ABOUT THIS MANUAL

This System Guide contains information about the CONTAK® RENEWAL™ TR CRT-P (cardiac resynchronization therapy pacemaker) device used with the Model 2865 CONSULT Software Application and the ZOOM® Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM).

All PRM screen illustrations in this manual show typical screens for the CONTAK RENEWAL TR pulse generator. The screens you see when interrogating or programming the pulse generator will be similar, depending on the programmed parameters.

Throughout this manual, the following text conventions will be used:

PRM KEYS	The names of the PRM keys will appear in capital letters (eg, PROGRAM, INTERROGATE).
Screen Text	When text appearing on the PRM screen is referred to in the manual, it will appear with the first letter of each word capitalized.
1., 2., 3.	Numbered lists indicate a series of instructions that should be followed in the order given.
•	Bullets precede items in a list, or a series that is not sequential.

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INFORMATION FOR USE

CHAPTER 1

This chapter contains the following topics:

- "Device Description" on page 1-2
- "Indications for Use" on page 1-2
- "Contraindications" on page 1-3
- "Precautions" on page 1-4
- "Potential Adverse Events" on page 1-14
- "Device Features" on page 1-32
- "Mechanical Specifications" on page 1-33
- "Items Included in Device Packaging" on page 1-33
- "Factory Ship Mode" on page 1-34
- "Maintaining Device Effectiveness" on page 1-34
- "X-Ray Identifier" on page 1-34
- "Pulse Generator Longevity" on page 1-35
- "Patient Counseling Information" on page 1-36

DEVICE DESCRIPTION

The Guidant CONTAK® RENEWAL™ TR Models H125 and H120 CRT-P devices are designed to provide cardiac resynchronization therapy by providing biventricular electrical stimulation to synchronize the right and left ventricular contractions. The device also provides adaptive-rate bradycardia therapy. The pulse generator has independent, programmable outputs for the atrium, right ventricle, and left ventricle, featuring LV-1[1] and/or IS-1 lead ports. The leads along with the device constitute the implantable portion of the CONTAK RENEWAL TR system. The device's small, physiologic shape minimizes pocket size and may minimize device migration.

The ZOOM® Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), the Model 2865 CONSULT Software Application, and an accessory telemetry wand, constitutes the external portion of the CONTAK RENEWAL TR 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 TR system can be programmed to provide a variety of therapy options. It also can provide noninvasive diagnostic testing and therapy history data.

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.

INDICATIONS FOR USE

The CONTAK RENEWAL TR pulse generator is indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms and remain symptomatic despite stable, optimal heart failure drug therapy (as defined in the clinical trials section).

1. LV-1 refers to the Guidant LV® proprietary connector. IS-1 refers to the international standard ISO 5841.3:1992.

The device provides atrial-ventricular tracking modes to help preserve AV synchrony and adaptive-rate pacing for patients who would benefit from adjusted pacing rates concurrent with physical activity.

CONTRAINDICATIONS

- This device is contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD).
- Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction.
- Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing.
- Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

WARNINGS

- **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.
- **Do not kink leads.** Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.
- **MRI exposure.** Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. (Refer to page 1-9 for more information about MRI.)
- **Therapeutic diathermy.** Do not expose a patient with an activated implanted pulse generator to diathermy. Diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pacemaker because of induced currents.
- **Atrial-only modes.** Do not use atrial-only modes in patients with heart failure because such modes do not provide cardiac resynchronization therapy.
- **Atrial pacing.** The clinical outcomes for patients with chronic refractory atrial tachyarrhythmias are not fully known. Safety and effectiveness studies have not

been conducted. However, if a chronic refractory atrial tachyarrhythmia develops in a patient implanted with this device, do not use dual-chamber or single-chamber atrial pacing.

- **Ventricular sensing.** Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. See "Sensitivity" on page 3-16 for more information.

PRECAUTIONS

Clinical Considerations

- STAT PACE will initiate unipolar pacing.
- Slow retrograde conduction combined with a short PVARP might induce pacemaker-mediated tachycardia.

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 temperature is 0°C to 50°C (32°F to 122°F). Allow the device to reach room temperature before programming or implanting the device because temperature extremes may affect initial device function.
- **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.

- **Device communication.** Use only a Guidant Programmer/Recorder/Monitor (PRM) and the Model 2865 Software Application to communicate with the CONTAK RENEWAL TR pulse generator.

- **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 tachyarrhythmia (SVTs), because drug-resistant SVTs 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 to allow the device to pace the ventricles.

- **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 back-up pacing is unavailable.

- **Pacing and sensing safety margins.** Consider lead maturation in choice of pacing amplitudes, pacing pulse widths, and sensing levels.
  - In the right ventricle, acute pacing threshold greater than 1.5 V or chronic pacing thresholds greater than 3 V can result in loss of capture because thresholds increase after implantation.
  - In the right ventricle, R-wave amplitude less than 5 mV or P-wave amplitude less than 2 mV can result in undersensing because sensed amplitude decreases after implantation.
- **Line-powered equipment.** Exercise extreme caution if testing leads using line-powered equipment because leakage current exceeding 10 mA can induce ventricular fibrillation.
- **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.
- **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.
- **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.
- **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.

- **Proper programming of the lead configuration.** If the Lead Configuration is programmed to Bipolar when a unipolar lead is implanted, pacing will not 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.

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.

- Return all explanted pulse generators and leads to Guidant.

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.

Hospital and Medical Environments

- **Internal defibrillation.** 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.** External defibrillation may damage the pulse generator. Attempt to minimize the current flowing through the pulse generator and lead system by following these precautions: position defibrillation paddles as far from the pulse generator as possible and perpendicular to the implanted pulse generator/lead system, and use the lowest clinically appropriate energy output (watt-seconds). Protective surge suppressors help shield pulse generator

circuitry from electrical damage during external defibrillation procedures up to 360 watt-seconds. However, the precautionary measures listed in the section "External Defibrillation Protection" on page 8-4 should be implemented.

Transcutaneous electrical nerve stimulation (TENS). TENS may interfere with pulse generator function. If necessary, the following measures may reduce interference: place the TENS electrodes as close to each other as possible and as far from the pulse generator/lead system as possible, and monitor cardiac activity during TENS use.

- **Electrical interference.** 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.** The use of electrosurgical cautery could induce ventricular arrhythmias and/or fibrillation, and may cause asynchronous or inhibited pulse generator operation. If electrocautery cannot be avoided, observe the following precautions to minimize complications:

  - Program Noise Response to VOO, AOO, or DOO and avoid direct contact with the pulse generator or leads.

  - Position the ground plate so that the current pathway does not pass through or near the pulse generator system.

  - Use short, intermittent, and irregular bursts at the lowest feasible energy levels.

  - Use a bipolar electrocautery system where possible.

