

BS EN ISO 21672-1:2012



BSI Standards Publication

# Dentistry — Periodontal probes

Part 1: General requirements  
(ISO 21672-1:2012)

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**EN ISO 21672-1**

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English Version

## Dentistry - Periodontal probes - Part 1: General requirements (ISO 21672-1:2012)

Médecine bucco-dentaire - Sondes parodontales - Partie 1:  
Exigences générales (ISO 21672-1:2012)

Zahnheilkunde - Parodontalsonden - Teil 1: Allgemeine  
Anforderungen (ISO 21672-1:2012)

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## Foreword

This document (EN ISO 21672-1:2012) has been prepared by Technical Committee ISO/TC 106 “Dentistry” in collaboration with Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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## Foreword

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ISO 21672-1 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

ISO 21672 consists of the following parts, under the general title *Dentistry — Periodontal probes*:

- *Part 1: General requirements*
- *Part 2: Designation*



# Dentistry — Periodontal probes —

## Part 1: General requirements

### 1 Scope

This part of ISO 21672 specifies general requirements and test methods for periodontal probes.

It is applicable to periodontal probes made of austenitic and martensitic stainless steel.

It is not applicable to periodontal probes with working ends made completely of plastics, nor to HAUER probes and periodontal probes with a defined probing force.

### 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 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 6892-1, *Metallic materials — Tensile testing — Part 1: Method of test at room temperature*

ISO 7153-1, *Surgical instruments — Metallic materials — Part 1: Stainless steel*

ISO 13402, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*

### 3 Terms, definitions and symbols

#### 3.1 Terms and definitions

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

##### 3.1.1

##### **periodontal probe**

dental hand instrument designed to measure subgingival pocket depth, used in dentistry for diagnostic purposes and assessment of the condition of periodontal pockets

##### 3.1.2

##### **furcation probe**

periodontal probe designed to probe the furcations of premolars and molars

#### 3.2 Symbols

$b_1$  blade thickness

$b_2$  blade width

$d_1$  diameter of spherical or round end

$d_2$  diameter of shank

$h_1$  blade height

$h_2$  shank height

$R_1$  radius of shank

$R_2$  radius of working end

$\alpha$  blade angle

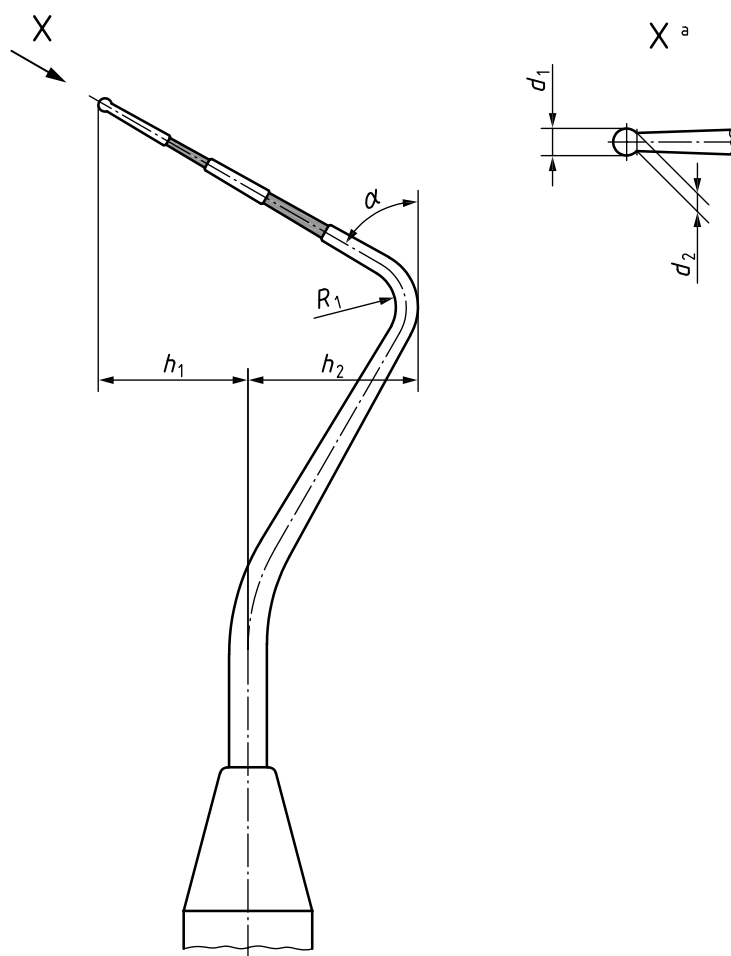
$\beta$  offset angle

#### **4 Classification**

For the purposes of this part of ISO 21672, periodontal probes are classified according to their intended function and their shapes into the following five types:

