



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of ISO 14243-1:2009+A1:2020. It supersedes BS ISO 14243-1:2009, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by **A1** **A1**.

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A list of organizations represented on this committee can be obtained on request to its secretary.

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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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.

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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 to entry: AP is an abbreviation for anterior posterior.

Note 2 to entry: 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 1 to entry: The force is considered to be positive when it acts from a posterior to an anterior direction on the tibial component. See [Figure 1](#).