PD ISO/TS 4549:2023



BSI Standards Publication

Orthotics — Method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthoses

National foreword

This Published Document is the UK implementation of ISO/TS 4549:2023.

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 committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 14200 6

ICS 11.040.40

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 July 2023.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TS 4549:2023

TECHNICAL SPECIFICATION

ISO/TS 4549

First edition
2023-07-24

Orthotics — Method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthoses

Reference number
ISO/TS 4549:2023(E)

© ISO 2023



COPYRIGHT PROTECTED DOCUMENT

© ISO 2023, 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

© ISO 2023 – All rights reserved

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Designations and symbols **2**
5 Requirements **3**
5.1 General 3
5.2 Definition of Test parameters 3
5.2.1 General 3
5.2.2 Test without integrated sensors 3
5.2.3 Example of a set of test levels 4
5.3 Test preparation 4
6 Set-up conditions **5**
6.1 General 5
6.2 Coordinate system 5
6.3 Leg dummy 5
6.4 Loading of the leg dummy 5
6.5 Essential properties of orthoses to test 6
6.6 Vertical loading of the Orthoses 6
6.7 Angular profile of the tilting plate 6
7 Test procedure **8**
7.1 Static test for motion resistance of the ankle joint dummy 8
7.2 Cyclic test 9
8 Test report **9**
9 Compliance **10**
9.1 Compliance to motion resistance of the ankle joint dummy 10
9.2 Compliance to cyclic test 10
9.3 Identifier of Compliance 10
9.3.1 General format 11
Annex A (informative) **Measurement system for the acquisition of load data of an orthosis for the lower limbs** **12**
Bibliography **15**

© ISO 2023 – All rights reserved

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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.*

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.

© ISO 2023 – All rights reserved

Introduction

Orthoses of the lower limb are used to treat a wide variety of pathologies. To partly compensate functional deficits, orthoses are used, which provide appropriate functions. The more functionality is provided by orthoses, the more important their functional reliability is.

Structural strength of orthoses, supporting the limb by stabilizing its joints against motion, is as important as stabilisation of movement of joints between limb segments, when mobility is aimed in rehabilitation.

Testing reliability of the controlled ankle moment units of orthoses, which stabilise joint movement, requires to introduce motion into the strength test.

The reliability of microprocessor-controlled ankle moment units of orthosis, supporting the anatomical ankle joint in plantar- and dorsiflexion motion, can be tested by repetitively loading and driving the ankle joint in an appropriate angular and force profile, resulting in the moment profile to test.

Current technologies for acquiring loading and motion-data of orthotic ankle joints in real use are the basis to derive test conditions, which simulate repetitive loading for the microprocessor-controlled ankle moment units in a laboratory environment.

Orthoses of the lower limb are operating aside the leg of the orthosis user. For testing the reliability of microprocessor-controlled ankle moment units in a laboratory test, it is essential to mimic the orthosis user's extremity in such a way, that the orthosis shows its functional capabilities and its reliability. The chapter “leg dummy” in this document describes essential properties of the leg dummy, mimicking the orthosis user's leg.

Covering high loading events during intended use, to be generated by the control elements repetitively in the test, provides a safety factor also for lower loading scenarios of less demanding pathologies.

The Osaka Electro-Communication University in Japan has developed a system of miniaturised sensors with associated data acquisition and data analysis, which can be integrated into an ankle-foot orthosis to measure the multi-axial loading and angular movement of orthotic ankle joints. This system has been used by 50 ankle-foot orthosis users to explore the assessment processes for the reliability of microprocessor-controlled ankle moment elements provided in this document.

© ISO 2023 – All rights reserved

TECHNICAL SPECIFICATION **ISO/TS 4549:2023**

Orthotics — Method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthoses

1 Scope

This document specifies a method for testing the reliability of microprocessor-controlled ankle moment units of ankle-foot orthosis, moving in plantar- and dorsiflexion direction.

This document specifies categories of locomotion profiles to be applied together with appropriate loading profiles, to generate plantar- and dorsiflexion ankle moment loads for the microprocessor-controlled ankle moment units. It also defines which measured outcome of the test allows to claim compliance to this document, and how the compliance is documented in the IFU.

This document solely addresses the resistance of microprocessor-controlled ankle moment units in motion. Geometrical constrains like end stops, where motion is stopped instead of sustaining it, can be tested in repetitive quasi static tests instead.

A method to derive test parameters for the reliability test of microprocessor-controlled ankle moment units is described.

This document is applicable to unilateral ankle-foot orthoses and to bilateral jointed orthoses where either both joints are controlled or where one joint is controlled and the other is not controlled.

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 22675:2016, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

ISO 22523:2006, *External limb prostheses and external orthoses — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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
microprocessor-controlled ankle moment unit
flexing and extending element, bearing loads and generating ankle moment, located medial or lateral to the anatomical upper ankle joint, providing or varying ankle moment when moved in the direction of dorsiflexion and plantarflexion

© ISO 2023 – All rights reserved