

**Intelligent** NF1200  
PUBLIC ACCESS DEFIBRILLATOR

**AED i-PAD**

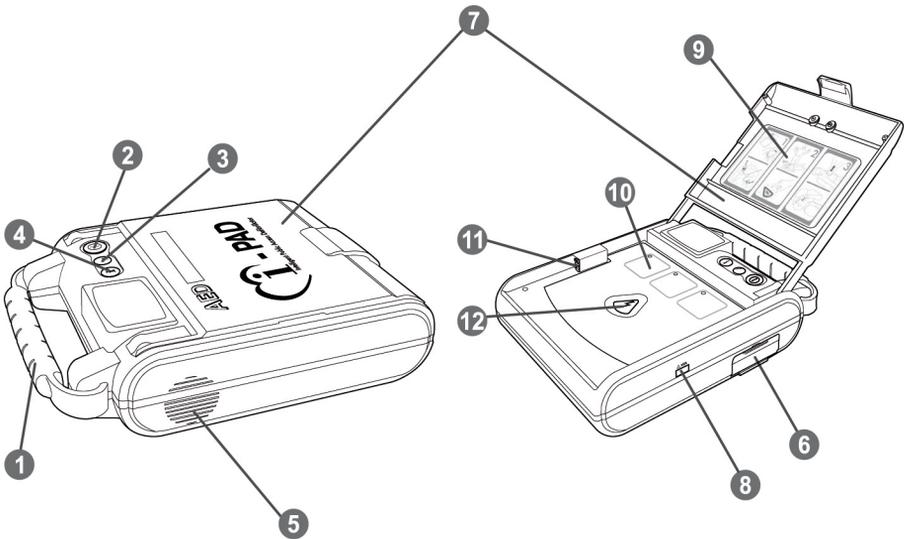
**Manual**



Medical Systems, Inc.

i-PAD NF1200 Operator's Manual CU Medical Systems, Inc.

## Intelligent Public Access Defibrillator



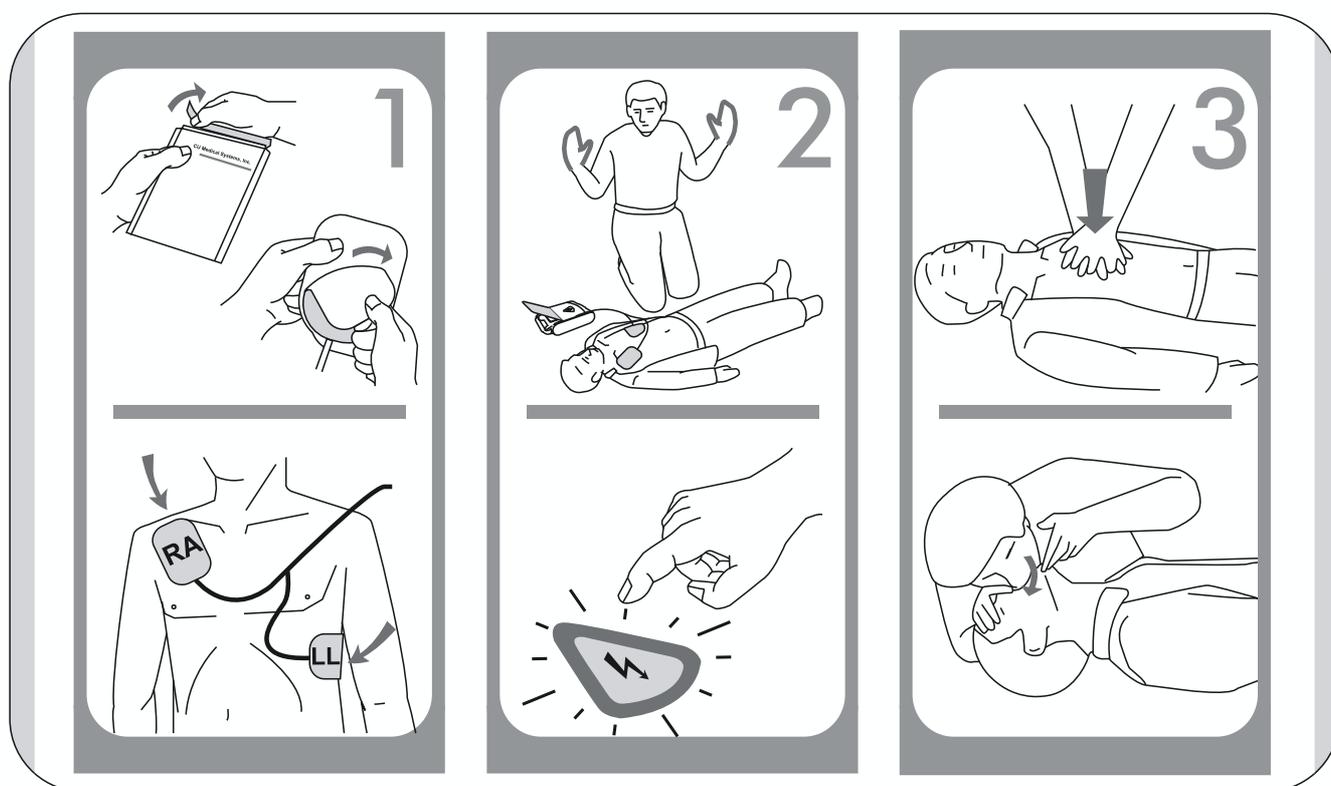
- 1 Handle
- 2 Power ON/OFF button
- 3 State LED
- 4 i-button
- 5 Speaker
- 6 Battery Pack
- 7 Cover
- 8 IrDA (Communication) Port
- 9 Quick Reference Guide
- 10 Graphical Rescue Guide
- 11 Pads Connector Port
- 12 Shock Button

# i-PAD Operator's Manual

Edition 1

## Rescue Steps

1. Connect the defibrillator pads to the i-PAD and then place on patient.
2. Stand clear and press the SHOCK button if instructed.
3. Administer CPR



Quick Reference Guide

# i-PAD Operator's Manual

Edition 1

## Notice

### i-PAD Operator's Manual

CU Medical Systems, Inc. reserves the right to make changes on the device specifications contained in this manual at any time without prior notice or obligation to customers.

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#### **Product and Order Inquiries:**

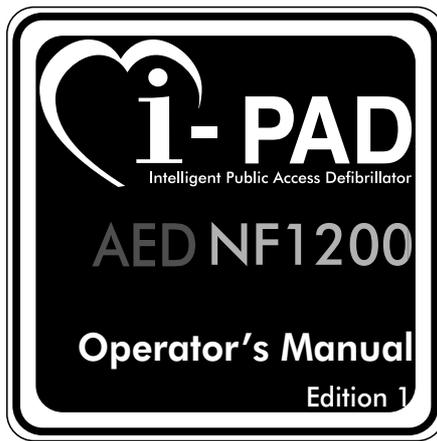
##### **Overseas Sales Team**

CU Medical Systems, Inc.  
#534, Dusan-Venturedigm B/D, 126-1, Pyeongchon-Dong,  
Dongan-Gu, Anyang-City, Gyeonggi-Do,  
Republic of Korea  
Tel : +82 31 478 5725 / Fax: +82 31 478 5729  
E-mail addresses : sales@cu911.com

#### **Service Request and Technical Support**

##### **Customer Service Team**

CU Medical Systems, Inc.  
Medical Industry Complex Bldg. No2. 1720-26 Taejang-Dong,  
Wonju-City, Gangwon-Do, 220-120,  
Republic of Korea  
Tel : +82 33 747 7657 / Fax: +82 33 747 7659  
E-mail addresses : service@cu911.com



**CU Medical Systems, Inc.**

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# Manual Conventions

This Operator's Manual uses the following conventions:

## WARNING

---

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

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## CAUTION

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

---

## NOTICE

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

---

# General

Thank you for choosing the i-PAD. The i-PAD is designed to meet your defibrillation needs, especially in the Public Access Defibrillation (PAD) setting.

---

** WARNING**

Please read this Operator's Manual carefully and thoroughly before attempting any use of the i-PAD.

High voltage and high current electrical energy is involved during defibrillation, be sure to fully understand all the instructions in this Operator's Manual before using this device.

---

In using this device:

- Follow all the operational instructions contained in this manual.
- The manufacturer shall not be liable for damages due to the improper operation of the device.
- Only authorized personnel may service this device. There are no user-serviceable parts in this device.
- If you intend to operate this device in conjunction with devices that are not mentioned in this manual, please consult with the manufacturer.
- When this device is not operating properly, please bring this to an authorized service center for immediate repair.

# 1. Introduction

## Product Description

The i-PAD is a semi-automated external defibrillator designed for minimally trained individuals. It provides simple and direct voice prompts and indications for a straightforward rescue operation. It is lightweight and battery powered for maximum portability.

The i-PAD is designed to treat Ventricular Fibrillation (VF) and Fast Ventricular Tachycardia. These two are the most common causes of sudden cardiac arrest (SCA). In SCA, the heart of the victim suddenly stops pumping. This condition occurs suddenly to any age group without any warning. The only effective treatment for this is the application of a defibrillating shock.

## Indications for Use

Use the i-PAD to treat a person that you think is suffering from sudden cardiac arrest (SCA). The following are symptoms of SCA:

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

## Required User Training

You must undergo training in the use of the i-PAD. You must also have training in cardiopulmonary resuscitation or other physician-authorized emergency response program.

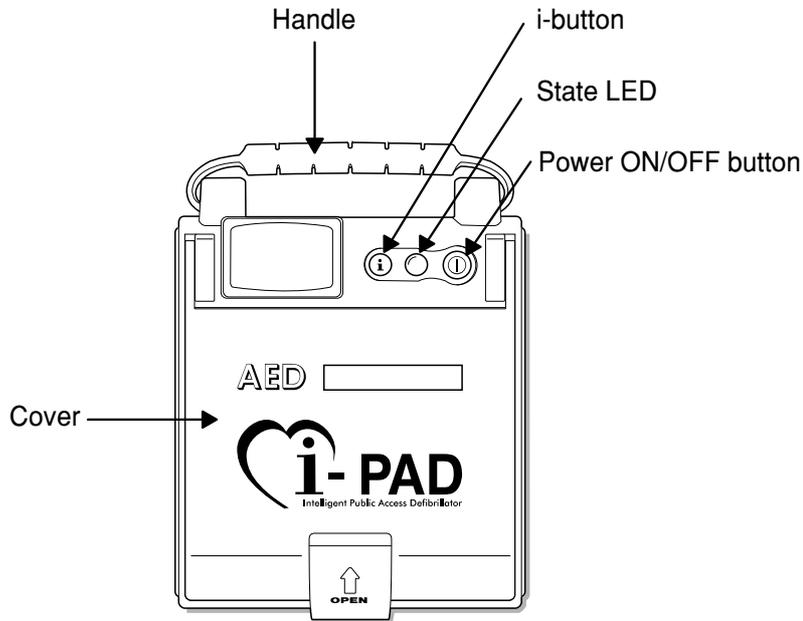
### NOTICE

The i-PAD may be used on children between 1 and 8 years old.

