INTERNATIONAL STANDARD

ISO 14242-1

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Implants for surgery — Wear of total hip-joint prostheses —

Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

Implants chirurgicaux — Usure des prothèses totales de l'articulation de la hanche —

Partie 1: Paramètres de charge et de déplacement pour machines d'essai d'usure et conditions environnementales correspondantes d'essai

Reference number
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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.ch
Web www.iso.ch

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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 3.

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 part of ISO 14242 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14242-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 14242 consists of the following parts, under the general title *Implants for surgery — Wear of total hip-joint prostheses*:

— *Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

— *Part 2: Methods of measurement*

Implants for surgery — Wear of total hip-joint prostheses —

Part 1:
Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

1 Scope

This part of ISO 14242 specifies the relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the wear testing of total hip-joint prostheses.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14242. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14242 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 7206-1:1995, *Implants for surgery — Partial and total hip-joint prostheses — Part 1: Classification and designation of dimensions*

ISO 14242-2:2000, *Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this part of ISO 14242, the terms and definitions given in ISO 7206-1 apply, together with the following.

3.1
abduction/adduction
angular movement shown in Figure 1 a)

3.2
flexion/extension
angular movement shown in Figure 1 b)

3.3
inward/outward rotation
angular movement shown in Figure 1 c)

3.4
polar axis
axis of the acetabular component which intersects the centre of the spherical articulating surface and is perpendicular to the plane of the flange, or if no flange is present, perpendicular to the plane of the entry diameter

[ISO 7206-1]

4 Principle

The femoral and acetabular components of a test specimen are placed in position in their normal configuration; the test apparatus transmits a specified time-varying force between the components, together with specified relative angular displacements. A control specimen, if polymers are the object of investigation, is subjected to the same time-varying force to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. The test takes place in a controlled environment simulating physiological conditions.

5 Reagents and materials

5.1 Fluid test medium, calf serum (25 % ± 2 %) diluted with deionized water (balance).

Normally the fluid test medium is filtered through a 2 µm filter, and has a protein mass concentration of not less than 17 g/l.

To minimize microbial contamination, the fluid test medium should be stored frozen until required for test. An anti-microbial reagent (such as sodium azide) may be added. Such reagents can be potentially hazardous.

Routine monitoring of the pH of the fluid test medium may be undertaken. If it is, the values should be included in the test report [see item 8 e) 5)].

NOTE The use of a fluid test medium of non-biological origin may be considered when performance requirements relating to this test method are being decided.

5.2 Test specimen, femoral head and acetabular components.

The acetabular component shall have the articulating surface attached by its normal immediate backing (for example bone cement or a machined replica of the inner surface of the backing) unless this is impractical due to physical features of the implant system. If the component forming the articulating surface is fixed to the backing by a rim/snap-fit system, the machined replica shall provide the same fixation conditions.

If it is not practical to use the normal backing or cement fixation, due to physical features of the implant system, the support system for the acetabular component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear without destruction.

5.3 Control specimen, identical to test specimen.

6 Apparatus

6.1 Testing machine, capable of producing the angular displacements specified in Figures 1 and 2 in association with the corresponding forces specified in Figures 1 and 3 and operating at a frequency of 1 Hz ± 0,1 Hz.

6.2 Means of mounting and enclosing the test specimen, using a corrosion-resistant material, capable of holding femoral and tibial acetabular components using attachment methods comparable to the intended anatomical fixation. An enclosure shall be provided which is capable of isolating the test specimen to prevent third-body contamination from the test machine and the atmosphere.

6.3 Means of aligning and positioning the femoral component of the test specimen in the inferior position, so that its axis is situated at the centre of the axes of rotation of the test machine and so that the same position and orientation may be reproduced following removal for measurement or cleaning if required.

6.4 Means of aligning and positioning the acetabular component of the test specimen, so that its axis is situated at the centre of the axes of rotation of the test machine and so that the same position and orientation may be reproduced following removal for measurement.

6.5 Motion control system, capable of generating the angular movements of the femoral component given in Figures 1 and 2 with an accuracy of ± 3° at the maxima and minima of the motion and ± 1 % of the cycle time for phasing.

