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

Part 1: Methodology for simulator wear testing of anatomic total shoulder-joint prostheses

Implants chirurgicaux — Usure des prothèses totales de l'articulation de l'épaule —

Partie 1: Méthodologie pour les essais d'usure sur simulateur des prothèses anatomiques totales de l'articulation de l'épaule

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Foreword

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Evaluation of the wear of shoulder-joint replacement prostheses plays an important role in the development of bearing materials and designs and in the continual assessment of current products.

This document is applied for the quantitative and qualitative assessment of the wear of anatomic total shoulder-joint prostheses.

A reliable testing method is provided that allows for testing on commonly used knee wear simulators (see ISO 14243-1:2009, 4.3). Other types of simulators can be used provided they meet the requirements described in this document.

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

Part 1: Methodology for simulator wear testing of anatomic total shoulder-joint prostheses

1 Scope

This document describes a wear testing method of anatomic total shoulder-joint prostheses that specifies relative motion between the implant components and the pattern of the applied forces. This document includes the basic configuration of the simulator, sample number and alignment, test environment, speed and duration of testing, verification of inputs, measurement of kinematics and other details of the procedure and reporting.

The primary outcome is the evaluation of wear performance of total anatomic shoulder-joint prostheses, which includes both qualitative and quantitative methods. The qualitative methods of wear evaluation are included in this document and the methods of quantitative wear measurement are covered in ISO 14243-2.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 14243-2:2016, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

ASTM F1378-18e1, *Standard Specification for Shoulder Prostheses*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ASTM F1378-18e1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
axial force
force applied to maintain contact between the glenoid liner and humeral head

Note 1 to entry: This force is applied orthogonally to the glenoid plane (see ASTM F1378-18e1, Figure 2) of the glenoid component of an anatomic total shoulder replacement (see Figure 9). The force is defined as positive when pushing the glenoid liner and humeral head together.

Note 2 to entry: The force vector applied to each component varies in direction relative to the configuration. In the context of this document the axial force refers to the axial force channel of the test machine.

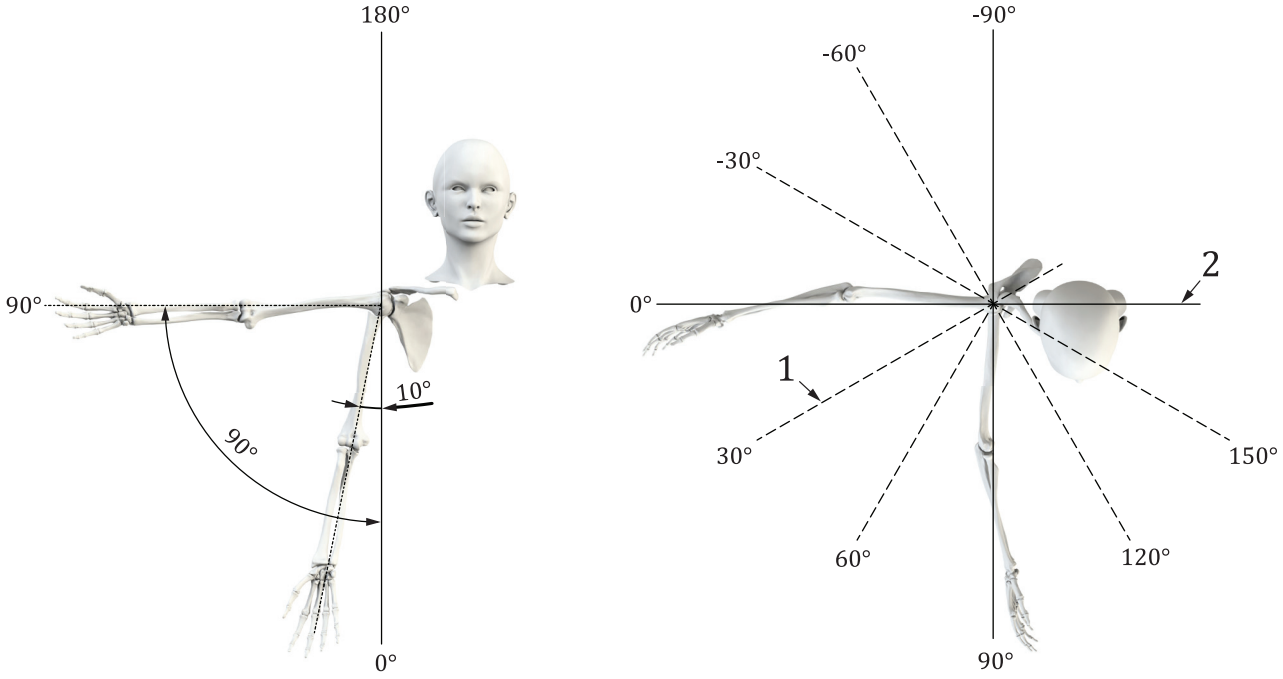
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3.2
elevation plane
one of the infinite planes passing through the fixed centre of rotation of the humeral head and the superior-inferior axis

