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(at 20°C) Long-life - At least 200 shocks for a new battery or 8 hours of operating time at room temperature(at 20°C)
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)

Instructions for Use

i-PAD CU-SP1

The information in these Instructions for Use applies to the i-PAD CU-SP1. This information is subject to change. Please contact CU Medical Systems, Inc. or its authorized representatives for information on revisions.

Revision History
Edition 3
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Medical Device Directive

The i-PAD CU-SP1 complies with the requirements of the Medical Device Directive 2007/47/EC and its revisions.

CE 0470

Important:

Quick defibrillation is needed if sudden cardiac arrest occurs. Since the chance of success is reduced by 7% to 10% for every minute that defibrillation is delayed, defibrillation must be performed promptly.

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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%

Ventricular Tachycardia: less than 150 bpm is non-shockable, greater than or equal to 150 bpm is shockable

For overall ECG waveform test result;

	VF and VT		All other ECG rhythms	
Shock	(A)	324 cases	(B)	6 cases
No shock	(C)	32 cases	(D)	445 cases

The sensitivity of the device for shockable rhythm is A/(A+C): 91.01% (324/356)

The true predictive value of the device is A/(A+B): 98.18% (324/330)

The specificity of the device for non shockable rhythm is D/(B+D): 98.67% (445/451)

The false positive rate of the device for shockable rhythm is B/(B+D): 1.33% (6/451)

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(at 20°C) New battery pack: 15th shock discharge 11 Seconds, typical (at 20°C)
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

CPR Detection Indicator	Indicates performance of CPR on the patient. (The indicator is lit if CPR is performed, and flashes if CPR is not performed)
Battery Pack	The disposable power source of the device.
IrDA Port	Transmits and receives treatment data between the device and a personal computer.
SD Card (External Memory) Port	Port for copying device records to a SD card.

⚠ WARNING

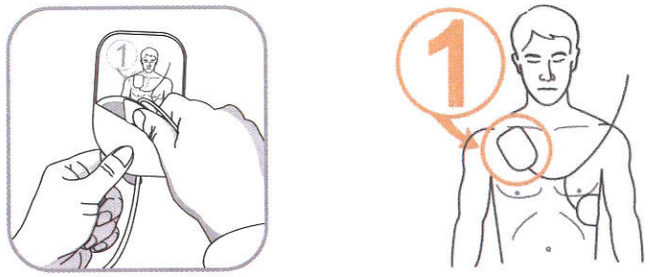
Do not open SHIELD RUBBER that covers IrDA port and SD card port during defibrillation therapy.

Pads Storage Compartment	Stores pads.

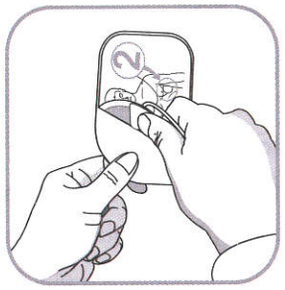
4.3 Defibrillation in Adult Mode

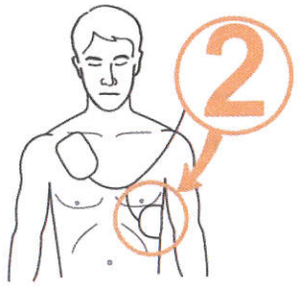
Step 1: Place pads on the patient.

① Remove **pad 1** from the single liner and stick the pad to the patient's upper chest as shown below.



② Remove **pad 2** from the single liner, and stick the pad to the patient's side torso as shown below.





③ If the device detects the connection with the patient after placing the pads, follow the voice instruction of the device.

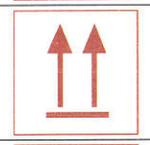
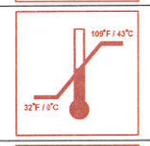
NOTICE

- Defibrillation can be done even if the pads are reversed. If the locations of pads are switched, follow the next voice instruction without changing the directions of pads. It is more important to begin defibrillation as soon as possible.
- In the event the pad is not adhering well, check if the adhesive side of the pads is dry. Each pad has an adhesive gel. If the gel does not adhere well, replace it with a new pads.

