PHYSIO CONTROL

LIFEPAK CR® Plus DEFIBRILLATOR
LIFEPAK EXPRESS® DEFIBRILLATOR

OPERATING INSTRUCTIONS

LIFEPAK CR®Plus DEFIBRILLATOR
LIFEPAK EXPRESS® DEFIBRILLATOR

OPERATING INSTRUCTIONS

Responsibility for Information

It is the responsibility of our customers to ensure that the appropriate person(s) who may use this defibrillator have access to the information in this manual, including general safety information provided in Section 1.

!USA Rx Only

Device Tracking

!USA 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, or use one of the postage-paid address change cards located in the back of this manual to update this vital tracking information.

Revision History

These operating instructions describe the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators with software Version 3.0 or later.

Publication Date: 01/2018

PN 3201686-034

TABLE OF CONTENTS

INTRODUCTION

This section provides background information about defibrillation and includes an overview of LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillator features.

ABOUT AUTOMATIC EXTERNAL DEFIBRILLATORS

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are automated external defibrillators (AEDs). For many years, defibrillators have been used only by medical professionals to treat victims in sudden cardiac arrest (SCA). Today, the ability of defibrillators to save lives is so widely recognized that people once trained to do only cardiopulmonary resuscitation (CPR) can now use defibrillators.

After electrode pads are applied to the victim's chest, the defibrillator analyzes the victim's heart rhythm. If a shockable rhythm is detected, the defibrillator will either deliver an intense pulse of electricity (shock) to the heart muscle (fully automatic model) or direct the responder to deliver the shock (semiautomatic model). The defibrillator delivers shocks through the electrode pads on the victim's chest.

When this pulse of electricity is delivered, it is called defibrillation. Defibrillation is recognized for treating life-threatening heart beat irregularities, such as ventricular fibrillation, that cause SCA.

Indications for Use

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are indicated for use on patients in cardiac arrest. The patient must be unresponsive (unconscious), not breathing normally, and showing no signs of circulation (for example, no pulse, no coughing, or no movement).

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use by personnel who have been trained in their operation. Users should have received training in basic life support/AED, advanced life support or a physician-authorized emergency medical response training program.

The defibrillators may be used with QUIK-PAK™ defibrillation pads only on adults and children who are 8 years old or more, or who weigh more than 25 kg (55 lbs). The defibrillators 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.

The defibrillators may be used with the CHARGE-PAK™ battery charger.

Contraindications

Do not use the LIFEPAK CR Plus and LIFEPAK EXPRESS device when the victim is conscious and responsive.

Why the Need for Defibrillators

The American Heart Association estimates that, in the USA alone, at least 250,000 people die each year of cardiac arrest. Of these, about 10,000 people might have been saved had they received immediate treatment from a defibrillator.

Sudden cardiac arrest is usually caused by a malfunction in the heart's electrical system. Called ventricular fibrillation, this critical condition prevents the heart from pumping blood throughout the body. Ventricular fibrillation can cause death within seconds.

Defibrillation is a relatively simple procedure that involves placing electrode pads on a victim's exposed chest and delivering an electrical shock to the heart. The externally-delivered shock often restores the heart's electrical system to normal rhythm. Combined with CPR, defibrillation provides the most effective care for victims in cardiac arrest.

Terminology

The following terms appear in this manual.

AED	Automated External Defibrillator. A device that evaluates the victim's heart rhythm and delivers an electrical shock to the heart if a shockable rhythm is detected.
Cardiac arrest	The termination of the heart's pumping action resulting in the lack of a heartbeat or pulse and breathing.
CPR	Cardiopulmonary resuscitation. This involves delivering rescue breathing and chest compressions to a victim in cardiac arrest.
Defibrillation	Delivery of an electrical shock to the heart for the purpose of reversing ventricular fibrillation.
ECG	Electrocardiogram. A composite picture of what is occurring electrically in the heart.
Fibrillation	Chaotic activity of the heart's electrical system. This condition can occur in the atria or the ventricles. When it occurs in the ventricles, they quiver in a rapid, chaotic manner, preventing them from pumping blood to the body.
Heart attack	A nonspecific term referring to the death of heart muscle resulting from interruption of blood supply, often confused with cardiac arrest.
Impedance	Resistance to the flow of electrical current through the body.
Joule	The basic unit of energy delivered by a defibrillator.
LED	Light emitting diodes.
Myocardial infarction	The specific term for what is usually meant by heart attack; death of heart muscle resulting from an interruption of the blood supply to that area of myocardium.
Nonshockable rhythm	A heart rhythm that is detected by the defibrillator that does not need a shock, but may need CPR.
Victim	In this manual, the person suffering from cardiac arrest.
Responder	In this manual, the person giving aid to a victim in cardiac arrest. Used interchangeably with user.
Shockable rhythm	A heart rhythm that is detected by the defibrillator as requiring a shock, for example, ventricular fibrillation.
User	In this manual, the person giving aid to a victim in cardiac arrest. Used interchangeably with responder.
Ventricular fibrillation	A life-threatening chaotic heart rhythm.
Ventricular tachycardia	Rapid heart rhythm originating in the ventricle.

Text Conventions

Throughout this manual, special text characters are used to indicate labels and voice instructions:

Operating control labels: CAPITAL LETTERS such as ON/OFF and SHOCK.

Voice instructions: *ITALICIZED CAPITAL LETTERS* such as *STAND CLEAR*.

SAFETY INFORMATION

This section provides important information to help you safely operate your defibrillator. Familiarize yourself with all of the terms, warnings, and symbols presented in this section.

Safety Terms

You may encounter the following terms in this manual and while using your defibrillator:

Danger	Immediate hazards that will result in serious personal injury or death to the user and/or the victim.
Warning	Hazards or unsafe practices that could result in serious personal injury or death to the user and/or the victim.
Caution	Hazards or unsafe practices that could result in minor personal injury to the user and/or the victim, product damage, or property damage.

General Warnings and Cautions

WARNINGS!

Shock hazard.

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

Do not insert a finger or any object other than the CHARGE-PAK battery charger into the well of the defibrillator.

Shock or fire hazard.

Do not immerse any portion of this defibrillator in water or other fluids. Avoid spilling any fluids on the defibrillator or its accessories. Do not clean with ketones or other flammable agents. Do not autoclave or sterilize this defibrillator or the accessories unless otherwise specified.

Possible fire or explosion.

Do not store this defibrillator in the presence of flammable gases or in direct contact with flammable material.

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

Possible device shutdown.

When the attention symbol ⚠ first appears on the readiness display, only a small number of shocks and monitoring time are available. Always keep a CHARGE-PAK™ battery charger in the defibrillator. Routinely check that the defibrillator is ready for use. Replace the CHARGE-PAK battery charger after each use of the defibrillator.

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, failure to detect a shockable rhythm, or cessation of pacing. Avoid operating the device near cauterizers, diathermy equipment, cellular phones, or other portable and mobile RF communications equipment. Maintain equipment separation of at least 1.2 m (4 ft) and do not rapidly key EMS radios on and off. Contact a technical support representative if assistance is required.

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 defibrillator or of equipment in close proximity. Use only parts and accessories specified in this manual.

Possible electrical interference.

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

WARNINGS!

Possible improper device performance.

Using other manufacturers' cables or electrodes may cause the defibrillator to perform improperly and invalidates the safety agency certification. Use only the parts and accessories specified in this manual.

Using damaged or expired equipment or accessories may cause the defibrillator to perform improperly and may injure the victim or the user.

Safety risk and possible equipment damage.

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

CAUTION!

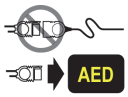
Possible equipment damage.

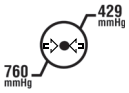
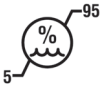
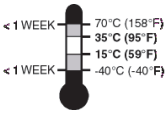
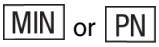
This defibrillator may be damaged by mechanical or physical abuse, such as immersion in water or dropping the defibrillator. If the defibrillator has been abused, remove it from use and contact a qualified technician.

SYMBOLS

The following symbols may appear in this manual and on the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators. For more information about the readiness display symbols, refer to Section 2, "Getting Started".

Symbol	Explanation
OK	OK Indicator. The defibrillator is ready for use.
	CHARGE-PAK battery charger indicator. On the readiness display—CHARGE-PAK battery charger needs to be replaced.
	Attention. On the readiness display—the internal battery is low. Refer to page 2-4 for more information about the readiness display.
	Wrench indicator. On the readiness display—there is a condition that prevents or could prevent normal defibrillator operation. Refer to page 5-8 for more information.
	On the CHARGE-PAK battery charger—consult the operating instructions. Refer to page 5-2 for more information about the CHARGE-PAK battery charger.
	On the back of the defibrillator—consult the operating instructions. Refer to page 1-5 for more information about the warnings and cautions.
	On the electrode pads—consult the operating instructions. Refer to page 2-6 for more information about electrode pads.
	Warning, high voltage.
	CHARGE-PAK battery charger.
	This end up.
	Fragile/breakable. Handle with care.
	Protect from water.
	Power On/Off button.
	Type BF patient connection.