3.3
elevation angle
angle between the humerus and vertical axis in the *elevation plane* (3.2) (humerothoracic elevation)

Note 1 to entry: In vivo, the humerothoracic angle is larger than the humeroscapular angle due to the relative motion between the scapula and the rest of the body (scapulohumeral rhythm). In this document, the scapulothoracic motion is neglected and the humeral elevation is regarded as the relative angulation between the humeral and glenoid component. The in-vivo elevation angle will therefore be slightly higher than given by the elevation angle in this document. Figure 8 displays the resulting approximate in-vivo movement including the scapulothoracic motion.

Note 2 to entry: See Figure 1 a) for a depiction of the elevation angle.



a) Humerus at elevation angles of 10° and 90°

b) Humerus at elevation plane angles of 0° and 90°

Key

1	*scapular plane* (3.11)
2	coronal plane

Figure 1 — Plane terminology described by Reference [8]

3.4
elevation plane angle
angle lying in a horizontal plane between the humerus and the coronal plane

Note 1 to entry: The overall elevation plane angle of the human shoulder is a combination of the glenohumeral joint elevation plane angle and scapular thoracic (bone) elevation plane angle. In this document, for simplicity, it is assumed that the scapular (bone) is not present or moving in any of the motions.

Note 2 to entry: When the patient elevates their humerus in the *elevation plane* (3.2) whose angle is zero, it means the elevation plane is coincident with the patient's coronal plane.

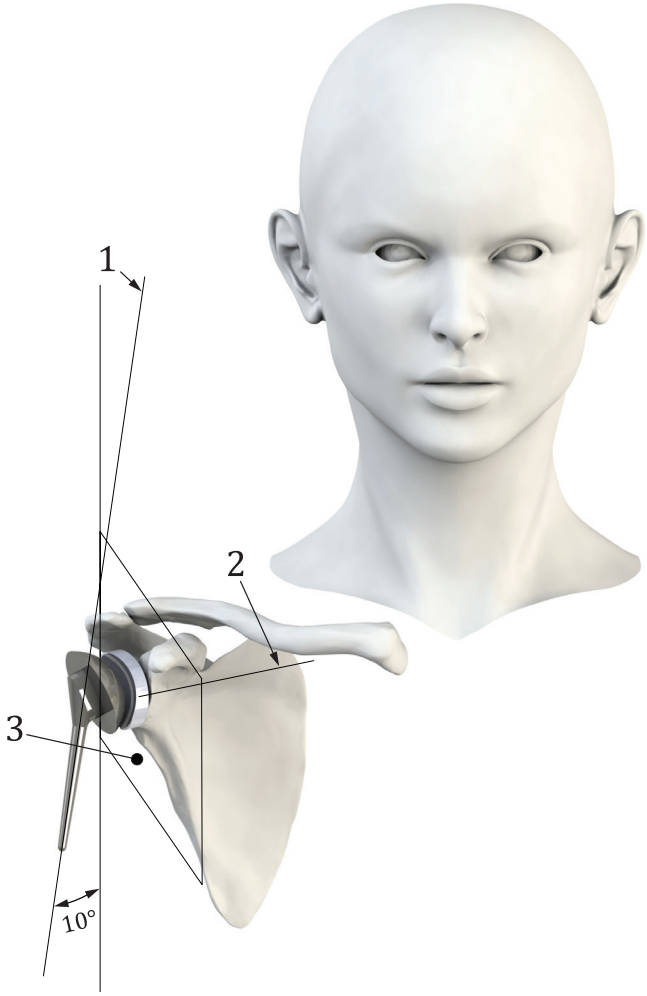
Note 3 to entry: See Figure 1 b) for a depiction of the elevation plane angle.

