TEST REPORT
ISO 80601-2-56
Medical electrical equipment —
Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature Measurement

Report Reference No..... :	EED33M00014102	
Compiled by (+ signature)..... :	Macy Yang	.....
Reviewed by(+ signature)..... :	Koke Liu	.....
Approved by(+ signature)..... :	Shine Yang	..... Lab Supervisor
Date of issue..... :	May 06, 2020	
Testing Laboratory..... :	Centre Testing International Group Co., Ltd.	
Address..... :	Hongwei Industrial Zone, Bao'an 70 District, Shenzhen, Guangdong, China	
Testing location / address..... :	Same as above	
Applicant's name..... :	Hunan Astiland Medical Aesthetics Technology Co., Ltd.	
Address..... :	Room 507, Floor 5, Building 13, Xinggong Technology Park, No.100 Luyun Road, Gaoxin Development District, Changsha, Hunan, China	
Test specification:		
Standard..... :	ISO 80601-2-56:2017+A1:2018	
Test procedure..... :	Test report only	
Non-standard test method..... :	N/A	
Test Report Form No..... :	ISO80601_2_56D	
Test Report Form(s) Originator..... :	SGS CEBEC	
Master TRF..... :	Dated 2019-10-11	
Test item description..... :	Infrared Thermometer	
Trade Mark..... :	/	
Manufacturer..... :	Hunan Astiland Medical Aesthetics Technology Co., Ltd.	
Address..... :	Room 507, Floor 5, Building 13, Xinggong Technology Park, No.100 Luyun Road, Gaoxin Development District, Changsha, Hunan, China	
Model/Type reference..... :	AS22	
Ratings..... :	DC3V (2 x 1.5V alkaline batteries, size AA)	

Check No.: 3177441443

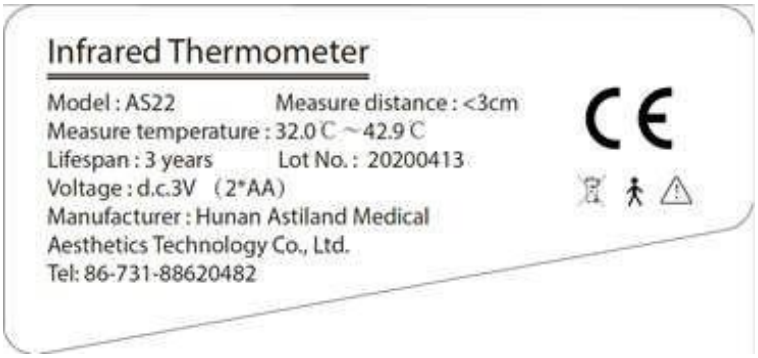
Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
All applicable tests were performed, and test results comply with the standard requirements **Exceptions:** **The following clause/ collaterals were not part of the manufacturers order and therefore excluded from this testing:** 1) Clause 201.11.7, Biocompatibility of ME EQUIPMENT and ME SYSTEMS. 2) Clause 201.12.2 and 206, Usability, not evaluated in this report, Refer to IEC 60601-1-6 test report. 3) 201.102 CLINICAL ACCURACY VALIDATION 4) Chapter 202, EMC, not evaluated in this report, Refer to IEC 60601-1-2 test report.	Centre Testing International Group Co., Ltd. Hongwei Industrial Zone, Bao' an 70 District, Shenzhen, Guangdong, China

Summary of compliance with National Differences

N/A

Copy of marking plate



Note: The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.

GENERAL INFORMATION	
Test item particulars:	
Classification of installation and use.....:	Hand-held
Supply connection .....:	Internal powered
Accessories and detachable parts included in the evaluation ..... :	Battery
Options included .....:	None
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A(N)
- test object does meet the requirement.....:	Pass (P)
- test object was not evaluated for the requirement.....:	N/E
- test object does not meet the requirement.....:	Fail (F)
Testing……:	
Date of receipt of test item.....:	Apr. 15, 2020
Date (s) of performance of tests.....:	Apr. 16, 2020 to Apr. 29, 2020

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tested sample(s) and the sample information are provided by the client.
This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.

This Test Report Form is intended for the evaluation of basic safety and essential performance of clinical thermometers for body temperature Measurement in accordance with ISO/ EN ISO 80601-2-56.
This Test Report Form can be used to complement the IEC/EN 60601-1 Test Report.

