INTERNATIONAL STANDARD

ISO 3630-5

First edition
2011-10-01

Dentistry — Endodontic instruments —

Part 5: Shaping and cleaning instruments

Médecine bucco-dentaire — Instruments d'endodontie —

Partie 5: Instruments de mise en forme et de nettoyage

Reference number
ISO 3630-5:2011(E)

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
Web www.iso.org

Published in Switzerland

Foreword

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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 3630-5 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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 hazards are not included in this part of ISO 3630. However, in assessing possible biological or toxicological hazards, it is recommended that 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.

Dentistry — Endodontic instruments —

Part 5: Shaping and cleaning instruments

1 Scope

This part of ISO 3630 specifies requirements and test methods for hand-held or mechanically operated shaping and cleaning instruments used to perform root canal procedures not cited in ISO 3630-1, ISO 3630-2, ISO 3630-3 or ISO 3630-4.

This part of ISO 3630 specifies requirements for size, marking, product designation, safety considerations, labelling and packaging.

2 Normative references

The following referenced documents are indispensable for the application 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 1942, *Dentistry — Vocabulary*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and ISO 3630-1 apply.

4 Classification

For the purposes of this document, shaping and cleaning instruments are classified into five types, as specified in ISO 3630-1:2008, Clause 4.

5 Requirements

5.1 Material

The materials used for the working part, the shank and the handle of shaping and cleaning instruments are left to the discretion of the manufacturer but shall meet the requirements of ISO 3630-1:2008, 5.7.

5.2 Dimensions

5.2.1 General

The dimensions for the nominal diameter and taper of shaping and cleaning instruments shall meet the requirements of ISO 3630-1:2008, Clause 5.

The allowable tolerance for the identified diameters of Types 2, 3, 4, and 5 shall be less than 50 % of the difference between the preceding size and the next larger size instrument of the available brand sizes.

5.2.2 Diameter

The diameter of the shaping and cleaning instrument shall be as specified in ISO 3630-1.

5.2.3 Length

The length of the shaping and cleaning instrument shall be as specified in ISO 3630-1 and shall be measured as specified in ISO 3630-1:2008, 7.3.

5.2.4 For Type 1

Working part length shall be at least 16 mm. Operative part length and overall length shall be left to the discretion of the manufacturer. The manufacturer shall specify operative end length, which shall be within 0,5 mm of the length specified. When provided by the manufacturer, the actual overall length shall be within 1,0 mm of the stated length.

5.2.5 For Types 2, 3, 4 and 5

Working part length, operative part length, and overall length shall be left to the discretion of the manufacturer. The manufacturer shall specify working part length as a minimum; operative part length shall be within 0,5 mm of the length specified. When provided by the manufacturer, the actual overall length shall be within 1,0 mm of the stated length.

5.3 Mechanical

5.3.1 Resistance to fracture by twisting and angular deflection

When tested in accordance with ISO 3630-1:2008, 7.4, the shaping and cleaning instrument shall not fracture at less than the minimum value specified for the resistance to fracture in twisting and angular deflection, given as follows:

a) for Type 1, standard instruments, in Table 1;

b) for Type 2, tapered instruments, in Table 2 and Table 3;

c) for Type 3, shaped instruments, in Table 1;

d) for Type 4, non-tapered instruments, in Table 1;

e) for Type 5, non-uniform tapered instruments, in Table 2 and Table 3.

5.3.2 Stiffness

The stiffness is tested as resistance to bending.

When tested as specified in ISO 3630-1:2008, 7.5, the shaping and cleaning instrument shall not fracture and the maximum value given shall not be exceeded, as follows:

a) for Type 1, standard instruments, in Table 4;

b) for Type 2, tapered instruments, in Table 5;

c) for Type 3, shaped instruments, in Table 6;

d) for Type 4, non-tapered instruments, in Table 4;

e) for Type 5, non-uniform tapered instruments, in Table 5.

