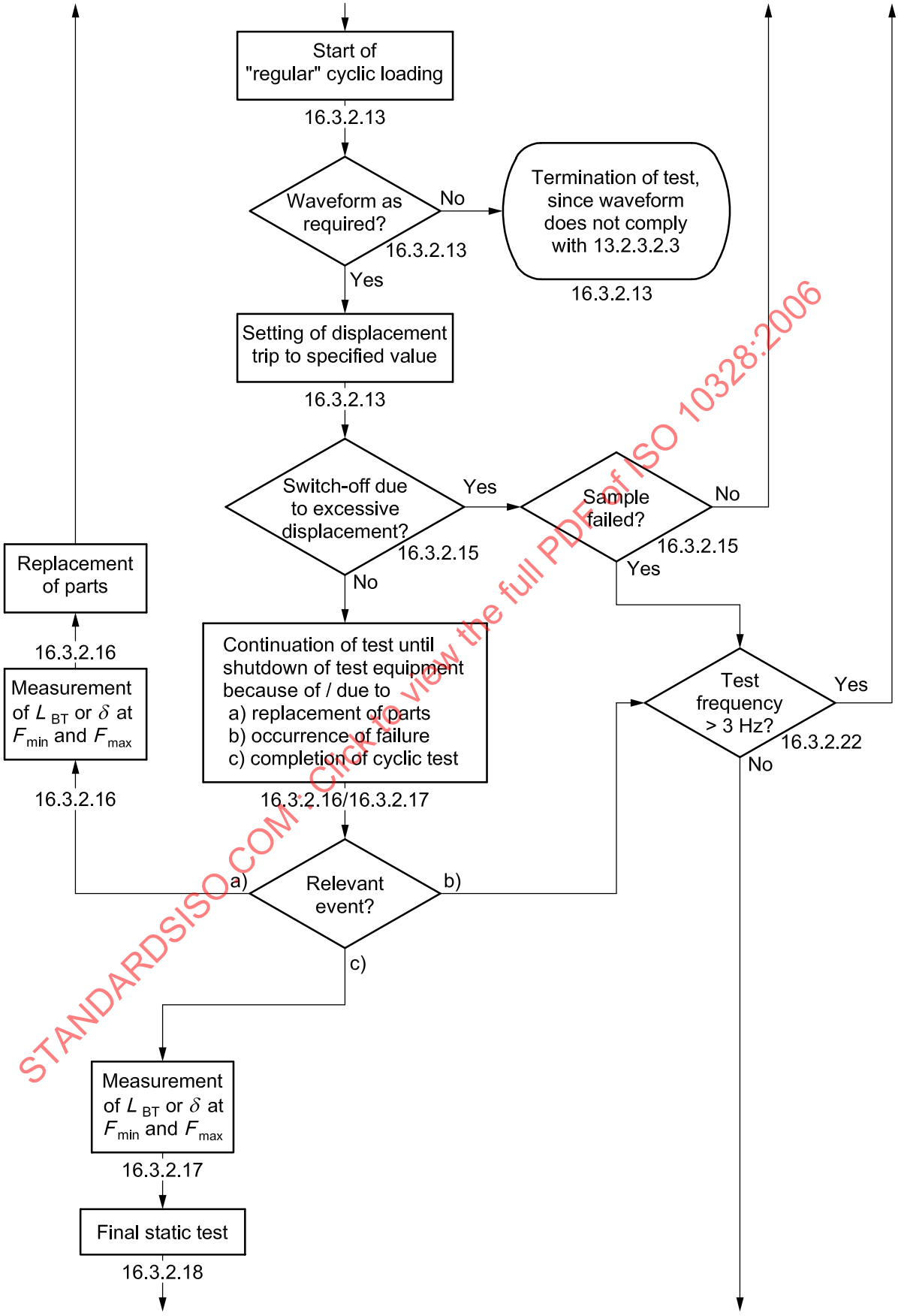


Figure 16 — Flowchart for the principal cyclic test, specified in 16.3.2
Continued from Figure 15 and continued on Figure 17

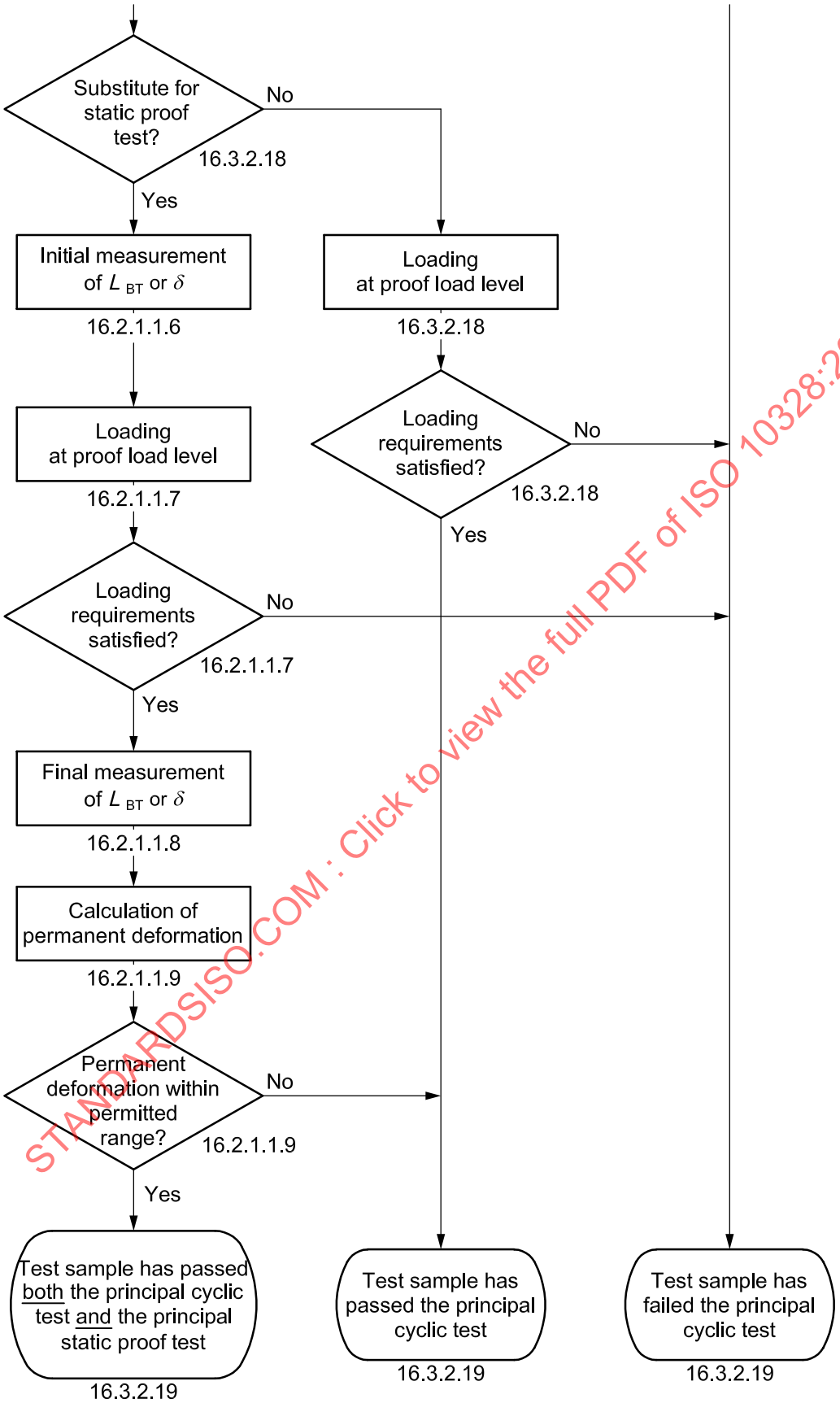


Figure 17 — Flowchart for the principal cyclic test, specified in 16.3.2
Continued from Figure 16

17 Test procedures – Separate structural tests

17.1 Separate static test in torsion

17.1.1 General

The requirements of this subclause shall apply to test samples of all prosthetic devices/structures submitted for test (see Table 15).

17.1.2 Purpose of test

Users can apply twisting loads to their prostheses which exceed the levels of the twisting moments (induced torque) generated by the test loading conditions of the principal structural tests, specified in this International Standard. To ensure the twisting strength of the prosthetic structure and the security of fixations against slippage, a static load in torsion alone is applied.

17.1.3 Test method

NOTE A flowchart for this test is shown in Figure 18.

17.1.3.1 Prepare (or check and, if necessary, correct) the assembly of a test sample from the batch specified in Table 16 for this test in accordance with the manufacturer's assembly instructions and 9.5, Clause 10, 11.4, 11.5 and 12.2.1.

Record the values of the tightening torque(s) of bolts of clamped connections specified in the test submission document (see 11.1 and 12.2.1) and of the twisting moments to be applied.

17.1.3.2 Set up the test sample with the knee unit in full extension and with all adjustable components in their mid-positions in accordance with the test submission document (see 12.3.6).

Where this can neither be established from the test submission document nor from examination of the test sample, then use the manufacturer's written alignment recommendations for the prosthesis to establish the mid-positions.

Record the set-up, including the mid-positions adjusted.

17.1.3.3 Mount the test sample in the test equipment with the effective ankle-joint centre (see 6.7.3) and the effective knee-joint centre (see 6.7.6) on the axis of torque application, in order to generate twisting about the u-axis (see 6.2.2).

17.1.3.4 Fix one end of the test sample and apply to the other end the settling twisting moment $M_{\text{u-set}}$ about the u-axis, specified in Table 9, in a selected direction of twisting designated positive.

Maintain this moment, $M_{\text{u-set}}$, at the prescribed value for a period of not less than 10 s and not more than 30 s and then remove it.

Allow the test sample to rest at zero load for a period of not less than 10 min and not more than 20 min before proceeding with 17.1.3.5.

Record the time for which the settling twisting moment $M_{\text{u-set}}$ has been maintained at the prescribed value and the time for which the test sample has been allowed to rest at zero load.

17.1.3.5 Apply to the test sample in the positive direction of twisting, the stabilizing twisting moment $M_{\text{u-stab}}$ about the u-axis, specified in Table 9, and maintain it until the markings and readings of 17.1.3.6 are completed.

17.1.3.6 Mark the initial relative angular positions at the junctions of all parts.

Measure and record the initial angular positions relevant to twisting about the u-axis of the bottom and top components of the test sample φ_{B1} and φ_{T1}, respectively.

17.1.3.7 Increase the twisting moment M_u about the u-axis in the positive direction of twisting smoothly at a rate not exceeding 4 N·m/s to the maximum twisting moment $M_{u\text{-}max}$, specified in Table 9.

Maintain this moment, $M_{u\text{-}max}$, at the prescribed value for (30 ± 3) s.

Decrease the twisting moment M_u to the stabilizing twisting moment $M_{u\text{-}stab}$.

If the test sample sustains the static loading at $M_{u\text{-}max}$ for the prescribed time, record this and proceed with 17.1.3.8.

If the test sample fails to sustain the static loading at $M_{u\text{-}max}$ for the prescribed time, record this together with the highest value of twisting moment reached or the time for which the prescribed value of the maximum twisting moment $M_{u\text{-}max}$ has been maintained and decide on the continuation of the test procedure in consideration of the statement given below. Record the decision.

The occurrence of failure in the test procedure in one direction of twisting prevents compliance with the performance requirements of this test being claimed for the test sample (see 17.1.5). For this reason the test shall be terminated, unless otherwise stated in the test submission document or agreed between the test laboratory/facility and the manufacturer/submitter (see 12.3.3).

17.1.3.8 Maintain the stabilizing twisting moment $M_{u\text{-}stab}$ until the measurements specified below are completed. Complete the measurements within 10 min in order to limit the effect of recovery on the relative angular movement (see 17.1.3.9).

Measure and record the final angular positions relevant to twisting about the u-axis of the bottom and top components of the test sample φ_{B2} and φ_{T2}, respectively.

Note and record the time taken for measuring.

17.1.3.9 Calculate and record the relative angular movement about the u-axis between the ends of the test sample $\Delta\varphi_1$ as follows:

$$\Delta\varphi_1 = |(\varphi_{B2} - \varphi_{B1}) - (\varphi_{T2} - \varphi_{T1})| \qquad (12a)$$

If the calculated value of relative angular movement $\Delta\varphi_1$ exceeds 3°, decide on the continuation of the test procedure in consideration of the statement given in the last paragraph of 17.1.3.7 and record the decision.

17.1.3.10 Check the results of steps 17.1.3.7 and 17.1.3.9 against the performance requirements of 17.1.4 and record the findings.

If the test sample has passed the test procedure in the positive direction of twisting, proceed with 17.1.3.12.

If the test sample has failed this test procedure, decide on the continuation of the test procedure in consideration of the statement given in the last paragraph of 17.1.3.7 and record the decision.

17.1.3.11 If the test sample fails to satisfy either of the performance requirements of 17.1.4, inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

If appropriate, use the markings of the initial angular positions at the junctions of all parts measured in 17.1.3.6 to establish where and what amount of slippage has occurred.

Record the results of the inspection of the test sample.

17.1.3.12 Carry out the test procedure specified in 17.1.3.4 to 17.1.3.9 in the negative direction of twisting.

Designate the angles for this direction of twisting as follows:

a) the initial angular positions (17.1.3.6) as φ_{B3} and φ_{T3};

b) the final angular positions (17.1.3.8) as φ_{B4} and φ_{T4};

c) the relative angular movement (17.1.3.9) as $\Delta\varphi_2$, to be calculated as

$$\Delta\varphi_2 = |(\varphi_{B4} - \varphi_{B3}) - (\varphi_{T4} - \varphi_{T3})| \quad (12b)$$

Record the application of the test procedure in the negative direction of twisting, together with all specific records called for.

17.1.3.13 Check the results of steps 17.1.3.7 and 17.1.3.9 of the test procedure in the negative direction of twisting against the performance requirements of 17.1.4 and record the findings.

17.1.3.14 If the test sample fails to satisfy either of the performance requirements of 17.1.4 in the test procedure in the negative direction of twisting, inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

If appropriate, use the markings of the initial angular positions at the junctions of all parts measured in 17.1.3.6/17.1.3.12 a) to establish where and what amount of slippage has occurred.

Record the results of the inspection of the test sample.

17.1.3.15 Decide and record whether or not the test sample has passed the test procedure specified in 17.1.3.4 to 17.1.3.9 in both directions of twisting, taking account of the findings of 17.1.3.10 and 17.1.3.13.

17.1.4 Performance requirements

In order to pass the separate static test in torsion, a test sample shall satisfy the following performance requirements:

a) the test sample shall sustain static loading in each of the two directions of twisting by the maximum twisting moment $M_{u\text{-}max}$ at the prescribed value of for (30 ± 3) s;

b) the values of relative angular movement $\Delta\varphi_1$ and $\Delta\varphi_2$ between the ends of the test sample occurring in the two directions of twisting shall not exceed 3°.

If any individual prosthetic component fails to satisfy either of the requirements specified in a) and b), this constitutes a failure only in the prosthetic assembly and alignment simulated in the test sample set-up.

17.1.5 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the separate static test in torsion according to 17.1.4, tests of this type, each successively applying the two directions of twisting to the same test sample, shall be passed (in the meaning of 17.1.4) by two test samples from the prescribed batch (see 9.4 and Table 16).

