INTERNATIONAL STANDARD

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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 2: Description of lower limb prosthetic components

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

Partie 2: Description des composants de prothèses des membres inférieurs

Reference number
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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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, *Prostheses and orthotics.*

This second edition cancels and replaces the first edition (ISO 13405-2:1996), which has been technically revised.

The major technical changes are the following:

a) classification tree for lower limb prosthetic components added in Clause 5;

b) levels of amputation extended to include all partial foot levels;

c) methods of socket suspension extended;

d) classification tree for functional components added in Clause 6;

e) range of types of ankle foot units, knee units, hip units, and external (side) joints extended;

f) load attenuators and turntables added to Clause 6.

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*

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Introduction

This part of ISO 13405 was the first internationally accepted standard method to describe the components of lower limb prostheses. It is designed to permit users to describe systematically each component which is incorporated in a finished prosthesis in a manner which clearly explains its principal characteristics. It 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.

Prosthetic technology has made considerable advances since the publication of this part of ISO 13405. This first revision is designed to include the new types of components which have come into use during this period.

Manufacturers' trade names and details of the materials and manufacturing methods employed have been avoided.

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Prosthetics and orthotics — Classification and description of prosthetic components —

Part 2: Description of lower limb prosthetic components

1 Scope

This part of ISO 13405 specifies a method for describing lower limb prosthetic components.

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 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 8549-2, *Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses*

ISO 8549-4:2014, *Prosthetics and orthotics — Vocabulary — Part 4: Terms relating to limb amputation*

ISO 13405-1:2014, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-2, and the following apply.

3.1
jointed ankle-foot unit
ankle-foot unit where motion(s) is (are) obtained by rotation at a joint(s) within the unit

3.2
unjointed ankle-foot unit
ankle-foot unit where motion(s) is (are) obtained by deformation of a part(s) of the unit

4 Classification and description

The components of lower limb prostheses include five classes identified in ISO 13405-1:2014, 3.1 shown in Figures 1 and 2 and described in Clauses 5 to 9.

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