ZOLL®

# R Series® ALS Operator's Guide


9650-0912-01 Rev. J

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If more than 3 years have elapsed since the issue date, contact ZOLL Medical Corporation to determine if additional product information updates are available.



**ZOLL Medical Corporation**
269 Mill Road
Chelmsford, MA USA
01824-4105

EC REP **ZOLL International Holding B.V.**
Newtonweg 18
6662 PV ELST
The Netherlands

CE
0123

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# Chapter 1
# General Information

## Product Description

The ZOLL® R Series® products combine a defibrillator, ECG display, advanced monitoring capabilities, and Noninvasive Transcutaneous Pacing (NTP) with communication, data printing and recording capabilities in a single lightweight portable instrument. The unit has been designed for all resuscitation situations and its small, compact, lightweight design makes it ideal for accompanying patients during transport. The product is powered by AC mains and an easily replaced battery pack that is quickly recharged in the device when it is connected to AC mains. In addition, the unit's battery may be recharged and tested using a ZOLL SurePower™ Battery Charger.

The product is designed for use in the hospital. All of its ruggedized features add to its durability in hospital applications.

**There are multiple models of the R Series defibrillator that can contain a variety of functions. Your model may not contain all of the functions that are documented in this manual. Those features that are not contained in all models are specified as optional.**

The R Series is a versatile manual/advisory external defibrillator. When operating in the manual configuration, the device operates as a conventional defibrillator where the device's charging and discharging are fully controlled by the operator. In advisory mode, some of the features of the device are automated and a sophisticated algorithm is used to identify shockable ECG rhythms (VF and wide complex VT >150 bpm) that should be treated by defibrillator shock delivery. Depending on local protocols, the unit may be configured to automatically analyze the ECG, charge the defibrillator (if appropriate), and prompt the operator to *PRESS SHOCK* between periods of CPR.

The R Series unit assists caregivers during cardiopulmonary resuscitation (CPR) by evaluating the rate and depth of chest compressions and providing feedback to the rescuer.

Real CPR Help® requires the use of OneStep™ CPR electrodes or OneStep Complete electrodes. When using these pads, the displayed ECG waveforms can be adaptively filtered, using the See-Thru CPR® feature, to reduce the artifact caused by chest compressions.

The R Series is a Code-Ready® defibrillator. It extends testing beyond shock delivery and checks more than 40 measures of readiness, including the presence of the correct cables and electrodes, the type of electrode, and other important electronic functions. The R Series also verifies the condition and expiration date of OneStep electrodes. This code readiness testing can occur automatically, without disconnecting electrodes or paddles, or requiring additional equipment to test shock delivery. The system also provides a printed, or electronic log to alert hospital personnel of any defibrillator functions or accessories that are compromised in advance of a code.

Some R Series models include an optional transcutaneous pacemaker consisting of a pulse generator and ECG sensing circuitry. The pacing option supports both demand and asynchronous noninvasive pacing for adult, pediatric, or neonatal patients. OneStep Pacing electrodes and OneStep Complete electrodes allow demand pacing and ECG monitoring without separate ECG electrodes when the R Series is used with the OneStep Pacing cable.

Information regarding the unit's operation, ECG, and other physiological waveforms are displayed on a large 6.5 inch (16.5 cm) diagonal display which provides high contrast and visibility under virtually all lighting conditions. Operating and warning messages are displayed on the monitor, and the unit can also be configured with voice prompts to alert the user to unit status. The R Series performs code readiness testing when the unit is OFF but connected to AC power, when the defibrillator is initially turned on, and periodically during operation.

An annotating strip chart recorder is included to provide immediate documentation as well as summary report functions about patient care and treatment.

A sophisticated data collection system, including summary report, printer, and multiple communication ports is available for this unit. The stored data can be reviewed and archived on a properly equipped personal computer using ZOLL CodeNet® Central software or ZOLL RescueNet® Code Review software. R Series data files may be transferred to a PC using USB or Compact Flash cards or Wi-Fi.

R Series products are intended for use in Manual mode by personnel certified by appropriate federal, state, or local government authority to provide advanced life support care.

# How to Use This Manual

The R Series Operator's Guide provides information operators need for the safe and effective use and care of the R Series products. It is important that all persons using this device read and understand all the information contained within.

Please read thoroughly the safety considerations and warnings section.

Procedures for daily checkout and unit care are located in "Maintenance" on page 12-1.

This manual is supplemented by manual inserts for options available on the R Series. These inserts contain additional warnings, precautions, and safety-related information.

# Operator's Guide Updates

An issue or revision date for this manual is shown on the front cover. If more than three years have elapsed since this date, contact ZOLL Medical Corporation to determine if additional product information updates are available.

All users should carefully review each manual update to understand its significance and then file it in its appropriate section within this manual for subsequent reference.

Product documentation is available through the ZOLL website at www.zoll.com. From the Products menu, choose Product Manuals.

