Organisation Internationale de Métrologie Légale

International Organization of Legal Metrology

COMMENTS TEMPLATE

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TC18_SC2_P4_N005

TC 18/SC 2/p 4:	**New Recommendation: *Contact medical thermometers***		
PG comments on 2WD:	TC18_SC2_P4_N003 – part 1 TC18_SC2_P4_N004 – part 2		
Circulation date:	24 August 2023	Convener: Brazil – Rafael F Farias	**Closing date for voting and/or comments: 24 November 2023 at 17:00 CET**
Date comments submitted:		Please type your comments into this form and upload it (in Word format) as soon as possible and no later than the closing date using the Workspace for this project (My access → PG Workspaces → TC 18/SC 2/p 4).	
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[1] 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,
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- enter the date on which you make the comments in the heading.

1 **Country Code** = 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/ Subclause	Paragraph / Figure/ Table/	Type of comment[2]	COMMENTS	PROPOSED CHANGE	OBSERVATIONS OF THE CONVENER/PG on each comment submitted
US			ge	06-Nov-2023	Thank you for the opportunity to comment, and my apologies as there are no headers on this template. The US is appreciative of the efforts put into the drafting of this 2WD recommendation. We provide below specific technical requirements that adhere to standards used in the US. These are more stringent than what is in the 2WD. We have a few considerations and questions: 1. What is the intent to harmonize with existing standards? 2. Is there an anticipated software component? We recognize that these are typically standalone devices, however, U.S. guidelines allow the provision for thermometers that communicate with other medical devices. If so, such sections will require detailed elaboration.	We suggest referencing the following standards: 1. 6-177 ASTM E1112-00(2018) Standard specification for electronic thermometer for intermittent determination of patient temperature 2. 6-123 ASTM E667-98 (Reapproved 2017) 3. Standard Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers 4. 6-421 ISO 80601-2-56 Second edition 2017-03: Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. [Including: Amendment 1 (2018)]. If any provisions are made for communication of the device to any sort of health informatics software, consideration may be given to 13-52 IEEE ISO 11073-10408 First edition 2010-05-01: Health informatics - Point-of-care medical device communication - Part 10408: Device specialization - Thermometer	Partially accepted Regarding the inclusion of references, item 6.4.5 of OIML B6-2:2023 only mentions the possibility of making references to International Standards such as, for example, ISO 80601-2-56 Regarding communication with other equipment – The scope of the Recommendation defines that it "does not apply to secondary indicators, printing devices or other auxiliary devices"
US	1	2	Te	07-Nov-2023	It might be worthwhile to give specific definitions for electronic thermometer and liquid in bulb thermometer.	Possible definition for electronic thermometer from ASTM E1112: instrument that provides a display of temperature sensed through the use of a transducer and electronic circuitry.	Reject The electronic thermometer and the liquid bulb thermometer are presented in clause 3.
IR	1	2		te	It is recommended to define "body site" or if it is possible to use "measuring site" instead (this term has been used by ISO 80601-2-56:2017.) It is better to use the same terms in standards of ISO, IEC and OIML to avoid ambiguity of users.	Body Site (Measuring site): part of a PATIENT where the temperature is measured [SOURCE: ISO 80601-2-56: 2017]	Partially accepted The ISO 80601-2-56 standard is under review.
IR	1	2		te	As the term "probe" has been used in the text, it is recommended to define it under TERMINOLY clause.	PROBE: part of a CLINICAL THERMOMETER that provides a thermal coupling between the SENSOR and the PATIENT Note 1 to entry: Thermal coupling can be contact or non-contact. [SOURCE: ISO 80601-2-56: 2017]	Partially accepted The ISO 80601-2-56 standard is under review.
IR	1	2		te	As term term "sensor" has been used in the text, it is recommended to define it under TERMINOLY clause.	SENSOR: part of the CLINICAL THERMOMETER that converts thermal energy into an electrical signal [SOURCE: ISO 80601-2-56: 2017]	Partially accepted The ISO 80601-2-56 standard is under review.
US	1	2.2	Te/Ed	22-Nov-2023	The term "non-automated measurement mode" is not typically used by the US health sector	Use "test mode" instead.	Reject Both terms are accepted

