

# DRAFT UGANDA STANDARD

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## Manual Toothbrush — Specification

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DRAFT UGANDA STANDARD

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## Foreword

Uganda National Bureau of Standards (UNBS) is a parastatal under the Ministry of Trade, Industry and Cooperatives established under Cap 327, of the Laws of Uganda, as amended. UNBS is mandated to co-ordinate the elaboration of standards and is

- (a) a member of International Organisation for Standardisation (ISO) and
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- (c) the National Enquiry Point on TBT Agreement of the World Trade Organisation (WTO).

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Draft Uganda Standards adopted by the Technical Committee are widely circulated to stakeholders and the general public for comments. The committee reviews the comments before recommending the draft standards for approval and declaration as Uganda Standards by the National Standards Council.

The committee responsible for this document is Technical Committee UNBS/TC5, *Chemicals and Environment*, Subcommittee SC3, *Plastics and Related products*.

This second edition cancels and replaces the first edition (US 466:2006), which has been technically revised.

# Manual toothbrush — Specification

## 1 Scope

This Draft Uganda standard specifies the requirements, sampling and methods of test for manual toothbrushes manufactured for oral hygiene.

## 2 Normative references

The following referenced documents 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 3696, *Water for analytical laboratory use — Specification and test methods*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

— ISO Online browsing platform: available at <http://www.iso.org/obp>

### 3.1

#### **toothbrush**

an implement comprising of the handle and head, designed to help in oral hygiene

### 3.2

#### **handle**

body of the toothbrush excluding the head

### 3.3

#### **lot**

quantity of toothbrushes of the same size, grade, materials and have the same batch identification, from one manufacturer, submitted at any one time for inspection and testing

### 3.4

#### **head**

stock and the filaments of the toothbrush

### 3.5

#### **shaft**

complete toothbrush except the tufts

### 3.6

#### **stock**

part supporting the tufts

**3.7**

**tuft**

cluster of aggregate of mono filaments/bristles fixed in one hole in the stock

**3.8**

**monofilaments**

single strand of material in a tuft

**3.9**

**cleaning element**

protrusions fixed on the brush head, which is designed to impart the cleaning of the tooth surface, interproximal spaces and near gum line. It consists of filaments; tufts made of filaments or specially designed elements (for example Lamella) of synthetic materials, see fig 1

**3.10**

**end rounding**

shape of the tip of a monofilament

**3.11**

**pull strength**

force required to pull out a tuft from the head of a toothbrush

**3.12**

**pendulum length (Lp)**

distance, expressed in metres, between the axis of rotation of the pendulum and the centre of percussion (3.13), equal to an equivalent theoretical pendulum mass concentrated at the point which gives the same period of oscillation, as the actual pendulum

**3.13**

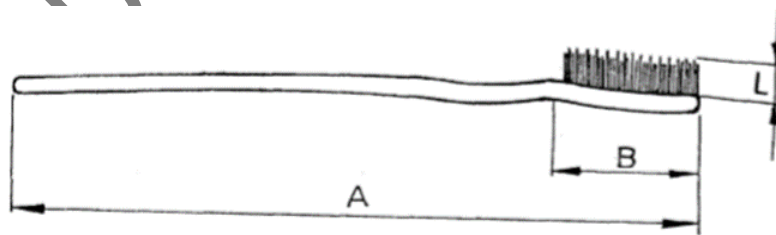
**centre of percussion**

point on pendulum at which a perpendicular impact in the plane of swing does not cause reaction forces at the axis of rotation of the pendulum

**3.14**

**period of oscillation of the pendulum (Tp)**

period, expressed in seconds, of a single complete oscillation (to and fro) of the pendulum, oscillating at angles of oscillation of less than 5° to each side of the vertical



**Figure1 — Brush handle and head**

**Key**

A shaft, excluding L

B stock

L cleaning element/ filaments

B and L head

## 4 Sizes

Toothbrushes shall be of the following sizes depending on their length.

**Table 1 — Length for toothbrushes**

Size	Minimum length of Toothbrushes
	mm
Adult (Above 18 years)	150
Junior (3 years to 17 years)	120
Baby (2 years and below)	90

## 5 Classification

A toothbrush shall be classified under the following types depending on the gauge of the filaments

- a) Super-soft;
- b) Soft;
- c) Medium;
- d) Hard and
- e) Dual/multi texture.

