DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Division of Cardiovascular Devices
Pacing, Defibrillator & Leads Branch

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TO: The Record

THRU: [redacted]
Chief, PDLB/DCD/ODE/CDRH

Initials Date

FROM: [redacted]

SUBJECT: P990001/S68 (Master file), P890003/S192, P970012/S68, P980016/S240, P980035/S168, P010015/S86P010031/S198
Multiple AVX Vendor changes for the Medtronic Implantable devices.

CONTACT: **Stacey Paetschow Wessman**
Senior Principal Regulatory Affairs Specialist
Medtronic, Inc.
8200 Coral Sea Street
Moundsview, MN 55112
Tel: [redacted]
Fax: [redacted]
Email: [redacted]

BACKGROUND/REASON FOR SUPPLEMENT

The subject master file (w/ the above referenced files) was submitted by Medtronic (the company), and it based the deficiencies stated in the FDA letter for the PMA annual report. In addition, those changes were mis-understood by the company inappropriately classified as the annual reportable changes. The following PG Models are impacted by the subject file:

Marquis DR Model 7274;
Marquis VR Models 7230Cx, 7230B, and 7230E;
Maximo DR Model 7278;
Maximo VR Models 7232Cx, 7232B, and 7232B;
Intrinsic 30/Intrinsic Models 7287 and 7288;

EnTrust Models D154VRC, D154DRG;
Maximo II Models D284DRG, D284VRC, D284TRK;
Virtuoso DR Models D154AWG, D154VWC;
EnTrust Models D153ATG, D153DRG, D153VRC, D154ATG;
InSync II Marquis Model 7289;
InSync III Marquis Model 7279;
InSync Sentry Models 7297, 7299;
InSync Maximo Models 7303, 7304;
Concerto Models C154DWK, C164AWK;
Concerto II Model D274TRK;
Consulta Model D224TRK;
Virtuoso II Models D274DRG, D274VRC;
Secura Models D224DRG, D224VRC;
Adapta Models ADD01, ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, ADSR01, ADSR03, ADSR06, ADVDD01;
Relia Models RED01, REDR01, RES01, RESR01, REVDD01;
Sensia Models SED01, SEDR01, SEDRL1, SES01, SESR01;
Versa Model VEDR01;
Kappa 400 IPG Models KDR401, KDR403, KSR401, KSR403;
Kappa 700/600 and Kappa 900/800 IPG Models KDR601, KDR603, KDR606, KDR651, KDR653, KDR721, KDR701, KDR703, KDR706, KDR731, KDR733, KD701, KD703, KD706, KVDD701, KSR701, KSR703, KSR706, KDR801, KDR803, KDR806, KDR921, KDR901, KDR903, KDR906, KDR931, KDR933, KD901, KD903, KD906, KVDD901, KSR901, KSR903, KSR906;
EnPulse IPG Models E2DR21, E2DR31, E2DR33, E2DR01, E2DR03, E2DR06, E2D01, E2D03, E2VDD01, E2SR01, E2SR03, E2SR06;
Sigma IPG Models: SDR303, SDR306, SDR203, SD303, SD203, SVDD303, SSR303, SSR306, SSR203, SS303, SS203, SS103, SS106, SVVI103, DR353, SR353, VDD353;
InSync CRT-P Model 8040;
InSync III CRT-P Model 8042;
Vitatron DA+ C Series and T Series IPG Models C20A1, C60A1, C20A3, C60A3, T20A1, T60A1;
Jade II, Topaz II, Vita IPG Models: 220,520, 522, 310;
Preva IPG Models 7088, 7089, 7078;
Prevade IPG Models 7068; and
Prodigy IPG Model 8158

The following are the capacitors been modified in the subject file:

The first change: The removal of the redundant incoming inspection for the following capacitors:

XT009, XT045, XT082, XT096, XT113, XTC002, XTC018, XTC029,
XT014, XT053, XT084, XT097, XT114, XTC004, XTC019, XTC030,
XT017, XT058, XT085, XT099, XT116, XTC005, XTC020, XT023,
XT060, XT086, XT103, XT118, XTC006, XTC021, XT027, XT067,

XT087, XT104, XT120, XTC007, XTC023, XT032, XT068, XT088, XT105, XT121, XTC008, XTC024, XT038, XT070, XT090, XT106, XT122, XTC009, XTC025, XT041, XT072, XT091, XT108, XT123, XTC010, XTC026, XT043, XT077, XT092, XT109, XT124, XTC013, XTC027**,** XT044, XT078, XT095, XT110, XTC001, XTC017, XTC028.

The second change: The improvement/change the AVX lead frame material for all the above listed capacitors; and

The third change: The modification for the AVX Capacitor power supply for the following capacitors:

XT097, XT118, XT009, XT017, XT044, XT070, XT085, XT087, and XT114.

REVIEW TEAM

CDRH/OC reviewed the manufacture information of this file. Based on the CRDH/OC reviewer comments, all the manufacture information in the subject file are acceptable. This includes the removal of the redundant incoming inspection at Medtronic for all the capacitors listed above.

INDICATIONS FOR USE

NOTE: The "indications for use" are unaffected by the purposed changes in this PMA/S, and are as follows:

Marquis DR 7274 and Marquis VR Models 7230Cx, 7230B, and 7230E (P980016)

Maximo DR 7278 and Maximo VR 7232Cx, 7232B, and 7232B (P980016)

Intrinsic 30/Intrinsic Models 7287 and 7288

EnTrust D154VRC, D154DRG (P980016)

The implantable cardioverter defibrillator is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias.

