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

**Part 1:  
Loading and displacement parameters  
for wear-testing machines and  
corresponding environmental  
conditions for test**

**AMENDMENT 1**

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<https://standards.iteh.ai/standards/iso/14242-1/2014-amd-1-2018>  
**Implants chirurgicaux — Usure des prothèses totales de l'articulation  
de la hanche —**

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

*AMENDEMENT 1*



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

## Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

### AMENDMENT 1

#### 3.1

Add “or Figure 1 e)” at the end of the definition.

#### 3.2

Add “or Figure 1 f)” at the end of the definition.

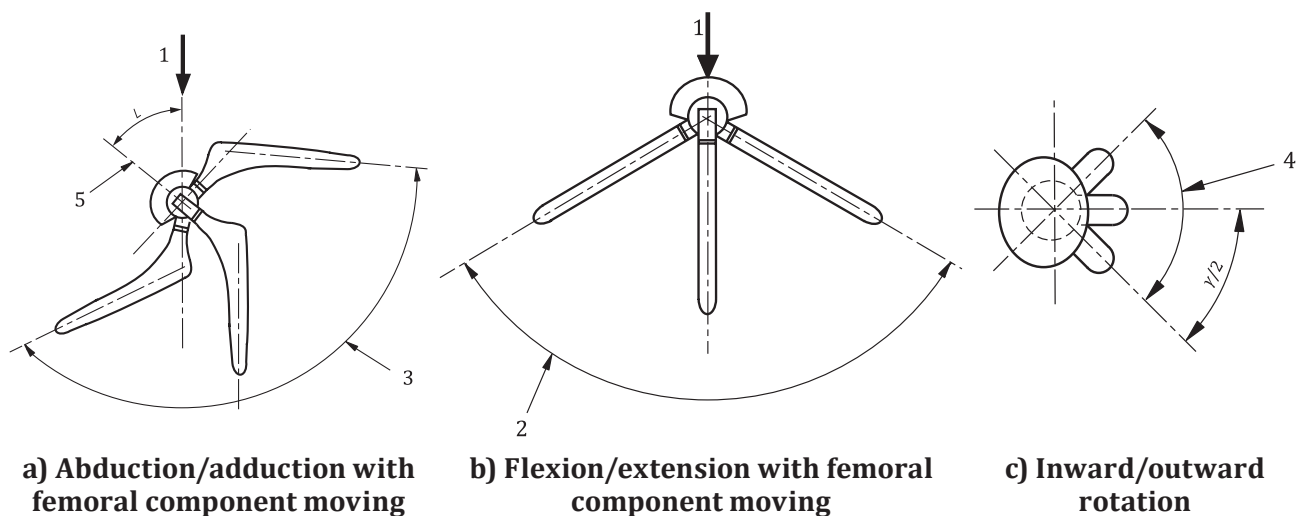
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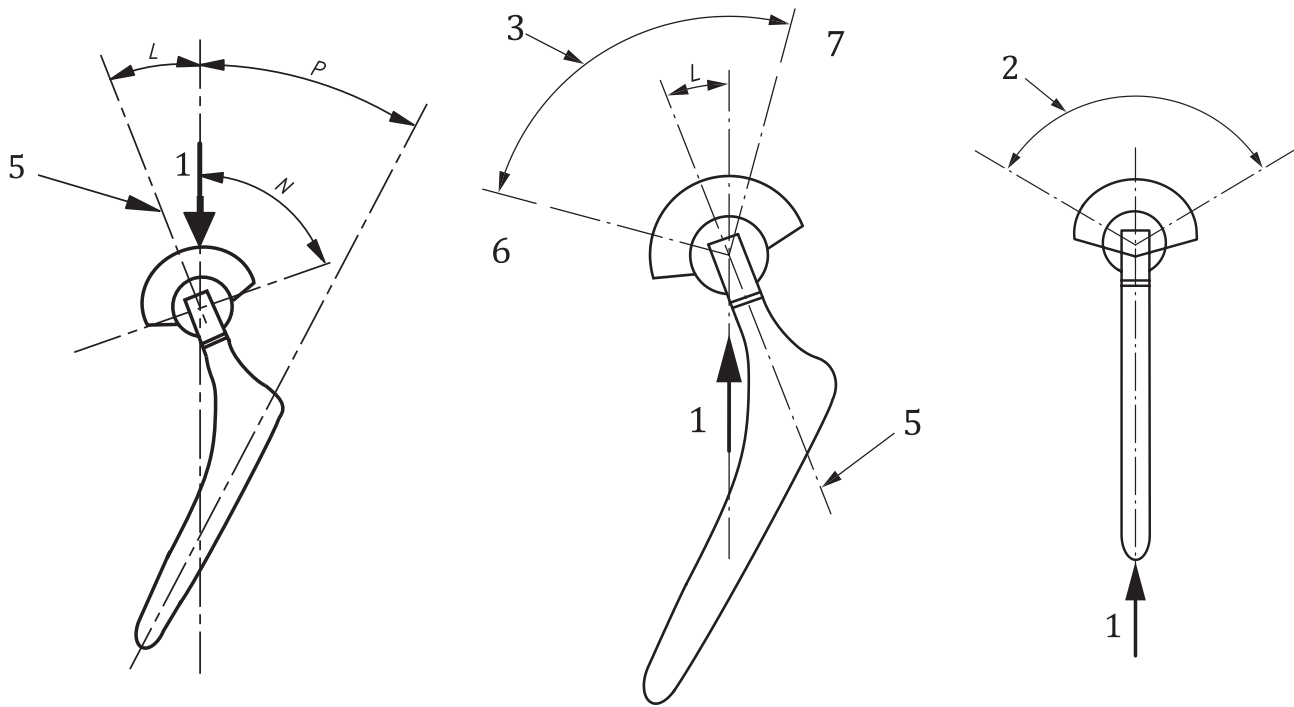
#### 6.5

