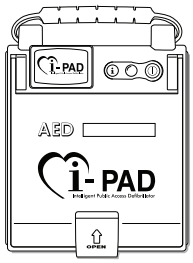
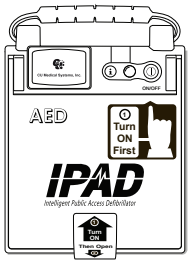
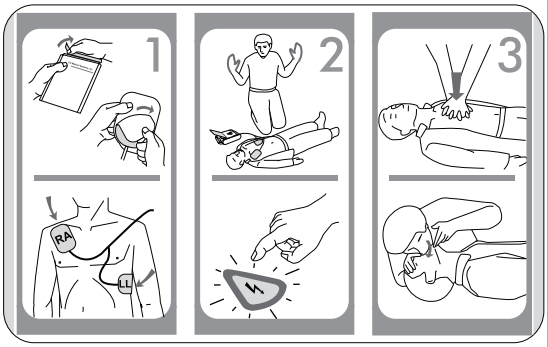
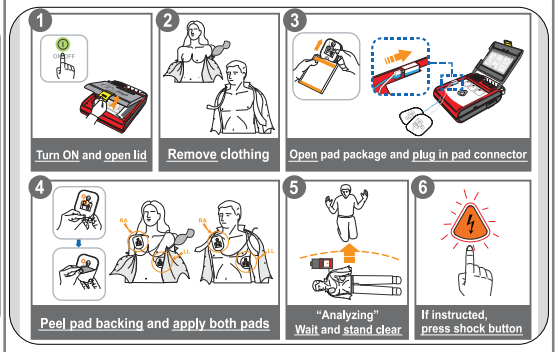
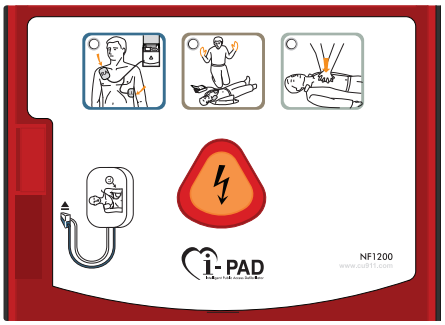
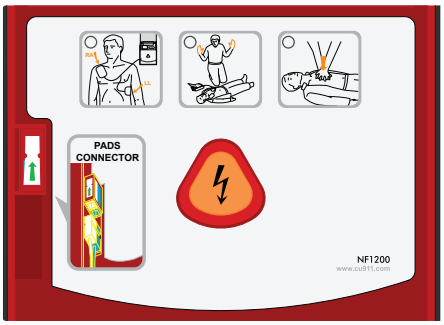
i-PAD NF1200 Interface Revision

