Chapter 9
ECG Monitoring

ECG leads are a defibrillation-protected Type CF patient connection.

The R Series products can be used for either short- or long-term ECG monitoring.

R Series products have built-in circuitry to prevent damage to their ECG monitoring circuits during defibrillation. Monitoring electrodes, however, can become polarized during defibrillator discharge, causing the ECG trace to briefly disappear from the screen. High-quality silver/silver chloride (Ag/AgCl) electrodes minimize this effect. Circuitry in the unit returns the ECG trace to the display within a few seconds.

You can monitor a patient's ECG using an ECG patient cable, hands-free therapy electrodes, or through standard defibrillation paddles.

During ECG monitoring, the R Series displays the following information:

- Five seconds of ECG waveforms
- Heart Rate
- Heartbeat indicator
- ECG source lead (I, II, III, aVR, aVL, aVF, or V with ECG cable; PADS, or PADDLES)
- ECG size (0.5, 1, 1.5, 2.0 or 3 cm/mV)
- Alarm indicator

Whenever more than one waveform is displayed, the selected ECG lead appears as the uppermost trace (unless the unit is configured for Filtered ECG).

Caution **ECG electrodes embedded in OneStep Pacing and Complete resuscitation pads produce non-standard ECG monitoring lead vectors, designated P1, P2 and P3. While ECG signals acquired from these leads are appropriate for ECG rhythm assessment and determining electrical capture during pacing, they should not be used for ECG morphological evaluations. Attach conventional ECG electrodes for diagnostic purposes**.

Preparations

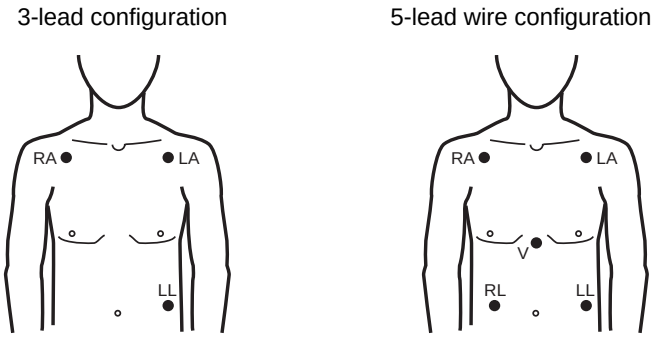
Proper application and placement of electrodes is essential for high quality ECG monitoring. Good contact between the electrode and skin minimizes motion artifact and signal interference. Remove all clothing covering the patient's chest. Dry chest if necessary. If the patient has excessive chest hair, clip or shave it to ensure proper adhesion of the electrodes.

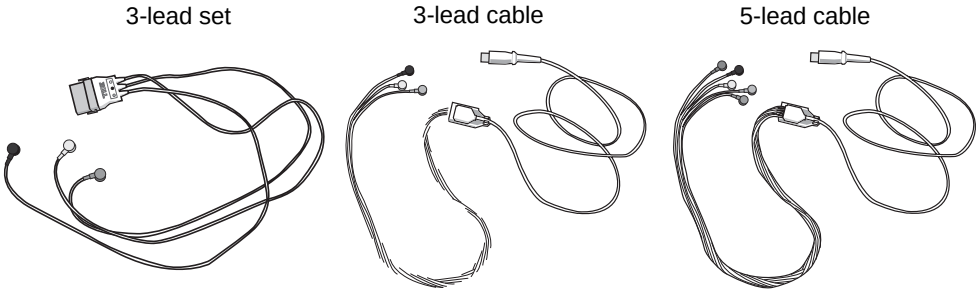
Electrode Placement

Depending upon local usage, the ECG leads are marked either RA, LA, LL, RL, and V or R, L, F, N and C. The following table shows the markings and color codes for the different lead sets.

IEC Color Coding	AHA Color Coding	Placement of Electrodes
R/Red Electrode	RA/White Electrode	Place near patient's right mid-clavicular line, directly below clavicle.
L/Yellow Electrode	LA/Black Electrode	Place near patient's left mid-clavicular line, directly below clavicle.
F/Green Electrode	LL/Red Electrode	Place between 6th and 7th intercostal space on patient's left mid-clavicular line.
N/Black* Electrode	RL/Green* Electrode	Place between 6th and 7th intercostal space on patient's right mid-clavicular line.
C/White* Electrode	V/Brown* Electrode	Single movable chest electrode.

* Not used for 3-lead monitoring





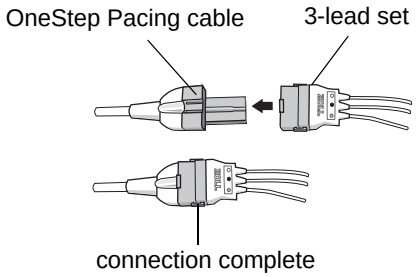
Note: Lead sets and lead cables are different accessories and are not interchangeable. For 5-lead monitoring, use a 5-lead cable.

Note: 3-lead cables are available with and without ESU noise suppression.

Monitoring Electrodes Attachment

Attach snap-on leads to electrodes and check for good contact between the electrode and the lead termination.

If you are using a 3-lead set, connect the end of the 3-lead set to a OneStep Pacing cable.



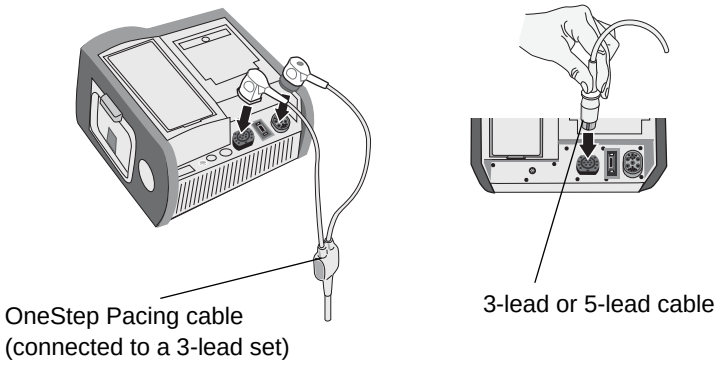
Peel the protective backing from the ECG electrode. Be careful to keep adhesive surface free of electrolyte gel.

Caution Only use electrodes that are well within the expiration date indicated on the package.

Apply the ECG electrodes firmly to the patient's skin, pressing around the entire perimeter of the electrodes.

Plug the patient cable connector into the black ECG input connector (located on the rear panel of the instrument).

Note: If you are using a 3-lead set that is connected to a OneStep Pacing cable, plug the red connector into the red OneStep cable input connector on the device, and plug the connector (that is black inside) into the black ECG input connector on the device.



Caution To avoid electrosurgery burns at monitoring sites, ensure proper connection of the electrosurgery return circuit so that the return paths cannot be made through monitoring electrodes or probes.

During electrosurgery, observe the following guidelines to minimize ESU interference and provide maximum user and patient safety:

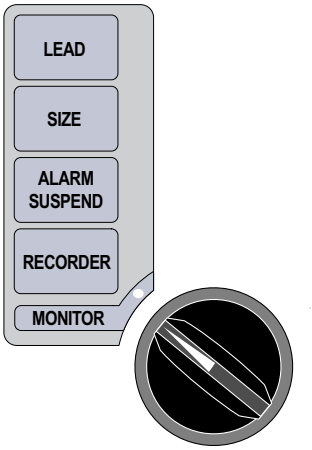
- Keep all patient monitoring cables away from earth ground, ESU knives, and ESU return wires.
- Use electrosurgical grounding pads with the largest practical contact area.

Always assure proper application of the electrosurgical return electrode to the patient.

Monitoring the Patient's ECG

Set the Controls

Set the Mode Selector to **MONITOR**, then press the **LEAD** button until the desired lead configuration is selected. The selected lead is indicated at upper right of the display.



If the unit displays the *ECG LEAD OFF, POOR LEAD CONTACT*, or *CHECK PADS* message, inspect the ECG electrodes or therapy electrodes, lead wires, and cables for proper connections.

If heart rate alarms are enabled with paddles selected, the unit displays the messages *SELECT LIMB LEADS* and *VF ALARMS OFF.* If you see these messages, select limb or precordial leads.

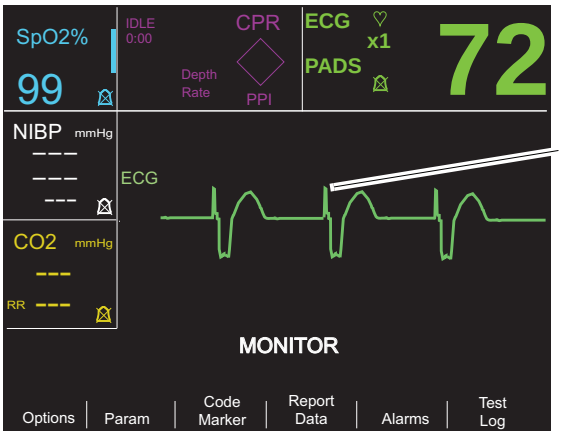
If you want to change the size of the displayed ECG waveform, press the **SIZE** button until the desired waveform size is displayed. Options are 0.5, 1, 1.5, 2, and 3 times the normal size (1 cm/mv).

If you want to shut off the heart rate beeper, press the **Options,** then the **QRS VOL OFF** softkeys. To turn it back on, press the **QRS VOL ON** softkey.

WARNING! Implanted pacemakers may cause the heart rate meter to count pacemaker pulses during incidents of cardiac arrest or other arrhythmias. Pacemaker patients should be carefully observed. Check the patient's pulse; do not rely solely on heart rate meters. Dedicated pacemaker detection circuitry may not detect all implanted pacemaker spikes; patient history and physical exam are important in determining the presence of an implanted pacemaker.

Implanted Pacemakers

The R Series device can be configured to detect pacemaker signals from a patient with an implanted pacemaker and indicate their presence on the display. When pacer pulses are detected, the device displays a 5mm, vertical, solid line on the ECG trace.



To disable detection of pacemaker spikes:

1. Press the **Param** softkey.
2. Press **ECG**.
3. Press **Disable Pacer Detect**.

To re-enable detection of pacemaker spikes:

1. Press the **Param** softkey.
2. Press **ECG**.
3. Press **Enable Pacer Detect**.

5-Lead Monitoring

You can perform 5-lead ECG monitoring with the appropriate ECG patient cable. The 5-lead cable allows you to monitor the following ECG leads:

- I, II, III
- aVR, aVL, aVF
- V1

Changing from 3-Lead Monitoring

To change from 3-lead to 5-lead monitoring, simply disconnect the 3-Lead ECG patient cable (or OneStep Pacing cable ECG connector) and connect the 5-lead ECG cable. Refer to the beginning of this section for appropriate preparations (i.e., placing electrodes, attaching electrodes, setting the controls, etc.).

If any ECG lead becomes disconnected during monitoring, an *ECG LEAD OFF* message appears on the display.

Changing from 5-Lead ECG Monitoring

To change from 5-lead monitoring to 3-lead monitoring, you must power off the unit for at least 10 seconds, remove the 5-lead cable, connect the 3-lead cable, then power on the unit again. If you fail to shut the unit off for at least 10 seconds, the unit displays the *ECG LEAD OFF* message after you disconnect the 5-lead wire cable, even if leads from a 3 lead ECG cable are properly attached to the patient.

Simultaneous 3-Lead Printing

The R Series unit can display and print three simultaneous ECG leads when using a 5 lead cable and an ECG lead is selected as the signal source (not PADS or PADDLES).

Note: This feature does not work with a 3 lead cable.

To display and print 3 simultaneous leads:

1. Press the **Options** softkey, then press the **Traces** softkey.
2. Press **3 Leads**.

Leads belong to two groups: limb leads (I, II and III) and augmented leads (aVR, aVL, and aVF). The selected lead is always displayed and printed in the Trace 1 uppermost position. The other two leads are displayed in the Trace 2 and 3 positions. For example, if aVL is the selected Trace 1 lead, the Trace 2 and 3 positions display aVR, and aVF respectively.

3 ECG leads will also be printed (when an ECG lead is selected) if the “Print 3 Leads When Leads are Sel.” configuration option is set to YES. Refer to the *R Series Configuration Guide* for instructions.

See-Thru CPR Filter (Optional)

When OneStep CPR electrodes or OneStep Complete electrodes are in use, the R Series unit allows simultaneous display and printing of the selected ECG lead and the same ECG lead with CPR filtering applied. The CPR filter uses signals from the electrode’s CPR sensor to help reduce artifact in the ECG signal caused by mechanical compressions of the chest, thereby providing a clearer view of the ECG during periods of CPR. For more detailed information on this feature, see Chapter 7, "See-Thru CPR (Optional)".

To apply the See-Thru CPR Filter to the selected ECG lead and display it:

1. Press the **Options** softkey, then press the **Traces** softkey.
2. Press the **Trace 2** or **Trace 3** softkey.
3. Press **Filt ECG**.

If Display Filtered ECG in Trace1 is configured, the unit displays the filtered ECG in Trace1. You can then switch between filtered and unfiltered ECG using the **Enable/Disable Filt ECG** softkey. With the unfiltered ECG displayed in Trace1, the user of the R Series unit can also enable the display of the filtered ECG in Trace2 or Trace3.

Adding Traces to Be Displayed

The screen can display up to three traces simultaneously. The trace for the selected ECG lead always appears in the Trace 1 uppermost position.

If optional physiological monitoring parameters are installed in the unit, the operator can select applicable traces to appear in the second or third position.

To select the display for the second or third trace:

1. Press the **Options** softkey, then press **Traces**.
2. Press **Trace 2** or **Trace 3** to select the position.
3. Press the softkey for the parameter or other waveform to display in the selected position (or **Off** to clear that position).

Note: Trace 3 is not available while the unit is in Pacer mode.

Printing the ECG on a Stripchart

The stripchart recorder documents the ECG trace with a 6 second delay at all times. To start the stripchart recorder, press the **RECORDER** button. The stripchart recorder runs continuously until you press the button again.

Each time the strip chart recorder is started, the time, date, ECG lead, size, and heart rate are printed on the top part of the paper. If the unit is pacing, the output current is also printed.

Note: Check the paper supply at the beginning of each shift and after each use to ensure adequate recording capability. A colored stripe on the paper means that the paper supply is low.

A *CHECK RECORDER* message appears on the display when the stripchart recorder is activated without paper. The stripchart recorder automatically shuts off when there is no paper.

After loading new paper, press the **RECORDER** button to start the strip chart recorder.

Diagnostic Bandwidth

When using an ECG cable for monitoring, you can switch the unit to diagnostic bandwidth (0.05-150 Hz) by pressing and holding the **RECORDER** button depressed. Diagnostic bandwidth is maintained and printing continues as long as the **RECORDER** button is held down. The unit reverts to standard monitoring bandwidth when you release the **RECORDER** button.

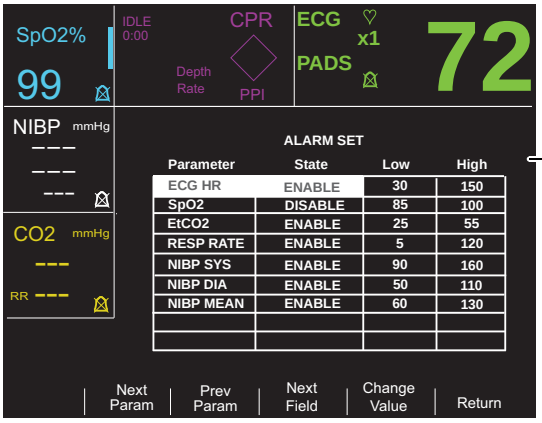
Alarms

Setting Alarm Limits

Unless configured otherwise, heart rate alarms are preset at 30 bpm (bradycardia) and 150 bpm (tachycardia). Refer to the *R Series Configuration Guide* for details on setting power-up alarm limits.

To set alarm parameters:

1. Press the **Alarms** softkey to view the Alarm Set screen and softkeys.



Each setting includes the alarm state (ENABLE, DISABLE, or AUTO) and the low and high limit of the acceptable range of values.

2. Press the **Next Param** or **Prev Param** softkey.

   This scrolls the highlighted area among the different available vital signs.

   If you want to change the state of the highlighted vital sign:

   a. Press the **Change Value** softkey.

   b. Press the **Inc** > or **Dec** < softkey to change the state value.

   c. Press the **Enter** softkey.

   The State field can be set to three possible values, Enable, Disable, or Auto.

   - Disable permanently turns off alarm processing for the selected physiological parameter.
   - Enable causes alarm processing to operate whenever alarms are activated via the front panel **ALARM** key.
   - Selecting AUTO sets the lower and upper alarm limits to 80% and 120% of the patient's currently measured heart rate, if valid measurements are present for the vital sign when the **Enter** softkey is pressed. (Refer to appropriate Operator's Guide parameter insert(s) for percentages associated with other parameters).

3. Press the **Next Field** softkey to move to the Low or High field for the highlighted vital sign; repeat steps 2a through 2c to change the Low or High value.

Note: To recalculate the Low and High limits for any parameter when these limits have previously been set using the AUTO State, follow the procedure above to select AUTO again, and then press the **Enter** softkey. The unit automatically resets the Low and High limits based upon the currently measured value of the selected physiological parameter.

4. Press the **Return** softkey to set all values and return to normal operating mode.

Heart Rate Alarm Limits

The heart rate is displayed in the upper right-hand corner of the screen.

Unless configured otherwise, heart rate alarms are preset at 30 bpm (bradycardia) and 150 bpm (tachycardia). The low heart rate alarm limit range is 20 bpm to 100 bpm.

When the unit is monitoring a patient's heart rate via ECG, the range for the high heart rate alarm limit is 60 to 280 bpm with a default setting of 150 bpm. When the unit is monitoring a patient's pulse rate via pulse oximetry (SpO_2), however, the unit automatically lowers the upper limit for the high heart rate alarm to 235 bpm. The unit restores the original high heart rate alarm limit when ECG monitoring resumes.

Vital Sign Alarms

Each vital sign has associated high and low alarm limits. You can set alarm limits for patient heart rate and other optional monitoring parameters such as pulse oximetry (SpO_2), non-invasive blood pressure (NIBP), or end-tidal carbon dioxide monitoring ($EtCO_2$), if available.

The R Series unit has three levels of alarms:

- **High Priority** — Reflects physiological parameters that are out of bounds. When these alerts occur, the unit emits a continuous audio tone, highlights the alarming parameter, and flashes the associated alarm bell.
- **Medium Priority** — Reflects equipment- related, user correctable faults such as *LEAD OFF*. The unit emits a two beep audio tone and displays a message for a timed period.
- **Low Priority** — Informational message only; the unit emits a two beep audio tone and displays a message for a timed period.

Suspending and Silencing Alarms

When a high priority alarm occurs, the unit emits a continuous alarm tone, highlights the value of the alarming parameter on the display, and flashes the bell icon associated with that parameter.

You can either suspend the alarm tone for 90 seconds or you can silence the alarm tone.

Suspending Alarm Tones

To suspend an alarm tone for 90 seconds, press and release the **ALARM SUSPEND** button in *less than 1 second*. The alarms tone stops, the unit displays an "X" across the alarm's flashing bell icon, and the value for the alarming parameter remains highlighted. (If you press the **ALARM SUSPEND** button again, alarm processing is reactivated.)

After 90 seconds, if the physiological parameter remains at a value that triggers the alarm, the unit sounds the alarm tone again.

If the alarm condition clears (the physiological parameter returns to a value within range) after you suspend the alarm tone, the unit resets the alarm and displays the bell icon (no flashing, no "X"). The alarm parameter displays normally (no highlighting).

If a second, different alarm occurs after you suspend an alarm tone, you can suspend the alarm tone for that second parameter by pressing and releasing the **ALARM SUSPEND** button again. The unit behaves the same as described above for the first alarm. Suspending a second alarm does not alter the timing or processing of the previously suspended alarm.

Silencing Alarm Tones

To silence the alarm tone, *press and hold down* the **ALARM SUSPEND** button for *between 1 and 3 seconds*. The alarm tone stops, the unit displays the alarm's bell icon in inverse video with an "X" across it, and the value of the alarm parameter remains highlighted. (If you press the **ALARM SUSPEND** button again, alarm processing is reactivated.)

The alarm tone will not sound again as long as the physiological parameter's value remains out of range.

If the alarm condition clears (the physiological parameter returns to a value within range) after you silence the alarm tone, the unit resets the alarm and displays the bell icon (no inverse video, no "X"). The alarm parameter value displays normally (no highlighting).

After the unit resets an alarm, should the physiological parameter again go out of range, it will trigger the alarm.

Activating and Deactivating Alarm Processing

To deactivate all alarms on the R Series unit, *press and hold down* the **ALARM SUSPEND** button *for 3 seconds or longer*. The bell icons for all alarms will have an "X" through them to indicate that the alarms are deactivated. Alarm parameter values display normally (no highlighting).

To reactivate the alarms, press and release the **ALARM SUSPEND** button in l*ess than 1 second*.

Smart Alarms

In **DEFIB** or **MONITOR** mode, ECG/heart rate alarm capabilities are enhanced with the defibrillation advisory feature called Smart Alarms. When alarms are operating, this feature triggers an audible alarm and displays the message *CHECK PATIENT* whenever the unit detects ventricular fibrillation or wide complex ventricular tachycardias. This message appears on the display and the stripchart recorder print out.

If alarms are operating in PACER mode, the unit displays *VF ALARMS OFF*, indicating that the Smart Alarms feature has been disabled.

The Smart Alarms feature is always disabled when augmented leads (aVR, aVL, aVF), V-leads, or PADDLES are selected for ECG monitoring. The messages *VF ALARMS OFF* and *SELECT LIMB LEADS* are alternately displayed when alarms are activated and augmented leads or V-leads are selected. These messages are displayed only the first time you select the augmented or V-leads. They are not redisplayed as you cycle through the lead selection.

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Chapter 10
Event Records and Reports

The R Series defibrillator records important event information during operation. You can retrieve this information in various forms:

- **Summary Report** — Summary report allows you to store and later retrieve important ECG and event information. You can print summary report information in various formats. For more information about Summary Report and how to print a report, refer to the Summary Report section below.
- **Full Disclosure Recording** — Full Disclosure waveforms along with event information are stored and may be reviewed using ZOLL CodeNet Central software. For information about Full Disclosure Recording, refer to “Full Disclosure Recording” on page 10-8.
- **Incident Log** — The Incident log is an abbreviated list of all major events recorded in Summary Report. For more information about the Incident log and how to print it, refer to “Printing an Incident Log” on page 10-8.

Summary Report

The R Series defibrillator automatically records defibrillation and cardioversion events, PACER mode information, heart rate alarms, and segments of ECG when the recorder is activated. Associated event information including device control settings, time, and date are also recorded.

