AED 20

Automated External Defibrillator

User's Manual

Part Number 990020 - Revision K

WelchAllyn®
AED20

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Welch Allyn AED 20 Users Manual

Revision K compatible with software version 07.02.XX

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Preface

Welch Allyn AED20 Users Manual

WARNING!

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

Manufacturer

Manufacturer	MRL, Inc. A Welch Allyn Company 1000 Asbury Drive Buffalo Grove, IL 60089 USA (847) 520-0300
Product Name	Welch Allyn AED20
Device Type	Automated External Defibrillator

FDA Medical Device Registration

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

Please fill out the enclosed FDA Medical Device Registration postcard and return it promptly to Welch Allyn.

This card must be filled in and returned within 30 days of product delivery.

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

Manufacturer's Responsibility

Welch Allyn, Inc. is responsible for the safety, reliability, and performance of the Welch Allyn AED20, only if the following conditions are met:

- Assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by Welch Allyn.
- The Welch Allyn AED20 equipment 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 Welch Allyn AED20 Users Manual. As with all other electronic patient care monitors, good clinical judgment should be used when operating the Welch Allyn AED20. 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 Welch Allyn AED20 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, Inc. if you have any questions regarding this notice.

Telephone	847.520.0300
Toll-free	800.462.0777
Fax	847.520.0303
Internet	www.welchallyn.com

Declaration of Conformity

Manufacturer:

Medical Research Laboratories, Inc.,
a Welch Allyn company
1000 Asbury Drive
Buffalo Grove, IL 60089
USA
Phone (847) 520-0300
Fax (847) 520-0303

Welch Allyn Ireland
Navan Business Park
Dublin Road
Navan, Co. Meath
Republic of Ireland
Phone 011-353-466-7775

declares that the CE-marketed product

Product Name:	Welch Allyn AED20
Device Type:	Defibrillator / ECG Monitor
Model Number:	972200
Accessories:	See list in manual

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

Standards		
General:	ISO 9001	
	EN 46001	
Safety:	EC 60601-1 / EN 60601-1	Class II, Type BF, Internally Powered Continuous operation Defibrillator Proof Operation
	IEC 60601-1-4 / EN 60601-1-4	
	IEC 60601-2-4 / EN 60601-2-4	
	IEC 1441 / EN1441	
EMC:	IEC 601-1-2 / EN 60601-1-2	

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Joel Orlinsky — Date
Director of Q.A. and Regulatory Affairs

Conventions Used in the Manual

This section includes a list of conventions used in this 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!
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 Welch Allyn AED20, 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:

If the Welch Allyn AED20 is used more than once per month, it is recommended that authorized service personnel perform a periodic inspection servicing at least once per year.

Voice Prompts

The Welch Allyn AED20 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

Safety information is organized in six groups:

- General Cautions and Notices
- Patient Safety
- Defibrillator and Electrode Pads
- Battery and Charger
- Care and Storage
- Safety Symbols

Dropped or Damaged

If the device has been dropped or damaged in any way, refer the device to qualified service personnel for servicing.

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 equipment and the MRI device.

Labels

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

Performance

The Welch Allyn AED20 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 device to use by or on the order of a physician. If the battery pack is removed for any reason, labeling of the Welch Allyn AED20 is required indicating out-of-service for battery operation.

Patient Safety

General

Warning **Not for use on pediatric patients**
This defibrillator is not to be used on patients less than 8 years old.

Caution **Patient Physical Harm**
Place the Welch Allyn AED20 in a position where it cannot harm the patient should it fall. Keep all cables and connectors away from the patient's neck.

Caution **Use Automated Mode only when these conditions have been met**
Use Automated Mode only on victims of cardiac arrest who exhibit unconsciousness, absence of breathing, and absence of pulse.

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 **Manual mode is for qualified users only**
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 users manual.

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 **Welch Allyn AED20 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 labeled

"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 defibrillation pads**
Improperly placed pads may produce incorrect analysis and an inappropriate shock or no shock decision advisory.

Warning **Do not move patient**
Handling or transporting the patient during ECG analysis can cause incorrect or delayed diagnosis. Follow all instructions in the Advanced Users Manual.

Warning **Cardiac pacemakers may affect rhythm analysis**
Patient pacemakers may reduce the sensitivity of the Welch Allyn AED20 analysis and errors in detecting shockable rhythms.

Warning **Radio frequency (RF) interference**
Do not operate the Welch Allyn AED20 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 Welch Allyn AED20 in the presence of flammable anesthetics or concentrated oxygen.

Electrical Shock or Fire Hazard

Warning **No internal, operator-serviceable parts**
Do not open unit, remove covers or attempt to repair the Welch Allyn AED20. All servicing must be performed by qualified personnel.

Warning **Improper use can cause injury**
The Welch Allyn AED20 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 Welch Allyn AED20 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 Device Performance

Warning **Use only Welch Allyn-approved accessories**
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 labeling instructions on the defibrillation pads and the rechargeable 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 defibrillatio n

pads. Do not use pads if the packaging has been previously opened. The Welch Allyn AED20 may interpret excessively dry defibrillation pads as an attached electrode monitoring cable.

Caution **Do not repeatedly charge and discharge 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 Advanced Users 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 and Charger

Battery Care

Caution **Battery is shipped discharged**
Charge 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 Welch Allyn AED20.

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

Caution **Replace 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.

Charger Care

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.

Cleaning and Sterilization

Caution **Clean and maintain the Welch Allyn AED20 according to instructions.**
See* Chapter 4, *Maintaining the Welch Allyn AED20.
Do not clean the Welch Allyn AED20 with alcohol, ketone, or any flammable agent. Do not autoclave the Welch Allyn AED20 or attempt to sterilize the Welch Allyn AED20 or any of its accessories.

Electrodes

Warning **Follow manufacturer's instructions for use of defibrillation electrodes**
Improper use of defibrillation electrodes may cause the Welch Allyn AED20 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 Welch Allyn AED20 prior to 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 Welch Allyn AED20 and accessories. Please note the use of these symbols for safe and proper use of the equipment. For a list of icons that display operating status information, see Chapter 1 *Introducing the WELCH ALLYN AED.*

Attention, consult accompanying documents

Auxiliary power operation

Caution, high voltage

Dangerous voltage

Defibrillator protected, type BF patient connection

Earth (ground)

Negative input terminal

Positive input terminal

Recycle battery

Chapter 1

Introducing the Welch Allyn AED20

Welch Allyn AED20 Users Manual

This chapter provides an introduction to the Welch Allyn AED20 system and presents an overview of the Welch Allyn AED20 controls, indicators, displays, and prompts. It also provides instructions for getting the Welch Allyn AED20 ready for use and preparing the unit for storage.

Overview of the Welch Allyn AED20

The Welch Allyn AED20 (automated external defibrillator) is a safe, easy to use defibrillation device designed for use by basic life support (BLS) personnel. The unit is lightweight and mobile and can be used in situations where there could be several minutes before the arrival of advanced life support (ALS) personnel.

The Welch Allyn AED20 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 without a pulse, the Welch Allyn AED20 analyzes the patient's heart rhythm, provides text and audio instruction prompts, determines if a shockable situation exists, and, if appropriate, automatically arms the **Shock** button.

The Welch Allyn AED20 delivers the defibrillation shock through two self-adhesive, pre-gelled, low-impedance electrode defibrillator pads. The pads, cable, and connector are sold as disposable kits.

The Welch Allyn AED conforms to the AAMI DF39, *AHA Scientific Statement AED: Specifying and Reporting Arrhythmia Analysis Algorithm Performance*, and the IEC standard 601-2-04 for AEDs currently under development.

Features

Welch Allyn AED20 features include:

- 3-step operation
- extensive voice and visual prompts for the operator
- continuous ECG, audio, and event recording for reporting each use to a printer or computer

- daily self-test to ensure readiness
- rechargeable battery
- biphasic energy output
- lock-out protection to prevent inadvertent defibrillation

System Upgrades and Options

The Welch Allyn AED20 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, showing a biphasic defibrillation waveform, and on-screen log data review. 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

The Welch Allyn AED permits trained users to administer a brief electrical shock to patients experiencing fibrillation or sudden cardiac arrest (SCA).

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).

Getting the Welch Allyn AED20 Ready

Carefully unpack and inspect all the Welch Allyn AED20 system components and accessories. If using the rechargeable NiMH PowerStick battery, charge the battery fully before installing it. Install the battery, run the self-test, and set the date and time (see chapter 3 for instructions) before putting the unit into service.

Unpacking and Inspecting

Visually inspect the carton for any signs of damage or mishandling (carton perforations, cuts, or dents; bent or collapsed corners; or broken carton seal). Remove the Welch Allyn AED 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, Inc. Service Department at 847.520.0300 if anything looks damaged or is missing.

Installing the Battery

The Welch Allyn AED20 can use either a NiMH (Nickel Metal Hydride) PowerStick rechargeable battery or an extended-life, Lithium PowerStick non-rechargeable battery.

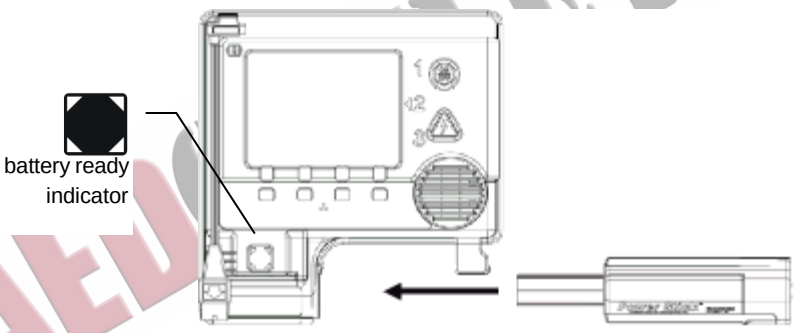
- Use the NiMH PowerStick rechargeable battery for applications involving frequent use.
- Use the Lithium PowerStick non-rechargeable battery for standby use.

The battery slides into the AED case and locks firmly in place. The battery forms the carrying handle of the Welch Allyn AED20 and therefore, you can always be sure that the battery is properly installed.

Using a non-rechargeable battery for training or testing will reduce the shelf-life and operating time of the battery.

To install the battery:

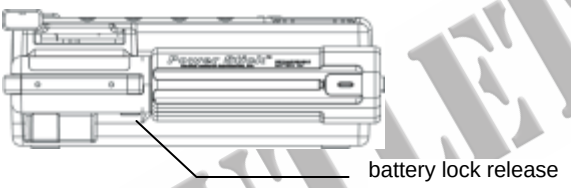
1. Align the thin, flat end of the battery with the opening in the lower front portion of the Welch Allyn AED case.
2. Push the battery in until it “clicks” and locks into place.



3. Make sure the battery ready indicator in the lower left of the display indicates that the battery has the sufficient charge. If the status indicator displays anything other than the Battery Ready icon, the Welch Allyn AED20 is not ready for use.

To replace the battery:

1. Push the lock release on the bottom of the Welch Allyn AED 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 Welch Allyn AED 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.

Getting to Know the Welch Allyn AED20

The Welch Allyn AED20 is an automated external defibrillation (AED) device designed for use by trained personnel. It features a straightforward, three-step operating design that uses extensive voice and visual prompts to assist the operator. With continuous ECG, audio, and event recording, the Welch Allyn AED20 maintains a detailed log that can be viewed on screen or reported directly to a computer or printer.

Welch Allyn AED20 Configurations

Three Welch Allyn AED configurations are available: Primary AED, Secondary AED, and Manual AED.

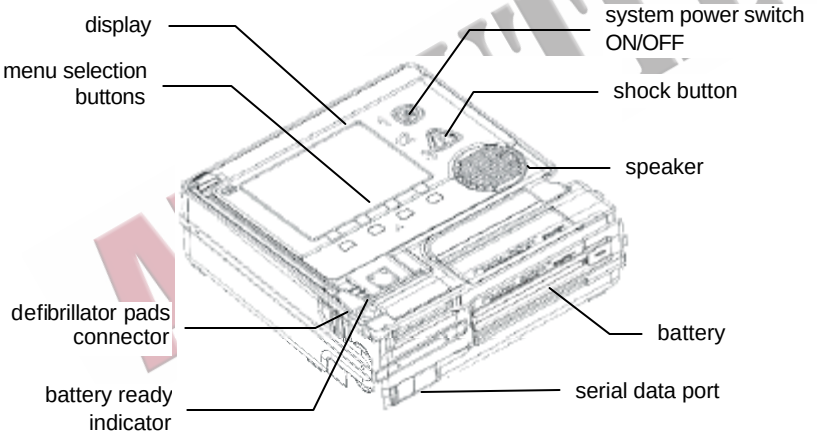
Primary AED	In this configuration, the unit provides automated text and voice prompts to guide the operator. It does not have an ECG tracing capability on the display.
Secondary AED	This configuration requires the optional ECG display upgrade. Automated Text and voice prompts are provided and a continuous ECG tracing displays on the LCD during operation.
Manual AED	This configuration requires the optional ECG display and Manual mode upgrades. This configuration includes 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 AED. This allows the user to manually select energy settings and administer defibrillation shocks.