Symbol	Explanation
	Defibrillation protected, type BF patient connection.
	Not intended for use on children who are less than eight years of age or who weigh less than 25 kg (55 lb).
	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.
	Not intended for use on adults.
	Physio-Control electrodes are latex-free.
	Arrow indicates ON/OFF button location.
	Symbol denoting a defibrillator and identifies the shock button.
LOT **YYWW**	Lot code.
	Do not reuse—single use only.
	Use By date shown: yyyy-mm-dd.
	Refer to instructions for recycling procedure, page 5-8.
	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 the proper disposal of this product.
	Symbol for China RoHS indicating the Environmentally Friendly Use Period (EFUP) denoting the number of years before any substance is likely to leak out into the environment.
	Mark of conformity according to the European Medical Device Directive 93/42/EEC.

Symbol	Explanation
	Canadian Standards Association certification for Canada and the United States.
	For USA audiences only.
	Atmospheric pressure limitation.
	Relative humidity range 5% to 95%.
	Do not store in direct sunlight.
	Recommended storage temperature: 15° to 35°C (59° to 95°F). Storage at extreme temperatures of -40° or 70°C (-40° or 158°F) is limited to seven days. If storage at these temperatures exceeds one week, the electrode shelf-life will be reduced.
	Date of manufacture.
	CAUTION - FIRE HAZARD Do not disassemble, heat above 100°C (212°F), or incinerate battery
	CAUTION - FIRE HAZARD Do not crush, puncture, or disassemble battery
	Federal (U.S.) law restricts this device to sale by, or on the order of, a physician.
	Manufacturer's Item Number (part number).
	Catalog number used for placing orders.
	Reorder number.
	Serial number.

ABOUT THE LIFEPAK CR PLUS AND LIFEPAK EXPRESS DEFIBRILLATORS

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are designed for indoor and outdoor use. The LIFEPAK CR Plus defibrillator has two models available—fully automatic and semiautomatic. The LIFEPAK EXPRESS defibrillator is semiautomatic. After the electrode pads are applied, the fully automatic model evaluates the heart rhythm and, if a shockable rhythm is detected, delivers a shock without any responder assistance. The semiautomatic models evaluate the heart rhythm but require the responder to press the shock button if a shockable rhythm is detected. All models have voice instructions that guide the responder through the defibrillation process.

Capabilities and Features

The following paragraphs introduce specific features found in the defibrillators.

Accessories

The defibrillator arrives with an installed CHARGE-PAK battery charger, one preconnected QUIK-PAK™ electrode packet, and the operating instructions. Refer to Section 5 for other accessories.

Automated Operation

Voice instructions guide the responder through the defibrillation process.

The **fully automatic** defibrillator requires no operator interaction beyond placing the electrode pads on the victim. If the defibrillator detects a shockable rhythm, it warns the responder prior to delivering any shock, and then delivers a shock without operator interaction.

The **semiautomatic** defibrillator has a highly visible shock button that the responder must press when the defibrillator issues a shock voice instruction.

Automatic Self-Tests

The defibrillator tests itself each week and every time you turn it on. In addition, every month, the defibrillator performs a more extensive self-test. This self-test checks the defibrillator's circuitry to verify that it is ready for use.

ClearVoice™ Technology

ClearVoice technology was created specifically for portable medical devices. This technology incorporates how the human ear interprets audio prompts and instructions within real world cardiac arrest response scenes such as shopping malls, on the freeway, or in an emergency room. ClearVoice technology minimizes distortion and enhances speech intelligibility so the user can clearly understand audio and instructional prompts in a chaotic and stressful environment.

Customized Setup

The defibrillator is shipped ready to use with the preprogrammed ADAPTIV™ biphasic escalating energy protocol and other operating settings. The operating settings are configured in accordance with customer order. Refer to Section 6, "Defibrillator Operating Settings".

Data Management

The defibrillator digitally stores data when it is turned on and the electrode pads are successfully applied to the victim. The stored data includes date and time, ECG data, and the number of shocks. The defibrillator also stores the results of the automatic self-tests.

Stored data can be transferred to a PC by means of a serial infrared link, the IrDA® port. A data transfer and management program running on the PC transfers event and test data from the defibrillator.

Defibrillation Electrodes (Pads)

When applied to the victim, Physio-Control QUIK-PAK defibrillation electrodes (pads) work with the defibrillator to monitor the heart rhythm and identify when a shock should be delivered. If victim care is transferred to emergency medical personnel, these electrode pads can be disconnected from the defibrillator and reconnected to other AEDs or defibrillators that are compatible with QUIK-COMBO® electrodes.

For infants or children who are less than eight years of age or weigh less than 25 kg (55 lb), use Infant/Child Reduced Energy Defibrillation Electrodes. These electrodes reduce the energy delivered by the AED to the victim by approximately 75%. Keep all electrode pads with the AED.

Defibrillation Waveform

The defibrillation shock, using ADAPTIV Biphasic technology, is delivered in the form of a biphasic truncated exponential (BTE) defibrillation waveform.

Heart Rhythm Analysis

The Physio-Control patented Shock Advisory System™ evaluates the victim's heart rhythm. Refer to "Appendix B" for further information.

Motion Detection

This patented motion system detects victim or operator motion that could affect the heart rhythm evaluation. Heart rhythm evaluation is interrupted if the defibrillator detects motion.

Readiness Display

This easy-to-read visual display indicates if the defibrillator is ready for use or if it needs attention.

SafeGuard™ Power System

The SafeGuard power system offers a dual layer of security as the CHARGE-PAK battery charger helps keep the rechargeable internal lithium battery at its optimum level. The internal battery supplies power to operate the defibrillator. It is important to keep a CHARGE-PAK battery charger in the defibrillator, even when the defibrillator is stored. Refer to "Replacing the CHARGE-PAK Battery Charger and the QUIK-PAK Electrode Packet" on page 5-2 for more information.

GETTING STARTED

This section provides an orientation to the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators and describes how to prepare the defibrillator for use.

UNPACKING AND INSPECTING YOUR LIFEPAK CR PLUS OR LIFEPAK EXPRESS DEFIBRILLATOR

To help ensure the integrity of your defibrillator and to verify that it is complete, perform the initial inspection as follows:

1 Remove your defibrillator and examine the outside for signs of damage that may have occurred during shipping.

2 Check the remaining contents in the box against the sales order.

3 View the OK symbol in the readiness display.
This indicates your defibrillator is ready for use. If the OK symbol is not visible, contact your local Physio-Control representative.

4 Notice the Use By date.
The Use By date is located below the readiness display. This date tells you when the electrode packet and battery charger must be replaced.

5 Check the defibrillator speaker by performing the following:

Note: This is only a speaker check. **Do not respond to the voice instructions.**

- Press the ON-OFF button to open and turn on your defibrillator.
  Confirm that the voice instructions sound.
- Press and hold the ON-OFF button for approximately 2 seconds to turn off your defibrillator.
  Three tones will sound.

6 Close and latch the lid. Do not reopen the lid unless necessary.
Doing so will reduce battery power.

If you have any questions about your defibrillator, please call your local Physio-Control representative.

CAUTION!

After completing an initial inspection, do not open the lid unnecessarily. Each time you open the lid, the defibrillator turns on and internal battery power is reduced. After 30 minutes of cumulative on time, the CHARGE-PAK indicator appears on the readiness display indicating the CHARGE-PAK battery charger and the QUIK-PAK electrode packet should be replaced.

Save the shipping container and inserts in case you need to reship the defibrillator in the future.

WHERE TO LOCATE YOUR LIFEPAK CR PLUS OR LIFEPAK EXPRESS DEFIBRILLATOR

The defibrillator should be easy to reach in a location free of obstacles. This could include a location near existing emergency equipment, such as fire extinguishers and first-aid kits. When considering location, avoid areas that expose the defibrillator to moisture, dust, or extreme temperatures. Recommended storage temperature is 15° to 35°C (59° to 95°F). Storage at higher temperatures will shorten the life of the battery and electrodes.

WARNING!

Possible fire or explosion.

Do not store this defibrillator in the presence of flammable gases or in direct contact with flammable material.

Although the defibrillator and electrodes are designed to withstand environmental temperature fluctuations between -40° to 70°C (-40° to 158°F), storage at extreme temperatures of -40° or 70°C (-40° or 158°F) is limited to one week. If storage at these temperatures exceeds one week, the electrode shelf-life will be reduced. Refer to Appendix A, page A-4 environmental specifications information. You can place your defibrillator on a stable surface, or you can mount it using the wall mount bracket accessory. Contact your local Physio-Control representative.

CONTROLS, INDICATORS, AND LABELS

This section introduces you to the controls, indicators, and labels on the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators.

Outside Controls, Indicators, and Labels

Controls, indicators, and labels on the outside of the defibrillator are identified in Figure 2-1 and described in Table 2-1.