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3.5
glenoid component axis
axis orthogonal to the glenoid plane which is aligned with the *scapular plane* (3.11) running through the centroid of the glenoid component

Note 1 to entry: See of ASTM F2028-25a, Figures 2 and 4 for further information.

Note 2 to entry: See Figure 2 for a depiction of the glenoid component axis.



Key

1	humerus axis and *humeral component stem axis* (3.7)
2	*glenoid component axis* (3.5)
3	glenoid plane

Figure 2 — Orientation of the humeral component stem axis at the reference position in the glenoid (scapular) plane

3.6
glenoid component SI-axis
superior-inferior axis of the glenoid component as defined by the manufacturer

Note 1 to entry: See of ASTM F2028-25a, Figure 4 for further information.

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3.7
humeral component stem axis
axis of the stem of the humeral component (if present) or theoretical axis of the humerus.

Note 1 to entry: In practice, it is possible that the humeral component stem axis is not aligned with the humerus axis. For simplification of the test procedure, those two axes are assumed to be aligned (see Figure 2).

3.8
loaded soak control specimen
sample(s) of the same test specimen used in the wear test to be immersed in the same fluid test medium at the same temperature for the same time as the wear test duration with the same time varying *axial force* (3.1) as the wear test, but without any articulating motions and without the *shear force* (3.12), such that the polymer articulating component(s) can be adjusted for fluid absorption

3.9
passive soak control specimen
sample(s) of the same polymer articulating component(s) used in the wear test that will be immersed in the same fluid test medium at the same temperature for the same time as the wear test duration, but without any loads or articulating motions, such that the polymer articulating component(s) can be adjusted for fluid absorption

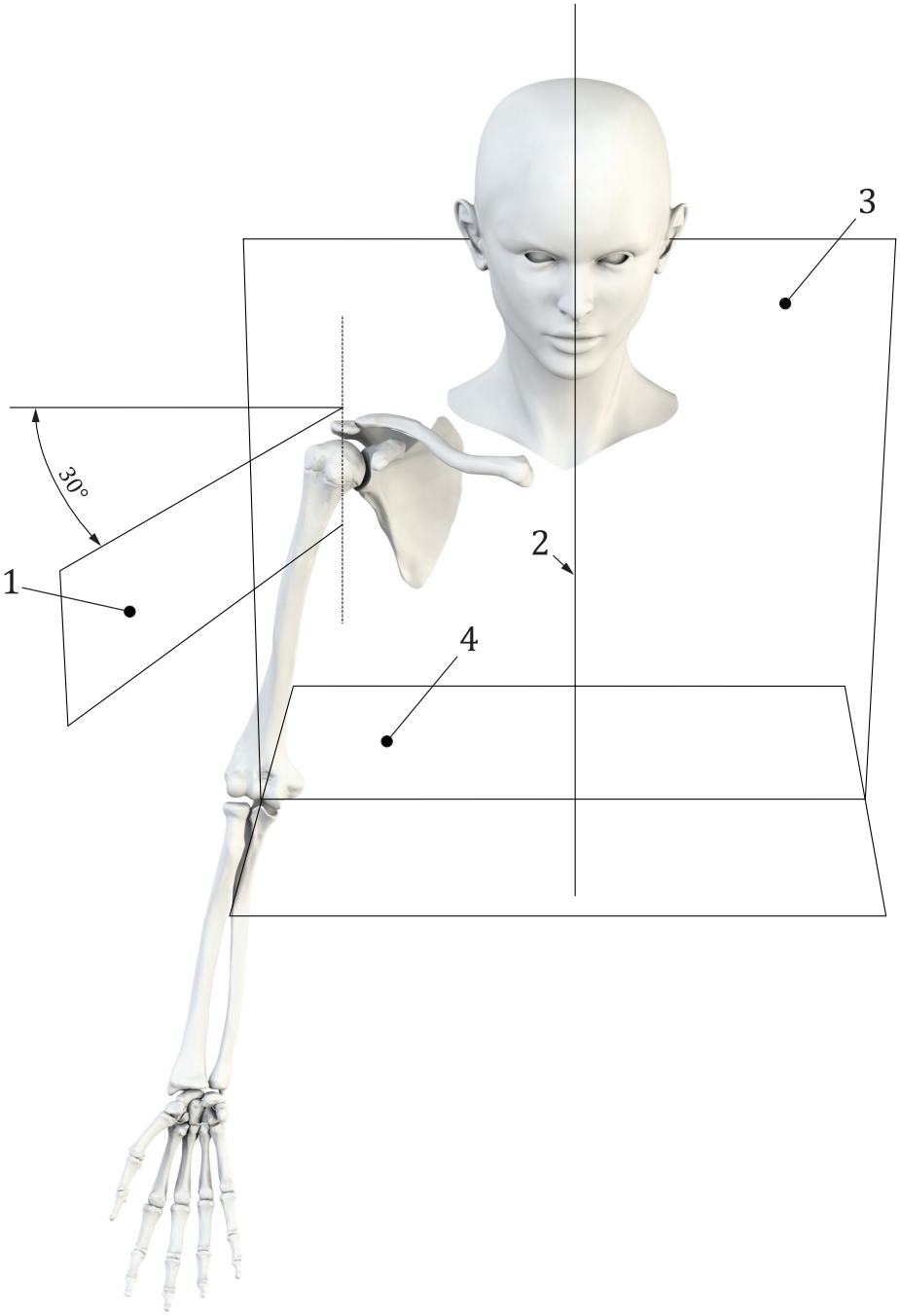
3.10
polymeric articulating component
anatomical shoulder polymeric component such as a humeral head or glenoid component that can wear, including the test specimens and the loaded or *passive soak control specimen(s)* (3.9)

