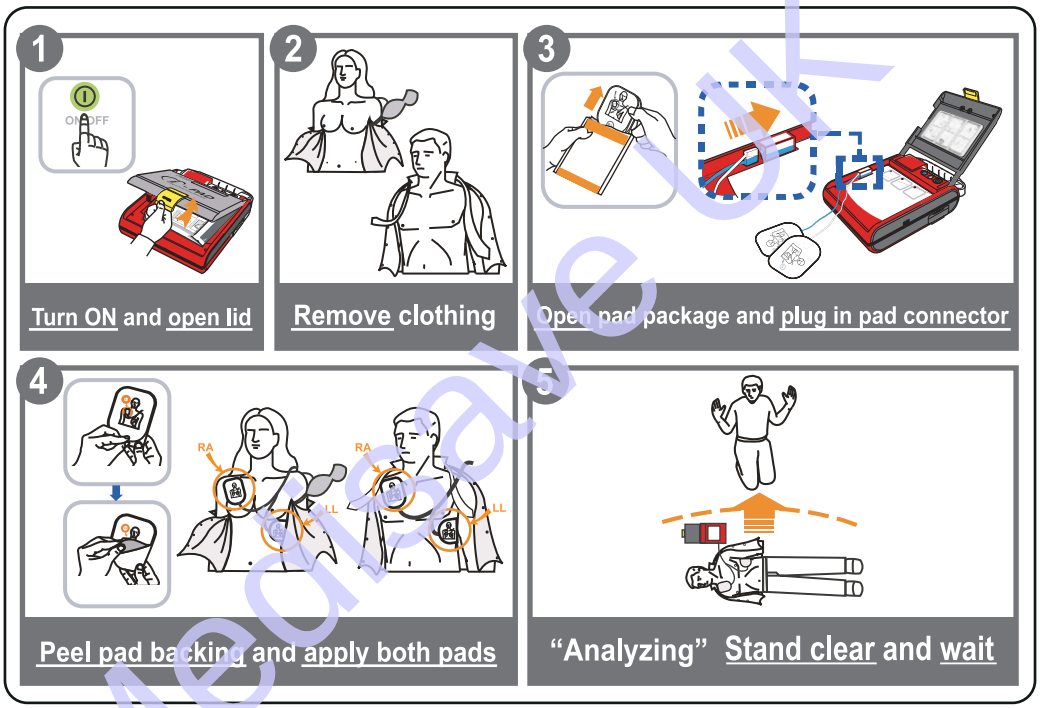
Rescue Steps

1. Connect the defibrillator pads to the i-PAD and then place on patient.

2. Automatic shock delivery if needed.

3. Administer CPR



Quick Reference Guide

The information in these Instructions for Use applies to the i-PAD NF1201. This information is subject to change.
Please contact CU Medical Systems, Inc. or its authorized representatives for information on revisions.
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Medical Device Directive

The i-PAD NF1201 complies with the requirements of the Medical Device Directive 93/42/EEC and its revisions.

CE 0470

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CU Medical Systems, Inc.

CU Medical Systems, Inc.

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APPENDICES

Instructions for Use Conventions

These Instructions for Use the following conventions:

⚠ 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 data stored in the device, particularly if precautionary steps are not taken.

NOTICE

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

Overview

Thank you for purchasing i-PAD. This product can be successfully and safely used for a long period if you familiarize yourself with the instructions and precautions by reading the user's manual prior to its use.
This Product is Fully Automatic External Defibrillator (AED: Automated External Defibrillator) that is used for sudden cardiac arrest patients. It can be easily used by laypersons or those who are not trained how to use the product.

⚠ Warnings

✓ A defibrillator uses the electric shock of the high voltage and current. Therefore, the user must be well-acquainted with the instructions and precautions by thoroughly reading this user's manual so as to understand safety cautions.

The user must follow the instructions below.

• The user must follow the instructions in the user's manual when using this Product.
• We are not responsible for any issues regarding the Product that are caused by the user's negligent operation or management.
• The repair services for this Product are only provided by us or authorized distributors.
• If the Product is intended to be connected to equipment other than those stated in this user's manual, please contact us prior to the use.
• If this Product does not operate properly, please contact us or a service center authorized by us.

1. Product Information

1.1 Product Description

This product model is the NF 1201 from the i-PAD product family. This product is an easy-to-use Fully Automatic External Defibrillator (AED) that is a small, light, portable equipment with a battery.
The AED is a defibrillator that delivers electric shock to a patient with arrhythmia in order to recover a normal heart rhythm. Sudden cardiac arrest can occur anytime to anyone at any place and may threaten the patient's life if the appropriate CPR and/or electric shock with a defibrillator are not applied within a few minutes.

1.2 Indications for use

This Product should be used for sudden cardiac arrest patients (ventricular fibrillation, ventricular tachycardia). A sudden cardiac arrest patient refers to a person with

No response
No normal breathing

1.3 User Credentials

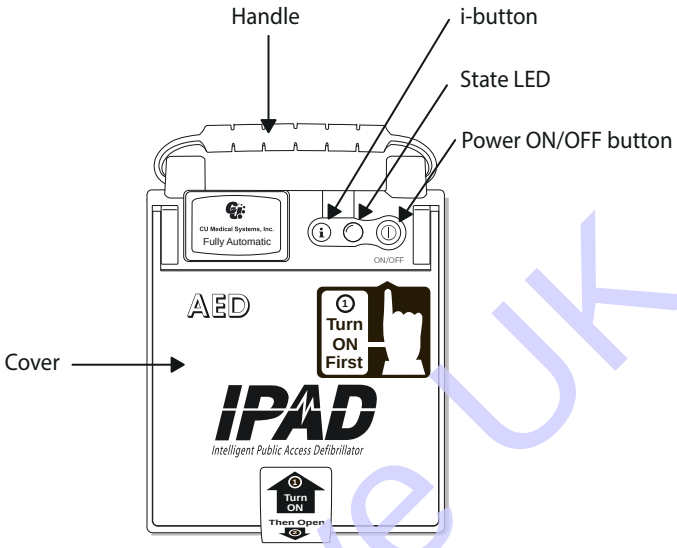
This product can be easily used by laypersons or those who are not trained how to use the Fully-Automated External Defibrillator (AED: Automated External Defibrillator). For those who have little or no understanding of the product use, education and training are recommended for proper use of the product and quick response to an emergency.

