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

Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

Implants chirurgicaux — Usure de prothèses totales de l'articulation du genou —

Partie 3: Paramètres de charge et de déplacement pour machines d'essai d'usure avec contrôle de déplacement et conditions environnementales correspondantes d'essais

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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 14243-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 14243 consists of the following parts, under the general title *Implants for surgery — Wear of total knee-joint prostheses*:

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

— *Part 2: Methods of measurement*

— *Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

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

Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test

1 Scope

This part of ISO 14243 specifies relative 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 knee-joint prostheses in wear-testing machines having axial load control, flexion/extension angular motion control, AP displacement control and tibial rotation control.

The kinematics of this part of ISO 14243 may not be applicable to knee designs with a high degree of constraint, which could result in damage to the articulating components in the early stages of the test that would not be representative of clinical service.

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 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14243-2:2000, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14243-1 and the following apply.

3.1
anterior posterior displacement
AP displacement
offset between the femoral component and the tibial component, measured in a direction which is perpendicular to both the force and flexion/extension axes

NOTE It is considered to be zero when the total knee-joint prosthesis is in the **reference position** (3.7) and is considered to be positive when the tibial component is anterior to its position with the total knee-joint prosthesis in the **reference position** (3.7).

3.2
anterior posterior force
AP force
shear force applied by the tibial on the femoral component along a line of action which is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis

NOTE It is considered to be positive when it acts in a posterior-to-anterior direction.

3.3
axial force
force applied by the tibial component of the knee-joint prosthesis on the femoral component in a direction parallel to the tibial axis

NOTE It is considered to be positive when it acts in an inferior-to-superior direction.

3.4
axial force axis
line of action of the axial force taken to pass through a point on the tibial component of the knee-joint prosthesis which is offset by 0,07 $w \pm 0{,}01\ w$ in the medial direction from the tibial axis, where w is the overall width of the tibial component, measured in accordance with ISO 7207-1

NOTE 1 The value of 0,07w offset equals 5 mm offset for a tibial component of average width, i.e. 74 mm.

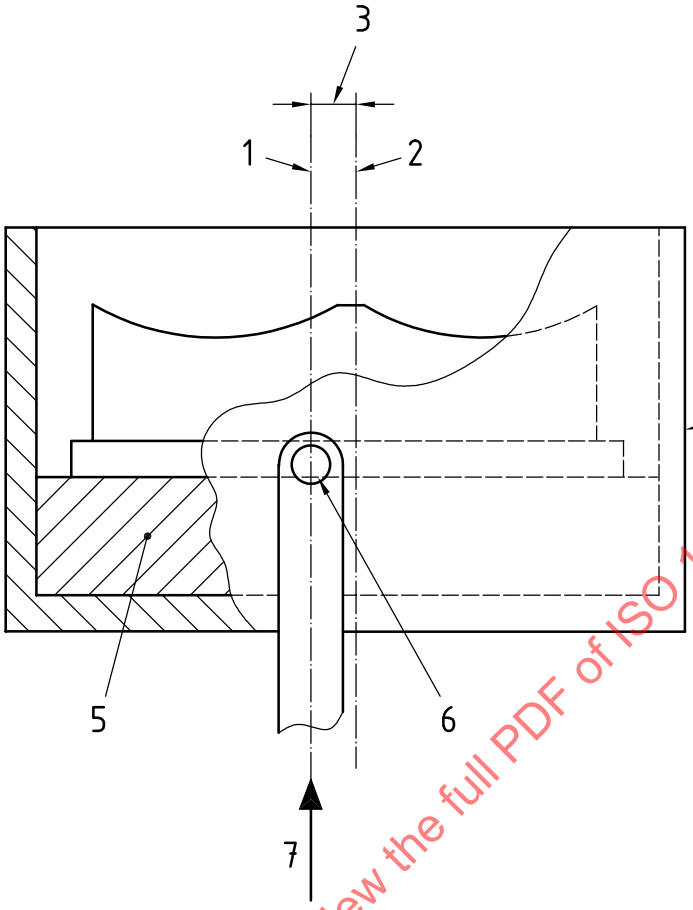
NOTE 2 See Figure 1.

