OPERATING INSTRUCTIONS

PHYSIO CONTROL

LIFEPAK® 500

automated external defibrillator

PMI
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VISTA, CA 92081
TEL:800-764-0636/760-597-5501
http://www.progressivemed.com

PHYSIO CONTROL

OPERATING INSTRUCTIONS

LIFEPAK® 500
automated external defibrillator

IMPORTANT

Federal (US) law restricts this device to sale by or on the order of a physician.

This instrument is to be used by authorized personnel only.

Device Tracking

(US only, including US government-owned units)
Under the Safe Medical Devices Act of 1990, defibrillator manufacturers and distributors are required to track the location of defibrillators. If your defibrillator has been sold, donated, lost, stolen, exported, or destroyed or if it was not obtained directly from Physio-Control Corporation, please notify Physio-Control Corporation at 1.800.442.1142, extension 4530.

Responsibility for Information

It is the responsibility of our customers to ensure that the appropriate person(s) within their organization have access to this information, including general safety information provided in Section 1.

Product Recycling Information

Recycle the device at the end of its useful life.

- **Preparation**

  The device should be clean and contaminant-free prior to being recycled.

- **Recycling Assistance**

  The device should be recycled according to national and local regulations. Contact your local Physio-Control representative for assistance.

- **Recycling of Disposable Electrodes**

  After disposable electrodes are used, follow your local clinical procedures for recycling.

- **Packaging**

  Packaging should be recycled according to national and local regulations.

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PREFACE

About Defibrillation

Defibrillation is a recognized means of terminating certain potentially fatal arrhythmias. A direct current defibrillator applies a brief, high-energy pulse of electricity to the heart muscle. The LIFEPAK® 500 automated external defibrillator (AED) delivers this energy through disposable QUIK-COMBO™ pacing/defibrillation/ECG electrodes applied to the patient's chest.

Defibrillation is only one aspect of the medical care required to resuscitate a patient with a shockable ECG rhythm. Depending on the situation, other supportive measures may include:

- Cardiopulmonary resuscitation (CPR)
- Administration of supplemental oxygen
- Drug therapy

It is recognized that successful resuscitation is related to the length of time between the onset of a heart rhythm that does not circulate blood (ventricular fibrillation, pulseless ventricular tachycardia) and defibrillation. The American Heart Association has identified the following as critical links in the chain of survival from cardiac arrest:

- Early access
- Early CPR by first responders or bystanders
- Early defibrillation
- Early advanced life support

The physiological state of the patient may affect the likelihood of successful defibrillation. Thus, failure to resuscitate a patient is not a reliable indicator of defibrillator performance. Often, patients will exhibit a muscular response (such as jumping or twitching) during energy transfer. The absence of such a response is not a reliable indicator of actual energy delivery or device performance.

Operator Considerations

The LIFEPAK 500 AED is a semi-automatic defibrillator that uses a patented Shock Advisory System™. This software algorithm analyzes the patient's electrocardiographic (ECG) rhythm and indicates whether or not it detects a shockable rhythm. The LIFEPAK 500 AED requires operator interaction in order to defibrillate the patient.

The LIFEPAK 500 AED is intended for use by personnel who are authorized by a physician/medical director and have, at a minimum, the following skills and training:

- CPR training
- AED training equivalent to that recommended by the American Heart Association
- Training in the use of the LIFEPAK 500 AED

Guidelines for Use

The LIFEPAK 500 AED is to be used only on patients in cardiopulmonary arrest. The patient must be unconscious, pulseless, and not breathing spontaneously before the device is used to analyze the patient's ECG rhythm. This device is not intended for use on children less than eight years of age.

The LIFEPAK 500 AED is intended for use in the hospital and out-of-hospital environments. It has been tested to RTCA/DO-160C, "Environmental Conditions and Test Procedures for Airborne Equipment." (Details available on request.)

Features of the LIFEPAK 500 automated external defibrillator

QUIK-COMBO Electrodes

The LIFEPAK 500 AED is a portable, battery-powered device that provides defibrillation therapy. The AED uses disposable QUIK-COMBO defibrillation/ECG electrodes with or without the REDI-PAK™ preconnect system. The use of QUIK-COMBO electrodes allows rapid transfer of care to other devices that also use QUIK-COMBO electrodes.

Automated Operation

The operator controls AED operation with three top-panel buttons (ON/OFF, ANALYZE, and SHOCK). The AED guides the operator through operating procedures with a combination of:

- Voice prompts
- Tones
- Flashing LEDs
- Screen messages

The screen messages appear on a two-line Liquid Crystal Display (LCD). Other LCD information includes:

- Real-time clock
- Cumulative shock counter
- Status and service messages

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Continuous Monitoring

The LIFEPAK 500 AED operates in two modes: ECG analysis and Continuous Patient Surveillance System (CPSS). During analysis, the AED indicates if it detects a shockable or nonshockable rhythm. The CPSS, which is active when the AED is not performing an analysis, automatically monitors for a potentially shockable rhythm. CPSS is not active during CPR Time.

Motion Detection

The LIFEPAK 500 AED includes a patented system that detects motion. When motion that could distort the ECG rhythm occurs, the ECG data is automatically excluded from analysis by the motion detection system.

Data Management

The LIFEPAK 500 AED digitally records patient data, including ECG rhythm and delivered shocks. A digital audio recording of scene activity is available as an option. Recorded data may be transferred by direct connection to a printer or computer or by a modem to a remote computer. Two optional, Microsoft Windows™-compatible data management software programs are available. The Data Transfer 500™ program transfers, stores, and prints AED reports. The QUIK-VIEW™ 500 data review program includes all of the Data Transfer 500 functions and the capability to review ECG and audio data.

Automatic Self-Test

The AED performs an automatic self-test every 24 hours and every time you turn on the AED. The AED displays a service icon to inform the operator when service is required.

Battery Options

A rechargeable sealed lead-acid battery or a nonrechargeable lithium battery provides power to the AED. The rechargeable battery may be recharged by an external battery charger.

Customized Setup

AED operation may be customized by accessing a setup mode. Definable operating features include the modem phone number, the time interval allowed for CPR, and other features.

Optional Accessories

An optional carrying case helps to protect the AED and provides a pouch to store electrodes. Use the Physio-Control LIFEPAK AED TRAINER to train operators to use the LIFEPAK 500 AED.

Text Conventions

Throughout this manual, special text characters are used to indicate labels, LCD messages, and voice prompts:

- Operating control labels: CAPITAL LETTERS such as ON/OFF and SHOCK.
- LCD messages: CAPITAL LETTERS such as CONNECT ELECTRODES.
- Voice prompts: *CAPITAL ITALICIZED LETTERS* such as *PUSH ANALYZE*.

DECLARATION OF CONFORMITY

according to ISO/IEC Guide 22 and EN 45014

Manufacturer's Name: Physio-Control International

Manufacturer's Address: 11811 Willows Road NE
P.O. Box 97006
Redmond, WA 98073-9706
USA

declares that the CE-marked product

Product Name: LIFEPAK® 500, automated external defibrillator

Model Number: 3005400

complies with: 93/42/EEC (Medical Device Directive) Class IIb

This product complies with:

Safety: EN60601-1:1990/ IEC 601-1:1988 with amendments 1&2
-Class II, Type BF Continuous operation.
IEC 601-2-4:1983

EMC: EN60601-1-2:1993/IEC 601-1-2:

EN 55011:1991	- Class B, Group 1
EN61000 PT4-2 1st edition	- 8kV CD, 15 kV AD
IEC 1000 PT4-3 1st edition	- 3 V/m
EN61000 PT4-4 1st edition	- Not Applicable
IEC 1000 PT4-5/EN61000 PT4-5 1st edition	- Not Applicable

Supplementary Information:

1) Included are the following accessories and interconnecting cables:
QUIK-COMBO™ electrode set, p/n 806086 or 3006478
Sealed lead-acid battery, p/n 3005379
Lithium battery, p/n 3005380
Battery Charger (non-medical), p/n 3006535
Data transfer cable (non-medical), p/n 3005381

2) This product also complies with:

UL 2601-1;1994,
CSA C22.2 No. 601.1 and CSA C22.2 No. 601.2.4,
AAMI ES1, AAMI DF39

Redmond, November 1, 1996 — Michael D. Willingham, VP Quality and Regulatory Affairs

DECLARATION OF CONFORMITY

Ault, Incorporated
7300 Boone Avenue North
Minneapolis, MN 55428-1028
U.S.A.

We hereby declare under our sole responsibility that the product model(s) BCWA-042000-100A and BCWA-042000-100N (PHYSIO-CONTROL LIFEPAK 500 Battery Charger), a power supply intended for use as a battery charger in household and other similar applications, to which this declaration relates, meets the requirements of the following New Approach Directives:

- **Electro-Magnetic Compatibility (EMC)** Directive 89/336/EEC as demonstrated by compliance to EN50082-1:1992 Generic Immunity, IEC 801-2:1991 and IEC 1000-4-2:1995 Electrostatic Discharge Immunity, ENV50140:1993 and IEC 1000-4-3:1995 Radiated Electromagnetic Field Immunity, IEC 801-4:1988 Electrical Fast Transient/Burst, and EN 55022:1994 Class B limits for Radiated and Conducted Emissions.
- **Low Voltage Directive (LVD)** 73/23/EEC as demonstrated by compliance with EN 60065/09.93 Safety requirements for mains operated electronic and related apparatus for household and similar general use.

This declaration is backed by third party assessments to the noted European Norm standards. Ault Incorporated is an ISO 9001 registered firm, Certificate Number FM11881.

Tim Cassidy
Product Safety Engineer
28 October 1996

Safety Information

1

SAFETY INFORMATION

This section provides important information to help you operate the LIFEPAK 500 automated external defibrillator (AED). Familiarize yourself with all of these terms, warnings, and symbols.

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Terms

The following terms are used either in this manual or on the LIFEPAK 500 AED:

Danger:	Immediate hazards that will result in serious personal injury or death.
Warning:	Hazards or unsafe practices that could result in serious personal injury or death.
Caution:	Hazards or unsafe practices that could result in minor personal injury, product damage, or property damage.

General Warnings and Cautions

The following section provides general warning and caution statements. Other specific warnings and cautions are provided as needed in other sections of this manual.

⚠ WARNINGS

Shock hazard.

When discharged, the AED delivers up to 360 joules of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause personal injury or death. Do not attempt to operate this device unless thoroughly familiar with the function of all controls, indicators, connectors, and accessories.

Shock hazard.

Do not disassemble the AED. It contains no operator serviceable components and dangerous high voltages are present. Refer service to qualified service personnel.

Possible fire or explosion.

Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing), flammable gases, and anesthetics.

Possible misinterpretation of data.

Do not analyze in a moving vehicle due to potential motion artifact affecting the ECG signal. Stop vehicle and stand clear of patient during analysis.

Shock or fire hazard.

Do not immerse any portion of this device in water or other liquids. Avoid spilling any liquids on device or accessories. Do not autoclave this device or accessories.

Possible electrical interference with ECG analysis.

Equipment operating in close proximity to this AED may emit radio frequency interference which could affect the performance of the AED. Performance degradations, including failure to shock a shockable rhythm, can generally be overcome by repositioning the equipment or cables to increase the distance between the AED and the other equipment. It is recommended to maintain equipment separation of at least four feet and not to rapidly key EMS radios on and off. Contact Technical Support if assistance is required.

Possible improper device performance.

Use only Physio-Control QUIK-COMBO electrodes and batteries mentioned in this manual. Substitution of non-Physio-Control electrodes or batteries may cause the device to operate improperly.

Possible defibrillator shutdown.

Always have access to a spare, fully-charged, properly-maintained battery. Replace the battery if the device displays the low battery warning.

⚠ WARNINGS

Safety risk and possible equipment damage.

Defibrillators and their accessories contain ferromagnetic materials. As with all ferromagnetic equipment, these products must not be used in the presence of the high magnetic field created by a Magnetic Resonance Imaging (MRI) device. The high magnetic field created by a MRI device will attract the equipment with a force sufficient to cause death or serious personal injury to persons between the equipment and the MRI device. This magnetic attraction may also damage the equipment. Consult the MRI manufacturer for more information.

Shock hazard.

Do not insert a hand, foot, or any object other than a battery into the battery well of this device.

⚠ CAUTIONS

Possible equipment damage.

This device may be damaged by mechanical or physical abuse such as immersion in water or dropping the device.

Possible equipment damage.

Before using this AED, disconnect all equipment from the patient that is not defibrillator-protected.

Symbols

The symbols below may be found in this manual or on various configurations of the LIFEPAK 500 AED and accessories:

Defibrillation protected, type BF patient connection

Attention, consult accompanying documents

Warning, high voltage

Indicator: battery voltage is low, replace battery

Indicator: device requires service

▲ ▶ Buttons for setting the clock, transferring data, and setting options

Type BF patient connection

Rechargeable battery: recycle battery

Battery Charger: green LED indicates power is on

Battery Charger: battery is charging; amber LED indicates fast charge, green LED indicates trickle charge

Indoor use only

Safety Class II equipment (reinforced insulation)

Data Cable: to printer

Data Cable: to PC

Data Cable: to modem

Lot code

Expiration date

REF.

Reorder number

Do not reuse

CE (European) certification symbol

NRTL/C

Canadian Standards Association certification for the United States (Nationally Recognized Test Laboratory) and Canada

Getting Ready

2

GETTING READY

This section provides a basic orientation to the LIFEPAK 500 automated external defibrillator (AED) and describes how to prepare the AED for use. Topics include:

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Unpacking and Initial Inspection

Remove the LIFEPAK 500 AED from the shipping container. Examine the AED and accessories for any sign of damage during shipping. Make sure that all the required supplies and accessories, including electrodes and batteries, are present. Save the shipping container and foam inserts for use in reshipping the AED.

Controls, Indicators, and Connectors

Figure 2-1 and Table 2-1 provide an overview of the LIFEPAK 500 AED controls, indicators, and connectors. Figure 2-2 and Table 2-2 provide an overview of the accessories.

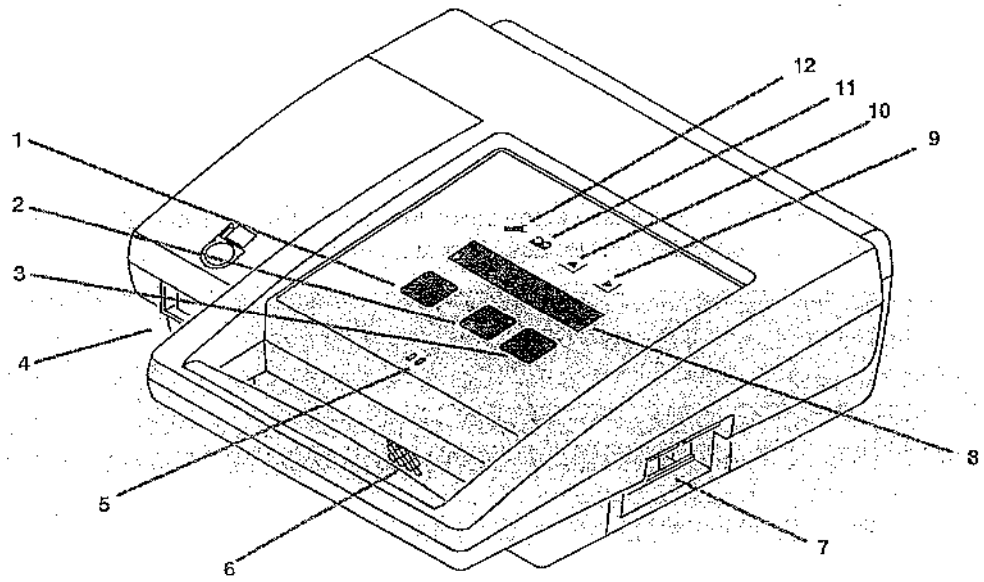

Figure 2-1 LIFEPAK 500 AED controls, indicators, and connectors

Table 2-1 Controls, Indicators, and Connectors

1		Green ON/OFF button turns the power on or off. The LED is lit whenever the AED is on.
2		Yellow ANALYZE button begins analysis of the patient's ECG rhythm. The LED is lit while the AED analyzes the rhythm. The LED flashes to prompt the operator to press ANALYZE.
3		Orange SHOCK button delivers energy. The LED flashes to prompt the operator to press SHOCK when the AED is fully charged.
4	Cable Connector	Allows connection to the following: • QUIK-COMBO electrodes • Cables for connection to a printer, computer, or modem • Test load for testing • Patient Simulator
5	Microphone	Allows input for audio recording.
6	Speaker	Provides audio voice prompts and tones.
7	Battery Compartment	Accommodates a single removable battery pak that provides power for the AED.
8	Liquid Crystal Display (LCD)	Provides operating messages on two 20-character lines.*
9	▶ Right arrow button	Used to set the clock, transfer data, and set options.
10	▲ Up arrow button	Used to set the clock, transfer data, and set options.
11	 Low battery indicator	Red backlit icon indicates the AED battery is low.
12	 Service indicator	Red backlit icon indicates the AED requires service by authorized service personnel.

*Accent marks are not included in operating message for international languages.

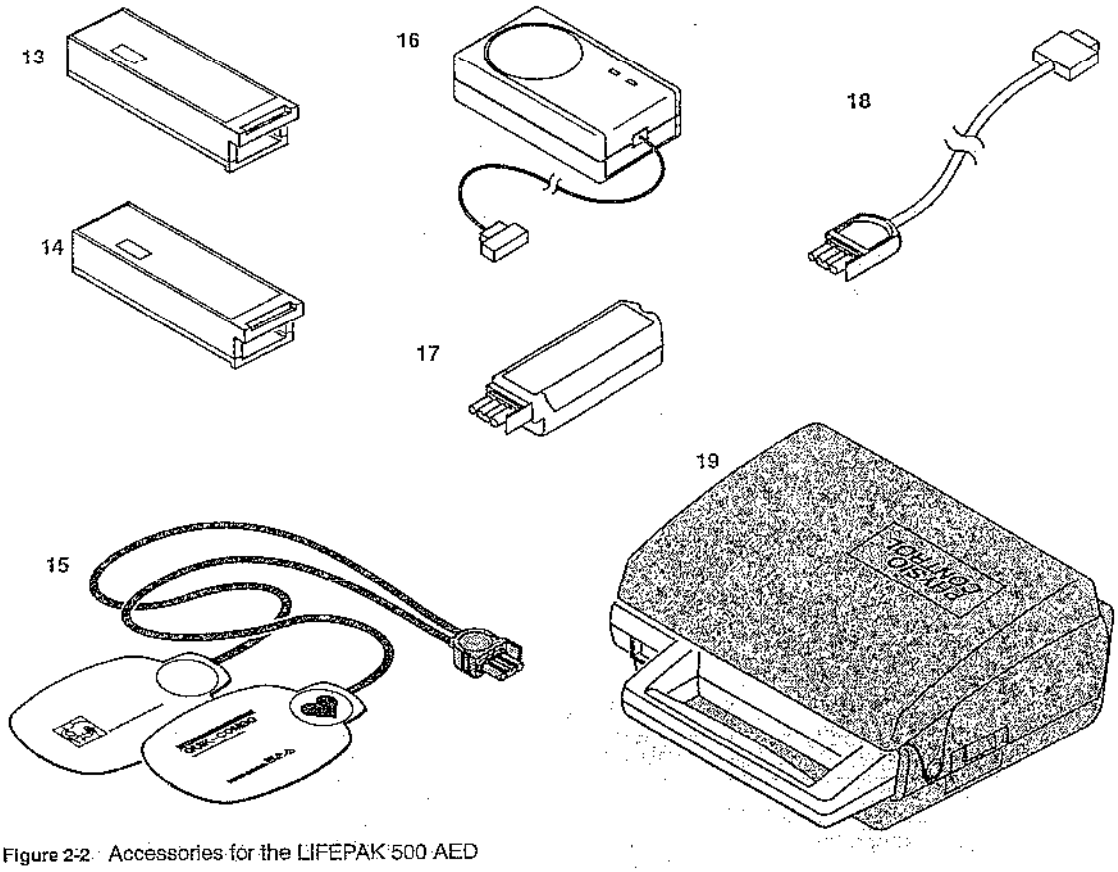

Figure 2-2 Accessories for the LIFEPAK 500 AED

Table 2-2 Accessories for the LIFEPAK 500 AED

13	LIFEPAK 500 nonrechargeable lithium battery pak	Provides power for the LIFEPAK 500 AED.
14	LIFEPAK 500 rechargeable SLA battery pak	Provides power for the LIFEPAK 500 AED. The SLA (Sealed Lead-Acid) battery pak is recharged by the battery charger listed below.
15	QUIK-COMBO defibrillation/ECG electrodes	Allows delivery of therapy to the patient. Connect to the cable connector on the AED.
16	Battery Charger	Provides power to recharge the rechargeable SLA battery pak.
17	Test Load	Provides an external test load for the AED. Connects to the cable connector on the AED.
18	Data cable	One of three available cables shown. Allows transfer of data from AED to PC, modem, or printer. Plugs into the cable connector on the AED.
19	Carrying case	Helps protect the AED and provides storage for electrodes.

About Batteries

Use either of the following battery types to power the LIFEPAK 500 AED:
- LIFEPAK 500 rechargeable SLA battery pak
- LIFEPAK 500 nonrechargeable lithium battery pak

To save battery life if the LIFEPAK 500 AED is accidentally turned on or left on, the AED has a battery conservation feature. If the AED is not connected to a patient and no buttons are pressed for 15 minutes, the AED will automatically turn off.

For information about maintaining or recharging the batteries, refer to page 5–7.

Battery Installation

To install a battery:
1 Insert the connector end of the battery into the battery compartment as shown in Figure 2-3.
2 Slide the battery all the way in until it latches securely.

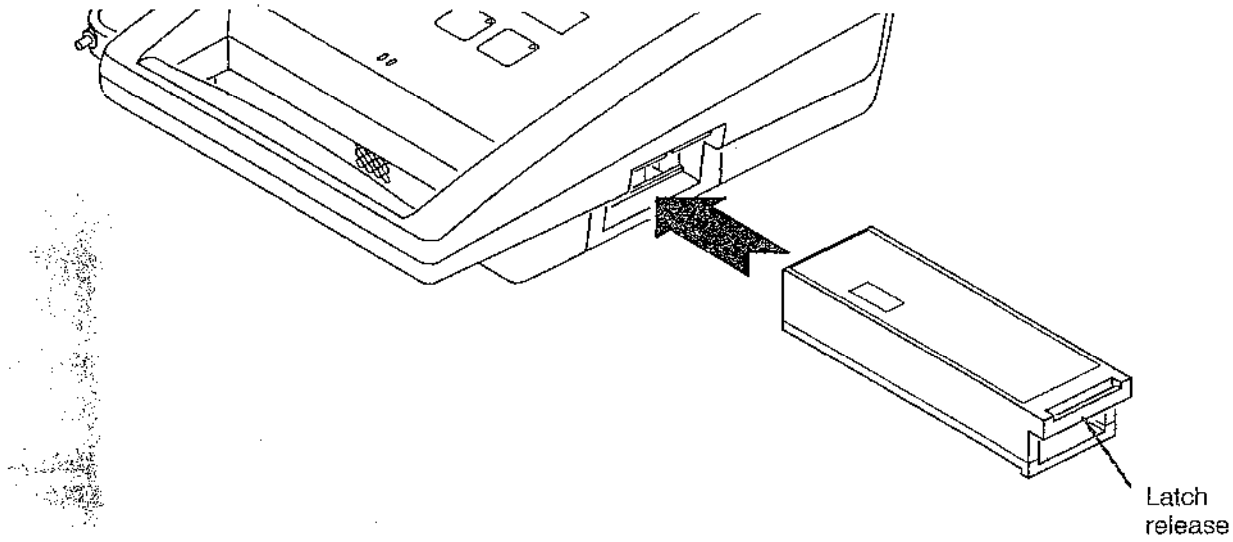

Figure 2-3 Battery installation

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Battery Removal

To remove the battery:

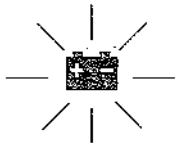
1 Turn off the AED.

2 Lift the latch release on the battery and slide it out.

Low Battery Detection

The AED monitors the battery power level and indicates when the battery should be replaced:

Indicator is lit and the LOW BATTERY message is displayed: battery is low.



Indicator flashes on and off and the REPLACE BATTERY message is displayed: battery is very low and should be replaced immediately.

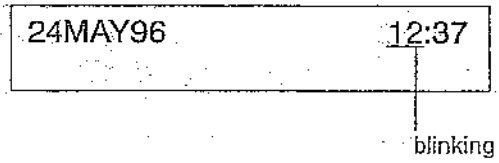
When the battery power is too low, the AED will automatically turn off.

Setting the Clock

To change the date and time:

1 Turn on the AED. (Be sure the AED has been off for at least 60 seconds and that nothing is connected to the AED.)

2 While the power is on, press the ▲ or ▶ button. The AED displays the date and time setting:



A number blinking on and off indicates that the number can be changed.

3 To change the displayed value:

- Press the ▲ button to increase the value.
- Press the ▶ button to advance to the next field.

4 Repeat Step 3 as needed to set the minutes, day, month, and year.

5 After the date and time are set, press ON/OFF to turn off the AED.

Defining Setup Options

With the setup options listed in Table 2-3, you can define some of the operating features for the LIFEPAK 500 AED.

Table 2-3 Setup options and factory default settings

Setup Options	Factory Default Settings
Device ID	AED serial number
Modem phone number	Blank
Modem selection	0
Modem initialization string	Blank
Energy sequence	300 joules
CPR time	60 seconds
Auto analyze	ON
Audio recording	ON

Device ID

Use the DEVICE ID option to assign a unique identifier that is printed at the top of each report. You can use up to 20 characters with any combination of numbers and upper-case letters (A-Z). The factory default setting is the AED serial number.

Modem Phone Number

The MODEM PHONE NUMBER option is the character string that the AED dials when it transfers data by modem. The dial string may include up to 20 characters as described in Table 2-4. The factory default dial string is blank.

Table 2-4 MODEM PHONE NUMBER dial string characters

Character	Description
P	Selects pulse dialing (only allowed as first character)
T	Selects tone dialing (only allowed as first character)
,	Inserts 2-second pause in dialing string
$	Waits for "bong" (calling card) tone
W	Waits for second dial tone
Numeric characters	Numbers 0 through 9 (no special function)
* # ( )	Other characters (no special function)

Modem Selection

The MODEM SELECTION option allows you to select the initialization string for one of the four modems listed in Table 2-5. Select the number that matches your modem. If you select 0, you must define the modem initialization string in the next option (MODEM INIT STRING). The factory default is 0. A Modem Selection Addendum will specify future and international modems that are compatible with the AED.

Table 2-5 MODEM SELECTION numbers

Number	Modem Type
0	No modem selected*
1	Hayes™ ACCURA™ External Fax Modem
2	USRobotics® Sportster® 28.8 Modem
3	Motorola Lifestyle 28.8 Dat/Fax Modem
4	SupraExpress™ 33.6 faxmodem

*You must specify the modem initialization string in the MODEM INIT STRING option.

Modem Initialization String

The MODEM INIT STRING option allows you to define the modem initialization string for a TIA/EIA-602 compatible modem. You can use up to 75 characters with any combination of displayable characters. The factory default string is blank.

Note: The AED does not display MODEM INIT STRING unless the MODEM SELECTION is 0.

Energy Sequence

The ENERGY SEQUENCE option defines the energy level for the second shock delivered. The choices are 200 joules and 300 joules. The factory default setting is 300 joules.

CPR Time

The CPR TIME option defines a time period following each three-shock set or NO SHOCK ADVISED message, during which the operator is prompted to perform CPR. The choices are 0, 15, 30, 45, 60, 90, 120, and 180 seconds. The factory default setting is 60 seconds. Check your local protocol for the appropriate CPR TIME.

If 0 is selected, the AED does not prompt the operator to perform CPR. Instead, the AED prompts the operator to CHECK FOR PULSE. IF NO PULSE, PUSH ANALYZE.

Auto Analyze

The AUTO ANALYZE option may be ON or OFF. If it is ON, the second and third rhythm analyses of each three-shock set start automatically without requiring the operator to press ANALYZE. (The operator must always press ANALYZE to start the first analysis of a three-shock set and to analyze after a NO SHOCK ADVISED message or CPR cycle.) If it is OFF, the operator must press ANALYZE to start every analysis. The factory default setting is ON.

Audio Recording

AUDIO RECORDING is only displayed if the option is installed. The AUDIO RECORDING option may be ON or OFF. If it is ON, the AED records the audio during patient care. If it is OFF, the AED does not record the audio. The factory default setting is ON.

Changing Setup Options

To change the setup options:

1. Make sure the LIFEPAK 500 AED power is off for at least 60 seconds and that nothing is connected to the AED.
2. Hold down the ANALYZE, ▲, and ▶ buttons. Then, press ON/OFF. Do not release ANALYZE, ▲, and ▶ until the SETUP MODE message appears.
3. Notice that the AED displays the SETUP MODE screen:

SETUP MODE
nnnnnnnn

The nnnnnnnn is the configuration code defined in Figure 2-4. This code, which appears at the top of each printed report, summarizes some of the setup and service settings.

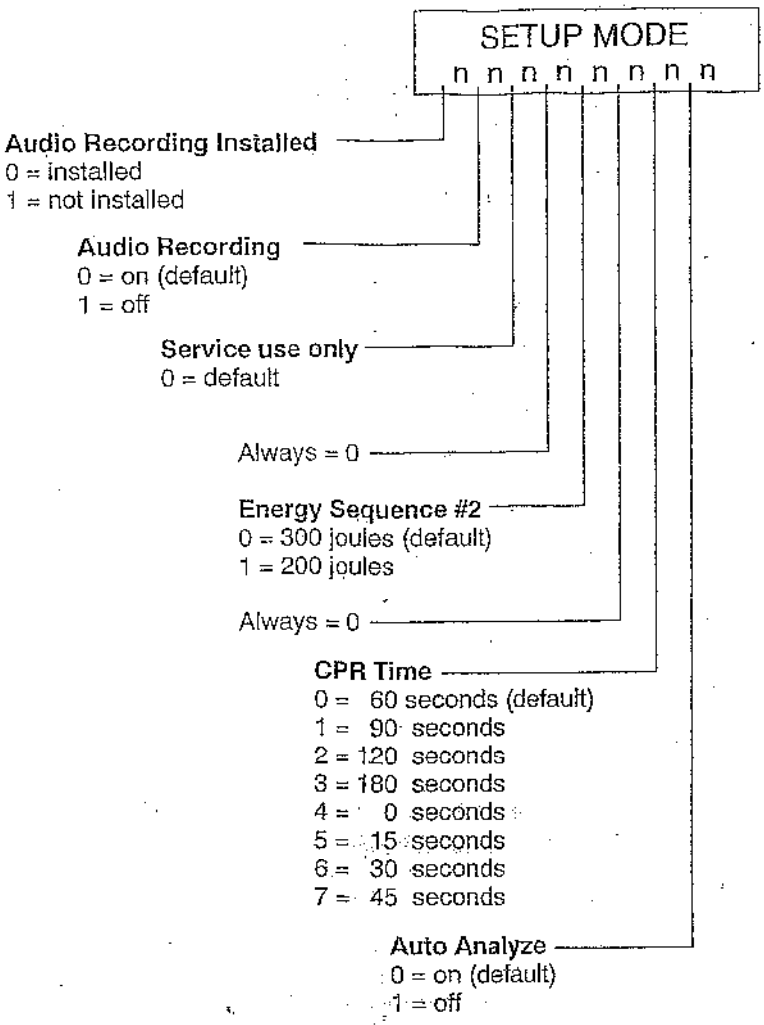
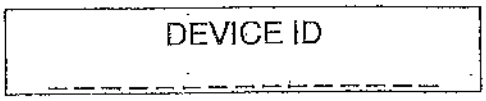


Figure 2-4 Configuration code

4 Press ANALYZE to advance to the DEVICE ID screen:

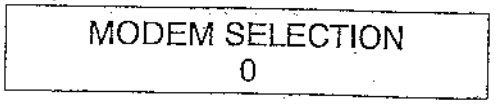


- Press the ▲ button to change the character (choices are 0-9, A-Z, #-., and space characters).
- Press the ▶ button to advance to the next space.

5 Press ANALYZE to advance to the MODEM PHONE NUMBER screen:

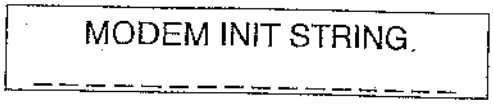
- Press the ▲ button to change the character. The characters available are: ()*,– 0 through 9 PTW#$.
- Press the ▶ button to advance to the next character location (20 characters maximum).

6 Press ANALYZE to advance to the MODEM SELECTION screen:



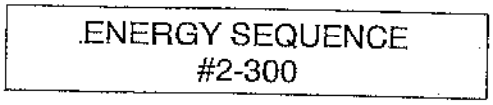
- Press the ▲ button to change the modem selection (choices are 0 through 4).

7 Press ANALYZE to advance to the MODEM INIT STRING screen if the MODEM SELECTION is 0 (or advance to the ENERGY SEQUENCE screen if the MODEM SELECTION is 1, 2, 3, or 4):



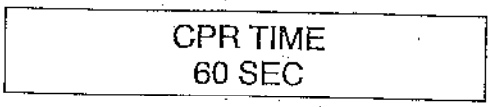
- Press the ▲ button to change the character (choices are all displayable characters).
- Press the ▶ button to advance to the next character location (75 characters maximum). Call your Physio-Control service representative for assistance with defining the correct initialization string.

8 Press ANALYZE to advance to the ENERGY SEQUENCE screen:



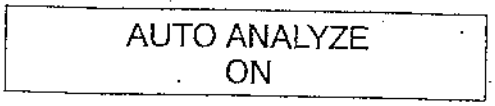
- Press the ▲ button to change the energy selection (choices are 200 and 300 joules).

9 Press ANALYZE to advance to the CPR TIME screen:



- Press the ▲ button to change the setting (choices are 0, 15, 30, 45, 60, 90, 120, and 180 seconds).

10 Press ANALYZE to advance to the AUTO ANALYZE screen:



- Press the ▲ button to turn the option ON or OFF.

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11 Press ANALYZE to advance to the AUDIO RECORDING screen:

AUDIO RECORDING ON

- Press the ▲ button to turn the option ON or OFF.

12 Press ON/OFF to turn off the AED. The settings are saved.

Connecting Electrodes to the AED

You can connect the QUIK-COMBO electrodes with the REDI-PAK preconnect system to the AED before patient care to save time. To connect the REDI-PAK-type QUIK-COMBO electrodes:

1 Inspect the electrode package and confirm that the expiration date has not passed.
2 Remove the clear plastic pouch to expose the QUIK-COMBO electrode connector.
3 Insert the electrode connector firmly into the QUIK-COMBO connector on the AED as shown in Figure 2-5.

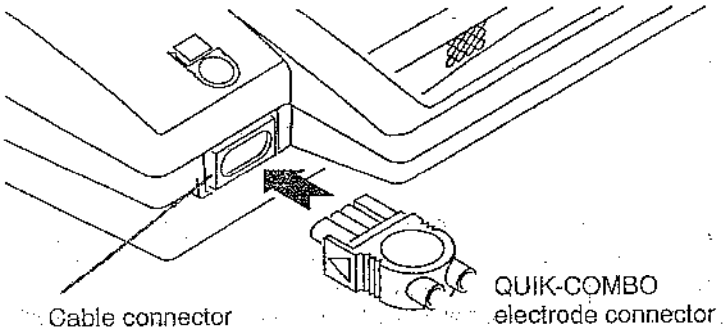

Figure 2-5 Connecting the QUIK-COMBO electrodes

4 Store the electrodes in the carrying case or the electrode storage tray.

Do not open the electrode package until immediately prior to patient use.

If you use QUIK-COMBO electrodes without the preconnect system, you should:

1 Not open the electrode package until immediately prior to patient use.
2 Inspect the electrode package and confirm that the expiration date has not passed.
3 Store the electrode package in the carrying case or electrode storage tray.
4 When ready for patient use, open the electrode package and connect the electrodes to the AED as shown in Figure 2-5 above.

Using the LIFEPAK 500 AED

3

USING THE LIFEPAK 500 AED

This section describes how to use the LIFEPAK 500 automated external defibrillator (AED) for ECG analysis and defibrillation. The actual clinical procedures that you use may vary according to your local protocol. Topics include:

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Warnings

⚠ WARNINGS

Possible shock.

During defibrillation, the AED delivers up to 360 joules of electrical energy. Do not touch the QUIK-COMBO electrodes when discharging the AED.

Possible shock.

To disarm and internally dissipate unwanted energy, turn the AED power off.

Possible shock.

If a person is touching the patient, bed, or any conductive material in contact with the patient during defibrillation, the delivered energy may be partially discharged through that person. Make sure that everyone is stands away from the patient, bed, and other conductive material before discharging the AED.

Possible skin burns and ineffective energy delivery.

Do not allow QUIK-COMBO electrodes to touch each other, ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Possible ECG misinterpretation.

Do not place QUIK-COMBO electrodes in the anterior-posterior position with this AED. A shock or no shock decision may be inappropriately advised. The Shock Advisory algorithm requires the electrodes to be placed in the anterior-lateral (Lead II) position.

Possible skin burns.

During defibrillation, air pockets between the skin and QUIK-COMBO electrodes can cause patient skin burns. Make sure self-adhesive QUIK-COMBO electrodes completely adhere to the skin. Do not reposition the electrodes after they are applied to the skin. If the position must be changed, remove and replace the electrodes.

Possible skin burns and ineffective energy delivery.

Use of QUIK-COMBO electrodes that are dried out or damaged may cause electrical arcing and patient skin burns, do not prevent drying or damage), do not use electrodes if they have been removed from their foil package for more than 24 hours. Replace after 50 shocks. Do not use electrodes beyond the expiration date. Inspect electrodes to make sure adhesive is intact and undamaged.

Pediatric patient safety risk.

The AED is not designed or tested to interpret pediatric arrhythmias or administer energy at pediatric joule settings. The American Heart Association recommends AEDs be used only on patients who are more than eight years old.

Possible interference with implanted devices.

When defibrillation is performed on a patient with an implanted device, avoid placing the electrodes over the implanted device. Defibrillation may cause device malfunction. Check the function of the device after defibrillation.

Preparing the AED for Operation

Follow these steps to make sure that the AED is always ready for use:

- Properly maintain the AED and batteries as described on page 5-6 of this manual.
- Make sure that the QUIK-COMBO electrodes are available and properly stored in the AED carrying case or electrode tray.
- Keep the following supplies readily accessible:
  - Spare, properly maintained battery
  - Spare QUIK-COMBO electrodes
  - Supplies to clean and shave the patient
- Keep the AED and accessories within an optimal temperature range of 15-35°C (40-95°F)

QUIK-COMBO electrodes are pre-gelled, self-adhesive electrodes that allow hands-free defibrillation. They are designed for use with devices equipped with a QUIK-COMBO connector or therapy cable. For more information about these electrodes, refer to the electrode operating instructions.

AED Operation

To prepare for ECG analysis and defibrillation:

1 Verify that the patient is in cardiac arrest (unconscious, no respiration, no pulse).

2 Press ON/OFF to turn on the AED (the green LED will light). The CONNECT ELECTRODES message and voice prompt will occur until the patient is connected to the AED.

3 Prepare the patient for electrode placement:
- If possible, place the patient on a hard surface away from standing water or conductive material.
- Remove clothing from the patient's upper torso.
- Remove excessive hair from the electrode sites. If shaving is necessary, avoid cutting the skin.
- Clean the skin and dry it briskly with a towel or gauze.
- Do not apply alcohol, tincture of benzoin, or antiperspirant to the skin.

4 Apply the electrodes to the patient's chest:
- Place the ♥ electrode lateral to the patient's left nipple with the center of the electrode in the midaxillary line, if possible.
- Place the other electrode on the patient's upper right torso, lateral to the sternum and below the clavicle.
- Starting from one end, press the electrodes firmly onto the patient's skin.

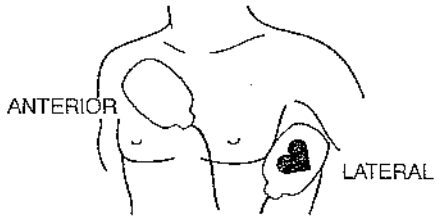


Figure 3-1 Electrode placement

5 Connect the electrode connector to the AED (if it is not already connected).

6 Follow the screen messages and voice prompts provided by the AED.

Special Situations for Electrode Placement

When placing electrodes on the patient, be aware of the following special situations.

Obese Patients or Patients with Large Breasts Apply the electrodes to a flat area on the chest, if possible. If skin folds or breast tissue prevent good adhesion, spread skin folds apart to create a flat surface.

Thin Patients Follow the contour of the ribs and spaces when pressing the electrodes onto the torso. This limits air space or gaps under the electrodes and promotes good skin contact.

Patients with Implanted Pacemakers If possible, place QUIK-COMBO electrodes away from the internal pacemaker generator. Treat this patient like any other patient requiring patient care. Pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm.

Patients with Implanted Defibrillators Apply the electrodes in the anterior-lateral position. Treat this patient like any other patient requiring emergency care.

AED Prompts

The following paragraphs describe typical scenarios that might occur during AED operation. Topics include:

- First analysis cycle
- Shock advised
- Subsequent analysis cycles
- No shock advised
- CPR Time
- Shock counter
- Motion detection
- Continuous Patient Surveillance System - Check Patient Alert
- Electrodes off detection

For a more detailed description of how the AED analyzes the patient ECG, refer to page A-2.

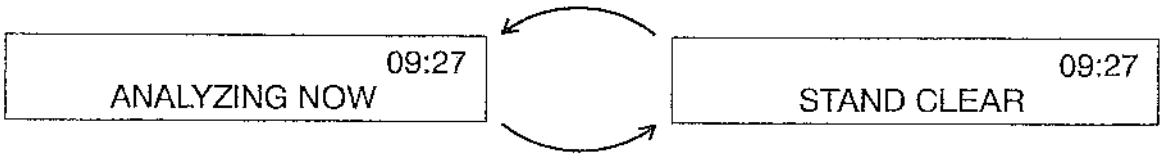
Note: Accent marks are not included in message prompts for international languages.

First Analysis Cycle

When you first apply electrodes to the patient and turn on the power, the AED will prompt you to press ANALYZE:

You will hear the *PUSH ANALYZE* voice prompt and see the ANALYZE LED flash.

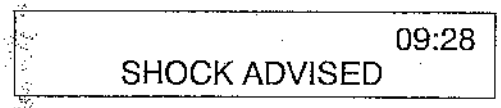
If you press ANALYZE, the AED will begin to analyze the patient's ECG. The AED alternately displays two messages:



You will hear the *ANALYZING NOW, STAND CLEAR* voice prompt. The ECG analysis requires about 6 to 9 seconds. The ANALYZE LED is on during analysis.

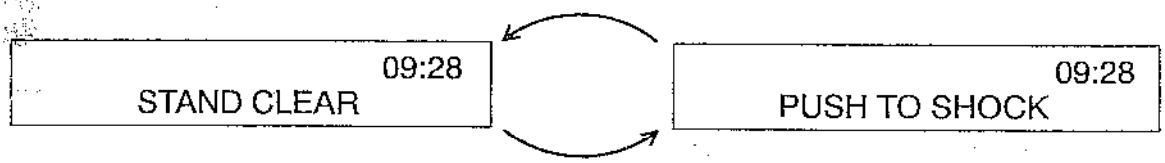
Shock Advised

If the AED detects a shockable ECG rhythm, it displays this message:



You will hear the *SHOCK ADVISED* voice prompt. The AED begins charging to 200 joules for Shock #1. A rising tone indicates that the AED is charging.

When charging is complete, the AED alternately displays two messages:



You will hear the *STAND CLEAR, PUSH TO SHOCK* voice prompt followed by the "shock ready" tone (a loud, high-pitched, two-tone sound). The SHOCK LED flashes.

- Press SHOCK to discharge the AED.
- If you do not press SHOCK within 15 seconds, the AED disarms the SHOCK button, and the CHARGE REMOVED message appears.

Subsequent Analysis Cycles

If the AUTO ANALYZE option is on, the AED automatically analyzes the patient's ECG rhythm after Shock #1 is delivered. If the AUTO ANALYZE option is off, the AED displays PUSH ANALYZE after Shock #1. (You will also hear the *PUSH ANALYZE* voice prompt and see the ANALYZE LED flash.) You must press ANALYZE to begin the analysis.

The second analysis and shock sequence is the same as that described for Shock #1. However, the energy level for Shock #2 is 200 or 300 joules, depending on the value selected for the ENERGY SEQUENCE option. (Refer to page 2–7 to check or redefine the selected value.) The energy level is 360 joules for Shock #3 and subsequent shocks.

No Shock Advised

If the AED detects a nonshockable ECG rhythm, it displays this message:

```
                09:28
NO SHOCK ADVISED
```

You will hear the *NO SHOCK ADVISED* voice prompt. The AED will not charge, and no shock can be delivered.

After NO SHOCK ADVISED, the AED enters CPR TIME if CPR TIME is set to 15 seconds or more. If CPR TIME is set to 0, the AED displays this message:

```
                09:28
CHECK FOR PULSE
```

You will hear the *CHECK FOR PULSE* voice prompt. After 5 seconds, the AED displays two messages:

```
                09:28
IF NO PULSE
```

```
                09:28
PUSH ANALYZE
```

You will hear the *IF NO PULSE, PUSH ANALYZE* voice prompt.

CPR Time

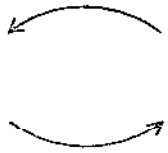
At the beginning of CPR TIME, the AED first displays this message:

```
                10:52
CHECK FOR PULSE
```

You will hear the *CHECK FOR PULSE* voice prompt.

After 5 seconds, the AED alternately displays two messages:

```
                10:52
IF NO PULSE
```



```
                10:52
START CPR
```

You will hear the *IF NO PULSE, START CPR* voice prompt. The messages alternate for the remaining CPR TIME. You can press ANALYZE to stop CPR TIME and start an analysis cycle.

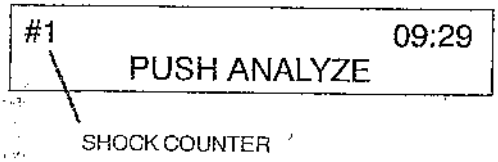
After CPR TIME, the AED displays this message:

You will hear the *CHECK FOR PULSE* voice prompt. After 5 seconds, the AED displays two messages:

You will hear the *IF NO PULSE, PUSH ANALYZE* voice prompt.

Shock Counter

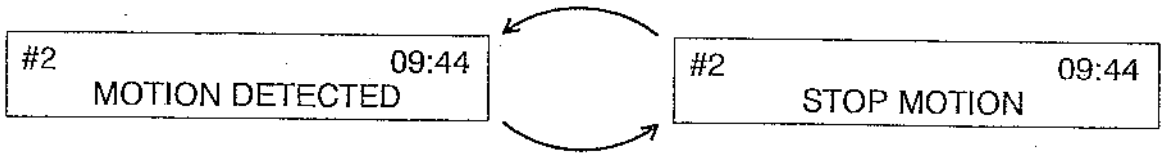
The AED displays the shock counter in the upper-left corner of the LCD:



The shock counter indicates how many shocks have been delivered to the patient. The shock counter resets to zero whenever the AED is turned off for at least 60 seconds.

Motion Detection

If the AED detects motion during the ECG analysis, the AED alternately displays two messages:



You will hear the *MOTION DETECTED, STOP MOTION* voice prompt, followed by a warning tone. If the motion ceases within 20 seconds, analysis will continue. If the motion does not cease within 20 seconds, analysis will stop. You must then push ANALYZE to restart analysis. Refer to troubleshooting on page 6-2 for possible causes and suggested solutions.

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Continuous Patient Surveillance System - Check Patient Alert

If the Continuous Patient Surveillance System (CPSS) detects a potentially shockable rhythm, the AED displays this message:

You will hear the *PUSH ANALYZE* voice prompt accompanied by a warning tone. You should:

- Stop all patient and vehicle movement.
- Confirm that the patient is in cardiac arrest.
- Press ANALYZE.
- Follow the screen messages and voice prompts provided by the AED.

Electrodes Off Detection

If the AED detects that the electrodes are not properly connected to the AED or the patient, the AED displays this message:

You will hear the *CONNECT ELECTRODES* voice prompt followed by three warning beeps. Refer to troubleshooting on page 6-2 for possible causes and suggested actions.

Transferring a Patient to a Different Device

The QUIK-COMBO electrodes allow rapid transfer of care to other devices that also use QUIK-COMBO electrodes. To transfer the patient from the LIFEPAK 500 AED to another device:

1. Turn off the LIFEPAK 500 AED power.
2. Disconnect the QUIK-COMBO electrodes from the LIFEPAK 500 AED. Leave the electrodes on the patient.
3. Connect the QUIK-COMBO electrodes to the QUIK-COMBO therapy cable on the next device.
4. Follow the operating instructions for the second device to deliver the desired therapy.

Troubleshooting During Patient Care

For troubleshooting during patient care, refer to Table 6-1, page 6-2.

4

DATA MANAGEMENT

This section describes how to store and transfer LIFEPAK 500 automated external defibrillator (AED) data to a computer or a printer. Topics include:

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Overview of Data Storage and Retrieval

Every time you use the LIFEPAK 500 AED on a patient, data is stored digitally inside the AED. This data allows post-incident review for quality control, training, and research purposes. Print or transfer this data as soon as possible to save the information.

The following paragraphs describe how the LIFEPAK 500 AED stores and retrieves data.

Overview of Data Storage

Whenever power is on, the LIFEPAK 500 AED automatically stores the data illustrated in Figure 4-1.

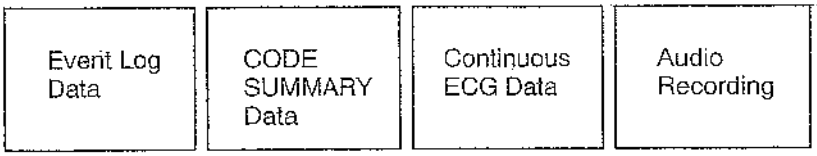

Figure 4-1 Data stored by the LIFEPAK 500 AED

- Event Log Data - A chronological log of all events. An event is a specific action by the operator or AED, such as:
  - Power on
  - Patient connected
  - Analysis started
  - Shock advised
  - Shock delivered

  Refer to page 6-6 for a list of all the event types.
- CODE SUMMARY Data - A summary of critical resuscitation events and the ECG rhythm segments associated with those events.
- Continuous ECG Data - Approximately 20 minutes of the patient ECG rhythm from the time of power-on to power-off.
- Audio Recording - Approximately 20 minutes of audio data recorded at the scene, such as operator remarks and AED voice prompts or tones. (The audio recording option must be installed and enabled.)

Patient Records A patient record is created when the AED is connected to a patient and begins to store data. The AED stores data from the time that you turn the AED on until you turn the AED off. The LIFEPAK 500 AED can store a maximum of two patient records:

- Current Patient - The most recent patient record stored
- Previous Patient - The patient record stored prior to the Current Patient

The data stored for the Current Patient and Previous Patient is illustrated in Figure 4-2.

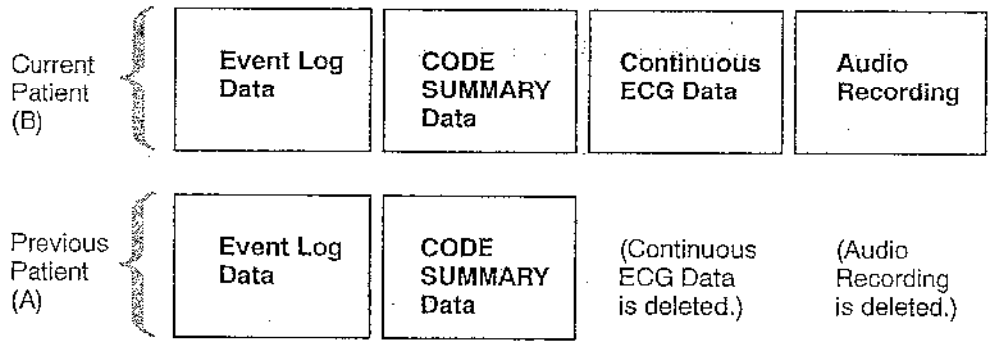

Figure 4-2 Comparison of data stored for the Current Patient and Previous Patient

The AED stores all data for the Current Patient (B). However, the AED only retains the Event Log and CODE SUMMARY data for the Previous Patient (A).

Information Stored When Creating a New Patient Record When the AED creates a new patient record, the following occurs:

- The AED stores all data for the newest patient record, Patient C (refer to Figure 4-3). Patient C is now the Current Patient.
- The AED deletes the ECG and audio recording data for Patient B. The AED retains only the Event Log and CODE SUMMARY data. Patient B is now the Previous Patient.
- The AED deletes all data for the oldest patient record, Patient A.

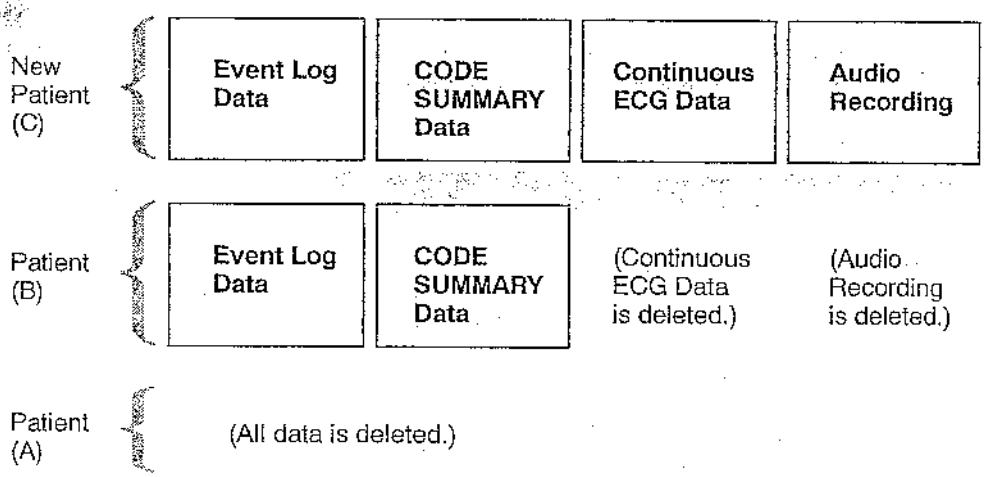

Figure 4-3 Data stored when the AED stores a new patient record

Conditions for Creating a New Patient Record To begin a new patient record, the following conditions must occur:

- The AED must be turned off for at least 60 seconds, then turned on
- Electrodes must be connected to the patient

You can turn off the AED briefly without affecting the Current Patient. For example, you can change the battery. If you restore power in less than 60 seconds, the AED resumes storing data for the Current Patient.

If you do not connect electrodes to a patient or a simulator, you can turn on the AED and not affect the Current Patient. For example, you can turn on the AED to test it with the external test load or to transfer data. As long as you do not connect the electrodes to a new patient or an ECG simulator, the AED does not create a new patient record.

As soon as you turn on the AED, the AED begins storing data for a new patient record. However, if you do not connect electrodes to a patient within 3 minutes, the AED stops storing data.

- If you then connect electrodes, the AED resumes storing data and creates a new Current Patient.
- If, however, you turn off the AED without ever connecting the electrodes, the AED does *not* create a new Current Patient. The AED will delete the initial 3 minutes of data, and all previously stored data will remain unchanged. This prevents erasing data each time you turn on the AED to transfer data or perform maintenance.

Test Log The LIFEPAK 500 AED also stores a Test Log, a list of the 30 most recent auto-tests and manual tests. The Test Log lists the test results and any fault codes detected. The Test Log is printed automatically when data is sent to a printer. As an option, the Test Log may be printed from a computer.

Overview of Data Retrieval

There are three ways you can retrieve data from the LIFEPAK 500 AED:

- Send the data to a computer by modem
- Send the data to a computer by direct connection
- Send the data to a printer

The AED does not delete data after it is transferred. Data is only deleted when new patient records are created. Table 4-1 describes the stored data and how you can retrieve it.

Table 4-1 LIFEPAK 500 AED data and retrieval

Type of Data	Retrieval: Modem	Computer	Printer
Event Log Data	Yes	Yes	Yes
CODE SUMMARY data	Yes	Yes	Yes
Continuous ECG[1]	Yes	Yes	No
Audio Recording[1]	Yes[2]	Yes[2]	No
Test Log	Yes	Yes	Yes

[1] Available for the Current Patient only.

[2] To play the audio recordings, a sound card, sound card software, and the QUIK-VIEW 500 data review program must be installed in the computer.

Sending Data to a Computer by Modem

These paragraphs describe the resources, equipment connections, and procedures required to send LIFEPAK 500 AED data to a computer by modem.

Required Resources

Table 4-2 summarizes the resources required to send data to a computer by modem.

Table 4-2 Required resources for sending data to a computer by modem

Description
Required Resources at Local Site
Modem Cable (for use with LIFEPAK 500 AED)
Modem that supports the TIA/EIA-602 command set
Modem power cord or power adapter (if required)
Telephone cord (with RJ11 connectors)
Analog telephone line[1]
Required Resources at Destination Site
Modem that supports the Hayes AT command set
Personal Computer: – DOS-compatible – QUIK-VIEW™ 500 data review program or CODE-STAT™ data management system program 2.0 or greater – Microsoft Windows 3.1 or greater for CODE-STAT, Data Transfer 500, and for QUIK-VIEW 500 if audio review is not needed. Microsoft Windows 95 for QUIK-VIEW 500 if audio review is needed
Cables as required
Analog telephone line[1]

[1] Most internal telephone lines for integrated office telephone systems are digital lines. Make sure that you connect the modem to an external analog telephone line like the type used for fax machines.

Setup Options

Make sure that the AED setup options are properly defined for the modem initialization string and destination phone number. Refer to page 2–7 for information about the modem setup options.

Note: Remember to include in the dial string any special characters that are required to dial the destination (such as "9" or a pause).

Procedure for Sending Data

Perform these steps to send the data:

1 Make sure that the equipment at the destination site is properly connected.
2 Make sure that the destination computer power is on and that the QUIK-VIEW 500 data review program or CODE-STAT program is ready to receive data.
3 Make sure that the modem and the AED are turned off.
4 At the local site, connect the equipment as shown in Figure 4-4.
   - Connect the Modem Cable to the AED and the modem.
   - Connect the telephone cord to the modem and the analog telephone line.
   - Connect the modem power cord or power adapter to a power source (if required).

