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Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications

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National foreword

This British Standard is the UK implementation of EN ISO 3665:2013. It is identical to ISO 3665:2011. It supersedes BS ISO 3665:2011 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/106, Dentistry.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Photography - Intra-oral dental radiographic film and film packets - Manufacturer specifications (ISO 3665:2011)

Photographie - Film et paquets de films pour la radiographie dentaire intrabuccale - Spécifications (ISO 3665:2011)

Fotografie - Intraorale dentale Röntgenfilme und Filmpackungen - Herstellerangaben (ISO 3665:2011)

This European Standard was approved by CEN on 1 March 2013.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 3665:2011 has been prepared by Technical Committee ISO/TC 42 “Photography” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 3665:2013 by Technical Committee CEN/TC 55 “Dentistry” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2013, and conflicting national standards shall be withdrawn at the latest by September 2013.

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Endorsement notice

The text of ISO 3665:2011 has been approved by CEN as EN ISO 3665:2013 without any modification.

Photography — Intra-oral dental radiographic film and film packets — Manufacturer specifications

1 Scope

This International Standard establishes a system for the classification of intra-oral radiographic film by the speed of the film/process system and by the size of the film. It specifies the sensitometric characteristics of the film/process systems, the physical characteristics of the film and packets, and it describes packaging and labelling requirements.

This International Standard is applicable to intra-oral dental radiographic film for manual or automatic processing. It does not apply to films intended to be exposed with fluorescent intensifying screens, or films intended to be viewed primarily by reflected light.

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 1, *Geometric Product Specifications (GPS) — Standard reference temperature for geometrical product specification and verification*

ISO 5-2, *Photography and graphic technology — Density measurements — Part 2: Geometric conditions for transmittance density*

ISO 5-3, *Photography and graphic technology — Density measurements — Part 3: Spectral conditions*

ISO 554, *Standard atmospheres for conditioning and/or testing — Specifications*

ISO 5799, *Photography — Direct-exposing medical and dental radiographic film/process systems — Determination of ISO speed and ISO average gradient*

ISO 8374, *Photography — Determination of ISO safelight conditions*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18906, *Imaging materials — Photographic films — Specifications for safety film*

3 Terms and definitions

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

3.1
expiry date
date, set by the manufacturer, beyond which the manufacturer does not guarantee the quality of the product when handled, shipped and stored according to his instructions

3.2
gray
Gy
dose of X and/or gamma radiation absorbed by 1 kg of air, which imparts 1 J of initial kinetic energy to those charged particles that it produces

NOTE Gy = 1 J/kg of air (equivalent to 114,5 R or to 0,029 5 C/kg).

3.3
packet
receptacle containing one or more radiographic films intended for intra-oral use

3.4
package
receptacle containing multiple packets

4 Film and packet classifications

4.1 Film speed groups

The speed of the film/process system shall be designated in terms of speed groups as specified in ISO 5799 and given in Table 1.

Table 1 — Speed groups

Speed group	Speed range ($Gy \times 10^2$)
D	14,0 to 27,9
E	28,0 to 55,9
F	56,0 to 111,9

4.2 Film size numbers

The size of intra-oral radiographic film shall be designated in terms of size numbers as given in Table 2.

Table 2 — Film sizes

Dimensions in millimetres

Size number	Dimensions of film (tol. ±0,5)	Approximate radius of corners (tol. ±2)
0	22,0 × 35,0	6
1	24,0 × 40,0	6
1A [a]	24,0 × 30,0	6
2	30,5 × 40,5	6
3	27,0 × 54,0	6
4	57,0 × 76,0	8
4A [a]	54,0 × 70,0	8
5 [a]	40,0 × 50,0	8

[a] These sizes are not common worldwide sizes but do exist in some markets.

4.3 Packet dimensions

The maximum width and length are designated in Tables 3 and 4.

Table 3 — Packet maximum width

Dimensions in millimetres

Size number	Maximum width of film	Maximum width of packet
0	22,5	26,5
1	24,5	28,5
1A [a]	24,5	28,5
2	31,0	35,0
3	27,5	31,5
4	57,5	61,5
4A [a]	54,5	58,5
5 [a]	40,5	44,5

[a] These sizes are not common worldwide sizes but do exist in some markets.

Table 4 — Packet maximum length

Dimensions in millimetres

Size number	Maximum length of film	Maximum length of packet
0	35,5	39,5
1	40,5	44,5
1A [a]	30,5	34,5
2	41,0	45,0
3	54,5	58,5
4	76,5	80,5
4A [a]	70,5	74,5
5 [a]	50,5	54,5

[a] These sizes are not common worldwide sizes but do exist in some markets.

