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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

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

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

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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 14243-1 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 14243-1:2002), which has been technically revised.

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

1 Scope

This part of ISO 14243 specifies the flexion/extension 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 knee-joint prostheses in wear-testing machines with load control.

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, *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 following terms and definitions apply.

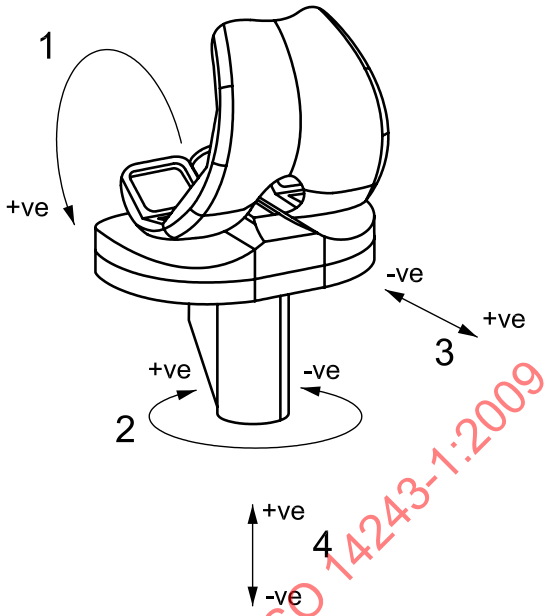
3.1
AP displacement
offset of the axial force axis from the flexion/extension axis measured in a direction that is perpendicular to both of these axes

NOTE 1 AP is an abbreviation for anterior posterior.

NOTE 2 The displacement 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 axial force axis is anterior to its position with the total knee-joint prosthesis in the **reference position** (3.7). See Figure 1.

3.2
AP force
force applied to the tibial component along a line of action that is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis

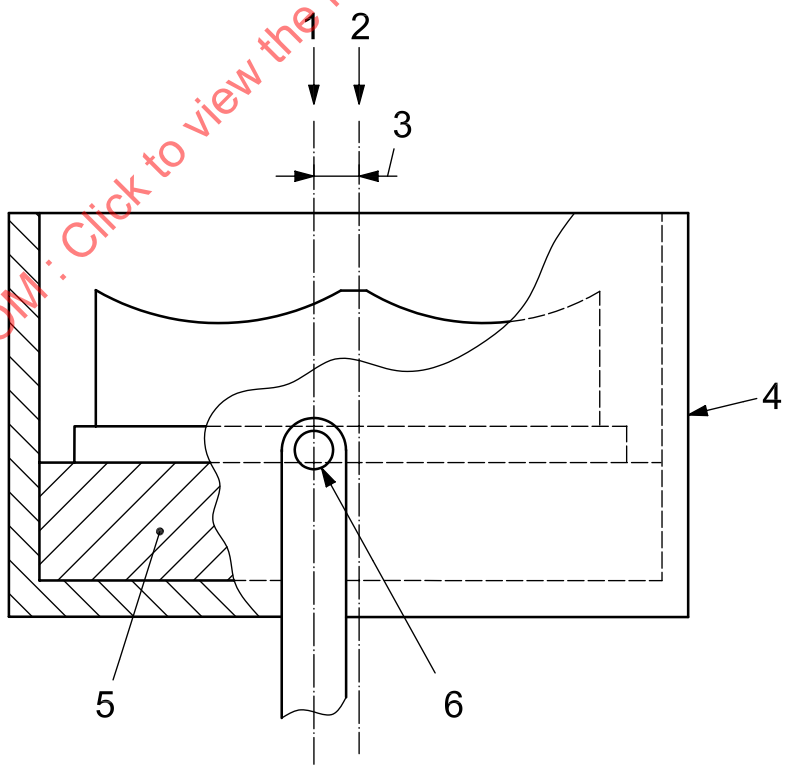
NOTE The force is considered to be positive when it acts from a posterior to an anterior direction on the tibial component. See Figure 1.



Key

1 flexion (of femoral component)
2 tibial rotation, tibial rotation torque
3 AP displacement by the tibial component, AP force on the tibial component
4 axial force

Figure 1 — Sign convention for the forces, torques and motions, shown for a left total knee replacement system



Key

1 axial force axis
2 tibial axis
3 0,07 w offset
4 holder of tibial component
5 cement mounting for tibial component
6 axial force applied through free turning pivot(s)

Figure 2 — Test specimen configuration

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

NOTE The force is considered to be positive when it acts in an inferior-to-superior direction (see Figures 1 and 2).

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, as designated in ISO 7207-1

NOTE 1 See Figure 2.

