

i-PAD NF1200



Service Manual

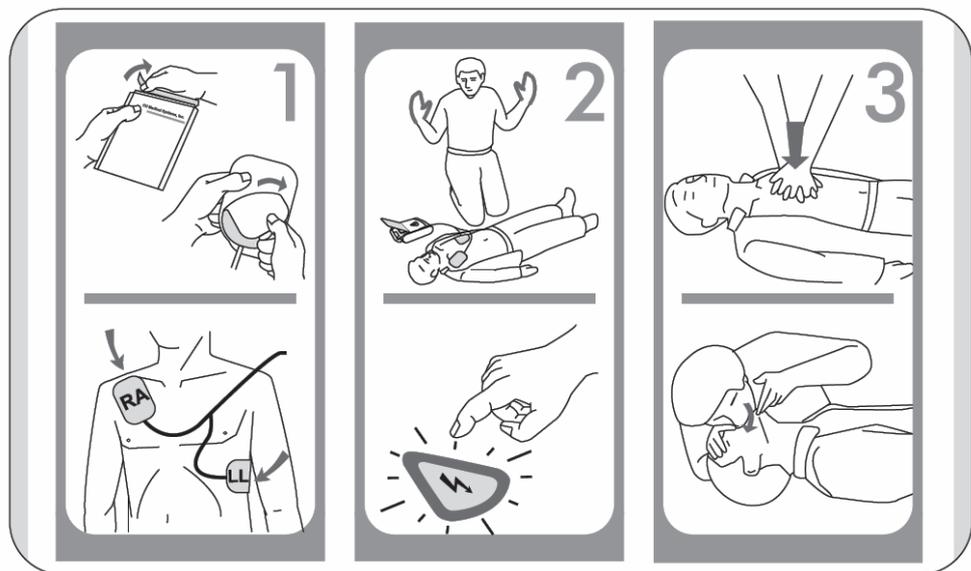
 **CU Medical Systems, Inc.**
Medical Systems, Inc.

i-PAD NF1200

Quick Reference Card

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



Notice

i-PAD NF1200 Service 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.

Printed in the Republic of Korea

Publication Date: March 2007

Service Manual Part No.:

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1. Introduction

1.1 The i-PAD NF1200

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.

1.2 Service Manual Overview

This Service Manual contains service information and instructions intended for qualified service personnel who will repair and service the i-PAD NF1200.

1.3 Warnings, Cautions, and Notes

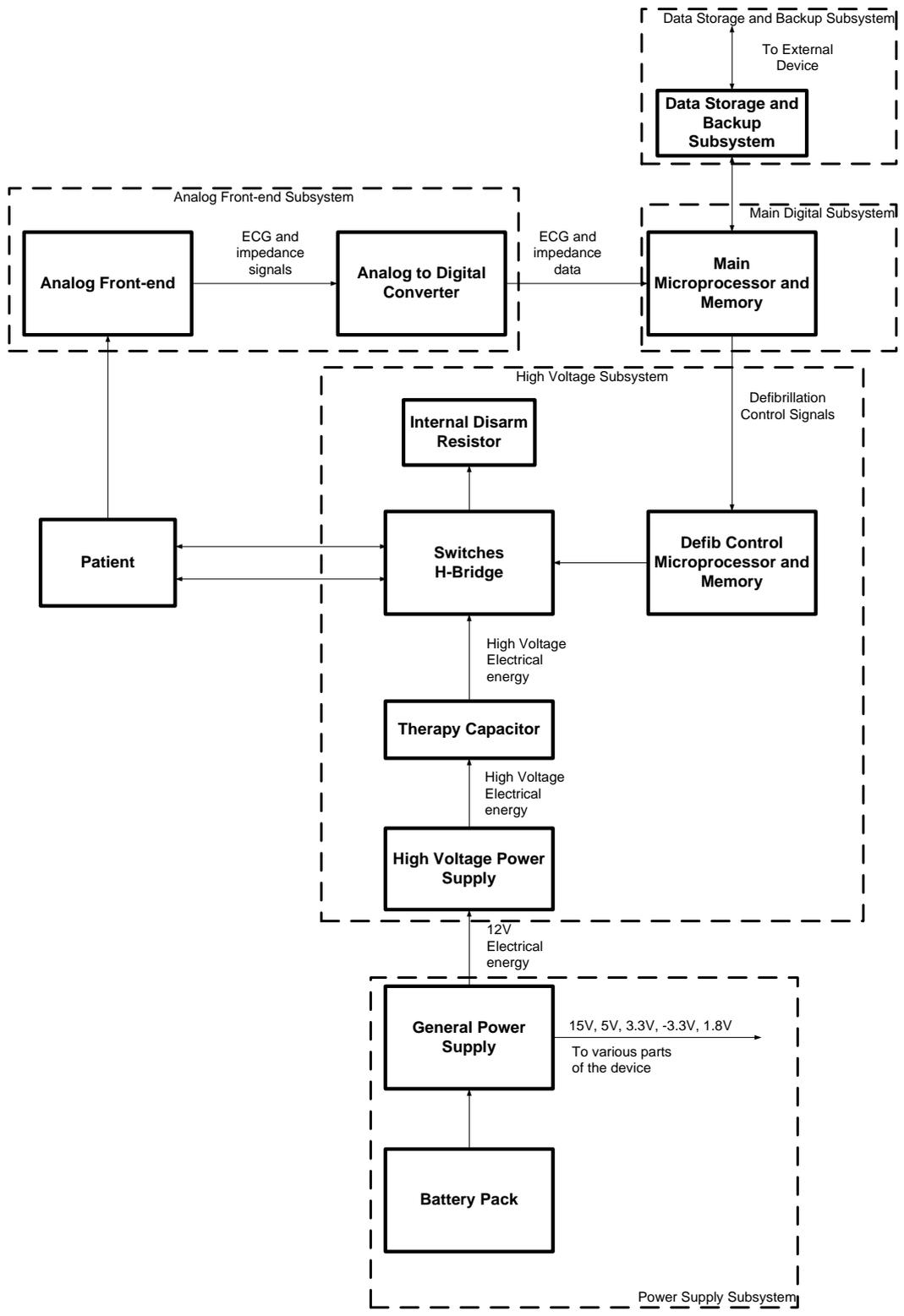
“**WARNING**” – used to denote conditions, hazards, or unsafe practices that can result in serious personal injury or death.

“**CAUTIONS**” – used to denote conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the i-PAD NF1200, or loss of data stored in it.

“**NOTES**” – used to denote items that are important during installation, operation, or maintenance of the i-PAD NF1200.

1.4 i-PAD NF1200 Device Details

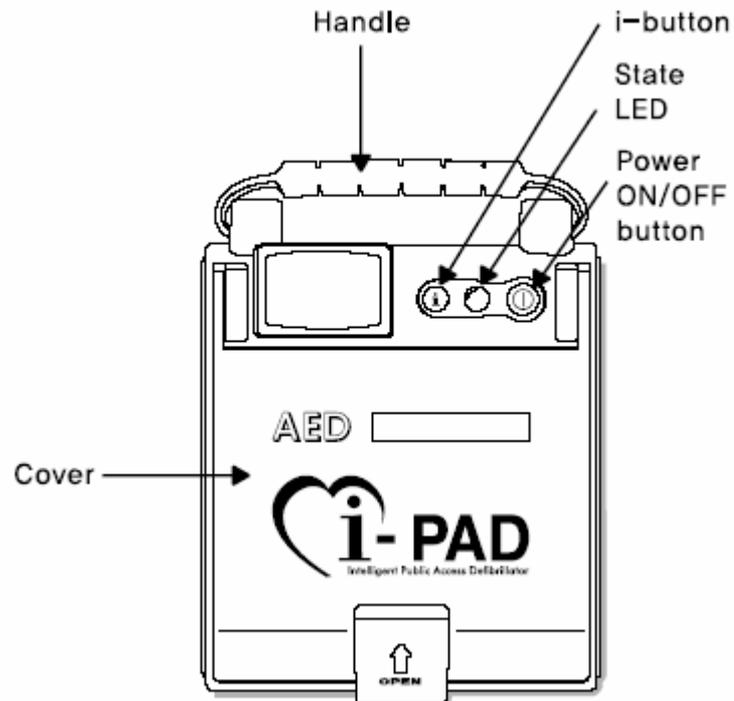
The following description and diagrams show the details of the i-PAD NF1200.



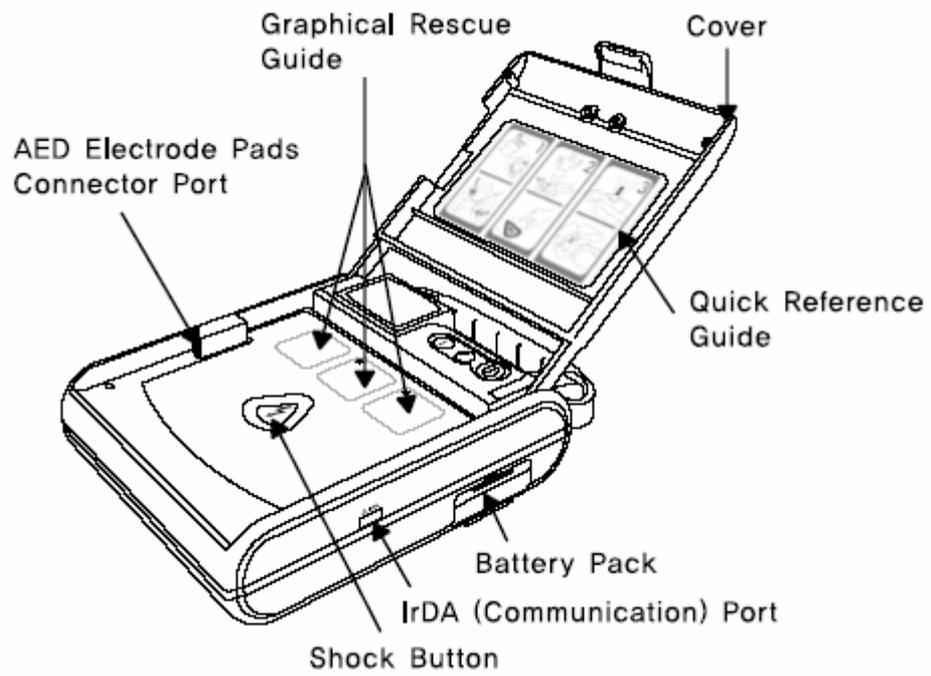
i-PAD NF1200 Functional Block Diagram

1.4.1 Operating Controls, Indicators and Accessories

1.4.1.1 Device Parts Illustration



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: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • 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". Pressing this button delivers a defibrillation shock to the patient.
AED electrode pads connector port	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.

