Appendix A: Specifications

Table 7: General Specifications

DEVICE	
Size (H x W x D)	5.25" x 9.50" x 11.50"; 13.3 cm x 24. 1 cm x 29.2 cm
Weight	6.7 lbs.; 3.1 kg
Power	User Replaceable Batteries. 10 Type 123A Photo Flash lithium manganese dioxide batteries
Device Classification	Class II and internally powered per EN60601-1
Design Standards	Meets applicable requirements of UL 60601-1,IEC 60601-2-4: 2010 (Third Edition) for use in conjunction with IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012
ENVIRONMENT	
Operating Temperature	PS Model: 32° to 122° F; 0° to 50° C
Storage Temperature	PS Model: -22° to 158° F; -30° to 70° C
Humidity	10 to 95% relative humidity, non-condensing
Vibration	MIL Std. 810F, Min Helicopter Test
Shock	PS Model: IEC 68-2-27; 100G
Altitude	PS Model: -300 to 15,000 ft.; -91m to 4573m
Aircraft	Method RTCA/DO-160G: 2010 Section 20, Category R – all operating modes Section 21, Category M – all operating modes
Particle and Water Ingress	IP-55
DEFIBRILLATOR	
Waveform	Rectilinear Biphasic™
Defibrillator Charge Hold Time	30 seconds
Energy Selection	Automatic pre-programmed selection (Adult mode: 120J, 150J, 200J; Pediatric mode: 50J, 70J, 85J)
Patient Safety	All patient connections are electrically isolated.
Charge Time	Less than 10 seconds with new batteries.
Maximum time from first rhythm analysis to unit charged and ready to shock	With new batteries: 12 seconds With batteries depleted by 15 200J discharges: 13 seconds

DEFIBRILLATOR (cont'd)	
Maximum time from power on to unit charged and ready to shock at 200J	22.6 seconds
Electrodes	ZOLL Stat-padz II, CPR-D-padz or Pedi-padz II
Built in Defibrillator Self Test	Included
CPR	*Metronome Rate: Variable 60 to 100 CPM Depth: ¾" to 3"; 1.9 to 7.6 cm
Defibrillation Advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required. Shockable Rhythms: Ventricular fibrillation with average amplitude>100 microvolts and wide complex ventricular tachycardia with rates greater than 150 BPM (adult mode) and 200 BPM (pediatric mode). Refer to ECG Analysis Algorithm Accuracy Section for sensitivity and specificity performance.
Electrode Patient Impedance Measurement Range	0 to 300 ohms
Defibrillator Electrode ECG Circuitry	Protected
ECG Bandwidth	2-30Hz
Display Format	Optional LCD with Moving Bar Size: 2.6" x 1.3"; 6.6 cm x 3.3 cm Viewing Time: 2.6 seconds
Display Sweep Speed	25 mm/sec
Battery Capacity	Typical new battery at +20° C (68° F): • 5 year stand-by life with batteries installed (weekly self-test), or • 225 ±5 continuous defibrillator discharges at maximum energy (200 joules); or • 13 hours of continuous monitoring (with 2-minute CPR periods). End of life designated by Red X (typical remaining shocks = 9).

*Testing reports validating performance and accuracy of CPR depth measurement capability, adaptive metronome feature function and rescuer performance, and the PASS (Passive Airway Support System) cover function are on file with ZOLL Medical Corporation and are available for review. Contact ZOLL Technical Support to request a copy of the following report(s) if desired:

- Using the AED Plus Cover to Aid in Airway Patency
- Depth and Compression Rate Response of Real CPR Help
- AED Plus Real CPR Help Test Results.

DEFIBRILLATOR (cont'd)	
PC Minimum Requirements	Windows® 98, Windows® 2000 Windows®NT, Windows® XP IBM-compatible PII with 16550 UART (or higher) computer 64MB RAM. VGA monitor or better IrDA™ port 20MB disk space
DATA RECORDING AND STORAGE	
Type	Nonvolatile memory
Capacity	7 hours of ECG and CPR data If audio recording option is installed and enabled: 20 minutes of audio recording, ECG, and CPR data

Guidance and Manufacturer's Declaration - Electromagnetic Compatibility

Table 8: EMC Specifications

The AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The AED Plus uses RF energy only for its internal function. 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 Voltage Fluctuations/Flicker Emission IEC 61000 3-3	Not applicable	The ZOLL AED Plus is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings for domestic purposes.
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.		

The AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The relative humidity should be at least 5%.
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 common mode	Not applicable Not applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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 sec	Not applicable Not applicable Not applicable Not applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

The AED Plus is intended for use in the electromagnetic environment specified below. Operation outside of this environment could result in the misinterpretation of the ECG rhythms or CPR signals, interference to the display or audio messages, or the inability to provide defibrillation therapy.

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 Plus, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance
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]	N/A N/A	The AED Plus is battery powered and has no cables longer than 1 meter in length.

Immunity test (cont'd)	IEC 60601 test level (cont'd)	Compliance level (cont'd)	Electromagnetic environment - guidance (cont'd)
			Recommended separation distance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.7 GHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m).[b] 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: 

NOTE 1 At 80 MHz, the higher frequency range applies.
NOTE 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 2.7 GHz are intended to decrease the likelihood that mobile/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/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 Plus is used exceeds the applicable RF compliance level above, the AED Plus should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the AED Plus.

[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 Plus

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

	Separation distance according to frequency of transmitter m			
Rated maximum output power of transmitter W	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800MHz to 2.7 GHz $d = 2.3\sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.7	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) 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 (W) according to the transmitter manufacturer.

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

NOTE 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.

NOTE 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 2.7 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 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 Rectilinear Biphasic waveform's characteristics when discharged into 25 ohm, 50 ohm, 100 ohm, and 125 ohm loads at a maximum energy setting of 200 joules.

Table 9: Biphasic Waveform

	Discharged into 25 ohm load	**Discharged into 50 ohm load**	**Discharged into 100 ohm load**	**Discharged into 125 ohm load**
First Phase Maximum Initial Current	32 A	26 A	21 A	17 A
First Phase Average Current	28 A	22A	16 A	13 A
First Phase Duration	6 ms	6 ms	6 ms	6 ms
Interphase duration between first and second phases	150 µsec	150 µsec	150 µsec	150 µsec
Second Phase Maximum Initial Current	33 A	19 A	12 A	11 A
Second Phase Average Current	21 A	14 A	11 A	10 A
Second Phase Duration	4 ms	4 ms	4 ms	4 ms

Table 10: Delivered Energy at Each Defibrillator Setting into a Range of Loads

Load	**Selected Energy**					
	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 efficacy of ZOLL's Rectilinear Biphasic Waveform has been clinically verified during a Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT) defibrillation study. This study (which was conducted using ZOLL M Series defibrillators) and the findings are described below. Since the AED Plus's 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, the M Series® and AED Plus defibrillation waveforms are considered substantially equivalent.

Figures 9 through 14 show the Rectilinear Biphasic waveforms that the AED Plus defibrillator produces when it discharges 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).

