



MAR - 8 2011

K110361

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824
U.S.A

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Eileen M. Boyle
(978) 421-9171

Date Summary Prepared:

January 26, 2011

Device:

ZOLL R Series® with 2010 AHA Guidelines Software Update

Classification:

Defibrillator, Low-energy – DC : Class II (21 CFR 870.5300)
Automatic External Defibrillators: Class III (21 CFR 870.5310)
Cardiopulmonary Resuscitation Aid: Class III (21 CFR 870.5200)
Cardiac Monitors (including Cardiometers and Rate Alarms): Class II (21CFR 870.2300)
External Transcutaneous Cardiac Pacemakers (Non-invasive): Class II (21 CFR 870.5550)
Oximeters: Class II (21 CFR 870.2700)
System, Measurement, Blood-Pressure, Non-Invasive: Class II (21 CFR 870.1130)
Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase: Class II (21 CFR 868.1400)

Description:

The ZOLL R Series® External Defibrillator is intended for the defibrillation, Noninvasive Transcutaneous Pacing, multi-parameter monitoring of patient vital signs, including ECG Monitoring, Pulse Oximetry, Non-Invasive Blood Pressure measurement, End Tidal CO₂, CPR performance and data printing and recording for resting patients in critical care and transport. The ZOLL R Series is intended for use by qualified medical personnel who are trained and authorized to respond to medical emergencies, to facilitate the ability to monitor and assess the physiological characteristics of the indicated patients in a critical care environment. The design facilitates table top use while still providing a light weight and easy to carry device for transport.

The recent 2010 American Heart Association Guidelines for CPR changed previous recommendations from 1.5"-2.0" inches compression depth to a depth of at least 2.0". The Guidelines also advise caregivers to allow full recoil of the patient's chest during CPR. As a result, we are proposing modifying the device's software to prompt caregivers to perform CPR in accordance with the new AHA guidelines.

The ZOLL R Series software, which currently supports the 2005 American Heart Association's (AHA) Guidelines for CPR, has been revised to optionally support the new revised 2010 AHA's Guidelines for CPR. The specific changes include:

- Adding, in the form of a configuration option, a minimum CPR target compression depth of at least 2.0 inches in addition to the 2005 AHA guidelines depth as described in Chapter 6 of the R Series ALS Operator's guide included in Attachment 11-1 and Chapter 7 of the R Series Plus/ R Series BLS Operator's Guide included in Attachment 11-2. Both depth configurations are necessary since the training to and implementation of the new guidelines occur over a number of years.
- Adding an optional configuration option to display an informational message to remind the users to release their hands from the chest between compressions in order to allow the chest to recoil. When the R Series is configured to display this new message, the message FULLY RELEASE will be displayed every 45 seconds, for 5 seconds, as long as CPR compressions are detected.

Intended Use: R Series ALS

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 of 2 inches (5 cm) minimum for adult patients.

Real CPR Help is not intended for use on patients under 8 years of age.

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 33 lb. (15 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 — SpO2 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 (SpO2) 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 — EtCO2 Monitoring

The ZOLL R Series EtCO2 option with Respirationics Novamatrix technology is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO2) and respiration rate in patients requiring ventilator support, in-hospital transport, or anesthesia.

This option uses the CAPNOSTAT 5 Mainstream CO2 sensor attached to an airway adapter that connects to an endotracheal tube, mask or disposable mouthpiece.

The R Series EtCO2 option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence CO2 measurements made with the CAPNOSTAT 5 CO2 sensor:

- elevated oxygen levels
- nitrous oxide
- halogenated agents

The R Series EtCO2 option provides settings for high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter CO2 readings, but the R Series unit will monitor CO2 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 EtCO2 option is intended for use only with the ZOLL/Respirationics Novamatrix CAPNOSTAT 5 Mainstream CO2 Sensor and mainstream airway adapters.

The R Series EtCO2 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.

R Series Plus and BLS Indications for Use:

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 — Semiautomatic Operation (AED)

R Series products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically-approved patient care protocol.

Use of the R Series in the Semiautomatic 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.

Specifications for the ECG rhythm analysis function are provided in the section, "ECG Rhythm Analysis Algorithm Accuracy" on page A-29.

When the patient is less than 8 years of age or weighs less than 55 lbs. (25 Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine patient's exact age or weight.

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 of 2 inches (5 cm) minimum for adult patients.

Real CPR Help is not intended for use on patients under 8 years of age.

Semiautomatic Operation Contraindications for Use

The rhythm analysis function may 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 implanted pacemakers.

Do not use the rhythm analysis function during patient movement on a stretcher or in an ambulance or other conveyance. A patient must be motionless during ECG analysis. Do not touch the patient during analysis. Cease all movement of the stretcher or vehicle prior to analyzing the ECG. If you are using the R Series in an emergency vehicle, bring the vehicle to a halt before activating the analysis function.

