

## SUMMARY

A Model 6860 magnet may be used with Boston Scientific pacemakers and CRT-Ps to alter the behavior of the pulse generator when a magnet is detected.

This article describes the various magnet response functions and how to use a magnet to perform these functions for products referenced below.

### Products Referenced

ADVANTIO<sup>®</sup>, INGENIO<sup>®</sup>, VITALIO<sup>™</sup>, FORMIO<sup>™</sup>, pacemaker families, INVIVE<sup>®</sup>, INTUA<sup>™</sup>, INLIVEN<sup>™</sup> CRT-Ps, Model 6860 Doughnut Magnet, ZOOM<sup>®</sup> LATITUDE<sup>®</sup> PRM

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Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: [www.bsci.com/ifu](http://www.bsci.com/ifu).

**CAUTION:** Federal (U.S.) law restricts this device to sale by or on the order of a physician.

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CRT-D: Cardiac Resynchronization Therapy Defibrillator  
 CRT-P: Cardiac Resynchronization Therapy Pacemaker  
 ICD: Implantable Cardioverter Defibrillator  
 S-ICD: Subcutaneous Implantable Defibrillator

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## Magnet Use with Boston Scientific Pacemakers and CRT-Ps

A Model 6860 doughnut magnet may be used with Boston Scientific pacemakers to provide asynchronous pacing support (e.g. in the presence of electromagnetic interference), and also enables clinicians to assess battery status, pacing output safety margin, and general device function without using a programmer. Additionally, the **Magnet Response** can be programmed to store a logbook episode in order to assess patient symptoms.

### Magnet Response Feature

The pulse generator Magnet Response settings can be programmed to control the behavior of the pulse generator when a magnet is detected. The following Magnet Response settings are available: Pace Async, Store EGM, and Off.

- Pace Async** (nominal setting) – If Magnet Response is programmed to Pace Async, magnet application will convert the programmed pulse generator Brady Mode to a fixed asynchronous pacing rate with a 100 ms AV Delay. For CRT-Ps, the pacing chamber is set to BiV and LV Offset is set to 0 ms. The pacing mode converts as follows:

If the programmed Brady Mode is	then the Magnet Mode will be
DDD, DDDR, DDI or DDIR	DOO
VDD, VDDR, VVI, VVIR	VOO
AAI and AAIR	AOO

The pacing rate activated by magnet application provides an indication of battery status, on the Battery Status Summary screen, and can be interpreted as follows:

If the Magnet Rate is	then the Battery Status summary will be
100 ppm	More than One Year Remaining
90 ppm	One Year or Less Remaining
85 ppm	Explant

- Store EGM** – If Magnet Response is programmed to Store EGM, magnet application will activate the **Patient Triggered Monitor (PTM)** functionality. The Patient Triggered Monitor feature allows the patient to manually place a magnet over the device and trigger the storage of EGMs, intervals, and marker data during a symptomatic episode. Instruct the patient to place the magnet over the device briefly (~2 seconds) and one time only. **NOTE: Only one EGM can be generated and stored. To store another EGM, the PTM feature must be re-enabled using the programmer.**

When in 'Store EGM' mode, initial application of the magnet will trigger EGM storage, but will not cause asynchronous pacing. However, after one PTM EGM is stored (or if a PTM is not stored within 60 days), Magnet Response mode will automatically revert to the nominal setting of 'Pace Async' and subsequent magnet applications will cause the device to pace asynchronously (until the PTM feature is re-enabled with a programmer).

- Off** – If Magnet Response is programmed to Off, the pulse generator will not revert to asynchronous operation in the presence of a magnet. Magnet application will have no effect on pulse generator operation.

## How to Program the Magnet Response Feature

The Magnet Response feature is nominally set to 'Pace Async,' however can be changed using a Model 3120 ZOOM<sup>®</sup> LATITUDE<sup>®</sup> programmer. From the Settings Summary Tab on the programmer's Main Screen, Select Brady/CRT Settings > Select 'Timing, Rate Enhancements, Magnet, Noise' > Select programmable value(s) (See Figure 1).

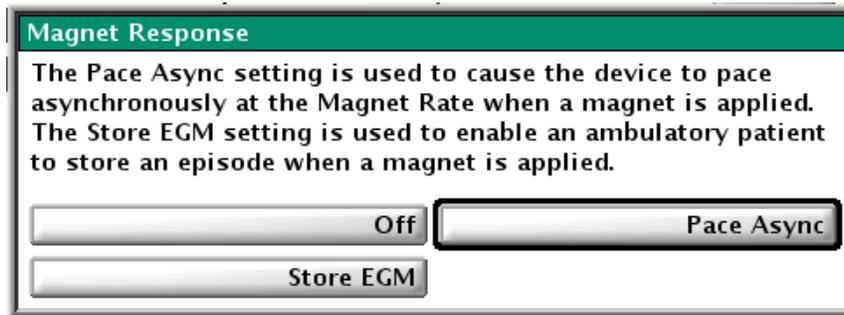


Figure 1. Magnet Response Settings Screen.

## How to Use the Model 6860 Doughnut Magnet

To use a Model 6860 magnet with a Boston Scientific pacemaker, position the magnet over the middle of the pulse generator, in close proximity (within 3 centimeters) from the pulse generator can, as seen in Figure 2.

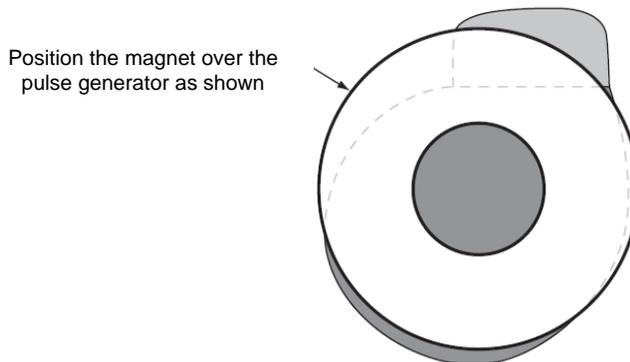


Figure 2. Proper position of the Model 6860 magnet to activate magnet features.