The following events trigger Summary Report to automatically record information:

- Power is turned on.
- Stripchart recorder is turned on.
- Defibrillator shock is administered.
- Code markers entered.
- ECG rhythm analysis is initiated.
- VF alarm is triggered.

- Parameter alarm is triggered.
- Mode Selector is turned to PACER.

Note: Diagnostic bandwidth recordings are not included in Summary Report.

The unit stores and prints summary information in chronological order. The memory allocated for summary data can hold up to 350 defibrillation or 350 recorder-activated events. All event data remains in memory and is accessible until data is manually erased or until the preconfigured time interval has elapsed. (The time interval is specified in the Set Report Restart Delay parameter; see the *R Series Configuration Manual* for more information). A new patient record is automatically created when the unit has been turned off for a configurable time period of 5 minutes to 72 hours. When all memory for code summary is used, the unit issues the message *REPORT FULL*.

To continue recording the code event after the memory has been filled or to prepare the unit for a new code, the operator can erase the stored records. (Refer to “Erasing Summary Report and Full Disclosure” on page 10-9.)

Summary Report Formats

This section describes the information included with each type of summary report record.

Each summary report begins with an overview of all events currently stored in memory including:

- Date and time
- Report start time (either when the unit was turned on or, if data was manually erased, when subsequent recording began)
- Time of the last recorded event
- Total number of shocks delivered
- Cumulative pacing time
- Device ID
- System serial number

Space is provided for patient name and comments. On the last event recorded, the unit prints “SUMMARY COMPLETE” on the bottom left of the stripchart.

Figure 10-1. Summary Report

Defibrillation Event Format

The summary report function records 6 seconds of pre-shock and 9 seconds of post-shock patient ECG data. Also recorded are joules selected, joules delivered, Sync if active (includes Sync markers), ECG lead, ECG size, patient current, defib impedance, actual time and date. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event.

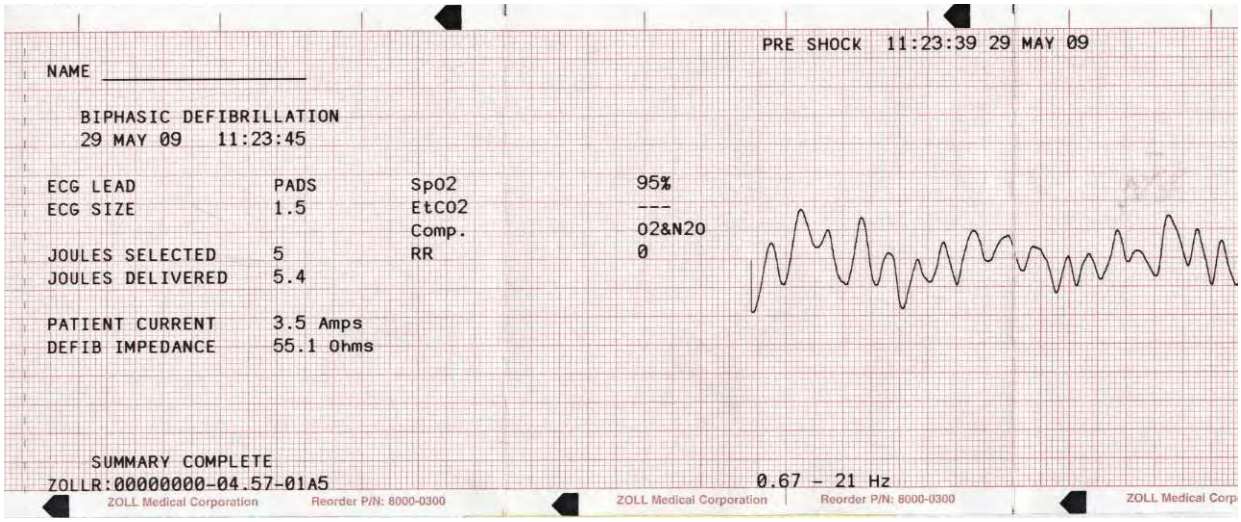


Figure 10-2. Defibrillation Event Format (Pre-Shock)

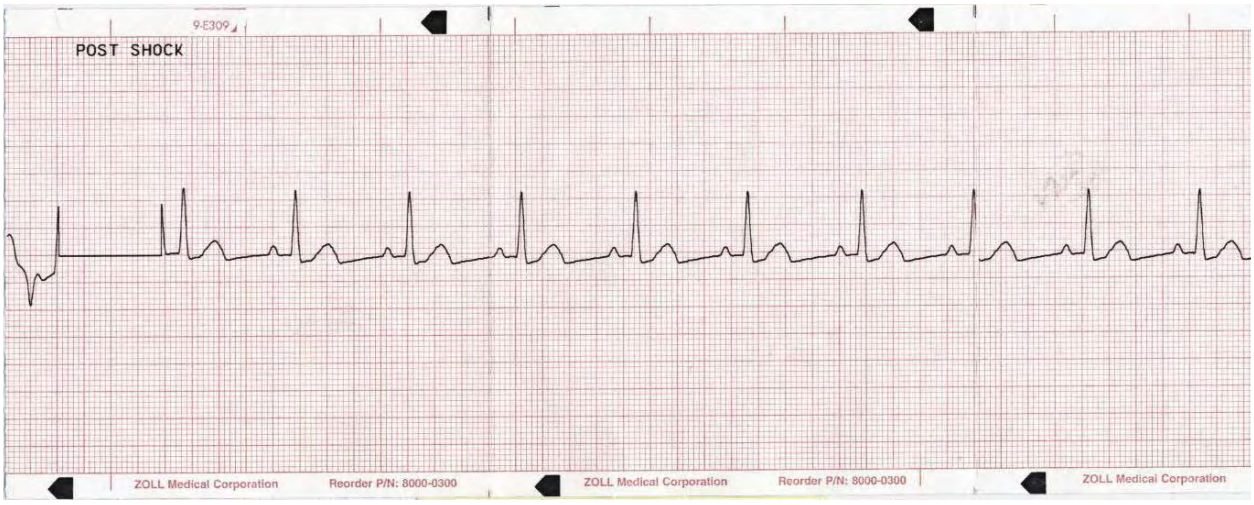


Figure 10-3. Defibrillation Event Format (Post Shock)

Pacer Mode Selected Format

The summary report function records 6 seconds of pre-pace patient ECG data. Also recorded are the ECG lead, ECG size, patient's heart rate, pace rate, pace current, time and date. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event.

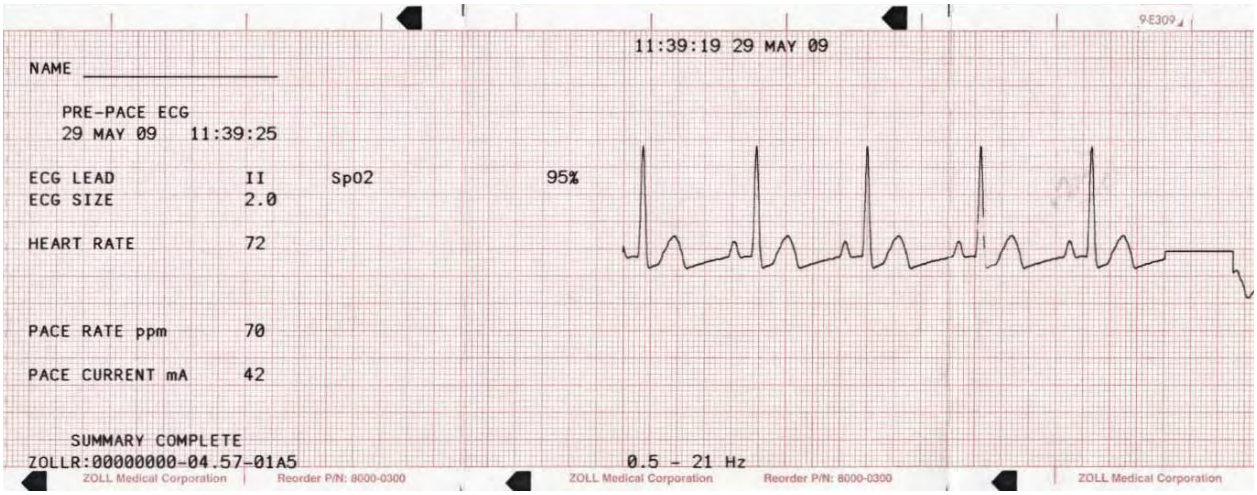


Figure 10-4. Pacer Mode Selected Format

After establishing a paced rhythm, turning the recorder on briefly records the paced rhythm for later reports. If Async pace is active, the annotation *ASYNC PACE* is also recorded and printed. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event.

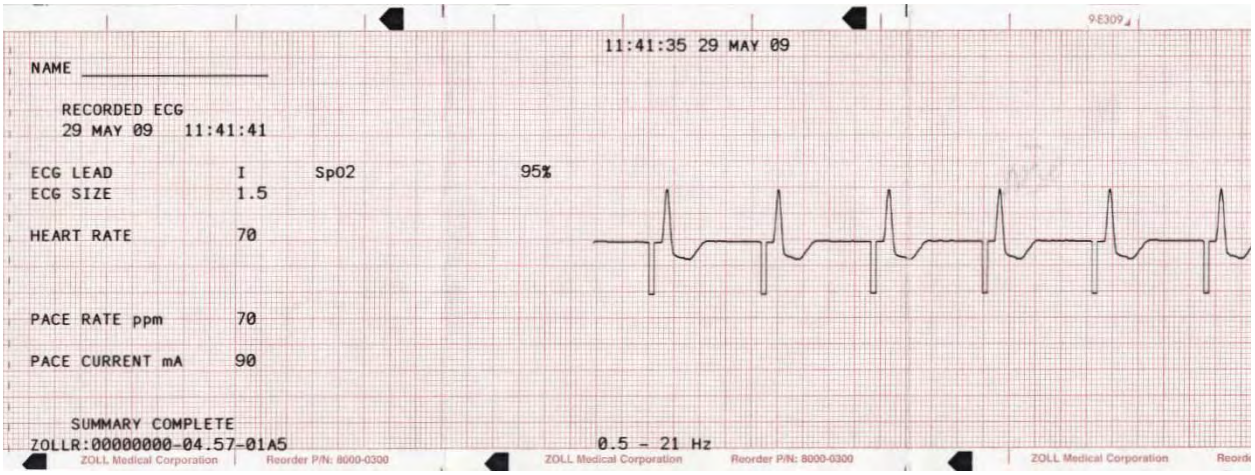


Figure 10-5. Pacer Mode Selected Format (Asynchronous Pacing)

Heart Rate Alarm Activated Format

The summary report function records 6 seconds of pre-alarm patient ECG. Also recorded are the ECG lead, ECG size, patient's heart rate, actual event time, and date. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event. If the pacer is on during this event, the pacing rate and pacing current are also recorded.

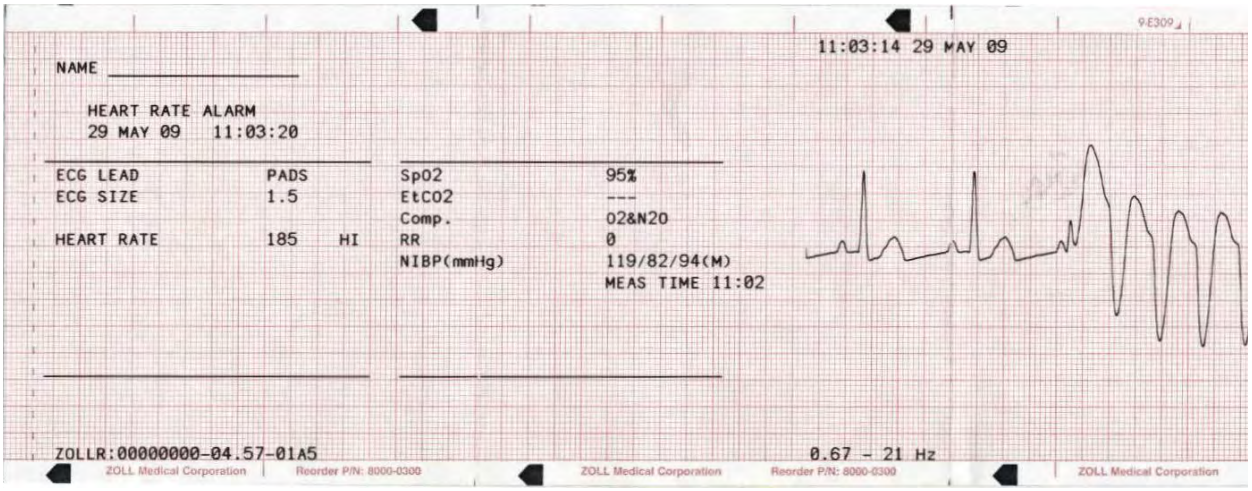


Figure 10-6. Heart Rate Alarm Activated Format

VF Alarm Activated Format

The summary report function records 18 seconds of patient ECG data associated with each VF alarm. Also recorded are the ECG lead, ECG size, actual event time, the number of noise events, and the message *CHECK PATIENT*. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event.

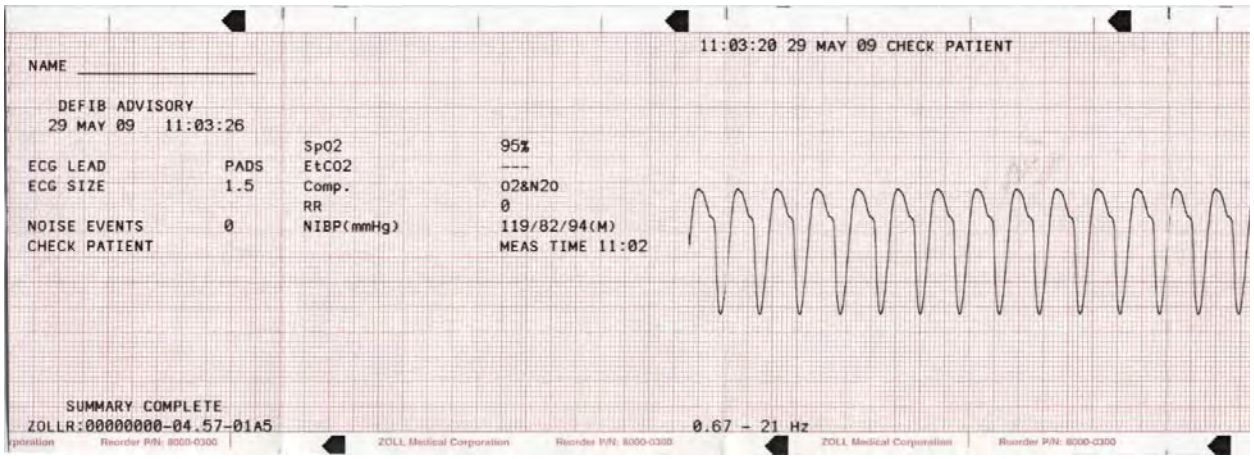


Figure 10-7. VF Alarm Activated Format

Recorder On Format

The summary report function records 6 seconds of patient ECG prior to turning on the recorder. Also recorded are the ECG lead, ECG size, patient's heart rate, actual event time, and date. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the event. If the pacer is on during this event, the pacing rate and current are also recorded. If Async pace is active, the annotation *ASYNC PACE* is recorded.

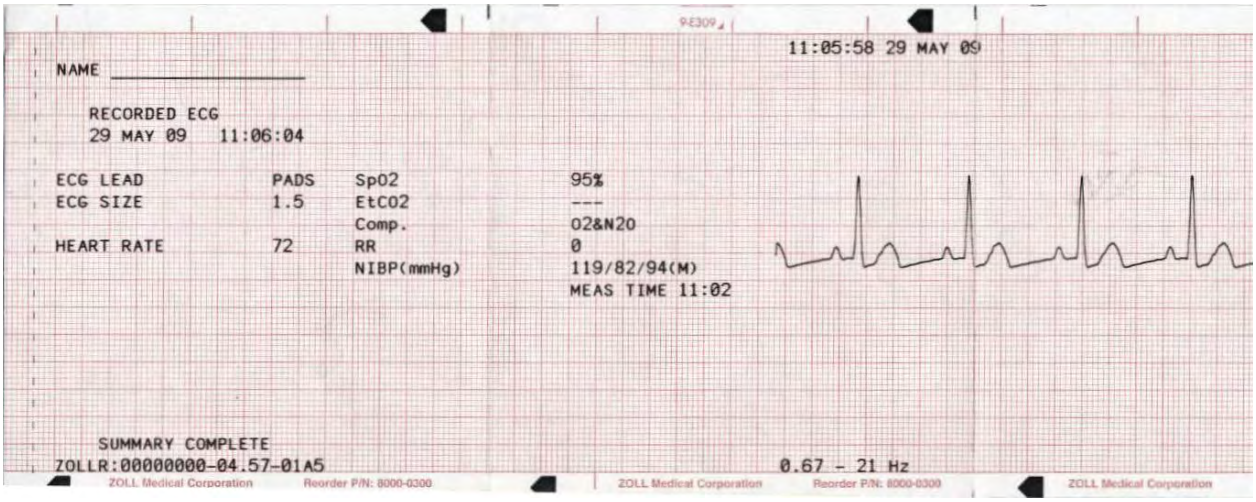


Figure 10-8. Recorder On Format

Analyze Format

The summary report function records six seconds of pre analysis ECG, 12 seconds of ECG recorded during the analysis and the annotation *SHOCK ADVISED* or *NO SHOCK ADVISED*. The date/time printed on the top of the strip corresponds to the ECG data occurring 6 seconds before the analysis was started.

The analysis normally consists of three consecutive 3-second ECG rhythm analyses. Each segment is represented at the top of the strip with either an asterisk (*) for shockable, or a dash (-) for non shockable. The unit automatically charges to the preconfigured energy level upon detection of the first shockable segment. If at least two of the three analyses determine that the patient has a shockable rhythm, the unit will prompt the operator to shock the patient. If two or more of the three 3-second ECG analyses do not detect a shockable rhythm, the unit alerts the operator that no shock is advised.

Note: If the first two segments are shockable, only two asterisks appear on the stripchart, and the third segment is not analyzed.

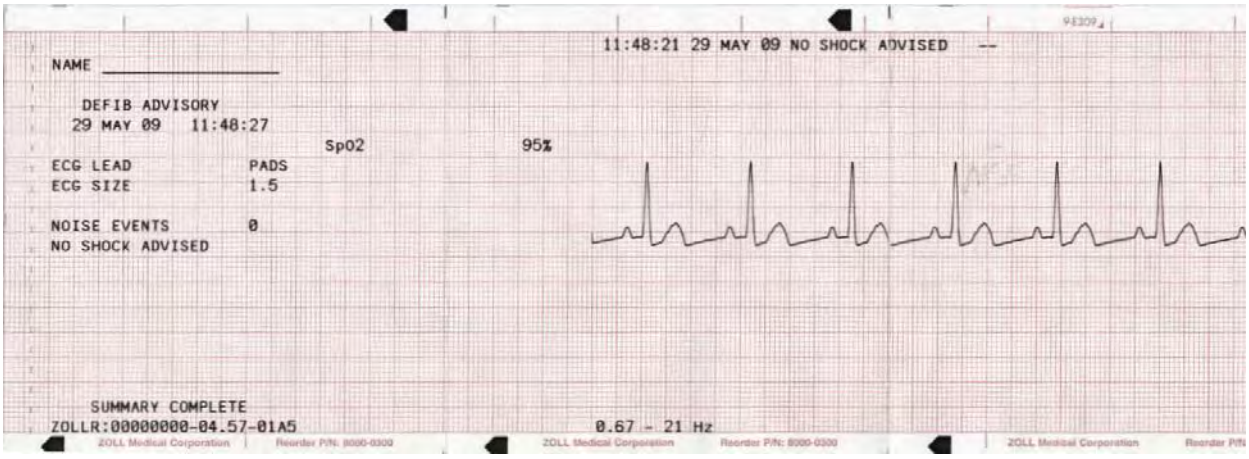


Figure 10-9. Analyze Format

In addition, the ECG rhythm analysis report can include the following annotations:

Annotation	Description
POOR PAD CONTACT	The hands-free therapy electrodes are improperly connected.
ANALYSIS HALTED	A fault condition occurred, or the operator pressed the **ANALYZE** button again.
NOISY ECG	Excessive noise was detected.
SHOCK ADVISED	A shockable rhythm was detected.
NO SHOCK ADV.	No shockable rhythm was detected.

Printing the Entire Summary Report

To print all summary report data:

1. Press the **Report Data** softkey, then press **Print Chart**.
2. Press the **Print All** softkey.

   The unit prints all stored code events and code markers in chronological order beginning with the oldest entry. If the stripchart recorder is on or the defibrillator is charged, summary report printing is disabled. To stop printing a report, press the **RECORDER** button or turn off the unit. You can print an unlimited number of copies of the report by repeating this procedure.

Note: Summary report printing is interrupted when a, ECG analysis is in progress, or the defibrillator is charging or charged. Also, if a summary report is printing and you press the **Report** softkey to print another type of report (such as the log report), the device stops printing the summary report and begins printing the selected report.

If the recorder is out of paper when the **Report Data** softkey and a corresponding print softkey are pressed, a *CHECK RECORDER* message appears on the display. Load paper and press the **Report Data** softkey again to select the report to print.

Printing a Partial Summary Report

To print a partial summary report:

1. Press the **Report Data** softkey, then press **Print Chart**.
2. Press the **Print Range** softkey.
3. Use the **First Event**, **Prev. Event**, **Next Event** and **Last Event** softkeys to locate the event from which printing will start (all subsequent events are also printed).
4. Press the **Print** softkey.

   The unit prints all records from the selected item to the most recent.

Note: The overview information (such as the number of shocks delivered) covers all stored summary data, not just the selected range.

Full Disclosure Recording

Along with event information captured in Summary Report, R Series also records the full disclosure CPR sensor and parameter waveforms. Full disclosure recordings are erased at the same times as Summary Reports.

Incident Logs

An incident log is an abbreviated list of all major events recorded in summary report. You can print an incident log that includes the following events and their time of occurrence.

- Unit powered on.
- Defibrillation advisory message issued (for example, *CHECK PATIENT* or *SHOCK ADVISED*)
- Shock delivered (and energy level)
- PACER mode selected
- Alarm triggered
- Stripchart printing started
- Code marker entered

In addition, the incident log lists the following:

- System serial number
- Device identification number
- Report start time (when the summary data was last erased)
- Time of the last recorded event
- Total number of shocks delivered
- Total cumulative pacing time

Printing an Incident Log

To print an incident log, press the **Report Data** softkey, then press the **Print Log** softkey.

The log is printed on the stripchart, starting with the oldest entry.

Erasing Summary Report and Full Disclosure

Summary information can be erased either manually or automatically.

Manual Erasure

You can manually erase summary records and full disclosure data from memory in preparation for collecting data for a new patient.