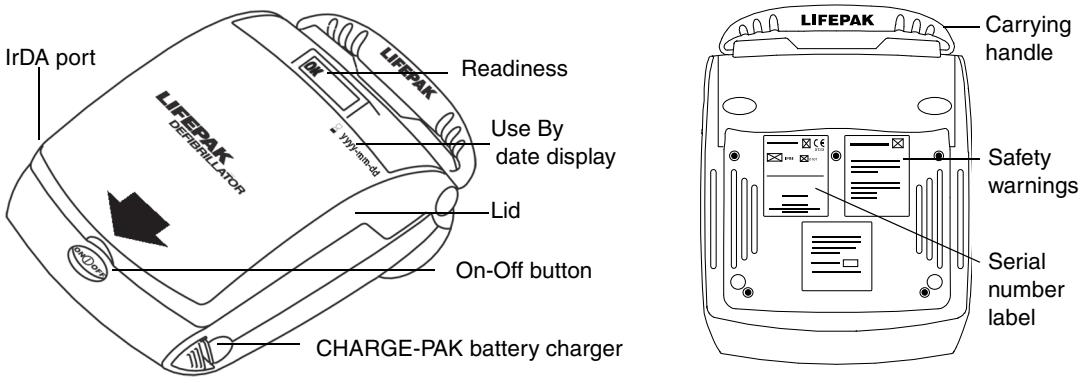


Figure 2-1 Outside Controls, Indicators, and Labels

Table 2-1 Outside Controls, Indicators, and Labels

Feature	Description
Readiness Display	There are four indicators that can appear when your defibrillator is turned off. These indicators allow you to determine, just by looking at the defibrillator, whether it's ready for use or needs attention. They include the following: **OK** The OK indicator appears when the defibrillator is turned off and ready for use. The CHARGE-PAK indicator appears when the CHARGE-PAK battery charger needs to be replaced or is not installed in the defibrillator. If needed, the defibrillator can be used in an emergency. The attention indicator appears when the internal battery is not fully charged. When this indicator first appears, the internal battery can power the defibrillator for a minimum of 6 shocks or 42 minutes. The wrench indicator appears when a condition prevents or could prevent the defibrillator from operating normally.
Lid	The top of the defibrillator.
ON-OFF button	The ON-OFF button opens the defibrillator lid and turns the defibrillator on. Pressing and holding the button for approximately 2 seconds after the lid is open turns off the defibrillator.

Table 2-1 Outside Controls, Indicators, and Labels (Continued)

Feature	Description
CHARGE-PAK battery charger	The CHARGE-PAK battery charger delivers a trickle charge to the internal battery. The battery charger can provide a charge for approximately two years, as long as the defibrillator is not used.
IrDA port	The Infrared Data Association defines specifications for infrared wireless communications. The IrDA port provides wireless communications for transferring data from your defibrillator to a PC.
Carrying Handle	The carrying handle is used to transport the defibrillator.
Safety Warnings	Safety warnings provide important information concerning the defibrillator's use and service.
Serial Number Label	The serial number label includes the defibrillator identification number.

Inside Features

The inside features of the defibrillator are designed to make it easy to use during a cardiac arrest event. When you press the ON-OFF button, the lid opens, the defibrillator turns on, and you see the electrode packet and its release handle as shown in Figure 2-2. Table 2-2 describes the inside features.

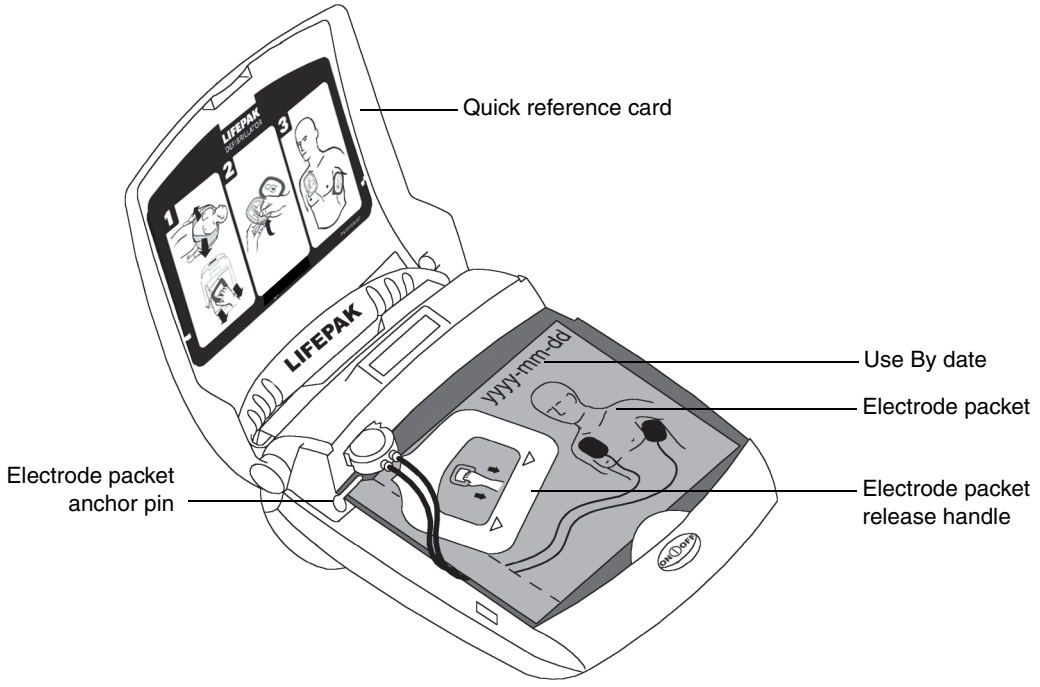


Figure 2-2 Inside Features

Table 2-2 Inside Features

Feature	Description
Quick reference card	This card provides abbreviated graphic directions for using your defibrillator to treat a victim in cardiac arrest.
Use By date	Use By date shown (yyyy-mm-dd) can be viewed through the defibrillator lid when it is closed.
Electrode packet	The QUIK-PAK electrode packet is preconnected to the defibrillator. This packet contains a set of electrode pads.
Electrode packet release handle	When you pull this handle, the electrode packet tears open.
Electrode packet anchor pin	This pin securely positions the electrode packet to the defibrillator.

After you pull the electrode packet release handle and tear open the electrode packet, you will see the features shown in Figure 2-3.

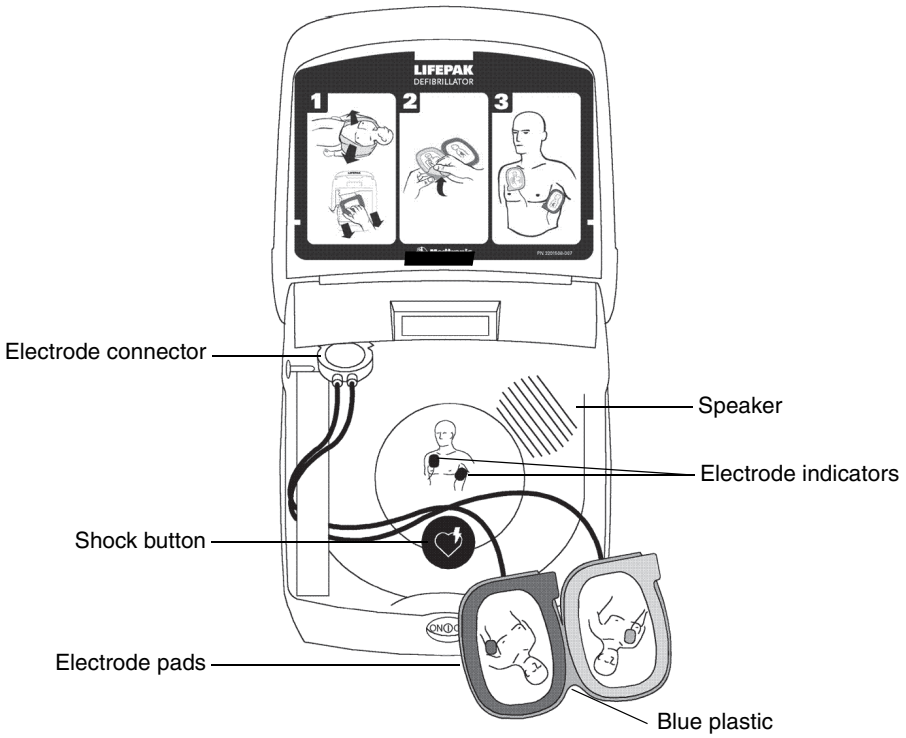


Figure 2-3 Inside Features After Releasing the QUIK-PAK Electrode Packet

Table 2-3 Inside Features After Releasing the QUIK-PAK Electrode Packet

Feature	Description
Speaker	This projects the voice instructions that lead you through the defibrillation process.
Electrode indicators	The electrode indicators flash red until the pads are applied to the victim's exposed chest. When the pads are successfully applied, the indicators turn solid green and the defibrillator can perform an analysis. In addition, electrode indicators briefly flash when the defibrillator performs an automatic self-test.
Blue plastic	The plastic liner protects the conductive adhesive gel until the electrode pads are used.
Electrode pads	The electrode pads are applied to the victim's exposed chest; they transfer the defibrillation energy (shock) to the victim. The electrode pads must be removed from the blue plastic before applying them to the victim.
SHOCK button	The SHOCK button is only provided on the semiautomatic model. When pressed, this button delivers a shock to the victim. You cannot deliver a shock to a victim unless the defibrillator instructs you to do so.
Electrode connector	The electrode connector is used to connect the electrode pads to the defibrillator. To aid in victim transport, the connector can be unplugged from the defibrillator and plugged into another AED or defibrillator equipped for QUIK-COMBO electrodes.

USING THE DEFIBRILLATOR

This section provides information and instructions for using the LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator on a victim in cardiac arrest.

WARNINGS AND CAUTIONS

To help ensure safe use of the defibrillator, completely familiarize yourself with the following warnings and cautions.

WARNINGS!

Incorrect rhythm interpretation.

Performing CPR or otherwise handling or transporting the victim while the defibrillator is evaluating the heart rhythm can cause an incorrect or delayed diagnosis. Keep the victim as still as possible while the defibrillator is attached and do not transport the victim.

