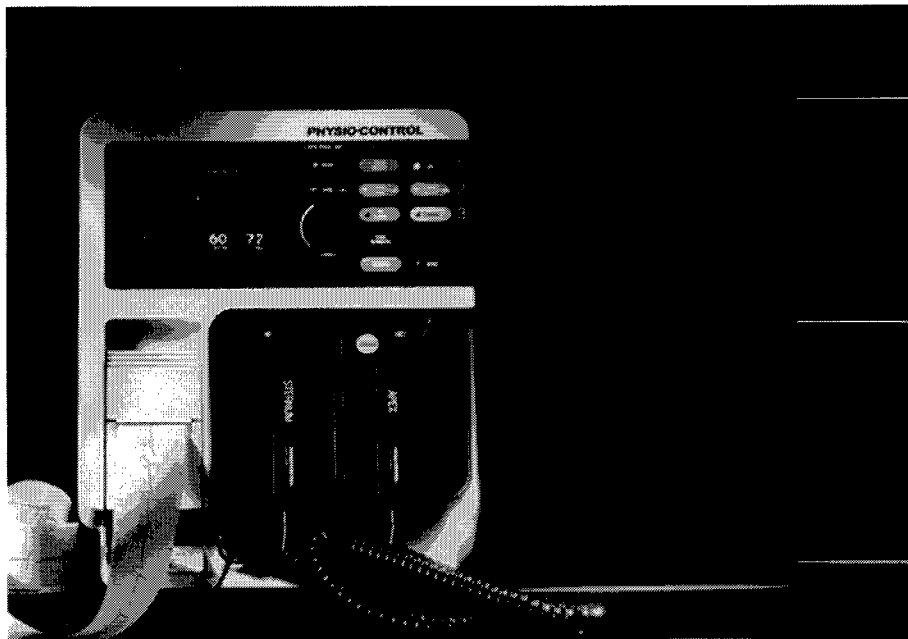


LIFEPAK® 9P

defibrillator/monitor/pacemaker

PHYSIO
CONTROL



LIFEPAK® 9P
defibrillator/monitor/pacemaker

**PHYSIO
CONTROL**

IMPORTANT

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

This instrument is to be used by authorized medical personnel only.

Device Tracking:

(USA only, including US government-owned units)
Under the Safe Medical Devices Act of 1990, defibrillator manufacturers and distributors are required to track the location of defibrillators. If your defibrillator has been sold, donated, lost, stolen, exported, or destroyed or if it was not obtained directly from Physio-Control, please notify Physio-Control at 1-800-442-1142, extension 4530.

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P/N 805455-003

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General Information

This manual provides information on the operation of the LIFEPAK® 9P defibrillator/monitor/pacemaker. This information is distributed in the following sections:

Section 1 Safety Information

This section contains general warnings which help the user operate the LIFEPAK 9P defibrillator/monitor/pacemaker safely.

Section 2 Basic Operations

This section provides descriptions of the basic operations of the LIFEPAK 9P defibrillator/monitor/pacemaker.

Section 3 Monitoring the Patient

This section describes patient monitoring with standard paddles and electrodes.

Section 4 Recording Patient Data

This section describes the recording feature of the LIFEPAK 9P defibrillator/monitor/pacemaker.

Section 5 Defibrillation and Pacing

This section provides information on patient defibrillation, synchronized cardioversion, and pacing.

Section 6 Maintaining the Equipment

This section describes periodic tests to help detect potential problems in a timely fashion.

Section 7 Appendices/Change Summary

This section contains supplemental information and a listing of all revisions to the manual.

Section 8 Index

The index provides a cross-reference of information in the manual.

The following sections provide a brief overview of the basic functions of the LIFEPAK 9P defibrillator/monitor/ pacemaker.

About Defibrillation

The LIFEPAK 9P defibrillator/monitor/pacemaker is a therapeutic medical device intended for use by or under the direction or guidance of a physician.

Direct current defibrillation is a recognized means of terminating certain potentially fatal cardiac dysrhythmias. A direct current defibrillator applies a brief, high-energy pulse of electricity to the heart. This energy may be delivered either through external paddles, electrodes on the chest, or through internal paddles applied directly to the heart.

Defibrillation is only one aspect of the medical care required to resuscitate a patient in ventricular fibrillation. Depending on the situation, other supportive measures may include:

- Establishment and maintenance of a patent airway
- Ventilation, including administration of oxygen
- Maintenance of blood circulation
- Pharmacologic measures

Among other factors, it is recognized that the likelihood of successful resuscitation of a patient is related to the length of time between the onset of ventricular fibrillation and defibrillation. Rapid defibrillation and prompt follow-up care are essential. The physiological state of the patient may affect the likelihood of successful defibrillation or skeletal muscle contractility. Thus, failure to convert the dysrhythmia or to resuscitate a patient is not a reliable indicator of defibrillator performance. Similarly, the patient's muscular response to the defibrillator shock is not a reliable indicator of the energy delivered. Refer to the "*Defibrillation: What You Should Know*" booklet for further information.

Daily testing is important to determine the state of readiness of the equipment. In addition, the device must be kept in proper operating condition at all times through routine maintenance and repair by a qualified service technician. Refer to the Service Manual for further service information.

About Pacing

Noninvasive pacing is a means of treating symptomatic bradycardia and asystole. A noninvasive pacemaker is a device which delivers an electrical stimulus to the heart causing cardiac depolarization and myocardial contraction. The energy is delivered through large adhesive electrodes placed on the chest. In addition to noninvasive pacing, other supportive measures may be necessary.

Among other factors, it is recognized that successful pacing of a patient is related to the length of time between the onset of a dysrhythmia and the initiation of pacing. Rapid pacing and prompt follow-up care are essential. The physiologic state of the patient may affect the likelihood of successful pacing or of skeletal muscle activity. The failure to successfully pace a patient is not a reliable indicator of pacemaker performance. Similarly, the patient's muscular response to pacing is not a reliable indicator of energy delivered. Refer to the *"Noninvasive Pacing: What You Should Know"* booklet for further information.

Symbols

The following symbols are found on various configurations of the LIFEPAK 9P defibrillator/monitor/pacemaker and accessories:



Off (power: disconnection from the ac mains)



On (power: connection to the ac power source)



Defibrillation protected, type BF patient connection



Defibrillation protected, type CF patient connection



Attention, consult accompanying documents.



Caution, high voltage



Protective earth (ground)



Fusible link



Equipotentiality connector



Recycle battery symbol



Output



AC current



ECG Out

Safety Information

1

Introduction

This section contains general warnings which help the user operate the LIFEPAK® 9P defibrillator/monitor/pacemaker safely. Become familiar with the following terms and General Warnings.

Terms

Terms used in this manual and on the LIFEPAK 9P defibrillator/monitor/pacemaker:

Danger: Immediate hazards which will result in serious personal injury or death.

Warning: Hazards or unsafe practices which could result in serious personal injury or death.

Caution: Hazards or unsafe practices which could result in minor personal injury or product/property damage.

Warnings

In addition to the following general warnings, other warnings are provided near the beginning of each section. Refer to Section 7, Appendix A for additional safety information.

⚠ WARNINGS

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

Shock or fire hazard. Do not immerse any portion of this device in water or other fluids. Avoid spilling any fluids on device or accessories.

Do not clean with alcohol, ketones, or other flammable agents. Do not autoclave this device or accessories unless otherwise specified.

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

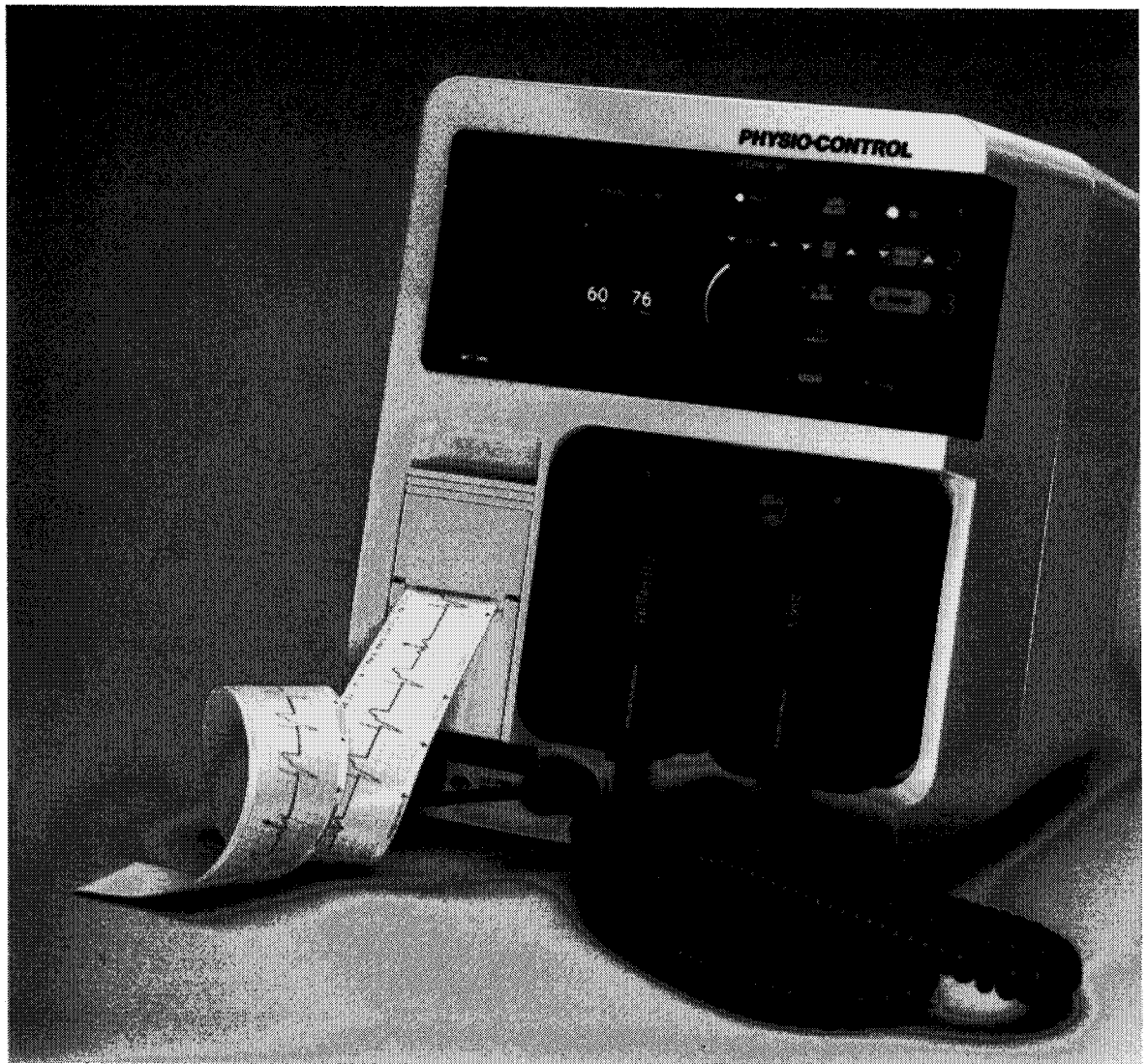
Safety risk. Use of non-Physio-Control defibrillation electrodes, batteries, accessories, or adapter devices may cause the device to operate improperly.

Possible interference with implanted devices. Magnets inside the standard defibrillation paddles may affect the function of an implanted pacemaker or implanted defibrillator if paddles are positioned over or near implanted devices. Have function of implanted device checked after using standard paddles.

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

2

Basic Operations



Introduction

The LIFEPAK 9P defibrillator/monitor/pacemaker is a complete cardiac life support system for crash cart needs used by hospital staff and other authorized healthcare providers.

This device is intended for use in the diagnosis and treatment of certain cardiac dysrhythmias. Refer to American Heart Association (AHA) or equivalent guidelines regarding standards of care for defibrillation, synchronized cardioversion, and pacing. The LIFEPAK 9P defibrillator/monitor/pacemaker offers the following options and features:

Pacing

The built-in noninvasive pacemaker allows switching between demand and non-demand pacing at the touch of a button, without the loss of valuable ECG information.

**CODE SUMMARY™
Critical Event Record**

Automatically stores, documents, and summarizes critical events. These events include defibrillation, cardioversion, pacing, heart rate alarm violations, and operator-selected ECG segments for concise, time saving documentation.

Programmable Options

These options offer flexibility through programmable feature selection. Factory, service or biomedical personnel may select options for diagnostic recording, lead available at power up, language, and others.

Heart Rate Alarms

An audible alarm informs clinicians of deviations outside the selected range of heart rate limits.

Shock Advisory Adapter

The Shock Advisory Adapter allows health care providers to use any of the LIFEPAK 9 family of defibrillators as Automatic External Defibrillators (AEDs). The Shock Advisory Adapter identifies shockable rhythms and provides messages on the monitor screen to guide first responders through proper operation of the defibrillator.

Defibrillation Adapter

The adapter provides discharge capability from the LIFEPAK 9P defibrillator/monitor/pacemaker using several paddle options.

Paddle Options

Physio-Control offers six different paddle options in addition to the standard hard paddles. These options allow clinicians to provide defibrillation therapy in a broad range of settings and can simplify the delivery of therapy. Standard hard paddles and the following three paddle options plug directly into the defibrillator:

- Pediatric paddles (attach to standard hard paddles)
- Posterior paddle (attaches to standard hard paddles)
- Internal paddles and handles *with* discharge control.

Each of the following paddle options must be used with the Defibrillation Adapter:

- FAST-PATCH® disposable defibrillation/ECG electrodes
- External sterilizable paddles
- Internal paddles and handles *without* discharge control.

Service Diagnostics

Device self-diagnostics automatically alert the operator at power up and during operation when certain service needs are identified. Defibrillation usage history is also automatically stored, and calibration is possible through onscreen tests which can be accessed by service or biomedical personnel.

Post-Sale Support

Physio-Control has one of the largest sales and technical service teams in the industry. Physio-Control responds to service calls as quickly as possible. Arrangements are made to perform repairs or a loaner is provided. Local sales and service representatives are available worldwide to offer support for inservicing and technical needs.

Educational Support

With each LIFEPAK 9P defibrillator/monitor/pacemaker, our customers receive an inservice videotape and a copy of our educational booklet “*Defibrillation: What You Should Know*” and “*Noninvasive Pacing: What You Should Know*.” For further information, contact your Physio-Control sales consultant.

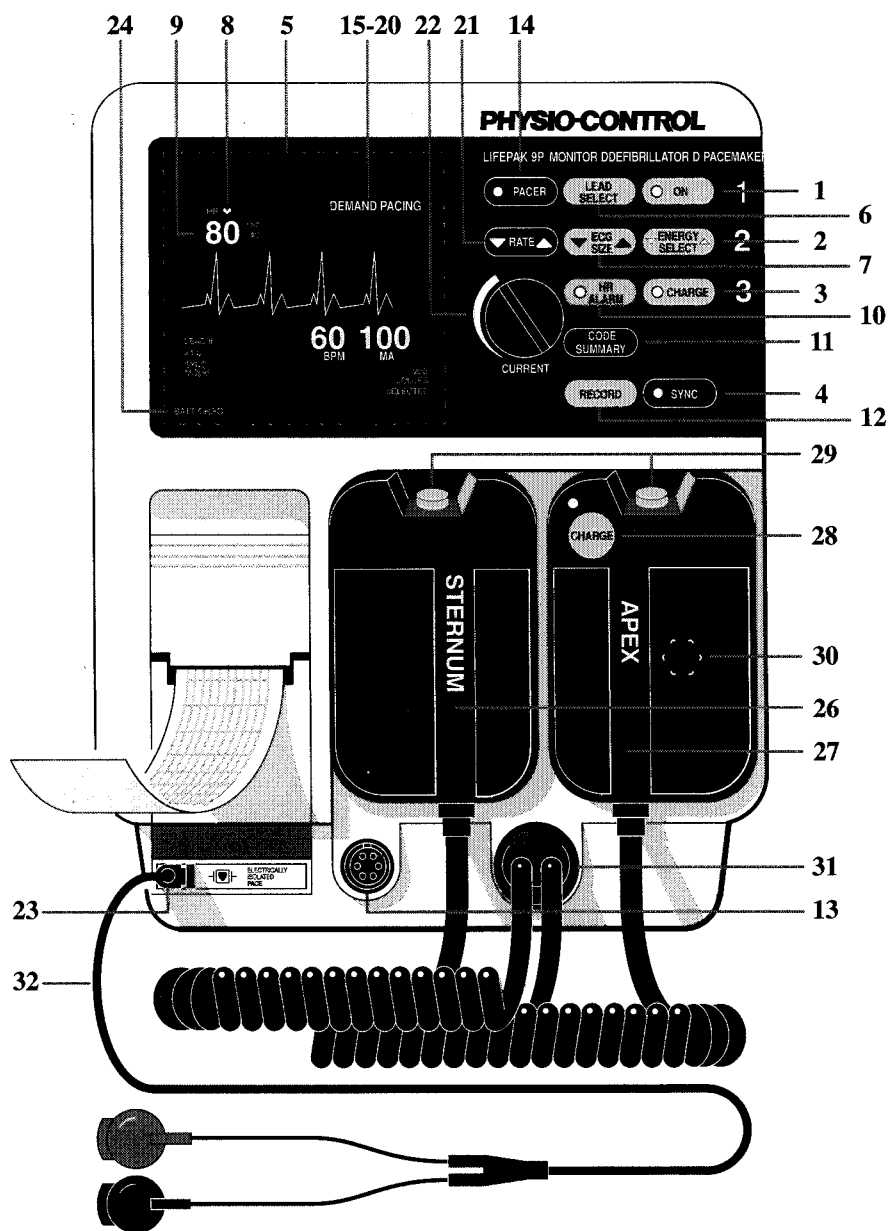


Figure 2-1 Front panel view (representation only)

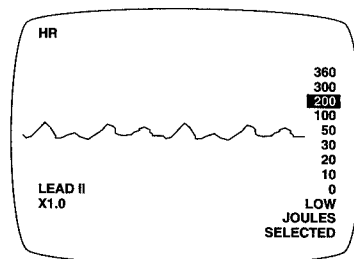
Controls and Indicators

This section describes the controls and indicators found on the LIFEPAK 9P defibrillator/monitor/pacemaker. Their locations are noted on Figure 2-1 and Figure 2-2. Table 2-1 and Table 2-2 contain operation descriptions.

