
**Dentistry — Endodontic
instruments —**

**Part 2:
Enlargers**

*Médecine bucco-dentaire — Instruments d'endodontie —
Partie 2: Élargisseurs*

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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

The main changes are as follows:

- symbols have been redefined;
- the test method has been redefined;
- this document has been harmonized with other parts of the ISO 3630 series.

A list of all parts in the ISO 3630 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this document 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 document specifies the requirements for enlargers not cited in ISO 3630-1, ISO 3630-3, ISO 3630-4, ISO 3630-5, ISO TR 3630-6¹⁾ or ISO 3630-7²⁾.

This document specifies the requirements for size, marking, product designation, safety considerations, and labelling and packaging, including the instructions for use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1797, *Dentistry — Shanks for rotary and oscillating instruments*

ISO 1942, *Dentistry — Vocabulary*

ISO 3630-1:2019, *Dentistry — Endodontic instruments — 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.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1.1 enlarger

engine-driven endodontic instrument used to improve 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](#)).

1) Under preparation. Stage at the time of publication: ISO/CD TR 3630-6:2023.

2) Under preparation. Stage at the time of publication: ISO/PWI 3630-7:2023.

D	nominal size
d_{tip}	diameter of the blunt tip of the enlargers type G, N and P
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 cutting blades (see [Figure 1](#)).

4.2 Enlarger Type B2

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

4.3 Enlarger Type G

Arc shape enlarger with three cutting blades including a guiding tip (see [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 cutting blades including a guiding tip (see [Figure 4](#)).

4.5 Enlarger Type P

Enlarger with helicoidal working part geometry with three cutting blades including a guiding tip (see [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

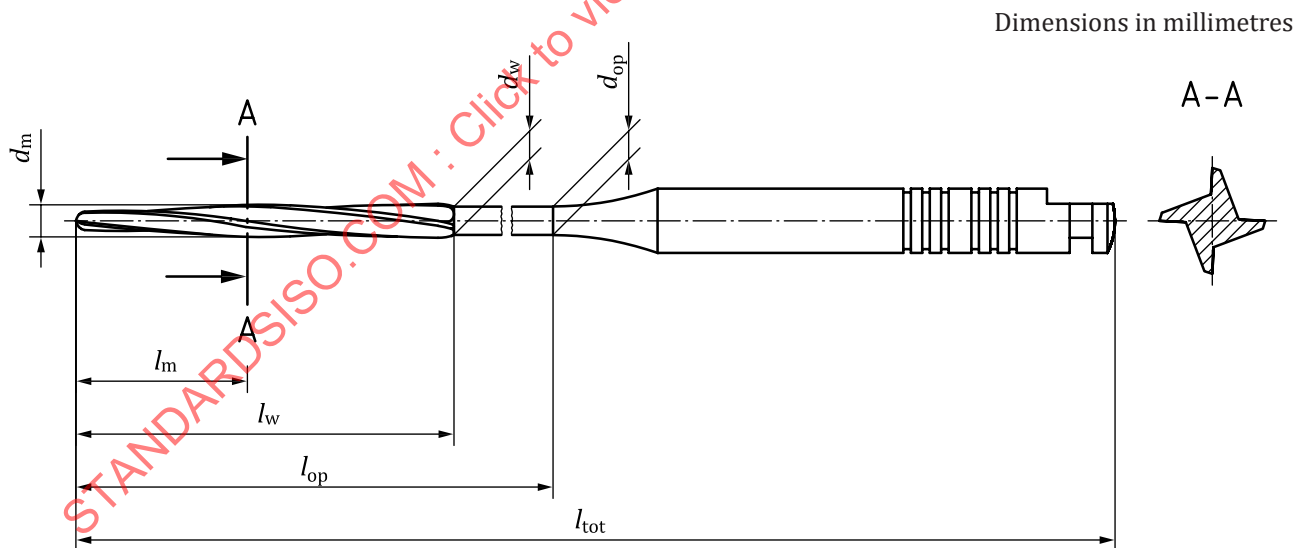
All linear dimensions are given in millimetres, all angles in degrees. The linear dimensions in millimetres shall comply with Figures 1 to 5, Figure 7, and Tables 1 to 8.

