



มาตรฐานผลิตภัณฑ์อุตสาหกรรม

THAI INDUSTRIAL STANDARD

มอก. 1981 เล่ม 1 – 2543

ISO 7785– 1 : 1997

## ด้ามจับหัวกรอฟัน

เล่ม 1 ด้ามจับหัวกรอฟันชนิดความเร็วสูงขับเคลื่อนด้วยลม

DENTAL HANDPIECES –

PART 1 : HIGH – SPEED AIR TURBINE HANDPIECES

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

กระทรวงอุตสาหกรรม

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# มาตรฐานผลิตภัณฑ์อุตสาหกรรม ด้ามจับหัวกรอพื้น

เล่ม 1 ด้ามจับหัวกรอพื้นชนิดความเร็วสูงขับเคลื่อนด้วยลม

มอก. 1981 เล่ม 1- 2543

สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม  
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วันที่ 18 ตุลาคม พุทธศักราช 2544



ด้ามจับหัวกรอฟัน เป็นเครื่องมือทันตกรรมที่ทันตแพทย์จำเป็นต้องใช้ในการรักษาผู้ป่วยแต่เนื่องจากเป็นเครื่องมือที่นำเข้ามาจากต่างประเทศ ซึ่งมีคุณภาพต่าง ๆ กัน เพื่อเป็นแนวทางให้ผู้ใช้นำมาเป็นเกณฑ์ในการเลือกใช้ผลิตภัณฑ์ที่ได้คุณภาพ จึงกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม ด้ามจับหัวกรอฟัน เล่ม 1 ด้ามจับหัวกรอฟันชนิดความเร็วสูงขับเคลื่อนด้วยลม ขึ้น

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้รับข้อกำหนดใน IEC 601-1 : 1988 มาตรฐานพื้นฐานเกี่ยวกับความปลอดภัยของบริษัทไฟฟ้าที่ใช้ทางการแพทย์มาใช้ โดยระบุข้อกำหนดต่าง ๆ ตามหมายเลขข้อกำหนดที่เกี่ยวข้องใน IEC 601-1 : 1988

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นโดยรับ ISO 7785-1 : 1997 Dental handpieces – Part 1 : High – speed air turbine handpieces มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO 7785-1 : 1997 ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นเพื่อให้ทันกับความต้องการของผู้ใช้และจักได้แปลเป็นภาษาไทยในโอกาสอันสมควร หากมีข้อสงสัยโปรดติดต่อสอบถามที่สำนักงานมาตรฐานผลิตภัณฑ์อุตสาหกรรม

คณะกรรมการมาตรฐานผลิตภัณฑ์อุตสาหกรรมได้พิจารณามาตรฐานนี้แล้ว เห็นสมควรเสนอรัฐมนตรีประกาศตาม มาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511



ประกาศกระทรวงอุตสาหกรรม

ฉบับที่ 2886 ( พ.ศ. 2544 )

ออกตามความในพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม

พ.ศ. 2511

เรื่อง กำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม

ด้ามจับหัวกรอฟัน

เล่ม 1 ด้ามจับหัวกรอฟันชนิดความเร็วสูงขับเคลื่อนด้วยลม

อาศัยอำนาจตามความในมาตรา 15 แห่งพระราชบัญญัติมาตรฐานผลิตภัณฑ์อุตสาหกรรม พ.ศ. 2511 รัฐมนตรีว่าการกระทรวงอุตสาหกรรมออกประกาศกำหนดมาตรฐานผลิตภัณฑ์อุตสาหกรรม ด้ามจับหัวกรอฟัน เล่ม 1 ด้ามจับหัวกรอฟันชนิดความเร็วสูงขับเคลื่อนด้วยลม มาตรฐานเลขที่ มอก. 1981 เล่ม 1-2543 ไว้ ดังมีรายการละเอียดต่อท้ายประกาศนี้

ประกาศ ณ วันที่ 4 กรกฎาคม พ.ศ. 2544

สุริยะ จึงรุ่งเรืองกิจ

รัฐมนตรีว่าการกระทรวงอุตสาหกรรม

# มาตรฐานผลิตภัณฑ์อุตสาหกรรม

## ด้ามจับหัวกรอฟัน

### เล่ม 1 ด้ามจับหัวกรอฟันชนิดความเร็วสูงขับเคลื่อนด้วยลม

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนดขึ้นโดยรับ ISO 7785-1 : 1997 Dental handpieces – Part 1 : High – speed air turbine handpieces มาใช้ในระดับเหมือนกันทุกประการ (identical) โดยใช้ ISO 7785-1 : 1997 ฉบับภาษาอังกฤษเป็นหลัก

