Aveir™ DR i2i Study

# Summary of Clinical Results and Adverse Events

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# Summary of Clinical Study

The Aveir™ DR i2i Study was performed to establish a reasonable assurance of safety and effectiveness of the Abbott Medical Aveir dual-chamber (DR) leadless pacemaker (LP) system in patients indicated for DDD(R) pacing in the US, Canada, Europe, and Asia Pacific. Data from this clinical study were the basis for the PMA approval decision.

The Aveir DR i2i Study was a first-in-human clinical evaluation of the Aveir DR LP system. The Aveir DR LP system is considered an expanded technology from the Abbott Medical Aveir single-chamber (VR) LP system.

The Aveir DR i2i Study met the specified performance goals for both the safety (freedom from serious adverse device effects) and effectiveness (acceptable atrial LP pacing and sensing, AV synchrony) endpoints. These results showed that the Aveir DR LP system is safe and effective for DDD(R) pacing, and the Aveir atrial LP is safe and effective for AAI(R) pacing. Finally, the results from the upgrade cohort supported the upgradeability of the Aveir VR LP to an Aveir DR LP system for subjects indicated for DDD(R) pacing.

# Study Design

The Aveir™ DR i2i study wasa prospective, multi-center, international, single-arm, pivotal investigational study designed to evaluate the safety and effectiveness of the Aveir DR system in a subject population indicated for a DDD(R) pacemaker. The primary objectives of this study were to evaluate the safety and effectiveness of the Aveir DR system through 3 months post-implant in a subject population indicated for a DDD(R) pacemaker system.

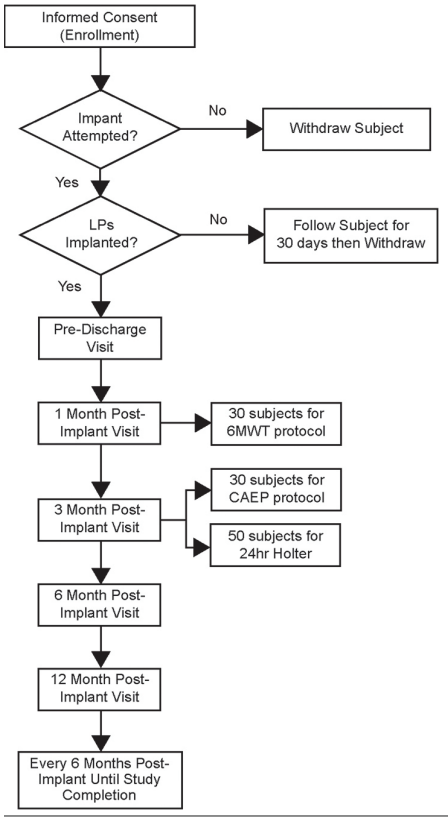
The clinical investigation was designed to enroll up to 550 subjects from up to 85 participating centers from the United States, Canada, Europe, and Asia Pacific. The 550 subjects included at least 300 *de novo* subjects (i.e., no prior pacemaker implantation) in a "full analysis population" to evaluate the primary endpoints and up to 200 additional *de novo* subjects that were enrolled continuously after the first 300 *de novo* subject enrollments. The additional 200 *de novo* subjects were included in the study design in the event more subjects were needed to evaluate the primary endpoints based on the results of a planned interim analysis.

In addition to the 300 enrolled *de novo* subjects, up to 50 subjects who were previously implanted with the Aveir VR LP single chamber system were also permitted to concurrently enroll with the *de novo* subjects from the full analysis population to evaluate the upgradeability to an Aveir DR LP system. This part of the study evaluated upgradeability, a key feature of the Aveir DR System, in which an atrial LP is implanted and functionally paired with a pre-existing Aveir VR LP, resulting in dual-chamber therapy in a DDD(R) (or other) pacing mode. Since the Aveir VR upgrade population is a separate population from the full analysis cohort, the clinical outcomes from this population did not contribute toward the primary or secondary endpoints and are thus reported separately.

The study used an independent Data Safety Monitoring Board (DSMB) that was responsible for informing Abbott Medical of any safety or compliance issues and a Clinical Events Committee (CEC) that was responsible for adjudicating adverse events reported during the IDE study. The study also used an independent ECG Core Laboratory that evaluated Holter data collected from sites to determine AV synchrony success.

The subject follow-up period was necessary to demonstrate safety and effectiveness. Additionally, during this follow-up period, the sponsor would identify any residual risks and complications. Subjects were to undergo the following assessments as described in the study flow diagram in the following figure.

Figure 1. Phase 2 Follow-Up Schedule Flowchart




## Clinical Inclusion and Exclusion Criteria

Enrollment in the study was limited to patients who all of the following inclusion criteria:

- Subject must have at least one of the clinical indications before device implant in adherence with ACC/AHA/HRS/ESC dual chamber pacing guidelines
- Subject is ≥18 years of age or age of legal consent, whichever age is greater
- Subject has a life expectancy of at least one year
- Subject is willing to comply with clinical investigation procedures and agrees to return to clinic for all required follow-up visits, tests, and exams
- Subject has been informed of the nature of the clinical investigation, agrees to its provisions and has provided a signed written informed consent, approved by the IRB/EC

Patients were not permitted to enroll in the study if they met any of the following criteria:

- Subject is currently participating in another clinical investigation that may confound the results of this study as determined by the sponsor
- Subject is pregnant or nursing and those who plan pregnancy during the clinical investigation follow-up period
- Subject has presence of anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator's opinion, could confound the assessment of the investigational device, implant procedure, or both; as well as limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements of the clinical investigation results
- Subject has a known allergy or hypersensitivity to <1 mg of dexamethasone sodium phosphate (DSP) or any blood- or tissue-contacting material listed in the IFU
- Subject has an implanted vena cava filter or mechanical tricuspid valve prosthesis
- Subject has pre-existing, permanent endocardial pacing or defibrillation leads (does not include lead fragments)
- Subject has current implantation of either conventional or subcutaneous implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT) device
- Subject has an implanted leadless cardiac pacemaker (except for an Aveir™ ventricular LP)
- Subject is implanted with an electrically-active implantable medical device with stimulation capabilities (such as neurological or cardiac stimulators)

  NOTE: Does not apply to a medical device with no known impact to the Aveir LP system, including the Aveir Link Module. Patient evaluation and the decision to implant the LP should include consideration of the presence of other active implantable devices and consultation with the sponsor or manufacturer of the co-existing device.

- Subject is unable to read or write

# Clinical Endpoints

The following sections summarize the clinical endpoints of the Aveir™ DR i2i Study.

## Primary Objectives

The primary objectives of this study were to evaluate the safety and effectiveness of the Aveir™ DR LP system through 3 months post-implant in a subject population indicated for a DDD(R) pacemaker system.

## Secondary Objectives

The secondary objectives of this study were to evaluate the safety and effectiveness of the Aveir™ atrial LP through 3 months post-implant in a subject population indicated for a DDD(R) pacemaker system to support an indication for AAI(R) pacing.

## Primary Safety Endpoint

The primary safety endpoint evaluated the 3-month Aveir™ DR LP system complication-free rate (CFR) based on CEC adjudication of adverse events. A complication is defined as a device-or-procedure-related serious adverse device effect (SADE), including those that prevented initial implantation (includes both atrial LP and ventricular LP complications and implant procedure-related complications).

The primary analysis population for the primary safety endpoint analysis was based on subjects in the full analysis population, and the analysis was conducted on all subjects with data available for the evaluation.

## Secondary Safety Endpoint

The secondary safety endpoint evaluated the 3-month Aveir™ atrial LP related CFR based on CEC adjudication of adverse events. The secondary safety endpoint was evaluated if the primary endpoints were met. An atrial LP complication was defined as an atrial device- or procedure-related SADE, including those that prevented initial LP implantation. Complications exclusively related to the ventricular LP or its delivery and retrieval were not considered atrial LP complications and were excluded from this evaluation. Complications where the relationship could not exclusively be determined to be related to the ventricular or atrial LP were considered atrial LP complications (e.g., femoral access complications, embolism, etc.).

The secondary safety endpoint analysis was based on *de novo* subjects in the full analysis population.

## Primary Effectiveness Endpoint #1

The primary effectiveness endpoint #1 evaluated the 3-month composite success rate (Rate) evaluating acceptable atrial pacing thresholds and P-wave amplitudes in *de novo* subjects. These *de novo* subjects are the evaluable population within the full analysis population.

The acceptable ranges for atrial sensing and pacing which define success criteria are shown in the following table.

Table 1. Acceptable Ranges for Sensing and Pacing

| Parameter | Acceptable Test Values |
|---|---|
| Pacing voltage | Pacing threshold ≤3.0 V at 0.4 ms |
| P Sensitivity | P-wave amplitude ≥1.0 mV |

## Primary Effectiveness Endpoint #2

The primary effectiveness endpoint #2 evaluated the 3-month AV synchrony success rate at rest/seated using a Holter monitor in-clinic. AV synchrony success was defined as subjects with a paced or sensed ventricular beat within 300 ms following a paced or sensed atrial beat for at least 70% of evaluable cardiac cycles.

## Secondary Effectiveness Endpoint

The secondary effectiveness endpoint included the evaluation of an appropriate and proportional rate response of the atrial LP during a Chronotropic Assessment Exercise Protocol (CAEP). The secondary effectiveness endpoint was evaluated if the primary endpoints and secondary safety endpoint were met.

# Subject Accountability

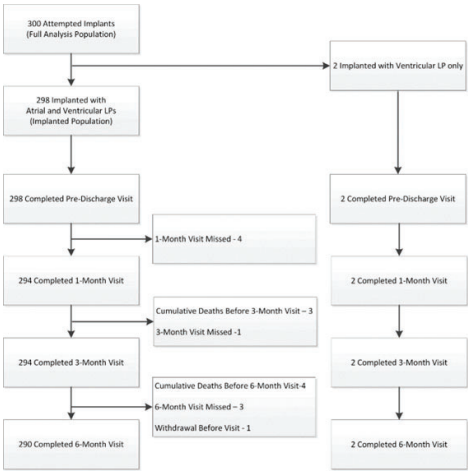
The Aveir™ DR i2i Study enrolled a total of 300 subjects within the full analysis population from 55 investigational sites. The full analysis population included the first 300 consecutive *de novo* subjects who provided written informed consent and had an attempted implant. A *de novo* subject was a subject who did not have an implanted pacemaker on the date of consent through the date of the attempted Aveir LP implant.

The study enrolled the first subject on February 2, 2022 and enrolled the final subject in the full analysis population on August 5, 2022. A total of 184 subjects (61.3%) were enrolled in the United States, 89 subjects (29.7%) were enrolled in Europe, and 27 subjects (9%) were enrolled in Canada. In total, 116 subjects (38.7%) were enrolled outside the United States (OUS).

The final 6-month follow-up visit for all subjects within the full analysis cohort occurred on February 1, 2023. The maximum enrollment per site was less than 15% of the total subjects required to evaluate the primary endpoints (i.e., 45 subjects). By the cut-off date of February 3, 2023, the full analysis population had a mean follow-up duration of 6.4±1.6 subject-months (median duration 6.0 subject-months) with a cumulative total of 1,907 subject-months.

The following figure shows the disposition of all 300 subjects within the full analysis population. All subjects within this population had an attempted implant procedure where there was an attempt to implant both the atrial and ventricular LPs. All subjects either completed their 6-month visit or passed the window for their 6-month visit by the data cut-off date

Figure 2. Disposition of subjects




The following table summarizes the reasons for all subject discontinuations and withdrawals.

Table 2. Subject withdrawals and discontinuation through 6 months (full analysis population)

| **Withdrawal Reason** | **Percent (Number) of Subjects (N=300)** |
|---|---|
| System explant and not re-implanted | 0.3% (1/300) |
| Subject death | 1.3% (4/300) |
| **Total** | **1.7% (5/300)** |

Five (5) subjects (1.7%) withdrew or discontinued from the study by the end of each subject's 6-month visit window (210 days post-implant). Four (4) subjects discontinued due to subject death. Among these 4 deaths, 3 subjects died prior to their 3-month visit, while 1 subject died between the 3-month and 6-month visits.

One subject discontinued due to system explant between the 3-month and 6-month visits. This subject had both atrial and ventricular LPs explanted due to a medical condition change and commercial CRT-P device upgrade and was not re-implanted with Aveir LPs.

## Study Population Demographics and Baseline Parameters

The following table shows the baseline demographics for all 300 subjects within the full analysis population. Overall, the demographics represent a typical dual-chamber pacemaker population, with a mean subject age of 69.2 ± 13.5 years (median age 72 years); 62.3% were male.

Race and ethnicity data were not collected at European centers due to local data privacy regulations. For this reason, the race and ethnicity data that follow represent the demographics from US and Canadian centers only.

Among the 211 subjects where demographic data was provided (excluding declined data), 94.8% identified as white or Caucasian, 2.8% identified as black or African American, and 2.4% identified as Asian. Additionally, 4.7% identified with the ethnicity of Hispanic or Latino. One subject who identified as white also identified as American Indian or Alaskan Native. This is similar to the typical US population who have recently received dual-chamber transvenous pacemakers. Among US Medicare Fee-For-Service patients implanted with dual-chamber pacemakers between January 2019 and December 2019, 88.8% identified as white or Caucasian, 5.7% identified as black, and 1.4% identified as Asian.

Table 3. Baseline demographics

| **Characteristics** | **All Subjects (N=300)** |
|---|---|
| **Gender** | |
| Male | 62.3% (187/300) |
| Female | 37.7% (113/300) |
| **Age (years)** | |
| Mean ± SD (n) | 69.2 ± 13.5 (300) |
| Median (Q1, Q3) | 72.0 (63, 79) |
| (Min, Max) | (20.0, 90.0) |
| **Height (cm)** | |
| Mean ± SD (n) | 171.6 ± 10.1 (300) |
| Median (Q1, Q3) | 172.7 (164.5, 180.0) |
| (Min, Max) | (20.0, 90.0) |
| **Weight (kg)** | |
| Mean ± SD (n) | 82.9 ± 19.1 (300) |

Table 3. Baseline demographics

| Characteristics | All Subjects (N=300) |
|---|---|
| Median (Q1, Q3) | 81.7 (70.0, 92.5) |
| (Min, Max) | (43.5, 163.3) |
| **BMI (kg/m²)** | |
| Mean ± SD (n) | 28.1 ± 5.6 (300) |
| Median (Q1, Q3) | 27.5 (24.4, 31.2) |
| (Min, Max) | (15.1, 49.7) |
| **Ethnicity** | |
| Hispanic or Latino | 3.3% (10/300) |
| Not Hispanic or Latino | 67.0% (201/300) |
| Declined/Unable to disclose | 29.7% (89/300) |
| **Race** | |
| American Indian or Alaska Native | 0.3% (1/300) |
| Asian | 1.7% (5/300) |
| Chinese | 60.0% (3/5) |
| Korean | 20.0% (1/5) |
| Other Asian | 40% (2/5) |
| Black or African American | 2.0% (6/300) |
| White | 66.7% (200/300) |
| Declined/Unable to disclose | 29.7% (89/300) |

The following table summarizes the medical history for all subjects in the full analysis population. Only subjects who had at least one of the indications in the ACC/AHA/HRS/ESC dual-chamber pacing guidelines were eligible to enroll.

The most common primary indication in the Aveir™ DR full analysis population was sinus node dysfunction (63.3%). This indication included patients with the following conditions: sinus bradycardia, sinus arrest, brady-tachy syndrome, sick sinus syndrome, supra-ventricular tachycardias alternating with periods of bradycardia or asystole, and symptomatic chronotropic incompetence. New sinus node dysfunction (SND) associated with symptoms or hemodynamic instability unresolved after surgery were also included within this population.

The second most common indication was AV block (33.3%). Among this population, the most predominant heart block severities were 3rd degree AV block (41.0%) and 2nd degree type 2 (34.0%), irrespective of symptoms. The AV block population also included symptomatic 1st degree AV block (11.0%) and symptomatic 2nd degree type 1 AV block (14.0%).

Finally, 2.0% and 1.3% of the population included those with vasovagal syncope and conduction disorders with 1:1 AV ventricular conduction, respectively. Subjects with these conduction disorders included those with alternating bundle branch block, Kearns-Sayre syndrome, and Anderson Fabry disease with QRS prolongation.

Table 4. Medical history (full analysis population)

| Characteristics | All Subjects (N=300) |
|---|---|
| **Primary pacemaker indication** | |
| Sinus node dysfunction | 63.3% (190/300) |
| Atrioventricular (AV) block | 33.3% (100/300) |
| 1st degree | 11.0% (11/100) |
| 2nd degree – type 1 | 14.0% (14/100) |
| 2nd degree – type 2 | 34.0% (34/100) |
| 3rd degree | 41.0% (41/100) |
| Conduction disorder with 1:1 AV conduction | 1.3% (4/300) |
| Vasovagal (reflex) syncope | 2.0% (6/300) |
| **Congestive heart failure** | |
| Congestive heart failure | 12.3% (37/300) |
| Class I | 18.9% (7/37) |
| Class II | 56.8% (21/37) |
| Class III | 8.1% (3/37) |
| NYHA assessment not done | 16.2% (6/37) |
| No congestive heart failure | 87.7% (263/300) |
| **LV ejection fraction** | |
| Mean ± SD (n) | 59.6 ± 6.9 (226) |
| Median (Q1, Q3) | 60.0 (55.0, 65.0) |

Table 4. Medical history (full analysis population)

| Characteristics | All Subjects (N=300) |
|---|---|
| (Min, Max) | (40.0, 77.0) |
| **History of tobacco use** | 35.7% (107/300) |
| **Hypertension** | 67.0% (201/300) |
| Controlled with medications | 95.0% (191/201) |
| Uncontrolled | 4.5% (9/201) |
| **Diabetes** | 25.0% (75/300) |
| Type I | 6.7% (5/75) |
| Type II | 93.3% (70/75) |
| **Diabetes current status** | |
| Controlled with diet | 12.0% (9/75) |
| Controlled with medications | 88.0% (66/75) |
| **Hyperlipidemia** | 61.3% (184/300) |
| Controlled with diet | 13.6% (25/184) |
| Controlled with medications | 82.1% (151/184) |
| Uncontrolled | 4.3% (8/184) |
| **Peripheral vascular disease** | 13.0% (39/300) |
| **Cardio-pulmonary history** | |
| Coronary artery disease | 34.0% (102/300) |
| Mycardial infarction | 11.7% (35/300) |
| Unstable angina | 5.7% (17/300) |
| **Prior ablation** | 20.0% (60/300) |
| AV junction | 1.7% (1/60) |
| AFib/Aflutter | 78.3% (47/60) |
| SVT | 11.7% (7/60) |
| Other | 13.3% (8/60) |
| **Tricuspid valve disease** | 24.3% (73/300) |
| Insufficiency/prolapse/regurgitation | 98.6% (72/73) |
| Repair/replacement | 4.1% (3/73) |
| **Arrhythmia history** | |
| Ventricular | 4.3% (13/300) |
| Nonventricular/supraventricular | 45.0% (135/300) |
| **Medications** | |
| Antiarrhythmics (Class I) | 4.7% (14/300) |
| Antiarrhythmics (Class III) | 9.7% (29/300) |
| Anticoagulants | 31.0% (93/300) |
| Antiplatelets | 39.0% (117/300) |
| ACE inhibitors | 22.0% (66/300) |
| Angiotensin II receptor blockers | 23.0% (69/300) |
| Beta blockers | 23.7% (71/300) |
| **Prior extractions** | |
| Transvenous lead extraction | 8.0% (24/300) |
| Leadless pacemaker extraction | 0.7% (2/300) |
| **Prior percutaneous procedures** | |
| TAVR | 2.3% (7/300) |
| Mitral valve replacement/repair | 2.7% (8/300) |
| Tricuspid valve intervention | 1.0% (3/300) |
| Percutaneous coronary intervention | 16.3% (49/300) |
| Left atrial appendage closure (LAAC) | 3.7% (11/300) |

Table 4. Medical history (full analysis population)

| Characteristics | All Subjects (N=300) |
|---|---|
| Peripheral vascular intervention of femoral veins | 2.3% (7/300) |
| **Prior open heart surgical procedures** | |
| CABG | 10.3% (31/300) |
| Heart transplant | 0.3% (1/300) |
| Ventricular assist device | 0.3% (1/300) |
| Aortic valve replacement | 4.7% (14/300) |
| ASD/PFO closure | 0.3% (1/300) |
| Other | 1.7% (5/300) |
| **Right atrial tissue modification** | 6.7% (20/300) |
| Right atrial appendix removed | 10.0% (2/20) |
| **Uncorrected atrial septal defect** | 0.3% (1/300) |

A majority of the full analysis population was comprised of patients with hypertension, hyperlipidemia, and a history of cardio-pulmonary disease with rates of 67.0%, 61.3%, and 51.3%, respectively. Additionally, at least 25% of subjects had any of the following comorbidities: diabetes, a history of nonventricular or supraventricular arrhythmias (or both), and a history of tobacco use. Thirty-nine percent (39.0%) and 31.0% of subjects were on antiplatelet or anticoagulation drug therapy at the time of consent, respectively.

Overall, 20.0% of the full analysis population had a prior history of ablation, of which 78.3% had prior atrial fibrillation or atrial flutter ablation.

Most of the subject population also had prior cardiovascular interventions or surgeries, including 26 subjects (8.7%) with a history of transvenous lead or leadless pacemaker extraction. There were 53 subjects (17.7%) with prior open heart surgical procedures. The study did not require a waiting period between prior percutaneous or surgical procedures and the Aveir DR implant procedure. Subjects were only excluded if, in the investigator's opinion, the presence of anatomic or comorbid conditions could confound the assessment of either or both the investigational device and implant procedure, or could limit the subject's ability to participate in the clinical investigation or to comply with follow-up requirements of the clinical investigation results.

Finally, there were 20 subjects (6.7%) with a history of a surgery or intervention where the right atrial tissue may have permanently been modified during the procedure, two of which had their right atrial appendix removed. These modification procedures also included right atrial ablation, Cox-maze, aortic valve replacement, and bypass surgery cannulation.

## Safety and Effectiveness Results

The following sections summarize the safety and effectiveness results of the Aveir™ DR i2i Study.

## Primary Safety Endpoint

The primary analysis population for the primary safety endpoint was based on subjects in the full analysis population. The full analysis population included the first 300 consecutive *de novo* subjects who provided written informed consent and had an attempted implant. The primary safety endpoint evaluated a 3-month complication-free rate (CFR) based on CEC adjudication of adverse events. In addition, a 6-month primary safety analysis evaluated a 6-month CFR based on CEC adjudication of adverse events. A complication was defined as a device-or-procedure-related serious adverse event. This definition of complication was equivalent to the term "SADE" (serious adverse device effect). Complications included atrial LP, ventricular LP, and implant procedure-related complications.

A serious adverse device effect (SADE) is any untoward medical occurrence that would happen in a subject or other person and related to the investigational device, comparator, or procedure, and meets the definition of serious, but is not unanticipated. Serious is defined as meeting at least one of the following criteria:

- Led to death
- Led to serious deterioration in the health of the subject that resulted in one of the following conditions:
  - Life-threatening illness or injury
  - Permanent impairment of a body structure or a body function
  - Inpatient or prolongation of existing hospitalization
  - Medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function
  - Chronic disease
- Led to fetal distress, fetal death, or a congenital abnormality or birth defect

The primary safety endpoint analysis was only conducted on subjects within the full analysis population with data available for evaluation. For the 3-month endpoint analysis, subjects who withdrew from the study or died prior to the 3-month follow-up visit (lower window) without an event (SADE) were excluded from this analysis. Only SADE events that occurred on or before the 3 months (up to 90 days from the attempted implant date) were included in the primary safety endpoint analysis. For the 6-month analysis, subjects who withdrew from the study or died prior to the 6-month follow-up visit (lower window) without an event (SADE) were excluded from this analysis. Only SADE events that occurred on or before the 6 months (up to 180 days from the attempted implant date) were included. To eliminate the possible impact of COVID-19, safety events (SADEs) that were adjudicated as related or possibly related to COVID-19 by the CEC were excluded from the analyses.

For the 3-month endpoint analysis, among the 300 evaluable subjects, 29 subjects experienced 35 complications (i.e., SADEs as adjudicated by the CEC). Therefore, 90.3% of subjects were free from complications within 3-months post-implant. The one-sided 97.5% lower confidence bound (or the lower bound of the two-sided 95% confidence interval) for the CFR was 87.0% and exceeded the performance goal of 78% ($p<0.0001$). Hence, the null hypothesis is rejected at the 2.5% significance level, and it is concluded that the primary safety endpoint was met. The following table summarizes these results.

For the 6-month analysis, among the 294 evaluable subjects, 32 subjects experienced 38 complications (i.e., SADEs as adjudicated by the CEC). Therefore, 89.1% of subjects were free from complications within 6-months post-implant. The one-sided 97.5% lower confidence bound (or the lower bound of the two-sided 95% confidence interval) for the CFR was 85.6%.

Table 5. Primary safety analysis

| Analysis | Number of Subjects in Analysis | Number of Events | Number of Subjects with Events | % Subjects Meeting Success Criteria | 95% Confidence Interval[1] | P-value[2] (PG=78 %) | Endpoint Met (Yes/No)? |
|---|---|---|---|---|---|---|---|
| Primary Safety Endpoint at 3 months | 300 | 35 | 29 | 90.3% | [87.0%, 93.7%] | <0.0001 | Yes |
| Primary Safety Endpoint at 6 months | 294 | 38 | 32 | 89.1% | [85.6%, 92.7%] | NA | NA |

[1] Normal approximation interval

[2] From Z-test

The following table summarizes all 40 SADEs that took place within the 6-month visit window among the full analysis population. Thirty-five (35) of the SADEs within the following table contributed toward the 3-month primary safety endpoint analysis; two events were not included. One pulmonary embolism complication was related to COVID-19 and therefore did not contribute toward the primary safety endpoint analysis. One pre-syncope complication took place after 90 days post-implant but was still within the 3-month visit window, and therefore it also did not contribute toward the primary safety endpoint analysis.

Thirty-eight (38) of the SADEs contributed toward the 6-month primary safety analysis; two events were not included. One pulmonary embolism complication was related to COVID-19 and therefore did not contribute toward the primary safety endpoint analysis. One oversensing complication took place after 180 days post-implant but was still within the 6-month visit window, and therefore it also did not contribute toward the primary safety analysis.

Table 6. Serious adverse device effects through 6 months (CEC adjudicated, full analysis population)

| Event Description[1] | Number of Events | Percent of Subject with Events % (n/N) | Related to Aveir Implant Procedure[2] | Related to Aveir Ventricular LP[2] | Related to Aveir Atrial LP[2] | Related to Aveir Delivery Catheter RV[2] | Related to Aveir Delivery Catheter RA[2] | Related to COVID-19[3] |
|---|---|---|---|---|---|---|---|---|
| Cardiac arrhythmia – atrial fibrillation | 9 | 3.0% (9/300) | 8 | 0 | 7 | 0 | 1 | 0 |
| Device dislodgement | 5 | 1.7% (5/300) | 0 | 0 | 5 | 0 | 0 | 0 |
| Inadequate fixation during implant without LP migration | 3 | 0.7% (2/300) | 3 | 0 | 1 | 0 | 2 | 0 |
| Urinary retention | 3 | 1.0% (3/300) | 3 | 0 | 0 | 0 | 0 | 0 |
| Threshold Elevation | 2 | 0.7% (2/300) | 0 | 1 | 1 | 0 | 0 | 0 |
| Pericardial effusion or rub | 2 | 0.7% (2/300) | 2 | 0 | 2 | 0 | 0 | 0 |
| Inadequate fixation during implant with LP migration | 2 | 0.7% (2/300) | 2 | 1 | 1 | 0 | 0 | 0 |
| False Magnet Mode | 1 | 0.3% (1/300) | 0 | 0 | 1 | 0 | 0 | 0 |
| Syncope | 1 | 0.3% (1/300) | 0 | 0 | 1 | 0 | 0 | 0 |
| Intermittent or loss of i2i™ communication | 1 | 0.3% (1/300) | 0 | 1 | 0 | 0 | 0 | 0 |
| Intermittent capture | 1 | 0.3% (1/300) | 0 | 1 | 0 | 0 | 0 | 0 |
| Oversensing | 1 | 0.3% (1/300) | 0 | 1 | 0 | 0 | 0 | 0 |
| Pre-syncope | 1 | 0.3% (1/300) | 0 | 1 | 0 | 0 | 0 | 0 |
| Access site bleeding event | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Heart failure | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Hematoma formation, including retroperitoneal hematoma/ hemorrhage | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Pain | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Pleural effusion | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Pulmonary embolism | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 1 |
| Other | 2 | | | | | | | |
| Mechanical device dislodgement | 1 | 0.3% (1/300) | 1 | 0 | 0 | 0 | 0 | 0 |
| Complete AV block | 1 | 0.3% (1/300) | 1 | 0 | 0 | 1 | 0 | 0 |

Table 6. Serious adverse device effects through 6 months (CEC adjudicated, full analysis population)

| Event Description[1] | Number of Events | Percent of Subject with Events % (n/N) | Related to Aveir Implant Procedure[2] | Related to Aveir Ventricular LP[2] | Related to Aveir Atrial LP[2] | Related to Aveir Delivery Catheter RV[2] | Related to Aveir Delivery Catheter RA[2] | Related to COVID-19[3] |
|---|---|---|---|---|---|---|---|---|
| **Total** | **40** | **11.0% (33/300)** | **26** | **6** | **19** | **1** | **3** | **1** |

[1] Subjects may experience more than one event.

[2] Related includes probably, possible, or causally related.

[3] COVID-related includes related or possibly related.

Forty (40) SADEs were reported in 30 subjects constituting 11.0% of the full analysis population. Twenty-six (26) events were considered to be related to the Aveir™ DR implant procedure, 19 events were related to the Aveir atrial LP, and 6 events were related to the Aveir ventricular LP. Additionally, 3 events were related to the Aveir Delivery Catheter used to implant the Atrial LP, while 1 event was related to the Aveir Delivery Catheter used to implant the ventricular LP. There was one pulmonary embolism event related to COVID-19.

The most frequent complications were 9 atrial fibrillation events in 9 subjects (3.0%), 5 device dislodgement events in 5 subjects (1.7%), and 5 inadequate fixation events in 4 subjects (1.3%), 2 of which resulted in LP migration.

Among all SADEs, 75% (30/37) were peri-procedural events that occurred within 30 days of the implant date (28 events occurred within 2 days of the implant date). The remaining 25% (10/40) all occurred between 32 and 200 days post-implant. Three (3) events of threshold elevation, false magnet mode, and oversensing took place between 3 and 6 months post-implant (after 120 days).

## Secondary Safety Endpoint

The primary analysis population for the secondary safety endpoint was based on subjects in the full analysis population, which included the first 300 consecutive *de novo* subjects who provided written informed consent and had an attempted implant. The secondary safety endpoint evaluated a 3-month Atrial LP related complication-free rate (CFRA) based on CEC adjudication of adverse events. In addition, a 6-month secondary safety analysis evaluated a 6-month CFRA based on CEC adjudication of adverse events. An Atrial LP complication was defined as an atrial device-or-procedure-related serious adverse event. This definition of complication was equivalent to the term "SADE" (Serious Adverse Device Effect).

The secondary safety endpoint analysis was only conducted on subjects with data available for evaluation. For the 3-month endpoint analysis, subjects who withdrew from the study or died prior to the 3-month follow-up visit (lower window) without an atrial complication were excluded from this analysis. For the 6-month analysis, subjects who withdrew from the study or died prior to the 6-month follow-up visit (lower window) without an atrial complication were excluded from this analysis.

For the 3-month endpoint analysis, among the 300 evaluable subjects, 26 subjects experienced 32 atrial device or procedure related complications. Therefore, 91.3% of subjects were free from atrial complications within 3 months post-implant. The one-sided 97.5% lower confidence bound (or the lower bound of the two-sided 95% confidence interval) for the $CFR_A$ was 88.1% and exceeded the performance goal of 84% (p=0.0003). Hence, the null hypothesis is rejected at the 2.5% significance level, and the secondary safety endpoint was met.

For the 6-month analysis, among the 293 evaluable subjects, 26 subjects experienced 32 atrial device or procedure related complications. Therefore, 91.1% of subjects were free from atrial complications within 6-months post-implant. The one-sided 97.5% lower confidence bound (or the lower bound of the two-sided 95% confidence interval) for the CFRA was 87.9%.

The following table summarizes these results.

Table 7. Secondary safety analysis

| Analysis | Number of Subjects in Analysis | Number of Events | Number of Subjects with Events | % Subjects Meeting Success Criteria | 95% Confidence Interval[1] | P-value[2] (PG=84%) | Endpoint Met (Yes/No)? |
|---|---|---|---|---|---|---|---|
| Secondary Safety Endpoint at 3-months | 300 | 32 | 26 | 91.3% | [88.1%, 94.5%] | 0.0003 | Yes |
| Secondary Safety Analysis at 6-months | 293 | 32 | 26 | 91.1% | (87.9%, 94.4%) | NA | NA |

[1] Normal approximation interval

[2] From Z-test

## Primary Effectiveness Endpoint #1

The primary effectiveness endpoint #1 analysis was based on subjects in the full analysis population. Subjects with unsuccessful implants due to reasons other than atrial pacing/sensing (e.g., cardiac anatomy) were excluded from the analysis. The primary effectiveness endpoint #1 evaluated the 3-month composite success rate (Rate) evaluating acceptable atrial pacing thresholds and P-wave amplitudes in de novo subjects. In addition, a 6-month primary effectiveness #1 analysis evaluated the 6-month composite success rate (Rate) evaluating acceptable atrial pacing thresholds and P-wave amplitudes in de novo subjects.

For the 3-month endpoint analysis, subjects who didn't meet pacing or sensing success criteria at 3 months or subjects with an unsuccessful implant solely due to inadequate atrial LP pacing or sensing were counted as failures. In addition, for subjects with missing 3-month pacing threshold or P-wave amplitude data, multiple imputation was used to impute success or failure. Of the 300 subjects in the full analysis population, 297 subjects were included within the primary effectiveness endpoint #1 analysis.

For the 3-month hypothesis-tested analysis, among the population with data available, there were 27 subjects who did not meet success criteria for the primary effectiveness endpoint #1. One subject who failed the success criteria had both their capture threshold and the P-wave amplitudes measured outside of their acceptable ranges. The remaining 26 subjects only failed one of the two electrical performance criteria. Five (5) subjects failed the capture threshold criteria only, and 21 subjects failed the P-wave amplitude criteria only. For the 6-month analysis, among the population with data available, there were 26 subjects who did not meet success criteria for the primary effectiveness #1 analysis. Two (2) subjects who failed the success criteria had both their capture threshold and the P-wave amplitudes measured outside of their acceptable ranges. The remaining 24 subjects only failed one of the two electrical performance criteria. Three (3) subjects failed the capture threshold criteria only, and 21 subjects failed the P-wave amplitude criteria only.

The rate of subjects who failed capture threshold criteria in this study and in the Leadless II – Phase 2 study at 6-months was similar. For the atrial LP, the rate of threshold failure among subjects with 6-month data available was 1.8% (5/281) and, similarly for the Aveir™ VR LP, the rate of threshold failure was 2.0% (4/196) based on 6-week data available from the Leadless II – Phase 2 Study.

