Seminar on Clinical Electrical Thermometers
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Practical Test Methods and Test Equipments for Clinical Thermometers

Speaker: Masami Horita

Chief of Calibration and Verification Section
Dissemination Technology Division

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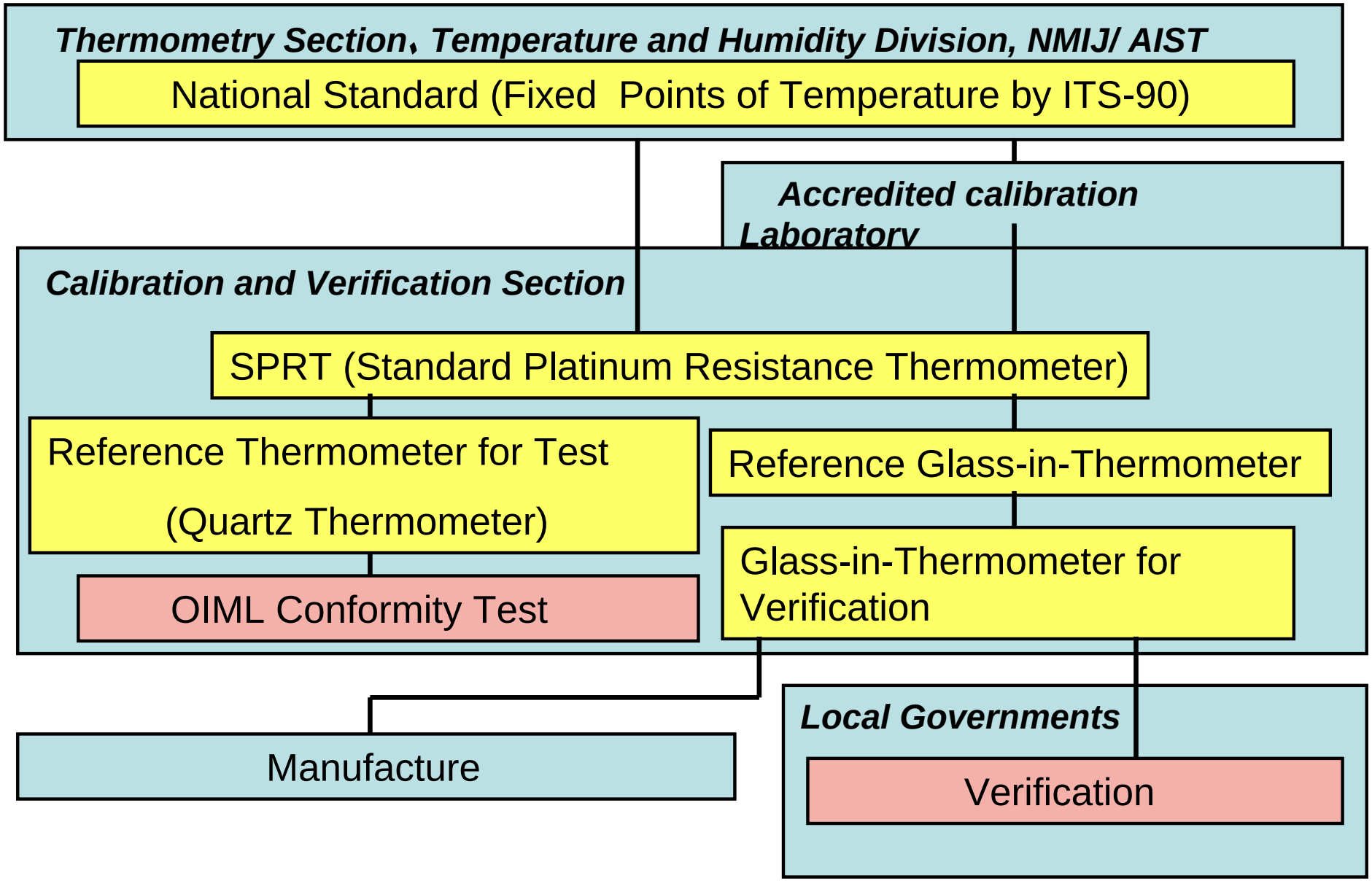
1.1. Traceability for Reference Temperature



1.2. Test Equipments for Complete thermometers

(1) Reference Thermometer

OIML R115; ANNEX A; A.1 Reference Temperature; A.1.2

Expanded uncertainty (k=3) ; 30 mK

- Temperature range ; -80 ℃～250 ℃
- Resolution ; 0.1 mK, 1 mK, 10 mK
- Calibrated range ; 30 ℃～43 ℃, Expanded uncertainty (k=3) ; 15 mK

(2) Reference Water bath with Special temperature control equipment for thermometer Testing

OIML R115, ANNEX A; A.1 Reference Temperature; A.1.1

Volume ; at least 1 L

Temperature stability ; within ±20 mK

Temperature distribution ; within ±10 mK

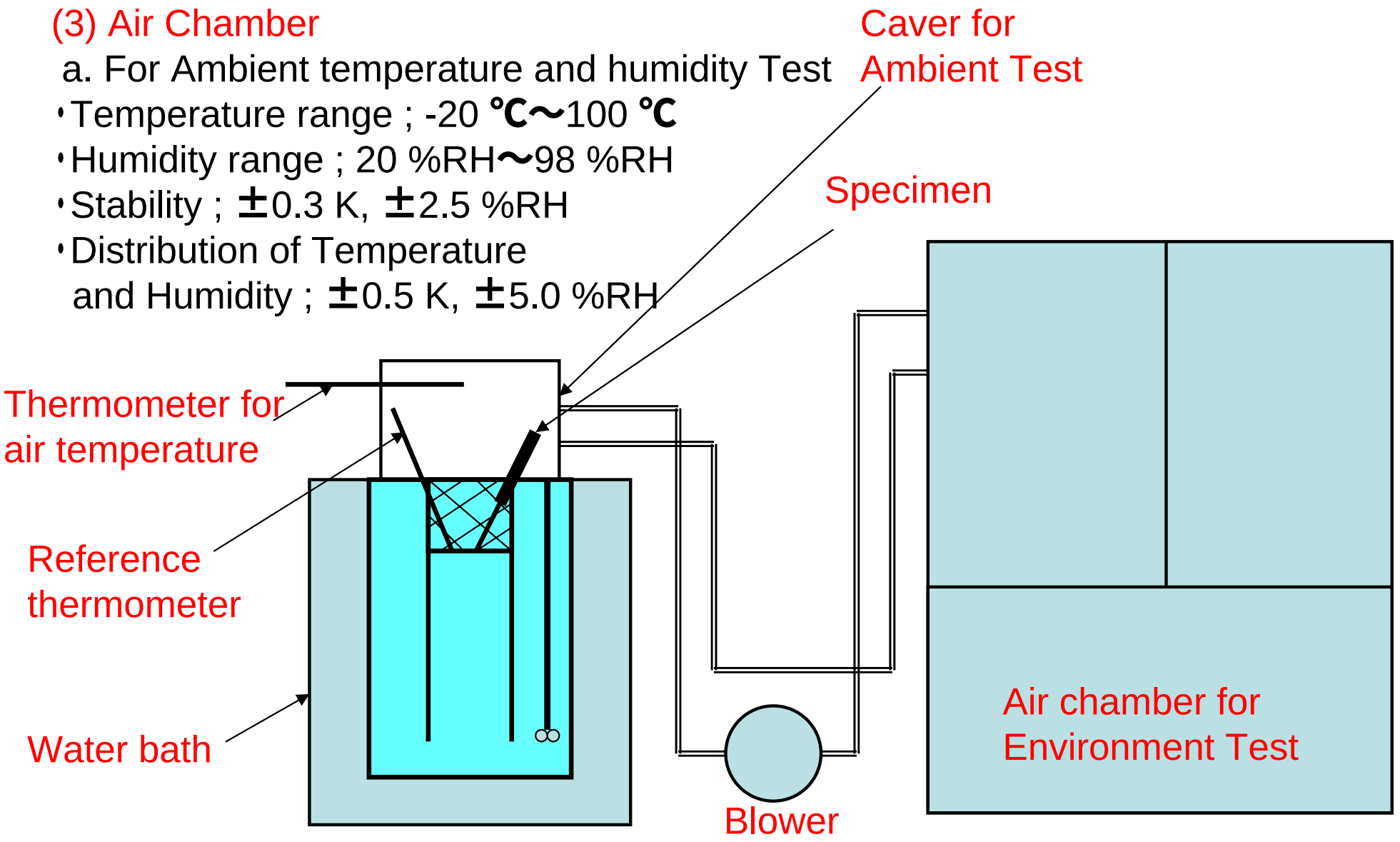
- Volume ; 35 L (Φ100mm ×400mm)
- Temperature range ; -30 ℃～100 ℃
- Temperature stability ; within ±2 mK/min
- Temperature distribution ; within ±5 mK

1.2. Test Equipments for Complete thermometers

(3) Air Chamber

a. For Ambient temperature and humidity Test

- Temperature range ; -20 ℃～100 ℃
- Humidity range ; 20 %RH～98 %RH
- Stability ; ±0.3 K, ±2.5 %RH
- Distribution of Temperature and Humidity ; ±0.5 K, ±5.0 %RH



1.2. Test Equipments for Complete thermometers

(3) Air chamber

b. For Thermal Shock Test etc.

○ Chamber1 (for High Temperature)

- Temperature range ; 30 ℃～260 ℃
- Stability ; within ±2 K/1 hour

○ Chamber2 (for Low Temperature)

- Temperature range ; -40 ℃～150 ℃
- Stability ; within ±1 K/1day
- Distribution of Temperature ; within ±1 K

(4) Thermometer for Ambient Test

- Temperature range ; -50 ℃～150 ℃
- Resolution ; 1 mK, 10mK
- Calibrated range ; -50 ℃～150 ℃, Expanded uncertainty (k=2) ; 15 mK

1.2. Test Equipments for Complete thermometers

(5) Hygrometer for Ambient Test

- Humidity range ; 0 % RH ～100%RH
- Resolution ; 1%RH
- Calibrated Humidity ; 50%RH, Expanded uncertainty (k=2) ; 2.4%RH
  95%RH, Expanded uncertainty (k=2) ; 3.5%RH

(6) Water bath for Water resistance Test

- Temperature range ; 0 ℃～80 ℃
- Temperature Stability ; within ±1 K/1 day
- Temperature distribution ; within ±0.2 K (at 20℃, 50℃)

(7) DC power supply for the Low battery indication test

- DC voltage ; 10 mV ～ 1199 V
- DC current ; 1 mA～ 119 mA
- Resolution ; 10nV, 1nA

2. Practical Test Method for Complete thermometers and Examples of Test Results

2. Practical Test Method for Complete thermometers and Examples of Test Results

TEST ITEMS (from OIML R115; 7.1.2)

Probes (at least ten probes shall be tested)

(1) Maximum permissible errors (4.2, A.2)
(2) Long term Thermal Stability (5.1.2)
(3) Electrical insulation and water tightness (5.1.3, B.2)
(4) Location of sensor (5.1.4)
(5) Mechanical strength (5.1.5)
(6) Electrical contact resistance of connector (5.1.6)
(7) Cleaning and disinfecting (5.1.7, B.3)
(6) Stability with change in temperature of cable (5.1.8)

