
**Dentistry — Root-canal instruments —
Part 1:
General requirements and test methods**

Art dentaire — Instruments pour canaux radiculaires —

Partie 1: Exigences générales et méthodes d'essai

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Published in Switzerland

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

This second edition cancels and replaces the first edition (ISO 3630-1:1992), which has been technically revised.

ISO 3630 consists of the following parts, under the general title *Dentistry — Root-canal instruments*:

- *Part 1: General requirements and test methods*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*
- *Part 4: Auxiliary instruments*

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Introduction

The reorganization of ISO 3630 is intended to present the requirements and test methods for root-canal instruments in an orderly manner. This part of ISO 3630 defines general requirements and test methods. Subsequent parts provide the specific requirements and test methods, if applicable, for two areas of endodontic procedures. These parts are enlargers, condensers and auxiliary instruments.

With current use of nickel-titanium (Ni-Ti) alloys for manufacture of root canal instruments a need for adequate expertise in their safe use is recommended. Instruments made of Ni-Ti can be easily broken near the tip if manufacturer's cautions are not understood and practiced. This part of ISO 3630 does not attempt to provide information for proper use of any instruments.

The sizes of the root-canal obturating points (cones) specified in ISO 6877^[4] have to be aligned with the corresponding sizes for root-canal instruments specified in ISO 3630.

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Dentistry — Root-canal instruments —

Part 1: General requirements and test methods

1 Scope

This part of ISO 3630 specifies general requirements and test methods for root-canal instruments used for endodontic purposes, e.g. enlargers, shaping and cleaning instruments, condensers, and accessory instruments. In addition it covers general size designations, colour coding, packaging and identification symbols.

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 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 1942, *Dental vocabulary (all parts)*
<https://standards.iteh.ai/catalog/standards/sist/291254a2-35d2-4662-b27c-72e803865094/iso-3630-1-2008>

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 3630-2:2000, *Dental root-canal instruments — Part 2: Enlargers*

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

ISO 6360-2, *Dentistry — Number coding system for rotary instruments — Part 2: Shapes*

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

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms, definitions and symbols

3.1 Terms and definitions

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

3.1.1

**root-canal instrument
endodontic instrument**

dental instrument designed to explore, shape, clean and fill root canal systems

3.1.2

standard-sized instrument

root-canal instrument throughout the range of sizes available having a uniform taper of 0,02 mm per millimetre of length

NOTE The nominal size of the root-canal instrument is listed in Table 1.

3.1.3

non standard-sized instrument

root-canal instrument which has other tip sizes than the standard-sized instrument

NOTE The nominal size of the root-canal instrument is not listed in Table 1.

3.1.4

taper-sized instrument

root-canal instrument the sizes of which are determined by the tip sizes that have tapers other than 0,02 mm per millimetre of length

3.1.5

shape-sized instrument

root-canal instrument having a contoured working part with continuously varying profile

3.1.6

non taper-sized instrument

root-canal instrument having a cylindrical form along the long axis

3.1.7

non-uniform taper-sized instrument

root-canal instrument having more than one taper along the working part

3.1.8

flexible instrument

root-canal instrument whose average test value when tested according to 7.5, shall be 65 %, or less, of the value listed in the appropriate bending or stiffness table of referenced specifications

3.1.9

guided tip instrument

root-canal instrument having a tip which guides access within root canal systems

3.1.10

tip portion of the instrument

that part of the root-canal instrument which is intended as the point, the shape of which is at the discretion of the manufacturer

3.1.11

working part

portion of the root-canal instrument with an active cutting surface

3.1.12

shank

part of the root-canal instrument to be connected to a handpiece

3.1.13

handle

part of the root-canal instrument to be manipulated by the user by hand

3.1.14**operative part**

portion of the root-canal instrument from the tip to the handle or shank

3.2 Symbols

For the purposes of this document, the following symbols apply.

d_1 diameter of the projection of the working part at the tip end (reference 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 part.

4 Classification

For the purposes of this document, root-canal instruments are classified according to the shape and taper of the tip size (see Figure 1) as follows.

- Type 1: standard-sized instruments (taper = 2 %);
- Type 2: taper-sized instruments (taper other than 2 %);
- Type 3: shape-sized instruments (arc shape);
- Type 4: non-taper-sized instruments (zero taper);
- Type 5: non-uniform taper-sized instruments (more than one taper).