มาตรฐานผลิตภัณฑ์อุตสาหกรรมนี้กำหนด การแบ่งประเภท คุณลักษณะที่ต้องการประกอบด้วย การออกแบบทั่วไป ที่ยึดหัวกรอฟัน (chuck) สมรรถนะ แหล่งจ่ายน้ำและลม ข้อต่อด้ามจับหัวกรอฟัน แรงดันลมที่จ่ายเข้าไปในด้ามจับ หัวกรอฟัน ระดับความดังของเสียงเมื่อใช้งาน ความทนต่อการกัดกร่อน ความทนทานต่อกระบวนการทำให้ปราศจาก เชื้อ พลังงานที่จ่ายให้หลอดไฟ(ถ้ามี) การชักตัวอย่าง การทดสอบ คำแนะนำในการใช้ การซ่อมบำรุงและบริการ เครื่องหมายและฉลาก และการบรรจุ รายละเอียดให้เป็นไปตาม ISO 7785-1 : 1997

## Introduction

This part of ISO 7785 takes priority over IEC 601-1:1988 as specified in the individual clauses of this part of ISO 7785.

Only the specifications laid down in this part of ISO 7785 are applicable.

This part of ISO 7785 refers to IEC 601-1:1988, the basic standard on safety of medical electrical equipment wherever relevant, by stating the respective clause numbers of IEC 601-1:1988.

# Dental handpieces —

## Part 1:

### High-speed air turbine handpieces

#### 1 Scope

This part of ISO 7785 specifies requirements and test methods for the application of high-speed air turbine dental handpieces (hereafter termed handpieces) to patients. It also contains specifications on manufacturer's instructions, packaging and marking.

This part of ISO 7785 is not applicable to single-use dental handpieces.

#### 2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7785. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7785 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 554:1976,	Standard atmospheres for conditioning and/or testing - Specifications.
ISO 1797-1:1992,	Dental rotary instruments - Shanks - Part 1: Shanks made of metals.
ISO 1942-3:1989,	Dental vocabulary - Part 3: Dental instruments.
ISO 3696:1987,	Water for analytical laboratory use - Specification and test methods.
ISO 6507-2:1983,	Metallic materials - Hardness test - Vickers test - Part 2: HV 0,2 to less than HV 5.
ISO 9168:1991,	Dental handpieces - Hose connectors.
ISO 9687:1993,	Dental equipment - Graphical symbols.
ISO 13402:1995,	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure.
IEC 651:1979,	Sound level meters.
IEC 601-1:1988,	Medical electrical equipment - Part 1: General requirements for safety.

#### 3 Definitions

For the purposes of this part of ISO 7785, the definitions given in ISO 1942-3 apply.

#### 4 Classification

High-speed air turbine handpieces are dental handpieces with a minimum free-running speed of 160 000 min<sup>-1</sup> (r/min).

Dental handpieces are classified according to their gear ratio (see table 1).

High-speed air turbine handpieces are usually type 2 handpieces.

Table 1 - Gear ratio

Type	Gear ratio
1	1 : < 1
2	1 : 1
3	1 : > 1



## 5 Requirements

### 5.1 General design

#### 5.1.1 General

The handpiece should be comfortable for the operator to use and easy to manipulate. The outside surface should be easy to clean and particular attention should be given to providing secure gripping surfaces for operator manipulation.

Compliance with these requirements cannot be objectively assessed.

If in addition the requirements of 5.1.2, 5.1.3 and 5.2 to 5.10 are complied with, the requirements of 5.1.1 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

#### 5.1.2 Materials

All materials used in the construction of the handpieces should be suitable for their intended use and should be resistant to cleaning, disinfecting and sterilizing procedures recommended by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

If in addition the requirements of 5.1.1, 5.1.3 and 5.2 to 5.10 are complied with, the requirements of 5.1.2 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

#### 5.1.3 Construction and layout

The construction of the handpiece should provide for safe and reliable operation and, if field-repairable, should be capable of being easily disassembled and reassembled for maintenance and repair, using readily available tools or those supplied by the manufacturer.

