

Appendix B Technical Specification

B.1 Specifications

B.1.1 Main Unit

Lead	Standard 12-lead
Acquisition Mode	Simultaneous 12-lead Acquisition
Sampling rate of signals	8000Hz
Record Mode	Auto
Rhythm Time	30s ~ 300s waveforms acquisition for rhythm analysis
Measurement Parameters	Ventricular Rate, PR Interval, QRS Time Limit, QT/QTc Interval, P/QRS/T Axis, RV5/SV1 Amplitude and RV5+SV1 Amplitude
Filters	AC Filter, Baseline Wander Filter, Low-pass Filter
Input CIR Current	$\leq 0.1 \mu\text{A}$
CMR	$> 110 \text{ dB}$
Polarizing Voltage	$\pm 550\text{mV}$
Patient Leak Current	$< 10 \mu\text{A}$
Time constant	$\geq 3.2 \text{ s}$
Frequency Response	0.01 Hz ~ 250 Hz
Noise Level	$\leq 30 \mu\text{V}_{\text{p-v}}$
Sensitivity Threshold	$20 \mu\text{V}_{\text{p-v}}$
Accuracy of Input Signal	Using the method described in 4.2.7.1 of AAMI EC11 to

Reproduction	<p>test the overall system error, which is within $\pm 5\%$;</p> <p>Using method A and D described in 4.2.7.1 of AAMI EC11 to test frequency response.</p> <p>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.</p>
Time Reference	6.25 mm/s, 12.5mm/s, 25 mm/s, 50 mm/s
Standard Sensitivity	10 mm/mV $\pm 3\%$
Sensitivity	1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10 mm/mV, 20 mm/mV, 10/5 mm/mV, 20/10 mm/mV $\pm 3\%$
Calibration Voltage	1 mV $\pm 3\%$
Input circuit	Floating circuit input

B.1.2 WiFi Network

Compliant Standard	IEEE 802.11b/g/n
Frequency	2.412 GHz~2.472 GHz
Transmission Distance	50m~100m (Barrier-free open area)

B.1.3 Other Specification

Acquisition Module	Standard 12-lead acquisition module with defibrillation-proof
Display on LCD	7-inch LCD Touch screen
Safety Classification	IEC60601-1, Class II, Type CF
AC Power Supply	100 V~240 V, 50 Hz/60 Hz
DC Power Supply	Rechargeable lithium battery, 3.7 V/ 5800mAh. In environment temperature $25\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and with the machine turning off, the charging time is not more than 4 hours to charge the battery to 90%.
	In environment temperature $25\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$, the continuous working time is not less than 5 hours while the ECG device is continuously printing.

B.2 Dimensions and Weight

Length × Width × Height	194 mm×117 mm×25 mm
Weight	About 0.5 kg

B.3 Environment Requirements

1	Transportation	
	Environment Temperature	-20 °C ~+55 °C
	Relative Humidity	≤95 % (No condensation)
	Air Pressure	70 kPa~ 106 kPa
	Transportation: avoid direct sunshine and rain.	
2	Storage	
	Environment Temperature	-20 °C ~+55 °C
	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	0 °C ~+40 °C
	Relative humidity	≤95 % (No condensation)
	Air pressure	70 kPa~ 106 kPa

B.4 Service Life

Service life of this product is 5 years.

B.5 Production Date

As for the production date, see the nameplate of the product or the relevant label on the package.

Appendix C List of Interpretation Codes and Corresponding Description

8 Arrhythmia	
8002	Marked rhythm irregularity
8110	Sinus rhythm
8102	Sinus arrhythmia
8108	Marked sinus arrhythmia
8120	Sinus tachycardia
8130	Sinus bradycardia
8200	Atrial rhythm
8210	Atrial fibrillation
82101	Atrial fibrillation with rapid ventricular response
82102	Atrial fibrillation with slow ventricular response
82103	Atrial fibrillation with aberrant conduction, or ventricular premature complexes
82108	Atrial fibrillation with rapid ventricular response with aberrant conduction, or ventricular premature complexes
82109	Atrial fibrillation with slow ventricular response with ventricular premature complexes
8220	Atrial tachycardia
8250	Atrial flutter
82503	Atrial flutter with aberrant conduction or ventricular premature complexes