DRAFT INTERNATIONAL STANDARD

ISO/DIS 14801

ISO/TC **106**/SC **8**

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Dentistry — Implants — Dynamic fatigue test for endosseous dental implants

Medecin bucco dentaire — Implants — Essai de fatigue dynamique pour implants dentaires endosseux

ICS: 11.060.15

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14801 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

This third edition cancels and replaces the second edition (ISO 14801:2007), has been technically revised.

Dentistry — Implants — Dynamic fatigue test for endosseous dental implants

1 Scope

This International Standard specifies a method of fatigue testing of single post endosseous dental implants of the transmucosal type and their premanufactured prosthetic components. It is most useful for comparing endosseous dental implants of different designs or sizes.

While it simulates the functional loading of an endosseous dental implant body and its premanufactured prosthetic components under "worst case" conditions, this International Standard is not applicable for predicting the *in vivo* performance of an endosseous dental implant or prosthesis, particularly if multiple endosseous dental implants are used for a prosthesis.

2 Normative references

The following referenced documents are indispensable for the application 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 1099, *Metallic materials — Fatigue testing — Axial force-controlled method*

ISO 1942, *Dentistry — Vocabulary*

ISO 4965, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — verification and calibration of the force-measuring system*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply / the terms and definitions given in ISO 1942 and the following apply.

3.1
endosseous dental implant system
device that consists of integrated components including the ancillary instruments and specific equipment necessary for the clinical and laboratory preparation and placement of the implant, and for the construction and insertion of the dependent prosthesis

Note 1 to entry: In addition to providing resistance to displacement of a dental prosthesis, an endosseous dental implant may be used as an anchorage for orthodontic appliances.

Note 2 to entry: An endosseous dental implant may consist of one or more parts.

Note 3 to entry: The term dental prosthesis includes crowns and fixed and removable prostheses.

3.2
load-cycle diagram
Diagram summarising the fatigue properties of an endosseous dental implant by showing for each value of the applied peak load the number of cycles endured by each specimen at the time of failure (see Annex A)

3.3
endosseous dental implant assembly

4 General Principles

4.1 Finished device testing

Testing shall be performed on specimens that are representative of the finished device (i.e. components that have undergone the same manufacturing process and sterilization as the device that is to be marketed). If the manufacturer intends the endosseous dental implant to be sterilised by the clinician prior to surgery, sterilization shall be carried out as specified in the manufacturer's instructions for use before testing. However, if there is evidence that the specified sterilization method has no significant effect on the properties of all the materials of the specimens being tested, then sterilization is not necessary prior to testing.

4.2 Multi-part endosseous dental implants

A multi-part endosseous dental implant shall be tested as assembled according to its intended use. An endosseous dental implant component recommended by its manufacturer to be used in conjunction with components of another manufacturer shall be tested as assembled according to the recommending manufacturer's statement. Where a multi-part device is assembled by means of screw joints, then these shall be used according to the manufacturer's recommendations and shall be tightened to the manufacturer's recommended torque using the equipment (screw driver, torque wrench) which is provided together with the implant system or using a device that provides torque within ± 5 % of the recommended value if no original instruments are available. The tightening sequence shall be as recommended by the manufacturer.

4.3 Worst-case testing

If a part of the endosseous dental implant system is available in various dimensions and/or configurations, testing shall be carried out for the worst-case conditions within the recommended use. The choice of worst case shall be justified and documented. Guidance on how to choose the worst case is given in Annex B.

5 Test methods

5.1 Testing machine

The testing machine shall have the following characteristics:

— be capable of applying the prescribed load with an error not exceeding ± 5 % at maximum load (in accordance with ISO 7500-1 and ISO 4965);

— be capable of applying the load at the prescribed frequency;

— include instrumentation to monitor the values of maximum and minimum loads and loading frequency and to detect failure of the specimen;

— be capable of recording the number of loading cycles during the test.

