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Interested committees:

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This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

## UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

## Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
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## Template for comments and secretariat observations

|                  |                        |
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| Date: xx/xx/20xx | Document: ISO/DIS xxxx |
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| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/ Figure/Table/Note | Type of comment | Comment (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |



# DRAFT International Standard

## ISO/DIS 16436-1

### Implants for surgery — Wear of total shoulder-joint prostheses — Part 1: Force and displacement parameters for wear-testing machines and corresponding environmental conditions for test of anatomic total shoulder-joint prostheses

ICS: 11.040.40

ISO/TC 150/SC 4

Secretariat: **BSI**

Voting begins on:  
**2024-05-02**

Voting terminates on:  
**2024-07-25**

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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](http://www.iso.org/members.html).

## 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 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 [4.3](#)) in accordance with ISO 14243-1. Other types of simulators may be used provided they meet the requirements described in this standard.



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

## Part 1: Force and displacement parameters for wear-testing machines and corresponding environmental conditions for test of anatomic total shoulder-joint prostheses

### 1 Scope

This part of ISO 16436 specifies the relative angular movement between articulating components, the pattern of the applied force, the speed and duration of testing, the specimen configuration, and the test environment to be used for the wear testing of anatomic total shoulder-joint prostheses.

### 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 14243-2, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

ISO 14243-1, *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*

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

ASTM F2028-17, *Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation*

### 3 Terms and definitions

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

#### 3.1 axial force

Force applied to maintain contact between the glenoid and humeral head

Note 1 to entry: This force applied orthogonally to the glenoid plane (see ASTM F1378, Figure 2) of the glenoid component of an anatomic total shoulder replacement (see [Figure 8](#)). The force is defined as positive when pushing the glenoid 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 standard the axial force refers to the axial force channel of the test machine.

#### 3.2 elevation plane

one of the infinite planes passing through the fixed center of rotation of the humeral head and the superior-inferior axis, and the particular plane is referred to by the elevation plane angle

**3.3****elevation angle**

Angle between the humerus and vertical axis in the elevation plane (see [Figure 1](#) - left) (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. 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 7](#) displays the resulting approximate in-vivo movement including the scapulothoracic motion.

**3.4****elevation plane angle**

angle lying in a horizontal plane between the humerus and the coronal plane (see [Figure 1](#) - right)

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 joint 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 arm in the elevation plane whose angle is zero, it means the elevation plane is coincident with the patient's coronal plane.

**3.5****glenoid component axis**

axis orthogonal to the glenoid plane (see figures 2 to 4 of ASTM F2028-17) which is typically aligned with the scapular plane (see [Figure 3](#))

**3.6****glenoid component SI-axis**

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

Note 1 to entry: See figure 3 of ASTM F2028-17 for further information.

**3.7****humeral component stem axis**

Axis of the stem of the humeral component (if present) or theoretical axis of the humerus (see [Figure 3](#))

Note 1 to entry: In practice, the humeral component stem axis may not be aligned with the humerus axis. For simplification of the test procedure, those two axes are assumed to be aligned (see [Figure 3](#)).

**3.8****scapular plane**

plane of the scapula in its resting position at 30° elevation plane angle (see [Figure 2](#)). In this standard, the scapular plane is assumed stationary relative to the human

**3.9****shear force**

force applied on the glenoid component parallel to its glenoid plane (see ASTM F1378, Figure 2)

Note 1 to entry: It is the force applied along the y-axis of the knee simulator (see [Figure 5](#)).

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.

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](#).

