

Appendix B Technical Specification

B.1 Specifications

B.1.1 Main Unit

Lead	Standard 12-lead
Acquisition Mode	Simultaneous 12-lead Acquisition
Record Format	1 × 12, 1 × 12+1R (iE 101)
	1 × 12, 1 × 12+1R, 3 × 4, 3 × 4+1R, 3/2 (iE 300)
Record Mode	Auto, Manual, Upload
Display Format	3 × 4, 3 × 4+1R, 6 × 2, 6 × 2+1R, 12 × 1
Rhythm Time	30~300s 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
	EMG Filter
Input CIR Current	≤0.1 μA
Input Impedance	≥30 MΩ (Full-band)
Time Constant	≥3.2 s
Frequency Response	0.05 Hz~250 Hz
Noise Level	≤12.5 μV _{p-p}
Sensitivity Threshold	≤20 μV _{p-p}
Sensitivity	Auto, 0.625 mm/mV, 1.25 mm/mV, 2.5 mm/mV, 5 mm/mV, 10/5 mm/mV, 10 mm/mV, 20/10mm/mV, 20 mm/mV, and 40 mm/mV
Standard Sensitivity	10 mm/mV ±2%
Calibration Voltage	1 mV ±3 %
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.
CMRR	> 115 dB
Patient Leak Current	< 10 μ A
Sampling rate of signals	8000Hz

B.1.2 Recorder Specification

Recorder	Thermal Dot Matrix Word Printing System
Recording Paper	50 mm, roll paper (iE 101) 80 mm, roll paper (iE 300)
Paper Speed	(5, 6.25, 10, 12.5, 25, 50)mm/s \pm 5%

B.1.3 Other Specification

Display on LCD	5-inch TFT LCD screen (iE 101)
	5-inch TFT LCD screen (iE 300)
Safety Classification	IEC60601-1, Class I, Type CF
AC Power Supply	100 V-240V, 50 Hz /60 Hz, 80 VA (iE 101)
	100 V-240V, 50 Hz /60 Hz, 80 VA (iE 300)
DC Power Supply	Rechargeable lithium battery, 11.1 V/ 2600mAh. In environment temperature 25 $^{\circ}$ C \pm 5 $^{\circ}$ C and with the machine turning off, the charging time is not more than 2 hours to charge the battery to 90%.
	In environment temperature 25 $^{\circ}$ C \pm 5 $^{\circ}$ C, 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 °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	+5 °C ~ +40 °C
	Relative humidity	≤95 % (No condensation)
	Air pressure	70 kPa ~ 106 kPa

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