Maximo II D284DRG and D284VRC (P980016)

The Maximo II DR system is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular tachyarrhythmias.

Virtuoso DR D154AWG (P980016)

The device is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure. In addition, the device is indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

Notes:

- The ICD features of the Virtuoso device function the same as other approved Medtronic market-released ICDs.
- Due to the addition of the OptiVol diagnostic feature, the Virtuoso device indication is limited to NYHA functional class II/III heart failure patients who are indicated for an ICD.
- The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.
- The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.
- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied.
- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2%, in the AF-only patient population studied.

Virtuoso DR D154VWC (P980016)

The device is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

- The ICD features of the Virtuoso device function the same as other approved Medtronic market-released ICDs.
- Due to the addition of the OptiVol diagnostic feature, the Virtuoso device indication is limited to NYHA functional class II/III heart failure patients who are indicated for an ICD.

- The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

EnTrust D153ATG, D153DRG, D153VRC, D154ATG (P980016)

The device is indicated for use in ICD patients with atrial tachyarrhythmias, or who are at significant risk of developing atrial tachyarrhythmias. The device is intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias.

In addition, the device is intended to provide pacing, cardioversion, and defibrillation for treatment of patients with:

- symptomatic, drug-refractory atrial fibrillation and/or
- life-threatening ventricular tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and one or more of the above ICD indications.

Notes:

- The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.
- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied.
- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2%, in the AF-only patient population studied.

InSync II Marquis 7289 (P010031)

The InSync II Marquis Model 7289 is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a QRS duration ≥ 130 ms.

InSync III Marquis 7279 (P010031)

The InSync III Marquis is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration.

InSync Sentry 7297, 7299 (P010031)

InSync Maximo 7303 (P010031)

The InSync Sentry is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction□35% and a prolonged QRS duration.

InSync Maximo 7304 (P010031)

The InSync Maximo is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction □35% and a prolonged QRS duration.

Concerto C154DWK, and C164AWK (P010031)

The Concerto is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. In addition, the deviceis indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction □35% and a prolonged QRS duration.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication

Concerto II D274TRK, and Consulta D224TRK (P010031)

The system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular

arrhythmias. In addition, the device is indicated for use in patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

Maximo II D284TRK (P010031)

The Maximo II CRT-D system is indicated for ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. The system is also indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration.

Virtuoso II D274DRG, and Secura D224DRG (P980016)

The device is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure. In addition, the device is indicated for use in the above patients with atrial tachyarrhythmias, or those patients who are at significant risk of developing atrial tachyarrhythmias.

Atrial rhythm management features such as Atrial Rate Stabilization (ARS), Atrial Preference Pacing (APP), and Post Mode Switch Overdrive Pacing (PMOP) are indicated for the suppression of atrial tachyarrhythmias in ICD-indicated patients with atrial septal lead placement and an ICD indication.

Notes:

- The ICD features of the device function the same as other approved Medtronic market-released ICDs.
- Due to the addition of the OptiVol diagnostic feature, the device indication is limited to NYHA functional class II/III heart failure patients who are indicated for an ICD.
- The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.
- The use of the device has not been demonstrated to decrease the morbidity related to atrial tachyarrhythmias.

- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 17%, and in terminating device classified atrial fibrillation (AF) was found to be 16.8%, in the VT/AT patient population studied.
- The effectiveness of high-frequency burst pacing (atrial 50 Hz Burst therapy) in terminating device classified atrial tachycardia (AT) was found to be 11.7%, and in terminating device classified atrial fibrillation (AF) was found to be 18.2%, in the AF-only patient population studied.

Virtuoso II D274VRC and Secura D224VRC (P980016)

The device is indicated to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias in patients with NYHA functional class II/III heart failure.

- The ICD features of the device function the same as other approved Medtronic market-released ICDs.
- Due to the addition of the OptiVol diagnostic feature, the device indications are limited to the NYHA functional class II/III heart failure patients who are indicated for an ICD.
- The clinical value of the OptiVol fluid monitoring diagnostic feature has not been assessed in those patients who do not have fluid retention related symptoms due to heart failure.

Adapta, Versa, Sensia, and Relia (P980035)

Models:

Adapta, ADD01, ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, ADSR01, ADSR03, ADSR06, ADVDD01

Relia, RED01, REDR01, RES01, RESR01, REVDD01

Sensia, SED01, SEDR01, SEDRL1, SES01, SESR01

Versa, VEDR01

Note:

This section contains information for all models of the Medtronic Adapta/Versa/Sensia/Relia implantable pulse generators. For information about a specific model or series, refer to the implant manual for that device.

These Medtronic Adapta/Versa/Sensia/Relia implantable pulse generators (IPGs) are indicated for use in patients who may benefit from rate responsive pacing to support cardiac output during varying levels of activity. These devices are indicated for use in patients who have experienced one or more of the following conditions:

- symptomatic paroxysmal or permanent second- or third-degree AV block

- symptomatic bilateral bundle branch block
- symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders
- bradycardia-tachycardia syndrome
- vasovagal syndromes or hypersensitive carotid sinus syndromes

These devices are also indicated for use in patients who may benefit from maintenance of AV synchrony through the use of dual chamber modes and atrial tracking modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony. Dual chamber modes are indicated for use in patients who have experienced one or both of the following conditions:

- various degrees of AV block
- VVI intolerance (for example, pacemaker syndrome) in the presence of a persistent sinus rhythm.
- This device is also indicated for VDD pacing in patients who have adequate rates and one or both of the following conditions.
- A requirement for ventricular pacing when adequate atrial rates and adequate intracavitary atrial complexes are present. This includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit or when pacemaker syndrome had existed or is anticipated.
- A requirement for intermittent ventricular pacing despite a normal sinus rhythm and normal AV conduction.

