

AED 20™

Automated External Defibrillator



User Manual

Software version 7.09X

WelchAllyn®

Advancing Frontline Care™

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Contents

Preface	v
1 - Safety	1
Conventions Used in the Manual	1
General Cautions and Notices	2
Patient Safety	2
Defibrillator and Electrode Pads	4
Battery Care	5
Care and Storage	6
Electrodes	6
Safety Symbols	6
2 - Introduction	9
Overview	9
Features	9
System Upgrades and Options	9
Qualified Operators	10
Preparing the Defibrillator for Use	10
Getting to Know the Defibrillator	11
Defibrillator Configurations	12
Functions	12
Battery Charging and Conditioning	17
Preparing the Defibrillator for Storage	19
3 - Operation	21
Overview	21
Operating Procedures—Quick Reference	22
Operating Procedures—Detail	23
4 - Programming	35
Menu Structure Diagram	36
Menu Structure Overview	37
Accessing the User Menu from Automated Mode	37
Accessing the User Menu from Manual Mode	37
User Menu	39
Supervisor Menu	46
5 - Maintenance	55
6 - Troubleshooting	65
Frequently Asked Questions	68

A - Glossary	69
B - Specifications	71
AED 20 Pediatric Energy Reducer	73
Display	73
C - Parts List	81
D - Summary Of Studies Of Waveform Safety & Effectiveness	83

Preface



WARNING Do not attempt to use this equipment without thoroughly reading and understanding these instructions.

Medical Device Registration

Welch Allyn and its distributors are required by FDA medical device tracking regulations and other national regulatory authorities to maintain records of end-users that purchase Welch Allyn's defibrillators. Please provide us with the information requested in the device registration card to assist us in complying with the defibrillator tracking requirement and to enable us to contact you promptly in the unlikely event that there is a problem with your defibrillator. If you transfer the defibrillator to another person or company please notify us of the new owner by calling Welch Allyn at 800-289-2501 (toll-free in USA) or 503-530-7500. Likewise, if the defibrillator is retired from use or otherwise permanently disposed of, please call and notify us and provide the date of retirement or disposition.

Manufacturer's Responsibility

Welch Allyn is responsible for the safety, reliability, and performance of the defibrillator only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Welch Allyn.
- The defibrillator is used in accordance with the instructions for use.

User's Responsibility

The user is required to be trained in basic monitoring, vital signs assessment, and emergency cardiac care. The user should be completely knowledgeable of the information in the Directions for Use. As with all other electronic patient care monitors, good clinical judgment should be used when operating the defibrillator. To ensure patient safety and proper operation, use only Welch Allyn-authorized parts and accessories.

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

Contact and Technical Support

Please contact Welch Allyn ([page ii](#)) if you have any questions regarding this notice.

Indemnification Against Defects

Welch Allyn Automated External Defibrillators (AED 20)

US Customers

Welch Allyn provides the following indemnity to persons or legal entities (the Purchaser) that originally purchase or lease a Welch Allyn AED 20 from Welch Allyn or an authorized distributor appointed by Welch Allyn.

Welch Allyn will, at its cost, defend, indemnify, and hold harmless the Purchaser from third-party claims or legal actions for liability or damages resulting from bodily injury or death caused by a mechanical or electrical failure of the Purchaser's Welch Allyn AED 20 or the malfunction of the Purchaser's Welch Allyn AED 20 due to a defect in its design or manufacture.

This indemnity does not extend to or cover any claim or legal action for liability or damages in connection with the use of the Purchaser's Welch Allyn AED 20 to the extent caused by: 1) negligent operation of the Welch Allyn AED 20, or failure to follow the sequential operating instructions for use of the Welch Allyn AED 20, or 2) failures or malfunctions of the Welch Allyn AED 20 that are due to improper maintenance, including without limitation, malfunctions of pads or batteries that occur after expiration of their shelf life or malfunctions of repairs, replacement parts, pads, or batteries that are not provided by Welch Allyn.

This indemnification is expressly conditioned on the Purchaser's fulfilling the following obligations with respect to any claim for which indemnification will be requested (the Claim). The Purchaser will send to Welch Allyn, at the address shown below, written notice of the Claim, promptly after the Purchaser obtains knowledge of the Claim. The Purchaser also will provide to Welch Allyn all assistance reasonably requested by Welch Allyn for evaluation of the Claim or defense of the Claim. Such assistance will include: 1) providing to Welch Allyn possession of the Welch Allyn AED 20 involved in the Claim (including any electronic record created by the Welch Allyn AED 20 of the event involved in the Claim) for analysis of the cause of any failure, and 2) providing to Welch Allyn and its counsel all other evidence relevant to the Claim, whether in the form of documents or testimony. Welch Allyn will promptly notify the Purchaser in writing if Welch Allyn determines that the Claim is not covered by this indemnity, and Welch Allyn shall have the unrestricted authority to defend or settle any Claims for which indemnification is required by this agreement. However, the Purchaser shall retain the right to participate, at its own expense, in the defense or settlement of any Claim that is covered by this indemnity.

Address for notification of Claims:

Welch Allyn
4341 State Street Road
Skaneateles Falls, NY 13153

Attn: General Counsel

Phone: 315-685-2500
Fax: 315-685-4496

1

Safety

Conventions Used in the Manual

Warnings

Warnings alert the user to a special condition that could result in serious personal injury or death. In this manual, warnings are displayed as shown in the following **example**:



WARNING Includes conditions, hazards, or unsafe practices that can result in serious personal injury or death.

Cautions

Cautions alert the user to a special condition that could result in minor personal injury or damage to the equipment. In this manual, cautions are displayed as shown in the following **example**:



Caution Conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the defibrillator, or loss of data.

Notes

Notes contain information that augments or clarifies an operating step. Notes do not normally contain actions. They follow the procedural steps to which they refer. In this manual, notes are displayed as shown in the following **example**:

Note The default supervisor password is 1-2-3.

Voice Prompts

The defibrillator provides audio instructions through the built-in speaker to provide operating instruction and assist the user during defibrillation. In this manual, voice prompts are displayed as shown in the following **example**:



“Low battery.”

General Cautions and Notices

Supervisor Menu

Advanced system operating options, such as Manual Mode and EMS Mode, are intended for use only by trained medical professionals. These options should be selected only if defined by a Supervisor as part of the usage protocol for this device.

Damaged

If the defibrillator has been damaged in any way, refer it to qualified service personnel.

Labels

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

Performance

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

Notices

U.S. Federal law restricts this defibrillator to be used by or on the order of a physician. If the battery pack is removed for any reason, the user must label the defibrillator as "Out of service due to battery operation."

Patient Safety

General



WARNING An accessory adapter is required for use on pediatric patients. The defibrillator is not to be used in Automated mode on patients younger than 8 years old or weighing less than 25 kg (55 lbs) unless it is equipped with the accessory AED 20 Pediatric Energy Reducer (part number 002174-U).

WARNING Do not use the AED 20 Pediatric Energy Reducer when the defibrillator is in Manual Mode.

WARNING Ferromagnetic equipment. ECG electrodes and cables contain ferromagnetic materials. They must not be used in the presence of large magnetic fields created by magnetic resonance imaging (MRI) equipment. The large magnetic fields generated by an MRI device could move ferromagnetic equipment with an extremely violent force that could cause serious personal injury or death to persons between the defibrillator and the MRI device.



Caution Patient physical harm. Place the defibrillator in a position where it cannot harm the patient should it fall. Do not use adjacent to or stacked with other equipment. Keep all cables and connectors away from the patient's neck.



Caution Manual mode is for use only by qualified operators who have been trained in rhythm recognition and treatment through manual charging and delivery of defibrillation shocks. Follow all instructions in this user manual.

Shock Hazard



WARNING Defibrillation current can cause injury. Do not touch the patient during defibrillation. Do not touch equipment connected to or metal objects in contact with the patient during defibrillation. Disconnect other electrical equipment from the patient before defibrillating.



Caution Use Automated Mode only on victims of cardiac arrest who are unconscious, not breathing and unresponsive.

Burns



WARNING Properly place defibrillation pads. Do not allow defibrillation pads to touch each other, or to touch other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause patient skin burns during defibrillation and may divert defibrillating current away from the heart.

Remove excessive body hair, which may cause skin burns or ineffective energy transfer.

WARNING Use Welch Allyn electrode monitoring cables only. Do not replace the electrode monitoring cable with a substitute. Using any other cable may cause burns to the patient.

Electrical Energy



WARNING The defibrillator can deliver 360 joules of electrical energy. Before charging the defibrillator, verify that the energy selected on the display is the desired output. Disconnect any medical electronic device that is not labelled “defibrillation protected” from the patient. If this electrical energy is not discharged properly, it could cause personal injury or death to the operator or bystander. During defibrillation, the operator and all other people must stand clear of the patient, bed, and all conductive surfaces in contact with the patient.

WARNING Properly place defibrillation pads. Do not place electrodes near the generator of an internal pacemaker. Always apply electrodes to flat areas of skin. Avoid application over folds of skin such as those underneath the breast or on obese patients. Excessive hair, poor adhesion, or air under electrode may produce burns.

ECG Misinterpretation



WARNING Properly place the defibrillation pads. Improperly placed pads may produce incorrect analysis and an inappropriate shock or no shock decision advisory.



WARNING Do not move the patient. Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis. Follow all instructions in the User Manual.

WARNING Cardiac pacemakers may affect rhythm analysis. Patient pacemakers may reduce the sensitivity of the defibrillator analysis and errors in detecting shockable rhythms.

WARNING Radio frequency (RF) interference. Do not operate the defibrillator in conjunction with electrocautery or diathermy equipment. Any equipment that emits strong radio frequency signals can cause electrical interference and distort the ECG signal to cause inaccurate interpretation of rhythm.



Caution Do not use the electrode monitoring cable for Automatic Rhythm Analysis. Proper skin preparation and the use of fresh, high-quality monitoring electrodes are imperative to minimize artifact when using the electrode monitoring cable.

Defibrillator and Electrode Pads

Explosion



WARNING Explosion hazard. Do not use the defibrillator in the presence of flammable anesthetics or concentrated oxygen.

Electrical Shock or Fire Hazard



WARNING No internal, operator-serviceable parts. Do not open the defibrillator, remove covers, or attempt to repair it. All servicing must be performed by qualified personnel.

WARNING Improper use can cause injury. The defibrillator contains an automatic disarm of the stored energy. If the operator has not delivered the energy to a patient or a test load, an internal timer will disarm the stored energy. This stored electrical energy can potentially cause death or injury if discharged improperly. Follow all instructions in this users manual.



Caution Do not immerse or expose the defibrillator to water or other liquids. Do not use the defibrillator if unit has been immersed in liquid or if excessive condensation is visible on the device.

Caution Conductive parts should not contact other conductive parts including the earth.

Improper Performance



WARNING Use only accessories approved by Welch Allyn. Do not use defibrillation pads, batteries, and other accessories not approved by Welch Allyn. Use of unauthorized accessories may cause the device to operate improperly and provide false measurements. Follow all labelling instructions on the defibrillation pads and the battery.

WARNING Do not administer a shock using the electrode monitoring cable. The electrode monitoring cable has protective circuitry that prevents defibrillation energy from being delivered to the patient. Always check the expiration date on defibrillation pads. Do not use pads if the packaging has been previously opened. The defibrillator may interpret excessively dry defibrillation pads as an attached electrode monitoring cable.



Caution Do not repeatedly charge and discharge the defibrillator in rapid succession. If a need for repetitive testing arises, wait at least 1 minute for every third discharge to avoid damaging equipment.

Caution Improper maintenance can cause improper performance. Follow instructions in the User Manual.

Caution Use Manual Mode properly. In the manual mode, if a new energy level is selected after the charge button is pushed and while the defibrillator is charging, the defibrillator will automatically charge to the new energy selection. The CHARGE button need not be pressed again to select the new energy level.

Battery Care



Caution The battery is shipped discharged. Charge the rechargeable battery fully before use.

Caution Use only Welch Allyn PowerStick batteries. Use either the rechargeable NiMH PowerStick or the non-rechargeable Lithium PowerStick. Use of any other battery can damage the defibrillator.

Caution Make sure the rechargeable battery is fully charged. Loss of power during patient care could result in injury. Always have a fully charged back-up battery available.

Caution Never attempt to recharge a non-rechargeable battery.

Caution Check the capacity of a non-rechargeable battery after each use. Replace the battery if "Low Battery" is indicated.

Caution Replace the rechargeable battery at 24 months. Battery replacement at 24 months is recommended due to degradation of the battery chemistry. Periodic maintenance and testing is highly recommended to ensure proper battery performance.

Caution Use the battery charger to maintain a full battery charge. Make sure the charger is plugged into an AC power source. Keep the charger in a dry, moisture-free location, away from direct sunlight or other heat sources. Do not block the ventilation slots or remove the cover.

Care and Storage



Caution Clean and maintain the defibrillator according to instructions. (See “Maintenance” on page 55.) Do not clean the defibrillator with alcohol, ketone, or any flammable agent. Do not autoclave the defibrillator or attempt to sterilize it or any accessories.

Electrodes


















WARNING Follow manufacturer’s instructions for use of defibrillation electrodes. Improper use of defibrillation electrodes may cause the defibrillator to function improperly or may cause skin burns. Do not use expired, dry electrodes. Do not reuse disposable electrodes. When obtaining a new supply, verify that the electrodes connect properly to the defibrillator before putting them into service.



Caution Properly store and use defibrillation pads. Store electrodes in a cool, dry location (between 60° and 95 °F or 15° and 35 °C.). Do not sterilize the pads, immerse, or clean the electrodes with alcohol or solvents.

Safety Symbols

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

	Consult accompanying documents		Earth (ground)
	Defibrillator protected, type BF patient connection		Defibrillator protected, type CF patient connection
	Dangerous voltage		Negative input terminal
	Altitude limit		Positive input terminal
	Fragile		Humidity limit
	Stacking limit by number		Temperature limits
	Keep away from rain		This way up
	Lithium Manganese Dioxide battery		Non-ionizing electromagnetic radiation



Separate batteries from other disposables for recycling



Recycle the defibrillator and battery separately from other disposables (www.welchallyn.com/weee)



This device has been tested and certified by the Canadian Standards Association International to comply with applicable U.S. and Canadian medical safety standards.



The CE Mark and Notified Body Registration Number signify the device has met all essential requirements of European Medical Device Directive 93/42/EEC.

2

Introduction

This chapter introduces the defibrillator system, introduces the controls, indicators, displays, and prompts, and provides instructions for preparing the defibrillator for use and for storage.

Overview

The AED 20 is a safe, easy-to-use defibrillator for use by basic life support (BLS) personnel. It is light and mobile and can be used where several minutes could elapse before the arrival of advanced life support (ALS) personnel.

The defibrillator recognizes ventricular fibrillation and other ventricular tachycardia, and guides operators through the defibrillation process. When properly connected to a patient who is unconscious, not breathing, and unresponsive (that is, without signs of circulation), the defibrillator analyzes the patient's heart rhythm, provides text and audio instruction prompts, determines whether a shockable situation exists and, if appropriate, arms the Shock button.

The defibrillator delivers the shock through two self-adhesive, pre-gelled, low-impedance electrode defibrillator pads. The pads, cable, and connector are sold as disposable kits.

Features

- 3-step operation
- Extensive voice and visual prompts for the operator
- Weekly and monthly self-test to ensure readiness
- Optional rechargeable battery
- Biphasic energy output
- Lock-out protection to prevent inadvertent defibrillation in manual mode

System Upgrades and Options

The defibrillator is an automated external defibrillator designed for easy operation. However, it is designed so that optional features can be added as simple software upgrades.

Display options include providing an ECG trace in automated mode and showing a biphasic defibrillation waveform. Another option allows the unit to be switched from automated mode to manual mode. Manual mode allows qualified users to set the defibrillation energy level, charge the unit, and deliver a shock.

Qualified Operators

A qualified operator is someone who has successfully completed a CPR AED training course (e.g., AHA Heartsaver course or the Red Cross CPR/AED course).

Preparing the Defibrillator for Use

Before using the defibrillator:

1. Carefully unpack and inspect all defibrillator system components and accessories.
2. Install the battery. (If using the rechargeable NiMH PowerStick battery, charge the battery fully before installing it.)
3. Run the self-test.
4. Set the date and time. (See [“Setting the Date”](#) on page 42.)

Unpacking and Inspecting

Visually inspect the carton for any signs of damage or mishandling (perforations, cuts, or dents; bent or collapsed corners; or broken carton seal). Remove the defibrillator from the carton and inspect it carefully.

Before proceeding:

1. Open and carefully unpack each carton.
2. Examine the instruments and accessories for signs of damage.
3. Check the packing list to determine that all accessories have been received.
4. Contact Welch Allyn (see [page ii](#)) if anything looks damaged or is missing.

Installing the Battery

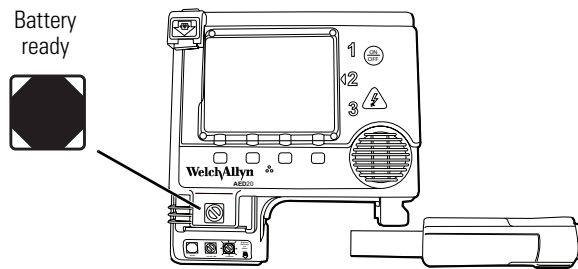
The defibrillator can use either a NiMH (Nickel Metal Hydride) PowerStick rechargeable battery or an extended-life, Lithium PowerStick non-rechargeable battery.

