



Automated External Defibrillator Technical Data

HeartSave Y | YA



ITALIANO

24654 EN
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Appendix A: Technical Data

DEFIBRILLATION

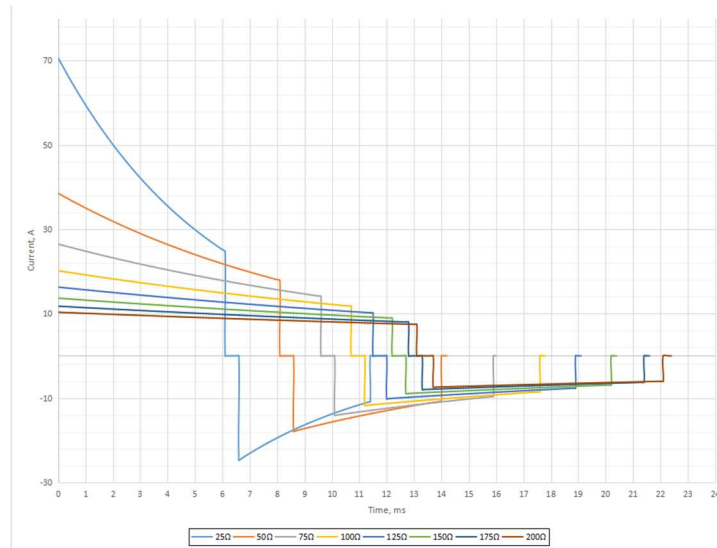
Operating modes	HeartSave Y series: semi-automated external defibrillator HeartSave YA series: fully-automated external defibrillator
Impulse shape	Biphasic truncated exponential, auto-compensation according to patient impedance.
Optional output energy	For adults: 100 J, 150 J, 170 J, 200 J, 300 J, 360 J For children: 10 J, 15 J, 20 J, 30 J, 50 J, 70 J, 100 J Refer to Chapter 8.3 for the configuration methods
Default Shock series	Default adult energy sequence: Level 1: 200 J Level 2: 300 J Level 3: 360 J Default children energy sequence: Level 1: 50 J Level 2: 70 J Level 3: 100 J Shocks: Level 1, level 2, and level 3 can be configured, 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

360J defibrillation waveform into impedance into of 25Ω, 50Ω, 75Ω, 100Ω, 125Ω, 150Ω, 175Ω

R (Ω)	25	50	75	100	125	150	175
10	9.7	10	9.7	9.3	8.9	8.5	8.1
15	15	15	15	14	13	13	12
20	20	20	20	19	18	17	16
30	29	30	29	28	27	25	24
50	49	50	49	47	45	43	41
70	68	70	68	65	62	60	57
100	97	100	97	93	89	85	81
150	146	150	146	140	134	128	122
170	166	170	166	159	151	145	138
200	195	200	195	187	178	170	163
300	292	300	292	280	267	255	244
360	351	360	350	336	321	306	293

Data in J with tolerance of $\pm 2J$ or $\pm 10\%$, the higher of the two.

Waveform parameters



Charge time

When bring the device from the specified AED wall cabinet, the parameter of HeartSave Y|YA charging for first shock as below:

1) new battery

From open device lid to charge 200 J done: no more than 7s
From open device lid to charge 360 J done: no more than 14s
From AED analysis to charge 200 J done: no more than 5s
From AED analysis to charge 360 J done: no more than 12s

2) new battery after 15 time of 360 J discharges

From open device lid to charge 200 J done: no more than 7s
From open device lid to charge 360 J done: no more than 14s
From AED analysis to charge 200 J done: no more than 5s
From AED analysis to charge 360 J done: no more than 12s

Applicable impedance range 25 - 300Ω

ELECTRODES

Manufacture

Model

Baisheng Medical Co., Ltd.

OBS-DE/P(303A1204): Disposable electrodes

OBS-DE/P(303A1205): Disposable electrodes with CPR feedback sensor

Lifetime with sealed pouch

at least 5 years

Total area

105 ± 10 cm²

Maximum number of
defibrillation shocks

Up to 50 shocks

SSCP

EUDAMED link preparation ongoing.

