Physician's Technical Manual

# CONTAK RENEWAL® 3 RF

MODELS H210/H215

# CONTAK RENEWAL® 3 RF HE

MODELS H217/H219

**Cardiac Resynchronization Therapy Defibrillator (CRT-D)**

Preliminary Draft

[redacted]

RESTRICTED DEVICE: Federal law (USA) restricts this device to sale, distribution, and use by, or on the lawful order of a physician trained or experienced in device implant and follow-up procedures.

GUIDANT

Preliminary Draft (partial)
[redacted]
See page 8.

## 1. DEVICE DESCRIPTION

The Guidant CONTAK RENEWAL® 3 RF cardiac resynchronization therapy defibrillator (CRT-D), Models H210 and H215, and CONTAK RENEWAL 3 RF HE CRT-D, Models H217 and H219, provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure (HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. The device also uses accelerometer-based adaptive-rate bradycardia therapy similar to Guidant's commercially available VENTAK® family of implantable cardioverter defibrillators (ICDs). The pulse generator has independently programmable outputs and accepts one IS-1 atrial lead, one LV-1 or one IS-1 coronary venous pace/sense lead, and one DF-1/IS-1 cardioversion/defibrillation lead[1]. The pulse generator and the leads constitute the implantable portion of the CONTAK RENEWAL 3 RF system. The device's small, physiologic shape minimizes pocket size and device migration.

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The CONTAK RENEWAL 3 RF device uses the Guidant TRIAD® electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK® two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. The CONTAK RENEWAL 3 RF device also offers a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing with cardiac resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The ZOOM® Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), the Model 2845 CONSULT Software Application, and an accessory telemetry wand, constitutes the external portion of the CONTAK RENEWAL 3 RF system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The CONTAK RENEWAL 3 RF system can be programmed to pro-

1. IS-1 refers to the international standard ISO 5841.3:2000. LV-1 refers to the Guidant LV® proprietary connector. DF-1 refers to the international standard ISO 11318:2002.

vide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

### 1.1. Related Manuals and Information Tools

The System Guide for the CONTAK RENEWAL 3 RF is a separate document and is used in conjunction with the Guidant PRM and the Model 2845 software. The System Guide includes product specifications, operating characteristics, implant procedure recommendations, programming instructions, and follow-up recommendations. Copies can be obtained by contacting your Guidant representative.

The Operator's Manual for the Programmer/Recorder/Monitor provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads.

## 2. INDICATIONS FOR USE

The CONTAK RENEWAL 3 RF CRT-D is indicated for use in the following:

Patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF $\leq$ 35%) and QRS duration $\geq$ 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy.

Patient populations at high risk of sudden cardiac death due to ventricular arrhythmias include, but are not limited to, those with:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia.
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT).

  ***NOTE:*** *The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.*

- Prior myocardial infarction, left ventricular ejection fraction of $\leq$ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients

suppressible with IV procainamide or an equivalent antiarrhythmic (drug) have not been studied.

## 3. CONTRAINDICATIONS

The CONTAK RENEWAL 3 RF CRT-D is contraindicated for use in the following:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or
- Patients whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning.

## 4. WARNINGS

### 4.1. General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.
- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.
- **Defibrillator paddles.** Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2[2] pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.
- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.
- **MRI exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.
- **Diathermy.** Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.

2. Trademark of R2 Corporation.

### 4.2. Programming and Device Operation

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.
- **Atrial only modes.** Do not use atrial only modes in patients with heart failure because such modes do not provide cardiac resynchronization therapy.
- **Ventricular sensing.** Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. See the System Guide for more information.
- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. See the System Guide for more information.

### 4.3. Implant Related

- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **Patch leads.** Do not use defibrillation patch leads with the CONTAK RENEWAL 3 RF system, or injury to the patient may occur.
- **Separate pacemaker.** Do not use the heart failure device with a separate pacemaker system. This combination could result in heart failure device/pacemaker interaction.
- **Emulator.** The emulator is not intended for use as a permanent lead electrode and must be removed from the patient. It is for one-time use only. Do not resterilize.

