ALTRUA™ 40 Pacing System

Specifications

ALTRUA 40 Models S401, S403, and S404

The ALTRUA 40 pacing system from Boston Scientific offers Minute Ventilation (MV) Blended Sensor technology, enabling the physician to customize adaptive-rate therapy to individual needs, restoring chronotropic competence[1]. All models offer atrial arrhythmia management features and leading-edge diagnostics, including stored EGMs with onset and event markers. Ease-of-use tools such as Auto Sense and Quick Check help to streamline patient follow-up visits. Lead configurations are IS-1 compatible and devices are programmable for either unipolar or bipolar pacing and sensing. All ALTRUA 40 pacemakers are programmed using the ZOOM® Programming System with the CONSULT™ Model 2892 software application.

MECHANICAL SPECIFICATIONS

Model	Type	Size (mm) (H × W × D)	Mass (g)	Volume (cc)	Projected Longevity (yrs)[2]	Connector
S401	SR	42 × 42 × 8	23.4	10.0	7.7	IS-1
S403	DR	44 × 42 × 8	25.4	10.8	5.9	IS-1
S404	DR	49 × 43 × 8	29.6	12.1	8.1	IS-1

ALL MODELS OF ALTRUA 40

Shape	Modified elliptical
Envelope	Hermetically sealed titanium
Sensors	Minute-ventilation sensor, integrated circuit accelerometer
Power Supply	2.8-V solid-state lithium-iodine battery
Setscrew Style	Preinserted captive setscrews and seal plugs
Lead Barrel	Various lead connectors accept IS-1 and 3.2 mm leads (IS-1 refers to the international standard ISO 5841.3:1992.)

BRADY ARRHYTHMIA PACING

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Mode	DDD(R), DDI(R), DOO(R), VDD, VVT, DDD VOO(R), AAT, AAI(R), AOO(R), SOO(R), SST, OSO (Modes beginning with O are available in temporary mode only)	SSI	VVI(R),
Lower Rate Limit (LRL)	30–50 ppm (5-ppm), 50–90 ppm (1-ppm), 90–150 ppm (5-ppm) (155–180 ppm [5-ppm], 180–300 ppm [10-ppm], 300–380 ppm [20-ppm] in temporary mode only and only in SSI, SOO, VVI, VOO, AAI, AOO modes)	60	60
Maximum Tracking Rate	80–185 ppm (5-ppm)	130	130
Maximum Sensor Rate	80–185 ppm (5-ppm)	130	130
A and V Pulse Width	0.05 ms, 0.1–1.0 ms (0.1-ms)	0.4	0.4
A and V Pulse Amplitude	0.1–3.5 V (0.1-V), 4.0–5.0 V (0.5-V), 6.5 V	3.5	3.5
AV Delay (Paced)	10–300 ms (10-ms)	150	■

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SENSORS

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Minute Ventilation			
Single chamber	OFF, ON, 4➔ON	■	OFF
Dual chamber	OFF, ON, 4➔ON–A, 4➔ON–V	OFF	■
Response Factor	Passive, 1–16 (1)	3	3
Auto Response Factor	ON, OFF, Reset	ON	ON
High Rate Response	OFF, 55%, 70%, 85%	70%	70%
High Rate Break Point	80–185 ppm (5-ppm)	110	110
Sensor Rate Target	70–175 ppm (5-ppm)	110	110
Accelerometer	ON, OFF, ATR only	OFF	OFF
Activity Threshold	V-low, Low, Med-low, Medium, Med-high, High, V-high	Med	Med
Reaction Time	10–50 sec (10-sec)	30	30
Response Factor	Passive, 1–16 (1)	8	8
Auto Response Factor	ON, OFF, Reset	ON	ON
Recovery Time	2–16 minutes (1-minute)	2	2
Time-Dependent Blended Sensor	ON, OFF	OFF	OFF

RATE ENHANCEMENTS

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Hysteresis Offset	OFF, -5 to -80 ppm (5-ppm)	OFF	OFF
Search Hysteresis	OFF, 256–4096 cycles (powers of 2)	OFF	OFF
Dynamic AV Delay	ON, OFF	ON	■
Maximum AV Delay	20–300 ms (10-ms)	150	■
Minimum AV Delay	10–290 ms (10-ms)	80	■
Sensed AV Offset	OFF; -100 to -10 ms (10-ms)	-30	■
AV Search Interval	OFF; 32–1024 cycles (powers of 2)	OFF	■
AV Delay Increase	10–100% (10% increments)	30	■
PVARP (fixed)	150–500 ms (10-ms)	250	■
Dynamic PVARP	ON, OFF	ON	■
Maximum PVARP	160–500 ms (10-ms)	250	■
Minimum PVARP	150–490 ms (10-ms)	240	■
PVARP after PVC/PAC	OFF, 150–500 ms (50-ms)	400	■

ATRIAL ARRHYTHMIA MANAGEMENT

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Ventricular Rate Regulation (VRR)	ON, OFF	ON	OFF
(VRR) Maximum Pacing Rate	60–150 ppm (5-ppm)	110	110
Sudden Bradycardia Response (SBR)	ON, OFF	OFF	■
SBR Detect Time	1–15 minutes (1 minute)	5	■
SBR Number of Beats	1–8 cycles (1)	4	■
SBR Therapy Duration	1–15 minutes (1 minute)	10	■
SBR Therapy Rate Offset	5–40 ppm (5-ppm)	5	■
SBR MV Offset	OFF, 10%–50% (10% increments)	OFF	■

