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
Смоленск (4812)29-41-54
Сочи (862)225-72-31
Ставрополь (8652)20-65-13
Сургут (3462)77-98-35
Сыктывкар (8212)25-95-17
Тамбов (4752)50-40-97
Тверь (4822)63-31-35
Тольятти (8482)63-91-07
Томск (3822)98-41-53
Тула (4872)33-79-87
Тюмень (3452)66-21-18
Ульяновск (8422)24-23-59
Улан-Удэ (3012)59-97-51
Уфа (347)229-48-12
Хабаровск (4212)92-98-04
Чебоксары (8352)28-53-07
Челябинск (351)202-03-61
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

портативные автоматические дефибрилляторы Propaq MD, аксессуары

компании ZOLL

Виды аксессуаров: кабели, наборы проводов прекардиального отведения, шланги, замки, одиночные трубки с разъемом Лауэра, комплекты неонатальных манжет, одноразовые датчики для пациентов, многоразовые датчики на палец, адгезивные датчики, многоразовые педиатрические зонды, многофункциональные терапевтические кабели, стерилизуемые внутренние ручки, итнерфейсные кабели, зонды, электроды и др.

Chapter 1
General Information

Product Description

The ZOLL® Propaq® MD unit is an easy-to-use portable defibrillator that combines defibrillation and external pacing with the following monitoring capabilities: ECG, CO-Oximeter, Non-invasive Blood Pressure, IBP, CO_2, Temperature, and Respiration. It has been designed for all resuscitation situations and its rugged, compact, lightweight design makes it ideal for transport situations. It is powered by auxiliary power and an easily replaced battery pack that is quickly recharged in the device when it is connected to auxiliary power. In addition, the unit's battery may be recharged and tested using a ZOLL *SurePower™ Battery Charger Station*.

Note: The Propaq MD has defibrillation and pacing functionality, but some of the monitoring functions are optional features. See the complete list of options in Fig. 1-1. All features are included in this manual, but only purchased features will be available on your unit.

The product is designed for use in hospital, EMS, and rugged military environments. The device is a versatile automated external defibrillator with manual capabilities and may be configured to operate in Manual, Advisory or Semiautomatic modes. It can be configured to start up in Semiautomatic (AED) mode or manual mode.

When operating in manual configuration, the device operates as a conventional defibrillator where the device's charging and discharging is fully controlled by the operator. In Advisory and AED modes, some features of the device are automated and a sophisticated detection algorithm is used to identify ventricular fibrillation and determine the appropriateness of defibrillator shock delivery. Units may be configured to automatically charge, analyze, recharge, and prompt the operator to "PRESS SHOCK", depending on local protocols. The unit is switched from AED mode to Manual mode for ACLS use by pressing the appropriate key on the front panel.

Appendix A Specifications

This chapter provides specification information for the Propaq MD Monitor/Defibrillator.

Defibrillator

Charge Time:

- Less than 7 seconds with a new, fully charged battery (first 15 charges to 200 joules).
- For the sixteenth discharge at maximum energy, the charge time is less than 10 seconds. Depleted batteries result in a longer defibrillator charge time.
- Less than 15 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage.
- Less than 25 seconds from the initial power on, with a new, fully charged battery pack (depleted by up to fifteen 200 joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage.

Rhythm Analysis and Charge Time in AED Mode

- Less than 30 seconds with a new, fully charged battery (first 15 charges to 200 joules).
- For the sixteenth discharge at maximum energy, the analysis and charge time is less than 30 seconds. Depleted batteries result in a longer defibrillator charge time.
- Less than 30 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage.
- Less than 40 seconds from the initial power on, with a new, fully charged battery pack (depleted by up to fifteen 200 joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage.

Patient Impedance Range: 10- 300 ohms

Synchronized Mode: Synchronizes defibrillator discharge to the patient's R wave. SYNC is indicated on the display with R wave markers above the ECG waveform on the screen and stripchart. When ECG is monitored by the device, meets the DF-80:2003 requirement of 60ms maximum time delay between the peak of the R wave and the delivery of energy.

Table A-1 shows the characteristics of the Propaq MD Rectilinear Biphasic™ waveform when discharged into 25 ohm, 50 ohm, 100 ohm, 125 ohm, 150 ohm and 175 ohm loads at the maximum energy setting of 200 joules.

Table A-1. Propaq MD Rectilinear Biphasic Waveform Characteristics

	200 J discharged into					
	25Ω	**50Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**
First phase						
Maximum initial current	31.4 A	30.4 A	19.7 A	19.4 A	16.7 A	15.6 A
Average current	27.1 A	24.9 A	17.5 A	16.2 A	14.4 A	13.2 A
Duration	6 ms	6 ms	6 ms	6 ms	6 ms	6 ms
Interphase duration (between first and second phases)	200 μs	200 μs	200 μs	200 μs	200 μs	200 μs
Second phase						
Initial current	29.2 A	18.8 A	15.1 A	13.2 A	12.1 A	11 A
Average current	14.7 A	13 A	12.5 A	11.3 A	10.7 A	9.9 A
Duration	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms

Table A-2. Delivered Energy at Every Defibrillator Setting into a Range of Loads

Selected Energy	Load							
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy*
1 J	1 J	1 J	1 J	1 J	1 J	1 J	1 J	±15%
2 J	1 J	2 J	2 J	2 J	2 J	2 J	2 J	±15%
3 J	2 J	3 J	3 J	3 J	3 J	3 J	3 J	±15%
4 J	3J	4 J	4 J	5 J	5 J	5 J	4 J	±15%
5 J	3 J	5 J	6 J	6 J	6 J	6 J	6 J	±15%
6 J	4 J	6 J	7 J	7 J	7 J	7 J	7 J	±15%
7 J	5 J	7 J	8 J	8 J	8 J	8 J	8 J	±15%
8 J	5 J	8 J	9 J	9 J	10 J	9 J	9 J	±15%
9 J	6 J	9 J	10 J	11 J	11 J	11 J	10 J	±15%
10 J	7 J	10 J	12 J	12 J	12 J	12 J	12 J	±15%
15 J	10 J	16 J	17 J	18 J	18 J	18 J	17 J	±15%
20 J	14 J	21 J	23 J	24 J	24 J	24 J	23 J	±15%
30 J	21 J	32 J	35 J	36 J	37 J	36 J	35 J	±15%
50 J	35 J	54 J	59 J	61 J	62 J	61 J	59 J	±15%
70 J	49 J	76 J	83 J	85 J	87 J	86 J	83 J	±15%
85 J	60 J	92 J	101 J	104 J	106 J	104 J	101 J	±15%
100 J	71 J	109 J	119 J	122 J	125 J	123 J	119 J	±15%
120 J	85 J	131 J	143 J	147 J	150 J	147 J	143 J	±15%
150 J	107 J	164 J	180 J	183 J	188 J	184 J	179 J	±15%
200 J	142 J	230 J	249 J	253 J	269 J	261 J	260 J	±15%

* For all energy levels, accuracy is equal to either ±15% or 3 joules, whichever is greater.

The Propaq MD 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 R Series® defibrillator. The R Series and Propaq MD defibrillation waveforms are considered substantially equivalent.

Figures A-1 through A-20 show the Rectilinear Biphasic waveforms that are produced when the Propaq MD defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting.