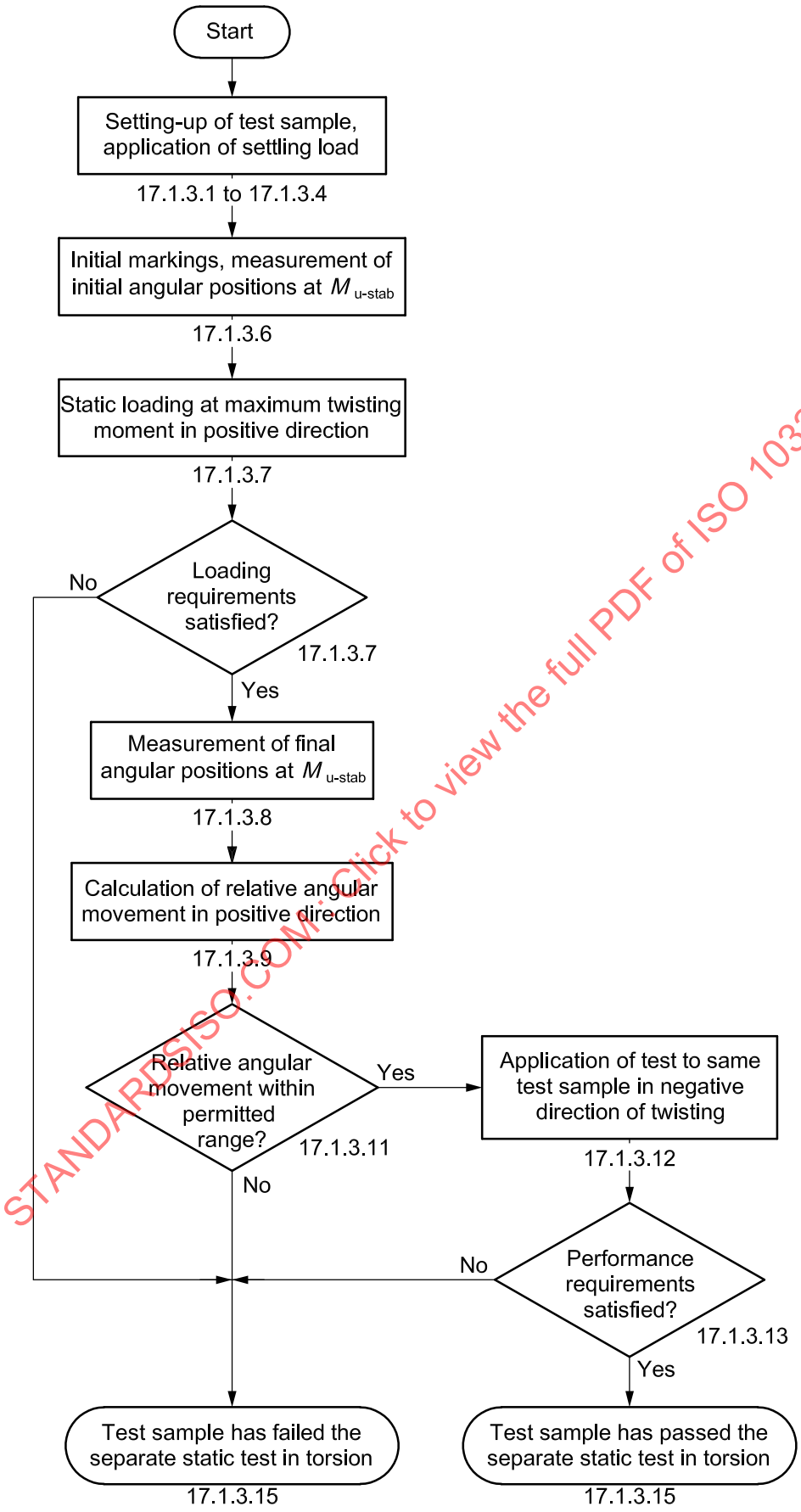


Figure 18 — Flowchart for the separate static test in torsion, specified in 17.1.3

17.2 Separate tests on ankle-foot devices and foot units

17.2.1 General

The tests specified in this subclause relate to ankle-foot devices and foot units and their connections to the remainder of the prosthesis. Any report relating to these tests should apply only to the specific ankle-foot device or foot unit in association with the specific connections submitted.

NOTE New static and cyclic tests on ankle-foot devices and foot units are specified in ISO 22675. For further details see last paragraph of Introduction.

17.2.2 Purpose of tests

Although ankle-foot devices and foot units, representing a part of a test sample or a single component according to 10.2.1, 10.2.2 or 10.2.3, can be subjected to the principal structural tests of Clause 16 in the test configurations of Clause 6 and in the test loading conditions and at the test loading levels of Clause 7, this subclause specifies special structural static and cyclic tests for ankle-foot devices and foot units in which the heel and forefoot are loaded successively or alternately.

To comply with the requirements of this International Standard, a batch of test samples of ankle-foot devices or foot units shall satisfy the performance requirements stated in 17.2.3.2, 17.2.4.2 and 17.2.5.2.

17.2.3 Separate static proof test for ankle-foot devices and foot units

17.2.3.1 Test method

17.2.3.1.1 The separate static proof test for ankle-foot devices and foot units shall be conducted as described in 17.2.3.1.2 to 17.2.3.1.10, initially applying the test force F_1 on the heel and subsequently applying the test force F_2 on the forefoot of the same test sample, or vice versa.

The separate static proof test for ankle-foot devices and foot units may be carried out as part of the alternative static ultimate strength test specified in Annex C [see also 17.2.4.1, Clause C.1 and C.2 c)].

NOTE A flowchart for this test is shown in Figure 19.

17.2.3.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test, in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10.

If a test sample which has completed the separate cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (see also 17.2.3.1.11). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the angles α and β and the test forces F_1 and F_2, determining the directions and magnitudes of heel and forefoot loading. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

17.2.3.1.3 For the test in heel loading set the angle of the line of application of the test force F_1 to α, specified in Table 10, and adjust the (heel) loading platform perpendicular to it.

Arrange the (heel) loading platform so that it supports the forefoot, if heel loading deforms the test sample to such an extent that forefoot support is necessary to avoid unrealistic conditions of loading.

If the test equipment uses a twin actuator set-up, ensure that the forefoot cannot contact the forefoot loading platform during heel loading.

17.2.3.1.4 Mount the test sample in the test equipment as illustrated in Figure 7.

17.2.3.1.5 Apply to the heel of the test sample the test force F_1 and increase it smoothly at a rate of between 100 N/s and 250 N/s to the proof test force F_{1sp} of the relevant test loading level, specified in Table 11 or Table D.3.

Maintain this force, F_{1sp}, at the prescribed value for (30 ± 3) s and then decrease the test force F_1 to zero.

If the test sample sustains the static heel loading at F_{1sp} for the prescribed time, record this and proceed with 17.2.3.1.7.

If the test sample fails to sustain the static heel loading at F_{1sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force F_{1sp} has been maintained and decide on the continuation of the test procedure in consideration of the statement given below (but see 17.2.3.1.11). Record the decision.

The occurrence of failure in the test procedure in one direction of loading prevents compliance with the performance requirements of this test being claimed for the test sample (see 17.2.3.3). For this reason the test shall be terminated, unless otherwise stated in the test submission document or agreed between the test laboratory/facility and the manufacturer/submitter (see 12.3.3).

17.2.3.1.6 If the test sample fails to satisfy the performance requirement of 17.2.3.2 in the test procedure of heel loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.2.3.1.7 For the test in forefoot loading set the angle of the line of application of the test force F_2 to β, specified in Table 10, and adjust the (forefoot) loading platform perpendicular to it.

If appropriate, remove the test sample from the test equipment during the setting and arrangement of the loading platform(s) and subsequently remount it.

Arrange the (forefoot) loading platform so that it supports the heel, if forefoot loading deforms the test sample to such an extent that heel support is necessary to avoid unrealistic conditions of loading.

If the test equipment uses a twin actuator set-up, ensure that the heel cannot contact the heel loading platform during forefoot loading.

17.2.3.1.8 Apply to the forefoot of the test sample that has completed the test procedure of heel loading without failing (see 17.2.3.1.5) the test force F_2 and increase it smoothly at a rate of between 100 N/s and 250 N/s to the proof test force F_{2sp} of the relevant test loading level, specified in Table 11 or Table D.3.

Maintain this force, F_{2sp}, at the prescribed value for (30 ± 3) s and then decrease the test force F_2 to zero.

If the test sample sustains the static forefoot loading at F_{2sp} for the prescribed time, record this.

If the test sample fails to sustain the static forefoot loading at F_{2sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force F_{2sp} has been maintained (but see 17.2.3.1.11).

17.2.3.1.9 If the test sample fails to satisfy the performance requirement of 17.2.3.2 in the test procedure of forefoot loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.2.3.1.10 Decide and record whether or not the test sample has passed the test procedure of heel loading (17.2.3.1.4 and 17.2.3.1.5) and the test procedure of forefoot loading (17.2.3.1.7 and 17.2.3.1.8), checking the results of 17.2.3.1.5 and 17.2.3.1.8 against the performance requirement of 17.2.3.2.

17.2.3.1.11 If a test sample that has already completed, without failing, the separate cyclic test procedure for ankle-foot devices and foot units (see 17.2.3.1.2), fails to satisfy the performance requirement of 17.2.3.2 in heel loading (17.2.3.1.4 and 17.2.3.1.5) or in forefoot loading (17.2.3.1.7 and 17.2.3.1.8), repeat the complete test (17.2.3.1.2 to 17.2.3.1.9) on a substitute test sample and record the failure and the repetition, including all specific records called for.

17.2.3.2 Performance requirement

In order to pass the separate static proof test for ankle-foot devices and foot units, a test sample shall sustain successive static heel and forefoot loading by the proof test forces F_{1sp} and F_{2sp} at the prescribed values and inclinations for (30 ± 3) s each.

17.2.3.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirement of the separate static proof test for ankle-foot devices and foot units of this International Standard according to 17.2.3.2 at a specific test loading level, tests of this type, each successively applying heel loading and forefoot loading to the same test sample, shall be passed (in the meaning of 17.2.3.2) by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 17.2.3.1.11 (see 9.4 and Table 16).

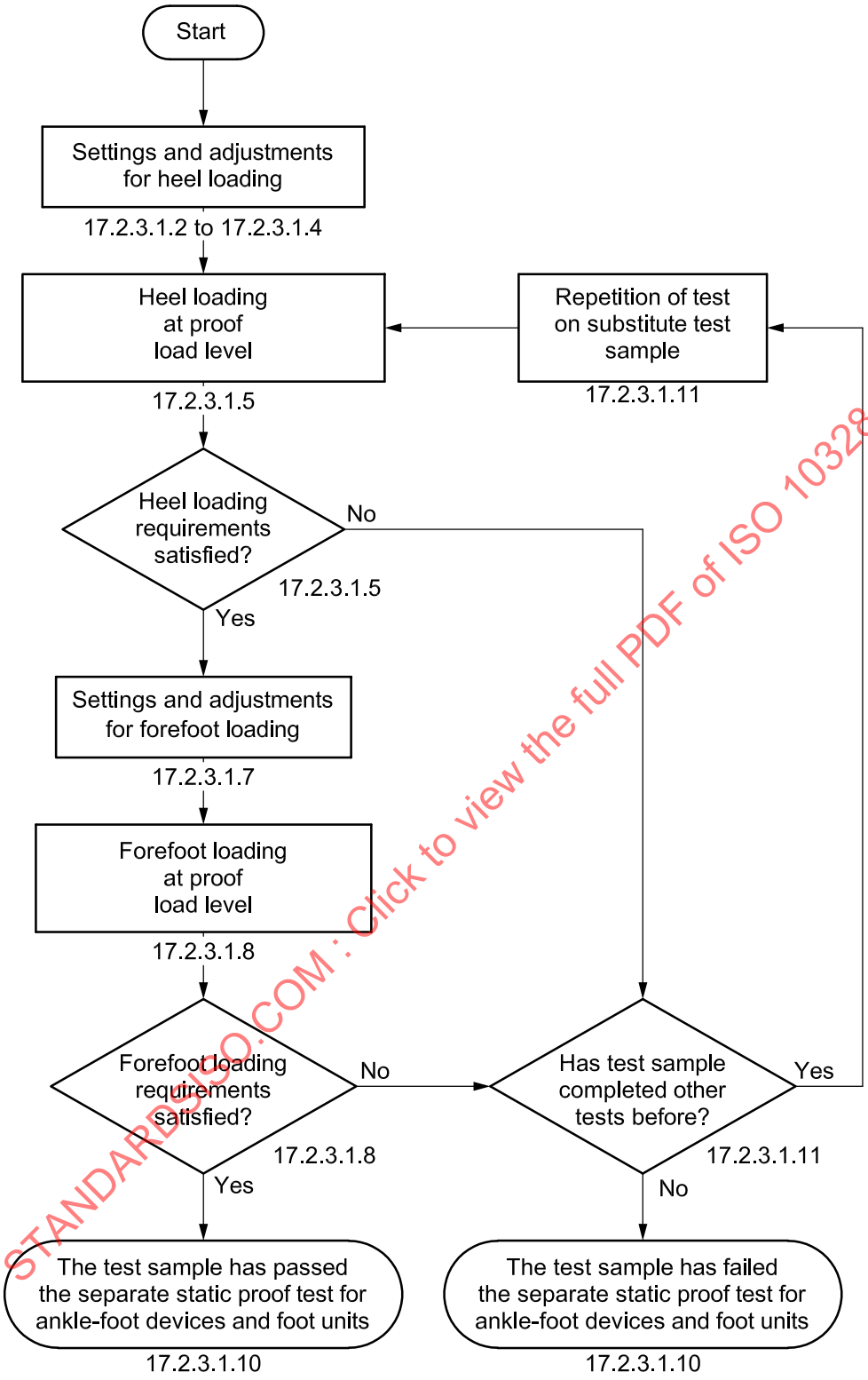


Figure 19 — Flowchart for the separate static proof test for ankle-foot devices and foot units, specified in 17.2.3.1

17.2.4 Separate static ultimate strength test for ankle-foot devices and foot units

17.2.4.1 Test method

17.2.4.1.1 The separate static ultimate strength tests for ankle-foot devices and foot units shall be conducted as described in 17.2.4.1.2 to 17.2.4.1.14, on different test samples, loading the first on the heel and the second on the forefoot, or vice versa.

A test sample which satisfies the requirements of this test in one direction of loading, may be used for this test in the other direction of loading (but see 17.2.4.1.16).

For test samples of lower limb prostheses with material properties and/or construction features which render them unable to sustain the required ultimate test force at a rate of loading of between 100 N/s and 250 N/s, specified in 17.2.4.1.5 and 17.2.4.1.11, Annex C offers guidance on the application of an alternative static ultimate strength test, in which a higher rate of loading is applied to the test sample.

The higher rate of loading shall either be specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed upon between the manufacturer/submitter and the test laboratory/facility (see also 17.2.4.1.5 and 17.2.4.1.11) and may be applied to the initial test sample or to a substitute test sample, if the initial test sample has failed at a rate of loading of between 100 N/s and 250 N/s (see 17.2.4.1.17).

NOTE A flowchart for this test is shown in Figure 20.

17.2.4.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10.

If a test sample which has completed the separate static proof test for ankle-foot devices and foot units, without failing, is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (see also 17.2.4.1.15). Record the re-use of the test sample.

If a test sample which has completed the separate cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (see also 17.2.4.1.15). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the angle α and the test force F_1, determining the direction and magnitude of heel loading. Make specific reference if the application of the additional test loading level P6 specified in Annex D is to be applied.

17.2.4.1.3 For the test in heel loading set the angle of the direction of loading to α, specified in Table 10, and adjust the (heel) loading platform perpendicular to it.

Arrange the (heel) loading platform so that it supports the forefoot, if heel loading by the test force F_1 deforms the test sample to such an extent that forefoot support is necessary to avoid unrealistic conditions of loading.

If the test equipment uses a twin actuator set-up, ensure that the forefoot cannot contact the forefoot loading platform during heel loading.

17.2.4.1.4 Mount the test sample in the test equipment, as illustrated in Figure 7.

17.2.4.1.5 Apply to the heel of the test sample the test force F_1 and increase it smoothly at a rate of between 100 N/s and 250 N/s until the test sample fails, or the test force F_1 attains the value of the ultimate test force $F_{1su,\ upper\ level}$ of the relevant test loading level, specified in Table 11 or Table D.3, without failure of the test sample.

If appropriate, apply the test force F_1 at a higher rate of loading, specified by or agreed with the manufacturer/submitter in accordance with Annex C (see 17.2.4.1.1).

Record the highest value of the test force F_1 reached during the test and whether failure has occurred. Make specific reference if the test force F_1 is to be applied at a higher rate of loading.

If expressly requested by the manufacturer/submitter or if requested in the test submission document [12.3.4 a)], continue the static ultimate strength test after the test sample has withstood the ultimate test force $F_{1su,\ upper\ level}$ until failure actually occurs and record the value of the load at failure.