3.11
scapular plane
plane of the scapula in its resting position at 30° *elevation plane angle* (3.4)

Note 1 to entry: In this document, the scapular plane is assumed stationary relative to the human.

Note 2 to entry: See Figure 3 for a depiction of the scapular plane.

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Key

1	*scapular plane* (3.11)
2	sagittal plane
3	coronal plane
4	transverse plane

Figure 3 — Orientation of the scapular plane with the elevation plane angle set to 30°

3.12
shear force
force applied on the glenoid component parallel to its glenoid plane

Note 1 to entry: It is the force applied along the y-axis of the knee simulator as defined in Figure 6.

Note 2 to entry: The shear force is defined as positive when the humeral head acts on the glenoid component from superior to inferior direction and from anterior to posterior direction.

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Note 3 to entry: The sign of the shear force command signal depends on the type of the knee simulator used and shall be selected to achieve the motion as described in 6.7.

Note 4 to entry: See ASTM F1378-18e1, Figure 2 for further information.

3.13
stemless humeral component
humeral component that achieves fixation within the humeral metaphysis, with no diaphyseal incursion

3.14
target waveform
time varying force and angular rotations with tolerance envelope

Note 1 to entry: The forces and rotations above are acting on the implant system.

Note 2 to entry: The simulator actuators and control systems might not be able to physically impose the target waveforms defined in Annexes A to D due to speed and other limitations. The user can exaggerate or attenuate the driving signals to such control systems in a process of tuning to bring the actual measured actuations closer to the target waveforms.

Note 3 to entry: See Figure 6 and Annexes A to D for further information.

4 Principle

4.1 Reference position

The reference position is defined in the scapular plane (see Figure 3).

For stemmed humeral components, the humeral component stem axis and the centre of the humeral head are in this plane. The humerus axis and the humeral component stem axis are then set to 10° in elevation (see Figure 4).

For stemless humeral components, the polar axis of the humeral head is angled 30° relative to the transverse plane or as defined by the manufacturer (see Figure 5). The centre and the polar axis of the humeral head of the stemless humeral component lie on the scapular plane.

NOTE 1 “10° in elevation” refers to an elevation angle of 10° in the elevation plane with an elevation plane angle of about 30° (the scapular plane).

Anatomic shoulder designs of stemmed and stemless humeral components with non-spherical heads can require a modification of the reference position to create a worst-case testing condition. The user shall provide a justification for the reference position and the orientation of the asphericity (if present) used.

The glenoid component axis is parallel to the intersection of the scapular plane and the transverse plane to represent the best possible reproduction of the natural glenoid.

NOTE 2 For a complete definition of the reference position, the rotation of the glenoid component around the glenoid component axis is needed. This rotation is provided by the test conditions defined in 7.3.1 and displayed in Figure 9.

For augmented glenoids, the alignment of the articulating surface with regard to the glenoid plane shall be the same as for the non-augmented design of this implant.

The reference position is defined as 0° of rotation and 10° of elevation.

NOTE 3 The reference position is a simplification of the anatomical position which can vary between manufacturers. A risk analysis can be necessary to determine the impact of deviations from the described reference position.

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