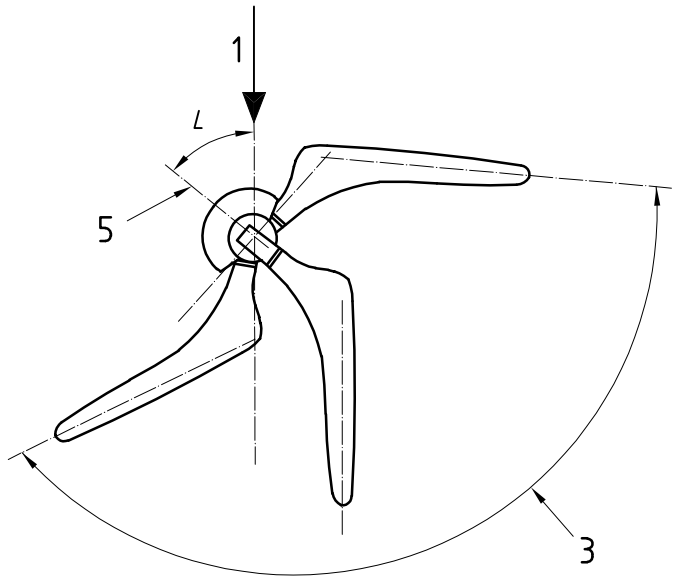
6.6 Force control system, capable of generating a force whose direction is shown in Figure 1 and which varies as shown in Figure 3, and maintaining the magnitude of the maxima and minima of this force cycle to a tolerance of ± 3 % of the maximum force value for the cycle and ± 1 % of the cycle time for phasing.

6.7 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium.

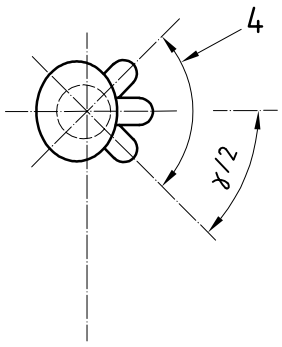
NOTE The use of sealed enclosures may prevent evaporation.

6.8 Temperature control system, capable of maintaining the temperature of the fluid test medium at (5.1) 37 °C ± 2 °C.

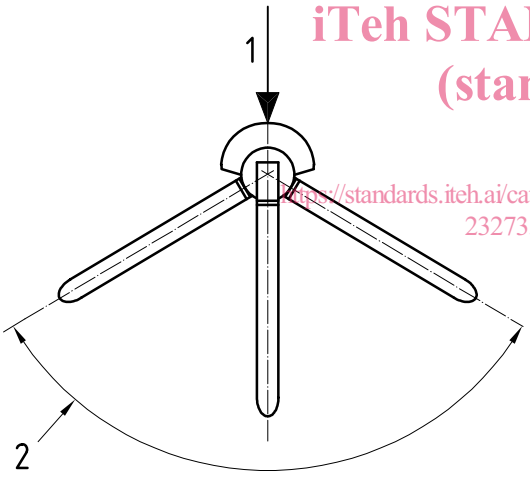
6.9 Control station(s), capable of applying the loading regime shown in Figures 1 and 3 without the angular displacements shown in Figures 1 and 2 and incorporating the provisions of 6.2, 6.3, 6.4, 6.6, 6.7 and 6.8.



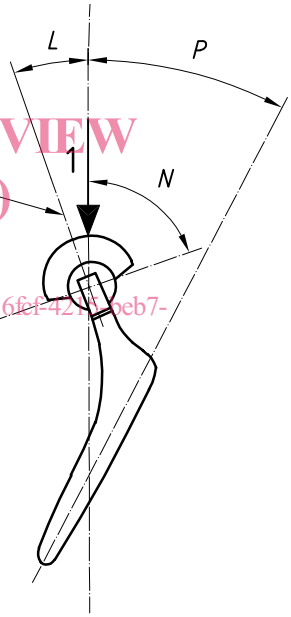
a) Abduction/adduction



c) Inward/outward rotation



b) Flexion/extension



d) Orientation of acetabular component and femoral component in mid-position relative to the load line