Kappa 400 IPGs (P970012)

Models: KDR401, KDR403, KSR401, KSR403

Kappa pacemakers are indicated for the following:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and/or minute ventilation.
- Accepted patient conditions warranting chronic cardiac pacing which include:
    - Symptomatic paroxysmal or permanent second or third degree AV block.
    - Symptomatic bilateral bundle branch block.
    - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders.
    - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.

- Vasovagal syndromes or hypersensitive carotid sinus syndromes.

Kappa pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output.
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Kappa 700/600 and Kappa 900/800 IPGs (P980035)

Models: KDR601, KDR603, KDR606, KDR651, KDR653, KDR721, KDR701, KDR703, KDR706, KDR731, KDR733, KD701, KD703, KD706, KVDD701, KSR701, KSR703, KSR706, KDR801, KDR803, KDR806, KDR921, KDR901, KDR903, KDR906, KDR931, KDR933, KD901, KD903, KD906, KVDD901, KSR901, KSR903, KSR906

Kappa 700/600 and900/800 Series pacemakers are indicated for the following uses:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity.
- Accepted patient conditions warranting chronic cardiac pacing which include:
- Symptomatic paroxysmal or permanent second or third-degree AV block.
- Symptomatic bilateral bundle branch block.
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders.
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.
- Vasovagal syndromes or hypersensitive carotid sinus syndromes.

Kappa 900/800 Series pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output.
- VVI intolerance (e.g., pacemaker)

EnPulse IPGs (P980035)

Models: E2DR21, E2DR31, E2DR33, E2DR01, E2DR03, E2DR06, E2D01, E2D03, E2VDD01, E2SR01, E2SR03, E2SR06

EnPulse pacemakers are indicated for use in patients who are experiencing accepted conditions warranting chronic cardiac pacing which include:

- Symptomatic paroxysmal or permanent second or third-degree AV block
- Symptomatic bilateral bundle branch block
- Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders.
- Bradycardia-tachycardia syndrome
- Vasovagal syndromes or hypersensitive carotid sinus
- syndromes.

EnPulse pacemakers are also indicated for use in patients who may benefit from rate responsive pacing to support cardiac output during varying levels of activity. Using rate response modes may restore heart rate variability by improving cardiac output.

These devices are also indicated for use in patients who may benefit from maintenance of AV synchrony through the use of dual chamber modes and atrial tracking modes. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony. Dual chamber modes are indicated for use in patients who have experienced one or both of the following conditions.

- Various degrees of AV block
- VVI intolerance (for example, pacemaker syndrome) in thepresence of persistent sinus rhythm. This device is also indicated for VDD pacing in patients who have adequate rates and one or both of the following conditions.
- A requirement for ventricular pacing when adequate atrial rates and adequate intracavitary atrial complexes are present. This includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit or when pacemaker syndrome had existed or is anticipated.
- A requirement for intermittent ventricular pacing despite a normal sinus rhythm and normal AV conduction.

Sigma IPGs (P980035)

Models: SDR303, SDR306, SDR203, SD303, SD203, SVDD303, SSR303, SSR306, SSR203, SS303, SS203, SS103, SS106, SVVI103, DR353, SR353, VDD353

Medtronic.Sigma pacemakers are indicated for the following:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity.
- Accepted patient conditions warranting chronic cardiac pacing which include:
    - Symptomatic paroxysmal or permanent second or third degree AV block.
    - Symptomatic bilateral bundle branch block.

    - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders.
- Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias. Medtronic.Sigma pacemakers are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:
    - Various degrees of AV block to maintain the atrial contribution to cardiac output.
    - VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. Medtronic.Sigma Series pacemakers are also indicated for VDD modes in patients having adequate atrial rates and the following indications:
    - Requirements for ventricular pacing when adequate atrial rates and adequate intracavitary atrial complexes are present. This includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit or when pacemaker syndrome has existed or is anticipated.
    - Normal sinus rhythm and normal AV conduction in patients needing ventricular pacing intermittently

InSync CRT-P (P010015)

Model: 8040

The InSync Model 8040 device is indicated for the reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection fraction ≤35% and a QRS duration ≥130 ms.

InSync III CRT-P (P010015)

Model: 8042

The Medtronic InSync III Model 8042 is indicated for NYHA Functional Class III and IV patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section), and have a left ventricular ejection fraction ≤35% and a prolonged QRS duration.

Rate adaptive pacing is provided for those patients developing a bradycardia indication who might benefit from increased pacing rates concurrent with increases in activity.

Dual chamber and atrial tracking modes are indicated for patients who may benefit from maintenance of AV synchrony.

Vitatron DA+ C Series and T Series IPGs (P990001)

Models: C20A1, C60A1

Dual chamber pacing is indicated if AV synchrony needs to be restored to optimize cardiac output (for example, in patients with symptomatic second or third degree AV block).

Dual chamber rate responsive pacing modes are of specific benefit to patients with chronotropic incompetence of the sinus node.

Rate responsive modes can help patients who have a requirement for an increase in pacing rate, in response to physical activity.

Single chamber ventricular pacing can help patients with permanent atrial tachyarrhythmias, including atrial fibrillation and flutter.

Single chamber atrial pacing can help patients with symptomatic bradyarrhythmias and normal AV conduction.

Vitatron DA+ C Series and T Series IPGs (P990001)

Models: C20A3, C60A3

Dual chamber pacing is indicated if AV synchrony needs to be restored to optimize cardiac output (for example, in patients with symptomatic second or third degree AV block).

Dual chamber rate responsive pacing modes are of specific benefit to patients with chronotropic incompetence of the sinus node.

Rate responsive modes can help patients who have a requirement for an increase in pacing rate, in response to physical activity.

Single chamber ventricular pacing can help patients with permanent atrial tachyarrhythmias, including atrial fibrillation and flutter.

Single chamber atrial pacing can help patients with symptomatic bradyarrhythmias and normal AV conduction.

Vitatron DA+ C Series and T Series IPGs (P990001)

Models: T20A1, T60A1

Dual chamber pacing is indicated if AV synchrony needs to be restored to optimize cardiac output (for example, in patients with symptomatic second or third degree AV block).

Dual chamber rate responsive pacing modes are of specific benefit to patients with chronotropic incompetence of the sinus node.

Rate responsive modes can help patients who have a requirement for an increase in pacing rate, in response to physical activity.

Single chamber ventricular pacing can help patients with permanent atrial tachyarrhythmias, including atrial fibrillation and flutter.

Single chamber atrial pacing can help patients with symptomatic bradyarrhythmias and normal AV conduction.

Jade II, Topaz II, Vita IPG (P990001)

Models: 220,520, 522, 310

The Diva Platform Implantable Pulse Generators are indicated for:

- Rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity and/or QT interval;
- Accepted patient conditions warranting chronic cardiac pacing which include:
  - Symptomatic paroxysmal or permanent second or third degree AV block;
  - Symptomatic bilateral bundle branch block;
  - Symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders;
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias; and
  - Vasovagal syndromes or hypersensitive carotid sinus syndromes;

Diva Platform Implantable Pulse Generators are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include:

- Various degrees of AV block to maintain the atrial contribution to cardiac output; and
- VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm.

Indications and Contraindications for Use

Models 7088 and 7089 are indicated to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders. More specific indications for bradycardia-related pacing are described under "General Pacing Indications" in the Appendix.

Rate response may be restored in patients with exercise intolerance or limitations by using activity modes to improve cardiac output. The clinical benefit of sensor-driven rate responsive dual chamber pacing to increase patient physical endurance has not been objectively demonstrated through comparative exercise tests. The use of sensor-driven rate responsive dual chamber pacing to control atrial arrhythmias has not yet been objectively demonstrated.

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implantation procedure used by the physician.

Rate responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate.

Models 7088 and 7089 can be programmed to a number of modes other than DDD or DDDR for therapeutic and diagnostic purposes. Indications and contraindications[1] for use of all programmable modes are listed below.

[1] Dreifus LS, Fisch C, Griffin JC, et al. Guidelines for implantation of cardiac pacemakers and antiarrhythmia devices. A report of the American College of Cardiology/ American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Pacemaker Implantation). *Journal of the American College of Cardiology*. 1991; 18: 1-13.

DDD / DDDR Modes

Indications for the DDD mode:

- Requirement for AV synchrony over a wide range of rates, e.g., the active or young patient who has atrial rates responsive to clinical need; the patient who has significant hemodynamic need; the patient who has experienced pacemaker syndrome during previous pacemaker experience or a reduction in systolic blood pressure > 20 mm Hg during ventricular pacing at the time of pacemaker implantation (with or without evidence of VA conduction).
- Complete heart block or sick sinus syndrome and stable atrial rates.
- When simultaneous control of atrial and ventricular rates can be shown to inhibit tachyarrhythmias or when the pacemaker can be adjusted to a mode designed to interrupt the arrhythmia.
- Intermittent drug-resistant and re-entrant tachycardias. (Short AV interval settings may be useful in responding to some re-entrant atrial tachycardias).

Indications for the DDDR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate or high level of physical activity and in whom there is a stable atrial rhythm; particularly applicable in the presence of persistent VA conduction during previous pacemaker experience.
- Intermittent atrial and ventricular ectopic arrhythmias.

DDI / DDIR Modes

Indications for the DDI mode:

- Useful in patients who require dual chamber pacing and who have frequent, but not constant, supraventricular arrhythmias.

Indications for the DDIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, particularly when there are fairly frequent atrial arrhythmias or when patients need dual chamber pacing intermittently.

DVI / DVIR Modes

Indications for the DVI mode:

- The need for synchronous atrial-ventricular contraction in symptomatic bradycardia and slow atrial rate.
- Previously documented pacemaker syndrome.
- Intermittent supraventricular arrhythmias in which combined pacing and drugs have been shown to be therapeutically effective.
- Bradycardia-tachycardia syndrome, provided adjustment of atrial rate and AV interval terminates or prevents the emergence of supraventricular arrhythmias with or without concomitant drug administration.
- Intermittent atrial and ventricular ectopic arrhythmias.

Indications for the DVIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.
- Inappropriate function in the DDDR, DDIR, DDD, or DDI modes when AV synchrony is desired.