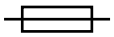
# Unpacking

Carefully inspect each container for damage. If the shipping container or cushion material is damaged, keep it until the contents have been checked for completeness and the instrument has been checked for mechanical and electrical integrity. If the contents are incomplete, if there is mechanical damage, or if the defibrillator does not pass its electrical self-test, U.S.A. customers should call ZOLL Medical Corporation (1-800-348-9011). Customers outside of the U.S.A. should contact the nearest ZOLL authorized representative. If the shipping container is damaged, also notify the carrier.

# Symbols Used on the Equipment

Any or all of the following symbols may be used in this manual or on this equipment:

| Symbol | Description |
|---|---|
|  | Dangerous voltage. |
|  | Attention, consult accompanying documents. |
|  | Fragile, handle with care. |
|  | Keep dry. |
|  | This end up. |
|  | Temperature limitation. |
|  | **Conformité Européenne** Complies with medical device directive 93/42/EEC. |

| Symbol | Description |
|---|---|
|  | Type B patient connection. |
|  | Type BF patient connection. |
|  | Type CF patient connection. |
|  | Defibrillator-proof type BF patient connection. |
|  | Defibrillator-proof type CF patient connection. |
|  | Fusible link. |
|  | Equipotentiality. |
|  | Alternating current (AC). |
|  | Direct current (DC). |
|  | Contains lithium. Recycle or dispose of properly. |
|  | Keep away from open flame and high heat. |
|  | Do not open, disassemble, or intentionally damage. |
|  | Do not crush. |
|  | Do not discard in trash. Recycle or dispose of properly. |

| Symbol | Description |
|---|---|
|  | Return to a collection site intended for waste electrical and electronic equipment (WEEE). Do not dispose of in unsorted trash. |
|  | Date of manufacture. |
|  | Use by. |
|   | Latex-free. |
|  | Do not reuse. |
|  | Do not fold. |
|   | Not sterile. |
|  | Nonionizing electromagnetic radiation from Wi-Fi during data transfer. |
|  | Manufacturer. |
|   | Authorized representative in the European Community. |
|   | Serial Number. |
|   | Catalogue number. |
|  | Consult instructions for use. |
|   | Prescription only. |

| Symbol | Description |
|---|---|
| E MAX = 200J | Maximum energy. |
|   | Test port. |

# Conventions

This guide uses the following conventions:

Within text, the names and labels for physical buttons and softkeys appear in **boldface** type (for example, “Press the **SHOCK** button or the **Code Marker** softkey”).

This guide uses uppercase italics for audible prompts and for text messages displayed on the screen (for example, *CHECK PATIENT*).

**WARNING!** **Warning statements alert you to conditions or actions that can result in personal injury or death.**

**Caution** Caution statements alert you to conditions or actions that can result in damage to the unit.

# Defibrillator Function

The R Series product contains a direct current (DC) defibrillator capable of delivering up to 200 joules. It may be used in synchronized mode to perform synchronized cardioversion using the patient’s R-wave as a timing reference. The unit uses paddles or disposable, pregelled electrodes for defibrillation.

## Intended Use — Manual Operation

Use of the R Series products in the manual mode for defibrillation is indicated on victims of cardiac arrest where there is apparent lack of circulation as indicated by:

- Unconsciousness.
- Absence of breathing.
- Absence of pulse.

This product should be used only by qualified medical personnel for converting ventricular fibrillation and rapid ventricular tachycardia to sinus rhythm or other cardiac rhythms capable of producing hemodynamically significant heart beats.

In manual mode, the unit can also be used for synchronized cardioversion of certain atrial or ventricular arrhythmias. A qualified physician must decide when synchronized cardioversion is appropriate.

The advisory function should be used to confirm ventricular fibrillation or wide complex ventricular tachycardia (greater than 150 beats per minute) in patients meeting the three conditions indicating lack of circulation (listed above).

## Intended Use — ECG Monitoring

The unit is intended for use when ECG monitoring is indicated to evaluate the patient's heart rate or ECG morphology. In ECG monitoring mode, the unit is intended to be used by personnel who are qualified by training in the use of the R Series defibrillator, basic life and/or advanced life support, or other physician-authorized emergency medical training.

## Intended Use — Real CPR Help

The Real CPR Help function provides visual and audio feedback designed to encourage rescuers to perform chest compressions at the AHA/ERC recommended rate of 100 compressions per minute. Voice and visual prompts encourage a compression depth in accordance with AHA and/or ERC recommendations of 2 inches (5 cm) minimum for adult patients.

## Defibrillator Complications

Inappropriate defibrillation or cardioversion of a patient (for example, with no malignant arrhythmia) may precipitate ventricular fibrillation, asystole, or other dangerous arrhythmias.