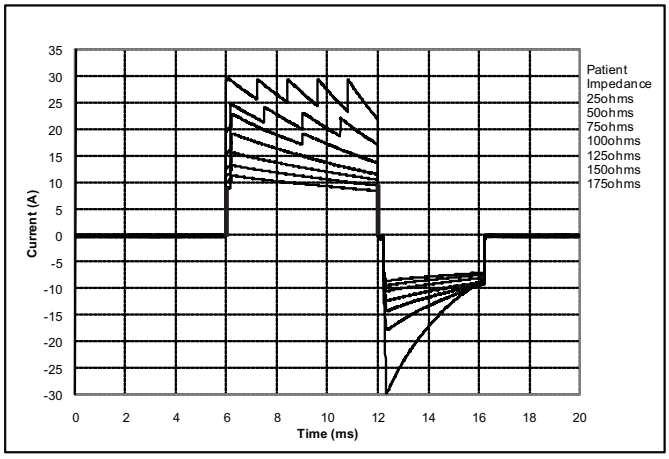

Figure 9: Rectilinear Biphasic Waveforms at 200 joules

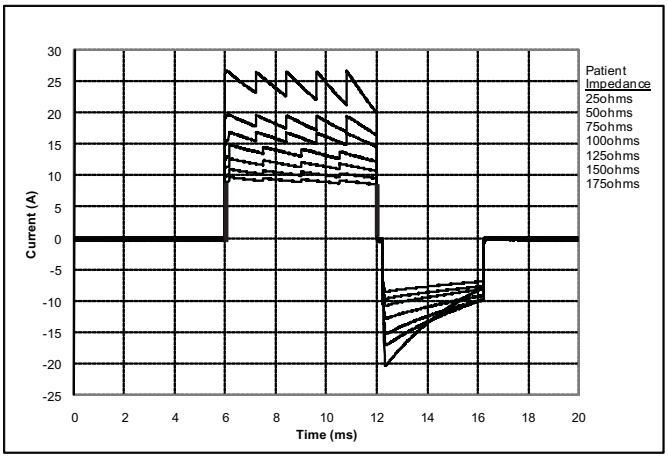

Figure 10: Rectilinear Biphasic Waveforms at 150 joules

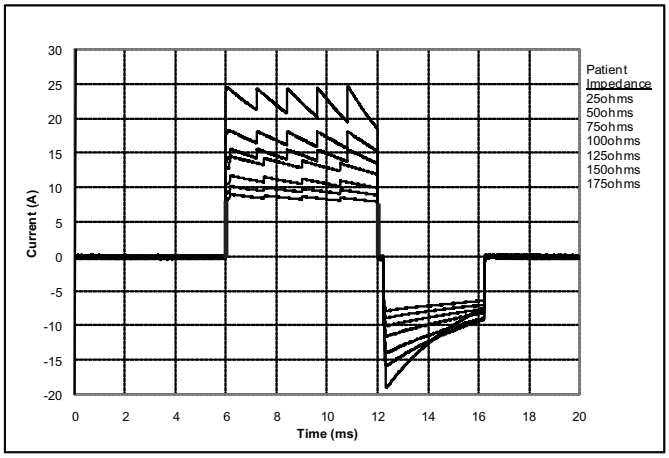

Figure 11: Rectilinear Biphasic Waveforms at 120 joules

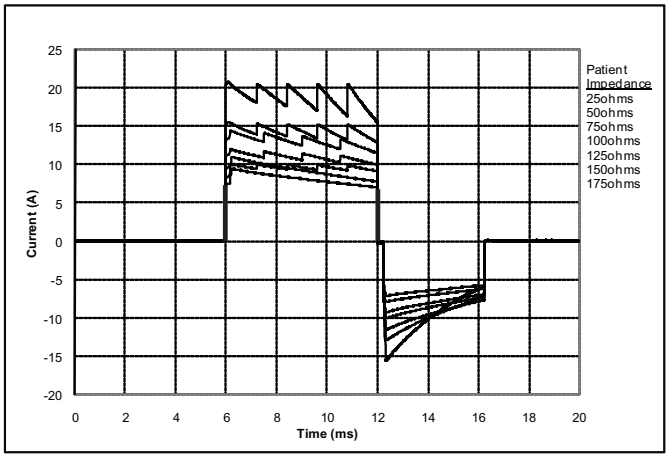

Figure 12: Rectilinear Biphasic Waveforms at 85 joules

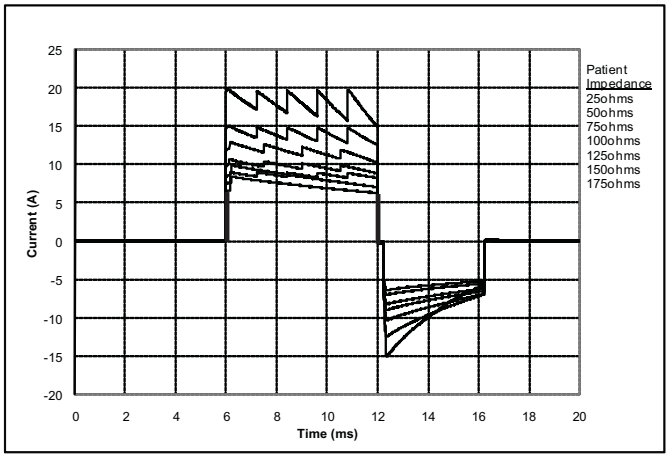

Figure 13: Rectilinear Biphasic Waveforms at 70 joules

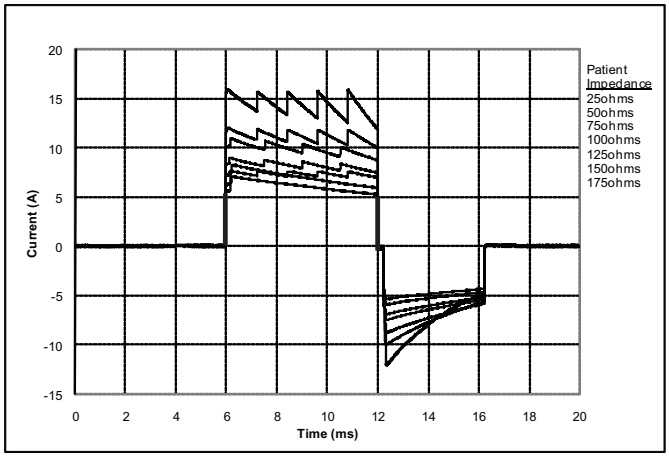

Figure 14: Rectilinear Biphasic Waveforms at 50 joules

Clinical Trial Results for the M Series Biphasic Waveform

The efficacy of ZOLL's Rectilinear Biphasic Waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF)/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, multi-center, 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 Multi-Function Pads.

