INTERNATIONAL STANDARD

**ISO 3630-2**

Fourth edition
2023-02

# Dentistry — Endodontic instruments —

## Part 2: Enlargers

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

*Partie 2: Élargisseurs*



Reference number
ISO 3630-2:2023(E)



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Published in Switzerland

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# Foreword

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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.

# 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 3630-6[1)] or ISO 3630-7[2)].

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.

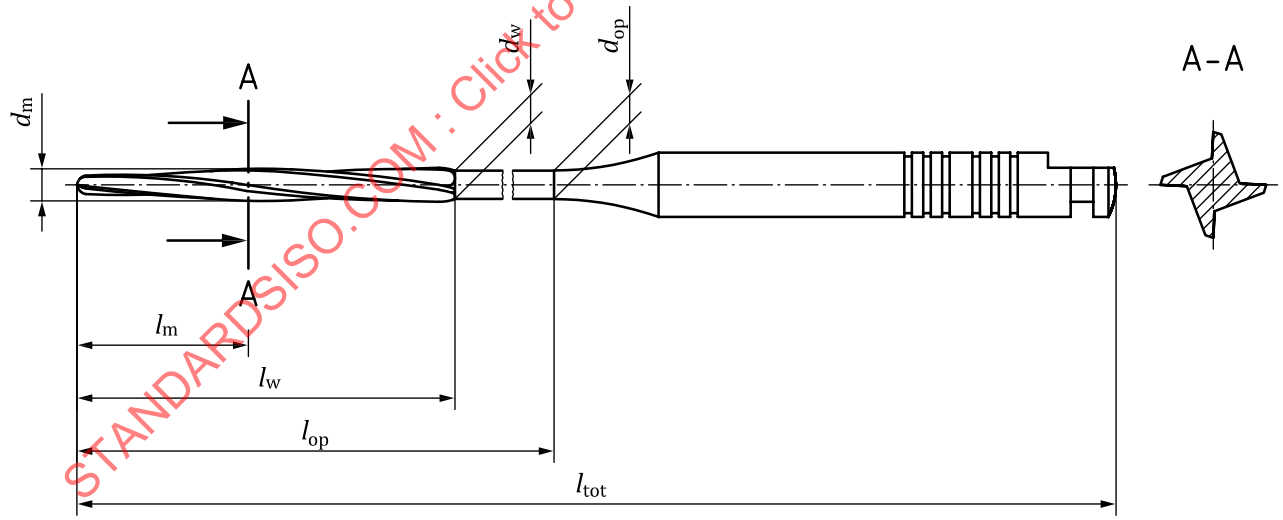
The lengths of the working part, operative part and total instrument shall be specified by the manufacturer and shall be within ±0,5 mm of the specified lengths.

**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.

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.