(Summary of safety and
clinical performance)

BATTERY

Model	Battery 1A (NRL01A), Battery 1C (NRL01C) (both model are applicable for all models of Heart Y YA series)
Battery type	LiMnO ₂ , 24V, 2.4Ah, non-rechargeable (NRL01A) LiMnO ₂ , 12V, 4.2Ah, non-rechargeable (NRL01C)
Standby life	at least 5 years
Operating time	150 times 360 J discharge by a new battery at 20 °C ± 5 °C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low. Operate 12 hours by a new battery at 20 °C ± 5 °C of ambient temperature, not performing defibrillation charges or discharges, voice volume set to low.
Remaining charge after < Battery low > is prompted	When the remaining battery capacity is significantly reduced, the device will announce < Battery low >. At least 6 times 360 J discharge or operate 30 minutes. (The device is powered by a battery at 20 °C ± 5 °C of ambient temperature, not performing defibrillation charges or discharges.). If charging is no longer possible, the device automatically switches to cardiopulmonary resuscitation.

USB SPECIFICATION


USB port	1 port: USB 2.0
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WLAN SPECIFICATION (only available on device with WLAN module)

WLAN standard	IEEE802.11 b/g/n
Frequency & channel	Station mode: 2.4 GHz, channel 1-13 Access Point mode: 2.4 GHz, channel 1-11
Maximum conducted output power	15dBm
Maximum radiated output power	18 dBm EIRP (RF power including maximum antenna gain (3 dBi))
Safety	WPA/WPA2/WPA3, EAP-TLS, PEAP

LTE SPECIFICATION (only available on device with LTE module)

Channel	LTE-FDD: B1/B3/B5/B7/B8/B20/B28 LTE-TDD: B38/B40 GSM: EGSM900/DCS1800
Transmission power	EGSM900: 33±2 dBm DCS1800: 30±2 dBm LTE-FDD: 23±2 dBm LTE-TDD: 23±2 dBm
Standard	3GPP E-UTRA Release 11

COLOUR DISPLAY	(only available on device with colour display)
Type	Colour LCD display
Working mode	Auto, indoor, outdoor (Self-adjust display brightness based on environment brightness)
Size	4.3 inch
Resolution	800 x 480
ECG Wave	1-Channel
DATA STORAGE	
ECG wave	10 hours
event	2000 events
Audio log	2 hours
self-test report	3650 reports
SAFETY	
Classification	Device with internal power supply, Defibrillation-proof type BF
Identification	 <p>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.</p>
Classification	IP55
ENVIRONMENT SPECIFICATION	
Operating conditions	-5°C to 55 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Transportation and storage conditions	Short term (≤ 1 week): -30 °C to 70 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa Long term (> 1 week): 15 °C to 35 °C, 5 to 95 % rel. humidity, but without condensation 570 hPa to 1062 hPa
Dimensions (L x W x H)	29.6 cm x 22.0 cm x 9.7 cm (± 0.1 cm)
Weight	approx. 2.5 kg (with energy module, battery and electrodes) (± 0.3 kg)
Minimum lifetime with combined device, electrodes and battery	At least 2 years with storage condition of temperature 15°C-35°C, humidity $\leq 80\%$, air pressure 570hPa to 1062hPa.

Shock test	Complies with requirements of 10.1.3a), IEC 60601-1-12:2014
Vibration test	Complies with requirements of 10.1.3b), IEC 60601-1-12:2014
Drop test	1.6m, complies with requirement of EN1789:2007+A2:2014
 OTHER	
Standards applied	Standards (for licensing in the EU, the corresponding harmonised European standards EN were used instead of the IEC standards): IEC 60601-1:2005+AMD1:2012+AMD2:2020 IEC 60601-1-2:2014+AMD1:2020 IEC 60601-2-4:2010+AMD1:2018 IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 IEC 62366-1:2015+A1:2020 IEC 62304: 2006+AMD1:2015 IEC 60601-1-12:2014+A1:2020



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