Compliance with these requirements cannot be objectively assessed.

If in addition the requirements of 5.1.1, 5.1.2 and 5.2 to 5.10 are complied with, the requirements of 5.1.3 are considered to be fulfilled.

Testing shall be carried out in accordance with 7.1.

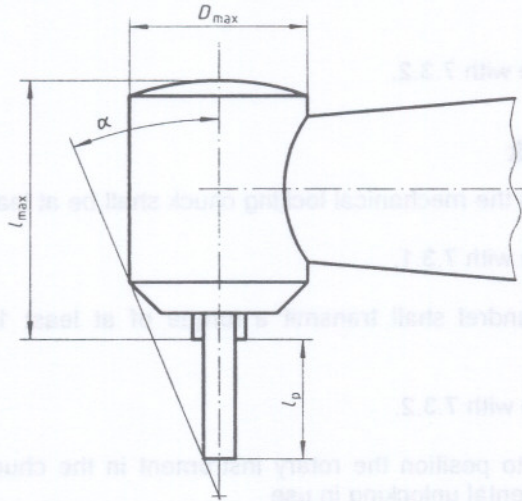
Table 1 - Gear ratio

Type	Gear ratio
1	1 : 1
2	1 : 2
3	1 : 3

**5.1.4 Head dimensions and nomenclature**

If the manufacturer includes the head dimensions in the operator's manual (see note in clause 8) they shall be the dimensions as shown in figure 1 and shall be expressed to an accuracy of  $\pm 0,1$  mm on lengths and  $\pm 1^\circ$  on angles using the nomenclature of figure 1.

Testing shall be carried out in accordance with 7.2.



- $D_{max}$  Maximum diameter
- $l_{max}$  Maximum length of non-rotating component
- $\alpha$  Visibility angle
- $l_p$  Projection using 19 mm test mandrel

**Figure 1 — Terminology for measuring head dimensions**

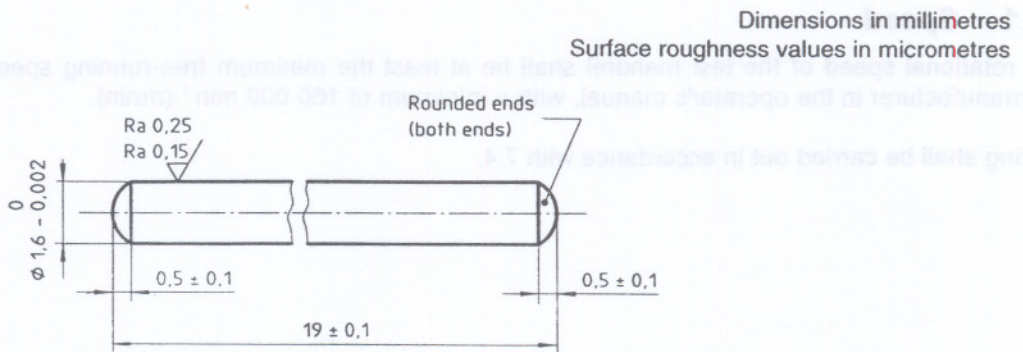
**5.2 Chuck**

**5.2.1 General**

The chuck shall be capable of accepting rotary instruments the shanks of which comply with ISO 1797-1.

**5.2.2 Test mandrel**

The test mandrel shall have the dimensions shown in figure 2.



**Figure 2 - Test mandrel**

### 5.2.3 Spring-type chuck, friction grip

The force to insert into, or to withdraw the test mandrel from, the spring-type chuck shall be between 22 N and 45 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

### 5.2.4 Mechanical locking chuck

The force to extract the test mandrel from the mechanical locking chuck shall be at least 22 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

The locking or unlocking force required to position the rotary instrument in the chuck should be the minimum force sufficient to prevent accidental unlocking in use.

### 5.2.5 Push-button locking chucks and other systems

The force to extract the test mandrel from the chuck system shall be at least 22 N.

Testing shall be carried out in accordance with 7.3.1.

When locked in the chuck, the test mandrel shall transmit a torque of at least 1,6 N·cm without slipping.