## 6 Requirements

### 6.1 General requirements

The toothbrush shall be intact and free from visible contamination, sharp and rough surfaces when examined

#### 6.1.1 Cleaning Element

**6.1.1.1** It shall consist of nylon filaments — 66; 610; 612, polyester filaments, poly butylene terephthalate filaments, thermoplastic elastomer, polyethylene filaments, polypropylene filaments, or any combinations of above materials

**6.1.1.2** It shall be free from any disagreeable odour, taste and toxic elements

**6.1.1.3** The colours used on the cleaning element shall be non-toxic

**6.1.1.4** The filaments shall be in the form of monofilament, co-extruded filaments, filled filaments, or structured filaments.

**6.1.1.5** The cross-section of the filaments shall be of circular, square, hexagonal, diamond, rectangular, or any other suitable shape.

**6.1.1.6** The diameter of filaments used as filling material in the cleaning element of the toothbrush, shall be as given in Table 2. Tolerance limit for individual filament shall be  $\pm 0.02$  mm of claimed diameter and average of fifty filaments shall fall in the range specified in Table 2

**Table 2 — Diameter and minimum number of monofilaments**

SN	Size	Type	Diameter of Filaments mm	Minimum number of monofilaments
1	Adult	Super soft	0.12 ≤ 0.15	300
2	Adult	Soft	0.15 ≤ 0.20	300
3	Adult	Medium	0.20 ≤ 0.25	300
4	Adult	Hard	0.25 ≤ 0.35	300
5	Junior	Soft	0.15 – 0.20	250
6	Baby	Soft	0.12 – 0.18	250

### 6.1.2 Shaft

6.1.2.1 The shaft shall be manufactured from the following plastic materials and shall be free from any odour

- a) Polystyrene moulding powder;
- b) Polypropylene moulding powder (Homo polymer, co-polymer);
- c) Cellulose acetate propionate moulding powder;
- d) Styrene acrylonitrile butadiene styrene (SAN);
- e) Polyethylene terephthalate;
- f) Polycarbonate;
- g) Acrylonitrile butadiene styrene (ABS);
- h) Methacrylate butadiene styrene (MBS);
- i) Poly methyl methacrylate and
- j) Thermoplastic elastomer (TPE).

The manufacturer may choose to design the shaft from one or more polymers from above list

6.1.2.2 For ease of handgrip during use, the shaft may have extra indentations or appendages

### 6.1.3 Anchor Wire

Anchor wire if used for toothbrush shall be manufactured by tufting/staple technology. It shall consist of aluminium, brass, nickel, silver, or any other suitable non-corrosive materials

### 6.1.4 Tufting

6.1.4.1 Cleaning element shall be fixed to brush head using a suitable technology such as staple technology using an anchor wire, welding technology, fusion technology, in mould welding technology etc.

6.1.4.2 In case of toothbrushes in which anchor wire is used for fixing each cleaning element which is in the form of a tuft, it shall be individually fixed in a suitable sized tuft hole on the brush head and sunk to the depth up to start of bottom cup of the hole.



**6.1.4.3** The maximum protrusion of the cleaning elements from surface of head shall be 13 mm. and the minimum shall be 7mm

**6.1.4.4** The tops of tufts may be trimmed to any profile to suit individual design but shall be in a manner, which does not injure the gums while brushing.

**6.1.4.5** The maximum width of head of the toothbrush shall not be more than 13 mm for rectangular head, in case of adult; 12 mm in case of junior and 9 mm in case of baby size.

### **6.1.5 Head**

The brush head shall not have any protruding parts that may injure the user.

## **6.2 Specific requirements**

### **6.2.1 End rounding**

The heads of monofilaments shall be polished to give them round shape. The end rounding shall not be less than 50 percent when determined according to the method given in Annex A

### **6.2.2 Tuft anchorage**

The force required for pulling out an individual tuft shall not be less than 10 N when tested according to the method given in Annex B.

