भारतीय मानक ब्यूरो

उपभोक्ता) मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार (

BUREAU OF INDIAN STANDARDS

(Ministry of Consumer Affairs, Food & Public distribution, Govt. of India)

मानक भवन, 9 बहादुरशाह जफर मार्ग, नई दिल्ली –110002
Manak Bhavan, 9 Bahadur shah Zafar Marg, New Delhi - 110002
दूरभाष Phones : 2323 0131 / 2323 3375 / 2323 9402
वेबसाईट Website : www.bis.org.in

व्यापक परिचलन मे मसौदा

संदर्भ	दिनांक
एम एच डी 05/ टी – 126	23-02-2018

तकनीकी समिति एम एच डी 05

पाने वालो के नाम

- नेत्र उपकरण एवम यंत्र विषय समिति, एम.एच.डी 05 के सभी सदस्य |
- चिकित्सा उपकरण एवम अस्पताल आयोजना विभाग परिषद |
- अन्य सभी रुचि रखने वाले |

प्रिय महोदय/महोदया,

निम्नलिखित प्रलेख सलग्न है :

प्रलेख सख्या : एम एच डी 05 (12439) [11.040.70]

शीर्षक : आइ एस /आइ एस ओ 12866 : 1999 'नेत्र उपकरण — परिमिती' की संशोधन सं. 1 का मसौदा

कृप्या इन मानक मसौदे का अवलोकन करे और अपनी सम्मतिया यह बताते हुए भेजे कि अंततः यदि ये मानक राष्ट्रीय मानक के रूप मे प्रकाशित हो जाये तो इन पर अमल करने मे आपके व्यवसाए अथवा कारोबार मे क्या कठिनाइयॉ आ सकती है | सम्मतिया यदि कोई हो तो कृप्या अगले पृष्ट पर दिये गये पत्र मे अधोहस्ताक्षरी को उपरिलिखित पते पर भेज दे |

सम्मतिया भेजने कि अंतिम तिथि : **22-03-2018**

यदि कोई सम्मति प्राप्त नही होती है अथवा सम्मति मे केवल भाषा संबंधि त्रुटि हुई तो उपरोक्त प्रलेख को यथावत अंतिम रूप दे दिया जायेगा | यदि कोई सम्मति तकनीकी प्रकृति की हुई तो विषय समिति के अध्यक्ष के परामर्श से अथवा उनकी इच्छा पर आगे की कार्यवाही के लिये विषय समिति को भेजे जाने के बाद प्रलेख को अंतिम रूप दे दिया जायेगा |

धन्यवाद

भवदीय

(प्रकाश बचानी)
वैज्ञानिक 'ई' एवं प्रमख (एम एच डी)
ई – मेल 1) hmhd@bis.org.im;
Note: Pl also send copy to: sempal@bis.org.in 2)mhd@bis.org.in
फोन : 011-23230910

संलग्नक : उपरोक्त

भारतीय मानक ब्यूरो
उपभोक्ता) मामले, खाद्य एवं सार्वजनिक वितरण मंत्रालय, भारत सरकार (
BUREAU OF INDIAN STANDARDS
(Ministry of Consumer Affairs, Food & Public distribution, Govt. of India)

मानक भवन, 9 बहादुरशाह जफर मार्ग, नई दिल्ली –110002
Manak Bhavan, 9 Bahadur shah Zafar Marg, New Delhi - 110002
दूरभाष Phones : 2323 0131 / 2323 3375 / 2323 9402
वेबसाईट Website : www.bis.org.in

DRAFTS IN WIDE CIRCULATION

DOCUMENT DESPATCH ADVICE	
Ref	**Date**
MHD 05/ T- 126	**23/02/2018**

TECHNICAL COMMITTEE: MHD 05

ADDRESSED TO:

- All members of Ophthalmic Instruments and Appliances Sectional Committee, MHD 05
- All Members of Medical Equipment and Hospital Planning Division Council, (MHDC)
- All others interested

Dear Madam/Sir(s),

Please find enclosed the following documents:

DOC NO: MHD 05(12439)] [11.040.70]
TITLE : Amendment No. 1 to IS/ISO 12866 : 1999 Ophthalmic instruments — Perimeters

Kindly examine the draft standards and forward your views stating any difficulties, which you are likely to experience in your business or profession, if these are finally adopted as National Standard.

