Welch Allyn

*Portable Intensive Care System*

# PIC30


# User Instruction Manual

***Welch Allyn Part Number 991022 – Revision C***

Welch Allyn®

# Portable Intensive Care System

*USER INSTRUCTION MANUAL*

Model: PIC 30

Software Revision W

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Welch Allyn Part Number 991022 - Revision C

# Foreword

This manual is intended to provide information for the proper operation of the Welch Allyn PIC 30.

DO NOT ATTEMPT TO USE THIS EQUIPMENT WITHOUT THOROUGHLY READING AND UNDERSTANDING THESE INSTRUCTIONS.

## USER'S RESPONSIBILITY

The user is required to be trained in basic monitoring, vital signs assessment, and emergency cardiac care. As with all other electronic patient care monitors, good clinical judgment should be used when operating the Welch Allyn PIC. The user should be completely knowledgeable of the information in the User Instruction Manual.

User must save all shipping containers and packaging materials. When shipping the PIC System and accessories for calibration, service, or upgrades, the original shipping containers and packaging materials must be used.

## MANUFACTURER'S RESPONSIBILITY

Welch Allyn is responsible for the safety, reliability, and performance of the Welch Allyn Portable Intensive Care System only if the following three conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Welch Allyn.
- The electrical installation of the relevant room complies with the appropriate requirements.
- The PIC equipment is used in accordance with the instructions for use.

To ensure patient safety and proper operation, use only Welch Allyn authorized parts and accessories.

# FDA Medical Device Registration

The FDA Safe Medical Device Act stipulates that each end-user is required under penalty of law to register with the manufacturer all information pertinent to each medical device.

Please fill out the attached FDA Medical Device Registration postcard and return it promptly to Welch Allyn. This card must be filled in and returned within 30 days of product delivery.

If the medical device is transferred from your possession, you must notify Welch Allyn of the new registration information.

Please contact Welch Allyn (800/462-0777) if you have any questions regarding this notice.

# Declaration of Conformity

Manufacturer:

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a Welch Allyn Company
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Fax (847) 520-0303

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**declares that the CE-marked product**

***Product Name: PIC30 (Portable Intensive Care)***

**Base Units**
972039 — PIC30, BIPHASIC, MONOCHROME DISPLAY
973039 — PIC30, BIPHASIC, COLOR DISPLAY

**Options**
971029 - Charger
971031 - Pacing
971032 - Advisory

***Device Type:*** Defibrillator / External Transcutaneous Pacemaker / Multifunction Monitor

**complies with Council Directive 93/42/EEC (Medical Device Directive) of 14 June 1993 class IIb Annex II**

***Standards:***

General: ISP 9001
EN 46001

Safety: IEC 601-1 / EN 60601-1 — Class I, Continuous operation
Type BF (with external paddles) or
Type CF (with internal paddles)

IEC 601-1-4 / EN 60601-1-4
IEC 601-2-4 / EN 60601-2-4
IEC 601-2-25 / EN 60601-2-25
EN 475

***EMC*** EC 601-1-2 / EN 60601-1-2

_____ _____

Huy Doan
Site Quality Manager

Date

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# Intended Use

The Welch Allyn PIC30 is intended for ECG monitoring, defibrillation, and transthoracic external pacing and can be use by trained, authorized medical personnel who are familiar with basic monitoring, vital signs assessment, and emergency cardiac care. The PIC30 is also intended for use by physicians at the scene of an emergency or in a hospital emergency room.

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

It is highly recommended that any person using the PIC30 should have been trained in CPR or be ACLS certified, and be completely knowledgeable of the information in this manual.

# Warnings, Cautions, and Notices

## WARNINGS

**WARNING:** If conductive gel forms a continuous path between the defibrillator electrodes, delivered energy to the heart muscle may be dramatically reduced, resulting in ineffective defibrillation. In this case, remove the gel by wiping the surface of the body and reposition the electrodes, to eliminate the shunting path before attempting additional shocks.

**WARNING:** The PIC30 can deliver 360 joules of electrical energy. If proper defibrillation protocol is not followed as described in this manual, the electrical energy could cause personal injury or death to the operator or a bystander.

**WARNING:** During defibrillation discharge, the operator and all other people must not contact the patient, the bed or any other conductive surfaces that are in contact with the patient. The electrical energy delivered to the patient could also be shunted to any other person who is in contact with the patient or the conductive surface.

**WARNING:** Do not use the defibrillator in the presence of oxygen sources (such as bag-valve-mask devices or ventilators), flammable gases or anesthetics. These environments can produce fire or explosion hazards. Remove all oxygen sources from the patient vicinity before discharge.

**WARNING:** Electrical shock hazard. DO NOT contact the patient during defibrillation. Otherwise, serious injury or death could result.

**WARNING:** NEVER position defibrillator paddles very close to or over ECG sensors or jewelry. Severe burns may result from improper placement of defibrillator paddles against the body surface.

**WARNING:** Hazardous voltage. To reduce the risk of electrical shock, DO NOT attempt to remove the cover of the PIC30 under any circumstances. Refer servicing to a qualified technician.

**WARNING:** If safety procedures are not performed, increased risk to patient, operator and device can occur.

**WARNING:** Shock hazard. Use of accessories, other than those specified in these operating instructions, or additional equipment attached to the patient may adversely affect safe levels of patient leakage currents.

**WARNING:** Defibrillator paddles should be kept clean and dry when not in use. When preparing electrodes and during defibrillation procedures, extreme care should be exercised to prevent gel or any conductive material from forming a pathway between the operator and metal electrodes of the paddles. Do not allow gel or any other conductive material to form an electrical bridge between the defibrillator electrodes or to the monitoring electrodes. Electrical arcing and/or patient burns could occur during defibrillation. Arcing and patient burns could prevent sufficient defibrillation energy from being delivered to the patient.

## GENERAL CAUTIONS

### ACCESSORIES

Use only authorized accessories (listed on page 1.2 of this manual). Use of unauthorized accessories may cause the device to operate improperly and provide false measurements.

### STERILIZATION

Do not attempt to sterilize any accessory or any equipment part.

### BATTERY CARE

Proper care and maintenance of the batteries is important to insure continuous operation during portable use of the PIC30. If the batteries are not maintained properly, loss of power during portable use could result, affecting patient care.

### DROPPED OR DAMAGED

If this device has been dropped or damaged in any way, refer the device to qualified service personnel for verification of performance and/or servicing.

### INGRESS OF LIQUIDS

To achieve the specified level of protection against spilled or splashed liquids, thoroughly dry all exposed surfaces of this device prior to operation or connection to mains power.

### DISPOSABLE ELECTRODES

When obtaining a new supply of disposable electrodes for monitoring, defibrillation or pacing, verify that they will properly connect to the existing cables prior to putting in service. Do not use these electrodes if gel is dry. Always verify expiration dates on dated items such as disposable defibrillation or pacing pads, monitoring electrodes and battery packs. If the expiration date has passed, replace the disposable items immediately.

### FERROMAGNETIC EQUIPMENT

Biomedical equipment and accessories, such as ECG electrodes and cables contain ferromagnetic materials. Ferromagnetic equipment must not be used in the presence of high magnetic fields created by magnetic resonance imaging (MRI) equipment. The large magnetic fields generated by an MRI device can move ferromagnetic equipment with an extremely violent force, which could cause serious personal injury or death to persons between the equipment and the MRI device.

### LABELS

Observe all CAUTION and WARNING labels on the equipment and accessories.

### PATIENT OR OPERATOR PHYSICAL HARM

Place the PIC30 System, accessories and cables in a position where they cannot harm the patient should they fall. Keep all cables away from the patient's neck and feet to prevent entanglement.

### PERFORMANCE

The PIC30 may not meet performance specifications if stored, transported or used outside the specified storage or operating environmental range limits.

### EVENT LOG SUMMARY

To prevent incorrect trending data from being printed, clear the Log from the Log menu prior to use on a new patient.

## MONITORING CAUTIONS

**CAUTION:** Use only PIC30 patient cables. Other cables can produce excessive artifact, causing an inability to interpret the ECG.

**CAUTION:** Use only ECG electrodes that meet the AAMI standard for electrode performance (AAMI EC-12). Use of electrodes not meeting this AAMI standard could cause the ECG trace recovery after defibrillation to be significantly delayed.

**CAUTION:** The type of surface ECG electrodes and the technique used in applying the electrodes are major factors in determining the quality of the signal obtained. Use high-quality, silver-silver chloride electrodes. These electrodes are designed to provide excellent baseline stability, and rapid recovery from defibrillation, and minimize artifacts from patient movement. Do not use electrodes if gel is dry.

**CAUTION:** When attempting to interpret subtle ECG changes (ST segments, etc.), use only the diagnostic frequency response mode. Other frequency response settings may cause misinterpretation of the patient's ECG. See Frequency Response section on page 3.6 for further details.

**CAUTION:** Excessive artifact can be the result of improper skin preparation of the electrode sites. Follow skin preparation instructions on page 4.2.

**CAUTION:** Do not operate the PIC30 in conjunction with electrocautery or diathermy equipment. Such equipment, as well as equipment that emits strong radio frequency signals, can cause electrical interference and distort the ECG signal displayed by the monitor, thereby preventing accurate interpretation of the rhythm.

**CAUTION:** Do not operate the PIC30 in close proximity to any other monitor with respiration measurements. The two devices could affect the respiration accuracy.

**CAUTION:** The following caution is in accordance with the disclosure requirement of AAMI Standard EC13-1992 section 3.1.2.1m: Certain line-isolation monitors may cause interference on the ECG display and may inhibit heart rate alarms.

***Note: This caution is an AAMI requirement that applies to all ECG monitors, regardless of make or model.***

**CAUTION:** Do not use the auto gain setting for diagnosing asystole.

**CAUTION:** Conductive parts of electrodes and conductors, for applied parts, should not contact other conductive parts including earth. (IEC 601-2-27).

## DEFIBRILLATION CAUTIONS

**CAUTION:** After a synchronized cardioversion, the SYNC mode can be configured to be cleared after each shock or disarm. The user may have to reselect (press) the SYNC switch after each synchronized cardioversion shock performed on a patient. The PIC30 can be configured in the Supervisor-Defibrillation Set-up menu to remain in the SYNC mode after each synchronized cardioversion.

**CAUTION:** Synchronized cardioversion can be performed in the paddle monitoring mode. However, it is possible that artifact can be produced by the moving paddles, which could cause the defibrillator to trigger on the artifact. It is recommended that monitoring in leads I, II or III be used during synchronized cardioversion. Paddle monitoring should not be used for elective cardioversion procedures.

**CAUTION:** To avoid damage to the defibrillator or the tester, never attempt to repeatedly charge and discharge the defibrillator in rapid succession. If a need for repetitive testing arises, allow a waiting period of at least 1 minute for every third discharge.

**CAUTION:** Monitoring ECG through the paddles may result in inaccurate heart rate display due to artifact.

**CAUTION:** In the SYNC mode the defibrillator will not discharge without a command (R-Wave) signal indicated by a SYNC marker, flashing SYNC indicator and an audible beep if the R-wave beeper is enabled.

**CAUTION:** Do not use the defibrillator if excessive condensation is visible on the device.

**CAUTION:** Use only Welch Allyn approved disposable defibrillation and pacing pads and cables. Ineffective pacing or defibrillation may result.

**CAUTION:** Improper defibrillation technique can cause skin burns. To limit possible skin burns, use only approved defibrillation gel on paddles, insure that the gel covers the entire paddle surface and press firmly against patient's bare chest (no electrodes or foreign objects underneath the paddles).

**CAUTION:** Disposable defibrillation electrodes must be used in accordance with the manufacturer's instructions. Do not use expired, dry electrodes or reuse disposable electrodes, as improper patient contact may result in patient burns and inability of the device to function properly and/or ineffective defibrillation..

**CAUTION:** The device contains an automatic disarm of the stored energy. If the operator has not delivered the energy to a patient or test load, an internal timer will disarm the stored energy 1 minute after the charge ready signal occurs. The charge ready signal is indicated by a continuous audible tone and the energy availability graph displayed on the monitor. The unit will indicate disarm activate with change in pitch 10 seconds prior to disarm

**CAUTION:** If a new energy level is selected after the charge button is pushed and while the defibrillator is charging, defibrillator will automatically charge to the new energy selection. The CHARGE button need not be pressed again to select the new energy level.

**CAUTION:** Any medical electronic device that is not labeled "defibrillation protected"must be disconnected from the patient. Otherwise damage or patient injury may occur.

**CAUTION:** Some erythema of the skin and/or minor burns may occur during defibrillation. Use proper defibrillation techniques, as outlined in this operating instruction manual, to minimize erythema/burns.

**CAUTION:** Decision to shock must be made by qualified medical personnel trained in CPR and advanced cardiac life support.

## PACER CAUTIONS (OPTIONAL FEATURE)

**CAUTION:** Defibrillation will take priority over external pacing. Should the defibrillator be charged during the administration of external pacing, the pacer will automatically be turned off and the defibrillator will charge to the selected energy.

**CAUTION:** Transcutaneous pacing should not be used to treat V FIB (ventricular fibrillation). In cases of V FIB, immediate defibrillation is advised.

**CAUTION:** Transcutaneous pacing may cause discomfort ranging from mild to severe, depending on the patient's tolerance level, muscle contractions and electrode placement. In certain cases, discomfort may be decreased by slightly relocating the pacing pads.

**CAUTION:** It is important to monitor the patient closely to verify that both mechanical and electrical capture are occurring. Electrical capture can be verified by observing the presence of a large ectopic beat after the pacing pulse is delivered. The size and morphology of the beat are dependent on the patient. In some instances the beat may appear as a relatively normal looking QRS pulse. Mechanical capture can be verified by checking for signs of increased blood flow i.e., reddening of the skin, palpable pulses, increased blood pressure, etc. Continuously observe the patient during pacing administration to insure capture retention. Do not leave the patient unattended when administering external pacing therapy.

**CAUTION:** Some erythema of the skin and/or minor burns may occur under the pacing electrodes in some patients. For prolonged periods of pacing (>4 hours), periodically inspecting the skin beneath the electrodes (when patient's condition allows) is recommended. Evaluate the patient's condition and if the skin is degrading discontinue external pacing if it is not required, repositioning is not possible and/or another form of pacing is available.

**CAUTION:** Disposable defibrillation/pacing electrodes must be used in accordance with the manufacturer's instructions. Do not use expired, dry electrodes or reuse disposable electrodes, as improper patient contact may result in patient burns, ineffective pacing and inability of the device to function properly.

**CAUTION:** The pacing rate determination can be adversely affected by artifact. If the patient's pulse and the heart rate display are significantly different, external pacing pulses may not be delivered when required. Ensure good ECG electrode contact.

**CAUTION:** Artifact and ECG noise can make R-wave detection unreliable, affecting the HR meter and the demand mode pacing rate. Always observe the patient closely during pacing operations. Consider using asynchronous pacing mode if a reliable ECG trace is unobtainable.

## ADVISORY CAUTIONS (OPTIONAL FEATURE)

**CAUTION:** Cardiac Pacemakers. The presence of an internal cardiac pacemaker may adversely affect analysis results. If it is known, or suspected, that the patient is fitted with a cardiac pacemaker, follow your own locally-established procedure for dealing with defibrillation of such patients.

**CAUTION:** The Advisory mode should only be utilized on victims of cardiac arrest who exhibit unconsciousness, absence of breathing, and absence of pulse.

**CAUTION:** Excessive motion may affect analysis results. ECG analysis should not be performed when the patient is being moved. Stop all patient movement and do not touch patient when the ECG analysis is in process. Take precautions to eliminate sources of motion or artifact before using the Advisory feature.

## BATTERY CAUTIONS

**CAUTION:** Battery is shipped discharged. Charge fully before use. Charge time to 100% is approximately 4 hours.

**CAUTION:** Use only Welch Allyn batteries in the PIC30. Use of any other battery can damage the PIC30 and/or not provide sufficient power, inhibiting patient care.

**CAUTION:** Due to the critical dependency on batteries, replacement of the battery is recommended at 24-month intervals due to self degradation of the battery chemistry. Periodic maintenance and testing is highly recommended to ensure proper battery performance.

## POWER SOURCE AND INTERNAL PIC30 DEFIB TESTER (OPTIONAL)

**CAUTION:** When testing the defibrillator, ensure that the paddle surface is positioned properly in the paddle holder test well. Do not use gel during this test. When discharging the paddles into the tester, press the paddles firmly onto the test points to prevent pitting the paddle surfaces.

**CAUTION:** Do not take the paddle holder apart or attempt to repair it yourself.

**CAUTION:** The power source should not be used in the presence of flammable anesthetics or materials.

## NOTICES

**NOTICE:** A battery is not mandatory for operation of the PIC30. The PIC30 will operate from an optional AC power source alone. Some defibrillation charging times will increase with no battery installed.

**NOTICE:** Do not place a used battery pack in your regular trash. The incineration, land filling, or mixing of NiCad batteries with municipal waste is PROHIBITED BY LAW in most areas. Return this battery pack to a government-approved battery recycler. Contact your local waste management officials for more information.

**NOTICE:** U.S. Federal law restricts this device to use by or on the order of a physician.

**NOTICE:** If the battery pack is removed for any reason, labeling of the PIC30 is required indicating out-of-service for battery operation.

# Definitions of Symbols Used

## SAFETY SYMBOLS

Graphical symbols, letter symbols and signs listed below may be found on the PIC30 and accessories. Please note the use of these symbols for safe and proper use of the equipment.

| | | | |
|---|---|---|---|
|  | Alternating current |  | Negative input terminal |
|  | Attention, consult accompanying documents |  | Positive input terminal |
|  | Auxiliary power operation |  | Power off |
|  | Caution, high voltage |  | Power on |
|  | Dangerous voltage |  | Recycle battery |
|  | Defibrillator protected, type BF patient connection |  | Protective earth (ground) |
|  | Defibrillator protected, type CF patient connection |  | Defibrillator discharge button |
|  | Earth (ground) |  | Release |

## CERTIFICATION SYMBOLS

This symbol on the device indicates that the device meets the requirements of Council Directive 93/42/EEC, MDD, Class IIb.

This symbol on the device indicates that the device meets the requirements of Council Directive 93/42/EEC, MDD, Class I.

Underwriters Laboratories Listed Device UL 544

Canadian Underwriters Laboratories Listed Device

## DISPLAY SYMBOLS

Graphical and text icons listed below may be found on the display of the PIC30 during operation.

| | | | |
|---|---|---|---|
|  | Alarm off |   | Auto heart rate undetermined |
|  | Alarm on |   | Internal log gauge |
|  | Alarm lower limit set |  | Mute |
|  | Alarm upper limit set |  | QRS beeper off |
|   | Automatic HR Alarm set |  | QRS beeper on |
|   | Alarm - push to disable |   | Volume level |
|   | Battery full |  | Supervisor menu locked |
|   | Battery low warning |  | Supervisor menu unlock |
|   | Battery (partially depleted) |  | Notch filter On |
|  | Calibration pulse |  | Brightness |
|  | Check chart recorder |   | Advisory (Optional) |

# Chapter 1 General Information

Congratulations on your purchase of a top quality Welch Allyn PIC30 defibrillator.

Your business is important to us. If you would like more information or if you have any questions, contact your local representative or call Welch Allyn, Inc. Technical Service Department at (800) 462-0777 or (847) 520-0300.

***CAUTION: Federal law restricts this device to use by or on the order of a physician.***


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# Accessories

## INCLUDED

| Part No. | Description |
|---|---|
| 001790 | 3-lead patient cable (AHA) |
| 001647 | Super Pac |
| 001725 | ECG electrodes |
| 002051 | Defibrillator gel (1 tube) |
| 800576 | Power cord (country dependent) |
| 001741 | ECG chart paper |
| 991022 | Operating manual |
| 971106 | Standard paddle set |
| 001853 | Defibrillation pads, adult |

## OPTIONAL

| Part No. | Description |
|---|---|
| 971107 | Pacing and hands-free adapter |
| 971125 | Internal paddle adapter |
| 570310 | Internal paddle cable |
| 001517 | Internal paddle electrode, adult (set) |
| 001516 | Internal paddle electrode, pediatric (set) |
| 001537 | Pediatric paddle adapters (set) |
| 980139 | 3LD Simulator |
| 001795 | 5 - lead AHA patient cables |
| 001796 | 5 - lead IEC patient cables |
| 001794 | 3 - lead IEC patient cables |
| 971108 | Deluxe paddle set |
| 971032 | Field upgrade, advisory option |
| 971031 | Field upgrade, pacer option |
| 001788 | Multipurpose electrodes, adult |
| 001781 | Multipurpose electrodes, pediatric |
| 001720 | Bitrode limb electrodes |
| 002052 | KLEAN TRACE™ conductive spray |
| 971029 | Paddle tray/charger |
| 001638 | SmartPak Plus battery |
| 971104 | Quick Charger |

# Inspection Upon Delivery

Your new PIC30 was carefully inspected before shipment. Inspect your unit upon delivery for any damage which may have occurred in transit. If you notice any damage, please contact your shipping agent.

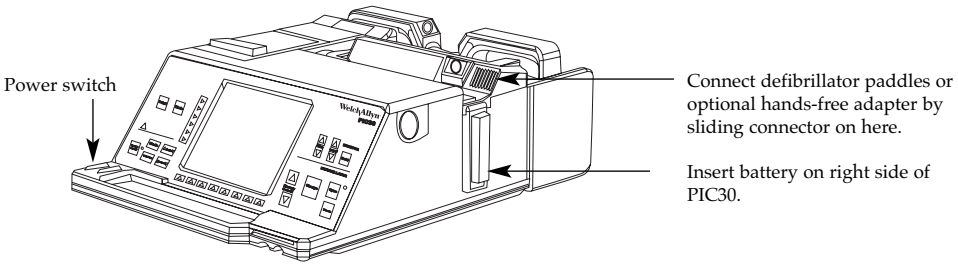
If items are missing, contact your local representative or call Welch Allyn, Inc. Technical Service Department at (800) 462-0777 or (847) 520-0300. To determine the initial installation condition of the PIC30 after shipment, follow the simple steps below:

1. Open and carefully unpack each carton.

2. Examine the instrument and accessories for signs of damage.

3. Check the packing list to determine that all accessories have been received.

Save all packing materials, invoicing, and any other paperwork in case discrepancies occur.




## DETERMINE SOFTWARE SETUP

In order to ensure that the device is running properly after shipping and the proper features are installed, follow the instructions below:

1. Connect defibrillator paddles or the multipurpose hands-free adapter.

2. Plug the AC power cord into the PIC30 and into a power outlet.

3. Insert a PIC30 battery into the battery slot and charge battery.

4. Press the PIC30 power switch to ON.

5. The PIC30 will perform a series of self-tests and a “Self-Test Passed” message will be printed on the chart recorder paper.

6. Installed features will appear on the display after the self-tests have been completed. Standard features are ECG monitor and defibrillator. Optional features are pacer and advisory function.

If you note any discrepancies, please contact Welch Allyn with your model and serial number.

## ADVISORY OPTION

The PIC30 is available with an advisory ECG analysis option. This option is an effective way of acquiring a second opinion of a patient’s ECG condition within seconds. Developed by Medical Research Laboratories, the Advisory option analyzes a patient’s ECG and displays a “Shock Advised” or “No Shock Advised” prompt within 4 - 16 seconds.

# General Description

## FLEXIBLE DESIGN

The PIC30 has been designed to allow additional options to be installed anytime in the future. This system can grow with your needs.

## SMALL, LIGHTWEIGHT

Weighing only 13.5 lb (6 kg), excluding battery, and not much larger than a cardiac monitor, this full-function intensive care tool is ideal for transport/portable applications.

## LARGE, 6.4" (16.2 CM) BRIGHT LCD DISPLAY

A large, bright display allows viewing the critical parameters from significant distance.

# Safety Features

**WARNING: Electrical shock hazard. DO NOT contact paddle electrodes or patient during defibrillation. Otherwise, serious injury or death could result.**

**WARNING: NEVER position defibrillator paddles very close to or over ECG electrodes. Severe burns may result from improper contact of defibrillator paddles. Before using defibrillator, consult these operating instructions for proper procedures.**

Includes electrically isolated patient inputs. This conforms to IEC and AAMI/ANSI requirements.

This symbol next to the patient cable connector indicates this equipment is classified as defibrillation-protected, Type CF equipment. The patient cable and input circuits are designed to prevent damage if the unit is connected to a patient during defibrillation.

# Equipment Setup

***Note: The battery that is shipped with your new PIC30 is not charged. To charge the battery and prepare the PIC30 for normal use, follow the instructions below.***

## INSERTING THE BATTERY INTO THE PIC30

To insert the battery, locate the battery slot on the right side of the PIC30 and slide the battery in, connectors first. Press the battery firmly back into the slot to assure proper connection of all 4 contact points on the battery.

## CHARGING A BATTERY

If paddle holder/charger is installed, plug the unit's AC power cord into a wall outlet and insert battery into the PIC30. Otherwise insert the battery into the quick charger. The yellow "charger" indicator will illuminate, indicating that the battery is being charged. This light will remain on for the duration of the charging cycle. When the battery is fully charged, the yellow light will flash to indicate that it is ready for use.

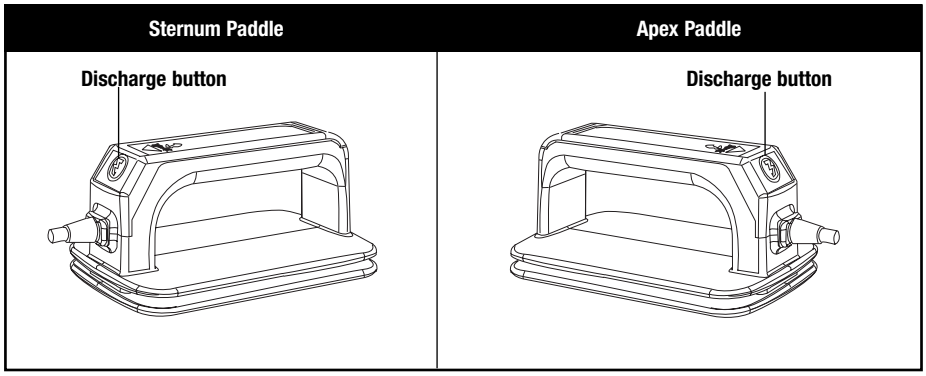
## CONNECTING THE PATIENT CABLE

Make sure the connector on the cable is firmly pushed into the patient connector interface.

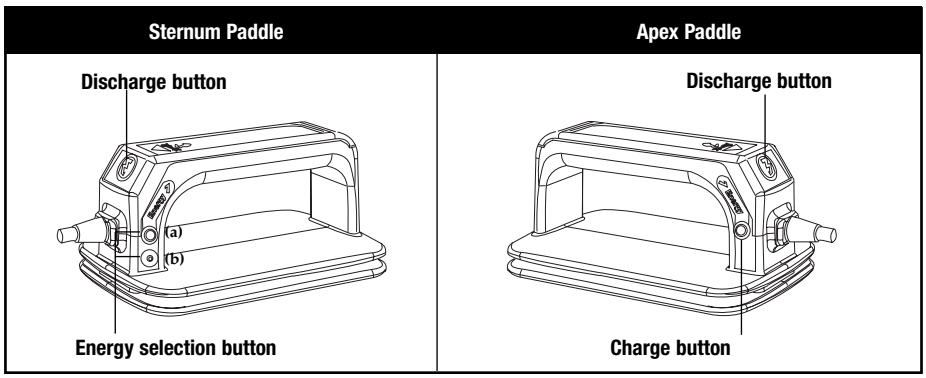
## CONNECTING THE DEFIBRILLATOR ADAPTER

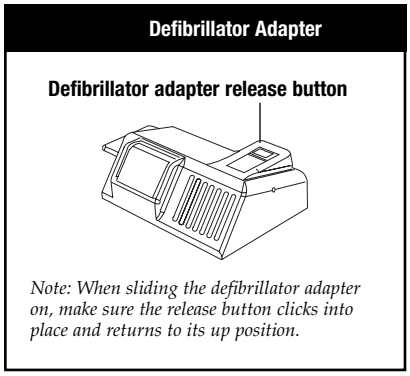
Slide the adapter inward along the guide plate on the defibrillator interface. Make sure the adapter is pushed snug against the plastic housing to assure a solid connection.