## 5. PRECAUTIONS

### 5.1. Sterilization, Storage, and Handling

- **For single use only—do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because Guidant cannot ensure that resterilization is effective.
- **If package is damaged.** Guidant sterilizes the pulse generator blister trays and contents with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile,

provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.

- **Storage temperature and equilibration.** Recommended storage temperatures are 0°C–50°C (32°F–122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **Device storage.** Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.
- **Use before date.** Implant the device system before the USE BEFORE date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 1.

### 5.2. Implantation and Device Programming

- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.
- **STAT PACE settings.** Do not leave the device programmed in STAT PACE settings; these settings may significantly reduce the lifetime of the device due to the high output.
- **Drug-resistant SVTs.** Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted device therapy.
- **AV Delay.** For delivery of cardiac resynchronization therapy, the programmed setting for the AV Delay must be less than the patient's intrinsic intracardiac AV interval.
- **Adaptive-rate pacing.** The clinical benefit of adaptive-rate pacing in heart failure patients has not been studied. The use of adaptive-rate pacing should be used with medical discretion only if the patient develops an indication for rate-responsive pacing, such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive adaptive-rate parameters in accordance with patient condition.

- **Atrial Tachy Response (ATR).** ATR should be programmed Off unless the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted.
- **Threshold test.** During the left ventricular threshold test, right ventricular backup pacing is unavailable.
- **Left ventricular pacing only.** The clinical effect of left ventricular pacing alone for heart failure patients has not been studied.
- **Do not bend the lead near the lead–header interface.** Improper insertion can cause insulation damage near the terminal ring that could result in lead failure.
- **Shock waveform polarity.** Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.
- **Absence of an LV lead.** Absence of an electrode or plug in the LV lead port may affect device performance. If an LV lead is not used, be sure to insert a plug.
- **Electrode connections.** Fully insert each IS-1 or LV-1 pace/sense lead into its lead port and then tighten the setscrews onto the electrodes. If the lead is not fully inserted, the setscrews might damage the lead body.
- **Tachy Mode to Off.** Ensure that the pulse generator's Tachy Mode is Off when not in use, before handling it, and before using electrosurgery to prevent inappropriate shocks. For tachyarrhythmia therapy, verify that the Tachy Mode is on.
- **Atrial oversensing.** Care must be taken to ensure that artifacts from the ventricles are not present on the atrial channel or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.
- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15-Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω, reposition the shocking electrodes to allow a greater distance between the shocking electrodes.

- **ATR Entry Count.** Exercise care when programming the Entry Count to low values in conjunction with a short duration. This combination allows mode switching with very few fast atrial beats. If the entry count were programmed to 2 and the duration to 0, for example, ATR mode switching could occur on two fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.
- **ATR Exit Count.** Exercise care when programming the Exit Count to low values. If the Exit Count were programmed to 2, for example, a few cycles of atrial undersensing could cause termination of mode switching.
- **Left ventricular lead configuration.** Proper programming of the LV coronary venous lead configuration is essential for proper LV lead function. Program the lead configuration in accordance with the number of electrodes on the LV lead; otherwise, erratic LV sensing, loss of LV pacing, or ineffective LV pacing might occur.
- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum left ventricular pacing rate and may inhibit cardiac resynchronization therapy at higher pacing rates.
- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during induction because it may shunt energy and result in less energy getting to the patient, and may damage the implanted system.
- **Sensing adjustment.** Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for HF/bradycardia pacing and tachycardia detection.

### 5.3. Follow-up Testing

- **Conversion testing.** Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively.

### 5.4. Pulse Generator Explant and Disposal

- **Incineration.** Be sure the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

- **Device handling.** Program the pulse generator Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.
- **Explanted devices.** Return all explanted pulse generators and leads to Guidant.