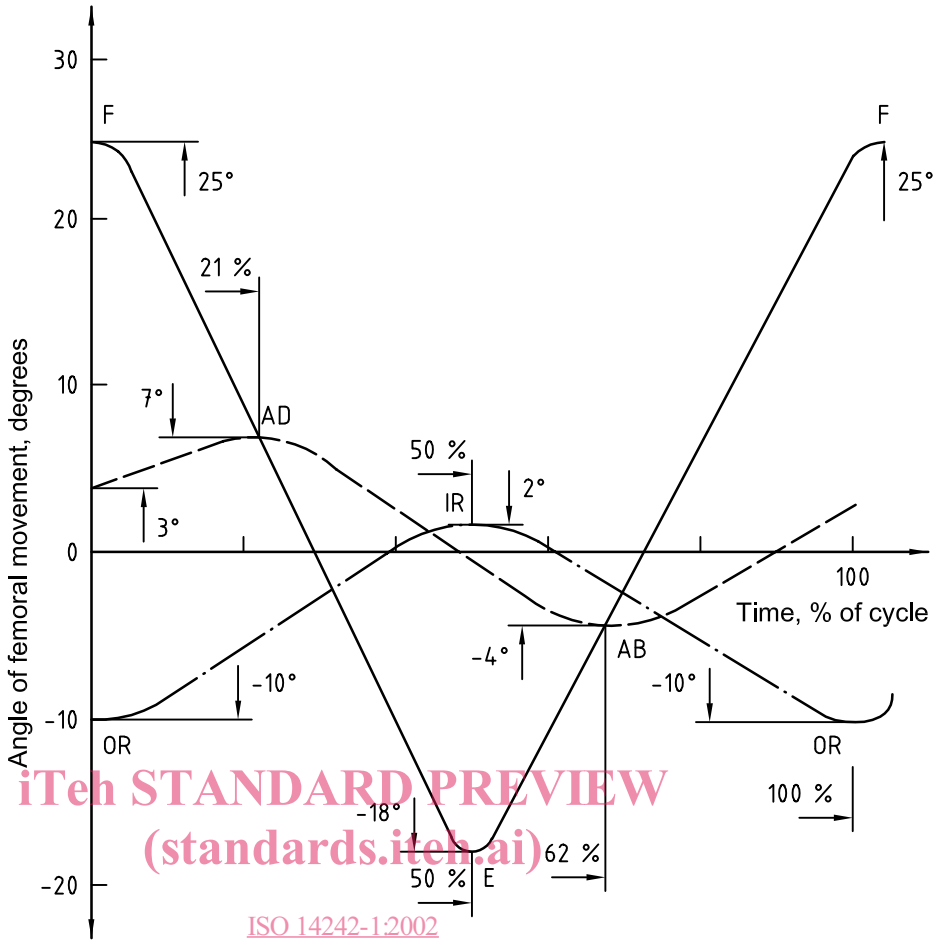
Key

1 Load axis
2 Flexion/extension angle
3 Abduction/adduction angle
4 Inward/outward rotation angle
5 Polar axis of acetabular component

L Inclination of the polar axis of the acetabular component to the load line
N Inclination of face of acetabular component equal to 60 ° ± 3 ° or as specified by the manufacturer
P Inclination of stem axis to load line in mid-position of abduction/adduction range

NOTE Angles N, L and P are specified in 7.3 and 7.4.

Figure 1 — Angular movement of femoral component and orientation of components relative to the load line



Key

AB - Abduction
AD - Adduction
E - Extension
F - Flexion
IR - Inward rotation
OR - Outward rotation

Time, % of cycle ± 1 %	0	21	50	62	100
Angle of flexion (+) or extension (–) ° ± 3 °	25		– 18		25
Angle of adduction (+) or abduction (–) ± 3 °	3	7		– 4	3
Angle of inward (+) or outward (–) rotation ± 3 °	– 10		2		– 10

Figure 2 — Variation with time of angular movement to be applied to the femoral test specimen