17.2.4.1.6 Check the results of step 17.2.4.1.5 against the performance requirements of 17.2.4.2 and record the findings.

If the test sample completes the test procedure of heel loading without failing, proceed with 17.2.4.1.8.

Take into account that, according to C.2 c), a test sample that has passed the test procedure specified in 17.2.4.1.2 to 17.2.4.1.5 with step 17.2.4.1.5 applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex C (see also 17.2.4.1.1), subsequently shall pass the separate static proof test for ankle-foot devices and foot units specified in 17.2.3.1 in the relevant direction of loading and at the relevant test loading level, in order to satisfy the requirements of the alternative static ultimate strength test of Annex C (see also 17.2.4.3).

If the test sample fails, decide on the continuation of the test procedure in consideration of the statement given below (but see 17.2.4.1.15). Record the decision.

The occurrence of failure in the test procedure in one direction of loading prevents compliance with the performance requirements of this test being claimed for the test sample (see 17.2.4.3). For this reason the test shall be terminated, unless otherwise stated in the test submission document or agreed upon between the test laboratory/facility and the manufacturer/submitter (see 12.3.3).

17.2.4.1.7 If the test sample fails to satisfy the performance requirements of 17.2.4.2 in the test procedure of heel loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.2.4.1.8 Prepare and align a fresh test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (but see 17.2.4.1.1/17.2.4.1.16).

If a test sample which has completed the separate static proof test for ankle-foot devices and foot units without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (see also 17.2.4.1.15). Record the re-use of the test sample.

If a test sample that has completed the separate cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11, 12.2.1 and 12.2.2 and Table 10 (see also 17.2.4.1.15). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the angle β and the test force F_2, determining the direction and magnitude of forefoot loading. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

17.2.4.1.9 For the test in forefoot loading set the angle of the direction of loading to β, specified in Table 10, and adjust the (forefoot) loading platform perpendicular to it.

Arrange the (forefoot) loading platform so that it supports the heel, if forefoot loading by the test force F_2 deforms the test sample to such an extent that heel support is necessary to avoid unrealistic conditions of loading.

If the test equipment uses a twin actuator set-up, ensure that the forefoot cannot contact the forefoot loading platform during heel loading.

17.2.4.1.10 Mount the test sample in the test equipment, as illustrated in Figure 7.

17.2.4.1.11 Apply to the forefoot of the test sample the test force F_2 and increase it smoothly at a rate of between 100 N/s and 250 N/s until the test sample fails, or the test force F_2 attains the value of the ultimate test force $F_{2su,\ upper\ level}$ of the relevant test loading level, specified in Table 11 or Table D.3, without failure of the test sample.

If appropriate, apply the test force F_2 at a higher rate of loading, specified by or agreed with the manufacturer/submitter in accordance with Annex C (see 17.2.4.1.1).

Record the highest value of the test force F_2 reached during the test and whether failure has occurred. Make specific reference if the test force F_2 is applied at a higher rate of loading.

If expressly requested by the manufacturer/submitter or if requested in the test submission document [12.3.4 a)], continue the static ultimate strength test after the test sample has withstood the ultimate test force $F_{2su,\ upper\ level}$, until failure actually occurs and record the value of the load at failure.

17.2.4.1.12 Check the results of step 17.2.4.1.11 against the performance requirements of 17.2.4.2 and record the findings.

Take into account that, according to C.2 c), a test sample that has passed the test procedure specified in 17.2.4.1.8 to 17.2.4.1.11 with step 17.2.4.1.11 applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex C (see also 17.2.4.1.1), subsequently shall pass the separate static proof test for ankle-foot devices and foot units specified in 17.2.3.1 in the relevant direction of loading and at the relevant test loading level, in order to satisfy the requirements of the alternative static ultimate strength test of Annex C (see also 17.2.4.3).

17.2.4.1.13 If the test sample fails to satisfy the performance requirements of 17.2.4.2 in the test procedure of forefoot loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.2.4.1.14 Decide and record whether or not the test sample referred to in 17.2.4.1.2 has passed the test procedure of heel loading (17.2.4.1.2 to 17.2.4.1.5) and the test sample referred to in 17.2.4.1.8 has passed the test procedure of forefoot loading (17.2.4.1.8 to 17.2.4.1.11), taking account of the findings of 17.2.4.1.6 and 17.2.4.1.12.

17.2.4.1.15 If a test sample that has already completed, without failing, the separate static proof test and/or the separate cyclic test procedure for ankle-foot devices and foot units (see 17.2.4.1.2), fails to satisfy either of the performance requirements of 17.2.4.2 in heel loading (17.2.4.1.2 to 17.2.4.1.5) or in forefoot loading (17.2.4.1.8 to 17.2.4.1.11), repeat the test on a substitute test sample in the failed direction of loading and record the failure and the repetition, including all specific records called for.

17.2.4.1.16 If a test sample that has already completed, without failing, the separate static ultimate strength test for ankle-foot devices and foot units in one direction of loading (see 17.2.4.1.1 and 17.2.4.1.6), fails this test in the other direction of loading (see 17.2.4.1.12), repeat the test on a substitute test sample in the failed direction of loading and record the failure and the repetition, including all specific records called for.

17.2.4.1.17 OPTION — If a test sample fails this test in one direction of loading at a rate of loading of between 100 N/s and 250 N/s, specified in 17.2.4.1.5 and 17.2.4.1.11, the test may be repeated on a substitute test sample in the failed direction of loading at an increased rate of loading in accordance with Annex C, specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed between the manufacturer/submitter and the test laboratory/facility. The failure and the repetition shall be recorded, including all specific records called for.

17.2.4.2 Performance requirements

In order to pass the separate static ultimate strength test for ankle-foot devices and foot units, a test sample shall satisfy one of the following performance requirements:

a) the test sample shall sustain either static heel loading by the ultimate test force F_{1su} at the value and inclination prescribed for $F_{1su,\ upper\ level}$ or static forefoot loading by the ultimate test force F_{2su} at the value and inclination prescribed for $F_{2su,\ upper\ level}$ without failing or

b) if the mechanical characteristics of the test sample prevent the requirement of a) to be satisfied, the maximum value of the ultimate test force F_{1su} or F_{2su} sustained by the test sample without loss of its structural integrity shall be either

   — $\geqslant$ the value $F_{1su,\ lower\ level}$ prescribed for static heel loading, or

   — $\geqslant$ the value $F_{2su,\ lower\ level}$ prescribed for static forefoot loading.

17.2.4.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the separate static ultimate strength test for ankle-foot devices and foot units of this International Standard according to 17.2.4.2 at a specific test loading level, the following shall apply.

a) If the test forces F_1 and F_2 have been applied at a rate of between 100 N/s and 250 N/s, tests of this type, each separately applying heel loading and forefoot loading to different test samples, shall be passed (in the meaning of 17.2.4.2) in each of these directions of loading by two test samples from the prescribed batch, the prescribed batch including the substitute test samples allowed by 17.2.4.1.15 and 17.2.4.1.16 (and also by 17.2.4.1.17 as an option) (see 9.4 and Table 16).

b) If the test forces F_1 and F_2 have been applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex C (see 17.2.4.1.1 and 17.2.4.1.5/17.2.4.1.11), the compliance condition of a) shall apply provided that the same test samples also pass (in the meaning of 17.2.3.2) the separate static proof test for ankle-foot devices and foot units of this International Standard in the relevant direction of loading and at the relevant test loading level (see 17.2.4.1.6/17.2.4.1.12 and Annex C).

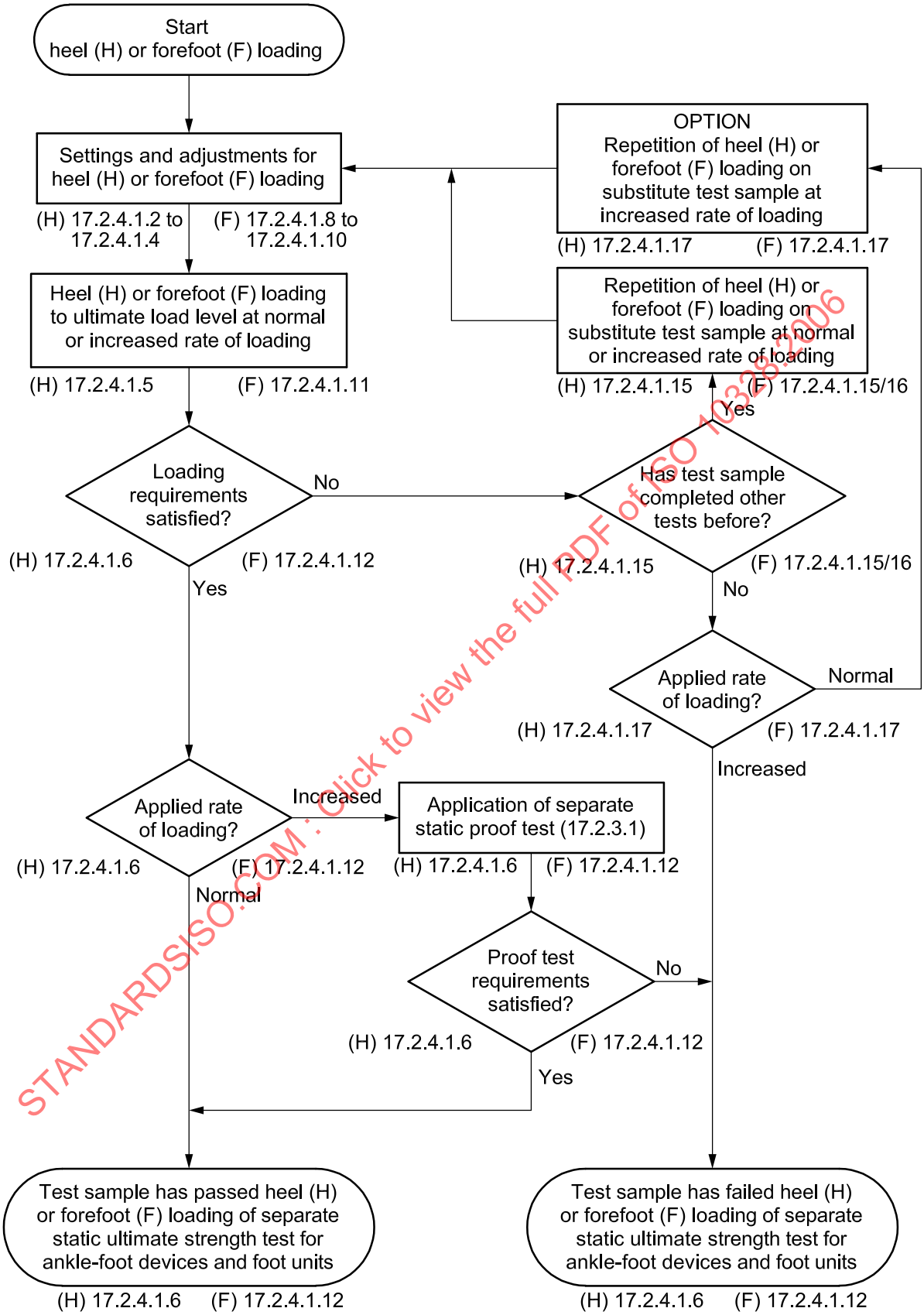


Figure 20 — Flowchart for the separate static ultimate strength test for ankle-foot devices and foot units, specified in 17.2.4.1

17.2.5 Separate cyclic test for ankle-foot devices and foot units

17.2.5.1 Test method

17.2.5.1.1 The separate cyclic test for ankle-foot devices and foot units shall be conducted by alternately loading on the heel and the forefoot of the same test sample, as described in 17.2.5.1.3 to 17.2.5.1.12.

NOTE A flowchart for this test is shown in Figures 21 and 22.

17.2.5.1.2 The following general requirements shall apply.

a) During the course of the cyclic test, specified parts shall be replaced when the number of cycles has reached a value at which such replacement is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b)]. All such replacements shall be recorded.

b) A test sample that completes the cyclic test without failing shall be subjected to final static heel and forefoot loading by the test forces F_{1fin} and F_{2fin}, successively applied at a rate of between 100 N/s and 250 N/s and maintained for (30 ± 3) s for each loading case.

c) A test sample that fails and/or a test sample that completes the cyclic test without failing shall, at the request of the manufacturer/submitter, be visually examined at the magnification specified in the test submission document [see 12.3.5 c)], and the presence, location and nature of any fractures and/or cracks be recorded, together with the magnification used.

17.2.5.1.3 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clause 10 and 11, 12.2.1 and 12.2.2 and Table 10.

Record the test loading level to be applied, together with the corresponding values of the angles α and β and the test forces F_1 and F_2, determining the directions and magnitudes of heel and forefoot loading, and the prescribed number of cycles. Make specific reference if the additional test loading level P6 specified in Annex D is to be applied.

17.2.5.1.4 Set the angle of the direction of heel loading to α and the angle of the direction of forefoot loading to β, specified in Table 10, and adjust the heel and forefoot loading platform(s) perpendicular to the directions of loading.

17.2.5.1.5 Mount the test sample in the test equipment as illustrated in Figure 7.

17.2.5.1.6 Apply to the test sample successively the maximum test force F_{1cmax} to the heel and the maximum test force F_{2cmax} to the forefoot in accordance with the values for the relevant test loading level, specified in Table 11 or Table D.3.

If the test sample sustains the successive static heel and forefoot loading at F_{1cmax} and F_{2cmax}, proceed with 17.2.5.1.7.

If the test sample fails to sustain the successive static heel and forefoot loading at F_{1cmax} and F_{2cmax}, record this together with the highest value of test force reached in each direction of loading and terminate the test.

17.2.5.1.7 Apply to the test sample alternately the pulsating test force $F_{1c}(t)$ to the heel and the pulsating test force $F_{2c}(t)$ to the forefoot in accordance with the requirements of 13.4.1.2 and the values for the relevant test loading level, specified in Table 11 or Table D.3, at a frequency of between 0,5 Hz and 3 Hz in accordance with the test submission document [see 12.3.5 a)] for a series of cycles, to allow the test sample and the test equipment to "settle down".

NOTE 1 The number of cycles required for the test to settle down will depend on the nature of the test sample and the test equipment control mechanism.

Take care that during this settling in period, the highest force applied to the heel and the forefoot of the test sample does not exceed the maximum test force F_{1cmax} or F_{2cmax} by more than 10 % (see 13.4.1.2.9).

NOTE 2 Experience has shown that repeated loading at values exceeding the relevant maximum test force by more than 10 % can cause early deterioration of the test sample.

Do not proceed with 17.2.5.1.8 until the test sample and the test equipment have settled down, and the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ have achieved the waveform specified in 13.4.1.2.4 and keep within the tolerances specified in 14.3 f) and g).

Record the frequency called for, together with the number of cycles required to settle down and whether the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ are applied in accordance with 13.4.1.2.4 and 14.3 f) and g).

If the frequency called for cannot be achieved or does not allow the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ to be applied as specified, repeat the preceding steps of 17.2.5.1.7 at a different frequency, preferably between 0,5 Hz and 3 Hz, to be agreed upon between the test laboratory/facility and the manufacturer/submitter.

Record any agreement on a frequency differing from the value called for.

If the pulsating test forces $F_{1c}(t)$ and/or $F_{2c}(t)$ cannot be applied at any frequency agreed between the test laboratory/facility and the manufacturer/submitter, record this and terminate the test.

17.2.5.1.8 Apply to the test sample alternately the pulsating test force $F_{1c}(t)$ to the heel and the pulsating test force $F_{2c}(t)$ to the forefoot in accordance with the requirements of 13.4.1.2 and the values for the relevant test loading level, specified in Table 11 or Table D.3, at a frequency of between 0,5 Hz and 3 Hz in accordance with the test submission document [see 12.3.5 a)] or any agreement on a frequency differing from the value called for therein, preferably between 0,5 Hz and 3 Hz (see 17.2.5.1.7), for the prescribed number of cycles specified in Table 11 or Table D.3.

Inspect the waveform of the applied test forces $F_{1c}(t)$ and $F_{2c}(t)$. Terminate the test if the waveform does not comply with 13.4.1.2.4.

Record the frequency applied, together with the results of the inspection of the waveform and the decision on the continuation of the test.

