BRITISH STANDARD

BS EN ISO 11953:2010

Dentistry — Implants — Clinical performance of hand torque instruments (ISO 11953:2010)

ICS 11.060.15

National foreword

This British Standard is the UK implementation of EN ISO 11953:2010.

The UK participation in its preparation was entrusted to Technical Committee CH/106/8, Dental implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 June 2010

ISBN 978 0 580 65542 5

Amendments/corrigenda issued since publication

Date	Comments

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11953

June 2010

ICS 11.060.15

English Version

Dentistry - Implants - Clinical performance of hand torque instruments (ISO 11953:2010)

Médecine bucco-dentaire - Implants - Performances cliniques des instruments de serrage (ISO 11953:2010)

This European Standard was approved by CEN on 19 May 2010.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 11953:2010: E

Foreword

This document (EN ISO 11953:2010) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2010, and conflicting national standards shall be withdrawn at the latest by December 2010.

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 11953:2010 has been approved by CEN as a EN ISO 11953:2010 without any modification.

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 11953 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 8, *Dental implants*.

Introduction

Screw-retained joints are used widely in dental implant systems and for their integrity depend on the creation and maintenance of an appropriate clamping force. Failure of such joints is a documented clinical problem that can have significant impact on the outcome of treatment. Manually operated, suitably calibrated torque wrenches or devices are widely employed in dental implant treatment to tighten screwed joints and should be capable of providing the desired torque in a consistent manner. There is, however, some evidence that this might not always be the case. This International Standard has, therefore, been developed to facilitate the availability of devices that meet the necessary clinical requirements and help ensure a successful clinical outcome.

INTERNATIONAL STANDARD **ISO 11953:2010(E)**

Dentistry — Implants — Clinical performance of hand torque instruments

1 Scope

This International Standard describes a classification system for hand-held torque wrenches intended for clinical use. It specifies their performance requirements in terms of accuracy and reproducibility and resistance to reprocessing. Test methods are described, and marking and labelling requirements are specified. This International Standard does not include electronically controlled devices.

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 1942, *Dentistry — Vocabulary*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

3 Terms and definitions

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

3.1
hand torque instrument
manually operated mechanical device used for the tightening of dental implants or parts of a dental implant system by displaying or limiting the rotational force of the instrument

3.2
usage
sequence of tightening and retightening operations followed by reprocessing (including disassembly, cleaning, disinfection and/or sterilization) in accordance with the manufacturer's instructions

4 Classification

4.1 General

Screw-retained joints are secured by a clamping force resulting from the amount of tension generated in the screw, each screw having an optimal value. Torque control using a hand torque instrument to which a screwdriver tip is attached, is the most widely used method in implant dentistry. The mechanical devices commonly employed utilize the following methods for torque control.

4.2 Type 1

These devices have a preset “break” mechanism. The break mechanism design incorporates either a hinge, located close to the central long-axis of the screwdriver tip, or a clutch located around the long-axis of the screwdriver tip. The locking mechanism is held rigidly by a compression spring acting on a cam or a clutch, so designed that at the desired torque it is unlocked, permitting a) flexure or b) slip of the handle (“break point”), and thus indicating to the operator that the desired torque has been achieved. Therefore, the instrument provides both tactile and auditory feedback to the operator.

4.3 Type 2

These devices operate as Type 1 but have an adjustable compression spring which allows the value of the “break” torque to be selected.

4.4 Type 3

These devices have a similar configuration to Type 1, but incorporate a torque beam rather than a “break” mechanism. This beam is deformed linearly in relation to the applied torque, which can be measured by the operator using a scale built into the instrument.

4.5 Type 4

These devices place the torque-limiting mechanism in a casing with an output shaft designed to couple with a customized contra-angle dental handpiece. A suitable screwdriver tip is placed in the handpiece and torque applied by rotating the casing of the torque applicator until the drive is decoupled by the torque-limiting mechanism. Both tactile and auditory feedback is provided.

5 Requirements — Accuracy and reproducibility

The accuracy and reproducibility of the torque at “break” or the indicated torque, when tested in accordance with 6.2, shall lie within the manufacturer's stated specification. For compliance, all values, both initial and after reprocessing, shall lie in that stated range. The number of usages before the device needs recalibrating or discarding shall be stated by the manufacturer. See 7 d).

