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 5

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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 2460

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.

The i-PAD CU-SP1 is manufactured by:

CU Medical Systems, Inc.

130-1 Donghwagongdan-ro, Munmak-eup, Wonju-si,

Gangwon-do, Republic of Korea

Authorized EU Representative

Medical Device Safety Service

Schiffgraben 41, 30175 Hannover, Germany

Contact Us

Product and Order Inquiries

Overseas Sales Team

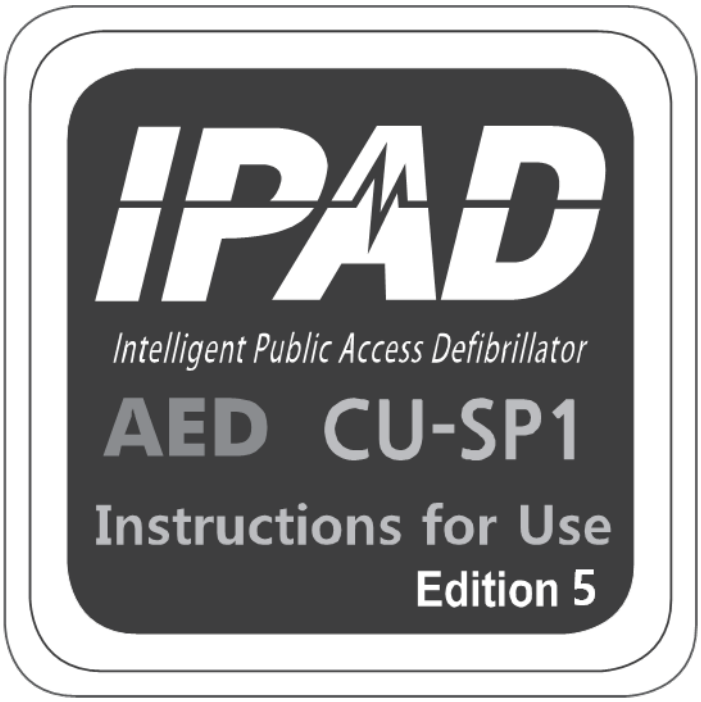
CU Medical Systems, Inc.
5F, Cheonggye Plaza, 221, Anyangpangyo-ro,
Uiwang-si, Gyeonggi-do, Republic of Korea
Tel : +82 31 421 9700 / Fax: +82 31 421 9911
E-mail addresses : sales@cu911.com

German Branch Office
CU Medical Germany GmbH, Cicero Str.26,
10709 Berlin, Germany
Tel: +49 30 6781 7804
Fax: +49 30 6782 0901

Service and Technical Support

Customer Service Team

CU Medical Systems, Inc.
5F, Cheonggye Plaza, 221, Anyangpangyo-ro,
Uiwang-si, Gyeonggi-do, Republic of Korea
Tel : +82 31 421 9700 / Fax: +82 31 421 9911
E-mail addresses : service@cu911.com



CU Medical Systems, Inc.

Table of contents

Introduction

These Instructions for Use contain information necessary for the correct use of this device. Please contact us regarding any questions or issues on the use of the device arising from information found in these Instructions for Use [Chapter 9: Device Service].

The company or its authorized distributor is not responsible for any injury incurred by the user or patient due to any apparent negligence or improper use by the user.

Hereinafter,

"device" refers to [CU-SP1]

"We" or “Us" refers to CU Medical Systems, Inc.

"Pads" refers to defibrillation electrode pads,

"Battery Pack" refers to a disposable battery pack.

These Instructions for Use emphasizes the safety procedures and precautions for the device use by using the terms below. Please acquaint yourself with the warnings, cautions and references stated in these Instructions for Use in order to safely use the device.

⚠ WARNING

Conditions, hazards, or unsafe practices that can result in serious personal injury or loss of life.

CAUTION

Conditions, hazards, or unsafe practices that can result in minor or moderate personal injury, damage to the device, or loss of treatment data stored in the device, particularly if precautionary steps are not taken.

NOTICE

Used to denote items that are important during installation, operation, or maintenance of the device.

Overview

Thank you for purchasing the i-PAD CU-SP1. This device can be effectively and safely used for a long period if you familiarize yourself with the instructions, warnings, precautions, and notices contained in these Instructions for Use prior to its use.

⚠ WARNING

- A defibrillator discharges electric shock with high voltage and current. You must be well-acquainted with the instructions, warnings, and precautions contained in these Instructions for Use.

- You must follow the instructions, warnings, cautions, and notices in these Instructions for Use when using this device.
- The manufacturer will not be responsible for any problems involving the device that are caused by the user's negligence.
- This device shall be serviced only by the manufacturer or its authorized service centers.
- If the Device is intended to be connected to equipment other than those stated in these Instructions for Use, contact the manufacturer.
- If this Device does not operate properly, contact the manufacturer or its authorized service center.

1. Introduction

1.1 Device Description

CU-SP1 is an easy-to-use Semi-Automated External Defibrillator (AED) that is small, light, and portable, and uses a battery.

The AED automatically reads the patient's electrocardiogram (ECG) and determines if a cardiac arrest that requires defibrillation has occurred, so that both medical professionals and the general public can easily operate it. Cardiac arrest can occur anytime to anyone at any place and may threaten the patient's life if the appropriate CPR and/or electric shock with a defibrillator are not applied within a few minutes.

The i-PAD CU-SP1 is a semi-automated external defibrillator (AED). If connected to a patient, the i-PAD CU-SP1 automatically acquires and analyzes the electrocardiogram (ECG) of the patient for the presence of Ventricular Fibrillation or Ventricular Tachycardia (also known as shockable rhythms). If a shockable rhythm is detected, the device automatically charges itself. Defibrillating shock is delivered when the you press the SHOCK button.

The i-PAD CU-SP1 is easy to use. It guides the you throughout a rescue operation using voice prompts and indicators (LED and graphical indicators).

The i-PAD CU-SP1 is small, light, highly portable, and battery powered. It is highly suitable for use in public, out-of-hospital settings.

1.2 Indicated Use

The **i-PAD CU-SP1** is indicated for use on patients that are exhibiting the symptoms of sudden cardiac arrest (SCA) with all of the following signs:

a) No movement and no response when shaken

b) No normal breathing

Do not use the i-PAD CU-SP1 on patients who show either of the following signs:

a) Movement or response when shaken

b) Presence of normal breathing

1.3 Intended Users

The **i-PAD CU-SP1** is intended for use in or out of the hospital by emergency care personnel or healthcare professionals or laypersons. The manufacturer recommends that users train on the use of the device.