Note: When the event summary memory and full disclosure memory are filled, data recording stops. You must erase the records to continue recording.

Make sure to print out any important summary records currently in memory. Transfer important full disclosure records to ZOLL CodeNet Central.

To manually erase stored data:

1. Press the **Report Data** softkey.
2. Press the **Erase** softkey, then the **Erase Report** softkey. To erase all reports stored in the unit, press **Erase All**.

Automatic Erasure

Automatic erasure of summary report and full disclosure data occurs if the R Series unit has been turned off for a user-configurable period of 5 minutes to 72 hours.

Formatting the Disk

The R Series uses an internal flash memory disk that stores the data in files similar in structure to those on a personal computer hard drive. Like a personal computer, there may be rare occasions when the internal disk requires formatting. For example, this may occur if all power (battery and AC) is removed while erasing a report. Under such a circumstance, the message *DISK FORMAT REQ.* will be displayed. Perform the following steps to format the flash memory disk. All patient data will be erased during this procedure. If possible, print out any important summary records currently in memory and transfer important full disclosure records to ZOLL CodeNet Central.

1. Press the **Report Data** softkey.
2. Press the **Erase** softkey, then the **Format Disk** softkey.
3. When you are ready, press the **Confirm Format** softkey.

The messages *FORMATTING DISK* and *DO NOT POWER OFF* will be displayed while the disk is formatting. This procedure may take several minutes to complete.

Related Messages

Message	Description
CHECK RECORDER	The paper supply in the stripchart printer is exhausted.

Message	Description
DISK FORMAT REQ.	The internal flash memory disk file system has been corrupted. Follow the procedure in the previous section, “Formatting the Disk.”
DO NOT POWER OFF	Do not remove power (both battery and AC) while the unit is erasing reports or formatting the disk.
ERASING REPORT	The unit is erasing the selected report data.
FORMATTING DISK	The internal flash memory disk is being formatted.

Chapter 11
File Transfer

This chapter describes procedures for transferring files from the R Series defibrillator to an external system, such as a personal computer or handheld device. It also explains how to remove, install and erase a Compact Flash card.

Transferring Files to an External Device

You can transfer the following files from the R Series defibrillator to an external device:

- Device check, activity log, and full disclosure waveforms
- Defibrillator test information

The unit includes the following data transfer features:

- 802.11 Wi-Fi (optional)
- USB device connector (optional)
- Compact flash card slot

To retrieve and review event files, you need one of the following software packages installed on the receiving equipment:

- ZOLL CodeNet Central software
- ZOLL RescueNet Code Review software

To retrieve and review maintenance files, you need ZOLL Defib Dashboard software installed on the receiving equipment.

R Series defibrillators use the Microsoft Windows file structure for stored records. Files can be transferred to a properly equipped Windows-based personal computer or handheld device. With CodeNet Central software, the personal computer allows the user to access the files for review.

Wi-Fi (Optional)

The R Series has an optional Wireless Ethernet function that transfers data files using the IEEE 802.11 protocol (Wi-Fi). This includes a ZOLL R Series Data COMM Card or ZOLL R Series Data COMM II card, and a protective guard that must be installed on the unit. See *R Series Data COMM Instructions for Use and Wi-Fi Guard Installation* (Part number 9652-000395) or *R Series Data COMM II Instructions for Use and Wi-Fi Guard Installation* (Part number 9652-000405) for instructions on how to install the Wi-Fi Guard.

Do not clean the Wi-Fi Data COMM or Data COMM II Card with isopropyl alcohol.

All file transfer operations are terminated when the defibrillator is switched to either Defib mode or Pacing mode, or powered off.

Installing or Removing a Compact Flash Card

Before you begin, check the card and its connector to ensure that they are clean and undamaged.

To install a compact flash card:

1. Insert the card, with its label side up, into the front slot on the lower left side of the unit. You can install a compact flash card while the unit is operating or while it is turned off.
2. Slide the card into the slot until it is firmly seated.

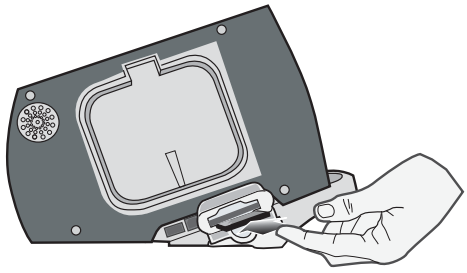


Figure 11-1. Inserting Compact Flash Card

To remove a compact flash card:

Press the release button and pull the card out of the slot.

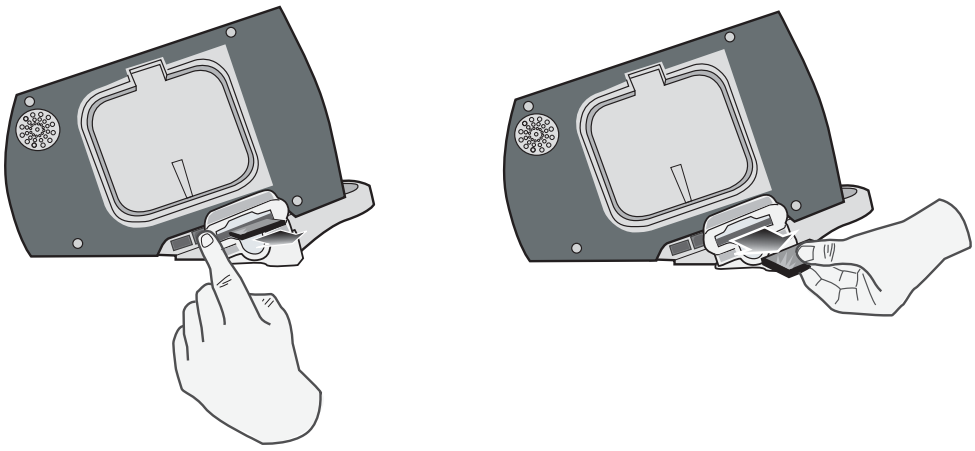


Figure 11-2. Removing a Compact Flash Card

Transferring a Full Disclosure File to a Compact Flash Card

Make sure that a compact flash card is installed in the slot on the left side of the device.

To transfer data to a compact flash card:

1. Turn the Mode Selector to **MONITOR**.
2. Press the **Report Data** softkey.
3. Press the **Transfer Mode** softkey.
4. Press the **Report to Card** softkey.

   The message *TRANSFERRING DATA* is displayed. All data is transferred to the installed CF data card.

Note: Do not remove the CF card while files are transferring. Corruption may result on the data card.

When all files are transferred, the message *DATA TRANSFERRED* is displayed. You can now remove the CF card from the R Series unit.

To exit Data Transfer mode, press the **Exit Transfer** softkey.

Transferring Device Check and Activity Log Files to a Compact Flash Card

Make sure that a compact flash card is installed in the slot on the left side of the device.

To copy the Code Readiness Log to a CF card:

1. Turn the mode selector to **MONITOR**.

2. Press the **Report Data** softkey.
3. Press the **Transfer Mode** softkey.
4. Press the **More** softkey.
5. Press the **Defib History to Card** softkey.

   The message *TRANSFERRING DATA* is displayed. All data is transferred to the installed CF data card.

Note: Do not remove the CF card while files are transferring. Corruption may result on the data card.

When all files are transferred, the message *DATA TRANSFERRED* is displayed. You can now remove the CF card from the R Series unit.

To exit the Data Transfer mode, press the **Return** softkey and then the **Exit Transfer** softkey.

Transferring Files Through the USB Port (Optional)

Before you begin, connect a USB cable from the Windows external device with USB host capability (for example, a Window PC), to the R Series defibrillator USB device port.

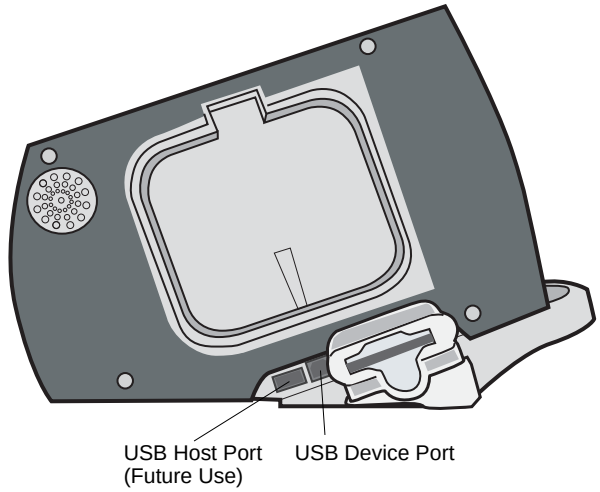


Figure 11-3. USB Ports

To transfer data through the USB port:

1. Turn the Mode Selector to **MONITOR**.
2. Press the **Report Data** softkey.
3. Press the **Transfer Mode** softkey.
4. Press the **More** softkey.
5. Press the **Enable USB** softkey.

   The R Series is now in USB Transfer Mode.
6. Initiate data transfer using ZOLL CodeNet Central.

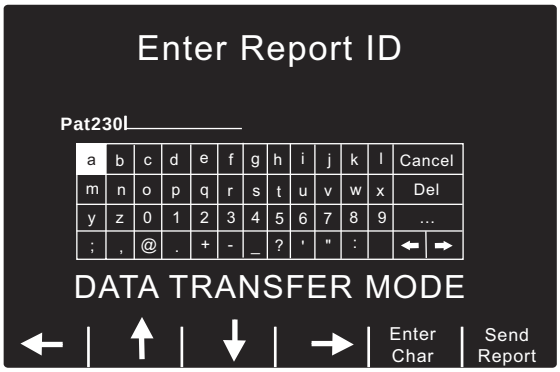
   To exit USB Transfer mode, press the **Disable USB** softkey or switch the Mode Selector to **DEFIB**, **PACER** or **OFF**.

Transferring Full Disclosure Files Through Wi-Fi (Optional)

Before you begin, ensure the Wi-Fi card is properly seated with the name R Series Data COMM or Data COMM II facing up in the compact flash slot. Make sure that the Wi-Fi guard has been attached.

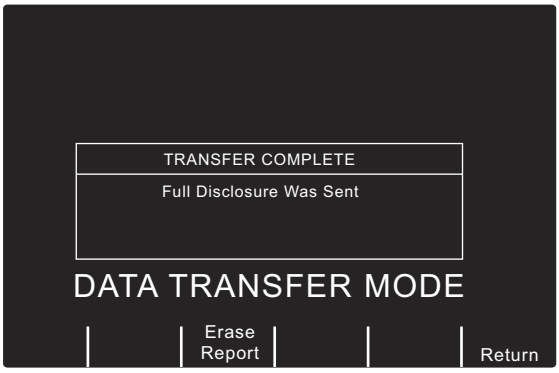
To transfer data through Wi-Fi:

1. Turn the Mode Selector to **MONITOR**.
2. Press the **Report Data** softkey.
3. Press the **Transfer Mode** softkey.
4. Press the **Report to Wi-Fi** softkey.
5. The Enter Report ID screen will appear, and you will be prompted to enter a unique report ID. Use the arrow keys to select the desired characters, then press the **Enter Char** softkey. Pressing the ... key will change the table to a different set of characters, including upper case letters. To cancel and return to the previous screen, use the arrow keys and select Cancel.



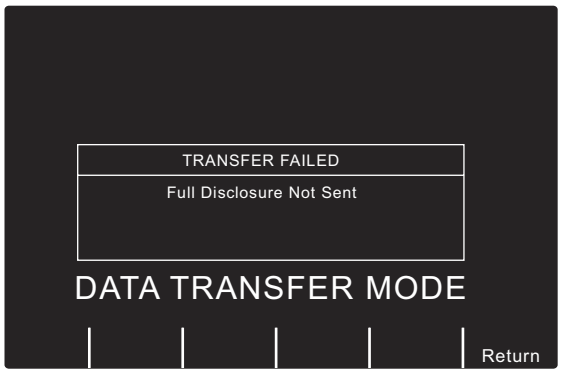
Note: Enable Report ID must be enabled in System Configuration mode for the report screen to appear (See the *R Series Configuration Guide*). If Enable Report ID is set to No, then the screen will not be displayed and the report will be sent immediately.

6. To send the report, press the **Send Report** softkey. The R Series is now in Wi-Fi Transfer Mode and a status text message box appears in the middle of the screen and describes the status of the file being sent. When the full disclosure file is transferred, the messages *TRANSFER COMPLETE* and *Full Disclosure Was Sent* are displayed.



7. To erase the report, press the **Erase Report** softkey. To keep the report and return to the Transfer Mode screen, press the **Return** softkey.

Note: If you are out of the range of an access point, the data will not be transferred and the message *Wi-Fi Network Not Found* is displayed. Press the **Return** softkey to return to the previous menu and try again.



To exit Wi-Fi/DataTransfer Mode, press the **Return** softkey and then the **Exit Transfer** softkey or switch the Mode Selector to **OFF**.

Transferring Device Check and Activity Log Files Through Wi-Fi (Optional)

Before you begin, ensure the Wi-Fi card is properly seated with the name R Series Data COMM or Data COMM II facing up in the compact flash slot. Make sure that the Wi-Fi guard has been attached.

To transfer data through Wi-Fi:

1. Turn the Mode Selector to **MONITOR**.
2. Press the **Report Data** softkey.
3. Press the **Transfer Mode** softkey.
4. Press the **More** softkey.
5. Press the **Defib History to Wi-Fi** softkey.

The R Series is now in Wi-Fi Transfer Mode and a status text message box appears in the middle of the screen and describes the status of the files being sent. When the files are transferred, the messages *TRANSFER COMPLETE, Device Check Was Sent*, and *Activity Log Was Sent* are displayed.

Note: If you are out of the range of an access point, the data will not be transferred and the message *Wi-Fi Network Not Found* is displayed.

To exit Wi-Fi/DataTransfer Mode, press the **Return** softkey and then the **Exit Transfer** softkey or switch the Mode Selector to **OFF**.

Related Wi-Fi Messages

Informational Message	**Description**
INITIALIZING NETWORK	A transfer has been initiated.
CONNECTING TO THE NETWORK	The association with the host network is being established.
CONNECTING TO SERVER	The unit is connecting to a remote system.
TRANSFER IN PROGRESS	The data transfer is in progress.
WAITING FOR SERVER RESPONSE	The unit is waiting for the final acknowledgment from a remote system.
TRANSFER COMPLETE *XX Was Sent* XX=file type (Full Disclosure, Activity Log, or Device check)	The data transfer is complete (and lists the file type that was sent).
Error Message	**Description/Action**
TRANSFER FAILED *Wi-Fi Card Not Detected* *Verify Installation of Wi-Fi Card*	The transfer failed because no Wi-Fi card is installed in the CF slot, or the card was ejected from the slot during transmission. **Action**: Make sure that the correct Wi-Fi card is properly installed in the unit.
WI-FI CARD NOT CONFIGURED *Contact Network Administrator*	The Wi-Fi card's configuration data is corrupt or blank. **Action**: Verify the configuration settings on the Wi-Fi card. Contact the Network Administrator for assistance.
TRANSFER FAILED *Invalid Wi-Fi configuration* *Error Number: N* *Contact Network Administrator*	The transfer failed because the Wi-Fi configuration was illegal. N indicates one of following error codes: *N = 1: Local Static IP settings* **Action:** 1) If running in Static IP mode, make sure that the relevant static IP addresses are not 0.0.0.0. 2) Make sure the subnet mask is in the correct format. *N = 2: Server Static IP address* **Action:** With DNS set to No, make sure that the IP addresses for the Full Disclosure Server and Defib History Server are not 0.0.0.0. *N = 3: Server Name* **Action:** With DNS set to Yes, make sure that valid names exist for the Full Disclosure Server and the Defib History Server. *N = 4: DNS IP address* **Action:** With DHCP set to No and DNS set to Yes, make sure that the DNS IP Address is not 0.0.0.0. N = 5: SSID **Action:** Make sure that there is at least one valid SSID for each desired mode (infrastructure and data management server).

	N = 6: Missing required configuration data for Network Profile 1 with Enterprise Authentication selected (Data COMM II only) **Action:** Check the following: If Authentication Protocol is set to PEAP, make sure that the following are configured: • User Identity • User Password If Authentication Protocol is set to TLS, make sure that the following are configured: • User Identity • Private Key Password • Client Certificate N = 7: Missing required configuration data for Network Profile 2 with Enterprise Authentication selected (Data COMM II only) **Action**: Same as above. N = 8: The Defib Upload Server's Username / Password are blank within the Full Disclosure and Defib History server configuration items Data COMM II only) **Action:** If Full Disclosure Transfer Mode is set to Server, make sure that the Username (Full Disclosure) and Password (Full Disclosure) entries are valid. If Defib History Transfer Mode is set to Manual, Automatic, or Both, make sure that the Username (Defib History) and Password (Defib History) entries are valid. N = 9: Missing required certificate file for Network Profile 1 with Enterprise Authentication selected (Data COMM II only) **Action:** If Authentication Protocol is set to PEAP, make sure that a root certificate has been added (if not using the default ZOLL root certificate). If Authentication Protocol set to TLS, make sure that a root certificate has been added (if not using the default ZOLL root certificate) and that the correct client certificate has been configured. N = 10: Missing required certificate file for Network Profile 2 with Enterprise Authentication selected (Data COMM II only) **Action:** Same as above.

TRANSFER FAILED *Network Error: General* *Errror Number: NNNN* *Contact Network Administrator*	The transfer failed because of a general network Wi-Fi error. NNNN may indicate one of the following error codes: N = 7004 N = 7010 N = 7011 N = 7015 N = 7016 **Action:** Install another ZOLL Data COMM card. N = 7500 N = 7501 N = 7502 N = 7503 N = 7504 N = 7505 N = 7506 N = 7507 **Action:** Install another Data COMM II card. N = 7017 **Action:** Make sure that the Defib Upload Server is running, is operational, and can be reached on the network.
TRANSFER FAILED *Network Error: Unknown [-7002]*	**Action**: Make sure that no illegal characters are used for the SSID names.
TRANSFER FAILED *Wi-Fi Network Not Found* *Contact Network Administrator*	The R Series could not associate with a Wi-Fi network. **Action:** 1) Make sure that the configuration values for the SSID names are correct. 2) Make sure that the R Series unit is within range of the wireless server. 3) Contact the Network Administrator for assistance.
TRANSFER FAILED *Could Not Connect To Server* *Contact Network Administrator*	The R Series could not communicate with the DefibUpload Server. **Action**: 1) Make sure that the DefibUpload Server is running, is operational, and can be reached on the network. 2) If WEP is enabled, make sure that the WEP keys on the R Series and Access Point match (value and slot location). 3) Make sure that the server port is correct.
TRANSFER FAILED *Network Error: DHCP* *Contact Network Administrator*	The DHCP request has failed. **Action:** 1) If WEP is enabled, make sure that the WEP keys on the R Series and Access Point match (value and slot location). 2) Make sure that the DHCP server is operational.

TRANSFER FAILED *Network Error: DNS* *Contact Network Administrator*	The DNS request has failed. **Action:** 1) Make sure that the DNS server is running, operational, and properly configured. 2) Make sure that the R Series configuration values pertaining to the server names (Full Disclosure and Defib History) are correct.
TRANSFER FAILED *Full Disclosure Service Not Available* *Contact Network Administrator*	The option to accept full disclosure files is not enabled on the server. **Action:** Contact the Network Administrator for assistance.
TRANSFER FAILED *Defib History Service Not Available* *Contact Network Administrator*	The option to accept Defib History files is not enabled on the server. **Action:** Contact the Network Administrator for assistance.
TRANSFER FAILED *Server Rejection* *Contact Network Administrator*	The server rejected the unit's request. **Action:** Contact the Network Administrator for assistance.
TRANSFER FAILED *Wi-Fi Card Not Detected* *Verify Installation of Wi-Fi Card*	The card installed in the CF slot is not an R Series Data COMM or Data COMM II card. **Action:** Install a ZOLL-approved Data COMM or Data COMM II card.
TRANSFER FAILED *Unsupported Wi-Fi Card* *Verify Installation of Wi-Fi Card*	The card installed in the CF slot is not an R Series Data COMM or Data COMM II card. **Action**: Make sure that the correct Wi-Fi card is properly installed in the unit.
TRANSFER FAILED *Authentication Error*	The encryption passphrase/key is incorrect. **Action*:*** Contact the Network Administrator for assistance.
TRANSFER FAILED *Invalid Certificate* *Contact Network Administrator*	Could not associate to an SSID using WPA/WPA2 Enterprise security because one or more of the certificates is invalid or expired. (Data COMM II only) **Action:** Contact the Network Administrator for assistance.
TRANSFER FAILED *Invalid Credentials* *Contact Network Administrator*	Could not associate to an SSID using WPA/WPA2 Enterprise security because one or more of the credentials were invalid. (Data COMM II only) **Action**: Contact the Network Administrator for assistance.

Chapter 12
Maintenance

Defibrillator equipment must be maintained to be ready for immediate use. The defibrillator should be tested daily. The R Series defibrillator gives you two readiness testing options:

- Automatic
- Manual

Note: Both automatic and manual test results are automatically recorded to internal memory.

Maintenance Frequency	
Visual Inspection	Once per day, inspect Code Readiness indicator.
Code Readiness Test (Automatic)	Once per day, unless configured Off, in which case, perform manual defibrillator testing daily.
Manual Defibrillator Testing	Once per week; daily if Code Readiness Test is configured Off.

When the R Series device ships from ZOLL, the Code Readiness indicator may show a red "X." A manual readiness test should be performed (in addition to other site-specific tests such as HiPot and Leakage) prior to putting the device into service. Follow the procedure on page 12-3, and verify that the Code Readiness indicator displays a green "✓."

Routine Procedures

Daily Visual Inspection

Equipment

Ensure that the unit is clean (with no fluid spills) and free of visible damage.

Inspect all cables, cords, and connectors for good condition (no cuts, fraying or bent pins).

Check that the paddle surfaces are clean and free of electrolyte gel and other contaminants.

Supplies and accessories

Verify the presence, proper condition and quantity of all disposable supplies (such as ECG monitoring electrodes, electrode gel, stripchart paper, alcohol swabs, razors, and antiperspirant).

Ensure that two sets of ZOLL therapy pads are available in sealed packages. Check the expiration date on all ZOLL therapy pad packages.

Batteries

Check that a fully charged battery pack is installed in the unit.

Check that a fully charged spare battery pack accompanies the unit.

Code Readiness status

Look at the ✓/x Code Readiness indicator on the R Series defibrillator. If the Code Readiness indicator displays a red “X” the unit is not ready for therapeutic use.

