



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 3630-2:2022**  
**01-marec-2022**

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**Zobozdravstvo - Instrumenti za zobni kanal - 2. del: Razširjevalniki (ISO/DIS 3630-2:2022)**

Dentistry - Endodontic instruments - Part 2: Enlargers (ISO/DIS 3630-2:2022)

Zahnheilkunde - Endodontische Instrumente - Teil 2: Erweiterer (ISO/DIS 3630-2:2022)

Médecine bucco-dentaire - Instruments d'endodontie - Partie 2 : Élargisseurs (ISO/DIS 3630-2:2022)

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# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 3630-2

ISO/TC 106/SC 4

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## Dentistry — Endodontic instruments —

### Part 2: Enlargers

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

*Partie 2: Élargisseurs*

ICS: 11.060.20

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## ISO/DIS 3630-2:2022(E)

## 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, Working Group 9 Endodontic instruments*.

This fourth edition cancels and replaces the third edition (ISO 3630-2:2013), which has been technically revised.

The following changes were made:

- redefinition of the symbols
- redefinition of the test method
- harmonization with other parts of the 3630 series

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

- *Part 1: General requirements*
- *Part 2: Enlargers*
- *Part 3: Compactors: pluggers and spreaders*
- *Part 4: Auxiliary instruments*
- *Part 5: Shaping and cleaning instruments*
- *Part 6: Numeric coding system*
- *Part 7: Ultrasonic inserts*
- *Part 8: Accuracy of apex locator*

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## 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.

The nominal size ( $D$ ) is not utilized in this document because of the nature of the enlargers. Therefore,  $d_m$  represents the nominal size for this document only.

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# 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, ISO 3630-5, ISO 3630-6 or ISO 3630-7. This part of ISO 3630 specifies requirements for size, marking, product designation, safety considerations, and their labeling 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, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2019, *Dentistry — Endodontic instruments — Part 1: General requirements*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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### 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.

ISO and IEC maintain terminological data basis for use in standardization at the following addresses:

- IEC electropedia: available at [www.electropedia.org](http://www.electropedia.org)
- ISO online browsing platform: available at [www.iso.org/obp](http://www.iso.org/obp)

##### 3.1.1 enlarger

engine-driven endodontic instrument used for improving access to the root canal system 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](#), [Figure 7](#), and [Tables 1 to 8](#)).

$d_{\text{tip}}$  tip diameter

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- $d_m$  nominal size defined as the maximum diameter of working part (head diameter);
- $d_w$  neck diameter, measured at the proximal tip of the working part;
- $d_{op}$  neck diameter, measured at the proximal tip of the operative part;
- $l_m$  distance from tip to section A-A (at maximum diameter  $d_m$ );
- $l_w$  length of working part and the measuring distance of  $d_w$  (head length);
- $l_{op}$  length of operative part from the tip to the measuring point  $d_{op}$ ;
- $l_{tot}$  total length of the instrument.

## 4 Classification

### 4.1 Enlarger Type B1

Enlarger with a helicoidal working part geometry with four (4) cutting blades ([Figure 1](#)).

### 4.2 Enlarger Type B2

Enlarger with a helicoidal working part geometry with two (2) cutting blades ([Figure 2](#)).

### 4.3 Enlarger Type G

Arc shape enlarger with three (3) cutting blades including a guiding tip ([Figure 3](#)).

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

### 4.4 Enlarger Type M

Enlarger with helicoidal working part geometry with three (3) cutting blades including a guiding tip ([Figure 4](#)).

### 4.5 Enlarger Type P

Enlarger with helicoidal working part geometry with three (3) cutting blades including a guiding tip ([Figure 5](#)).

Note This enlarger is also known as a Peeso drill or a Peeso reamer.

## 5 Requirements

### 5.1 Materials

**5.1.1 Shank** The material(s) of the shank shall be left to the discretion of the manufacturer but shall meet the **requirement in ISO 3630-1:2019, 5.7**.

The shank of the enlarger shall be Type 1 of ISO 1797.

### 5.1.2 Working part

The working part of the enlarger shall be made of stainless steel, corrosion-resistant metal, or any other material, provided it meets the requirements given in [5.3](#) and [5.4](#).

## 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](#), [Figure 7](#), and [Tables 1 to 8](#).

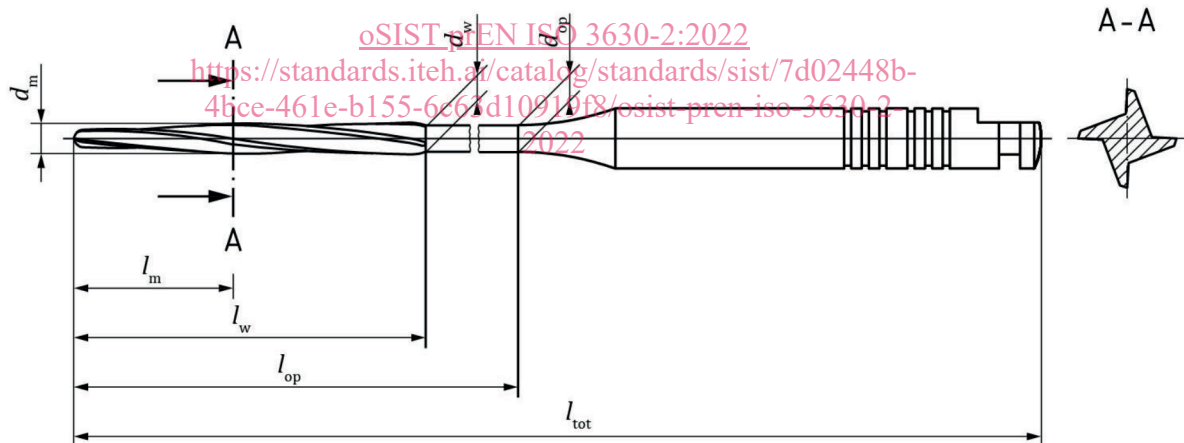
The lengths of the working part, operative part, and total instrument shall be specified by the manufacturer and shall be within  $\pm 0,5$  mm of the specified lengths:

**Table 1 — Lengths: working, operative and total**

Type	Working part $l_w$	Operative part $l_{op}$	Total $l_{tot}$
B1	Max 10 mm	Min 13 mm	34 mm
B2	see <a href="#">Table 3</a>	Min 17.5 mm	33 mm
G	See <a href="#">Table 4</a>	See <a href="#">Table 5</a>	See <a href="#">Table 5</a>
M	Min 13 mm	Min 19 mm	33 mm
P	See <a href="#">Table 7</a>	Min 13 mm	See <a href="#">Table 8</a>

Test compliance in accordance with ISO 3630-1. ISO 3630-1:2019, 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 are permitted.



#### Key

A section

A-A cross-section

NOTE The shank shown is an example of Type 1 of ISO 1797 with ring markings.

**Figure 1 — Enlarger Type B1**