INTERNATIONAL STANDARD

ISO 14242-1

Second edition
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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

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Foreword

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

This second edition cancels and replaces the first edition (ISO 14242-1:2002), which has been technically revised.

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*

— *Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

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, the speed and duration of testing, the sample configuration and the test environment to be used for the wear testing of total hip-joint prostheses.

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

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1 and the following apply.

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

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 Test and control specimens and test fluid

5.1 Fluid test medium, calf serum diluted with deionized water (see ISO 3696).

The fluid test medium should be filtered through a 2 µm filter and have a protein mass concentration of 30 g/l ± 2 g/l. To minimize microbial contamination, the fluid test medium should be stored frozen until required for testing. An antimicrobial reagent (such as sodium azide) may be added.

WARNING — Antimicrobial reagents can be potentially hazardous.

Routine monitoring of the pH of the fluid test medium may be undertaken. If so, the values and the relevant number of load cycles should be included in the test report [see 8 f) 6)].

NOTE The use of a fluid test medium of non-biological origin can 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 reproduce the design features and conditions intended for clinical use but should allow removal of the component for measurement of wear without destruction.

The features connecting the acetabular component to the test rig shall prevent any movement and should not apply forces in restricted regions that might develop localized points of high stress.

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 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 can 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 can be reproduced following removal for measurement.

NOTE It is advisable that care be taken during start-up and operation of the test so that air does not accumulate in the acetabular cup and deprive portions of the articulating surfaces of lubricant.

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. The angles are specified to produce three-dimensional angular movements. The sequence of the angular transformation is: abduction/adduction, followed by flexion/extension, followed by internal/external rotation. Other sequences should be documented in the test report.

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 ±3 % of the cycle time for phasing.

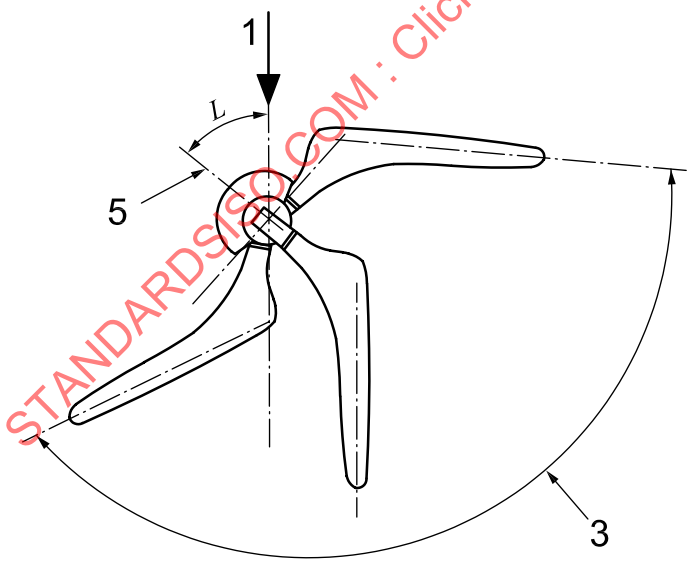
6.7 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium.

NOTE It is advisable to use sealed enclosures in order to prevent evaporation.

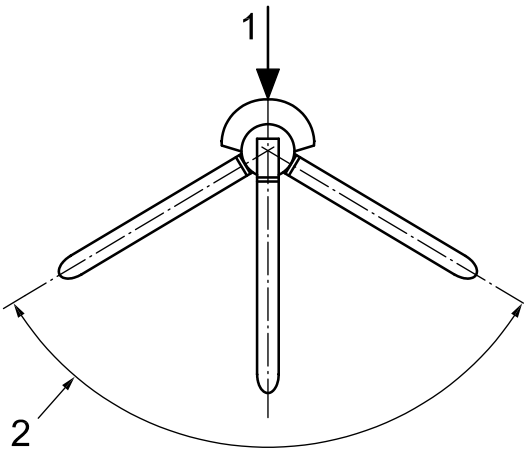
6.8 Temperature control system, capable of maintaining the temperature of the fluid test medium at 37 °C ± 2 °C.

The test shall be closely monitored for evidence of excessive temperatures and corrective measures taken if needed. These can include stopping the test periodically to allow the bearing and lubricant to cool, and cooling the lubricant bath by, for example, circulating it through a cooling apparatus.

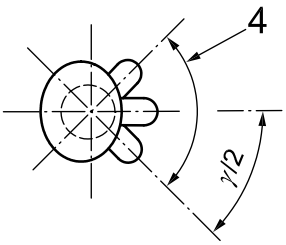
6.9 Control station(s), capable of applying the loading regime shown in Figures 1 and 3 without the angular displacements shown in Figures 1 and 2, and incorporating the provisions of 6.2, 6.3, 6.4, 6.6, 6.7 and 6.8.