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 Table 3	min. 17,5 mm	33 mm
G	see Table 4	see Table 5	see Table 5
M	min. 13 mm	min. 19 mm	33 mm
P	see Table 7	see Table 8	see Table 8

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. 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.

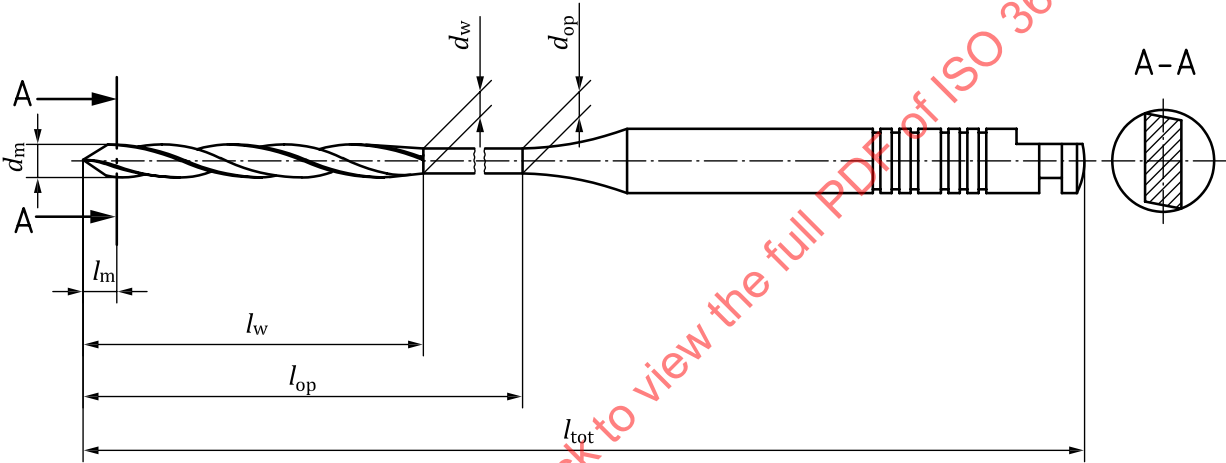
Figure 1 — Enlarger Type B1

Table 2 — Enlarger Type B1: Dimensions and designations

Dimensions in millimetres

Nominal size	d_m $\pm 0,05$	d_w $+0,05$ -0	d_{op} $+0$ $-0,05$	l_m NA	Colour	Ring markings
90	0,90	0,75	0,75	4,50	white	I
100	1,00	0,85	0,85	4,50	yellow	II
120	1,20	1,05	1,05	4,50	red	III
140	1,40	1,20	1,20	4,75	blue	III I
160	1,60	1,40	1,40	4,75	green	III II
180	1,80	1,60	1,60	4,75	black	III III