Note

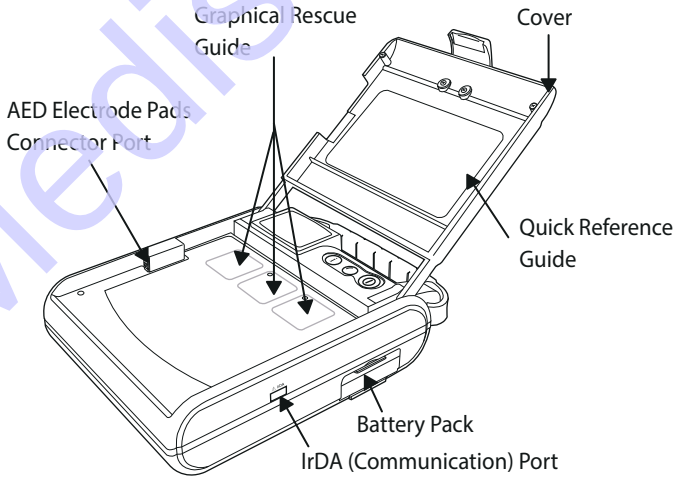
✓ When delivering shocks to children who are older than 1 year and younger than 8 years as well as lighter than 25 kg, use pediatric pads that are sold separately.

MEMO

2. Device Orientation



Top view of the i-PAD NF1201 with its cover closed



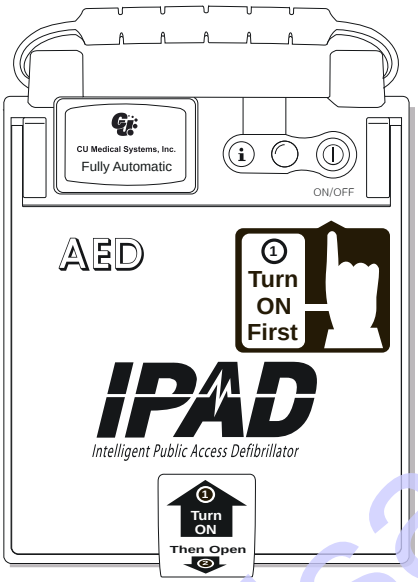
Perspective view of the i-PAD NF1201 with its cover open

Power Button	Turns the equipment on or off.
i-Button	Reports equipment usage (the total hours of the last usage and number of shocks), sets the CPR guide (breath guide, chest compression rate per minute, default guide mode), and checks for errors.
Status Indicator	Indicates the current status of the equipment by lighting or flashing in different colors. - Flashing in green: Normal. (In standby mode) - Green lighting: Normal operation. - Flashing in red: Low battery or equipment error. - Blue lighting: Running a self-diagnostic test. - White lighting: Administrator mode. This is for either information regarding the last use of the equipment or communication with a PC (personal computer). - Flashing in yellow: Abnormality in either pads or connection between pads and equipment. (In standby mode)
Handle	For carrying the equipment.
Cover	Stores pads.
Defibrillator Pads Insert	Connects the connectors of the pads.
Order Indicator	Notifies of the current step while operating the equipment.
Quick Guide	Provides a brief guide on how to use the equipment during an emergency.
Battery Pack	Supplies power with disposable batteries.
Infrared Data Association (IrDA) Port	Transmits and receives data between the equipment and a PC.

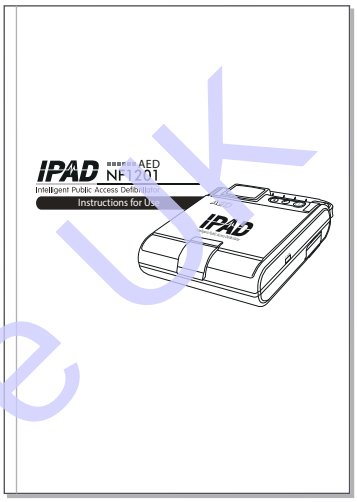
3. Setting up the i-PAD

Package Contents

The i-PAD NF1201 packaging box contains the following items.

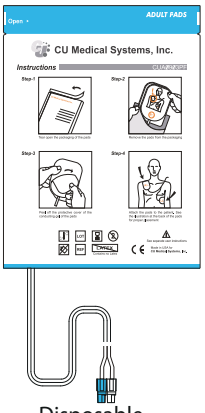


i-PAD NF1201
Fully-automated External Defibrillator



Instructions for Use

Disposable,
non-rechargeable Battery Pack



Disposable
Adult Defibrillator Pads

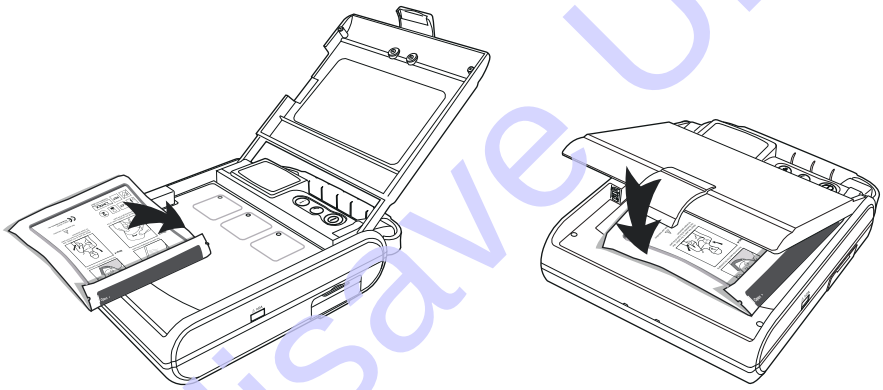
These items are the minimum requirements for the operation of the i-PAD . For optional accessories, see Appendix A.

Setting up the i-PAD

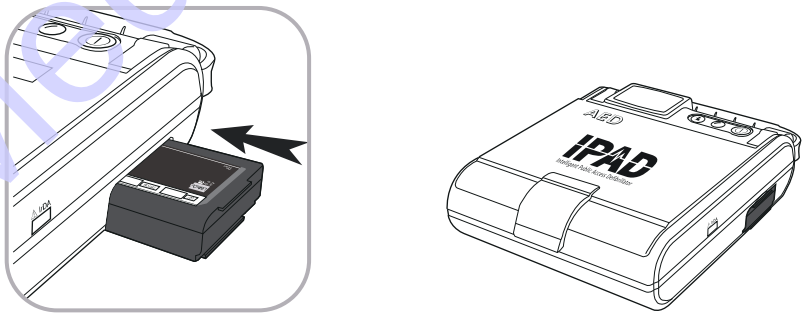
① Upon opening the packaging box, verify that it contains all the items listed in the packing list.

