



SLOVENSKI STANDARD

SIST ENV 14027:2001

01-november-2001

Metoda za simulacijo obrabe pred odkritjem sproščanja niklja iz prevlečene kovine in kombiniranih okvirov očal

Method for the simulation of wear before the detection of nickel release from coated metal and combination spectacle frames

Verfahren zur Simulation des Tragegebrauchs von beschichteten Metall-Brillenfassungen und kombinierten Brillenfassungen vor der Bestimmung der Nickellässigkeit

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Ta slovenski standard je istoveten z: **ENV 14027:2001**

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST ENV 14027:2001

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EUROPEAN PRESTANDARD
PRÉNORME EUROPÉENNE
EUROPÄISCHE VORNORM

ENV 14027

January 2001

ICS 11.040.70

English version

Method for the simulation of wear before the detection of nickel release from coated metal and combination spectacle frames

This European Prestandard (ENV) was approved by CEN on 14 January 2001 as a prospective standard for provisional application.

The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into a European Standard.

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 170 "Ophthalmic optics", the secretariat of which is held by DIN.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This European Prestandard specifies a method for accelerated wear to simulate two years use to be applied before the detection of nickel release from those parts of coated metal and combination spectacle frames that come into direct and prolonged contact with the skin. This European Prestandard applies to frames used in medical devices or personal protective equipment, including sunglasses, and may be used as part of the test procedure to ensure compliance with clause 3 of the annex of the European Parliament and Council Directive 94/27/EC.

NOTE Metal frames which are uncoated and made of homogeneous alloys or metals do not require a wear pre-treatment, and should be tested directly by the method in EN 1811 or other equivalent test method.

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2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 1811, *Reference test method for release of nickel from products intended to come into direct and prolonged contact with the skin.*

EN ISO 12870:1997, *Ophthalmic optics - Spectacle frames - General requirements and test methods.*

3 Nickel release

Those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall have a nickel release of less than $0,5 \mu\text{g}/\text{cm}^2/\text{week}$ when tested according to EN 1811 or other equivalent test method.

Frames having a non-nickel coating shall be subject to the wear pre-treatment in clause 4 which simulates two years typical wear.

Parts to be tested shall include:

- the rear surface of rims;
- nasal bearing surfaces, including metal nose pads;
- sides, excluding the zone immediately around the joints, and parts intended to be protected by plastics endcovers (tips).

4 Method for the abrasion of metal spectacle frames before the determination of nickel release

4.1 Materials

4.1.1 Abrasive paste

Inorganic abrasive paste produced for dry tumbling barrels.

The abrasive paste shall be made of the following components:

- a) Pumice (Al and Si Oxide) powder, where the abrasive particles have dimensions of $200 \mu\text{m} \pm 15 \mu\text{m}$;
- b) mixture of emulsifying agents, mineral oils and water, having the following physical properties:

softening point: 30 °C to 35 °C
flammability point: above 250 °C
pH: 6 to 7

The ratio of a) to b) shall be 4:1.

NOTE Information on sourcing a suitable paste is available from the CEN Management Centre.

4.1.2 Wood granules

This material shall be made of the following components:

Outer shells of coconuts, walnuts, peanuts, almond, mixed in a ratio 1:1:1:1 by weight, ground and sieved to give a mixture of particles having dimensions between 0,8 mm and 1,3 mm.

Equilibrium moisture at a temperature of 30 °C and a relative humidity of 75 %: 14 %.