Should the automatic Code Readiness test fail, the R Series unit sets its Code Readiness indicator to a red “X”. If the failed unit is connected to AC power, it will also display a Code Readiness status report highlighting the defibrillator functions or accessories that are compromised. If the failed unit is not connected to AC power, only the red “X” will display. Connect the unit to AC power. Turn the unit to MONITOR mode, then press the **Test Log** softkey to determine the problem. Readiness test reports can be displayed and printed as described in “Code Readiness Log” on page 12-6.

Take corrective actions (for example, replace electrodes), or remove the unit from service, and consult “Troubleshooting” on page 13-1.

While a red “X” indicates the unit is not ready for therapeutic use, the device will not prevent a user from attempting to deliver therapy. An example of a condition in which therapy delivery may still be possible is when expired electrodes are connected to the device.

Code Readiness Test

The R Series defibrillator performs Code Readiness tests automatically to verify its integrity and readiness for emergency use. These tests verify the following:

- Battery — Verifies that the battery state of charge is sufficient for at least one hour of continuous monitoring and ten shocks at maximum energy.
- Therapy Electrodes— Verifies that OneStep Pacing, CPR, or Complete electrodes are attached to the unit, have not expired, and that the electrode gel has not dried out.

Note: The Code Readiness system automatically verifies the integrity of the specific electrodes listed above. Other electrodes (including members of the OneStep family) should be verified manually for connection, condition, and expiration date.

- ECG circuitry — Verifies that the ECG signal acquisition and processing electronics are functional.
- Defibrillator charge and discharge circuitry — Verifies that the defibrillator electronics are functional and can charge and discharge at 30 joules through the patient cable and into paddles, OneStep electrodes, or the Test Port.
- Microprocessor hardware and software — Verifies the proper function of the microprocessor electronics and the integrity of software.
- CPR circuitry and sensor — Verifies that the Real CPR Help circuits are functional (when OneStep CPR or Complete electrodes are attached).

To prepare for Code Readiness tests, do the following:

1. Connect the R Series to AC mains.
2. Do one of the following:
   - Connect unopened OneStep electrodes to the OneStep cable,
     (Unopened OneStep electrodes act as a test port. The test port capability no longer functions once the electrode package is opened and electrodes are deployed.)
   - Connect the OneStep cable to paddles, and seat the paddles in the paddle wells,
     (Verify adult paddles are installed and pushed all the way into the paddle wells.)

   or

   - Connect the OneStep cable to the test port.

After the successful completion of the readiness check, the Code Readiness indicator displays a green check, indicating that the unit is ready for therapeutic use. If configured, the R Series will print a test record following automatic test completion.

The unit performs an automatic device check, if configured to do so, once per day at the configured time. For information, refer to the *R Series Configuration Guide*.

Manual Defibrillator Testing

The following test performs:

- Power-on sequence check.
- **SHOCK** button and delivered energy check.
- Pacer check.
- Recorder check.

If a *LOW BATTERY* message appears during testing, the battery is close to depletion and should be replaced or recharged.

Before you begin

1. Connect the R Series to AC mains.
2. Do one of the following:
   - Connect unopened OneStep electrodes to the OneStep cable,
     (Unopened OneStep electrodes act as a test port. The test port capability no longer functions once the electrode package is opened and electrodes are deployed.)
   - Connect the OneStep cable to paddles, and seat the paddles in the paddle wells,
     (Verify adult paddles are installed and pushed all the way into the paddle wells.)

   or

   - Connect the OneStep cable to the test port.

Follow the instructions in either the next section, "Procedure for Testing with Paddles," or in "Defibrillator Testing with Hands-Free Therapy Electrodes" on page 12-5.

Defibrillator Testing with Paddles

WARNING! When performing this check, use your thumbs to operate the SHOCK buttons in order to avoid inadvertent shock. No portion of the hand should be near the paddle electrode plates.

To test the manual defibrillation function using paddles:

1. Turn the unit off for at least 10 seconds.
2. Turn the Mode Selector to **DEFIB**.

   The unit emits a four-beep tone indicating successful completion of the power-on self-test. The ECG source is PADDLES, and ECG size is X1. "*DEFIB 120J SE*L" appears on the display. The ECG trace appears as a solid line while the paddles are seated in the paddle wells.
3. Press the **ENERGY SELECT** buttons to set the energy to 30 joules.
4. Press the **CHARGE** button on the apex handle.
5. When the charge-ready tone sounds, press the **ENERGY SELECT** buttons to change the selected energy to 20 joules.

   The defibrillator will disarm itself.
6. Press the **ENERGY SELECT** buttons to reset the energy to 30 joules.

Note: For testing, the unit discharges the defibrillator only if the energy is set to 30 joules.

7. Press the **CHARGE** button.

   When the charge-ready tone sounds, the message *DEFIB 30J READY* appears.

8. Press paddles firmly into their wells and using your thumbs, simultaneously press and hold the **SHOCK** buttons (one on each paddle) until the shock is delivered.

   The unit displays the message *30J TEST OK* and prints a stripchart indicating *30J TEST OK* and the delivered energy.

   If the message *30J TEST FAILED* appears, contact appropriate technical personnel or the ZOLL Technical Service Department.

Defibrillator Testing with Hands-Free Therapy Electrodes

To test the manual defibrillation function using hands-free therapy electrodes:

1. Turn the unit off for at least 10 seconds.
2. Turn the Mode Selector to **DEFIB**.

   The unit emits a four-beep tone indicating successful completion of the power-on self-test. The ECG source is PADS, and ECG size is X1. "DEFIB 120J SEL," and *DEFIB PAD SHORT* appear on the display. The ECG trace appears as a solid line while the OneStep cable is connected to either the Test Port or OneStep electrodes.
3. Press the **ENERGY SELECT** buttons to set the energy to 30 joules.
4. Press the **CHARGE** button on the front panel.
5. When the charge-ready tone sounds, press the **ENERGY SELECT** buttons to set the energy to 20 joules.

   The defibrillator will disarm itself.
6. Press the **ENERGY SELECT** buttons to reset the energy to 30 joules

Note: For testing, the unit discharges the defibrillator only if the energy is set to 30 joules.

7. Press the **CHARGE** button on the front panel.
8. When the Ready tone sounds, press the **SHOCK** button on the front panel until the shock is delivered.

   The unit displays the message *30J TEST OK* and prints a stripchart indicating *30J TEST OK* and the delivered energy.

   If the message *30J TEST FAILED* appears, contact appropriate technical personnel or the ZOLL Technical Service Department.

Pacer Testing

1. Turn the Mode Selector to **PACER**.
2. Turn the **PACER RATE** control to 150 ppm, then press the **RECORDER** button.

   On the stripchart, verify that pacing stimulus markers (⌐╨¬) occur approximately every centimeter (10 small divisions or 2 large divisions).
3. Press and hold the **4:1** button.

   The frequency of the pacing stimulus markers decreases, occurring approximately every 4 centimeters (40 small divisions or 8 large divisions).
4. Turn the **PACER OUTPUT** control to 0 mA.

   There should be no *CHECK PADS* or *POOR PAD CONTACT* messages.
5. Disconnect the OneStep cable from the test port or OneStep electrodes, and slowly turn the **PACER OUTPUT** control to 16 mA or more.

The messages *CHECK PADS* and *POOR PAD CONTACT* appear alternately. The pace alarm sounds, and the **Clear Pace Alarm** softkey flashes.

6. Reconnect the OneStep cable, and press the **Clear Pace Alarm** softkey.

   The messages *CHECK PADS* and *POOR PAD CONTACT* disappear, and the alarm tone stops.

Recorder Check

1. Check the printer for an adequate supply of paper, then press the **RECORDER** button.
2. Press and hold the **SIZE** button for at least 2 seconds.

   A calibration pulse of 1 mV appears on the display while the button is held. The amplitude of the calibration pulse is independent of the SIZE setting.
3. Inspect the recorder waveform for uniformity and darkness.
4. Inspect for uniformity of annotated characters and completeness of words.
5. Check the printer speed by verifying that the calibration pulse is:
   - 2.5 mm ±0.5 mm wide
   - 10 mm ±1.0 mm high

Code Readiness Log

Each automatic and manual defibrillation test result is stored in internal non-volatile memory, the Code Log. A total of 1000 Code Readiness test records can be stored in internal memory. When the Code Readiness Log is full, the oldest records are erased on a first-in-first-out (FIFO) basis.

The Code Readiness Log can be transferred to an external computing device (see “Transferring Files to an External Device” on page 11-1).

If configured, the R Series prints a Code Readiness Test Report following the completion of each automatic defibrillator test.

To print the Code Readiness Log:

1. In MONITOR mode, press the **Report Data** softkey, then the **Test Log** softkey.

   A menu appears with the print options.
2. To print a specific test, use the **Prev Test** and **Next Test** softkeys to select the test, then press **Print Test,** or press **Print Test Log** to print the log of all of the tests.

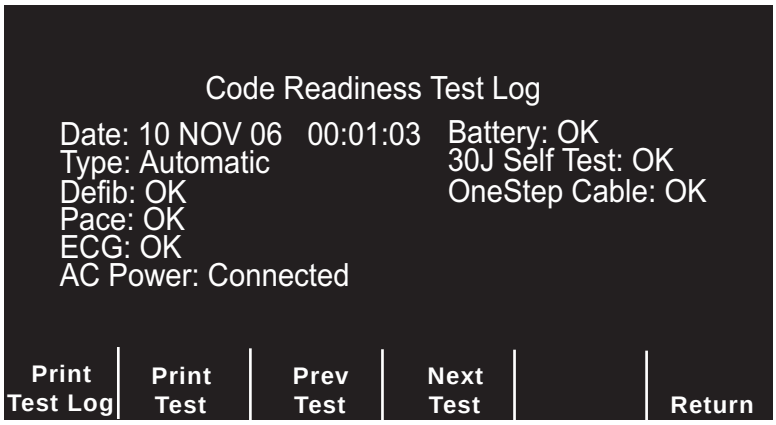


Figure 12-1. Code Readiness Test Log Print Display

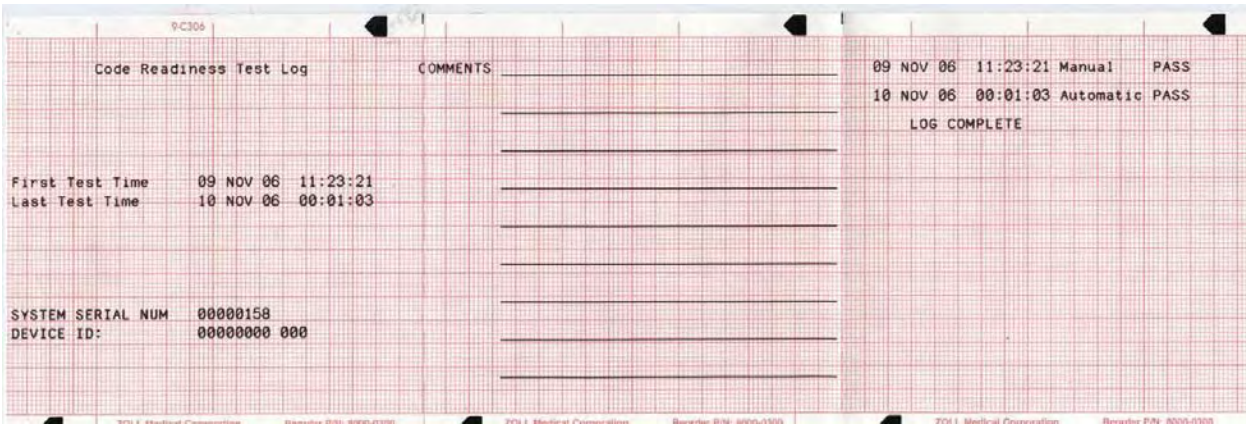


Figure 12-2. Code Readiness Test Log

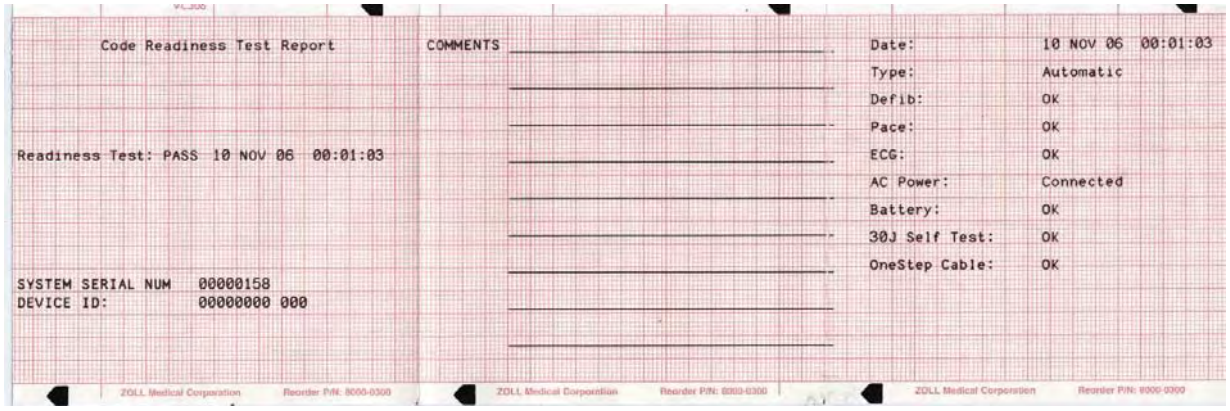


Figure 12-3. Code Readiness Test Report

Setting Time and Date

To set the unit's time and date:

1. Set the Mode Selector to **MONITOR**.
2. Press the **Options** softkey.
3. Press **More**.
4. Press **Set Clock**.

   The month field will be highlighted.

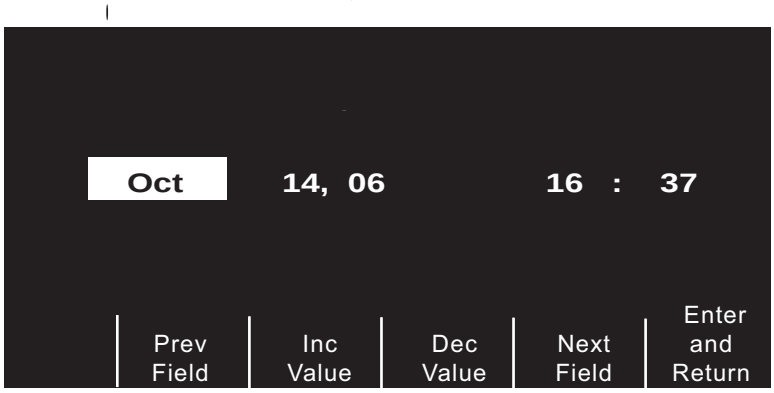


Figure 12-4. Set Time Screen

5. Press the **Inc Value** or **Dec Value** softkeys to select the appropriate month.
6. Press the **Next Field** softkey to set the selected month, and move the highlight to the next field (day).
7. Repeat steps 5 and 6 to set the correct day, year, hours, and minutes values.

Note: The last field does not automatically scroll (wrap) to the beginning. You must press the **Prev Field** softkey to enter the values for the previous field. If you need to make corrections, press the **Prev Field** softkey to move the highlight to the field previously entered.

8. Press the **Enter and Return** softkey to set all values and return to normal monitoring mode.

Note: Note: The R Series unit may be configured to synchronize the time automatically with a data server in the Wi-Fi Data Transfer configuration settings. See the *R Series Configuration Guide* for more information.

Cleaning the R Series Unit

R Series products and accessories are chemically resistant to most common cleaning solutions and noncaustic detergents. The following cleaning solutions are approved:

- 90% isopropyl alcohol (except on adapters, patient cable and Wi-Fi Data COMM Card)
- Soap and water
- Chlorine bleach solution of 30 milliliters per liter of water (except on Sync In/Marker Out connector, battery compartment pins and Wi-Fi cards)

ZOLL recommends cleaning the device, paddles, and cables with a soft damp cloth using the approved cleaning agents. The external printer parts should be cleaned with a damp, soft cloth only.

Do not immerse any part of the defibrillator (or its accessories) in water. Do not use ketones (such as acetone or MEK) on the defibrillator. Do not sterilize the defibrillator. Avoid using abrasives (including paper towels) on the display window.

Take special care to clean the defibrillation paddles after each use. The buildup of gel can interfere with ECG monitoring through the paddles, can adversely effect energy delivery and may reduce operator safety. Keep the paddle handles clean as well.

Loading Stripchart Paper

The unit displays the message *CHECK RECORDER* when the printer is activated without paper or if the supply runs out during printing.

Use ZOLL stripchart paper (Part number 8000-0300).

To load paper into the stripchart printer:

1. Press the release button and allow the printer door to open, then remove any paper.

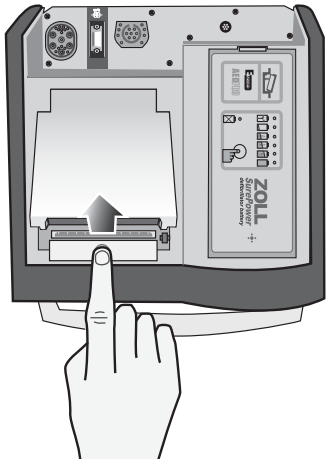


Figure 12-5. Opening the Printer Door

2. Refer to the illustration inside of the paper compartment for proper paper orientation, and place a new pad of stripchart paper in the tray.

Note: Paper feeds from the top of the stack with gridlines facing down.

3. Pull enough paper off the pad so that paper extends out of the unit when the printer cover is closed.
4. Close the printer cover by pressing down lightly on the edge of the cover next to the release button. Be sure the cover is flush with the top of the device.

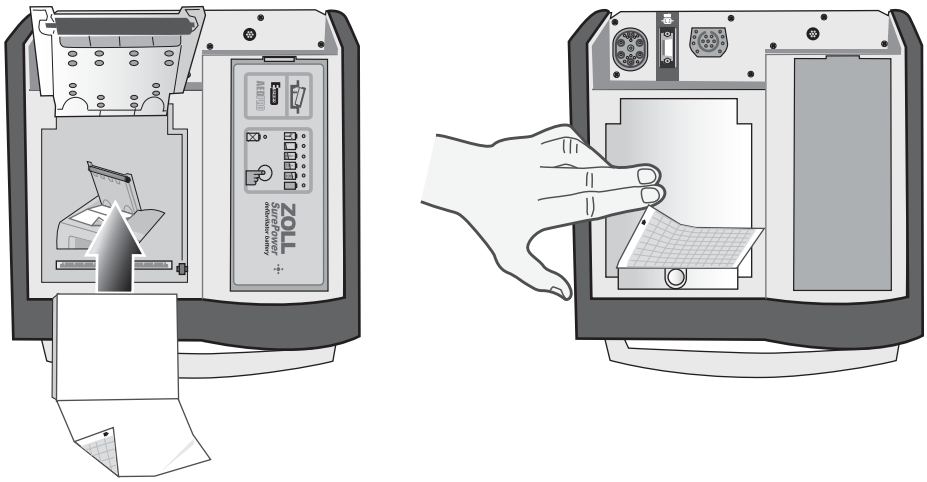


Figure 12-6. Inserting the Paper and Closing Printer Door

After the paper is loaded, press the **RECORDER** button to resume printing.

Note: To ensure you have loaded the paper properly, check to make sure the arrows printed on the red, grid side of the paper point upward.

Cleaning the Print Head

To clean the recorder print head, perform the following steps:

1. Press the release button, and allow the printer door to open (see Figure 12-5); then remove any paper.
2. Locate the printhead along the front floor of the printer compartment, just below the release button.
3. Gently wipe the printhead with a cotton swab moistened with isopropyl alcohol, and dry any residual alcohol with another dry cotton swab.

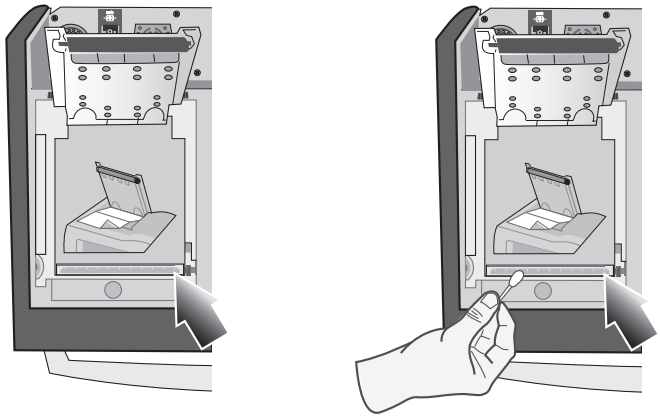


Figure 12-7. Cleaning the Print Head

4. Place the paper back into the unit and close the cover (see Figure 12-6).

Operator’s Checklist for R Series Product

Recommended checks and procedures to be performed daily or weekly, depending on Automatic Test configuration.

Date _____

Location _____

Unit Serial Number _____

		Remarks
1. Condition		
Unit clean, no spills, clear of objects on top, case intact		
2. Hands-free Therapy electrodes		
1 set preconnected / 1 spare		
3. Paddles		
Paddles clean, not pitted		
Release from housing easily		
4. Inspect cables for cracks, broken wires, connector		
A ECG electrode cable, connector		
B Defibrillator paddle cables		
C OneStep cable, connector		
D Other patient cables		
5. Batteries		
A Fully charged battery in unit		
B Fully charged spare battery available		
6. Disposable supplies		
A Defib gel or gel patches		
B Hands-free therapy electrodes in **sealed** packages — 2 sets		
C ECG electrodes		
D Recorder paper		
E Alcohol wipes		
F Razors		
7. Operational checks		
A Power On Sequence		
Turn unit to MONITOR, 4-beep tone heard		
“MONITOR” message on display		
ECG size X 1		
“PADDLES” or ‘PADS” as lead selected		
B Paddles		
Paddles in holder: Set defib energy level to 30 joules, press paddles firmly into the side wells, and simultaneously press and hold both defib discharge buttons; “30J TEST OK” message on Recorder.		
C Defibrillator		
OneStep cable connected to test connector, or OneStep electrodes**.** Set defib energy level to 30 joules, press **SHOCK** button; “30J TEST OK” message on Recorder		
D Pacer Operation (Optional)		
OneStep cable not connected to Test Connector or OneStep electrodes		
Turn to PACER, set pacer rate to 150 ppm, press **RECORDER** button		
Pacer pulses occur ever 2 large divisions (10 small divisions)		
Press **4:1** button, pulses occur every 8 large divisions		
Set PACER OUTPUT to 0 mA, no *CHECK PADS* message		
Set PACER OUTPUT to 16 mA, *CHECK PADS* message and alarm		
Reconnect OneStep cable to test connector, or OneStep electrodes. Press **Clear Pace Alarm** softkey; *CHECK PADS* message disappears and Pace alarm stops.		
E Recorder		
Press **RECORDER** button; Recorder runs. Press again; Recorder stops.		
Inspect Recorder printing		

8. Please check the appropriate box after each use of this checklist.

Signature

_____

No action required	
Minor problem(s) corrected	
Disposable supplies replaced	
Major problem(s) identified — UNIT OUT OF SERVICE	

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Chapter 13
Troubleshooting

The troubleshooting information provided in this chapter is intended for use by nontechnical medical personnel during device operation. This chapter answers many of the common problems or questions that may arise during operation.

