Device Specifications

General	
Size (height • width • length)	3 in • 9.24 in • 9.4 in 7.62 cm • 23.47 cm • 23.88 cm
Weight	5.19 lb. (2.35 kg) without battery pack 5.97 lb. (2.70 kg) with nonrechargeable battery pack
Power	Battery pack
Device classification	Class II and internally powered per EN 60601-1
Design standards	Meets applicable requirements of UL 2601, AAMI DF80, IEC 60601-2-4, EN 60601-1, IEC 60601-1-2
Patient safety	All patient connections are electrically isolated.
Environmental	
Temperature	Operating: 0°C to 50°C Storage and shipping: –30°C to 70°C
Humidity	10% to 95% relative humidity, noncondensing
Vibration	MIL-STD-810F, Integrity Test for Helicopters
Shock	IEC 60068-2-27; 100G
Altitude	Height: –300 to 15,000 ft; –91 to 4573 m Pressure: 768 to 429 mmHg; 1024 to 572 millibars
Particle and water ingress	IEC 60529, IP 55
Drop test	1.5 m per IEC 68-2-32
Defibrillator	
Waveform	ZOLL rectilinear biphasic waveform
Energy selection	Configurable preset energy levels for adult and pediatric patients in three-shock stacks.
Charge time	Less than 10 seconds with a new, fully charged battery; with depleted battery packs, the charge time will be longer. For the fifteenth discharge at maximum energy (200 joules), the charge time is less than 10 seconds.
Charge hold time	Semiautomatic mode: 30 seconds Manual mode: 60 seconds
Energy display	Display screen shows selected energy level (manual mode only).
Charge controls	Semiautomatic mode: Automated Manual mode: Softkey

Defibrillation electrode pads	ZOLL single-use, pregelled electrode pads: • *CPR-D•padz* (includes CPR sensor) • Adult *stat•padz* II • Pediatric *pedi•padz* II
Built-in defibrillator self-test	Verifies proper charging and discharging of the defibrillator.
Defibrillation advisory	Evaluates electrode attachment and patient ECG to determine if defibrillation is needed. Shockable arrhythmia: • Ventricular fibrillation (VF) with amplitude greater than 100 μV • Wide-complex ventricular tachycardia (VT) Adult: greater than 150 beats per minute Pediatric: greater than 200 beats per minute
Valid patient impedance range	10Ω to 300Ω
CPR Monitoring	
Compression depth	0.75 to 3 inches ±0.25 inches 1.9 to 7.6 cm ±0.6 cm
Compression rate	50 to 150 compressions per minute
ECG Monitoring	
Input protection	Fully defibrillation-protected.
Bandwidth	1.4 to 22 Hz with defibrillation electrode cable 1.4 to 22 Hz (default) with AED Pro ECG cable; 0.7 to 30 Hz as a configurable option
ECG lead	Lead II
ECG amplitude range	±5 mV
Heart rate range	30 to 300 beats per minute
Heart rate accuracy	±5 beats per minute
Heart rate resolution	1 beat per minute
Heart rate alert	• Configurable low heart rate limit in the range 30 to 100 beats per minute • Off
Data Recording and Storage	
Type	Nonvolatile memory
Capacity	7 hours of ECG data

Display Screen	
Display type	Liquid crystal display (LCD) High resolution, 320 pixels by 240 pixels
Viewable area (height • width)	2.27 in • 3.02 in 5.76 cm • 7.68 cm
Sweep speed	25 mm/s ±5%
Viewing time	2.96 seconds (if CPR gauge displayed) 3.2 seconds (without CPR gauge)

Battery Pack Specifications

	Sealed lead acid
Type	Rechargeable sealed lead acid
Weight	1 kg 2.2 lb.
Nominal voltage	10 V
Recharge time	4 hours or less with: ZOLL Base PowerCharger 4x4 ZOLL Base PowerCharger 1x1
Operating time	For a new, fully charged battery pack at 20°C: 170 defibrillator discharges at maximum energy (200 joules) or 6 hours of continuous ECG monitoring. The *CHANGE BATTERY* warning appears after 115 maximum-energy discharges.
Standby life	3 months before recharge or retest

Guidance and Manufacturer's Declaration — Electromagnetic Emissions

The ZOLL AED Pro device is intended for use in the electromagnetic environment specified below. The customer or operator should ensure that the device is used in such an environment.