Name and address of factory (ies) :	Hunan Astiland Medical Aesthetics Technology Co., Ltd. Room 507, Floor 5, Building 13, Xinggong Technology Park, No.100 Luyun Road, Gaoxin Development District, Changsha, Hunan, China

General product information and considerations:

1. The infrared thermometer is supplied by 3V d.c batteries, which are intended to be replaced by user.
2. The operating condition specified in instruction manual:
   Operating environment: Temperature: 16℃~35℃;
   Humidity: ≤85%;
   Atmospheric pressure: 70kPa~106kPa.
3. The Number of the Risk Management File is AS22 V1.0.0, Ver: A/0.

ISO 80601-2-56			
Clause	Requirement + Test	Result - Remark	Verdict
201.4	**GENERAL REQUIREMENTS**		P
201.4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS		P
201.4.2.101	Additional requirements for RISK MANAGEMENT PROCESS for ME EQUIPMENT or ME SYSTEMS		P
	The RISKS of changing environmental conditions for the CLINICAL THERMOMETER are considered in RISK MANAGEMENT PROCESS	Refer to Risk Management File	P
	Guidance regarding the RESIDUAL RISKS is provided in the instruction for use	Refer to chapter 12 “Troubleshooting” in user manual	P
201.4.3	ESSENTIAL PERFORMANCE		P
201.4.3.101	Additional requirements for ESSENTIAL PERFORMANCE		P
	At least one of the following functions is identified as essential performance in risk management file:	See Appended Table 4.3 and RM Results Table 4.3 in part 1	P
	– accuracy of the CLINICAL THERMOMETER,	Refer to 201.101.2	P
	– generation of a TECHNICAL ALARM CONDITION,		N
	– not providing an OUTPUT TEMPERATURE.		P
201.7	**ME EQUIPMENT IDENTIFICATION, MARKING AND DOCUMENTS**		P
201.7.2.1	Minimum requirements for marking on ME EQUIPMENT and interchangeable parts		P
201.7.2.1.101	Additional requirements for minimum requirements for marking on ME EQUIPMENT and interchangeable parts, marking of the packaging		P
	The packaging of the CLINICAL THERMOMETER and PROBE is marked as following:		P
	a) MEASURING SITE and REFERENCE BODY SITE		P
	b) mode of operation of the CLINICAL THERMOMETER; and		P
	– the contents of the packaging		P
	c) appropriate symbol from ISO 15223:2016 used for sterile packaging (See Table 201 D.2.101, symbols 3-8).....:	No sterile packaging	N
	d) Symbol 5.1.4 of ISO 15233-1:2016 used for clinical thermometer or Probe with expiration date (see Table 201.D.2.101, symbol 2).....:		N
	e) Packaging marked with special storage and/or handling instructions.....:	See the packaging	P
	For a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.		N

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Clause	Requirement + Test	Result - Remark	Verdict
201.7.2.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
201.7.2.101	Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
	The following markings provided on the CLINICAL THERMOMETER are CLEARLY LEGIBLE:		P
	a) symbol "°C" or "°F" marked adjacent to the OUTPUT TEMPERATURE or indicated at the display.:	"°C" indicated on display screen	P
	– if switching between units is possible, the respective displayed unit is indicated unambiguously		N
	b) the intended MEASURING SITE is marked		P
	c) if necessary to maintain ESSENTIAL PERFORMANCE, it is indicated to use a new PROBE COVER prior to next measurement	No PROBE COVER used	N
201.7.4.3	Unit of measure		P
201.7.4.3.101	Additional requirements for unit of measure		P
	OUTPUT TEMPERATURE expressed in degrees Celsius, °C or degrees Fahrenheit, °F.....:	"°C"	P
	Unit of measure clearly indicated.....:	Clearly indicated on display screen	P
201.7.9	ACCOMPANYING DOCUMENT		P
201.7.9.1	the accompanying document contains — name or trade name and address of — the MANUFACTURER, and — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale to which the RESPONSIBLE ORGANIZATION can refer;	Refer to the back cover of user manual	P
201.7.9.2	Additional requirements for instructions for use		P
201.7.9.2.101	Instructions for use		P
	Instructions for use include:		P
	a) a summary of the USE SPECIFICATION as determined for IEC 62366-1:2015;		P
	b) MEASURING SITE and REFERENCE BODY of CLINICAL THERMOMETER specified	Refer to chapter 8 "Parameters" in user manual	P
	c) recommended minimum measuring time and minimum time between measurements for each intended MEASURING SITE, if applicable..... :		N/A
	d) RATED OUTPUT RANGE for each intended REFERENCE BODY SITE specified.....:	Refer to chapter 8 "Parameters" in user manual	P