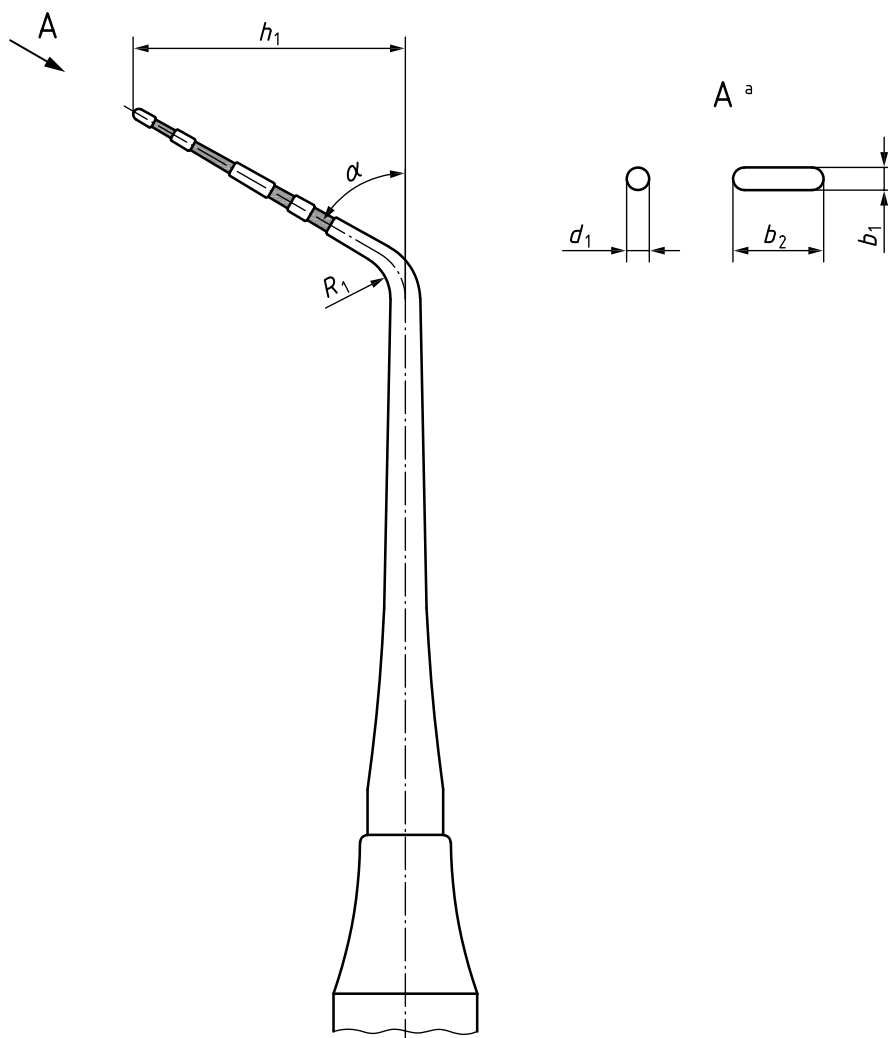
- Type 1, in accordance with Figure 1;
- Type 2, in accordance with Figure 2;
- Type 3, in accordance with Figure 3;
- Type 4, in accordance with Figure 4;
- Type 5, furcation probe, in accordance with Figure 5.