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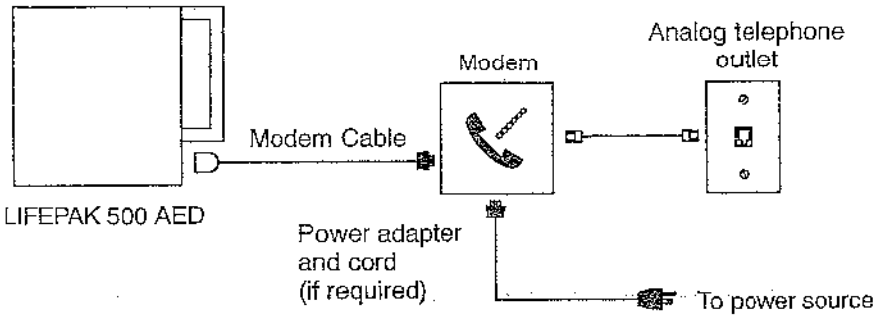

Figure 4-4 Equipment connections for data transfer by modem

5 Turn on the modem.

6 Press ON/OFF to turn on the AED. You will see:

BATTERY status message

SELF-TEST xx.xx message

7 After a few seconds, you will see the message:

TO SEND PUSH ▶

- Press ▶ to send the Current Patient.
- Press ▲ to send the Previous Patient.
- Press both ▶ and ▲ to send the Current and Previous Patients.

While the data is being transferred, the AED displays the following message to indicate progress:

SENDING
XX%COMPLETE

After the AED successfully completes the data transfer, it displays the SEND COMPLETE message.

If you do not perform any other AED operations, the AED automatically turns off 15 minutes after completing the data transfer. If the AED automatically turns off, it will display either the SEND COMPLETE or CANNOT SEND message the next time you turn on the AED without connecting electrodes.

Troubleshooting During Data Transfer

If you cannot transfer data, refer to Table 6-2 on page 6-3 for troubleshooting tips.

Sending Data to a Computer by Direct Connection

These paragraphs describe the resources, equipment connections, and procedures required to send AED data to a computer by direct connection.

Required Resources

Table 4-3 summarizes the resources required to send data to a computer by direct connection.

Table 4-3 Required resources for sending data to a computer by direct connection

Description
PC Cable (for use with the LIFEPAK 500 AED)
Personal Computer: – DOS-compatible – QUIK-VIEW 500 data review program or CODE-STAT data management system program 2.0 or greater – Microsoft Windows 3.1 or later for CODE-STAT, Data Transfer 500, and for QUIK-VIEW 500 if audio review is not needed. Microsoft Windows 95 for QUIK-VIEW 500 if audio review is needed

Procedure for Sending Data

Perform these steps to send the data:

1. Make sure that the AED is turned off.
2. Connect the equipment as shown in Figure 4-5.
3. Make sure that the computer power is on and that the application program is open.
4. Press ON/OFF to turn on the AED. The CONNECT ELECTRODES message will appear and remain until data transfer begins.
5. The computer controls the data transfer. Refer to the application program operating instructions for information about data transfer commands. The AED will not display any status messages during the data transfer.

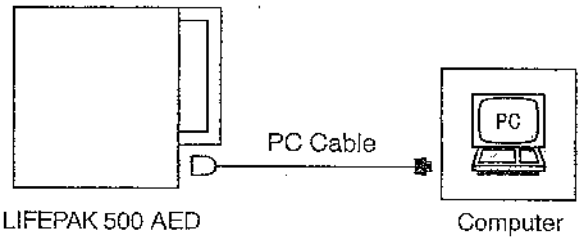

Figure 4-5 Equipment connections for data transfer by direct connection to a computer

Troubleshooting During Data Transfer

If you cannot transfer data, refer to the application program operating instructions for troubleshooting information.

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Sending Data to a Printer

These paragraphs describe the resources, equipment connections, and procedures required to print AED data on a printer.

Required Resources

Table 4-4 summarizes the resources required to print AED data.

Table 4-4 Required resources for printing data

Description
Printer Cable (for use with the LIFEPAK 500 AED)
Printer (EPSON LX-300-compatible): – EPSON ESC/P protocol for 9-pin printheads – 25-pin D style connector

Procedure for Printing

Perform these steps to print AED data:

1 Make sure that the AED is turned off.

2 Connect the equipment as shown in Figure 4-6.
- Connect the Printer Cable to the AED and the printer.

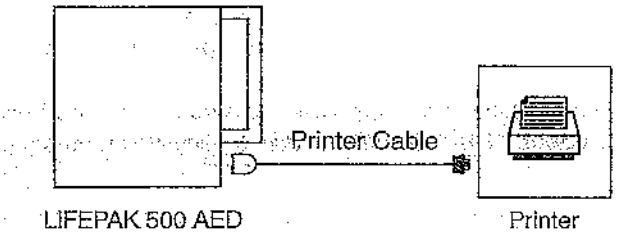


Figure 4-6 Connecting the AED to a printer

3 Make sure that the printer is turned on.

4 While holding down the ▶ button, press ON/OFF to turn on the AED. Do not release the ▶ button until the AED displays:

BATTERY status message

SELF-TEST xx.xx message

5 After a few seconds, you will see the message:

TO PRINT PUSH ▶
- Press ▶ to print the Current Patient.
- Press ▲ to print the Previous Patient.
- Press both ▶ and ▲ to print the Current and Previous Patients.

While the data is being transferred, the AED displays the following message to indicate progress:

SENDING

After the AED successfully completes the data transfer, it displays the SEND COMPLETE message.

Troubleshooting During Printing

If the data does not print, refer to Table 6-3 on page 6-3 for troubleshooting tips.

Examples of Printed Reports

The following pages present examples of printed reports:

- Figure 4-7, page 4–10 Event Log Report and Event Log Summary
- Figure 4-8, page 4–11 CODE SUMMARY Report
- Figure 4-9, page 4–14 Test Log Report

You cannot modify the format of the reports that the AED sends directly to the printer.

Event Log Report This report lists all of the events that occurred during a patient use. The clock time and elapsed time are listed for each event. The box at the top of the report includes device and patient information. Some of the entries, such as the patient ID and name, are always blank for reports printed directly from the AED. (If you send AED data to a computer, the Data Transfer 500 program or QUIK-VIEW 500 data review program allows you to fill in the blank spaces with information.)

Event Log Summary This report summarizes important events for a particular patient record.

CODE SUMMARY Report This report includes the ECG segments associated with key events such as analysis or shock.

Test Log Report This report lists the time and results of the Auto Tests (AUTO TEST) and Test Load Tests (MANUAL TEST). If a test fails, the report lists fault codes that can help authorized service personnel troubleshoot and repair the AED.

Event Log Report

Incident ID No:	Patient ID No:
Incident Date: 15MAY96	Patient Name:
Operator ID No:	Age:
Device Type: LIFEPAK 500	Sex:
Device Serial No: 00001203	Race:
Device ID: RFD#6	Software REV: 3005360-000 REV. 0.35
	Configuration: 00000000

00:00	09:47:08	POWER ON
01:07	09:48:15	PATIENT CONNECTED
01:07	09:48:15	"PUSH ANALYZE"
01:10	09:48:18	ANALYSIS 1
01:16	09:48:24	SHOCK ADVISED
01:25	09:48:33	"PUSH TO SHOCK"
01:25	09:48:33	SHOCK 1 - 200J
01:30	09:48:38	ANALYSIS 2
01:36	09:48:44	NO SHOCK ADVISED
01:39	09:48:47	CPR PROMPT
02:39	09:49:47	"PUSH ANALYZE"
03:03	09:50:11	CHECK PATIENT
03:03	09:50:11	"PUSH ANALYZE"
03:05	09:50:13	ANALYSIS 3
03:11	09:50:19	SHOCK ADVISED
03:21	09:50:29	"PUSH TO SHOCK"
03:36	09:50:44	CHARGE REMOVED
03:40	09:50:48	ANALYSIS 4
03:46	09:50:54	NO SHOCK ADVISED
03:47	09:50:55	CPR PROMPT
03:52	09:51:00	LOW BATTERY
04:10	09:51:18	BATTERY REMOVED
04:43	09:51:51	POWER ON
04:43	09:51:51	BATTERY REPLACED
04:47	09:51:55	"PUSH ANALYZE"
04:50	09:51:58	ANALYSIS 5
04:52	09:52:00	POWER OFF

Event Log Summary

01:10	09:48:18	FIRST ANALYSIS
01:25	09:48:33	FIRST SHOCK
		1 SHOCK DELIVERED

Comments: _____

_____

_____

_____

END OF REPORT

PAGE 1

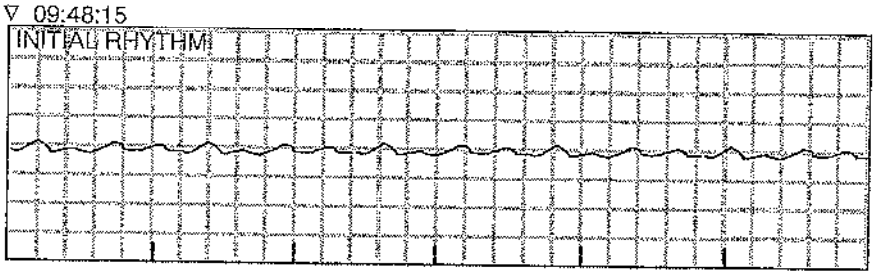
Figure 4-7 Example of Event Log Report and Event Log Summary

CODE SUMMARY Report

Incident ID No:	Patient ID No:
Incident Date: 15MAY96	Patient Name:
Operator ID No:	Age:
Device Type: LIFEPAK 500	Sex:
Device Serial No: 00001203	Race:
Device ID: RFD#6	Software REV: 3005360-000 REV. 0.35
25mm/sec, 1.0 cm/mV	Configuration: 00000000

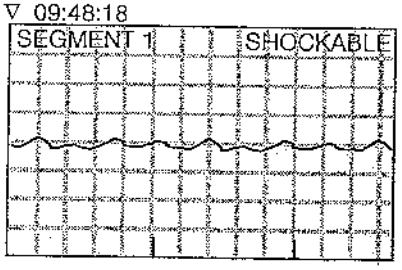
09:48:15 PATIENT CONNECTED

▽ 09:48:15

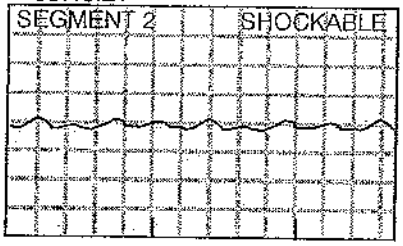


09:48:18 ANALYSIS 1

▽ 09:48:18



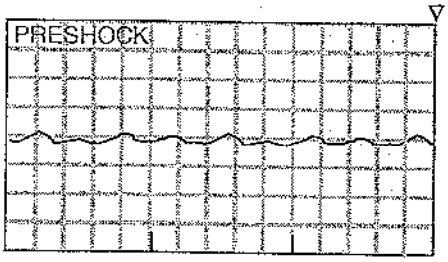
▽ 09:48:21



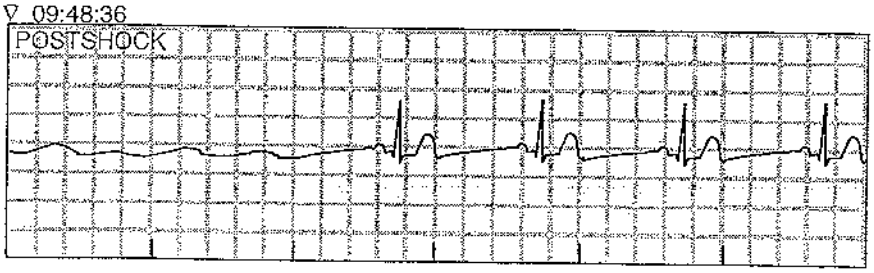
09:48:24 SHOCK ADVISED

09:48:33 SHOCK 1 - 200J

▽ 09:48:33



▽ 09:48:36



PAGE 1

Figure 4-8 Example of CODE SUMMARY report

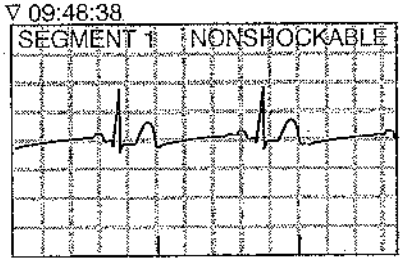
CODE SUMMARY Report

Incident ID No:
Incident Date: 15MAY96

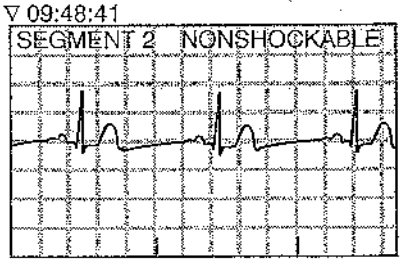
Patient ID No:
Patient Name:

09:48:38 ANALYSIS 2

▽ 09:48:38



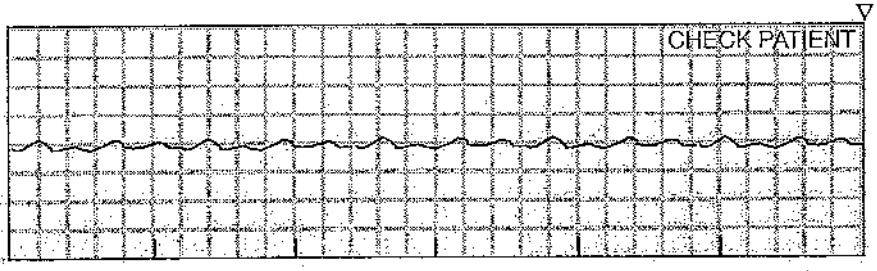
▽ 09:48:41



09:48:44 NO SHOCK ADVISED

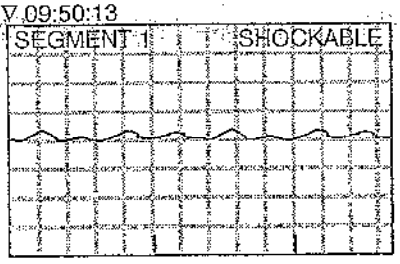
09:50:11 CHECK PATIENT

▽ 09:50:11

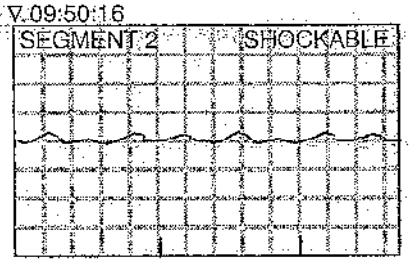


09:50:13 ANALYSIS 3

▽ 09:50:13



▽ 09:50:16



09:50:19 SHOCK ADVISED

09:50:44 CHARGE REMOVED

PAGE 2

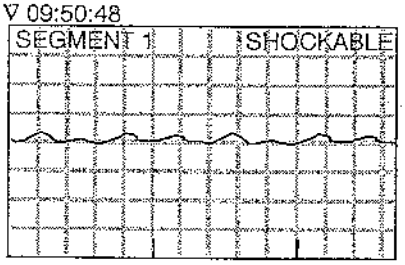
Figure 4-8 Example of CODE SUMMARY Report (cont.)

CODE SUMMARY Report

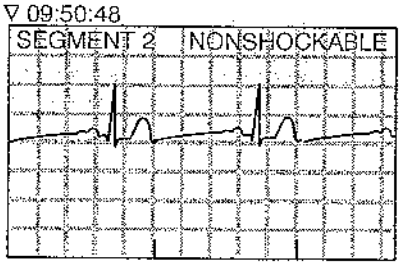
Incident ID No:	Patient ID No:
Incident Date: 15MAY96	Patient Name:

09:50:45 ANALYSIS 4

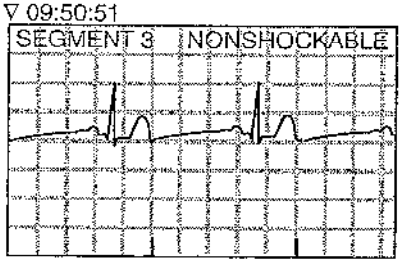
▽ 09:50:48



▽ 09:50:48



▽ 09:50:51



09:50:54 NO SHOCK ADVISED
09:51:58 ANALYSIS 5

END OF RE-
PORT

PAGE 3

Figure 4-8 Example of CODE SUMMARY Report (cont.)

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Test Log Report

Device Type: LIFEPAK 500	Software REV: 3005360-000 REV. 0.35
Device Serial No: 00001203	Configuration: 000000
Device ID: RFD#6	

Test Log History:

03 JAN 96 03:00:00	AUTO TEST: PASS
14 JAN 96 03:00:00	AUTO TEST: FAIL
	FAULT CODES: 4704, 0711, 6302

Major Fault Log:
No entries found

Minor Fault Log:

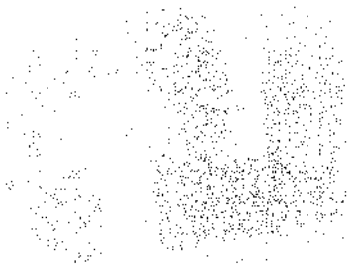
14 JAN 96 03:00:00	FAULT CODES: 4704, 0711, 6302

END OF REPORT

PAGE 1

Figure 4-9 Example of Test Log Report

5



MAINTENANCE

This section describes how to perform operator-level maintenance and testing on the LIFEPAK 500 automated external defibrillator (AED). For troubleshooting information, refer to page 6-1. Topics in this section include:

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Maintenance and Testing Scheduling

The LIFEPAK 500 AED performs an automatic self test every 24 hours. If service is required, the AED activates an alarm. The AED also performs a self test every time you turn on the AED.

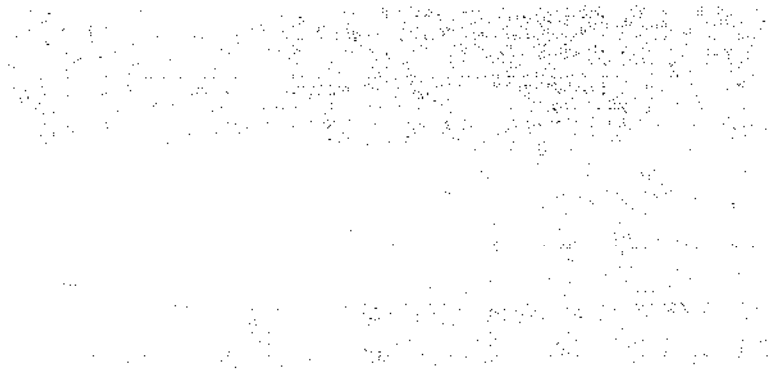
These self-tests do not eliminate the need for regular maintenance. You should do the following on a regular basis and after each time the AED is used:

- Inspect the AED as described in Table 5-1.
- Clean the AED as described in Table 5-2.
- Check to make sure that all necessary supplies and accessories (such as properly-maintained batteries and QUIK-COMBO electrodes) are readily accessible.

When establishing your local operator maintenance schedule, consider how often the AED is used and how familiar the operators are with AED operation. For example:

- If the AED is used on a weekly basis, daily inspections may be appropriate.
- If the AED is used on a monthly basis, weekly inspections may be appropriate.
- If the AED is used very infrequently, such as once a year, monthly inspections may be appropriate.

Authorized service personnel should regularly perform additional periodic preventive maintenance and testing such as electrical safety tests, performance maintenance, and required calibration. Contact a local Physio-Control representative for more information.



Inspection

Follow the instructions in Table 5-1 to inspect the LIFEPAK 500 AED, accessories, and cables.

Table 5-1 LIFEPAK 500 AED inspection

Instruction	Inspect for	Recommended Corrective Action
Examine the AED case, connector, battery well, battery pins, and accessories.	Foreign substances.	Clean the device as described in Table 5-2.
	Damage or cracks.	Contact authorized service personnel to troubleshoot and repair parts.
	Battery pins bent or discolored.	Contact authorized service personnel to replace or repair parts.
	Expired batteries or QUIK-COMBO electrodes.	Replace.
With the battery installed, press ON/OFF to turn on the AED.	BATTERY OK SELF-TEST xx.xx message.	None needed.
	Illumination of each LED and all LCD segments.	Contact authorized service personnel to repair or replace parts.
	BATTERY LOW or REPLACE BATTERY SELF-TEST xx.xx message.	Replace the battery immediately.
	Service indicator or CALL SERVICE message.	Contact authorized service personnel to troubleshoot and repair the device.
Examine accessory cables.	Foreign substances.	Clean the cables as described in Table 5-2.
	Bend and flex the cable and inspect for cracks, damage, extreme wear, broken or bent connectors and pins.	Replace damaged or broken parts.
	Confirm that connectors engage securely.	Replace damaged or broken parts.

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Cleaning

Clean the LIFEPAK 500 AED and accessories as described in Table 5-2. Use only the cleaning agents listed in the table.

⚠ CAUTION **Possible equipment damage.**

Do not clean any part of the AED or accessories with bleach, bleach dilution, or phenolic compounds. Do not use abrasive or flammable cleaning agents. Do not steam, autoclave, or gas sterilize the LIFEPAK 500 AED or accessories.

Table 5-2 Recommended cleaning methods

Items	Cleaning Practice	Recommended Cleaning Agent
LIFEPAK 500 AED case, display, crevices, and accessories	Clean with damp sponge or cloth.	• Quaternary ammonium compounds • Rubbling (isopropyl) alcohol • Peroxide (peracetic acid) solutions

Testing

This section describes the AED automatic self tests and the test load test. If testing indicates a problem, refer to Troubleshooting on page 6-1. If you cannot correct the problem, remove the AED from active service and contact authorized service personnel.

The AED stores the results of auto tests and the external test load test in a Test Log. For information about retrieving Test Log data, refer to page 4–4.

Service Indicator and Message

The service indicator appears above the LCD if the AED detects a problem that requires service, but does not prevent AED use (such as an audio recording problem).

 Service indicator is on

(LCD)

If the service indicator is on (but not flashing), you can still use the AED if it is needed for patient therapy. However, you should contact authorized service personnel to correct the problem as soon as possible. The service indicator will remain on until the problem is corrected.

If the AED detects a problem that requires immediate service (such as a malfunctioning charging circuit), the service indicator flashes and the CALL SERVICE message appears.

Service indicator flashes

CALL SERVICE

Turn the AED off and on. If the CALL SERVICE message disappears, you can still use the AED if it is needed for patient therapy. However, you should contact authorized service personnel to correct the problem as soon as possible. If the CALL SERVICE message reappears, the service indicator will continue to flash and the message will remain on. Contact authorized service personnel immediately to correct the problem. You should not use the AED until the problem is corrected.

Power-On Self Test

Whenever the AED is turned off for at least 60 seconds and then turned on, the AED performs a "cold start." During a cold start, the AED performs internal self-tests to check that internal electrical components and circuits work properly. During the self-test, the AED displays the following messages:

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BATTERY OK SELF-TEST xx.xx

The xx.xx is the software version installed.

If the AED requires service, the service indicator appears. Contact authorized service personnel to perform service.

Note: If the battery has been properly maintained, the BATTERY OK message indicates that the battery will provide approximately 11 or more shocks with a nonrechargeable battery pak or six or more shocks with a rechargeable battery pak. If less than 11 shocks are available, the AED displays the LOW BATTERY or REPLACE BATTERY message.

Auto Tests

The AED periodically performs auto tests.

If the AED detects a problem during an auto test that requires service but does not prevent AED use, it displays the service indicator the next time you turn on the AED.

If the AED detects a problem during an auto test that requires immediate service, it activates an intermittent, audible alarm.

Note: It is important that the AED is stored at the operating temperature range (0-50°C) when the battery is installed. If the AED is stored outside this temperature range, the auto tests may erroneously detect a problem.

Daily Auto Test Every day at 0300 (3:00 am) the AED automatically performs the following tasks:

- Turns itself on
- Performs self-test
- Stores the results in the Test Log
- Turns itself off

The Daily Auto Test is not performed if the AED is already turned on at 0300 or if the battery is not installed. If the AED is turned on while the Daily Auto Test is in progress, the test is halted; the AED will turn on normally.

Extended Auto Test The AED automatically turns on and performs the Extended Auto Test on a regular basis at 0300. In the Extended Auto Test, the AED performs the following tasks:

- Turns itself on
- Performs self-test
- Charges to about 50J and discharges internally (this energy is not accessible at the cable connector)
- Stores the results in the Test Log
- Turns itself off

To use the AED when the Extended Auto Test is in progress, push ON or connect the electrodes to the patient. The test will be halted and the AED will operate normally. The Extended Auto Test is not performed if the AED is already turned on at 0300 or if the battery is not installed.

External Test Load Test

The external test load test checks the AED charging circuits and the operator's response during a typical ECG analysis and charging cycle. During this test, the AED charges for a low energy test shock. The usual messages and audio prompts are provided.

To perform the test load test:

1. Make sure that the AED is turned off.
2. Connect the Physio-Control test load to the cable connector on the AED.

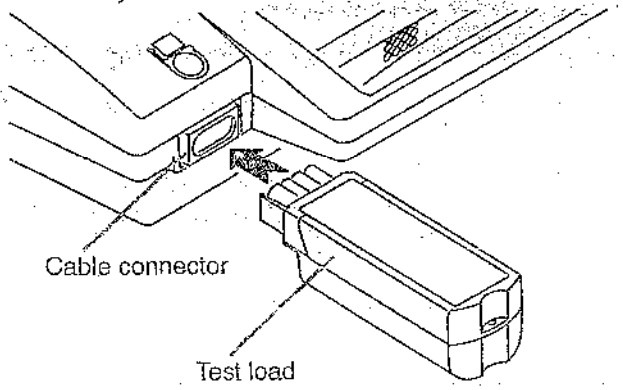

Figure 5-1 Test load connection

3. Press ON/OFF and observe that the TEST MODE message appears. (The TEST MODE message is displayed throughout the test.) If the TEST MODE message does not display, reconnect the test load and try again. After a few seconds you will see and hear:

   PUSH ANALYZE message

   PUSH ANALYZE voice prompt

4 Press ANALYZE. You will see and hear:

ANALYZING NOW and STAND CLEAR messages

ANALYZING NOW, STAND CLEAR voice prompts

After a few seconds you will see and hear:

SHOCK ADVISED message

SHOCK ADVISED voice prompt

A rising charging tone that simulates a typical charge time

5 When the AED is fully charged, you will see and hear:

STAND CLEAR and PUSH TO SHOCK messages

STAND CLEAR and *PUSH TO SHOCK* voice prompts

6 Press SHOCK to discharge the energy into the test load.

7 Confirm that the AED displays the TEST OK message.

8 Disconnect the test load.

9 Press ON/OFF to turn off the AED.

10 Prepare the AED for the next patient use.

After the test is complete, the AED records the results in the Test Log. If the AED detects a problem during the test, the service indicator and CALL SERVICE message appear. Contact authorized service personnel to perform service. To repeat the test, turn off the AED and then turn it on again.

Battery Maintenance

The LIFEPAK 500 AED can be powered by two types of batteries:

- LIFEPAK 500 nonrechargeable lithium battery pak
- LIFEPAK 500 rechargeable SLA (Sealed Lead-Acid) battery pak

Either type of battery may be installed. Follow the guidelines described in this section to help maximize battery life and performance. Use only these Physio-Control Battery Pak batteries with the LIFEPAK 500 AED.

⚠ WARNINGS

Possible AED shutdown.

When the LIFEPAK 500 AED displays the REPLACE BATTERY message, replace the battery immediately.

Possible loss of power during patient care.

Using an improperly maintained battery to power the AED may cause premature power loss.

Nonrechargable Battery Pak

The nonrechargeable lithium battery pak requires less maintenance than the rechargeable SLA battery pak since it never requires recharging. With the lithium battery pak installed, the LIFEPAK 500 AED automatically turns on to test it as part of the Extended Auto Test. The AED performs the battery test during each charge/discharge cycle and the first time the AED is turned on after a new battery has been installed.

To check the battery level, turn on the AED for at least 10 seconds and look for the BATTERY status message during the self-test. If there is no message, turn off the AED for at least one minute and

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then turn it on again. The battery status message should display following the self-test. Do not check the status of more than two lithium or three SLA batteries within a 15-minute period. The AED may not accommodate more frequent battery checks.

A new lithium battery pak has a shelf life of 5 years if stored at the proper temperature. At room temperature (+20°C or +68°F), a new lithium battery pak can typically deliver 312 discharges at 360 joules, with a minimum of 230 discharges at 360 joules.

To properly maintain nonrechargeable lithium battery paks:

- Do not attempt to recharge (lithium battery paks cannot be connected to the battery charger used to recharge the rechargeable SLA battery paks).
- Do not use beyond the expiration date marked on the battery label.
- Do not expose to temperatures greater than +50°C (+122°F).
- Do not allow electrical connection between the battery contacts.

⚠ WARNING **Possible explosion, fire, or noxious gas.**

Attempting to recharge a LIFEPAK 500 nonrechargeable lithium battery pak can cause an explosion or fire or release noxious gas. Dispose of expired or depleted lithium battery paks as described in these Operating Instructions.

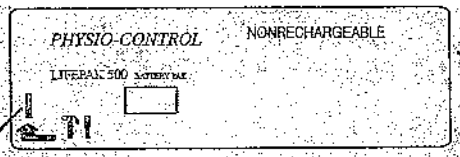
⚠ CAUTION **Possible battery damage.**

Electrical connection between battery contacts can blow an internal fuse and permanently disable the battery.

Discharging Nonrechargeable Batteries Before disposing of lithium battery paks, make sure that they are fully discharged. To discharge a lithium battery pak, follow this procedure:

1 Place the battery pak with the label side up on a firm, flat surface such as a table top or floor.

2 Locate the small slot on the corner marked by the arrow:



Nonrechargeable lithium battery pak label

Slot

3 Place the tip of a flat-tipped screwdriver on the slot.

4 Using a hammer, strike a moderate blow straight down on the top of the screwdriver handle. Make sure that the tip of the screwdriver breaks the label and penetrates approximately 3mm (1/8 inch). This will strike an internal pin, initiate full discharge, and permanently disable the battery.

5 Set the battery pak aside. Wait for at least 1 week to make sure that the battery pak is fully discharged before disposing.

Disposing of Nonrechargeable Batteries After fully discharging a lithium battery pak as described previously, dispose of the battery pak. Follow your national, regional, and local regulations for disposal. Contact a local Physio-Control representative for more information.

In the US, Environmental Protection Agency and Department of Transportation regulations allow disposal of lithium batteries with ordinary household waste **provided that they are fully discharged**. Be sure to comply with any other local or regional regulations before disposal. For more information or assistance, contact your local Physio-Control representative or call 1-800-442-1142.

Rechargeable Battery Pak

The rechargeable SLA battery pak requires more maintenance than a lithium battery pak since it must be recharged periodically. The SLA battery pak should be recharged monthly or after each use. SLA battery paks are most appropriate when the LIFEPAK 500 AED is used on a frequent basis and for those who use the AED with a simulator for training. With an SLA battery pak installed, the LIFEPAK 500 AED automatically turns on to test it as part of the Extended Auto Test. To check the battery level, turn on the AED and look for the BATTERY OK message during the self-test.

SLA battery paks should be replaced every two years or after 200 charge cycles. At room temperature (+20°C or +68°F), a new, fully-charged SLA battery pak can deliver approximately 59 discharges at 360 joules, with a minimum of approximately 43 discharges at 360 joules.

To properly maintain SLA battery paks:

- Recharge after each use or once a month, whichever comes first. Maintain a battery recharge record.
- Use only the Physio-Control battery charger designed for use with the LIFEPAK 500 AED. Do not use any other charger.
- Recharge until the battery charger charge LED is green. This indicates that the battery charger has completed the fast-charge cycle. Undercharging can cause battery damage.
- Recharge only at temperatures between +15° and +35°C (+59° and +95°F).
- Do not expose battery paks to temperatures greater than +50°C (+122°F).
- Do not allow electrical connection between the battery contacts.

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⚠ WARNING — Possible loss of power during patient care:
Stored batteries lose charge. Failure to charge a rechargeable battery pak before use may cause premature AED power loss. Always charge a stored battery pak before returning it to active service.

⚠ CAUTIONS

Possible battery damage:
Recharge the battery until the battery charger charge LED is green. Undercharging can cause battery damage.

Possible battery damage:
Charging batteries outside the temperature range of +15° to +35°C (+59° to +95°F) may cause improper charging and shorten battery life.

Possible battery damage:
Electrical connection between battery contacts can blow an internal fuse and permanently disable the battery.

Recharging a Rechargeable Battery Pak The battery charger fully charges a connected SLA battery in about 10 hours. The battery charger applies a high-level, fast charge for the first 10 hours that the battery is connected. If the battery remains connected, the battery charger applies a low-level trickle-charge to maintain a full charge. Agency approval markings are provided on the bottom of the battery charger.

To charge a battery:

1. Connect the battery charger to an appropriate ac power source (100 to 240Vac, 50 or 60Hz). The green LED (marked by the ▮ symbol) appears when the power is connected.
2. Connect the battery to the battery charger.
3. Confirm that the charge LED (marked by the symbol) is amber. This indicates that the battery charger is applying a fast charge.
4. Wait at least 10 hours. Then, confirm that the charge LED is green. The green LED indicates that the fast-charge cycle is complete and the battery is receiving a trickle-charge to maintain full charge.
5. Disconnect the battery.

A fully-charged battery is not harmed if it remains connected to the battery charger. However, if a battery is disconnected and then reconnected, the battery charger begins the 10 hours of fast charge again. Additional battery charge cycles without discharging can reduce battery life.

Recycling Rechargeable Batteries Recycle SLA battery paks locally according to national, regional, and local governmental regulations. If recycling is not possible, contact a Physio-Control representative for information or assistance. In the US, call 1-800-442-1142.

To promote awareness of battery recycling, SLA battery paks are marked with this label:

Storage

When the LIFEPAK 500 AED is not in service, follow these recommendations for storage:

- AED with lithium battery pak:
  - Store AED with battery pak installed in temperatures between 0° and +35°C (+32° and +95°F)
  - Store AED with battery pak not installed in temperatures between -30° and +65°C (-22° and +149°F)
- AED with SLA battery pak:
  - Store AED with battery pak installed in temperatures between 0° and +35°C (+32° and +95°F)
  - Store AED with battery pak not installed in temperatures between -30° and +65°C (-22° and +149°F)
  - Recharge any stored SLA battery pak once a month

For information about QUIK-COMBO electrode storage, refer to the operating instructions for the QUIK-COMBO electrodes.

Service and Repair

⚠ WARNING Possible shock

Do not attempt to remove the instrument cover to service or repair this device. High voltage may be present. Contact authorized service personnel for service or repair.

If the LIFEPAK 500 AED requires service as indicated by testing, troubleshooting, or the service indicator, contact authorized service personnel. In the US, call Physio-Control Technical Support at 1-800-442-1142. When you call Physio-Control to request service, provide the following information:

- Model number and part number
- Serial number
- Observation of the problem that led to the call

If the device must be shipped to a service center or the factory, pack the device in the original shipping container. If this is not possible, ship the device in protective packing to prevent shipping damage.

The *LIFEPAK 500 AED Service Manual* provides detailed technical information to support service and repair by authorized service personnel.

Warranty

Refer to the product warranty statement included in the accessory kit shipped with the product. For duplicate copies, contact your local Physio-Control representative. In the US, call 1-800-442-1142.

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Supplies, Accessories, and Training Tools

Table 5-3 lists supplies, accessories, and training tools for the LIFEPAK 500 AED. For information about ordering, contact your local Physio-Control representative. In the US, call 1-800-442-1142.

Table 5-3 Supplies, accessories, and training tools

Description	Part Number
LIFEPAK 500 nonrechargeable lithium battery pak	3005380
LIFEPAK 500 rechargeable SLA battery pak	3005379
QUIK-COMBO pacing/defibrillation/ECG electrodes with REDI-PAK pre-connect system	3008497
QUIK-COMBO pacing/defibrillation/ECG electrodes LLW (3.5 ft.) (1.07m)	3008826
LIFEPAK 500 battery charger	3006535
Physio-Control Test Load	3005389
QUIK-COMBO Patient Simulator	803499-09
QUIK-COMBO extension cable (For use with QUIK-COMBO simulator. Not for patient use.)	3009864
Physio-Control Patient Simulator (requires use of the QUIK-COMBO test post adapter)	803499-00
QUIK-COMBO test post adapter Lanyard Kit (includes QUIK-COMBO test post adapter)	3005302
Data Transfer 500 information management program	3005332
QUIK-VIEW 500 data review program	3005335
LIFEPAK 500 Carrying Case	3005343
LIFEPAK 500 Electrode Storage Tray	3008374
LIFEPAK AED TRAINER	3005578
AED TRAINER training electrodes	3006007
Wall mount bracket	3009767
Spare battery pouch	3009933
Cables:	
LIFEPAK 500 Printer Cable	3005381-002
LIFEPAK 500 Modem Cable	3005381-001
LIFEPAK 500 PC Cable	3005381-000
Literature:	
LIFEPAK 500 AED Operating Instructions	3005338
LIFEPAK 500 AED Service Manual	3005339
Defibrillation: What You Should Know	805662

Specifications

Table 5-4 lists the specifications for the LIFEPAK 500 AED.
Table 5-5 lists the specifications for the LIFEPAK 500 AED Battery Charger.

Table 5-4 LIFEPAK 500 AED Specifications[1]

AED	
Input	ECG via QUIK-COMBO disposable electrodes. Standard placement (anterior-lateral).
Electrode Cable Length	1.1m (3.5ft)
Electrical Protection	Input protected against high voltage defibrillator pulses per IEC 601
Safety Classification	Internally powered equipment IEC 601-1, 5.1
Waveform	Monophasic pulse (Edmark) per AAMI DF2-1989, 3.2.1.5.1
Output Energy Sequence	200, 200, 360 joules (360 joules thereafter) or 200, 300, 360 joules (360 joules thereafter)
Charge Time	With a new, nonrechargeable battery pak, or a new, fully-charged rechargeable battery pak: 200 joules in less than 9 seconds 360 joules in less than 15 seconds
Controls	
ON/OFF	Turns device power on or off.
ANALYZE	Starts ECG analysis.
SHOCK	Delivers defibrillation energy. Active only when Shock Advisory System advises defibrillation.
Clock Set	Two switches (▲ and ▶) are provided to set the clock.
Display	Two-line, 20-character per line dot matrix Liquid Crystal Display
Low Battery Indicator	Low battery icon
Service Indicator	Service icon
Displayed Messages	Messages prompt user through complete operating sequence
Audible Tones	Coded tones assist user through device operation and alert operator of display messages
Voice Prompts	Prompt user through complete operation sequence: *PUSH ANALYZE* *SHOCK ADVISED* *NO SHOCK ADVISED* *MOTION DETECTED, STOP MOTION* *STAND CLEAR, PUSH TO SHOCK* *CHECK FOR PULSE* *IF NO PULSE, START CPR* *IF NO PULSE, PUSH ANALYZE* *ANALYZING NOW, STAND CLEAR* *CONNECT ELECTRODES* *REPLACE BATTERY*
EVENT DOCUMENTATION	
Type	Internal digital memory
Memory Capacity	20 minutes audio recording (optional) At least 20 minutes ECG and event log of operator/device actions
Report Types	CODE SUMMARY report, Event Log report, Test Log report
Capacity	300 Event Log events 30 Test Log device tests (assuming no fault codes)
Playback Device	IBM compatible personal computer with sound card (for audio playback) and QUIK-VIEW 500 Data Review software
Communications	Serial port support for: Personal Computer operating Microsoft® Windows™ TIA/EIA-602 compatible modem (at least 9600 baud) EPSON® ESC/P protocol for printers with 9-pin printheads

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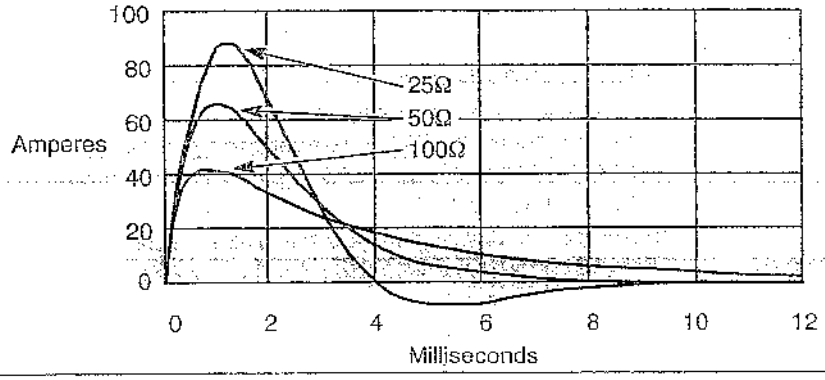
Table 5-4 LIFEPAK 500 AED Specifications[1] (continued)

ENVIRONMENTAL	
Operating Temperature	0° to +50°C (+32° to +122°F)
Storage Temperature	-30° to +65°C (-22° to +149°F) without battery and electrodes
	-30° to +65°C (-22° to +149°F) with battery and electrodes, maximum exposure time limited to one week
Atmospheric Pressure	760 to 429mmHg (0 to +15,000 ft above sea level)
Relative Humidity	10 to 95% (non-condensing)
Water Resistance	IEC 529 IPX4 "Splash-proof" with electrodes or connector cover installed
Shock	MIL-STD-810E, Method 516.4, Procedure 1 (40g, 6-9ms pulse, 1/2 sine each axis)
Vibration	MIL-STD-810E, Method 514.4, Category 10
GENERAL	
Rechargeable SLA battery pak	
Type	Sealed lead-acid, 8V, 2.5 amp hours
Capacity	Typical: 59 full discharges with a new, fully-charged battery at +20°C (+68°F).
	Minimum: 43 full discharges with a new, fully-charged battery at +20°C (+68°F).
Battery Charge Time	10 ±1 hours. Battery charging limited to +15° to +35°C (+59° to +95°F).
Weight	0.9kg (1.9lb)
Nonrechargeable lithium battery pak	
Type	Lithium, 12V, 7.5 amp hours
Capacity	Typical: 312 full discharges with a new battery at +20°C (+68°F).
	Minimum: 230 full discharges with a new battery at +20°C (+68°F).
Weight	0.5kg (1.2lb)
Physical Characteristics	
Height	10.2cm (4.0in)
Width	26.7cm (10.5in)
Depth	29.5cm (11.6in) including handle
Weight	2.76kg (6.1lb) without battery or electrodes
	Defibrillation protected, type BF patient connection
DEFIBRILLATOR	
Waveform	Monophasic pulse (Edmark) per AAMII DF2-1989



1 All specifications at 20°C (68°F) unless otherwise stated. All performance specifications assume the device has been stored (two hours minimum) at the operating temperature prior to operation.

Table 5-5 LIFEPAK 500 AED Battery Charger Specifications

GENERAL	
Safety Classification	Class II, IEC 601-1, 5.1
Input	100-240V 0.7-0.4A 50/60 Hz
Output	9.9V/9.2V dc
Output Protection	Current limited, short circuit protected
ENVIRONMENTAL	
Operating Temperature	15° -35°C (50° - 95°F)
Water Resistance	IEC 520 IPX0 (Indoor Use Only)

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To place unit in Service Mode
Press ↑, → & Shock → Turn on
Pass Word
↑ - Analyze - → → - Shock - Analyze

TROUBLESHOOTING

This section describes how to troubleshoot LIFEPAK 500 automated external defibrillator (AED) operating problems. This section also describes screen messages, voice prompts, and event types.

If you cannot correct the problem, follow these steps:

- Remove the AED from active service.
- Contact authorized service personnel for service and repair.

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Table 6-1 Troubleshooting during patient care

Observation	Possible Cause	Corrective Action
1 CONNECT ELECTRODES message appears.	Inadequate connection to AED.	• Check for complete insertion of connector to AED.
	Electrode does not adhere properly to the patient.	• Press electrodes firmly on patient's skin. • Clean, shave, and dry the patient's skin as recommended.
	Electrodes are dry, damaged, or out-of-date.	• Replace the electrodes.
2 MOTION DETECTED and STOP MOTION messages appear during analysis.	Patient movement.	• Stop CPR during analysis. • When patient is being manually ventilated, press ANALYZE after complete exhalation.
	Patient movement because of agonal respirations.	• Press ANALYZE immediately after exhalation or wait until agonal respirations are slower or absent.
	Electrical/radio frequency interference.	• Move hand-held communication devices or other suspected devices away from the AED when possible.
	Vehicle motion.	• Stop vehicle during analysis. • Move patient to stable location when possible.
3 REPLACE BATTERY or LOW BATTERY message or indicator appears.	Low battery.	• Replace the battery immediately.
4 Service indicator appears (CALL SERVICE message *not* displayed).	A fault requiring service.	• Continue to use the AED if it is needed. Contact authorized service personnel as soon as possible to repair the AED.
5 Service indicator flashing and CALL SERVICE message appears.	A fault requiring immediate service.	• Turn AED off and on. If the CALL SERVICE message appears again, remove the AED from active service. Immediately contact authorized service personnel to repair the AED.
6 AED displays no messages after you repeatedly press ON/OFF.	Depleted battery. AED needs service.	• Replace the battery immediately. • Contact authorized service personnel.
7 CHARGE REMOVED message appears.	Electrode disconnects from patient or AED.	• Replace electrode and press ANALYZE.
	SHOCK button not pressed within 15 seconds.	• Press SHOCK within 15 seconds after the PUSH TO SHOCK message appears.
8 Displayed time is incorrect.	Time is incorrectly set in the AED.	• Change the AED time setting.
9 Date printed on report is incorrect.	Date is incorrectly set in the AED.	• Change the AED date setting.
10 Displayed messages are faint or flicker.	Low battery power. Out of Temperture Range.	• Replace the battery immediately.
11 Voice prompts sound faint or distorted.	Low battery power.	• Replace the battery immediately.
12 AED operates but LCD is blank.	Operating temperature is too low or too high.	• Operate the AED between 0° and +50°C (+32° to +122°F).
	LCD not operating properly.	• Contact authorized service personnel.
13 AED turns off or will not turn on.	Depleted battery. Disconnected battery.	• Replace the battery immediately. • Install battery.

