Instructions for Use

i-PAD CU-SP2

The information in these Instructions for Use applies to the i-PAD CU-SP2. This information is subject to change. Please contact CU Medical Systems, Inc. or its authorized representatives for information on revisions.

Revision History

Edition 3.1

Publication Date: April 2, 2018

Document No.: SP2-OPM-E-03

Published by: CU Medical Systems, Inc.

Printed in the Republic of Korea

Medical Device Directive

The i-PAD CU-SP2 complies with the requirements of the Medical Device Directive 93/42/EEC and its revisions.

CE 2460

Important:

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

However, defibrillation may not work on some patients even when administered promptly due to the fundamental causes of SCA.

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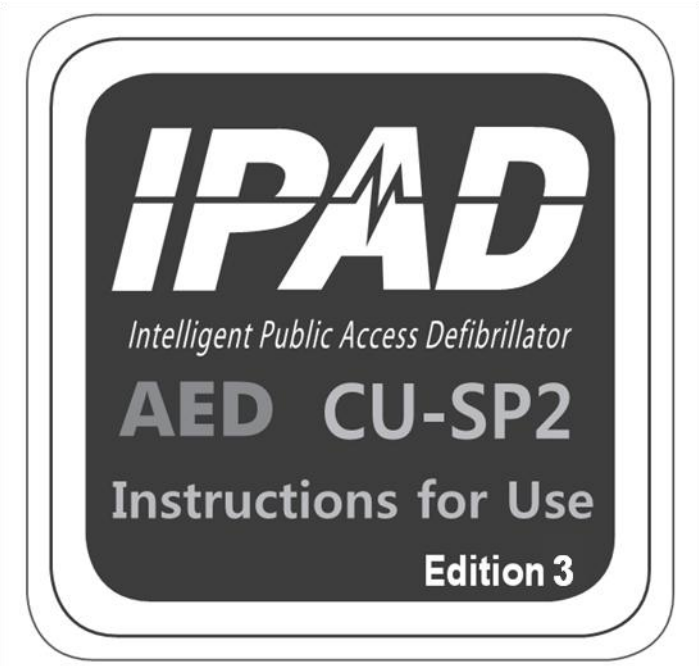


CU Medical Systems, Inc.

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 8: 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-SP2], "We" or “Us" refers to CU Medical Systems, Inc., "Pads" refers to disposable defibrillation electrode pads for adult or pediatric modes, and "Battery Pack" refers to the rechargeable or disposable battery pack.
These Instructions for Use emphasize 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-SP2. 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.
This device is a semi-automated external defibrillator that can be administered on sudden cardiac arrest (SCA) patients.

⚠ 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.

Users of this device must follow these instructions.

- You must follow the instructions, warnings, cautions, and notices in these Instructions for Use when using this device.
- The manufacturer or its authorized distributor 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. The manufacturer or its authorized service centers will not be liable for devices serviced at the user’s own discretion.
- If the device is intended to be connected to equipment other than that 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. Product Information

1.1 Device Description

The i-PAD **CU-SP2** is an easy-to-use dual mode (Semi-Automated and Manual) Defibrillator. It is small, light, portable, and internally powered by a battery pack.

① Semi-Automated Mode

The AED automatically reads the sudden cardiac arrest (SCA) patient's electrocardiogram (ECG) and determines if a cardiac arrest that requires defibrillation has occurred, so that licensed emergency medical technicians, medical professionals and the general public can easily operate it. SCA 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.

② Manual Mode

In manual mode, the user determines whether the patient needs a defibrillation shock or not.

1.2 Indicated Use

① Semi-Automated Mode

The i-PAD CU-SP2 is indicated for use on patients that are exhibiting the symptoms of sudden cardiac arrest (SCA) with all of the following signs:

- **No movement and no response when shaken**
- **No normal breathing**

If the patient is suspected of displaying the symptoms above, attach the pads and use the defibrillator according to each step of the voice instructions.

② Manual Mode

- **Asynchronous defibrillation:** The same indicated use as in Semi-Automated Mode.
- **Synchronous cardioversion:** The i-PAD CU-SP2 is indicated for the treatment of atrial fibrillation. During synchronous cardioversion, the shock is delivered within 60 milliseconds of the occurrence of a QRS peak in the patient’s ECG.

1.3 Intended Users

① Semi-Automated Mode

In this mode, the i-PAD CU-SP2 is intended for use by licensed emergency medical technicians or medical professionals. Also, the general public untrained in CPR or the use of the defibrillator may use this device according to its settings. However, the manufacturer recommends that inexperienced users complete training in CPR or the use of the defibrillator for quick and systematic emergency treatment.

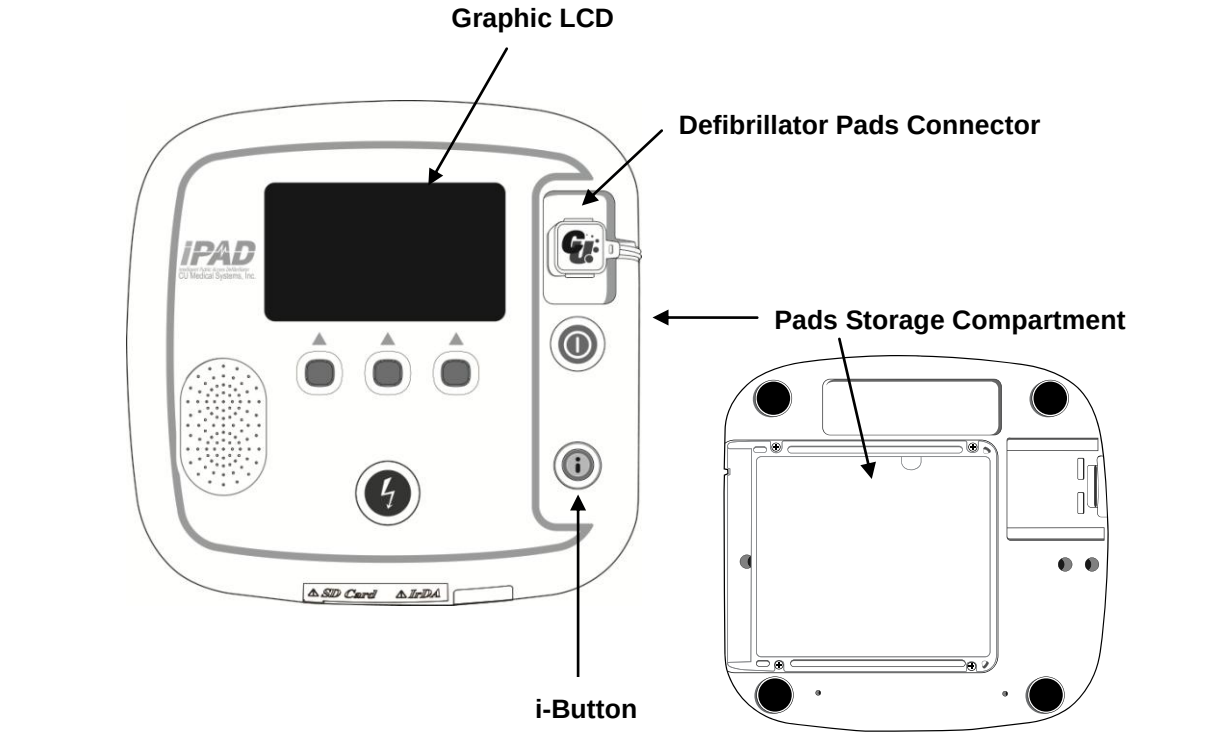
② Manual Mode

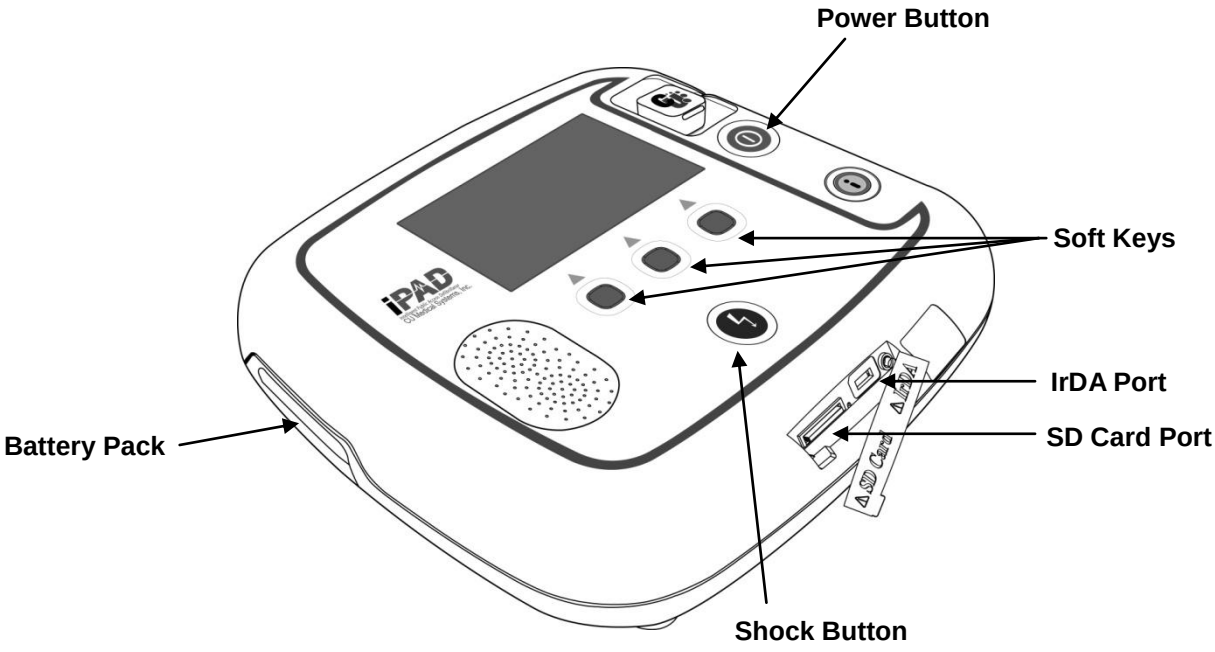
In this mode, the i-PAD CU-SP2 is intended for use by health care professionals and emergency rescue personnel who have been trained in advanced cardiac life support.

1.4 Additional Information

Please contact CU Medical Systems, Inc. or its local distributors for any additional information on the i-PAD **CU-SP2**.

2. Device Features





Power Button	Turns the device on or off. (When the device is on, a green LED backlight is lit.)

i-Button	• Provides the following information by voice and LCD screen
	  • Reports device usage
	  (the total hours of the last usage and number of shocks)
	  • Checks the S/W version
	  • Checks for errors
	• Transmits event and ECG data through IrDA and SD Card
	• Mode Change(Adult / Pediatric Mode, AED / Manual Mode)

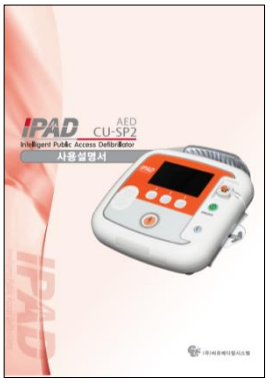
Graphic LCD	Displays the current status of the device, user's guide, ECG, heart rate, etc.
Shock Button	Delivers defibrillating shock when pressed.
Defibrillator Pads Connector	Connects with the connectors of the pads.
Battery Pack	The rechargeable (disposable is optional) power source of the device.
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 an SD card.
Soft Keys	Three buttons that control device settings and operation
Pads Storage Compartment	Stores pads.

3. Preparation for Use

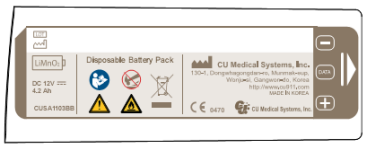
3.1 Standard Package Contents

The following are the standard package contents of this device.

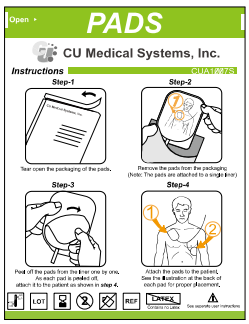
CU-SP2 Semi-automated / Manual External Defibrillator



Instructions for Use

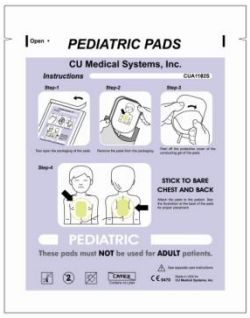


1 Battery Pack (Disposable)



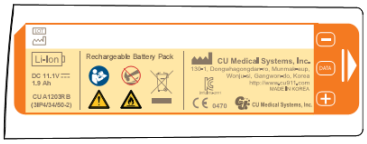
1 Pack of Adult Pads (Disposable)

3.2 Key Accessories



1 Pack of Pediatric Pads

IrDA Adapter



1 Battery Pack (Rechargeable)

SD Card

Printer

CU-EM1 (ECG Transmission Device)

Battery Charge Dock

Battery Charger

The accessories above are not included in the standard package contents.

Please contact us after referring to [Appendix A: Parts and Accessories] for additional supplies.

NOTICE

- Please keep spare pads and battery packs handy to quickly respond to emergency situations.

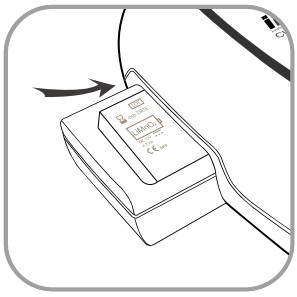
3.3 Preparation for Use

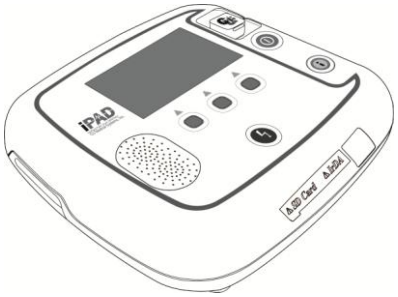
Do the following to set up the i-PAD CU-SP2.

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 figures below.





As the battery pack is inserted, the device starts a self-test and displays the following on the Monitor LCD.

After the self-test is complete, the device will automatically shut down.

If the self-test fails, please refer to [Chapter 7: 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: Parts and Accessories] of these Instructions for Use.

⑤ Store the device referring to the following considerations.

- You must store the defibrillator according to the storage conditions specified in [Section 6.1: Device Storage].
- Store the defibrillator in an easy-to-access location where its technical alarms can be easily heard (e.g. alarm on low battery or other device problems).
- Store the accessories along with the device in the device's carrying case for easy and quick access.

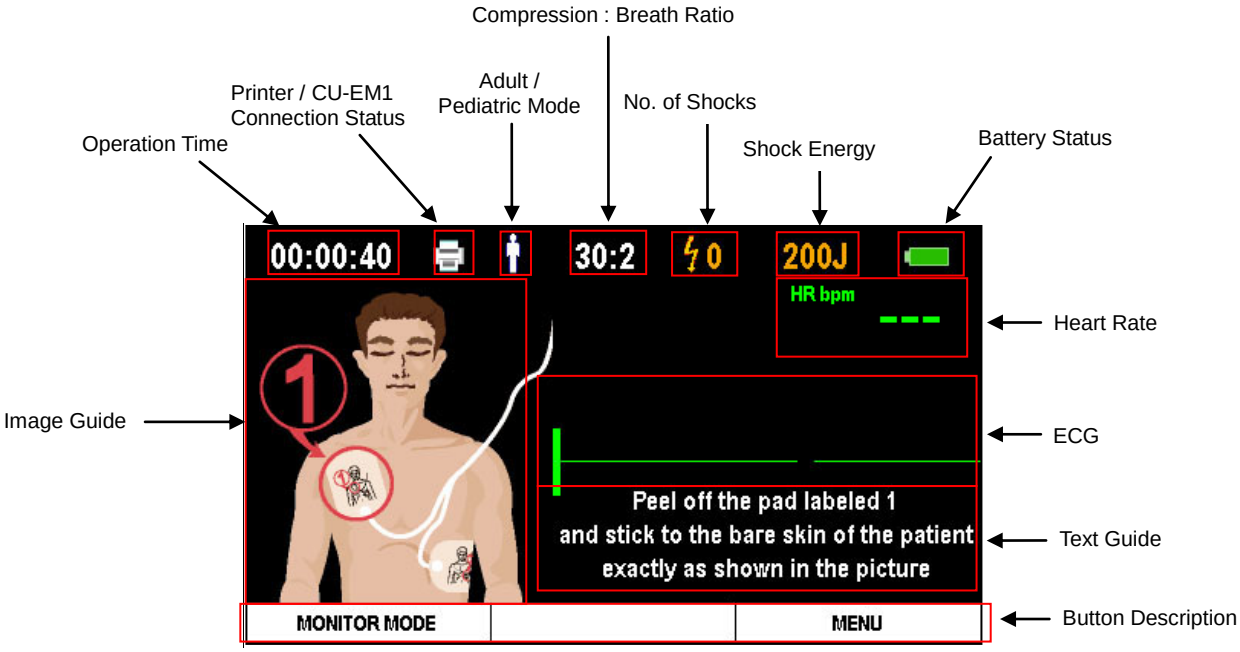
⚠ WARNING

- 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. Please refer to [Appendix D: 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-SP2.
- When the product is used for asynchronous defibrillation treatment in Manual mode, do not use it on patients who show any of the following symptoms:
  - responsiveness, normal movement, normal breathing and detectable pulse.
- There is a possibility of explosion or fire if the product is used in the presence of flammable agents or in an OXYGEN enriched atmosphere due to the arc discharged caused by electric shock.
- Do not deliver an electric shock when the patient's ECG signal is in the asystole state. It may lead to a failure to restore cardiac pacemaker functions in the heart, meaning the cardiac function will not be restored.
- This product must not be applied on patients implanted with the implantable pacemaker. If patients show all of the symptoms including no response, and abnormal breathing, use the product in the following ways:
  - Attach the pad at least 3cm away from the implantable pacemaker attached to the patient.
  - Do not attach the pad right on the area implanted with the implantable pacemaker.