If trouble persists after consulting this guide, contact the appropriate technical personnel or ZOLL Technical Service Department. Refer to the *R Series Service Manual* for more detailed troubleshooting information.

Code-Ready

Symptom	Recommended Action
1. Code Readiness indicator displays a red “X” while unit is turned off.	Turn the unit on. Print Code Readiness log as described on page 12-6. Follow messages and prompts to resolve the problem.
2. Code Readiness indicator displays a red “X” while unit is powered on.	Turn the unit off and then on again. Follow messages and prompts to resolve the problem. Perform a Manual Defibrillator test as described in “Manual Defibrillator Testing” on page 12-3. If the unit continues to fail, take it out of service and contact ZOLL Technical Service.

Symptom	Recommended Action
3. Pad Expired; Replace Pads	Check the expiration date on OneStep electrodes, and replace them if they are expired.
4. Poor Pad Condition; Replace Pads	OneStep electrode condition sensor indicates that the electrode gel has dried or aged beyond its specifications. The electrodes may no longer provide optimal therapy. Replace therapy electrodes. (If emergency defibrillation is required and spare hands-free therapy electrodes or paddles are not immediately available, it may be advisable to use the pads in question rather than delay therapy.)

Monitor

Symptom	Recommended Action
1. Unit does not turn on or unexpectedly shuts off.	• Check that battery pack is properly installed. • Verify the unit is plugged into AC power. • Replace battery pack with a fully charged battery pack.
2. *X FAULT XX* message	• A fault has been detected. • Attempt to clear the *X FAULT XX* message by turning the Mode Selector to **OFF** for more than 10 seconds, then back to the desired operating mode. **Note:** Some settings (e.g. alarm settings, lead selection, ECG size) may need to be restored.
3. *SET CLOCK* message	• Set time and date information. • Verify that the internal lithium battery has been replaced within the last 5 years. Contact ZOLL Technical Service Department for assistance
4. *ECG LEAD OFF* message	• Check that ECG cable or OneStep Pacing cable is connected to patient and instrument. • Check that ECG electrodes or OneStep Pacing or Complete electrodes are making good contact and are not dried out. • If changing from 5-lead ECG patient cable to 3-lead ECG patient cable, remove the 5 lead cable then turn unit **OFF** for at least 10 seconds. • Replace ECG cable or OneStep cable.
5. *POOR LEAD CONTACT* message	• Check that ECG cable or OneStep Pacing cable is connected to patient and instrument. • Check that ECG electrodes or OneStep Pacing or Complete electrodes are making good contact and are not dried out. • If changing from 5-lead ECG patient cable to 3-lead ECG patient cable, remove the 5 lead cable then turn unit **OFF** for at least 10 seconds. • Replace ECG cable or OneStep cable.

Symptom	Recommended Action
6. Noisy ECG, artifact, wandering baseline	• Consider 1 – 21Hz filter bandwidth (see *R Series Configuration Manual*). • Prepare the patient's skin prior to electrode attachment. • Check for proper adhesion of electrodes to patient. • Reduce or eliminate ECG artifact due to electrode or patient cable movement. Route cables so that they don't pull on electrodes or swing excessively. • Ensure patient is motionless. • Check for possible excessive radio frequency interference.
7. Poor ECG signal amplitude, calibration pulse normal	• Select another lead. • Apply new electrodes using different placement.
8. Inconsistent QRS beep or heart rate	• Select another lead. • Alter ECG electrode placement.
9. Sync marker is absent or inconsistent with QRS waveform on display and recorder	• Ensure device is in Sync mode. • Ensure that device in NOT in Remote Sync mode. • Change ECG lead selection. • Alter ECG electrode placement. • Paper too narrow. It should be 90 mm wide.
10. No ECG trace or dashed line on display	• Device is in Remote Sync mode. Press the **Sync On/Off** softkey to exit Remote Sync mode.

Recorder

Symptom	Recommended Action
1. *CHECK RECORDER* message	• Recorder out of paper. • Remove paper, check paper type, check recorder for paper jam, and reload paper. • Recorder door is open. • Paper is loaded upside down.
2. Recorder makes stuttering sound when activated.	• Check recorder for paper jam.
3. Light or poor quality printing	• Ensure correct paper is in use. • Ensure paper is installed grid side against recorder print head. • Recorder print head requires cleaning.
4. Summary Report will not print when **Report/Print Chart** softkeys are activated.	• 15 seconds have **not** elapsed since one of the events that trigger Summary Report to record have occurred. Wait 15 seconds, then try again.

Pacer

Symptom	Recommended Action
1. *CHECK PADS* message	• Ensure therapy electrodes are connected to the OneStep cable. • Ensure electrode gel is not dry. Replace therapy electrodes if necessary. • Ensure good electrode-to-patient contact. • Check integrity of OneStep cable by plugging into test connector. *CHECK PADS* should disappear.
2. No stimulus marker (⎍) is present on the ECG trace.	• Ensure unit is in **PACER** mode. • Ensure **PACER RATE** (ppm) is set greater than patient heart rate.
3. No ventricular capture beat appears after stimulus marker on ECG display.	• Check patient's pulse. • Increase output current. • Ensure therapy electrodes are making good contact with the patient. • Select different ECG Lead configuration. • Review therapy electrode placement.
4. Patient on "Standby" pacing gets paced intermittently.	• Ensure proper ECG electrode or OneStep Pacing/ Complete electrode connection and placement. If ECG lead wire comes off, pacer will automatically pace asynchronously. • Check ECG cable for damage. • Patient R-to-R interval varying. Pace rate close to patient's heart rate. • Verify rate is set appropriately.
5. Heart rate display reads 0 with proper pacing capture displayed on ECG trace.	• Check patient's pulse. • Select different ECG Lead configuration.
6. Bedside/Central Station/Telemetry ECG display becomes erratic when pacing.	None, the patient monitor ECG inputs are overloaded by pacer signals. ECG can only be monitored by the R Series or pacing device while pacing.

Defibrillator

Symptom	Recommended Action
1. Excessive artifact detected when using paddles as ECG source.	• Ensure “PADDLES” is selected. • Firmly press paddles against patient skin. • Use gel on paddles. • Clean paddle surface. • Check and clean between adult and pediatric shoe. • Check cable for damage. • Use ECG electrodes.
2. Defibrillator will not charge (energy level does not increment on display).	• Ensure that **SHOCK** button(s) on paddles or front panel are not stuck on. • Replace the battery pack.
3. Charge time to 200 J exceeds 10 seconds.	• Typical in a low battery condition (up to 20 seconds) • Plug device into AC power. • Install fully charged battery pack.
4. Energy does not discharge when the **SHOCK** button(s) is pressed.	• 60 seconds have elapsed in manual mode since initial charge ready. Energy was internally discharged. • Device is in Sync mode or Remote Sync mode and no QRS complex is detected. • Energy internally discharged because energy selection was changed during charge or after the device was ready. • Unit was not completely charged when **SHOCK** button(s) were pressed. Wait for *DEFIB XXXJ READY* message and ready tone. • Press and hold **SHOCK** button(s) until energy is delivered to the patient. • Pads or paddles not making good contact with patient.
5. Unable to **SHOCK** when in Sync mode	• Ensure *SYNC XXXJ SEL* is displayed on monitor. • Make sure ECG signals are displayed. • Check for Sync markers (arrow above R wave). If not present, change lead selection, or electrode placement. • Press and hold **SHOCK** button(s) until energy is delivered to the patient. • Alter ECG electrode placement.

Symptom	Recommended Action
6. Unable to **SHOCK** when in Remote Sync mode	• Ensure *REMOTE SYNC* is displayed in place of the ECG waveform and that *REMOTE SYNC XXXJ SEL.* is displayed. • Ensure that a remote device conforming with the Sync In/Marker Out specifications in Appendix A is properly connected. • Ensure that Sync markers appear with each R-wave on the remote device's display. If Sync markers are not present on the remote device's display or do not appear to be nearly simultaneous with each R-wave, do not proceed with synchronized cardioversion. • Press and hold **SHOCK** button(s) until energy is delivered to the patient.
7. No apparent energy delivery to patient	• Under certain circumstances, some patients will not show a physical reaction when energy is delivered. • Perform defibrillator self-test. • Check for *CHECK PADS* and *POOR PAD CONTACT* messages alternating on the monitor. • If hands-free therapy electrodes are used, ensure proper placement and contact. • Review the discharge stripchart for Joules/current delivered.
8. *CHECK PADS* or *ATTACH PADS* message	• Verify proper OneStep cable / hands-free therapy electrode connection by disconnecting and reconnecting the OneStep cable and hands-free therapy electrodes. • Ensure proper contact of hands-free therapy electrodes and that the patient does not have excessive hair beneath the electrodes. • OneStep cable is defective. If message persists, disconnect OneStep cable from therapy pads, and plug cable into test connector. *CHECK PADS* or *ATTACH PADS* should change to *DEFIB PAD SHORT* (Manual mode only). • Try using paddles to defibrillate.
9. *SELECT PADS* message	• ECG Analysis will operate only when hands-free therapy electrodes are attached to the patient. • Disconnect paddle, and connect hands-free therapy electrodes for use in Advisory defibrillation. • Activate manual mode to use Paddles.
10. *NOISY ECG* *RETRY ANALYSIS* message	• Check for proper application and adhesion of hands-free therapy electrodes. • Check to make sure that nobody is touching the patient and that the patient is motionless.

Symptom	Recommended Action
11. No 30J *TEST OK* message is displayed when performing a manual defibrillator self-test.	• Check to make sure unit is set to 30 joules. • If testing with OneStep electrodes, make sure that the OneStep cable patient connector is firmly inserted into the electrode connector. Ensure the OneStep electrode package is sealed. • If testing with the Test Port, make sure the OneStep cable is firmly inserted into the Test Port. • If testing with paddles, make sure to press the paddles firmly into the paddle wells while discharging.
12. *DEFIB MAINT. REQ.* message	• Contact ZOLL Technical Service Department.

AC Charger

Symptom	Recommended Action
1. The Battery indicator is alternately illuminating green and yellow.	• Verify battery is installed. • Turn unit **ON** to identify the fault condition. • Replace battery pack with a fully charged battery pack. • If problem persists, replace battery pack, unplug device from AC mains for more than 10 seconds and plug device back into AC mains.
2. *LOW BATTERY* message appears on monitor when unit is plugged into AC mains.	• Verify that the AC Power Indicator is illuminated. • If not, check AC power cord connection at the wall outlet and at the rear of the device. • Replace battery pack with a fully charged battery pack. • Unplug device from AC mains, and plug device back into AC mains. • Verify AC mains is working properly.
3. Neither the Battery, nor AC Power indicator is illuminated when the device is plugged into AC mains.	• Unplug device from AC mains, and plug device back into AC mains. • Verify AC mains is working properly.

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Appendix A Specifications

This section describes the specifications for the R Series Defibrillator as well as the ECG rhythm analysis algorithm.

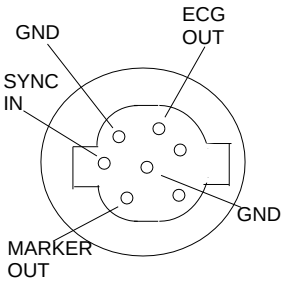
Defibrillator Specifications

General	
Size (height • width • length)	8.2 in. • 10.5 in. • 12.5 in. with handle or 10.0 in. without handle 20.8 cm • 26.7 cm • 31.7 cm with handle or 25.4 cm without handle
Weight	13.6 lb (6.17 kg) with OneStep cable and battery pack 15.2 lb (6.89 kg) with paddles
Power (for R Series ALS, BLS and Plus models)	Battery: Rechargeable lithium ion battery pack AC Power Requirements: 100-120 Vrms, 50/60 Hz 220-240 Vrms, 50 Hz AC Power Consumption: 275 VA maximum
Device classification	Class I and internally powered per EN 60601-1.
Design standards	Meets or exceeds applicable requirements of UL 60601, AAMI DF80, IEC 60601-2-4, EN 60601-2-25, and EN 60601-2-27.
Patient safety	All patient connections are electrically isolated.
Environmental	
Operating temperature	0°C to 40°C (32°F to 104°F)
Storage and shipping temperature	–20°C to 60°C (-4°F to 140°F)
Humidity	5% to 95% relative humidity, noncondensing
Vibration	IEC 68-2-6 and IEC 68-2-34
Shock	IEC 68-2-27, 50 g 6ms half sine
Operating pressure	594 to 1060 millibars (-1253 to 14046 ft.)
Particle and water ingress	IEC 529, IP 22
Electromagnetic compatibility (EMC)	CISPR 11 Class B - radiated and conducted emissions
Electromagnetic immunity	AAMI DF80; EN 61000-4-3 to 10 V/m
Electrostatic discharge	AAMI DF80; EN 61000-4-2
Conducted susceptibility	EN 61000-4-4, 61000-4-5, 61000-4-6
Display	
Screen type	High-resolution, liquid crystal display (LCD)
Screen size	6.5 inches (16.5 cm) diagonally
Display format	Nonfade moving bar display.
Sweep speed	25 mm/s
Viewing time	5 seconds 4 seconds with certain monitoring parameter options

Messages	ERASING REPORT, INSERT CARD, REPLACE BATTERY, LOW BATTERY, PERFORM CPR, NOISY ECG, RETRY ANALYSIS, CHECK PATIENT, ANALYSIS HALTED, PRESS ANALYZE, NO SHOCK ADV., SHOCK ADVISED, PRESS CHARGE, SELECT PADS, SELECT ECG LEADS, SELECT DEFIB MODE, VF ALARMS OFF, REMOVE SYNC, CHECK PADS, ATTACH PADS, POOR PAD CONTACT, DEFIB PAD SHORT, PADDLE FAULT, ECG LEAD OFF, USE PADDLE DISCHG, CANNOT CHARGE, RELEASE SHOCK, PRESS SHOCK, 30J TEST OK, TEST FAILED, PACER DISABLED, DEFIB DISABLED, SET PACE MA, CHECK RECORDER, ANAYLZING ECG, FULLY RELEASE
Electrodes	
Hands-free therapy electrodes	• OneStep electrodes • pro-padz • stat-padz • Adult stat-padz II • Pediatric pedi-padz
Defibrillator	
Waveform	Rectilinear Biphasic
Energy selection (Adult)	Selection through front panel buttons or paddle buttons: • **ADULT:** 1, 2, 3, 4, 5, 6, 7 8, 9, 10, 15, 20, 30, 50, 75, 100, 120, 150, 200 joules • **PEDIATRIC:** 1, 2, 3, 4, 5, 6, 7 8, 9, 10, 15, 20, 30, 50, 70, 85, 100, 120, 150, 200 joules
Charge Time	• Less than 7 seconds with a new, fully charged battery (first 15 charges to 200 joules). • For the fifteenth discharge at maximum energy, the charge time is less than 10 seconds. Depleted batteries result in a longer defibrillator charge time. • Less than 15 seconds when operating without a battery, using AC power alone at 90% of the rated mains voltage. • Less than 25 seconds from the initial power on, with a new, fully charged battery pack (depleted by up to fifteen 200 Joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage. • Less than 30 seconds from initiation of rhythm analysis (advisory mode) with a new, fully charged battery pack, (depleted by up to fifteen 200 Joule discharges) or when operating without a battery, using AC power alone at 90% of the rated mains voltage.
Patient Impedance Range	15 - 300 ohms
Energy display	Screen shows selected and delivered energy.
Synchronized mode	Synchronizes defibrillator discharge to the patient's R wave. SYNC is indicated on the display with R wave markers above the ECG waveform on the screen and stripchart. When ECG is monitored by the device, meets the DF-80:2003 requirement of 60ms maximum time delay between the peak of the R wave and the delivery of energy.
Charge controls	**CHARGE** button on front panel and apex paddle.
Paddles	Standard apex/sternum paddles. Adult plate slides off to expose smaller plate for pediatric patients.

Automatic Defibrillator Test	Verifies defibrillator charging and discharging without removing paddles from storage wells or with OneStep cable connected to the Test Port or OneStep electrodes.
Defibrillation advisory	Evaluates electrode connection and patient ECG to determine if defibrillation is required. Shockable rhythms: • Ventricular fibrillation (VF) with amplitude > 100 μV • Wide-complex ventricular tachycardia (VT) with rates greater than 150 beats per minute (adult), or 200 beats per minute (pediatric). Refer to "ECG Rhythm Analysis Algorithm Accuracy" on page A-29 for sensitivity and specificity performance.
CPR Monitoring	
Compression depth	0.75 to 3 inches ±0.25 inches 1.9 to 7.6 cm ±0.6 cm
Compression rate	50 to 150 compressions per minute
ECG Monitoring	
Patient connection	3-lead cable, 5-lead cable, paddles, or hands-free therapy electrodes
Input protection	Fully defibrillator-proof. Special circuitry prevents distortion of ECG during pacer pulse.
Implanted pacemaker spike display	Dedicated circuitry detects most implanted pacemaker spikes and provides standard display marker of spike on ECG trace.
Implanted Pulses Detected	±2 mV to ±700mV amplitude, 0.1ms to 2ms width, with a recharge constant of 0 to 100ms. **Note:** The pacemaker pulse rejection capability for the R Series with pacemaker pulses alone includes pulses between +/-2mV and +/-700mV amplitude, with widths between 0.1ms and 2ms and overshoot from 0 to 100ms. The pacemaker pulse rejection capability for the R Series with pacemaker pulses and a normally paced QRS and T wave includes pulses between +/-2mV and +/-700mV amplitude, with widths between 0.1ms and 2ms and overshoot from 0 to 100ms. The pacemaker pulse rejection capability for the R Series with pacemaker pulses with an ineffectively paced QRS pattern includes pulses between +/-2mV and +/-700mV amplitude, with widths between 0.1ms and 2ms and overshoot from 0 to 100ms. The R Series is not capable of rejecting A-V Sequential pacemaker pulses.
Bandwidth	0.5 Hz to 21 Hz standard; 0.05 Hz to 150 Hz diagnostic 0.5 Hz to 40 Hz, and 1 Hz to 21 Hz as configurable options
Lead selection	I, II, III, aVR, aVL, aVF, V, PADS, PADDLES, INTL PADDLES P1, P2, P3 with OneStep Pacing electrodes
ECG size	0.5, 1, 1.5, 2, or 3 cm/mV Current value shown on display.
Heart rate range	0 to 300 beats per minute

Heart rate accuracy	±5%
Heart rate alarm	Screen icon indicates activated/deactivated status. User selectable. Tachycardia: 60 to 280 beats per minute Bradycardia: 20 to 100 beats per minute
Tall T-wave Rejection	≤ 0.8 mV
Heart Rate Averaging	The R Series averages the interval between the last 5 detected beats. On startup, the R Series averages the rate between detected beats once two beats are detected, until a full 5 beats have been received. The rate is updated every beat. After this condition is met, the meter is updated every beat with an average of the last 5 beats. If a period of time greater than 5 seconds elapses without a beat detected, the heart rate meter reports a rate of 0 bpm, which is repeated every 5 seconds.
Accuracy and Response Time to Irregular Rhythm	Averaging over 5 R -R intervals, per AAMI EC 13:2002: • Ventricular bigeminy (Figure 3a) - 80.5 bpm • Slow alternating ventricular bigeminy (Figure 3b) - 60.5 bpm • Slow alternating ventricular bigeminy (Figure 3c) - 120.5 bpm • Bidirectional systoles (Figure 3d) - 93.3 bpm
Response Time to Change in Heart Rate	Average response time: 3.37 seconds
Time to Alarm for Tachycardia	Minimum time to alarm: 3.66 seconds Maximum time to alarm: 8.41 seconds
Leads Off Sensing	A dc current of 0.04 uA per lead wire is supplied to the patient.
Active Noise Suppression	The sum of all leadwire currents is returned via the active noise suppression leadwire: • 0.08 uA DC in 3 lead mode • 0.16 uA DC in 5 lead mode
Pacemaker option	
Type	VVI demand; asynchronous (fixed rate) when used without ECG leads or in asynchronous (Async) pacing mode
Pulse type	Rectilinear, constant current
Pulse duration	40 ms ±2 ms
Pulse amplitude (output)	Variable 0 mA to 140 mA ±5% or 5 mA, whichever is greater Increments/decrements by a value of 2 mA
Pacing rate	30 to 180 pulses per minute (ppm) ±1.5% Increments/decrements by a value of 2 ppm
Output protection	Fully defibrillator-protected and isolated
Recorder and Stripchart Printer	
Paper	80 mm thermal (grid width) 90 mm (paper width)
Speed	25 mm/s
Delay	6 seconds
Annotations	Time, date, defibrillation energy, heart rate, pacer output, QRS synchronization marker, ECG size, ECG lead, alarm, defibrillator test result, analyze ECG, diagnostic bandwidth Messages: *ANALYSIS HALTED*, *NOISY ECG*, *SHOCK ADVISED*, *NO SHOCK ADV.*

Printing method	High-resolution, thermal array print head	
Printout modes	Manual or automatic; user-configurable	
Data card		
Type	Compact flash card	
Sync in / Marker out / ECG out		
Sync In	0-5 V (TTL Level) pulse, active high, 5 to 15 msec in duration, no closer than 200 ms apart. Energy transfer begins within 25 ms of the leading edge of the external sync pulse.	**R Series Connector Pinout**  SWITCHCRAFT CONXALL 17982-7SG-300 Mating Connector: SWITCHCRAFT CONXALL 16982-7PG-522
Marker Out	0-5 V (TTL Level) pulse, active high, 10 ms in duration, the leading edge of the pulse occurs within 35 ms of the peak of the R-wave)	
ECG Out	1.0 V/cm of deflection on stripchart recorder <25 ms delay from patient ECG input	
Wi-Fi Card		
ZOLL R Series Data COMM	Model: 802.11 abgn Wireless LAN Compact Flash Card	

Battery Pack Specifications

Type	Rechargeable lithium ion
Weight	1.7 lb (0.77 kg)
Nominal voltage	10.6 V
Recharge time	4 hours or less within R Series.
Operating time	For a new, fully charged battery at 20°C: • 100 defibrillator discharges at maximum energy (200 joules), or • 4 hours of continuous ECG monitoring, or • 3.5 hours of continuous ECG monitoring and pacing at 60 mA, 80 pulses per minute
Low battery indicator	The message *LOW BATTERY* is displayed on the screen when there is approximately 15 minutes of ECG monitoring time left on the battery. Two-beep low battery tone sounds once a minute until just before shutdown when the unit beeps twice every 2 seconds. The time from display of the message *LOW BATTERY* or *REPLACE BATTERY* until the defibrillator shuts down varies depending on the battery age and condition.
Battery Shelf Life	3 months before retest and recharge

IEC 60601-1-2 Specifications

This section provides specification tables for the R Series as per IEC 60601-1-2.