Randomized Multi-Center Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multi-center study of patients undergoing ventricular defibrillation for VF/VT during electro-physiological studies, ICD implants and test. A total of 194 patients were enrolled in the study. 10 patients who did not satisfy all protocol criteria were excluded from the analysis.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120J Rectilinear Biphasic Waveform with a 200J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, 170J) efficacy of the Rectilinear Biphasic Waveform with that of a monophasic waveform (three consecutive 200, 300, 360J). 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%* 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. 143 patients were males. There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120J was 99% versus 93% for monophasic shocks at 200J (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%).

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14 ±1 vs. 33 ±7 A, 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 -0.021% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

A single patient required a second biphasic shock at 150J to achieve 100% efficacy versus six patients for whom monophasic shocks of up to 360J 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 the rectilinear biphasic waveform.

* Kerber, R., et. al., AHA Scientific Statement, Circulation, 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% (i.e., alternative is greater than standard)."

Pre-Clinical Study

To support pediatric usage for the ZOLL Rectilinear Bi-Phasic Waveform, ZOLL submitted pre-clinical data to the FDA as part of a 510(k) submission for its AED Plus device (cleared by the FDA under K033474). The protocol for this pre-clinical study, along with a summary of the results, have been submitted to FDA under AED Plus PMA application (P160015). A summary of this study is presented below.

To demonstrate the safety and efficacy of our Rectilinear Bi-Phasic Waveform when used to treat pediatric VF patients, ZOLL conducted a study using a porcine model of pediatric patients less than 8 years of age. This study included 18 piglets in three (3) size groups (two (2) animals weighing 4 kg, eight (8) animals weighing 8 kg, and eight (8) animals weighing 16 kg) and compared the defibrillation dose/response curves observed using proposed biphasic waveform with those observed using a standard monophasic damped sine wave (DSW) defibrillator to treat short duration (~ 30 seconds) ventricular fibrillation. The study demonstrated that the biphasic waveform defibrillates pediatric pigs with equal efficacy but lower energy (on a Joules/kg basis) than traditional monophasic damped sine wave defibrillators. To confirm the safety of the proposed biphasic waveform in pediatric patients, we studied and compared measures of cardiac function before and after both DSW and Rectilinear Bi-Phasic Waveform defibrillation shocks over a range of relevant energies. The study demonstrated that the biphasic defibrillation produced equivalent or milder disturbances of cardiac function when compared to traditional DSW defibrillation at the same energies.

Another animal study compared the ZOLL rectilinear biphasic (RLB) waveform to a biphasic truncated exponential (BTE) waveform. The study, using an immature porcine model (n=21), was a prospective, randomized, controlled design to determine the dose response curves for the RLB and BTE defibrillation waveforms. A weight range from 4 to 24 Kg for an animal represented a pediatric patient. The weight ranging from 4 to 8 Kg represented a patient less than 1 year old (infant subgroup), and the weight range from 16 to 24 Kg represented a pediatric patient between the ages of 2 and 8 years (young children subgroup).

The ZOLL RLB waveform demonstrated a superior capability to defibrillate a porcine pediatric model with < 90% of the D50 energy required for a BTE waveform (D50 energy: RLB 25.6 ± 15.7 J, BTE 28.6 ±17.0 J, P ? 0.0232; D90 energy: RLB 32.6 ± 19.1 J, BTE 37.8 ± 23.2 J, P ? 0.0228).

The ECG ST segment changes (mV) and LV pressure changes (dP/dt) following a defibrillation shock were compared between the RLB waveform to the BTE waveform. The RLB waveform had an average ST segment increase above baseline of 0.138 ± 0.136 mV (N=401 shocks) compared to the BTE waveform's average increase of 0.146 ± 0.148 mV (N=396 shocks). The RLB waveform had an average dP/dt at the 40 mmHg threshold (the point in time when an animal's blood pressure exceeded 40 mmHg spontaneously) of 1987 ± 411 mmHg/s (N=496 shocks) compared to the BTE waveform's average dP/dt of 2034 ± 425 mmHg/s (N=496 shocks).