**STANDARD ADULT PADDLES**




**DELUXE ADULT PADDLES** (optional)




*Note: When sliding the defibrillator adapter on, make sure the release button clicks into place and returns to its up position.*

Pressing (a) will increase energy selection. Pressing (b) will decrease energy selection.

### Multipurpose Hands-Free Adapter and Electrodes (optional)

1. Multipurpose Pads

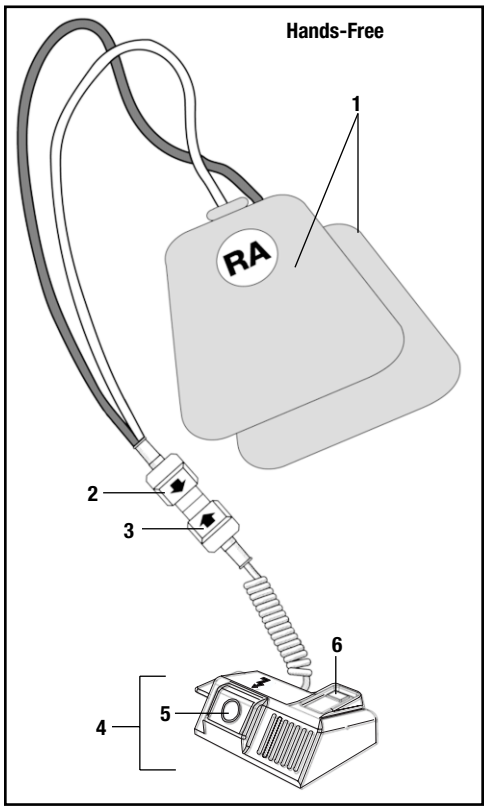
2. Pad Connector
   Connects to patient connector.

3. Patient Connector
   Accepts disposable monitoring / defibrillation /non-invasive pacing pads.

4. Multipurpose Hands-Free Adapter

5. Hands-Free Discharge Button

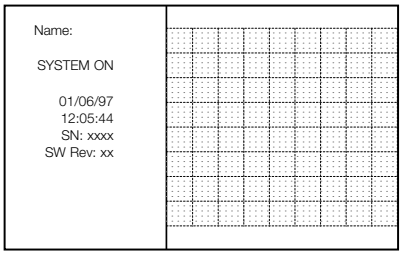
6. Adapter Release Button
   Unlocks the adapter connector from the defibrillator to allow removal.




***Note: When sliding the multipurpose hands-free adapter on make sure the release button clicks into place and returns to its up position.***

## TURNING THE UNIT ON AND OFF

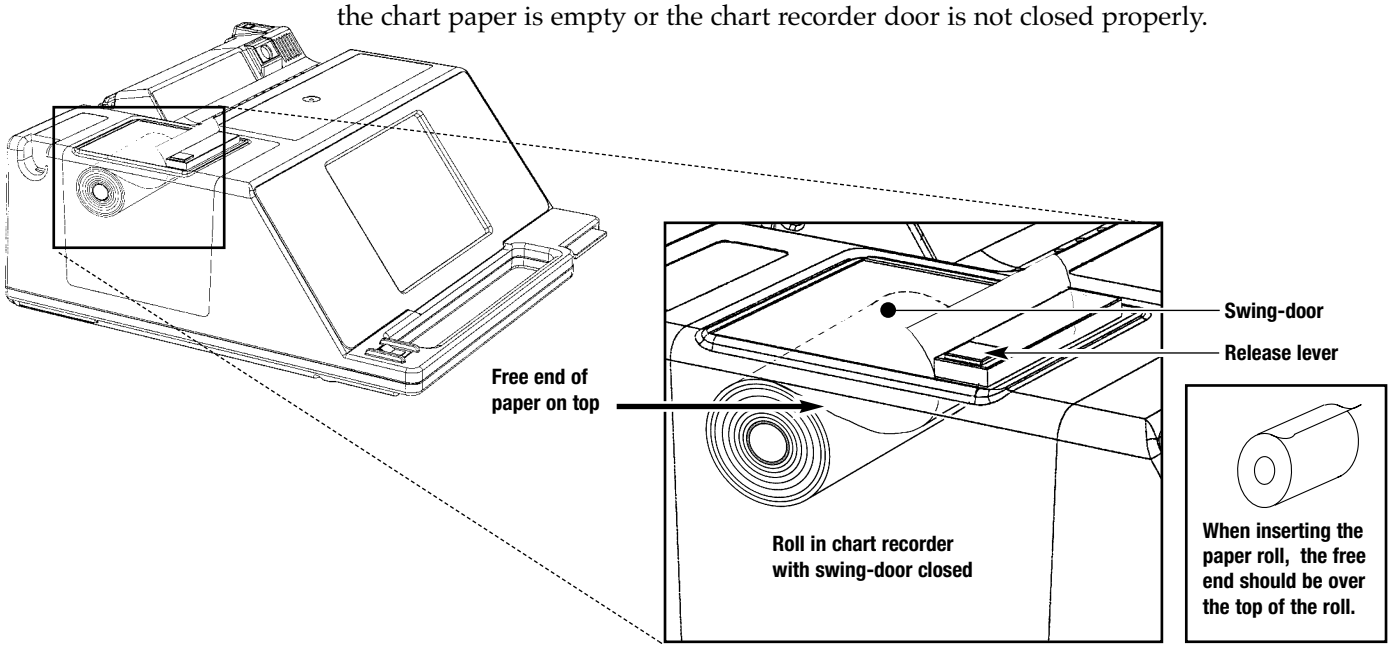
Press the Power switch on the PIC30. The unit performs a self-test and prints out the strip. To power off the unit press the Power switch on the PIC30.




**Test Strip**

# Loading Recording Paper

The check recorder icon ( ) will appear in the message window of the display when the chart paper is empty or the chart recorder door is not closed properly.




***Note: The low paper indicator is signified by a black or red strip at the top of the chart recorder paper. When the indicator appears, approximately 8 ft (2.4 m) of paper is left on the roll.***

***Note: USE only Welch Allyn approved paper.***

1. Open the door by pushing on the release lever located on the side of the chart recorder.
2. Remove the empty spool core. Place the new roll of ECG paper with the free end of the paper on top of the roll. Insert the new spool until it snaps onto the spool retaining arms. The spool should be positioned so the inside or shiny side of the paper contacts the thermal array print head. The spool should feed paper from the top.
3. Pull out approximately 2"-3" (5-7 cm) of paper and bring the free end of the paper around to the front of the swing-out door; then completely close the door.
4. With the power switch on, press the **Print** button and allow the paper to feed through the roller automatically. Press **Print** again to stop paper feed.

***Note: If icon flashes on the display, the paper is probably not moving freely through the slot in the door or the door is not completely shut. Open the door and make sure the paper moves freely through the slot after closing the door again.***

If the chart recorder runs, but nothing is printed, the paper is in backwards. Rotate the spool so the inside of the paper contacts the print head.

# Summary of Operations

***CAUTION: The Summary of Operations should be used as a reference only by those who have already read the User Instruction Manual. Please read the User Instruction Manual completely before using the PIC30.***

## SYSTEM SET-UP

1. Press Power switch to OFF.
2. Connect appropriate options and accessory equipment.
3. Install charged battery or axillary AC power source.
4. Press Power switch to ON.
5. Clear log if the log gauge indicates a previous patient's events are in the log.
6. Verify that the configuration menus are set appropriately.

## ECG MONITORING

1. Connect ECG patient cable, multipurpose hands-free adapter or paddles to the PIC30 System.
2. Prep patient's skin and connect electrodes to patient.
3. Select appropriate Lead .
4. Adjust Size as necessary.

## DEFIBRILLATING

1. Monitor patient's ECG on the display using the patient cable, multipurpose hands-free adapter or paddles.
2. Apply gel to paddles or apply Multipurpose electrodes to patient.
3. Select energy by pressing the energy up/down buttons.
4. Press Charge button on front panel or on apex paddle (deluxe paddles).
5. After the defibrillator charges to the selected energy (a continuous charge tone will be heard and the selected energy will be highlighted on the energy bar graph), visually and verbally clear the patient area.

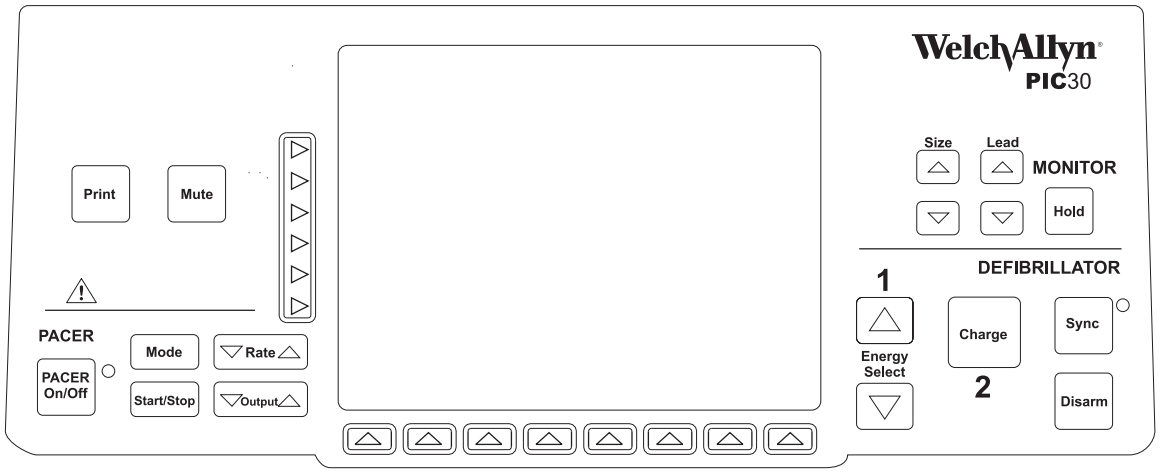
6 Place the paddles firmly on the patient's chest at apex and sternum.

7. To discharge the defibrillator, press both SHOCK buttons on the paddles or press the SHOCK button on the multipurpose hands-free adapter .

## PACING (NON-INVASIVE PACING) – OPTIONAL

1. Monitor patient's ECG using the ECG patient cable and display. Set lead to I, II or III.
2. Apply multipurpose pads to patient as illustrated on the package.
3. Connect multipurpose pads to multipurpose hands-free adapter .
4. Press pacer Pacer button to turn on pacer.
5. Press pacer Mode button to select either DEMAND or ASYNC modes.
6. Press pacer Rate button to select the desired rate.
7. Press pacer Start/Stop button to initiate pacing.
8. Press pacer Output up arrow to increase the pacing output current, until capture is obtained. Note: If the defibrillator is charged, the pacer will automatically turn off.

# Chapter 2 *Control Panel and Display*





Overview of Interfaces . . . . . 2.2

Overview of Controls and Display . . . . . 2.3

Understanding ECG Monitoring Controls and Display . . . . . 2.4

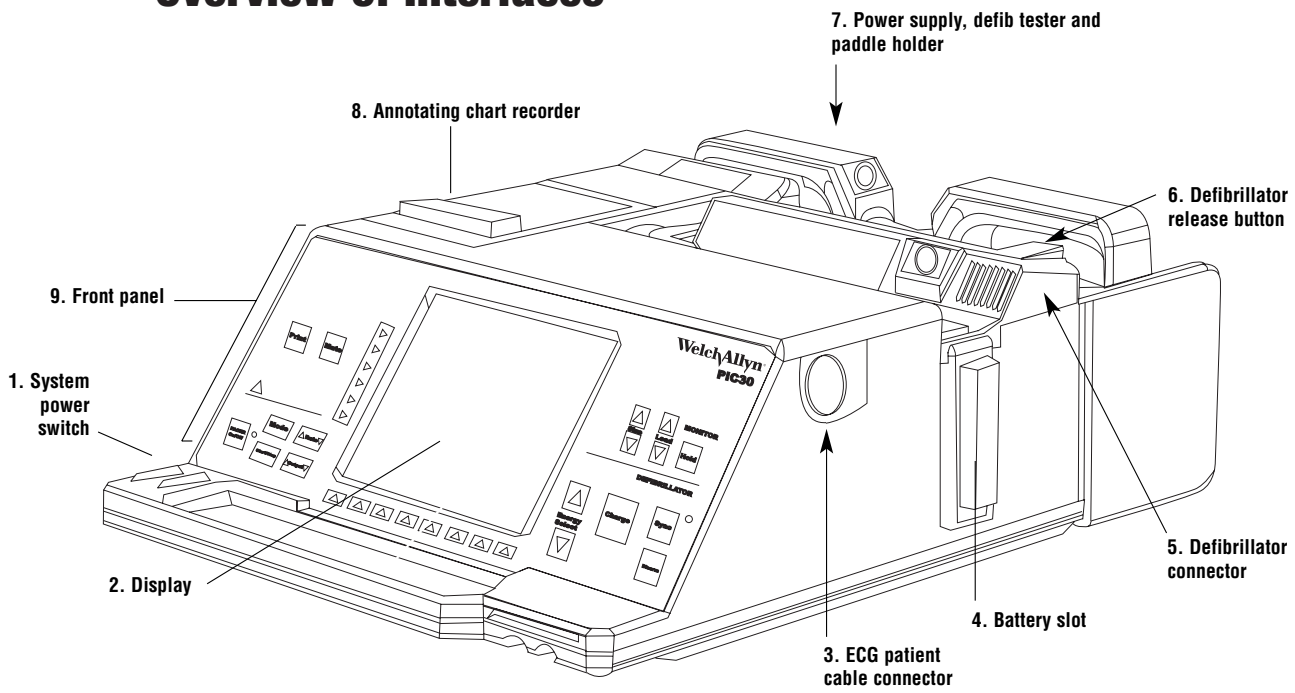
Understanding the Quick Access Buttons and Features . . . . . 2.6

Understanding the Defibrillator Controls and Display . . . . . 2.9

Understanding the Pacer Controls and Display (optional) . . . . . 2.11

Understanding the Menu Controls . . . . . 2.13

# Overview of Interfaces




1. **System power switch**
   Switch for main system power.

2. **Display**
   6.4" (16.2 cm) screen that displays ECG and other parameter information.

3. **ECG patient cable connector**
   Accepts 3-lead or 5-lead PIC30 patient cables.

   ***Note: Only use PIC30 patient cables. Excessive artifact could result from use of non-approved cables.***

4. **Battery slot**
   Accepts PIC30 batteries

5. **Defibrillator connector**
   Allows connection of external paddles, hands-free adapter or internal paddles.

6. **Defibrillator release button**
   Unlocks the defibrillation connector from the defibrillator, to allow removal of external paddles, hands-free adapter or internal paddles.

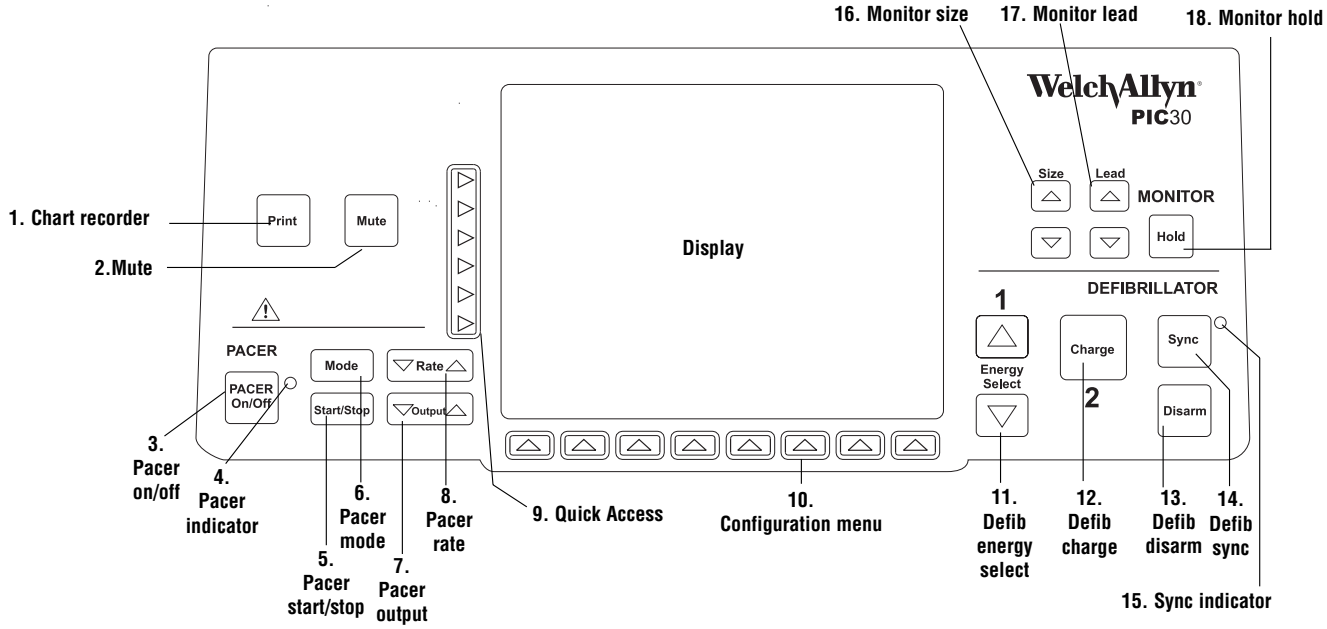
   ***Note: When sliding the defibrillation connector on, make sure the release button clicks into place and returns to its up position.***

7. **Power supply, defib tester and paddle holder.**

8. **Annotating chart recorder**
   Use Welch Allyn approved 50 mm thermal paper.

9. **Front panel**
   Control panel with buttons for PIC30 operation.

# Overview of Controls and Display




1. **Chart recorder print**
   Activates and deactivates the chart recorder.

2. **Mute**
   Pressing the MUTE button once causes all audio alarms and tones to be muted for 90 seconds (except defibrillator charge tones).

3. **Pacer on/off – optional**
   Turns on/off pacer circuit.

4. **Pacer indicator – optional**
   Automatically illuminates during pacing activity.

5. **Pacer start/stop – optional**
   Delivers pacing stimulus to the patient or pauses delivering pacing stimulus to the patient.

6. **Pacer mode – optional**
   Changes pacing mode from DEMAND to Async.

7. **Pacer output – optional**
   Selects pacing output current.

8. **Pacer rate – optional**
   Selects pacing output rate.

9. **Quick access**
   Initiates menu functions appearing adjacent to each button on the display when the PIC30 is on.

10. **Configuration menu**
    Allows documentation of ECG sample events and access to setup menu windows.

11. **Defib energy select**
    Select defibrillation energy levels.

12. **Defib charge**
    Initiates defibrillator charge to selected energy.

13. **Defib disarm**
    Disarms charged defibrillator internally.

14. **Defib sync**
    Activates the synchronization mode.

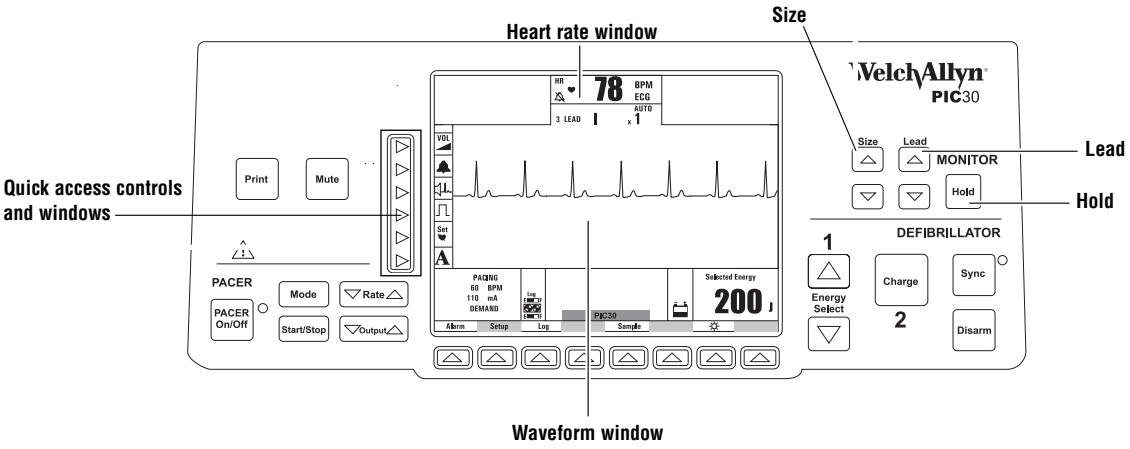
15. **Sync indicator**
    Light that indicates sync activation.

16. **Size**
    Selects ECG trace sizes.

17. **Lead**
    Selects ECG input source.

18. **Hold**
    Holds the traces on the display while pressing.

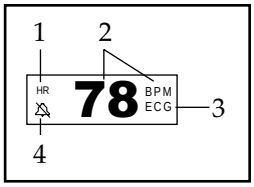
# Understanding ECG Monitoring Controls and Display




ECG monitoring functions on the PIC30 are viewed and controlled by the areas indicated above.

***Note: The following description and operation of the ECG monitoring portion of the PIC30 depict normal factory default settings. Later in this chapter we will discuss user configurations of the ECG monitoring system.***

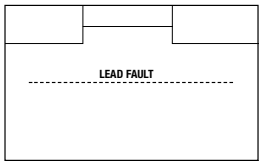
### Heart Rate Display




1. HR Indicates "Heart Rate window."
2. 78 BPM indicates heart rate, displayed in beats per minute. (flashing heart rate indicates an alarm limit has been exceeded)
3. ECG abbreviation indicates the origin of the heart rate. In this case, the source of the heart rate is derived from the ECG electrodes.
4. Bell symbols in the "Heart Rate window" indicate the status of the HR alarm: (alarm off), (alarm on), (alarm upper limit set), (alarm lower limit set), (automatic HR alarm set).

### Lead Fault Display

The ECG trace will be replaced with a dotted line and the words LEAD FAULT to indicate a lead fault condition. Lead fault condition may have occurred due to improper connections on the patient cable lead wires and should be inspected for proper contact and connection. Replace the electrodes if necessary. In rare cases, an excessive offset voltage on the ECG electrodes may cause a lead fault condition. This condition could result in recovery time up to 20 seconds after defibrillation.



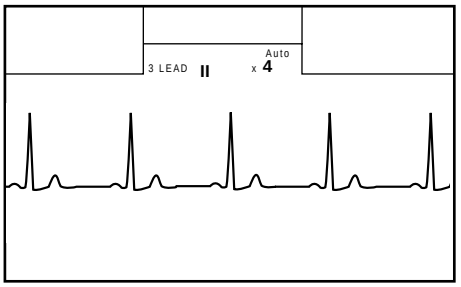
Size

### Size Control and Display

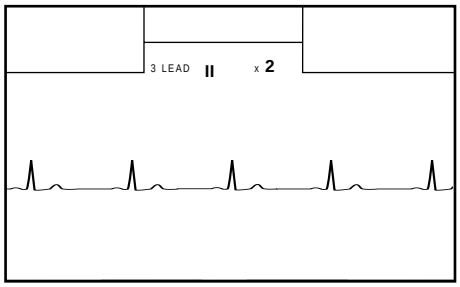
Pressing the Size button selects ECG trace sizes from 0.125cm/mv to 4cm/mv and automatic trace sizing. Pressing the up arrow will increase the ECG size. Pressing the down arrow will decrease the ECG size. The AUTO size setting will automatically select the proper gain to fit the ECG in the waveform window. When the PIC30 is turned on, the default setting is AUTO.

***CAUTION: Do not use the auto size setting for diagnosing asystole. Set the size to 1cm/mV to maintain a fixed ECG display gain.***

**example: Auto size is set and 4cm / mV was selected**




**Manual size set at 2cm / mV**




Lead

### Lead Control and Display

Pressing the Lead button selects the ECG input. Pressing up or down lead arrows will change the lead selection.

If the 3-lead cable is configured in the "patient cable" menu, leads I, II, III are available :


**Lead I selected**


**Lead II selected**


**Lead III selected**

If the 5-lead cable is configured in the "patient cable" menu, leads aVL, aVF, aVR, and V leads are available in addition to leads I, II, III:


**Lead AVR selected**


**Lead AVF selected**


**Lead AVL selected**


**Lead V selected**

If a paddle set (PDL) or hands-free adapter (PAD) is connected, either PDL or PAD lead option will be available, in addition to 3-lead or 5-lead lead patient cable options:


**Lead paddles selected**
(paddle set attached)

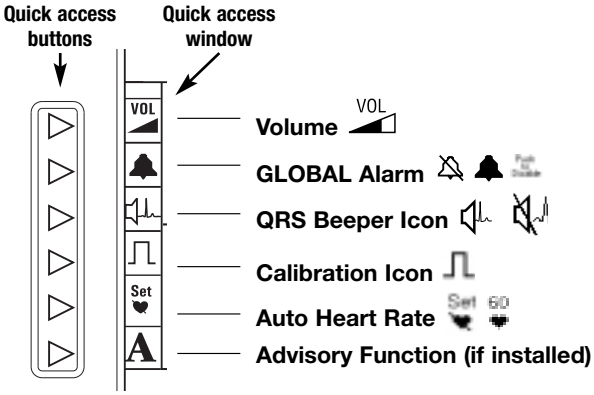

**Lead pads selected**
(hands-free adapter attached)

Hold

### Hold Control

Pressing and holding the Hold button will hold the trace(s) in the trace window. When the Hold button is released the traces will resume.
(chart recorder is not affected by the hold button)

# Understanding the Quick Access Buttons and Features




## QUICK ACCESS BUTTONS

The quick access buttons are used to operate both the quick access features, shown at right, and to navigate through menu "pop-up" windows (see chapter 3).

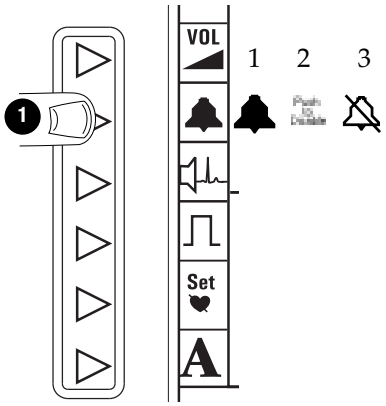
## QUICK ACCESS FEATURES

### Volume Control

The quick access volume control increases and decreases the volume of the PIC30. There are four volume settings that can be selected. Each press of the the volume button increments the volume to the next level. The volume ramp ( ) indicates the volume level selected.

### Global Alarm Control

The quick access global alarm enables or disables all set alarm parameters. When the PIC30 is turned on, the global alarm will default to the last setting at system shutdown, either enabled ( ) or disabled ( ).




**To enable global alarms,** press the global alarm button (1) to display the alarm on icon ( ). (With the global alarms enabled, any set alarm parameter will be enabled.)

**To disable global alarms,** press the global alarm button two times. The first press of the button (2) will change the icon to PUSH TO DISABLE ( ). The second press (3) will change the alarm icon to OFF ( ). If the button is not pressed a second time within 10 seconds, global alarms will automatically revert to enabled ( ). (With the global alarm disabled, all parameter alarms will be disabled)

### QRS Beeper Control

The quick access QRS beeper control, turns the beeper on and off.

Beeper OFF =

Beeper ON =

### Calibration Control

The quick access calibration control is used to send a calibration signal to the monitor and chart recorder.

***Note: Cal button is disabled in x4 gain setting.***

### Auto Heart Rate Control

The quick access auto heart rate (HR) control is used to set the automatic HR alarm. The auto HR icon ( ) appears only if "auto" is selected in the HR alarm menu. (See page 3.3 for HR alarm menu.)

**In order to set the auto HR alarm limits:**
1. There must be a valid heart rate displayed in the HR window

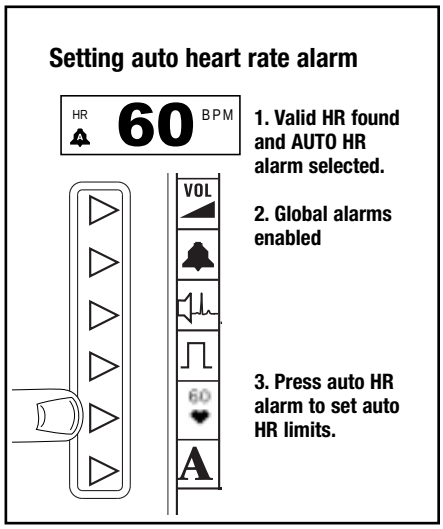
2. Auto HR alarm must be selected in the HR alarm configuration menu.

