INTERNATIONAL STANDARD

ISO 3630-2

Second edition
2000-12-01

Dental root-canal instruments —

Part 2: Enlargers

Instruments pour canaux radiculaires utilisés en art dentaire —

Partie 2: Élargisseurs

Reference number
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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 3.

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 part of ISO 3630 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

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

This second edition cancels and replaces the first edition (ISO 3630-2:1986), which has been technically revised, including the following changes:

— addition of requirements for enlarger type M;

— addition of requirements and test methods for resistance to fracture in torque and angular deflection;

— specification of requirements for resistance to bending for enlarger types G and B2;

— specification of requirements for resistance to fatigue for enlarger types G and B1.

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*

Introduction

This part of ISO 3630 covers significant features of hand- and power-operated dental root-canal instruments which are used by the dentist for the preparation of root canals for treatment. In dentistry these instruments are also referred to as endodontic instruments.

This part of ISO 3630 describes enlargers which are used for gaining access to the root canal and enlarging the opening of the coronal portion of the root canal.

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

Dental root-canal instruments —

Part 2:
Enlargers

1 Scope

This part of ISO 3630 specifies requirements for dental root-canal enlargers of the following types:

— Type G;

— Type P;

— Type B1;

— Type B2;

— Type M.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 3630. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 3630 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

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

ISO 3630-1:1992, *Dental root-canal instruments — Part 1: Files, reamers, barbed broaches, rasps, paste carriers, explorers and cotton broaches.*

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

3 Term, definition and symbols

3.1 Term and definition

For the purposes of this part of ISO 3630, the following term and definition applies.

3.1.1
dental root-canal enlarger
hand- and power-operated endodontic instrument used for gaining access to the root canal and for enlarging the opening of the coronal portion of the root canal

3.2 Symbols

For the purposes of this part of ISO 3630, the following symbols apply (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 end of the working part;

d_3 neck diameter, measured at the 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 length of working part; head length;

l_3 length of operative end;

l_4 overall length.

4 Requirements

4.1 Materials

4.1.1 Shank

The material of the shank shall be left to the discretion of the manufacturer (see ISO 1797-1 and ISO 1797-2).

4.1.2 Working part

The working part of the instruments shall be made of tool steel or corrosion-resistant metal produced to meet the requirements given in 4.2 and 4.3 of this part of ISO 3630.

4.2 Dimensions, designation and number of blades

4.2.1 General

All linear dimensions are given in millimetres, all angles in degrees.

4.2.2 Shank

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

4.2.3 Working part

4.2.3.1 General

The linear dimensions of the enlargers shall comply with Figures 1 to 5 and Tables 1 to 10. Variations in shape and design within the limited dimensions and the description in the subclause titles are permitted. Compliance shall be tested in accordance with ISO 3630-1.

Table 1 of ISO 3630-1:1992 gives the series of nominal diameters for the working part, and the corresponding designation to be used, for all types of dental root-canal instruments specified in ISO 3630-1, ISO 3630-2 and ISO 3630-3.

4.2.3.2 Enlarger type G

Requirements for enlargers of type G are given in Figure 1 and Tables 1 and 2.

4.2.3.3 Enlarger type P

Requirements for enlargers of type P are given in Figure 2 and Tables 3 and 4.

4.2.3.4 Enlarger type B1

Requirements for enlargers of type B1 are given in Figure 3 and Tables 5 and 6.

4.2.3.5 Enlarger type B2

Requirements for enlargers of type B2 are given in Figure 4 and Tables 7 and 8.

4.2.3.6 Enlarger type M

Requirements for enlargers of type M are given in Figure 5 and Tables 9 and 10.

4.3 Mechanical requirements

4.3.1 Resistance to fracture in torque and angular deflection

When tested in accordance with 6.3, the instrument shall not fracture at less than the minimum value for the resistance to fracture in torque and the minimum angular deflection given in Table 11, and shall meet the requirements of 4.3.4.

4.3.2 Resistance to bending

When tested in accordance with 6.4, the instrument shall not fracture and shall not exceed the values specified in Table 11.

4.3.3 Resistance to fatigue

When tested in accordance with 6.5, the instrument shall meet the requirements of 4.3.4. The minimum number of test revolutions shall be the value given in Table 11.

4.3.4 Position of fracture point

When tested for requirements 4.3.1 and 4.3.3, the instruments shall fracture within 4 mm of the junction of the operative end of the shank, as shown in Figures 1 to 4.