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Clause	Requirement + Test	Result - Remark	Verdict
	e) the LABORATORY ACCURACY in the RATED OUTPUT RANGE and, if equipped, the LABORATORY ACCURACY in the RATED EXTENDED OUTPUT RANGE:	Refer to chapter 8 "Parameters" in user manual	P
	f) for CLINICAL THERMOMETERS for use with PROBE COVER:	NO PROBE COVER used	N
	1) instruction how to apply PROBE COVER		N
	2) information about the behaviour of the CLINICAL THERMOMETER when used without PROBE COVER		N
	g) mode of operation of the CLINICAL THERMOMETER (DIRECT MODE or ADJUSTED MODE) :	ADJUSTED MODE Refer to chapter 8 "Parameters" in user manual	P
	h) instructions for selection and replacement of INTERNAL ELECTRICAL POWER SOURCES, if applicable	Refer to chapter 8 "Parameters" in user manual	P
	i) Instructions provided on nature of maintenance and/or calibration needed to ensure proper function and its frequency.....:	Refer to chapter 11 "Maintenance and storage" in user manual	P
	j) information about disposal of the CLINICAL THERMOMETER and its components.....:	Refer to chapter 1 "Attention" in user manual	P
	k) if the CLINICAL THERMOMETER and/or its components are intended for single use only, information on characteristics and technical factors that could pose a RISK is provided in instructions for use	Not for single use	N
201.7.9.101	The ACCOMPANYING DOCUMENT includes a description of the correction method to derive unadjusted temperatures from OUTPUT TEMPERATURE measured in the ADJUSTED MODE, except when the CLINICAL THERMOMETER is equipped with a TEST MODE or DIRECT MODE	Direct mode is provided	N
201.11	**Protection against excessive temperatures and other HAZARDS**		P
201.11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEM		P
	The surfaces of the CLINICAL THERMOMETER, PROBE and ACCESSORIES that can become contaminated with body fluids during NORMAL CONDITION or SINGLE FAULT CONDITION was designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in IEC 60601‑1:2005+A1:2012, 11.6.7 and IEC 60601‑1‑11:2015, Clause 8).	Complied Refer to IEC 60601-1 report No.: EED33M00014101	P
	The CLINICAL THERMOMETER is dismantled during the decontamination PROCESS.		N
	ACCESSORIES not intended for re‑use are exempt from this requirement.		N

