Алматы (7273)495-231
Ангарск (3955)60-70-56
Архангельск (8182)63-90-72
Астрахань (8512)99-46-04
Барнаул (3852)73-04-60
Белгород (4722)40-23-64
Благовещенск (4162)22-76-07
Брянск (4832)59-03-52
Владивосток (423)249-28-31
Владикавказ (8672)28-90-48
Владимир (4922)49-43-18
Волгоград (844)278-03-48
Вологда (8172)26-41-59
Воронеж (473)204-51-73
Екатеринбург (343)384-55-89
Иваново (4932)77-34-06
Ижевск (3412)26-03-58
Иркутск (395)279-98-46
Казань (843)206-01-48
Калининград (4012)72-03-81
Калуга (4842)92-23-67
Кемерово (3842)65-04-62
Киров (8332)68-02-04
Коломна (4966)23-41-49
Кострома (4942)77-07-48
Краснодар (861)203-40-90
Красноярск (391)204-63-61
Курск (4712)77-13-04
Курган (3522)50-90-47
Липецк (4742)52-20-81
Магнитогорск (3519)55-03-13
Москва (495)268-04-70
Мурманск (8152)59-64-93
Набережные Челны (8552)20-53-41
Нижний Новгород (831)429-08-12
Новокузнецк (3843)20-46-81
Ноябрьск (3496)41-32-12
Новосибирск (383)227-86-73
Омск (3812)21-46-40
Орел (4862)44-53-42
Оренбург (3532)37-68-04
Пенза (8412)22-31-16
Петрозаводск (8142)55-98-37
Псков (8112)59-10-37
Пермь (342)205-81-47
Ростов-на-Дону (863)308-18-15
Рязань (4912)46-61-64
Самара (846)206-03-16
Саранск (8342)22-96-24
Санкт-Петербург (812)309-46-40
Саратов (845)249-38-78
Севастополь (8692)22-31-93
Симферополь (3652)67-13-56
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Тольятти (8482)63-91-07
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Тула (4872)33-79-87
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Череповец (8202)49-02-64
Чита (3022)38-34-83
Якутск (4112)23-90-97
Ярославль (4852)69-52-93

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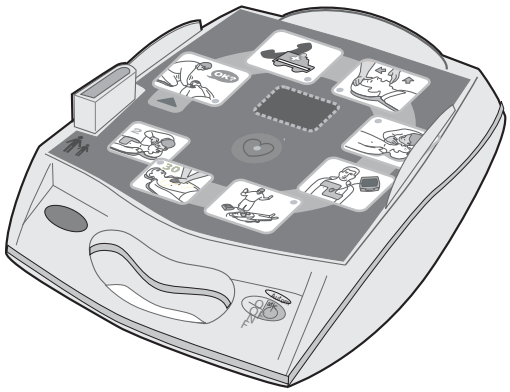
Технические характеристики на полностью автоматические наружные дефибрилляторы Fully Automatic AED Plus компании ZOLL



Introduction

Using the Fully Automatic AED Plus

The Fully Automatic AED Plus is an automatic external defibrillator (AED) that uses voice prompts and visual indicators to guide the rescuer through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR). The unit incorporates the ZOLL Rectilinear Biphasic Defibrillation waveform, and operates in either adult or pediatric mode.

The Fully Automatic AED Plus supports both adult and pediatric defibrillation electrode pads, and automatically adjusts the defibrillation energy based on the type of electrode pads connected to it. Following attachment of electrodes to a victim's chest, the defibrillator monitors the electrocardiographic (ECG) rhythm of the victim's heart, analyzes that rhythm, and determines whether the rhythm is shockable or non-shockable. When needed, defibrillation energy is delivered automatically by the device without the user taking any action, through these same electrodes. When the unit detects a shockable rhythm, it charges and issues the warning SHOCK WILL BE DELIVERED IN THREE (TWO), (ONE), followed by a loud shock tone. A shock is then delivered automatically by the unit. The rescuer will then be prompted to perform CPR for a period of two minutes, after which the unit automatically initiates a new ECG analysis.
Some versions of the Fully Automatic AED Plus include a cover that can also be used as a PASS (Passive Airway Support System) to support the victim's neck and shoulders in a position that assists in maintaining an open airway. Some versions also contain disposable accessories (razor, barrier mask, scissors, and a towel). The Fully Automatic AED Plus is powered by ten commercially available consumer brand lithium-manganese dioxide batteries.