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

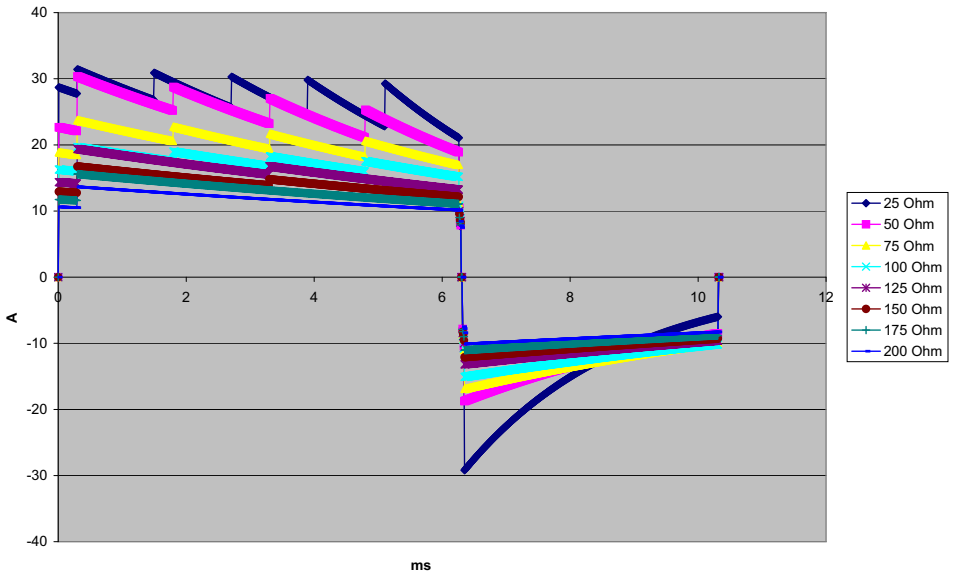


Figure A-1. Rectilinear Biphasic Waveform at 200 Joules

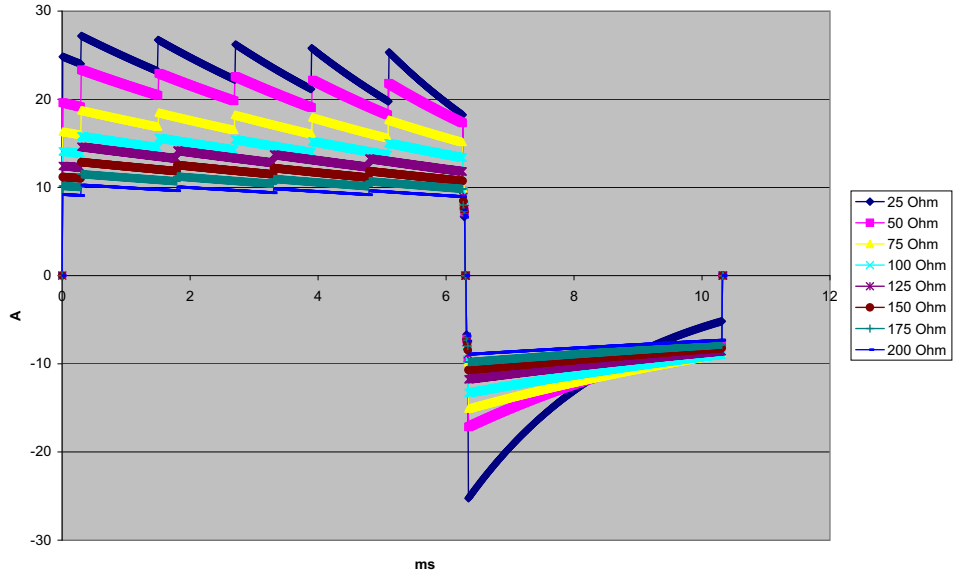


Figure A-2. Rectilinear Biphasic Waveform at 150 Joules

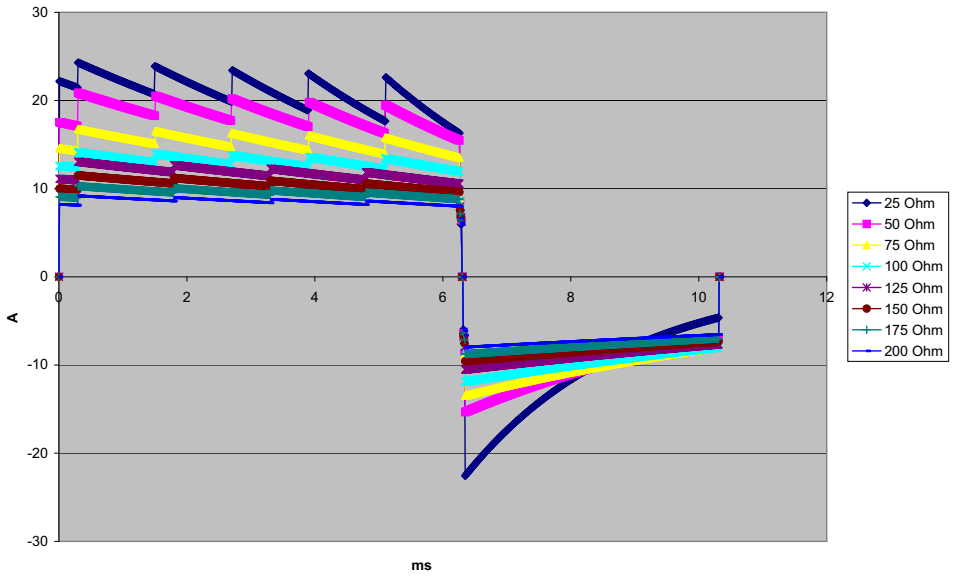


Figure A-3. Rectilinear Biphasic Waveform at 120 Joules

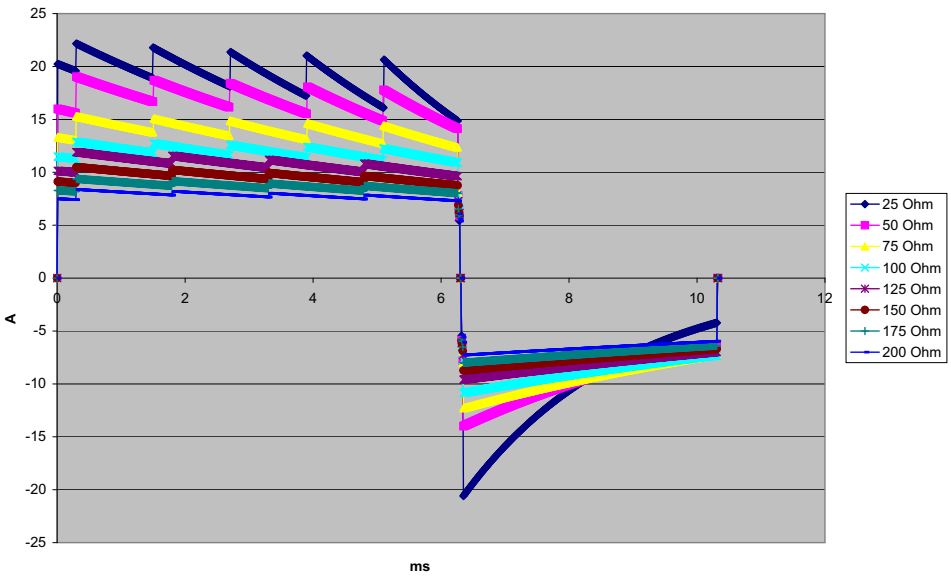


Figure A-4. Rectilinear Biphasic Waveform at 100 Joules

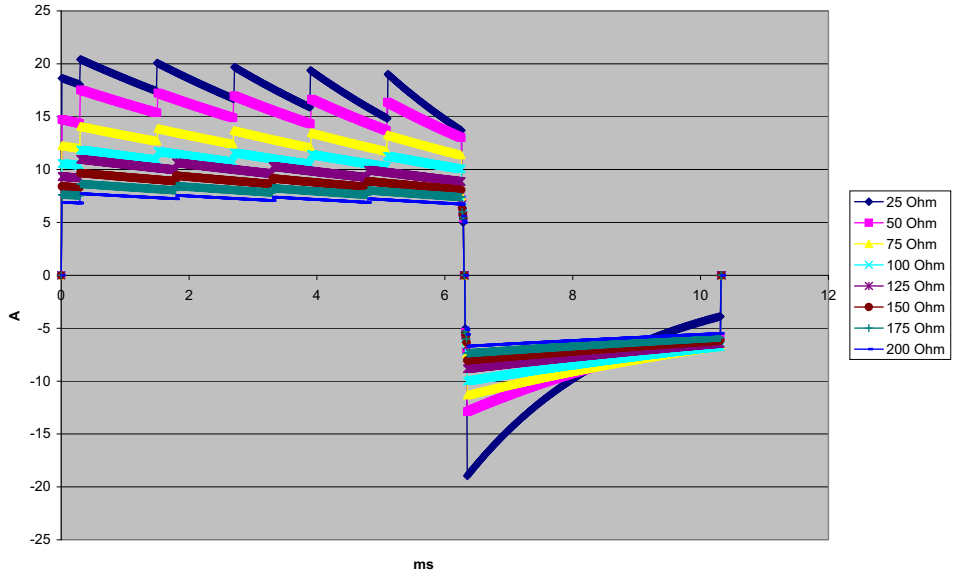


Figure A-5. Rectilinear Biphasic Waveform at 85 Joules

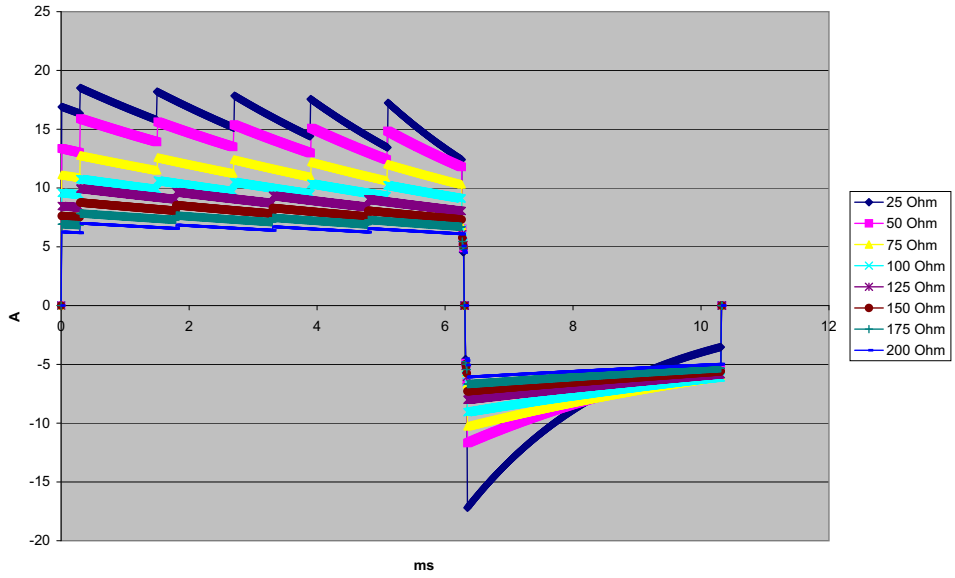


Figure A-6. Rectilinear Biphasic Waveform at 70 Joules

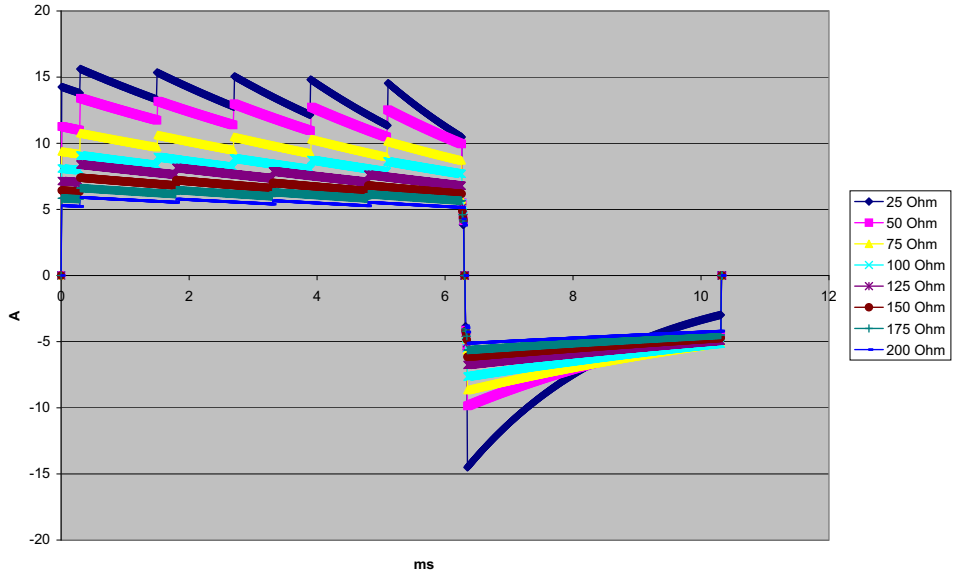


Figure A-7. Rectilinear Biphasic Waveform at 50 Joules

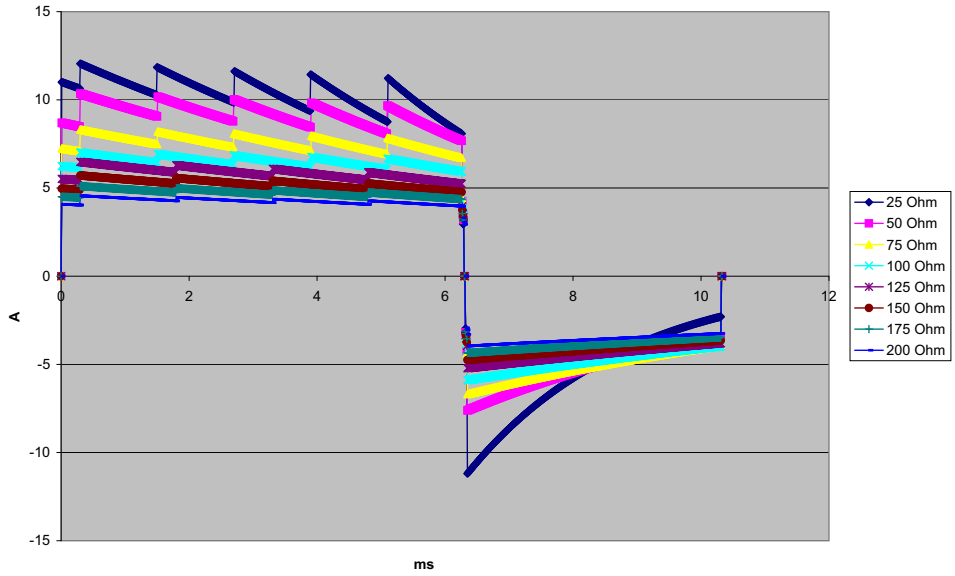


Figure A-8. Rectilinear Biphasic Waveform at 30 Joules

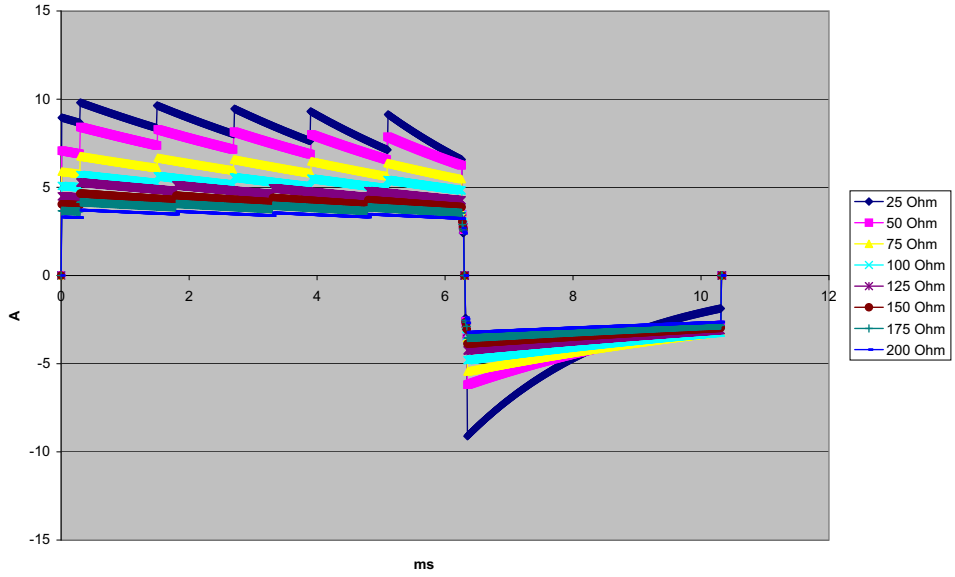


Figure A-9. Rectilinear Biphasic Waveform at 20 Joules

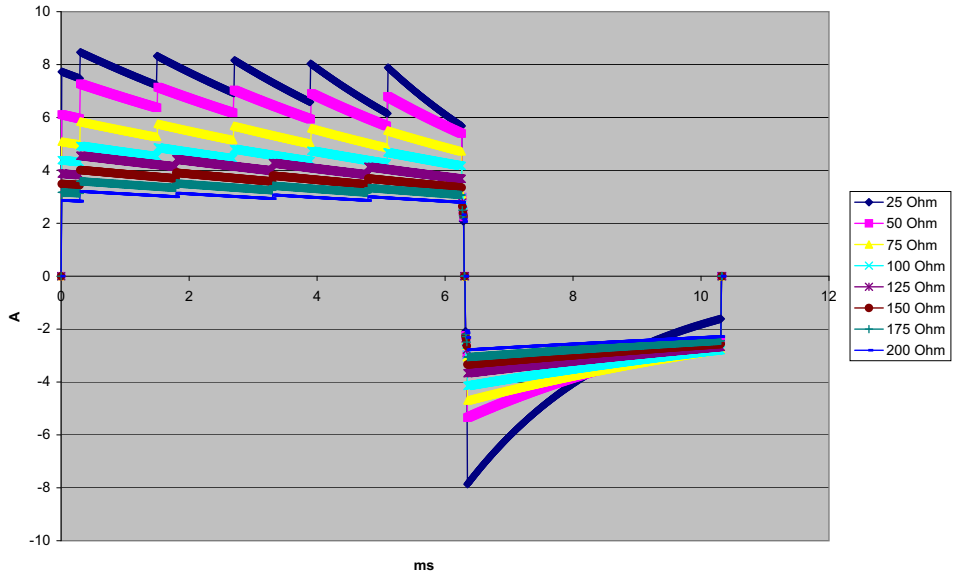