5 Sampling

For each test, unless otherwise specified, more than 90 % of the samples tested shall comply with the requirements. The sampling plan is as follows:

Test ten enlarger of each size. If all ten enlarger pass, the product passes. If eight or fewer enlarger pass, the product fails.

If nine enlargers pass, test five additional enlargers. If five additional enlargers need to be tested, all five shall pass for the product to be accepted.

6 Testing

6.1 General

Equipment and instrument samples shall be conditioned at (20 ± 5) °C for a period of at least 10 h prior to testing.

6.2 Dimensions

6.2.1 Diameters

Measure the diameters d_1, d_2 and d_3. Record the dimensions of the 10 instruments of each size to be tested.

6.2.2 Tip

Following the procedure given in 6.2.1, rotate the instrument until the tip length is at the maximum. Measure the tip diameter d_4, tip angle and tip length as shown in Tables 1, 3 and 9 and Figures 1, 2 and 5.

6.2.3 Shank

Measure the shank dimensions in accordance with ISO 1797-1 or ISO 1797-2. Determine the dimensions shown in Figures 1 to 5 and check if they comply with the dimensions specified in ISO 1797-1 or ISO 1797-2.

6.2.4 Length

Following the procedure given in 6.2.2, measure the head length by locating the longest end of the blade as listed in Tables 1, 3, 5, 7 and 9 and shown in Figures 1 to 5. Measure lengths l_3 and l_4 as listed in Tables 2, 4, 6, 8 and 10.

6.2.5 Blades

Hold the instrument and visually determine the number of blades when viewing around the circumference.

6.3 Resistance to fracture

Twist 10 instruments in a clockwise direction until fracture (see Tables 11 to 14), using the apparatus for torque test as shown in ISO 3630-1:1992, Figures 6 and 7, and positioned in the chuck as shown in Figure 6 of this part of ISO 3630. Record the torque in millinewton metres (mN·m) and the angular deflection in degrees. Only test instruments up to a nominal diameter of 1,10 mm.

6.4 Resistance to bending

Bend 10 instruments (see Tables 11 to 14) using the apparatus for bend test shown in ISO 3630-1:1992, Figure 8. Record the permanent angular deflection in degrees. Only test instruments having a nominal diameter of up to 1,10 mm.

6.5 Resistance to fatigue

Test 10 instruments. Grip the shaft of the instrument in the chuck of a variable-speed motor (see Figure 7). Place the head in a ball-bearing ring. The centre of the ball bearing shall be located at l_1, as specified in Figures 1, 2 and 3 for types G, P and B1. For type B2, the centre of the ball bearing shall be located 1,1 mm from the tip. Then deflect the ball bearing 2 mm away from an axial alignment with the motor (see Figure 8). Count the total number of revolutions (see Tables 11 to 14). The motor rotational speed shall be 4 000 r/min ± 10 %. Only test enlargers having a nominal diameter of up to 1,10 mm.

6.6 Position of fracture

Measure and record the operative length as described in Figures 1 to 4 prior to testing to 6.3, 6.4 and 6.5. After testing, measure the distance from the instrument tip to the fracture point. Record the numerical difference between the operative length and the distance to the fracture point as the fracture location.

7 Marking of the shank

The nominal sizes of the enlargers shall be indicated by marking the shank with colour and/or rings in accordance with Table 15.

8 Packaging

Dental root-canal enlargers are supplied at the discretion of the manufacturer as single instruments or in sets.

9 Labelling

Each package shall be labelled with at least the following information:

a) name of manufacturer or distributor;

b) type of enlarger;

c) length of operative end;