NOTE 2 The value of 0,07 w offset is equivalent to 5 mm offset for a tibial component of average width, i.e. 74 mm.

3.5
condylar centres
centres of two circles which are a best fit to the sagittal sections through the curved surfaces of the posterior regions of the two condyles of the femoral component of a condylar or meniscal total knee-joint prosthesis

3.6
flexion/extension axis
nominal axis of rotation of the femoral component relative to the tibial component

NOTE 1 For hinged knees, the flexion/extension axis is the hinge axis.

NOTE 2 For condylar and meniscal knees, the flexion/extension axis may be determined by:

— considering the condyles of the femoral component to be in contact with an imaginary plane perpendicular to the tibial axis when the femoral component is at 30° and when it is at 60° of flexion; and then

— visualising four lines (contact normals) normal to the imaginary plane running through the points where the two femoral components would contact the plane at each of these flexion angles.

The flexion/extension axis is then the line intersecting all four contact normals.

NOTE 3 The axis of rotation of the femoral component relative to the machine frame does not necessarily coincide with, but can be made to approximate to, the flexion/extension axis.

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 (i.e. full extension) *in vivo.*

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 may 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 co-ordinate 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 can span a large (flat) range of anterior-posterior positions, or would not exist (no dish effect). In such a situation, this definition of reference position cannot apply. In such situations, the prosthesis manufacturer should be consulted to decide what neutral position should be set and this should be 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 the axial force axis

NOTE The rotation is considered to be zero when the total knee-joint prosthesis is in the **reference position** (3.7). This rotation is +ve when it is internal (see Figure 1). This means that for a left-sided total knee-joint prosthesis, the tibial rotation is positive when a view from a superior position on the tibial component shows the tibial component rotated clockwise from its position with the total knee-joint prosthesis in the **reference position** (3.7).

3.10
tibial rotation torque
torque applied to the tibial component of the total knee-joint prosthesis around the axial force axis

NOTE From a plan view on the tibial component, the axial torque is +ve when it acts clockwise on a left-sided total knee-joint prosthesis (see Figure 1) and +ve 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 which applies a cyclic variation of flexion/extension angle and contact force to the interface between tibial and femoral components, simulating normal human walking. The tibial component is free to move relative to the femoral component under the influence of the applied contact forces, this motion having all degrees of freedom except for the flexion/extension angle which follows a specified cyclic variation.

The applied contact force actions are axial force, anterior posterior (AP) force and tibial rotation torque. The axial force follows a specified cyclic variation. The AP force comprises two components, one being a specified cyclic variation and the other having a magnitude which depends on, and is in the opposite direction to, AP displacement. Similarly, the tibial rotation torque comprises two components, one being a specified cyclic variation and the other a rotation torque having a magnitude that depends on, and is in the opposite direction to, tibial rotation. The load actions that depend on the AP displacement and tibial rotation correspond to the tensions transmitted by anatomical ligaments in normal knee-joint function. The restraint as a function of AP displacement and rotation is described in 6.9 and 6.10.

The contacting surfaces of the femoral and tibial components are immersed in a fluid test medium simulating human synovial fluid. If polymers are the object of investigation, a control specimen is subjected to the fluid medium and, optionally, 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 Specimens and lubricants

5.1 Fluid test medium, calf serum diluted with deionized water to have a protein mass concentration of 20 g/l.

Normally the fluid test medium is filtered through a 2 µm filter.

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 measured values should be included in the test report (see Clause 8).

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 and tibial component.

These components should be chosen so that their size combination and design detail represent the worst expected case for wear of the total knee replacement system being tested. 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 wear (if required) without destruction.

The components shall be sterilized in the same way as for clinical use because this might affect the wear properties of the materials. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container) when possible, to minimize variation.

5.3 Control specimen, identical to test specimen.

5.4 Number of test specimens, at least three test specimens and two passive (unloaded) soak control specimens (or one loaded control specimen) shall be tested to represent the wear of each type of prosthesis.

6 Apparatus

6.1 Testing machine, capable of applying the forces and torque prescribed in association with corresponding flexion/extension (Figures 1 and 2) 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 which is capable of isolating the test specimen to prevent third body contamination from the testing 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 of wear.

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 3 b) and maintaining the magnitude of this force to a tolerance of ± 5 % of the maximum value specified throughout the cycle. The axial force is applied along the axial force axis by applying the axial force to the tibial component of the total knee-joint prosthesis (see Figure 2).

6.6 Motion control system, capable of generating the flexion/extension motion given in Figure 3 a) and maintaining the magnitude of this motion to a tolerance of ± 5 % of the maximum value specified throughout the cycle. 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 in the designed fully extended state.