Figure A-10. Rectilinear Biphasic Waveform at 15 Joules

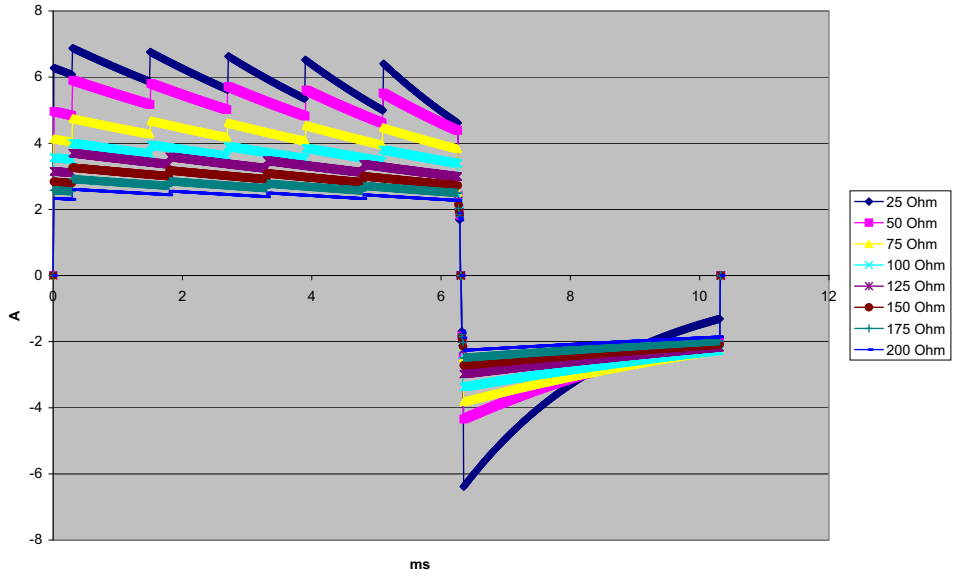


Figure A-11. Rectilinear Biphasic Waveform at 10 Joules

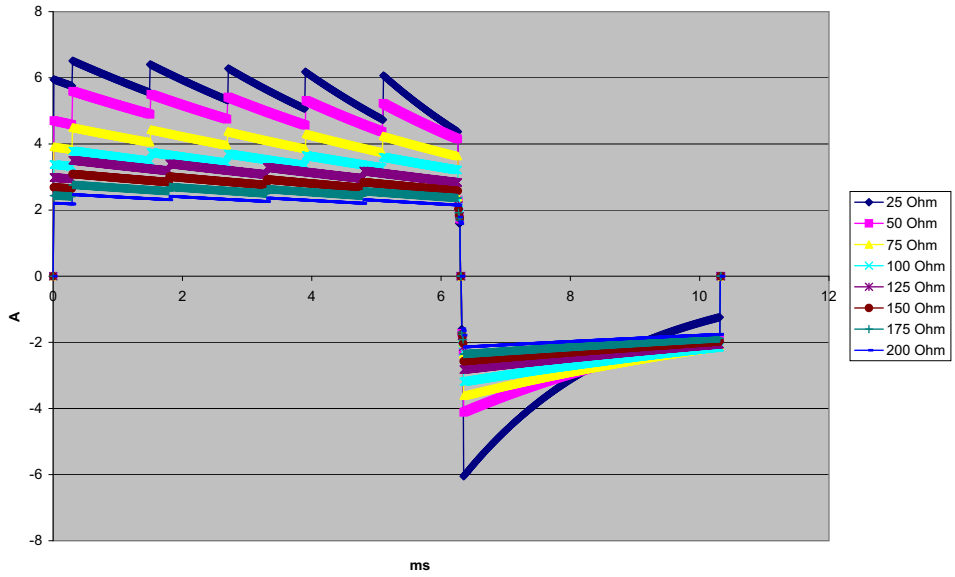


Figure A-12. Rectilinear Biphasic Waveform at 9 Joules

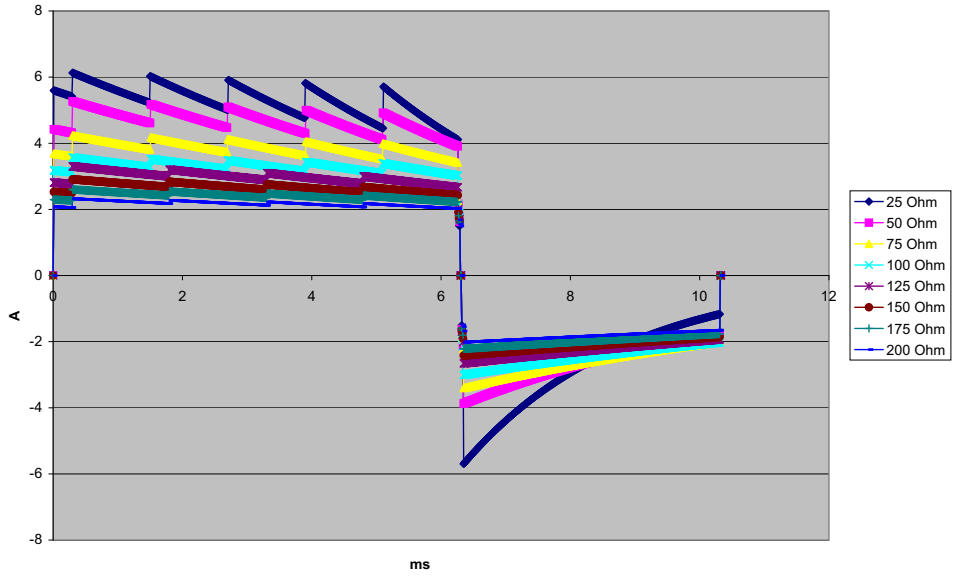


Figure A-13. Rectilinear Biphasic Waveform at 8 Joules

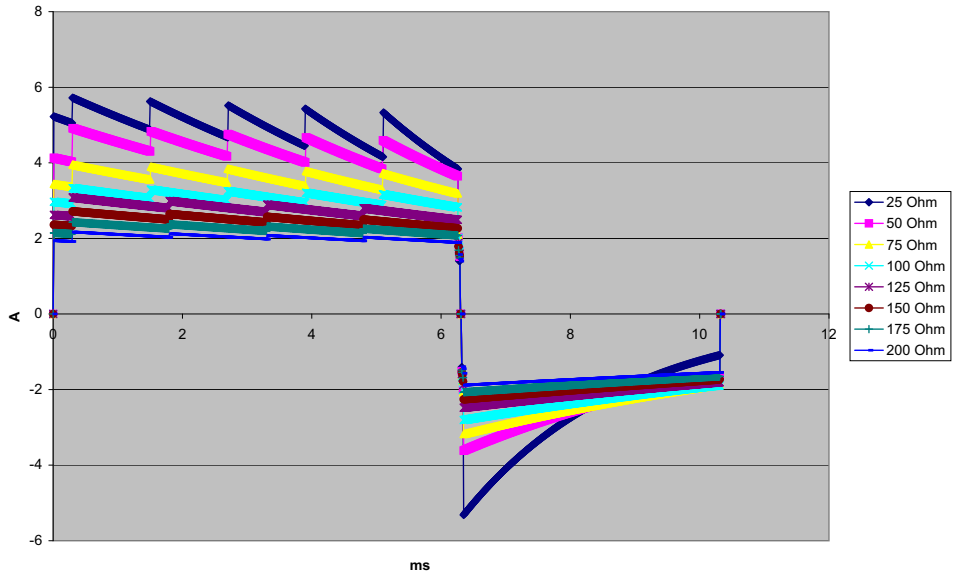


Figure A-14. Rectilinear Biphasic Waveform at 7 Joules

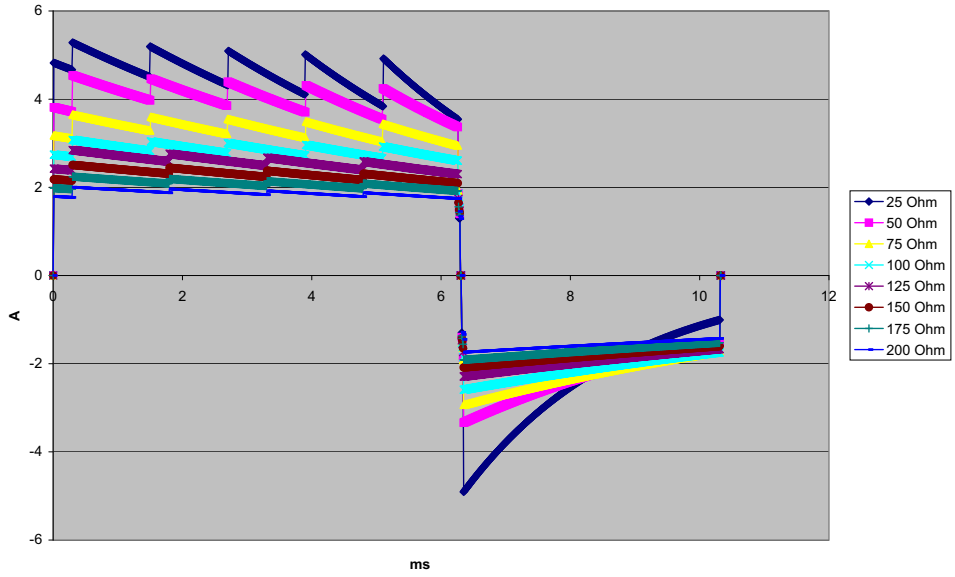


Figure A-15. Rectilinear Biphasic Waveform at 6 Joules

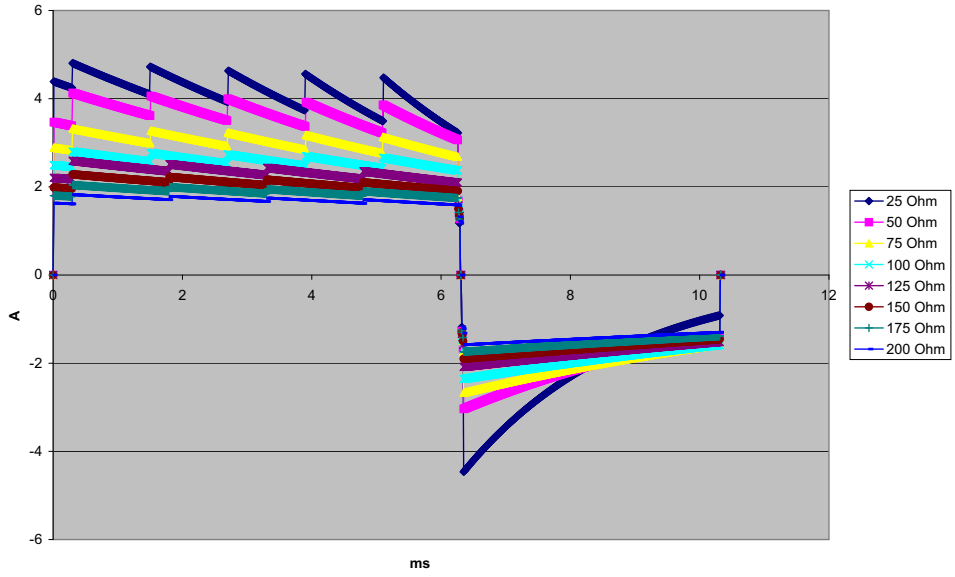


Figure A-16. Rectilinear Biphasic Waveform at 5 Joules

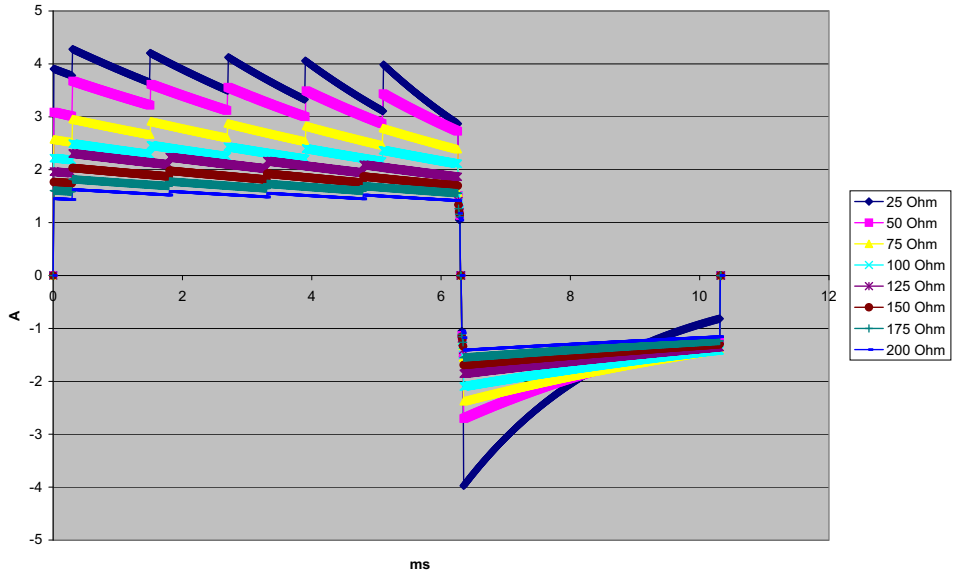


Figure A-17. Rectilinear Biphasic Waveform at 4 Joules

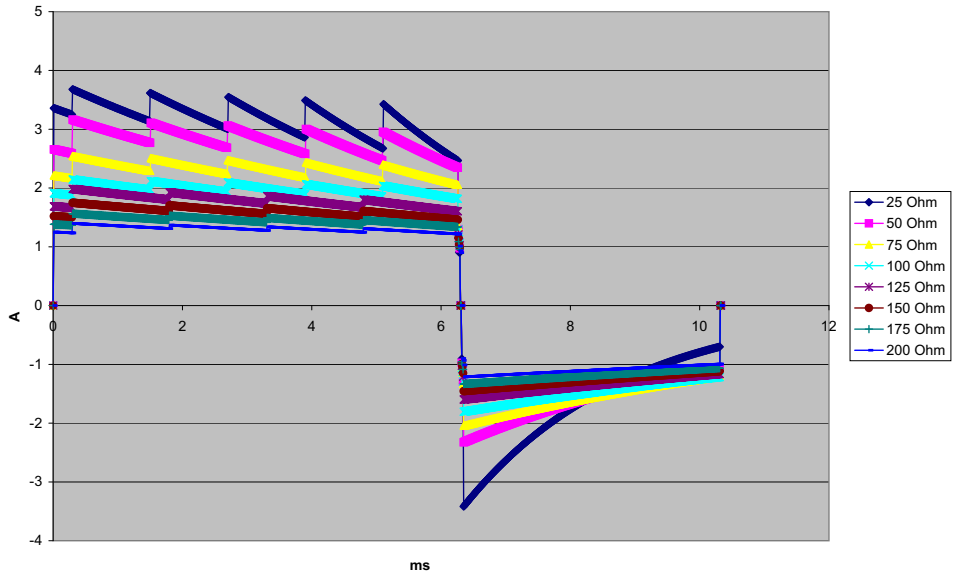


Figure A-18. Rectilinear Biphasic Waveform at 3 Joules

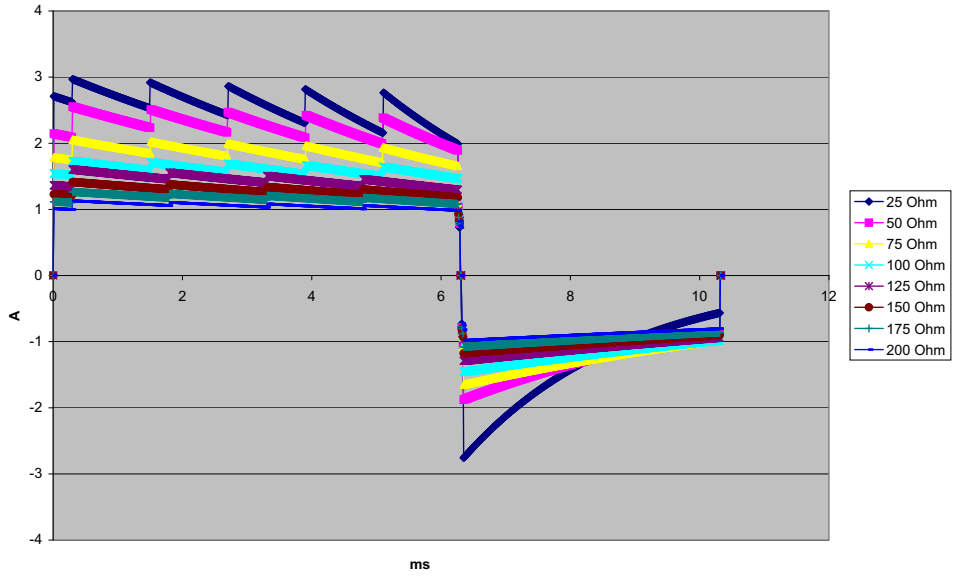


Figure A-19. Rectilinear Biphasic Waveform at 2 Joules