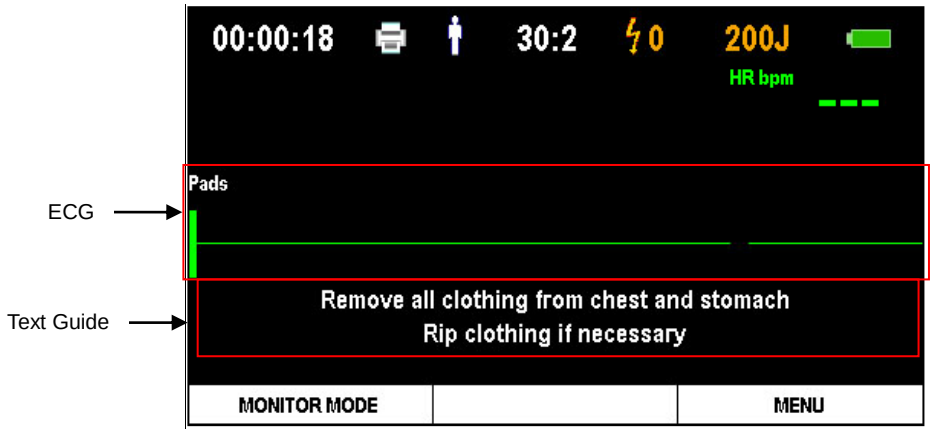
4. How to Use the i-PAD CU-SP2

4.1 LCD Screen

The configuration of the Graphic LCD Screen is as shown below. The screen configuration can be changed according to the 'Graphic Instruction'. For detailed instructions on setting the 'Graphic Instruction', please refer to [Section 5.4: Device Setup] of these Instructions for Use.



[Screen configuration: Image guide ON]



[Screen configuration: Image guide OFF]

Image Guide	Guides the user in operating the device.
Operation Time	Displays the actual operation time of the device.
Printer / CU-EM1 Connection Status	Displayed when using the Printer / CU-EM1. • Printer:  • CU-EM1: 
Adult / Pediatric Mode	Changes based on the Adult / Pediatric Mode of the device. • Adult:  • Pediatric: 
Compression : Breath Ratio	• Displays the CPR setting of the device. • Can be changed by pressing the Soft Keys during operation when in Pediatric Mode. • The chest compression number is fixed to 30 when in Adult Mode.
No. of Shocks	Displays the number of administered shocks.
Shock Energy	Displays the amount of shock energy administered to the patient.
Battery Status	Displays the status of the battery in 4 steps. Step 1:  - The battery is full. Step 2:  - Less than half of the battery is remaining. Step 3:  - Less than ¼ of the battery is remaining. Step 4:  - The battery is almost depleted.
Heart Rate	Displays the heart rate of the patient after the pads are attached.
ECG	Displays the ECG of the patient after the pads are attached.
Text Guide	Uses the text to guide the user in operating the device.
Button Description	Describes the functions of the three Soft Keys.

NOTICE

- The Graphic LCD Screen illustrated in these Instructions for Use may not match the actual screen during operation depending on the device settings.
- The Printer and CU-EM1 are not a part of the standard package contents. If you want to purchase them, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

4.2 Soft Keys

There are three Soft Keys in the center of the i-PAD CU-SP2, which operate the device and the menu mode. The Soft Keys operate in two modes: Operation Mode and Menu Mode.
When in Operation Mode, the functions of the Soft Keys are changed according to the 'Manual Override'. For further details on 'Manual Override', please refer to [Section 5.4: Device Setup] of these Instructions for Use.

※ Soft Keys are labeled 1~3 from left to right.

Soft Key Functions in Menu Mode		
Button 1		Moves left/up on the menu.
Button 2		Selects or sets the current item.
		Plays ECG (used when loading previous ECG).
		Pauses ECG (used when loading previous ECG).
Button 3		Moves right/down on the menu.

For further details on the Menu Mode and the use of Soft Keys in Menu Mode, please refer to [Section 5.4: Device Setup] of these Instructions for Use.

※ Soft Keys are labeled 1~3 from left to right.

Soft Key Functions in Operation Mode (Before attaching pads on the patient)		
Button	**Indication**	**Function**
Button 1	MONITOR MODE	When pressed, the i-PAD CU-SP2 will attempt to establish Bluetooth connection to the CU-EM1 (ECG transmission device). If successful, the device will operate in Monitor Mode. In Monitor Mode, ECG analysis and shock treatment will not be available.
	SEMI-AUTO	The i-PAD CU-SP2 operates in Monitor Mode. When pressed, the i-PAD CU-SP2 will disconnect from the CU-EM1 and switch to Semi-automated mode
Button 2	30:x	This function is activated when the 'No. of Chest Compressions' under the CPR setting of the device is set to '15 times'. When pressed, the setting will change to '30 times'. (The 'x' refers to the 'No. of Artificial Respirations' under the CPR setting.)
	15:x	This function is activated when the 'No. of Chest Compressions' under the CPR setting of the device is set to '30 times'. When pressed, the setting will change to '15 times'.

		(The 'x' refers to the 'No. of Artificial Respirations' under the CPR setting.)
Button 3	MENU	When pressed, the device will enter the Menu Mode. For further details on the Menu Mode, please refer to [Section 5.4: Device Setup] in these Instructions for Use.

※ Soft Keys are labeled 1~3 from left to right.

Soft Key Functions in Operation Mode (After attaching pads on the patient)		
Button	**Indication**	**Function**
Button 1	ANALYZE	When pressed, the device will start analyzing the patient's ECG.
	STOP ANALYZE	This function is activated while the device is analyzing the patient's ECG. When pressed, the device will stop analyzing the patient's ECG.
	CHARGE	When pressed, the device will start charging energy for administering a shock.
	DISARM	This function is activated while the device is charging energy. When pressed, the device will stop charging and internally discharge the energy stored within the device.
Button 2	30:x	This function is activated when the 'No. of Chest Compressions' under the CPR setting of the device is set to '15 times'. When pressed, the setting will change to '30 times'. (The 'x' refers to the 'No. of Artificial Respirations' under the CPR setting.)
	15:x	This function is activated when the 'No. of Chest Compressions' under the CPR setting of the device is set to '30 times'. When pressed, the setting will change to '15 times'. (The 'x' refers to the 'No. of Artificial Respirations' under the CPR setting.)
Button 3	START CPR	When pressed, the device will guide you through CPR.
	STOP CPR	This function is activated while the device is guiding you through CPR. When pressed, the device will stop the CPR Guidance.

For further details on the functions of the Soft Keys, please refer to [Section 4.5: Defibrillation in Adult Mode] and [Section 4.6: Defibrillation in Pediatric Mode] in these Instructions for Use.

NOTICE

- Button 2 is activated only when the device is set to Pediatric Mode.
- When 'Manual Override' is set to 'OFF', Soft Keys 1 and 3 will be deactivated after attaching the pads on the patient.

4.3 Mode Change

The operation mode change is accomplished by pressing the i-button while the device is on. Soft Keys 2 and 3 are activated by pressing the i-button. By pressing the i-button and a soft key at the same time, operation mode will be changed.

Soft keys for mode changes are as follows:

※ Soft Keys are labeled 1~3 from left to right.

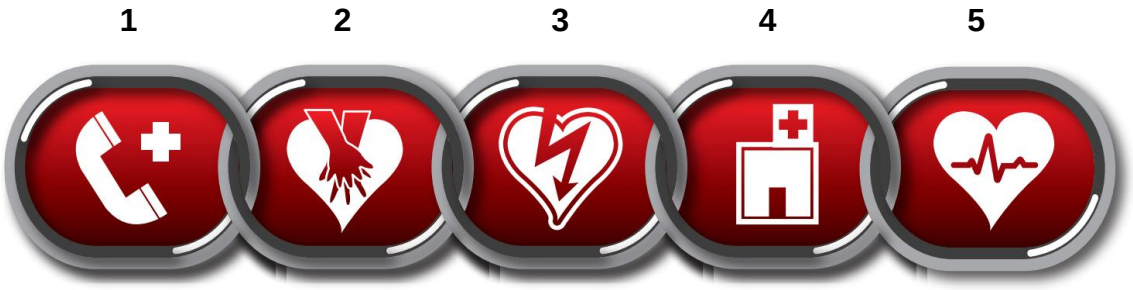
Soft Key Functions in Operation Mode (Pressed the i-button to change the mode)		
Button	**Indication**	**Function**
Button 2	Adult	This function is activated when the i-button is pressed while the device is in pediatric mode. When pressed, mode is changed to adult mode.
	Pediatric	This function is activated when the i-button is pressed while the device is in adult mode. When pressed, mode is changed to pediatric mode.
Button 3	Manual Mode	This function is activated when the i-button is pressed while the device is in AED mode. When pressed, mode is changed to Manual mode.
	AED Mode	This function is activated when the i-button is pressed while the device is in Manual mode. When pressed, mode is changed to AED mode.

NOTICE

- Button 3 is activated only when manual mode is installed. When the equipment security mode setting is activated, changing the mode asks you to enter the password. For further details on the security mode, please refer to [Section 5.4: Device Setup] in the Instructions for Use.
- When pediatric pads are connected, the button 2 is not activated.

4.4 Procedure for Using the Device

If you think that you are witnessing someone suffering from sudden cardiac arrest, perform the chain of actions recommended by the Korean Association of Cardiopulmonary Resuscitation (KACPR) and the American Heart Association (AHA) in their Chain of Survival emergency response to sudden cardiac arrest.



1. Immediate recognition and activation of the emergency response system – 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-SP2).**
   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 when 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

- When you witness someone suffering from sudden cardiac arrest, you must perform the chain of actions recommended by the Korean Association of Cardiopulmonary Resuscitation (KACPR) and the American Heart Association (AHA) in their Chain of Survival emergency response to sudden cardiac arrest. If finding and/or operating the defibrillator takes time, monitor the patient's status and activate the emergency response system until the defibrillator is available, and perform CPR if necessary.

4.5 Preparation for Defibrillation

① Turn the device on by pressing the Power Button.

When the power turns ON the following occurs in sequence:

- Beeper: The beeper will beep for 1 second.
- A self-test will be initiated.
- The device will give voice instructions to call emergency medical services and on the 'Adult / Pediatric Mode'.
- The guide on how to use the device will be given through the LCD Screen and by voice.

⚠ WARNING

- Never perform defibrillation in pediatric mode to a patient who is either heavier than 25 kg or older than 8 years old.
- You can change the adult/pediatric mode under Menu Mode after turning on the i-PAD CU-SP2. 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 / 200J) or pediatric value (50 J).
- For further details on setting the menu, please refer to [Section 5.4: Device Setup] of these Instructions for Use.

② Remove clothes from patient's chest.

CAUTION

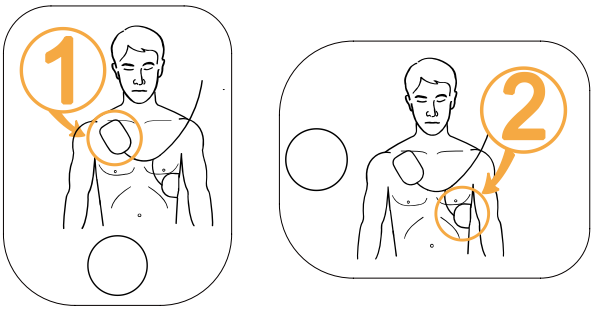
- Time is essential for the cardiac arrest patient. Thus, time should not be wasted in completely removing their clothes. Tear or cut clothes to attach the pads as soon as possible, if removing them will take too much time.
- Dry the patient's skin such that the pads can adhere well on the chest. Shave chest hair if necessary.
- Avoid laying the patient on conductive locations, such as metal, an electric pad, and water.

③ Remove the pads package from the Pads Storage Compartment at the bottom of the device.

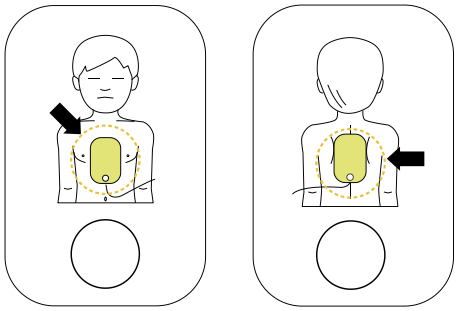
④ Open the pads package and take out the pads.

⑤ **Refer to the pictures on both pads and accurately identify the locations where the pads will be attached.**

Adult Pads



Pediatric Pads



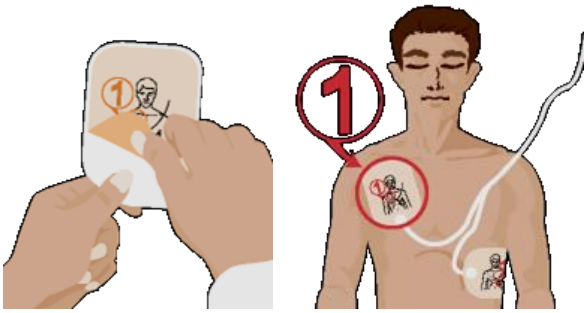
CAUTION

- The adhesive material on the pads starts to dry out as soon as the package is opened. Use immediately after opening.
- For procedures on checking the expiration date of the pads and maintaining them, please refer to [Section 6.2: Maintenance] of these Instructions for Use.

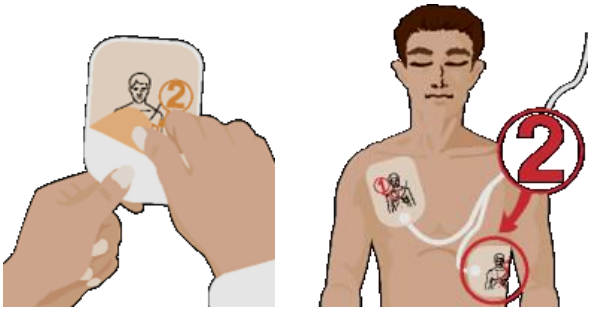
4.6 Defibrillation in Adult Mode

Step 1: Place pads on the patient.

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



② Remove pad **2** from the single liner and stick the pad to the patient's left side torso in line with the armpit as shown below.



③ If the device detects the connection to the patient after placing the pads, follow the voice instructions of the device.

⚠ WARNING

- Keep the pads well clear of other electrodes or metal parts in contact with the patient.

NOTICE

- Defibrillation can be done even if the pads are reversed. If the locations of the 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 pads are 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 pad.

Step 2: Press the Shock Button when instructed.

The device acquires and analyzes the patient's ECG immediately after being connected. According to the device settings, automatic analysis will become available, along with ANALYZE and CHARGE. If the device is set to automatic analysis, the device will automatically start analyzing the ECG as soon as the pads are attached to the patient.

⚠ WARNING

- Do not touch the patient when the device instructs you not to touch the patient. The ECG analysis may become inaccurate if you touch the patient during the analysis.

If the patient needs defibrillation after the ECG analysis, the device will do the following:

- The device announces that a defibrillation shock is needed, and instructs you to keep away from the patient.
- When armed, the device will continuously 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 issues voice instructions on CPR.

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. Then the voice instruction for CPR starts.

⚠ WARNING

- When administering defibrillation, do not position the patient on conductive fluids. If the patient's skin is wet, remove the moisture prior to using the device.
- When administering defibrillation, disconnect from the patient all other medical equipment that have no defibrillation-proof applied parts.
- The user and everyone near the patient must avoid making the following contacts.
  - Do not touch any body parts of the patient, such as the body, head, arms, and legs.
  - Do not touch any conductive fluids, such as gel, blood, and saline.
  - Do not touch any conductive metal objects, such as a stretcher or wheelchair.

  Making such contacts may provide unwanted pathways for the defibrillating current.
- The user must not touch the patient when pressing the Shock Button. The defibrillating shock may harm the user or bystanders.
- Use of a defibrillator in the presence of flammable agents or in an oxygen enriched atmosphere presents an explosion and fire hazard.