⚠ WARNING

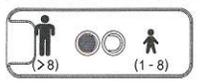
- Ensure the patient is not on a wet surface when performing defibrillation. If the patient's skin is wet, dry the skin first prior to using the device.
- Keep the pads well clear of other electrodes or metal parts in contact with the patient.

C.2 i-PAD CU-SP1 Packaging

Symbol	Description
	Stack up to 6 cartons high only
	This side up
	Keep dry
	Fragile; breakable
	Use no hooks
	Storage Temperature limits: 0℃ to 43℃(32°F to 109°F)
	Recyclable
CE 0470	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
EC REP	Authorized EU Representative
SN	Serial Number
	Manufactured Date

C. Description of Symbols

C.1 i-PAD CU-SP1 Defibrillator

Symbol	Description
	Power ON/OFF button
	i-Button
	SHOCK button
	Adult / Pediatric Selection Switch
	Do-Not-Touch-Patient Indicator
	CPR Detection Indicator
	BF type, defibrillation-proof equipment
	Attention: Refer to accompanying documents.
CE 0470	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
SN	Serial Number
	Date of manufacture
EC REP	Authorized EU Representative
	Do not discard the battery indiscriminately. Discard in accordance with local regulations.
	Manufacturer
	Refer to instruction manual/booklet
	General warning sign

If the patient does not need defibrillation, the device will do the following in sequence:

- the device announces that the patient does not need a defibrillating shock and that you may touch the patient.
- the CPR Mode Indicator is lit.
- voice instruction for CPR starts.

⚠ WARNING

- Do not touch (you or anybody else) the patient during shock delivery.
- Do not open SHIELD RUBBER that covers IrDA port and SD card port during defibrillation therapy.

❗ CAUTION

- While analyzing ECG, keep the patient still and minimize movements around the patient. Do not touch the patient and pads while the Do-Not-Touch-Patient Indicator is on. Electrical noise (interference) may delay the ECG analysis.
- As a safety measure, the device will not deliver a shock until the flashing orange SHOCK button is pressed. If the SHOCK button is not pressed within 15 seconds of the voice instruction to press the SHOCK button, the device will disarm itself (dumps the shock energy in its internal load) and will instruct you to make sure that emergency medical services have been called. The device will then instruct you to begin CPR.
- During defibrillation, disconnect other medical electrical equipment which has no defibrillation-proof applied parts from the patient.
- If the device malfunctions during a rescue operation, it will instruct you to get a replacement defibrillator and will start the voice instruction for CPR. Have CPR performed until the replacement defibrillator is ready to use.
- Before defibrillation, make sure that there is no contact which may provide unwanted pathways for the defibrillating current; patient's body (such as exposed skin or head or limbs), conductive fluids (such as gel, blood, or saline), metal objects (such as bed frame or stretcher)

NOTICE

- By default, Detailed Guide Selection is OFF during CPR so that you can concentrate on the compression rate and ventilation guidance. If you want the Detailed Guide Selection to be ON during CPR, set it ON as outlined in the previous pages.
- If the Detailed Guide Selection is OFF and the Number of ventilation is set to 0, the CU-SP1 provides only chest compression guidance for 2 minutes. After 2 minutes, the CU-SP1 automatically reanalyzes the patient's ECG.
- The CPR Chest Compression Rate can only be set in Pediatric mode. In Adult mode, the chest compression rate is fixed at 30 regardless of the set chest compression rate.

Service

- The i-PAD CU-SP1 must be serviced only by authorized personnel.
- The i-PAD CU-SP1 will be serviced free of charge during the warranty period. After the warranty period, the cost of material and service shall be shouldered by the user.
- When the i-PAD CU-SP1 is not operating properly, immediately bring it for servicing to an authorized service center.
- Please fill out the following table with the necessary information when requesting for service.

