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AMENDMENT 1
2019-01

**Implants for surgery — Wear of total
hip-joint prostheses —**

**Part 3:
Loading and displacement parameters
for orbital bearing type wear testing
machines and corresponding
environmental conditions for test**

AMENDMENT 1

*Implants chirurgicaux — Usure des prothèses totales de l'articulation
de la hanche —*

*Partie 3: Paramètres de charge et de déplacement pour machines
d'essai d'usure du type orbital de maintien et conditions
environnementales correspondantes d'essai*

AMENDEMENT 1



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

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

Part 3:

Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test

AMENDMENT 1

2 Normative references

Add the following at the end of the Normative references (referenced in 5.1):

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

4 Principle

Replace “in position in their normal configuration” in the first sentence with the following:

in either an “inverted” position, that is, head above liner [Figure 4 a)]; or an “anatomical” position, that is, head below liner [Figure 4 b)]

5.1

Replace

“, calf serum approximately 25 % volume fraction diluted with de-ionized water (balance).

The fluid test medium should be filtered through a filter of pore size 2 µm and have a protein mass concentration of not less than 17 g/l.”

with

“, calf serum diluted with deionized water in accordance with ISO 3696.

The fluid test medium shall be filtered through a 2 µm filter and have a protein mass concentration of $30 \text{ g/l} \pm 2 \text{ g/l}$.”

6.2

Add the following at the end of 6.2 and before the NOTE:

One testing setup, sometimes used for wear testing incorporating 3rd-body particles, is the “inverted position”, that is, head above liner [Figure 4 a)]. Another testing setup is the “anatomical position,” that is, head below liner [Figure 4 b)]. The 23° angle block provides swivel to result in a 46° rocking motion, which is equivalent to an actuation of $\pm 23^\circ$ in flexion/extension and abduction/adduction (see Figure 2).

6.3

Replace the text (but not the NOTE) with the following:

6.3 Means of aligning and positioning the acetabular and femoral component of the test specimen [for Figure 4 a), the inverted position], so that its centre lies on the axis of rotation [key 7 in Figure 4 a)] of the test machine. This is achieved by calculation based on engineering drawings and setting a suitable thickness of the cement base [key 8 in Figure 4 a)] to achieve the requirement above. The femoral component is assembled to a stem connected to a self-alignment device. The ball bearings in the self-alignment device allow the stem construct to be mobile while aligned with the compressive load.

6.4

Replace the text with the following:

6.4 Means of aligning and positioning the acetabular and femoral component [for Figure 4 b), the anatomic position], to ensure that its centre lies along the axis of rotation [key 7 in Figure 4 b)] of the test machine. This is achieved by calculating and setting the thickness of the femoral fixture base [key 8 in Figure 4 b)] based on engineering drawings to achieve the alignment sought above. The acetabular component is assembled to the self-alignment device and along the axis of compressive load.

Figure 1

Delete the NOTE.

7.4

Replace the text (but not NOTE 1 and NOTE 2) with the following:

“7.4 Assemble the femoral component to the fixture in the test machine for the inverted [Figure 4 a)] and anatomic [Figure 4 b)] positions.”

7.5

Replace the text with the following:

“7.5 Mount the acetabular component in the cup holder for the inverted [Figure 4 a)] and anatomic [Figure 4 b)] positions.”

NOTE For all setup positions, the key is to maintain the centres of the femoral head and acetabular component aligned with the centre of rotation of the machine and axial load line, within the tolerance range of the self-alignment device [Key 1 in both Figure 4 a) and Figure 4 b)].”

Clause 8, c)

Add “whether the “inverted” [Figure 4 a)] or “anatomic” [Figure 4 b)] configuration was used for testing,” between “range of motions and forces, type of systems used for measuring motions and forces,” and “, arrangement for mounting specimen (5.2),” to make c) as follows:

c) a description of the test machine including number of stations, type of systems used for generating motions and forces, range of motions and forces, type of systems used for measuring motions and forces, whether the “inverted” [Figure 4 a)] or “anatomic” [Figure 4 b)] configuration was used for testing, arrangement for mounting specimen (5.2), arrangement for lubrication of articulating surfaces, arrangement for temperature control, and arrangement for the exclusion of contaminant particles;