When the magnet is removed, the pulse generator automatically resumes operation according to previously programmed parameters (note that if the Magnet Response was programmed to Store EGM, device Magnet Response mode will automatically be set to Pace Async following EGM storage or 60 days without EGM storage).

### NOTES:

- A pace threshold test determines the minimum output needed to capture in a specific chamber. The third pulse during the Pace Async Magnet Response will be issued at 50% of the programmed Pulse Width. If loss of capture is observed at the third beat after magnet application, consider re-assessing the pacing energy safety margin. A minimum 2X voltage or 3X pulse width safety margin is recommended for each chamber based on the capture thresholds, which should provide an adequate safety margin yet help preserve battery longevity.
- Magnet Response behavior and terminology is different for older generations of Boston Scientific pacemakers and CRT-Ps. For example, differences for the INSIGNIA<sup>®</sup> and ALTRUA<sup>®</sup> families of pacemakers include:
  - Magnet Response settings are referred to as 'Async', 'EGM', and 'Off'
  - When a magnet is applied, VVT pacing mode reverts to VOO, and AAT pacing mode reverts to AOO
  - Battery Status terminology: 100 ppm = GOOD, 90 ppm = ERN, 85 = ERT, <= 85 = EOL
  - More than one EGM can be stored in EGM mode, and Magnet Response mode will not change following EGM storage.

Please contact Technical Services for additional information or reference the applicable Instructions for Use.

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## ZOOM® LATITUDE® Programming System from Boston Scientific

### Intended Use

The Model 3120 Programmer/Recorder/Monitor (PRM) is intended to be used as a complete system to communicate with Guidant or Boston Scientific implantable pulse generators. The software in use controls all communication functions for the pulse generator. For detailed software application instructions, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

### Contraindications

The Model 3120 PRM is contraindicated for use with any pulse generator other than a Guidant or Boston Scientific device. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the Guidant or Boston Scientific pulse generator being interrogated.

### Warnings

There are no warnings associated with this programming system.

### Precautions

For specific information on precautions, read the following sections of the product labeling: General, Preparation for Use, Maintenance and Handling.

### Adverse Effects

None known.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse effects. Rx only. (Rev. E)

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## CRT-P Systems from Boston Scientific – INVIVE™ and INTUA™

### Indications

The INVIVE™ and INTUA™ cardiac resynchronization therapy pacemakers (CRT-Ps) are indicated for patients who have moderate to severe heart failure (NYHA Class III/IV) including left ventricular dysfunction (EF  $\leq$  35%) and QRS duration  $\geq$  120 ms and remain symptomatic despite stable, optimal pharmacologic therapy 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 physical activity.

### Contraindications

These devices are contraindicated in patients who have a separate implanted cardioverter-defibrillator (ICD). Single-chamber atrial pacing is contraindicated in patients with impaired AV nodal conduction. Atrial tracking modes are contraindicated for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which might trigger ventricular pacing. Asynchronous pacing is contraindicated 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. For singleuse only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable non-recoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Do not use atrial only modes in patients with heart failure. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of  $\leq$  200  $\Omega$  or  $\geq$  2000  $\Omega$ . If programmed to a fixed atrial sensitivity value of 0.15 mV, 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. Left ventricular (LV) lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition.

### 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. Advise patients to avoid sources of electric or magnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

### 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 (pacing/sensing), infection, lead tip deformation and/or breakage, 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. C)

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## Pacing Systems from Boston Scientific – INGENIO™, ADVANTIO™, and VITALIO™

### Indications

INGENIO™, ADVANTIO™, and VITALIO™ 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 exhibiting chronotropic incompetence and 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 or low cardiac output or congestive heart failure secondary to bradycardia.

### Contraindications

Pacemakers are contraindicated for the following patients under the circumstances listed: patients who have a separate implanted cardioverter-defibrillator (ICD); use of Minute Ventilation in patients with both unipolar atrial and ventricular leads; single-chamber atrial pacing in patients with impaired AV nodal conduction; atrial tracking modes for patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), 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. For single use only. Do not reuse, reprocess or resterilize. Always have external defibrillation protection available during implant and electrophysiologic testing. Do not use this pulse generator with another pulse generator. In response to applicable nonrecoverable or repeat fault conditions, the pulse generator will switch irreversible to Safety Core operation. Do not kink, twist, or braid leads. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. In devices with the lead safety switch programmed to On, the lead polarity will switch to unipolar in the presence of a lead impedance of  $\leq$  200  $\Omega$  or  $\geq$  2000  $\Omega$ . If programmed to a fixed atrial sensitivity value of 0.15 mV, 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; home and occupational environments; follow up testing; explant and disposal; supplemental precautionary information. Advise patients to avoid sources of electric or magnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

### Potential Adverse Events

Potential adverse events include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, 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. C)

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## Pacing Systems from Boston Scientific ALTRUA® and INSIGNIA®

### 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 (INSIGNIA® Plus,

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ALTRUA® 20/40); MV mode in patients with both unipolar atrial and ventricular leads (INSIGNIA® Ultra, ALTRUA® 60); 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. For single use only-do not resterilize devices. 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 specific information on precautions, refer to the following sections of the product labeling: MV sensor calibration at implant; clinical considerations; sterilization, storage and handling; lead evaluation and connection; implantation; programming and pacemaker operation; MV initialization; environmental and medical therapy hazards; elevated pressure; explanted pacemakers. 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 include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, 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. R)