Shock hazard.

When instructed “Do not touch patient,” “Stand by,” or “Everyone clear,” remain still, do not touch the defibrillator, patient, electrode pads or any material in contact with the patient. Make sure no one is touching the patient when the defibrillator shocks the patient.

Shock hazard.

To remove an unwanted charge, disconnect the electrode cable from the defibrillator, wait for the defibrillator to automatically remove the charge, or turn off the defibrillator.

Possible fire, burns, and ineffective energy delivery.

During defibrillation, material in contact with the electrode pads can cause electrical sparks, skin burns, and divert important defibrillating energy away from the heart. Place electrode pads so that they adhere to the skin completely. Do not allow the electrode pads to touch each other, medication patches, dressings, metal objects, other electrodes, or any other material on the patient’s chest.

During defibrillation, air pockets between the skin and electrode pads can cause skin burns. To help prevent air pockets, make sure electrode pads completely adhere to the skin. Do not use damaged, expired, or dried-out electrode pads.

CAUTION!

Possible equipment damage.

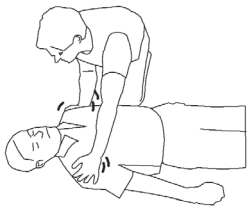
Before using the defibrillator, disconnect all equipment from the patient that is not defibrillator-protected.

RESPONDING TO A SUDDEN CARDIAC ARREST EMERGENCY

If not treated, sudden cardiac arrest (SCA) will cause death. In an SCA situation, it is important to remember to immediately call for help and activate your emergency response system.

Basic Steps for Using the LIFEPAK CR Plus or LIFEPAK EXPRESS Defibrillator

Responding to an SCA emergency using the defibrillator involves these basic steps:

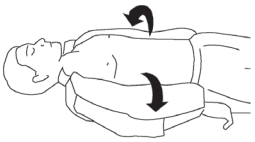


Determine if the victim is in SCA. A person in SCA will not respond when you try to shake him or her.

Check for breathing by listening next to the victim's mouth and looking for chest movement.

Use your defibrillator only if the victim is not responding, not moving, and not breathing normally or not breathing at all. If in doubt, use your defibrillator.

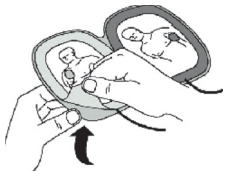
Place your defibrillator near the victim and on the side next to you. Press the ON/OFF button to open the lid and turn on your defibrillator. Remain calm. Your defibrillator will guide you through the defibrillation process.



Expose the victim's chest. If the chest is excessively hairy, quickly shave the hair in the area where you will place the pads. If the chest is dirty or wet, wipe the chest clean and dry. If there are medicine patches on the victim's chest, remove them.

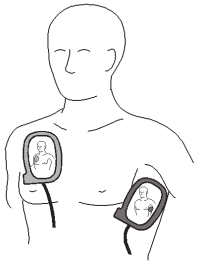
Hold down the left side of the electrode packet with one hand and pull the red packet handle down with the other. The electrode packet tears open.

Tear open the packet completely to remove the pads. A small piece of the packet will remain attached to your defibrillator.



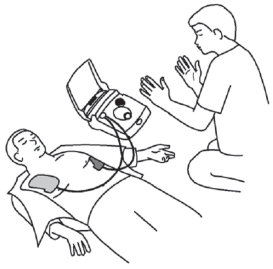
Separate the electrode pads, one at a time, from the blue plastic. Use these pads on adults or children 8 years of age or more, who weigh 25 kg (55 lb) or more. For infants or children who are less than 8 years of age or who weigh less than 25 kg (55 lb), special electrodes are needed. Refer to page 5-9 for more information.

WARNING!
If you cannot determine a child's age or weight, or if special infant/child electrodes are not available, proceed with the existing electrode pads, and continue on to the next step.

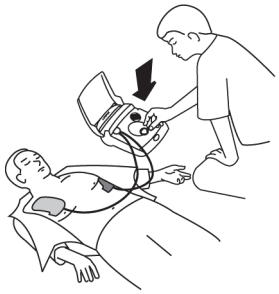


Apply the electrode pads to the victim's bare chest (exactly as shown in the picture on the pads). Be sure to press firmly so that the pads completely adhere to the victim's chest.

Note: Be sure you do not place the electrode pads over an implanted device such as an implanted pacemaker or ICD. An indication of an implant is a protrusion in the chest skin and a scar. If you are in doubt, apply the pads as shown on the labels.



Listen to voice instructions and do not touch the victim unless instructed to do so.



If the defibrillator heart rhythm analysis determines that a shock is needed, the defibrillator will announce *PREPARING TO SHOCK*, and then instruct you to *PRESS FLASHING BUTTON* to administer a shock (semiautomatic model) or it will announce *PREPARING TO SHOCK*, and then automatically administer a shock without requiring further action (fully automatic model).

Do not touch the victim while a shock is delivered.

Regardless of which model you have, continue to follow the voice instructions.

Do not remove the pads or disconnect them from the defibrillator until emergency medical personnel arrive. If the victim starts moving, coughing, or breathing regularly, place the victim in the recovery position (as instructed in CPR training) and keep him or her as still as possible.

What to Do After Emergency Medical Personnel Arrive

When emergency medical personnel arrive, tell them what actions you have taken. Tell them how long the victim has been unconscious, if you delivered shocks, the number of shocks delivered, and if you performed CPR.

Do not worry if you cannot recall precisely what happened. Your defibrillator makes a digital recording of heart rhythms and shocks that can be transferred to a computer at a later time. Refer to Section 4 for information on transferring victim data.

Without removing the electrode pads from the victim, emergency medical personnel can disconnect the electrode pads from the defibrillator and reconnect them to another defibrillator or AED that has a compatible QUIK-COMBO cable.

To disconnect the electrode pads:

1 Pull the electrode cable straight out from the defibrillator.

2 Remove the electrode packet anchor pin from the slot in the defibrillator.

3 Press the ON-OFF button and close the lid to turn off the defibrillator.

What to Do After Using Your Defibrillator

After you use your defibrillator to respond to an SCA emergency, complete the following tasks:

1 If the defibrillator is turned on, press and hold the ON-OFF button for approximately 2 seconds to turn it off.

2 Clean the defibrillator and its accessories according to the instructions provided in Table 5-1, page 5-7. Use only the cleaning agents identified in Table 5-1.

3 Transfer data, if desired.

4 Replace the CHARGE-PAK battery charger. (Refer to page 5-4.)

5 Install a new QUIK-PAK electrode packet. (Refer to page 5-6.)

6 Close the lid and verify that the OK symbol appears in the readiness display, indicating that the defibrillator is ready for use. If the attention symbol ⚠ appears after you replace the battery charger, the internal battery needs additional time to reach an adequate charge capacity.

7 Dispose of the used electrode pads, any unused spare electrode pads, and the battery charger. (Refer to "Recycling Information" on page 5-8.)

VOICE INSTRUCTIONS AND TONES

Defibrillator voice instructions provide clear, step-by-step instructions for responding to a victim in cardiac arrest. In addition, your defibrillator may emit sounds that alert you to the actions that the defibrillator is performing.

Note: A few seconds may pass between voice instructions and tones. Always wait for further instructions before taking action.

Note: Some voice instructions will repeat during the defibrillation process.

TROUBLESHOOTING

This section explains problems you may encounter while using the LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator. For information about keeping your defibrillator in a state of readiness, refer to Section 5.

Table 3-1 Troubleshooting During Victim Use

Problem	Possible Cause	What To Do
CHECK PADS FOR GOOD CONTACT or *CHECK CONNECTOR* voice instructions are heard	Inadequate connection to the defibrillator	• Be sure that the connector is completely inserted.
	Electrode pads are not properly adhered to the victim	• Firmly press the pads on the victim's skin. • Clean, shave, and dry the victim's skin before placing pads on skin.
	Electrode pads are dry, damaged, or have passed the expiration date	• Replace the pads.
	Electrode pads are not removed from the blue plastic	• Remove the pads from the blue plastic and apply them to the victim's chest.
Defibrillator cannot deliver the required shock	Defibrillator internal battery power is low	• Administer CPR if the victim is not responding, not breathing normally, or not moving.
Voice instructions sound faint or distorted	Defibrillator internal battery power is low	• Administer CPR if the victim is not responding, not breathing normally, or not moving.
MOTION DETECTED and *STOP MOTION* voice instructions are heard	Victim movement because of location	• Move the victim to a stable location, if possible.
	Victim movement because of breathing	• Stop CPR during analysis. • Check victim for normal breathing.
	Vehicle motion	• Stop vehicle during analysis, if possible.
	Electrical/radio frequency interference	• Move communication or other suspected devices away from the defibrillator when possible.

Table 3-1 Troubleshooting During Victim Use (Continued)

Problem	Possible Cause	What To Do
Defibrillator does not deliver voice instructions or beeping tones after you open it (turn it on)	Depleted internal battery	• Administer CPR if the victim is not responding, not breathing normally, or not moving. • Replace the CHARGE-PAK battery charger as soon as possible. After the OK symbol appears on the readiness display, return the defibrillator to service. • Contact authorized service personnel.
	Speaker system failure	• Administer CPR if the victim is not responding, not breathing normally, or not moving. • 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 or too high	• Operate the defibrillator within 0° to 50°C (32° to 122°F).
	LCD not operating properly	• Contact authorized service personnel.