2. Practical Test Method for Complete thermometers and Examples of Test Results

TEST ITEMS (from OIML R115; 7.1.2)

Indicating unit (at least one unit shall be tested)

(1) Maximum permissible errors (4.2, A.2)
(2) Power provided to probe (5.2.1, B.1)
(3) Indication when connected to battery charger(5.2.2)
(4) Display of digital indicating device (5.2.3)
(5) Indication if the thermometer is outside the specified measuring range (5.2.4)
(6) Self-checking device (5.2.5)
(7) Display of predicating thermometer (5.2.6)

2. Practical Test Method for Complete thermometers and Examples of Test Results

TEST ITEMS (from OIML R115; 7.1.2)

Complete thermometer (at least one thermometer shall be tested)

(1) Maximum permissible errors (4.2, A.2)
(2) Low battery indication (5.3.1, B.4)
(3) Ambient temperature (5.3.2, B.5)
(4) Thermal shock (5.3.3, B.6)
(5) Storage temperatures (5.3.4)
(6) Humidity (5.3.5, B.7)
(7) Electromagnetic radiation interference (5.3.6, B.8)
(8) Mechanical shock (5.3.7, B.9)
(9) Water resistance (5.3.8, F)

2. Practical Test Method for Complete thermometers and Examples of Test Results

TEST ITEMS (from OIML R115; 7.1.3)

Interchangeable probes

(1) Maximum permissible errors (4.2, A.2)

(2) Maximum power to be supplied by an indicating unit to meet energy dissipation requirement(5.1.1, B.1)

2. Practical Test Method for Complete thermometers and Examples of Test Results

(1) Maximum permissible errors (4.2, A.2)

(1.1) Determination of “Difference temperature”

In OIML Annex A A.2.1.1 is described how to obtain the difference between the measured and reference temperature. The difference is described with “Difference temperature” in this text.

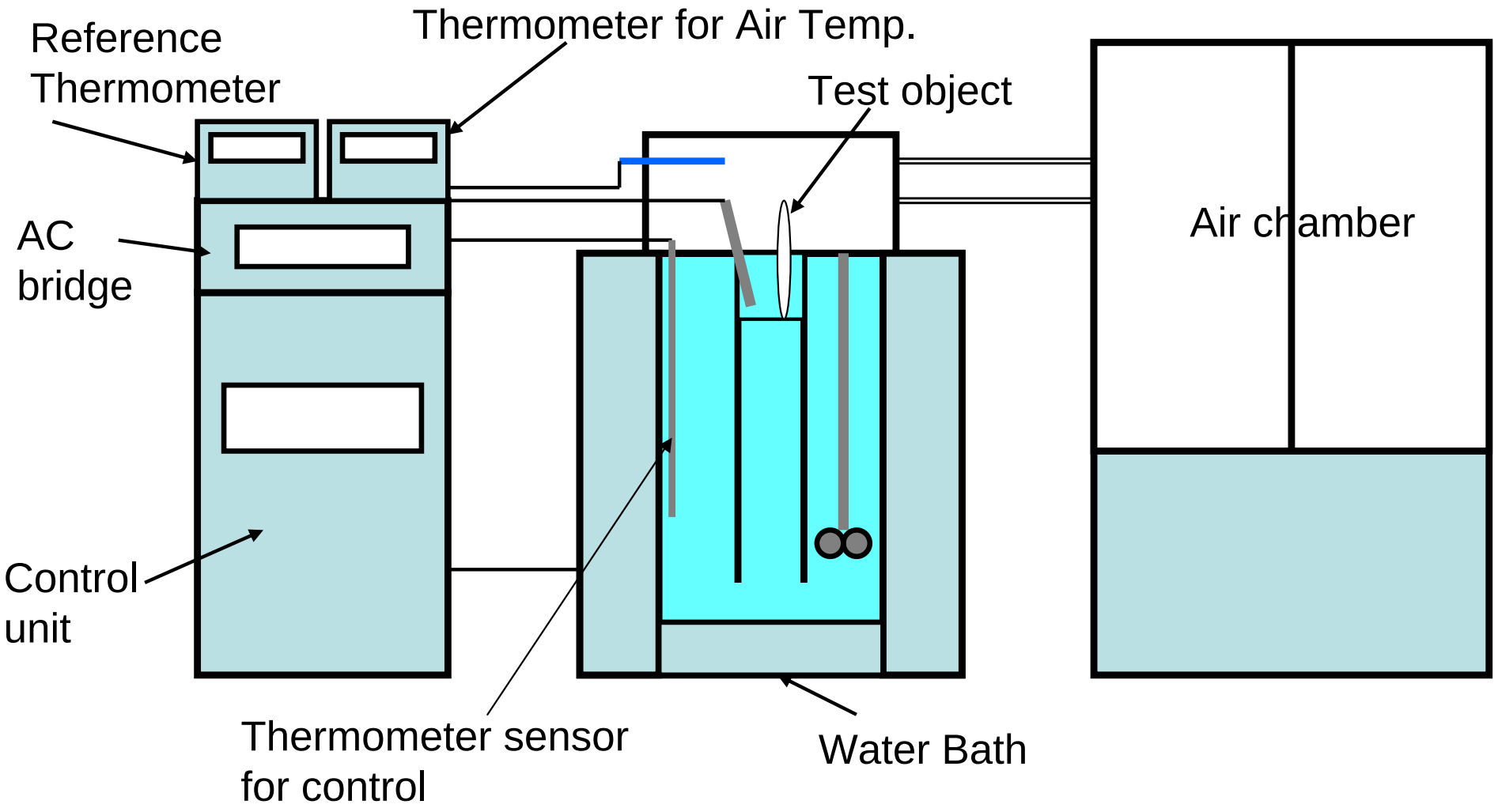
Difference temperature (E)

= Measured Temperature (I) – Reference Temperature (S)

2. Practical Test Method for Complete thermometers and Examples of Test Results

(1) Maximum permissible errors (4.2, A.2)

(1.2) Sketch of test equipment



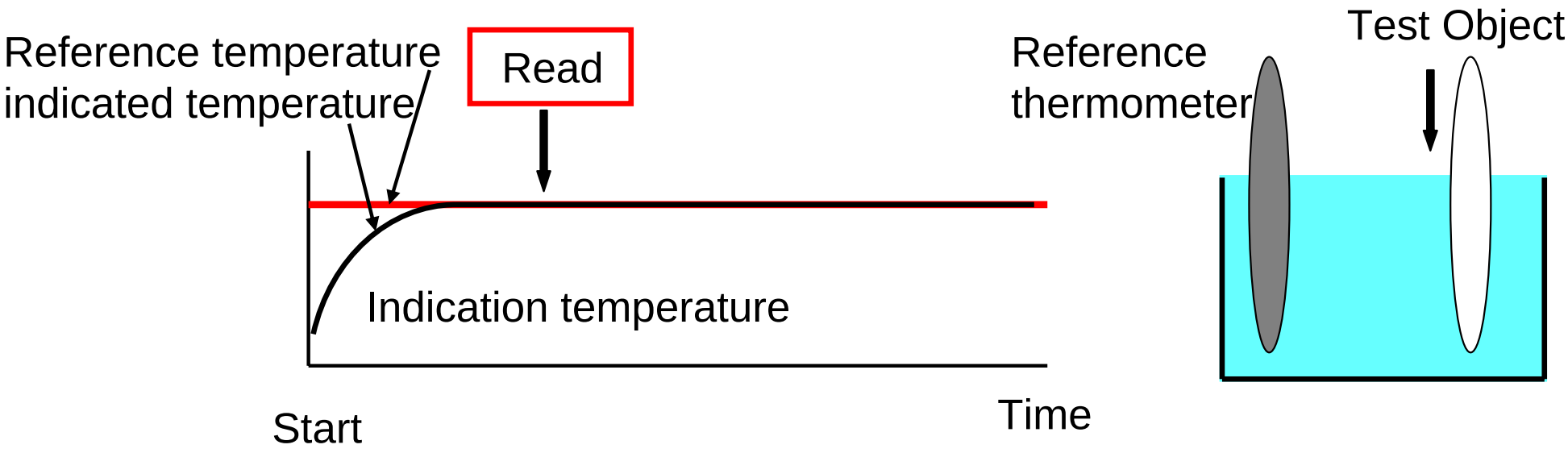
2. Practical Test Method for Complete thermometers and Examples of Test Results

(1) Maximum permissible errors (4.2, A.2)

(1.3) Procedure of test for “Difference temperature” in NMIJ

① The temperature probe of a complete thermometer shall be immersed in a reference water bath at a constant temperature until temperature equilibrium is established.

② The temperature indicated by the thermometer shall be compared to that indicated by reference thermometer.

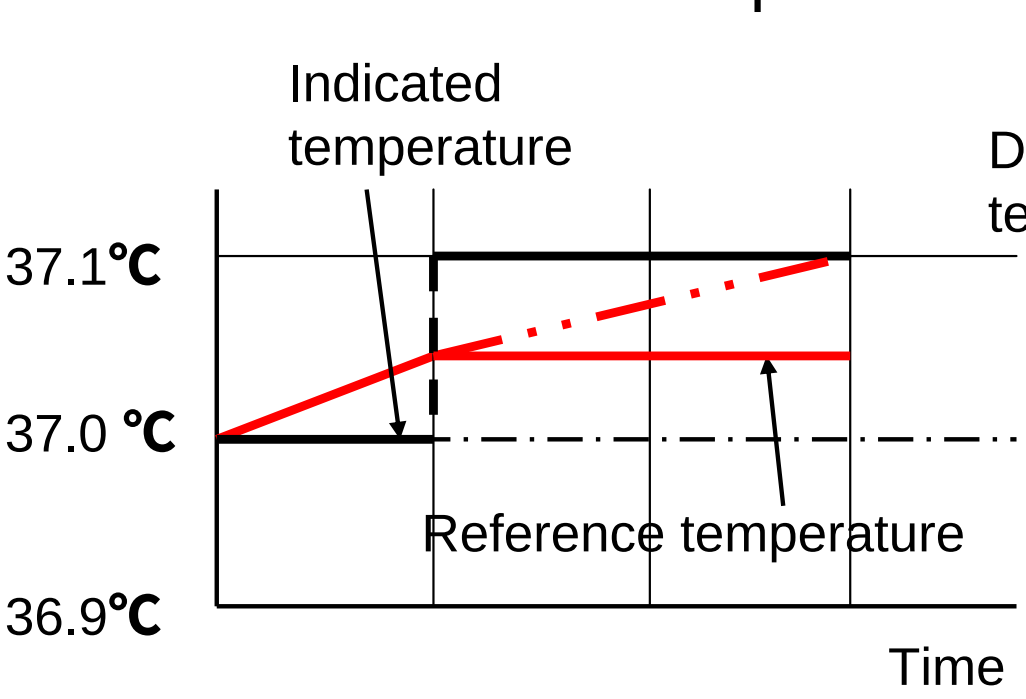


2. Practical Test Method for Complete thermometers and Examples of Test Results

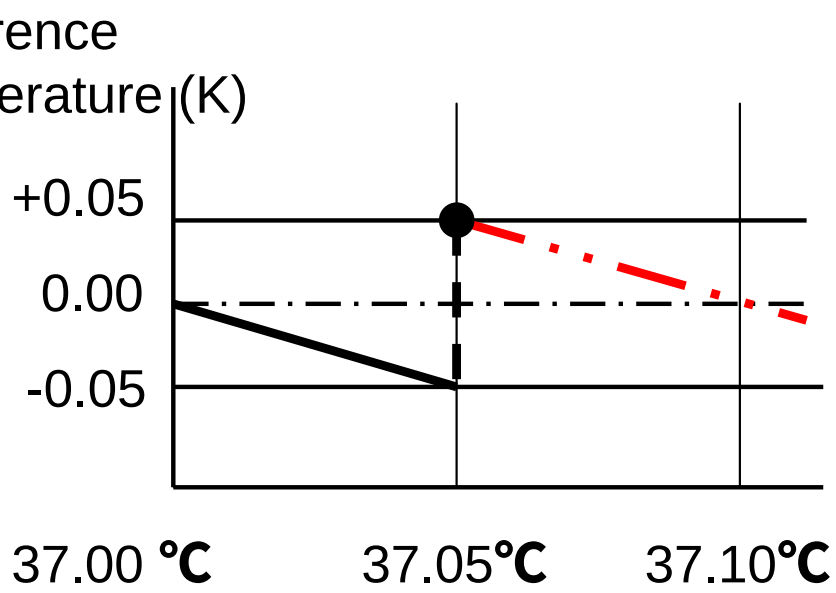
(1) Maximum permissible errors (4.2, A.2)