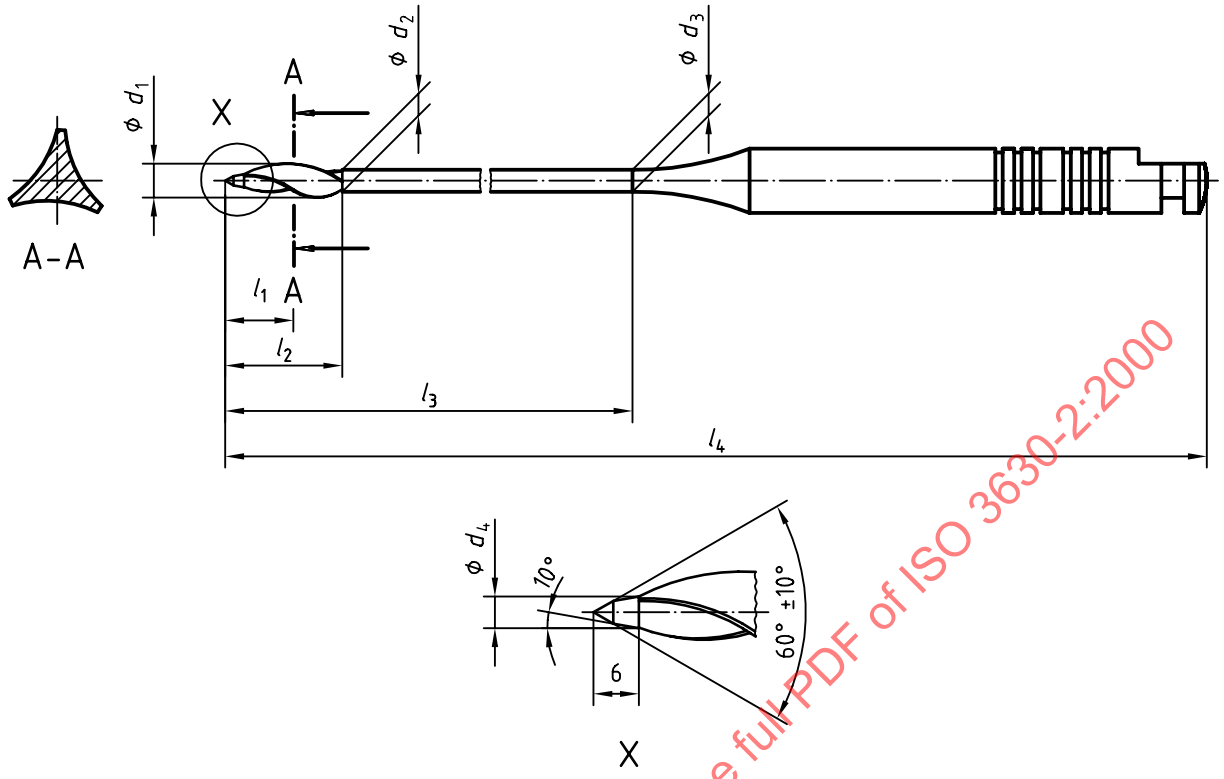
d) nominal diameter;

e) date of packaging, expressed, if applicable, in accordance with ISO 8601;

f) lot number (batch number);

g) type of material of the operative end.

Dimensions in millimetres



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

Figure 1 — Enlarger type G

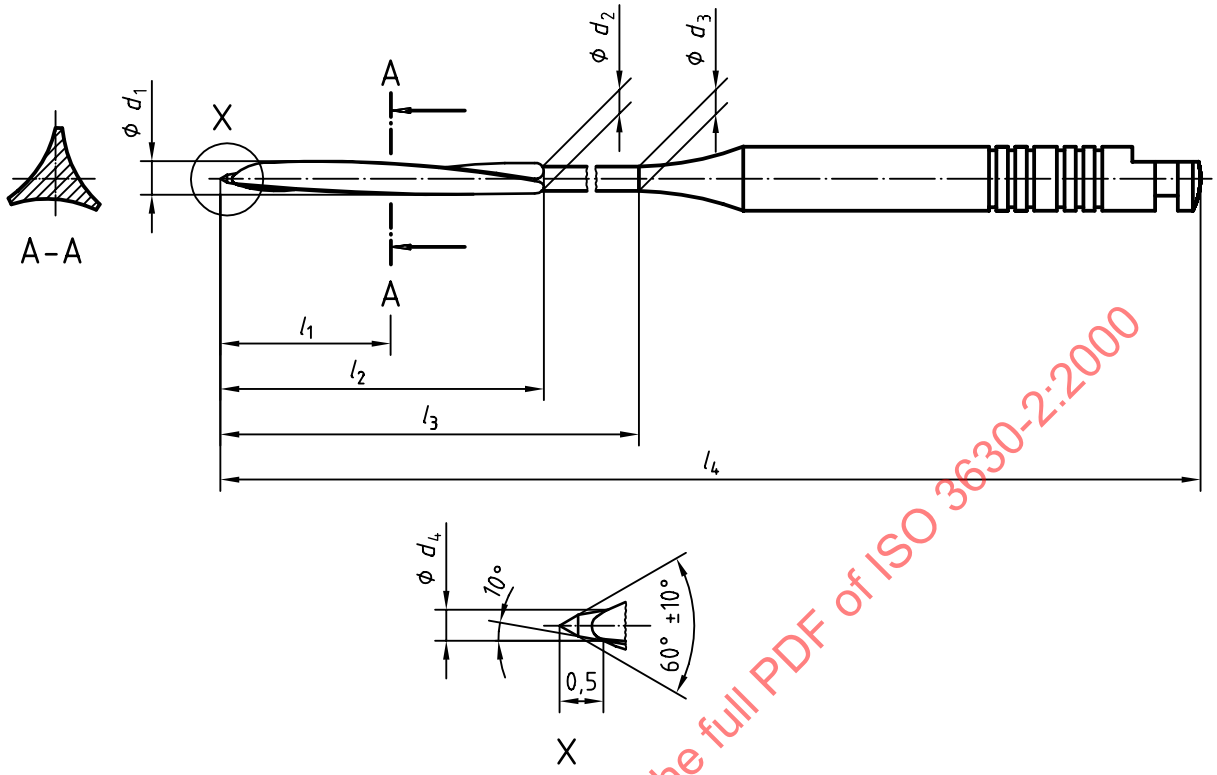
Table 1 — Enlarger type G — Dimensions, number of blades and designation