Electromagnetic Emissions Declaration

Guidance and manufacturer's declaration — electromagnetic emissions for the R Series.

The R Series is intended for use in the electromagnetic environment specified below. The customer or user of the R Series should ensure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11	Group 1	The R Series uses RF energy for its internal function only. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The R Series is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Electromagnetic Immunity Declaration (EID)

Guidance and manufacturer's declaration — electromagnetic immunity for the R Series.

The R Series is intended for use in the electromagnetic environment specified below. The customer or user of the R Series should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the R Series requires continued operation during power mains interruptions, it is recommended that the R Series be powered by an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical commercial or hospital environment.
NOTE: U_T is the AC mains voltage prior to the application of the test level.			

EID for Life-Support Functions

Guidance and manufacturer's declaration – electromagnetic2 immunity – for life-supporting equipment and systems.

The life-support functions[a] of the R Series are intended for use in the electromagnetic environment specified below. The customer or user of the R Series should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the R Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[b]	3 Vrms	$d = 1.17\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands[b.]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters.[c] Field strengths from fixed RF transmitters, as determined by electromagnetic site survey,[d] should be less than the compliance level in each frequency range.[e] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a. The life-support functions on the R Series are defined to be any function associated with ECG monitoring, pacing, defibrillation, and shock analysis. Specifically, these functions include, but are not limited to, the ECG waveform monitoring from leads or pads, the pacing pulse output, QRS detection, defibrillation energy discharge, and shock advisory functions.

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

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

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

e. Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 10 V/m.

Recommended Separation Distances from RF Equipment for the R Series Life-Support Functions

Recommended separation distances between portable and mobile RF communications equipment and the R Series.

The life-support functions[a] of the R Series are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the R Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the R Series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment (in watts)	**Separation distance according to frequency of transmitter (in meters)**			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	**150 kHz to 80 MHz in ISM bands** $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

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

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

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

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

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

a. The life-support functions on the R Series are defined to be any function associated with ECG monitoring, pacing, defibrillation, and shock analysis. Specifically, these functions include, but are not limited to, the ECG waveform monitoring from leads or pads, the pacing pulse output, QRS detection, defibrillation energy discharge, and shock advisory functions.

EID for Non–Life-Support Functions

Guidance and manufacturer's declaration – electromagnetic immunity – for non–life-supporting equipment and systems.

The non–life-support functions[a] of the R Series are intended for use in the electromagnetic environment specified below. The customer or user of the R Series should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the R Series, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.6 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters. Field strengths from fixed RF transmitters, as determined by electromagnetic site survey,[b] should be less than the compliance level in each frequency range.[c] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a. The non–life-support functions on the R Series are defined to be any function not listed as a life-support function in the "EID for Life-Support Functions" table (Note a). Specifically, this function is SpO_2.

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

c. Over the frequency ranges 150 kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances from RF Equipment for the R Series Non–Life-Support Functions

Recommended separation distances between portable and mobile RF communications equipment and the R Series.

The non–life-support functions[a] of the R Series are intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the R Series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the R Series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment (in watts)	**Separation distance according to frequency of transmitter (in meters)**		
	150 kHz to 80 MHz $d = 1.2\ \sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\ \sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\ \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

a. The non–life-support functions on the R Series are defined to be any function not listed as a life-support function in the "EID for Life-Support Functions" table (Note a). Specifically, this function is SpO_2.

R Series Rectilinear Biphasic Waveform Characteristics

Table A-1 shows the characteristics of the R Series Rectilinear Biphasic™ waveform when discharged into 25 ohm, 50 ohm, 100 ohm, 125 ohm, 150 ohm and 175 ohm loads at the maximum energy setting of 200 joules.

Table A-1. R Series Rectilinear Biphasic Waveform Characteristics

	200 J discharged into					
	25Ω	**50Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**
First phase						
Maximum initial current	31.4 A	30.4 A	19.7 A	19.4 A	16.7 A	15.6 A
Average current	27.1 A	24.9 A	17.5 A	16.2 A	14.4 A	13.2 A
Duration	6 ms	6 ms	6 ms	6 ms	6 ms	6 ms
Interphase duration (between first and second phases)	200 μs	200 μs	200 μs	200 μs	200 μs	200 μs
Second phase						
Initial current	29.2 A	18.8 A	15.1 A	13.2 A	12.1 A	11 A
Average current	14.7 A	13 A	12.5 A	11.3 A	10.7 A	9.9 A
Duration	4 ms	4 ms	4 ms	4 ms	4 ms	4 ms

Table A-2. Delivered Energy at Every Defibrillator Setting into a Range of Loads

Selected Energy	**Load**							
	25Ω	**50Ω**	**75Ω**	**100Ω**	**125Ω**	**150Ω**	**175Ω**	**Accuracy***
1 J	1 J	1 J	1 J	1 J	1 J	1 J	1 J	±15%
2 J	1 J	2 J	2 J	2 J	2 J	2 J	2 J	±15%
3 J	2 J	3 J	3 J	3 J	3 J	3 J	3 J	±15%
4 J	3J	4 J	4 J	5 J	5 J	5 J	4 J	±15%
5 J	3 J	5 J	6 J	6 J	6 J	6 J	6 J	±15%
6 J	4 J	6 J	7 J	7 J	7 J	7 J	7 J	±15%
7 J	5 J	7 J	8 J	8 J	8 J	8 J	8 J	±15%
8 J	5 J	8 J	9 J	9 J	10 J	9 J	9 J	±15%
9 J	6 J	9 J	10 J	11 J	11 J	11 J	10 J	±15%
10 J	7 J	10 J	12 J	12 J	12 J	12 J	12 J	±15%
15 J	10 J	16 J	17 J	18 J	18 J	18 J	17 J	±15%
20 J	14 J	21 J	23 J	24 J	24 J	24 J	23 J	±15%
30 J	21 J	32 J	35 J	36 J	37 J	36 J	35 J	±15%
50 J	35 J	54 J	59 J	61 J	62 J	61 J	59 J	±15%
70 J	49 J	76 J	83 J	85 J	87 J	86 J	83 J	±15%
75 J	53 J	81 J	89 J	91 J	93 J	92 J	89 J	±15%
85 J	60 J	92 J	101 J	104 J	106 J	104 J	101 J	±15%
100 J	71 J	109 J	119 J	122 J	125 J	123 J	119 J	±15%
120 J	85 J	131 J	143 J	147 J	150 J	147 J	143 J	±15%

Table A-2. Delivered Energy at Every Defibrillator Setting into a Range of Loads

Selected Energy	Load							
	25Ω	50Ω	75Ω	100Ω	125Ω	150Ω	175Ω	Accuracy*
150 J	107 J	164 J	180 J	183 J	188 J	184 J	179 J	±15%
200 J	142 J	230 J	249 J	253 J	269 J	261 J	260 J	±15%

* For all energy levels, accuracy is equal to either ±15% or 3 joules, whichever is greater.

The R Series Rectilinear Biphasic waveform employs the same first and second phase timing, similar first and second phase currents/voltages, and essentially the same mechanisms for controlling defibrillation waveshape as the ZOLL M Series® defibrillator. The M Series and R Series defibrillation waveforms are considered substantially equivalent.

Figures A-1 through A-21 show the Rectilinear Biphasic waveforms that are produced when the R Series defibrillator is discharged into loads of 25, 50, 75, 100, 125, 150, and 175 ohms at each energy setting.

The vertical axis shows the current in amperes (A); the horizontal axis shows the duration of time in milliseconds (ms).