The Fully Automatic AED Plus can:

- Perform periodic self tests to ensure its continual readiness.
- Use a one-piece electrode assembly (CPR-D-padz) that facilitates proper electrode placement and that is easy to apply to the victim.
- Analyze heart rhythm and inform the rescuer if the rhythm is shockable or non-shockable.
- Deliver defibrillation treatment to victims of cardiac arrest who exhibit shockable ECG rhythms.
- Provide voice prompts and graphics to guide the rescuer regarding what to do and when to do it during a cardiac emergency, such as calling for help or giving CPR to the victim.
- Provide audible beeps to encourage rescuers to provide CPR compressions at 100 CPM (requires CPR-D-padz).
- Monitor the depth of chest compressions during CPR and provide voice prompts, if compression depth is inadequate (requires CPR-D-padz).
- Provide a unit cover that functions as a Passive Airway Support System (PASS). (Note the PASS feature is standard with some versions of the product and optional with others.)
- Upload data from the defibrillator to a computer to store events or print event reports.
- Use commercially available batteries.

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 2601, AAMI DF-39, IEC 601-2-4, EN 60601-1, IEC 60601-1-2
ENVIRONMENT	
Operating Temperature	PS Model: 32° to 122° F; 0° to 50° C
Storage Temperature	PS Model: -22° to 158° F; -30° to 60° 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-160D: 1997 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
Data Recording and Storage	50 minutes of ECG and CPR data. If audio recording option is installed and enabled: 20 minutes of audio recording, ECG, and CPR data. If audio recording is disabled: 7 hours of ECG and CPR data.
Battery Capacity	Typical new battery (20° C): • stand-by life with batteries installed: 5 years, or • 300 ±5 continuous shocks: 250 ±5 shocks before "change battery" indicator and 50 ±5 shocks after "change battery" indicator; or • at least 13 hours of continuous Monitoring time

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

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Table 8: EMC Specifications

The Fully Automatic AED Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Fully Automatic AED Plus should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR11	Group 1	The Fully Automatic 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	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.		

The Fully Automatic AED Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Fully Automatic AED Plus should assure that it 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 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% Ut (>95% dip in Ut) for 0.5 cycle 40% Ut (60% dip in Ut) for 5 cycles 70% Ut (30% dip in Ut) for 25 cycles <5% Ut (>95%dip in Ut) for 5 sec	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
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

The Fully Automatic AED Plus is intended for use in the electromagnetic environment specified below. The customer or the user of the Fully Automatic AED Plus should assure that it is used in such an 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 Fully Automatic 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]	3 Vrms 10 Vrms	$d = 1.17 \sqrt{P}$ $d = 1.20 \sqrt{P}$

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 2.5 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 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 2.5 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 Fully Automatic AED Plus is used exceeds the applicable RF compliance level above, the Fully Automatic 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 Fully Automatic 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 Fully Automatic AED Plus

The Fully Automatic AED Plus is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Fully Automatic AED Plus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Fully Automatic 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 $d = [\frac{3.5}{3}] \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{10}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{10}] \sqrt{P}$	800MHz 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 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 2.5 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	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**
Ω25	40 J	61 J	66 J	95 J	111 J	146 J
Ω50	51 J	80 J	85 J	124 J	144 J	183 J
Ω75	64 J	89 J	111 J	148 J	172 J	204 J
Ω100	62 J	86 J	108 J	147 J	171 J	201 J
Ω125	63 J	89 J	110 J	137 J	160 J	184 J
Ω150	67 J	93 J	116 J	127 J	148 J	168 J
Ω175	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 Fully Automatic 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 Fully Automatic 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).

