

CU's Emergency Responder 1

CU – ER1



Operator's Manual

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

Paramedic Series AED

Paramedic CU-ER1 Quick Reference Card

IF PATIENT IS UNRESPONSIVE AND NOT BREATHING NORMALLY:

1 TURN ON

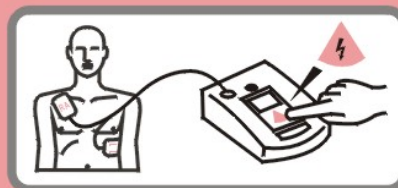


2 FOLLOW PROMPTS



Remove Pads / Peel off backing / Apply Pads / Plug in Pads connector

3 PRESS SHOCK
BUTTON IF
INSTRUCTED



Notice

Paramedic CU-ER1 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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● General

Thank you for choosing the Paramedic CU-ER1

Please read this Operator's Manual carefully and thoroughly before using the Paramedic CU-ER1 to be fully acquainted with its operating and maintenance instructions.

CU Medical Systems, Inc. designs and manufactures all of its products in accordance with international standards (NS-EN ISO9001:2000/ ISO13485:2003-MDD 93/42/EEC). This ensures that CU Medical Systems, Inc. provides products of high quality and reliability. In this regard:

- Only persons authorized by CU Medical Systems, Inc. may service this device. There are no user serviceable parts in this device.
- You must operate this device in accordance with the instructions specified in this manual.

To ensure safety and reliability, use only parts and accessories recommended by CU Medical Systems, Inc.

If you intend to use this device in conjunction with other devices not specified in this manual, please notify the manufacturer.

● 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 us or to our 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 an entity other than CU Medical Systems, Inc. or its authorized representatives. IN NO EVENT SHALL CU MEDICAL SYSTEMS, INC. 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 Paramedic CU-ER1 must be serviced only by authorized personnel. Unauthorized servicing during the warranty period renders the warranty null and void.
- The Paramedic CU-ER1 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 Paramedic CU-ER1 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 : Paramedic		Model: CU-ER1
Serial No.:		Date of Purchase:
Sales Representative / Authorized Dealer		
Customer Information	Address	
	Name	
	Contact No.	
Brief Description of Problems		

● CONTACT US

You may contact us at the following address and telephone number for services and supplies.

Product and Order Inquiries:

International Marketing Team
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1 How to Use This Manual

1.1 Contents of This Manual

- This Operator's Manual contains all the information a user needs to operate the Paramedic CU-ER1 properly.
- In case you have any problems regarding the operation of the device, please don't hesitate to contact the manufacturer.

1.2 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.

NOTICE

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

2 Device Operation Guidelines

2.1 General Guidelines

	<p>Do not operate or store the device in conditions that are beyond the following specified limits.</p> <p>Operating Conditions</p> <p>Temperature 32 °F to 104 °F (0 °C to 40 °C)</p> <p>Humidity 5 % to 95 % (non-condensing)</p> <p>Standby conditions (Stored with defibrillator electrode pads, ready for rescue)</p> <p>Temperature 32 °F to 109 °F (0 °C to 43 °C)</p> <p>Humidity 5 % to 95 % (non-condensing)</p> <p>Storage Conditions (Device only, no defibrillator electrode pads)</p> <p>Temperature -4 °F to 140 °F (-20 °C to 60 °C)</p> <p>Humidity 5 % to 95 % (non-condensing)</p>
	<p>Do not store the device in areas that are directly exposed to sunlight</p>
	<p>Do not store the device in areas with highly fluctuating temperatures</p>
	<p>Do not store the device near heating equipment or appliances.</p>
	<p>Do not store the device in areas where there is high vibration (in excess of Category 10 of MIL-STD-810F Method 514.5)</p>
	<p>Do not operate or store the device in environments with high concentration of flammable gas, anesthetics, or other flammable chemicals.</p>
	<p>Do not operate or store the device in areas with high concentration of dust</p>
	<p>Only personnel authorized by the manufacturer may open the device for servicing. There are no user serviceable components inside the device.</p>

⚠ WARNING

There is a possibility of explosion or fire if the Paramedic CU-ER1 is used in the presence of flammable agents or in an OXYGEN enriched atmosphere.

⚠ WARNING

Do not use the Paramedic CU-ER1 if it has been submerged in water. Call immediately for service assistance.

⚠ CAUTION

To ensure safety and reliability, use only parts and accessories approved by CU Medical Systems, Inc.

2.2 Electrical Safety Guidelines

- Use the correct power supply during recharging. See the Chapter on Power Supply for more details.
- During recharging, do not place the device where the environmental conditions exceed the operating conditions specified in the Device Operation Guidelines

⚠ WARNING

Electromagnetic interference may alter device performance. During operation, the device 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.

NOTICE

The Paramedic CU-ER1 is classified as follows:

- It is a Class I, BF equipment in terms of electrical shock prevention (EN 60601-1). Therefore this device is not rated for use around combustible anesthetic or solvents.
- The Electromagnetic emission level is Class B according to EN 60601-1 (Safety of Electric Medical Equipment), and the noise redemption is B level according to the EN 60601-1-2 (Electromagnetic Compatibility Requirements).

3. Introduction

3.1 Product Description

The **Paramedic CU-ER1** is a semi-automated external defibrillator (AED). If connected to a patient, it automatically acquires and analyzes the electrocardiogram (ECG) of the patient for the presence of Ventricular Fibrillation or Ventricular Tachycardia (also known as shockable rhythms).

If a shockable rhythm is detected, the **Paramedic CU-ER1** automatically charges itself and then prompts you to press the SHOCK button. When you press the SHOCK button after being prompted to press it, the **Paramedic CU-ER1** delivers a defibrillating shock. After delivering a shock, the **Paramedic CU-ER1** allows you to administer CPR (cardiopulmonary resuscitation) according to the AHA 2005 Guidelines on CPR.

The **Paramedic CU-ER1** is easy to use. It guides you throughout a rescue operation using voice and text prompts. The SHOCK button that commences a shock delivery is clearly marked and is fitted with a backlight that flashes when the button has to be pressed.

The **Paramedic CU-ER1** may also be used for ECG monitoring only. To enter this mode, the ECG Monitoring Cable and Connector Assembly must be connected to it. In this mode, the Paramedic CU-ER1 only monitors the ECG and does not deliver a shock.

The **Paramedic CU-ER1** enables you to review the critical events and data acquired during a rescue or an ECG monitoring operation. The ECG of the patient and critical events (charging, shock delivery, etc.) are automatically recorded in the internal memory of the device. Voice recording may also be done if the optional removable flash memory card is used.

The ECG data acquired by the **Paramedic CU-ER1** may be reviewed and printed directly using the device or may be transferred to a personal computer for archiving, review, and printing.

The **Paramedic CU-ER1** is used with disposable multifunction defibrillator pads. The electrical signal from the patient's heart is acquired through these pads. The defibrillating shock is delivered also through these pads. Replacement pads are available from CU Medical Systems, Inc.

The **Paramedic CU-ER1** is easy to troubleshoot and maintain. It is programmed to conduct automatic Power On, Run Time, Daily, Weekly, and Monthly self tests. During these tests, the critical subsystems of the device are tested for functionality. If a fault is detected, the device informs you of the fault through audible and visible indicators.

The **Paramedic CU-ER1** is powered by a versatile power supply system. It is equipped with an internal rechargeable 12V DC Nickel Metal Hydride battery pack. This internal battery pack may be recharged using the AC/DC adapter or the car cigar lighter jack power cord. The internal battery pack has a capacity of 200 shocks when new and fully charged (150J into 50Ω). The Paramedic CU-ER1 may also be powered using the external, disposable LiMnO₂ battery pack available from CU Medical Systems, Inc. The battery pack has a capacity of 200 shocks (150J into 50Ω) when used at an ambient temperature of 25 °C.

3.2 Indicated Use

The **Paramedic CU-ER1** is indicated for use on patients that are exhibiting the symptoms of sudden cardiac arrest (SCA).

The Paramedic CU-ER1 is to be used on patients that are suspected of suffering from sudden cardiac arrest with all of the following signs:

- a) **Unresponsiveness**
- b) **Absence of normal breathing**

Do not use the Paramedic CU-ER1 on patients who show either of the following signs:

- a) **Responsiveness**
- b) **Presence of normal breathing**

NOTICE

The Paramedic CU-ER1 may be used on children under 8 years old or under 25kg (55 lb) in weight.

If the patient appears to be less than 8 years old or under 25kg (55 lb), use the reduced-energy defibrillator pads.

NOTICE

The Paramedic CU-ER1 may be used to monitor the ECG of a responsive and breathing patient. Use the optional ECG monitoring cable and connector assembly.

3.3 Intended Users

The **Paramedic CU-ER1** is intended for use by emergency care personnel who have been trained in the use of the **Paramedic CU-ER1** and qualified by any of the following:

- a. Training in the administration of basic life support or advanced life support
- b. Training in other physician-authorized emergency medical response.

4. Device Orientation

4.1 Device Parts Illustration

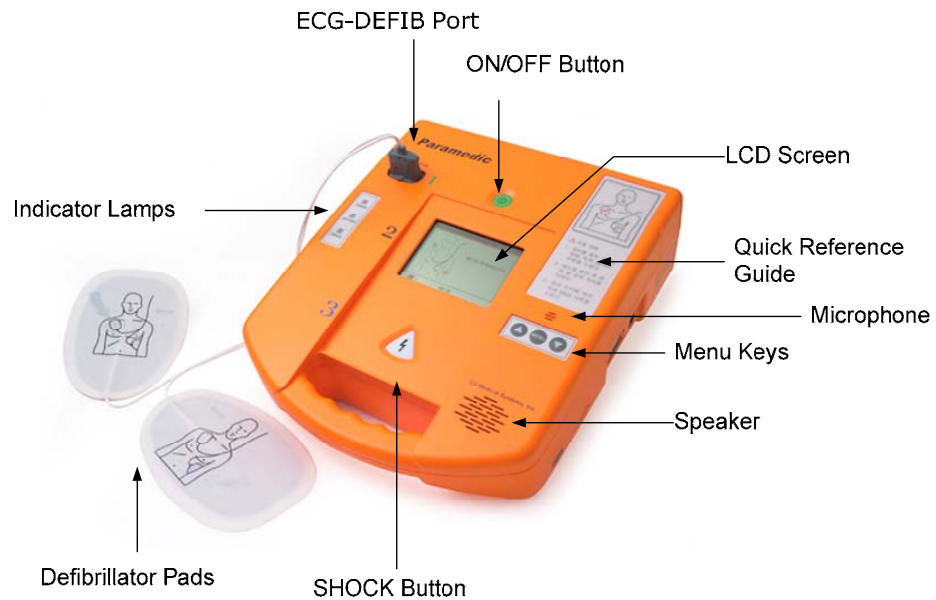


Figure 4-1. The Paramedic CU-ER1

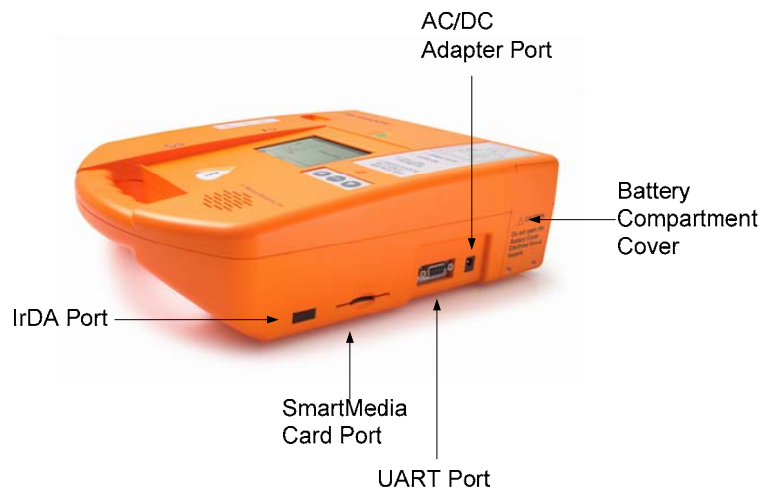


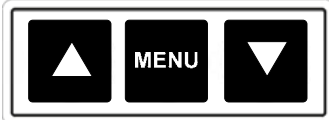



Figure 4-2. Side view of the Paramedic CU-ER1

Device Parts Explanation		
LCD Screen	Displays the ECG of the patient and the various prompts and indicators.	
Microphone	Captures audio signals during a rescue operation.	
Speaker	Plays voice prompts during rescue operation and recorded audio signal during recording playback.	
Quick Reference Guide	Outlines the steps to be taken during a rescue operation	
Operating Controls		
 ON/OFF Switch	Turns the power of the Paramedic CU-ER1 ON or OFF.	
 SHOCK button	Flashes its red backlight when the Paramedic CU-ER1 is ready to deliver a shock. Delivers the shock when pressed while the backlight is flashing.	
 MENU keys	Controls special functions such as device setup and data management and review.	
	UP Button	May be used to increase the volume of the speaker for louder voice prompts
	DOWN Button	May be used to decrease the volume of the speaker for softer voice prompts
Indicator Lamps		
	POWER	Indicates that the source of power is external to the device (either the AC/DC adapter or the external battery pack).
	BATTERY	Indicates that the source of power is a battery pack (either the internal battery pack or the external battery pack). This lamp indicator also flashes in red when the internal battery is being charged.
	ERROR	Indicates that a system error occurred. If the error lamp is ON, see Chapter 10 – Troubleshooting, for appropriate remedial action.

Device Parts Explanation, continued	
Input/Output Ports	
ECG-DEFIB port	<p>Used to connect the Defibrillator Electrode Pads assembly to the Paramedic CU-ER1.</p> <p>Also used to connect the custom made ECG MONITORING CABLE AND CONNECTOR ASSEMBLY to the Paramedic CU-ER1.</p>
SmartMedia CARD port	Receptacle for the SmartMedia card.
IrDA port	Used to transfer ECG monitoring and rescue data from the Paramedic CU-ER1 to a personal computer.
UART port	<p>Used for:</p> <ul style="list-style-type: none"> • transfer of ECG monitoring and rescue data from the Paramedic CU-ER1 to a personal computer • connection to a stand-alone printer for the printing of ECG monitoring and rescue data. • acquisition of identification data from an external disposable battery pack
AC/DC Adapter port	<ul style="list-style-type: none"> • receptacle for the 12V DC power supply from an AC/DC Adapter unit or a car cigar lighter jack. • input connector for the external disposable battery pack.
Others	
Battery Pack Compartment Cover	Access cover to the battery pack compartment. Only authorized technicians must open this if the need arises.

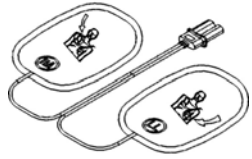
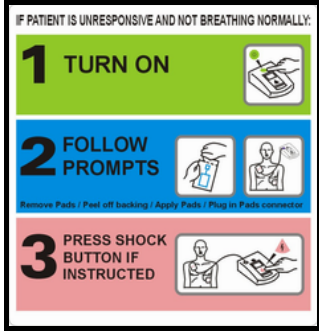

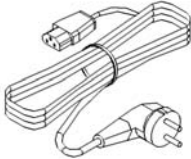

4.2 Accessories





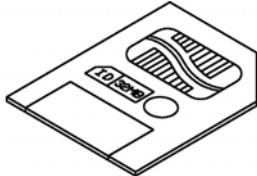
Only parts and accessories approved by CU Medical Systems, Inc. must be used with the **Paramedic CU-ER1**. Using parts and accessories that are not approved by CU Medical Systems, Inc. may degrade performance.

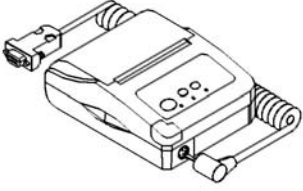
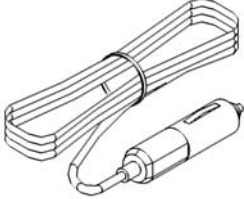
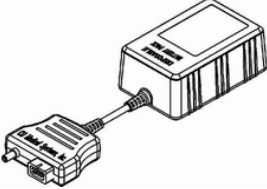


**WARNING**


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 Paramedic CU-ER1

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

Standard Accessories	
 <p data-bbox="400 631 738 685"> Defibrillator Electrode Pads and Connector Assembly </p>	<p data-bbox="770 533 1342 629"> 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 data-bbox="437 1077 699 1106"> Quick Reference Card </p>	<p data-bbox="770 884 1310 943"> A reference card that enumerates the steps to be done during a rescue operation. </p>
 <p data-bbox="392 1303 743 1357"> Nickel-Metal Hydride Battery Pack </p>	<p data-bbox="770 1171 1342 1328"> Power source of the Paramedic CU-ER1. This battery is inside the case of the device. RETURN the Paramedic CU-ER1 to an authorized service representative if the battery pack needs to be replaced. </p>
 <p data-bbox="496 1559 639 1588"> Power Cord </p>	<p data-bbox="770 1458 1355 1516"> Used to connect the AC/DC adapter unit to the mains power supply. </p>
 <p data-bbox="475 1771 663 1800"> AC/DC Adapter </p>	<p data-bbox="770 1632 1297 1691"> Used for charging the rechargeable Nickel-Metal Hydride battery pack. </p> <p data-bbox="770 1727 1339 1785"> May also be used to power the Paramedic CU-ER1 during rescue operation. </p>

Optional Accessories	
 <p>ECG Monitoring Cable and Connector Assembly</p>	<p>The cable and connector assembly that must be used if it is desired to run the Paramedic CU-ER1 in ECG monitoring mode.</p>
 <p>ECG Monitoring Electrodes</p>	<p>Used for the ECG Monitoring Cable and Connector Assembly</p>
 <p>Reduced-energy Pediatric Defibrillator Electrode Pads</p>	<p>The defibrillator electrode pads that must be used when the patient appears to be less than 8 years old or 25kg (55 lb).</p>
 <p>Pediatric Defibrillator Electrode Pads Connector Adapter</p>	<p>An adapter that enables you to connect the Reduced-energy Pediatric Defibrillator Pads to the ECG-DEFIB port of the Paramedic CU-ER1</p>
 <p>SmartMedia Card</p>	<p>Used for storage of rescue data (ECG, Rescue Event Highlights, and Voice).</p> <p>Only SMCs supplied by CU Medical Systems, Inc. are compatible with the Paramedic CU-ER1.</p> <p>Do not use any other kind of flash memory card.</p>

Optional Accessories, continued	
 <p data-bbox="485 680 675 707">Thermal Printer</p>	<p data-bbox="794 533 1364 636">A stand-alone thermal printer that enables you to print the ECG and rescue data stored in the internal and removable flash memories of the Paramedic CU-ER1</p>
 <p data-bbox="405 978 758 1030">Car Cigar Lighter Jack Power Cord</p>	<p data-bbox="794 768 1364 873">Used to connect the device to a car cigar lighter jack for recharging the batteries. In the emergency vehicle, the batteries can be charged by connecting the device to the car cigar lighter jack (12V Only).</p> <p data-bbox="794 898 1364 1003">Use this accessory only for recharging the battery pack of the Paramedic CU-ER1. Do not use the Paramedic CU-ER1 in a rescue operation while being connected to a car cigar lighter power jack.</p>
 <p data-bbox="421 1249 740 1301">Disposable LiMnO₂ Battery Pack</p>	<p data-bbox="794 1158 1364 1209">An external, disposable battery pack that may be used to provide power to the Paramedic CU-ER1</p>
 <p data-bbox="509 1541 651 1568">UART Cable</p>	<p data-bbox="794 1413 1364 1487">Used to connect the Paramedic CU-ER1 to a personal computer for rescue and ECG monitoring data transfer</p>
 <p data-bbox="400 1765 759 1792">IrDA COM Port Serial Adapter</p>	<p data-bbox="794 1657 1364 1731">Used to connect the Paramedic CU-ER1 to a personal computer for rescue and ECG monitoring data transfer.</p>

Optional Accessories, continued	
 <p>Carrying Case</p>	<p>Used to store the Paramedic CU-ER1 and the accessories needed for a rescue operation.</p>

4.3 Screen Display Views

4.3.1 Initial Screen Display

Turn on the **Paramedic CU-ER1** and observe the initial screen display shown on Figure 4-3. This screen is shown right after the **Paramedic CU-ER1** is done with its Power-On Self-Test (Power-On Self-Test is indicated by a text prompt "STARTING UP").

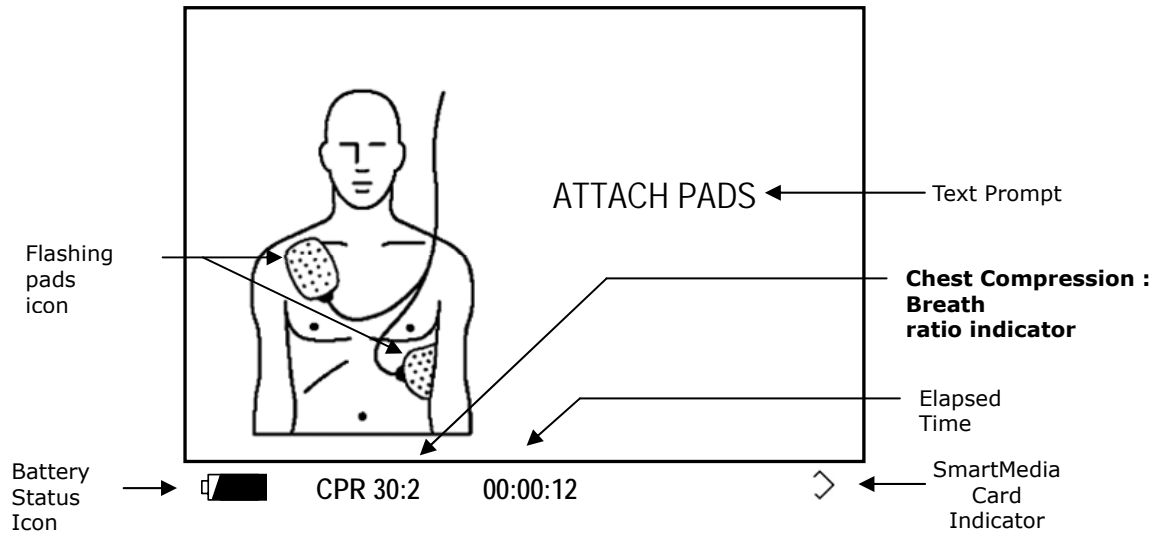










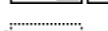


Figure 4.3: Initial Screen Display

Initial Screen Display Legend

Flashing pads icon	Indicate the location where the defibrillator electrode pads must be placed
Battery Level Indicator: Power provided by the internal battery pack	
Shows the charge status of the battery pack of the Paramedic CU-ER1	
	The battery is fully charged
	Battery level is 80% of full charge
	Battery level is 65% of full charge
	Battery level is 50% of full charge
	Battery is almost empty. CAUTION Recharge the battery pack when this icon is displayed. Do not wait for the battery pack to be totally drained.
	the device is powered by an AC adapter or a Car cigar lighter jack
Battery Level Indicator: Power provided by the external battery pack	
Shows the power level of the external battery pack of the Paramedic CU-ER1.	
	Battery level > 90% of full level.
	90% > Battery level > 60% of full level.
	60% > Battery level > 30% of full level.
	30% > Battery level > 10% of full level.
	Battery level < 10% of full level. CAUTION When this is displayed, the battery pack must be replaced. Do not wait for the battery pack to be drained below the level wherein the Paramedic CU-ER1 could not operate anymore.
Elapsed time	The time that elapsed since the Paramedic CU-ER1 was turned ON during the current rescue operation.
Chest Compression : Breath ratio indicator	This is the indicator on the screen that tells you the current setting of the chest compression : breath ratio
Text Prompt	Indicates actions that you need to do.

4.3.2 Screen Display; Rescue Operation Ongoing

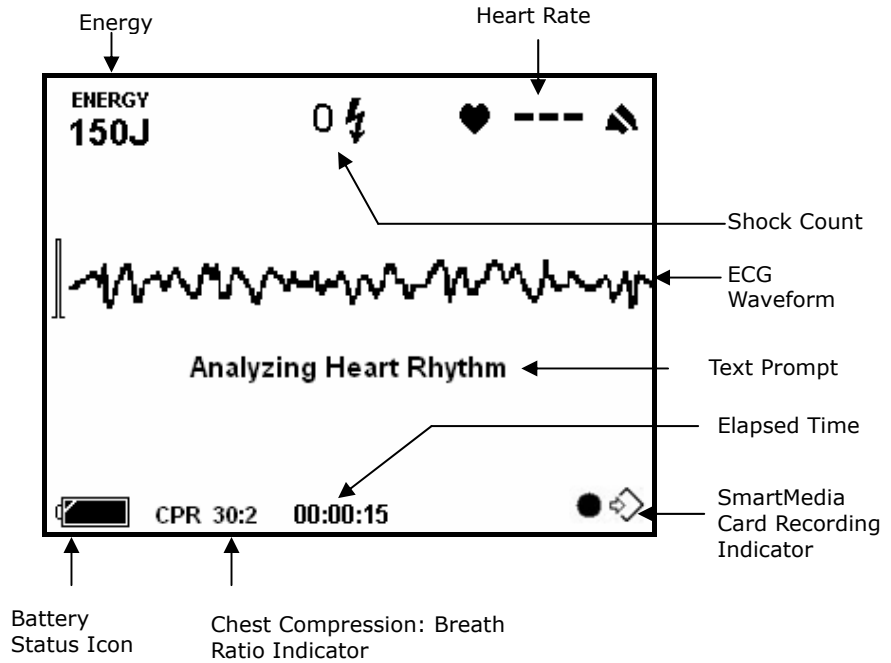




Figure 4-4. Screen Display During Rescue Operation

Energy	Indicates the amount of energy to be delivered to the patient
Shock Count	Indicates the number of shocks that have been delivered during the current rescue session.
Heart Rate	Indicates the heart rate of the acquired ECG in beats per minute (bpm)
ECG Waveform	Displays the ECG waveform acquired from the patient
Battery Status Icon	See explanation in Figure 4.3
Text Prompt	Displays the action that you have to do.
Elapsed Time	Indicates the time that elapsed since the device was turned on during the current rescue process.
Chest Compression : Breath ratio indicator	This is the indicator on the screen that tells you the current setting of the chest compression : breath ratio

SmartMedia Card Recording Indicator

Indicates that the SmartMedia card is in its port and recording of ECG waveform, voice, and event data is being done.

When  is displayed, the voice recording option is ON and audio signals in the vicinity of the rescue operation are being recorded.

When  is displayed, the voice recording option is OFF and the voice signals in the vicinity of the rescue operation are not recorded. All the other rescue data are recorded.

4.4 Voice and Text Prompts

Prompt	Type/Meaning
ATTACH PADS	Voice and Text Indicates that you have to attach the defibrillator electrode pads to the bare chest wall of the patient.
DO NOT TOUCH THE PATIENT	Voice and Text Indicates that the Paramedic CU-ER1 is analyzing the ECG signal acquired from the patient. You must not touch the patient to minimize artifacts. Motion during ECG acquisition introduces artifacts.
ANALYZING HEART RHYTHM	Voice and Text Indicates that the device is doing an analysis of the patient's ECG.
SHOCK ADVISED	Voice and Text Indicates that the patient has a shockable ECG rhythm.
STAND CLEAR	Voice and Text Indicates that everybody in the vicinity of the patient must stand clear and not touch the patient.
CHARGING	Text Indicates that the Paramedic CU-ER1 is charging its capacitor to prepare for a shock delivery.
CHARGING COMPLETE	Text Indicates that the Paramedic CU-ER1 has finished charging its capacitor. This prompt is in text form only.
PRESS THE FLASHING RED BUTTON, NOW	Voice and Text Indicates that you have to press the SHOCK button for the delivery of a defibrillation shock. At this time, the SHOCK button is flashing and the beeper is beeping.
SHOCK DELIVERED	Voice and Text Indicates that the Paramedic CU-ER1 has delivered a defibrillation shock.

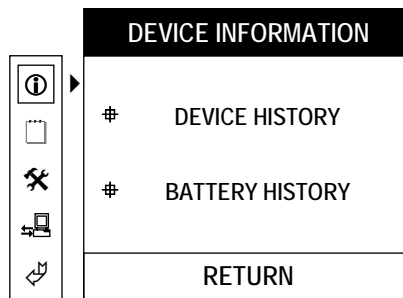
Voice and Text Prompts, continued

Prompt	Indication
BEGIN CPR, NOW	Voice and Text You must administer cardiopulmonary resuscitation (CPR)
PUSH THE CHEST DOWN FAST TWO INCHES	Voice and Text Do compression by pushing the chest down fast two inches.
GIVE TWO BREATHS.	Voice and Text Indicates that you must give respiration to the patient.
BREATH. BREATH	Voice Guides you with on the correct respiration delivery rhythm.
NO SHOCK ADVISED	Indicates that the patient has a non-shockable ECG rhythm.
CHECK PULSE	Voice and Text You must check the pulse of the patient.
IF NO PULSE, BEGIN CPR	Voice and Text If there is no pulse, you must begin CPR
THE SHOCK BUTTON WAS NOT PRESSED	Voice and Text Indicates that a shockable rhythm has been detected and a prompt to press the SHOCK button has been given but the SHOCK button is not pressed within 15 seconds. The device will discharge through its internal circuit.
ECG MONITORING MODE	Text This indicates that the custom designed ECG MONITORING CABLE AND CONNECTOR ASSEMBLY is attached to the ECG-DEFIB port. In this mode, the Paramedic CU-ER1 can do only acquisition and display of ECG. It does not analyze the ECG for a shockable rhythm and it can not deliver a defibrillating shock.

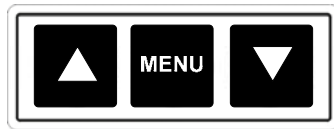
4.5 Menu Operation

Enter Menu Operation by pressing the MENU key button after turning the device ON without connecting any connector into the ECG-DEFIB port.

Upon entering Menu Operation, the Paramedic CU-ER1 displays the following screen:



To navigate through the menu, use the UP, MENU, and DOWN buttons on the keypad of the device.



The UP (▲) key and DOWN (▼) key are used for scrolling the menu highlight bar and the MENU key is used for selecting the highlighted option in the MENU.

There are 4 top level menus:

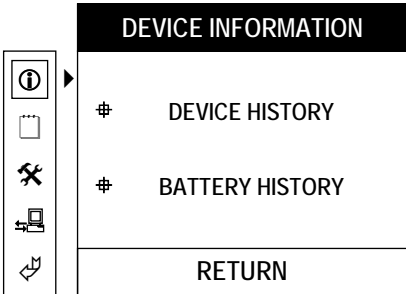
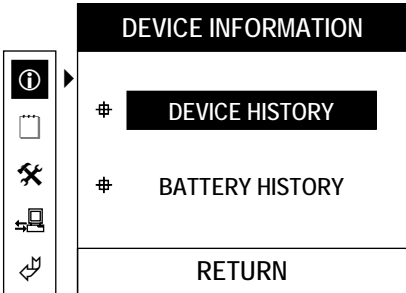
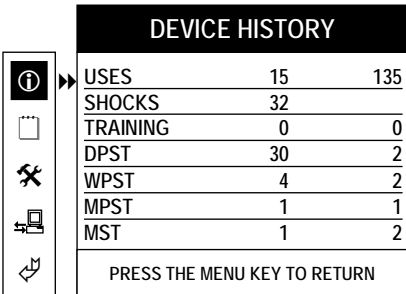
DEVICE INFORMATION
 REVIEW INCIDENT
 DEVICE SETUP
 COMMUNICATION.

4.5.1 Device History

Device History contains the history of the device during its lifetime. The following data are displayed on the LCD:

- a. number and total elapsed time of device usage
- b. number of shocks delivered
- c. number and total elapsed time of trainings conducted using the device
- d. number and total elapsed time of the different tests (daily, weekly, monthly, and manual tests)

To access Device History turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
1 MENU Button	
2 Menu Button	
3 Menu Button	

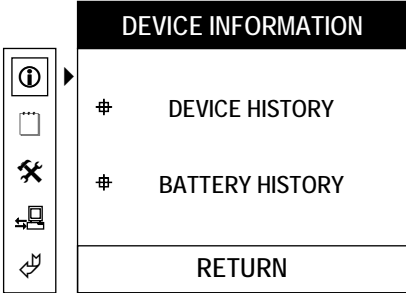
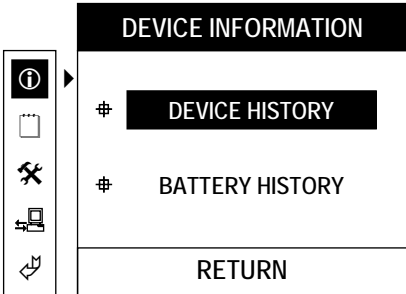
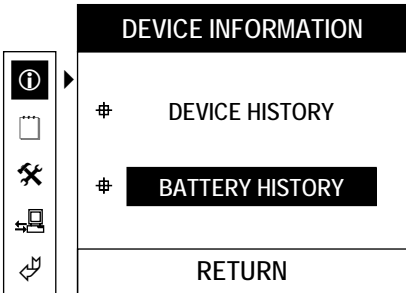
In this example the **Device History** indicates the following:

Uses	
Middle column	Number of times the Paramedic CU-ER1 was used in RESCUE operations. In this example, the Paramedic CU-ER1 was used 15 times in rescue operations. A rescue operation is counted when the following conditions occur: <ol style="list-style-type: none"> 1. The Paramedic CU-ER1 is turned ON. 2. The Paramedic CU-ER1 is able to acquire an ECG signal. 3. The Paramedic CU-ER1 is turned OFF.
Right column	Total elapsed time (minutes) that the device was used in RESCUE operations. In this example, the device was used for a total of 135 minutes in 15 rescue operations.
Shocks	
Middle column	Total number of shocks delivered since the device was put into use.
Training – this option is not implemented in this version of the Paramedic CU-ER1	
Middle column	Number of training uses. For future versions. Not implemented in this version of the Paramedic CU-ER1
Right column	Total elapsed time of training sessions (minutes). For future versions. Not implemented in this version of the Paramedic CU-ER1
Self-Tests DPST =Daily; WPST=Weekly; MPST=Monthly; MST>manual tests.	
Middle column	Number of self-tests conducted.
Right column	The total elapsed time (minutes) of the particular self-test.

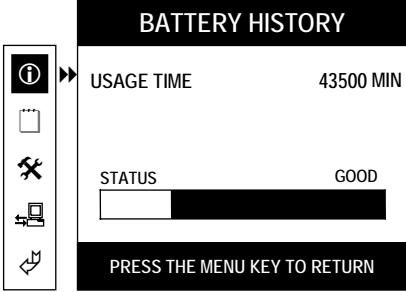
4.5.2 Battery History

The battery history indicates the number of minutes that the battery has been in use and the current state of the battery (GOOD or LOW).

To access Battery History turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
1 MENU Button	 <p>The diagram shows a vertical keypad with five buttons: an information icon (i), a menu icon, a battery icon, a device icon, and a return icon. An arrow points from the information icon to a screen titled 'DEVICE INFORMATION'. The screen lists two options: '# DEVICE HISTORY' and '# BATTERY HISTORY', with a 'RETURN' button at the bottom.</p>
2 Menu Button	 <p>The diagram shows the same keypad as above. An arrow points from the menu icon to the 'DEVICE INFORMATION' screen. In this screen, the 'DEVICE HISTORY' option is highlighted with a black background.</p>
3 Down Button	 <p>The diagram shows the same keypad as above. An arrow points from the battery icon to the 'DEVICE INFORMATION' screen. In this screen, the 'BATTERY HISTORY' option is highlighted with a black background.</p>

Battery History, continued

<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>
<p>5 Menu Button</p>	

Battery History indicates the following:

- USAGE TIME** Total time that the internal battery pack is used as the power supply of the **Paramedic CU-ER1**. This time is accumulated from the time the **Paramedic CU-ER1** is first used. Only the elapsed time when the **Paramedic CU-ER1** is powered ON is counted
- STATUS** Battery power state: Indicates the power level of the internal battery pack

CAUTION

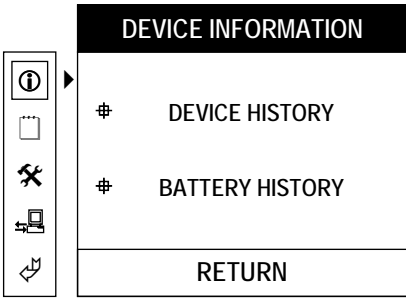
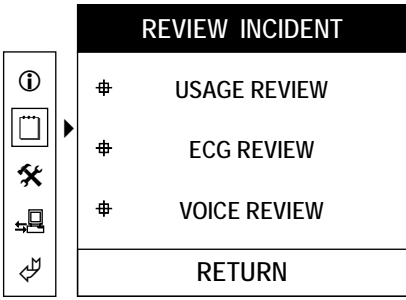
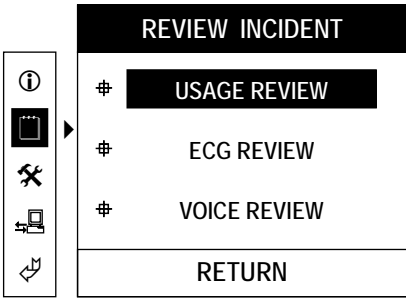
If the Status indicates LOW, recharge the internal battery pack

4.5.3 USAGE REVIEW

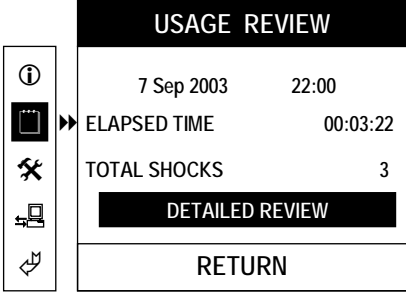
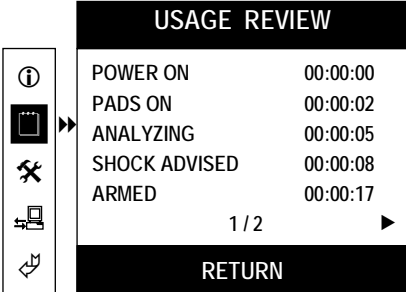
USAGE REVIEW displays the list of Rescue Events recorded together with their time stamp. The list of Rescue Events is given in the following table.

Name of Event	Event
Power ON	Indicates the time when the Paramedic CU-ER1 is turned ON.
Power OFF	Indicates the time when the Paramedic CU-ER1 is turned OFF
Pads ON	Indicates the time when the Paramedic CU-ER1 senses a connection to the patient through the defibrillator electrode pads.
Pads OFF	Indicates the time when the Paramedic CU-ER1 senses a disruption in the connection to the patient through the defibrillator electrode pads.
Armed	Indicates the time when the defibrillating capacitor of the Paramedic CU-ER1 is fully charged.
Disarmed	Indicates the time when the charge in the defibrillating capacitor is dumped to the internal dump resistance of the Paramedic CU-ER1 . The charge in the defibrillating capacitor is automatically dumped when the SHOCK button is not pressed within 15 seconds after the prompt to press the SHOCK button is given.
Shock # X	Indicates the time when the Xth shock is delivered by the Paramedic CU-ER1 .
Analyzing	Indicates the time when the Paramedic CU-ER1 is analyzing the ECG of the patient.
No Shock Advised	Indicates the time when the Paramedic CU-ER1 issues the "NO SHOCK ADVISED" prompt.
Shock Advised	Indicates the time when the Paramedic CU-ER1 issues the "SHOCK ADVISED" prompt.
Paused for CPR	Indicates the time when the Paramedic CU-ER1 pauses to give way to CPR administration
ECG Pads On	Indicates the time when the ECG monitoring cable and connector assembly is connected to the Paramedic CU-ER1
ECG Pads Off	Indicates the time when the ECG monitoring cable and connector assembly is disconnected from the Paramedic CU-ER1

To access **Usage Review** turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 Menu Button</p>	
<p>2 Down Button</p>	
<p>3 Menu Button</p>	

Usage Review, continued

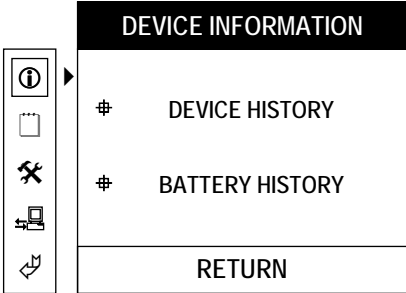
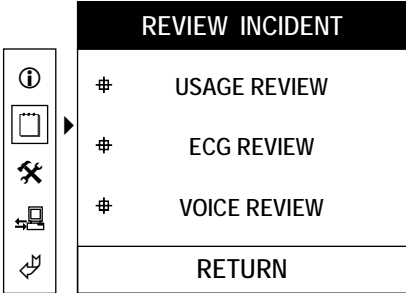
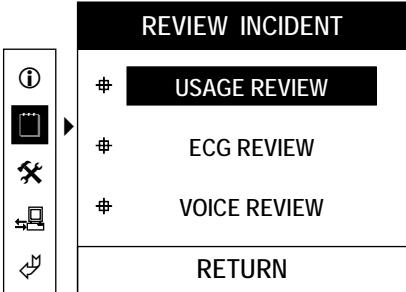
<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>															
<p>4 Menu Button</p>	 <p>The screenshot shows a vertical toolbar on the left with icons for help, menu, settings, and return. The main screen displays 'USAGE REVIEW' with the following data:</p> <table border="1"> <tr> <td colspan="2">7 Sep 2003</td> <td>22:00</td> </tr> <tr> <td>ELAPSED TIME</td> <td></td> <td>00:03:22</td> </tr> <tr> <td>TOTAL SHOCKS</td> <td></td> <td>3</td> </tr> <tr> <td colspan="3" style="text-align: center;">DETAILED REVIEW</td> </tr> <tr> <td colspan="3" style="text-align: center;">RETURN</td> </tr> </table>	7 Sep 2003		22:00	ELAPSED TIME		00:03:22	TOTAL SHOCKS		3	DETAILED REVIEW			RETURN		
7 Sep 2003		22:00														
ELAPSED TIME		00:03:22														
TOTAL SHOCKS		3														
DETAILED REVIEW																
RETURN																
<p>5 Menu Button</p>	 <p>The screenshot shows the same vertical toolbar. The main screen displays 'USAGE REVIEW' with the following data:</p> <table border="1"> <tr> <td>POWER ON</td> <td>00:00:00</td> </tr> <tr> <td>PADS ON</td> <td>00:00:02</td> </tr> <tr> <td>ANALYZING</td> <td>00:00:05</td> </tr> <tr> <td>SHOCK ADVISED</td> <td>00:00:08</td> </tr> <tr> <td>ARMED</td> <td>00:00:17</td> </tr> <tr> <td colspan="2" style="text-align: right;">1 / 2 ▶</td> </tr> <tr> <td colspan="2" style="text-align: center;">RETURN</td> </tr> </table>	POWER ON	00:00:00	PADS ON	00:00:02	ANALYZING	00:00:05	SHOCK ADVISED	00:00:08	ARMED	00:00:17	1 / 2 ▶		RETURN		
POWER ON	00:00:00															
PADS ON	00:00:02															
ANALYZING	00:00:05															
SHOCK ADVISED	00:00:08															
ARMED	00:00:17															
1 / 2 ▶																
RETURN																

4.5.4 ECG REVIEW

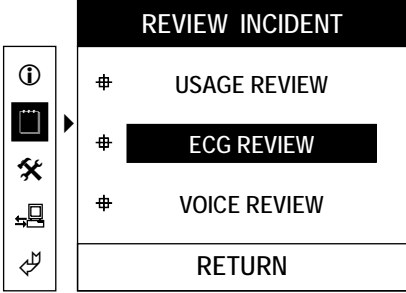
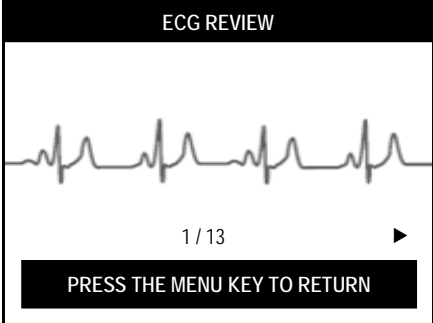
ECG REVIEW

- Displays the ECG record stored in the internal memory or the SmartMedia Card memory.
- ECG data from the latest rescue operation can be scrolled to the right or to the left (earlier or later part of the recording, respectively).
- Scroll the data by pushing the UP or DOWN arrow button.

To access **ECG Review**, turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 Menu Button</p>	
<p>2 Down Button</p>	
<p>3 Menu Button</p>	

ECG Review, continued

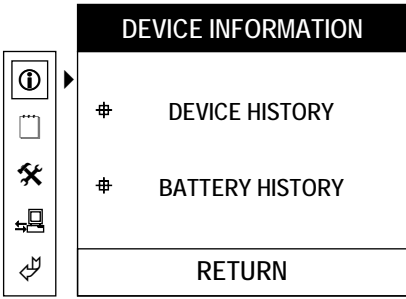
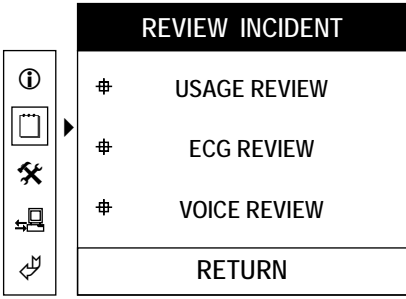
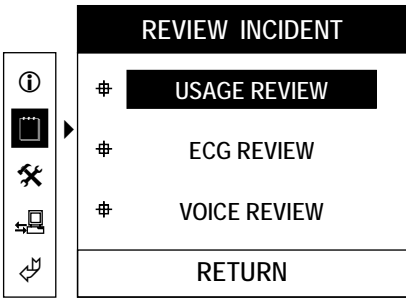
<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>
<p>4 Down Button</p>	
<p>5 Menu Button</p>	

4.5.5 VOICE REVIEW

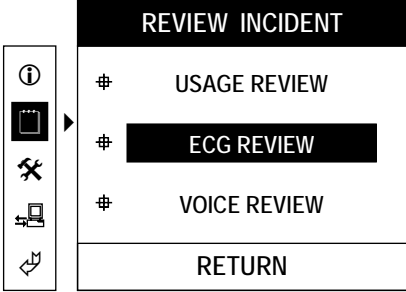
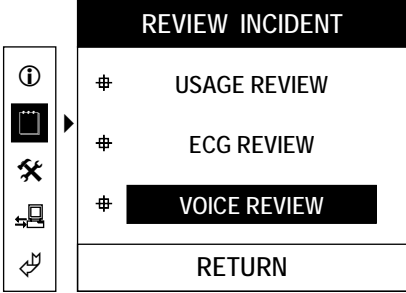
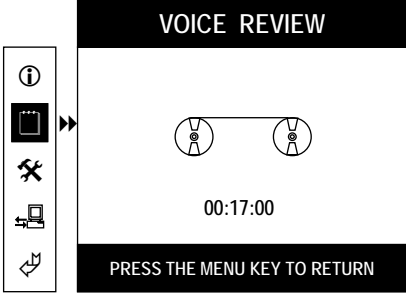
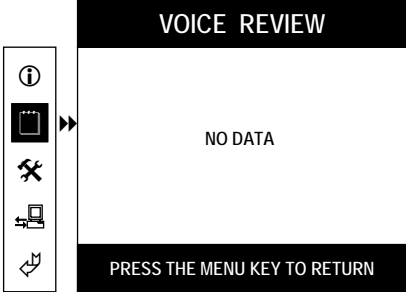
VOICE REVIEW

- Plays back the voice recorded during a rescue operation.
- Works only if the SmartMedia Card is inserted (Voice record can be stored only in the SmartMedia Card).

To access **Voice Review**, turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 Menu Button</p>	
<p>2 Down Button</p>	
<p>3 Menu Button</p>	

Voice Review, continued

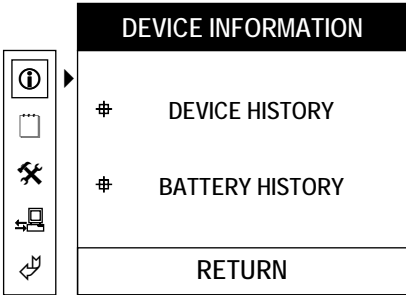
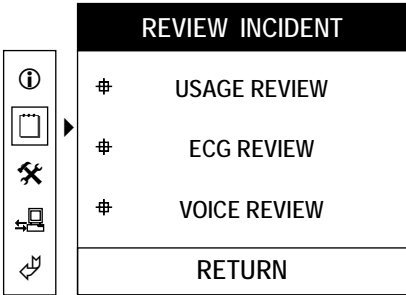
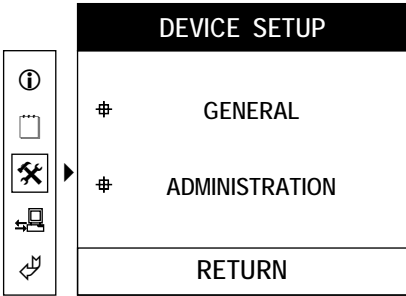
Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>4 Down Button</p>	 <p>The screenshot shows a vertical toolbar on the left with five icons: an information icon, a highlighted down button, a wrench icon, a printer icon, and a return icon. An arrow points from the down button to the main screen. The main screen has a black header 'REVIEW INCIDENT'. Below it are three menu items: '# USAGE REVIEW', '# ECG REVIEW' (highlighted with a black background), and '# VOICE REVIEW'. At the bottom is a 'RETURN' button.</p>
<p>5 Down Button</p>	 <p>The screenshot is identical to the previous one, but the 'VOICE REVIEW' menu item is highlighted with a black background.</p>
<p>6a Menu Button (SmartMedia Card is inserted)</p>	 <p>The screenshot shows the same vertical toolbar. An arrow points from the menu button to the main screen. The main screen has a black header 'VOICE REVIEW'. Below the header is a timer showing '00:17:00' between two circular icons. At the bottom is a black bar with the text 'PRESS THE MENU KEY TO RETURN'.</p>
<p>6b Menu Button (No SmartMedia card is inserted)</p>	 <p>The screenshot is identical to the previous one, but the main screen displays 'NO DATA' instead of a timer.</p>

4.5.6 GENERAL DEVICE SETUP

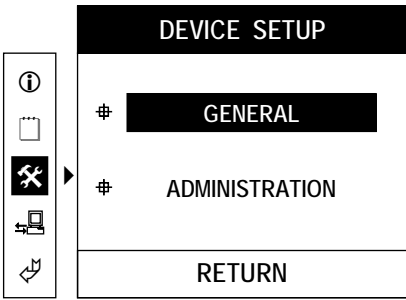
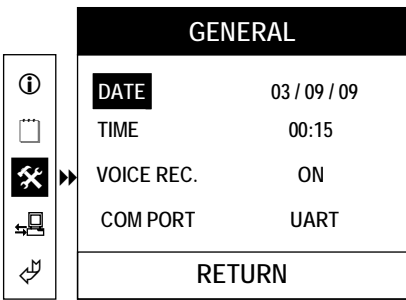
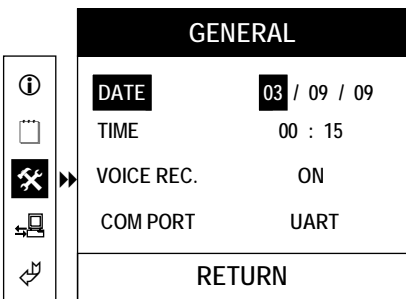
GENERAL DEVICE SETUP

- enables you to change or adjust operating parameters such as date, time, and voice recording.

To access **General Device Setup**, turn ON the device and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 Menu Button</p>	
<p>2 Down Button</p>	
<p>3 Down Button</p>	

General Device Setup, continued

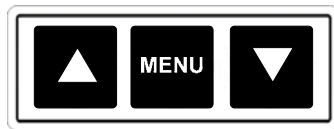
<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>
<p>4 Menu Button</p>	
<p>5 Menu Button</p>	
<p>6 Menu Button</p>	

General Device Setup, continued

The parameter variables are highlighted one by one by pressing the MENU button while the parameter is highlighted.

For example, when DATE is highlighted, the day, month, or year can be highlighted by pressing the MENU button repeatedly until the desired variable is reached.

When a variable (such as day for DATE) is highlighted, its value can be changed by pressing the UP or DOWN button on the MENU Keypad.



UP increases the value,
DOWN decreases the value.

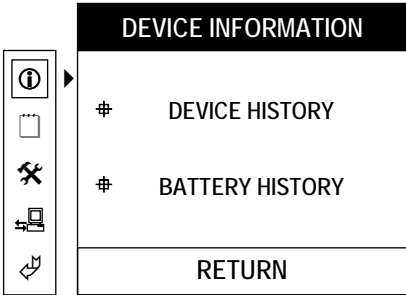
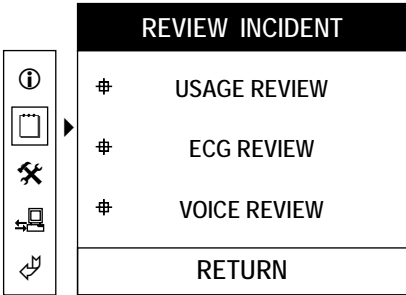
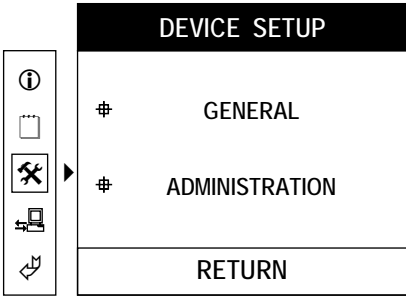
When the boundary of the value is reached the value wraps around. For example for the MONTH variable of DATE:

- a. When 12 is reached while pressing the UP button, one more press of the UP button wraps the value to 01
- b. When 01 is reached while pressing the DOWN button, one more press of the DOWN button wraps the value to 12

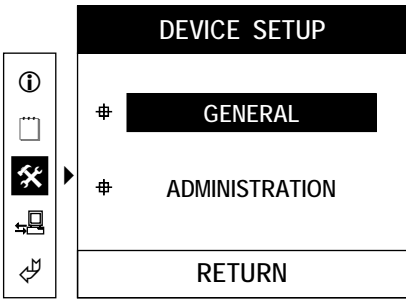
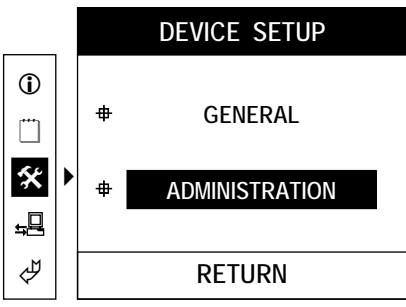
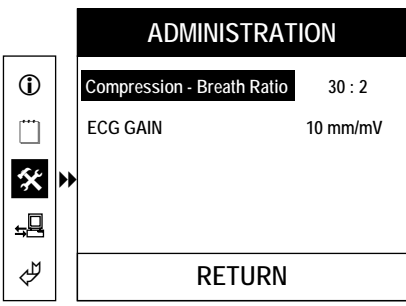
4.5.7 ADMINISTRATION DEVICE SETUP

In the DEVICE SETUP, ADMINISTRATION, you may set or adjust operating parameters such as Compression:Breath Ratio and ECG Gain.

To access **Device Setup, Administration**, turn ON the device without connecting any connector into the ECG-DEFIB port and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 Menu Button</p>	
<p>2 Down Button</p>	
<p>3 Down Button</p>	

Device Setup, Administration, continued

<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>
<p>4 Menu Button</p>	 <p>The diagram shows a vertical toolbar on the left with four icons: an information icon, a home icon, a settings icon, and a return icon. An arrow points from the settings icon to the 'ADMINISTRATION' option in the 'DEVICE SETUP' menu. The 'DEVICE SETUP' menu has a title bar, a 'GENERAL' option, an 'ADMINISTRATION' option, and a 'RETURN' button at the bottom.</p>
<p>5 DOWN Button</p>	 <p>The diagram shows the same vertical toolbar as above. An arrow points from the 'ADMINISTRATION' option in the 'DEVICE SETUP' menu to the 'ADMINISTRATION' screen. The 'ADMINISTRATION' screen has a title bar, 'Compression - Breath Ratio' (30 : 2), 'ECG GAIN' (10 mm/mV), and a 'RETURN' button at the bottom.</p>
<p>6 MENU Button</p>	 <p>The diagram shows the same vertical toolbar as above. An arrow points from the 'RETURN' button in the 'ADMINISTRATION' screen to the 'ADMINISTRATION' option in the 'DEVICE SETUP' menu.</p>

You may scroll the highlighter between Compression-Breath ratio and ECG GAIN by pressing the UP or DOWN key button.

You may change the Compression-Breath ratio or ECG GAIN setting by pressing the Menu button while Compression-Breath ratio or ECG GAIN is highlighted, respectively. When the parameter variable is highlighted, change its value by pressing the UP or DOWN button.

Compression Breath Ratio setting allows you to change the chest compression to respiration ratio setting.

Two settings are available for Compression Breath Ratio:

- 30 : 2 -> CPR guide allocates time and beat for 30 chest compressions and 2 respirations per CPR cycle.
- 15 : 2 -> CPR guide allocates time and beat for 15 chest compressions and 2 respirations per CPR cycle.

ECG GAIN allows you to set the gain of the ECG display.

The possible ECG GAIN values are:

- a. 5 mm/mV
- b. 10 mm/mV
- c. 20 mm/mV
- d. AUTO

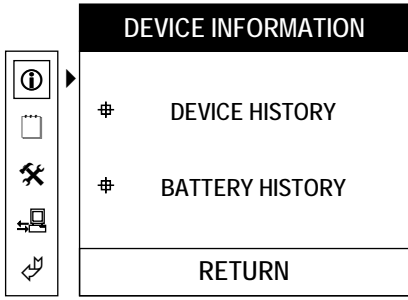
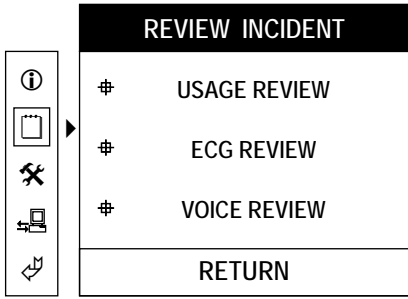
AUTO displays the ECG autoscaled (0.3 to 1 mV signals are displayed with 10mm/mV gain, outside of that range, the peak to peak value is displayed as 10 mm on the LCD display).

4.5.8 Printing and Transferring Data

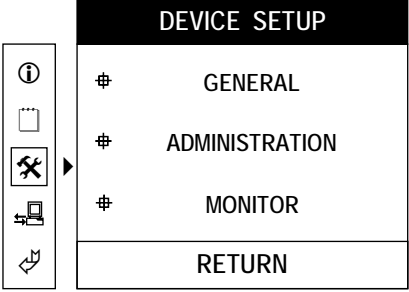
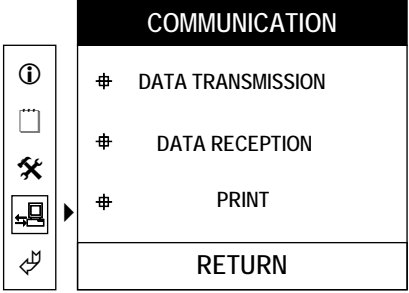
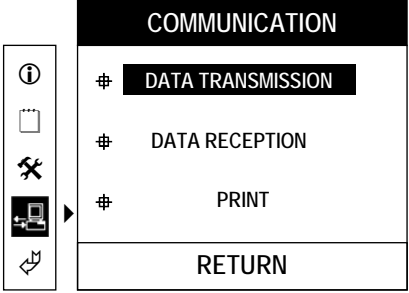
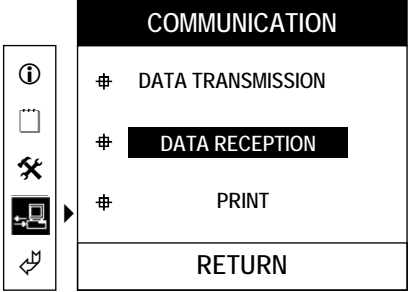
The ECG and rescue data stored in the internal flash memory or the SmartMedia Card may be printed through the optional stand-alone thermal printer or transferred to a personal computer.

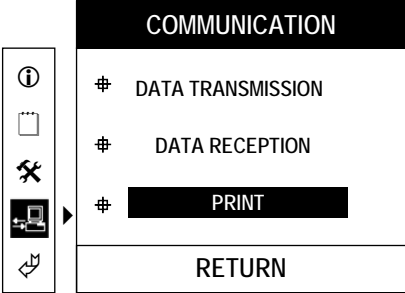
If the SmartMedia Card is not inserted, the data stored in the internal flash memory is printed. If the SmartMedia Card is inserted, the ECG data stored in it is printed.

To access the **Communication** menu, turn ON the device without connecting any connector into the ECG-DEFIB port and press the sequence of keypad buttons shown in the following table.

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>1 MENU Button</p>	
<p>2 DOWN Button</p>	

Communication-Print, continued

Press the following button(s) in sequence:	The Paramedic CU-ER1 displays the following screen(s) in sequence:
<p>3 DOWN Button</p>	
<p>4 DOWN Button</p>	
<p>5 MENU Button</p>	
<p>6 DOWN Button</p>	

<p>Press the following button(s) in sequence:</p>	<p>The Paramedic CU-ER1 displays the following screen(s) in sequence:</p>
<p>7 DOWN Button</p>	

The data transmission and printing processes are discussed thoroughly in Chapter 11 – Data Management and Review.

4.5.9 RETURN

To return to a higher level in the MENU system during menu operation, highlight the RETURN option or icon then press the MENU button. You will then be taken to the next higher level in the system.

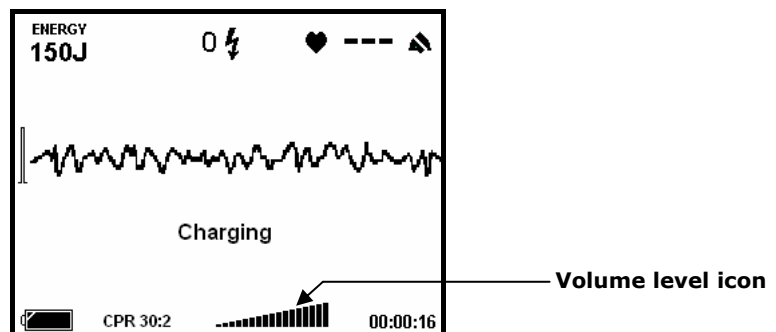
If you are in the highest sublevel, highlighting the RETURN icon and then pressing the MENU button takes you to the Initial Screen Display.

4.5.10 Speaker Volume Adjustment

In the middle of a rescue operation, the volume of the speaker of the **Paramedic CU-ER1** may be adjusted by pressing the UP or DOWN button.

Pressing the UP button increases the volume while pressing the DOWN button decreases the volume.

The volume level is shown by an icon on the screen display. This is shown in the following figure.



5 Device Setup and Storage

5.1 Unpacking

- Carefully inspect the packing container and the device for any damage that might have been sustained during shipping.
- Check the shipping list to ensure that the unit comes with the complete accessories.

A yellow rectangular box with a black border containing a black triangle with an exclamation mark and the word "CAUTION" in bold black text.

It is important to have all the necessary accessories all the time. Make sure that you have the complete accessories during unpacking.

If there are problems with the shipment, contact the distributor that shipped the product to you.

5.2 Setup

The **Paramedic CU-ER1** is a self contained portable device. Please follow the following setup procedures upon receiving your unit to ensure that the device is always ready for any emergency.

5.2.1 Manual Self-Test

Conduct a Manual Self-Test to verify that the device is in good order. Initiate a Manual Self-Test by performing the following steps:

- a. Press the UP and DOWN keypad buttons simultaneously.
- b. Press the ON/OFF button without releasing the UP and DOWN buttons.
- c. The **Paramedic CU-ER1** turns ON and displays the text prompt "SYSTEM CHECK"
- d. Follow the text prompts displayed by the device that tell you to press the Menu Keys and the Shock Button one by one.
- e. Verify that the **Paramedic CU-ER1** displays the text prompt "SYSTEM OK". The **Paramedic CU-ER1** shuts down automatically after the Manual Self-Test.
- f. If the **Paramedic CU-ER1** detects any fault in its system, it emits a beep and turns the error indicator light ON momentarily (see section 9.1 – Self-Tests, for more details).
- g. If a fault is detected, turn the **Paramedic CU-ER1** ON to see the error code.
- h. If a battery failure is detected, recharge the battery pack (see section 8.2 – Internal Battery Pack Recharging, for details). For any other failure, contact CU Medical Systems, Inc. or its authorized representative.

5.2.2 Battery Charge Check

The internal battery pack of the **Paramedic CU-ER1** is fully charged before leaving the factory. In the course of storage in the distribution system, the battery pack may be depleted when the **Paramedic CU-ER1** reaches you.

The Manual Self-Test in the previous section can detect a drained battery pack condition. At this condition, the **Paramedic CU-ER1** displays an error message when it is turned ON and it can not be used in a rescue operation. If a low battery error occurs during the manual self-test in the previous section, recharge the battery pack.

When the battery pack is not fully drained, check the battery level by activating the Menu and accessing Battery History (see section 4.5.2 – Battery History). If the battery status is LOW, recharge the battery pack.

5.2.3 Battery Charging

Charge the internal battery pack of the **Paramedic CU-ER1** if the Manual Self-Test indicates a Battery Failure error or if the indicator in the Battery History Menu indicates LOW battery status.

To charge the battery pack, see Section 8.2 – Internal Battery Pack.

5.2.4 Configuration Settings

You must set the following parameters of the Paramedic CU-ER1 before deploying it for use.

Time and Date Settings

The **Paramedic CU-ER1** is equipped with a timer integrated circuit that continuously keeps track of time and date.

You must set the timer when you receive the **Paramedic CU-ER1**.

To set the time and date, see section 4.5.6 – General Device Setup

5.3 Storage

Place the **Paramedic CU-ER1** in an accessible place so that it can be used readily during emergencies.

Do not open the Battery Compartment Cover.

Do not disconnect the internal battery pack during storage.

The internal battery pack must be connected all the time so that:

- The **Paramedic CU-ER1** can be readily turned ON during emergencies.
- The **Paramedic CU-ER1** can conduct automatic, periodic self-tests. The battery pack powers the **Paramedic CU-ER1** during these tests.

Check the status of the **Paramedic CU-ER1** daily by turning it ON. Pay close attention to the power level of the battery pack (see section 4.3 – Screen Display Views, on how to interpret the Battery Status Icon and Chapter 8 Power Supply, on how to recharge the batteries).

Store the **Paramedic CU-ER1** within the environmental conditions specified in section 2.1 – General Guidelines.

CAUTION

Do not connect the defibrillator pad assembly to the Paramedic CU-ER1 during storage. Do not open the sealed container of the pads until ready for use to prevent them from drying out.

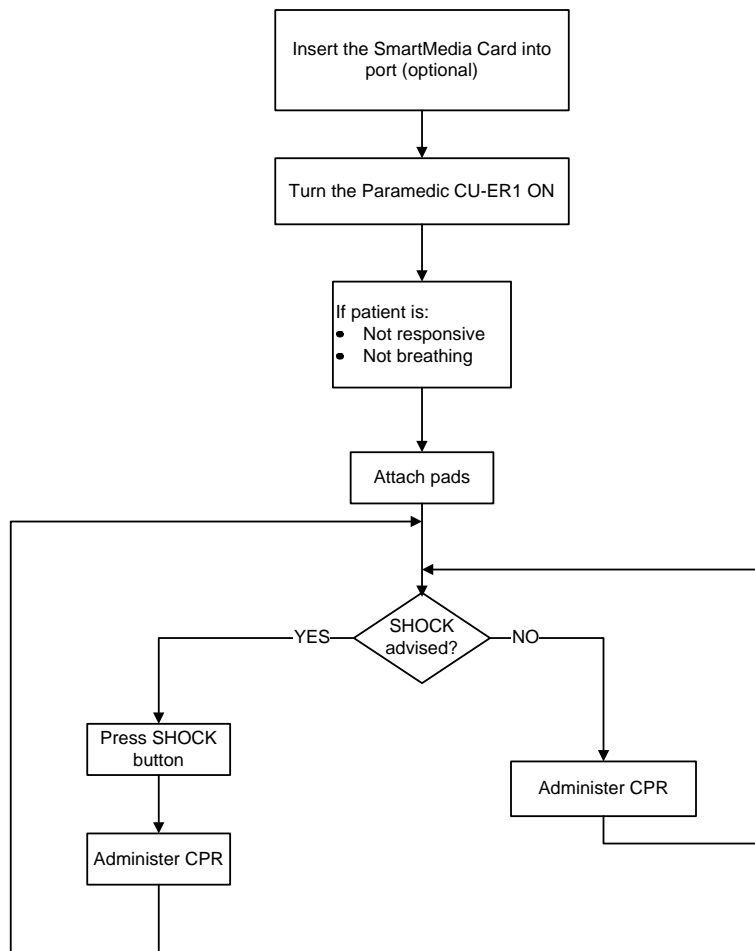
6. Using the Paramedic CU-ER1 in Emergencies Overview

This chapter discusses the steps during a rescue operation.

Read Appendix B to familiarize yourself with all the possible prompts and other indicators that the **Paramedic CU-ER1** gives during a rescue operation. The complete step by step rescue protocol of the **Paramedic CU-ER1** is shown in this Appendix.

For quick reference, refer to the laminated Quick Reference Guide which is a standard accessory of the **Paramedic CU-ER1**.

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



AED Operation Flowchart

6.1 Step 1: Preparation

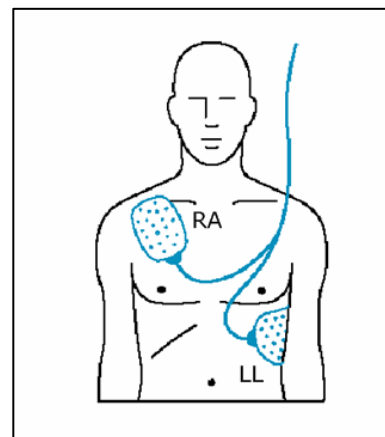
1. Insert the SmartMedia Card, if desired.
2. **TURN ON the Paramedic CU-ER1 by pressing the ON/OFF button.**
3. Assess the condition of the patient. Make sure that the patient is in a state indicated for defibrillation (see Section 3.2).

The patient must exhibit all of the following signs:

- **Unresponsiveness**
 - **Absence of normal breathing**
4. Assess the age and weight of the patient.
 - If the patient is an adult, proceed to instructions on ADULT DEFIBRILLATION
 - If the patient appears to be younger than 8 years old or weighs less than 25 kg (55 lb), proceed to instructions on CHILD DEFIBRILLATION.
 - Do not delay the rescue operation with an exact determination of age and weight. If the child appears to be older than 8 years old or heavier than 25 kg, proceed to instructions on ADULT DEFIBRILLATION.

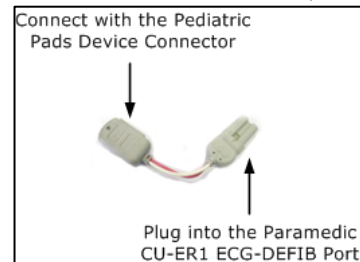
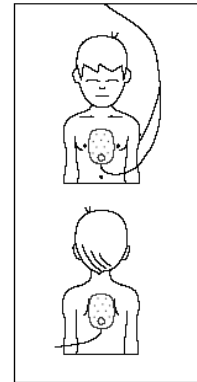
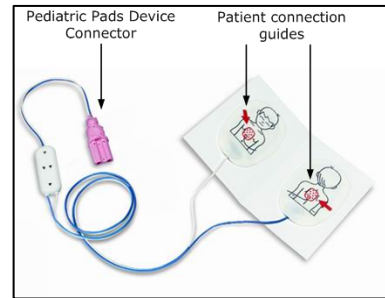
ADULT DEFIBRILLATION

1. Remove clothing from the patient's upper body.
2. Remove excess hair and wipe moisture off the skin of the patient on the area where the defibrillator pads are to be attached.
3. Open the defibrillator pads package.
4. Peel off the protective backing of the defibrillator pads. Check that the conductive gel has not dried out.
5. Place the defibrillator pads on the patient.
 - a. The pads must be placed with the sticky side on the skin of the patient.
 - b. The pads must be placed in an anterior-anterior position as shown in the figure at the right:
 - c. The reverse side of each pad indicates its position on the patient.
6. Plug the connector of the defibrillator pads into the ECG-DEFIB port of the **Paramedic CU-ER1.**



CHILD DEFIBRILLATION

1. Remove clothing from the patient's upper body.
2. Wipe moisture off the skin of the patient on the area where the defibrillator pads are to be attached.
3. Use the Reduced-energy Pediatric Defibrillator Pads as shown in the figure at the right.
4. Open the defibrillator pads package.
5. Peel off the protective backing of the defibrillator pads. Check that the conductive gel has not dried out.
6. Place the defibrillator pads on the patient.
 - a. The pads must be placed with the sticky side on the skin of the patient.
 - b. The pads must be placed in an anterior-posterior position as shown in the figure at the right:
 - c. The reverse side of each pad indicates its position on the patient.
7. Connect the device connector of the pads to the Pediatric Pads Connector Adapter.
8. Connect the appropriate end of the Pediatric Pads Connector Adapter to the ECG-DEFIB port of the Paramedic CU-ER1. See figure at the right.



CAUTION

The Paramedic CU-ER1 shuts down 1 minute after it is turned ON if it is not connected to the patient.

If the patient preparation takes more than 1 minute and the Paramedic CU-ER1 shuts down before the defibrillator pads can be connected to the ECG-DEFIB port, simply TURN ON the Paramedic CU-ER1 again by pressing the ON/OFF button.

6.2 Step 2: ECG Acquisition and Analysis

Follow the instructions provided by the voice and text prompts of the Paramedic CU-ER1

- The **Paramedic CU-ER1** automatically acquires and analyzes the ECG of the patient when:
 1. The pads are correctly attached to the patient
 2. And the plug of the pads connector is connected to the ECG-DEFIB port of the **Paramedic CU-ER1**.
- Do not touch the patient during ECG acquisition and analysis.

WARNING

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

WARNING

Electronic devices that may interfere with the ECG-signal should be turned off or moved to a safe distance during signal acquisition and analysis.

- The **Paramedic CU-ER1** decides and gives the prompt "**SHOCK ADVISED**" or "**NO SHOCK ADVISED**" after ECG analysis.

If the decision is **SHOCK ADVISED**:

1. The **Paramedic CU-ER1** charges itself in preparation for shock delivery.
 - The **Paramedic CU-ER1** emits a warning tone during charging.
 - The **Paramedic CU-ER1** gives the text prompt "CHARGING COMPLETE" at the end of the charging process.
2. The **Paramedic CU-ER1** gives the prompt "PRESS THE FLASHING RED BUTTON, NOW" after charging.

NOTICE

While the **Paramedic CU-ER1** 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 **Paramedic CU-ER1** disarms itself.

If the decision is NO SHOCK ADVISED:

1. The **Paramedic CU-ER1** gives the prompts "CHECK PULSE" and "IF NO PULSE, BEGIN CPR".
2. Check the patient and do CPR if the patient has no pulse. Attend to the patient according to CPR guidelines on AED Treatment.

6.3 Step 3: Shock Delivery

Press the SHOCK Button if instructed.

- **You must press the SHOCK button when the Paramedic CU-ER1 gives the prompt to press the SHOCK button in order to deliver the shock.**
- The **Paramedic CU-ER1** gives the following indications to signify that you must press the SHOCK button.
 1. A voice prompt telling you to "Press the flashing red button, now"
 2. A text prompt displayed on the LCD screen telling you to "Press the flashing red button, now"
 3. The red backlight of the SHOCK button is flashing and the beeper is beeping.

⚠ WARNING

The Paramedic CU-ER1 does not automatically deliver the shock after charging. It waits for you to press the SHOCK button.

⚠ WARNING

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

- The **Paramedic CU-ER1** gives the prompt "SHOCK DELIVERED" (voice and text) after the shock is delivered to the patient.
- The **Paramedic CU-ER1** also shows the cumulative number of shocks delivered during the rescue operation.
- After a shock is delivered, the **Paramedic CU-ER1** guides you through CPR administration.
- The **Paramedic CU-ER1** continues to provide the appropriate prompts to guide you properly.

⚠WARNING

The patient should be kept motionless during signal acquisition and analysis. If the patient is being transported in an emergency vehicle, the vehicle should be stopped during ECG signal acquisition and analysis.

⚠WARNING

Attach the defibrillator electrode pads as described on their reverse sides.

⚠WARNING

Make sure that there is good contact between the defibrillator pads and the patient's skin.

Ensure that there are no air pockets between the skin and the pads. Air pockets increase skin resistance to current flow and may cause burns.

⚠WARNING

If it is necessary to use another defibrillator on the patient, do not leave the Paramedic CU-ER1 connected to the patient. Disconnect the Paramedic CU-ER1 from the patient before using any other defibrillator.

⚠WARNING

Disconnect from the patient any MEDICAL ELECTRICAL EQUIPMENT which has no DEFIBRILLATION-PROOF applied parts when using the Paramedic CU-ER1.

⚠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.

6.4 Cardiopulmonary Resuscitation (CPR)

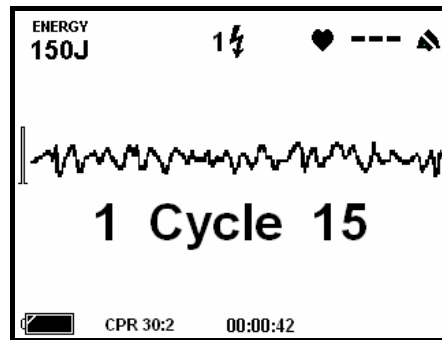
After delivery of a shock, the **Paramedic CU-ER1** pauses for you to administer CPR to the patient.

Check the patient for signs of circulation after delivering a shock. In the absence of circulation, administer 5 cycles of cardiopulmonary resuscitation (CPR).

The Paramedic CU-ER1 gives the following signals for CPR administration:

If a shock is delivered:

1. The voice and text prompt "BEGIN CPR, NOW".
2. The voice and text prompt "PUSH THE CHEST DOWN FAST TWO INCHES" immediately after the prompt in no. 1 above is given.
3. A CYCLE NO. and COMPRESSION NO. indicator keeps track of the progress of the CPR. This is shown in the figure below.
4. Beat guide from the beeper accompanies the CYCLE NO. and COMPRESSION NO. indicator.



5. The Paramedic CU-ER1 lets you perform 5 cycles of CPR.

If a shock is not delivered (decision is NO SHOCK ADVISED):

1. The voice and text prompt "CHECK PULSE"
2. The Paramedic CU-ER1 gives you 10 seconds to check the pulse of the patient.
3. The voice and text prompt "IF NO PULSE, BEGIN CPR"
4. The voice and text prompt "PUSH THE CHEST DOWN FAST TWO INCHES".
5. A CYCLE NO. and COMPRESSION NO. indicator keeps track of the progress of the CPR. This is shown in the figure above.
6. Beat guide from the beeper accompanies the CYCLE NO. and COMPRESSION NO. indicator.
7. The Paramedic CU-ER1 lets you perform 5 cycles of CPR.

After the administration of CPR, the **Paramedic CU-ER1** goes into another cycle of ECG acquisition and analysis.

7. ECG Monitoring Mode

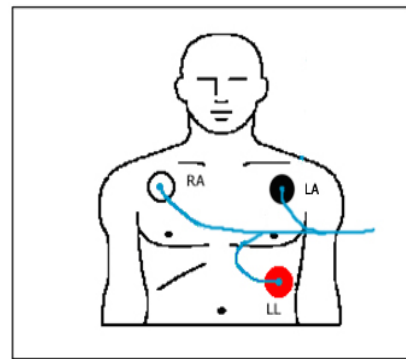
You may activate the ECG Monitoring Mode by connecting the custom-made ECG Monitoring Cable and Connector Assembly provided by CU Medical Systems, Inc.

In this mode, the Paramedic CU-ER1 does not do any arrhythmia analysis. Only the ECG and the calculated heart rate of the patient are shown on the screen display.

No defibrillation shock may be delivered when the device is in ECG MONITORING MODE.

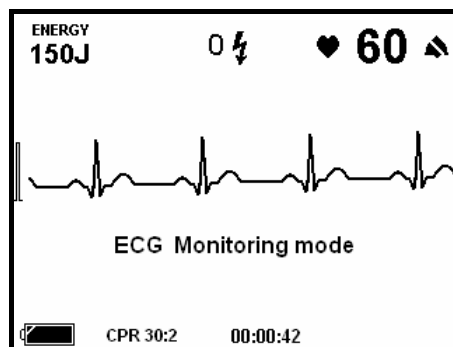
7.1 Patient Preparation

- a. Remove clothing from the patient's chest. Wipe moisture and clip or shave excessive chest hair.
- b. Open the package of the disposable ECG MONITORING electrodes and peel off their protective sheets.
- c. Attach the ECG MONITORING electrodes to the patient. The sticky side must be in contact with the patient's skin. The placement is shown in the figure at the right.
- d. Connect the snap connector of the ECG Monitoring Cable and Connector Assembly to the corresponding snap connector at the back of the electrodes.



7.2 ECG Monitoring

When the Paramedic CU-ER1 detects the ECG of the patient, it computes the heart rate and displays both the ECG trace and the heart rate value on the screen display. The display is shown in the figure below:



When in defibrillating mode, the device can be switched to ECG MONITORING MODE by replacing the defibrillator electrode pads with the ECG MONITORING electrodes.

When in ECG Monitoring Mode, it can be switched back to defibrillating mode by replacing the ECG Monitoring Cable and Connector Assembly with the Defibrillator Electrode Pads Assembly.

When the Paramedic CU-ER1 is switched between ECG MONITORING MODE and RESCUE MODE, all the relevant events (e.g. Pads On, etc) are recorded. The ECG waveforms and the voice signals are recorded in sequence from one mode to the other.

During the operation of the Paramedic CU-ER1, the device can be switched from one mode to the other as often and as many times as the operator wants.

The ECG waveform and the voice signal will also be recorded up to the recording capacity of the Paramedic CU-ER1.

NOTICE

Use only the ECG MONITORING electrodes that are recommended by CU Medical Systems, Inc.

CAUTION

Do not attempt to operate the Paramedic CU-ER1 in ECG MONITORING MODE using cable and connector assemblies other than the proper cable and connector assembly supplied by CU Medical Systems, Inc.

CAUTION

During ECG MONITORING MODE, the Paramedic CU-ER1 does not do any analysis of the ECG waveform. Thus, the Paramedic CU-ER1 is not able to prompt you about the presence of a shockable rhythm.

WARNING

During ECG MONITORING MODE, the Paramedic CU-ER1 is not able to deliver a defibrillating shock.

8 Power Supply

8.1 Power Sources

The Paramedic CU-ER1 may be powered by the following power sources

- a. Internal Battery Pack
- b. External Battery Pack
- c. AC/DC Adapter (mains powered)
- d. Car Cigar Lighter Jack

8.2 Internal Battery Pack

The default power supply of the Paramedic CU-ER1 is its internal battery pack, which is made of rechargeable Nickel Metal Hydride cells. It has a capacity of 200 shocks (150 Joules into 50 Ω) when new and fully charged.

The internal battery pack is connected to the circuit boards of the Paramedic CU-ER1 at the factory by default. Do not disconnect the internal battery pack from the circuit board of the Paramedic CU-ER1.

NOTICE

The Paramedic CU-ER1 is shipped with the internal battery pack connected. The battery must be kept connected when the device is not in use so that it could perform all the programmed self-tests regularly. The battery powers the device during these self-tests.

8.2.1 Internal Battery Pack Charge Status

The charge status of the internal battery pack is checked by the Paramedic CU-ER1 everyday. The status is indicated in the battery history in the device menu and on the LCD screen through the battery status icon. See section 4.3 for the explanation of the battery status icon.

If the voltage level of the internal Battery pack falls below the minimum tolerable level, the Paramedic CU-ER1 is going to be inoperative. When this is detected during the Daily Self-test, the Paramedic CU-ER1:

- a. Turns the ERROR indicator light ON then OFF
- b. Emits a single beep

After the low battery condition is detected, the Paramedic CU-ER1 turns the ERROR indicator light ON then OFF and emits a single beep every minute.

When the Paramedic CU-ER1 is turned ON after a low battery condition is detected, it does the following:

- a. Display the text prompt "LOW BATTERY CODE:0001".
- b. Turn the ERROR indicator light ON.
- c. Emit short beeps at a regular interval.

When the Paramedic CU-ER1 displays the flashing empty battery icon, have its internal battery pack recharged immediately. Do not wait for the voltage level to fall below the minimum tolerable voltage level because the Paramedic CU-ER1 will be inoperative.

8.2.2 Recharging of the Internal Battery Pack

There are two ways to recharge the internal battery pack:

- a. Using the AC/DC adapter
- b. Using the Car Cigar Lighter Jack Power Cord

Recharging Using the AC/DC adapter

The internal battery pack is recharged by connecting the AC/DC adapter output to the AC/DC adapter port of the Paramedic CU-ER1. The AC/DC adapter is powered through the AC mains with the following specifications:

- a. Frequency: 50Hz to 60Hz
- b. Voltage: 100V to 240V

Minimum recharging time is 4 hours. When the battery is fully charged, the Paramedic CU-ER1 automatically shuts down the recharging system, thus, you do not have to worry about overcharging the battery pack. However, the AC/DC adapter must be pulled off the mains when recharging is over.

Recharging Using the Car Cigar Lighter Jack Power Cord

- a. Turn the engine of the vehicle ON.
- b. Connect the appropriate end of the cigar lighter jack power cord to the cigar lighter jack of the vehicle.
- c. Connect the other end of the power cord to the AC/DC adapter port of the Paramedic CU-ER1.
- d. Disconnect the power cord from the AC/DC adapter port before turning the engine of the vehicle OFF

Internal Battery Charging Indicator

The Paramedic CU-ER1 indicates that charging is in progress through the Battery Indicator lamp. When charging is in progress, the Battery Indicator lamp is red and flashing. When charging is finished, the Battery Indicator lamp is green and non-flashing.

NOTICE

Do not remove or change the internal battery pack. If the battery pack reaches the end of its lifecycle, have it changed and disposed of by the manufacturer or any of its authorized representatives.

⚠ WARNING

The internal battery pack is not to be disposed of in fire nor incinerated. It is not to be shorted nor disassembled. It is not to be taken off its compartment and recharged with a charger other than the built-in charger of the Paramedic CU-ER1. If the internal battery pack leaks, call the manufacturer or any of its authorized representatives immediately.

⚠ WARNING

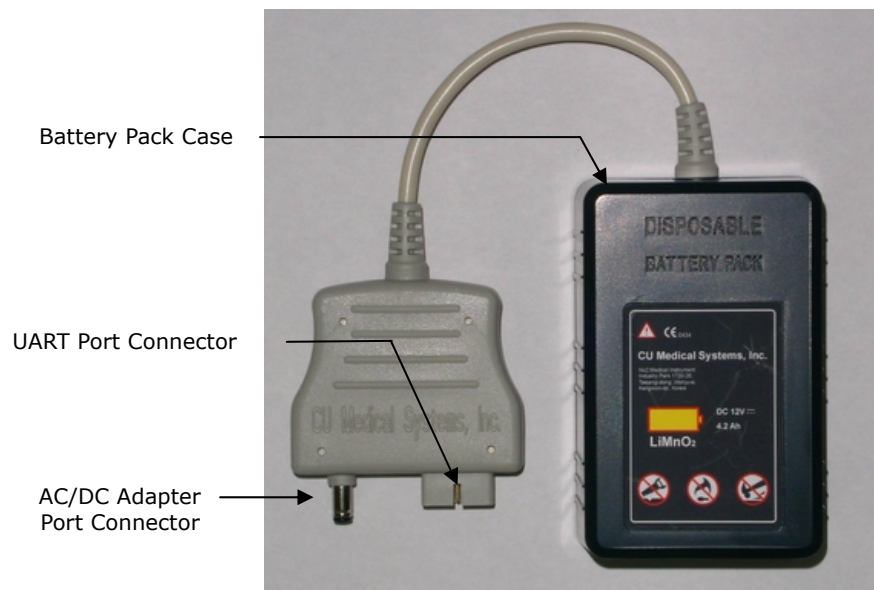
When the operating time of the internal battery pack becomes much shorter than its initial operating time, have it replaced by the manufacturer or any of its authorized representatives

⚠ CAUTION

The battery pack is not to be subjected to sharp impacts or concussions. The battery pack is to be recharged within the temperature range 0° to 40°. Recharging beyond this range may cause leakage of battery fluid or heat generation. The performance and life of the battery pack may also be impaired.

8.3 External Battery Pack

An optional disposable external LiMnO₂ battery pack is available from CU Medical Systems, Inc. This battery pack has a capacity of 200 shocks (150J into 50Ω) when used before the recommended usage date. The battery pack is shown in the following figure:



The external battery pack is fitted with a circuitry that relays signals to the Paramedic CU-ER1 indicating that an external battery pack is connected to its AC/DC Adapter port. The signal is transmitted through the UART port.

Do not attempt to use external battery packs from other sources. External battery packs from other sources will not be able to indicate to the Paramedic CU-ER1 that a battery pack is connected at the AC/DC adapter port. When an external battery pack from other sources is connected to the AC/DC adapter port of the Paramedic CU-ER1, the Paramedic CU-ER1 treats the battery pack as if it is an output from either the AC/DC adapter or the car cigar lighter jack cord. When this happens, the battery pack will not only be used to power the Paramedic CU-ER1, it will also be used to charge the internal battery pack of the device.

External Battery Pack Status

The energy level of the external battery pack is monitored by the Paramedic CU-ER1. The status of the external battery pack is indicated by the battery status icon which is displayed on the LCD screen during operation. See section 4.3 for the explanation of the battery status icon.

Connecting the External Battery Pack to the Paramedic CU-ER1

- a. Turn the Paramedic CU-ER1 OFF.
- b. Connect the connector of the battery pack to the AC/DC Adapter and UART ports of the Paramedic CU-ER1.
- c. Turn the Paramedic CU-ER1 ON.

If the external battery pack is connected while the Paramedic CU-ER1 is ON, the Paramedic CU-ER1 automatically switches its power supply circuit to use the external battery pack.

⚠ WARNING

The external battery pack is non rechargeable. Recharging poses risks of fire, heat generation, leakage or bursting.

⚠ WARNING

Read the instructions on the installation, usage, and storage of the external, disposable battery pack on this User's Manual before the said battery pack

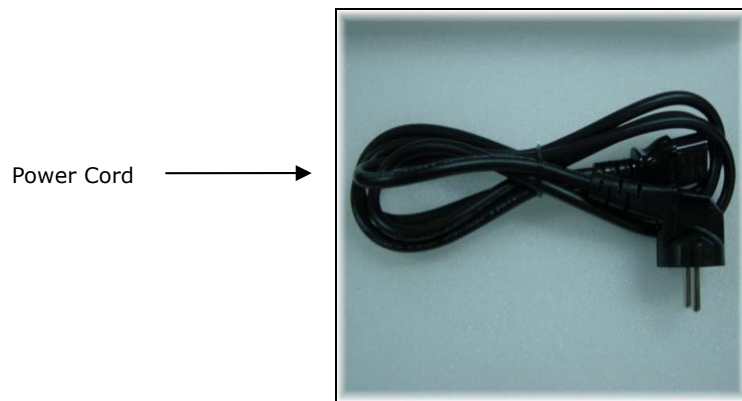
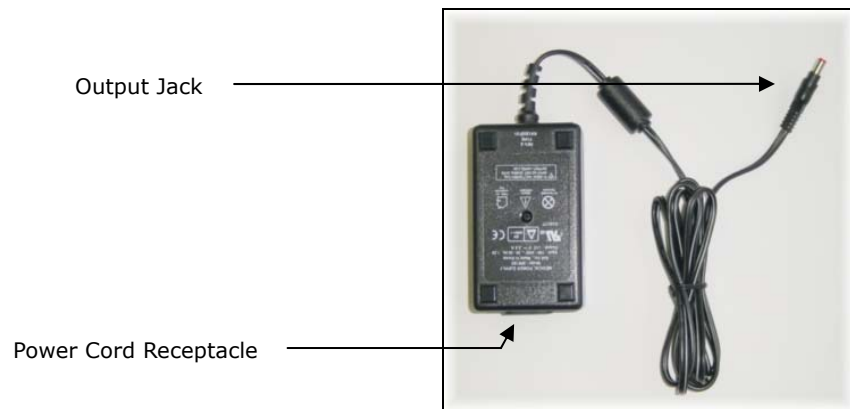
⚠ WARNING

Do not open the case of the battery pack.
Do not saw 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.
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 Paramedic CU-ER1.

8.4 AC/DC Adapter

The AC/DC Adapter is primarily used for recharging the internal battery pack. However, it may also be used to power the Paramedic CU-ER1 during rescue operations. It has medical device grade isolation properties (passes the requirements of EN 60601-1).

The AC/DC Adapter and the power cord are shown in the following figures



The AC/DC Adapter power supply derives power from the AC mains with the following specifications:

- a. Frequency: 50Hz to 60Hz
- b. Voltage: 100V to 240V

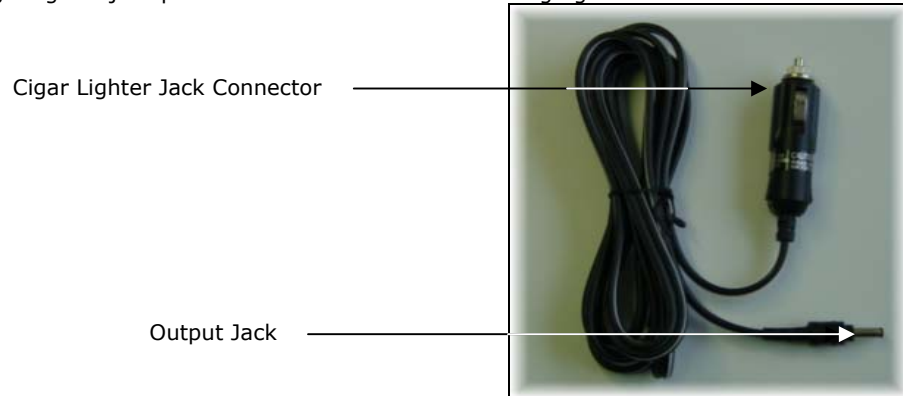
Connecting the AC/DC Adapter

- a. Connect the power cord to the adapter.
- b. Plug the power cord to the power mains.
- c. Connect the output jack of the adapter to the AC/DC port of the Paramedic CU-ER1.

CAUTION
Do not connect or disconnect the AC adapter plug while the device is being used, the transients during power changeover in the middle of a rescue operation may cause some problems in the operation of the device.

8.5 Car Cigar Lighter Jack

The Car Cigar Lighter Jack is another convenient power source for the Paramedic CU-ER1. This is to be connected to the cigar lighter jack of a vehicle (12V DC) The cigar lighter jack power cord is shown in the following figure.



Connecting the Cigar Lighter Jack Connector

- a. Turn the engine of the vehicle ON.
- b. Plug the appropriate end of the connector to the cigar lighter jack of the vehicle.
- c. Connect the output jack of the connector to the AC/DC Adapter port of the Paramedic CU-ER1.

CAUTION
When using the car cigar lighter jack for recharging, the vehicle must be started before the plug is connected and when the recharging is finished, the plug must be pulled out before the vehicle engine is turned off

Use the car cigar lighter jack only for recharging the battery pack of the Paramedic CU-ER1. Do not use the Paramedic CU-ER1 in a rescue operation when it is connected to a car cigar lighter power jack.

NOTICE
When the Paramedic CU-ER1 is powered using the AC/DC Adapter Port, the level of the internal battery pack does not affect the defibrillating capacitor charging time

9 TESTING, MAINTENANCE, AND TROUBLESHOOTING

9.1 Testing

To ensure that the **Paramedic CU-ER1** is always ready for any emergencies, self tests and interactive tests are performed by the device. If the ERROR LED is ON, consult the chapter on Troubleshooting.

9.1.1 Automatic Self-Tests

The Paramedic CU-ER1 performs automatic self-tests. These tests are automatic and these are done without your intervention. When Automatic Self-tests are performed, the green lamp of the ON/OFF button is turned ON but the LCD screen display is off.

9.1.2 Power On Self Test

Whenever the **Paramedic CU-ER1** is turned on, it initiates a self-test to ensure that the whole system is ready for use in emergencies. The following tests are performed:

- a) SHOCK Button functionality test: verifies that the SHOCK button is in proper condition for operation.
- b) Charging and Discharging test: verifies the proper functioning of the charging and discharging subsystems.
- c) Impedance Calibration Test: verifies that the impedance measuring subsystem is working properly. This is done by measuring the impedance of a reference load.
- d) Battery capacity test: verifies that battery capacity is sufficient for proper operation. If the battery level becomes too low, the device prompts you of the low battery condition when you turn the Paramedic CU-ER1 ON.
- e) Random Access Memory (RAM) test: verifies that the RAM chip is in working condition.
- f) Real Time Clock (RTC) chip test: verifies that the real time clock chip is in working condition

The Paramedic CU-ER1 displays the text prompt "STARTING" when the Power On Self-Test is conducted. This is shown in the following figure:



9.1.3 Periodic Self-Tests

When the **Paramedic CU-ER1** is stored with a charged battery pack connected to it, it performs periodic self-tests to ensure that it is ready for use in emergencies. Three types of periodic self-tests are done. These are:

a) Daily Periodic Self-Test – this is done daily. The following are checked during this test

- i. Battery capacity: This test is the same as the one done during power on self test. When the device is turned ON, if the "LOW BATTERY CODE:0001" message is displayed on the LCD screen, recharge the battery.
- ii. RAM – same test as the one done during Power On Test.
- iii. RTC – same test as the one done during Power On Test.

b) Weekly Periodic Self-Test – This is done weekly.

- i. All the subsystems tested under the Daily Periodic Self-Test.
- ii. Read Only Memory test: verifies the functionality of the read only flash memories.
- iii. High Voltage Subsystem test: tests the critical components of the high voltage subsystem. These are the SCR (silicon controlled rectifier) and IGBT (insulated gate bipolar transistor) switches in the H-bridge circuit that controls the discharging of the defibrillating capacitor, the comparator that checks the voltage level of the defibrillating capacitor, the internal load dumping components, and the relay that connects the front end amplifier, high voltage circuit , and the patient
- iv. Impedance Calibration Test: same test as the one done during Power On Test.
- v. RTC: same test as the one done during Power On Test.
- vi. CPLD test: tests the complex programmable logic device (CPLD) for functionality.

c) Monthly Periodic Self Test – this automatic self-test is done once a month. The following subsystems are tested:

- i. All the subsystems tested under the Weekly Periodic Self-Test.
- ii. Capacitor charging test: tests the charging function of the Paramedic CU-ER1's defibrillating capacitor.

9.1.4 Run Time Self-Test

Aside from the Power On Self-Test, the **Paramedic CU-ER1** performs a Run Time Self-Test continuously whenever it is operating after checking that the defibrillator electrode pads are properly attached to the patient. The following are checked during a Run Time Self-Test:

- a) Battery Capacity Check: same as the one done during Power On Self-Test.
- b) Capacitor charging and discharging: charging and discharging are verified when these actions are carried out by the Paramedic CU-ER1 during a rescue operation. If charging or discharging fails, the operator is prompted of the failure.
- c) CPLD: the functionality of the CPLD is verified whenever any function using the said logic device is carried out.

9.1.5 Manual Self-Test

The **Paramedic CU-ER1** can also run a manual self-test that requires your intervention. The manual mode test evaluates all functions tested in all the automated test modes (Power On Self-Test, Run Time Self-Test, Daily/Weekly/Monthly Periodic Self-Test,).

To initiate a Manual Self-Test:

1. Press the UP(▲) and DOWN(▼) keys in the MENU keypad simultaneously.
2. Turn ON the **Paramedic CU-ER1** without releasing the UP and DOWN buttons.
3. The **Paramedic CU-ER1** turns ON and displays the text prompt "SYSTEM CHECK".
4. The **Paramedic CU-ER1** prompts you to press the Menu Keys and the SHOCK button one by one. You must press the particular key/button under test within 10 seconds of the prompt. If you do not press the key/button within 10 seconds, the **Paramedic CU-ER1** will interpret it as a button/key failure.

The "SYSTEM OK" prompt will be displayed on the LCD if the **Paramedic CU-ER1** detects no failure during a Manual Self-Test.

9.2 Maintenance

Although there are no user-serviceable parts inside the **Paramedic CU-ER1**, you can perform simple maintenance tasks to help prolong the life of the device and to help ensure that the device is in working condition. The following are the activities, together with frequency, that you can perform.

Used consumables should be disposed of in accordance with local regulations. Care should be taken in disposing of the used defibrillator electrode pads so as not to contribute to the pollution of the environment.

Maintenance Activities

Frequency	Activity	Actions to be Taken
Daily	Check the Paramedic CU-ER1 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.
	<p>Check the case of the Paramedic CU-ER1 and the accessories for any sign of apparent damage.</p> <p>Check for dirt contamination.</p>	<p>If there is any apparent damage to the case of the device, consult the manufacturer.</p> <p>If there is dirt contamination, clean the case as suggested in the section on Cleaning.</p>
After each use.	Ensure that the connector of the defibrillator pad assembly is disconnected from the ECG-DEFIB port of the Paramedic CU-ER1 .	Disconnect the pad assembly from the ECG-DEFIB port

MAINTENANCE CHECKLIST

Paramedic CU-ER1

Serial Number: _____ Location/Vehicle ID: _____

Date			
Scheduled Frequency			
Paramedic CU-ER1: 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			

9.3 Cleaning the Paramedic CU-ER1

After each use, clean the **Paramedic CU-ER1** 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 Paramedic CU-ER1 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 Paramedic CU-ER1.

10 Troubleshooting

10.1 Self-Tests

The **Paramedic CU-ER1** executes automated and manual self-tests to verify the functionality of its major subsystems.

The **Paramedic CU-ER1** raises alarms if it detects a fault during those self-tests. It raises more alarms when it is turned ON after a fault is detected.

Alarms

Alarms raised after a failure is detected during Power On or Run Time Test:

1. The **Paramedic CU-ER1** displays the error name and code on the LCD screen
2. The ERROR indicator light turns ON.
3. The beeper emits short beeps at regular intervals

Alarms raised after a fault is detected during self-tests (automatic and manual):

1. The ERROR indicator light turns ON then OFF.
2. The beeper emits a single beep.
3. The alarms stated in 1 and 2 are repeated every minute while the Paramedic is OFF.

Alarms raised when the **Paramedic CU-ER1** is turned ON after a fault is detected during automatic or manual self-test:

1. The **Paramedic CU-ER1** displays the error name and code on the LCD screen
2. The ERROR indicator light turns ON.
3. The beeper emits short beeps at regular intervals

Self-Test Errors			
Error Name	Code	Fault	Remedial Action
LOW BATTERY	0001	Low battery charge	Recharge the battery
SYSTEM ERROR	0002	NAND Flash memory failure	Return to an authorized service center for repair
SYSTEM ERROR	0004	Random Access Memory (RAM) Failure	Return to an authorized service center for repair
SYSTEM ERROR	0008	Real Time Clock (RTC) Failure	Return to an authorized service center for repair
SYSTEM ERROR	0016	Complex Programmable Logic Device	Return to an authorized service center for repair

Self-Test Errors, continued			
Error Name	Code	Fault	Remedial Action
SYSTEM ERROR	0032	Capacitor charge comparator failure	Return to an authorized service center for repair
SYSTEM ERROR	0064	ECG relay failure	Return to an authorized service center for repair
SYSTEM ERROR	0128	Impedance Measurement System Failure	Return to an authorized service center for repair
SYSTEM ERROR	0256	Shock Engine Failure	Return to an authorized service center for repair
SYSTEM ERROR	0512	Charge Failure	Return to an authorized service center for repair
SYSTEM ERROR	1024	Internal Discharge Failure	Return to an authorized service center for repair
SYSTEM ERROR	2048	Key Button Failure	<p>Make sure that the Key Button Failure is not caused by a failure of the operator to press the Key Button during Manual Self-Testing. Do this by running a Manual Self-Test and pressing the buttons as prompted.</p> <p>If the error is not due to a failure to press the buttons during Manual Self-Test, return the device to an authorized service center for repair.</p>

10.2 Prompts During Rescue Operation

If there are problems during a rescue operation that prevents the Paramedic CU-ER1 from successfully operating, the Paramedic CU-ER1 gives voice and text prompts to inform you of the problems.

These prompts, together with the remedial actions are shown in the following table.

ERROR PROMPT	POSSIBLE CAUSES	REMEDIAL ACTION
THE SHOCK BUTTON WAS NOT PRESSED	The Paramedic CU-ER1 detected a shockable rhythm, gave the prompt to "PRESS THE FLASHING RED BUTTON FOR DELIVERING A SHOCK TO PATIENT." but you did not press the SHOCK BUTTON within 15 seconds from the time the prompt was given.	The Paramedic CU-ER1 disarms (dumps the charge in its internal disarm resistance load) and proceeds to CPR guidance. Remedial action: Be sure to press the SHOCK button within 15 seconds when the Paramedic CU-ER1 issues the prompt "PRESS THE FLASHING RED BUTTON FOR DELIVERING A SHOCK TO PATIENT" if it is your intention to deliver a shock.
ATTACH PADS	The defibrillator electrode pads are not attached to the patient's bare chest.	Remedial action: Attach the defibrillator electrode pads to the bare chest of the patient. Follow the graphic direction provided at the back of each defibrillator electrode pad. Patients with excessive chest hair must be shaved.
	The defibrillator electrode pads assembly is not connected to the ECG-DEFIB port of the Paramedic CU-ER1.	Remedial Action: Confirm that the connector of the defibrillator electrode pads assembly is firmly connected to the ECG-DEFIB port of the Paramedic CU-ER1.

11 Data Management and Review

11.1 Overview

The Paramedic CU-ER1 stores the following rescue operation data

1. ECG data – the ECG signal acquired from the patient during an entire rescue operation.
2. Rescue Events Data – the significant events during a rescue operation. These include events such as POWER ON, PADS ON, etc.
3. Audio Signal Data – this is a recording of the audio signals in the vicinity of the rescue operation. These include the voice prompts given by the device and the audio signals generated by sources close to the rescue operation (e.g. voice of the rescue administrator)

The Paramedic CU-ER1 stores the rescue operation data in the following locations.

1. Internal Data Flash Memory – this is the nonvolatile, default data storage location of the Paramedic CU-ER1. Audio signal data can not be recorded here. It is nonvolatile, thus, the stored data is not erased when the device is turned OFF.

The Internal Data Flash Memory has a capacity of 12 hours of ECG and Event data recording. The whole memory location is erased at the beginning of a rescue operation, thus, data stored from a previous rescue operation is overwritten. To keep previously recorded data from being lost, these must be transferred to a personal computer using the CU Expert ECG Data Management software.

2. SmartMedia Flash Memory Card – this is the optional, removable, nonvolatile memory card available from CU Medical Systems, Inc. Audio signals may be stored here. This card is also erased during the start of a rescue operation if it is inserted in its port before the Paramedic CU-ER1 is turned ON. The data has to be transferred to a PC the same way as described above.

The SmartMedia card has a recording capacity of 42 hours of ECG and Events data or 1 hour of ECG, Event data, and Audio Signal Data.

When used, the SmartMedia card has to be installed in its port before the Paramedic CU-ER1 is turned ON. The Paramedic CU-ER1 has to be turned OFF before removing the SmartMedia card from its port.

11.2 DATA REVIEW USING THE PARAMEDIC CU-ER1

11.2.1 Internal Flash Memory

Data from the latest rescue operation is stored in the internal flash memory of the **Paramedic CU-ER1** if the SmartMedia Card is not present in its port. The data stored in the internal flash memory may be displayed and reviewed on the LCD screen of the device.

To review the stored data, perform the following steps:

- a. Turn the Paramedic CU-ER1 ON without inserting the SmartMedia Card and without connecting any ECG Monitoring/Defibrillator Electrode pads connector assembly to the ECG-DEFIB port.
- b. Activate the menu by turning the Paramedic CU-ER1 and pressing the MENU button. Go to REVIEW INCIDENT – USAGE REVIEW or REVIEW INCIDENT – ECG REVIEW.

11.2.2 SmartMedia Card (Optional Accessory)

Data from the latest rescue operation is stored in the SmartMedia flash memory card if it is installed in its port before the Paramedic CU-ER1 is turned ON.

Installation of a SmartMedia Card

- a) Ensure that the SmartMedia Card is clean and dry.
- b) Turn the **Paramedic CU-ER1** OFF.
- c) Load the SmartMedia Card with the metallic strip facing down and the notched end going in first. Push the card all the way in until the card hits a stop. The SmartMedia Card is ready to record data when the **Paramedic CU-ER1** is turned ON for use.
- d) When the device is turned ON with the SmartMedia Card inserted, the SmartMedia card data recording symbol is displayed on the right bottom side of the LCD display.



is displayed when the Voice Recording option is ON.

is displayed when the Voice Recording option is OFF

- d. Only SmartMedia Cards supplied by CU Medical Systems, Inc. are compatible with the Paramedic CU-ER1. Do not use any other kind of flash memory card.

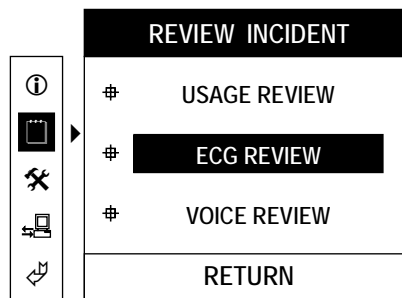
Removal of a SmartMedia Card

- a) Turn the **Paramedic CU-ER1** OFF
- b) Pull out the SmartMedia Card from the SmartMedia Card port.

NOTICE
<p>Make sure that the SmartMedia Card is loaded before turning ON the device. Do not pull out the SmartMedia Card before turning OFF the device. Loading or pulling out the SmartMedia Card while the power is ON will cause data error and may damage the SmartMedia card</p>

Reviewing Data Using a SmartMedia Card

After installing the SmartMedia Card, turn ON the Paramedic CU-ER1. Activate the menu by pressing the MENU button. Go to REVIEW INCIDENT. The following screen is displayed



3 submenu listings (Usage Review, ECG Review, Voice Review) of the recorded incident data are then shown.

Scroll the highlighter bar through the choices (Usage Review, ECG Review, Voice Review).

Press the MENU key to enter the chosen sublevel.

The data (Usage, ECG waveform, voice) will be displayed on the LCD or played back on the speaker. You may scroll through the ECG and Event data by pressing the UP(▲) or DOWN(▼) key.

NOTICE

When the SmartMedia Card is inserted into the Paramedic CU-ER1 for recording of rescue data, all the data present in the SmartMedia Card are overwritten with data from the current rescue operation. The previous data are no longer retrievable.

To preserve data through a series of rescue operations, the data must be transferred to a personal computer before using the SmartMedia card again.

The same is true with the internal flash memory. Previously recorded data are overwritten every time new data are recorded in the internal flash memory during a rescue operation.

Stored data in the internal flash memory are not overwritten if the data in a current rescue operation are stored in a SmartMedia Card. Thus, the data in the internal flash memory are still available for review when the Paramedic CU-ER1 is turned ON without the SmartMedia Card inserted.

11.3 DATA TRANSFER TO PERSONAL COMPUTER

The data from the previous rescue operation stored in the internal flash memory or the SmartMedia card are overwritten every time the Paramedic CU-ER1 is used in a rescue operation.

To keep data permanently, it must be transferred to a computer that is running the CU Expert ECG Data Management Software. The CU Expert is an optional data management software available from CU Medical Systems, Inc.

Data transfer can be done through the IrDA port or the UART port of the Paramedic CU-ER1.

11.3.1 IrDA

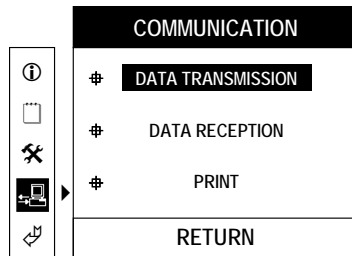
Connect the IrDA transceiver to the COM1 or COM2 serial port of the PC hosting the CU Expert ECG Data Management Software.

Align the IrDA transceiver with the IrDA port of the Paramedic CU-ER1. Insert the SmartMedia Card if the data to be transferred is in the SmartMedia Card. See the illustrations on the CU Expert User's Manual

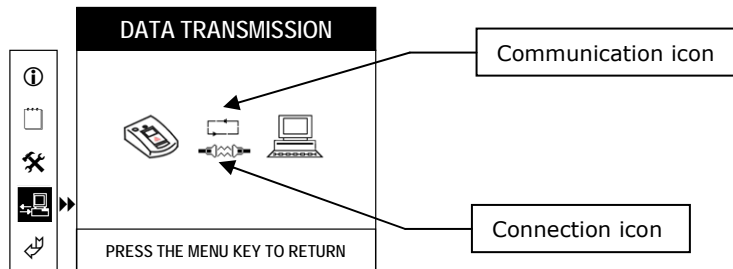
The Paramedic CU-ER1 must be set to communicate through its IrDA port by setting the COM PORT to IrDA as outlined in the GENERAL DEVICE SETUP of the section on MENU OPERATION.

Transmit the data from the Paramedic CU-ER1 through the following steps:

1. Open the CU Expert ECG Data Management Software in the host personal computer.
2. Do not connect any cable connector to the ECG-DEFIB port (defibrillator electrode pads assembly or ECG Monitoring Cable Connector assembly.). Turn the Paramedic CU-ER1 ON and press the Menu button.
3. Go to the CU Expert and begin data reception by executing the instructions given in its User's Manual.
4. Go back to the Paramedic CU-ER1. Go to COMMUNICATION-DATA TRANSMISSION. The following screen should be displayed.






Push the MENU button. The data transmission screen is displayed



When the Paramedic CU-ER1 is communicating, the Communication icon shows moving arrow tips.

The Connection icon shows the status of the connection of the Paramedic CU-ER1 with the PC during data transmission


Icon	Meaning
	<p>Before the start of data transmission: A connection has not been made yet.</p> <p>At the end of data transmission: Data transfer has been finished.</p>
	A connection has been established and communication is ongoing. When this icon is shown, a progress bar is also shown underneath the Paramedic CU-ER1 icon.
	<ul style="list-style-type: none"> • The attempt to make a connection has failed. • When this is shown, the Communication icon also stops moving the arrow tips. • Attempts to establish a connection is stopped if no connection is made in 1 minute. This icon is also shown if data transfer is cancelled due to interference

The progress of the data transmission is tracked by a progress bar in the LCD display of the Paramedic CU-ER1.

5. The order of device activation may also be reversed. It is possible to set the Paramedic CU-ER1 first to transmit data and then set the CU Expert to receive data.
6. When the data transmission is completed, the CU Expert ECG Data Management Software prompts you about the completion of the transmission. The completion of the data transmission is also shown by a full progress bar in the LCD display of the Paramedic CU-ER1.
7. When the transmission is finished, the Paramedic CU-ER1 may be turned OFF.

11.3.2 UART Port

The UART port may be used to transmit data to a PC running the CU Expert ECG Data Management Software.

 CAUTION
<p>If it is needed to transfer data while the patient is connected to the Paramedic CU-ER1, the computer used in the transfer of data through the UART port must comply with the requirements of the IEC 60601-1 Standard: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.</p>

Connect the Paramedic CU-ER1 to the PC as specified in the User's Manual of the CU Expert Data Management Software. Insert the SmartMedia Card if the data to be transferred is in the SmartMedia Card.

The Paramedic CU-ER1 must be set to communicate through its UART port by setting the COM PORT to UART as outlined in the GENERAL DEVICE SETUP of the section on MENU OPERATION.

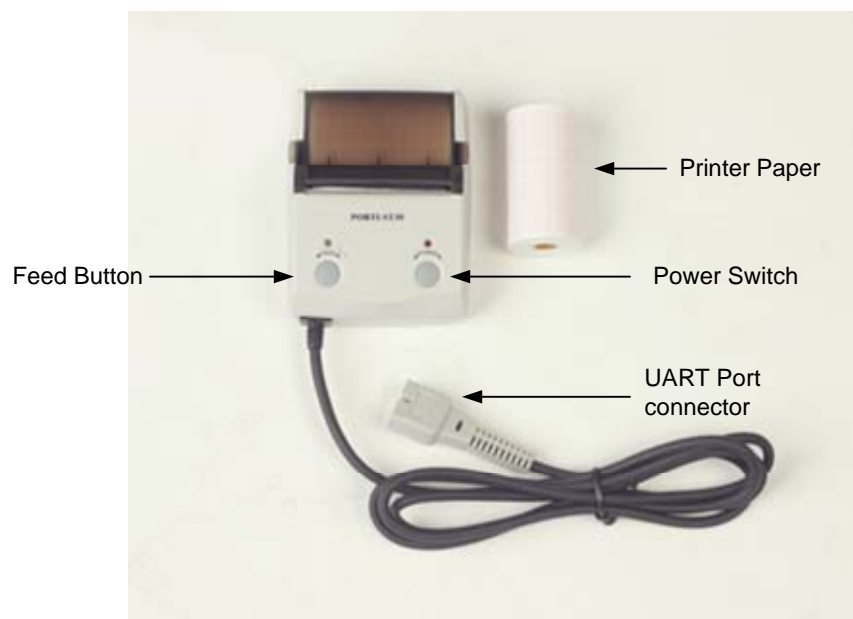
Proceed with data transmission as enumerated in the data transmission steps of section 11.3.1 IrDA port.

11.4 Printing Using a Stand-alone Serial Printer

The UART port may also be used to transmit data to a stand-alone serial printer.

Stand-alone Serial Thermal Printer

The optional stand-alone printer is a serial printer configured to receive data using RS232 protocol.



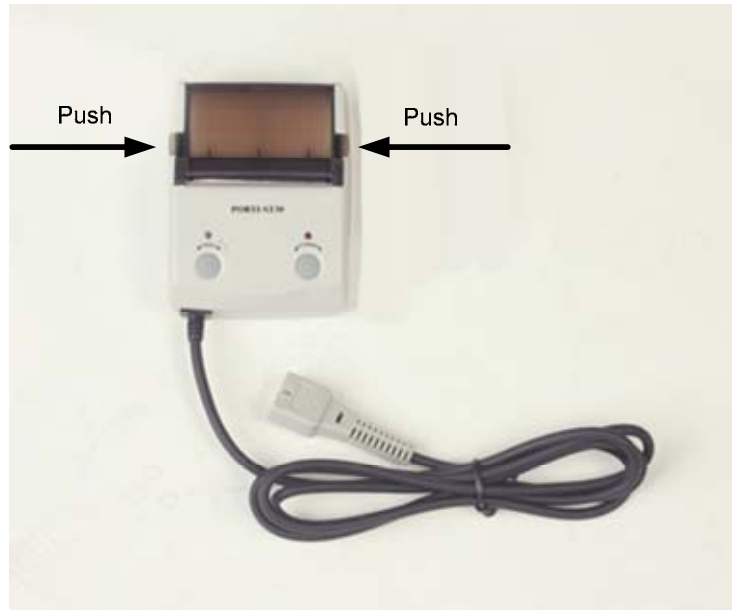
Stand-alone Thermal Printer

Power Switch	Used to turn the printer ON or OFF
Feed Button	Used to advance the printer paper.
UART Port Connector	Used to connect the printer to the UART Port of the Paramedic CU-ER1

The printer is powered by the Paramedic CU-ER1 through the UART Port Connector

Loading Paper into the Printer

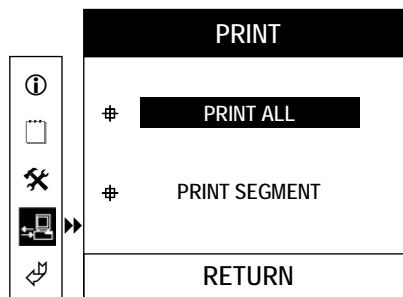
- a. Open the paper compartment of the printer by pushing the locks inward simultaneously. When the locks are disengaged, pull the paper compartment lid upward. This is shown in the following figure.



- b. Place a roll of printer paper into the compartment. The printing surface must face the paper cutter of the printer.
- c. Close down the lid of the printer paper compartment. Allow around ¼ inch of printer paper to go past the paper cutter to ensure that the paper will feed properly during printing.

Printing Data from the Paramedic CU-ER1

1. Connect the UART Port connector of the printer to the Paramedic CU-ER1's UART port.
2. Do not connect any connector (defibrillator electrode pads assembly or ECG monitoring electrodes assembly connector) to the ECG-DEFIB port of the Paramedic CU-ER1.
3. If it is desired to print data contained in the SmartMedia card, insert the SmartMedia card into its port in the Paramedic CU-ER1, otherwise, do not insert the SmartMedia card and the data in the internal flash memory will be printed.
4. Turn the Paramedic CU-ER1 ON and press the MENU button. Go to COMMUNICATION menu (see section 4.5.8 – Printing and Transferring Data), highlight PRINT then press the MENU button. The following screen is displayed

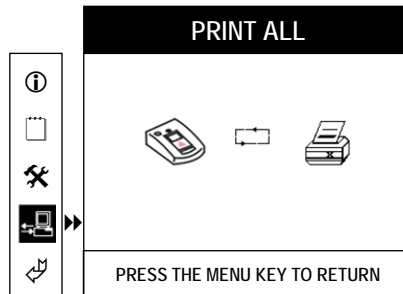


PRINT ALL prints all the data (ECG and event) stored in the active data memory (internal data flash memory if no SmartMedia card is present; SmartMedia card if it is in its port)

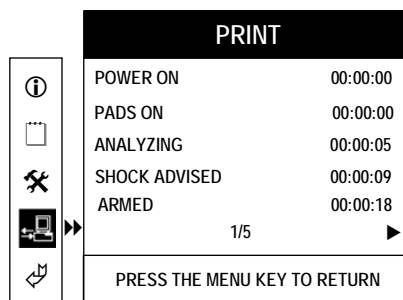
PRINT SEGMENT prints a selected range of the stored data.

5. Press the MENU button while PRINT ALL is highlighted if it is desired to print all of the data.

The **Paramedic CU-ER1** displays the following figure during printing (PRINT ALL).



If it is desired to print only a segment of the stored ECG data, highlight PRINT SEGMENT, then press the MENU button. The Paramedic CU-ER1 displays the following screen:



The event highlights are displayed.

6. Choose the starting point of the segment to be printed by pressing the UP or DOWN button.

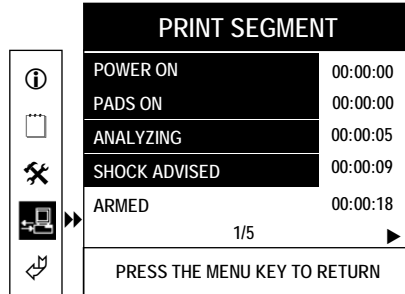
A highlighter bar appears and scrolls UP or DOWN.

7. Mark the starting Event point by highlighting it with the highlighter bar and pressing the MENU button.

8. Choose the ending Event point by pressing the DOWN button.

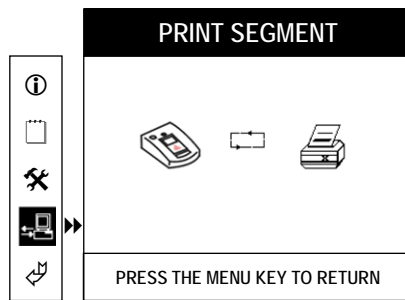
As the DOWN button is pressed, the Events included in the segment to be printed are highlighted. The ending point will be the last highlighted event.

After choosing the range to be printed, the screen display will look like this:



9. Press the MENU button to print the chosen segment.

While the segment is being printed, the Paramedic CU-ER1 displays the PRINT SEGMENT screen.



Notes

APPENDIX A



e~cube Biphasic Technology

1. What is Defibrillation?

Sudden cardiac arrest (SCA) associated with ventricular fibrillation (VF) remains a leading cause of unexpected death in the Western world. It has been estimated that chances for survival from SCA decrease approximately 7% to 10% with each passing minute and that survival rates after 12 minutes are only 2% to 5%.

The most common cause of SCA is ventricular fibrillation (VF), a lethal heart rhythm, and survival depends on the rapid treatment called *de*-fibrillation, an electrical shock sent to the heart to resume normal and healthy heart rhythm.

So early defibrillation is the sole definitive determinant of survival and is the key factor in cardiopulmonary resuscitation. Currently, fewer than 5% of the 250,000 persons who experience out-of-hospital cardiac arrest each year survive to hospital discharge.

2. How does the *e-cube* Biphasic waveform Defibrillate?

For defibrillation to be successful, a sufficient amount of electrical current must be delivered to the heart muscle. How to deliver the electrical current to the heart muscle is the core technique to defibrillate the heart.

Successful defibrillation would be done when the cell membranes of the heart are "coated" with positive ions on one side and negative ions on the other side, enough to depolarize nearly 100 percent of the cardiac cells at the same instant. Optimal current is determined with the pressure (this means electric Voltage) that controls what an amount of current can be pushed and the duration of time the current flows. This defibrillation current is commonly described in joules of energy. Energy is a measure of the amount of current, voltage, and duration of time the current flows.

$$\text{Energy(joules)} = \text{Current(amps)} \times \text{Voltage(volts)} \times \text{Time(sec)}$$

When the Defibrillation shock is delivered, current flow is affected by transthoracic impedance, the body's resistance from electrode to heart. Impedance is dependent on the anatomy of the chest, skin surface, air in the chest, hair, fat and bone, as well as the size and location of the defibrillation electrodes.

$$\text{Current(amps)} = \frac{\text{Voltage(volts)}}{\text{Resistance(ohms)}}$$

Research has shown that chest resistance can vary significantly from patient to patient. Patients with low impedance are generally easier to defibrillate because the flow of current meets little resistance. Those with higher impedance may be more difficult to defibrillate. According to the International Guidelines 2000 by the American Heart Association (AHA) in collaboration with the International Liaison Committee On Resuscitation (ILCOR), average adult impedance is 70-80 ohms. Defibrillation energy should be designed to optimize the delivery of current over a wide range of patient impedances. Too much current to the myocardial cells can cause damage to the cells and result in an unsuccessful defibrillation. Too little current to the myocardial tissue cells will not depolarize the cells and result in an unsuccessful defibrillation.

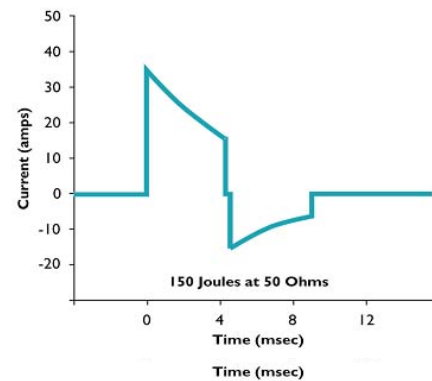


◆ **e~cube** Biphasic technology:

1. makes it **E**asy to compensate the shock waveform to match the patient's impedance.
2. is more **E**fficient than monophasic technology
3. delivers **E**nough energy for restoring heart rhythm.

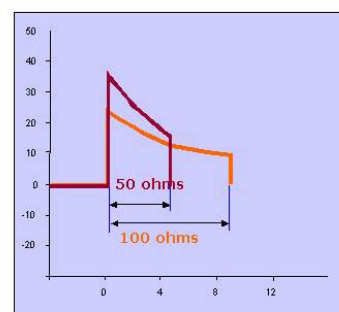
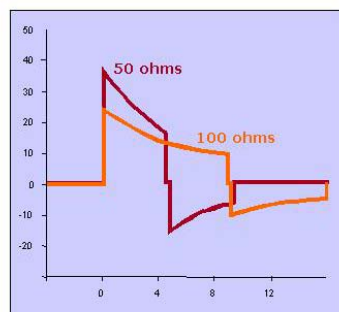
1. Ease in compensation of patient impedance variance.

Through e-cube Biphasic technology, defibrillation shock delivery is controlled while taking into consideration the patient's impedance. The patient's impedance is measured through the defibrillator electrodes. According to the measured patient's impedance, e-cube Biphasic technology adjusts the duration of current flow to optimize the effectiveness of the shock delivery. E-cube Biphasic technology is based on 3 core technologies.



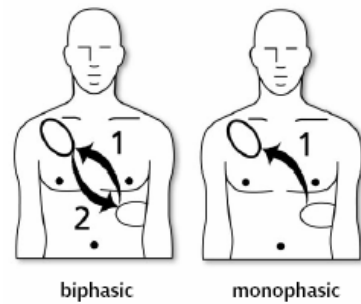
1. The technology for measuring the patient's impedance.
2. The technology for controlling the voltage level to be delivered.
3. The technology for controlling the duration of current flow.

These technologies can adjust the parameters of the shock waveform to match the transthoracic impedance of the patient. E-cube Biphasic technology increases the duration of current flow for patients with high impedance. When escalating energy, for example 150J to 180J, it delivers the electrical energy with higher voltage level if the patient's impedance does not vary.

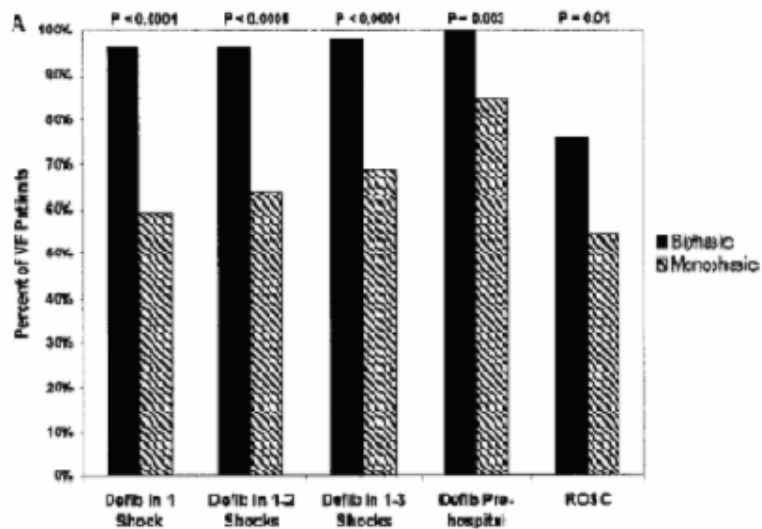


2. more Efficient than monophasic waveform

The electrical therapy delivered by transthoracic cardiac defibrillators has changed little since the introduction of direct-current defibrillation more than 30 years ago. Throughout this time, the industry-standard shock waveform for external defibrillators has been a monophasic damped sine (MDS) waveform, in which current flows in one direction throughout the shock. Many well-organized emergency medical systems, using monophasic devices for early defibrillation, have documented better than 20% survival to hospital discharge for cardiac arrest patients found in ventricular fibrillation (VF). Attempts to improve this survival rate have adapted proposals to change the waveform and energy level of defibrillation shocks. [6]



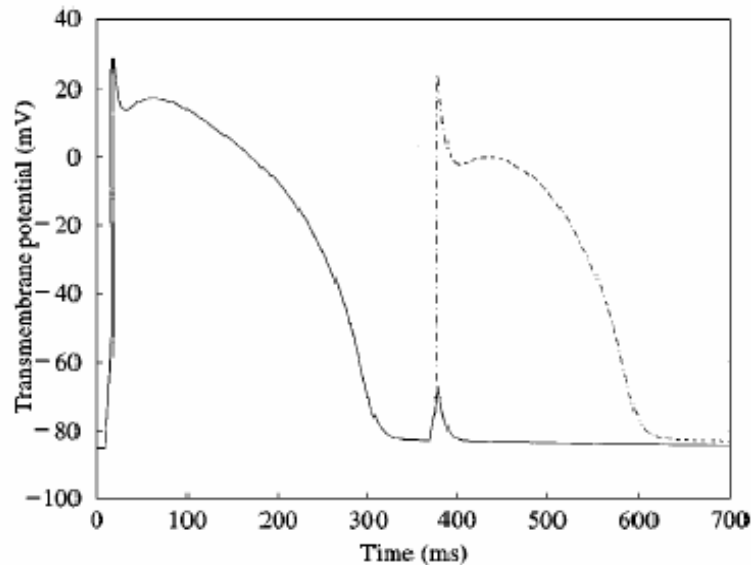
Biphasic waveform defibrillators incorporate two-way current flow in which electrical current first flows in one direction, then reverses direction approximately midway through the shock delivery.



Prehospital defibrillation and resuscitation efficacy for 115 patients who presented with VF
Schwartz et al. Circulation. 2000;102:1780-1787

Extensive animal and human data with implanted devices demonstrate that biphasic waveforms offer substantial reductions in defibrillation thresholds and produce less myocardial dysfunction than monophasic waveforms. [1], [2], [3], [4]

The defibrillation efficacy of the 150-J biphasic waveform was superior to that of the 200-J to 360-J conventional escalating-energy monophasic waveforms for 115 patients who presented with VF. [5]

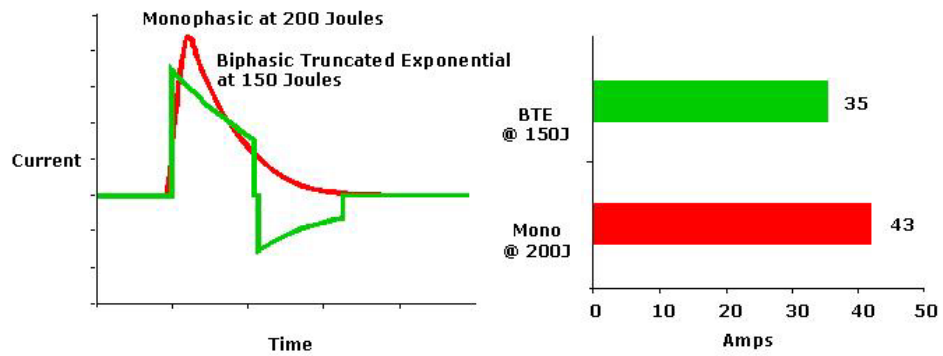


Transmembrane potential for a single Beeler-Reuter cell subject to monophasic and biphasic. Each stimulus amplitude (A) is 17.0 mV, duration is 10 ms and is applied 360 ms after the initial action potential. Notice that for a stimulus of the same amplitude, duration and timing, the biphasic stimulus is successful at activating the cell, whereas the monophasic stimulus fails to activate the cell. Monophasic (—); biphasic (---). Keener et al, *J. theor. Biol.* (1999) 200, 1-17

The difference between monophasic and biphasic waveform is qualitatively similar but varies quantitatively for different parameter values. The fundamental difference is that first phase of the biphasic pulse acts as a pre-pulse to remove inactivation from the heart cell, accelerating its recovery, and thereby lowering the activation threshold for defibrillation prior to second phase of biphasic pulse which is reversed current flow. This means that Biphasic shock is more effective than a monophasic shock at eliminating reentrant electrical activity in an ionic model of cardiac ventricular electrical activity. [7]

3. Enough energy for restoring heart rhythm

The Biphasic Truncated Exponential waveform uses lower energy than the Monophasic waveform. But the lower energy of biphasic shock is more efficient than high energy of the monophasic shock for defibrillation to restore heart rhythm.



In a multicenter, randomized, controlled trial of 150J biphasic waveform compared with 200J and 360J monophasic waveforms done in humans, Schneider et al [5] showed that “the 150-J biphasic waveform defibrillated at higher rates, resulting in more patients who achieved a return of spontaneous circulation. Although survival rates to hospital admission and discharge did not differ, discharged patients who had been resuscitated with biphasic shocks were more likely to have good cerebral performance.”