3. Global alarms must be enabled.

**To set the automatic HR alarm limits,** press the quick access auto HR button. The patient's heart rate, at the moment the button was pressed, will be displayed above the "heart" ( ). The monitor automatically sets the upper and lower heart rate alarms, at 20% of that heart rate **set point** or 10 beats. Each press of the auto HR button will adjust the heart rate **set point** and reset the auto HR alarm limits.

If an alarm parameter is exceeded, an audible tone will sound and the heart rate will flash.

If there is no heart rate in the HR window, the upper and lower heart rate limits will be undetermined and the "set heart rate icon" ( ) will appear.




**Advisory Control (Optional)**
The "A" icon control will appear if the advisory option has been installed and enabled. To initiate an ECG analysis cycle follow the instructions below.

1. Stop CPR and stand clear of the patient.

2. Press the "A" icon. The trace section of the screen will be reformatted with the ECG trace in the upper half and the advisory prompts in the lower half.

If good patient electrode contact is detected, an "Analyzing" prompt will be displayed. Within 4 - 16 seconds a "Shock Advised" or "No Shock Advised" prompt will be displayed. The "A" icon will remain highlighted during the duration of the analysis cycle. The split screen and prompts will remain for 12 seconds after the completion of the analysis cycle.

Pressing the "A" icon control again while the split screen is displayed will abort the analysis cycle and return the trace to its normal configuration.

***Note: All personnel must stand clear of the patient during the duration of the analysis cycle. Only use the advisory option to analyze ECG on pulseless, apneic, motionless patients.***

***Note: The Lead Select and Size controls will be locked out during analysis. The PIC30 will automatically select lead II or Pads and will set the size to 1 cm/mV.***

***Note: The Advisory control is inhibited while pacing.***

Advisory prompts are displayed in the lower half of the trace screen. These prompts are listed below

**– Analyzing LD II or Analyzing PADs**
Indicates the PIC30 is analyzing the patient's ECG to assess if it is a shockable rhythm. Avoid touching or moving the patient. Touching or moving the patient can cause artifact which may interfere with the analysis process.

**– No Shock Advised**
Indicates the PIC30 has completed analyzing the patient's ECG and that No Shock was advised. Two BEEPs will be heard, signifying the completion of the analysis.

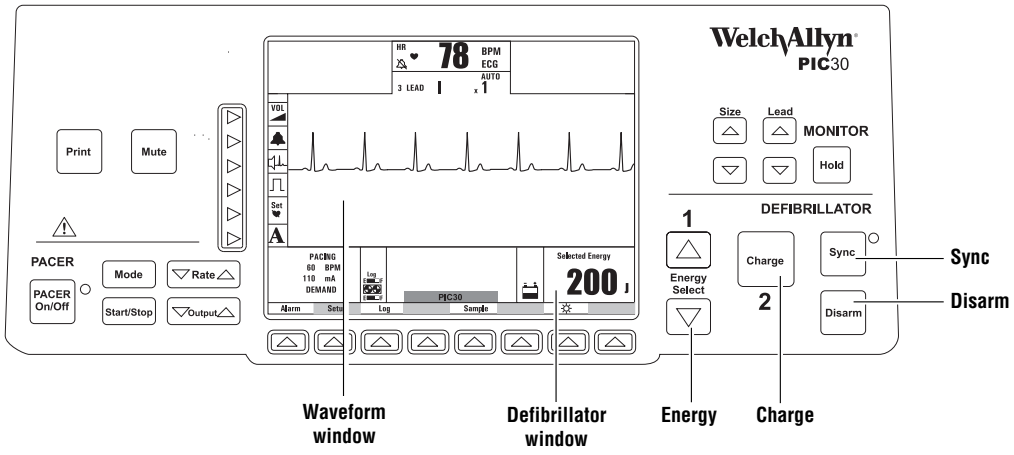
**– Shock Advised**
Indicates the PIC30 completed analyzing the patient's ECG and that a shockable rhythm was detected. The display will indicate SHOCK ADVISED. The PIC30 will NOT automatically charge the defibrillator or shock the patient. For instructions on how to defibrillate a patient refer to chapter 6.

**– Motion Detected**
Indicates the PIC30 has detected motion artifact or noise. Check electrode contact and make sure that the patient is motionless and personnel are not in contact with patient.

**– Attach Defib Pads**
Indicates that PIC30 has sensed that the defibrillator paddle set or pads are not attached properly.

**– Attach Electrodes**
Indicates the PIC30 has detected a lead fault on the patient cable ECG electrodes.

# Understanding the Defibrillator Controls and Display

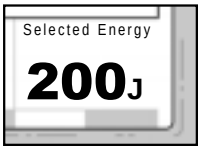



Defibrillation functions on the PIC30 are viewed on and controlled by the areas indicated above.

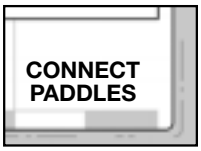
*Note: The following operations of the defibrillator depict normal factory default settings. Later in this chapter we will discuss user configurations of the defibrillator.*

### Initial defibrillator display upon unit startup

When the PIC30 is turned on the selected energy default is displayed. The defibrillator is not charged.




**CONNECT PADDLES** in the defibrillator window indicates the defibrillator paddles, multipurpose hands-free adapter or internal paddles are not attached or are not seated firmly in the defibrillator connector.

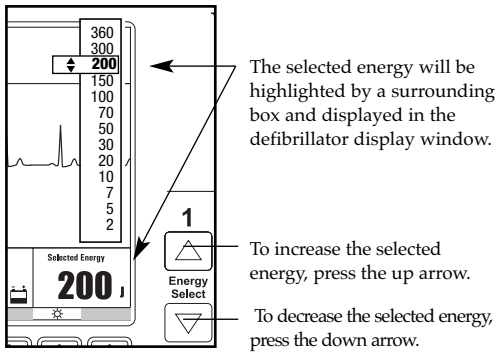




### Energy Selection Control and Display

The Energy Select button is used to select defibrillator energy. Pressing either the up or down arrow will cause the **Energy Range Bar** to be displayed on the right side of the display. Press up arrow to increase and down arrow to decrease the energy setting.

*Note: The default energy level, upon power start up, can be changed to a lower or higher setting. See page 3.11.*




**ENERGY RANGE BAR**

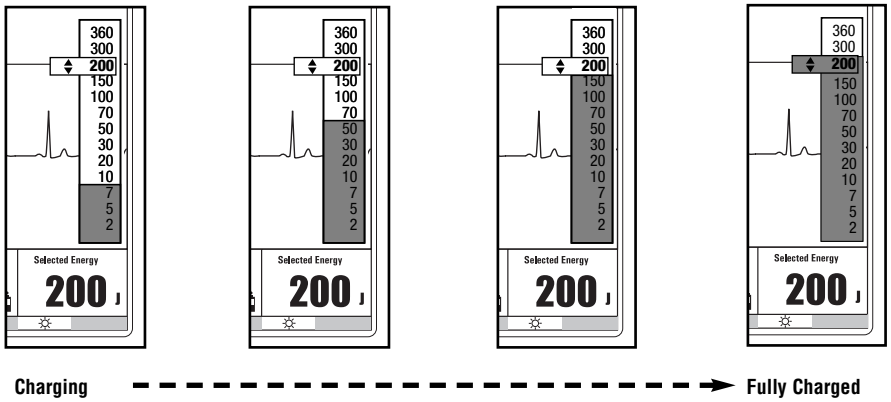
Charge

### Charge Control and Display

The Charge button initiates the defibrillator charge cycle. When the charge button is pressed, a periodic audible tone will sound; the energy range bar graph will highlight the relative charge state until it reaches the selected energy.

When the defibrillator is fully charged, the periodic tone will change to a continuous tone and the highlighted energy range bar graph will include the selected energy.

***Note: If the energy selection is changed during the charge sequence, the unit will automatically charge to the new energy level and the display will be updated accordingly.***




Disarm

### Disarm Control

Pressing the Disarm button will safely discharge the defibrillator internally and the energy range bar display will disappear.

***Note: The unit contains an automatic disarm of the defibrillator. If the operator has not delivered the energy to a patient or load, an internal timer will disarm the defibrillator 1 minute after reaching a fully charged state.***

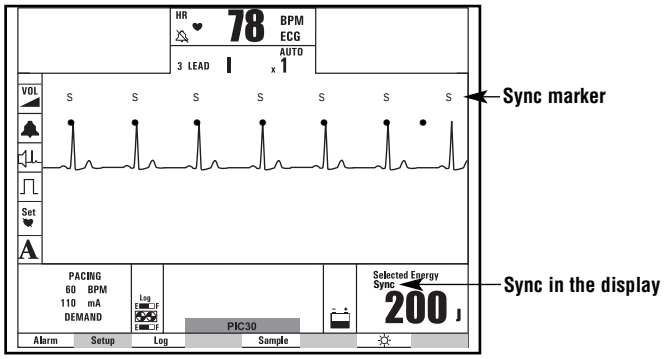
Sync

### Synchronization Control

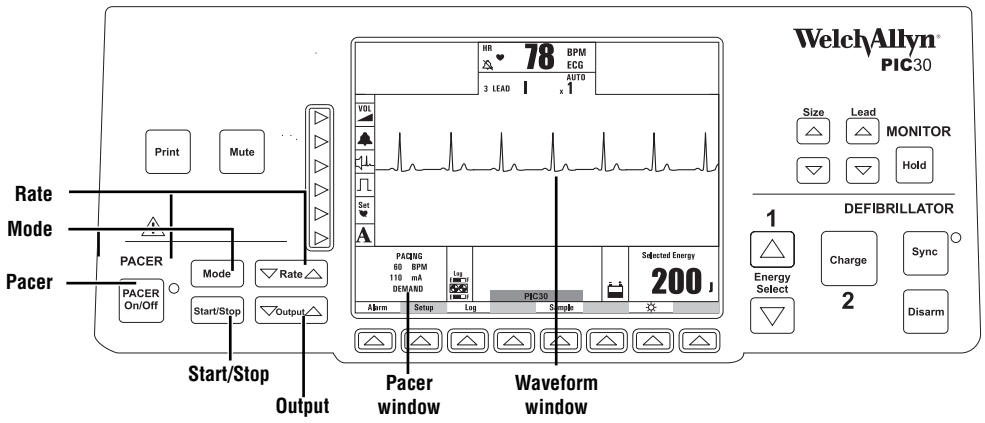
Pressing the sync button activates the synchronization mode and illuminates the SYNC indicator light, which flashes off when a QRS has been detected. Sync will appear on the display and a SYNC marker will also appear over the portion of the ECG that the defibrillator will trigger on. Pressing the sync button again reverts to the asynchronous mode.

***Note: After synchronized cardioversion discharge, the defibrillator can be configured to remain in the Sync mode or revert to the asynchronous mode.***

***Note: The factory default Sync setting after discharge is the asynchronous mode.***



# Understanding the Pacer Controls and Display (optional)



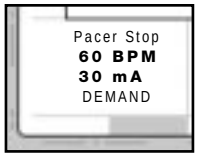

***Note: The external pacer is optional. To add pacing capability to your PIC30, contact your Welch Allyn customer service representative.***

External pacing functions on the PIC30 are viewed on and controlled by the areas indicated above.

***Note: The following operations of the external pacer depict normal factory default settings. Later in this chapter we will discuss supervisor configurations of the external pacer.***

### Initial pacer display upon pacer power on

When the PIC30 is powered on, the external pacer default position is off. To turn on the external pacer press the pacer On/Off button. When the pacer turns on, the default parameters will be displayed in the pacing window.

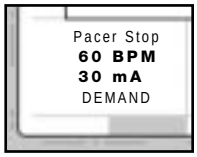



**Factory Pacer Defaults**

## Pacer Display Messages

### Pacer Stop

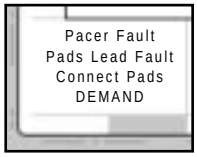
Pacer Stop indicates that pacer is on and paused (will not deliver pacing pulses to patient). 60 BPM indicates pacing rate set at 60 beats per minute. 30 mA indicates the pacer output in milliamperes. Demand indicates that the pacer is set in demand mode.




***Note: Pacer Fault messages may appear if the pacer detects a fault condition.***

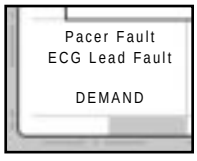
### Pads Lead Fault

The pads lead fault indicates that the multipurpose hands-free adapter has not been installed or that the multipurpose pads have not been attached to the patient or multipurpose hands-free adapter. To correct fault, install the multipurpose hands-free adapter and connect the hands free pads to the adapter and patient.



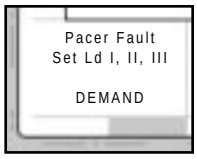

### ECG Lead Fault

The ECG lead fault occurs when lead wires are not properly connected to the ECG electrodes. To correct fault, confirm the ECG lead wires are attached to the ECG electrodes and the electrodes are properly applied to the patient.



### Lead Selector Fault

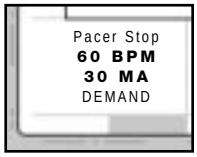
This display indicates that the lead selector is not set to leads I, II or III. Select lead I, II, or III to allow pacing.




## Pacer Controls


### Pacer Control

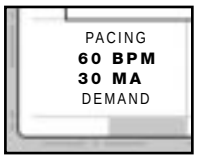
Pressing the pacer [pacer] button activates the pacer, but does not deliver pulses. The initial pacing parameters will be displayed in the pacing window. Pressing the [pacer] button again will turn off the pacer.



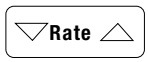

***Note: When the pacer is on and the defibrillator has been charged, the pacer will automatically be turned off for safety reasons.***


### Mode Control

Pressing the [Mode] button changes the pacing mode from demand to async mode. The selected mode will be displayed in the pacing window.



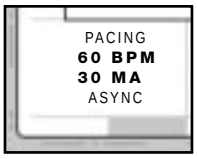

**Demand mode**



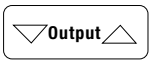

***Note: The initial pacing mode can be set in the pacing Setup Menu. See page 3.12.***

### Rate Control

Pressing the [Rate] button selects the pacing output rate measured in beats per minute (BPM). Pressing the up ( △ ) arrow will increase the rate. Pressing the down ( ▽ ) arrow will decrease the rate. When the pacing rate is below 100 BPM , each press of the [Rate] buttons will change the pacing rate by 5 BPM. When the pacing rate is above 100 BPM , each press of the [Rate] buttons will change the pacing rate by 10 BPM.



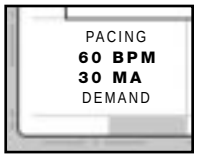

**Async mode**




***Note: The initial pacing output rate can be set in the pacing Setup Menu.. See page 3.12.***

### Output Control

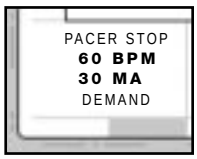
Pressing the [Output] button selects the pacing output current measured in milliamperes (mA). Pressing the up arrow will increase the selected output by 10 mA. Pressing the down arrow will decrease the selected rate by 5 mA. Default is 30 mA.




**PACING**


### Start/Stop Control

Pressing the [Start/Stop] button will allow pacing or pause the delivery of pacing stimulus to the patient. When the pacer is in the paused mode, a PACER STOP message will be displayed in the Pacer Window. When the pacer is not paused, a PACING message will be displayed in the pacer window.




**PACING STOPPED (paused)**

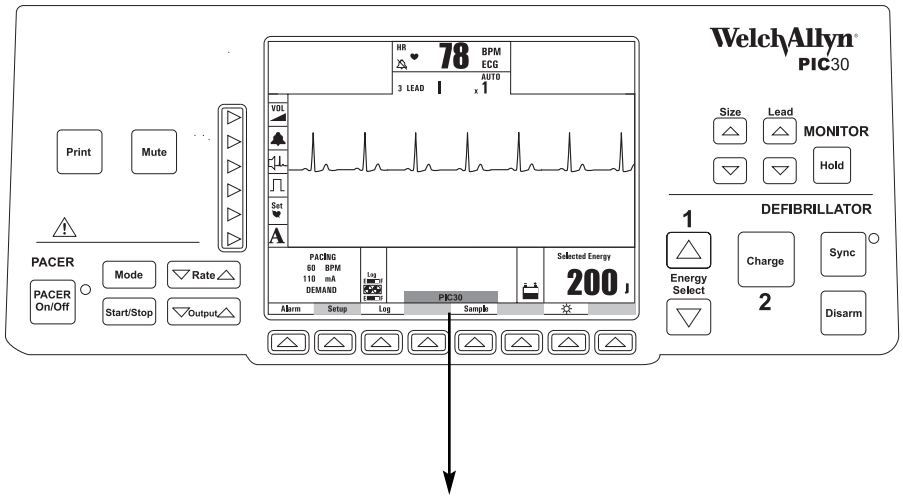
***Note: Whenever a pacer or ECG lead fault occurs, the pacer will automatically stop and a fault message will be displayed in the pacer window.***

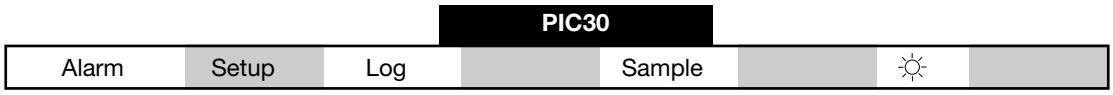
# Understanding the Menu Controls

The menu controls and functions are controlled by and viewed in the areas indicated below.

### Initial menu items displayed upon unit startup

When the PIC30 is powered on, the initial startup menu is displayed. Pressing any of the menu controls under the function displayed will allow the operator to setup the PIC30 according to their preferences. The PIC30 menus are discussed in detail in the next Chapter.



# Chapter 3 *Program Menu Setup*


Basic Menu Structure . . . . . 3.2

PIC30 Menu – Heart Rate Alarm . . . . . 3.3

PIC30 Menu – Log Menu, Sample, and Bright Functions . . . . . 3.5

Setup Menu – ECG Configuration Menus . . . . . 3.6

Setup Menu– Grid, Time, Date, and Supervisor Code Menus . . . . . 3.8

Overview of Supervisor Menus . . . . . 3.10

Supervisor – Defibrillator Menu . . . . . 3.11

Supervisor – Pacer Menu (optional) . . . . . 3.12

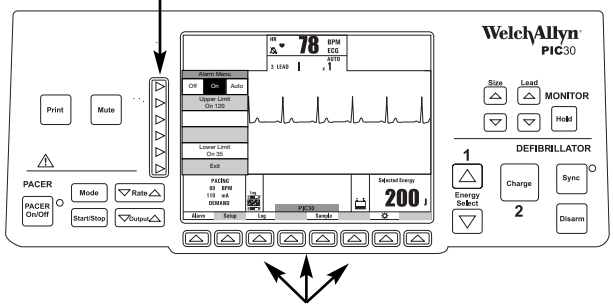
Supervisor – Diag Menu . . . . . 3.13

Supervisor – Setup Menu . . . . . 3.14

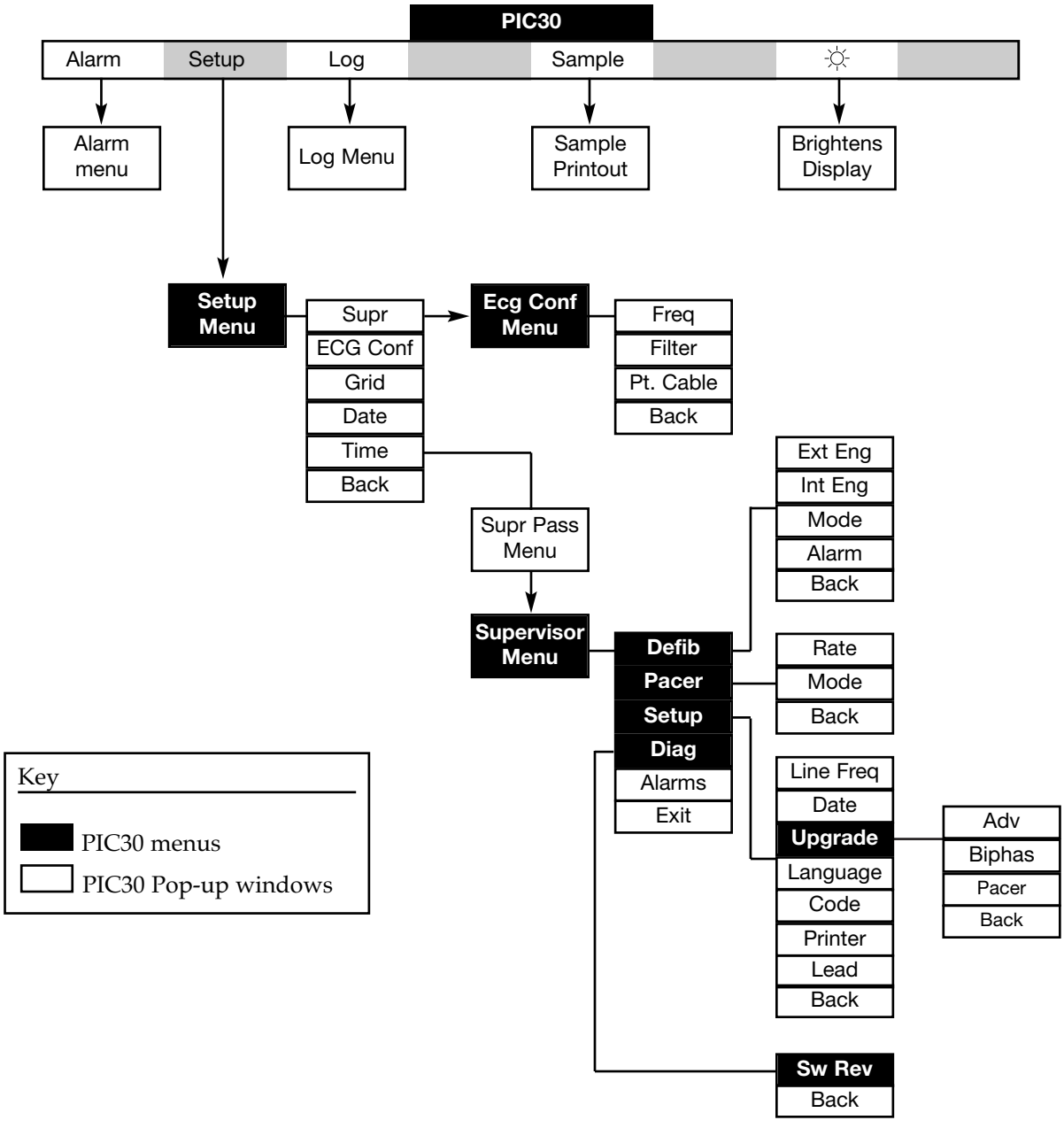
Supervisor – Upgrade Menu . . . . . 3.16

# Basic Menu Structure

**Quick Access Buttons:** After selecting one of the menu buttons, use the quick access buttons to navigate though the pop-up programmable menus.




**Menu Buttons:** Pressing the menu buttons allows the user to navigate through the PIC30 Menu options.



# PIC30 Menu – Heart Rate Alarm

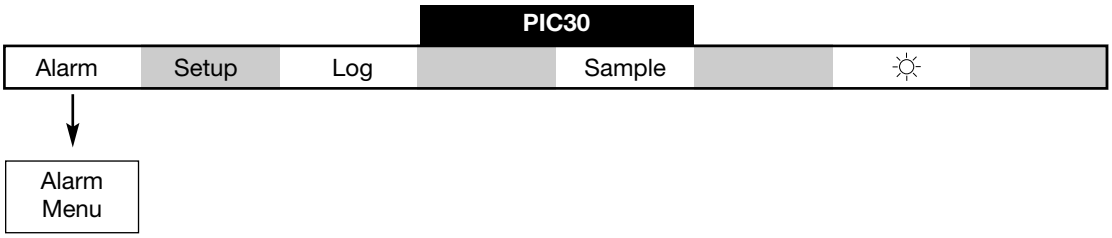
= Off

= On

= Auto

= lower limit set, upper limit disabled

= upper limit set, lower limit disabled

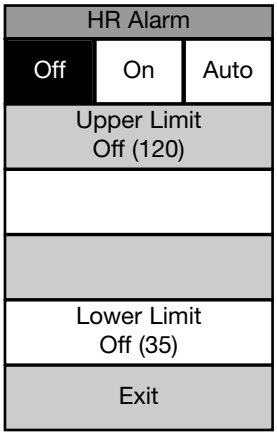



This is the menu which appears at startup. From here the user can navigate through the program menus to set up unit functions.

### Alarm Menu

The alarm menu sets the heart rate (HR) alarm. The HR alarms can be set to either OFF, ON or AUTO. The appropriate alarm icon appears in the heart rate window indicating the current state of the alarm.

**Heart Rate Window**

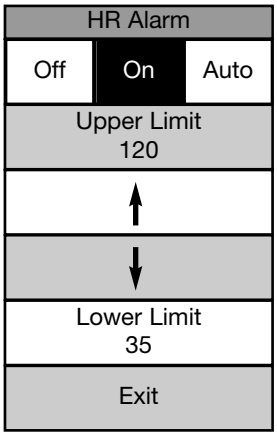

### Turning Off the HR Alarm

To set the HR alarm to off press the Off / On / Auto button until Off is highlighted. When the HR alarm is set to Off the upper and lower limits will each display Off and a number in parenthesis. The number indicates the currently set HR limit that will be active when the HR alarm is turned back on.

Example:
HR alarm off, the upper limit setting is 120

HR alarm off, the lower limit setting is 35

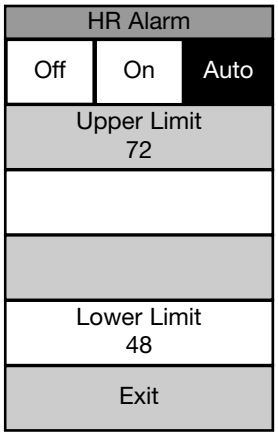
**Heart Rate Window**


### Turning On the HR Alarm

1. Set the HR alarm to on by pressing the Off / On / Auto button until On is selected. If the upper and lower limits are set, the alarm on icon ( ) will appear in the HR window and the global alarms will be enabled.
2. Set the upper limit. The upper limit can be either set or disabled. To set the upper limit, press the upper limit button. A bold line will appear around the box. Press the up or down arrow to increase or decrease the upper limit value. You can disable the upper limit by pressing the upper limit button again to display Disabled below the words Upper Limit. The alarm icon in the heart rate window will display the appropriate status.
3. Set the lower limit. The lower limit can be either set or disabled. To set the lower limit press the lower limit button. A bold line will appear around the box . Press the up or down arrow to increase or decrease the lower limit value. You can disable the lower limit by pressing the lower limit button again to display Disabled below the words Lower Limit. The alarm icon in the heart rate window will display the appropriate status.
4. Exit. Press Exit to leave menu.

### Turning on and setting the Auto HR alarm




1. Set the HR alarm to auto by pressing the Off / On / Auto button until Auto is selected. When the HR alarm is set to auto, the auto alarm icon ( ) will appear in the HR window and the global alarms will be turned On.

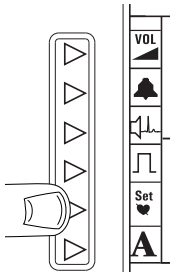
   ***Note: The upper and lower limits will be undetermined if a valid ECG is not present.***

2. Exit. Press Exit to leave the HR alarm menu.

3. To set the automatic HR alarm limits, press the quick access "Auto" button next to the icon. The patient's heart rate, at the moment the button was pressed, will be displayed above the "heart" ( ). The HR alarm monitor automatically sets the upper and lower heart rate limits at ±20% of that heart rate set point or ±10 beats whichever is greater. Each press of the "Auto" button will adjust the heart rate set point and reset the auto HR alarm limits.