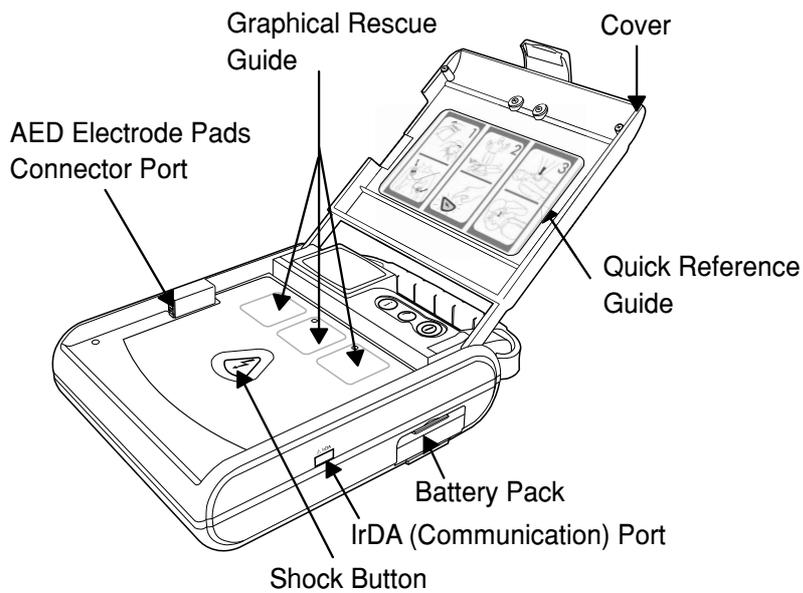
- If the patient appears to be from about 1 year of age to about 8 years of age, use the reduced- energy defibrillator pads.
- For children older than 8 years old, the American Heart Association (AHA) recommends using the adult Chain of Survival and resuscitation sequence (2005 AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care.).

**M E M O**

## 2. Device Orientation



Top view of the i-PAD NF1200 with its cover closed



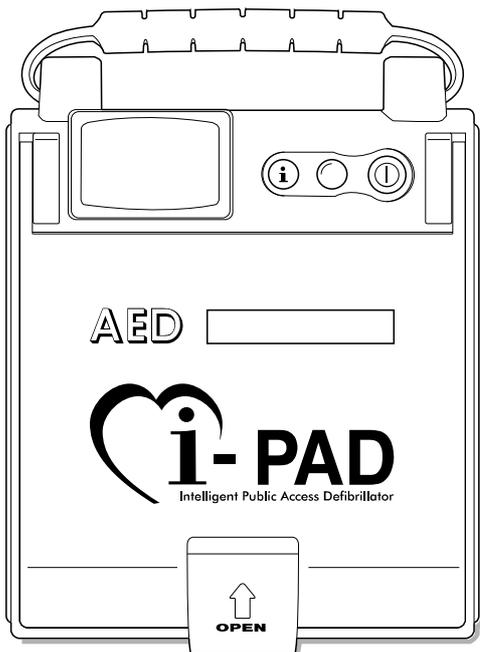
Perspective view of the i-PAD NF1200 with its cover open

|  |   |
|--|---|
| <b>Power On/Off Button</b>               | Press this button to turn the i-PAD ON or OFF.  |
| <b>i-Button</b>                          | Press this button to: <ul style="list-style-type: none"><li>• Get information regarding the i-PAD's last usage (usage time and number of shocks delivered).</li><li>• Get information regarding errors that were detected during self-tests.</li><li>• Toggle between compression-to-breathing ratios during CPR (30:2 and 15:2)</li></ul>  |
| <b>State LED</b>                         | Indicates the status of the i-PAD <ul style="list-style-type: none"><li>• <b>blinking green:</b> the i-PAD is in standby mode and ready for a rescue operation</li><li>• <b>solid green:</b> the i-PAD is in rescue mode.</li><li>• <b>blinking red:</b> the i-PAD detected a system error or low battery level during a self-test.</li><li>• <b>solid blue:</b> the i-PAD is conducting a self-test.</li><li>• <b>solid white:</b> the i-PAD is in administration mode. It announces last use information and it senses and waits for a possible data transfer to a personal computer.</li></ul> |
| <b>Handle</b>                            | An easy-grip carrying handle for increased portability of the i-PAD.  |
| <b>Cover</b>                             | Covers the front panel of the i-PAD and retains the defibrillator electrode pads package.   |
| <b>SHOCK button</b>                      | Press this button when the i-PAD prompts you to "Press the flashing orange button now".   |
| <b>AED electrode pads connector port</b> | Pressing this button delivers a defibrillation shock to the patient. Plug the connector of the AED electrode pads into this port.   |
| <b>Graphical Rescue Guide</b>            | Guides you by indicating the current step in the rescue process.  |
| <b>Quick Reference Guide</b>             | A printed card that summarizes the steps of a rescue process using the i-PAD.   |
| <b>Battery Pack</b>                      | Provides power to the i-PAD.<br>Initiates a self-test upon insertion  |
| <b>IrDA Communication Port</b>           | Port for sending and receiving data to and from a personal computer.  |

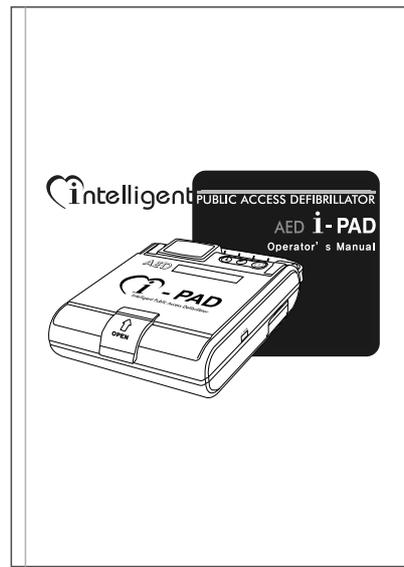
# 3. Setting up the i-PAD

## Package Contents

The i-PAD NF1200 packaging box contains the following items.



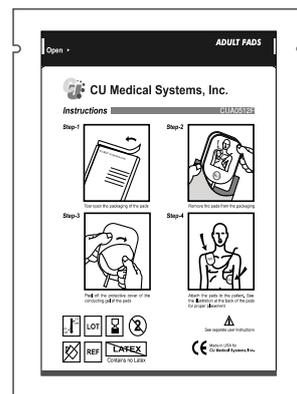
i-PAD NF1200  
Semi-automated External Defibrillator



Operator's Manual



Disposable,  
non-rechargeable Battery Pack

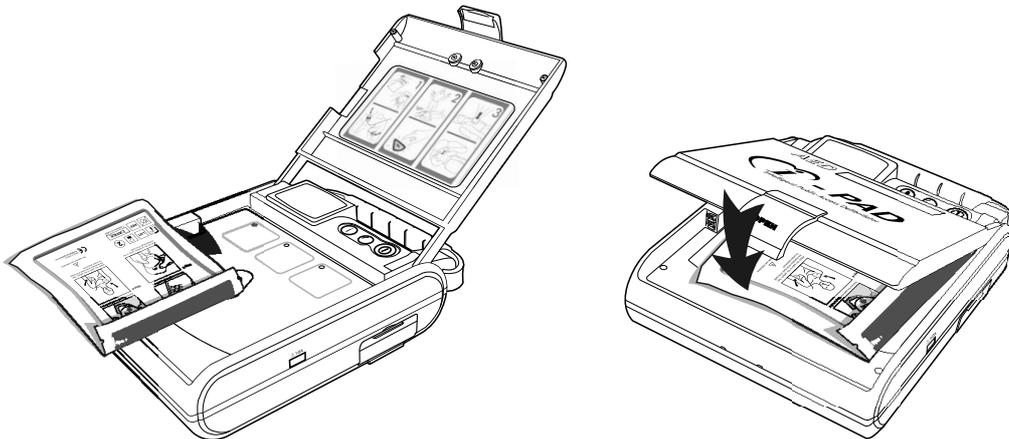


Disposable  
Adult Defibrillator Pads

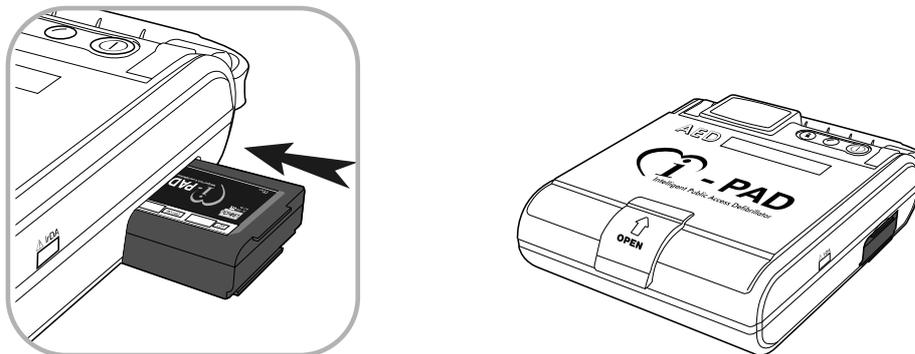
These items are the minimum requirements for the operation of the i-PAD . For optional accessories, see Appendix A.

## Setting up the i-PAD

- ① Upon opening the packaging box, verify that it contains all the items listed in the packing list.
- ② Familiarize yourself with the controls and features of the i-PAD. Study the functions of the buttons, switches, indicators, and connection ports.
- ③ Place the defibrillator pads package as shown in the following figure. Do not open the packaging pouch of the pads until you are about to use them.



- ④ Install the battery pack.



After battery insertion, the i-PAD runs an automatic self-test that verifies its readiness for rescue operations. Passing the battery insertion test is indicated by the State LED blinking in green.

## 3. Setting up the i-PAD

- ⑤ Place the i-PAD inside the carrying case if you have purchased this optional accessory.
- ⑥ Store the i-PAD in accordance with your emergency response protocol. The following must be taken into consideration when the storing the i-PAD.
  - The conditions in the area must not exceed the environmental limits of the i-PAD. See the General Operating Guidelines in Chapter 6.
  - It must be convenient to check the indicators of the i-PAD to ensure that it is always ready for emergencies.
  - A telephone must be located close to the storage area so that you can easily call emergency medical service.