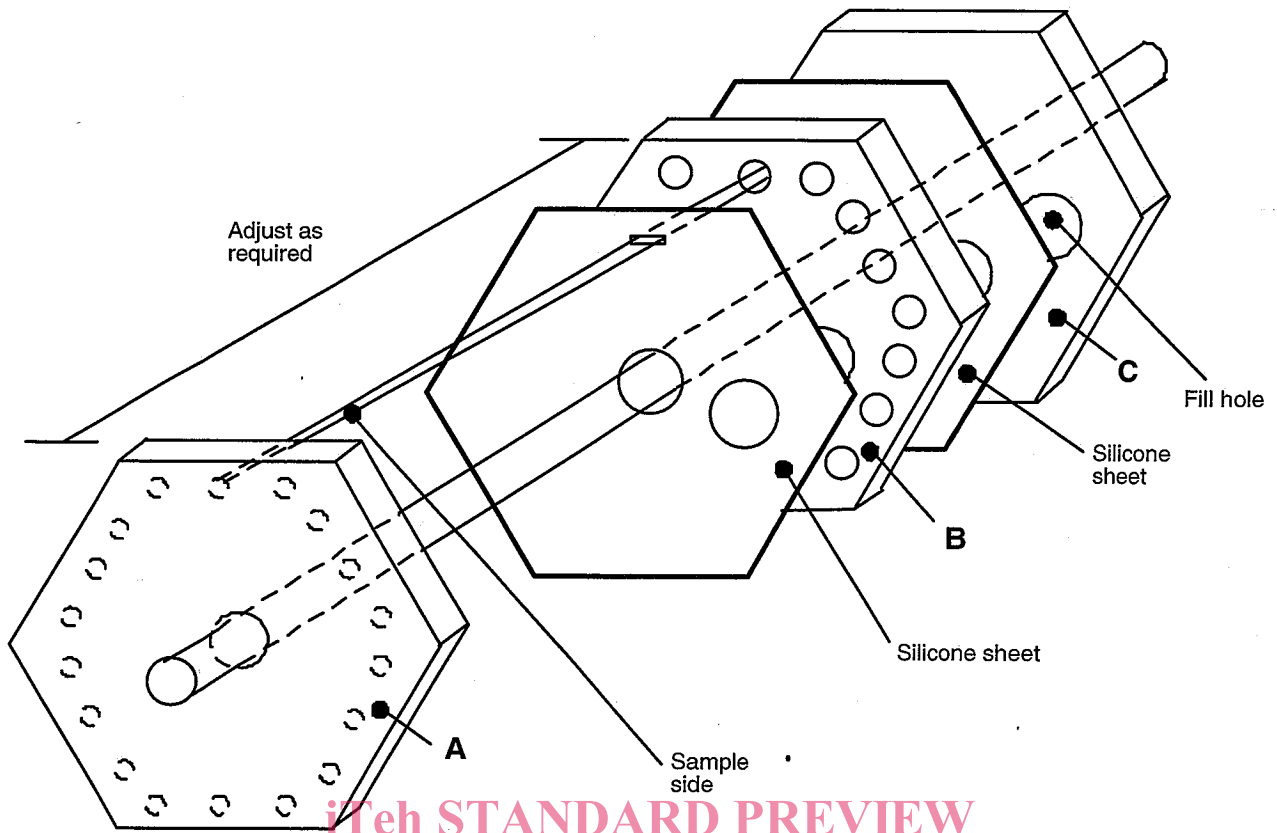
Before use, the required amount of granulate shall be conditioned in standard laboratory conditions for at least 24 h.

NOTE Information on sourcing suitable granules is available from the CEN Management Centre.

4.1.3 Tumbling barrel

The tumbling barrel and retaining assembly shall be in accordance with the following description:

Barrel of hexagonal cross-section designed to rotate around its axis of symmetry, which is orientated horizontally. The spectacle fronts or sides are mounted in a retaining assembly which slides into the barrel. For use with spectacle sides, the assembly consists of a threaded rod which carries three metal hexagonal plates - see figures 1 and 2. The end plate (A) is drilled part way through with holes of nominal diameter 1,5 mm, or as appropriate, to take the ends of the tips of the sides. The next plate (B) is perforated with holes of nominal diameter 5,0 mm, or as appropriate, to take the joint ends of the sides, together with an aperture of 40 mm nominal diameter to act as a filling hole for the abrasive mixture. The final plate (C) is undrilled apart from the filling hole. Threaded nuts either side of the last two plates hold them the required distance from plate A, while silicone rubber sheets hold the sides firmly to prevent them from rotating in the assembly. The volume between the first and second plates is $5 \text{ l} \pm 0,5 \text{ l}$.



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Figure 1 — Exploded schematic illustration of the assembly for holding sides, which inserts into the tumbling barrel

