



TC 18/SC 2/p 4:	New Recommendation: <i>Contact medical thermometers</i>		
PG comments on 1CD:	TC18_SC2_P4_N037 – part 1 TC18_SC2_P4_N038 – part 2 TC18_SC2_P4_N039 – part 3		
Circulation date:	28 May 2024	Convener: Brazil – Rafael F Farias	Closing date for voting and/or comments: 28 August 2024 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 <u>no later than the closing date</u> using the Workspace for this project (My access → PG Workspaces → TC 18/SC 2/p 4).	

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 Code¹ 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	1	2	2.2	Te	The terms of “non-automated measurement mode” and “automated measurement mode” are confusing and the definitions are not clear. From the name, the difference between “non-automated” and “automated” is whether human intervention is involved. However, the definitions focus on whether algorithms are applied, which doesn’t necessarily relate to human intervention.	Suggest changing “non-automated measurement mode” to “direct mode” and use the following definition: Direct mode: Operating mode of a thermometer where the output temperature is an unadjusted temperature that represents the temperature of the thermometer probe (equal to the temperature of the measuring site to which the probe is coupled after thermal equilibrium).	Accepted
US	1	2	2.3	Te	The terms of “non-automated measurement mode” and “automated measurement mode” are confusing and the definitions are not clear. From the name, the difference between “non-automated” and “automated” is whether human intervention is involved. However, the definitions focus on whether algorithms are applied, which doesn’t necessarily relate to human intervention.	Suggest changing “automated measurement mode” to “predictive mode” and use the following definition: Predictive mode: Operating mode of a thermometer where the output temperature is calculated with an algorithm before the thermal equilibrium between the thermometer probe and the thermometer is achieved and represents the predicted temperature at the measurement body site or a reference body site.	Partially accepted. The term used will be “indirect mode.”
US	1	2	2.4	Te	Consider renaming the “body site” the “measurement site”. See the following elaboration, as it provides clarification on the difference between the two: “Body temperature can be measured at different body sites. These measurements can be used to impute temperatures at other body sites that are more meaningful, but less convenient to access. The site where the temperature is acquired is called the measurement site, whereas the site to which the device output temperature refers is called the reference site. For example, a non-contact infrared thermometer (NCIT) might measure skin temperature on the forehead and convert this value to an imputed oral temperature for display. In this case, the forehead-center is the measurement site and the oral cavity (e.g., sublingual) is the reference site. The process of imputing reference site temperature from measurement site temperature is called site conversion. The measurement and reference sites can be the same (same-site measurement) or different (cross-site measurement).” (https://doi.org/10.3390/s22010215)	Use the term “measurement site” rather than “body site.”	Accepted
US	1	2	2.7	Ed	As defined, “test mode” is only given as “non-automated mode”. The definition as written does not serve a purpose of clarification.	Either eliminate the term or clarify. If the latter, consider the use of “direct mode” as offered above.	Accepted. The definition of the term will be rewritten for clarification.