NOTICE

- After starting the ECG analysis, the device will continue the analysis up to the point of pressing the Shock Button. If the patient’s ECG changes to a non-shockable rhythm before the Shock Button is pressed, the device will disarm itself. It will then reanalyze the patient's ECG.
- 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 and instruct you to make sure that emergency medical services have been called. The device will then instruct you to begin CPR.
- 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. Perform CPR until the replacement equipment is ready to use.

Step 3: Perform CPR.

The user must immediately perform CPR while temporarily suspending emergency treatment on the patient. During this step, the device will give voice instructions for the pause period. When voice instruction for CPR is needed, press the flashing blue i-Button within 15 seconds.

For further details on CPR, please refer to the [CPR Method] below.

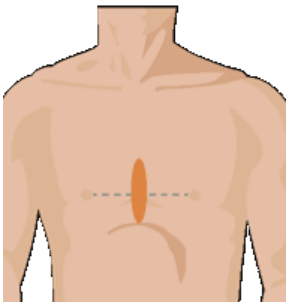
[CPR Method]

1. Compression Point

Place the heel of your hand in the middle of the patient's chest between the 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 overlapping and parallel. Then, spread or lock your fingers without touching the chest. Keep your elbows straight and your arms vertical to the ground, and use your weight to start the compression.

2. Compression Speed and Depth

Compress the chest at least 5cm (up to 6cm) deep, and at a rate of at least 100 compressions per minute (up to 120 times).



3. Opening the Airway

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

4. Artificial Respiration Method

Pinch the patient's nose as shown in the figure below, place your mouth over the patient's mouth, and blow in sufficient air to make the chest rise significantly.

CAUTION

- After the CPR Guidance, the device automatically starts reanalysis of the patient's ECG according to the device settings, or the user can press 'ANALYZE' button to start the reanalysis. Do not touch the patient once the device starts to reanalyze the patient's ECG.

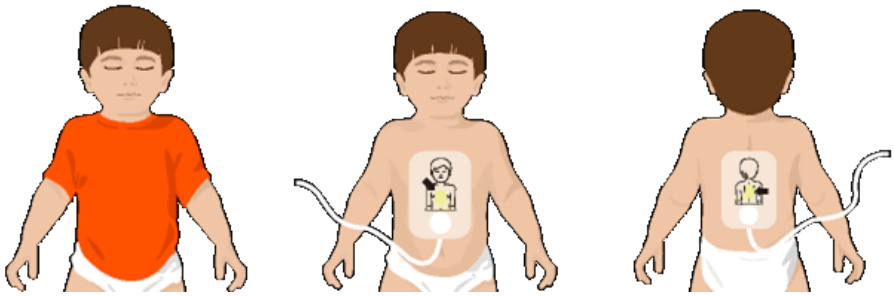
NOTICE

- If you have not been trained in CPR or are not confident at administering artificial respiration, 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 capable of performing artificial respiration, perform chest compression along with artificial respiration.
- The CPR Guidance can be set under Menu Mode. For further details, please refer to [Section 5.4: Device Setup] on these Instructions for Use.
- In order to safely turn the device off after use, press the Power Button for at least 1 second.

4.7 Defibrillation in Pediatric Mode

When the patient is between 1 year old and 8 years old, defibrillation can be done using the pediatric pads. When the device is connected through **pediatric pads**, it automatically sets the defibrillation energy to 50J and provides pediatric CPR Guidance.

Turn on the device and remove clothes as directed by the voice instructions to expose the patient's chest and back. Place pads on the middle of the chest and back as illustrated below. Pads are not specific to either chest or back. You may attach them regardless of direction.



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

NOTICE

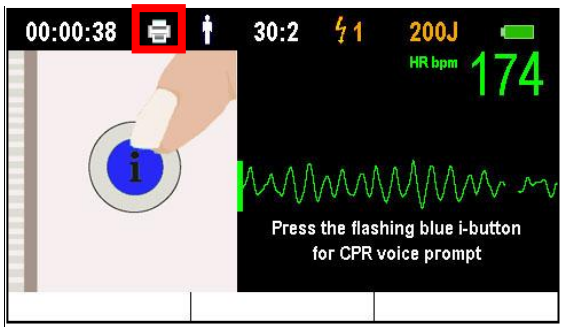
- Follow the instructions below when giving first aid during a pediatric cardiac arrest.
  - When giving first aid during a pediatric cardiac arrest, ask others to call the emergency medical center and to bring an i-PAD CU-SP2 while you are performing pediatric CPR.
  - Since most pediatric cardiac arrests are caused by suffocation rather than heart failure, when there is no one else around, perform CPR for 1 to 2 minutes, call the emergency medical services, and then get an i-PAD CU-SP2.
- The Adult / Pediatric Mode can be changed under Menu Mode. For further details, please refer to [Section 5.4: Device Setup] in these Instructions for Use.

4.8 Printer

The i-PAD CU-SP2 supports connection to an external Bluetooth printer. Please familiarize yourself with the User's Manual for the printer prior to use.

To use the printer, you must first pair the CU-SP2 and the printer in Menu Mode. For further details on pairing the printer, please refer to [Section 5.4: Device Setup].
A printer needs to be paired only once, and will be automatically connected in the future. However, you will need to do pairing again for a different printer.

If the printer is in use, you can check the printer icon on top of the LCD Screen while the device is operating.



When a paired printer is turned on while administering defibrillation on the patient, ECG and event analysis from the point of the ECG analysis to the defibrillation will be printed.

NOTICE

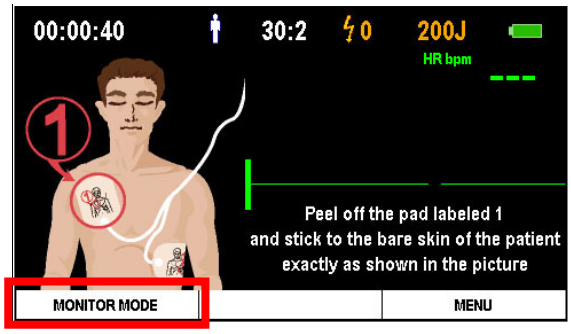
- Printers not designated by the manufacturer are not compatible with the i-PAD CU-SP2.
- Turn on the printer prior to use.
- The printer can be connected and used with up to 10m of open space between the printer and the i-PAD CU-SP2.
- The printer is not a part of the standard package contents. If you want to purchase the printer, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

4.9 Monitor Mode

Monitor Mode is used in connection with the CU-EM1 (ECG transmission device). In Monitor Mode, the i-PAD CU-SP2 uses Bluetooth to receive ECG data from the CU-EM1 and displays it on the LCD Screen. When using Monitor Mode, the pads cannot be used and defibrillation cannot be performed. If you think that defibrillation is necessary while using Monitor Mode on the patient, immediately turn Monitor Mode off and administer defibrillation.

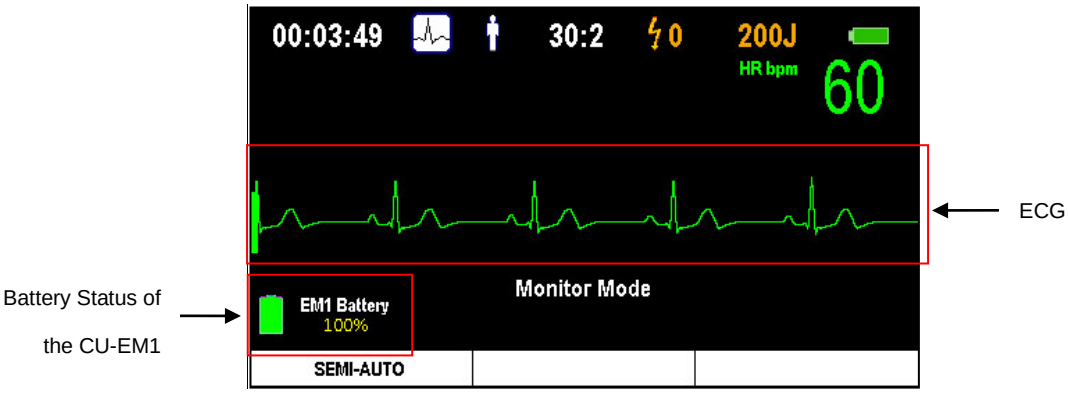
To use the CU-EM1, you must first pair the CU-SP2 and the CU-EM1 in Menu Mode. For further details on pairing the CU-EM1, please refer to [Section 5.4: Device Setup] in these Instructions for Use.
The CU-EM1 needs to be paired only once, and will be automatically connected in the future. However, you will need to do pairing again for a different CU-EM1.

To use Monitor Mode, press Soft Key 1, which reads 'MONITOR MODE', without attaching the pads on the patient.



When pressed, the device will attempt to connect with the CU-EM1.

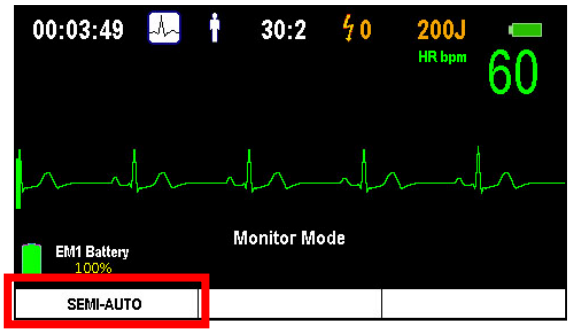
After connecting to the CU-EM1, the device will shift into Monitor Mode, receive ECG data from the CU-EM1, and display the data on the LCD Screen.



- Screen configuration for Monitor Mode -

ECG	Displays the ECG data received from the CU-EM1 via Bluetooth.
Battery Status of the CU-EM1	Displays the battery status of the connected CU-EM1 from 0% to 100% in 10% units.

To turn off Monitor Mode, press Soft Key 1, which reads 'SEMI-AUTO'. When pressed, the device will shift into defibrillation mode.

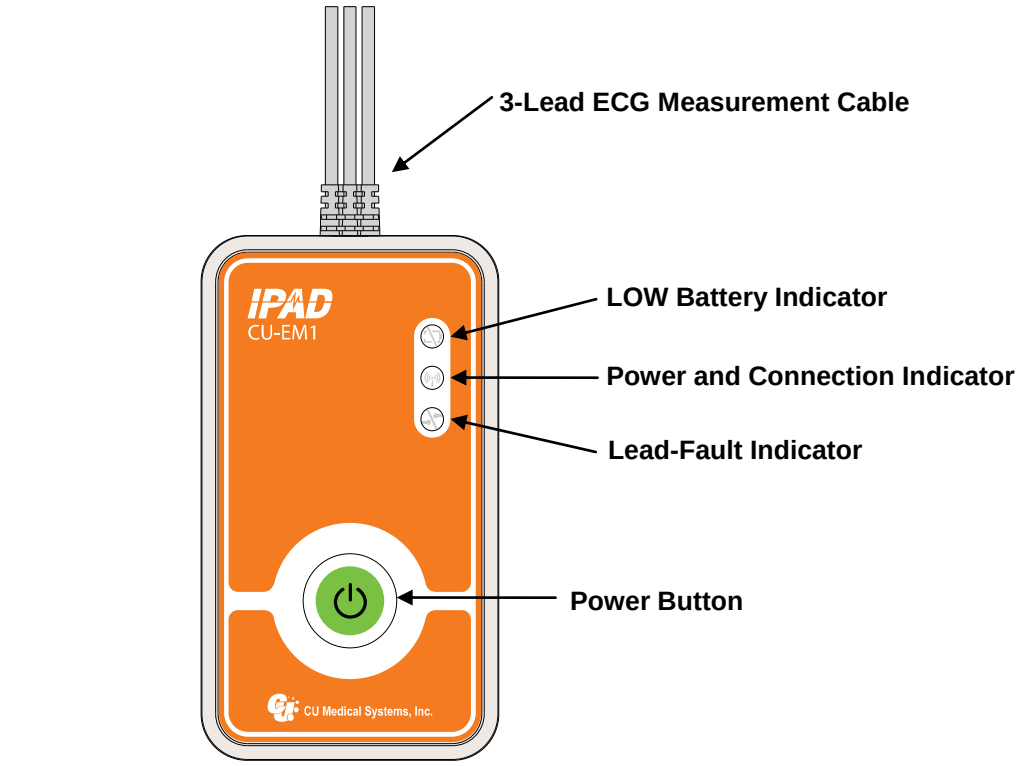


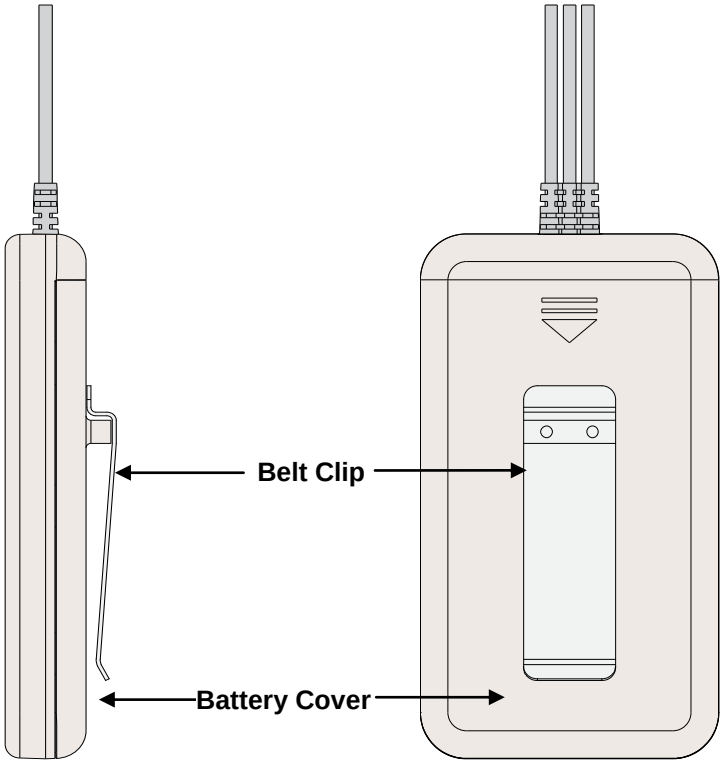
N O T I C E

- ECG transmission devices not designated by the manufacturer are not compatible with the i-PAD CU-SP2.
- Turn on the CU-EM1 prior to use.
- The CU-EM1 can be connected and used with up to 10m of open space between the CU-EM1 and the i-PAD CU-SP2.
- The CU-EM1 is not a part of the standard package contents. If you want to purchase the CU-EM1, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

4.10 CU-EM1 (ECG Transmission Device)

4.10.1Device Features





4.10.2Button and Indicators

Indicator	Description
	**Power Button** This button turns the CU-EM1 on and off.
	**LOW Battery Indicator** The red indicator will light when the remaining battery of the CU-EM1 falls below 10%. You need to recharge the battery when the LOW Battery Indicator is on.
	**Power and Connection Indicator** The blue indicator will light when the CU-EM1 is turned on. When the CU-SP2 is switched to Monitor Mode and transmitting via Bluetooth, the blue indicator will blink in 1 second intervals.
	**Lead-Fault Indicator** The green indicator on Lead-Fault will light if the ECG Measurement Cable is not properly connected to the patient, the cable is faulty, or the ECG pads are faulty.

4.10.3Beeper

Indicator	Description
1 long beep	Beeps when the CU-EM1 is turned on.
2 long beeps	Beeps when the CU-EM1 is turned off.
3 long beeps	Beeps when the CU-EM1 is paired with the CU-SP2.
1 short beep	Beeps in 10 second intervals when in standby for connecting to the CU-SP2 in Monitor Mode.
2 short beeps	Beeps when connecting to the CU-SP2 in Monitor Mode.
3 short beeps	Beeps when disconnecting Monitor Mode or the Bluetooth connection, including unstable Bluetooth connections or communication problems.

4.10.4How to Use the CU-EM1

① Turn the device on by pressing the Power Button.

When the power of the CU-EM1 is turned ON, the following occurs in sequence:

- Beeper: The beeper will beep for 0.5 seconds.
- Connection Indicator: The blue indicator will light.

② Attach the 3-Lead ECG Measurement Cable to the patient.

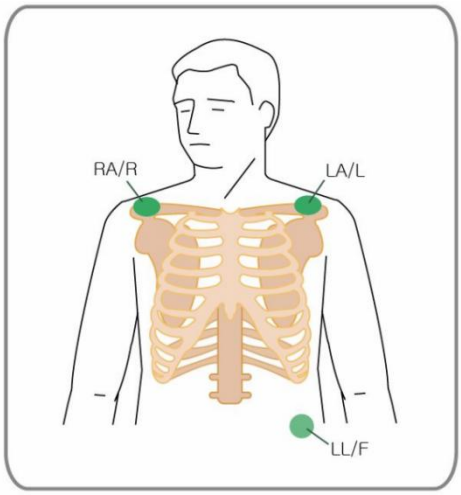
Attach the 3-lead disposable ECG pads.

③ Turn on the Monitor Mode in the CU-SP2.

For further details on using the Monitor Mode, please refer to [Section 4.8: Monitor Mode] in these Instructions for Use.