DATA STORAGE

This section describes the data that the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators store when used in an SCA event.

This manual does not provide instructions for how to hand off defibrillation data to the emergency medical system or hospital personnel. Because this process varies from area to area, check with the emergency medical system administration for information and directions.

OVERVIEW OF DATA STORAGE

Each time you use the LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator, it digitally saves data about the victim that can be transferred to a PC. This data can be provided to emergency medical personnel or hospital personnel to aid in case review for quality control, training, and research purposes. We recommend that you become familiar with their local requirements for reporting a use of the defibrillator and for providing use data. For assistance in retrieving data from the defibrillator, contact your local Physio-Control sales or service representative.

Data Stored by Your Defibrillator

Whenever you turn on your defibrillator and connect it to a victim, it automatically stores data about the victim. When this data is transferred to a data management system for review, three reports are available: an Event Log, Continuous ECG, and a 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	Twenty minutes of the victim's ECG rhythm beginning when the victim is connected to the defibrillator and ending when the defibrillator is turned off.
Summary	Combines the Event Log and a sampling of continuous ECG rhythms associated with certain events.

Your defibrillator can store up to two records: one for the current victim and one for the previous victim. When you use your defibrillator, it is important that you transfer this data as soon as possible after use to free up storage.

The Complete Record for the current victim includes the Continuous ECG and Event Log. If you treat a second victim, the first victim's Complete Record will be reformatted into a Summary report. If you treat a third victim, all of the first victim's data will be deleted and the second victim's Complete Record will be reformatted into a Summary Report. Refer to Table 4-2.

Table 4-2 Defibrillator Patient Records

	Complete Record	Summary
Current Victim	✔	✔
Previous Victim	Ø	✔

If you turn your defibrillator on and off without attaching electrode pads to a victim, the defibrillator will not create a new record and the records in the defibrillator will not be altered. The defibrillator deletes previous data only after it is connected to a new victim.

After you transfer data records to a PC, the defibrillator will disallow repeat transmissions. However, service personnel may access device records, if necessary.

Test and Service Data

Your defibrillator stores a test log consisting of the most recent auto-tests, power cycles, and CHARGE-PAK battery charger replacements. The test log lists the test results and any errors detected. The test log data is available only to service personnel or to users through the data management system.

Event and Test Log

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

Table 4-3 Event and Test Log Reports

Event Log	Test Log
Power On	Self-Test Power On
Connect Electrodes	Self-Test Pass/Fail
Patient Connected	User Power On
Initial Rhythm*	CHARGE-PAK Changed
Analysis X*	CHARGE-PAK
Shock Advised	Fault Log
Charge Complete	
SHOCK X-XXXJ*	
Shock X Abnormal	
No Shock Advised	
CPR Prompt	
Stop CPR Prompt	
Check Patient*	
Charge Removed	
Low Battery	
Motion	
Analysis Stopped*	
Out of Event Memory	
Out of Waveform Memory	
Power Off	

*These events include ECG samples in the Summary Report.

CARING FOR YOUR DEFIBRILLATOR

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

MAINTAINING A STATE OF READINESS

Your LIFEPAK CR Plus or LIFEPAK EXPRESS defibrillator does not require routine maintenance. It performs an automatic self-test once a week and every time you turn it on. The electrode indicators briefly flash during the test. If the automatic self-test detects a condition that requires attention, the OK symbol in the readiness display will fade and either the CHARGE-PAK symbol, the ATTENTION symbol, or the WRENCH symbol will appear, depending on the type of condition detected.

On a regular basis, you should do the following:

- Check to make sure that the OK symbol is visible in the readiness display.
- Check the Use By date on the electrode packet (visible through the defibrillator lid in the upper right corner) and all other electrode packets. If the date has passed, replace the electrode packet and the battery charger. Refer to "Replacing the CHARGE-PAK Battery Charger and the QUIK-PAK Electrode Packet" below for more information.
- Check other emergency supplies that may be stored with your defibrillator.

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

REPLACING THE CHARGE-PAK BATTERY CHARGER AND THE QUIK-PAK ELECTRODE PACKET

The CHARGE-PAK battery charger is a replaceable, nonrechargeable battery cell that charges your defibrillator's internal battery. The internal battery provides the power for your defibrillator. To prevent damage to the internal battery, always keep the battery charger in place, including during storage or shipping.

The QUIK-PAK electrode packet contains the pads that transfer the defibrillation energy to the victim. The packet should remain connected to the defibrillator and unopened until required for an SCA emergency. QUIK-PAK electrode pads are not reusable.

When installed, these two accessories allow your defibrillator to stand by for use for approximately two years. The electrode packet Use By date is programmed into the battery charger. When the date is reached, the CHARGE-PAK symbol appears in the readiness display, indicating both the battery charger and electrode packet need to be replaced.

WARNING!

Possible device shutdown.

Always replace the CHARGE-PAK battery charger and QUIK-PAK electrodes at the same time.

The CHARGE-PAK battery charger and QUIK-PAK electrodes are a set and have the same expiration date. Always replace the CHARGE-PAK battery charger and QUIK-PAK electrodes at the same time to keep the replacement cycles in sync.

Use the Physio-Control replacement kit to replace the CHARGE-PAK battery charger and the QUIK-PAK electrode packet as follows:

- After using the defibrillator
- If the CHARGE-PAK symbol appears in the readiness display
- When the Use By date is reached or passed

The replacement kit includes a CHARGE-PAK battery charger, one or two QUIK-PAK electrode packets, and a CHARGE-PAK battery discharger. The discharger depletes a used battery charger so that it is ready for recycling or disposal.

Note: Always keep the CHARGE-PAK battery charger with its original defibrillator. When a CHARGE-PAK battery charger is inserted into a defibrillator, it becomes internally linked to that device. If the CHARGE-PAK battery charger is inserted into a second device, the device will not function correctly. If this occurs, obtain a new replacement kit and replace both the CHARGE-PAK battery charger and the QUIK-PAK electrodes at the same time.

Follow instructions provided in the replacement kit for battery charger and electrode packet recycling/disposal.

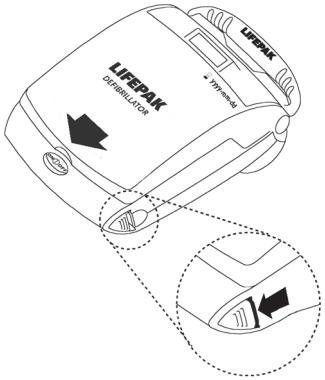
WARNING!

Possible explosion or fire.

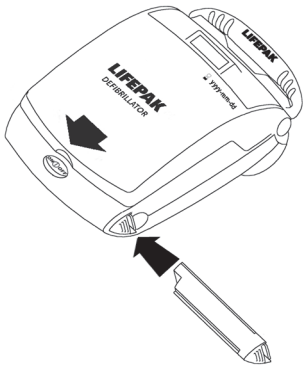
The CHARGE-PAK battery charger is not rechargeable. Do not attempt to recharge, open, crush, or burn the battery, or it may explode or catch fire.

Replacing the CHARGE-PAK Battery Charger

To replace the CHARGE-PAK Battery Charger:



1 Press the **release latch** (in the direction of the arrow) to remove the used battery charger. The battery charger springs outward from the defibrillator.



2 Insert the new battery charger into your defibrillator and push until you hear it click into position.

3 Confirm that the symbol disappears and that the **OK** symbol appears in the readiness display.

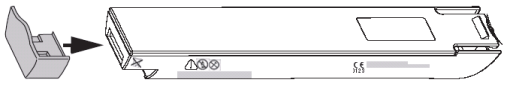
Note: If the symbol appears after you replace the battery charger, the internal battery is very low and needs time to charge. It may take up to three days if you had the defibrillator on for a long time or if you delivered many shocks. The **OK** symbol appears when the internal battery is charged.

Remember: If the defibrillator is needed for an emergency, attempt to use it even if the symbol is visible.

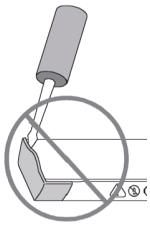
CAUTION!

Keep the defibrillator at temperatures between 0° – 50°C (32° – 122°F) while the new battery charger charges the internal battery. The internal battery may not charge effectively at lower temperatures. Temperatures exceeding 50°C (122°F) for longer than seven days can permanently damage the internal battery.

To discharge and dispose of a used battery charger:

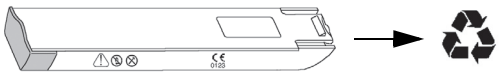


1 Insert the discharger into the used battery charger.



Note: Do not attempt to remove the discharger once it is in place.