17.2.5.1.9 During the course of the cyclic test, replace any parts which would be replaced in normal service. Proceed as follows.

Stop the test equipment when the number of cycles of load has reached a value at which the exchange/replacement of these parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b) and 17.2.5.1.2 a)]. Record the number of cycles at shutdown.

Exchange/replace the specified parts in accordance with the manufacturer's/submitter's service instructions and/or the test submission document.

Restart the test from 17.2.5.1.3 or 17.2.5.1.7, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

Record the details of the exchange/replacement and the resulting conditions of the restart, together with the number of the corresponding clause.

17.2.5.1.10 Continue the test until failure occurs or the prescribed number of cycles specified in Table 11 or Table D.3 has been reached for both the heel and the forefoot. Record the number of cycles at shutdown and whether failure has occurred.

17.2.5.1.11 Subject a test sample that completes the cyclic test without failing to the final static test force F_{1fin} in the direction of heel loading determined by the angle α and subsequently to the final static force F_{2fin} in the direction of forefoot loading determined by the angle β in accordance with the values for the relevant test loading level, specified in Table 11 or Table D.3, applied at a rate of between 100 N/s and 250 N/s. For each loading case maintain the load at the maximum value for (30 ± 3) s and record the results [see 17.2.5.1.2 b)].

If the test sample fails to sustain the successive final static heel loading at F_{1fin} and forefoot loading at F_{2fin} for the prescribed time in either of the directions of loading, record this together with the highest value of test force reached in each direction of loading or the time for which the prescribed values of the final static test forces F_{1fin} and F_{2fin} have been maintained.

17.2.5.1.12 Decide and record whether the test sample has passed or failed the test procedure specified in 17.2.5.1.2 to 17.2.5.1.11, checking the results of steps 17.2.5.1.6, 17.2.5.1.10 and 17.2.5.1.11 against the performance requirements of 17.2.5.2.

17.2.5.1.13 If the test sample fails to satisfy any of the performance requirements of 17.2.5.2, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.2.5.1.14 At the request of the manufacturer/submitter, visually examine a test sample that fails and/or a test sample that completes the separate cyclic test for ankle-foot devices and foot units and the final static test without failing, to detect the presence, location and nature of any fractures and/or cracks [see 17.2.5.1.2 c)].

Carry out the examination at the magnification specified in the test submission document [see 12.3.5 c)] or decided according to circumstances in agreement with the manufacturer/submitter.

Record the magnification used and the information obtained, taking account of the manufacturer's/submitter's instructions concerning the documentation of test results [see 12.3.5 c)].

17.2.5.2 Performance requirements

In order to pass the separate cyclic test for ankle-foot devices and foot units, a test sample shall satisfy the following performance requirements:

a) the test sample shall sustain successive static heel and forefoot loading by the maximum test forces F_{1cmax} and F_{2cmax} at the prescribed values and inclinations;

b) the test sample shall sustain alternating cyclic heel and forefoot loading by the pulsating test forces $F_{1c}(t)$ and $F_{2c}(t)$ at the prescribed levels and ranges for the prescribed number of cycles;

c) the test sample shall sustain successive static heel and forefoot loading by the final static test forces F_{1fin} and F_{2fin} at the prescribed values and inclinations for (30 ± 3) s each.

17.2.5.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the separate cyclic test for ankle-foot devices and foot units of this International Standard according to 17.2.5.2 at a specific test loading level, tests of this type shall be passed (in the meaning of 17.2.5.2) by two test samples from the prescribed batch (see 9.4 and Table 16).

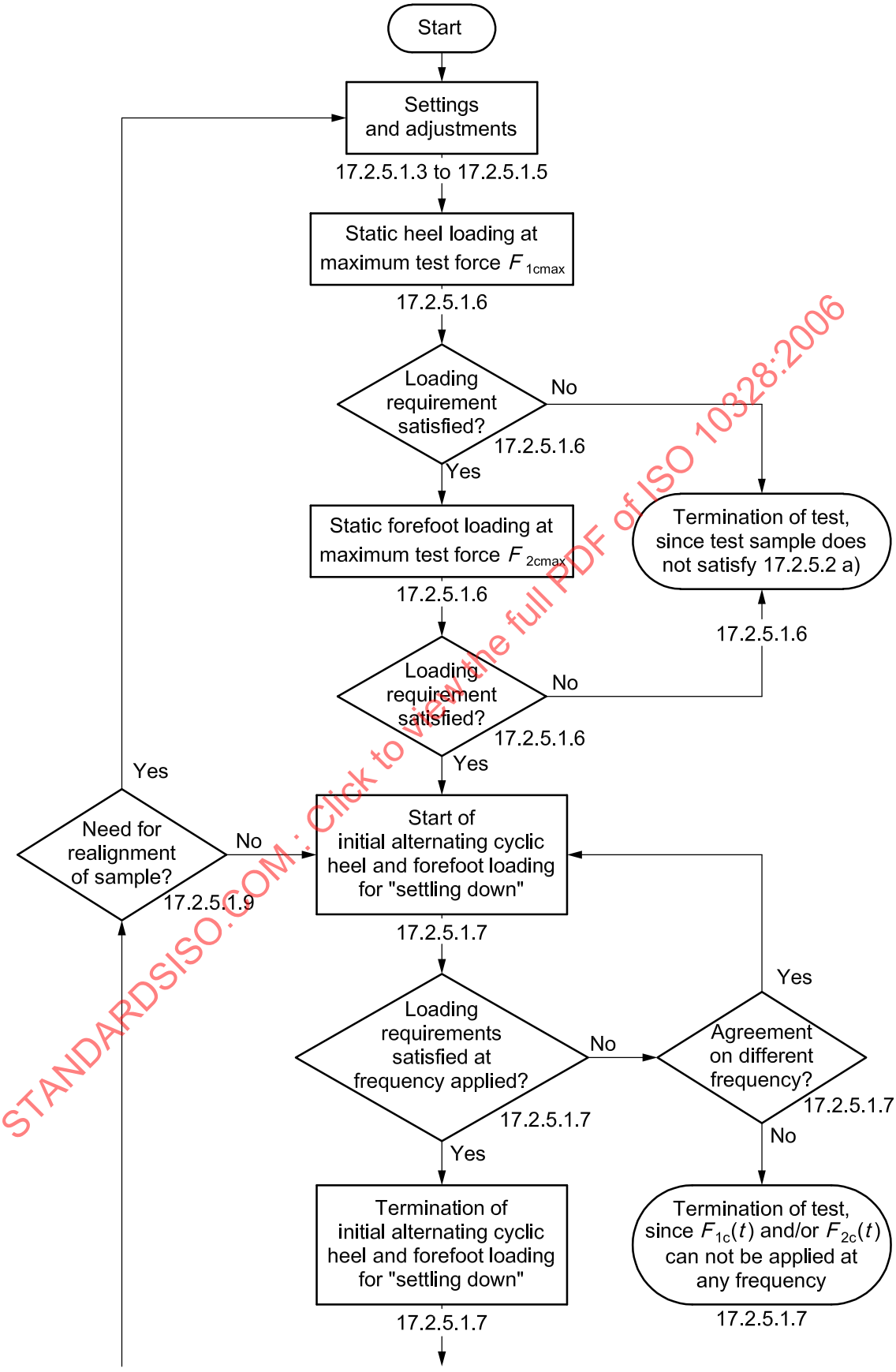


Figure 21 — Flowchart for the separate cyclic test for ankle-foot devices and foot units, specified in 17.2.5.1

Continued on Figure 22

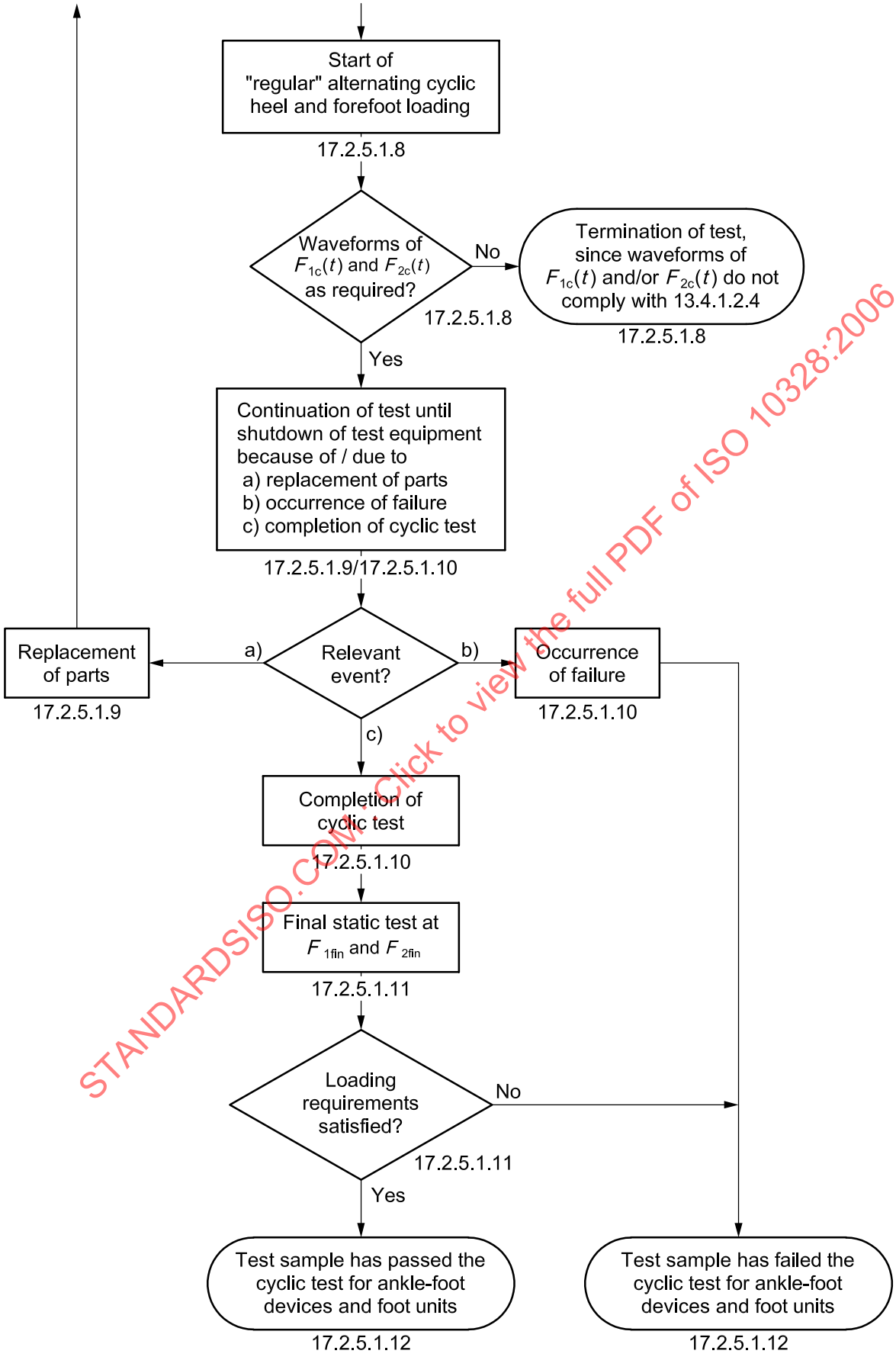


Figure 22 — Flowchart for the separate cyclic test for ankle-foot devices and foot units, specified in 17.2.5.1 Continued from Figure 21

17.3 Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts

17.3.1 General

The requirements of this test shall apply to all assemblies of knee joints and associated parts that normally provide the knee flexion stop (see 17.3.3.1) on a complete prosthesis, comprising

— assemblies of knee units and adjacent components required for their attachment to the proximal and distal part of a prosthesis and/or their alignment within a prosthesis;

— knee-shin assemblies, including adjacent components required for their attachment to the proximal part of a prosthesis and/or their alignment within a prosthesis.

17.3.2 Purpose of test

Users can apply high loads to prostheses in full flexion when kneeling or squatting (deep knee bend). A structural test is required, in order to ensure an adequate level of safety during normal use.

17.3.3 Applicability of the test to specific test samples

17.3.3.1 The decisive criterion for the applicability of the test specified in 17.3.4 to specific test samples is their involvement in the provision of the knee flexion stop.

NOTE 1 The term “knee flexion stop” used here and in the introductory paragraph of 17.3.1 covers any physical boundaries provided by the assemblies stated in 17.3.1, which stop the angular movement of the knee joint in the position of maximum knee flexion of a complete prostheses. It is not limited to specific knee flexion stop buffers included in some knee joint designs.

In consideration of the complexity of this criterion, for the purposes of this International Standard the decision on the applicability of this test is based on the conditions specified in 17.3.3.2 and 17.3.3.3.

NOTE 2 In some prostheses the maximum knee flexion allowed by the assemblies stated in 17.3.1 is reduced by contact on surfaces of other parts, as e.g. cosmetic components, the socket or the heel of the foot. In these cases the test in maximum knee flexion is not applicable.

17.3.3.2 The separate static ultimate strength test in maximum knee flexion specified in 17.3.4 shall be applied to a specific knee unit or knee-shin-assembly only if the knee flexion stop is incorporated in the knee mechanism or provided by the adjacent components listed in 17.3.1.

This shall be determined as prescribed in 17.3.4.1 and 17.3.4.2, also taking account of the information given in the test submission document (see 12.2.3).

17.3.3.3 The test shall not be applied to a specific knee unit or knee-shin-assembly, if the manufacturer/submitter provides a certificate stating that

a) either kneeling or squatting (deep knee bend) is expressly excluded from its intended use within a complete prosthesis, according to the manufacturer’s written instructions supplied with every component of the type or

b) the knee unit or knee-shin-assembly, together with the adjacent components listed in 17.3.1, does not provide the knee flexion stop on a complete prostheses in any application which is in accordance with the manufacturer’s instructions regarding

— the type(s) of prosthesis (knee-disarticulation, transfemoral and/or hip-disarticulation prosthesis);

— the attachment of the assembly to the proximal and distal part of the prosthesis;

— the alignment of the knee joint within the prosthesis.

The reasons for not testing a submitted sample or not continuing the test shall be recorded.

17.3.4 Test method

NOTE A flowchart for this test is shown in Figure 23.

17.3.4.1 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11, 12.2.1 and 12.2.3 and Table 12.

Record the values of the length L_e and the test force F_{su} to be applied.

Ensure that the posterior contour/shape and extension of the structures representing the thigh and shin portion within the length L_e (including the extension pieces) is of the smallest dimensions possible in accordance with the manufacturer's instructions, so that the test sample reaches the highest possible value of knee flexion occurring in a normal prosthesis, taking account of

— the use of the knee unit or knee-shin assembly in knee disarticulation, transfemoral and/or hip disarticulation prostheses;

— the attachment of these assemblies to the proximal and distal part of the prosthesis and the alignment of the knee joint within the prosthesis;

— the groups of amputees for whom the use of these assemblies within a complete prosthesis is intended.

Record the parameters of the posterior shape of the structures representing the thigh and shin portion within the length L_e.

17.3.4.2 Move the test sample to the position of maximum knee flexion and detect the location/position of the parts of the test sample which stop further flexion.

Record the location/position of the parts providing the knee flexion stop and proceed as follows.

a) If the knee flexion stop is provided by any parts of the knee unit and adjacent attachment/alignment components or by any parts of the knee-shin assembly listed in 17.3.1, proceed with 17.3.4.3.

b) If the knee flexion stop is not provided by any parts listed in 17.3.1, terminate the test and record that the separate static ultimate strength test in maximum knee flexion is not applicable to the specific structure submitted for test in the specific application, attachment and alignment within a complete prosthesis, simulated in the test sample.

Record the decision on the continuation of the test procedure.

17.3.4.3 Mount the test sample in the test equipment as illustrated in Figure 8.

17.3.4.4 Apply to the ends of the extension pieces the test force F, smoothly and at a rate of between 100 N/s and 250 N/s until the test sample fails, or the test force F attains the value of static test force F_{su}, specified in Table 12, without failure of the test sample.

Record the highest value of the test force F reached during the test and whether failure has occurred.

17.3.4.5 Decide and record whether the test sample has passed or failed the test procedure specified in 17.3.4.3 and 17.3.4.4, checking the results of step 17.3.4.4 against the performance requirement of 17.3.5.