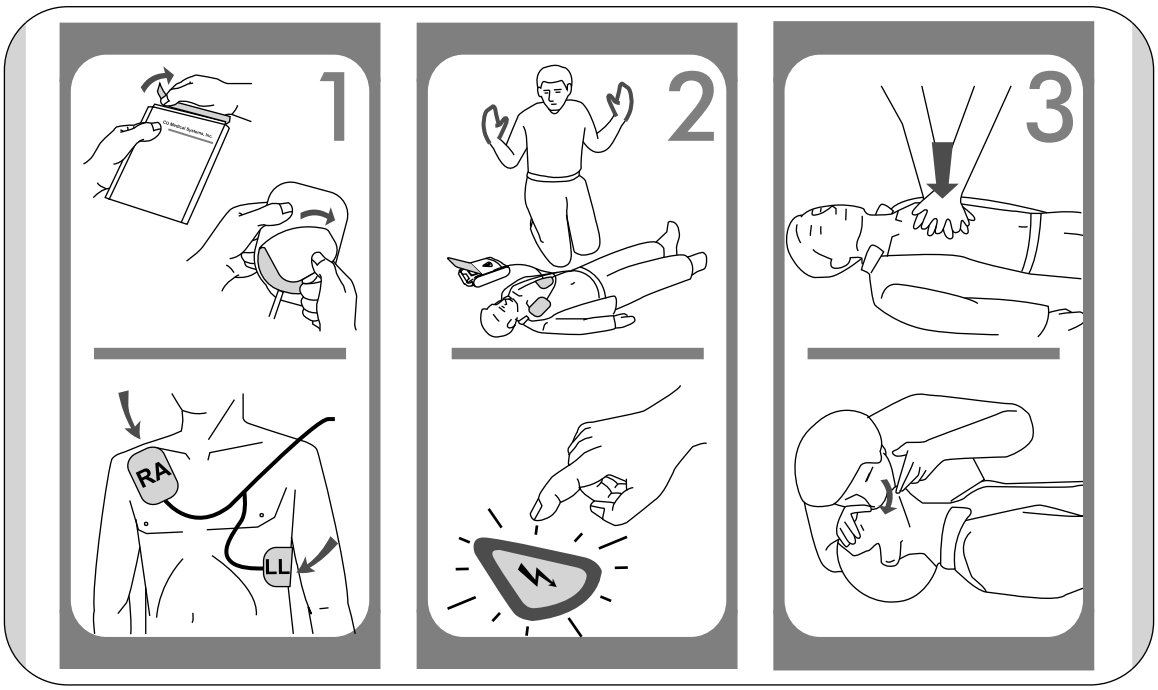
April 24, 2008

The interface of the i-PAD NF1200 has been changed to enhance its usability. The following table shows the interface before and after revision.

Before revision	After revision
Cover 	Cover 
Quick reference guide 	Quick reference guide 
Panel 	Panel 

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

CU Medical Systems, Inc.

Intelligent Public Access Defibrillator

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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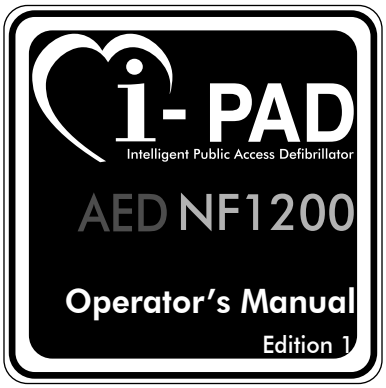


CU Medical Systems, Inc.

CU Medical Systems, Inc.

Table of Contents

Table of Contents

A P P E N D I C E S

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.

⚠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.

N O T I C E

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.

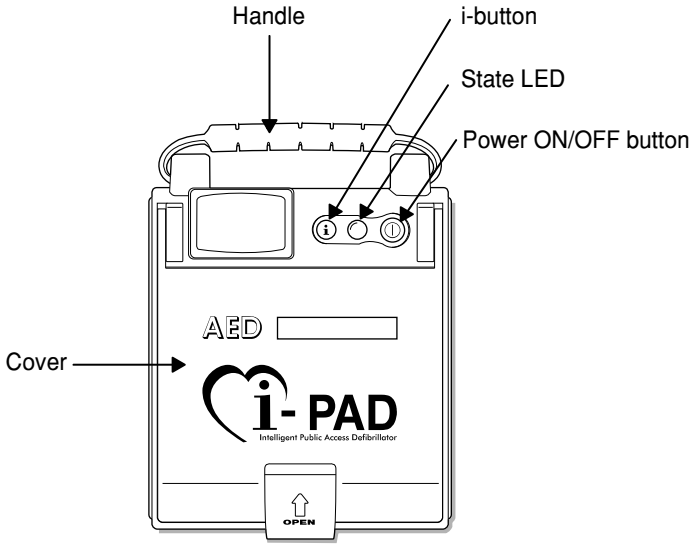
NOTICE

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

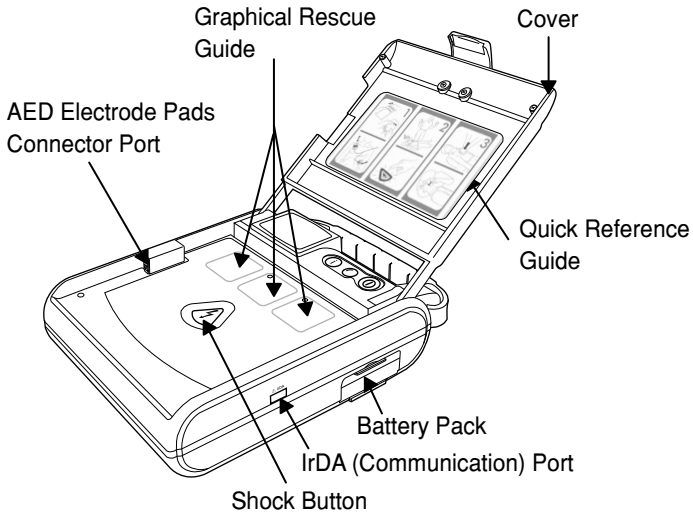
- If the patient appears to be from about 1 year of age to about 8 years of age, use the reduced- energy defibrillator pads.
- For children older than 8 years old, the American Heart Association (AHA) recommends using the adult Chain of Survival and resuscitation sequence (2005 AHA Guidelines for Cardiopulmonary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