2 Let the discharger fully deplete the battery charger. Wait at least 9 days.

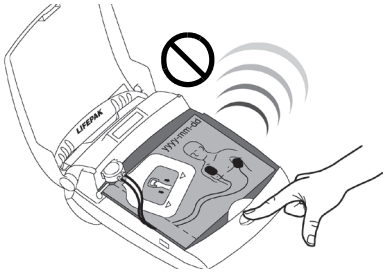


3 Recycle the battery according to national and local regulations. Refer to page 5-8 for more information.

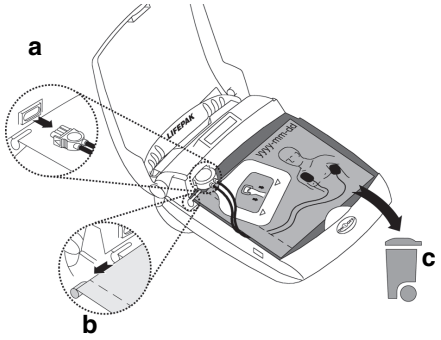
Replacing the QUIK-PAK Electrode Packet

To replace the QUIK-PAK Electrode Packet:

1 Press the ON/OFF button to open the defibrillator lid (voice instructions will sound).

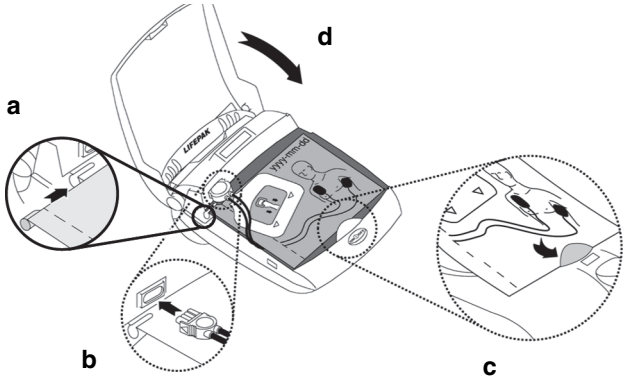


2 Press and hold down the ON/OFF button for 2 seconds to turn off the defibrillator and save battery power.



3 Remove the outdated or used electrode packet:

- a Unplug the electrode connector from the connector receptacle.
- b Slide the anchor pin from the slot.
- c Discard the outdated or used electrode packet according to local regulations.



4 Install the new electrode packet:

- a Slide the anchor pin into the slot.
- b Plug the electrode connector into the receptacle.
- c Ensure that the new electrode packet is centered on the defibrillator and is tucked behind the lip before closing the lid.
- d Close the lid. Confirm that the packet Use By date is visible through the upper right-hand corner of the lid.

STORING YOUR DEFIBRILLATOR

Always store your defibrillator according to the temperature ranges recommended in Appendix A, "Specifications".

WARNING!

Possible fire or explosion.

Do not store this defibrillator in the presence of flammable gases or in direct contact with flammable material.

CLEANING YOUR DEFIBRILLATOR

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 its accessories.

Table 5-1 Cleaning Methods

Item	Cleaning Method	Cleaning Agent
Exterior case, readiness display, and crevices	Clean with damp sponge or cloth	Nonabrasive soap and water Quaternary ammonium compounds Rubbing (isopropyl) alcohol Peroxide (peracetic acid) solutions
CHARGE-PAK battery charger	None	None, dispose of/recycle after use
Electrode Pads	None, do not remove electrode pads from the packet	None, dispose of/recycle after use
Carrying case	Wipe with damp cloth or sponge	Water
Quick Reference Card	Wipe with damp cloth or sponge	Water

OBTAINING AUTHORIZED SERVICE

WARNING!

Shock hazard.

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

The WRENCH indicator appears on the readiness display if the defibrillator requires service. Contact your local Physio-Control representative or authorized service provider. Be prepared to provide the following information:

- Model number and MIN number (part number)
- Serial number
- Description of the problem based on your observations

RECYCLING INFORMATION

Recycle the defibrillator and its accessories at the end of their useful lives. Do not dispose of this product in the unsorted municipal waste stream.

Recycling Assistance

Items 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.

Preparation

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

Recycling of Disposable Electrodes

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

Packaging

Packaging should be recycled according to national and local regulations.

SUPPLIES, ACCESSORIES, AND TRAINING TOOLS

If possible, we recommend that you have an extra QUIK-PAK Electrode Packet and CHARGE-PAK Battery Charger on hand. In addition, there are other useful accessories available. For example, you can buy Infant/Child Reduced Energy Defibrillation Electrodes for use with your defibrillator on children who are less than 8 years of age or weigh less than 25 kg (55 lb). Contact your local Physio-Control representative.

Table 5-2 Supplies and Accessories

Item Description
CHARGE-PAK Battery Charger
QUIK-PAK Pacing/Defibrillation/ECG Electrodes
Infant/Child Reduced Energy Defibrillation Electrodes
Battery Discharger
Replacement Kit for CHARGE-PAK Battery Charger (includes CHARGE-PAK Battery Charger, Battery Discharger, and QUIK-PAK Electrodes)

WARRANTY INFORMATION

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

DEFIBRILLATOR OPERATING SETTINGS

This section introduces the operating settings that are adjustable on the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators.

OPERATING SETTINGS AND SETUP CONFIGURATION

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators have several operating settings. The settings range from defining the time and date used by the defibrillator, to the energy sequence and protocol of the shocks delivered. This group of operating settings are the defibrillator's setup configuration.

Table 6-1 identifies operating settings in the setup configuration, describes each setting, including possible options, and identifies the preset defaults. These settings can be specially configured in accordance with customer order.

Table 6-1 Operating Settings

Operating Settings	Description	Default Setting
Device ID	Device ID is a unique identifier (ID) assigned to each defibrillator used for tracking the location of defibrillators. When you transfer event data from the defibrillator to a PC, the defibrillator ID will be included in the transferred data.	Serial Number
Energy Sequence	Energy sequence defines the energy levels used by the defibrillator. The energy level choices are: 150, 175, 200, 225, 250, 275, 300, 325, 360.	Level 1 – 200 joules Level 2 – 300 joules Level 3 – 360 joules
Energy Protocol	Energy protocol determines how the defibrillator delivers successive shocks. There are two options for this setting: flexible or fixed. Flexible sequence means the energy delivered for a shock increases only if an analysis immediately following a shock results in another SHOCK ADVISED decision. For example, if the defibrillator energy sequence is set up as 200, 300, 360, flexible sequence means that the energy delivered for the first shock is 200 joules. If the arrhythmia is terminated by shock 1 and the next analysis results in a NO SHOCK ADVISED decision, the energy will not increase for the next shock. However, if the arrhythmia is not terminated by shock 1 and the next analysis results in a SHOCK ADVISED decision, the energy will increase to 300 joules, and so on. Fixed sequence means that the energy delivered after the first shock of 200 joules increases from 200 to 300, and then to 360 joules, regardless of the post-shock ECG rhythm and subsequent analysis.	Flexible
CPR Time 1 CPR Time 2	The CPR Time 1 and CPR Time 2 settings define the time interval for performing CPR after a shock or after a no shock advised decision. The choices for CPR Time 1 and CPR Time 2 are 15, 30, 45, 60, 90, 120, and 180 seconds.	CPR Time 1–120 sec* CPR Time 2–120 sec*

*The default setting for Arabic, Finnish, Icelandic, and Slovenian is 60 sec.

Table 6-1 Operating Settings (Continued)

Operating Settings	Description	Default Setting
Device Date Device Time	The device date and device time are used to time stamp patient reports and to control when the automatic self tests are performed. The date and time can be set when you retrieve data from the defibrillator.	Pacific Standard Time and Date
Turn-On Prompt	This setting determines whether you hear only tones, or tones and the voice prompt, CALL FOR HELP NOW, when you open the lid and the defibrillator turns on. Choices are Voice and Tones.	Voice
Voice Prompt Volume	This setting sets the voice prompt volume to MEDIUM or HIGH.	High
Pulse Prompt	The pulse prompt setting determines whether the defibrillator prompts you to check the victim's pulse (appropriate for medically trained users) or to check the victim for signs of circulation such as breathing and movement (appropriate for lay users). Choices are Check Pulse, Check Breathing, or Check Circulation.	Per customer order
Stack Shocks	When set to OFF, the Stack Shocks option eliminates the analysis after each shock and inserts prompting for CPR after each (a single) shock. This eliminates the three-shock stack. CPR is prompted regardless of the ECG rhythm after the shock. The CPR time following the shock is determined by the CPR Time 1 setting selected. Choices for Stack Shocks option are ON or OFF. When set to ON, an analysis will occur after shocks, and up to three shocks in a row may be delivered (three-shock stack).	Off*
Pulse Check	When set to Never, the Pulse Check option removes all prompting for pulse checks. The other Pulse Check settings available allow pulse checks only after every No Shock Advised (NSA) decision, after the second NSA decision and thereafter, or Always (after shocks, NSA and CPR).	Never**
	*The default setting for Arabic, Finnish, Icelandic, and Slovenian is ON. **The default setting for Arabic, Finnish, Icelandic, and Slovenian is ALWAYS.	

Table 6-1 Operating Settings (Continued)

Operating Settings	Description	Default Setting
Motion Detection	The motion detection setting is used to determine if motion detection is active or not active during analysis. When motion detection is On, the defibrillator stops analysis for up to 10 seconds if it detects any victim motion. The defibrillator notifies the responder of the problem. The defibrillator will resume analysis after 10 seconds, even if motion is still present.* When motion detection is Off, analysis is not inhibited, regardless of any victim motion.	On
Time Zone	This setting sets the time zone for the location of the defibrillator. Choices are 74 time zones with universal time code (UTC).	None
	*Device behavior may vary for Arabic, Finnish, Icelandic, and Slovenian.	

