CU-SPT
Version 1.00E

AED Trainer

i-PAD CU-SPT

Instructions for Use

ICU Medical Systems, Inc.

CU Medical Systems, Inc.
www.cu911.com

CU Medical Systems, Inc.

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Overview

Thank you for purchasing the i-PAD CU-SPT.
i-PAD CU-SPT is a training product designed to provide training on a semi-automated external defibrillator.

⚠ Warning

- The device is intended to provide education and training on the defibrillator and must not be used for emergency measures in case of emergency.

These Instructions for Use contain information necessary for the correct use of the device.
Hereinafter,
"device" refers to [CU-SPT]
"We" or “Us" refers to CU Medical Systems, Inc.
Please read these Instructions for Use carefully before use to ensure safe operation without problems and familiarize yourself with operations and safety precautions.

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

1. Introduction

1.1 Device Description

CU-SPT is training product designed to provide training on the use of a semi-automated external defibrillator and help users respond to emergencies more swiftly.

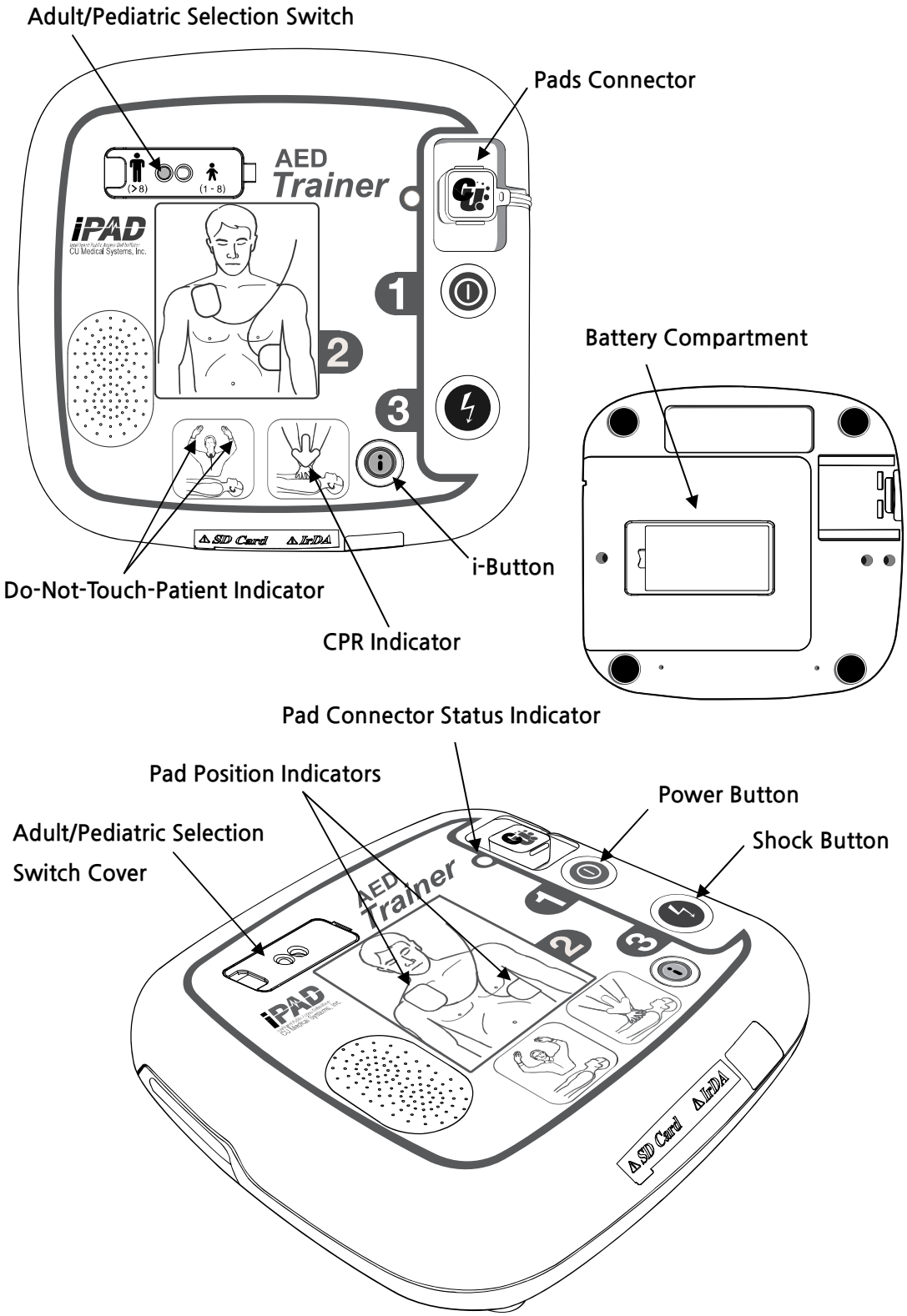
1.2 Features

- The device provides eight scenarios for more swift response to emergency situations.
- The device does not require an additional device for education and is easy to use.
- The device is powered by six AA batteries (disposable or rechargeable), and easy to carry.
- Users can set the scenarios of the device with the remote controller.