4.10.5Where to Attach ECG Pads

- **RA/R**: Below the right collarbone
- **LA/L**: Below the left collarbone
- **LL/F**: Left side torso



⚠ CAUTION

- Using expired disposable ECG electrodes with damaged packaging will not guarantee accurate measurement of ECG.
- The disposable ECG electrodes must be firmly adhered to the patient's skin. Keep the attachment areas dry.
- The conductive parts of the ECG electrodes and associated connectors for applied parts, including the neutral electrode, should not contact any other conductive parts including earth.
- The ECG electrodes are disposable. Do not reuse them.

NOTICE

- For further details on charging the battery of the CU-EM1, please refer to [Section 6.2: Maintenance] of these Instructions for Use.
- In order to turn the CU-EM1 off after use, press the Power Button for at least 1 second.
- The CU-EM1 is defibrillation proof. It does not have to be disconnected from the patient during defibrillation.

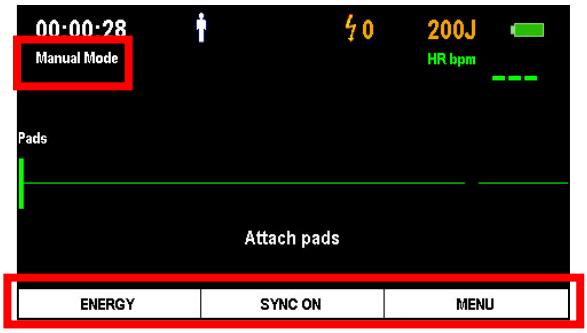
4.11 Manual Mode (Optional)

This function will be installed by default if manual mode has been optionally added upon purchasing the CU-SP2.

To use the manual mode, you must set the device mode to Manual Mode. For further details on setting the manual mode, please refer to [Section 5.4: Device Setup] in these Instructions for Use.

When the device mode has been changed to manual mode, **'Manual Mode'** will be displayed on the upper-left corner of the LCD Screen. Also, the Soft Keys will be activated as follows:

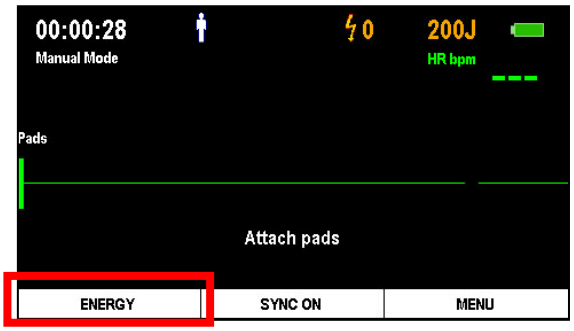
- Soft Key 1: **ENERGY**
- Soft Key 2: **SYNC ON**
- Soft Key 3: **MENU / CHARGE**



4.11.1 Changing the Energy Value

When in manual mode, the user can set the energy value for defibrillation. The range of the output energy will change depending on Adult / Pediatric Mode. For further details on changing the Adult / Pediatric Mode, please refer to [Section 5.4: Device Setup] in these Instructions for Use.

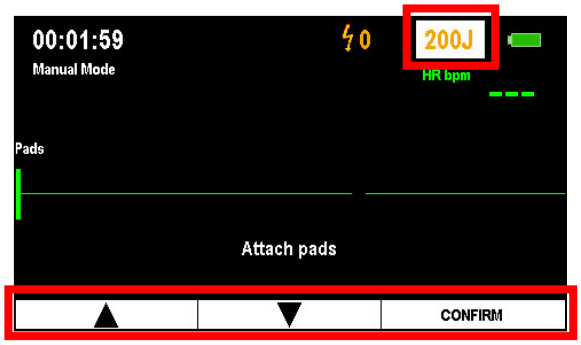
Press Soft Key 1, which reads **'ENERGY'**, to change the energy setting.



When pressing Soft Key 1, the output energy value displayed on the upper-right corner of the LCD Screen will be highlighted in white. Also, the Soft Keys will be activated as follows:

- Soft Key 1: ▲ **(INCREASE ENERGY)**
- Soft Key 2: ▼ **(DECREASE ENERGY)**
- Soft Key 3: **CONFIRM**

At this time, use Soft Keys 1 and 2 to change the energy value and press Soft Key 3 to confirm.



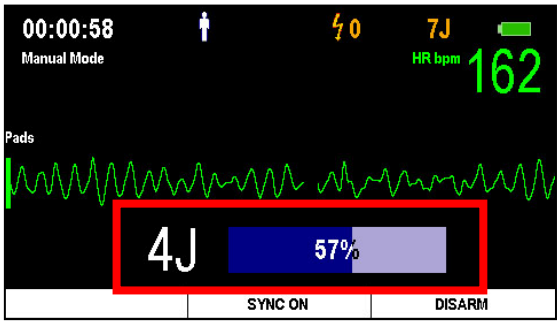
[Output energy values for Adult / Pediatric Mode]

Adult / Pediatric Mode	Output Energy
Adult	2J, 3J, 5J, 7J, 10J, 20J, 30J, 50J, 70J, 100J, 150J, 200J
Pediatric	2J, 3J, 5J, 7J, 10J, 20J, 30J, 50J

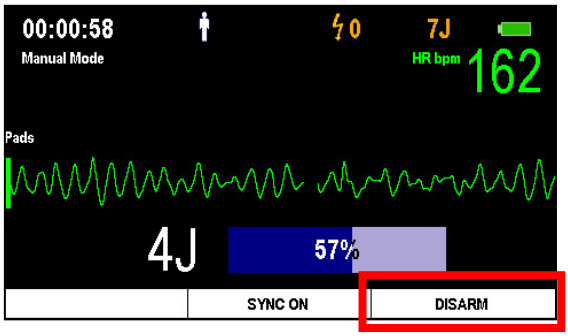
4.11.2 Charging the Device and Administering Electric Shock Treatment

In manual mode, the user may, in his/her own discretion, charge the i-PAD CU-SP2 and administer defibrillation.

After attaching the pads on the patient, press ‘CHARGE’ using Soft Key 3 if the patient’s ECG is shockable. When pressing Soft Key 3, the device will start charging according to the set energy level along with a charging sound. The charged energy amount can be checked on the LCD Screen.



If you want to stop charging, press the 'DISARM' button using Soft Key 3. When pressed, the device will cease charging and dump the shock energy internally.



When armed, the Shock Button will flash in orange to signal readiness for defibrillation. At this time, you can administer defibrillation by pressing the Shock Button.

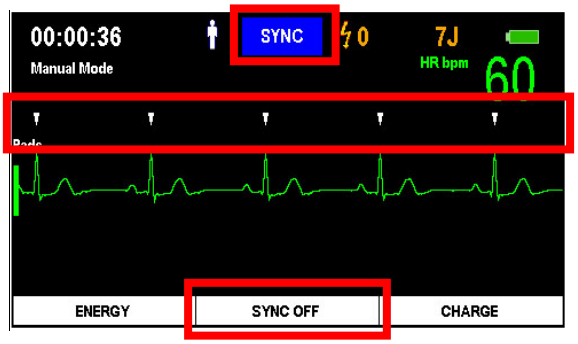
If the flashing Shock Button is not pressed within 15 seconds, the device will automatically cancel the shock delivery and disarm.

4.11.3 Using R-Sync

When the device is switched to manual mode, Soft Key 2 will be activated as ‘SYNC ON’.

Pressing Soft Key 2 will display the SYNC symbol in the upper-center of the LCD Screen and enable administration of R-Sync energy.

Using R-Sync will detect the R-wave of the patient's ECG, and display the R-Sync mark on the LCD Screen with a short beep.



At this time, you may charge shock energy by pressing 'CHARGE' using Soft Key 3 if you think that synchronous cardioversion is necessary.

Press the Shock Button to administer synchronous cardioversion. The device will automatically administer synchronous cardioversion if R-wave is detected.

To stop using R-Sync, press ‘SYNC OFF’ using Soft Key 2.

⚠ CAUTION

- **The usage authority differs for each device mode.**
- **Manual Mode**: Only medical professionals may use this mode.
- **AED Mode**
  - **ANALYZE**: Only licensed emergency medical technicians or medical professionals may use this mode.
  - **CHARGE**: Only medical professionals may use this mode.
  - **OFF**: Licensed emergency medical technicians, medical professionals and the general public may use this mode.

⚠ CAUTION

- **In case where the patient's ECG signal is in the asystole state, the asynchronous defibrillation therapy may lead to a failure to restore cardiac pacemaker function so the cardiac function will not be restored. Therefore, do not deliver electric shock to patients with asystole.**
- **When administering R-Sync energy, the patient may be administered with defibrillation energy, recognized as R-waves, if there is interference resulting from external contact or if the patient is moved while the pads are attached. Avoid moving or touching the patient while administering R-Sync energy.**

N O T I C E

- Manual Mode is an additional option. If you want to add the manual mode option, please contact us after referring to [Section A.3: Service Center] in these Instructions for Use.

5. After Using the i-PAD CU-SP2

5.1 Maintenance After Each Use

Check the device for signs of damage and contamination. If there is any damage or contamination, please refer to [Section 6.2.3: Cleaning the i-PAD CU-SP2] in these Instructions for Use.

Conduct a self-test on the battery by referring to [Section 7.1: Self-Tests] in these Instructions for Use. If the device shuts down normally after running a self-test on the battery, the device status is normal. The i-PAD CU-SP2 uses disposable pads. Dispose of the used pads and replace them with new pads after checking their expiration date. For further details on replacing the pads, please refer to [Section 6.2.2: Replacing the Pads] in these Instructions for Use.

⚠ WARNING

- You should use only the defibrillator pads provided by the manufacturer.
- Do not open the pad packaging until immediately before use. Since the adhesive material on the disposable pads starts to dry out as soon as the package is opened, the pads will become unusable after a certain amount of time has elapsed, 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 saved in the internal memory. This data can be transferred to a personal computer (PC) and is not erased even if the device is turned off.

⚠ CAUTION

- The i-PAD CU-SP2 saves the 3 most recent treatments and is able to save up to 17 hours for each event. If more than 17 hours of ECG data are recorded for one event, any ECG data over 17 hours will not be recorded.
- When the device is used more than 3 times, it overwrites the oldest treatment data with the newest data. Therefore, we recommend you to save the recorded treatment data by transferring it to a PC after using the device.
- If the battery pack is removed while the device is operating, the treatment data will not be properly recorded. If you wish to remove the battery pack, turn the power off by pressing the Power Button for more than 1 second, and then remove the battery pack.

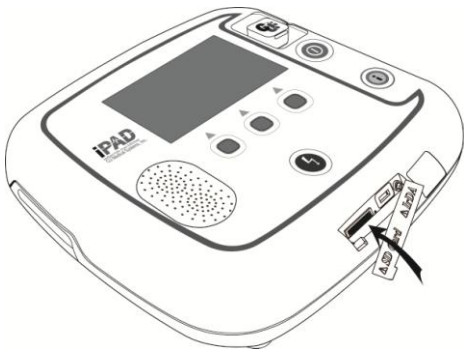
5.2.2 Transferring Treatment Data

The treatment data may be transferred via an SD card or IrDA. The treatment data of all patients recorded on the device is transferred using the SD card method, whereas the treatment data of one patient is selectively transferred with the IrDA method.

1. Copying Treatment Data by Using an SD Card

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

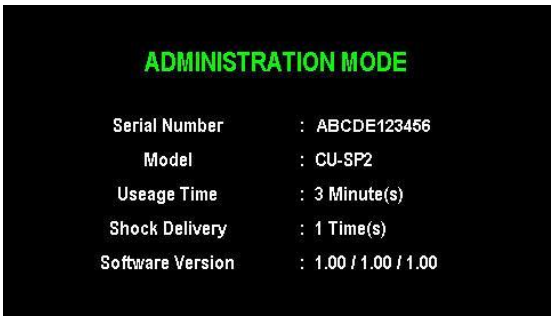
② Open the SD card cover on the device and insert an SD card into the port.



③ If the i-Button is pressed for more than 1 second in standby mode, the device will switch to Administration Mode and give instructions by voice and LCD Screen.

④ The device displays the summary (the total hours of the last device usage and the number of defibrillation shocks delivered) of the device usage on the LCD Screen.

⑤ The device displays the S/W version on the LCD Screen.

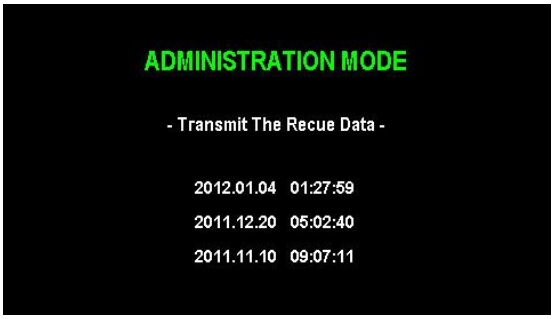


⑥ When the voice guide instructs to transfer the treatment data, press the i-Button to copy the data onto the SD card.

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

The device starts to copy the data after informing the user by voice that the treatment data is being copied onto the SD card.

When copying is completed, the device informs you by voice and automatically shuts down.



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

The device informs you by voice that no treatment data exists and automatically shuts down.

NOTICE

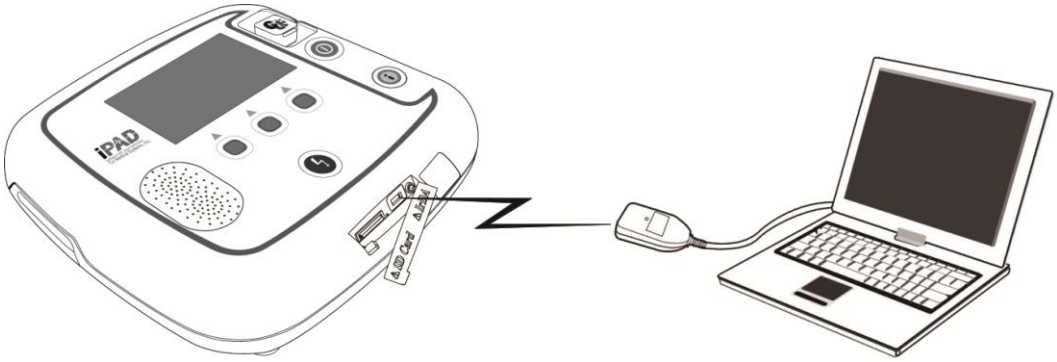
- If the SD card already has the same treatment data file, the device informs the user that the same file already exists upon copying the treatment data onto the SD card. Press the Shock Button to overwrite the existing file or press the i-Button to cancel copying the file.

2. Transferring Data via IrDA

The data may be transferred to the PC by using the PC software (CU Expert Ver.3.70 or higher), which is provided by the manufacturer. [CU Expert] is a PC software that includes ECG review and printing functions.

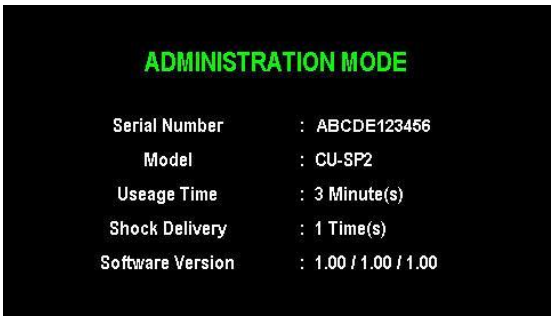
① Position the IrDA adapter to face the IrDA port on the device as shown in the figure below.

② If the i-Button is pressed for more than 1 second in standby mode, the device will switch to Administration Mode and give instructions by voice and LCD Screen.



③ The device displays the summary (the total hours of the last device usage and the number of defibrillation shocks delivered) of the device usage on the LCD Screen.

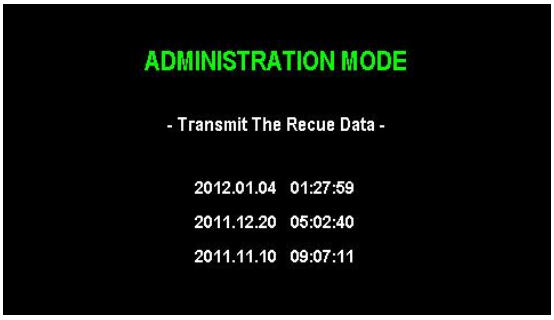
④ The device displays the S/W version on the LCD Screen.



⑤ When the voice guide instructs to transfer the treatment data, press the i-Button to transfer the data.

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

① The device informs the total number of treatments and information saved on the device by voice and LCD Screen.



② There are at most 3 treatment data. The first treatment data is the most recent.

③ Press the Shock Button to change the transfer order of the treatment data as follows:
1st treatment data → 2nd treatment data → 3rd treatment data → 1st treatment data →..

④ If you wish to transfer the selected treatment data, press the i-Button.

⑤ Run [CU Expert] on the PC. Please refer to the [CU Expert] manual for further details.

⑥ The device is connected to [CU Expert] within a few seconds, and treatment data is automatically transferred.