MEMO

2. Device Orientation



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



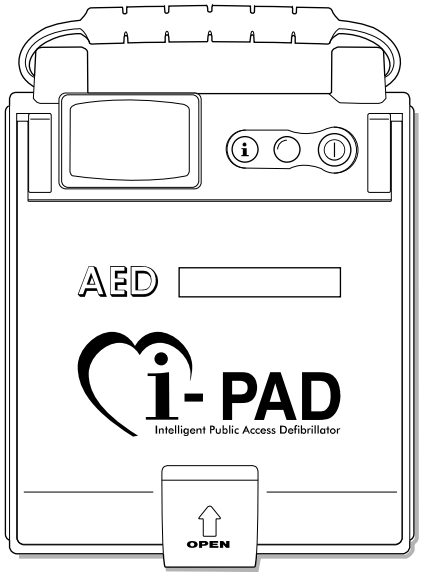
Perspective view of the i-PAD NF1200 with its cover open

Power On/Off Button	Press this button to turn the i-PAD ON or OFF.
i-Button	Press this button to: ・Get information regarding the i-PAD's last usage (usage time and number of shocks delivered). ・Get information regarding errors that were detected during self-tests. ・Toggle between compression-to-breathing ratios during CPR (30:2 and 15:2)
State LED	Indicates the status of the i-PAD ・**blinking green**: the i-PAD is in standby mode and ready for a rescue operation ・**solid green**: the i-PAD is in rescue mode. ・**blinking red**: the i-PAD detected a system error or low battery level during a self-test. ・**solid blue**: the i-PAD is conducting a self-test. ・**solid white**: 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.
Handle	An easy-grip carrying handle for increased portability of the i-PAD.
Cover	Covers the front panel of the i-PAD and retains the defibrillator electrode pads package.
SHOCK button	Press this button when the i-PAD prompts you to "Press the flashing orange button now".
AED electrode pads connector port	Pressing this button delivers a defibrillation shock to the patient. Plug the connector of the AED electrode pads into this port.
Graphical Rescue Guide	Guides you by indicating the current step in the rescue process.
Quick Reference Guide	A printed card that summarizes the steps of a rescue process using the i-PAD.
Battery Pack	Provides power to the i-PAD. Initiates a self-test upon insertion
IrDA Communication Port	Port for sending and receiving data to and from a personal computer.

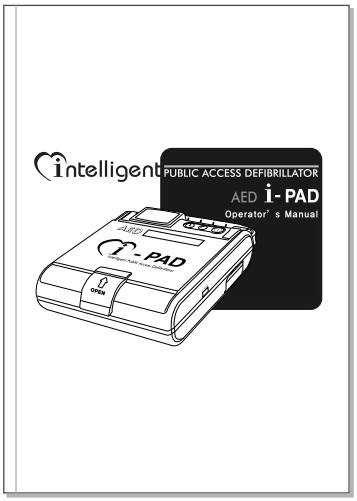
3. Setting up the i-PAD

Package Contents

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

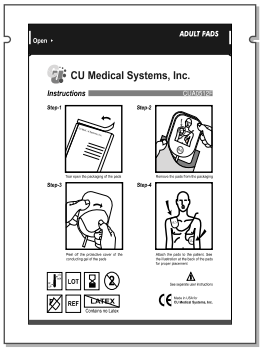


i-PAD NF1200
Semi-automated External Defibrillator



Operator's Manual

Disposable,
non-rechargeable Battery Pack



Disposable
Adult Defibrillator Pads

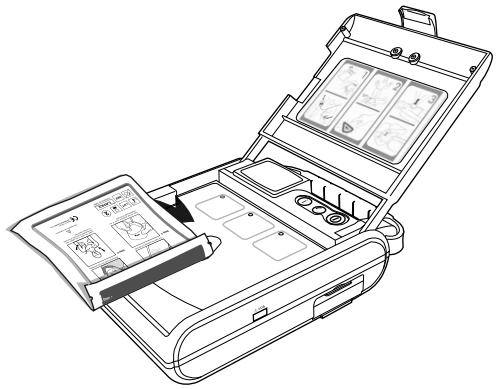
These items are the minimum requirements for the operation of the i-PAD . For optional accessories, see Appendix A.