1.3 Additional Information

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

2. Device Features



Power Button	Turns the device on or off (When the device is on, a green LED is lit).
i-Button	• Administration Mode • checks the S/W version • sets the CPR mode (the number of compressions, breaths and cycles; compression rate per minute; pausing time; detailed guide on/off) • Turns on or off the voice instructions for CPR. •
Shock Button	Delivers defibrillating shock when pressed while flashing in orange.

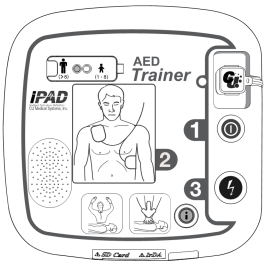
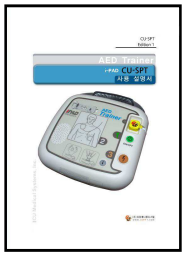
⚠ Note

• The device does not supply electric shock.

Adult/Pediatric Selection Switch	Selects Adult/Pediatric modes.
Adult/Pediatric Selection Switch Cover	Covers the Adult/Pediatric Selection Switch to prevent accidental switching.
Pads Connector	Connects with the connectors of the pads.
Pads Connector Status Indicator	Indicates the connection status of the pads connector.
Pads Position Indicators	Indicates the pads position on the patient.
Do-Not-Touch-Patient Indicator	Warns when not to touch the patient.
CPR Indicator	Indicates performance of CPR on the patient.
Battery Compartment	Supplies power to the device.

3. Preparation for Use

3.1 Standard Package Contents

	i-PAD CU-SPT
 Training Pads	Training pad for i-PAD CU-SPT **⚠ Warning** • Do not use the pads for i-PAD CU-SPT, an actual defibrillator. The pads cannot apply electric shock.
 Instructions for Use	i-PAD CU-SPT Instructions for Use
 Carrying Case	For device carrying and storage

AA Batteries	Used with the battery compartment **⚠ Caution** • Do not mix new with old batteries or disposable with rechargeable batteries. • Remove the batteries from the device during storage to prevent battery leakage. • Never recharge disposable batteries. • If using rechargeable batteries, carefully read and follow all instructions provided with the batteries and the battery charger. • Always remove old or discharged batteries promptly and recycle or dispose of them in accordance with Local and National Disposal Regulations. **⚠ Note** • The disposable batteries last up to 8 hours for continuous use. • When the device is used in a cold place, the battery life may shorten. • If the i-button turns red, this indicates battery shortage. In this case, the batteries must be replaced with new ones.
 Infrared Remote Controller	Used to control the CU-SPT Battery: 2 AAA batteries • Key Features • Power OFF, PADS ON/OFF, Low battery error, Scenarios, Volume control **⚠ Note** • Do not use the controller farther than 5m from the device. • Do not place any objects that infrared cannot penetrate between the device and controller.

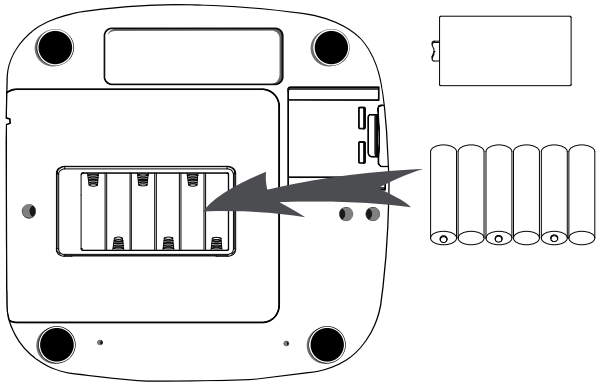
3.2 Setting up the i-PAD CU-SPT

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

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 AA batteries into the battery compartment on the back of the device as shown in the figure.



⚠ Note

- When inserting batteries, check the direction of the batteries. If the batteries are incorrectly inserted, the device may not properly operate.