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.

⚠ 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.

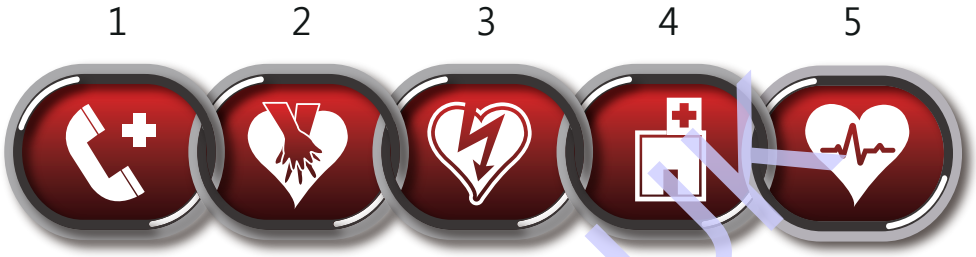
⚠ CAUTION

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. How to Use the Product

4.1 Product Use Procedures

When a sudden cardiac arrest patient is found, perform the Chain of Survival that is recommended by American Heart Association (AHA).



1. Call 911 - Request help from an emergency rescue team or a person with an equivalent qualification.
2. Early CPR – Perform CPR.
3. Early defibrillation - Use this product (i-PAD).
4. Early medical treatment - Transfer a patient to a medical institute for treatment.
5. Integrated treatment after cardiac arrest - Perform treatment after cardiac arrest at a specialized treatment facility.

3. Early defibrillation - Use this product (i-PAD).

The procedures for the use of this product can be summarized in 3 steps as follows:
After pressing the Power Button,

Step 1: Place pads on the patient.
Step 2: Automatic shock delivery if needed.
Step 3: Perform CPR.

⚠ Warnings

✓ Do not use this product with infants under 1 year old.

✓ When delivering shocks to children who are older than 1 year and younger than 8 years as well as lighter than 25 kg, use pediatric pads that are sold separately. However, do not use pediatric pads on adults.

⚠ Warnings

✓ Do not place the patient in a wet location when performing an electric shock.

4. How to Use the Product

⚠ Warnings

✓ Remove all other medical devices, which are not protected from the defibrillator, from the patient when performing an electric shock.

⚠ Warnings

✓ The user or other people near the patient should avoid a contact with the patient as follows:

- Do not touch any parts of the patient such as the patient's torso, head, arms, and/or legs.
- Do not touch conductive liquid such as gel, blood (body fluid) and/or saline solution.
- Do not touch conductive metallic objects such as a stretcher and/or wheelchair.

Such contacts may create an unexpected current path.

4.2 Preparation for Defibrillation

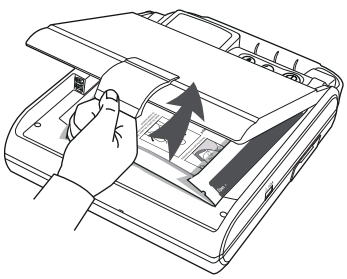
① Turn the equipment on by pressing the Power Button.

When the power is on, the equipment works as follows:

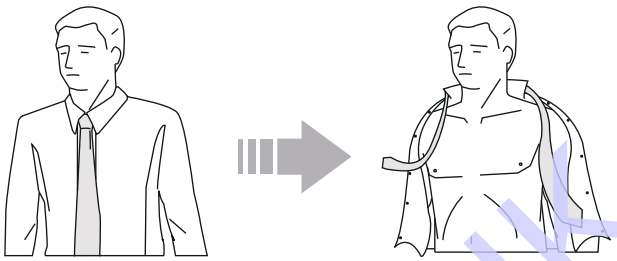
- Status Indicator: Blue lights on to indicate a self-diagnostic test
- Beeper: Rings for 1 to 2 seconds
- Status Indicator: Green lights on to indicate normal operation
- Voice Instruction: "Attach pads."

This voice instruction will repeat until the user places pads on the patient and connects pads to the equipment with the pad connectors. However, if pads are not connected within 10 minutes, the equipment will automatically turned off.

② Open the cover.



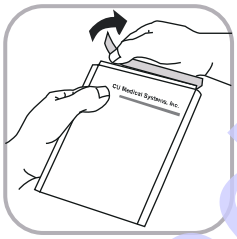
③ Remove the clothing of the patient



CAUTION

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

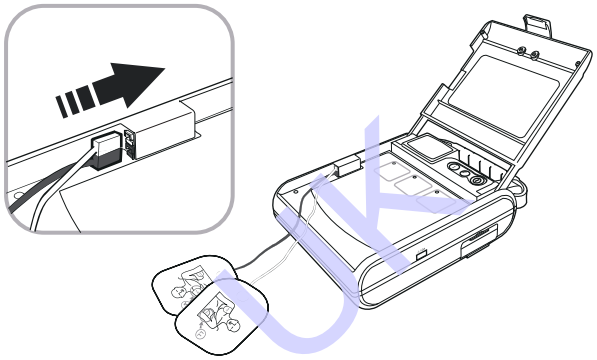
④ Tear open the packaging of the pads



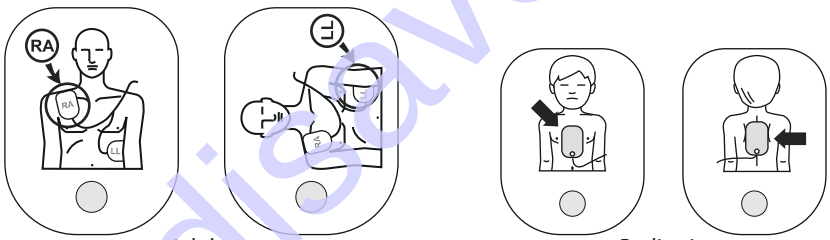
⑤ Take the pads out of its packaging

4. How to Use the Product

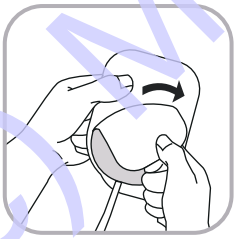
⑥ If the pad connectors are not connected to the pad insert, connect the pad connectors to the pad insert on the defibrillator.



⑦ Check where pads will be placed by referring to the pictures on the pads.



⑧ Remove the protective film on the 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: Automatic shock delivery if needed.

