

## CRT-D Systems from Boston Scientific CRM

### Indications and Usage

Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF  $\leq$  35%) and QRS duration  $\geq$  120 ms.

### Contraindications

There are no contraindications for this device.

### Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. 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. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another CRM pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

### Precautions

For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

### Potential Adverse Events

Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

### Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. K)

# COGNIS®

## Cardiac Resynchronization Therapy Defibrillator (CRT-D)

## Specifications

The COGNIS CRT-D is the smallest, thinnest high-energy device in the world, featuring innovative new technologies with excellent longevity.



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## Customize without compromise

The COGNIS CRT-D provides ventricular tachyarrhythmia therapy and cardiac resynchronization therapy (CRT) for the treatment of ventricular tachycardia, ventricular fibrillation, and heart failure. COGNIS CRT-Ds are the smallest (32.5 cc) and thinnest (9.9 mm) high-energy CRT devices, and offer excellent battery longevity, self-correcting software, and improved programming technology. In addition, COGNIS hardware includes Safety Core™ technology, which is intended to provide lifesaving shock therapy and basic pacing functionality in the unlikely event that the main system fails. Other advances in the COGNIS device include the SmartDelay™ algorithm, which quickly provides recommended settings for programming paced and sensed AV Delays with the intent of providing optimally timed CRT, enabling individualized pacing therapy. And Boston Scientific CRM's Electronic Repositioning™ feature has been expanded to provide six configurations for noninvasively stimulating the left side of the heart, even after implant.

### Model Number: **COGNIS N119**

#### Physical Specifications

Volume (cc)	32.5
H x W x D (mm)	79.5 x 61.7 x 9.9
Weight (g)	72
Lead Connections	IS-1/DF-1 : IS-1*
Telemetry	Inductive & RF
*Also available in IS-1/DF-1: LV-1 Model N118.	

#### Tachy Therapy

Max Shock Delivered (J)	35
Shocking Electrode Configurations	RV Coil to RA Coil and Can; RV Coil to Can; RV Coil to RA Coil
Waveform	Biphasic; Monophasic
Lead Polarity	Initial; Reversed
Zone Configuration	1(VF) ; 2(VF & VT); 3(VF, VT, & VT-1)
Rhythm Discriminators	Rhythm ID; Onset/Stability
ATP in the VF Zone	Quick Convert™
Programmable ATP (VT-1 & VT zones)	Off; Burst; Ramp; Scan; Ramp/Scan

Monitor Only Zone is available in the lowest zone of a multi-zone configuration.

#### Cardiac Resynchronization Therapy

AV Optimization Algorithm	SmartDelay
Electronic Repositioning	LVtip>>Can; LVtip>>RV;
Pacing Configuration (bipolar LV lead)	LVring>>Can; LVring>>RV;
Electronic Repositioning	LVtip>>LVring; LVring>>LVtip
Pacing Configuration (unipolar LV lead)	LVtip>>Can; LVtip>>RV
Ventricular Pacing Chamber	RV Only; BiV
LV Offset	-100, -90,...0
BiV Trigger	Off; On
Programmable LV Pacing Parameters	Pulse Amplitude; Pulse Width LV-Blank after A-Pace; LVPR; LVPP; LV Electrode Configuration

#### Bradycardia Pacing

Normal Pacing Modes	DDD(R); DDI(R); VDD(R); VVI(R); AAI(R); Off
Temporary Pacing Modes	DDD; DDI; DOO; VDD VVI; VOO; AAI; AOO; Off
Programmable Rate Parameters	Lower Rate Limit (LRL); Max Tracking Rate (MTR); Max Sensor Rate (MSR); Pulse Amplitude; Pulse Width; Atrial Pace/Sense Configuration; Activity Threshold; Reaction Time; Response Factor; Recovery Time; Maximum PVARP; Minimum PVARP; PVARP after PVC; RV-Blank after A-Pace; A-Blank after V-Pace; A-Blank after RV-sense; Maximum VPR; Minimum VPR; Maximum Paced AV Delay; Minimum Paced AV Delay; Maximum Sensed AV Delay; Minimum Sensed AV Delay; Tracking Preference Rate Hysteresis Hysteresis Offset; Rate Hysteresis Search Hysteresis; Rate Smoothing; Noise Response; Maximum Pacing Rate (MPR); Post-therapy Pacing Period

#### Magnet / Beeper Functions

Magnet Response	Off; Stored EGM; Inhibit Therapy
Beep During Capacitor Charge	Off; On
Beep When Explant Is Indicated	Off; On

#### Atrial Arrhythmia Management

ATR Mode Switch	On; Off
ATR Fallback Mode	VDI; DDI; VDIR; DDIR
ATR VRR	Off; Min; Med; Max
ATR BiV Trigger	Off; On
Programmable ATR Parameters	ATR Trigger Rate; ATR Duration; Entry Count; Exit Count; ATR Fallback Time; ATR/VTR Fallback LRL; ATR Max Pacing Rate; Atrial Flutter Response; PMT Termination; VRR

#### Device Testing & Induction Methods

Programmable Testing & Induction Parameters	Ventricular Commanded ATP; Manual Burst Pacing; Ventricular Commanded Shock; Ventricular Fibrillation Induction; Shock on T Induction; Programmable Electrical Stimulus (PES)
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#### Sensitivity Adjustment

Atrial Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ...AGC 1.0, AGC 1.5
Right Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ...AGC 1.0, AGC 1.5
Left Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ...AGC 1.0, AGC 1.5

#### Electrograms and Diagnostics

Stored Electrograms – Up to 17 minutes with all EGM sources always turned on  
 Arrhythmia Logbook – Sortable display of stored events  
 HRV Footprint – Stores the current plot and a reference plot for comparison  
 Histograms and Counters  
 Trends – Daily values stored for the following trends: Activity Level, Atrial Burden, Heart Rate, SDANN, HRV Footprint, Events, ABM, P-wave Amplitude, A-Pace Impedance, R-wave Amplitude, RV-Pace Impedance, R-wave (LV) Amplitude, LV-Pace Impedance, Shock Impedance

## COGNIS®

Cardiac Resynchronization Therapy Defibrillator (CRT-D)

#### Longevity Projections (years)

Pacing Amplitude		Longevity (years) at 500 ohms and 700 ohms Pacing Impedance (RV and LV)	
RA/RV	LV	500 ohms	700 ohms
2.5 V	3.0 V	6.6	6.9
2.5 V	3.5 V	6.2	6.6
3.5 V	3.5 V	5.5	5.9
3.5 V	5.0 V	4.6	5.0

For RF-enabled models, assumes ZIP™ telemetry use for 3 hours at implant time and for 20 minutes during each quarterly follow-up.

The longevity expectations, which account for the energy used during manufacture and storage, apply at the conditions shown in the table along with:

- Assumes 70 ppm LRL; DDDR mode; 100% biventricular pacing; 15% atrium pacing and 0.4 ms pacing pulse width (RA, RV, LV); RA impedance 500.
- Projected longevity is calculated at 6 to 14 maximum energy charging cycles per year (depending on battery status) with automatic capacitor/battery management and maximum energy charges, and 3-channel EGM Onset set to On.

#### Warranty

Product	Warranty Period	Full Replacement Cost	Prorated Replacement Cost
<b>COGNIS</b>	5 years	First 3 years	Last 2 years

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#### Cardiac Rhythm Management

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CRM3-1115-0609