E . Device Specifications

Model Name: CU-SP1

Physical	
Category	Nominal Specifications
Dimensions	260㎜ x 256㎜ x 69.5㎜ (Width x Length x Height)
Weight	2.4㎏ (Including the battery pack and pads)

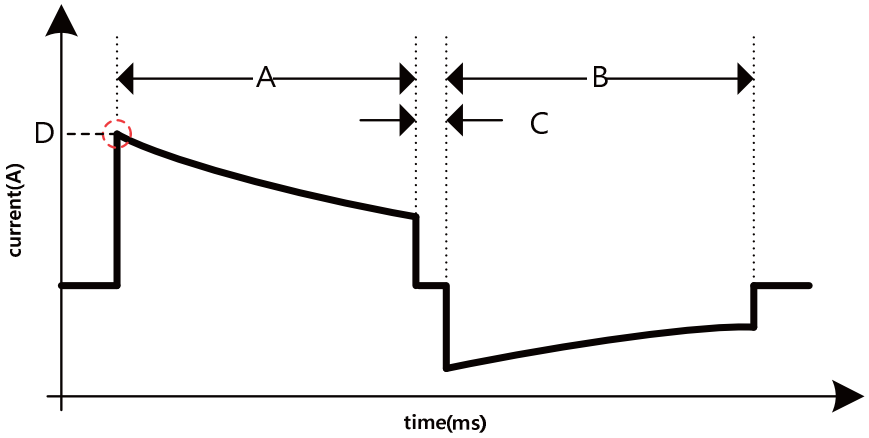
Environmental	
Category	Nominal Specifications
Operational Status (The device is in emergency use)	
	Temperature: 0℃ ~ 43℃ (32˚F ~ 109˚F)
	Humidity: 5% ~ 95% (non condensing)
Storage Status (The device is stored together with the defibrillator pads and the battery pack is inserted - ready to be used in an emergency)	
	Temperature: 0℃ ~ 43℃ (32˚F ~ 109˚F)
	Humidity: 5% ~ 95% (non condensing)
Transport Status (device only, no defibrillator pads and battery pack included)	
	Temperature: -20℃ ~ 60℃ (-4˚F ~ 140˚F)
	Humidity: 5% ~ 95% (non condensing)
Altitude	0 to 15,000 feet (operational and storage)
Drop	Withstands 1.2-meter drop to any edge, corner, or surface
Vibration	Operating: Meets MIL-STD-810G Fig.514.6E-1, random
	Standby: Meets MIL-STD-810G Fig.514.6E-2, swept sine(helicopter)
Sealing	IEC 60529: IP55
ESD	Meets IEC 61000-4-2:2001
EMI (Radiated)	Meets IEC 60601-1-2 limits, method EN 55011:2007 +A2:2007, Group 1, Class B
EMI (Immunity)	Meets IEC 60601-1-2 limits, method EN 61000-4-3:2006 +A1:2008 Level 3 (10V/m 80MHz to 2500MHz)

Defibrillator

Category	Nominal Specifications
Operating Mode	Semi-automated
Waveform	e-cube biphasic (Truncated exponential type)
Output Energy	150 J at 50 Ω load for adults 50 J at 50 Ω load for children
Charge Control	Controlled by an automated patient analysis system
Charging Time	Within 10 seconds from when the voice instruction, "An electric shock is needed." is issued.

Time from initiation of rhythm analysis (voice instruction: "DO NOT TOUCH PATIENT, ANALYZING HEART RHYTHM") to readiness for discharge (voice instruction: "PRESS THE FLASHING ORANGE BUTTON, NOW. DELIVER SHOCK, NOW")	New battery pack 10 Seconds, typical New battery pack: 16th shock discharge 11 Seconds, typical
Time from Power ON to readiness for discharge (voice instruction: "PRESS THE FLASHING ORANGE BUTTON, NOW. DELIVER SHOCK, NOW")	New battery pack: 16th shock discharge 25 Seconds, typical

Charging Indicator	• Voice Instruction "Press the Flashing Orange Button, Now. Deliver Shock, Now" • Flashing Shock Button • Beeper
Time from CPR to Shock	At least 6 seconds from the completion of CPR to shock delivery
Discharge	The device performs a self-discharge in the following events: • When the patient's ECG changes to a rhythm that does not require defibrillation. • When the Shock Button is not pressed within 15 seconds from the completion of the charge. • When the device is turned off by pressing the Power Button for at least second. • When the pads is detached from the patient's body or the pads connector is detached from the device. • When the impedance of the patient is out of the range of defibrillation (25 Ω ~ 175 Ω)
Shock Delivery	Shock is delivered if the SHOCK button is pressed while the CU-SP1 is armed.
Shock Delivery Vector	• Adult pads in the anterior-anterior position • Pediatric pads in the anterior-posterior position
Patient Isolation	Type BF, defibrillation protected



Biphasic Truncated Exponential Type.

The shock waveform profile is automatically compensated for the patient's transthoracic impedance.