### **6.2.3 Handle impact strength**

When tested in accordance with the test method given in Annex C, the handle should not fracture. If the handle does fracture, however, the minimum absorbed energy at fracture shall be 0.8 J

### **6.2.4 Chemical challenge**

The toothbrush shall comply with 6.2.5 after being subjected to a chemical challenge as given in Annex E

### **6.2.5 Fatigue Resistance**

The toothbrush shall complete 75 000 cycles without breaking when tested in accordance to test method given in Annex D

NOTE: A cycle is one application of force followed by removal of the force

## **7 Labelling**

The container for each toothbrush shall be legibly and indelibly marked with the following information:

- a) manufacturer's name and physical address;
- b) type of brush e.g. soft, hard;
- c) country of origin;
- d) size of brush e.g. Adult, Junior, Baby;
- e) batch number;
- f) composition of monofilaments e.g. ABS, MBS,OR ABS and MBS and

g) type of polymer

## **8 Packaging**

The packaging shall be such that it will neither contaminate nor permit contamination of the toothbrush. The head of the toothbrush shall be visible when it is in the container and each toothbrush shall be individually packed.

## **9 Sampling**

Sampling shall be done in accordance with Annex F.

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## Annex A (normative)

### Determination of end rounding

#### A.1 Test specimen

Three of the toothbrushes in the sample taken in accordance with Annex F

#### A.2 Apparatus

Simple or compound microscope (advisable) with adequate magnification to observe the end rounding of filament tips

#### A.3 Procedure

**A.3.1** Remove the filaments from three tufts in each of the toothbrushes under test. By means of a microscope, examine the free end of each filament. Record the appearance of each filament free end as acceptable (including ideal) or not acceptable, using the examples depicted in Fig.A1 as criteria for judgement.

Retain the toothbrushes for the test described in Annex C

**A.3.2** Count the number of tips of monofilaments in each selected tufts;  $E_1$ ,  $E_2$ ,  $E_3$

where

$E_1$  Number of tips of monofilament in first tuft

$E_2$  Number of tips of monofilament in second tuft and

$E_3$  Number of tips of monofilament in third tuft.

**A.3.3** Strand Count =  $E_1$  or  $E_2$  or  $E_3$

**A.3.4** Observe the end rounding of the tips of monofilament from each selected tufts under microscope and count the number of tips with acceptable end rounding. The tips of monofilament with any sort of sharp angles/corners or edges shall be unacceptable and those without any such sharp angles/corners or edges shall be acceptable, note down the findings  $OK_1$ ,  $OK_2$  and  $OK_3$

where:

$OK_1$  Number of tips of acceptable monofilament in first tuft;

$OK_2$  Number of tips of acceptable monofilament in second tuft, and

$OK_3$  Number of tips of acceptable monofilament in third tuft.

#### A.4 Calculation

A.4.1 End rounding, percent

$$\frac{OK_1 + OK_2 + OK_3}{E_1 + E_2 + E_3} \times 100$$

A.4.2. Repeat the same procedure for two more toothbrushes from a lot

A.4.3 Take average of end rounding of three toothbrushes.