---

### WARNING

#### **Electromagnetic interference may alter device performance.**

During operation, the i-PAD should be placed away from sources of electromagnetic interference such as motors, generators, X-Ray equipment, radio transmitters, cellular mobile telephones and others, as these might interfere with the signals being acquired and analyzed.

See Appendix E. Electromagnetic Compatibility for details.

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### WARNING

**Using accessories and cables other than the ones specified in this manual may result in increased ELECTROMAGNETIC EMISSIONS or may decrease the ELECTROMAGNETIC IMMUNITY of the i-PAD.**

**Replacement accessories and consumables must be sourced only from CU Medical Systems, Inc. or its authorized representatives.**

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### CAUTION

Do not connect the defibrillator pad assembly to the i-PAD during storage. Do not open the sealed container of the pads until ready for use to prevent the AED electrode pads from drying out.

---

## 4. Using the i-PAD

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



1. EARLY ACCESS - Recognize the emergency and call 9-1-1 (or the equivalent EMS in your area)
2. EARLY CPR - Begin Cardiopulmonary Resuscitation.
3. EARLY DEFIBRILLATION - Use the i-PAD.
4. EARLY ADVANCED CARE - Transfer the patient to the care of highly trained EMS personnel upon their arrival.

### **Link 3: EARLY DEFIBRILLATION** - Use the i-PAD

There are three basic steps in using the i-PAD:

**Step 1 : Attach the pads.**

**Step 2 : Press the SHOCK button if instructed.**

**Step 3 : Perform CPR.**

#### **⚠ WARNING**

Do not use the i-PAD for children below 1 year old.

For children from 1 to 8 years old or for patients weighing less than 25 kg, use the pediatric reduced energy defibrillator pads supplied by CU Medical Systems, Inc.

Do not use the pediatric reduced energy defibrillator pads on adult patients.

---

#### **⚠ WARNING**

Do not place the patient on a wet surface during defibrillation.

---

## 4. Using the i-PAD

### WARNING

Disconnect from the patient any MEDICAL ELECTRICAL EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts when using the i-PAD.

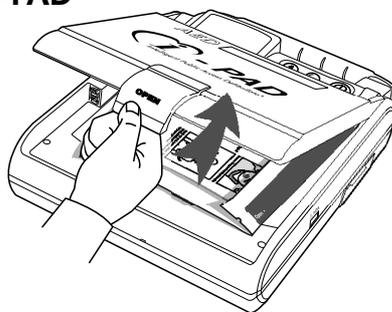
### WARNING

During defibrillation, you and other rescue personnel and bystanders on the scene, must avoid contact:

- between parts of the patient's body such as exposed skin of head or limbs
- with conductive fluids such as gel, blood, or saline solutions
- with metal objects connected with the patient, such as a bed frame or a stretchers which may provide unwanted pathways for the defibrillating current.

### Rescue Preparation

#### 1. Open the cover of the i-PAD



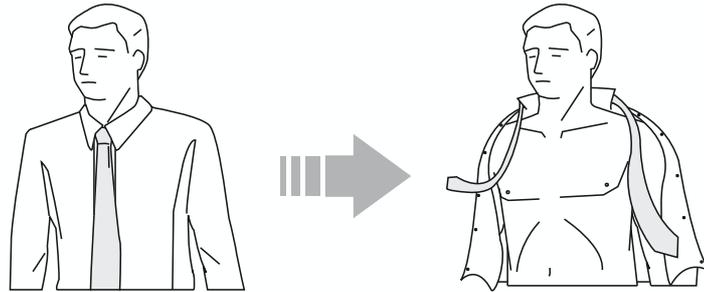
#### 2. Press the ON/OFF button to turn the i-PAD ON

The i-PAD activates the following Indicators and Voice Prompt, in sequence:



- **State LED:** turns solid blue to indicate a power ON self-test
  - **Beeper:** emits a short continuous beep
  - **State LED:** turns solid green to indicate the start of a rescue operation
  - **Voice prompt:** "Attach pads"
- The voice prompt is played until you connect the i-PAD to the patient. If no connection is made in 3 minutes, the i-PAD automatically turns OFF.

### 3. Remove the clothing of the patient



**⚠ CAUTION**

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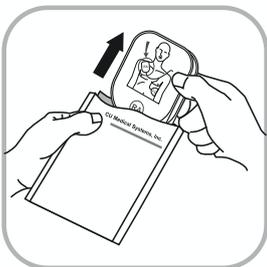
Do not waste time in removing the patient's clothing. If necessary, rip off or cut off the patient's clothing.

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### 4. Tear open the packaging of the pads

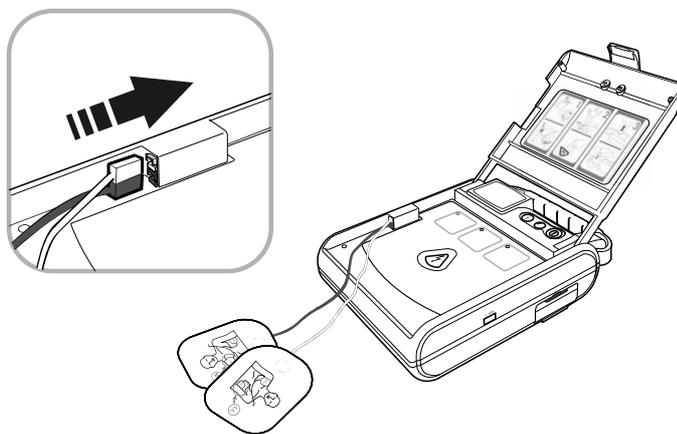


### 5. Take the pads out of its packaging

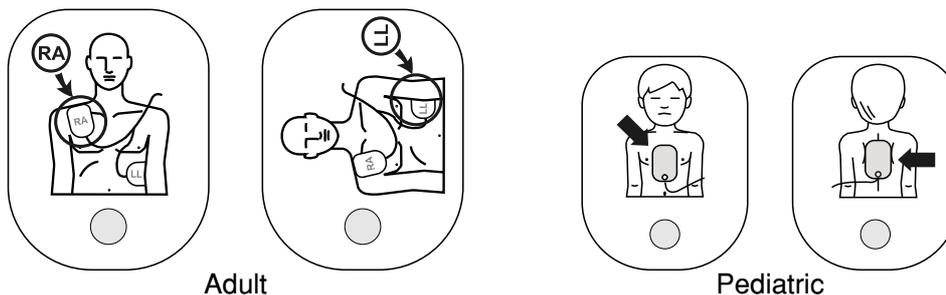


# 4. Using the i-PAD

6. Plug the connector of the pads into the AED electrode pads connector port of the i-PAD



7. Look at the graphics on the back of the pads. The graphics indicate the positions of the pads on the patient's body.



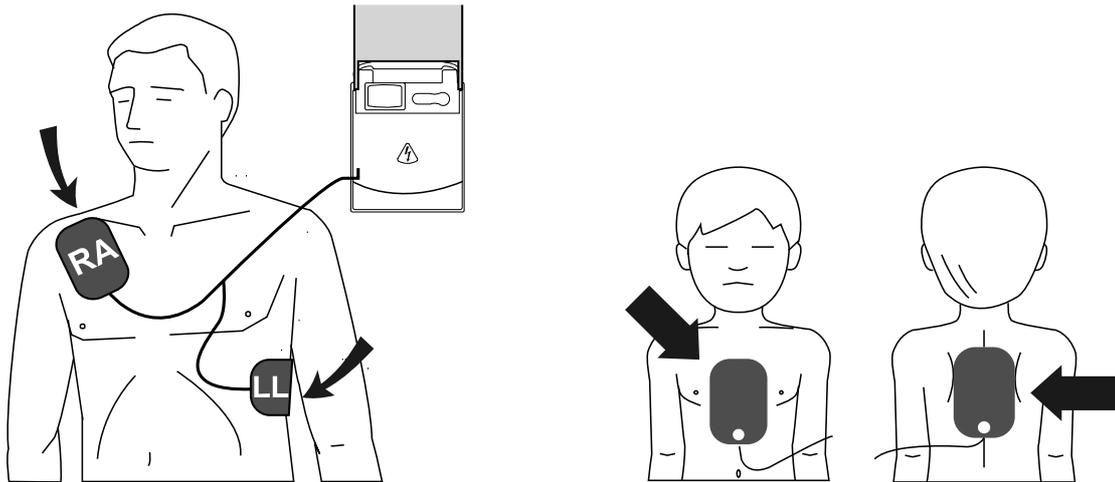
8. Peel off the protective sheets of the pads.



## ⚠ CAUTION

Check to see that the pads are not damaged and the gel has not dried out.

If the pads are damaged or the gel has dried out, use a new set of pads.

**Main Rescue Sequence****STEP 1: Attach the pads**

The i-PAD prompts you with “Do not touch the patient” if it senses a connection to the patient.

**⚠ WARNING**

The patient should be still during ECG signal acquisition and analysis to minimize motion artifacts in the signal.

**STEP 2: Press the SHOCK button if instructed**

The i-PAD begins rhythm analysis as soon as it is connected to the patient.

The i-PAD activates the following Indicators and Voice prompt during rhythm analysis:

- **Voice prompt:** “Analyzing heart rhythm”
- **Graphical Rescue Guide:** lights up the second step of the rescue operation.

After rhythm analysis, the i-PAD decides whether the patient needs a shock or not.

## 4. Using the i-PAD

### If a shock is needed:

#### Indicators and Voice prompts:

- **Beeper:** 1 second continuous beep
- **Voice prompt:** “Shock advised”
- **Beeper:** beeps continuously until the SHOCK button is pressed or until it disarms itself if the SHOCK button is not pressed within 15 seconds.
- **Voice prompt:** “Press the flashing orange button, now. Delivery shock, now”
- **SHOCK button backlight:** flashing orange.

### You must press the SHOCK button to deliver the shock.



- If you press the SHOCK button, the i-PAD delivers a defibrillating shock. It informs you of the shock delivery with the voice prompt: “Shock delivered”
- If you do not press the SHOCK button within 15 seconds, the i-PAD disarms itself and proceeds to CPR Guidance.

### If a shock is not needed:

#### Indicator:

- **Voice prompt:** “No shock advised”

#### NOTICE

While the i-PAD is charging after a shockable rhythm is detected, the ECG of the patient is continuously acquired and analyzed. If the ECG rhythm changes to a non shockable rhythm, the i-PAD disarms itself.

#### WARNING

Do not let anybody touch the patient when you press the SHOCK button. Defibrillation shock can cause operator or bystander injury.

### **STEP 3: Perform CPR**

The i-PAD directs you to do CPR after delivering one shock.