Defibrillation without proper application of electrodes or paddle electrolyte gel might be ineffective and cause burns, particularly when repeated shocks are necessary. Erythema or hyperemia of the skin under the paddles, or electrodes often occurs; this effect is usually enhanced along the perimeter of the paddles or electrodes. This reddening should diminish substantially within 72 hours.

## Defibrillator Output Energy

R Series defibrillators can deliver as much as 200 joules into a 50 ohm impedance. The energy delivered through the chest wall, however, is determined by the patient's transthoracic impedance. An adequate amount of electrolyte gel must be applied to the paddles and a force of 10 to 12 kilograms (22 to 26.4 pounds) must be applied to each paddle in order to minimize this impedance. If hands-free therapy electrodes are used, make sure that they are properly applied. (Refer to the instructions on the electrode package).

# External Pacemaker (Optional)

Some R Series products include an optional transcutaneous pacemaker consisting of a pulse generator and ECG-sensing circuitry. Noninvasive transcutaneous pacing (NTP) is an established and proven technique. This therapy is easily and rapidly applied in both emergency and nonemergency situations when temporary cardiac stimulation is indicated.

The output current of the pacemaker is continuously variable from 0 to 140 mA. The rate is continuously variable from 30 to 180 pulses per minute (ppm), by increments of 2.

The pacing output pulse is delivered to the heart via ZOLL hands-free defibrillation/pacing electrodes placed on the patient's back and the precordium.

The characteristics of the output pulse, together with the design and placement of the electrodes, minimize cutaneous nerve stimulation, cardiac stimulation threshold currents, and reduce discomfort due to skeletal muscle contraction.

The unique design of the R Series products allow clear viewing and interpretation of the electrocardiogram on the display without offset or distortion during external pacing.

Proper operation of the device, together with correct electrode placement, is critical to obtaining optimal results. Every operator must be thoroughly familiar with these operating instructions.

## Intended Use — Pacemaker

This product can be used for temporary external cardiac pacing in conscious or unconscious patients as an alternative to endocardial stimulation.

The purposes of pacing include:

- Resuscitation from standstill or bradycardia of any etiology.

  Noninvasive pacing has been used for resuscitation from cardiac standstill, reflex vagal standstill, drug-induced standstill (due to procainamide, quinidine, digitalis, b-blockers, verapamil, etc.) and unexpected circulatory arrest (due to anesthesia, surgery, angiography, and other therapeutic or diagnostic procedures). It has also been used for temporary acceleration of bradycardia in Stokes-Adams disease and sick-sinus syndrome. It is safer, more reliable, and more rapidly applied in an emergency than endocardial or other temporary electrodes.

- As a standby when standstill or bradycardia might be expected.

  Noninvasive pacing can be useful as a standby when cardiac arrest or symptomatic bradycardia might be expected due to acute myocardial infarction, drug toxicity, anesthesia, or surgery. It is also useful as a temporary treatment in patients awaiting pacemaker implants or the introduction of transvenous therapy. In standby pacing applications, noninvasive pacing might provide an alternative to transvenous therapy that avoids the risks of displacement, infection, hemorrhage, embolization, perforation, phlebitis, and mechanical or electrical stimulation of ventricular tachycardia or fibrillation associated with endocardial pacing.

- Suppression of tachycardia.

  Increased heart rates in response to external pacing often suppress ventricular ectopic activity and might prevent tachycardia.

**WARNING! This device must not be connected to internal pacemaker electrodes.**

## Pacemaker Complications

Ventricular fibrillation does not respond to pacing and requires immediate defibrillation. Therefore, the patient's dysrhythmia must be determined immediately, so that you can employ appropriate therapy. If the patient is in ventricular fibrillation and defibrillation is successful but cardiac standstill (asystole) ensues, you should use the pacemaker.

Ventricular or supraventricular tachycardias can be interrupted with pacing, but in an emergency or during circulatory collapse, synchronized cardioversion is faster and more certain.

Pulseless electrical activity (PEA) can occur following prolonged cardiac arrest or in other disease states with myocardial depression. Pacing might then produce ECG responses without effective mechanical contractions, making other effective treatment necessary.

Pacing can evoke undesirable repetitive responses, tachycardia, or fibrillation in the presence of generalized hypoxia, myocardial ischemia, cardiac drug toxicity, electrolyte imbalance, or other cardiac diseases.

Pacing by any method tends to inhibit intrinsic rhythmicity. Abrupt cessation of pacing, particularly at rapid rates, can cause ventricular standstill and should be avoided.

Noninvasive temporary pacing can cause discomfort of varying intensity, which occasionally can be severe and preclude its continued use in conscious patients.

Similarly, unavoidable skeletal muscle contraction might be troublesome in very sick patients and might limit continuous use to a few hours. Erythema or hyperemia of the skin under the hands-free therapy electrodes often occurs; this effect is usually enhanced along the perimeter of the electrode. This reddening should lessen substantially within 72 hours.