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Clause	Requirement + Test	Result - Remark	Verdict
	CLINICAL THERMOMETER and PROBE ENCLOSURES is designed to allow for surface cleaning and disinfection to reduce to acceptable levels the RISK of infection of OPERATORS, bystanders, or the PATIENT.	Complied	P
	Instructions for processing and REPROCESSING the CLINICAL THERMOMETER, PROBE and ACCESSORIES complied with ISO 17664:2004 and ISO 14937:2009 and is disclosed in the instructions for use.	No Sterilization	N
	When compliance with this document is affected by the cleaning or the disinfecting of the CLINICAL THERMOMETER, PROBE or its parts or ACCESSORIES, clean and disinfect them 100 times in accordance with the methods indicated in the instruction for use, including any cooling or drying period.		N
201.11.7	Biocompatibility of ME EQUIPMENT and ME SYSTEMS		N/E
	The ACCESSIBLE PARTS of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES that contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction is marked as containing phthalates on the device itself or on the packaging.		N/E
	The symbol of EN 15986:2011 (see Table 201.D.2.101, Symbol 10) is used.		N/E
	If the INTENDED USE of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates is included in the RISK MANAGEMENT FILE.		N/E
	The instructions for use of a CLINICAL THERMOMETER, PROBE, its parts or ACCESSORIES that contain such phthalates contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.		N/E
201.12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
201.12.1	Accuracy of controls and instruments		P
201.12.1.101	Additional requirements for accuracy of controls and instruments		P
	If the CLINICAL THERMOMETER cannot indicate a temperature within the LABORATORY ACCURACY, it fulfils one of the following items:		P
	– either it provides a TECHNICAL ALARM CONDITION		N
	– or it does not provide an OUTPUT TEMPERATURE;	No output temperature	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Minimum RATED OUTPUT RANGE of the CLINICAL THERMOMETER is from 34°C to 42°C..... :	34.0°C to 42.0°C	P
	Note In some applications, a wider rated output range can be utilized.	32.0°C to 33.9°C 42.1°C to 42.9°C	P
	For some intended uses, a narrower rated output range may be utilized.		N
201.12.2	USABILITY		N/E
201.12.2.101	Additional requirements for USABILITY		N/E
	CLINICAL THERMOMETERS intended for home healthcare use require the display of OUTPUT TEMPERATURE of at least 4mm or the value is optically magnified to this height. This is indicated in USABILITY ENGINEERING PROCESS.	See Report based on IEC 60601-1-6	N/E
	CLINICAL THERMOMETERS with a segmented indication display perform a functional test of all segments after activation.		N/E
201.101	**LABORATY PERFORMANCE REQUIREMENTS**		P
201.101.1	General test requirements		P
	Laboratory performance is assessed in DIRECT MODE or in TEST MODE under the same conditions	Direct mode was used for Laboratory performance test	P
	Alternatively correction method is used to derive unadjusted temperatures from OUTPUT TEMPERATURE in accordance with the ACCOMPANYING DOCUMENT		N
	If the CLINICAL THERMOMETER is intended for use with a PROBE COVER as indicated in the instructions for use, a new PROBE COVER is used for each OUTPUT TEMPERATURE measurement	NO PROBE COVER used	N
201.101.2	LABORATORY ACCURACY		P
	The LABORATORY ACCURACY within the RATED OUTPUT RANGE in NORMAL USE is within ±0,3 °C.	See Appended Table 201.101.2	P
	The LABORATORY ACCURACY, within the RATED EXTENDED OUTPUT RANGE in NORMAL USE, is not greater than 0,4 °C unless CLINICAL THERMOMETER indicates that the measured temperature is outside of the RATED OUTPUT RANGE.	See Appended Table 201.101.2	P
	If the PROBE is separable from the CLINICAL THERMOMETER, they may be tested separately	Non-separable	N
	Calculated equation for CLINICAL THERMOMETER.. :	See Appended Table 201.101.2	P
201.101.3	**Time response for a DIRECT MODE CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER**		N

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Clause	Requirement + Test	Result - Remark	Verdict
	The transient response for a DIRECT MODE CLINICAL THERMOMETER that is not an ADJUSTED MODE CLINICAL THERMOMETER is characterized and disclosed in the instructions for use.		N
	Transient time lower than recommended minimum measuring time for both heating and cooling indicated in ACCOMPANYING DOCUMENT.... :		N
201.102	**CLINICAL ACCURACY VALIDATION**		N/E
201.102.1	Method		N/E
	ADJUSTED MODE CLINICAL THERMOMETER are VALIDATED for CLINICAL ACCURACY in each ADJUSTED MODE in accordance with ISO 14155:2011.		N/E
	The results of clinical accuracy validation is disclosed in the accompanying document, including the CLNICAL BAIS (Δ_{cb}), with its LIMITS OF AGREEMENT (L_A), the CLINICAL REPEATABILITY(σ_r), the REFERENCE BODY SITE, and, MEASURING SITE for each OPERATING MODE		N/E
	If the CLINICAL THERMOMETER is intended for use with a PROBE COVER as indicated in the instructions for use, a new PROBE COVER is used for each OUTPUT TEMPERATURE measurement		N/E
	Requirements of clauses 201.102.2, 201.102.3, 201.102.4 and 201.102.5 are fulfilled		N/E
	CLINICAL ACCURACY validated..... :	See Appended Table 201.102.1	N/E
201.102.2	Human subject population requirements		N/E
	Total number of febrile subjects not less than 30 % and not greater than 50 % of all subjects in the selected age group.....:		N/E
	CLINICAL ACCURACY VALIDATION carried out on all age groups indicated in the instructions for use...:		N/E
	Number of subjects in each age group is sufficiently large to minimize the effect of random components of measurement error (minimum of all groups is 105; minimum in age group is 35; minimum 15 subjects in A1 or A2 if subgroup A is not excluded):		N/E
	– age group A1 (0-3 months).....:		—
	– age group A2 (3-12 months)..... :		—

