INTERNATIONAL STANDARD

ISO 3630-3

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Dental root-canal instruments —

Part 3:
Condensers, pluggers and spreaders

Instruments pour canaux radiculaires utilisés en art dentaire —
Partie 3: Condenseurs, axial et latéral

Reference number
ISO 3630-3:1994(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.

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.

International Standard ISO 3630-3 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 *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*

It is anticipated that additional types of instruments will form the subject of additional future parts.

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Introduction

This International Standard covers significant features of hand-operated dental root-canal instruments which are used by the dentist for the mechanical preparation of root canals for treatment. In dentistry these instruments are also referred to as endodontic instruments.

Part 1, in addition to the specific instruments, includes general specifications, requirements and test methods which are applicable to all types of root-canal instruments.

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

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Dental root-canal instruments —

Part 3:
Condensers, pluggers and spreaders

1 Scope

This part of ISO 3630 specifies requirements and test methods for pluggers and spreaders, used to condense root-canal filling materials. In addition to standard sizes, this International Standard includes a secondary size system referred to as "taper size". These "taper size" sizes are identifiable by tapers which vary with instrument size.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 3630. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 3630 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 1942-3:1989, *Dental vocabulary — Part 3: Dental instruments.*

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

ISO 6360-1:1985, *Dental rotary instruments — Number coding system — Part 1: General characteristics.*

ISO 6360-2:1986, *Dental rotary instruments — Number coding system — Part 2: Shape and specific characteristics.*

3 Definitions

For the purposes of this part of ISO 3630, the following definitions apply. They go beyond those of ISO 1942 by being more precise.

3.1 root-canal filling condenser: Hand instrument the working part of which is cylindrical or tapered, and circular in cross-section. It is designed to condense the filling material in a root canal in the axial and/or lateral direction. Condensers are commonly used as pluggers or spreaders.

3.2 root-canal filling plugger: Hand instrument the working part of which is cylindrical or tapered, circular in cross-section and has a flat tip end. It is designed to compress filling materials in a root canal mainly in an axial direction.

3.3 root-canal filling spreader: Hand instrument the working part of which is tapered, circular in cross-section and has a pointed tip end. It is designed to compress filling materials in a root canal mainly in a lateral direction.

4 Requirements

4.1 Material

The working part and the shank of the instrument shall be made from corrosion-resistant material. The type and the treatment of the material is left to the discretion of the manufacturer.

The handles or shanks shall be made of plastics material or other corrosion-resistant materials at the discretion of the manufacturer.

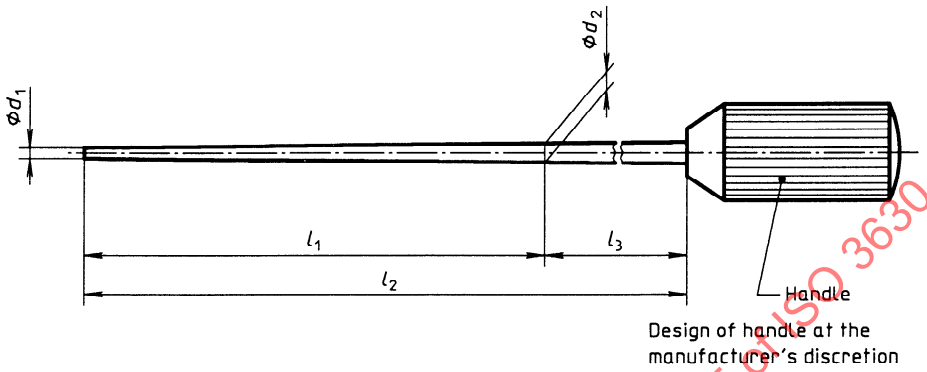
4.2 Dimensional requirements for standard-type pluggers and spreaders

The dimensions are given in millimetres.

The dimensional requirements shall comply with the appropriate tables and figures. Within the dimensional requirements, variations in shape and design are permitted.

Testing shall be carried out in accordance with ISO 3630-1:1992, subclauses 6.1 and 6.2.

4.2.1 Pluggers



The tip shall be flat and perpendicular to the axis of the instrument. The working part shall be either cylindrical or tapered with a taper of 0,02:1 along l_1 based on d_1 and d_2 of table 1.