  - Have temporary pacing and defibrillation equipment available.

- **Ionizing radiation therapy.** 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.

- **Diagnostic x-ray and fluoroscopic radiation.** Diagnostic x-ray and fluoroscopic radiation should not affect the pulse generator. For high radiation sources, refer to ionizing radiation therapy caution above.

- **Lithotripsy may damage the pulse generator.** If lithotripsy must be used, avoid focusing near the pulse generator site. The lithotriptor is designed to trigger off the R-wave on the ECG resulting in shock waves being delivered during the ventricular refractory period. Program to VVI/VOO mode because atrial pacing pulses can trigger the lithotriptor.

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

- **Radio-frequency (RF) ablation.** RF ablation may cause asynchronous or inhibited pulse generator operation, and possible reset of the pulse generator. During RF ablation, the current path (electrode tip to ground plate) should be kept as far away from the pulse generator and leads as possible, and the output amplitude of the pulse generator should be programmed to the 5-V setting, or greater. Avoid direct contact between the ablation catheter and the implanted lead and pulse generator.

- **Magnetic resonance imaging.** MRI for patients with implantable pulse generators has been contraindicated by MRI manufacturers. Clinicians should carefully weigh the decision to use MRI with pacemaker patients.

    - Magnetic and RF fields produced by MRI may increase ventricular sensing beyond the rate limit, which results in total inhibition of pacing output, pacing at random rates, or asynchronous pacing.

    - Magnetic fields may activate magnet mode operation and cause asynchronous pacing.

    - MRI can irreversibly damage the pulse generator.

    - Patients treated with MRI should be closely monitored and programmed parameters should be verified upon cessation of MRI.

Home and Occupational Environments

- **Home appliances.** Appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with pulse generator operation. There are reports of pulse generator disturbances caused by electric hand tools or electric razors used directly over the pulse generator implant site.

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.

ADVERSE EVENTS

Observed Adverse Events

Guidant conducted an Exercise Performance Sub-Study in the COMPANION trial (CONTAK TR Clinical Study) to demonstrate the safety and effectiveness of a CRT pacing system and to demonstrate, with reasonable assurance, the safety and effectiveness of biventricular stimulation, or cardiac resynchronization therapy (CRT), using the Guidant CONTAK TR CRT-P (Model 1241) along with the EASYTRAK (Models 4510, 4511, 4512, 4513) coronary venous steroid-eluting single-electrode pace/sense lead. The Exercise Performance Sub-Study in COMPANION was a prospective, randomized, controlled, multi-center study conducted at 67 sites in the United States and enrolled 448 patients.

Guidant's CONTAK TR and CONTAK RENEWAL TR devices provide the same cardiac resynchronization therapy (biventricular pacing). Therefore, the CONTAK TR Clinical Study data also applies to CONTAK RENEWAL TR. The primary difference between the two devices is that CONTAK TR utilizes an electrically common RV and LV sensing/pacing circuit whereas

CONTAK RENEWAL TR incorporates an independent RV and LV sensing/pacing circuit.

Table 1-1 provides information on adverse events reported in patients randomized to a CONTAK TR device for a six-month period beginning from randomization.

Table 1-1. Adverse Events Through Six Months
(CONTAK TR Exercise Performance Sub-Study Patients, N=185)

	Total Number of Events (Number of Patients)	% Comps (Patients) N=185 Patients	N Comps/ 100 Device Months 4008 Months	% Obs (Patients) N=185 Patients	N Obs/ 100 Device Months 4008 Months
Total Device-Related Adverse Events	**194 (103)**	**23.2 (43)**	**1.5 (59)**	**45.4 (84)**	**3.4 (135)**
LV Lead–Related Events					
Brady capture - LV	44 (32)	13.5 (25)	0.7 (28)	7.6 (14)	0.4 (16)
CPI PG anomaly related to event	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Inappropriate shock above rate cutoff	3 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.1 (3)
Insulation breech observed	2 (2)	1.1 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Multiple counting - brady	9 (8)	0.0 (0)	0.0 (0)	4.3 (8)	0.2 (9)
Multiple counting - tachy	3 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.1 (3)
Phrenic nerve/diaphragm stimulation	17 (14)	1.1 (2)	0.0 (2)	6.5 (12)	0.4 (15)
PG-Related Events					
Migration of device	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Pacemaker-mediated tachycardia (PMT)	4 (4)	0.0 (0)	0.0 (0)	2.2 (4)	0.1 (4)
Pocket erosion/extrusion	3 (2)	1.1 (2)	0.1 (3)	0.0 (0)	0.0 (0)
Pocket infection	6 (5)	0.5 (1)	0.0 (1)	2.2 (4)	0.1 (5)
Rate response too agressive - brady	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Setscrew, stripped	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Procedure-Related Events					
Allergic reaction	9 (7)	0.0 (0)	0.0 (0)	3.8 (7)	0.2 (9)
Cardiac tamponade	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Dissection, coronary sinus	4 (4)	0.0 (0)	0.0 (0)	2.2 (4)	0.1 (4)
Hematoma	11 (10)	1.1 (2)	0.0 (2)	4.3 (8)	0.2 (9)
Hemorrhage	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Hypotension	5 (5)	0.0 (0)	0.0 (0)	2.7 (5)	0.1 (5)
Perforation, cardiac	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Perforation, coronary venous	7 (7)	0.0 (0)	0.0 (0)	3.8 (7)	0.2 (7)
Pericardial effusion	5 (3)	1.1 (2)	0.1 (3)	1.1 (2)	0.0 (2)
Pericarditis	2 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.0 (2)

Table 1-1. Adverse Events Through Six Months
(CONTAK TR Exercise Performance Sub-Study Patients, N=185)