The battery slides into the defibrillator case and locks firmly in place. The battery forms the carrying handle of the defibrillator and therefore, you can always be sure that the battery is properly installed.

- Use the NiMH PowerStick rechargeable battery for applications involving frequent use.
- Use the Lithium PowerStick non-rechargeable battery for standby use.
- Using a non-rechargeable battery for training or testing will reduce the shelf-life and operating time of the battery.

To install the battery:

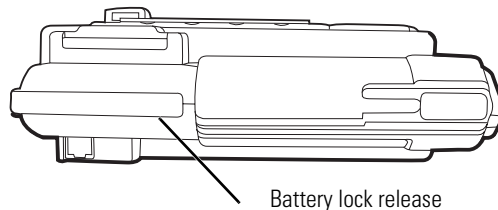
1. Align the thin, flat end of the battery with the opening in the lower front portion of the defibrillator case.
2. Push the battery in until it clicks into place.



3. Make sure the battery ready indicator in the lower left of the display indicates that the battery has sufficient charge. If the status indicator displays anything other than the Battery Ready icon, the defibrillator is not ready for use.

To replace the battery:

1. Push the lock release on the bottom of the defibrillator case where the battery inserts into the unit.



2. Replace the battery with a backup. Recharge the removed battery, if it is a rechargeable battery.

Running a Self-Test

After installing the battery, press the ON button to power-up the defibrillator and automatically perform a self-test. At power-up, the following tests are performed: battery, main processor, memory and program, stuck key, ECG preamp, and defibrillator.

If the built-in sensors in the defibrillator detect a problem prior to or during operation, the unit provides a voice or screen prompt indicating the problem.

[“Troubleshooting”](#) on page 65 lists fault indicators and determines possible corrective actions.

Setting the Time and Date

See [“Setting the Date”](#) on page 42.

Getting to Know the Defibrillator

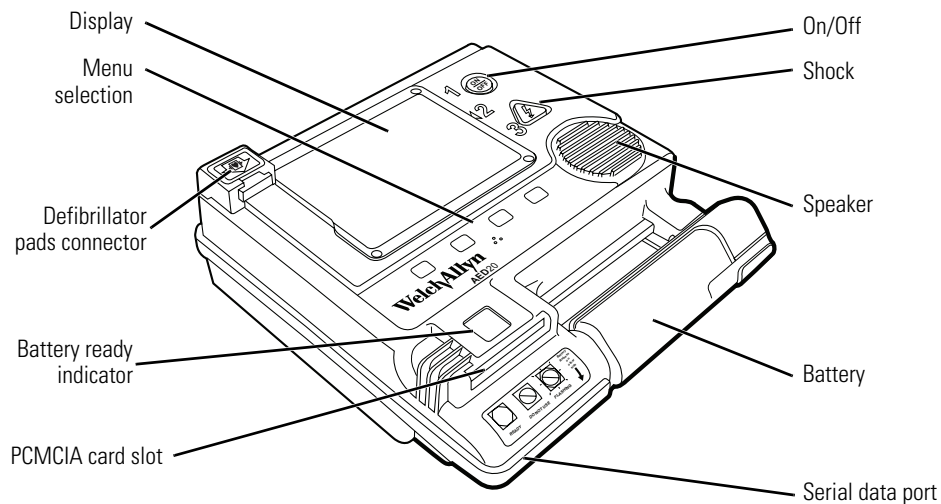
The defibrillator features straightforward, three-step operation using extensive voice and visual prompts to assist the operator. With ECG and event recording, the defibrillator maintains a detailed log that can be sent to a computer for review and printing.

Defibrillator Configurations

Available defibrillator configurations are ECG Display and Manual Mode.

ECG Display	Provides automated Text and voice prompts and continuous ECG tracing displays on the LCD during operation.
Manual Mode	Provides automated text and voice prompts and an ECG tracing display. In addition, an authorized operator/supervisor with the proper pass code can manually override the automated operation of the defibrillator. This allows the user to manually select energy settings and administer defibrillation shocks.

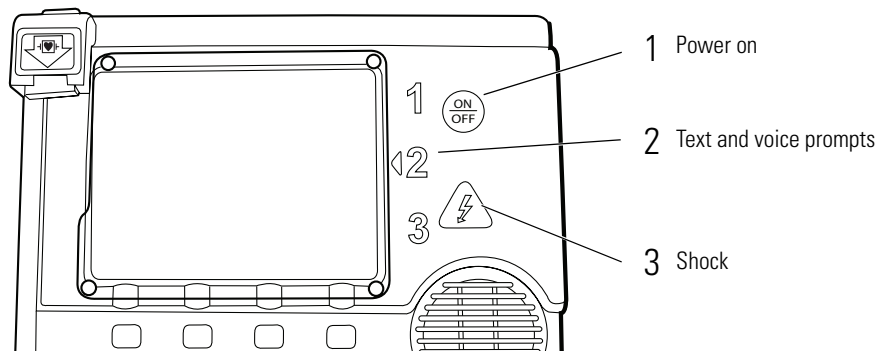
Functions



Controls

The defibrillator is designed for ease of operation. After putting the defibrillator pads on the patient and connecting them to the defibrillator, the operator performs this simple three-step process:

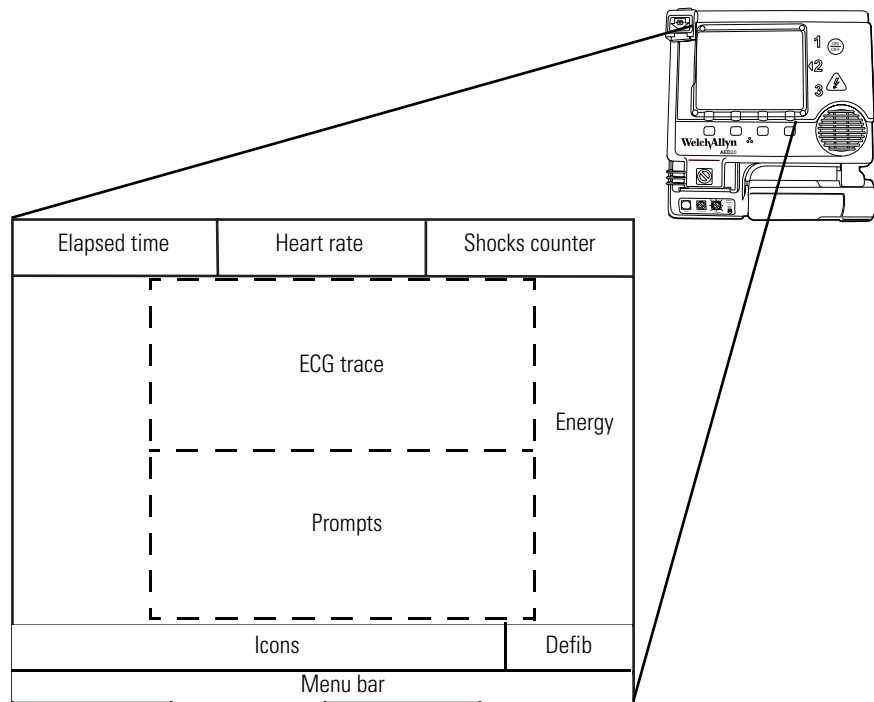
1. Turn the power ON.
2. Follow text prompts on the screen and voice prompts from the speaker.
3. If prompted, deliver shock by pressing the flashing red Shock button.



- Power ON/OFF Green ON/OFF button to toggle system power on/off
- Shock Red Shock button to discharge defibrillator; red LED flashes when defibrillator is fully charged
- Menu selection Four soft buttons located in the case below the display; programmable functionality to make menu selections in manual mode.

Display

Text prompts, patient data, and event information appear on the screen, which is divided into functional areas of operating information and user instructions.



- Shocks Counter Number of shocks administered to the current patient.
- Defib Energy level selected or delivered, and status messages.

ECG Trace	(ECG or manual mode add-on option) ECG trace as a moving waveform. If the defib pads are not properly attached to the patient or connected to the unit, a dashed line is drawn.
Prompts	Up to three lines of text (user instructions, directions for patient care, error messages). See descriptions below.
Elapsed Time	Time elapsed since the system was powered ON, or time used on current patient. The time format is HH:MM:SS by default, but can be changed by the user.
Energy	(Manual Mode only) Temporary window when the Charge button is pressed or a Shock Advised situation is detected. The selected energy level is highlighted.
Heart Rate	(ECG or Manual Mode add-on option) Heart rate (beats per minute). A dashed line appears when the heart rate is out of range or when a defibrillation pad fault exists.
Icons	System status prompts, such as Charging and Energy Delivered.
Menu Bar	Areas corresponding to four buttons on the case below the LCD.
Menu Selection	Manual Mode or Supervisor Mode menu choices. (See “Programming” on page 35.)

Graphical screen icons provide system operational information. The defibrillator operator or supervisor can use a simple menu-driven structure to set charge protocols and system configurations, set system operating parameters such as display contrast and volume, select the language used for text and voice, and install upgrade options.

Text Prompts

Text prompts provide operating information and instructions. The prompts display in the lower half of the LCD above the icon window.

ANALYZING	Defibrillator pads are properly connected and the system is accessing the patient's heart rhythm.
ATTACH DEFIB PADS	Attach the defibrillation pads according to the instructions given on the package.
CHARGING	System is automatically charging the defibrillator to the energy level pre-set in the shock protocol.
CHECK PATIENT	Prompt to press the Analyze button.
CHECK RESPONSE (UK:CHECK CIRCULAT.)	Check the patient for responsiveness or signs of circulation.
BEGIN CPR	Begin CPR in accordance with the procedures and techniques presented in your training.
MONITORING ECG, PRESS TO ANALYZE	Defibrillator is silently monitoring the patient's heart rhythm and will perform a full analysis if the Analyze button is pressed.
MOTION DETECTED	System has detected movement of the electrodes or the patient as indicated by inconsistent data readings.

NO SHOCK ADVISED	System has analyzed the patient's heart rhythm and determined that a shockable condition does not exist.
SHOCK ADVISED	System has analyzed the patient's heart rhythm and determined that a shockable condition exists.
SHOCK NOW	Prepare to administer the shock.
STAND CLEAR	Defibrillator is charged and ready for shock. Do not touch or move the patient.

Voice Prompts

The defibrillator provides audio instructions through the built-in speaker to provide operating instruction and assist the user during defibrillation. The voice prompts listed in the following table parallel the text and icon displays shown on the LCD.

Analyzing heart rhythm. Do not touch the patient.	Defibrillator pads are properly attached and connected; assessing heart rhythm.
Analyzing interrupted. Motion detected.	Patient or electrode moved; check the defibrillation pads.
Check patient.	Prompt to press the Analyze button.
Check airway, check breathing, check for responsiveness (check circulation).	(3-Shock mode) Check patient's airway, breathing, and responsiveness or signs of circulation.
Apply defib pads to patient's bare chest. Connect cable	(at unit power up) Attach electrode pads to the patient and connect cables to the defibrillator.
If not breathing and unresponsive (if needed), begin CPR.	(3-Shock mode) Check the patient for responsiveness or signs of circulation and begin a 60-second CPR cycle.
Apply defib pads. Connect cable.	Defibrillator pads are not properly attached to the patient or properly connected to the defibrillator.
Begin CPR.	Begin CPR in accordance with the procedures and techniques presented in your training.
Low battery.	Low battery charge. Replace or recharge the battery.
Memory card full.	Internal memory card is full.
No shock advised.	A shockable condition does not exist.
Shock advised.	A shockable condition exists.
Shock now. Press the red button now.	Push the red SHOCK button.
Stand clear.	The defibrillator is charged and ready to shock. Do not touch or move the patient.
Stop CPR.	Stop CPR. Wait for further instructions.
It is safe to touch the patient.	The defibrillator shock has been delivered or a non-shockable condition was detected and it is safe to touch the patient.

Change to (UK: defibrillation) pads

The electrode monitoring cable is attached. Change to the defibrillation pads.

Shock not delivered.

Attempted shock did not deliver the expected amount of energy.

Status Indicators



Optional auxiliary power unit is plugged in.



Battery is fully charged.



Battery is partially depleted.



Battery is low.



Non-rechargeable battery.



Rechargeable battery.



Contrast level (1-9).



User-adjustable CPR Timer (seconds).



Memory available for log entries.



Memory available in the optional memory card.



Log is printing. (Flashing indicates printer error.)



Speaker volume level (1-4).

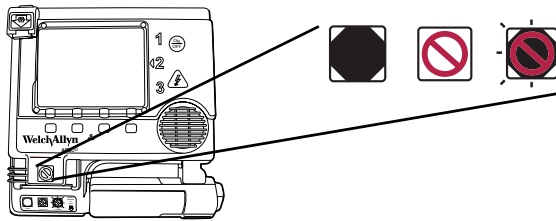





Memory card is locked.



Memory card is recording.

System Ready Indicator



- | | | |
|-----------------------------------------------------------------------------------|--------------------------|---------------------------------------------------------------------------------------------------------------------|
|  | Ready | Battery is properly installed and charged. |
|  | Do Not Use | Battery is not properly installed or is too low for effective operation, or some other system failure has occurred. |
|  | Do Not Use
(Flashing) | Battery is low and requires changing or charging. |

Serial Data Port

The built-in Serial Data Port provides a direct connection to a computer.

Event Documentation

The defibrillator stores event documentation including patient status, ECG traces, and treatment summary. The information is stored in an internal log or an optional PCMCIA external memory card. Event documentation is time stamped and can be downloaded to a computer through the serial port on the defibrillator.

Battery Charging and Conditioning

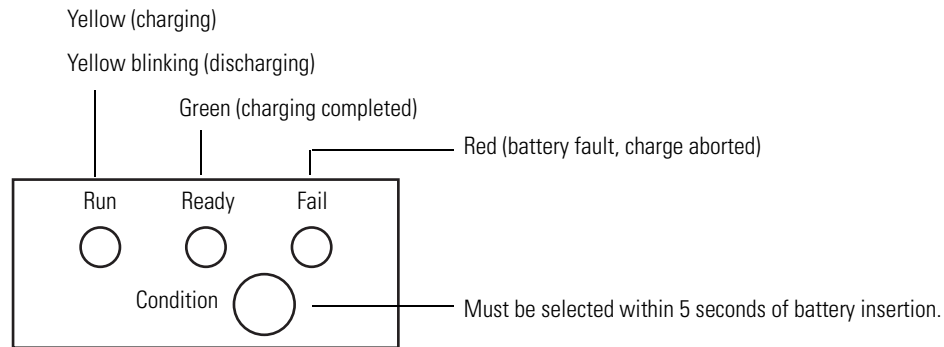
This section provides procedures for charging and conditioning the **NiMH** PowerStick rechargeable battery.

Note Do not attempt to recharge the **Lithium** PowerStick non-rechargeable battery.

Battery maintenance is critical to ensure the defibrillator operates reliably. Periodically check the battery to ensure the recommended replacement date has not elapsed. Over time and through use, the capacity of a battery will degrade. Properly maintaining a battery is crucial to maximizing 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. An old Powerstick rechargeable battery should be replaced with a new one every 24 months.

Note A completely discharged battery requires approximately 1.5 to 2.5 hours to recharge. 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.

Quick Charger/Conditioner



The Welch Allyn Quick Charger/Conditioner is easy to use. The NiMH PowerStick is inserted directly into the charger, and status lights indicate the condition of the battery.

Charging an NiMH Battery

To charge a NiMH battery using the Welch Allyn Quick Charger/Conditioner:

1. Insert the battery into the charger. When the battery is firmly seated, the yellow Run light illuminates.
2. Monitor the status lights. A steady yellow Run light means the battery is charging. A red Fail light means that the battery is not charging due to a fault condition.

The Run light will turn off and the green Ready light will turn on to indicate that the battery is fully charged.

- Charging the battery at temperatures above 30 °C (86 °F) increases the charging time and may result in a gradual decline in battery capacity.
- When removing a battery from the charger, always allow at least 3-5 seconds for the system to reset prior to inserting another battery.

Conditioning an NiMH Battery

The effective life of the NiMH PowerStick battery can be prolonged by periodic conditioning.

To initiate an NiMH battery conditioning cycle:

1. Insert the battery into the charger.
2. Press the conditioning button on the charger control panel within 5 seconds of insertion. The yellow Run light blinks as the battery is being discharged.

At the end of the conditioning, the charger automatically begins a normal charge cycle.

3. Monitor the charging light. The yellow Run light turns off and the green Ready light turns on when the battery is fully charged.

Preparing the Defibrillator for Storage

After each use, any event documentation should be retrieved from the internal log or external memory card and printed. Any error messages or malfunctions should be reported and corrective actions taken before storing the unit for reuse. Then, the defibrillator should be inspected, cleaned, and a new supply of electrode pads restocked to prepare the unit for its next use.

During storage, the defibrillator performs periodic self-tests including the functionality of the unit and the status of the battery and internal circuitry. A more detailed test of the unit's operation and battery status should be performed on a regular basis. See ["Maintenance"](#) on page 55 for more information.

3

Operation

This chapter provides information for using the defibrillator with a patient. It also provides instructions for operating the defibrillator in automated or manual mode and the procedures to follow after using the unit.

Overview

The defibrillator can operate in automated or in manual mode. In either, the operator must be trained to use the unit and understand the indications and contraindications for use.