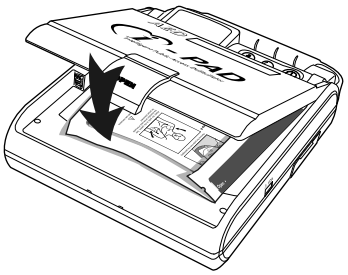
Setting up the i-PAD

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

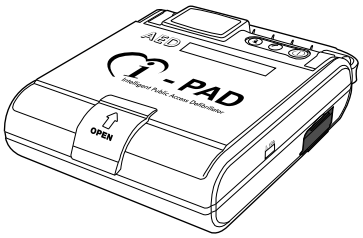
② Familiarize yourself with the controls and features of the i-PAD. Study the functions of the buttons, switches, indicators, and connection ports.

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.

⚠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.

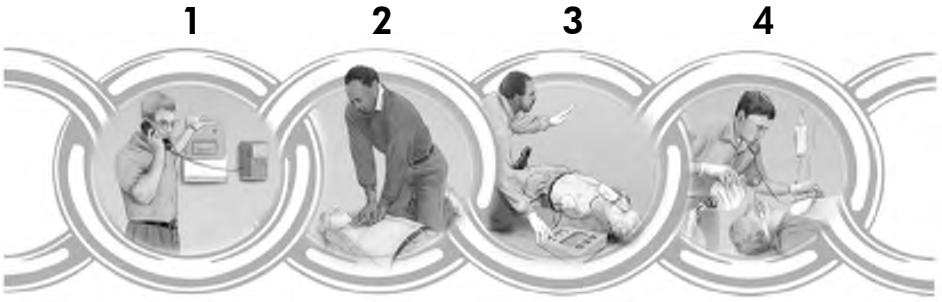
Replacement accessories and consumables must be sourced only from CU Medical Systems, Inc. or its authorized representatives.

⚠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. 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.

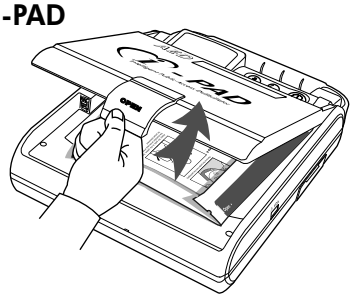
⚠WARNING

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 stretcher which may provide unwanted pathways for the defibrillating current.

Rescue Preparation

1. Open the cover of the i-PAD

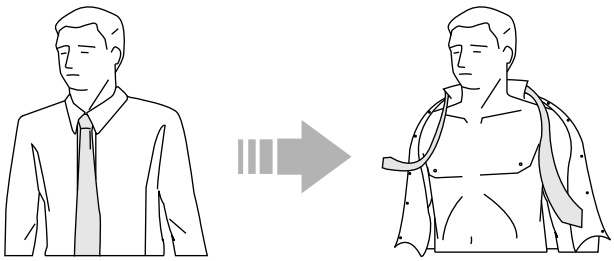


2. Press the ON/OFF button to turn the i-PAD ON

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.