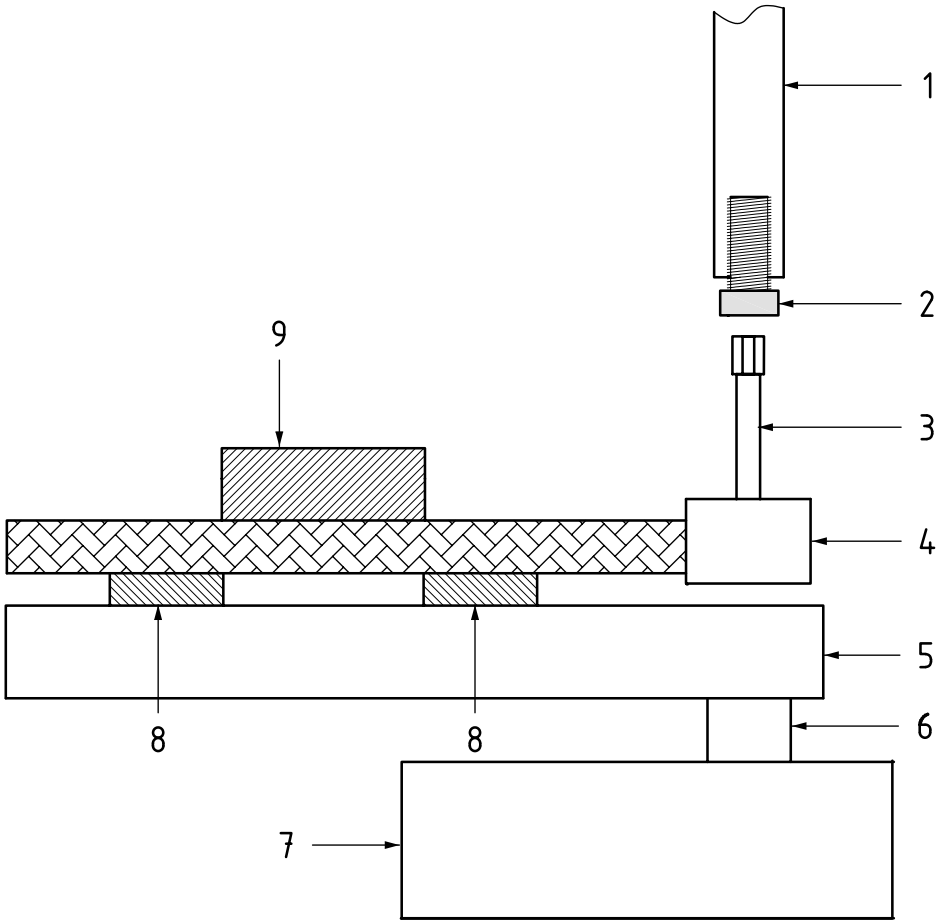
6 Test methods

6.1 Apparatus

6.1.1 Test rig

Examples of test rigs suitable for this purpose are shown in Figures 1 and 2.

For devices incorporating a hinge break mechanism, it is necessary to impart freedom so that a break may occur.

