TECHNICAL SPECIFICATION

ISO/TS 24348

Second edition
2007-07-15

Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames

Optique ophtalmique — Montures de lunettes — Méthode de simulation de l'usure et de détection de la libération du nickel de montures de lunettes en métal et combinées

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

— an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 24348 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This second edition cancels and replaces the first edition (ISO/TS 24348:2003), which has been technically revised.

Introduction

Adverse skin reaction to nickel has been known for many decades. Nickel is now the most frequent cause of contact allergy, and a significant proportion of the female population is allergic to nickel. Skin absorption of nickel ions, which are released from some nickel-containing materials in direct and prolonged contact with the skin, causes sensitization. Further exposure to soluble nickel salts results in allergic contact dermatitis. It is known that sensitization to nickel requires higher exposure levels than does the elicitation in already sensitized individuals. There is a large variation in the degree of sensitivity to nickel between individuals.

This widespread health problem has forced the introduction of a number of measures designed to reduce its prevalence. They include this Technical Specification which provides two procedures for testing those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin.

Clause 4 specifies a method for accelerated wear to simulate two years' use of coated metal and combination spectacle frames. The coatings may include rolled gold covering, electro- and other plating methods, varnish and other organic treatments. Clause 5 attempts to provide an *in-vitro* chemical test that correlates as far as possible with the variable human biological reactions that occur when metallic articles containing nickel are in direct and prolonged contact with the skin. It provides a measure of the amount of nickel release from a spectacle frame when immersed for one week in artificial sweat.

Clinical patch-testing of a selection of nickel-containing alloys and coatings on nickel-sensitized persons indicates that high and low results achieved with the present analytical method correspond closely with patch-test reactivity. Moreover, a nickel release rate threshold of 0,5 µg/cm^2/week has been set in the European Parliament and Council Directive 94/27/EC (OJ No. L188 of 1994-07-22). In order to ensure that articles yielding values near this figure are not unnecessarily excluded from European trade as a result of the difficulties inherent in the test method, particularly when applied to intricately-shaped articles, the measured release figures are multiplied by a factor of 0,1. Materials recognised as causing sensitization to nickel would not become acceptable by use of this adjustment. Application of this Technical Specification is confidently expected to significantly reduce the development of allergic contact dermatitis due to nickel.

NOTE Experience of its use and further epidemiological and clinical research may justify changes to test procedure and/or interpretation of the test result.

Ophthalmic optics — Spectacle frames — Method for the simulation of wear and detection of nickel release from metal and combination spectacle frames

1 Scope

This Technical Specification specifies methods for accelerated wear and corrosion, to be used prior to the detection of nickel release from coated metal and combination spectacle frames, and for detecting the release of nickel from those parts of metal and combination spectacle frames, whether coated or not, intended to come into direct and prolonged contact with the skin, in order to determine whether such parts release nickel at a rate greater than 0,5 µg/cm^2/week.

This Technical Specification aims to control those spectacle frames that, if produced with materials and/or surface treatments containing nickel, can be worn by nickel-sensitized persons.

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 12870, *Ophthalmic optics — Spectacle frames — Requirements and test methods*

3 Requirement

Those parts of metal and combination spectacle frames that come into direct and prolonged contact with the skin of the wearer shall not have a nickel release greater than 0,5 µg/cm^2/week when tested according to this Technical Specification.

Spectacle frames having a non-nickel coating shall be subject to the corrosion and wear pretreatment in Clause 4 which simulate two years' typical wear.

Spectacle frames that are made of homogeneous alloy or pure metal and are uncoated go directly to the nickel release test procedure in Clause 5.

The parts to be tested shall include:

— the rear surface of rims;

— the rear and lower surface of the bridge, the rear and upper surface of any brace bar and any other nasal-bearing surfaces, including metal nose pads;

— sides, excluding the joints and the zone immediately around the joints, and parts intended to be protected by plastic endcovers (tips).

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

4.1 Principle

The items to be tested are exposed to a corrosive atmosphere before being placed in a tumbling barrel together with a wear medium of abrasive paste and granules. The barrel is rotated so as to subject the test pieces to wear from the wear medium. The items are then tested for nickel release in accordance with Clause 5.

4.2 Reagents and materials

4.2.1 General

Except where indicated, all reagents and materials that can come into contact with samples or reagents shall be demonstrably free of nickel, and all reagents shall be of recognised analytical grade or better.

4.2.2 Reagents and materials for the corrosion procedure

4.2.2.1 **Container**, with a lid and a device for suspending the test pieces, and all parts made of inert material (e.g. glass or plastic).