Dimensions in millimetres



Key

- A section
- A-A cross-section

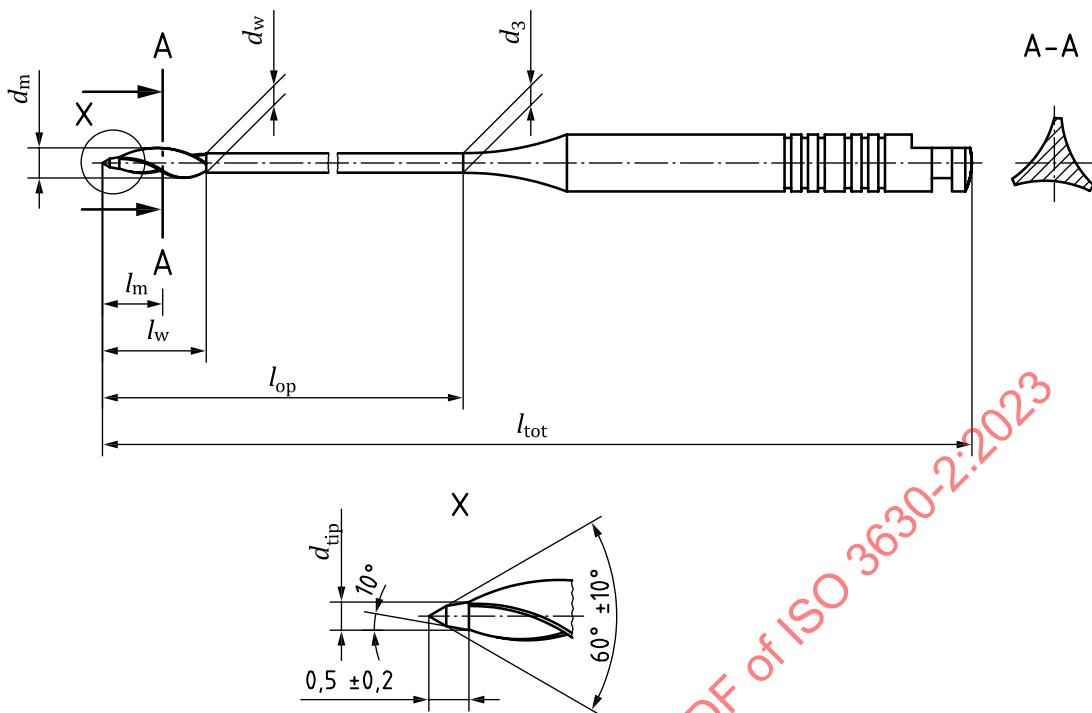
NOTE The shank shown is an example of Type 1 of ISO 1797 with ring markings.

Figure 2 — Enlarger Type B2

Table 3 — Enlarger Type B2: Dimensions and designations

Dimensions in millimetres

Nominal size	d_m $\pm 0,05$	d_w $+0,05$ -0	l_m	d_{op} 0 $-0,05$	l_w min.	Colour	Ring markings
30	0,30	0,20	0,50	0,20	7,5	purple	0
35	0,35	0,26	0,50	0,26	8,0	white	I
45	0,45	0,36	0,50	0,36	8,0	yellow	II
60	0,60	0,46	0,70	0,46	8,0	red	III
75	0,75	0,56	0,80	0,56	9,0	blue	III I
90	0,90	0,66	1,00	0,66	9,0	green	III II
105	1,05	0,76	1,10	0,76	10,0	black	III III