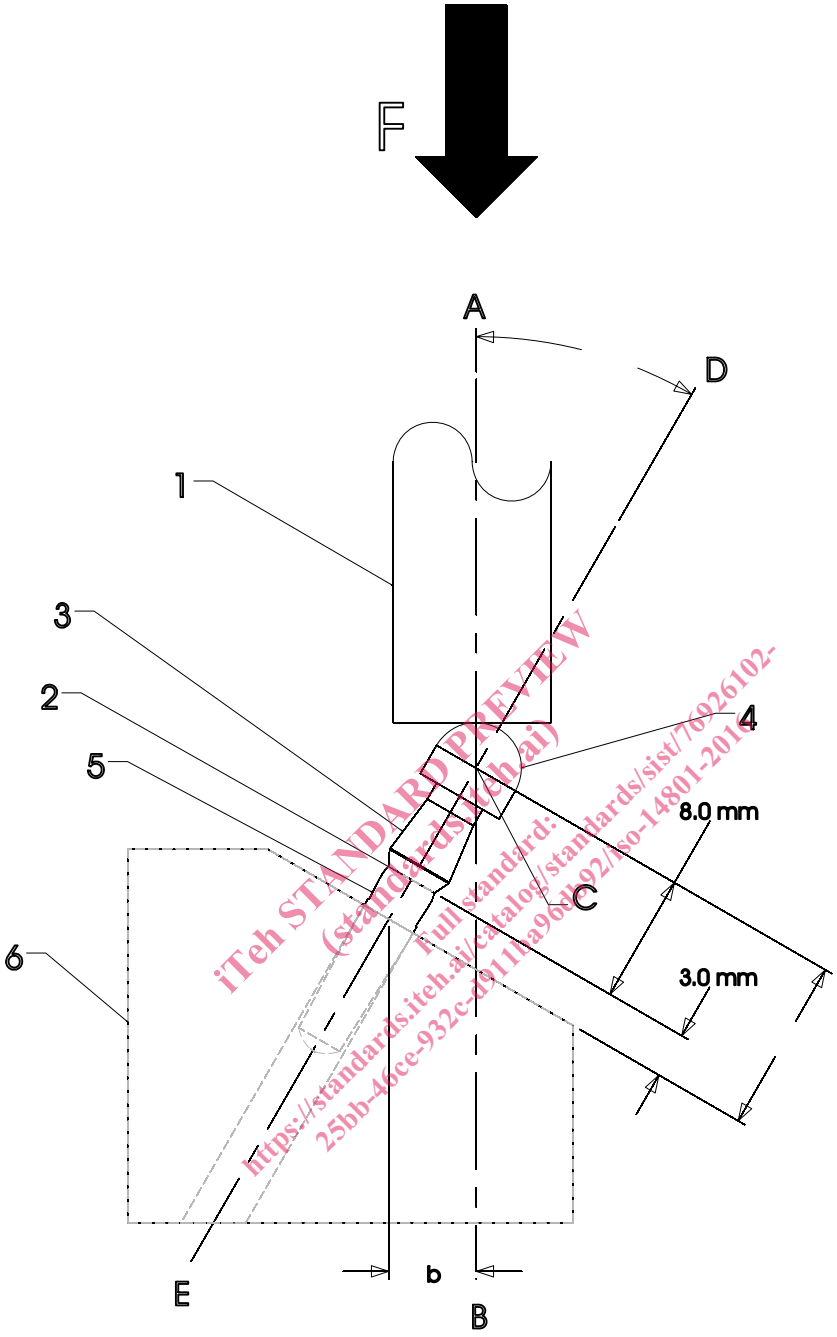
5.2 Loading geometry

5.2.1 The loading force (*F*, see Figures 1 and 2) of the testing machine shall be applied in such a way that:

— no lateral constraint occurs;

— the loading centre (Point C, Figures 1 and 2), being the intersection of the loading axis (Line AB) with the axis of the endosseous dental implant (Line DE), is well-defined, such that the moment arm (*y*) can be measured or calculated.

5.2.2 For dental implant systems that include no pre-angled connecting parts, these requirements will be met by the test set-up shown schematically in Figure 1.



Key

1 loading device [a]
2 nominal bone level [b]
3 abutment
4 hemispherical loading member
5 dental implant body
6 specimen holder
a Shall be allowed free movement transverse to loading direction (see 5.2.6).
b See 5.3.2.