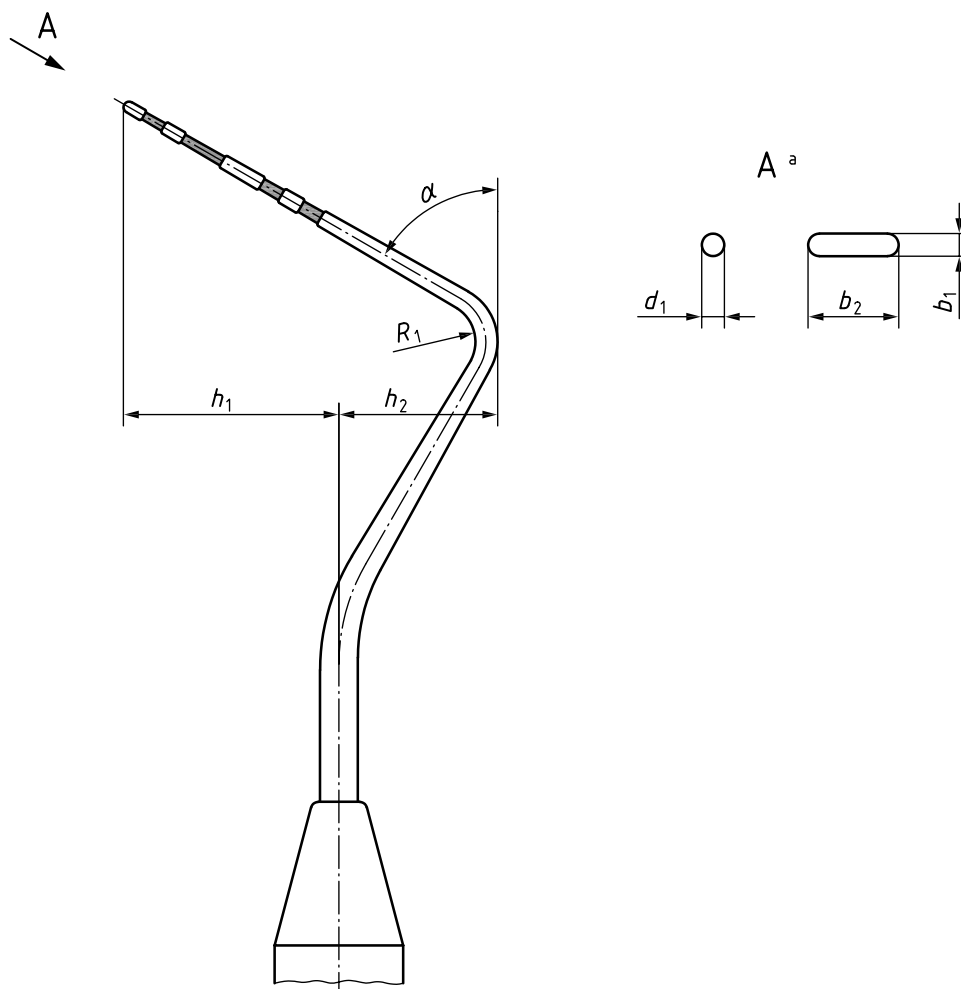
a Enlarged view of the working end.

**Figure 1 — Dimensions of Type 1 probes**



<sup>a</sup> Enlarged view of the two possible versions for the working end: spherical ( $d_1$ ) or oval ( $b_1$ ,  $b_2$ ).

**Figure 2 — Dimensions of Type 2 probes**



<sup>a</sup> Enlarged view of the two possible versions for the working end: spherical ( $d_1$ ) or oval ( $b_1$ ,  $b_2$ ).