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Add “and/or acetabular” between the words “femoral” and “component”.

Add two subfigures to Figure 1, and add two keys, and replace the title of Figure 1 “Angular movement of femoral component and orientation of components relative to the load line” with “Angular movement of the femoral and/or acetabular component and orientation of components relative to the load line” to make the Figure as follows:





**d) Orientation of acetabular component and femoral component in mid-position relative to the load line**

**e) Abduction/adduction with the acetabular component moving**  
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**f) Flexion/extension with the acetabular component moving (right hip depicted)**

**Key**

- |   |                                    |          |   |
|---|------------------------------------|----------|---|
| 1 | load axis                          | 6        | adduction (through motion of the cup/liner)   |
| 2 | flexion/extension angle            | 7        | abduction (through motion of the cup/liner)   |
| 3 | abduction/adduction angle          | <i>L</i> | inclination of the polar axis of the acetabular component to the load line  |
| 4 | inward/outward rotation angle      | <i>N</i> | inclination of the face of the acetabular component equal to $60^\circ \pm 3^\circ$ or as specified by the manufacturer |
| 5 | polar axis of acetabular component | <i>P</i> | inclination of stem axis to load line in mid-position of abduction/adduction range                                      |

NOTE 1 Angles *N*, *L*, and *P* are specified in 7.3 and 7.4.

NOTE 2 A full configuration can either be [a) b) c) and d)] or [a) b) e) and f)] as the other configuration.

**Figure 1 — Angular movement of the femoral and/or acetabular component and orientation of components relative to the load line**

**7.4**

Add references to Figures 1 f) and 1e to make it read as follows:

**7.4** Mount the acetabular component of the testing specimen in the test machine with the polar axis vertical, as illustrated in Figure 1 b) or in the alternative configuration of Figure 1 f), and inclined at an angle *L*, as shown in Figure 1 a) or in the alternative configuration of Figure 1 e), where *L* equals  $30^\circ \pm 3^\circ$ . These two configurations are separate and cannot be mixed, so if the configuration of Figure 1 a) is used, that of Figure 1 b) shall be used with it also. Similarly, if Figure 1 e) is used, then Figure 1 f) shall be used with it. Alternatively, if the manufacturer specifies an angle of inclination of the component on surgical implantation to be *N*, as shown in Figure 1 d), then  $L = (75 - N)^\circ \pm 3^\circ$ .

Add the following NOTE at the end of 7.4 as follows:

NOTE The two configurations described above can be different enough such that wear results from them will not be directly comparable.

*Clause 8 item c)*

Replace “types of systems used for generating motions and forces, range of motions and forces, sequence of angular transformations,” with “overall system configuration (based on Figures 1 a) and b) or 1 e) and f)) and a brief justification or rationale as to why that was chosen,” and replace “types of systems used for measuring motions and forces,” with “types of systems used for generating and sensing motions and forces, range of motions and forces, sequence of angular transformations,” to make it read as follows:

**c)** a description of the testing machine, including number of stations, overall system configuration (based on Figures 1 a) and b) or 1 e) and f)) and a brief justification or rationale as to why that was chosen, types of systems used for generating and sensing motions and forces, range of motions and forces, sequence of angular transformations, arrangement for mounting of specimen (see 5.2), arrangement for lubrication of articulating surfaces, arrangement for temperature control, and arrangement for the exclusion of contaminant particles;

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