Trained Operators

The defibrillator is intended to treat patients in cardiopulmonary arrest. It is for use in either in-hospital or out-of-hospital arrests. It is intended that the operator is authorized by a physician/medical director, and has the following training skills:

Manual Mode

- American Heart Association Advanced Cardiac Life Support certification or equivalent.
- Training in the use of the defibrillator.

Automated Mode

- American Heart Association Heartsaver course, American Red Cross CPR/AED course or equivalent
- Training in the use of the defibrillator.

Fibrillation and Defibrillation

Ordinarily the heart produces regular electrical activity—normal sinus rhythm (NSR). Fibrillation is an abnormal heart rhythm that replaces the normal rhythmic contraction of the heart. During fibrillation, irregular cardiac electrical activity causes rapid, uncoordinated twitching movements. As a result, the heart cannot pump blood effectively causing a lack of appropriate circulation and pulse.

Defibrillation is the delivery of a brief, high-energy pulse of electricity to the heart muscle using a device called a defibrillator. Defibrillation restores the normal cardiac electrical activity and allows the heart's natural pacemaker areas to regain normal function.

The defibrillator, using direct current, applies a brief, high-energy pulse of electricity to the heart to counteract fibrillation of the heart muscle and restore a normal heartbeat.

The defibrillator will only administer a defibrillation pulse to a patient exhibiting a shockable cardiac rhythm. Shockable rhythms are described in Appendix A. All other rhythms are determined “non-shockable” and the patient is not a candidate for defibrillation. Cardiopulmonary resuscitation (CPR), medication, and supplemental oxygen may also be required to effectively resuscitate the patient.

Indications and Contraindications for Use

Once the defibrillator is connected via the defibrillation electrode pads to the patient, the instrument assesses the patient’s cardiac status and indicates whether the patient is a candidate for defibrillation. The defibrillator administers a defibrillation pulse (shock) only to a patient exhibiting a shockable cardiac rhythm. All other rhythms are non-shockable and the patient is not a candidate for defibrillation. Cardiopulmonary resuscitation (CPR), medication, and supplemental oxygen may also be required to effectively resuscitate a patient. Do not use this defibrillator in Automated Mode on patients younger than 8 years or weighing less than 25 kg (55 lbs) unless it is equipped with the accessory AED 20 Pediatric Energy Reducer (002172).

Defibrillation may be effective against cardiac arrhythmias such as:

- Cardiac arrest
- Ventricular fibrillation
- Ventricular tachycardia

Indications

Before using the defibrillator, the patient should be assessed by a trained person (see [“Trained Operators”](#) on page 21). If defibrillation with the defibrillator is indicated, all of the following signs should be present during patient assessment:

- Unconsciousness
- Absence of breathing
- Unresponsiveness (no signs of circulation)

Contraindications

The defibrillator should NOT be used if the patient exhibits any of the following signs:

- Patient is conscious
- Patient is breathing
- Patient is responsive (has signs of circulation)

Operating Procedures—Quick Reference

The following instructions provide an experienced operator with the main steps for using the defibrillator in Automated Mode and Manual Mode. Detailed operating information and procedures are described in [“Operating Procedures—Detail”](#) on page 23.

Automated Mode - Quick Reference

1. Assess the patient.
See [“Operating Procedures—Detail”](#) on page 23.

2. Attach the electrodes.
See [“Operating Procedures—Detail”](#) on page 23.
3. Start the defibrillator and deliver a shock.
 - a. Push the green ON/OFF button located at the upper right corner of the defibrillator next to the large number “1.”
 - b. Listen to voice prompts and read text instructions on the screen next to the large number “2.”
 - c. If prompted press the red Shock button next to the large number “3.”
4. Perform CPR, if prompted.

Manual Mode - Quick Reference

1. Assess the patient.
See [“Operating Procedures—Detail”](#) on page 23.
Attach the electrode pads and connect the cable.
See [“Operating Procedures—Detail”](#) on page 23.
2. Start the defibrillator and deliver a shock.
 - a. Push the green ON/OFF button located at the upper right corner of the defibrillator next to the large number “1.”
 - b. Press the button below Manual to display the manual mode password screen.
 - c. Enter the numeric manual mode passcode. Press Enter to accept the passcode and display the Manual Mode operating screen.
 - d. Select energy with the up and down arrows.
 - e. Press the Charge button.
 - f. Press the red flashing Shock button next to the large number “3” to deliver the shock.

Operating Procedures—Detail

1. Assess the patient.
Use the defibrillator only if the patient is:
 - Unconscious
 - Not breathing
 - Unresponsive (showing no signs of circulation)
2. Start the defibrillator.
Push the green ON/OFF button next to the large number “1” to power-on the defibrillator.
The unit starts in Automated Mode. To operate the unit in Manual Mode:

- a. Press the button below Manual on the status bar to display the manual mode passcode screen.
 - b. Use the buttons below the arrows on the display to select the numeric passcode.
 - c. Press the button below Enter to accept the passcode and display the manual mode operating screen.
3. Attach the electrode pads and connect the cable.

For defibrillation to be effective, it is important to correctly place the pads on the patient and connect the electrodes to the defibrillator.

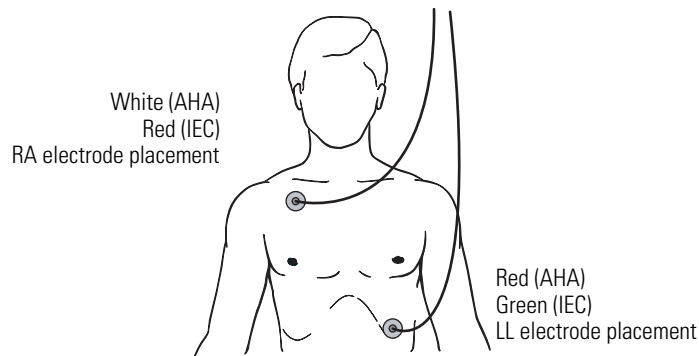
Before applying pads to the patient's chest:

- a. Remove all clothing covering the patient's chest.
- b. Wipe off any water, moisture, or perspiration.
- c. Press the pads firmly to make sure they adhere securely to the chest.

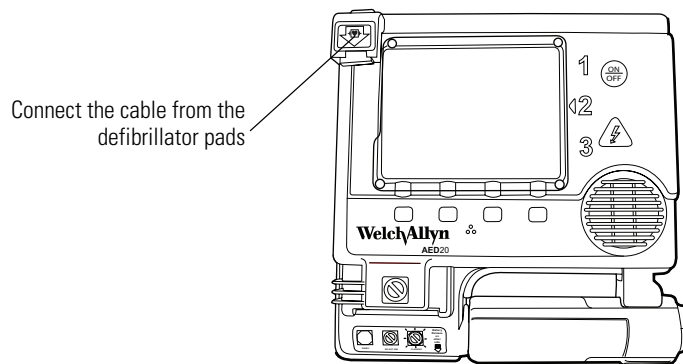


WARNING Excessive body hair may affect the operation of the electrodes or cause skin burns on the patient. Remove body hair as needed to ensure that the electrode pads make proper contact with the patient's chest.

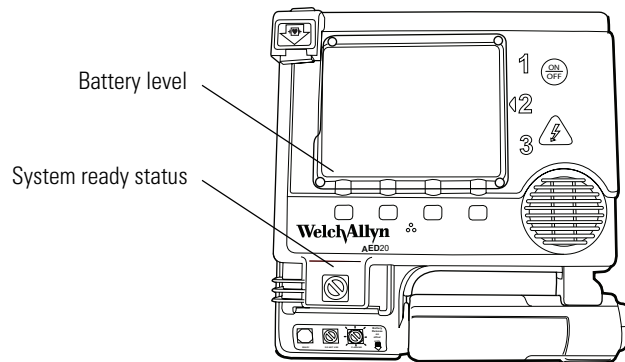
- d. Open the package containing the defibrillation pads and cable.
- e. Peel off the backing from the electrode pad labelled RA. Place this pad just below the patient's right collar bone (sternum).



- f. Peel off the backing from the electrode pad labelled LL. Place this pad over the ribs on the patient's left side below the breast (apex).
- g. Plug the pad connector into the defibrillator on the left side of the unit.



- h. Check the battery level icon above the Menu bar on the display screen to make sure there is sufficient power to charge the defibrillator.



If pads are not properly applied or the cable is not properly connected to the defibrillator, it will alert the user with text and voice.

- i. Apply the pads to patient's bare chest and connect the pads to the cable.
j. Analyze the patient's heart rhythm.

When the pads are properly applied and connected, the defibrillator announces, and then analyzes the patient's heart rhythm to determine whether a shock is indicated:



Analyzing heart rhythm. Do not touch the patient.



Caution Do not touch or move the patient while the defibrillator is analyzing the heart rhythm.

Rhythm analysis takes approximately 12 to 16 seconds. During this time, any movement, including CPR and patient transport, may interrupt analysis and delay the defibrillation prompts. Text and voice prompts alert the user if the patient or the electrodes move:




Motion detected. Analyzing interrupted. (Check the pads).


Deliver Shock—Automated Mode

The defibrillator administers a shock only to a patient exhibiting a shockable cardiac rhythm. For all other rhythms (those determined to be non-shockable) the patient is not a candidate for defibrillation.

If the condition is not shockable, the defibrillator alerts the user with text and voice:

 No shock advised.

If a shockable condition is detected, the defibrillator will alert user with text and voice:

 Shock advised.


To deliver a shock

1. Make sure the Shock button next to the large number “3” is flashing to indicate that the unit is properly charged.



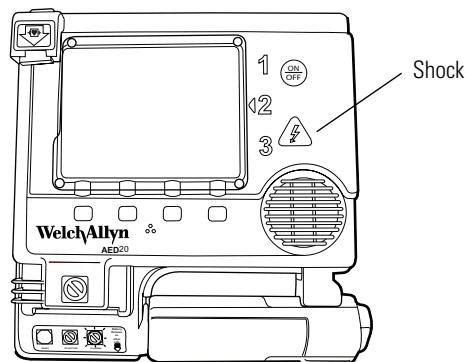
WARNING Make sure no one is touching the patient before you press the Shock button. Loudly announce, “Stand back! Do not touch the patient.” Look down the entire length of the patient to ensure there is no contact with a bystander or conductive surface before pressing the Shock button.

The defibrillator will alert user with text and voice:

 Stand clear.

 Shock now. Press the red button now.

2. Press Shock to deliver a shock.



The defibrillator does not allow the operator to charge or discharge the defibrillator unless a shockable rhythm is detected while in automated mode.

After delivering a shock, the defibrillator will prompt for immediate CPR. (Note: In the 3-shock cycle configuration, the defibrillator continues to analyze the heart rhythm and determine whether additional shocks are indicated in 3-shock mode. In 1-shock mode, the defibrillator will prompt for immediate CPR). The defibrillator is programmed for a

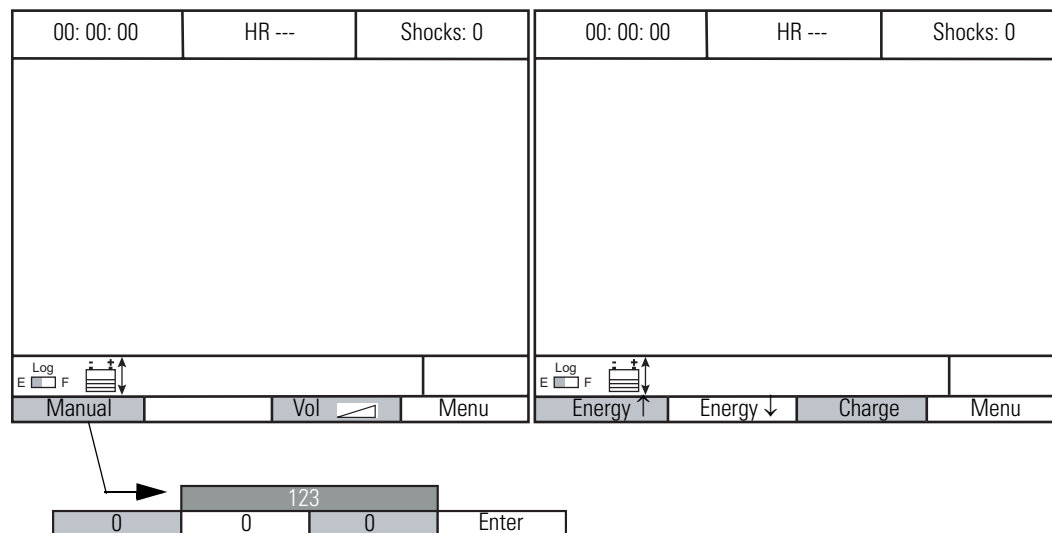
supervisor-configurable protocol that indicates the number of shocks delivered, the energy of each shock, and possible CPR interventions.

Deliver Shock—Manual Mode

The defibrillator can operate as a manual AED when it is configured with the manual mode options.

1. Enter Manual Mode.

When the power is on the defibrillator starts in automated mode. It may be switched to manual mode at anytime during the use in automated mode by pressing the Manual button and entering a password. Press Enter to accept the manual mode password. If the number is correct, the manual mode operating screen is displayed.



From the manual mode screen, the operator can Charge or Disarm the defibrillator and adjust the energy level of the charge to be delivered.

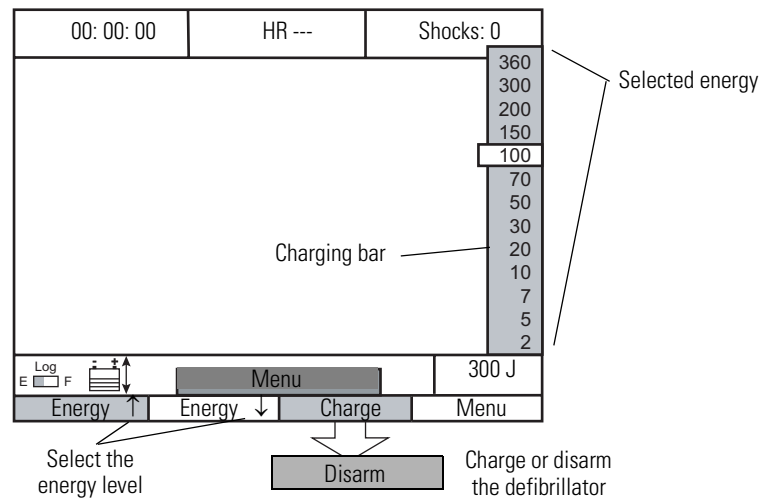
2. Select the energy level.

Press the buttons under the up/down energy arrows to increase or decrease the energy level of the charge. The energy charge levels available are: 2, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, and 360 Joules. The energy level selected displays in the lower right corner of the LCD.

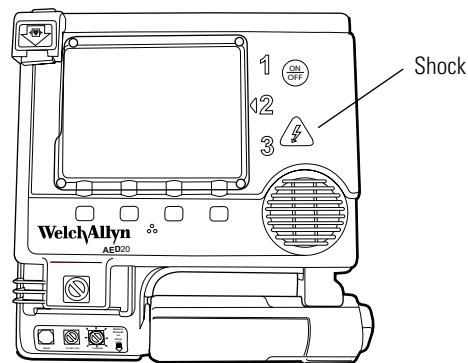
3. Charge the defibrillator.

Press the Charge button to charge the defibrillator. An intermittent tone sounds as the defibrillator charges. A bar extends upward on the right side of the display until it reaches the selected energy level. When the selected energy level is reached, a steady tone sounds and the red Shock button flashes.

Charge time is approximately 8 seconds. The unit can deliver back-to-back shocks in less than 30 seconds.



4. Deliver a shock.
 - a. Make sure the Shock button next to the large number "3" is flashing to indicate that the unit is properly charged.
 - b. Push Shock to deliver a shock.



WARNING Make sure no one is touching the patient before you press the Shock button. Loudly announce, "Stand back! Do not touch the patient." Look down the entire length of the patient to ensure there is no contact before pressing the Shock button.

Defibrillator Disarm

If the defibrillator is charged and the Shock button is not pressed, the defibrillator must be disarmed.

The defibrillator automatically discharges in Automated Mode (30 seconds) or Manual Mode (60 seconds).

- In Automated Mode after 25 seconds, a warning tone indicates that the defibrillator will disarm automatically.
- In Manual Mode, the operator can disarm the defibrillator by pressing the Disarm button.

The operator can press the ON/OFF button and turn off the unit.

Perform CPR

If the patient is unconscious, not breathing and unresponsive, when directed, perform cardiopulmonary resuscitation in accordance with the procedures and techniques presented in your CPR training. During the CPR cycle, the defibrillator will not assess the patient's heart rhythm unless the user presses the Analyze button to initiate an analysis cycle.

As an optional feature, a metronome tone can be used to provide timing while administering chest compressions to a patient. See ["To set CPR Tempo"](#) on page 51 for more information.

At the end of the CPR Cycle (15, 30, 60, 90, 120, 150 or 180 seconds), the defibrillator will prompt you to stop CPR and not touch the patient so it can assess the heart rhythm, confirm its analysis, and determine if a shockable rhythm exists.



Stop CPR.



Analyzing heart rhythm.



Do not touch the patient.

If the heart rhythm is not treatable with defibrillation, the defibrillator displays and announces the message No Shock Advised in 1-Shock CPR mode. The defibrillator will direct the user to perform a cycle of cardiopulmonary resuscitation.



No shock advised.



It is safe to touch the patient.



Begin CPR.

If a shockable rhythm is detected, the defibrillator will charge and prompt the user to deliver a shock in 1-Shock CPR mode.