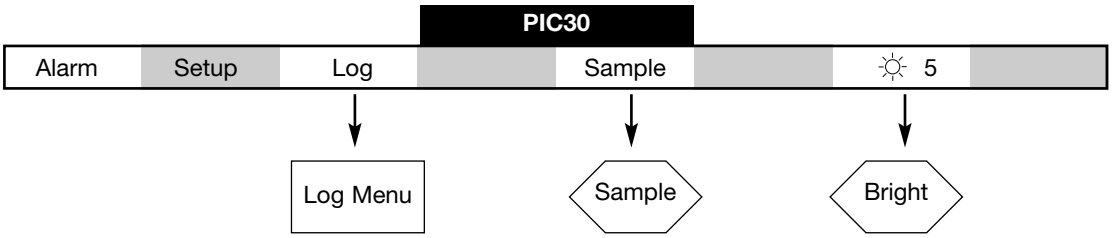
4. You can view the upper and lower limits that were set by going back to the HR alarm menu. The undetermined upper and lower limits have been replaced with automatically set values.

   ***Note: In either the On or Auto mode, if the alarm parameters have been exceeded, an audible tone will sound and the patient's heart rate measurement will flash in the heart rate window.***



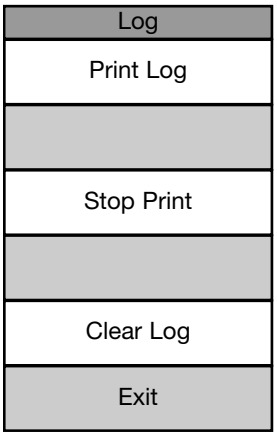

**Heart Rate Window**

# PIC30 Menu – Log Menu, Sample, and Bright Functions




This is the menu which appears at startup. From here the user can navigate through the program menus to set up unit functions.

### Log Menu




To print out or clear the log, press LOG to enter the Log Menu. From the Log menu the user can print the log, stop printing the log or clear the log. To exit, press Exit.

To stop printing the Event Log while it is printing, press Stop Print. The information in the log will not be affected.

To clear the Event Log press the Clear log button.

***Note: To prevent a previous patient's Event Log Data from being printed with a new patient's data, always clear the log prior to treating a new patient.***

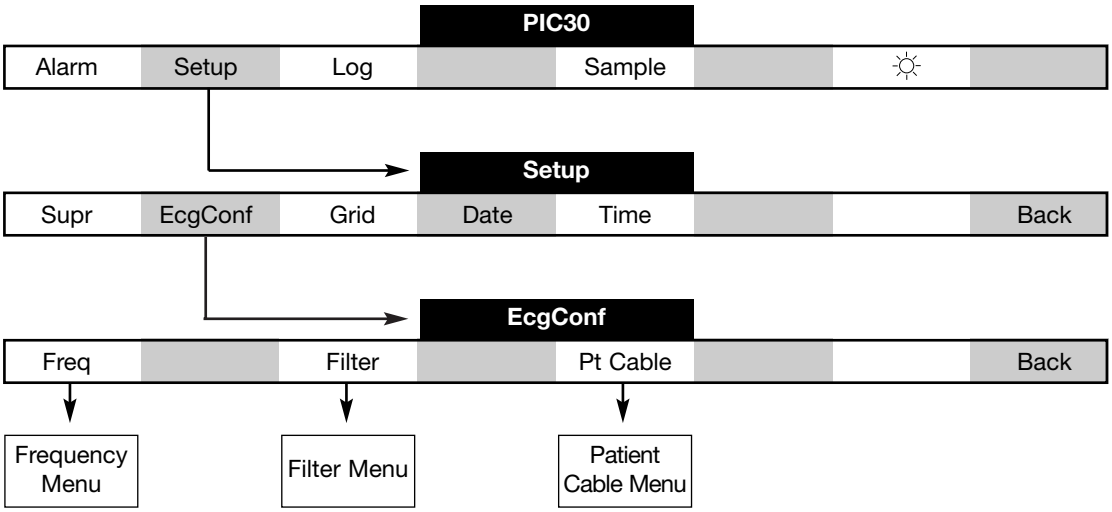
### Sample

Pressing the sample button stores a 4 second ECG sample internally and prints "Sample Event" on the chart recorder with 6 seconds of ECG.

### Bright ☼

Pressing the bright button brightens the display. There are 5 brightness settings. The current brightness setting is displayed on the menu. Each press of the button increases the brightness of the display, once the highest brightness setting (5) is reached the next press of the button returns the brightness setting to the lowest setting (1).

# Setup Menu – ECG Configuration Menus

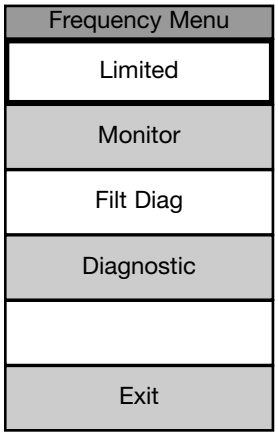



### Setup Menu

The Setup Menu appears when the setup control button is pressed.

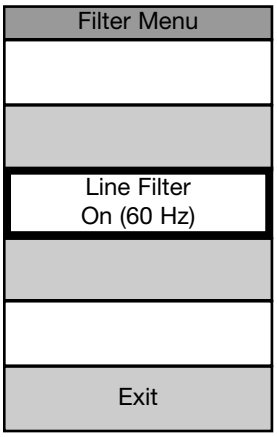
### ECG Configuration Menu

The ECG Configuration menu allows the operator to set frequency response, line filter, and select patient cable type.



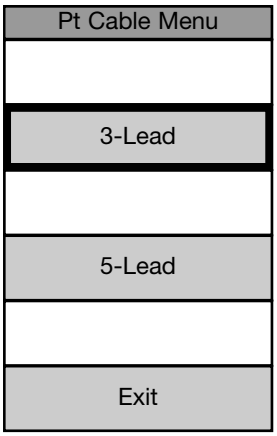

### Frequency Response (Freq)

In the Frequency Menu, the user can choose between four frequencies: Limited, Monitor, Filtered Diagnostic, and Diagnostic. The currently selected frequency will be highlighted with a bold outlined box. Press Limited, Monitor, Filt. Diag, or Diagnostic to choose a different frequency. Pressing Exit will return you to the Display Configuration Menu. The frequency response selection will set the display and the chart recorder response. “Limited” response is automatically selected for paddle monitoring applications. “Monitoring” response is recommended for general ECG monitoring applications. "Filt. Diag" (Filtered Diagnostic) 0.05-40 Hz to choices of frequency response.. “Diagnostic” response should be used when attempting to interpret subtle ECG changes (ST segments). For optimal diagnostic response, the line filter should be turned off. Only “Limited” response is available when lead select is set to PDL. Only “Monitor” and “Limited” response are available when lead select is set to PADS.




**Filters**

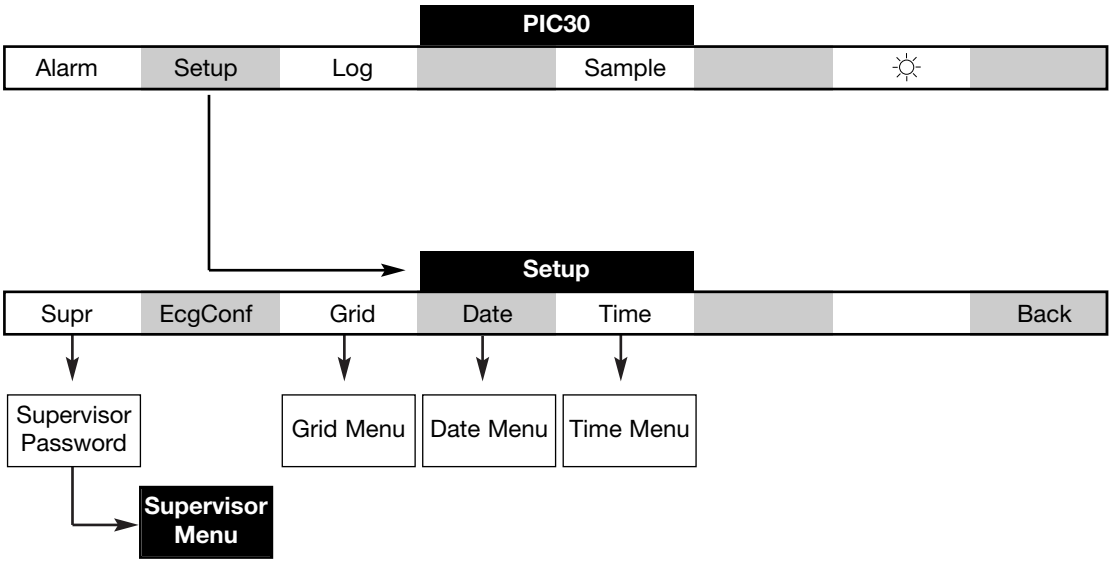
In the Filter Menu, the user can choose between line filter on or off by pressing the corresponding quick access button. The currently selected line filter state is written below the words "Line Filter." The line filter frequency (selectable from the supervisor menu) is displayed in parentheses. To choose a different line filter configuration, press the corresponding quick access button. Pressing Exit will return you to the Display Configuration Menu. Line filters will remove AC (mains) line interferences emitted from power lines and other electrical apparatus.

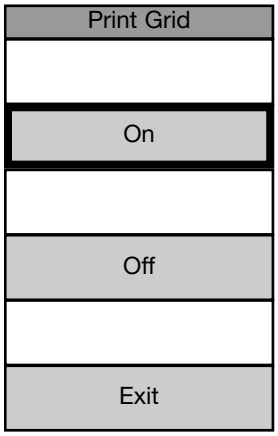



**Patient Cable (Pt. Cable)**

In the Patient Cable Menu, the user can choose between either 3-lead or 5-lead patient cable. The currently selected lead configuration is highlighted with a bold outlined box. To choose a different lead configuration, press the corresponding quick access button. Pressing Exit will return you to the Display Configuration Menu. If the patient cable inserted into the PIC30 does not match the patient cable configuration selected, a lead fault alarm may sound.

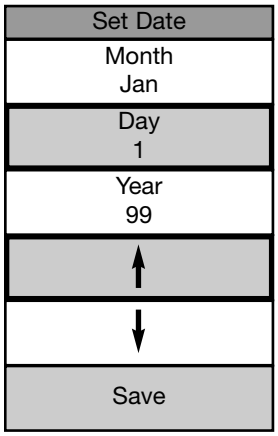
# Setup Menu – Grid, Time, Date, and Supervisor Code Menus



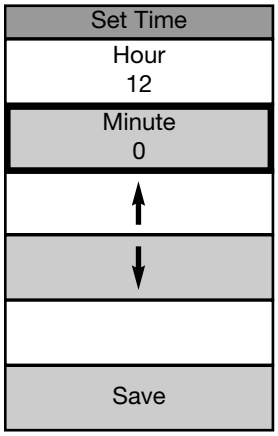

**Print Grid**

In the Print Grid menu, the user can choose to print or not to print grid on chart paper by turning the print grid on or off. In the Print Grid ON mode, the chart recorder will print a grid on plain white paper. The current selection will be highlighted with a bold outlined box. To choose a different option, press the corresponding button. Pressing Exit will return you to the Setup Menu.



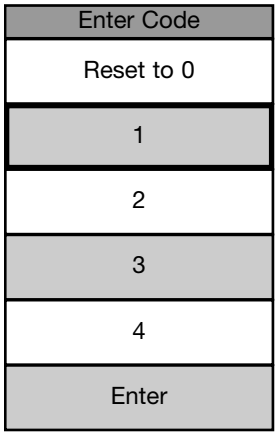

**Set Date**

To set the month, press the corresponding button. A bold outlined box will appear around the month window. Press the up or down arrow to select the month. Follow the same procedure to set the day and year. When finished, press save.




**Set Time**

To set the hour press the corresponding button. A bold outlined box will appear around the hour window. Press the up or down arrow to select the hour. Follow the same procedure to set the minute. When finished, press Save.



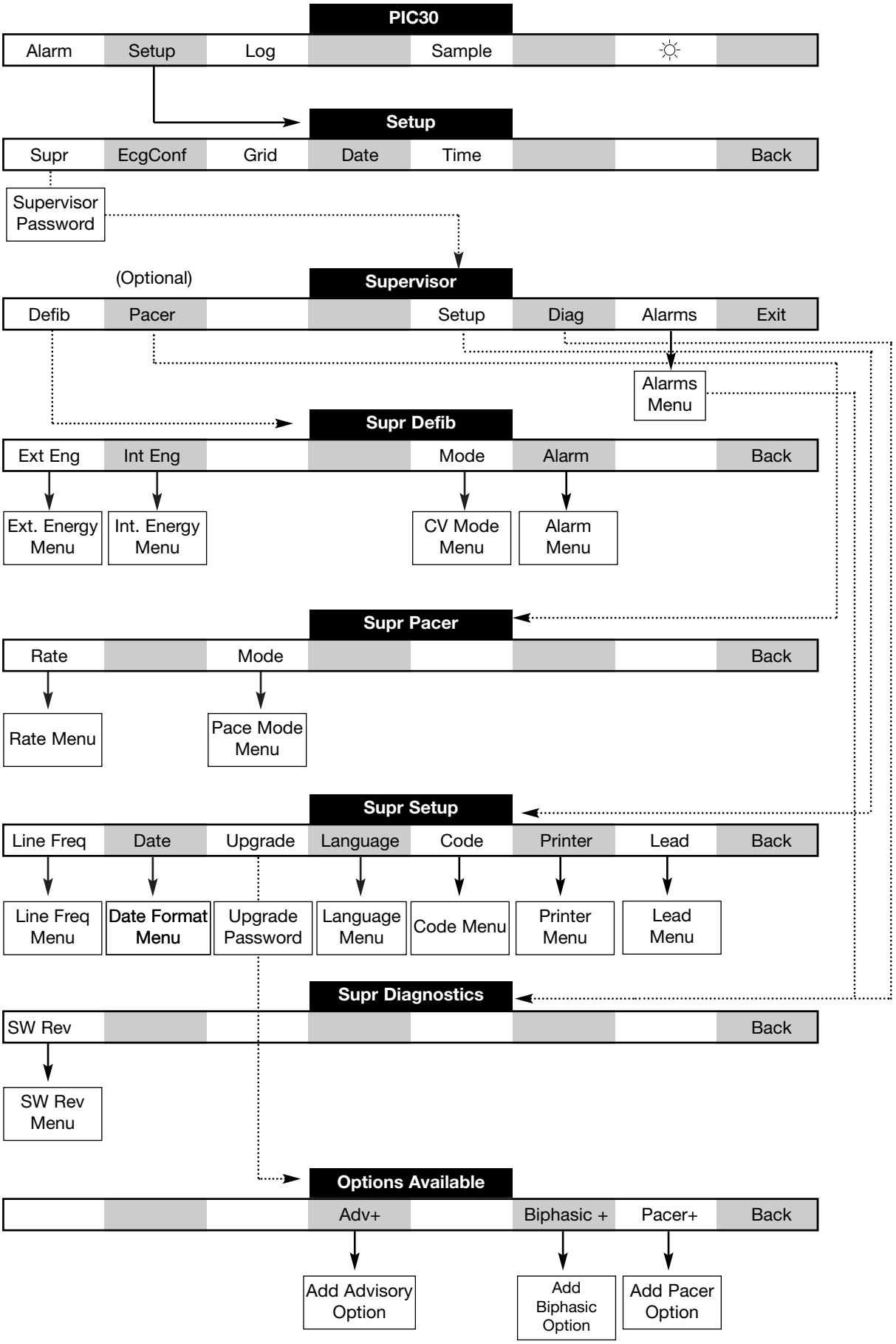

**Entering the Supervisor Menus**

The default access code for entering the supervisor menus is 1, 2, 3, 4. This code may be changed by the supervisor (see 3.14). Pressing each button will increment the corresponding digit. To reset the code, press Reset to 0. When all four digits are entered, press Enter to enter the supervisor menu. The Lock ( ) icon on the supervisor menu title block will open ( ) if the correct code has been entered.

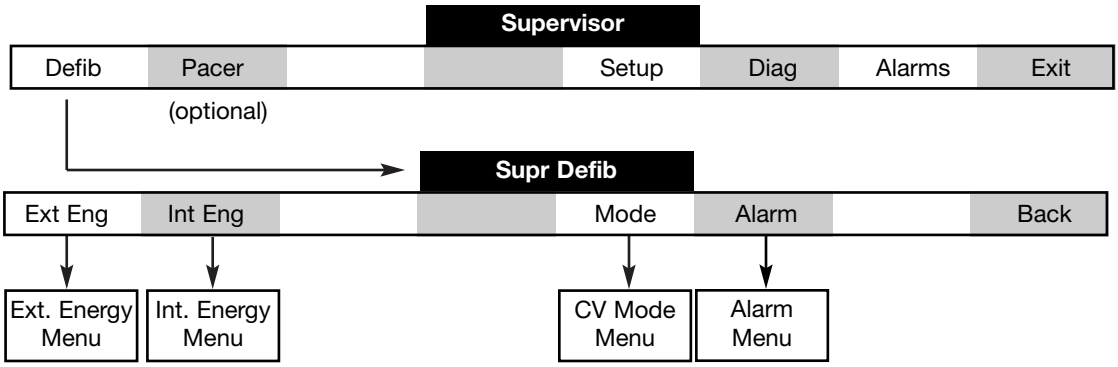
If the code is lost, contact your Welch Allyn authorized service representative.

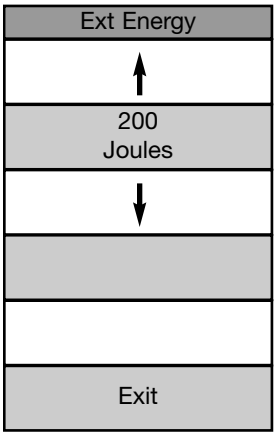
***Note: Be sure to write down the new supervisor code in a safe place.***

# Overview of Supervisor Menus



# Supervisor – Defibrillator Menu

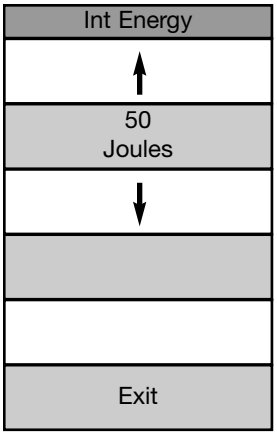



**External Energy Menu**

The external energy menu sets the default energy selected when the PIC30 is first turned on with external paddles connected. The default selected energy setting is displayed in this menu.

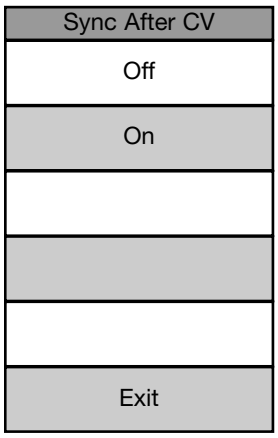
To change the default energy setting, press either the up arrow to increase, or down arrow to decrease energy selection. Available options are 2, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, or 360 Joules. Press Exit to return to the Supervisor menu.




**Internal Energy Menu**

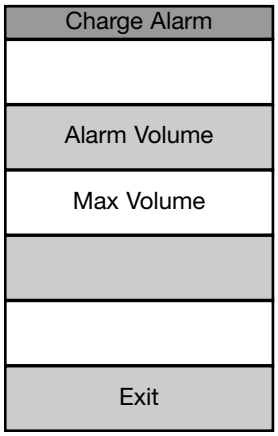
The internal energy menu sets the default internal energy selected when the PIC30 is first turned on without paddles or when internal paddles are first attached. The current selected default energy setting is displayed in this menu.

To change the default energy setting, press either the up arrow to increase or down arrow to decrease energy selection. Available options are 2, 3, 4, 5, 6, 7, 8, 9, 10, 20, 30, or 50 Joules. (To prevent possible cardiac tissue damage, the energy output is limited to 50 Joules.) Press Exit to return to the Supervisor menu.




**Sync After CV Menu**

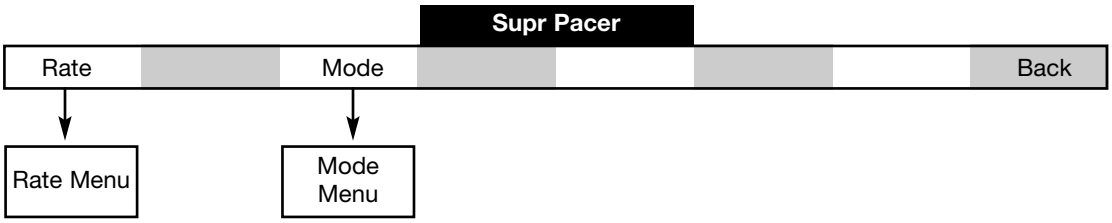
The Sync after CV (cardioversion) menu allows the user to configure the defibrillator to stay in the sync mode after each synchronized cardioversion. If the "Sync After CV" is off, the defibrillator will revert to the asynchronous mode. If the "Sync After CV" is on, the defibrillator will remain in the Sync mode after each cardioversion. Press Exit to return to the Supervisor menu.

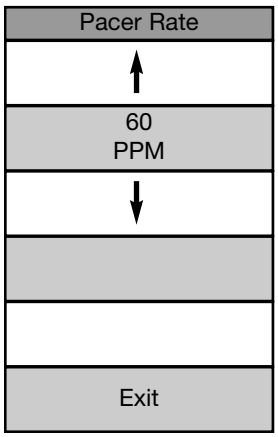



**Alarm Menu**

The Charge Alarm menu allows the user to select the Charge Alarm volume setting. Press ALARM VOLUME to use the Volume icon in the Quick Access window to adjust the charging tone. Press MAX VOLUME to set the charging tone to the maximum volume and by-pass the Volume icon.

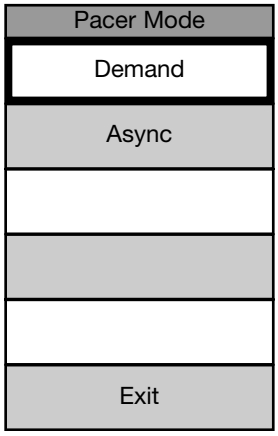
# Supervisor – Pacer Menu (optional)




**Rate Menu**

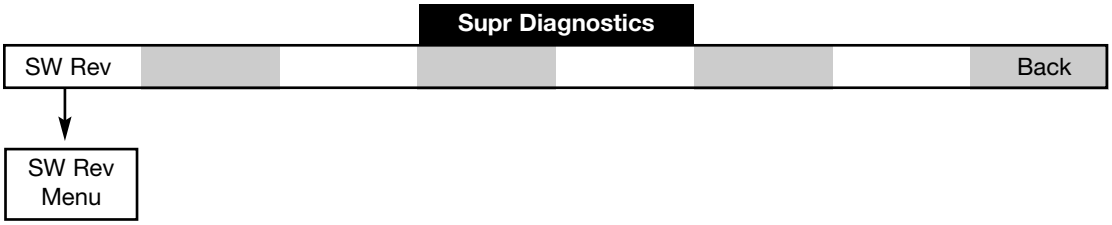
To set the default pacer rate setting, press either up arrow to increase, or down arrow to decrease the pulse per minute (PPM) selection (Range is from 30 to 180 PPM). Press Exit to close the pacer rate menu.

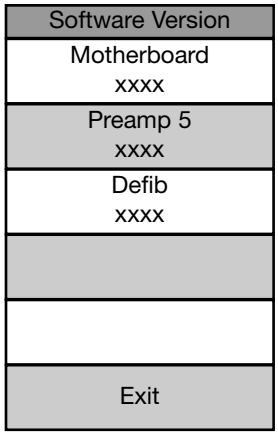



**Mode Menu**

To set the default pacing mode, press either demand or async. Pressing either demand or async will highlight your selection with a bold surrounding box. Press Exit to close the pacer mode menu.

# Supervisor – Diag Menu

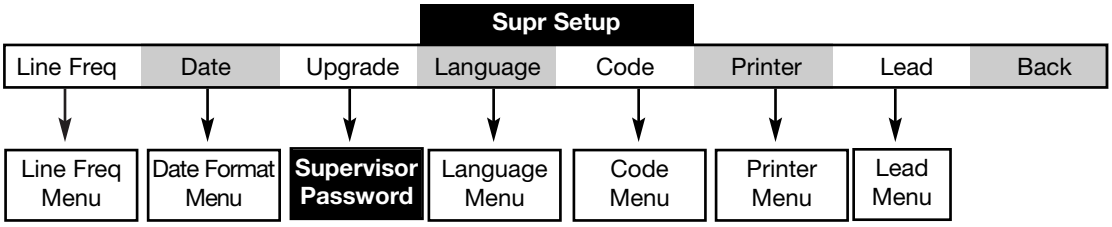


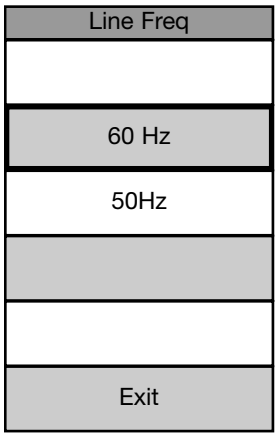




**Software Rev Menu**

Displays the software version for the microprocessor in the PIC30.

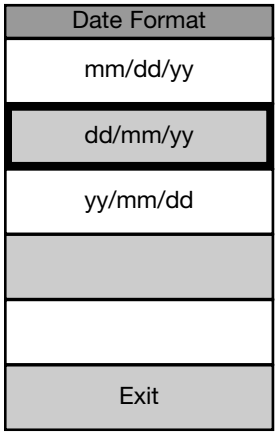
# Supervisor – Setup Menu




**Line Frequency Menu**

The line filter frequency must be set to match the frequency of the AC line current. In countries where the line current is 60 Hz (i.e. USA), set the selection to 60 Hz. In countries where the line current frequency is 50 Hz, select 50 Hz. A bold outline will appear around the selected frequency.




**Date Format**

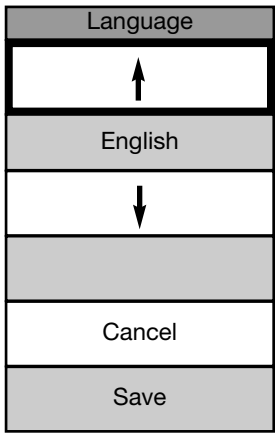
Date format is used to set how the month, day and year will be displayed.

mm/dd/yy = month/day/year

dd/mm/yy= day/month/year

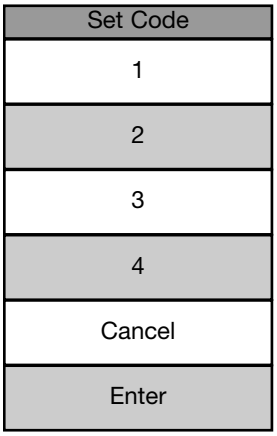
yy/mm/dd = year/month/day

To select a format, press the corresponding button to highlight your choice, then press Exit.




**Language Menu**

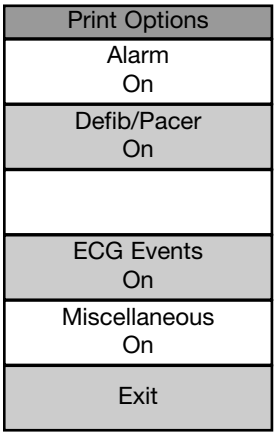
The PIC30 display and chart printouts can be displayed in multiple languages. To select a new language press the up and down arrows until the desired choice is displayed. Then press "Save" to save your selection. The unit must be powered off, then on again for the language change to take effect. To restore the PIC30 language setting to English, press the "Mute" and "VOL" button at the same time.




### Code Menu

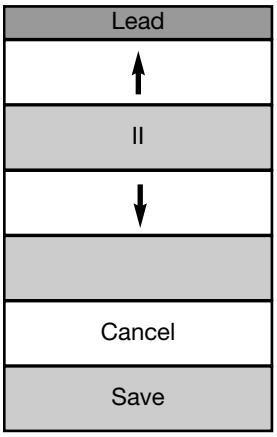
The default access code for supervisor configurations is 1, 2, 3, 4. To set a new supervisor code enter the numbers of your choice, 0-9, in all four number areas. To cancel the number code selection, press Cancel; to save your code press Enter.

