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AMENDMENT 1
2018-07

**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

*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



Reference number
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Part 1:

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AMENDMENT 1

3.1

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

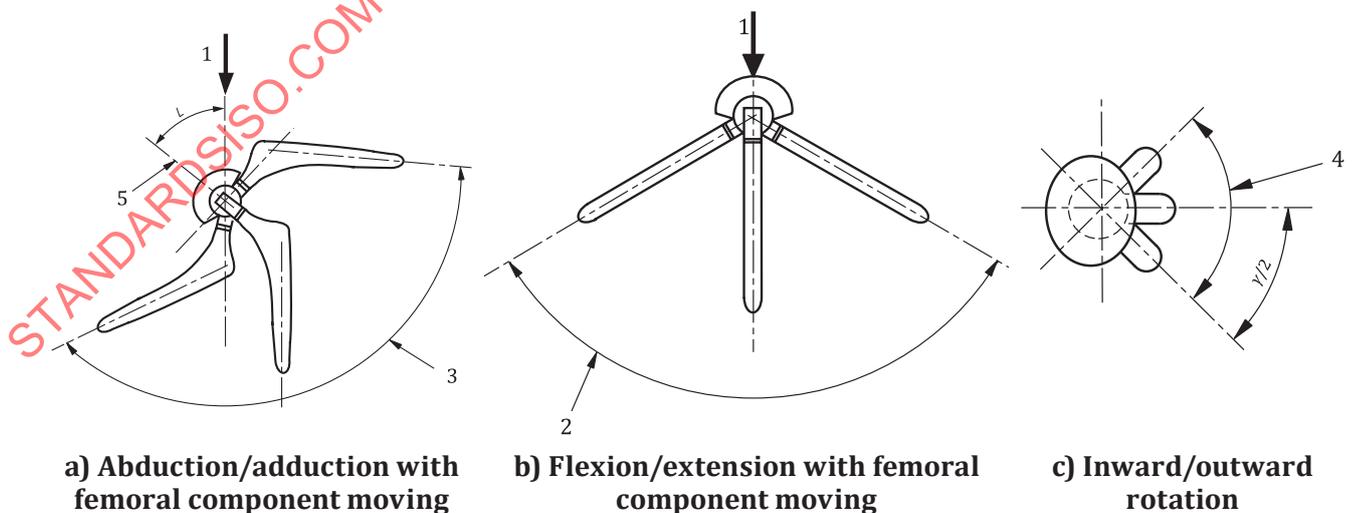
3.2

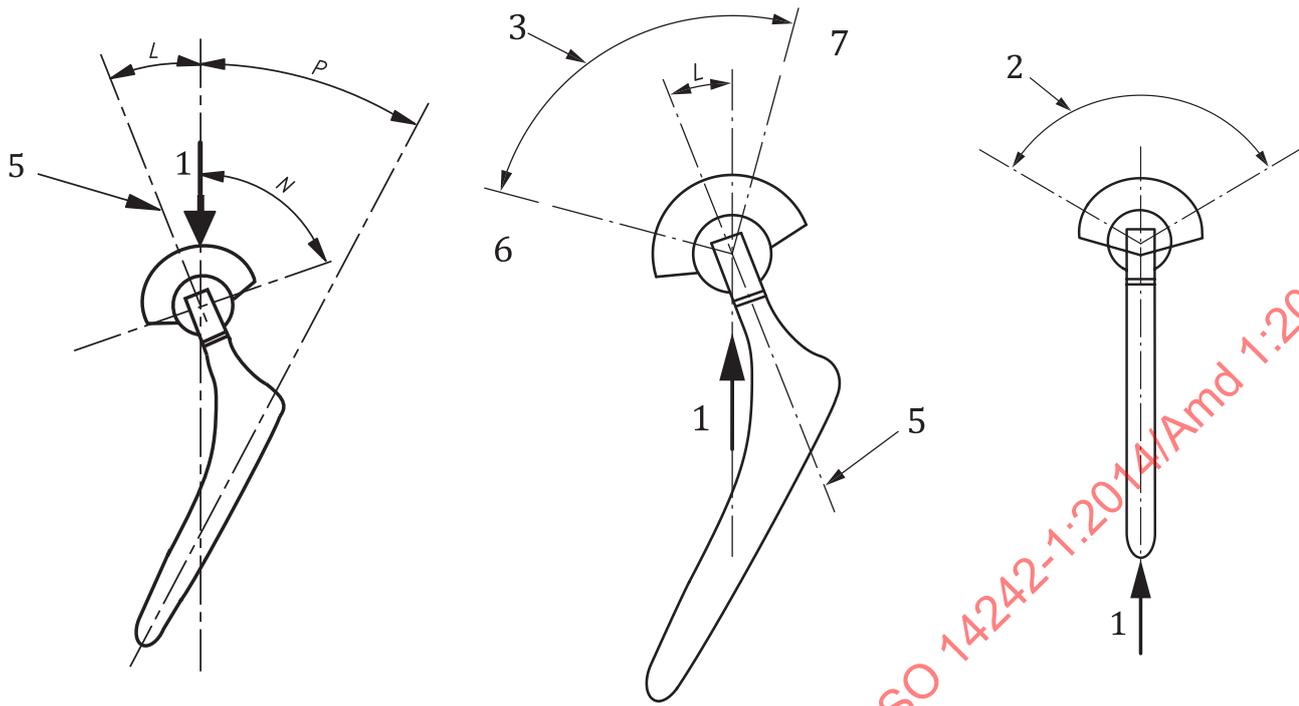
Add “or Figure 1 f)” at the end of the definition.

6.5

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

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: