PHYSIO CONTROL

LIFEPAK® 1000 DEFIBRILLATOR

OPERATING INSTRUCTIONS

LIFEPAK® 1000 DEFIBRILLATOR

OPERATING INSTRUCTIONS

Important

This instrument is to be used by authorized personnel only.

!USA Rx Only

!USA Device Tracking

The U.S. Food and Drug Administration requires defibrillator manufacturers and distributors to track the location of their defibrillators. If the device is located somewhere other than the shipping address or the device has been sold, donated, lost, stolen, exported, destroyed, permanently retired from use, or if the device was not obtained directly from Physio-Control, please do one of the following: register the device at http://www.physio-control.com, call the device registration phone line at 1.800.426.4448, or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

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 cautions and warnings provided throughout this manual.

Applicable Products

These operating instructions are for use with the following products catalog numbers.

REF

99425-000023, 99425-000025, 99425-000205, 99425-000206

Publication Date: 11/2018

PN 3205213-014

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PREFACE

This section provides information about defibrillation and an overview of the LIFEPAK® 1000 defibrillator.

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® 1000 defibrillator is an automated external defibrillator (AED) that delivers this energy through disposable defibrillation 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 measures may include:

- Cardiopulmonary resuscitation (CPR)
- 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 sudden cardiac arrest (SCA).

- 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 delivered or defibrillator performance.

INDICATIONS FOR USE

Defibrillation

The defibrillator is to be used in AED mode only on patients who are in cardiopulmonary arrest. The patient must be unresponsive, not breathing normally, and showing no signs of circulation.

The defibrillator may be used with QUIK-COMBO® Electrodes with REDI-PAK® Preconnect System only on adults and children who are 8 years old or more or who weigh more than 25 kg (55 lbs). The defibrillator may be used on children who are less than 8 years old or weigh less than 25 kg (55 lbs) with Infant/Child Reduced Energy Defibrillation Electrodes.

ECG Monitoring

ECG monitoring is for use on conscious and unconscious patients of all ages for the purpose of ECG rhythm recognition and heart rate monitoring.

CONTRAINDICATIONS

None known.

OPERATOR CONSIDERATIONS

The LIFEPAK 1000 defibrillator requires operator interaction to defibrillate the patient.

The defibrillator is intended for use by personnel who are authorized by a physician or medical director and have, at a minimum, the following skills and training.

- CPR training
- Defibrillator training equivalent to that recommended by the American Heart Association
- Training in the use of the LIFEPAK 1000 defibrillator

The LIFEPAK 1000 defibrillator is intended for use in hospital and out-of-hospital environments.

Manual mode is intended for use by personnel trained in ECG recognition who want to use the defibrillator to deliver a shock independent of AED mode. The operator has control over the charging and delivery of shocks.

ECG mode provides a nondiagnostic ECG display and is intended for use by personnel trained in ECG recognition to allow for rhythm and heart rate monitoring using standard ECG electrodes. When in ECG mode, the defibrillator's shock capability is disabled; however, the LIFEPAK 1000 defibrillator continues to analyze the patient's ECG for a potentially shockable rhythm.

ABOUT THE LIFEPAK 1000 DEFIBRILLATOR

The LIFEPAK 1000 defibrillator is a semiautomatic model that can be operated in either of three modes: AED mode, Manual mode, and ECG mode. The defibrillator uses the Physio-Control patented Shock Advisory System™ to analyze the patient's electrocardiographic (ECG) rhythm and prompts you when it detects a shockable rhythm and when it does not detect a shockable rhythm. Responder interaction is required to provide therapy (defibrillation) to the patient.

Defibrillator Features

The following paragraphs introduce the LIFEPAK 1000 defibrillator features.

Heart Rhythm Analysis

The Physio-Control patented Shock Advisory System evaluates the patient's heart rhythm.

ECG Display (optional)

This feature allows display of the ECG using the 3-wire (Lead II) cable and when using the defibrillator in AED mode. This feature is also necessary to use the defibrillator in Manual mode.

Defibrillation Waveform

The defibrillation shock, using ADAPTIV™ Biphasic technology, is delivered in the form of a biphasic truncated exponential (BTE) defibrillation waveform. LIFEPAK biphasic defibrillators measure the patient's transthoracic impedance and automatically adjust the defibrillation waveform current, duration, and voltage to meet the needs of the individual patient. Patient impedance is measured whenever defibrillation electrodes are in contact with the patient.

cprMAX™ Technology

The cprMAX technology is designed to allow resuscitation protocols to maximize the amount of CPR administered during treatment using the LIFEPAK 1000 defibrillator.

When used with the factory default settings enabled, the defibrillator allows AED protocols to be consistent with the 2015 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care and European Resuscitation Council Guidelines for Resuscitation.

Data Management

The LIFEPAK 1000 defibrillator digitally records patient data, including ECG rhythm and delivered shocks. Recorded data may be transferred from the defibrillator to a PC using an infrared connection. The PC must have one of our LIFENET® products installed to collect and review the recorded patient data.

Battery Options

A nonrechargeable lithium manganese dioxide (Li/MnO_2) battery or a rechargeable Lithium-ion (Li-ion) battery provides power to the defibrillator. Both batteries have indicators that show the approximate state of charge. The nonrechargeable battery is best suited for low-use applications. The rechargeable battery is best suited for high-use defibrillator applications, such as fire departments and ambulance services. It requires periodic recharging by an external battery charger. To save battery life if the defibrillator is accidentally turned on or left on, the defibrillator automatically turns off if it is not connected to a patient and no buttons are pressed for 5 minutes.

Daily Self-Test

The defibrillator performs a daily self-test every 24 hours and every time you turn on the defibrillator. This feature tests the most important circuitry in the defibrillator to give the responder a high degree of confidence that it is ready for use.

Readiness Display

The LIFEPAK 1000 defibrillator includes a readiness display. The **OK** symbol appears in the display if the daily self-test is completed successfully. A battery symbol that approximates the remaining state of charge is also visible. If the self-test detects that service is required, the **OK** symbol disappears and the service symbol appears.

TEXT CONVENTIONS

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

Operating control labels:	**CAPITAL LETTERS** such as **ON/OFF** and **SHOCK**.
Screen messages, and voice prompts:	***CAPITAL ITALICIZED LETTERS*** such as ***PUSH ANALYZE*** and ***CONNECT ELECTRODES***.

SAFETY

This section provides important information to help you operate the LIFEPAK 1000 defibrillator. Familiarize yourself with all of these terms, warnings, and symbols.

TERMS

The following terms are used either in this manual or on the LIFEPAK 1000 defibrillator.

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.
The defibrillator delivers up to 360 joules of electrical energy. Unless properly used as described in these operating instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this device unless thoroughly familiar with these operating instructions, and the function of all controls, indicators, connections, and accessories.

Shock hazard.
Do not disassemble the defibrillator. It contains no responder-serviceable components and dangerous high voltages may be present. Contact authorized service personnel.

Shock or fire hazard.
Do not immerse any portion of this device in water or other fluids. Avoid spilling any fluids on device or accessories. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this device or accessories unless otherwise specified.

Possible fire or explosion.
Do not use this device in the presence of flammable gases or anesthetics. Use care when operating this device close to oxygen sources (such as bag-valve-mask devices or ventilator tubing). Turn off gas source or move source away from patient during defibrillation.

Possible device failure.
Do not modify this device.

Possible electrical interference with device performance.
Equipment operating in close proximity may emit strong electromagnetic or radio frequency interference (RFI) which could affect the performance of this device. RFI may result in improper device operation, distorted ECG, or failure to detect a shockable rhythm. Avoid operating the device near cauterizers, diathermy equipment, cellular phones, metal detectors, or electronic articles surveillance gates. Do not rapidly key EMS radios on and off. Refer to the Recommended Separation Distances table (on page 100) for recommended distances of equipment. Contact authorized service personnel if assistance is required.

Possible electrical interference with device performance.
Portable radio frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than the distance listed in the Recommended Separation Distances table (on page 100) to any part of the LIFEPAK 1000 defibrillator, including cables specified by Physio-Control. Shorter distances may result in compromised performance.

WARNINGS! (CONTINUED)

Possible electrical interference.

Using cables, electrodes, or accessories not specified for use with this device may result in increased emissions or decreased resistance to electromagnetic interference which could affect the performance of this device or of equipment in close proximity. Use only parts and accessories specified in these operating instructions.

Possible electrical interference.

This defibrillator may cause electromagnetic interference (EMI) especially during charge and energy transfers. EMI may affect the performance of equipment operating in close proximity. Verify the effects of defibrillator discharge on other equipment prior to using defibrillator in an emergency situation, if possible.

Possible device shutdown.

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

Possible improper device performance.

Using other manufacturers' cables, electrodes, or batteries may cause the device to perform improperly and invalidates the safety agency certification and may invalidate the warranty. Use only the accessories specified in these operating instructions.

Safety risk and possible equipment damage.

MR unsafe: keep the defibrillator away from magnetic resonance imaging (MRI) equipment.

CAUTION!

Possible equipment damage.

This device may be damaged by mechanical or physical abuse such as immersion in water or dropping the device. If the device has been abused, remove it from use and contact authorized service personnel.

SYMBOLS

The following symbols may be found in this manual or on various configurations of the LIFEPAK 1000 defibrillator and its accessories.

Defibrillation-proof type BF applied part

Operating instructions

Warning. High voltage

Caution

Type BF applied part


Menu button


Battery status symbol


Service symbol

OK
Symbol indicating self-test completed successfully


Use By date shown: yyyy-mm-dd


Fragile. Handle with care.


Keep dry


Do not reuse


Mark of conformity to applicable European Directives


Canadian Standards Association certification mark for Canada and the United States


Underwriters Laboratories recognized component mark for Canada and the United States


Not made with natural rubber latex


Cable Connector


For USA audiences only


Manufacturer


Date of manufacture shown: YYYY-MM-DD

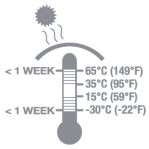
Power On/Off

Shock button (Symbol has a red background and graphical symbol is white.)

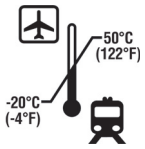
Shock symbol

Symbol indicating location of battery compartment

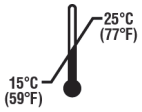
Keep away from sunlight



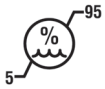
Recommended storage temperature: 15° to 35°C (59° to 95°F). Storage at extreme temperatures of -30° and 65°C (-22° and 149°F) is limited to seven days. If storage at these temperatures exceeds one week, the electrode shelf-life will be reduced.



Recommended shipping temperature range: -20° to 50°C (-4° to 122°F).



Recommended storage temperature range: 15° to 25°C (59° to 77°F).



Relative humidity range 5% to 95%

Recommended storage atmospheric pressure range 1060 to 575 hPa

Do not place near an open flame, heat above 100°C (212°F), or incinerate

Do not crush, puncture, or disassemble battery

FIRE OR BURN HAZARD - Do not charge

FIRE OR BURN HAZARD - Do not deform or damage

EXPLOSION HAZARD - Do not dispose of in fire or heat above 100°C (212°F)

FIRE OR BURN HAZARD - Do not open or dismantle

Non-rechargeable battery. Do not charge.

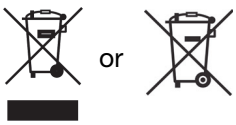
Lithium manganese dioxide battery

Rechargeable battery

Battery for use with the LIFEPAK 1000 defibrillator

Battery charger for use with Lithium-ion battery

AC to DC power adapter



Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See www.physio-control.com/recycling for instructions on disposing of this product.

Symbol for China RoHS indicating Environmentally Friendly Use Period (EFUP) denoting the number of years before any substance is likely to leak out into the environment.

Infant Child Reduced Energy Defibrillation Electrodes are not compatible with QUIK-COMBO® defibrillation and therapy cables. To use Infant/Child Electrodes, connect Infant/Child electrodes directly to the AED.

Lot number (batch code)

Part number

Catalog number

Serial number

By prescription only

See website for patent information

IP55

Protected against dust and jets of water.

Assembled in Mexico

Lithium metal battery

CONTROLS AND INDICATORS

This section provides a description of each of the LIFEPAK 1000 defibrillator primary controls and indications.

CONTROLS AND INDICATORS

This section introduces you to the controls and indicators on the LIFEPAK 1000 defibrillator.

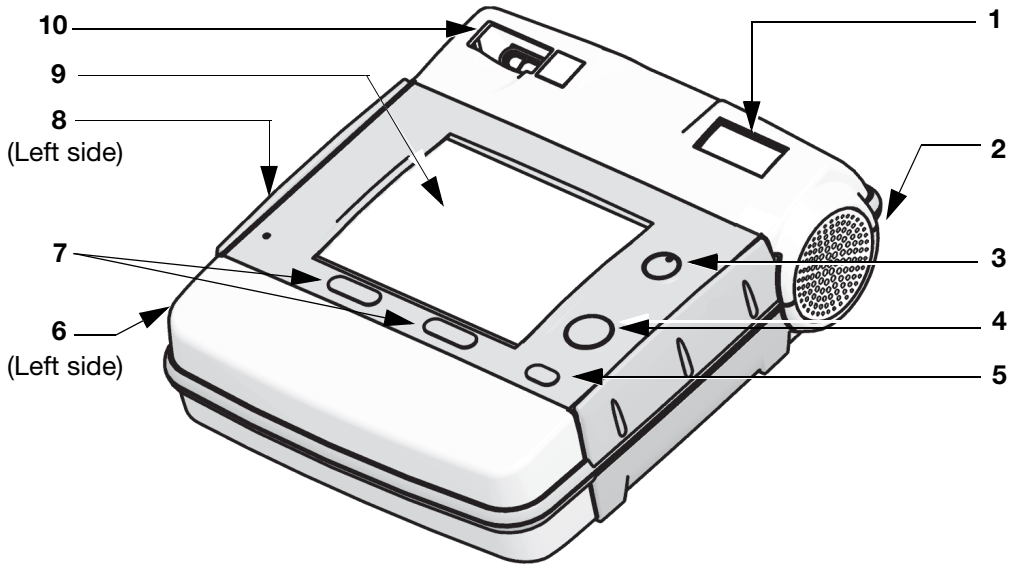


Figure 2-1 Controls and Indicator

Table 2-1 Controls and Indicators

	Feature	Description
1	Readiness display	The readiness display alerts you to the defibrillator's readiness status. Three symbols ( , OK, ) allow you to determine whether the defibrillator is ready for use or needs attention. The following defines what each symbol represents and when/where each appears.
		The wrench indicator appears on the readiness display when a condition exists that prevents or could prevent normal defibrillator operation.
	OK	The OK symbol indicates that the defibrillator is ready for use. It is visible only when the defibrillator is off. The OK symbol will not appear if the battery is low or the device requires service.
		The battery symbol appears on the readiness display when the defibrillator is off. When one bar is visible in the symbol, the battery is low and should be replaced.
2	Speaker	Provides audio voice prompts and tones.