Designation of nominal diameter	d_1 ± 0,05	d_2 $^{+0,05}_{0}$	d_3 $^{0}_{-0,07}$	d_4 ± 0,05	l_1 (approx.)	l_2 min.	**Number of blades** min.	**Colour**	**Ring marking on shank**
050	0,50	0,38	0,38	0,25	1,50	2,30	3	white	I
070	0,70	0,48	0,48	0,30	1,70	2,70	3	yellow	II
090	0,90	0,58	0,58	0,35	1,90	3,10	3	red	III
110	1,10	0,68	0,68	0,40	2,10	3,50	3	blue	III I
130	1,30	0,78	0,78	0,45	2,30	3,90	3	green	III II
150	1,50	0,87	0,87	0,50	2,50	4,30	3	black	III III

Table 2 — Enlarger type G — Lengths l_3 and l_4

Shank (ISO 1797)	l_3 ± 0,5	l_4
Type 1	15,2	32 ± 0,5
Type 2	15,2	60,5 ± 1

Dimensions in millimetres



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

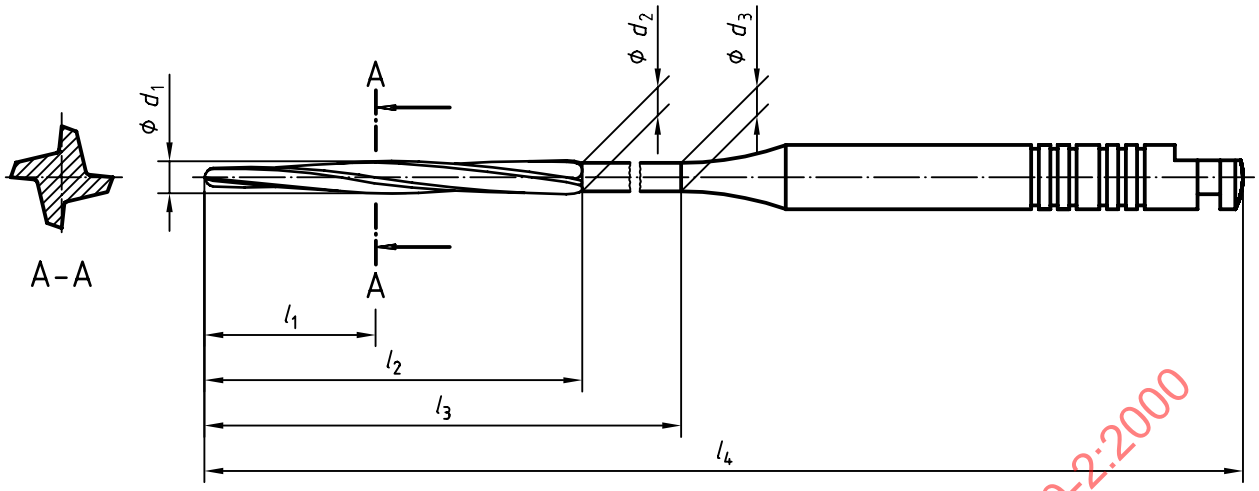
Figure 2 — Enlarger type P

Table 3 — Enlarger type P — Dimensions, number of blades and designation

Designation of nominal diameter	d_1 ± 0,05	d_2 $^{+0,05}_{0}$	d_3 $^{0}_{-0,05}$	d_4 ± 0,05	l_1 (approx.)	l_2 min.	**Number of blades** min.	**Colour**	**Ring marking on shank**
070	0,70	0,60	0,60	0,25	4,50	8,5	3	white	I
090	0,90	0,65	0,65	0,30	4,50	8,5	3	yellow	II
110	1,10	0,75	0,75	0,35	4,50	8,5	3	red	III
130	1,30	0,90	0,90	0,40	4,75	9,0	3	blue	III I
150	1,50	1,00	1,00	0,45	4,75	9,0	3	green	III II
170	1,70	1,10	1,10	0,50	4,75	9,0	3	black	III III