Key

A section

A-A cross-section

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

Figure 3 — Enlarger Type G

Table 4 — Enlarger Type G: Dimensions and designations

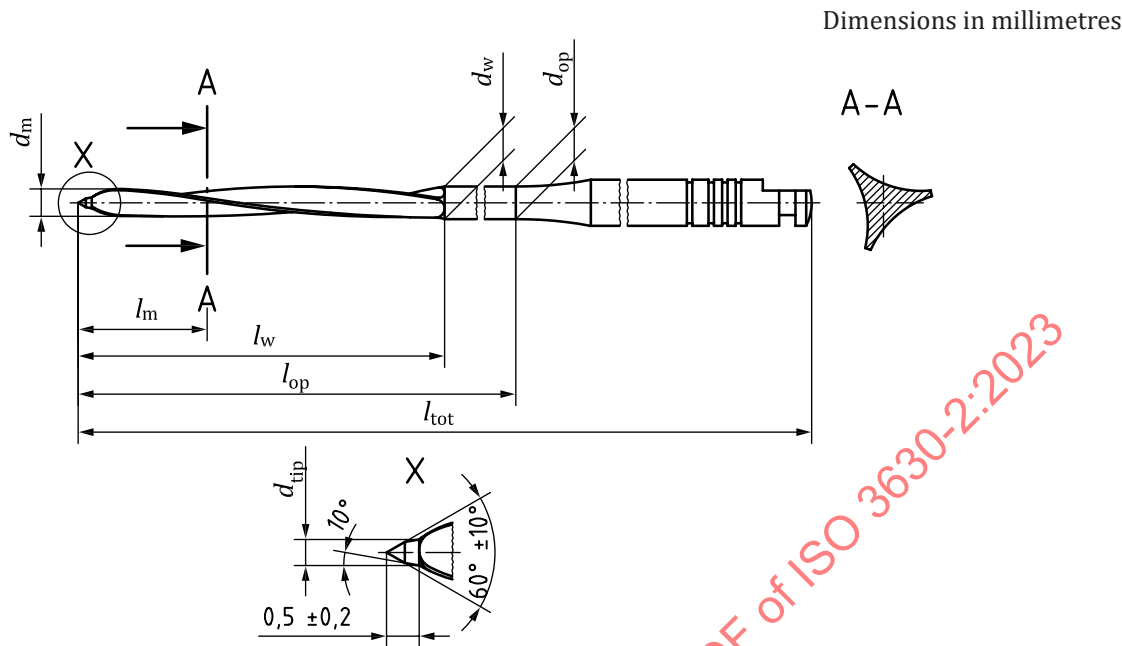
Dimensions in millimetres

Nominal size	d_m $\pm 0,05$	d_w $+0,05$ -0	d_{op} $+0$ $-0,05$	d_{tip} $\pm 0,05$	l_m $\pm 0,05$	l_w min.	Colour	Ring markings
50	0,50	0,38	0,38	0,25	1,50	2,3	white	I
70	0,70	0,48	0,48	0,30	1,70	2,7	yellow	II
90	0,90	0,58	0,58	0,35	1,90	3,1	red	III
110	1,10	0,68	0,68	0,40	2,10	3,5	blue	III I
130	1,30	0,78	0,78	0,45	2,30	3,9	green	III II
150	1,50	0,87	0,87	0,50	2,50	4,3	black	III III

Table 5 — Enlarger Type G: Lengths l_{op} and l_{tot}

Dimensions in millimetres

l_{op} min.	l_{tot}
11,2	$28 \pm 0,5$
15,2	$32 \pm 0,5$
17,2	$34 \pm 0,5$
21,2	$38 \pm 0,5$



Key
A section
A-A cross-section

X tip

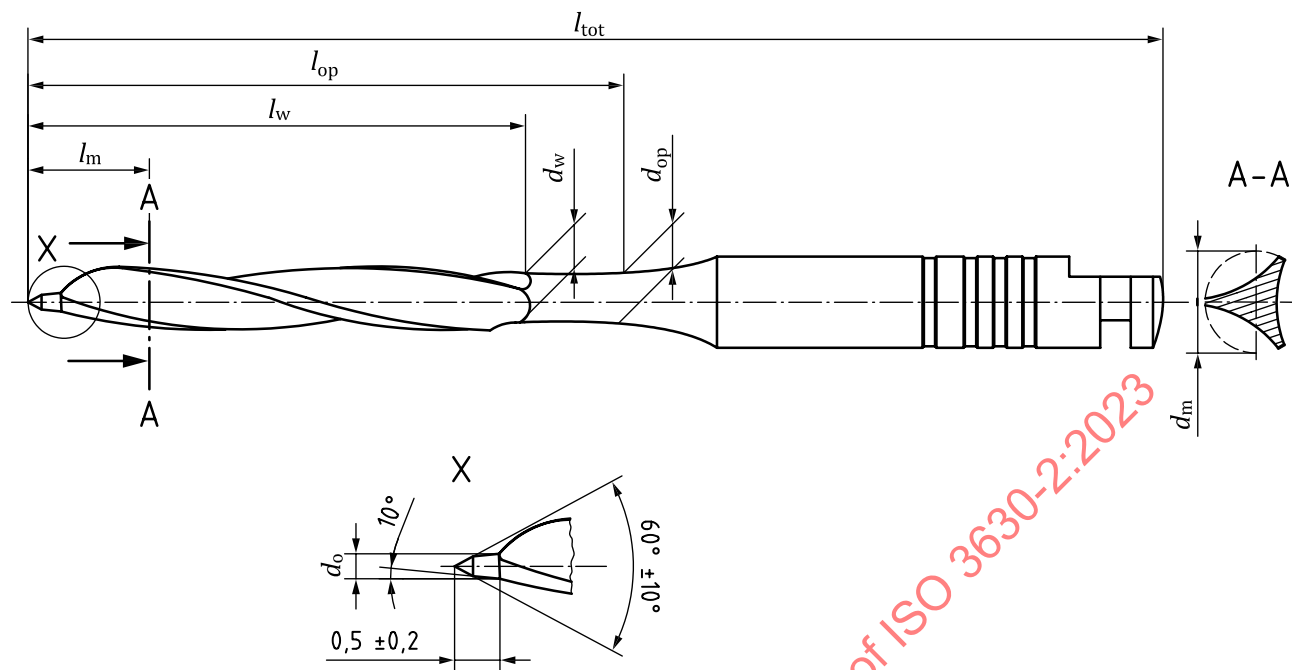
NOTE The shank shown is an example of Type 1 of ISO 17921 with ring markings.