Table 2-1 Controls and Indicators (Continued)

	Feature	Description
3	 **ON/OFF** button	Green **ON/OFF** button turns the power on or off. The button is lit whenever the defibrillator is on.
4	 SHOCK button	Pressing the **SHOCK** button (when flashing) delivers a shock to the patient.
5	 **MENU** button	Used to select operating modes (Manual or AED) and enter information in Setup mode.
6	Battery compartment	Accommodates a single battery.
7	 Softkeys	Two softkeys work in conjunction with the screen, providing a way for you to make selections while using the defibrillator. The softkey functions vary, depending on the task you are performing at the time. Their function is identified by the label above them on the screen.
8	IrDA port	Infrared Data Association. This port provides wireless communications for transferring data from the defibrillator to a PC.
9	Screen	Displays pertinent information for use during all modes of operation. Figure 2-2 defines the information displayed on the screen.
10	Cable receptacle	Allows direct connection to therapy electrodes (black), ECG cable (green), Infant/Child electrodes (pink), and QUIK-COMBO therapy electrodes (gray).

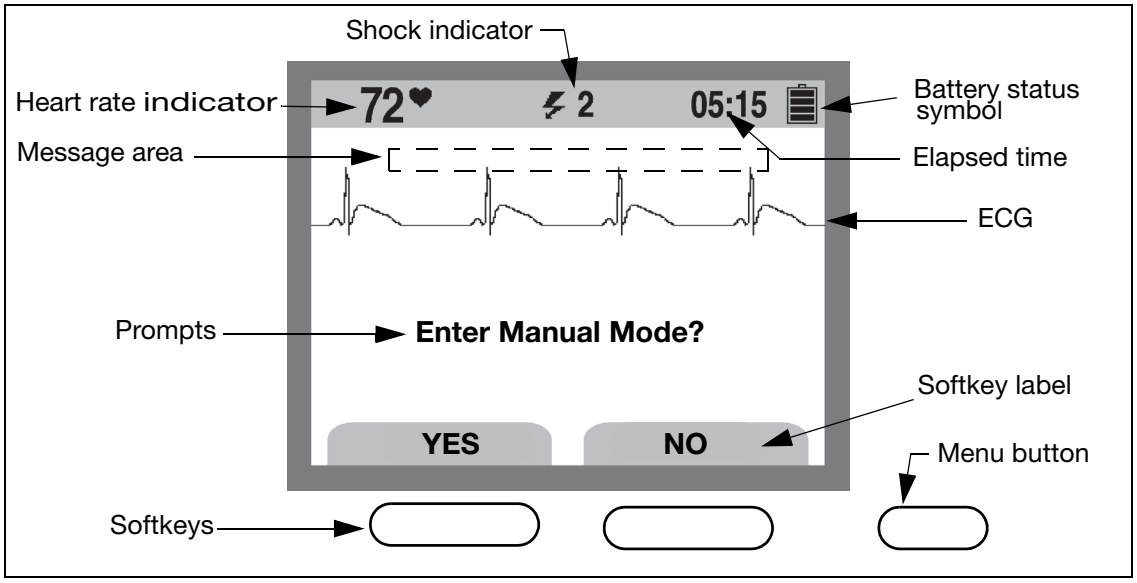


Figure 2-2 Defibrillator Screen

Heart rate indicator. The heart rate indicator displays heart rates between 20 – 300 bpm. Indicator is present in Manual mode or when the 3-wire ECG cable is used.

Battery status symbol. When the defibrillator is turned on, this symbol appears on the screen indicating the relative level of charge. One bar indicates the battery is low and should be replaced. When the battery is very low, the symbol is blank and a ***REPLACE BATTERY*** message appears on the screen.

ECG. The ECG appearing on the screen is a nondiagnostic ECG, obtained by means of the therapy electrodes or the Lead II ECG cable. The presence of an ECG does not ensure that the patient has a pulse.

Softkey labels. These labels define the function that can be activated by pressing the softkey. **ANALYZE** and **DISARM** are function examples.

BATTERY INDICATORS

The LIFEPAK 1000 defibrillator can be powered by two types of batteries:

- A nonrechargeable Lithium manganese dioxide battery
- A rechargeable Lithium-ion battery

Battery Charge Level Indicators

Both battery types have a fuel gauge that indicates the approximate charge level of the battery when it is not installed in a defibrillator. Push the gray button below the battery symbol to check the battery's charge level before installing it in the defibrillator.

Note: Always carry a spare, fully-charged battery.

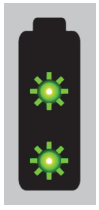
For **both battery types**, the four battery indicators shown here represent approximate charge.

Figure 2-3 Battery Charge Indicators

Note: The fuel gauge on a new rechargeable battery will not function until the battery has been charged for the first time.

Battery Warning Indicators

For **both battery types**, a single flashing LED indicates the battery charge level is very low. Replace battery immediately.



For **rechargeable** batteries only, two flashing LEDs indicate the battery is faulty and should be returned to your local Physio-Control representative.

Figure 2-4 Battery Warning Indicators

The **nonrechargeable** battery is shipped to customers fully charged. All four LEDs should illuminate when the fuel gauge is activated. Check the charge level of a new nonrechargeable battery before putting it into service. When optimally maintained, a new nonrechargeable battery can provide approximately 17 hours of "ON time" **or** 440 discharges at 200 joules.

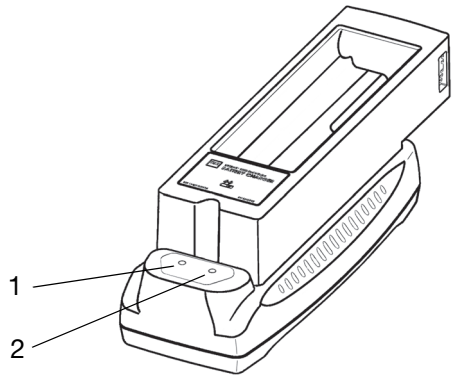
The **rechargeable** battery is shipped to customers at approximately 25% charge and must be fully charged before use. Charge the battery fully within six months of when you receive it and at

least once every six months thereafter. When optimally maintained, a **new** fully-charged battery provides approximately ten hours on “ON time” **or** 261 discharges at 200 joules. Since all rechargeable batteries permanently lose battery capacity over time, and because battery capacity together with the level of battery charge determines how long a rechargeable battery will provide defibrillator power, you can expect that a fully-charged battery’s “ON time” will decrease with age.

BATTERY CHARGER INDICATORS

The LIFEPAK 1000 Defibrillator Battery Charger is intended for use with LIFEPAK 1000 defibrillator Lithium-ion (Li-ion) rechargeable batteries. No other batteries are compatible with this charger. For complete battery charger information, refer to the *LIFEPAK 1000 Defibrillator Battery Charger Instructions for Use* provided with the charger.

When power is applied to the battery charger, both LEDs on the charger flash briefly and then turn off. Before inserting a battery, inspect the battery contacts for obvious damage or foreign substances. Figure 2-5 describes the LEDs on the battery charger when a rechargeable battery is inserted.



LED	Behavior	Definition	Explanation
1	Flashing green	Battery is charging.	A fully depleted battery takes approximately 4 hours to charge.
1	Steady green	Battery charging is complete.	If the battery is kept in the charger, the battery will remain in an optimally charged condition. The charger enters “maintenance” mode after charging completes, automatically providing periodic top-off charging.
2	Red	Battery or charger is faulty.	To test the battery: Remove battery and check fuel gauge; two flashing LEDs indicate a faulty battery. To test the charger: Reinstall a functional battery; a persistent red charger LED indicates a faulty charger. Contact your authorized service personnel for assistance with a faulty battery or charger.

Figure 2-5 Battery Charger Indicators

For details on batteries and instructions for disposal, see "Battery Maintenance" on page 5-4 and "Product Recycling Information" on page 5-8.

HOW TO USE THE LIFEPAK 1000 DEFIBRILLATOR

This section provides an overview of information and instructions for using the LIFEPAK 1000 defibrillator.

MODES OF OPERATION

You can use the LIFEPAK 1000 defibrillator for:

- Automated external defibrillation (AED mode)
- Manual defibrillation therapy (Manual mode) (Requires ECG display option)
- ECG monitoring (ECG mode) (Requires ECG display option)

Defibrillation Warnings and Cautions

WARNINGS!

Shock hazard.

The defibrillator delivers up to 360 J of electrical energy. When discharging the defibrillator, do not touch the disposable therapy electrodes.

Shock hazard.

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. Clear everyone away from contact with the patient, bed, and other conductive material before discharging the defibrillator.

Possible skin burns.

During defibrillation, air pockets between the skin and therapy electrodes may cause patient skin burns. Apply therapy electrodes so that entire electrode adheres to skin. Do not reposition the electrodes once applied. If the position must be changed, remove and replace with new electrodes.

Possible skin burns and ineffective energy delivery.

Therapy electrodes that are dried out or damaged may cause electrical arcing and patient skin burns during defibrillation. Do not use therapy electrodes that have been removed from foil package for more than 24 hours. Do not use electrodes beyond expiration date. Check that electrode adhesive is intact and undamaged. Replace therapy electrodes after 50 shocks.

Possible interference with implanted electrical device.

Defibrillation may cause implanted devices to malfunction. Place therapy electrodes away from implanted devices if possible. Check implanted device function after defibrillation, if possible.

Possible misinterpretation of data.

Do not analyze in a moving vehicle. Motion artifact may affect the ECG signal resulting in an inappropriate shock or no shock advised message. Motion detection may delay analysis. Stop vehicle and stand clear of patient during analysis.

Possible misinterpretation of data.

Do not move the AED during analysis. Moving the AED during analysis may affect the ECG signal resulting in an inappropriate shock or no shock advised decision. Do not touch the patient or the AED during analysis.

CAUTION!

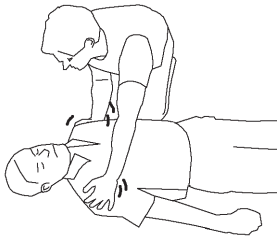
Possible equipment damage.

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

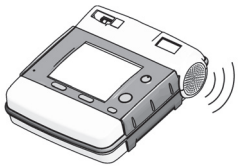
DEFIBRILLATION IN AED MODE

The LIFEPAK 1000 defibrillator uses the Physio-Control patented Shock Advisory System to evaluate the patient's heart rhythm. The LIFEPAK 1000 defibrillator has an optional feature that displays the ECG waveform and Heart Rate Indicator in AED mode. The operation in AED mode remains the same whether or not the defibrillator displays the ECG waveform. When **ECG DISPLAY** is set to **ON**, the ECG appears with all of the AED messages and prompts. When **ECG DISPLAY** is set to **OFF**, the messages and prompts fill the screen.

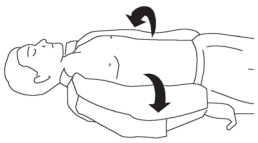
Basic Steps for Using the LIFEPAK 1000 Defibrillator



1 Establish that the patient is in cardiopulmonary arrest (the patient must be unresponsive, not breathing normally and showing no signs of circulation).



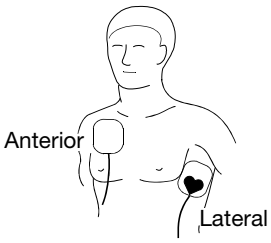
2 Press **ON/OFF** to turn on the defibrillator (the green LED illuminates). Voice prompts will sound, guiding you through the rescue process.



3 Prepare the patient for therapy electrode placement.

- If possible, place the patient on a hard surface away from standing water.
- 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 Open the therapy electrode packet and remove the electrodes. Slowly peel back the protective liner on the electrodes, beginning with the cable connection end. Safely discard the liner to prevent slipping.



5 Apply the therapy electrodes to the patient's chest. Starting from one end, press the electrodes firmly onto the patient's skin, as shown.

WARNING!
Excessive Energy Delivery.
For children less than 8 years of age or 55 lbs (25 kg), use Infant/Child Reduced Energy Defibrillation electrodes. Do not use Pediatric QUIK-COMBO electrodes; these electrodes do not attenuate the energy delivery by this defibrillator.

6 Connect the electrodes to the defibrillator (if they are not already connected).

7 Follow the screen messages and voice prompts provided by the defibrillator.

Voice Prompts and Messages in AED Mode

The following descriptions of voice prompts and messages are based on the default settings for AED mode. Changing the setup options may result in different AED behavior.

CONNECT ELECTRODES	Voice prompt and message when a patient has not been connected to the defibrillator.
STAND CLEAR, ANALYZING NOW, STAND CLEAR	Voice prompt and message when a patient is connected to the defibrillator. Do not touch or move the patient, or therapy cables, during analysis. ECG analysis requires 6–9 seconds.
PREPARING TO SHOCK	Message displayed if the defibrillator detects a shockable rhythm. The defibrillator charges to the joule setting for that shock number. A rising tone and a charging bar on the screen indicate that the defibrillator is charging.
STAND CLEAR, PUSH SHOCK BUTTON	Voice prompt and message when charging is complete. The shock button flashes. *Clear everyone away from the patient, bed, or any equipment connected to the patient.* Press the shock button to discharge the defibrillator. The energy level for shocks depends on the energy protocol setup option and the analysis decision after shocks. If the shock button is not pressed within 15 seconds, the defibrillator disarms the shock button, and the ***DISARMING...*** message appears on the screen.
ENERGY DELIVERED	Message displayed after each shock.
START CPR	A message and countdown timer (min:sec format) appears for the CPR time.
NO SHOCK ADVISED	Voice prompt and message when the defibrillator detects a nonshockable rhythm. The defibrillator will not charge, and a shock cannot be delivered. When a ***NO SHOCK ADVISED*** prompt follows a shock and CPR, the energy level will not increase for the next shock.