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

6.7 AP force control system, capable of generating an AP force following the cycle given in Figure 4 a) and maintaining the magnitude of this force to a tolerance of ± 5 % of the maximum value of the force specified throughout the cycle. The AP force is applied along the line of action that is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis.

6.8 Tibial torque control system, capable of generating a tibial torque following the cycle given in Figure 4 b) and maintaining the magnitude of this torque to a tolerance of ± 5 % of the maximum value specified throughout the cycle. The tibial torque is applied about the axial force axis.

6.9 AP motion restraint system, capable of applying a restraining AP force along its line of action (see 6.7). The direction of the restraining AP force is such as to oppose AP movement of the tibial component. It should be zero when the total knee-joint prosthesis is in, or within 2,5 mm in either direction of, the reference position.

The magnitude of the restraining AP force (outside the ± 2,5 mm range) is proportional to the AP displacement of the tibial component, the magnitude of the constant of proportionality being (9,3 ± 0,5) N/mm for prostheses requiring resection of both cruciate ligaments.

For a posterior cruciate ligament (PCL) retaining prosthesis, the constant of proportionality should be (44 ± 2,2) N/mm for negative AP motion (simulating PCL action), while keeping 9,3 N/mm restraint stiffness against positive (anterior) AP motion of the tibial component (simulating the capsule and other secondary soft tissue restraint).

NOTE The restraining AP force may be generated by an elastic spring element.

6.10 Tibial rotation restraint system, capable of applying a restraining tibial rotation torque about the same axis as that of the tibial torque (6.8). The direction of the tibial rotation torque is such as to oppose rotation of the tibial component. It should be zero when the total knee-joint prosthesis is in, or within ± 6° either sense away from, the reference position.

The magnitude of the restraining tibial rotation torque (outside the ± 6° range) is proportional to the tibial rotation, the magnitude of the constant of proportionality being (0,13 ± 0,01) Nm/° for a PCL sacrificing prosthesis, and (0,36 ± 0,02) Nm/° for a PCL retaining prosthesis.

NOTE The restraining torque may be generated by an elastic spring element.

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

NOTE The use of sealed enclosures might prevent evaporation.

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

6.13 Control station(s), capable of applying the loading regime shown in Figure 3 b), without the loading regime shown in Figures 4 a) and b) and without the angular displacement shown in Figure 3 a), and incorporating the provisions of 6.2, 6.3, 6.4, 6.5, 6.11 and 6.12. Alternatively unloaded (passive soak) controls may be used which are immersed in the fluid test medium incorporating the provisions of 6.11 and 6.12.

6.14 Measuring systems for AP displacement and tibial rotation (optional).

The recommended accuracy for the AP displacement measuring system is at least ± 0,2 mm and for the tibial rotation measuring system at least ± 0,5°. If the testing machine is intended to accommodate multiple total knee-joint prostheses, then it should be possible to measure the AP displacement and tibial rotation individually for each specimen.

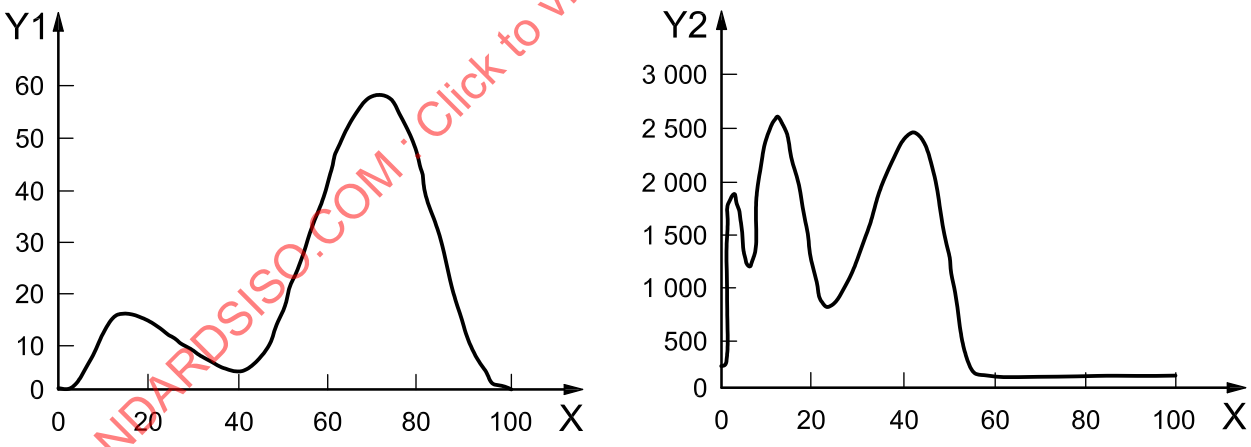
NOTE Such measurements might be of value for monitoring the sliding motion of the total knee-joint prosthesis during the course of testing so as to determine whether this motion remains within the design limits for the type of total knee-joint prosthesis under test. The measuring system can also be used to verify the forces and torques applied by the motion restraint systems (6.9 and 6.10).