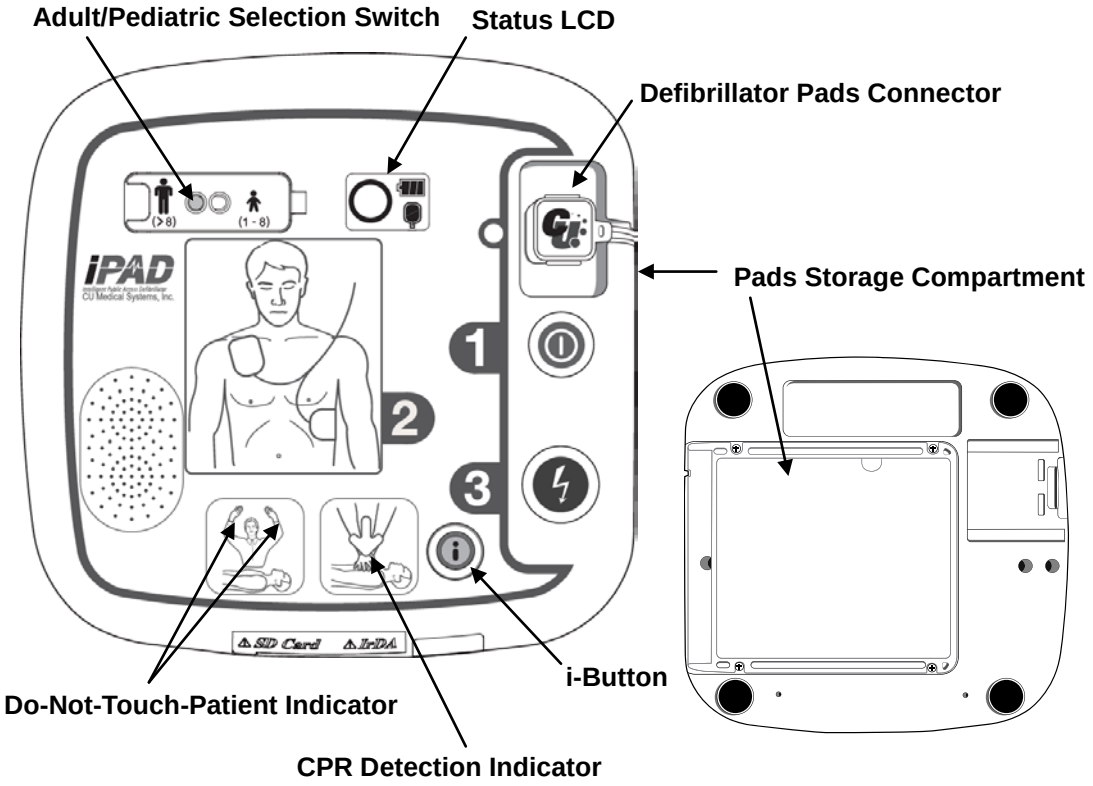
1.4 Local Protocol

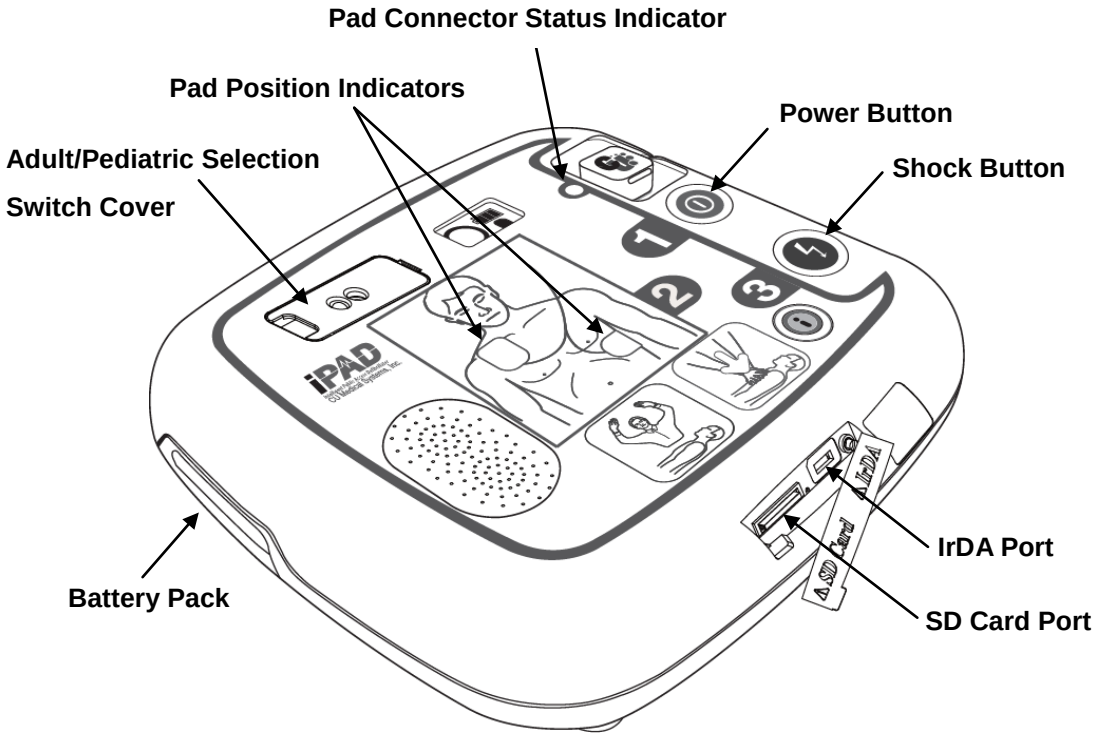
Please contact your local health authority for information on the requirements of ownership and usage of defibrillators.

1.5 Additional Information

Please contact CU Medical Systems, Inc. or its local distributors for any additional information on the i-PAD CU-SP1.

2. Device Features





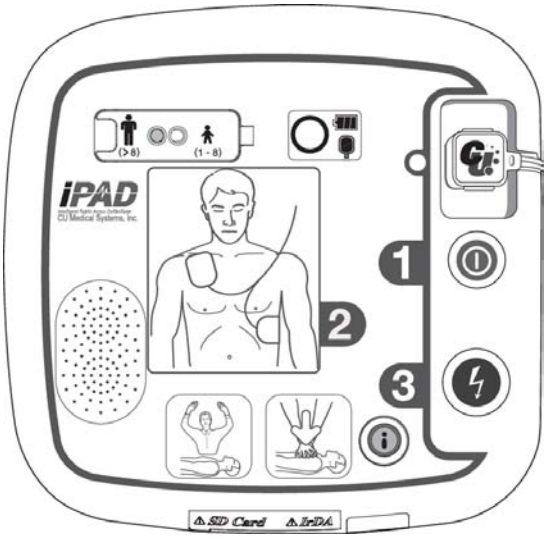
Power Button	Turns the device on or off. (When the device is on, a green LED is lit)
i-Button	• Reports device usage (the total hours of the last usage and number of shocks) • checks the S/W version • downloads events and ECG data via an IrDA and SD Card • sets the CPR mode (the number of compressions, breaths and cycles; compression rate per minute; pausing time; detailed guide on/off) • and checks for errors
Status LCD	Displays the current status of the device, battery and pads.
Shock Button	Delivers defibrillating shock when pressed while flashing in orange.
Adult/Pediatric Selection Switch	Selects Adult/Pediatric modes.
Adult/Pediatric Selection Switch Cover	Covers the Adult/Pediatric Selection Switch to prevent accidental switching.
Defibrillator Pads Connector	Connects with the connectors of the pads.
Pads Connector Status Indicator	Indicates the connection status of the defibrillator pads connector.
Pads Position Indicators	Indicates the pads position on the patient.
Do-Not-Touch-Patient Indicator	Warns when not to touch the patient.

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.
Pads Storage Compartment	Stores pads.

3. Preparation for Use

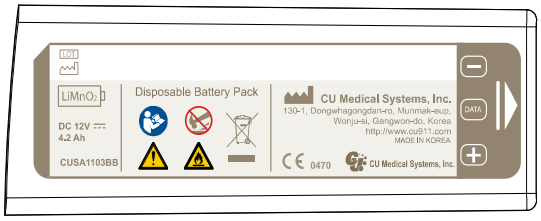
3.1 Standard Package Contents

The following are the standard package contents of this device

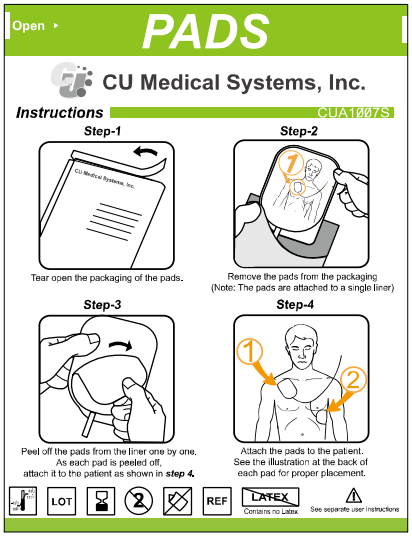


CU-SP1 Semi-automated External Defibrillator

Instructions for Use



1 Battery Pack (Disposable)



1 Pack of Adult Pads (Disposable)

Please contact the manufacturer for replacement supplies (refer to [Appendix B: Parts and Accessories] of these Instructions for Use).

⚠ WARNING

✓ Only parts and accessories recommended and approved by CU Medical Systems, Inc. must be used with the i-PAD CU-SP1. Using unapproved parts and accessories may compromise the safety and effectiveness of the i-PAD CU-SP1.

NOTICE

✓ Extra battery packs and pads are recommended.

3.2 Setting up the i-PAD CU-SP1

Do the following to set up the i-PAD CU-SP1

① Open the package and verify that it contains all the items listed in the packing list.

② Familiarize yourself with the device features by referring to [Chapter 2: Device Features] of these Instructions for Use.

③ Insert the battery pack into the battery compartment on the device as shown in the figure below.

As the battery pack is inserted, the device starts a self-test. If the device status is normal, ○ is shown on the Status LCD. If ✕, ▯ or ▭ is displayed on the Status LCD after the self-test, please refer to [Chapter 8: Troubleshooting] of these Instructions for Use.

④ If you have a carrying case, please safely store the Device in the carrying case. If you want to purchase the carrying case, please contact us by referring to [Appendix A: Accessories] of these Instructions for Use.

⑤ Storage and maintenance considerations:

- Refer to [Section 6.1: Device Storage] for proper device storage instructions.
- When the device is in storage, check the Status LCD periodically to ensure that the device is in good condition.
- Store the CU-SP1 in accordance with your local emergency first aid protocol.
- Store the device in an easy-to-access location where its Status LCD can be checked periodically and its technical alarms can be easily heard (e.g. alarm on low battery or other device problems).
- It is also recommended to place an emergency use telephone near the device's storage area so that emergency medical services can be easily called during emergencies.
- Store the accessories along with the device in the device's carrying case for easy and quick access.

⚠ WARNING

- **Electromagnetic interference may affect the performance of the device.** While the device is in use, it should be kept away from devices that cause electromagnetic interference. Devices that may cause such interference include motors, X-ray equipment, radio transmitters, and cell phones. Refer to [Appendix E: Electromagnetic Compatibility] of these Instructions for Use for more information.
- The use of accessories or cables other than those referred to in these Instructions for Use may increase electromagnetic radiation from the device or reduce the device's electromagnetic immunity. Only accessories and cables that are authorized by the manufacturer should be used with the i-PAD CU-SP1.

4. How to Use the i-PAD CU-SP1

4.1 Chain of Survival

If you think that you are witnessing someone go down in sudden cardiac arrest, perform the chain of actions recommended by the American Heart Association (AHA) in its Chain of Survival emergency response to sudden cardiac arrest.

1. Immediate recognition and activation of the emergency response system.
   - Check for a response by tapping the victim on the shoulder and shouting at the victim.
   - Activate the community emergency response system (e.g. call 911 or the equivalent service in your locality)
2. Early CPR
   - Perform CPR.
3. **Early defibrillation**
   - **Use this device (i-PAD CU-SP1).**

   Using this device can be summarized in 3 steps:

   After pressing the Power Button,

   Step 1: Place pads on the patient.

   Step 2: Press the Shock Button if instructed by the device.

   Step 3: Perform CPR.
4. Effective advanced life support – Perform advanced care in order to restore spontaneous circulation.
5. Integrated post-cardiac arrest care – Transfer the patient to a medical institution or a specialized facility

NOTICE

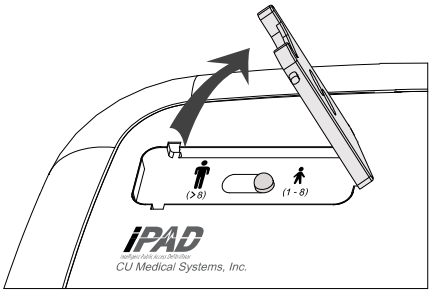
- If finding and/or operating the defibrillator takes time, monitor the patient's status until the defibrillator is available, perform CPR if necessary.

4.2 Preparation for Defibrillation

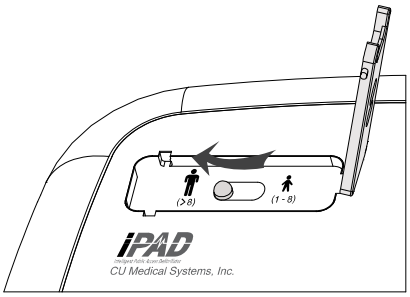
① Set the Adult/Pediatric Selection Switch to match the victim.