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. How to Use the Product

If a shock is needed:

Indicators and Voice prompts:

- Beeper: continuous beep
- Voice prompt: "Stand by for automatic shock delivery. Warning: No one should be touching the patient."
- Beeper: beeps continuously until the SHOCK deliver
- Voice prompt: "Shock will be delivered in (3-2-1)"
- After the countdown (3 – 2 – 1), the i-PAD NF1201automatically delivers a shock.
- It informs you of ••the shock delivery with the voice prompt: "Shock delivered"

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 during automatic shock delivery. 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

CPR Protocol

· Voice Instruction: "Begin CPR, now"

· Beeper: Beeps for 1 second

· CPR Guide

CPR Guide		
Category	**Setting Range**	**Default**
Breathing / Not Breathing	Breathing guide; No breathing guide	Voice instruction mode; Pause mode
Chest Compression Rate	100, 110, or 120 pushes per minute	110
Default Guide Settings	Voice instruction mode; Pause mode	Pause mode

Note

✓Refer to [CPR Guide Settings] on page 24 for detailed CPR guide settings.

✓Refer to [CPR Guide] on page 25 for detailed CPR guide.

4. How to Use the Product

CPR Guide Settings

This is the CPR Guide Settings mode. Set the guide as follows:

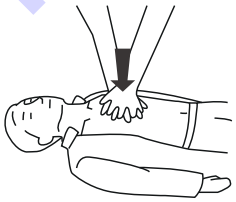
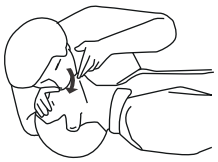
Step	Explanation	User's Action
1	Enter CPR Guide Settings mode Voice Guide: CPR guidance setup mode.	- Enter administrator's mode by pressing the i-button for longer than 1 second. (Status Indicator: white lighting) - After a voice guide gives information on the version and usage of the equipment, press the i-button for longer than 3 seconds in order to enter the CPR guidance setup mode. (Status Indicator: purple lighting)
2	Set Breathing Guide Voice Guide: Set the ventilation guidance. Voice Guide: Ventilation guidance on / off.	- Set to enable or disable the breathing guide. - Press the i-button to apply the setting and wait for 3 seconds. (When applied, the purple status indicator flashes twice)
3	Set Compression Rate per Minute Voice Guide: Set the compression rate. Voice Guide: 100, 110, or 120 compressions per minute.	- Set a chest compression rate. - Press the i-button to apply the setting and wait for 3 seconds. (When applied, the purple status indicator flashes twice)
4	Set Default Voice Guide Voice Guide: Set to the default guidance. Voice Guide: Voice guidance mode. Pause time countdown mode.	- Set to the default guidance for CPR. - Press the i-button to apply the setting and wait for 3 seconds. (When applied, the purple status indicator flashes twice) - In voice guidance mode, a voice guide gives the CPR instructions. - When instructing CPR in pause time countdown mode, the guide pauses for 2 minutes and notifies the remaining paused time.(1 minute 30 seconds, 1 minute, 40 seconds, 20 seconds) If the user presses the i-button while it is flashing in blue within 20 seconds after pausing, the voice guide starts according to the settings above.
5	Voice guide to either reset or save and exit after confirming settings: (Guide for the settings above) The CPR guidance settings will be modified to the following. Setting ventilation guidance. Ventilation guidance off. Setting compression rate. 110 compressions per minute. Setting to the default guidance. Pause time countdown mode. Voice Guide: To shutdown and save the CPR guidance settings, press the power button. To change the CPR guidance settings, press the i-button	- After the voice guide announces the CPR guide settings, the user may either reset or save and exit at this step. - After the settings guide, press i-button to reset settings and to go back to step 2. - After the settings guide, press the power button to save the settings; a purple status indicator changes to white and flashes 3 times. After completing all steps, the equipment switches to standby mode.

Note

✓ If no breathing guide is selected on the CPR guide settings, then a beat sound plays for 2 minutes at the set chest compression rate after giving a detailed description of chest compressions.

CPR Guide

While performing CPR, the equipment gives a guide with a beat sound and voice instructions according to the user's CPR guide settings. The default on the equipment is pause mode. When the user presses the i-button within 20 seconds by following the default guide in pause mode, the voice guide explains how to do chest compressions and guides the user only to compress the chest to the beat for 2 minutes.
The typical CPR order is as follows:

Step	Explanation	User's Action
1	Voice Instruction: "Begin CPR, now"	- Place both hands in the middle of the patient's chest between the nipples, and prepare for chest compressions.
2	Beat sound: depending on the setting, a beat sound plays 100, 110, or 120 beats per minute.	- According to the beat sound of the equipment, compress the patient's chest at least 5 cm deep. 
3	Beeper: briefly beeps once	- While swiftly lifting the patient's chin up, tilt the head backward to open the airway. - Prepare for artificial respiration.
4	Voice Instruction: Breathe~ Breathe~	- When performing artificial respiration, breathe longer than 1 second according to the "Breathe~" sound. - When performing artificial respiration, give the patient enough breath to make the chest significantly rise. - Breathe twice in 7 seconds. 
5	Cycle: One cycle is composed of steps 1 through 4.	- Perform 5 cycles of CPR. - When the chest compression rate is set to 120 pushes per minute, perform an additional chest compression after 5 cycles.

Note

✓ When the default guide is set to pause mode, the equipment announces only the remaining time of CPR. (1 minute 30 seconds, 1 minute, 40 seconds, 20 seconds)

4. How to Use the Product

⚠ 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. Product Care After Use

5.1 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.

5.2 Data Storage and Transfer

5.2.1 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.

⚠ Cautions

✓ This equipment can save up to 75 minutes of ECG data. If the ECG data are recorded for more than 75 minutes, the ECG data after 75 minutes will not be recorded.

✓ This equipment saves the usage history and multiple ECG records. When using the product for less than 5 minutes each time, up to 7 entries can be saved.

✓ After saving the usage data for 7 times, new data replaces the oldest data. Hence, we recommend to transfer and save the data from the equipment to a PC after each use.