## Primary Effectiveness Endpoint #2

The primary effectiveness endpoint #2 analysis was based on subjects in the full analysis population. Subjects with unsuccessful implants solely due to a failure to establish i2i™ communication at the end of the implant procedure were included and imputed as failures. Subjects with unsuccessful implants due to reasons other than AV Synchrony (e.g., cardiac anatomy) were excluded from the analysis. Among the 300 subjects in the full analysis population, 2 subjects were excluded from the evaluable population. Two of these subjects were those who had an unsuccessful atrial device implant. Within this cohort, there were 277 subjects with AV Synchrony data available to define endpoint success.

The primary effectiveness endpoint #2 evaluated the 3-month AV synchrony success rate ($Rate_{AV}$) at rest while seated in *de novo* subjects. AV synchrony success was defined as subjects with a paced or sensed ventricular beat within 300 ms following a paced or sensed atrial beat (i.e., a synchronous cycle) for at least 70% of evaluable cardiac cycles. An independent core laboratory evaluated collected Holter data from sites and determined AV synchrony success in subjects.

Among the 277 subjects in the evaluable population, the success $Rate_{AV}$ was 98.2%. The one-sided 97.5% lower confidence bound for the success $Rate_{AV}$ was 96.6% and exceeded the performance goal of 83% ($p<0.0001$). Hence, the null hypothesis is rejected at the 2.5% significance level, and it is concluded that the primary effectiveness endpoint #2 was met.

## Secondary Effectiveness Endpoint

Rate-response pacing for patients programmed in an AAIR pacing mode is driven by the sensor in the Aveir™ atrial LP. The secondary effectiveness endpoint evaluated the temperature-based rate response feature in the Aveir atrial LP only. All capable subjects at participating centers were asked to perform a 6-minute walk test (6MWT) simulating daily walking activity to identify the appropriate sensor parameters for each subject prior to conducting the graded exercise test. All capable subjects who completed a 6MWT were subsequently asked to perform a maximal effort CAEP to demonstrate an appropriate and proportional response of sensor-indicated rate in graded exercise tests.

A total of 22 subjects underwent the CAEP assessment. Among the 22 subjects, 20 completed at least stage 3 of the CAEP exercise protocol, thus achieving a workload of at least 3.6 metabolic equivalent of task (METs). Two of the 14 subjects who completed stage 3 did not optimize the sensor gain as intended during the 6MWT, and therefore the CAEP was not performed using an optimized sensor gain. For this reason, these two subjects were not considered to be analyzable. Therefore, a total of 18 subjects were considered analyzable ("analyzable subjects") for the secondary effectiveness endpoint and exceeded the minimum sample size of 8 required for this assessment.

The mean slope, through the origin, from this population was 0.94±0.07. The 95% confidence interval for the mean slope was (0.80, 1.08), which fell within the 35% equivalence margin (0.65, 1.35) ($p=<0.001$). Hence, the null hypothesis is rejected, and it is concluded that the secondary effectiveness endpoint was met.

# Summary of Supplemental Clinical Information

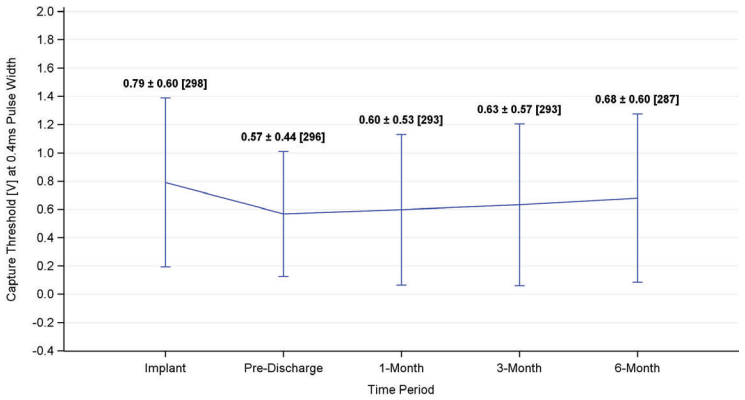
## Device Electrical Measurements: PMA Cohort

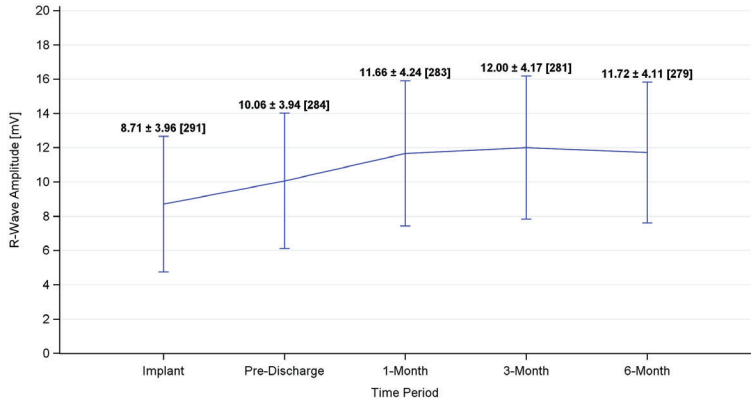
The following figures summarize the critical device electrical measurements for each LP among the implanted population (n=298).

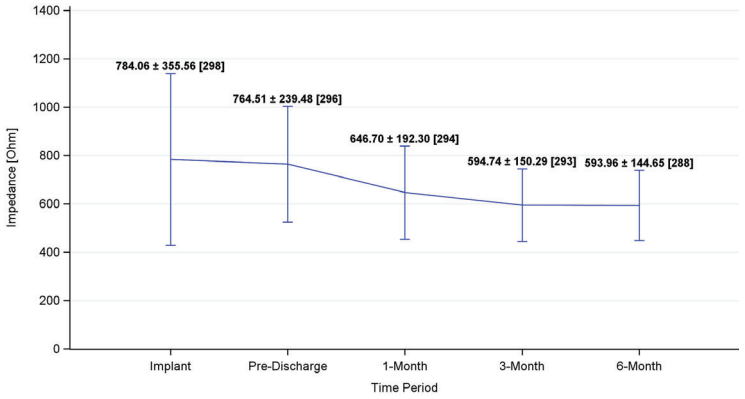
### Ventricular LP Electrical Measurements

The following figure shows the trends of device electrical measurements from implant through the 6-month post-implant visit for the ventricular LP. (Mean ± standard deviation [STD] is shown.)

Figure 3. Ventricular LP device electrical measurements summary (implanted population)



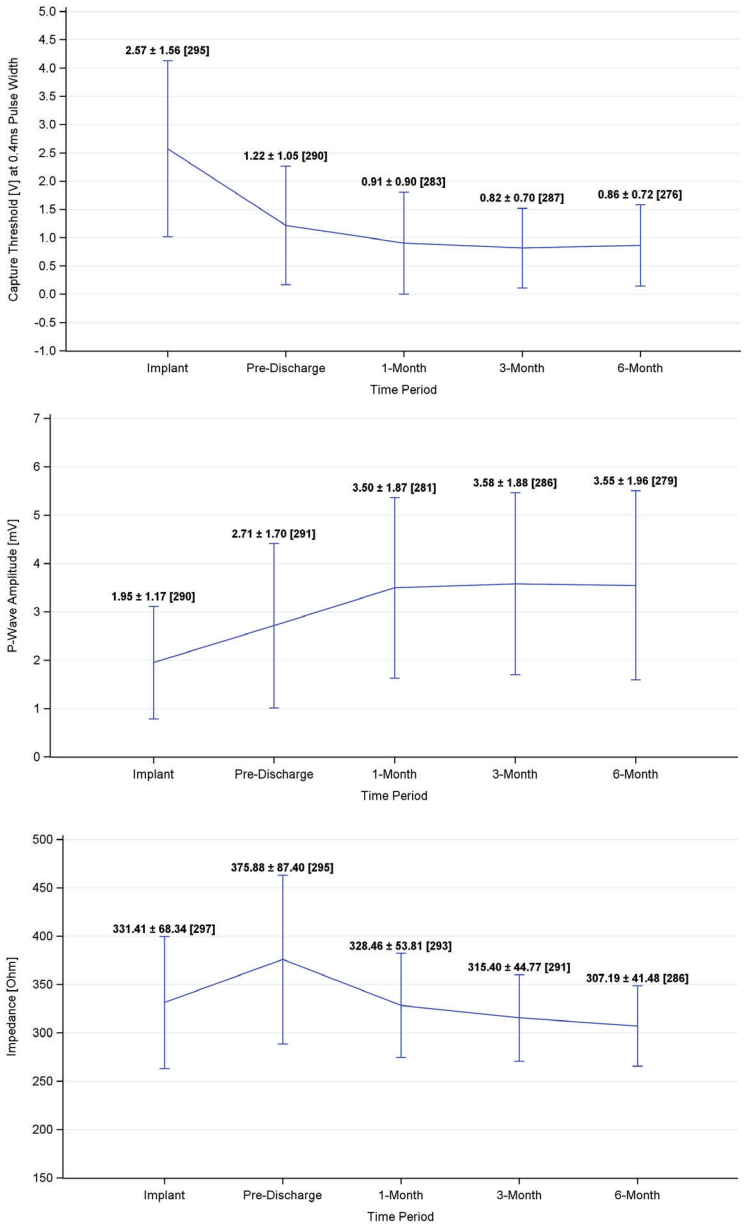




## Atrial LP Electrical Measurements

The following figure shows the trends of device electrical measurements from implant through the 6-month post-implant visit for the atrial LP. (Mean ± STD is shown.)