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 can only be used for external pacing of patients and cannot be used for internal pacing. Do not connect internal pacing lead wires to the ZOLL defibrillator.

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 can only be used for external pacing of patients and cannot be used for internal pacing. Do not connect internal pacing lead wires to the ZOLL defibrillator.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33 lb. (15 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 — SpO₂ 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 (SpO₂) 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 — EtCO₂ Monitoring

The ZOLL R Series EtCO₂ option with Respirationics Novamatrix technology is indicated for the continuous noninvasive monitoring of end tidal carbon dioxide (EtCO₂) and respiration rate in patients requiring ventilator support, in-hospital transport, or anesthesia.

This option uses the CAPNOSTAT 5 Mainstream CO₂ sensor attached to an airway adapter that connects to an endotracheal tube, mask or disposable mouthpiece.

The R Series EtCO₂ option is designed to monitor adult, pediatric, and neonatal patients.

The following substances can influence CO₂ measurements made with the CAPNOSTAT 5 CO₂ sensor:

- elevated oxygen levels
- nitrous oxide
- halogenated agents

The R Series EtCO₂ option provides settings for high oxygen and/or nitrous oxide compensation. Halogenated anesthetic agents alter CO₂ readings, but the R Series unit will monitor CO₂ 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 EtCO₂ option is intended for use only with the ZOLL/Respirationics Novamatrix CAPNOSTAT 5 Mainstream CO₂ Sensor and mainstream airway adapters.

The R Series EtCO₂ 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

Substantial Equivalence:

The features and functions of the proposed ZOLL R Series (with 2010 AHA Guidelines software update) are substantially equivalent to the ZOLL R Series (K081574, cleared for use on 9/8/2008 and K081828, cleared for use on 12/9/2008).

Comparison of Technological Characteristics

The technological characteristics of the proposed ZOLL R Series (with 2010 AHA Guidelines software update) are substantially equivalent to the currently marketed ZOLL R Series (K081574, cleared for use on 9/8/2008 and K081828, cleared for use on 12/9/2008).

Performance Testing:

Extensive performance testing ensures that the ZOLL R Series Defibrillator meets all of its functional requirements and performance specifications.

Conclusion

Performance testing of the ZOLL R Series Defibrillator demonstrates that its features and functions are substantially equivalent to that of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Zoll Medical Corporation
c/o Ms. Eileen M. Boyle
Regulatory Affairs Specialist
269 Mill Road
Chelmsford, MA 01824-4105

MAR - 8 2011

Re: K110361
Trade/Device Name: Zoll R Series with 2010 AHA Guidelines Software Update
Regulation Number: 21 CFR 870.5310
Regulation Name: Automated External Defibrillator
Regulatory Class: Class III (three)
Product Code: MKJ
Dated: January 26, 2011
Received: February 7, 2011

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.


If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K110361

Device Name: **ZOLL R Series**

Defibrillator Function

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 – Semiautomatic Operation (AED)

The R Series products are designed for use by emergency care personnel who have completed training and certification requirements applicable to the use of a defibrillator where the device operator controls delivery of shocks to the patient.

They are specifically designed for use in early defibrillation programs where the delivery of a defibrillator shock during resuscitation involving CPR, transportation, and definitive care are incorporated into a medically approved patient care protocol.

Use of the R Series in the Semiautomatic 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

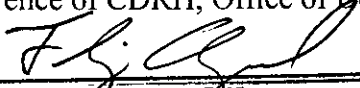
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K110361

Indications for Use

Specifications for the ECG rhythm analysis function are provided in the section, "ECG Rhythm Analysis Algorithm Accuracy" on page A-26.

When the patient is less than 8 years of age or weighs less than 55lbs (25Kg), you must use ZOLL pediatric defibrillation electrodes. Do not delay therapy to determine the patient's exact age or weight.

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 – CPR Monitoring

The CPR monitoring 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 of 1.5 to 2 inches (3.8 to 5.0 cm) for adult patients.

The CPR monitoring function is not intended for use on patients under 8 years of age.

External Pacemaker (Pacer Version Only)

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 may 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 may 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 may prevent tachycardia.

Pediatric Pacing

Pacing can be performed on pediatric patients weighing 33lb. (15kg) or less using ZOLL pediatric hands-free therapy electrode pads.. Prolonged pacing (in excess of 30 minutes), particularly in neonates, could cause burns. Periodic inspection of the underlying skin is recommended.

Intended Use - SpO2 Monitoring

The R Series pulse oximeter, with the Masimo® SET® technology and the LNOP® series of oximeter sensors, is indicated for the continuous, noninvasive monitoring of arterial oxygen saturation (SpO2) 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.