The neck shall be either cylindrical or tapered. The diameter d_1 shall not exceed d_2 when cylindrical.

d_1 diameter of the working part at the tip end (nominal size)

d_2 diameter at the end of working part

l_1 length for measuring point d_2 and minimum length of working part

l_2 length of operative end

l_3 neck portion

Figure 1 — Plugger

Table 1 — Diameters and designation for standard pluggers

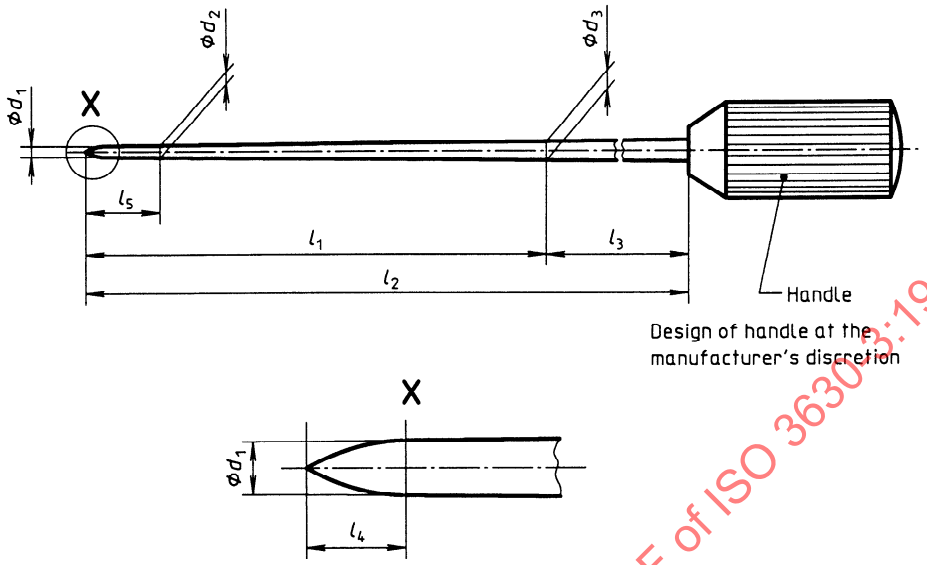
Nominal size	d_1 ± 0,02	d_2 ± 0,02	Colour designation
015	0,15	0,47	white
020	0,20	0,52	yellow
025	0,25	0,57	red
030	0,30	0,62	blue
035	0,35	0,67	green
040	0,40	0,72	black
045	0,45	0,77	white
050	0,50	0,82	yellow
055	0,55	0,87	red
060	0,60	0,92	blue
070	0,70	1,02	green
080	0,80	1,12	black
090	0,90	1,22	white
100	1,00	1,32	yellow
110	1,10	1,42	red
120	1,20	1,52	blue
130	1,30	1,62	green
140	1,40	1,72	black

Table 2 — Lengths

l_1 min.	l_2 ± 0,5
16	21
	25
	28
	31

NOTE — Lengths not listed shall be within ± 0,5 mm of the stated length.

4.2.2 Spreaders



The taper along l_1 is specified by d_2 and d_3 of table 3. The tip end shall be rounded or angled. The neck shall be either continuously tapered, cylindrical or a combination.

d_1 diameter of the projection of the working part at the tip end (nominal size)

d_2 diameter at length l_5

d_3 diameter at length l_1

l_1 length for measuring point d_3 and minimum length of working part

l_2 length of operative end

l_3 neck portion

l_4 length of tip

l_5 length for measuring point d_2

Figure 2 — Spreader

Table 3 — Diameters and designation for standard spreaders

Nominal size	d_1 ref.	d_2 ± 0,02	d_3 ± 0,02	Colour designation
010	0,10	0,16	0,42	purple
015	0,15	0,21	0,47	white
020	0,20	0,26	0,52	yellow
025	0,25	0,31	0,57	red
030	0,30	0,36	0,62	blue
035	0,35	0,41	0,67	green
040	0,40	0,46	0,72	black
045	0,45	0,51	0,77	white

Table 4 — Lengths

l_1 min.	l_2 ± 0,5	l_4	l_5
16	21 25 28 31	d_1 to 3 × d_1	3

NOTE — Lengths not listed shall be within ± 0,5 mm of stated length.

