

Automated External Defibrillator Technical Data

HeartSave myPAD



ITALIANO

24548 EN
Revision: F
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PRIMEDIC
Saves Life. Everywhere.

 **KC4**

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.

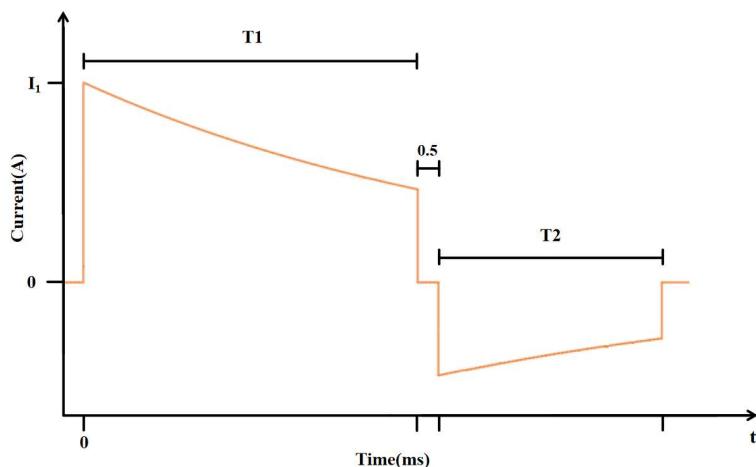
Meeting ERC guidelines 2021 and AHA guidelines 2020 by default

Delivered Energy Accuracy

| Mode | Impedance Energy | 25Ω | 50Ω | 75Ω | 100Ω | 125Ω | 150Ω | 175Ω |
|-------------------|------------------|-----|-----|-----|------|------|------|------|
| 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 $\pm 15\%$.

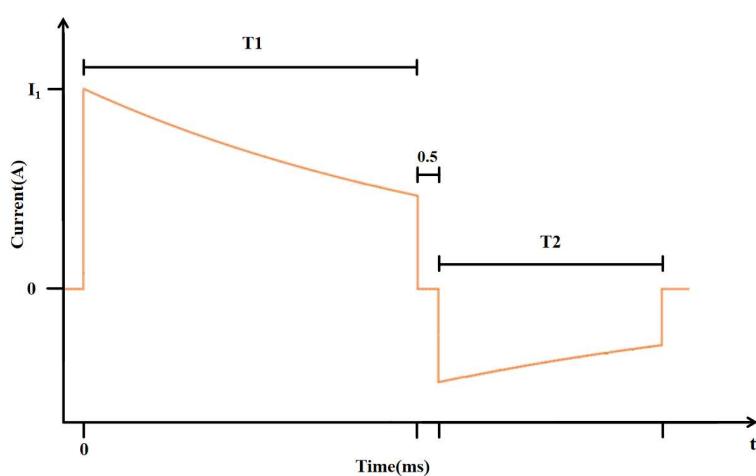
Waveform parameters (200J)



| 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 |

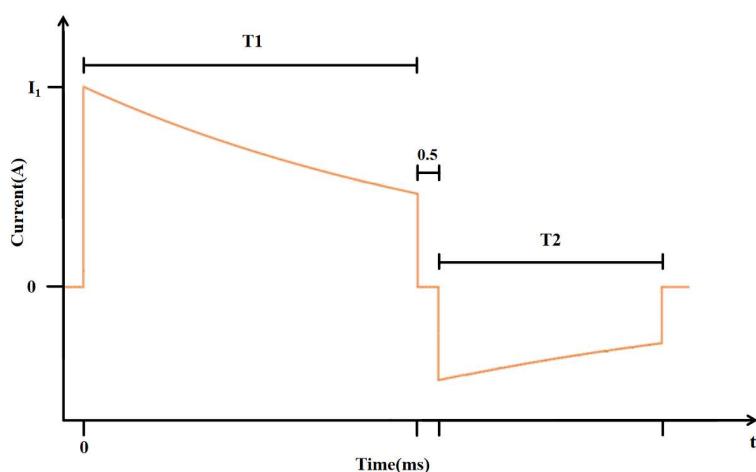


Waveform parameters
(170J)

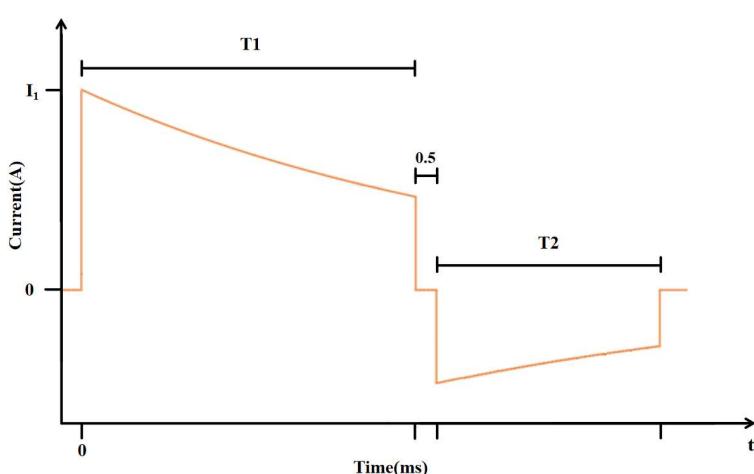


| Impedance | I1/A | T1/ms | T2/ms | Energy/J |
|-----------|------|-------|-------|----------|
| 25Ω | 59 | 2.8 | 2.8 | 147 |
| 50Ω | 35 | 4.1 | 4.1 | 170 |
| 75Ω | 25 | 6.3 | 4.3 | 178 |
| 100Ω | 19 | 8.4 | 5.6 | 184 |
| 125Ω | 16 | 10.4 | 7 | 188 |
| 150Ω | 13 | 12 | 8 | 189 |
| 175Ω | 11 | 12 | 8 | 184 |

Waveform parameters
(150J)



| Impedance | I1/A | T1/ms | T2/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
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

| | |
|-------------------------------|-------------------------------------------------------------------|
| 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

| | |
|--------------------|-------------------------------------------------------------------------|
| Channel | (if available) 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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