Organisation Internationale de Métrologie Légale

International Organization of Legal Metrology

COMMENTS TEMPLATE

Template revision date: 2020-01-10

TC 18/p 2:	**New Recommendation: Ophthalmic instruments-non-contact tonometers**		
PG vote/comments on:	TC18_P2_N005		
Circulation date:	15 January 2020	Convener: Germany: Dana Rosu	**Closing date for voting and/or comments: 13 March 2020 at 17:00 CET**
Date comments submitted:	**11 March 2020**	Please type your comments in this form and post it (in Word format) as soon as possible and no later than the closing date using the CD vote and comment page on the OIML website (My access → CD vote & comment).	
PLEASE INSERT THE COUNTRY CODE AND THE PART AND CLAUSE NUMBER IN EACH ROW. PLEASE DO NOT MODIFY THE NUMBER OF COLUMNS IN THE TABLE.			

Instructions for using this template:

The structure of this table allows for the automatic collation of all the comments posted by the participants. However, this is only possible if the following instructions are followed. Please

- do not add any columns to the table,
- do not merge any of the cells,
- add the Country Code in each row,
- fill in the Part number in each row (if the document to be commented has no parts, leave this column blank),
- enter one reference per row in the Clause/Sub clause column. If your comment applies to more than one clause, please repeat the row or make the reference in the Comments column,
- do not embed other tables in the table,
- enter the date on which you make the comments in the heading.

1 **MB** = Member body (enter the ISO 3166 two-letter country code, e.g. CN for China)

2 **Type of comment**: ge = general te = technical ed = editorial

Country Code[1]	Part	Clause/ Sub clause	Paragraph / Figure/ Table/	Type of comment[2]	COMMENTS	PROPOSED CHANGE	OBSERVATIONS OF THE CONVENER/PG on each comment submitted
CZ	1	6.3		Ed	Add “at least” to the sentence	The manufacturer shall demonstrate, on the basis of design compliance testing as specified in Clause 4.2 of ISO 8612, that at least 95 %	Accepted
CZ	1	6.4.1	Parag. 2	Ed	Remove the 4th bullet point	Remove the 4th bullet point	Accepted
CZ	1	8.1		Ed	Change the title to “Marking of the device”	Inscription of the device → Marking of the device”	Not accepted. Marking refers in general to certification markings (e.g. CE Marking or other equivalent markings). Inscription is a general term that also includes name of the manufacturer and serial number.
CZ	1	8.2.	Bullet points	Ed	Add punctuation marks to the bullet points, comma or semicolon (to be consistent with the rest of the document)	Add a punctuation marks to the bullet points, comma or semicolon (to be consistent with the rest of the document)	Accepted
CZ	1	8.3		Ed	Delete comma (,) in to “…to an, identically…”	Instead, traceability is ensured, via a transfer standard, to an, identically manufactured device in its performance and components and clinically tested in conformity with ISO 8612. → Instead, traceability is ensured, via a transfer standard, to an identically manufactured device in its performance and components and clinically tested in conformity with ISO 8612.	Accepted
CZ	1	A 1.4		Ed	Height of 1.0 m (m is missing)	The IOP testing equipment shall operate correctly following a free fall from a height of 1.0 ± 0.1 m → The IOP testing equipment shall operate correctly following a free fall from a height of 1.0 m ± 0.1 m	Accepted.
JP	1	7.1 Mechanical strength of non-contact tonometers	2nd para.	te	Because the non-handheld NCT (non-contact tonometer) is a stationary type, there is no need for a free fall test.	Delete the second paragraph for testing non-handheld NCT.	Accepted after consulting IEC 60601-1.
JP	1	A1.4 Mechanical strength of IOP testing equipment	1st line	te	If the second paragraph of 7.1 is deleted (see JP1), the testing equipment for drop test should be applied only to handheld IOP.	The first line should be corrected as “The handheld IOP testing equipment shall …”.	Accepted.