#### **Indicators and Voice Prompts**

- **Graphical Rescue Guide:** lights up the third step of the rescue operation.
- **For other indicators and voice prompts, see CPR Protocol**

The CPR protocol depends on the following settings:

1. Rescue Provider
  - Lay Rescuer
  - Healthcare Provider
2. Compression-Ventilation Ratio
  - 30:2 (30 compressions, 2 breaths)
  - 15:2 (15 compressions, 2 breaths)

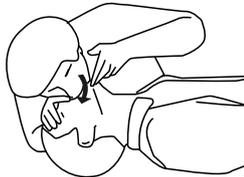
# 4. Using the i-PAD

## CPR Protocol

| Rescue Provider Setting               |   |
|---------------------------------------|---|
| Lay Rescuer Mode                      | <p>Scenario 1: The ECG rhythm of the patient is shockable and a shock has been delivered.</p> <ul style="list-style-type: none"> <li>• <b>Voice Prompt:</b> “Begin CPR, now”</li> <li>• <b>Beeper:</b> 1 second continuous beep</li> <li>• <b>CPR Guidance:</b> played on the speaker, see following pages for complete description</li> </ul>  |
|                                       | <p>Scenario 2: The ECG rhythm of the patient is nonshockable and no shock has been delivered.</p> <ul style="list-style-type: none"> <li>• <b>Voice Prompt:</b><br/>                     “Begin CPR, now” (ECG Rhythm is Asystole)<br/>                     “If needed, begin CPR” (ECG Rhythm is other than Asystole)</li> <li>• <b>Beeper:</b> 1 second continuous beep</li> <li>• <b>CPR Guidance:</b> played on the speaker, see following pages for complete description</li> </ul>  |
| Healthcare Provider Mode              | <p>Scenario 1: The ECG rhythm of the patient is shockable and a shock has been delivered.</p> <ul style="list-style-type: none"> <li>• <b>Voice Prompt:</b> “Begin CPR, now”</li> <li>• <b>Beeper:</b> 1 second continuous beep</li> <li>• <b>CPR Guidance:</b> played on the speaker, see following pages for complete description</li> </ul>  |
|                                       | <p>Scenario 2: The ECG rhythm of the patient is nonshockable and no shock has been delivered.</p> <ul style="list-style-type: none"> <li>• <b>Voice Prompt:</b> “Check pulse”</li> <li>• <b>Beeper:</b> 1 second continuous beep</li> <li>• i-PAD pauses for 10 seconds to allow you to check the pulse</li> <li>• <b>Voice Prompt:</b><br/>                     “Begin CPR, now” (ECG Rhythm is Asystole)<br/>                     “If no pulse, begin CPR” (ECG Rhythm is other than Asystole)</li> <li>• <b>CPR Guidance:</b> played on the speaker, see following pages for complete description</li> </ul> |
| Compression-Ventilation Ratio Setting |   |
| 30:2                                  | Thirty chest compressions for every 2 breaths delivered to the patient.   |
| 15:2                                  | Fifteen chest compressions for every 2 breaths delivered to the patient.  |

## CPR Guidance

The i-PAD gives guidance in the form of prompts and beat rhythm during CPR. Following is a description of the guidance sequence.

| Step | Description  | Your Action(s)   |
|------|--|--|
| 1    | <b>Voice Prompt:</b><br>Push the chest down fast two inches  | <ul style="list-style-type: none"> <li>Place your hands, one on top of another on the area between the nipples of the patient</li> <li>Push the chest down 2 inches</li> </ul>   |
| 2    | <b>Beat sound:</b><br>Rhythm beat sound played at 100 beats per minute. The number of beats depends on the Compression - Ventilation ratio setting<br><br>30:2 setting : 30 beats<br>15:2 setting : 15 beats | <ul style="list-style-type: none"> <li>Push the chest of the patient hard and fast in time with the beat provided by the i-PAD.</li> </ul>    |
| 3    | <b>Voice Prompt:</b><br>Give two breaths   | <ul style="list-style-type: none"> <li>Immediately open the airway using a head tilt-chin lift maneuver.</li> </ul>  |
| 4    | <b>Voice Prompt:</b><br>Breath, breath   | <ul style="list-style-type: none"> <li>Give two breaths</li> <li>Each breath must last for 1 second.</li> <li>Each breath must have enough volume to produce visible chest rise</li> <li>Give the two breaths within 5 seconds</li> </ul>  |
| 5    | <b>Cycles:</b><br>Steps 1 to 4 are repeated for 5 cycles   | <ul style="list-style-type: none"> <li>Do 5 cycles of CPR sequence.</li> </ul>   |

## 4. Using the i-PAD

### CAUTION

- The i-PAD temporarily stops analyzing the ECG of the patient during the duration of the CPR.
  - It automatically resumes ECG analysis after CPR
- 

### WARNING

If it becomes necessary to use another defibrillator on the patient, do not leave the i-PAD connected to the patient. Disconnect the i-PAD from the patient before using any other defibrillator.

---

## 5. After Using the i-PAD

### After Each Use

1. Check the i-PAD for signs of damage and contamination.
  - Run the battery insertion test, see section on maintenance in Chapter 6.
  - Verify that the State LED is blinking in green to signify that the i-PAD is ready for a rescue operation.
  - If there is dirt contamination, see section on how to clean the i-PAD in Chapter 6.
2. Replace the AED electrode pads, see section on maintenance in Chapter 6. The pads are for single use only. Do not reuse the pads.

---

**⚠ CAUTION**

- Use only the AED electrode pads recommended by CU Medical Systems, Inc.
  - Do not open the packaging of the pads during storage. Open the packaging only when you are about to use them during rescue operations.
- 

### Data Storage and Transfer

#### Last Use Data

The i-PAD automatically stores the following data during rescue operations.

- ECG data
- Rescue event data
- setup information of the i-PAD

These data are stored in the internal memory of the i-PAD and may be transferred to a personal computer. The internal memory of the i-PAD is nonvolatile, thus, the stored data stay in memory even when the i-PAD is turned OFF

---

**⚠ CAUTION**

Do not uninstall the battery pack while the i-PAD is acquiring data. If you do so, you will lose the data in that particular rescue operation. If you must uninstall the battery pack, turn OFF the i-PAD properly by pressing the Power ON/OFF button before removing the battery pack.

---

## 5. After Using the i-PAD

### NOTICE

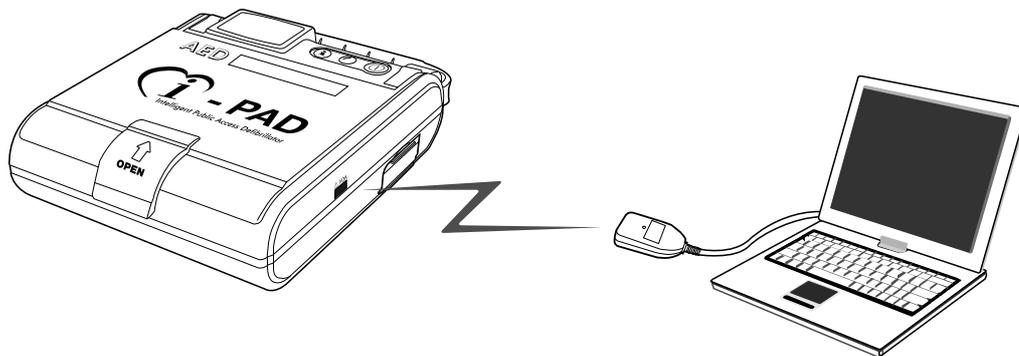
- The i-PAD has a memory capacity of 40 minutes for recording ECG and rescue event data. If the data collected during a rescue operation exceeds the capacity, the data in excess of the capacity is not recorded.
- When used in a rescue operation, the i-PAD overwrites the data it stored in the previous operation. Thus, you must transfer the data to a personal computer after every use to avoid losing rescue operation data.

### Data Transmission

Rescue operation data may be transferred to a personal computer for review, printing, and archiving using CU Expert - the data management software from CU Medical Systems, Inc.

#### To transfer data:

1. Run the CU Expert in the personal computer. Please see the CU Expert Operator's Manual for more details. Set it to receive data.
2. Point the IrDA adapter at the IrDA port of the i-PAD.



3. Press the i-button for at least 1 second while the i-PAD is in stand-by mode (State LED is blinking in green).
4. The State LED turns solid white and the i-PAD prompts you that it is in administration mode.
5. The i-PAD informs you of the last usage information (usage time and the number of shocks delivered)

6. The i-PAD waits for three minutes for communications from the personal computer. If you have set the CU Expert correctly, data transfer begins shortly.
7. The i-PAD automatically turns OFF when the data transmission is finished.

### Device Configuration

The following device configuration data can be set and changed using the CU Expert Data Management Software (ver 3.0 or higher). See the CU Expert Manual for details.

| Configuration Data    | Default   | Possible Settings  |
|-----------------------|---|--|
| Volume Setting        | 10  | 0 to 10  |
| Date and time Setting | Year/Month/Day<br>hour:minute:second<br>set to current date | Year/Month/Day<br>hour:minute:second<br>date and time from 1900 to<br>2099 |
| CPR Mode              | Healthcare Provider Mode                                    | Healthcare Provider Mode<br>Lay Rescuer Mode                               |

# 6. Maintaining the i-PAD

## General Operating Guidelines

The following table shows the General Operating Guidelines of the i-PAD. Be sure that you do not subject the i-PAD to conditions that are beyond the limits specified below.



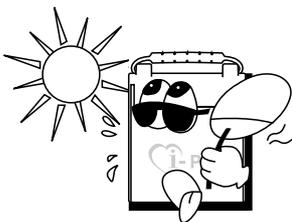
Do not operate or store the device in conditions that are beyond the following specified limits.

### Operating Conditions

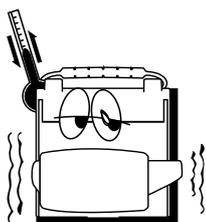
Temperature 32 °F to 104 °F (0 °C to 40 °C)  
Humidity 5 % to 95 % (non-condensing)

### Storage Conditions

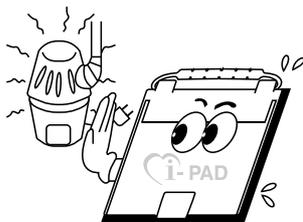
Temperature 32 °F to 104 °F (0 °C to 40 °C)  
Humidity 5 % to 95 % (non-condensing)



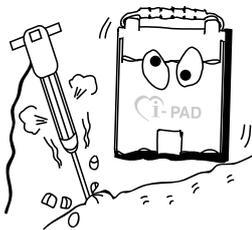
Do not store the device in areas that are directly exposed to sunlight.



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 Category 10 of MIL-STD-810E).