**Figure 3 — Dimensions of Type 3 probes**

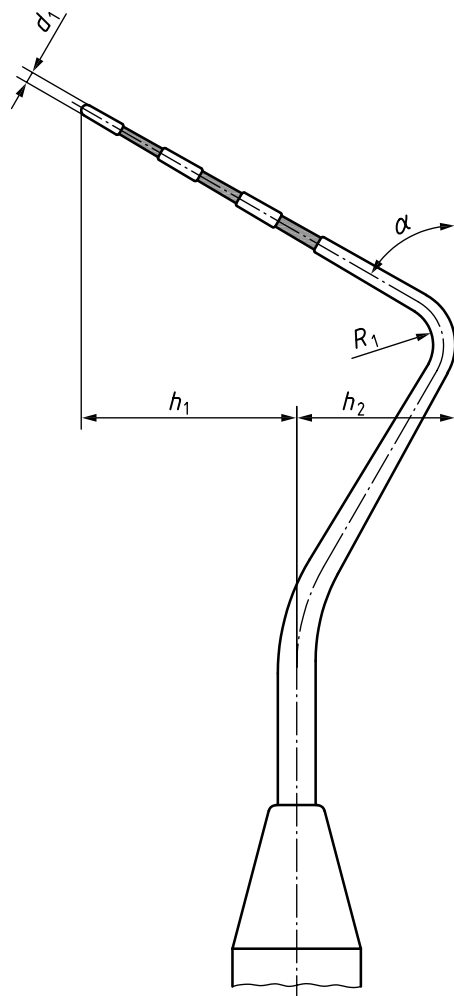


Figure 4 — Dimensions of Type 4 probes

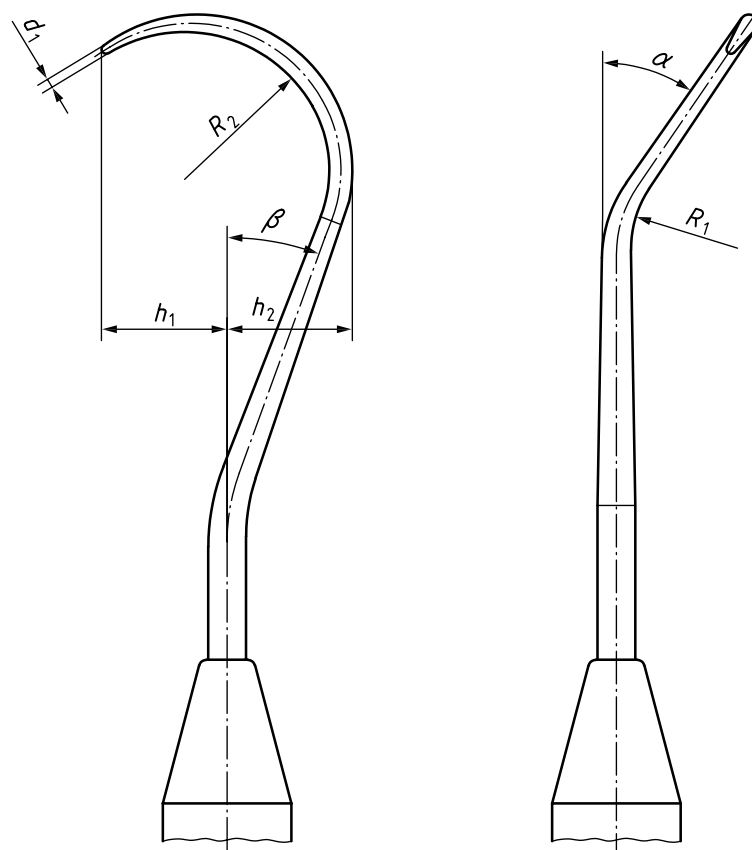


Figure 5 — Dimensions of Type 5 probes

## 5 Requirements

### 5.1 Design and dimensions

Periodontal probes shall have one of the designs shown in Figure 1 to Figure 5 and the dimensions given in Table 1.

Table 1 — Dimensions for periodontal probes

Dimensions in millimetres  
Angles in degrees

Type of probe	Quantity and tolerance									
	$b_1^a$ $\pm 0,1$	$b_2^a$ $\pm 0,1$	$d_1$ $\pm 0,05$	$d_2$ $\pm 0,05$	$h_1$ $\pm 2$	$h_2$ $\pm 2$	$R_1$ $\pm 1$	$R_2$ $\pm 1$	$\alpha$ $\pm 5$	$\beta$ $\pm 5$
1	—	—	0,6	0,4	6,6	7,5	2	—	60	—
2	0,5	1,5	0,5	—	12,0	—	2	—	60	—
3	0,5	1,5	0,5	—	8,4	4,5	2	—	60	—
4	—	—	0,5	—	9,5	7,0	2	—	60	—
5	—	—	0,4	—	6,2	6,3	4,7	6,5	35	20

<sup>a</sup> The working end of Type 2 and Type 3 has a cross-section that is either  
— circular, or  
— rectangular and flat with rounded corners.

## 5.2 Working end

### 5.2.1 Graduated scale

The working end of the periodontal probe shall have a graduated scale, in order to allow the measurement of periodontal pockets. The tolerances of each graduation, measured from the distal end of the tip, shall be  $\pm 0,2$  mm. The graduated scale may be colour-coded or non-colour-coded.

The periodontal probes specified in Table 2 shall have a graduated scale in accordance with Table 2. Graduated scales for other periodontal probes are at the discretion of the manufacturer.