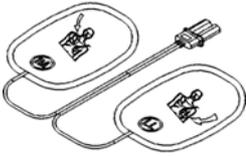
1.4.1.2 Accessories

Only parts and accessories approved by CU Medical Systems, Inc. must be used with the **i-PAD NF1200**. Using parts and accessories that are not approved by CU Medical Systems, Inc. may degrade performance.

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 NF1200**

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

Standard Accessories	
 <p>Defibrillator Electrode Pads and Connector Assembly</p>	<p>Self adhesive, pre-gelled defibrillator electrode pads used to acquire the ECG signal from the patient and to deliver the defibrillation shock to the patient.</p>
 <p>Disposable, non-rechargeable, LiMnO2 battery pack</p>	<p>Power source of the i-PAD NF1200. This battery is inside the case of the device. RETURN the i-PAD NF1200 to an authorized service representative in case the battery pack needs to be replaced.</p>
Optional Accessory	
 <p>Carrying Case</p>	<p>Used to store the i-PAD NF1200 and the accessories needed for a rescue operation.</p>

1.4.2 Voice and Text Prompts

Prompts

The i-PAD NF1200 guides you throughout a rescue operation using voice prompts and other audio-visual indicators. The following table lists the voice prompts of the i-PAD NF1200.

Table: Voice prompts and their meanings.	
Prompt	Meaning/Definition
Attach pads	<ul style="list-style-type: none"> Indicates that you have to attach the defibrillator electrode pads to the bare chest of the patient and to the i-PAD NF1200
Do not touch the patient	<ul style="list-style-type: none"> Indicates that you or any bystander must not touch the patient.
Analyzing heart rhythm	<ul style="list-style-type: none"> Indicates that the i-PAD NF1200 is analyzing the ECG of the patient. Nobody must touch the patient.
Shock advised	<ul style="list-style-type: none"> Indicates that a shockable ECG rhythm has been detected and the i-PAD NF1200 is preparing for a shock delivery.
Stand clear	<ul style="list-style-type: none"> Emphasizes the need to stay clear of the patient. Given just before the prompt to deliver shock is given.
Press the flashing orange button, now. Deliver shock, now.	<ul style="list-style-type: none"> Indicates that you have to press the shock button in order for the shock to be delivered. The shock will only be delivered if you press the shock button.
Shock delivered	<ul style="list-style-type: none"> Indicates that a shock has been delivered to the patient.
Begin CPR, now	<ul style="list-style-type: none"> Indicates the start of CPR. You may touch the patient after this prompt is given.
Push the chest down, fast, two inches	<ul style="list-style-type: none"> Indicates that you have to push the chest down for about two inches during CPR. The chest has to be pushed down fast.
Give two breaths. Breath, breath	<ul style="list-style-type: none"> Indicates that you have to give artificial breaths to the patient. Time the breaths with the breathing guide.
The shock button was not pressed	<ul style="list-style-type: none"> Indicates that you did not press the shock button within 15 seconds when the i-PAD NF1200 prompted you to do so.
No shock advised	<ul style="list-style-type: none"> Indicates that the i-PAD NF1200 detected a nonshockable rhythm.
Check pulse	<ul style="list-style-type: none"> Indicates that you have to check the pulse of the patient.
If no pulse, begin CPR	<ul style="list-style-type: none"> Indicates that if there is no pulse, you have to begin CPR.
System shutting down	<ul style="list-style-type: none"> Indicates that the ON/OFF button of the i-PAD NF1200 has been pressed to turn it OFF.
Press the flashing orange button, now	<ul style="list-style-type: none"> Given during battery insertion test. Indicates that you have to press the SHOCK button so that the i-PAD NF1200 can test its functionality.
Press the flashing blue i-Button	<ul style="list-style-type: none"> Given during battery insertion test. Indicates that you have to press the i-Button button so that the i-PAD NF1200 can test its functionality.
Administration mode	<ul style="list-style-type: none"> Indicates that the i-PAD NF1200 is in administration mode

Table: Voice prompts and their meanings, continued	
Prompt	Meaning/Definition
Device usage time is 10 minutes	<ul style="list-style-type: none"> Given during administration mode. Indicates the duration (in minutes) that the i-PAD NF1200 was ON. In this case, the i-PAD NF1200 was ON for 10 minutes during its previous usage.
Shock delivery is 4 times	<ul style="list-style-type: none"> Given during administration mode. Indicates the number of shocks that the i-PAD NF1200 delivered. In this case, the i-PAD NF1200 delivered four shocks during its previous usage.

2. Routine Maintenance

2.1 Overview

The i-PAD NF1200 does not need any routine maintenance or calibration of its internal electronic subsystems. Whenever service is necessary, please contact CU Medical Systems, Inc. or any of its authorized representatives.

2.2 Cleaning the i-PAD NF1200

After each use, clean the **i-PAD NF1200** using a soft, damp cloth moistened with any of the following solvents:

Soap and water

70% solution isopropyl alcohol

Chlorine bleach and water mixture (30 ml bleach/liter of water)

Ammonia-based cleaners

Hydrogen peroxide

CAUTION

Do not immerse any part of the i-PAD NF1200 in fluids

Do not let any fluid 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 LCD display and the infrared filter on the IrDA port.

Do not sterilize the i-PAD NF1200.

2.3 Periodic Safety and Functional Checks

It is recommended that the following periodic checks be performed to ensure that the device and its accessories are in good condition and ready for any emergency.

Maintenance Activities

Frequency	Activity	Actions to be Taken
Daily	Check the i-PAD NF1200 for any error messages that might have been generated during the Daily Periodic Self-Test.	If a message that the battery is low is displayed, recharge the battery. For any other error messages, please call the manufacturer or its designated service center.
Monthly and after each use	Check supplies, accessories, and spare parts for damage and expiration.	If any supplies have expired, replace them immediately.
	Initiate complete self-test by doing a Manual Self-Test.	If the self test detects any problem, see the chapter on Troubleshooting.
	Check the case of the i-PAD NF1200 and the accessories for any sign of apparent damage. Check for dirt contamination.	If there is any apparent damage to the case of the device, consult the manufacturer. If there is dirt contamination, clean the case as suggested in the section on Cleaning.
After each use.	Ensure that the connector of the defibrillator pad assembly is disconnected from the ECG-DEFIB port of the i-PAD NF1200 .	Disconnect the pad assembly from the ECG-DEFIB port

MAINTENANCE CHECKLIST

i-PAD NF1200

Serial Number _____ Location/Vehicle ID _____

Date			
Scheduled Frequency			
i-PAD NF1200: Clean, no signs of damage, free of excessive wear			
Supplies Available -2 sets of defibrillator electrode pads, undamaged, sealed, within expiration date -supplementary supplies (razor, scissors, gloves, gauze)			
Remarks, Problems, Corrective Actions			
Inspected by Signature of operator doing the inspection			

2.4 Batteries

The i-PAD NF1200 is equipped with LiMnO₂ battery cells. These batteries are nonrechargeable. The status of the battery charge is monitored by periodic tests (daily, weekly, monthly), power ON test, run-time test, and battery insertion test. The i-PAD NF1200 indicates through the State LED and the i-Button if the battery pack needs to be replaced.

If the voltage level of the internal Battery pack falls below the minimum tolerable level, the i-PAD NF1200 is going to be inoperative.

If this is detected during automatic self-test, the i-PAD NF1200:

- a. Flashes the State LED in red
- b. Emits a burst of beeps every minute.

When the i-PAD NF1200 is turned ON after a low battery condition is detected, the i-PAD NF1200:

- a. Turns the State LED momentarily in blue.
- b. Then turns the State LED in solid red.
- c. Flashes the i-Button in red
- d. Gives the prompt: "Press the flashing red i-Button".
- e. After the i-Button is pressed, the i-PAD NF1200 gives the prompt: "Low battery. Replace the battery with a new one."

The sequence of indications from a to e above is also given when the low battery level is detected during battery insertion test.

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.

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 NF1200.

3 Performance Verification

3.1 Self-Tests

The i-PAD NF1200 conducts automatic self-tests and a battery insertion test to verify the functionality of its subsystems. The automatic tests are conducted at Power On, Run-time, and daily, weekly, and monthly. It is important to have the battery connected to the i-PAD NF1200 all the time so that it could conduct the automatic self-tests.

The battery insertion test conducts all the tests done during automatic self-tests. You have to insert a functioning battery pack to initiate a battery insertion test.

Daily self-tests, as the name indicates, are conducted daily. A test counter is incremented whenever an automatic self-test is conducted. Reckoning of self-test timing starts whenever a battery pack is inserted. For example, if the battery pack is inserted at 11 am on January 1, the next self-test is at 11 am on January 2.