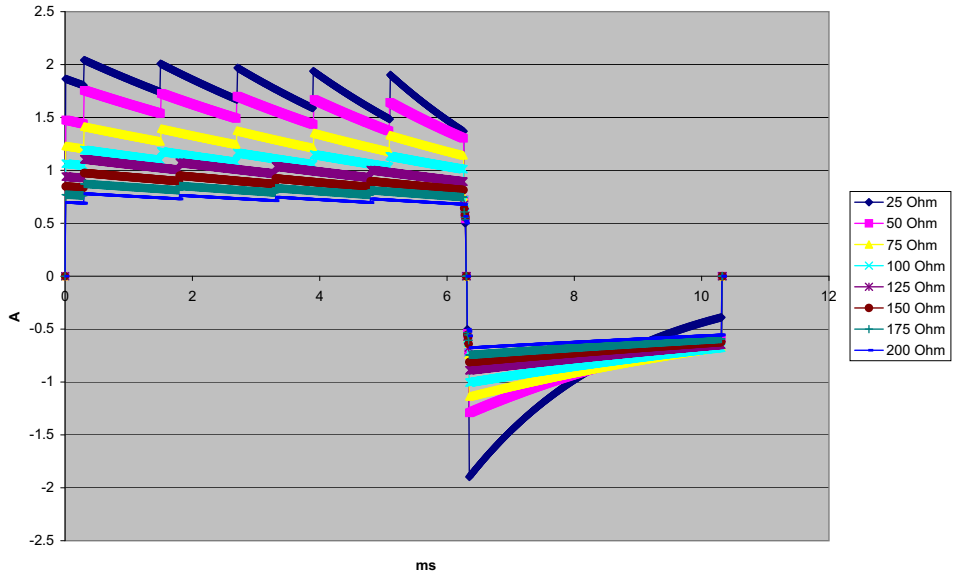


Figure A-20. Rectilinear Biphasic Waveform at 1 Joule

Monitor/Display

Input: 3-lead, 5-lead, or 12-lead patient cable, paddles, Multifunction or OneStep electrodes.

Type: Color LCD, 640 x 480 pixels, 800 MCD

Sweep Speed: 25 mm / sec or 50 mm / sec (User Selectable)

Lead Selections: Paddles (Pads), I, II, III, AVR, AVL, AVF, V1-6.

Frequency Response:

Pads/Paddles:

0.67 to 20Hz Limited response

3/5/12 Lead Continuous Monitoring (user selectable):

0.67 to 20Hz Limited response

0.67 to 40Hz Monitor response

Acquired 12-lead snapshots (supervisor selectable):

0.525 to 40Hz Filtered Diagnostic response

0.525 to 150Hz Diagnostic response

Per methods a, b, c of EC11 3.2.7.2

(Automatically sets chart recorder response)

Common Mode Rejection:

Complies with AAMI EC13-2002 section 4.2.9.10.

Tall T-Wave Rejection:

Meets AAMI EC13-2002, section 4.1.2.1c for 0.9 mV

T-wave (0.8 mV with diagnostic response) and 1mV QRS.