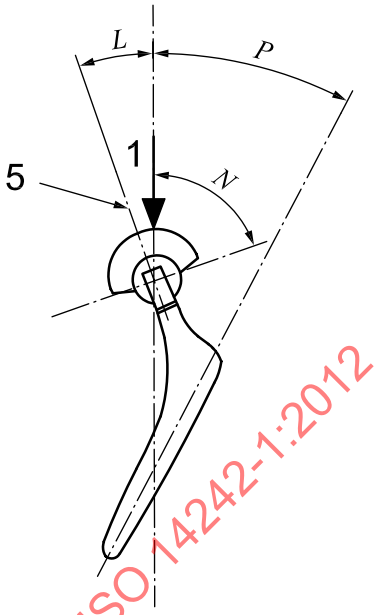
a) **Abduction/adduction**



b) **Flexion/extension**



c) Inward/outward rotation



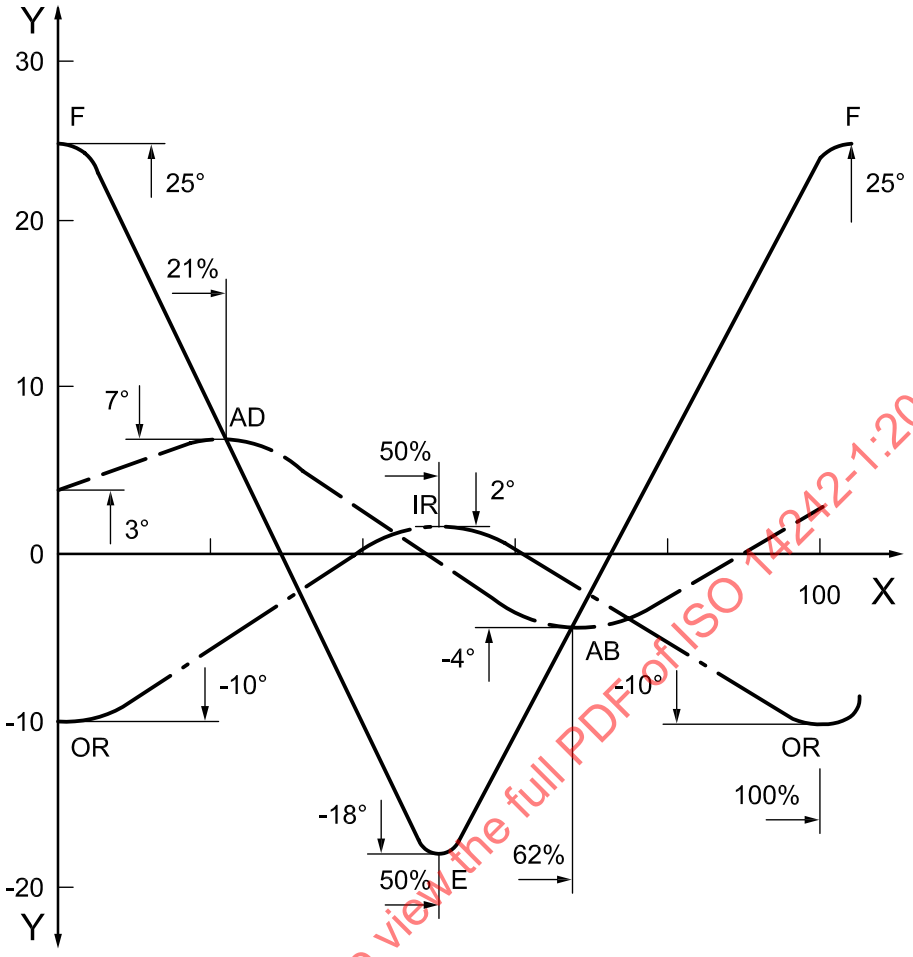
d) Orientation of acetabular component and femoral component in mid-position relative to the load line

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 the face of the 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

