



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of ISO 21063:2017.

The UK participation in its preparation was entrusted to Technical Committee CH/168, Prosthetics and orthotics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2017
Published by BSI Standards Limited 2017

ISBN 978 0 580 93049 2

ICS 11.040.40

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2017.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

INTERNATIONAL
STANDARD

ISO
21063

First edition
2017-07-15

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

*Prothèses et orthèses — Orthèses souples — Utilisations, fonctions,
classification et description*



Reference number
ISO 21063:2017(E)



COPYRIGHT PROTECTED DOCUMENT

© ISO 2017, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Uses	1
5 Functions	2
6 Classification of devices	2
7 Description	2
7.1 Type of fabrication.....	2
7.2 Types of orthotic component.....	3
7.3 Description of orthotic components.....	3
7.3.1 Interface components.....	3
7.3.2 Orthotic joints.....	3

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 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

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

Introduction

No internationally accepted method is available to describe externally applied devices constructed from flexible materials which apply pressure to the body segments which they encompass. In some countries these devices are referred to as “bandages”.

This situation has created problems for practitioners prescribing these devices, for manufacturers when describing their products and for those reporting on the devices used in the treatment of their patients and their effects.

This document proposes the adoption of the term “soft orthoses” for this group of devices. It specifies their uses and functions, and classifies and describes the devices and their components.

Manufacturers’ trade names and details of materials and manufacturing processes have been avoided.

Prosthetics and orthotics — Soft orthoses — Uses, functions, classification and description

1 Scope

This document specifies the uses and functions of soft orthoses. It also classifies and describes the devices and their components. It does not describe the materials or manufacturing methods used for their fabrication.

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 external 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 13404, *Prosthetics and orthotics — Categorization and description of external orthoses and orthotic components*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1, ISO 8549-3, ISO 8551 and ISO 13404 and the following apply.

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

- ISO Online browsing platform: available at <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

soft orthoses

orthoses whose soft interface materials apply pressure circumferentially and, if required, locally (using pads and/or inserts) to the surface of the body segments which they encompass

Note 1 to entry: They can incorporate orthotic joints and/or other components intended to control the motion and/or alignment of joints. Taping, stockings and garments used to treat burns are excluded.

4 Uses

Soft orthoses may be used to achieve the following clinical objectives:

- a) to stimulate motor-sensory feedback;
- b) to prevent or reduce swelling;
- c) to control the motion(s) of a joint(s);

- d) to control the alignment of a joint(s);
- e) to relieve pain;
- f) to promote healing;
- g) to protect tissues.

5 Functions

Soft orthoses can have the following functions:

- a) to provide continuous circumferential pressure on the underlying tissues;
- b) to control the motion(s) of a joint(s);
- c) to control the alignment of a joint(s);
- d) to apply pressure on tissue locally.

6 Classification of devices

Classify the soft orthosis by reference to the body segment(s) and joint(s) which it encompasses, using the terminology defined in ISO 8549-3 and shown in Table 1.

Table 1 — Terminology defined in ISO 8549-3

Device	Abbreviation
Foot orthosis	FO
Ankle-foot orthosis	AFO
Knee orthosis	KO
Hip orthosis	HpO
Finger orthosis	FiO
Hand orthosis	HdO
Wrist-hand orthosis	WHO
Elbow orthosis	EO
Shoulder orthosis	SO
Sacro-iliac orthosis	SIO
Lumbo-sacral orthosis	LSO
Thoraco-lumbo-sacral orthosis	TLSO

NOTE Some soft orthoses encompass only the digits while others encompass multiple body segments (e.g. full body suits).

7 Description

7.1 Type of fabrication

Soft orthoses can be either

- a) custom fabricated, or
- b) prefabricated.

Prefabricated orthoses may require adjustment for the individual user. State whether the orthosis is custom fabricated or prefabricated.

7.2 Types of orthotic component

Soft orthoses comprise the following types of component:

- a) interface components;
- b) orthotic joints.

7.3 Description of orthotic components

7.3.1 Interface components

Interface components of soft orthoses are those in direct contact with the user. They are manufactured from soft material which can be:

- a) non-elastic;
- b) elastic;
- c) part elastic/part non-elastic.

The direction of action of the elastic part can be:

- circumferential;
- longitudinal;
- both.