Diagnostic Signals Applied to Patient Connections:

Leads off / active noise suppression sensing circuit is < 0.1 microamps DC. The impedance /respiration detector signal frequency is 72 ± 7 kHz at 77 microamps RMS pseudo-sinewave into 100 ohms.

Heart Rate Range: 30 to 300 BPM.

Heart Rate Accuracy: +/- 3% or +/- 3BPM, whichever is greater.

Displayed Heart Rate: Average of last 5 beat-to-beat intervals.

Heart Rate Alarms: User-selectable.

Size: 0.125, 0.25, 0.5, 1, 2, 4 cm/mv and auto-ranging.

Heart Rate Meter Response Time:

Responds to a 40 BPM step increase in heart rate within 4.5 seconds per AAMI EC-13-2002, section 4.1.2.1.f. Responds to a 40 BPM step decrease within 3.9 seconds per AAMI EC-13-2002, section 4.1.2.1.f. Response times include a 1.0-second display update interval.

Heart Rate Response to Irregular Rhythm: (AAMI EC13-2002, section 4.1.2.1.e.)

Ventricular Bigeminy: 80 BPM (expected)

Slow Alternating Ventricular Bigeminy: 60 BPM (expected)

Rapid Alternating Ventricular Bigeminy: 120 BPM (expected)

Bidirectional Systole: 45 BPM (expected)

Tachycardia Response Time:

Response time to tachycardia alarm is on average 3.4 seconds per AAMI EC-13-2002, section 4.1.2.1.g, and IEC 60601-2-27:2011, subclause 201.7.9.2.9.101 b) 6). Response times include a 1.0 second display update interval.

Pacemaker Pulse Rejection:
(In accordance with AAMI EC13:2002, section 4.1.4 and IEC 60601-2-27:2011, subclause 201.12.1.101.13)

- Pulses without overshoot: Rejects all pulses with amplitude of +2 mV to +700 mV and duration of 0.1 ms to 2 ms, with no tail.
- Pulses with overshoot: Rejects all pulses with amplitude of +2 mV to +700 mV and duration of 0.1 ms to 2 ms, with overshoot up to 100 ms.
- A-V sequential pulses: A-V sequential pacemaker pulses may not be rejected.
- Fast ECG signals: Approximately 50% of ECG input pulses with a slew rate of 3 V/s RTI may trigger the pacemaker pulse detector.

Electrosurgery Protection: The Propaq MD is suitable for use in the presence of electrosurgery as specified in IEC 60601-2-27. Burn hazard protection via a 1K current limiting resistor contained in each ECG leadwire.

Impedance Pneumography

Displayed Data: Numeric breath rate, Impedance waveform

Breath rate range: Adult, Ped: 2 to 150 breaths / minute

Neonates: 3 to 150 breaths / minute

Breath rate accuracy: 2% or +/- 2 breaths / minute, whichever is greater

Displayed Breath Rate: Average of last 10 breath-to-breath rates.

Leads: Lead I (RA – LA), Lead II (RA – LL)

Sweep Speed: 3.13, 6.25, 12.5 mm/sec

Alarm settings: High, low and no breath rate alarm

Alarms

Heart Rate Alarms:

Audible: 5 pulse, 900 Hz tone, with a PW of 125 msec, a PRI of 250 msec, and a repetition interval of 15 seconds.

Visual: Heart Rate Alarm causes the heart rate to be displayed in red, with a white background.

The red device status LED will flash a rate of 1.7 Hz.

Lead Fault Alarm:

Audible: 3 pulse, 500 Hz, triplet tone with a PW of 200 msec, a PRI of 200 msec. The lead fault tone repeats at a repetition interval of 30 seconds.

Visual: Lead Fault condition causes a LEAD FAULT message to be displayed on the trace along with a dashed line the width of the trace.

Physiological Alarms (NIBP, SpO_2, Resp, CO_2, IP & Temp):

Audible: Same as Heart Rate Alarm

Visual: Physiological alarms cause the alarming parameter to be displayed in Red with a white background. The red device status LED will flash at a rate of 1.7 Hz.

Audio Pause (Silence) Duration: 90 seconds.

Invalid Operation Alert Tone:

A short, low-pitched tone is audible when a selected control button is unavailable for use or an invalid entry is detected. Tone frequency is 160 Hz. Duration is 250 msec.

Maximum Alarm Delay (Includes Alarm Condition Delay and Signal Generation Delay):

Heart rate/pulse rate:

- if source is ECG, 9 seconds
- if source is SpO_2, 10 seconds
- if source is IBP, 6 seconds
- if source is NIBP, no hold off

SpO_2, SpCO, and SpMet Saturation: 10 seconds

$EtCO_2$: 7 seconds

$FiCO_2$: 5 seconds

IBP (Systolic, Diastolic, Mean): 3 seconds

Temperature: 2 seconds

Recorder

Type: High-resolution thermal array.

Annotation: Time, date, ECG lead, ECG gain, heart rate, defibrillation and pacing parameters and treatment summary events.

Paper Width: 80 mm.

Paper Speed: 25 mm/sec, 50 mm/sec

Delay: 6 seconds.

Frequency Response: Automatically set to monitor's frequency response.

Treatment Summary:

10 switches to record key ACLS events (IV, INTUB, EPI, LIDO, ATROP, etc.). Automatically logs into memory the type of event, time and ECG sample.

Full Disclosure Case Log: A combination of 32 monitor snapshots; 500 non-ECG events; and 24 hours of continuous ECG (4 waveforms), Capnography, IBP (3 channels), and Pads Impedance. The actual information stored can be more or less depending on the use profile and the log configuration settings.

Record Modes: Manual and automatic (User-configurable).

Battery

Type: Rechargeable Lithium-Ion, 11.1Vdc, 6.6 Ah, 73Wh

Capacity:

With a new, fully charged battery operating at room temperature:

- At least 6 hours of continuous monitoring of ECG, SpO_2, CO_2, three Invasive Pressure channels, and 2 channels of Temperature, with NIBP measurements every 15 minutes and 10 200 J shocks (display set to 30%).
- At least 100 discharges at maximum shock energy (200 joules).
- At least 3.5 hours pacing, with ECG, SPO_2, CO_2, three Invasive Pressures, temperature, NIBP every 15 minutes and pacing at 180 ppm, and 140 mA.
- At least 300 discharges at maximum shock energy (200 joules) with no parameters and 70% brightness.
- At least 10 discharges at maximum shock setting (200 joules) after a Low Battery indication.

Note: Proper battery care is required to maintain maximum available capacity.

Battery Indicators:

5 Battery capacity LED indicators, Fault indicator, Recalibration indicator

Recharge Rate: 100% in 4 hours, when initiated at Low Battery indication.

General

Weight:

10.6 lbs.without battery and paper

11.7 lbs.with battery and paper

Dimensions:

Without Handle: 8.9” x 8.75” x 7.9”

With Handle: 8.9” x 10.4” x 7.9”

Operating:

Temperature: 0 to 50° C

Humidity: 15 to 95% RH (non-condensing)

Vibration:

- EN ISO 9919 (per IEC 60068-2-64)
- RTCA/DO-160G (multiple helicopter frequencies)
- EN 1789 for ambulance

Shock: IEC 60068-2-27, 100g, 6ms half sine

Bump: EN 1789 (IEC 60068-2-29)

Drop: EN 1789, 30” functional drop

IEC 60601-1, Tested at 2 meters

Altitude: -170 M to 4572 M (-557 feet to 15,000 feet)

Transport and Storage:

Temperature: -30 to 70°C

Note:	The Propaq MD device may not perform to specifications when stored at the upper or lower extreme limits of storage temperature and immediately put into use.

Humidity: 15 to 95% RH (non-condensing)

Atmospheric pressure: 572 mbar to 1034 mbar

Shock/vibration: MIL STD 810G, Method 514.6, 4.4.2, Procedure II

Safety Classification: Class 1 and internal power per IEC/EN 60601-1

Enclosure Protection:

Solid Foreign Object: IEC 60529, IP5X

Water: IEC 60529, IPX5

Auxiliary Operating Power:

Auxiliary Power Adapter, 8300-0004

Input: 100-240V ∿ 50-60 Hz, 2A

100-115V ∿ 400 Hz, 2A

Output: 14.5V ⎓ 4.15A

80W (peak)

IP Rating: IP23

Pacer

Type: External transcutaneous pacing

Pacer Rate: 30 to 180 BPM ± 1.5%.

Output Current: 0 to 140 mA ± 5% or 5 mA (whichever is greater)

Modes: Demand and Fixed

Status Indicators:

ECG lead fault, pace marker on monitor and chart, start/stop indicator on display.

Pulse Type: Rectilinear, constant current

Pulse Width: 40 ms +/-2 ms

CO_2

Range: 0 to 150 mmHg

Accuracy CO_2:

CO_2 Partial Pressure*	**Accuracy ****
0-38 mmHg	± 2 mmHg
39-99 mmHg	± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)
100-150 mmHg	± (5% of reading + 0.08% for every 1 mmHg above 38 mmHg)

* At sea level.

** Accuracy applies for breath rates of up to 80 bpm. For breath rates above 80 bpm, accuracy is 4 mmHg or ±12% of reading whichever is greater, for $EtCO_2$ values exceeding 18 mmHg. This is tested according to and is compliant with ISO 21647. To achieve the specified accuracies for breath rates above 60 breaths/minute, the Microstream FilterLine H Set for Infant/Neonatal must be used. Above 40 C, ± 1mmHg or ± 2.5% (whichever is greater) has to be added to the tolerance of the accuracy specs.

CO2 Sampling Rate: 50 msec

Drift of Measurement Accuracy: Over any 24-hour period, the accuracy claims listed above are maintained.

The accuracy specification is maintained to within 4% for the following gas mixtures (all values are in Vol.%).

CO_2	**N_2**	**O_2**	**N_2O**	**H_20**	**Anesthetic Agents**
1.0 to 13	0 to 97.5	0 to 100	0 to 80	Dry to saturated	According to EN 21647

Respiration Range: 0 to 149 breaths per minute

Respiration Rate Accuracy:

0 to 70 bpm: ±1 bpm

71 to 120 bpm: ±2 bpm

121 to 149 bpm: ±3 bpm

Flow rate: 50 ml/min -7.5 + 15 ml/min, flow measured by volume.

Total System Response Time: 2.9 seconds typical, 3.9 seconds maximum.

Pulse Oximeter

Range:

Oxygen Saturation (% SpO_2)	0% - 100%
Carboxyhemoglobin Saturation (% SpCO)	0% - 99%
Methemoglobin Saturation (% SpMet)	0% - 99%
Total Hemoglobin (g/dL SpHb)	0 – 25 g/dL
Total Oxygen Content (% SpOC)	0 – 35 ml/dL
Perfusion Index (% PI)	0.02% - 20%
Pleth Variable Index (% PVI)	0% - 100%
Pulse Rate (bpm)	25 - 240 beats per minute

Accuracy:

Oxygen Saturation (% SpO_2) - During No Motion Conditions

Adults, Pediatrics[1]	70% - 100%, ±2 digits 0% - 69%, unspecified
Neonates[2]	70% - 100%, ±3 digits 0% - 69%, unspecified

Oxygen Saturation (% SpO_2) - During Motion Conditions[3]

Adults, Pediatrics	70% - 100%, ±3 digits 0% - 69%, unspecified
Neonates	70% - 100%, ±3 digits 0% - 69%, unspecified

Oxygen Saturation (% SpO_2) - During Low Perfusion Conditions[4]

Adults, Pediatrics	70% - 100%, ±2 digits
Neonates	70% - 100%, ±3 digits

Carboxyhemoglobin Saturation (% SpCO)[5]	1% - 40% ±3 digits
Methemoglobin Saturation (% SpMet)[5]	1% - 15% ±1 digit

Total Hemoglobin (ml/dL SpHb)[6]

Adults, Pediatrics 8 – 17 ±1 g/dL (arterial or venous)

Pulse Rate (bpm) - During No Motion Conditions[1]

Adults, Pediatrics, Neonates 25 - 240 ±3 digits

Pulse Rate (bpm) - During Motion Conditions[3]

Adults, Pediatrics, Neonates 25 - 240 ±5 digits

Resolution:

SpO_2: 1%
SpCO: 1%
SpMet: 0.1% for range up to 9.9%, 1% for range 10 - 99%
SpHb: 0.1 g/dL
SpOC: 0.1 ml/dL
PVI: 1%
PI: 0.1%
Pulse rate: 1 bpm (beats per minute)

Alarm Limits: On/Off displayed on monitor. User selectable.