A = first phase duration

B = second phase duration0

C = interphase duration

D = peak current

Output Waveform for Adult (150 Joules)

Patient Impedance (Ohms, Ω)	First Phase duration (milliseconds, ms)	Second Phase duration (milliseconds, ms)	Peak Current (A)	Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.4	2.4	64.5	147.8	150(±15%)
50	4.4	4.4	32.7	149.7	150(±15%)
75	6.3	6.3	22.5	151.5	150(±15%)
100	8.8	8.8	15.9	148.1	150(±15%)
125	10.7	10.7	13.0	149	150(±15%)
150	12.7	12.7	11.0	148.2	150(±15%)
175	15.0	15.0	9.5	148.8	150(±15%)

Output Waveform for Child (50 Joules)

Patient Impedance (Ohms, Ω)	First Phase duration (milliseconds, ms)	Second Phase duration (milliseconds, ms)	Peak Current (A)	Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.3	2.3	35.4	50.2	50(±15%)
50	4.3	4.3	18.4	50.7	50(±15%)
75	6.3	6.3	12.3	49.7	50(±15%)
100	8.5	8.5	9.1	49.5	50(±15%)
125	10.6	10.6	7.3	50.3	50(±15%)
150	12.7	12.7	5.8	49	50(±15%)
175	15.0	15.0	4.9	49.6	50(±15%)

ECG Acquisition

Category	Nominal Specifications
Acquired ECG Lead	Lead II
Frequency Response	1 Hz to 30 Hz

ECG Analysis System

Category	Nominal Specifications
Function	Determines the impedance of the patient and evaluates the ECG of the patient to determine whether it is shockable or non shockable
Impedance Range	25Ω to 175Ω (shock will not be delivered if the patient's impedance is beyond this range).
Shockable Rhythms	Ventricular Fibrillation or Fast Ventricular Tachycardia
Non Shockable Rhythms	ECG rhythms excluding ventricular fibrillation and ventricular tachycardia When a rhythm that does not require defibrillation is detected, the device directs you to perform CPR.
Analysis Protocol	Prepare for shock delivery of pause for CPR, depending on the results of analysis.
Sensitivity and Specificity	Meets ANSI/AAMI DF80 guidelines

ECG Analysis System - ECG Database Test

ECG Rhythm Class	Rhythms	Minimum test sample size	Performance goal	Test sample size	Shock Decision	No Shock Decision	Observed Performance	90% One Sided Lower Confidence Limit
SHOCKABLE	Coarse VF	200	>90% sensitivity	219	213	6	97.26% (213/219) sensitivity	95%
	Fast VT	50	>75% sensitivity	137	111	26	81.02% (111/137) sensitivity	76%
NON SHOCKABLE	Normal Sinus Rhythm	100 minimum (arbitrary)	> 99% specificity	100	0	100	100% (100/100) specificity	97%
	AF,SB, SVT, heart block, idioven-tricular PVC's	30 (arbitrary)	> 95% specificity	219	1	218	99.54% (218/219) specificity	98%
	Asystole	100	> 95% specificity	132	5	127	96.21% (127/132) specificity	93%

Control Devices, Indicators, Voice Instructions

Category	Nominal Specifications
Control Devices	Power Button, i-Button, Shock Button, Adult/Pediatric Selection Switch
Status LCD	Displays device status, battery level and pads status
Indicator	**Do-Not-Touch-Patient Indicator**: Lights when the defibrillator is analyzing or delivering an electric shock. **Pads Patch Position Indicators**: Flashes when the defibrillator is turned on; turns off when the pads is attached on the patient. **Pads Connector Status Indicator**: Flashes when the defibrillator is turned on and the pads connector is not connected; lights when the pads connector is connected. **CPR Detection Indicator**: Lights if CPR is detected; flashes if CPR is not detected. **Shock Button**: Flashes orange when the defibrillator is charged and ready to deliver a shock. **Blue i-Button**: Flashes when guiding CPR, transferring the treatment history and setting the CPR mode. **Red i-Button**: Flashes when an error occurs.
Speaker	Plays back voice instructions. The CU-SP1 analyzes the ambient noise level during a treatment operation. If ambient noise level is high, it automatically increases the voice instructions volume so that you can hear them clearly.
Beeper	Various beeping output
Battery Level	The battery level is automatically performed during periodic self tests, power ON self-test, and run-time self-test.
Low Battery Indicator	Shown on the Status LCD, announced via voice instruction, and indicated via the flashing red i-Button
Voice Instruction	Guides the user via voice instructions.

Self-Diagnostic Test

Auto	• Power On Self-Test, Run-time Self-Test • Daily, Weekly, and Monthly Self-Test
Manual	Battery Pack Insertion Test (done when the user inserts the battery pack into the battery pack compartment of the device)

Disposable Battery Pack

Category	Nominal Specifications
Battery Type	12V DC, 2.8Ah $LiMnO_2$, Disposable: Standard 12V DC, 4.2Ah $LiMnO_2$, Disposable: Long-life
Capacity	Standard - At least 50 shocks for a new battery or 4 hours of operating time at room temperature Long-life - At least 200 shocks for a new battery or 8 hours of operating time at room temperature
Standby Life (After Inserting the Battery)	Standard - At least 3 years from the date of manufacture if stored and maintained in accordance with the instructions in this document. Long-life - At least 5 years from the date of manufacture if stored and maintained in accordance with the instructions in this document.
Temperature Ranges	• Operating Temperature: 0℃ ~ 43℃ (32°F ~ 109°F) • Storage Temperature: -20℃ ~ 60℃ (-4°F ~ 140°F)

Adult Defibrillation Pads (CUA1007S)

Category	Nominal Specifications
Type	Adult
Electrode Area	120 cm^2
Cable Length	Total 120 cm (Inside the pouch: 95 cm, Outside the pouch: 25 cm)
Shelf life	At least 36 months from the date of manufacture

Pediatric Defibrillation Pads (CUA1102S)

Category	Nominal Specifications
Type	Pediatric
Electrode Area	46.43 cm^2
Cable Length	Total 120 cm (Inside the pouch: 80 cm, Outside the pouch: 40 cm)
Shelf life	At least 30 months from the date of manufacture

Data Storage and Transfer

Category	Nominal Specifications
IrDA	For PC communications
Internal Memory Data Capacity	5 individual treatments, up to 3 hours per treatment
SD Card	External memory. Data may be copied from the internal memory to the SD Card.