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



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



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

## 6. Maintaining the i-PAD

### Routine Maintenance

#### Device Status Monitoring

The i-PAD conducts automated self-tests while on standby mode. It is on standby mode if the battery pack is inserted and the State LED is blinking in green. The automated self-tests are conducted daily, weekly, and monthly.

If a fault is detected during the automated self-tests, the i-PAD raises an alarm. See section on troubleshooting in Chapter 7.

Periodically check the State LED of the i-PAD to ensure that it is always ready for an emergency.

#### Consumables

There are two important consumables that must be monitored while the i-PAD is stored on standby mode. These are: the battery pack and the AED electrode pads.

#### Battery Pack

- Replace the battery pack if a low battery level condition is indicated by the i-PAD.
- Use only battery packs that are recommended by the manufacturer.
- Make sure that the replacement battery pack is not yet past its expiration date which is indicated by the “Install by: date” marking.
- The battery pack of the i-PAD is disposable and must not be recharged.

#### Battery Pack Replacement

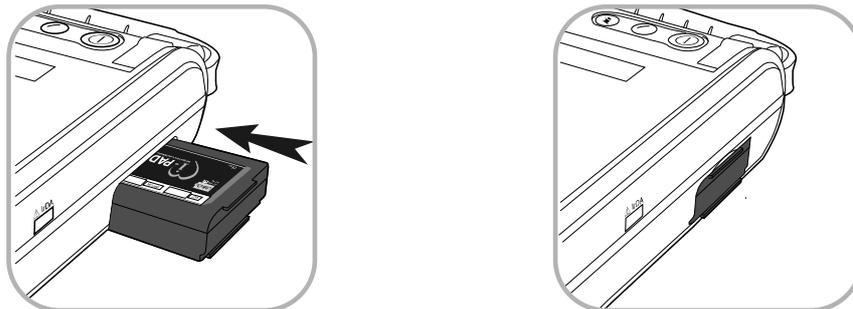
1. Remove the spent battery pack. Disengage its lock by pressing the locking mechanisms towards each other while simultaneously pulling the battery pack out of its compartment. These are shown below.



2. Insert the new battery pack with the label facing up and in the direction indicated by the guiding arrow printed on the label.



3. Push all the way in until you hear the locking mechanism click.



## WARNING

- Do not charge the battery pack
- Do not open the case of the battery pack.
- Do not saw off or break apart the case of the battery pack.
- Do not let the battery pack come into contact with open flames and other hot objects. Do not dispose of in fire
- Do not short-circuit the terminals of the battery pack.
- Do not subject the battery pack to serious physical impact. Do not hit it with a hammer.
- In case of leakage or strange smell, keep away from fire to prevent ignition of any leaked electrolyte.

# 6. Maintaining the i-PAD

## WARNING

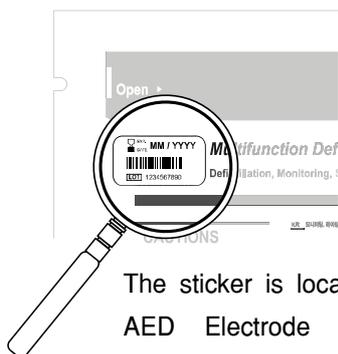
- Keep the battery pack out of children’s reach.
- If the battery pack, leaks and the leaked liquid gets in the eyes, wash them with clean water and consult a physician immediately.
- Do not leave the battery pack in direct sunlight or in high temperature areas.
- Do not have the battery pack in contact with water.
- Keep the battery pack away from direct sunlight, high temperature, and humidity.
- Follow local regulations when disposing of the battery pack.
- Do not subject the battery pack to conditions beyond the safe environmental conditions for the i-PAD.

### AED Electrode Pads

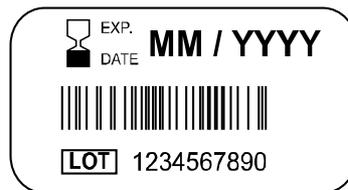
- Regularly check the expiration date of the AED electrode pads. Make sure that the set of AED electrode pads stored with the i-PAD is not expired.
- Check the integrity of the packaging of the AED electrode pads.
- Use only AED electrode pads that are recommended by the manufacturer for use with the i-PAD.

### AED Electrode Pads Replacement

1. Verify that the replacement pads are not expired. The expiration date is indicated using a sticker as shown below.



The sticker is located beside the AED Electrode Pads labeling “Multifunction Defibrillation ADULT PADS”



Details of the expiry date sticker

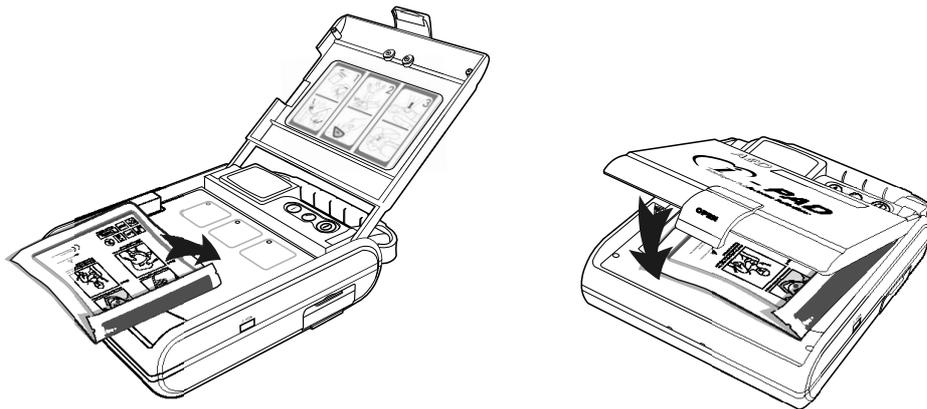
Expiry Date

**YYYY-MM**

**YYYY** - Year

**MM** - Month

2. Place the AED electrode pads on top of the front panel of the i-PAD. Close the cover down on the pads.



## Cleaning the i-PAD

Clean the i-PAD after each use with a soft cloth which has been moistened with any one of these approved solutions:

- Dilute soap and water
- Dilute Chlorine bleach and water mixture (30 ml bleach/liter of water)
- Dilute ammonia-based cleaners
- Dilute hydrogen peroxide

### CAUTION

- Do not immerse any part of the i-PAD in fluids.
- If the i-PAD has been submerged in water, call CU Medical Systems, Inc. or an authorized representative for service assistance
- Do not allow fluid to enter the case of the device.
- Do not spill liquids on the case of the device.
- Do not use strong, acetone-based cleaners in cleaning the device.
- Do not use abrasive materials in cleaning the unit, especially on the infrared filter of the IrDA port.
- Do not sterilize the i-PAD.

# 7. Troubleshooting

## Automated Tests

The i-PAD conducts the following tests to verify its readiness for emergency rescue operations:

| Test                                      | Test Details   |
|---|--|
| <p><b>Battery insertion test</b></p>      | <p>Runs when the battery is inserted.</p> <p>Conduct this test:</p> <ul style="list-style-type: none"> <li>• When the i-PAD is first placed into service.</li> <li>• After the i-PAD is used in an emergency rescue operation.</li> <li>• When the battery pack is replaced.</li> <li>• When you suspect that your i-PAD is damaged.</li> </ul> <p>Do not run this test when you are about to conduct a rescue operation because this test takes time.</p> <p>If a new battery is inserted at the start of a rescue operation, press the Power ON/OFF button to bypass the test. Wait for the i-PAD to turn OFF. Press the ON/OFF button again to turn the i-PAD ON.</p> <p>The i-PAD tests the SHOCK button and the i-button during this test; you must press the buttons one by one when the i-PAD prompts you to do so.</p> <p>The following prompts are given:<br/>                     “Press the flashing orange button”<br/>                     “Press the flashing blue i-button”</p> <p>If no fault is detected, the i-PAD goes into standby mode with the State LED blinking in green.</p> <p>If a fault is detected, the i-PAD gives the prompt “Press the flashing red i-button”. This is aside from activating the State LED and the beeper.</p> |
| <p><b>Power On Test</b></p>               | <p>Runs when the i-PAD is turned ON.</p>   |
| <p><b>Run-time test</b></p>               | <p>Runs when the i-PAD is used in a rescue operation. Monitors the performance of critical components.</p>   |
| <p><b>Daily, Weekly, Monthly test</b></p> | <p>Runs daily, weekly, and monthly to check the functionality of important subsystems.</p>   |

The State LED is solid blue when the i-PAD conducts a test.

If no fault is detected, the i-PAD activates the State LED to blink in green.

If a fault is detected, the i-PAD activates the State LED to blink in red. It also activates the beeper to beep every minute. At this state, the i-PAD is inoperable and can not be used in rescue operations. If the fault is detected during a battery insertion test, the i-PAD prompts you to “Press the flashing red i-button”

To determine the cause of an error, press the i-Button when the State LED is blinking in red. The i-PAD informs you of the cause of the error through voice prompts. See the section on Troubleshooting in Chapter 7 for more details.

# 7. Troubleshooting

## Device Status

The following indicators tell you of the current status of the i-PAD:

- State LED
- Beeper
- Graphical Rescue Guide
- i-Button
- SHOCK button

| Indicator/Indication  | Meaning   |
|---|---|
| <b>State LED:</b> blinking green  | The i-PAD is in normal condition and ready for a rescue operation.  |
| <b>State LED:</b> solid green   | The i-PAD is currently used in a rescue operation and it is operating normally.   |
| <b>State LED:</b> blinking red<br><b>Beeper:</b> bursts of 3 beeps; bursts spaced 1 minute apart                        | The i-PAD has detected a fault during a self-test.  |
| <b>State LED:</b> solid red<br><b>i-button:</b> flashing in red<br><b>Voice prompt:</b> "Press the flashing red button. | <ul style="list-style-type: none"> <li>• The i-PAD has detected a fault during Battery Insertion Test.</li> <li>• The i-PAD has detected a fault during operation.</li> </ul> |
| <b>State LED:</b> solid blue  | The i-PAD is currently performing a self-test.  |
| <b>State LED:</b> solid white   | The i-PAD is currently in administration mode.  |
| <b>Graphical Rescue Guide:</b><br><b>1<sup>st</sup></b>   | Connect the pads to the patient and the i-PAD.  |
| <b>Graphical Rescue Guide:</b><br><b>2<sup>nd</sup></b>   | The i-PAD is analyzing the ECG of the patient.  |
| <b>Graphical Rescue Guide:</b><br><b>3<sup>rd</sup></b>   | Perform CPR. This indicator flashes while the CPR is ongoing.   |
| <b>i-button: blinking red</b>   | An error has occurred. Press the i-button for more information.   |
| <b>SHOCK button: flashing orange</b>  | Press the SHOCK button in order to deliver the shock to the patient.  |

## Troubleshooting the i-PAD

The i-PAD makes troubleshooting easy by providing indicators whenever

- a fault in any of its subsystems is detected
- or conditions that prevent the successful administration of a rescue operation occur.