SpO_2: High 72 - 100% saturation, Low 70 - 98% saturation
SpCO: High 2 - 100% saturation, Low 0 - 99% saturation
SpMet: High 1 - 100% saturation, Low 0 - 99% saturation
SpHb: High 2 - 25 g/dL, Low 0 - 24.9 g/dL
SpOC: High 0.1 – 35 ml/dL, Low 0 – 34.9 ml/dL
PVI: High 2 – 100%, Low 0 – 98%
PI: 0.2 – 20%, Low 0 – 19.8%
Pulse Rate: High 60 - 235 beats per minute, Low 20 - 100 beats per minute

SpO_2 Wavelength for LNCS Sensors:

Nominal Red LED Wavelength: 660 nanometers
Nominal Infrared LED Wavelength: 905 nanometers

Energies (Radiant Power) of light for LNCS Sensors at 50 mA pulsed:

≤ 15 mW

SpO_2 Wavelength for Rainbow Sensors:

The Rainbow sensors use 8 different LEDs with wavelengths of 610 - 905 nanometers

Energies (Radiant Power) of light for Rainbow Sensors at 100 mA pulsed:

≤ 25 mW

Bio-Compatibility:

Patient contacting material meets requirements of ISO 10993-1, Biological Evaluation of Medical Device - Part I, for external devices, intact surfaces and short-term exposure

Environmental:

Operating Temperature: 0° to 50° C (32° to 122° F)
Storage Temperature: -40° to 70° C (-40° to 158° F)

Electromagnetic Immunity (SpO_2 Option Only):

AAMI DF-80; EN61000-4-3:2002 to 10 V/m

Note: The Propaq MD Pulse Oximetry Option is calibrated for functional saturation.

1 The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory CO-oximeter and ECG monitor.

2 The Masimo SET Technology with LNOP sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

3 The Masimo SET Technology with LNOP sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory CO-oximeter and ECG monitor. 1% has been added to the saturation accuracy to account for the effects of fetal hemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

4 The Masimo SET Technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and a Masimo simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

5 The Masimo SET Rainbow Technology with Rainbow DC-dc sensors have been validated in human blood on healthy adult volunteers against a laboratory CO-oximeter from 1 - 40% for carboxyhemoglobin and 1 - 15% for methemoglobin. This variation equals plus or minus one standard deviation, which encompasses 68% of the population.

6 SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range o 8-17 g/dL SpHb against a laboratory CO-oximeter. This variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

Non-Invasive Blood Pressure

Technique: Non-invasive oscillometric method

Operating Modes: Automatic and manual

Automatic Intervals: 1, 2, 3, 5, 10, 15, 30 and 60 minute intervals.

Turbocuf: Maximum measurements allowable in a 5 minute period

Pressure Measurement Range:

Systolic: 20 to 260 mmHg

Diastolic: 10 to 220 mmHg

Mean: 13 to 230 mmHg

Static Pressure Accuracy: +/- 3 mmHg

Pulse Rate Range:

Adult: 30 to 200 +/- 5 BPM

Pediatric: 30 to 200 +/- 5 BPM

Neonatal: 35 to 220 +/- 5 BPM

Default Cuff Inflation Pressure:

Adult: 160 mmHg

Pediatric: 120 mmHg

Neonatal: 90 mmHg

Maximum Cuff Inflation Pressure:

Adult: 270 mmHg

Pediatric: 170 mmHg

Neonatal: 130 mmHg

Single Fault Backup Overpressure Limit:

Adult: 308 mmHg

Pediatric: 205 mmHg

Neonatal: 154 mmHg

Typical Determination time without Artifact:

Measurements on the deflation: 30 to 45 seconds

Measurements on the inflation (SureBP)*: 15 to 30 seconds

* using dual lumen cuffs

Maximum Determination Time - Measurement on the Inflation

Adult: 150 seconds

Pediatric: 120 seconds

Neonatal: 80 seconds

Blood Pressure Validation:

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method for adults and pediatric patients and equivalent to an intra-arterial measurement for neonatal patients, within the limits prescribed by the American National Standards Institute (ANSI-AAMI SP10). To receive a copy of the report containing the AAMI SP10 results, contact the ZOLL Technical Service Department.

NIBP Accuracy:

NIBP accuracy has been verified utilizing clinical test methods which have been determined to meet the requirements of EN ISO 81060-2:2012.

Invasive Pressures

Number of Channels: 3

Pressure range: -30 to 300 mmHg

Pressure Accuracy: +/- 2 mmHg or 2% of reading, whichever is greater, plus transducer error.

Pulse Rate Range: 25 to 250 BPM

Pulse Rate Accuracy: +/- 3 BPM, or +/- 3% of value whichever is greater

Pulse Rate Display: Average of last 4 beat-to-beat intervals.

Zero Adjust: + / - 200 mmHg

Transducer:

Sensitivity: 5uV/V/mmHg

Offset: +/- 125 mmHg including transducer offset

Excitation Impedance Range: 150 to 10,000 ohms

Excitation Voltage: 4.75 +/- 0.25 VDC

Connector: 6-pin circular MS3100 series

Connect to:	A	B	C	D	E
Signal Type	Sig (-)	Exc (+)	Sig (+)	Exc (-)	shield

Temperature

Number of Channels: 2

Measurement Range: 0° to 50° C

Accuracy:

± 0.1° C from 10° C to 50° C, plus probe error

± 0.2° C from 0° C to 10° C, plus probe error

Resolution: 0.1° C

Scale: Fahrenheit or Celsius.

Temperature Display Signal: 20Hz, no averaging.

Probe: YSI 400 and 700 series

Mode of Operation: Direct mode

Display: T1, T2, ΔT

Minimum Measurement Time: See the probe's Instructions for Use to obtain minimum measurement times for accurate readings. The Propaq MD does not add any clinically significant time to obtain accurate readings.

Clinical Trial Results for the 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 electrodes.

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	–0.021% 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.

Randomized Multi-Center Clinical trial for Cardioversion of Atrial Fibrillation (AF)

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 cardioversion of their atrial fibrillation. A total of 173 patients entered the study. Seven (7) patients who did not satisfy all protocol criteria were excluded from the analysis. ZOLL disposable gel electrodes with surface areas of 78 cm^2 (anterior) and 113 cm^2 (posterior) were used exclusively for the study.

Objective: The primary goal of the study was to compare the total efficacy of four consecutive rectilinear biphasic shocks (70J, 120J, 150J, 170J) with four consecutive monophasic shocks (100J, 200J, 300J, 360J). The significance of the multiple shocks efficacy was tested statistically via two procedures, the Mantel-Haenszel statistic and the log-rank test, significance level of p=0.05 or less was considered statistically significant. The data are completely analogous to the comparison of two “survival” curves using a life-table approach where shock number plays the role of time.

The secondary goal was to compare the first shock success of rectilinear biphasic and monophasic waveforms. A significance level of p=0.05 or less was considered statistically significant using Fisher Exact tests. Also, differences between the two waveforms were considered statistically significant when the 95% confidence interval between the two waveforms was greater than 0%.

Results: The study population of 165 patients had a mean age of 66±12 years with 116 male patients.

The total efficacy of consecutive rectilinear biphasic shocks was significantly greater than that of monophasic shocks. The following table displays the Kaplan-Meier (product-limit) "survival" curves for each of the two waveforms. As all patients begin in the failure mode, the estimated life-table probabilities refer to the chance of still being in failure after the k^{th} shock (k=1,2,3,4):

Table A-3. Kaplan-Meier Estimate for the Probability of Shock Failure

Shock #	Biphasic	Monophasic
0	1.000	1.000
1	0.318	0.792
2	0.147	0.558
3	0.091	0.324
4	0.057	0.208

As can be seen from the table, the Biphasic experience is superior over the entire course of shocks delivered. The one degree of freedom chi-square statistic for the Mantel-Haenszel test is 30.39 ($p<0.0001$). Similarly, the log-rank test, also a one degree of freedom chi-square statistic, is 30.38 ($p<0.0001$). The residual number of patients not successfully treated after four shocks is 5.7% for biphasic compared to 20.8% for monophasic.

There was a significant difference between the first shock efficacy of biphasic shocks at 70J of 68% and that of monophasic shocks at 100J of 21% ($p=0.0001$, 95% confidence interval of the difference of 34.1% to 60.7%).

Successful cardioversion with rectilinear biphasic shocks was achieved with 48% less delivered current than with monophasic shocks (11±1 vs. 21±4 A, $p<0.0001$).

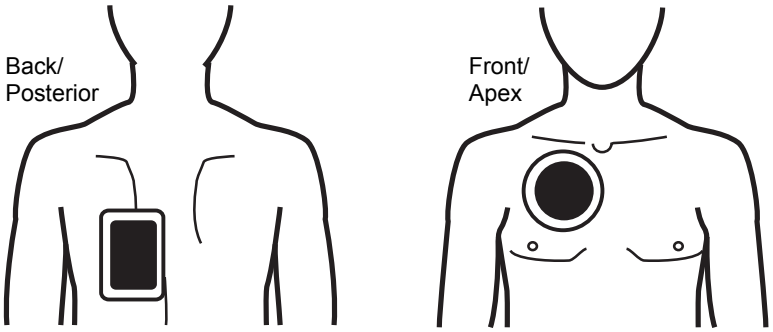
One half of the patients who failed cardioversion after four consecutive escalating monophasic shocks were subsequently successfully cardioverted using a biphasic shock at 170J. No patient was successfully cardioverted using a 360J monophasic shock after the patient had failed cardioversion with biphasic shocks.

Conclusion: The data demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to high energy monophasic shocks for transthoracic cardioversion of atrial fibrillation. There were no unsafe outcomes or adverse events due to the use of Rectilinear Biphasic Waveform.

Synchronized Cardioversion of Atrial Fibrillation

Cardioversion of atrial fibrillation (AF) and overall clinical effectiveness is enhanced by proper pad placement. Clinical studies (refer to above) of the M Series Biphasic Defibrillator Waveform demonstrated that high conversion rates are achieved when defibrillation pads are placed as shown in the following diagram.

Recommended Anterior/Posterior Placement



Place the front (apex) pad on the third intercostal space, mid clavicular line on the right anterior chest. The back/posterior pad should be placed in the standard posterior position on the patient's left as shown.