Adult victim

• Open the switch cover



• Set the switch to adult defibrillation mode as shown in the following picture

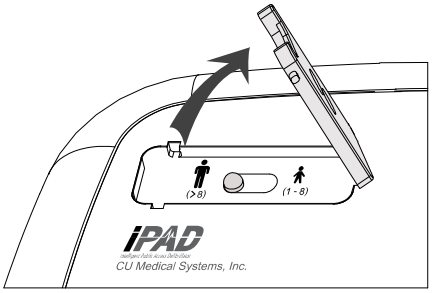


Child victim (victim is under 25kg or 8 years old)

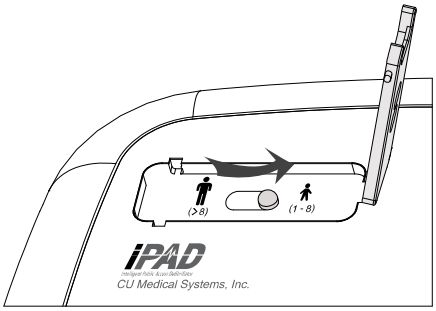
If the pediatric pads are attached, the i-PAD CU-SP1 automatically adjusts its defibrillation energy output for pediatric defibrillation regardless of the position of the Adult/Pediatric Selection Switch (i.e. the output will be pediatric even if the selection switch is set to adult)

If there are no pediatric pads for the pediatric patient, adult pads may be used. Ensure that the Adult/Pediatric Selection Switch is set to Pediatric Mode. If the switch has not been set yet, move it to Pediatric Mode as shown in the figures below

• Open the switch cover



• Set the switch to pediatric defibrillation mode as shown in the following picture

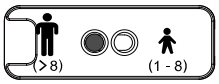


If a young victim is over 25kg or 8 years old, or if you are not sure of the exact weight or age:

- **DO NOT DELAY TREATMENT**
- Set the Adult/Pediatric Selection Switch to Adult mode.
- Use the adult pads.

⚠ WARNING

- Never perform defibrillation in pediatric mode to a patient who is either heavier than 25 kg or older than 8 years old. Ensure the slide key for Adult/Pediatric Mode is as shown on the bottom.



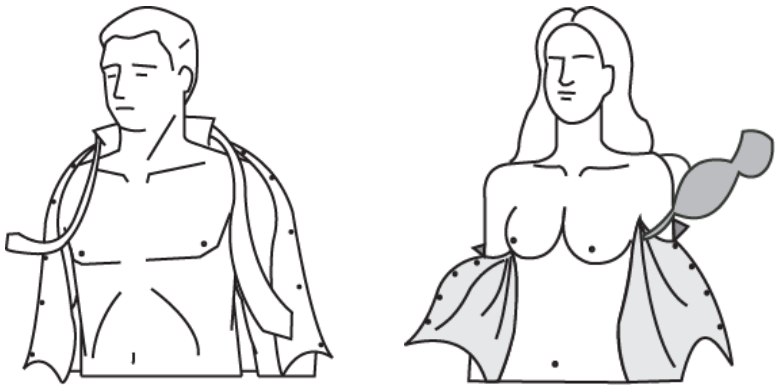
- You can switch the adult/pediatric selection switch before or after turning on the i-PAD CU-SP1. However, the defibrillation mode should be changed before placing the pads on the patient. Once the pads are in place, you cannot change the defibrillation mode anymore. When the mode is correctly selected, the defibrillation energy is set to an adult value (150 J) or pediatric value (50 J).

② Turn the device on by pressing the Power Button.

When the power turns ON the following occurs in sequence:

- the beeper will beep for 1 seconds
- Voice instruction: “Call emergency Medical services, now”

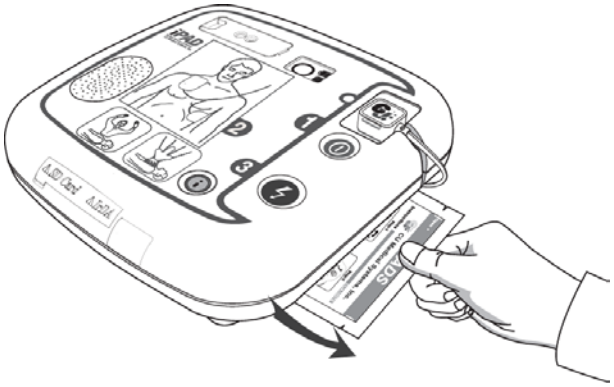
③ Remove clothes from patient's chest.



CAUTION

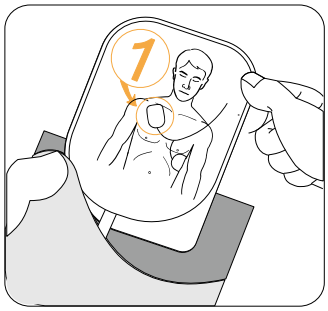
- Time is essential for the cardiac arrest patient. Tear or cut clothes if removing them will take time.
- Dry the patient's skin such that pads can adhere well on the chest. Shave hair on the chest if necessary.

④ Remove the pads package from the Pads Storage Compartment at the bottom of the device.



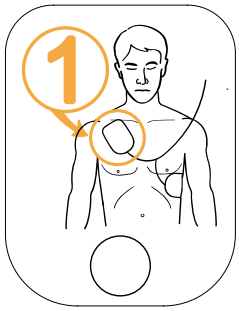
⑤ Open the pads package.

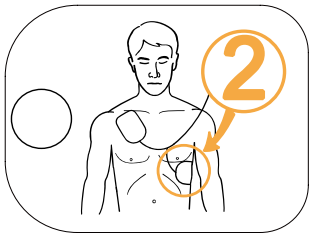
⑥ **Take pads out of the pads package.**



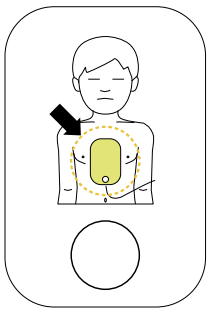
⑦ **Refer to the pictures on both pads.**

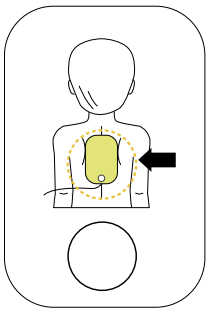
Adult Pads





Pediatric Pads





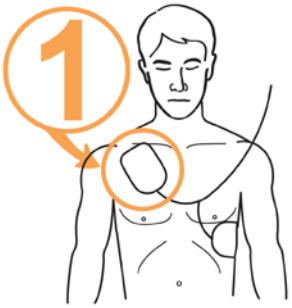
CAUTION

- The adhesive material on the pads starts to dry out as soon as the package is opened. Use immediately after opening. Refer to [Section 6.2: Maintenance] of these Instructions for Use for procedures on how to check the expiration date of the pads and pads maintenance.

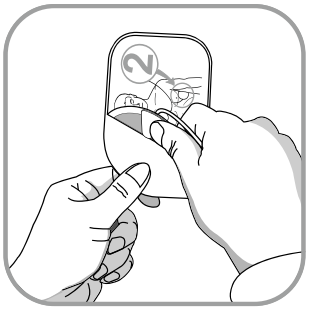
4.3 Defibrillation in Adult Mode

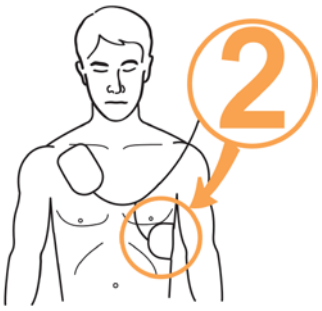
Step 1: Place pads on the patient.

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.

Step 2: Press the Shock Button if instructed.

The device acquires and analyzes the patient's ECG immediately after being connected. The device will instruct you not to touch the patient by flashing the Do-Not-Touch-Patient Indicator and by issuing the voice prompt: “Do not touch the patient, analyzing heart rhythm”. After analyzing the ECG, the device will determine whether or not the patient needs defibrillation.

⚠ WARNING

- Do not move or touch the patient during ECG analysis.

If the patient needs defibrillation, the device will do the following:

The device announces that a defibrillation shock is needed, and instructs you to keep away from the patient.

CAUTION

- While the device is charging after a shockable rhythm is detected, the ECG of the patient is continuously acquired and analyzed. The device disarms itself if the ECG rhythm changes to a non-shockable rhythm before shock delivery.

When it is charged, the device activates the following indicators in sequence:

- continuous beep while the Shock Button flashes in orange.
- the device instructs you to press the flashing orange Shock button; you should press the Shock Button at this time.

When the Shock Button is pressed, the device delivers a defibrillating shock to the patient. If defibrillation is properly done, the device reports that an electric shock has been delivered.

After shock delivery, the device indicates that you may touch the patient, and the CPR Mode Indicator is lit. Then, the voice instruction for CPR starts.

If the flashing Shock Button is not pressed within 15 seconds, the device will cancel the shock delivery and disarm. Then, the device issues CPR instructions.

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.
- Before defibrillation, make sure that there is no contact between 1 and 2 below which may provide unwanted pathways for the defibrillating current.
  - the 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)

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.

Step 3: Perform CPR.

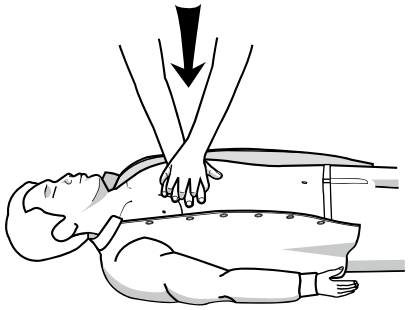
Perform CPR when the i-PAD CU-SP1 instructs you to do so.

By default, the CU-SP1 gives voice instruction for CPR during pause for CPR after a shock delivery. When voice instruction for CPR is needed outside of the default setting, press the flashing blue i-Button for at least 15 seconds.

[CPR Method]

1. Compression Point

Place the heel of your hand in the middle of the patient's chest between nipples (which is the lower half of the sternum), and put the heel of your other hand on top of the first so that your hands are overlapped and parallel.



2. Compression Speed and Depth

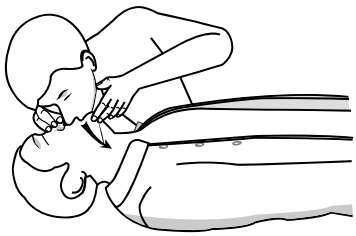
Compress the chest at least 5 cm deep, and at a rate of at least 100 compressions per minute.

3. Opening the Airway

While lifting the patient's chin up, tilt the head backward to open the airway.