Testing shall be carried out in accordance with 7.3.2.

### 5.2.6 Eccentricity

The eccentricity of the test mandrel in rotation and without applied load shall not exceed a total indicated run-out of 0,03 mm.

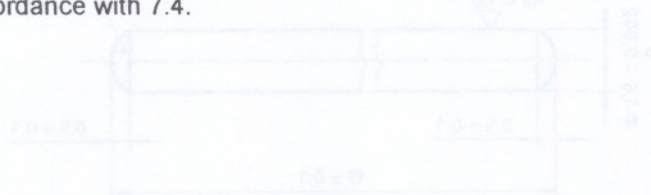
Testing shall be carried out in accordance with 7.3.3.

## 5.3 Performance

### 5.3.1 Speed

The rotational speed of the test mandrel shall be at least the minimum free-running speed stated by the manufacturer in the operator's manual, with a minimum of 160 000 min<sup>-1</sup> (r/min).

Testing shall be carried out in accordance with 7.4.



### 5.3.2 Stall torque

The stall torque shall be at least 0,05 N·cm.

Testing shall be carried out in accordance with 7.5.

## 5.4 Water and spray air supply

### 5.4.1 General

The handpiece shall provide cooling capability at the operating area.

Testing shall be carried out in accordance with 7.1 and 7.6.

### 5.4.2 Water cooling

The handpiece shall provide water coolant capability at the operating area of the rotary instrument. The handpiece shall have a capability of attaining a water flowrate of at least 50 ml/min at 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 7.6.2.1.

### 5.4.3 Air cooling

Air coolant capability may be provided at the discretion of the manufacturer. Handpieces having air coolant capability shall direct air to the operating area of the rotary instrument. If water and air are used simultaneously, a cooling mist shall be created and transmitted to the cutting area of the rotary instrument. The handpiece shall be capable of attaining an air flowrate of at least 1,5 l/min at 200 kPa (2,0 bar).

Testing shall be carried out in accordance with 7.6.2.2.

## 5.5 Handpiece connector

The configuration, dimensions and tolerances of connections for drive air, exhaust air, spray air, cooling water and fibre optic light, as appropriate, shall be in accordance with ISO 9168.

Testing shall be carried out by inspection and measurement in accordance with 7.1.

## 5.6 Air pressure

Handpieces shall remain intact, i.e. it shall not rupture or burst, when subjected to an air pressure 50 % above the recommended operating pressure.

Testing shall be carried out in accordance with 7.7.

## 5.7 Noise level

The A-weighted sound pressure value generated by the handpiece shall not exceed 80 dB.

NOTE — It is recommended to reduce the noise level to 65 dB.

Testing shall be carried out in accordance with 7.9.

## 5.8 Resistance to corrosion

Handpieces shall be corrosion-resistant, i.e. the construction materials shall show no visible signs of corrosion after having been subjected to the autoclave procedure specified in 7.8.

Visual inspection shall be carried out in accordance with 7.1.

## 5.9 Resistance to sterilizing procedure

Handpieces shall be capable of being subjected to a minimum of 250 cycles of the manufacturer's recommended sterilizing procedure without signs of deterioration.

If a part of handpieces, totally or partially nonreparable, are of single-use type, the disposable part shall be sold sterile or shall be sterilizable once before use, according to the manufacturer's instructions.

Testing shall be carried out in accordance with the manufacturer's instructions.

Visual inspection to indicate any signs of deterioration shall be carried out in accordance with 7.1.

## 5.10 Energy for light supply (if applicable)

The voltage shall not exceed a nominal value of 25 V a.c or 60 V d.c. at rated supply voltage on the transformer or converter, between conductors in an earth-free circuit which is isolated from the supply mains by a safety transformer or by a device with an equivalent separation.

Testing shall be carried out in accordance with 7.10.

# 6 Sampling

At least one handpiece for each model series shall be evaluated for compliance with this part of ISO 7785.

# 7 Test methods

All tests described are type tests.

## 7.1 Visual inspection

Carry out visual inspection at normal visual acuity without magnification.

## 7.2 Head dimensions

### 7.2.1 Apparatus

- a) **Measuring device** such as gauge, dial indicator, etc. with an accuracy of  $\pm 0,01$  mm for linear dimension and  $\pm 1^\circ$  for angles;
- b) **Test mandrel** as shown in figure 2. The test mandrel shall be straight to within 0,0025 mm and shall have a hardness of at least 610 HV 5.

