

Automated External Defibrillator Technical Data

HeartSave myPAD



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PRIMEDIC
Saves Life. Everywhere.



Technical Data

DEFIBRILLATION

Operating modes	HeartSave myPAD Semi-automated external defibrillator HeartSave myPAD Fully-automated external defibrillator
Waveform type	Biphasic truncated exponential, auto-compensation according to patient impedance
Optional output energy	For adults: 150 J, 170 J, 200 J For children: 50 J
Default shock series	Default adult energy sequence: Level 1: 150 J Level 2: 170 J Level 3: 200 J

Default children energy sequence:

Level 1: 50 J

Level 2: 50 J

Level 3: 50 J

The energy configuration of the latter level must be greater than or equal to the energy of the previous level.

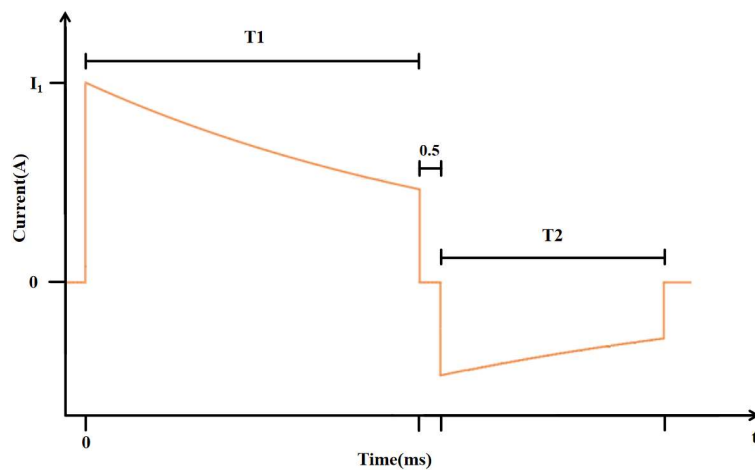
Meeting ERC guidelines 2021 and AHA guidelines 2020 by default

Delivered Energy
Accuracy

Mode	Impedance	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω
	Energy							
Child mode	50J	43	50	52	52	52	50	48
	150J	128	150	155	157	159	160	158
Adult mode	170J	147	170	178	184	188	189	184
	200J	173	200	209	216	222	223	217

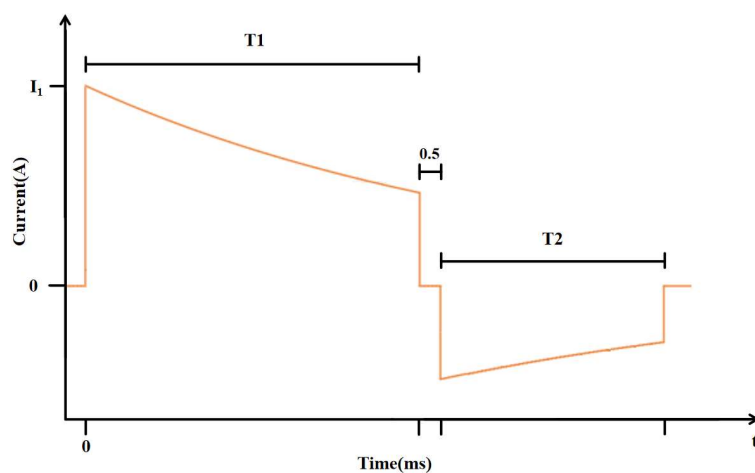
Data in J with tolerance of $\pm 15\%$.

Waveform parameters
(200J)



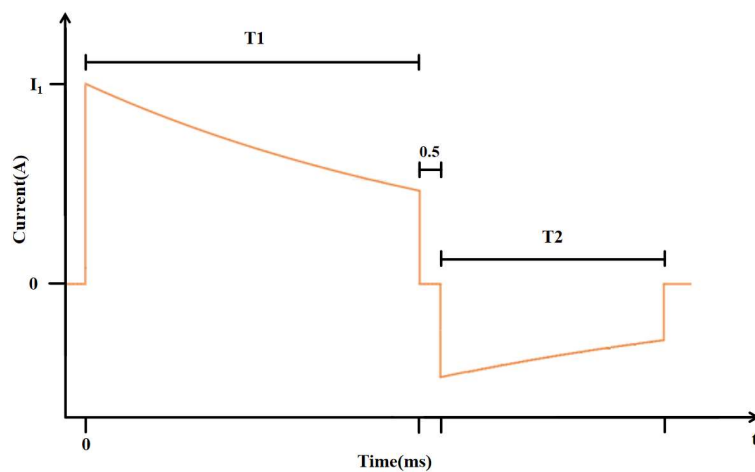
Impedance	I1/A	T1/ms	T2/ms	Energy/J
25Ω	64	2.8	2.8	173
50Ω	38	4.1	4.1	200
75Ω	27	6.3	4.3	209
100Ω	21	8.4	5.6	216
125Ω	17	10.4	7	222
150Ω	14	12	8	223
175Ω	13	12	8	217