4. Ventilation Method

Pinch the patient's nose as shown in the figure below, and give the patient enough breath to make the chest rise significantly.



NOTICE

- If you have not been trained in CPR, you should perform only chest compression or follow the instructions of the emergency medical services' agent on the phone.
- If you are trained for CPR and able to perform ventilation, perform the chest compression along with ventilation.
- The CPR guide can be set on an administrator's mode. Refer to [Section 5.3: Device Setting] for more information.

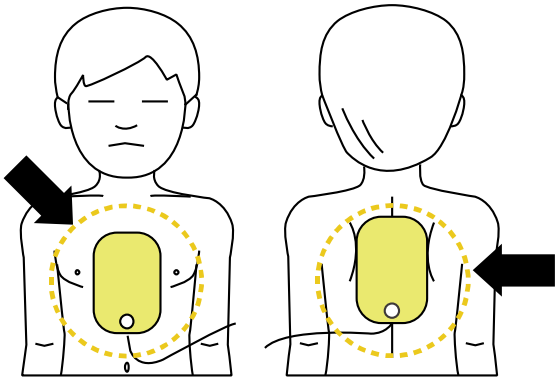
CAUTION

- While playing the CPR guide, the device does not analyze the patient's ECG. After the CPR guide, the device automatically starts the reanalysis of the patient's ECG.

NOTICE

- In order to turn the device off after use, press the Power Button for at least 1 second.

4.4 Defibrillation Procedures in Pediatric Mode



When the patient is older than 1 year and younger than 8 years, defibrillation can be done using the pediatric pads. When the device is in pediatric mode (pediatric pads are connected to the device or the Adult/Pediatric Selection Switch is set to Pediatric), it automatically sets the defibrillation energy to 50 J and provides pediatric CPR guide.

Place pads on the middle of the chest and back as illustrated above. Pads are not specific to either chest or back.

If there are no pediatric pads for the pediatric patient, use adult pads but set the Adult/Pediatric Selection Switch to Pediatric Mode, and then perform defibrillation according to the voice instructions.

NOTICE

- Follow the instructions below when giving first aid during pediatric cardiac arrest.
  - When giving first aid during a pediatric cardiac arrest, ask others to call the emergency medical center and to bring the i-PAD CU-SP1 while you are performing pediatric CPR.
  - When there is no one else around, perform CPR for 1 to 2 minutes, call emergency medical services, and then get the i-PAD CU-SP1.
  - If you witnessed the child's collapse, call emergency medical services immediately, and then get the i-PAD CU-SP1.

5. After Using the i-PAD CU-SP1

5.1 Maintenance After Each Use

- Check if the device for signs of damage and contamination.
- If there is dirt contamination, see Section 6.2.3 on how to clean the device.
- Run a battery insertion test. Refer to Section [8.1: Self-Tests] for the procedure.
  If ◯ is displayed on the Status LCD after running the test, the device status is normal.
- Dispose of the used pads properly. Place a new pouch of defibrillator pads into the pads storage compartment. See to it that the pads are not beyond their expiration date.
  The i-PAD CU-SP1 uses disposable pads. Do not reuse them. Refer to Section [6.2.2: Replacing Supplies] on how to replace the pads.

⚠WARNING

- You should use only the defibrillator pads provided and recommended by the manufacturer.
- Do not open the pads package until immediately before use. Since the adhesive material on the pads starts to dry out as soon as the package is opened, the pads may not be usable regardless of the expiration date.

5.2 Saving and Transferring Treatment Data

5.2.1 Device Usage

This device automatically saves the following treatment data:

- ECG data
- Usage information

The treatment data is automatically recorded in the internal memory. This data is not erased even if the device is turned off. The recorded treatment data may be transferred to a personal computer (PC).

CAUTION

- This i-PAD CU-SP1 keeps the data of the 5 most recent treatment operations and can save up to 3 hours of ECG data for each rescue operation. ECG data beyond 3 hours will not be recorded.
- When the device is used more than 5 times, it deletes the oldest treatment data to make room for data from a new treatment operation. It is recommended to transfer treatment data to a PC after each use of the device.
- If the battery pack is removed while the device is operating, treatment data cannot be properly recorded. If you wish to remove the battery pack, turn the power off by pressing the Power Button for at least 1 second before removing the battery pack.

5.2.2 Transferring Treatment Data

The treatment data may be transferred via a SD card or IrDA. The entire treatment data of all patients that is recorded on the device is transferred using only the SD card method, while the treatment data of one patient can be transferred using only the IrDA method.

1. Copying Treatment Data by Using the SD Card

① Format the SD card on the PC to FAT (FAT16) format.

② Open the SD Card Cover on the device and insert the SD card into the port.

③ When the i-Button is pressed for more than 1 second in standby mode, the mode changes into administrator mode with voice guide.

④ The device then gives you a summary (the total hours of the last device use and the number of defibrillation shocks delivered).

⑤ The voice guide gives the S/W version of the device.

⑥ When instructed by the voice guide to transfer the treatment history, press the i-Button to copy the data onto the SD card.

If there is treatment data in the device's internal memory:

- The device informs you that copying of the treatment data onto the SD card has started, and starts to copy the data.
- When copying is completed, the device mode changes to CPR guide setting mode. Refer to [Section 5.3: Device Setting] for details regarding CPR guide setting.

If there is no treatment data in the device's internal memory:

- The device mode changes to CPR guide setting mode after informing you that no treatment data exists.

NOTICE

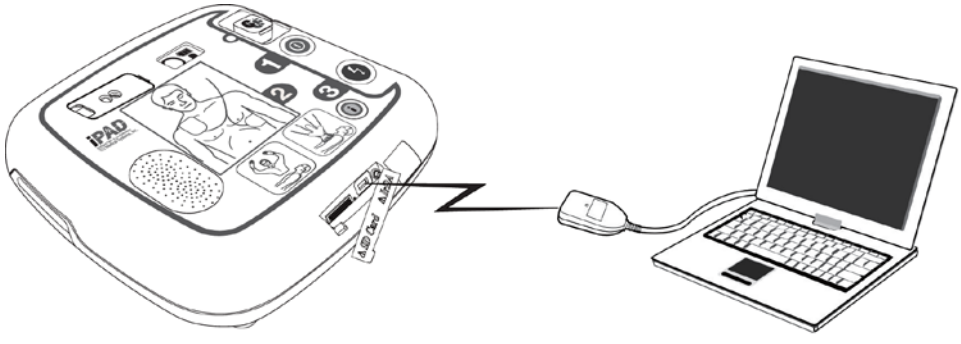
- If the file has already been transferred, the device will inform you that the same file exists in the PC. Press the Shock Button to overwrite the existing file in the PC or press the i-Button to cancel the copying of the file.

2. Transferring Treatment Data via IrDA

The data may be transferred to a PC using the data management software (CU Expert Ver.3.50 or higher) from the manufacturer. CU Expert includes ECG review and printing functions.

① Position the IrDA adapter to face the IrDA port on the device as shown in the figure below.

② When the i-Button is pressed for at least 1 second in standby mode, the mode changes to administrator mode with a voice guide.



③ The device gives the you a summary (the total hours of the last device use and the number of defibrillation shocks delivered).
④ The voice guide gives the S/W version of the device.
⑤ When instructed to transfer the treatment history, press the i-Button to transfer the data.

If there is treatment data in the device's internal memory:

① The voice guide reports the total number of individual treatment data recorded in the device.
② By default, of a maximum of 5 individual treatment data, the first on the list is the most recent.
③ In order to rearrange the order for copying to a PC, press the Shock Button to change the order to most recent last, and then press the i-Button to transfer the selected data.
④ Run CU Expert on the PC. Refer to the CU Expert manual for detailed information regarding how to receive data.
⑤ The device will be connected with the CU Expert within a few seconds, and data will be automatically transferred.
⑥ When copying is completed, the mode changes to CPR guide setting mode. Refer to [Section 5.3: Device Setting] for details regarding changing CPR guide setting.

If there is no treatment data in the device's internal memory:

The device mode changes to CPR guide setting mode after informing you that no treatment data exists.

CAUTION

- The distance between the IrDA port on the device and the IrDA adapter should be within 30 cm, while their angle should be within ±15°. Also, since external light source affects the IrDA, try to use it in indoors and away from fluorescent and/or incandescent lamps.

5.3 Device Setting

5.3.1 CPR Guide Setting

The default CPR setting on CU-SP1 is 5 cycles with 30 chest compressions and 2 breaths in accordance with the American Heart Association (AHA) 2010 CPR Guidelines. However, you may customize these.

You can set the following:

- Number of chest compressions
- Number of ventilation
- Number of cycles
- Number of chest compressions per minute
- Pausing time
- Detailed guide selection

5.3.2 Setting the CPR Guide

① When the i-Button is pressed for at least 1 second in standby mode, the mode changes into administrator mode with a voice guide.

② The device gives you a summary (the total hours of the last device use and the number of electric shocks).

③ When instructed to transfer the treatment data, do not press the i-Button, but instead wait for 5 seconds.

④ When instructed to set the CPR guide, press the i-Button to enter the CPR guide setting mode.

⑤ When instructed to enter a password, enter **the set password.**

NOTICE

• Password: press the following buttons in sequence:

i-Button → i-Button → Shock Button → i-Button → Shock Button → Shock Button

⑥ The voice guide will give information regarding the current CPR guide setting.

⑦ Press the Shock Button to change the setting, or press the i-Button to proceed to the next step.

⑧ Settings can then be changed in the following order: Number of Chest Compressions, Number of Ventilation, Chest Compression rate, Pausing Time, and Detailed Guide Selection. Refer to [**Table 1] CPR Guide Setting Options** below.

⑨ When the setting is completed, the voice guide will give information regarding the set CPR guide, which may be saved or canceled.

⑩ Press the i-Button to save or the Shock-Button to cancel according to voice instructions.

⑪ When the CPR guide setting is either saved or canceled, the device automatically shuts down.

