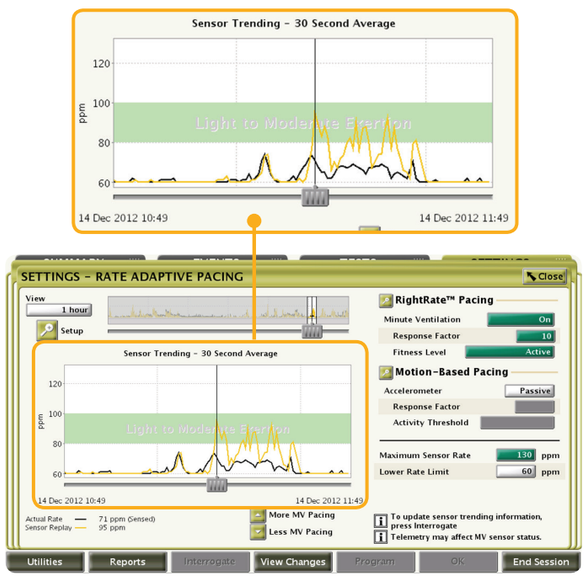
# Programming Overview

**Step 1** Assess Chronotropic Competence

**Step 2** Prepare Calibration and Sensor Baseline

**Step 3** Optimize Sensor Trending Data




## Rate Adaptive Pacing

A motion-based accelerometer may not always detect when the patient is exercising, potentially resulting in inadequate rate response.

- Riding a bicycle
- Holding a grandchild
- Carrying groceries
- Working in the garden
- Using a walker
- Swimming
- Lifting weights

## RightRate™

- RightRate is a physiologic minute ventilation sensor that is highly correlated with breathing.
- The only sensor clinically proven to restore chronotropic competence.[1]
- VISIONIST™ X4 is labeled for up to 13.1 years[2] projected longevity even when RightRate is turned ON.

1. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176–180.
2. Assumes: 2.0V RA/RV/LV, RA 500Ω, RV/LV 700Ω, No LATITUDE, 0.4ms pulse width, 100% BiV pacing, 15% atrial pacing, 70 ppm LRL.

**CRT-P Systems – VISIONIST™, VISIONIST™ X4, VALITUDE™, VALITUDE™ X4, INTUA™, INVIVE™**

**Indications and Usage** Boston Scientific cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients with 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 pharmacological therapy (OPT) for heart failure. Atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Adaptive-rate pacing is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with increases in minute ventilation and/or physical activity.

**Contraindications** These Boston Scientific pulse generators have the following contraindications: • In patients who have a separate implanted cardioverter defibrillator (ICD) with transvenous leads; • Unipolar pacing or use of the MV/Respiratory Sensor with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) is contraindicated because it may cause inappropriate therapy or inhibition of appropriate S-ICD therapy; • Minute ventilation is contraindicated in patients with both unipolar atrial and ventricular leads; • Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction; • Atrial tracking modes are contraindicated in patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing; • And asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms.

**Warnings** Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Always have external defibrillation equipment available during implant and electrophysiologic testing. Using multiple pulse generators could cause pulse generator interaction, resulting in patient injury or a lack of therapy delivery. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversibly to Safety Core operation. Safety Core pacing may be unipolar, which may interact with an ICD. Safety Core behavior is affected by MRI Protection Mode. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. For leads that require the use of a Connector Tool, use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the IS4–LLLL lead terminal, other than the terminal pin, even when the lead cap is in place. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial-only modes in patients with heart failure. Lead Safety Switch should be programmed Off for patients with an ICD. Unipolar pacing due to Lead Safety Switch is contraindicated for patients with an ICD. Automatic Lead Recognition should be programmed to Off before implant with patients with an ICD. Unipolar pacing due to RAAT is contraindicated and should be programmed off for patients with an ICD. Left ventricular lead dislodgement to a position near the atria can result in atrial oversensing and left ventricular pacing inhibition. If programmed to a fixed atrial Sensitivity value of 0.15 mV, or a fixed sensitivity value of 2.0 mV or less in a unipolar lead configuration in any chamber, the pulse generator may be more susceptible to electromagnetic interference. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device. VISIONIST X4 and VALITUDE X4 devices are considered MR Conditional. For these devices, unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system. Significant harm to or death of the patient and /or damage to the implanted system may result. All other devices covered by this statement are not MR conditional. Do not expose patients with non-MR Conditional devices to MRI scanning. For potential adverse events when Conditions of Use are met or not met, refer to the MRI Technical Guide. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

**Precautions** For specific information on precautions, refer to the following sections of the product labeling: clinical considerations, sterilization and storage, implantation, device programming, environmental and medical therapy hazards, hospital and medical environments, home and occupational environments, follow up testing, explant and disposal, supplemental precautionary information. These pulse generators are compatible for use with a Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) when implanted with bipolar leads and programmed to a bipolar pacing configuration.