Table 1 — Resistance to fracture by twisting and angular deflection
(***applicable to Type 1, Type 3 and Type 4 instruments***)

Nominal size mm	Resistance to fracture (torque) mN·m, min.			Angular deflection Degrees (°), min.	
Instrument	**K File**	**H File**	**K Reamer**	**K File and K Reamer**	**H File**
06	0,34	0,34	0,34	360	180
08	0,50	0,50	0,50	360	180
10	0,60	0,60	0,60	360	180
15	0,80	0,80	0,80	360	180
20	1,76	1,18	1,18	360	180
25	2,94	1,96	1,96	360	180
30	4,42	3,43	3,43	360	180
35	6,36	4,91	4,91	360	180
40	9,81	6,37	6,87	360	120
45	11,78	8,82	9,32	360	120
50	16,68	11,78	11,78	360	120

Table 2 — Resistance to fracture by twisting
(***applicable to Type 2 and Type 5 instruments***)

Diameter of instrument at test location mm	Resistance to fracture (torque) mN·m, min.		
Instrument	**K File**	**H File**	**K Reamer**
< 0,124	0,34	n/a [a]	0,34
0,124 to < 0,164	0,59	0,49	0,59
0,164 to < 0,214	0,79	0,79	0,79
0,214 to < 0,264	1,77	1,18	1,18
0,264 to < 0,314	2,94	1,96	1,96
0,314 to < 0,364	4,42	3,43	3,43
0,364 to < 0,414	6,38	4,91	4,91
0,414 to < 0,464	9,81	6,38	6,87
0,464 to < 0,514	11,78	8,83	9,32
0,514 to < 0,564	16,68	11,78	11,78

[a] n/a = not applicable.

Table 3 — Angular deflection
(***applicable to Type 2 and Type 5 instruments***)

Diameter of instrument at test location (d_2) mm	Angular deflection Degrees (°), min.		
Instrument	**K File**	**H File**	**K Reamer**
< 0,414	360	180	360
0,414 to < 0,564	360	120	360
0,564 to 0,764	360	90	360

Table 4 — Bending moments
(***applicable to Type 1 and Type 4 instruments***)

Nominal size mm	Bending moment mN·m, max.		
Instrument	**K File**	**H File**	**K Reamer**
06	1,47	n/a [a]	1,47
08	1,96	1,96	1,96
10	2,45	1,96	2,45
15	4,91	3,43	4,91
20	7,85	6,37	7,85
25	11,78	9,80	11,78
30	14,72	13,23	14,72
35	18,65	16,66	21,59
40	24,53	21,59	31,40
45	35,33	31,36	36,80
50	44,16	50,96	40,24

[a] n/a = not applicable.

Table 5 — Bending moments
(***applicable to Type 2 and Type 5 instruments***)

Diameter of instrument at test location (d_2) mm	Bending moment mN·m, max.		
Instrument	**K File**	**H File**	**K Reamer**
< 0,124	1,47	n/a [a]	1,47
0,124 to < 0,164	2,45	1,96	2,45
0,164 to < 0,214	4,91	3,43	4,91
0,214 to < 0,264	7,85	6,38	7,85
0,264 to < 0,314	11,78	9,81	11,78
0,314 to < 0,364	14,72	13,25	14,72
0,364 to < 0,414	18,65	16,68	21,59
0,414 to < 0,464	24,53	21,59	31,40
0,464 to < 0,514	35,33	31,40	36,80
0,514 to < 0,564	44,16	51,03	40,24

[a] n/a = not applicable.

Table 6 — Bending moments
(***applicable to Type 3 instruments***)

Nominal size mm	Bending moment mN·m, max.
20	6,55
25	8,19
30	8,73
35	10,91
40	12,00
45	13,10
50	14,75

5.3.3 Position of fracture point (Type 3 only)

Fracture location of the “shaped” instrument when tested for the requirements given in 5.3.1 and 5.3.2 shall be 4 mm or less from the junction of the handle or shank with the instrument, when tested as specified in 7.2.

5.3.4 Handle or plastics shank security

The handle or plastics shank shall meet the requirements given in ISO 3630-1:2008, 5.8.3.

5.4 Chemical

5.4.1 Resistance to corrosion

The shaping and cleaning instrument shall meet the requirements given in ISO 3630-1:2008, 5.10.1.