(1.3) Procedure of test for “Difference temperature” in NMIJ

③ The bath temperature shall then be increased with the speed at 0.001 ℃/s by 1 count change of indication, the temperature equilibrium re-established, and the measurement process repeated.



A example of Class Ⅱ



2. Practical Test Method for Complete thermometers and Examples of Test Results

(1) Maximum permissible errors (4.2, A.2)

(1.3) Procedure of test for “Difference temperature” in NMIJ

④ The difference between the measured and reference temperatures (Errors of the thermometer) shall meet the requirements for maximum permissible errors specified in 4.2.

Difference temperature ≦0.15 ℃(Class Ⅰ)
0.2 ℃(Class Ⅱ)

⑤ Number of temperature

Measuring range	Number of Temperature
≦ 10 ℃	3
＞ 10 ℃	5

A example of NMIJ, Max., 35℃, 37℃, 38℃, Min.

(1) Maximum permissible errors (4.2, A.2)

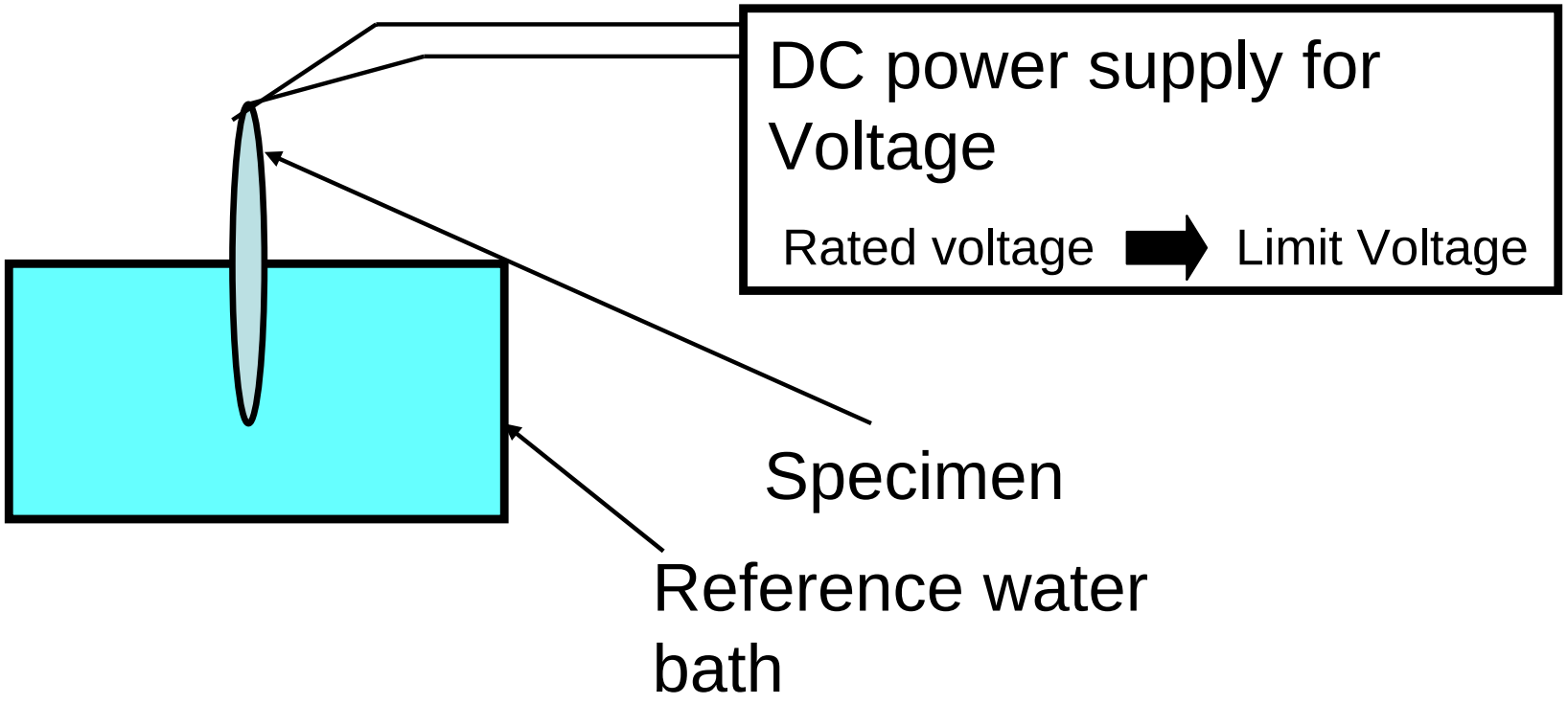
(1.4) Observation sheet of NMIJ

Sample No.××

	Min. range				Max. range
Simulated temp.	34℃	35℃	37℃	38℃	40℃
1r					
Temp. of bath	34.05	35.05	37.05	38.05	39.95
Indicated temp.	34.06	35.06	37.06	38.06	39.96
Difference temp.	0.01	0.01	0.01	0.01	0.01
2r					
Temp. of bath	34.05	35.05	37.05	38.05	39.95
Indicated temp.	34.06	35.06	37.06	38.06	39.96
Difference temp.	0.01	0.01	0.01	0.01	0.01
Ave.	0.01	0.01	0.01	0.01	0.01

(2)Low battery indication (5.3.1, B.4)

The thermometer shall provide a clear indication or warning signal when the battery voltage is outside the specified limits and it shall meet the requirements specified in 4.2 when the voltage is within these limit.



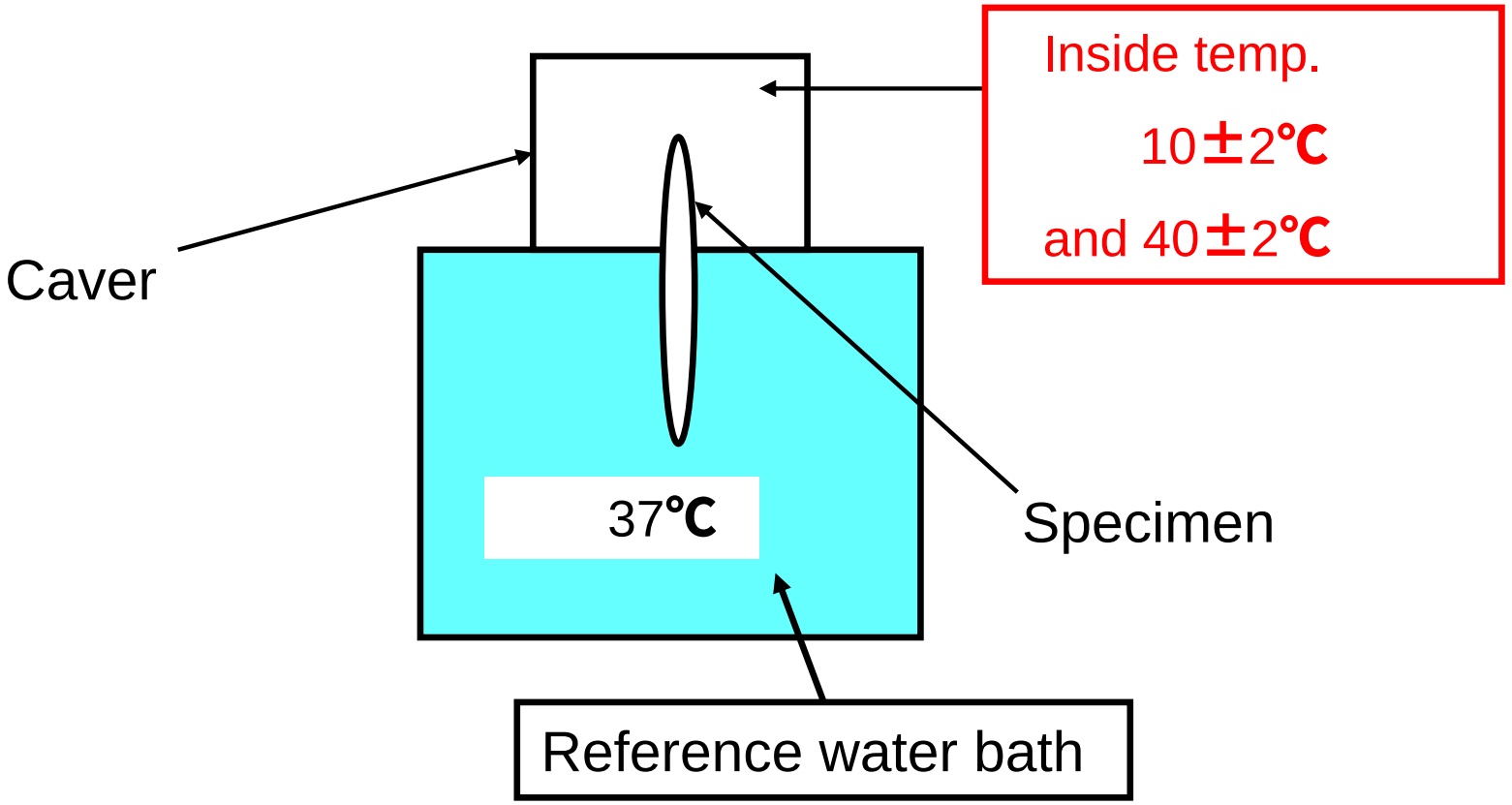
(2)Low battery indication (5.3.1, B.4)

Sample No.××

	Min. range				Max. range
Simulated temp.	34℃	35℃	37℃	38℃	40℃
Rated vol.	6V				
Temp. of bath	34.05	35.05	37.05	38.05	39.95
Indicated temp.	34.06	35.06	37.06	38.06	39.96
Difference temp.	0.01	0.01	0.01	0.01	0.01
Limit vol.	2.6V				
Temp. of bath	34.05	35.05	37.05	38.05	39.95
Indicated temp.	34.06	35.06	37.06	38.06	39.96
Difference temp.	0.01	0.01	0.01	0.01	0.01

(3) Ambient temperature (5.3.2, B.5)

The indicated temperature shall not vary by more than ±0.1℃ from the reference temperature when the temperature of the thermometer casing varies from 10℃ to 40℃.