There have been reports of burns under the anterior electrode when pacing adult patients with severely restricted blood flow to the skin. Prolonged pacing should be avoided in these cases and periodic inspection of the underlying skin is advised.

There are reports of transient inhibition of spontaneous respiration in unconscious patients with previously available units when the anterior electrode was placed too low on the abdomen.

**WARNING! This device must not be connected to internal pacemaker electrodes.**

## Pediatric Pacing

Pacing can be performed on pediatric patients weighing 55 lb. (25 kg) or less using ZOLL pediatric hands-free therapy electrodes. Prolonged pacing (in excess of 30 minutes), particularly in neonates, can cause burns. Periodic inspection of the underlying skin is recommended.

# Intended Use — $SpO_2$ Monitoring

The R Series pulse oximeter, with the Masimo® SET® technology and the LNCS® series of oximeter sensors, is indicated for the continuous, noninvasive monitoring of arterial oxygen saturation ($SpO_2$) and pulse rate during both no motion and patient motion conditions for adult patients, and no motion conditions for pediatric and neonatal patients in a hospital or prehospital environment.

# Intended Use — $EtCO_2$ Monitoring

The ZOLL R Series $EtCO_2$ option with Respironics Novametrix technology is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide ($EtCO_2$) and respiration rate in patients requiring ventilator support, in-hospital transport, or anesthesia.

This option uses the CAPNOSTAT 5 Mainstream $CO_2$ sensor attached to an airway adapter that connects to an endotracheal tube, mask or disposable mouthpiece.

The R Series $EtCO_2$ option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence $CO_2$ measurements made with the CAPNOSTAT 5 $CO_2$ sensor:

- elevated oxygen levels
- nitrous oxide
- halogenated agents

The R Series $EtCO_2$ option provides settings for high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter $CO_2$ readings, but the R Series unit will monitor $CO_2$ within specifications when these agents are present at normal clinical levels. The presence of Desflurane in the exhaled breath beyond normal values (5%) may positively bias measured carbon dioxide values by up to an additional 3 mmHg.

The R Series $EtCO_2$ option is intended for use only with the ZOLL/Respironics Novametrix CAPNOSTAT 5 Mainstream $CO_2$ Sensor and mainstream airway adapters.

The R Series $EtCO_2$ option can be used on adult patients (21 years of age and older) and on pediatric patients, as described in the following table:

| Pediatric Subpopulation | Approximate Age Range |
|---|---|
| Newborn (neonate) | Birth to 1 month of age |
| Infant | 1 month to 2 years of age |
| Child | 2 to 12 years of age |
| Adolescent | 12-21 years of age |

# Intended Use — NIBP

The ZOLL R Series NIBP option is indicated for the non-invasive measurement of arterial blood pressure for resting patients in critical care and in-hospital transport.

The R Series NIBP option is designed to measure blood pressure for adult patients (21 years of age and older) and for pediatric patients, as described in the following table:

| Pediatric Subpopulation | Approximate Age Range |
|---|---|
| Newborn (neonate) | Birth to 1 month of age |
| Infant | 1 month to 2 years of age |
| Child | 2 to 12 years of age |
| Adolescent | 12-21 years of age |

# ECG Monitoring

The patient's ECG is monitored by connecting the patient to the unit via a 3- or 5-lead patient cable, hands-free therapy electrodes, or through paddles. Five seconds of ECG is presented on the display along with the following information:

- averaged heart rate, derived by measuring R to R intervals
- lead selection - I, II, III, aVR, aVL, aVF, V (with ECG cable), PADDLES or PADS, P1, P2, P3 (when using OneStep Pacing cable with OneStep Complete electrodes).

  P1, P2, and P3 are non-standard ECG leads derived from electrodes within particular OneStep electrodes. While ECG signals acquired from these leads are appropriate for rhythm assessment and determining electrical capture during pacing, they should not be used for ECG morphological evaluation. Attach conventional ECG electrodes for diagnostic purposes.
- ECG size - 0.5, 1, 1.5, 2, 3 cm/mV
- other operational prompts, messages, and diagnostic codes

Monitoring or diagnostic ECG bandwidth is selectable.

# Recorder Function

The strip recorder is provided to document events. The strip recorder normally operates in the delay mode (6 seconds) to ensure the capture of ECG information immediately preceding critical events. The recorder may be activated manually by pressing the **RECORDER** button. It is activated automatically whenever a defibrillation **SHOCK** is delivered, a heart rate alarm occurs, or the rhythm analysis function is activated. The strip recorder may also be configured not to print during these events.

# Paddles and Electrodes

The R Series will defibrillate, cardiovert, and monitor ECG using either defibrillation paddles or hands-free therapy electrodes.

The pacer version of the R Series will pace using ZOLL hands-free therapy electrodes.