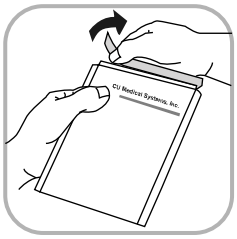
3. Remove the clothing of the patient



⚠ CAUTION

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

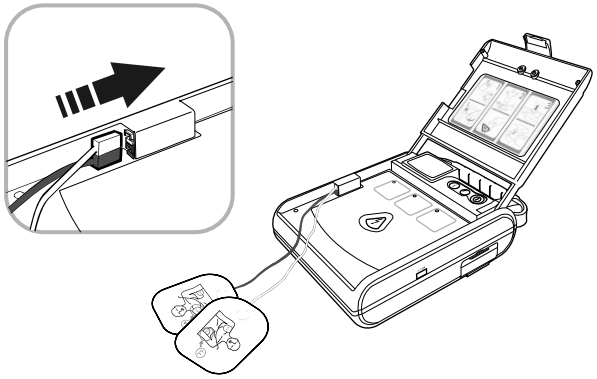
4. Tear open the packaging of the pads



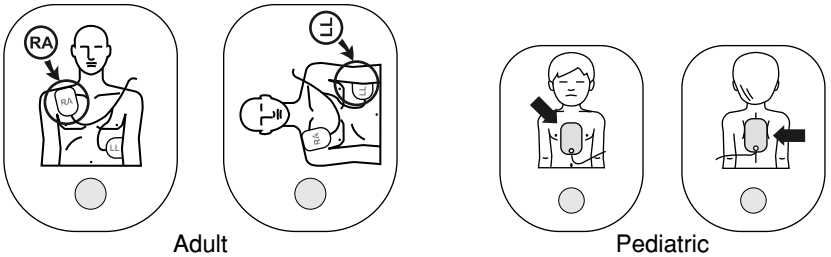
5. Take the pads out of its packaging

4. Using the i-PAD

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

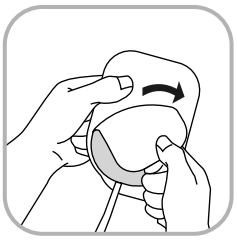


7. Look at the graphics on the back of the pads. The graphics indicate the positions of the pads on the patient's body.



Adult Pediatric

8. Peel off the protective sheets of the pads.



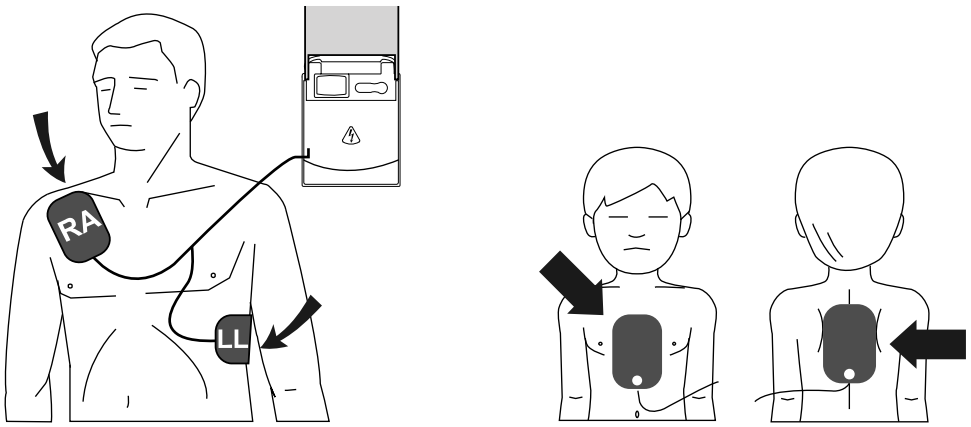
⚠ CAUTION

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)

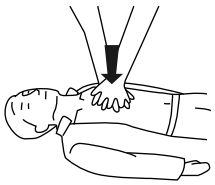
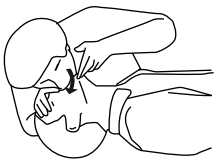
4. Using the i-PAD

CPR Protocol

Rescue Provider Setting	
Lay Rescuer Mode	Scenario 1: The ECG rhythm of the patient is shockable and a shock has been delivered. · **Voice Prompt**: "Begin CPR, now" · **Beeper**: 1 second continuous beep · **CPR Guidance**: played on the speaker, see following pages for complete description
	Scenario 2: The ECG rhythm of the patient is nonshockable and no shock has been delivered. · **Voice Prompt**: "Begin CPR, now" (ECG Rhythm is Asystole) "If needed, begin CPR" (ECG Rhythm is other than Asystole) · **Beeper**: 1 second continuous beep · **CPR Guidance**: played on the speaker, see following pages for complete description
Healthcare Provider Mode	Scenario 1: The ECG rhythm of the patient is shockable and a shock has been delivered. · **Voice Prompt**: "Begin CPR, now" · **Beeper**: 1 second continuous beep · **CPR Guidance**: played on the speaker, see following pages for complete description
	Scenario 2: The ECG rhythm of the patient is nonshockable and no shock has been delivered. · **Voice Prompt**: "Check pulse" · **Beeper**: 1 second continuous beep · i-PAD pauses for 10 seconds to allow you to check the pulse · **Voice Prompt**: "Begin CPR, now" (ECG Rhythm is Asystole) "If no pulse, begin CPR" (ECG Rhythm is other than Asystole) · **CPR Guidance**: played on the speaker, see following pages for complete description
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	**Voice Prompt:** Push the chest down fast two inches	· Place your hands, one on top of another on the area between the nipples of the patient · Push the chest down 2 inches
2	**Beat sound:** Rhythm beat sound played at 100 beats per minute. The number of beats depends on the Compression - Ventilation ratio setting 30:2 setting : 30 beats 15:2 setting : 15 beats	· Push the chest of the patient hard and fast in time with the beat provided by the i-PAD. 
3	**Voice Prompt:** Give two breaths	· Immediately open the airway using a head tilt-chin lift maneuver.
4	**Voice Prompt:** Breath, breath	· Give two breaths · Each breath must last for 1 second. · Each breath must have enough volume to produce visible chest rise · Give the two breaths within 5 seconds 
5	**Cycles:** Steps 1 to 4 are repeated for 5 cycles	· Do 5 cycles of CPR sequence.