VDD Mode

Indications for the VDD mode:

- Requirements for ventricular pacing when adequate atrial rates and adequate atrial sensing are present; includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit and when pacemaker syndrome has been present or is anticipated.
- Normal sinus rhythm and normal AV conduction in patients needing periodic ventricular pacing.

VVI / VVT / VVIR Modes

Indications for the VVI / VVT modes:

- Any symptomatic bradyarrhythmias, but particularly when there is no significant atrial hemodynamic contribution, as in persistent or paroxysmal atrial flutter/fibrillation or the presence of giant atria.
- No evidence of pacemaker syndrome due to loss of atrial contribution or negative atrial kick.
- Symptomatic bradycardia where pacing simplicity is the prime concern, e.g., in cases of senility, terminal disease, inaccessibility to a follow-up center, or absent retrograde ventriculoatrial (VA) conduction.
- Patients in whom it is necessary to disable the atrial circuit, e.g., lead fracture, inappropriate function, etc.
- Certain atrial and ventricular ectopic arrhythmias including chronic atrial fibrillation and flutter.

Indications for the VVIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.

AAI / AAT / AAIR Modes

Indications for the AAI /AAT modes:

- Symptomatic sinus node dysfunction, provided AV conduction is shown to be adequate by appropriate studies.
- Hemodynamic enhancement through rate adjustment in patients who have bradycardia and symptoms of impaired cardiac output, provided AV conduction is shown to be adequate by appropriate studies.

Indications for the AAIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, normal AV conduction, and little likelihood of progression to AV block or induction of AV block as the result of drug therapy.

DOO / DOOR, VOO / VOOR, AOO / AOOR Asynchronous Modes

Indications for the DOO / VOO / AOO asynchronous modes:

- These modes may be used intraoperatively to reduce the likelihood of triggering pacing outputs from electrocautery.
- *Asynchronous modes may also be used in patients who exhibit* inappropriate inhibition due to muscle tremors, etc., or in patients who work in environments with excessive electromagnetic interference (EMI).

Indications for the DOOR / VOOR / AOOR asynchronous modes:

- These modes provide asynchronous AV sequential, atrial, or ventricular rate responsive pacing where synchronous pacing is not possible or practical, such as for patients who exhibit inappropriate inhibition due to muscle tremors and so forth or in patients who work in environments with excessive electromagnetic interference. These sensor-driven modes are intended primarily for use on a temporary basis and may be used in patients in whom there is little or no intrinsic cardiac activity, thereby minimizing the possibility of competitive rhythms. Use of asynchronous modes on a chronic basis may result in potentially dangerous competitive pacing.

ODO / OVO / OAO Diagnostic Modes

Indications for the ODO / OVO / OAO diagnostic modes (Pacing outputs are disabled.)

- These modes are primarily intended for temporary use only in those situations where the physician wishes to program diagnostics, diagnose, and/or troubleshoot the pacemaker's operation without any pacing output from the pacemaker. Continuous patient monitoring is necessary when this mode is used. Only in certain clinical situations of limited duration, e.g., when patients are receiving alternative hemodynamic support or undergoing diagnostic or therapeutic procedures, would the permanent programming of this mode be warranted.

Indications and Contraindications for Use

The Model 7068 pacemaker is indicated to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders. More specific indications for bradycardia-related pacing are described under "General Pacing Indications" in the Appendix.

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implantation procedure used by the physician.

The Model 7068 can be programmed to a number of modes other than DDD for therapeutic and diagnostic purposes. Indications and contraindications[1] for use of all programmable modes are listed below.

DDD Modes

Indications for the DDD mode:

- Requirement for AV synchrony over a wide range of rates, e.g., the active or young patient who has atrial rates responsive to clinical need; the patient who has significant hemodynamic need; the patient who has experienced pacemaker syndrome during previous pacemaker experience or a reduction in systolic blood pressure > 20 mm Hg during ventricular pacing at the time of pacemaker implantation (with or without evidence of VA conduction).
- Complete heart block or sick sinus syndrome and stable atrial rates.
- When simultaneous control of atrial and ventricular rates can be shown to inhibit tachyarrhythmias or when the pacemaker can be adjusted to a mode designed to interrupt the arrhythmia.
- Intermittent drug-resistant and re-entrant tachycardias. (Short AV interval settings may be useful in responding to some re-entrant atrial tachycardias).

DDI Modes

Indications for the DDI mode:

- Useful in patients who require dual chamber pacing and who have frequent, but not constant, supraventricular arrhythmias.

DVI Modes

Indications for the DVI mode:

- The need for synchronous atrial-ventricular contraction in symptomatic bradycardia and slow atrial rate.
- Previously documented pacemaker syndrome.
- Intermittent supraventricular arrhythmias in which combined pacing and drugs have been shown to be therapeutically effective.
- Bradycardia-tachycardia syndrome, provided adjustment of atrial rate and AV interval terminates or prevents the emergence of supraventricular arrhythmias with or without concomitant drug administration.
- Intermittent atrial and ventricular ectopic arrhythmias.

VDD Mode

Indications for the VDD mode:

- Requirements for ventricular pacing when adequate atrial rates and adequate atrial sensing are present; includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit and when pacemaker syndrome has been present or is anticipated.
- Normal sinus rhythm and normal AV conduction in patients needing periodic ventricular pacing.

VVI / VVT Modes

Indications for the VVI / VVT modes:

- Any symptomatic bradyarrhythmias, but particularly when there is no significant atrial hemodynamic contribution, as in persistent or paroxysmal atrial flutter/fibrillation or the presence of giant atria.
- No evidence of pacemaker syndrome due to loss of atrial contribution or negative atrial kick.
- Symptomatic bradycardia where pacing simplicity is the prime concern, e.g., in cases of senility, terminal disease, inaccessibility to a follow-up center, or absent retrograde ventriculoatrial (VA) conduction.
- Patients in whom it is necessary to disable the atrial circuit, e.g., lead fracture, inappropriate function, etc.
- Certain atrial and ventricular ectopic arrhythmias including chronic atrial fibrillation and flutter.

AAI / AAT Modes

Indications for the AAI /AAT modes:

- Symptomatic sinus node dysfunction, provided AV conduction is shown to be adequate by appropriate studies.
- Hemodynamic enhancement through rate adjustment in patients who have bradycardia and symptoms of impaired cardiac output, provided AV conduction is shown to be adequate by appropriate studies.

DOO / VOO / AOO Asynchronous Modes

Indications for the DOO / VOO / AOO asynchronous modes:

- These modes may be used intraoperatively to reduce the likelihood of triggering pacing outputs from electrocautery.
- Asynchronous modes may also be used in patients who exhibit inappropriate inhibition due to muscle tremors, etc., or in patients who work in environments with excessive electromagnetic interference (EMI).

ODO / OVO / OAO Diagnostic Modes

Indications for the ODO / OVO / OAO diagnostic modes (Pacing outputs are disabled.)

- These modes are primarily intended for temporary use only in those situations where the physician wishes to program diagnostics, diagnose, and/or troubleshoot the pacemaker's operation without any pacing output from the pacemaker. Continuous patient monitoring is necessary when this mode is used. Only in certain clinical situations of limited duration, e.g., when patients are receiving alternative hemodynamic support or undergoing diagnostic or therapeutic procedures, would the permanent programming of this mode be warranted.

Indications and Contraindications for Use

The Model 7078 pacemaker is indicated to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders. More specific indications for bradycardia-related pacing are described under "General Pacing Indications" in the Appendix.

Rate response may be restored in patients with exercise intolerance or limitations by using activity modes to improve cardiac output. The clinical benefit of sensor-driven rate responsive dual chamber pacing to increase patient physical endurance has not been objectively demonstrated through comparative exercise tests. The use of sensor-driven rate responsive dual chamber pacing to control atrial arrhythmias has not yet been objectively demonstrated.

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implantation procedure used by the physician.

Rate responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate.

The Model 7078 can be programmed to a number of modes other than DDD or DDDR for therapeutic and diagnostic purposes. Indications and contraindications[1] for use of all programmable modes are listed below.

DDD / DDDR Modes

Indications for the DDD mode:

- Requirement for AV synchrony over a wide range of rates, e.g., the active or young patient who has atrial rates responsive to clinical need; the patient who has significant hemodynamic need; the patient who has experienced pacemaker syndrome during previous pacemaker experience or a reduction in systolic blood pressure > 20 mm Hg during ventricular pacing at the time of pacemaker implantation (with or without evidence of VA conduction).
- Complete heart block or sick sinus syndrome and stable atrial rates.
- When simultaneous control of atrial and ventricular rates can be shown to inhibit tachyarrhythmias or when the pacemaker can be adjusted to a mode designed to interrupt the arrhythmia.
- Intermittent drug-resistant and re-entrant tachycardias. (Short AV interval settings may be useful in responding to some re-entrant atrial tachycardias).

Indications for the DDDR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate or high level of physical activity and in whom there is a stable atrial rhythm; particularly applicable in the presence of persistent VA conduction during previous pacemaker experience.
- Intermittent atrial and ventricular ectopic arrhythmias.

DDI / DDIR Modes

Indications for the DDI mode:

- Useful in patients who require dual chamber pacing and who have frequent, but not constant, supraventricular arrhythmias.

Indications for the DDIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, particularly when there are fairly frequent atrial arrhythmias or when patients need dual chamber pacing intermittently.

DVI / DVIR Modes

Indications for the DVI mode:

- The need for synchronous atrial-ventricular contraction in symptomatic bradycardia and slow atrial rate.
- Previously documented pacemaker syndrome.
- Intermittent supraventricular arrhythmias in which combined pacing and drugs have been shown to be therapeutically effective.
- Bradycardia-tachycardia syndrome, provided adjustment of atrial rate and AV interval terminates or prevents the emergence of supraventricular arrhythmias with or without concomitant drug administration.
- Intermittent atrial and ventricular ectopic arrhythmias.

Indications for the DVIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.
- Inappropriate function in the DDDR, DDIR, DDD, or DDI modes when AV synchrony is desired.

VDD Mode

Indications for the VDD mode:

- Requirements for ventricular pacing when adequate atrial rates and adequate atrial sensing are present; includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit and when pacemaker syndrome has been present or is anticipated.
- Normal sinus rhythm and normal AV conduction in patients needing periodic ventricular pacing.