APPENDIX A

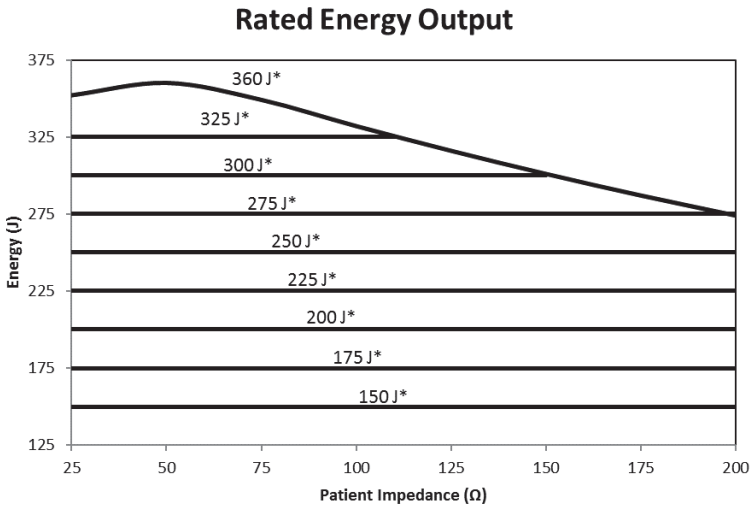
SPECIFICATIONS

SPECIFICATIONS

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

Defibrillator

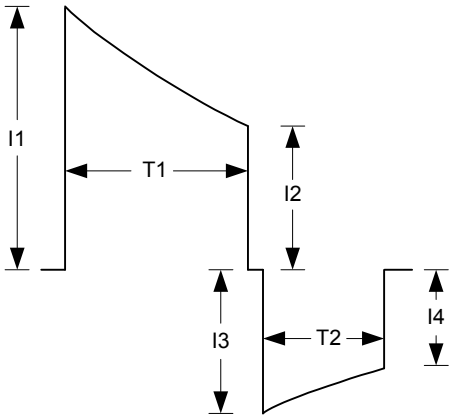
Waveform:	Biphasic Truncated Exponential, with voltage and duration compensation for patient impedance. See Figure A-2, "Biphasic Waveform".
Patient Impedance Range:	7–300 ohms. If the detected impedance is outside this range, defibrillation is inhibited and the user is prompted to connect electrodes. The following specifications apply from 25 to 200 ohms.
Output Energy Sequence:	Multiple energy levels from 150 to 360 joules. Refer to Section 6, Defibrillator Operating Settings.
Output 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.



*Energy setting selected

Figure A-1 Rated Energy Output

Waveform Parameters:



Patient Impedance (Ω)	I1 (A)	I2 (A)	I3 (A)	I4 (A)	T1 (ms)	T2 (ms)	Delivered Energy
25	69.5	28.3	28.3	15.5	5.6	3.7	357
50	37.9	19.8	19.8	12.8	7.4	4.9	361
75	26.1	15.6	15.6	11.0	8.5	5.7	350
100	19.9	12.7	12.7	9.4	9.7	6.5	335
125	16.0	10.9	10.9	8.4	10.4	6.9	317
150	13.5	9.5	9.5	7.6	11.0	7.4	302
175	11.6	8.5	8.5	6.9	11.6	7.7	288
200	10.1	7.6	7.5	6.2	12.2	8.1	274

Note: Table values are nominal for a 360 joule energy setting.

Figure A-2 Biphasic Waveform

Shock Advisory System: An ECG analysis system that advises whether a shock is appropriate, meets rhythm recognition criteria specified in the American Association of Medical Instrumentation standard DF39.

The device allows a defibrillation shock only if the Shock Advisory System advises defibrillation.

Device Capacity: LIFEPAK CR Plus defibrillator — Thirty (30) full discharges or 210 minutes of “ON time” with a fully charged device.

LIFEPAK EXPRESS defibrillator — Twenty (20) full discharges or 140 minutes of “ON time” with a fully charged device.

Charge Ready Time:

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	Defibrillator charge time applies when the device is fully charged or has been discharged up to 15 times.
Power on to charge ready time	Less than 26 seconds	Less than 32 seconds	Power on to charge ready time applies when a shockable rhythm is detected and no motion is detected, and when the device is fully charged or has been discharged up to 15 times.
*Behavior may vary for Arabic, Finnish, Icelandic, and Slovenian.			

System Recharge Times:

Recharge times with a fully discharged device:

Able to deliver 6 shocks or provide 42 minutes of operating time after 24 hours of recharge and 20 shocks or 140 minutes of operating time after 72 hours of recharge time with a new CHARGE-PAK battery charger at temperatures above 15°C (59°F).

Controls:

LID RELEASE/ON-OFF button—Controls device power.

SHOCK button (semiautomatic version)—Delivers defibrillation energy.

After electrodes are attached to a victim, an automatic version of the device delivers a shock, if appropriate, not requiring operator intervention.

Electrical Protection:

Input protected against high voltage defibrillator pulses per IEC60601-1/EN60601-1. See Figure A-3.

Figure A-3 Defibrillation-protected, Type BF Patient Connection

Safety Classification:

Internally powered equipment. IEC60601-1/EN60601-1.

User Interface

User Interface:	The user interface includes voice instructions, audible tones, and graphical prompts.
Readiness Display	The readiness display shows the device status. 
OK Indicator:	Indicates OK when the last self test was completed successfully. When the OK indicator is visible, all other indicators are not visible. The OK indicator is not displayed during device operation.
CHARGE-PAK Indicator:	When displayed, replace the CHARGE-PAK battery charger.
Attention Indicator:	When first displayed, at least 6 discharges or 42 minutes of operating time will remain.
Service Indicator:	Service required when displayed.

Environmental

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

Operating Temperature:	0° to 50°C (32° to 122°F)
Long-term Storage Temperature:	15° to 35°C (59° to 95°F)
Short-term Storage Temperature:	-40° to 70°C (-40° to 158°F) for a maximum of 1 week.
Atmospheric Pressure:	760 mmHg to 429 mmHg, 0 to 15,000 feet above sea level.
Relative Humidity:	5 to 95% (non-condensing)
Water Resistance:	IEC60529/EN60529 IPX4 “Splash proof” with electrodes connected and CHARGE-PAK installed.
EMC:	Refer to Appendix D for EMC information as defined in IEC 60601-1-2.

Physical Characteristics

Height:	10.7 cm (4.2 in)
Width:	20.3 cm (8.0 in)
Depth:	24.1 cm (9.5 in), excluding handle
Weight:	2.0 kg (4.5 lb) with CHARGE-PAK and electrodes

Accessories

CHARGE-PAK Battery Charger

Type:	Li/SO_2Cl_2 Lithium Sulfuryl Chloride, 11.7V, 1.4 amp-hours.
Replacement:	Replace after each use or when CHARGE-PAK indicator is visible (typically after 2 years)
Weight:	80.5 grams (0.18 lb)

QUIK-PAK Electrode Pads

Pads:	Pacing/defibrillation/ECG electrodes.
Pads Packaging:	User-intuitive, rapid-release QUIK-PAK electrodes allow the electrode pads to be pre-connected to the device and protected under a top cover.
Pads Shelf Life:	Two years typical.
Electrode Shape:	Oval-rectangular.
Electrode Size:	11.2 cm (4.4 in) × 18.5 cm (7.3 in)
Lead Wire:	1.067 meters (3.5 feet)
Conductive Adhesive Gel Contact Area:	82 cm^2 (12.8 in^2)
Maximum Adhesion Time:	24 hours
Maximum ECG Monitoring Time:	24 hours
Maximum Number of Defibrillation Pulses:	50 at 360 joules
Maximum Pacing Duration:	Up to 12 hours

ECG is received from disposable defibrillation electrodes, standard placement (anterior-lateral), or anterior/posterior placement.

Data Storage

Memory Type:	Internal digital memory.
ECG Storage:	Dual victim Data Storage. Minimum 20 minutes of ECG stored for the current victim. Summarized data stored for the previous victim.
Report Types:	Continuous ECG—A continuous ECG report for the victim. Summary—A summary of critical resuscitation events and ECG waveform segments associated with these events. Event Log report—A report of time stamped markers, which reflect operator and device activity. Test Log report—A device self test activity report.
Capacity:	Minimum 200 time stamped Event Log markers.
Communications:	Wireless transfer to a personal computer.
Data Review:	Physio-Control provides an array of tools to meet customer needs for data viewing and analysis.

CLINICAL SUMMARY: MONOPHASIC VS. BIPHASIC WAVEFORMS: IN-HOSPITAL-TRIAL

Background

This prospective, double-blinded, randomized clinical trial compared the first shock efficacies of Physio-Control ADAPTIV 200 J biphasic truncated exponential (BTE) waveform, 130 J BTE and 200 J monophasic damped sine shocks (MDS) in the electrophysiology lab, delivered from modified LIFEPAK 7 defibrillators (an early defibrillator cleared under 510(k) K810154, but modified to have the same BTE waveform as the LIFEPAK CR Plus and LIFEPAK EXPRESS).

Methods

VVF was induced in 154 patients. After 19±10 seconds of VF, a randomized transthoracic shock was administered. Mean first shock success rate for the three (3) groups were compared.

Results

First shock VF termination rates were 61/68 (90%) for the 200 J monophasic, 39/39 (100%) for the 200 J biphasic, and 39/47 (83%) for the 130 J biphasic shocks.