Weekly self-tests are conducted whenever the test counter is a multiple of 7 and not a multiple of 28.

Monthly self-tests are conducted whenever the test counter is a multiple of 28.

3.2 Automatic Self-Tests

When the i-PAD NF1200 conducts an automatic self-test (Daily, Weekly, Monthly), it wakes up automatically and turns the State LED solid blue during the duration of the test. It goes back to standby mode after the test.

3.3 Battery Insertion Test

Insert a functioning battery pack to initiate a battery insertion test.

3.3 Self Test Results

3.4.1 Automatic Self Tests

When no problem is detected during automatic self tests, the i-PAD NF1200 does nothing but increment the test counter. On the other hand, when a problem is detected, the i-PAD NF1200 does the following:

- a. Upon detecting the problem
 - i. Beeper emits bursts of three successive beeps. Bursts are spaced one minute apart.
 - ii. State LED flashes in red.
- b. When the i-PAD NF1200 is turned ON while the State LED is flashing in red:
 - i. The State LED turns solid blue then solid red.
 - ii. The i-Button flashes in red.
 - iii. The beeper emits a short beep and the i-PAD NF1200 gives the voice prompt: "Press the flashing red i-Button"
 - iv. After the i-Button is pressed, the beeper emits a short beep and the i-PAD NF1200 gives either of the following voice prompts: "Low battery level. Replace the battery with a new one." – if the i-PAD NF1200 detected a low battery level.
"System failure. Error code is 2". – if the i-PAD NF1200 detected a system failure. The error code is a number from 2 to 128.
 - v. The i-PAD NF1200 turns off automatically.
 - vi. The State LED flashes in red every 5 seconds and the beeper emits three successive beeps every minute to signify the occurrence of an error.

3.4.2 Battery Insertion Test

If no problem is detected, the i-PAD NF1200 activates the following indicators and voice prompts:

- a. Beeper beeps for 1 second. State LED turns ON in blue for the duration of the self-test.
- b. Shock button flashes in orange. At the same time, the i-PAD NF1200 gives the voice prompt: "Press the flashing orange button, now". The voice prompt is looped until the shock button is pressed. Beeper emits a short beep when the flashing shock button is pressed.
- c. After the shock button is pressed, the i-Button backlight flashes in blue. At the same time, the i-PAD NF1200 gives the voice prompt: "Press the flashing blue i-Button". The voice prompt is looped until the i-Button is pressed. Beeper emits a short beep when the flashing i-Button is pressed.
- d. After the i-Button is pressed, the State LED turns OFF then flashes in green three times to signify the end of the battery insertion test. The State LED then flashes every 5 seconds to signify that it is in standby mode.

If a problem is detected, the i-PAD NF1200 activates the following indicators and voice prompts:

- a. i-Button turns ON in blue.
- b. Beeper emits bursts of three successive beeps. Bursts are spaced one minute apart. State LED flashes in red. Flashes are spaced 5 seconds apart.
- c. When the power is turned ON, the State LED turns solid blue then solid red. The i-Button flashes in red, the beeper emits a short beep, and the i-PAD NF1200 gives the voice prompt: "Press the flashing red i-Button."
- d. After you press the flashing red i-Button, the beeper emits a short beep and the i-PAD NF1200 gives any of the following voice prompts
 "Low battery level. Replace the battery with a new one" – given if the cause of the error is low battery level
 "System failure. Error code is 2" – given if the cause of the error is a system error. The error code is a number between 2 and 128.
- e. The i-PAD NF1200 turns OFF automatically.
- f. The State LED flashes in red every 5 seconds and the beeper emits three successive beeps every minute to signify the occurrence of an error.

The list of ERRORS and the corresponding meanings are given in the following table.

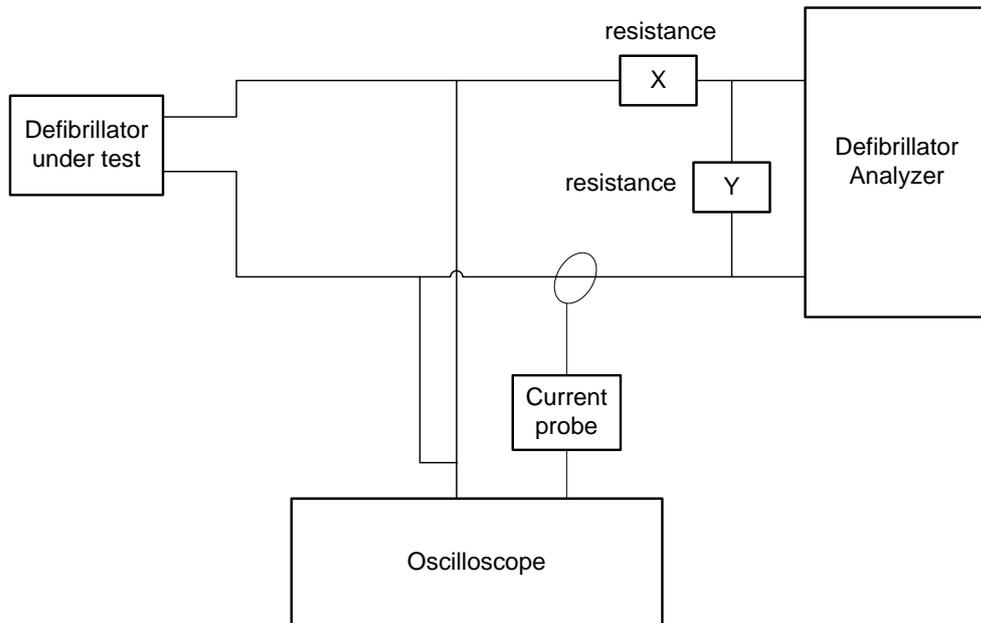
Table: Self-Test Error Codes			
Error Name	Error Code	Fault	Remedial Action
LOW BATTERY	0001	Low battery charge	Replace the battery pack with a new one.
SYSTEM ERROR	0002	ROM chip 1 fault	See Troubleshooting in Chapter 4
SYSTEM ERROR	0004	ROM chip 2 fault	See Troubleshooting in Chapter 4
SYSTEM ERROR	0016	Error in communication between the main and HV micros	See Troubleshooting in Chapter 4
SYSTEM ERROR	0032	Charging failure	See Troubleshooting in Chapter 4
SYSTEM ERROR	0064	Discharging failure	See Troubleshooting in Chapter 4
SYSTEM ERROR	0128	Disarming failure	See Troubleshooting in Chapter 4

3.5 Shock Waveform Verification Test

Equipment needed

Defibrillator Analyzer with energy measurement function	
Oscilloscope with high voltage probes (up to 2500 V capacity) and current probe (up to 100 A capacity)	
Various 100-Watt resistances	X 25Ω 1% 100W Wire-Wound 50Ω 1% 100W Wire-Wound 100Ω 1% 100W Wire-Wound 125Ω 1% 100W Wire-Wound 150Ω 1% 100W Wire-Wound
	Y 50Ω 1% 100W Wire-Wound

Test Setup



Test Procedure

1. Set the load impedance from 25Ω to 175Ω. As most defibrillator analyzers have only 50Ω of load impedance, achieve the other values by varying resistances X and Y. For example, if the defibrillator analyzer has a 50Ω impedance, to get a total impedance load of 25Ω, short resistance X and set resistance Y to 50Ω.
2. Connect the defibrillator analyzer to the i-PAD NF1200 (DUT – defibrillator under test) using banana-type connectors (defibrillator side end – defibrillator electrode pads connector, analyzer side end – banana-type connector).
3. Adjust the values of resistances X and Y (hereinafter to be referred as the load adjustment network) to achieve the desired impedance load.
4. Hook the current probe to the connector between the DUT and the impedance load adjustment network.
5. Connect the high voltage probe to the connector as shown in the test setup above.
6. Set the output of the i-PAD NF1200.
7. Set the defibrillator analyzer to output a shockable rhythm.
8. Set the defibrillator analyzer to measure the energy of the DUT output.
9. Set the oscilloscope for a single sequence operation and set the trigger level accordingly.
10. Set the oscilloscope horizontal scale to 4 ms/div. Set the vertical scale so that the oscilloscope could accommodate at least 4000 V peak to peak.
11. Turn the setup ON.
12. Press the shock button when prompted in order to deliver the shock.

After the test, there must be measurements for all the combinations in the following matrix.

		Output, Energy in Joules
		200
Impedance Load Ω	25	
	50	
	75	
	100	
	125	
	150	
	175	

13. Verify that the energy of the shock delivered is within ±15% of 200 Joules.
14. Verify from the oscilloscope display that a biphasic shock waveform is delivered.

3.6 Data Transmission Test

The i-PAD NF1200 is capable of transmitting data that has been recorded during a rescue operation to a personal computer. The transfer of data to a personal computer is necessary if it is desired to archive the data recorded during rescue operations. The SmartMedia card or the internal memory flash is overwritten during a rescue operation. The data in the data memory will no longer be accessible once it has been overwritten.

The data is transferred to a personal computer through the use of CU Expert; a Windows based ECG Data Management Software that is designed to run in the personal computer.