Table 6-2 Troubleshooting during modem data transfer

Observation	Possible Cause	Corrective Action
1 BUSY and WILL RE-DIAL IN XX SECONDS messages	Destination number is busy, the AED is preparing to retry.	• Wait for the AED to retry the data transfer. • AED will retry up to three times.
2 TRY AGAIN, TO SEND PUSH or CANNOT SEND messages	Wrong phone number.	• Check the destination phone number and MODEM PHONE NUMBER setup option.
	Cable is not properly connected.	• Check connections.
	Modem is not connected to an analog telephone line.	• Confirm that the telephone line is analog (not digital).
	Incorrect modem selected in Setup menu.	• Check modem selected in SETUP OPTIONS menu
	Custom Modem Init String is incorrect.	• Check MODEM INIT STRING.
	Dial string for destination site is incorrect.	• Check the AED MODEM PHONE NUMBER setup option.
	Computer power at destination is not on.	• Make sure the computer power is on.
	Computer application program is not ready.	• Make sure the program is ready to receive data.
	Connection is busy. AED has tried to send data three times.	• Resend the data.
3 CONNECT ELECTRODES message	AED was turned on before modem.	• Turn off the AED for one minute. Then, turn on the modem *before* the AED power and resend the data.

Table 6-3 Troubleshooting during printing

Observation	Possible Cause	Corrective Action
1 Printer does not print	No printer power	• Make sure the printer cord is connected. • Make sure the printer switch is on.
	No printer paper	• Check the printer paper.
	Printer cable not connected	• Check the printer cable connections.
	Wrong type of printer	• Check the printer to make sure that it is EPSON ESC/P-compatible.
2 CONNECT ELECTRODES message	The ▶ button was not held down when the AED was turned on.	• Hold down the ▶ button while turning on the AED.

Table 6-4 LIFEPAK 500 AED screen messages

Screen Message	Description
ANALYZING NOW	The AED is analyzing the patient ECG rhythm.
AUDIO RECORDING	Setup mode message for the audio recording option.
AUTO ANALYZE	Setup mode message for the auto analyze option.
BATTERY OK	The battery voltage is ok.
BUSY	While attempting to transfer data by modem, the AED detected that the destination phone number was busy.
CALL SERVICE	The AED detected a fault requiring immediate service during self-tests.
CANNOT SEND	The AED could not print a report or transfer data through a modem.
CHARGE REMOVED	The SHOCK button has been disarmed.
CHECK FOR PULSE	AED prompt after each standard three-shock sequence or NO SHOCK ADVISED message.
CONNECT ELECTRODES	The AED has detected that the electrodes are disconnected.
CPR TIME xx SEC	Setup mode message for the CPR timer option.
DEVICE ID xxxxxxxxx	Setup mode message for device ID option.
ENERGY SEQUENCE #2-xxx	Setup mode message for energy sequence option.
IF NO PULSE	AED prompt that follows the CHECK FOR PULSE message.
LOW BATTERY	The battery voltage is low.
MODEM INIT STRING xxxxxxxxxxxxxxxxxxxxx	Setup mode message for the modem initialization string option.
MODEM PHONE NUMBER xxxxxxxxxxxxxxxxxxxxx	Setup mode message for the modem phone number option.
MODEM SELECTION #:xx	Setup mode message. You may select the configuration for one of nine Hayes AT-compatible modems.
MOTION DETECTED	The AED detects motion during ECG analysis, thereby inhibiting analysis.
NO SHOCK ADVISED	The AED has analyzed the patient ECG and detected a nonshockable ECG rhythm.
PUSH ANALYZE	Press ANALYZE to begin ECG analysis.
PUSH TO SHOCK	The AED is fully charged and ready to provide therapy. This is the AED prompt to press SHOCK to discharge.
REPLACE BATTERY	The battery voltage is very low.
SELF-TEST xx.xx	The self-test is being performed and software version xx.xx is installed.
SEND COMPLETE	The AED successfully transferred data to a printer or by modem.
SENDING xx% COMPLETE	The AED is transferring data by modem or to a printer. The transfer is xx% complete.
SETUP MODE nnnnnnnn	The AED is in the setup mode. The nnnnnnnn is the Device Configuration code.
SHOCK ADVISED	The AED has analyzed the patient ECG rhythm and detected a shockable ECG rhythm.
STAND CLEAR	The AED prompt to move everyone away from the patient.
START CPR	The AED prompt that follows the IF NO PULSE message.
STOP MOTION	See MOTION DETECTED.
TEST MODE	The AED has entered the test mode.
TEST OK	The external test-load test has been successfully completed.
TO PRINT PUSH ▶	The AED is connected to a printer and ready to print a report.
TO SEND PUSH ▶	The AED is connected to a modem and ready to transfer data.
TRY AGAIN	The AED is ready for you to retry transferring data by modem.
WILL RE-DIAL IN xx SECONDS	While attempting to transfer data by modem, the AED detected that the destination phone number was busy. The AED will try again in xx seconds.

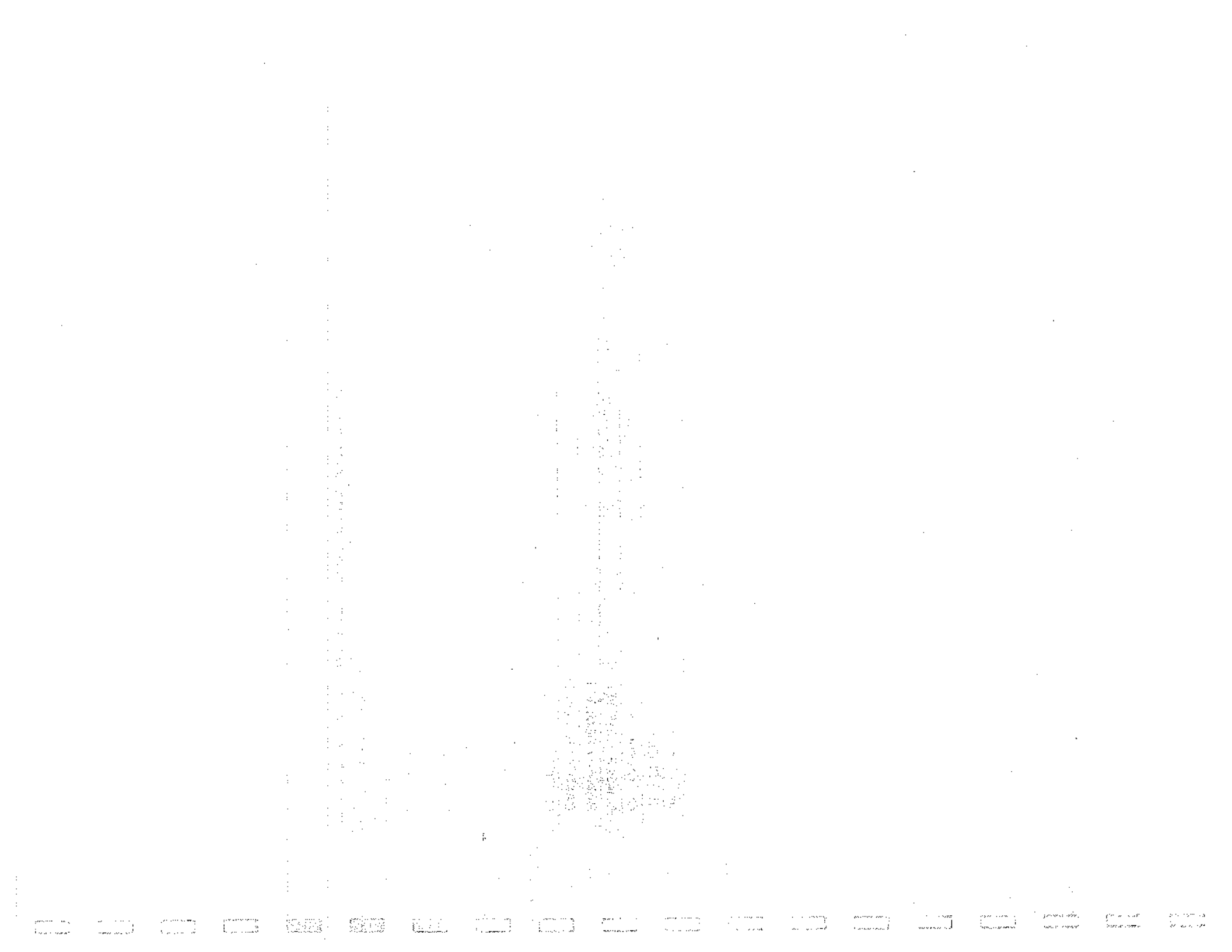
Table 6-5 LIFEPAK 500 AED voice prompts

Voice Prompt	Description
ANALYZING NOW, STAND CLEAR	The AED is analyzing the patient ECG rhythm.
CHECK FOR PULSE	Check the patient for a pulse.
CONNECT ELECTRODES	The AED detects that the electrodes are disconnected.
IF NO PULSE, START CPR	If patient pulse is not present, start CPR.
IF NO PULSE, PUSH ANALYZE	If patient pulse is not present, press ANALYZE.
MOTION DETECTED, STOP MOTION	The AED detects motion during ECG analysis.
NO SHOCK ADVISED	The AED has analyzed the patient ECG and detected a non-shockable ECG rhythm.
PUSH ANALYZE	Press ANALYZE to begin ECG analysis.
REPLACE BATTERY	The battery voltage is low and must be replaced immediately.
SHOCK ADVISED	The AED has analyzed the patient ECG and detected a shockable ECG rhythm.
STAND CLEAR, PUSH TO SHOCK	The AED is fully charged and ready to provide therapy. This is the AED prompt to move everyone away from the patient, then press SHOCK to discharge.

Table 6-6 LIFEPAK 500 AED event types[1]

Possible Event Types
Event Log Report
POWER ON
PATIENT CONNECTED
ANALYSIS X
SHOCK X - XXXJ
CPR PROMPT
CHECK PATIENT
CHARGE REMOVED
BATTERY REMOVED
BATTERY REPLACED
MOTION DETECTED
ANALYSIS STOPPED
OUT OF EVENT MEMORY
OUT OF ECG MEMORY
OUT OF SCENE AUDIO MEMORY
POWER OFF
Event Log Summary
FIRST ANALYSIS
FIRST SHOCK
SHOCK(S) DELIVERED

[1] These events and all voice prompts may appear in the Event Log Report.



Appendix

SHOCK ADVISORY SYSTEM

This section describes the basic function of the Shock Advisory System (SAS).

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Overview of the Shock Advisory System

The Shock Advisory System (SAS) is an ECG analysis system built into the LIFEPAK 500 AED that advises the operator if it detects a shockable or nonshockable rhythm. This system makes it possible for individuals not trained to interpret ECG rhythms to provide potentially-lifesaving therapy to victims of ventricular fibrillation or pulseless ventricular tachycardia. The Shock Advisory System contains the following features:

- Electrode contact determination
- Automated interpretation of the ECG
- Operator control of shock therapy
- Continuous Patient Surveillance System
- Motion detection

Electrode Contact Determination

The patient's transthoracic impedance is measured through the QUIK-COMBO electrodes. If the baseline impedance is higher than a maximum limit, it is determined that the electrodes are not in sufficient contact with the patient or not properly connected to the AED. ECG analysis and shock delivery are inhibited. The operator is advised to connect electrodes any time electrode contact is inadequate.

Automated Interpretation of the ECG

The Shock Advisory System is designed to recommend a shock if it detects the following:

- **Ventricular fibrillation** - with a peak-to-peak amplitude of at least 0.08mV
- **Ventricular tachycardia** - defined as having a heart rate of at least 120 beats per minute, QRS width of at least 0.16 seconds, and no apparent P waves.

The Shock Advisory System is designed to recommend no shock for all other ECG rhythms including asystole, pulseless electrical activity, idioventricular rhythms, bradycardia, supraventricular tachycardias, and normal sinus rhythms.

ECG analysis is performed on consecutive 2.7-second segments of ECG. The analysis of two out of three consecutive segments must agree before a decision (SHOCK ADVISED or NO SHOCK ADVISED) is made.

Operator Control of Shock Therapy

The Shock Advisory System causes the AED to charge automatically when it detects the presence of a shockable rhythm. When a shock is advised, the operator remains in control of when the shock is delivered.

Continuous Patient Surveillance System

The Continuous Patient Surveillance System (CPSS) automatically monitors the patient's ECG rhythm for a potentially shockable rhythm while the electrodes are attached and the AED is turned on. CPSS is not active during ECG analysis or when the operator is in a CPR cycle.

Motion detection is not active during the CPSS. Therefore, there is a chance that motion distortion in the ECG rhythm may be interpreted by CPSS as a potentially shockable rhythm.

Motion Detection

The Shock Advisory System detects patient motion independent of ECG analysis. A motion detector is designed into the LIFEPAK 500 AED.

Motion can be caused by CPR, rescuer movement, patient movement, vehicle movement, or other causes. If variations in the transthoracic impedance signal exceed a maximum limit, it is determined that patient motion of some kind is present. ECG analysis is inhibited until the motion ceases. The operator is advised any time motion is detected during an analysis by a displayed message, a voice prompt, and an audible alert. If the motion does not cease within 20 seconds, analysis attempts will stop until the operator presses the ANALYZE button again. If the motion does cease within 20 seconds, ECG analysis proceeds automatically.

There are two reasons why ECG analysis is inhibited when motion is detected:

1 Such motion may cause artifact in the ECG signal. This artifact can cause a nonshockable ECG rhythm to look like a shockable rhythm. For example, chest compressions during asystole can look like shockable ventricular tachycardia. Artifact can also cause a shockable ECG rhythm to look like a nonshockable rhythm. For example, chest compressions during ventricular fibrillation can look like an organized and, therefore, nonshockable rhythm.

2 The motion may be caused by a rescuer's interventions. To reduce the risk of inadvertently shocking a rescuer, the motion alert prompts the rescuer to move away from the patient. This will stop the motion and ECG analysis will proceed.

Index/Change Summary

INDEX