	Total Number of Events (Number of Patients)	% Comps (Patients) N=185 Patients	N Comps/ 100 Device Months 4008 Months	% Obs (Patients) N=185 Patients	N Obs/ 100 Device Months 4008 Months
Physiological reaction	2 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.0 (2)
Pneumothorax	5 (5)	2.2 (4)	0.1 (4)	0.5 (1)	0.0 (1)
Post-surgical wound discomfort	21 (21)	0.0 (0)	0.0 (0)	11.4 (21)	0.5 (21)
Renal failure	2 (2)	0.5 (1)	0.0 (1)	0.5 (1)	0.0 (1)
Transient heart block	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Ventricular fibrillation	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Ventricular tachycardia	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
RA Lead-Related Events					
Brady capture - atrium	6 (6)	2.2 (4)	0.1 (4)	1.1 (2)	0.0 (2)
Intermittent sensing - atrium rate	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Oversensing - atrium pace sense	2 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.0 (2)
Oversensing - atrium rate sense - brady	2 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (2)
Undersensing - atrium pace sense - brady	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Undersensing - atrium rate sense - brady	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
RV Lead–Related Events					
Brady capture - RV	3 (3)	1.1 (2)	0.0 (2)	0.5 (1)	0.0 (1)
High DFTs - tachy	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Materials unretrieved in body	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Oversensing - ventricle pace sense	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Phantom shock	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Total Patient-Related Adverse Events	**1146 (173)**	**47.6 (88)**	**4.0 (161)**	**90.3 (167)**	**24.6 (985)**
Cardiovascular-Related Events					
AV Block - heart block, complete	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Air embolism	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Aneurysm	2 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.0 (2)
Arrhythmia - atrial fibrillation	43 (31)	2.7 (5)	0.1 (5)	15.1 (28)	0.9 (38)
Arrhythmia - atrial flutter	9 (7)	1.1 (2)	0.0 (2)	3.2 (6)	0.2 (7)
Arrhythmia - sinus tachycardia	3 (3)	0.0 (0)	0.0 (0)	1.6 (3)	0.1 (3)
Cardiac arrest	8 (7)	3.8 (7)	0.2 (8)	0.0 (0)	0.0 (0)
Change in arrhythmia - SVT	13 (12)	0.0 (0)	0.0 (0)	6.5 (12)	0.3 (13)
Change in arrhythima - brady	16 (16)	1.1 (2)	0.0 (2)	7.6 (14)	0.3 (14)
Change in arrhythmia - junctional	3 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.1 (3)

Table 1-1. Adverse Events Through Six Months
(CONTAK TR Exercise Performance Sub-Study Patients, N=185)

	Total Number of Events (Number of Patients)	% Comps (Patients) N=185 Patients	N Comps/ 100 Device Months 4008 Months	% Obs (Patients) N=185 Patients	N Obs/ 100 Device Months 4008 Months
Chest pain	70 (40)	3.8 (7)	0.3 (13)	20.5 (38)	1.4 (57)
Claudication	4 (3)	0.5 (1)	0.0 (1)	1.6 (3)	0.1 (3)
Coagulopathy	3 (3)	0.5 (1)	0.0 (1)	1.1 (2)	0.0 (2)
Congestive heart failure	118 (68)	9.2 (17)	0.4 (18)	33.5 (62)	2.5 (100)
Dizziness, cause undetermined	40 (33)	0.5 (1)	0.0 (1)	17.3 (32)	1.0 (39)
Dyspnea (shortness of breath)	66 (36)	1.1 (2)	0.0 (2)	18.4 (34)	1.6 (64)
Fatigue	22 (21)	0.0 (0)	0.0 (0)	11.4 (21)	0.5 (22)
Hypertension	8 (7)	0.0 (0)	0.0 (0)	3.8 (7)	0.2 (8)
Hypotension	29 (25)	0.0 (0)	0.0 (0)	13.5 (25)	0.7 (29)
Intracranial hemorrhage	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Ischemia	8 (6)	3.2 (6)	0.2 (8)	0.0 (0)	0.0 (0)
Myocardial infarction	6 (5)	2.7 (5)	0.1 (6)	0.0 (0)	0.0 (0)
Pacemaker syndrome	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Palpitations	13 (12)	0.0 (0)	0.0 (0)	6.5 (12)	0.3 (13)
Pulmonary edema	3 (3)	0.5 (1)	0.0 (1)	1.1 (2)	0.0 (2)
Shock	1 (1)	0.5 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Stroke syndrome or CVA	1 (1)	0.0 (0)	0.0 (0)	0.5 (1)	0.0 (1)
Syncope	8 (7)	0.5 (1)	0.0 (1)	3.8 (7)	0.2 (7)
Thrombosis	2 (2)	1.1 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Transient ischemic attack (TIA)	2 (2)	0.0 (0)	0.0 (0)	1.1 (2)	0.0 (2)
Vascular-related	11 (11)	2.7 (5)	0.1 (5)	3.2 (6)	0.1 (6)
Ventricular fibrillation	3 (3)	1.6 (3)	0.1 (3)	0.0 (0)	0.0 (0)
Ventricular tachycardia	39 (29)	7.6 (14)	0.4 (15)	9.2 (17)	0.6 (24)
Non-cardiovascular–Related Events	**588 (147)**	**23.8 (44)**	**1.6 (66)**	**77.8 (144)**	**13.0 (522)**

A total of 18 deaths occurred in the Exercise Performance Sub-Study. These are presented in Table 1-2 stratified by treatment group and cause of death (as adjudicated by an independent events committee).

Table 1-2. Deaths in the Exercise Performance Sub-Study (0–6 months)

Cause of Death	CONTAK TR (N=185)	OPT (N=87)
Cardiac: Cardiac procedure[a]	4 (2%)	0 (0%)
Cardiac: Pump failure	4 (2%)	3 (3%)
Cardiac: Sudden, unexpected	6 (3%)	1 (1%)
Total Deaths	**14 (8%)**	**4 (5%)**

a. Defined as any death that occurs within 30 days of the device implant procedure.

Potential Adverse Events

Based on the literature and pulse generator implant experience, the following alphabetical list includes possible adverse events associated with implantation of a cardiac resynchronization therapy system:

- Acceleration of arrhythmias
- Bleeding
- Cardiac tamponade
- Death
- Dehydration
- Embolism, thrombolytic and air
- Erosion
- Fibrillation or other arrhythmias
- Fluid accumulation
- Heart block
- Hematoma/seroma
- Inability to pace
- Inappropriate pacing
- Infection
- Lead abrasion
- Lead displacement/dislodgment
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Migration of pulse generator
- Muscle or nerve stimulation

- Myocardial trauma (eg, cardiac perforation, irritability, injury)
- Myopotential sensing
- Nerve damage
- Pacemaker mediated tachycardia
- Pericardial rub
- Pneumothorax
- Random component failures
- Rejection phenomena (local tissue reaction, allergic reaction, fibrotic tissue formation, keloid formation)
- Threshold elevation
- Thrombosis
- Valve damage
- Venous occlusion
- Venous trauma (eg, perforation, dissection, erosion)

In addition to the implantation of a cardiac resynchronization therapy system, potential adverse events associated with implantation of a coronary venous lead system are listed below in alphabetical order:

- Allergic reaction to contrast media
- Breakage/failure of implant tools
- Coronary venous occlusion
- Coronary venous trauma (eg, perforation, dissection, erosion)
- Prolonged exposure to fluoroscopic radiation
- Renal failure from contrast media used to visualize coronary veins

SUMMARY OF CLINICAL STUDIES

Guidant conducted an Exercise Performance Sub-Study in the COMPANION trial (CONTAK TR Clinical Study) to demonstrate the safety and effectiveness of a CRT pacing system and to demonstrate, with reasonable assurance, the safety and effectiveness of biventricular stimulation, or cardiac resynchronization therapy (CRT), using the Guidant CONTAK TR CRT-P (Model 1241) along with the EASYTRAK (Models 4510, 4511, 4512, 4513) coronary venous steroid-eluting single-electrode pace/sense lead.