Figure 1 — Schematic of test set-up for systems with no pre-angled connecting parts

5.2.3 An endosseous dental implant from a system that includes no pre-angled connecting parts shall be clamped such that its axis makes a 30° ± 2° angle with the loading direction of the testing machine (see Figure 1).

5.2.4 An endosseous dental implant body of a system that includes pre-angled connecting parts shall be clamped such that the angle with the loading direction of the testing machine is 10° +2°/-1° greater than the angle between the implant axis and the axis of the angled portion of the connecting part, designated as α in Figure 2. This represents a simulated undercorrection of 10 degrees. The loading method shall be the same as that shown in Figure 1. The loading centre shall be located at the intersection of the central longitudinal axis of the free end of the connecting part and the plane normal to the longitudinal axis of the implant and located 11 mm (*l*, Figure 2) from the support level of the implant.

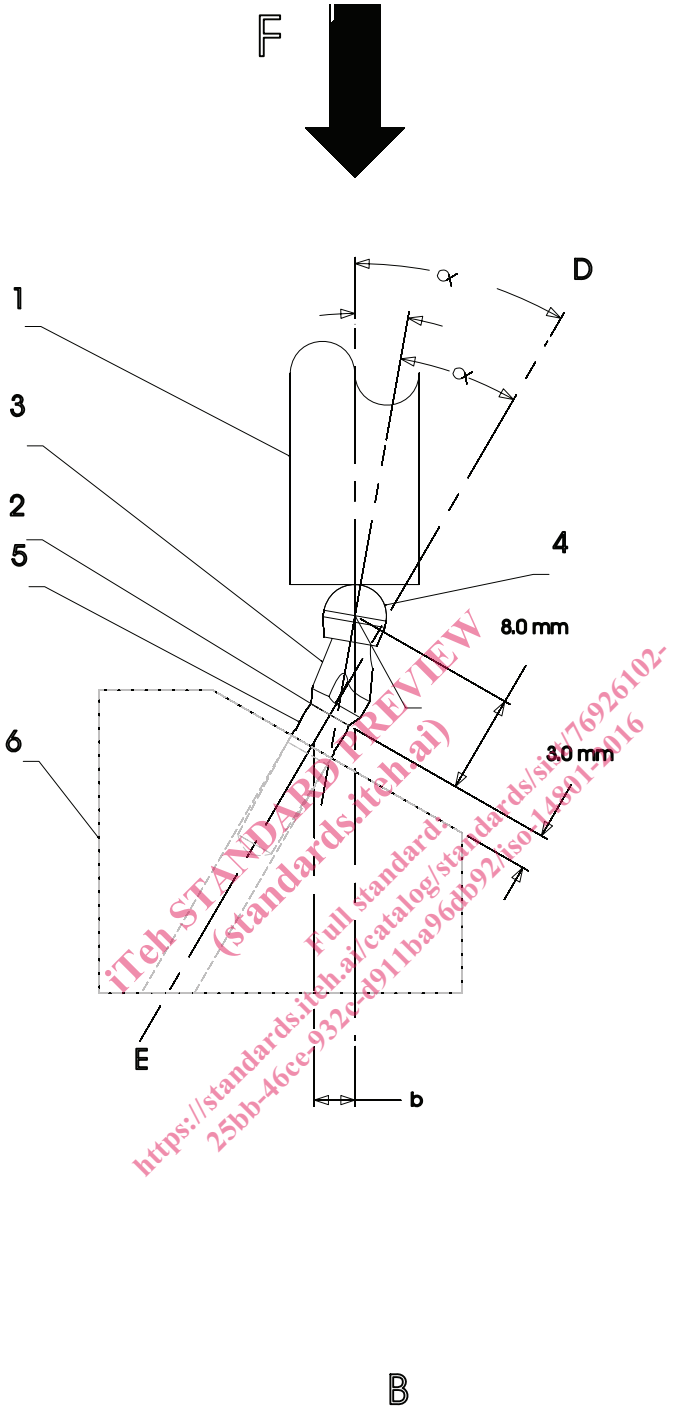


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Figure 2 — Schematic of test set-up for systems with pre-angled connecting parts