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International

ISO 10328

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai

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This third edition cancels and replaces the second edition (ISO 10328:2016), which has been technically revised.

The main changes are as follows:

— Offsets for P3 and P4 are combined into the test offset for P5 in Table 6 and have been removed from document. Geometry of the test setup has been revised by moving the outward offset at bottom reference plane over the forward axis, resulting in the offset changing from –19 mm to +19 mm to align with results from modern gait analysis. Outwards offsets knee and ankle have been adjusted accordingly.

— Test load levels P6 through P8 previously in former Annex D have been included in Tables 5, 8 and 11 and the Annex removed from the document. Former Annex E and F have been renamed to Annex D and E and references updated. Former Annex G has been removed. New Annex F, Annex G and Annex H have been added.

— Test Ranges (R) for the strength test have been introduced, related to the intended use of the device. The ranges differ by different loading factors, while tests load levels remain unchanged apart from rounding and accommodation to changed offsets (see below).

— Test forces in Table 11 have been adjusted for P3 and P4.

— A method to analyse shock absorption capacity has been added, which eliminates the difficulty to decide whether a device passes or fails above the ultimate static lower load level.

— Separate tests on knee locks are now optional tests and the test methods on separate tests on knee locks have been removed from the document.

— Test geometry defined in this document is limited to 150 mm above knee-joint centre.

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— Table 1, Table 4, Table 5, Table 6, Table 7, Table 8, Table 9, Table 10 and Table 11 have been updated and forces adjusted for new unified offsets.

— Table B.1, Table B.2, Table B.3 and Table B.4 have been updated.

— The rate of loading of between 100 N/s and 10 kN/s is now normative.

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.

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As a result of concern in the international community about the need to provide prostheses that are safe in use, and also because of an awareness that test standards would assist the development of better prostheses, a series of meetings was held under the aegis of the International Society for Prosthetics and Orthotics (ISPO). The final one was held in Philadelphia, PA, USA in 1977 at which a preliminary consensus was reached on methods of testing and the required load values. From 1979 onwards this and following work led to the development of the ISO 10328:1996 series and consequent revisions. The test procedures might not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subjected to a series of load actions, each varying individually with time. The test methods specified in this document use static and cyclic strength tests which typically produce compound loadings by the application of a single test force.

The static tests relate to the worst loads generated in any activity. The cyclic tests relate to normal walking activities where loads occur regularly with each step. This document specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of lower-limb prostheses and their components requires controlled field trials in addition to the laboratory tests specified in this document.

The laboratory tests and field trials should be repeated when significant design changes are made to a load-bearing part of a prosthesis.

Ideally, additional laboratory tests should be carried out to deal with function, wear and tear, new material developments, environmental influences and user activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be determined.

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