Functions

This section describes the following Welch Allyn AED features:

- Controls
- Display
- Text Prompts
- Voice Prompts
- Icons
- System Ready Indicator
- Serial Data Port
- Event Documentation

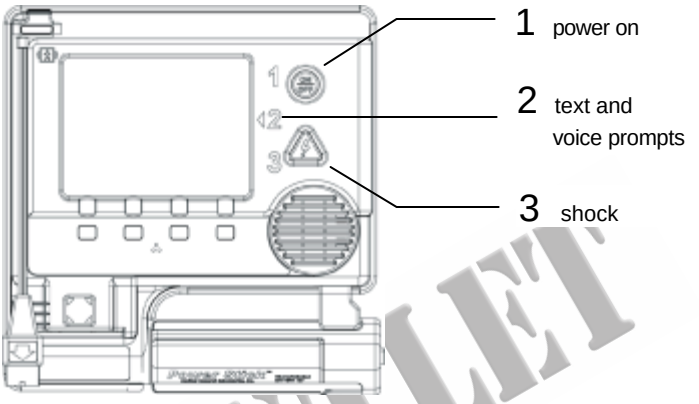
Detailed information on using, programming, and maintaining the Welch Allyn AED are presented in Chapters 2, 3, and 4, respectively.



Controls

The Welch Allyn AED20 is designed for ease of operation. After putting the defibrillator pads on the patient and connecting them to the Welch Allyn AED unit, the operator performs this simple three-step process:

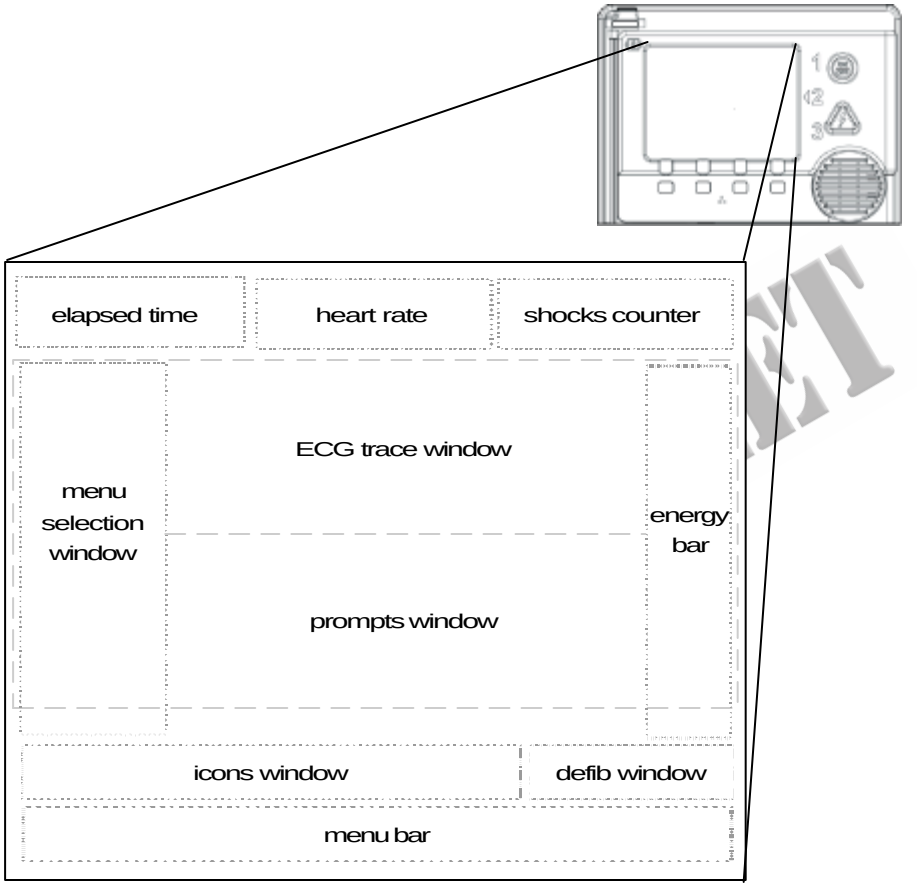
1. Turn the power ON.
2. Follow text prompts on the screen and voice prompts from the speaker.
3. If prompted, deliver shock by pressing the flashing red **Shock** button.



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 display on the liquid crystal display (LCD) screen. The display is a VGA, monochrome liquid crystal display (LCD) measuring 320 x 240 pixels. The display is divided into ten functional areas. Operating information and user instructions display in these areas.



The table below explains the function of each area.

Shocks Counter	Displays the number of shocks administered.
Defib Window	Displays the energy level selected or delivered. Also displays status messages.
ECG Trace (ECG or manual mode add-on option)	Displays ECG trace as a moving waveform, if option is installed. If the defib pads are not properly attached to the patient or connected to the unit, a dashed line is drawn.
Prompts	Displays up to three lines of text (user instructions, directions for patient care, error messages). See descriptions below.
Elapsed Time	Displays the time elapsed since the system was powered ON, or time used on current patient. The time format is HH:MM:SS.
Energy Bar (Manual Mode only)	Temporary window located to the right of the ECG Trace 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)	Displays number representing heart rate (beats/minute). Dashed line displays when rate is out of range or when defib pad fault exists.
Icons	Displays operating status icons. See descriptions below.
Menu Bar	Displays four areas corresponding to four buttons on the case below the LCD.
Menu Selection	Displays Manual Mode or Supervisor Mode

menu choices. See Chapter 3.

If the optional ECG or manual mode upgrade is installed, an electrocardiogram trace is also displayed on a continuous basis. Graphical screen icons provide system operational information. The Welch Allyn AED20 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.

Text Prompts	Descriptions
ANALYZING PADS	ECG leads 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 PULSE	Check the patient's pulse.
IF NO PULSE - START CPR	Check the patient's pulse and begin a 60-second CPR cycle.
MONITORING ECG, PRESS TO ANALYZE	AED is silently monitoring the patient's heart rhythm and will perform a full

Text Prompts	Descriptions
	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 Welch Allyn AED voice prompt feature provides instructional prompts to guide the user through the defibrillation process without relying solely on text prompts.

The Welch Allyn AED 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.

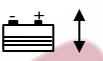
In the following table, the voice prompts in brackets are for the UK version of the Welch Allyn AED20 only.

Voice Prompt	Description
Analyzing heart rhythm, do not touch the patient	Defibrillator pads properly attached and connected; assessing heart rhythm
Analyzing interrupted, motion detected	Patient or electrode moved
Check airway, check breathing, check pulse [Check airway, check breathing, check circulation]	Check patient's airway, breathing and pulse
Check Patient	Prompt to press the *Analyze* button
Apply defib pads to patient's bare chest, connect pad to cable	Attach electrode pads to the patient and connect cables to the Welch Allyn AED (prompt at unit power up)
Apply defib pads, connect cable	Defibrillator pads are not properly attached to the patient or properly connected to the Welch Allyn AED
If no pulse Start CPR [Begin CPR]	Check the patient's pulse and begin 60-second CPR cycle
Low battery	Low battery charge. Replace battery.
Memory Card full	Internal memory card full
No shock advised	Shockable condition does not exist
Shock advised	Shockable condition exists
Shock now, press the red button now	Push the red SHOCK button
Stand clear	Defibrillator charged and ready to shock; do not touch or move patient

Stop CPR	Stop CPR, wait for further instructions
It is safe to touch the patient	Defibrillator shock has been delivered
Change to pads	Electrode monitoring cable is attached, change to defibrillator pads
Shock not delivered	Attempted shock did not deliver any energy to the patient

Icons

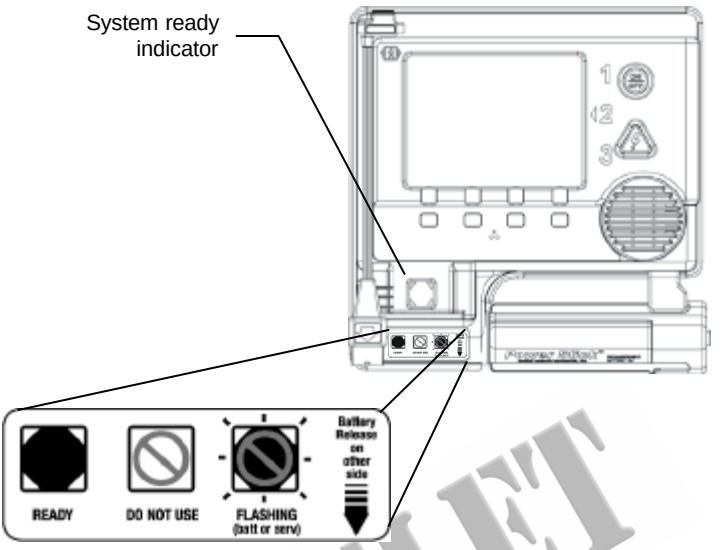
Icons provide operating status information. The icons are displayed at the bottom of the LCD just above the menu bar.

Icon	Name	Description
	Auxiliary Power	Indicates the optional auxiliary power unit is plugged in.
	Battery Level Indicator	Indicates the charge left in the battery is full.
	Battery Level Indicator	Indicates the charge left in the battery is partially depleted.
	Battery Level Indicator	Indicates the charge left in the battery is low.
	Battery Level Indicator	Indicates non-rechargeable, single use battery.
	Battery Level Indicator	Indicates rechargeable battery.
	Contrast	Indicates the level of contrast; levels are 1 through 9.
	CPR Timer	Represents a user adjustable second clock used to time CPR.
	Log Level	Indicates the amount of memory remaining for entries in to the log.

Icon	Name	Description
	Memory Card Level	Indicates the amount of memory remaining for entries in to the optional Memory Card.
	Printer Status	Indicates log printing. Flashing icon indicates printer error.
	Volume	Indicates the speaker volume; 4 levels are indicated.
	Lock	Memory card locked.
	Recording	Memory card is recording.

System Ready Indicator

The battery ready indicator display, located on the lower left corner of the Welch Allyn AED, represents the operational readiness of the battery.



Ready	Battery is properly installed, charged, and system is ready for use.
Do Not Use	System is not ready for use. Battery may not be properly installed, battery charge is too low for effective operation, or system failure.
Flashing	Battery is low and requires changing.

Serial Data Port

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

Event Documentation

The Welch Allyn AED 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 printer or to a computer through the serial port on the Welch Allyn AED.

Battery Charging and Conditioning

This section provides procedures for charging and conditioning the NiMH PowerStick rechargeable battery. Do not attempt to recharge the Lithium PowerStick non-rechargeable battery.

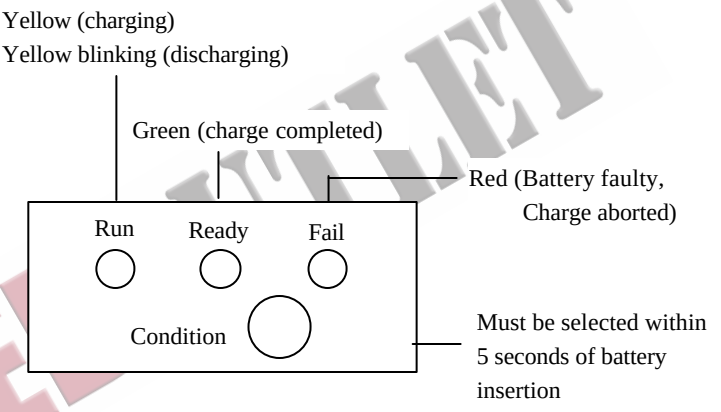
Battery maintenance is critical to ensure that the Welch Allyn AED20 operates reliably. Periodically check the battery to ensure that the recommended replacement date has not elapsed. Over time and through use, the capacity of a battery will degrade. Properly maintaining a battery is crucial to maximizing 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.