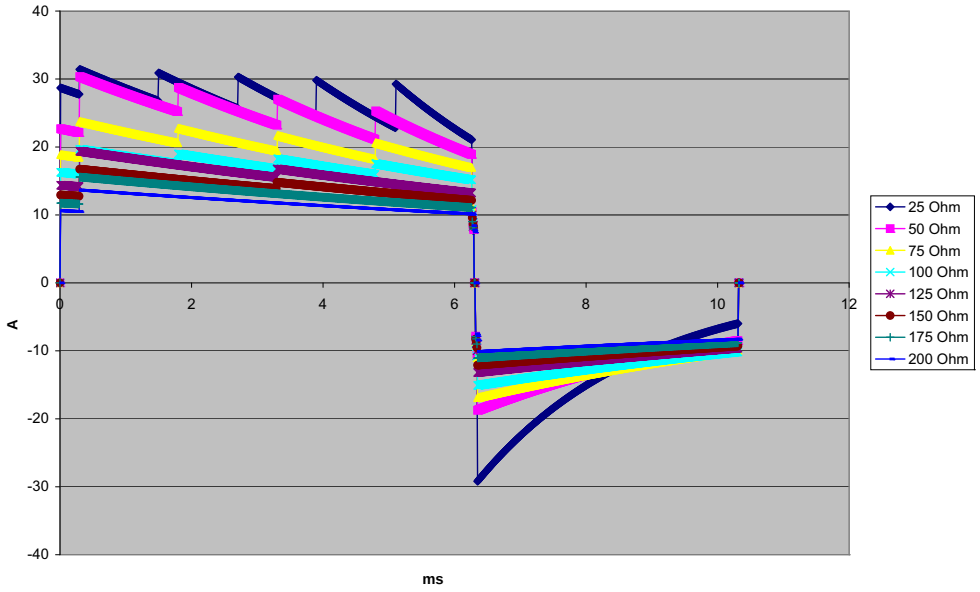


Figure A-1. Rectilinear Biphasic Waveform at 200 Joules

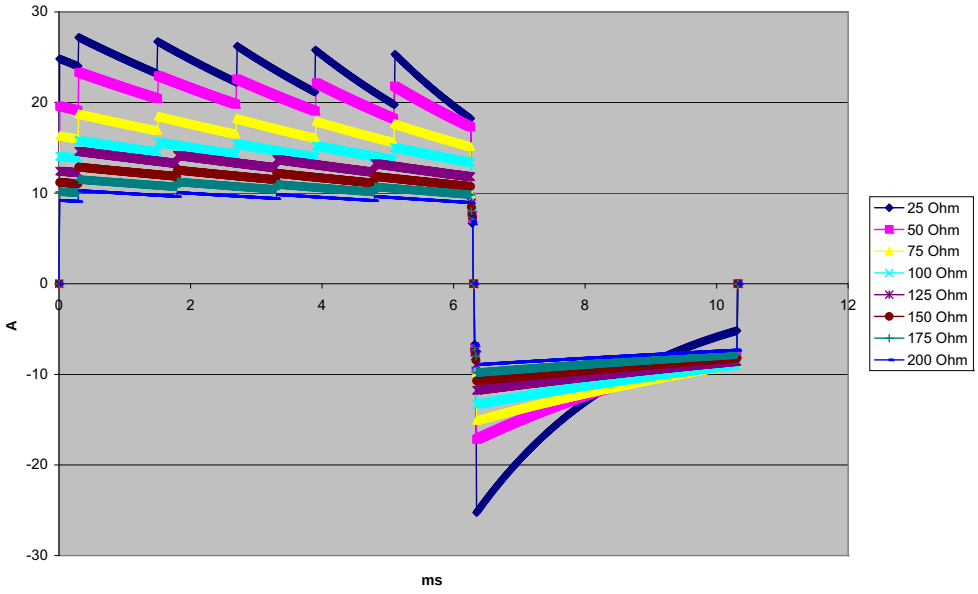


Figure A-2. Rectilinear Biphasic Waveform at 150 Joules

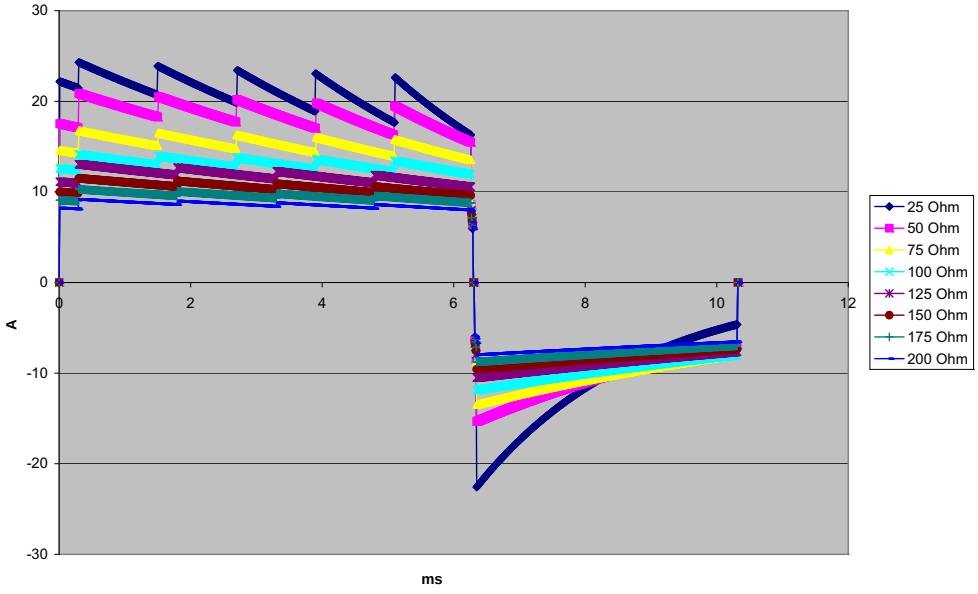


Figure A-3. Rectilinear Biphasic Waveform at 120 Joules

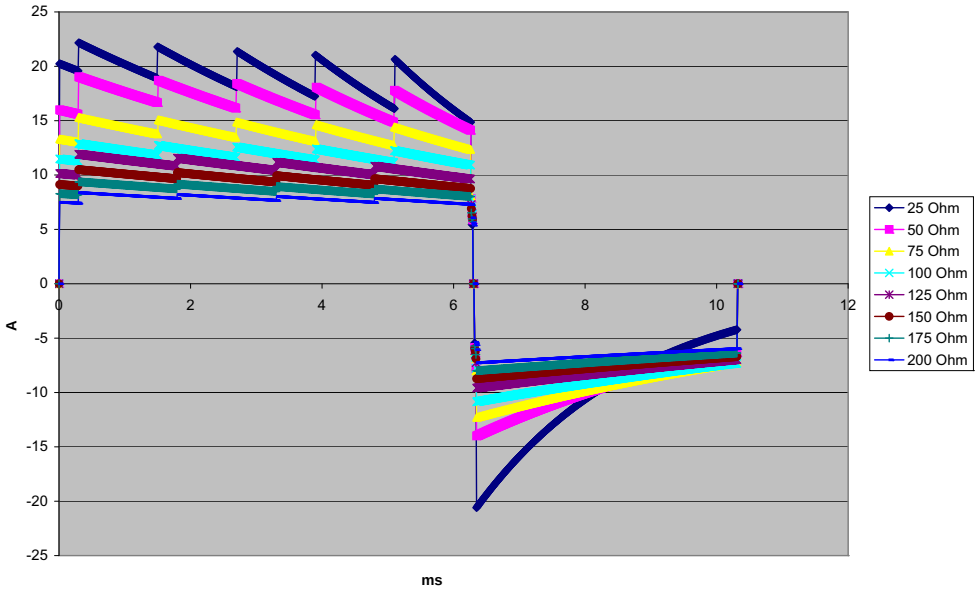


Figure A-4. Rectilinear Biphasic Waveform at 100 Joules

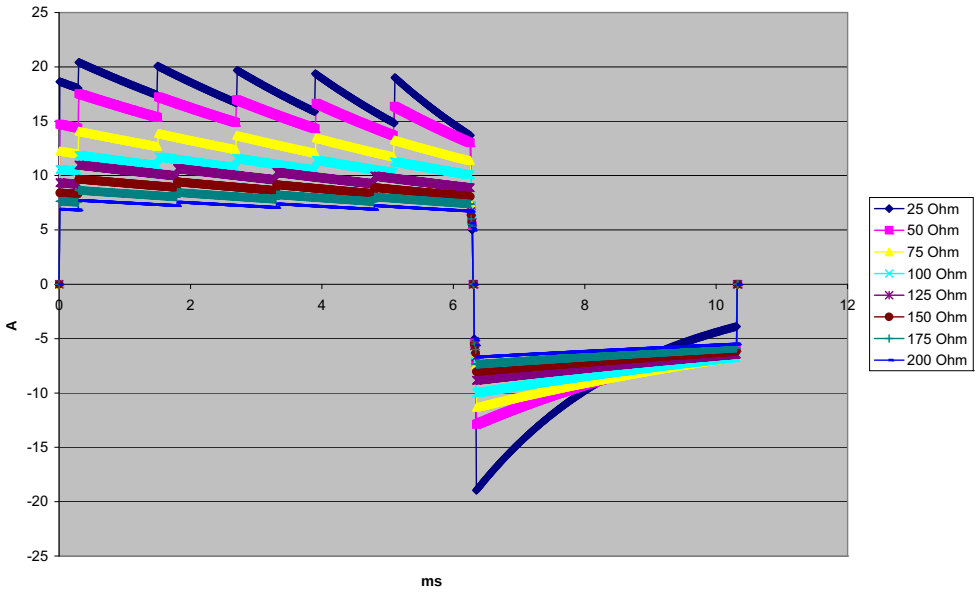


Figure A-5. Rectilinear Biphasic Waveform at 85 Joules

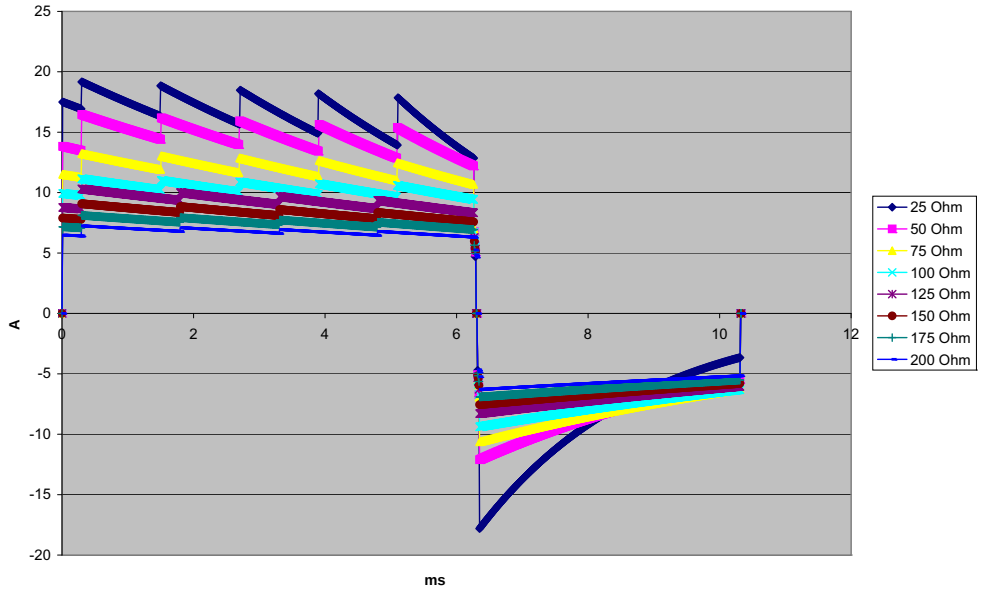


Figure A-6. Rectilinear Biphasic Waveform at 75 Joules

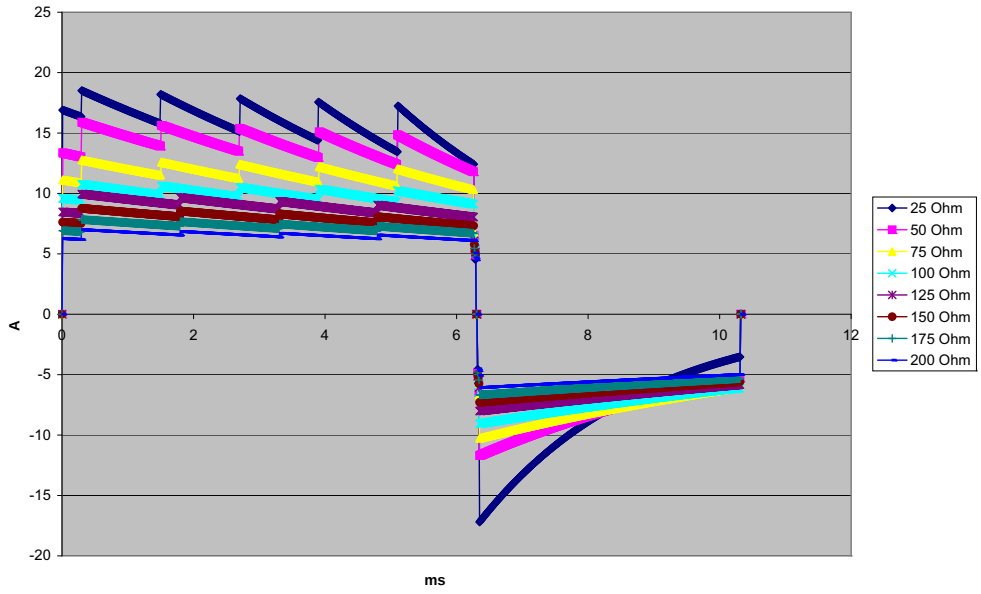


Figure A-7. Rectilinear Biphasic Waveform at 70 Joules

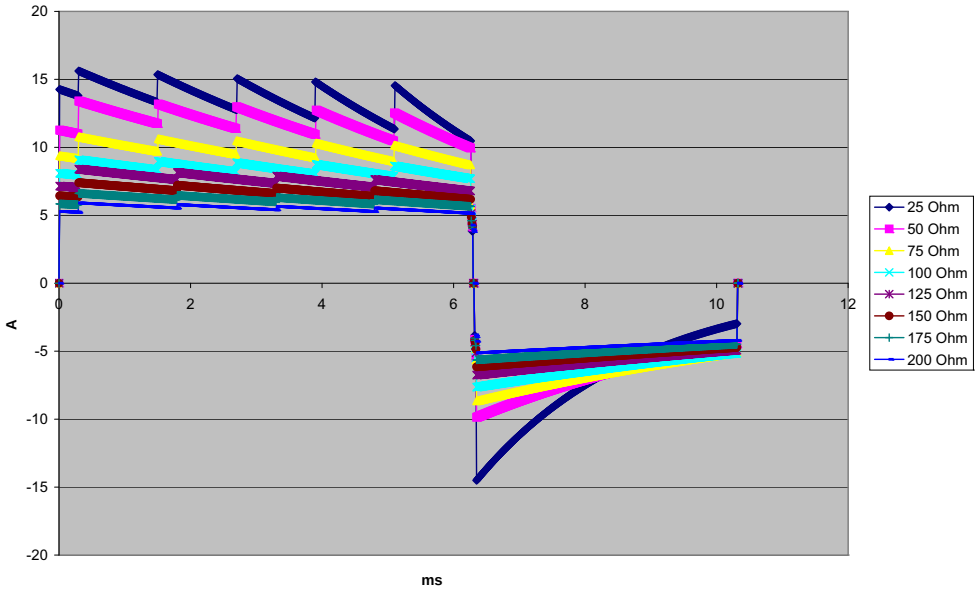


Figure A-8. Rectilinear Biphasic Waveform at 50 Joules

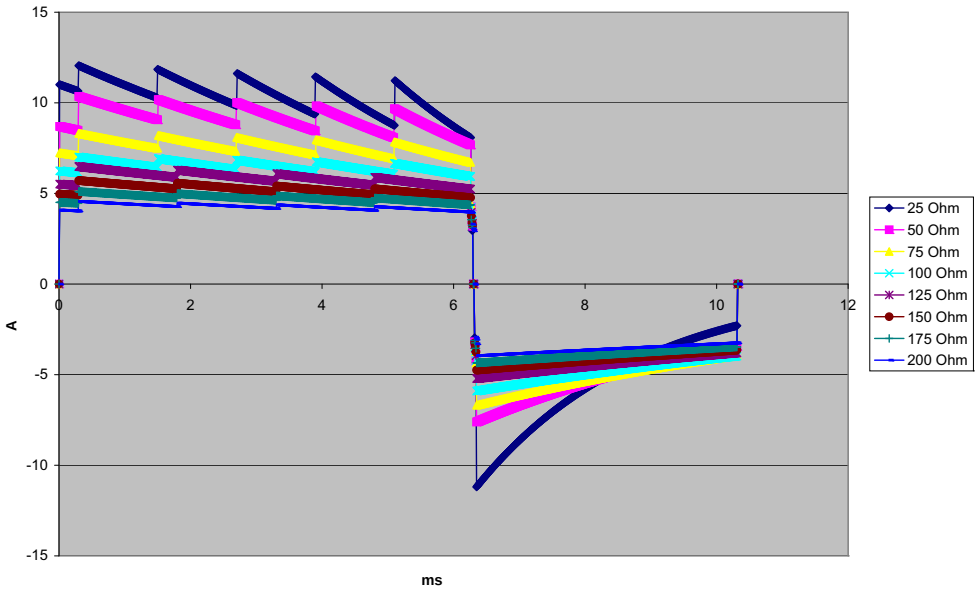


Figure A-9. Rectilinear Biphasic Waveform at 30 Joules

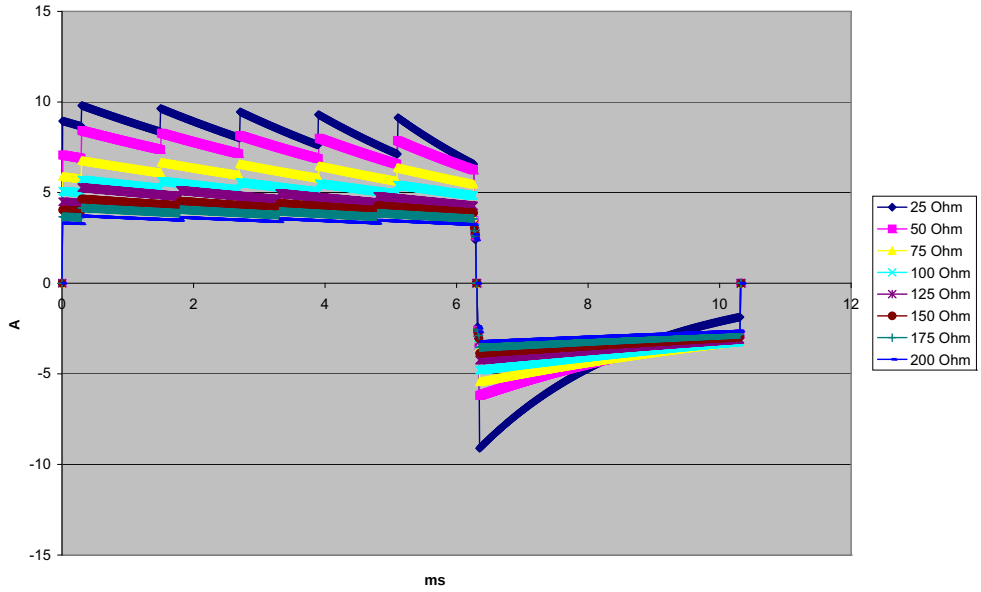


Figure A-10. Rectilinear Biphasic Waveform at 20 Joules

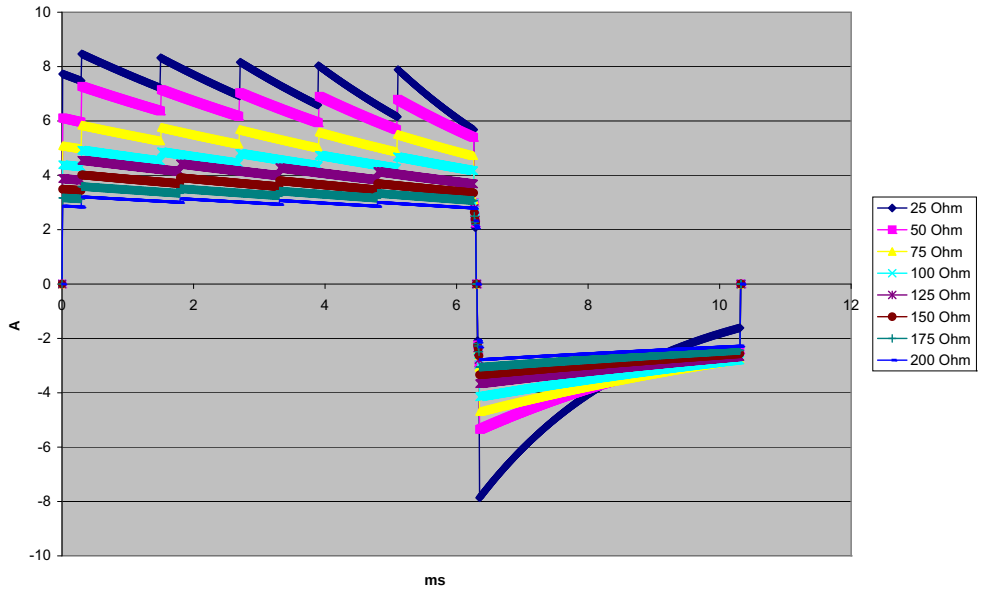


Figure A-11. Rectilinear Biphasic Waveform at 15 Joules

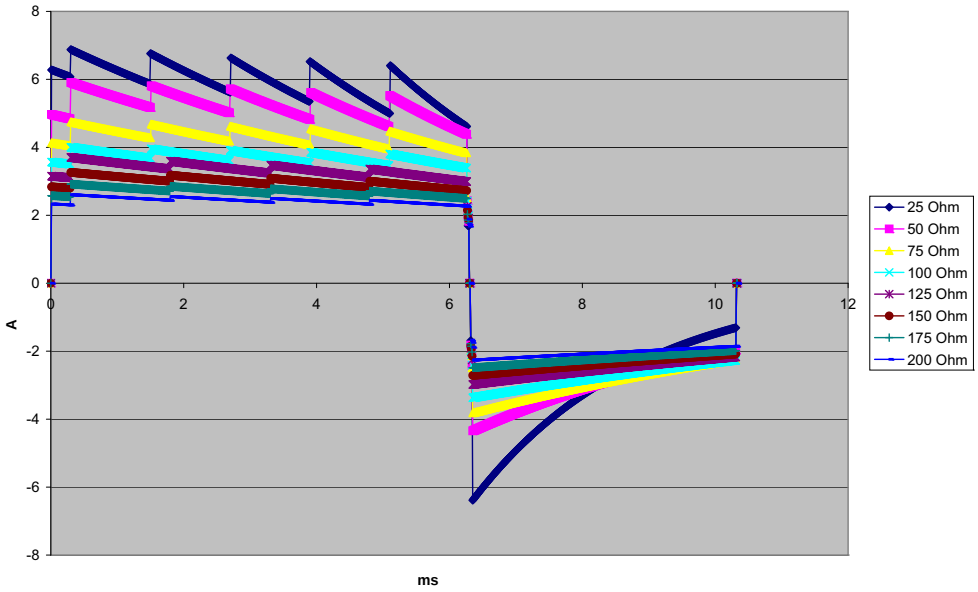


Figure A-12. Rectilinear Biphasic Waveform at 10 Joules

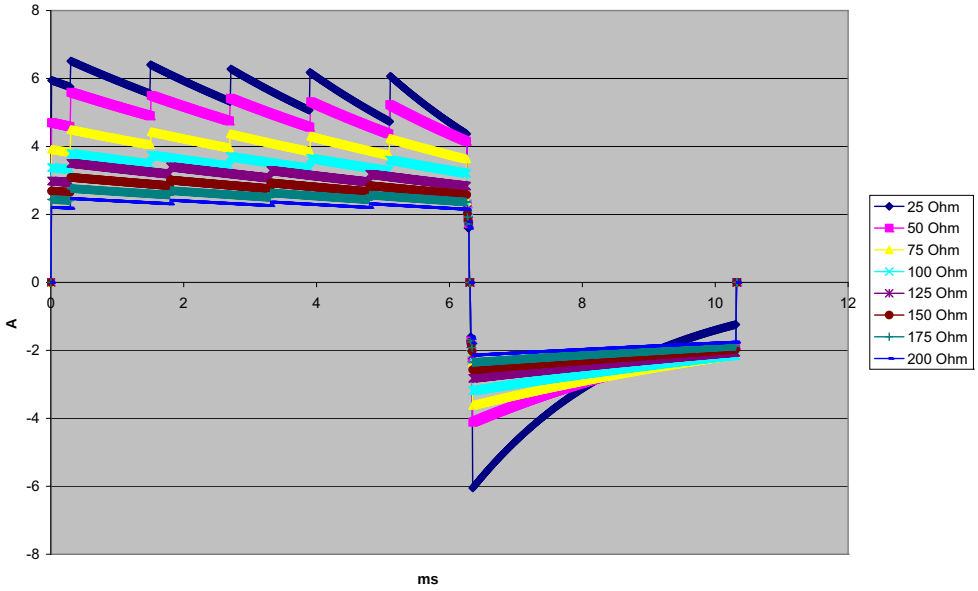


Figure A-13. Rectilinear Biphasic Waveform at 9 Joules

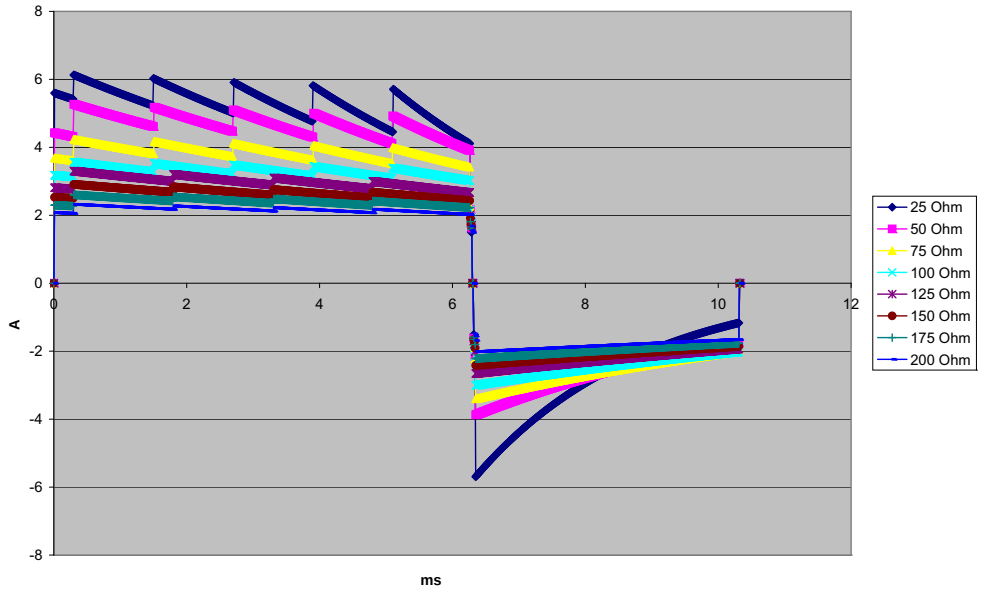


Figure A-14. Rectilinear Biphasic Waveform at 8 Joules

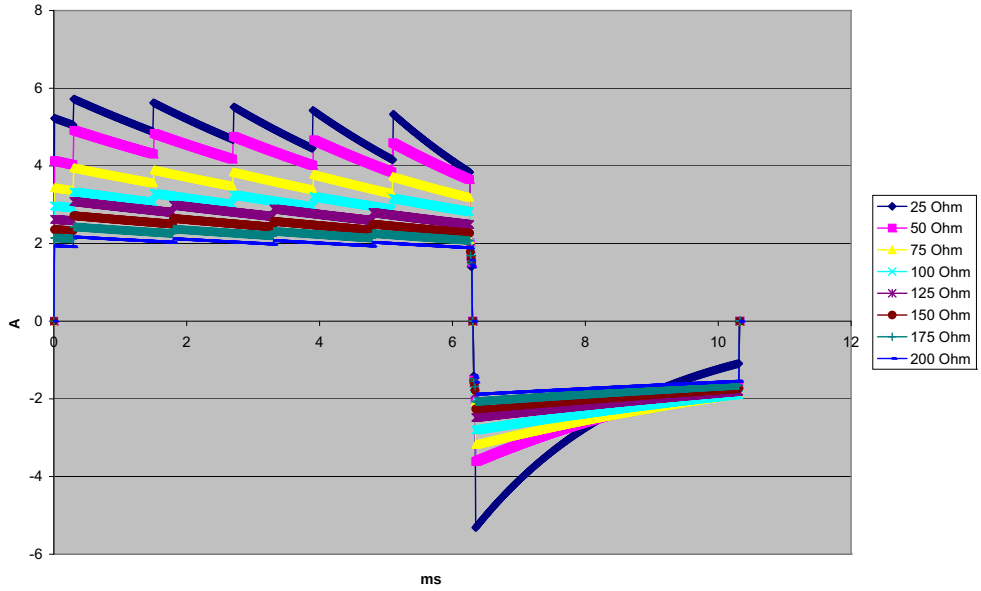


Figure A-15. Rectilinear Biphasic Waveform at 7 Joules

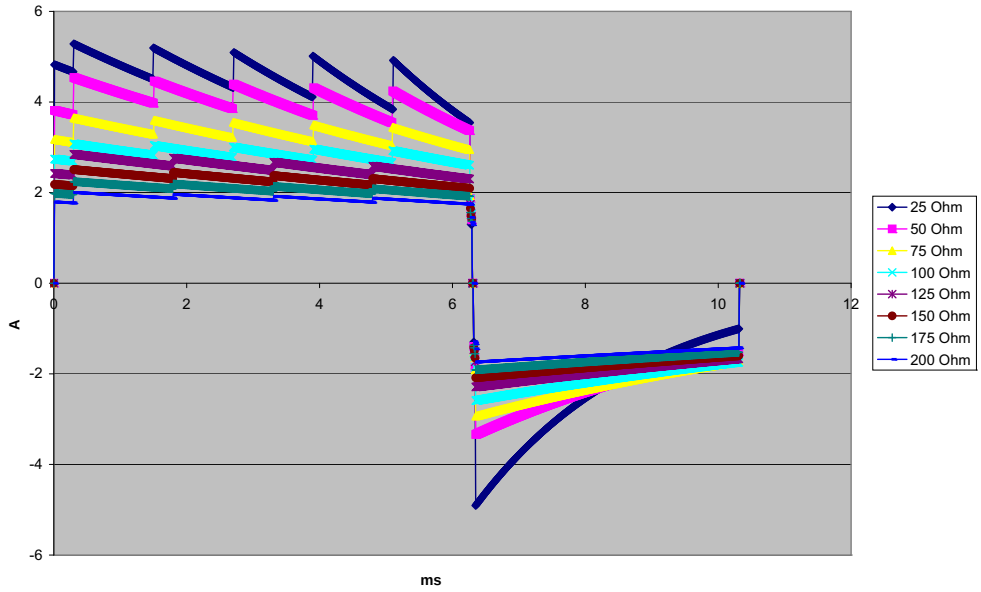


Figure A-16. Rectilinear Biphasic Waveform at 6 Joules

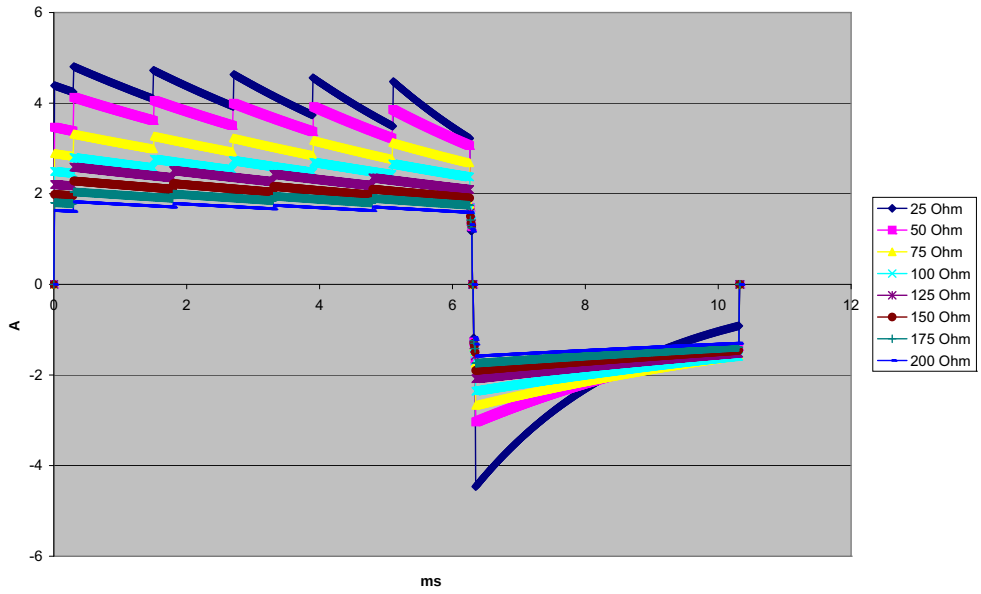


Figure A-17. Rectilinear Biphasic Waveform at 5 Joules

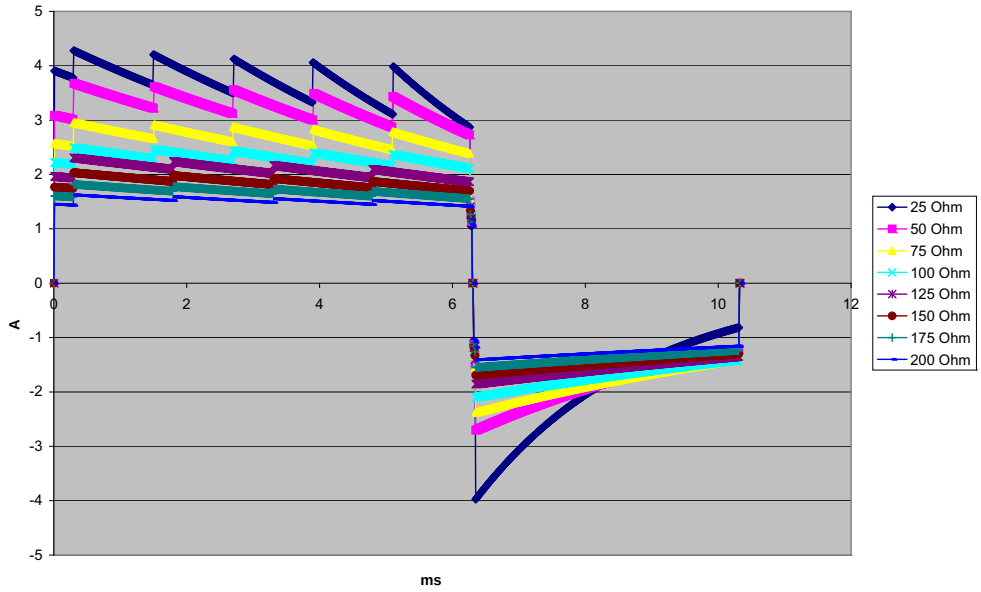


Figure A-18. Rectilinear Biphasic Waveform at 4 Joules

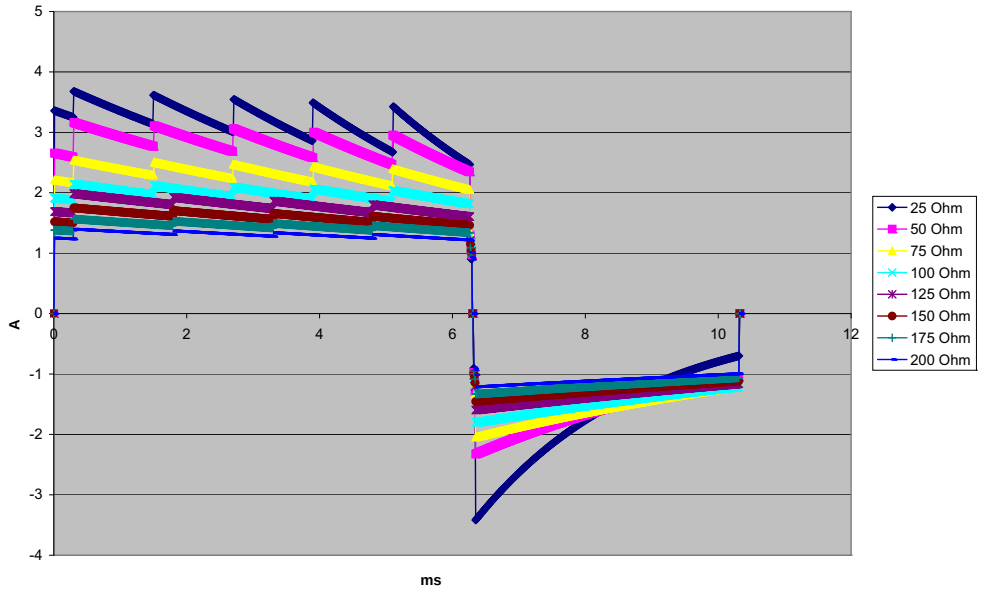


Figure A-19. Rectilinear Biphasic Waveform at 3 Joules

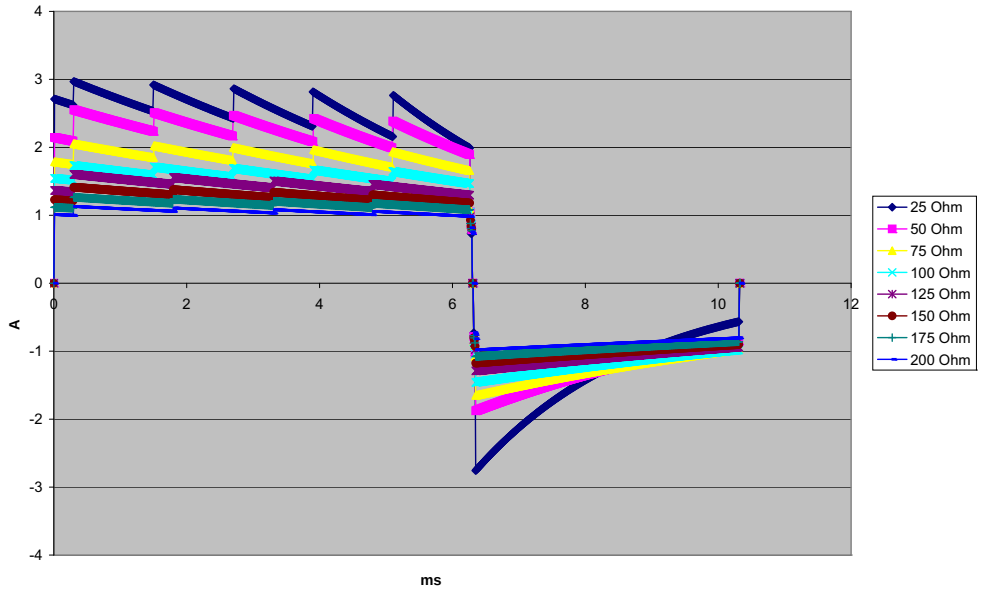


Figure A-20. Rectilinear Biphasic Waveform at 2 Joules

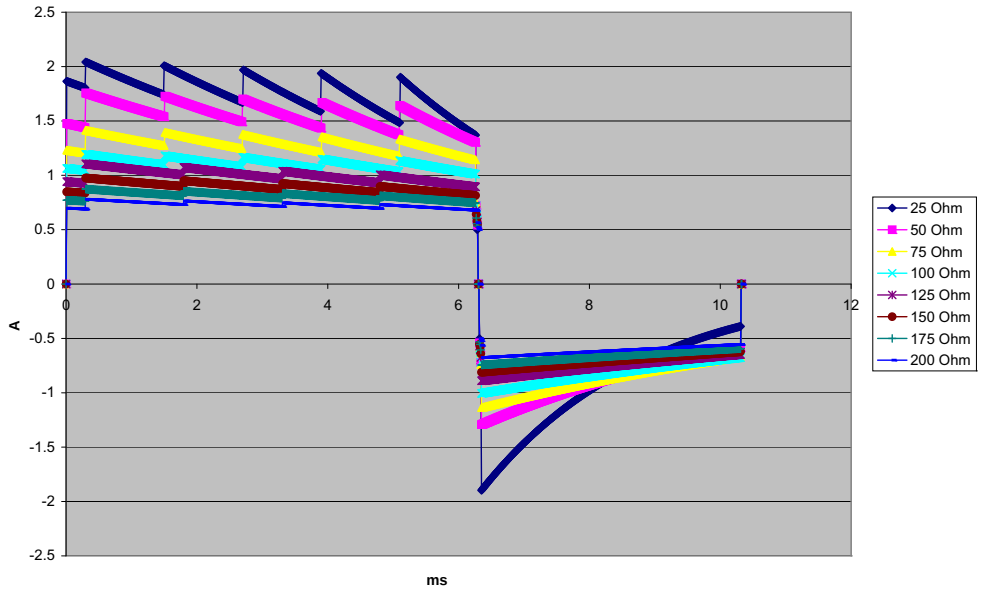


Figure A-21. Rectilinear Biphasic Waveform at 1 Joule

Clinical Trial Results for the Biphasic Waveform

The efficacy of the ZOLL Rectilinear Biphasic waveform has been clinically verified during a study of defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT). A feasibility study was performed initially for defibrillation of VF/VT (n=20) on two separate groups of patients to ensure waveform safety and energy selection. Subsequently, a separate, multicenter, randomized clinical trial was performed to verify the waveform's efficacy. A description of this study is provided below. The study was performed using ZOLL defibrillation systems consisting of ZOLL defibrillators, the ZOLL Rectilinear Biphasic waveform, and ZOLL defibrillation electrodes.

Randomized Multicenter Clinical Trial for Defibrillation of Ventricular Fibrillation (VF) and Ventricular Tachycardia (VT)

Overview: The defibrillation efficacy of the ZOLL Rectilinear Biphasic waveform was compared to a monophasic damped sine waveform in a prospective, randomized, multicenter study of patients undergoing ventricular defibrillation for VF/VT during electrophysiological studies, ICD implants, and test. A total of 194 patients were enrolled in the study. Ten patients who did not satisfy all protocol criteria were excluded from the analysis, leaving a study population of 184.

Objectives: The primary goal of this study was to compare the first shock efficacy of the 120 J rectilinear biphasic waveform with a 200 J monophasic waveform. The secondary goal was to compare all shock (three consecutive 120, 150, and 170 joules) efficacy of the rectilinear biphasic waveform with that of a monophasic waveform (three consecutive 200, 300, and 360 joules). A significance level of p=0.05 or less was considered statistically significant using Fischer's Exact test. Also, differences between the two waveforms were considered statistically significant when the customary 95% or AHA-recommended 90%[1] confidence interval between the two waveforms was greater than 0%.

Results: The study population of 184 patients had a mean age of 63±14 years. Of these, 143 patients were male. 98 patients were in the biphasic group (ventricular fibrillation/flutter, n=80; ventricular tachycardia, n=18) and 86 patients were in the monophasic group (ventricular fibrillation/flutter, n=76; ventricular tachycardia, n=10). There were no adverse events or injuries related to the study.

The first shock, first induction efficacy of biphasic shocks at 120 J was 99% versus 93% for monophasic shocks at 200 J (p=0.0517, 95% confidence interval of the difference of –2.7% to 16.5% and 90% confidence interval of the difference of –1.01% to 15.3%).

	Monophasic	Biphasic
First shock efficacy	93%	99%
p-value	0.0517	
95% confidence interval	–2.7% to 16.5%	
90% confidence interval	–1.01% to 15.3%	

1. Kerber RE, et al., "Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety," *Circ J Am Heart Assoc.* 1997;95:1677-1682.

"… the task force suggests that to demonstrate superiority of an alternative waveform over standard waveforms, the upper boundary of the 90% confidence interval of the difference between standard and alternative waveforms must be <0% (ie, alternative is greater than standard)."

Successful defibrillation with rectilinear biphasic shocks was achieved with 58% less delivered current than with monophasic shocks (14±1 amperes versus 33±7 amperes, p=0.0001).

The difference in efficacy between the rectilinear biphasic and the monophasic shocks was greater in patients with high transthoracic impedance (greater than 90 ohms). The first shock, first induction efficacy of biphasic shocks was 100% versus 63% for monophasic shocks for patients with high impedance (p=0.02, 95% confidence interval of the difference of –0.0217% to 0.759% and 90% confidence interval of the difference of 0.037% to 0.706%).

	Monophasic	Biphasic
First shock efficacy (high impedance patients)	63%	100%
p-value	0.02	
95% confidence interval	–0.021% to 0.759%	
90% confidence interval	0.037% to 0.706%	

A single patient required a second biphasic shock at 150 joules to achieve 100% efficacy versus six patients for whom monophasic shocks of up to 360 joules were required for 100% total defibrillation efficacy.

Conclusion: The data demonstrate the equivalent efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks for transthoracic defibrillation for all patients at the 95% confidence level. The data also demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to standard high energy monophasic shocks in patients with high transthoracic impedance at the 90% confidence level. There were no unsafe outcomes or adverse events due to the use of rectilinear biphasic waveform.

Randomized Multi-Center Clinical trial for Cardioversion of Atrial Fibrillation (AF)

Overview: The defibrillation efficacy of ZOLL's Rectilinear Biphasic Waveform was compared to a monophasic damped sine waveform in a prospective randomized multi-center study of patients undergoing cardioversion of their atrial fibrillation. A total of 173 patients entered the study. Seven (7) patients who did not satisfy all protocol criteria were excluded from the analysis. ZOLL disposable gel electrodes with surface areas of 78 cm^2 (anterior) and 113 cm^2 (posterior) were used exclusively for the study.

Objective: The primary goal of the study was to compare the total efficacy of four consecutive rectilinear biphasic shocks (70J, 120J, 150J, 170J) with four consecutive monophasic shocks (100J, 200J, 300J, 360J). The significance of the multiple shocks efficacy was tested statistically via two procedures, the Mantel-Haenszel statistic and the log-rank test, significance level of p=0.05 or less was considered statistically significant. The data are completely analogous to the comparison of two "survival" curves using a life-table approach where shock number plays the role of time.

The secondary goal was to compare the first shock success of rectilinear biphasic and monophasic waveforms. A significance level of p=0.05 or less was considered statistically significant using Fisher Exact tests. Also, differences between the two waveforms were considered statistically significant when the 95% confidence interval between the two waveforms was greater than 0%.

Results: The study population of 165 patients had a mean age of 66±12 years with 116 male patients.

The total efficacy of consecutive rectilinear biphasic shocks was significantly greater than that of monophasic shocks. The following table displays the Kaplan-Meier (product-limit) "survival" curves for each of the two waveforms. As all patients begin in the failure mode, the estimated life-table probabilities refer to the chance of still being in failure after the k^{th} shock (k=1,2,3,4):

Table A-3. Kaplan-Meier Estimate for the Probability of Shock Failure

Shock #	Biphasic	Monophasic
0	1.000	1.000
1	0.318	0.792
2	0.147	0.558
3	0.091	0.324
4	0.057	0.208

As can be seen from the table, the Biphasic experience is superior over the entire course of shocks delivered. The one degree of freedom chi-square statistic for the Mantel-Haenszel test is 30.39 ($p<0.0001$). Similarly, the log-rank test, also a one degree of freedom chi-square statistic, is 30.38 ($p<0.0001$). The residual number of patients not successfully treated after four shocks is 5.7% for biphasic compared to 20.8% for monophasic.

There was a significant difference between the first shock efficacy of biphasic shocks at 70J of 68% and that of monophasic shocks at 100J of 21% ($p=0.0001$, 95% confidence interval of the difference of 34.1% to 60.7%).

Successful cardioversion with rectilinear biphasic shocks was achieved with 48% less delivered current than with monophasic shocks (11 ± 1 vs. 21 ± 4 A, $p<0.0001$).

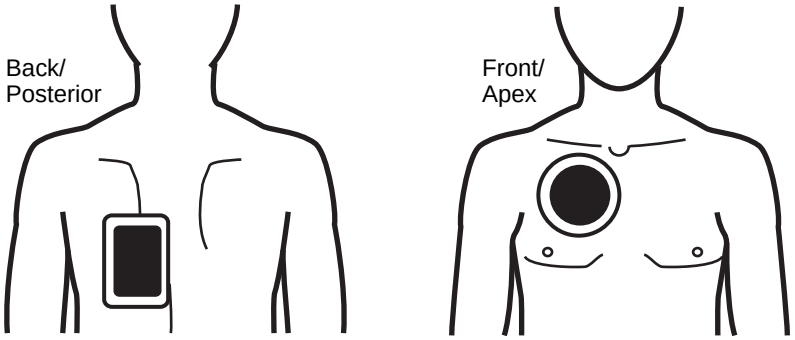
One half of the patients who failed cardioversion after four consecutive escalating monophasic shocks were subsequently successfully cardioverted using a biphasic shock at 170J. No patient was successfully cardioverted using a 360J monophasic shock after the patient had failed cardioversion with biphasic shocks.