Shock advised.



Stand clear.



Shock now. Press the red button now.

SAED Shock Mode

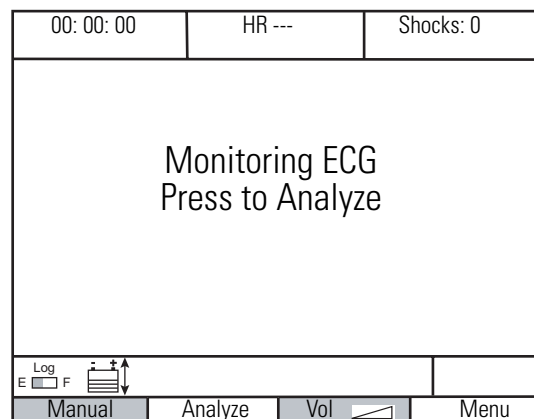
The defibrillator supports three automated modes of operation: 3-Shock Analyze, 3-Shock CPR and 1-Shock CPR. The Shock mode determines the defibrillator's response to a heart rhythm that does not require defibrillation. In 3-Shock Analyze mode, the defibrillator will respond with the events previously described in the Perform CPR section and continue to analyze during CPR. In 3-Shock CPR, detection of a heart rhythm that does not require defibrillation causes the defibrillator to immediately enter a CPR cycle. The defibrillator will not analyze during the CPR cycle. In 3 Shock mode, if a shockable rhythm is detected the defibrillator will deliver three shocks if needed (as defined by the protocol configuration established by the supervisor), and then enter a CPR cycle.

In 1-Shock CPR mode, the defibrillator behaves as if in 3-Shock CPR mode except every shock will be followed by a CPR cycle.

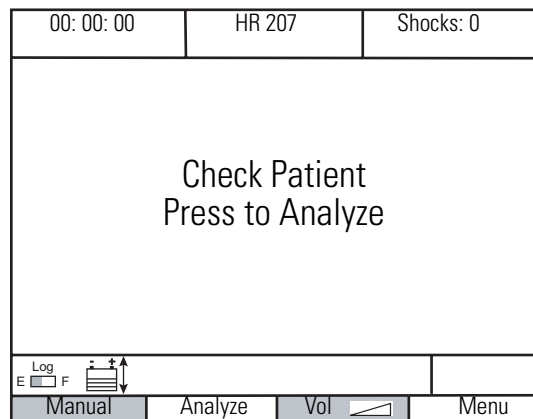
EMS Mode

EMS mode is a feature specifically designed for use by an Emergency Medical Technician. EMS mode is recommended when continuous defibrillator mode analysis is required while transporting a patient or performing another procedure such as intubation. EMS Mode is a supervisor selectable mode of operation that performs continuous background analysis, but requires the user to press the Analyze button for full analysis in response to a prompt from the defibrillator. The following section describes the operation and various features of EMS mode.

When the defibrillator is powered on in EMS mode, it is automatically set to a Voice Off mode. The defibrillator analyzes silently (without voice prompts) unless it detects a shockable rhythm.



If a shockable rhythm is detected, the screen changes and the defibrillator speaks and displays CHECK PATIENT.



When the “CHECK PATIENT” prompt is spoken, verify that the patient is unconscious, not breathing and unresponsive, and eliminate sources of motion artifact before pressing the Analyze button to Enter Voice On mode. In Voice On mode, the defibrillator will issue verbal prompts, fully analyze the patient’s heart rhythm and charge the defibrillator if necessary. Follow normal defibrillator mode operating procedures in Voice On mode.

Note The Analyze button can be pressed at any time in EMS mode to perform a full analysis of the patient’s heart rhythm.

Note The “Check Patient” prompt may be spoken in response to excessive motion artifact or CPR. Eliminate sources of motion artifact before pressing the Analyze button.

If defibrillation is necessary, the defibrillator performs the normal 1-Shock or 3-Shock SAED protocol set by the supervisor. If a patient is successfully defibrillated, the defibrillator returns to Voice Off mode. In 3-Shock mode, after three successive shocks are delivered (or one shock in 1-Shock mode), the CPR timer begins after the final shock. Following completion of CPR, the unit speaks “Stop CPR” and returns to Voice Off mode to continue background monitoring.

Electrode Monitoring (option)

An optional electrode monitoring cable (002128, 002130) is available for use with the defibrillator. The operator uses low-cost standard ECG electrodes (001726) to assess patients who do not meet the criteria for using the automated mode; for example, a patient who is responsive, or is conscious, but has chest pains.

Electrode monitoring is recommended for use in manual mode for extended monitoring or monitoring while in transport. When the electrode monitoring cable is attached, the defibrillator analyzes the patient’s rhythm while in automated mode but does not charge the defibrillator or allow the operator to deliver a shock.



WARNING Do not administer a shock using the electrode monitoring cable. The electrode monitoring cable has protective circuitry that prevents defibrillation energy from being delivered to the patient.

WARNING Always check the expiration date on defibrillation pads and do not use pads if the packaging has been previously opened. The defibrillator may interpret excessively dry defibrillation pads as an attached electrode monitoring cable.

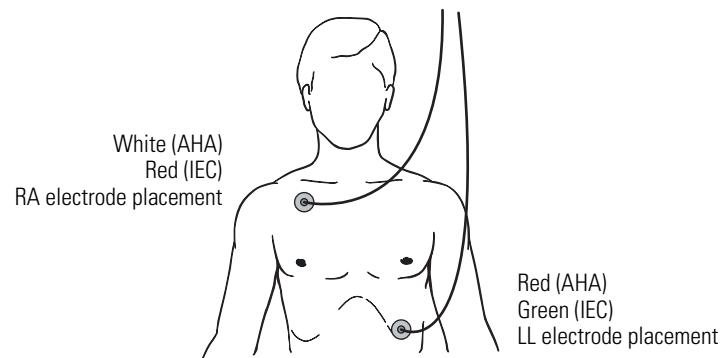
Using the Electrode Monitoring Cable

To use electrode monitoring

1. Attach an electrode monitoring cable to the defibrillator.
2. Properly prepare the patient's skin prior to attaching the electrodes. Clean the skin sites with a coarse, dry terry cloth. Then, clean the skin with alcohol and allow to dry completely before applying the electrodes.
3. Connect each lead of the electrode monitoring cable to the appropriate disposable electrode. Arrange the electrodes as shown below. Attach an electrode to the sternum (RA) area of chest and the other to the apex area (LL) of the chest.

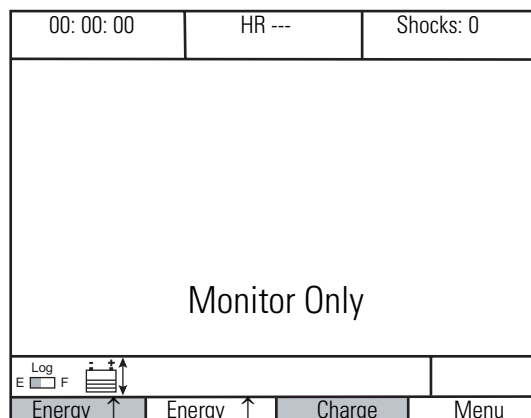


Caution Do not use the electrode monitoring cable for Automatic Rhythm Analysis due to the possibility of artifact. Proper skin preparation and the use of fresh, high-quality monitoring electrodes are imperative to minimize artifact when using the electrode monitoring cable.

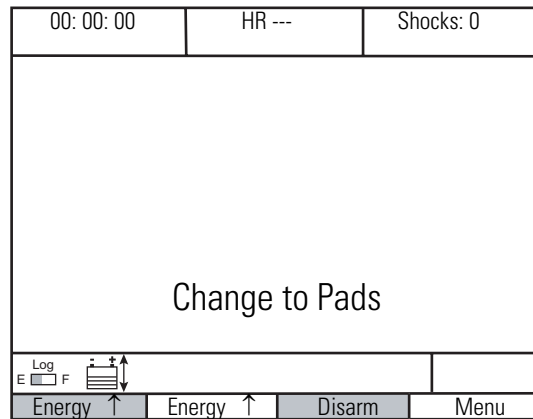


Using the Electrode Monitoring in Manual Mode

The defibrillator displays MONITOR ONLY at the bottom of the prompts window during normal Manual Mode operation.



When the operator presses the Charge button, an audible tone sounds and CHANGE TO PADS flashes on the display.



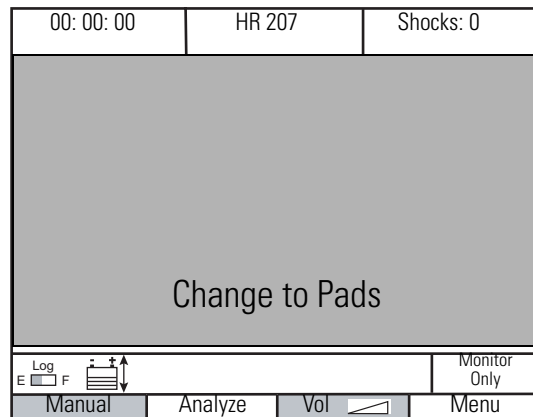
If the operator attempts to deliver a shock using the electrode monitoring cable, SHOCK NOT DELIVERED displays on the screen and no energy is delivered to the patient.



Caution Do not replace the electrode monitoring cable with a substitute. Using any other cable may cause burns to the patient.

Attempting to Use Electrode Monitoring in Automated Mode

Do not use the electrode monitoring cable for Automatic Rhythm Analysis. If the defibrillator is set to Automated Mode when the electrode monitoring cable is attached, MONITOR ONLY flashes in the Defib window.



While the electrode monitoring cable is attached, the defibrillator analyzes the heart rhythm only when the Analyze button is pressed. Do not move or touch the patient while analyzing with the electrode monitoring cable. When the Analyze button is pressed, the defibrillator begins an analysis cycle.

Press the Analyze button and the defibrillator speaks Analyzing and displays ANALYZING and STAND CLEAR and goes through the analysis cycle.



Analyzing heart rhythm.

If the result is a non-shockable waveform, the defibrillator sounds a double beep and displays NO SHOCK ADVISED. If the result is a shockable waveform, the defibrillator

speaks Change to Pads, sounds 5 beeps, and displays CHANGE TO PADS, CHECK PATIENT, IF NEEDED, BEGIN CPR.



Change to (defibrillation) Pads.

The defibrillator continues to wait for the Analyze button to be pushed while in Automated Mode. It does not allow the user to shock the patient with the monitoring cable attached.

Post-Use Procedures

After each use, the defibrillator should be inspected, cleaned, and a new supply of electrode pads restocked to prepare the unit for its next use. Any event documentation should be retrieved from the internal log or external memory card and printed.

Print or transfer the log information from the internal memory or the external memory PCMCIA card. After data retrieval, clear the internal memory. Any error messages or malfunctions should be reported and corrective actions taken before storing the unit for reuse.

During storage, the defibrillator performs periodic self-tests including the functionality of the unit and the status of the battery and internal circuitry. A more detailed test of the unit's operation and battery status should be performed on a regular basis. See ["Maintenance"](#) on page 55.

4

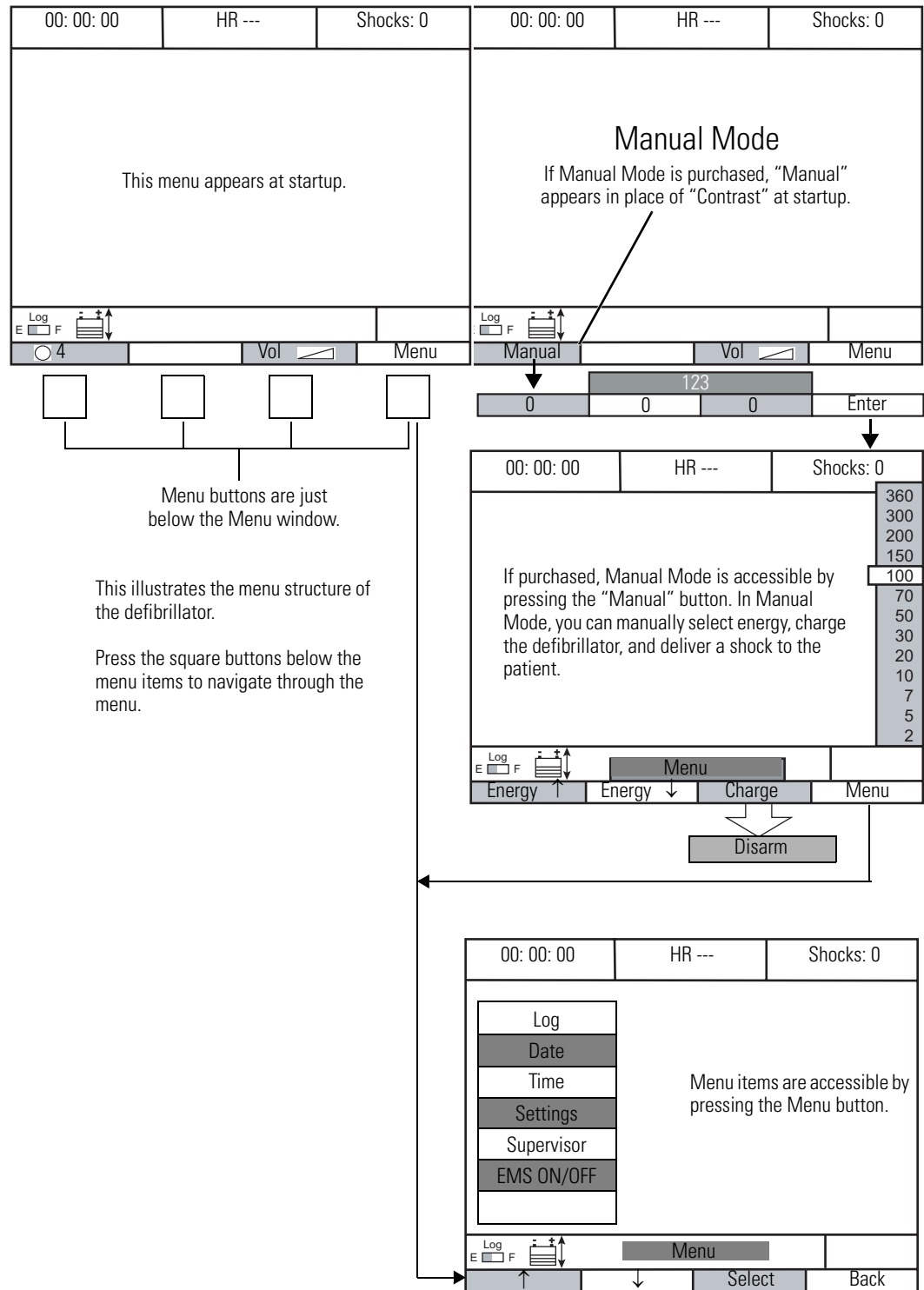
Programming

This chapter explains how to set the basic system operating options through the User Menu (Automated or Manual Mode). It also provides information on accessing and setting the advanced system operating options using the Supervisor Menu.



Caution Advanced system operating options, such as Manual Mode and EMS Mode, are intended for use only by trained medical professionals. These options should be selected only if defined by a Supervisor as part of the usage protocol for this device.

Menu Structure Diagram



This illustrates the menu structure of the defibrillator.

Press the square buttons below the menu items to navigate through the menu.

Menu buttons are just below the Menu window.

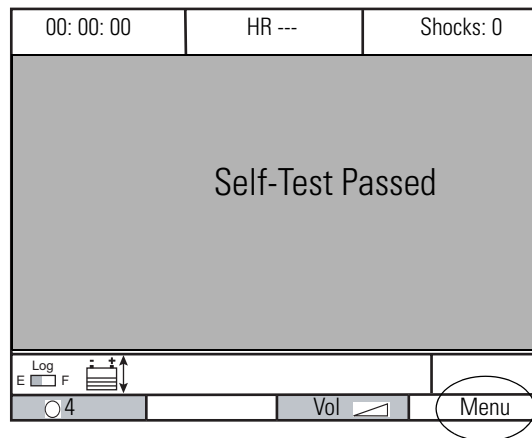
Menu Structure Overview

The operating options are available to the operator through a simple menu structure. The basic system operating options are accessed through the User Menu in either Automated or Manual Mode. The advanced system operating options are accessed through the Supervisor Menu.

The defibrillator has the capability for certain menu buttons to auto repeat. Buttons with more than one choice will auto repeat, and the up and down arrows will scroll through the choices for a selection. To make a button auto-repeat, hold it down until the desired choice is selected.

Accessing the User Menu from Automated Mode

When the defibrillator is powered-up, the defibrillator performs a self test and the start-up screen displays. Access the User Menu by pressing "Menu" in the lower right corner.

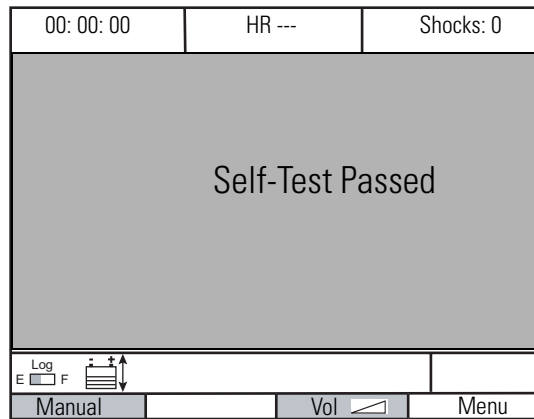


If the Manual Mode is purchased, MANUAL appears in place of the contrast menu on the start-up screen.