Guidant's CONTAK TR and CONTAK RENEWAL TR devices provide the same cardiac resynchronization therapy (biventricular pacing). Therefore, the

CONTAK TR Clinical Study data also applies to CONTAK RENEWAL TR. The primary difference between the two devices is that CONTAK TR utilizes an electrically common RV and LV sensing/pacing circuit whereas CONTAK RENEWAL TR incorporates an independent RV and LV sensing/pacing circuit.

Guidant also conducted the CONTAK RENEWAL Holter Study, which verified that the enhancements made to the delivery of biventricular pacing do not interfere with the therapy the patient receives. These enhancements, i.e., independent sensing inputs and pacing outputs, were incorporated into both the CONTAK RENEWAL and the CONTAK RENEWAL TR design to allow greater diagnostic and system evaluation, while still providing continuous appropriate biventricular pacing. Because both devices incorporate the same independent sensing/pacing design, the CONTAK RENEWAL Holter Study data apply to CONTAK RENEWAL TR.

CONTAK TR Clinical Study

Study Design

This was a multi-center, prospective, clinical investigation (conducted at 67 sites in the United States with 448 patients enrolled), evaluating CRT as a treatment modality combined with optimal pharmacological therapy in patients with chronic heart failure by measuring improvement in exercise performance. Exercise performance was measured via peak VO_2 and Six-Minute Walk (6MW) in patients who had a qualifying baseline visit. These patients were then randomized on a 1:2:2 basis to optimal pharmacological therapy alone or CRT (CONTAK TR CRT-P or CONTAK CD CRT-D) combined with optimal pharmacological therapy. All device recipients were implanted with the commercially available EASYTRAK coronary venous pace/sense lead and commercially available right ventricular and atrial pace/sense leads.

The effectiveness data was pooled for the CRT arm using patients that were implanted with either a CONTAK TR or CONTAK CD device. Patients underwent repeat exercise performance testing at three and six months of follow-up. Effectiveness data were collected from patients (OPT and CRT) who had a qualifying baseline peak VO_2 (< 22 ml/kg/min) and 6MW (150 meters ≤ Six-Minute Walk distance ≤ 425 meters) test and went on to complete a qualifying (maximal effort) peak VO_2 and/or 6MW at the three- and/or six-month follow-up. Device safety data were reported on all patients in the Exercise Performance Sub-Study who were randomized to a CONTAK TR device and had a qualifying baseline peak VO_2 and 6MW test.

Inclusion/Exclusion Criteria

Patients enrolled in the study were required to meet the following inclusion criteria:

- Moderate or severe heart failure, defined as symptomatic heart failure for at least six months with NYHA class III or IV symptoms at the time of enrollment, and at least one of the following events in the previous 12 months:
  - Hospitalization for heart failure management
  - Outpatient visit in which intravenous (IV) inotropes or vasoactive infusion were administered continuously for at least four hours
  - Emergency room visit of at least 12 hours duration in which IV heart failure medications were administered (including diuretics)
- QRS ≥ 120 ms and PR interval > 150 ms from any two leads of a 12 lead ECG
- Left ventricular ejection fraction ≤ 35%
- Left ventricular end diastolic dimension ≥ 60 mm (required only if LVEF measured by echo) or > 3.0 cm/m^2 [The cm/m^2 is calculated by LVEDD (in cm) divided by BSA (body surface area)]
- Age ≥ 18 years
- Optimal pharmacologic therapy for heart failure (beta-blocker, ACE inhibitor, Diuretic, and Spironolactone)

Additional eligibility criteria for the Exercise Performance Sub-Study:

- Understand the nature of the sub-study and provide informed consent
- Have been enrolled at a participating sub-study investigational center
- Have no neuromuscular or vascular disability that prevents normal walking (e.g., intermittent claudication, arthritis, residual stroke weakness)
- Have no history of angina during previous exercise testing
- Have no cardiac disabilities that would ordinarily contraindicate exercise testing:
  - changing pattern on the ECG
  - changing pattern of chest discomfort
  - decompensated heart failure
  - uncontrolled arrhythmias
- $FEV_1/FVC \geq 50\%$
- 150 m ≤ Six-Minute Walk distance ≤ 425 m
- Baseline Peak VO_2 < 22 ml/kg/min

Patients were excluded from the investigation if they met any of the following criteria:

- Unable or unwilling to undergo device implant and follow-up testing
- Meet the general indications for an implantable cardioverter defibrillator
- Meet the general indications for antibradycardia pacing
- Expected to receive a heart transplant in the next six months
- Chronic, medically refractory atrial tachyarrhythmias
- Unexplained syncope
- Myocardial infarction within 60 days of randomization
- History of non-compliance with oral heart failure therapy
- Progressive or unstable angina
- Uncontrolled blood pressure: Systolic BP > 160 mm Hg or < 85 mm Hg or diastolic BP > 90 mm Hg
- Patients with a hypersensitivity to 0.7 mg nominal dose of dexamethasone acetate
- Surgically uncorrected primary valvular disease
- Coronary artery disease (CAD) in which surgical or percutaneous correction is recent (within 60 days of randomization)
- Women who are pregnant or not using medically acceptable birth control
- Hypertrophic obstructive cardiomyopathy
- Amyloid disease
- Hospitalization for heart failure or IV inotropic or vasoactive therapy in excess of four hours in the 30 days prior to enrollment
- Involved in any other investigational studies
- Life expectancy < 6 months due to any other medical conditions

Follow-up schedule

Enrollment	Initial assessment of patient eligibility; taking of patient history.
Baseline Screening	Special testing[a]
Randomization	Randomization status (OPT, CRT-P, or CRT-D) was assigned.
Implant (CRT-P or CRT-D arm)	Implant of investigational devices and acute device testing for those randomized to a CRT therapy arm.
Routine Follow-up	Routine evaluation of device function and patient condition at pre-discharge, one week, and one month.

Three- and six-month Visits	Evaluation of randomized therapy with Special Testing[a] and device function at three and six months after the Post-Recovery Visit.
Quarterly Visits	After the six-month visit, patients were seen for routine evaluation of device function and patient condition.

a. Special Testing included a Symptom-Limited Treadmill Test with measurement of oxygen uptake (Peak VO_2), a Six-Minute Walk, Quality of Life (QOL) questionnaire and New York Heart Association Classification.

Endpoints

The Exercise Performance Substudy consisted of:

CRT Effectiveness:

Primary: Co-primary endpoint consisting of Peak VO_2 derived from a symptom-limited exercise test and Six-Minute Walk, with CRT results pooled from the CONTAK TR and CONTAK CD arms.