Conclusion: The data demonstrate the superior efficacy of low energy rectilinear biphasic shocks compared to high energy monophasic shocks for transthoracic cardioversion of atrial fibrillation. There were no unsafe outcomes or adverse events due to the use of Rectilinear Biphasic Waveform.

Synchronized Cardioversion of Atrial Fibrillation

Cardioversion of atrial fibrillation (AF) and overall clinical effectiveness is enhanced by proper pad placement. Clinical studies (refer to above) of the M Series Biphasic Defibrillator Waveform demonstrated that high conversion rates are achieved when defibrillation pads are placed as shown in the diagram below.

Recommended Anterior/Posterior Placement



Place the front (apex) pad on the third intercostal space, mid clavicular line on the right anterior chest. The back/posterior pad should be placed in the standard posterior position on the patient's left as shown.

ECG Rhythm Analysis Algorithm Accuracy

Sensitivity and specificity are expressions of ECG rhythm analysis algorithm performance when compared to ECG interpretation by a clinician or expert. Sensitivity refers to the algorithm's ability to correctly identify shockable rhythms (as a percentage of the total number of shockable rhythms). Specificity refers to the algorithm's ability to correctly identify nonshockable rhythms (as a percentage of the total number of nonshockable rhythms).

The data in Table A-4 and Table A-5 summarize the accuracy of the ECG rhythm analysis algorithm as tested against ZOLL's ECG rhythm database. Rhythm sources included data records from ZOLL devices and public domain databases recorded with electrode systems and ECG signal processing characteristics similar to the R Series. Data records were of appropriate length to allow for satisfactory analysis.

The algorithm sequence takes approximately 9 seconds and proceeds as follows:

- Divides the ECG rhythm into 3-second segments
- Filters and measures noise, artifact, and baseline wander
- Measures baseline content ("waviness" at the correct frequencies – frequency domain analysis) of signal
- Measures QRS rate, width, and variability
- Measures amplitude and temporal regularity (autocorrelation) of peaks and troughs
- Determines if multiple 3-second segments are shockable and then prompts the operator to treat the patient

Table A-4. Clinical Performance Results (Adult Patients)

Rhythms	Sample Size	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable		**Sensitivity**		
Coarse VF	536	>90%	100.0%	99.4%
Rapid VT	80	>75%	100.0%	96.3%
Nonshockable		**Specificity**		
NSR	2210	>99%	100.0%	99.9%
AF, SB, SVT, heart block, idioventricular, PVCs	819	>95%	99.9%	99.4%
Asystole	115	>95%	100.0%	97.4%
Intermediate				
Fine VF	69	Report only	89.9%	81.8%
Other VT	28	Report only	96.4%	84.2%

Table A-5. Clinical Performance Results (Pediatric Patients)

Rhythms	Sample Size (9 second records)	Performance Goals	Observed Performance	90% One-sided Lower Confidence Limit
Shockable (49 patients)		**Sensitivity**		
Coarse VF	42	>90%	100.0%	93.1%
Rapid VT	79	>75%	100.0%	96.3%
Nonshockable (155 patients)		**Specificity**		
NSR	208	>99%	100.0%	98.6%
AF, SB, SVT[a], heart block, idioventricular, PVCs	348	>95%	99.4%	98.2%
Asystole	29	>95%	100%	90.2%
Intermediate (16 patients)				
Fine VF	0	Report only	—	—
Other VT	44	Report only	84.1%	72.2%

a. 161 of the 348 abnormal rhythm records were SVT (72 patients). The SVT heart rates ranged from 152 to 302 beats per minute.

Arrhythmia performance is reported according to the article, Kerber RE, Becker LB, Bourland JD, Cummins RO, Hallstrom AP, Michos MB, Nichol G, Ornato JP, Thies WH, White RD, Zuckerman BD. “Automated External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms, and Enhancing Safety,” *Circ J Am Heart Assoc.* 1997;95:1677-1682.

References

Young KD, Lewis RJ. “What is confidence? Part 2: Detailed definition and determination of confidence intervals”. *Ann Emerg Med.* September 1997;30:311-318.

Beyer WH. Percentage Points, F-Distribution Table. *CRC Standard Mathematical Tables*. 28th ed. Boca Raton, Fla: CRC Press; 1981:573.

Appendix B
R Series Accessories

The following accessories are compatible for use with R Series products. To order any of these items, contact your local ZOLL representative.

Electrodes/Pads, Paddles, and Connectors	**REF**
OneStep resuscitation electrodes	8900-0211-01
OneStep pacing/defibrillation electrodes with Monitor while Pace (MwP)	8900-0212-01
OneStep resuscitation electrodes with CPR	8900-0213-01
OneStep pacing/defibrillation electrodes with CPR and Monitor while Pace (CPR/MwP)	8900-0214-01
OneStep pediatric resuscitation electrodes	8900-0215-01
OneStep pediatric resuscitation electrodes with CPR	8900-000219-01 (1 per box) 8900-000220-01 (8 per box)
Adult, Multi-Function Pacing/Defibrillation stat-padz (12 pair/box)	8900-4003
Pediatric, Multi-Function Pacing/Defibrillation pedi-padz®	8900-0218-40 (1 per box) 9600-0215-40 (8 per box)
External Paddle Assembly Apex/Sternum with built in pediatric electrodes	8000-1010-01
External autoclavable paddles	8011-0503
Internal autoclavable handles, no switch	8011-0505
Internal autoclavable handles, with switch	8011-0501-01
Molded autoclavable internal handles, no switch	8011-0140-XX

Molded autoclavable internal handles, with switch	8011-0141-XX
Cables	**REF**
OneStep Cable (100-240V, 50/60Hz)	8009-0749
OneStep Pacing Cable (100-240V, 50Hz)	8009-0750
AAMI 3-Lead Wire ECG Patient Cable	8000-0025-02 (6’) 8000-0025 (12”)
AAMI 3-Lead Wire ECG Patient Cable, ESU	9500-000693
IEC 3-Lead ECG Patient Cable	8000-0026
AAMI 5-Lead Wire ECG Patient Cable	8000-1005-01
IEC 5-Lead Wire ECG Patient Cable	8000-0091
Power Cord Extension Cable (12”)	8000-0730
AC power cord	0500-0028
Batteries and Chargers	**REF**
SurePower Charger	8050-0030-XX
SurePower Battery	8019-0535
SpO_2 Sensors and Cables	**REF**
LNCS Adtx Single use sensor for patients > 30 kg	8000-0320
LNCS Pdtx Single use sensor for Pediatrics and Slender Adults 10-50 kg	8000-0321
LNCS Inf-L Single use sensor for Infants 3-20 kg	8000-0322
LNCS Neo-L Single use sensor for Neonates < 3 kg	8000-0323
LNCS NeoPt-L Single use sensor for Neonates < 1 kg (Pre-term)	8000-0324
LNCS DCI Reusable sensor for Adults and Pediatrics > 30 kg	8000-0294
LNCS DCIP Reusable sensor for Pediatrics 10-50 kg	8000-0295
LNC-4 4’ Reusable Patient Cable	8000-0298
LNC-10 10’ Reusable Patient Cable	8000-0293
LNC Ext LNC Extension Cable, DB-9 Termination, 4ft	8000-0325
LNCS-to-LNOP Adapter Cable, LNCS Sensor to LNOP Patient Cable	8000-0327
LNOP DC-12 LNOP Adult Reusable Direct Connect 12’ Cable	8000-0296

$EtCO_2$ Sensors and Cables	**REF**
CAPNOSTAT 5 CO_2 Sensor and Cable	8000-0312-01
SPU Pediatric/Adult Airway Adapter	8000-0260-01
SPU Neonatal/Pediatric Airway Adapter	8000-0261-01
Reusable Adult Airway Adapter	8000-0262-01
Reusable Neonatal/Pediatric Airway Adapter	8000-0263-01
SPU Pediatric/Adult Airway Adapter with Mouthpiece	8000-0265-01
$CAPNO_2$*mask*, Large Adult	8000-0761
$CAPNO_2$*mask*, Standard Adult	8000-0760
$CAPNO_2$*mask*, Pediatric	8000-0762
NIBP Cuffs and Hoses	**REF**
Thigh, reusable: 38 to 50 cm (14.96 to 19.69 in.)	8000-1654
Large Adult, reusable: 31 to 40 cm (12.20 to 15.75 in.)	8000-1653
Adult, reusable: 23 to 33 cm (9.06 to 12.99 in.)	8000-1651
Small Adult, reusable: 17 to 25 cm (6.69 to 9.84 in.)	8000-1650
Child, reusable: 12 to 19 cm (4.72 to 7.48 in.)	8000-1655
Neonate #5, disposable: 8.0 cm to 15.0 cm (3.1 to 5.9 in.)	8000-0644
Neonate #4, disposable: 7.0 to 13.0 cm (2.8 to 5.1 in.)	8000-0643
Neonate #3, disposable: 6.0 to 11.0 cm (2.4 to 4.3 in.)	8000-0642
Neonate #2, disposable: 4.0 to 8.0 cm (1.6 to 3.1 in.)	8000-0641
Neonate #1, disposable: 3.0 to 6.0 cm (1.2 to 2.4 in.)	8000-0640
Air hose with pneumatic fittings 3 m (9.8 ft.)	8000-0662
Air hose with pneumatic fittings 1.5 m (4.9 ft.)	8000-0655
Miscellaneous	**REF**
Recorder Paper, 80mm Fan Fold	8000-0301 (20 pkgs) 8000-0302 (10 pkgs)
R Series Data COMM Card	8005-000101-01
R Series Data COMM II Card	8005-000102-01

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Appendix C
Wi-Fi Radio Module Information

If this defibrillator contains an optional low power Wi-Fi radio module, it transmits information between the defibrillator and a wireless network (infrastructure mode). The module complies with the following standards:

- Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation (of the radio function).
- RSS 247 of Industry & Science Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received including interference that may cause undesired operation (of the radio function). (Article RSS 247 de la norme Industrie et Sciences Canada. Le fonctionnement de cet appareil est soumis aux deux conditions suivantes : (1) cet appareil ne doit pas provoquer d'interférences nuisibles ; et (2) il doit accepter toutes les interférences reçues, y compris celles susceptibles d'être à l'origine d'un fonctionnement non approprié (de la fonction radio).)

Changes or modifications to Wi-Fi settings on R Series wireless communication accessories not expressly approved by the administrator responsible for compliance could void the user's authority to operate the equipment. (Les modifications des paramètres Wi-Fi sur des accessoires de communication sans fil R Series non explicitement approuvées par l'administrateur responsable de la conformité pourraient annuler l'autorisation de l'utilisateur à employer l'équipement.)

The user is cautioned to maintain 8 inches (20 cm) of space from the product to ensure compliance with FCC requirements. (L'utilisateur est informé de conserver une distance de 20 cm (8 pouces) à partir du produit pour garantir la conformité aux normes de la FCC.)

FCC/IC/EU: This device is limited to indoor use in the 5150MHz to 5250MHz band. (FCC/IC/UE: Cet appareil est limité à une utilisation à l'intérieur dans une plage de fréquence située entre 5 150 et 5 250 MHz.)

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