Published Clinical Data

Additional clinical data was included with PMA application P160015 to support out-of-hospital use of ZOLL's Rectilinear Bi-Phasic defibrillation waveform. The data reported by Hess et al in Resuscitation (82 (2011) 685–689) is considered sufficient to support ZOLL's defibrillation waveform in the out-of-hospital environment. The resulting clinical paper, "Performance of a rectilinear biphasic waveform in defibrillation of presenting and recurrent ventricular fibrillation: A prospective multicenter study," was included with PMA application P160015. A summary of the study is presented below:

Objectives: The study tested the hypothesis that shock success differs with initial and recurrent episodes of ventricular fibrillation (VF).

Methods: From September 2008 to March 2010 out-of-hospital cardiac arrest patients with VF as the initial rhythm at 9 study sites were defibrillated by paramedics using a rectilinear biphasic waveform. Shock success was defined as termination of VF within 5 s post-shock. The study used generalized estimating equation (GEE) analysis to assess the association between shock type (initial versus defibrillation) and shock success.

Results: Ninety-four patients presented in VF. Mean age was 65.4 years, 78.7% were male, and 80.9% were bystander-witnessed. VF recurred in 75 (79.8%). There were 338 shocks delivered for initial (n = 90) or recurrent (n = 248) VF available for analysis. Initial shocks terminated VF in 79/90 (87.8%) and subsequent shocks in 209/248 (84.3%). GEE odds ratio (OR) for shock type was 1.37 (95% CI 0.68–2.74). After adjusting for potential confounders, the OR for shock type remained insignificant (1.33, 95% CI 0.60–2.53). The study observed no significant difference in ROSC (54.7% versus 52.6%, absolute difference 2.1%, p = 0.87) or neurologically intact survival to hospital discharge (21.9% versus 33.3%, absolute difference 11.4%, p = 0.31) between those with and without VF recurrence.

Conclusions: Presenting VF was terminated with one shock in 87.8% of cases. The study observed no significant difference in the frequency of shock success between initial versus recurrent VF. VF recurred in the majority of patients and did not adversely affect shock success, ROSC, or survival.

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 non-shockable rhythms (as a percentage of the total number of non-shockable rhythms). The data in Table 11 and Table 12 summarizes the accuracy of the ECG analysis algorithm as tested against ZOLL's ECG Rhythm Database.

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

- Divides the ECG rhythm into three-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 ("auto-correlation") of peaks and troughs.
- Determines if multiple 3 second segments are shockable then prompts the user to treat patient.
- Stops analyzing the ECG after detecting a shockable rhythm and theAED Plus unit is charged and ready to deliver a shock.

Table 11: Clinical Performance Results (Adult Patients)

Rhythms	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Performance (%)**	**90% One-sided Low Confidence Limit (%)**
Coarse VF	536	536	0	100	99.44
Rapid VT	80	79	1	98.75	99.21
NSR	2210	2209	1	99.95	99.79
AF, SB, SVT, Heart block, idioventricular, PVCs	819	819	0	100	99.63
Asystole	115	115	0	100	97.43
Fine VF	69	85	4	94.20	87.22
Other VT	28	28	0	100	89.85
		No Shock Advised	**Shock Advised**		
Overall Performance	**Non Shockable**	3171	1		
	Shockable	5	680		

Table 12: Clinical Performance Results (Pediatric Patients)

Rhythms	**Total Segments**	**Correctly Analyzed**	**Incorrectly Analyzed**	**Observed Performance (%)**	**90% One-sided Low Confidence Limit (%)**
Coarse VF	49	42	0	100	93.12
Rapid VT	79	79	0	100	96.28
NSR	208	208	0	100	98.57
AF, SB, SVT, Heart block, idioventricular, PVCs	348	346	2	99.43	98.20
Asystole	29	29	0	100	90.19
Fine VF	0	0	0	N/A	N/A
Other VT	44	36	8	81.82	89.58
		No Shock Advised	**Shock Advised**		
Overall Performance	**Non Shockable**	619	10		
	Shockable	0	121		

1. Arrhythmia Performance is reported according to the article, RE Kerber, LB Becker, JD Bourland, RO Cummins, AP Hallstrom, MB Michos, G Nichol, JP Ornato, WH Thies, RD White, BD Zuckerman, “Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporation New Waveforms, and Enhancing Safety”, Circulation 1997, Vol 95, No 6, 1677-1681

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“CRC Standard Mathematical Tables 28th Edition”, William H. Beyer, Ph.D., CRC Press, Inc, Boca Raton, FL., 1981, Percentage Points, F-Distribution Table, pg 573.