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Clause	Requirement + Test	Result - Remark	Verdict
	– age group B (>1 and <5 years).....:		—
	– age group C (>5 years).....:		—
201.102.3	Calculated CLINICAL BIAS for the OPERATING MODE being evaluated (Δ_{cb}) ..... :		N
201.102.4	Calculated LIMITS OF AGREEMENT (L_A)..... :		N
201.102.5	Calculated CLINICAL REPEATABILITY for particular OPERATING MODE (σ_r).....:		N
	An ADJUSTED MODE CLINICAL THERMOMETER that makes continuous estimates of the REFERENCE BODY SITE temperature is exempt from the requirements of this subclause		N
201.103	**PROBES, PROBE CABLE EXTENDERS AND PROBE COVERS**		P
201.103.1	General		P
	PROBES, PROBE CABLE EXTENDERS and PROBE COVERS comply with the requirements of this particular standard	Probe is integrated with the THERMOMETER	P
	MANUFACTURERS of PROBES, PROBE CABLE EXTENDERS and PROBE COVERS conduct tests to ensure that all CLINICAL THERMOMETER specifications are met with each MODEL OR TYPE REFERENCE of CLINICAL THERMOMETER with which they are intended to be used		N
	All CLINICAL THERMOMETERS with which compatibility to the PROBES, PROBE CABLE EXTENDERS and PROBE COVERS is claimed are listed in the ACCOMPANYING DOCUMENT.....:		N
	It is the responsibility of the MANUFACTURER of a PROBE, PROBE CABLE EXTENDER and PROBE COVER, including a REPROCESSED PROBE, PROBE CABLE EXTENDER and PROBE COVER, to have their PROCESSES VALIDATED to ensure that any new or REPROCESSED product complies with the requirements of this particular standard		P
201.103.2	Labelling		N
	At least one MODEL OR TYPE REFERENCE of CLINICAL THERMOMETER is included in the ACCOMPANYING DOCUMENT provided with each PROBE, PROBE CABLE EXTENDER and PROBE COVER, compliant with 201.103.1.	Probe is integrated with the THERMOMETER	N
	The following statements can be found in the ACCOMPANYING DOCUMENT of each PROBE, PROBE CABLE EXTENDER and PROBE COVER:		N

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Designed for use with specific thermometer or monitoring equipment;		N
	b) The OPERATOR is responsible for checking the compatibility of the thermometer or monitoring equipment, PROBE, PROBE CABLE EXTENDER AND PROBE COVER before use; and		N
	c) Incompatible components can result in degraded performance.		N
202	**Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests**		N/E
	IEC 60601 - 1 - 2:2014 applies except as follows:		N/E
202.4.3.1	**Configurations**		N/E
	— if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CLINICAL THERMOMETER;		N/E
202.8.1.101	**Additional general requirements**		N/E
	The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, is not allowed:		N/E
	— component failures;		N/E
	— changes in programmable parameters or settings;		N/E
	— reset to default settings;		N/E
	— change of OPERATING MODE;		N/E
	— change in LABORATORY ACCURACY at any point in the RATED OUTPUT RANGE and in the RATED EXTENDED OUTPUT RANGE greater than permitted in 201.101.2 without the generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation.		N/E
	The CLINICAL THERMOMETER exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use during IMMUNITY testing), which does not require OPERATOR intervention and that does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.		N/E
	In the event of disruption during IMMUNITY tests, the CLINICAL THERMOMETER recover from any disruption within 30 s.		N/E
206	**Usability**		N/E