Last date for comments**:** **22/03/2018**

Comments if any, may please be made in the format indicated and mailed to the undersigned at the above address. In case no comments are received or comments received are of editorial nature, you will kindly permit us to presume your approval for the above document as finalized. However, in case comments of technical nature are received then it may be finalized either in consultation with the Chairman, Sectional Committee or referred to the Sectional committee for further necessary action if so desired by the Chairman, Sectional Committee.

Thanking you,

Yours sincerely,

(Prakash Bachani)
Scientist 'E' & Head (MHD)

Encl: As above

email: 1) hmhd@bis.org.in;
Note: Pl also send copy to: 2) sempal@bis.org.in 3) mhd@bis.org.in
Phone: 011-23230910

Draft for Comments only

(Not to be reproduced without permission of BIS or used as standard)
Last date of receipt of comments is **22-03-2018**

Doc. No. : MHD 05(12439)

Amendment No. 1 February 2018
TO
IS/ISO 12866 : 1999
OPHTHALMIC INSTRUMENTS — PERIMETERS

(*Page* 1, *Clause* **2**) **—** Update the dated normative references to ISO 15004-1 and IEC 60601-1 with their new editions:

'ISO 15004-1 : 2006, Ophthalmic instruments — Fundamental requirements and test methods — Part 1: General requirements applicable to all ophthalmic instruments

IEC 60601-1 : 2005, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance'

(*Page* 5, *Clause* **4.4.2**) **—** Add the following new clauses after 4.4.2:

'4.4.3 For typical stimulus and background parameters the instrument shall be capable of comparing the result of each tested location with the age-specific normal value.

NOTE Typical parameters are those that are recommended by the manufacturer for routine use.

4.4.4 The version of the normal value table shall be specified by an ordinal version number and the date of issue of this table. Specification shall include the size and the age range of the normative database. The normative database shall fulfill the minimum requirements given in Annex C.

4.4.5 Printouts shall contain the version number of the normal value table used.

4.4.6 When new normal value table versions are implemented into an instrument by software update or other means, the user shall be notified.'

(*Page* 7, *Clause* **6**) — Substitute the following for the existing:

‘6 Accompanying documents

The perimeter shall be accompanied by documents containing instructions for use. In addition to the requirements laid down in 4.2.3, 4.2.4, 4.2.5, 4.4.1, 4.4.2 and 4.4.4 this information shall contain:

a) name and address of the manufacturer;
b) if appropriate, a statement that the perimeter in its original packaging conforms to the transport conditions as specified in 5.3 of ISO 15004-1 : 2006;
c) any additional documents as specified in 7.9 of IEC 60601-1 : 2005;
d) specification of examination strategies.’

(*Page* 10) — Add a new Annex C:

Annex C
(normative)

Minimum requirements for a normative database

Normal values for perimeters shall be based on a study that fulfils the following criteria

a) Predefined criteria for healthy eyes that are included in the database, covering at least the following items:

   — minimum visual acuity;
   — maximum spherical and cylindrical correction;
   — pathological conditions that lead to exclusion, independent of whether they are previously known or detected in the course of examination, and that are based on findings other than the visual field;

b) predefined criteria for the minimum experience in perimetric testing;
c) predefined method to choose the eye to be examined; only one eye of each subject can be included;
d) predefined criteria of unreliable examinations, which may cover the following items:

   — fixation behaviour;
   — false positive responses;
   — false negative responses;
e) no exclusion of examinations for reasons other than the predefined criteria;

   NOTE Exclusion of examinations based only on the results is not allowed. The exclusion of examinations based on pathological conditions that are found with the help of the result and that fulfil predefined criteria of exclusion is allowed.

f) a minimum sample size of 60 eyes;
g) a minimum of ten eyes of subjects younger than 30 years;
h) a minimum of ten eyes of subjects older than 60 years.

FORMAT FOR SENDING COMMENTS ON BIS DOCUMENTS

(Please use A4 size sheet of paper only and type within fields indicated. Comments on each clauses/sub-clauses/table/fig. etc be started on a fresh box. Information in Column 4 should include reasons for the comments and suggestions for modified wording of the clauses when the existing text is found not acceptable. Adherence to this format facilitates Secretariat's work)

Doc No.: MHD 05 (12439)
TITLE: Amendment No. 1 to IS/ISO 12866 : 1999 Ophthalmic instruments — Perimeters

LAST DATE OF COMMENTS: **22-03-2018**

NAME OF THE COMMENTATOR/ORGANIZATION:
_____

Sl. No.	Clause/Sub clause /Para/table/Fig. No. commented	Commentator/ Organization/ Abbreviation	Type of Comments (General/Editorial/ Technical)	Justification	Proposed change