**Table 2 — Graduated scales for periodontal probes**

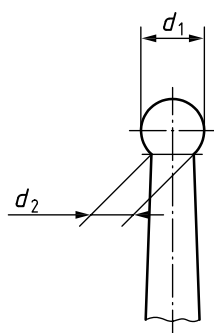
Dimensions in millimetres

Type	Pattern name	Figure	Graduated scale
1	WHO, PCP 11,5	Figure 1	3,5 – 5,5 – 8,5 – 11,5
2	Merritt, PCP 10	Figure 2	1 – 2 – 3 – 5 – 7 – 8 – 9 – 10
3	Goldman-Fox	Figure 3	1 – 2 – 3 – 5 – 7 – 8 – 9 – 10
4	PCP 11 or PCP 12 or PCP N 22 or QOW	Figure 4	3 – 6 – 8 – 11 or 3 – 6 – 9 – 12 or 2 – 4 – 6 – 8 – 10 – 12
5	Nabers	Figure 5	3 – 6 – 9 – 12

### 5.2.2 Shape of the working end

The shape of the working end of periodontal probes shall have one of the following profiles (see Figure 6):

- spherical end (circular cross-section);
- domed end (rectangular cross-section);
- flat end with rounded corners (rectangular cross-section).



a) Spherical end



b) Domed end



c) Flat end with rounded corners

**Figure 6 — Profiles of the working end**

### **5.2.3 Material of the working end**

The working ends of periodontal probes shall be made of stainless steel complying with ISO 7153-1. Other stainless steel materials may also be used provided the periodontal probes made of these materials meet the requirements of Clause 5.

### **5.2.4 Hardness and tensile strength of the working end**

#### **5.2.4.1 Martensitic stainless steel — Vickers hardness**

The Vickers hardness of the working end of the periodontal probe made of martensitic stainless steel shall be within the following range: 500 HV 1 to 650 HV 1.

The Vickers hardness shall be measured in accordance with ISO 6507-1 or, alternatively, ISO 15087-1:1999, Annex B.

#### **5.2.4.2 Austenitic stainless steel — Tensile strength**

The tensile strength of the working end of the periodontal probe made of austenitic stainless steel shall be within the following range: 1 600 MPa to 1 800 MPa based on wire diameter.

The wire diameter is at the discretion of the manufacturer.

The tensile strength shall be measured in accordance with ISO 6892-1.

### **5.2.5 Rigidity**

The working end of the periodontal probe shall not fracture when a rigidity test is performed in accordance with 6.4.

The tip of the working end shall not exhibit permanent deformation of more than 0,05 mm measured along the axis of the handle.

## **5.3 Handle**

The material of the handle of the periodontal probe, selected at the discretion of the manufacturer, shall meet the requirements of 6.2.

## **5.4 Surfaces**

### **5.4.1 All surfaces**

All surfaces shall be visibly free from pores, crevices, grinding marks, residual scales, acid, grease and residual grinding and polishing materials.

Surfaces shall be tested in accordance with 6.1.

### **5.4.2 Satin finish**

If a satin finish is used on any part of the instrument, it shall be both uniform and smooth and shall reduce glare.

Satin finishes shall be tested in accordance with 6.1.

## **5.5 Maximum overall length**

The maximum overall length of the periodontal probe shall be less than 178 mm.

NOTE This size limitation is intended to make the instrument compliant with current designs of autoclave trays and cassettes.

## 5.6 Resistance to reprocessing procedures

When tested in accordance with 6.2.2, there shall be no visible signs of deterioration. When tested in accordance with 6.3, there shall be no deterioration in tensile load or torque and no change in hardness value or rigidity.

## 5.7 Resistance to corrosion and thermal exposure

When tested in accordance with 6.2.3, there shall be no visible signs of corrosion. When tested in accordance with 6.3, there shall be no deterioration in tensile load or torque and no change in hardness value or rigidity.

## 5.8 Union of working end and handle

The tested working end of the periodontal probe shall not separate from the handle or become loose under tensile load when tested in accordance with 6.3.1, and under torque when tested in accordance with 6.3.2.

# 6 Test methods

## 6.1 Visual inspection

Conduct visual inspection at normal acuity at no more than  $\times 10$  magnification.

## 6.2 Resistance tests

### 6.2.1 Test sequence and cycles

Perform one of the two tests given in 6.2.2 and 6.2.3, in one continuous sequence of operation, for five cycles. After completing the test, rub the instrument vigorously with a cloth to remove blemishes.

### 6.2.2 Autoclave test

Carry out the autoclave test as specified in ISO 13402.

### 6.2.3 Boiling water test and thermal exposure test

Carry out the boiling water test and the thermal exposure test as specified in ISO 13402.