***Note: Be sure to write down the new supervisor code in a safe place.***




### Printer Menu

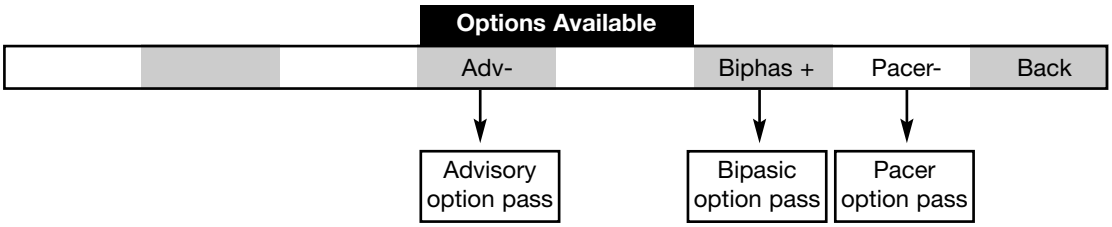
The printer menu allows the supervisor to disable hardcopy printouts when specific events occur. Setting the selections in the printer menu to "Off" will disable printouts for those events at the time the event occurs. Chart printouts for these events can only be obtained when the event log is printed. Selections set to "On" will generate printouts both at the time the event occurred and when the event log is printed. ECG Events are events generated by pressing the "Sample" button. Miscellaneous events are system status events such as "System On" and "Low Battery" messages.

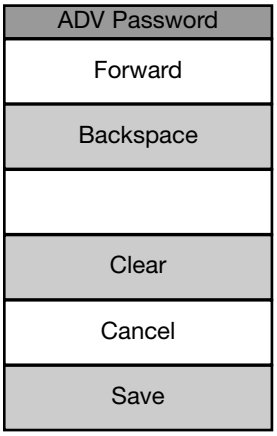



### Lead Menu

The lead menu allows the supervisor to change the default lead displayed on the start-up.

# Supervisor – Upgrade Menu




### Upgrade Password Menu

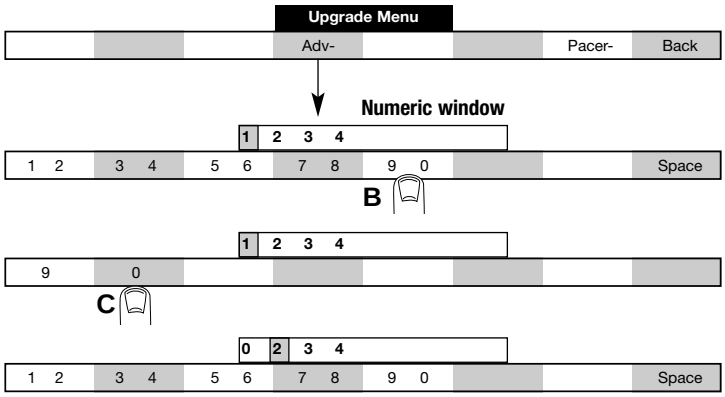
The Upgrade Menu allows the addition of options to the PIC30 in the field. Contact your Welch Allyn customer service representative for instructions on upgrading the PIC30.

**Entering the upgrade password**

The ADV Password menu gives the operator the option of moving the cursor forward or Backward; or clearing, canceling or saving the entry.

1. Enter a new character by pressing once on the group of characters containing the character of your choice (B). (In this case we want to change the "1" to a "0")

***Note: The upgrade menu window is replaced by a numeric window. The password is displayed just above the numeric window with an active cursor in the first space.***




2. Press on the actual character (C). Your selection will be entered and the cursor will move to the next character in the identifier. Continue this procedure to complete the password.

3. Press the **SAVE** button in the ADV Password menu to save the selection and return to the Upgrade menu. A “+” symbol should now appear after ADV, indicating that the option was successfully installed.

# Chapter 4 *Patient Preparation*

Preparing Patients for ECGs. . . . . 4.2
Applying ECG Sensors . . . . . 4.3
Using Disposable ECG Sensors . . . . . 4.3

# Preparing Patients for ECGs

You will obtain the highest quality ECGs when your patient is relaxed. Assure your patient that there is no danger or pain involved, and that his or her cooperation will assist in producing a valuable diagnostic record.

Make the patient comfortable on a cot or padded table which is large enough to support arms and legs. The patient's arms should rest at his or her sides and the legs should lie flat, not touching one another. Use a pillow to support the patient's head. Also, try to avoid factors like cold drafts which could cause discomfort. Leaving the chest and sensor sites exposed, cover your patient with a blanket to prevent shivering.

## CHOOSING THE ENVIRONMENT

**WARNING: Explosion hazard. DO NOT use in the presence of flammable anesthetics.**

***CAUTION: Although the PIC30 is designed to meet IEC 601-1-1-2 EMC immunity requirements, the presence of strong EMI field generated by electronic, surgical or diathermy instruments close to the unit, may cause trace noise or input overload conditions.***

The PIC30 is a high fidelity instrument which responds to the minute voltages of the heart. Since it is such a sensitive instrument, take care to avoid interference which can be produced by muscle tremor and AC signals. To minimize interference, locate the defibrillator and patient away from power cords and other electrical devices.

## PREPARING THE SKIN

***Note: In some cases skin irritation can occur from site preparation and sensor electrolyte solutions.***

You are more likely to get a stable baseline and clean trace if you prepare your patient's skin properly at sensor sites.

**For the best contact:**

1. Clean the skin with alcohol or acetone and let dry completely.
2. Abrade the skin slightly with a dry, heavy gauze or similar alternative.

# Applying ECG Sensors

Apply sensors and connect the patient cable to them. Make sure the lead cables follow the contours of the patient's body and lie flat. If any lead wire is too long, as with a short patient or child, take up the length by making a small “stress loop” (see figure).


When applying sensors to sites with a lot of hair, the following techniques may improve contact:

1. Use the thumb and forefinger to spread the hair before applying the sensor to the skin.
2. Abrade the skin slightly with a dry, heavy gauze or similar alternative.
3. If the sensor does not adhere well, it may be necessary to shave the site.

# Using Disposable ECG Sensors

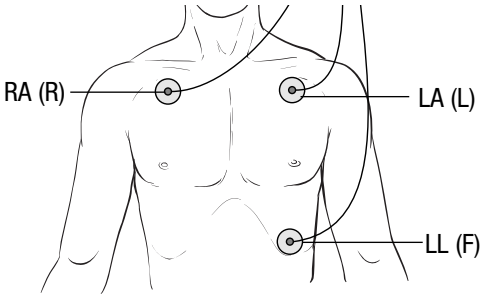
Disposable sensors save time and are an affordable alternative to bulbs, plates, straps, creams and gels. Disposable sensors utilize a highly conductive, natural adhesive for good results.

Disposable sensors should be stored according to the guidelines on the packaging and should not be used after the expiration date. Never mix sensor types or brands. Incompatibilities can cause baseline drift and can increase trace recovery time after defibrillation, or cause unstable baseline.

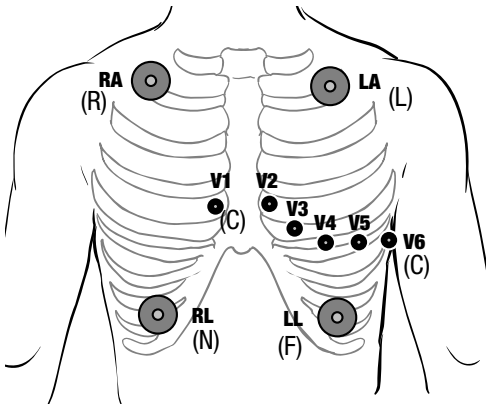
### Applying Chest Sensors

1. Expose the chest.
2. Locate the electrode positions on the patient's chest, see illustration below.
3. Apply the sensors.
4. Ensure that the leads conform to body contours and that no strain is placed on the sensors.

**3-LEAD ELECTRODE PLACEMENT**




**5-LEAD ELECTRODE PLACEMENT**




| Color lead | | Location |
|---|---|---|
| AHA<br>Green (RL) | IEC<br>Black (N) | Right mid-clavicular line, between 6th and 7th intercostal space |
| Red (LL) | Green (F) | Left mid-clavicular line, between 6th and 7th intercostal space |
| White (RA) | Red (R) | Right mid-clavicular line, directly below clavicle |
| Black (LA) | Yellow (L) | Left mid-clavicular line, directly below clavicle |
| Brown (V) | White (C) | Chest - Place per figure at left for V1-V6 |
| | | V1 - 4th Intercostal space at right sternal margin |
| | | V2 - 4th Intercostal space at left sternal margin |
| | | V3 - Midway between V2 and V4 leads |
| | | V4 - 5th Intercostal space at mid-clavicular line |
| | | V5 - Same transverse level as V4 at left anterior-axillary line |
| | | V6 - Same transverse level as V4 at left mid-axillary line |

## PEDIATRIC LEAD PLACEMENT

When acquiring a pediatric ECG, you may use an alternative V3 placement. Place the sensor in the V4 position (See figure above). Improper placement will result in inaccurate waveform labeling.

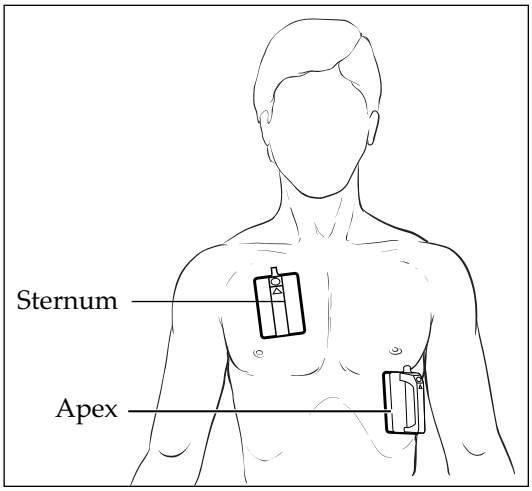
# Chapter 5 *ECG Monitoring*

Monitoring with Defibrillator Paddles . . . . . 5.2
Monitoring with 3-lead Patient Cable . . . . . 5.2
Monitoring with 5-lead Patient Cable . . . . . 5.3
Monitoring with "Hands-Free" Defibrillation Pads (optional) . . . . . 5.4

# Monitoring with Defibrillator Paddles

1. Press Power switch on. Set the Lead to PDL (paddles).
2. Apply gel to paddles and place the sternum paddle firmly against the patient's chest inferior to the right clavicle and lateral to the upper sternum; place the apex paddle in the anterior-axillary line, inferior and lateral to the patient's left nipple.
3. Observe the patient's electrocardiogram on the display. Adjust size of the ECG trace with the Size control button as necessary.

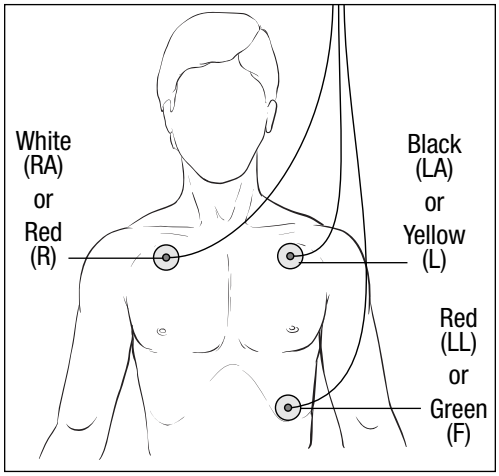
**PADDLE PLACEMENT**




# Monitoring with 3-Lead Patient Cable

1. Press Power switch on.
2. Insure that the display indicates a 3-lead patient cable has been configured. If not, see page 3.7 for setting patient cable type.
3. Thoroughly prep patient skin for electrode attachment. Clean and dry skin sites, preferably with a coarse, dry terry cloth. Next, clean skin with alcohol and allow to dry completely before applying pads.

**3-LEAD ELECTRODE PLACEMENT**




***Note: The type of electrode and the technique used in preparing the skin are major factors in determining the quality of the ECG signal obtained. Use high-quality, silver-silver chloride electrodes. These electrodes are designed to provide excellent baseline stability, rapid recovery from defibrillation, and minimize artifact from patient movement. Do not use electrodes if gel is dry.***

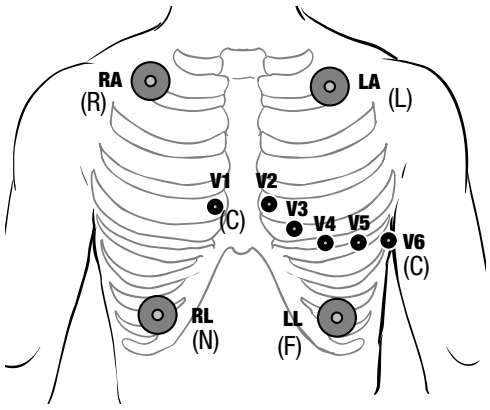
4. Connect each lead of the 3-lead patient cable to the appropriate electrode. Arrange the electrodes as shown above. (Make sure that the ECG electrodes are placed to allow defibrillation if necessary).
5. Insert the patient cable plug into the input ECG connector on the PIC30.
6. Select the proper lead setting for the desired lead configuration by pressing the Lead button to the appropriate position: I, II, or III.
7. Observe the patient's electrocardiogram on the display. Adjust size of the ECG trace with the Size button as necessary.

# Monitoring with 5-lead Patient Cable

1. Press Power switch on.
2. Insure that the display indicates a 5-lead patient cable has been configured. If not, see page 3.7 for setting patient cable.
3. Thoroughly prep patient skin for electrode attachment. Clean and dry skin sites, preferably with a coarse, dry terry cloth. Next, clean skin with alcohol and allow to dry completely before applying pads.
4. Connect each lead of the 5-lead patient cable to the appropriate disposable electrode. Arrange the electrodes as shown below. (Make sure that the ECG electrodes are placed to allow defibrillation if necessary). The V (or C) lead may be repositioned as indicated to view V1 - V6.
5. Insert the patient cable plug into the input ECG connector on the PIC30.
6. Select the proper lead setting for the desired lead configuration. Press the Lead button to the appropriate position corresponding to the desired configuration.
7. Observe the patient's electrocardiogram on the display. Adjust size of the ECG trace with the Size button as necessary.

For lead placement follow lead color code below.

**5-LEAD ELECTRODE PLACEMENT**

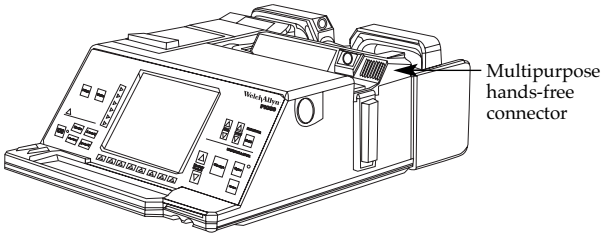



| Color lead | | Location |
|---|---|---|
| AHA<br>Green (RL) | IEC<br>Black (N) | Right mid-clavicular line, between 6th and 7th intercostal space |
| Red (LL) | Green (F) | Left mid-clavicular line, between 6th and 7th intercostal space |
| White (RA) | Red (R) | Right mid-clavicular line, directly below clavicle |
| Black (LA) | Yellow (L) | Left mid-clavicular line, directly below clavicle |
| Brown (V) | White (C) | Chest - Place per figure at left for V1-V6 |
| | | V1 - 4th Intercostal space at right sternal margin |
| | | V2 - 4th Intercostal space at left sternal margin |
| | | V3 - Midway between V2 and V4 leads |
| | | V4 - 5th Intercostal space at mid-clavicular line |
| | | V5 - Same transverse level as V4 at left anterior-axillary line |
| | | V6 - Same transverse level as V4 at left mid-axillary line |

# Monitoring with "Hands-Free" Defibrillation Pads (optional)

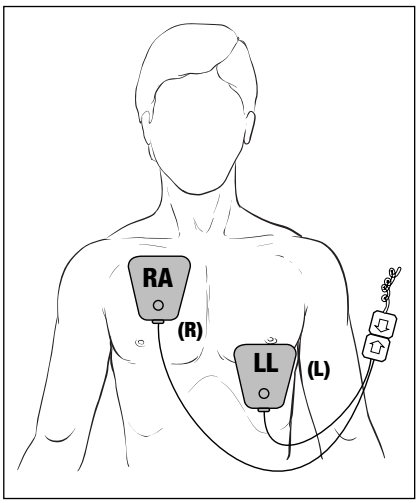
***CAUTION: Be sure that the hands-free adapter is firmly seated in the defib connector before monitoring with "hands-free" defibrillation pads.***

***CAUTION: Use only Welch Allyn approved multifunction pads with PIC30 hands-free adapter. Do not connect unapproved ECG sets to the PIC30 hands-free adapter; an ECG will not be obtained.***




1. Press Power switch on. Press the Lead Button to the PAD position.
2. Connect the disposable defibrillation pads to the hands-free adapter cable.
3. Remove or loosen clothing if necessary for application of pads. Clean and dry skin sites, preferably with a coarse, dry terry cloth.
4. Check expiration date on the multipurpose pads package, if the expiration date has passed do not use the pads. Remove the multipurpose defibrillation pads from packaging. Remove the protective cover and apply the pads to the patient in the position illustrated here. Do not use if gel area is dry.

**HANDS-FREE PAD PLACEMENT**




5. When applying pad, gently adhere opposite edge of pad to patient and lightly roll pad against patient's skin.
6. Observe the patient's electrocardiogram on the monitor scope.
7. Adjust Size control as necessary.

***Note: Apex-anterior or apex-posterior placement of pads results in a modified Lead II ECG trace.***

# Chapter 6 *Defibrillation*

Defibrillation with External Paddles . . . . . 6.2
Defibrillation with Pediatric Adapter . . . . . 6.3
Defibrillation with Multipurpose Hands-Free Pads (optional) . . . . . 6.4
Performing Synchronized Cardioversion . . . . . 6.5

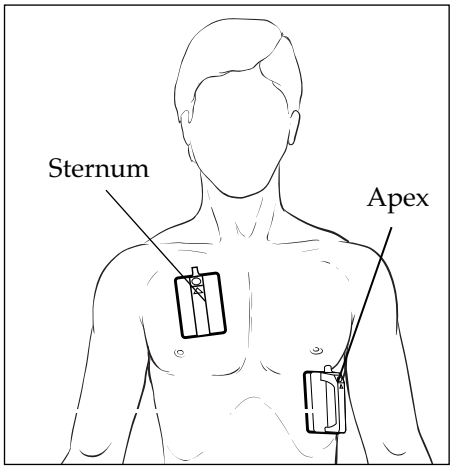
# Defibrillation with External Paddles

1. Press Power switch to On.
2. Apply electrode gel to the center of one paddle electrode. Lightly press the paddle electrodes together and spread the gel evenly over both paddle surfaces. Make sure gel covers the entire paddle surface. Do not allow any gel to touch the paddle handle or the operator's hands.
3. Press Energy Select button on the front panel up or down to select the desired energy level (energy selection is also available on the deluxe paddle set).
4. Press the Charge button on the defibrillator panel to charge the defibrillator (charge selection is also available on the deluxe paddle set). An audible periodic tone will sound indicating that the unit is charging. The energy range bar graph on the right side of the display will highlight the relative charge state until it reaches the selected energy. When the unit is fully charged, the periodic tone will change to a continuous tone and the highlighted energy range bar graph will include the selected energy.

   ***Note: If the selected energy is changed after charging has been activated, additional time may be required to charge to the new energy.***

5. Place the sternum paddle firmly against the patient's chest inferior to the patient's right clavicle and lateral to the upper sternum; place the apex paddle in the anterior-axillary line, inferior and lateral to the patient's left nipple.

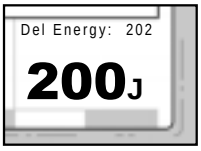
**PADDLE PLACEMENT**




6. With the paddles in proper position, clear all personnel, visually ensure all personnel are clear (including the operator) from patient contact. Press the SHOCK button on each paddle simultaneously.

   ***Note: If defibrillation is not required, pressing the Disarm button located on the front panel will discharge the energy internally.***

**DELIVERED ENERGY**




7. Observe the effect of the delivered countershock by observing the patient's ECG on the display. The amount of energy delivered will appear in the defibrillation display window. Verify that the proper amount of energy has been delivered.
8. For additional counter shocks, repeat steps 3-7.
9. To secure the instrument, turn the power switch to Off. Clean the paddle electrodes, patient cables and controls as outlined in chapter 11.
10. If battery power was used, recharge the battery by connecting the PIC30 to AC power or replace the used battery with a fully charged battery and check that there are sufficient supplies for the next use (defib gel, recorder paper, ECG electrodes, etc.)

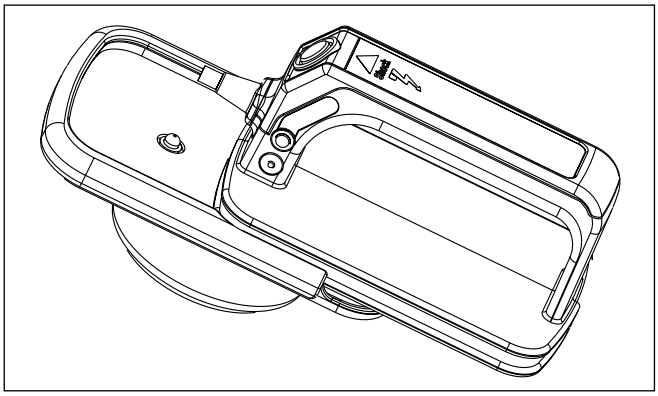
# Defibrillation with Pediatric Adapter

***CAUTION: There is no energy limit for pediatric electrodes. Care should be exercised to insure appropriate selection of defibrillation energy level for pediatric patients.***

***Note: To facilitate rapid defibrillation for pediatric use, the power on default defibrillation energy can be auto set in the supervisor-defib menu.***

1. Shut the unit off before attaching the pediatric electrodes to the paddles.
2. Slide the pediatric electrode onto the adult paddle set. Be sure to slide the electrode to the end for a snug fit.
3. Refer to page 6.2 and follow instruction for defibrillating with external paddles, to defibrillate patient.

**PEDIATRIC ELECTRODES**

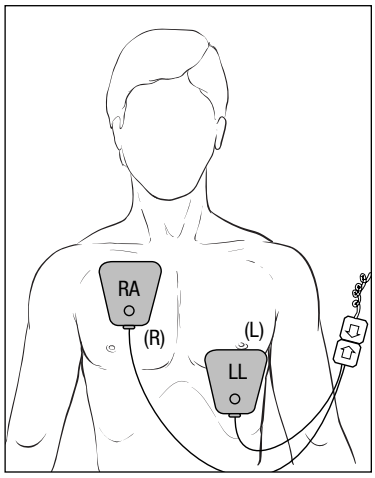


# Defibrillation with Multipurpose Hands-Free Adapter (optional)

Connect the multipurpose hands-free adapter by sliding it onto the defibrillator guide plate. Make sure the release button clicks into place and is in the up position.

1. Press Power switch to On and ensure lead selector is set to PAD.
2. Remove or loosen patient's clothing if necessary for application of pads. Clean and dry skin sites, preferably with a coarse, dry terry cloth. Shave patient if appropriate. To remove lotions or moisturizer, clean patient's skin with alcohol and allow to dry completely before applying pads.

**HANDS-FREE PAD PLACEMENT**



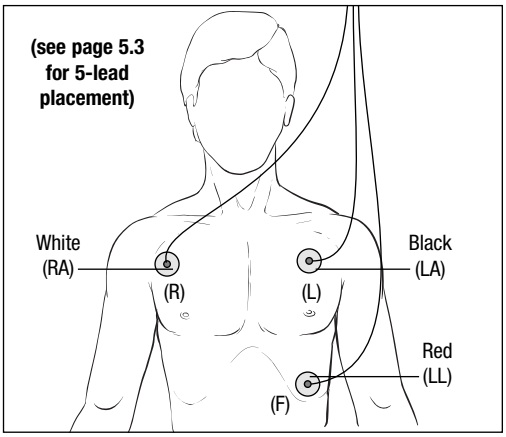

3. Check expiration date; do not use pads that have expired. Remove disposable multipurpose pads from packaging. Use adult multipurpose electrodes (P/N 001853) for adult patients, pediatric multipurpose electrodes (P/N 001828) for pediatric patients (<10kg). Remove the protective cover from the pads and apply the pads to the patient in the position illustrated or according to pad package. Do not use if gel area is dry.
4. Press Energy Select button on the front panel up or down to select the desired energy level.
5. Press the Charge button on the defibrillator panel to charge the defibrillator. An audible tone will sound periodically indicating that the unit is charging. The energy range bar on the right side of the display will highlight the relative charge state until it reaches the selected energy. When the unit is fully charged, the periodic tone will change to a continuous tone and the highlighted energy range bar will include the selected energy.
6. Visually and verbally ensure that all personnel (including the operator) are clear from the patient. Press the SHOCK button on the multipurpose hands-free adapter to deliver energy.
7. Observe the effect of the delivered countershock by observing the patient's ECG on the display. The amount of energy delivered will appear in the defibrillation display window. Verify that the proper amount of energy has been delivered.
8. For additional counter shocks, repeat steps 4 through 7.
9. To secure the instrument, turn the power switch to Off. Clean the patient cables and controls as outlined in chapter 11.
10. If battery power was used, recharge the battery by connecting the PIC30 to AC power or replace the used battery with a fully charged battery and check that there are sufficient supplies for the next use.

# Performing Synchronized Cardioversion

**WARNING: Elective cardioversion should only be performed while monitoring patient with patient cable and electrodes or hands-free defibrillator pads. Although the device will allow synchronized cardioversion in the PDL (paddle) lead selection, it is not recommended that Sync be performed in the PDL lead. Artifact can be generated from the paddle cables, which could cause the defibrillator to discharge on the artifact.**

1. Press Power switch to On.
2. Attach the electrodes to the patient. Position the electrodes to allow immediate placement of the defibrillator paddles. Attach an ECG electrode to each lead of the patient cable.
3. Connect the ECG patient cable plug to the ECG input connector. Press the Lead button to select lead II position (if using the hands-free defibrillator pads, select PAD lead position). If using 5-lead patient cable see page 3.7 to change 3-lead selection to 5-lead. Observe the patient's ECG on the display.
4. If using paddles, apply electrode gel to the center of one paddle electrode. Lightly press the paddle electrodes together and spread the gel evenly over both paddle surfaces. Make sure the gel covers the entire paddle surface. Do not allow any gel to touch the paddle handle or the operator's hands.

**ELECTRODE PLACEMENT**

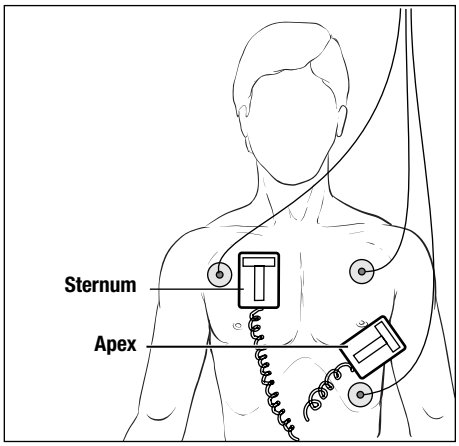



5. Press the sync button to engage the synchronizer. The light next to the Sync button will illuminate and an "S" marker will appear over the portion of the ECG that the defibrillator will trigger on. The Sync light will flash off with each Sync marker.

***Note: If the marker pulse does not appear over the R wave, turn lead select to another position (I, II, III) or adjust ECG size. If the Sync marker is not obtained, the defibrillator will not discharge. Do not switch the lead from PADS if monitoring with hands-free defibrillation pads.***

6. Press Energy Select button on the front panel up or down to select the desired energy level.

**CARDIOVERSION PADDLE PLACEMENT**




7. Charge the defibrillator by pressing the Charge button on the defibrillator panel, or the Charge button on the deluxe apex paddle. An audible tone will sound periodically, indicating that the unit is charging. The energy range bar on the right side of the display will highlight the relative charge state, until it reaches the selected energy. When the unit is fully charged, the periodic tone will change to a continuous tone and the highlighted energy range bar will include the selected energy.

8. If using paddles, place the sternum paddle firmly against the patient's chest inferior to the patient's right clavicle and lateral to the upper sternum; place the apex paddle in the anterior-axillary line, inferior and lateral to the patient's left nipple.

9. To discharge, hold the paddles firmly in place, then press and hold both SHOCK buttons down until the defibrillator discharges. If using the hands-free defibrillator pads, press and hold the SHOCK button on the multipurpose hands-free adapter.