A completely discharged battery will require approximately 1.5 to 2 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.

The Welch Allyn Quick Charger/Conditioner

Please refer to the picture seen below. If the controls on your charger are different than the ones shown here, see "The Alternate Welch Allyn Quick Charge/Conditioner" section below.

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



Charging a Battery

To charge a 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
3. The **Run** light will turn off and the green **Ready** light will turn on to indicate that the battery is fully charged.

Charging battery at temperatures above 30ºC (86ºF) 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 a Battery

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

To initiate a battery conditioning cycle:

1. Insert the battery into the charger.

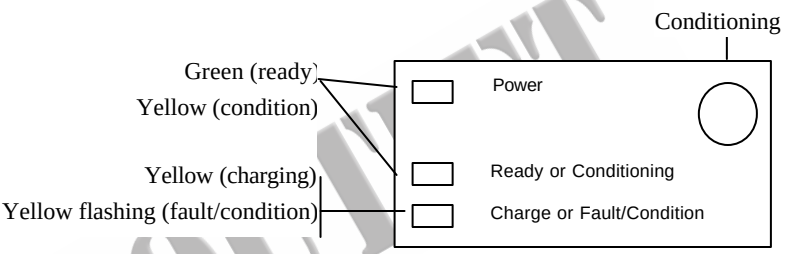
2. Press the conditioning button on the charger control panel within 5 seconds of insertion. The yellow **Run** light blinks as the battery is being discharged.

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.

The Alternate Welch Allyn Quick Charger/Conditioner

The Alternate Welch Allyn Quick Charger/Conditioner is easy to use. The PowerStick is inserted directly into the charger. Status lights indicate the condition of the battery.



Charging a Battery

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

1. Insert the battery into the charger. When the battery is firmly seated, the yellow **Charge** light illuminates.
2. Monitor the charging light. Steady yellow means charging. Flashing yellow means that the battery is not charging due to a **Fault** condition.
3. The **Charge** light turns off and the green **Ready** light turns on when the battery is fully charged.

Charging battery at temperatures above 30ºC (86ºF) 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 a Battery

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

To initiate a battery conditioning cycle:

1. Insert the battery into the charger.
2. Press the conditioning button on the charger control panel. The yellow ready-conditioning light illuminates solid and the yellow charge/fault/conditioning flashes.

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

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

Preparing the Welch Allyn AED20 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 Welch Allyn AED should be inspected, cleaned, and a new supply of electrode pads restocked to prepare the unit for its next use.

During storage, the Welch Allyn AED 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 Chapter 4 *Maintaining the Welch Allyn AED* for more information.

Welch Allyn AED20 Accessories Part List

Welch Allyn AED20

970200	Welch Allyn AED with two defibrillation pads and operations manual.

Welch Allyn AED20 Options

970201	ECG Display
970202	Manual Override with ECG Display (970201)
970203	Log Review

Welch Allyn AED20 Accessories

001829	Welch Allyn PowerStick - Rechargeable battery
001830	Welch Allyn PowerStick - Non-rechargeable battery
981125E	Battery Charger, 1Bay (to be used with 001829)
981123E	Battery Charger, 2Bay (to be used with 001829)
900216	Welch Allyn AED Carrying Case
001855	Multipurpose Defibrillation Pads (10 pair / box)
002119	Welch Allyn AED Parallel Communications Kit
002120	Welch Allyn AED PC Data Transfer / Serial Comm Kit
002128	IEC Electrode Monitoring Cable
002130	AHA Electrode Monitoring Cable
980136	Welch Allyn Cardiolog Datacard – 4 MB
980143	Welch Allyn AED Trainer
001910	Welch Allyn Smartview Software Review Program
001962	Welch Allyn Smartlink Software
980139	Welch Allyn Patient Simulator
900165	Data Printer

Chapter 2

Using the Welch Allyn AED20

Welch Allyn AED20 Users Manual

This chapter provides information for using the Welch Allyn AED20 with a patient. It also provides the instructions for operating Welch Allyn AED20 in automated or manual mode and the procedures to follow after using the unit.

Overview

The Welch Allyn AED20 is capable of operating in an automated and in a manual mode. In either mode, the operator must be trained to use the unit and understand the indications and contraindications for use.

Trained Operators

The Welch Allyn AED20 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 Welch Allyn AED20.

Automated Mode:

- American Heart Association Heartsaver course, American Red Cross CPR/AED course or equivalent
- Training in the use of the Welch Allyn AED20.

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 Welch Allyn AED20, 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 Welch Allyn AED20 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 Welch Allyn AED20 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 Welch Allyn AED20 will only administer a defibrillation pulse (shock) 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. This defibrillator should not be used in automated mode on patients less than 8 years old.

Defibrillation may be effective against cardiac arrhythmias such as:

- Cardiac arrest
- Ventricular fibrillation
- Ventricular tachycardia

The biphasic waveform employed by the Welch Allyn AED20 has not been clinically tested on pediatric patients. The Welch Allyn AED20 has not been evaluated for cardioversion of atrial fibrillation.

Indications

Prior to using the Welch Allyn AED20, the patient should be assessed by a trained person as described on page 2-3. If defibrillation with the Welch Allyn AED20 is indicated, all of the following signs should be present during patient assessment:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Contraindications

The Welch Allyn AED20 should NOT be used if the patient exhibits any of the following signs:

- Patient is conscious
- Patient is breathing
- Patient has a pulse

Welch Allyn AED20 Operating Procedures — Quick Reference

The following instructions provide an experienced operator with the main steps for using the Welch Allyn AED20 in Automated Mode and Manual Mode. Detailed operating information and procedures are given in the next subsection (pages 2-8 through 2-18.)

Automated Mode - Quick Reference

Assess the Patient

See the instructions in the detailed information in the next subsection (page 2-8).

Attach Electrodes

See the instructions in the detailed information in the next subsection (page 2-9).

Start the Welch Allyn AED20 and Deliver a Shock

1. Push the green **ON/OFF** button located at the upper right corner of the Welch Allyn AED20 next to the large number "**1**".
2. Listen to voice prompts and read text instructions on the screen next to the large number "**2**".
3. If prompted press the red **Shock** button next to the large number "**3**".

Perform CPR, if prompted.

Assess the Patient

See the instructions in the detailed information in the next subsection (page 2-8).

Attach the Electrode Pads and Connect the Cable

See the instructions in the detailed information in the next subsection (page 2-9).

Start the Welch Allyn AED20 and Deliver a Shock

1. Push the green **ON/OFF** button located at the upper right corner of the Welch Allyn AED20 next to the large number "**1**".
2. Press the button below **Manual** to display the manual mode password screen.
3. Enter the numeric manual mode passcode. Press **Enter** to accept the passcode and display the Manual Mode operating screen.
4. Select energy with the up and down arrows.
5. Press the Charge button.
6. Press the red flashing **Shock** button next to the large number "**3**" to deliver the shock.

Welch Allyn AED20 Operating Procedures – Detailed Information

The Quick Reference operating procedures in the preceding subsection provide the main steps when operating the Welch Allyn AED20 in Automated or Manual Mode.

- Assess the Patient
- Start the Welch Allyn AED20
- Attach the Electrodes and Connect the Cable
- Analyze Patient's Heart Rhythm
- Deliver the Shock (Automated or Manual Mode)
- Perform CPR

For each step, detailed operating information or procedures follow.

Assess the Patient

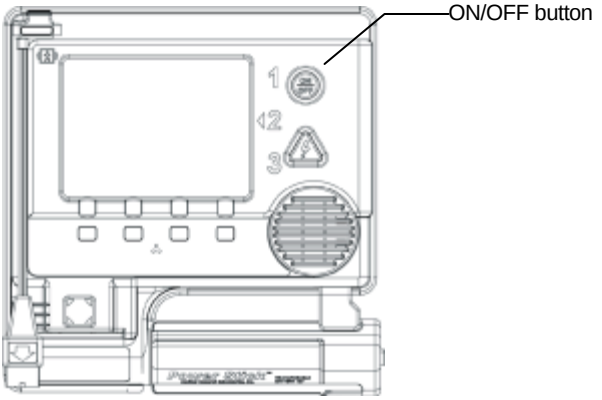
Before using the Welch Allyn AED20, assess the patient's condition. Use the unit only if all of the following patient signs are present:

- Unconsciousness
- Absence of breathing
- Absence of pulse

Start the Welch Allyn AED20

Push the green ON/OFF button next to the large number "**1**" to power-on the Welch Allyn AED20. The unit will start in Automated Mode.

To operate the unit in Manual Mode, press the button below Manual on the status bar to display the manual mode passcode screen. Use the buttons below the arrows on display to select the numeric passcode. Press the button below Enter to accept the passcode and display the manual mode operating screen.



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 Welch Allyn AED20.

Before applying pads to the patient's chest be sure to:

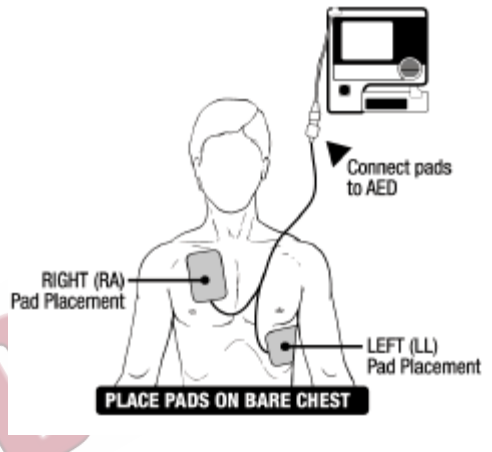
- Remove all clothing covering chest
- Wipe off any water, moisture, or perspiration
- Press the pads firmly to make sure they adhere securely to the chest.

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.

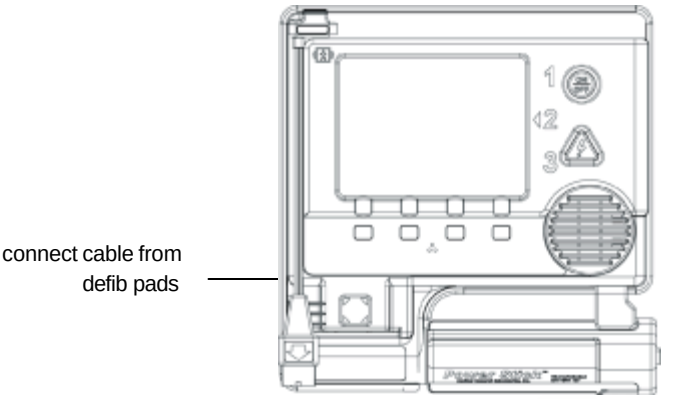
To attach electrodes and connect cable:

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

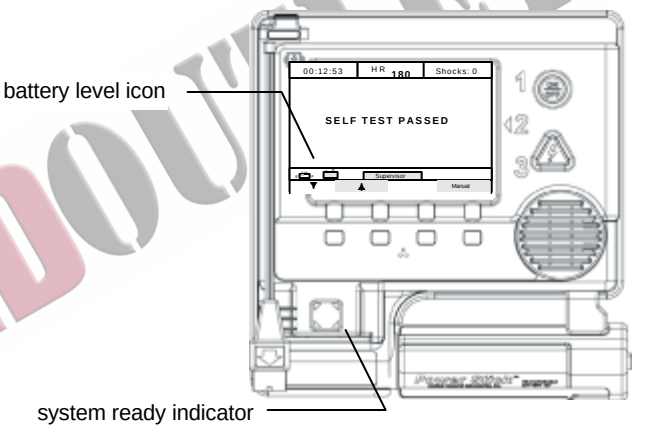


3. Peel off the backing from the electrode pad labeled LL. Place this pad over the ribs on the patient's left side below the breast (apex).

4. Plug the pad connector into the Welch Allyn AED20 on the left side of the unit.



5. 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 Welch Allyn AED20, it will alert the user with text and voice.

Apply pads to patient's bare chest, connect defib pads to cable

Analyze Patient's Heart Rhythm

When the pads are properly applied and connected, the Welch Allyn AED20 announces then automatically analyzes the patient's heart rhythm to determine if a shock is indicated.

Analyzing heart rhythm. Do not touch the patient

Caution

Do not touch or move the patient while the Welch Allyn AED20 is analyzing the heart rhythm.

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

Analyzing interrupted, motion detected

Deliver Shock — Automated Mode

The Welch Allyn AED20 will only administer a shock to a patient exhibiting a shockable cardiac rhythm. All other rhythms are determined "non-shockable" and therefore the patient is not a candidate for defibrillation.