Waveform parameters
(170J)



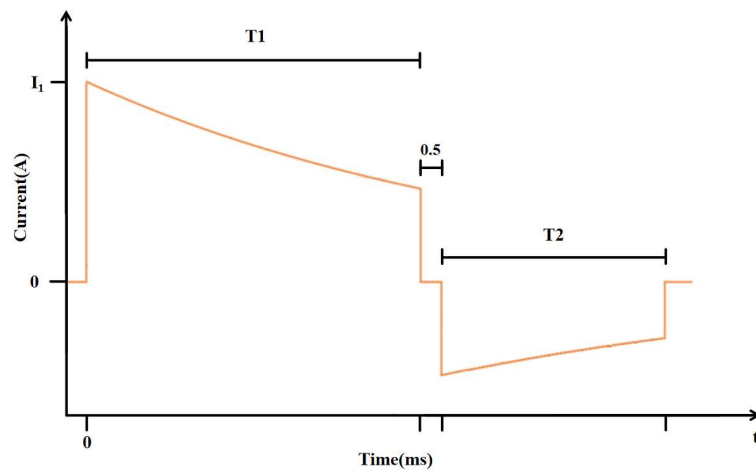
Impedance	I_1/A	T_1/ms	T_2/ms	Energy/J
25Ω	59	2.8	2.8	147
50Ω	35	4.1	4.1	170
75Ω	25	6.3	4.3	178
100Ω	19	8.4	5.6	184
125Ω	16	10.4	7	188
150Ω	13	12	8	189
175Ω	11	12	8	184

Waveform parameters
(150J)



Impedance	I_1/A	T_1/ms	T_2/ms	Energy/J
25Ω	55	2.8	2.8	128
50Ω	32	4.5	4.5	150
75Ω	23	6.3	5.0	155
100Ω	18	8.0	5.3	157
125Ω	14	9.7	6.4	159
150Ω	12	11.5	7.7	160
175Ω	11	12.0	8.0	158

Waveform parameters (50J)



Impedance	I_1/A	T_1/ms	T_2/ms	Energy/J
25Ω	32	2.8	2.8	43
50Ω	19	4.5	4.5	50
75Ω	13	6.3	5.0	52
100Ω	10	8.0	5.3	52
125Ω	8	9.0	6.0	52
150Ω	7	9.0	6.0	50
175Ω	6	9.0	6.0	48

Charge duration

Parameter of HeartSave for charging to first shock:

1) new BATTERY 3C

From switch on to charge 150/200 J done: no more than 17/22 s

From AED analysis to charge 150/200 J done: no more than 8/12 s

2) new BATTERY 3G

From switch on to charge 150/200 J done: no more than 13/16 s

From AED analysis to charge 150/200 J done: no more than 5/8 s

3) BATTERY 3C after 15 times of max energy discharges

From switch on to charge 150/200 J done: no more than 17/22 s

From AED analysis to charge 150/200 J done: no more than 8/12 s

4) BATTERY 3G after 15 times of max energy discharges

From switch on to charge 150/200 J done: no more than 13/16 s

From AED analysis to charge 150/200 J done: no more than 5/8 s

Applicable impedance range 25 - 200Ω

ELECTRODES

Manufacture	Baisheng Medical Co., Ltd.
Trade name and model	SavePads PLUS C OBS-DE/P 303A1206 (Adult and child without CPR feedback sensor) SavePads PLUS CS OBS-DE/P 303A1207 (Adult and child with CPR feedback sensor)
Standby life	Up to 48 months + 12 months shelf life (Standby life duration verified under environment condition of 25°C, higher ambient temperature may reduce lifetime)
Total area	117 ± 10 cm ²
Effective area	86 ± 10 cm ²
Cable length	1.40 ± 0.2 m
Maximum number of defibrillation shocks	50 shocks
Positioning of electrodes	Electrode placement depends on the patient's age. Refer to Section 7.5.2 for details
CPR feedback sensor	1 cable connected (for electrodes with CPR feedback sensor only)

SSCP
 (Summary of safety and clinical performance)

EUDAMED link preparation ongoing.

BATTERY

Model	BATTERY 3C (NRL03C) BATTERY 3G (NRL03G)
Battery type	LiMnO ₂ , 12V, 2.8Ah, non-rechargeable (NRL03C) Li-ion, 14.4V, 2.95Ah, rechargeable (NRL03G)
Standby life	BATTERY 3C: Up to 48 months + 12 months shelf life Condition: The device is powered by a new battery at 20 °C ± 5 °C of ambient temperature, weekly self-test, no switch on of device, no network connection. BATTERY 3G: Up to 12 years Condition: The device is powered by a new battery at 20 °C ± 5 °C of ambient temperature, weekly self-test, no switch on of device, no network connection, with charging cycle of no more than 500 times.
Operating time	BATTERY 3C Operate 9 hours by a new battery at 20°C ± 5°C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low, display brightness set to indoor. BATTERY 3G Operate 14 hours by a new battery at 20°C ± 5°C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low, display brightness set to indoor.
Discharge times	BATTERY 3C