[Table 1] CPR Guide Setting Options

Number	Setting Option	Range	Unit	Default	Description
1	Number of Chest Compression	15, 30	15	30	Perform 30 compressions.
2	Number of Ventilation	0 to 2	1	2	Give 2 breaths.
3	Number of Cycles	2 to 10	1	5	Perform 5 cycles of chest compression and ventilation.
4	Chest Compression Rate	100 to 120	5	100	Compress the chest at a rate of 100 compressions per minute.
5	CPR Pause time	30 to 180 sec.	30 sec.	120 sec.	Pause for 120 seconds (2 minutes).
6	Detailed Guide Selection	On/Off		Off	Turns ON or OFF detailed voice instructions for the chest compression and ventilation when performing CPR.

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.

6. Maintenance

6.1 Device Storage

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

- 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℉ ~ 109℉)

    Humidity: 5% ~ 95% (non condensing)
  - **Transport Environment**

    device only, no defibrillator pads and battery pack included

    Temperature: -20℃ ~ 60℃ (-4℉ ~ 140℉)

    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.

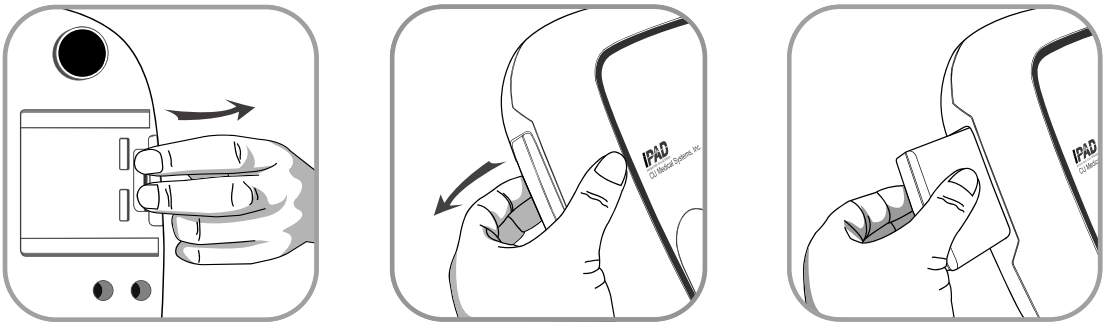
Disposable Battery Pack

Replacement of the Disposable Battery Pack

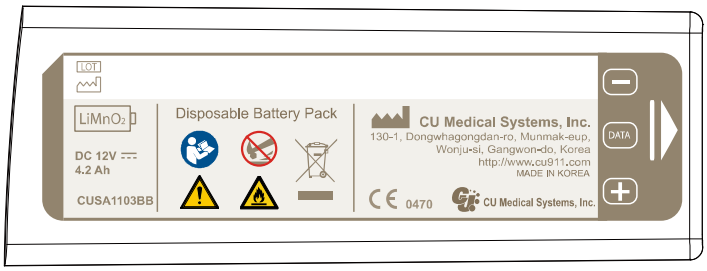
- Replace the battery pack when it becomes depleted. Refer to [Chapter 8: Troubleshooting] on how to check the battery status.
- Dispose of depleted battery packs in accordance with local environmental regulations.
- Use only the battery packs recommended and provided by the manufacturer.
- The battery pack is disposable. Do not recharge.

Replacing the Disposable Battery Pack

1. Remove the discharged battery pack by pulling it out while pressing the lock 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.

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.

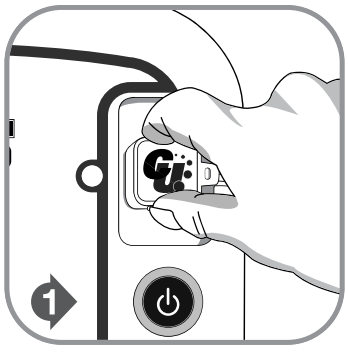
Replacing Pads

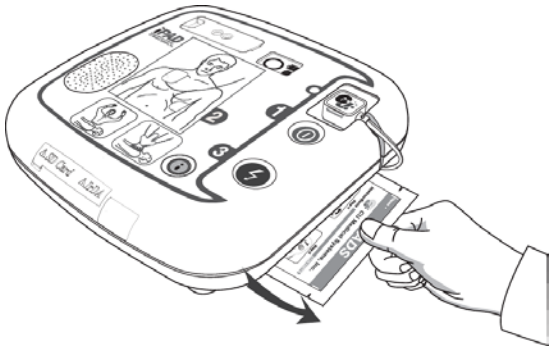
1. Check the expiration date of the pads. Refer to the figure below for checking the expiration date.

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

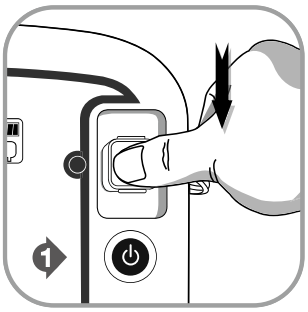
The expiration date is marked as follows:
MM / YYYY
YYYY – Year
MM – Month

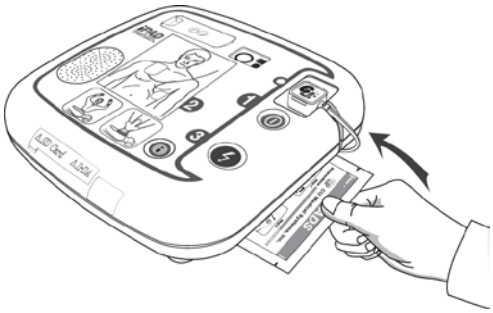
2. Used or expired pads should be replaced. Hold the top and bottom of the pads connector with your fingers, pull it out, and take the pads out from the Pads Storage Compartment as illustrated below.





3. Insert the pads connector of the new pads into the Defibrillator Pads Connector , and then put the pads package in the Pads Storage Compartment as illustrated below.





6.2.3 Cleaning the i-PAD CU-SP1

Clean the device with a soft cloth. The following detergents may be used to clean the exterior of the device:

- Dilute soap and water
- Dilute chlorine bleach (dilute 30 ml of chlorine bleach in one liter of water)
- Dilute ammonia-based cleaners
- Dilute hydrogen peroxide

CAUTION

- Do not immerse the device or its accessories in liquids.
- Be careful not to allow any liquids to get into the device.
- If the device is immersed in liquids, immediately contact the manufacturer or its authorized service center.
- Giving excessive force or shock while cleaning the device may cause damage.
- Do not use an acetone-based strong detergent or abrasive when cleaning the device. In particular, the filter on the IrDA port may be damaged.
- Do not use a detergent containing abrasive ingredients.
- Do not sterilize the i-PAD CU-SP1.

7. Disposal

Dispose of CU-SP1 and its accessories in accordance with local regulations.

8. Troubleshooting

8.1 Self-Tests

The following table lists the self-tests done by the device.

Self-Test Type	Description
Battery Insertion Test	Runs when the battery pack is inserted into the device. Perform this test: • Before the device is deployed • After each use • When replacing the battery • When the device is suspected to be damaged CAUTION Do not run this test when you are about to use the device to treat a sudden cardiac arrest victim because this test takes time (around 20 seconds). If a new battery pack is inserted just before a treatment, do the following to cancel this test: • Press the Power Button • Wait for the device to turn OFF. • Press the Power Button again to turn the device ON. Aside from testing its internal systems, the device also tests the following during this self-test: • Shock Button and i-Button – press the buttons one by one when instructed • Defibrillator pads status – the device tests the connection status (whether connected or not) and the expiration date of the defibrillator pads. If no error is detected, ○ will be displayed on the Status LCD. If an error is detected, ✕ will be displayed on the Status LCD and the i-Button will flash in red. When the i-Button is pressed as directed by the voice instructions, the device will report the error and turn itself off. Refer to [Section 8.3: Troubleshooting] for more information.

Self-Test Type	Description
Power ON Test	The device performs a self-diagnostic test when the Power Button is pressed
Run-time Test	The device monitors itself in real-time during its operation.
Periodic Self-Diagnostic Test	This device performs self-diagnostic tests daily, weekly and monthly. The periodic self-test checks important features of the device such as the battery status, pads status and internal circuits.

If the device fails to perform any self-test during use and is unable to defibrillate, it will instruct the you to replace the device and start the voice instruction for CPR. In order to check the error, turn the device off by pressing the Power Button. If you press and hold the i-button, the voice will direct the you to press the blinking red i-Button. You can verify the cause of the error via the voice instruction by pressing the i-Button. Refer to [Section 8.3: Troubleshooting] for more information.

CAUTION

- It is recommended to run the battery insertion test only during the times enumerated in the table above. The battery insertion test consumes battery power and will shorten battery life if done more frequently than necessary.

8.2 Device Status

The status of the device is indicated by the following symbols:

Indicator	Description	Note
Status LCD Device Operation 	The device is functioning normally.	
Status LCD Device Operation 	The device has an error.	
Status LCD Battery Level Indicator 	The battery is fully charged.	
Status LCD Battery Level Indicator 	Less than half battery power remains.	
Status LCD Battery Level Indicator 	Less than quarter battery power remains.	
The battery symbol in Status LCD blinks yellow 	Less than 15% of battery power remains.	
Status LCD Battery Level Indicator 	Battery is low.	
Status LCD Pads Status 	The expiration date of the pads is more than 3 months.	
Status LCD Pads Status 	The pads will expire within 3 months.	
Status LCD Pads Status 	The pads is used or expired.	
Do-Not-Touch-Patient Indicator: Off	You may touch the patient.	
Do-Not-Touch-Patient Indicator: Light	You may not touch the patient.	
CPR Detection Indicator: Light	Indicates that CPR is being performed.	
CPR Detection Indicator: Flashing	Indicates that CPR is not performed or not properly performed.	
i-Button: Flashing in Red	The device detected an error. Press the i-Button for more information.	
Shock Button: Flashing in Orange	The device is ready to deliver a defibrillating shock. Press the Shock Button to deliver a shock.	