**ENERGY SELECT**, **CHARGE** and **SHOCK** controls are located on the paddles and front panel. When using hands-free therapy electrodes, you must use the controls on the front panel of the unit. To switch between paddles and hands-free therapy electrodes, remove the OneStep cable from the apex paddle and connect the hands-free therapy electrodes to the cable.

The Advisory function cannot be activated unless hands-free therapy electrodes are attached to the OneStep cable and used as the ECG monitoring lead.

The R Series can monitor the patient's ECG while9650-0912-01 Rev. J pacing without the need for a separate ECG cable and ECG electrodes. This also allows demand pacing when separate ECG electrodes are either not connected, or unavailable. OneStep pacing capability requires the OneStep Pacing cable along with OneStep Pacing electrodes, or OneStep Complete electrodes.

**Note:** The ZOLL OneStep electrodes, MFE Pads, Pediatric MFE Pads, stat-padz®, and ECG electrodes are disposable, single-use items.

You should always check the expiration date on the electrode packaging. Do not use expired electrodes, which might result in false patient impedance readings and affect the level of delivered energy, or cause burns.

This symbol on the electrode package is accompanied by the expiration date.

The R Series defibrillator reads and reports the expiration date for all OneStep electrodes (except for OneStep Basic). When these electrodes exceed their expiration date, the Code Readiness indicator will change to a red "X."

**Note:** ZOLL electrodes contain no hazardous materials and may be disposed of in general trash unless contaminated with pathogens. Use appropriate precautions when disposing of contaminated electrodes.

When the patient is less than 8 years old or weighs less than 55 lb. (25 kg), use ZOLL OneStep pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

# Batteries

R Series products use an easily replaced rechargeable lithium-ion battery pack (the ZOLL *SurePower* battery pack). A new, fully charged battery pack typically delivers more than 5 hours of ECG monitoring. Use of other functions (such as the defibrillator, printer, or pacemaker) reduces this time.

When a *LOW BATTERY* message appears on the display and the unit emits two beeps in conjunction with the displayed message, the battery must be replaced and recharged.

You can charge the battery by either of the following methods:

- **Internal charging** — plug the R Series into an AC power supply to automatically begin charging the installed battery pack. The front panel battery indicator operates as follows:

| When the indicator is: | It means: |
|---|---|
| Steady yellow | Battery is charging |
| Steady green | Battery is charged |
| Alternating yellow and green | No battery is installed or a battery charging fault has been detected. |
| Not lit | The defibrillator is not connected to AC mains. |

**Note:** Upon power up, it takes approximately 45 seconds for the LEDs on the battery to accurately display run time.

- **External charging** — use the ZOLL SurePower Battery Charger to charge the battery pack and test the battery's capacity. For details, refer to the *ZOLL SurePower defibrillator battery Operator's Manual*.

# Code-Ready System

The R Series defibrillator's Code-Ready system tests the defibrillator whenever the unit is turned on, periodically during operation, whenever manual testing is initiated by the operator, and automatically, at pre-configured intervals.

The code readiness indicator on the front panel shows the result of the most recent readiness check. Also, OneStep Pacing, CPR or Complete electrodes provide an interface that communicates the electrode's expiration date and condition to the defibrillator.

The Defib Test Log stores the results for as many as 1000 defibrillator tests in internal memory. Each log entry shows the time and date of the defibrillator test. The Defib Test Log can be printed on the stripchart or transferred to a personal computer for printing and archiving.

# Safety Considerations

All operators should review these safety considerations before using the R Series.

R Series products are high-energy defibrillators capable of delivering 200 joules. To completely deactivate the unit, turn the Mode Selector to OFF.

To manually disarm a charged (or charging) defibrillator, do one of the following:

- Turn the Mode Selector to **OFF**, **MONITOR**, or **PACER**.
- Change the selected defibrillator energy.

For safety, the R Series unit automatically disarms if left charged for more than either 60 or 120 seconds (user configurable) if the **SHOCK** button is not pressed.

# Warnings

### General

Federal (U.S.A.) law restricts this defibrillator to use by or on the order of a physician.

Only appropriately trained, skilled personnel who are familiar with equipment operation should perform emergency defibrillation. The prescribing physician should determine what training, such as Advanced Cardiac Life Support (ACLS) or Basic Life Support (BLS) certification, is appropriate.

Only skilled personnel trained in Advanced Cardiac Life Support (ACLS) and who are familiar with equipment operation should perform synchronized cardioversion. The precise cardiac arrhythmia must be determined before attempting defibrillation.

These operating instructions describe the functions and proper operation of the R Series products. They are not a substitute for a formal patient care training course. Operators should obtain formal training from an appropriate authority before using this defibrillator for patient care.

Proper operation of the unit and correct electrode placement is critical to obtaining optimal results. Operators must be thoroughly familiar with proper device operation.