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Clause	Requirement + Test	Result - Remark	Verdict
	IEC 60601‐1‐6:2010+A1:2013 applies except as follows:		N/E
	For a CLINICAL THERMOMETER, the following is considered PRIMARY OPERATING FUNCTIONS	See IEC 60601-1-6 report	N/E
	a) observing the OUTPUT TEMPERATURE;		N/E
	b) properly positioning CLINICAL THERMOMETER or PROBE at the MEASURING SITE;		N/E
	c) starting the CLINICAL THERMOMETER from power off;		N/E
	d) turning off the CLINICAL THERMOMETER;		N/E
	e) performing a basic pre‐use functional check of the CLINICAL THERMOMETER.		N/E
	The following functions, if available, also is considered PRIMARY OPERATING FUNCTIONS:		N/E
	a) observing the OUTPUT TEMPERATURE;		N/E
	f) performing a basic pre‐use functional check of the ALARM SIGNALS;		N/E
	g) configuring the ACCESSORIES including connection of the detachable parts to the CLINICAL THERMOMETER;		N/E
	h) REPROCESSING the ACCESSORIES;		N/E
	i) setting the OPERATOR‐adjustable controls: — switching between MEASURING SITES; — setting CLINICAL THERMOMETER control parameters; — setting ALARM LIMITS; — inactivating ALARM SIGNALS.		N/E
208	**General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**		N
	IEC 60601‐1‐8:2006+A1:2012 applies except as follows:		N
208.6.1.2	**Determination of ALARM CONDITIONS and assignment of priority**		N
	A CLINICAL THERMOMETER need not have a PHYSIOLOGICAL ALARM CONDITION.	No alarm system	N
211	**Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment**		N
	IEC 60601‐1‐11:2015 applies except as follows:		N
211.4.2.3.1	**Continuous operating conditions**		N

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Clause	Requirement + Test	Result - Remark	Verdict
	— a temperature range of at least +15 °C to +40 °C;		N
211.10.1.1	**General requirements for mechanical strength**		N
	The tests of IEC 60601-1-11:2015, Clause 10 and IEC 60601‑1:2005+A1:2012, 15.3 is performed on the same sample of the CLINICAL THERMOMETER after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this document have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use.		N
	If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE is so tested.		N
	A separate sample of the CLINICAL THERMOMETER is used for each specified PROCEDURE.		N
212	**Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment**		N
212.10.1.1	**General requirements for mechanical strength**		N
	— if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the CLINICAL THERMOMETER;		N
	The tests of IEC 60601-1-12:2014, Clause 10 and IEC 60601-1:2005+A1:2012, 15.3 is performed on the same sample of the CLINICAL THERMOMETER after the cleaning and disinfection PROCEDURES of 201.11.6.6 of this document have been performed unless there are no cleaning and disinfection PROCEDURES specified in the instructions for use.		N
	If more than one PROCEDURE is specified in the instructions for use, each PROCEDURE is so tested.		N
	A separate sample of the CLINICAL THERMOMETER is used for each specified PROCEDURE.		N

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Clause	Requirement + Test	Result - Remark	Verdict

201.101.2	TABLE: Laboratory accuracy		P
	RATED OUTPUT RANGE (°C)....:	34.0°C to 42.0°C	—
	RATED EXTENDED OUTPUT RANGE (°C)....:	32.0°C to 33.9°C 42.1°C to 42.9°C	—
	Ambient conditions of CLINICAL THERMOMETER (°C / %rH)..... :	5℃ to 35℃, ≤85%RH	—
	Total uncertainty of REFERENCE TEMPERATURE SOURCE (°C)..... :	≦0.07	—