8.3 Troubleshooting

The device informs you of its current status or of problems via status indicators, beeps, and/or voice instruction. Refer to the following for details:

8.3.1 Troubleshooting While the Device is Operating

Symptom/Voice Instruction	Cause	Resolution
Status LCD Device Operation 	An error has occurred in the device.	Immediately replace the defibrillator and perform CPR if appropriate.
Status LCD Battery Level Indicator 	The battery is low.	Replace the battery with a new one.
The battery symbol in Status LCD blinks yellow 	The battery is low.	Recommend replacing the new battery.
Status LCD Pads Status 	The pads is expired. The pads has been used.	Replace the pads with a new one.
Voice Prompt : “Low battery”, “Replace the battery with a new one.”	The battery is low.	Replace the battery with a new one.
Voice Prompt : “Plug the pads connector into the device.”	The Pads Connector is disconnected	Ensure the Pads Connector is properly connected.
Voice Prompt : ” Used pads”, “Replace the pads with a new one”	The pads has been previously used.	Replace the pads with a new one.
Voice Prompt : ” The pads are beyond their expiration date”, “Replace the pads with a new one”	The pads has expired.	Replace the pads with a new one.
Voice Prompt : ” Press the pads firmly to the bare skin of the patient”	The pads is not properly attached to the patient's skin.	Check if the pads is securely attached to the patient's skin.
Voice Prompt : ” No shock delivered”	The pads is not properly adhering to the patient's skin.	Press the pads firmly to the patient's skin. Shave chest hair or wipe off moisture if necessary before attaching the pads.
Voice Prompt : ” Shock button was not pressed”	Although an electric shock is needed, the Shock Button was not pressed within 15 seconds.	Deliver an electric shock by pressing the Shock Button with the next voice instruction.

• If the problem cannot be solved during an emergency, you should follow the following steps:

① Quickly replace the defibrillator if possible.

② If no replacement device is available, check the patient's condition and perform CPR as necessary. Continuously check the patient's condition and perform CPR until the emergency medical services arrives.

8.3.2 Troubleshooting While the Device is not Operating

Symptom	Cause	Resolution
Status LCD **Device Operation** 	System error	Press the i-Button and hold for at least 1 second. The device then goes into Administration Mode. After going into Administration Mode, the device will issue the voice instruction “Press the flashing red i-Button” Press the flashing red i-Button and the device will then announce system error and the associated error code. Contact us by referring to [Chapter 9: Device Service].
Status LCD **Battery Level Indicator** 	The battery is low.	Replace the battery with a new one.
The battery symbol in Status LCD blinks red 	The battery is not enough.	Recommend replacing the new battery.
Status LCD **Pads Status** 	The pads is expired.	Replace the pads with a new one.
	The pads has been used.	

• If the problem is not resolved or if no replacement battery is available, contact the manufacturer (refer to [Chapter 9: Device Service])

9. Device Service

Device Warranty

Device Name		Model Name	
Purchase Name		Serial No.	
Distributor		Person in Charge	

- This device is warranted by CU Medical Systems, Inc. against defects in materials and workmanship for five full years from the date of original purchase. During the warranty period, we will repair or, at our option, replace at no charge a device that proves to be defective, provided you return the device, shipping prepaid, to us or to our authorized representative.
- This warranty does not apply if the device has been damaged by accident or misuse or as the result of service or modification by entities other than CU Medical Systems, Inc. or its authorized representatives. IN NO EVENT SHALL CU MEDICAL SYSTEMS BE LIABLE FOR CONSEQUENTIAL DAMAGES.
- Only devices with serial numbers and their accessories are covered under this warranty. PHYSICAL DAMAGE CAUSED BY MISUSE OR PHYSICAL ABUSE IS NOT COVERED UNDER THE WARRANTY. Items such as cables and modules without serial numbers are not covered under this warranty.

Warranty Disclaimer

The following renders this warranty null and void:

- Servicing by unauthorized personnel.
- If the factory seal is broken without proper authorization from CU Medical Systems, Inc.
- Failure or damage caused by a fall or external shock after purchase
- Damage by natural disasters such as fire, earthquake, flood and/or lightning
- Failure or damage by environmental pollution or abnormal voltage
- Damage caused by storage in conditions beyond the specified limits.
- Failure due to depletion of consumables
- Failure caused by sand and/or soil getting inside the device
- The purchase date, customer name, distributor name, batch number and other listed information being arbitrarily changed
- No proof of purchase provided along with the device warranty
- Usage of accessories and parts not recommended by the manufacturer.
- Other failure or damage caused by inappropriate operation.

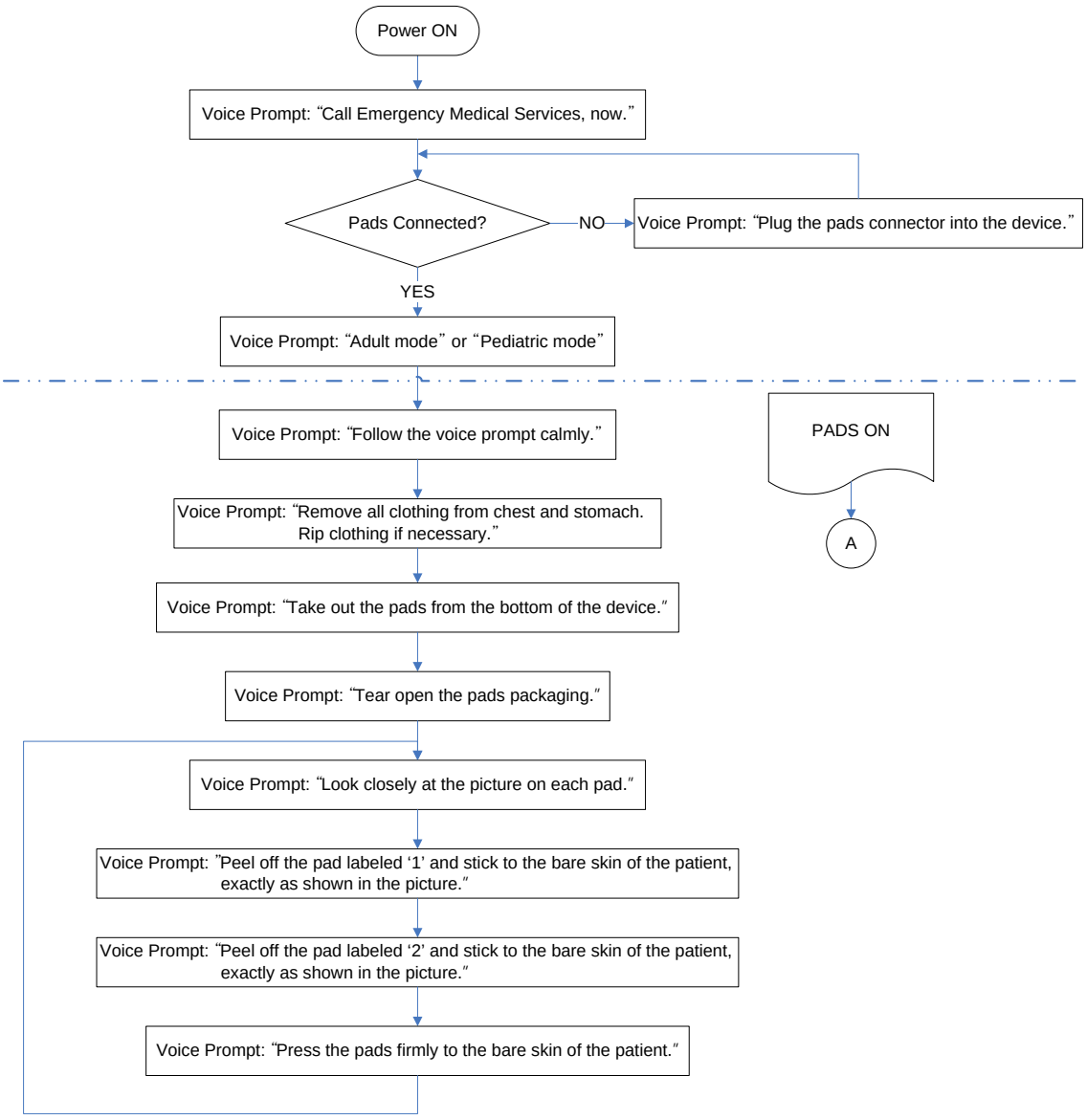
Service

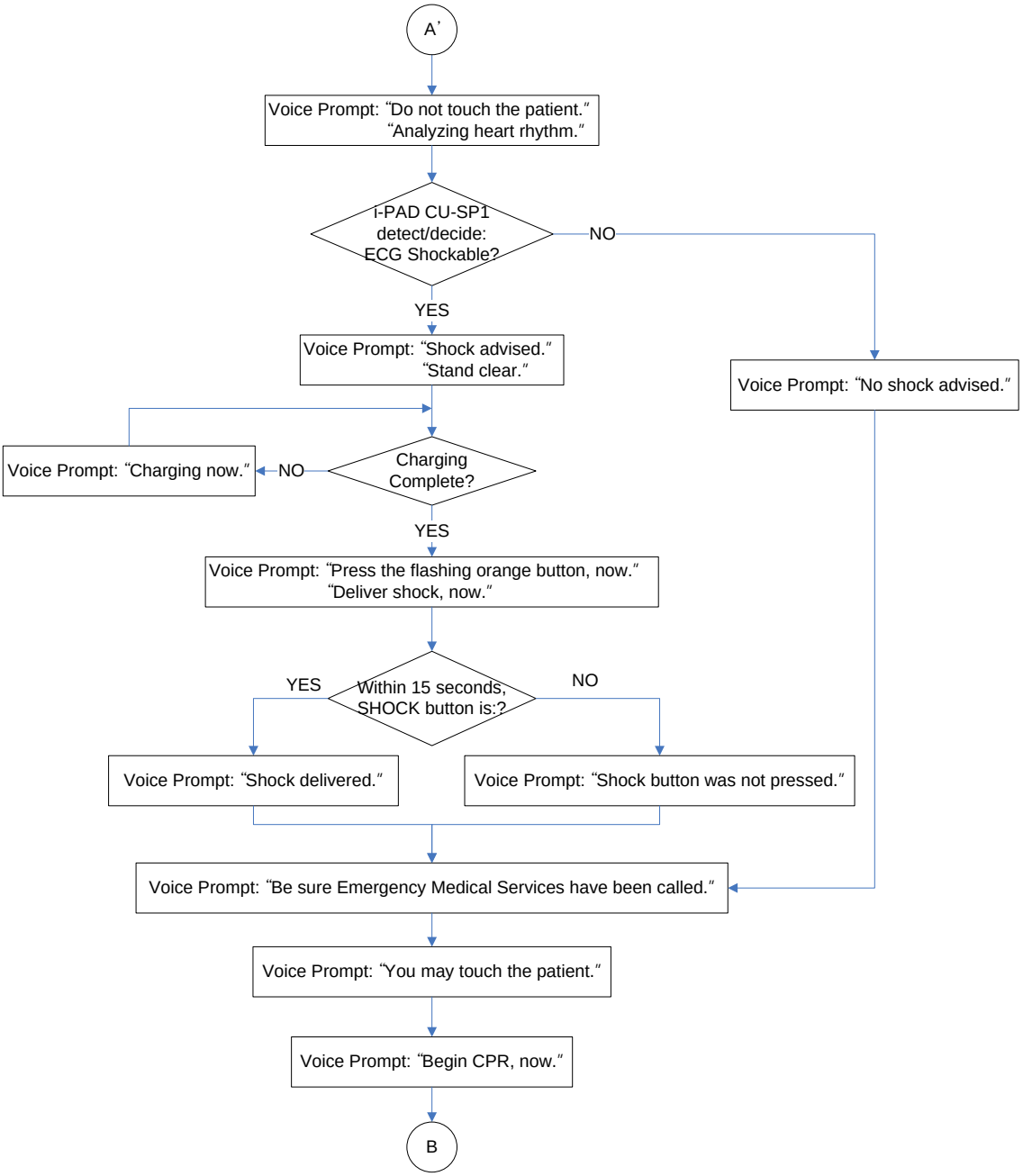
- The i-PAD CU-SP1 must be serviced only by authorized personnel.
- The i-PAD CU-SP1 will be serviced free of charge during the warranty period. After the warranty period, the cost of material and service shall be shouldered by the user.
- When the i-PAD CU-SP1 is not operating properly, immediately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