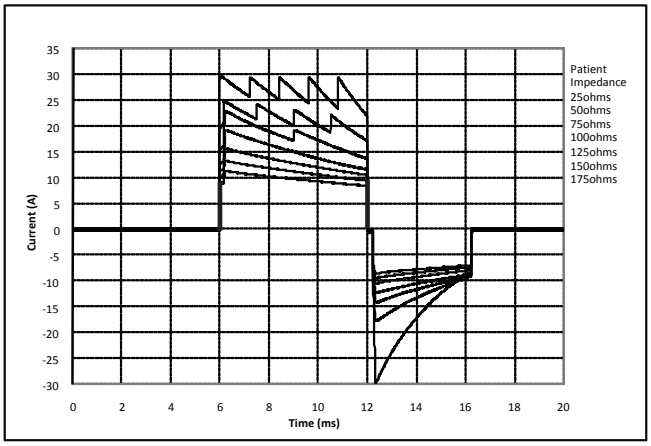


Figure 9: Rectilinear Biphasic Waveforms at 200 joules

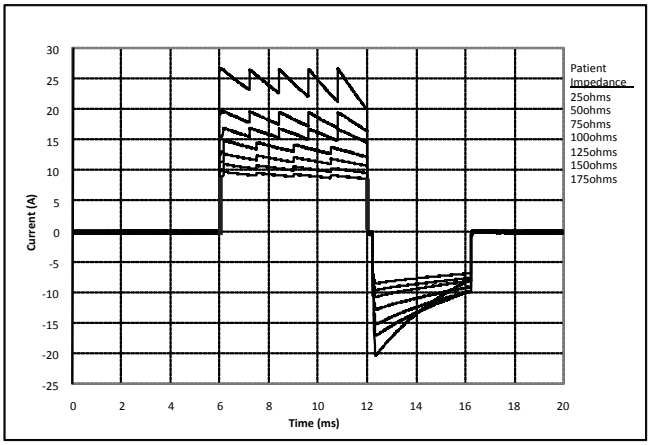


Figure 10: Rectilinear Biphasic Waveforms at 150 joules

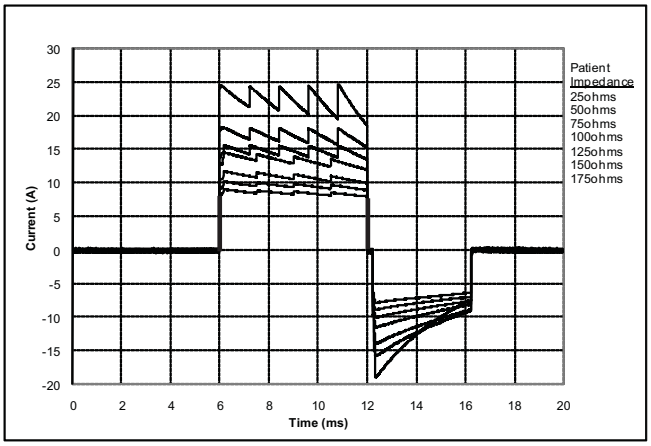


Figure 11: Rectilinear Biphasic Waveforms at 120 joules

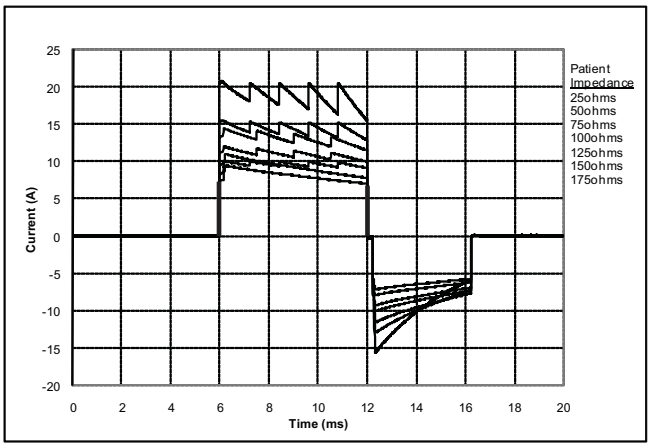


Figure 12: Rectilinear Biphasic Waveforms at 85 joules

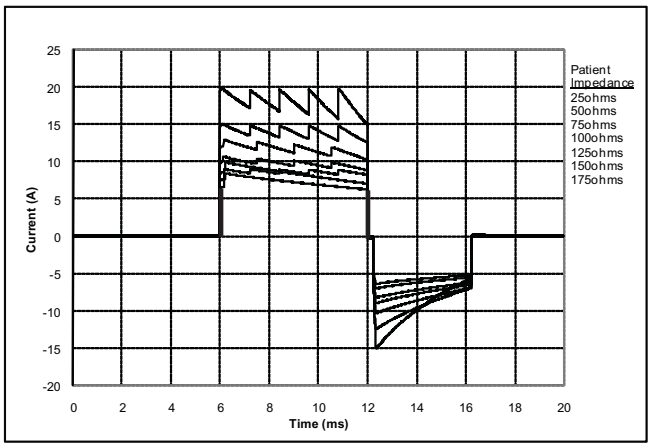


Figure 13: Rectilinear Biphasic Waveforms at 70 joules

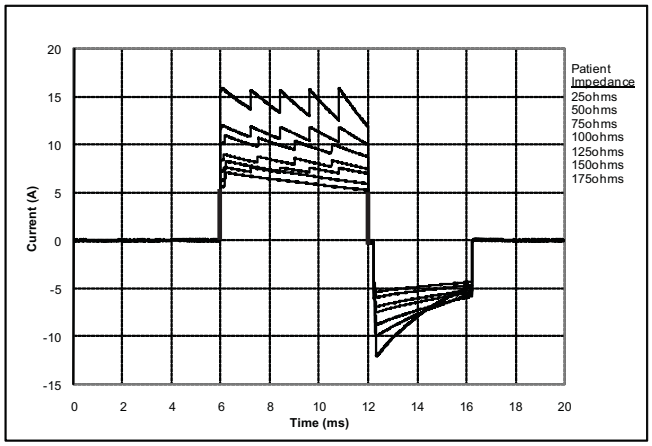


Figure 14: Rectilinear Biphasic Waveforms at 50 joules

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. 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 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%).

	Monophasic	**Biphasic**
1st Shock Efficacy	93%	99%
p-value	0.0517	
95% Confidence Interval	-2.7% to 16.5%	
90% Confidence Interval	-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%).

	Monophasic	**Biphasic**
1st Shock Efficacy (High Impedance Patients)	63%	100%
p-value	0.02	
95% Confidence Interval	-0.021% to 0.759%	
90% Confidence Interval	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)."

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 the AED Plus unit is charged and automatically delivers a shock.