Study carefully the following guides. Apply the recommendations when appropriate.

## Troubleshooting During Emergencies

| Indication(s)  | Possible Cause(s)   | Remedial Action(s)  |
|--|---|---|
| <b>Device Mode;</b><br><b>Standby Mode</b><br><b>State LED:</b> Flashing Red                                 | <ul style="list-style-type: none"> <li>· Low battery level.</li> </ul>  | <ul style="list-style-type: none"> <li>· Replace the battery pack of the i-PAD with a new battery pack</li> </ul>   |
|  | <ul style="list-style-type: none"> <li>· An error in the i-PAD is detected.</li> </ul>  | <ul style="list-style-type: none"> <li>· Replace the i-PAD with a functioning defibrillator. Bring the malfunctioning device to a service center for repair.</li> </ul>   |
| <b>Device Mode;</b><br><b>Operation Mode</b><br><b>State LED:</b> Flashing Red                               | <ul style="list-style-type: none"> <li>· Low battery level.</li> </ul>  | <ul style="list-style-type: none"> <li>· The i-PAD shuts down automatically after 10 minutes or after delivering 10 shocks.</li> <li>· Replace the battery pack of the i-PAD with a new battery pack</li> <li>· If no new battery pack or no other defibrillator is available, check the patient and begin CPR if needed until the EMS team arrives.</li> </ul> |
| <b>Device Mode;</b><br><b>Operation Mode</b><br><b>State LED:</b> Solid Red<br><b>i-button:</b> Flashing red | <ul style="list-style-type: none"> <li>· An error in the i-PAD is detected.</li> <li>· The i-PAD is unusable for a rescue operation in this condition.</li> </ul> | <ul style="list-style-type: none"> <li>· Perform CPR on the patient.</li> <li>· Use another defibrillator</li> <li>· If there is no other defibrillator available, continue performing CPR until the EMS team arrives.</li> </ul>   |

-> continued

# 7. Troubleshooting

## Troubleshooting During Emergencies

-> continued

| Indication(s)   | Possible Cause(s)   | Remedial Action(s)   |
|---|---|--|
| <b>Voice Prompt:</b><br>"No shock delivered."<br>"Press the pads firmly to the bare skin" | <ul style="list-style-type: none"> <li>The pads are not attached firmly to the skin of the patient.</li> </ul>                            | <ul style="list-style-type: none"> <li>Press the pads firmly on the patient's skin.</li> <li>If needed, shave hair or wipe excess moisture off the skin of the patient and then reattach the pads.</li> <li>Get another set of pads immediately if the pads you are using do not stick to the bare and dry skin of the patient.</li> </ul> |
| <b>Voice Prompt:</b><br>"The SHOCK button not pressed."                                   | <ul style="list-style-type: none"> <li>You did not press the SHOCK button when the prompt to press the shock button was given.</li> </ul> | <ul style="list-style-type: none"> <li>Press the SHOCK button if you intend to deliver a SHOCK</li> </ul>  |
|   | <ul style="list-style-type: none"> <li>You pressed the SHOCK button but it is defective.</li> </ul>                                       | <ul style="list-style-type: none"> <li>Replace the defibrillator with a functional one.</li> </ul>   |

## Troubleshooting Outside of Emergencies

| Indication(s)   | Possible Cause(s)  | Remedial Action(s)   |
|---|--|--|
| <p><b>Device Mode;</b><br/> <b>Standby Mode</b><br/> <b>State LED:</b> Flashing Red</p>   | <ul style="list-style-type: none"> <li>• Low battery level.</li> <li>• An error in the i-PAD is detected.</li> </ul> | <ul style="list-style-type: none"> <li>• Press the Power ON/OFF button</li> <li>• After turning ON, the i-PAD prompts you to:<br/> “Press the flashing red i-button.”</li> <li>• After pressing the i-button, the i-PAD delivers any of the following prompts:<br/> If the cause of the error is low battery level, the prompt is:<br/> “Low Battery Level, Replace the battery with a new one.”<br/> If the cause of the error is a fault in one of its subsystems, the prompt is:<br/> “System Failure. Error code is XXXX”</li> <li>• If the cause of the error is low battery level, replace the battery pack. Use only battery packs supplied by CU Medical Systems, Inc.</li> <li>• If the cause of the error is a system failure, bring the i-PAD to an authorized service center.</li> </ul> |
| <p><b>Device Mode;</b><br/> <b>Operation Mode</b><br/> <b>State LED:</b> Flashing Red</p> | <ul style="list-style-type: none"> <li>• Low battery level.</li> </ul>   | <ul style="list-style-type: none"> <li>• The i-PAD shuts down automatically after 10 minutes or after delivering 10 shocks.</li> <li>• Replace the battery pack of the i-PAD with a new battery pack</li> <li>• Use only battery packs supplied by CU Medical Systems, Inc.</li> </ul>   |

-> continued

# 7. Troubleshooting

## Troubleshooting Outside of Emergencies

-> continued

| Indication(s)  | Possible Cause(s)  | Remedial Action(s)  |
|--|--|---|
| <b>Device Mode;</b><br><b>Operation Mode</b><br><b>State LED:</b> Solid Red<br><b>i-button:</b> Flashing red | <ul style="list-style-type: none"><li>• An error in the i-PAD is detected.</li><li>• The i-PAD is unusable for a rescue operation in this condition.</li></ul> | <ul style="list-style-type: none"><li>• The i-PAD prompts you to:<br/>“Press the flashing red i-button”</li><li>• After you press the flashing red i-button, the i-PAD delivers the following prompt:<br/>“System Failure. Error code is XXXX”</li><li>• Bring the i-PAD to an authorized service center.</li></ul> |

**M E M O**

## 8. Servicing the i-PAD

### Warranty

- This 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 product that proves to be defective, provided you return the product, shipping prepaid, to CU Medical Systems, Inc. or its authorized representative.
- This warranty does not apply if the product has been damaged by accident or misuse or as the result of service or modification by other than CU Medical Systems, Inc. or its authorized representatives. IN NO EVENT SHALL CU MEDICAL SYSTEMS BE LIABLE FOR CONSEQUENTIAL DAMAGES.
- Only products 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

- Servicing by unauthorized personnel renders this warranty null and void.
- If the factory seal is broken without proper authorization from CU Medical Systems, Inc., this warranty becomes null and void.

## Service

- The i-PAD must be serviced only by authorized personnel. Unauthorized servicing during the warranty period renders the warranty null and void.
- The i-PAD 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 is not operating properly, immediately bring it for servicing to an authorized service center.
- Please fill up the following table with the necessary information when requesting for service.

|                                  |             |   |               |
|----------------------------------|-------------|---|---------------|
| Product classification           |             | Semi - Automated External Defibrillator |               |
| Product Name                     |             | <b>i-PAD</b>                            | Model Name    |
|                                  |             |   | <b>NF1200</b> |
| Serial Number                    |             | Date of Purchase                        |               |
| Sales Representative             |             |   |               |
| User Information                 | Name        |   |               |
|                                  | Address     |   |               |
|                                  | Contact no. |   |               |
| Brief description of the problem |             |   |               |

## How to Contact Us

### CU Medical Systems, Inc.

Medical Instrument Industry Park 1720-26, Taejang-dong, Wonju-si, Gangwon-do, Korea

TEL : +82 33 747 7657 / FAX : +82 33 747 7659 / Homepage : [www.cu911.com](http://www.cu911.com)

Sales inquiries : [sales@cu911.com](mailto:sales@cu911.com)

Technical inquiries : [techinfo@cu911.com](mailto:techinfo@cu911.com)

Service : [service@cu911.com](mailto:service@cu911.com)

# A. Accessories

## A.1 Standard Accessories

- Adult defibrillator electrode pads [CUA0512F]
- Battery pack [CUSA0601F]
- Operator's Manual

## A.2 Optional Accessories

- Pediatric defibrillator electrode pads
- Wall mounted cabinet
- Carrying case
- Rechargeable battery pack
- Battery charger
- IrDA Adapter
- PC S/W (CU Expert Version 3.00)
- i-PAD Trainer

## A.3 Service Center

### Customer Service

|          |   |  |
|----------|---|--|
| Homepage | : | www.cu911.com  |
| Address  | : | CU Medical Systems, Inc.<br>Medical Instrument Industry Park 1720-26, Taejang-dong, Wonju-si,<br>Gangwon-do, Korea |
| Tel      | : | +82 33 747 7657  |
| Fax      | : | +82 33 747 7659  |

### Sales Inquiries

|        |   |                 |
|--------|---|-----------------|
| E-mail | : | sales@cu911.com |
| Tel    | : | +82 33 747 7657 |

### Service Request

|        |   |                   |
|--------|---|-------------------|
| E-mail | : | service@cu911.com |
| Tel    | : | +82 33 747 7657   |

## B. Equipment Symbols

### B.1 i-PAD NF1200 Defibrillator

| Symbol  | Description   |
|---|---|
|    | The cover of the i-PAD opens if the yellow lid is lifted. |
|    | Power ON/OFF button                                       |
|    | i-button  |
|  | State LED   |
|  | SHOCK button  |
|  | BF type, defibrillation-proof equipment                   |
|  | Attention: Refer to accompanying documents.               |
|  | CE Mark   |
|  | Serial Number   |
|  | Date of manufacture                                       |

## B. Equipment Symbols

### B.2 i-PAD Packaging

| Symbol  | Description                       |
|---|-----------------------------------|
|    | Stack up to 6 cartons high only   |
|    | This side up                      |
|    | Keep dry                          |
|  | Fragile; breakable                |
|  | Use no hooks                      |
|  | Temperature limits: -20°C to 60°C |
|  | CE Mark                           |
|  | Serial Number                     |

### B.3 Symbols on Accessories

#### B.3.1 Battery [CUSA0601F]

| Symbol   | Description  |
|--|--|
|   | Lithium Manganese Dioxide battery  |
|   | Lot Number   |
|   | Option Number  |
| <br> | Expiration date  |
|   | Do not mutilate the battery or open the battery case   |
|   | Do not expose the battery to high heat or open flames.<br>Do not incinerate the battery.           |
|   | Do not crush the battery   |
|   | Do not dispose of the battery in municipal waste.<br>Follow local regulations on battery disposal. |
|   | Attention: Refer to accompanying documents   |
|   | CE Mark  |