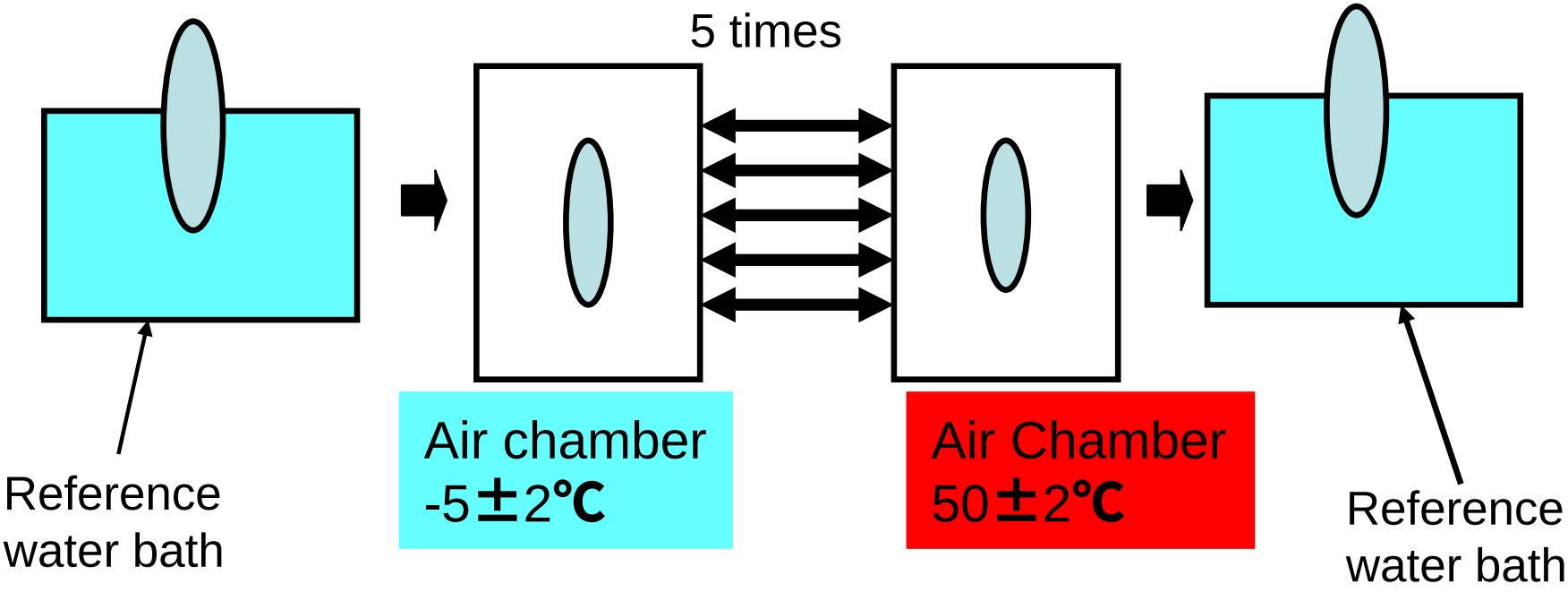
(3) Ambient temperature (5.3.2, B.5)

Sample No. ××

Simulated temp.	37℃			
	Reference temp.	indicated temp.	Difference temp.	Change of Difference temp.
10 ℃	37.050	37.06	0.010	
40 ℃	37.050	37.06	0.010	0.000

(4) Thermal shock (5.3.3, B.6)

The indicated temperature shall not vary by more than ±0.1℃ from the reference temperature after a thermal shock resulting from an abrupt change in temperature from −5℃ to +50℃.



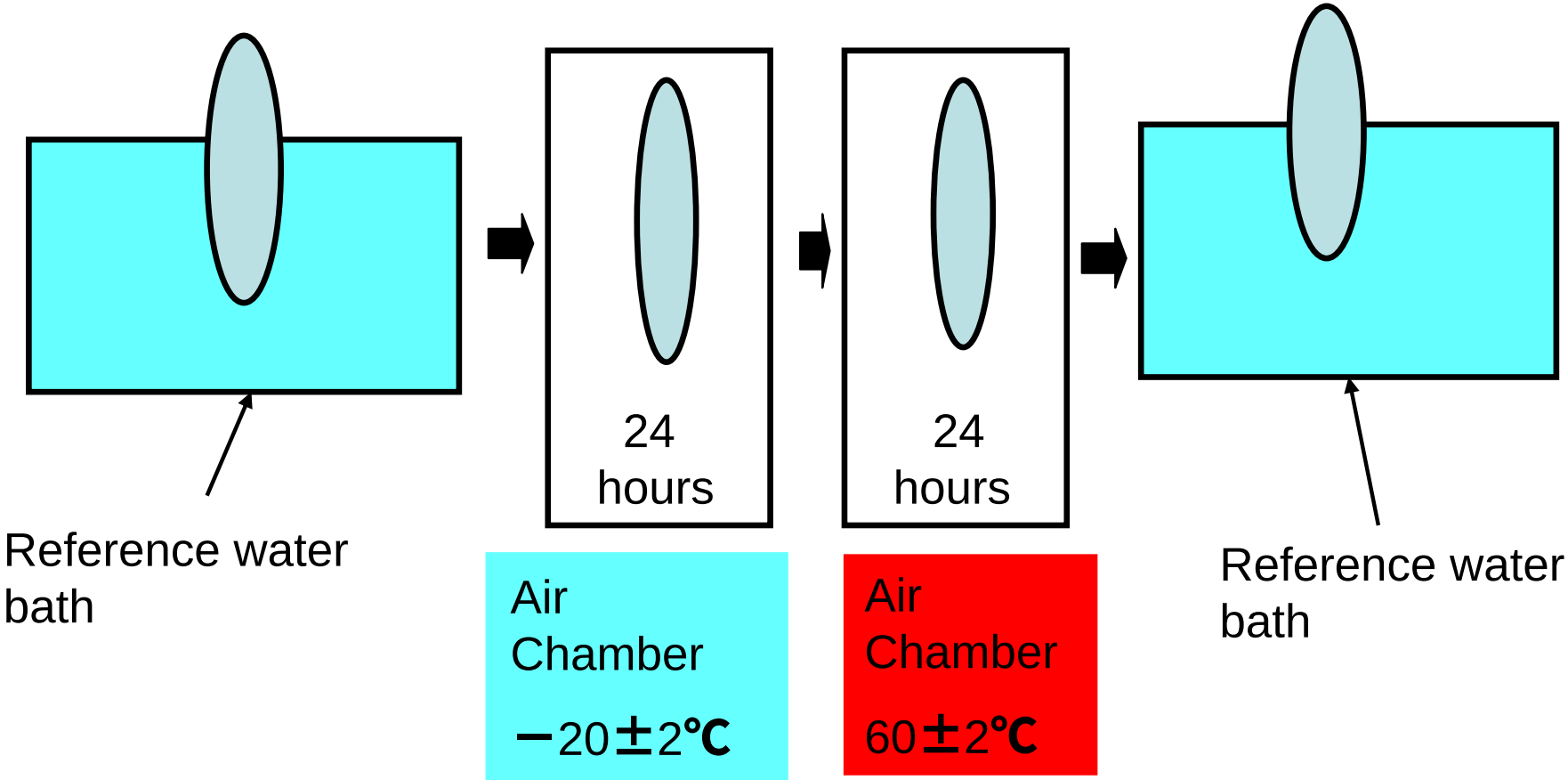
(4) Thermal shock (5.3.3, B.6)

Sample No. ××

Simulated temp.	37℃			
	Reference temp.	indicated temp.	Difference temp.	Change of Difference temp.
1r	37.05	37.06	0.01	
2r	37.05	37.06	0.01	
Ave.			0.01	
After	37.05	37.06	0.01	0.00

(5) Storage temperatures (5.3.4)

The indicated temperature shall not vary by more than ±0.1℃ from the reference temperature after storage for 24 hours at −20±2℃ and at 60±2℃.



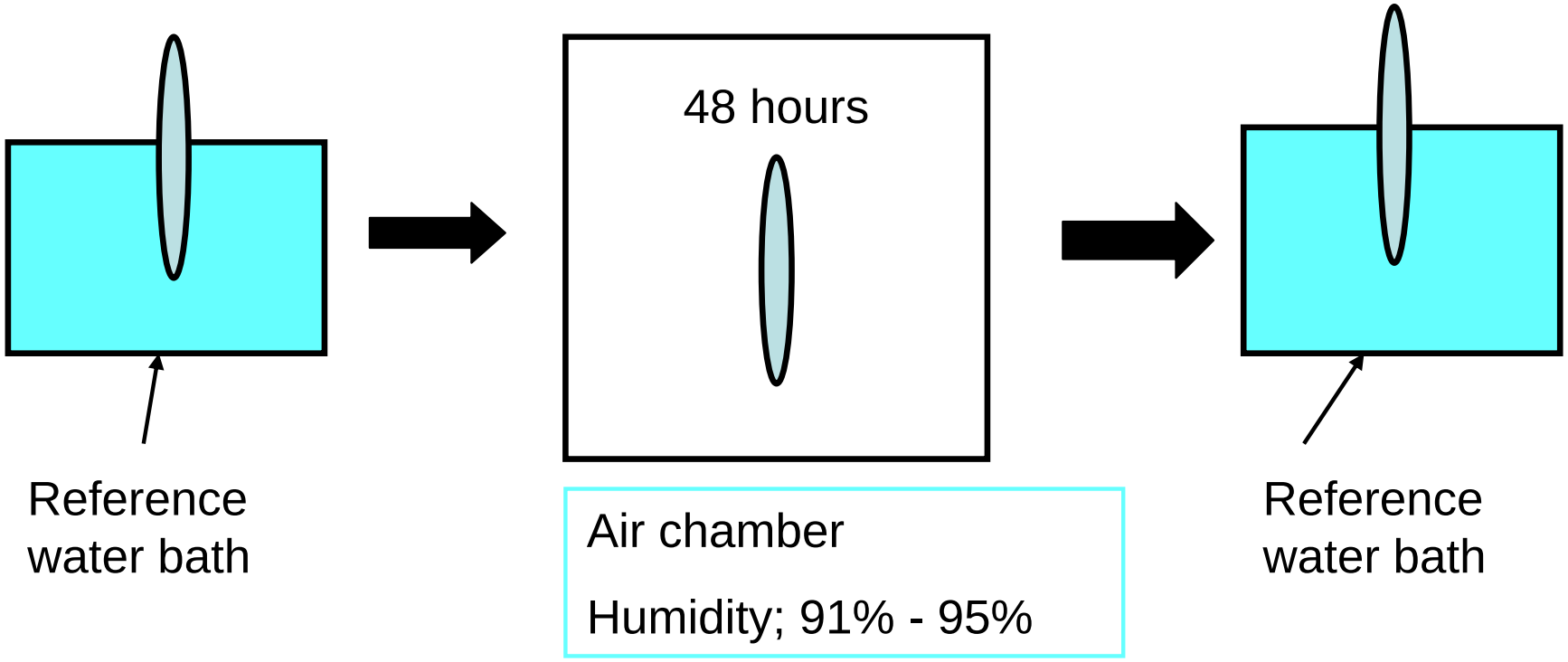
(5) Storage temperatures (5.3.4)