Accessing the User Menu from Manual Mode

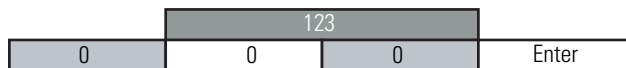
(Available only on defibrillators with Manual Mode.)

When the defibrillator is powered up with the Manual Mode option installed, the defibrillator performs a self test and the manual mode start-up screen displays.

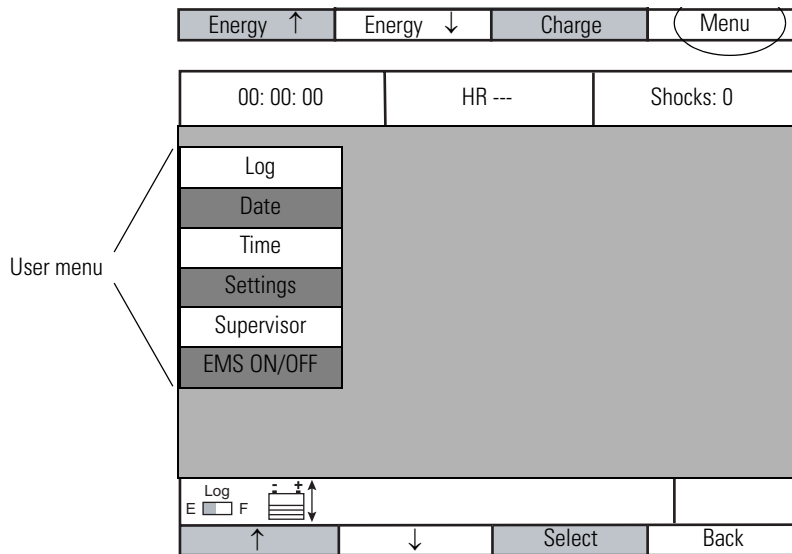


To access the Manual Mode Menu

1. Press **Manual** to display the manual mode passcode screen.



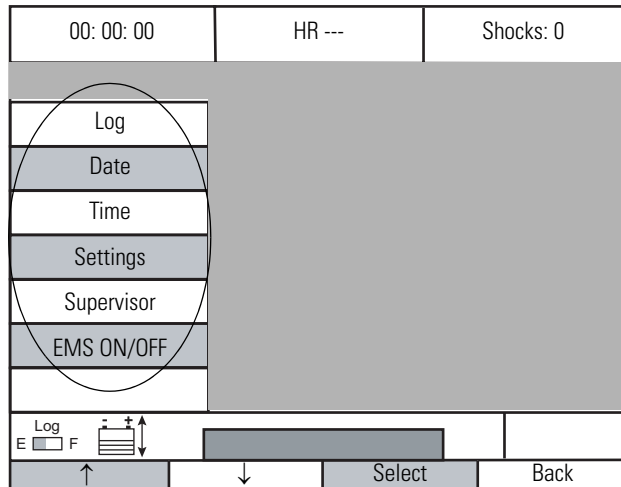
2. Press the button below the corresponding number to select that digit of the manual mode passcode.
3. Repeat Step 2 for each digit of the passcode until the correct number displays.
The default password is **1-2-3**.
4. Press **Enter** to accept the passcode. If the number is correct, the defibrillator enters manual mode.
5. Press **Menu** to display the User Menu screen.



Note Press **Back** to return to the Manual Mode operating screen.

User Menu

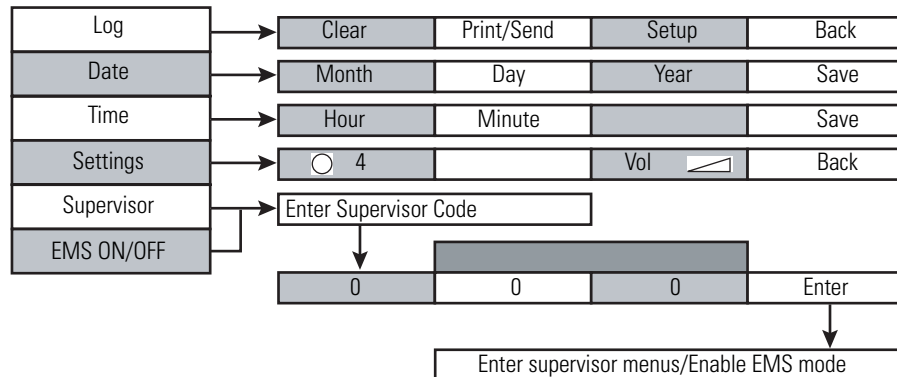
Use the two arrow buttons on the bottom menu to move from one menu selection to the next. The selected menu item is highlighted by a black box. Push the Select button to select the highlighted menu item.



Log	Enable viewing, hearing, printing, or transferring of the internal log.
Date	Display the current date, and set and save a new date (month, day, year) using the buttons below the Menu Bar.
Time	Display the current time, set, and save a new time (hour, minute) using the buttons below the Menu Bar.
Settings	Adjust the LCD contrast and adjust the volume of the system audio and save the settings.
Supervisor	Enter the password code using the buttons below the Menu Bar to display the Supervisor Menu selections.
EMS	Will toggle between "EMS ON" and "EMS OFF" after user enters valid passcode. The active EMS mode is the value displayed on the menu.

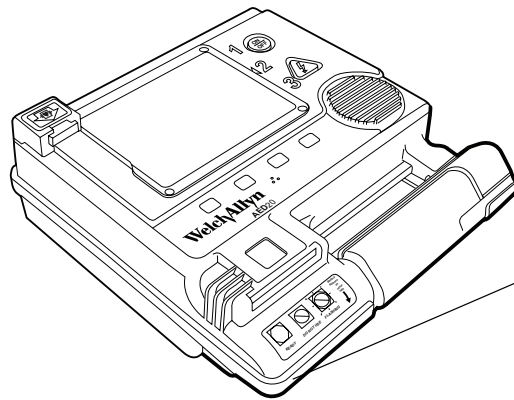
For each menu item selected, the corresponding option appears at the bottom of the display. If Supervisor or EMS is selected, the user must enter the correct supervisor passcode in order to enter the Supervisor Menu selection screen or to change the EMS mode.

User Menu Structure Overview



Working with the Log

The log contains a record of ECG tracings and time-stamped system status events. The log can be transferred to a PCMCIA card or transferred to a PC for viewing. Use the appropriate setup procedure to connect the PC to the defibrillator, then follow the instructions for printing.



Connect cable end with bead to the data port

To set up a PC for viewing

Note The Welch Allyn AED PC Data Transfer/Serial Communication Kit (002170-E or 002171-E) is required for this connection.

ECG or Text can be used to transfer data to a PC or the RS232 option with Welch Allyn Smartlink software can be used for easy data archiving and playback.

1. Connect the Serial Communication Cable (551778) into the defibrillator serial data port and the other end into the PC Data Transfer Adapter (520468).
2. Connect the PC Data Transfer Adapter to the 9-pin serial port on your PC.
3. Use the Terminal or Serial Communications program on the PC to set the port settings to 57600 baud, N, 8, 1.

When the printer or PC is properly set up, turn on the output device and the defibrillator.

To print the log text report or ECG report

1. Access the User's Menu. Select **Log** to display the Log menu bar.



2. Press **Setup** to display the Print Setup menu bar.
3. Select **Text**, **ECG 112**, **ECG A4** or **ECG 8.5** and the appropriate serial port rate. Press **Back** to return to the Log menu bar.

Note ECG 112 setting prints on 4 3/8" (112mm) continuous roll thermal paper. This option is only supported for 112mm printers with a printing resolution of 8 dots/mm and Seiko ESC/P printer command-language conformity. Use 38400 bps for the Seiko DPU-3445-20A microprinter.

ECG A4 setting prints on A4 size paper (210mm x 297mm) printers with a printing resolution of 300 dpi and HP PCL3-6 printer command language conformity.

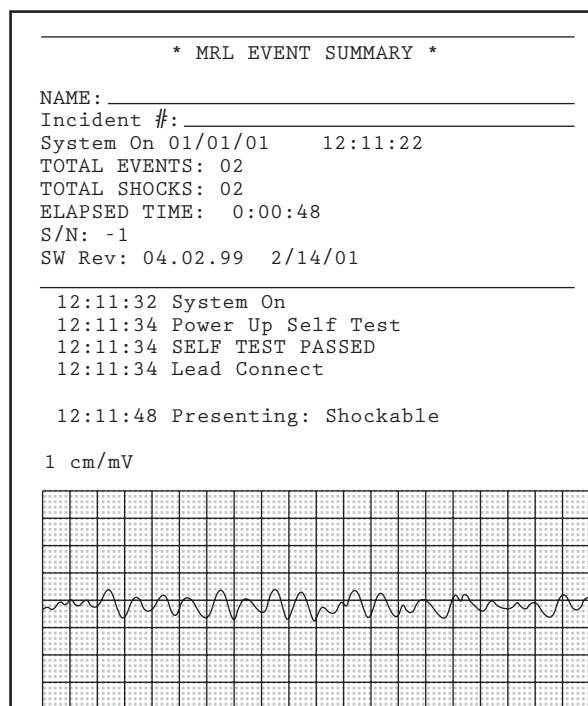
ECG 8.5 setting prints on 8.5 x 11 inch paper (216mm x 279mm) printers with a printing resolution of 300 dpi and HP PCL3-6 printer command language conformity.

4. Press **Print** to print the log report. A steady printer icon replaces the log icon to confirm printing. Stop printing by turning off the printer and pressing **Stop**.

Note A flashing printer icon indicates an error. Verify that the cable and adapter are connected correctly and check that the printer is online and has paper.

The "No Shock Advised" chart message has been changed to also show the heart rate with format "HR= nn." If the heart rate is out of range, the format is "HR= ---"

An example of a log ECG report with typical information is shown here.



5. Press **Clear** to remove all log entries.
6. Press **Back** to return to the Main Menu.

Setting the Date

Use the date screen to change the date. Use the menu selection buttons below the menu bar to change the date displayed.

To set a new date

1. Access the User Menu. Select **Date** and display the Date menu bar.



2. Press the buttons below the month, date, and year to change the date displayed.
3. Press **Save** to enter the date displayed and return to the User Menu.

Note Setting the date will force a new patient into the entry log.

Setting the Time

The defibrillator time-stamps events saved to the log. A 24-hour clock is used for time displays (e.g., 14:24 is used for 2:24 p.m.). Use the time screen and the menu selection buttons below the menu bar to change the time displayed.

To set a new time

1. Access the User Menu. Select **Time** to display the Time menu bar.



2. Press the buttons below the hour and minute to change the time displayed.
3. Press **Save** to enter the time displayed and return to the User Menu.

Note Setting the time will force a new patient into the entry log.


Adjusting the Contrast

The contrast of the defibrillator liquid crystal display can be adjusted. There are nine pre-set contrast levels available. Use the contrast screen and the menu selection button below the menu bar to change the contrast of the LCD.

To adjust the LCD contrast

1. Access the User Menu. Select **Settings** to display the Settings screen and menu bar.



2. Press the contrast button  to change the contrast of the LCD. The number next to the contrast icon changes corresponding to increases in the contrast (1-9).
3. Press **Back** to return to the User Menu.

Adjusting the Date Format

The date format used for printing reports with the defibrillator can be adjusted. There are six pre-set date formats available. Use the Settings screen and the menu selection button below the menu bar to change the date format used for printing reports.

To adjust the Date Format

1. Access the User Menu. Select **Settings** to display the Settings screen and menu bar.



2. Press the Date Format button (mm/dd/yy) to change the date format used for printing reports. The date format changes to one of six formats.
3. Press **Back** to return to the User's Menu.

Adjusting the Speaker Volume

The volume of the voice prompts through the speaker can be adjusted. There are four pre-set volume levels available. Use the volume screen and the menu selection button below the menu bar to change the volume of the voice prompts.

To adjust the volume

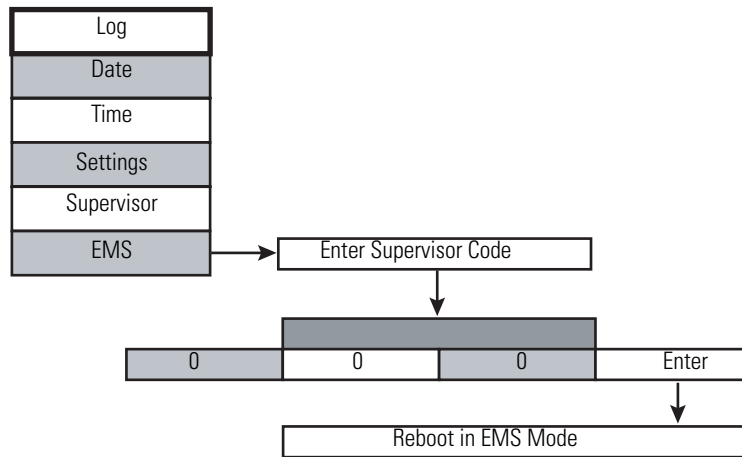
1. Access the User Menu. Select **Settings** to display the Settings screen and menu bar.



2. Press **Vol** to change the volume of the voice prompts through the speaker. The indicator in the volume icon changes to one of four positions.
3. Press **Back** to return to the User Menu.

Enabling EMS Mode

EMS mode is a feature specifically designed for use by an Emergency Medical Technician. EMS mode is recommended when continuous defibrillator mode analysis is required while transporting a patient or performing another procedure such as intubation. EMS Mode is a supervisor selectable mode of operation that performs continuous background analysis, but requires the user to press the Analyze button for full analysis in response to a prompt from the defibrillator.

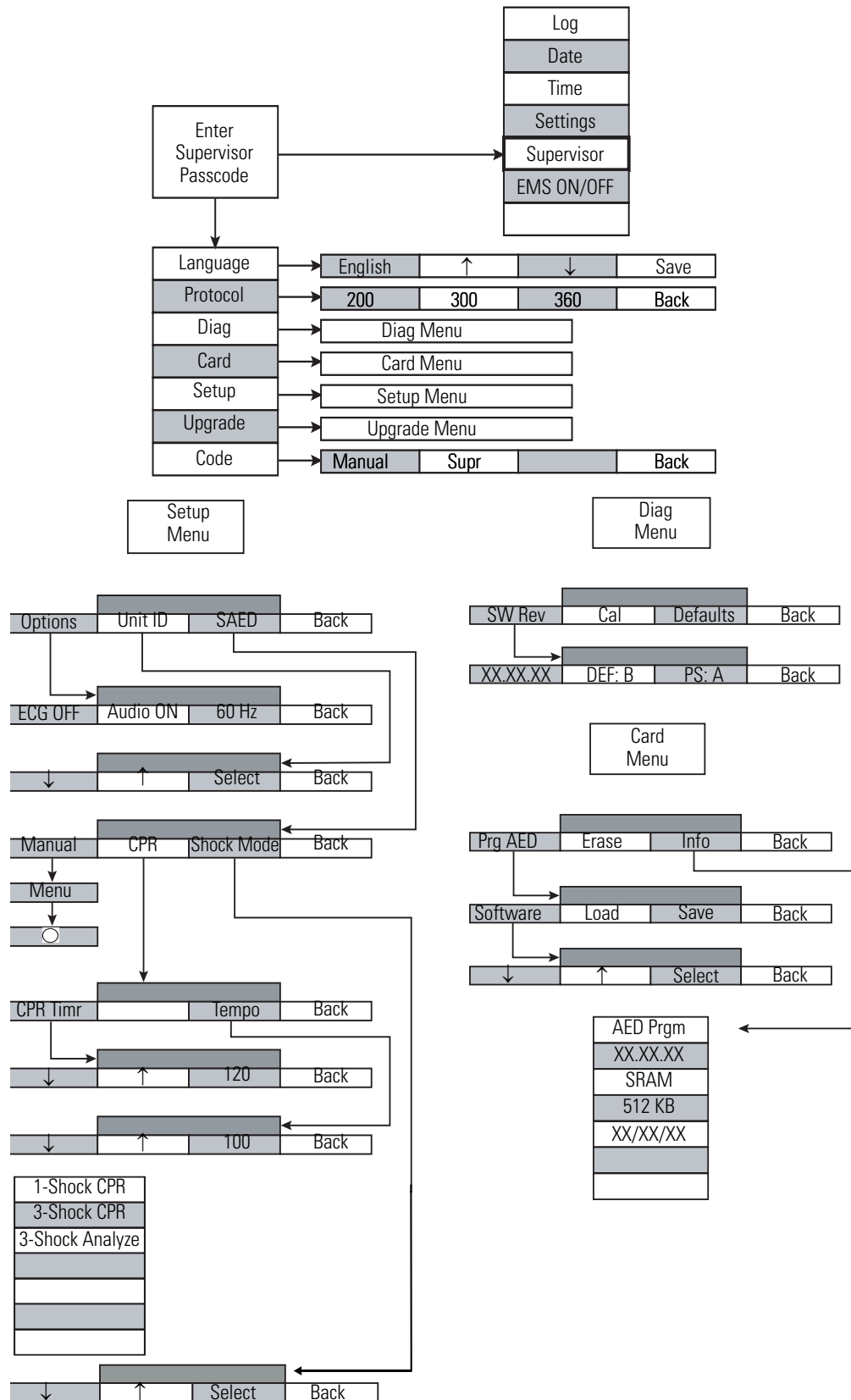


To Enable EMS Mode

1. Access the User Menu. Select **EMS Off** to display the Passcode Entry screen.
2. Enter the Supervisor passcode.
3. If the passcode is correct, the defibrillator reboots with EMS Mode ON.