If it is not a shockable condition, the Welch Allyn AED20 will alert the user with text and voice.

No shock advised

If a shockable condition is detected, the Welch Allyn AED20 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. This indicates that the unit is properly charged.

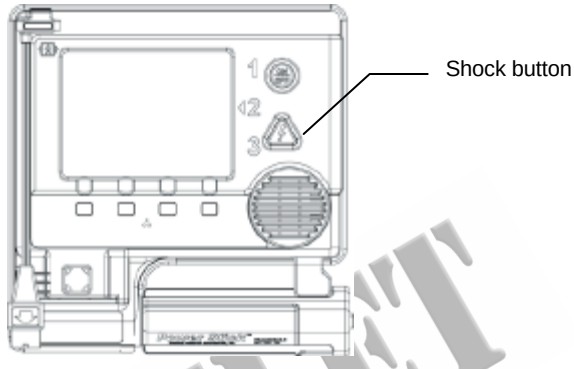
WARNING!

Make sure no one is touching the patient before you press the Shock button. Loudly announce, "Stand back! Do not touch the patient." and 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.

Stand clear

Shock now, press the red button now

2. Push Shock to deliver a shock.



The Welch Allyn AED20 will not allow the operator to charge or discharge the defibrillator unless a shockable rhythm is detected while in automated mode.

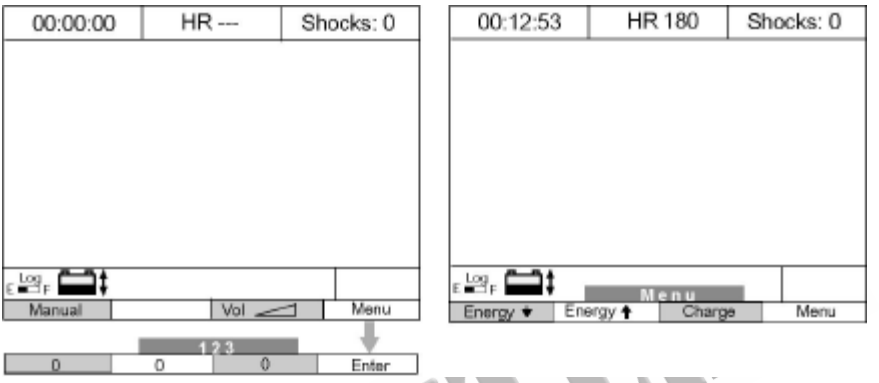
After delivering a shock, the Welch Allyn AED20 continues to analyze the heart rhythm and determines whether additional shocks are indicated. The unit is programmed for a supervisor-configurable protocol that indicates the number of shocks delivered, the energy of each shock, and possible CPR interventions.

Deliver Shock — Manual Mode

The Welch Allyn AED20 can operate as a manual AED when it is configured with the manual mode options.

Enter Manual Mode

When the power is on the Welch Allyn AED20 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 displays.



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

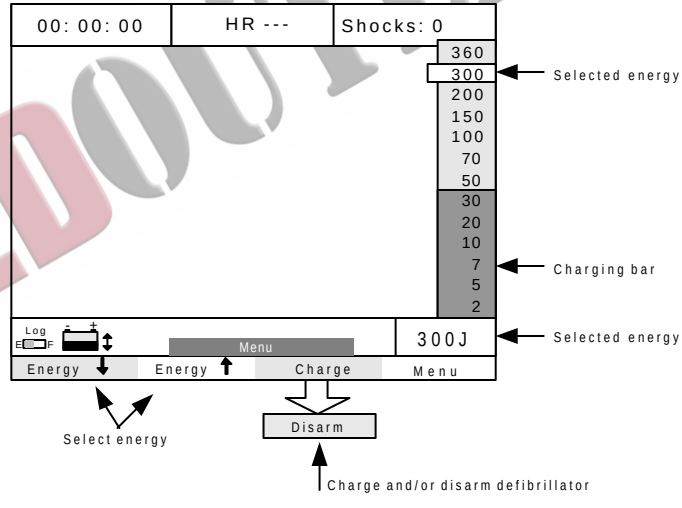
Select Energy Level

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 is the lower right corner of the LCD.

Charge Defibrillator

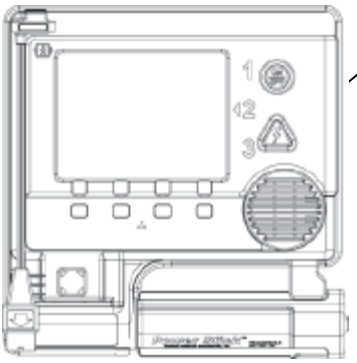
Press the **Charge** button to charge the defibrillator. An intermittent tone will sound as the defibrillator charges. A bar will extend upwards on the right side of the display until it reaches the selected energy level. Once the selected energy level is reached, a solid tone will sound and the red **Shock** button will flash.

Charge time is approximately 8 seconds. The unit is capable of delivering back-to-back shocks in less than 30 seconds.



To deliver a shock:

1. Make sure the **Shock** button next to the large number "**3**" is flashing. This indicates that the unit is properly charged.
2. 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." and look down the entire length of the patient to ensure there is no contact before pressing the Shock button.

After delivering a shock, the Welch Allyn AED20 continues to analyze the heart rhythm and prompts the operator if additional shocks are indicated.

Defibrillator Disarm

If the defibrillator is charged and the **Shock** button is *not* pressed, the Welch Allyn AED20 must be disarmed.

- The unit will automatically discharge in Automated Mode (30 seconds) or Manual Mode (60 seconds). In Automated Mode after 25 seconds, there will be a warning tone to indicate 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 heart rhythm is not treatable with defibrillation, the Welch Allyn AED20 displays and announces the message *No Shock Advised*. The Welch Allyn AED20 will direct the operator, every minute, to perform cardiopulmonary resuscitation (CPR) to effectively resuscitate the patient.


No shock advised (Only Spoken once)


It is safe to touch the patient


Check airway, check breathing, check pulse (circulation)


If no pulse start (begin) CPR

The Welch Allyn AED20 will continue to assess the patient's heart rhythm. If the signal is non-shockable, *No Shock Advised*

will continue to flash on the display, but if the Welch Allyn AED20 detects a shockable rhythm it will direct the operator to stand back as it begins to analyze the patient's heart rhythm.

Analyzing heart rhythm. Do not touch the patient

If the patient is pulseless, apneac, and unconscious, when directed, perform cardiopulmonary resuscitation in accordance with the procedures and techniques presented in your CPR training. The Welch Allyn AED20 also directs the operator to perform CPR after three consecutive, delivered shocks. During the CPR cycle, the Welch Allyn AED20 will not be assessing the patient's heart rhythm.

At the end of the CPR cycle (15, 30, 60, or 90 seconds), the Welch Allyn AED20 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 condition exists.

Stop CPR

A CPR cycle can be interrupted and analysis resumed at any time by pressing the ANALYZE button.

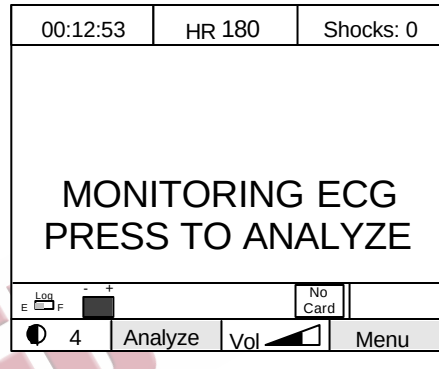
EMS Mode

EMS mode is a feature specifically designed for use by an Emergency Medical Technician. EMS mode is recommended when continuous AED 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 AED20. The following section describes the operation and various features of EMS mode.

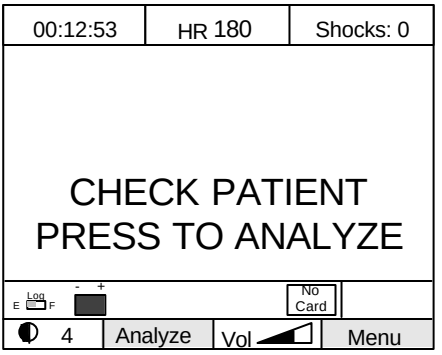
Background Monitoring

When the unit is powered on in EMS mode, it is automatically set to a *Voice Off* mode. This means that the AED will analyze silently and will not speak any voice prompts unless it detects a shockable rhythm. A screen similar to the one seen below will be displayed.



When this screen is active, no voice prompts will be spoken, but the AED will continuously analyze the patient's heart rhythm.

If a shockable rhythm is detected, the screen will change and the AED will speak and display **CHECK PATIENT.**



When the “CHECK PATIENT” prompt is spoken, the user should verify that the patient is pulseless, apneac, and unconscious, and eliminate sources of motion artifact before pressing the **Analyze** button to Enter *Voice On* mode. In *Voice On* mode, the AED will issue verbal prompts, fully analyzing the patient’s heart rhythm and charging the defibrillator if necessary. Follow normal AED mode operating procedures in *Voice On* mode.

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

- *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 AED will perform the normal three-shock SAED protocol set by the supervisor. If a patient is successfully defibrillated, the AED will return to *Voice Off* mode. If three successive shocks are delivered, the CPR timer will begin after the third shock. Following

completion of CPR, the unit will speak “Stop CPR” and return to *Voice Off* mode to continue background monitoring.

Electrode Monitoring (option)

An optional electrode monitoring cable (002128-IEC, 002130-AHA) is available for use with the Welch Allyn AED20. The operator uses low cost standard ECG electrodes to assess patients who do not meet the criteria for using the automated mode, for example, a patient who has a pulse, 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 Welch Allyn AED20 analyzes the patient’s rhythm while in automated mode, but will 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.

Always check the expiration date on defibrillation pads and do not use pads if the packaging has been previously opened. The Welch Allyn AED20 may interpret excessively dry defibrillation pads as an attached electrode monitoring cable.

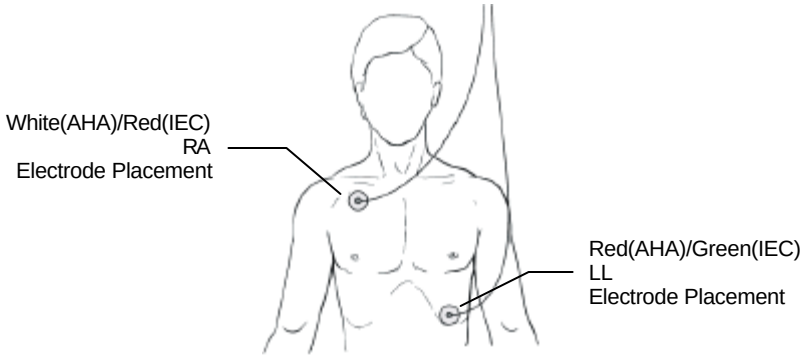
Using the Electrode Monitoring Cable

To use electrode monitoring:

1. Attach electrode monitoring cable to Welch Allyn AED20.
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.

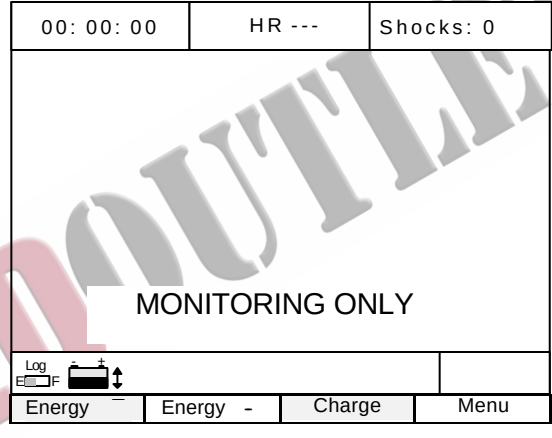
Caution

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.

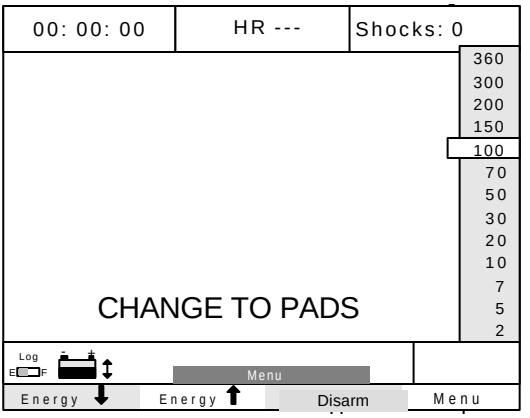


Using the Electrode Monitoring in Manual Mode

The Welch Allyn AED20 displays MONITORING 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.