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JP2	1	2.2 non-automated measurement mode	1st paragraph	te	The given definition is inaccurate. The test mode is described as the mode that indicates the temperature of a BODY SITE. However, in reality, this mode simply indicates the temperature measured by the PROBE or SENSOR without any algorithm to estimate the actual BODY SITE temperature, regardless of whether they have achieved thermal equivalence with the BODY SITE or not.	It is suggested to change “temperature of the body site” to simply “temperature,” or specify as “temperature of the probe” or “temperature of the sensor.”	Accept
ES	1	2.2		TE	The definition for “non automated measurement mode” is correct, however they are other standards or documents that use different terminology (for instance ISO 80601-2-56:2017)	To make a comment referring to other terminologies (direct mode), if possible	Partially accepted The ISO 80601-2-56 standard is under review.
US	1	2.3	Ed	22-Nov-2023	Additionally, the terms used here are usually “rapid mode” or “predicted mode”	Edit terms as described. Use “rapid mode” or “predicted mode” as the definition. Include the statement, “This mode of operation does not require human intervention.” The alternative terms may also be included in the definition.	Partially accepted The terms “rapid mode” or “predicted mode” limit the modes that can be developed by manufacturers
ES	1	2.3		TE	The definition for “automated measurement mode” is correct, however they are other standards or documents that use different terminology (for instance ISO 80601-2-56:2017)	To make a comment referring to other terminologies (adjusted mode, indirect mode), if possible	Reject The ISO 80601-2-56 standard is under review.
US	1	3	Ed	22-Nov-2023	The description in the last sentence of the second paragraph is confusing and does not align with the definitions in the previous section. This definition is under revision in ISO, but it should be clarified that automated measurement mode does not require human intervention.	As described, the “estimate of the temperature of body site with which the probe is not in contact” is usually called “closed-site measurement.”	Partially accepted Considering the other comments, this text will be rewritten.
US	1	3	Ed	22-Nov-2023	In this area, “continuous” is different from “intermittent”. The sentence requires clarification as to which method is being used.	“or simply the body site temperature with intermittent measurements.”	Partially accepted Considering the other comments, this text will be rewritten.
JP3	1	3 Description of the category of instrument	2nd paragraph	ed	The description is somewhat unclear. It seems that “automated mode” is associated with site conversion, and “test mode” is related to non-mathematical interventions. However, it is not apparent whether time-reduction is included in “automated mode” or not.	Add “(automatic mode)” or “(test mode)” after “criterion or algorithm to reduce the measurement time,” too.	Partially accepted Considering the other comments, this text will be rewritten.
IR	1	3		te	Considering that the sensor generally converts a physical quantity into an electrical signal, it is better to use this term only for electrical thermometers.	In sentence “Any contact clinical thermometer contains at least a sensor and an output means” it is recommended to replace “sensor” with “sensing part”	Accept