Figure 4 — Enlarger Type M

Table 6 — Enlarger Type M: Dimensions and designations

Dimensions in millimetres

Nominal size	d_m $\pm 0,05$	d_w $+0,05$ -0	d_{tip} $\pm 0,05$	l_m NA	l_w min.	Colour	Ring markings
120	1,20	1,00	0,40	4,75	13,0	white	I
140	1,40	1,15	0,45	4,75	13,0	yellow	II
165	1,65	1,30	0,50	4,75	13,0	red	III
190	1,90	1,45	0,55	4,75	13,0	blue	III I

**Key**

A section

X tip

A-A cross-section

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

Figure 5 — Enlarger Type P**Table 7 — Enlarger Type P: Dimensions and designations**

Dimensions in millimetres

Nominal size	d_m $\pm 0,05$	d_w $+0,05$ 0	d_{op} 0 $-0,05$	d_{tip} $\pm 0,05$	l_m $\pm 0,05$	l_w min.	Colour	Ring markings
70	0,70	0,55	0,55	0,25	4,50	8,5	white	I
90	0,90	0,62	0,62	0,30	4,50	8,5	yellow	II
110	1,10	0,75	0,75	0,35	4,50	8,5	red	III
130	1,30	0,85	0,85	0,40	4,75	9,0	blue	III I
150	1,50	1,00	1,00	0,45	4,75	9,0	green	III II
170	1,70	1,10	1,10	0,50	4,75	9,0	black	III III

Table 8 — Enlarger Type P: Lengths l_{op} and l_{tot}

Dimensions in millimetres

l_{op} min.	l_{tot}
11,2	$28 \pm 0,5$
15,2	$32 \pm 0,5$
17,2	$34 \pm 0,5$
21,2	$38 \pm 0,5$

5.3 Mechanical requirements

5.3.1 Resistance to fracture by twisting and angular deflection

When tested in accordance with 7.3, the enlarger shall not fracture at less than the minimum values for resistance to fracture and for angular deflection given in Table 9 and shall meet the requirements of 5.3.4. Enlarger Type M is excluded from these requirements.

5.3.2 Resistance to bending

When tested in accordance with 7.4, the enlarger shall not fracture and shall not exceed the values specified in Table 9.

NOTE Enlarger Type M is excluded from this requirement.

5.3.3 Resistance to fatigue

When tested in accordance with 7.5, the enlarger shall meet the requirements of 5.3.4. The minimum number of test revolutions shall be the value given in Table 9.

NOTE Enlarger Type M is excluded from this requirement.

Table 9 — Resistance to fracture by twisting, bending and fatigue test

Enlarger type	Nominal size d_m	Resistance to fracture		Bending test	Fatigue test revolutions min.
		torque mN·m min.	angular deflection degrees min.	torque mN·m min.	
Type B1	90	10	90	65	1 000
Type B1	100	40	90	75	1 000
Type B2	30	1,8	360	5	100
Type B2	35	3,0	360	7	100
Type B2	45	9,8	360	10	100
Type B2	60	15,7	360	20	100
Type B2	75	24,5	360	35	100
Type B2	90	29,4	360	65	100
Type B2	105	49	360	90	100
Type G	50	10	360	14	3 500
Type G	70	23	360	30	2 000
Type G	90	43	360	55	950
Type G	110	73	180	95	300
Type P	70	17,6	240	35	200
Type P	90	54	240	65	130
Type P	110	84	240	85	30

5.3.4 Fracture location

When tested for requirements 5.3.1 and 5.3.3, the enlarger shall fracture in operative part within 4 mm of the shank, as shown in Figures 1 to 4. Enlarger Type M is excluded from this requirement.