X time, as a percentage of cycle time

Y angle of femoral movement, in degrees

AB – Abduction

AD – Adduction

E – Extension

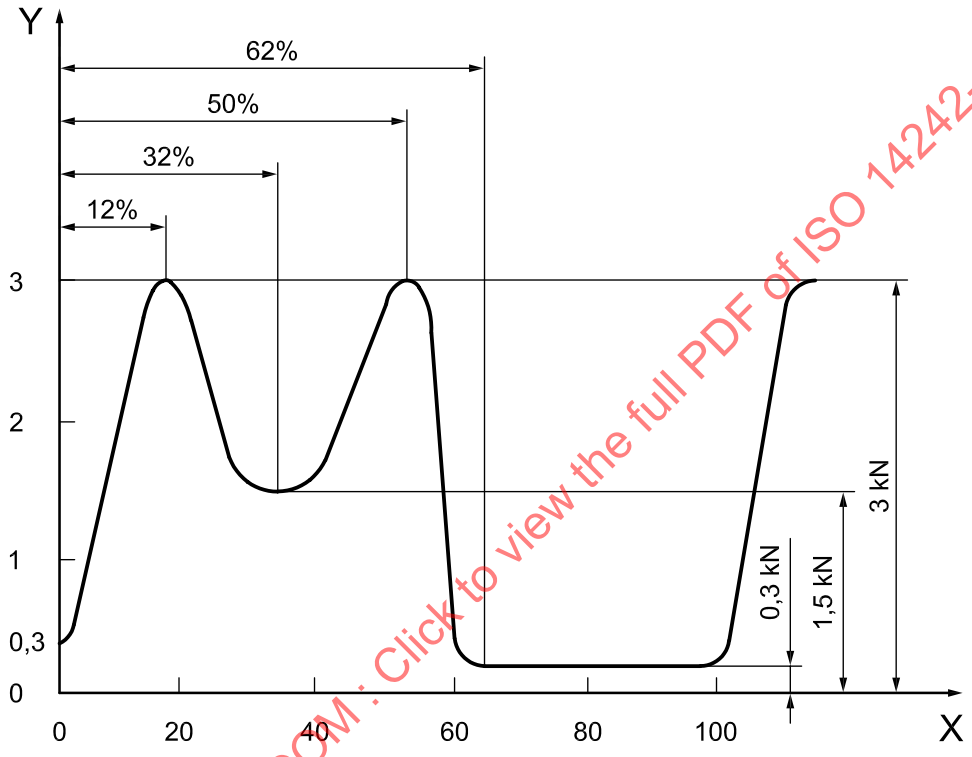
F – Flexion

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



Key

X time, as a percentage of cycle time

Y angle of femoral movement, in degrees

Time, % of cycle (±3 %)	0	12	32	50	62	100
Applied force, kN (±90 N)	0,3	3,0	1,5	3,0	0,3	0,3

Figure 3 — Variation with time of the force to be applied along the loading axis

7 Procedure

7.1 Make any initial measurements required to determine the subsequent amount of wear and/or creep and calibrate each test station using a load cell. Undertake this calibration while the load is being developed at other stations, if any, in the test rig to simulate working conditions of the test frame.

NOTE Methods of measurement of wear are given in ISO 14242-2.

7.2 Following the initial measurements, clean the test specimen as specified in ISO 14242-2.

7.3 Mount the femoral component of the testing specimen in the test machine in the inferior position with its stem in the abduction/adduction position of $P = 10° \pm 3°$, as shown in Figure 1 a), and in the inward/outward rotation position, $\gamma/2$, as shown in Figure 1 c).

NOTE For a modular component, the stem of the implant can be replaced by a support which has an identical cone and ensures the same head positioning so that test conditions remain unchanged.

7.4 Mount the acetabular component of the testing specimen in the test machine with the polar axis vertical, as illustrated in Figure 1 b), and inclined at an angle L, as shown in Figure 1 a), where L equals 30° ± 3°. Alternatively, if the manufacturer specifies an angle of inclination of the component on surgical implantation to be N, as shown in Figure 1 d), then $L = (75 - N)° \pm 3°$.

7.5 Take the control specimen and repeat the steps described in 7.1, 7.2, 7.3 and 7.4. For implants of a specific design with the same material, shape and dimensions, control data from previous tests may be used.

7.6 Introduce the fluid test medium (5.1) to completely immerse the contact surfaces of the test specimen and the control specimen. Maintain the temperature of the fluid test medium at 37 °C ± 2 °C, taking the measurement at a location representative of the bulk temperature of the fluid.

7.7 Start the testing machine and adjust it so that the loads and displacements specified in Figures 1, 2 and 3 are applied to the test specimen (6.5, 6.6) and the loads specified in Figures 1 and 3 are applied to the control specimen. The curves between the defined maxima and minima in Figures 2 and 3 shall be smooth with no overshoots. Record the displacement and load waveforms at start-up and after each change of fluid test medium.

7.8 Operate the testing machine at a frequency of 1 Hz ± 0,1 Hz.

7.9 Replace the fluid lost by evaporation during the test at least daily, by adding deionized water. Replace the fluid test medium completely at least every 5×10^5 cycles.

7.10 Stop the test for measurements at least at 5×10^5 cycles, 1×10^6 cycles, and at least every 1×10^6 cycles thereafter until the test is terminated (see 7.14).

7.11 Remove the test specimen and control specimen from the testing machine and take wear measurements.

7.12 Following wear measurements, clean the test specimen and control specimen as specified in ISO 14242-2 and reinstall in the testing machine (see 7.3, 7.4 and 7.5).

7.13 Repeat the steps given in 7.6 to 7.12 until the test is terminated (see 7.14).

7.14 Continue the test until one of the following occurs:

a) completion of 5×10^6 cycles;

NOTE At the request of the party submitting the specimen, the test can be continued beyond this limit. If the test is continued after 5 million cycles, it is advisable that the number of cycles at which the test was stopped be disclosed to the submitter of the implant.

b) break-up or delamination of the articulating surfaces;

c) failure of the testing machine to maintain the force and displacement parameters within the given tolerances (see 6.5, 6.6).