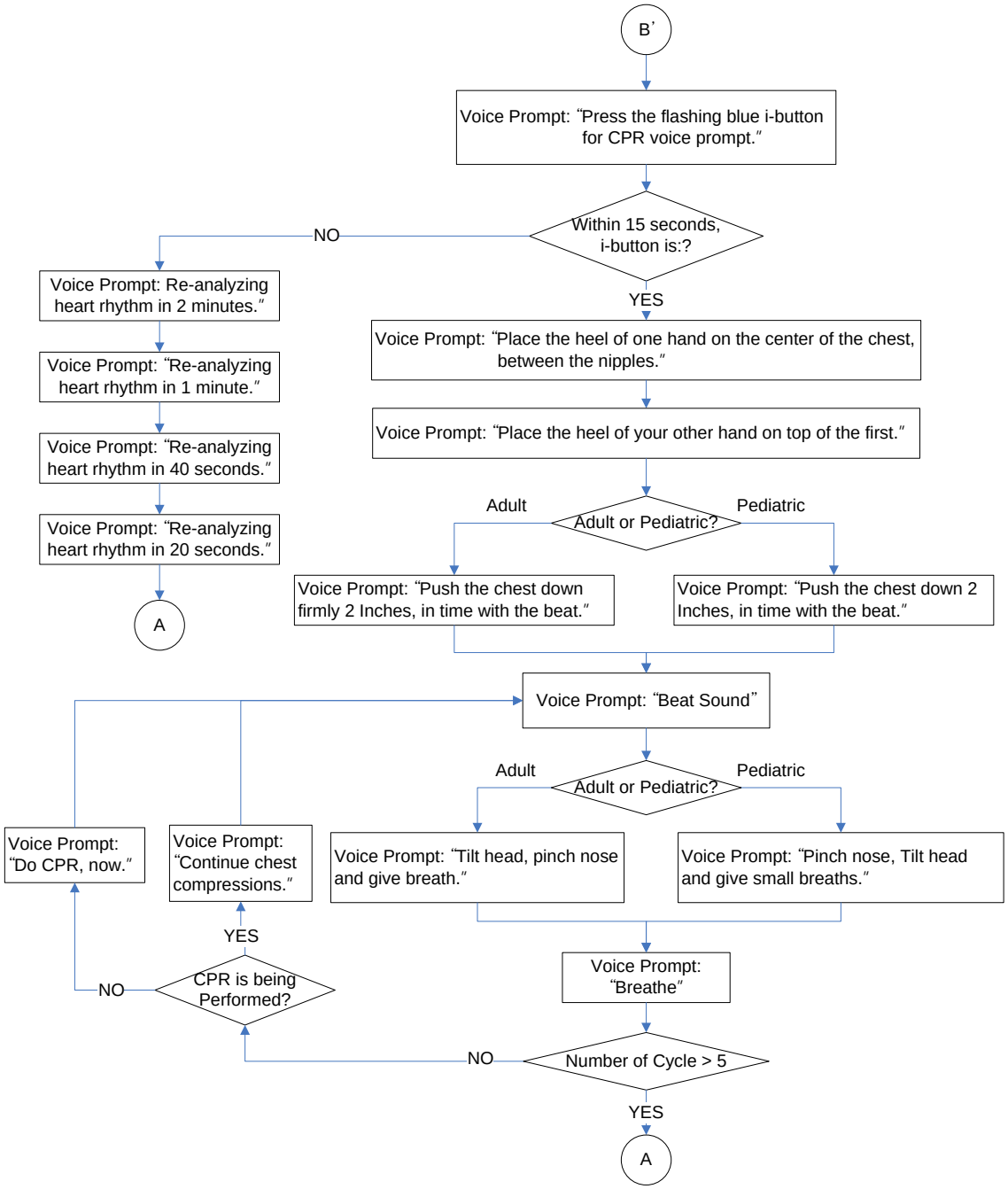
Device classification		Semi-Automated External Defibrillator		
Device Name		i-PAD	Model Number	CU-SP1
Serial Number			Date of Purchase	
Sales Representative				
User Information	Name			
	Address			
	Contact no.			
Brief description of the problem				

Appendix

A . Rescue Protocol




A'
Voice Prompt: "Do not touch the patient."
"Analyzing heart rhythm."
i-PAD CU-SP1
detect/decide:
ECG Shockable?
NO
YES
Voice Prompt: "Shock advised."
"Stand clear."
Voice Prompt: "No shock advised."
Voice Prompt: "Charging now."
NO
Charging
Complete?
YES
Voice Prompt: "Press the flashing orange button, now."
"Deliver shock, now."
YES
Within 15 seconds,
SHOCK button is:?
NO
Voice Prompt: "Shock delivered."
Voice Prompt: "Shock button was not pressed."
Voice Prompt: "Be sure Emergency Medical Services have been called."
Voice Prompt: "You may touch the patient."
Voice Prompt: "Begin CPR, now."
B


B'
Voice Prompt: "Press the flashing blue i-button for CPR voice prompt."
Within 15 seconds, i-button is:?
NO
YES
Voice Prompt: Re-analyzing heart rhythm in 2 minutes."
Voice Prompt: "Re-analyzing heart rhythm in 1 minute."
Voice Prompt: "Re-analyzing heart rhythm in 40 seconds."
Voice Prompt: "Re-analyzing heart rhythm in 20 seconds."
A
Voice Prompt: "Place the heel of one hand on the center of the chest, between the nipples."
Voice Prompt: "Place the heel of your other hand on top of the first."
Adult
Adult or Pediatric?
Pediatric
Voice Prompt: "Push the chest down firmly 2 Inches, in time with the beat."
Voice Prompt: "Push the chest down 2 Inches, in time with the beat."
Voice Prompt: "Beat Sound"
Adult
Adult or Pediatric?
Pediatric
Voice Prompt: "Do CPR, now."
Voice Prompt: "Continue chest compressions."
Voice Prompt: "Tilt head, pinch nose and give breath."
Voice Prompt: "Pinch nose, Tilt head and give small breaths."
YES
NO
CPR is being Performed?
Voice Prompt: "Breathe"
NO
Number of Cycle > 5
YES
A

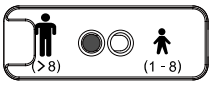
B . Parts and Accessories

To order replacement parts and accessories, cite the part and ordering numbers given in the following table.

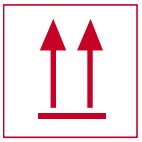
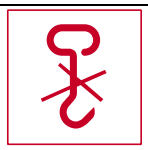
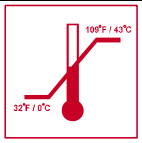
B.1 Standard Accessories		
Name	Part Number	Ordering Number
Adult Pads (disposable)	CUA1007S	SP1-OA04
Disposable Battery Pack(Long-life)	CUSA1103BB	SP1-OA03
Instructions for Use	SP1-OPM-E-02	-
B.2 Optional Accessories		
Carrying Case	SP1-A-BAG-3010	SP1-OA01
Disposable Battery Pack(Standard)	CUSA1103BS	SP1-OA02
Pediatric Pads (disposable)	CUA1102S	SP1-OA05
IrDA Adapter	IR-220LPLUS	SP1-OA06
PC S/W	CU Expert ver. 3.50 or higher	SP1-OA07
SD Card	HD1-CARD-SD	SP1-OA10
SD Card Reader	HD1-CARD-READER	-

C . Description of Symbols

C.1 i-PAD CU-SP1 Defibrillator

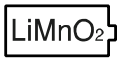
Symbol	Description
	Power ON/OFF button
	i-Button
	SHOCK button
	Adult / Pediatric Selection Switch
	Do-Not-Touch-Patient Indicator
	CPR Detection Indicator
	BF type, defibrillation-proof equipment
	Attention: Refer to accompanying documents.
CE 2460	CE Mark; meets the requirements of the European Medical 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
	General prohibition sign

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℉ to 109℉)
	Recyclable
CE 2460	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.3 Accessories

C.3.1 Disposable Battery Pack (CUSA1103BB, CUSA1103BS)

Symbol	Description
	Lithium Manganese Dioxide Battery
	LOT Number
	Manufactured Date
	Manufacturer
	Do not break or apply pressure on the battery.
	Do not discard the battery indiscriminately. Discard in accordance with local regulations.
	Refer to instruction manual/booklet
	General warning sign
	Warning: Flammable material
	CE Mark

C.3.2 Pads (CUA1007S, CUA1102S)