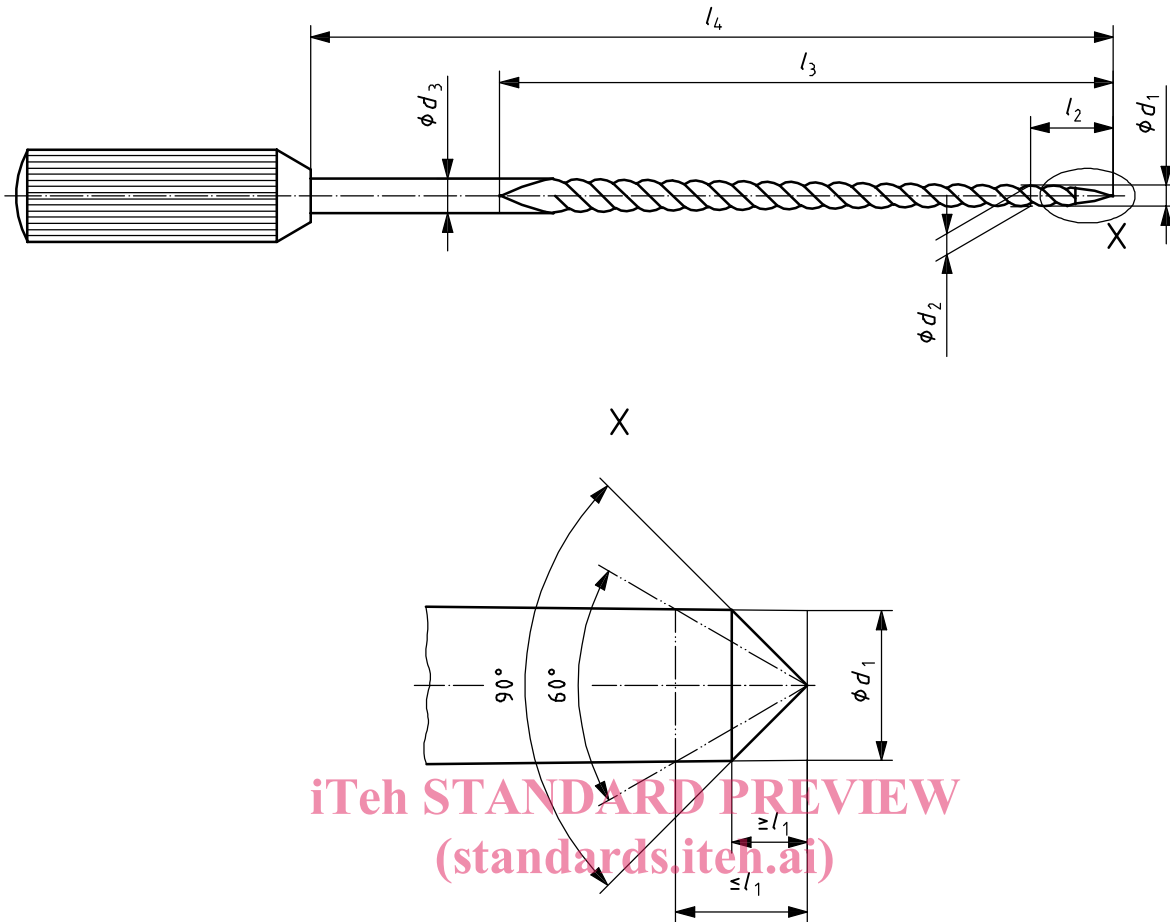
5 Requirements**5.1 General**

Specific root-canal instrument types, such as enlargers, have unique shapes which are not included here. These cases are covered in ISO 3630-2 and ISO 3630-3.

5.2 Type 1: standard-sized instruments**5.2.1 Length**

The length of the working part, l_3 , shall be a minimum of 16 mm unless otherwise specified by the manufacturer. The lengths of the working part, when specified, and of the operative part, l_4 , shall be within $\pm 0,5$ mm of the specified lengths.

Test in accordance with 7.3.



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Figure 1 — Dimensions and locations for Type 1
 (standard-sized instruments; taper = 2 %)

5.2.2 Size designation and diameters

Table 1 gives the nominal sizes and dimensions for the working part to be used for Type 1 (standard-sized instruments). Tip sizes (d_1) other than those listed in Table 1 are permitted. Figure 1 shows the position of the diameters and lengths for all Type 1 root-canal instruments. The nominal sizes shall correspond to the values of the extended diameters at the tip of the working part in hundredths of a millimetre.

NOTE The designation (code number) with three digits is part of the 15-digit identification number specified in ISO 6360-1 and ISO 6360-2.

5.2.3 Colour designation

Table 1 gives the colour designation for each size of Type 1 instrument. These colours are used on the handle or shank and specify the size identification of the working part. Colours of sizes not included in Table 1 are at the discretion of the manufacturer.

5.2.4 Tip shape

The shape of the tip is at the discretion of the manufacturer.

5.2.5 Tip length and angle

The tip length shall be within the limits specified by the minimum and maximum angle ($l_{1min.}$ to $l_{1max.}$) as shown in Figure 1.

Table 1 — Dimensions, size designation, and colour designation for Type 1
(standard-sized instruments)

Dimensions in millimetres

Nominal size	d_1 ref.	d_2	Tolerance	d_3	Tolerance	l_2	l_3 min.	Colour designation
006	0,06	012	± 0,01	0,38	± 0,02	3	16	pink
008	0,08	014		0,40				grey
010	0,10	016		0,42				purple
015	0,15	0,21	± 0,02	0,47				white
020	0,20	0,26		0,52				yellow
025	0,25	0,31		0,57				red
030	0,30	0,36		0,62				blue
035	0,35	0,41		0,67				green
040	0,40	0,46		0,72				black
045	0,45	0,51		0,77				white
050	0,50	0,56		0,82				yellow
055	0,55	0,61		0,87				red
060	0,60	0,66		0,92				blue
070	0,70	0,76		1,02				green
080	0,80	0,86		1,12				black
090	0,90	0,96	1,22	white				
100	1,00	1,06	± 0,04	1,32	± 0,04	yellow		
110	1,10	1,16		1,42		red		
120	1,20	1,26		1,52		blue		
130	1,30	1,36		1,62		green		
140	1,40	1,46		1,72		black		

5.3 Type 2: taper-sized instruments

5.3.1 Length

The lengths of the working part and of the operative part shall be specified by the manufacturer, and shall be within $\pm 0,5$ mm of the specified lengths. The length l_2 shall be 3 mm. The length l_3 shall be 16 mm unless otherwise specified by the manufacturer.

Test in accordance with 7.3.

5.3.2 Tip length and angle

The tip length and angle shall be at the discretion of the manufacturer.

5.3.3 Size designation

The designated instrument size shall be presented as “xxx yy”, where “xxx” is the diameter identification (5.3.4) and “yy” is taper identification (5.3.5).

NOTE This instrument size designation is part of the 15-digit identification number defined in ISO 6360-1.