	130 times 200 J discharge by a new battery at 20°C ± 5°C of ambient temperature, voice volume set to low, display brightness set to indoor.
	BATTERY 3G
	230 times 200 J discharge by a new battery at 20°C ± 5°C of ambient temperature, voice volume set to low, display brightness set to indoor.
Discharge times after shelf-life time	After shelf-life time of standby under storage condition, BATTERY 3C is expected to support approximately 6 times of shocks. BATTERY 3G is expected to support more than 6 times of shocks if fully charged.
Remaining charge after < Battery low > is prompted	When the remaining battery capacity is low, the device will announce < Battery low > when device switched on. Device can keep standby mode for more than 1 month. The device can perform at least 10 times 150J or 6 times 200 J discharge, then operate 40 minutes. (The device is powered by a battery at 20 °C± 5 °C of ambient temperature). If charging is no longer possible, the device automatically switches to cardiopulmonary resuscitation mode.
CPR FEEDBACK SPECIFICATION	Range of compression frequency: 100-120cpm. Accuracy of compression frequency: ±3cpm. Range of compression depth:50-60mm. Accuracy of compression depth: ±5 mm or ±10%, whichever is larger.
USB SPECIFICATION	
USB port	1 x USB Electrodes socket: serial communication port
WLAN SPECIFICATION	(if available)
WLAN standard	IEEE 802.11 b/g/n
Frequency	2.4 GHz
Maximum radiated output power	20.5 dBm EIRP (RF power including maximum antenna gain (3.37 dBi)
Wireless transmission rate	Max. 150 Mbps
LTE SPECIFICATION	(if available)
Channel	LTE-FDD: B1/B3/B7/B8/B20/B28A LTE-TDD: B38/B40/B41
Transmission power	LTE-FDD: 23±2 dBm LTE-TDD: 23±2 dBm
Standard	3GPP E-UTRA Release 11

COLOUR DISPLAY (if available)

Type	Colour LCD display (only for 675, 675A) Touch LCD display (only for 678, 678A)
Working mode	Auto, in-door, outdoor (Self-adjust display brightness based on environment brightness)
Size	4.3 inch (10,9 cm)
Resolution	800 x 480
ECG waveform animation	1-Channel

DATA STORAGE

Internal storage	8G
ECG wave	160 hours
Event	10 000 events
Audio log	32 hours
CPR data	160 hours
Self-test report	Minimum of 3,650 reports
Log data	100 000 events

MYPRIMEDIC CONFIG APP

Minimum requirement of device	iOS	Android
CPU	2.5 GHz	2.0 GHz
RAM	3 GB	6 +1 GB
Storage	64 GB	64 GB
Display	1792 x 828	2408 x 1080
Bluetooth	5.0	5.1
OS	iOS14	Android 11

SAFETY

Classification Device with internal power supply, Defibrillation-proof type BF

Identification

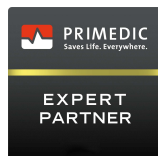


The product bears CE mark indicating its conformity with the provisions of the Medical Device Regulation (EU) 2017/745 concerning medical devices and fulfil the essential requirements of Annex I of this directive.

Classification IP66

ENVIRONMENT SPECIFICATION

Operating conditions	-5 °C to 55 °C, 0 to 95 % rel. humidity, but without condensation 540 hPa to 1062 hPa (The device supports operate at least 20 minutes under -20 °C if device is stored in terms of storage condition before)
Short term transport and storage conditions (<1 week)	-30 °C to 70 °C, 0 to 95 % rel. humidity, but without condensation 510 hPa to 1062 hPa
Long term transport and storage conditions (≥1 week)	-5 °C to 55 °C, 0 to 95 % rel. humidity, but without condensation 510 hPa to 1062 hPa
Dimensions (L x W x H)	670, 671, 670A, 671A: 151 mm x 151 mm x 73 mm (±2 mm) 675, 678, 675A, 678A: 151 mm x 151 mm x 76 mm (±2 mm)
Weight	670, 671, 670A, 671A: approx. 1.0 kg (±0.2 kg) 675, 678, 675A, 678A: approx. 1.1 kg (±0.2 kg)
Minimum lifetime with combined device, electrodes and battery	At least 4 years with storage condition of temperature 15°C-35°C, humidity ≤ 80%, air pressure 540hPa to 1060hPa.
Drop test	Test with height 1.6m.
Shock test	Complies with requirements of 10.1.3a), IEC 60601-1-12:2014+AMD1:2020 and 10.1.3, IEC 60601-1-11:2015+AMD1:2020 CSV
Vibration test	Complies with requirements of 10.1.3b), IEC 60601-1-12:2014+AMD1:2020 and 10.1.3, IEC 60601-1-11:2015+AMD1:2020 CSV
SOFTWARE INFORMATION OF THE DEVICE	AED embedded software (version: 01.00.00.00)



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