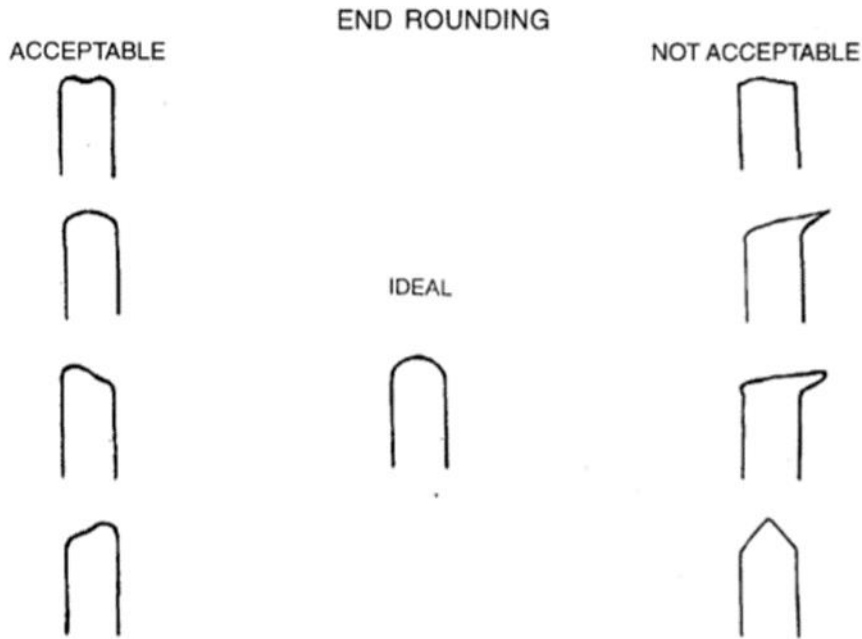


Figure A1 — Guidelines for acceptable and unacceptable end rounding

## Annex B (Normative)

### Tuft anchorage test

#### B.1 Apparatus

**B.1.1** A simple instrument as shown in Figure B1 can be used for testing the pull strength. This unit is suitable for mounting on a wall. It consists of dial force gauge/weighing scale operating on spring (B) mounted on wooden ply (B). A tubular tuft-holder (C) is hung on the hook of dial gauge. A clamp for holding toothbrush (E) is provided which is movable downward and upward with a screw (G).

**NOTE** — Manufacturer may use sophisticated electronic instrument available in market to determine the tuft anchorage strength

**B.1.2** A water bath containing distilled water maintained at  $60 \pm 2^\circ\text{C}$ .

**B.1.3** A water bath containing distilled water maintained at  $4 \pm 1^\circ\text{C}$ .

#### B.2 Procedure

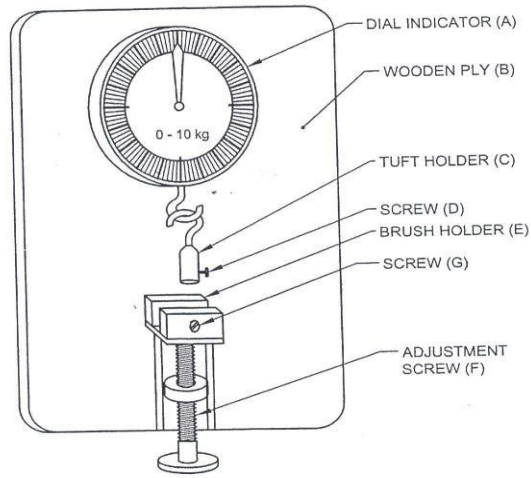
**B.2.1** Immerse the head of the toothbrush under test in the water bath at  $60 \pm 2^\circ\text{C}$  for a period of 2 min After 2 min remove the toothbrush from the water and place it in the water bath at  $4 \pm 1^\circ\text{C}$  for a further 2 min

**B.2.2** Immediately completing B.2.1 fix the toothbrush head with tufts in upward direction in the toothbrush holder with the help of screw (F).

**B.2.3** Insert all filaments of one tuft in the hole provided at the bottom of tubular tuft-holder (C). Care should be taken not to allow filaments from adjacent tuft to enter into the hole. Fix the tuft firmly with the help of screw (D).

**B.2.4** Adjust the pointer on dial to zero by adjustment of screw (G)

**B.2.5** Move down the toothbrush holder slowly with screw (G) watching the pointer on dial carefully. Note down the reading on dial at which the tuft comes out of the hole. This is the pull strength of the tuft.



FigureB1 — Instrument for determination of pull strength

## Annex C (normative)

### Handle impact test

#### C.1 Apparatus

**C.1.1** Clamping unit, to hold the toothbrush handle (see Figure C1). The clamping unit consists of the main block (key item 4) and the holding blocks (key items 6 and 7). The holding blocks can be moved by screws. The radius of the internal edges of the main block and the holding blocks should be  $(4.0 \pm 0.1)$  mm.

**C.1.2** **Impact tester**, with the striker for the pendulum

**C.1.3** **Striker for pendulum** made of hardened steel, with a cylindrical surface having a radius of curvature of  $(0.80 \pm 0.20)$  mm, with its axis horizontal and perpendicular to the plane of swing of the pendulum.

#### C.2 Procedure

Hold the toothbrush handle using the clamping unit (C.1.1) with a clamping torque of  $(0.70 \pm 0.03)$  Nm. Ensure that the tuft-hole plane (key item 1) is perpendicular to the bottom plane of the clamping unit (key item 5). The metal plate(s) can be used as the spacer to adjust the angle. Set the clamping unit on the impact tester so that the striker edge can hit the toothbrush handle at the centre of the tuft-hole area (key item 8) from the opposite side of the tuft-hole surface (key item 2).