	Combination of ambient condition [1)]	T_{RTS} (°C)	T_{TUT} (°C)	T_{RCT} (°C)	Equation (°C)
Midpoint of RATED OUTPUT RANGE	**1**	38.00	38.0/38.0/38.0	38.00	0.0
	2	38.00	38.1/38.0/38.0	38.00	Max.+0.1
	3	38.00	38.0/38.0/38.0	38.00	0.0
	4	38.00	38.0/37.9/38.0	38.00	Max.-0.1
	5	38.00	38.0/38.0/38.0	38.00	0.0
Upper limit of RATED OUTPUT RANGE	**1**	42.00	42.0/42.0/42.0	42.00	0.0
	2	42.00	42.0/42.0/42.0	42.00	0.0
	3	42.00	42.0/42.0/42.1	42.00	Max.+0.1
	4	42.00	42.0/42.0/42.0	42.00	0.0
	5	42.00	42.0/42.0/42.0	42.00	0.0
Lower limit of RATED OUTPUT RANGE	**1**	34.00	34.0/34.0/34.1	34.00	Max.+0.1
	2	34.00	34.1/34.0/34.1	34.00	Max.+0.1
	3	34.00	34.0/34.0/34.0	34.00	0.0
	4	34.00	34.1/34.0/34.1	34.00	Max.+0.1
	5	34.00	34.0/34.0/34.0	34.00	0.0
Upper limit of RATED EXTENDED OUTPUT RANGE	**1**	42.90	42.9/42.8/42.9	42.90	Max.-0.1
	2	42.90	42.9/42.9/42.9	42.90	0.0
	3	42.90	42.9/42.9/42.9	42.90	0.0
	4	42.90	42.9/42.7/42.9	42.90	Max.-0.2
	5	42.90	42.9/42.9/42.9	42.90	0.0
Lower limit of RATED EXTENDED OUTPUT RANGE	**1**	32.00	32.0/32.0/32.1	32.00	Max.+0.1
	2	32.00	32.1/32.0/32.1	32.00	Max.+0.1
	3	32.00	32.0/32.1/32.0	32.00	Max.+0.1
	4	32.00	32.1/32.0/32.0	32.00	Max.+0.1

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Clause	Requirement + Test	Result - Remark	Verdict

	5	32.00	32.1/32.1/32.0	32.00	Max.+0.1

Supplementary information:

[1)] Combination of upper and lower limits of environmental temperature and humidity ranges:

1. **Midpoint of humidity and ambient temperature**
2. **Upper limit of humidity + upper limit of ambient temperature**
3. **Upper limit of humidity + lower limit of ambient temperature**
4. **Lower limit of humidity + upper limit of ambient temperature**
5. **Lower limit of humidity + lower limit of ambient temperature**

T_{RTS} – Measured temperature of REFERENCE TEMPERATURE SOURCE
T_{TUT} – Measured temperature of CLINICAL THERMOMETER under test
T_{RCT} – Measured temperature of REFERENCE CLINICAL THERMOMETER

201.101.3A	**TABLE: Time response – heating transient time**					N
	Minimum measuring time (s).....:					—
	RATED OUTPUT RANGE (°C)..... :					—
CLINICAL THERMOMETER	**T_{RTS1} (°C)**	**t_1 (s)**	**T_{RTS2} (°C)**	**t_2 (s)**	**heating transient time (s)**	

Supplementary information:

T_{RTS1} – temperature of first REFERENCE TEMPERATURE SOURCE
t_1 – time until thermal equilibrium is reached
T_{RTS2} – temperature of second REFERENCE TEMPERATURE SOURCE
t_2 – time until temperature reading remains within the LABORATORY ACCURACY limits of the second REFERENCE TEMPERATURE SOURCE

201.101.3B	**TABLE: Time response – cooling transient time**					N
	Minimum measuring time (s).....:					—
	RATED OUTPUT RANGE (°C)..... :					—
CLINICAL THERMOMETER	**T_{RTS1} (°C)**	**t_1 (s)**	**T_{RTS2} (°C)**	**t_2 (s)**	**cooling transient time (s)**	

Supplementary information:

T_{RTS1} – temperature of first REFERENCE TEMPERATURE SOURCE
t_1 – time until thermal equilibrium is reached
T_{RTS2} – temperature of second REFERENCE TEMPERATURE SOURCE
t_2 – time until temperature reading remains within the LABORATORY ACCURACY limits of the second REFERENCE TEMPERATURE SOURCE

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Clause	Requirement + Test	Result - Remark	Verdict

201.102.1	**TABLE: CLINICAL ACCURACY VALIDATION**				N/E
	Minimum measuring time of TUT (s)..... :				—
	Required time between measurements (s).... :				
	Procedures..... :	**1)** **2)** **3)**			
Subject #	**Measured OUTPUT TEMPERATURE (°C) - RCT**	**Measured OUTPUT TEMPERATURE (°C) - TUT**			**Remark**
		Procedure 1	**Procedure 2**	**Procedure 3**	

Supplementary information:

TUT – CLINICAL THERMOMETER under test

RCT – REFERENCE CLINICAL THERMOMETER

*** End of Report ***

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