NOTE The combination of the boiling water test and thermal exposure test is used to evaluate the leakage resistance of hollow handles and the tolerance to dry-heat sterilization methods.

## 6.3 Test of union of working end and handle

### 6.3.1 Under tensile force

Subject the union between the working end and handle to a tensile force of 50 N, applied in the direction parallel to the centre line of the handle, for a duration of at least 5 s.

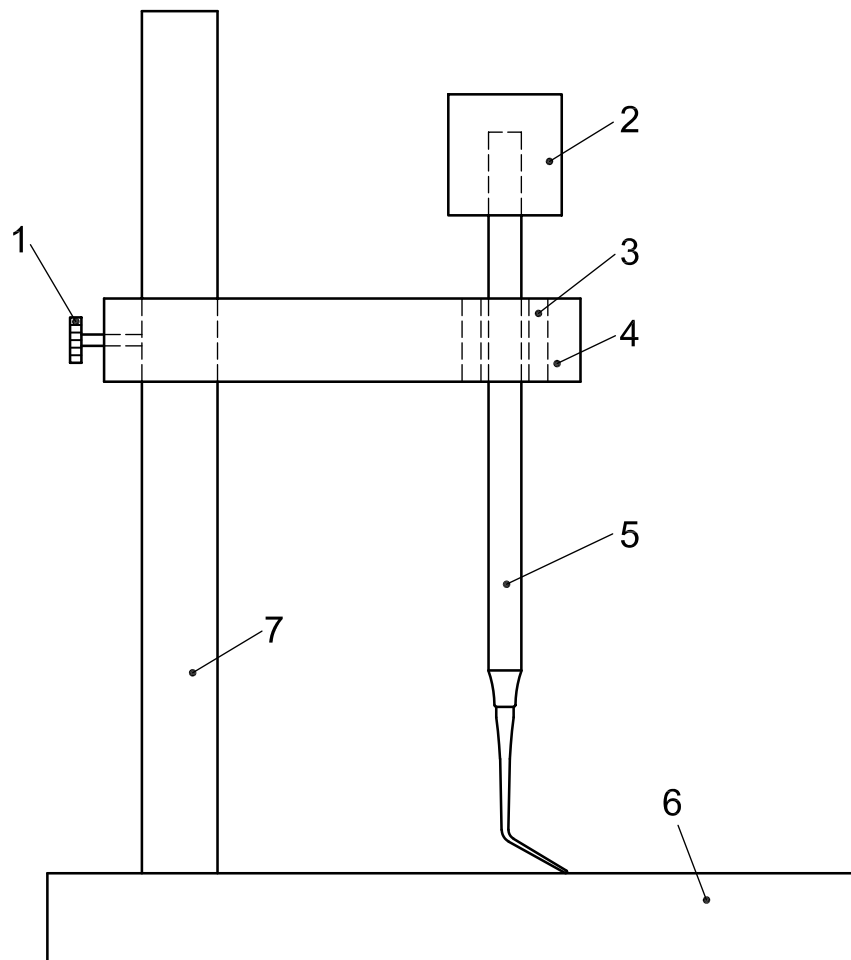
### 6.3.2 Under torque

Subject the union between the working end and the handle to a torque of 5 N-cm for a duration of at least 5 s.

## 6.4 Rigidity test

Subject the working end to a load of 50 g, applied in the direction parallel to the centre line of the handle, with the test apparatus illustrated in Figure 7 for a duration of 60 s.





**Key**

- 1 clamping knob
- 2 mass of 50 g
- 3 guide bushing with an inner diameter of 3,7 mm
- 4 supporting arm
- 5 periodontal probe under test
- 6 flat base
- 7 round shaft

**Figure 7 — Test apparatus for measurement of tip resistance to static loading**

## 7 Designation, labelling and marking

If the periodontal probe meets the requirements of this part of ISO 21672, then the manufacturer may include in the catalogue, on the package of the product, and/or on the instrument itself, a reference to this part of ISO 21672, i.e. ISO 21672-1:2012.

Information regarding the reprocessing of periodontal probes should conform to guidance given in ISO 17664. This information is not required to be included in the packaging of each instrument but should be available from the manufacturer upon request.

## Bibliography

- [1] ISO 15087-1:1999, *Dental elevators — Part 1: General requirements*
- [2] ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable devices*







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