⑦ When the transfer is completed, the device automatically shuts down.

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

The device informs you by voice that no treatment data exists and automatically shuts down.

⚠ CAUTION

- Maintain a distance of 30cm and an angle of ±15° between the IrDA port on the device and the IrDA adapter. Also since external light sources affect the IrDA, try to use it indoors and away from fluorescent and/or incandescent lamps.

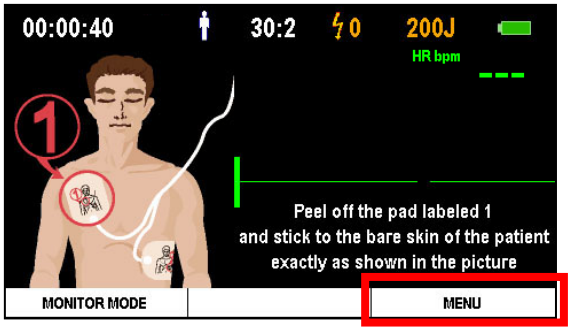
NOTICE

- The PC software (CU Expert Ver.3.70 or higher) and the IrDA adapter are not a part of the standard package contents. If you want to purchase them, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

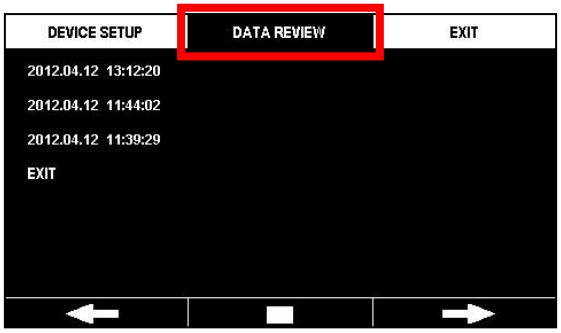
5.3 Data Review

If the Defibrillator Pads Connector has not been inserted or the pads have not yet been attached to the patient, you can press Soft Key 3 on the device to enter Menu Mode. In Menu Mode, you can easily check the device setup and the treatment data saved on the device.

① Press the MENU button to enter Menu Mode.

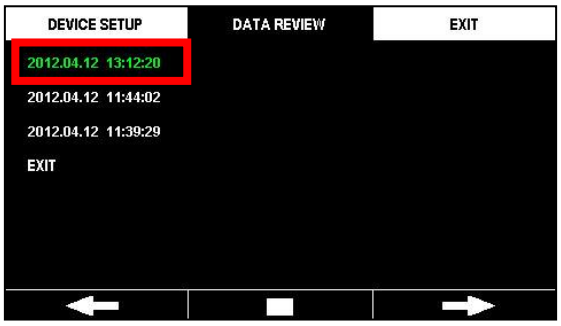


② After entering Menu Mode, press the right arrow button to move to the second tab, 'DATA REVIEW'.

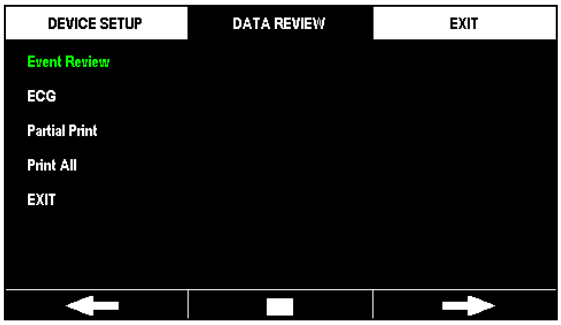


③ The saved treatment data is displayed on the left side of the screen.

④ Press the confirm button in the center to select the treatment data to review.



⑤ Select the review method. The options are 'Event Review', 'ECG', 'Partial Print', and 'Print All'.



- **Event Review**: Displays the list of events saved on the device.
- **ECG**: Displays the ECG data saved on the device.
- **Partial Print**: The user selects and prints the segment to review.
- **Print All**: Prints all usage data.

5.3.1 Event Review

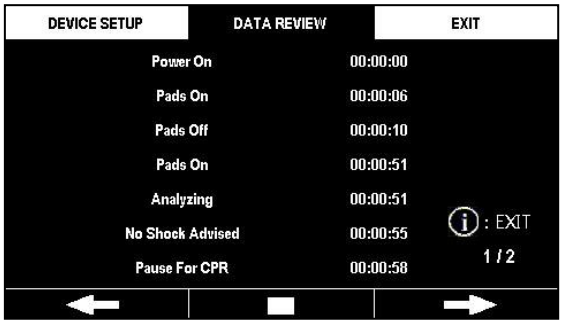
Select 'Event Review' to check the list of events saved on the device.

You can move to the next or previous page by using the Left/Right arrow buttons.

'Event Review' displays the history of events on the left and the time elapsed since the last usage of the device on the right.

Select ‘Event Review’ to review the history of events. You can move to next or previous page by using the Left/Right arrow buttons and play or pause ECG by using the Play/Pause buttons.

Press the i-Button to exit 'Event Review' or ‘ECG’.



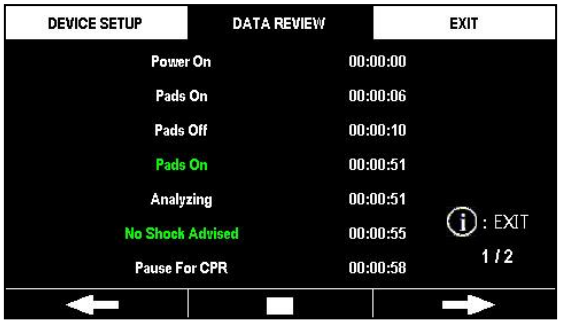
5.3.2 ECG

You can check the ECG saved in the internal memory of the device. Select 'ECG' to play the saved ECG. You can press the pause button in the center to stop playing. After stopping, you can move to the next or previous page by using the Left/Right arrow buttons.

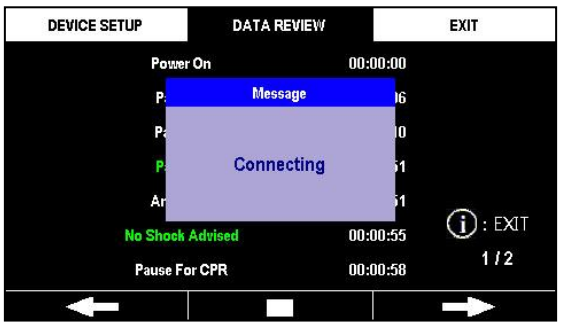
Press the i-Button to exit 'ECG'.

5.3.3 Partial Print

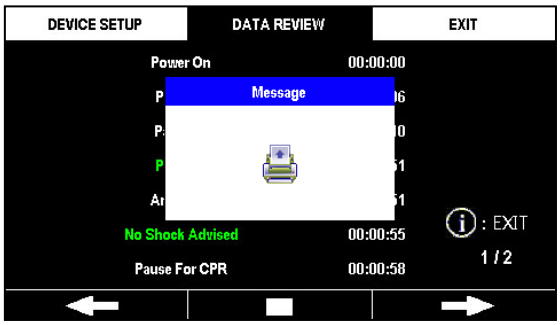
Select 'Partial Print' to choose and print a segment in the event list.



You can only select two events in order to identify the start and end of the segment. Once the first event is selected, the device will automatically attempt to connect to the printer after you have selected the second event.



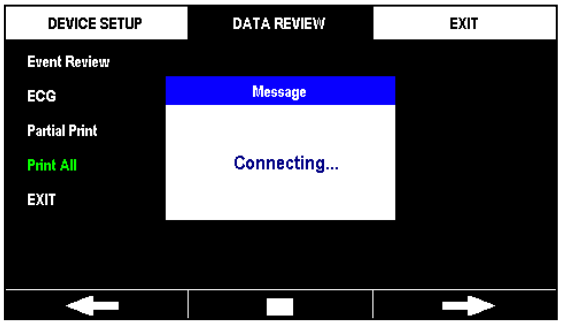
Once connected, the printer will print the ECG and event list of the selected segment.
Press the i-Button to stop printing.

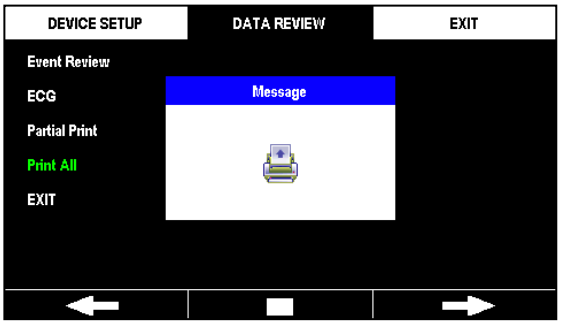


5.3.4 Print All

Select 'Print All' to directly connect to the printer. When connected, the device will print all saved events and ECGs.

Press the i-Button to stop printing.



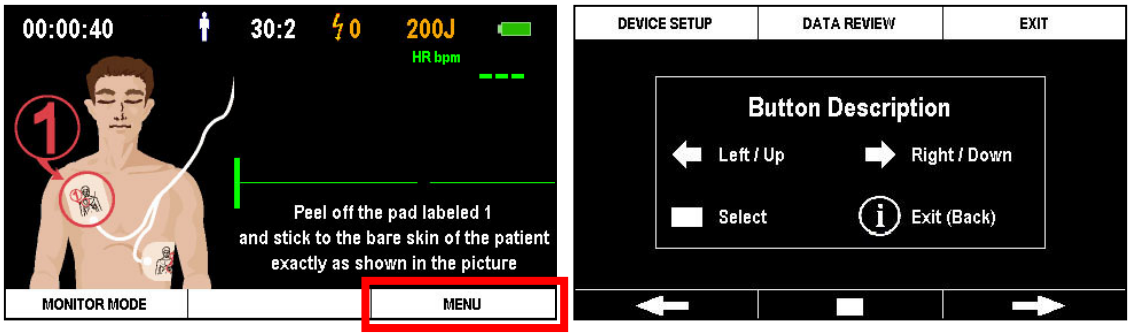


NOTICE

- If the device is not paired with a printer, you cannot access 'Segment Print' or 'Print All'.
- For further details on using the printer, please refer to the printer's manual and [Section 4.7: Printer] in these Instructions for Use.
- The printer is not a part of the standard package contents. If you want to purchase a printer, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

5.4 Device Setup

In i-PAD CU-SP2, you can set the operation of the device and the CPR Guidance under Menu Mode. If the Defibrillator Pads Connector has not been inserted or the pads have not yet been attached to the patient, you can press Soft Key 3 on the device to enter Menu Mode.



Once you enter Menu Mode, the 'Button Description' page is displayed. Press any of the 3 Soft Keys to close the page. In Menu Mode, you can set the operation of the device and the CPR Guidance, or check the saved treatment data using the three buttons.

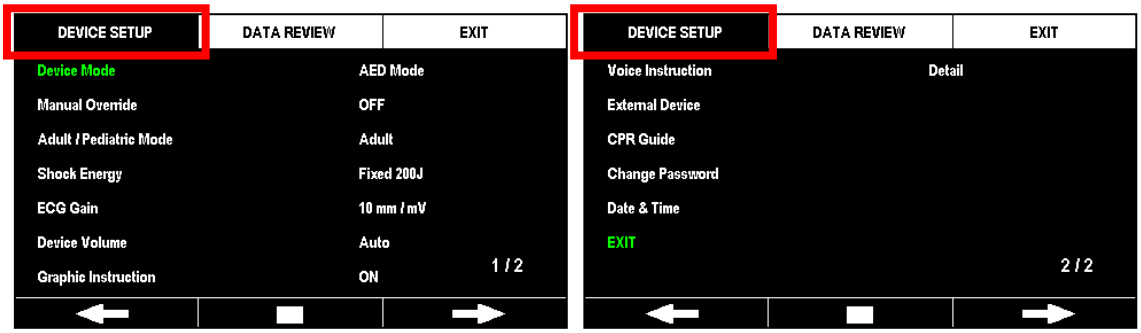
The basic functions of the Soft Keys are as shown below:

- **Soft Key 1:** Left / Up
- **Soft Key 2:** Select / Confirm
- **Soft Key 3:** Right / Down
- **i-Button:** Exit (Back)

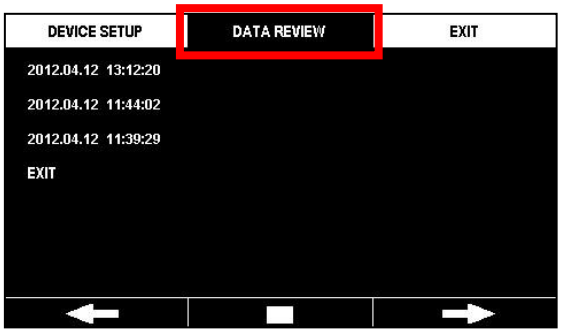
5.4.1 Configuring the Menu Mode

Menu Mode is comprised of three tabs.

The first tab is comprised of two pages. You can set the operation of the device, add external devices, set the CPR Guide, change the password, and set the date & time.



The second tab displays the treatment data saved on the device. For further details on 'DATA REVIEW' on the second tab, please refer to [Section 5.3: Data Review] in these Instructions for Use.



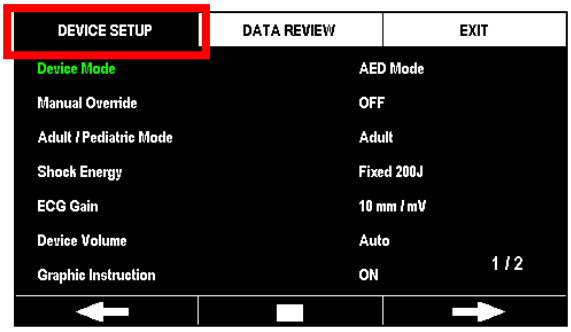
The third tab is for exiting Menu Mode.

N O T I C E

- If pads are attached to the patient while the device is in Menu Mode, the device will automatically switch from Menu Mode into Operation Mode to enable defibrillation.

5.4.2 Setting the Operation of the Device

The user can set the options below under the 'DEVICE SETUP' tab of Menu Mode.



- **Device Mode**
  - With the security mode activated, you should enter the password to change the Device Mode. The default password of the device is Soft Key '**1→1→1→1**'. (Soft Keys are labeled 1~3 from left to right.)
  - **AED Mode:** The device manually or automatically executes ECG analysis and defibrillation.
  - **Manual Mode:** The user can manually set the device's shock energy and administer defibrillation based on user judgment.

NOTICE

- The Device Mode setup is an additional option. This function will not be installed by default if Manual Mode has not been optionally added upon purchasing the CU-SP2. If you want to purchase the Device Mode option, please contact us by referring to [Appendix A.3: Service Center] of these Instructions for Use.

- **Manual Override**
  - With the security mode activated, you should enter the password to change the Manual Override. The default password of the device is Soft Key '**1→1→1→1'**. (Soft Keys are labeled 1~3 from left to right.)
  - **Analyze**: The user can choose to monitor the patient's ECG through the pads, start analyzing the patient's ECG, and start/end the CPR Guidance.
  - **Charge**: The user can monitor and analyze the patient's ECG through the pads to determine whether to start charging the device's energy for defibrillation. Also, the user can choose to start/end the CPR Guidance.
  - **OFF**: The device automatically analyzes the patient's ECG when the pads are attached. If defibrillation is necessary, the device will automatically charge the energy necessary for defibrillation and direct the user to administer defibrillation.

⚠ WARNING

- **The usage authority differs for Device Mode and Manual Override setup, and requires a password. The default password is vulnerable to exposure. We recommend that you change the password on a regular basis.**
- **Manual Mode**: Only medical professionals may use this mode.
- **AED Mode**
  - **Analyze**: Only licensed emergency medical technicians or medical professionals may use this mode.
  - **Charge**: Only medical professionals may use this mode.
  - **OFF**: Licensed emergency medical technicians, medical professionals and the general public may use this mode.

- **Adult / Pediatric Mode**
  - **Adult**: The device will operate in Adult Mode. In the case of a pediatric patient, connecting the device with the pediatric pads connector will automatically switch the device to Pediatric Mode.
  - **Pediatric**: The device will operate in Pediatric Mode. When set to Pediatric Mode, the device will maintain the mode even if it is connected to the adult pads connector.

- **Shock Energy**
  - **Fixed 150J**: The patient will be delivered with 150J of shock energy.
  - **Fixed 200J**: The patient will be delivered with 200J of shock energy.
  - **Escalating (150J-200J)**: The patient will be delivered with 150J of shock energy for the first time, and then 200J of shock energy in subsequent shocks.
  - **Escalating (150J-150J-200J)**: The patient will be delivered with 150J of shock energy for the first and second time, and then 200J of shock energy in subsequent shocks.

- **ECG Gain**
  - **5mm/mV**: The ECG graph will be indicated as 5mm/mV on the Graphic LCD Screen.
  - **10mm/mV**: The ECG graph will be indicated as 10mm/mV on the Graphic LCD Screen.
  - **20mm/mV**: The ECG graph will be indicated as 20mm/mV on the Graphic LCD Screen.
  - **Auto**: The device will automatically set the ECG gain and the ECG graph will be indicated as 10mm/mV on the Graphic LCD Screen.