Special Situations for Electrode Placement

When placing electrodes on the patient, be aware of 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 defibrillation electrodes away from the internal pacemaker generator. Treat this patient like any other patient requiring emergency care.

Patients with Implanted Defibrillators

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

Alternate Anterior-Posterior Electrode Position

The electrodes may be placed in an anterior-posterior position as follows:

1 Place either the ♥ or **+** therapy electrode over the left precordium as shown in Figure 3-1. The upper edge of the electrode should be below the nipple. Avoid placement over the nipple, the diaphragm, or the bony prominence of the sternum if possible.

2 Place the other electrode behind the heart in the infrascapular area as shown in Figure 3-1. For patient comfort, place the cable connection away from the spine. Do not place the electrode over the bony prominences of the spine or scapula.

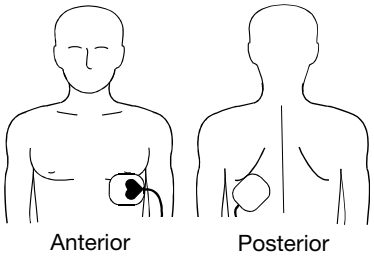


Figure 3-1 Anterior-Posterior Placement

DEFIBRILLATION IN MANUAL MODE

The LIFEPAK 1000 defibrillator provides a Manual mode to override the AED features of the defibrillator. Manual mode provides operator-initiated analysis, charge, shock, and disarm functions. This mode is useful in a tiered response system when a provider trained in manual defibrillation and authorized to place the defibrillator in Manual mode takes over the scene from a BLS-AED trained provider.

To use Manual mode:

1 Press the Menu button.

2 Select **YES** to enter Manual mode. The ECG trace and Heart Rate Indicator appear on the screen.

3 If the displayed ECG rhythm appears shockable, press **CHARGE** to initiate charging of the defibrillator. The screen will indicate that the defibrillator is charging and a charge tone will sound.

4 Clear everyone away from the patient, bed, or any equipment connected to the patient.

5 When the charge is complete, press the flashing shock button to deliver energy to the patient.

6 After delivering a shock, the energy for each subsequent shock is automatically selected based on the energy level configured in Setup.

Note: To remove an unwanted charge at any time, press **DISARM**.

Analysis

The LIFEPAK 1000 defibrillator can be set up to display an **ANALYZE** softkey when in Manual mode.

To initiate an analysis:

1 Confirm that the patient is unresponsive, not breathing, and without a pulse.

2 Press **ANALYZE**.

3 If the rhythm analysis results in a No Shock Advised decision, the defibrillator remains in Manual mode without further prompts.

4 If the rhythm analysis results in a Shock Advised decision, the defibrillator automatically begins charging accompanied by a charge tone. If you determine that a shock is not warranted, press **DISARM**.

5 When the charge is complete, clear everyone away from the patient, bed, or any equipment connected to the patient.

6 Press the flashing shock button to deliver energy to the patient.

7 After delivering a shock, the defibrillator remains in Manual mode.

TROUBLESHOOTING TIPS FOR DEFIBRILLATION

This section explains problem conditions that you may encounter while using the defibrillator.

Table 3-1 Troubleshooting Tips for Defibrillation

Observation	Possible Cause	What To Do
Screen blank and **ON** LED lit.	Screen not functioning properly.	• AED and therapy functions may still operate. If needed for therapy, follow voice prompts and continue to use device to treat patient. If unable to use voice prompts for any reason, administer CPR if the patient is not responding, not breathing normally, and showing no signs of circulation. • Contact authorized service personnel.
CONNECT ELECTRODES voice prompt is heard.	Poor electrode-to-skin contact.	• Firmly press electrodes on patient's skin. • Clean, shave, and dry the patient's skin prior to placing pads on skin.
	Electrode pads are dry, damaged, or have passed the expiration date.	• Replace the electrode pads.
	Electrode pads are not removed from the liner.	• Remove the electrode pads from the liner and apply them to the patient's chest
CHECK CONNECTOR AND ELECTRODES voice prompt is heard.	Connection to the defibrillator is inadequate.	• Check to be sure that the electrode connector is completely inserted.
Defibrillator cannot deliver the required shock.	Defibrillator battery power is low.	• Administer CPR if the patient is not responding, not breathing normally, and showing no signs of circulation. • Check battery indicator. Replace battery if one bar or less is visible.
Voice prompts sound faint or distorted.	Defibrillator battery power is low.	• Administer CPR if the patient is not responding, not breathing normally, and showing no signs of circulation. • Check battery indicator. Replace battery if one bar or less is visible.

Table 3-1 Troubleshooting Tips for Defibrillation (Continued)

Observation	Possible Cause	What To Do
MOTION DETECTED and ***STOP MOTION*** voice prompts are heard.	Patient movement because of location.	• Move patient to stable location, if possible.
	Patient movement because of breathing.	• Check patient for normal breathing.
	CPR being performed during analysis.	• Stop CPR during analysis.
	Vehicle motion.	• Stop vehicle during analysis, if possible.
	Electrical/radio frequency interference.	• Move communication or other suspected devices away from the defibrillator when possible.
Defibrillator does not deliver voice prompts or beeping tones after you turn it on.	Speaker not functioning.	• AED and therapy functions may still operate. If needed for therapy, follow screen prompts and continue to use device to treat patient. If unable to use screen prompts for any reason, administer CPR if the patient is not responding, not breathing normally, and showing no signs of circulation. • Contact authorized service personnel.
	Depleted battery.	• Administer CPR if the patient is not responding, not breathing normally, and showing no signs of circulation. • Check battery indicator. Replace battery if one bar or less is visible. • Contact authorized service personnel.
The readiness display is blank.	The defibrillator has been turned on.	• Normal condition when the defibrillator is in use.
	Operating temperature is too low.	• Operate the defibrillator within the specified temperature range.
	LCD not operating properly.	• Contact authorized service personnel.
Rechargeable battery requires frequent charging.	Battery is near end of service life and has lost capacity.	• Consider replacing the battery. See "To determine when to replace rechargeable batteries:" on page 5-6 for more information.

ECG MONITORING (ECG MODE)

WARNING!

Possible misinterpretation of ECG data.

The frequency response of the screen is intended only for basic ECG rhythm identification; it does not provide the resolution required for pacemaker pulse visibility, accurate measurements, such as QRS duration, and ST segment interpretation. For such purposes, use ECG monitors with an appropriate frequency response.

Possible delay in therapy.

Do not attempt to connect a 3-wire ECG cable to a QUIK-COMBO therapy cable or any other AED. The ECG cable is functional only with the LIFEPAK 1000 defibrillator.

The LIFEPAK 1000 defibrillator provides nondiagnostic ECG display of the patient's heart rhythm when the ECG cable is connected and the electrodes are applied.

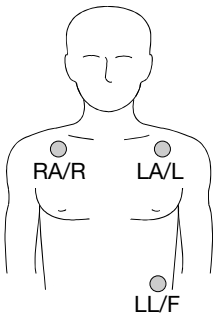
Note: You do not have to turn the defibrillator off before changing from therapy electrodes to the ECG cable or vice versa.

To use ECG monitoring mode:

1 Connect the ECG cable.

Note: The ECG cable uses the same receptacle used by the therapy electrodes.

2 Apply ECG electrodes to the patient's chest as shown in Figure 3-2



AHA Labels		IEC Labels	
RA	Right Arm	**R**	Right
LA	Left Arm	**L**	Left
LL	Left Leg	**F**	Foot

Figure 3-2 Connecting the ECG Electrodes for use with ECG cable

After the ECG electrodes are connected, the defibrillator displays the patient's heart rhythm and heart rate in a lead II configuration. Lead II is the only lead available with this cable.

While in ECG mode, the defibrillator's shock capability is disabled; however, the defibrillator continues to evaluate the patient's ECG for a potentially shockable rhythm. Remember that the presence of an ECG rhythm does not ensure that the patient has a pulse.

If a shockable rhythm is detected, the defibrillator prompts ***CONNECT THERAPY ELECTRODES***.

1 Confirm the patient's condition: Not responsive? Not breathing? No signs of circulation?

2 Remove the ECG cable and connect the therapy electrodes to the defibrillator.

3 Apply the therapy electrodes to the patient's chest, keeping them at least 2.5 cm (one inch) away from the ECG electrodes. If necessary, remove the ECG electrodes.

4 Follow the defibrillator's voice and screen prompts.

Troubleshooting Tips for ECG Monitoring Mode

If problems occur while monitoring the ECG, check this list of observations for troubleshooting assistance.

Table 3-2 Troubleshooting Tips for ECG Monitoring Mode

Observation	Possible Cause	What to Do
Screen blank and **ON** LED lit.	Screen not functioning properly.	• Contact authorized service personnel. • AED and therapy functions may still operate. If needed for therapy, continue to use device to treat patient.
CONNECT ECG LEADS message appears	One or more ECG electrodes are disconnected.	• Confirm ECG electrode connections.
	Poor electrode-to-skin contact.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. • Clean, shave, and dry the patient's skin as recommended on page 3-3. • Replace electrodes. • Change cable.
	Broken ECG cable lead wire.	• Check ECG cable continuity. If lead wire is broken, replace ECG cable.

Table 3-2 Troubleshooting Tips for ECG Monitoring Mode

Observation	Possible Cause	What to Do
Poor ECG signal quality.	Poor electrode-to-skin contact.	• Reposition cable and/or lead wires to prevent electrodes from pulling away from patient. Secure cable clasp to patient's clothing. • Clean, shave, and dry the patient's skin as recommended on page 3-3. • Replace electrode(s).
	Outdated, corroded, or dried-out electrodes.	• Check date codes on electrode packages. • Use only silver/silver chloride electrodes with Use By dates that have not passed. • Leave electrodes in sealed packet until time of use.
	Loose connection.	• Check/reconnect cable connections.
	Damaged cable or connector/lead wire.	• Inspect ECG and therapy cables. • Replace if damaged. • Check cable with simulator and replace if malfunction observed.
	Noise because of radio frequency interference (RFI).	• Check for equipment causing RFI (such as a radio transmitter) and relocate or turn off equipment power.
Baseline wander (low frequency/high amplitude artifact).	Inadequate skin preparation. Poor electrode-to-skin contact.	• Clean, shave, and dry the patient's skin as recommended on page 3-3. • Replace electrodes.
Fine baseline artifact (high frequency/low amplitude).	Inadequate skin preparation. Isometric muscle tension in arms or legs.	• Clean, shave, and dry the patient's skin as recommended on page 3-3. • Replace electrodes. • Confirm that limbs are resting on a supportive surface. • Check electrodes for proper adhesion.

DATA MANAGEMENT

This section introduces data management for the LIFEPAK 1000 defibrillator.

MANAGING DEFIBRILLATOR DATA

The LIFEPAK 1000 defibrillator provides an infrared method to transfer defibrillator data.

Overview of Data Storage

Every time you use the defibrillator, it digitally saves patient data that can be transferred to a PC. You can provide patient data to aid in case review for quality control, training, and research purposes. You should become familiar with local requirements for reporting a use of the LIFEPAK 1000 defibrillator and for providing use data. For assistance in retrieving data from the defibrillator, contact your local Physio-Control sales representative or authorized service personnel.

Data Stored by the LIFEPAK 1000 Defibrillator

Whenever you turn on the defibrillator and connect it to a patient, it automatically stores data about the patient. When this data is transferred to a data management system for review (for example, CODE-STAT™ software), three patient reports are available: Event Log, Continuous ECG, and CODE SUMMARY. Table 4-1 describes these reports.

Table 4-1 Patient Reports

Report Type	Description
Event Log	A chronological log of all events. An event is a condition noted by the defibrillator. Events are listed on page 4-3.
Continuous ECG	Forty minutes of the patient's ECG rhythm beginning when the patient is connected to the defibrillator and ending when the defibrillator is turned off.
CODE SUMMARY	Combines the Event Log and a sampling of continuous ECG rhythms associated with certain events, such as defibrillation.

The LIFEPAK 1000 defibrillator can store up to two patient records: one for the current patient and one for the previous patient. When you use the defibrillator, it is important to transfer the patient data as soon as possible after use. The Complete Record for the current patient includes the Continuous ECG and Event Log. If you treat a second patient, the first patient's Continuous ECG is reformatted into a CODE SUMMARY™ report. If you treat a third patient, all of the first patient's data is deleted and the second patient's Continuous ECG is reformatted into a CODE SUMMARY report.

Table 4-2 Patient Records

	Complete Record	Summary	Continuous ECG
Current Patient	X	X	X
Previous Patient	Ø	X	Ø

If you turn the defibrillator on and off without attaching electrodes to a patient, the defibrillator does not create a new patient record and the patient records in the defibrillator are not altered.

The LIFEPAK 1000 defibrillator does not delete patient data after you transfer the data to a PC. The defibrillator deletes previous patient data only when it is connected to a new patient or a simulator.

Test and Service Data

The LIFEPAK 1000 defibrillator stores a test log consisting of the most recent auto-tests, power cycles, and battery replacements. The test log lists the test results and any errors detected. The test log data is available only to authorized service personnel or to responders who are using the appropriate LIFENET system product.

Event and Test Log

Table 4-3 and Table 4-4 list the types of events that may be annotated on event and test log reports.

Table 4-3 Events

Events	Events	Events
Power On	Shock X Abnormal	Motion
Connect Electrodes	No Shock Advised	Analysis Stopped*
Patient Connected	CPR Prompt	Low Battery
AED Mode	Stop CPR Prompt	ECG Mode
Initial Rhythm*	Check Patient*	Out of Event Memory
Analysis X*	Charge Removed	Out of Waveform Memory
Shock Advised	Manual Mode	Power Off
Charge Complete	Replace Battery	Recovery Time*
SHOCK X-XXXJ*	Charge Button Pressed	

* **These events include ECG samples in the Summary Report.**

Table 4-4 Test Log Report

Test Log
Self Test Power On
Self Test Pass/Fail
User Power On/Off
Battery Changed

Overview of Connections for Transmitting Reports

Patient, test, and service data can be transmitted from the LIFEPAK 1000 defibrillator to a PC-compatible computer equipped with CODE-STAT software, version 6.0 or later, a LIFENET system product.

