Boston Scientific
Advancing science for life™

PERCIVA™ ICD

Models D400, D401, D412, and D413

- HeartLogic™ Heart Failure Diagnostic for detecting indications of worsening heart failure status.
- ImageReady™ MR Conditional Systems allow patients to safely undergo 1.5T Full Body MRI scans.*
- Projected to last up to 9.3 years for VR devices and 8.5 years for DR devices.**
- This small (28.5 cc) and thin (9.9 mm) high-energy device is designed to enhance patient comfort.

*When conditions of use are met.

**Assumes: 2.0V RA, 2.0V RV, 0% pacing, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

HeartLogic™
Heart Failure Diagnostic

ImageReady™
MR-Conditional Systems

Mechanical Specifications

Model	Type	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type	MR Conditional	C-Codes
D400	VR	5.23 x 7.14 x 0.99	61.9	28.5	RV: IS-1/DF-1	No	C1722
D401	DR	5.23 x 7.14 x 0.99	62.3	28.5	RA: IS-1; RV: IS-1/DF-1	No	C1721
D412	VR	5.23 x 6.71 x 0.99	60.0	26.5	RV: DF4	Yes	C1722
D413	DR	5.23 x 7.03 x 0.99	62.5	28.0	RA: IS-1; RV: DF4	Yes	C1721

Pulse Generator Longevity (All Models)

The following tables represent example pulse generator life expectancy estimation (implant to explant) as provided in product labeling. For specific programmable parameter ranges, refer to product labeling at ***www.bostonscientific.com/manuals***, or contact Boston Scientific technical services or your local representative.

Projected Longevity[a]	Type	Pacing Amplitude	Pacing	500Ω with LATITUDE™[b]	700Ω with LATITUDE™[b]	900Ω with LATITUDE™[b]	700Ω no LATITUDE™, RS, or HFSS[c]
VR							
Typical programmed setting	VR	2.5 V	15%	8.0	8.0	8.1	9.1
Maximum labeled longevity	VR	2.0 V / Off	0%	8.2	8.2	8.2	9.3
DR							
Typical programmed setting	DR	2.5V	15%	7.2	7.3	7.3	8.1
Maximum labeled longevity	DR	2.0V	0%	7.5	7.5	7.6	8.5

- Assumes 70 PPM LRL; DDDR mode; 0.4 ms Pulse Width (RA, RV); sensors On, Heart Failure Sensor Suite On.
- Projected longevity is calculated assuming 2 maximum energy charging cycles per year, including automatic capacitor re-forms and therapeutic shocks. These calculations also assume 3-channel EGM Onset is on and that the pulse generator spends 3 months in Storage mode during shipping and storage.

a. Assumes ZIP telemetry use for 2 hours at implant and for 40 minutes annually for in-clinic follow-up checks.

b. Assumes standard use of the LATITUDE™ Communicator as follows: Daily Device Check on, quarterly scheduled remote follow ups, and other typical interrogations.

c. Assumes LATITUDE™ Communicator is not used, Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.

Additional Longevity Information

- Boston Scientific devices have corporate warranties at 5 years in available geographies. Warranty information available at www.bostonscientific.com/warranty.
- Devices use Li/MnO_2 chemistry.
- The Usable Battery Capacity is 1.0 Amp-hours (typical implant to battery capacity depleted).
- Shelf life is 2 years (before use by).

PERCIVA™
Models D400, D401, D412, and D413

Pacing Therapy

Brady Modes	Normal: DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off
AT/AF Management	ATR Mode Switch, Ventricular Rate Regulation (VRR), Atrial Flutter Response (AFR), PMT Termination, Rate Smoothing
Automaticity	PaceSafe Right Ventricular Automatic Threshold (RVAT), PaceSafe Right Atrium Automatic Threshold (RAAT)
Rate Adaptive Pacing	Accelerometer with sensor trending function
RV Pacing Reduction	AV Search+, RYTHMIQ™, AV Delays to 400 ms, Rate Hysteresis

Patient Diagnostics

Daily Trends for Last 365 Days	Events, lead impedances and amplitudes, RA Pace Threshold, RV Pace Threshold
AT/AF Diagnostics	Atrial Arrhythmia Report, AT/AF Burden, RV Rate During AT/AF, Percent Pacing
Arrhythmia Logbook	Events summary, Stored Electrograms with Annotated Markers, (Intervals and approximately 17 minutes of multichannel EGM, always with 10 seconds Onset and event storage prioritization). Implant activation of all available EGMs. On screen measurement of all stored signal amplitudes and timing.
Histograms & Counters	Tachy Events and Brady Counters
Heart Failure Trends and Diagnostics	Heart Failure Management Report, Weight, Blood Pressure, Events, Activity Level, AT/AF Burden, Respiratory Rate, Heart Rate, Heart Rate Variability (SDANN), HRV Footprint, Thoracic Impedance, Night Heart Rate, Sleep Incline ***To note: Weight and Blood Pressure are only available via LATITUDE™.***

