

---

---

**Dentistry — Endodontic  
instruments —**

**Part 2:  
Enlargers**

*Médecine bucco-dentaire — Instruments d'endodontie —*

*Partie 2: Élargisseurs*  
**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 3630-2:2013

<https://standards.iteh.ai/catalog/standards/sist/d9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013>



**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 3630-2:2013

<https://standards.iteh.ai/catalog/standards/sist/df9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2013

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
<b>Foreword</b> .....	<b>iv</b>
<b>Introduction</b> .....	<b>v</b>
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms, definitions and symbols</b> .....	<b>1</b>
3.1 Terms and definitions.....	1
3.2 Symbols.....	2
<b>4 Classification</b> .....	<b>2</b>
4.1 Enlarger Type B1.....	2
4.2 Enlarger Type B2.....	2
4.3 Enlarger Type G.....	2
4.4 Enlarger Type M.....	2
4.5 Enlarger Type P.....	2
<b>5 Requirements</b> .....	<b>2</b>
5.1 Materials.....	2
5.2 Dimensions, designation and number of blades.....	3
5.3 Mechanical requirements.....	9
<b>6 Sampling</b> .....	<b>10</b>
<b>7 Testing</b> .....	<b>10</b>
7.1 General.....	10
7.2 Dimensions.....	10
7.3 Resistance to fracture by twisting and angular deflection.....	11
7.4 Resistance to bending.....	11
7.5 Resistance to fatigue.....	11
7.6 Fracture location.....	11
<b>8 Designation, marking and identification</b> .....	<b>13</b>
<b>9 Packaging</b> .....	<b>14</b>
<b>10 Labelling</b> .....	<b>14</b>
<b>Bibliography</b> .....	<b>15</b>

## 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 3630-2 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

This third edition cancels and replaces the second edition (ISO 3630-2:2000), which has been technically revised.

The following changes were made:

a) tolerances for diameter measurements were aligned;

b) test procedures were aligned with ISO 3630-1.

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

- *Part 1: General requirements and test methods*
- *Part 2: Enlargers*
- *Part 3: Condensers, pluggers and spreaders*
- *Part 4: Auxiliary instruments*
- *Part 5: Shaping and cleaning instruments*

## Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

Attention is drawn to ISO 6360 (all parts) which specifies a 15-digit number for the identification of dental rotary instruments of all types.

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[ISO 3630-2:2013](https://standards.iteh.ai/catalog/standards/sist/df9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013)

<https://standards.iteh.ai/catalog/standards/sist/df9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

ISO 3630-2:2013

<https://standards.iteh.ai/catalog/standards/sist/df9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013>

# Dentistry — Endodontic instruments —

## Part 2: Enlargers

### 1 Scope

This part of ISO 3630 specifies requirements for enlargers not cited in ISO 3630-1, ISO 3630-3, ISO 3630-4 or ISO 3630-5.

This part of ISO 3630 specifies requirements for size, marking, product designation, safety considerations, and their labelling and packaging, including the instructions for use.

### 2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1797-1, *Dentistry — Shanks for rotary instruments — Part 1: Shanks made of metals*

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

ISO 1942, *Dentistry — Vocabulary* [ISO 3630-2:2013](https://standards.iteh.ai/catalog/standards/sist/d9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013)

ISO 3630-1:2008, *Dentistry — Root-canal instruments — Part 1: General requirements and test methods*

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, ISO 3630-1 and the following apply.

##### 3.1.1

##### **enlarger**

hand- or power-operated endodontic instrument used for improving access to the root canal by enlarging its coronal opening

### 3.2 Symbols

For the purposes of this document, the following symbols apply. All dimensions are in millimetres (see [Figures 1 to 5](#) and [Tables 1 to 10](#)).

- $d_1$  diameter of working part (head diameter);
- $d_2$  neck diameter, measured at the proximal end of the working part;
- $d_3$  neck diameter, measured at the proximal end of the operative end;
- $d_4$  tip diameter;
- $l_1$  distance from tip to section A-A (at maximum diameter  $d_1$ );
- $l_2$  maximum length of working end and the measuring distance of  $d_2$  (head length);
- $l_3$  minimum length of operative end and the measuring distance of  $d_3$ ;
- $l_4$  total length of the instrument.

## 4 Classification

### 4.1 Enlarger Type B1

This enlarger has no other name attributed to it.

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

### 4.2 Enlarger Type B2

This enlarger has no other name attributed to it.

