INTERNATIONAL STANDARD

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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 1: Classification of prosthetic components

Prothèses et orthèses — Classification et description des composants de prothèses —

Partie 1: Classification des composants de prothèses

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Foreword

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword - Supplementary Information.

The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics.*

This second edition cancels and replaces the first edition (ISO 13405-1:1996), which has been technically revised with the following changes:

a) liner added to the list of interface components;

b) functional components divided into lower and upper limb and listed.

ISO 13405 consists of the following parts, under the general title *Prosthetics and orthotics — Classification and description of prosthetic components*:

— *Part 1: Classification of prosthetic components*

— *Part 2: Description of lower limb prosthetic components*

— *Part 3: Description of upper limb prosthetic components*

Introduction

This part of ISO 13405 was the first internationally accepted standard method of classifying the components of prostheses. It is designed to permit the users to classify systematically each component which is incorporated in a finished prosthesis. This part of 13405 is envisaged as being suitable for use by both manufacturers producing literature describing their products and practitioners who are reporting on the components used in the treatment of persons requiring prosthesis.

Prosthetics and orthotics — Classification and description of prosthetic components —

Part 1: Classification of prosthetic components

1 Scope

This part of ISO 13405 specifies a means of classifying the components of limb prostheses and their construction.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
axial stabilization
attribute of interface components which relates to the transmission of longitudinal (proximally directed) forces from the prosthesis to the body

2.2
transverse stabilization
attribute of interface components which relates to the transmission of transversely directed forces between the prosthesis and the body

Note 1 to entry: Three forms of stabilization are required: anteroposterior, mediolateral, and rotational.

2.3
suspension
attribute of interface components concerned with the retention of the prosthesis on the body, i.e. the transmission of longitudinal (distally directed) forces from the prosthesis to the body

2.4
adjustable component
prosthetic component whose features can be changed before use by the manufacturer, prosthetist, or user

2.5
adaptable component
prosthetic component whose features can be changed by the user to make it suitable for different situations

2.6
auto-adaptive component
prosthetic component whose features change automatically in response to varying situations

2.7
liner
removable lining worn between the stump and the inner surface of the socket

Note 1 to entry: It is used to modify the distribution of the forces associated with axial and transverse stabilization and it can additionally form a part of the prosthetic suspensory system.

3 Classification

3.1 General

Prostheses are externally applied devices used to replace wholly, or in part, an absent or deficient limb segment. They are integrated constructions comprising the following classes of components:

a) interface components;

b) functional components;

c) alignment components;

d) structural components;

e) finishing (cosmetic) components.

NOTE Some components can belong to more than one class, e.g. alignment components can also serve as structural components.

3.2 Interface components

Interface components of a prosthesis are in direct contact with the wearer. They are the means of achieving axial stabilization, transverse stabilization, and suspension (see Clause 3). Interface components include:

a) the socket;

b) suspensory components, which maintain the prosthesis relative to the body;

c) the liner.

NOTE Interface components can contain elements which contribute to the activation and/or control of functional components.

3.3 Functional components

3.3.1 Functional components of a prosthesis substitute for some of the dynamic and sensory attributes of the normal limb.

3.3.2 Lower limb prosthetic functional components include:

a) ankle-foot units;

b) knee units;

c) hip units;

d) torque reducers;

e) load attenuators (shock absorbers);

f) turntables;

g) external (side) joints.

3.3.3 Upper limb prosthetic functional components include:

a) terminal devices and digits;

b) wrist units;

