INTERNATIONAL STANDARD

ISO 3665

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

Photographie — Film et paquets de films pour la radiographie dentaire intrabuccale — Spécifications

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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.

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 3665 was prepared by Technical Committee ISO/TC 42, *Photography*, in collaboration with Technical Committee ISO/TC 106, *Dentistry*.

This third edition cancels and replaces the second edition (ISO 3665:1996), which has been technically revised.

The following significant changes have been made from the second edition.

— In 7.2, the elevated temperature storage test and storage abuse test have been removed and replaced by a requirement for manufacturers to clearly stipulate the shipping, handling, and storage conditions required, ensuring that the diagnostic quality of the film is maintained up to the expiry date of the film.

— In 5.2.7, the base plus fog density has been reviewed and a maximum level has been set for the point of manufacture.

— In 5.2.8, the base plus fog density has been reviewed and a maximum has been set for the manufacturer to use in order to set the expiry date of the product.

— In 7.3, in recognition that background radiation can reduce the expiry date of a film, information to this effect has been included.

— In Table 1, the requirements for C speed film have been removed, as use of this film is no longer justified on radiological and clinical grounds.

— In 7.2, the requirements for film sizes have been rationalized to conform with current manufacturing practice.

— In 7.1, no requirement for a colour coding system for films has been included; instead it is the responsibility of the manufacturer to provide a clear explanation in the instructions if a colour coding system is used.

— In 7.1, films requiring the use of an external attenuation device have been included.

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 × 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.

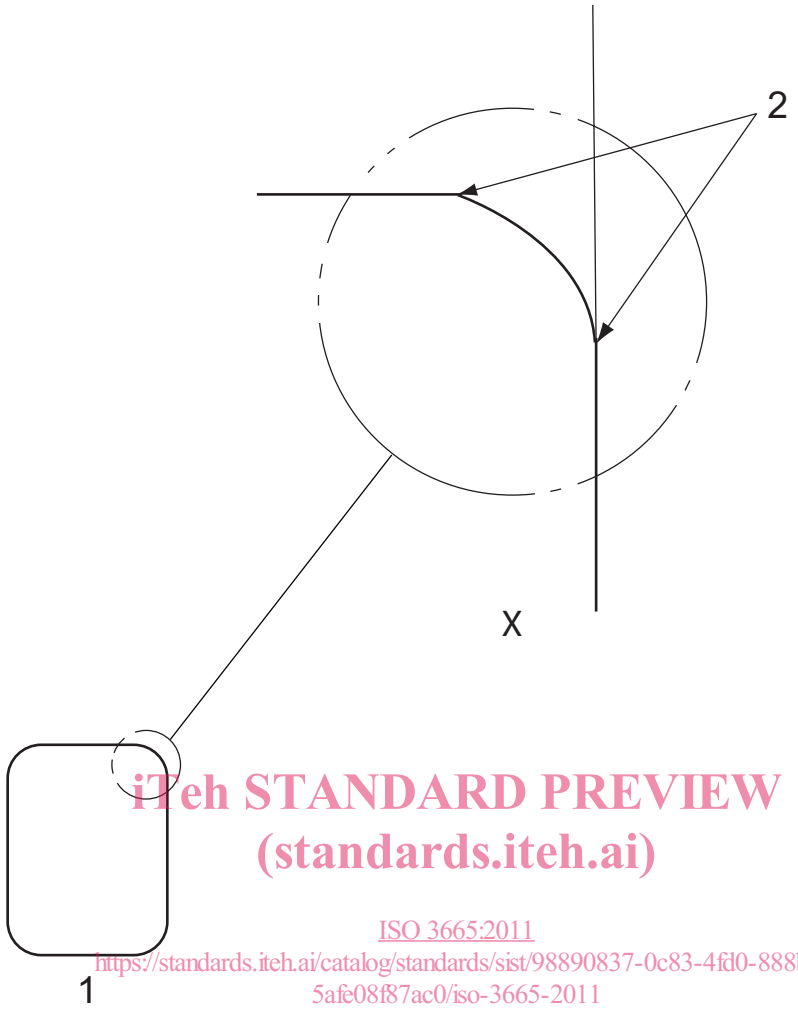
5.2 Film requirements

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.