3.5
flexion/extension axis
nominal axis of rotation of the femoral component relative to the tibial component

NOTE 1 For condylar and meniscal knees, the flexion/extension axis can be estimated by first considering the condyles of the femoral component in contact with an imaginary plane perpendicular to the tibial axis when the femoral component is at 30° and 60° of flexion, and then visualizing four lines (contact normals) perpendicular to the imaginary plane running through the points where the two femoral condyles would contact the imaginary plane at each of these flexion angles. The flexion/extension axis is then the line that would intersect all four of the contact normals.

NOTE 2 It is recognized that the axis of rotation of the femoral component in the test will not exactly match the theoretical flexion/extension axis. The coincidence of the flexion/extension axis and the axis of rotation of the test machine should be as close as possible within reasonable laboratory practice.

3.6
load and displacement control wear-testing machine
wear-testing machine having axial load control, flexion/extension angular motion control, AP displacement control and tibial rotation control as its control parameters



Key

1 axial force axis

2 tibial axis

3 0,07w offset

4 holder of tibial component

5 cement mounting for tibial component

6 axial force applied through free-turning pivot(s)

7 force

Figure 1 — Test specimen configuration

3.7
reference position
angular and linear alignment of the tibial component relative to the femoral component which gives static equilibrium of the tibial component when it is loaded against the femoral component by a positive axial force applied along the axial force axis, with the most distal points on the femoral bearing surface resting on the lowest points on the tibial bearing surface

NOTE 1 The reference position is equivalent to the position of 0° flexion.

NOTE 2 For the purpose of determining the reference position, the effect of friction between the tibial and femoral components is ignored.

NOTE 3 The reference position can be determined by geometrical calculations based on the three-dimensional form of the tibial and femoral surfaces. For the purpose of these calculations, the form of the tibial and femoral surfaces can be taken either from design data or from coordinate measurements of an unworn total knee-joint prosthesis.

NOTE 4 In a moderately constrained or flat design of tibial component, and/or installation of the tibial component with a large posterior slope (see 7.4), the lowest points on the tibial bearing surface may span a large (flat) range of anterior-posterior positions, or be the most posterior edge of the tibial component (no dish effect). In such a situation, the above definition of reference position cannot apply. In such situations, the prosthesis manufacturer is consulted to decide what neutral position should be forced/set, and the conclusions noted in detail in the test report.

3.8
tibial axis
nominal longitudinal axis of the tibia, corresponding to the central axis of the medullary cavity of the proximal tibia

3.9
tibial rotation
rotation of the tibial component of the knee-joint prosthesis about an axis parallel to the tibial axis

NOTE The rotation is considered to be zero when the total knee-joint prosthesis is in the **reference position** (3.7). For a right-sided total knee-joint prosthesis, the tibial rotation is positive when a view from a superior position onto the tibial component shows the tibial component rotated anti-clockwise from its position with the total knee-joint prosthesis in the **reference position** (3.7).

3.10
tibial rotation torque
torque applied by the tibial component on the femoral components of the total knee-joint prosthesis about an axis parallel to the tibial axis

NOTE When seen from a position superior to the tibial component, the axial torque is positive when it acts clockwise on a left-sided total knee-joint prosthesis and positive when it acts anti-clockwise on a right-sided total knee-joint prosthesis.

4 Principle

The total knee-joint prosthesis is mounted in an apparatus that applies cyclic variations of flexion/extension angle, tibial rotation angle, AP displacement and axial force to the interface between tibial and femoral components, simulating normal human walking. The tibial component moves relative to the femoral component under the influence of the applied flexion/extension rotation, tibial rotation, AP displacement, and axial forces. The applied contact force/displacement actions are axial force, flexion/extension rotation, AP displacement and tibial rotation. All the applied force/displacement actions follow a specified cyclic variation, with a fixed relationship between the phases of the actions.