- **Device Volume**
  - **1~10**: Sets the volume of the device between 1~10 in units of 1.
  - **Auto**: The default volume is set to 7, and automatically changes depending on the level of surrounding noise.

- **Graphic Instruction**
  - **ON**: Includes an image guide when the device is operated.
  - **OFF**: Does not include an image guide when the device is operated.

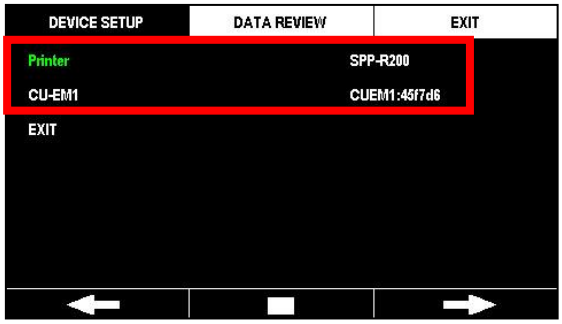
- **Voice Instruction**
  - **Detail:** Gives detailed guidance on how to operate the device.
  - **Simple:** Gives simple guidance on how to operate the device. This option is not recommended to the general public who are not licensed in rescue procedures.

• **Date & Time**

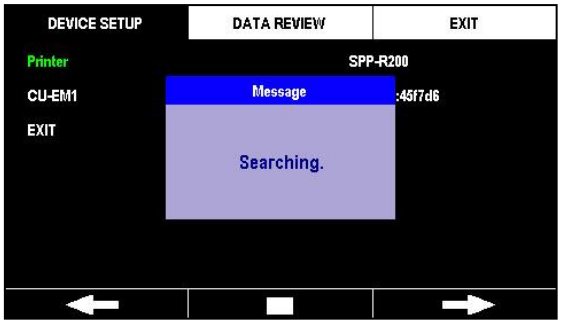
  • Set the date and time of the CU-SP2.

• **External Device**

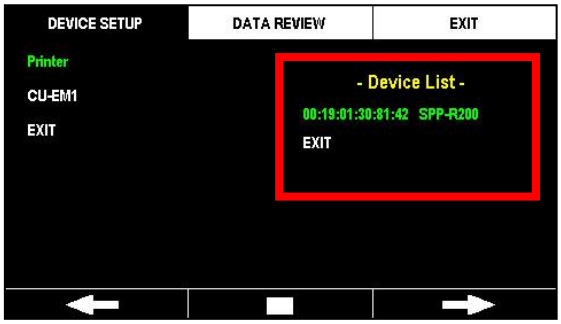
This setting pairs the CU-SP2 with the printer and CU-EM1 (ECG transmission device). Selecting 'External Device' displays 'Printer' and 'CU-EM1' on the left side of the screen. The model numbers of devices currently connected to the CU-SP2 are displayed on the right. If no device is paired, the right spaces will be left blank.



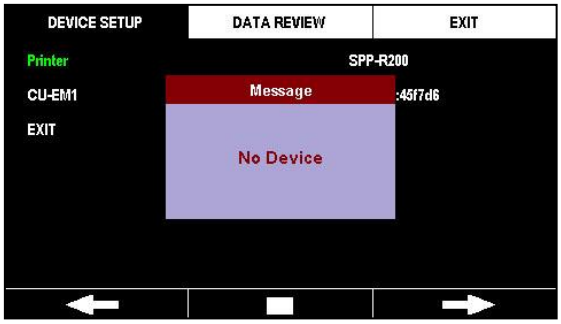
First, select the device to pair from the options on the left. After selecting, the CU-SP2 will search for nearby devices. (Searches up to 5 devices.)



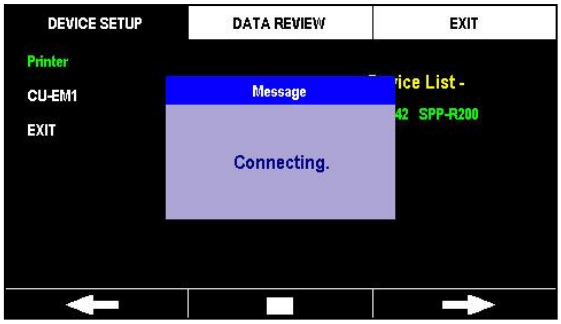
After searching, the CU-SP2 displays the list of searched devices on the right side of the screen.

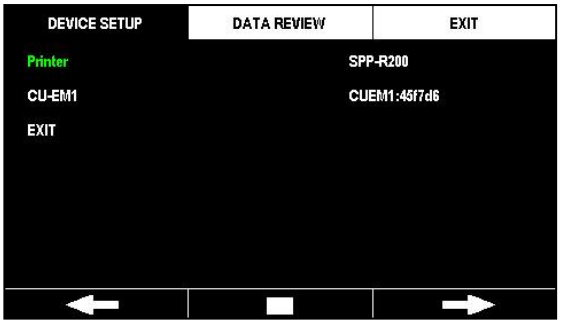


If no device is found, the CU-SP2 will display the following message for 3 seconds and return to the previous page.

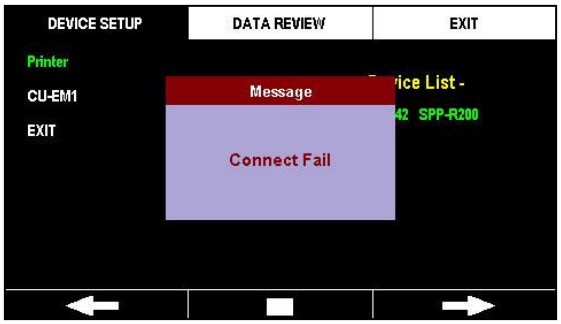


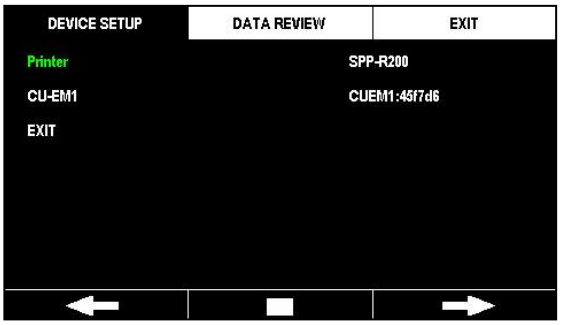
Check and select a device from the list to pair with the CU-SP2. After selecting, the CU-SP2 will test connection with the selected device. After testing, the CU-SP2 will save the connection information and return to the previous page.





If connection fails during the test, the CU-SP2 will display the following message for 3 seconds and return to the previous page.





NOTICE

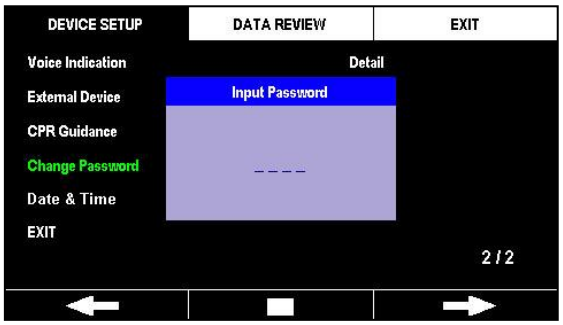
- The CU-SP2 can only communicate with the devices designated by the manufacturer.
- Before pairing the CU-SP2 with an external device (Printer, CU-EM1), turn on the power of the device to be connected.
- When the CU-SP2 is paired with an external device, the external device will operate as follows:
  - Printer: Displays the message “You can use this printer!”
  - CU-EM1: 3 long beeps.
- The Printer and CU-EM1 are not part of the standard package contents. If you want to purchase them, please contact us by referring to [Appendix A: Parts and Accessories] of these Instructions for Use.

- **CPR Guide**
  - Refer to [Section 5.4.3: Setting the CPR Guide] in these Instructions for Use.

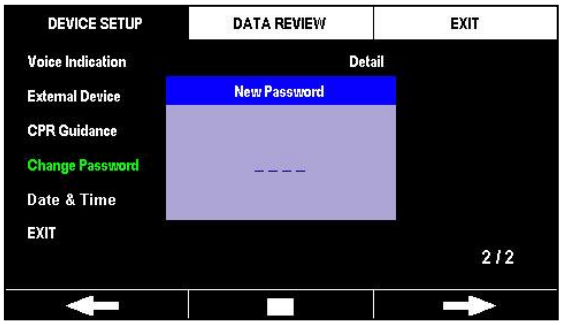
- **Change Password**

The default password of the device is Soft Key **'1→1→1→1'**, (Soft Keys are labeled 1~3 from left to right.) and the password is a combination of the three Soft Keys. In the Device Setup, ‘Device Mode’ and ‘Manual Override’ have different user rights depending on the setting. For more on the rights to use the product, refer to the Instructions for Use, [4.11: Manual Override (Options)]. When you activate the security mode, you should enter the password to change ‘Device Mode’ and ‘Manual Override’. We recommend having the password changed after receiving the CU-SP2 in order to prevent access by unauthorized users. Also we recommend that you change the password on a regular basis to prevent password exposure. The password is changed in the following 4 steps:

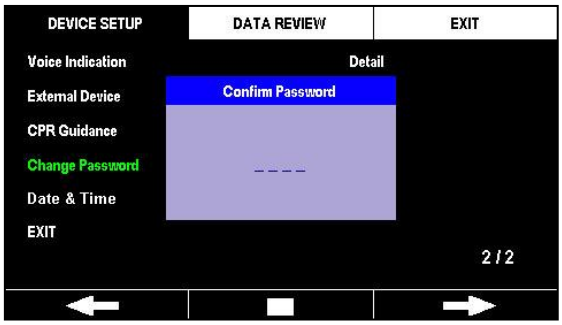
① Input Password



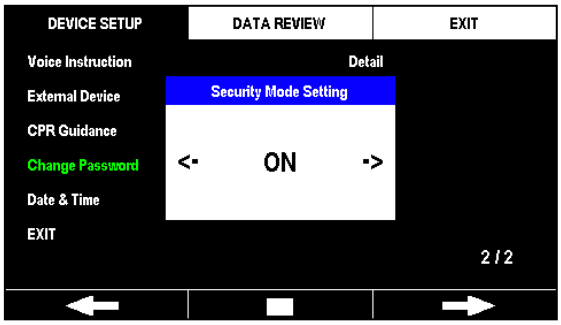
② New Password

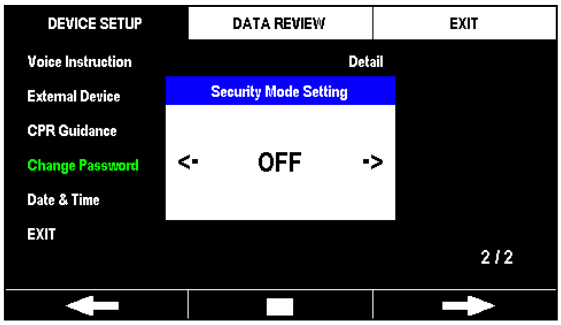


③ Confirm Password



④ Security Mode Setting (ON/OFF)





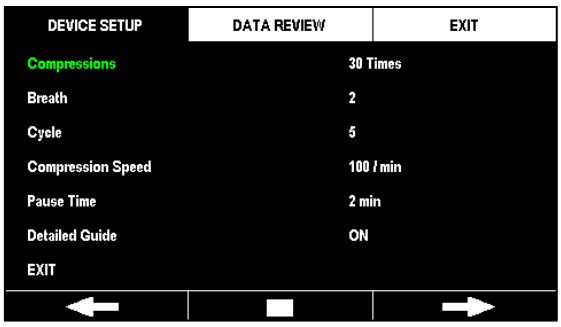
[Device Setup]

No.	Setup Option		Set Value	Default
1	Device Mode		AED Mode Manual Mode	AED Mode
2	Manual Override		Analyze, Charge, OFF	OFF
3	Adult / Pediatric Mode		Adult, Pediatric	Adult
4	Shock Energy		Fixed 150J, Fixed 200J, Escalating (150J-200J), Escalating (150J-150J -200J)	Fixed 150J
5	ECG Gain		5mm/mV, 10mm/mV, 20mm/mV, Auto	10mm/mV
6	Device Volume		1~10, Auto	Auto
7	Graphic Instruction		ON, OFF	OFF
8	Voice Instruction		Detail, Simple	Detail
9	External Device		-	-
10	CPR Guide		-	Refer to [Table 2] of [Section 5.4.3: Setting the CPR Guide]
11	Change Password	Password	-	Soft Key ‘1-1-1-1’
		Security Mode Setting	ON/OFF	ON
12	Date & Time		yy/mm/dd, hh:mm:ss	

5.4.3 Setting the CPR Guide

The CU-SP2 complies with the 2011 Korea Guidelines for CPR recommended by the Korean Association of Cardiopulmonary Resuscitation (KACPR) and the 2010 Guidelines for CPR recommended by the American Heart Association (AHA). The default CPR is set to 5 cycles of 30 chest compressions followed by 2 artificial respirations. Also, the CU-SP2 provides the user with a function enabling CPR Guidance. The user can set the following items at 'CPR Guide' under 'Device Setup' in Menu Mode.

- **Compressions**
- **Breath**
- **Cycle**
- **Compression Speed**
- **Pause Time**
- **Detailed Guide**



[Setting the CPR Guidance]

No.	Setup Option	Range	Unit	Default	Default Description
1	Compressions	15, 30 times	15 times	30 times	Executes 30 chest compressions. In Adult Mode, the number of chest compressions is fixed to 30 times.
2	Breath	0~2 times	1	2	Executes 2 artificial respirations.
3	Cycle	2~10 times	1	5	Executes 5 cycles of chest compression and artificial respiration.
4	Compression Speed	100~ 120 times	5/m	100/m	Executes chest compression at a speed of 100 times per minute.
5	Pause Time	30~180 sec.	30 sec.	120 sec.	Pauses CPR for 120 sec. (2 min.)
6	Detailed Guide	ON, OFF	-	OFF	Does not provide detailed voice guidance on chest compression and artificial respiration during CPR.

NOTICE

- The CU-SP2 does not provide Detailed Guide on chest compression and artificial respiration during CPR by default. To receive Detailed Guide, change the Detailed Guide setting to 'ON'. Once Detailed Guide is set to 'ON', the device will provide detailed voice instructions on CPR.
- The CU-SP2 will give voice instructions on applying chest compression for 2 minutes when setting Detailed Guide to 'OFF' and Breath to '0', regardless of other CPR settings. It will then automatically reanalyze the patient's ECG. Once the device starts to reanalyze the patient's ECG, immediately stop applying chest compressions and do not touch the patient.
- 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.

• Do not store in an environment with large fluctuations in temperature.

- **Storage Environment**

  The device is connected to the pads and battery pack, and is ready for immediate use in case of an emergency.

  Temperature: 0℃ ~ 43℃ (32℉ ~ 109℉)

  Humidity: 5% ~ 95% (a location with no condensation)

- **Transportation Environment**

  The device is not connected to the pads and battery pack, and is separately stored for a long period of time or while being transported.

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

  Humidity: 5% ~ 95% (a location with no condensation)

• Do not store the device under direct sunlight.

• Do not store the device in a moist environment.

• Do not store the device near electric heating appliances.

• Do not store the device where it is susceptible to excessive shock or vibration.

• Do not store the device where it is exposed to chemicals or explosive gas.

• Take care not to allow dust, particularly metallic particles, into the device.

• Do not dismantle or disassemble the device. The manufacturer will not be held liable in such cases.

6.2 Maintenance

6.2.1 Device Inspection

This device provides a self-test. The device performs a self-test as soon as the battery is inserted, automatically turns off after the test is completed, and regularly turns on to perform the self-test. If the user wants to initiate the self-test, remove the battery and then reinsert. For further details on self-tests, please refer to [Section 7.1: Self-Tests] in these Instructions for Use.

⚠ CAUTION

- We recommend regular inspection of this device in order to ensure that it is always ready for any emergency.

There are two supplies that must always be inspected upon storing the device.

- Since the device cannot be used in an emergency if the battery level is low, you must regularly check the self-test results.
- Since the appropriate amount of energy cannot be delivered to the patient in an emergency if the pads are in poor condition, you must regularly check the expiration date of the pads and the integrity of the pads packaging.

6.2.2 Recharging and Replacing the Battery

① Battery Pack (Rechargeable)

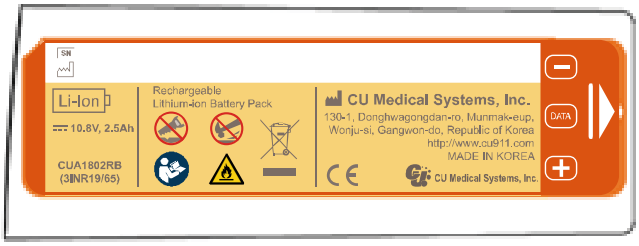
Replacing the battery pack

- If the battery pack is low replace it with a fully charged battery pack. Recharge the low battery pack. For further details on checking the battery status, please refer to [Chapter 7: Troubleshooting] in these Instructions for Use.
- You must use only battery packs provided by the manufacturer.