4.3 Dimensional requirements for taper size pluggers and taper size spreaders

The dimensions are given in millimetres.

The dimensional requirements shall comply with the respective tables and figures in 4.2.1 and 4.2.2 and table 5. Within the dimensional requirements, variations in shape and design are permitted.

Testing shall be carried out in accordance with ISO 3630-1:1992, subclauses 6.1 and 6.2.

Taper size pluggers and taper size spreaders have the nominal sizes for d_1 and taper selected from table 5 at the discretion of the manufacturer.

They have tapers different from standard type instruments.

There is no restriction regarding size. For example if $d_1 = 0{,}22$ and taper = 0,037, then the size designation would be 022 37.

Taper portion is uniform along the working length.

If the working part length, l_1, is less than 16 mm (see table 5), use the length to the maximum diameter along the taper.

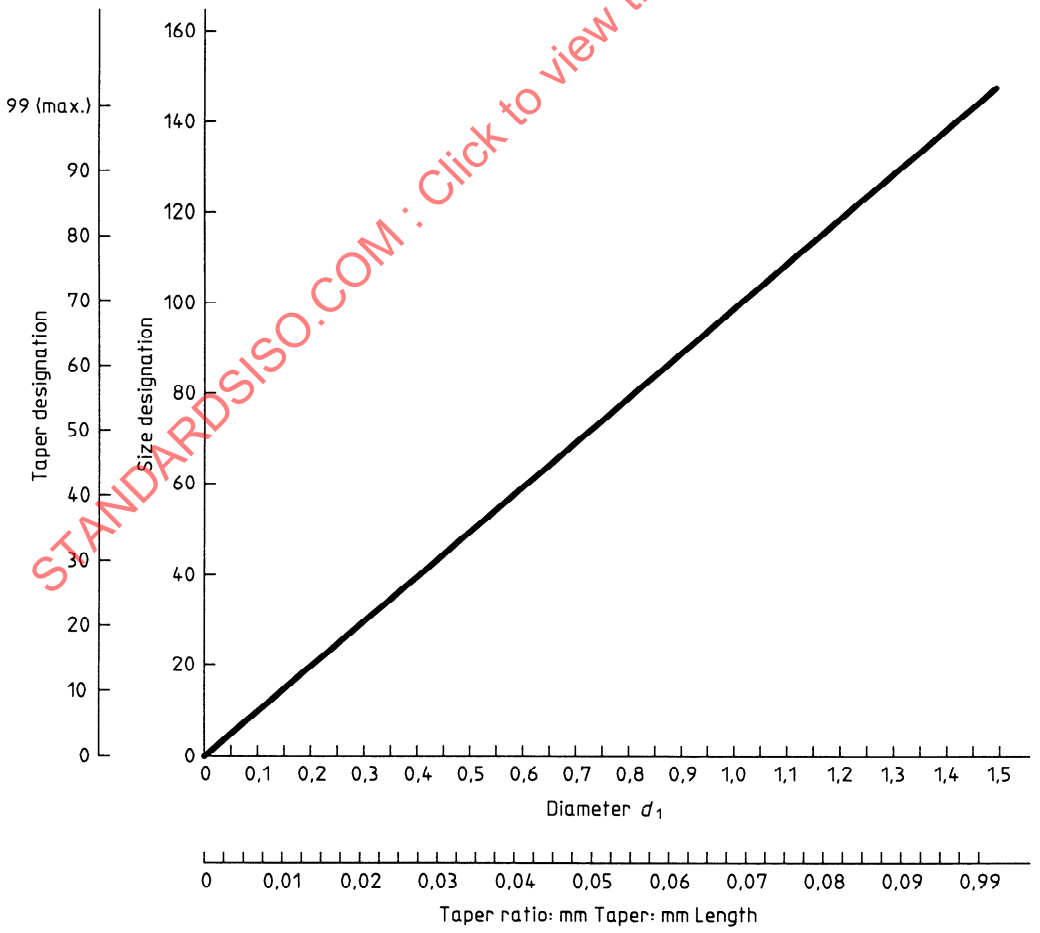
4.4 Pluggers and spreaders fitted in long handles (hand-type instruments)

The symbols and terms in 4.2.1, 4.2.2 and 4.3 also apply to instruments fitted in long handles.

The length and the diameter of the handle shall be at the manufacturer's discretion.