5.2.2 Data Transfer

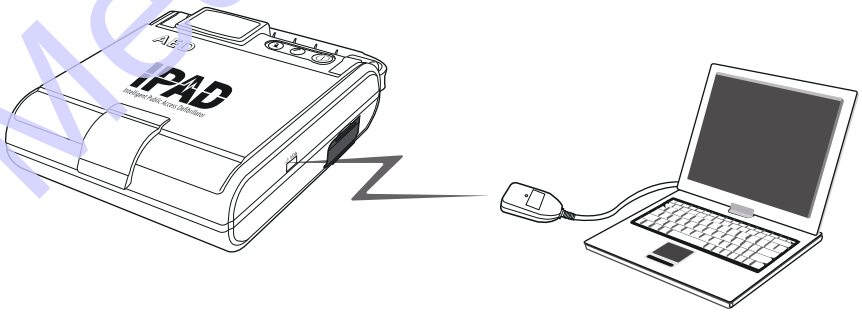
The data may be transferred to the PC by using the PC software (CU Expert Ver. 3.60 or higher) that is provided by us. [CU Expert] is a PC software that includes ECG review and printing functions.

Data Transfer

① Run [CU Expert] on a PC. Refer to the [CU Expert] manual for detailed information regarding how to receive data.

② Position the IrDA adapter to face the IrDA port on the equipment as shown in the figure below.

③ Press the i-button for longer than 1 second in standby mode
(the status indicator flashes in green).



④ The white status indicator lights with a guide phrase "Administration mode."

⑤ The equipment gives the user a summary
(the total hours of the last equipment use and the number of electric shocks).

5. Product Care After Use

⑥ Wait for 3 minutes when connecting to a PC. If settings on [CU Expert] are proper, the equipment connects to a PC in several seconds.

⑦ After transferring data, the equipment automatically turns off.

5.2.3 Equipment Settings

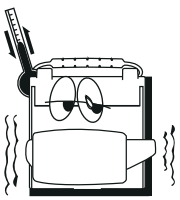
The user may set the volume on the equipment by using PC software (CU Expert Ver. 3.60 or higher). Refer to the [CU Expert] manual for details.

Equipment Settings	Default	Setting Range
Volume	10	0 ~ 10

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.

Standby conditions

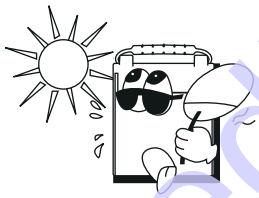
Temperature	0 ℃ to 43 ℃ (32 ℉ to 109 ℉)
Humidity	5 % to 95 % (non-condensing)

Operating Conditions (The equipment contains pads combined with batteries; available immediately in emergency)

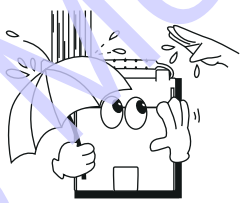
Temperature	0 ℃ to 40 ℃ (32 ℉ to 104 ℉)
Humidity	5 % to 95 % (non-condensing)

Storage Conditions (The equipment does not contain pads and batteries; only the equipment is kept for an extended period of time or moved)

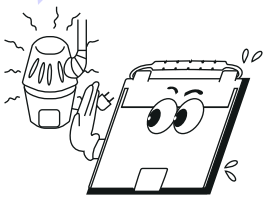
Temperature	-20 ℃ to 60 ℃ (-4 ℉ to 140 ℉)
Humidity	5 % to 95 % (non-condensing)



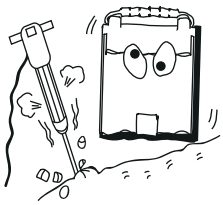
Do not store the device in areas that are directly exposed to sunlight.



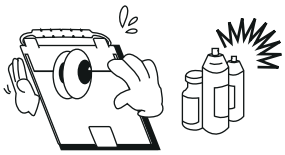
Do not store the device in areas with highly fluctuating temperatures.



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 trouble-shooting in Chapter 7.

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

Consumables

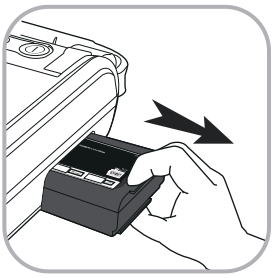
There are two important consumables that must be monitored while the i-PAD is stored on standby mode. These are: the battery pack and the AED electrode pads.

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.

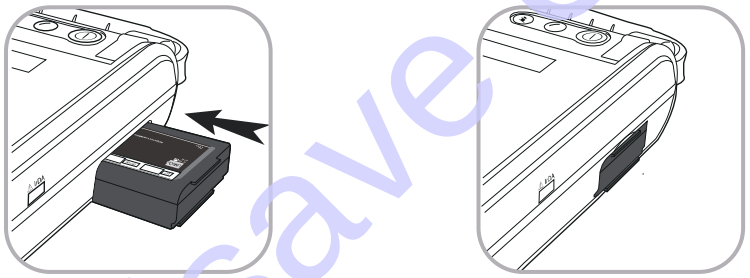
Battery Pack Replacement

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.

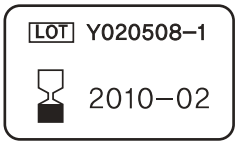
AED Electrode Pads

- 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

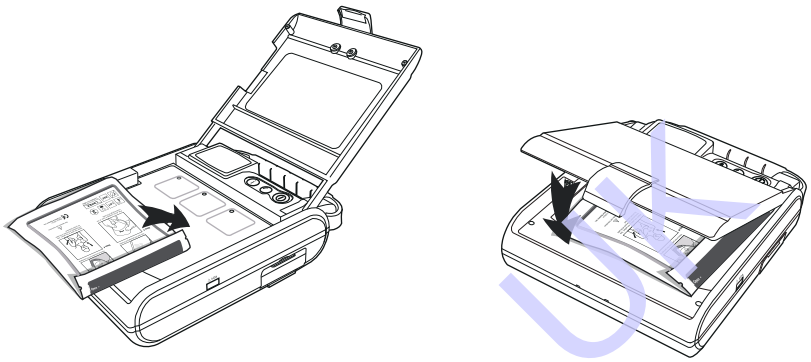
1. Verify that the replacement pads are not expired. The expiration date is indicated using a sticker as shown below.

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 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
Battery insertion test	Runs when the battery is inserted. Conduct this test: ・When the i-PAD is first placed into service. ・After the i-PAD is used in an emergency rescue operation. ・When the battery pack is replaced. ・When you suspect that your i-PAD is damaged. Do not run this test when you are about to conduct a rescue operation because this test takes time. 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. The i-PAD tests the i-button during this test; you must press the button when the i-PAD prompts you to do so. The following prompts are given: "Press the flashing blue i-button" If no fault is detected, the i-PAD goes into standby mode with the State LED blinking in green. 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.
Power On Test	Runs when the i-PAD is turned ON.
Run-time test	Runs when the i-PAD is used in a rescue operation. Monitors the performance of critical components.
Daily, Weekly, Monthly test	Runs daily, weekly, and monthly to check the functionality of important subsystems.

