भारतीय मानक

Indian Standard

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नेत्र संबंधी प्रकाशिकी — संपर्क लेंस और संपर्क लेंस देखभाल उत्पाद लेबलिंग

Ophthalmic Optics — Contact Lenses and Contact Lens Care Products Labelling

ICS 11.040.70

भारतीय मानक ब्यूरो
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Ophthalmic Instruments and Appliances Sectional Committee, MHD 05

NATIONAL FOREWORD

This Indian Standard which is identical to ISO 11978 : 2017 ‘Ophthalmic optics — Contact lenses and contact lens care products Labelling’ issued by the International Organization for Standardization was adopted by Bureau of Indian Standards on the recommendation of the Ophthalmic Instruments and Appliances Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

Amendment 1 published in 2020 to ISO 11978 : 2017 is given at the end of the publication.

The text of ISO standard has been approved as suitable for publication as an Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

a) Wherever the words ‘International Standard’ appear referring to this standard, they should be read as ‘Indian Standard’; and

b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

In this adopted standard, reference appears to certain International Standards for which Indian Standards also exist. The corresponding Indian Standards which are to be substituted in their respective places are listed below along with their degree of equivalence for the editions indicated:

International Standards	*Corresponding Standards*	*Degree of Equivalence*
ISO 15223–1 : 2012 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General Requirements	IS/ISO 15223-1 : 2016 Medical Devices — Symbols to be used with medical device labels, labelling and information to be supplied: Part 1 General requirements (*second revision*)	Identical
ISO 18369–1 Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications	IS/ISO 18369-1 : 2017 Ophthalmic optics contact lenses: Part 1 Vocabulary classification system and recommendations for labelling specifications (*first revision*)	Identical

Contents

Page

Introduction

This document attempts to harmonize requirements, whenever possible, for labelling of contact lenses and contact lens care products with national laws, regulations, or guidelines that might exist in countries throughout the world. Where national laws and labelling requirements exist in countries for medical devices, they are often developed by legislative bodies or regulatory authorities independently from the development process for International Standards. Therefore, labelling requirements established by an individual country cannot always be readily integrated into International Standards.

The information given in this document provides a suitable framework for developing labelling for contact lenses and contact lens care products. Conformance to the elements herein is intended to be sufficient for developing appropriate labelling for countries without existing laws or regulations for medical device labelling. However, conformance with the elements of this document might not be sufficient for full compliance with additional labelling requirements mandated by an individual country. Where national laws or regulations mandate additional labelling requirements or conflict with elements of this document, the national law or regulation is intended to be followed and is intended to take precedence over the elements of this voluntary document.

The manufacturer should provide more information to the contact lens professional upon request.

Indian Standard

OPHTHALMIC OPTICS — CONTACT LENSES AND CONTACT LENS CARE PRODUCTS LABELLING

1 Scope

This document specifies the information to be provided by the manufacturer of contact lenses and contact lens care products to ensure the correct and safe use of these devices and their accessories by both types of user of contact lenses: the eye care professional and the contact lens wearer.

This document does not specify the format in which such information shall be provided.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15223–1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18369–1, *Ophthalmic optics — Contact lenses — Part 1: Vocabulary, classification system and recommendations for labelling specifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18369–1 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

4 Labelling requirements

4.1 General

Where practicable and possible, the information supplied by the manufacturer shall be provided in the language of the country in which the device is distributed. Where appropriate, this information should take the form of symbols. Symbols used shall conform to ISO 15223–1. Where a symbol is not described in ISO 15223–1, it shall be described in the documentation supplied with the device.

Provided the minimum essential requirements are fulfilled, the manufacturer may use his discretion as to the format in which the information is provided, e.g. product-specific information either on the packaging for each unit or on the sales packaging, or in separated leaflets, brochures, booklets, or generic handling guides. These may be supplied as hard copy, electronic format, video, etc.

All symbols and written information shall be a minimum of 0,7 mm in height and be legible at a reading distance of 30 cm under the illumination of 215 lx, except for Trademarks and any manufacturing part numbers.

4.2 Contact lenses

The labelling shall include at least the following (indicated in Table 1 by an "X"), exceptions as noted.