The length,  $L_1$ , between the top plane of the clamping unit (key item 3) and the centre of the tuft-hole area (key item 8) is 55 mm. Any curvature of the corners of the clamping unit shall not be taken into account for  $L_1$ .

**NOTE 1** The impact velocity of the striker is dependent on the height of the striker at the beginning of the test, or the vertical distance of fall of the pendulum striking edge. This height is a function of the length of the pendulum arm and the angle of the arm at the beginning of the test. The velocity of the striker edge at impact can be calculated by the following equation:

$$V = (2gh)^{0.5}$$

where

$V$  is the velocity of the striker at the moment of impact, in metres per second

$g$  is the local gravitational acceleration, in metres per second squared

$h$  is the vertical distance of fall of the pendulum striking edge, in metres

**NOTE 2** ASTM D256-06 sets the vertical distance of the pendulum striking edge to be  $(610 \pm 2.0)$  mm, which will produce a velocity of the striking edge at the moment of impact of approximately 3.5 m/s.

Ensure that the distance between the line of contact of the pendulum striking edge and the centre of percussion of the pendulum is less than 2.54 mm

**NOTE 3** ISO 13802 states that the impact length shall be within 1 % of the pendulum length. Since the pendulum length may vary with machines, the ASTM D256-06 value of  $\pm 2.54$  mm was chosen to be consistent across laboratories instead of the 1 % value specified in ISO 13802.

Determine the pendulum length,  $L_p$  (3.12), in metres, from the period of oscillation of the pendulum,  $T_p$  in seconds, using the following equation:

$$L_p = (g/4\pi^2)T_p^2$$

where

$g$  is the local gravitational acceleration, in metres per second squared and

$4\pi^2$  Equals 39.48.

Apply an energy (initial potential energy) of  $(2.75 \pm 0.10)$  J

The test result is divided into fractured (F) or not fractured (NF). When the toothbrush is fractured, measure the angle of the pendulum and calculate the absorbed energy,  $E_a$  from the following equation:

$$E_a = WR(Cos\beta - Cos\alpha)$$

where

$W$  is the striker weight, in newtons;

$R$  is the distance between the axis of rotation and the centre of gravity, in metres;

$\alpha$  is the angle at the test starting position, in degrees;

$\beta$  is the angle after breakage of the specimen, in degrees.

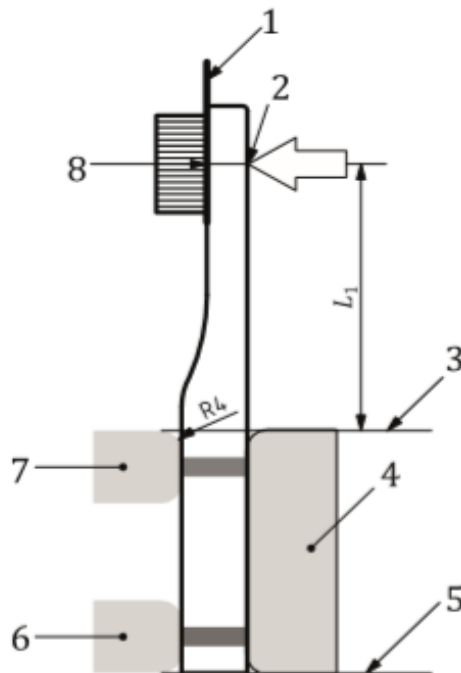


Figure C1 — Clamping unit to hold the toothbrush



**Key**

- 1 Tuft-hole plane
- 2 Hitting point for striker edge
- 3 Top plane of the clamping unit
- 4 Main block
- 5 Bottom plane of the clamping unit
- 6 Lower holding block
- 7 Upper holding block
- 8 Centre of tuft-hole area

**NOTE** The open arrow in the figure shows the striker direction.

**C.3 Test report**

The test report shall include the following information:

- a) The number of this Standard, i.e. US 466:2020;
- b) An identification of the toothbrush;
- c) The results and
- d) Any unusual features noted during the test

## Annex D (normative)

### Fatigue resistance test

#### D.1 Apparatus

**D.1.1** Block for holding the toothbrush body stationary, having a ridge for supporting the toothbrush at  $(55 \pm 1)$  mm from the centre of the brush head and a gripping unit for locking the handle of the toothbrush in place.