Test Procedure

Equipment needed

Personal Computer running CU Expert

IrDA Com-Port Serial Adapter

Defibrillator Analyzer

1. Connect the Defibrillator Analyzer to the i-PAD NF1200. Set the defibrillator analyzer to output a 60 bpm normal sinus rhythm ECG waveform.
2. Let the setup run for at least 1 minute.
3. Turn the setup OFF.
4. Disconnect the defibrillator analyzer from the i-PAD NF1200
5. Connect the i-PAD NF1200 to the personal computer through any desired COM Port using the IrDA Com-Port Serial Adapter.
6. Set the options of the CU Expert for a data reception in accordance with the instructions in its user's manual. Do not begin data reception yet.
7. Set the CU Expert to begin data reception.
8. Go back to the i-PAD NF1200. While in standby mode, press the i-Button.
9. The i-PAD NF1200 announces Last-Use-Data.
10. After Last-Use-Data announcement, the i-PAD NF1200 tries to sense for a connection with a personal computer.
11. When a connection is sensed, the i-PAD NF1200 proceeds with data transmission.
12. Monitor the progress of the data transmission in the CU Expert.
13. Disconnect the i-PAD NF1200 from the personal computer when the data transmission is finished.
14. Go to the personal computer and open the data file received from the i-PAD NF1200. Verify that the 60 bpm normal sinus rhythm ECG waveform is correctly transmitted. Verify that the QRS peaks are 1 second apart.

3.7 Impedance Measurement Test

The i-PAD NF1200 is designed to work on patients with transthoracic impedances that fall within the range of 25Ω to 175Ω. Beyond this range, the i-PAD NF1200 does not proceed with ECG analysis.

Test Procedure

Equipment needed

Variable resistive impedance load (10Ω to 200Ω) with 5Ω steps

1. Connect the i-PAD NF1200 to the variable resistive impedance load.
2. Set the impedance of the variable resistive impedance load to 10Ω.
3. Turn the i-PAD NF1200 ON.
4. Verify that the i-PAD NF1200 does not go beyond the prompt "ATTACH PADS". The i-PAD NF1200 senses that the impedance is outside the acceptable limits and it interprets the situation as having the pads not attached to the patient.
5. Turn the i-PAD NF1200 OFF.
6. Do steps 2 to 5. Vary the setting in step 2 from 10Ω to 200Ω.
7. Verify that the i-PAD NF1200 does not go past the prompt "ATTACH PADS" when the impedance load is beyond the range 25Ω to 175Ω.
8. Verify that the i-PAD NF1200 goes through ECG analysis in when the impedance load is within the range of 25Ω to 175Ω.

3.8 Voice and Text Prompt Testing

The i-PAD NF1200 is designed to guide the operator during rescue operations through voice prompts. The voice and text prompts indicate the status of the rescue operation and the actions that the operator and bystanders must do during a rescue operation.

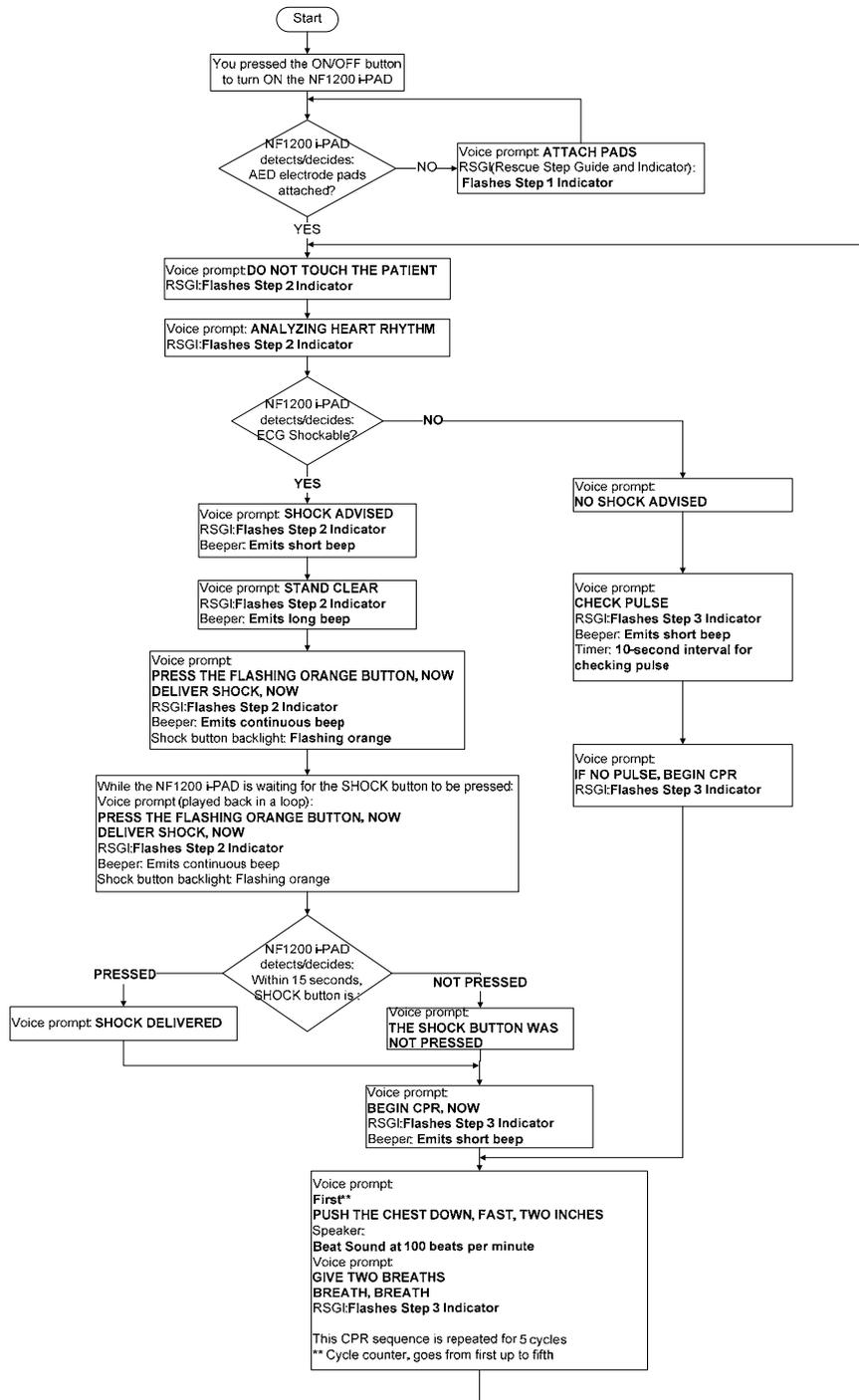
Test Procedure

Equipment needed

Defibrillating ECG Pads Assembly

Defibrillator Analyzer

1. Set the defibrillator analyzer to output an 80 bpm, 1 mV normal sinus rhythm ECG waveform. Connect the i-PAD NF1200 to the defibrillator analyzer.
2. Verify that the i-PAD NF1200 goes through the protocol shown in the figure in the next page.



i-PAD NF1200 Rescue Protocol

4 TROUBLESHOOTING

4.1 How to Use This Section

This section explains how to identify the causes of problems that may occur during the lifetime of the i-PAD NF1200. Use this section in conjunction with the sections on Performance Verification and Disassembly Guide.

4.2 Who Must Perform Repairs

Only authorized personnel must service the device. Unauthorized personnel must not open the case of the i-PAD NF1200 or the cover of its battery compartment.

4.3 Replacement Level Supported

Due to the high density of surface mount components, CU Medical Systems, Inc. recommends that all repairs shall be done on the printed circuit board (PCB) level. It is not recommended to replace individual components on the PCBs with the exception of easy to replace items like fuses.

4.4 Troubleshooting Guide

Failure: i-PAD NF1200 does not turn ON

Possible Causes		Action(s)
1	Low Battery Charge This condition is detectable by the self - tests.	<ul style="list-style-type: none">• Perform a battery insertion test using a new battery pack.
2	Discontinuity between the battery pack and the power board	<ul style="list-style-type: none">• Check the condition of the battery pack contact spring J8 on the power board. If damaged, replace the spring.
3	The fuse between the battery pack and the Power supply subsystem is busted	<ul style="list-style-type: none">• Check fuse F1 or F2• Replace if busted• Do not use any fuse other than the one recommended by the manufacturer.
4	Power Switch failure	<ul style="list-style-type: none">• Check the operation of the ON/OFF switch SW2 on the main PCB board. Check that the poles are shorted when the switch is pressed.• Replace the switch if there is a fault.
5	Power subsystem fault	<ul style="list-style-type: none">• Change the main power board. If the problem persists, replace the original power board and contact the manufacturer.

Failure: Failure detected during Automatic or Manual Self Tests. ERROR code given through voice prompt.

Table: Self-Test Error Codes			
Error Name	Error Code	Fault	Remedial Action
LOW BATTERY	0001	Low battery charge	Replace the battery pack with a new one.
SYSTEM ERROR	0002	ROM chip 1 fault	Replace the main PCB board
SYSTEM ERROR	0004	ROM chip 2 fault	Replace the main PCB board
SYSTEM ERROR	0016	Error in communication between the main and HV micros	<ul style="list-style-type: none"> • Check the continuity of the flat cable connector between terminal J3 on the main PCB board and terminal J7 on the power board. If there is a fault, change the connector. • If the problem is not with the flat cable connector, change the power board. • If the problem is not with the cable connector and the power board, change the main PCB board.
SYSTEM ERROR	0032	Charging failure	<ul style="list-style-type: none"> • Replace the power board. • If the problem is not with the power board, replace the main PCB.
SYSTEM ERROR	0064	Discharging failure	<ul style="list-style-type: none"> • Replace the power board. • If the problem is not with the power board, replace the main PCB.
SYSTEM ERROR	0128	Disarming failure	<ul style="list-style-type: none"> • Replace the power board. • If the problem is not with the power board, replace the main PCB.

Failure: The i-PAD NF1200 does not go beyond the “ATTACH PADS” prompt even though it is connected to the patient.