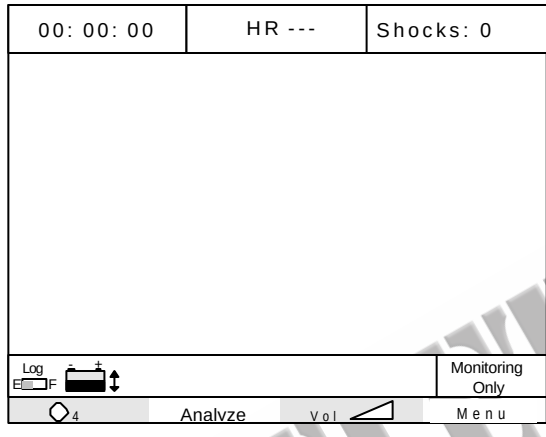
If the operator attempts to deliver a shock using the electrode monitoring cable, SHOCK NOT DELIVERED displays on the screen and no energy is delivered to the patient.

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

It is recommended not to use the electrode monitoring cable for Automatic Rhythm Analysis. If the Welch Allyn AED20 is set to Automated Mode when the electrode monitoring cable is attached, MONITORING ONLY will flash in the Defib window.



While the electrode monitoring cable is attached, the Welch Allyn AED20 will only analyze the heart rhythm 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 Welch Allyn AED20 will begin an analysis cycle.

Press the Analyze button, the Welch Allyn AED20 will speak Analyzing and display ANALYZING and STAND CLEAR and go through the analysis cycle.

	Analyzing

If the result is a non-shockable waveform, the AED will sound a double beep and display NO SHOCK ADVISED. If the result is a shockable waveform, the AED will speak Change to Pads, sound 5 beeps, and display CHANGE TO PADS, CHECK PATIENT, IF NO PULSE START CPR.

Change to Pads

The Welch Allyn AED20 will continue to wait for the Analyze button to be pushed while in Automated Mode. The AED will not allow the user to shock the patient with the monitoring cable attached.

Post-Use Procedures

After each use, the Welch Allyn AED20 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 Welch Allyn AED20 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 Chapter 4 *Maintaining the Welch Allyn AED20* for more information.

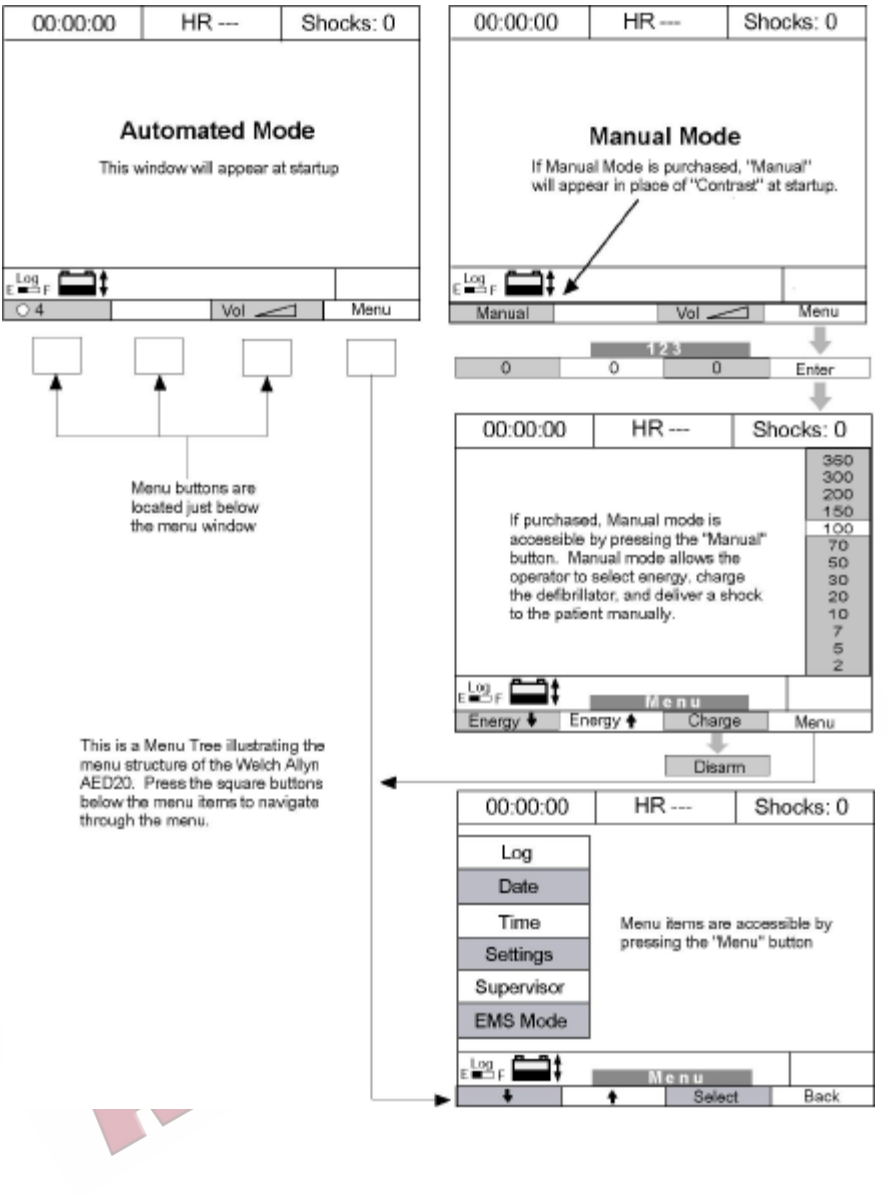
Chapter 3

Programming the Welch Allyn AED20

Welch Allyn AED20 Users Manual

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.

Menu Structure Diagram



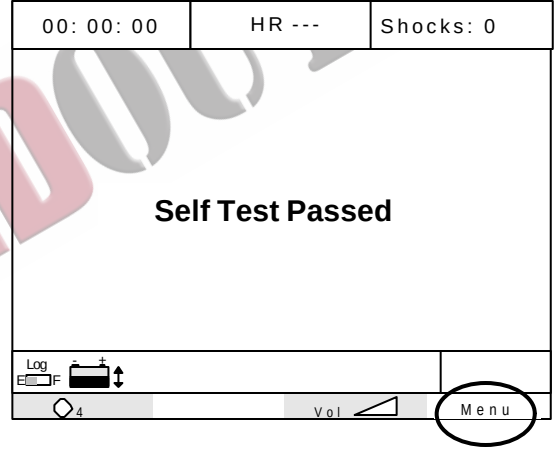
Menu Structure Overview

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 Welch Allyn AED20 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 Welch Allyn AED20 is powered-up, the unit performs a self test and the start-up screen displays. Access the User Menu by pressing "Menu" in the lower right corner.

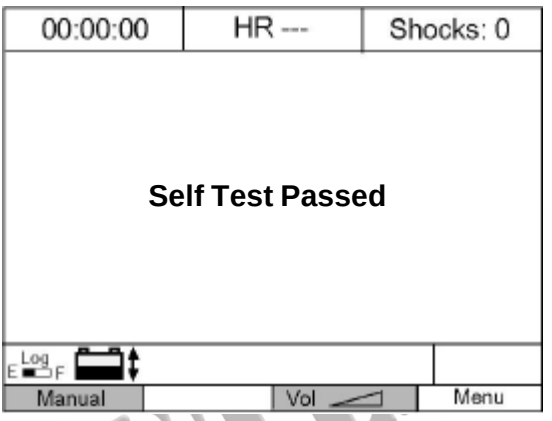


If the Manual Mode is purchased, MANUAL appears in place of the contrast menu on start-up screen. .

Accessing the User Menu from Manual Mode

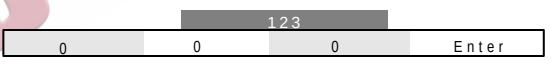
Only available on units with Manual Mode purchased.

When the Welch Allyn AED20 is powered-up with the Manual Mode option installed, the unit performs a self test and the manual mode start-up screen displays.



To access the Manual Mode Menu:

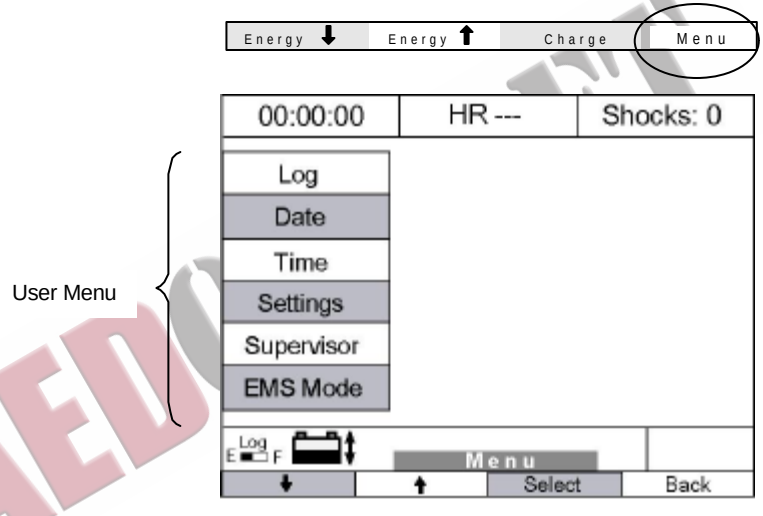
1. Press **Manual** to display the manual mode passcode screen.



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 123.

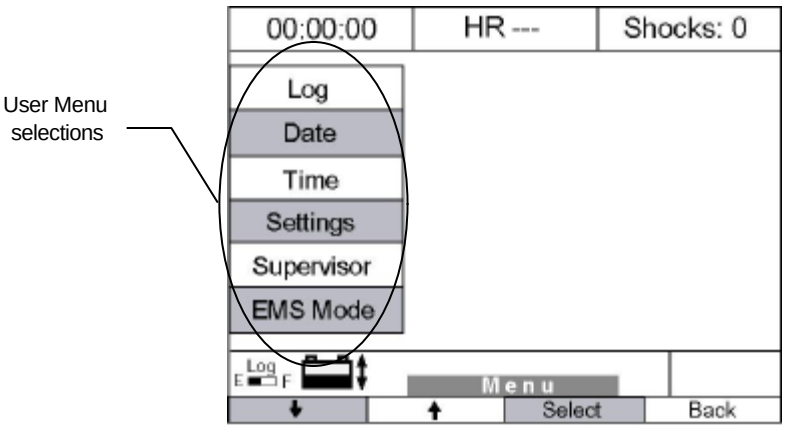
4. Press **Enter** to accept the passcode. If the number is correct, the Welch Allyn AED20 enters manual mode.
5. Press **Menu** to display the User Menu screen.



*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 Allows viewing, hearing, pointing, 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.

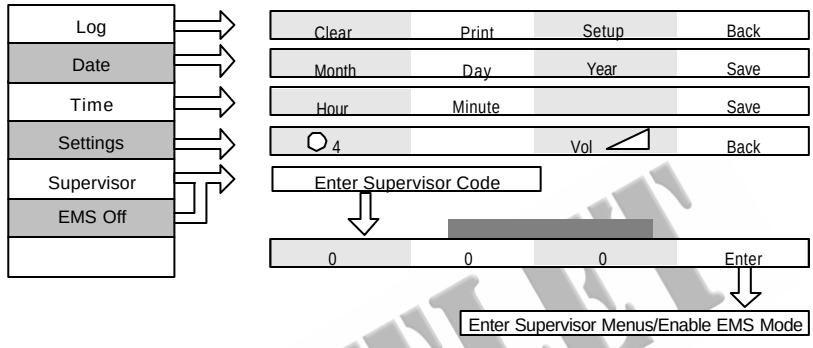
Time Display the current time, set, and save a new time (hour, minute) using the buttons below the Menu Bar.

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.