Table 1 — Labelling requirements for contact lenses

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
1	Name or trade name and address of manufacturer[c]	X[a]	X	X	
2	Detailed requirements for the user to identify the device and the contents of the packaging, such as:				
a)	product identification and/or material name;	X	X	X	
b)	contact lens parameters;	X	X		
c)	number of contact lenses;	X[a]	X		
d)	packaging solution (e.g. phosphate-buffered saline solution) and identification of any preservative if present	X[a]	X	X	In exceptional cases, if the size of the primary container does not allow information regarding composition of storage solution, this information may be incorporated in the "Instructions for use".
3	The word "Sterile" together with method of sterilization	X	X	X	If applicable
4	Lot number prefixed by the word "LOT" or the symbol for "LOT"	X	X		
5	Expiry date	X	X		
6	The statement "For single use only"[d]	X[a]	X	X	If applicable
7	The statement "Custom made device"	X[a]	X	X	If applicable
8	Intended use or application			X	
9	The indication that the device is exclusively for use in a clinical investigation according to applicable regulations	X[a]	X	X	If applicable
10	Any special storage and/or handling conditions (e.g. Do not freeze.); any special operating instructions (e.g. Do not use if tamper-evident seal is damaged.)	X[a]	X	X	
11	The statement "Attention: See instructions for use." or the recognized symbol (see ISO 15223-1:2012, 5.4.3)	X[a]	X		
12	Replacement frequency, e.g. daily disposable, weekly disposable, or monthly disposable		X[b]	X	If applicable
13	Schedule for wear, e.g. daily wear and/or extended wear, as applicable			X	
14	Recommended and if relevant, contra-indicated care regimens			X	

Table 1 *(continued)*

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
15	Date of issue or the latest revision of the instruction for use			X	
16	Contraindications, warnings and precautions or any other information deemed necessary by the manufacturer for the safe use of his contact lenses				
a)	Possible or known adverse reactions and side effects, and instructions to the wearer on the action to be taken if a problem occurs			X	
b)	Recommendations to follow the eye care professional's instructions for duration of use of the contact lens(es) on a daily basis, follow-up visits and emergency procedures			X	
c)	Any directions or information necessary for the safe use of contact lenses if they have not been worn for a length of time			X	
d)	The information that contact lenses should be removed immediately after contact with noxious vapour, e.g. chemical or hazardous substances, or hazardous environment with ocular impact			X	
e)	The information that direct exposure of contact lenses to non-sterile water (e.g. tap water, whirlpool bath, swimming, participating in water sports) increases the risk of microbial infection			X	
f)	The information that the use of non-sterile water (e.g. tap water) in the handling of contact lenses and contact lens cases increases the risk of serious microbial infection			X	
g)	Instructions on cleaning and maintenance of contact lenses and contact lens cases			X	
h)	Instruction not to change the contact lens care system without consulting an eye care professional			X	
i)	Instruction not to change lens type or parameters without consulting an eye care professional			X	

Table 1 *(continued)*

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
j)	Instructions regarding the hygienic handling of contact lenses			X	
k)	Instructions for insertion and removal of contact lenses			X	

[a] If contact lenses are not supplied with a secondary packaging, the required information shall be given on the primary container label.

[b] If the size of the secondary packaging does not allow the above information to be displayed, the relevant information shall appear on the "Instructions for use" leaflet.

[c] In those markets that require name and address of an authorized representative, this information shall be included.

[d] For the countries of the European Union, EU Directive 93/42/EEC stipulates that "A manufacturer's indication of single use must be consistent across the Community". Note that for contact lenses, "single use" implies a single wearing period, the maximum duration of which will be specified by the manufacturer.

4.3 Contact lens care products

The labelling shall include at least the following (indicated in Table 2 by an "X"), exceptions as noted.

Table 2 — Labelling requirements for contact lens care products

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
1	Name or trade name and address of manufacturer[c]	X[b]	X	X	
2	Detailed requirements for the user to identify the product and the contents of the packaging, such as:				
a)	product name;	X[b]	X	X	
b)	total contents in the packaging (e.g. number, mass, or volume);	X[a]	X		
c)	qualitative and quantitative details of all active ingredients and preservatives (for other ingredients, qualitative details only)	X[a]	X	X	
3	The word "Sterile" together with method of sterilization	X[b]	X	X	
4	Lot number prefixed by the word "LOT" or the symbol for "LOT"	X[b]	X		
5	Expiry date of unopened container	X[b]	X		
6	The statement "Custom made device"	X[a]	X	X	If applicable
7	The indication that the device is exclusively for use in a clinical investigation according to applicable regulations	X[a]	X	X	If applicable
8	Instructions for use or, where appropriate, the words "Attention: See instructions for use.", or the recognized symbol (see ISO 15223-1:2012, 5.4.3)	X[b]	X		
9	Indications for use, in clear and understandable language	X[a]	X	X	