HeartLogic™ Heart Failure Diagnostic

HeartLogic™ Heart Failure Diagnostic	The HeartLogic Index and Alert are a validated diagnostic tool to detect gradual worsening of heart failure over days or weeks using multiple physiological measurements. The HeartLogic Index aggregates measurements from multiple device-based sensors (Heart Sounds, Thoracic Impedance, Respiration, and Night Heart Rate) and reflects changes over time in the patient's sensor trend data from their respective baseline values.
HeartLogic™ Heart Failure Management Report	HeartLogic™ composite index and alert, S3 Heart Sound, S1 Heart Sound, Thoracic Impedance, Respiratory Rate, Night Heart Rate, Sleep Incline, Activity Level, AT/AF Burden, V Therapy, RV Rate During AT/AF, Mean Heart Rate, % LV Paced, Heart Rate Variability (SDANN), Weight, Blood Pressure ***To note: HeartLogic™ composite index and alert, heart sounds, weight, and blood pressure are only available through LATITUDE™.***

Tachyarrhythmia Therapy

Sensing/Detection	Zones VF only, or VF and VT or VF, VT, VT-1. Lowest Zone can be Monitor Only
Shock Reduction and Appropriate Therapy	AcuShock™ Advanced Technology including Onset/Stability™, RhythmID™ with RhythmMatch™, Dynamic Noise Algorithm (DNA) for sensing, Automatic Gain Control (AGC) with programmable sensing floor, Narrow Band Pass Filter
Antitachycardia Pacing Therapy (ATP) Termination	Quick Convert™ in VF Zone. Two programmable ATP schemes in both VT and VT-1 zones. Burst, Ramp, Scan, Ramp-Scan
Shock Energy	41 J stored, 35 J delivered. First two shocks in each zone programmable. VT-1 has 5 shocks. VT has 6 shocks and VF has 8 shocks. Reverse Last Shock Polarity in zone. Programmable RV Coil to RA Coil and Can (TRIAD), RV Coil to Can, RV Coil to RA Coil (COLD CAN)
Nominals	VF Zone (200 bpm)–Detection: Rate and Duration, Therapy: Quick Convert, 8 high energy shocks VT Zone (160 bpm)–Detection: RhythmID or Onset/Stability, Therapy: ATP x 2, 6 high energy shocks

Device Testing/Induction Methods

Induction Methods	Vfib Induction, Shock on T Induction, Programmed Electrical Stimulation (PES), 50 Hz/Manual Burst Pacing
Commanded Therapy Methods	Commanded Shock, Commanded ATP

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	Wireless ECG

Remote Follow-Up

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
Beeper Feature (Patient Alerts)	Beep during capacitor charge, beep when explant is indicated, beep when lead impedance measurement (shock or pace) is out-of-range
Magnet Feature	Magnet Response (Off, Store EGM, Inhibit Therapy)
Remote Monitoring	This device is designed to be LATITUDE™ enabled; LATITUDE™ 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)

ImageReady™ MR Conditional System

MRI Lead Selection	RELIANCE™4-SITE defibrillation leads - active and passive fixation, single and dual coil, 59 cm, 64 cm and 70 cm INGEVITY™ and FINELINE™ II pacing leads – active and passive fixation, straight and J, 45 cm, 52 cm, 58 cm, and 59 cm
MRI Conditions	1.5T, SAR 2 W/Kg
MRI Protection Mode	Asynchronous pacing during scan (DOO, VOO, and AOO) Programmable time out: Off, 3, 6, 9, and 12 hours

ICD Systems – RESONATE™ HF, RESONATE™ EL, PERCIVA™ HF, PERCIVA™, VIGILANT™ EL, MOMENTUM™ EL

INDICATIONS AND USAGE Boston Scientific implantable cardioverter defibrillators (ICDs) are intended to provide ventricular antitachycardia pacing (ATP) and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

CONTRAINDICATIONS Use of these Boston Scientific pulse generators are contraindicated for the following: patients whose ventricular tachyarrhythmias may have reversible cause, such as: digitalis intoxication, electrolyte imbalance, hypoxia, sepsis; or patients whose ventricular tachyarrhythmias have a transient cause, such as: acute myocardial infarction (MI), electrocution, drowning; or patients who have a unipolar pacemaker.

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. Always have external defibrillation equipment available during implant and electrophysiologic testing. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not use this pulse generator with another pulse generator. Program the pulse generator Tachy Mode(s) to Off during implant, explant, or postmortem procedures to avoid inadvertent high voltage shocks. 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 directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4–LLHH or DF4–LLHO 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. Tracking of atrial arrhythmias could result in ventricular tachyarrhythmias. 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. RESONATE HF, RESONATE, PERCIVA HF, PERCIVA, and VIGILANT devices with a DF4 right ventricular lead connection 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, and significant harm to or death of the patient and/or damage to the implanted system may result. For potential adverse events applicable when the 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. If desired, ensure that Patient Triggered Monitor is enabled prior to sending the patient home. Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the patient should not apply the magnet.

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, and supplemental precautionary information.

POTENTIAL ADVERSE EVENTS Potential adverse events 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, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. 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 B)

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