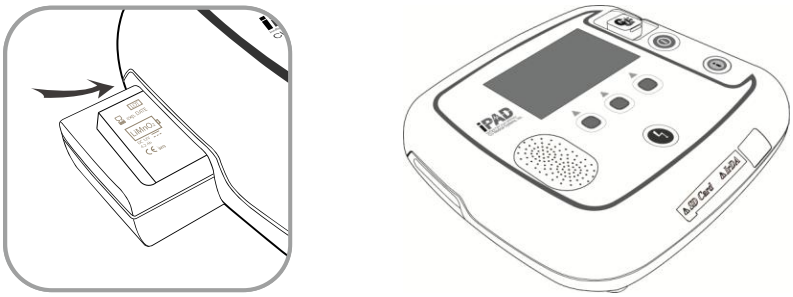
How to replace the battery pack

1. Remove the spent battery pack by pulling it out while pressing the locking mechanism 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.

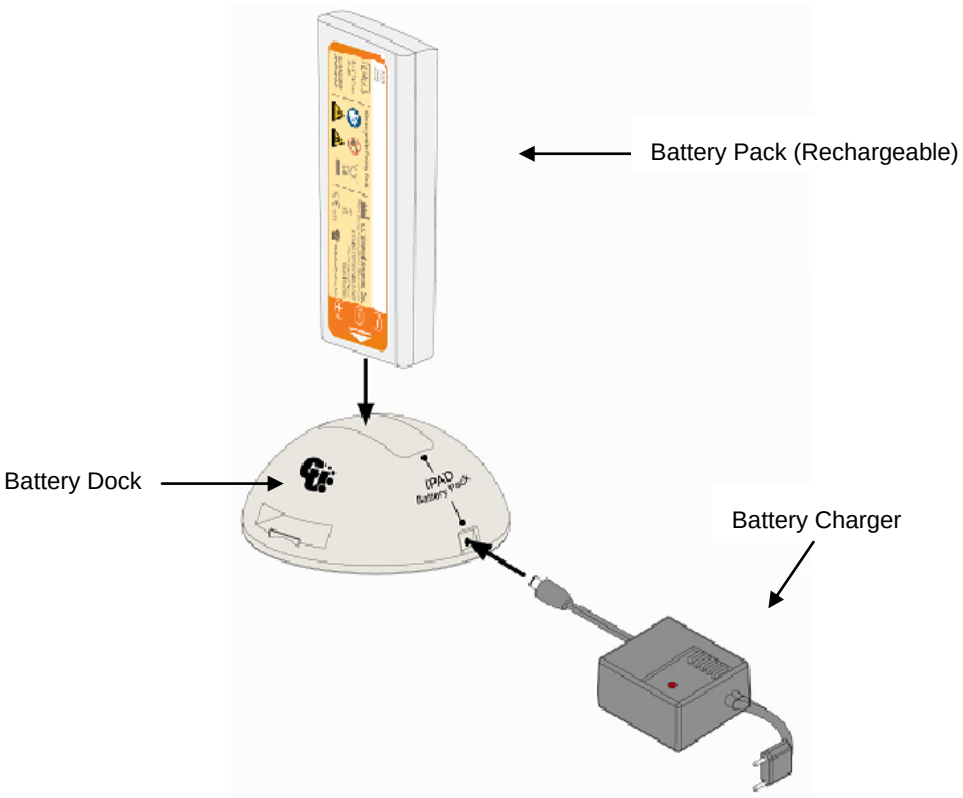


3. Push the battery pack in until you hear a "click".



How to recharge the battery pack

- Rechargeable batteries that are low can be reused after recharging.
- You can recharge the battery by using the Battery Charger and Battery Charge Dock provided by the manufacturer.
- Familiarize yourself with the Battery Charger manual before use.
- The red LED lights up on the Battery Charger when charging, and the green LED lights up when charging is complete.
- Refer to the figure below for charging the Battery Pack (Rechargeable).



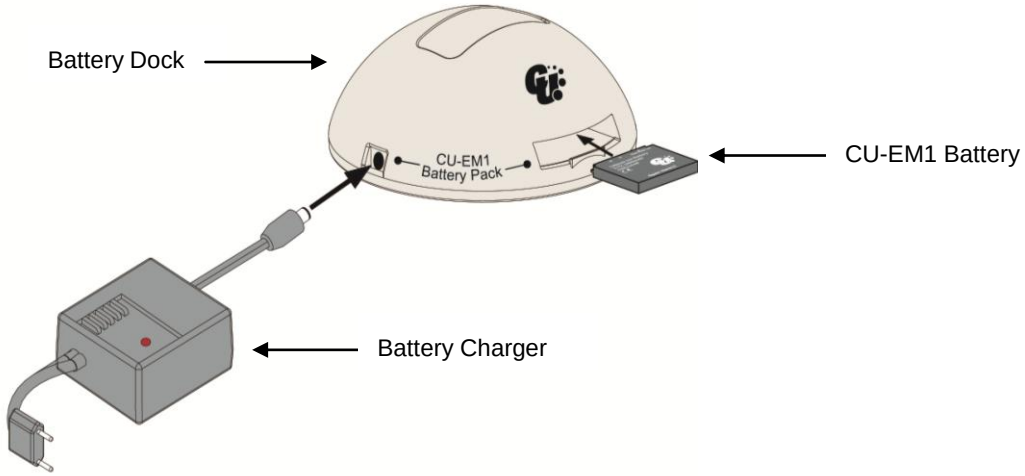
② Battery Pack (Disposable)

Replacing the battery pack

- The battery pack should be replaced if the battery is low. For further details on checking the battery status, please refer to [Chapter 7: Troubleshooting] in these Instructions for Use.
- You must use only battery packs provided by the manufacturer.
- The disposable battery pack used in this device is not rechargeable. Do not insert the disposable battery pack into the Battery Charge Dock.
- The Battery Pack (Disposable) can be replaced in the same manner as the Battery Pack (Rechargeable).

③ Charging the CU-EM1 Battery

- Rechargeable batteries that are low can be reused after recharging.
- You can recharge the battery by using the Battery Charger and Battery Charge Dock provided by the manufacturer.
- The red LED lights up on the Battery Charger when charging, and the green LED lights up when charging is complete.
- Refer to the figure below for charging the Battery Pack (Rechargeable).



⚠ CAUTION

• Precautions for using the battery pack

- Do not subject to impact, disassemble or damage the device.
- Do not place the device near hot objects such as heating appliances.
- Do not keep the battery pack near metal objects. This may cause a short-circuit.
- Keep out of the reach of children.
- Do not use a battery pack that is externally damaged (e.g., leakage); replace it with a new one.

  If the leakage gets into the eye, immediately wash with water and consult with a physician.
- Do not store the device under direct sunlight.
- Do not store the device in a wet or highly humid place.
- Comply with local regulations when disposing of the device.
- Do not burn or make a hole in the device.
- Do not insert the disposable battery pack into the Battery Charge Dock to recharge.

• Rechargeable batteries may induce hazards including inflammation, fire, and explosion. Please comply with the following:

- Batteries whose casing is visibly swollen may be hazardous. Immediately contact the manufacturer or distributor.
- Use only a genuine Battery Charger designated by the manufacturer.
- Do not leave the battery inside a vehicle during summer.
- Use a lithium secondary battery guaranteed by the manufacturer.
- Do not expose the battery to high heat above 60℃.

• The battery's performance may temporarily drop in low temperatures. We recommend not to store or use the battery in a low temperature environment.

• If the CU-SP2 is to be stored and not used for a long time, remove any battery pack (disposable or rechargeable) to prevent damage in case the battery pack leaks.
(Important! Take note that this should be done only if the CU-SP2 is stored and not used. If the CU-SP2 is on standby for emergencies, a battery pack must be installed at all times.)

6.2.3 Replacing the Pads

- You cannot use expired pads.
- Check if the pads package is damaged.
- You should use only the pads provided by the manufacturer.

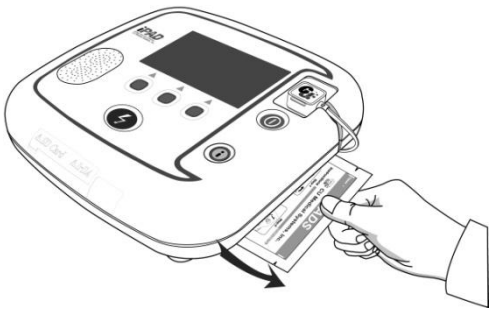
How to replace pads

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

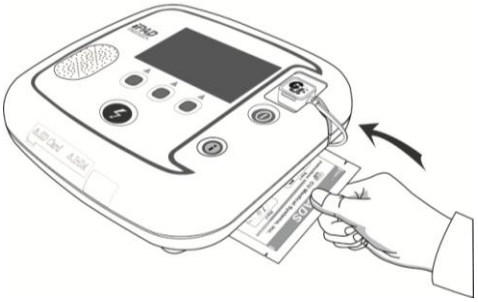
The expiration date is marked to the left of the “Multifunction Defibrillation ADULT PADS” label on the pads package.

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

2. Used or expired pads should be replaced. Pull out the top and bottom of the pads connector with your fingers and take the pads out from the Pads Storage Compartment. Refer to the figure below.



3. Insert the pads connector of the new pads into the Pads Connector Insert, and then put the Pads Package in the Pads Storage Compartment. Refer to the figure below.



6.2.4 Cleaning the i-PAD CU-SP2

Always clean the device and accessories with a soft cloth. The following detergents may be used to clean the exterior surface of the device:

- Light soapy water
- Light chlorine bleach (dilute 30ml of chlorine bleach per 1 liter of water)
- Light ammonia compound
- Light hydrogen peroxide

⚠ CAUTION

- Do not immerse the device or accessories in liquid or detergent.
- Be careful not to allow any liquids to get into the device.
- If the device is immersed, immediately contact the manufacturer or a service center certified by the manufacturer.
- Applying excessive force or shock while cleaning the device may result in malfunction.
- Do not use an acetone-based strong detergent or abrasive to clean the device.
- Do not use a detergent containing abrasive ingredients.
- Do not sterilize this device.

6.2.5 Disposal

Appropriately dispose of the CU-SP2 and accessories in accordance with local regulations.

7. Troubleshooting

7.1 Self-Tests

There are several types of self- test. Each self-test examines different contents. Refer to the table below for details.

Self-Test Type	Description
Battery Pack Self-Test	Perform the battery self-test of inserting the battery pack in the following events: • When initially purchasing the device • When inspecting the equipment after use • When replacing the battery pack • When the device is damaged The device checks the Shock Button, i-Button, and Soft Keys during the self-test. During the battery self-test, the user should perform the device check by pressing buttons according to the voice or screen instructions. Also, check the connection status of the pad connector as well as the pad status during the self-test. If the self-test is successful, the device will automatically shut down. If the self-test is not successful, the i-Button flashes in red. When pressing the i-Button according to the voice instruction, the device will automatically shut down after reporting the error by voice and LCD Screen. For further details, please refer to [Section 7.3: Troubleshooting] in these Instructions for Use. The battery self-test performs a very detailed inspection, which takes about 20 seconds. If an emergency occurs during the battery self-test, turn the device off by pressing the Power Button. Then, turn it back on by pressing the Power Button and quickly respond to the emergency by following the voice instructions.
Power Self-Test	The device performs a power self-test when turning on the device by pressing the Power Button.
Real-time Self-Test	The device checks itself in real-time during operation.
Periodic Self-Test	This device periodically performs a self-test once every day, week and month. The periodic self-test checks important features of the device, such as the battery status, pad status and internal circuits.

If the self-test fails during operation and defibrillation cannot be administered, the device will instruct you to get a replacement defibrillator and will guide CPR by voice. To learn more about the error, first press the Power Button to turn off the device. Press and hold down the i-Button, and the device will notify the error by voice and LCD Screen, and then automatically shut down. For further details, please refer to [Section 7.3: Troubleshooting] of these Instructions for Use.

⚠ CAUTION

- Since the CU-SP2 performs a self-test on a daily basis, you do not need to frequently perform a self-test for the battery pack. Frequently self-testing the battery pack consumes battery power and shortens the battery life.
- Periodically check if the i-Button flashes in red in order to prepare for emergencies.
  If the i-Button flashes in red, please refer to [Section 7.3: Troubleshooting] in these Instructions for Use.

7.2 Device Status

The device notifies the user of its status in the following ways:

Indicator	Description	Remarks
i-Button: Flashing in red	The device detected an error (e.g., low battery). Press the i-Button to identify the error.	
Shock Button: Flashing in orange	The device is ready to deliver an electric shock. Press the Shock Button to deliver an electric shock.	

7.3 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:

Symptom/Voice Instruction	Cause	Resolution
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 have 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 have expired.	Replace the pads with a new one.
Voice Prompt : ” Press the pads firmly to the bare skin of the patient”	The pads are not properly attached to the patient's skin.	Check if the pads are securely attached to the patient's skin.
Voice Prompt : ” No shock delivered”	The pads are 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. 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-SP2 must be serviced only by authorized personnel.
- The i-PAD CU-SP2 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-SP2 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		Dual Mode External Defibrillator		
Device Name		i-PAD	Model Number	CU-SP2
Serial Number			Date of Purchase	
Sales Representative				
User Information	Name			
	Address			
	Contact no.			
Brief description of the problem				

Appendix

A. Parts and Accessories

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

A.1 Standard Accessories		
Name	Part Number	Ordering Number
Adult Defibrillation Pads (disposable)	CUA1007S	
Disposable Battery Pack(Long-life)	CUSA1103BB	
Instructions for Use	SP2-OPM-E-03	
A.2 Optional Accessories		
Carrying Case	SP2-A-BAG-3010	
Rechargeable Battery Pack	CUA1802RB	
Pediatric Defibrillation Pads (disposable)	CUA1102S	
IrDA Adapter	IR-220LPLUS	
PC S/W	CU Expert ver. 3.70 or higher	
SD Card	HD1-CARD-SD	
SD Card Reader	HD1-CARD-READER	
Printer	SPP-R200BGS/CUM	
Printer Paper	PAPER-5740	
ECG Transmission Device	CU-EM1	
ECG Transmission Device Rechargeable Battery Pack	CUA1204B	
ECG electrodes (disposable)	SEN-2237	
Battery Adapter	K-CU-820 Charger	
Battery Charge Dock	CUA1207CH	

B. Description of Symbols

B.1 CU-SP2 Defibrillator

Symbol	Description
	Power Button (ON/OFF)
	i-Button
	Shock Button
	Caution: Refer to related documents.
IP55	Protected against dust limited ingress(no harmful deposit) Protected against low pressure jets of water from all directions – limited ingress
	BF Type, defibrillation-proof equipment
	Refer to instruction manual/booklet
CE 2460	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
	Manufacturer
EC REP	EU Representative
SN	Serial Number
	Manufactured Date
	General warning sign
	General prohibition sign

B.2 CU-SP2 Packaging

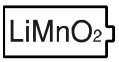
Symbol	Description
	Stacking No. (Up to 6)
	Load Upwards
	Avoid Moisture
	Fragile
	No Hooking
	Temperature Limit: Store at a temperature between 0℃ ~ 43℃.
	Recyclable
EC REP	EU Representative
CE 2460	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.
	Manufactured Date
	Manufacturer
SN	Serial Number

B.3 Accessories

B.3.1 Rechargeable Battery Pack

Symbol	Description
	Lithium Ion 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; meets the requirements of the applicable European directive

B.3.2 Disposable Battery Pack(CUSA1103BB)

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; meets the requirements of the applicable European directive

B.3.3 Pads

Symbol	Description
	Temperature Limit: Store at a temperature between 0℃ ~ 40℃.
	LOT Number
	Expiration Date
	Reference Order Number
	Disposable (Do Not Reuse)
	Do not fold or crush this product.
	Contains no Latex
	Expiration Date
	Caution: Refer to related documents.
	CE Mark; meets the requirements of the European Medical Device Directive 2007/47/EC and its revisions.

C. 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 5.4: Device Setup] 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 are 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 you to perform CPR immediately after one defibrillation 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 5.4: Device Setup] for the CPR setting. Please contact the manufacturer for additional information.
Arrhythmia	An abnormal heart rhythm.
Battery Pack	A disposable or rechargeable battery pack that supplies power to the device.