The LIFEPAK 1000 defibrillator (see Figure 2-1) supports wireless, infrared communications for transmitting data from the defibrillator to your computer. To receive the transmission, your computer must have an operational IrDA port.

If your computer does not have an IrDA port, you can install an IrDA adapter to provide the needed interface. Physio-Control recommends installing an IrDA adapter on all computers to ensure successful communication connections and data transmissions.

IrDA adapters are available for serial or USB computer ports. Follow the installation and usage instructions provided with the adapter, ensuring that the adapter mount (receiving end) is positioned on a stable surface. Figure 4-1 provides guidelines to follow for positioning the defibrillator and the IrDA adapter before initiating a transmission.

Note: The shaded cone in Figure 4-1 represents the approximate parameters for positioning the defibrillator's IrDA port opposite the IrDA adapter. As the distance between the two increases, so does the possible range for aligning them.

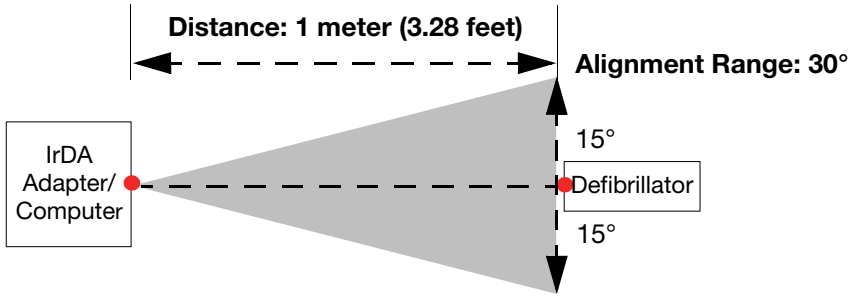


Figure 4-1 IrDA Connections

You initiate and control transmission of device data at your computer using a LIFENET system product. This includes initiating data download, selecting reports to be transmitted, and monitoring transmission progress. More information about configuring your LIFENET system product and instructions for transmitting device data are provided in the users guide and reference cards that accompany the LIFENET system product.

CARING FOR THE LIFEPAK 1000 DEFIBRILLATOR

This section explains how to help keep your LIFEPAK 1000 defibrillator in good working condition. Cared for properly, the defibrillator is built to give you many years of service.

MAINTENANCE AND TESTING SCHEDULE

Use the following schedule in conjunction with the internal quality assurance program of the hospital, clinic, or emergency medical service where the defibrillator is used.

On a regular basis, you should do the following:

- Check the readiness display to determine the level of battery charge and that the OK symbol is visible.
- Check the Use By date on the therapy electrode packet.
- Check other emergency supplies that may be stored with the defibrillator.

The defibrillator needs attention if any of the following conditions occur:

- The OK symbol is not visible.
- The level of battery charge is one bar or less.
- The electrode Use By date has passed.

Replace the battery or electrode packet as indicated. If the OK symbol does not appear, call your authorized service personnel.

When establishing your local inspection schedule, consider how often the defibrillator will be used and how familiar the operators are with using a defibrillator. For example, if the defibrillator is used rarely, weekly inspections are appropriate. An inspection checklist is provided in Appendix E.

Table 5-1 Recommended Maintenance Schedule

Operation	After Use	As Required	Weekly
Complete Operator's Checklist (see Appendix E).		X	
Inspect defibrillator.	X	X	
Clean defibrillator.	X	X	
Check that all necessary supplies and accessories, such as electrodes, are present.	X	X	

SELF-TEST PERFORMANCE

Whenever the LIFEPAK 1000 defibrillator is turned on after it has been off for at least 60 seconds, it takes approximately 5 seconds to complete a self-test and to indicate a low or replace battery condition.

Self-Tests

Each time you turn it on, the defibrillator performs internal self-tests to check that internal electrical components and circuits work properly. The defibrillator stores the results of all user power on self-tests in a test log. When the defibrillator is on and a problem requires immediate service, such as a malfunctioning charging circuit, the defibrillator prompts ***CALL SERVICE***. Attempt to use the defibrillator if needed for an emergency; otherwise, remove the defibrillator from active use and contact authorized service personnel to correct the problem as soon as possible. The service symbol will remain visible until the problem is corrected.

Auto Tests

The defibrillator performs automatic self-tests daily and monthly at 0300 (3:00 a.m.) if not in use. During the automatic self-test, the defibrillator turns itself on (ON/OFF LED illuminates) briefly and completes the following tasks:

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

If the defibrillator detects a problem during an auto test that requires service, it displays the service symbol. If the service symbol is visible, you should attempt to use the defibrillator, if needed, for a cardiac emergency. However, you should contact authorized service personnel to correct the problem as soon as possible. The service symbol will remain visible until the problem is corrected.

The automatic self-test is not performed if the defibrillator is already turned on at 0300 or if the battery is not installed. If the defibrillator is turned on while a self-test is in progress, the test is halted; the defibrillator will turn on normally.

INSPECTION

Routinely inspect all devices, accessories, and cables by following the instructions in Table 5-2.

Table 5-2 LIFEPAK 1000 Defibrillator Inspection

Instruction	Inspect For	Recommended Corrective Action
Examine the defibrillator case, connector, battery well, battery pins, and accessories.	Foreign substances.	Clean the device as described in Table 5-3.
	Damage or cracks.	Contact authorized service personnel to troubleshoot.
	Battery pins bent or discolored.	Contact authorized service personnel.
	Expired batteries or defibrillation electrodes.	Replace.
Observe readiness display	**OK** symbol.	None needed.
	Battery status indicator shows one bar or less.	Replace battery immediately.
	Service symbol displayed.	Contact authorized service personnel.
Examine accessory cables.	Foreign substances.	Clean the cables as described in Table 5-3.
	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.

CLEANING

Clean the LIFEPAK 1000 defibrillator accessories as described in Table 5-3. Use only the cleaning agents listed in the table.

CAUTION!

Possible equipment damage.

Do not clean any part of the defibrillator 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 defibrillator or accessories.

Table 5-3 Recommended Cleaning Methods

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

BATTERY MAINTENANCE

The LIFEPAK 1000 defibrillator can be powered by either of two types of batteries:

- A nonrechargeable Lithium manganese dioxide battery
- A rechargeable Lithium-ion battery

Follow the guidelines described in this section to help maximize battery life and performance. Use only Physio-Control batteries designed for use with the LIFEPAK 1000 defibrillator. Do not use any other batteries.

Note: Always carry a spare, fully charged battery.

WARNINGS!

Safety risk and possible equipment damage.

- Damaged batteries may leak and cause personal injury or equipment damage. Handle damaged or leaking batteries with extreme care.
- Do not carry a battery where metal objects (such as car keys or paper clips) could short-circuit the battery terminals. The resulting excessive current flow can cause extremely high temperatures and may result in damage to the battery, or cause fire or burns.
- Keep batteries away from children.

Possible defibrillator shutdown.

When the LIFEPAK 1000 defibrillator displays the **REPLACE BATTERY** message, replace the battery immediately.

Possible loss of power during patient care.

Using an improperly maintained battery to power the defibrillator may cause power failure without warning. Maintain batteries as described in these operating instructions.

Note: When a battery is removed from the defibrillator, battery and service symbols appear on the readiness display. After replacing the battery, the device resets the readiness display.

LIFEPAK 1000 Defibrillator Nonrechargeable Battery

The nonrechargeable battery never requires recharging. The approximate level of charge in the battery is indicated by the fuel gauge on the battery, on the readiness display when the defibrillator is off, or on the screen when the defibrillator is in use.

The fuel gauge on the nonrechargeable battery provides an easy way to determine the available battery capacity, which is equivalent to the level of battery charge for this type of battery. The nonrechargeable battery is shipped to customers fully charged. Push the gray button below the battery symbol to check the charge level of a new nonrechargeable battery before installing it in a defibrillator. All four LEDs should illuminate.

When optimally maintained, a new nonrechargeable battery pak can provide approximately 17 hours of "ON" time **or** 440 discharges at 200 joules. Turning the defibrillator on ("ON" time) uses battery capacity. Battery charge decreases while the battery is in the defibrillator because of the battery's normal self-discharge rate and the energy used by the defibrillator auto tests. If installed in a defibrillator that is not used, the battery has a standby life of five years. Any patient or training use of the defibrillator, including "ON" time and shocks, reduces the battery's standby and useful life.

A new nonrechargeable battery has a shelf life of five years if stored at the proper temperature. The battery (stored outside the defibrillator) self-discharges over time; therefore, when the battery is eventually placed in the defibrillator, its useful life will be reduced depending on how long it was stored.

To properly maintain nonrechargeable batteries:

- Do not attempt to recharge.
- Do not allow electrical connection between the battery contacts.
- Use and store batteries at temperatures specified in Appendix A. Higher temperatures accelerate the loss of charge and decrease battery life. Lower temperatures reduce battery capacity.

WARNING!

Possible explosion, fire, or noxious gas.

Attempting to recharge a nonrechargeable battery can cause an explosion or fire or release noxious gas. Dispose of expired or depleted nonrechargeable batteries as described in these operating instructions.

CAUTION!

Possible battery damage.

Electrical connection between battery contacts can permanently disable the battery.

LIFEPAK 1000 Defibrillator Lithium-ion Rechargeable Battery

The Lithium-ion (Li-ion) rechargeable battery is the appropriate battery option when the LIFEPAK 1000 defibrillator is used on a frequent basis, or is used with a simulator for training. When optimally maintained, a new fully-charged battery can provide approximately ten hours of "ON" time **or** 261 discharges at 200 joules. The rechargeable battery is shipped to customers at approximately 25% charge and must be fully charged before use. Charge the battery fully within 6 months of when you receive it and at least once every 6 months thereafter. Use only the LIFEPAK 1000 Defibrillator Battery Charger to charge the battery.

Any patient or training use of the defibrillator, including “ON” time and shocks, reduces the battery’s charge level. Battery charge also decreases while the battery is in the defibrillator because of the battery’s normal self-discharge rate and the energy used by the defibrillator auto tests.

The approximate level of charge in the battery is indicated by the battery fuel gauge, on the readiness display when the defibrillator is off, or on the screen when the defibrillator is in use. The rechargeable battery should be recharged when the battery indicators show the charge level is low, or at least every six months.

Battery capacity **and** the level of battery charge are two important factors that determine the useful life of a rechargeable battery. Battery capacity is the amount of energy a battery is capable of holding, while charge is the proportion of capacity that is filled with energy at a particular point in time. During battery charging, the charger adds energy to the battery up to its capacity limit. Since all rechargeable batteries permanently lose battery capacity over time, you can expect that a fully-charged battery’s “ON” time will decrease with age. You should consider replacing the battery when it requires frequent charging.

Always have access to a spare, fully charged battery, and install the charged battery when the ***LOW BATTERY*** message appears on the defibrillator screen.

To properly maintain rechargeable batteries:

- Recharge when the battery fuel gauge shows that the battery charge level is low.
- Use only the Physio-Control battery charger designed for use with the LIFEPAK 1000 defibrillator. Do not use any other charger. Refer to the *LIFEPAK 1000 Defibrillator Battery Charger Instructions for Use*.
- Use, recharge, and store batteries at temperatures specified in Appendix A. Higher temperatures accelerate the loss of charge and wear out the battery sooner. Lower temperatures reduce battery capacity.
- Do not allow electrical connection between the battery contacts.

To determine when to replace rechargeable batteries:

Physio-Control recommends that rechargeable batteries be replaced every two years. Properly cared for batteries may last longer. A battery has reached the end of its useful life if *one or more* of the following circumstances occur:

- The battery case is damaged (for example, cracks or a broken clip).
- The battery is leaking.
- The battery fuel gauge displays two flashing LEDs.
- The battery requires frequent charging.
- The battery fuel gauge illuminates fewer than two LEDs after the battery completes a charge cycle.

WARNINGS!

Possible fire, explosion, and burns.

- The Li-ion rechargeable battery for the LIFEPAK 1000 defibrillator cannot be charged using battery chargers that are designed for other LIFEPAK devices. Use only the LIFEPAK 1000 Defibrillator Battery Charger to charge the Li-ion battery.
- Do not disassemble, puncture, crush, heat above 100°C (212°F), or incinerate the battery.

WARNINGS!

Possible loss of power and delay of therapy during patient care.

- Using an improperly maintained battery to power a defibrillator may cause power failure without warning. Follow these instructions for proper care of the battery.
- Stored batteries lose charge. Failure to charge a stored rechargeable battery before use may cause device power failure without warning. Always charge a stored rechargeable battery before placing it in active use.

CAUTIONS!

Possible battery damage.

- Electrical connection between battery contacts can permanently disable the battery.
- Charging batteries outside the specified temperature range may cause improper charging and shorten battery life.

ELECTRODE CARE AND STORAGE

To help prevent therapy electrode damage:

- Only open the electrode package immediately prior to use.
- Slowly peel back the protective liner on the electrodes, beginning with the cable connection end.
- Do not trim therapy electrodes.
- Do not crush, fold, or store the electrodes under heavy objects.
- Store therapy electrodes in a location where temperatures are between 15° and 35°C (59° and 95°F). Continuous exposure to the higher temperatures within this range will shorten the life of the electrodes.

SERVICE

WARNING!

Shock hazard.

Do not disassemble the defibrillator. It contains no responder-serviceable components and dangerous high voltages may be present. Contact authorized service personnel.

If the LIFEPAK 1000 defibrillator requires service as indicated by testing, troubleshooting, or the service symbol, contact authorized service personnel. In the USA, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative. 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 defibrillator must be shipped to a service center or to the factory, pack it in the original shipping container. If this is not possible, ship the defibrillator in protective packing to prevent shipping damage.

PRODUCT RECYCLING INFORMATION

All materials should be recycled according to national and local regulations. Contact your local Physio-Control representative for assistance or refer to www.physio-control.com/recycling for instructions on disposing of this product.