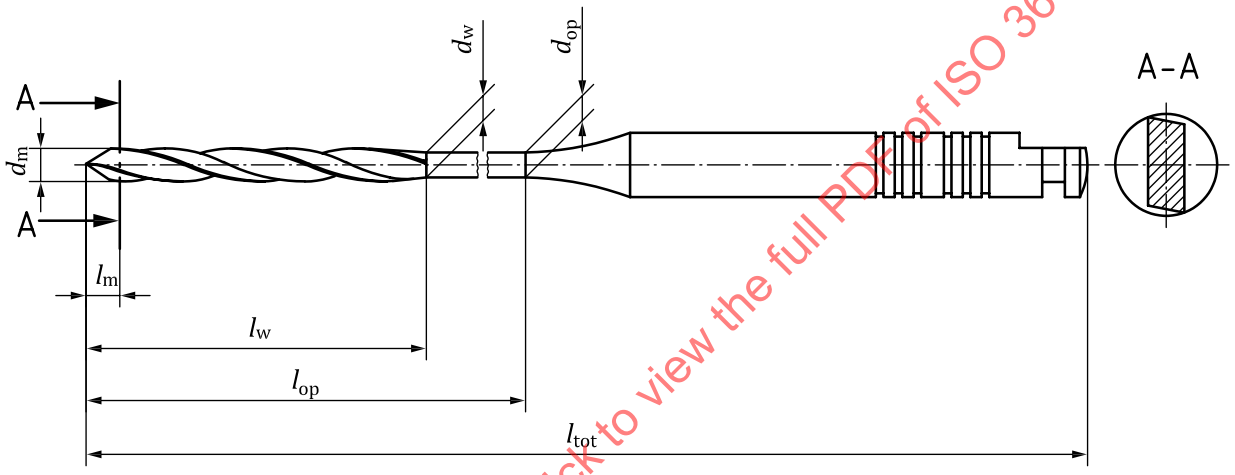
**Figure 1 — Enlarger Type B1**

**Table 2 — Enlarger Type B1: Dimensions and designations**

Dimensions in millimetres

| Nominal size | $d_m$ ±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

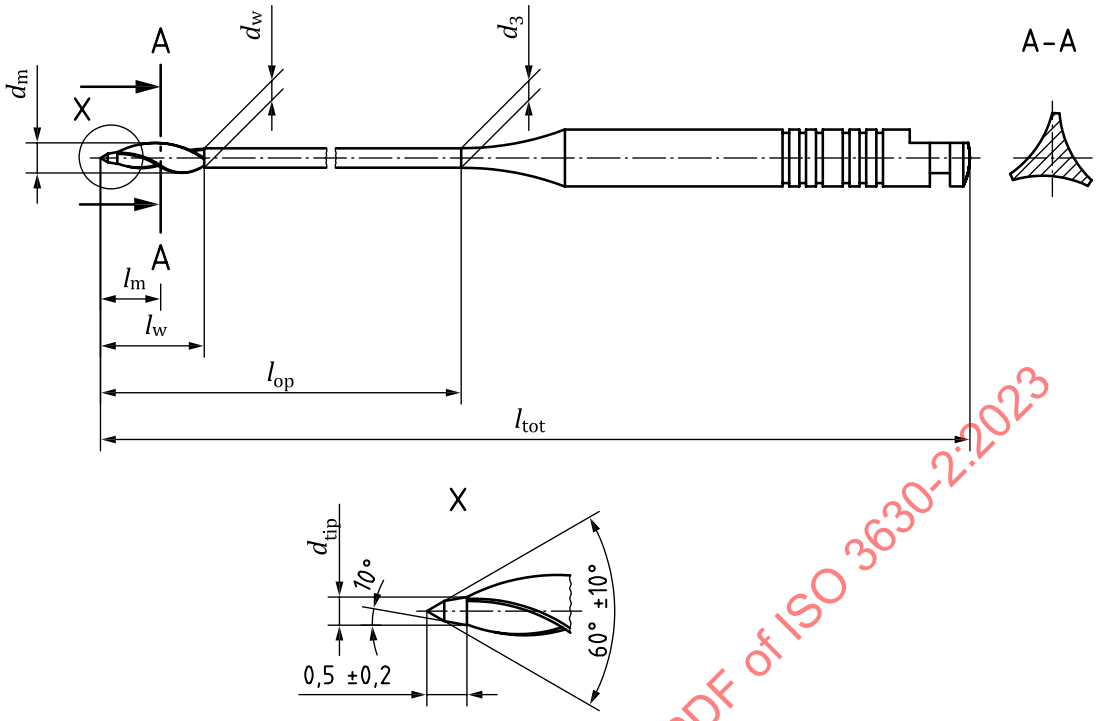
NOTE The shank shown is an example of Type 1 of ISO 1797 with ring markings.

**Figure 2 — Enlarger Type B2**

**Table 3 — Enlarger Type B2: Dimensions and designations**

Dimensions in millimetres

| Nominal size | $d_m$ ±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
X tip

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

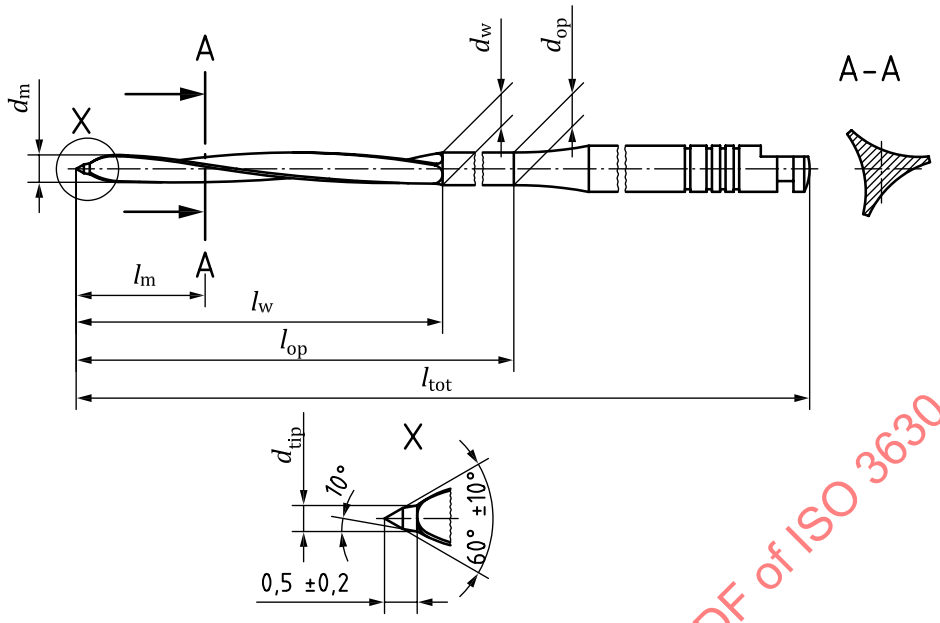
| Nominal size | $d_m$ ±0,05 | $d_w$ +0,05 −0 | $d_{op}$ +0 −0,05 | $d_{tip}$ ±0,05 | $l_m$ ±0,05 | $l_w$ min. | Colour | Ring markings |
|---|---|---|---|---|---|---|---|---|
| 50 | 0,50 | 0,38 | 0,38 | 0,25 | 1,50 | 2,3 | white | I |
| 70 | 0,70 | 0,48 | 0,48 | 0,30 | 1,70 | 2,7 | yellow | II |
| 90 | 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 ± 0,5 |
| 15,2 | 32 ± 0,5 |
| 17,2 | 34 ± 0,5 |
| 21,2 | 38 ± 0,5 |