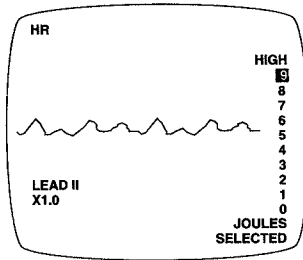
Table 2-1 Front panel controls and indicators

1	ON	Button activates the instrument. Indicator light shows power on status. (For IEC devices, ac power selection is controlled via MAINS POWER switch on rear panel.)
2	▼ ENERGY SELECT ▲	<p>Button selects energy levels. Energy levels appear on right side of the monitor screen. Two ranges, high and low, are available. Energy level selected is highlighted on monitor screen. At power on, 200 joules is selected with standard paddles (defaults to 10 joules when internal defibrillation handles are installed).</p> <p>Energy selection range stays on screen for 10 seconds following the last energy level selected or until another button is pressed.</p>

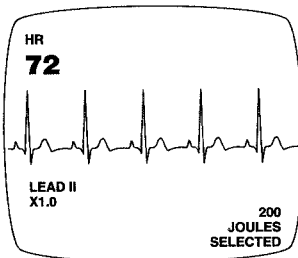
High Range Energy Select



High range energy display shows LOW, 0, 10, 20, 30, 50, 100, 200, 300, and 360 joules. When in high range, selecting the LOW setting causes the low energy selection range to appear.

Table 2-1 Front panel controls and indicators, *continued***Low Range Energy Select**

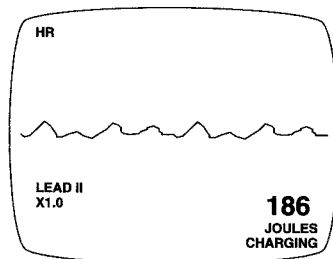
Low range energy display shows 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, and HIGH joules. When in low range, selecting HIGH setting causes the high energy selection range to appear.

JOULES SELECTED Message

Message appears in lower right corner of the monitor screen indicating the number of joules selected. At power on, 200 joules is selected with standard paddles (defaults to 10 joules when internal defibrillation handles are installed).

3 CHARGE

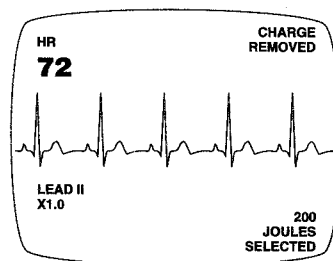
Button initiates defibrillator charge cycle. Button indicator light flashes when device is charging and glows steadily when selected energy is reached. Charged energy is available for approximately one minute.

Table 2-1 Front panel controls and indicators, *continued***JOULES CHARGING Message**

Message appears in lower right corner of the monitor screen while defibrillator charges. Increasing numbers indicate energy level as defibrillator charges.

**JOULES AVAILABLE Message
(not shown)**

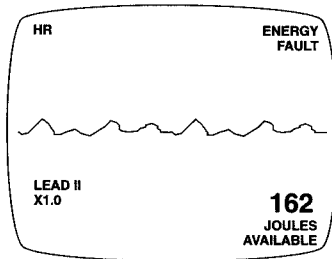
Message appears in lower right corner of the monitor screen when defibrillator is charged to selected energy. Message is accompanied by a charge complete tone. The amount of stored energy appears in bold numbers above JOULES AVAILABLE message.

CHARGE REMOVED Message

When defibrillator charge is no longer available, the CHARGE REMOVED message appears in the upper right corner of the monitor screen for five seconds.

If standard or optional paddles become disconnected when device is charging or charged, energy is removed and CHARGE REMOVED message is displayed for five seconds or until CHARGE is pressed again.

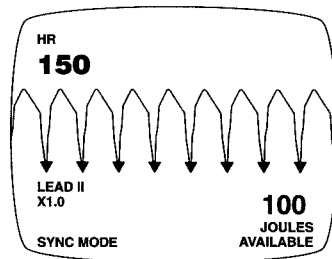
If defibrillator is charging or charged, pressing ENERGY SELECT causes the charge to be removed. A CHARGE REMOVED message will appear in the upper right corner of the monitor screen for five seconds or until CHARGE is pressed again.

Table 2-1 Front panel controls and indicators, *continued***ENERGY FAULT Message**

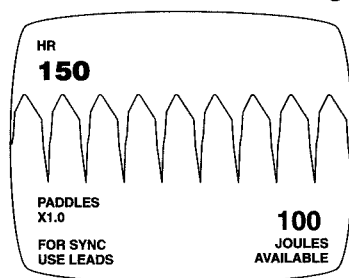
If selected energy and stored energy disagree, a flashing ENERGY FAULT message appears in the upper right corner of the monitor screen, accompanied by an audible tone. Message remains until energy is delivered or removed automatically (after approximately 60 seconds), new energy is selected, or power is turned off. Message indicates that system requires examination by a qualified service technician. If the defibrillator is discharged into open air, the ENERGY FAULT message appears accompanied by an audible tone. (This applies to LIFEPAK 9P defibrillator/monitor/pacemakers with P/N 805460-16 and higher or P/N 805460-01 devices with the automatic printing upgrade, P/N 805460-02 devices with serial number 4484 or higher, or P/N 805460-10 with serial number 4430 or higher.)

4 SYNC

Button selects synchronized mode and indicator light illuminates. Whenever a QRS is detected the indicator light flashes. To return to defibrillate (asynchronous) mode, press SYNC again.

SYNC MODE Message

Message appears in lower left corner of the monitor screen when sync mode is selected. Sync markers (▼) appear on each detected QRS.

Table 2-1 Front panel controls and indicators, *continued***FOR SYNC: USE LEADS Message**

While monitoring with standard paddles, message appears in lower left corner of the monitor screen when sync mode is attempted. Message flashes for three seconds, accompanied by three short tones. Sync mode is not activated.

- | | | |
|----------|------------------------|--|
| 5 | Monitor Screen | Monitor screen has a non-fade display. ECG trace moves from right to left. |
| 6 | ▼ LEAD SELECT ▲ | Button selects ECG input: Standard (STD), PADDLES, and LEADS I, II, III. Press to advance one position. SETUP menu (described in Service Manual) allows selection of LEAD II or PADDLES as the default lead setting available at power on. Alphanumerics on screen indicate lead selected. |
| 7 | ▼ ECG SIZE ▲ | Control adjusts vertical size of ECG trace on monitor screen and recorder. X1.0 gain selected automatically at power on. Alphanumerics on screen quantify actual gain selected from 0.2 cm/mV to 4.0 cm/mV. |
| 8 | ♥ | QRS sense symbol (♥) flashes when QRS is detected. |
| 9 | Heart Rate | Digital display of heart rate from 20-300bpm. |

Table 2-1 Front panel controls and indicators, *continued*

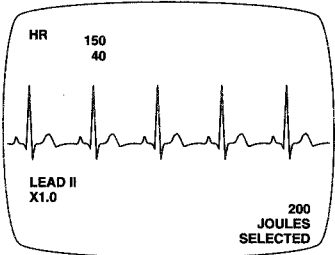
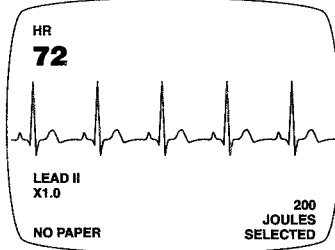
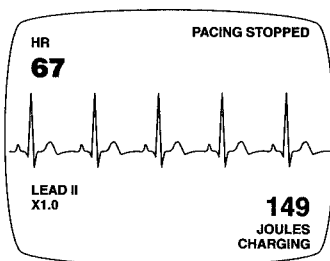
10	HR ALARM	<p>Button turns alarms on and off and selects high-low alarm limit settings of 150-40, 120-60, or 160-90. Indicator light illuminates when alarms are set. Preselected settings may be adjusted via the SETUP menu (refer to Service Manual).</p> <p>Alphanumeric on screen indicate selected high and low limits: a violated limit flashes and is accompanied by an alarm tone.</p>
 <p>The image shows a rectangular monitor screen. In the top left corner, 'HR' is displayed above the numbers '150' and '40'. The '150' is larger and appears to be flashing. In the bottom left corner, 'LEAD II' and 'X1.0' are displayed. In the bottom right corner, '200' and 'JOULES SELECTED' are displayed. A continuous ECG waveform is visible across the center of the screen.</p>		<p>Button prints summarized documentation of critical events: pre- and post- defibrillation/cardioversion ECG, pacing, heart alarm violations, and selected recorded ECG segments.</p>
11	CODE SUMMARY	<p>Button prints ECG on ECG paper designed for thermal array recorders. Pressing the RECORD button annotates time, date, ECG lead, ECG gain, heart rate, defibrillation, pacing, and heart rate alarm when violated.</p>
12	RECORD	<p>The NO PAPER message flashes in the lower left corner of the monitor screen accompanied by three short tones whenever ECG paper is depleted and RECORD or CODE SUMMARY is pressed.</p>
<p>NO PAPER Message</p>  <p>The image shows a rectangular monitor screen. In the top left corner, 'HR' is displayed above the number '72'. In the bottom left corner, 'LEAD II' and 'X1.0' are displayed. In the bottom right corner, '200' and 'JOULES SELECTED' are displayed. In the bottom left corner, 'NO PAPER' is displayed. A continuous ECG waveform is visible across the center of the screen.</p>		

Table 2-1 Front panel controls and indicators, *continued*

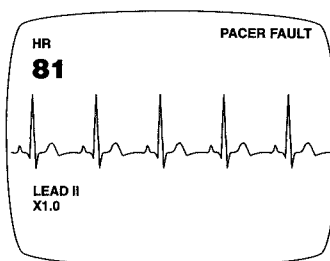
13	Patient ECG Cable Connector	Connector links the Physio-Control 3-lead 6-pin patient ECG cable to the electrodes.
14	PACER	<p>Button turns pacemaker power and indicator light on. Pacemaker power can be turned off by:</p> <ul style="list-style-type: none"> - pressing PACER button again. - pressing the ENERGY SELECT button. - pressing CHARGE. - pressing ANALYZE or CHARGE on the Shock Advisory Adapter.
15	DEMAND PACING Message	Message appears in the upper right corner of the monitor screen when the LIFEPAK 9P defibrillator/monitor/pacemaker is in the demand mode. Sense markers appear on the intrinsic beats when the pacemaker is in demand mode.
16	NON-DEMAND PACING Message (not shown)	<p>Message appears in the upper right corner of the monitor screen when the LIFEPAK 9P defibrillator/monitor/pacemaker is in non-demand (asynchronous) mode. Non-demand mode is selected by pressing the NON-DEMAND button on the back panel.</p> <p>Demand mode is automatically selected when the pacemaker is powered on. Pacing also returns to demand mode if the NON-DEMAND button on the back panel is pressed when the defibrillator/monitor/pacemaker is in non-demand (asynchronous) mode.</p>

Table 2-1 Front panel controls and indicators, *continued***17** PACING STOPPED Message

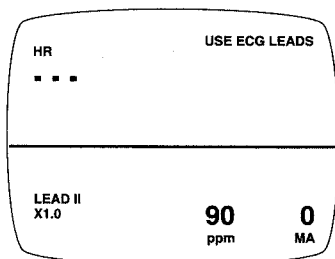
Message appears in the upper right corner of the monitor screen whenever pacing is halted by:

- pressing ENERGY SELECT.
- pressing CHARGE.
- pressing ANALYZE on Shock Advisory Adapter.
- reconnecting pacing cable or pacing electrode after PACING LEADS OFF.

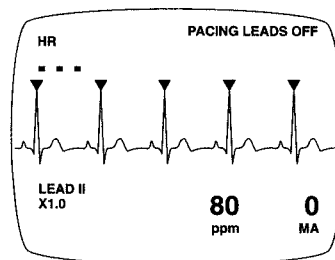
This message appears until another button is pressed, the action initiated is completed (e.g., energy becomes available), or pacing current is increased.

18 PACER FAULT Message

Message appears and flashes in the upper right corner if the self-diagnostic routines detect a fault. The pacemaker is inactive while the PACER FAULT message is displayed, although defibrillator/monitor function remains available. PACER FAULT messages indicate a condition requiring examination by a qualified service technician.

Table 2-1 Front panel controls and indicators, *continued***19** USE ECG LEADS Message

Message advises use of 3-lead patient ECG cable whenever PADDLES or STD lead is selected and PACER is pressed. Audible tone accompanies message. PADDLES or STD LEAD is automatically changed to LEAD II.

20 PACING LEADS OFF Message

Message appears whenever pacing cable or pacing electrodes become disconnected from the patient or when pacing current is increased without pacing electrode connected. An audible tone accompanies the message.

21 RATE

Button selects pacing rate: 40-170 pulses per minute (ppm) selectable in 10ppm increments. Press ▲ to increase rate; press ▼ to decrease rate. The LIFEPAK 9P defibrillator/monitor/pacemaker automatically defaults to 60ppm whenever pacemaker power is initiated. If pacing is interrupted because one or both of the pacing leads have been disconnected, the pacing rate retains its setting and the pacing current returns to 0mA.

Table 2-1 Front panel controls and indicators, *continued*

22	CURRENT	Rotary control knob increases or decreases pacing current. The current setting appears in the lower right corner of the monitor screen. The LIFEPAK 9P defibrillator/monitor/pacemaker automatically defaults to a current of 0mA whenever pacemaker power is turned on, pacing electrodes or cable become detached, or pacing is interrupted. Current is adjustable from 7 to 200mA in 1mA increments.
23	Pacing Cable Connector	Connector links the Physio-Control pacing cable to the electrodes.
24	BATT CHRG Indicator (yellow backlight)	When illuminated, the message indicates battery is charging and power source is ac line.
	LOW BATTERY: CONNECT AC POWER Message	Message appears in lower left corner of monitor screen, accompanied by three short tones every 20 seconds. Message indicates minimum battery reserve is available and ac power should be connected promptly. Message blanks when ac power is connected.

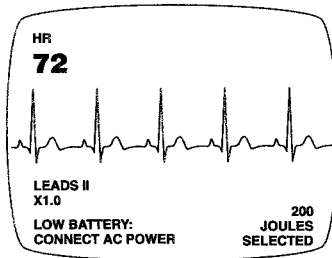
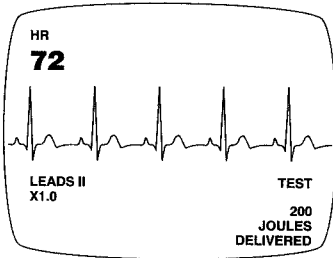


Table 2-1 Front panel controls and indicators, *continued*

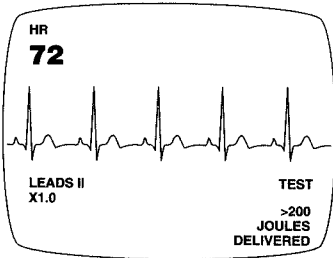
25	SERVICE Message (not shown)	Whenever a SERVICE message flashes in the lower left corner of the monitor screen, there is a condition requiring examination by a qualified service technician.
26	STERNUM Paddle	QUIK-LOOK® defibrillation paddle with one discharge button serves as negative ECG electrode during paddle monitoring.
27	APEX Paddle	QUIK-LOOK, QUIK-CHARGE® defibrillation paddle with second discharge button serves as positive ECG electrode during paddle monitoring.
28	CHARGE (QUIK-CHARGE Control)	Button charges defibrillator from APEX paddle. Button indicator light flashes during charge cycle and glows steadily when energy has reached preselected level.
29	Discharge Buttons	Buttons discharge defibrillator. <i>Both</i> buttons must be pressed <i>simultaneously</i> to deliver energy to the paddles. Energy will not be delivered unless device is fully-charged to preselected level.

Table 2-1 Front panel controls and indicators, *continued*

30	Test Load Contacts	Contacts supply 50 ohm defibrillator test load. Metal contacts under paddles receive defibrillation pulse from paddles and tests at 200 joules only.
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TEST 200 JOULES DELIVERED Message

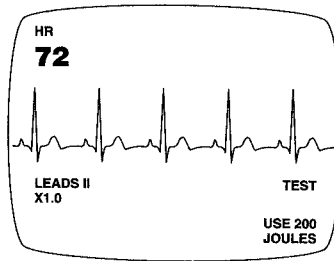
Message appears for five seconds in the lower right corner of the monitor screen, indicating successful completion of test. Recorder prints time, date, defibrillator mode, and TEST 200 JOULES DELIVERED.

TEST < 200 (or > 200) JOULES DELIVERED Message

Message appears in the lower right corner of the monitor screen, indicating test is unsuccessful. Recorder prints time, date, defibrillator mode, and TEST < 200 (or > 200) JOULES DELIVERED.

Table 2-1 Front panel controls and indicators, *continued***TEST USE 200 JOULES Message**

If test is attempted with energy levels other than 200 joules, message appears in the lower right corner of the monitor screen.

**31** Defibrillation Output
Connector

Connector connects the following directly into the defibrillator/monitor/pacemaker: Physio-Control standard hard paddles, internal handles with discharge control, Defibrillation Adapter, and Shock Advisory Adapter.

32 Pacing Cable

Cable, with snap connectors on end which attach to pacing electrodes, links pacemaker to electrodes.

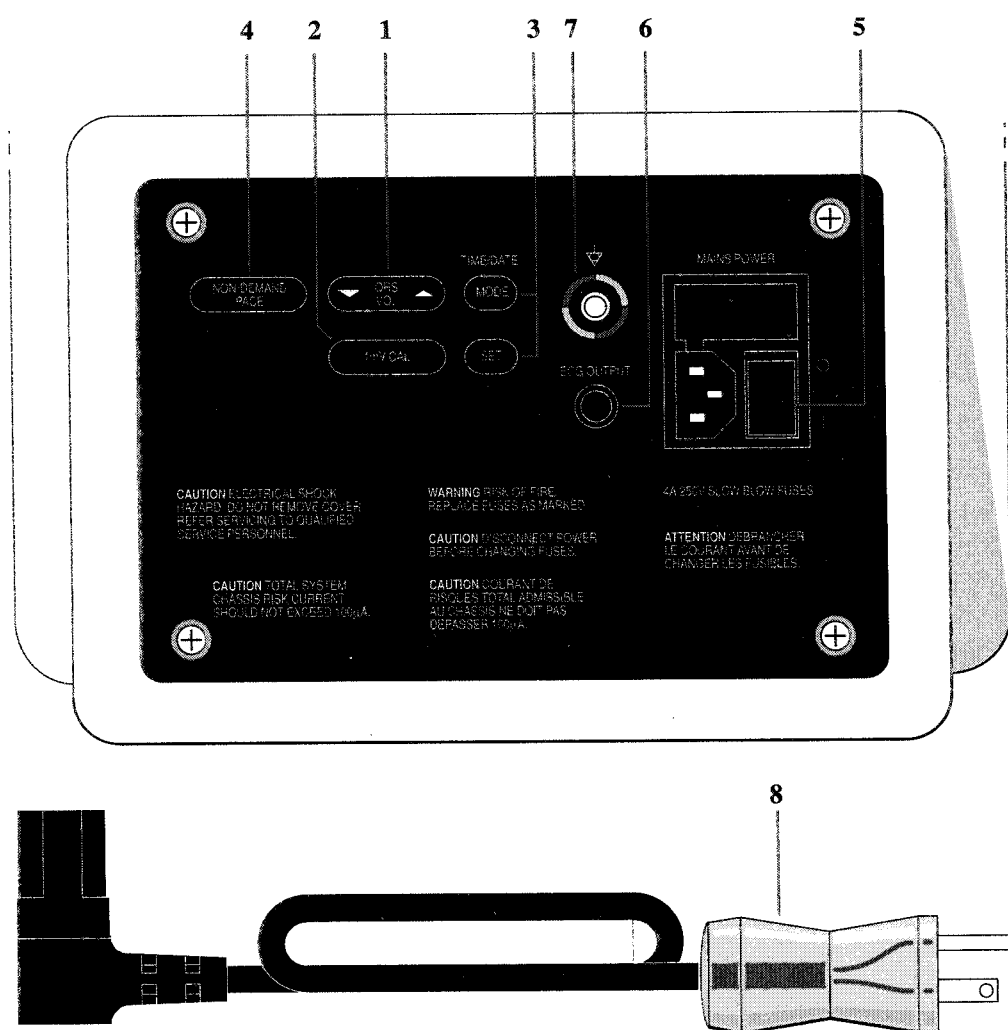


Figure 2-2 Rear panel view

Table 2-2 Rear panel controls and indicators

1	▼QRS VOL▲	Button adjusts the volume of systole “beeper”. Last setting remains in memory at power off.
2	1mV CAL	When pressed, button superimposes 1mV calibration signal on monitor screen and recorder.
3	TIME/DATE MODE and SET	Buttons set date and time.
4	NON-DEMAND PACING	Button selects non-demand (asynchronous) pacing when pressed. Press again to return the device to demand pacing.
5	MAINS POWER (IEC devices only)	Rocker switch selects ac line power with battery charging (ON or I position) or battery power with ac power off (O position). Battery will not charge if MAINS POWER switch is left in off or O position (refer to AC Line and Battery Operation, page 2-20 for more information). On USA devices, this switch is locked in ON or I position.
6	ECG OUTPUT	Label identifies ECG output (1V/1mV) source.
7	Ground	Label identifies equipotential ground tie point.
8	Power Cord	Cable connects to grounded ac receptacle. Check that label on bottom of instrument matches available voltage/frequency.

AC Line and Battery Operation

The LIFEPAK 9P defibrillator/monitor/pacemaker may be operated using ac line or dc battery power.

WARNING

Possible defibrillator shutdown. When operating on battery power, the large current draw required for defibrillator charging may cause the defibrillator to reach shutdown voltage levels with no low battery warning. If the defibrillator shuts down without warning, or if a LOW BATTERY CONNECT AC POWER message appears on the monitor screen, immediately connect the ac power cord to an outlet.

Refer to Section 7, Appendix A for additional safety information.

AC Operation

The LIFEPAK 9P defibrillator/monitor/pacemaker operates on ac line power when the power cord is connected to an ac outlet. IEC devices must also have the rear panel AC MAINS POWER switch set to I (ON). When the power cord is connected to an ac outlet, the battery charges and the BATT CHRG message on the monitor screen illuminates. When the device is not being used, the battery charge will be maintained if the power cord is connected to an ac outlet with the device power off.

Battery Operation

The LIFEPAK 9P defibrillator/monitor/pacemaker automatically operates on battery power when the power cord is disconnected from an ac outlet. A new, fully-charged battery will typically provide seventy-five 360 joule discharges, 75 minutes of pacing, or approximately 90 minutes of continuous monitoring before the device powers off.

When the LOW BATTERY CONNECT AC POWER message appears on the monitor screen, immediately plug power cord into an ac outlet to continue use; this supplies power and begins recharging the battery. Frequently occurring low battery messages indicate that the battery may need to be replaced.

Recharge fully-depleted batteries to full capacity whenever possible. A fully-depleted battery can be recharged to 90% capacity in three hours. Charge time to full capacity is 24 hours.

New batteries, or batteries which have been stored for a prolonged time, need to be charged by installing them in the LIFEPAK 9P defibrillator/monitor/pacemaker with the power cord plugged into an ac outlet.

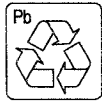
For further information regarding battery performance, see General Specifications, page 6-26.

Battery Life

The LIFEPAK 9P defibrillator/monitor/pacemaker has a sealed lead-acid battery which is intended to be used for standby operation and performs best when the device is plugged into an ac outlet when not in use. Frequent use of the battery when it is at minimum reserve capacity will reduce the battery life.

End of battery life is inevitable. As batteries age, their charge capacities diminish. Batteries should be replaced every two years as a preventive maintenance measure.

Recycling Batteries



In the USA, recycle batteries locally according to state, and local regulations when batteries are no longer useful. If local recycling is not possible, contact Physio-Control customer service specialists at 1-800-442-1142 for information on returning batteries.

Outside the USA, recycle batteries according to local regulations. Otherwise, contact the local Physio-Control service technician for information on returning batteries.

Setting the Clock

To set the clock:

- 1** Press ON.
- 2** Press TIME/DATE MODE button on rear panel. Day, month, year, hours, and minutes will be displayed in the lower left corner of monitor screen. The single minutes field will be highlighted.
- 3** Press TIME/DATE SET button on rear panel to change the single minute setting. Each time the button is pressed, the value of the field increases by one increment. When the maximum value for a field is reached, the display rolls over to the lowest value for that field.
- 4** Press MODE again to advance to next time/date field. Press SET to increase values. Repeat process to adjust year, month, and day.
- 5** After proper day has been selected, press MODE again to remove clock setting display from the monitor screen.
- 6** Confirm proper clock setting by pressing RECORD. The printed strip should include proper time/date annotation.

If any front panel button is pressed or the device is turned off while setting the clock, the clock set mode will be terminated without implementing any changes.

3

Monitoring the Patient

Monitoring the Patient

Patient ECG can be monitored with standard paddles using the QUIK-LOOK defibrillation paddle feature, the 3-lead patient ECG cable, or through FAST-PATCH disposable defibrillation/ECG electrodes. For information regarding disposable defibrillation electrodes refer to the Operating Instructions for defibrillation electrodes.

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

Refer to Section 7, Appendix A for additional safety information

WARNINGS

Safety risk. Use only Physio-Control ECG cables listed in this manual. Substitution of non-Physio-Control ECG cables may result in inaccurate ECG data.

Possible misinterpretation of monitor screen ECG data. The monitor screen frequency response is only intended for rhythm identification. Use the recorder in DIAG mode for diagnostic interpretations.

Possible misinterpretation of ECG recordings. When attempting to visually detect subtle ECG characteristics such as ST segment abnormalities, use the recorder only in diagnostic frequency response mode (DIAG). The recorder normally operates in monitor frequency response mode. It does not provide the resolution required for diagnostic and ST segment interpretation, and is intended only for basic ECG rhythm identification.

⚠ WARNING

Possible electrical interference with ECG monitoring. Do not operate this device in conjunction with electrocautery or diathermy equipment. Such equipment, as well as equipment which emits strong radio frequency signals, can cause electrical interference and distort the displayed or recorded ECG signal, thereby preventing accurate rhythm analysis.

Monitor Lead Mode

The monitor will power on in one of two leads as described below. The preselected lead (mode) may be selected by a qualified service technician using the SETUP menu.

- Mode 1: The monitor preselects PADDLES lead.
- Mode 2: The monitor preselects Lead II.

For information on how to change the modes, see the Service Manual, or contact a qualified service technician.

Standard Paddles Monitoring Procedure

To monitor through QUIK-LOOK paddles:

- 1** Press ON. The device performs a self-diagnostic test; all indicator lights and all status display messages illuminate momentarily.
- 2** Press LEAD SELECT to PADDLES position.
The device will preselect LEAD II whenever it is powered on. For information on how to change this selection to PADDLES, contact a qualified service technician.
- 3** Apply conductive gel over entire paddle electrode surface.
- 4** Place paddles firmly on patient's bare torso. The standard paddle placement is STERNUM to the patient's right upper torso below the clavicle and the APEX lateral to the patient's left nipple in the midaxillary line.
- 5** Observe monitor screen to evaluate patient's rhythm.

When the device is turned on, the ECG gain will be at X1.0. ECG SIZE may need to be adjusted if QRS complex is not clearly visible on monitor screen.

ECG monitoring after defibrillation is usually delayed by a defibrillation recovery time of a few seconds. During this time, it may not be possible to determine defibrillation results from the monitor trace.

Using the Three-Lead Patient ECG Cable

The LIFEPAK 9P defibrillator/monitor/pacemaker has a shielded 3-lead ECG cable. The cable allows patient monitoring of leads I, II, or III.

ECG Electrode Requirements

Electrode quality is critical for obtaining a clean ECG signal. Always check the date code on electrode containers for expiration date before patient use. Do not use electrodes with expired date codes.

For best ECG monitoring results, silver/silver chloride (Ag/AgCl) electrodes such as Physio-Control LIFE•PATCH® ECG electrodes should be used with this equipment. Post-defibrillation visualization of ECG on the monitor screen using silver/silver chloride electrodes will be much faster than with other electrode types.

Color Coding for ECG Leads

The lead wires are color coded according to AHA or IEC standards. When other lead configurations are desired, use the following information as a guide.

Table 3-1 ECG leads color codes

Lead	Bipolar Lead and Reference	AHA	IEC
I	RA Negative Electrode	White	Red
	LA Positive Electrode	Black	Yellow
	LL Reference	Red	Green
II	RA Negative Electrode	White	Red
	LA Reference	Black	Yellow
	LL Positive Electrode	Red	Green
III	RA Reference	White	Red
	LA Negative Electrode	Black	Yellow
	LL Positive Electrode	Red	Green

RA= Right Arm LA= Left Arm LL= Left Leg

When electrodes and lead wires are attached as above, leads I, II, or III are obtained by pressing LEAD SELECT.

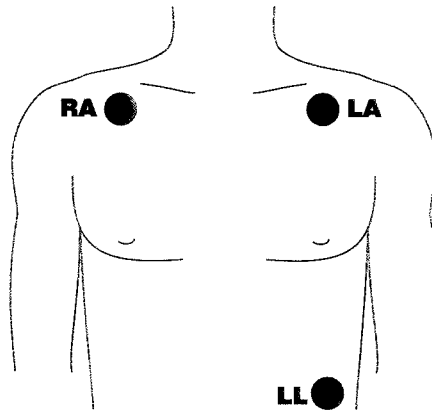


Figure 3-1 ECG electrode placement for leads I, II, and III

Skin Preparation

Monitoring results will be best when the skin electrode sites are properly prepared as follows:

- 1** Shave excessive hair at electrode site. Avoid locating electrodes over tendons and major muscle masses.
- 2** For oily skin, clean skin with alcohol pad and let dry completely.
- 3** Prepare site with brisk dry rub. Avoid damage or abrasion of skin surface.
- 4** Carefully tear open foil package and remove electrode carrier.
- 5** Attach lead wire to electrode.
- 6** Grasp electrode tab and peel electrode from carrier.
- 7** Apply to patient only if gel is in solid state.
- 8** Hold electrode taut with both hands. Apply the electrode flat to skin. Smooth tape outwardly in all directions. Do not press center of electrode.

ECG Cable Monitoring Procedure

To monitor the ECG cable:

- 1** Attach 6-pin ECG cable to ELECTRICALLY ISOLATED ECG connector located on the front panel.
- 2** Prepare patient's skin for electrode application and apply electrodes. Refer to Skin Preparation, above.
- 3** Press ON.
- 4** Press LEAD SELECT to select desired lead.
- 5** Adjust ECG SIZE if necessary. Size is automatically set to gain of X1.0 at power up. To properly count heart rate during routine monitoring and to accurately detect QRS complexes during synchronized cardioversion, the ECG size may need to be adjusted as follows:
 - Press QRS VOL ▲ or ▼ until audible.
 - Press ECG SIZE ▲ or ▼ until systole beeper coincides with every QRS complex.
 - Adjust QRS VOL ▲ or ▼ as desired.
- 6** Secure and support the ECG cable.

QRS Detection

QRS detection is essential for use of the digital heart rate display, systole tone (QRS VOL), synchronized cardioversion, and demand pacing.

The QRS detector in the LIFEPAK 9P defibrillator/monitor/pacemaker selectively detects QRS complexes. It discriminates against most noise, muscle artifact, T-waves, and other false signals.

Detection of QRS complexes and rejection of other signals depends on setting the ECG size control properly. If ECG size is set too low, QRS complexes will not be detected; no systole tones or sense (synchronizer) markers appear and heart rate display is incorrect. If ECG size is set too high, systole tones and sense (synchronizer) markers may occur on spurious signals and the heart rate display may be incorrect.

The LIFEPAK 9P defibrillator/monitor/pacemaker displays a heart rate between 20 and 300bpm. Patient rates outside this range do not yield valid systole tones or heart rate display. The heart rate is not displayed during pacing; instead, the symbol “---” appears during pacing.

Monitoring Patients with Invasive Pacemakers

WARNING

Possible interference with implanted devices.

Magnets inside the standard defibrillation paddles may affect the function of an implanted pacemaker or implanted defibrillator if paddles are positioned over or near implanted devices. Have function of implanted device checked after using standard paddles.

The LIFEPAK 9P defibrillator/monitor/pacemaker rejects most pacemaker pulses from internally-implanted pacemakers. It does not use the pacemaker pulse for heart rate calculation or synchronization. Large amplitude pacemaker spikes can overload the QRS complex detector circuitry so no paced QRS complexes are counted, resulting in blanking (heart rate displays “---”) of the heart rate display.

The following may be helpful to minimize ECG pickup of large pacemaker pulses when monitoring patients with internal pacemakers:

- Place ECG electrodes so a straight line drawn between the positive electrode and negative electrode intersects a line between the pacemaker generator and the heart at right angles. Electrode placement is not as critical when the pacemaker is bipolar.