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

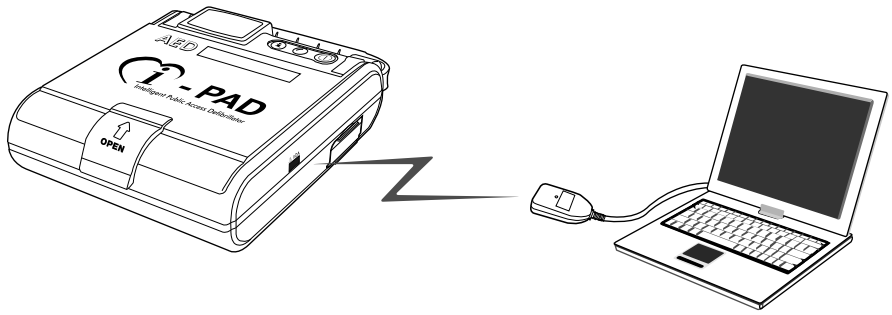
- The i-PAD has a memory capacity of 40 minutes for recording ECG and rescue event data. If the data collected during a rescue operation exceeds the capacity, the data in excess of the capacity is not recorded.
- When used in a rescue operation, the i-PAD overwrites the data it stored in the previous 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 hour:minute:second set to current date	Year/Month/Day hour:minute:second date and time from 1900 to 2099
CPR Mode	Healthcare Provider Mode	Healthcare Provider Mode 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.

Standby conditions

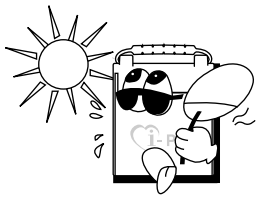
Temperature	0 ℃ to 43 ℃ (32 ℉ to 109 ℉)
Humidity	5 % to 95 % (non-condensing)

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

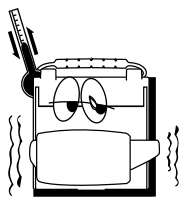
Temperature	0 ℃ to 40 ℃ (32 ℉ to 104 ℉)
Humidity	5 % to 95 % (non-condensing)

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

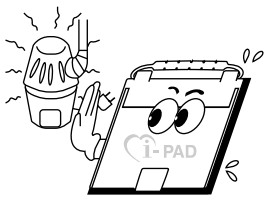
Temperature	-20 ℃ to 60 ℃ (-4 ℉ to 140 ℉)
Humidity	5 % to 95 % (non-condensing)



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



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

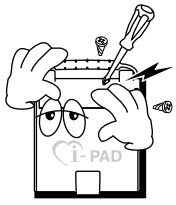


Do not store the device near heating equipment.

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 troubleshooting in Chapter 7.

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

Consumables

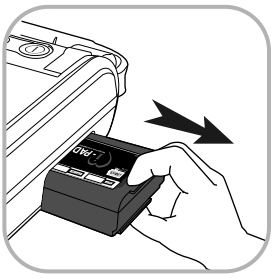
There are two important consumables that must be monitored while the i-PAD is stored on standby mode. These are: the battery pack and the AED electrode pads.

Battery Pack

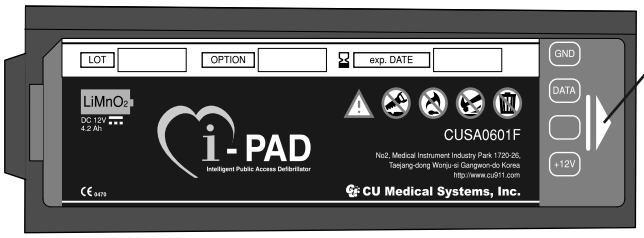
- Replace the battery pack if a low battery level condition is indicated by the i-PAD.
- Use only battery packs that are recommended by the manufacturer.
- Make sure that the replacement battery pack is not yet past its expiration date which is indicated by the “Install by: date” marking.
- The battery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