Effectiveness was determined by assessing both Peak VO_2 and Six-Minute Walk distance improvements with CRT compared to OPT. Prospectively, success was defined as occurring if:

- Peak VO_2 improved $\geq$ 0.7 ml/kg/min ($p < 0.05$) and 6 MWD improvement resulted in $p < 0.10$, or
- Peak VO_2 improved $\geq$ 0.5 ml/kg/min ($p < 0.10$) and 6 MWD improvement resulted in $p < 0.05$.

Additional: Quality of Life as measured by the Minnesota Living with Heart Failure Questionnaire© and NYHA Class.

Safety:

Primary: System-related complication-free rate.

Primary: Incidence of lead-related adverse events.

Lead Effectiveness:

Secondary: Left ventricular pacing thresholds, biventricular sensing, and biventricular lead impedance.

NOTE: *During the course of the COMPANION trial, the EASYTRAK Coronary Venous pace/sense lead was established as safe and effective in a separate clinical study and was approved for commercial distribution (P010012, 05/02/02). Refer to the commercially available EASYTRAK Coronary Venous pace/sense lead labeling for clinical safety and performance characteristics.*

Study Results

Patient Accountability

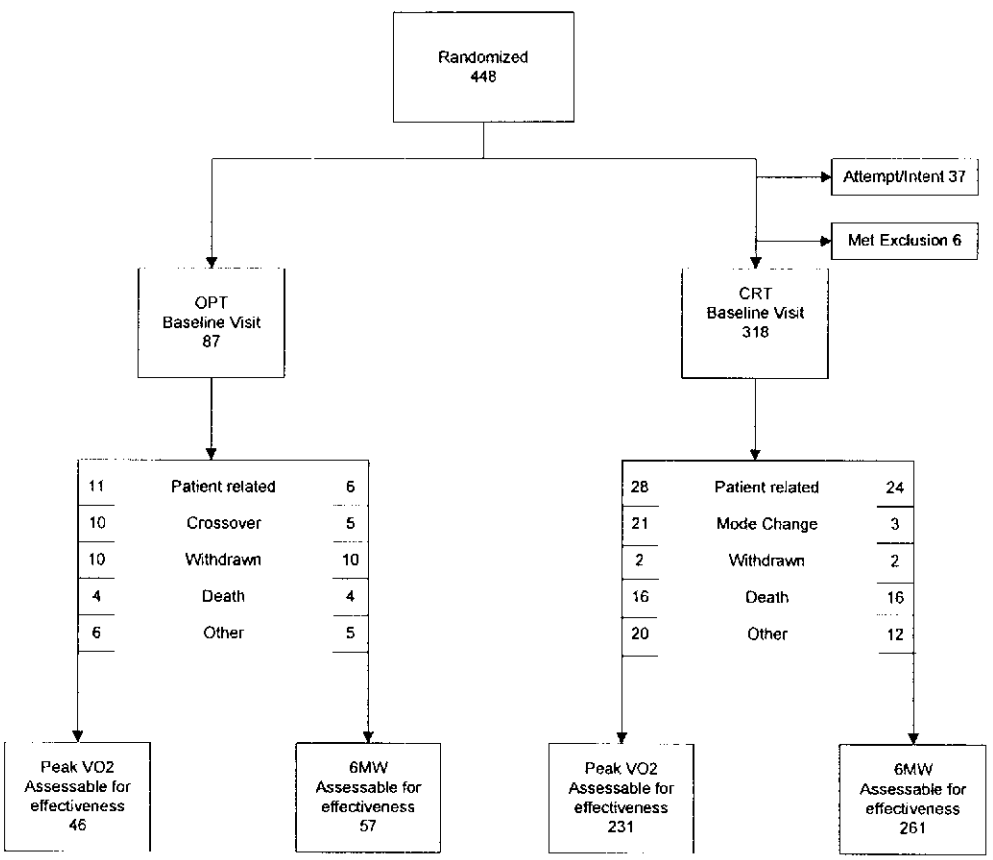


Figure 1-1. Enrollment and follow-up of randomized patients.

Baseline Characteristics

Table 1-3. Characteristics of Patient Population

Characteristic		CRT (N=318)	OPT (N=87)	P-value[a]
Age (years)	Mean ± SD	62.1 ± 11.8	63.1 ± 10.6	0.48
	Range	32.0–86.0	27.0–85.0	
Gender [N (%)]	Female	109 (34.3)	24 (27.6)	0.24
	Male	209 (65.7)	63 (72.4)	
NYHA Classification [N (%)]	III	294 (92.5)	79 (90.8)	0.61
	IV	24 (7.5)	8 (9.2)	
Ischemic Etiology	Ischemic	141 (44.3)	42 (48.3)	0.51
	Non-ischemic	177 (55.7)	45 (51.7)	
LVEF (%)	Mean ± SD	22.5 ± 6.9	22.2 ± 8.0	0.79
	Range	5.0–35.0	5.0–35.0	
Resting Heart Rate (bpm)	Mean ± SD	73.1 ± 12.8	73.5 ± 11.5	0.78
	Range	46.0–122.0	54.0–103.0	
QRS Width (ms)	Mean ± SD	159.2 ± 25.0	155.7 ± 25.8	0.26
	Range	120.0–276.0	120.0–224.0	
LBBB/NSIVCD (%)	LBBB	230 (72.3)	62 (71.3)	0.60
	Nonspecific	54 (17.0)	18 (20.7)	
	RBBB	34 (10.7)	7 (8.0)	
Peak VO_2 (ml/kg/min)	Mean ± SD	12.7 ± 3.3	12.4 ± 3.3	0.42
	Range	3.0–21.2	4.8–21.5	
Six-Minute Walk Distance (m)	Mean ± SD	292.4 ± 65.5	291.6 ± 70.5	0.92
	Range	152.0–411.5	162.4–414.0	
Quality of Life Score (points)	Mean ± SD	59.8 ± 23.1	55.4 ± 23.3	0.12
	Range	0.0–105.0	0.0–97.0	
Heart Failure Medications [N (%)]	Diuretic	300 (94.3)	82 (94.3)	0.98
	ACE Inhibitor or ARB	286 (89.9)	82 (94.3)	0.22
	Beta Blockers	240 (75.5)	60 (69.0)	0.22
	Aldosterone Antagonist	178 (56.0)	51 (58.6)	0.66
	Digoxin	239 (75.2)	65 (74.7)	0.93

a. Continuous data were analyzed using a two-tailed t-test procedure, and categorical data were analyzed using a two-tailed chi-square procedure. A p-value < 0.05 is considered significant.

CRT Effectiveness

Peak VO_2

Peak VO_2 was determined from a standardized protocol for exercise testing as a means of measuring a patient's capacity for performing physical activity.