Table 4 — Enlarger type P — Lengths l_3 and l_4

Shank (ISO 1797)	l_3 min.	l_4
Type 1	13	32 ± 0,5
Type 2	26	60,5 ± 1



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

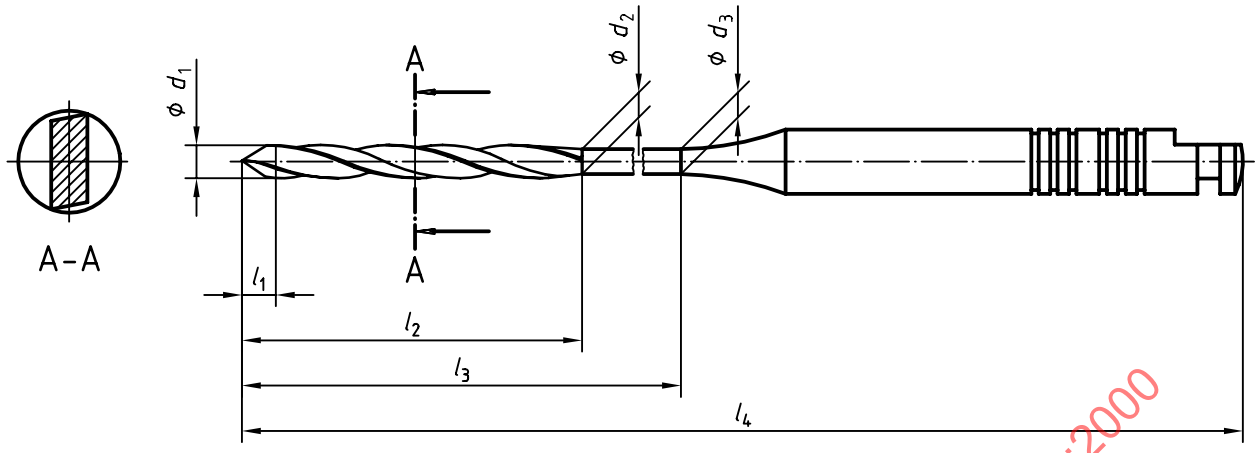
Figure 3 — Enlarger type B1

Table 5 — Enlarger type B1 — Dimensions, number of blades and designation

Designation of nominal diameter	d_1 $\pm$ 0,05	d_2 $^{+0,05}_{0}$	d_3 $^{0}_{-0,05}$	l_1 (approx.)	l_2 min.	**Number of blades** min.	**Colour**	**Ring marking on shank**
090	0,90	0,75	0,75	4,50	10,0	4	white	I
100	1,00	0,85	0,85			4	yellow	II
120	1,20	1,05	1,05			4	red	III
140	1,40	1,20	1,20	4,75		4	blue	III I
160	1,60	1,40	1,40			4	green	III II
180	1,80	1,60	1,60			4	black	III III

