INTERNATIONAL STANDARD

ISO 29782

Second edition
2022-12

Prostheses and orthoses — Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation

Prothèses et orthèses — Facteurs à prendre en considération lors de la spécification d'une prothèse pour une personne ayant subi une amputation d'un membre inférieur

Reference number
ISO 29782:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC *168*, *Prosthetics and orthotics*.

This second edition cancels and replaces the first edition (ISO 29782:2008), which has been technically revised.

The main changes are as follows:

— Clauses 4, 5 and 8 have been updated according to the latest standard terminology;

— revision of Clause 7.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The selection of components used in a prosthesis for a person takes into account their amputation level, stump and general physical characteristics, general clinical condition, functional capabilities, motivation and needs, anticipated activities and social and economic circumstances. The environmental conditions to which the prosthesis will be exposed and the locally available supply and maintenance arrangements are also important factors. At one extreme, the person is unable to use a functional prosthesis but desires a cosmetic replacement. At the other extreme, they desire and are able to achieve high levels of activity and require an appropriate prosthesis. Some people wish to engage in specific activities that require particular components. The prosthetic team with their educational and clinical experience makes a choice of components based on this information.

Multiple factors influence the selection of components used in a prosthesis. The aim of prosthetic treatment is to manage these impairments, reduce the limitations and thus improve participation in all aspects of daily living (ADL).

The overall result is dependent on personal factors as well as on environmental factors (e.g. relatives) which are overall referred to as context factors.

The source of funding for a prosthesis, the availability of prosthetic supply and maintenance arrangements, and the environmental conditions to which the prosthesis will be exposed also impact decision-making.

Prostheses and orthoses — Factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation

1 Scope

This document lists factors to be considered when specifying a prosthesis for a person who has had a lower limb amputation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8548-2, *Prosthetics and orthotics — Limb deficiencies — Part 2: Method of describing lower limb amputation stumps*

ISO 8548-5, *Prosthetics and orthotics — Limb deficiencies — Part 5: Description of the clinical condition of the person who has had an amputation*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8548-2 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
balance
ability to maintain the body's mass over its base of support

3.2
coordination
ability to execute smooth, accurate, controlled movements

3.3
endurance
ability to sustain repeated muscular effort

4 Stump characteristics

4.1 General

ISO 8548-2 shall be used as method of describing a lower limb amputation stump.

The characteristics listed in 4.2 to 4.7 require particular consideration.

4.2 Length and shape

a) Too long or too short;

NOTE 1 Where the stump length might preclude the use of particular prosthetic components.

b) Cylindrical/conical/bulbous;

NOTE 2 Where the stump shape might require special socket fitting procedures.

c) Bony prominences (not prominent/prominent);

d) Volume fluctuation.

4.3 Soft tissues

a) Inadequate/excessive;

b) Flabby/indurated;

c) Excessive movement at the bone/soft tissue interface.

4.4 Skin

a) Breaks in continuity;

b) Adherent to bone;

c) Scarred;

d) Grafts;

e) Impaired sensation;

f) Dermatological conditions.

4.5 Circulation

a) Impaired arterial/venous/lymphatic.

4.6 Pain

a) Stump pain;

1) Spontaneous;

2) Upon loading.

b) Neuromata;

c) Phantom pain.

4.7 Proximal joint(s)

a) Range of motion abnormalities;

b) Instability (of bony or ligamentous origin);

c) Muscle weakness or hyperactivity;

d) Pain.

5 General physical characteristics

ISO 8548-5 shall be used as method of describing the clinical condition of the person who has had an amputation

The following characteristics require particular consideration.

a) Body mass;

b) Height;

c) Gender;

d) Age;

e) Upper limb impairments and limitations;

f) Trunk mobility limitations;

g) Contralateral lower limb;

   1) circulatory impairments;

   2) neurological impairments.

      i) muscle weakness or impaired motor control;

      ii) abnormal proprioception;

      iii) abnormal sensation.

   3) musculoskeletal impairments;

      i) joint range of motion abnormalities;

      ii) bony or ligamentous instability.

         a) skin impairments;

         b) pain;

         c) amputation level.

6 General clinical conditions

Any significant disorder of any of the following (including the effects of medication) requires special consideration.

a) The cardiovascular system;

b) The respiratory system;

c) The neurological system;

d) The special senses;

e) The nutritional status;

f) The cognitive status;

g) The mental and psychological status;

h) Other systems.