The condensers shall be either straight or bent as shown in figure 3. Length l_1 may be less than 16 mm at the discretion of the manufacturer.

Table 5 — Dimensions of taper size pluggers and taper size spreaders



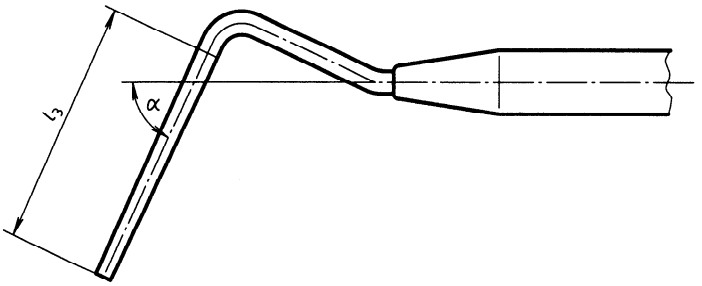


Figure 3 — Bent condenser

The angle α shown in figure 3 shall be consistent within the tolerance as specified in table 6 for any specific size within a brand.

Table 6 — Angle tolerance

Angle range α	Tolerance
$\alpha \leqslant 10°$	± 1°
$11° \leqslant \alpha \leqslant 25°$	± 2°
$26° \leqslant \alpha \leqslant 45°$	± 3°
$46° \leqslant \alpha$	± 5°

4.5 Mechanical requirements

4.5.1 Resistance to bending, finger-type instruments

After a deflection of 7°, the handle shall return to its original position on removal of the force; after a deflection of 9°, it shall return to within 2° of its original position. After a deflection of 18°, there shall be no sign of fracture. The condenser shall be deemed not to comply with this requirement if it fractures or if the permanent set is in excess of the figures stated.

Testing shall be carried out in accordance with 6.1.2.

4.5.2 Resistance to bending, hand-type instruments

After a deflection of 15 mm, the handle shall return to its original position on removal of the force; after a deflection of 20 mm, it shall return to within 4,5 mm of its original position. After a deflection of 40 mm there shall be no sign of fracture. The condenser shall be deemed not to comply with this requirement if it fractures or if the permanent set is in excess of the figures stated.

Testing shall be carried out in accordance with 6.1.3.

4.5.3 Handle security

Handles when affixed to the operative end shall be securely and permanently affixed. The instrument shall have no axial movement from the handle and shall not twist within the handle when torque is applied.

Testing shall be carried out in accordance with ISO 3630-1:1992, subclause 6.5.

4.5.4 Surface finish

The operative end shall have a smooth finish when visually inspected under × 4 magnification.

4.5.5 Chemical requirements, corrosion-resistance

Instruments shall not show evidence of corrosion when undergoing one of the corrosion tests specified in ISO 3630-1:1992, subclause 6.6.

4.5.6 Heat-carrier condenser

When instruments are indicated by the manufacturer as being heat-carriers, the instruments shall meet the requirements of 4.5.2.

Testing shall be carried out in accordance with 6.1.3.

5 Sampling

For each test, if not specified differently, more than 90 % of the samples tested shall comply. The sampling plan is as follows:

Test at least 10 instruments of each size to be tested. If all 10 instruments pass, the product passes. If eight

or fewer instruments pass, the product fails. If nine instruments pass, test five additional instruments. In this case, all five shall pass for the product to be accepted.

6 Testing

6.1 Resistance to bending, stiffness

6.1.1 Size

Measure d_1 and d_2 for pluggers, and d_2 and d_3 for spreaders. Record the diameters and the calculated taper for 10 instruments of each type to be tested.

6.1.2 Bend stiffness for finger-type instruments

Bend 10 instruments at 3 mm from the tip, to a total of 45° using the stiffness test apparatus shown in figure 4 and specified in ISO 3630-1:1992, subclause 6.4. Record the load in N·cm. Remove the instrument. Measure and record the permanent set using angle β of the shaft as shown in figure 5.