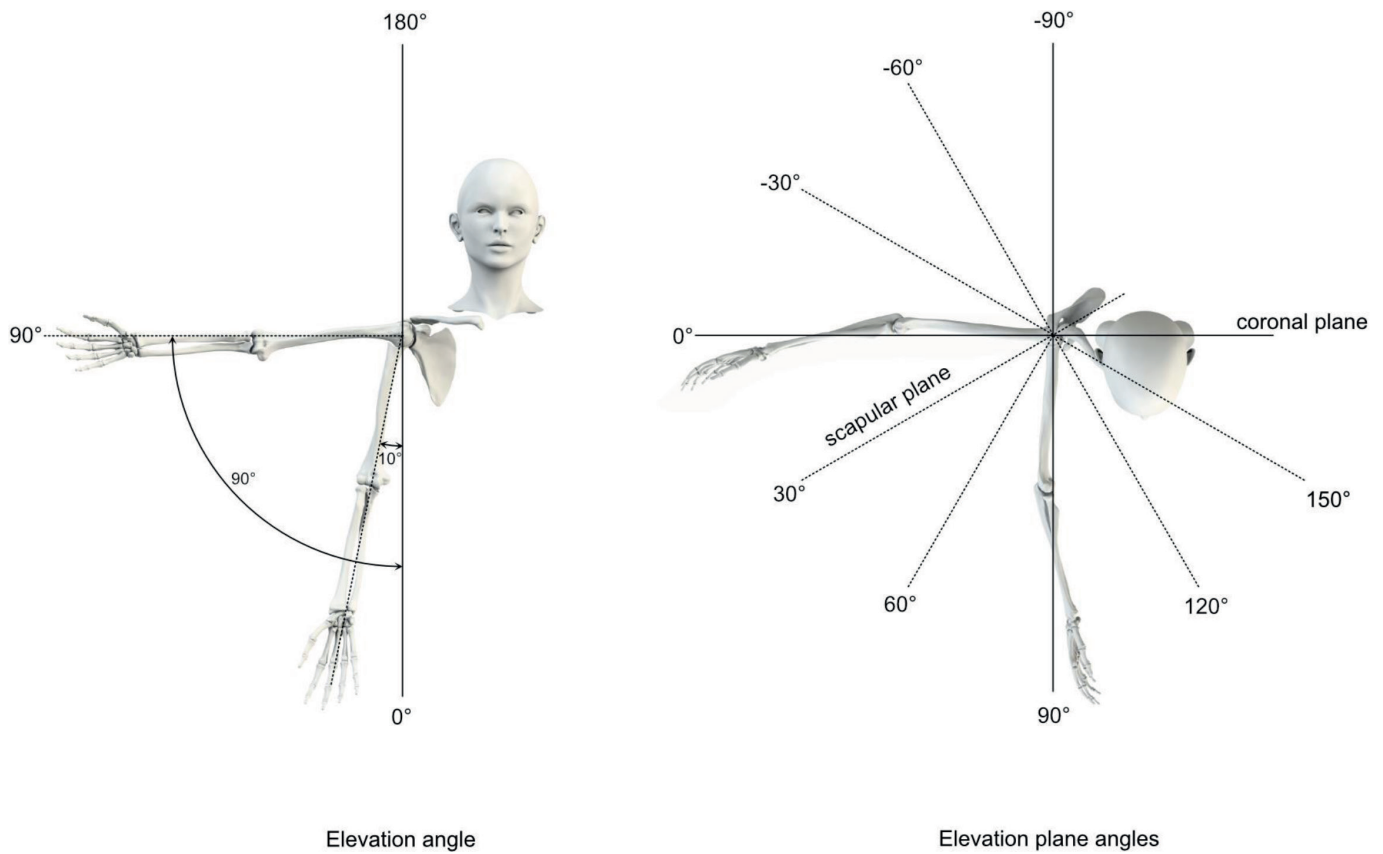


**Figure 1 — Plane terminology described by Matsen et al. (Matsen, et al. 1994).**

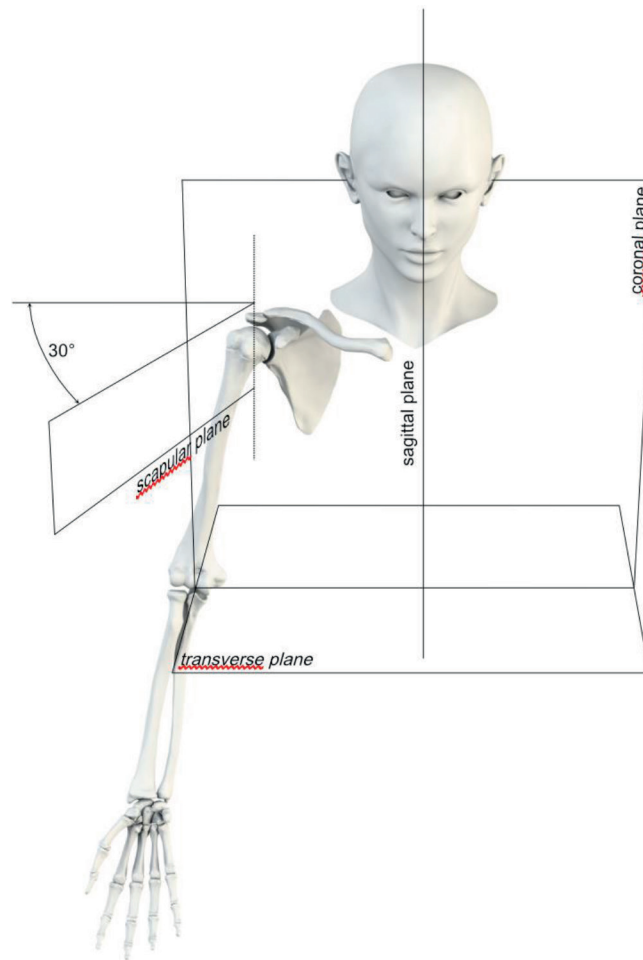


Figure 2 — Orientation of the scapular plane with the elevation plane angle set to 30 degrees.