Table A-1. EMC Specifications

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The ZOLL AED Pro unit uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emission IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Not applicable	
Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.		

Electromagnetic Immunity Declaration (EID)

The ZOLL AED Pro device is intended for use in the electromagnetic environment specified below. The customer or operator should ensure that the device is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable ±1 kV I/O	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV for common mode	Not applicable Not applicable	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% *U*t (>95% dip in *U*t) for 0.5 cycle 40% *U*t (60% dip in *U*t) for 5 cycles 70% *U*t (30% dip in *U*t) for 25 cycles <5% *U*t (>95% dip in *U*t) for 5 seconds **Note**: *U*t is the ac mains voltage prior to application of the test level.	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AED Pro device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands[a]	3 Vrms 10 Vrms	Recommended separation distance (*d*) in meters[b]: $d = 1.17\sqrt{P}$ outside ISM bands $d = 1.20\sqrt{P}$ within ISM bands
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.20\sqrt{P}$ 80 MHz to 800 MHz $d = 2.30\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Notes (1) At 80 MHz and 800 MHz, the higher frequency range applies. (2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

a. The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile or portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c. Field strengths from fixed transmitters, such as base stations for radio (cellular or cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED Pro unit is used exceeds the applicable RF compliance level above, the AED Pro unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AED Pro unit.

d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the AED Pro unit

The AED Pro unit is intended for use in an environment in which radiated RF disturbances are controlled. The customer or operator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED Pro unit as recommended below, according to the maximum output power of the communications equipment.

	Separation distance in meters (m) according to frequency of transmitter			
Rated maximum output power of transmitter in watts (W)	150 kHz to 80 MHz outside ISM bands $d = [\frac{3.5}{3}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{10}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{10}]\sqrt{P}$	800 MHz to 2.5 GHz $d = [\frac{23}{10}]\sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.17	1.20	1.20	2.3
10	3.69	3.79	3.79	7.27
100	11.70	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

Notes

(1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

(2) The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

(3) An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile or portable communications equipment could cause interference if it is inadvertently brought into patient areas.

(4) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Rectilinear Biphasic Waveform Characteristics

The following table shows the characteristics of the rectilinear biphasic waveform when discharged into 25 ohm, 50 ohm, 100 ohm, and 125 ohm loads at the maximum energy setting of 200 joules.

Table A-2. Rectilinear Biphasic Waveform Characteristics

	200 J discharged into			
	25Ω	**50Ω**	**100Ω**	**125Ω**
First phase				
Maximum initial current	32 A	26 A	21 A	17 A
Average current	28 A	22 A	16 A	13 A
Duration	6 ms	6 ms	6 ms	6 ms
Interphase duration (between first and second phases)	200 μs	200 μs	200 μs	200 μs
Second phase				
Initial current	33 A	19 A	12 A	11 A
Average current	21 A	14 A	11 A	10 A
Duration	4 ms	4 ms	4 ms	4 ms

Table A-3. Delivered Energy at Each Defibrillator Setting into a Range of Loads

	Selected Energy					
Load	**50 J**	**70 J**	**85 J**	**120 J**	**150 J**	**200 J**
25Ω	40 J	61 J	66 J	95 J	111 J	146 J
50Ω	51 J	80 J	85 J	124 J	144 J	183 J
75Ω	64 J	89 J	111 J	148 J	172 J	204 J
100Ω	62 J	86 J	108 J	147 J	171 J	201 J
125Ω	63 J	89 J	110 J	137 J	160 J	184 J
150Ω	67 J	93 J	116 J	127 J	148 J	168 J
175Ω	61 J	86 J	107 J	119 J	138 J	155 J
Accuracy	±15%	±15%	±15%	±15%	±15%	±15%

The AED Pro rectilinear biphasic waveform employs the same first and second phase timing, similar first and second phase currents/voltages, and essentially the same mechanisms for controlling defibrillation waveshape as the ZOLL M Series. The ZOLL M Series and AED Pro defibrillation waveforms are considered substantially equivalent.