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IR	1	3		ed	The word “integrates a probe” should be change to “integrates with a probe”	For electrical thermometers, the sensor (e.g., thermistor or thermopile) usually integrates with a probe which can be …..	Accept
US	1	5.1	te	06-Nov-2023	The US uses the standards highlighted above for regulation of thermometers for clinical use. The ASTM standard specifies a temperature range of 35.5°C to 41.0°C	Consider this temperature range.	Accept
US	1	5.2	Te/Ed	22-Nov-2023	The terms that are typically used are “lab accuracy” which relates to accuracy of the water bath in the lab, and “clinical accuracy” according to the ISO standard. Most labels on thermometers are actually lab accuracy, which is how this requirement is written.	Refer to the type of accuracy here as “lab accuracy” so that product labels derived from this are clear. Alternatively, describe clinical bias, which refers to the difference between lab accuracy and clinical accuracy.	Reject “Lab accuracy” is not a term belonging to the International Vocabulary of Legal Metrology
US	1	5.2	te	06-Nov-2023	ASTM E1112-00(2018) specifies a range of 15-95% relative humidity (non-condensing).	Consider this humidity range for MPE.	Reject The specified humidity range complies with OIML D11:2013 guidance (e.g. table 8).
US	1	5.2	te	06-Nov-2023	E1112-00(2018) specifies the following MPEs: < 35.8°C ± 0.3°C 35.8°C ≤ T < 37.0°C. ± 0.2°C 37.0°C ≤ T < 39.0°C. ± 0.1°C 39.0°C ≤ T < 41.0°C. ± 0.2°C > 41.0°C ± 0.3°C	Consider these MPEs for the requirements.	Reject International standards (e.g. ISO/IEC 80601-2-56) do not define different limits within the minimum measurement range
US	1	5.4	Te/Ed	22-Nov-2023	This is written in a way that is confusing. Is the thermometer meant to be read at ambient temperature (t1) or the immersion temperature?	Specify that the thermometer should initially be at ambient temperature.	Partially accepted Considering the other comments, this text will be rewritten.
US	1	5.4	Te/Ed	22-Nov-2023	To which error does the description in the first error refer? Is it the temperature associated with immersing the thermometer in the water bath, or at the ambient temperature?	Consider clarifying in subsequent version.	Partially accepted Considering the other comments, this text will be rewritten.
US	1	5.4	Te/Ed	22-Nov-2023	20s is not sufficient for the thermometer to stabilize at t2 (second bullet). What is the intent of the procedure as far as testing?	Consider clarifying in subsequent version.	Partially accepted Considering the other comments, this text will be rewritten.
KR	1	5.4		te	It is not clear what is the aim of this procedure. The clinical thermometers go through t_1 (for unspecified duration) → t_2 (for 20 s) → ambient temperature. Then the deviation from the stabilised reading for t_2 are observed. Is the reading made last moment of 20 s duration at t_2? (It is rather difficult to do for analogue thermometers to reading the indication instantly with a good precision.) Is the clinical thermometer assumed to be a maximum device? (Then, it makes more sense.)	State the procedure more clearly.	Partially accepted Considering the other comments, this text will be rewritten.

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KR	1	5.4	Second bullet point	ed	0.005 C ($t_2 - t_1$) seems to be typographical error for 0.005 × ($t_2 - t_1$).	Correct to 0.005 × ($t_2 - t_1$) if this is what is intended.	Partially accepted Considering the other comments, this text will be rewritten.
ES	1	5.4	3	ED	Is ° missed in the unit °C after 0.005? Or is the expression 0.005 × (t_2-t_1)?	To correct the expression	Partially accepted Considering the other comments, this text will be rewritten.
ES	1	5.4	3	ED	This paragraph is not clear. It is said "This stabilized reading is the thermometer reading obtained when the thermometer has been cooled to ambient temperature". What does "this stabilized reading" refer to in this sentence?	To modify this sentence: "This stabilized reading (*include t_2 or $t_2 - t_1$ or whatever this is*) is the thermometer reading obtained when the thermometer has been cooled to ambient temperature"	Partially accepted Considering the other comments, this text will be rewritten.
US	1	5.5	te	06-Nov-2023	The ASTM standard referenced specifies that the device shall meet requirements after storage at a temperature range of -20°C to 50°C, relative humidity of 15-95% for a period of one month.	Consider these requirements for conformance of the device.	Reject
US	1	5.5	Te	22-Nov-2023	From where are the temperature, humidity and time conditions derived?	Consider clarifying in subsequent version.	The requirements were defined based on the current Recommendations on clinical thermometers
US	1	5.8	Ed	22-Nov-2023	"mains supply"	Perhaps change to "main supply".	Accept
JP1	1	5.8 Electromagnetic interference	all	te	The description, meaning the performance assessment before and after the test is acceptable for transient phenomena, have been added to power (reductions, spikes and bursts) and discharge. However, not added to all immunity tests like the 14th paragraph of clause 8.1 of the IEC 60601-1-2:2014+A1:2020.	Extend the application of the description to cover all immunity tests, including the electromagnetic field in the 1st bullet and the use with high-frequency surgical equipment in the 4th bullet.	Reject The 1st and 4th bullet produce effects that can only be evaluated while they are applied
US	1	5.9	te	06-Nov-2023	The device indication in the ASTM standard is at least 2.5mm high, 1.5mm wide and separated by a space of 0.7 mm.	Consider these requirements for the device.	Not accepted because it was not clear whether the requirement refers to a mechanical thermometer, a digital thermometer or both
US	1	5.9	Ed/Te	22-Nov-2023	Resolution of thermometer: Does this mean that the accuracy display of 0.01C is unacceptable? Is there a lower bound to the accuracy (e.g. 1C or 2C)?	Consider including more specific language for this requirement.	Accept
IR	1	6.3		te	It is recommends to replace "water" with "water resistancy"		Reject The term is correct
IR	1	6.3		te	It should be better to describe more about "reduced dimention"		Accept