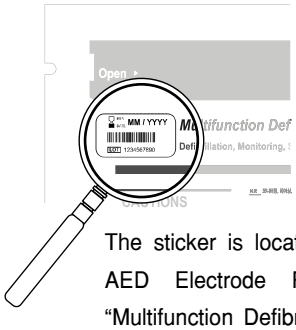
- Keep the battery pack out of children's reach.
- If the battery pack, leaks and the leaked liquid gets in the eyes, wash them with clean water and consult a physician immediately.
- Do not leave the battery pack in direct sunlight or in high temperature areas.
- Do not have the battery pack in contact 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

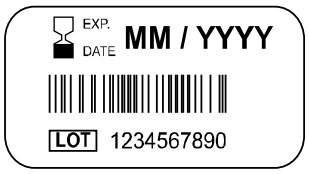
- Regularly check the expiration date of the AED electrode pads. Make sure that the set of AED electrode pads stored with the i-PAD is not expired.
- Check the integrity of the packaging of the AED electrode pads.
- Use only AED electrode pads that are recommended by the manufacturer for use with the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



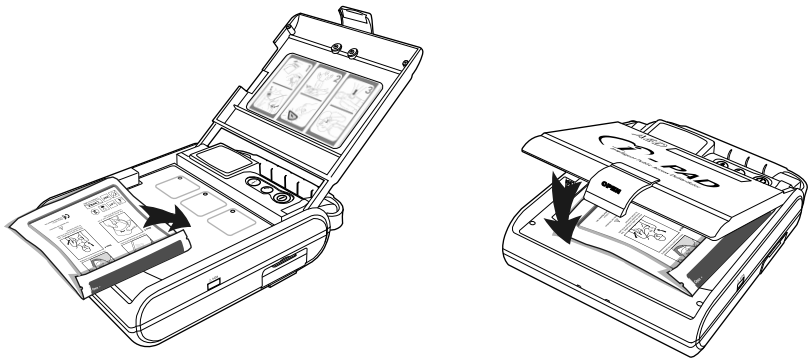
The sticker is located beside the AED Electrode Pads labeling "Multifunction Defibrillation ADULT PADS"



Details of the expiry date sticker
Expiry Date
YYYY-MM
YYYY - Year
MM - Month

CU Medical Systems, Inc.

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
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 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. The following prompts are given: "Press the flashing orange button" "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 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
State LED: blinking green	The i-PAD is in normal condition and ready for a rescue operation.
State LED: solid green	The i-PAD is currently used in a rescue operation and it is operating normally.
State LED: blinking red **Beeper**: bursts of 3 beeps; bursts spaced 1 minute apart	The i-PAD has detected a fault during a self-test.
State LED: solid red **i-button**: flashing in red **Voice prompt**: "Press the flashing red button.	• The i-PAD has detected a fault during Battery Insertion Test. • The i-PAD has detected a fault during operation.
State LED: solid blue	The i-PAD is currently performing a self-test.
State LED: solid white	The i-PAD is currently in administration mode.
Graphical Rescue Guide: 1st	Connect the pads to the patient and the i-PAD.
Graphical Rescue Guide: 2nd	The i-PAD is analyzing the ECG of the patient.
Graphical Rescue Guide: 3rd	Perform CPR. This indicator flashes while the CPR is ongoing.
i-button: blinking red	An error has occurred. Press the i-button for more information.
SHOCK button: flashing orange	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)
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.
Voice Prompt: "The SHOCK button not pressed."	· You did not press the SHOCK button when the prompt to press the shock button was given.	· Press the SHOCK button if you intend to deliver a SHOCK
	· You pressed the SHOCK button but it is defective.	· Replace the defibrillator with a functional one.

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.

MEMO

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		i-PAD	Model Name	NF1200
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.
Dongwha Medical Instrument Complex 1647-1 Dongwha, Munmak, Wonju, Gangwon, Republic of Korea
TEL : +82 33 747 7657 / FAX : +82 33 747 7659 / 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 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. Dongwha Medical Instrument Complex 1647-1 Dongwha, Munmak, Wonju, Gangwon, Republic of 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 0470	CE Mark
SN	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℃ to 60℃
CE 0470	CE Mark
SN	Serial Number

B.3 Symbols on Accessories

B.3.1 Battery [CUSA0601F]

Symbol	Description
$LiMnO_2$	Lithium Manganese Dioxide battery
LOT	Lot Number
OPTION	Option Number
exp. DATE	Expiration date
	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 0470	CE Mark

B. Equipment Symbols

B.3.2 Pads [CUA0512F]

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

C. Glossary

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)	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.
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.
Semi Automated External Defibrillator	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.
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.