4.2.2.2 **Corrosive medium**, prepared by dissolving 50 g DL-lactic acid, > 85 % purity, and 100 g sodium chloride in 1 000 ml deionized water.

4.2.2.3 **Degreasing solution**, being an appropriately diluted, neutral, commercially available detergent, e.g. a 0,5 % aqueous solution of sodium dodecylbenzene sulfonate.

4.2.2.4 **Deionized water**, specific conductivity maximum 1 µS/cm.

4.2.2.5 **Laboratory oven**, capable of maintaining a temperature of (50 ± 2) °C.

4.2.3 Reagents and materials for the wear procedure

4.2.3.1 **Tumbling barrel and retaining assembly**, in accordance with the following description:

— barrel of hexagonal cross-section and internal diameter of 19 cm perpendicular distance between opposite sides designed to rotate around its axis, which is orientated horizontally (see Figure 1);

— retaining assembly, suitable for attaching the test items so that they do not come into contact with each other during tumbling;

— retaining assembly, with items attached, to be inserted into the barrel for tumbling.

NOTE Information on sourcing suitable equipment is available from the ISO Central Secretariat.

4.2.3.2 **Rotating system**, capable of imparting to the barrel (4.2.3.1) a constant (30 ± 2) rotations per minute. The rotating system shall be capable of allowing the direction of rotation to be reversed.

NOTE Information on sourcing suitable equipment is available from the ISO Central Secretariat.

4.2.3.3 **Abrasive paste**, produced for dry-tumbling barrels and comprising:

— 6 % to 8 % ester wax of montanic acids – Wax E [CAS No. 73138-45-1];

— 3 % octadecanoic acid (stearic acid) [CAS No. 57-11-4];

— 30 % to 35 % petroleum distillates, hydrotreated light paraffinic [CAS No. 64742-55-8];

— 2 % polyethylene glycol cetyl/oleyl ether [CAS No. 68920-66-1] or triethanolamine [CAS No. 102-71-6];

— 48 % silicon dioxide (quartz) 200 µm mesh size [CAS No. 14808-60-7];

— 6 % to 9 % deionized water.

NOTE Information on sourcing a suitable paste is available from the ISO Central Secretariat.

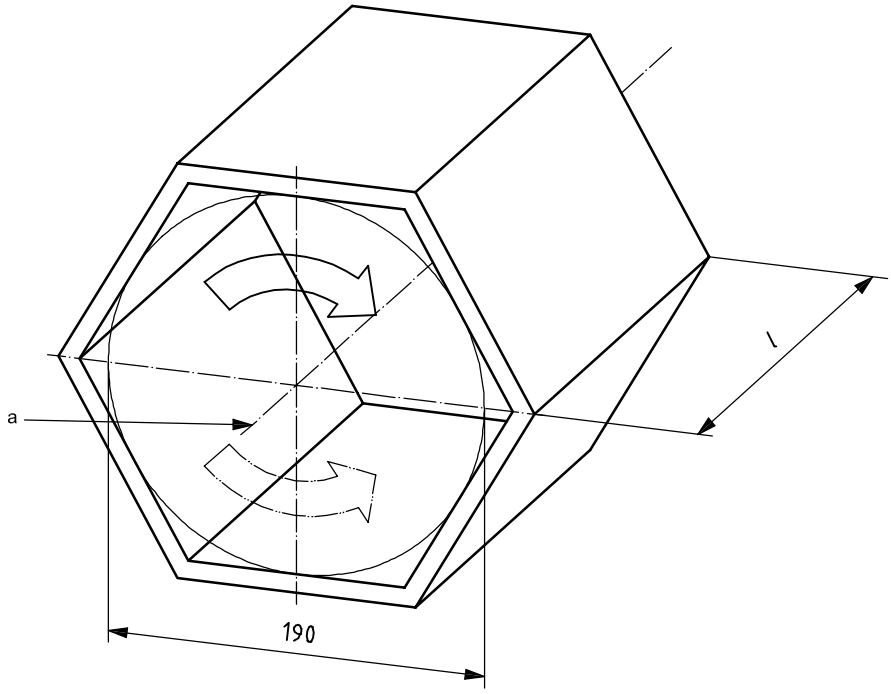
4.2.3.4 Granules, composed of outer shells of coconuts, walnuts, peanuts and almonds, mixed in a ratio 1:1:1:1 by weight, ground and sieved to give a mixture of particles having dimensions between 0,8 mm and 1,3 mm.