   ***Note: Discharge may not be immediate upon pressing the paddle SHOCK buttons. This is normal. Keep the fire buttons pressed until the defibrillator discharges.***

   ***Note: For any additional shocks, the sync button may or may not need to be pressed. This depends on the supervisor cardioversion mode setting.***

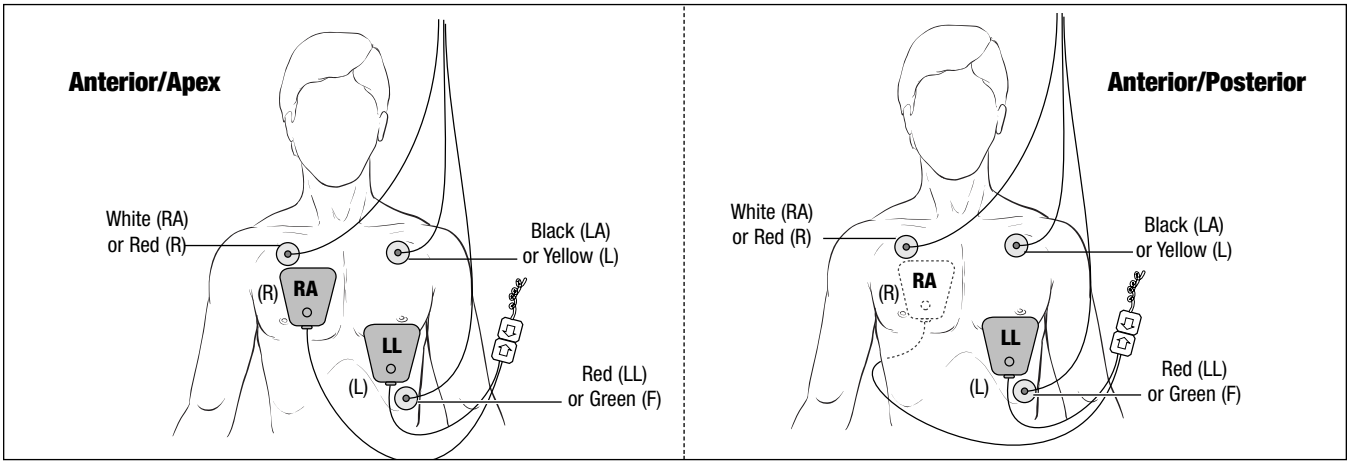
10. To negate the cardioversion after the SHOCK buttons are pressed but before the next QRS wave is detected and the defibrillator discharges, merely release both SHOCK buttons. The defibrillator will not fire. When ready to defibrillate again, firmly position the paddles, then press and hold the SHOCK buttons until a QRS wave is detected and the defibrillator delivers the energy.

11. Press the Disarm button on the front panel to disarm the defibrillator at any time during the procedure.

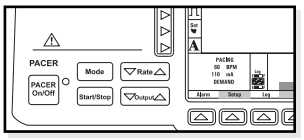
# Chapter 7 *External Pacing (optional)*

External Pacer Operation Procedures (optional) . . . . . 7.2

**MULTIPURPOSE DEFIB/ELECTRODE PLACEMENT**




# External Pacer Operation Procedures (optional)




1. Press pacer switch to turn on pacer.
2. Apply ECG monitoring electrodes as illustrated above.
3. Connect PIC30 ECG patient cable to the patient and the PIC30.
4. Connect the multipurpose hands-free adapter to the PIC30. Make sure the connector locks into place and that the release button returns to its up position.
5. Apply multipurpose defibrillation/pacing electrodes to patient as illustrated on the electrode package. Use PIC30 Adult Multipurpose electrodes (P/N 001853) for adult patients and Pediatric Multipurpose Electrodes (001781) for pediatric patients (<10kg).
6. Connect multipurpose defibrillation/pacing electrodes to the multipurpose hands-free adapter.
7. Press Lead and select I, II or III to provide the largest-amplitude QRS complex.
8. Press Size and adjust size to insure proper sensing of the patient's heart rate. Confirm that the displayed heart rate coincides with the patient's heart rate.
9. Press Start/Stop to turn pacer on, the pacer window will become active. The pacer indicator next to the Pacer button will illuminate orange, indicating that the pacer is stopped and that no pacer pulses are being delivered to the patient.

   ***Note: When the pacer is on, the lead selection will be restricted to Leads I, II or III.***

10. Press Rate button to select the desired pacing rate.

    ***Note: The initial pacing output rate can be set in the pacing supervisor menus.***

11. Press the Mode button to select the appropriate therapy. Each time the MODE button is pressed, the pacing mode will change between demand and async mode. The selected mode will be displayed in the pacing window.

    ***Note: The initial pacing mode can be set in the pacing supervisor menus.***

In Demand Mode, pacing pulses will be inhibited by the patient's QRS complexes that occur during a time interval that is dependent on the setting of the rate control. If during that interval no QRS complexes occur, a pacing pulse will be delivered to the patient. In the demand mode, the pacer supplies the required number of pacing pulses to maintain the patient's heart rate at approximately the rate selected in the pacing rate window. Due to the delay between delivered pacing pulse and the patient's response, the heart rate display may read less than what is selected on the pacer rate window. How much less will depend on the time it takes the heart to respond to the pacing stimulus.

In the Async Mode, pacing pulses are not dependent on the patient's cardiac activity. The pacer will deliver pacing pulses at the selected pacing rate.

12. Press the Start/Stop button to initiate pacing. The pacing display will indicate PACING and the orange pacing light will change to green, indicating the pacer is active. Each time a pacing pulse is delivered to the patient, the green light will flash off briefly.
13. Ensure that the pacing pulses are occurring in the appropriate position of the cardiac cycle.
14. Press the Output button to adjust the pacing current output. Pressing the up arrow will increase the current by 10 mA. Pressing the down arrow will decrease the current by 5 mA. Slowly increase the output current while observing the ECG for evidence of electrical capture. Check patient's pulse or blood pressure to verify mechanical capture. Select the lowest output current that will achieve both electrical and mechanical capture.

**Electrical Capture** can be verified by noting a large ectopic beat approximately 100 msec after the pacing pulse is delivered to the patient. The morphology of this pulse may vary widely from patient to patient, sometimes appearing as a relatively normal QRS complex.

**Mechanical Capture** can be verified by monitoring the physical condition of the patient. Check for the following physiological signs: reddening of the skin, palpable pulses, increased blood pressure and other signs of increased blood flow.

***Note: The initial pacing output rate will automatically be set to the lowest current output to prevent accidental high currents from being delivered to the patient. External transcutaneous pacing may be uncomfortable for certain patients. Depending upon local protocol, consider administering a sedative or analgesic should the pacing therapy become uncomfortable.***

15. To stop (pause) the delivery of pacing pulses momentarily , press the Start/Stop button. The pacing display will indicate Pacer Stop and the pacing indicator light will change from green to orange. The rate and output settings will remain the same as what was selected prior to the Start/Stop button being pressed. To re-initiate pacing, press the Start/Stop button again.

    ***Note: Should the patient require defibrillation during pacing, follow the defibrillation procedure as outlined in chapter 6. When the defibrillator is charged the pacer will automatically be turned off for safety reasons.***

If a Lead Fault occurs, the display will indicate the faulting leads (ECG or pads). During lead fault conditions, the pacer light will illuminate red to caution the operator that a lead fault condition exists. In an ECG Lead Fault condition check that the ECG electrodes and patient cable are connected properly. In a Pads Lead Fault condition,

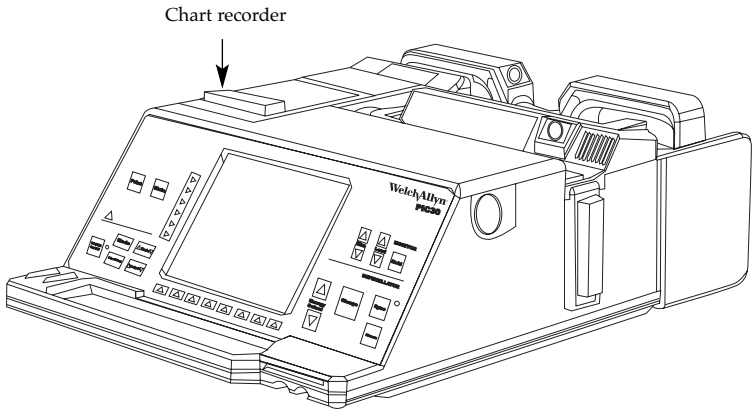
check to see that the multipurpose electrodes and multipurpose hands-free adapter are connected properly. When the lead fault has been corrected, the lead fault message will be removed from the display and the pacing indicator next to the pacer On/Off button will change from red to orange. To begin pacing again, press the Start/Stop button.

***Note: Should a lead fault occur after you have achieved capture, the pacer will automatically revert to the stop mode. The rate and output current settings will remain at the last settings used before the lead fault occurred. To resume pacing, correct the lead fault and press the Start/Stop button.***

# Chapter 8 *Event Documentation*

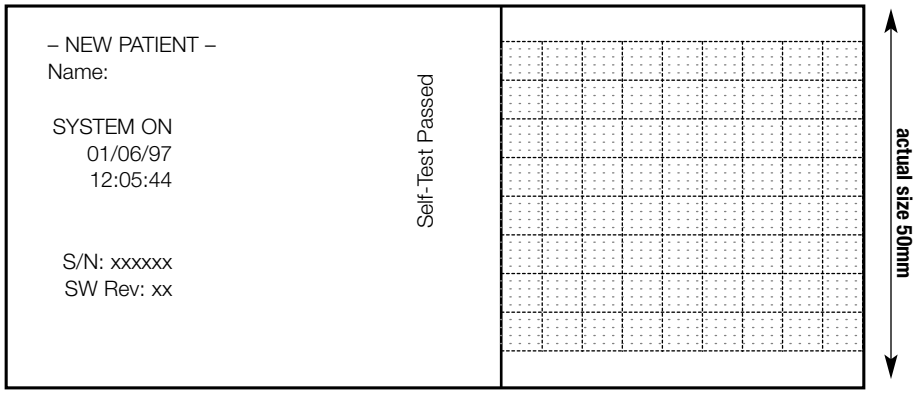
Chart Recorder Startup Printout . . . . . 8.2
Turning On/Off the Chart Recorder . . . . . 8.3
Automatic Printing . . . . . 8.4
Event Log Summary . . . . . 8.5

# Chart Recorder Startup Printout

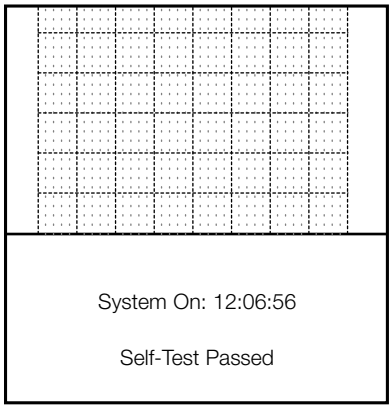



**"System On" Header**

Each time the PIC30 is powered on, the unit will perform a self-test and the results of the test will be printed on the header. The date and time the system was turned on, the unit serial number and software revision level will be printed on the header (if the device has been turned off for more than 2 minutes).




If the device was switched off briefly, for less than 2 minutes (e.g. to change the battery), the device will assume that the same patient is being monitored and the startup header, shown at right, will be displayed when turned on.



# Turning On/Off the Chart Recorder

Print

1. Press **Print** Button to begin printing.
2. Press **Print** Button again to stop printing.

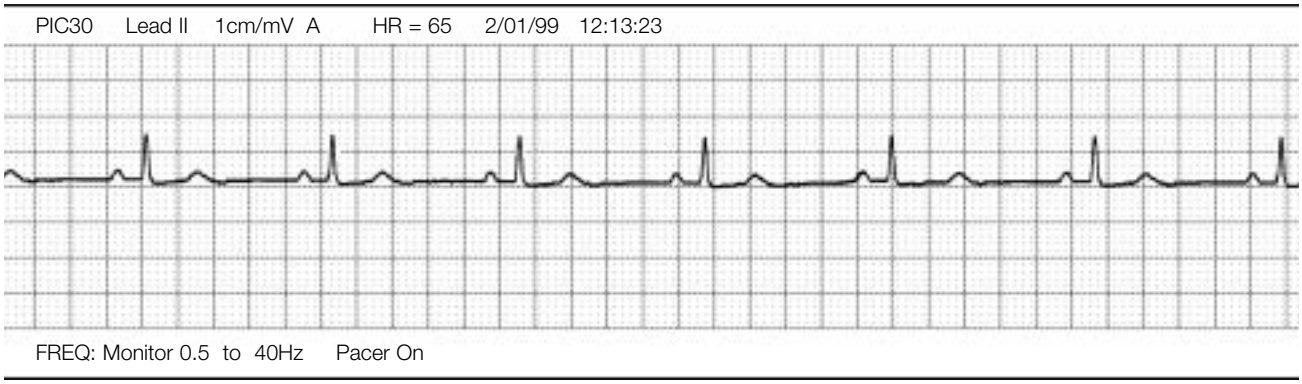
### Manual printout

Each time the chart recorder button is pressed, the following information will be printed:

**Top Line:**
PIC30, ECG Lead (LEAD), ECG Size (“A” indicates AUTO sizing setting), Heart Rate (HR), Sync on (if activated),Date , Time.

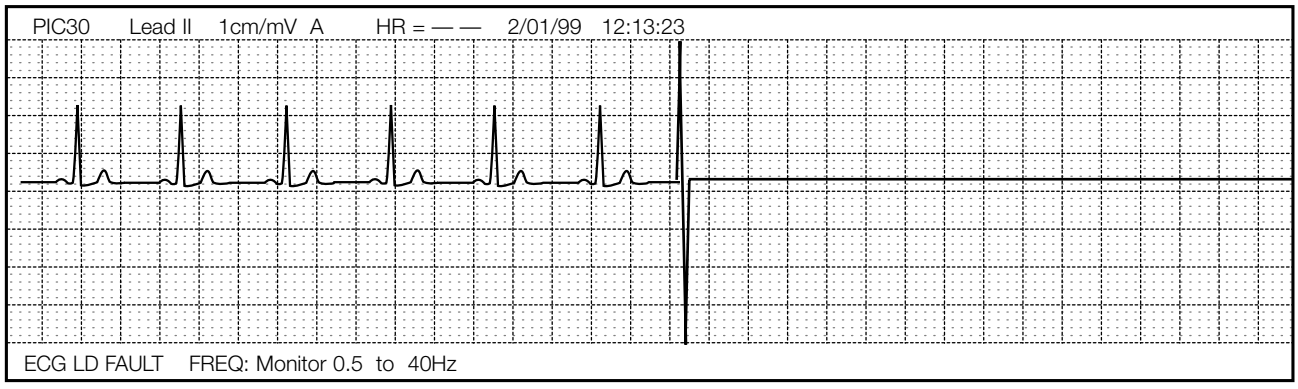
**Bottom Line:**
Lead fault status, frequency response, pacer status (if on and option is installed), notch filter status (Ñ when the notch is on), any error messages.

**Normal Printout**




**(optional)**

**ECG Lead Fault**



# Automatic Printing

The following printouts will be generated automatically if the Defib/Pacer, ECG Events, or Alarm options are On in the Supervisor - Setup - Printer menu.

Each time an automatic printout is generated, the following information will be printed:

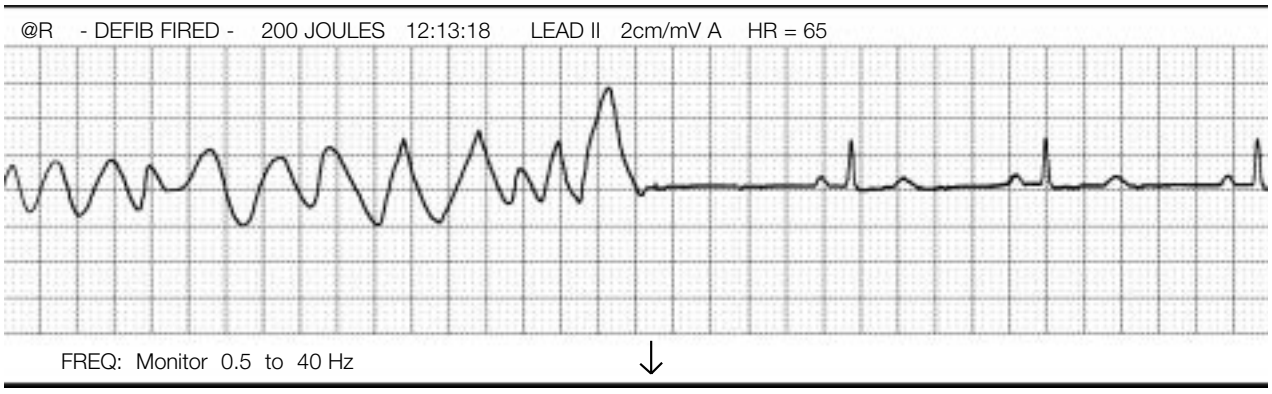
Top line: @R (for Real-Time) or @P (for Playback if printed from the log), event type, Time, ECG lead, ECG Size, and Heart Rate.

Bottom line: Frequency and pacer status

### Defibrillation

After the defibrillator has been discharged, the chart recorder will automatically run for 12 seconds, providing 4 seconds of pre-shock ECG and 8 seconds of post-shock ECG. In addition, the selected defibrillation energy will be printed. A 12 - second ECG sample will be stored in the Event Log.

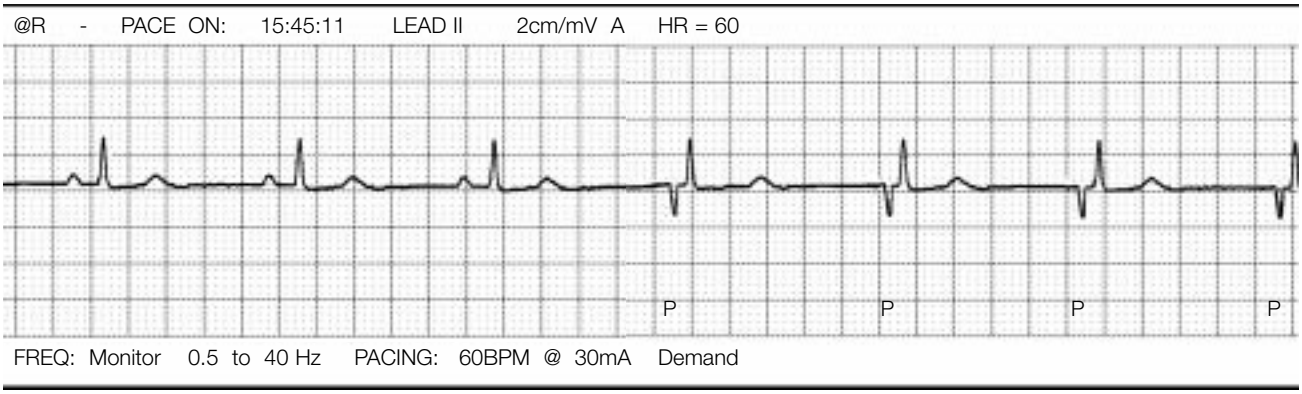
**Defibrillation**




### Pacer Activation (optional)

After the pacer has delivered pacing pulses, the chart recorder will automatically run for 8 seconds, providing 4 seconds of pre-pace ECG and 4 seconds of post-pace ECG. In addition to the standard chart annotation, the pacing rate, output and mode information will be printed. An 8 - second ECG sample will be stored in the Event Log.

**Pacer**

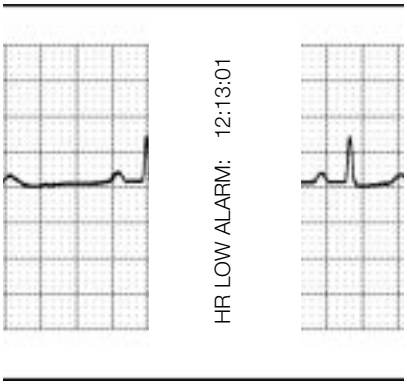



### Analysis Event (advisory option optional)

After the [A] Quick Access button has been pushed and an analysis cycle has been completed, the chart recorder will automatically run providing a 6 - second ECG trace. A 4 - second ECG sample will be stored in the Event Log.

### Alarm Condition

If the global alarms are enabled and a parameter's alarm limit is exceeded, the alarm condition and the time will be printed on the chart recorder.




### Miscellaneous Status Events

Certain system status events will generate a time-stamped text printout on the chart recorder. These events include: Low battery, defib disarm, lead fault during pacing, pacer off, self-test results, advisory mode status, time change and log full.

## Event Log Summary

The Event Log provides a summary of key treatment events including defibrillator and pacing events, ECG sample events, alarms and system status. The Event Log has a capacity of thirty-eight 4 - second ECG events and three hundred time-stamped events.

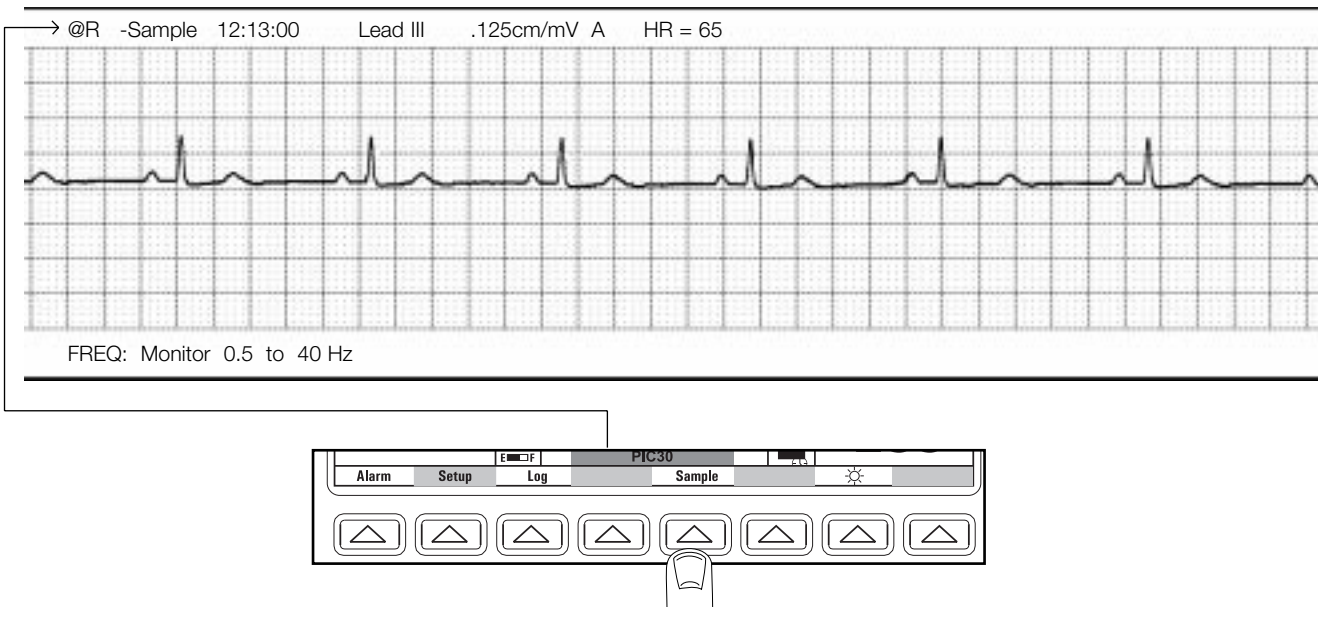
> ***Note: Defibrillation events store 12 seconds of ECG, consisting of three 4-second ECG events, 4 seconds pre-shock, and 8 seconds post shock. Pacing start events store 8 seconds of ECG, consisting of two 4-second ECG events.***

### Sample

To assist in providing a Summary of the incident, the "Sample" button is available to document Advance Cardiac Life Support (ACLS) or other events. Pressing the "Sample" button will store a 4-second ECG sample in memory along with the type of event, time, date, as well as other status and annotation information.

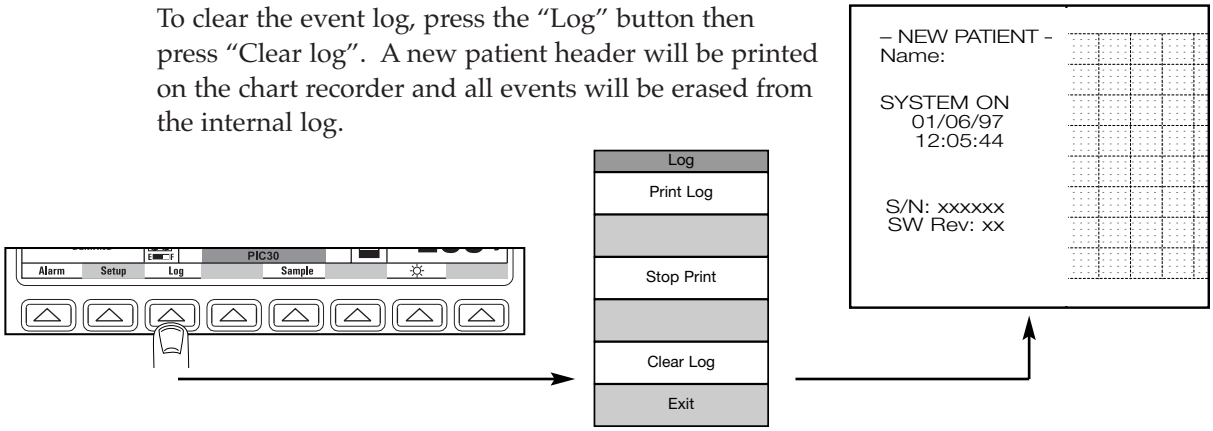
> ***Note: If a subsequent ACLS treatment event button is pressed before the chart recorder has completed printing the information of the previous ACLS treatment event, a low tone will sound indicating that the second event was not stored into the log or printed on the chart recorder.***

**Sample Event**



### Clearing The Log

To clear the event log, press the "Log" button then press "Clear log". A new patient header will be printed on the chart recorder and all events will be erased from the internal log.

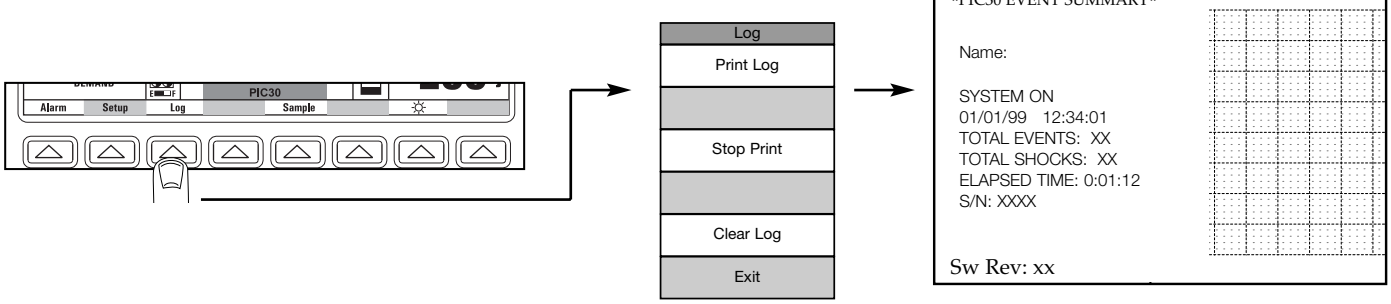



**Sample Event**

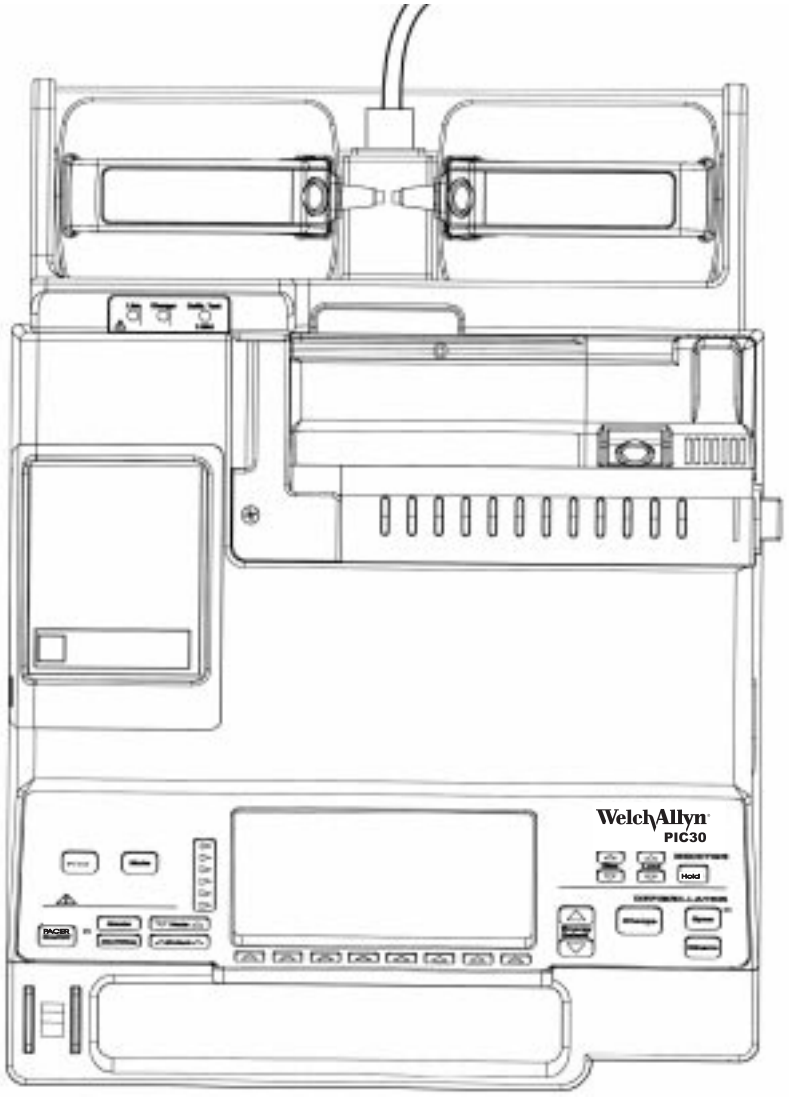

If the Log is full and the sample event button is pressed, "Sample" will be printed along with "Log Full." The event will not be saved in the Treatment Summary log. "Log Full" printouts should be saved and added to the log printout to provide a complete history of the event.

