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Prosthetics and orthotics — External orthoses and orthotic components —

Part 1: Uses, functions, classification and description of lower limb orthoses

Prothèses et orthèses — Orthèses externes et composants d'orthèses —

Partie 1: Utilisations, fonctions, classification et description des orthèses pour les membres inférieurs

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Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Uses **3**
5 Functions **4**
6 Classification **5**
7 Description **5**
7.1 Method of fabrication 5
7.2 Type 5
8 Components of orthoses **5**
8.1 General 5
8.2 Structural components 6
8.3 Interface components 6
8.4 Orthotic joints 6
8.4.1 General description 6
8.4.2 Motions 7
8.4.3 Mode of motion 7
8.4.4 Axis of rotation 7
8.4.5 Control and activation 7
8.5 Functional electrical stimulators 8
8.6 Finishing components 9
Bibliography **10**

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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).

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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 first edition of ISO 13404-1 cancels and replaces ISO 13404:2007, which has been technically revised.

The main changes are as follows:

— introduction of a new Clause 4 on uses;

— update of Clause 5;

— 8.4.5 has been renamed “Control and activation” and its content has been updated to reflect the development of modern orthotic components;

— addition of functional electrical stimulators to Clause 8.

— a focus on lower limb orthoses.

A list of all parts in the ISO 13404 series can be found on the ISO website.

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.

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Introduction

This document is intended for practitioners prescribing and/or providing external lower limb orthoses, for manufacturers describing their products, and for those researching and reporting on orthotic use.

External lower limb orthoses are used to treat a wide range of impairments of body functions and structures that impact the lower limb and to assist in overcoming limitations during everyday activities.

Definitions of prefabricated, adaptable, user-matched and custom-made orthoses were changed due to international regulations. Users can refer to the applicable national regulatory documents for details in definitions and local differences in terminology and responsibilities.

Uses, functions, classification, method of fabrication, types, and components of the orthotic device should be described within general healthcare procedures.

For further specifics on foot orthoses, refer to ISO 21064 and for further specifics on soft orthoses for the lower limb, refer to ISO 21063.

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Prosthetics and orthotics — External orthoses and orthotic components —

Part 1:
Uses, functions, classification and description of lower limb orthoses

1 Scope

This document specifies the uses and functions of external lower limb orthoses. It classifies and describes the devices and their components. It permits the systematic classification and description of both the finished orthosis and the components from which it is assembled in a manner that clearly explains their principal characteristics.

This document does not specify the materials or manufacturing methods used for the fabrication of lower limb orthoses.

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

ISO 8549-3, *Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to orthoses*

ISO 8551, *Prosthetics and orthotics — Functional deficiencies — Description of the person to be treated with an orthosis, clinical objectives of treatment, and functional requirements of the orthosis*

ISO 21063, *Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description*

ISO 21064, *Prosthetics and orthotics — Foot orthotics — Uses, functions, classification and description*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3, ISO 8551, ISO 21063, ISO 21064 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/

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