Device classification		Semi-Automated External Defibrillator		
Device Name		i-PAD	Model Number	CU-SP1
Serial Number			Date of Purchase	
Sales Representative				
User Information	Name			
	Address			
	Contact no.			
Brief description of the problem				

CAUTION

- If there is a device problem (except battery pack and defibrillation electrode problems) please contact service center

Replacing the Pads

- **Check the pads status on the Status LCD daily.** Do not use pads that are beyond the expiration date.
- Check the pads package for damage.
- Check the cable outside the packaging pouch for possible defects.
- Only pads provided by the manufacturer should be used with the i-PAD CU-SP1.

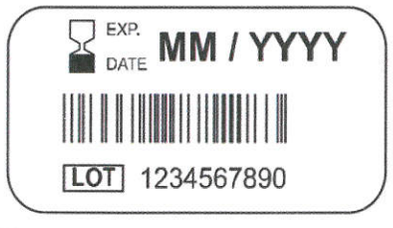
⚠ WARNING

- Only pads provided by the manufacturer should be used with the i-PAD CU-SP1. Using pads other than the one specified by the manufacturer may affect defibrillation effectiveness.

Replacing Pads

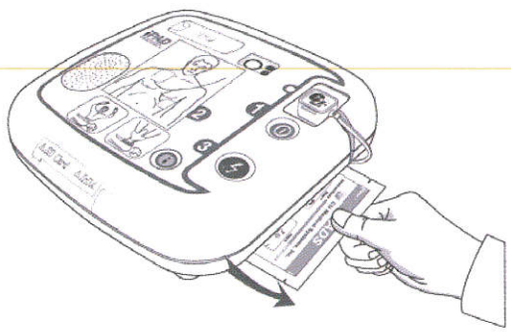
1. Check the expiration date of the pads. Refer to the figure below for checking the expiration date.

The expiration date is marked to the left of the "Multifunction Defibrillation ADULT PADS" label on the pads package.



The expiration date is marked as follows:
MM / YYYY
YYYY – Year
MM – Month

2. Used or expired pads should be replaced. Hold the top and bottom of the pads connector with your fingers, pull it out, and take the pads out from the Pads Storage Compartment as illustrated below.



6. Maintenance

6.1 Device Storage

Please refer to the precautions below when storing the Device in order to avoid device damage.

⚠ WARNING

- No modification of this equipment is allowed.

- Do not operate or store the device in conditions that are beyond the following. specified limits.
  - **Storage Conditions**
    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 Environment**
    device only, no defibrillator pads and battery pack included
    Temperature: -20℃ ~ 60℃ (-4°F ~ 140°F)
    Humidity: 5% ~ 95% (a location with no condensation)

- Do not store the device in areas that are directly exposed to sunlight
- Do not store the device in areas with highly fluctuating temperatures
- Do not store the device near heating equipment
- Do not store the device in areas where there is high vibration (in excess of Road Transportation and Helicopter Minimum Integrity of MIL-STD-810G Method 514.5C)
- Do not operate or store the device in environments with high concentration of flammable gas or anesthetics.
- Do not operate or store the device in areas with high concentration of dust
- Only personnel authorized by the manufacturer may open the device for servicing. There are no user serviceable components inside the device.

6.2 Maintenance

6.2.1 Device Inspection

The i-PAD CU-SP1 has self-testing capability. The device performs a self-test as soon as the battery is inserted, turns itself off when the test is done, and periodically wakes up to perform the daily, weekly, and monthly self-tests. To initiate a battery insertion self test, remove the battery pack and reinsert. Refer to [Section 8.1: Self-Tests] for more information.

CAUTION

- Inspect the i-PAD CU-SP1 daily to ensure that it is always ready for an emergency. Check the current status of the device, battery, and pads as displayed on the Status LCD.
- Refer to [Section 8.2: Device Status] for information regarding the Status LCD.

6.2.2 Replacing Supplies

When the device is in storage, check the battery level indicator and the pads status on the Status LCD daily to ensure that the device is always ready for an emergency. Replace the battery pack or the defibrillator pads when it is depleted or when they go beyond their expiration date, respectively.