Note Follow the same procedure to turn EMS Mode OFF.

Supervisor Menu Tree



Supervisor Menu

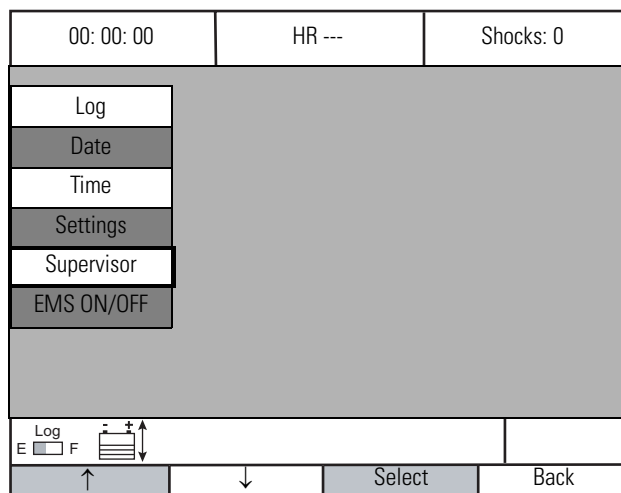
This explains how to access the Supervisor Mode Menu and set the options available through that menu.

Accessing the Supervisor Menu

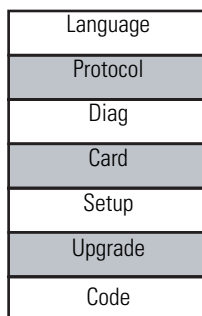
The Supervisor Menu is accessed from the User Menu screen.

To access the Supervisor Menu:

1. Go to the User Menu as described earlier in this chapter.
2. Use the up and down arrows to choose **Supervisor**, and press **Select**.



3. Enter the passcode and press **Enter**. The Supervisor menu appears.



- Language Select text and audio language using the buttons below the Menu Bar. (Restart the defibrillator to activate the language selected.)
- Protocol Select the energy level protocol using the buttons below the Menu Bar. Standard (default) protocol is 200J, 300J, and 360J (150J, 200J, 300J in the UK).
- Diag View software revisions/reset factory defaults.

Card	Access PCMCIA card functions.
Setup	Enable or disable the ECG trace and audio recording, 50/60 Hz., set unit ID, set time duration for the CPR timer, set CPR metronome tempo or select 1- or 3-Shock protocol.
Upgrade	Add upgrade options to the system.
Code	Set both the Manual Mode and the Supervisor Mode pass code numbers using the buttons below the Menu Bar.

Selecting a Language

The language used for text on icons, screen displays, and prompts as well as used for voice prompts can be changed in the defibrillator.

To select a different language

1. Access the Supervisor Menu. Select **Language** and display the Language screen and menu bar.



2. Press the buttons below the arrows to change the language.
3. Press **Save** to select the language displayed and return to the Supervisor Menu.
4. Restart the defibrillator to activate the language selected and change the screen text and voice prompts.

Setting the Charge Protocol

The defibrillator energy protocol is controlled solely by the Supervisor > Protocol menu. The default energy protocol is 200 Joules, 300 Joules, and 360 Joules. Use the menu selection button below the menu bar to change the shock charge displayed.

To set a new shock charge

1. Access the Supervisor Menu. Select **Protocol** and display the protocol menu bar.



2. Press the button below the digit to toggle the values.
3. Press **Save** to enter the charge displayed and return to the Supervisor Menu.

Energy Selections Available

Shock 1	Shock 2	Shock 3
150 J	150 J	150 J
200 J	200 J	200 J
	300 J	300 J
		360 J

Using **Supervisor > Language** to select a different language no longer causes a change in the energy protocol for any language. Before installing software from a PCMCIA card, it is necessary to record the energy protocol setting, load the software and restore the energy protocol setting if it is not the default.

Diagnostics

Use the diagnostics screen to view the installed versions of the software and restore factory defaults.

Note Battery and threshold calibration must be performed by authorized service personnel only.

To view software revisions

1. Access the Supervisor Menu. Select **Diag** to display the Diagnostics screen and menu bar.



2. Press **SW Rev** to display the revisions of the current software for the motherboard (xx.xx.xx), defibrillator (DEF:), and the power supply (PS).



Note Pressing the leftmost button while the motherboard software revision is displayed displays the FPGA device revision.

3. Press **Back** to return to the Diag menu. Press **Back** again to return to the Supervisor Menu.

To restore factory defaults

1. Access the Supervisor Menu. Select **Diag**. to display the Diagnostics Menu.

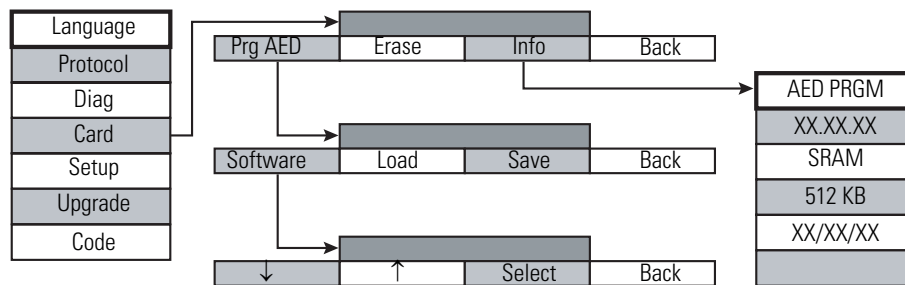


2. Press **Defaults** to return the values to the factory settings.
3. Press **Back** to return to the Supervisor Menu.

Viewing Information on the PCMCIA Memory Card

The internal memory can record and output event documentation to a printer. Additional memory storage is available using a removable PCMCIA memory storage card. Use the card screen and the menu selection button below the menu bar to erase the external memory card and program the defibrillator for software upgrades.

Note Erase the card before first use to format it.



To view information on the PCMCIA memory card

1. Access the Supervisor Menu screen. Select **Card** to display the Card menu bar.



2. Press **Info** to view the size, type, contents, and format date.
3. Press **Back** to return to the Supervisor Mode Menu.

To Program the defibrillator from a Memory Card

1. Access the Supervisor Menu screen. Select **Card** to display the Card Menu bar.
2. Insert a program card into the memory card slot.
3. Press **PrgAED** to access the ProgAED Menu.
4. Select **Software**.
5. Enter the Reprogram code and press **Save**. The defibrillator reprograms and reboots with new software.

To Format a Memory Card

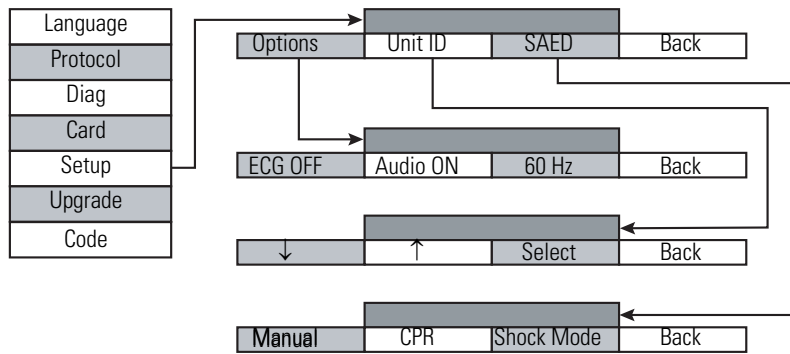
1. Access the Supervisor Menu screen.
2. Select **Card** to display the Card Menu.
3. Insert a Memory Card with Write Protect off in the memory card slot.
4. Press **Erase**. The card formats.
5. When complete, press **Back** to return to the Supervisor Menu.

Note After exiting the card menu, the card must be removed and reinserted before collecting any data.

Setting Options

Use the Setup screen to access system options and parameters. From this screen:

- Enable or disable the ECG trace, audio prompts, and adjust the notch filter.
- Assign a unit ID number to this defibrillator for the log record.
- Access the SAED menu to enable setting of the CPR timer, the Shock Mode and SAED-Manual mode Main Menu button configuration.



To enable/disable Options (ECG trace, audio, notch filter)

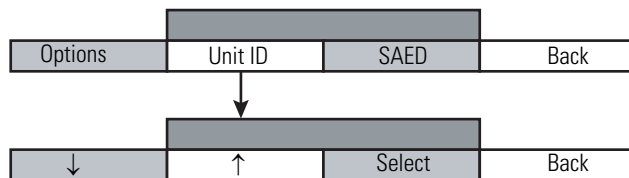
1. Access the Supervisor Menu screen. Select **Setup** to display the setup menu bar.
2. Press **Options** to display the options menu bar.
3. Press **ECG** to toggle between ECG trace ON and ECG trace OFF.

Note This option appears only when ECG tracing has been purchased.

4. Press **Aud ON** to toggle between Audio Recording ON and Audio Recording OFF.
5. Press **notch filter** to toggle between 50 Hz and 60 Hz.
6. Press **Back** to return to the Setup screen.

To set Unit ID

1. Access the Supervisor Menu screen. Select **Setup** to display the setup menu bar.
2. Press **Unit ID** to display the Unit ID menu bar.



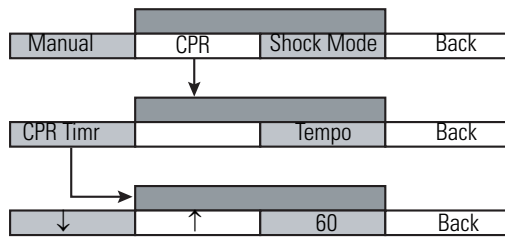
3. Press the up/down arrows to enter the code numbers of the Unit ID.

Note There are 16 available characters for the Unit ID.

4. Press **Save** to save the number and return to the Setup screen.

To set CPR Timer

1. Access the Supervisor Menu screen. Select **Setup** to display the Options setup screen and menu bar.
2. Press **SAED** to display the SAED menu which presents the CPR selection.
3. Press **CPR** to display the CPR menu bar. Press **CPR Tmr** to display the CPR Timer screen and menu bar.



4. Press the up/down arrows to change the time displayed for the CPR Timer.

Note Values available are 15, 30, 60, 90, 120, 150, and 180 seconds.

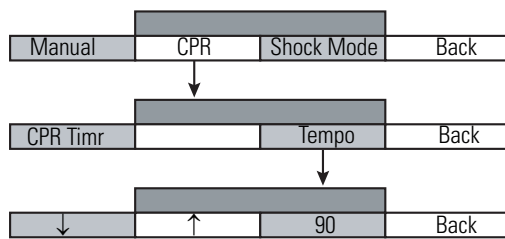
5. Press **Save** to accept the time set and return to the CPR screen (Manual Mode only).

Note In Automated Mode, pressing Save resets the CPR Timer and restarts the defibrillator.

To set CPR Tempo

Note Selection of a CPR Tempo option (other than Disable) provides an audible tone that assists in regulating the tempo of compressions administered during CPR.

1. Access the Supervisor Menu screen. Select **Setup** to display the Options setup screen and menu bar.
2. Press **SAED** to display the SAED menu which presents the CPR selection.
3. Press **CPR** to display the CPR menu bar. Press **CPR Tempo** to display the CPR Tempo screen and menu bar.



4. Press the up/down arrows to change the compressions per minute of the CPR Tempo.

Note Values available are 90, 95, 100, 105, 110, 115, 120, (compressions per minute) and Disable.

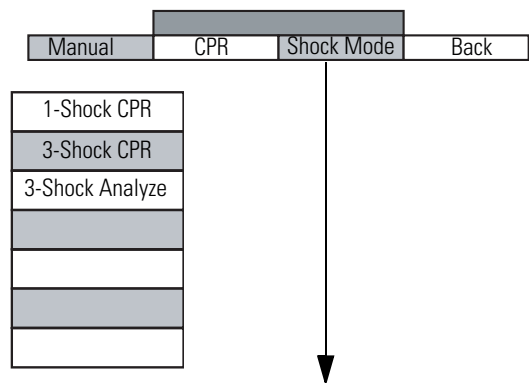
5. Press **Save** to accept the set CPR Tempo and return to the CPR screen.

To set Shock Mode

1. Access the Supervisor Menu screen. Select **Setup** to display the Options setup screen and menu bar.
2. Press **SAED** to display the SAED menu which presents the Shock Mode selection.



3. Press **Shock Mode** to display the Shock Mode menu which presents the shock variables.



4. Use the up and down arrows to select either 1-Shock CPR, 3-Shock CPR or 3-Shock Analyze and press select to make a selection.

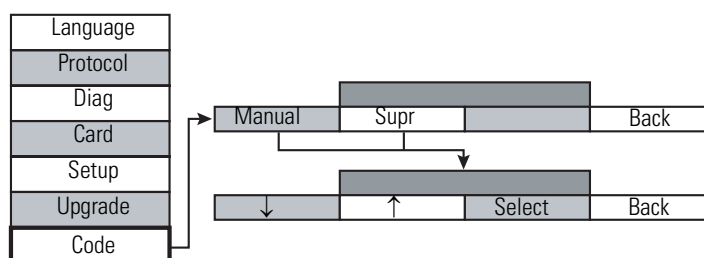
In 3-Shock Analyze mode, the defibrillator continues to analyze after detection of a heart rhythm not treatable with defibrillation. In 3-Shock CPR mode, detection of a heart rhythm not treatable with defibrillation causes the defibrillator to immediately enter a CPR cycle, and does not analyze until the CPR cycle is complete. In 1-Shock CPR mode, the behavior of the defibrillator will be similar to that on 3-Shock CPR mode, but the unit will require a CPR period after every shock delivered. Some of the prompts are also shortened in 1-Shock CPR mode.

Changing Manual and Supervisor Passcodes

Access to the manual mode and the manual/supervisor menus are protected by passcodes. The supervisor can change the passcodes. Use the code screen and the menu selection buttons below the menu bar to change the manual mode and supervisor mode passcodes.

To change a passcode

1. Access the Supervisor Menu. Select **Code** to display the Code setup menu bar.
2. Press either **Manual** or **Supr** to set code.



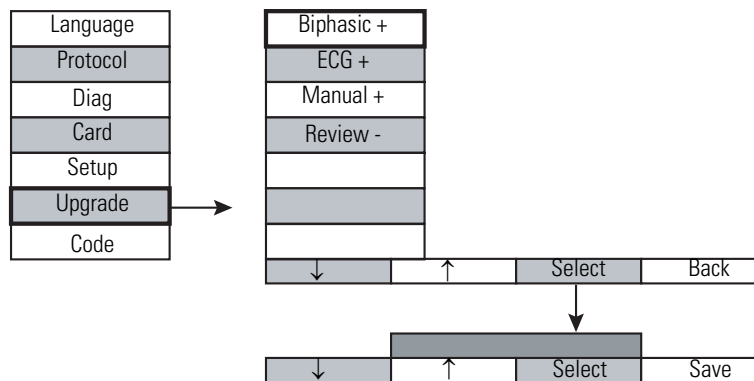
3. Press the up/down arrows to select the new passcode number.
4. Press **Save** to accept the new passcode and return to the Code Menu.

Upgrading the defibrillator

Upgrade options are currently available and new options available in the future can be added to the defibrillator system. Updating the software can be performed through the memory card port. Use the upgrade screen and the menu selection buttons below the menu bar to add or change the features of the defibrillator.

To upgrade the defibrillator

1. Access the Supervisor Menu screen. Select **Upgrade** and display the Upgrade screen and menu bar.



Note A plus (+) indicates that an option is currently installed and a minus (-) indicates that the option is not installed.

2. Choose the option to purchase, and press **Select**.

Note Each upgrade purchased has a unique upgrade password code that must be entered before the upgrade can be installed on the defibrillator.

3. Press the up/down arrows to select each the upgrade passcode digit.
4. Press **Select** to accept the digit entered.
5. Repeat steps 3 – 4 for each passcode digit.
6. Press **Save** to accept the new passcode.
7. Restart the defibrillator to enable/disable the option.

Setting the SAED-Manual mode Main Menu configuration:

The Supervisor > Setup > SAED > Manual/Menu/Contrast menu item is used to reconfigure the SAED-Manual mode Main menu. The default setting of this menu item is "Manual."

To set the SAED-Manual mode Main Menu configuration

1. Access the Supervisor Menu screen. Select **Setup** to display the Setup screen and menu bar.
2. Press **SAED** to display the SAED menu which presents the SAED-Manual mode Main Menu configuration selection.



3. Press the left button to toggle from “Manual” (default setting) to “Menu” to the Contrast icon.

The default SAED-Manual mode Main Menu has “Manual” on the left and “Menu” on the right. (Versions 07.01.01, 06.01.01, and later).



SAED-Manual Mode Main Menu when Manual is selected.

If the Supervisor > Setup > SAED > Manual/Menu/Contrast menu item is set to “Menu,” then the Main menu has “Menu” on the left and “Manual” on the right:



SAED-Manual Mode Main Menu when Menu is selected.

If the Supervisor > Setup > SAED > Manual/Menu/Contrast menu item is set to “○,” then the Main Menu has “○” on the left and “Manual” on the right. (Versions 05.XX.XX, 04.XX.XX, and earlier). If supervisors select this configuration, then entry into Manual mode with a password is necessary to access any menu.



SAED-Manual Mode Main Menu when the Contrast Icon is selected.

5

Maintenance

This section contains information on inspecting, maintaining, cleaning, and servicing the defibrillator.