5 Requirements

5.1 Symbols

The symbols used shall be in accordance with ISO 15223-1.

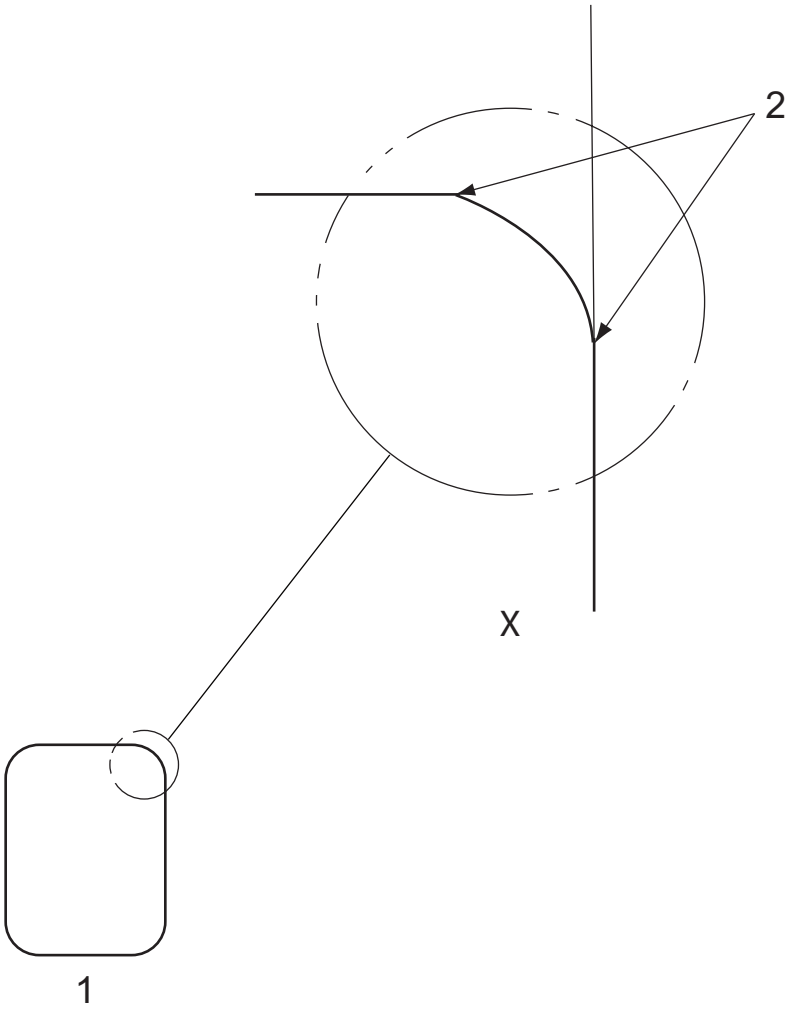
5.2 Film requirements

5.2.1 Film type

The film shall be of the safety type defined in ISO 18906 and shall be housed within the light-tight enclosure.

5.2.2 Film corner dimensions

Due to the manufacturing process for the packet, there may be a slight ledge or step on the film itself. The step shall be no greater than 0,2 mm (see Figure 1).



Key

X enlarged view of the film chip
1 size 2 film
2 step

NOTE Maximum step 0,2 mm.

Figure 1 — Film corner characteristics

5.2.3 Film thickness

Film thickness shall not be greater than 0,25 mm.

5.2.4 Film safelight sensitivity

When testing a film by means of the procedures described in ISO 8374, no portion of the film exposed to the safelight recommended by the manufacturer shall have any visible or measurable difference in density when compared to that portion not exposed to the safelight.

5.2.5 Film identification of the radiation side of the processed film

The film shall have an indicator at or near one edge denoting the side intended to be towards the radiation source. A preferred means is an embossed dot with the raised portion indicating the irradiated side.

NOTE An alternative means used by some manufacturers is to place radiopaque numbers on the packet. The number can be read correctly on the irradiated side of the film.

5.2.6 Sensitometric properties of the film

5.2.6.1 The film shall exhibit a uniform response to radiation.

5.2.6.2 The speed classification shall be in accordance with ISO 5799.

5.2.6.3 The average gradient in accordance with ISO 5799 shall be greater than 1,50.

5.2.7 Base plus fog density at the point of manufacture

Base plus fog density of the film shall be no greater than 0,25.