The blue status indicator lights in all self-diagnostic tests except "real-time self-diagnostic test."

When the equipment successfully completes a "battery pack self-diagnostics test" or "periodic self-diagnostics test", the status indicator flashes in green while the equipment switches to standby mode.

When a self-diagnostic test fails, the status indicator flashes in red. Also, the beeper beeps every minute. The equipment is unavailable for emergency while in this state.
When the i-button flashes in red, the user should press the i-button. After pressing it, the equipment will inform the user on the cause of an error via the voice instruction. Refer to [Section 7.3: Trouble-shooting] of this document for more information.

If the status indicator flashes in yellow after performing the "periodic self-diagnostic test", this indicates a problem with the pads such as a connection problem between the equipment and pads. Since the equipment does not have any problem, check pads and resolve relevant problems; either take out the battery and reinsert or turn on the equipment in order to perform a "battery pack self-diagnostic test" or "power self-diagnostic test." When problems are resolved, the status indicator flashes in green in standby mode.

7. Troubleshooting

Equipment Status

This equipment has different indicators to inform the user regarding the equipment conditions.

- Status Indicator
- Order Indicator
- Beeper
- i-Button

Indicator	Description	Remark
Status Indicator: Flashing in green	The equipment is available for a normal operation.	
Status Indicator: Green lighting	The equipment is properly functioning.	
Status Indicator: Flashing in red Beeper: Beeping 3 times in a 1 minute interval	The equipment detected an error during the self-diagnostic test; the power is off.	
Status Indicator: Red lighting i-Button: Flashing in red Voice Instruction: "Press the flashing red i-button"	The equipment detected an error while operating.	
Status Indicator: Blue lighting	The equipment is performing a self-diagnostic test.	
Status Indicator: White lighting	The equipment is currently on administrator mode.	
First, the order indicator is flashing	The pads are not connected to either the equipment or the patient.	
Second, the order indicator is flashing	The equipment is analyzing the patient's ECG.	
Third, the order indicator is flashing	The equipment is in CPR mode.	
i-Button: Flashing in red	The equipment detected an error. In order to identify the error, press the i-button.	
Status Indicator: Flashing in yellow	The pads are not properly connected to the equipment, or the pads have a problem.	

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)
Device Mode; Standby Mode State LED: Flashing Red	• Low battery level.	• Replace the battery pack of the i-PAD with a new battery pack
	• An error in the i-PAD is detected.	• Replace the i-PAD with a functioning defibrillator. Bring the malfunctioning device to a service center for repair.
Device Mode; Operation Mode State LED: Flashing Red	• Low battery level.	• The i-PAD shuts down automati cally after 10 minutes or after delivering 10 shocks. • Replace the battery pack of the i-PAD with a new battery pack • If no new battery pack or no other defibrillator is available, check the patient and begin CPR if needed until the EMS team arrives.
Device Mode; Operation Mode State LED: Solid Red i-button: Flashing red	• An error in the i-PAD is detected. • The i-PAD is unusable for a rescue operation in this condition.	• Perform CPR on the patient. • Use another defibrillator • If there is no other defibrillator available, continue performing CPR until the EMS team arrives.

-> continued

7. Troubleshooting

Troubleshooting During Emergencies

-> continued

Indication(s)	Possible Cause(s)	Remedial Action(s)
Voice Prompt: "No shock delivered." "Press the pads firmly to the bare skin"	· The pads are not attached firmly to the skin of the patient.	· Press the pads firmly on the patient's skin. · If needed, shave hair or wipe excess moisture off the skin of the patient and then reattach the pads. · Get another set of pads immediately if the pads you are using do not stick to the bare and dry skin of the patient.

Troubleshooting Outside of Emergencies

Indication(s)	Possible Cause(s)	Remedial Action(s)
Device Mode; Standby Mode State LED: Flashing Red	・Low battery level. ・An error in the i-PAD is detected.	・Press the Power ON/OFF button ・After turning ON, the i-PAD prompts you to: "Press the flashing red i-button." ・After pressing the i-button, the i-PAD delivers any of the following prompts: If the cause of theerror is low battery level, the prompt is: "Low Battery Level, Replace the battery with a new one." If the cause of the error is a fault in one of its subsystems, the prompt is: "System failure. Error code is XXXX" ・If the cause of the error is low battery level, replace the battery pack. Use only battery packs supplied by CU Medical Systems, Inc. ・If the cause of the error is a system failure, bring the i-PAD to an authorized service center.
Device Mode; Operation Mode State LED: Flashing Red	・Low battery level.	・The i-PAD shuts down automatically after 10 minutes or after delivering 10 shocks. ・Replace the battery pack of the i-PAD with a new battery pack ・Use only battery packs supplied by CU Medical Systems, Inc.

-> continued

7. Troubleshooting

Troubleshooting Outside of Emergencies

-> continued

Indication(s)	Possible Cause(s)	Remedial Action(s)
Device Mode; Operation Mode State LED: Solid Red i-button: Flashing red	• An error in the i-PAD is detected. • The i-PAD is unusable for a rescue operation in this condition.	• The i-PAD prompts you to: "Press the flashing red i-button" • After you press the flashing red i-button, the i-PAD delivers the following prompt: "System failure. Error code is XXXX" • Bring the i-PAD to an authorized service center.

For Non-emergency Situations

Symptom	Cause	Resolution
Equipment Mode: Standby Mode Status Indicator: Flashing in red	The battery is low. Or a system failure.	Press the power button. Press the i-Button by following the instruction, "Press the flashing red i-Button." When the instruction says "Low battery level. Replace the battery with a new one." then replace the battery. When the instruction says "System failure. Error code is OOOO,"then contact us by referring to [Product Service].
Equipment Mode: peration Mode Status Indicator: Flashing in red	The battery is low.	The equipment is turned off in 10 minutes or after 10 electric shocks. Immediately replace the battery with a new one.
Equipment Mode: Operation Mode Status Indicator: Red lighting i-Button: Flashing in red	System failure.	Press the i-Button by following the instruction, "Press the flashing red i-Button." When the instruction says "System failure. Error code is OOOO," then contact us by referring to [Product Service].
Equipment Mode: Standby Mode Status Indicator: Flashing in yellow	The pads are not properly connected to the equipment, or the pads have a problem.	Check the connection between the pads and equipment, and connect the pad connectors to the pad insert on the equipment. Reinsert the battery or turn on the equipment in order to perform a "battery pack self-diagnostic test" or "power self-diagnostic test." If problems are resolved, the status indicator flashes in green in standby mode. If the status indicator continues to flash in yellow in standby mode, replace the pads with new pads.

