Boston Scientific
Advancing science for life™

VISIONIST™ X4 CRT-P AND VISIONIST™ CRT-P

Models U225, U226, U228

- ImageReady™ 1.5T and 3T MR-Conditional System[1]
- 17 pacing vectors in VISIONIST X4 and 6 pacing vectors in VISIONIST
- RightRate™ MV sensor, the only sensor clinically proven to restore chronotropic competence[2]
- Labeled longevity up to 13.8 years
- Remote patient monitoring with the LATITUDE™ NXT Patient Management System
- Post-Operative System Test (POST) to facilitate patient follow-up with a fully automatic device and lead check

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RA RV LV)	C-Code
U225	CRT-P	4.45 x 6.13 x 0.75	30.6	15.2	RA: IS-1; RV: IS-1; LV: IS-1	C2621
U226	CRT-P	4.45 x 6.13 x 0.75	31.1	15.2	RA: IS-1; RV: IS-1; LV: LV-1	C2621
U228	X4 CRT-P	4.45 x 6.17 x 0.75	33.0	16.6	RA: IS-1; RV: IS-1; LV: IS4	C2621

Projected Longevity	RA/RV	LV	500Ω	700Ω	700Ω, no MV/RS
Typical programmed setting	2.5V	3.0V	10.3	11.2	11.7
Maximum labeled longevity	2.0V	2.0V	12.4	13.1	13.8

Additional Projected Longevity Information

- 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. These calculations also assume that the pulse generator spends 6 months in Storage mode during shipping and storage, the ZIP™ telemetry use for 3 hours at implant time and for 40 minutes annually for in-clinic follow-up checks.
- The following LATITUDE usage will decrease longevity by approximately 7 months: Daily device check on, monthly full interrogations (scheduled remote follow-ups, and quarterly patient-initiated interrogations). Daily device checks and quarterly full interrogations will decrease longevity by approximately 6 months.
- Power Supply: lithium-carbon monofluoride cell; Boston Scientific; 402294.

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Pacing Therapy

Brady Modes	Normal:DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), DOO,VOO, AOO, Off Temporary: DDD-DDI-VDD-VVI-AAI-DOO-VOO-AOO-Off
AT/AF Management	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Rate Smoothing
Automaticity	Automatic Gain Control (AGC) for sensitivity Right Atrial Automatic Threshold (RAAT) Right Ventricular Automatic Threshold (RVAT)
Rate Adaptive Pacing	Accelerometer
Rate Management	Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
RA/RV Pace-Sense Configuration	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch

Heart Failure Therapy

Heart Failure Therapy Optimization	SmartDelay™ (AV Optimization), BiV Trigger, LV Offset, LV Sensing
LV Lead Options	Unipolar or Bipolar LV1 LV Lead (U226) Unipolar or Biploar IS1 LV Lead (U225) Quadripolar LV Lead (U228)
LV Pacing Vector Options	6 vectors (U225, U226) 17 vectors (U228)
LV Sensing Vector Options	8 vectors plus OFF

Patient Diagnostics

Arrhythmia Logbook	Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes of multi channel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On-screen measurements of all stored signal, amplitudes and timing. Snapshot Function (up to 12 seconds trace of ECG/EGM display stored)
Histograms & Counters	Ventricular Tachy Counter, Brady/CRT Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful)
Therapy/Diagnostics	Heart Rate Variability (HRV) with SDANN and ABM, Respiratory Rate Trend, Signal Artifact Monitor, AT/AF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure*
Atrial Arrythmia Report	AT/AF% and Total Time in AT/AF, AT/AF Burden Trend, RV Rate during AT/AF Trend, Pacing Percent Trend, Heart Rate Trend, Activity Level and Respiratory Rate Trends, RV Rate during AT/AF Histogram. Timeline history of interrogations, programming, and counter resets for one year. Longest AT/AF, Fastest RVS rate in AT/AF, and most recent episode.
DAILY TREND for last 365 Days	Events, Activity Level, AT/AF Burden, Pacing Percent, Respiratory Rate, Heart Rate, SDANN, HRV Footprint, ABM, Lead Impedance and Amplitude, RAAT Trend, RVAT Trend

*Weight and Blood Pressure are only available via LATITUDE NXT.

ImageReady™ MR-Conditional Pacing System

MRI Lead Selection	MR-Conditional Pulse Generator U228 combined with: Pacing Lead: FINELINE™ II, INGEVITY™ LV Lead: ACUITY™ X4
MRI Conditions	1.5T and 3T
MRI Mode	Pacing Mode: AOO, VOO, DOO, Off Protection Mode Time Out: Off, 3,6,9,12,24,48 hours

Implant/In-Clinic Follow-Up

Implant Communication Mode	Programmable values: Enable use of ZIP™ telemetry (MICS) (Requires initial use of wand for device ID) or use wand for all telemetry Nominal: Enable use of ZIP telemetry (Requires initial use of wand for device ID)
In-Clinic Follow-Up	Snapshot Function up to 12 seconds trace of ECG/EGM display stored POST (Post-Operative System Test): provides an automatic device/lead check at a pre-determined time post-implant to help document proper system functionality without requiring manual system testing
Indications-Based Programming (IBP)	Tool that provides specific programming recommendations based on the patient's clinical needs and primary indications

Remote Follow-Up

Remote Monitoring	This device is designed to be LATITUDE™ NXT enabled; LATITUDE NXT availability varies by region
Thresholds	Automatic storage of last successful daily PaceSafe™ threshold test for all active chambers
Wireless	Remote follow-up for all devices (MICS)
Patient-Triggered Monitor (PTM)	Triggers the storage of two minutes onset and one minute post – EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device

Safety Functions**

Safety Core	Is intended to provide life-sustaining therapy if certain nonrecoverable or repeat fault conditions occur. Safety Core operates independently and acts as a backup to these components
Electrocautery Protection Mode	Provides asynchronous pacing at the programmed outputs and LRL when commanded by the programmer

**The Safety Functions do not have programmable parameters.

1. When conditions of use are met.
2. 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.

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:

- The device is contraindicated 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;
- 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.

Refer to the MRI Technical Guide at www.bostonscientific-elabeling.com for a comprehensive list of Warnings and Precautions, and Conditions of Use that are applicable to MRI scanning of patients implanted with an ImageReady MR Conditional Pacing System.

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.

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