- If internal pacemaker pulse artifact continues to disrupt the heart rate display or synchronizes function when monitoring with defibrillation electrodes and the Defibrillation Adapter, monitoring with the ECG cable may improve pacemaker pulse rejection.
- Smaller amplitude internal pacemaker pulses may not be visualized on the monitor screen and/or the recording strip in leads or paddles monitoring modes. To improve the visualization of internal pacemaker pulses on the recorder, try using the diagnostic mode. Refer to the LIFEPAK 9P defibrillator/monitor/pacemaker Service Manual or contact a qualified service technician to engage the diagnostic frequency response for the recorder.

Heart Rate Alarms

The factory settings for heart rate alarm limits for the LIFEPAK 9P defibrillator/monitor/pacemaker are: 150/40, 120/60, and 160/90bpm. These preset heart rate alarm limits are changeable and can be programmed by a qualified service technician using the SETUP menu. Heart rate alarms are not functional during pacing.

When an alarm limit has been violated, the violated limit flashes and a continuous alarm sounds. The recorder also automatically prints eight seconds of pre-alarm ECG data and eight seconds of post-alarm ECG data. The alarm tone will stop when the alarm limit is no longer being violated or HR ALARM is pressed again.

Setting Alarm Limits

To set the alarm limits:

- 1 Press HR ALARM. The button illuminates when alarm is on. The high-low limits appear beside the heart rate display.
- 2 While limits remain highlighted, press HR ALARM again to change high-low limits.
- 3 Press HR ALARM again to turn off or silence alarms.

4

Recording Patient Data

Recording Patient Data

The recorder is equipped with an out-of-paper sensor to protect recorder print head. The sensor automatically turns off recorder if it runs out of paper or if recorder door is opened.

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

Printing a Recording

Recording can be done in any lead selected. The recorder operates in an eight-second delayed ECG mode.

- 1** Press RECORD.
- 2** Adjust ECG SIZE if necessary.
- 3** Press RECORD to stop printing.

Recorder Annotation

The annotating recorder prints the following: time, date, ECG lead, ECG size, heart rate, defibrillation/synchronization, pacing parameters, heart rate alarm violations, test load data, and CODE SUMMARY record.

The beginning of each annotation is marked by the symbol ►. Updated annotation information prints every 20 seconds when recorder is on. Changes made in lead selection, sync mode, pacing parameters, or an activated heart rate alarm will update the annotation.

Discharging defibrillator while recorder is on updates time, date, joules, and synchronize (if selected) annotation.

Diagnostic Recording

If the diagnostic frequency response mode (DIAG) has been enabled during SETUP, the ECG signal will be recorded at a frequency response of 0.05 -100Hz.

Care of Recordings

To help prevent the ECG annotation and tracing from fading or disappearing, follow these guidelines for thermal sensitive paper:

- Do not apply tape or other adhesives over printed information (adhesives may be applied to back of the paper).
- Store only in paper folders; do not store or file with plastics; avoid storing in temperatures exceeding 26.7°C (80°F) and relative humidity exceeding 70%.
- Avoid extended exposure to sunlight.

Paper Loading

⚠ CAUTION

To load paper into the recorder (see Figure 4-1):

- 1 Pull out top of recorder; recorder will open for paper insertion.
- 2 Remove old paper roll.
- 3 Insert new paper roll with grid facing up.
- 4 Pull out a short length of paper.
- 5 Close recorder case. Press bottom recorder door up (see 1, Figure 4-1) and in and press top recorder door down (see 2, Figure 4-1).
- 6 Press RECORD to print and advance paper.

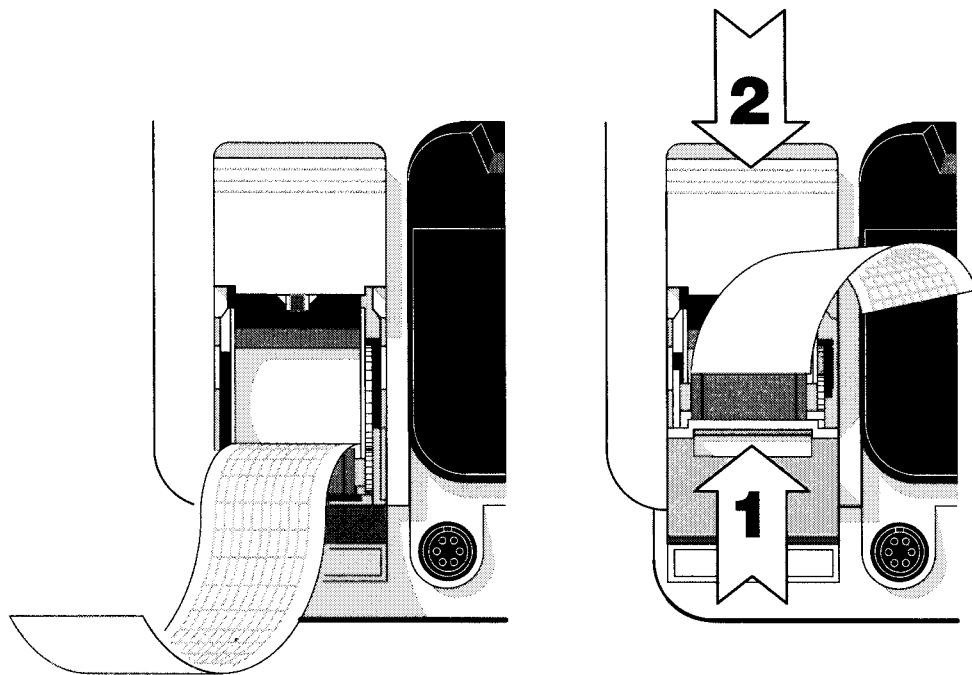


Figure 4-1 Loading paper into the recorder

CODE SUMMARY Critical Event Record

The CODE SUMMARY critical event record feature documents critical events during resuscitation. It records defibrillation and cardioversion details, operator-selected ECG segments, heart rate alarm ECG segments, and pacing events in chronological order. Resuscitation details are prioritized for retention of the most critical events.

The CODE SUMMARY record stores ECG data only in the monitoring frequency response mode. Test load data is not stored in the CODE SUMMARY memory.

Printing a CODE SUMMARY Record

To print a CODE SUMMARY record:

- 1** Press CODE SUMMARY to print a full report of information stored in memory.
- 2** To interrupt printing, press CODE SUMMARY again.

The CODE SUMMARY report will also be interrupted if RECORD is activated or if recorder paper is depleted.

If the CODE SUMMARY record is restarted after being interrupted, the report will be resumed at the previous event unless it was interrupted by paper depletion; in which case it prints a full report of information stored in memory.

For examples of the CODE SUMMARY record formats, refer to Section 7, Appendix B.

Event Storage**Storing Information**

The CODE SUMMARY feature automatically stores events whenever the device is powered on. These events include: defibrillation/synchronized cardioversion, pacing, heart rate alarm violations, and patient ECG segments. ECG segments are stored in the CODE SUMMARY record by pressing RECORD.

Conditions for Storing Events

The CODE SUMMARY feature will continue to store existing information and accept new information while the CODE SUMMARY record is printing. A standard recording can also be made while the CODE SUMMARY record is printing by pressing RECORD. This does not delete information already stored in the CODE SUMMARY record.

Automatic Printing

The CODE SUMMARY record is automatically printed when an attempt is made to power off the device and the CODE SUMMARY record has not previously been printed. The device will remain on until the ON button is pressed again. Press ON, after printing is complete, to power off the device.

To interrupt or stop automatic printing, press CODE SUMMARY. Because the stored data is now considered printed, the device will power off when ON is pressed again.

Pressing ON while the CODE SUMMARY record is printing will also power off the device.

The automatic printing feature applies to LIFEPAK 9P defibrillator/monitor/pacemakers with P/N 805460-16 and higher or P/N 805460-01 devices with the automatic printing upgrade, P/N 805460-02 devices with serial number 4484 or higher, or P/N 805460-10 with serial number 4430 or higher.

Erasing Events

When the device is powered off, the memory in the CODE SUMMARY record clears, erasing all stored events.

Event Storage Priority

The critical event memory stores information for approximately 20 ECG events (i.e., defibrillation, heart rate alarm violations, pacing, or recording), and 50 event preambles (annotation to the left of the ECG segment). Events are stored in chronological order.

If CODE SUMMARY memory is full, information is retained in the following priority:

- 1** First and last defibrillation event preambles with ECG segments.
- 2** Defibrillation and pacing event preambles only, without ECG segments.
- 3** Defibrillation and pacing event preambles with ECG segments.
- 4** Recorded ECG event preambles without ECG segments.
- 5** Recorded ECG event preambles with ECG segments.

To allow for preambles that have priority over ECG segments, ECG segments are erased in reverse chronological order.

5

Defibrillation and Pacing

Defibrillation

Defibrillation success depends upon many factors; only device operational factors are addressed here. Refer to the “*Defibrillation: What You Should Know*” booklet for additional information. (See page 6-22 for order information.)

This section covers defibrillation using standard paddles, pediatric paddles, and posterior paddle. For defibrillation using internal handles *with* discharge control, internal handles *without* discharge control, external sterilizable paddles, or FAST-PATCH disposable defibrillation/ECG electrodes, refer to the specific operating instructions for each paddle option.

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

For additional safety information, refer to Section 7, Appendix A.

WARNINGS

Shock hazard. When discharged, this defibrillator delivers up to 360 joules of electrical energy. Do not touch the paddle electrode surface or defibrillation electrodes.

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

⚠ WARNINGS**Possible burns and ineffective energy delivery.**

Do not allow physical contact between the ECG electrodes and the paddles, defibrillation electrodes, or defibrillation gel. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Shock hazard. Conductive gel (wet or dry) on the paddle handles can allow the electrical energy to discharge through the operator during defibrillation. Be sure to completely clean the paddle electrode surfaces, handles, and paddle storage area after defibrillation.

Possible skin burns. During defibrillation, air pockets between the skin and paddle electrode surfaces or defibrillation electrodes can cause patient skin burns. To help prevent air pockets, completely cover paddle electrode surfaces with conductive gel and press paddles firmly against the patient, or make sure self-adhesive defibrillation electrodes completely adhere to the skin. The conductive gel or electrodes must not be dried out.

Possible interference with implanted pacemakers.

When cardioversion or defibrillation is performed on patients with permanent pacemakers, care should be taken to avoid placing the paddles/defibrillation electrodes near the pacemaker's generator since defibrillation can cause pacemaker malfunction. Check pacing thresholds for implanted pacemaker patients.

Possible interference with implanted devices.

Check function of implanted devices after defibrillation or synchronized cardioversion.

Possible burns and ineffective energy delivery.

A gel pathway on the skin between the paddles will cause the current to arc between paddles and divert defibrillating energy away from the heart muscle. Do not allow conductive gel (wet or dry) to become continuous between paddle sites.

⚠ WARNINGS

Possible paddle damage and skin burns. Do not discharge the defibrillator with the paddle electrode surfaces together because this may pit or damage the paddle plate surfaces. Pitted or damaged paddle electrode surfaces can cause patient skin burns during defibrillation.

Shock hazard. Do not discharge the defibrillator into the open air. To remove an unneeded charge, press ENERGY SELECT or remove defibrillator power by pressing the ON button.

Paddle Options

The LIFEPAK 9 defibrillator/monitor standard paddles are for use on adults. They may also be used for any pediatric patient as long as the paddles fit completely on the chest and there is at least one inch of space between the paddle electrodes. Pediatric paddles should be used for patients whose chests cannot accommodate the space required for standard paddles.

Options that Connect to the Defibrillator

In addition to standard paddles there are six paddle options for special needs. The first three are color coded with *black* connectors and are plugged directly into the *black* defibrillator output connector.

- Pediatric paddles (attaches to standard hard paddles)
- Posterior paddle (attaches to standard hard paddles)
- Internal paddles and handles with discharge control.

Options that Connect to the Defibrillation Adapter

The next three options are color coded with *gray* connectors and require the use of the Defibrillation Adapter.

- FAST-PATCH disposable defibrillation/ECG electrodes
- External sterilizable paddles
- Internal paddles and handles without discharge control.

Each adapter and paddle option has its own Operating Instructions; refer to these instructions before use.

Paddle Placement

Anterior-Lateral

The standard paddle placement is (see Figure 5-1):

- STERNUM paddle to the patient's right upper torso, lateral to the sternum and below the clavicle
- APEX paddle lateral to the patient's left nipple in the midaxillary line, with the center of the paddle electrode in the midaxillary line if possible.

Anterior-Posterior

There are two possible anterior-posterior paddle placements.

The preferred position is to place the STERNUM paddle anteriorly over the left precordium and the APEX paddle posteriorly behind the heart in the infrascapular area.

An alternative is to place the STERNUM paddle over the cardiac apex and the APEX paddle on the patient's right posterior infrascapular area.

Special Placement Situations

Patients with implanted pacemaker. If possible, place paddles away from internal pacemaker generator to help prevent damage to the pacemaker.

Patients with implanted defibrillators. Apply paddles in the preferred placement, anterior-lateral (sternum-apex), and treat this patient as any other patient requiring emergency care. If defibrillation is unsuccessful, it may be necessary to increase the energy level or to use the alternate electrode placement (anterior-posterior) due to the insulative properties of implanted defibrillator electrodes.

Standard Paddles Defibrillation Procedure

When employing standard defibrillation paddles, a conductive interface designed for defibrillation such as defibrillation gel, paste, or gel pads must be used between the paddle electrode surface and the skin. Disconnect any equipment from patient which may be damaged by defibrillator shock. This may include external transvenous pacing devices.

- 1** Press ON. 200 JOULES SELECTED will appear in lower right corner of the monitor screen.
- 2** Apply defibrillation gel over entire paddle electrode surface.
- 3** If other than 200 joules is desired, press ENERGY SELECT and select the energy to be delivered.
- 4** Press CHARGE on defibrillator front panel or on APEX paddle. Indicator lights on CHARGE and APEX paddle will flash while device is charging. A JOULES CHARGING message will appear in lower right corner of the monitor screen. Increasing numbers indicate energy level as the defibrillator charges.
- 5** Place defibrillator paddles firmly on patient's chest.

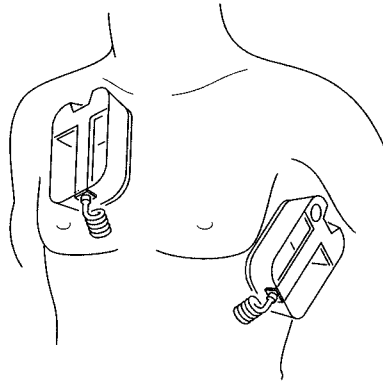


Figure 5-1 Anterior-lateral (sternum-apex) placement

- 6** Make certain all personnel, including operator, are clear of patient, bed, and any equipment that might be connected to patient.
- 7** Discharge defibrillator by simultaneously pressing both paddle discharge buttons when it reaches full charge. The defibrillator will not discharge until it completes charging to the selected energy level. If paddle discharge buttons are not pressed within 60 seconds, stored energy is removed automatically.
- 8** Observe patient and monitor screen to determine results. If additional countershock is necessary, repeat from step 3 above.
- 9** To remove unwanted charge, press ENERGY SELECT. A CHARGE REMOVED message will appear in upper right corner of the monitor screen for five seconds accompanied by three beep tones.
- 10** If CODE SUMMARY record is desired, press CODE SUMMARY.
- 11** To turn off defibrillator, press ON again.
- 12** Thoroughly clean defibrillator paddles and store them in paddles storage area.

Using Pediatric Paddles

For detailed instructions regarding pediatric paddles, refer to the Pediatric Paddles Operating Instructions.

- 1** Slide pediatric paddles over clean standard paddles. An audible click will be heard when fully engaged.
- 2** Apply defibrillation gel to pediatric paddle electrode surface and place in the standard defibrillation position.
- 3** Select appropriate energy for weight of child per AHA recommendations (or equivalent guidelines).
- 4** Follow Standard Paddles Defibrillation Procedure (page 5-5).

Using the Posterior Paddle

For detailed instructions regarding the posterior paddle, refer to the Posterior Paddle Operating Instructions.

- 1** Slide posterior paddle attachment over clean, standard APEX paddle. An audible click will be heard when fully engaged.
- 2** Apply defibrillation gel to posterior paddle electrode surface.
- 3** Lift or turn patient and position the posterior paddle.
- 4** Apply defibrillation gel to STERNUM paddle electrode surface.
- 5** Follow Standard Paddles Defibrillation Procedure (page 5-5), using the anterior-posterior paddle placement (page 5-4).

Synchronized Cardioversion

Asynchronous (defibrillation) mode is automatically selected when the defibrillator is powered on. Device automatically returns to asynchronous mode after each synchronized discharge.

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

Monitoring During Synchronized Cardioversion

There are two ways to monitor ECG for synchronized cardioversion:

- Use 3-lead patient ECG cable and electrodes and select lead I, II, or III.
- Use the Defibrillation Adapter with the FAST-PATCH disposable defibrillation/ECG electrodes. Refer to the Defibrillation Adapter and FAST-PATCH disposable defibrillation/ECG electrodes Operating Instructions.

For proper synchronization, ECG size must be adjusted correctly. Refer to QRS Detection, page 3-5 for more details.

Sync markers indicate the time of QRS detection used to synchronize discharge of the defibrillator. Markers may appear to move slightly from complex to complex; this is normal.

Sync mode will not operate using standard paddles in paddles lead. If attempted, a FOR SYNC: USE LEADS message will appear in the lower left corner of the monitor screen.