ATRIAL ARRHYTHMIA MANAGEMENT (continued)

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Atrial Tachy Response (ATR)	ON, OFF	ON	■
Trigger Rate	100–200 ppm (5-ppm)	170	■
Fallback Mode	VDI(R), DDI(R)	VDI(R)	■
Duration	0, 8–2048 cycles (powers of 2)	8	■
Fallback Time	0–120 sec (5-sec)	30	■
ATR Entry Count	1–8 cycles (1)	8	■
ATR Exit Count	1–8 cycles (1)	8	■
ATR Lower Rate Limit	30–50 ppm (5-ppm), 50–90 (1-ppm), 90–150 (5-ppm). ATR Lower Rate Limit must be equal to or greater than the permanent Lower Rate Limit.	70 ppm	■
Atrial Flutter Response	OFF, 130–230 ppm (10-ppm); DDI(R) mode only: 230 ppm	OFF	■
Rate Smoothing	OFF; 3%–24% (3% increments). Separately programmable for increase and decrease.	OFF	OFF
Maximum Pacing Rate	80–185 ppm (5-ppm)	130	130

SENSITIVITY ADJUSTMENT

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
Atrial Sensitivity	Auto, 0.15, 0.25, 0.5, 0.75, 1.0–8.0 mV (0.5-mV), 9.0, 10.0 mV	0.75	■
Ventricular Sensitivity	Auto, 0.25, 0.5, 0.75, 1.0–8.0 mV (0.5-mV), 9.0, 10.0 mV	2.5	2.5

LEAD CONFIGURATION

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
A or V Lead Configuration	Unipolar, Bipolar, Split	BI	BI

REFRACTORY

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
A Refractory Period	150–500 ms (10-ms)	300	■
V Refractory Period	200–500 ms (10-ms)	250	250
A Blanking after V Pace	30–200 ms (10-ms)	120	■
V Blanking after A Pace	30–200 ms (10-ms)	40	■

OTHER FEATURES

Parameter	Programmable Range (Increments)	Nominal by Device Type DR	SR
PMT Termination	ON, OFF	ON	■
Magnet Response	OFF, ASYNC, EGM	ASYNC	ASYNC
A or V Lead Safety Switch	ON, OFF, RESET	OFF	OFF
Runaway Protection	Not Programmable (ppm)	203	203

[1]Chronotropic competence is defined by: Wilkoff BL, Corey J, Blackburn G. A mathematical model of cardiac chronotropic response to exercise. J Electrophysio. 1989;3(3):176–180. Refer to Physician's System Guide for more information on adaptive-rate therapy. Additional clinical performance was assessed using INSIGNIA Ultra clinical data with the AutoLifestyle feature programmed On. Data on file.

[2]Longevity projection as described in user manual. Settings: 60 ppm, A=2.5 V, V=2.5 V, 500 ohms, 100% paced, **MV Blended Sensor ON, Onset EGMS ON.**

Pacing Systems from Boston Scientific CRM

Indications
Pacemaker indications include: symptomatic paroxysmal or permanent second- or third-degree AV block; symptomatic bilateral bundle branch block; symptomatic paroxysmal or transient sinus node dysfunction with or without associated AV conduction disorders; bradycardia-tachycardia syndrome, to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; neurovascular (vaso-vagal) syndromes or hypersensitive carotid sinus syndromes. Adaptive-rate pacing is indicated for patients who may benefit from increased pacing rates concurrent with increases in minute ventilation and/or level of physical activity. Pacemakers' dual-chamber and atrial tracking modes are also indicated for patients who may benefit from maintenance of AV synchrony. Dual-chamber modes are specifically indicated for: conduction disorders that require restoration of AV synchrony, including varying degrees of AV block; VVI intolerance (eg, pacemaker syndrome) in the presence of persistent sinus rhythm.

Contraindications
Pacemakers are contraindicated for the following patients under the circumstances listed: patients with unipolar pacing leads or in MV mode with an implanted ICD because it may cause unwanted delivery or inhibition of ICD therapy; use of the MV sensor in patients with only unipolar leads, because a bipolar lead is required in either the atrium or the ventricle for MV detection; single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias, which might trigger ventricular pacing; dual-chamber and single-chamber atrial pacing in patients with chronic refractory atrial tachyarrhythmias; asynchronous pacing in the presence (or likelihood) of competition between paced and intrinsic rhythms.

Warnings
Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death Inappropriate sustained high-rate pacing occurred in the PULSAR MAX clinical study in 5 out of 130 patients with MV ON, 4 to 14 days after implant. If sustained high-rate pacing could be of concern, consider programming a reduced Max Sensor Rate or MV to Passive. These programming recommendations are intended to assure that MV calibration is evaluated and, if necessary, recalibrated (4→ON) when the patient and pacing system have stabilized post implant. Continued monitoring of the MV sensor performance should be performed at all follow-up visits until implant stabilization has occurred.

Precautions
For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards. Advise patients to avoid sources of electric or magnetic interference (EMI). If the pacemaker inhibits or reverts to asynchronous operation at the programmed pacing rate or at the magnet rate while in the presence of the EMI, moving away from the source or turning it off will usually allow the pulse generator to return to its normal mode of operation.

Potential Adverse Events
Potential adverse events from implantation of the pacing system 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 (pacing/sensing), infection, procedure related, and component failure. 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. K)

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C2-189-0409