3.3 Device Storage

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

- Do not operate or store the device in conditions that are beyond the following. Specified limits.
  - **Operational Environment**
    Temperature: 15℃ ~ 35℃ (59℉ ~ 95℉)
    Humidity: 5% ~ 95% (non condensing)
  - **Storage Environment**
    Temperature: 0℃ ~ 43℃ (32℉ ~ 109℉)
    Humidity: 5% ~ 95% (non condensing)
  - **Transport Environment**
    Temperature: -20℃ ~ 60℃ (-4℉ ~ 140℉)
    Humidity: 5% ~ 95% (non condensing)

- Do not store the device in areas that are directly exposed to sunlight.

- Do not store the device in areas with highly fluctuating temperatures.

- Do not store the device near heating equipment.

- Do not store the device in areas where there is high vibration (in excess of Road Transportation and Helicopter Minimum Integrity of MIL-STD-810G Method 514.5C).

- Do not operate or store the device in environments with high concentration of flammable gas or anesthetics.

- Do not operate or store the device in areas with high concentration of dust.

- Only personnel authorized by the manufacturer may open the device for servicing. There are no user serviceable components inside the device.

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

4.1 Scenario Setting

4.1.1 Scenario Selection

① When the device is turned on by pressing the power button, it reproduces scenario 6 by default.

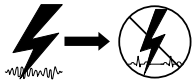
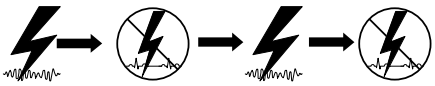
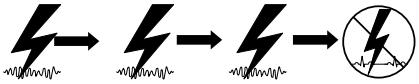
② **If you want to change the scenario, use the remote controller.**

> ⚠ Note
>
> • Please refer to [Section 4.1.2: Scenario] for details.

③ **There are 8 types of scenarios.**

④ When the desired scenario is selected, operate the device by referring to [Section 4.3: Procedures using the device] of these Instructions for Use.

4.1.2 Scenario

Scenario 1 (S1) 	① Apply first shock, CPR ② Reproduce normal rhythm, CPR
Scenario 2 (S2) 	① Apply first shock, CPR ② Apply second shock, CPR ③ Reproduce normal rhythm, CPR
Scenario 3 (S3) 	① Reproduce normal rhythm, CPR ② Apply first shock, CPR ③ Reproduce normal rhythm, CPR
Scenario 4 (S4) 	Reproduce normal rhythm continuously, CPR
Scenario 5 (S5) 	① Apply first shock, CPR ② Reproduce normal rhythm, CPR ③ Apply second shock, CPR ④ Reproduce normal rhythm, CPR
Scenario 6 (S6) 	Reproduce ventricular fibrillation continuously, CPR
Scenario 7 (S7) 	① Apply first shock, CPR ② Apply second shock, CPR ③ Reproduce normal rhythm, CPR ④ Apply third shock, CPR ⑤ Reproduce normal rhythm, CPR
Scenario 8 (S8) 	① Apply first shock, CPR ② Apply second shock, CPR ③ Apply third shock, CPR ④ Reproduce normal rhythm, CPR

4.2 Infrared Remote Controller

4.2.1 Infrared Remote Controller Control

With the remote controller, you can reproduce various emergency situations such as Power OFF, PADS ON/OFF, Low battery, and other scenarios as well as controlling the volume.

Infrared Remote Controller

⚠ Note

- Please be careful to not lose the remote controller. When you cannot control the device with the remote controller, replace the controller's batteries. If the problem persists after the battery replacement, please contact us.
- Please use the remote controller within 5 m from the device.
- Point toward the device with the remote controller from the location where the device is visible.

4.2.2 Infrared Remote Controller Button Functions

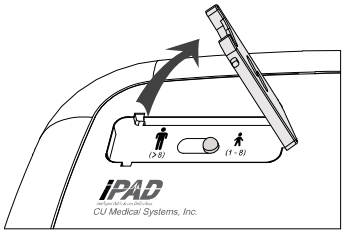
Button	Button Functions
POWER OFF	Turns off the device.
PADS ON/OFF	Controls the PADS ON/OFF status. Executes scenario 6 when pressed while PADS OFF. Switches to PADS OFF when pressed while PADS ON.
LOW BAT	Reproduces the "Low Battery" situation when pressed. The "Low Battery" situation that is caused by pressing the i-button does not mean that the battery is actually low. ⚠ Note • When a "Low Battery" error occurs without pressing the "LOW BAT" button, replace batteries in the device.
Volume Control	The ▲ button increases the volume, while the ▼ button reduces the volume. ⚠ Note • The default volume on the device is level 7. The volume can be adjusted from 0 to 10 with the remote controller. • As the volume increases, the battery life may shorten.
Training Scenario	The "S1 ~ S8" buttons reproduces emergency scenarios programmed in the device. Please refer to [Section 4.1.2: Scenario] for details.