Sample No. ××

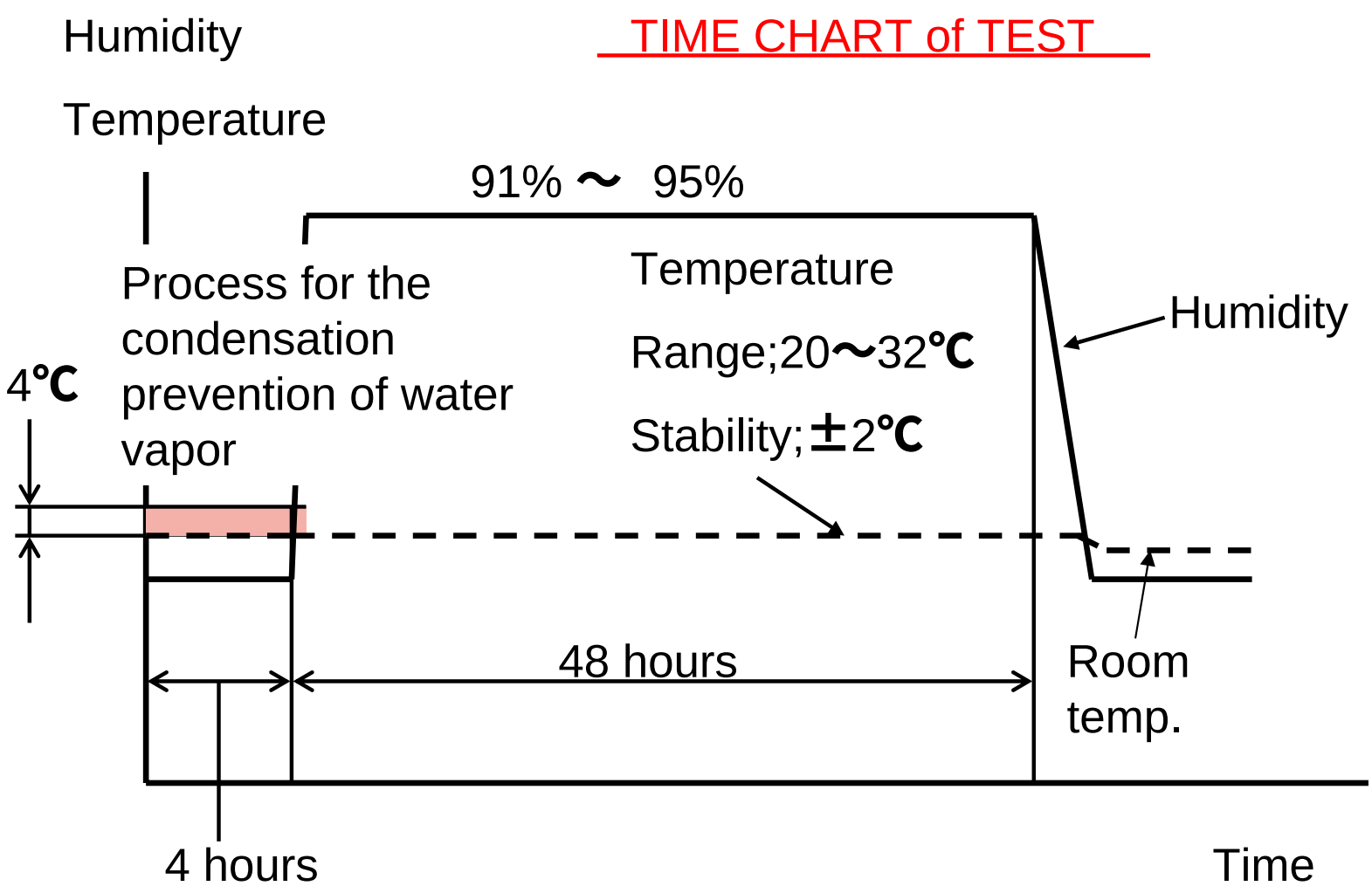
Simulated temp.	37℃			
	Reference temp.	indicated temp.	Difference temp.	Change of Difference temp.
1r	37.05	37.06	0.01	
2r	37.05	37.06	0.01	
Ave.			0.01	
After	37.05	37.06	0.01	0.00

(6) Humidity (5.3.5, B.7)

The indicated temperature shall not vary by more than ±0.1℃ from the reference temperature after storage at a relative humidity of 91% to 95% at a temperature constant within ±2℃ in the range 20 to 32℃.



(6) Humidity (5.3.5, B.7)



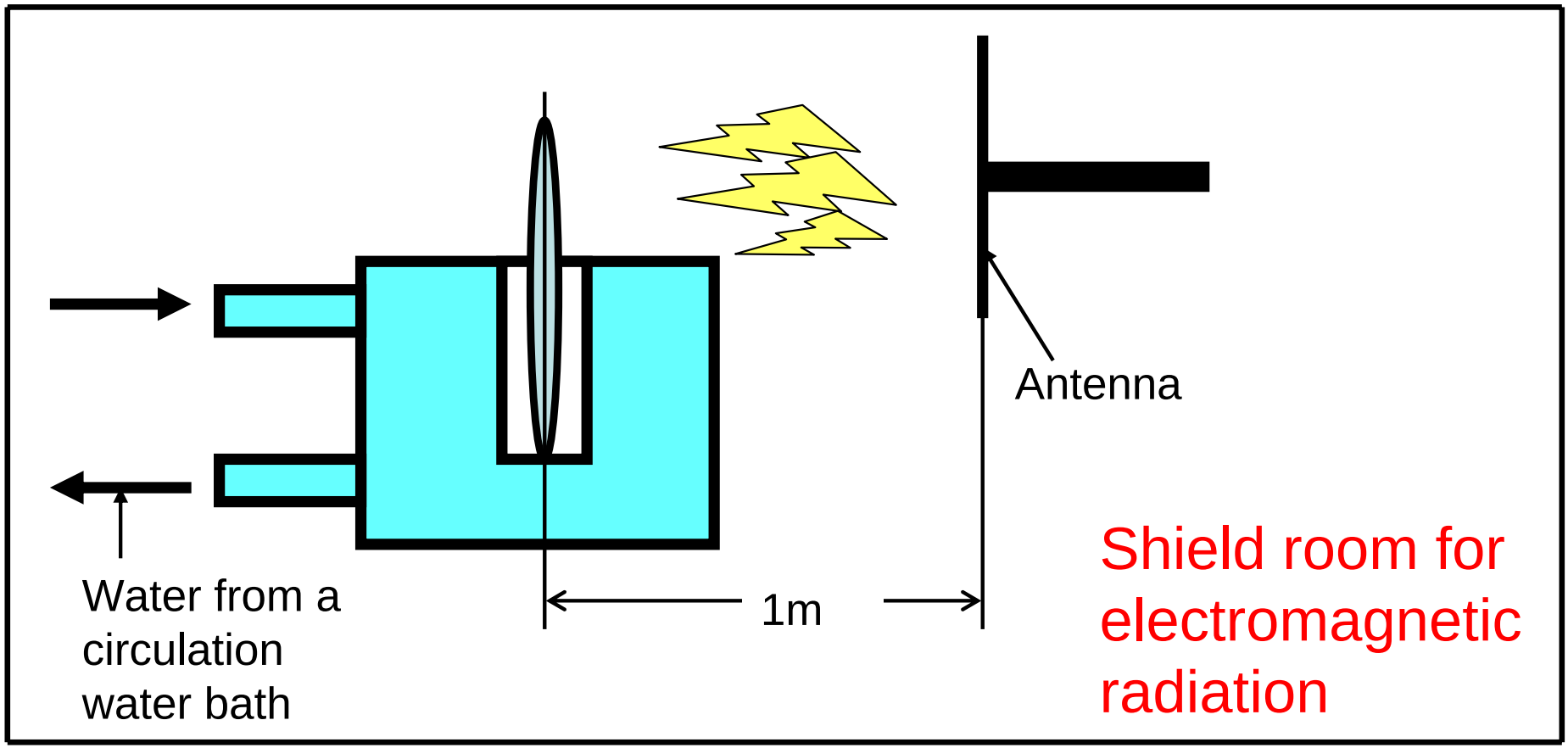
(6) Humidity (5.3.5, B.7)

Sample No. ××

Simulated temp.	37℃			
	Reference temp.	indicated temp.	Difference temp.	Change of Difference temp.
1r	37.05	37.06	0.01	
2r	37.05	37.06	0.01	
Ave.			0.01	
After	37.05	37.06	0.01	0.00

(7) Electromagnetic radiation interference (OIMLR115；5.3.6, B.8)

The indicated temperature shall not vary by more than ±0.3℃ from the reference temperature during exposure to an electromagnetic field having a frequency between 150kHz and 500MHz and a field strength of 10V/m.