ISO 3630-2:2013

<https://standards.iteh.ai/catalog/standards/sist/d9db0ee-beb4-4b0e-8f56-36e7dc93d187/iso-3630-2-2013>

### 4.3 Enlarger Type G

This enlarger is also known as a Gates-Glidden drill.

### 4.4 Enlarger Type M

This enlarger has no other name attributed to it.

### 4.5 Enlarger Type P

This enlarger is also known as a Peeso drill.

## 5 Requirements

### 5.1 Materials

#### 5.1.1 Shank or handle

The material(s) of the shank or handle shall be left to the discretion of the manufacturer but shall meet the requirement in ISO 3630-1:2008, 5.7.

The shank or handle of the enlarger shall be Type 1 or Type 2 of ISO 1797-1 or ISO 1797-2.



### 5.1.2 Working part

The working part of the instrument shall be made of stainless steel, corrosion-resistant metal, or any other material, provided it meets the requirements given in [5.2](#) and [5.3](#).

## 5.2 Dimensions, designation and number of blades

### 5.2.1 General

All linear dimensions are given in millimetres, all angles in degrees. The linear dimensions in millimetres shall comply with [Figures 1](#) to [5](#) and [Tables 1](#) to [10](#).

The lengths of the working part and the operative part shall be specified by the manufacturer and shall be within  $\pm 0,5$  mm of the specified lengths.

Test compliance in accordance with ISO 3630-1. ISO 3630-1:2008, Table 1, gives the series of nominal diameters for the working part and the corresponding designation to be used, for all Types of dental endodontic instruments specified in ISO 3630-2, ISO 3630-3, ISO 3630-4 and ISO 3630-5.

NOTE Variations in shape and design within the limits of the dimensions and the subclass titles are permitted.

### 5.2.2 Enlarger types

#### 5.2.2.1 Enlarger Type B1

Requirements for enlargers of Type B1 are given in [Figure 1](#) and [Tables 1](#) and [2](#).

#### 5.2.2.2 Enlarger Type B2

Requirements for enlargers of Type B2 are given in [Figure 2](#) and [Tables 3](#) and [4](#).

#### 5.2.2.3 Enlarger Type G

Requirements for enlargers of Type G are given in [Figure 3](#) and [Tables 5](#) and [6](#).

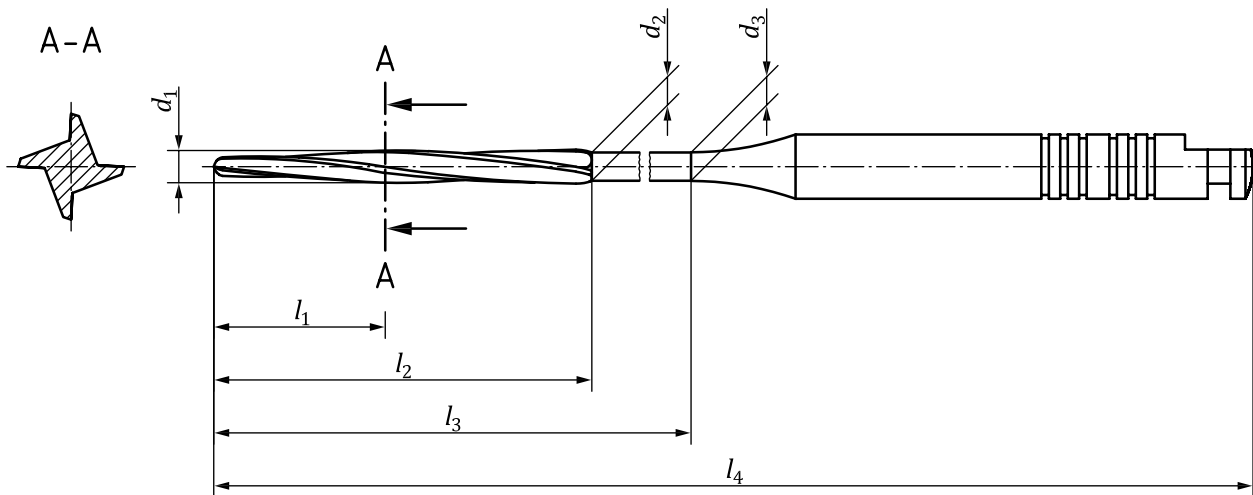
#### 5.2.2.4 Enlarger Type M

Requirements for enlargers of Type M are given in [Figure 4](#) and [Tables 7](#) and [8](#).