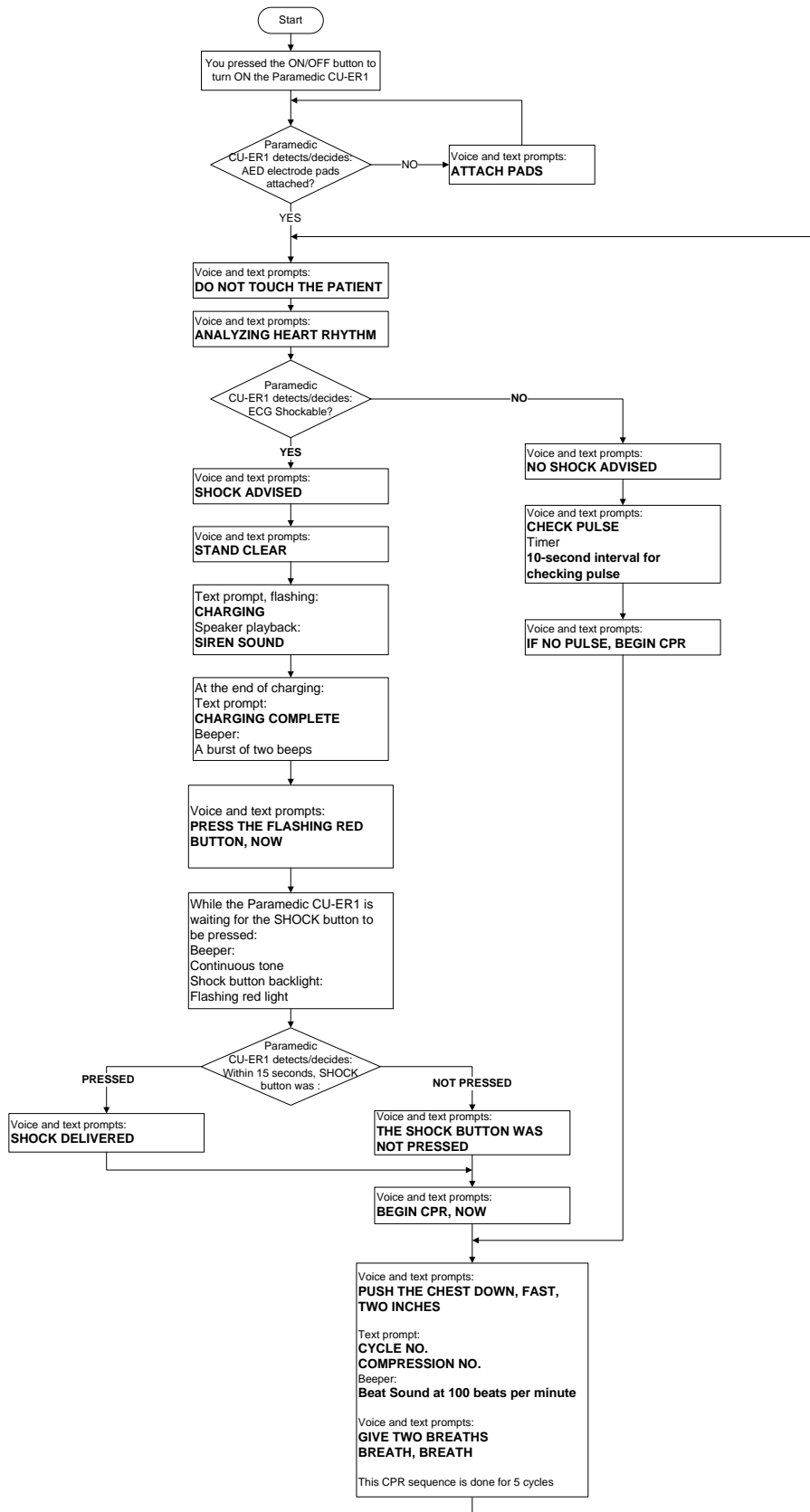
Positive evidence for safety and clinical effectiveness of biphasic truncated exponential waveforms for internal and external use was ascertained by the AHA ECC committee. [8], [9]

REFERENCES

1. Chapman PD, Vetter JW, Souza JJ, Wetherbee JN, Troup PJ. Comparison of monophasic with single and dual capacitor biphasic waveforms for nonthoracotomy canine internal defibrillation. *J Am Coll Cardiol.* 1989;14:242.5.
2. Kavanagh KM, Tang ASL, Rollins DL, Smith WM, Ideker RE. Comparison of the internal defibrillation thresholds for monophasic and double and single capacitor biphasic waveforms. *J Am Coll Cardiol.* 1989;14:1343.9.
3. Winkle RA, Mead RH, Ruder MA, et al. Improved low energy defibrillation efficacy in man with the use of a biphasic truncated exponential waveform. *Am Heart J.* 1989;117:122.7.
4. Ruppel R, Siebels J, Schneider MA, Kuck KH. The single endocardial lead configuration for ICD implantation: biphasic versus monophasic waveform [abstract]. *J Am Coll Cardiol.* 1993;21:128A.
5. T. Schneider, et al. Multicenter, Randomized, Controlled Trial of 150-J Biphasic Shocks Compared With 200- to 360-J Monophasic Shocks in the Resuscitation of Out-of-Hospital Cardiac Arrest Victims. *Circulation.* 2000;102:1780-1787.)
6. Steven L. Higgins, et al. A comparison of biphasic and monophasic shocks for external defibrillation. *Prehospital Emergency Care* 2000;4:305.313
7. J. P. KEENER , T. J. LEWIS. The Biphasic Mystery: Why a Biphasic Shock is More Effective than a Monophasic Shock for De5brillation. *J. theor. Biol.* (1999) 200, 1-17
8. AHA, Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care: an international consensus on science. *Circulation* 2000;102 (Suppl 1).
9. U. Achleitner, et al. Waveform analysis of biphasic external defibrillators, *Resuscitation* 50 (2001) 61–70

APPENDIX B

Rescue Protocol



APPENDIX C

Parts and Accessories Number

To order replacement parts and accessories, please cite the part numbers given in the table below.

Standard Parts	
Name	Part Number
Paramedic CU-ER1	
2 sets of Multifunction Defibrillator Electrode Pads CUA05080	ER1-NSP1
Power Cord	
AC/DC Adapter	
Operator's Manual	
Quick Reference Card	
Nickel Metal Hydride rechargeable battery pack	
Optional Accessories	
Carrying Case	ER1-OA01
SmartMedia Card (32M)	ER1-OA02
External Thermal Printer (Wire)	ER1-OA03
Car Cigar Lighter Jack Power Cord	ER1-OA04
1 Set of Multifunction Defibrillator Electrode Pads CUA05080	ER1-OA05
External Thermal Printer Paper (10 rolls)	ER1-OA06
ECG Cable (3 lead)	ER1-OA07
ECG Electrodes	ER1-OA08
Disposable Battery Pack (Li-ion)	ER1-OA09
Data management software with Key File (UART Cable Included)	ER1-OA10
Reduced-energy Pediatric Defibrillator Electrode Pads	ER1-PP01
Pediatric Pads Connector Adapter	ER1-OA12

APPENDIX D

TECHNICAL SPECIFICATIONS

Physical

Category	Nominal Specifications
Size	305 mm X 250 mm X 95 mm (L X W X H)
Weight	Approximately 2.7 kg

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 defibrillator electrode pads)	Temperature	32 °F to 109 °F (0 °C to 43 °C)
	Humidity	5 % to 95 % (non-condensing)
Storage Conditions (device only, no defibrillator electrode pads)	Temperature	-4 °F to 140 °F (-20 °C to 60 °C)
	Humidity	5 % to 95 % (non-condensing)
Shock/Drop/Abuse Tolerance	Meets IEC 60601-1 clause 21 (Mechanical Strength)	
Vibration	Meets MIL-STD-810E Method 514.4 Category 10	
Sealing	Meets IEC 60601-1 clause 44 (Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, and disinfection)	
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 Modes	Semi automatic
Waveform (Manual and AED Modes)	<i>e-cube</i> biphasic (Truncated exponential type); impedance compensated
Shock Delivery	Via multi-function defibrillator electrode pads
Patient Impedance Range	25Ω to 175Ω

Delivered Energy (Joules) VS Load Impedance (Ω)

Nominal Energy Setting (J)	Load Impedance (Ohms)							Accuracy
	25	50	75	100	125	150	175	
150	150	150	150	150	150	150	150	±15 %

Charging Time

Time from activation of RHYTHM RECOGNITION DETECTOR to the DEFIBRILLATOR being ready for discharge at 150 Joules	Less than 9 seconds	Using new, fully charged NiMH internal battery pack
	Less than 9 seconds	Using new, disposable, external LiMnO ₂ battery pack
	Less than 9 seconds	Using AC power at 100% of rated mains voltage
	Less than 9 seconds	Using new, fully charged NiMH internal battery pack, depleted by 15 discharges at 150 Joules per discharge.
	Less than 9 seconds	Using new LiMnO ₂ battery pack, depleted by 15 discharges at 150 Joules per discharge.
	Less than 9 seconds	Using AC power at 90% of rated mains voltage
Time from initially switching power ON, or from within any OPERATOR programming mode, to the DEFIBRILLATOR being ready at 150 Joules	Less than 27 seconds	Using new, fully charged NiMH internal battery pack
	Less than 27 seconds	Using new, disposable, external LiMnO ₂ battery pack
	Less than 27 seconds	Using AC power at 100% of rated mains voltage
	Less than 27 seconds	Using new, fully charged NiMH internal battery pack, depleted by 15 discharges at 150 Joules per discharge.
	Less than 27 seconds	Using new LiMnO ₂ battery pack, depleted by 15 discharges at 150 Joules per discharge.
	Less than 27 seconds	Using AC power at 90% of rated mains voltage

AED Energy Profile	Fixed energy at 150 Joules
Text and Voice Prompts	Provided to user in every step of a rescue operation
AED Controls	Power On/Off, SHOCK button, Volume control
Indicators	Electroluminescent back lit Liquid Crystal Display for ECG waveform and text prompts. AC Power, Battery, and ERROR indicator lamps
Armed Indicators	"Charging complete" text prompt Continuous tone from the beeper Flashing red backlight of the SHOCK button
Patient Analysis	<ul style="list-style-type: none"> • Detects and evaluates connection impedance for proper defibrillator electrode pads contact. • Analyzes patient's ECG to determine if a shock is necessary.
Shockable rhythms	<ul style="list-style-type: none"> • Ventricular Fibrillation • Ventricular Tachycardia with rates > 220 bpm
Sensitivity and Specificity	Meets AAMI guidelines

ECG Monitoring Mode

Input	Single channel ECG (Lead II) may be viewed on LCD and printed. Lead II ECG is acquired using a 3-wire ECG cable and connector assembly
Lead Fault	"ATTACH PADS" prompt and dashed line on BPM value are displayed when the ECG cable and connector assembly is disconnected from the ECG-DEFIB port.
Heart Rate Display	Digital readout display from 30 to 300 bpm with an accuracy of $\pm 2\%$
ECG Cable Length	3 meters
Common mode rejection	Greater than 90 dB measured per AAMI EC 13
ECG size	<ul style="list-style-type: none"> • 5 mm/mV • 10 mm/mV • 20 mm/mV • AUTO: 0.3 to 1 mV signals are displayed with 10mm/mV gain, outside of that range, the peak to peak value is displayed as 10 mm on the LCD display.
Frequency Response	ECG Monitoring Mode: 0.3 to 40 Hz (-3 dB) AED Mode (EMS): 1 Hz to 30 Hz

Patient Isolation

AED Mode	BF
ECG Monitoring Mode	BF

Event Storage

Internal Flash Memory	12 hours of event and ECG recording
SmartMedia Card (32MB):	42 hours of event and ECG recording or 1 hour if voice recording is enabled
ECG Record Printing	<ul style="list-style-type: none"> • May be printed directly from the Paramedic CU-ER1 using a portable thermal printer. • May also be printed using a personal computer by downloading the data to the PC using the data management software from CU Medical Systems, Inc. (CU Expert)

External Links

UART Port / IrDA Port

Display

Type	Liquid Crystal Display with electroluminescent backlight
Size	4 inches (10.16 cm) diagonal
Resolution	320X240 pixels
Sweep speed	25 mm/s nominal, stationary trace, sweeping erase bar
Viewing Time	3.2 seconds

Battery

Internal Battery Pack	
Type	4500mAh, 12V, rechargeable, Nickel Metal Hydride
Dimensions	89mmX36mmX69mm (LXWXH)
Weight	About 620grams
Charge time	4 to 5 hours
Capacity	200 shocks at 150 Joules
Battery Indicators	Battery level indicator Battery charging indicator
Battery Storage	Should not be stored beyond 40 °C for extended periods (more than 90 days)
Charger output	Unit can be used while the internal battery is being recharged
External Battery Pack	
Type	4200mAh, 12V, Non rechargeable, LiMnO ₂ ,
Dimensions	104mm X 67mm X 42mm (LXWXH)
Weight	Approximately 423 grams including connector
Capacity	200 shocks at 150 Joules
Battery Indicators	Battery level indicator
Battery Operating Temperature	-40 °C to 60 °C

Thermal Array Printer

Printing method	Direct thermal line printing
Resolution	230dpi, 8 dots/mm
Printing Speed	50mm/s
Dimensions	75mmX95mmX35mm
Weight	169g (including roll paper)
Input power	12V DC, Standby current 60mA, maximum current 3A
Operating Temperature	-10 °C to 40 °C
Storage Temperature	-10 °C to 70 °C

Electromagnetic Compatibility


Guidance and manufacturer's declaration – electromagnetic emissions		
The Paramedic CU-ER1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Paramedic CU-ER1 should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF Emissions CISPR 11	Group 1	The Paramedic CU-ER1 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 Paramedic CU-ER1 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

WARNING

The Paramedic CU-ER1 should not be used adjacent to or stacked with other equipment.
If adjacent or stacked use is necessary, the Paramedic CU-ER1 should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic immunity			
The Paramedic CU-ER1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Paramedic CU-ER1 should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 0,5 cycles	<5 % U_T (>95% dip in U_T) for 0,5 cycles 40 % U_T (60% dip in U_T) for 5 cycles 70 % U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 0,5 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Paramedic CU-ER1 requires continued operation during power mains interruptions, it is recommended that the Paramedic CU-ER1 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- for LIFE SUPPORTING EQUIPMENT and SYSTEMS

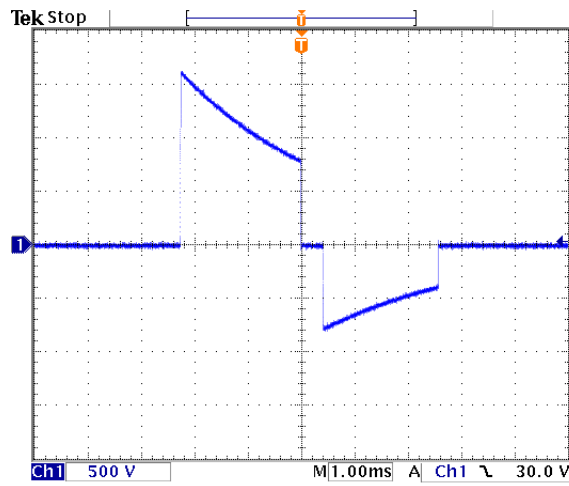
Guidance and manufacturer's declaration – electromagnetic immunity			
The Paramedic CU-ER1 is intended for use in the electromagnetic environment specified below. The customer or the user of the Paramedic CU-ER1 should assure that it is used in such an environment.			
Immunity Test	IEC 60601-1 test level	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 Paramedic CU-ER1 , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.16\sqrt{P}$
	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	$d = 1.2\sqrt{P}$ 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: 
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 Paramedic CU-ER1 is used exceeds the applicable RF compliance level above, the Paramedic CU-ER1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Paramedic CU-ER1.		
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 Paramedic CU-ER1 – LIFE SUPPORTING FUNCTIONS

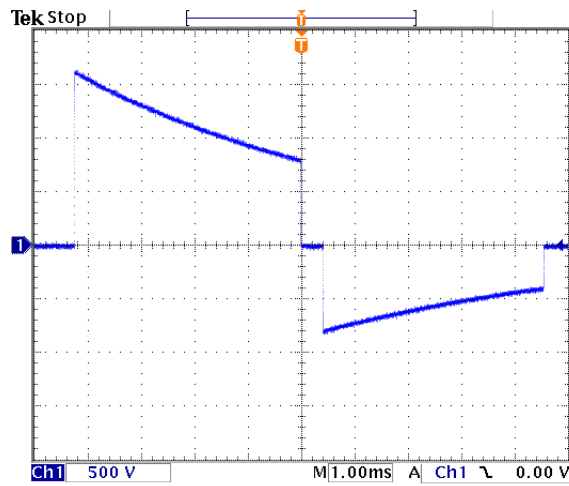
Recommended separation distances between portable and mobile RF communications equipment and the Paramedic CU-ER1				
<p>The Paramedic CU-ER1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Paramedic CU-ER1 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Paramedic CU-ER1 as recommended below, according to the maximum output power of the communications equipment.</p>				
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
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>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.</p> <p>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.</p> <p>NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>				

Paramedic CU-ER1 Shock Waveform Plots

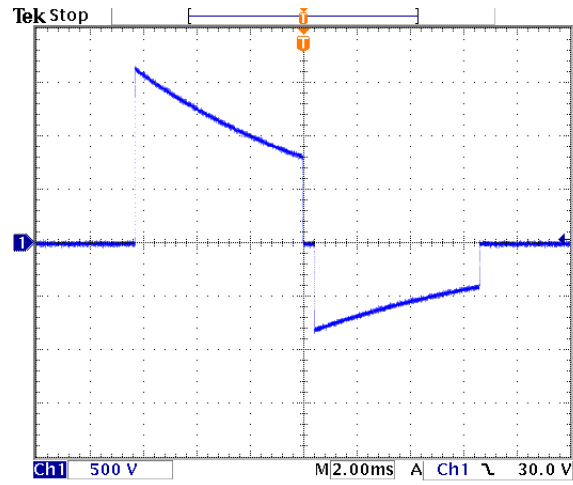
**25Ω Impedance Load
150 Joules output**



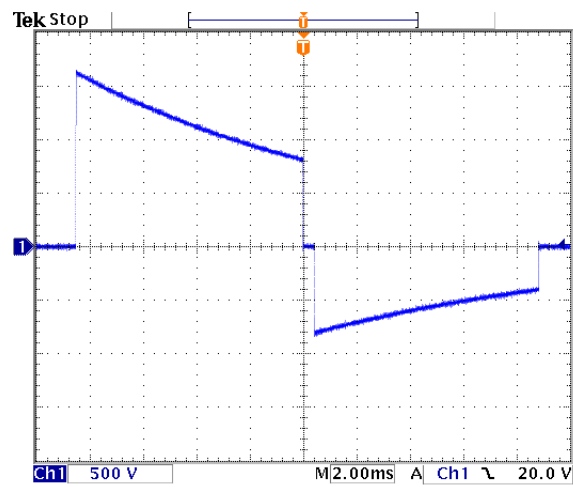
**50Ω Impedance Load
150 Joules output**



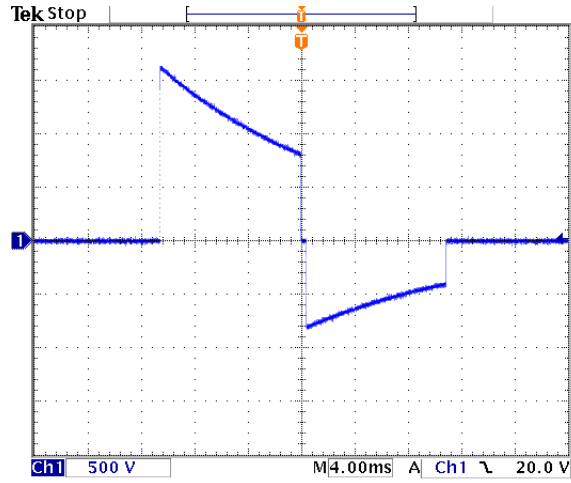
**75Ω Impedance Load
150 Joules output**



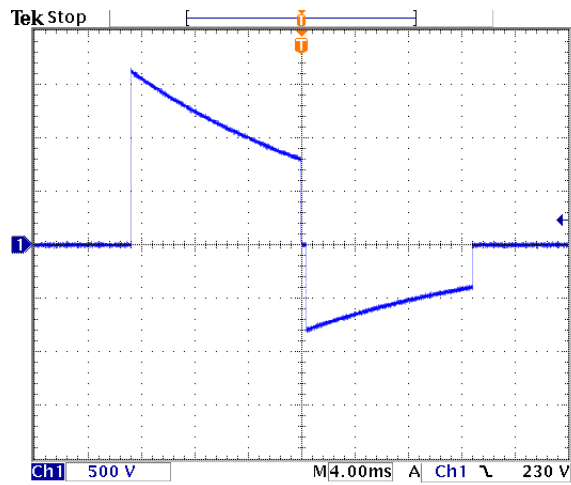
**100Ω Impedance Load
150 Joules output**



**125Ω Impedance Load
150 Joules output**



**150Ω Impedance Load
150 Joules output**



**175Ω Impedance Load
150 Joules output**