Table 1

Percentage of cycle time	Flexion angle in degrees ± 5 % (of maximum value)
0	0
15	16
40	5
72	58

Table 2

Percentage of cycle time	Axial force in newtons ± 5 % (of maximum value)
0	168
3	1 887
7	1 175
13	2 600
25	838
45	2 433
60	168
100	168



a) Variation of flexion angle with time

b) Variation of axial force with time

Key

X percentage of cycle time

Y1 flexion/extension angle, degrees

Y2 axial force, newtons

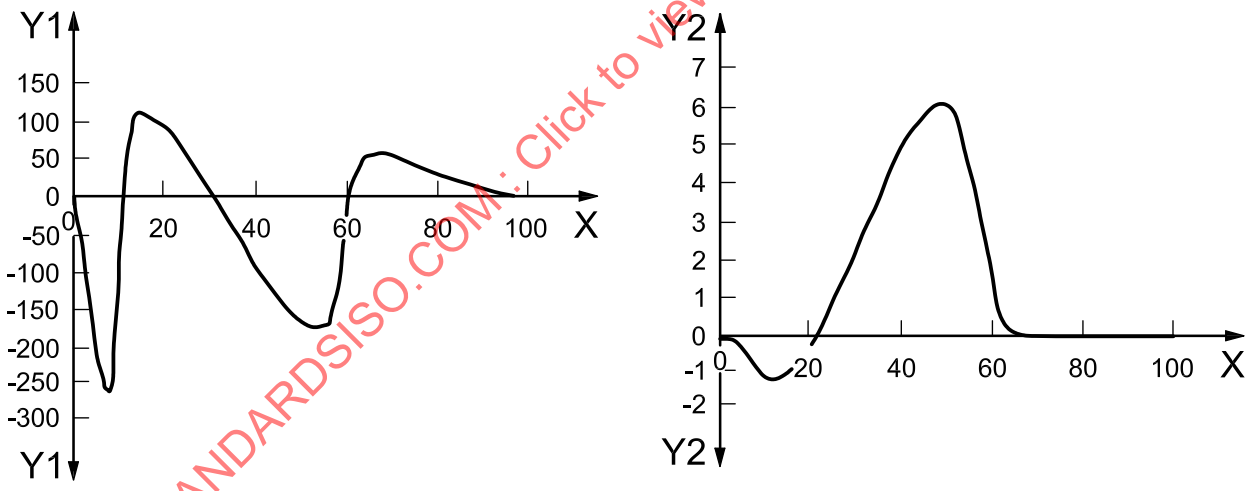
Figure 3 — Variation with time of flexion angle and axial force

Table 3

Percentage of cycle time	AP force in newtons ± 5 % (of maximum value)
0	0
5	–265
12	110
55	–177
65	52
100	0

Table 4

Percentage of cycle time	Rotation torque in newton metres ± 5 % (of maximum value)
0	0
10	–1
50	6
65	0
100	0



a) Variation of AP force with time

b) Variation of rotation torque with time

Key

X percentage of cycle time

Y1 AP force, newtons

Y2 rotational torque, newton metres

Figure 4 — Variation with time of AP force and rotational torque

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.

NOTE A method of measurement of wear is given in ISO 14243-2.

7.2 Following the initial measurements, clean the test specimen as specified in ISO 14243-2.

7.3 Mount the femoral component of the test specimen in the testing machine with an alignment such that the AP motion restraining forces and tibial rotation restraining torque can be set to within the specified tolerances (see 6.9 and 6.10).

NOTE Depending on the design of the testing machine, this might 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 testing machine. The quality of this alignment will affect the motions (kinematics) that would result under the force control regime, and in turn can adversely affect the resultant wear rate.

7.4 Mount the tibial component of the test specimen in the testing machine with an alignment such 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 while the cement sets.

7.5 Place the passive soak control specimen in a container and place the latter in a location with a temperature of ± 2 °C relative to the test specimens. In the case of an active soak control specimen, repeat the steps in 7.1 to 7.4.