Table 11: Clinical Performance Results (Adult Patients)

Rhythms	**Sample Size**	**Performance Goals**	**Observed Performance**	**90% One-sided Lower Confidence Limit**
Shockable (250 Total min.)	**618**			
Coarse VF	535	>90% sensitivity	97.38%	95.65%
Rapid VT	83	>75% sensitivity	91.57%	83.39%
Non-shockable (300 Total min.)	**3039**			
NSR	2205	>99% specificity	99.86%	99.60%
AF, SB, SVT, Heart block, idioventricular, PVCs	770	>95% specificity	100%	99.52%
Asystole	64	>95% specificity	100%	99.40%
Intermediate	**88**			
Fine VF	64	Report only	93.75% sensitivity	84.76%
Other VT	24	Report only	91.67% sensitivity	73.00%

Table 12: Clinical Performance Results (Pediatric Patients)

Rhythms	Sample Size (9 second records)	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable (23 Patients)				
Coarse VF (1)	42	>90% sensitivity	100% (42/42)	93.1%
Rapid VT (2)	51	>75% sensitivity	92.2% (47/51)	82.9%
Non-shockable (121 Patients)				
NSR (3)	229	>99% specificity	100% (229/229)	98.7%
AF, SB, SVT*, Heart block, idioventricular, PVCs (4)	415	>95% specificity	100% (415/415)	99.3%
Asystole (5)	14	>95% specificity	100% (14/14)	80.7%
Intermediate (15 Patients)				
Fine VF (6)	0	Report only	NA	---
Other VT (7)	22	Report only	77.3% (17/22)	58.0%

*155 of the 415 abnormal rhythm records were SVT (39 patients).