Dimensions in millimetres

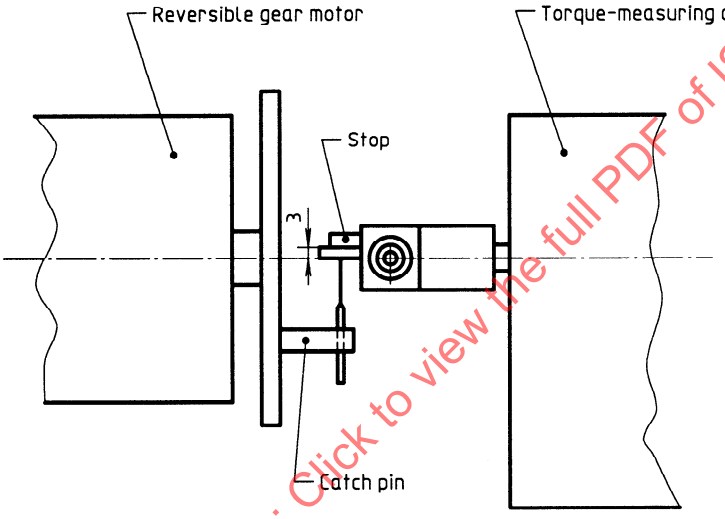


Figure 4 — Apparatus for bending test

Dimensions in millimetres

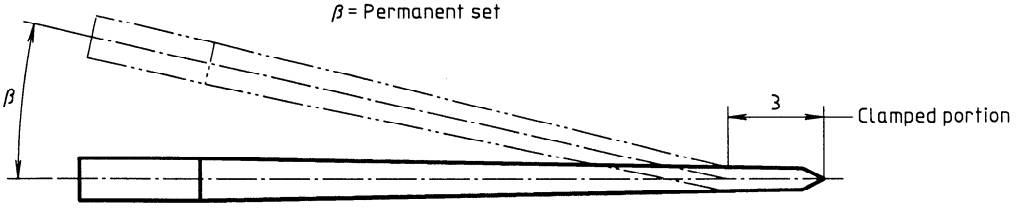


Figure 5 — Measurement of permanent set

6.1.3 Bend stiffness for hand-type instruments

Using stiffness test apparatus similar to figure 6 and described below, measure the applied load and the permanent set identified by the distance from the original position after the deflections of 15 mm, 20 mm and 40 mm. Note any sign of instrument failure. Test 10 instruments.

NOTE 1 Although this test may be carried out with any suitable clamp, it is strongly recommended that the apparatus illustrated in figure 6 be used.

Hold the tine of the condenser firmly, over a distance of 3 mm from the tip, in a suitable clamp or device so that the tip is not free to move appreciably during the test. Hold the condenser and clamp with the handle of the condenser pointing vertically upwards. Apply a force perpendicular to the axis of the handle, and in such a direction that the least possible torsion is applied to the tine. Measure the deflection at right angles to the original line of the handle at a point on the handle 125 mm from the point of entry of the tine into the clamp.

In order to determine the effect of heat on heat-carrier instruments, heat five instruments to a cherry-red colour on a Bunsen burner or other suitable source of heat. Keep them at room temperature for at least 10 min before testing.

7 Designation and identification

7.1 Standard type pluggers and spreaders

The designation of the size of standard type pluggers and spreaders is indicated by the diameter d_1 (nominal size) in a 3-digit number in accordance with table 1 or 3.

The handle shall be colour-coded in accordance with table 1 or 3 at the discretion of the manufacturer.

For sizes less than 100, the first digit 0 may be omitted.

For heat-carrier condensers, the marking on the handle shall include "HC" or "heatable".

7.2 Taper size pluggers and spreaders

The designation of the size of taper size pluggers and spreaders is indicated by the diameter d_1 (nominal size) in a 3-digit number in accordance with table 5.

In addition the designation of taper size pluggers and spreaders contains the selected taper, according to table 5, given in a 2-digit number.

EXAMPLE

022 37

In this case, the 022 is the diameter d_1 (nominal size) and 37 is the taper in thousandths of a millimetre.

For sizes less than 100, the first digit 0 may be omitted. For heat-carrier condensers the marking on the handle shall include "HC" or "heatable".

For taper size instruments, no colour designation is envisaged.

8 Packaging

Root-canal condensers are supplied, at the discretion of the manufacturer, as single instruments or in sets.