### 5.5. Environmental and Medical Therapy Hazards

- **Avoiding EMI.** Advise patients to avoid sources of EMI (electromagnetic interference) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are: electrical power sources, arc welding equipment and robotic jacks, electrical smelting furnaces, large RF transmitters such as RADAR, radio transmitters including those used to control toys, electronic surveillance (anti-theft) devices, and an alternator on a car that is running.
- This device complies with Part 15 of the Federal Communications Commission (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.

**CAUTION:** Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.



#### *5.5.1. Hospital and Medical Environments*

- **Do not use internal defibrillation** paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.
- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator–lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a manual capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.

- **Electrical interference** or “noise” from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.
- **Electrosurgical cautery.** Do not use electrosurgery devices until the pulse generator’s tachyarrhythmia therapy is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.
- **Ionizing radiation therapy may adversely affect device operation.** During ionizing radiation therapy (e.g., radioactive cobalt, linear accelerators, and betatrons), the pulse generator must be shielded with a radiation-resistive material, regardless of the distance of the device to the radiation beam. Do not project the radiation port directly at the device. After waiting a minimum of one hour following radiation treatment (to allow for a device memory check to occur), always evaluate device operation including interrogation and sensing and pacing threshold testing. At the completion of the entire course of treatments, perform device interrogation and follow-up, including sensing and pacing threshold testing and capacitor re-formation.
- **Lithotripsy may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site.
- **Therapeutic ultrasound energy may damage the pulse generator.** If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.
- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy, or may cause inhibition of pacing therapy. Minimize risks by following these steps:

— Program the Tachy Mode to Off to avoid inadvertent tachycardia detection (sensing) or therapy.

— Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.

— Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.

— Have external defibrillation equipment available.

— Consider the use of external pacing support for pacemaker-dependent patients.

### 5.6. Home and Occupational Environments

- **Static magnetic fields.** Advise patients to avoid equipment or situations where they would have extended exposure to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. To prevent mode change in the presence of magnets, the Change Tachy Mode With Magnet feature may be programmed Off. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game “Bingo.”

#### *5.6.1. Electronic Article Surveillance (EAS)*

- Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.

#### *5.6.2. Cellular Phones*

- Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

**Guidant Corporation**
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

**24-Hour Consultation**
1.800.CARDIAC (227.3422)
Worldwide: +1.651.582.4000
www.guidant.com

Preliminary Draft



357016-001 A US 2/04

FCC ID: ESCCRMH21004

GUIDANT

**Guidant Corporation**
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA

**24-Hour Consultation**
1.800.CARDIAC (227.3422)
Worldwide: +1.651.582.4000
www.guidant.com



357015-001 A US 02/04

FCC ID: ESCCRMH21004

Preliminary Draft

[redacted]

GUIDANT

CONTAK RENEWAL® 3 RF
CONTAK RENEWAL® 3 RF HE

GUIDANT

# System Guide

## CONTAK RENEWAL® 3 RF

MODELS H210/H215

## CONTAK RENEWAL® 3 RF HE

MODELS H217/H219

**Cardiac Resynchronization Therapy Defibrillator (CRT-D)**

Preliminary Draft

[redacted]

GUIDANT

# INFORMATION FOR USE

## CHAPTER 1

This chapter contains the following topics:

# DEVICE DESCRIPTION

The Guidant CONTAK RENEWAL® 3 RF cardiac resynchronization therapy defibrillator (CRT-D), Models H210 and H215, and CONTAK RENEWAL 3 RF HE CRT-D, Models H217 and H219, provide ventricular tachyarrhythmia and cardiac resynchronization therapies. Ventricular tachyarrhythmia therapy is for the treatment of ventricular tachycardia (VT) and ventricular fibrillation (VF), rhythms that are associated with sudden cardiac death (SCD). Cardiac resynchronization therapy is for the treatment of heart failure (HF) and uses biventricular electrical stimulation to synchronize ventricular contractions. The device also uses accelerometer-based adaptive-rate bradycardia therapy similar to Guidant's commercially available VENTAK® family of implantable cardioverter defibrillators (ICDs). The pulse generator has independently programmable outputs and accepts one IS-1[1] atrial lead, one LV-1 or one IS-1 coronary venous pace/sense lead, and one DF-1/IS-1 cardioversion/defibrillation lead. The pulse generator and the leads constitute the implantable portion of the CONTAK RENEWAL 3 RF system. The device's small, physiologic shape minimizes pocket size and device migration.

Cardioversion/defibrillation therapies include a range of low- and high-energy shocks using either a biphasic or monophasic waveform. The CONTAK RENEWAL 3 RF device uses the Guidant TRIAD, electrode system for defibrillation energy delivery. By using the metallic housing of the pulse generator as an active electrode, combined with the Guidant ENDOTAK® two-electrode defibrillation lead, energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case. The CONTAK RENEWAL 3 RF device also offers a wide variety of antitachycardia pacing schemes to terminate slower, more stable ventricular tachyarrhythmias. Bradycardia pacing with cardiac resynchronization therapy, including adaptive-rate features, is available to detect and treat bradyarrhythmias and to support the cardiac rhythm after defibrillation therapy.

The ZOOM® Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), the Model 2845 CONSULT Software Application, and an accessory telemetry wand, constitutes the external portion of the CONTAK RENEWAL 3 RF system. The external components allow interrogation and programming of the pulse generator as well as access to the device's diagnostic features. The CONTAK RENEWAL 3 RF system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

1. IS-1 refers to the international standard ISO 5841.3:2000. LV-1 refers to the Guidant LV® proprietary connector. DF-1 refers to the international standard ISO 11318:2002.

## Related Manuals and Information Tools

The Operator's Manual for the Guidant Programmer/Recorder/Monitor provides information specific to the programmer, such as setting up the system, maintenance, and handling. Physician's manuals for the leads provide specific information and instructions regarding the implanted leads. The Physician's Technical Manual is packaged with the pulse generator and provides the information needed to implant the device at nominal parameter settings. All information in the Physician's Technical Manual is also included in this manual.

## INDICATIONS FOR USE

The CONTAK RENEWAL 3 RF CRT-D is indicated for use in the following:

Patients who are at high risk of sudden cardiac death due to ventricular arrhythmias and who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF $\leq$ 35%) and QRS duration $\geq$ 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy.

Patient populations at high risk of sudden cardiac death due to ventricular arrhythmias include, but are not limited to, those with:

- Survival of at least one episode of cardiac arrest (manifested by the loss of consciousness) due to a ventricular tachyarrhythmia.
- Recurrent, poorly tolerated sustained ventricular tachycardia (VT).

  ***NOTE:*** *The clinical outcome of hemodynamically stable, sustained-VT patients is not fully known. Safety and effectiveness studies have not been conducted.*

- Prior myocardial infarction, left ventricular ejection fraction of $\leq$ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia. Patients suppressible with IV procainamide or an equivalent antiarrhythmic (drug) have not been studied.

## CONTRAINDICATIONS

The CONTAK RENEWAL 3 RF CRT-D is contraindicated for use in the following:

- Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or

- Patients whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning.

# WARNINGS

## General

- **Labeling knowledge.** Read this manual thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to or death of the patient.

- **Avoid shock during handling.** Program the pulse generator Tachy Mode to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks.

- **Defibrillator paddles.** Always have sterile external and internal defibrillator paddles or an equivalent (eg, R2[2] pads) immediately available during conversion testing. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death.

- **Resuscitation availability.** Ensure that an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are present during post-implant device testing should the patient require external rescue.

- **Magnetic resonance imaging (MRI) exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient.