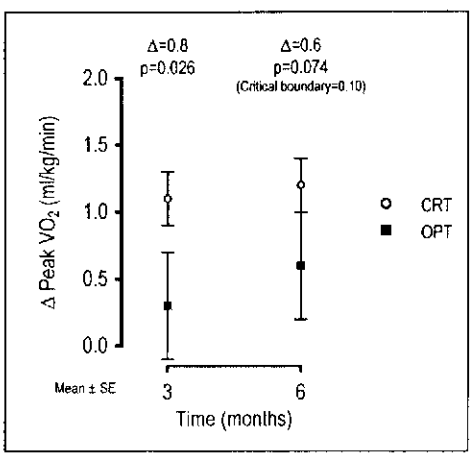


Figure 1-2. Maximal Oxygen Consumption Results.

Table 1-4. Maximal Oxygen Consumption Results

Peak VO_2 (ml/kg/min)	CRT		OPT		P-value[a]
	N	Mean ± S.E.	N	Mean ± S.E.	
Δ at 3 months	247	1.1 ± 0.2	52	0.3 ± 0.4	0.026
Δ at 6 months	230	1.2 ± 0.2	46	0.6 ± 0.4	0.074

a. P-values obtained using one-tailed longitudinal analysis methods.

The longitudinal analysis was performed on all available data. The percentages of missing data at the six-month endpoints for Peak VO_2 and Six-Minute Walk were 36 percent and 28 percent for the CRT arm and 47 percent and 34 percent for the OPT arm. The longitudinal analysis performed is most appropriate when missing data occurs at the percentages found in this trial.

Six-Minute Walk

The Six-Minute Walk test is a measure of a patient's ability to sustain exercise during an activity similar to that which a patient may typically perform on a daily basis. For this test, patients are instructed to walk as far as possible in 6 minutes in a level corridor.

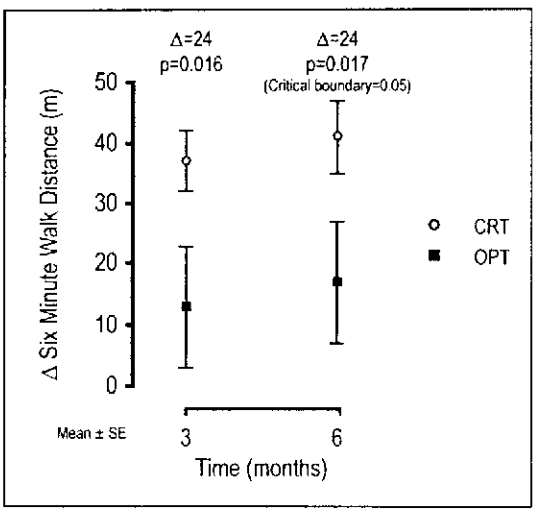


Figure 1-3. Change in Six-Minute Walk.

Table 1-5. Change in Six-Minute Walk

Six-Minute Walk (m)	CRT		OPT		P-value[a]
	N	Mean ± S.E.	N	Mean ± S.E.	
Δ at 3 months	274	37 ± 5	63	13 ± 10	0.016
Δ at 6 months	260	41 ± 5	57	17 ± 10	0.017

a. P-values obtained using one-tailed longitudinal analysis methods.

NYHA Class

The determination for New York Heart Association (NYHA) Class is based on mutual assessment, by the patient and physician, of the patient's heart failure symptoms both at rest and while performing ordinary physical activity.

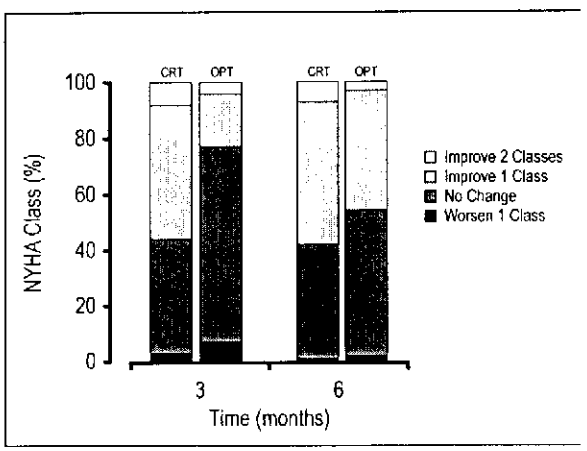


Figure 1-4. Change in NYHA.

Table 1-6. Change in NYHA

NYHA Classification	Change	CRT		OPT		P-value[a]
		N	Patients	N	Patients	
3 months	Improve 2 Classes	294	22 (7.5%)	69	3 (4.4%)	< 0.01
	Improve 1 Class		142 (48.3%)		13 (18.8%)	
	No Change		122 (41.5%)		48 (69.6%)	
	Worsen 1 Class		8 (2.7%)		5 (7.3%)	
6 months	Improve 2 Classes	291	20 (6.9%)	65	2 (3.1%)	0.032
	Improve 1 Class		149 (51.2%)		28 (43.1%)	
	No Change		118 (40.6%)		34 (52.3%)	
	Worsen 1 Class		4 (1.4%)		1 (1.5%)	

a. P-values are not adjusted for multiplicity and were obtained using a one-tailed Mantel-Haenszel chi-square method.

Quality of Life

Quality of Life (QOL) was assessed using the 21-question Minnesota Living with Heart Failure questionnaire. Each question, answered by the patient, is ranked on a scale ranging from 0 to 5. A lower total score indicates an improved quality of life.

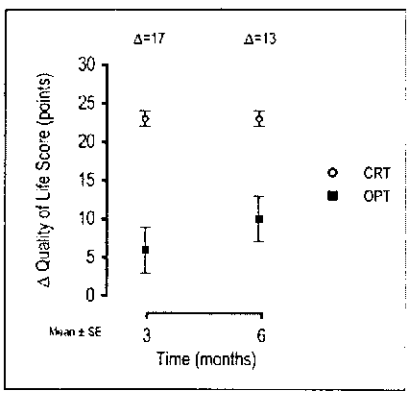


Figure 1-5. Quality of Life Score.

Table 1-7. Quality of Life Score

Quality of Life (points)	CRT		OPT		P-value[a]
	N	Mean ± S.E. (95% CI)	N	Mean ± S.E. (95% CI)	
Δ at 3 months	289	23 ± 1 (20.1, 25.7)	72	6 ± 3 (0.6, 11.3)	< 0.001
Δ at 6 months	279	23 ± 1 (19.7, 25.4)	66	10 ± 3 (4.2, 15.2)	< 0.001

a. P-values are not adjusted for multiplicity and were obtained using one-tailed longitudinal analysis methods.