Figure 4. Atrial LP device electrical measurements summary (implanted population)




## Upgrades From the Aveir™ VR LP to the Aveir™ DR LP

There were 25 subjects with a pre-existing Aveir™ VR LP who had an attempted upgrade to an Aveir DR LP system through the period that the full analysis population was enrolled.

Among the 25 subjects with an attempted upgrade from a pre-existing Aveir VR LP to an Aveir DR LP system, 92% (23/25) were successfully implanted with an Aveir atrial LP. The Aveir VR LP was successfully programmed to a dual-chamber pacing mode in all successfully implanted subjects.

## Study Conclusions

In the clinical study, the primary safety endpoint was met as the 3-month complication free rate (CFR) among 300 evaluable subjects in the full analysis population was 90.3%, of which the one sided 97.5% lower confidence bound (or the lower bound of the two-sided 95% confidence interval) for the CFR was 87.0% and exceeded the performance goal of 78% ($p<0.0001$). The secondary safety endpoint was also met, as the 3-month Atrial LP related complication-free rate ($CFR_A$) among the full analysis population was 91.3%, of which the one sided 97.5% lower confidence bound for the CFRA was 88.1% and exceeded the performance goal of 84% ($p=0.0003$). A 6-month primary safety analysis and 6-month secondary safety analysis were consistent with the 3-month results.

The rate response assessment for the secondary effectiveness endpoint demonstrated an appropriate and proportional rate response during graded exercise testing. The mean slope of the normalized increase in sensor-indicated rate versus normalized CAEP workload for each subject among 18 analyzable subjects was 0.94±0.07 with a 95% confidence interval (0.80, 1.08), which fell within the pre-specified success criterion of a 35% equivalence margin (0.65, 1.35), with statistical significance ($p=0.001$).

The data in this application support the reasonable assurance of safety and effectiveness of this device when used in accordance with the indications for use. The Aveir DR i2i Study met the pre-specified performance goals for both the safety (freedom from serious adverse device effects) and effectiveness (acceptable atrial LP pacing and sensing, AV synchrony) endpoints. These results showed that the Aveir™ dual-chamber LP system is safe and effective for DDD(R) pacing, and the Aveir atrial LP is safe and effective for AAI(R) pacing. Finally, the results from the upgrade cohort supported the upgradeability of the Aveir VR LP to an Aveir DR LP system for subjects indicated for DDD(R) pacing.

The totality of the evidence provided in this PMA demonstrates a reasonable assurance of the safety and effectiveness of the Aveir DR LP system and provides valid scientific evidence to conclude that the probable benefit to health from the use of the Aveir DR LP outweighs any probable risk or injury.

Abbott Medical
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

www.abbott.com

2023-07
ARTEN600284318 B

Abbott

# Aveir™

Leadless Pacemaker, Model LSP201A, LSP202V

# Aveir™

Delivery Catheter, Model LSCD201

# Instructions for Use

Abbott

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

# Contents

# System Description

The Aveir™ leadless pacemaker system supports the implantation and use of an Aveir™ Leadless Pacemaker (LP) within the targeted chamber(s) of the heart for monitoring a patient's heart rate and providing rate-responsive bradycardia pacing therapy to regulate heart rate.

These are the supported clinical use configurations:

Table 1. Supported system configurations

| **Most comprehensive mode** | **Clinical use** | **Description** |
|---|---|---|
| DDDR | Dual-chamber bradycardia therapy | Two functionally-paired co-implanted LPs, one in the right ventricle (RV) and one in the right atrium (RA), to provide dual-chamber pacing and sensing. |
| AAIR | Right-atrial single-chamber bradycardia therapy | A single LP implanted independently in the RA to provide atrial-only pacing and sensing. |
| VVIR | Right-ventricular single-chamber bradycardia therapy | A single LP implanted independently in the RV to provide |

Table 1. Supported system configurations

| Most comprehensive mode | Clinical use | Description |
|---|---|---|
| | | ventricular-only pacing and sensing. |

NOTE: The Aveir™ leadless pacemaker system provides the capability to upgrade a patient's single-chamber system to a dual-chamber (DDDR) configuration at a later time with the addition of a co-implanted LP that can be functionally paired with an already-implanted LP to provide dual-chamber pacing therapy.

The system comprises these components:

Table 2. System components

| Product | Description | |
|---|---|---|
| Aveir™ Leadless Pacemaker | Leadless pacemaker, RA | Deployable into the heart's right atrium.<br>In this manual, a right-atrial LP implant is referred to as "RA LP". |

Table 2. System components

| Product | Description | |
|---|---|---|
| Aveir™ Leadless Pacemaker | Leadless pacemaker, RV | Deployable into the heart's right ventricle.<br>In this manual, a right-ventricular LP implant is referred to as "RV LP". |
| Aveir™ Delivery Catheter | Delivery catheter | Catheter used to deliver the LP into the target heart chamber.<br>Each LP is supplied inside its own loading tool, used to help connect the LP to the delivery catheter. |
| Aveir™ Retrieval Catheter | Catheter used to retrieve and manipulate an LP. | |
| Aveir™ Introducer | Introducer sheath used as a guiding sheath to provide access to the venous vasculature. | |
| Merlin™ Patient Care System (PCS) | Programmer and software used to display patient electrocardiogram (ECG) and the status of an implanted LP, and to program an LP according to the clinical use. | |

Table 2. System components

| Product | Description |
|---|---|
| Aveir™ Link Module | Programmer communication unit, with a USB interface to the Merlin™ PCS programmer, used to enable conducted communication bidirectionally between an LP and the programmer.<br>NOTE: In this manual, a Merlin PCS programmer connected to a Link Module is referred to as “the programmer system”. |

# Prescription and Safety Information

Read this section to gather important prescription and safety information.

## Intended Use

The Aveir™ Leadless Pacemaker (LP) is designed to provide bradycardia pacing as a pulse generator with built-in battery and electrodes for implantation in the right ventricle and the right atrium. The LP is intended to provide sensing of intrinsic cardiac signals and delivery of cardiac pacing therapy within the implanted chamber for the target treatment group. The LP is also intended to operate optionally with another co-implanted LP to provide dual-chamber pacing therapy.

The Aveir™ Delivery Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to deliver and manipulate an LP. Delivery and manipulation includes implanting an LP within the target chamber of the heart.

## Indications for Use

The Aveir™ Leadless Pacemaker system is indicated for management of one or more of the following permanent conditions:

- Syncope
- Pre-syncope
- Fatigue
- Disorientation

**Rate-modulated pacing** is- indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity.

**Dual-chamber pacing** is indicated for patients exhibiting:

- Sick sinus syndrome
- Chronic, symptomatic second- and third-degree AV block
- Recurrent Adams-Stokes syndrome
- Symptomatic bilateral bundle-branch block when tachyarrhythmia and other causes have been ruled out

**Atrial pacing** is indicated for patients with:

- Sinus node dysfunction and normal AV and intraventricular conduction systems

**Ventricular pacing** is indicated for patients with:

- Significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest
- Chronic atrial fibrillation
- Severe physical disability

**MR Conditional:** The Aveir™ Leadless Pacemaker is conditionally safe for use in the MRI environment and according to the instructions in the MRI-Ready Leadless System Manual.

## Contraindications

Use of the Aveir™ Leadless Pacemaker is contraindicated in these cases:

- Use of any pacemaker is contraindicated in patients with a co-implanted ICD because high-voltage shocks could damage the pacemaker and the pacemaker could reduce shock effectiveness.
- Single-chamber ventricular demand pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde (VA) conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.
- Programming of rate-responsive pacing is contraindicated in patients with intolerance of high sensor-driven rates.
- Use is contraindicated in patients with an implanted vena cava filter or mechanical tricuspid valve because of interference between these devices and the delivery system during implantation.
- Persons with known history of allergies to any of the components of this device may suffer an allergic reaction to this device. Prior to use on the patient, the patient should be counseled on the materials (listed in Product Materials (page 78)) contained in the device and a thorough history of allergies must be discussed.

## MRI Safety Information

The Aveir™ Leadless Pacemaker is conditionally safe for use in the MRI environment when used according to the instructions in the MRI-Ready Leadless System Manual (which includes equipment settings, scanning procedures, and a listing of conditionally approved components). Scanning under different conditions may result in severe patient injury, death, or device malfunction.

## Pre-Implantation Considerations

Consider the following before implanting the Aveir™ Leadless Pacemaker.

**Co-existing active implantable medical devices.** The LP has not been tested in the presence of other electrically-active, non-Aveir™, implantable medical devices (such as neurostimulators). Patient evaluation and the decision to implant the LP should take into account the presence of other active implantable devices and should include consultation with the involved physician(s) or manufacturer of the co-existing device.