NOTE This requirement applies only to the manufacturer of the film. The manufacturer shall retain testing data and results, should national bodies require verification for audit purposes.

5.2.8 Film expiry date

The manufacturer shall use a maximum base plus fog density of 0,40 to set the expiry date of the film.

NOTE A manufacturer's recommended monobath process may produce an increase in fog value of 0,05.

5.3 Packet requirements

5.3.1 General

Each packet shall contain one or more sheets of radiographic film, together with the components that limit film bending and provide a light-tight enclosure.

When X-ray attenuation is provided by an internal mechanism, a sheet of lead foil or other material with equivalent X-ray attenuation characteristics shall be included in each packet.

If attenuation is provided by an external mechanism, this shall be clearly stated on the package and the recommended method shall be included in the instructions for use.

The covering of the packets shall have high visibility under the recommended safelight illumination.

The edges of the packets should be smoothly rounded and sufficiently blunt to avoid discomfort to the patient.

Each packet shall be provided with a means for easily unwrapping film.

If present, the lead foil or equivalent material shall be positioned on that side of the film intended to face away from the radiation source. A material other than lead shall provide the same level of attenuation.

NOTE 1 The lead foil of 0,038 mm or equivalent material provides protection from back scatter radiation to allow 19 lp/mm. Thicker foils can be used but do not provide any significant improvement in image quality or shielding.

NOTE 2 Alternatively, a radiopaque number on the front of each packet can be used to indicate exposure technique error on a processed film.

5.3.2 Packet width and length

The maximum width or length of the packets shall not be more than 4,0 mm greater than the corresponding width or length of the film. This does not apply to the holding tab attached to the packet.

5.3.3 Packet thickness

The maximum thickness of the packet not counting any tab used for positioning shall be 2,0 mm. For interproximal film, the tab shall have a minimum length and width of 20 mm.

5.3.4 Moisture protection

The packets should be able to withstand the moisture in a mouth during an X-ray procedure and shall be able to be disinfected with a liquid disinfectant.

NOTE Concern regarding the possible transmission of communicable diseases has introduced the need to disinfect film packets prior to processing in dental practice. Protection from damage by the disinfection solution can be achieved by using a protective barrier or plastic foil overwrap on each packet. The process of disinfection and the necessary precautions to be taken in the handling of packets and film fall outside the scope of this International Standard.

6 Sampling, inspection and testing

6.1 Sampling

At least six unopened packages of film packets shall be obtained for testing. Each test shall be performed on samples from three separate packages. Approximately 50 packets will be needed from each package for testing. Should a product be supplied with fewer packets per package, a proportionately larger number of packages shall be obtained for testing.

The films shall be stored in accordance with the manufacturer's recommendations.

6.2 Inspection

Visual inspection shall be used to determine compliance with 5.2.5 and 5.3.

6.3 Testing

6.3.1 Base plus fog density, film speed and average gradient

Three independent determinations of base plus fog density, film speed and average gradient shall be made using the methods described in ISO 5799, using film from at least three separate packages.

For base plus fog density, each film shall comply with the requirements given in 5.2.7 and 5.2.8.

For film speed and average gradient, take the average of the three determinations as the test result. Each determination, however, shall not differ from the average by more than ± 20 %.

6.3.2 Size numbers

The length, width and corner radius of a film from three separate film packages shall be measured by means of a ruler with 0,5 mm calibrations, or by other means of at least equivalent accuracy.

Size numbers shall be determined from Table 2.

Each film shall correspond to a size number and its package shall be marked as indicated in 7.2.

The dimensions and tolerances specified in this International Standard apply at the time of manufacturing, measured under atmospheric conditions of (23 ± 2) °C and (50 ± 5) % relative humidity, as specified in ISO 554.

All measuring instrument calibrations shall be referred to a temperature of 20 °C, as specified in ISO 1, and a relative humidity of 50 %.

6.3.3 Squareness and edge straightness

Squareness, edge straightness, shape and compliance with specified dimensions shall be checked at the same time by comparison of any given film with two perfect rectangles, independently located: one made to the minimum dimensional tolerance specified in this International Standard, and the other to the maximum tolerance. No point on the perimeter of the film shall fall within the smaller rectangle, nor shall any point fall outside the larger rectangle.

6.3.4 Uniformity

Three film packets, one from each of three separate packages, shall be exposed and processed in accordance with the methods given in ISO 5799 to produce an ISO 5 standard visual density of 1,0 ± 0,3 above fog and base on the film measured in accordance with ISO 5-3.