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 NF1200 Specifications

Model: NF1200

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 5.29 lbs (2.4 kg) with battery pack installed

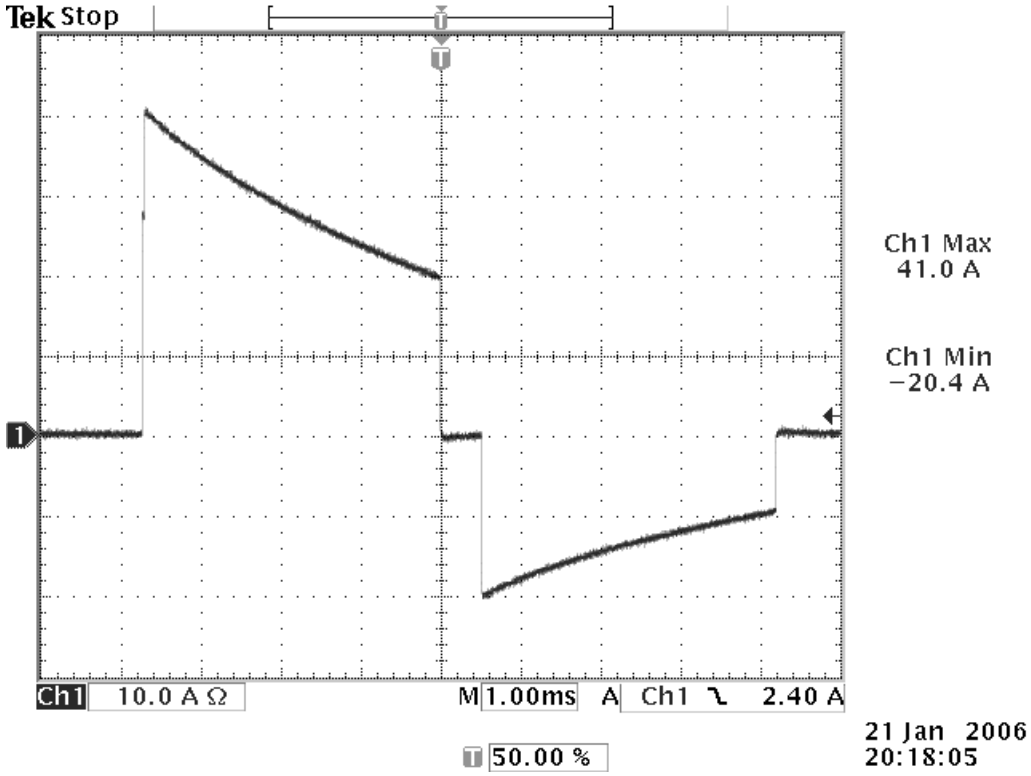
Environmental

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	Semi-automated
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 "Shock Advised"	< 10 seconds, typical
Charge complete indicator	・Text prompt (PRESS THE FLASHING ORANGE BUTTON, NOW) ・Flashing backlight of SHOCK button ・Beep from the beeper
Disarm	Once charged, the i-PAD disarms itself if: ・Patient's heart rhythm changes to non-shockable rhythm, or ・The SHOCK button is not pressed within 15 seconds after the i-PAD is armed, 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
Shock Delivery	Shock is delivered if the SHOCK button is pressed while the i-PAD is armed.
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 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

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 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,SVT, heart block, idioventricular PVC's	30 (arbitrary)	> 95% specificity	219	1	218	99.54% (218/219) specificity	98%
	Asystole	100	> 95% specificity	132	5	127	96.21% (127/132) specificity	93%

Controls, Indicators, and Prompts

Category	Nominal Specifications
Controls	Power On/Off Button, i-Button, Shock 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 NF1200 Specifications

Defibrillator Pads (CUA0512F)

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 : 110cm^2 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 : 80cm^2 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	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 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	Not Applicable	
Voltage fluctuations / flicker emissions 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) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 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 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
			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**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands [a]	3 Vrms	$d = 1.16\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands	10 Vrms	$d = 1.2\sqrt{P}$
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.

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

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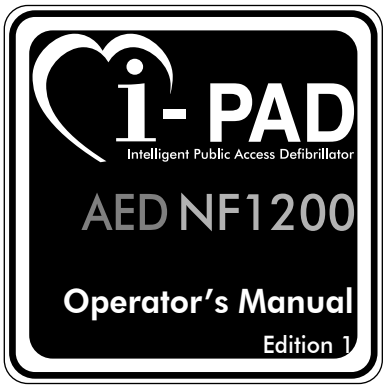

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