NOTE Information on sourcing suitable granules is available from the ISO Central Secretariat.

4.2.3.5 Wear medium, composed of abrasive paste (4.2.3.3) and wear granules (4.2.3.4) which are mixed as indicated in 4.5.1. Before use, the required amount of granulate shall be conditioned in standard laboratory conditions for at least 24 h.

4.2.3.6 Retaining assembly, consisting of a threaded rod which carries three metal hexagonal plates (see Figures 2 and 3). The end plate, A, is drilled part way through with holes of nominal diameter 1,5 mm, or as appropriate, positioned 10 mm to 15 mm from the edge of the plate, 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, positioned 10 mm to 15 mm from the edge of the plate, 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. A silicone rubber sheet with small holes matching the position of those in plate B holds the sides to prevent them from rotating in the assembly. The final plate, C, is undrilled apart from the hole for the threaded rod. A threaded nut on the inside of the last two plates holds them the required distance from plate A, while a second nut on the outside clamps the assembly together. The volume between plates A and B is approximately 5 l ± 0,5 l, but will vary depending upon the length of the sides or width of the spectacle fronts to be tested.

Dimensions in millimetres



Key

l length of barrel, as required

[a] Axis of rotation.

Figure 1 — View of tumbling barrel

Dimensions in millimetres

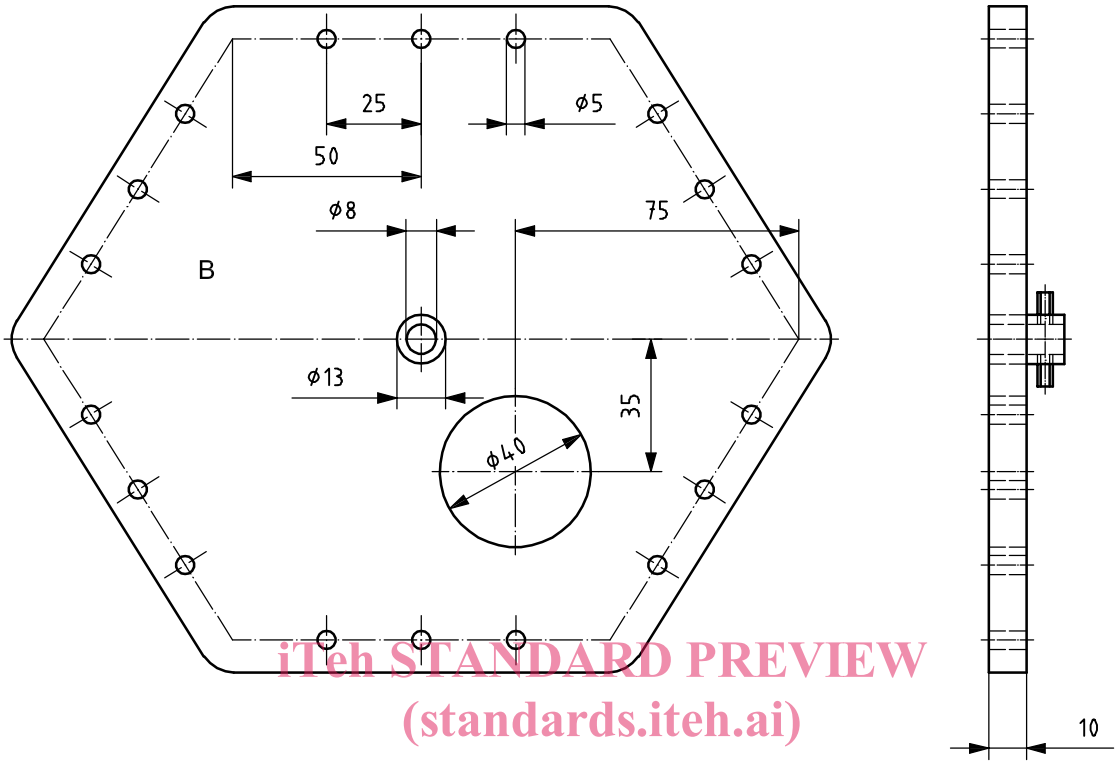
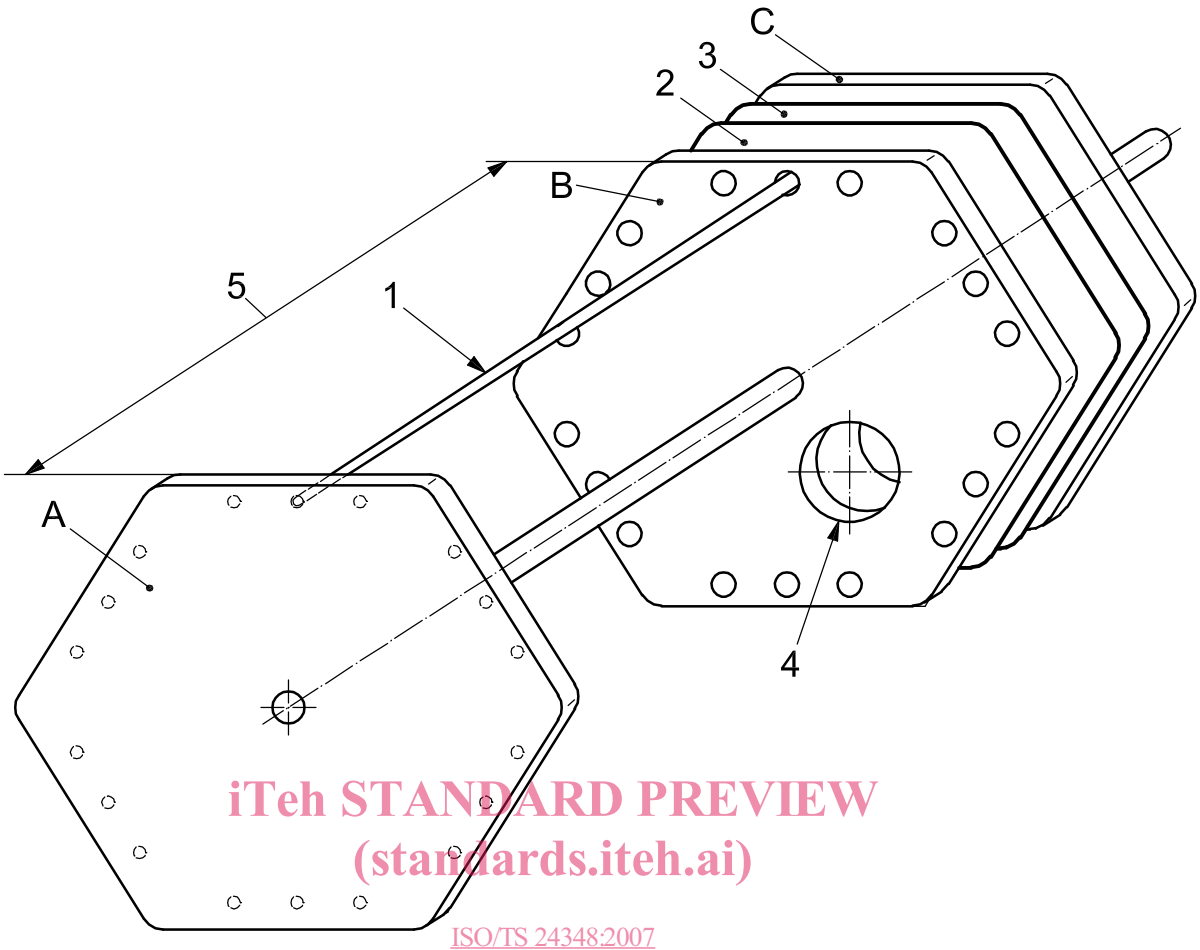


Figure 2 — Plan view of the upper part of the tumbling barrel — Component B



Key

1 sample side
2 silicone sheet, perforated
3 silicone sheet, plain
4 fill hole
5 adjust as required

Figure 3 — Exploded diagram of retaining assembly for spectacle sides

4.3 Sample preparation

Before being subjected to the corrosion procedure (see 4.4) and the wear procedure (see 4.5), spectacle sides and fronts shall be separated from each other, and endcovers (side tips) removed from sides and nose pads from fronts where appropriate. If the spectacle frame is to be subject to the accelerated wear procedure given in this Technical Specification, then it shall be fitted with test lenses as specified in ISO 12870 before being subjected to the accelerated wear procedure.

NOTE 1 Parts of items which are not intended to come into prolonged contact with the skin can be removed before being subjected to corrosion and/or wear.

Gently swirl the sample(s) for 2 min in degreasing solution (4.2.2.3) at room temperature. Rinse thoroughly with deionized water (4.2.2.4) and gently dry with absorbent paper. After degreasing, samples should be handled with plastic forceps or clean protective gloves.

NOTE 2 This cleaning stage is intended to remove extraneous grease and skin secretions due to handling, but not any protective coatings.