### Printing out the Log

A header is printed for each patient when the Log is printed out. The header includes a place for the patient's name, the time and date that system power was turned on, the total number of ECG events stored for that patient, the total number of defibrillator shocks delivered to that patient, and the elapsed time the system was on. The Log is followed by a printout of all the ECG samples stored for that patient. At the end of the ECG traces, a System Off message will be printed along with the time the system was powered down. If the system was powered down for more than two minutes, a new patient is assumed and a new event summary is generated. If the system is powered down for less than 2 minutes (e.g. for a battery change), it is assumed that the same patient is being monitored and subsequent events will be added to the current Log. Multiple copies of the Log can be printed by printing the Log again after the System Off message is printed.



# Chapter 9 *Power Source*




General Precautions . . . . . 9.2

PIC30 Power Supply/Paddle Holder (optional) . . . . . 9.2

Battery Operation and Maintenance . . . . . 9.3

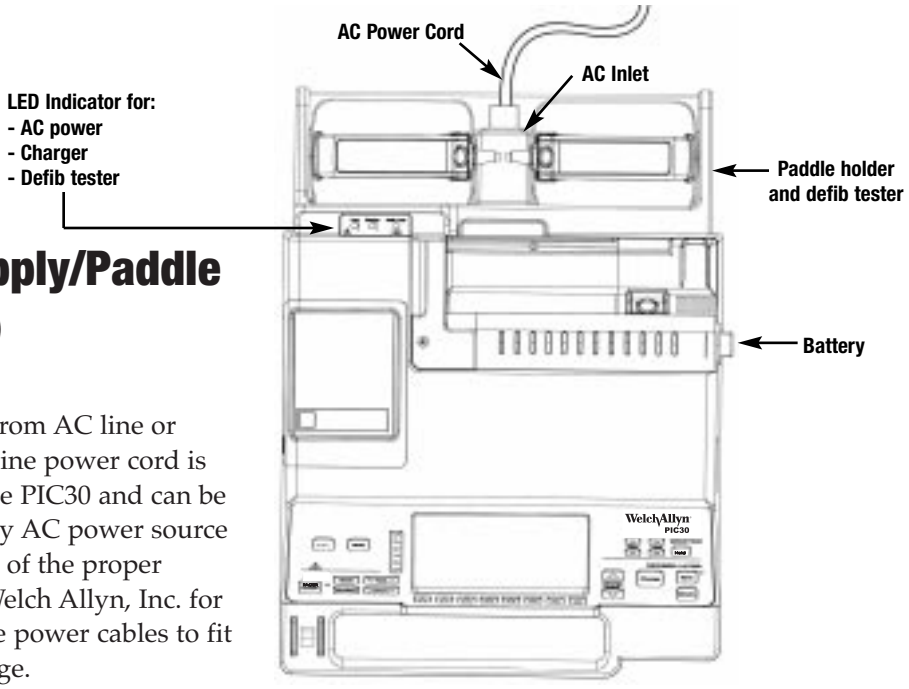
# General Precautions

**The PIC30 Batteries**

- Do not incinerate.
- Do not directly connect the negative and positive terminals together.
- Use only the internal charger to charge the battery.

**To prevent deterioration or damage to the battery:**

- Do not drop or subject to strong physical shock.
- Do not use the PIC30 battery to power equipment other than the PIC30.




# PIC30 Power Supply/Paddle Holder (optional)

The PIC30 can operate from AC line or battery power. The AC line power cord is located in the back of the PIC30 and can be connected directly to any AC power source worldwide with the use of the proper power cable. Contact Welch Allyn, Inc. for more information on the power cables to fit your standard AC voltage.

**AC Power Indicator:**
The line power indicator is illuminated green when the unit is plugged into an AC outlet.

**Charge Indicator:**
Yellow light is illuminated continuously to indicate that a battery is charging. The yellow light will flash when the battery is fully charged.

**Defibrillator Test Indicator:**
Green light is briefly illuminated to indicating that 200J or more has been delivered when testing the defibrillator.

**Defibrillator Test Paddle Trays:**
Paddle trays contain discharge contacts used for testing the defibrillator.

**AC Inlet:**
Connector accepts standard IEC 320 line cord with earth ground.

**AC Power Cord:**
A variety of cords are available to allow for connection of the PIC30 to virtually any worldwide AC line power source.

# Battery Operation and Maintenance

## BATTERY PAK

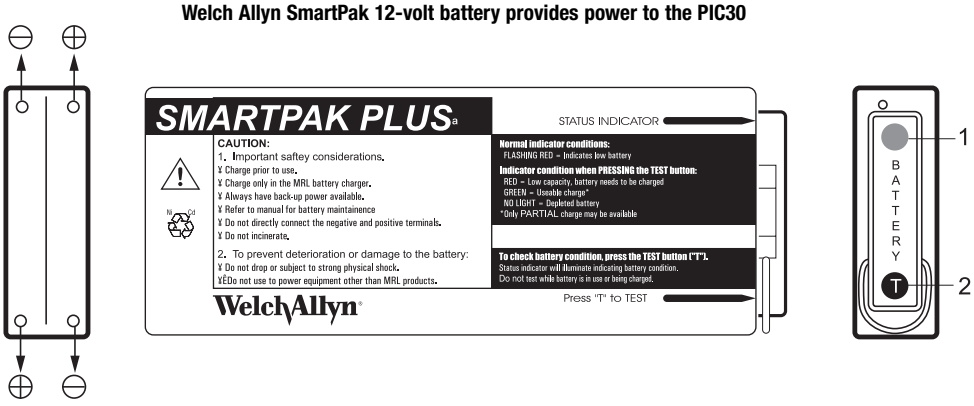
The battery pak should be inserted in the PIC30 at all times. This will allow for the battery to be charged whenever the AC line power cord is plugged in.

***Note: It is recommended that a fully charged battery be inserted in the PIC30 when operating on AC line power.***

***NOTICE: If the battery pack is removed for any reason, labeling of the PIC30 is required indicating out-of-service for battery operation.***

**Welch Allyn SmartPak 12-volt battery provides power to the PIC30**

**Multiple paired contacts: Four contacts ensure swift, error-free battery insertion and backup reliability.**




## WELCH ALLYN SUPERPAC BATTERY

The Welch Allyn SuperPac™ battery is a nickel metal hydride (NiMH) battery. NiMH batteries are less suseptible to the memory effect associated with NiCd batteries. It weighs only a few ounces more than the SmartPak yet provides twice the capacity. There are no light indicators as on the SmartPak batteries due to space limitations inside the battery case. Therefore, use the battery status icon on the display to determine battery charge status.


## UNDERSTANDING BATTERY CAPACITIES

Each new battery is capable of 2 hours of monitoring or 40 - 360J shocks. Over time and use the capacity of batteries will degrade. Thus it is important to properly maintain your battery to maximize the battery's capacity throughout its life. The amount of capacity degradation varies from battery to battery due to the conditions in which the batteries are used and maintained. It is recommended that all batteries be replaced every 24 months.

## CHARGING THE BATTERY

### Paddle Holder/Charger

The PIC30 charger is built into the the optional paddle holder area of the unit. When installed, the charger will charge a battery that is inserted into the PIC30 whenever the AC line power cord is connected to an outlet or the battery can be charged in the quick charger. The yellow "charge" light on the paddle holder is illuminated continuously to indicate that a battery is charging. The yellow light will flash whenthe battery is fully charged.

### Welch Allyn Quick Charger/Conditioner

The Welch Allyn Quick Charger/Conditioner is able to charge three standard Welch Allyn battery packs simultaneously in approximately 4 hours.

1. To initiate a battery pack charge cycle, insert the Welch Allyn battery into any of the three numbered slots in the front of the charger. When the battery has been firmly seated into the contacts at the back of the slot, the yellow light behind the slot will illuminate, indicating that the battery is being charged. This light will remain on for the duration of the charging cycle. When the battery is fully charged, the yellow light will flash to indicate it is ready for use.

2. A completely discharged battery pack will require approximately 4 hours or less to recharge and a WelchAllyn SuperPac requires approximately 8 - 10 hours. Charging time varies depending on battery capacity and state of charge. Deeply discharged batteries and those with higher capacity will take longer to charge; partially discharged batteries and those with lower capacity will require less time to charge.

***Note: Charging battery packs at temperatures above 30˚ C (86˚ F) will prolong the charging time and may result in a gradual decline in battery capacity.***

3. If a fully charged battery is inserted into the charger, it will be charged for a short period of time while the charger determines its state of charge. When it is determined that the battery is fully charged, the yellow light will begin to flash. This process may take several minutes.

4. Welch Allyn SmartPak contain NiCad batteries, which tend to lose charge capacity if they are repeatedly charged after not being fully discharged or are charged at high temperatures. In order to counteract these cumulative deteriorating effects, it is recommended that you periodically exercise the SmartPak by deeply discharging it in the Reconditioning Slot (Slot #3) before recharging. See reconditioning schedule later in this chapter.

5. Slot #3 on the Welch Allyn Battery Charger has dual charging and reconditioning capabilities. To use slot #3 only to charge a battery pack, follow the directions above.

### Conditioning Battery Packs with the Welch Allyn Quick Charger/Conditioner

(Important)

To initiate a battery conditioning cycle:

1. Insert the battery into slot #3.
2. Press the red push-button switch on the top of the charger behind slot #3.
3. The red reconditioning light next to the push-button will light, indicating that the battery pack is being exercised.

At the end of the exercise period the charger will automatically begin a normal charge cycle and will illuminate the yellow battery light indicating that the battery is charging. When the yellow battery light begins to flash, the conditioning cycle is complete. The red conditioning light will remain on until the battery is removed to serve as a reminder

that the battery has been exercised. If an additional conditioning cycle is desired, press the push-button again. Allow the battery to remain in the charger until the yellow battery light begins to flash again.

The time required for the discharge cycle to be completed varies depending on battery capacity and state of charge. A fully charged battery with normal capacity will require approximately 8 hours to discharge in the reconditioning slot and a high capacity battery will require 18 hours. Partially discharged batteries will require less time. After the discharge portion of the reconditioning cycle has been completed, the battery pack will undergo a normal charging cycle.

## BATTERY TESTS

It is important to test the batteries every 90 days to determine battery capacity for monitoring. This will help you approximate the amount of time available for monitoring when the battery icon is displayed.

## ICONS

When the PIC30 is operating from battery power only, a battery icon will be displayed on the unit to give a rough estimate of the remaining capacity of the battery.


**Aux Power:**
This icon will appear whenever the PIC30 is operating from AC line power.


**Battery:**
This icon will appear whenever the AC line power is disconnected and the PIC30 is running from the battery.

***Note: The battery icon gives the operator a rough estimate of remaining battery capacity of an inserted battery. Through proper maintenance of the battery you can determine approximately the capacity of your battery throughout the battery's life. Thus, when the icon is displayed at 50% full you can roughly determine, based on your most recent maintenance test, how much actual capacity is remaining in the battery.***

## CHARGER AND BATTERY CARE

To achieve optimum performance from your PIC30 battery packs:

- Charge battery packs in a moderately cool environment, 5˚ to 30 °C (41˚ to 86˚F). All NiCad batteries are adversely affected by charging at extreme temperatures and will exhibit a significant decline in useful operating time if charged at temperatures above 35°C (95°F) or below 0°C (32°F).
- Perform periodic conditioning cycles on battery packs.

# Chapter 10 *Troubleshooting*

Troubleshooting Basic Unit Problems . . . . . 10.2
Troubleshooting Trace Problems . . . . . 10.3
Recognizing and Reducing ECG Artifacts . . . . . 10.4

# Troubleshooting Basic Unit Problems

| PROBLEM | PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|---|
| Unit will not turn on | -AC line power cord is disconnected.<br>-Battery is depleted or defective. | - Check power cord and AC PWR Light.<br>- Replace Battery. |
| Display quality is poor | -Brightness and contrast controls need to be adjusted. | - Adjust brightness and contrast using front panel controls. |
| Defibrillator won't charge ("CONNECT PADDLES" message is displayed.) | -Paddle set is not connected to the unit. | - Make sure paddle connector is properly seated. |
| Defibrillator energy select switch does not respond when pressed. | -Paddle set is not connected to the unit. | - Make sure paddle connector is properly seated. |
| AC power indicator does not illuminate. | -Bad line power (wall outlet)<br>-Failed power supply | - Plug unit into different wall outlet.<br>- Contact qualified service provider. |
| Battery icon is displayed when AC line power cord is connected. | -Bad line power (wall outlet)<br>-Failed power supply | - Plug unit into different wall outlet.<br>- Contact qualified service provider. |
| Charge light does not illuminate when AC line power is connected. | -Battery missing or not properly seated.<br>-Auxiliary power cable from paddle tray is not connected.<br>-Failed charger. | - Make sure battery is properly seated.<br>- Connect Aux power cable.<br>- Contact qualified service provider. |
| Chart recorder icon is flashing. | -No chart paper.<br>-Paper jam.<br>-Chart recorder door is open. | - Replace chart paper.<br>- Open door and clear paper jam.<br>- Close chart recorder. |
| Pacer does not turn on. | -Hands-free pad set not connected to unit.<br>-Lead select set to PADS.<br>-ECG or PADS lead fault.<br>-Pacing option not installed in unit. | - Make sure hands-free connector is properly seated.<br>- Set lead select to leads I, II, or III.<br>- Check pads and ECG electrodes. |

# Troubleshooting Trace Problems

| PROBLEM | PROBABLE CAUSE | CORRECTIVE ACTION |
|---|---|---|
| "LEAD FAULT" and dashed lines displayed. | - Patient cable not properly connected to unit. | - Make sure patient cable is properly connected. |
| "LEAD FAULT" and dashed lines displayed for one or more leads. All others are OK. | - Lead wire(s) disconnected from patient.<br>- Damaged lead wire(s). | - Check electrodes and leads.<br>- Replace the patient cable. |
| Baseline is drifting in waveform for one or more leads. | - Poor patient preparation.<br>- Use of dissimilar sensors or sensors not recommended for use with PIC30.<br>- Poor sensor contact with skin. | - Refer to instructions for patient prep in section 4.<br>- Only use electrodes recommended for use with the PIC30.<br>- Refer to instructions on page 4.3 |
| Trace is “noisy.” The waveform is not a single, clean line. | - AC interference from lighting, cables, or equipment near patient.<br>- Improper line filter setting | - Re-position ECG cables.<br>- Check line filter setting in the SETUP/ECG CONFIG menu. |
| Occasional noise or artifact in the waveform for one or more leads. | - Patient movement.<br>- Muscle tremor noise.<br>- Improperly applied sensors.<br>- Electrical interference.<br>- Poor sensor contact with skin.<br>- Ineffective baseline filter setting. | - Refer to instructions for monitoring ECG in sections 4 and 5. |

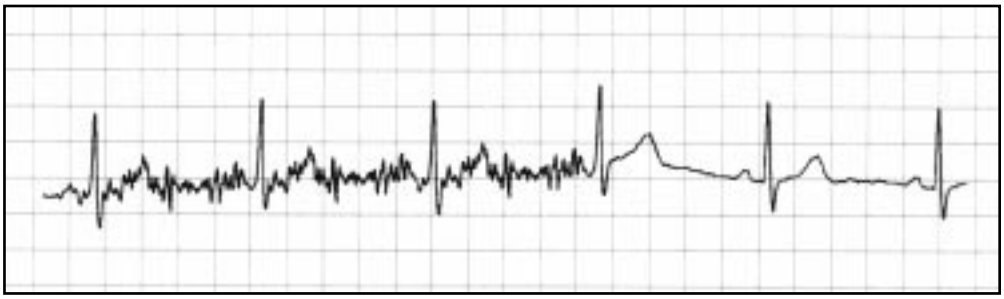
# Recognizing and Reducing ECG Artifacts

### Rapid, large and erratic defections

A broken wire in the patient lead or a poorly applied sensor may cause rapid, large and erratic trace deflections.

### Irregular frequency or amplitude

Patient movement and muscle tremor may result in abnormal traces. Attempt to gain the patient's cooperation in staying very relaxed and still. Sometimes, somatic tremor is unavoidable but its effects may be minimized by having the patient place his/her hands under the buttocks.

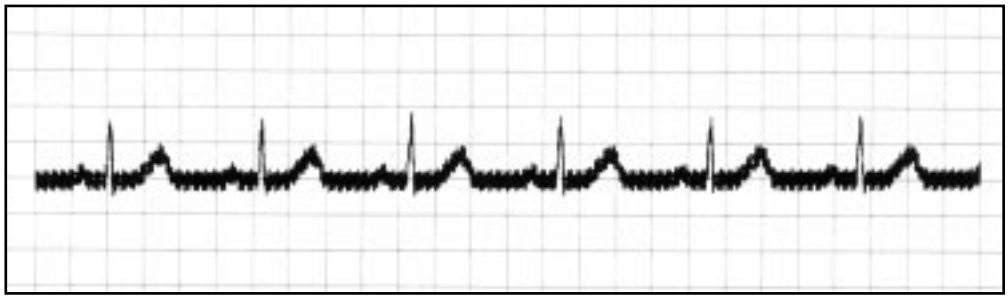


### Baseline wander

Poorly affixed sensors may cause the baseline to wander. Normally, the baseline will stabilize within a few seconds. If the baseline shifts up and down, it may be due to the patient's breathing or to loose or corroded sensors.

### Wide baseline

Electrical interference may produce a wide baseline. Its amplitude depends on the strength of the current source and the lead being recorded. In any one lead, the amplitude of the interfering signal is uniform.



**To reduce electrical interference:**

- Keep the power cord away from the patient and patient cable.
- Connect the unit to a properly grounded wall outlet.
- Arrange the patient cable leads together, closely following the body contour.
- Ensure X-ray equipment in adjacent rooms is not operating. Other electrical equipment including electrical beds and lighting fixtures may also generate interference (even when not in use).
- Try moving the patient to another place in the room. Sometimes, electrical wiring in walls and ceilings causes interference.

# Chapter 11 *Maintenance and Service*

Testing Equipment . . . . . 11.2
Inspecting for Damage . . . . . 11.4
Functional Tests . . . . . 11.5
Cleaning and Disinfecting the PIC30 . . . . . 11.9

# Testing Equipment

The Welch Allyn PIC30 performs a computer self-test every time it is powered up. Complete safety and component checks should be performed at least annually by a qualified service technician.

## DAILY/SHIFT CHECK PROCEDURE

To insure the readiness and optimum working condition of the PIC30, the following inspections and tests should be performed daily or at each shift change. **In addition to daily, monthly, three-month tests, it is recommended that Welch Allyn performance verification procedure be completed by a qualified Biomedical Equipment Technician (BMET) every year or according to local requirements.**

### FDA Checklist

An important part of a successful maintenance program is the creation of a maintenance log in which information is recorded on a regular basis. This allows for verification of necessary maintenance and for scheduling periodic requirements such as calibration and certification. Additionally, the log can be used to track the age of accessories such as batteries, which require periodic testing and replacement.

In accordance with the recommendations of the Defibrillator Working Group of the Food and Drug Administration, Welch Allyn has provided an operator's shift check list, which can be copied for use as needed (see page 11.8).

### Visual Inspection:

1. Inspect the PIC30's Performance Calibration Log (located on the bottom of the unit to insure that a PM/Calibration has been performed within one year.
2. Visually inspect the AC power cord, ECG patient cable, hands-free and/or paddles adapter for signs of wear or damage. Replace if damaged.
3. Locate and inspect the batteries, monitoring electrodes, multipurpose electrodes and paddle gel and ensure they are within the expiration date stamped on the package.
4. **Verify that a charged battery has been fully inserted into the battery compartment of the PIC30.**
5. Inspect the PIC30 to insure it is clean, that no liquid has been spilled on the device and that it has not been damaged.
6. Inspect the chart recorder to insure there is an adequate amount of chart paper.
7. Perform the functional tests as described on the following pages.

## TESTING THE PATIENT CABLE

If the patient cable appears damaged in any way, contact your local representative for replacement.

- Visually inspect the cable for cracks, stress marks and broken or bent pins.
- Connect the patient cable to the PIC30 and attach each sensor lead to an electronic heart signal simulator such as the 3LD Simulator (P/N 980139). (If a simulator is not available, a test subject may be used.)
- Check the signal transmission through the cable by flexing the cable and electrode lead wires and observing the ECG rhythm for irregular tracings.

  ***Note: If using a test subject, be sure not to disturb the sensor site since common baseline artifact will occur. This should not be confused as a broken wire.***

## BATTERY TESTS AND RECONDITIONING

It is important to test the batteries every 90 days to determine battery capacity for monitoring. If batteries are charged in a high temperature environment (above 30°C, 80°F) or normally encounter more than one charge/discharge cycle per day, recondition battery packs once every 30 days. This test will help you approximate the amount of time available for monitoring when the battery icon is displayed. Because this test completely drains the battery, it also serves as an important reconditioning cycle that will help ensure maximum capacity.

| Battery Type | SmartPak | SmartPak Plus | SuperPac |
|---|---|---|---|
| Minimum Time (hours) | 2 | 2.5 | 5 |

**Capacity test (perform test with a fully charged battery)**

1. Disconnect the unit from AC power
2. Turn on the monitor and note the starting time.
3. Verify continued operation every 30 minutes or less.
4. When the battery runs out, note the time. This will give you a duration of time that relates to the current battery capacity. Compare this run time to the value given in the table above that corresponds to the battery type being used.

**Acceptable Results**

Battery run time must meet or exceed the minimum time given table above.

Recharge the battery, connect AC power and allow the battery to fully charge or insert the battery in the Welch Allyn Quick Charger.

**Corrective Action**

If the operating time is less than the specified time above, repeat the test to determine if reconditioning was effective. If the operating time remains short, remove the battery from service and replace it.

Verify that the battery is fully charged and the correct battery type has been selected on the table above prior to the capacity test.

Consider the age of the battery and the frequency of its use. The recommended replacement interval, in this critical application is every 2 years as indicated on the battery label.

**Due to the critical nature of battery packs, replacement of the battery is recommended every 24 months. Do not use the battery after the "Do Not use after:_____" date labeled on the battery pack.**

## DEFIBRILLATOR TESTING

The PIC30 paddle holder and the Welch Allyn Quick Charger contain a defibrillator testers for verifying the operation of the PIC30 defibrillator.

**WARNING: Hazardous high voltage is present when the defibrillator is discharged during this test. Observe safety precautions regarding the use of a defibrillator.**

**To test the defibrillator:**

1. Charge the defibrillator to 200 Joules.
2. Place the defibrillator paddles in the Paddle Holder tray or apply the defibrillation paddles to the test contacts on the Welch Allyn Quick Charger/Conditioner.
3. Discharge the defibrillator into the paddle tray.
4. The defibrillator test light at the back of the charger should flash indicating that the defibrillator has delivered 180 Joules or greater.
5. Verify that the delivered energy displayed on the defibrillator screen is 200± 10%.

***Note: Periodically test your defibrillator with a calibrated defibrillator tester to verify the accuracy of its energy output.***

# Inspecting for Damage

**WARNING: Hazardous voltage. To reduce the risk of electrical shock, do not attempt to remove the cover under any circumstances. Refer servicing to a qualified technician.**

Before every use, check the power cord, power plug, power connector, and power input jack for signs of damage.

**Contact an authorized service agent immediately if:**

- The equipment falls from a cart or is subject to some other extreme mechanical stress.
- Liquid is spilled on the equipment
- The equipment is not functioning properly
- Any connector or cord shows signs of deterioration such as cracking.