Conclusion

The 200 J biphasic shocks were superior in first-shock efficacy to both 200 J MDS shocks and 130 J BTE shocks. There were no significant differences in hemodynamic parameters between the three (3) groups after successful shocks. The 200 J biphasic shocks were more effective than monophasic and the 130 J BTE shocks and may allow earlier termination of VF in cardiac arrest patients.

CLINICAL SUMMARY: 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.

CLINICAL SUMMARY: PEDIATRIC DEFIBRILLATION - ANIMAL STUDY

To support a pediatric indication for use for the ADAPTIV™ biphasic waveform, Physio-Control submitted an animal study to the FDA as part of a 510(k) submission (K022732). The results of the animal study were submitted in the test report titled “Pediatric Defibrillation Dosing Summary: Summary of Results” as well as a published article (“Attenuated adult biphasic shocks compared with weight-based monophasic shocks in a swine model of prolonged pediatric ventricular fibrillation”).

The safety and effectiveness of monophasic 2-4 J/kg and attenuated biphasic shocks (ADAPTIV biphasic waveform) were studied in the resuscitation of 48 immature swine from 7 minutes of untreated ventricular fibrillation. The weights of the animals studied were representative of the weights of newborn, 3-year-old, and 8-year-old children.

In this animal model of pediatric cardiac arrest, the attenuated biphasic shocks were superior to the monophasic 2-4 J/kg shocks in two (2) ways: (1) they provided a significantly higher survival rate and (2) they were associated with significantly better cardiac function 4 hours after the cardiac arrest. Furthermore, fewer biphasic than monophasic shocks were required during the resuscitation of these animals.

CLINICAL SUMMARY: PEDIATRIC DEFIBRILLATION - POSTMARKET SURVEILLANCE STUDY

In addition to the above animal study, Physio-Control included a postmarket surveillance study to support the safety and effectiveness of pediatric defibrillation using the proposed devices. The Infant/Child Electrode postmarket surveillance study was initiated in February 2003 and ended in February 2006. The goal of the surveillance activity was to characterize device performance, usage patterns, and customer acceptance of the Infant/Child Electrodes and to identify any unforeseen performance characteristics that could potentially impact the safe and effective use of the attenuated energy Infant/Child Electrode.

The incidence of pediatric cardiac arrest is relatively low in comparison to that of the adult population. Accordingly, a low usage rate of Infant/Child Electrodes was anticipated during the surveillance period. The surveillance incorporated two (2) endpoints, 50 uses or 3 years, whichever was achieved first. During the 3-year surveillance period, Physio-Control received 21 reports: 19 confirmed uses of the Infant/Child Electrodes with AEDs and two (2) attempts to use the Infant/Child Electrodes with incompatible products. A use was defined as the application of Infant/Child Electrodes to a patient during a resuscitation attempt with or without electrical therapy. Most of the uses involved electrode application appropriate to the age/weight labeling, specifically up to 8 years old or up to 25 kg (55 lbs); two (2) other uses occurred with children at the upper end of the labeled age range who exceeded the electrodes' weight range category. The Physio-Control defibrillation shock terminated VT/VF in all patients treated.

POTENTIAL ADVERSE EFFECTS

Below is a list of potential adverse effects (for example, complications) associated with the use of the device.

- Failure to identify shockable arrhythmia
- Failure to deliver a defibrillation shock in the presence of VF or pulseless VT, which may result in death or permanent injury
- Inappropriate energy delivery which could cause failed defibrillation or post-shock dysfunction
- Myocardial damage
- Fire hazard in the presence of high oxygen concentration or flammable anesthetic agents
- Electromagnetic interference from the defibrillator impacting other devices especially during charge and energy transfers
- Incorrectly shocking a pulse-sustaining rhythm and inducing VF or cardiac arrest
- Bystander shock from patient contact during defibrillation shock
- Interaction with pacemakers
- Skin burns around the electrode placement area
- Allergic dermatitis due to sensitivity to materials used in electrode construction
- Minor skin rash

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 CR Plus and LIFEPAK EXPRESS 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 appendix.

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 CR Plus and LIFEPAK EXPRESS defibrillators 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 CR Plus and LIFEPAK EXPRESS defibrillators 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

Shockable

- Coarse ventricular fibrillation (VF) (≥0.20 mV peak-to-peak amplitude)
- Rapid ventricular tachycardia, pulseless (VT) (HR ≥120 bpm, QRS duration ≥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 CR Plus and LIFEPAK EXPRESS defibrillators are shown below in the context of requirements from IEC 60601-2-4 and the recommendations from the American Heart Association.

Table B-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
Posititve Predictive Value	Report Only	>90%
False Positive Rate	Report Only	<5%

Table B-2 AHA Recommendations and SAS Performance for Adult and Pediatric Patients

Rhythm Category	Performance Goal	Minimum Sample Size	Sample Size Tested	Test Result (Goal and Sample Size)
Shockable (Sensitivity)				
Coarse VF	>90%	200	261	Met
Rapid VT, pulseless	>75%	50	65	Met
Nonshockable (Specificity)	None	300		Met
Normal Sinus Rhythm	>99%	100	578	Met
Other QRS	>95%	30	1251	Met
Asystole	>95%	100	184	Met
Intermediate				
Fine VF	Report Only	25	33	>40% shocked
Other VT	Report Only	25	27	>20% shocked

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

Table B-3 IEC 60601-2-4 Requirements and SAS Performance for Pediatric Patients

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

Table B-4 SAS Performance for Pediatric Patients

Rhythm Category	Performance Goal	Sample Size Tested	Test Result (Goal)
Shockable (Sensitivity)			
Coarse VF	>90%	63	Met
Nonshockable (Specificity)	None		Met
Normal Sinus Rhythm	>99%	69	Met
Other QRS	>95%	507	Met
Asystole	>95%	60	Met

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 B-5 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 automatically delivers a shock or 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 victim motion independent of ECG analysis. MOTION DETECTION can be configured to be ON or OFF. Refer to Section 6, "Defibrillator Operating Settings".

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.

*Behavior may vary for Arabic, Finnish, Icelandic, and Slovenian.

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

USER'S CHECKLIST

This User's Checklist may be reproduced.

LIFEPAK CR® PLUS LIFEPAK EXPRESS® DEFIBRILLATOR

USER'S CHECKLIST

Unit Serial Number _____

Department/Location _____

Instruction	Recommended Corrective Action	Date							
		Initials							
1 Check readiness display for:									
OK indicator	None.								
CHARGE-PAK indicator	Replace CHARGE-PAK™ Battery Charger and QUIK-PAK™ Electrode Packet.								
ATTENTION indicator	Refer to operating instructions.								
WRENCH indicator	Contact authorized service personnel.								
2 Check Use By date on all Electrode Packets.	Replace electrode packet and CHARGE-PAK if date passed.								
3 Check additional supplies.	Replenish as needed.								
4 Check defibrillator for:									
Damage or cracks	Contact authorized service personnel.								
Foreign substances	Clean the device.								
5 Other:									

APPENDIX D

ELECTROMAGNETIC COMPATIBILITY GUIDANCE

Table D-1 Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use in the electromagnetic environment specified below. The customer or the user of the defibrillator should ensure that the defibrillator is used in such an environment.		
Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The 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 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	

Essential Performance

The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators maintain safe and effective performance of the defibrillation therapy and patient monitoring functions when operated in the electromagnetic environment specified in Tables 2 through 4.

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.

Table D-2 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use in the electromagnetic environment specified below. The customer or the user of the defibrillator should ensure that the defibrillator is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	The 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	<5 % U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5 % U_T (>95% dip in U_T) for 5 s	Not Applicable	Not Applicable
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Table D-3 Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
The LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators are intended for use in the electromagnetic environment specified below. The customer or the user of the defibrillator should ensure that the defibrillator is used in such an environment.			
			Portable and mobile RF communications equipment should be used no closer to any part of the defibrillator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands*	Not Applicable	Not Applicable
	10 Vrms 150 kHz to 80 MHz in ISM bands*	Not Applicable	Not Applicable
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ for specified frequencies in the range 800 MHz to 2.5 GHz $d = 7.7\sqrt{P}$ 870 MHz to 900 MHz Where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m).† Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,‡ should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

* 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 compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

‡ Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitter, an electromagnetic site survey should be considered. If the measured field strength in the location in which the defibrillator is used exceeds the applicable RF compliance level above, the defibrillator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the defibrillator.

Table D-4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the LIFEPAK CR Plus and LIFEPAK EXPRESS defibrillators

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

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	80 MHz to 870 MHz, 900 MHz to 2.5 GHz $d = 2.3\sqrt{P}$	870 MHz to 900 GHz $d = 7.7\sqrt{P}$
0.01	Not Applicable	0.12	0.23	0.77
0.1	Not Applicable	0.38	0.73	2.43
1	Not Applicable	1.2	2.3	7.7
10	Not Applicable	3.8	7.3	24.3
100	Not Applicable	12	23	77

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

Note 3: An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note 4: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

INDEX

Physio-Control, Inc.
11811 Willows Road NE
Redmond, WA 98052 USA
Telephone: 425.867.4000
Fax: 425.867.4121
www.physio-control.com

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards
NSW 2065
Australia

Physio-Control, Inc., 11811 Willows Road NE, Redmond, WA 98052 USA

EC REP Physio-Control Operations Netherlands B.V., Galjoenweg 68, 6222 NV Maastricht, The Netherlands

CE 0123

Publication date: 01/2018

PN 3201686-034