State if the interface material is elastic or non-elastic; if elastic, describe the position of the elastic part and its direction of action.

The interface component pressure distribution can be modified by the inclusion of pads, inserts and straps.

State, if appropriate, how the interface component is modified.

7.3.2 Orthotic joints

Orthotic joints are described by reference to the anatomical joints whose motions they are intended to control. They include:

- a) ankle joint;
- b) knee joint;
- c) hip joint;
- d) wrist joint;
- e) elbow joint;
- f) shoulder joint.

State the type of orthotic joint.

British Standards Institution (BSI)

BSI is the national body responsible for preparing British Standards and other standards-related publications, information and services.

BSI is incorporated by Royal Charter. British Standards and other standardization products are published by BSI Standards Limited.

About us

We bring together business, industry, government, consumers, innovators and others to shape their combined experience and expertise into standards-based solutions.

The knowledge embodied in our standards has been carefully assembled in a dependable format and refined through our open consultation process. Organizations of all sizes and across all sectors choose standards to help them achieve their goals.

Information on standards

We can provide you with the knowledge that your organization needs to succeed. Find out more about British Standards by visiting our website at bsigroup.com/standards or contacting our Customer Services team or Knowledge Centre.

Buying standards

You can buy and download PDF versions of BSI publications, including British and adopted European and international standards, through our website at bsigroup.com/shop, where hard copies can also be purchased.

If you need international and foreign standards from other Standards Development Organizations, hard copies can be ordered from our Customer Services team.

Copyright in BSI publications

All the content in BSI publications, including British Standards, is the property of and copyrighted by BSI or some person or entity that owns copyright in the information used (such as the international standardization bodies) and has formally licensed such information to BSI for commercial publication and use.

Save for the provisions below, you may not transfer, share or disseminate any portion of the standard to any other person. You may not adapt, distribute, commercially exploit, or publicly display the standard or any portion thereof in any manner whatsoever without BSI's prior written consent.

Storing and using standards

Standards purchased in soft copy format:

- A British Standard purchased in soft copy format is licensed to a sole named user for personal or internal company use only.
- The standard may be stored on more than 1 device provided that it is accessible by the sole named user only and that only 1 copy is accessed at any one time.
- A single paper copy may be printed for personal or internal company use only.

Standards purchased in hard copy format:

- A British Standard purchased in hard copy format is for personal or internal company use only.
- It may not be further reproduced – in any format – to create an additional copy. This includes scanning of the document.

If you need more than 1 copy of the document, or if you wish to share the document on an internal network, you can save money by choosing a subscription product (see 'Subscriptions').

Reproducing extracts

For permission to reproduce content from BSI publications contact the BSI Copyright & Licensing team.

Subscriptions

Our range of subscription services are designed to make using standards easier for you. For further information on our subscription products go to bsigroup.com/subscriptions.

With **British Standards Online (BSOL)** you'll have instant access to over 55,000 British and adopted European and international standards from your desktop. It's available 24/7 and is refreshed daily so you'll always be up to date.

You can keep in touch with standards developments and receive substantial discounts on the purchase price of standards, both in single copy and subscription format, by becoming a **BSI Subscribing Member**.

PLUS is an updating service exclusive to BSI Subscribing Members. You will automatically receive the latest hard copy of your standards when they're revised or replaced.

To find out more about becoming a BSI Subscribing Member and the benefits of membership, please visit bsigroup.com/shop.

With a **Multi-User Network Licence (MUNL)** you are able to host standards publications on your intranet. Licences can cover as few or as many users as you wish. With updates supplied as soon as they're available, you can be sure your documentation is current. For further information, email subscriptions@bsigroup.com.

Revisions

Our British Standards and other publications are updated by amendment or revision.

We continually improve the quality of our products and services to benefit your business. If you find an inaccuracy or ambiguity within a British Standard or other BSI publication please inform the Knowledge Centre.

Useful Contacts

Customer Services

Tel: +44 345 086 9001

Email (orders): orders@bsigroup.com

Email (enquiries): cservices@bsigroup.com

Subscriptions

Tel: +44 345 086 9001

Email: subscriptions@bsigroup.com

Knowledge Centre

Tel: +44 20 8996 7004

Email: knowledgecentre@bsigroup.com

Copyright & Licensing

Tel: +44 20 8996 7070

Email: copyright@bsigroup.com

BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK