INTERNATIONAL STANDARD

ISO 3630-1

First edition
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Dental root-canal instruments —

Part 1:
Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches

Instruments pour canaux radiculaires utilisés en art dentaire —

Partie 1: Limes, alésoirs, broches barbelées, râpes, bourre-pâtes, sondes exploratrices et broches porte-coton

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Contents

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Annex

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.

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.

International Standard ISO 3630-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 4, *Dental instruments*.

This first edition of ISO 3630-1 cancels and replaces ISO 3630:1984, of which it constitutes a technical revision.

ISO 3630 consists of the following parts, under the general title *Dental root-canal instruments*:

— *Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches*

— *Part 2: Enlargers*

— *Part 3: Condensers, pluggers and spreaders*

It is anticipated that additional types of instruments will form the subject of additional future parts.

Annex A of this part of ISO 3630 is for information only.

Introduction

This International Standard covers significant features of hand- and power-operated dental root canal instruments which are used by the dentist for the mechanical preparation of root canals for treatment. In dentistry these instruments are also referred to as endodontic instruments.

Part 1, in addition to the specific instruments indicated, includes general specifications, requirements and test methods which are applicable to all types of root-canal instruments.

Attention is drawn to the International Standard on a number coding system, ISO 6360, which specifies a 15-digit number for the identification of dental rotary instruments of all types.

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Dental root-canal instruments —

Part 1:
Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches

1 Scope

This part of ISO 3630 specifies requirements and test methods for files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches. In addition it covers general specifications, test methods, information on the designation code and identification symbols for root-canal instruments independent of specific types.

The requirements of this part of ISO 3630 shall become effective two years from the date of publication.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 3630. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 3630 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1797-1:1992, *Dental rotary instruments — Shanks — Part 1: Shanks made of metals.*

ISO 1797-2:1992, *Dental rotary instruments — Shanks — Part 2: Shanks made of plastics.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 6360-1:1985, *Dental rotary instruments — Number coding system — Part 1: General characteristics.*

ISO 6360-2:1986, *Dental rotary instruments — Number coding system — Part 2: Shape and specific characteristics.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Nominal sizes, designation (code number) and corresponding diameters

Table 1 gives the nominal sizes for the working parts to be used for all dental root-canal instruments regardless of the type of instrument.

The nominal sizes usually correspond to the values of the extended diameters at the tip or the working part in hundredths of a millimetre.

The designation (code number) with three digits is part of the 15-digit identification number laid down in ISO 6360-1.

Table 1 — Nominal sizes, designation (code number) and corresponding diameters

Nominal size: designation (code number)	Corresponding diameter mm
008	0,08
010	0,10
012	0,12
015	0,15
017	0,17
020	0,20
025	0,25
030	0,30
035	0,35
040	0,40
045	0,45
050	0,50
055	0,55
060	0,60
070	0,70
075	0,75
080	0,80
090	0,90
100	1,00
105	1,05
110	1,10
120	1,20
130	1,30
140	1,40
150	1,50
160	1,60
170	1,70
190	1,90

4 Requirements

4.1 Material

4.1.1 Working part

The working part and the shaft, if one part, shall be made of stainless steel or carbon steel. The type of steel and the treatment shall be at the discretion of the manufacturer.

4.1.2 Handle, shank

The handle, or shank, when affixed to the shaft, shall be made of metal or plastics material (see ISO 1797-1 and ISO 1797-2 respectively) of a quality suitable to withstand normal operative procedures. The type of material and the treatment shall be at the discretion of the manufacturer.

If the requirements of 4.2 to 4.4 are fulfilled, the instruments are considered also to comply with the requirements of 4.1.2.

4.2 Dimensional requirements

The dimensions are given in millimetres.

The dimensional requirements of the instruments shall comply with the respective tables and figures; within the dimensional requirements, variations in shape and design are permitted.

Testing shall be carried out in accordance with 6.1 and 6.2.

4.2.1 Shanks

Shanks shall be type 1 or 2 as specified in ISO 1797-1. Instruments used with type 1 or 2 shanks shall be operated with handpieces that are restricted to operate at slow speed. Except for paste carriers the handpieces shall have only an action of pulling motion and/or reciprocating motion (90° maximum) unless otherwise specified.

4.2.2 Files and reamers

This clause covers the following types of instruments:

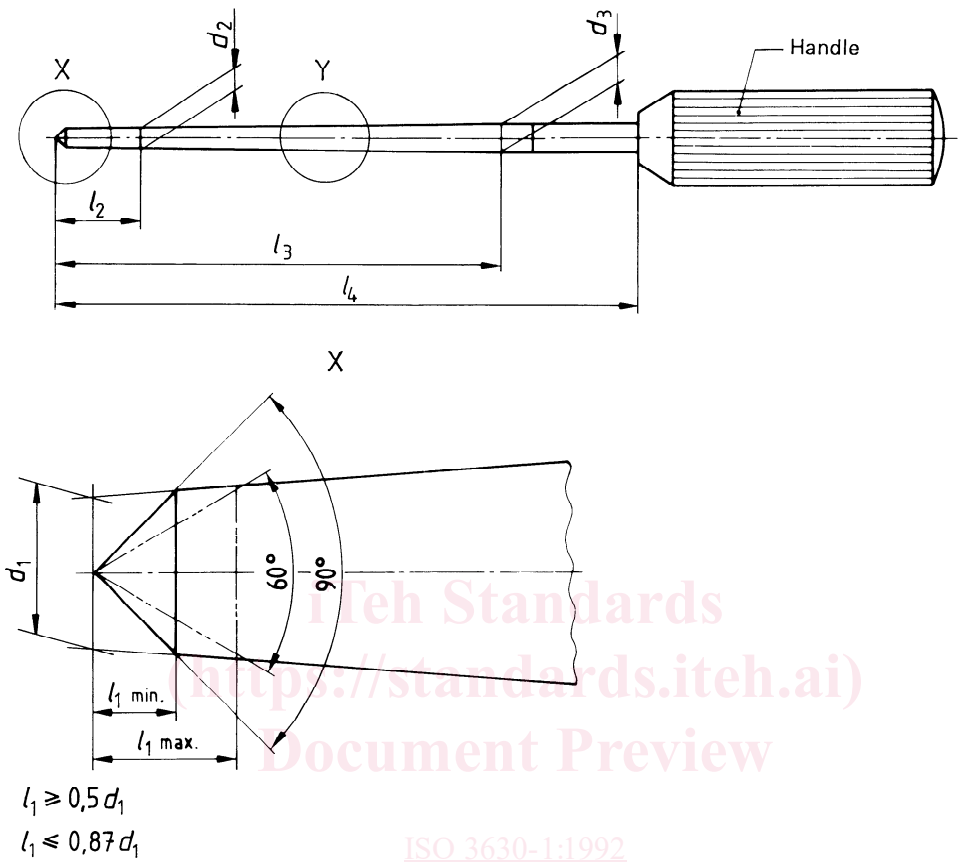
Files, type H

Files, type K

Reamers, type K

These files and reamers shall be in accordance with figure 1 and tables 2 to 4.

NOTE 1 The dimensions are aligned with those of the dental obturating points (see ISO 6877) and dental absorbent points (see note 6).



The tip length shall be within the limits specified by the minimal and maximal angle (l_1 min. to l_1 max.).

Shape and tip at the manufacturer's discretion.

Handle or shank (type 1 or 2 of ISO 1797-1) at the manufacturer's discretion.

Taper along working part 0,02:1

Detail Y: see table 2

- d_1 diameter of the projection of the working part at the tip end (nominal size)
- d_2 diameter at length l_2
- d_3 diameter at the end of minimum length of working part, length l_3
- l_1 tip length
- l_2 length for measuring point d_2
- l_3 length for measuring point d_3 and minimum length of working part
- l_4 length of operative end

Figure 1 — Files, type H; files, type K; reamers, type K