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

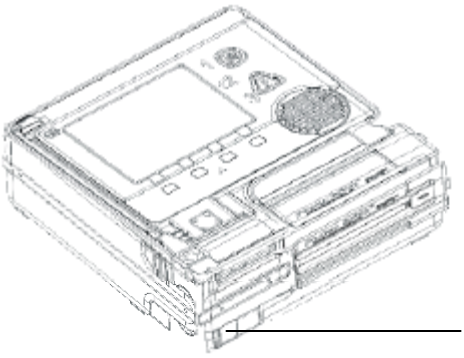
User Menu Structure Overview



The subsections that follow explain how to set the options available through the User Menu. The procedures included are:

- Working with the log
- Setting the date
- Setting the time
- Adjusting the contrast
- Adjusting the speaker volume
- Enabling EMS Mode

The log contains a record of ECG tracings and time-stamped system status events. The log can be printed to a parallel printer, printed to a serial printer, or transferred to a PC for viewing. Use the appropriate setup procedure to connect the printer or PC to the Welch Allyn AED20, then follow the instructions for printing.



To setup a parallel printer:

The Welch Allyn AED Parallel Communication Kit (002119) is required for this connection.

1. Connect the male end of the DB25-Modular adapter (550790) to the DB25 female end of the Serial to Paralle l converter (900412 or 900416). Connect the Serial Cable (551778) into the AED20 serial data port and to the DB25-Modular adapter (550790)

2. Connect the Serial to Parallel converter to the parallel printer port on your printer. Connect the AC Power adapter to the Serial to Parallel converter and plug in the AC Power adapter to a wall outlet.
3. Make sure the Serial to Parallel converter dip switches are set to 57600 baud. See the instructions included with the communication kit for details.

To setup a serial printer:

The Welch Allyn AED PC Data Transfer/Serial Communication Kit (002120) is required for this connection.

1. Connect the Serial Communication Cable (551778) into the Welch Allyn AED20 serial data port and the other end to the Serial Printer Transfer Adapter (520469).
2. Connect the Serial Printer Transfer Adapter to the serial printer.

To setup a PC for viewing:

The Welch Allyn AED PC Data Transfer/Serial Communication Kit (002120) is required for this connection.

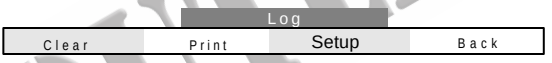
ECG or Text can be used to transfer data to a PC or the RS232 option with Welch Allyn Smartlink software can be used for easy data archiving and playback.

1. Connect the Serial Communication Cable (551778) into the Welch Allyn AED20 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 setup, turn on the output device and the Welch Allyn AED20. Use the following procedure to print the log.

To print the log or ECG data:

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



2. Press **Setup** to display the Output Mode menu bar.

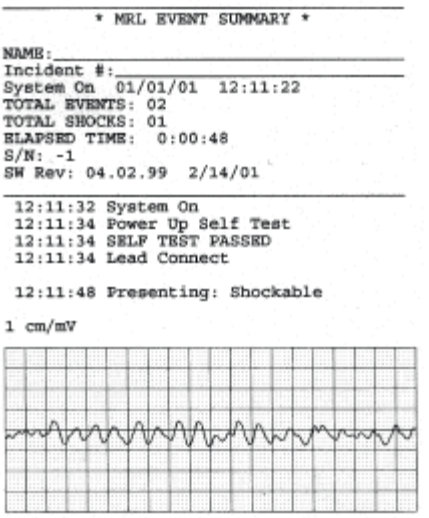
3. Select **Text** or **ECG** and the appropriate baud rate. Press **Back** to return to the Log menu bar.

ECG Setting only works with a parallel printer.

4. Press **Print** to print the log entries. A steady printer icon replaces the log icon to confirm printing.

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.

An example printout with typical information is shown below.



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.

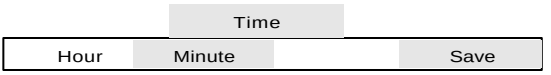
Setting the date will force a new patient into the entry log.

Setting the Time

The Welch Allyn AED20 time-stamps are events saved to the log. A 24-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.

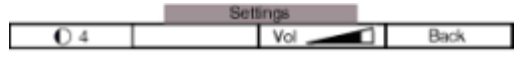
Setting the time will force a new patient into the entry log.

Adjusting the Contrast

The contrast of the Welch Allyn AED20 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.



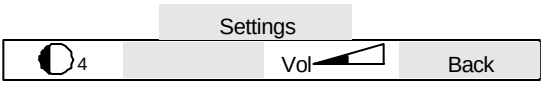
2. Press the contrast button (◐) to change the contrast of the LCD. The number next to the contrast icon changes corresponding to increases in the contrast (1-9).
3. Press **Back** to return to the User Menu.

Adjusting the Speaker Volume

The volume of the voice prompts through the Welch Allyn AED20 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:

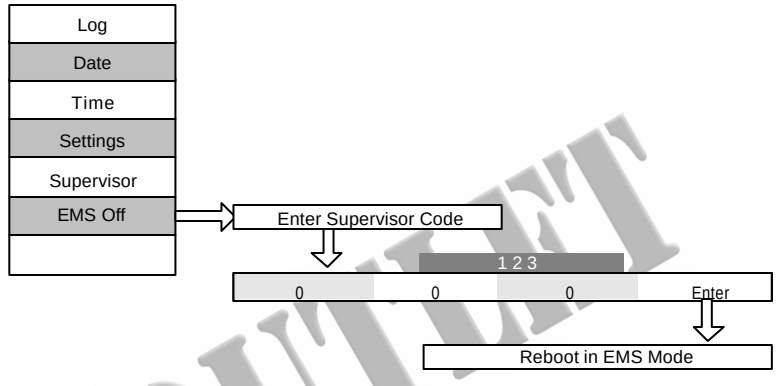
1. Access the User Menu. Select **Settings** to display the Settings screen and menu bar.



2. Press **Volume** ( ) to change the volume of the voice prompts through the Welch Allyn AED20 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 AED 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 AED20.

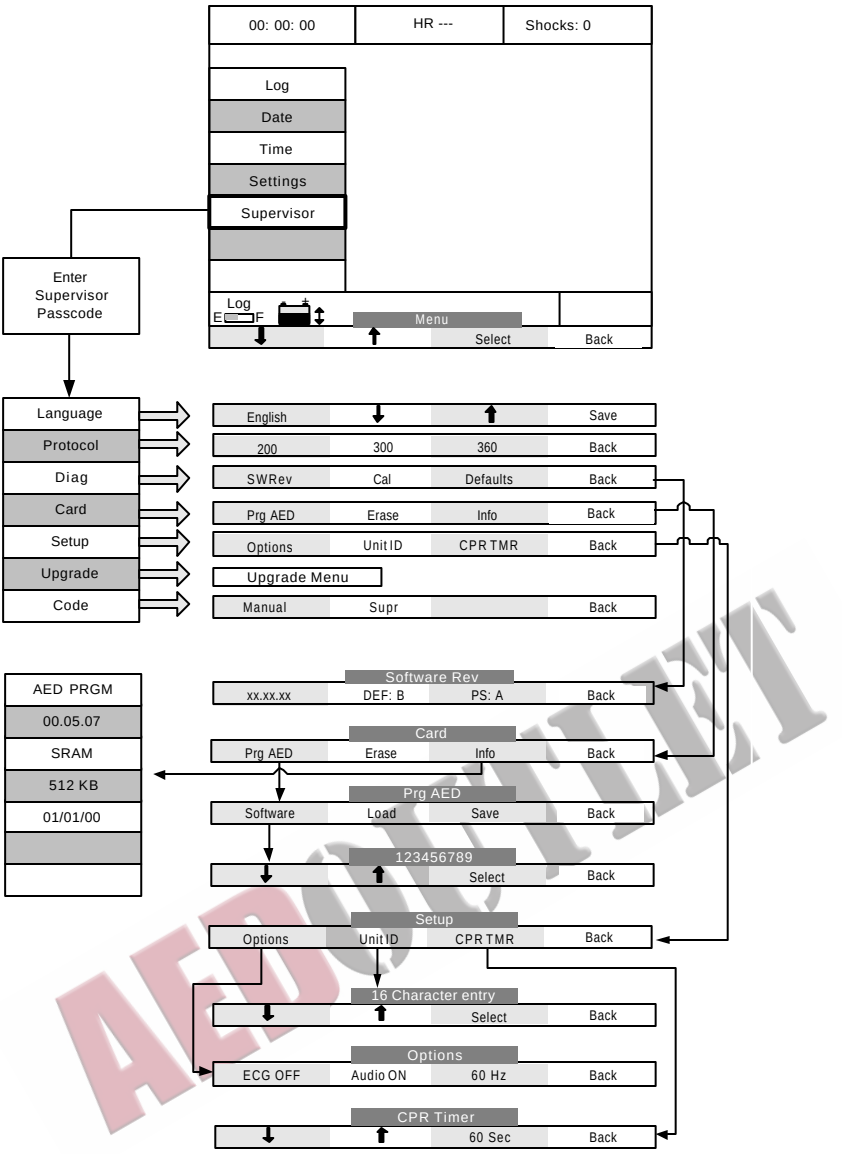


To Enable EMS Mode:

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 unit will reboot with EMS Mode ON.

Follow the same procedure to turn EMS Mode OFF.

Supervisor Menu Tree



Supervisor Menu

The subsections that follow explain how to access the Supervisor Mode Menu and set the options available through that menu. The procedures included are:

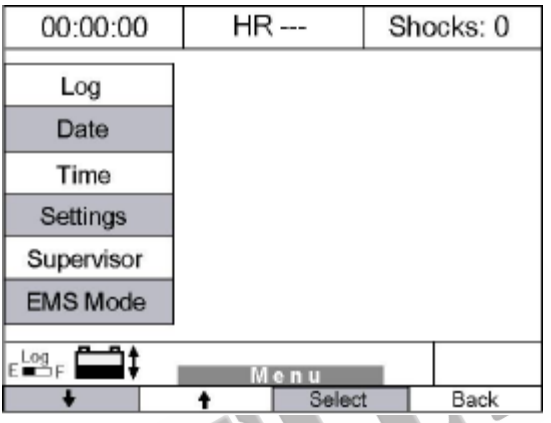
- Accessing the supervisor menu
- Selecting a language
- Setting the charge protocol
- Viewing software revisions
- Enabling/disabling the memory card
- Enabling/disabling ECG and audio options
- Changing manual/supervisor password codes
- Upgrading the Welch Allyn AED20 system

Accessing the Supervisor Menu

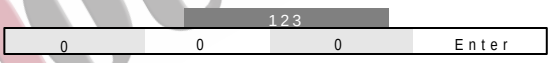
The Supervisor Menu is accessed from the User Menu screen.

To access the Supervisor Menu:

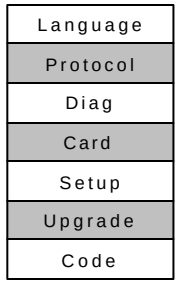
1. Go to the User Menu as described earlier in this chapter.
2. Use the up and down arrows to choose **Supervisor,** and press select.



3. Enter the passcode and press enter. If passcode is correct, the Supervisor menu will appear.



Supervisor Menu Items



Language Select text and audio language using the buttons below the Menu Bar. (Restart the Welch Allyn AED20 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 and set time for the CPR timer.

Upgrade Add upgrade options to the system.

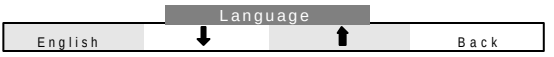
Code Set both the Manual Mode and the Supervisor Mode pass code numbers using the buttons below the Menu Bar.

Selecting a Language

The language used for text on icons, screen displays, and prompts and used for voice prompts can be changed if the Welch Allyn AED20 has the language option upgrade installed.

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 Welch Allyn AED20 to activate the language selected and change the screen text and voice prompts.

Setting the Charge Protocol

The standard Welch Allyn AED20 charge protocol provides a sequence of three defibrillator shocks. The default protocol setting is 200 Joules, 300 Joules, and 360 Joules (150 Joules, 200 Joules, and 300 Joules for the UK). 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 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		
First Shock	Second Shock	Third Shock
150 J	150 J	150 J
200 J	200 J	200 J
	300 J	300 J
		360 J

Diagnostics

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

To view software revisions:

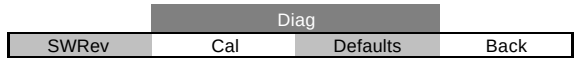
1. Access the Supervisor Menu. Select **Diag** to display the Diagnostics screen and menu bar.

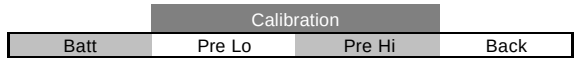
2. Press **SWRev** to display the revisions of the current software for the motherboard xx.xx.xx, defibrillator DEF: and the power supply PS.