Possible Causes		Action
1	Pads are not properly attached to the patient.	Attach the pads firmly. Make sure that the skin surface is clean and dry.
2	Pads are defective.	Verify that there is no apparent damage to the pads. Verify that the gel of the pads has not dried out. Verify that the connector from the pads to the ECG-DEFIB port is not damaged.
3	Failure of the connector between the ECG-DEFIB port and the power board	Verify the continuity of the connector between the ECG-DEFIB port and the power board. If there is a fault in the connection, replace the ECG-DEFIB port assembly.
4	Impedance signal path failure in the power board.	Replace the power board with a new one. Check the operation of the i-PAD NF1200 by doing either of the following: <ul style="list-style-type: none"> a. Connect the i-PAD NF1200 to an AED analyzer. Set the analyzer to output a normal sinus rhythm (any rate between 40 and 150 bpm). Verify that the i-PAD NF1200 goes past the “ATTACH PADS” prompt. b. Connect a 50Ω resistor across the ECG-DEFIB port. Verify that the i-PAD NF1200 goes past the “ATTACH PADS” prompt. If the problem persists after the replacement of the power board, put the original power board back in place.
5	Failure of the connector between the power board (J5 and J6 connectors) and the main PCB (J4 and J5 connectors)	Verify the continuity of the connectors. Replace the connector if there is a fault.
6	Failure of the impedance measuring subsystem.	Replace the front end analog subsystem hybrid integrated circuit. Verify the operation of the i-PAD NF1200 by doing the verification steps in possible cause no. 4 above.
7	Impedance signal path failure in the main board.	Replace the main board with a new one. Verify the operation of the i-PAD NF1200 by doing the verification steps in possible cause no. 4 above. If the problem persists, contact the manufacturer.

Failure: No voice prompt is heard when the i-PAD NF1200 is used.

Possible Causes		Action
1	Speaker failure	Replace the speaker. Verify that the problem is solved by turning the i-PAD NF1200 ON. The voice prompt to "ATTACH PADS" should be heard.
2	J1 header of the wire to board connector on the main PCB is loose (this is the header that receives the wire coming from the speaker)	Check the connection of the J1 header. Repair the solder connection if it is loose.
3	Audio circuit failure; Microprocessor audio codec interface failure	Change the main PCB. Verify the solution by doing the verification step in possible cause no. 1. If the problem is not solved, contact the manufacturer.

Failure: Beeper is not working.

Possible Causes		Action
1	Beeper failure	Replace the Beeper. Verify that the problem is solved by running the i-PAD NF1200 with a Ventricular Fibrillation input from a defibrillator analyzer. Verify that the beeper emits beeps after the charging of the capacitor and during the time when the SHOCK button has to be pressed.
2	Beeper controller failure	Replace the main board. Verify the solution by doing the verification step in possible cause no. 1. If the problem is not solved, contact the manufacturer.

Failure: No shock is delivered when the SHOCK button is pressed after the i-PAD NF1200 issues the prompt to “PRESS THE FLASHING ORANGE BUTTON, NOW. DELIVER SHOCK, NOW”.

Possible Causes		Action
1	SHOCK button failure.	Verify the operation of the SHOCK button by checking the continuity of the poles of SW4 when it is pressed. If the poles are not continuous when the SHOCK button is pressed (SW4), replace SW4 with a new one.
3	Keypad controller failure;	Replace the main PCB with a new one. Verify the solution by running the i-PAD NF1200 with a Ventricular Fibrillation input from a defibrillator analyzer. Verify that a shock is delivered when the SHOCK button is pressed after the i-PAD NF1200 issues the prompt to “PRESS THE SHOCK BUTTON”.
4	Failure of connector between the main PCB (J3) and the power board (J7).	Verify the continuity of the connector between the main board and the power board. If a fault exists, replace the connector with a new one. Verify the solution by running the verification test in possible cause no. 3 above.
5	High voltage subsystem failure.	Replace the power board with a new one. Verify the solution by running the verification in possible cause no. 3 above. If the problem persists, put the original power board back.
6	Defibrillating capacitor failure.	Replace the defibrillating capacitor with a new one. Verify the solution by running the verification step in possible cause no. 3 above. If the problem persists, put the original defibrillating capacitor back and contact the manufacturer.

Failure: Incorrect ECG Review: The ECG displayed during ECG review is not the same as the ECG recorded.

Possible Causes		Action
1	ECG review only: Internal flash memory chip failure.	Replace the main board with a new one. Verify that the solution works by doing the following: <ul style="list-style-type: none"> a. Turn the i-PAD NF1200 with a normal sinus rhythm input from a defibrillator analyzer. b. Let the i-PAD NF1200 run for at least 2 minutes. c. Turn the i-PAD NF1200 OFF. Disconnect the defibrillator analyzer then turn the i-PAD NF1200 ON. d. Transfer data to a personal computer (PC) using CU Expert and verify that the data recorded is the same as the data displayed in the CU Expert.

Failure: Automatic periodic self- tests are not running

Possible Causes		Action
1	Battery pack is not inserted into the i-PAD NF1200 during storage	Verify that the battery pack is inserted into the i-PAD NF1200 during storage. Turn the i-PAD NF1200 and verify that it turns ON. Insert the battery pack if it is not inserted.
2	Real time clock battery is dead.	The real time clock chip is powered by a separate 3V Toshiba Coin Battery (CR1220) (BT1 on the main PCB). If the coin battery voltage falls below 2.5 V, replace it with a new one.
3	Real time clock chip failure	Replace the main board. Verify the solution by making the i-PAD NF1200 conduct automatic self-tests. If the problem persists, put the original main board back and contact the manufacturer.

Failure: The i-PAD NF1200 keeps incorrect date and time.

Possible Causes		Action
1	Real time clock chip battery failure.	Replace the dedicated real time clock battery cell. Verify the solution by doing the following: <ol style="list-style-type: none"> 1. Synchronize the i-PAD NF1200 with a clock using the CU Expert. 2. Turn the i-PAD NF1200 OFF. 3. After one hour, determine the time setting of the i-PAD NF1200 using the CU Expert. Verify that the time indicated is synchronized with the clock used in step 1.
2	Real time clock chip failure; Microprocessor failure	Replace the main PCB. Verify the solution by doing the verification steps in possible cause no. 1 above.

Failure: No data transmitted when transferring data to a PC.

Possible Causes		Action
i-PAD NF1200 side		
1	IrDA transceiver is out of range	Verify that the IrDA transmitter is within range of the IrDA port of the i-PAD NF1200. The transmitter of the COM Port Serial Adapter should be within 5 to 30 cm away from the IrDA port of the i-PAD NF1200. The transmitter must also be within $\pm 15^\circ$ of the horizontal plane passing through the IrDA port of the i-PAD NF1200.
2	Transmission done in the presence of intense ambient light	Verify that data transmission is not done in the presence of intense ambient light. Intense ambient light will interfere with data transmission through the IrDA port.
3	Transmission done in the presence of strong vibration	Verify that data transmission is not done in the presence of strong vibration. Strong vibration will interfere with data transmission through the IrDA port.
4	Pathway between the IrDA port and the IrDA COM Port Serial Adapter is blocked	Verify that the pathway between the IrDA port of the i-PAD NF1200 and the IrDA COM Port Serial Adapter is not blocked.
5	IrDA COM Port Serial Adapter failure	Replace the IrDA COM Port Serial Adapter
6	IrDA port controller failure	Replace the main board.
PC side		
8	Incorrect COM Port setting	Verify that the COM Port set on the Options dialog of the CU Expert matches the PC COM Port that is used to connect with the i-PAD NF1200.
9	Incorrect baud rate setting	Verify that the baud rate setting on the Options dialog of the CU Expert is compatible with the baud rate capabilities of the PC. If you are not sure about the baud rate capabilities of the PC, try the baud rate setting options one by one.
10	No key file; key file does not match the i-PAD NF1200	Ensure that the key file for the particular i-PAD NF1200 that you are using is in the key file folder of the CU Expert. The key files are device specific. If you do not have the key file, you should get it from CU Medical Systems, Inc.
11	CU Expert is corrupted	Uninstall then reinstall the CU Expert.

5 Disassembly and Repair

This section is a guide on how to disassemble and reassemble the i-PAD NF1200. Do not attempt to disassemble the i-PAD NF1200 if you have not received any training on servicing the device.

DANGER

The energy stored in the defibrillating capacitor of the i-PAD NF1200 is lethal. The voltage across the capacitor reaches more than 1500V during operation.

The i-PAD NF1200 is designed to dump the charge in the defibrillating capacitor if the SHOCK button is not pressed 15 seconds after a prompt to press the shock button is given. It is also designed to dump the charge if it is turned OFF while the defibrillating capacitor contains a charge. Thus, under normal circumstances, no charge will be stored in the defibrillating capacitor if it is turned OFF. However, in cases when the device malfunctions, the internal dumping functionality of the device might be impaired.

When the device is opened for servicing, be sure to discharge any charge that may still be in the defibrillating capacitor.