Preparing for Disposal of Nonrechargeable Batteries

Nonrechargeable batteries should be fully discharged before disposal.

Before disposing of nonrechargeable battery paks, cover the battery terminals with the plastic discharger cap provided with the new battery. Refer to the battery discharge instructions included with your new battery.

Disposing of Batteries

Follow your national, regional, and local regulations for battery disposal. Contact a local Physio-Control representative for more information.

Recycling the Defibrillator

Recycle the defibrillator at the end of its useful life. It should be clean and contaminant-free prior to being recycled.

Recycling Disposable Electrodes

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

Recycling Packaging

Packaging should be recycled according to national and local regulations.

SUPPLIES, ACCESSORIES, AND TRAINING TOOLS

Table 5-4 lists supplies, accessories, and training tools for the LIFEPAK 1000 defibrillator. To order in the USA, call 1.800.442.1142. Outside the USA, contact your local Physio-Control representative.

Table 5-4 Supplies, Accessories, and Training Tools

Item Description
QUIK-COMBO Electrodes with REDI-PAK™ Preconnect System
Infant/Child Reduced Energy Defibrillation Electrodes (not compatible with QUIK-COMBO defibrillation cable)
Infant/Child Electrodes Starter Kit (English, Dutch, French, German, Spanish, Italian, Danish, Norwegian, Finnish, Swedish)
Infant/Child Electrodes Starter Kit (English, Hungarian, Polish, Brazilian Portuguese, Iberian Portuguese, Spanish, Korean, Japanese, Mandarin Chinese)
LIFEPAK 1000 Nonrechargeable Lithium Manganese Dioxide Battery
LIFEPAK 1000 Rechargeable Lithium-ion Battery
LIFEPAK 1000 Defibrillator Battery Charger
Carrying Case
3-Wire Monitoring Cable

Table 5-4 Supplies, Accessories, and Training Tools (Continued)

Item Description
3-Wire Monitoring Cable (IEC)
Quick Reference Card
IrDA Adapter (attachment for a PC)
CODE-STAT Data Review Software
DT EXPRESS™ Data Transfer Software

WARRANTY INFORMATION

To obtain a detailed warranty statement, contact your local Physio-Control representative or go to www.physio-control.com.

APPENDIX A
SPECIFICATIONS

SPECIFICATIONS

All specifications are at 20°C (68°F) unless otherwise stated.

Defibrillator

Waveform

Biphasic Truncated Exponential with voltage and duration compensation for patient impedance.

With Adult Pads:

Patient Impedance Range: 10 – 300 ohms

The following specifications apply from 25 to 200 ohms.

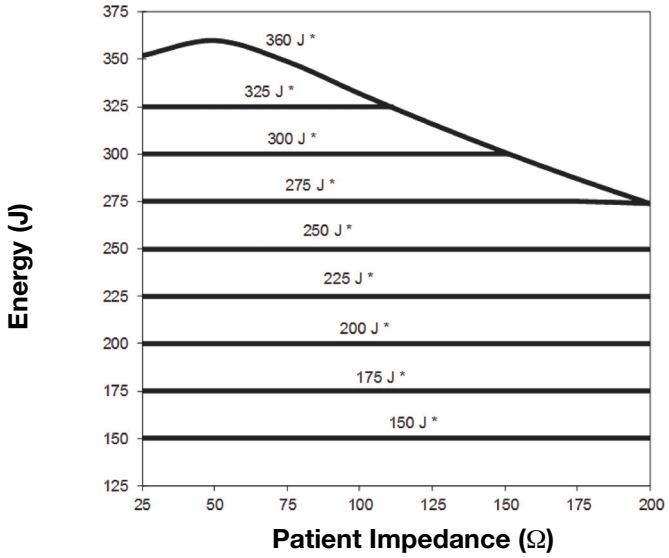
Energy Accuracy:

10% of the energy setting into 50 ohms

15% of the rated energy output into 25 – 200 ohms

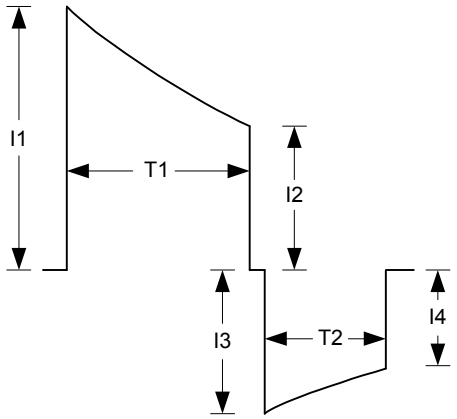
Rated energy output is the nominal delivered energy based on the energy setting and patient impedance, as defined in the following chart.

Rated Energy Output



* Energy setting selected

Waveshape and Measured Parameters:



Patient Impedance (Ω)	I1 (A)	I2 (A)	I3 (A)	I4 (A)	T1 (ms)	T2 (ms)	Delivered Energy (Joules)
25	50.3	20.1	19.7	10.7	5.9	3.9	199
50	28.2	14.6	14.5	9.3	7.5	5.0	204
75	19.8	11.7	11.7	8.2	8.7	5.8	201
100	15.5	10.0	9.9	7.3	9.7	6.5	200
125	12.9	8.7	8.7	6.6	10.4	7.0	201
150	11.1	7.8	7.7	6.2	11.1	7.4	200
175	9.8	7.1	7.1	5.7	11.7	7.8	199
200	8.7	6.5	6.5	5.3	12.2	8.1	199

Note: Table values are nominal for a 200-joule shock.

Waveform (continued)

With Infant/Child pads:

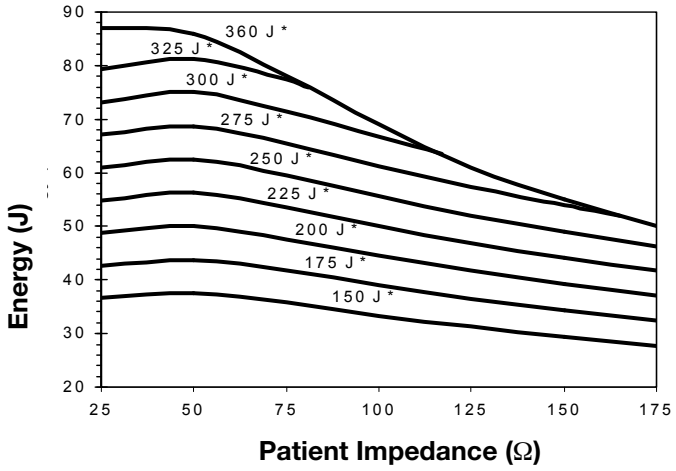
The following specifications apply from 25 to 175 ohms.

Energy Accuracy (into 50 ohms):

Selected energy ÷ 4 +/- 15%; 86 joules +/- 15% maximum

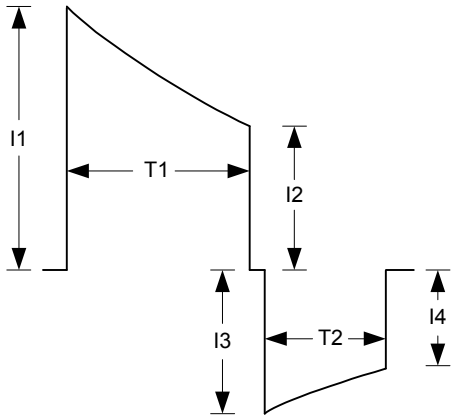
Rated energy output is the nominal delivered energy based on the energy setting and patient impedance, as defined in the following chart.

Rated Energy Output



* Energy setting selected

Waveshape and Measured Parameters:



Patient Impedance (Ω)	I1 (A)	I2 (A)	I3 (A)	I4 (A)	T1 (ms)	T2 (ms)
25	19.4	10.2	10.1	6.6	7.6	5.1
50	13.2	7.4	7.3	5.0	8.1	5.4
75	10.1	5.8	5.7	4.0	8.3	5.6
100	8.3	4.8	4.8	3.3	8.6	5.7
125	7.0	4.2	4.1	2.9	8.8	5.9
150	6.2	3.7	3.7	2.6	8.8	5.9
175	5.5	3.3	3.3	2.3	8.9	6.0

Note: Table values are nominal for a 50-joule shock (200 ÷ 4).

Electrical Protection:	Input protected against high voltage defibrillator pulses per IEC 60601-1. See Figure A-1.

Figure A-1 Defibrillation–proof type BF applied part

Safety Classification:	Internally powered equipment. IEC 60601-1

AED Mode

Shock Advisory System:	ECG Analysis system that advises whether a shock is appropriate, meets rhythm recognition criteria specified in DF80 and IEC 60601-2-4. In AED mode, the device allows a shock only if Shock Advisory System advises defibrillation.
Energy Sequence:	Multiple levels, configurable from 150 to 360 joules
Shock-to-Shock cycle time (200J to 300J):	Less than 25 seconds
Time for a 3-shock sequence (200J/300J/360J):	Less than 70 seconds

Manual Mode

Energy Sequence	Delivers energy at levels selected in Setup mode.

Shock Ready Times

Timing Parameter	200 Joules	360 Joules	Comments
Analysis time	Less than 10 seconds	Less than 10 seconds	Analysis time applies if no motion is detected. If the device detects motion, analysis may be delayed by up to 10 seconds.*
Defibrillator charge time	Less than 9 seconds	Less than 15 seconds	Applies for a new fully charged battery or after 15 full energy discharges.
Power on to shock ready time (Manual mode)	Less than 20 seconds	Less than 25 seconds	Applies for a new fully charged battery or after 15 full energy discharges.
Analysis initiation to shock ready time (AED mode)	Less than 25 seconds	Less than 30 seconds	Applies for a new fully charged battery or after 15 full energy discharges.
Power on to shock ready time (AED mode)	Less than 25 seconds	Less than 30 seconds	Applies for a new fully charged battery or after 15 full energy discharges.
*Device behavior may vary for Arabic, Finnish, Icelandic, and Slovenian.			

ECG Mode

ECG Display	Provides nondiagnostic ECG display of the patient's heart rhythm.

Display

Size (Active viewing area)	120 mm (4.7 in.) x 89 mm (3.5 in.)
Display Type	320 dot x 240 dot LCD with backlight
Frequency Response	0.55 Hz to 21 Hz (-3 dB), nominal
Waveform Sweep Speed	25 mm/sec for ECG, nominal
Waveform viewing time	Minimum 4 seconds
Waveform Amplitude	1 cm/mV, nominal Display Range Differential: ±1.4 mV full scale, nominal
Heart Rate	20 to 300 bpm digital display. Display "---" if heart rate is less than 20 bpm. Heart symbol flashes for each QRS detection Accuracy: ±4% or ±3 bpm, whichever is greater
Displayed ECG	ECG information is received from therapy pads in anterior-lateral or anterior-posterior positions, or from the 3-wire ECG cable in Lead II.

Controls

On/Off	Controls device power
Shock	Controls the delivery of defibrillation energy
Soft Keys	Used during device setup and during patient use: Analyze, Charge, Disarm
Menu button	Used to access additional device features

Readiness Display

The readiness display shows device status

OK Indicator	Indicates OK when the last self-test was completed successfully.
Battery Capacity Indicator	Segmented display showing battery capacity
Service Indicator	Service required when displayed

Environmental

Note: All performance specifications defined assume that the device has been stored (two hours minimum) at the operating temperature prior to operation.

Operating Temperature	0° to 50°C (32° to 122°F)

One-Hour Operating Temperature	From room temperature to temperature extreme, one-hour duration: -20° to 60°C (-4° to 140°F)
Storage Temperature	With nonrechargeable (Li/MnO_2) battery and electrodes, maximum exposure time limited to seven days: -30° to 60°C (-22° to 140°F)
Atmospheric Pressure	575 hPa to 1060 hPa, 4572 to -382 meters (15,000 feet to -1250 feet)
Relative Humidity	5% to 95% (noncondensing)
Dust/Water	IEC 60529 IP55 with battery and REDI-PAK electrodes installed
Shock	MIL-STD-810F, Method 516.5, Procedure 1, (40g peak, 15–23 msec pulse, 45 Hz crossover frequency)
Bump	EN 1789 and IEC 60068-2-29, Test Eb: (1000 bumps, 15g, 6 ms, vertical direction)
Drop	• 18-inch drop onto each surface, repeated 5 times each, 30 drops total • EN 1789 0.75 meter drop onto each surface, 6 drops total • MIL-STD-810F, 516.5 Procedure IV, 1 meter drop on each corner, edge, and surface
Vibration	MIL-STD-810F, Method 514.5, Category 20 Ground Vehicle: Random vibration test, 1 hour per axis, 3.15g rms
EMC	For EMC information, refer to the *Electromagnetic Compliance Guidance* provided with the device.

Physical Characteristics

Weight	3.2 kg (7.1 lb) with nonrechargeable battery and REDI-PAK electrodes
Height	8.7 cm (3.4 in.)
Width	23.4 cm (9.2 in.)
Depth	27.7 cm (10.9 in.)

Data Storage

Memory Capacity	• Dual patient storage • Minimum of 40 minutes of ECG for the current patient • Summarized data stored for the previous patient
Report Types	• Continuous ECG—Continuous patient ECG report • Summary—Summary of critical resuscitation events and associated ECG waveforms • Event Log report—Report of time-stamped markers reflecting operator and device activity • Test Log report—Device self-test activity report
Capacity	Minimum 100 time-stamped event log entries
Data Review	CODE-STAT 6.0 (minimum) or DT EXPRESS 2.0 (minimum) software

Communications	Infrared wireless transfer to a personal computer

Batteries

Nonrechargeable Batteries:

Type	Lithium Manganese Dioxide (Li/MnO_2), 12.0 V, 4.5 amp-hours (nonrechargeable)
Capacity	Typically will provide 440 200-joule discharges or 1030 minutes of operating time with a new battery (370 200-joule shocks or 900 minutes of operating time at 0°C (32°F)).
Weight	0.45 kg (1.0 lb)
Shelf Life (prior to installation)	After the battery is stored for 5 years at 20° to 30°C, the device will provide 48 months of standby life.
Standby Life	A new battery provides device power for 5 years.
Low Battery Indicator	At least 30 200-joule shocks or 75 minutes of operating time remain when low battery is first indicated.

