TECHNICAL SPECIFICATION

ISO/TS 4549

First edition
2023-07

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

Reference number
ISO/TS 4549:2023(E)

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

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.

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.

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

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 1 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 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 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_u
1st and 2nd maximum value of pulsating test force	F_{1cmax}, F_{2cmax}
Minimum moment measured	M_{min}
Maximum moment measured	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 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 loads already 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.

5.2.2 Test without integrated sensors

For testing test samples from normal production, where integrated sensors influence the structure of the orthosis, equivalent sensors shall be installed in the test setup, which provide an equivalent to the ankle moment measured, proportional to the ankle moment. These sensors are validated with the orthoses used to acquire the data in use. The transfer function of characteristics and magnitudes is documented in the test report prior test. The test then can be conducted, using samples from production without modification.

NOTE Suitable equivalent sensors are for example, force plates in the tilting plate, measuring the trajectory of the centre of pressure or force sensors measuring the force applied by the upper brace of the orthosis to the outer shank element in transversal plane.

5.2.3 Example of a set of test levels

For testing the reliability of the motion resistance of the microprocessor-controlled ankle moment units for slow walking on level ground only, the following test conditions were derived from the results gained by the system shown in Annex A:

a) Force of body mass: F_U 500 [N];

b) Level of vertical force on load distribution ring F_B: L_2 (see Table 2);

c) Angular range: A_1 (see Table 3);

d) Cycle number related to expected service life: C_5 (see Table 4);

e) Level of adjusted Dorsiflexion resistance: D_4 (see Table 5);

f) Level of adjusted plantarflexion resistance: P_2 (see Table 6).

5.3 Test preparation

The orthosis is applied to the leg dummy by using the interface components (upper brace, footplate) of the orthoses and/or footwear, which should be used when using the orthosis.

Table 2 — Vertical load applied to the load distribution ring related to the maximum vertical load F_{1cmax}

Level	L_0	L_1	L_2	L_3	L_4
%	0	10	20	50	100

Table 3 — Levels of Angular range

Level	A_1	A_2	A_3	A_4
Min. Angle, static and cyclic [deg.]	-5	-10	-15	-20
Max. Angle, static and cyclic [deg.]	10	20	30	40
Angle F_{1cmax} [deg.]	-3,75	-7,5	-11,25	-15
Angle F_{2cmax} [deg.]	5	10	15	20

Table 4 — Levels of cycle numbers

Level	C_1	C_2	C_3	C_4	C_5	C_6	C_7	C_8	C_9	C_{10}
1	2 000	5 000	$1x10^4$	$2x10^4$	$5x10^4$	$1x10^5$	$2x10^5$	$5x10^5$	$1x10^6$	$2x10^6$

Table 5 — Levels dorsiflexion resistance

Level	D_1	D_2	D_3	D_4	D_5	D_6	D_7
Nm	10	20	30	40	60	80	100

Table 6 — Levels plantarflexion resistance

Level	P_1	P_2	P_3	P_4	P_5	P_6	P_7
Nm	5	10	15	20	30	40	50

6 Set-up conditions

6.1 General

Plantar and dorsiflexion movement of an ankle regularly occurs in the rollover process during each step. The cyclic test of ISO 22675 defines both, the rollover motion and the loading throughout stance-phase. Prosthetic feet provide stabilization of the body during gait and in addition store and restore energy in that phase. Therefore, an adapted ISO 22675 Test procedure is defined in this document to test the reliability of microprocessor-controlled ankle moment units of ankle foot orthosis. Necessary adaptations to test controlled ankle moment units are described below.

6.2 Coordinate system

The coordinate system and test configurations specified in ISO 22675:2016, Clause 6, are used, except that the top load application point, P_T, is placed parallel to the u-axis above midfoot at a fixed height of 700 mm, see ISO 22675:2016, Figure 2.

6.3 Leg dummy

The leg dummy is an assembly of a modified prosthetic foot, an ankle joint, a shank element, an outer shank element and a load distribution ring. These Elements are mounted in the test frame to load and orientate the orthosis under test.

The (modified) prosthetic foot (dummy foot) applies loading and provides geometrical alignment to the sole element of the orthosis.

a) To distribute the loading from the ankle joint dummy to the sole of that foot, its connection to the heel, to midfoot and to the ball of the foot shall be sufficiently stiff to keep the ankle joint dummy aside or within the orthotic joint(s) under load. The ankle moment unit shall not move more than 20 mm away from its unloaded position in the plane of motion, in relation to the ankle moment unit.

b) The foot-dummy shall be equipped with very soft or jointed toes, which do not stiffen the toe region of the foot plate of the orthosis. If the ankle moment unit is coupled to the toe elements, supporting the ankle moment unit, the independent movement of the toes is to be demonstrated with the procedure defined in 7.1 but rolling over on the ball of the foot.

c) The mechanical height and design of the foot dummy shall allow for positioning the modified ankle joint dummy aside or within the orthotic ankle moment unit(s).

The ankle joint simulates the ankle joint of the orthosis user. It does not limit the motion of the joint(s) of the orthoses under load in the intended range of motion. The appropriate low resistance of the dummy ankle joint is demonstrated by the static test defined in 7.1.

A shank element transfers the load from the dummy's knee to the dummy's foot and guides the load distribution ring. The guiding mechanism is a low friction unit, which does not apply forces along the shank element above 20 N for unloaded guiding.

Loading the load distribution ring eccentrically generates tilting moments, which tend to increase friction between the shank element and the load distribution ring. It shall be validated that the load applied by the load distribution ring loads the upper brace of the orthosis as intended.

The assembled leg dummy including the orthosis is illustrated in Figure 1.

6.4 Loading of the leg dummy

The cyclic loading specified in ISO 22675:2016, 7.2, loads the leg dummy. Its maximum value F_{1cmax} is adapted according to the intended use and documented prior test. The loading profile is specified between heel strike angle and toe-off angle.