Refer to the Aveir™ Link Module Instructions for Use for additional safety information regarding possible interference with other active implantable devices during implantation or follow-up telemetry. For further questions on co-existing Abbott Medical implantable devices, contact Abbott Medical Technical Support (page 80).

## Warnings

The following warnings apply to the Aveir™ Leadless Pacemaker:

**Prior surgical intervention.** Careful consideration should be given to patients who have had cardiovascular or peripheral vascular surgery/intervention within the last 30 days because these patients may have a higher risk of complications.

**Previous clinical events.** Implant of an LP should not be attempted in the presence of an active perforation. Implant sites where a previous clinical intervention or event (e.g., lead extraction, perforation, infarct, etc.) should be avoided as this may result in a higher rate of perforation.

**Risk of perforation.** Do not put excessive forward pressure on the protective sleeve or the delivery catheter when implanting the LP because perforation may result.

Do not turn the LP more than $1\ ^{1}/_{2}$ turns during implantation, because perforation may result.

**Risk of dislodgement.** Use of an LP could involve risk of dislodgement resulting in inadvertent migration of the pacemaker into the lungs and possible compromised pulmonary reserve.

**Contact between devices.** When implanting a new LP in the presence of a previously-implanted LP, the LPs should not be touching. The consequences of potential short-term and long-term mechanical and electrical interactions between the LPs are not known.

**Venous tortuosity.** Careful consideration should be given to patients with severe venous tortuosity because catheter performance for delivery and implantation could be adversely affected.

During the implant procedure, avoid contact between the delivery catheter or its attached LP and any previously-implanted LP as this could result in dislodgement of the existing LP and possible embolization.

Do not implant a new LP in the presence of an implanted transvenous lead because this has not been tested.

When implanting a new traditional implant (pacemaker or ICD) in the presence of a previously-implanted LP, the transvenous leads associated with the new implant should not come in contact with the LP. The combination of a deactivated LP and a transvenous lead has not been tested and could result in patient injury.

**Delivery catheter use in dual-chamber implant procedures.** Dual-chamber implant procedures should use a new delivery catheter for each target chamber implantation. Using the same catheter to implant LPs within multiple chambers could lead to catheter damage and result in spontaneous release of the LP from the catheter, inability to release the LP from the catheter, or tether fracture.

**Chronic retrievals.** Limited testing has been performed for retrieval of a chronically implanted LP. Attempted removal of an LP that has been implanted chronically could result in patient injury.

## Precautions

The following precautions apply to the Aveir™ Leadless Pacemaker:

**Patient selection.** Patients with coagulopathy, including those who are chronically anticoagulated, or other conditions that could add significant risk in the unlikely event of surgical management of an incident such as perforation, should be evaluated carefully for suitability for leadless pacing.

**Cover the fixation helix during implantation.** Only advance the LP through the vasculature with the delivery catheter's protective sleeve fully covering the LP fixation helix. Damage to the LP helix and injury to peripheral structures and heart structures may occur if the LP helix is not covered.

**Use fluoroscopy to confirm LP placement.** Confirm the placement of the LP at the desired implant site in the endocardium of the target heart chamber, via multiple fluoroscopic views prior to fixation and release of the LP from the delivery catheter. Verify that inadvertent placement of the LP through a patent foramen ovale or septal defect did not occur.

**Use by a single operator.** When the LP is in the heart, the delivery catheter should only be manipulated by a single operator.

**LP deployment.** Do not turn the LP release knob until ready to deploy the LP after fixation in the endocardium; otherwise, loss of pacing and embolization could result.

## Physician Training

This product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths should be employed. Individual patient anatomy and physician technique may require procedural variations. Physicians should be familiar with percutaneous retrieval procedures and follow-up evaluation.

## Storage and Handling

Store the LP at room temperature of 20°C to 25°C (68°F to 77°F). Storage excursions are permitted between 15°C and 30°C (59°F and 86°F).

During transportation and handling, the LP can be safely exposed to temperatures between -20°C and 50°C (-4°F and 122°F). Transportation excursions outside of this range may result in LP reset.

Store the LP in a clean area, away from magnets, kits containing magnets, and sources of electromagnetic interference to avoid device damage.

Do not implant an LP that has been dropped on a hard surface while outside of its intact shelf package, or from a height of more than 24 inches (61 cm) while within its intact shelf package. Sterility, integrity, or function cannot be guaranteed under these conditions, and the LP should be returned to Abbott Medical for inspection.

Keep the delivery catheter in a cool, dry place. Do not expose to sunlight.

## Sterilization

The package contents have been sterilized with ethylene oxide before shipment. The LP and delivery catheter are FOR SINGLE USE ONLY and are not intended to be resterilized.

Any attempt to resterilize and reuse may compromise the integrity of this system. Adverse effects associated with resterilization and reuse of components may include, but are not limited to:

- Local or systemic infection
- Mechanical damage
- Inaccurate functionality

Do not implant the LP when the sterility indicator within the inner package is purple, because it might not have been sterilized, or when the storage package has been pierced or altered, because this could have rendered it non-sterile.

## Package Inspection

Before opening any sterile package, inspect the sales packaging carefully to ensure they have not been opened, punctured, or in any way compromised. If damage is suspected, contact Abbott Medical Technical Support (page 80) for return instructions.

Do not use the system after the expiration (use by) date printed on the sales package label and sterile package label.

## Disposal

After use, this product may be a potential biohazard. Dispose of the loading tool, delivery catheter and packaging following normal hospital procedures and local laws and regulations.

## Environmental and Medical Therapy Hazards

Abbott Medical devices are equipped with special shielding and filters which significantly reduce the adverse effects of electromagnetic interference (EMI) on the operation of the LP.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the LP inhibits or reverts to asynchronous operation while in the presence of EMI, the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments which could adversely affect the operation of the LP, including areas protected by a warning notice preventing entry by pacemaker patients.

### Medical Procedures and Environments

In general, pacemaker patients should not be exposed to hospital equipment that produces high electromagnetic field strength signals, such as diathermy machines and electrosurgical units. Exposure to devices that generate strong electric or magnetic interference (EMI) could cause LP reset, malfunction or damage. Contact Abbott Medical Technical Support (page 80) for additional information.

**External defibrillation.** The electronic circuitry in the LP provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the LP. Following defibrillation, ensure that the LP is operating correctly.

**Magnetic resonance imaging (MRI).** Leadless Pacemakers are conditionally safe for use in the MRI environment when used according to the instructions in the MRI-Ready Leadless System Manual.

**Ionizing Radiation.** Therapeutic ionizing radiation (for example, used in linear accelerators and cobalt machines) can permanently damage the LP's circuitry. The effect of ionizing radiation is cumulative; the potential for damage to the LP is proportional to the patient's total radiation dosage. If the patient must be exposed to ionizing radiation, protect the LP during the procedure with local radiation shielding. Before and after exposure to radiation, evaluate the LP operation to identify any adverse consequences.

**Transcutaneous electrical nerve stimulation (TENS).** To reduce the possibility of interference with LP operation, place the TENS electrodes close to one another and as far from the LP as possible. Before allowing unrestricted use of TENS in a home or other setting, screen the patient in a monitored environment for possible interaction.

**Therapeutic diathermy.** Avoid diathermy, even if the LP is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the LP.

**Electrosurgical cautery.** This can induce ventricular arrhythmias and fibrillation or may cause asynchronous or inhibited LP operation. If use of electrocautery is necessary, the current path and ground plate should be kept as far away from the LP as possible. The axis of the electrocautery should be perpendicular to the electrode axis. A bipolar cauterizer may minimize these effects. Following electrocautery, conduct a thorough assessment of the LP.

**RF ablation.** Delivery of intra-cardiac radiofrequency (RF) energy during an RF ablation procedure in patients with a cardiac implantable electronic device may cause:

- Pacing above or below the programmed rate

- Reversion to asynchronous operation
- LP electrical reset
- Premature triggering of the recommended replacement (RRT) indicator
- Permanent LP malfunction or damage

RF ablation risks may be minimized by:

- Programming an asynchronous, non-rate responsive pacing mode prior to the RF ablation procedure
- Avoiding direct contact between the ablation catheter tip and the LP
- Positioning the grounding patch/pad so that the current pathway does not pass through or near the LP (for example, placing the ground plate under the patient's buttocks or legs)
- Having a programmer system readily available
- Monitoring the patient during and immediately after the procedure
- Having external pacing or defibrillation equipment available

**Therapeutic ultrasound.** The LP should not be exposed to therapeutic levels of ultrasound energy, as the LP can inadvertently concentrate the ultrasound field and cause harm that might not be immediately detectable. Diagnostic ultrasound treatment is not known to affect the operation of the LP.

**Temporary pacing.** Care should be taken when implanting a new LP in conjunction with a temporary pacing lead to avoid any electrical or mechanical interaction.

### Patient Environments

Advise patients to exercise reasonable caution in avoidance of strong electric or magnetic fields. Exposure to these strong electric or magnetic fields could result in LP reset.