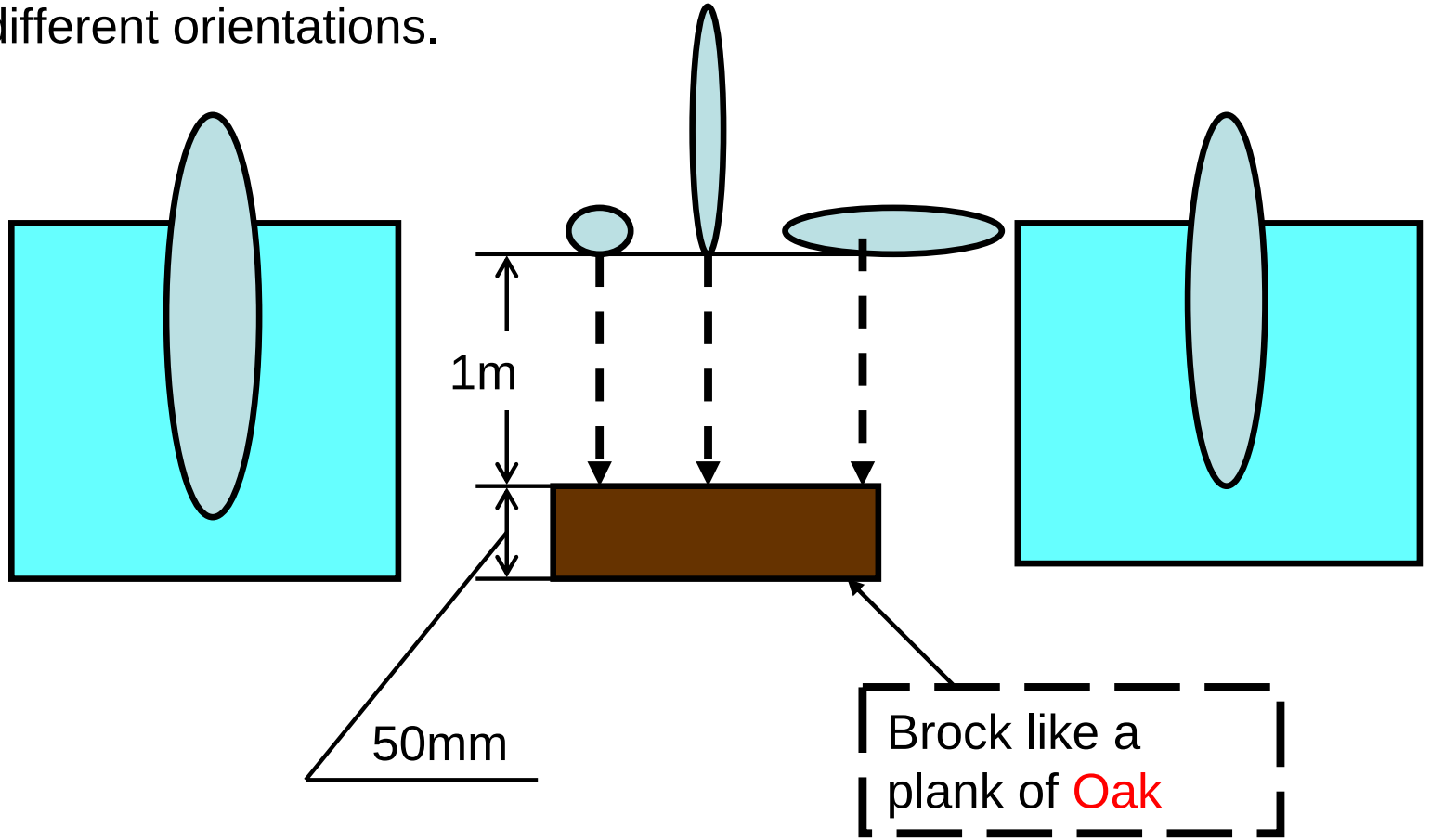
(7) Electromagnetic radiation interference (IEC60601-1-2＋OIMLR115；5.3.6, B.8)

Sample No. ××

Simulated temp.	37℃		
	Reference temp.	indicated temp.	Difference temp.
1r	37.05	37.06	0.01
2r	37.05	37.06	0.01
Ave.			0.01
After	37.05	37.06	0.01

(8) Mechanical shock (5.3.7, B.9)

The indicated temperature shall not vary by more than ±0.1℃ from the reference temperature after fall on to a hard surface a height of 1m from three different orientations.



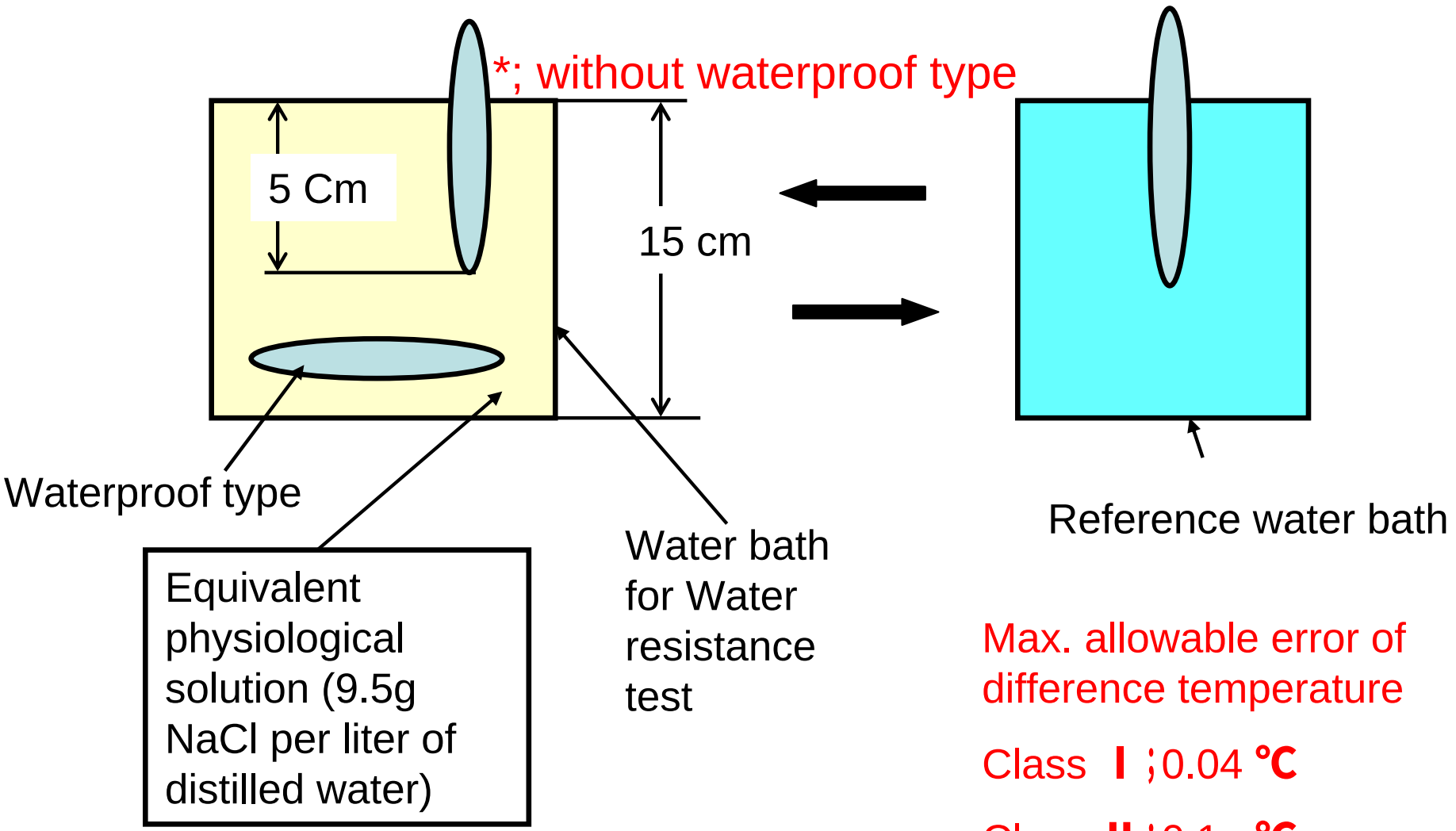
(8) Mechanical shock (5.3.7, B.9)

Sample No. ××

Simulated temp.	37℃			
	Reference temp.	indicated temp.	Difference temp.	Change of Difference temp.
1r	37.05	37.06	0.01	
2r	37.05	37.06	0.01	
Ave.			0.01	
After	37.05	37.06	0.01	0.00

(9) Water resistance (5.3.8, F)

Small and compact complete thermometers shall be water resistant.



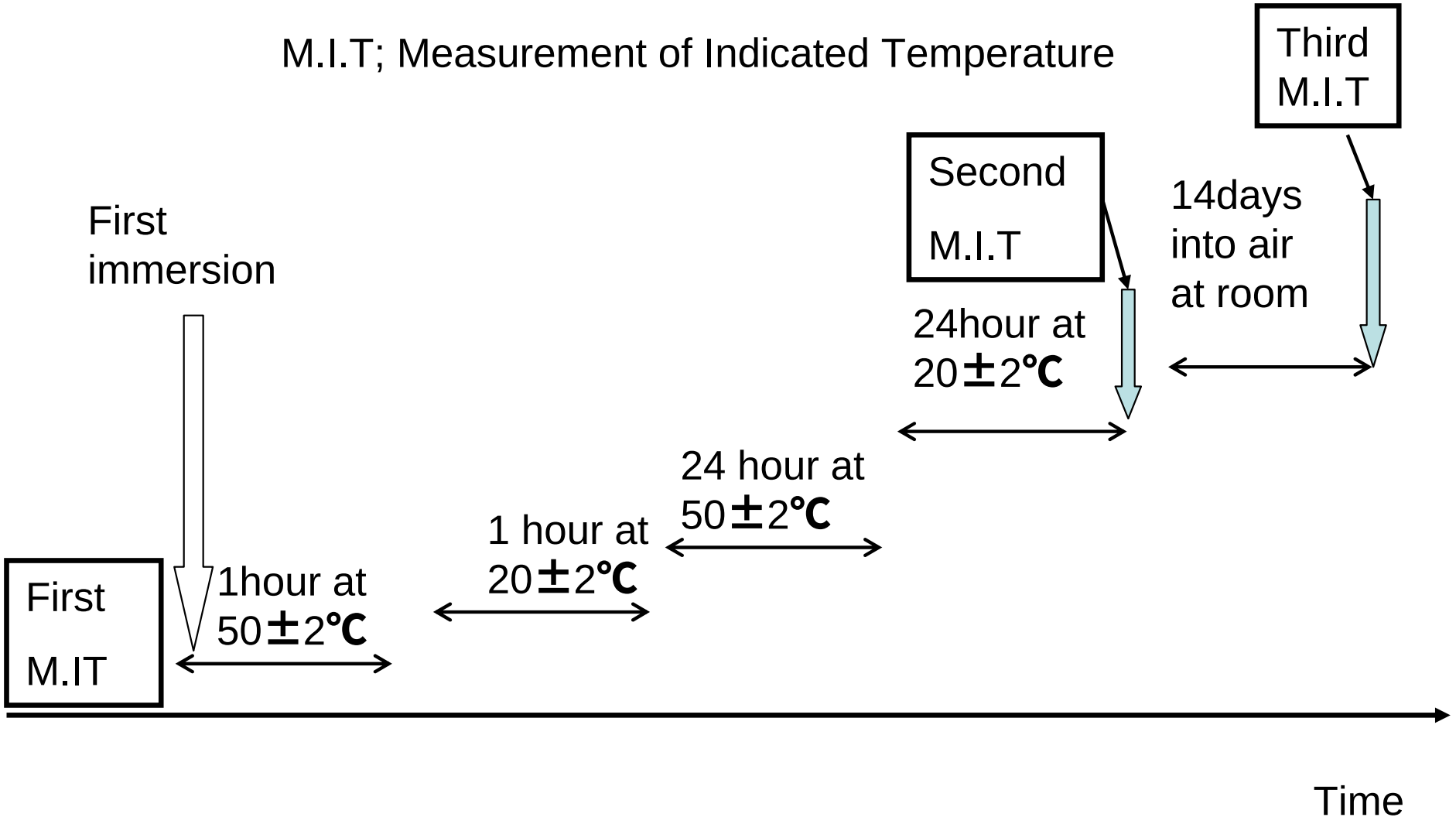
Max. allowable error of difference temperature

Class Ⅰ ¦0.04 ℃

Class Ⅱ ¦0.1 ℃

(9) Water resistance (5.3.8, F)

TEST PROCESS



(9) Water resistance (5.3.8, F)

Sample No. ××

Min. temp.	34℃			
	Reference temp.	indicated temp.	Difference temp.	Change of D.T
1r	34.05	34.06	0.01	
2r	34.05	34.06	0.01	
Ave.			0.01	
After1r	34.05	34.06	0.01	
After2r	34.05	34.06	0.01	
Ave.			0.01	0.00
Max. temp.	40℃			
	Reference temp.	indicated temp.	Difference temp.	Change of D.T
1r	39.95	39.96	0.01	
2r	39.95	39.96	0.01	
Ave.			0.01	
After1r	39.95	39.96	0.01	
After2r	39.95	39.96	0.01	
Ave.			0.01	0.00