Rechargeable Batteries:

Type	Lithium-ion, 11.1 V, 4.8 amp hours
Capacity	Typically will provide 261 200-joule discharges or 608 minutes of operating time with a new fully-charged battery (247 200-joule shocks or 576 minutes of operating time at 0°C (32°F)).
Battery Charging Time	Within 4.5 hours
Weight	0.45 kg (1.0 lb), maximum
Standby Life	A new fully-charged battery provides device power for 6 months.
Low Battery Indicator	At least 30 200-joule shocks or 75 minutes of operating time remain when low battery is first indicated.

APPENDIX B
SHOCK ADVISORY SYSTEM

OVERVIEW OF THE SHOCK ADVISORY SYSTEM

The Physio-Control patented Shock Advisory System (SAS™) is an ECG analysis system built into the LIFEPAK 1000 defibrillators that advises the operator whether 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
- Motion detection

Electrode Contact Determination

The victim's transthoracic impedance is measured through the defibrillation electrodes. If the baseline impedance is higher than a maximum limit, it is determined that the electrodes are not in sufficient contact with the victim or not properly connected to the defibrillator. 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 defibrillator recommends a shock if either of the following rhythms is detected:

- Ventricular fibrillation
- Rapid ventricular tachycardia (see below for definition)

The defibrillator recommends no shock for nonshockable ECG rhythms as indicated in the Shock Advisory System Performance Report in this document.

The defibrillator is designed to detect and remove pacemaker pulses from the ECG so that an accurate decision can be reached while a pacemaker is functioning. Some pacemaker pulses may prevent advisement of an appropriate shock, regardless of the patient's underlying rhythm. If this occurs, the rescuer is advised to continue chest compressions.

PERFORMANCE VERIFICATION

The Shock Advisory System (SAS) in the LIFEPAK 1000 defibrillator was verified by inputting specific ECG waveform segments from Physio-Control databases through the electrode connector and recording the SAS decision of 'shock' or 'no shock.' The 'shock' or 'no shock' decision made by the SAS for each ECG waveform segment was compared to the treatment recommendation by clinical experts when they classified these individual ECG segments into rhythm groups and made a treatment recommendation of 'shock' or 'no shock.'

The main ECG database used to verify the performance of the LIFEPAK 1000 defibrillator for SAS is named the Physio-Control Test Set. In addition, the ECG database named SAS Test Set was used to provide samples of shockable rapid ventricular tachycardia from pulseless patients for verification purposes. The following information about the test sets and the Summary Performance Report is provided in accordance with AHA recommendations[1] and IEC requirements[2] for reporting performance data for a rhythm recognition detector.

A. Acquisition and Annotation Methodology

This section includes recording methods, rhythm source, rhythm selection criteria, annotation methods, and annotation criteria for the Shock Advisory System test sets.

Physio-Control Test Set

The Physio-Control Test Set includes ECG segments gathered from a variety of sources. The test set includes both adult and pediatric ECG segments, ECGs from the standard anterior-lateral (AL, AA) defibrillation electrode placement, ECGs from anterior-posterior (AP) defibrillation electrode placement, and ECGs from patients who have a pacemaker. Each ECG segment is 10 seconds in duration. Sources for the ECGs include:

- AHA Ventricular Arrhythmia Database (Holter recordings)
- MIT-BIH Arrhythmia Database (Holter)
- MIT-BIH Malignant Ventricular Arrhythmia Database (Holter)
- Creighton University Ventricular Tachyarrhythmia Database (hospital monitor)
- A series of consecutive LIFEPAK 500 automated external defibrillator recordings collected by Physio-Control
- DiMarco AA-AP ECG Database (simultaneous AA and AP defibrillation leads, recorded in the electrophysiology laboratory)
- Vanderbilt Pediatric ECG Database (AA and/or AP defibrillation leads, recorded in the pediatric intensive care unit, the pediatric electrophysiology laboratory, and the pediatric operating room during open heart surgery)
- A series of 12-lead recordings from consecutive chest pain patients, recorded in the pre-hospital setting with the LIFEPAK 11 monitor/defibrillator.

SAS Test Set

The SAS Test Set includes 65 ECG samples of shockable rapid ventricular tachycardia from pulseless patients recorded during pre-hospital use of LIFEPAK 5 defibrillators by paramedics. Selected ECG segments were sampled and the ECG rhythm was classified by clinical experts. Each ECG segment is 5 seconds in duration.

B. ECG Rhythm Types

The ECG rhythms were placed into the following categories by the clinical experts.

Shockable

- Coarse ventricular fibrillation (VF) ($\geq$0.20 mV peak-to-peak amplitude)
- Rapid ventricular tachycardia, pulseless (VT) (HR $\geq$120 bpm, QRS duration $\geq$160 ms, no apparent P waves, patient reported to be pulseless by paramedics)

Nonshockable

- Normal sinus rhythm (NSR) (sinus rhythm, heart rate 60-100 bpm)
- Asystole (<0.08 mV peak-to-peak amplitude)
- Other organized rhythms including 30 or more of each of the following rhythms: atrial fibrillation, atrial flutter, 2nd degree atrioventricular block, 3rd degree atrioventricular block, idioventricular rhythms, sinus bradycardia, supraventricular tachycardia, and rhythms with premature ventricular complexes

Intermediate

- Fine ventricular fibrillation (VF) (<0.20 and ≥0.08 mV peak-to-peak amplitude)
- Other VT (ventricular tachycardia that does not meet criteria for VT in the shockable rhythms category)

Also included are coarse VF with pacemaker pulses and nonshockable rhythms with pacemaker pulses.

C. Summary Shock Advisory System Performance Report

The results of tests with the SAS and Physio-Control test sets in the LIFEPAK 1000 defibrillator are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association.

Table 1 IEC 60601-2-4 Requirements and SAS Performance for Adult and Pediatric Patients

Rhythm Category	Requirement	Test Result
Shockable (Sensitivity)		
Coarse VF	>90%	Met
Rapid VT, pulseless	>75%	Met
Nonshockable (Specificity)	>95%	Met
Positive Predictive Value	Report Only	>90%
False Positive Rate	Report Only	<5%

Table 2 AHA Recommendations and SAS Performance for Adult Patients

Rhythm Category	Performance Goal	Minimum Sample Size	Sample Size Tested	Test Result (Goal and Sample Size)
Shockable (Sensitivity)				
Coarse VF	>90%	200	206	Met
Rapid VT, pulseless	>75%	50	65	Met
Nonshockable (Specificity)	>95%	300		Met
Normal Sinus Rhythm	>99%	100	509	Met
Other QRS	>95%	30	749	Met
Asystole	>95%	100	124	Met
Intermediate				
Fine VF	Report Only	25	32	>40% shocked
Other VT	Report Only	25	27	>20% shocked

The Shock Advisory System was also tested using ECGs acquired from hospitalized pediatric patients ranging in age from <1 day old to 17 years old. The results are summarized in the following table.

Table 3 SAS Performance for Pediatric Patients

Rhythm Category	Performance Goal	Sample Size Tested	Test Result (Goal)
Shockable (Sensitivity)			
Coarse VF	>90%	63	Met
Nonshockable (Specificity)	>95%		Met
Normal Sinus Rhythm	>99%	69	Met
Other QRS	>95%	507	Met
Asystole	>95%	60	Met
Intermediate			
Fine VF	Report Only	1	>20% shocked

The Shock Advisory System was also tested using paced rhythms recorded at high-fidelity from patients with implanted pacemakers. The high-fidelity pacemaker spikes were also added to samples of ventricular fibrillation to test the defibrillator's ability to reach a shock decision in the case of ventricular fibrillation with an implanted, active pacemaker. The results are summarized in the following table.

Table 4 SAS Performance with Active Pacemakers

Rhythm Category	Performance Goal	Sample Size Tested	Test Result
Shockable (Sensitivity)			
Coarse VF	>90%	35	Met
Nonshockable (Specificity)	>95%	35	Met

CONTROL OF SHOCK THERAPY

The Shock Advisory System causes the defibrillator to charge automatically when it detects the presence of a shockable rhythm. When a shockable rhythm is detected, the defibrillator instructs the user to deliver the shock by pressing the shock button.

Note: If the shock button is not pressed within 15 seconds, the system disarms and repeats the analysis. The system also disarms if the patient impedance decreases suddenly or the patient impedance goes outside the acceptable range for analysis. If none of these occur, the shockable rhythm decision is not revised during charging or prior to shock.

MOTION DETECTION

The Shock Advisory System detects patient motion independent of ECG analysis. MOTION DETECTION can be set up to be ON or OFF. For more information, see “Changing Setup Options” in the *LIFEPAK 1000 Defibrillator Operating Instructions.*

A number of activities can create motion, including CPR, rescuer movement, patient movement, and vehicle movement. If variations in the transthoracic impedance signal exceed a maximum limit, the Shock Advisory System determines that patient motion of some kind is present. If motion is detected, the ECG analysis is inhibited. The operator is advised by a voice prompt. After 10 seconds, if motion is still present, the motion alert stops and the analysis always proceeds to completion. This limits the delay in therapy in situations where it may not be possible to stop the motion. However, the rescuer should remove the source of motion whenever possible to minimize the chance of artifact in the ECG.

There are two reasons why ECG analysis is inhibited when the motion alert occurs, and why the rescuer should remove the source of the motion whenever possible:

- Such motion may cause artifact in the ECG signal. This artifact may occasionally cause the Shock Advisory System to reach an incorrect decision.
- 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.

DEFINITIONS AND REFERENCES

A true positive (A) is a correct classification of a shockable rhythm. A true negative (D) is a correct classifications of all rhythms for which a shock is not indicated. A false positive (B) is an organized or perfusing rhythm or asystole that has been incorrectly classified as a shockable rhythm. A false negative (C) is a VF or VT associated with cardiac arrest that has been incorrectly classified as non-shockable.

The sensitivity of the device for shockable rhythms is A/(A+C). The true predictive value is expressed as A/(A+B). The specificity of the device for non-shockable rhythms is D/(B+D). The false positive rate is expressed as B/(B+D).[3]

1 Kerber RE, et al, "Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety: A Statement for Health Professionals from the American Heart Association Task Force on Automatic External Defibrillation", Subcommittee on AED Safety and Efficacy. Circulation, 1997: Vol. 95: 1677-1682.

2 Clause 201.7.9.3.103, "Essential Performance data of the Rhythm Recognition Detector," International Electrotechnical Association, *IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators*: 2010

3 Quoted from clause 201.107, "Requirements for Rhythm Recognition Detector," International Electrotechnical Association, *IEC 60601-2-4, Medical Electrical Equipment – Part 2-4: Particular Requirements for the Basic Safety and Essential Performance of Cardiac Defibrillators*: 2010.

APPENDIX C
cprMAX™ TECHNOLOGY

ABOUT cprMAX TECHNOLOGY

The cprMAX technology from Physio-Control is designed to allow resuscitation protocols to maximize the quantity of CPR administered during treatment with an AED, consistent with the 2015 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (AHA Guidelines) and the European Resuscitation Council Guidelines for Resuscitation 2015 (ERC Guidelines).

Setup options should be changed only under the direction of a physician knowledgeable in cardiopulmonary resuscitation who is familiar with the literature in this area.

The cprMAX technology includes the following setup options:

- **INITIAL CPR**. Prompts the user to perform an initial period of CPR. Applies only to immediately after turning on the AED or after the first analysis.
- **PRESHOCK CPR** Time. Prompts for CPR after a shockable ECG rhythm is detected, before the shock is delivered. If **INITIAL CPR** is set to **OFF**, then **PRESHOCK CPR** applies to all shock advised decisions (including the first analysis).
- **CPR TIME 1** and **2**. CPR time periods after shocks or no shock advised decisions respectively.
- **STACKED SHOCKS**. Eliminates the analysis after each shock and inserts prompting for CPR after each shock; when set to **OFF**, eliminates the three-stack shock.
- **PULSE CHECK**. Indicates when, if ever, the device is to prompt for pulse checks.

AED protocols are aligned with the AHA and ERC Guidelines when the setup options are set as follows:

- Initial CPR: **OFF**
- PreShock CPR Time: **OFF**
- CPR Times 1 and 2: **120 SECONDS**
- Stacked Shocks: **OFF**
- Pulse Check: **NEVER**

The above options are the factory default settings for cprMAX technology. Your medical director protocols should determine whether or not to change the options and should ensure that you receive training.

AED OPERATION WITH cprMAX TECHNOLOGY

The following paragraphs describe AED operation with cprMAX technology setup options.

Initial CPR

The **INITIAL CPR** option prompts the user to perform an initial period of CPR. The choices are: **OFF, ANALYZE FIRST** and **CPR FIRST**. The factory default is **OFF**.

- The **OFF** setting has no prompting for an initial CPR period.
- The **ANALYZE FIRST** setting prompts for analysis and then CPR. If the analysis determines that a shock is needed, the AED will prompt, ***IF YOU WITNESSED THE ARREST, PUSH CANCEL***, which provides the opportunity to end CPR early and proceed directly to delivering a shock.

- The **CPR FIRST** setting prompts the user to perform CPR immediately after the defibrillator is powered on. The AED will also prompt, ***IF YOU WITNESSED THE ARREST, PUSH CANCEL***, which provides the opportunity to end CPR early and proceed directly to analysis.

Organizations that choose to implement this option should develop a protocol and provide training to responders instructing them when to end the initial CPR interval early. Potential situations for instructing responders to end CPR early include:

- The patient's collapse was witnessed by the responder.
- The responder ascertains that fewer than four or five minutes have elapsed since the patient's collapse.
- The patient exhibits agonal breathing, an indicator of a short downtime.
- The responder ascertains that CPR of adequate quality and duration has already been provided before attaching the AED electrodes.

Initial CPR Time

The **INITIAL CPR TIME** option applies when **INITIAL CPR** is set to **ANALYZE FIRST** or **CPR FIRST**. It sets the CPR time for that CPR period. The time choices for **INITIAL CPR TIME** are: **15**, **30**, **45**, **60**, **90**, **120**, and **180 SECONDS**. The default setting is **120 SECONDS**.