Electromagnetic Compatibility Guidance and Manufacturer's Declaration

In-Flight Use (RTCA/DO-160):

The Propaq MD unit complies with RTCA/DO-160, Environmental Conditions and Test Procedures for Airborne Equipment, using the methods in Section 21, Category M for Radiated and Conducted Radio Frequency Energy.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Propaq MD unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Propaq MD unit should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF Emissions CISPR 11</td><td>Group 1</td><td>The Propaq MD unit 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.</td></tr>
<tr><td>RF emissions CSPR 11</td><td>Class B</td><td rowspan="3">The Propaq MD unit 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 used for domestic purposes.</td></tr>
<tr><td>Harmonic emission IEC 6100-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC 61000-3-3</td><td>Complies</td></tr>
<tr><td colspan="3">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.</td></tr>
</table>

Electromagnetic Immunity (IEC 60601-1-2)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Propaq MD unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Propaq MD 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	± 2 kV for power supply lines ± 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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	<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	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Propaq MD unit requires continued operation during power mains interruptions, it is recommended that the Propaq MD unit be powered from an uninterruptible power supply or a battery.
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: U_T is the AC mains voltage prior to application of the test level.			

Electromagnetic Immunity: Life-Supporting Functions

Life-supporting functions of the Propaq MD include: ECG waveform monitoring from leads or pads, the pacing pulse output, QRS detection, defibrillation energy discharge, and shock advisory functions.

Guidance and manufacturer's declaration – electromagnetic immunity – for life-supporting equipment and systems

The life-supporting functions of the Propaq MD are intended for use in the electromagnetic environment specified below. The customer or user of the Propaq MD should ensure 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 Propaq MD, 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]	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters.[b] Field strengths from fixed RF transmitters, as determined by 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 and 800 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 Propaq MD is used exceeds the applicable RF compliance level above, the Propaq MD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Propaq MD.

d. Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 10 V/m.

Electromagnetic Immunity: Non Life-Supporting Functions

Non life-supporting functions of the Propaq MD include: 12-lead ECG, $EtCO_2$, SpO_2, SPCO, SpMet, NIBP, IBP, Temp, Impedance Respiration.

Guidance and manufacturer's declaration – electromagnetic immunity – for non–life supporting equipment and systems

The non life-supporting functions of the Propaq MD are intended for use in the electromagnetic environment specified below. The customer or user of the Propaq MD should ensure 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 Propaq MD, 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[a]	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3 (IBP)	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3 (all other non-life supporting functions)	3 V/m 80 MHZ to 2.5 GHz	10V/m	$d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and *d* is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 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. 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 Propaq MD is used exceeds the applicable RF compliance level above, the Propaq MD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Propaq MD.

b. Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances from RF Equipment for the Propaq MD Life-Supporting Functions

Life-supporting functions of the Propaq MD include: ECG waveform monitoring from leads or pads, the pacing pulse output, QRS detection, defibrillation energy discharge, and shock advisory functions.

Recommended separation distances between portable and mobile RF communications equipment and the Propaq MD

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

Rated maximum output power of equipment (in watts)	Separation distance according to frequency of transmitter (in meters)			
	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 $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	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 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.

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 distances 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.

Recommended Separation Distances from RF Equipment for the Propaq MD IBP Non Life-Supporting Function

Non life-supporting functions of the Propaq MD include: 12-lead ECG, $EtCO_2$, SpO_2, SPCO, SpMet, NIBP, IBP, Temp, Impedance Respiration.

Recommended separation distances between portable and mobile RF communications equipment and the Propaq MD

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

Rated maximum output power of equipment (in watts)	Separation distance according to frequency of transmitter (in meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.
NOTE 1: At 80 MHz and 800 MHz, the separation distance for 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.

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 the following table 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 displays *SHOCK ADVISED* message.

Clinical Performance Results

The performance of the incorporated analysis algorithm in a single analysis sequence satisfies the applicable requirements specified in ANSI/AAMI DF80 (section 6.8.3) and the recommendations by Kerber et al. (Circulation. 1997;95(6):1677).

Table A-4. Clinical Performance Results with Standard Analysis Algorithm

Rhythms	Sample Size	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	536	>90%	>99%	>99%
Rapid VT	80	>75%	>99%	>96%
Non-shockable		**Specificity**		
NSR	2210	>99%	>99%	>99%
AF, SB, SVT, Heart block, idioventricular, PVCs	819	>95%	>99%	>99%
Asystole	115	>95%	>99%	>97%
Intermediate			**Sensitivity**	
Fine VF	69	Report only	>89%	>81%
Other VT	28	Report only	>96%	>84%

Table A-5. Clinical Performance Results with ExpressShock

Rhythms	Sample Size	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	342	>90%	>98%	>97%
Rapid VT	58	>75%	>98%	>94%
Non-shockable		**Specificity**		
NSR	419	>99%	>99%	>99%
AF, SB, SVT, Heart block, idioventricular, PVCs	1631	>95%	>99%	>98%
Asystole	841	>95%	>99%	>99%
Intermediate			Sensitivity	
Fine VF	50	Report only	>92%	>82%
Other VT	51	Report only	>98%	>91%

References:

Young KD, Lewis RJ: “What is confidence? Part 2: Detailed definition and determination of confidence intervals”. Annals of Emergency Medicine, September 1997; 30; 311-218

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

Shock Conversion Estimator

Use of a defibrillator shock is currently the best option for terminating ventricular fibrillation and restoring a life sustaining ECG rhythm [1]. Maintaining blood flow through the heart via cardiopulmonary resuscitation (CPR) has been shown to improve the chances of a successful defibrillation [1]. The cessation of blood flow through the heart that occurs when CPR is stopped decreases the likelihood of a successful shock in proportion to the amount of time that has elapsed without CPR [1]. The repeated use of defibrillator shocks that do not restore a life sustaining rhythm may cause additional damage to the myocardium and reduce the patient's chances for survival. The use of an accurate shock outcome predictor can help reduce the duration of CPR interruptions and the number of ineffective (non-converting) shocks delivered.

Properly performed CPR has been shown to increase blood flow to the heart and increase the neurologically intact patient survival rate [2]. The rescuer must stop CPR while the patient's rhythm is analyzed to determine whether it is shockable. If the rhythm can be identified as unlikely to convert, CPR can be resumed faster rather than delivering ineffective shocks. This reduction in total shocks delivered reduces the damage sustained by the heart during resuscitation.

The Shock Conversion Estimator (SCE) is applied to the analysis result. SCE computes a Shock Prediction Index (SPI) number which measures the probability that a shockable rhythm will be successfully converted by immediate defibrillation. The SPI number is directly related to the AMSA measure developed by the Weil Institute of Critical Care Medicine [3].

The Shock Conversion Estimator algorithm was developed and tested using data collected from a registry of ZOLL AED Pro® and AED Plus® defibrillator field cases. Since the AED Pro and AED Plus defibrillators are first responder units, all patient records correspond to first responder cardiac arrest situations. The defibrillator shock results from these cases were annotated as “converted” if a transient return of spontaneous circulation (tROSC) occurred following the shock. tROSC was defined as post shock ECG rhythms meeting both of the following characteristics:

1. Spontaneous ECG rhythms lasting at least 30 seconds that began within 60 seconds after shock delivery; and
2. Rhythms exhibiting a heart rate of 40 beats per minute or more.

The post shock rhythm was annotated as “non-converted” if it exhibited any other conversion outcome, e.g. VF, VT, and asystole.

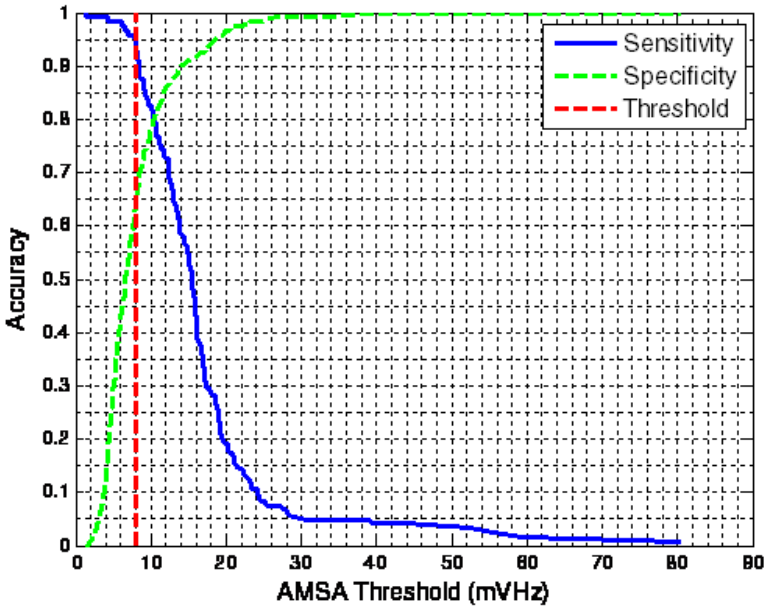
The total database consisted of 258 patient records containing 586 shocks. The first 109 patient records were used in the Validation Database which consisted of 251 delivered shocks. The Development Database was constructed from the remaining patient records, 149 patients, resulting in 335 delivered shocks.The Development Database was used to develop the algorithm and the Test Database was used to validate the performance of the algorithm.

The figure below presents the sensitivity and specificity curves for the combined datasets. The vertical line indicates the position of the 7.9 mV-Hz threshold. 7.9 mV-Hz correlates to a sensitivity and specificity of 95% and 63%, respectively.

The preferred treatment for non-converting rhythms may be the delivery of aggressive CPR. The use of the SPI measure to determine when shock treatments are likely to succeed will help minimize time between the advisory decision and the start of CPR. Minimizing non-perfusing time during resuscitation is a key contributor to improving patient outcomes [4].

$$\text{Sensitivity} = \frac{\text{Number of ECG Rhythms with SPI} > \text{Threshold that were successfully converted}}{\text{Total number of ECG rhythms that were successfully converted}}$$

$$\text{Specificity} = \frac{\text{Number of ECG rhythms with SPI} \leq \text{Threshold that did not convert}}{\text{Total number of ECG rhythms that did not convert}}$$



Sensitivity and Specificity Curves vs. SPI (mV-Hz) for the Combined Database

References:

[1] Eftestol T, Sunde K, Steen PA. Effects of Interrupting Precordial Compressions on the Calculated Probability of Defibrillation Success during Out-of-Hospital Cardiac Arrest. Circulation 2002; 105:2270-2273.

[2] Sota Y, Weil MH, Sun S, Tang W. Xie J, Noc M, Bisera J. Adverse effects of interrupting precordial compression during cardiopulmonary resuscitation. Critical Care Medicine 1997; 25:733-736.

[3] Young C, Bisera J, Gehman S, Snyder D, Tang W, Weil MH. Amplitude spectrum area: measuring the probability of successful defibrillation as applied to human data. Critical Care Medicine 2004; 32:S356-S358.

[4] Wik L. Rediscovering the importance of chest compressions to improve the outcome from cardiac arrest. Resuscitation 2003; 58:267-269.

Wireless Output Guidance and Manufacturer's Declaration

RF Transmission Emitted (IEC 60601-1-2)

The Propaq MD unit complies with IEC 60601-1-2 for medical electrical equipment and medical electrical systems that include RF transmitters as specified below.

