Delivering More

MORE Implant Efficiency

Up to 20% more pacing vector options than any other CRT-P on the market[1-3]

MORE Proactive Patient Management

Automatic Daily Monitoring with advanced diagnostic reports that can support earlier intervention

MORE Battery Life

The industry's longest projected longevity at 10.3 years[2-4]

SOURCES

1. Boston Scientific VALITUDE X4 Reference Guide – 359242-001 EN US 2014-04
2. Medtronic: VIVA™ CRT-P C6TR01, M956337A001 C, 2014-06-10, p. 329
3. St Jude Medical: Allure QuadraTM RF Cardiac Resynchronization Therapy Pacemaker - http://professional.sjm.com/resources/cardiac-rhythm-management/cardiac-resynchronization-therapy-crt-devices/crt-pacemaker/allure-quadra-rf-cardiac-resynchronization-therapy-pacemaker. US-2000335 A EN (2/14). Accessed 11/20/14.
4. Boston Scientific Physician Technical Manual – 359252-001 EN US 2014-05

VALITUDE™ X4 CRT-P

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 i ndicated 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 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 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; • 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. Such damage 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. Do not kink, twist, or braid the lead with other leads. 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. 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. Do not expose a patient to MRI scanning. 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; 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: Potential adverse events include, but are 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 (pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of s hocking, fear of device failure, or imagined s hocking. 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 A)

Boston Scientific
Advancing science for life™

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Boston Scientific
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VALITUDE™ X4 CRT-P

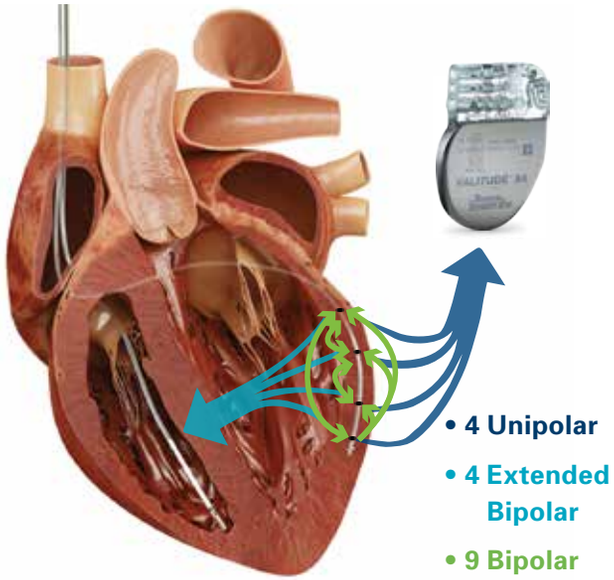
Delivering More

MORE Implant Efficiency

Maximum Flexibility when Choosing Lead Position

With **17 Pacing Vector Options**, VALITUDE X4 CRT-P offers more options to:

- Pace in an optimal location
- Manage phrenic nerve stimulation
- Manage pacing thresholds



Efficient Port Usage

The new **EasyView™ Header** with port labels aids with quick and easy identification of the appropriate port and verification of full lead insertion.

MORE Proactive Patient Management

A Comprehensive View of Your Patient's AT/AF Status

The new **Atrial Arrhythmia Report**, can be used for screening of arrhythmias that may enable earlier intervention:

- Assess AF status and treatment efficacy
- Determine length and burden of episodes
- Correlate patient symptoms to rates

Automatic Daily Monitoring

Wireless, hands-free remote monitoring with LATITUDE™ NXT can increase your confidence in patient compliance with:

- Automatic and customizable alerts
- Automatic device interrogation

Automatic System Evaluation

The new **Post Operative System Test (POST)** facilitates same-day discharge with automatic system evaluation, including:

- Lead impedances
- Intrinsic amplitudes
- Capture thresholds

MORE Battery Life

Industry-Leading Projected Longevity

The VALITUDE X4 CRT-P includes the industry's greatest battery capacity at 1.6 Amp hours with the longest projected longevity[2-4]

10.3 YEARS*

Efficient Circuitry

+ Greatest Battery Capacity

Industry Leading Projected Longevity

**Settings: DDDR mode, 100% biventricular pacing, 15% atrial pacing, pulse width 0.4ms (RA, RV, LV), Impedance 500Ω, LRL 70bpm, Sensor On, EGM Onset On.*