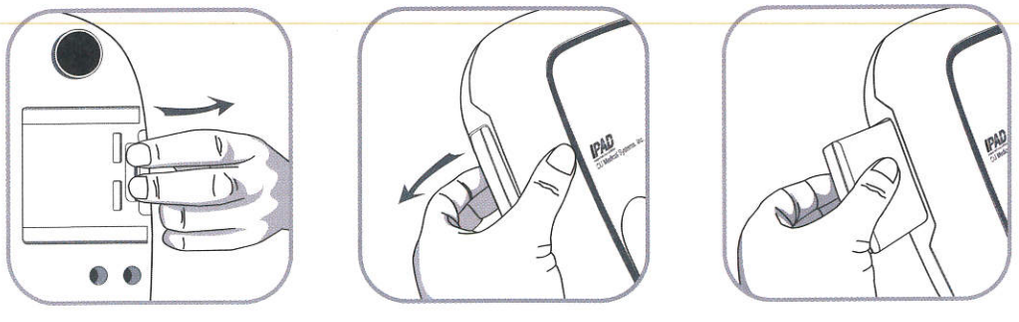
Disposable Battery Pack

Replacement of the Disposable Battery Pack

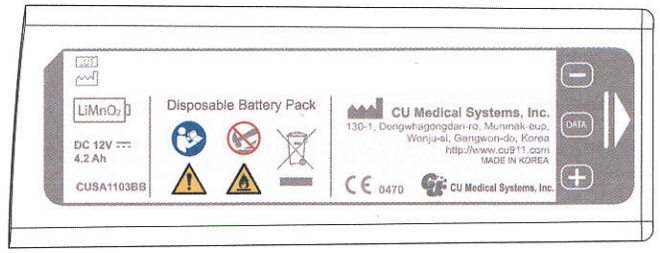
- Replace the battery pack when it becomes depleted. Refer to [Chapter 8: Troubleshooting] on how to check the battery status.
- Dispose of depleted battery packs in accordance with local environmental regulations.
- Use only battery packs recommended and provided by the manufacturer. Using battery packs not recommended and provided by the manufacturer will result in abnormal operation.

Replacing the Disposable Battery Pack

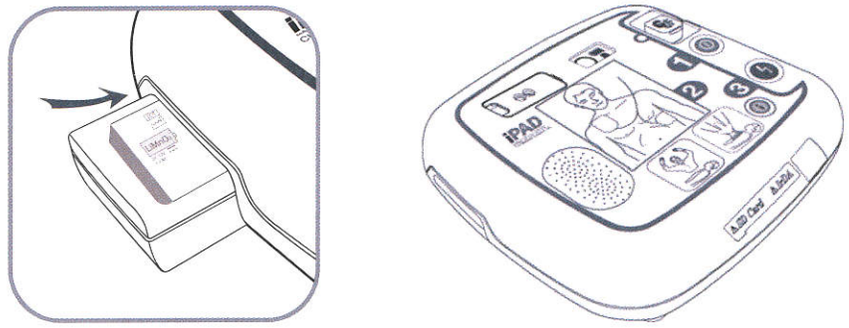
1. Remove the discharged battery pack by pulling it out while pressing the latch on the bottom of the device. Refer to the figure below.



2. Insert a new battery pack in the direction of the arrow with the label facing upward as shown in the figure below.



3. Push the battery pack until you hear it click into place.



CAUTION

- **Battery Pack Precautions**
  - Do not subject the battery pack to serious physical impact.
  - Do not attempt to open or break apart the battery pack
  - Do not let the battery pack come into contact with open flames or hot objects.
  - Do not short-circuit the terminals of the battery pack.
  - Keep out of the reach of children.
  - If any leakage gets in the eye, immediately clean the eye with water and consult with a doctor.
  - Do not store the battery pack under direct sunlight.
  - Do not store the battery pack in a wet or very humid place.
  - Comply with local regulations when disposing of the battery pack.
  - Do not destroy or incinerate the battery pack.
  - Never attempt to recharge the disposable battery pack.