

# Inspection Report for Finished Product

No.: 202507713

1. Name of Product: Electrocardiograph
2. Model: E3 (NV-Y010 YECG-3)
3. Executive standard: CMS08.10.524 Ver.:2
4. Batch No.: 250703 (25070300001-25070300012)
5. Quantity (batch): 12
6. Conclusion (batch):  Qualified  Unqualified

Inspector: 武龍博      Date: 2025.07.26  
Reviewer: 周款邦      Date: 2025.07.26  
Approval: 李楠      Date: 2025.07.26

Contec Medical Systems Co., Ltd.

## Factory Inspection Report for E Series Electrocardiograph

Inspection precondition	Environment: Temperature: <u>25</u> °C      Relative humidity: <u>60</u> %RH				
	Inspection equipment: <input checked="" type="checkbox"/> Verification instrument <u>A070</u> <input checked="" type="checkbox"/> Vernier caliper <u>C266</u> <input checked="" type="checkbox"/> Computer <u>DN-02</u> <input type="checkbox"/> Others				
Inspection scheme	4.1 and 4.2 Inspection items: LEVEL S-2, AQL=2.5 GB/T2828.1-2012	Sample quantity n	5	Accept/Reject [Ac Re]	0, 1
	Other inspection items: LEVEL S-2, AQL=1.5 GB/T2828.1-2012	Sample quantity n	8	Accept/Reject [Ac Re]	0, 1
Inspection items	Requirements			Inspection results	Item conclusion
4.1 Packaging and accessories	1) The packaging is not damaged or stained. Text information on the packaging is clear. 2) Accessories (including device accessories and accompanying documents) are intact, and the model and quantity are right. 3) The labeling (including device name and model, etc.) is correct.			meet	compliance
4.2 Appearance and main components	1) Appearance: no scratch, damage, deformation, crack and other defects appear; the surface is smooth, color is uniform, no stain or impurity; the words and labels on the panel are legible; the labels are pasted firmly and smoothly. 2) Main components: the assembling is intact, no visible mechanical deformation or loose, for example, batteries and printing rubber roller are well installed, the paper cabinet cover is well fixed and moved flexibly; the operations of each function button and touchpad are flexible; the junction between front and rear enclosure is tight.			meet	compliance
4.3.1 ON/OFF and charging function	ON/OFF and charging function are normal.			meet	compliance
4.3.2 Button operation	This function is normal.			meet	compliance
4.3.3 Touch function	This function is normal. (Only for E6, E12, E18M)				
4.3.4 Printing function	This function is normal.			meet	compliance
4.3.5 Cable Network	This function is normal. (Only for E12, E18M)				
4.3.6 Wireless network	This function is normal. (Only for E12, E18M)				
4.3.7 4G function	This function is normal. (Optional for E12, E18M)				
4.3.8 USB interface	This function is normal.			meet	compliance
4.4.1 Input dynamic range	The ECG device shall be capable of responding to and displaying differential voltages of $\pm 5$ mV varying at a rate up to 320 mV/s from a dc offset voltage in the range of -300 mV ~ +300 mV, when applied to any lead. The time-varying output signal amplitude shall not change by more than $\pm 5\%$ over the specified range of dc offset.			-0.4%~0	compliance
4.4.2 Sensitivity Control	2.5mm/mV, 5mm/mV, 10mm/mV, 20mm/mV, 40mm/mV, 10/5mm/mV, 20/10 mm/mV, totally seven gears; (Only for E3, E6, E12, E18M)			meet	compliance
	2.5mm/mV, 5mm/mV, 10mm/mV, 20 mm/mV, totally four gears; (Only for E3M)				
	Accuracy: $\pm 5\%$ , Input 1mV signal, Sensitivity is set to 10mm/mV, the amplitude of corresponding output waveform should be 10mm $\pm$ 0.5mm.			0	compliance
4.4.3 Time base selection and accuracy	Range from 0.2 s to 2.0 s, error range: $\pm 5\%$ .	Input a 25Hz, 0.5mV triangular signal; Time base is set to 25mm/s.	The distance of 10 consecutive peaks is 10mm $\pm$ 0.5mm	10.0mm	compliance
			The distance of 20 consecutive peaks is 20mm $\pm$ 1.0mm	20.0mm	compliance
			The distance of 40 consecutive peaks is 40mm $\pm$ 2.0mm	40.0mm	compliance

(see next page)

## Factory Inspection Report for E Series Electrocardiograph

(Continued)

Inspection items	Requirements		Inspection results	Item conclusion	
4.4.3 Time base selection and accuracy	Range from 0.2 s to 2.0 s, error range:±5%.	Input a 25Hz, 0.5mV triangular signal; Time base is set to 50mm/s.	The distance of 10 consecutive peaks is 20mm±1.0mm	20.0mm	compliance
			The distance of 20 consecutive peaks is 40mm±2.0mm	40.0mm	compliance
			The distance of 40 consecutive peaks is 80mm±4.0mm	80.0mm	compliance
4.4.4 Frequency and impulse response	Input 1mV,0.67Hz/40Hz sine signals, its response amplitude should be between + 5% and - 10% of the response amplitude when the frequency is 10Hz.		-2%~0	compliance	
	Input 0.5mV,40Hz/100Hz sine signals, its response amplitude should be between + 5% and - 10% of the response amplitude when the frequency is 10Hz.		-4%~0	compliance	
	Input 0.5mV,150Hz sine signals, its response amplitude should be between + 5% and - 30% of the response amplitude when the frequency is 10Hz. (Only for E3,E6,E12,E18M)		-14%~ -12%	compliance	
	Input 0.5mV,150Hz sine signal, its response amplitude should be between + 10% and - 100% of the response amplitude when the frequency is 10Hz. (Only for E3M)		/	/	
4.4.5 Standardizing voltage	Amplitude of standardizing voltage is within ± 2 % of the amplitude obtained when a 1 mV signal is applied.		0	compliance	
4.4.6 CMRR	CMRR of each lead shall be greater than 123 dB. Namely Sensitivity: 40 mm/mV (20mm/mV for E3M) , amplitude of recording waveform shall not exceed 1.17 mm . (0.77mm for E3M ) (Including basic line width 0.375mm) .		0.4mm~ 0.6mm	compliance	
4.4.7 Noise	When gain is set to 40 mm/mV (20mm/mV for E3M) , the amplitude of the output waveform shall be not more than 0.85 mm (0.6mm for E3M) (Including basic line width 0.375mm) .		0.4mm~ 0.6mm	compliance	
Conclusion and Date		See the first page			
Remark					

In "Inspection result", fill in "meet" or "not meet" for qualitative inspection items and the measured data for quantitative inspection items; Fill in "compliance" or "noncompliance" in the "Item conclusion".