9 Marking

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

a) type of instrument, product identification;

b) length of operative end;

c) nominal size of instrument (The first digit "0" may be omitted for sizes less than 100);

d) name of manufacturer or distributor;

e) packaging date (coded or in plain language), expressed, if applicable, in accordance with ISO 8601;

f) number of instruments in unit package, unless visually obvious;

g) material of the operative end;

h) whether the instruments are sterile;

i) when the package is marked sterilized, the wording: "Sterility is not guaranteed after opening the package", or equivalent;

j) for heat-carrier instruments the letters "HC" or the word "heatable".

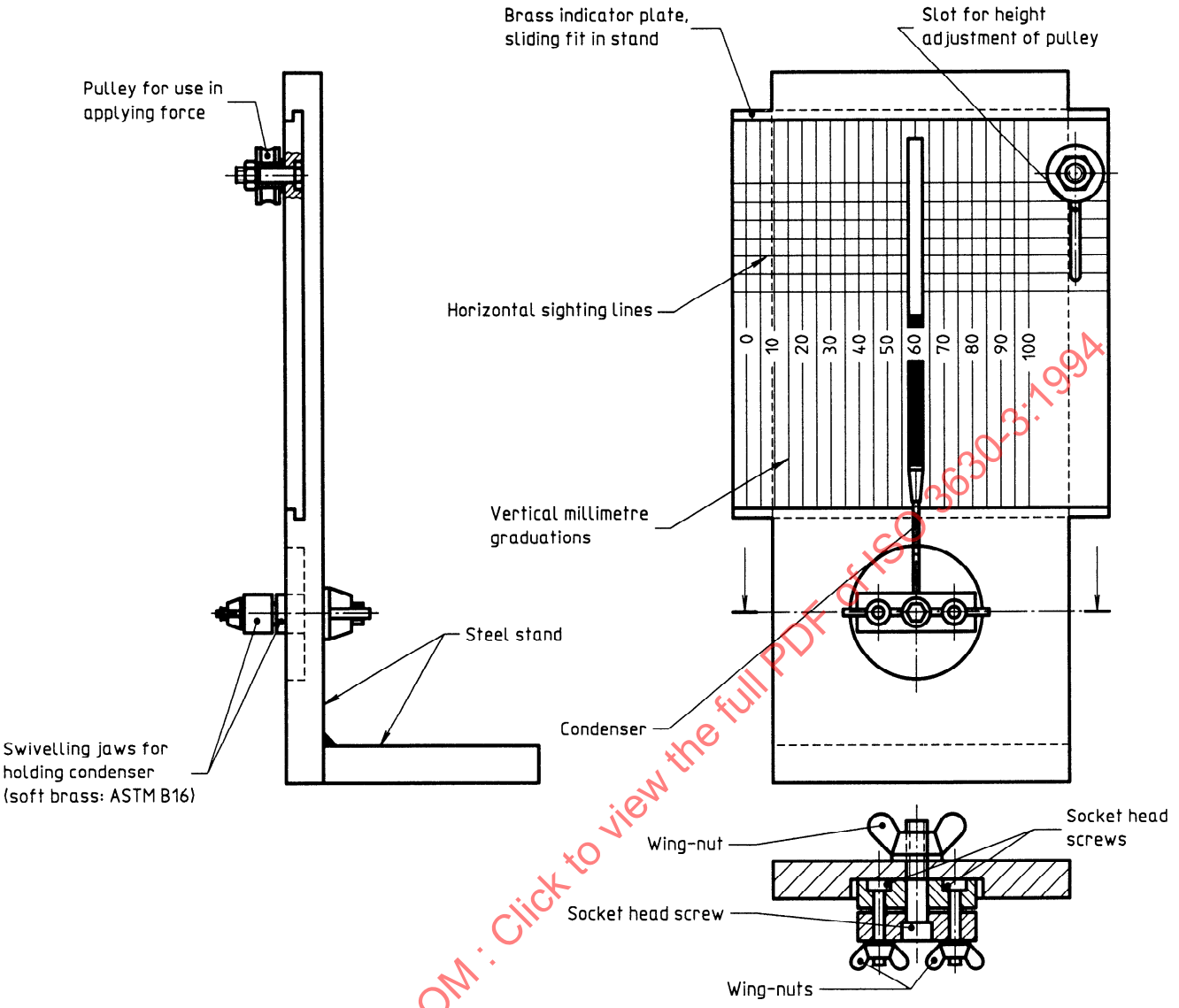


Figure 6 — Apparatus for resistance to bend testing, hand type