4.3 Procedures using the i-PAD CU-SPT

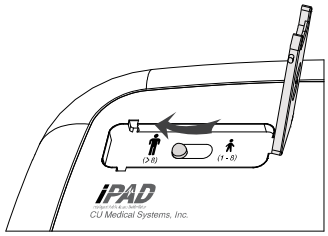
① Set the Adult/Pediatric Selection Switch to match the victim.

Adult victim

Ensure that the Adult/Pediatric Selection Switch is set to Adult Mode. If the switch has not been set yet, move it to Adult Mode as shown in the figures below.



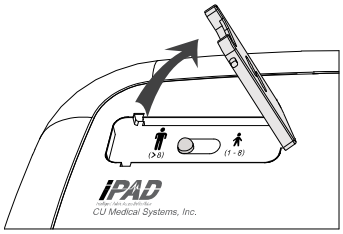
Open the switch cover.



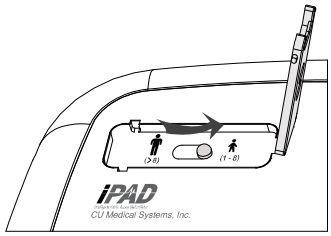
Set the switch to adult defibrillation mode as shown in the following picture.

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

Ensure that the Adult/Pediatric Selection Switch is set to Pediatric Mode. If the switch has not been set yet, move it to Pediatric Mode as shown in the figures below.



Open the switch cover.



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

⚠ Note

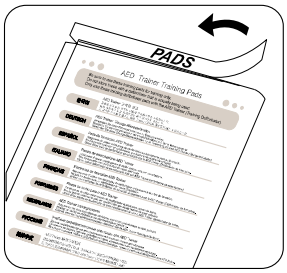
- You can switch the adult/pediatric selection switch before or after turning on the i-PAD CU-SPT. However, you should change it prior to PADS ON. After PADS ON, you cannot change the mode. For a proper operation of the device, it is recommended to select an appropriate mode prior to PADS ON.
- The Adult/Pediatric Selection Switch is affected by magnetic fields. Do not use the device in a strong magnetic field.

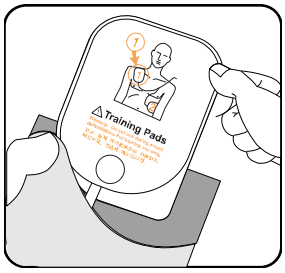
② Turn the device on by pressing the Power Button.

When the power turns ON the following occurs in sequence:

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

③ Open the pads and take out the training pads package.

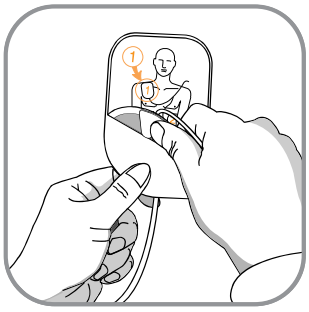


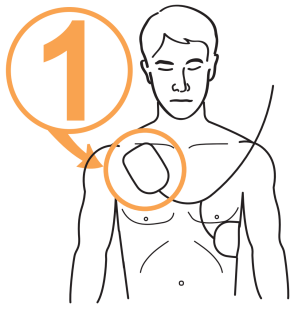


④ Refer to the pictures on both pads.

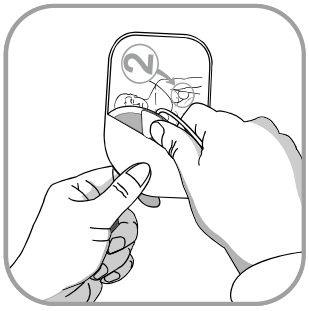
⑤ Place pads on the mannequin.

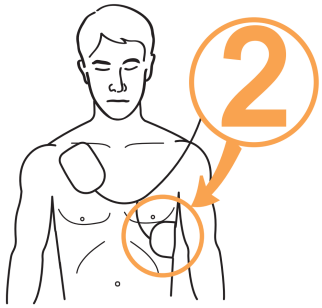
- Remove **pad 1** from the single liner and stick the pad to the mannequin’s upper chest as shown below.



