Appendix B Technical Specification

B.1 Specifications

B.1.1 Main Unit

Lead	Standard 12-lead, Nehb
Acquisition Mode	Simultaneous 12-lead
Record Format	Standard leads: 3×4, 3×4+1R, 3×4+3R, 6×2, 6×2+1R, 6×2+3R, 12×1
	Nehb lead: 6×1, 3×2
	VCG: 6×1+3, 3×2+3, 3×2+3+1R, 3×2+3+3R, Frank
Record Mode	Economic, Auto, Manual, Upload, Cycle, Trigger
Lead Format	Standard leads: 3×4, 3×4+1R, 6×2, 6×2+1R, 12×1
	Nehb lead: 6×1, 3×2
	VCG: 3×2+3, 6×1+3, Frank
Long-term Recording	Record for a long term (30 s～300 s) and rhythm analysis
Measurement Parameters	Standard leads: HR, PR interval, QRS duration, QT/QTC interval, P/QRS/T axis, RV5/SV1 voltage and RV5+SV1 voltage
	Nehb lead: HR, PR interval, P duration, T duration, QRS duration, QT/QTC interval, P/QRS/T axis, P amplitude
Filters	AC, low-pass and high-pass filters
CMRR	>89 dB >100 dB (with AC interference filter)
Input CIR current	≤0.1 μA
Patient Leak Current	<10 μA
Time Constant	≥3.2 s
Frequency Response	0.05 Hz～250 Hz

Noise Level	≤15 μV_{p-v}
Sensitivity Threshold	20 μV_{p-v}
Signal Gain	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 40 mm/mV, 10/5 mm/mV, 20/10 mm/mV, Auto Gain (Auto Gain is just for the Automatic mode)
Calibration Voltage	1 mV±5 %
Accuracy of Input Signal Reproduction	Using the method described in 4.2.7.1 of AAMI EC11 to test the overall system error, which is within ±5%; Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response. Because of sampling characteristics and the asynchronism between sample rate and signal rate of the ECG machine, digital systems may produce a noticeable modulating effect from one cycle to the next, particularly in pediatric recordings. This phenomenon, which is not physiologic, shall be clearly described in the operator's and service manuals.
Input Circuit:	Floating circuit input
Input Impedance	≥2.5MΩ (full-band)
Sampling Rate of Signals	8000 Hz

B.1.2 Recorder Specification

Recorder	Thermal Dot Matrix Word Printing System 8 points/mm (perpendicular) 40 points/mm (horizontal, 25 mm/s)
Recording Paper	210mm×140mm-140P (recommended) or 210mm×150mm-140P Z-fold paper
Paper Speed	(5, 6.25, 10, 12.5, 25, 50) mm/s, ±3%

B.1.3 Wireless Network (Optional)

Applicable Standard	IEEE 802.11b/g/n (2.4G)	IEEE 802.11a/n (5G)
Frequency Range	2.412 GHz～2.472 GHz	4.9 GHz～5.975 GHz
Band Width	20~40MHz	20~40MHz
Radiated Power	+18dBm	+13.5dBm
Signal Path	1-13 (China)	
Type and Frequency Characteristics of the Modulation	CCK/DSSS/OFDM/MCS7/MCS0	

B.1.4 Other Specification

Patient Cable	Standard 12-lead cable with defibrillation-proof
Display on LCD	1280×800, 9-inch LCD touch screen, the whole instrument work status, time, heart rate, and with the backlight
Safety Classification	IEC60601-1 Class I　Type CF
AC Power Supply	100 V~240 V, 50 Hz /60 Hz, 110 VA
DC Power Supply	Rechargeable lithium battery, 14.8 V/ 4400mAh. In environment temperature ranging from 20 ℃ to 30 ℃ and with the machine turning off, the charging time is not more than 4 hours to charge the battery to 90%.
	In environment temperature ranging from 20 ℃ to 30 ℃, the continuous working time is not less than 3 hours while the ECG device is continuously printing.

B.2 Environment Requirements

1	**Transportation**	
	Environment Temperature	-20 ℃～+55 ℃
	Relative Humidity	≤95 % (No condensation)
	Air Pressure	70 kPa～106 kPa
	Transportation: avoid direct sunshine and rain.	
2	**Storage**	
	Environment Temperature	-20 ℃～+55 ℃
	Relative Humidity	≤95 % (No condensation)
	Air Pressure	70 kPa～106 kPa
	The packed ECG should be stored in the well-ventilated room without corrosive gases.	
3	**Using**	
	Environment temperature	+5 ℃～+40 ℃
	Relative humidity	≤95 % (No condensation)
	Air pressure	70 kPa～106 kPa