The contacting surfaces of the femoral and tibial components are immersed in a fluid test medium simulating human synovial fluid. A control specimen is subjected to the axial force for reference purposes. 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 after dilution and prior to use 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 antimicrobial reagent (such as sodium azide) may be added. Such reagents may be hazardous.

Routine monitoring of the pH of the fluid test medium may be undertaken. If it is, results should be included in the test report (see Clause 8).

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

5.2 Test specimen, femoral and tibial components.

The tibial component should have the articulating surface attached by its normal immediate backing (for example bone cement or a machined replica of the inner surface of the tibial tray) unless this is impractical due to physical features of the implant system. If the component forming the articulating surface is fixed to the tibial tray 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 tibial component should represent normal design features and conditions of use but should allow removal of the component for measurement of mass loss (if required) without destruction.

5.3 Control specimen, identical to the test specimen.

6 Apparatus

6.1 Testing machine, capable of applying the forces specified (Figure 2) in association with corresponding displacements, 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 components using attachment methods comparable to the intended anatomical fixation.

An enclosure shall be provided that 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 reference position, so that the same position and orientation can be reproduced following the removal of the tibial component for measurement.

6.4 Means of aligning and positioning the tibial component of the test specimen in the inferior position, so that the same position and orientation can be reproduced after its removal for measurement.

6.5 Axial force control system, capable of generating an axial force following the cycle given in Figure 2 and maintaining the magnitude of this force to a tolerance of ± 5 % of the maximum value and ± 3 % of the full cycle time for phasing. The axial force is applied along the axial-force axis to the tibial component of the total knee-joint prosthesis through freely turning pivots which are offset from the tibial axis (see Figure 2 and Table 1).

NOTE The maximum force will be reconsidered when more information is available.

6.6 Flexion/extension rotation control system, capable of generating the flexion/extension motion as shown in Figure 3 and maintaining the magnitude of this motion to a tolerance of ± 5 % of the maximum value and ± 3 % of the full cycle time for phasing. The flexion/extension motion is measured about the flexion/extension axis as a relative angular motion between the femoral and tibial components. Provision shall be included for the adjustment of the zero position of the motion control system so that when the applied flexion/extension motion reaches zero flexion angle, as shown in Figure 3, the total knee-joint prosthesis is at the designed fully extended state.

NOTE For total knee-joint prostheses which include a positive extension stop, a device may be included to limit the extension moment which can be applied by over-extension.

6.7 AP displacement control system, capable of generating an AP motion following the cycle given in Figure 4 and maintaining the magnitude of this motion to a tolerance of ± 5 % of the maximum value and ± 3 % of the full cycle time for phasing. The AP displacement is applied along the line of action which is perpendicular to both the tibial axis and the flexion/extension axis, and which passes through the axial-force axis.

6.8 Tibial-rotation control system, capable of generating a tibial rotation following the cycle given in Figure 5 and maintaining the magnitude of this rotation to a tolerance of ± 5 % of the maximum value and ± 3 % of the full cycle time for phasing. The signs of the tibial rotation extremes are disregarded in determining the tolerance. The tibial rotation is applied about an axis parallel to the tibial axis and the positive direction is defined in 3.8.

6.9 AP force measurement system, capable of measuring the force along the line of action of the AP motion (see 6.7).

This system is required only for component mounting, and is optional during testing.

6.10 Tibial-torque measurement system, capable of measuring the tibial rotational torque about the same axis as that of the applied tibial rotation (see 6.8). The recommended accuracy for the tibial-torque measuring system is at least ± 0,3 N·m, and it should be possible to measure each specimen individually.

This system is required only for component mounting, and is optional during testing.

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

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

6.13 Control station(s), capable of applying the loading cycle shown in Figure 2. The control station shall incorporate the provisions of 6.2, 6.3, 6.4, 6.11 and 6.12.

NOTE Application of the load will only cause a small increase in fluid uptake, relative to the amount that is caused by lubrication and temperature control. It may not be necessary to use the applied load in the control samples if it has been demonstrated that this contribution is less than 5 % of the fluid uptake, for the materials being tested.

