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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 31181-2014

**Prosthetics Testing of ankle-foot devices and foot units --
Requirements and test methods**

假肢 踝足装置和足部组件 要求和试验方法

(English Translation)

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References

Referring to FIG. 1 has parameters of the coordinate system

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8 Static load test program test preparation [see 16.1.1a)]
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14 Label layout style layout
Different component shown in Figure A.1 loading force
Effect
Can illustration
[See E.3.4.2c) 2)]
Specify prosthetic foot length L of the bottom offsets fB1, L (heel) and fB2, L (forefoot)
values \u200b\u200brelated to (see 13.2.2)
Coordinates
And 16.4)
10 Table 3 dynamic load test threshold curve

Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules.

This standard uses the translation method identical with ISO 22675:2006 "prosthetic ankle-foot devices and foot assembly requirements and test methods." Correspondence between the consistency of the standards of international documents and normative references of the following documents.

--- GB/T 14191.1-2009 Prosthetics and orthotics academic language - Part 1. external limb prostheses and external orthoses group the term (ISO 8549-1. 1989, IDT).

Please note that some of the content of this document may involve patents. Release mechanism of the present document does not assume responsibility for the identification of these patents.

The standard proposed by the People's Republic of China Ministry of Civil Affairs.

This standard by the national rehabilitation and special equipment Standardization Technical Committee on Persons with Disabilities (SAC/TC148) centralized.

This standard was drafted. national rehabilitation aids research center.

Introduction

This standard gives the ISO 10328:2006 alternative ankle-foot device specified in 17.2 and foot assembly of structural surveys, ISO 10328:2006 test method specified in 17.2 less than the following.

a) before the heel and forefoot test force action line and ISO 10328:2006 16.2 (static test) and 16.3 (dynamic test) prescribed Master structure test test force loading conditions I and II line of action is inconsistent;

During b) palm loaded before loading the dynamic test the heel and foot, respectively, the instantaneous maximum load and load size sub-process actual;

c) while the front heel and forefoot loading from different angles, resulting in cyclical phenomenon "false step" that appear in the dynamic test and the like.

Test methods specified in this standard has the following characteristics.

a) dynamic test, can simulate heel to toe off the ground to support the entire travel period and the strength, durability and service life performance is Seeking to verify the actual load conditions, which for various types of ankle foot only in the actual loading conditions in order to play its special properties Performance evaluation apparatus and foot assembly, this feature is very important;

b) the static test, and the line of action to produce dynamic tests before the maximum heel and forefoot loading moment consistent test force heels and forefoot test force.

About the relationship between the two, important to note that the test equipment specified in this standard test ankle-foot devices and foot assembly is not complicated, ISO 10328 is similar to the corresponding sub-structure test equipment inspection requirements. Outside, these two basic components of similar test equipment, After the modification may be used.

Finally, to be noted that the basic concept of the test procedure specified in this standard can be used in the future for about ankle-foot devices and foot assembly Specific performance evaluation.

In order to ensure the continuity of ankle-foot devices and foot assembly inspection, a transition period will be set aside. During the transition period these two test methods are Efficiency, control by ISO 10328:2006 test method specified in 17.2, check this standard test methods. According to the transition period ISO 10328:2006 and the present time standard assessment system adjustments. Through systematic assessment of these two criteria, this show is expected to draw Some other research results of the test method standards for suitability.

Note: The test loading conditions and test the load levels and test equipment design guidelines, see separate document "Technical Report" (see References).

Prosthetic ankle-foot devices and foot assembly Requirements and test methods

1 Scope

Important. This standard applies to ISO 22523:2006 (see Note 1) 4.4 conformity assessment specified strength requirements ankle-foot devices and foot assembly set. The market has passed the relevant tests of ISO 10328 test, and demonstrate compliance with EN12523. 4.4 specified strength requirements of fake 1999 Limb ankle-foot devices and foot components do not need to re-examination in accordance with this standard.

Warning. This standard does not apply to guidelines issued as the choice of the lower limb prosthesis prescription ankle-foot device or foot assembly. Regardless of any warning Behavior may pose a security risk to the amputee.

This standard specifies the lower limb prosthetic ankle-foot devices and foot assembly dynamic testing, static verification and static ultimate strength test test program.

Dynamic and static test procedures specified in this standard, the test applied for each submission of ankle-foot device or foot assembly unified sample applied Load conditions characteristic curve is represented by a standardized format and load movement curve.

Ankle-foot devices and foot assembly inspection of each sample in the load can be free to play their own performance.

Note 1: ISO 22523 (previously EN12523) describes the "European Medical Devices Guideline 93/42/EEC" groups listed in Appendix I applies to the prosthetics and orthotics this requirement.

Note 2: The static test procedure specified in this standard produced the heel and forefoot test force action line, close to the main structure test sample is determined as specified in ISO 10328 Sagittal line of action of load test loading conditions I and II, and does not change the ISO 10328 provisions ankle-foot devices and foot and heel components of structural tests Foot forefoot loading platform angle.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

ISO 8549-1 prosthetics and orthotics - Vocabulary - Part 1. External prostheses and orthopedic devices external general term (Prostheticsandorthotics-Vocabulary-Part 1. Generaltermsforexternallimbprosthesesand externalorthoses) ISO 10328:2006 Prosthetics - Structural testing of lower limb prostheses - Requirements and test methods (Prosthetics-Structuraltestingof lowerlimbprostheses-Requirementsandtestmethods) ISO 22523:2006 Prosthetics and orthotics - Requirements and test methods (Externallimbprosthesesandexternalortho-ses-Requirementsandtestmethods)