

The Report of
ISO/TC 121/SC3-IEC TC/SC62D JWG Thermometer

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Background

OIML/TC18/SC2 “Medical Thermometers”

**Decided to prepare the joint OIML-ISO/IEC recommendations
in the field of medical thermometer : 2004-06-25**

N1203 NWIP “Clinical Thermometers – Part 1: General Requirements”

**Proposed project leader: Dr.Jurgen Hartmann PTB in Berlin
Convenor of CEN/TC 205/WG12**

Date of presentation: 2005-03-03

Scope of proposed project

This International Standard specifies the general, metrological and technical requirements for clinical thermometers. This International Standard applies to all clinical thermometers that are used for measuring the body temperature of patients, whether contact or non-contact.

This International Standard applies to clinical thermometers that are operated without an electrical power supply as well as those powered either by mains or internal electrical power sources.

The clinical thermometers can be equipped to accommodate secondary indicators, printing devices, and other auxiliary devices. This International Standard does not apply to the metrological requirements for such accessories.

62D/528/NP NWIP “Clinical Thermometers”

Circulation Date: 2005-04-08

Closing Date: 2005-07-08

62D/539/RVN Result of Voting on NWIP “Clinical Thermometers”

Circulation Date: 2005-09-02 as “IEC 60601-2-56”

Proposed target date for submission of CD: 2006-10-01

CDV: 2007-10-01

FDIS: 2008-10-01

IS: 2009-03-01

Document ISO TC121/SC3 N1217 & IEC 62D/528e/CC

“Comments to SC3 N1203 ISO/WD for NWIP, Clinical thermometers & IEC 62D/528e/NP ” issued on 2005-07-12

Meeting of ISO/TC 121/SC3-IEC TC/SC 62D JWG on “Clinical thermometers” held on 12 Dec., 2005 in Berlin

Date: 12~16 Dec., 2005

Place: DIN in Berlin

**Attendees: Germany 7, U.S.A 4, U.K. 2, Japan 2, Singapore 2, Slovenia 2
(included the persons of NIST, NPL, PTB, NMIJ and Spring)**

1. 12th Dec.

The Clinical Thermometer Group and the Thermography Group were invited and the meeting started together with all members in a room.

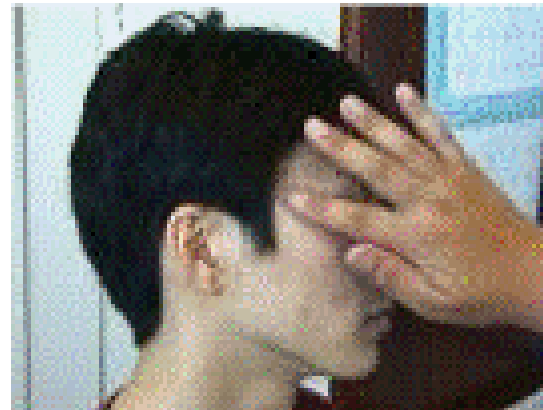
- 1) Prof.Hedley-Whyte John of Harvard Univ. explained the background of this meeting and the importance of thermography because of the defense against SARS.**
- 2) All attendee told their basic opinion regarding to this meeting.**
- 3) There were some important opinions as following.**
 - > This standard should be separated into few standards like EN or OIML.**
 - >Should be separated into two standards: ①pre screening or screening use, ② clinical diagnosis use**
 - >Should be separated into three standards: ①predictive type with no offset, ②predictive type, ③with offset**

- 4) Prof. Francis J. Ring of Glamorgan Univ. in U.K. presented "Thermal Imaging of the Human Face"
- 5) We discussed regarding the Risk Analysis which will be conducted at next morning.

2. 13th Dec.

The meeting was held separately as "Clinical Thermometer Group" and "Thermography Group" from beginning this morning.

- 1) Dr. Hartmann who is the chairman of ISO side introduced the existing thermometer standards such as EN, OIML, ASTM, JIS. And he also talked about some new or special thermometers that is basal body temperature thermometer, deep body temperature and temporal artery thermometer. He explained strongly the importance to conduct our standardization including all these thermometers.