7 Procedure

7.1 Make any initial measurements required to determine the subsequent amount of wear, 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.

NOTE Methods of measurement are given in ISO 14243-2.

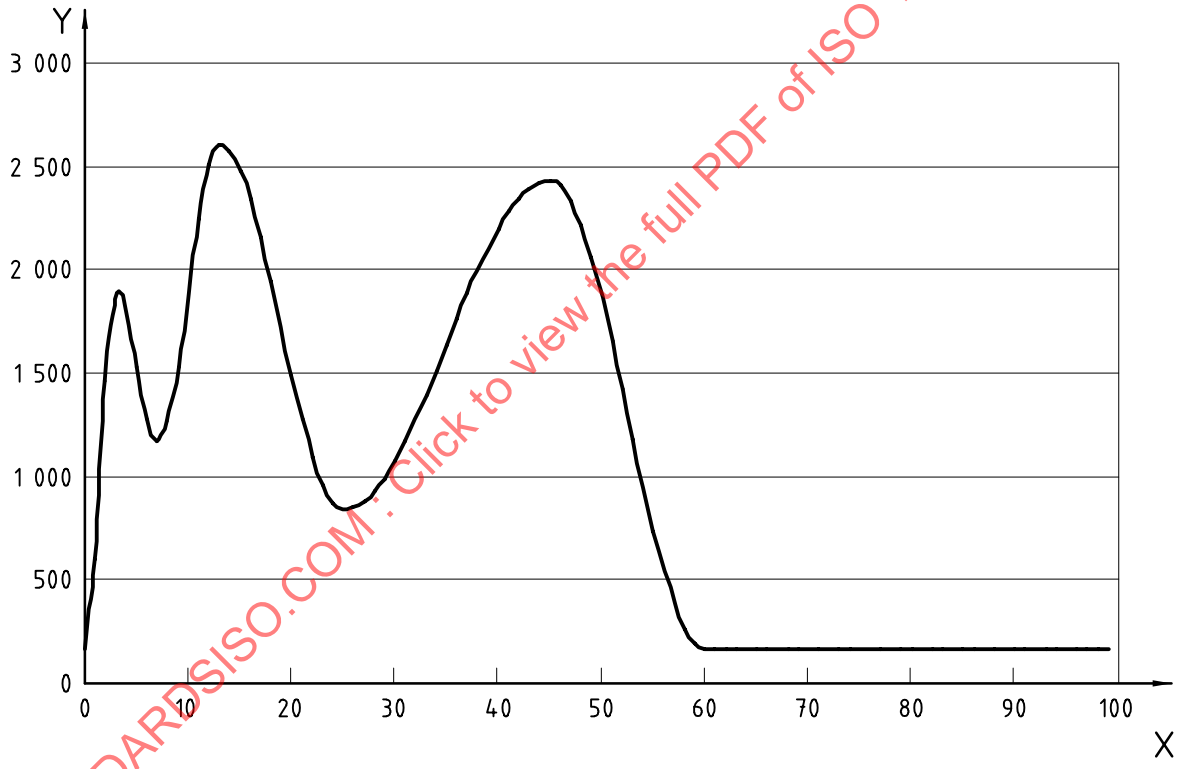
7.2 Following the initial measurements, clean the test specimen as specified in 4.4.1 to 4.4.5 of ISO 14243-2:2000.

7.3 Mount the femoral component of the test specimen in the test machine, aligning it so that the AP force measurement system and the tibial torque measurement system show zero force and torque.

NOTE Depending on the design of the testing machine, this may require the mounting of the femoral component to be adjusted so that the flexion/extension axis coincides with the actual rotation axis of the flexion/extension motion applied by the test machine.