Testing of hardness shall be carried out in accordance with ISO 6507-2.

### 7.2.2 Procedure

Fully insert the test mandrel in the chuck. Measure and record the dimensions shown in figure 1.

## 7.3 Chuck

### 7.3.1 Insertion and extraction forces

#### 7.3.1.1 Apparatus

- a) **Spring force gauge** with an accuracy of  $\pm 0,5$  N, to measure the insertion and extraction forces.
- b) **Test mandrel**, as shown in figure 2.

### 7.3.1.2 Procedure

Install the test mandrel in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece at the recommended maximum speed for at least 10 s and brake the test mandrel through a radial force so that the speed is reduced by at least 50 %. Adjust the force gauge to register the maximum force exerted. The force either to insert or to extract the test mandrel shall be increased gradually until movement of the test mandrel occurs. Record the maximum force required either to insert or to extract the test mandrel.

### 7.3.2 Torque test

Apply the torque stated in 5.2.3, 5.2.4 or 5.2.5, at which the mandrel shall not slip in the chuck.

### 7.3.3 Eccentricity

#### 7.3.3.1 Apparatus

- a) **Non-contacting gauging system**, e.g. magnetic proximity gauge, with an accuracy of  $\pm 10\%$  of the measured value.
- b) **Test mandrel**, as shown in figure 2, to measure the dynamic eccentricity.

#### 7.3.3.2 Procedure

Install the test mandrel in the handpiece in accordance with the manufacturer's instructions. Operate the handpiece with the recommended speed range and without any applied load and record the maximum total indicated run-out at a point on the mandrel 6 mm from the proximal face of the spindle.

## 7.4 Speed

### 7.4.1 Apparatus

- a) **Non-contacting tachometer**, e.g. magnetic proximity gauge or photo-optic tachometer or spectrum analyzer with appropriate transducer, accurate to 5 %.
- b) **Test mandrel**, as shown in figure 2.

### 7.4.2 Procedure

Using the test mandrel, operate the handpiece at the maximum recommended operating pressure. Measure the speed and record the speed in reciprocal minutes (revolutions per minute).

## 7.5 Stall torque

### 7.5.1 Apparatus

**Torque watch** or **dynamometer**, capable of measuring the stall torque in newton-centimetres to an accuracy of 10 %.

### 7.5.2 Procedure

Rotate the torque watch slowly and record the maximum value.

## 7.6 Water and spray air supply

### 7.6.1 Apparatus

- a) **Volumetric measuring jar**, with an accuracy of 5 %, to measure the volume of cooling water.
- b) **Flow meter**, with an accuracy of 5 %, to measure the spray air flowrate.
- c) **Pressure gauge**, with an accuracy of 5 %, to measure the air and water supply pressures to the handpiece inlet.

### 7.6.2 Procedure

#### 7.6.2.1 Measurement of cooling water flow

Adjust the water supply pressure at the handpiece inlet to 200 kPa (2,0 bar) and operate the handpiece for 1 min. Record the volume of water collected.

#### 7.6.2.2 Measurement of cooling air flow

Adjust the air supply at the handpiece inlet to 200 kPa (2,0 bar). Connect a flow meter to the handpiece air outlet tube. Record the air flowrate.

## 7.7 Air pressure

### 7.7.1 Apparatus

Pressure gauge capable of measuring the supply pressure to an accuracy of 5 % of the measured value.

### 7.7.2 Procedure

Operate the handpiece at 50 % above the recommended operating pressure for a period of 10 min and record any signs of failure.

## 7.8 Resistance to corrosion

### 7.8.1 Apparatus

- a) **Autoclave**, capable of being operated at  $(136 \pm 2) ^\circ\text{C}$  and 220 kPa (2,2 bar).
- b) Distilled or deionized water of grade 3 in accordance with ISO 3696.

### 7.8.2 Procedure

Subject the touchable surface of the handpiece to an autoclave test of 10 cycles at  $(136 \pm 2) ^\circ\text{C}$ .

Testing shall be carried out in accordance with ISO 13402.

## 7.9 Noise level

### 7.9.1 Apparatus

- a) **Precision sound level meter**, meeting the requirements for a type 1 instrument as specified in IEC 651
- b) **Non-rigid suspension system**.