Synchronized Cardioversion Procedure

If using defibrillation electrodes, refer to the Synchronized Cardioversion Procedure in the Defibrillation Adapter Operating Instructions.

- 1** Press ON.
- 2** Attach ECG cable and ECG electrodes. For proper placement of electrodes refer to Color Coding for ECG Leads, page 3-3.
- 3** Select lead with optimum QRS complex amplitude (positive or negative).
- 4** Press SYNC. The amber light on the SYNC button blinks with each detected QRS complex.
- 5** Observe monitor screen. Confirm that the sync marker appears on the QRS complex. If the marker does not appear or appears on the T-wave: adjust ECG SIZE ▲ or ▼, change to another lead, or reposition the ECG electrodes so sync markers occur only on the QRS complex.

Occasionally, sync markers may occur near the end of the QRS complex. Sometimes, adjusting ECG size to minimum, then adjusting upward will move the marker closer to the middle of the QRS.
- 6** Prepare and position paddles on patient's torso. Refer to Standard Paddles Defibrillation Procedure, page 5-5.
- 7** Press ENERGY SELECT to choose the energy to be delivered.
- 8** Press CHARGE. A single tone sounds when charge is complete. Make certain all personnel, including operator, are clear of patient, bed, and any equipment that might be connected to patient.
- 9** Press and *hold* paddle discharge buttons until discharge occurs with next detected QRS complex.
- 10** Observe patient and monitor screen. If synchronized cardioversion needs to be reattempted, Press SYNC again. Device automatically returns to asynchronous mode after each synchronized discharge.
- 11** To remove an unwanted charge, press ENERGY SELECT.
- 12** To turn off defibrillator, press ON.
- 13** Thoroughly clean paddles and store them in storage area.

Noninvasive Pacing

This section covers noninvasive pacing in the demand and non-demand mode, including monitoring, pacing electrode placement, pacing procedure, and defibrillation during pacing.

Refer to the “*Noninvasive Pacing: What You Should Know*” booklet for additional information (see Literature, page 6-22 for order information).

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

Refer to Section 7, Appedix A for additional safety information.

WARNINGS

Possible interruption of therapy. Do not leave patient unattended while pacemaker is in use. Observe the patient continuously to assess any changes in patient response to pacing therapy.

Possible skin burns and ineffective pacing therapy. Pacing electrodes which are dried or damaged may not adhere properly and may delay therapy delivery or cause patient skin burns. To help prevent drying or damage, do not use pacing electrodes if they have been removed from the foil package for more than 24 hours or if the protective liner has been removed for more than 60 minutes. Do not use electrodes beyond expiration date. Inspect electrodes to make sure adhesive is intact and undamaged.

⚠ WARNINGS

Possible patient skin burns during prolonged pacing. Prolonged noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Discontinue noninvasive pacing if skin becomes irritated and another method of pacing is available.

Possible inhibition of pacing therapy. Do not substitute ECG electrodes or defibrillation electrodes for pacing electrodes.

Possible improper pacing. In the demand mode, the ECG SIZE must be properly adjusted to detect intrinsic complexes and deliver pacing pulses when appropriate. If ECG SIZE is set too high or too low, pacing pulses may not be delivered when required.

Demand and Non-Demand Pacing

The LIFEPAK 9P defibrillator/monitor/pacemaker can be used for either demand or non-demand (asynchronous) pacing.

The demand mode is used for most patients. In the demand mode, the LIFEPAK 9P pacemaker inhibits pacing output when it “senses” intrinsic QRS activity. In demand mode, if the ECG SIZE is set too low to detect QRS activity, or if an ECG lead becomes detached so that QRS activity is not sensed, the pacemaker will generate pacing pulses asynchronously.

In the non-demand mode, the pacemaker will generate pacing pulses at a selected rate regardless of the patient’s intrinsic QRS activity. The non-demand mode can be used if noise or artifact interferes with proper sensing of QRS complexes.

ECG Monitoring During Pacing

Monitoring during pacing must be performed through the 3-lead patient ECG cable in leads I, II, or III, rather than through the paddles. During pacing, the monitor screen displays pace markers each time a pacing pulse is delivered. The recorder annotates pacing information and documents each delivered pacing stimulus with a boldfaced arrow (↑) immediately below the stimulus. Monitoring or recording from systems other than the LIFEPAK 9P defibrillator/monitor/pacemaker will be difficult due to the large offsets produced by pacing currents.

The following information may be useful in obtaining the best ECG signal possible during pacing:

- Use Physio-Control 3-lead patient ECG cable.
- See Section 3, Monitoring the Patient, for monitoring electrode placement and skin preparation information.
- Minimize signal distortion (pacing distortion), keep ECG electrodes away from pacing electrodes by applying: RA to **far upper right** torso beneath the clavicle; LA to the **far upper left** torso beneath the clavicle; LL to **lower left** torso. These locations may minimize signal distortion (see Figure 5-2).

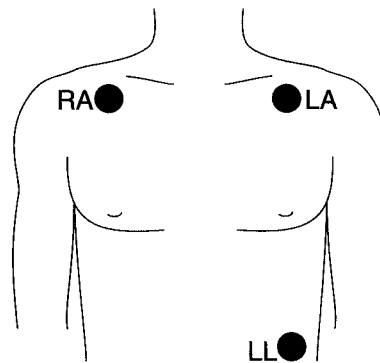


Figure 5-2 ECG electrode placement

- Select Lead I, II, or III for the most prominent QRS display. If pacing distortion obscures the ECG signal in Lead II, select Lead I. Lead I provides a clearer ECG signal in some patients.

About QUIK-PACE Electrodes

Pacing electrodes are an important part of the pacing system. They are constructed of materials specifically designed to produce uniform current density and minimize patient discomfort.

For best results, make sure pacing electrodes:

- Fit flat on torso with no air gaps.
- Have a minimum of one to two inches of space between electrodes.
- Do not overlap bony prominences of the sternum or spine.
- Are used on patients weighing more than 15kg (33lbs).

Conscious patients may experience discomfort during pacing. Sedation or analgesia may be needed before pacing.

The placement of pacing electrodes affects current threshold and may affect patient comfort. Do not reverse the pacing electrodes or pacing cable snap connectors. This leads to higher capture thresholds, more patient discomfort, and possible failure to capture.

For optimum storage life, store QUIK-PACE electrodes in a cool, dry location. Do not use beyond their labeled shelf life.

Pacing Electrode Placement

Anterior-Posterior Placement (Preferred Position)

The preferred placement of the pacing electrodes is anterior-posterior. This position is less likely to cause pectoral muscle stimulation and less likely to interfere with placement of defibrillation paddles or defibrillation electrodes.

- 1 Remove all clothing from patient's torso. Do not place electrodes over tape or bandages.
- 2 Clip or shave excessive torso hair. Avoid nicks or cuts to skin which may increase patient discomfort.
- 3 Clean and dry skin. Briskly wipe skin dry with towel or gauze to abrade skin and remove oils, dirt, etc. If ointments are on torso where electrodes will be applied, remove with soap and water. Do not use alcohol or tincture of benzoin to prepare skin.
- 4 Remove paper covering from each electrode post.
- 5 Firmly press cable snap connector onto electrode post. Match electrode color to cable connector color: *red to red* and *black to black*.
- 6 Remove protective liner from electrode.
- 7 Place the black ANTERIOR (-) electrode on the left anterior torso, halfway between the xiphoid process and the left nipple at apex of the heart. The upper edge of electrode should be below the nipple (see Figure 5-3). Avoid placement over the nipple, diaphragm, or sternum, if possible.

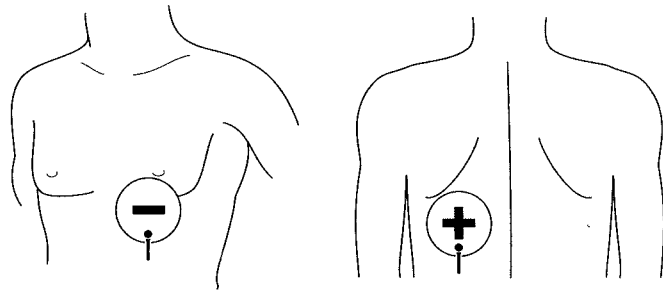


Figure 5-3 Anterior-posterior electrode placement for pacing

- 8** Place red POSTERIOR (+) electrode on left posterior torso beneath the scapula and lateral to the spine at heart level. Avoid placement of the electrode over the bony prominences of the spine or scapula (see Figure 5-3).
- 9** Firmly press electrode center and edges onto torso for proper adhesion.
- 10** Replace electrodes after 24 hours.
- 11** Apply a new set, adjusting the position slightly to avoid placing electrodes over irritated skin.
- 12** To remove electrode, slowly peel back from skin and discard.

**Anterior-Lateral Placement
(Alternate Placement)**

If anterior-posterior placement is contraindicated, the alternate anterior-lateral placement may be used. Follow the steps for anterior-posterior placement, replacing steps 7 and 8 with 7A and 8A below.

- 7A** Place the black ANTERIOR (-) electrode on the left anterior torso, just lateral to the left of the nipple in the midaxillary line. This corresponds to the V₆ electrode position (see Figure 5-4).
- 8A** Place the red POSTERIOR (+) electrode on the right anterior upper torso subclavicular area lateral to the sternum (see Figure 5-4).

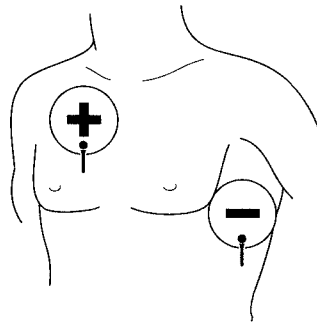


Figure 5-4 Anterior-lateral electrode placement for pacing

Anterior-lateral positioning should only be used if anterior-posterior positioning interferes with defibrillator paddle placement.

Special Placement Situations

Female patients. To place the ANTERIOR (-) electrode, lift the breast and place electrode directly below breast tissue.

Obese patients. Place electrodes over a flat area if possible. If skin folds preclude good adhesion, it may be necessary to spread the folds apart to create a flat surface.

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

Response to Noninvasive Pacing

Externally applied pacing stimuli will produce skeletal muscle contraction. It may be necessary to secure tubing, cables, etc. to prevent their displacement.

When using noninvasive pacing on unconscious patients, the patient's level of consciousness may improve during pacing. Patient discomfort associated with noninvasive pacing may occur. Discomfort may be minimized by administration of a sedative or analgesic or movement of the anterior (negative) pacing electrode to the V₆ electrode position (see Figure 5-4). Repositioning of the negative pacing electrode may result in a lower capture threshold, thus reducing discomfort.

If pacing electrodes remain in place 24 hours, remove them and apply a new set, adjusting the position slightly to avoid placing electrodes over irritated skin.

Pacing Procedure

To pace a patient:

- 1** Press ON.
- 2** Connect ECG electrodes to ECG cable and apply to patient. Refer to Skin Preparation, page 3-5.
- 3** Select LEAD I, II, or III on monitor.
- 4** Connect pacing cable to PACE connector below the LIFEPAK 9P defibrillator/ monitor/pacemaker recorder.
- 5** Connect pacing electrodes to pacing cable and position electrodes on patient (see Pacing Electrode Placement, page 5-14). Match electrode color to cable connector color, red to red and black to black.
- 6** Press PACER.
- 7** Indicator light illuminates. Demand pacing message appears in the upper right corner of the monitor screen. Press NON-DEMAND button on the back of the defibrillator/monitor/pacemaker if non-demand pacing is desired.
- 8** The heart rate will show "---", because the heart rate meter and heart rate alarms are inactive during pacing.
- 9** Select desired pacing rate. (Pacemaker powers up at a rate of 60ppm.)
- 10** CURRENT level begins at 0mA.
- 11** Observe monitor screen. Sense marker (▼) should appear on each QRS complex. If sense marker is not present on QRS or appears elsewhere, adjust ECG SIZE for optimal sensing. If this fails, select another lead or reposition the ECG electrode and readjust ECG SIZE. If intrinsic beats are not present, or if non-demand pacing has been selected, omit this step.
- 12** When the defibrillator/monitor/pacemaker is sensing properly, activate pacing by turning the CURRENT dial clockwise. The first current setting after 0mA is 7mA; current increases in 1mA increments thereafter. Increase the current slowly. The PACER indicator light flashes and a positive spike appears with each pacing pulse when current is greater than zero. Consider using sedation or analgesia if patient is uncomfortable.

- 13 Observe monitor screen for evidence of electrical pacing capture. Palpate patient's pulse or check blood pressure to assess for perfusion (mechanical capture). See Assessing for Capture, below.
- 14 When activated, recorder will document pacing parameters. Each pacing stimulus is marked with an arrow (↑) on the lower edge of the ECG paper.
- 15 To stop pacing, press PACER again. The indicator light will go out. Alternately, reduce pacing current to zero (the indicator light stays on).

Possible Causes of Pacing Interruption

If the pacing cable, pacing cable snap connector, or a pacing electrode becomes detached during pacing, the PACING LEADS OFF message is displayed in the upper right corner of the monitor screen and an audible alarm sounds. The pacing rate maintains its pre-alarm setting; however, the current resets to 0mA. Reattaching the pacing cable or QUIK-PACE electrode silences the audible alarm. A PACING STOPPED message appears in the upper right portion of the monitor screen.

To restart pacing, the operator *must* increase the pacing current.

Assessing for Capture

During pacing, the patient should be visually monitored at all times, and should be assessed for both electrical and mechanical (ventricular) capture. Skeletal muscle twitching should be expected. The muscle response can be quite vigorous, but it is **not** an indication of pacing capture.

Electrical capture stimulated by noninvasive pacing is usually shown by a widening of the QRS complex followed by a tall, broad T-wave. The complexes can be positive (upward) or negative (downward) deflections. In either case, the most distinctive evidence of electrical capture is the presence of a tall, broad T-wave. It is much like capture seen in temporary transvenous or permanent pacing. In some patients, capture may be less obvious, noted only as a change in QRS configuration.

Many patients achieve capture at 50 to 90mA; however, individual thresholds vary markedly. Hypoxia, acidosis, and other physiologic variables may lead to high capture thresholds. Current **must** be adjusted upward until capture is achieved.

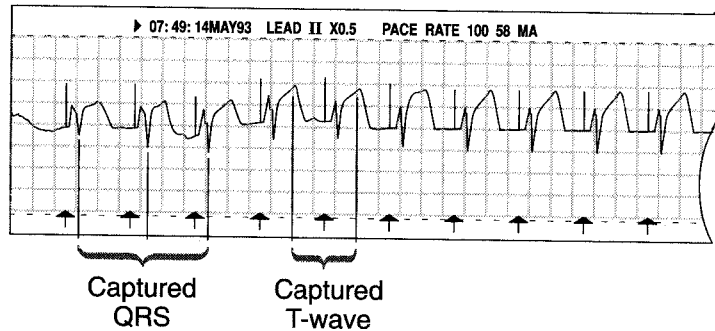


Figure 5-5 ECG recording of electrical capture (not to scale)

Mechanical or ventricular capture is evidenced by the presence of a pulse and signs of improving cardiac output. Palpate for a carotid or femoral pulse (right side preferred). Check color and temperature of skin, improvement of blood pressure, and level of consciousness.

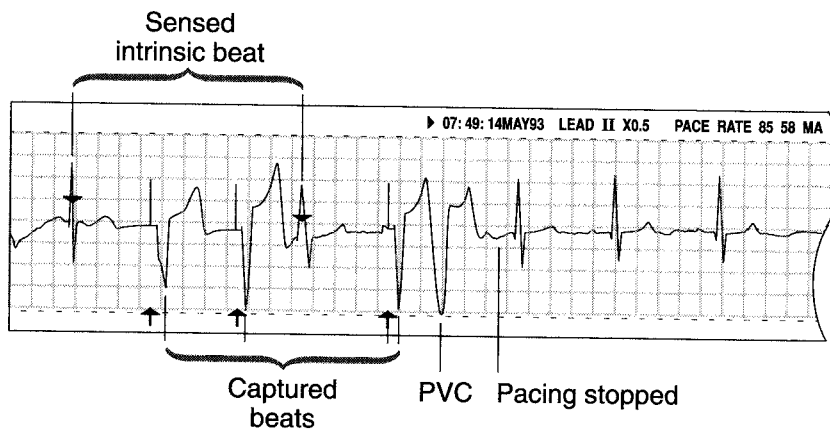


Figure 5-6 Electrical capture with intrinsic beat activity (not to scale)

ECG Distortion During Pacing

ECG electrodes pick up pacing current; therefore, ECG distortion during pacing is sometimes evident. It is important to distinguish between electrical capture and ECG distortion from pacing current to avoid misinterpretation.

When present, ECG distortion occurs immediately following the pacing stimulus. ECG distortion morphology is variable, however, ECG distortion without electrical capture returns to the ECG baseline *without* evidence of a T-wave.

Electrical capture is accompanied by a pulse unless the patient is suffering from pulseless electrical activity (electro-mechanical disassociation). Pacing distortion is *not* accompanied by a pulse.

If ECG distortion is severe, select another lead or reposition ECG electrodes away from pacing electrodes.