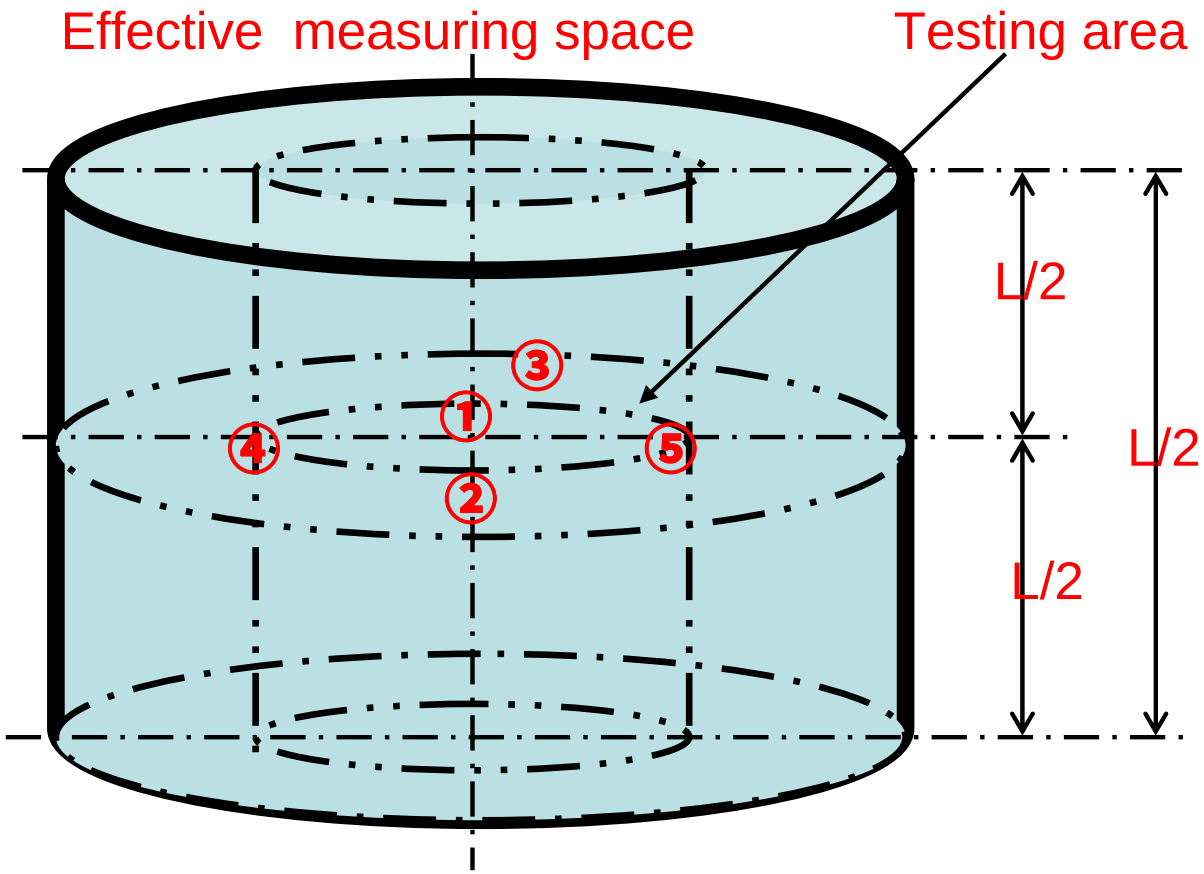
(9) Water resistance (5.3.8, F)

After 14 days				
Min. temp.	34℃			
	Reference temp.	indicated temp.	Difference temp.	Change of D.T
1r	34.05	34.06	0.01	
2r	34.05	34.06	0.01	
Ave.			0.01	
After1r	34.05	34.06	0.01	
After2r	34.05	34.06	0.01	
Ave.			0.01	0.00
Max. temp.	40℃			
	Reference temp.	indicated temp.	Difference temp.	Change of D.T
1r	39.95	39.96	0.01	
2r	39.95	39.96	0.01	
Ave.			0.01	
After1r	39.95	39.96	0.01	
After2r	39.95	39.96	0.01	
Ave.			0.01	0.00