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US	1	7.3	Ed	22-Nov-2023	"… the metrological control marks shall prevent the opening of the casing." This phrasing could be refined.	"… the metrological control marks shall *be in place* to prevent the opening of the casing."	Accept
US	1	7.4.1	te	06-Nov-2023		Consider also including the model designation as part of the markings. The lot number as an alternative to serial number may be an option.	Accept
JP4	1	7.4.1 Marking of the device	all	te	The number of information to be marked on the device body has significantly increased, from 5 (as specified in section 7.2.2 of R115) to 9. It is not feasible to include all 9 pieces of information on a small clinical thermometer.	The unit of measurement should be indicated on a display (e.g., LCD) with the measurement result. The measurement range should be indicated on the package and accompanying documents. Delete the items which may be separately required by national regulations (e.g., type approval number, year of fabrication and country of origin).	Partially accepted The subclause already allows the measurement unit to be indicated on the display
JP5	1	7.4.2 Markings required on the interchangeable probe	all	te	The number of information to be marked on the interchangeable probe has significantly increased, from 3 (as specified in section 7.2.3 of R115) to 7. It is not feasible to include all 7 pieces of information on a small interchangeable probe.	It should be allowed to be marked on a plastic bag or a package for the interchangeable probe. Delete the items which may be differently required by national regulations (e.g., type approval number and year of fabrication).	Partially accepted
US	1	7.4.2	Te	06-Nov-2023		Consider also a lot number marking as an alternative to the serial number.	Accept
JP6	1	7.5 Manufacturer's information	1st bullet	ed	The 1st bullet is not one of the bulleted items.	Move the 1st bullet to the main text.	Accept
JP7	1	7.5 Manufacturer's information	5th bullet	te	The "accordingly to 5.2" is confusing with following two reasons. 1. The specified error in the instruction may be smaller (more accurate) than the numbers in 5.2. 2. The clinical investigation is not in 5.2. It is in 7.1.	Delete "accordingly to 5.2."	Accept
JP8	1	7.5 Manufacturer's information	16th bullet	te	The information regarding applied laws is typically unnecessary for individual operators or patients.	Delete the 16th bullet or add "if national regulation requires the disclosure" to the end.	Accept
KR	1	7.5	The sentence before the first bullet point	ed	"givenin" seems to be a typographical error.	"given in" (a space between the two words)	Accept

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ES	1	7.5	12	TE	Maybe the sentence “Description of transition from calculated temperature to temperature after thermal equilibrium, if applicable”; should be change after removing thermal equilibrium issues in the definitions.	To remove this sentence	Accept