VVI / VVT / VVIR Modes

Indications for the VVI / VVT modes:

- Any symptomatic bradyarrhythmias, but particularly when there is no significant atrial hemodynamic contribution, as in persistent or paroxysmal atrial flutter/fibrillation or the presence of giant atria.
- No evidence of pacemaker syndrome due to loss of atrial contribution or negative atrial kick.
- Symptomatic bradycardia where pacing simplicity is the prime concern, e.g., in cases of senility, terminal disease, inaccessibility to a follow-up center, or absent retrograde ventriculoatrial (VA) conduction.
- Patients in whom it is necessary to disable the atrial circuit, e.g., lead fracture, inappropriate function, etc.
- Certain atrial and ventricular ectopic arrhythmias including chronic atrial fibrillation and flutter.

Indications for the VVIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.

AAI / AAT / AAIR Modes

Indications for the AAI /AAT modes:

- Symptomatic sinus node dysfunction, provided AV conduction is shown to be adequate by appropriate studies.
- Hemodynamic enhancement through rate adjustment in patients who have bradycardia and symptoms of impaired cardiac output, provided AV conduction is shown to be adequate by appropriate studies.

Indications for the AAIR mode:

- Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, normal AV conduction, and little likelihood of progression to AV block or induction of AV block as the result of drug therapy.

DOO / DOOR, VOO / VOOR, AOO / AOOR Asynchronous Modes

Indications for the DOO / VOO / AOO asynchronous modes:

- These modes may be used intraoperatively to reduce the likelihood of triggering pacing outputs from electrocautery.
- Asynchronous modes may also be used in patients who exhibit inappropriate inhibition due to muscle tremors, etc., or in patients who work in environments with excessive electromagnetic interference (EMI).

Indications for the DOOR / VOOR / AOOR asynchronous modes:

- These modes provide asynchronous AV sequential, atrial, or ventricular rate responsive pacing where synchronous pacing is not possible or practical, such as for patients who exhibit inappropriate inhibition due to muscle tremors and so forth or in patients who work in environments with excessive electromagnetic interference. These sensor-driven modes are intended primarily for use on a temporary basis and may be used in patients in whom there is little or no intrinsic cardiac activity, thereby minimizing the possibility of competitive rhythms. Use of asynchronous modes on a chronic basis may result in potentially dangerous competitive pacing.

ODO / OVO / OAO Diagnostic Modes

Indications for the ODO / OVO / OAO diagnostic modes (Pacing outputs are disabled.)

- These modes are primarily intended for temporary use only in those situations where the physician wishes to program diagnostics, diagnose, and/or troubleshoot the pacemaker's operation without any pacing output from the pacemaker. Continuous patient monitoring is necessary when this mode is used. Only in certain clinical situations of limited duration, e.g., when patients are receiving alternative hemodynamic support or undergoing diagnostic or therapeutic procedures, would the permanent programming of this mode be warranted.

Prodigy (P980003)
Model 8158

1. Indications and Contraindications For Use of the Thera DR (i series)

The following indications and contraindications are presented as they appear in the Thera DR (i series) Product Information Manual.

Indications and Contraindications for Use

Thera DR (i series) pacemakers are indicated to improve cardiac output, prevent symptoms, or protect against arrhythmias related to cardiac impulse formation or conduction disorders.

Rate response may be restored in patients with exercise intolerance or limitations by using activity modes to improve cardiac output. The clinical benefit of sensor-driven rate responsive dual chamber pacing to increase patient physical endurance has not been objectively demonstrated through comparative exercise tests. The use of sensor-driven rate responsive dual chamber pacing to control atrial arrhythmias has not yet been objectively demonstrated.

There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implantation procedure used by the physician.

Rate responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate.

Thera DR (i series) pacemakers can be programmed to a number of modes other than DDD or DDDR for therapeutic and diagnostic purposes. Indications and contraindications* for use of all programmable modes are listed below.

* Dreifus LS, Fisch C, Griffin JC, et al. Guidelines for implantation of cardiac pacemakers and antiarrhythmia devices. A report of the American College of Cardiology/American Heart Association Task Force on Assessment of Diagnostic and Therapeutic Cardiovascular Procedures (Committee on Pacemaker Implantation). *Journal of the American College of Cardiology*. 1991; 18: 1-13.

DDD / DDDR Modes

Indications for the DDD mode:

Requirement for AV synchrony over a wide range of rates, e.g., the active or young patient who has atrial rates responsive to clinical need; the patient who has significant hemodynamic need; the patient who has experienced pacemaker syndrome during previous pacemaker experience or a reduction in systolic blood pressure > 20 mm Hg during ventricular pacing at the time of pacemaker implantation (with or without evidence of VA conduction).

Complete heart block or sick sinus syndrome and stable atrial rates.

When simultaneous control of atrial and ventricular rates can be shown to inhibit tachyarrhythmias or when the pacemaker can be adjusted to a mode designed to interrupt the arrhythmia.

Intermittent drug-resistant and reentrant tachycardias. (Short AV interval settings or use of mode switching may be useful in responding to some reentrant atrial tachycardias).

Indications for the DDDR mode:

Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate or high level of physical activity and in whom there is a stable atrial rhythm; particularly applicable in the presence of persistent VA conduction during previous pacemaker experience.

Intermittent atrial and ventricular ectopic arrhythmias.

DDI / DDIR Modes

Indications for the DDI mode:

Useful in patients who require dual chamber pacing and who have frequent, but not constant, supraventricular arrhythmias.

Indications for the DDIR mode:

Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, particularly when there are fairly frequent atrial arrhythmias or when patients need dual chamber pacing intermittently.

DVI / DVIR Modes

Indications for the DVI mode:

The need for synchronous atrial-ventricular contraction in symptomatic bradycardia and slow atrial rate.