## 7.9.2 Test environment

The measurements shall be taken in a room with dimensions greater than 2,5 m x 2,5 m x 2,5 m, or in a chamber with a free-field radius of at least 1 m. The background A-weighted noise level shall be less than 65 dB. There shall be no hard reflective surface within a 1 m envelope of the handpiece under test. Foam or non-reflective material may be used to reduce reflections from hard surfaces.

## 7.9.3 Procedure

Suspend the handpiece in the centre of the chamber by means of a non-rigid suspension system. Operate the handpiece at the maximum recommended pressure. Using the sound level meter, measure the maximum A-weighted sound pressure level value generated from the handpiece at a distance of 0,45 m from the head.

## 7.10 Energy for light supply (if applicable)

### 7.10.1 Power supply

The handpiece shall be designed to operate from supply mains as described by the manufacturer.

The requirements given in IEC 601-1:1988, clause 19.1 c) apply.

Testing shall be carried out in accordance with clause 8 using readily available measuring instruments.

### 7.10.2 Continuous leakage currents and patient auxiliary currents

Test the patient leakage current and the patient auxiliary current with the complete light system

- a) after the handpiece has been brought to normal operating temperature in accordance with the requirements of IEC 601-1:1988, clause 7;
- b) after moisture preconditioning treatment as described in IEC 601-1:1988, clause 4.10. The measurements shall be carried out with equipment located outside the humidity cabinet and shall commence 1 h after equipment has been taken out of this cabinet, and has been placed in an environment with a temperature less than or equal to the temperature of the humidity cabinet. During testing, those measurements which do not energize equipment shall be made first.

The requirements given in IEC 601-1:1988, clause 19.4 apply.

### 7.10.3 Dielectric strength, creepage distances and air clearances

Apply the test voltage of 500 V to the insulation parts of the complete handpiece system as described in IEC 601-1:1988, clause 20.2 but without test B-d, during 1 min and according to table V of IEC 601-1:1988:

- a) immediately after warming up to operating temperature and switching off the equipment and
- b) immediately after moisture preconditioning treatment (as described in IEC 601-1:1988, clause 4.10) with the equipment de-energized during the test and kept in the humidity cabinet, and after the first required sterilization procedure with the equipment de-energized (see IEC 601-1:1988, clause 44.7).

Apply initially not more than half the prescribed voltage, then raise it over a period of 10 s to the full value, and maintain for 1 min.

IEC 601-1:1988, clause 20.4 and clause 57.10 d) apply.



## 8 Instructions for use, maintenance and service

Each handpiece shall be accompanied by documents containing instructions for operation, operator maintenance, lubrication, safety and servicing.

Instructions shall include at least the following information:

- a) Name and/or trademark and address of manufacturer or distributor;
- b) type classification (free-running maximum operating speed);
- c) minimum fitting length of shank (see ISO 1797-1);
- d) maximum overall length of rotary instrument;
- e) recommended operating pressures;
- f) coupling identification;
- g) air consumption, in litres per minute, at the recommended operating pressures;
- h) statement as to whether the tool for changing the handpiece and bur is sterilizable, and by what methods;
- i) recommended cleaning and/or, if applicable, disinfecting agent;
- j) recommended sterilizing instructions;
- k) statement as to whether the handpiece is field-repairable;
- l) recommended light-supply, if applicable;
- m) statement of regular maintenance required to maintain the handpiece in good working order when the handpiece is to be subject to repeated steam sterilization, and a statement of the frequency required for this maintenance.

NOTE - The head dimensions may be included at the discretion of the manufacturer.

Testing of compliance with the requirements shall be carried out in accordance with 7.1.

## 9 Marking

Handpieces shall be marked as follows:

- a) manufacturer's name or trademark;
- b) serial number;
- c) model or type reference;
- d) mark to indicate autoclaveability, if applicable;
- e) for parts of single-use handpieces, if sold as sterile product, the packaging must specify the "use by" date.

Graphical symbols used for marking shall be in accordance with ISO 9687.

Testing of compliance with the requirements shall be carried out in accordance with 7.1.

## 10 Packaging

Handpieces should be packet for transportation in such a way that no damage can occur during anticipated transport conditions.