ISO/DTS 4549:20222023(E)

ISO TC 168/WG 3

Date: 2022-10-312023-01-29

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

DTS stage

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Contents

Foreword

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

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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 ~~users~~user's extremity in such a way, that the orthosis shows its functional capabilities and ~~it´s~~its reliability. The chapter “leg dummy” in this document describes essential properties of the leg dummy, mimicking the orthosis ~~users~~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 ~~process of~~ assessment ~~of~~processes for the reliability of microprocessor-controlled ankle moment elements~~,~~ provided in this document.

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~~ is described, how~~ 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 ~~either~~ 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:~~2006~~2016, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

~~ISO 10328, *Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods*~~

~~ISO~~ 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 terminological databases for use in standardization at the following addresses:

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

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

Field Code Changed

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.

3.2
passive ankle joint
flexing and extending element, located preferably medial to the ankle joint, mainly bearing loads parallel to its plane of motion

Note to entry: The passive ankle joint stabilises the controlled ankle moment unit on the opposite side of the anatomical ankle joint with regard to forces and rotational moments, especially in frontal- and transversal plane.

3.3
load distribution ring
rigid ring, located above the proximal end of the orthosis, to distribute the test force on the orthosis upper brace and to avoid pressure spots.

3.4
shank element
strait rod or tube, located in the tibia region of an anatomical leg, which transfers the load from the dummy's knee to the dummy's foot. It; it also guides the load distribution ring and aligns the ring in the transverse plane on a level, suitable to load the interface component of the orthoses parallel to the shank element.

3.5
outer shank element
ring, connected to the lower surface of the load distribution ring, which positions the upper brace of the orthosis relative to the shank element

Note 1 to entry: The height of the ring is adapted to the height of the upper brace of the orthosis.

Note 2 to entry: The contour and compliance of the outer shank element may not stabilize the orthotic frame with regards to its deflection in either plane.

3.6
orthotic frame
connecting element(s) which connect the upper brace of the orthosis to the ankle joint element(s).)

Note 1 to entry: The frame can be designed by using side bars or by a brace structure.

3.7
leg dummy
an assembly of modified prosthetic componentry, mimicking the lower leg of the user of an orthosis in the test setup

3.8
ankle moment measured
readout of the ankle moment value, measured with calibrated and validated sensors, which are integrated in the orthotic systems bearing structure for studies and/or for testing or which are part of the microprocessor-controlled ankle moment units

4 ~~Designation~~Designations and symbols

The designations and symbols of all relevant test forces and moments are listed in Table 1.

Table 1 — Designations and symbols of test forces and moments

Designation	Symbol
Test force	~~F~~F_u
1st and 2nd maximum value of pulsating test force	F_{1cmax}, F_{2cmax}
Minimum moment measured Maximum moment measured	M_{min} M_{max}

5 Requirements

5.1 General

The selection of test levels and test force related to the intended use~~,~~ are defined by the manufacturer/submitter with justification and documented in the test report prior testing (see Clause 8).

In order to claim compliance with this document, all relevant settings in the specific adjustments shall be tested and the strength requirements specified in ISO 22523:2006, 4.4 shall be met.

The selection criteria for the samples to be tested shall be in accordance with ISO 22675.

In order to test the reliability of microprocessor-controlled ankle moment units, the ankle joint of the leg dummy shall not limit the motion of the orthotic joint(s) under load. Suitability of an ankle joint in the leg dummy shall be demonstrated in the static test for motion-resistance of the ankle joint dummy, defined in 7.1 before conducting the cyclic test.

5.2 Definition of Test parameters

5.2.1 General

Depending ~~to~~on the intended use, the manufacturer/submitter provides sufficient information to derive the appropriate test parameters by defining angular range, loading parameters and cycle number to generate the ankle moment loading of the microprocessor-controlled ankle moment unit in the laboratory test for the test lab. This information can be gained with orthoses which are equipped with calibrated and validated sensors, worn by the intended user group, performing the intended use in a representative size of the user group. The orthoses used to acquire the data in use, fitted to the leg dummy (see below) also provides the data which is needed to adapt the angular range and the test load profile to simulate the ankle moment loadings for further test samples. The chosen test force reference value (F), F_{1cmax}, shall be documented in the test report and indicated on the identifier.

If parameters are derived in studies~~,~~ using criteria of lower levels where higher levels are intended for use, the levels of the intended use apply.

If parameters derived in studies are between the defined test levels of this document, the reliability of the motion resistance has to be tested on the next higher test level.

Test forces and ~~Test~~test loads already ~~are including~~include a safety factor for walking on level ground. A higher safety margin shall be tested by testing on a single higher level or on a variety of higher test levels.