3. Test Report (from ANNEX C)

4. A example of Evaluation Method for Test Equipments

-Reference Water Bath -



Test Temperature

30 ℃

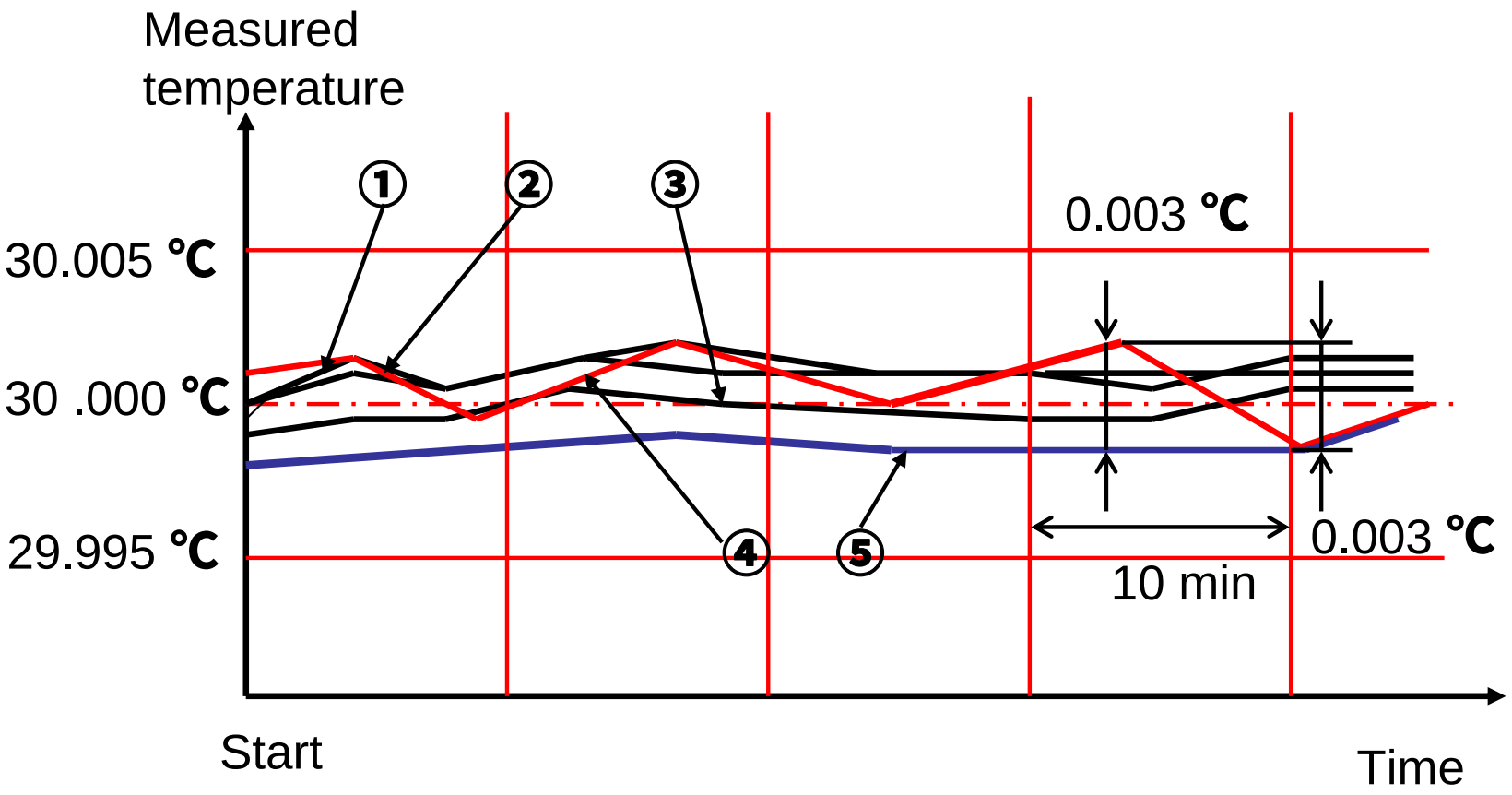
37 ℃

43 ℃

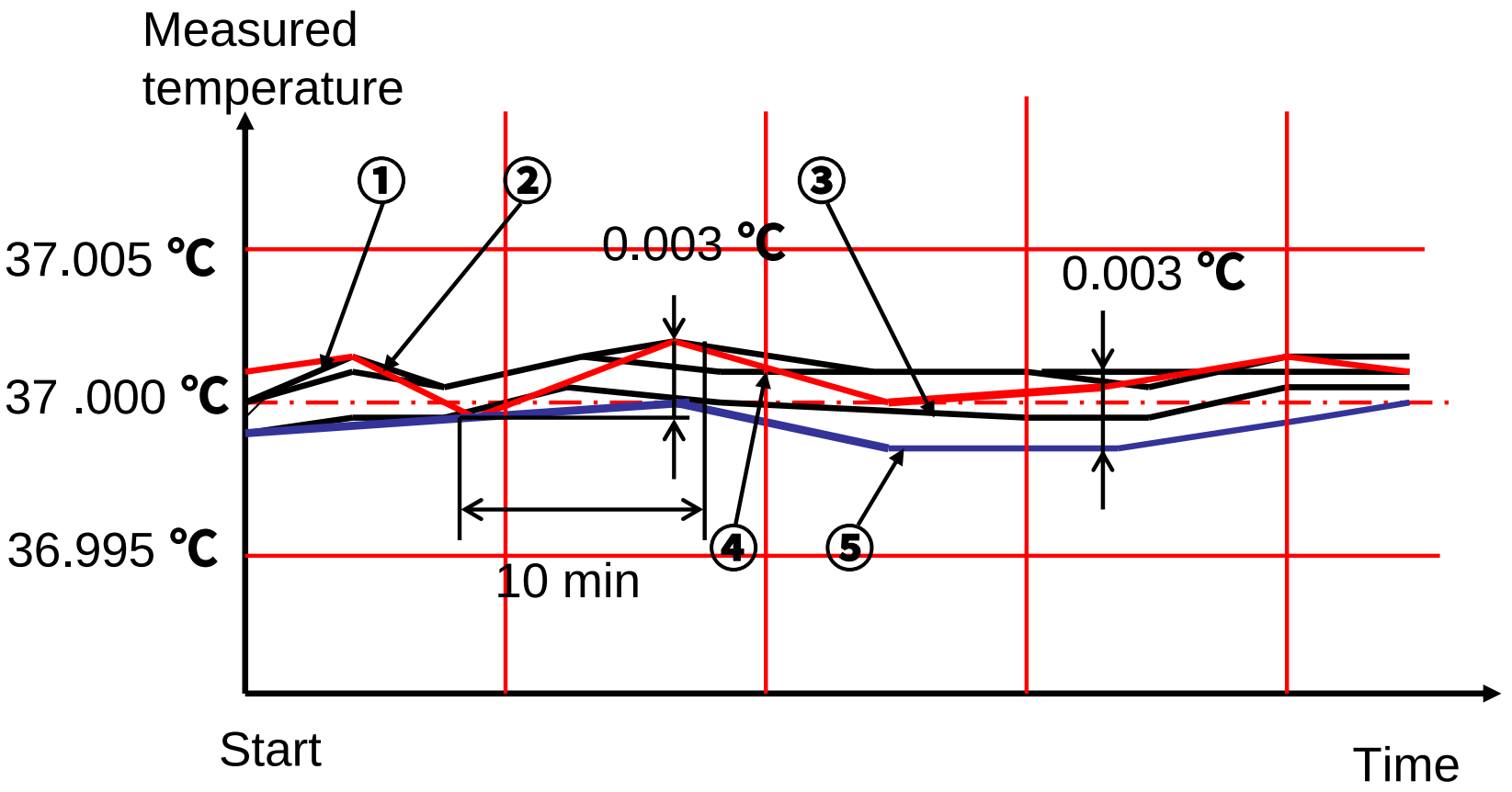
Sensors position

① ② ③ ④ ⑤

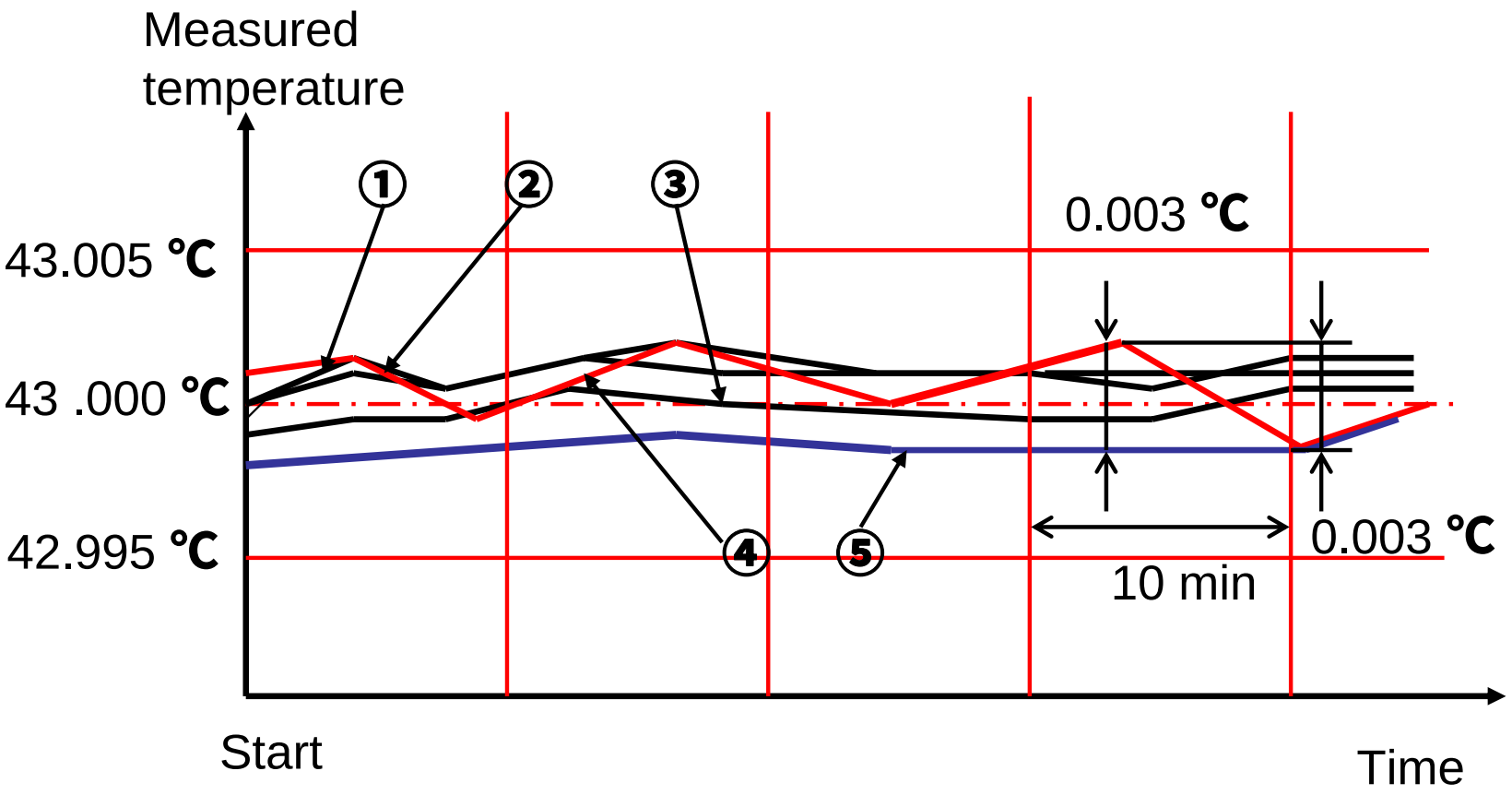
4. A example of Evaluation Method for Test Equipments



4. A example of Evaluation Method for Test Equipments



4. A example of Evaluation Method for Test Equipments



4. A example of Evaluation Method for Test Equipments

Evaluation result

(30 ℃)
- Temperature stability ; within ±0.003 ℃/10 min
- Temperature distribution ; within ±0.003 ℃

(37 ℃)
- Temperature stability ; within ±0.003 ℃/10 min
- Temperature distribution ; within ±0.003 ℃

(43 ℃)
- Temperature stability ; within ±0.003 ℃/10 min
- Temperature distribution ; within ±0.003 ℃

4. A example of Evaluation Method for Test Equipments

Evaluation result

- Temperature range ; 30 ℃～43 ℃
- Temperature stability ; within ±0.003 ℃/10 min
- Temperature distribution ; within ±0.003 ℃

- Standard uncertainty by Temperature stability ;

u_{ts}^2 = ($0.003^2/3$ ＋2× (Standard uncertainty of Sensor)^2)

- Temperature distribution ;

u_{td}^2 = ($0.003^2/3$ ＋2× (Standard uncertainty of Sensor)^2)

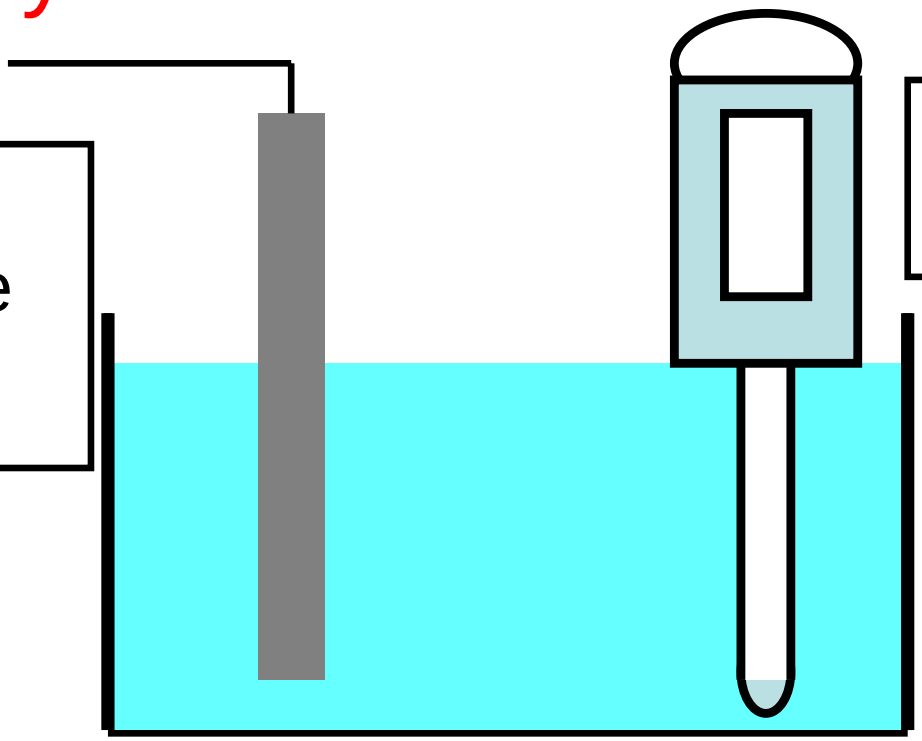
5. A example of Uncertainty for Thermometer

-Uncertainty source-

Resolution

Reproducibility of measurement

Reference temperature (Standard)



water bath (Distribution and Stability of Temperature)

-Model equation for Calibration and Testing-

$$I = E + S + \delta_{RB} + \delta_{R} + \delta_{Resolution} \qquad (1)$$

I; The measured values of thermometer

E; The difference temperature (Unknown value)

S; The reference temperature (Standard)

δRB; Uncertainty relation to water bath

δR; Reproducibility of measurement

δRound; Uncertainty relation to Resolution

-Model equation of “error of themometer”-

From (1)

$$E = I - S - \delta_{RB} - \delta_{R} - \delta_{Resolution} \qquad (2)$$

I; The measured values of thermometer

E; The difference temperature (Unknown value)

S; The reference temperature (Standard)

δ_{RB}; Uncertainty relation to water bath

δ_{R}; Reproducibility of measurement

$\delta_{Resolution}$; Uncertainty relation to Resolution

-Uncertainty of "Difference temperature"-

From (2)

$$u^2_E = u^2_S + u^2_{RB} + u^2_R + u^2_{Resolution} \qquad (3)$$

u_E; Standard uncertainty of "the Difference temperature"

(1) $u^2_S = u^2_{RT} + u^2_{time}$;

Standard uncertainty of the reference temperature (Standard)

・u_{RT}; Standard uncertainty relation to reference thermometer (Standard)

(Expansion uncertainty of Standard)/2

・u_{time}; Secular change of Calibration value of Reference thermometer by time

((Changed value between calibration and recalibration)/2)/$\sqrt{3}$

-Uncertainty of “error of thermometer”-

(2) $u^2_{RB} = u^2_{ts} + u^2_{tb}$

Standard uncertainty relation to water bath

- u_{ts}; Standard uncertainty by Temperature stability
- u_{tb}; Temperature distribution

(3) u_R; Reproducibility of measurement

“Standard deviation of measured value ”

(4)$u_{Resolution}$; Uncertainty relation to Resolution

(Resolution/ 2)/$\sqrt{3}$

(1)The example of Reference thermometer in NMIJ

Source of uncertainty Xi	Standard uncertainty ui (mK)
・Standard	2.5
・Secular change of Standard	1.2
Reference bath	
・Temperature stability	0.6
・Temperature distribution	0.6
・Reproducibility	3.7
・Resolution	1.4
Combined standard uncertainty	4.9
Expanded uncertainty (k=3)	14.7

(2)The example of testing in NMIJ

(without the reproducibility)

Source of uncertainty Xi	Standard uncertainty ui (mK)
・Standard ・Secular change of Standard	4.9 1.2
Reference bath ・Temperature stability ・Temperature distribution	 2.9 2.9
・Resolution	2.9
Combined standard uncertainty Expanded uncertainty (k=2)	7.1 14.2 (k=3；21.3)

Thank you very much

END