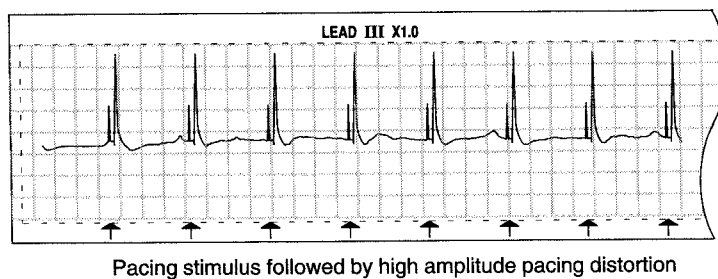


Figure 5-7 ECG recording with distortion (not to scale)

The ECG rhythm strip in Figure 5-7 shows pacing pulses followed by high amplitude pacing distortion.

Pacemaker Refractory Period

The LIFEPAK 9P pacemaker has a refractory period which is a brief, variable (rate-dependent) period of time following the pacing pulse during which the pacemaker will not sense electrical activity. Sense markers do not appear on intrinsic complexes which occur during this period. The presence of the refractory period allows the set pacing rate to be maintained. The refractory period for each pacing rate is listed in Table 6-11, page 6-28.

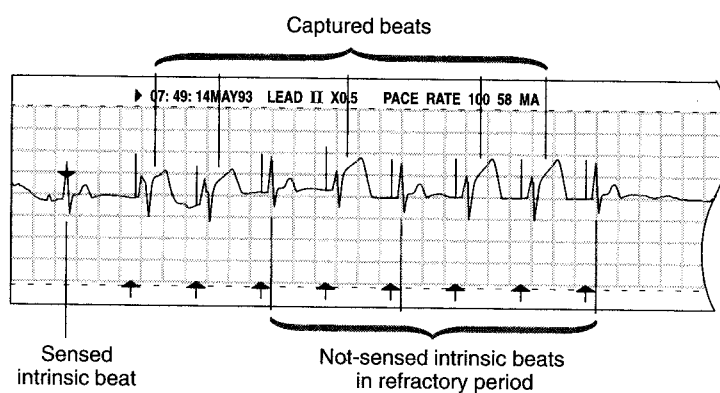


Figure 5-8 Pacemaker refractory period (not to scale)

Defibrillation During Noninvasive Pacing

It is not necessary to power off the pacemaker during defibrillation. It is usually not necessary to remove the pacing electrodes, because paddle position for defibrillation differs from that of standard pacing electrode position. Remove the pacing electrodes only if they interfere with defibrillator paddle placement. Do not defibrillate over pacing electrodes.

To defibrillate during noninvasive pacing, follow the defibrillation procedure outlined in Defibrillation, page 5-1.

When CHARGE or ENERGY SELECT are pressed during pacing:

- Pacing immediately stops.
- PACING STOPPED appears in the upper right corner of the monitor screen accompanied by an audible tone.
- Pacing indicator light goes off.

Pressing CHARGE on the Defibrillation Adapter or pressing ANALYZE or CHARGE on the Shock Advisory Adapter also interrupts pacing.

Immediately following defibrillation:

- 1 Assess patient and observe the monitor screen to determine results.
- 2 If another countershock is necessary, confirm proper energy level is selected, press CHARGE and repeat defibrillation procedure.
- 3 Evaluate patient's rhythm. If noninvasive pacing is indicated, repeat the pacing procedure starting at step 6.

Pacing settings default to 60ppm and 0mA whenever pacing is reactivated.

6

Maintaining the Equipment

Testing

Periodic testing of the LIFEPAK 9P defibrillator/monitor/pacemaker and accessories helps to detect possible electrical and mechanical problems, and keeps personnel acquainted with normal operating procedures. Contact a qualified service technician if device or accessory discrepancies are noted. Refer to the Maintenance and Testing Schedule, page 6-8.

For testing information regarding accessories, refer to their individual Operating Instructions.

Note. Text references to buttons and displayed messages are indicated in CAPITAL LETTERS.

Refer to Section 7, Appendix A for additional safety information.

WARNINGS

Possible paddle damage and patient burns. Be sure paddles are secured firmly and placed properly (STERNUM on left, APEX on right) in the paddles storage area when discharging. This helps prevent arcing and formation of pits on paddle electrode surfaces. Pitted or damaged paddle electrode surfaces can cause patient skin burns during defibrillation.

Monitor/Recorder Test**Equipment Needed**

The LIFEPAK 9P defibrillator/monitor/pacemaker, an ECG cable, and an ECG simulator are the equipment needed to perform a monitor/recorder test.

Test Procedure

To test the monitor/recorder:

- 1** Connect power cord to grounded ac receptacle. BATT CHRG indicator light should illuminate.
- 2** Press ON.
- 3** Press LEAD SELECT to STD.
- 4** Attach 3-lead patient ECG cable. Do not connect cable to patient or simulator.
- 5** Press and release rear panel CAL button. Calibration signal should appear on monitor screen.
- 6** Adjust rear panel QRS VOL so that sound is heard with each calibration signal.
- 7** Press HR ALARM. Alarm should sound and recorder should print out a 16-second strip. Press HR ALARM again to power off.
- 8** Attach 3-lead patient ECG cable to ECG simulator. Power on simulator and set rate to 80.
- 9** Advance LEAD SELECT through leads I, II, and III. A simulated normal sinus rhythm should appear on the monitor screen.
- 10** Select LEAD I. Removing the reference lead, LL, should not affect the ECG display. Verify that removing either RA or LA leads results in loss of ECG rhythm.
- 11** Select LEAD II. Removing the reference lead, LA, should not affect the ECG display. Verify that removing either RA or LL leads results in loss of ECG rhythm.
- 12** Select LEAD III. Removing the reference lead, RA, should not affect the ECG display. Verify that removing either LL or LA leads results in loss of ECG rhythm.
- 13** Advance LEAD SELECT to PADDLES. Remove standard paddles from paddle storage area. Gentle paddle shaking should result in interference on the monitor screen. Placing paddle electrode surfaces together should result in a flat trace on the monitor screen.

- 14 Advance LEAD SELECT to the STD position.
- 15 Press RECORD. Recorder should run and trace should appear within one second. Press rear panel CAL button several times. Calibration signal should appear on scope and be recorded on ECG paper approximately eight seconds later. Signal recorded should match Figure 6-1 when monitor frequency response is selected on SETUP menu.

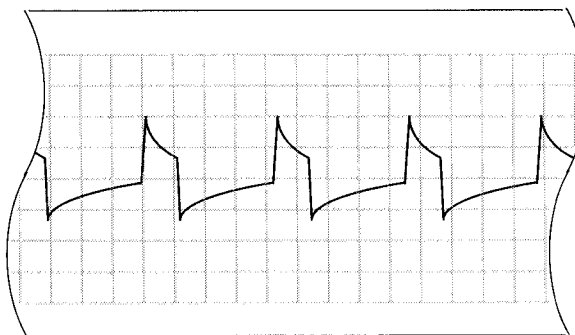


Figure 6-1 Calibration signal at monitor frequency response

If diagnostic frequency response is selected in SETUP, the calibration signal will match Figure 6-2.

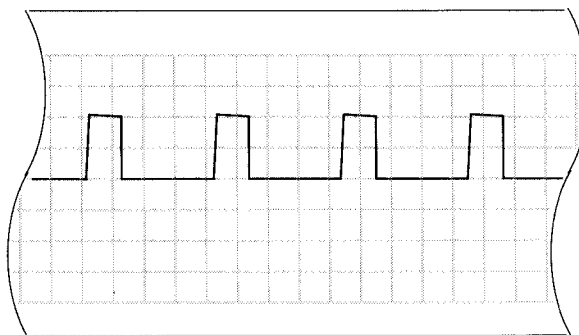


Figure 6-2 Calibration signal at diagnostic frequency response

- 16 Press RECORD again to power off the recorder.

Defibrillator Test

⚠ CAUTION



Equipment Needed

The LIFEPAK 9P defibrillator/monitor/pacemaker is the only equipment needed.

Test Procedure

To test the defibrillator:

- 1** Paddles should be firmly seated in paddle storage area.
- 2** Press ON.
- 3** Press ENERGY SELECT. 200 JOULES SELECTED will appear in the lower right corner of monitor screen.
- 4** Press CHARGE. JOULES CHARGING will appear in lower right corner of monitor screen. Increasing numbers indicate energy level as defibrillator charges. Defibrillator is ready when the selected energy and the JOULES AVAILABLE messages appear in the lower right corner of monitor screen. CHARGE button indicator light will glow steadily accompanied by a charge complete tone. Charging should take 10 seconds or less.
- 5** Press the APEX discharge button only and confirm that the device does not discharge.
- 6** Press the STERNUM discharge button only and confirm that the device does not discharge.
- 7** Discharge defibrillator by pressing both paddle discharge buttons simultaneously.

The TEST 200 JOULES DELIVERED message should appear in the lower right corner of screen for approximately four seconds. Recorder will print time, date, and DEFIB TEST 200 JOULES DELIVERED message.

An unsuccessful test will cause a TEST < 200 (or > 200) JOULES DELIVERED message to appear in lower right corner of monitor screen. Recorder will print time, date, and DEFIB TEST < 200 (or > 200) JOULES DELIVERED message.

Synchronizer Function Test

Equipment Needed

The LIFEPAK 9P defibrillator/monitor/pacemaker, ECG cable, and ECG simulator are the equipment needed to perform a synchronizer function test.

Test Procedure

To test the synchronizer:

- 1** Connect 3-lead patient ECG cable to ECG simulator. Select rate of 40.
- 2** Press ON.
- 3** Select LEAD II (provides tall QRS).
- 4** Press SYNC. SYNC MODE message will appear in lower left corner of monitor screen. Adjust ECG size to minimum gain of X0.2 and advance slowly until marker appears within each QRS complex. SYNC button indicator light will flash with each detected QRS.
- 5** Leave paddles in storage area. Select 200 joules by pressing ENERGY SELECT.
- 6** Press CHARGE.
- 7** Press RECORD.
- 8** Press and hold *both* paddle discharge buttons simultaneously until defibrillator discharges on next detected QRS. Wait approximately eight seconds for the recorder to annotate the synchronized defibrillation event. The annotation identifier ► will appear over the QRS complex and align with the sync marker ▼.
- 9** Defibrillator should return to asynchronous mode. SYNC MODE message no longer appears in lower left corner of monitor screen.

Noninvasive Pacemaker Function Test

Equipment Needed

The LIFEPAK 9P defibrillator/monitor/pacemaker, pacing cables, and PaceMate™ simulator are the equipment needed to perform a noninvasive pacemaker function test. Testing with the PaceMate simulator should be performed semi-annually (see Table 6-1 on page 6-9).

Test Procedure

To test the pacemaker:

- 1** Connect the LIFEPAK 9P defibrillator/monitor/pacemaker pacing and ECG patient cables to the PaceMate simulator and the defibrillator/monitor/pacemaker.
- 2** Press ON.
- 3** Power on the pacing simulator and set the rate at 40ppm.
- 4** Press PACER. The DEMAND PACING message will appear in the upper right corner of monitor screen. Pacing rate should be 60ppm. Pacing current display should be 0mA.
- 5** Observe monitor screen to confirm the ECG signal from the PaceMate simulator is displayed. Sense marker (▼) should appear on each QRS complex. If sense marker does not appear appropriately on the ECG, reduce ECG SIZE to its minimum setting, then gradually increase until proper QRS sensing is attained.
- 6** Press RATE ▲ and ▼ to confirm the selected rate changes on the monitor screen.
- 7** Turn CURRENT control clockwise until the monitor screen displays 125mA. The PACER indicator light should flash with every delivered pacer current stimulus greater than 0mA.
- 8** Observe monitor screen for electrical capture. Indicator light between pacing cable connectors on PaceMate simulator should flash with each pacing stimulus.

- 9 Press NON-DEMAND button on the rear panel. The NON-DEMAND PACING message will appear in the upper right corner of the monitor screen. The pacemaker should generate pacing pulses at the selected rate regardless of simulator activity. Simulator sense markers should not appear on simulated QRS complexes. Press NON-DEMAND button again. The DEMAND PACING message should reappear on the monitor screen.
- 10 Remove one pacing lead from the simulator. The pacemaker should stop pacing, the PACING LEADS OFF message should appear in the upper right corner of the monitor screen, and an audible alarm should sound. Pacing current output should default to 0mA.
- 11 Replace the pacing lead to silence the alarm.
- 12 Remove one pacing lead and attempt to initiate pacing by increasing the CURRENT control. The PACING LEADS OFF message should appear in the upper right corner of the monitor screen and an audible alarm should sound. When this occurs, current cannot be increased.
- 13 Reattach both pacing leads. Increase current to 125mA. Press ENERGY SELECT. The PACER indicator light should go out. The PACING STOPPED message should appear in the upper right corner of the monitor screen. The ENERGY SELECT menu should appear on the right side of the monitor screen. The PACING STOPPED message should remain for 20 seconds or until another button is pressed.

Maintenance and Testing Schedule

The following guideline outlines functional and electrical safety testing of the defibrillator/monitor/pacemaker at periodic intervals. It complements the internal quality assurance programs of the hospital or clinic.

Testing should be preceded by a thorough visual inspection of the defibrillator/monitor/pacemaker. Examine the device and accessories for cracks in the case and cables, pitted paddle electrode surfaces, presence of gel on paddles or paddle storage area, and for proper function of controls. If damage is suspected, corrective action should be taken immediately.

While examining the device, the operator should check that all accessories are present and functional.

Physio-Control recommends a minimum program of routine maintenance and testing for clinical personnel (refer to Table 6-1 on page 6-9). Additional preventive maintenance and testing such as electrical safety tests, performance inspection, and calibration should be performed routinely by biomedical personnel. Contact a qualified service technician immediately if device or accessory discrepancies are noted.

A separate checklist entitled “*Manual Defibrillators: Operators Shift Checklist*” is included with shipment of your LIFEPAK 9P defibrillator/monitor/pacemaker.

Table 6-1 Recommended maintenance and testing for clinical personnel

	Daily	After Use	As Required	Semi-Annually
Clean defibrillator/monitor/pacemaker.		●	●	
Check that all necessary supplies and accessories are present (e.g., gel, ECG paper, ECG and pacing cable, electrodes, etc.).	●	●	●	
Check/change recorder paper.	●		●	
Operational tests: monitor function, defibrillator/sync discharge function with standard paddles, adapters, or paddles options.	●		●	
Test noninvasive pacing function using PaceMate simulator.				●
Inspect case, cables, connectors, and accessories for damage.	●			
Verify paddles are clean.	●	●		

Troubleshooting

This brief checklist is intended for nontechnical personnel. If trouble persists after consulting the following checklist, contact a qualified service technician.

Table 6-2 Troubleshooting the monitor

Observation	Possible Cause/Corrective Action
1 Device does not function when ON is pressed. No trace on monitor screen. ON button does not illuminate.	<ul style="list-style-type: none"> • Battery discharged below operating level. Test by using line power. • Confirm device is plugged in. (Check that BATT CHRG lamp is on.) • Check for damaged power cord. Replace if necessary. • Check for failed fuse or tripped circuit breaker in building electrical lines.
2 Interference on monitor screen when using 3-lead patient cable for ECG input.	<ul style="list-style-type: none"> • Confirm that 3-lead patient ECG cable is connected to device and lead I, II, or III is selected. • Check patient skin preparation, electrode contact, electrode placement, or outdated electrodes. • Inspect patient cable. Use only Physio-Control 3-lead patient ECG cable. • Check for the presence of a strong radio frequency electrical field (such as diathermy). Power off noise-generating equipment. • If excessive line (50 or 60Hz) frequency interference is suspected, enable the built-in notch filter via the SETUP menu. Contact a qualified service technician for assistance.
3 Excessive interference on monitor screen when using paddles.	<ul style="list-style-type: none"> • Check for dirty paddles. • Check that LEAD SELECT is set to PADDLES. • If using FAST-PATCH disposable defibrillation/ECG electrodes, check for poor skin preparation, electrode placement, or outdated electrodes. • Check that appropriate conductive gel is between paddles and skin.

Table 6-2 Troubleshooting the monitor, *continued*

Observation	Possible Cause/Corrective Action
4 No ECG signal on monitor screen when using 3-lead patient ECG cable.	<ul style="list-style-type: none"> • Confirm that LEAD SELECT is set to I, II or III (not STD or PADDLES). • Check patient ECG cable for damage and replace if necessary.
5 No ECG signal on monitor screen with QUIK-LOOK paddle monitoring.	<ul style="list-style-type: none"> • Confirm that PADDLES is selected. • Confirm that paddles connector is in place and locked (twist clockwise 1/8 turn). • Inspect paddles and cables for damage and replace if necessary.
6 Recorder does not operate.	<ul style="list-style-type: none"> • Confirm that recorder has paper and doors are closed.
7 Straight line on monitor screen and recorder when signal is applied or 1mVCAL is pressed.	<ul style="list-style-type: none"> • ECG size may be set too low. Increase ECG size.
8 No systole sound.	<ul style="list-style-type: none"> • Increase volume (QRS VOL). • Increase ECG size. • Amplitude of ECG signal is too low in that lead. Select another lead or move electrodes.
9 QRS indicator (♥) fails to flash with each QRS.	<ul style="list-style-type: none"> • Increase ECG size. • Amplitude of ECG signal is too low in that lead. Select another lead or move electrodes.
10 Heart rate is not present or displays “- - -”.	<ul style="list-style-type: none"> • Increase ECG size. • Amplitude of ECG signal is too low in that lead. Select another lead or move electrodes. • Heart rate is below 20bpm or above 300bpm • Pacemaker is on: Heart rate is not displayed when pacemaker is activated.