Symbol	Description
	Temperature limits: 0℃ to 43℃(32℉ to 109℉)
	Lot number
	Expiration date
	Order reference number
	Single use only; do not reuse
	Do not fold or bend.
	Contains no latex
	Expiration Date and Lot number sticker
	Attention: Refer to accompanying documents
	CE Mark; meets the requirements of the applicable European directive

D . Glossary

1 CPR	1 CPR consists of 5 cycles. (When the device is set to 5 cycles as default)
1 Cycle	Refers to 30 chest compressions followed by 2 breaths during CPR. (When the device is set to the default setting [30:2]) If you specify the number of compression and number of breath, the cycle is performed in accordance with the specified protocol. Refer to [Section 5.3: Device Setting] for detailed setting method.
Abrasive	A material used to sharpen and clean the surface of metal, glass, stone and wood, which includes emery, quartz powder and glass dust. Do not use these abrasives to clean the device.
Adhesive Material on the Pads (Gel)	The adhesive material on the pads is very important for maintaining the optimum adhesion between the skin and pads. Therefore, never open the pads package when the pads is not needed, and periodically check the expiration date of the pads.
Adult	The adult in these Instructions for Use is defined as a person who is older than 8 years or heavier than 25 kg.
American Heart Association (AHA) 2010 CPR Guidelines	The default settings of this device direct the you to perform CPR immediately after one electric shock in accordance with the 2010 CPR Guidelines. Also, the CPR guide is composed of 5 cycles with the chest compression to ventilation ratio of 30:2 (if the device is set to a default setting of 5 cycles, 30:2). If you are not trained in ventilation, perform only the chest compression. Refer to [Section 5.3: Device Setting] for the CPR setting. Please contact the manufacturer for additional information.

Arrhythmia	An abnormal heart rhythm.
Battery Pack	A disposable battery that supplies power to the i-PAD CU-SP1.
Cardiac Arrest Patient	A patient with cardiac arrest symptoms. This device should be used for the patient with the following symptoms: No response, no movement and no normal breathing.
Communication Port	A port that sends and receives data between the device and PC.
Condensation	Moisture has an adverse effect on the device when condensation is formed on the device surface. The device should be stored in a dry environment without excessive humidity.
CPR Mode	The device provides guidance for CPR while pausing analysis of the patient's ECG such that you can easily perform CPR. The CPR mode on this device complies with AHA's 2010 CPR Guidelines. Refer to [Section 4.3., Step 3: Perform CPR] for more information.
Defibrillation	Is a process in which an electronic device gives an electric shock to the heart. This helps reestablish normal contraction rhythms in a heart having dangerous arrhythmia or in cardiac arrest.
Defibrillator Pads Connector	A connector on the device that is used to connect the device with defibrillator pads.
Disposable Battery Pack	A disposable battery pack that provides power to the device. Never charge this battery pack.
ECG	An abbreviation for electrocardiogram. A record of the heart's electrical rhythm as detected by the defibrillation pads.

Electric Shock	This device charges large energy in a short time and performs defibrillation via an electric shock.
Error	A status in which the device does not properly operate. Refer to [Section 8.3: Troubleshooting] for more information.
Fibrillation	Refers to an irregularity of the heart causing ineffective circulation. Ventricular fibrillation is accompanied with an acute cardiac arrest.
Flashing	A status in which the indicator is flashing.
i-Button	A button to check the most recent device usage, to report error messages, to transfer the ECG and event data, and to change the CPR guide settings.
IrDA Port	A communication port that sends and receives data between the device and computer. Since this IrDA port utilizes light (infrared), care needs to be taken to reduce interference. Refer to the [CU Expert] manual for more information.
Light	A status in which the indicator is lit.
Operation Mode	An ○ on the Status LCD while the device is on indicating that the device is properly operating.
Pads	The pads stated in these Instructions for Use refers to a pads (disposable) for defibrillation.
Pad 1	Refers to a pad that is placed under the right clavicle. Please refer to the picture on the pad. (The position may be switched with pad 2.)
Pad 2	Refers to a pad that is placed on the ribs on the patient's lower left chest directly under the armpit. Please refer to the picture on the pads (the position may be switched with pad 1).

Pads Connector	The connector on the pads that is used to connect the pads with the i-PAD CU-SP1.
PC S/W CU Expert (CU-EX1)	PC software used to modify the settings of the i-PAD CU-SP1 and to manage treatment data. Refer to the appendix on accessories if you want to purchase this software.
Pediatric	The child in these Instructions for Use is defined as a person who is older than 1 year and younger than 8 years as well as lighter than 25 kg.
Power Button	A green button on the front of the device. The device turns on when the Power Button is pressed during Standby Mode, and it turns off when the Power Button is pressed for one second while the device is on. If the Power Button is pressed during the battery insertion test, the battery insertion test is canceled.
Device	The Device referred to in these Instructions for Use is the i-PAD CU-SP1 Semi-Automated External Defibrillator (AED).
Pads liner	The liner that protects the conductive gel of the pads during storage inside the pads pouch.
SD Card	An external memory card that could be used to store treatment data (ECG and event) from the internal memory of the device.
Self- Test	Self diagnostic tests that verify the proper operation of the subsystems of the device.
Internal discharge (disarm)	The i-PAD CU-SP1 dumps the charge in its defibrillating capacitor into an internal load If you do not press the Shock Button or if the device determines that the patient does not need an electric shock due to the change in the patient's ECG.

Semi-Automated External Defibrillator (AED)	A device that delivers a defibrillating shock after analyzing and recognizing a shockable rhythm. You must concur with the shock delivery by pressing the SHOCK button.
Shock Button	The button that you must press to deliver an electric shock to a cardiac arrest patient.
Standby Mode	The mode of the i-PAD CU-SP1 when the Power Button is OFF but the battery pack is inserted. If ○ is shown on the Status LCD while the device is in standby mode, the device is ready to be used as needed in an emergency).
We	Refers to CU Medical Systems Inc.

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)

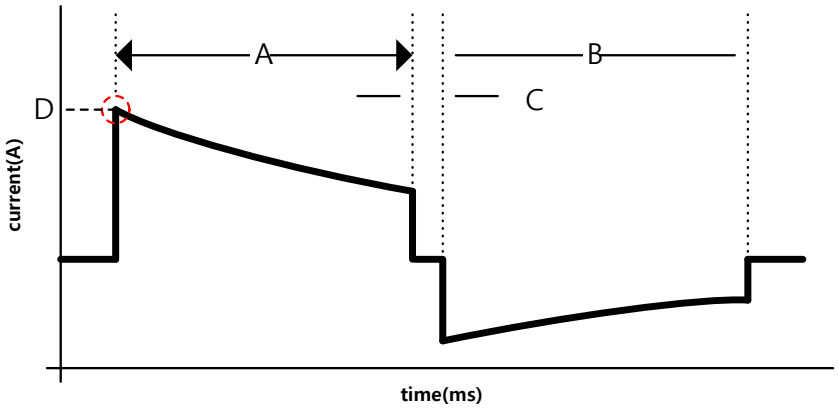
Environmental	
Category	Nominal Specifications
Operational Status (The device is in emergency use)	
	Temperature: 0℃ ~ 43℃ (32℉ ~ 109℉)
	Humidity: 5% ~ 95% (non condensing)
Storage Status (The device is stored together with the defibrillator pads and the battery pack is inserted - ready to be used in an emergency)	
	Temperature: 0℃ ~ 43℃ (32℉ ~ 109℉)
	Humidity: 5% ~ 95% (non condensing)
Transport Status (device only, no defibrillator pads and battery pack included)	
	Temperature: -20℃ ~ 60℃ (-4℉ ~ 140℉)
	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 The battery symbol in Status LCD blinks when battery is not enough.
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 When the device detects Low Battery, it warrants 10 shocks and 30 minutes of operation.
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℉ ~ 109℉) • Storage Temperature: -20℃ ~ 60℃ (-4℉ ~ 140℉)

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.

F . Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions

The i-PAD CU-SP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD CU-SP1 should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The i-PAD CU-SP1 uses RF energy only for its internal function. Therefore, its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The i-PAD CU-SP1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	

⚠ WARNING

- The i-PAD CU-SP1 should not be used adjacent to or stacked with other equipment.

  If adjacent or stacked use is necessary, the i-PAD CU-SP1 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic immunity

The i-PAD CU-SP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD CU-SP1 should assure that it is used in such an environment.

Immunity Test	IEC 60601-1 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV Contact ±8 kV air	±6 kV Contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0.5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the i-PAD CU-SP1 image intensifier requires continued operation during power mains interruptions, it is recommended that the i-PAD CU-SP1 image intensifier be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The i-PAD CU-SP1 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD CU-SP1 should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the i-PAD CU-SP1, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	$d = [\frac{3,5}{V1}]\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	10 Vrms	$d = [\frac{12}{V2}]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = [\frac{12}{E1}]\sqrt{P}$ 80 MHz ~ 800 MHz
	20 V/m 80 MHz to 2,5 GHz	20 V/m	$d = [\frac{23}{E1}]\sqrt{P}$ 800 MHz ~ 2,5 GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m)[b] Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 80 MHz and 800 MHz, the higher frequency range applies.	
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people.	
a	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz
b	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges
c	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the i-PAD CU-SP1 is used exceeds the applicable RF compliance level above, the CU-SP1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the i-PAD CU-SP1
d	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V / m.

Recommended separation distances between portable and mobile RF communications equipment and the CU-SP1

The i-PAD CU-SP1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the i-PAD CU-SP1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the i-PAD CU-SP1 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]					
	150 kHz to 80 MHz outside ISM bands $d = [\frac{3,5}{V1}]\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [\frac{12}{V2}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{12}{E1}]\sqrt{P}$		800 MHz to 2,5 GHz $d = [\frac{23}{E1}]\sqrt{P}$	
	V1 = 3 Vrms	V2 = 10 Vrms	E1 = 10 V/m	E1 = 20 V/m	E1 = 10 V/m	E1 = 20 V/m
0.01	0.06	0.12	0.12	0.06	0.23	0.16
0.1	0.11	0.38	0.38	0.19	0.73	0.36
1	0.35	1.20	1.20	0.60	2.3.0	1.15
10	1.11	3.79	3.79	1.90	7.27	3.64
100	3.50	12.00	12.00	6.00	23.00	11.50

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1) At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3) An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and refection from structures, objects and people