

INTERNATIONAL STANDARD

ISO
20127

First edition
2005-03-15

Dentistry — Powered toothbrushes — General requirements and test methods

*Art dentaire — Broses à dents électriques — Exigences générales et
méthodes d'essai*



Reference number
ISO 20127:2005(E)

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Published in Switzerland

Foreword

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ISO 20127 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 7, *Oral hygiene products*.

Introduction

Powered toothbrushes are used for the removal of dental plaque and oral debris in order to facilitate oral hygiene.

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Dentistry — Powered toothbrushes — General requirements and test methods

1 Scope

This International Standard specifies requirements and test methods for the physical properties of powered toothbrushes in order to promote the safety of these products for their intended use.

Specifically excluded are other types of powered oral hygiene devices (such as powered interdental brushes) and manual toothbrushes.

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 3696:1987, *Water for analytical laboratory use — Specification and test methods*

IEC 60335-1:2004, *Household and similar electrical appliances — Safety — Part 1: General requirements*

IEC 60335-2-52, *Household and similar electrical appliances — Safety — Part 2-52: Particular requirements for oral hygiene appliances*

3 Terms and definitions

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

3.1

powered toothbrush

hand-held electrically-powered appliance, the brush head of which carries filaments, used primarily for cleaning surfaces within the oral cavity

3.2

brush head

fixed or removable working end of an electrically-powered toothbrush to which the filaments are attached

3.3

filament

single strand within the brush head

3.4

tuft

group of filaments gathered together and attached to the brush head

3.5

tuft removal force

force required to remove one tuft from the brush head

4 Requirements

4.1 Pass-fail criteria

Eight electrically-powered toothbrushes shall be tested. If none of the eight sampled powered toothbrushes fail, the powered toothbrush passes. If one toothbrush does not meet the minimum requirement, another eight powered toothbrushes shall be tested. If no more toothbrushes fail, the powered toothbrush passes. If a total of two or more powered toothbrushes of the sixteen fail, the powered toothbrush fails.

4.2 Physical inspection

The powered toothbrush, its components and all accessories shall be intact and free of visible contamination and sharp or rough surfaces when examined according to 5.3.

4.3 Electrical safety

All the powered toothbrushes and related accessories shall conform to the requirements described in IEC 60335-1 and IEC 60335-2-52.

4.4 Tuft retention

The tuft removal force shall not be less than 15 N when tested according to 5.4.

4.5 Mechanical strength

All powered toothbrushes and related accessories shall conform to the requirements described in IEC 60335-1:2004, Clause 21 and IEC 60335-2-52.

4.6 Resistance to chemical challenge

After being subjected to a chemical challenge test according to 5.5, the brush head shall conform to the requirements of the spring operated impact test as described in IEC 60335-1:2004, Clause 21, and the brush head shall be operational and free of sharp or rough surfaces when examined.

5 Test methods

5.1 Sampling

The powered toothbrushes obtained for testing shall be as manufactured and not modified in any way except as specified for this International Standard. Eight powered toothbrushes of each type shall be tested.

5.2 General test conditions

All tests shall be conducted using dry brushes at $(23 \pm 5) ^\circ\text{C}$ and relative humidity $(50 \pm 10) \%$.

5.3 Physical inspection

Inspection of the powered toothbrush and related accessories shall be performed using normal visual acuity without magnification. Tactile inspection shall also be performed to detect sharp or rough surfaces.

5.4 Tuft retention

5.4.1 Apparatus

5.4.1.1 Gripping unit, to secure the brush head, having a structure such that compressive force is not induced on the brush head (Figure A.1).

5.4.1.2 Clamp for securely holding all of the filaments in one tuft, for example a tuft gripping clamp (see Figure A.2). A collet chuck can also be used.

5.4.1.3 Apparatus for applying, measuring and indicating the removal force, a digital force gauge or a universal testing machine (force range from 5 N to 50 N, accurate to 0,1 N and a range of pulling speed from 20 mm/min to 100 mm/min).

5.4.2 Procedure

Place the brush in the gripping unit (5.4.1.1) and lock into place so that the clamp (5.4.1.2) pulls the tuft along the long axis of the tuft without any twisting. The brush head shall not be compressed during and after the placement.

Place the clamp on the filament tuft. Be sure to clamp all of the filaments from one tuft only; do not include filaments from the surrounding tufts. The filaments from one tuft should be secured at approximately the midpoint of the tuft length. Record the force required to pull out the tuft using the testing apparatus (5.4.1.3). Test two tufts of each tuft type (if available). The tufts should be non-adjacent.

5.5 Resistance to chemical challenge

5.5.1 Apparatus and chemicals

5.5.1.1 Apparatus for mixing the chemical challenge, for example stirring bar or mixer.

5.5.1.2 Container which can be sealed and is chemically inert, for example a polypropylene bottle.

5.5.1.3 Chemicals, of minimum purity and of the amounts listed in the Table 1.

Table 1 — Quantity and purity of products used

Chemicals	Minimum purity	Amount g
Ethanol	98,5 %	100
L-carvone	98,0 %	1,5
L-menthol	98,0 %	1,5
Sodium lauryl sulfate	95,0 %	15,0
Glycerine	98,0 %	200
Water	ISO 3696:1987, Grade 3	682

5.5.2 Procedure

Add 1,5 g L-carvone, 1,5 g L-menthol, 15 g sodium lauryl sulphate to 100 g ethanol in the container and stir well. Add 250 g water (ISO 3696:1987, Grade 3) and stir well to obtain a clear solution. Add 200 g glycerine and 432 g water (ISO 3696:1987, Grade 3) and stir to obtain a clear solution.