- **Diathermy.** Do not subject a patient with an activated implanted pulse generator to diathermy since diathermy may damage the pulse generator.

## Programming and Device Operation

- **Atrial tracking modes.** Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.

- **Atrial only modes.** Do not use atrial only modes in patients with heart failure because such modes do not provide cardiac resynchronization therapy.

2. Trademark of the R2 Corporation.

- **Ventricular sensing.** Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. See Sensitivity Adjustment on page 10-4 for more information.

- **Slow VT.** Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. See CRT Delivery Zone and Tachyarrhythmia Zones on page 3-5 for more information.

### Implant Related

- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

- **Patch leads.** Do not use defibrillation patch leads with the CONTAK RENEWAL 3 RF system, or injury to the patient may occur.

- **Separate pacemaker.** Do not use the CRT-D device with a separate pacemaker system. This combination could result in CRT-D/pacemaker interaction.

- **Emulator.** The emulator is not intended for use as a permanent lead electrode and must be removed from the patient. It is for one-time use only. Do not resterilize.

## PRECAUTIONS

### Sterilization, Storage, and Handling

- **For single use only—do not resterilize devices.** Do not resterilize the device or the accessories packaged with it because Guidant cannot ensure that resterilization is effective.

- **If package is damaged.** Guidant sterilizes the pulse generator blister trays and contents with ethylene oxide gas before final packaging. When the pulse generator is received, it is sterile, provided the container is intact. If the packaging is wet, punctured, opened, or otherwise damaged, return the device to Guidant.

- **Storage temperature and equilibration.** Recommended storage temperatures are 0–50°C (32–122°F). Allow the device to reach room temperature before

programming or implanting the device because temperature extremes may affect initial device function.

- **Device storage.** Store the pulse generator in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference (EMI) to avoid device damage.

- **Use before date.** Implant the device system before the USE BEFORE date on the package label because this date reflects a validated shelf life. For example, if the date is January 1, do not implant on or after January 1.

## Implantation and Device Programming

- **Lead system.** Do not use any lead with this device without first verifying connector compatibility. Using incompatible leads can damage the connector or result in potential adverse consequences, such as undersensing of cardiac activity or failure to deliver necessary therapy.

- **STAT PACE settings.** Do not leave the device programmed in STAT PACE settings; these settings may significantly reduce the lifetime of the device due to the high output.

- **Drug-resistant SVTs.** Determine if the device and programmable options are appropriate for patients with drug-resistant supraventricular tachyarrhythmias (SVTs), because drug-resistant SVTs can initiate unwanted tachyarrhythmia therapy or can cause inhibition of cardiac resynchronization therapy.

- **AV Delay.** For delivery of cardiac resynchronization therapy, the programmed setting for the AV Delay must be less than the patient's intrinsic intracardiac AV interval.

- **Adaptive-rate pacing.** The clinical benefit of adaptive-rate pacing in heart failure patients has not been studied. The use of adaptive-rate pacing should be used with medical discretion only if the patient develops an indication for rate-responsive pacing, such as chronotropic incompetence. Patients with heart failure may have hemodynamic compromise at rapid sensor-driven rates, and the physician may wish to program less aggressive adaptive-rate parameters in accordance with patient condition.

- **Atrial Tachy Response (ATR).** ATR should be programmed Off unless the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted.

- **Threshold test.** During the left ventricular threshold test, right ventricular backup pacing is unavailable.

- **Left ventricular pacing only.** The clinical effect of left ventricular pacing alone for heart failure patients has not been studied.

- **Do not bend the lead near the lead–header interface.** Improper insertion can cause insulation damage near the terminal ring that could result in lead failure.

- **Shock waveform polarity.** Never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if polarity is switched physically.

- **Absence of an LV lead.** Absence of an electrode or plug in the LV lead port may affect device performance. If an LV lead is not used, be sure to insert a plug.