The films shall be evaluated visually on a uniformly illuminated film viewer. Each film shall comply with the requirements.

6.3.5 Safelight sensitivity

Safelight sensitivity shall be determined by the methods described in ISO 8374.

A set of films from at least three separate packages shall be exposed in accordance with ISO 5799.

After removal of the films from the packets in total darkness, approximately one half of each film shall be covered by an optically opaque material and then exposed to the safelight set-up under test, using the type of safelight filter recommended by the manufacturer.

The films shall be processed in accordance with ISO 5799.

The standard visual diffuse transmission density of the covered and uncovered portion of each film shall be measured in accordance with ISO 5-2. Alternatively, each film shall be inspected for a visible line of demarcation between the covered and uncovered portions.

Each film shall comply with the requirements given in 5.2.4.

6.3.6 Film packets and lead foil dimensions

The unprocessed film thickness, the lead foil thickness and the packet thickness shall be measured for a film packet from three separate packages by means of a micrometer, or other means of at least equivalent accuracy.

The maximum packet length and width, the packet corner radius and the tab length (where applicable) shall be measured for a film packet from three separate packages by means of a ruler with 0,5 mm calibrations, or by other means of at least equivalent accuracy.

Each film, film packet and lead foil or other material shall comply with the requirements given in 5.2 and 5.3.

7 Marking and instructions for use

7.1 Data on packet

Each film packet shall be marked with:

a) product trade name;

b) speed group in accordance with ISO 5799;

NOTE 1 This is dependent on processing conditions for some films [see 7.3 b)].

c) number of films in the packet;

NOTE 2 If a colour coding system is used to indicate the film type and/or number of films in the packet, an explanation is in the instructions for use [see 7.3 e)].

d) indication of which side should be placed away from the radiation source, such as a coloured tab or "opposite side towards the tube" or "back". Alternatively, the packet could be marked as to which side should be placed towards the tube.

NOTE 3 An indication of where the radiation side dot is on the film can be marked on the package.

NOTE 4 If the attenuation mechanism is outside the packet, a mark can be applied to the packet to facilitate consistent orientation by the practitioner.

7.2 Data on package

Sufficient data shall be given on the package to inform the user of the product's proper use and handling. Packages are marked for the purpose of identifying the product name, size and conditions of shipping and storage.

Packaging shall be identified using the appropriate entries from the following list:

NOTE 1 These may be indicated by wording or codes.

a) product name or trade name;

b) name or trade name of the manufacturer/supplier;

c) manufacturer's/supplier's catalogue identification number;

d) number of films in the packet;

e) quantity of packets in the package;

f) speed group;

g) size number and/or nominal product dimensions, in metric units, with the smaller dimension first (either a prefix or suffix "W" should be used if the packet has an interproximal film);

h) lot number of the production batch;

i) expiry date;

NOTE 2 An hourglass symbol can be used, in accordance with ISO 15223-1.

j) bar-code information;

NOTE 3 Barcode requirements can vary in different countries.

k) manufacturer's recommended storage conditions;

l) if the packet does not contain an internal attenuation device, a clear statement to this effect;

m) where a packet contains an internal attenuation device and is not explicitly marked "opposite side towards the tube" or "back", the indicator or orientation for its correct use;

n) where a radiopaque number is on the front of the packet, the wording "to expose, face the lead number towards the X-ray source".

NOTE 4 There might be legal requirements in certain countries for additional data to be marked on the package.

7.3 Instructions for use

Instructions shall be printed on, or enclosed in, each package, or otherwise made readily available to the user at no expense. The instructions shall include the following:

a) manufacturer's recommended safelight filter;

b) processing instructions;

c) representative exposure times for various oral locations based upon technique factors of 65 kV, 10 mA or 8 mA, 1,5 mm total aluminium equivalent filtration, and a 200 mm source-to-skin distance;

d) conversion factors by graphs or tables by which users can estimate exposure times for technique factors other than those given above (e.g. for a source-to-skin distance of 400 mm);

e) an explanation of any colour coding of packets where it is used to differentiate between packets of different speed groups and numbers of films;

f) an explanation that in certain parts of the world high levels of background radiation can reduce the expiry date of the product;

g) if the packet does not contain an internal attenuation device, instructions regarding the recommended method for external attenuation.

7.4 Compliance

If it is desired to indicate compliance of a product with this International Standard, the following wording shall be used:

"Complying with ISO 3665:2011".

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Price based on 9 pages

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BSI Group Headquarters

389 Chiswick High Road London W4 4AL UK

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