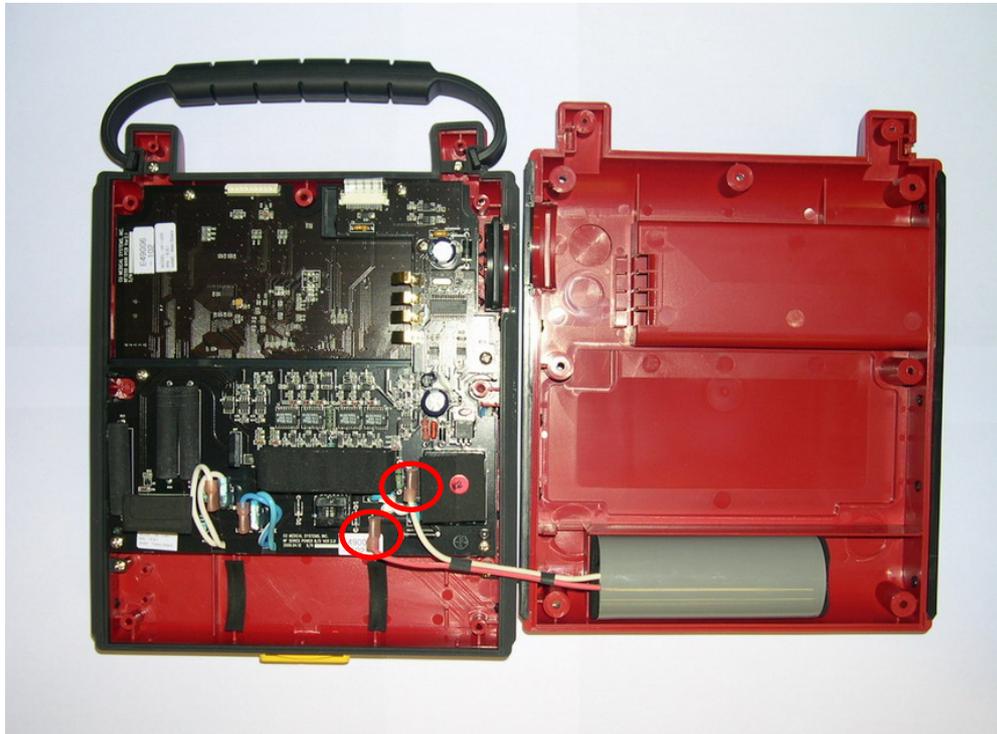
Discharge the defibrillating capacitor by placing a 10 Watt 50 Ohm resistor across its terminals.

5.1 Disassembly

1. Remove the battery pack from its receptacle.
2. Remove the screws at the bottom of the chassis of the device. These screws hold the top and bottom cases of the device together. The locations of the screws are shown encircled in the figure below.



3. Lift the bottom cover. After lifting the bottom cover, you will see the following:



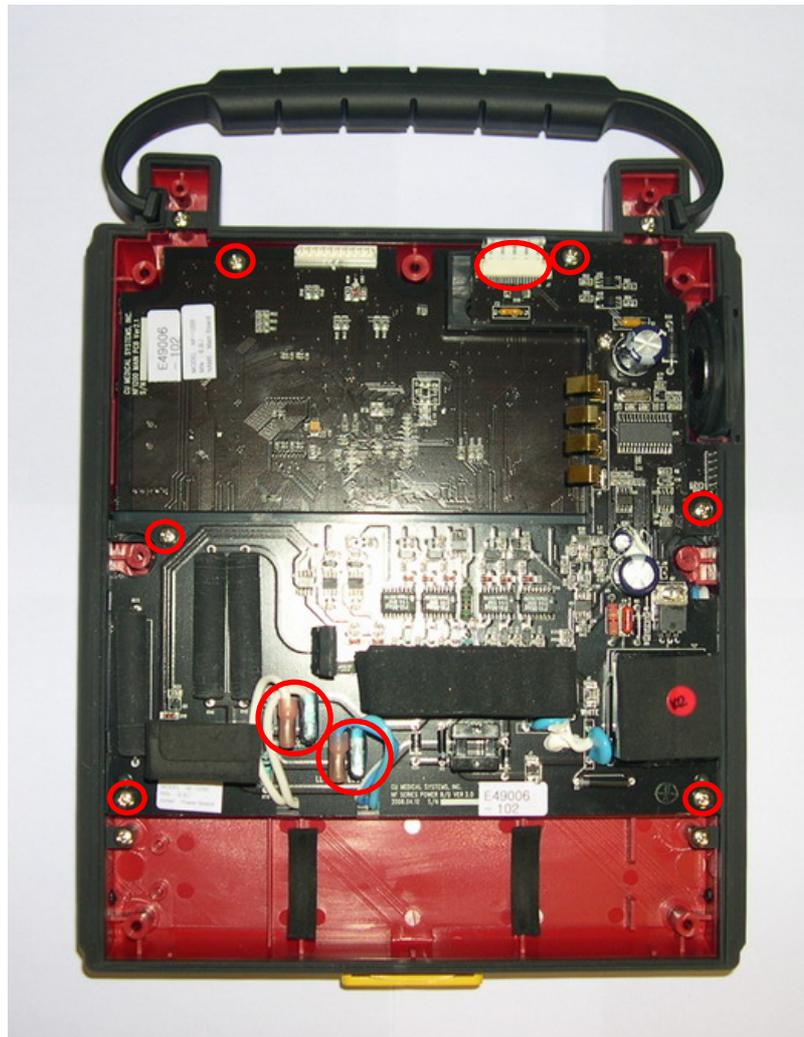
Discharge the defibrillating capacitor. Disconnect the defibrillating capacitor connector shown encircled above.

⚠ WARNING

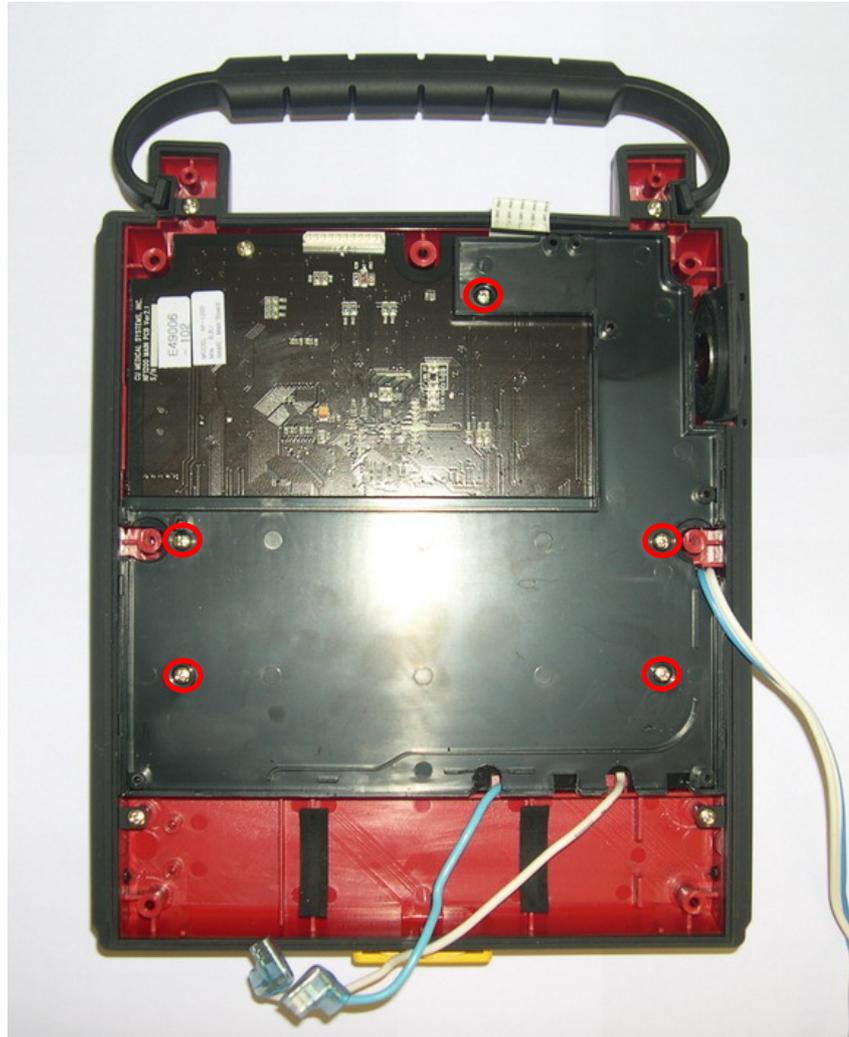
The **ENERGY** stored in the **DEFIBRILLATING CAPACITOR** is **LETHAL**.

To prevent any chance of unintentional **SHOCK**, the **DEFIBRILLATING CAPACITOR** **MUST BE DISCHARGED** before handling