Previously documented pacemaker syndrome.

Intermittent supraventricular arrhythmias in which combined pacing and drugs have been shown to be therapeutically effective.

Bradycardia-tachycardia syndrome, provided adjustment of atrial rate and AV interval terminates or prevents the emergence of supraventricular arrhythmias with or without concomitant drug administration.

Intermittent atrial and ventricular ectopic arrhythmias.

Indications for the DVIR mode:

Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.

Inappropriate function in the DDDR, DDIR, DDD, or DDI modes when AV synchrony is desired.

VDD Mode

Indications for the VDD mode:

Requirements for ventricular pacing when adequate atrial rates and adequate atrial sensing are present; includes the presence of complete AV block when atrial contribution is needed for hemodynamic benefit and when pacemaker syndrome has been present or is anticipated.

Normal sinus rhythm and normal AV conduction in patients needing periodic ventricular pacing.

VVI / VDI / VVT / VVIR / VDIR Modes

Indications for the VVI / VDI / VVT modes:

Any symptomatic bradyarrhythmias, but particularly when there is no significant atrial hemodynamic contribution, as in persistent or paroxysmal atrial flutter/fibrillation or the presence of giant atria.

No evidence of pacemaker syndrome due to loss of atrial contribution or negative atrial kick.

Symptomatic bradycardia where pacing simplicity is the prime concern, e.g., in cases of senility, terminal disease, inaccessibility to a follow-up center, or absent retrograde ventriculoatrial (VA) conduction.

Patients in whom it is necessary to disable the atrial circuit, e.g., lead fracture, inappropriate function, etc.

Certain atrial and ventricular ectopic arrhythmias including chronic atrial fibrillation and flutter.

Indications for the VVIR / VDIR modes:

Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity.

AAI / ADI / AAT / AAIR / ADIR Modes

Indications for the AAI / ADI / AAT modes:

Symptomatic sinus node dysfunction, provided AV conduction is shown to be adequate by appropriate studies.

Hemodynamic enhancement through rate adjustment in patients who have bradycardia and symptoms of impaired cardiac output, provided AV conduction is shown to be adequate by appropriate studies.

Indications for the AAIR / ADIR modes:

Includes the above indications in patients who have chronotropic incompetence and an anticipated moderate to high level of physical activity, normal AV conduction, and little likelihood of progression to AV block or induction of AV block as the result of drug therapy.

DOO / DOOR, VOO / VOOR, AOO / AOOR Asynchronous Modes

Indications for the DOO / VOO / AOO asynchronous modes:

These modes may be used intraoperatively to reduce the likelihood of triggering pacing outputs from electrocautery.

Asynchronous modes may also be used in patients who exhibit inappropriate inhibition due to muscle tremors, etc., or in patients who work in environments with excessive electromagnetic interference (EMI).

Indications for the DOOR / VOOR / AOOR asynchronous modes:

These modes provide asynchronous AV sequential, atrial, or ventricular rate responsive pacing where synchronous pacing is not possible or practical, such as for patients who exhibit inappropriate inhibition due to muscle tremors and so forth or in patients who work in environments with excessive electromagnetic interference. These sensor-driven modes are intended primarily for use on a temporary basis and may be used in patients in whom there is little or no intrinsic cardiac activity, thereby minimizing the possibility of competitive rhythms. Use of asynchronous modes on a chronic basis may result in potentially dangerous competitive pacing.

ODO / OVO / OAO Diagnostic Modes

Indications for the ODO / OVO / OAO diagnostic modes (Pacing outputs are disabled.)

These modes are primarily intended for temporary use only in those situations where the physician wishes to program diagnostics, diagnose, and/or troubleshoot the pacemaker's operation without any pacing output from the pacemaker. Continuous patient monitoring is necessary when this mode is used. Only in certain clinical situations of limited duration, e.g., when patients are receiving alternative hemodynamic support or undergoing diagnostic or therapeutic procedures, would the permanent programming of this mode be warranted.

PRECLINICAL/BENCH

BIOCOMPATIBILITY/MATERIALS: N/A

ANIMAL STUDIES: N/A

COMPONENT TESTING

Medtronic and AVX conducted the tests to verify the changes in this file. Those are: Lead Pull test; Weibull burn-in; QCII; Function Tests; Solderability; X-ray; Vibration.

In addition to the above, FDA has requested the characterization test report for every family of the capacitors listed above. All the characterization reports contain the following tests. Those are: verification of the component specifications; burn-in ((b) (4) hr at (b) (4)C to (b) (4)C continuously); life testing (b) (4) hr at (b) (4)C to (b) (4)C continuously); (b) (4) Level testing; (b) (4) .

Dielectric Aging test (Part of the Group B)

Based on the characterization test report, the equivalency of (b) (4) Test, the relative capacitance change measured at one week at (b) (4) ^{0}C for (b) (4) hrs. was conducted, and the results indicate the equivalency at (b) (4) C for over (b) (4) years.

Based on the test reports, all the pre-market component tests are passed. Therefore, the design changes for the capacitors listed above are acceptable.

SOFTWARE: N/A

CLINICAL DATA: N/A

CONCLUSION

Based on the information in the file, the company has provided appropriate data to demonstrate the design changes in the file are acceptable to be used in the pulse generator systems.

RECOMMENDATION – Approval based on the information from CDRH/OC.

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Date

Reviewer

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Date

Chief, PDLB