Table 2 *(continued)*

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
10	Type(s) of contact lens(es) for which the product is suitable and those contraindicated for use with the product	X[a]	X	X	
11	Any special operating instructions, e.g. "Close bottle after use.", "Do not use if tamper-evident seal is damaged."	X[a]	X	X	
12	Maximum period of use after the container has first been opened	X[a]	X	X	
13	A statement that unit dose containers are "For single use only". This indication shall be consistent over all countries where the product is placed to market.	X[b]	X	X	
14	Storage or handling conditions	X[a]	X	X	If applicable
15	The statement "Keep out of reach of children."	X[a]	X	X	
16	A statement that the product is part of a system and shall only be used with the manufacturer's recommended component(s)	X[a]	X	X	
17	For regimen products, an instruction to the contact lens wearer to ensure adherence to the regimen procedure		X	X	
18	The term "Contact lens disinfection solution" (see ISO 14729:2001,5.1 + Amd.1:2010)	X[a]	X	X	If applicable
19	Any warnings and/or precautions to take	X[a]	X	X	
20	Contraindications, or any other information necessary for the safe use of the product			X	
21	Possible adverse reactions and side effects			X	
22	Recommendations in case of problems			X	
23	The warning "Not to be used in the eye", and if space allows, any action to be taken if this has happened	X	X	X	If applicable
24	Any directions or information necessary for contact lens care and the safe use of contact lenses if the contact lenses have not been used for a length of time			X	
25	Any mechanism or action(s) necessary to ensure cleaning efficacy			X	
26	Date of issue or the latest revision of the instruction for use			X	

Table 2 *(continued)*

No.	Content	Label		Instructions for use	Comments
		Primary container	Secondary packaging		
27	Instruction not to change the contact lens care system without consulting an eye care professional	X[a]	X	X	
28	The labelling and instructions for use shall clearly state all steps required to ensure care of each contact lens for wearer safety. The omission of any step, such as rubbing the lens, shall not be emphasized or highlighted in the labelling and instructions for use.	X[a]	X	X	

[a] If contact lens care products are not supplied with secondary packaging, the required information shall be given on the primary container label.

[b] Containers of volume 15 ml or less and unit dose containers shall bear at least this information.

[c] In those markets that require name and address of an authorized representative, this information shall be included.

Bibliography

[1] ISO 14534, *Ophthalmic optics — Contact lenses and contact lens care products — Fundamental requirements*

[2] ISO 14729:2001+Amd.1:2010, *Ophthalmic optics — Contact lens care products — Microbiological requirements and test methods for products and regimens for the hygienic management of contact lenses*

Ophthalmic optics — Contact lenses and contact lens care products — Labelling

AMENDMENT 1

4.1, third paragraph

Replace the third paragraph with the following:

"All written information and symbols intended for the user shall be designed to have a minimum height of 0,7 mm for black text or black symbol on a white background. All other colour combinations shall be designed with a minimum height of 0,7 mm and a contrast of at least 3:1 between the colour of the text or symbol and the colour of the background as computed using the colours' red, green, and blue (RGB) values.

Convert cyan, magenta, yellow and black (CMYK) printed colour values to RGB values using a conversion tool.

NOTE See Annex A for information on and examples for the calculation of contrast between text or symbol and background. Online calculators exist to compute contrast based on RGB values."

Annex A

Add a new Annex A as follows:

Annex A
(informative)

Calculation of contrast between text or symbol and background

A.1 General

This annex provides guidance on calculating contrast between text or symbol and background based on the colour of both the text or symbol and the background.

A.2 Principle

A.2.1 RGB colour space model

The RGB colour space basis is the three colours red, green, and blue. The colour space model utilizes intensity values for each colour to describe a gamut of colours. The gamut is created by adding varying amounts of red, green, and blue. The amounts vary from 0, black, to a set value for the maximum intensity and fully saturated colour. A common scheme is to use 8 bits, the integer values from 0 to 255, to specify the amount of red, green, and blue.

A.2.2 sRGB colour space model

The standard RGB (sRGB) colour space is a device-independent model. The model uses the same colourimetric RGB definitions as the RGB colour space, but further specifies display and reference conditions.

A.3 Computing contrast

A.3.1 General

In the sRGB colour space model with 8-bit values for each colour ranging from 0 to 255, the transformation from RGB 8-bit to sRGB is nonlinear:

$$\begin{aligned} R'_{\mathrm{sRGB}} &= R_{8\mathrm{bit}}/255 \\ G'_{\mathrm{sRGB}} &= G_{8\mathrm{bit}}/255 \\ B'_{\mathrm{sRGB}} &= B_{8\mathrm{bit}}/255 \end{aligned} \tag{A.1}$$