17.3.4.6 If the test sample fails to sustain the performance requirement of 17.3.5, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.3.5 Performance requirement

In order to pass the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, a test sample shall sustain static loading by the static test force F_{su} at the prescribed value.

17.3.6 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirement of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts of this International Standard according to 17.3.5, tests of this type shall be passed (in the meaning of 17.3.5) by two test samples from the prescribed batch (see 9.4 and Table 16).

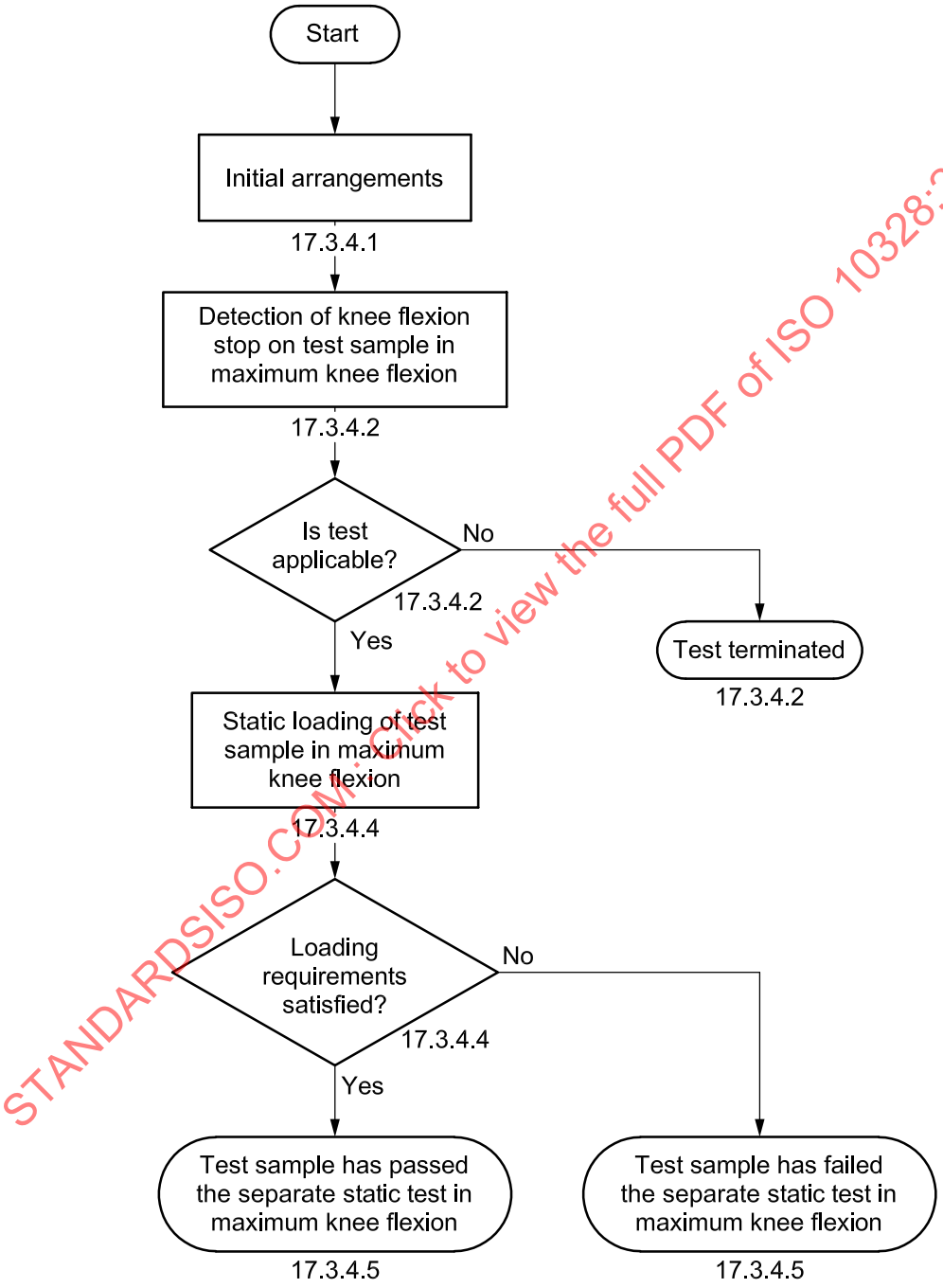


Figure 23 — Flowchart for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, specified in 17.3.4

17.4 Separate tests on knee locks

17.4.1 General

The requirements of this subclause shall apply to all knee units incorporating mechanisms which lock the knee in the extended position.

17.4.2 Purpose of tests

Locked knee units are subject to flexion loading during the stance phase of walking, and a failure of the knee lock mechanism during this phase is potentially hazardous. A structural test is required in order to ensure an adequate level of safety during normal use.

17.4.3 Separate static proof test for knee locks

17.4.3.1 Test method

17.4.3.1.1 Subject to request in the test submission document [see 12.3.5 d)] or agreement between the manufacturer/submitter and the test laboratory/facility, the separate static proof test for knee locks may be covered by the final static test to be applied to a test sample which has completed the separate cyclic test for knee locks without failing [see 17.4.5.1.1 c) and 17.4.5.1.18). This requires the application of the final static test in the manner specified in 17.4.3.1.6 to 17.4.3.1.9.

The setting, adjustment and/or measurement of segment lengths and/or offsets [see 17.4.3.1.2, 17.4.3.1.5 and 17.4.3.1.8 b)] shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing test force F_{stab} (see 13.2.2).

NOTE A flowchart for this test is shown in Figure 24.

17.4.3.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5 Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13.

If a test sample that has completed the separate cyclic test procedure for knee locks (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13 (see also 17.4.3.1.12). Record the re-use of the test sample.

Record the values of offsets and test forces to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K, see 6.8.1) are in accordance with the values specified in Table 13.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 17.4.3.1.3.

Record whether a special jig is used.

17.4.3.1.3 Apply to the test sample the settling test force F_{set}, specified in Table 14.

Maintain this force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period not less than 10 min and not more than 20 min before proceeding with 17.4.3.1.3. Record the time at rest.

17.4.3.1.4 Apply to the test sample and maintain during the adjustments of 17.4.3.1.5 and the measurements and recordings of 17.4.3.1.6 the stabilizing test force F_{stab}, specified in Table 14.

If the adjustments of 17.4.3.1.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig upon transfer of the test sample from the test equipment to the jig after having completed 17.4.3.1.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 17.4.3.1.6.

Record whether a special jig is used.

17.4.3.1.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values specified in Table 13 at the stabilizing test force F_{stab}.

Record the final values of offsets set.

17.4.3.1.6 Carry out the following.

a) Measure and record the distance L_{BT} (see 6.8.4) as L_9 or the displacement δ of the moving load application point from its reference position in the test equipment as δ_9.

b) If requested by the manufacturer/submitter, measure and record the effective lever arms L_A and L_K (see 6.8.3).

   Take into account that the data to be acquired are irrelevant to the performance requirements of 17.4.3.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 17.4.3.1.8 b) particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated.

   NOTE In principle, the measurement and recording of the effective lever arms L_A and L_K is not necessary here. They are identical to the ankle and knee offsets f_A and f_K, since these are set to the same value in the same plane (o_A and o_K are set to zero), so that the load line passes parallel to the u-axis. This may, however, have changed after the application of the proof load [see 17.4.3.1.8 b)].

17.4.3.1.7 Increase the test force F smoothly at a rate of between 100 N/s and 250 N/s to the proof test force F_{sp}, specified in Table 14.

Maintain this force, F_{sp}, at the prescribed value for (30 ± 3) s.

Decrease the test force F to F_{stab}.

If the test sample sustains the static loading at F_{sp} for the prescribed time, record this and proceed with 17.4.3.1.8.

If the test sample fails to sustain the static loading at F_{sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force F_{sp} has been maintained and terminate the test (but see 17.4.3.1.12).

17.4.3.1.8 Maintain (or, if a special jig is used, apply and maintain) the test force F_{stab} until the measurements and records of a) [and b)] specified below are completed.

a) Measure and record the distance L_{BT} as L_{10} or the displacement δ of the moving load application point from its reference position in the test equipment as δ_{10}. Complete the measurement within 5 min (see NOTE).

b) If requested by the manufacturer/submitter, measure and record the offsets f_A, f_K, o_A and o_K, and/or the effective lever arms L_A and L_K. Complete the measurements within 15 min (see NOTE).

Take into account that the data to be acquired are irrelevant to the performance requirements of 17.4.3.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 17.4.3.1.6 b) particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated. See also NOTE to 17.4.3.1.6 b).

If the measurements of b) are carried out with the test sample placed in a special jig, remove the stabilizing test force F_{stab} and re-apply it by the jig upon transfer of the test sample from the test equipment to the jig after having completed a).

Note and record the interval of time after decreasing the test force F to F_{stab} (17.4.3.1.7), at which each of the measurements of a) and b) is taken.

Record whether a special jig is used.

NOTE The time limits are set in order to limit the effect of recovery on the permanent deformation (17.4.3.1.9) and on the ankle and knee offsets and effective lever arms. The different values of time limit specified for the measurements of a) and b) take account of the different amounts of time required for the measurement and recording.

17.4.3.1.9 Calculate and record the permanent deformation, D_4, between the bottom and top load application points:

$$D_4 = L_9 - L_{10} \text{ or } D_4 = \delta_{10} - \delta_9. \quad (13)$$

17.4.3.1.10 Decide and record whether the test sample has passed or failed the test procedure specified in 17.4.3.1.2 to 17.4.3.1.9, checking the results of steps 17.4.3.1.7 and 17.4.3.1.9 against the performance requirements of 17.4.3.2.

17.4.3.1.11 If the test sample fails to satisfy either of the performance requirements of 17.4.3.2, inspect it to detect the nature and, if possible, the location of any damage, and record the results.

17.4.3.1.12 If a test sample that has already completed the separate cyclic test procedure for knee locks without failing (see 17.4.3.1.2), fails to satisfy either of the performance requirements of 17.4.3.2, repeat the test on a substitute test sample and record the failure and the repetition, including all specific records called for.

17.4.3.2 Performance requirements

In order to pass the separate static proof test for knee locks, a test sample shall satisfy the following performance requirements:

a) the test sample shall sustain static loading by the proof test force F_{sp} at the prescribed value for (30 ± 3) s.

b) The value of permanent deformation D_4 of the test sample shall not exceed

- 2 mm for a total sample length $(u_T - u_B)_{specified}$ = 650 mm or
- 2 mm multiplied by the ratio $[(u_T - u_B)_{actual}/(u_T - u_B)_{specified}]$ for values of total sample length exceeding 650 mm (see Footnote b of Table 5).

17.4.3.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the separate static proof test for knee locks of this International Standard according to 17.4.3.2, tests of this type shall be passed (in the meaning of 17.4.3.2) by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 17.4.3.1.12 (see 9.4 and Table 16).

Compliance with the performance requirements of the separate static proof test for knee locks can also be claimed, if the final static test [17.4.5.1.1 c)/17.4.5.1.18] as part of the separate cyclic test procedure for knee locks (17.4.5) is applied in the manner specified in 17.4.5.1.5 to 17.4.5.1.8 (see also 17.4.5.2 and 17.4.5.3).

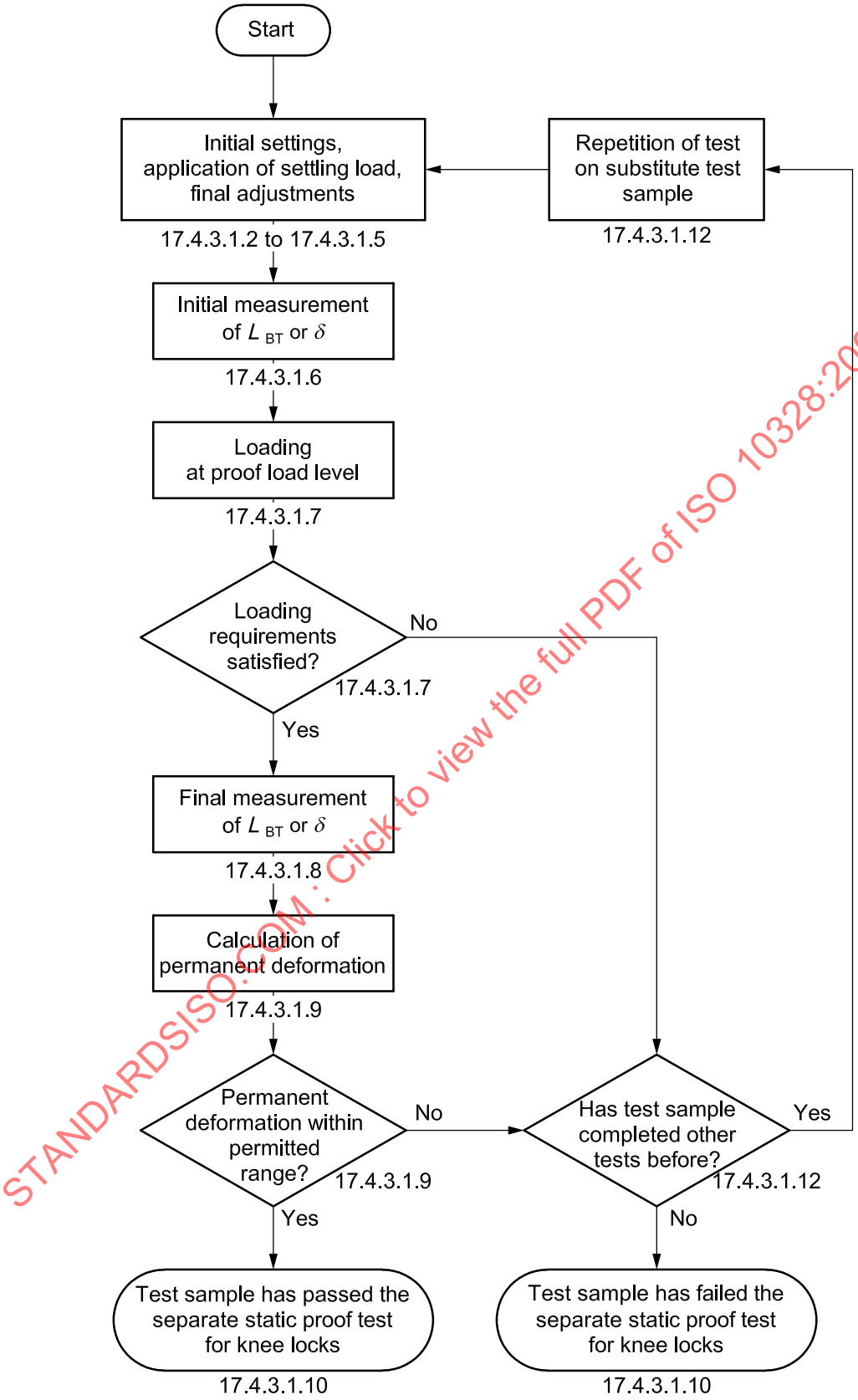


Figure 24 — Flowchart for the separate static proof test for knee locks, specified in 17.4.3.1

17.4.4 Separate static ultimate strength test for knee locks

17.4.4.1 Test method

17.4.4.1.1 The setting and adjustment of segment lengths and/or offsets (see 17.4.4.1.2 and 17.4.4.1.5) shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing test force F_{stab} (see 13.2.2).

NOTE A flowchart for this test is shown in Figure 25.

17.4.4.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13.

If a test sample that has completed the separate static proof test for knee locks without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13 (see also 17.4.4.1.9). Record the re-use of the test sample.

If a test sample that has completed the separate cyclic test procedure for knee locks (including the final static test) without failing is used for this test in accordance with 9.5.1, re-align it in accordance with Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13 (see also 17.4.4.1.9). Record the re-use of the test sample.

Record the values of offsets and test forces to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K) (see 6.8.1) are in accordance with the values specified in Table 13.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 17.4.4.1.3.

Record whether a special jig is used.

17.4.4.1.3 Apply to the test sample the settling test force F_{set}, specified in Table 14.

Maintain this force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period not less than 10 min and not more than 20 min before proceeding with 17.4.4.1.4. Record the time at rest.