Figures A-1 through A-6 show the rectilinear biphasic waveforms that are produced when the AED Pro defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting (200, 150, 120, 85, 70, and 50 joules).

The vertical axis shows the current in amperes (A); the horizontal axis shows the duration in milliseconds (ms).

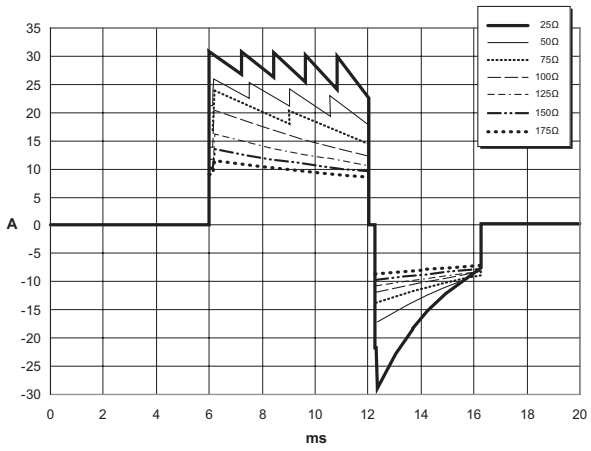

Figure A-1. Rectilinear Biphasic Waveforms at 200 Joules

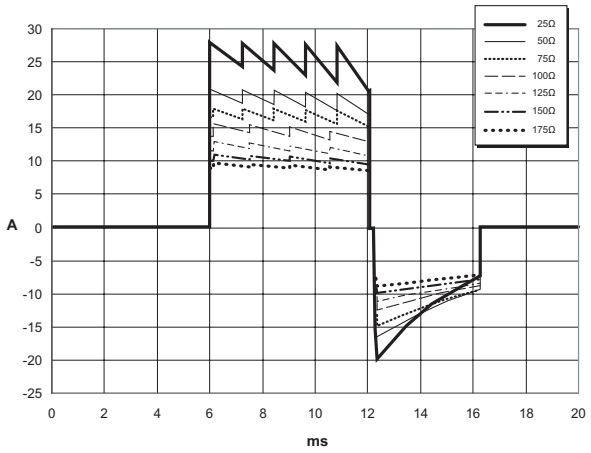

Figure A-2. Rectilinear Biphasic Waveforms at 150 Joules

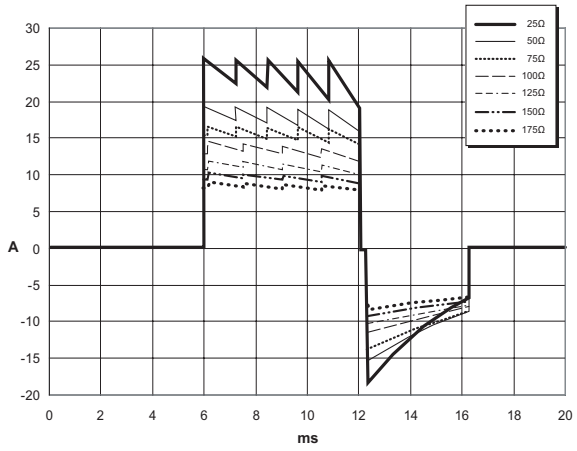

Figure A-3. Rectilinear Biphasic Waveforms at 120 Joules

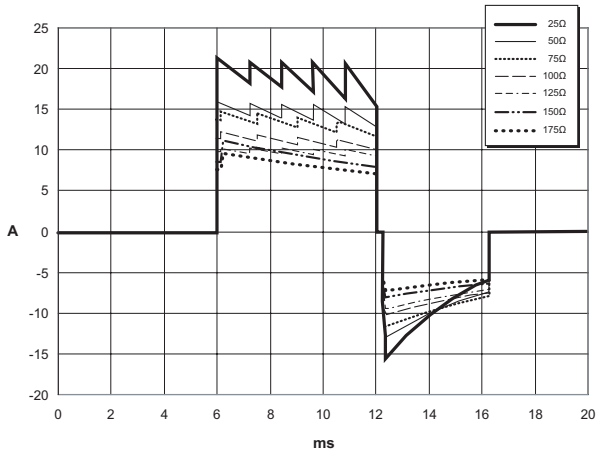

Figure A-4. Rectilinear Biphasic Waveforms at 85 Joules

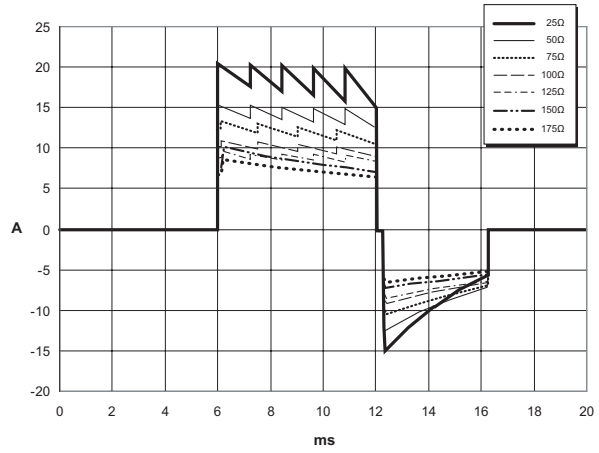

Figure A-5. Rectilinear Biphasic Waveforms at 70 Joules

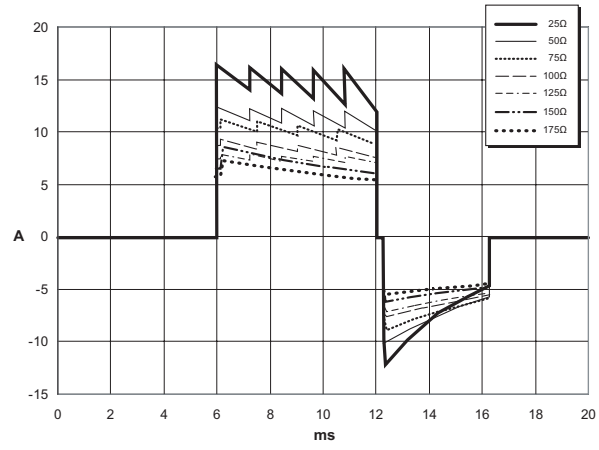

Figure A-6. Rectilinear Biphasic Waveforms at 50 Joules

Clinical Trial Results for the M Series Biphasic Waveform

The efficacy of the ZOLL rectilinear biphasic waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). A feasibility study was performed initially for defibrillation of VF/VT (n=20) on two separate groups of patients to ensure waveform safety and energy selection. Subsequently, a separate, multicenter, randomized clinical trial was performed to verify the waveform's efficacy. A description of this study is provided below. The study was performed using ZOLL defibrillation systems consisting of ZOLL defibrillators, the ZOLL rectilinear biphasic waveform, and ZOLL defibrillation pads.

Randomized Multicenter Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of the ZOLL rectilinear biphasic waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multicenter study of patients undergoing ventricular defibrillation for VF/VT during electrophysiological studies, ICD implants, and test. A total of 194 patients were enrolled in the study. Ten patients who did not satisfy all protocol criteria were excluded from the analysis, leaving a study population of 184.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120 J rectilinear biphasic waveform with a 200 J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, and 170 joules) efficacy of the rectilinear biphasic waveform with that of a monophasic waveform (three consecutive 200, 300, and 360 joules). A significance level of p=0.05 or less was considered statistically significant using Fischer's Exact test. Also, differences between the two waveforms were considered statistically significant when the customary 95% or AHA-recommended 90%[1] confidence interval between the two waveforms was greater than 0%.

Results: The study population of 184 patients had a mean age of 63±14 years. Of these, 143 patients were male. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80; ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76; ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120 J was 99% versus 93% for monophasic shocks at 200 J (p=0.0517, 95% confidence interval of the difference of –2.7% to 16.5% and 90% confidence interval of the difference of –1.01% to 15.3%).