**Potential Adverse Events** Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse evets associated with the included devices: Air embolism; Allergic reaction; Bleeding; Bradycardia; Cardiac tamponade; Chronic nerve damage; Component failure; Conductor coil fracture; Death; Electrolyte imbalance/dehydration; Elevated thresholds; Erosion; Excessive fibrotic tissue growth; Extracardiac stimulation (muscle/nerve stimulation); Fluid accumulation; Foreign body rejection phenomena; Formation of hematomas or seromas; Heart block; Inability to pace; Inappropriate pacing; Incisional pain; Incomplete lead connection with pulse generator; Infection including endocarditis; Lead dislodgement; Lead fracture; Lead insulation breakage or abrasion; Lead perforation; Lead tip deformation and/or breakage; Local tissue reaction; Loss of capture; Myocardial infarction (MI); Myocardial necrosis; Myocardial trauma (e.g., tissue damage, valve damage); Myopotential sensing; Oversensing/undersensing; Pacemaker-mediated tachycardia (PMT); Pericardial rub, effusion; Pneumothorax; Pulse generator migration; Shunting current during defibrillation with internal or external paddles; Syncope; Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation; Thrombosis/thromboemboli; Valve damage; Vasovagal response; Venous occlusion; Venous trauma (e.g., perforation, dissection, erosion); Worsening heart failure.

For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide.

Patients may develop psychological intolerance to a pulse generator system and may experience the following: Dependency; Depression; Fear of premature battery depletion; Fear of a device malfunction.

Additionally, potential adverse events associated with the implantation of a coronary venous lead system include: Allergic reaction to contrast media; Breakage/failure of implant instruments; Prolonged exposure to fluoroscopic radiation; Renal failure from contrast media used to visualize coronary veins.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only. (Rev E) 046774 AH

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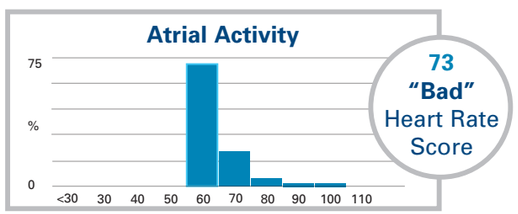
# RightRate™

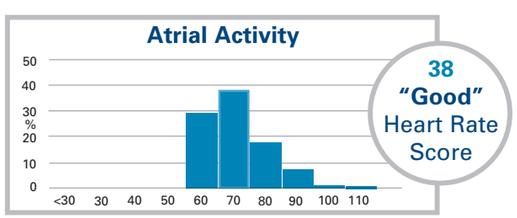
Respiration-Based Pacing

## A Change of Pace

# RightRate™ and Heart Rate Score Clinical Data

**Heart Rate Score** is defined as the height of the tallest atrial histogram bin.

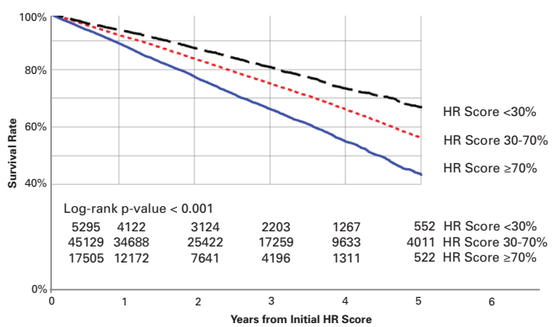



A broader range of HR is typically better for the patient. Therefore, a lower HR Score is preferred.

**Heart Rate Score** was an independent predictor of **mortality.**[3]

## Heart Rate Score and Mortality




### LATITUDE™ analysis of 67,929 CRT-D patients

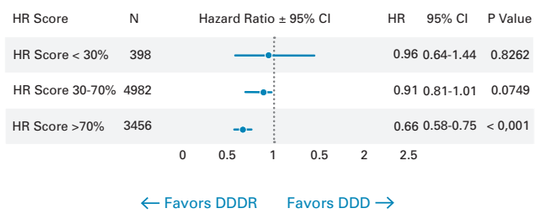
Patients with a HR Score ≥ 70 had a 43% 5-year survival rate.

Patients with a HR Score < 30 had a 68% 5-year survival rate.

3. Wilkoff et al., A Device Histogram based Simple Predictor of Mortality Risk in ICD and CRT-D Patients: The Heart Rate Score. Pace 2017.

**Mortality** improved with DDDR.[4]

## Impact of Rate Responsive Programming on survival based on Heart Rate Score




### LATITUDE™ analysis of 6,164 patients

For patients with Heart Rate Score > 70, switching to DDDR was associated with improved mortality.

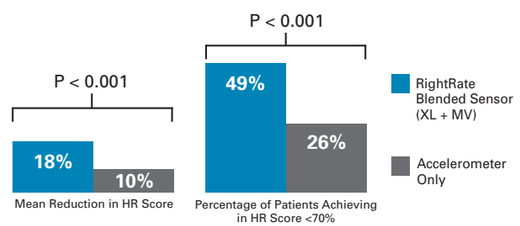
Patients with baseline Heart Rate Score > 70% significantly improved their Heart Rate Score with DDDR (from 88±9% to 78±15%; P<0.001).

4. Olshansky, et al., Survival After Rate-Responsive Programming in Patients With Cardiac Resynchronization Therapy-Defibrillator Implants Is Associated With a Novel Parameter: The Heart Rate Score. Circ Arrhythm Electrophysiol. 2016;9:.

**RightRate™ Blended Sensor** was shown to **improve Heart Rate Score** more than accelerometer alone.[5]

## Impact of Rate Responsive Programming on Heart Rate Score

(among patients with baseline heart rate score of ≥70%)




### Analysis of 501 patients from the LIFE Study

RightRate Blended sensor (MV+XL) resulted in:

- Heart Rate Score reduction of 18%.
- Converted almost twice as many patients to Heart Rate Score < 70% when compared to XL only.

5. Richards, et al., The Addition of Minute Ventilation to Rate Responsive Pacing Improves Heart Rate Score More than Accelerometer Alone. Heart Rhythm 2018. https://doi.org/10.1016/j.hrthm.2018.06.021.