- **Electrode connections.** Fully insert each IS-1 or LV-1 pace/sense lead into its lead port and then tighten the setscrews onto the electrodes. If the lead is not fully inserted, the setscrews might damage the lead body.

- **Tachy Mode to Off.** Ensure that the pulse generator's Tachy Mode is Off when not in use, before handling it, and before using electrosurgery to prevent inappropriate shocks. For tachyarrhythmia therapy, verify that the Tachy Mode is on.

- **Atrial oversensing.** Care must be taken to ensure that artifacts from the ventricles are not present on the atrial channel or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.

- **Defibrillation lead impedance.** Never implant the device with a lead system that has less than 15-Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω, reposition the shocking electrodes to allow a greater distance between the shocking electrodes.

- **ATR Entry Count.** Exercise care when programming the Entry Count to low values in conjunction with a short duration. This combination allows mode switching with very few fast atrial beats. If the entry count were programmed to 2 and the duration to 0, for example, ATR mode switching could occur on two fast

atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.

- **ATR Exit Count.** Exercise care when programming the Exit Count to low values. If the Exit Count were programmed to 2, for example, a few cycles of atrial undersensing could cause termination of mode switching.

- **Left ventricular lead configuration.** Proper programming of the LV coronary venous lead configuration is essential for proper LV lead function. Program the lead configuration in accordance with the number of electrodes on the LV lead; otherwise, erratic LV sensing, loss of LV pacing, or ineffective LV pacing might occur.

- **Left Ventricular Protection Period (LVPP).** Use of a long LVPP reduces the maximum left ventricular pacing rate and may inhibit cardiac resynchronization therapy at higher pacing rates.

- **Shunting energy.** Do not allow any object that is electrically conductive to come into contact with the lead or device during induction because it may shunt energy and result in less energy getting to the patient, and may damage the implanted system.

- **Sensing adjustment.** Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing for HF/ bradycardia pacing and tachycardia detection.

## Follow-up Testing

- **Conversion testing.** Successful conversion of ventricular fibrillation or ventricular tachycardia during arrhythmia conversion testing is no assurance that conversion will occur post-operatively. Be aware that changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold (DFT), which may result in nonconversion of the arrhythmia post-operatively.

## Pulse Generator Explant and Disposal

- **Incineration.** Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

- **Device handling.** Program the pulse generator Tachy Mode to Off, disable the magnet feature, and disable the Beep When ERI Is Reached beeper before explanting, cleaning, or shipping the device to prevent unwanted shocks, overwriting of important therapy history data, and audible tones.

- **Explanted devices.** Return all explanted pulse generators and leads to Guidant.



## Environmental and Medical Therapy Hazards

- **Avoiding electromagnetic interference** (**EMI).** Advise patients to avoid sources of EMI because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Examples of EMI sources are: electrical power sources, arc welding equipment and robotic jacks, electrical smelting furnaces, large RF transmitters such as RADAR, radio transmitters including those used to control toys, electronic surveillance (anti-theft) devices, and an alternator on a car that is running.

- This device complies with Part 15 of the Federal Communications Commission (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.

**CAUTION:** Changes or modifications not expressly approved by Guidant could void the user's authority to operate the equipment.

### Hospital and Medical Environments

- **Do not use internal defibrillation** paddles unless the pulse generator is disconnected from the leads because it may shunt energy causing injury to the patient, and may damage the pulse generator.

- **External defibrillation.** Use of external defibrillation can damage the pulse generator. To help prevent defibrillation damage to the pulse generator: position the defibrillation paddles as far from the pulse generator as possible, position the defibrillation paddles perpendicular to the implanted pulse generator–lead system, and set energy output of defibrillation equipment as low as clinically acceptable.

Following any external defibrillation episode, verify pulse generator function since external defibrillation may have damaged the pulse generator. To verify proper function: interrogate the device, perform a manual capacitor re-formation, verify battery status, check the shock counters, and ensure that programmable parameters did not change.