17.4.4.1.4 Apply to the test sample, and maintain during the adjustments of 17.4.4.1.5, the stabilizing test force F_{stab}, specified in Table 14.

If the adjustments of 17.4.4.1.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig, upon transfer of the test sample from the test equipment to the jig after having completed 17.4.4.1.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 17.4.4.1.6.

Record whether a special jig is used.

17.4.4.1.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values specified in Table 13 at the stabilizing test force F_{stab}.

Record the final values of offsets set.

17.4.4.1.6 Increase the test force F smoothly at a rate of between 100 N/s and 250 N/s until the test sample fails, or the test force F attains the value of the ultimate test force F_{su}, specified in Table 14, without failure of the test sample.

Record the highest value of the test force F reached during the test and whether failure has occurred.

If expressly requested by the manufacturer/submitter, or if requested in the test submission document [12.3.4 a)], continue the separate static ultimate strength test for knee locks after the test sample has withstood the ultimate test force F_{su} until failure actually occurs and record the value of the load at failure.

Take into account that in this case the end attachments used need a higher value of stiffness and ensure that the values of their deflection and permanent deformation keep within the limits specified in 13.2.1.2.10 at a higher proof load than is specified in Table 4 (see second paragraph of 13.2.1.2.1).

17.4.4.1.7 Decide and record whether the test sample has passed or failed the test procedure specified in 17.4.4.1.2 to 17.4.4.1.6, checking the results of step 17.4.4.1.6 against the performance requirement of 17.4.4.2.

17.4.4.1.8 If the test sample fails to satisfy the performance requirement of 17.4.4.2, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.4.4.1.9 If a test sample that has already completed the separate static proof test and/or the separate cyclic test procedure for knee locks without failing (see 17.4.4.1.2), fails to satisfy the performance requirement of 17.4.4.2, repeat the test on a substitute test sample and record the failure and the repetition, including all specific records called for.

17.4.4.2 Performance requirement

In order to pass the separate static ultimate strength test for knee locks, the test sample shall sustain static loading by the ultimate test force F_{su} at the prescribed value.

17.4.4.3 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirement of the separate static ultimate strength test for knee locks of this International Standard according to 17.4.4.2, tests of this type shall be passed (in the meaning of 17.4.4.2) by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 17.4.4.1.9 (see 9.4 and Table 16).

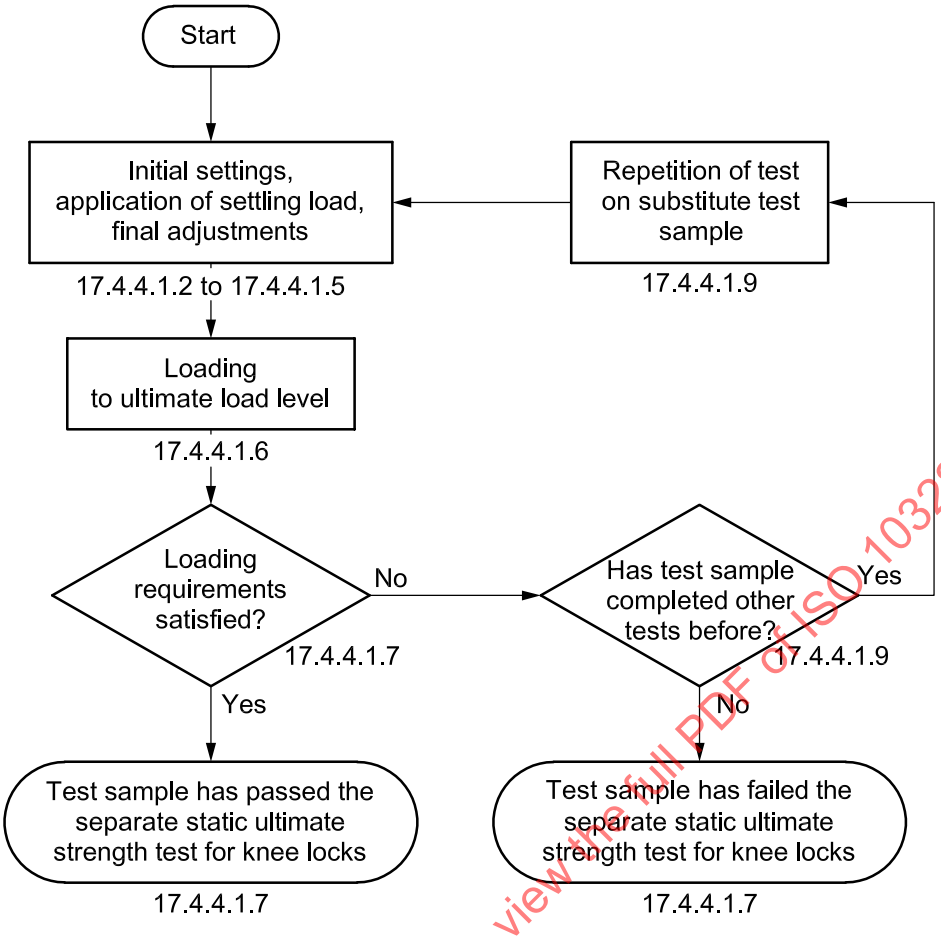


Figure 25 — Flowchart for the separate static ultimate strength test for knee locks, specified in 17.4.4.1

17.4.5 Separate cyclic test for knee locks

17.4.5.1 Test method

17.4.5.1.1 The following general requirements shall apply:

a) If the test frequency selected is higher than 1 Hz, then the maximum frequency shall be below the level at which dynamic mass effects begin to affect the maximum load value or the waveform.

b) During the course of the cyclic test, specified parts shall be replaced when the number of cycles has reached a value at which such replacement is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b)]. All such replacements shall be recorded.

c) A test sample that completes the cyclic test without failing shall be subjected to final static loading by the test force F_{fin}, applied at a rate of between 100 N/s and 250 N/s and maintained for (30 ± 3) s.

Subject to request in the test submission document [see 12.3.5 d)] or agreement between the manufacturer/submitter and the test laboratory/facility, the final static test may also cover the separate static proof test for knee locks, if applied without re-alignment of the test sample in the manner specified in 17.4.3.1.6 to 17.4.3.1.9.

d) A test sample that fails and/or a test sample that completes the cyclic test without failing shall, at the request of the manufacturer/submitter, be visually examined at the magnification specified in the test

submission document [see 12.3.5 c)], and the presence, location and nature of any fractures and/or cracks be recorded, together with the magnification used.

e) The settings, adjustments and/or measurements of segment lengths and offsets [see 17.4.5.1.2, 17.4.5.1.4, (17.4.5.1.16 and 17.4.5.1.18)] shall be carried out with the test sample mounted either in the test equipment or in a special jig capable of applying the stabilizing test force F_{stab} (see 13.2.2).

NOTE A flowchart for this test is shown in Figures 26 to 28.

17.4.5.1.2 Prepare and align a test sample from the batch specified in Table 16 for this test in accordance with 9.5, Clauses 10 and 11 and 12.2.1, NOTE 1 of 16.1.1 and Table 13.

Record the values of offsets, test forces and prescribed number of cycles to be applied.

At zero load, set (or check and, if necessary, correct) the test sample segment lengths ($u_A - u_B$, $u_K - u_A$ and $u_T - u_K$ or any other specific combination) (see 10.3.6) in accordance with the values specified in Table 5.

Record the combinations and values of the segment lengths set.

At zero load, initially set (or check and, if necessary, correct) the bottom and top load application levers until the initial values of the ankle and knee offsets (f_A, f_K, o_A and o_K) (see 6.8.1) are in accordance with the values specified in Table 13.

Record the initial values of offsets set.

If the setting of the segment lengths and offsets at zero load has been carried out with the test sample placed in a special jig, transfer the test sample from the jig to the test equipment before proceeding with 17.4.5.1.3.

Record whether a special jig is used.

17.4.5.1.3 Apply to the test sample the settling test force F_{set}, specified in Table 14.

Maintain this force, F_{set}, at the prescribed value for a period not less than 10 s and not more than 30 s and then remove it. Record the elapsed time.

Allow the test sample to rest at zero load for a period not less than 10 min and not more than 20 min before proceeding with 17.4.5.1.4. Record the time at rest.

17.4.5.1.4 Apply to the test sample and maintain during the adjustments of 17.4.5.1.5 and the measurements and recordings of 17.4.5.1.6 the stabilizing test force F_{stab}, specified in Table 14.

If the adjustments of 17.4.5.1.5 are carried out with the test sample placed in a special jig, apply the stabilizing test force F_{stab} by the jig upon transfer of the test sample from the test equipment to the jig after having completed 17.4.5.1.3 and then remove F_{stab} and re-apply it by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 17.4.5.1.6.

Record whether a special jig is used.

17.4.5.1.5 Finally adjust the bottom and top load application levers until the final values of the ankle and knee offsets (f_A, f_K, o_A and o_K) are in accordance with the values specified in Table 13 at the stabilizing test force F_{stab}.

Record the final values of offsets set.

17.4.5.1.6 Carry out the following.

a) Measure and record the distance L_{BT} (see 6.8.4) as L_{11} or the displacement δ of the moving load application point from its reference position in the test equipment as δ_{11}.

b) If requested by the manufacturer/submitter, measure and record the effective lever arms L_A and L_K (see 6.8.3).

Take into account that the data to be acquired are irrelevant to the performance requirements of 17.4.5.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 17.4.5.1.8 b), 17.4.5.1.16 and 17.4.5.1.17 particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/submitter, as indicated.

NOTE In principle, the optional measurement and recording of the effective lever arms L_A and L_K is not necessary here. They are identical to the ankle and knee offsets f_A and f_K, since these are set to the same value in the same plane (o_A and o_K are set to zero), so that the load line passes parallel to the u-axis. This may, however, have changed after the application of other loading conditions [see 17.4.5.1.8 b), 17.4.5.1.16 and 17.4.5.1.17].

17.4.5.1.7 Apply to the test sample the maximum test force F_{cmax}, specified in Table 14.

Maintain this force, F_{cmax}, until step 17.4.5.1.8 is completed.

17.4.5.1.8 Carry out the following.

a) Measure and record the distance L_{BT} as L_{12} or the displacement δ of the moving load application point from its reference position in the test equipment as δ_{12}.

b) If requested by the manufacturer/submitter (see NOTE to 17.4.5.1.6), measure and record the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K.

Take into account that the data to be acquired are irrelevant to the performance requirements of 17.4.5.2, although they may provide interesting and useful information in conjunction with the data to be acquired according to 17.4.5.1.6 b), 17.4.5.1.16 and 17.4.5.1.17 particularly on the deformation of the test sample under load. For this reason, carry out these measurements and recordings only if requested by the manufacturer/ submitter, as indicated. See also NOTE to 17.4.5.1.6 b).

17.4.5.1.9 Decrease the test force F to the minimum test force F_{cmin}, specified in Table 14.

If the test sample sustains the static loading at F_{cmax} until step 17.4.5.1.8 is completed, proceed with 17.4.5.1.10.

If the test sample fails to sustain the static loading at F_{cmax} until step 17.4.5.1.8 is completed, record this together with the highest value of test force reached or the time for which the prescribed value of the maximum test force F_{cmax} has been maintained and terminate the test.

17.4.5.1.10 Apply to the test sample the pulsating test force $F_c(t)$ in accordance with the requirements of 13.6.3.2/13.2.3.2 and 17.4.5.1.1 a) and the values specified in Table 14, at the frequency called for in the test submission document [see 12.3.5 a)] for a series of cycles, in order to allow the test sample and the test equipment to "settle down".

NOTE 1 The number of cycles required for the test to settle down will depend on the nature of the test sample and the test equipment control mechanism.

Take care that during this settling-in period, the highest force applied to the test sample does not exceed the maximum test force F_{cmax} by more than 10 % (see 13.6.3.2.2/13.2.3.2.8).

NOTE 2 Experience has shown that repeated loading at values exceeding the maximum test force F_{cmax} by more than 10 % can cause early deterioration of the test sample.

Do not proceed with 17.4.5.1.11 until the test sample and the test equipment have settled down, and the pulsating test force $F_c(t)$ has achieved the waveform specified in 13.6.3.2.2/13.2.3.2.3 and keeps within the tolerances specified in 14.3 f) and g).

Stop the test equipment and record the frequency called for, together with the number of cycles required to settle down and whether the pulsating test force $F_c(t)$ is applied in accordance with 13.2.3.2.3 and 14.3 f) and g).

If the frequency called for cannot be achieved or does not allow the pulsating test force $F_c(t)$ to be applied as specified, repeat the preceding steps of 17.4.5.1.10 at a different frequency, to be agreed upon between the test laboratory/facility and the manufacturer/submitter.

Record any agreement on a frequency differing from the value called for.

If the pulsating test force $F_c(t)$ cannot be applied at any frequency agreed upon between the test laboratory/facility and the manufacturer/submitter, record this and terminate the test.

17.4.5.1.11 Apply to the test sample the maximum test force F_{cmax}.

Measure and record the initial value of the distance L_{BT} as L_{13} or the displacement δ of the moving load application point from its reference position in the test equipment as δ_{13}.

17.4.5.1.12 Decrease the test force F to the minimum test force F_{cmin}.

17.4.5.1.13 Apply to the test sample the pulsating test force $F_c(t)$ in accordance with the requirements of 13.6.3.2/13.2.3.2 and 17.4.5.1.1 a) and the values specified in Table 14, at the frequency called for in the test submission document [see 12.3.5 a)] or at a different frequency agreed between the test laboratory/facility and the manufacturer/submitter (see 17.4.5.1.10) for the prescribed number of cycles specified in Table 14.

Inspect the waveform of the applied pulsating test force $F_c(t)$. Terminate the test if the waveform does not comply with 13.6.3.2.2/13.2.3.2.3.

Record the frequency applied, together with the results of the inspection of the waveform and the decision on the continuation of the test.

Set the test equipment displacement trip to 5 mm below the value of the initial distance L_{13} at F_{cmax} or 5 mm above the value of the initial displacement δ_{13} at F_{cmax} determined in 17.4.5.1.11.

17.4.5.1.14 Record the durations and reasons for all occurrences of switch-off, together with the number of cycles of load applied up to that time.

17.4.5.1.15 Examine the test sample for damage if the test equipment has switched off due to excessive displacement and proceed as follows:

a) If there is no sign of failure, restart the test from 17.4.5.1.10 and apply the prescribed number of cycles reduced by the number of cycles completed before the test equipment tripped. Record the restart.

b) If the test sample has failed, record this together with the number of cycles at switch-off and terminate the test (but see 17.4.5.1.22).

17.4.5.1.16 During the course of the cyclic test, replace any parts which would be replaced in normal service. Proceed as follows.

Stop the test equipment when the number of loading cycles has reached a value at which the exchange/replacement of these parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b) and 17.4.5.1.1 b)]. Record the number of cycles at shutdown.

Measure and record the distance L_{BT} or the displacement δ and, if requested by the manufacturer/submitter [note the additional instructions of 17.4.5.1.6 b) and 17.4.5.1.8 b)], the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K with the test force F_{cmin} applied and subsequently with the test force F_{cmax} applied.

Exchange/replace the specified parts in accordance with the manufacturer's/submitter's service instructions and/or the test submission document.

Restart the test from 17.4.5.1.2, 17.4.5.1.3 or 17.4.5.1.10, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

Record the details of the exchange/replacement and the resulting conditions of the restart, together with the number of the corresponding clause.

17.4.5.1.17 Continue the test until failure occurs or the prescribed number of cycles specified in Table 14 has been completed.

If failure occurs, record this together with the number of cycles at switch-off of the test equipment and terminate the test (but see 17.4.5.1.22).

If the prescribed number of cycles has been completed, stop the test equipment and measure and record the distance L_{BT} or the displacement δ and, if requested by the manufacturer/submitter [note the additional instructions of 17.4.5.1.6 b) and 17.4.5.1.8 b)], the offsets f_A, f_K, o_A and o_K and/or the effective lever arms L_A and L_K with the test force F_{cmin} applied and subsequently with the test force F_{cmax} applied. Record the number of cycles at shutdown.