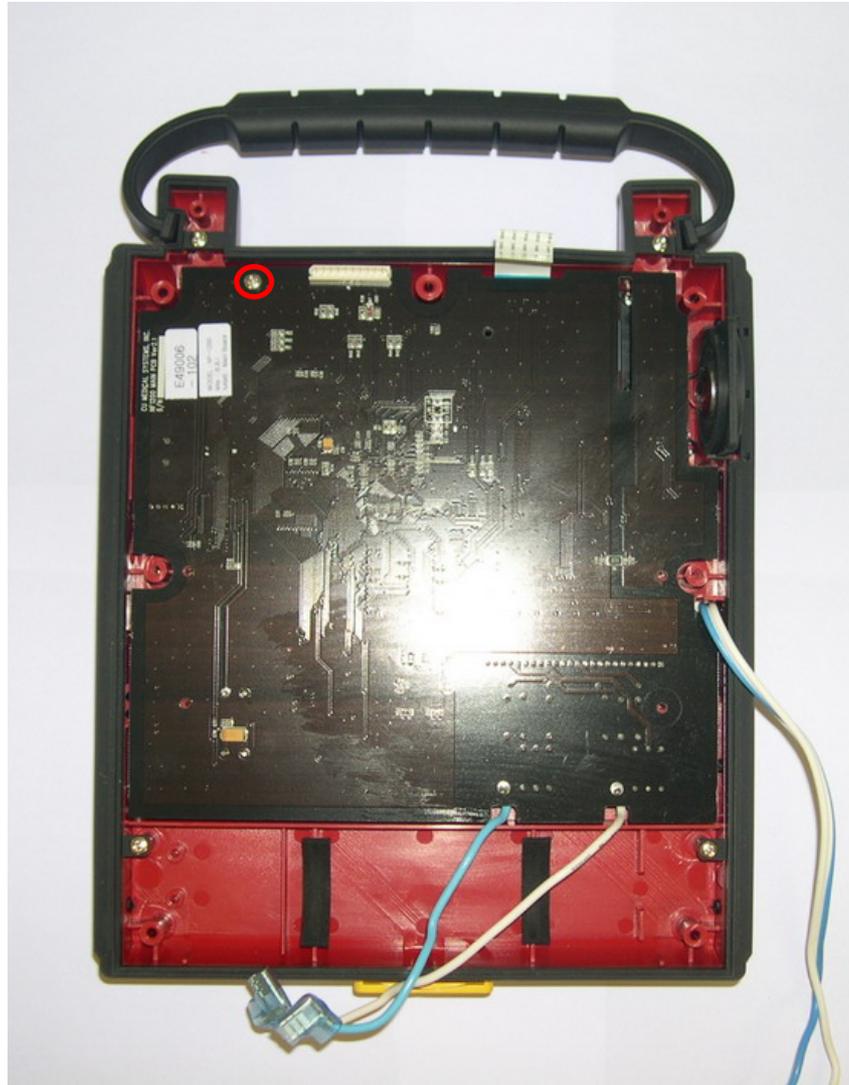
4. Disconnect the flat printed cable connection between the power board and the main board. Disconnect the connectors between the power board and the ECG-Defib port and the ECG Hybrid circuit. Remove the screws that hold down the power board. These are encircled in the picture below.



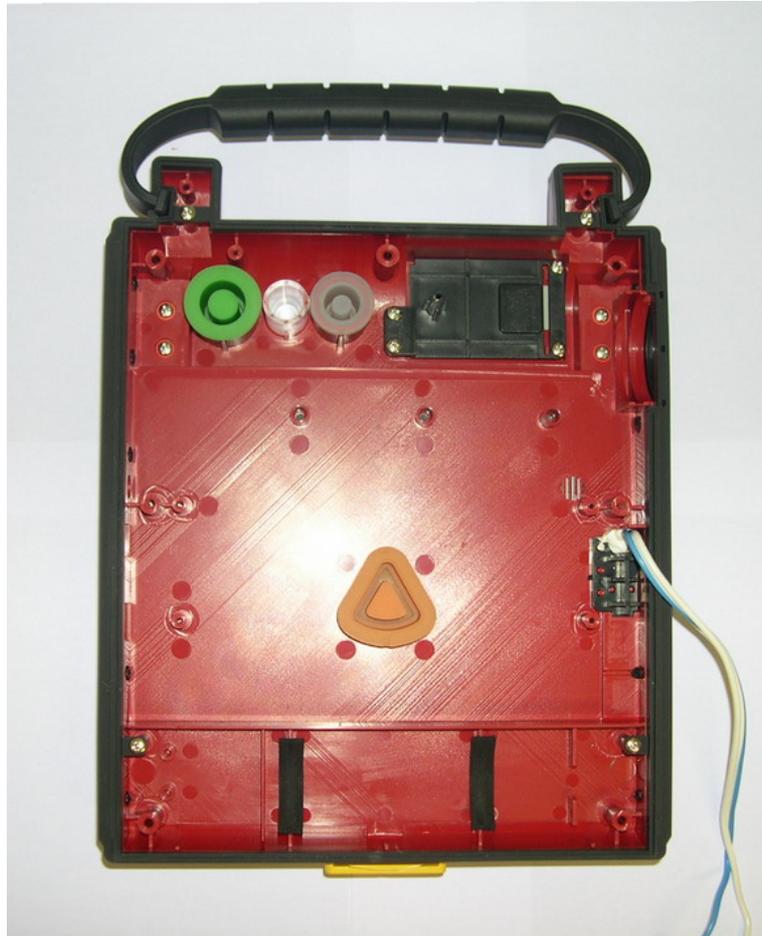
5. Lift the power board.
6. Remove the insulator between the power board and the main PCB board by removing the screws encircled in the picture below.



7. Remove the screw that holds the main PCB board to the i-PAD NF1200 chassis. This screw is shown encircle below. Then lift the main PCB board off the chassis.



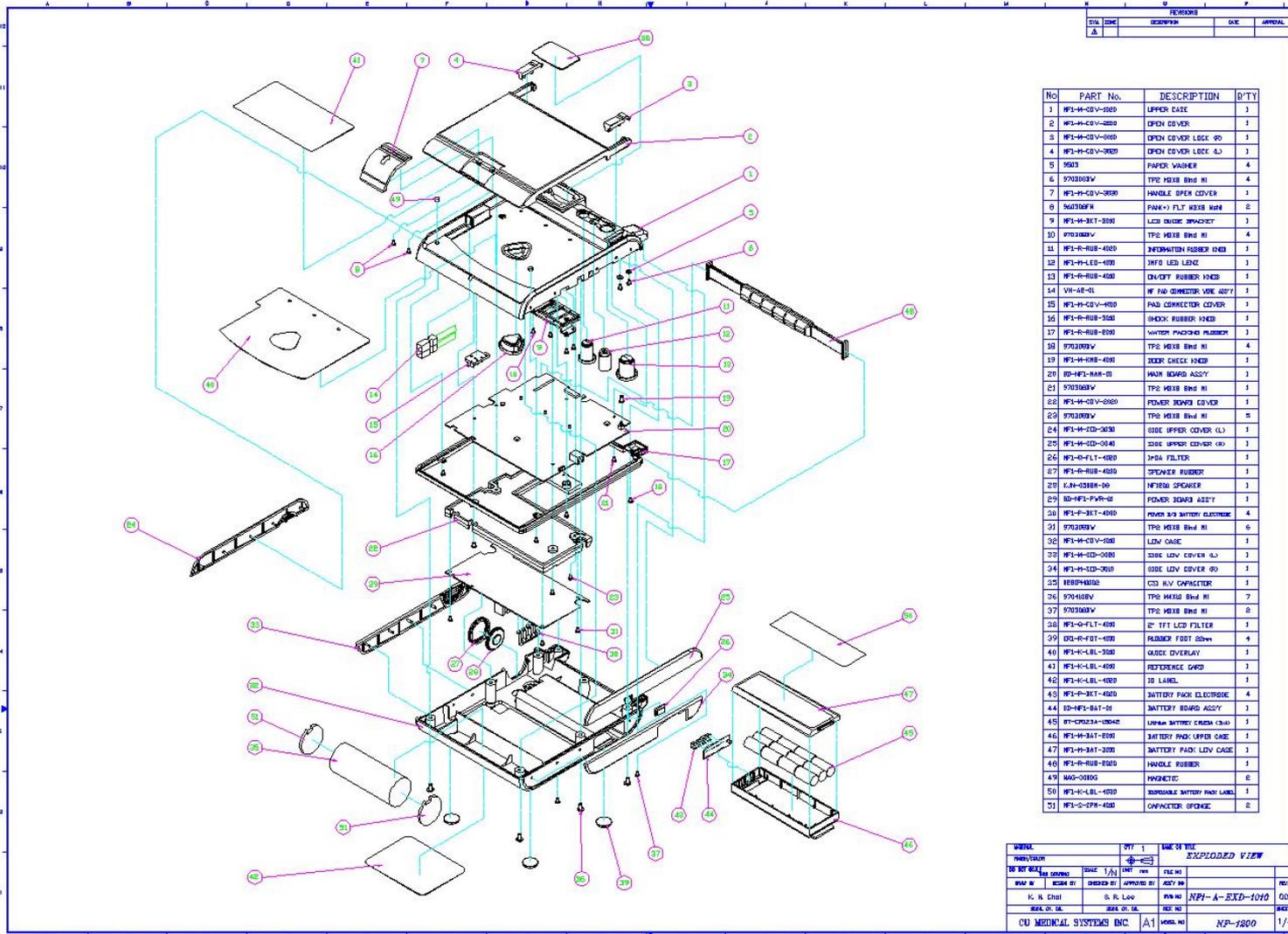
8. You will see the top case after you lift up the main PCB board. This is shown in the picture below.



5.2 Reassembly

1. Reverse the disassembly process. Place the boards and the screws and reconnect the connectors in reverse order of the disassembly process.