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.
Device	The Device referred to in these Instructions for Use is a Semi-Automated External Defibrillator (AED) for which the model name is CU-SP2, a product from the i-PAD product family of the manufacturer.
Disposable Battery Pack	A disposable battery pack that supplies power to the device and cannot be recharged. Replace expired or spent batteries with a new 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 7.3: 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	The button for checking the most recent device usage, displaying error messages, transferring ECG and event data, etc.
Internal discharge (disarm)	The i-PAD CU-SP2 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.
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.
Manual External Defibrillator	Manual External Defibrillator is a device that can perform asynchronous defibrillation and synchronous cardioversion
Operation Mode	The mode in which the device monitors the patient or executes CPR/defibrillation when turned on.
Pads	The pads stated in these Instructions for Use refers to electrode 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-SP2.
Pairing	The process of connecting the Device with an external Bluetooth device for communication.
PC S/W CU Expert (CU-EX1)	PC software used to manage treatment data. Refer to the appendix on accessories if you want to purchase this software.
Pediatric	A pediatric patient 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.
Pads liner	The liner that protects the conductive gel of the pads during storage inside the pads pouch.
Rechargeable Battery Pack	A rechargeable battery pack that supplies power to the device, which can be reused after recharging. Recharge and reuse low batteries.
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.
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 where the power of the device is OFF but the device executes periodic self-tests to ensure that the device is always ready for use in emergency situations.
We	Refers to CU Medical Systems Inc.

D. Device Specifications

Model Name: CU-SP2

Product Exterior

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

Environmental Conditions

Category	General Specifications
Operating Environment	(The device can be used immediately in case of an emergency.)
	Temperature: 0°C ~ 40°C (32°F ~ 104°F)
	Humidity: 5% ~ 95% (a location with no condensation)
Storage Environment	(The device has pads and a battery and is ready to be used for an emergency.)
	Temperature: 0°C ~ 43°C (32°F ~ 109°F)
	Humidity: 5% ~ 95% (a location with no condensation)
Transportation Environment	(The device does not have pads and a battery and is separately stored or transported over a long period of time.)
	Temperature: -20°C ~ 60°C (-4°F ~ 140°F)
	Humidity: 5% ~ 95% (a location with no condensation)
Altitude	0 to 5,000 m (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	General Specifications
Operation Type	Dual Mode (semi-automated, manual) External Defibrillator
Output Type	e-cube biphasic (Truncated exponential type)

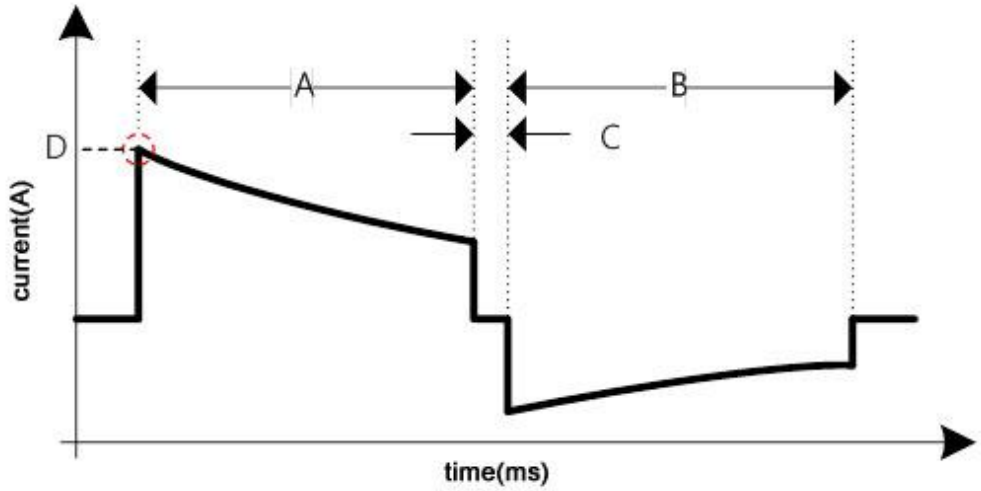
Output Energy	• AED Mode
	  • 150J±4J, 200J±6J at 50Ω load for adults
	  • 50J±2J at 50Ω load for children
	• Manual Mode (Optional)
	  • 2J±1J, 3J±1J, 5J±1J, 7J±1J, 10J±1J, 20J±2J, 30J±2J, 50J±2J, 70J±2J, 100J±4J, 150J±4J, 200J±6J at 50Ω load

Charge Control	Controlled by an automated patient analysis system

Charge Time

• Manual Mode	
• Charging time, set to maximum energy output, new fully charged battery pack	New battery pack 12 Seconds, typical
• Charging time, set to maximum energy output, 15th shock discharge from a new fully charged battery pack	New battery pack: 15th shock discharge 14 Seconds, typical
• Time from initially switching power ON to ready for discharge, set to maximum energy output, 15th shock discharge from a new fully charged battery pack	New battery pack: 15th shock discharge 24 Seconds, typical
• AED Mode	
• Time from initiation of rhythm analysis to readiness for discharge, set to maximum energy output, new fully charged battery pack	New battery pack 12 Seconds, typical
• Time from initiation of rhythm analysis to readiness for discharge, set to maximum energy output, 15th shock discharge from a new fully charged battery pack	New battery pack: 15th shock discharge 14 Seconds, typical
• Time from initially switching power ON to ready for discharge, set to maximum energy output, 15th shock discharge from a new fully charged battery pack	New battery pack: 15th shock discharge 25 Seconds, typical

Arming Indicator	• Voice instruction (Press the flashing orange button.) • Flashing Shock Button • Beeper
Time from End of CPR to Administering Shock	At least 6 seconds from the completion of CPR to the shock delivery
Disarm	The device disarms the electric load under the following situations: • When the patient's ECG is changed into a status that does not require defibrillation. • When the Shock Button is not pressed within 15 seconds from the completion of the charge. • When the equipment is turned off by pressing the Power Button for over 1 second. • When the pad 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. (25Ω ~ 175Ω)
Electric Shock	After charging is completed, the device delivers a defibrillating shock to the patient when the Shock Button is pressed.
Vector for Administering Shock	• The pads (Lead II) are placed anterior-anterior for the adult. • The pads are placed anterior-posterior for the child.
Patient Isolation	BF Type, defibrillation protected
Sync	
• **Delay between synchronization pulse and shock delivery**	The shock is delivered within 60 milliseconds of the occurrence of a QRS peak in the patient's ECG



Biphasic Truncated Exponential Type

The shape of the waveform is automatically adjusted according to the patient's defibrillation impedance. In the graph, A is the duration of the first phase of the waveform, B is the duration of the second phase, C is the delay between phases (500μs), and D is the peak current.

Output Waveform for Adults (200 Joules)

Patient Impedance (Ohms, Ω)	First Phase Interval (milliseconds, ms)	Second Phase Interval (milliseconds, ms)	Peak Current (A)	Discharging Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.4	2.4	67.5	196.2	200 (±6J)
50	4.4	4.4	36	199.5	200 (±6J)
75	6.5	6.5	25	200.7	200 (±6J)
100	8.7	8.7	18.2	201.1	200 (±6J)
125	10.9	10.9	14.8	201.3	200 (±6J)
150	12.5	12.5	12.6	201.1	200 (±6J)
175	14.9	14.9	10.8	200.9	200 (±6J)

Output Waveform for Adults (150 Joules)

Patient Impedance (Ohms, Ω)	First Phase Interval (milliseconds, ms)	Second Phase Interval (milliseconds, ms)	Peak Current (A)	Discharging Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.4	2.4	64.5	147.8	150 (±4J)
50	4.4	4.4	32.7	149.7	150 (±4J)
75	6.3	6.3	22.5	151.5	150 (±4J)
100	8.8	8.8	15.9	148.1	150 (±4J)
125	10.7	10.7	13.0	149	150 (±4J)
150	12.7	12.7	11.0	148.2	150 (±4J)
175	15.0	15.0	9.5	148.8	150 (±4J)

Output Waveform for Children (50 Joules)

Patient Impedance (Ohms, Ω)	First Phase Interval (milliseconds, ms)	Second Phase Interval (milliseconds, ms)	Peak Current (A)	Discharging Energy (Joules, J)	Energy Accuracy (Joules, J)
25	2.3	2.3	35.4	50.2	50 (±2J)
50	4.3	4.3	18.4	50.7	50 (±2J)
75	6.3	6.3	12.3	49.7	50 (±2J)
100	8.5	8.5	9.1	49.5	50 (±2J)
125	10.6	10.6	7.3	50.3	50 (±2J)
150	12.7	12.7	5.8	49	50 (±2J)
175	15.0	15.0	4.9	49.6	50 (±2J)

ECG Accuracy

Category	General Specifications
ECG Acquisition Route	Lead II
Response Frequency	1 Hz ~ 30 Hz

ECG Analysis System

Category	General Specifications
Function	Analyzes whether the rhythms of the patient's impedance and ECG require a defibrillation
Measured Impedance Range	25Ω ~ 175Ω
Rhythm Requiring Defibrillation	• Ventricular fibrillation and several ventricular tachycardia including ventricular flutter • The CU-SP2 uses multiple variables to determine the shockability of the heartbeat. • Some extremely low amplitudes or low frequency heartbeats are not interpreted as shockable VF beats. Also, some VT beats are not interpreted as rhythms requiring defibrillation.
Rhythm Not Requiring Defibrillation	• ECG rhythms excluding those requiring a defibrillation • When a rhythm that does not require a defibrillation is detected, the device informs the user by voice to perform CPR.
Analysis Protocol	Prepares to administer shock or give voice instructions on CPR according to the analysis result
Algorithm sensitivity and specifications that require defibrillation	Satisfies AAMI DF80

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, idioventricular 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%

a. A Statement for Health Professionals from the AHA (American Heart Association) Task Force on AED, Subcommittee on AED Safety and Efficacy. Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety. Published 1997; 95:1677-1682.

b. According to AHA Recommendations (a) and AAMI-based DF80, SVT is clearly included in the non shockable rhythm grade.

Control Devices, Indicators, Voice Instructions

Category	General Specifications
Control Devices	Power Button, i-Button, Shock Button, 3 Soft Keys
Graphic LCD	Displays the operating status of the device and instructions
Indicators	• Shock Button: Flashes in orange when the defibrillator is charged and ready to deliver a shock. • Blue i-Button: Flashes when guiding CPR, transferring treatment data or setting the CPR mode. • Red i-Button: Flashes when an error occurs.
Speakers	Outputs voice instructions • If the device determines, based on its settings, that the surrounding environment is noisy and it cannot give accurate voice instructions, it will automatically increase the volume for the user.
Beeper	Outputs various beeps
Low Battery Check	The check is automatically performed through periodical self-tests as well as in real-time when the equipment is in use or the power is turned on.
Low Battery Indicator	The Graphic LCD on the device indicates low battery along with voice instructions and a flashing red i-Button.
Voice Instruction	Detailed voice instructions during defibrillation and CPR.

Self-Tests

Auto	• Power Self-Test / Real-time Self-Test • Daily / Weekly / Monthly Self-Test
Manual	Battery Pack Self-Test (performed when the user inserts the battery pack)

CU-SP2 Battery Pack (Rechargeable)

Model	CUA1802RB (3INR/19/65)
Battery Type	10.8VDC, 2.5Ah Li-ion, rechargeable
Capacity	For fully charged new batteries, at least 60 shocks or 3 hours of operation at 25°C (77°F)
Charging Time with device off	Approximately 3 hours to 100%. Approximately 2.8 hours to 90%. Charging the battery at temperatures above 45℃ may degrade battery life. (for standard battery)
Standby Life (After Inserting the Battery)	If stored and managed in accordance with instructions in the document: At least 2 years from the date of installation into the i-PAD CU-SP2
Temperature Ranges for Storage and Use	• Operating Environment Temperature: 0°C ~ 40°C (32°F ~ 104°F) • Storage Environment Temperature: -20°C ~ 60°C (-4°F ~ 140°F)

CU-SP2 Battery Pack (Disposable)

Model	CUSA1103BB
Battery Type	12V DC, 4.2Ah $LiMnO_2$, disposable
Capacity	For fully charged new batteries, at least 130 shocks or 5 hours of operation at 25°C (77°F)
Standby Life (After Inserting the Battery)	If stored and managed in accordance with instructions in the document: At least 5 years from the date of installation into the i-PAD CU-SP2
Temperature Ranges for Storage and Use	• Operating Environment Temperature: 0°C ~ 43°C (32°F ~ 109°F) • Storage Environment Temperature: -20°C ~ 60°C (-4°F ~ 140°F)

Adult Defibrillation Pads

Category	General Specifications
Type	Adult
Pad Size	110 cm^2 ± 10%
Cable Length	120cm ± 5cm
Pad Storage Life	At most 36 months from the date of manufacture
Bio-Compatibility	Patient contacting material meets requirements of ISO 10993-5,-10 (Biological Evaluation of Medical Device)

Pediatric Defibrillation Pads

Category	General Specifications
Type	Pediatric
Pad Size	50 cm^2 ± 10%
Cable Length	120cm ± 5cm
Pad Storage Life	At most 30 months from the date of manufacture
Bio-Compatibility	Patient contacting material meets requirements of ISO 10993-5,-10 (Biological Evaluation of Medical Device)

Data Storage and Transmission

Category	General Specifications
Infrared Data Association	Able to communicate with a PC via IrDA
Data Storage	Saves 3 events on the internal memory (up to 17 hours per event)
SD Card	Stores the ECG and event data from the device's internal

	memory through the PC software (CU-Expert).
Bluetooth	• Bluethooth 2.1 + EDR, class 2 module • Operating Frequency Range(OFR): 2402 – 2480 MHz • Modulation: GFSK, π/4 DQPSK, 8DPSK • Uses Bluetooth to communicate with the Printer or the CU-EM1 (ECG transmission device)
Communication speed	9,600bps or higher

CU-EM1 (ECG Transmission Device)

Category	General Specifications
ECG Input	• ECG Type: 3-Lead (Lead II) • Able to see ECG results using the CU-SP2 LCD
Lead Fault	Detects when the ECG cable(s) is detached (if the ECG cable is disconnected from the patient or the device).
Heart rate display	30 ~ 300 bpm (Accuracy: ±3 bpm)
ECG Size	• 5 mm/mV, 10 mm/mV, 20 mm/mV • AUTO: 0.3 ~ 5.5mV, Display inputted ECG signals as 10mm on the screen.
Frequency Range	1 ~ 30 Hz (-3 dB)
Patient Isolation	CF Type
Operating Time	At least 10 Hours
Battery Charge Time	Within 3 Hours
Sweep speed	23 mm/sec

CU-EM1 Battery Pack (Rechargeable)

Model	NMB-I102FP (1ICR6/34/46)

Battery Type	3.7V DC, 1.0Ah Li-ion, rechargeable
Capacity	For fully charged new batteries, at least 10 hours of operation at 25°C (77°F)
Standby Life (After Inserting the Battery)	If stored and managed in accordance with instructions in the document: At least 6 months from the date of installation into the i-PAD CU-SP2
Temperature Ranges for Storage and Use	• Operating Environment Temperature: 0°C ~ 40°C (32°F ~ 104°F) • Storage Environment Temperature: -20°C ~ 60°C (-4°F ~ 140°F) • Charging Environment Temperature: 10°C ~ 43°C (50°F ~ 109°F)

Battery Charger

Model	K-CU-820 Charger + Battery Charger Dock
Product Assemblage	Battery Charger Dock + Charger + AC Cord + User Manual
Operating Voltage	• Input 100V ~ 240V, 50/60Hz • Output 600mA Mode (3.7V~12.6V)
Rechargeable Batteries	• SP2 rechargeable battery pack: CUA1802RB • EM1 rechargeable battery pack(optional): NMB-I102FP

E. Electromagnetic Compatibility

Guidance and manufacturer's declaration

The i-PAD CU-SP2 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD CU-SP2 should assure that it is used in such an environment.

Phenomenon	Basic EMC standard or test method	Compliance level
Radiated disturbance	CISPR 11:2015 Group1, Class B	Group1, Class B
Electrostatic Discharge Immunity (ESD)	IEC 61000-4-2:2008	±8kV / Contact ±2, ±4, ±8, ±15 kV / Air
Radiated RF Electromagnetic Field Immunity	IEC 61000-4-3:2006+A2:2010	10 V/m, 20 V/m (SP2 only) 80MHz – 2.7 GHz 80% AM at 1 kHz, 5 Hz
Immunity to Proximity Fields from RF wireless Communications Equipment	IEC 61000-4-3:2006+A2:2010	Table 9 in IEC 60601-1-2:2014
Immunity to Conducted Disturbances Induced by RF fields	IEC 61000-4-6:2013	3V (EM1 only) 0.15 MHz – 80 MHz 6V in ISM and amateur radio bands between 0.15 MHz and 80MHz 80% AM at 1 kHz, 5 Hz
Power Frequency Magnetic Field Immunity	IEC 61000-4-8:2009	30 A/m 50 Hz and 60 Hz

⚠ WARNING

- The i-PAD CU-SP2 should not be used adjacent to or stacked with other equipment.
  If adjacent or stacked use is necessary, the i-PAD CU-SP2 should be observed to verify normal operation in the configuration in which it will be used.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Portable RF communications equipment (including peripherals such as antenna cable and external antennas) should be used no closer than 30 cm (12 inches) to any part of the CU-SP2, including cables specified by the CU Medical Systems, Inc. Otherwise, degradation of the performance of this equipment could result.