- **Electrical interference** or “noise” from devices such as electrosurgical and monitoring equipment may interfere with establishing or maintaining telemetry for interrogating or programming the device. In the presence of such interference, move the programmer away from electrical devices and ensure that the wand cord and cables are not crossing one another.

- **Electrosurgical cautery.** Do not use electrosurgery devices until the pulse generator’s tachyarrhythmia therapy is deactivated. If active, the pulse generator may deliver an inappropriate shock to the patient. Remember to reactivate the pulse generator after turning off the electrosurgery equipment.

- **Ionizing radiation therapy may adversely affect device operation.** During ionizing radiation therapy (eg, radioactive cobalt, linear accelerators, and betatrons), the pulse generator must be shielded with a radiation-resistive material, regardless of the distance of the device to the radiation beam. Do not project the radiation port directly at the device. After waiting a minimum of one hour following radiation treatment (to allow for a device memory check to occur), always evaluate device operation including interrogation and sensing and pacing threshold testing. At the completion of the entire course of treatments, perform device interrogation and follow-up, including sensing and pacing threshold testing and capacitor re-formation.

- **Lithotripsy may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site.

- **Therapeutic ultrasound energy may damage the pulse generator.** If therapeutic ultrasound energy must be used, avoid focusing near the pulse generator site.

- **Radio frequency ablation.** Exercise caution when performing radio frequency ablation procedures in device patients. If the pulse generator Tachy Mode is programmed On during the procedure, the device may inappropriately declare a tachycardia episode and deliver therapy, or may cause inhibition of pacing therapy. Minimize risks by following these steps:

- Program the Tachy Mode to Off to avoid inadvertent tachycardia detection (sensing) or therapy.
- Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.
- Keep the current path (electrode tip to ground) as far away from the pulse generator and leads as possible.
- Have external defibrillation equipment available.
- Consider the use of external pacing support for pacemaker-dependent patients.

## Home and Occupational Environments

- **Static magnetic fields.** Advise patients to avoid equipment or situations where they would have extended exposure to strong (>10 gauss or 1 mTesla) magnetic fields since the pulse generator mode could change. To prevent mode change in the presence of magnets, the Change Tachy Mode With Magnet feature may be programmed Off. Examples of magnetic sources are: industrial transformers and motors, magnetic resonance imaging (MRI) devices, large stereo speakers, telephone receivers if held within 0.5 inches (1.27 cm) of the pulse generator, and magnetic wands such as those used for airport security and in the game "Bingo."

### Electronic Article Surveillance (EAS)

- Advise patients to avoid lingering near anti-theft devices, such as those found in entrances and exits of department stores and public libraries, and to walk through them at a normal pace, because such devices may cause inappropriate pulse generator operation.

### Cellular Phones

- Advise patients to hold cellular phones to the ear opposite the side of the implanted device. Patients should not carry a cellular phone in a breast pocket or on a belt over or within 6 inches (15 cm) of the implanted devices since some cellular phones may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

# Limited Warranty

## CONTAK RENEWAL® 3 RF
MODELS H210/H215

## CONTAK RENEWAL® 3 RF HE
MODELS H217/H219

**Cardiac Resynchronization Therapy Defibrillator (CRT-D)**

Preliminary Draft

GUIDANT

The purchaser must comply with the terms and conditions in this document for this limited warranty to apply.

This limited warranty is available if the Guidant device fails to function within normal tolerances due to defects in materials, workmanship, or design during the first 5 years (60 months) for CONTAK RENEWAL 3 RF devices (Models H210/H215) or during the first 4 years (48 months) for CONTAK RENEWAL 3 RF HE devices (Models H217/H219) after date of implantation.