## B. Equipment Symbols

### B.3.2 Pads [CUA0512F]

| Symbol  | Description                                |
|---|--|
|    | Temperature limits: 0°C to 43°C            |
|    | Lot Number                                 |
|    | Expiration date                            |
|  | Order reference number                     |
|  | Single use only; do not reuse              |
|  | Do not fold or bend.                       |
|  | Contains no latex                          |
|  | Expiration Date and Lot number sticker     |
|  | Attention: Refer to accompanying documents |
|  | CE Mark                                    |

## C. Glossary

|   |  |
|---|--|
| <b>1 Cycle</b>  | CPR consisting of 30 chest compressions and two breaths (or 15 compressions and two breaths , if set by the user).           |
| <b>CPR Episode</b>  | CPR consisting of 5 cycles.  |
| <b>American Heart Association (AHA) 2005 Guidelines for CPR and ECC</b> | Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiac Care published by the American Heart Association in 2005. |
| <b>Sudden Cardiac Arrest victim</b>                                     | A patient with the following symptoms:<br>No Response, No movement, No pulse, No normal breathing                            |
| <b>Company</b>  | CU Medical Systems, Inc.   |
| <b>Device Mode: Standby mode</b>  | Device Power is OFF but the battery pack is inserted.  |
| <b>Device Mode: Operation mode</b>                                      | Device Power is ON.  |
| <b>Battery</b>  | The battery pack that is used to provide power to the i-PAD.   |
| <b>State LED</b>  | Indicates the state of the device.   |
| <b>Adult patient</b>  | Patients older than 8 years or weighing greater than 25 kg.  |
| <b>Pediatric patient</b>  | Patients 8 years old or younger or weighing 25 kg or less.   |
| <b>Shock Button</b>   | The button that you must press to deliver the shock.   |
| <b>Graphical Rescue Guide</b>   | Graphics that guide you through the rescue protocol. Its indicator LED lights up to indicate the current rescue step.        |
| <b>CPR Mode</b>   | The i-PAD temporarily stops ECG analysis to let you perform CPR.   |
| <b>Error Mode</b>   | The i-PAD has detected an error in its circuitry.  |
| <b>Quick Reference Guide</b>  | Printed card that outlines the steps that you have to take during a rescue operation.  |

## C. Glossary

|  |   |
|--|---|
| <b>Self-Test</b>                             | Automated self diagnostic tests that verify the proper operation of the subsystems of the i-PAD so that it is always ready for a rescue operation. The i-PAD indicates the error when you press the i-button after an error has occurred. |
| <b>Internal discharge (disarm)</b>           | The i-PAD dumps the charge in its defibrillating capacitor into an internal load if the SHOCK button is not pressed within 15 seconds after the prompt to press the SHOCK button is given.  |
| <b>IrDA Port</b>                             | Port that is used to connect the i-PAD to a personal computer for data transfer.  |
| <b>Shock</b>                                 | The shock that is delivered to defibrillate the heart of a patient. Charging Time: less than 12 seconds.  |
| <b>Solid</b>                                 | The State LED is always ON.   |
| <b>Blinking</b>                              | The State LED is turned ON and OFF regularly.   |
| <b>i-button</b>                              | Last usage data or error codes or CPR guide prompts are played on the speaker when this button is pressed.  |
| <b>Product</b>                               | The i-PAD defibrillator of CU Medical Systems, Inc. with model name i-PAD.  |
| <b>Semi Automated External Defibrillator</b> | A device that delivers a defibrillating shock after analyzing and recognizing a shockable rhythm. You must agree with the shock delivery by pressing the SHOCK button before a shock can be delivered.                                    |
| <b>Carrying Case</b>                         | A case that is used to store the i-PAD and all of the accessories needed for a rescue operation.  |
| <b>Communications port</b>                   | The port that is used to connect the i-PAD to a personal computer for data transfer.  |
| <b>AED electrode pads</b>                    | Electrode pads that are used in the acquisition of ECG and the delivery of defibrillating shock to a patient.   |
| <b>Pads Connector</b>                        | The connector in the defibrillator pads assembly that is used to connect the pads to the i-PAD.   |

|                                      |  |
|--------------------------------------|--|
| <b>Pads Packaging</b>                | The pouch that is used to contain the pads. It prevents the pads from drying out. Instructions for the usage of the pads are printed on this packaging.                                      |
| <b>Electrode pads conducting gel</b> | The coating on the electrodes that facilitates the conduction of electrical signals and energy between the patient's skin and the electrodes.  |
| <b>LL</b>                            | Left leg electrode   |
| <b>RA</b>                            | Right arm electrode  |
| <b>PC S/W CU Expert (CU-EX1)</b>     | The data management software that is used for the transfer of data from the i-PAD to a personal computer. Also used for reviewing, printing, and archiving of data in the personal computer. |
| <b>Pads Connector Socket</b>         | The port in the i-PAD that mates with the pads connector.  |
| <b>EMS</b>                           | Emergency Medical Service  |

# D. i-PAD NF1200 Specifications

**Model: NF1200**

## Physical

|                 |  |
|-----------------|--|
| <b>Category</b> | Nominal Specifications   |
| <b>Size</b>     | 3.19 in high X 8.66 in wide X 11.06 in deep<br>(81 mm high X 220 mm wide X 281 mm deep)<br>- without handle and battery pack |
| <b>Weight</b>   | Approximately 4.84 lbs (2.2 kg) with battery pack installed  |

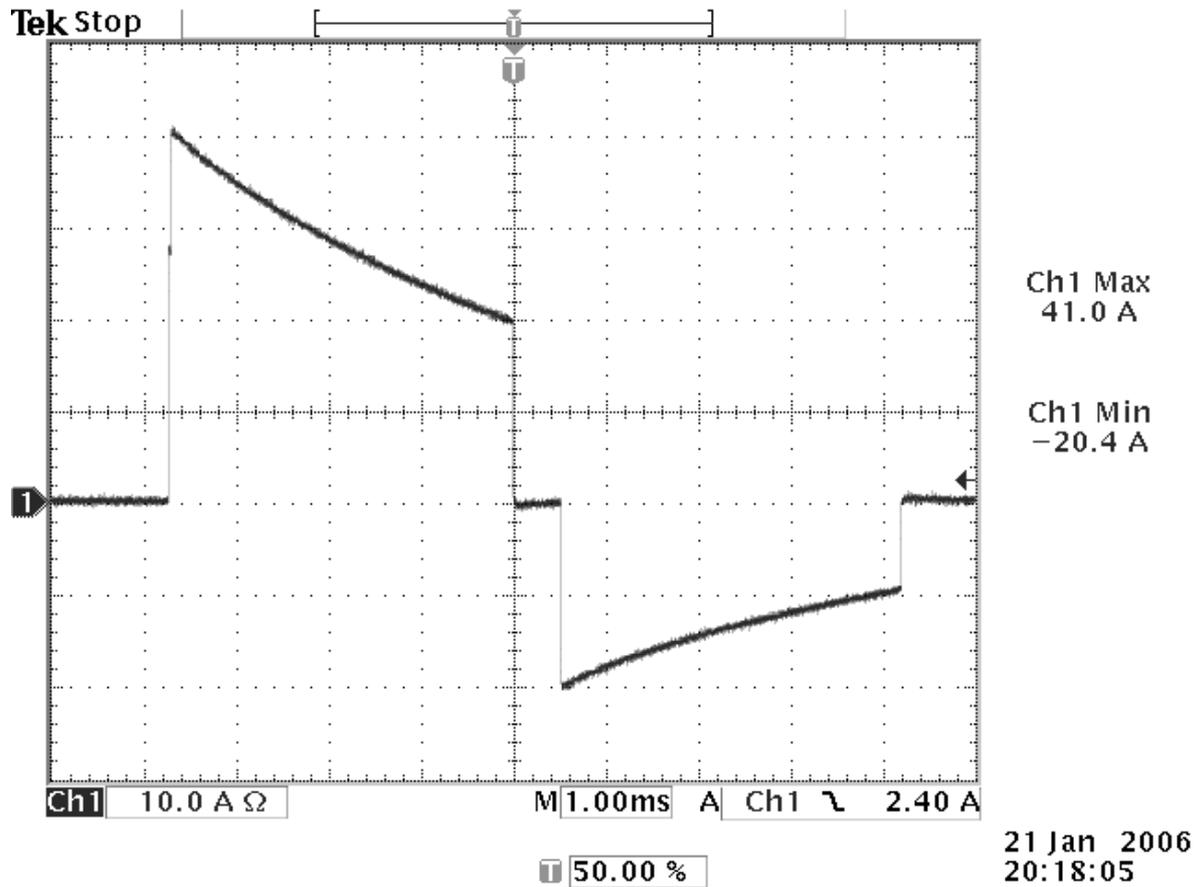
## Environmental

|                                   |   |
|-----------------------------------|---|
| <b>Category</b>                   | Nominal Specifications  |
| <b>Operating Conditions</b>       |   |
| <b>Temperature</b>                | 32 °F to 104 °F (0 °C to 40 °C)   |
| <b>Humidity</b>                   | 5 % to 95 % (non-condensing)  |
| <b>Storage Conditions</b>         |   |
| <b>Temperature</b>                | 32 °F to 104 °F (0 °C to 40 °C)   |
| <b>Humidity</b>                   | 5 % to 95 % (non-condensing)  |
| <b>Shock/Drop/Abuse Tolerance</b> | Meets IEC 60601-1 clause 21 (Mechanical Strength)   |
| <b>Vibration</b>                  | Meets EN1789 random and swept sine, road ambulance specification in operating and standby states. |
| <b>Sealing</b>                    | IEC 60529: IP54   |
| <b>ESD</b>                        | Meets IEC 61000-4-2:2001  |
| <b>EMI (Radiated)</b>             | Meets IEC 60601-1-2 limits, method EN 55011:1998+ A1:1999 +A2:2002, Group 1, Class B              |
| <b>EMI (Immunity)</b>             | Meets IEC 60601-1-2 limits, method EN 61000-4-3: 2001 Level 3 (10V/m 80MHz to 2500MHz)            |