Safety

CONTAK TR System Safety

The system-related complication-free rate for the CRT group at the lower confidence bound was 81.1 percent through six months (Figure 1-6). This exceeds the acceptance criterion of 70 percent established to demonstrate safety for the CONTAK TR and EASYTRAK pace/sense lead CRT-P system. Table 1-8 summarizes the system-related complications documented through six months of follow-up.

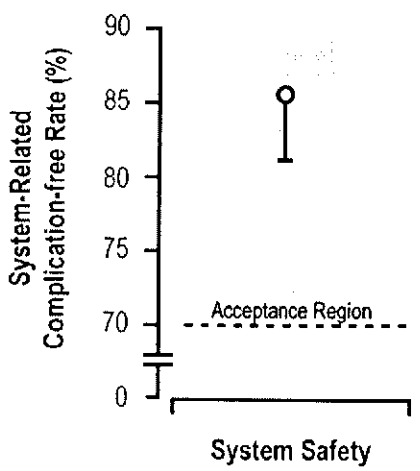


Figure 1-6. System-Related Complication-Free Rate

Table 1-8. System-Related Complications by Category (0–6 months)
(CONTAK TR Exercise Performance Sub-Study Patients, N=185[a])

	Total Number of Events	Total Number of Patients	Complication-Free Rate	Lower 95% Confidence Bound
Total System-Related Adverse Events	34	27	85.4	81.1
LV Lead–Related Events				
Brady capture - LV	13	12	93.5	90.5
Insulation breach suspected	1	1	99.5	98.6
Phrenic nerve/diaphragm stimulation	2	2	98.9	97.7
PG-Related Events				
Migration of device	1	1	99.5	98.6
Pocket erosion/extrusion	1	1	99.5	98.6
Pocket infection	1	1	99.5	98.6
Procedure-Related Events				
Cardiac tamponade	1	1	99.5	98.6
Perforation, coronary venous	1	1	99.5	98.6
Pneumothorax	3	3	98.4	96.9
Respiratory related	2	2	98.9	97.7
RA Lead–Related Events				
Brady capture - atrium	2	2	98.9	97.7
Intermittent sensing - atrium rate	2	2	98.9	97.7
RV Lead–Related Events				
Brady capture - RV	2	2	98.9	97.7
Materials unretrieved in body	1	1	99.5	98.6
Oversensing - ventricle pace sense	1	1	99.5	98.6

a. Patients may have events in multiple categories.

CONTAK RENEWAL Holter Study

Study Design

The CONTAK RENEWAL Holter Study was a prospective, multi-center, non-randomized evaluation conducted in Europe, in which 46 patients completed testing. The purpose of the study was to demonstrate continuous appropriate biventricular (BiV) pacing over a 24 hour period and during exercise using Holter monitor recordings. All patients had been implanted with a CONTAK RENEWAL for a minimum of one month at the time of the study initiation.

Inclusion/Exclusion Criteria

Patients who were enrolled in the study were required to meet the following inclusion criteria:

- Availability for 24 hours follow-up at an approved study center
- Willingness and ability to participate in all testing associated with this study
- Age 18 or above, or of legal age to give informed consent as specified by national law
- Implanted with the CONTAK RENEWAL system for at least 1 month
- Stable when programmed according to labeled recommendations for continuous BV pacing
- Sinus rhythm at follow-up
- Active atrial lead implanted

Patients were excluded from the investigation if they met any of the following criteria:

- Life expectancy of less than six months due to other medical conditions
- Concurrent participation in any other clinical study, including drug study
- In atrial fibrillation at follow-up
- Inability or refusal to sign the Patient Informed Consent
- Inability or refusal to comply with the follow-up schedule
- Known pregnancy

Baseline Demographics

The patient characteristics at study entry are summarized in Table 1-9.

Table 1-9. Preimplant Characteristics of Study Patients

Characteristics		Patient Data
N patients		46
Gender		Male: 40 (87%), Female: 6 (13%)
Age (years)		60.9 ± 9.0
NYHA at implant [N (%)]	I	0 (0%)
	II	5 (10.9%)
	III	34 (73.9%)
	IV	7 (15.2)%
NYHA current [N (%)]	I	9 (19.6%)
	II	25 (54.3%)
	III	11 (23.9%)
	IV	1 (2.2%)
Duration implanted (months)	Mean ± SD	8.3 ± 4.1
	Range	1.5 — 15.0
	Median	9.0

Programming Parameters

Refer to Chapter 3 for information about programming to maintain CRT. Programming recommendations in this study were consistent with the recommendations in Chapter 3.

Endpoints

The study had two primary endpoints: 1) continuous appropriate BiV pacing during activities of daily living and 2) continuous appropriate BiV pacing during exercise. The mean percentage of sinus beats appropriately BiV paced was measured by a Holter monitor over a 24 hour period and during exercise. Exercise intensity was measured using the Borg rating of perceived exertion (RPE) 6-20 scale. Patients were asked to exercise to a Borg level of 15 (difficult). The exercise protocol used was left to the discretion of the physician based on the patients' functional status. The type of exercise performed, duration and intensity of exercise testing is listed in Table 1-10 and Table 1-11.

Table 1-10. Type of Exercise Testing Performed

Exercise Performed	Number of Patients
Bicycle Ergometry	24 (52.2%)
Hall Walk	8 (17.4%)
Stair Climbing	14 (30.4%)
Total	46

Table 1-11. Duration and Intensity of Exercise Testing

		Results (N=46)
Borg RPE Rating Obtained	Mean ± SD	15 ± 1
	Median	15
	Range	7 – 18
Duration of Exercise (minutes)	Mean ± SD	6.6 ± 3.3
	Median	6.0
	Range	1 – 17
Maximum HR Obtained (bpm)	Mean ± SD	103 ± 20
	Median	105
	Range	60 – 156

Study Results

Pacing during activities of daily living

The mean percentage of appropriately continuously paced beats during daily living was calculated as 99.6 ± 1.3% with a median of 100% and is summarized in Table 1-12. Continuous appropriate BiV pacing is defined as pacing provided between the lower rate limit and the MTR, excluding PVCs.

Table 1-12. Activities of Daily Living: Continuous Appropriate BiV Pacing

	Statistic	P-value[a]
Mean ± SD	99.6 ± 1.3	--
Range	91.4 – 100	--
Median[b]	100	<0.01

a. The p-value is based on the sign-rank test.
b. Due to the non-normality of the data a non-parametric test of the median was performed comparing the median to 90%.

Pacing During Exercise

The mean percentage of appropriately continuously paced beats during exercise was calculated as 98.3 ± 5.6% with a median of 100% and is summarized in Table 1-13. Continuous appropriate BiV pacing is defined as pacing provided between the lower rate limit and the MTR, excluding PVCs.

Table 1-13. Exercise: Continuous Appropriate BiV Pacing

	Statistic	P-value[a]
Mean ± SD	98.3 ± 5.6	--
Range	68.1 – 100	--
Median[b]	100	<0.01

a. The p-value is based on the sign-rank test.
b. Due to the non-normality of the data a non-parametric test of the median was performed comparing the median to 90%.