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US	1	3		Ed	If the terms used above (“direct mode” and “predictive mode”) are favored, please edit the text of the last sentence of this section accordingly.	The text would read (bold text indicates the changes): “The temperature indication may either provide an estimate of the body site temperature with which the probe is or not in contact (predictive mode), or the immediate body site temperature (direct mode) or thermodynamic system (the thermostatic water bath is an example) with which the probe is in contact (test mode).”	Accepted
US	1	5	5.2	Te	The maximum permissible errors in test mode (direct mode) are less important than the errors in predictive mode that is not defined.	Include a paragraph/section elaborating on the MPEs for predictive mode.	Not accepted. The errors for “predictive” mode are defined in the clinical investigation.
JP	1	5.8		te	To ensure accurate temperature indication within the specified working voltage range, it is necessary to account for a margin. However, the current text does not permit such a margin because it sets different requirements for voltages within and outside the working range, leading to an unfeasible requirement.	Change “Outside this working range no temperature indication shall be displayed” to “When the clinical thermometer is not capable of indicating an accurate temperature, no temperature indication shall be displayed.”	Partially accepted. Replace the term “working range” with “nominal range”.
JP	1	5.10		te	The minimum indication time of one second should apply to the final indication, not to any transient indications during measurement.	Change “the display of temperature shall last at least one second” to “the display of temperature, excluding any transient displays during measurement, shall last at least one second”	Accepted
JP	1	6.2		te	The clinical thermometers that have both automated and non-automated measurement modes do not need any test mode; however, the current text does not clarify it.	Change “the instrument shall have a test mode which shall be accessed by the operator without additional tools” to “the instrument shall have a test mode or a non-automated measurement mode which shall be accessed by the operator without additional tools”.	Accepted
JP	1	6.3		te	Interpretating with the test method in Part 2 clause 11.2, the requirement is equivalent to IPX7. It is too strict considering the IEC of medical electrical equipment requires up to IP33 for emergency environment and up to IP22 for home environment.	Change “water resistant” to “falling water resistant”.	Partially accepted. Rewrite the text of item 6.3 to require the water test only when the manual states that the thermometer is immersion-resistant.
JP	2	11.2		te	The test method of immersing in water at a depth of 15 cm for 30 min is equivalent to IPX7. It is too strict considering the IEC of medical electrical equipment requires up to IP33 for emergency environment and up to IP22 for home environment.	Change all main text in 11.2 Procedure to “Conduct the test of IEC 60529 for at least IPX2.	Not accepted. The water test will only be performed when the manual states that the thermometer is immersion-resistant.
JP	1	5.4		te	If “module” in 5.4 has the same meaning as “absolute value” in Part 2.3.3 c), it should be amended to “absolute value”.	Present: The <u>module</u> of the difference between thermometer readings ($R_2 - R_1$) must be less than or equal to $0.005 \times (t_2 - t_1)$. Revised: The <u>absolute value</u> of the difference between thermometer readings ($R_2 - R_1$) must be less than or equal to $0.005 \times (t_2 - t_1)$.	Accepted

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JP	1	5.5		te	The conditions in 5.5 need to be amended to be consistent with Part 2.4.2	Present: For electrical contact clinical thermometers, the maximum permissible error for the indication after storage for 24 h at -20 °C ± 2 °C, followed by additional storage for 24 h at 60 °C ± 2 °C (non-condensing) shall be comply with 5.2. Revised: For electrical contact clinical thermometers, the maximum permissible error for the indication after storage for 24 h at -20 °C ± 2 °C, followed by additional storage for 24 h at 60 °C ± 2 °C (non-condensing) <u>and cooling to ambient temperature</u> shall be comply with 5.2.	Accepted
JP	1	5.6		te	In a climatic chamber, it would be easy to control the temperature between 20 and 32°C, so it may be possible to narrow the temperature range.	Revised: For electrical contact clinical thermometer, the maximum permissible error for the indication after 4 h at <u>temperature range ± 2°C at an initial ambient temperature between 20°C and 32 °C</u> an ambient temperature between 20 °C and 32 °C and a relative humidity of 50 %,	Accepted
JP	2	5.2		te	The “48 hours” in “reference conditions” in Part 1.5.6 is too long, so it will be changed to “1 hour” as in Part 2.4.2.	Present: Return the relative humidity to the initial conditions, and keep it there for <u>48 h</u> . Revised: Return the relative humidity to the initial conditions, and keep it there for <u>1 h</u> .	Not accepted. 48 hours is a more conservative timeframe to ensure that moisture has completely evaporated from the thermometer's electronic boards.
JP				general	There have been international meetings for the WD or CD in the past. Please tell us, if there are any plans for an online conference for the 1CD this time.		Yes, we will propose a virtual meeting to evaluate the comments that arise regarding the 2CD.
KR				ge	It seems to be covered by the existing ISO 80601-2-56 standard.	We suggest that any additions or changes be added to ISO 80601-2-56.	Standard 80601-2-56 is in the final stage of revision (FDIS); therefore, it is not possible to submit technical suggestions.