Table 1 — Variation of axial force with cycle time

Percentage of time cycle %	Axial force N
0	168
3	1 887
7	1 175
13	2 600
25	838
45	2 434
60	168
100	168



Key

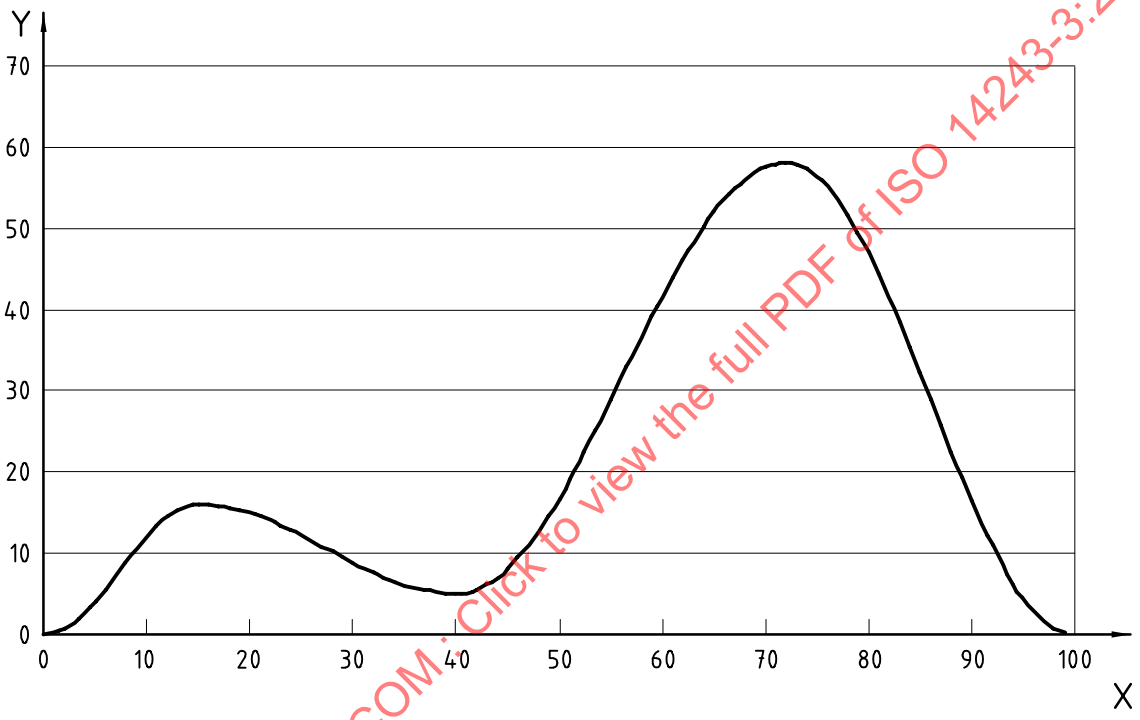
X percentage of time cycle, %

Y axial force, N

Figure 2 — Control parameters — Variation of axial force with cycle time

Table 2 — Variation of flexion angle with cycle time

Percentage of time cycle %	Flexion angle degrees
0	0
16	16
41	5
73	58
100	0



Key

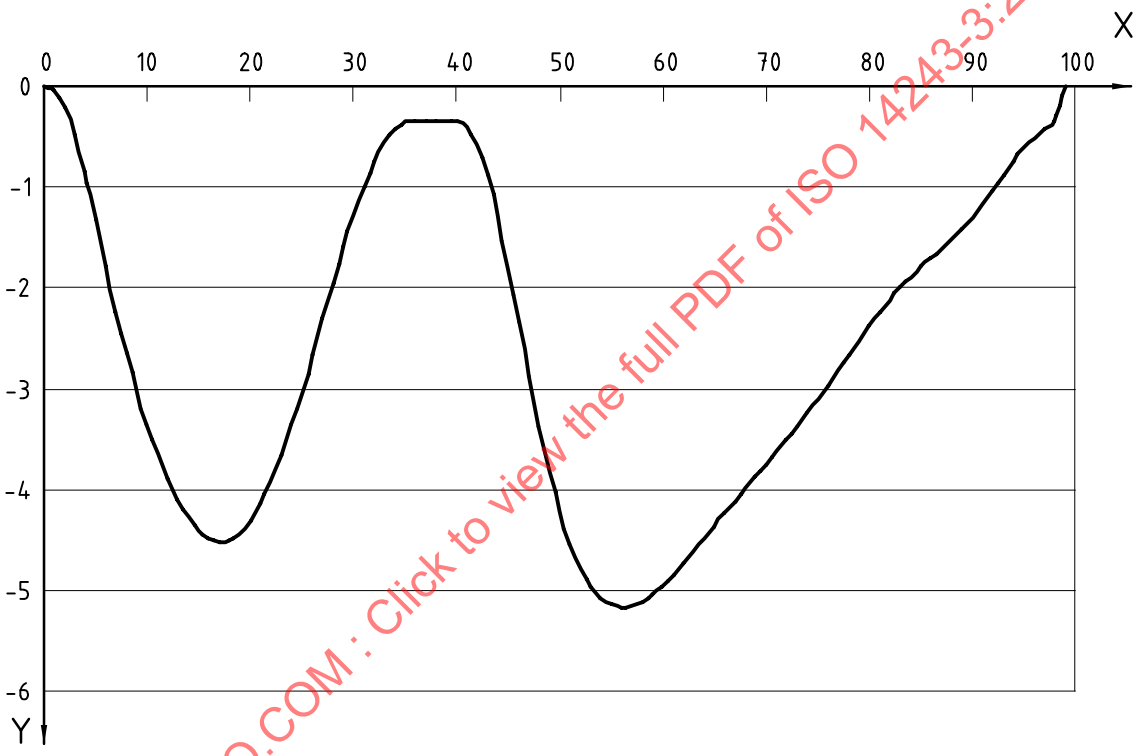
X percentage of time cycle, %

Y flexion angle, degrees

Figure 3 — Control parameters — Variation of flexion angle with cycle time

Table 3 — Variation of AP motion with cycle time

Percentage of time cycle %	AP motion mm
0	0
17	– 4,5
38	– 0,3
56	– 5,2
100	0



Key

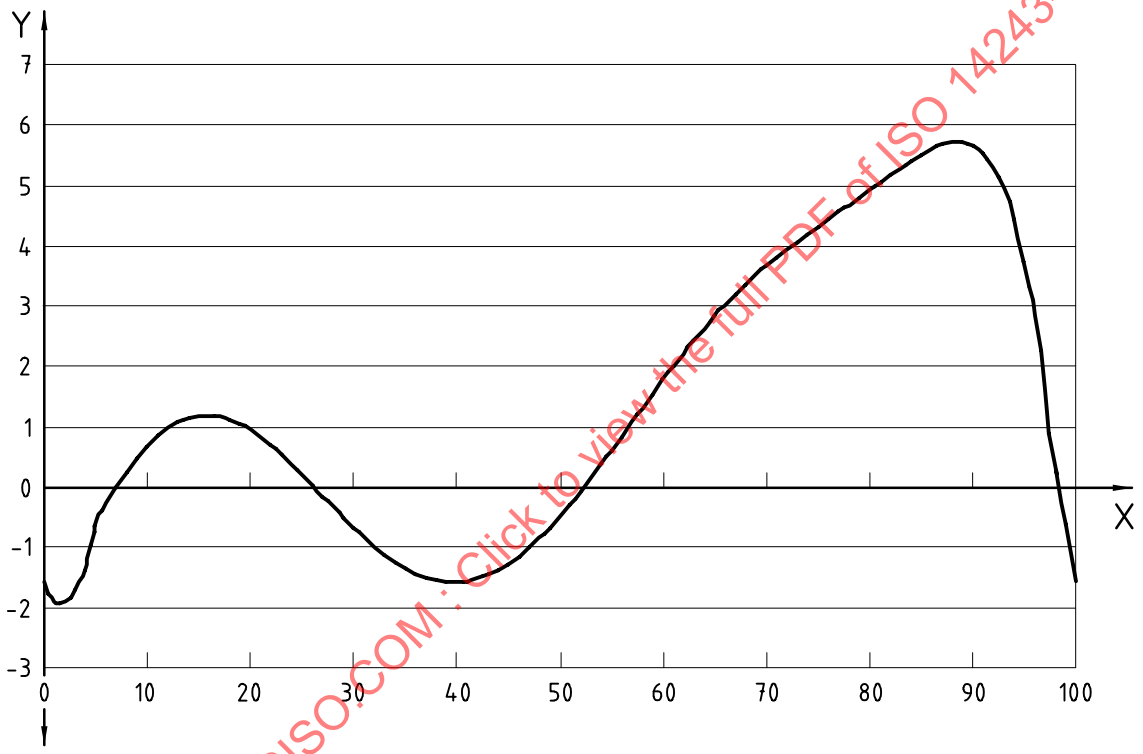
X percentage of time cycle, %

Y AP motion, mm

Figure 4 — Control parameters — Variation of AP motion with cycle time

Table 4 — Variation of tibial rotation with cycle time

Percentage of time cycle %	Tibial rotation degrees
0	– 1,6
2	– 1,9
16	1,2
40	– 1,6
88	5,7
100	– 1,6



Key

X percentage of time cycle, %

Y tibial rotation, degrees

Figure 5 — Control parameters — Variation of tibial rotation with cycle time

7.4 Mount the tibial component of the test specimen in the test machine, aligning it so that the direction of the axial force applied by the machine is parallel to the tibial axis to within ± 1. Incline the tibial component to the tibial axis at the angle recommended by the manufacturer for clinical use.

If the tibial component comprises an insert with a metal or other tray, the test should be conducted with the tray in place.