Table 6-2 Troubleshooting the monitor, *continued*

Observation	Possible Cause/Corrective Action
11 No sync markers on monitor screen.	<ul style="list-style-type: none"> • PADDLES lead selected while standard paddles connected. Monitor with 3-lead ECG cable or Defibrillation Adapter and defibrillation electrodes. • Press SYNC. • Increase ECG size. • Amplitude of ECG signal is too low in that lead. Select another lead or move electrodes.
12 Sync marker (▼) not positioned within QRS complex.	<ul style="list-style-type: none"> • Adjust ECG size to minimum gain (X0.2) and gradually increase until QRS indicator is properly positioned. • Amplitude of ECG signal is too low in that lead. Select another lead or move electrodes.
13 LOW BATTERY: CONNECT AC POWER message remains illuminated despite charging attempts. Device operates normally on line power (ac).	<ul style="list-style-type: none"> • Battery may be depleted. Contact a qualified service technician.
14 BATT CHRГ indicator light fails to illuminate when device connected to ac line power. Device otherwise operational.	<ul style="list-style-type: none"> • Possible battery charge indicator light failure. • Inspect ac power cord for damage. Check that it is properly connected. • Check fuse or tripped circuit breaker in building electrical lines. Device operating from internal battery. • Battery not charging properly. Contact a qualified service technician. • Have battery inspected for proper installation. • For 220V devices (IEC international), confirm that mains power switch is in the on (I) position.

Table 6-2 Troubleshooting the monitor, *continued*

Observation	Possible Cause/Corrective Action
15 ECG recording appears smudged.	<ul style="list-style-type: none">• Confirm that ECG paper for thermal array recorders is in use.
16 SERVICE message appears in lower left corner of the monitor screen.	<ul style="list-style-type: none">• Contact a qualified service technician.
17 Time or date on recorder incorrect.	<ul style="list-style-type: none">• Time or date not set properly. Adjust using TIME/DATE MODE and SET buttons on rear panel.
18 Indicator lamps momentarily flash at power on.	<ul style="list-style-type: none">• Normal operation of self test.

Table 6-3 Troubleshooting the pacemaker

Observation	Possible Cause/Corrective Action
1 Pacemaker stops unexpectedly.	<ul style="list-style-type: none"> • Confirm PACER indicator light is on (pacemaker may have been inadvertently powered off). • Battery may be depleted. Connect to line power. • The pacemaker is inoperative and the PACER FAULT message appears accompanied by a warning tone. This indicates continuous self-diagnostic routines have detected improper operation requiring the attention of a qualified service technician. • Check for PACING LEADS OFF message. Inspect pacing cable and pacing electrode connections. • ENERGY SELECT pressed (JOULES SELECTED message displayed on monitor screen). To return to pacing, press PACER and increase CURRENT. • CHARGE pressed (JOULES CHARGING or JOULES AVAILABLE message displayed on monitor screen accompanied by an energy available tone). To return to pacing, press PACER and increase CURRENT. • ANALYZE pressed on Shock Advisory Adapter (ANALYZING NOW message displayed on monitor screen accompanied by analysis tone). To return to pacing, press PACER and increase CURRENT.
2 USE ECG LEADS message appears.	<ul style="list-style-type: none"> • Confirm 3-lead patient ECG cable is attached. Select lead I, II, or III.
3 No ECG trace on monitor.	<ul style="list-style-type: none"> • Confirm ON indicator light is illuminated. • Confirm ECG leads are connected; proper lead is selected. Inspect 3-lead patient ECG cable and patient/electrode connection.
4 Current defaults to 0mA	<ul style="list-style-type: none"> • Pacing electrode, snap cable connector, or cable connector have become detached. To restart, reattach and increase current by rotating the dial clockwise.

Table 6-3 Troubleshooting the pacemaker, *continued*

Observation	Possible Cause/Corrective Action
5 Intrinsic QRS complexes not sensed when in demand pacing mode.	<ul style="list-style-type: none"> Adjust ECG size to minimum gain (X0.2) and gradually increase until QRS indicator is properly positioned. Amplitude of ECG signal too low in that lead. Select another lead or move electrodes.
6 Monitor screen displays interference while pacing.	<ul style="list-style-type: none"> ECG electrodes not optimally placed with respect to QUIK-PACE electrodes. See Noninvasive Pacing, page 5-13 for electrode placement suggestions. Select another lead (I, II, or III).
7 Capture does not occur with pacing stimulus.	<ul style="list-style-type: none"> Increase current level (administer sedation/analgesia if needed). Check that electrode placement and cable polarity are correct. See page 5-13. Cardiac muscle unable to respond due to extensive myocardial damage. Verify pacemaker is delivering energy with PaceMate simulator (see Pacemaker Testing, page 6-6).
8 Pacemaker generates pacing pulse "unexpectedly"	<ul style="list-style-type: none"> Patient's intrinsic rate drops below set pace rate. Non-demand mode inadvertently activated. QRS complexes not sensed, see observation 5.
9 No skeletal muscle response to pacing	<ul style="list-style-type: none"> Patients in prolonged cardiac arrest may have diminished or absent skeletal muscle response to pacing. Increase current. Check that cable, connectors, and electrodes are connected. Verify pacemaker is delivering energy: check that mA readings are above zero and PACER FAULT message is not displayed.

Table 6-4 Troubleshooting the defibrillator

Observation	Possible Cause/Corrective Action
1 Charge time to 360 joules exceeds 10 seconds.	<ul style="list-style-type: none"> Battery may be depleted. Connect to line power. Allow battery to charge for 24 hours.
2 Numbers in JOULES CHARGING message scroll very slowly when CHARGE is pressed.	<ul style="list-style-type: none"> Battery may be depleted. Connect to line power. Allow battery to charge for 24 hours.
3 Energy is not delivered to patient when both paddle discharge buttons are pressed simultaneously.	<ul style="list-style-type: none"> Device in Sync mode, but no QRS detected. Adjust ECG size, select another lead, move ECG electrodes, or exit Sync mode. Defibrillator has not reached full energy selected. Wait for JOULES AVAILABLE message on the monitor screen and charge complete tone. More than one minute has elapsed and energy has been removed. ENERGY SELECT was pressed and charge was removed. Press CHARGE again. Confirm that standard paddles are properly connected and locked into position.
4 Displayed JOULES AVAILABLE does not match energy selected. Accompanied by ENERGY FAULT message and warning tone.	<ul style="list-style-type: none"> Perform a test load discharge. Defibrillator energy storage may not meet specifications. Contact a qualified service technician.
5 JOULES CHARGING message does not appear when CHARGE is pressed.	<ul style="list-style-type: none"> Battery may be depleted. Connect to line power. Allow battery to charge for 24 hours.

Table 6-4 Troubleshooting the defibrillator, *continued*

Observation	Possible Cause/Corrective Action
6 TEST < 200 (or > 200) JOULES DELIVERED message displays when test load discharge performed.	<ul style="list-style-type: none"> Defibrillator energy output may not meet specifications. Contact a qualified service technician.
7 SYNC MODE message does not appear when SYNC mode is selected.	<ul style="list-style-type: none"> LEAD SELECT set to PADDLES or STD when using standard paddles. Use 3-lead patient ECG cable and select lead I, II, or III, or use Defibrillation Adapter with defibrillation electrodes.
8 Device does not charge.	<ul style="list-style-type: none"> Confirm that standard hard paddles, Defibrillation Adapter, or Shock Advisory Adapter are fully connected and locked to defibrillator. Selected energy is 0 joules. Change energy selection. Confirm that standard hard paddles are connected directly into defibrillator/monitor/pacemaker, not into Defibrillation Adapter or Shock Advisory Adapter. Use only the defibrillation cable with the adapters and check that adapter and cable are locked in place.

Warranty Policy

Refer to the warranty statement shipped with the product. Duplicate copies may be obtained by contacting your local Physio-Control sales or service office. In the USA, call the Physio-Control PARTSLINE™ at 1-800-442-1142.

Use of non-Physio-Control defibrillation electrodes, pacing electrodes, batteries, accessories, parts, or adapter devices may void Safety Agency Certifications and warranty.

Service

If the LIFEPAK 9P defibrillator/monitor/pacemaker requires service, contact a Physio-Control service representative or a qualified service technician. When calling Physio-Control to request service, please identify model and serial number and describe observation. If the device must be shipped to the service center or factory, special packing is necessary to prevent shipping damage.

Circuit diagrams, component parts lists, calibration instructions, and other relevant technical information are found in the LIFEPAK 9P defibrillator/monitor/pacemaker Service Manual.

For technical consultation, manuals, or parts (PARTSLINE), contact your local Physio-Control sales or service office. In the USA, call Technical Services at 1-800-442-1142 .

Cleaning

The LIFEPAK 9P defibrillator/monitor/pacemaker case, paddles, cables, test load contacts, and monitor screen should be cleaned with mild soap and water. Use a damp sponge or towel to clean.

Do not clean with alcohol, ketones, or other flammable agents.

The recorder parts should be cleaned with a damp, soft cloth. Do not use abrasive agents. Do not autoclave or gas sterilize the LIFEPAK 9P defibrillator/monitor/pacemaker or Physio-Control accessories unless otherwise stated.

Replacement Items and Accessories

Contact Physio-Control for the complete part number.

Adapter Options

Defibrillation Adapter.	803747
Shock Advisory Adapter.	803732

Paddles and Electrodes

LIFE-PATCH ECG electrodes, adult

Case of 300 electrodes (10 boxes per case).	800139-300
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Box of 30 electrodes, adult (three electrodes per package; 10 packages per box).	800139-030
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QUIK-PACE disposable external pacing electrodes

One set (two pacing electrodes).	803377-101
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Five sets (10 pacing electrodes).	803377-501
-----------------------------------	------------

Ten sets (50 pacing electrodes).	803377-251
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Accessories that Require Defibrillation Adapter:

FAST-PATCH disposable defibrillation/ECG electrodes. Requires defibrillation electrode cable.	804089
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One set (two electrodes).	804545-001
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10 sets (20 electrodes).	804545-010
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50 sets (100 electrodes).	804545-050
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External Sterilizable Paddles.	804507
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Internal Handles without discharge control (gas sterilize only).	800441
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Internal Paddles for use with Internal Handles without discharge control (steam or gas sterilizable):

2.5 cm (1.0 in.) diameter, pair.	802154-10
3.8 cm (1.5 in.) diameter, pair.	802154-11
5.1 cm (2.0 in.) diameter, pair.	802154-12
6.4 cm (2.5 in.) diameter, pair.	802154-13
8.9 cm (3.5 in.) diameter, pair.	802154-14

Accessories that Do Not Require Defibrillation Adapter:

Internal Handles with discharge control (gas or steam sterilizable).	805249
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Internal Paddles for use with Internal Handles with discharge control (steam or gas sterilizable):

2.5 cm (1.0 in.) diameter, pair.	805355-10
3.8 cm (1.5 in.) diameter, pair.	805355-11
5.1 cm (2.0 in.) diameter, pair.	805355-12
6.4 cm (2.5 in.) diameter, pair.	805355-13
8.9 cm (3.5 in.) diameter, pair.	805355-14
Pediatric paddles, external one each (two required).	800418

Posterior paddle, external adult.	802461
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Cables

Defibrillation cable. For use with FAST-PATCH disposable defibrillation/ECG electrodes.	804089
AHA 3-lead patient ECG cable, 6-pin connector, snap type, low noise.	9-10418
IEC 3-lead patient ECG cable, 6-pin connector, snap type, low noise.	800947
Pacing cable.	802905

Literature

Product literature for the LIFEPAK 9P defibrillator/
monitor/pacemaker is available in the following languages:

Table 6-5 LIFEPAK 9P product literature

Title	P/N#	English	French	Spanish	German	Italian	Swedish	Japanese
LIFEPAK 9P defibrillator/monitor/ pacemaker Operating Instructions	805455	•	•	•	•	•	•	
LIFEPAK 9P defibrillator/monitor/ pacemaker Service Manual	805454	•						
Booklet: "Defibrillation: What You Should Know"	805662	•	•	•	•	•		•
Booklet: "Noninvasive Pacing: What You Should Know"	805074	•	•	•	•			•

Videos

LIFEPAK 9P defibrillation/monitor/pacemaker Inservice
Video Program

- English (NTSC format) 805459-00
- English (PAL format) 805459-01

Miscellaneous

DERMA JEL® electrode gel.

- 4 oz. tube. 9-10236-00
- 12 tubes/case. 9-10236-012

Power cord. (for LIFEPAK 9P defibrillator/monitor/pacemaker). 803619

ECG paper.

(chemical, 50 mm x 30 m (100 ft.), 40 mm grid).

- One box; three rolls/box (three rolls). 804700-003
- 50 boxes/case (150 rolls). 804700-150

Accessory bag (mounts on side of device). 805485-00

Emergency cart. 800539

- One red security tie for emergency cart (50 ties/package). 200349-001

Patient simulator. 803499

Simulates ventricular fibrillation, motion distortion, and normal sinus rhythm to facilitate training. Includes four AA batteries and two Operating Instructions. Tests function of defibrillation cable, Defibrillation Adapter, and Shock Advisory Adapter.

PaceMate™ simulator. 804820

Simulates normal sinus rhythm, sinus bradycardia, and captured paced beats when pacing current applied. Tests 3-lead patient ECG cable, Physio-Control noninvasive pacemakers, and pacing cable.

Consult your Physio-Control representative regarding other available replacement items and accessories.

Specifications

Table 6-6 ECG Monitor specifications

INPUT	Isolated ECG via QUIK-LOOK defibrillator paddles, FAST-PATCH disposable defibrillation/ECG electrodes, 3-lead patient cable.
ECG LEAD SELECTION	Std, Paddles, I, II, III
PATIENT CABLE LENGTH	4.0m (13 ft.); cable 3.1m (10 ft.); leads 0.9m (3 ft.).
COMMON MODE REJECTION	With notch filter engaged, minimum 100dB with respect to chassis ground and 65dB minimum with respect to isolated ground when measured at 60Hz. Common mode range for patient cable input ≥ 10 volts peak with respect to isolated ground.
MONITOR SCREEN	
Size:	102 mm (4 in.) wide x 76mm (3 in.) tall, non-fade.
Frequency Response:	Non-diagnostic
ECG Leads:	1.0Hz to 40Hz (-3dB).
Paddles:	2.2Hz to 20Hz (-3dB).
Sweep Speed:	25mm/sec.
ECG SIZE	Adjusts amplitude of ECG trace on monitor screen, strip chart recorder, and ECG output.
HEART RATE ALARMS	User-selectable alarm limits. Three high-low settings: 150/40, 120/60, 160/90. Other limit options available through the SETUP menu. Heart rate alarms are disabled during pacing.

Table 6-6 ECG Monitor specifications, *continued*

HEART RATE METER	Three-digit readout displays rates from 20 to 300bpm. Heart rates outside this range do not yield valid systole tones or heart rate display. Heart rate meter is disabled during pacing.
ECG OUTPUT	1V/1mV at X1.0 gain.
1 mV Cal	Button on rear panel simulates a 1mV signal pulse to the ECG input.
CODE SUMMARY critical event record	Digitally-stored record of ECG and device parameters

Table 6-7 Thermal Array Printer specifications

PAPER:	
Size:	50mm x 30m (100 ft.)
Speed:	25 mm/sec.
Delay:	ECG prints eight seconds after first appearing on the monitor screen.
FREQUENCY RESPONSE:	Non-diagnostic. Diagnostic available through the SETUP menu.
ECG Leads: (non-diagnostic)	1.0Hz to 40Hz (-3dB)
ECG Leads: (diagnostic)	0.05Hz to 100Hz (-3dB)
Paddles:	2.2Hz to 20Hz (-3dB).
ANNOTATION	Time, date, ECG lead, ECG gain, heart rate, defibrillation parameters, pacing parameters, and test load discharges.

Table 6-8 General specifications

SIZE		
Height:	35.2cm (13.9 in.)	
Width:	29.7cm (11.7 in.)	
Depth:	31.0cm (12.2 in.)	
Weight:	13.2kg (29.0 lbs.)	
AC INPUT OPTIONS	120 or 240Vac nominal line voltage without adjustment. 50 or 60Hz, with adjustment in SETUP menu.	
POWER CORD LENGTH	3m (10 ft.)	
BATTERY TYPE	Sealed lead-acid, 3 A-hr; 16 Vdc nominal.	
BATTERY CAPACITY	A new, fully-charged battery will provide one of the following prior to shut down:	
	<u>Typical</u>	<u>Minimum</u>
360J discharges	75	40
Minutes of monitoring	90	70
Minutes of pacing	75	50
LOW BATTERY INDICATOR:	Advises operator to connect ac power.	
BATTERY CHARGE INDICATOR:	Illuminates when battery is charging.	
SERVICE INDICATOR:	Indicates self-diagnostic routines have detected improper operation requiring service attention.	
BATTERY CHARGE TIME	Full charge in 24 hours.	
POWER CONSUMPTION	160 watts maximum while monitoring with recorder on and defibrillator charging.	
STANDARD PADDLE ELECTRODE AREA	82 square cm	

Table 6-9 Environmental specifications

ATMOSPHERIC PRESSURE	797mmHg to 500mmHg (-570 to 11,000 ft.).
RELATIVE HUMIDITY	0 to 95% (non-condensing) between 0 to 34°C (32 to 94°F). 0 to 80% (non-condensing) between 35 to 45°C (95 to 113°F).
TEMPERATURE	
Operating Range:	0 to 45°C (32 to 113°F).
Storage:	-30 to 65°C (-22 to 149°F).