7.6 Introduce the fluid test medium (5.1) to completely immerse the contact surfaces of the test specimen and the container of the soak control specimen. Maintain the temperature of the fluid test medium at 37 °C ± 2 °C, taking the measurement at a point 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 Tables 1 to 4 and Figures 3 and 4 are applied to the test specimen, and the loads specified in Table 2 and Figure 3 b) are applied to the control specimen. The curves between the defined maxima and minima in each figure shall be smooth with no overshoots. Record the displacement and load waveform at the start-up and after each change of fluid test medium.

NOTE Annex A gives details of a typical set of test parameters equivalent to those described in Figures 3 and 4.

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

7.9 Replace 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 and take wear measurements.

7.12 Following wear measurements, clean the test specimen and control specimen as specified in ISO 14243-2 and re-install in the testing machine (see 7.3 to 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 events occurs.

a) Completion of 5×10^6 load cycles.

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

b) Break-up or delamination of the articulating surfaces.

c) Failure of the testing machine to maintain the force and displacement within the given tolerances (see 7.6 to 7.9).

8 Test report

The test report shall include the following information:

a) a reference to this part of ISO 14243, i.e. ISO 14243-1:2009;

b) the identity of the test specimens, as stated by the party submitting the specimen for test, including size, material, type, manufacturer, sterilization method and its parameters such as radiation type, dose, fluid test, medium and time;

c) a description of the testing machine, including number of stations, type of systems used for generating motions, torque and forces, range of motions, torque and forces, type of system used for measuring motion, torque and forces, arrangement for mounting specimen (see 5.2), arrangement for lubrication of articulating surfaces, arrangement for temperature control and arrangement for the exclusion of contaminant particles;

d) clear graphical plots of the "measured" flexion, forces and torque input waveforms that were logged at the start of the test, and at the start and end of every run period between wear measurements; these plots should be superimposed graphically against the "desired" input waveforms to assess how closely the inputs were controlled and this would verify the validity of actuation of these inputs in terms of magnitudes and relative phase relationships;

e) whether control specimens were used, and if not, the reference to the tests from which the control data were taken;

f) a statement of results including:

   1) the total number of cycles applied;

   2) the reason for terminating the test if fewer 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 sub-components, if the components were of modular construction;

   5) the values of pH if routine monitoring of the fluid test medium was undertaken (see 5.1);

g) details on the measurement of wear and the results obtained (ISO 14243-2), namely:

   1) the method of wear measurement (i.e. gravimetric);

   2) the change of mass for each measurement using the gravimetric method;

   3) the gravimetric wear rate.

9 Disposal of test specimen

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

Annex A
(informative)

Details of load and displacement parameters for the test cycle described in Figures 3 and 4

Percentage of cycle time %	Flexion/extension angle ° [Figure 3 a)]	Axial force N [Figure 3 b)]	AP force N [Figure 4 a)]	Rotational torque Nm [Figure 4 b)]
0,00	0,00	167,6	0,00	0,000 0
1,00	0,17	597,5	–25,31	–0,024 5
2,00	0,69	1 457,4	–91,56	–0,095 5
3,00	1,53	1 887,3	–173,44	–0,206 1
4,00	2,65	1 782,9	–239,69	–0,345 5
5,00	4,00	1 530,9	–265,00	–0,500 0
6,00	5,53	1 278,9	–246,43	–0,654 5
7,00	7,16	1 174,6	–194,40	–0,793 9
8,00	8,84	1 270,1	–119,22	–0,904 5
9,00	10,47	1 530,9	–35,78	–0,975 5
10,00	12,00	1 887,3	39,40	–1,000 0
11,00	13,35	2 243,6	91,43	–0,989 2
12,00	14,47	2 504,5	110,00	–0,956 9
13,00	15,31	2 600,0	109,62	–0,903 3
14,00	15,83	2 570,0	108,47	–0,828 7
15,00	16,00	2 482,0	106,57	–0,733 6
16,00	15,96	2 342,0	103,92	–0,618 5
17,00	15,83	2 159,5	100,53	–0,484 2
18,00	15,61	1 947,1	96,43	–0,331 6
19,00	15,32	1 719,1	91,64	–0,161 4
20,00	14,95	1 491,1	86,18	0,025 1
21,00	14,51	1 278,6	80,08	0,226 9
22,00	14,01	1 096,2	73,37	0,442 8
23,00	13,45	956,2	66,10	0,671 3
24,00	12,84	868,2	58,29	0,911 0
25,00	12,20	838,2	50,00	1,160 6
26,00	11,53	848,0	41,25	1,418 4
27,00	10,85	877,2	32,11	1,682 9
28,00	10,15	925,1	22,62	1,952 5