PreShock CPR Time

The **PRESHOCK CPR** time option inserts prompting for CPR when a shockable ECG rhythm is detected and during the time the AED is charging. It applies only when analysis results in ***SHOCK ADVISED*** decisions. When **INITIAL CPR** is set to **OFF** or **CPR FIRST**, **PRESHOCK CPR** time applies to the first and all subsequent shocks. When **INITIAL CPR** is set to **ANALYZE FIRST**, **PRESHOCK CPR** time applies to the second and all subsequent shocks. The choices for **PRESHOCK CPR** time are: **OFF, 15,** and **30 SECONDS**. To prompt for CPR only for the time the capacitor is charging, select the 15-seconds CPR interval. The **SHOCK** button is not enabled until charging and CPR time are completed. The default setting for **PRESHOCK CPR** time is **OFF**.

Note: Although the **SHOCK** button is disabled during the **PRESHOCK CPR** interval, it becomes active as soon as the **PRESHOCK CPR** interval ends. To minimize the interval between the final chest compression and shock delivery (while maintaining responder safety), protocols that select this option should provide specific training and protocols to address the rapid transition from **PRESHOCK CPR** to shock delivery.

Stacked Shocks

When set to **OFF**, the **STACKED SHOCKS** option inserts prompting for CPR after each (a single) shock. This eliminates the three-shock stack. CPR is prompted after the shock regardless of the ECG rhythm. The CPR time following the shock is determined by the **CPR TIME 1** setting selected. Choices for the **STACKED SHOCKS** option are **ON** or **OFF**. The default setting is **OFF**.

When this option is set to **ON**, the defibrillator follows the previously traditional stacked shock protocol and delivers up to three consecutive shocks, as necessary, without interposed CPR.

Pulse Check

The **PULSE CHECK** option inserts prompting to check for a pulse or check the patient, depending on the **PULSE PROMPT** setting. The choices for **PULSE CHECK** are: **ALWAYS, AFTER EVERY NSA, AFTER SECOND NSA**, and **NEVER**. The default setting is **NEVER**.

- The **ALWAYS** option prompts for a pulse check after **CPR TIME 1** and **2**, after a ***NO SHOCK ADVISED*** decision, after a single ***SHOCK ADVISED*** decision with **STACKED SHOCKS OFF**, or after three consecutive ***SHOCK ADVISED*** decisions if **STACKED SHOCKS** is **ON**.
- The **AFTER EVERY NSA** option prompts for a pulse check after every ***NO SHOCK ADVISED*** decision.
- The **AFTER SECOND NSA** option prompts for a pulse check after the second analysis if the second analysis results in a ***NO SHOCK ADVISED*** decision, regardless of the first analysis decision (***SHOCK ADVISED*** or ***NO SHOCK ADVISED***).
- The **NEVER** option eliminates all **PULSE CHECK** prompts.

APPENDIX D
CHANGING SETUP OPTIONS

CHANGING SETUP OPTIONS

Setup options allow you to define operating features for your defibrillator, such as CPR intervals. Setup options are listed in tables beginning with Table D-1.

To enter Setup mode:

1 Ensure that no electrodes or cables are connected to the defibrillator.

2 Press and hold both softkeys and press the ON/OFF button. The Enter Setup Mode screen appears.

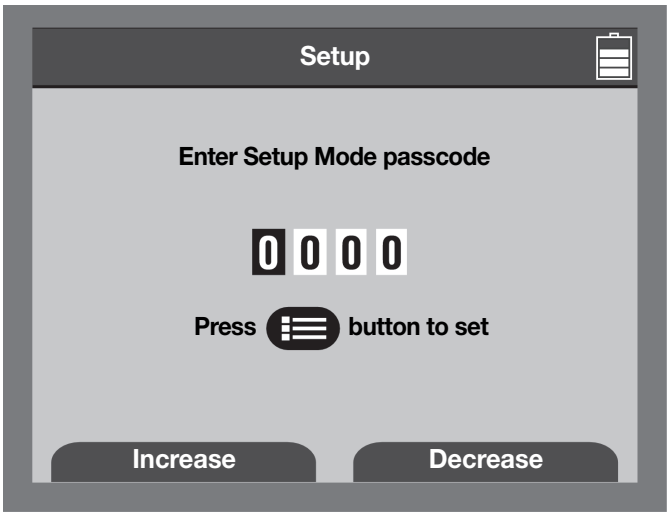


Figure D-1 Enter Setup Mode

3 Enter the Setup mode passcode. The factory default passcode is 0000—press the MENU button four times to accept the default passcode. For information on how to change the passcode, see page A-6.

Note: To exit Setup mode, turn the defibrillator off. If you changed the setup options, the changes are saved and will appear the next time you turn the defibrillator on. (Refer to Setup menu options that follow.)

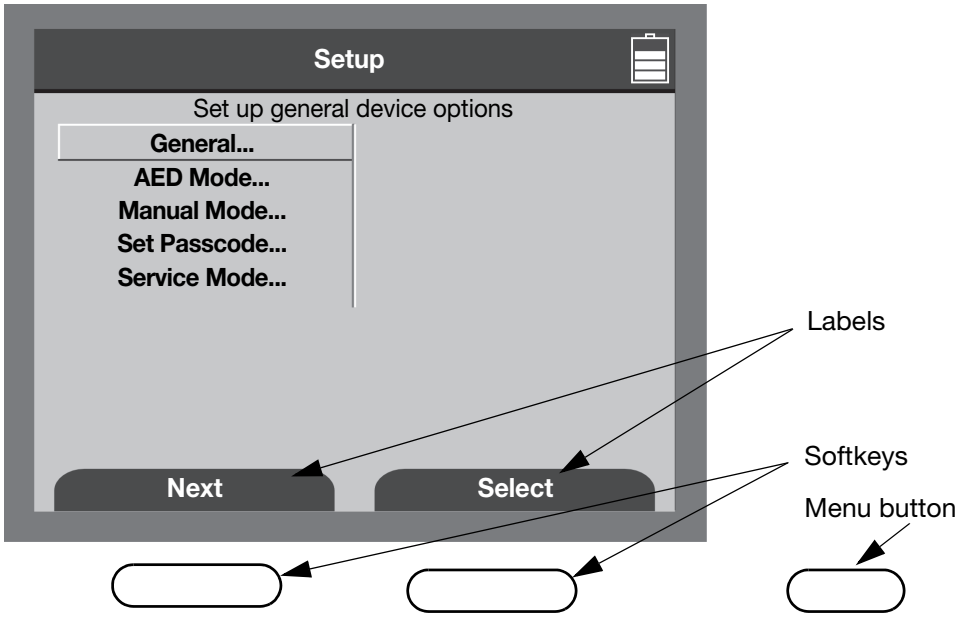


Figure D-2 Setup Mode Screen

Setup Menu Options

All setup options for your defibrillator are grouped under these top-level headings.

- General
- AED Mode
- Manual Mode
- Set Passcode
- Service Mode

Use the softkeys to navigate and make selections on the Setup screen. The label on the screen and above each softkey identifies the current softkey function.

Press NEXT to advance through the menu options.

When an option is highlighted, a Help message about the option appears at the top of the screen, as shown in Table D-1.

Table D-1 Top-Level Setup Menu

Menu Item	Help Message	Options
GENERAL	Set up general device options.	See How to Enter and Delete Device Information, page A-7.
AED MODE	Set up AED mode defaults.	
MANUAL MODE	Set up Manual mode defaults.	
SET PASSCODE	Set passcode to enter Setup mode.	
SERVICE MODE	View service options.	

To choose an option, highlight your choice on the screen and press SELECT.

Access the General Setup menu from Setup to view general purpose settings. The underlined bold options in Table D-2 are the factory default settings.

Table D-2 General Setup Menu

Menu Item	Help Message	Options
DEVICE ID	Set the device ID.	User selectable, 0-9, A-Z, up to 20 characters. Default is **SERIAL NUMBER**.
DATE/TIME	Set current date and time.	Default is **PACIFIC TIME**.
AUDIO	Set audio parameters.	See Table D-3.
DEVICE DATA	Display device data.	
DELETE AFTER SEND	Delete patient data after sending.	ON, **OFF**.
PREVIOUS PAGE	Go back to previous page.	

Access the audio options from Audio on the General Setup menu. The underlined bold options in Table D-3 are the factory default settings.

Table D-3 General Setup Menu—Audio Setup Submenu

Menu Item	Help Message	Options
PROMPT VOLUME	Set volume for alerts, tones, and voice prompts.	MEDIUM, **HIGH**.
SHOCK TONE	Enable shock tone.	ON, **OFF**.
SERVICE ALERT	Enable the service alert tone.	**ON**, OFF.
PREVIOUS PAGE	Go back to previous page.	

Access the AED menu from the AED Mode option in Setup. The underlined bold options in Table D-4 are the factory default settings.

Table D-4 AED Setup Menu

Menu Item	Help Message	Options
ENERGY PROTOCOL	Set the defibrillation energy sequence.	See Table D-5.
CPR	Set CPR options for AED mode.	See Table D-6.
PULSE	Set pulse prompt options for AED mode.	See Table D-7.
ECG DISPLAY	Display ECG waveform in AED mode.	**ON**, OFF.
AUTO ANALYZE	Select analyze option.	**ON**, AFTER FIRST SHOCK, OFF.
MOTION DETECTION	Alert when motion is detected.	**ON**, OFF.
PREVIOUS PAGE	Go back to previous page.	

Access Energy Protocols from the AED menu. The underlined bold options in Table D-5 are the factory default settings.

Table D-5 AED Setup Menu—Energy Protocols Submenu

Menu Item	Help Message	Options
ENERGY 1	Select energy level for shock 1.	150, 175, **200**, 225, 250, 275, 300, 325, 360* joules.
ENERGY 2	Select energy equal to or greater than Energy 1.	150, 175, 200, 225, 250, 275, **300**, 325, 360 Joules.
ENERGY 3	Select energy equal to or greater than Energy 2.	150, 175, 200, 225, 250, 275, 300, 325, **360** joules.
FLEXIBLE PROTOCOL	Repeat previous energy after ***NO SHOCK ADVISED*** (only when ***NO SHOCK ADVISED*** follows a shock).	**ON**, OFF.
STACKED SHOCKS	Enable consecutive shocks without CPR.	ON, **OFF**.
PREVIOUS PAGE	Go back to previous page.	

* When selecting 360 joules for energy 1, consider AED use in children.

Access CPR Setup from the AED menu. The underlined bold options in Table D-6 are the factory default settings.

Table D-6 AED Setup Menu—CPR Submenu

Menu Item	Help Message	Options
CPR TIME 1	Set CPR interval after shocks.	15, 30, 45, 60, 90, **120**, 180 seconds.
CPR TIME 2	Set CPR interval after ***NO SHOCK ADVISED***.	15, 30, 45, 60, 90, **120**, 180 seconds.
INITIAL CPR	Enable Initial CPR.	**OFF**, ANALYZE FIRST, CPR FIRST.
INITIAL CPR TIME	Set CPR interval after first analysis.	15, 30, 45, 60, 90, **120**, 180 seconds.
PRESHOCK CPR	Set CPR interval before ***SHOCK ADVISED*** decisions.	**OFF**, 15, 30 seconds.
CPR PROMPT	Enable extended CPR prompt: ***PROVIDE RESCUE BREATHS AND CHEST COMPRESSIONS***	ON, **OFF**.
PREVIOUS PAGE	Go back to previous page.	

Access Pulse Setup from the AED menu. The underlined bold options in Table D-7 are the factory default settings.

Table D-7 AED Setup Menu—Pulse Setup Submenu

Menu Item	Help Message	Options
PULSE CHECK	Enable pulse check prompt.	**NEVER**: Never prompt for ***PULSE CHECK***. AFTER SECOND NSA: After every NSA except for first analysis NSA result. AFTER EVERY NSA: Only after ***NO SHOCK ADVISED***. ALWAYS: After every stack of shocks and every NSA finding.
PULSE PROMPT	Select prompt for patient vital signs.	**CHECK PULSE**, CHECK BREATHING, CHECK CIRCULATION, OPEN AIRWAY.
AED MONITORING	Enable monitoring while in AED mode.	ON, **OFF**.
MONITORING REPEAT	Select AED monitoring prompt repeat time.	OFF, **1**, 2, 3, or 5 minutes.
PREVIOUS PAGE	Go back to previous page.	

Access the Manual menu from the Manual Mode option in Setup. The underlined bold options in Table D-8 are the factory default settings.

Table D-8 Manual Setup Menu

Menu Item	Help Message	Options
MANUAL ACCESS	Enable Manual mode access.	ON, **OFF**.
ANALYZE	Enable Shock Advisory System analysis in Manual mode. (An ANALYZE softkey is provided in Manual mode.)	ON, **OFF**.
PREVIOUS PAGE	Go back to previous page.	

Access the Set Passcode screen, shown in Figure D-3, from the top-level Setup menu.

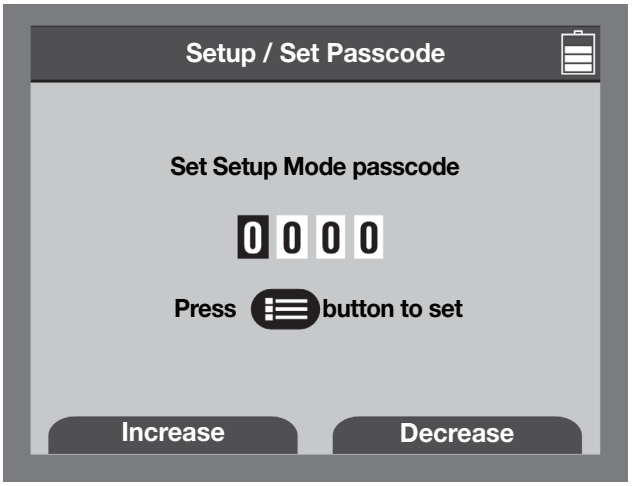


Figure D-3 Set Passcode Screen

Use the INCREASE and DECREASE softkeys and the MENU button to set the passcode. Be sure to record the new passcode—the passcode is required each time you enter Setup mode.

Access Service mode, shown in Table D-9, from the top-level Setup menu.