Inspection

To ensure the readiness and optimum working condition of the defibrillator, it should be inspected and tested daily, weekly, or monthly, depending on the frequency of its use. The checks outlined in the operator checklists should be planned according to the inspection schedule outlined below. The goal is to maintain the defibrillator in an operation-ready state.

Also check new pads or other accessories for compatibility with the defibrillator when they are first received.

Scheduling Inspections

Inspect each defibrillator regularly to ensure that it is ready for service when needed. The following table presents guidelines for determining an appropriate inspection schedule for your defibrillators.

Frequency of Use	Inspection Schedule
Weekly	Daily
Monthly	Weekly
Rarely	Monthly

Note When powered by a non-rechargeable battery, the defibrillator must be used very infrequently to prolong battery life.

Note If the defibrillator is used more than once per month, it is recommended that authorized service personnel perform a periodic inspection servicing at least once per year.

Power-Up and Self-Test

Press the ON button to power-up the defibrillator and automatically perform a self-test. At power-up, the following tests are performed: battery, main processor, memory and program, stuck key, ECG preamp, and defibrillator.

If the built-in sensors in the defibrillator detect a problem prior to or during operation, the defibrillator provides a voice or screen prompt indicating the problem.

“[Troubleshooting](#)” on page 65 lists fault indicators and determines possible corrective actions.

Inspecting for Damage

Before every use, inspect the defibrillator, the pad connector, and battery. Look for signs of damage.

Note See the preparedness checklists later in this chapter for specific inspection requirements.

Contact an authorized service agent immediately if:

- The defibrillator is not functioning properly.
- Any connector or cord shows signs of deterioration.
- The defibrillator was subjected to extreme mechanical stress (e.g., falling from a cart).
- Liquid was spilled on the defibrillator.

Service and Repair



WARNING Hazardous voltage. To reduce the risk of electrical shock, do not attempt to remove the cover under any circumstances. There are no operator serviceable components and only a qualified technician should service the defibrillator.

WARNING Do not disassemble the defibrillator. There are no operator serviceable components. Service and repair should be performed only by authorized service personnel.

If a defibrillator needs servicing, contact a Welch Allyn authorized service agent (see page ii). Be prepared to provide the following information:

- Model
- Serial number
- Description of the problem

If the defibrillator needs to be returned for servicing, use the original shipping container. If the shipping container is not available, please contact Welch Allyn ([page ii](#)) for packing instructions prior to shipping so that the defibrillator is not damaged in shipping.

Note Information such as circuit diagrams, parts lists, descriptions, and calibration procedures needed to aid in repairing components designated as field repairable may be requested from Welch Allyn.

Checklists for Preparedness

Use the FDA Checklist and Automated External Defibrillators: Operator’s Checklist to help maintain the defibrillator in an operation-ready condition.

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. The log provides a:

- Record of the maintenance performed, who performed it, and when it was completed.
- Schedule of periodic requirements such as calibration and certification.
- Tracking of accessories, such as batteries, that require periodic testing and replacement.

Automated External Defibrillators Operator’s Checklist

In accordance with the recommendations of the Defibrillator Working Group of the Food and Drug Administration (FDA), Welch Allyn provides this operator’s checklist. Use the Frequent Use Checklist if rechargeable NiMH batteries are used. Use the Infrequent Use Checklist for standby units utilizing non-rechargeable lithium batteries.

Automated External Defibrillator Operator’s Checklist Infrequent Use (Non-Rechargeable Battery)

Date: _____ Shift: _____ Location: _____
Welch Allyn AED Serial No. or Facility ID No. _____

Description	OK as found	Corrective Action/Remarks
Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
Cables/Connectors		
Inspect for cracks, broken wire, or damage		
Connectors are engaged securely and are not damaged		
Supplies		
Two sets of pads in sealed packages within expiration date		
Hand towel		
Scissors		
Razor		
Alcohol wipes		
Spare battery		
Spare PCMCIA data card (optional)		
Power Supply		
Verify non-rechargeable (long storage life) battery inserted and within the expiration date		
Verify that the system ready indicator shows READY		
_____ Signature	_____ Print Name	

Automated External Defibrillator Operator's Checklist Infrequent Use (Rechargeable Battery)

Date: _____ Shift: _____ Location: _____
Welch Allyn AED Serial No. or Facility ID No. _____

Description	OK as found	Corrective Action/Remarks
Defibrillator Unit		
Clean, no spills, clear of objects on top, casing intact		
Cables/Connectors		
Inspect for cracks, broken wire, or damage		
Connectors are engaged securely and are not damaged		
Supplies		
Two sets of pads in sealed packages within expiration date		
Hand towel		
Scissors		
Razor		
Alcohol wipes		
Spare battery		
Spare PCMCIA data card (optional)		
Power Supply		
Fully charged battery inserted and within the expiration date		
Spare charged battery available		
Battery rotation/conditioning schedule has been followed		
System-ready indicator shows READY		
Indicators/ECG Display		
Remove the PCMCIA card (if used)		
Power on and verify display is on		
Self-test passed		
"Apply Defibrillation Pads" is spoken		
Correct time displayed		
Charge/Display Cycle: Attach the simulator		
Detects, charges, and delivers shock for VF		
Responds correctly to non-shockable rhythms		
Enter manual override mode, connect the defibrillation test load, charge to 360 J, and fire the defibrillator		
Verify delivered energy = 360 J \pm 36 J		
Replace the PCMCIA card (if used)		
Major problems identified (out of service)		
Signature _____	Print Name _____	

Maintenance Schedule



Caution Improper maintenance may cause the defibrillator to malfunction. Maintain the defibrillator as described in this manual.

Prepare a customized maintenance schedule for the defibrillator to reflect how the unit will be used. The schedule should account for how often the defibrillator is used and where it is used. In addition, the schedule should consider how familiar the operators are with the operation of the defibrillator. Here are some guidelines for preparing a maintenance schedule at your facility:

Note When powered by a non-rechargeable battery, the defibrillator must be used infrequently to prolong battery life.

Frequency	Observe	Action
Daily and after each use	Check the status indicator. Verify that the “ready to use” status indicator on the front of the defibrillator is operating.	If the status indicator is flashing, replace the battery. If a solid red symbol appears, remove defibrillator from service and contact Welch Allyn customer service.
Weekly and after each use	Inspect exterior of the defibrillator and pad connector for any signs of damage.	Clean the defibrillator. If damaged, remove defibrillator from service and contact Welch Allyn customer service.
Monthly	Capacity Test for rechargeable batteries	See “Battery Capacity Test—Rechargeable Batteries” on page 61.
After each use	Make sure that all supplies and accessories are present and in proper operating condition. Inspect the defibrillation pad packages, and battery packs for “install before dates” and any signs of damage. Recharge/replace battery.	Do not use damaged or expired supplies or accessories. Replace any used supplies and accessories such as razors, gloves, and pads. If using a rechargeable battery, place a fully charged battery into the defibrillator and recharge the used battery to full. If using a non-rechargeable battery, check the battery capacity shown in the battery gauge on the display. If “Low Battery” is indicated, remove the battery and replace with a new battery. Dispose of the battery properly according to local authority disposal standards. Always verify that a fully charged spare battery is available for use.
	PCMCIA data card (if used).	Remove the PCMCIA data card and replace it with a blank card. Apply a patient ID label to the removed card and deliver it for review.
	Steady red status indicator symbol.	Replace/recharge battery. Turn on the defibrillator, if possible, and note the self-test result.

Battery Maintenance

Two types of batteries can power the defibrillator:

- Rechargeable NiMH (Nickel Metal Hydride) PowerStick battery for frequent use.

- Non-rechargeable Lithium PowerStick battery for standby use. This type of battery cannot be recharged. The charger does not attempt to charge a non-rechargeable battery.

Either type of battery may be installed in the defibrillator.



Caution Use only Welch Allyn PowerStick batteries in the defibrillator.

Caution Using an improperly maintained battery may result in power failure without warning when operating the defibrillator.

Charger and Battery Care for Rechargeable Batteries

To achieve optimum performance from the Welch Allyn Charger/Conditioner and PowerStick battery:

- Charge battery packs in a moderately cool environment, 5 °C to 30 °C (41°F to 86 °F). Charging batteries outside the recommended temperature range may cause improper charging and shorten battery life. All NiMH 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).
- Place the charger in an area where air is allowed to circulate freely on all sides.
- Do not place the charger near a heat source or in direct sunlight.
- Always charge stored batteries prior to use. Stored batteries lose charge and may cause the defibrillator to fail without warning.
- Recharge a rechargeable battery until it is fully charged and the Ready light on the charger indicates a solid green.
- Perform periodic conditioning cycles on batteries.

Recommended Conditioning Schedule (Rechargeable Batteries Only)

- If batteries are charged in moderate temperatures and are used with low to medium frequency (one or less charge/discharge cycles per day), recondition battery packs every 90 days.
- 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 every 30 days. (See [“Battery Charging and Conditioning”](#) on page 17.)

Guidelines for Maintaining Peak Battery Performance

Note These procedures apply only to the rechargeable battery.

- Each battery should be identified with a number or letter. An identification mark will be useful in tracking battery performance.
- Keep spare batteries in a Welch Allyn charger where their status can be quickly determined. This is the most positive means of maintaining a fully charged battery.

- Always carry at least one fully charged spare battery.
- Rotate spare batteries routinely. The charge level gradually diminishes in a battery after it is removed from the charger.
- Whenever possible, recharge a partially depleted battery. This can be accomplished following any incident that involves patient monitoring. It will ensure maximum operating time for each use, without reliance on spares. The need for a spare can then serve as an alert when an aging battery fails to provide normal operating time.

Battery Contact Maintenance

When using a rechargeable battery (001829) in the defibrillator, battery contact cleaning is recommended once a month. If a battery is installed more than twice in a day, cleaning is recommended once a week. Using a dry cotton swab, insert cotton swab into the battery compartment and make several passes over the spring loaded battery contact to remove any visual signs of foreign material. Using another dry cotton swab, clean the contacts on both sides of the battery and check for any visual signs of foreign material on the contacts.

Battery Capacity Test—Rechargeable Batteries

Test the PowerStick rechargeable batteries monthly to determine battery capacity for monitoring. This helps the user approximate the amount of time available for monitoring when the battery icon is displayed.

Note Perform the capacity test with a fully charged rechargeable battery. Do NOT perform this test on a non-rechargeable battery.

To perform a battery capacity test

1. Connect a patient simulator or a defibrillator test load to the connector cable. Without the simulated patient connection, the monitor automatically shuts off in ten minutes. Turn on the monitor and note the starting time.
2. Verify continued operation every 30 minutes or less.
3. Note the time when the battery runs out. This duration of time relates to the current battery capacity. A typical battery should provide at least 2.5 hours of monitoring time.
4. If the operating time is less than 2.5 hours, recharge the battery and repeat the test. If the operating time remains less than 2.5 hours, remove the battery from service and replace it.
5. Fully recharge the battery prior to returning it for use.

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.

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

Recycling Defibrillator Components

Within the European Union

Do not dispose of this product as “unsorted municipal waste.” Prepare it for reuse or separate collection as specified by Directive 2002/96/EC of the European Parliament and the Council of the European Union on Waste Electronic and Electrical Equipment (WEEE).

If the defibrillator or battery (NiMH or Li) is contaminated, this directive does not apply.

For more specific information, see www.welchallyn.com/weee, or contact Welch Allyn Customer Service.

Recycle defibrillator batteries (NiMH or Li) according to the Directive 91/157/EEC (Batteries and accumulators containing certain dangerous substances) and Directive 93/86/EEC (Labelling of batteries and accumulators containing certain dangerous substances).

Outside the European Union

When the defibrillator or the battery (NiMH or Li) reaches end of life, recycle it locally according to national, state, and local regulations, or return it to Welch Allyn.

Cleaning and Disinfecting

Clean and disinfect the defibrillator regularly and observe the following cleaning and disinfecting guidelines:

- Clean the defibrillator with the battery in place to keep liquids out of the battery contact area. Make sure liquid does not get into the electrode pads connector or the RJ45 connector.
- Use a soft cloth. Do not use abrasive materials, cleaners, or strong solvents such as acetone or acetone-based cleaners.



Caution Do not immerse any portion of the defibrillator in water or other liquids. Avoid spilling any liquids on the defibrillator or accessories. Liquids may damage the defibrillator or present a fire or shock hazard.

Caution Do not autoclave or gas sterilize the defibrillator or accessories.

The following are recommended cleaning agents for use on the exterior of the defibrillator:

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

Never use any of the following cleaning agents on the defibrillator:

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

6

Troubleshooting

This chapter provides information on how to troubleshoot situations and conditions that arise during the operation of the defibrillator and gives answers to frequently asked questions.

Overview

If the built-in sensors in the defibrillator detect a problem before or during operation, the unit provides a voice or screen prompt indicating the problem.

Use the information in the following tables to troubleshoot. The tables list fault indicators and possible corrective actions.

Note In some situations, the operator will be instructed to change the battery or defibrillation pads. It is important to always have spare batteries, PCMCIA cards, and other accessories available.

Attaching Defibrillation Pads

Indicator/Possible Cause	Corrective Action
Defibrillation pad does not adhere properly to the patient.	Wipe moisture from chest and/or shave excessive hair from chest.
Defibrillation pads are dry, damaged, or out-of-date.	Replace the defibrillation pads.
Improper pad placement or pads touching each other.	Check pad placement; make sure pads are in the correct location.
Inadequate connection to defibrillator.	Check for proper insertion of defibrillation pads connector into defibrillator.
Pads connector not connected or properly inserted into the connector socket.	Push pads connector firmly into the connector socket.
Poor defibrillation pad contact with the patient's bare chest.	Press firmly on defibrillation pads to improve adherence to patient's skin.

Analyzing Interrupted

Indicator/Possible Cause	Corrective Action
Defibrillator pad removed.	Press defibrillation pad to firmly attach it to patient's skin. If needed, replace the pad.
Electrical interference or radio transmissions.	Remove possible sources of electrical or radio interference.
Electrical/radio frequency interference.	Move hand-held communication devices or other suspected devices away from the defibrillator.

Electrode disconnected from patient or defibrillator.	Check the connection to the defibrillator.
Patient movement.	Move patient to stable location when possible.
Patient motion (CPR, seizures, etc.).	Stop patient motion if possible.
Transportation of the patient during vehicle motion.	Stop patient movement or, if possible, stop vehicle transportation during analysis.

Printing Problems

Indicator/Possible Cause	Corrective Action
Flashing Printer Icon. Incorrect or broken adapter.	Check adapter and baud rate settings.
Flashing Printer Icon. Incorrect or broken cable.	Check or replace with correct cable.
Defibrillator will not print. Incompatible printer, printer is off-line, or no paper.	Check for Welch Allyn-approved printer. Put printer in on-line mode. Replace paper in tray.
Defibrillator prints unreadable characters. Incorrect baud rate settings.	Ensure adapter and defibrillator have matching baud rate settings.
Error Tone. Incorrect Log Setup selection.	Select Text or ECG and the correct Baud Rate in the Log>Setup Menu.

Low Energy Delivered

Indicator/Possible Cause	Corrective Action
Improper pad placement or pads touching each other.	Check pad placement. Use the pictures on the pads to make sure they are in correct location.
Defective defibrillator.	Contact Welch Allyn Service.

No Shock Delivered

Indicator/Possible Cause	Corrective Action
Defibrillation pad connector not properly connected to the socket.	Push pads connector firmly into the connector socket.
Improper pad placement or pads touching each other.	Check pad placement. Use the pictures on the pads to make sure they are in correct location.
Pads, cable, or connector damaged.	Replace pads.
Poor defibrillation pad contact with patient's bare chest.	Press pads firmly to patient's bare chest. Wipe moisture from chest and/or shave excessive hair from chest. Replace the pad, if needed.
Shock button not pressed within fixed time limit.	Press Shock button within 30 seconds (Automated Mode) or 60 seconds (Manual Mode) after the ready message.
Electrode disconnected from patient or defibrillator.	Check the connection to the defibrillator.
Electrode Monitoring Cable is attached.	Connect defibrillator pads to defibrillator.

Defibrillator

Indicator/Possible Cause

Defibrillator operates, but LCD is too dark or too light.

Defibrillator turns off or will not turn on.

Battery depleted or disconnected.

Displayed time or date is incorrect.

Electrical/radio frequency interference.

Operating temperature is too low or too high.

Corrective Action

Adjust the contrast setting.

Reinstall or replace the battery.

Reinstall or replace the battery.

Change the defibrillator time setting. Verify that time is correct after a power ON/OFF cycle. If not, the internal 3V battery may need to be replaced.

Move hand-held communication devices or other suspected devices away from the defibrillator.

Operate the defibrillator between 0° to 50°C (32° to 122°F).

Battery

Indicator/Possible Cause

Defibrillator needs service.

Depleted battery.

No display or messages after ON button is pushed.

Low battery charge.

Battery not properly charged.

Operating time is short when using a rechargeable battery.

Corrective Action

Replace battery. If condition is not corrected, contact authorized service personnel.

Replace battery. If condition is not corrected, contact authorized service personnel.

Replace the battery.

Recondition the battery and run the battery capacity test. If operating time is still short, replace the battery.

Other Problems

Indicator/Possible Cause

A fault requires service.

Defibrillator operates, but LCD is blank.

Operating temperature is too low or too high.

LCD not operating properly.

Corrective Action

Continue to use the defibrillator if it is possible and needed. Contact authorized service personnel as soon as possible to repair the defibrillator.