Pressing the leftmost button while the motherboard software revision is displayed will display the FPGA device revision.

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

Calibration





Battery and threshold calibration should be performed by authorized service personal only.

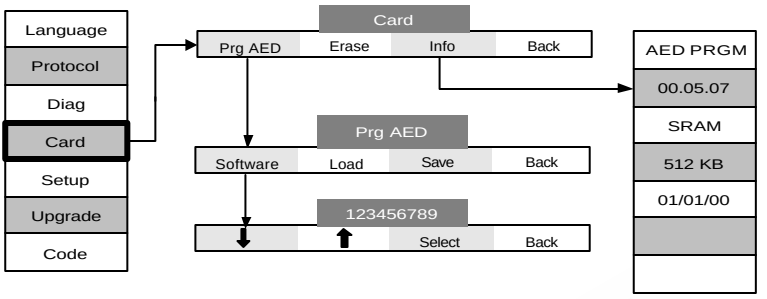
To restore factory defaults

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.

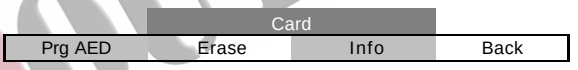
Viewing Information on the PCMCIA Memory Card

The Welch Allyn AED20 has an internal memory capable of recording and outputting 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 (erase card prior to first use to format the card), program the unit for software upgrades.



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 AED 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 unit will reprogram and reboot with new software.

To Format a Memory Card:

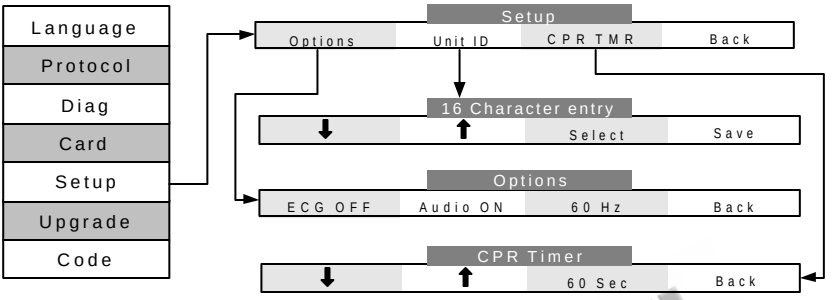
1. Access the Supervisor Menu screen.
2. Select **Card** to display the Card Menu.
3. Insert a Memory Card with Write Protect off in the memory card slot.
4. Press **Erase**. The card will begin to format.
5. When complete, press **Back** to return to the Supervisor Menu.

After the card menu is exited, 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 Welch Allyn AED20 unit for the log record
- Adjust the CPR timer



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.

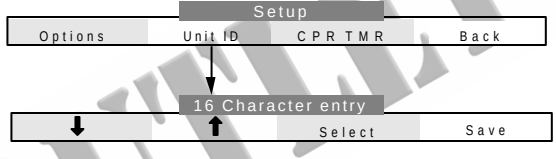
This option only appears when ECG tracing has been purchased.

4. Press **Audio** to toggle between Audio Recording ON and Audio Recording OFF.
5. Press notch filter to toggle between 50Hz and 60Hz.
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.

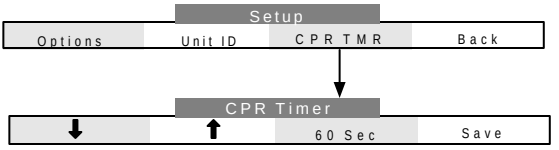
There are 16 available characters for the Unit ID.

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 **CPR Timer** to display the CPR Timer screen and menu bar.



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

Values available are 15, 30, 45, 60, and 90 seconds.

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

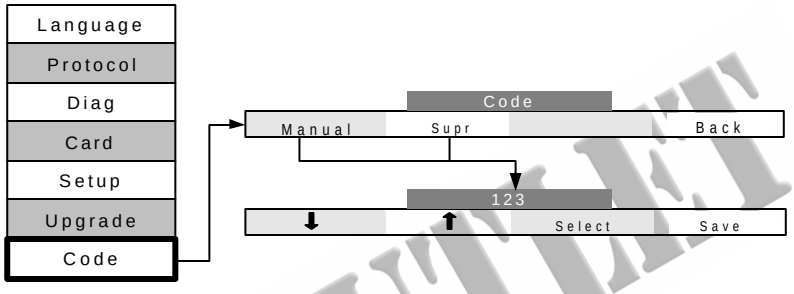
In Automated Mode, pressing Save resets the CPR Timer and restarts the defibrillator.

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.



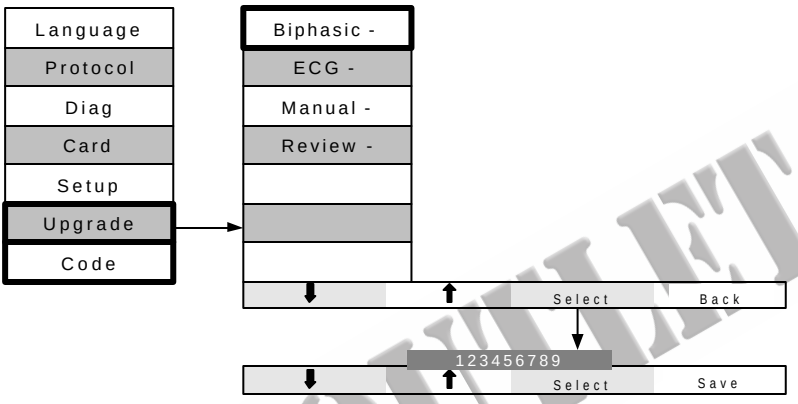
3. Press the up/down arrows to move to select the new passcode number.
4. Press **Save** to accept the new passcode and return to the Code Menu.

Upgrading the Welch Allyn AED20 System

Upgrade options are currently available and new options available in the future can be added to the Welch Allyn AED20 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 Welch Allyn AED20.

To upgrade the Welch Allyn AED20:

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



A plus (+) displays if an option is currently installed and a minus (-) displays if the option is not installed.

2. Choose the option to purchase, and press select.

Each upgrade purchased has a unique upgrade password code that must be entered before the upgrade can be installed on the Welch Allyn AED20.

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 unit to enable/disable the option.

Chapter 4

Maintaining the Welch Allyn AED20

Welch Allyn AED20 Users Manual

This section contains information on inspecting, maintaining, cleaning, and servicing the Welch Allyn AED20.

Inspection

To ensure the readiness and optimum working condition of the Welch Allyn AED20, the unit 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 unit in an operation ready state.

Also, new pads or other accessories should be checked for compatibility with the Welch Allyn AED20 when they are first received.

Scheduling Inspections

Each Welch Allyn AED should be inspected on a regular basis to ensure that the unit is ready for service when needed. The following table presents guidelines for determining an appropriate inspection schedule for your Welch Allyn AED20 units.

Frequency of Use	Inspection Schedule
weekly	daily
Monthly	weekly
infrequently, such as once a year	monthly

When powered by a non-rechargeable battery, the Welch Allyn AED20 must be used very infrequently to prolong battery life.

If the Welch Allyn AED20 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 Welch Allyn AED20 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.

Inspecting for Damage

Before every use, inspect the Welch Allyn AED20, the pad connector, and battery. Look for signs of damage.

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

Contact an authorized service agent immediately if:

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

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 Welch Allyn AED20.

Do not disassemble the Welch Allyn AED20. There are no operator serviceable components. Service and repair should be performed only by authorized service personnel.

If an Welch Allyn AED needs servicing, contact an Welch Allyn authorized service agent. In the United States, call Welch Allyn at 847-520-0300. Be prepared to provide the following information:

- Model
- Serial number
- Description of the problem

If the Welch Allyn AED20 needs to be returned for servicing, use the original shipping container. If the shipping container is not available, please contact Welch Allyn for packing instructions prior to shipping so that the unit is not damaged in shipping.

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 Welch Allyn AED20 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 has provided the following 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 Defibrillators Operator's Checklist

Infrequent Use (Non-Rechargeable Battery)

Date: _____ Shift: _____ Location: _____

Welch Allyn AED20 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 a. Inspect for cracks, broken wire, or damage b. Connectors engaged securely and are not damaged		
Supplies a. Two sets of pads in sealed packages within expiration date b. Hand towel c. Scissors d. Razor e. Alcohol wipes f. Spare battery g. Spare PCMCIA data card		
Power Supply a. Verify non-rechargeable (long storage life) battery inserted and within the expiration date. b. Verify that the system ready indicator shows READY.		

_____ _____

Signature Print Name

Automated External Defibrillators Operator's Checklist

Frequent Use (Rechargeable Battery)

Date: _____ Shift: _____ Location: _____

Welch Allyn AED20 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 a. Inspect for cracks, broken wire, or damage b. Connectors engaged securely and are not damaged		
Supplies a. Two sets of pads in sealed packages within expiration date b. Hand towel c. Scissors d. Razor e. Alcohol wipes f. Spare battery g. Spare PCMCIA data card		
Power Supply a. Verify fully charged battery inserted and within expiration date. b. Spare charged battery available c. Follow battery rotation/conditioning schedule d. Verify that system ready indication indicates READY.		

Description	OK as found	Corrective Action/Remarks
Indicators/ECG Display a. Remove PCMCIA card b. Power on system. Verify display is on. c. Self test passed d. Verify “Attach Defib Pads” message is spoken. e. Correct time displayed		
Charge/Display Cycle a. Attach simulator b. Detects, charges, and delivers shock for VF c. Responds correctly to non-shockable rhythms d. Enter manual override mode e. Connect defibrillation test load. f. Charge the unit to 360J. Fire the defibrillator and verify delivered energy is 360J +/- 36J. g. Replace PCMCIA data card		
Major Problem(s) Identified (out of service)		

Signature _____ Print Name _____

Caution

Improper maintenance may cause the Welch Allyn AED20 to malfunction. Maintain the Welch Allyn AED20 as described in this manual.

General

Prepare a customized maintenance schedule for the Welch Allyn AED20 to reflect how the unit will be used. The schedule should account for how often the unit is used and where it is used. In addition, the schedule should consider how familiar the operators are with the operation of the unit. Here are some guidelines for preparing a maintenance schedule at your facility:

When powered by a non-rechargeable battery, the AED 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 unit is operating.	If the status indicator is flashing, replace the battery. If a solid red symbol appears, remove AED from service and contact Welch Allyn customer service.
Weekly and after each use	Inspect exterior of Welch Allyn AED20 and pad connector for any signs of damage.	Clean the Welch Allyn AED20. If damaged, remove AED from service and contact Welch Allyn customer service.

Frequency	Observe	Action
Monthly	Capacity Test for rechargeable batteries	See Battery Capacity Test later in this chapter.
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.	Do not use damaged or expired supplies or accessories. Replace any used supplies and accessories such as razors, gloves, and pads.
	Recharge/replace battery	If using a rechargeable battery, place a fully charged battery into the Welch Allyn AED20 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	Remove the PCMCIA data card and replace it with a new card. Apply a patient ID label to the removed card and deliver it for review.

Frequency	Observe	Action
	Steady red status indicator symbol.	Replace/recharge battery. Turn on the AED, if possible, and note the self-test result.

Battery Maintenance

Two types of batteries can power the Welch Allyn AED20:

- 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 will **NOT** attempt to charge a non-rechargeable battery.

Either type of battery may be installed in the Welch Allyn AED20.

Caution

Use only Welch Allyn PowerStick batteries in the Welch Allyn AED20. Using an improperly maintained battery may result in power failure without warning when operating the Welch Allyn AED20.

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 charger near a heat source or in direct sunlight.
- Always charge stored batteries prior to use. Stored batteries lose charge and may cause the Welch Allyn AED20 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 Battery 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 Chapter 1 Introducing the Welch Allyn AED20 *for instructions on how to recharge and condition the battery.*

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 an 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 lest 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 insure maximum operating time fore 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 Capacity Test — Rechargeable Batteries

It is important to 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.

Perform the capacity test with a fully charged rechargeable battery. Do not perform this test on a disposable 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 3 hours of monitoring time.
4. If the operating time is less than 3 hours, recharge the battery and repeat the test. If the operating time remains less than 3 hours, remove the battery from service and replace it.
5. Recharge the battery fully 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.

Cleaning and Disinfecting the Welch Allyn AED20

Clean and disinfect the Welch Allyn AED20 regularly and observe the following cleaning and disinfecting guidelines:

- Clean the unit 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 Welch Allyn AED20 in water or other liquids. Avoid spilling any liquids on the Welch Allyn AED20 or its accessories. Liquids may damage the unit or present a fire or shock hazard.