	Monophasic	Biphasic
First shock efficacy	93%	99%
p-value	0.0517	
95% confidence interval	–2.7% to 16.5%	
90% confidence interval	–1.01% to 15.3%	

1. Kerber RE, et al., "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circ J Am Heart Assoc.* 1997;95:1677-1682.

"… the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be <0% (ie, alternative is greater than standard)."

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14±1 amperes versus 33±7 amperes, p=0.0001).

The difference in efficacy between the rectilinear biphasic and the monophasic shocks was greater in patients with high transthoracic impedance (greater than 90 ohms). The first shock, first induction efficacy of biphasic shocks was 100% versus 63% for monophasic shocks for patients with high impedance (p=0.02, 95% confidence interval of the difference of –0.0217% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

	Monophasic	**Biphasic**
First shock efficacy (high impedance patients)	63%	100%
p-value	0.02	
95% confidence interval	–0.0217% to 0.759%	
90% confidence interval	0.037% to 0.706%	

A single patient required a second biphasic shock at 150 joules to achieve 100% efficacy versus six patients for whom monophasic shocks of up to 360 joules were required for 100% total defibrillation efficacy.

Conclusion: The data demonstrate the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of rectilinear biphasic waveform.

ECG Analysis Algorithm Accuracy

Sensitivity and specificity are expressions of ECG analysis algorithm performance when compared to ECG interpretation by a clinician or expert. Sensitivity refers to the algorithm's ability to correctly identify shockable rhythms (as a percentage of the total number of shockable rhythms). Specificity refers to the algorithm's ability to correctly identify nonshockable rhythms (as a percentage of the total number of nonshockable rhythms).

The data in Table A-4 and Table A-5 summarize the accuracy of the ECG analysis algorithm as tested against the ZOLL ECG rhythm database.

The algorithm sequence takes approximately 9 seconds and proceeds as follows:

- Divides the ECG rhythm into 3-second segments.
- Filters and measures noise, artifact, and baseline wander.
- Measures baseline content ("waviness" at the correct frequencies – frequency domain analysis) of signal.
- Measures QRS rate, width, and variability.
- Measures amplitude and temporal regularity (autocorrelation) of peaks and troughs.
- Determines if multiple 3-second segments are shockable and then prompts the operator to treat the patient.

Table A-4. Clinical Performance Results (Adult Patients)

Rhythms	Sample Size	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable	**466**	**Sensitivity**		
Coarse VF	403	>90%	96.28%	94.33%
Rapid VT	63	>75%	100.0%	95.36%
Nonshockable	**2305**	**Specificity**		
NSR	1659	>99%	100.0%	99.82%
AF, SB, SVT, heart block, idioventricular, PVCs	604	>95%	100.0%	99.51%
Asystole	42	>95%	100.0%	93.12%
Intermediate	**68**			
Fine VF	50	Report only	92.00%	82.62%
Other VT	18	Report only	88.89%	68.97%

Table A-5. Clinical Performance Results (Pediatric Patients)

Rhythms	Sample Size (9 second records)	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable (49 patients)		**Sensitivity**		
Coarse VF	42	>90%	100% (42/42)	93.1%
Rapid VT	82	>75%	93.9% (77/82)	87.6%
Nonshockable (155 patients)		**Specificity**		
NSR	208	>99%	100% (208/208)	98.6%
AF, SB, SVT[a], heart block, idioventricular, PVCs	348	>95%	99.4% (346/348)	98.2%
Asystole	29	>95%	100% (29/29)	90.2%
Intermediate (16 patients)				
Fine VF	0	Report only	—	—
Other VT	40	Report only	90% (36/40)	78.6%

a. 161 of the 348 abnormal rhythm records were SVT (72 patients). The SVT heart rates ranged from 152 to 302 beats per minute.

Arrhythmia performance is reported according to the article, Kerber RE, Becker LB, Bourland JD, Cummins RO, Hallstrom AP, Michos MB, Nichol G, Ornato JP, Thies WH, White RD, Zuckerman BD. "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circ J Am Heart Assoc.* 1997;95:1677-1682.

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