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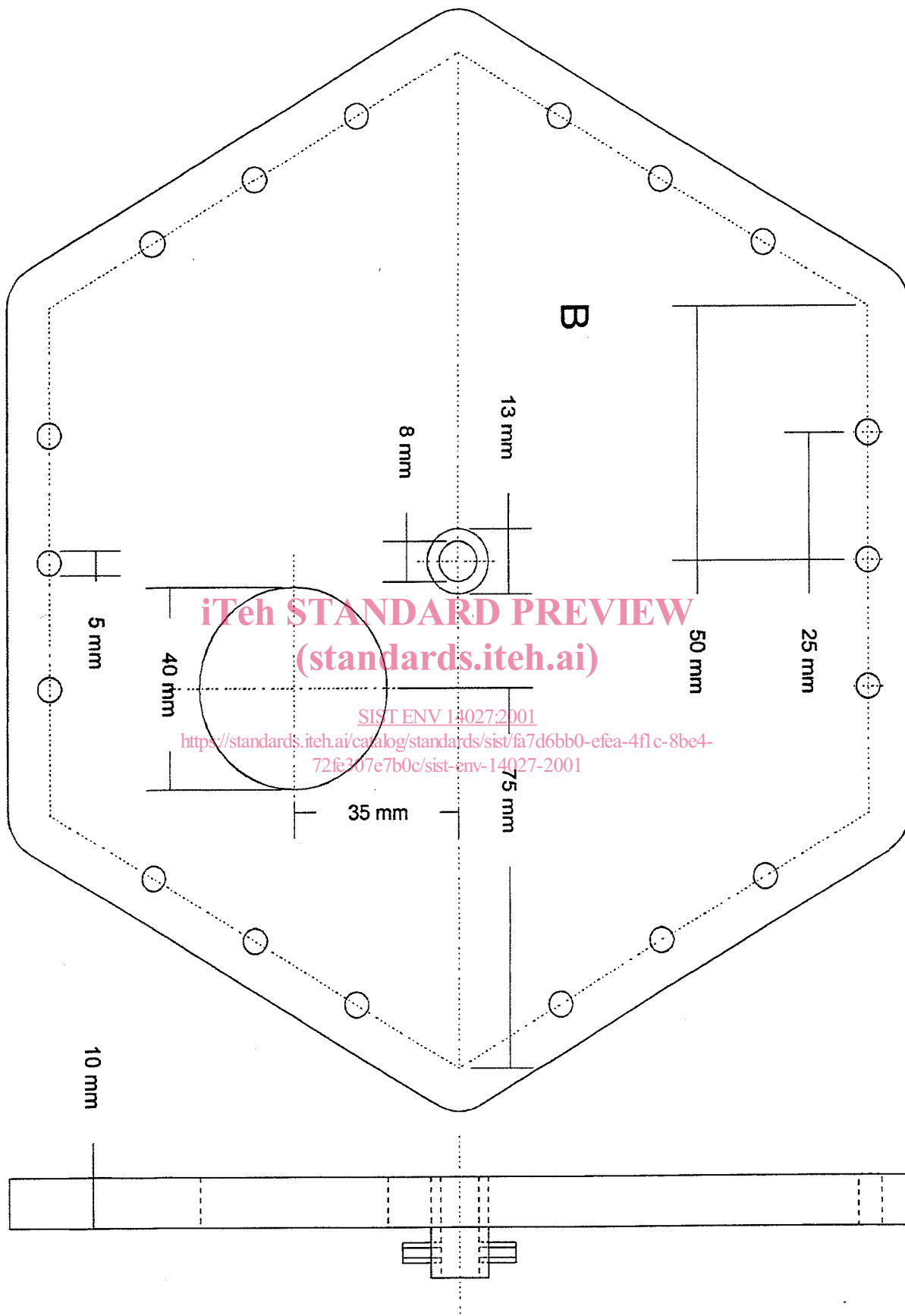


Figure 2 — Plan view of upper part of tumbling barrel

4.2 Test method

4.2.1 Preparation

Weigh a sufficient quantity of wood granules in order to fill the tumbling barrel (4.1.3) to half its volume - approximately 2,5 l. Add 7,5 g of abrasive paste (4.1.1) for every kg of wood granules (4.1.2) and homogenise by rotating in the barrel for 48 h.

NOTE This coats the granules with the abrasive paste, thus forming the abrasive material which is used to simulate wear.

After 10 h of use, add 7,5 g more abrasive paste for every kg of wood granules.

After 20 h of use, discard the abrasive material and prepare fresh material.

4.2.2 Spectacle fronts

Before testing, spectacle fronts shall be glazed with test lenses in accordance with clause 6 of EN ISO 12870:1997.

4.2.3 Tumbling

Spectacle sides and fronts shall be separated from each other, and side tips (endcovers) removed from sides, where appropriate. Fix the test samples into the two hexagonal flanges of the barrel positioning them with the inside face of sides or the posterior face of fronts turned towards the rotation axis. The samples shall be fitted so that they do not move. Fill any vacant positions with waste samples.

Half fill the tumbling barrel with the abrasive mixture (4.2.1).

Close the tumbling barrel and place it on the rotating system.

Rotate the tumbling barrel at a speed of (30 ± 2) rotations per minute for $5 \text{ h} \pm 5 \text{ min}$.

When the tumbling process is completed, remove the test samples and clean them with a smooth cloth without further damaging the surface with the abrasive. Only those parts of spectacle frames liable to come into close and prolonged contact with the skin shall be tested for nickel release. Following tumbling, the samples shall therefore be masked with wax or lacquer to prevent nickel release from parts not likely to come into close and prolonged contact with the skin before testing in accordance with either EN 1811 or equivalent test method.

NOTE Parts typically needing masking are the pad arms, joints and the inside and front surfaces of rims - see Figure 3.

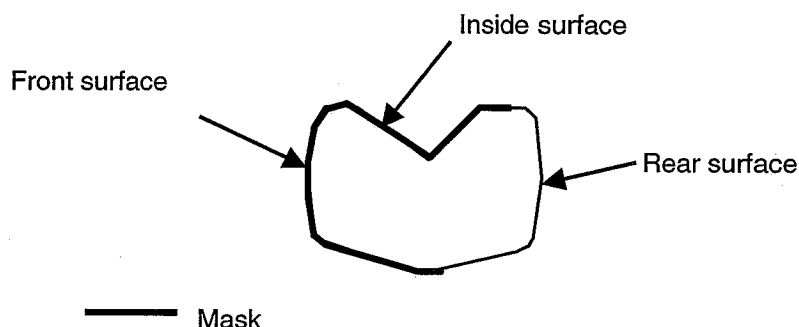


Figure 3 — Cross-section of rim showing those parts of the rim which need to be masked