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## Dental handpieces — Air-powered scalers and scaler tips

*Pièces à main dentaires — Instruments dentaires pour détartrage,  
actionnés par air comprimé, et parties actives de l'instrument pour  
détartrage*

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

International Standard ISO 15606 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 4, *Dental instruments*.

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## Introduction

This International Standard takes priority over IEC 60601-1:1988 as specified in the individual clauses of this International Standard.

Only the specifications laid down in this International Standard are applicable.

This International Standard refers to IEC 60601-1:1988, the basic standard on safety of medical electrical equipment, wherever relevant, by stating the respective clause numbers of IEC 60601-1:1988.

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# Dental handpieces — Air-powered scalers and scaler tips

## 1 Scope

This International Standard specifies requirements and tests methods for dental air-powered scalers and scaler tips, operated by connection to dental units, for use on patients. It also contains specifications concerning manufacturers' instructions, marking and packaging.

## 2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard 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 1942-3, *Dental vocabulary — Part 3: Dental instruments*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*.

ISO 9168, *Dental handpieces — Hose connectors*.

ISO 9687, *Dental equipment — Graphical symbols*.

ISO 13402:1995, *Surgical and dental hand instruments — Determination of resistance against autoclaving, corrosion and thermal exposure*.

ISO/TR 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*.

IEC 60651, *Sound level meters*.

## 3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 1942-3 and the following apply.

### 3.1

#### **scaler tip**

fixed or interchangeable dental instrument used in an air-powered scaler and consisting of a shaft and a working part for dental procedures of air scaling

## 4 Requirements and recommendations

### 4.1 General design

#### 4.1.1 General

Dental air-powered scalers should be comfortable for the operator to use and easy to manipulate. The outside surface of the scaler should be easy to clean, and particular attention should be given to providing secure gripping surfaces for operator manipulation. In order to reduce glare, highly polished surfaces should be avoided.

Dental air-powered scalers normally comprise a handpiece into which scaler tips are interchangeably inserted.

Internal parts should be designed in such a way that either penetration of liquids or particles is impossible or the scalers are easy to clean.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed. All tests described in this International Standard are type tests.

#### 4.1.2 Materials

All materials used in the construction of dental air-powered scalers should be suitable for their intended use.

When tested in accordance with 6.10, dental air-powered scalers shall be resistant to cleaning, disinfecting and sterilizing procedures recommended by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed.

#### 4.1.3 Construction and layout

The construction of dental air-powered scalers should provide for their safe and reliable operation. If field-repairable, the scalers should be capable of being easily disassembled and reassembled for maintenance and repair, utilizing either readily available tools or special tools supplied by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

They are considered as fulfilled if all tests specified in clause 6 are passed.

#### 4.1.4 Dimensions

If the manufacturer includes the dimensions of the scaler tip in the operator's manual, they shall be the dimensions 2 and 3 named in Figure 1 and shall be expressed to an accuracy of  $\pm 0,2$  mm, using the nomenclature of Figure 1.

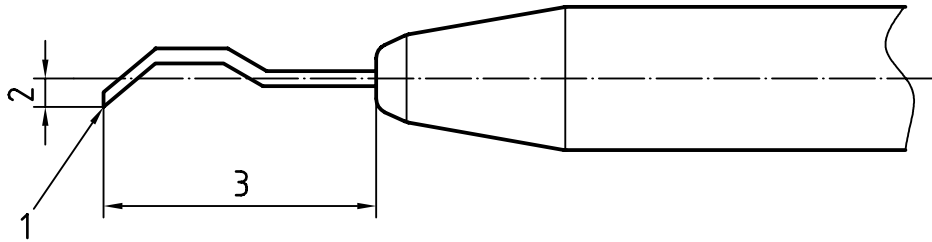
Testing shall be carried out by inspection and measurement in accordance with 6.2.

#### 4.1.5 Handpiece connection

The configuration, dimensions and tolerances of hose connections shall be in accordance with ISO 9168.

Testing shall be carried out by inspection and measurement in accordance with 6.1.



**Key**

- 1 Scaler tip
- 2 Offset
- 3 Length

**Figure 1 — Terminology for measuring dimensions**

## 4.2 Scaler tip

### 4.2.1 Extraction force

When installed in accordance with the manufacturer's instructions, scaler tips shall withstand, without displacement, a minimum axial (extraction) force of 20 N.

Testing shall be carried out in accordance with 6.3.1.

### 4.2.2 Torque

When installed in accordance with the manufacturer's instructions, scaler tips shall withstand, without displacement, a minimum torque of 200 N · mm.

Testing shall be carried out in accordance with 6.3.2.

### 4.2.3 Insertion force

The insertion force required to fit scaler tips to the handpiece shall not exceed a force of 50 N and/or a torque of 700 N · mm.

Testing shall be carried out in accordance with 6.3.3.

## 4.3 Performance

### 4.3.1 Frequency

The frequency of scaler tips shall be between 4 000 Hz and 40 000 Hz, when operated at the air flowrate and air pressure specified by the manufacturer.

Testing shall be carried out in accordance with 6.4.

### 4.3.2 Amplitude

The maximum amplitude of the scaler tip shall not normally exceed 200 µm, when operated at the air flowrate and air pressure as recommended by the manufacturer.

If the maximum amplitude of scaler tips exceeds 200 µm in any direction, the manufacturer's instruction shall include a corresponding warning.

Testing shall be carried out in accordance with 6.5.