6 Assembly Diagram



REVISIONS			
REV	DESCRIPTION	DATE	APPROVAL
A			

No	PART No.	DESCRIPTION	QTY
1	NP1-M-COV-3000	UPPER CASE	1
2	NP1-M-COV-3000	OPEN COVER	1
3	NP1-M-COV-3000	OPEN COVER LOCK RD	1
4	NP1-M-COV-3000	OPEN COVER LOCK LD	1
5	5003	PAPER WASHER	4
6	5703000V	TPE HEX6 BSHd RI	4
7	NP1-M-COV-3000	HANDLE OPEN COVER	1
8	1603000H	PAK(+) FLT HEX6 WHN	2
9	NP1-M-3ET-3000	LED INDIC IMPACTKEY	1
10	5703000V	TPE HEX6 BSHd RI	4
11	NP1-R-RUB-4000	INFORMATION RUBBER INHD	1
12	NP1-R-LED-4000	INFO LED LENS	1
13	NP1-R-RUB-4000	ON/OFF RUBBER INHD	1
14	VR-48-01	RF PAD CONNECTOR VIBE ASSY	1
15	NP1-R-RUB-4000	PAD CONNECTOR COVER	1
16	NP1-R-RUB-3000	SHOCK RUBBER INHD	1
17	NP1-R-RUB-8000	WATER PACKING RUBBER	1
18	5703000V	TPE HEX6 BSHd RI	4
19	NP1-M-RIB-4000	LOCK CHECK INHD	1
20	SD-NP1-MAR-01	MAIN BOARD ASSY	1
21	5703000V	TPE HEX6 BSHd RI	1
22	NP1-M-COV-2000	POWER BOARD COVER	1
23	5703000V	TPE HEX6 BSHd RI	15
24	NP1-M-SD-0000	SIDE UPPER COVER (L)	1
25	NP1-M-SD-0000	SIDE UPPER COVER (R)	1
26	NP1-R-FLT-4000	HPA FILTER	1
27	NP1-R-RUB-4000	SPEAKER RUBBER	1
28	LIN-0300N-00	MPHSP SPEAKER	1
29	SD-NP1-PWR-01	POWER BOARD ASSY	1
30	NP1-P-3ET-4000	POWER 3/2 BATTERY ELECTRODE	4
31	5703000V	TPE HEX6 BSHd RI	6
32	NP1-M-COV-1000	LOW CASE	1
33	NP1-M-SD-0000	SIDE LOW COVER (L)	1
34	NP1-M-SD-0000	SIDE LOW COVER (R)	1
35	180000000	CO3 0.1V CAPACITOR	1
36	5703000V	TPE HEX6 BSHd RI	7
37	5703000V	TPE HEX6 BSHd RI	2
38	NP1-G-FLT-4000	2" TFT LCD FILTER	1
39	DD-R-FIT-4000	RUBBER FOOT 20mm	4
40	NP1-R-LBL-3000	GUIDE OVERLAY	1
41	NP1-R-LBL-4000	REFERENCE CARD	1
42	NP1-R-LBL-4000	IS LABEL	1
43	NP1-P-3ET-4000	BATTERY PACK ELECTRODE	4
44	SD-NP1-BAT-01	BATTERY BOARD ASSY	1
45	BT-CR023A-120042	LIPOH BATTERY CR023A (3.6V)	1
46	NP1-M-BAT-8000	BATTERY PACK UPPER CASE	1
47	NP1-M-BAT-3000	BATTERY PACK LOWER CASE	1
48	NP1-R-RUB-3000	HANDLE RUBBER	1
49	1603-0000	MAGNETIC	2
50	NP1-R-LBL-4000	REPERABLE BATTERY PACK LABEL	1
51	NP1-S-07H-4000	CAPACITOR SPONGE	2

REVISION	REV	DATE	BY	CHKD	EXPLODED VIEW
	A				
DESIGNED BY	DATE	APP'D BY	DATE	REV	
DESIGNED BY	DATE	DESIGNED BY	DATE	REV	
K. H. Choi	S. R. Lee	REV NO	NP1-A-EXD-1010	00	
DATE OF DL	DATE OF DL	REV NO			
CU MEDICAL SYSTEMS INC	A1	ISSUE NO	NP1-1800	1/1	

TECHNICAL SPECIFICATIONS

Physical

Category	Nominal Specifications
Size	2.75 in high X 8.66 in wide X 10.23 in deep (70 mm high X 220 mm wide X 260 mm deep)
Weight	Approximately 4.84 lbs (2.2 kg) with battery pack installed

Environmental

Category	Nominal Specifications	
Operating Conditions	Temperature	32 °F to 104 °F (0 °C to 40 °C)
	Humidity	5 % to 95 % (non-condensing)
Standby Conditions (Ready for rescue, stored together with AED Pads)	Temperature	32 °F to 109 °F (0 °C to 43 °C)
	Humidity	5 % to 95 % (non-condensing)
Storage Conditions (device only, no AED pads)	Temperature	-4 °F to 140 °F (-20 °C to 60 °C)
	Humidity	5 % to 95 % (non-condensing)
Altitude	Operating: 0 to 15,000 feet Storage: 0 to 15,000 feet	
Shock/Drop/Abuse Tolerance	Withstands 1.2-meter drop to any edge, corner, or surface MIL-STD-810F Method 516.5, Procedure IV	
Vibration	Meets MIL-STD-810F Method 514.5 <ul style="list-style-type: none"> • Road Transportation • Air Transportation • Road Operation • Helicopter Minimum Integrity Test 	
Sealing	IEC 60529: IP43	
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)	

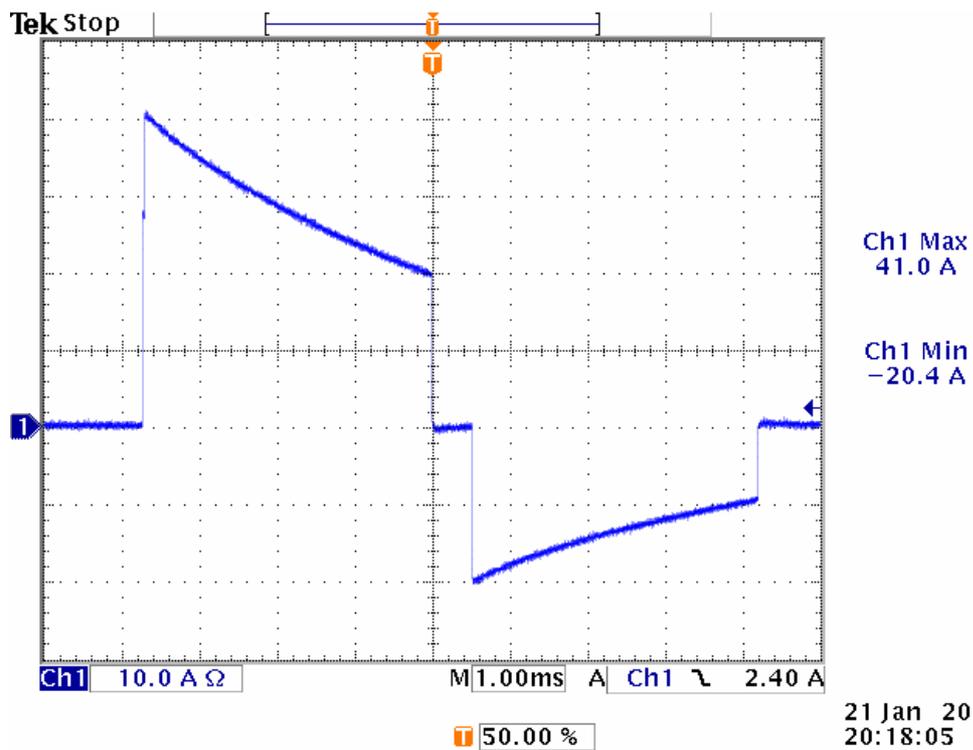
Arrhythmia Detector Performance

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,S VT, 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%

Defibrillator

Category	Nominal Specifications
Operating Mode	Semi-automated
Waveform	<i>e-cube</i> biphasic (Truncated exponential type); impedance compensated
Energy	200 Joules nominal into a 50Ω load
Charge Control	By pulse width modulation (PWM) provided by HV micro. HV micro is activated by arrhythmia detector
Charge time from “Shock Advised”	< 10 seconds, typical
Charge complete indicator	<ul style="list-style-type: none"> • Text prompt (PRESS THE FLASHING ORANGE BUTTON, NOW) • flashing backlight of SHOCK button • beep from the beeper
Disarm	<p>Once charged, the i-PAD disarms itself if:</p> <ul style="list-style-type: none"> • 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 • The battery pack is removed or is completely depleted.
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.
Patient Isolation	Type BF, defibrillation protected



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 DF80 guidelines

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, weekly, and monthly testing, 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	<ul style="list-style-type: none"> • Power On Self-Test / Run Time Self-Test • Daily / Weekly/ Monthly
User Initiated	Battery Insertion Test

Battery Pack

Category	Nominal Specifications
Battery Type	12 Volt DC, 4.2 Ah, lithium manganese dioxide, disposable long-life primary cell.
Capacity	Minimum 200 shocks or 10 hours of operating time.
Temperature Range	14 °F to 140 °F (-20 °C to 60 °C)

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

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.

Electromagnetic Compatibility

Guidance and manufacturer's declaration – electromagnetic emissions		
The i-PAD NF1200 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD NF1200 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 NF1200 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 NF1200 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.**

Guidance and manufacturer's declaration – electromagnetic immunity			
The i-PAD NF1200 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD NF1200 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	There are no special requirements with respect to electrostatic discharge.
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 % UT (>95% dip in UT) for 0,5 cycles 40 % UT (60% dip in UT) for 5 cycles 70 % UT (30% dip in UT) for 25 cycles <5 % UT (>95% dip in UT) 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 NF1200 requires continued operation during power mains interruptions, it is recommended that the i-PAD NF1200 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. There are no special requirements for non-commercial/non-hospital environments

Guidance and manufacturer's declaration – electromagnetic immunity			
The i-PAD NF1200 is intended for use in the electromagnetic environment specified below. The customer or the user of the i-PAD NF1200 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	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the i-PAD NF1200, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.16\sqrt{P}$ $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2,5 GHz 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: 
	10 Vrms 150 kHz to 80 MHz in ISM bands ^a	10 Vrms	
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz	10 V/m	
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 NF1200 is used exceeds the applicable RF compliance level above, the i-PAD NF1200 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the i-PAD NF1200.		
d	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.		

Recommended separation distances between portable and mobile RF communications equipment and the i-PAD NF1200

The i-PAD NF1200 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the i-PAD NF1200 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the i-PAD NF1200 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	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2,5 GHz
	$d = 1.16\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
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 metres (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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