# Functional Tests

**POWER SYSTEM:**

| Function | Response |
|---|---|
| 1. Verify that the AC power cord is firmly connected to the paddle tray or the Welch Allyn Quick Charger with the AC cord holder, and that the power cord is connected to the appropriate outlet. | Green AC PWR light on the PIC30 paddle tray or on the Welch Allyn Quick Charger is illuminated. |
| 2. Insert a battery in the unit and check for battery charging indicator. | The Batt Charger light will illuminate if a battery is inserted in the PIC30. The light illuminates steadily if battery is charging. It should begin to blink when battery is charged. |
| 3. Press the system POWER switch on. | The PIC30 will perform a number of self-tests and print out the results (pass or fail) on the chart recorder.<br>Verify that the AUX power icon is displayed in the Message window. |
| 4. With no patient cable attached to the PIC30, press the LEAD Selector button to select Lead I, II or III. | Verify that a lead fault message is displayed in the waveform window. |
| 5. Press the LEAD Selector button to select PDL (paddles). | Verify that a lead fault message is displayed in the waveform window. |
| 6. Apply the paddles to the test contacts on the paddle tray or Welch Allyn Quick Charger. | Verify that the lead fault message disappears from the waveform window and that the trace is in the center of the waveform window. |
| 7. Press the up or down ENERGY select arrow to select 200 Joules on the defibrillator. | Verify that the energy graph is displayed on the right side of the display and that 200J has been selected. |
| 8. Press the CHARGE button on the front panel or on the deluxe apex paddle | Verify that the energy graph highlights as it charges up to 200J. A periodic tone will sound while the defibrillator is charging. At the completion of the charge cycle, the tone will be constant and the energy graph will fill up to and include 200J. The charge time should be less than 7 seconds for SmartPak batteries, 9 seconds for SuperPac batteries, or 15 seconds if no battery is installed. |

**WARNING: Keep hands and fingers away from paddle electrodes.**

| | |
|---|---|
| 9. Ensuring the paddles are properly applied to the test contacts, press only the sternum paddle SHOCK button and release. Then press only the apex paddle SHOCK button and release. | The defibrillator should not discharge. |
| 10. Press both the sternum and apex paddle SHOCK buttons. Return the paddles to their holder. | The defibrillator should discharge and the defibrillator test light on the top of the paddle tray must flash indicating defibrillator discharge. Verify that the Del. Energy in the Defib window is between 180 J and 220 J. |
| 11. Press the SYNC button. | The Defib window should indicate Sync and the Sync Indicator light should illuminate. |
| 12. Press the CHARGE button on the front panel. Apply the paddles to the test contacts on the paddle tray or Welch Allyn Quick Charger. | Verify that the energy graph highlights as it charges up to 200J. A periodic tone will sound while the defibrillator is charging. At the completion of the charge cycle, the tone will be constant and the energy graph will fill up to and include 200J. |
| 13. Ensuring that the paddles are properly applied to the test contacts, press both the sternum and apex paddle discharge buttons. | The defibrillator should not discharge. |
| 14. Press the DISARM button on the front panel. | The defibrillator should discharge internally and the charge done tone and graph will disappear. |
| **Pacer Test (Optional) steps 15 - 21** | |
| 15. Remove the paddles from the PIC30 and connect the hands-free adapter to the defibrillator. Connect the 3LD Simulator (P/N 980139) to the patient end of the hands-free adapter. | "Connect Paddles" message should appear in the defibrillation window when the paddles have been removed. The "Connect Paddles"message should disappear when the hands-free adapter has been installed. |

| | |
|---|---|
| 16. Press LEAD select button until PAD is selected. | The lead fault message should disappear. |
| 17. Press PACER button. | The Pace indicator should illuminate red and "Pacer Fault, Set Lead to I, II, III" should be displayed in the Pacer window. |
| 18. Connect ECG patient cable to the PIC30 and to the 3LD Simulator (P/N 980139). Press the LEAD button to select lead I. | An ECG trace should appear in the ECG window. In the Pacer window, "Pacer Stop" should appear with the default pacing parameter (ie. rate and output setting). |
| 19. Press pacer Start/Stop button on the pacer controls. | The pacer window will indicate pacing. The pacer indicator light will illuminate green and flash to verify output. |
| 20. While the pacer is pacing, disconnect the patient cable from the PIC30. | The pacer window should indicate "Pacer Fault, ECG Lead Fault," also "Lead Fault" should appear in the ECG window. The pacer indicator lights red indicating the fault condition and that the pacing output has been suspended. |
| 21. Press PACER button. | Pacer indicator light should turn off and pace window should be blank. |
| 22. Press the Print button until the header and footer are printed out completely. | Verify that the date and time are properly set. |
| 23. Press the NEXT button on the treatment summary menu. Then press Recorder and Log. | The Log menu should appear next to the quick access buttons. |
| 24. Press CLEAR LOG button to erase the log. | Clearing event storage will be printed to confirm clear. |
| 25. Turn the PIC30 off. | |

# MANUAL DEFIBRILLATORS: OPERATORS SHIFT CHECKLIST

Date: _____ Shift: _____ Location: _____

Mfr/Model No.: _____ Serial No. or Facility ID No.: _____

At the beginning of each shift, inspect the unit. Indicate whether all requirements have been met.
Note any corrective actions taken. Sign the form.

| | Okay as found | Corrective Action/Remarks |
|---|---|---|
| **1. Defibrillator Unit** | | |
| Clean, no spills, clear of objects on top, casing intact | | |
| **2. Paddles (including pediatric adapters)** | | |
| a. Clean, not pitted<br>b. Release from housing easily<br>c. If internal paddles are included, verify their availability in a sterile package. Periodically inspect as with external paddles. | | |
| **3. Cables/Connectors** | | |
| a. Inspect for cracks, broken wire or damage<br>b. Connectors engage securely | | |
| **4. Supplies** | | |
| *a. Two sets of pads in sealed packages within expiration date<br>b. Monitoring electrodes<br>c. Alcohol wipes<br>d. Hand towels<br>e. Scissors<br>f. Razor<br>g. Spare ECG paper<br>*h. Spare charged battery available<br>*i. Cassette tape<br>*j. Gel or other conductive medium present and stored properly | | |
| **5. Power Supply** | | |
| a. Battery-powered units<br>(1) Verify fully charged battery in place<br>(2) Spare charged battery available<br>(3) Follow appropriate battery rotation schedule per manufacturer's recommendations<br>b. AC/Battery backup units<br>(1) Plugged into live outlet and maintain battery charge<br>(2) Test on battery power and reconnect to line power | | |
| **6. Indicators/ECG Display** | | |
| a. Power-On display<br>*b. Self-test OK<br>c. Monitor display functional<br>*d. "Service" message display off<br>*e. Battery charging; low battery light off<br>*f. Correct time display-set with dispatch center | | |
| **7. ECG Recorder** | | |
| a. Adequate ECG paper b. Recorder prints | | |
| **8. Charge/Display Cycle for Paddle or Adhesive Pad Defibrillation** | | |
| a. Disconnect AC plug-battery backup units<br>b. Charge to manufacturer's recommended test energy level<br>c. Charge indicators working<br>d. Discharge per manufacturer's instructions<br>e. Reconnect line power | | |
| **9. Pacemaker*** | | |
| *a. Pacer output cable intact<br>*b. Pacer pads present (set of two)<br>*c. Inspect per manufacturer's operational guidelines | | |
| _____ **Major problem(s) identified (OUT OF SERVICE)** | | |

* Applicable only if the unit has this supply or capability

Signature: _____

# Cleaning and Disinfecting the PIC30

Clean and disinfect the unit any time it is deemed necessary.

## THE ENCLOSURE

**Use only the recommended cleaning agents listed below:**

- Warm water
- Hydrogen peroxide solution
- Coverage
- Liquid soap
- Wex-cide®
- Formula 409®
- Fantastik®
- Windex®
- T.B.Q.®
- INCIDIN®

**Never use these cleaning agents**

- Butyl alcohol
- Denatured ethanol
- Freon
- Mild chlorine bleach solution
- Isopropyl alcohol
- Trichloroethane, trichloroethylene
- Acetone
- Vesphene II
- Enviroquat
- Staphene
- Misty
- Glutaraldehyde
- Ether
- Benzene

## CLEANING

Apply the cleaning solution to a clean, soft cloth and gently rub the outer enclosure.

***CAUTION: Do not immerse the PIC30 or apply liquids directly to the device.***
***Note: Do not use cleaners which contain ammonia to clean the display.***

**Disinfection**

Gently rub the housing with INCIDIN or similar product.

## THE PATIENT CABLE, PADDLE SETS, AND REUSABLE SENSORS

NEVER immerse cables in fluid, or use hot sterilization. Do not use ether. Do not use bleach, acetone or similar harsh chemicals or solvents.

**Cleaning and disinfection**

Rub with a clean cloth moistened with any of the recommended cleaning agents listed above.

# Chapter 12 *Specifications*

**General:**

Weight: . . . . . .13.5 lbs (6 kg) (excluding battery)

Size: . . . . . .16.7 x 12.5 x 5.3 inches (424 x 318 x 135 mm.)

**Environmental:**

Operating Temperature*: . . . . . 0 to 45˚C

Storage Temperature: . . . . . .-30 to 70˚C

Humidity *(Non-condensing): . . . . . 15 to 95% RH

Vibration *: . . . . . MIL - STD 810E

Shock/Drop *: . . . . . MIL - STD 810E

Enclosure Protection*: . . . . . .Solid Foreign Object: IEC 529, IP2X
Water: IEC 529, IPX4.

Atmospheric Pressure: . . . . . .15,000 Ft Altitude

*Tests performed per AAMI DF-2 Defibrillation Standard.

**Defibrillator:**

Waveform: . . . . . .Precise Trapezoidal (per AAMI Standard for Truncated Exponential Waveforms).

Waveform Details:

Peak current ($I_p$) and duration (t) at 360 Joules delivered energy.
(The values shown are within 10%)

| Load (Ohms) | $I_p$ (Amps) | t (ms) |
|---|---|---|
| 25 | 53.1 | 10.0 |
| 50 | 27.1 | 18.8 |
| 100 | 13.7 | 36.4 |

Waveform: . . . . . Truncated Exponential Biphasic (where available).

Waveform Details: 2 - 360 joules

| Patient Resistance | Phase 1 Duration (ms) | | Phase 2 Duration (ms) | | Tilt (%) | |
|---|---|---|---|---|---|---|
| | Min | Max | Min | Max | Min | Max |
| 25 | 5.1 | 6 | 3.2 | 4.6 | 74.8 | 82.9 |
| 50 | 6.8 | 7.9 | 4.9 | 5.6 | 63.9 | 71 |
| 100 | 8.6 | 10.6 | 5.8 | 7.1 | 50.7 | 56.5 |
| 125 | 9.5 | 11.2 | 6.3 | 7.4 | 46.3 | 51.6 |

Energy Select: . . . . . .2, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, 360 J.

Charge Time: . . . . . .< 7 seconds @ 360 J (with a SmartPak Plus battery after 15 discharges).
< 9 seconds @ 360 J (with a SuperPac battery after 15 discharges).
< 15 seconds @ 360 J (AC power @ 90% voltage or battery power after 15 max. energy discharge)

Charge Indicator: . . . . . .Audible and graphic. Periodic tone while charging, continuous tone while charged.

Output: . . . . . .Adult paddles, internal paddles, pediatric adapter and multipurpose hands-free adapter available.

Synchronizer: . . . . . .Delivers energy within 60 msec of R-wave detection.

Disarm: . . . . . .Front panel switch or auto after 60 seconds. Indication: Charged tone pitch increases with 10 seconds remaining, then stops on disarm.

Tester (optional): . . . . . .Integrated defibrillator tester in paddle tray verifies defibrillator output ≥200J.

**Applicable Performance Standards:**
AAMI EC13, AAMI DF2, AAMI ES1
EN 60601-2-27, EN 60601-1-2, EN 60601-1-4
UL 544
CSA 22.2, No. 125
ISTA-1A

**Monitor / Display:**

Input: . . . . . .3-lead or 5-lead patient cable, paddles, or multipurpose hands-free adapter.

Size: . . . . . .6.4 inch (16.2 cm) diagonal, non-fade.

Type: . . . . . .Color (TFT) or Monochrome LCD.

Resolution: . . . . . .640 x 480 pixels.

Sweep Speed: . . . . . .25 mm / sec.

Lead Selections: . . . . . .Paddles (Pads), I, II, III, AVR, AVL, AVF, V.

Frequency Response: . . . . . .(User-selectable).

| | |
|---|---|
| 2 to 20 Hz | Limited mode |
| 0.5 to 40 Hz | Monitor mode |
| 0.05 to 150 Hz | Diagnostic mode |

(automatically sets chart recorder response)

Common Mode Rejection: . . . . . .Complies with AAMI EC13-1992 section 3.2.9.10.

Tall T-Wave Rejection: . . . . . .Meets AAMI EC13-1992, section 3.1.2.1c for 1.2 mV T-wave (1.0 mV with diagnostic response) and 1mV QRS.

Diagnostic Signals Applied to Patient Connections: . . . . . .Leads off / active noise suppression sensing circuit is < 0.1uA DC. The impedance detector signal frequency is 45±4kHz at 78uA RMS (117mV RMS into an impedance of 1.5k) pseudo-sinewave.

Heart Rate Meter: . . . . . .20 to 300 BPM. Complies with AAMI EC 13-1992 sections 3.2.6 & 3.2.7.

Heart Rate Alarms: . . . . . .User-selectable (Low range: 20 - 120 BPM. High range: 60 - 300 BPM), or automatic based on heart rate at time of setting.

Size: . . . . . .0.125, 0.25, 0.5, 1, 2, 4 cm/mV and auto-ranging.

Aspect Ratio: . . . . . .0.05, 0.1, 0.4, 0.8, 1.6 per AAMI EC-13-1992 section 3.2.9.1f.

Heart Rate Meter Response Time: . . .Responds to a 40 BPM step increase in heart rate in 2 to 4.5 seconds per AAMI EC-13-1992, section 3.1.2.1.f. Responds to a 40 BPM step decrease in 1.4 to 3.9 seconds per AAMI EC-13-1992, section 3.1.2.1.f. Response times include a 2.5-second display update interval.

Heart Rate Response to Irregular Rhythm: . . . . . .Complies with AAMI EC13-1992, section 3.1.2.1.e.

Ventricular Bigeminy: . . . . . .80 BPM (expected)

Slow Alternating Ventricular Bigeminy: . . . . . .60 BPM (expected)

Rapid Alternating Ventricular Bigeminy: . . . . . .120 BPM (expected)
Bidirectional Systole: 45 BPM (expected)

Tachycardia Response Time: . . . . . .Response time to tachycardia alarm is on average 3.43 seconds (with a range of 1.15 to 10.69 seconds) per AAMI EC-13-1992, section 3.1.2.1.g. Response times include a 2.5-second display update interval.

**Alarms:**

Heart Rate Alarm: . . . . . .Audible: 5 pulse, 2 frequency 800 - 400 Hz alternating tone, with a PW of 200 msec, a PRI of 400 msec, and a repetition interval of 3 seconds.

Visual: . . . . . .Heart Rate Alarm causes the displayed heart rate to flash at 2 Hz. This 1 cm display is located at the top of the display and is .4" high and .28 to .840" (0.7 TO 2 cm) wide depending on number of digits in the heart rate. Color is black on white.

Lead Fault Alarm: . . . . . .Audible: 3 pulse, 500 Hz, triplet tone with a PW of 300 msec, a PRI of 600 msec. When the HR alarm is set or the pacer is on, the lead fault tone repeats at a repetition interval of 6 seconds.

Visual: . . . . . .Lead Fault condition causes a "LEAD FAULT" message to be displayed on the trace along with a dashed line the width of the trace. The text is .18" (0.46 cm) high and is the color of the display text. The dashed line is 5" (12 cm) long, the width of the display. The signal is not modulated.

Mute Duration: . . . . . .90 seconds.

Enable/Disable: . . . . . .Global alarm disable via 2-step Quick Access icon controls, or individual High/Low limit disable via configuration menus.

**Recorder:**

Type: . . . . . .High-resolution thermal array (800dpi [31.5 dpmm) Horizontal, 244 dpi [9.6 dpmm] Vertical).

Annotation: . . . . . .Time, date, ECG lead, ECG gain, heart rate, defibrillation and pacing parameters and event type.

Paper Width: . . . . . .50 mm.

Paper Speed: . . . . . .25 mm/sec.

Delay: . . . . . .6 seconds.

Frequency Response: . . . . . .Automatically set to monitor's frequency response.

Event Log: . . . . . .Records defibrillation, pacing, and status events. Automatically logs into memory the type of event, time and ECG sample.

Event Log Capacity: . . . . . .28 ECG events or 300 non-ECG events .

Recorder Modes: . . . . . .Manual and automatic

Grid: . . . . . .User selectable Grid On/Off

**Power:**

Mains (Line) Voltage: . . . . . .100 to 240 VAC ± 10% (auto ranging) .

Mains (Line) Frequency: . . . . . .50 to 60 Hz ± 5 %

AC Power Consumption: . . . . . .Monitoring Only: 12W (typical ), Maximum: 190W

**Battery:**

Type: . . . . . .User-replaceable Nicad 12 volt., SmartPak, SmartPak+ or SuperPac.

Low Battery Indicator: . . . . . .Audible tone, chart printout (if automatic printing enabled), and low-battery icon on display. Audible tone repeats every 2 minutes. Audible tone and flashing low battery icon on display 1 minute before shutdown.

Multiple Paired Contacts: . . . . . .Insures quick, error-free insertion and backup reliability.

Recharge Rate: . . . . . .<3 hours to 80%; <4 hours to 100% for SmartPak.

3.5 hours to 80%; 4.5 hours to 100% for SmartPak+.

7.5 hours to 80%; 9.5 hours to 100% for SuperPac.

Run Time on Battery Power: . . . . . .2 Hours monitoring only, for SmartPak.

2.5 Hours monitoring only, for SmartPak+

5 Hours monitoring only, for SuperPac.

Full Energy Shocks: . . . . . .> 40 @360J for SmartPak

>60 @360J for SmartPak+

>110 @360J for SuperPac

Battery Life: . . . . . .2 years

Data Retention Battery: . . . . . .3V Lithium

Data Retention Battery Life: . . . . . .5 Years

**Pacer (Optional):**

Type: . . . . . .External transcutaneous pacing.

Pacer Rate: . . . . . .30 to 180 BPM ± 5% .

Output Current: . . . . . .30 to 180 mA ± (10% or 5 mA whichever is greater).

Modes: . . . . . .Demand or Asynchronous.

Status Indicators: . . . . . .ECG lead fault, pace lead fault, pace marker on monitor and chart, start/stop LED

Pulse Type: . . . . . .Rectangular, constant current.

Pulse Width: . . . . . .20 ms.

Refractory Period: . . . . . .250ms.

Output Protection: . . . . . .360 Joules.

Option upgrade capability: . . . . . .Unit can be upgraded to add pacing option in the field.

**Advisory Module (Optional)**

Operation: . . . . . .Pushbutton initiates a single ECG analysis cycle. Advises defibrillation on VFIB or shockable VTACH.

Analysis Time: . . . . . .4-16 seconds.

Outputs: . . . . . .Visual Display of Analysis results and prompts.

Prompts: . . . . . ."Analyzing – Stand Back"
"No Shock Advised"
"Shock Advised"
"Motion Detected"
"Lead Fault"
"Attach Defib Pads"

Option upgrade capability: . . . . . .Unit can be upgraded to add an advisory option in the field.

**WELCH ALLYN QUICK CHARGER**

Mains (Line) Voltages: . . . . . .100 to 240 VAC (four user-selectable ranges: 100, 120, 220, 240 VAC)

Mains (Line) Frequency: . . . . . .50 to 60 Hz

AC Power Consumption: . . . . . .50 W-while charging batteries only
70 W-while powering monitor
300 W-while charging defibrillator

Charger Bays: . . . . . .Three (charges three batteries concurrently).

Indicators: . . . . . .Battery Charging/Ready
Reconditioning
Defibrillation Test Indicator
Power On

Reconditioner: . . . . . .Simple, one button operation.

Reconditioning Load: . . . . . .220 mA ± 10% constant.

Recondition Cycle Time: . . . . . .Dependent on battery capacity and state of charge (typically < 12 hours).

External Power Output Voltage: . . . . . .13 Volts ± 0.65 V.

| | |
|---|---|
| Fuse Ratings: | Dual Line Fuses<br>120 VAC-2 Amp SB (Welch Allyn # 500218)<br>220 VAC-1 Amp SB (Welch Allyn # 500241) |
| General Charger: | Operating Temperature: 0 to 45˚C<br>Humidity: 15 to 95%<br>Size: 11.5 x 7.25 x 4.4 inches<br>(29.2 x 18.4 x 11.2 cm) |
| Defibrillator Tester: | Built-in 50 Ohm load. |

### PADDLE HOLDER/CHARGER

| | |
|---|---|
| Mains (Line) Voltage: | 100 to 240 VAC + 10% (autoranging) |
| Mains (Line) Frequency: | 50 to 60 Hz + 5% |
| AC Power Consumption: | 18 W (typical), Maximum 190 W<br>(while charging defib) |

# Summary of Studies of Waveform Safety and Effectiveness

## INTRODUCTION

Over 30 years ago, Medical Research Laboratories (MRL) patented a unique monophasic truncated exponential waveform, which utilized a low peak current, impedance compensated defibrillation waveform. The MRL monophasic waveform was developed as an alternative to the monophasic damped sine (MDS) waveform (often referred to as the Edmark waveform) defibrillator, which was associated with higher peak currents and did not actively compensate for varying patient impedances. In fact, the MRL monophasic waveform defibrillator delivers less than half of the peak current of an MDS waveform defibrillator at equal delivered energies. A new Welch Allyn defibrillator (the Welch Allyn PIC) has been introduced, which offers a biphasic truncated exponential waveform that incorporates MRL's original low peak current, impedance compensation design. The MRL Orbital™ biphasic truncated exponential waveform has been extensively tested in multiple scientific safety and effectiveness studies. Over 524 fibrillation/defibrillation shock episodes have been conducted using the MRL Orbital™ Biphasic waveform comparing it to MDS, MTS and another commercially available 2kV biphasic (360 J capable) defibrillators. Results of three of the scientific safety and effectiveness studies are summarized below.

## STUDY 1

**Objective** - To evaluate the MRL Orbital™ Biphasic waveform defibrillator against a monophasic damped sinusoidal waveform defibrillator.

**Methods** - A canine model (n=5, 71±7 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The external jugular vein was cannulated and a bipolar pacing catheter was introduced under fluoroscopic control and advanced into the right ventricle. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes (R2 part number 3200-1715) were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the right ventricular electrode. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 50 to 70 joules was used. If successful, VF is reinduced after a 4 minute rest period, and the shock strength is reduced by approximately 20% for the next defibrillation attempt. If the initial shock fails, a rescue shock is delivered, and after a rest period, VF is again induced. The energy is now increased about 20% for the next defibrillation attempt. This procedure was continued until at least 3 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested.

**Results** - The study consisted of 82 total fibrillation/defibrillation episodes. ID50 peak currents and ED50 delivered energies are shown below for each group. The mean impedance for these animals was 62 ohms. The mean ED50 energies were compared and

were found to be significantly different. The significance of difference (p-value) was calculated by the Wald test in each case, and are shown below. The mean ED50 peak current for the biphasic waveform was 39 percent of that required with the MDS waveform.

| Summary Table - ED50 & ID50 | | |
|---|---|---|
| Mean | Welch Allyn PIC Biphasic | Monophasic Damped Sine |
| ID50 Peak Current (Amps) | 6.4 | 16.6 |
| Significance of difference (p-value) | <0.001 | |
| ED50 Delivered Energy (Joules) | 26.3 | 35.3 |
| Significane of difference (p-value) | 0.014 | |
| Study 1 | | |

**Conclusion** - The MRL Orbital™ Biphasic waveform is capable of converting fibrillation episodes using less energy than the MDS waveform, and requires lower peak currents than MDS waveform defibrillators.

## STUDY 2

**Objective** - Comparison of the defibrillation effectiveness of the MRL Orbital™ Biphasic waveform defibrillator, with a commercially available Biphasic 2KV defibrillator capable of 360 J and a monophasic truncated exponential defibrillator.

**Methods** - A canine model (n=6, 61.6 ± 5.5 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with an intravenous injection of 20 mg/kg sodium pentothal. They were then intubated with a cuffed endotracheal tube, and maintained on isoflurane gaseous anesthetic. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure, and for acquiring samples for arterial blood gas and electrolyte monitoring. The chest was shaved and adhesive defibrillating electrode pads were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the external electrodes. The ED50 energy (that required to defibrillate with 50% probability) was determined by a protocol modeled after that of Dixon. An initial shock strength of 30 joules was used, which was applied after 15 seconds of ventricular fibrillation (VF). If successful, VF was re-induced after a 4 minute rest period, and the shock strength was reduced by one energy step for the next defibrillation attempt. If the initial shock failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased one energy step for the next defibrillation attempt. This procedure was continued until a nominal sample size of six episodes was achieved (both sides of the first reversal in result, plus 4 episodes). Three ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. After each of the three independent ED50 estimation procedures had been completed, the entire protocol was repeated twice more, each time starting all devices at an energy of 30 joules. The ED50 peak current and energy was then estimated for each animal by logistic regression

analysis. Individual phase durations and overall pulse durations were measured and recorded on each shock.

**Results** - The study consisted of 344 total fibrillation/defibrillation episodes. The mean ED50 and ID50 estimates (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and are shown below. Also shown are the mean total durations measured for each device.

| **Summary Table - ED50 & ID50 & Duration** | | | |
|---|---|---|---|
| Mean | Monophasic Waveform | Welch Allyn PIC Biphasic | 2kV Biphasic Wavform |
| ID50 Peak Current (Amps) | 9.0 | 6.4 | 8.3 |
| Significance of difference (p-value) | <0.001 (PIC vs 2kV Monophasic | | <0.001 (PIC vs 2kV Biphasic |
| ED50 Delivered Energy (Joules) | 40.2 | 21.4 | 22.7 |
| Significane of difference (p-value) | <0.001 (PIC vs 2kV Monophasic) | | <0.4937 (PIC vs 2kV Monophasic) |
| Significane of difference (p-value) | 11.9 | 11.9 | 11.9 |
| Study 2 | | | |

**Conclusion** - The MRL Orbital™ Biphasic waveform was as effective as the Biphasic 2KV waveform, and more effective than the monophasic waveform. While both biphasic waveforms required less peak current than the monophasic waveform, the MRL Orbital™ Biphasic waveform required statistically less peak current than the 2 KV biphasic waveform defibrillator.

## STUDY 3

**Objective** - Comparison of the defibrillation effectiveness of the Welch Allyn Orbital™ Biphasic waveform defibrillator, with a commercially available Biphasic 2KV defibrillator capable of 360 J in a simulated higher impedance model.

**Methods** - A canine model (n=6, 53.7 ± 6.1 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with 20 mpk sodium pentothal i.v., and maintained as required through an intravenous catheter in the foreleg. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure. The chest was shaved and defibrillating patch electrodes were placed on the left and right chest walls.

Fibrillation was induced by delivering 60 Hz current to the chest electrodes. The energy required to defibrillate was determined by a protocol that has been used in several other biphasic comparison studies. An initial shock strength of 70 to 100 joules was used. If successful, VF was re-induced after a 5 minute rest period, and the shock strength was reduced by approximately 20% for the next defibrillation attempt. If the initial shock

failed, a rescue shock was delivered, and after a rest period, VF was again induced. The energy was now increased about 20% for the next defibrillation attempt. This procedure was continued until approximately 4 reversals in result were observed with each waveform. Two ED50 estimation procedures were run in parallel, with the device being used alternated on each shock. In practice, actual clinical units were used, so the energy steps were limited to those selectable on the devices tested. The ED50 peak current and energy was then estimated for each animal by logistic regression analysis.

This study simulated a higher impedance patient by having a 32 ohm resistor placed in series with each subject.

**Results** - The study consisted of 98 total fibrillation/defibrillation episodes. The mean ED50 and ID 50 estimates for peak current and energy for each animal (to one decimal place) are shown below. The significance of difference (p-value) was calculated by the Wald test in each case, and are shown below. Also shown are the mean total durations measured for each device.

| **Summary Table - ED50 & ID50** | | |
|---|---|---|
| Mean | Welch Allyn PIC Biphasic | 2kV Biphasic Waveform |
| ID50 Peak Current (Amps) | 5.8 | 7.4 |
| Significance of difference (p-value) | <0.001 | |
| ED50 Delivered Energy (Joules) | 34.3 | 32.0 |
| Significane of difference (p-value) | 0.885 | |
| Significane of difference (p-value) | 21.3 | 15.6 |
| Study 3 | | |

**Conclusion** - The MRL Orbital™ Biphasic waveform was as effective as the 2KV Biphasic waveform in this model of a higher impedance patient. When these devices are compared on the basis of peak current, the MRL Orbital™ Biphasic required less peak current than the 2KV Biphasic waveform.

## RATIONALE FOR ANIMAL STUDIES

Electrical waveforms for transthoracic ventricular defibrillation have been well studied for nearly 50 years. These studies led to the development of monophasic waveforms such as the Edmark, Lown, and truncated exponential waveforms which have now been used in humans for over 30 years. Starting in the early 1980s, biphasic waveforms have been extensively studied in animal models of transthoracic ventricular defibrillation. These studies have shown that a wide variety of biphasic waveforms exhibited superior defibrillation effectiveness to these conventional monophasic waveforms. In many cases, the waveform comparisons performed in animals were repeated in clinical trials involving humans. These studies have conclusively demonstrated that well-designed animal studies can and do predict the results that will be observed in humans.

The reasons for conducting animal trials (as opposed to additional human clinical studies) are:

1. Animal studies can use a much larger sample size (more shocks per subject), and thus, result in far more accurate comparisons.

2. Animal studies do not place human subjects at risk from additional (and clinically unneeded) shocks.

3. The animal hearts can be inspected for damage after the defibrillation studies.

## WAVEFORM SAFETY AND EFFECTIVENESS CONCLUSIONS:

These scientific studies have demonstrated that:

1. The data suggests that the MRL Orbital™ Biphasic waveform in the Welch Allyn PIC is at least as effective as, and may be more effective than either of the two tested monophasic waveforms, appearing to allow termination of fibrillation episodes using lower energies.

2. The MRL Orbital™ Biphasic waveform in the Welch Allyn PIC is as effective as the 2KV biphasic truncated exponential waveform in another commercially available defibrillator.

3. The MRL Orbital™ Biphasic waveform in the Welch Allyn PIC requires less peak current to achieve defibrillation effectiveness than either of the two monophasic waveforms or the 2KV biphasic truncated exponential waveform that is used in another commercially available defibrillator.