Bibliography

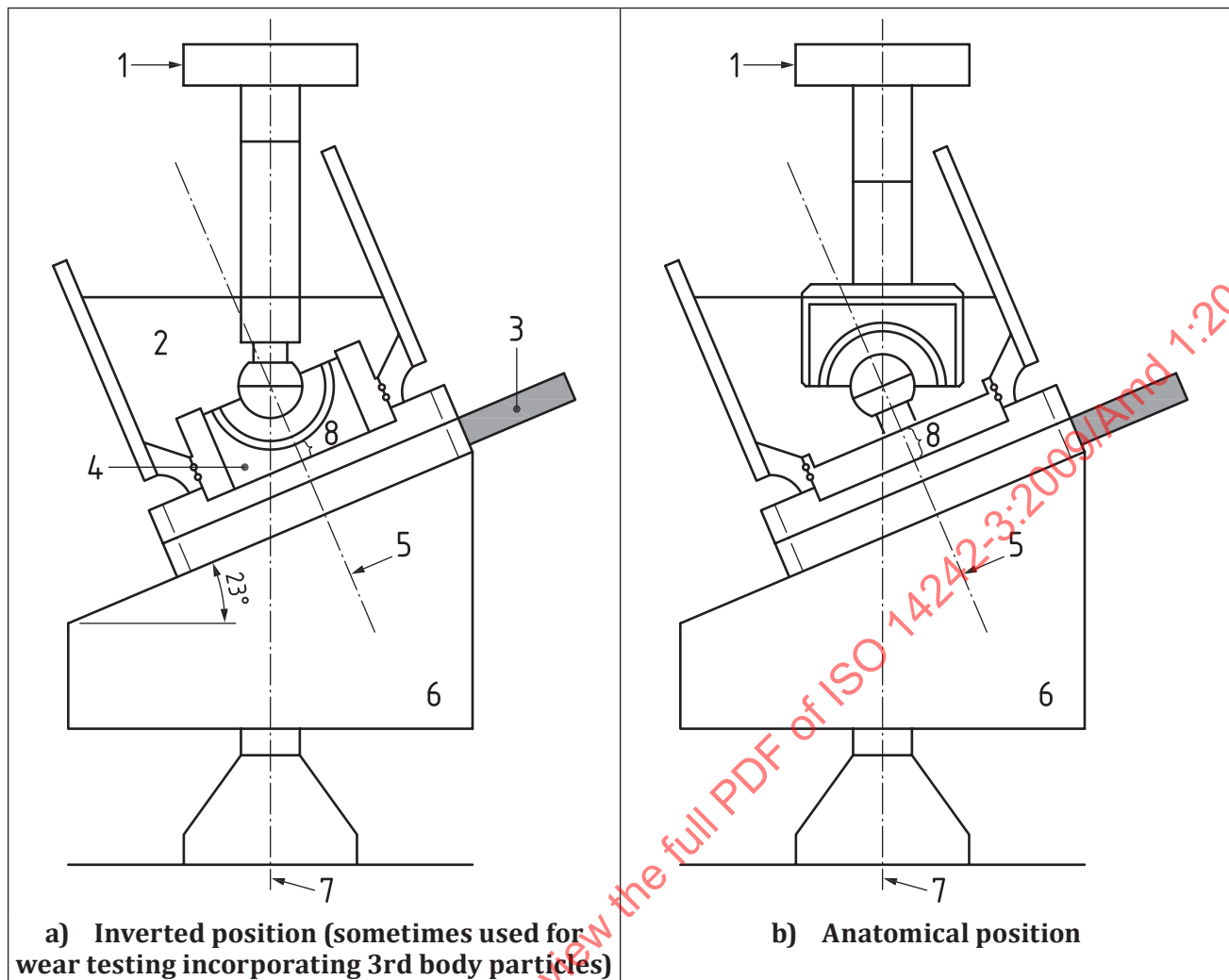
Add the following to the Bibliography:

[14] Aehle et al., 2006 SFB, p546

[Figure 4](#)

Replace the figure with the following:

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Key

- | | |
|-------------------------|---|
| 1 self-alignment device | 5 centre line of base |
| 2 lubricant | 6 angle block |
| 3 anti-rotation bar | 7 centre line of rotation for the station |
| 4 bone cement | 8 specific height required for the centre of the acetabulum/head to stay in Key 7 |

Figure 4 — Schematic of an orbital bearing machine configuration with two test sample setups