## Defibrillator

|   |  |
|---|--|
| <b>Category</b>                         | Nominal Specifications   |
| <b>Operating Mode</b>                   | Semi-automated   |
| <b>Waveform</b>                         | <i>e~cube</i> biphasic (Truncated exponential type); impedance compensated   |
| <b>Energy</b>                           | 200 Joules nominal into a 50Ω load   |
| <b>Charge Control</b>                   | Automatic by Software (Arrhythmia Detection System and Charging Control)   |
| <b>Charge time from “Shock Advised”</b> | < 10 seconds, typical  |
| <b>Charge complete indicator</b>        | <ul style="list-style-type: none"> <li>• Text prompt (PRESS THE FLASHING ORANGE BUTTON, NOW)</li> <li>• Flashing backlight of SHOCK button</li> <li>• Beep from the beeper</li> </ul>  |
| <b>Disarm</b>                           | <p>Once charged, the i-PAD disarms itself if:</p> <ul style="list-style-type: none"> <li>• Patient's heart rhythm changes to non-shockable rhythm, or</li> <li>• The SHOCK button is not pressed within 15 seconds after the i-PAD is armed, or</li> <li>• The ON/OFF button is pressed to turn OFF the i-PAD, or</li> <li>• The defibrillator pads are removed from the patient or the pads connector is disconnected from the i-PAD</li> </ul> |
| <b>Shock Delivery</b>                   | Shock is delivered if the SHOCK button is pressed while the i-PAD is armed.  |
| <b>Shock Delivery Vector</b>            | Via adult defibrillator pads in the anterior-anterior (Lead II) position or via Reduced-energy pediatric pads in the anterior-posterior position.  |
| <b>Patient Isolation</b>                | Type BF  |

## D. i-PAD NF1200 Specifications



### Waveform Specifications (200 Joules)

| Patient Impedance (Ohms) | Phase A, Duration (milliseconds) | Phase B, Duration (milliseconds) | Energy Delivered (Joules) |
|--------------------------|----------------------------------|----------------------------------|---------------------------|
| 25                       | 1.9                              | 1.9                              | 200                       |
| 50                       | 3.8                              | 3.8                              | 200                       |
| 75                       | 5.7                              | 5.7                              | 200                       |
| 100                      | 7.3                              | 7.3                              | 199                       |
| 125                      | 9.2                              | 9.2                              | 199                       |
| 150                      | 11.0                             | 11.0                             | 200                       |
| 175                      | 12.8                             | 12.8                             | 200                       |

### ECG Acquisition

|                           |                        |
|---------------------------|------------------------|
| <b>Category</b>           | Nominal Specifications |
| <b>Acquired ECG Lead</b>  | Lead II                |
| <b>Frequency Response</b> | 1 Hz to 30 Hz          |

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### ECG Analysis System

|                                       |  |
|---------------------------------------|--|
| <b>Category</b>                       | Nominal Specifications   |
| <b>Function</b>                       | Determines the impedance of the patient and evaluates the ECG of the patient to determine whether it is shockable or non shockable |
| <b>Impedance Range</b>                | 25Ω to 175Ω  |
| <b>Shockable Rhythms</b>              | Ventricular Fibrillation or Fast Ventricular Tachycardia   |
| <b>Non Shockable Rhythms</b>          | ECG rhythms other than Ventricular Fibrillation or Fast Ventricular Tachycardia  |
| <b>Sensitivity &amp; Specificity:</b> | Meets AAMI DF39 guidelines   |

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# D. i-PAD NF1200 Specifications

## 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,SV T, 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%                                  |

### Controls, Indicators, and Prompts

---

|                              |   |
|------------------------------|---|
| <b>Category</b>              | Nominal Specifications  |
| <b>Controls</b>              | Power On/Off Button,<br>i-Button,<br>Shock Button               |
| <b>Indicators</b>            | State LED, Graphical Rescue Guide LED                           |
| <b>Audio Speaker</b>         | Provides voice prompts  |
| <b>Beeper</b>                | Provides various audible indications                            |
| <b>Low Battery Detection</b> | Automatic during daily testing and Power ON and runtime testing |
| <b>Low Battery Indicator</b> | State LED and Voice Prompt                                      |
| <b>Prompts</b>               | Voice prompts guide the user throughout a rescue operation      |

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### Self-Tests

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|                       |   |
|-----------------------|---|
| <b>Automatic</b>      | <ul style="list-style-type: none"> <li>• Power On Self-Test / Run Time Self-Test</li> <li>• Daily / Weekly / Monthly</li> </ul> |
| <b>User Initiated</b> | Battery Insertion Test  |

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### Battery Pack [CUSA0601F]

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|                          |   |
|--------------------------|---|
| <b>Category</b>          | Nominal Specifications  |
| <b>Battery Type</b>      | 12 Volt DC, 4.2 Ah, lithium manganese dioxide, disposable long-life primary cell. |
| <b>Capacity</b>          | Minimum 200 shocks or 4 hours of operating time.                                  |
| <b>Temperature Range</b> | 14 °F to 140 °F (-20 °C to 60 °C)   |

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## D. i-PAD NF1200 Specifications

### Defibrillator Pads (CUA0512F)

|                     |  |
|---------------------|--|
| <b>Category</b>     | Nominal Specifications   |
| <b>Type</b>         | self-adhesive, disposable, non-polarized defibrillation pads                           |
| <b>Adult Pads</b>   | Defibrillation pads for patients 8 years of age and older or 55 lbs. (25 kg) and over. |
| <b>Surface Area</b> | Adult : 110cm <sup>2</sup> each  |
| <b>Cable Length</b> | 1.5m   |

### Data Recording and Transmission

|                    |  |
|--------------------|--|
| <b>Category</b>    | Nominal Specifications   |
| <b>InfraRed</b>    | Wireless transmission of event data to PC through IrDA port.                     |
| <b>Data Stored</b> | First 40 minutes of ECG and the entire incident's events and analysis decisions. |

# E. Electromagnetic Compatibility

## Guidance and manufacturer's declaration - electromagnetic emissions

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

| Emissions Test  | Compliance     | Electromagnetic environment - guidance   |
|---|----------------|--|
| RF Emissions<br>CISPR 11                                      | Group 1        | The i-PAD is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| RF Emissions<br>CISPR 11                                      | Class B        |  |
| Harmonic Emissions<br><br>IEC 61000-3-2                       | Not Applicable |  |
| Voltage fluctuations / flicker emissions<br><br>IEC 61000-3-3 | Not Applicable |  |

 **WARNING**

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

If adjacent or stacked use is necessary, the NF1200 should be observed to verify normal operation in the configuration in which it will be used.

## E. Electromagnetic Compatibility

### Guidance and manufacturer’s declaration - electromagnetic immunity

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

| Immunity Test  | IEC 60601-1 test level  | Compliance level                         | Electromagnetic environment - guidance   |
|--|---|--|--|
| Electrostatic discharge (ESD)<br>IEC 61000-4-2   | $\pm 6$ kV contact<br><br>$\pm 8$ kV air  | $\pm 6$ kV contact<br><br>$\pm 8$ kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.  |
| Electrical fast transient/burst<br>IEC 61000-4-4   | $\pm 2$ kV for power supply lines<br><br>$\pm 1$ kV for input/output lines  | Not Applicable                           | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5   | $\pm 1$ kV differential mode<br><br>$\pm 2$ kV common mode  | Not Applicable                           | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11 | $<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0,5 cycles<br><br>$40\% U_T$ (60% dip in $U_T$ ) for 5 cycles<br><br>$70\% U_T$ (30% dip in $U_T$ ) for 25 cycles<br><br>$<5\% U_T$ ( $>95\%$ dip in $U_T$ ) for 0,5 cycles | Not Applicable                           | Mains power quality should be that of a typical commercial or hospital environment. If the user of the i-PAD requires continued operation during power mains interruptions, it is recommended that the i-PAD be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8   | 3 A/m   | 3 A/m                                    | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |

**Guidance and manufacturer’s declaration - electromagnetic immunity**

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

| Immunity Test                 | IEC 60601-1 test level  | Compliance level | Electromagnetic environment - guidance  |
|-------------------------------|---|------------------|---|
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>outside ISM bands <sup>a</sup> | 3 Vrms           | Portable and mobile RF communications equipment should be used no closer to any part of the i-PAD, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br><b>Recommended separation distance</b><br>$d = 1.16\sqrt{P}$  |
|                               | 10 Vrms<br>150 kHz to 80 MHz in<br>ISM bands                  | 10 Vrms          |   |
| Radiated RF<br>IEC 61000-4-3  | 10 V/m<br>80 MHz to 2.5 GHz                                   | 10 V/m           | $d = 1.2\sqrt{P}$ 80MHz to 800MHz<br>$d = 2.3\sqrt{P}$ 800MHz to 2,5GHz<br><br>where <b>P</b> is the maximum output power rating of the transmitter in watts ( <b>W</b> ) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in metres (m) <sup>b</sup><br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>c</sup> , should be less than the compliance level in each frequency range <sup>d</sup> .<br><br>Interference may occur in the vicinity of equipment marked with the following symbol: <div style="text-align: right;">  </div> |

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

|          |  |
|----------|--|
| <b>a</b> | The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40,66 MHz to 40.70 MHz.  |
| <b>b</b> | The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.  |
| <b>c</b> | Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the i-PAD is used exceeds the applicable RF compliance level above, the i-PAD should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as or relocating the i-PAD. |
| <b>d</b> | Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.   |

## E. Electromagnetic Compatibility

### Recommended separation distances between portable and mobile RF communications equipment and the i-PAD

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

| Rated maximum output power of transmitter W | Separation distance according to frequency of transmitter<br>m |   |  |   |
|---|--|---|--|---|
|   | 150 kHz to 80 MHz outside ISM bands<br>$d = 1.16\sqrt{P}$      | 150 kHz to 80 MHz in ISM bands<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2,5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01  | 0.116 m  | 0.12 m  | 0.12 m                                 | 0.23 m                                  |
| 0.1   | 0.37 m   | 0.38 m  | 0.38 m                                 | 0.73 m                                  |
| 1   | 1.16 m   | 1.2 m   | 1.2 m                                  | 2.3 m                                   |
| 10  | 3.67 m   | 3.79 m  | 3.79 m                                 | 7.27 m                                  |
| 100   | 11.6 m   | 12 m  | 12 m                                   | 23 m                                    |

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

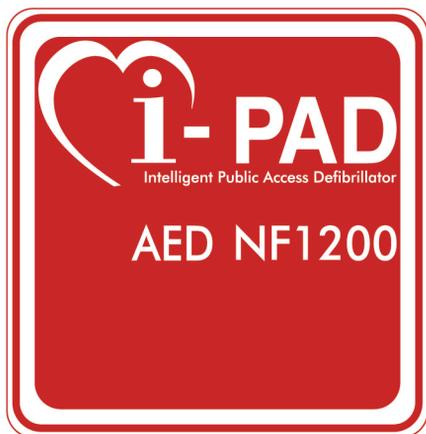
**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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

**NOTE 3** An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

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

**M E M O**



**CU Medical Systems, Inc.**

Medical Instrument Industry Park 1720-26, Tæjang-dong,  
Wonju-si, Gangwon-do, Korea

TEL : +82 33 747 7657 / FAX : +82 33 747 7659

Homepage : [www.cu911.com](http://www.cu911.com)