Device Counters

Finally, during the study CONTAK RENEWAL device counters were found to correlate highly to the data collected on the independent Holter monitors

Table 1-14. Correlation Between Holter and Device

	Mean ± SD	Correlation (P-value)
Holter	97,536 ± 13,307	0.97 (<0.01)
Device	100,143 ± 13,373	--

DEVICE FEATURES

By programming device parameters, the pulse generator provides cardiac resynchronization therapy for the treatment of heart failure using biventricular electrical stimulation to synchronize ventricular contractions for the intent of providing mechanical synchronization. Left ventricular stimulation is delivered using a compatible Guidant LV lead. The pulse generator also detects and treats bradycardia conditions with pacing pulses in both the atrium and ventricles.

Pulse generator memory provides a record of patient data, therapy delivery counts, and a log of arrhythmia episode data and stored electrograms (EGMs). The pulse generator automatically provides diagnostic data for evaluating battery status, lead integrity, and pacing thresholds.

The total system allows the physician to noninvasively interact with the pulse generator as listed below:

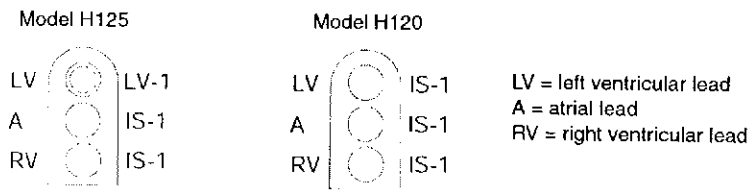
- Interrogate and program the pulse generator's cardiac resynchronization therapy parameters
- Interrogate and program the pulse generator's bradycardia therapy parameters
- Test the leads (atrial, right ventricular, and left ventricular) and program stimulation voltages and pulse widths using independently programmable outputs
- Deliver emergency VVI pacing with the STAT PACE command
- Divert therapy delivery
- Access the pulse generator memory to review patient clinical data, therapy history, and stored electrograms
- View real-time electrograms and event markers
- Induce, monitor, and terminate arrhythmias during electrophysiologic testing
- Program optional features such as magnet use
- Review the pulse generator battery status
- Print reports and save patient information on disk

Mechanical Specifications

Table 1-15. Nominal Mechanical Specifications

CONTAK RENEWAL TR Models H125 and H120	
Dimensions, W x H x D	45 x 54 x 8.5 mm
Volume	14 cc
Mass	26 g
Connector Type: (LV, A, RV)	
Model H125	LV-1, IS-1, IS-1
Model H120	IS-1, IS-1, IS-1
Case Electrode Surface Area	3320 mm^2
Case Material	Hermetically sealed titanium
Header Material	Implantation-grade polymer
Power Supply (WGT)	Lithium carbon monofluoride cell

Lead Connections



- The device uses the pulse generator case as a pacing electrode in unipolar configurations.
- LV-1 refers to the Guidant LV® proprietary connector. IS-1 refers to the international standard ISO 5841.3:1992.

ITEMS INCLUDED IN DEVICE PACKAGING

The following items are packaged with the pulse generator: one torque wrench and product literature.

NOTE: *Wrenches are intended for one-time use only and should not be resterilized or reused.*

OPENING INSTRUCTIONS

The outer package and sterile trays should be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile trays are opened by peeling back the covers.

FACTORY SHIP MODE

The pulse generator is shipped in a power-saving shipping (SHIP) mode to extend its shelf life. All features are inactive except telemetry support (allowing interrogation, programming), real-time clock, and the STAT PACE command. The device will leave the shipping mode when a STAT PACE is commanded or when any parameter is programmed. Once programmed out of the power-saving shipping mode, the programmer cannot return the pulse generator to that mode. Appendix A provides a complete list of parameters and available programmable values.

NOTE: *The rate-sensing circuits may take up to three seconds to begin tracking the cardiac signal after leaving the power-saving shipping mode. HF/Brady pacing is inhibited during this period. The device should always be programmed out of the power-saving shipping mode before connection to the patient leads.*

MAINTAINING DEVICE EFFECTIVENESS

Perform follow-up testing to maintain continued verification of therapy efficacy. Refer to the section "Follow-up Testing" on page 8-2.

X-RAY IDENTIFIER

The pulse generators have an identifier that is visible on x-ray film or under fluoroscopy. This provides noninvasive confirmation of manufacturer. The identifier consists of the letters "GDT" to identify the manufacturer (Guidant), followed by "204," identifying the Model 2865 programmer software application needed to communicate with the pulse generator.

Refer to the section "Quick Start" on page 2-5 for information on identifying the device via the programmer.

The model number of the pulse generator is stored in the device's memory and is available on the About screen selectable through the Utilities menu when the pulse generator is interrogated.

PULSE GENERATOR LONGEVITY

Based on simulated studies, it is anticipated that CONTAK RENEWAL TR pulse generators have average longevity to ERI as indicated below. The longevity expectations, accounting for the energy used during manufacture and storage (approximately six months), apply at the conditions shown below. Values apply whether Electrogram Storage options are programmed On or Off.

Table 1-16. Device Longevity at 100% LV and RV paced; Pulse Width 0.4 ms; LRL 70 ppm; 700 Ω RV and LV lead impedance; 550 Ω A lead impedance, DDD(R) mode

	Years
3.5 V Amplitude LV, A, RV	
15% Atrial Paced	7.6
100% Atrial Paced	6.1
2.6 V Amplitude A, RV; 5 V Amplitude LV	
15% Atrial Paced	6.7
100% Atrial Paced	6.0

NOTE: *The energy consumption in the longevity table is based upon theoretical electrical principles and verified via bench testing only.*

The longevity of the pulse generator decreases with an increase in the pacing rate, pacing pulse amplitude, pacing pulse width, percentage of paced to sensed events, or with a decrease in pacing impedance.

Warranty Information

A limited warranty certificate for the pulse generator accompanies the pulse generator. For additional copies, please contact Guidant Corporation at the address and phone number on the back cover of this manual.

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PATIENT COUNSELING INFORMATION

The following are topics that the clinician might want to discuss with the patient prior to discharge:

- Signs and symptoms of infection
- Symptoms that should be reported (eg, sustained high-rate pacing requiring reprogramming)
- Activity restrictions (if applicable)
- Minimum heart rate (lower rate limit of the pulse generator)
- Frequency of follow-up

Patient Manual

Guidant recommends that the physician discuss the information in the patient manual with concerned individuals both before and after pulse generator implantation so they are fully familiar with the operation of the device. For additional copies of the patient manual, contact the nearest Guidant sales representative or contact Guidant at the phone number on the back cover of this manual.