Operate the defibrillator between 0° and 50 °C (32° and 122 °F).

Contact authorized service personnel.

Frequently Asked Questions

Will the defibrillator function correctly if I have reversed the placement of the electrode pads when I placed them on the patient's chest? Yes. The defibrillator's ability to analyze the rhythm and to deliver shocks is independent of the polarity of the electrode pads. (See ["Operating Procedures—Detail"](#) on page 23.)

Do I select the energy level with successive shocks? No. The energy level is pre-set when operating the defibrillator in Automated Mode. You can override the pre-set levels in manual mode. (See ["Operating Procedures—Detail"](#) on page 23.)

What do I do if a shock is advised while I am transporting a patient? Avoid shocking a patient during transport; movement may interfere with the accuracy of the rhythm analysis. Stop the transport if possible and allow the defibrillator to reconfirm the shockable condition.

Does the defibrillator battery have to be recharged? It depends on which battery is being used. The rechargeable NiMH PowerStick battery needs to be recharged. The non-rechargeable Lithium PowerStick battery should not be placed in the charger. (See ["Battery Charging and Conditioning"](#) on page 17 for information on charging the battery.)

What is the capacity of the battery? Battery capacity depends on the battery type and how long the battery has been in storage. See ["Specifications"](#) on page 71 for battery capacity specifications. When the unit is in storage, battery capacity will diminish over time. The defibrillator continuously monitors and reports battery capacity while in storage. The battery level status indicator alerts you when the battery needs to be replaced.

A

Glossary

AED Automated external defibrillator

AHA American Heart Association

ALS Advanced life support

arrhythmia Irregular rhythm of the heart muscle

BLS Basic life support

bradycardia Abnormally slow heart rate

cardiac arrest Cessation of the heart muscle

CPR Cardiopulmonary resuscitation

defibrillation High energy pulse of electricity (shock) delivered to the heart muscle to restore normal cardiac activity

defibrillation protocol Pre-set order and level of the shock energy delivered at defibrillation (i.e. 150, 200, 300 J)

ECG Electrocardiogram

ECG trace Waveform displayed on the LCD representing the heart rhythm

electrocardiogram Curve traced by an electrocardiograph

electrocardiograph Instrument used to record electrical currents associated with heart muscle activity

EMS Emergency medical services

erythema Redness of the skin

fibrillation Rapid twitching movements that replace the normal rhythmic contraction of the heart and may cause a lack of circulation and pulse

LCD Liquid crystal display (defibrillator screen)

log List of ECG samples and time-stamped system events

Manual AED Defibrillator mode that provides text and voice prompts and ECG tracing; can be operated in manual mode

nonshockable rhythm Patient heart rhythms that are not a candidate for defibrillation pulse

NSR Normal sinus rhythm

Primary AED Defibrillator mode that provides text and voice prompts; does not provide ECG tracing

protocol See defibrillation protocol

RF Radio frequency

RJ45 port Connector located in the front of the defibrillator case used to transfer data from the log to a computer

SCA Sudden cardiac arrest

Secondary AED Defibrillator mode that provides text and voice prompts and ECG tracing

self-test Automatic test performed at system power-up to check readiness of battery, internal circuitry, main processor, and defibrillator

shock Defibrillation electrical pulse

shockable rhythm Abnormal heart rhythm which is a candidate for defibrillation pulse

tachycardia An abnormally fast heart rate

trace ECG waveform displayed on the screen

B

Specifications

Physical

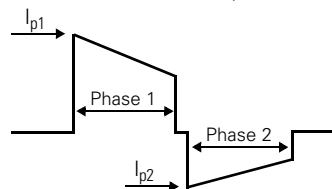
Dimensions	9.4"L x 8.9"W x 3.3"H (23.9L x 22.6W x 8.4 H cm)
Weight	Less than 5.4 pounds (2.45 kg) without battery
Operating temperature	32 °F to 122 °F (0 °C to 50 °C)
Storage temperature (without battery)	-22 °F to 150 °F (-30 °C to 65 °C)
Humidity	Up to 95% (non-condensing)
Altitude	-500 to 15,000 feet (-150 to 4570 m)
Shock	Mil Std 810E method 516.4, procedure 1 (40G, 6-9 ms pulse, 1/2 sine each axis)
Vibration	Mil Std 810E method 514.4, category 10 (minimum integrity test for helicopters)
Water resistance	IEC 60529 IPX4
In-flight use	Complies with RTCA/DO-160E, Section 21, Category M limits for radio frequency interference

Data Management

Event documentation	Internal and via Welch Allyn Datacard
Internal memory capacity	1MB: 75 4-sec ECG samples or 500 time-stamped events
Datacard capacity	4MB - 90 min of Continuous ECG 40 min of ECG and audio 8MB - 3 hrs of Continuous ECG 80 min of ECG and audio 16MB - 6 hrs of Continuous ECG 2.5 hrs of ECG and audio
Playback	Welch Allyn PIC or Smartview
Quick report	Treatment Summary, Event Log, Test Log
Datacard compatibility	Compatible with Welch Allyn PIC Advance Life Support Defibrillator
Communication	Serial port via RS-232 to PC and printer

Defibrillator

Output	Biphasic Truncated exponential
Energy sequence (user configurable)	Shock 1: 150 J, 200 J Shock 2: 150 J, 200 J, 300 J Shock 3: 150 J, 200 J, 300 J, 360 J
Manual energy selection (J)	2, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, 360
Automatic energy selection (J)	2, 5, 7, 10, 20, 30, 50, 70, 100, 150, 200, 300, 360
Manual lockout	Via passcode
Charge time to maximum energy (manual operation)	Frequent use: Less than 8 seconds with a fully charged battery; Less than 8 seconds with a battery depleted by 15 maximum-energy discharges. Infrequent use: Less than 8 seconds with a battery depleted by six maximum-energy discharges; Less than 8 seconds with a battery depleted by 15 maximum-energy discharges.
Charge time to maximum energy from initially switching power on, or from within any operator programming mode (manual operation)	Frequent use: Less than 25 seconds with a battery depleted by 15 maximum-energy discharges. Infrequent use: Less than 30 seconds with a battery depleted by six maximum-energy discharges; Less than 35 seconds with a battery depleted by 15 maximum-energy discharges.
Charge time to maximum energy from activation of the rhythm recognition detector (AED operation)	Frequent use: Less than 30 seconds with a battery depleted by 15 maximum-energy discharges. Infrequent use: Less than 35 seconds with a battery depleted by six maximum-energy discharges; Less than 40 seconds with a battery depleted by 15 maximum-energy discharges.
Charge time to maximum energy from initially switching power on, or from within any operator programming mode (AED operation)	Frequent use: Less than 40 seconds with a battery depleted by 15 maximum-energy discharges. Infrequent use: Less than 45 seconds with a battery depleted by six maximum-energy discharges; Less than 50 seconds with a battery depleted by 15 maximum-energy discharges.
Analysis time	12 to 16 sec.
Audible prompts	Minimum of 20 audible prompts
Visual prompts	Minimum of 13 text screen prompts
Controls	2 buttons - On/Off, Discharge 4 software-configurable buttons
Waveform details	The table below provides details of the biphasic truncated exponential waveform delivered by the defibrillator when set to the maximum energy selection and connected to resistive loads. The waveforms are characterized by typical values for peak current (I_p), duration of the first output phase ($t_{\text{phase 1}}$), and duration of the second output phase ($t_{\text{phase 2}}$). Values shown are accurate to within +15%.



Patient Impedance (Ω)	I_{p1} (Amps)	I_{p2} (Amps)	t_{phase1} (ms)		t_{phase2} (ms)	
			Max	Min	Max	Min
25	52	34	5.96	10.14	3.38	5.75
50	26	17	11.45	19.02	6.49	10.01
75	18	11	15.46	21.99	8.63	10.01
100	13	9	18.96	21.99	10.01	10.01
125	11	8	21.99	21.99	10.01	10.01
150	9	7	21.99	21.99	10.01	10.01
175	8	6	21.99	21.99	10.01	10.01

Output energy accuracy

Test Load	Energy Selections ^a												
	2	5	7	10	20	30	50	70	100	150	200	300	360
25 Ω	2	5	7	10	20	30	50	70	100	150	200	300	360
50 Ω	2	5	7	10	20	30	50	70	100	150	200	300	360
75 Ω	2	5	7	10	20	30	50	70	100	150	200	300	330
100 Ω	2	5	7	10	20	30	50	70	100	150	200	300	310
125 Ω	2	5	6	9	18	27	45	63	90	135	180	270	280
150 Ω	2	5	6	9	18	27	45	63	90	135	180	250	250
175 Ω	2	4	6	8	17	25	42	59	84	126	168	230	230

a. Values shown are accurate to within $\pm 15\%$ or 3 joules, whichever is greater.

AED 20 Pediatric Energy Reducer

Energy attenuation factor 25% at 25 Ω , 50 Ω , and 75 Ω
 20% at 100 Ω and 125 Ω
 15% at 150 Ω and 175 Ω

Display

Type 1/4 VGA Monochrome LCD
 Size 5.7" (145 mm) diagonal
 Resolution 320 x 240
 Freq response 0.5 - 40 Hz
 Heart rate 20 - 300 bpm, user-configurable
 ECG input Via defib pads, isolated, type BF, defibrillator-proof
 ECG sweep speed 25 mm/sec
 Low battery indicator Battery Icon gauge on display with 10 capacity levels
 Backlight (optional) EL backlight

Battery

Rechargeable	NiMH 12V, 2.1 Ah	
Capacity	80 discharges at 360 Joules or 120 discharges at 200 Joules or 150 discharges at 150 Joules or 3 hours ECG monitoring	
Charge time	1.5 - 2.5 hr	
Non-rechargeable	Lithium 12V, 5.2 Ah	
Capacity	AED Mode 200 discharges at 360 Joules or 285 discharges at 200 Joules or 300 discharges at 150 Joules or 6 hours ECG monitoring	Manual Mode 150 discharges at 360 Joules or 215 discharges at 200 joules or 225 discharges at 150 Joules or 6 hours of ECG monitoring
Shelf life (25 °C ± 15 °C)	10 years (5 years storage + 5 years standby) 5 years (standby after installation)	

Capacity may be diminished at extremes of operating temperature.

Electromagnetic Compatibility

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment. The AED 20 complies with IEC EN 60601-1-2:2001 and the requirements of EN60601-2-4:2003.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document and the *Welch Allyn AED 20 User Manual*.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The defibrillator complies with all required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is safe to operate the defibrillator in the presence of high-frequency surgical equipment.

However, it is good practice to avoid using the defibrillator in extremely close proximity to other equipment.

Guidance and manufacturer's declaration—electromagnetic emissions (IEC 60601-1-2 Table 201)

The Welch Allyn AED 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 20 should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Welch Allyn AED 20 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CSPP 11	Class B	
Harmonic Emission IEC 6100-3-2	No connection to mains (battery operated)	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	No connection to mains (battery operated)	

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in this document.

Guidance and manufacturer's declaration—electromagnetic immunity (IEC 60601-1-2 Table 202)

The Welch Allyn AED 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 20 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) ^a IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	No connection to mains (battery operated)	Since there is no connection to the mains, there is no requirement for mains quality.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	No connection to mains (battery operated)	
Voltage dips, short interruptions, and voltage variations on power supply input lines. IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	No connection to mains (battery operated)	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: U_T is the a.c. mains voltage prior to application of the test level.

- a. ESD ±4 kV air and ±2 kV contact allows no equipment change per EN60601-2-4:2003; follows normal EN60601-1-2:2001 criteria otherwise.

Guidance and manufacturer's declaration—electromagnetic immunity (IEC 60601-1-2 Table 203)

The Welch Allyn AED 20 is intended for use in the electromagnetic environment specified below. The customer or the user of the Welch Allyn AED 20 should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Portable and mobile RF communications equipment should be used no closer to any part of the Welch Allyn AED 20, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.			
			Recommended separation distance
Conducted RF IEC 61000-4-6	3 V _{rms} 150 kHz to 80 MHz outside ISM bands ^a	3V _{rms}	$d = 1.2 \sqrt{P}$
	10 V _{rms} 150 kHz to 80 MHz in ISM bands ^a	10V _{rms}	$d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m ^b 80 MHz to 2.5GHz	20 V/m	$d = 1.2 \sqrt{P}$ 80 to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz

Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).^c

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^d, should be less than the compliance level in each frequency range.^e



Interference may occur in the vicinity of equipment marked with this symbol.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

- The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.
- No unintended energy delivered at 20 V/m per EN60601-2-4:2003.
- The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
- Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the defibrillator is used exceeds the applicable RF compliance level above, the defibrillator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the defibrillator.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Welch Allyn AED 20 (IEC 60601-1-2 Table 205)

The Welch Allyn AED 20 is intended for use in an environment in which radiated RF disturbances are controlled. The customer or the user of the Welch Allyn AED 20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Welch Allyn AED 20 as recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)				
Rated maximum output power of transmitter (W)	150 kHz to 80 MHz outside ISM bands $d = [3.5/3] * \sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = [12/10] * \sqrt{P}$	80 MHz to 800 MHz $d = [12/10] * \sqrt{P}$	800MHz to 2.5 GHz $d = [23/10] * \sqrt{P}$
0.01	0.17	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.7	3.8	3.8	7.3
100	11.7	12.0	12.0	23.0

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

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

NOTE 2: The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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

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

Rhythm Recognition Performance

Standards

The defibrillator algorithm exceeds the requirements of ANSI/AAMI DF39-1993 section 3.3.18 and the sensitivity and specificity levels recommended by the AHA *Automatic External Defibrillators for Public Access Use: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance*. The test database includes shockable rhythms consisting of ventricular fibrillation rhythms (> 99 μ V) and wide-complex ventricular tachycardia at a rate greater than 160 BPM. Non-shockable rhythms include various sinus rhythms including supraventricular tachycardia, atrial fibrillation, atrial flutter, sinus rhythm with PVC's, asystole, pacemaker rhythms, and ventricular tachycardia with a rate less than 160 BPM and/or narrow complexes.

Performance

Rhythm Class	ECG Test Sample Size	Performance Goal	90% one-sided lower confidence level	Conclusion
Shockable: VF	90	>90% sensitivity	97.2%	Meets the AAMI DF39 requirement and AHA recommendation
Shockable: VT	33	>75% sensitivity	84.6%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: NSR	349	>99% specificity (AHA)	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: asystole	10	>95% specificity	100%	Meets the AAMI DF39 requirement and AHA recommendation
Nonshockable: all other rhythms	242	>95% specificity	97.8%	Meets the AAMI DF39 requirement and AHA recommendation

C**Parts List**

001829	Welch Allyn NiMH PowerStick - Rechargeable battery
001830	Welch Allyn PowerStick - Non-rechargeable battery
981125E	Battery Charger, 1Bay (to be used with 001829)
900216	Welch Allyn AED Carrying Case
001855	Multipurpose Defibrillation Pads (10 pair / box)
002120	Welch Allyn AED PC Data Transfer / Serial Comm Kit
002170	AED 20 Serial Communication Kit with SmartLink Event Reporting Software program
002171	AED 20 Serial Communication Kit with SmartLink Lite Reporting Software program
002128	IEC Electrode Monitoring Cable
002130	AHA Electrode Monitoring Cable
001726	Welch Allyn multi-purpose electrodes
980136	Welch Allyn Cardiolog Datacard – 4 MB
980143	Welch Allyn AED Trainer
001910	Welch Allyn Smartview Software Review Program
980139	Welch Allyn Patient Simulator
002174	AED 20 Pediatric Energy Reducer (p/n 002172), carrying pouch and instructions for use.

To purchase Welch Allyn accessories, contact your local Welch Allyn distributor (see [page ii](#)).

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Summary Of Studies Of Waveform Safety & 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 defibrillator (the Welch Allyn AED 20) 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 here.

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 Ω . 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 is 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 AED 20	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
Significance 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 \pm 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 is shown below. Also shown are the mean total durations measured for each device.

Summary Table -ED50, ID50, & Duration

Mean	Monophasic Waveform	Welch Allyn AED 20	2kV Biphasic Waveform
ID50 Peak Current (Amps)	9.0	6.4	8.3
Significance of difference (p-value)	<0.001 (Welch Allyn AED 20 vs. Monophasic)		<0.001 (Welch Allyn AED 20 vs. 2kV Biphasic)
ED50 Delivered Energy (Joules)	40.2	21.4	22.7
Significance of difference (p-value)	<0.001 (Welch Allyn AED 20 vs. Monophasic)		<0.4937 (Welch Allyn AED 20 vs. 2kV Biphasic)
Total Duration (msec)	11.9	12.3	13.1

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 MRL 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-Ω 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 is shown below. Also shown are the mean total durations measured for each device.

Summary Table -ED50, ID50, & Duration

Mean	Welch Allyn AED 20	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
Significance of difference (p-value)		0.885

Mean	Welch Allyn AED 20	2kV Biphasic Waveform
Total Duration (msec)	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 that 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 & Effectiveness Conclusions:

These scientific studies have demonstrated that:

- The data suggests that the MRL Orbital Biphasic waveform in the Welch Allyn AED 20 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.
- The MRL Orbital Biphasic waveform in the Welch Allyn AED 20 is as effective as the 2KV biphasic truncated exponential waveform in another commercially available defibrillator.
- The MRL Orbital Biphasic waveform in the Welch Allyn AED 20 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 defibrillators.