Do not autoclave or gas sterilize the Welch Allyn AED20 or accessories.

The following are recommended cleaning agents for use on the exterior of the Welch Allyn AED20:

- 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 Welch Allyn AED20:

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

Chapter 5

Troubleshooting the Welch Allyn AED20

Welch Allyn AED20 Users Manual

This chapter provides information on how to troubleshoot situations and conditions that arise during the operation of the Welch Allyn AED20 and gives answers to frequently asked questions.

Troubleshooting the Welch Allyn AED20

If the built-in sensors in the Welch Allyn AED20 detect a problem prior to 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 determine possible corrective actions.

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

Attaching Electrode Pads

Indicator/Possible Cause	Corrective Action
Electrode pad does not adhere properly to the patient.	Wipe moisture from chest and/or shave excessive hair from chest.
Electrode pads are dry, damaged, or out-of-date.	Replace the electrode pads.
Improper pad placement or pads touching each other.	Check pad placement; make sure pads are in the correct location.
Inadequate connection to AED.	Check for proper insertion of defibrillation pads connector into AED.

Indicator/Possible Cause	Corrective Action
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 electrode pads to improve adherence to patient's skin.

Analyzing Interrupted

Indicator/Possible Cause	Corrective Action
Defibrillator pad removed.	Press electrode 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 AED.
Electrode disconnected from patient or AED.	Check the connection to the AED.
Patient movement.	Move patient to stable location when possible.
Patient's 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 correct cable.
AED 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.
AED prints unreadable characters. Incorrect baud rate settings.	Ensure adapter and AED 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.

No Shock Delivered

Indicator/Possible Cause	Corrective Action
Electrode pad connector not properly connected to the Welch Allyn AED20 socket.	Push pads connector firmly into Welch Allyn AED20 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.

Indicator/Possible Cause	Corrective Action
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 AED.	Check the connection to the AED.
Electrode Monitoring Cable is attached	Connect defibrillator pads to Welch Allyn AED20.

Defibrillator

Indicator/Possible Cause	Corrective Action
AED operates, but LCD is too dark or too light.	Adjust the contrast setting.
AED turns off or will not turn on.	Reinstall or replace the battery.
Battery depleted or disconnected.	Reinstall or replace the battery.

Indicator/Possible Cause	Corrective Action
Displayed time or date is incorrect.	Change the AED time setting. Verify that time is correct after a power ON/OFF cycle. If not, the internal 3V battery may need to be replaced.
Electrical/radio frequency interference.	Move hand-held communication devices or other suspected devices away from the AED.
Operating temperature is too low or too high.	Operate the AED between 0° to 50°C (32° to 122°F).

Battery

Indicator/Possible Cause	Corrective Action
AED needs service.	Replace battery. If condition is not corrected, contact authorized service personnel.
Depleted battery. No display or messages after ON button is pushed.	Replace battery. If condition is not corrected, contact authorized service personnel.
Low battery charge. Battery not properly charged.	Replace the battery immediately.
Operating time is short when using a rechargeable battery.	Recondition the battery and run the battery capacity test. If operating time is still short, replace the battery.

Other Problems

Indicator/Possible Cause	Corrective Action
A fault requires service.	Continue to use the AED if it is possible and needed. Contact authorized service personnel as soon as possible to repair the AED.
AED operates, but LCD is blank. Operating temperature is too low or too high.	Operate the AED between 0° and 50°C (32° and 122°F).
LCD not operating properly.	Contact authorized service personnel.

Will the Welch Allyn AED20 function correctly if I have reversed the placement of the electrode pads when I placed them on the patient's chest?

Yes. The Welch Allyn AED's ability to analyze the rhythm and to deliver shocks is independent of the polarity of the electrode pads. (See Chapter 2 *Using the Welch Allyn AED20, Applying Electrode Pads.*)

Do I select the energy level with successive shocks?

No. The energy level is pre-set when operating the Welch Allyn AED20 in Automated Mode. You can override the pre-set levels in manual mode. (See Chapter 2 *Using the Welch Allyn AED20, Selecting the Energy Level.*)

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 Welch Allyn AED20 to reconfirm the shockable condition.

Does the Welch Allyn AED20 battery have to be recharged?

It depends on which battery is being used. The Welch Allyn AED20 rechargeable NiMH PowerStick battery needs to be recharged. The Welch Allyn AED20 non-rechargeable Lithium PowerStick battery should not be placed in the charger. (See Chapter 1 *Introducing the Welch Allyn AED20, Battery Charging and Conditioning* 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. Refer to Appendix A for battery capacity specifications. When the unit is in storage, battery capacity will diminish over time. The Welch Allyn AED20 continuously monitors and reports battery capacity while in storage. The battery level status indicator alerts you when the battery needs to be replaced.

Appendix A

Specifications

Welch Allyn AED20 Users Manual

Physical

Category	Specification
Dimensions	9 3/8" x 9" x 3" (238 x 229 x 76 mm)
Weight	Less than 5 pounds (2.3 kg)
Operating Temperature	32° to 122°F (0° to 50°C)
Storage Temperature (without battery)	-22° to 150°F (-30° 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, 6-9ms pulse, 1/2 sine each axis)
Vibration	Mil Std 810E method 514.4, category 10
Water resistance	IEC 529 IPX4
In-Flight Use	Complies with RTCA/DO-160D, Section 21, Category M limits for radio frequency interference

Data Management

Category	Specification
Event Documentation	Internal and via Welch Allyn Datacard

Internal Memory Capacity	1MB: 100 4-sec ECG samples or 300 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

Category	Specification
Output	Biphasic Truncated exponential
Energy Sequence	Shock 1: 150 J, 200 J
(user configurable)	Shock 2: 150 J, 200 J, 300 J
	Shock 3: 150 J, 200 J, 300 J, 360 J
Manual Energy Selection	2,5,7,10,20,30,50,70,100,150,200,300,360J
Auto Energy Selection	2,5,7,10,20,30,50,70,100,150,200,300,360J
Manual Lockout	Via Pass code
Charge Time	Less than 8 sec.
Analysis Time	12-16 sec.

Audible Prompts 13 audible prompts

Visual Prompts 13 test screen prompts

Controls Two buttons-On/Off, Discharge
4 software configurable buttons

Waveform Details The table below provides details of the waveforms delivered by the Welch Allyn AED20 when connected to resistive loads of 25, 50, and 100 Ohms and set to its maximum output. The waveforms are characterized by typical values for peak current (I_p), duration of the first output phase (t_{phase1}), and duration of the second output phase (t_{phase2}). Values are within 10%.

Biphasic Waveforms

Load (Ohms)	I_p(Amps)	t_{phase1} (ms)	t_{phase2} (ms)
25	52.24	5.64	3.78
50	26.50	11.58	7.68
100	13.33	17.40	9.36

Output Energy Accuracy ±10% or 1J (whichever is greater) at 50Ù
±15% or 1J (whichever is greater) at 25-100Ù

Display

Category	Specification
Type	¼ VGA monochrome LCD
Size	5.7" (145 mm) Diagonal
Resolution	320x240
Freq Response	0.5 to 40 Hz
Heart Rate	20 to 300 BPM, user configurable displayed
ECG Input	Via defib pads, isolated, Type BF, defibrillator-proof
ECG Sweep Speed	22.5 mm/second
Low Battery Indicator	Battery Icon gauge on display with 10 capacity levels
Backlight (optional)	EL Backlight

Battery

Category	Specification
Rechargeable	NiMH 12V, 2.1Ah
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 to 2 hours
Non-Rechargeable	Lithium 12V, 5.2 Ah
Capacity	200 discharges at 360 Joules or
	285 discharges at 200 Joules or

	350 discharges at 150 Joules or 6 hours 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 operating temperature extremes.

Electromagnetic Compatibility

Category	Standard	Level
Radiated Emissions	EN55011	CISPR11
Conducted Emissions	EN55011	CISPR11
ESD	EN61000-4-2	8KV air 6KV contact
Radiated Susceptibility	EN61000-4-3	3 V/M (10 v/m AAMI DF2 4.3.18.1)
Electrical Fast Transients	EN61000-4-4	1KV
Electrical Fast Surges	EN61000-4-5	2KV
Conducted Susceptibility	EN61000-4-6	3 V/M, 10 V/M
Magnetic Field Emissions	MIL STD RE101	(AAMI DF2 4.3.18.1)
Magnetic Field Susceptibility	MIL STD RS101	1 Gauss, 47 Hz-1.8 KHz

Rhythm Recognition Performance

Standards

The Welch Allyn AED20 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 (>150uV) 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

Rhythm Recognition 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

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 AED20) has been introduced, which offers a biphasic truncated exponential waveform that incorporates MRL's original low peak current, impedance compensation design. The MRL Orbital™ biphasic truncated exponential waveform has been extensively tested in multiple scientific safety and effectiveness studies. Over 524 fibrillation/defibrillation shock episodes have been conducted using the MRL Orbital™ Biphasic waveform comparing it to MDS, MTS and another commercially available 2kV biphasic (360 J capable) defibrillators. Results of three of the scientific safety and effectiveness studies are summarized below.

STUDY 1

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

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

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

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

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

Summary Table - ED50 & ID50

Mean	Welch Allyn AED20	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 ± 5.5 lbs) was used in a study that was approved by the Institutional Animal Care and Use Committee. The animals were anesthetized with an intravenous injection of 20 mg/kg sodium pentothal. They were then intubated with a cuffed endotracheal tube, and maintained on isoflurane gaseous anesthetic. The femoral artery was cannulated and an intra-arterial line was placed for continuous measurement of arterial blood pressure, and for acquiring samples for arterial blood gas and electrolyte monitoring. The chest was shaved and adhesive defibrillating electrode pads were placed on the left and right chest walls.

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

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

Summary Table -ED50, ID50, & Duration

Mean	Monophasic Waveform	Welch Allyn AED20	2kV Biphasic Waveform
ID50 Peak Current (Amps)	9.0	6.4	8.3
Significance of difference (p-value)	<0.001 (Welch Allyn AED20 vs. Monophasic)		<0.001 (Welch Allyn AED20 vs. 2kV Biphasic)
ED50 Delivered Energy (Joules)	40.2	21.4	22.7
Significance of difference (p-value)	<0.001 (Welch Allyn AED20 vs. Monophasic)		0.4937 (Welch Allyn AED20 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 ohm resistor placed in series with each subject.

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

Summary Table - ED50 & ID50

Mean	Welch Allyn AED20	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	
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 which have now been used in humans for over 30 years. Starting in the early 1980s, biphasic waveforms have been extensively studied in animal models of transthoracic ventricular defibrillation. These studies have shown that a wide variety of biphasic waveforms exhibited superior defibrillation effectiveness to these conventional monophasic waveforms. In many cases, the waveform comparisons performed in animals were repeated in clinical trials involving humans. These studies have conclusively demonstrated that well-designed animal studies can and do predict the results that will be observed in humans.

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

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

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

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

Waveform Safety & Effectiveness Conclusions:

These scientific studies have demonstrated that:

1. The data suggests that the MRL Orbital™ Biphasic waveform in the Welch Allyn AED20 is at least as effective as, and may be more effective than either of the two tested monophasic waveforms, appearing to allow termination of fibrillation episodes using lower energies.

2. The MRL Orbital™ Biphasic waveform in the Welch Allyn AED20 is as effective as the 2KV biphasic truncated exponential waveform in another commercially available defibrillator.

3. The MRL Orbital™ Biphasic waveform in the Welch Allyn AED20 requires less peak current to achieve defibrillation effectiveness than either of the two monophasic waveforms or the 2KV biphasic truncated exponential waveform that is used in another commercially available defibrillator.

Appendix B

Glossary

Welch Allyn AED20 Users Manual

A-D

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)

E-K

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

L-R

LCD	liquid crystal display (Welch Allyn AED20 screen)
log	list of ECG samples and time-stamped system events
Manual AED	AED mode that provides text and voice prompts and ECG tracing; can be operated in manual mode
non-shockable rhythm	patient heart rhythms that are not a candidate for defibrillation pulse
NSR	normal sinus rhythm
Primary AED	AED 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 Welch Allyn AED20 case used to transfer data from the log to a computer

S-Z

SCA	sudden cardiac arrest
Secondary AED	AED 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 LCD screen