The use of external pacing/defibrillation electrodes or adapter devices from sources other than ZOLL is not recommended. ZOLL makes no representations or warranties regarding the performance or effectiveness of its products when used with pacing/defibrillation electrodes or adapter devices from other sources. Defibrillator failures attributable to the use of pacing/defibrillation electrodes or adapters not manufactured by ZOLL might void ZOLL's warranty.

Do not disassemble the unit. A shock hazard exists. Refer all problems to authorized service personnel.

Follow all recommended maintenance instructions. If a problem occurs, obtain service immediately. Do not use the defibrillator until it has been inspected by appropriate personnel.

The R Series unit might not perform to specifications when stored at the upper or lower extreme limits of storage temperature and then immediately put into use.

Avoid using the R Series adjacent to, or stacked on, other equipment. If unavoidable, verify that the R Series operates normally in this configuration before clinical use.

The R Series should be installed and put into service according to the EMC information in Appendix A of this manual.

Assess the Wi-Fi performance for the possibility of RFI in your environment of use.

If multiple devices are transmitting simultaneously to the same access point, Wi-Fi data transfer will be slowed down. If the access point is too overloaded, data transmission failures can occur.

The use of accessories, transducers, and cables other than those specified in this manual and related R Series option manual inserts may result in increased emissions or decreased immunity of the R Series.

Do not use or place the unit in service if the Code Readiness indicator (at the upper right of the front panel) displays a red "X".

Carefully route patient cables to avoid tripping over them, or inadvertently pulling the unit onto the patient.

Always inspect the unit for damage if it has been dropped.

### ECG Analysis, Defibrillating, Pacing and CPR

Prior to attempting synchronized cardioversion, ensure the ECG signal quality is good and that sync markers are displayed above each QRS complex.

Do not use the unit in advisory mode during patient movement. A patient must be motionless during ECG rhythm analysis. Do not touch the patient during analysis. If transporting the patient, cease all movement before beginning ECG analysis.

ECG rhythm analysis does not warn of patient asystole, which is not a shockable rhythm.

The ECG rhythm analysis function might not reliably identify ventricular fibrillation in the presence of an implanted pacemaker. Inspection of the electrocardiogram and clinical evidence of cardiopulmonary arrest should be the basis for any treatment of patients with an implanted pacemaker.

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

Do not place electrodes directly over an implanted pacemaker.

The R Series unit detects ECG electrical signals only. It does not detect a pulse (effective circulatory perfusion). Always verify pulse and heart rate by physical assessment of the patient. Never assume that the display of a nonzero heart rate means that the patient has a pulse.

To avoid possible damage to the R Series unit, turn off pacing before defibrillating the patient with a second defibrillator.

Do not use the unit’s ECG-out signal as a synchronization pulse for another defibrillator or cardioverter.

Place the patient on a firm surface before performing CPR.

### Battery

Do not operate the unit without a battery. Keep a fully charged spare battery pack with the defibrillator at all times.

Test battery packs regularly. A battery that does not pass the ZOLL charger’s capacity test might cause the R Series unit to shut down unexpectedly.

When the warning *LOW BATTERY* appears, plug the R Series unit into a power source or install a fully charged battery pack. When the warning *REPLACE BATTERY* appears, immediately replace the battery pack with a fully charged pack or plug the R Series unit into a power source, as unit shut down due to a low battery condition is imminent.

If mistreated, a battery pack might explode. Do not disassemble a battery pack or dispose of it in fire.

## Operator Safety

Do not use R series products in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Using the unit in such environments might cause an explosion.

Do not use the unit near or within standing water. Electrical safety might be compromised when the defibrillator is wet.

Never discharge the unit with the defibrillation electrodes or paddles shorted together or in open air.

Do not discharge the defibrillator except as indicated in the instructions. Discharge the defibrillator only when defibrillation electrodes or paddles are properly applied to the patient.

To avoid risk of electrical shock, do not touch the gelled area of the hands-free therapy electrodes during pacing or defibrillation.

To avoid risk of electrical shock, do not allow electrolyte gel to accumulate on hands or paddle handles.

To avoid risk of electrical shock, do not allow patient connectors to contact other conductive parts, including earth.

For defibrillation using paddles, use only high-conductivity electrolyte gel specified for such use by the manufacturer.

When using paddles for defibrillation, use your thumbs to operate the **SHOCK** buttons. Doing so avoids inadvertent shock to the operator and unintentional depression of an **ENERGY SELECT** button, which causes the defibrillator to disarm. Keep your hands and fingers away from the paddle plates.

The use of accessory equipment that does not comply with the equivalent safety requirements of the R Series defibrillator could reduce the level of safety of the combined system. When choosing accessory equipment, consider the following:

- Use of the accessory in the patient vicinity.
- Evidence that the safety certification of the accessory has been performed in accordance with the appropriate IEC (EN) 60601-1 and/or IEC (EN) 60601-1-1 harmonized national standards.

Always check that the equipment functions properly and is in proper condition before use.