17.4.5.1.18 Subject a test sample that completes the cyclic test without failing to the final static test force F_{fin}, specified in Table 14, applied at a rate of between 100 N/s and 250 N/s and maintained for (30 ± 3) s and record the results.

If the test sample fails to sustain the final static loading at F_{fin} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the final static test force F_{fin} has been maintained.

If the final static test is intended also to cover the separate static proof test for knee locks specified in 17.4.3.1 [see 17.4.5.1.1 c)], follow the instructions given in 17.4.3.1.6 to 17.4.3.1.9.

17.4.5.1.19 Decide and record whether the test sample has passed or failed the test procedure specified in 17.4.5.1.2 to 17.4.5.1.18, checking the results of steps 17.4.5.1.9, 17.4.5.1.15, 17.4.5.1.17 and 17.4.5.1.18 against the performance requirements of 17.4.5.2.

17.4.5.1.20 If the test sample fails to satisfy any of the performance requirements of 17.4.5.2, inspect it to detect the nature and, if possible, the location of any damage and record the results.

17.4.5.1.21 At the request of the manufacturer/submitter, visually examine a test sample that fails and/or a test sample that completes the separate cyclic test for knee locks and the final static test without failing, to detect the presence, location and nature of any fractures and/or cracks [see 17.4.5.1.1 d)].

Carry out the examination at the magnification specified in the test submission document [see 12.3.5 c)] or decided according to circumstances in agreement with the manufacturer/submitter, if appropriate.

Record the magnification used and the information obtained, taking account of the manufacturer's/submitter's instructions concerning the documentation of test results [see 12.3.5 c)].

17.4.5.1.22 If a test sample being tested at a frequency of 3 Hz or higher fails to satisfy any of the performance requirements of 17.4.5.2, repeat the test on a substitute test sample at a frequency less than 3 Hz, specified in the test submission document [see 12.3.5 e)] or agreed upon between the test laboratory/facility and the manufacturer/submitter and record the failure and the repetition, including all specific records called for.

17.4.5.2 Performance requirements

17.4.5.2.1 In order to pass the separate cyclic test for knee locks, a test sample shall satisfy the performance requirements listed in a) to c).

a) The test sample shall sustain static loading by the maximum test force F_{cmax} at the prescribed value for the time required for measurements and records of 17.4.5.1.8.

b) The test sample shall sustain cyclic loading by the pulsating test force $F_c(t)$ at the prescribed level and range for the prescribed number of cycles.

c) The test sample shall sustain static loading by the final static test force F_{fin} at the prescribed value for (30 ± 3) s.

17.4.5.2.2 In order to also pass the separate static proof test for knee locks specified in 17.4.3.1 when being subjected to the final static test applied in the manner specified in 17.4.3.1.6 to 17.4.3.1.9 for the separate static proof test for knee locks [see 17.4.5.1.1 c) and 17.4.5.1.18], the test sample shall satisfy 17.4.5.2.1 c) [which is identical to 17.4.3.2.a)], together with the following requirement [which is identical to 17.4.3.2 b)].

— The value of permanent deformation D_4 of the test sample shall not exceed 2 mm.

If the test sample satisfies the performance requirement of 17.4.5.2.1 c) but fails to satisfy the performance requirement of 17.4.5.2.2, the separate static proof test for knee locks shall be carried out as specified in 17.4.3.1.

17.4.5.3 Compliance conditions

17.4.5.3.1 In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 complies with the performance requirements of the separate cyclic test for knee locks of this International Standard according to 17.4.5.2.1, tests of this type shall be passed (in the meaning of 17.4.5.2.1) by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 17.4.5.1.2.2 (see 9.4 and Table 16).

17.4.5.3.2 In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.4 also satisfies the compliance conditions of the separate static proof test for knee locks of this International Standard according to 17.4.3.3, 17.4.5.3.1 shall apply provided that the test samples also comply with the performance requirement according to 17.4.5.2.2.

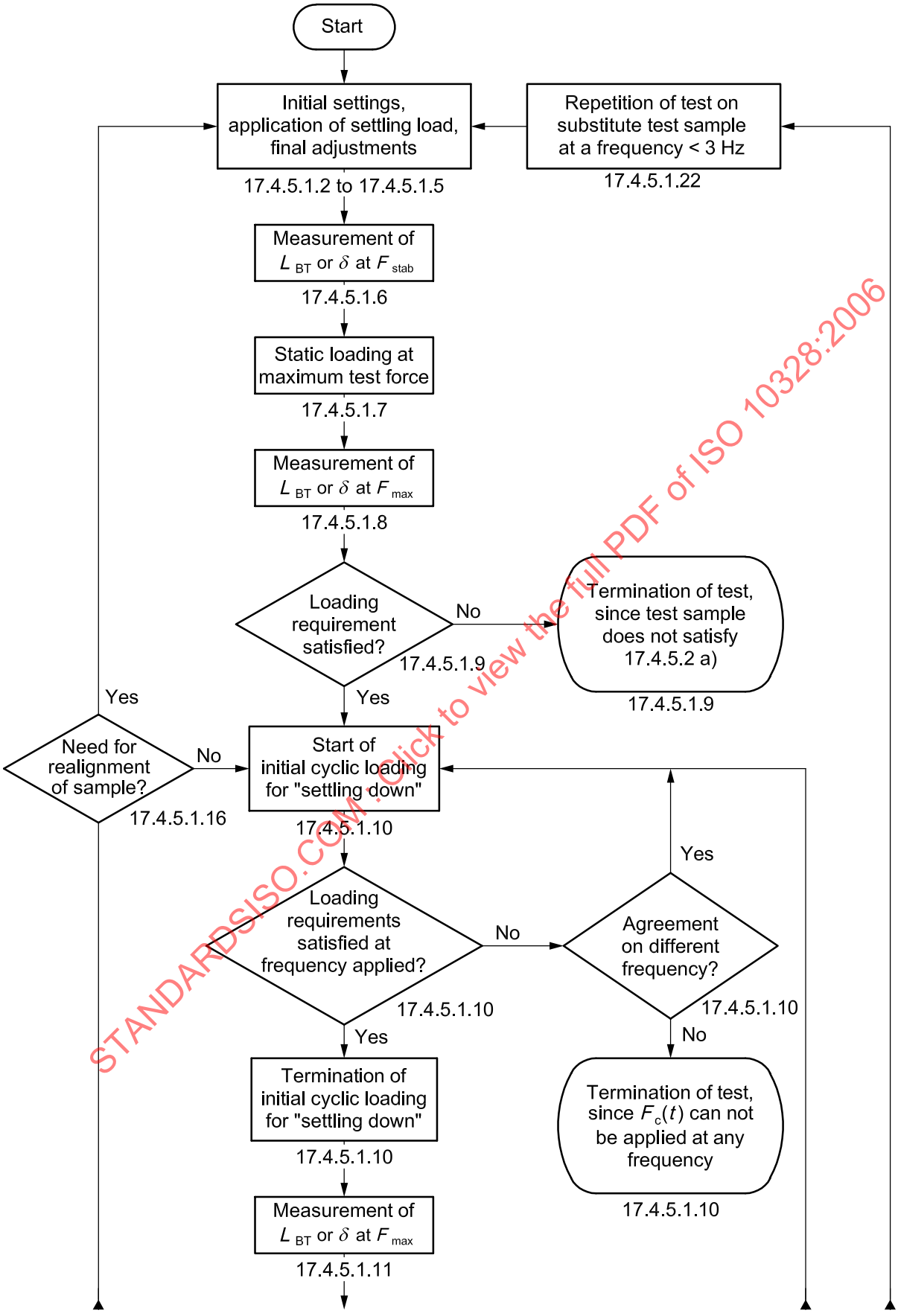


Figure 26 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1
Continued on Figures 27 and 28

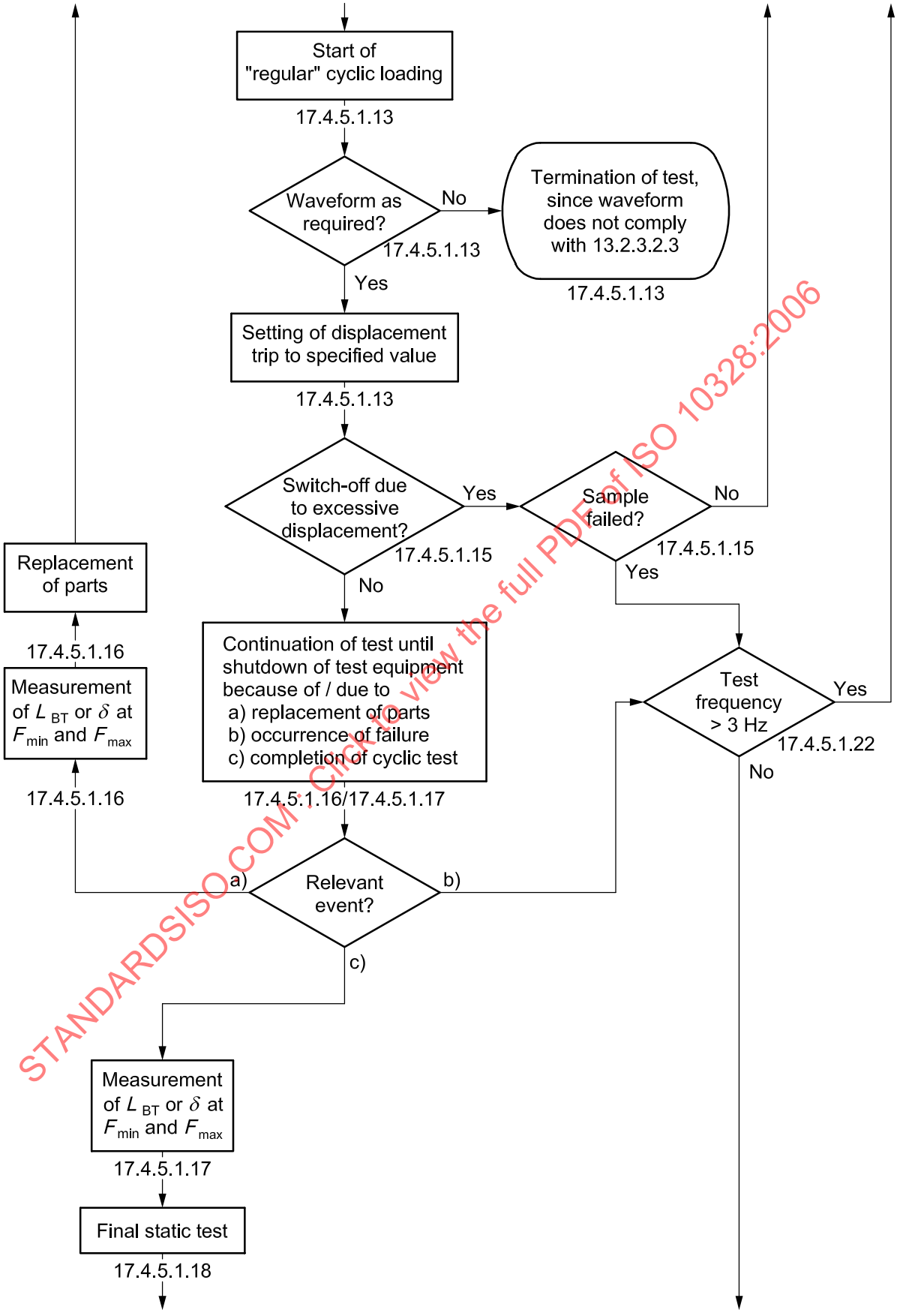


Figure 27 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1
Continued from Figure 26 and continued on Figure 28

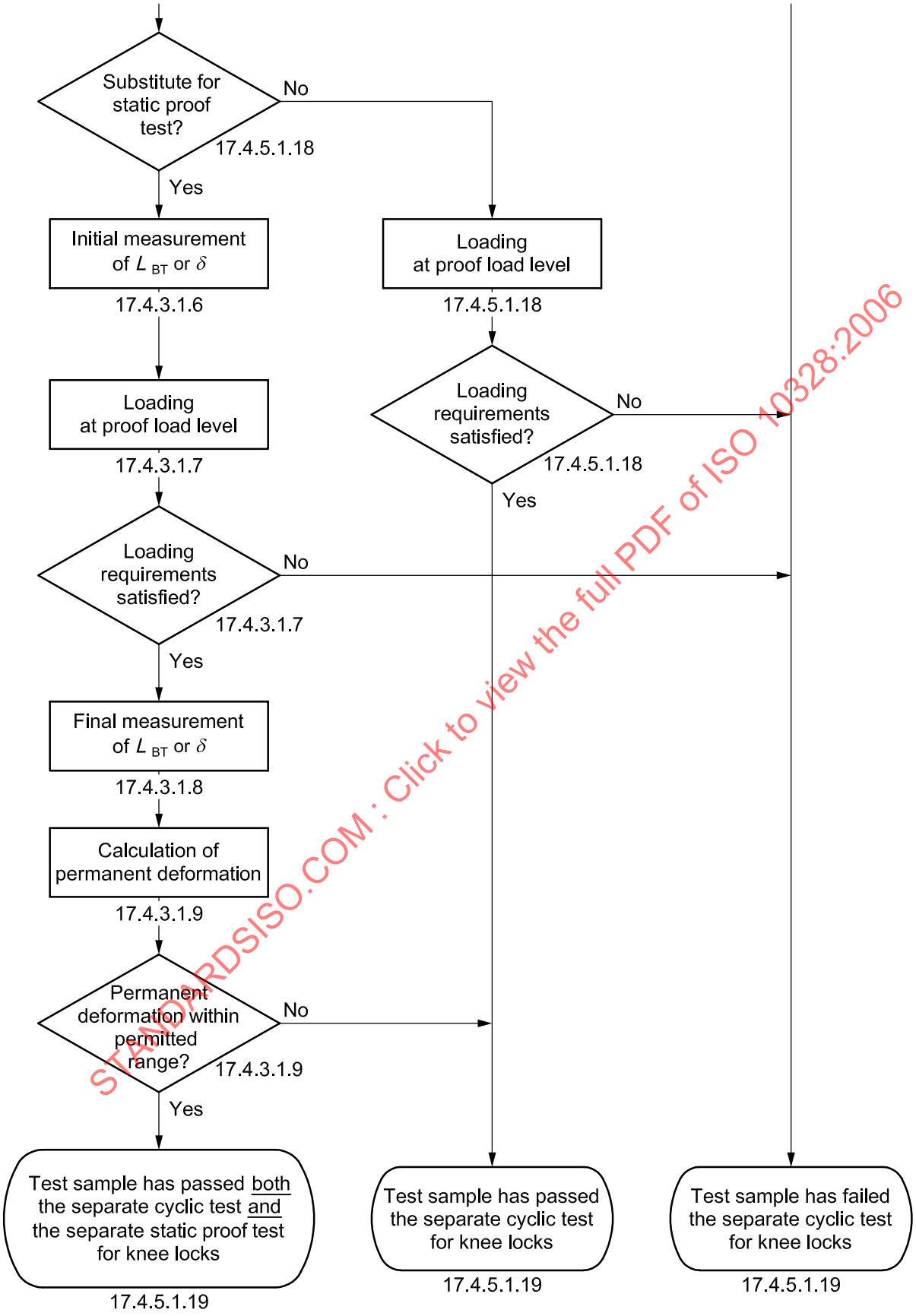


Figure 28 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1
Continued from Figure 27

18 Test laboratory/facility log

18.1 General requirements

18.1.1 The test laboratory/facility carrying out the tests specified in this International Standard and indicated in the test submission document shall ensure that all records called for in this International Standard are entered in the test laboratory/facility log.

18.1.2 The submitter of test samples and the identification of the test submission document shall be clearly indicated and the date or dates of receipt be recorded.

18.1.3 The identification of the test report or reports (such as serial number) shall be clearly indicated and the dates of preparation and submission be recorded.

18.2 Specific requirements

According to the instructions of this International Standard, specific records shall be entered in the test laboratory/facility log for:

a) the identification (number) of the test equipment used and the reference (number) of the end attachments, jig and measuring devices (if used);

b) the selection, type, preparation, identification and alignment of test samples;

c) the conduct of specific tests, selected in accordance with this International Standard and the test submission document;

d) any unusual features observed during the test(s).