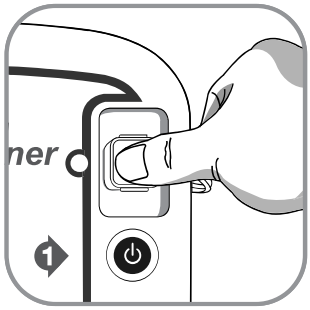


• Remove **pad 2** from the single liner, and stick the pad to the mannequin's side torso as shown below.





⑥ Connect the pad connector to the Pads Connector insert on the device.



⑦ When the pad connector is connected, the device operates according to the selected scenario as follows:

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

- The device announces that a defibrillation shock is needed, and instructs you to keep away from the mannequin.
- Continuous beep while the Shock Button flashes in orange.
- The device instructs you to press the flashing orange Shock button; you should press the Shock Button at this time.

When the Shock Button is pressed, the device delivers a simulated defibrillating shock to the mannequin. If defibrillation is properly done, the device reports that an electric shock has been delivered. After shock delivery, the device indicates that you may touch the patient, and the CPR Mode Indicator is lit. Then, the voice instruction for CPR starts.

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

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

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

⑧ Perform CPR.

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

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

Refer to your Local training program for details regarding CPR.

⚠ Note

- The CPR guide can be set on an administrator's mode. Refer to [Section 5: Device Setting] for more information.

5. After Using the i-PAD CU-SPT

5.1 Device Setting

5.1.1 CPR Guide Setting

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

You can set the following:

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

5.1.2 Setting the CPR Guide

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

② The device gives you a summary (Software Version).

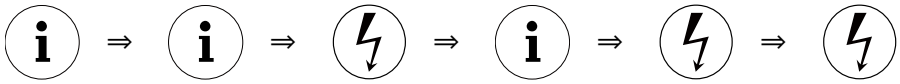
③ When instructed to set the CPR guide, press the i-Button to enter the CPR guide setting mode.

④ When instructed to enter a password, enter **the set password.**

⚠ Note

• Password: press the following buttons in sequence:

• **i-Button → i-Button → Shock Button → i-Button → Shock Button → Shock Button**



⑤ The voice guide will give information regarding the current CPR guide setting.

⑥ Press the Shock Button to change the setting, or press the i-Button to proceed to the next step.

⑦ Settings can then be changed in the following order: Number of Chest Compressions, Number of ventilation, Chest Compression rate, Pausing Time, and Detailed Guide Selection. Refer to **[Table 1] CPR Guide Setting Options** below.

⑧ When the setting is completed, the voice guide will give information regarding the set CPR guide, which may be saved or canceled.

⑨ Press the i-Button to save or the Shock-Button to cancel according to voice instructions.

⑩ When the CPR guide setting is either saved or canceled, the device automatically shuts down.

[Table 1] CPR Guide Setting Options

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

⚠ Note

- By default, Detailed Guide Selection is OFF during CPR so that you can concentrate on the compression rate and ventilation guidance. If you want the Detailed Guide Selection to be ON during CPR, set it ON as outlined in the previous pages.
- If the Detailed Guide Selection is OFF and the Number of ventilation is set to 0, the CU-SPT provides only chest compression guidance for 2 minutes. After 2 minutes, the CU-SPT automatically proceeds to the next sequence.

6. Safety Precautions

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

⚠ 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.

⚠ Note

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

7. Device Service

Device Warranty

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

The device is warranted by CU Medical Systems, Inc. against defects in materials and workmanship for two 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-SPT must be serviced only by authorized personnel.
- The i-PAD CU-SPT 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-SPT 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.

Technical Support and Service

Website

http://www.cu911.com

Online Support

www.cu911.com → Customer Service → Online Support

CU Medical Systems/Customer Service Team

5F, Cheonggye Building, 221,Anyangpangyo-ro,
Uiwang-si, Gyenggi-do, Korea
Tel: +82 31 421 9700 / Fax: +82 31 421 9911

Europe

Authorized EU Representative of CU Medical Systems, Inc.
Medical Device Safety Service Schiffgraben 41,
30175 Hannover, Germany
TEL: +49 511 6262 8630
FAX: +49 511 6262 8633

CU Medical Germany GmbH, Ernst-Augustin-Str.5-11,
12489 Berlin, Germany
TEL : +49 511 848 6054 / FAX : +49 30 6782 0901

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Fax:+82 31 421 9911

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