Disconnect all electro-medical equipment that is not defibrillation-protected from the patient prior to defibrillation.

Before discharging the defibrillator, warn everyone to STAND CLEAR of the patient.

Do not touch the bed, patient, or any equipment connected to the patient during defibrillation. A severe shock can result. To avoid hazardous pathways for the defibrillation current, do not allow exposed portions of the patient's body to touch any metal objects, such as a bed frame.

When the R Series is performing a Code Readiness test, as indicated on the display, do not touch the connected paddles, electrodes, or OneStep cable connector.

## Patient Safety

This equipment should be connected to only one patient at a time.

Use only OneStep Pediatric electrodes to defibrillate patients under 8 years of age in Advisory modes. Use of adult electrodes, or pediatric electrodes other than OneStep Pediatric electrodes, can result in the delivery of excessive energy doses.

Neonatal and pediatric defibrillation energy level settings should be based on site-specific clinical protocols.

To ensure patient safety, connect the R Series only to equipment with galvanically isolated circuits.

Use only high-quality ECG electrodes. ECG electrodes are for rhythm acquisition only; you cannot use ECG electrodes for defibrillation or pacing.

Do not use therapy or ECG electrodes if the gel is dried, separated, torn or split from the foil; patient burns may result from using such electrodes. Poor adherence and/or air pockets under therapy electrodes can cause arcing and skin burns.

Check the expiration date on the electrode packaging. Do not use electrodes after their expiration date.

Excessive body hair or wet, diaphoretic skin can inhibit electrode coupling to the skin. Clip excess hair and dry any moisture from the area where an electrode is to be attached.

Therapy electrodes should be replaced periodically during continuous pacing. Consult electrode directions for proper replacement instructions.

Prolonged pacing (more than 30 minutes), particularly in neonates or adults with severely restricted blood flow, may cause burns. Periodically inspect the skin under the electrodes.

Carefully route the patient cables to reduce the possibility of patient entanglement or strangulation.

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

During electrosurgery, observe the following guidelines to minimize electrosurgery unit (ESU) interference and provide maximum operator 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 ensure proper application of the electrosurgical return electrode to the patient.

Check electrical leakage levels before use. Leakage current may be excessive if more than one monitor or other piece of equipment is connected to the patient.

Do not use the ZOLL OneStep Pacing cable (**REF** 1009-0913-02) or the ZOLL Multi-Function Cable (**REF** 1009-0913-03) in a 220/240 VAC 60Hz power environment. Patient leakage current may be excessive.

# Cautions

If the unit is to be stored longer than 90 days, remove the battery pack.

Do not sterilize the defibrillator, or its accessories unless the accessories are labelled as sterilizable.

Do not immerse any part of the defibrillator in water.

Do not use ketones (such as acetone or MEK) on the defibrillator.

Avoid using abrasives (including paper towels) on the display window.

Grounding reliability can be achieved only when the equipment is connected to a receptacle marked “HOSPITAL ONLY,” “HOSPITAL GRADE,” or equivalent. If the grounding integrity of the line cord or AC receptacle is questionable, operate the defibrillator using battery power only.

To protect the unit from damage during defibrillation, for accurate ECG information, and to protect against noise and other interference, use only internal current-limiting ECG cables specified or supplied by ZOLL.

For continued safety and EMI performance, use only the line cord supplied by ZOLL.

Dispose of battery packs in accordance with national, regional and local regulations. Battery packs should be shipped to a reclamation facility for recovery of metal and plastic compounds as the proper method of waste management.

# Restarting the Defibrillator

Certain events require the R Series products to be restarted after they shut off or become inoperative (for example, when the battery runs down and the unit shuts off).

In such a case, always try to restore defibrillator operation as follows:

1. Turn the Mode Selector to **OFF**.
2. If necessary, replace a depleted battery with a fully charged pack, or connect the defibrillator to AC mains.
3. Turn the Mode Selector to the desired operating mode to restart the unit.

This sequence is necessary to restart the defibrillator and can also be used to clear some fault messages when immediate use of the defibrillator is required.

If restarted after a shutdown period of 10 seconds or more, the unit restores all settings (such as ECG lead, ECG size, and alarm state and limits) to their power-up default values. After restoring device operation, you might need to reinstate previously selected, non-default settings.

# FDA Tracking Requirements

U.S. Federal Law (21 CFR 821) requires the tracking of defibrillators. Under this law, owners of this defibrillator must notify ZOLL Medical Corporation if this product is

- received
- lost, stolen, or destroyed
- donated, resold, or otherwise distributed to a different organization

If any such event occurs, contact ZOLL Medical Corporation in writing with the following information:

1. Originator's organization – Company name, address, contact name, and contact phone number
2. Model number, and serial number of the defibrillator
3. Disposition of the defibrillator (for example, received, lost, stolen, destroyed, distributed to another organization), new location and/or organization (if known and different from originator's organization) – company name, address, contact name, and contact phone number
4. Date when the change took effect

Please address the information to:

**ZOLL Medical Corporation**
**Attn: Tracking Coordinator**
**269 Mill Road**
**Chelmsford, MA 01824-4105**

Fax: (978) 421-0025
Telephone: (978) 421-9655

## Notification of Adverse Events

As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA), for reporting to ZOLL Medical Corporation, and possibly to the FDA, the occurrence of certain events.