NOTE Annex E offers a summary of the records to be entered in the test laboratory/facility log, for general information and guidance of test laboratory/facility staff and submitters (see 19.3).

19 Test report

19.1 General requirements

19.1.1 The test laboratory/facility shall prepare a test report for the test(s) conducted and shall provide at least one copy to the submitter of the test sample.

NOTE The test laboratory/facility should maintain another copy of the test report with the test log. This will simplify the reply to possible further inquiries of the manufacturer/submitter.

19.1.2 The test report shall be signed and dated on behalf of the test laboratory/facility by a designated person.

19.1.3 The test laboratory/facility shall clearly indicate a name and address for communication.

19.1.4 The test laboratory/facility shall provide a unique and traceable identification and date for the test report (such as serial number) including identification of each page, and the total number of pages of the report. The test laboratory/facility shall maintain a record of such identification and date.

19.1.5 The submitter of the test sample, the manufacturer, if known, and the test laboratory/facility identification shall be clearly indicated.

19.1.6 The date of receipt of test samples and date(s) of preparation of the test report shall be clearly indicated.

19.2 Specific requirements

19.2.1 For each type of test conducted (see 9.4), the test report shall specifically refer to this International Standard, the clauses related to the specific type of test performed, and the test loading condition or direction of loading, the test loading level applied and which special test set-ups were used. This particularly applies to tests that are conducted at the additional test loading level P6 according to Annex D (see 16.2.1.1.2, 16.2.2.1.2 and 16.3.2.2 and/or 17.2.3.1.2, 17.2.4.1.2 and 17.2.5.1.3), and to the alternative static ultimate strength test according to Annex C (see 16.2.2.1.1 and 16.2.2.1.6 and/or 17.2.4.1.1 and 17.2.4.1.5/17.2.4.1.11).

19.2.2 The test report shall include any statements (with justification) of why the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts should not be applied to test samples of a specific prosthetic structure including a knee unit or a knee-shin-assembly (see 17.3.3.3).

19.2.3 For each prosthetic device/structure for which an appropriate batch or batches of test samples have been submitted for test, the test report shall state the tests in which compliance with requirements of this International Standard has been demonstrated. The test report shall also state the tests conducted, in which compliance has not been demonstrated.

If one or more test samples of the prosthetic device/structure submitted for test has/have failed a specific type of test, the test report shall include details of the failure.

19.3 Options

19.3.1 The test report shall include any additional information, specifically requested in the test submission document (see 12.1.2 and 12.1.3).

19.3.2 Upon request of the submitter, the test laboratory/facility shall copy from the test log to the test report any further records of samples and test results called for. Annex E gives details of the records to be entered in the test laboratory/facility log according to the instructions of this International Standard.

20 Classification and designation

20.1 General

A lower limb prosthetic device/structure

a) for which compliance with the requirements of this International Standard is claimed (see 9.1, 9.2 and 9.3) for a specific test loading level "P" (see 7.2) and

b) which is suitable for lower limb amputees with a body mass not exceeding a specific value of maximum body mass "m" kg according to the manufacturer's written instructions on the intended use of that device,

shall be classified and designated as shown below.

ISO 10328 - "P" - "m" kg

20.2 Examples of classification and designation

EXAMPLES 1 to 3 illustrate variations of classification/designation for lower limb prosthetic devices/structures that comply with the requirements of this International Standard for one and the same test loading level (P4).

These examples are distinguished by different values of maximum body mass (70 kg, 80 kg, 90 kg), which indicate differences in the intended use of the devices concerned, depending on their individual design.

EXAMPLE 1 ISO 10328 - P4 - 70 kg

EXAMPLE 2 ISO 10328 - P4 - 80 kg

EXAMPLE 3 ISO 10328 - P4 - 90 kg

In consideration of the background information given in Annex B, the following can be stated.

a) The classification/designation according to EXAMPLE 1 is typical of a lower limb prosthetic device/structure intended to be used for active amputees, who are expected to load their lower limb prosthesis at a higher level than those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 70 kg, which is 10 kg below the maximum body mass of those amputees (80 kg).

b) The classification/designation according to EXAMPLE 2 is typical of a lower limb prosthetic device/structure intended to be used for amputees, who are expected to load their lower limb prosthesis at the same level as those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 80 kg, which is identical with the maximum body mass of those amputees (80 kg).

c) The classification/designation according to EXAMPLE 3 is typical of a lower limb prosthetic device/structure intended to be used for amputees, who are expected to load their lower limb prosthesis at a lower level than those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 90 kg, which is 10 kg above the maximum body mass of those amputees (80 kg).

All examples of classification/designation illustrated in EXAMPLES 1 to 3 and commented on in a) to c) require the manufacturer to specify, with justification, the conditions of use in his written instructions on the intended use of the lower limb prosthetic device/structure.

NOTE The above classifications/designations are also used in the examples of label layout (see 21.3 and Figure 30).

21 Labelling

21.1 General

Each lower limb prosthetic device/structure

a) for which compliance with the requirements of this International Standard is claimed (see 9.1, 9.2 and 9.3) for a specific test loading level "P" (see 7.2) and

b) which is suitable for lower limb amputees with a body mass not exceeding a specific value of maximum body mass "m" kg according to the manufacturer's written instructions on the intended use of that device,

shall be labelled in accordance with the classification/designation specified in 20.1. If appropriate, the label may include further information as shown in Figure 29 and addressed in 21.2.

The statements on the label shall be given independent of any specific information on the intended use of the prosthetic device/structure supplied by the manufacturer with the device/structure.

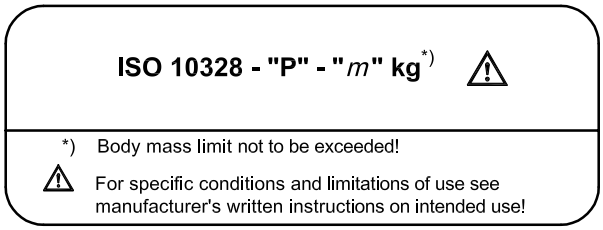


Figure 29 — General concept for the label layout

21.2 Use of mark "*)" and warning symbol

The **mark "*)"** behind "kg" shall allow reference to a brief statement on the label that the value "m" stated specifies the body mass limit not to be exceeded and that further important information on the specific conditions of use is given in the manufacturer's written instructions on the intended use of the device.

The **warning symbol** to be used in addition to the mark "*)" shall allow reference to a brief statement on the label regarding particular limitations of use, e.g. limitations concerning the activity of amputees. This is, for instance, the case if the stated body mass limit "m" exceeds the body mass limit of those amputees on whose locomotion data the stated test loading level "P" is based.

The use of mark "*)" and warning symbol is illustrated in the label models a) to c) of Figure 30, commented on in 21.3.

21.3 Examples of label layout

The layout of the label shall conform to any of the models a) to c) of Figure 30. The examples of classification/designation used in these models correspond to those used in EXAMPLES 1 to 3 of 20.2.

— The label according to model a) of Figure 30 shall apply to lower limb prosthetic devices/structures corresponding to EXAMPLE 1 of 20.2, commented on in 20.2 a).

— The label according to model b) of Figure 30 shall apply to lower limb prosthetic devices/structures corresponding to EXAMPLE 2 of 20.2, commented on in 20.2 b).

— The label according to model c) of Figure 30 shall apply to lower limb prosthetic devices/structures corresponding to EXAMPLE 3 of 20.2, commented on in 20.2 c).

21.4 Label placement

The label shall be placed on the device and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the label shall be placed in the information leaflet supplied with one or more devices.

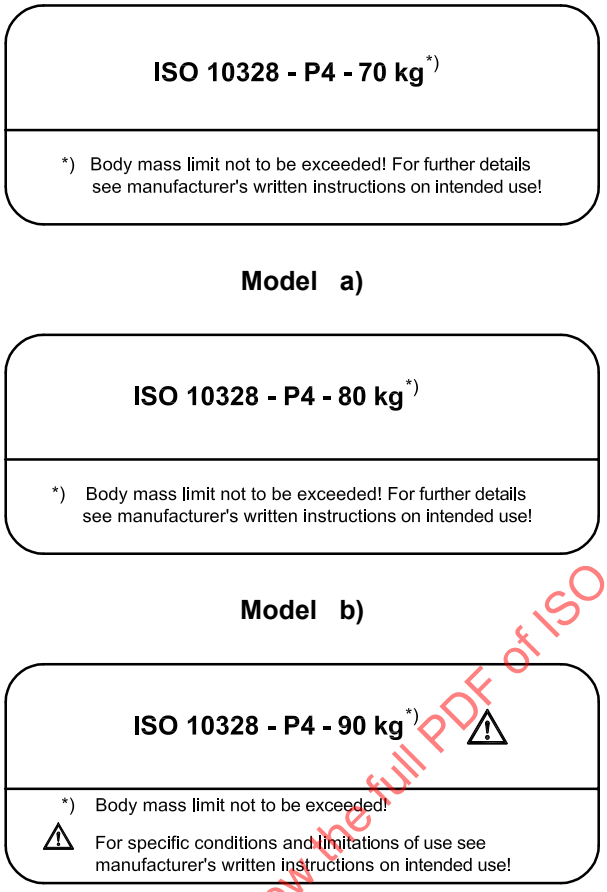


Figure 30 — Models for the label layout

Annex A
(informative)

Description of internal loads and their effects

A.1 General

The test loading conditions of the principal (and separate) structural tests specified in the main body of this International Standard are based on internal reference loads, consisting of an axial force (axial compression), bending moments and a twisting moment (induced torque) indicated in Clause A.3.

The reference forces and moments act respectively along and about reference lines.

A.2 Moment reference lines

A.2.1 General

The moment reference lines are those lines about which the moments specified in clause A.3 act. They are specified as follows using the elements of the geometric system described in Clause 6.

A.2.2 Ankle moment reference lines

A.2.2.1 The ankle moment reference line A_f is the line of intersection of the ankle reference plane (A) with the f-u plane.

A.2.2.2 The ankle moment reference line A_o is the line of intersection of the ankle reference plane (A) with the o-u plane.

A.2.3 Knee moment reference lines

A.2.3.1 The knee moment reference line K_f is the line of intersection of the knee reference plane (K) with the f-u plane.

A.2.3.2 The knee moment reference line K_o is the line of intersection of the knee reference plane (K) with the o-u plane.

A.3 Internal loads

A.3.1 General

The internal forces and moments are indicated in A.3.2 and A.3.3, together with anatomical descriptions of their effects. Table A.1 contains a list of these together with alternative descriptions for the movements that positive forces, bending and twisting moments tend to cause.

For a left-sided application, the axial force and all moments shall be positive as illustrated in Figures A.1 and A.2.

For a right-sided application, the mirror image applies (see 6.1 and Figures 1, 2 and 3). As a consequence, the moments M_{Af}, M_{Kf} and M_u are positive in the opposite direction.

A.3.2 Axial force F_u (axial compression)

The axial force F_u is the force component along the u-axis. Positive F_u tends to compress the prosthesis in its longitudinal direction.

A.3.3 Moments

A.3.3.1 Ankle bending moment, M_{Ao}

The ankle bending moment M_{Ao} is the moment about the ankle moment reference line A_o. Positive M_{Ao} tends to cause dorsiflexion at the ankle joint.

A.3.3.2 Ankle bending moment, M_{Af}

The ankle bending moment M_{Af} is the moment about the ankle moment reference line A_f. Positive M_{Af} tends to cause inversion at the ankle joint.

A.3.3.3 Knee bending moment, M_{Ko}

The knee bending moment M_{Ko} is the moment about the knee moment reference line K_o. Positive M_{Ko} tends to cause extension at the knee joint.

A.3.3.4 Knee bending moment, M_{Kf}

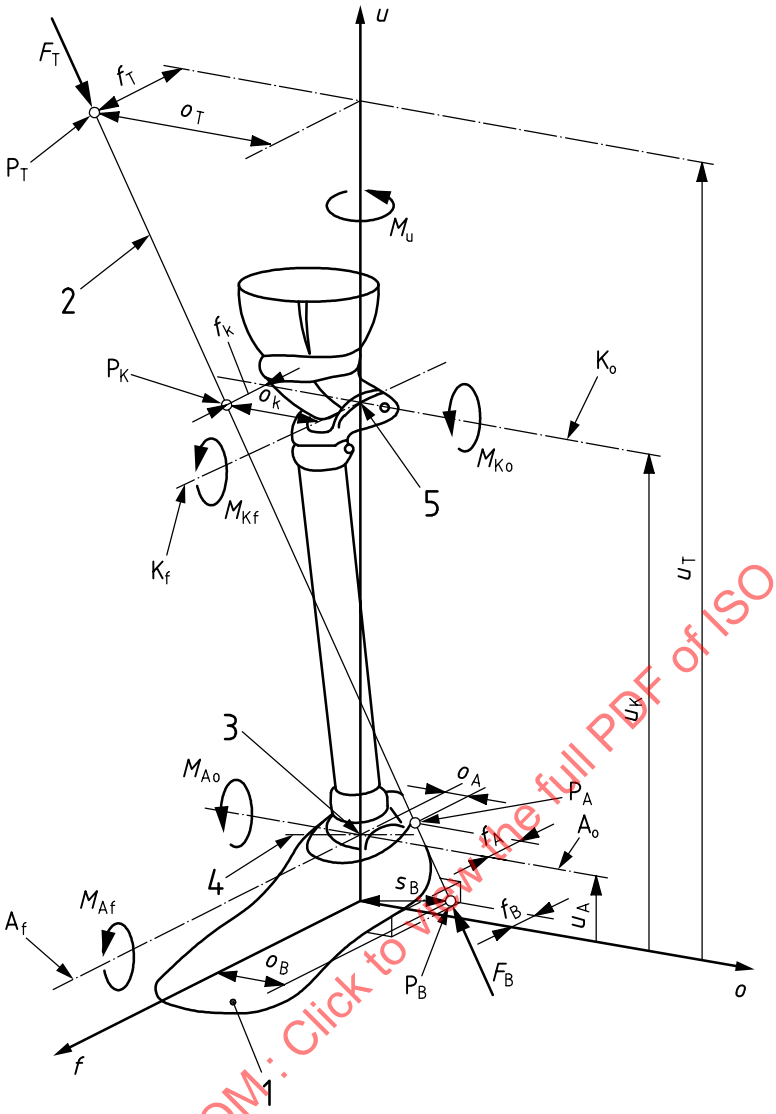
The knee bending moment M_{Kf} is the moment about the knee moment reference line K_f. Positive M_{Kf} tends to cause a lateral movement of the knee relative to foot and hip (tends to cause adduction at the knee joint).

A.3.3.5 Twisting moment (torque), M_u

The twisting moment M_u is the moment about the u-axis. Positive M_u tends to cause internal rotation of the distal end of the leg relative to the proximal end.

Table A.1 — Positive internal forces and moments with descriptions of their effects

Internal load		Anatomical description	Alternative description
		Positive load tends to	
Axial force	F_u	compress the leg in its longitudinal direction	
Ankle bending moment	M_{Ao}	cause dorsiflexion at the ankle joint	move the ankle to raise the toes
Ankle bending moment	M_{Af}	cause inversion at the ankle joint	move the ankle to raise the inside of the foot
Knee bending moment	M_{Ko}	cause extension at the knee joint	straighten the knee
Knee bending moment	M_{Kf}	cause a lateral movement at the knee relative to foot and hip (cause adduction at the knee joint)	move the knee in an outward direction relative to foot and hip
Twisting moment	M_u	cause internal rotation of the distal end of the leg relative to the proximal end	twist the leg to turn the forefoot inwards



Key

1	left leg
2	load line
3	effective ankle-joint centre
4	effective ankle-joint centreline
5	effective knee-joint centre
A_f	ankle moment, M_{Af}, reference line
A_o	ankle moment, M_{Ao}, reference line
K_f	knee moment, M_{Kf}, reference line
K_o	knee moment, M_{Ko}, reference line and effective knee-joint centreline
P_T	top load application point
P_K	knee load reference point
P_A	ankle load reference point
P_B	bottom load application point

Application of a specific test loading condition I to left-sided test sample, showing the coordinate system with u_B = 0 with reference planes, reference lines, reference points and components of internal loading generated by application of the test force F.

Figure A.1 — Test loading condition I
[see 7.1.2 a)]