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Zobozdravstvo - Fizikalne lastnosti električnih zobnih ščetk (ISO/DIS 20127:2019)

Dentistry - Physical properties of powered toothbrushes (ISO/DIS 20127:2019)

Zahnheilkunde - Physikalische Eigenschaften von elektrischen Zahnbürsten (ISO/DIS 20127:2019)

Médecine bucco-dentaire - Caractéristiques physiques des brosses à dents électriques (ISO/DIS 20127:2019)

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee [or Project Committee] ISO/TC 106, Subcommittee SC 7, Oral care products.

This second edition cancels and replaces the first edition (ISO 20127:2005), which has been technically revised.

The main changes compared to the previous edition are as follows:

- a requirement and a test method for toothbrush head plate retention have been added;
- clarification in Scope to fulfil all types of powered toothbrushes.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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 — Physical properties of powered toothbrushes

1 Scope

This document 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.

There are different technologies of power toothbrushes. Common features of those powered toothbrushes for which this document applies:

- a battery;
- a motor;
- a mechanical or magnetic drive system;
- a moving brush head with tufts.

Power toothbrushes may have different motions of the moving brush head (e.g. oscillating-rotating, side-by-side) and may have different frequencies and velocities for the moving brush head.

The requirements listed in this document shall be fulfilled for all types of power toothbrushes if applicable. However, some requirements may not be applicable for all types, e.g. brush head retention can only be applied if the brush has a head portion that might get detached from the brush tube.

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

2 Normative references 19555595c/sist-en-iso-20127-2020

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 60068-2-75, Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests

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

 $\label{lem:condition} \begin{tabular}{l} \textbf{IEC 60335-2-52}, \textit{Household and similar electrical appliances} \textbf{---} \textit{Safety ---} \textit{Part 2-52: Particular requirements} \\ \textit{for oral hygiene appliances} \end{tabular}$

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

brush head

working end of an electrically powered toothbrush to which the filaments are attached

[SOURCE: ISO 22254:2005, 3.2, modified]

3.2

filament

single strand within the brush head

[SOURCE: ISO 22254:2005, 3.3]

3.3

powered toothbrush

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

3.4

toothbrush head removal force

force required to remove the toothbrush tuft plate from the toothbrush shaft

3.5

tuft

group of filaments gathered together and attached to the brush head

[SOURCE: ISO 22254:2005, 3.4]

3.6

tuft removal force

force required to remove one tuft from the brush head

[SOURCE: ISO 20126:2012, 3.5]

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4 Requirements

4.1 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 6.2 and 6.3.

4.2 Electrical safety

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

4.3 Tuft retention

The tuft removal force shall not be less than 15 N when tested according to 6.4.

4.4 Mechanical strength

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

The retention force of the toothbrush head plate shall not be lower than 50 N for each individual sample when tested according to 6.5.

4.5 Resistance to chemical degradation

Subject the brush head to a chemical degradation test according to <u>6.6</u>. After this test, the brush head shall conform to the requirements of the spring-operated impact test as described in IEC 60335-1 and the brush head shall be operational and free of sharp or rough surfaces when examined.

5 Sampling and pass-fail criteria

5.1 Sampling

Eight powered toothbrushes of each type shall be tested.

The powered toothbrushes sampled for testing shall be as manufactured and not modified in any way except as specified for this document.

5.2 Pass-fail criteria

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.

6 Test methods | STANDARD PREVIEW

6.1 General test conditions and ards. iteh.ai)

All tests shall be conducted using dry brushes at (23 ± 5) °C and relative humidity (50 ± 10) %.

6.2 Visual inspection site hai/catalog/standards/sist/3244fb16-5a0c-44a7-ad9e-

Perform visual inspection of the powered toothbrush and related accessories using normal visual acuity without magnification.

6.3 Tactile inspection

Perform tactile inspection of the powered toothbrush and related accessories in order to detect sharp or rough surfaces.

6.4 Tuft retention

6.4.1 Apparatus

- **6.4.1.1 Gripping unit, to secure the brush head,** having a structure such that compressive force is not induced on the brush head (<u>Figure A.1</u>).
- **6.4.1.2** Clamp for securely holding all of the filaments in one tuft, for example a tuft gripping clamp (see Figure A.2) or a collet chuck.
- **6.4.1.3 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).