Table D-9 Service Setup Menu

Menu Item	Help Message	Options
DEFIB CAL	Start defibrillator calibration.	
PIXEL TEST	Test display pixels.	
SERVICE LOG	Show service log.	
SERVICE DATA	Show device data.	
DEVICE LOG	Display device log.	
SET PASSCODE	Set Service mode access passcode.	
SETUP MODE	Go back to Setup mode.	

How to Enter and Delete Device Information

Figure D-4 shows the Device ID screen used to enter device information into the defibrillator.

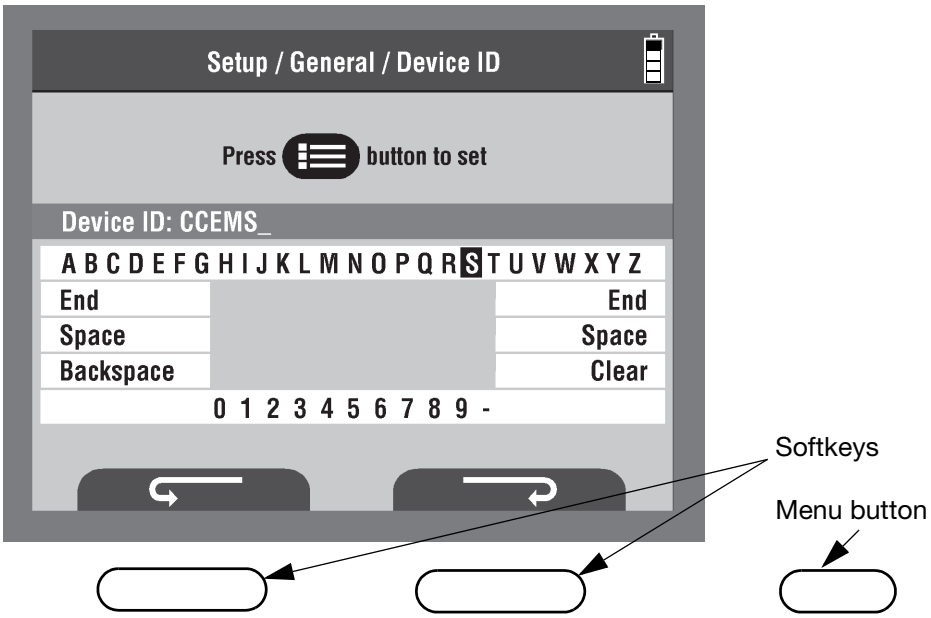


Figure D-4 Device ID Screen

To enter device information:

1 Use the softkeys under the clockwise and counterclockwise arrows to navigate to the character or number you want to enter.

Note: Pressing the clockwise arrow moves the cursor forward one space at a time; the counterclockwise arrow moves it back one space at a time.

2 Press the MENU button to choose the character. The character appears on the screen above the alphabet area.

3 Continue adding characters to complete your entry.

4 When your completed entry is composed on the screen, select END.

To delete device information:

1 Use the clockwise or counterclockwise arrows to navigate to the BACKSPACE option.

2 Navigate to the CLEAR option and press the MENU button again. The character no longer appears on the screen.

APPENDIX E
USER'S CHECKLIST

LIFEPAK® 1000 DEFIBRILLATOR
USER'S CHECKLIST

PHYSIO CONTROL

Unit Serial Number_____

Department/Location_____

Instruction	Recommended Corrective Action	Date							
		Initials							
1 Check readiness display for:									
WRENCH symbol	Contact authorized service personnel.								
OK symbol	None.								
Battery level	Replace if one bar or less on battery status indicator.								
2 Check Use By date on electrode packet.	Replace electrode packet if date has passed.								
3 Check spare battery.	Ensure spare, fully charged battery is available.								
4 Check additional supplies.	Replenish as needed.								
5 Check defibrillator for:									
Damage or cracks	Contact authorized service personnel.								
Foreign substances	Clean the device.								
6 Comments:									

APPENDIX F
DEFIBRILLATION CLINICAL SUMMARIES

DEFIBRILLATION OF VENTRICULAR FIBRILLATION AND VENTRICULAR TACHYCARDIA

Background

Physio-Control conducted a multi-centered, prospective, randomized and blinded clinical trial of biphasic truncated exponential (BTE) shocks and conventional monophasic damped sine wave (MDS) shocks. Specifically, the equivalence of 200 J and 130 J BTE shocks to 200 J MDS shocks[1] was tested.

Methods

Ventricular fibrillation (VF) was induced in 115 patients during evaluation of implantable cardioverter defibrillator function and 39 patients during electrophysiologic evaluation of ventricular arrhythmias. After 19±10 seconds of VF, a customized defibrillator delivered an automatically randomized shock. Efficacy was based on success of this shock. To demonstrate equivalence of test shocks to control shocks, the 95% upper confidence limit of the difference in efficacy (95UCLD), control minus test, was required to be less than 10%.

Results

Ventricular Fibrillation

The efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks (95UCLD=2%). The difference in success rates of 200 J MDS minus 200 J BTE shocks was -10% (exact 95% confidence interval from -27% to 4%). The 130 J BTE shocks were not demonstrated equivalent to 200 J MDS shocks (95UCLD=22%). However, neither was their efficacy significantly lower than that of the 200 J MDS shocks (statistical power limited by small sample sizes). For all shock types, hemodynamic parameters (oxygen saturation and systolic and diastolic blood pressure) were at or near their pre-induction levels by 30 seconds after successful shocks.

Shock	Ventricular Fibrillation 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	61/68 (90%)	80-96%
200 J BTE	39/39 (100%)	91-100%
130 J BTE	39/47 (83%)	69-92%

[1] S.L. Higgins et al., "A comparison of biphasic and monophasic shocks for external defibrillation," *Prehospital Emergency Care*, 2000, 4(4):305-13.

Ventricular Tachycardia

Seventy-two episodes of ventricular tachycardia (VT), induced in 62 patients, were treated with randomized shocks. High rates of conversion were observed with biphasic and monophasic shocks. Sample sizes were too small to statistically determine the relationship between success rates of the waveforms tested.

Shock	Ventricular Tachycardia 1st Shock Success	Exact 95% Confidence Interval
200 J MDS	26/28 (93%)	77-99%
200 J BTE	22/23 (96%)	78-100%
130 J BTE	20/21 (95%)	76-100%

Conclusions

In this double-blinded study, the efficacy of the 200 J BTE shocks was demonstrated to be at least equivalent to the efficacy of 200 J MDS shocks for defibrillation of short duration, electrically-induced VF. However, the comparison of efficacy of 130 J biphasic and 200 J monophasic shocks for VF was inconclusive. All waveforms tested provided a high rate of termination of VT. The VT sample sizes were too small to statistically determine the relationship between VT success rates of the waveforms tested.

Compared to conventional shocks for VF, we found no positive or negative effect of biphasic shocks for VF on hemodynamic parameters following the defibrillating shock. It is possible that, compared to 200 J monophasic shocks, 200 J biphasic shocks will in some cases enable earlier termination of VF. Therefore, we conclude that biphasic shocks for VF delivered at conventional energy levels have the potential to improve outcome in resuscitation of patients with cardiac arrest.

MONOPHASIC VS. BIPHASIC WAVEFORMS: OUT-OF-HOSPITAL TRIAL

Background

In a publication by Van Alem et al., the authors noted "Evidence suggests that biphasic waveforms are more effective than monophasic waveforms for defibrillation in out-of-hospital cardiac arrest (OHCA), yet their performance has only been compared in un-blinded studies."[1]The authors subsequently conducted and reported on a randomized clinical trial comparing the effectiveness of the LIFEPAK 500 defibrillation waveform (monophasic versus biphasic). Specifically, the success of biphasic truncated exponential (BTE) and monophasic damped sine wave (MDS) shocks for defibrillation were compared in a prospective, randomized, double-blinded clinical trial of out-of-hospital (OOH) cardiac arrest patients.

Note: The identical ECG analysis Shock Advisory System and BTE (ADAPTIV biphasic waveform) used in the LIFEPAK 500 AED is also used in the LIFEPAK CR Plus and LIFEPAK EXPRESS AEDs.

Methods

First responders were equipped with either a Physio-Control LIFEPAK 500 MDS or BTE (ADAPTIV biphasic waveform) AED in a random fashion. Patients in VF received BTE or MDS first shocks of 200 J. The ECG was recorded for subsequent analysis continuously. The success of the first shock as a primary endpoint was removal of VF and required a return of an organized rhythm for at least two (2) QRS complexes, with an interval of <5 seconds, within 1 minute after the first shock. The secondary endpoint was termination of VF at 5 seconds.

Results

VF was the initial recorded rhythm in 120 patients in OHCA, 51 patients received BTE and 69 received MDS shocks. The median time from collapse to first shock was 9 minutes for the monophasic shock and 11 minutes for the BTE. The success rate of 200 J first shocks was significantly higher for BTE than for MDS shocks, 35/51 (69%) and 31/69 (45%), p=0.01. Termination of VF at 5 seconds after the first shock was 91% for the monophasic shock and 98% for BTE waveform. Return of spontaneous circulation was 61% for the Physio-Control defibrillation shock. In a logistic regression model, the odds ratio of success for a BTE shock was 4.01 (95% CI 1.01-10.0), adjusted for baseline cardiopulmonary resuscitation, VF-amplitude and time between collapse and first shock. No difference was found with respect to the secondary endpoint, termination of VF at 5 seconds (RR 1.07 95% CI: 0.99-1.11) and with respect to survival to hospital discharge (RR 0.73 95% CI:0.31-1.70).

Conclusion

The authors concluded that BTE-waveform AEDs provide significantly higher rates of successful defibrillation with return of an organized rhythm in OHCA than MDS waveform AEDs. This supports the safety and effectiveness of the LIFEPAK CR Plus and LIFEPAK EXPRESS AEDs.

[1]Van Alem AP, Chapman FW, Lank P, Hart AAM, Koster RW. A prospective, randomised and blinded comparison of first shock success of monophasic and biphasic waveforms in out-of-hospital cardiac arrest. *Resuscitation* 2003;58(1):17-24

APPENDIX G
ELECTROMAGNETIC COMPATIBILITY GUIDANCE

ELECTROMAGNETIC EMISSIONS

The LIFEPAK® 1000 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 1000 defibrillator should ensure that the device is used in such an environment.

Table 1 Guidance and Manufacturer's Declaration - Electromagnetic Emissions

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The LIFEPAK 1000 defibrillator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The LIFEPAK 1000 defibrillator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

Limitations Affecting Immunity to Electromagnetic Disturbances

The level of protection from electromagnetic disturbances is limited by several factors, including requirements for protection from third-party defibrillators, patient safety isolation, and maintenance of adequate signal-to-noise ratios for processing patient signals.

ELECTROMAGNETIC IMMUNITY

Essential Performance

The LIFEPAK 1000 defibrillator maintains safe and effective performance of the defibrillation therapy and patient monitoring functions when operated in the electromagnetic environment specified in Tables 2 through 4.

The LIFEPAK 1000 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 1000 defibrillator should ensure that the device is used in such an environment.

Table 2 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact* ±2 kV, ±4 kV, ±8 kV, ±15 kV air*	The LIFEPAK 1000 defibrillator is suitable for use in a dry environment.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	Not Applicable	Not Applicable
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not Applicable	Not Applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T during 1/2 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 70% U_T during 25/30 cycles Single phase at 0°	Not Applicable	Not Applicable
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

* Uninstalled battery pack is ±6 kV contact, ±8 kV air.

The LIFEPAK 1000 defibrillator is intended for use in the electromagnetic environment specified below. The customer or the user of the LIFEPAK 1000 defibrillator should ensure that the device is used in such an electromagnetic environment.

Table 3 Guidance and Manufacturer's Declaration - Electromagnetic Immunity

Immunity Test	IEC 60601 Test Level	Compliance Level
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[1] 6 Vrms 150 kHz to 80 MHz in ISM and amateur bands[1]	3 Vrms 10 Vrms ISM 6 Vrms amateur
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m

1. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7.0 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14.0 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz, and 50.0 MHz to 54.0 MHz.

SEPARATION DISTANCES

The LIFEPAK 1000 defibrillator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the LIFEPAK 1000 defibrillator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LIFEPAK 1000 defibrillator as recommended below, according to the maximum output power of the communications equipment.

The LIFEPAK 1000 defibrillator was tested to various RF wireless communication environments to meet a minimum separation distance as recommended by 60601-1-2:2014 The following table describes the environments and the equation for calculating the recommended separation distance at the maximum power level for each band.

Table 4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the LIFEPAK 1000 Defibrillator

Band (MHz)	Service	Maximum Power (W)	Distance (m)	Equation
380-410	TETRA 400 T-GSM-380 T-GSM-410	1.8	0.3	$d = 6/27 \sqrt{P}$
430-470	GMRS 460 FRS 460 LTE Band 31 4G/LTE-A	2.0	0.3	$d = 6/28 \sqrt{P}$
470-500	GSM-480	1.8	0.3	$d = 6/27 \sqrt{P}$
704-787	LTE Band 12, 13, 17, 20, 26 GSM-710 GSM-750	0.2	0.3	$d = 6/9 \sqrt{P}$
800-960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5, 8, 27 PRS-900 T-GSM-810 GSM-850 P-GSM-900 E-GSM-900/UTRA R-GSM-900 T-GSM-900 UTRA Band 5	2.0	0.3	$d = 6/28 \sqrt{P}$
1480-1530	UTRA Band 11/LPDC (Japan)	2.0	0.3	$d = 6/28 \sqrt{P}$

Band (MHz)	Service	Maximum Power (W)	Distance (m)	Equation
1700-2100	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS DCS-1800 PCS-1900 UTRA Band 1, 2, 4, 9	2.0	0.3	$d = 6/9 \sqrt{P}$
2400-2570	Bluetooth WLAN 802.11 b/g/n RFID 2450 LTE Band 7 4G/LTE-A	2.0	0.3	$d = 6/28 \sqrt{P}$
5100-5800	WLAN 802.11 a/n	0.2	0.3	$d = 6/9 \sqrt{P}$

For transmitters in the frequency ranges listed above, the recommended separation distance *d* in meters (m) can be determined using the equation in the table above with the known power, *P* of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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Physio-Control is now part of Stryker.

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