$$\begin{aligned} &\text{If } R'_{\mathrm{sRGB}} \leq 0{,}040\,45 \text{ then } R_{\mathrm{sRGB}} = R'_{\mathrm{sRGB}}/12{,}92 \\ &\text{else } R_{\mathrm{sRGB}} = [(R'_{\mathrm{sRGB}} + 0{,}055)/1{,}055]\text{^}2{,}4 \\ &\text{If } G'_{\mathrm{sRGB}} \leq 0{,}040\,45 \text{ then } G_{\mathrm{sRGB}} = G'_{\mathrm{sRGB}}/12{,}92 \\ &\text{else } G_{\mathrm{sRGB}} = [(G'_{\mathrm{sRGB}} + 0{,}055)/1{,}055]\text{^}2{,}4 \\ &\text{If } B'_{\mathrm{sRGB}} \leq 0{,}040\,45 \text{ then } B_{\mathrm{sRGB}} = B'_{\mathrm{sRGB}}/12{,}92 \\ &\text{else } B_{\mathrm{sRGB}} = [(B'_{\mathrm{sRGB}} + 0{,}055)/1{,}055]\text{^}2{,}4 \end{aligned} \tag{A.2}$$

The relative luminance (L) from IEC 61966-2-1 for a given colour in the sRGB colour space model is:

$$L = 0,2126R_{\text{sRGB}} + 0,7152G_{\text{sRGB}} + 0,0722B_{\text{sRGB}} \quad \text{(A.3)}$$

NOTE The term "luminance" in this use represents the Y tristimulus value from CIE 1931 as stated in IEC 61966-2-1.

The contrast between the text or symbol and the background is:

If $L_{\text{test}} > L_{\text{background}}$ then

$$Contrast = \frac{(L_{\text{text}} + 0,05)}{(L_{\text{background}} + 0,05)} \quad \text{(A.4)}$$

Or if $L_{\text{background}} > L_{\text{text}}$ then

$$Contrast = \frac{(L_{\text{background}} + 0,05)}{(L_{\text{text}} + 0,05)} \quad \text{(A.5)}$$

Note that for the given definitions, contrast will always be greater than 1, and is typically written as a ratio of Contrast:1. Black text or black symbol on a white background has a contrast of 21:1, which is the maximum.

A.3.2 Example of text and background colours with acceptable contrast

Starting with descriptions of colour in the RGB 8-bit colour space, assume text that is a shade of orange (R = 255, G = 144, B = 51) on a background that is a shade of blue (R = 4, G = 16, B = 240).

The computed contrast between text and background is 3,974:1. This is an example of an acceptable combination of text and background colours since the contrast is greater than 3:1.

The computed values leading to contrast are given in Table A.1 and Table A.2.

Table A.1 — Example text and background colour values in RGB 8-bit and sRGB colour space models

Parameter	RGB 8-bit	sR'G'B'	sRGB
Text			
R	255	1,0000	1,0000
G	144	0,5647	0,2789
B	51	0,2000	0,0331
Background			
R	4	0,0157	0,0012
G	16	0,0627	0,0052
B	240	0,9412	0,8714

Table A.2 — Luminance and contrast for example text and background colours in Table A.1

Parameter	Luminance	Contrast
Text	0,4145	—
Background	0,0669	—
Contrast	—	3,974

A.3.3 Example of text and background colours with unacceptable contrast

Starting with descriptions of colour in the RGB 8-bit colour space, assume text that is a shade of greenish-blue (R = 0, G = 152, B = 175) on a background that is a shade of orange (R = 255, G = 215, B = 130).

The computed contrast between text and background is 2,495:1. This is an example of an unacceptable combination of text and background colours since the contrast is less than 3:1.

The computed values leading to contrast are given in Table A.3 and Table A.4.

Table A.3 — Example text and background colour values in RGB 8-bit and sRGB colour space models

Parameter	RGB 8-bit	sR'G'B'	sRGB
Text			
R	0	0,0000	0,0000
G	152	0,5961	0,3140
B	175	0,6863	0,4287
Background			
R	255	1,0000	1,0000
G	215	0,8431	0,6795
B	120	0,4706	0,1878

Table A.4 — Luminance and contrast for example text and background colours in Table A.3

Parameter	Luminance	Contrast
Text	0,2555	—
Background	0,7122	—
Contrast	—	2,495

Bibliography

Add the following references to the Bibliography:

[3] IEC 61966-2-1, *Multimedia systems and equipment — Colour measurement and management — Part 2-1: Colour management — Default RGB colour space — sRGB*

[4] W3C. 2018. Web Content Accessibility Guidelines (WCAG) 2.1. [online]. 2018. [Accessed 28 December 2018]. Available from: http://www.w3.org/TR/WCAG21/

[5] CIE 1931: *International Commission on Illumination: Color Spaces*

[6] DeCusatis, C. [ed], Handbook of Applied Photometry. AIP Press, 1997

[7] Marucco, Stoddard, Ferenbach & Walsh, Inc. Color Contrast Ratio Calculator. [online]. [Accessed 28 December 2018]. Available from: http://www.msfw.com/Services/ContrastRatioCalculator

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Review of Indian Standards

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