✓ If the problem is not solved with the resolution or if no battery is available to replace, contact us by referring to [Product Service].

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		Fully Automated External Defibrillator		
Product Name		i-PAD	Model Name	NF1201
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.
5F Cheonggye Bldg., 221, Anyangpangyo-ro, Uiwang-si, Gyeonggi-do, Korea
TEL : +82 31 421 9700 / FAX : +82 31 421 9911 / Homepage : www.cu911.com

Sales inquiries : sales@cu911.com
Technical inquiries : techinfo@cu911.com
Service : service@cu911.com

A. Accessories

A.1 Standard Accessories

-. Adult defibrillator electorde Pads [CUA0903PF]
-. Disposable Battery Pack [CUSA0601F]
-. Instructions for Use

A.2 Optional Accessories

-. Pediatric defibrillator electorde Pads [CUA0512P]
-. Wall mounted cabinet
-. Carrying case
-. IrDA Adapter
-. PC S/W (CU Expert Version 3.60 or higher)
-. i-PAD Trainer

A.3 Service Center

Customer Service
Homepage : http://www.cu911.com
Address : 5F Cheonggye Bldg., 221, Anyangpangyo-ro,
Uiwang-si, Gyeonggi-do, Korea
Tel : +82-31-421-9700
Fax : +82-31-421-9911

Product Purchase
E-mail : sales@cu911.com
Tel : +82-31-421-9700

Service Request
E-mail : service@cu911.com
Tel : +82-31-421-9700

B. Equipment Symbols

B.1 i-PAD NF1201 Defibrillator

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

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℃ to 60℃
CE 0470	CE Mark
SN	Serial Number

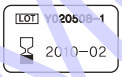
B. Equipment Symbols

B.3 Symbols on Accessories

B.3.1 Disposable Battery Pack [CUSA0601F]

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

B.3.2 Adult defibrillator electorde Pads [CUA0903PF]

Symbol	Description
	Temperature limits: 0℃ to 43℃
	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

1 Cycle	Refers to 30 chest compressions followed by 2 breaths during CPR.
1 CPR	1 CPR consists of 5 cycles.
American Heart Association (AHA) 2010 CPR Guidelines	This product instructs to compress the chest immediately after one electric shock according to the 2010 CPR Guidelines. Also, the user may change the CPR guide depending on the user's CPR proficiency. Please contact us for additional questions.
Condensation	If you take a cold water bottle out from the refrigerator, dewdrops form on the surface of the water bottle. Likewise, since moisture has an adverse effect on the equipment when it is formed on the cold equipment surface by condensing moisture in the warm air, the Product should be stored in a place without condensation.
Sudden Cardiac Arrest Patient	A patient with symptoms of a sudden cardiac arrest. This product is intended to be used on patients with the following symptoms: First, this product should be used on patients with no response and no normal breathing.
We	Refers to CU Medical Systems, Inc.
Standby Mode	In this mode, the status indicator flashes in green while the equipment is turned off. The equipment is available for a normal operation.
Operation Mode	In this mode, the green status indicator lights while the equipment is turned on. The equipment is properly operating.
Battery Pack	This equipment uses a disposable battery. Never try to recharge the battery.
Status Indicator	This indicator indicates the current status of the equipment with various colors and flashing.
Adult	The adult referred in this manual is defined as a person who is older than 8 years or heavier than 25 kg.
Pediatric	The child referred in this manual is defined as a person who is older than 1 year and younger than 8 years as well as lighter than 25 kg.

Self-Test	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.
Internal discharge (disarm)	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.
IrDA Port	Port that is used to connect the i-PAD to a personal computer for data transfer.
Shock	The shock that is delivered to defibrillate the heart of a patient. Charging Time: less than 12 seconds.
Solid	The State LED is always ON.
Blinking	The State LED is turned ON and OFF regularly.
i-button	Last usage data or error codes or CPR guide prompts are played on the speaker when this button is pressed.
Product	The i-PAD defibrillator of CU Medical Systems, Inc. with model name i-PAD.
Fully Automatic External Defibrillator	A device that automatically defibrillating shock after analyzing and recognizing a shockable rhythm.
Carrying Case	A case that is used to store the i-PAD and all of the accessories needed for a rescue operation.
Communications port	The port that is used to connect the i-PAD to a personal computer for data transfer.
AED electrode pads	Electrode pads that are used in the acquisition of ECG and the delivery of defibrillating shock to a patient.
Pads Connector	The connector in the defibrillator pads assembly that is used to connect the pads to the i-PAD.

C. Glossary

Pads Packaging	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.
Electrode pads conducting gel	The coating on the electrodes that facilitates the conduction of electrical signals and energy between the patient's skin and the electrodes.
LL	Left leg electrode
RA	Right arm electrode
PC S/W CU Expert (CU-EX1)	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.
Pads Connector Socket	The port in the i-PAD that mates with the pads connector.
EMS	Emergency Medical Service

D. i-PAD NF1201 Specifications

Model: NF1201

Physical

Category	Nominal Specifications
Size	3.19 in high X 8.66 in wide X 11.06 in deep (81 mm high X 220 mm wide X 281 mm deep) - without handle and battery pack
Weight	Approximately 4.85 lbs (2.2 kg) with battery pack installed