NOTE If the tibial component is mounted in a bed of cement, the alignment can be achieved by holding the tibial component with an adjustable temporary support with the cement in place and allowed to set.

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

7.6 Introduce the fluid test medium 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 temperature of the bulk fluid.

7.7 Start the testing machine and adjust it so that the loads and displacements specified in Figures 2 to 5 are applied to the test specimen and the loads specified in Figure 2 are applied to the control specimen, with tolerances ± 3% of the maximum force value and ± 5% of the maximum angular and linear displacement values.

NOTE 1 Annex A gives details of a typical set of test parameters equivalent to those described in Figure 1.

NOTE 2 For knee designs with a high level of constraint, it may be possible to determine the appropriate displacement values for the AP motion and tibial rotation using those displacement values that create the peak AP force values and rotational torque values given in Table 2 of ISO 14243-1:2000.

7.8 Operate the testing machine at a frequency of 1 Hz ± 0,1 Hz. The times of occurrence for the maxima and minima specified in Figures 2 to 5 shall be controlled within ± 3 % of the cycle time.

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

7.10 Stop test for measurements 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 and take wear measurements.

7.12 Following wear measurements, clean the test specimen and control specimen as appropriate for the material of construction and re-install in the test machine.

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 events occurs:

a) completion of 5 x 10^6 load cycles;

NOTE At the request of the party submitting the specimen for test, the test may be continued beyond this point.

b) breaking up or delamination of the articulating surfaces that disrupt normal function of the implants;

c) failure of the test machine to maintain the test conditions within the given tolerances (see 7.6, 7.7, 7.8 and 7.9).

8 Test report

The test report shall include the following information:

a) a reference to this part of ISO 14243;

b) the identity of the test specimens as stated by the party submitting the specimen for test, including size, material, type and manufacture;

c) description of the test machine, including number of stations, type of system used for generating motions and forces, range of motions and forces, type of system used for measuring motions and forces, arrangement for mounting specimen, arrangement for lubrication of articulating surfaces, arrangement for temperature control, and arrangement for the exclusion of contaminant particles;

d) a statement of results, including:

   1) the number of cycles applied;

   2) the reason for terminating the test if less than 5×10^6 cycles were applied;

   3) a description of all the surfaces of both components at which relative movement has occurred;

   4) a description of the condition of the interfaces between subcomponents, if the components are of modular construction.

The test report shall be combined with the report of wear measurement compiled in accordance with ISO 14243-2.

9 Disposal of test specimen

No part of the test specimen or control test specimen shall be used for clinical purposes after testing.