

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

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|------------------------------|-----------------------------------|
| 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

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