

## VISIONIST™ X4 CRT-P and VISIONIST™ CRT-P

Models U225, U226, U228

- Provides an ImageReady™ MR Conditional system\* at 3T and 1.5T, full body, with no time limitations, with automatic MRI timeout feature to optimize workflow in the MR environment
- Extended Longevity device projected to last up to 13.8 years\*\*
- The X4 CRT-P and ACUITY™ X4 lead portfolio features:
  - electrodes on a 3D spiral designed to allow pacing from a basal location without sacrificing fixation or thresholds
  - 17 pacing options to manage phrenic nerve stimulation and high thresholds
  - multiple lead shapes with a 2.6F (0.86 mm) tapered lead tip to improve predictability of accessing target vessels
- Advanced AF and HF diagnostic reports provide a comprehensive and proactive approach for comorbidity management
- RF telemetry for wireless transmission of information and efficiency in the operating room and follow-up setting
- Remote patient monitoring with the LATITUDE™ NXT Patient Management System
- RightRate™ MV sensor is the only MV sensor clinically proven to restore chronotropic competence<sup>1</sup>
- Enhanced features and diagnostics, including AP Scan™ and Respiratory Rate Trend, designed to provide you with greater insight into your patient's disease progression based on the patient's own respiration
- POST function to facilitate patient follow up with a fully automatic device and lead check
- EASYVIEW™ header with port identifiers designed to make the implant experience more efficient



\*Model U228 only. When conditions of use are met, please refer to MRI Technical Guide.

\*\*Assumes 70 min-1 LRL, DDDR mode; 100% biventricular pacing; 15% atrium pacing and 0.4 ms pacing. Pulse Width (RA, RV, LV); RA 500 Ω; RV/LV 700Ω; sensors Off, EGM Onset On.

### Mechanical Specifications

Model	Size (cm) Type	(W x H x D)	Mass (g)	Connector Type Volume (cc)	(RA RV LV)
U225 (non-MRI model)	CRT-P	4.45 x 6.13 x 0.75	30.6	15.2	RA/RV/LV: IS1
U226 (non-MRI model)	CRT-P	4.45 x 6.13 x 0.75	31.1	15.2	RA/RV: IS1 – LV:LV1
U228	X4 CRT-P	4.45 x 6.17 x 0.75	33.0	16.6	RA/RV: IS1 – LV:IS4

### Longevity

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 Longevity Information

- Assumes 70 min-1 LRL, DDDR mode; 100% biventricular pacing; 15% atrium pacing and 0.4 ms pacing. Pulse Width (RA, RV, LV); RA Impedance 500 Ω; sensors 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.
- Power Supply: lithium-carbon monofluoride cell; Boston Scientific; 40229.

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## Pacing Therapy

<b>Brady Modes</b>	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
<b>AT/AF Management</b>	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), Atrial Pacing Preference (APP), ProACT, Rate Smoothing
<b>Automaticity</b>	Automatic Gain Control (AGC) for sensitivity Right Atrial Automatic Threshold (RAAT) Right Ventricular Automatic Threshold (RVAT) Left Ventricular Automatic Threshold (LVAT)*
<b>Rate Adaptive Pacing</b>	Accelerometer, RightRate™ (Minute Ventilation) or blended sensors with sensor trending function
<b>Rate Management</b>	Sudden Brady Response (SBR), PMT Termination, PVARP after PVC, Dynamic PVARP
<b>RA/RV Pace-Sense Configuration</b>	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off, Lead Safety Switch, Automatic Lead Recognition

\*Models U225 and U226 only

## Heart Failure Therapy

<b>Heart Failure Therapy Optimization</b>	SmartDelay™ (AV Optimization), BiV Trigger, LV Offset, LV Sensing
<b>LV Lead Options</b>	Quadripolar LV lead (VISIONIST X4 CRT-P) Bipolar and Unipolar LV lead (VISIONIST CRT-P)
<b>LV Pacing Vector Options</b>	17 options (VISIONIST X4 CRT-P) 6 options (VISIONIST CRT-P)
<b>LV Sensing Vector Options</b>	8 options plus OFF (VISIONIST X4 CRT-P) 5 options plus OFF (VISIONIST CRT-P)

## Patient Diagnostics

<b>Arrhythmia Logbook</b>	Event Summary, Stored Electrograms with Annotation Markers (Intervals and approximately 14 minutes all 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)
<b>Histograms &amp; Counters</b>	Ventricular Tachy Counter, Brady/CRT Counter, Histograms, Intrinsic Promotion (Rate Hysteresis % successful)
<b>HF Therapy / Diagnostics</b>	Heart Rate Variability (HRV) with SDANN and ABM, Respiratory Rate Trend, AP Scan, AT/AF Burden, Activity Level, A & V Arrhythmias, Weight and Blood Pressure**
<b>Atrial Arrhythmia Report</b>	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.
<b>DAILY TREND for last 365 Days</b>	Events, Activity Level, AT/AF Burden, Pacing Percent, Respiratory Rate, AP Scan, Heart Rate, SDANN, HRV Footprint, ABM, Lead Impedance and Amplitude, RAAT Trend, RVAT Trend, LVAT Trend

\*\*Weight and Blood Pressure are only available via Latitude.

## ImageReady™ MR-Conditional Pacing System

<b>MRI Lead Selection</b>	MR Conditional Pulse Generator U128 and U228 combined with: Pacing Lead: FINELINE™ II, INGEVITY™ LV Lead: ACUITY™ X4
<b>MRI Conditions</b>	1.5T and 3T Full body
<b>MRI Mode</b>	Pacing Mode: AOO, VOO, DOO, Off Ventricular Pacing Chamber: BiV, RV-Only Protection Mode Time Out: Off, 3,6,9,12,24,48 hours

## Implant/In Clinic Follow Up

<b>Implant Communication Mode</b>	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)
<b>In Clinic Follow Up</b>	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
<b>Indications-Based Programming (IBP)</b>	Tool that provides specific programming recommendations based on the patient's clinical needs and primary indications

## Remote Follow Up

<b>Remote Monitoring</b>	This device is designed to be LATITUDE™ NXT enabled; LATITUDE™ NXT availability varies by region
<b>Thresholds</b>	Automatic storage of last successful daily PaceSafe threshold test for all active chambers
<b>Wireless</b>	Remote follow-up for all devices (MICS)
<b>Patient Triggered Monitor (PTM)</b>	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\*\*\*

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

\*\*\*The Safety Functions do not have programmable parameters.

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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.

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CRM-251102-AC Produced by Gosling.

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DINCRM0851EB