- 2) Later we entered into the discussion of risk analysis of thermometers.

3. 14th Dec.

- 1) Basal body temperature thermometer and Deep body temperature monitor as the special thermometer are introduced by Terumo Corporation.**
- 2) Later we discussed regarding the document ISO TC121/SC3 N1217 & IEC 62D/528e/CC“Comments to SC3 N1203 ISO/WD for NWIP, Clinical thermometers & IEC 62D/528e/NP ”**
- 3) Following matters were decided.**
 - >The standardization of clinical thermometer is conducted separately as “Electrical Clinical Thermometers” and “Mechanical Clinical Thermometers”.**
 - >Liquid crystal thermometer is excluded from “Mechanical Thermometers”.**
 - >About 30 to 40% matters in many kinds of thermometers are common.**
Then we conduct the standardization of “Electrical Thermometers” as a single standards.

4. 15th Dec.

- 1) We discussed of the U.K. comments regarding N1203 NWIP.**
- 2) We continued the discussion of the document ISO TC121/SC3 N1217 & IEC 62D/528e/CC“Comments to SC3 N1203 ISO/WD for NWIP, Clinical thermometers & IEC 62D/528e/NP ”**
- 3) Three Taskgroups were set up as following:**
 - ① Definition、**
 - ② Laboratory Requirement、**
 - ③ Clinical Requirement**

5. 16th Dec.

1) We reviewed the risk analysis results discussed on 13th Dec again.

Some matters are decided to be discussed in each taskgroup until end of January 2006.

2) We decided rough future schedule as following:

>Next meeting will be held on 20th to 23rd March 2006 in Gaithersburg U.S.A.

>The expected time of first CD document is July 2006. Because the deadline of this standardization is October 2007.

(The standardization of ISO or IEC has to complete within three years.

When we couldn't complete, the standardization will be aborted.)

Summary

1) Many kinds of electric thermometers will be standardized as a single standard.

2) The thought of "Risk Management" will be brought in this standardization.

3) The thought of "Clinical Evaluation" will be brought in this standardization.

4) The standardization of clinical thermometer will advance rapidly.

Please watch carefully the condition of this standardization.

7.14 Testing for compliance with maximum permissible clinical repeatability

- Procedure perform the test in accordance with ISO 14155.

Perform the clinical trial separately on all age groups with which the thermometer is intended for use. The number of subjects of each age group shall be sufficiently large to minimize the effect of random components of measurement error, i.e. at least 50. The total number of subjects shall be not less than 100. In each age group at least 30% of the subjects shall be febrile (temperature above 38°C).

Define age group as follows:

- 1) newborn up to 1 year
- 2) between one year and five years
- 3) older than five years

HAZARD AND CAUSE	CONTROL STRATEGIES / MITIGATION		C ^a	O ^b	R ^c
	METHOD OF CONTROL (RATIONALE STATEMENT)	REQUIREMENT (CLAUSE NUMBER OF STANDARD)			
Mistreatment (Accuracy)					
Misinterpretation of value due to wrong unit	ok	4 Units	M	O	III
Measuring range to narrow	ok	5.2.1 Measuring range	CR	P	I
Mistreatment due to inaccuracy	ok	5.2.2 Maximum permissible error under reference conditions	CR	P	I
	Taskgroup 2	5.5 Long term stability (measurement)	CR	O	II
	ok	5.6 Environmental requirements	CR	O	II
	ok	5.7.1 Electrical performance requirements	CR	O	II
	No requirement yet	?6.5? Testing for compliance of maximum permissible error under changing environmental conditions for contact and non-contact thermometer	CR	O	II
	Rationale why testing	Old requirement from 12470-5 (6.3.3) for portable devices only			
	ok	7.3 Instructions for use	CR	R	III
Delayed treatment due to time response	Taskgroup 2	5.4 Time response	CR	F	I