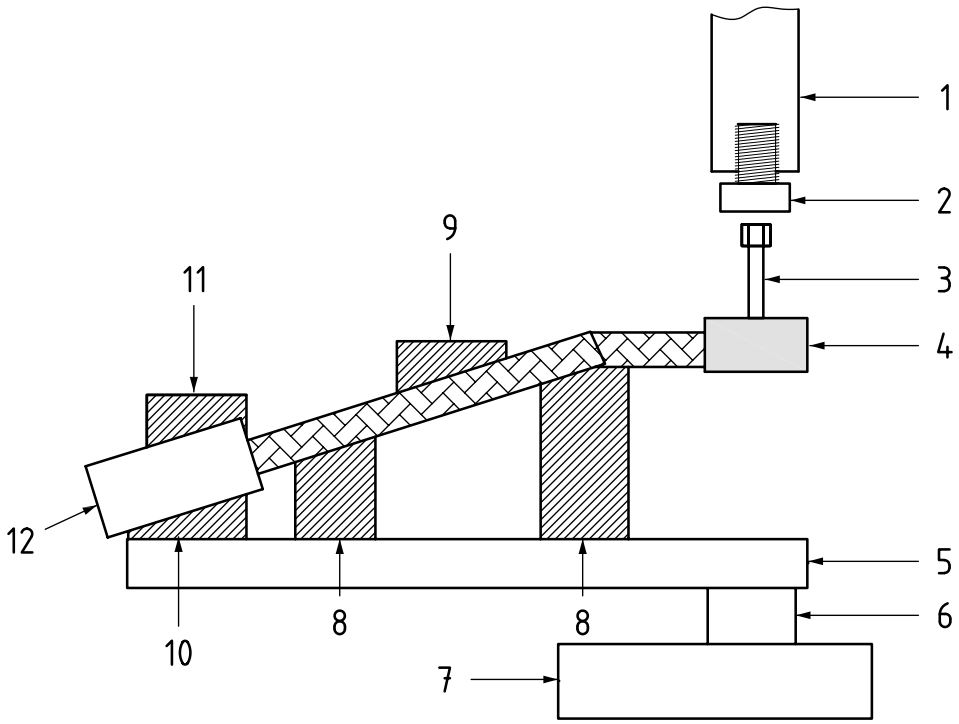


Key

1 drive shaft
2 prosthetic screw
3 screwdriver tip
4 tightening device
5 support beam
6 support shaft
7 torque measuring device
8 supports
9 clamp

NOTE 1 and 2 can be a single unit if desired.

Figure 1 — Test rig: Type 1, 2 and 3 devices



Key

1 drive shaft
2 prosthetic screw
3 screwdriver tip
4 contra-angle handpiece
5 support beam
6 support shaft
7 torque measuring device
8 handpiece supports
9 handpiece clamp
10 torque applicator support
11 torque applicator clamp
12 torque applicator

Figure 2 — Test rig: Type 4 devices

The two principal components are:

a) a horizontal support beam (5) secured on a vertical support shaft (6) which is free to rotate around its central vertical axis. The bearings in which the shaft rotates shall be capable of withstanding vertical loads of 20 N;

b) a torque measuring device (7) mounted on the support shaft, which imparts a rotational stiffness to the assembly similar to that of an integrated dental implant. This device shall be capable of measuring the torque with an accuracy of 0,1 N·cm ±5 %.

The test rig shall be calibrated and the accuracy of the assembly validated both before and after each test series.

The tightening device (4) is secured horizontally to the support beam by means of supports (8) and a clamp (9) so that with a screwdriver tip (3) in place it shall be aligned vertically upwards and concentric with the central long axis of the support shaft (6). For Type 4 devices the drive sleeve of the torque limiting mechanism shall be secured so as to prevent its rotation relative to the handpiece.

A vertical (drive) shaft (1) is arranged so that its central long axis is concentric with that of the support shaft and is capable of rotation up to 0,25 s^{-1} (15 r/min) to simulate clinical use. This shaft has a mechanism for holding a prosthetic screw (2) concentric with its long axis. The mounting for the vertical shaft may be moved vertically so that its central long axis remains concentric with that of the support shaft. The screwdriver tip shall be subjected in function to a downward force of 10 $\pm$ 1 N.

The test rig shall be equipped with a mechanism to stop the rotation of the drive shaft at a torque in excess of the target torque level. This torque is dependent on the design of the tightening device and shall be set as follows:

— **Type 1**: at a minimum level so as to consistently cease rotation of the drive shaft immediately after the break action;

— **Type 2**: at a level in accordance with the manufacturer's instructions, using hand-held magnification (2×) to read the scale;

— **Type 3**: at a level in accordance with the manufacturer's instructions, using an electrical contact to provide control of the tightening system by detection of the indicated torque;

— **Type 4**: at a minimum level so as to consistently cease rotation of the drive shaft immediately after the break action.

6.1.2 Prosthetic screw

The prosthetic screw shall be as supplied by the manufacturer for use with the screwdriver tip employed in the test rig. Where the screw and drive shaft are a single unit, the features that are designed to engage with the screwdriver tip shall be of the same dimensions as those of the prosthetic screw as supplied by the manufacturer.