**D.1.2** Apparatus for applying a  $(4.0 \pm 0.1)$  N force to the brush head and then fully relieving the force.

**D.1.3** Apparatus for counting the number of cycles completed.

**D.1.4** Apparatus for stopping the application of force when either of the following conditions has occurred:

- a) Completion of the required number of cycles;
- b) Handle breakage.

#### D.2 Procedure

Cut the filaments, and any other attachments, flush to the brush head. Protect the brush head by covering the head with adhesive tape (thickness: less than 0.2 mm). Place the toothbrush against the block with the tuft-hole plane perpendicularly facing the applied force. Lock the toothbrush in place, ensuring that the ridge is at  $55 \text{ mm} \pm 1 \text{ mm}$  from the centre of the brush head.

**NOTE** If the test specimen cannot be locked in place due to its configuration, embed the specimen in epoxy resin or dental stone, ensuring that the surface level of epoxy resin or dental stone is at  $55 \text{ mm} \pm 1 \text{ mm}$  from the centre of the brush head.

Apply a  $4.0 \text{ N} \pm 0.1 \text{ N}$  force to the centre of the brush head perpendicularly to the tuft-hole plane with minimal impact and then fully relieve the force. Repeat a maximum of 75 000 cycles at  $50 \text{ cycles} \pm 10$  cycles/min or until the handle breaks. Record the breakage if it is induced at less than 75 000 cycles.

## Annex E (normative)

### Resistance to chemical challenge

#### E.1 Apparatus and chemicals

**E.1.1** Apparatus for mixing the chemical-challenge solution, e.g. stirring bar or mixer.

**E.1.2** Container, that can be sealed and is chemically inert, e.g. a glass bottle.

**E.1.3** Chemicals, as listed in Table E1

**Table E1 — Components of chemical challenge solution**

Chemical	Minimum purity %
Ethanol	98.5
L-carvone	98.0
L-menthol	98.0
Sodium lauryl sulphate	95.0
Glycerine	98.0
Water	ISO 3696, Grade

#### E.2 Procedure

**E.2.1** Add 1.5 g of L-carvone, 1.5 g of L-menthol and 15 g of sodium lauryl sulphate to 100 g of ethanol in the container (E.1.2) and stir well using the mixing apparatus (E.1.1). Add 250 ml of Grade 3 water in accordance with ISO 3696 and stir well to obtain a clear solution. Add 200 g of glycerine and 432 ml of Grade 3 water in accordance with ISO 3696 and stir to obtain a clear solution.

**E.2.2** Place the brush head and at least 80 % of a total length of the toothbrush in the chemical challenge solution. After 24 h without agitation, remove the toothbrush, rinse with Grade 3 water in accordance ISO 3696 and shake off excess water. Perform the test as required in Annex D (fatigue resistance test)

## Annex F (Normative)

### Sampling and criteria for conformity

#### F.1 Scale of sampling

**F.1.1** lot — In any consignment, all the brushes of the same size and quality shall be divided into groups and each such group shall constitute a lot. Care shall be taken to ensure that brushes included in a lot do not differ in construction as far as possible.

**F.1.2** the conformity of the brushes in a lot to the requirements of this specification shall be ascertained for each lot separately. The number of brushes to be selected for this purpose shall be in accordance with Table F1

Table.F1 — Scale of sampling toothbrushes

S/N	Number of brushes in the lot (N)	Number of brushes to be selected (n)
I.	Up to 50	2
II.	51 to 150	3
III.	151 to 200	4
IV.	201 to 300	5
V.	301 to 500	6
vi	501 and above	9

**F.1.3** the toothbrushes shall be selected at random from the top, middle and bottom portion of the package. If the toothbrushes in a lot are packed in more than one package approximately equal number of brushes shall be selected at random from as many packages as possible so as to obtain the required number of toothbrushes for tests, as given in Table F1

**F.1.4** for declaring the conformity of the lot to the requirements of this specification, all the brushes selected according to F.1.2 and F.1.3 shall satisfy the relevant requirements for this standard

## Bibliography

- [1] IS 3387:2004, *Toothbrush — Specification*
- [2] ISO 20126, *Dentistry — Manual toothbrushes — General requirements and test methods*
- [3] US 466:2006, *Toothbrush — Specification*

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