Table 6-10 Defibrillator specifications

DEFIBRILLATOR WAVEFORM	5 millisecond monophasic pulse (Edmark).
ENERGY SELECT	
External Paddles	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 50, 100, 200, 300, 360 joules
Internal Paddles	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, 50 joules
CHARGE TIME	Charge to 360 joules in less than 10 seconds with a fully-charged battery.
CHARGE CONTROLS	Independent momentary button controls on front panel and APEX paddle.
CHARGE INDICATORS	Flashing lamps on paddle and front panel button along with increasing stored energy display on monitor screen indicate charge in progress. Upon full charge, energy available is displayed on the monitor screen and charge completed tone sounds.
PADDLE CORD LENGTH	3 meters (10 feet)
SYNC	Synchronizes defibrillator pulse to patient-generated QRS complex.
SYNC INDICATOR	Inverted triangle marker (▼) on displayed ECG waveform identifies synchronizer trigger point with respect to patient's QRS complex.

Table 6-11 Noninvasive Pacemaker specifications

OUTPUT RATE	40 to 170ppm
OUTPUT WAVEFORM	Monophasic, truncated, exponential current pulse (15 to 25% droop).
OUTPUT CURRENT	0 to 200mA.
REFRACTORY PERIOD	
40 to 100ppm:	300msec
110 to 120ppm:	250msec
130 to 140ppm:	220msec
150 to 170ppm:	200msec
MODE	Demand or non-demand.

All specifications at 20°C unless otherwise stated. Specifications subject to change without notice.

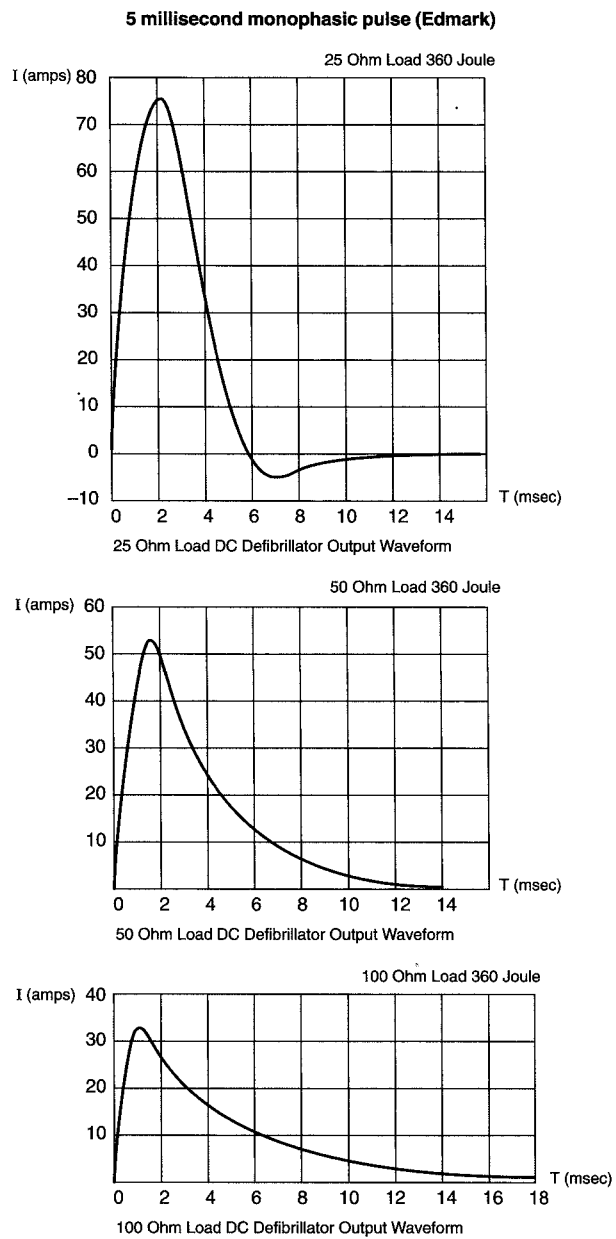


Figure 6-3 Defibrillation waveforms

Appendices / Change Summary

Appendix A

Warning Reference Guide

All of the warnings provided in the previous sections of this manual are reproduced for reference in this appendix.

General Warnings

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

Shock or fire hazard. Do not immerse any portion of this device in water or other fluids. Avoid spilling any fluids on device or accessories.

Do not clean with alcohol, ketones, or other flammable agents. Do not autoclave this device or accessories unless otherwise specified.

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

Safety risk. Use of non-Physio-Control defibrillation electrodes, batteries, accessories, or adapter devices may cause the device to operate improperly.

**General Warnings
Continued****Possible interference with implanted devices.**

Magnets inside the standard defibrillation paddles may affect the function of an implanted pacemaker or implanted defibrillator if paddles are positioned over or near implanted devices. Have function of implanted device checked after using standard paddles.

Safety risk and possible equipment damage.

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

Battery Warning

Possible defibrillator shutdown. When operating on battery power, the large current draw required for defibrillator charging may cause the defibrillator to reach shutdown voltage levels with no low battery warning. If the defibrillator shuts down without warning, or if a LOW BATTERY CONNECT AC POWER message appears on the monitor screen, immediately connect the ac power cord to an outlet.

Monitoring Warnings

Safety risk. Use only Physio-Control ECG cables listed in this manual. Substitution of non-Physio-Control ECG cables may result in inaccurate ECG data.

Possible misinterpretation of monitor screen ECG data. The monitor screen frequency response is only intended for rhythm identification. Use the recorder in DIAG mode for diagnostic interpretations.

Possible misinterpretation of ECG recordings. When attempting to visually detect subtle ECG characteristics such as ST segment abnormalities, use the recorder only in diagnostic frequency response mode (DIAG). The recorder normally operates in monitor frequency response mode. It does not provide the resolution required for diagnostic and ST segment interpretation, and is intended only for basic ECG rhythm identification.

Possible electrical interference with ECG monitoring. Do not operate this device with electrocautery or diathermy equipment. Such equipment, as well as equipment which emits strong radio frequency signals, can cause electrical interference and distort the displayed or recorded ECG signal, thereby preventing accurate rhythm analysis.

Defibrillation Warnings

Shock hazard. When discharged, this defibrillator delivers up to 360 joules of electrical energy. Do not touch the paddle electrode surface or defibrillation electrodes.

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

Possible burns and ineffective energy delivery. Do not allow physical contact between the ECG electrodes and the paddles, defibrillation electrodes, or defibrillation gel. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating energy away from the heart muscle.

Shock hazard. Conductive gel (wet or dry) on the paddle handles can allow the electrical energy to discharge through the operator during defibrillation. Be sure to completely clean the paddle electrode surfaces, handles, and paddle storage area after defibrillation.

Possible skin burns. During defibrillation, air pockets between the skin and paddle electrode surfaces or defibrillation electrodes can cause patient skin burns. To help prevent air pockets, completely cover paddle electrode surfaces with conductive gel and press paddles firmly against the patient, or make sure self-adhesive defibrillation electrodes completely adhere to the skin. The conductive gel or electrodes must not be dried out.

**Defibrillation Warnings
Continued****Possible interference with implanted pacemakers.**

When cardioversion or defibrillation is performed on patients with permanent pacemakers, care should be taken to avoid placing the paddles/defibrillation electrodes near the pacemaker's generator since defibrillation can cause pacemaker malfunction. Check pacing thresholds for implanted pacemaker patients.

Possible interference with implanted devices.

Check function of implanted devices after defibrillation or synchronized cardioversion.

Possible burns and ineffective energy delivery.

A gel pathway on the skin between the paddles will cause the current to arc between paddles and divert defibrillating energy away from the heart muscle. Do not allow conductive gel (wet or dry) to become continuous between paddle sites.

Possible paddle damage and skin burns. Do not discharge the defibrillator with the paddle electrode surfaces together because this may pit or damage the paddle plate surfaces. Pitted or damaged paddle electrode surfaces can cause patient skin burns during defibrillation.

Shock hazard. Do not discharge the defibrillator into the open air. To remove an unneeded charge, press ENERGY SELECT or remove defibrillator power by pressing ON button.

Pacing Warnings

Possible interruption of therapy. Do not leave patient unattended while pacemaker is in use. Observe the patient continuously to assess any changes in patient response to pacing therapy.

Possible skin burns and ineffective pacing therapy. Pacing electrodes which are dried or damaged may not adhere properly and may delay therapy delivery or cause patient skin burns. To help prevent drying or damage, do not use pacing electrodes if they have been removed from the foil package for more than 24 hours or if the protective liner has been removed for more than 60 minutes. Do not use electrodes beyond expiration date. Inspect electrodes to make sure adhesive is intact and undamaged.

Possible patient skin burns during prolonged pacing. Prolonged noninvasive pacing may cause patient skin irritation and burns, especially with higher pacing current levels. Discontinue noninvasive pacing if skin becomes irritated and another method of pacing is available.

Possible inhibition of pacing therapy. Do not substitute ECG electrodes or defibrillation electrodes for pacing electrodes.

Possible improper pacing. In the demand mode, the ECG SIZE must be properly adjusted to detect intrinsic complexes and deliver pacing pulses when appropriate. If ECG SIZE is set too high or too low, pacing pulses may not be delivered when required.

Testing Warning**Possible paddle damage and patient burns.**

Be sure paddles are secured firmly and placed properly (STERNUM on left, APEX on right) in the paddles storage area when discharging. This helps prevent arcing and formation of pits on paddle electrode surfaces. Pitted or damaged paddle electrode surfaces can cause patient skin burns during defibrillation.

Appendix B

CODE SUMMARY Record Formats

Formats for each code event record printed on paper designed for thermal array recorders.

Initial Format

The first section of the printed CODE SUMMARY record is an overview of the use of the defibrillator/monitor/pacemaker, including:

- Space for patient's name
- CODE SUMMARY critical event record label
- Date
- Power on time
- Shock tally
- Total time paced
- Time from power on to print of CODE SUMMARY record.

NAME		COMMENTS
CODE SUMMARY™		
CRITICAL EVENT RECORD		
19 NOV 93		
POWER ON	13:43:41	
TOTAL SHOCKS	1	
TOTAL TIME PACED	00:02:28	
ELAPSED TIME	00:00:49	

Figure 7-1 CODE SUMMARY record, initial format (not to scale)

Defibrillation Format

The defibrillation format is printed for each shock delivered.

The defibrillation format includes:

- Space for patient's name
- DEFIBRILLATION label
- Date
- Shock number and time delivered
- Energy selected
- SYNC mode (if engaged)
- Type of paddle used to deliver shock
- Three seconds of ECG preceding defibrillation
- Five and one half seconds of ECG following defibrillation
- Annotation of lead and gain settings.

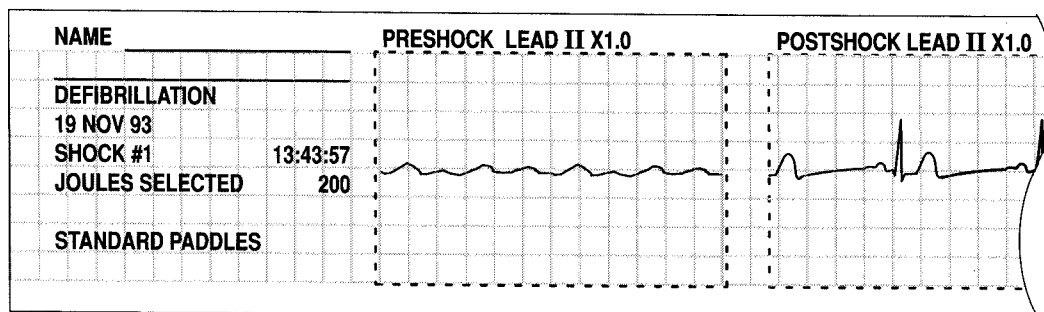


Figure 7-2 CODE SUMMARY record, defibrillation format (not to scale)

Recorder Format

The recorder format summarizes recorder usage including:

- Space for patient's name
- RECORDED ECG label
- Date
- How the recorder was activated (operator, high or low HR alarm) and time activated
- Heart rate
- Six seconds of ECG: three seconds preceding and three seconds following recorder activation
- Annotation of lead and gain settings
- SUMMARY COMPLETED is printed on the last CODE SUMMARY segment.

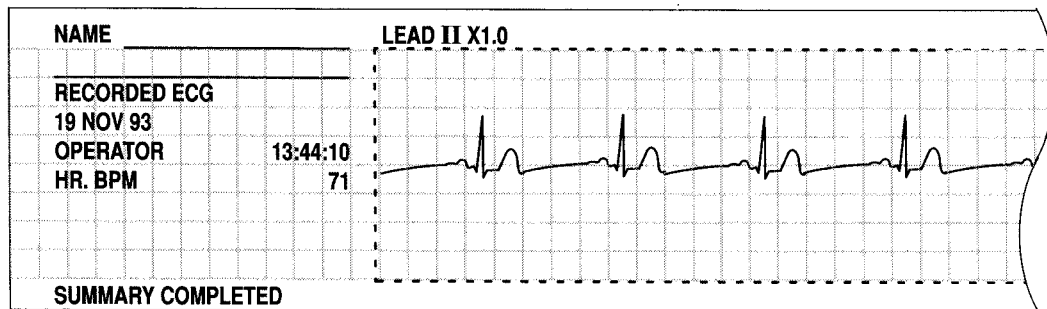


Figure 7-3 CODE SUMMARY record, recorder format (not to scale)

Noninvasive Pacing Format

There are two types of pacing formats:

The first format occurs when pacing is initiated and current exceeds 7mA (see Figure 7-4). The first format includes:

- Space for the patient name
- PACING EVENT label
- Date and time pacemaker activated
- Demand or non-demand pacing mode
- Pacemaker rate (ppm) and current (mA) parameters
- Three seconds of ECG immediately preceding pacing current delivery labeled PREPACE
- Five and one-half seconds of ECG acquired immediately after pacing rate or current adjustments have stabilized for 10 seconds
- Each pacing stimulus is identified by an arrow (↑) in the lower margin
- Annotation of time, lead, and gain settings.

If memory capacity is reached, the preamble will be printed without the associated pacing segments.

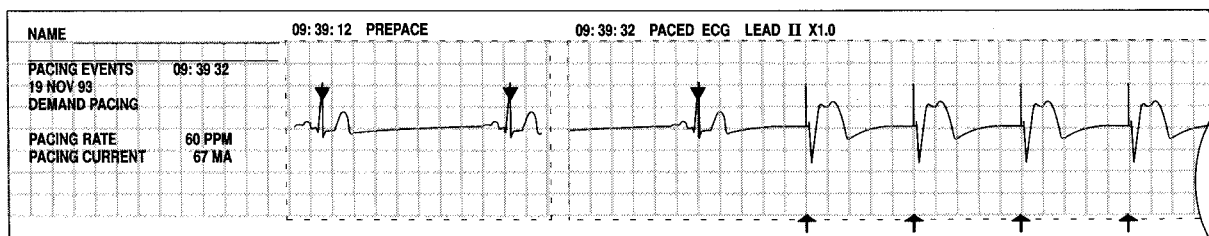


Figure 7-4 CODE SUMMARY record, noninvasive pacing format, current exceeds 7mA (not to scale)

The second type of pacing format occurs whenever pacing rate or current adjustments have changed (see Figure 7-5). The preamble includes:

- Same preamble information as in the first format
- Six seconds of ECG acquired immediately after pacing rate or current adjustments have stabilized for 10 seconds
- Each pacing energy stimulus is identified by an arrow (↑) in the lower margin
- Annotation of lead and gain settings.

Whenever pacing current returns to 0mA, a preamble and a print with six seconds of ECG is generated indicating the time pacing stopped.

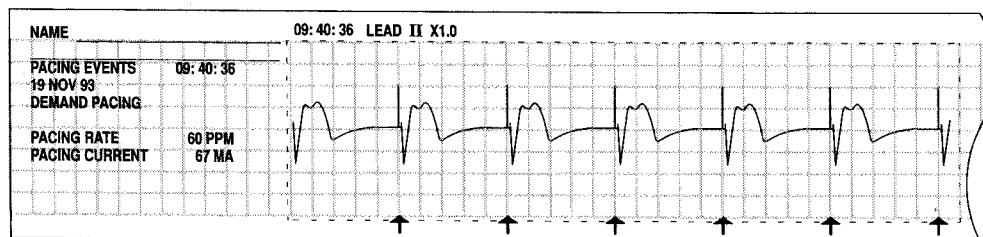


Figure 7-5 CODE SUMMARY record, noninvasive pacing format, with pacing rate/current adjustments (not to scale)

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