6.1.3 Screwdriver tip

The screwdriver tip shall be as supplied by the manufacturer for use with the hand torque instrument being tested.

6.2 Test procedure

6.2.1 Mechanical test

6.2.1.1 Type 1 and Type 4 devices

Fit the tightening device and apply it to the prosthetic screw. Rotate it until the desired torque has been reached. Counter-rotate the drive shaft until the instrument is unloaded and then re-tighten. Repeat the tightening/torque-releasing sequence twenty times (or as deemed appropriate) and record the torque achieved at the break point at the end of each sequence. Repeat in accordance with 6.2.2.

6.2.1.2 Type 2 and Type 3 devices

Carry out the procedure as for Type 1 devices at the minimum and the maximum torque settings as stated by the manufacturer. In the case of Type 3 (torque beam) devices this is the point at which the scale indicates the desired torque, as derived from the closing of the electrical contact.

6.2.2 Reprocessing

Carry out reprocessing of the tightening device in accordance with the manufacturer's instructions, which shall comply with the requirements of ISO 17664, then repeat the procedure described in 6.2.1. The cycle should be repeated for the permitted number of times before recalibration or discarding the device as stated by the manufacturer.

Record the torque at break readings or the indicated torque for each process and compare with the manufacturer's stated data.

Record the number of usages tested and a justification, if required, for the recommended number of usages.

7 Marking, labelling and manufacturer's instructions for use

In addition to statutory requirements, these shall include the following:

a) lot number;

b) the range of the torque value; in the case of adjustable torque devices this information shall show the range at the minimum and maximum values permitted;

c) reprocessing instructions to enable the device to be decontaminated and rendered sterile;

d) recommended number of usages including reprocessing before device needs recalibrating or discarding;

e) any requirements for the maintenance of the accuracy of the device;

f) name and address of the manufacturer or of the responsible distributor.

Bibliography

[1] ISO 6789, *Assembly tools for screws and nuts — Hand torque tools — Requirements and test methods for design conformance testing, quality conformance testing and recalibration procedure*

[2] ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

BSI - British Standards Institution

BSI is the independent national body responsible for preparing British Standards. It presents the UK view on standards in Europe and at the international level. It is incorporated by Royal Charter.

Revisions

British Standards are updated by amendment or revision. Users of British Standards should make sure that they possess the latest amendments or editions.

It is the constant aim of BSI to improve the quality of our products and services. We would be grateful if anyone finding an inaccuracy or ambiguity while using this British Standard would inform the Secretary of the technical committee responsible, the identity of which can be found on the inside front cover. Tel: +44 (0)20 8996 9000. Fax: +44 (0)20 8996 7400.

BSI offers members an individual updating service called PLUS which ensures that subscribers automatically receive the latest editions of standards.

Buying standards

Orders for all BSI, international and foreign standards publications should be addressed to Customer Services. Tel: +44 (0)20 8996 9001. Fax: +44 (0)20 8996 7001 Email: orders@bsigroup.com You may also buy directly using a debit/credit card from the BSI Shop on the Website http://www.bsigroup.com/shop

In response to orders for international standards, it is BSI policy to supply the BSI implementation of those that have been published as British Standards, unless otherwise requested.

Information on standards

BSI provides a wide range of information on national, European and international standards through its Library and its Technical Help to Exporters Service. Various BSI electronic information services are also available which give details on all its products and services. Contact Information Centre. Tel: +44 (0)20 8996 7111 Fax: +44 (0)20 8996 7048 Email: info@bsigroup.com

Subscribing members of BSI are kept up to date with standards developments and receive substantial discounts on the purchase price of standards. For details of these and other benefits contact Membership Administration. Tel: +44 (0)20 8996 7002 Fax: +44 (0)20 8996 7001 Email: membership@bsigroup.com

Information regarding online access to British Standards via British Standards Online can be found at http://www.bsigroup.com/BSOL

Further information about BSI is available on the BSI website at http://www.bsigroup.com.

Copyright

BSI Group
Headquarters 389
Chiswick High Road,
London, W4 4AL, UK
Tel +44 (0)20 8996 9001
Fax +44 (0)20 8996 7001
www.bsigroup.com/
standards