During the operating life of these devices, battery energy is consumed to monitor the patient's ECG continuously, thus reducing the number of defibrillatory pulses that can be delivered. On the basis of individual patient physiology, certain patients may require a large number of defibrillatory pulses, thus requiring replacement of the CONTAK RENEWAL 3 RF device in less than 60 months or the CONTAK RENEWAL 3 RF HE device in less than 48 months. Although this is considered normal for those patients and not a malfunction or defect, the Guidant 60-month warranty for the CONTAK RENEWAL 3 RF device will still apply or the Guidant 48-month warranty for CONTAK RENEWAL 3 RF HE device will still apply.

Upon the purchaser's compliance with the terms and conditions of this warranty, Guidant will issue a replacement credit to the hospital on behalf of the original patient for the purchase of a new Guidant device. The credit will be either a full or prorated credit depending on the replacement date of the device:

| Credit Amount | Replacement Date |
|---|---|
| **CONTAK RENEWAL 3 RF (H210/H215)** | |
| Full purchase price of either the original unit or the replacement unit, whichever is less | 1 to 36 months after implant |
| 50 percent of the above amount decreased on a pro rata daily basis over this 24-month period | > 36 to 60 months after implant |

| Credit Amount | Replacement Date |
|---|---|
| **CONTAK RENEWAL 3 RF HE (H217/H219)** | |
| Full purchase price of either the original unit or the replacement unit, whichever is less | 1 to 36 months after implant |
| 50 percent of the above amount decreased on a pro rata daily basis over this 12-month period | > 36 to 48 months after implant |

**Guidant does not warrant the suitability of a device for any specific patient, since fitness for use is a medical decision.**

**GUIDANT WILL NOT BE LIABLE FOR ANY DAMAGES, WHETHER DIRECT, CONSEQUENTIAL, OR INCIDENTAL, CAUSED BY DEVICE DEFECTS, FAILURES, OR MALFUNCTIONS, WHETHER SUCH A CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.**

**THIS WARRANTY REPRESENTS THE ENTIRE OBLIGATION OF GUIDANT AND IS MADE IN LIEU OF ANY OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.**

**THE REMEDIES SET FORTH IN THIS WARRANTY SHALL BE THE ONLY REMEDIES AVAILABLE TO ANY PERSON. NO PERSON HAS ANY AUTHORITY TO BIND GUIDANT TO ANY WARRANTY OR REPRESENTATION EXCEPT THOSE SPECIFICALLY CONTAINED HEREIN.**

Some states do not allow limitations on how long an implied warranty lasts, so the preceding limitation may not apply to you. Some states do not allow the exclusion of incidental or consequential damages, so the preceding limitation or exclusion may not apply to you.

**Other Terms and Conditions**

1. This warranty applies only for a device replacement in the original patient.

2. The device must be replaced with a Guidant CRT-D.
3. The device must be implanted before the “USE BEFORE” date marked on the package.
4. The completed Warranty Validation and Lead Registration form must be returned to Guidant at the time of device implantation, or no warranty exists.
5. The device must be returned to Guidant Corporation Cardiac Rhythm Management, 4100 Hamline Avenue North, St. Paul, MN 55112-5798 USA within forty-five (45) days after removal from the patient along with an Observation/Complication Out-of-Service Reporting Form completed by the hospital or physician.
6. Guidant will inspect the device and determine whether a warranty credit is due.
7. No credit allowance will be made where evidence appears of improper handling, exposure to temperatures above 50°C, improper storage, subjection to shock or electrical abuse, or defacing or altering of the device.
8. The purchaser must inspect the device upon receipt. If the device is received in a damaged condition, Guidant will replace it at no charge to the purchaser if the damage is reported to Guidant within fifteen (15) days of receipt of the device and it is promptly returned to Guidant.
9. All devices returned to Guidant become its property.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

**Guidant Corporation**
4100 Hamline Avenue North
St. Paul, MN 55112-5798 USA


357017-001A US 11/03

**24-Hour Consultation**
US: 1.800.CARDIAC (227.3422)
Worldwide: +1.651.582.4000
www.guidant.com

FCC ID: ESCCRMH21004