Place the removable brush head in the chemical-challenge solution. Ensure that the portion of the head containing filaments and at least 80 % of the total length of the removable head is immersed. If the head is not

removable, immerse the portion of the head containing filaments and an additional 80 % of the portion of the head exposed to a chemical challenge during normal toothbrushing. After immersion seal container. After 24 h without agitation, remove the toothbrush, rinse with water (ISO 3696:1987, Grade 3) and shake off excess water.

Perform the spring-operated impact test as described in IEC 60335-1:2004, Clause 21.

6 Test report

The test report shall contain the following information:

- a) identification of the powered toothbrush;
- b) results and the units of measure used;
- c) any unusual features noted during the test;
- d) reference to this International Standard (ISO 20127:2004);
- e) statement of conformance with this International Standard.

7 Marking and labelling

7.1 Powered toothbrush components

The powered toothbrush, all components and related accessories shall be marked in accordance with IEC 60335-1 and IEC 60335-2-52. The powered toothbrush shall also be marked with a manufacturer's tracking code.

7.2 Instructions for use

The product shall be supplied with instructions for use, maintenance and disposal and information on electrical safety (including warnings).

7.3 Marking and labelling

The packaging of powered toothbrushes shall be marked or labelled with the following information:

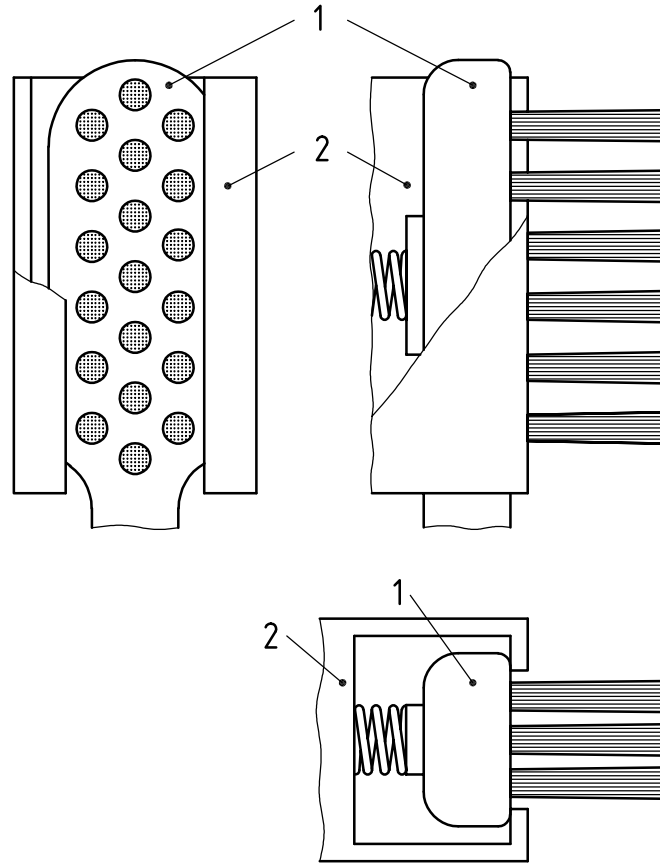
- a) name and address of manufacturer and/or responsible distributor;
- b) trade name;
- c) list of contents;
- d) tracking code.

8 Packaging

The packaging shall be such that it will neither contaminate nor permit contamination of the powered toothbrush when examined in accordance with 5.3.

Annex A
(informative)

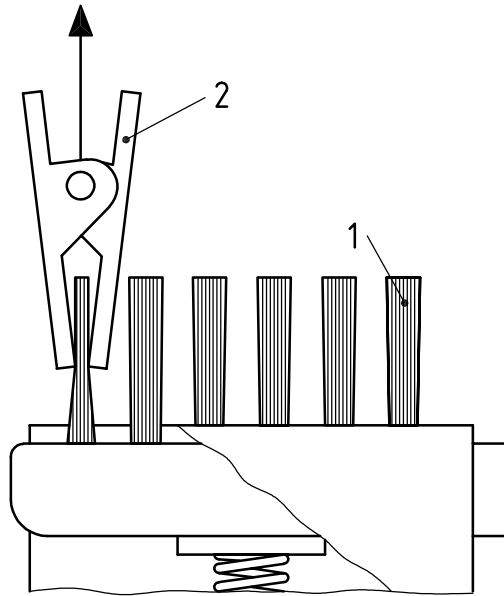
Gripping devices



Key

- 1 brush head
- 2 brush-head gripping device

Figure A.1 — Brush-head gripping unit



Key

- 1 tuft
- 2 tuft gripping clamp

Figure A.2 — Tuft gripping clamp

ICS 97.170

Price based on 6 pages