Table 6 — Enlarger type B1 — Lengths l_3 and l_4

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



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

Figure 4 — Enlarger type B2

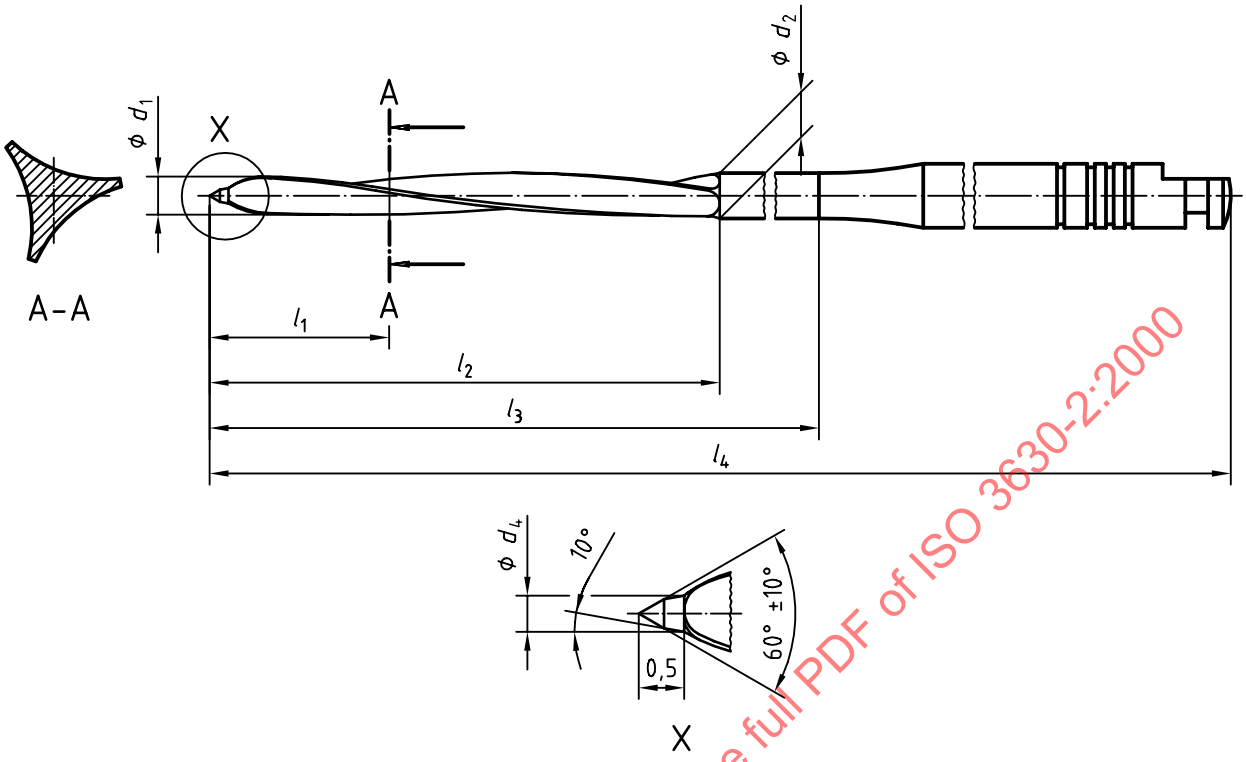
Table 7 — Enlarger type B2 — Dimensions and designation

Designation of nominal diameter	d_1 ± 0,05	d_2 ± 0,05	d_3 ± 0,05	l_1 (approx.)	l_2 min.	**Colour**	**Ring marking on shank**
030	0,30	0,20	0,20	0,50	7,5	purple	—
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	9,0	black	III III

Table 8 — Enlarger type B2 — Lengths l_3 and l_4

Shank (ISO 1797)	l_3	l_4 min.
Type 1	18 ± 0,5	33
Type 2	25 min.	61

Dimensions in millimetres



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

Figure 5 — Enlarger type M

Table 9 — Enlarger type M — Dimensions and designation

Designation of nominal diameter	d_1 ± 0,05	d_2 ± 0,05	d_4 ± 0,05	l_1 (approx.)	l_2 min.	Colour	Ring marking on shank
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

Table 10 — Enlarger type M — Lengths l_3 and l_4

Shank (ISO 1797)	l_3 min.	l_4 ± 0,5
Type 1	19	33

Table 11 — Torsion, bend and fatigue tests for enlarger type G

Nominal size	Torsion test		Bend test angular deflection	Fatigue test revolutions
	torque mN·m [a] min.	angular deflection degrees min.	degrees max.	min.
050	10	360	22	3500
070	23	360	26	2000
090	43	360	30	950
110	73	180	30	300

[a] 1 mN·m = 10,19 g·cm

Table 12 — Torsion, bend and fatigue tests for enlarger type P

Nominal size	Torsion test		Bend test angular deflection	Fatigue test revolutions
	torque mN·m [a] min.	angular deflection degrees min.	degrees max.	min.
070	17,6	90	35	200
090	54	240	35	130
110	84	240	35	30

[a] 1 mN·m = 10,19 g·cm

Table 13 — Torsion, bend and fatigue tests for enlarger type B1

Nominal size	Torsion test		Bend test angular deflection	Fatigue test revolutions
	torque mN·m [a] min.	angular deflection degrees min.	degrees max.	min.
090	10	90	30	1000
110	40	90	35	1000

[a] 1 mN·m = 10,19 g·cm