

Finished digital thermometer factory inspection record

temperature: 25°C humidity: 46%

Lot No.	20250428			Model	MC-201	Order No.									
Inspection standard	GB/T 21416, ASTM E 1112-00, EN 80601-2-56, 浙械注准 20192070364			Batch	4000	Remark	The number of samples is greater than thirteen								
Inspection method: sampling level: S-3 AQL:0.65 AC:RE% sampling quantity: 20															
Inspection Item	Inspection requirement					Actual measurement/defect					Judgment OK/NG				
accuracy	0.1°C/0.1°F					Pass					OK				
repeatability	S ≤ 0.2°C					Pass					OK				
Inspection equipment	Ultra high precision constant temperature bath: CGJDHWC-14 (32.5); CGJDHWC-12, (35), CGJDHWC-02 (37), CGJDHWC-15 (41.5), CGJDHW-10 (42.5)														
Indicating value max error	Precision error requirement: ± 0.1°C (35.0°C ~ 42.0°C) ± 0.2°C (<35.0°C / >42.0°C)	Sample quantity													
		thermostatic water bath temperature	1	2	3	4	5	6	7	8	9	10	11	12	13
		32.5°C/90.5°F													
		35°C/95°F													
		37°C/98.6°F													
		41.5°C/106.7°F													
42.5°C/108.5°F															
Inspection method: sampling level: I AQL:1.0 AC:RE 2/3 package sampling quantity: 20															
Inspection Item	Inspection requirement					Actual measurement/defect					judgment OK/NG				
exterior	Outer looking should be clean, there can't be scratch, glue and destroy on the body, there won't be plastic overlap and salient point on the LCD display, there won't be obvious wear trace on the shell.					Pass					OK				
	Color of the body and cap should be same in one batch, there shouldn't be obvious color deviation.					Pass									
	Sensor top should be smooth, no burr on the edge.					Pass									
	Button should be flexible and firm.					Pass									
Logo, package, label	Files of the package, label, instrument, logo printing should meet customer's requirement.					Pass					OK				
	Printing of the box, instrument and label should be clear, correct, papers should be clean.					Pass					OK				
	Box bond place should be smooth and firm.					Pass					OK				
Inspection method: sampling level: S-3 AQL:0.65 AC:RE% function indicate sampling quantity required: 20															
Inspection Item	Inspection requirement					Actual measurement/defect					judgment OK/NG				
Function indicating requirem	Self inspection and memory function: when the thermometer is turned on, the LCD display of the thermometer should be clear, without any defects such as blurring, missing stroke, stroke deformation, etc., and then the last measured value should be displayed.					Pass					OK				
	Buzzing prompt function: When the thermometer reaches a stable measurement value, it should give a prompt and a beeping prompt voice.					Pass					OK				
	Automatic shutdown function: thermometer shall be automatically shut down within 8~10 minutes after measurement.					Pass					OK				



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Function indicating requirement	High and low temperature display function: when the measured temperature of the thermometer is lower than 32 °C, the LCD will display "LO °C". When the measured temperature is higher than 42.9 °C, the LCD will display "Hi °C".	Pass	OK
	Low voltage prompt function: When the voltage of the thermometer is lower than 90% (or meets the low voltage value of 1.25 V proposed by the manufacturer, but should not be higher than 90% of the rated value), the low voltage prompt should appear	Pass	OK
	Indication range: 32°C~42.9°C, 90°F~109.9°F	Pass	OK
	The shell of the thermometer shall be able to withstand biological and physical cleaning without functional degradation	Pass	OK
	High temperature alarm: when the temperature measured by the thermometer is ≥ 37.8 °C, the thermometer will emit a warning voice with high frequency.	Pass	OK
	Measurement time: Normal type ≤ 50S Fast type ≤ 30S	Pass	OK

Inspection method: sampling level: S-2 AQL:0.65 AC:RE % function indicate sampling quantity required: 13

Inspection Item	Inspection requirement	Actual measurement/defect	judgment OK/NG
Inspection equipment	Medical leakage current tester: YYLDLSY-02; Programmable voltage withstand insulation tester: CKNYJYCSY-01		
Withstand voltage test	Basic voltage DC1.5V Test voltage AC1500V No breakdown and flashover after 1min	Pass	OK

Leakage current test	Continuous leakage current at normal operating temperature under AC/DC: Shell leakage current under normal condition ≤ 0.1mA	1	2	3	4	5	6	7	OK
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	
		8	9	10	11	12	13	14	
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA		
	Continuous leakage current at normal operating temperature under AC/DC: Auxiliary leakage current of patients in normal state ≤ 0.01mA	1	2	3	4	5	6	7	OK
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	
		8	9	10	11	12	13	14	
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA		
	Continuous leakage current at normal operating temperature under AC/DC: Shell leakage current under single fault condition ≤ 0.5mA	1	2	3	4	5	6	7	OK
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	
		8	9	10	11	12	13	14	
		0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA		
Continuous leakage current at normal operating temperature under AC/DC: Auxiliary leakage current under single fault state ≤ 0.05mA	1	2	3	4	5	6	7	OK	
	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA		
	8	9	10	11	12	13	14		
	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA	0.001mA			

C
AS
NO.

QC
PASS
NO. 01

Judgment: Pass Default

Inspector/Date: Bai Hoi xia
Jul. 7. 2025

Auditor/Date: Jiang Long
Jul 7. 2025.

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Attached page:

Inspection Item	Inspection requirement	sampling quantity Standard value	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
			Indicating value max error	Precision error requirement: ± 0.1 °C (35.0 ~ 42.0 °C) ± 0.2 °C (<35.0 °C / >42.0 °C)	32.5°C/90.5°F	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.5	32.4	32.5	32.5	32.5	32.5
35°C/95°F	35.0	35.0			35.0	35.0	35.0	35.0	35.0	35.0	34.9	35.0	35.0	35.0	35.0	35.0	35.0	35.0
37°C/98.6°F	37.0	37.0			37.0	37.0	37.0	37.0	37.0	37.0	36.9	37.0	37.0	37.0	37.0	37.0	37.0	37.0
41.5°C/106.7°F	41.5	41.5			41.5	41.5	41.5	41.5	41.5	41.5	41.4	41.5	41.5	41.5	41.5	41.5	41.5	41.5
42.5°C/108.5°F	42.5	42.5			42.5	42.5	42.5	42.5	42.5	42.5	42.4	42.5	42.5	42.5	42.5	42.5	42.5	42.5
32.5°C/90.5°F	32.5	32.5			32.5	32.6	32.6											
35°C/95°F	35.0	35.0			35.0	35.1	35.0											
37°C/98.6°F	37.0	37.0			37.0	37.1	37.0											
41.5°C/106.7°F	41.5	41.5			41.5	41.6	41.5											
42.5°C/108.5°F	42.5	42.5			42.5	42.6	42.5											
32.5°C/90.5°F																		
35°C/95°F																		
37°C/98.6°F																		
41.5°C/106.7°F																		
42.5°C/108.5°F																		
		sampling quantity Standard value		31	32	33	34	35	36	37	38	39	40	41	42	43	44	45
		32.5°C/90.5°F																
		35°C/95°F																
		37°C/98.6°F																
		41.5°C/106.7°F																
		42.5°C/108.5°F																
		sampling quantity Standard value	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	
		32.5°C/90.5°F																
		35°C/95°F																
		37°C/98.6°F																
		41.5°C/106.7°F																
		42.5°C/108.5°F																

IS/1

QC
PASS
NO. 01

Inspector/Date: Bai Hai xia
Jul. 7. 2025

Auditor/Date: Jianglong
Jul. 7. 2025.