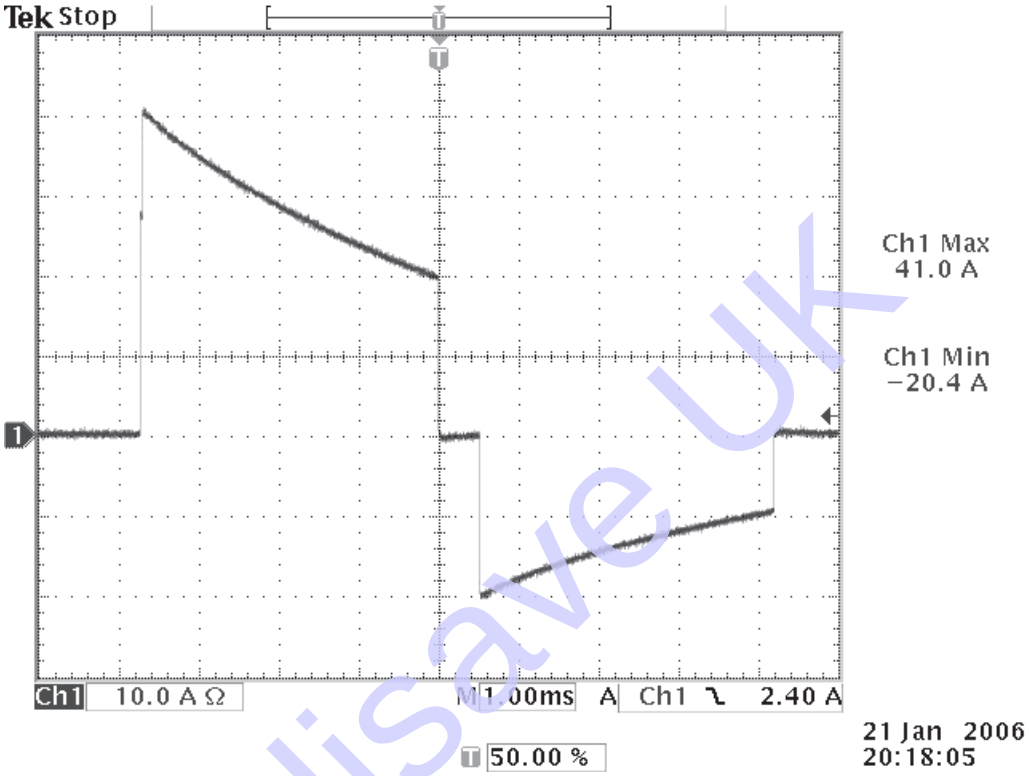
Environmental

Category	Nominal Specifications
Operating Conditions	(The equipment contains pads combined with batteries, available immediately in emergency)
Temperature	0 ℃ to 40 ℃ (32 ℉ to 104 ℉)
Humidity	5 % to 95 % (non-condensing)
Storage Conditions	(The equipment does not contain pads and batteries; only the equipment is kept for an extended period of time or moved)
Temperature	-20 ℃ to 60 ℃ (-4 ℉ to 140 ℉)
Humidity	5 % to 95 % (non-condensing)
Shock/Drop/Abuse Tolerance	Meets IEC 60601-1 clause 21 (Mechanical Strength)
Vibration	Meets EN1789 random and swept sine, road ambulance specification in operating and standby states.
Sealing	IEC 60529: IP54
ESD	Meets IEC 61000-4-2:2001
EMI (Radiated)	Meets IEC 60601-1-2 limits, method EN 55011:1998+ A1:1999 +A2:2002, Group 1, Class B
EMI (Immunity)	Meets IEC 60601-1-2 limits, method EN 61000-4-3: 2001 Level 3 (10V/m 80MHz to 2500MHz)

Defibrillator

Category	Nominal Specifications
Operating Mode	Fully automatic
Waveform	*e~cube* biphasic (Truncated exponential type); impedance compensated
Energy	200 Joules nominal into a 50Ω load
Charge Control	Automatic by Software (Arrhythmia Detection System and Charging Control)
Charge time from "Stand by, for automatic shock delivery."	< 10 seconds, typical
Charge complete indicator	・Text prompt (SHOCK WILL BE DELIVERED IN, 3-2-1) ・Beep from the beeper
Disarm	Once charged, the i-PAD disarms itself if: ・Patient's heart rhythm changes to non-shockable rhythm, or ・The ON/OFF button is pressed to turn OFF the i-PAD, or ・The defibrillator pads are removed from the patient or the pads connector is disconnected from the i-PAD
Automatic Shock Delivery	Shock is automatically delivered if a shockable rhythm is detected.
Shock Delivery Vector	Via adult defibrillator pads in the anterior-anterior (Lead II) position or via Reduced-energy pediatric pads in the anterior-posterior position.
Patient Isolation	Type BF

D. i-PAD NF1201 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

Category	Nominal Specifications
Acquired ECG Lead	Lead II
Frequency Response	1 Hz to 30 Hz

ECG Analysis System

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

D. i-PAD NF1201 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,SVT, heart block, idioventricular PVC'	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

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

Self-Tests

Automatic	・Power On Self-Test / Run Time Self-Test ・Daily / Weekly / Monthly
User Initiated	Battery Insertion Test

Battery Pack [CUSA0601F]

Category	Nominal Specifications
Battery Type	12 Volt DC, 4.2 Ah, lithium manganese dioxide, disposable long-life primary cell.
Capacity	Minimum 200 shocks or 4 hours of operating time.
Temperature Range	・Operating Conditions Temperature: 0 ℃ to 40 ℃ (32 ℉ to 104 ℉) ・Storage Conditions Temperature: -20 ℃ to 60 ℃ (-4 ℉ to 140 ℉)

D. i-PAD NF1201 Specifications

Defibrillator Pads (CUA0903PF)

Category	Nominal Specifications
Type	self-adhesive, disposable, non-polarized defibrillation pads
Adult Pads	Defibrillation pads for patients 8 years of age and older or 55 lbs. (25 kg) and over.
Surface Area	Adult : 110cm² each
Cable Length	1.5m

Defibrillation Pads for infants/children (CUA0512P)

Category	Nominal Specifications
Type	self-adhesive, disposable, non-polarized defibrillation pads
For infants/children	Use on children up to 8 years old or up to 55lbs (25kg).
Surface Area	For infants/children : 80cm² per piece
Cable Length	1.5m

Data Recording and Transmission

Category	Nominal Specifications
InfraRed	Wireless transmission of event data to PC through IrDA port.
Data Stored	Maximum 75 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 CISPR 11	Group 1	The i-PAD uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The i-PAD is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

⚠ WARNING

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

If adjacent or stacked use is necessary, the NF1201 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) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 0,5 cycles	<5 % U_T (>95% dip in U_T) for 0,5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 0,5 cycles	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 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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a] 10 Vrms 150 kHz to 80 MHz in ISM bands	3 Vrms 10 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. Recommended separation distance $d = 1.16\sqrt{P}$ $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2,5GHz
			where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and ***d*** is the recommended separation distance in metres (m)[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
b	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the i-PAD 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.
d	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 m			
	150 kHz to 80 MHz outside ISM bands $d = 1.16\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
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.

MEMO

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