Standard	Frequency Range	Effective Radiated Power	Modulation Type	Data Rates
802.11b	2412-2472 MHz	100 mW	DSSS	1, 2, 5.5, 11 Mbps
802.11g	2412-2472 MHz	32 mW	OFDM	6, 9, 12, 24, 36, 48, 54 Mbps
802.11n	2412-2472 MHz	32 mW	OFDM	6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps
Bluetooth	2400-2483.5 MHz	10 mW	FHSS; GFSK/ DQPSK/8DPSK	1, 3 Mbps
802.11a	5180-5320 MHz 5500-5700 MHz 5745-5825 MHz	32 mW	OFDM	6, 9, 12, 24, 36, 48, 54 Mbps
802.11n	5180-5320 MHz 5500-5700 MHz 5745-5825 MHz	32 mW	OFDM	6.5, 13, 19.5, 26, 39, 52, 58.5, 65 Mbps

FCC Notice

ZOLL Medical Corporation has not approved any changes or modifications to this device by the user. Any changes or modifications could void the user's authority to operate the equipment. See 47 CFR Section 15.21.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. See 47 CFR Section 15.19(a)(3).

The user is cautioned to maintain 20cm (8 inches) of space from the product to ensure compliance with FCC requirements.

This device is limited to indoor use in the 5150MHz to 5250MHz band.

Canada, Industry Canada (IC) Notices

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Appendix B
Accessories

The following accessories are compatible for use with the Propaq MD unit. To order any of these items, contact your local ZOLL representative.

ECG Accessories
ECG, 3-Lead Cable, AAMI
ECG, 3-Lead Cable, IEC
ECG, 5-Lead Cable, AAMI
ECG, 5-Lead Cable, IEC
ECG, 12-Lead “Breakaway” Patient Cable Complete (Trunk Cable, 4-lead wire set with detachable 6 “V” precordial lead wire set), AAMI
ECG, 12-Lead “Breakaway” Patient Cable Complete (Trunk Cable, 4-lead wire set with detachable 6 “V” precordial lead wire set), IEC
ECG, 4-Lead “Breakaway” Trunk Cable and 4 lead wire set only, AAMI
ECG, 4-Lead “Breakaway” Trunk Cable and 4 lead wire set only, IEC
ECG, Detachable 6 precordial lead wire set for “Breakaway” 12-Lead Patient Cable, AAMI
ECG, Detachable 6 precordial lead wire set for “Breakaway” 12-Lead Patient Cable, IEC

CO_2 Accessories (Oridion Filterlines)
Smart CapnoLine Plus, Non-intubated filterline with O_2 Delivery, Adult, box of 25
Smart CapnoLine Plus, Non-intubated filterline with O_2 Delivery, Pediatric, box of 25
FilterLine H Set, Adult/Pediatric, box of 25
FilterLine H Set, Infant/Neonate, box of 25
FilterLine Set, Adult/Pediatric, box of 25
VitaLine H set Adult/Pediatric, box of 25
NIBP Accessories
Hoses
Hose, Infant/Neonate, 8', w/ female luer cuff connector, single lumen
Hose, Adult/Pediatric, 10', w/ “twist lock” cuff connector, dual lumen
Hose, Adult/Pediatric, 5', w/ “twist lock” cuff connector, dual lumen
Reusable Cuffs (Welch Allyn Blood Pressure Flexiport Cuffs)
Neonate #1, 3.3 - 5.6 cm single tube w/ male luer connector, box of 10
Neonate #2, 4.2 - 7.1 cm single tube w/ male luer connector, box of 10
Neonate #3, 5.4 - 9.1 cm single tube w/ male luer connector, box of 10
Neonate #4, 6.9 - 11.7 cm single tube w/ male luer connector, box of 10
Neonate #5, 8.9 - 15.0 cm single tube w/ male luer connector, box of 10
Neonatal Cuff Kit, one each of sizes #1 - #5, single tube w/ male luer connector, bag of 5
Welch Allyn REUSE-07-2MQ Cuff, Infant, 2-Tube, Twist lock connector
Welch Allyn REUSE-08-2MQ Cuff, Small Child, 2-Tube, Twist lock connector
Welch Allyn REUSE-09-2MQ Cuff, Child, 2-Tube, Twist lock connector
Welch Allyn REUSE-10-2MQ Cuff, Small Adult, 2-Tube, Twist lock connector
Welch Allyn REUSE-11-2MQ Cuff, Adult, 2-Tube, Twist lock connector
Welch Allyn REUSE-11L-2MQ Cuff, Adult Long, 2-Tube, Twist lock connector
Welch Allyn REUSE-12-2MQ Cuff, Lg Adult, 2-Tube, Twist lock connector
Welch Allyn REUSE-12L-2MQ Cuff, Lg Adult Long, 2-Tube, Twist lock connector
Welch Allyn REUSE-13-2MQ Cuff, Thigh, 2-Tube, Twist lock connector

SpO_2 Accessories
Rainbow R25, Single use sensor for patients > 30 kg
Rainbow R25-L, Single use sensor for patients < 3kg, > 30 kg
Rainbow R20, Single use sensor for Pediatrics 10 - 50 kg
Rainbow R20-L, Single use sensor for Infants 3 - 10 kg
Rainbow Patient Cable RC-4, 4' Reusable Patient Cable
Rainbow Patient Cable RC-12, 12' Reusable Patient Cable
Rainbow DCI-dc8, 8' Adult Reusable Patient Cable / Sensor
Rainbow DCI-dc12, 12' Adult Reusable Patient Cable / Sensor
Rainbow DCIP-dc8, 8' Pediatric Reusable Patient Cable / Sensor
Rainbow DCIP-dc12, 12' Pediatric Reusable Patient Cable / Sensor
Red DBI-dc8, 8’ Reusable Direct Connect Sensor, Masimo Rainbow Set
Rainbow DCI Adult Reusable Patient Cable/Sensor (12 ft)
Rainbow Adult Reusable Sensor (3 ft)
SpO2/SpCO/SpMet Rainbow DCI Adult Reusable Patient Cable/Sensor (12 ft)
Rainbow DCI SC-200 Adult Reusable Finger Sensor (SpHb, SpMet, SpO2), 3 ft. Sensor includes 200 SpHb Tests.
Rainbow DCI SC-200 Pediatric Reusable Finger Sensor (SpHb, SpMet, SpO2), 3 ft. Sensor includes 200 SpHb Tests.
Rainbow DCI SC-400 Adult Reusable Finger Sensor (SpHb, SpMet, SpO2), 3ft. Sensor includes 400 SpHb Tests.
Rainbow DCI SC-400 Pediatric Reusable Finger Sensor (SpHb, SpMet, SpO2), 3ft. Sensor includes 400 SpHb Tests.
Rainbow R1-25L Adult Adhesive Sensors - SpHb, SpO2, SpMet box of 10
Rainbow R1-20L Infant Adhesive Sensors - SpHb, SpO2, SpMet box of 10
Rainbow R1-25 Butterfly Adult Adhesive Sensors (SpHb, SpO2, SpMet) box of 10
Rainbow R1-20 Butterfly Pediatric Adhesive Sensors (SpHb, SpO2, SpMet) box of 10
M-LNCS™ ADTX, Adult SpO2 adhesive sensor, > 30 kg. Single-patient use only
M-LNCS™ Pdtx-3, Pediatrics SpO2 adhesive sensor, 3 ft. cable, 10-50 kg. Single-patient use only
M-LNCS™ NeoPt-3, Neonatal SpO2 adhesive sensor, 3 ft. cable, < 1 kg. Single-patient use only
M-LNCS™ Inf-3, Infant SpO2 adhesive sensor, 3 ft. cable, 3-20 kg. Single-patient use only

Temperature Accessories
YSI Reusable Adult, Skin Probe
YSI Reusable Pediatric, Skin Probe
YSI Reusable Adult, Esophageal/Rectal
YSI Reusable Pediatric, Esophageal/Rectal
Sensor Adapter Cable for Disposable Probes
YSI Disposable Esophageal/Rectal Probe
YSI Disposable Skin Probe
Defibrillation Accessories
Propaq MD Multifunction Therapy Cable - allows use of disposable multifunction electrodes and ZOLL M Series CCT External and Internal paddles (sold separately)
M Series External Paddles set with controls and built-in pediatric electrodes
ZOLL Sterilizable Internal Handle (black), with Switch, 1.0" spoon, 10' cable (US only) or 7’ cable
ZOLL Sterilizable Internal Handle (black), with Switch, 1.6" spoon, 10' cable (US only) or 7’ cable
ZOLL Sterilizable Internal Handle (black), with Switch, 2.0" spoon, 10' cable (US only) or 7’ cable
ZOLL Sterilizable Internal Handle (black), with Switch, 2.7" spoon, 10' cable (US only) or 7’ cable
ZOLL Sterilizable Internal Handle (black), with Switch, 3.0" spoon, 10' cable (US only) or 7’ cable
ZOLL Sterilizable Internal Handle (black), without Switch, 1.0" spoon, 10' cable
ZOLL Sterilizable Internal Handle (black), without Switch, 1.6" spoon, 10' cable
ZOLL Sterilizable Internal Handle (black), without Switch, 2.0" spoon, 10' cable
ZOLL Sterilizable Internal Handle (black), without Switch, 2.7" spoon, 10' cable
ZOLL Sterilizable Internal Handle (black), without Switch, 3.0" spoon, 10' cable
ZOLL Defibrillation Gel
ZOLL OneStep cable
ZOLL Multifunction Therapy Cable with CPR-D connector
ZOLL Multifunction Therapy Cable CPRD Adapter
CPR stat-padz HVP Multifunction CPR Electrodes - 8 pair/case
CPR stat-padz HVP Multifunction CPR Electrodes - 1 pair
Electrode, pedi-padz II, NO OVERBOX, single
Electrode, pedi-padz II, NO OVERBOX, 6/case
OneStep Resuscitation Electrode (8 per case)
OneStep Pacing Resuscitation Electrode (8 per case)

OneStep CPR Resuscitation Electrode (8 per case)
OneStep Complete Resuscitation Electrode (8 per case)
OneStep CPR AA Electrode (8 per case)
Electrodes, OneStep Basic, Single, R Series
Electrodes, OneStep Pacing, Single, R Series
Electrodes, OneStep CPR, Single, R Series
Electrodes, OneStep Complete, Single, R Series
Electrodes, OneStep CPR AA, Single
Electrodes, OneStep Pediatric
Electrodes, OneStep Pediatric with CPR
Electrodes, OneStep BASIC, Single
CPR-D•padz One Piece Electrode Pad With Real CPR Help
Electrodes, CPR-D-padz w/o Accessory Kit
Set of 12 electrodes, stat-padz
Single, stat-padz
IBP Accessories
Transducer Interface cable – Abbott
Transducer Interface cable - Edwards
Transducers: 5 μV/V/mm Hg, IEC 60601-2-34 and AAMI BP-22 compliant
Compatible IBP Transducers
Abbott Transpac® IV
Edwards Truwave®
To purchase these transducers, contact your local Abbott or Edwards distributor.
CPR Accessories
CPR-D-padz
CPR-stat-padz
CPRD-to- Mulitfunction Therapy Cable Adapter
stat-padz
pedi-padz II
OneStep electrodes

Power Accessories
ZOLL SurePower II Rechargable Battery
SurePower Charger Station
SurePower II Battery Charger Battery Adapter
Auxiliary Power Adapter, 8300-0004
Replacement Power Cord – U.S.
Replacement Power Cord – Japan
Other Accessories
Propaq MD Soft Carrying Case
Propaq MD Backpack
ECG 80 mm Chart Recorder Paper
Cable adapter, USB to Ethernet
Multi-Tech Cell Modem; GSM Version
Multi-Tech Cell Modem; CDMA Version
Pre-Grid Paper
USB Cable Extension
Multi-Tech Cell Modem; GSM Version
Multi-Tech Cell Modem; CDMA Version
Multi-Tech Cell Modem External Antenna Kit, GSM Version
Pre-Grid Paper