These events, described in 21 CFR Part 803, include device-related death and serious injury or illness. In addition, as part of our Quality Assurance Program, ZOLL Medical Corporation requests to be notified of device failures or malfunctions. This information is required to ensure that ZOLL Medical Corporation provides only the highest quality products.

# Software License

**Note:** Read this Operator's Guide and License agreement carefully before operating any of the R Series products.

Software incorporated into the system is protected by copyright laws and international copyright treaties as well as other intellectual property laws and treaties. This software is licensed, not sold. By taking delivery of and using this system, the Purchaser signifies agreement to and acceptance of the following terms and conditions:

1. **Grant of License:** In consideration of payment of the software license fee which is part of the price paid for this product ZOLL Medical Corporation grants the Purchaser a non-exclusive license, without right to sublicense, to use the system software in object-code form only.
2. **Ownership of Software/Firmware:** Title to, ownership of and all rights and interests in the system software and all copies thereof remain at all times vested in the manufacturer, and Licensors to ZOLL Medical Corporation and they do not pass to purchaser.
3. **Assignment:** Purchaser agrees not to assign, sublicense or otherwise transfer or share its rights under the license without the express written permission of ZOLL Medical Corporation.
4. **Use Restrictions:** As the Purchaser, you may physically transfer the products from one location to another provided that the software/firmware is not copied. You may not disclose, publish, translate, release or distribute copies of the software/firmware to others. You may not modify, adapt, translate, reverse engineer, decompile, crosscompile, disassemble or create derivative works based on the software/firmware.

### NO IMPLIED LICENSE

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

# Service

The R Series does not require periodic recalibration or adjustment. Appropriately trained and qualified personnel should, however, perform periodic tests of the defibrillator to verify proper operation.

If a unit requires service, contact the ZOLL Technical Service Department.

| For customers In the U.S.A. | | For customers outside the U.S.A. |
|---|---|---|
| Telephone: | 1-800-348-9011<br>1-978-421-9655 | Call the nearest authorized ZOLL Medical Corporation representative. |
| Fax: | 1-978-421-0010 | To locate an authorized service center, contact the International Sales Department at<br><br>ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br><br>Telephone: 1-978-421-9655 |

When requesting service, please provide the following information to the service representative:

- Unit serial number
- Description of the problem
- Department using the equipment and name of the person to contact
- Purchase order to allow tracking of loan equipment
- Purchase order for a unit with an expired warranty
- Sample ECG or other stripcharts demonstrating the problem (if available and applicable), less any confidential patient information.

### Returning a unit for service

Before sending a unit to the ZOLL Technical Service Department for repair, obtain a service request (SR) number from the service representative.

Remove the battery pack from the unit. Pack the unit with its cables and battery in the original containers (if available) or equivalent packaging. Be sure the assigned service request number appears on each package.

| For customers | Return the unit to |
|---|---|
| In the U.S.A. | ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br>Attention: Technical Service Department (*SR number*)<br>Telephone: 1-800-348-9011 |
| In Canada | ZOLL Medical Canada Inc.<br>1750 Sismet Road, Unit #1<br>Mississauga, ON L4W 1R6<br>Attention: Technical Service Department (*SR number*)<br>Telephone: 1-866-442-1011 |
| In other locations | The nearest authorized ZOLL Medical Corporation representative.<br>To locate an authorized service center, contact the International Sales Department at<br>ZOLL Medical Corporation<br>269 Mill Road<br>Chelmsford, MA 01824-4105<br>Telephone: 1-978-421-9655 |

# The ZOLL Serial Number

Each ZOLL product displays a serial number that contains information about that product. From left to right, ZOLL serial numbers are structured as follows:

- A two-character product code
- A three-character date-of-manufacture code
- A product serial number of six or more alphanumeric characters

The product code for the R Series defibrillator is AF.

The first two characters of the date-of-manufacture code give the last two digits of the year (for example, “06” appears for products manufactured in 2006). The last character of the date-of-manufacture code gives the month in which the product was manufactured. The month appears in the form of a single alphanumeric character: “A” for January, “B” for February, “C” for March, and so on through “L” for December.

The product serial number is a unique set of alphanumeric characters that ZOLL assigns to each individual unit.

# 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 210 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).

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.

The user is cautioned to maintain 8 inches (20 cm) of space from the product to ensure compliance with FCC requirements.

FCC/IC/EU: This device is limited to indoor use in the 5150MHz to 5250MHz band.

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