5.4 Resistance to reprocessing

Enlargers shall meet the requirements of ISO 3630-1:2019, 5.10. Test in accordance with ISO 3630-1:2019, Clause 7.

6 Sampling

The sampling plan is as follows. Test 10 enlargers of each size. If all 10 samples pass, the product passes. If eight or fewer samples pass, the product fails. If nine samples pass, test 10 additional samples. When 10 additional samples are to be tested, all 10 shall pass for the product to comply.

7 Testing

7.1 General

The enlarger samples and equipment shall comply with ISO 3630-1:2019, Clause 7.

7.2 Dimensions

7.2.1 Diameters

Measure the diameters d_m , d_{tip} , d_w and d_{op} . Record the dimensions of the 10 enlargers in millimetres of each size to be tested.

7.2.2 Tip

Rotate the enlarger until the tip length is at the maximum. For enlargers types G, M and P, measure the tip diameter d_{tip} , as shown in [Tables 4, 6 and 7](#) as well tip angle and tip length as shown in [Figures 3, 4 and 5](#).

7.2.3 Shank

Measure the shank dimensions in accordance with ISO 1797. Determine the dimensions in millimetres shown in [Figures 1 to 5](#) and check if they comply with the dimensions specified in ISO 1797.

7.2.4 Lengths

Following the procedure given in [7.2.2](#), measure the working part, l_w , in millimetres by locating the longest tip of the blade as listed in [Tables 1, 2, 4, 6 and 7](#) and shown in [Figures 1 to 5](#). Measure operative part length l_{op} and total length l_{tot} in millimetres as listed in [Tables 1 and 5](#).

7.2.5 Blades

Hold the enlarger and count the number of blades when viewing around the circumference (see [4.1 to 4.5](#)).

7.3 Resistance to fracture by twisting and angular deflection

Grip the working part of the enlarger in the chuck according to [Figure 6](#). Grip the shaft of the enlarger in the chuck of a variable-speed motor. Twist the enlarger in a clockwise direction in accordance with ISO 3630-1:2019, 7.4. Record the torque in millinewton metres and the angular deflection in degrees.

Test only enlargers up to a nominal size 110.

7.4 Resistance to bending

Bend the enlarger (see [Table 8](#)) using the apparatus for the torque test as shown in ISO 3630-1:2019, 7.5. Record the torque in millinewton metres as a maximum value.

Test only enlargers up to a nominal size 110.

7.5 Resistance to fatigue

Test 10 enlargers. Grip the shaft of the enlarger in the chuck of a variable-speed motor (see [Figure 7](#)) and place the head in the ball-bearing ring. Locate the centre of the ball bearing at l_m as specified in [Figures 1, 2, 3](#) and [5](#) for Types B1, B2, G, respectively P. Deflect the ball-bearing 2 mm away from the axial alignment with the motor (see [Figure 7](#)). Rotate the motor at $(4\,000 \pm 400)$ rpm for enlargers up to and including nominal size, d_m , 070, and $(1\,000 \pm 100)$ rpm for enlargers above nominal size 070 and up to and including nominal size 110. Count the total number of revolutions until failure (see [Table 9](#)).

7.6 Fracture location

Measure and record the operative length in millimetres as described in [Figures 1](#) to [4](#) prior to testing in accordance with [7.3](#), [7.4](#) and [7.5](#). After testing, measure the distance from the enlarger tip to the fracture point. Record the difference between the operative length and the distance to the fracture point as the fracture location.

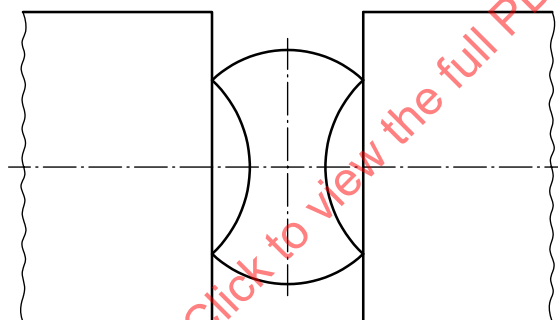


Figure 6 — Chucking position of enlarger for testing twisting and angular deflection