Dimensions in millimetres




**Key**

A section
A-A cross-section
X tip

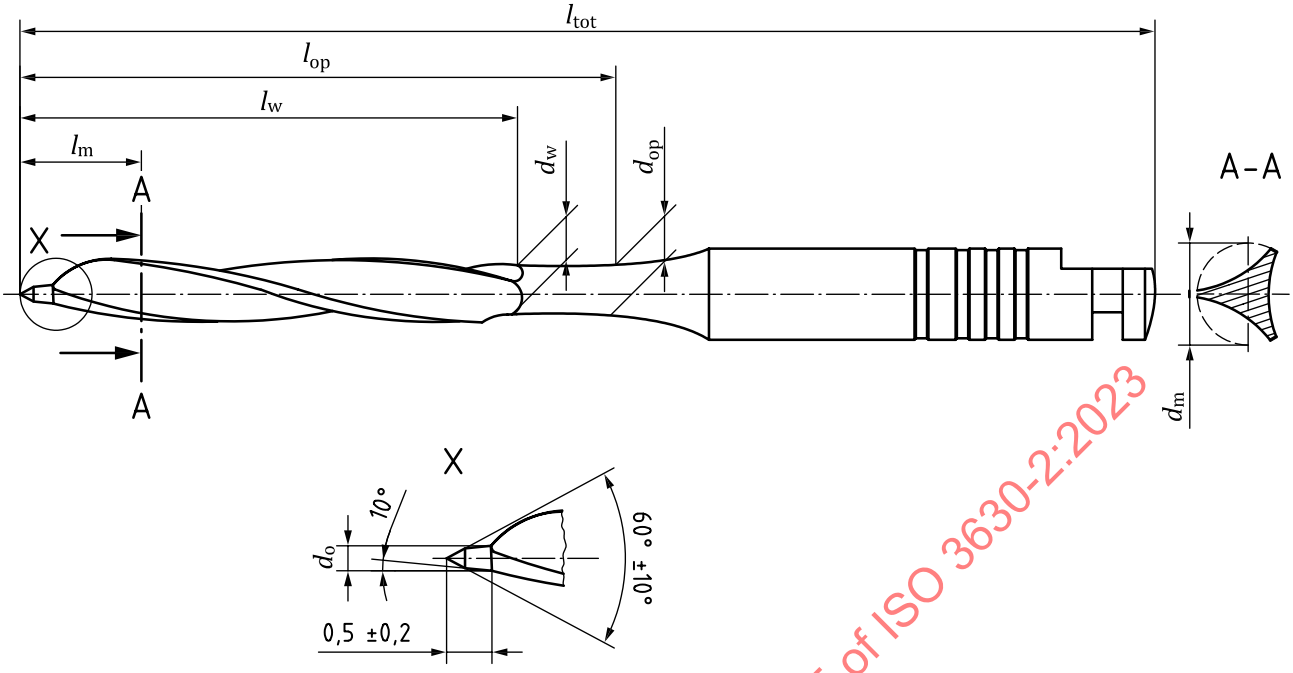
NOTE The shank shown is an example of Type 1 of ISO 1797 with ring markings.

**Figure 4 — Enlarger Type M**

**Table 6 — Enlarger Type M: Dimensions and designations**

Dimensions in millimetres

| Nominal size | $d_m$ ±0,05 | $d_w$ +0,05 −0 | $d_{tip}$ ±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
A-A cross-section
X tip

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 | $d_m$ ±0,05 | $d_w$ +0,05 0 | $d_{op}$ 0 −0,05 | $d_{tip}$ ±0,05 | $l_m$ ±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 ± 0,5 |
| 15,2 | 32 ± 0,5 |
| 17,2 | 34 ± 0,5 |
| 21,2 | 38 ± 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 | Resistance to fracture | | Bending test | Fatigue test |
|---|---|---|---|---|---|
| | $d_m$ | torque | angular deflection | torque | |
| | | mN·m | degrees | mN·m | revolutions |
| | | min. | min. | min. | 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 ± 400) rpm for enlargers up to and including nominal size, $d_m$, 070, and (1 000 ± 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.

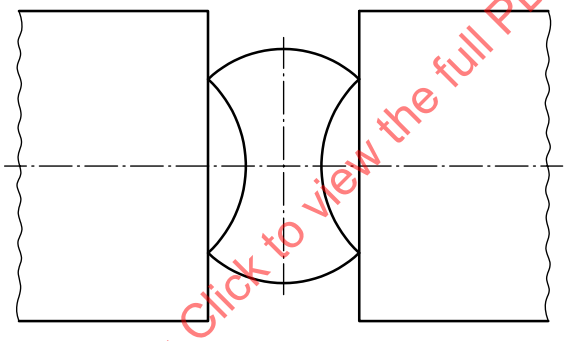


**Figure 6 — Chucking position of enlarger for testing twisting and angular deflection**