#### 5.2.2.5 Enlarger Type P

Requirements for enlargers of Type P are given in [Figure 5](#) and [Tables 9](#) and [10](#).

Dimensions in millimetres



NOTE The shank shown is an example of Type 1 of ISO 1797-1 with six-ring marking.

Figure 1 — Enlarger Type B1

Table 1 — Enlarger Type B1: Dimensions, number of blades and designation

Dimensions in millimetres

iTeh STANDARD PREVIEW  
(standards.iteh.ai)

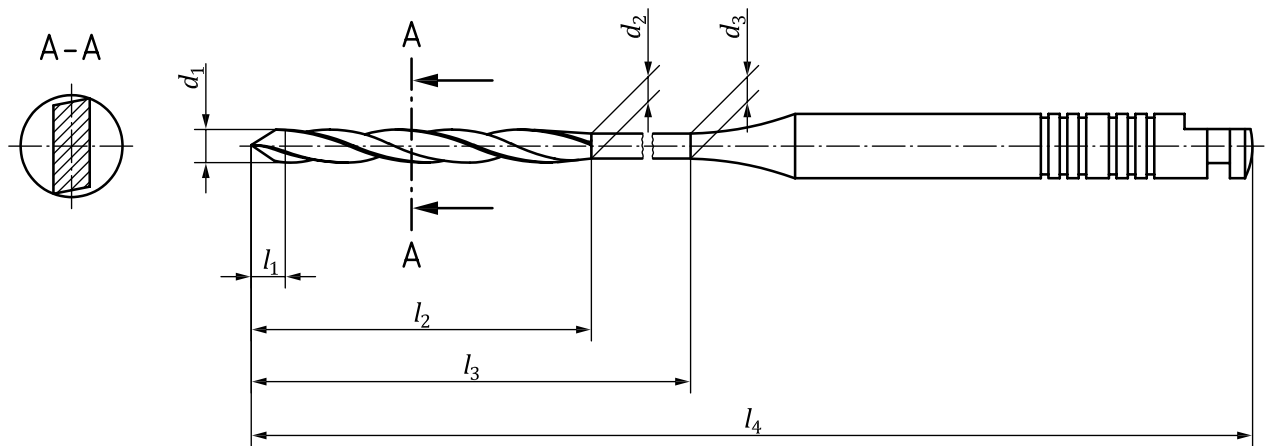
Nominal size	$d_1$	$d_2$	$d_3$	$l_1$	$l_2$	Number of blades	Colour	Ring marking
	$\pm 0,05$	$+0,05$ $-0$	$+0$ $-0,05$	$\pm 0,05$	min.			
090	0,90	0,75	0,75	4,50	10,0	4	white	I
100	1,00	0,85	0,85	4,50		4	yellow	II
120	1,20	1,05	1,05	4,50		4	red	III
140	1,40	1,20	1,20	4,75		4	blue	III I
160	1,60	1,40	1,40	4,75		4	green	III II
180	1,80	1,60	1,60	4,75		4	black	III III

Table 2 — Enlarger Type B1: Lengths  $l_3$  and  $l_4$

Dimensions in millimetres

Shank (ISO 1797-1)	$l_3$ min.	$l_4$
Type 1	13	$34 \pm 0,5$
Type 2	26	$65 \pm 1,0$

Dimensions in millimetres



NOTE The shank shown is an example of Type 1 of ISO 1797-1 with six-ring marking.

Figure 2 — Enlarger Type B2

Table 3 — Enlarger Type B2: Dimensions and designation

Dimensions in millimetres

Nominal size	$d_1$	$d_2$	$d_3$	$l_1$	$l_2$	Colour	Ring marking
	$\pm 0,05$	$+0,05$ $-0$	$+0$ $-0,05$	$\pm 0,05$	min.		
030	0,30	0,20	0,20	0,50	7,5	purple	0
035	0,35	0,26	0,26	0,50	8,0	white	I
045	0,45	0,36	0,36	0,50	8,0	yellow	II
060	0,60	0,46	0,46	0,70	8,0	red	III
075	0,75	0,56	0,56	0,80	9,0	blue	III I
090	0,90	0,66	0,66	1,00	9,0	green	III II
105	1,05	0,76	0,76	1,10	10,0	black	III III

Table 4 — Enlarger Type B2: Lengths  $l_3$  and  $l_4$

Dimensions in millimetres

Shank (ISO 1797-1)	$l_3$	$l_4$
Type 1	$18 \pm 0,5$	$33 \pm 0,5$
Type 2	min. 25	$61 \pm 1,0$