If the LP inhibits or reverts to asynchronous operation while in the presence of electromagnetic interference (EMI), the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the LP, including areas protected by a warning notice preventing entry by pacemaker patients.

**High-voltage transmission lines and equipment, arc or resistance welders, induction furnaces,** and similar equipment may generate substantial EMI fields which may interfere with LP operation.

**Communication equipment** such as microwave transmitters [1], linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with LP operation. Advise patients to move away from this equipment to resume normal LP operation.

**Home appliances** that are in good working order and properly grounded do not usually produce enough EMI to interfere with LP operation. Electric vibrators, razors, and hand tools held directly over the device may disturb LP operation.

**Security and Logistical Systems (SLS).** Advise patients that Security and Logistical Systems (SLS) emit signals that may interact with pacemakers. These systems include, Electronic Article Surveillance (EAS) systems, EAS Tag Deactivators, Radio Frequency Identification (RFID) Systems, and Metal Detectors like those at the point of sale and entrances or exits of stores, libraries, banks, etc., used to detect uniquely identifiable tags attached to objects for the purposes of security, or used to detect the presence of metal objects.

It is very unlikely that these systems will interact with their LP significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.

**No Pacer symbol.** Caution patients implanted with an LP to avoid areas marked with the No Pacer symbol.

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[1] Home appliance microwave ovens do not interfere with LP operation.

Figure 1. No Pacer symbol

**Cellular phones.** The LP has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of ISO 14117. This testing covered the operating frequencies (385 MHz-3 GHz). Based on the results of this testing, the normal operation of cellular phones should not affect the LP.

- Advise patients not to carry a cellular phone in a breast pocket or other location if they are over the LP. Some accessories for cellular phones may contain magnets, such as cases with magnetic clasps. See Pacing Rates Following Magnet Detection (page 76).
- Advise patients to avoid interference between cell phones or smart watches and the LP by keeping them at least 15 centimeters (6 inches) away from the LP.

**Portable electronic devices.**

- Advise patients not to carry electronic portable devices such as e-cigarettes, or key cards, credit cards or other items with magnetic strips in their breast pocket or near the heart.
- Advise patients not to carry earbuds or headphones in their breast pocket or near the heart, and not to allow earbuds or headphones to drape around the patient's neck so they hang on the chest. These devices may contain a magnet or magnetic material, or may emit RF signals that can interfere with the LP.

For further questions, contact Abbott Medical Technical Support (page 80).

**Environmental conditions.** Advise patients to avoid environments that may cause a sudden change in body temperature (e.g., hot tub or cold bath), which could affect rate response if Sensor mode is turned on.

The LP is designed to withstand absolute ambient pressures between at least 50 kPa (0.5 atm) and 304 kPa (3 atm). Advise patients to avoid environments that could subject the LP to atmospheric pressures outside of this range.

## Adverse Events

Potential complications associated with the use of the Aveir™ Leadless Pacemaker system are the same as with the use of single or dual chamber pacemakers with active fixation pacing leads including, but not limited to:

- Cardiac perforation
- Cardiac tamponade
- Pericardial effusion
- Pericarditis
- Endocarditis
- Valve damage or regurgitation
- Heart failure
- Pneumothorax/hemothorax
- Cardiac arrhythmias
- Diaphragmatic/phrenic nerve stimulation / extra-cardiac stimulation
- Palpitations
- Hypotension

- Syncope
- Cerebrovascular accident
- Infection
- Hypersensitivity reaction to device materials, contrast media, medications, or direct toxic effect of contrast media on kidney function
- Pacemaker syndrome
- Inability to interrogate or program the LP due to programmer or LP malfunction
- Intermittent or complete loss of capture, pacing or sensing (non-battery related)
- Oversensing
- Increased capture threshold
- Inappropriate sensor response
- Corrupted, intermittent, or loss of i2i communications
- Interruption of desired LP function due to electrical interference, either electromyogenic or electromagnetic
- Battery malfunction/ premature battery depletion
- Device-related complications:
  - Premature deployment
  - Device dislodgement/embolization of foreign material
  - Inability to release/re-dock of the LP from catheter
  - Helix distortion

- Additional surgery or intervention
- Death

As with any percutaneous catheterization procedure, potential complications include, but are not limited to:

- Vascular access complications, such as perforation, dissection, puncture, groin pain
- Bleeding or hematoma
- Thrombus formation
- Thromboembolism
- Air embolism
- Local and systemic infection
- Peripheral nerve damage
- General surgery risks and complications from comorbidities; such as, dyspnea, respiratory failure, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death

## Incident Reporting

If, in the course of use of this device, you have reason to believe that a serious incident occurred, please report it to the manufacturer. For customers in the European Union, report the serious incident to your national authority as well as to the manufacturer.

# Product Description

This manual provides instructions for use for the Aveir™ Leadless Pacemaker and Aveir™ Delivery Catheter.

Table 3. Product models

| Name | Model | Description | |
|---|---|---|---|
| Aveir™ Leadless Pacemaker | LSP201A | Leadless pacemaker, RA | Right atrial |
| | LSP202V | Leadless pacemaker, RV | Right ventricular |
| Aveir™ Delivery Catheter | LSCD201 | Delivery catheter | |

## Leadless Pacemaker

The Aveir™ Leadless Pacemaker (LP) provides bradycardia pacing as a self-contained pulse generator with built-in battery and electrodes for direct implantation into the target heart chamber (right atrium or right ventricle). Each LP is designed to provide single-chamber pacing as well as support pairing with another active co-implanted LP to provide dual-chamber pacing therapy.

As a leadless device, the LP does not need a connector, pacing lead, or pulse generator pocket. The LP is delivered to the target heart chamber percutaneously via the femoral vein using an Aveir™ Introducer and Aveir™ Delivery Catheter.

The proximal end of the LP has a feature for docking to delivery and retrieval catheters, providing for repositioning and retrieval capability.

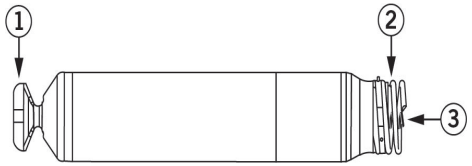
A distal non-retractable helix affixes the LP to the endocardium of the target heart chamber. Three additional features on the outside of the LP nosecone are designed to provide secondary fixation securement. The tip

electrode includes a single dose of dexamethasone sodium phosphate (DSP), intended to reduce inflammation.

Sensing and pacing occur between a distal electrode near the fixation helix and the external can of the LP. The LP senses local blood pool temperature to provide modulated pacing rates with changes in metabolic demand.

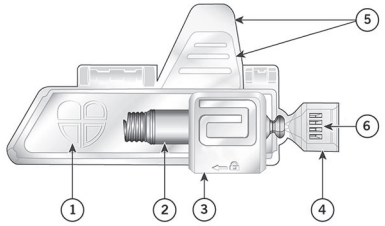
Each LP is supplied contained inside a loading tool to hold the LP until the implantation procedure.

Figure 2. LSP201A - LP proximal and distal features



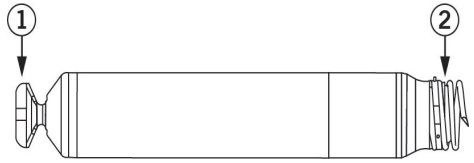

1. Docking button
2. Outer fixation helix
3. Inner helix tip electrode

Figure 3. LSP201A - LP inside the loading tool




1. Chamber icon (right atrium)
2. LP inside loading tool
3. White latch
4. Funnel
5. Curved wings
6. Docking cap retention feature

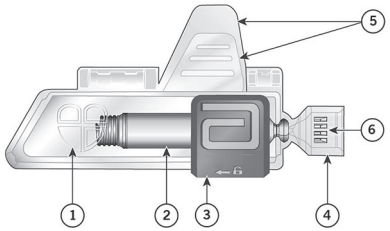
Figure 4. LSP202V - LP proximal and distal features




1. Docking button
2. Fixation helix [2]

[2] Distal dome tip electrode not pictured.

Figure 5. LSP202V - LP inside the loading tool




1. Chamber icon (right ventricle)
2. LP inside loading tool
3. Blue latch
4. Funnel
5. Curved wings
6. Docking cap retention feature

## Communication Between Pacemaker and Programmer

Each LP communicates bidirectionally with the programmer system via electrical signals transthoracicly conducted between the implanted LP's electrodes and skin electrodes applied to the patient's chest. The LP transmits signals using circuits and electrodes already provided for pacing, with data encoded in low-current pulses delivered during the heart's refractory period.

## Communication Between LPs (i2i™ Communication)

To support dual-chamber therapy, each LP communicates beat-to-beat with a paired, co-implanted LP. Through i2i™ (implant-to-implant) communication via the electrodes already provided for pacing, electrical signals are output with data encoded in a series of short pulses delivered concurrently with each local paced or sensed event.

Generally, in a dual-chamber operating mode, the RV-implanted LP manages overall pacing and timing functions, while the pacing and timing functions of the RA-implanted LP are managed indirectly by the

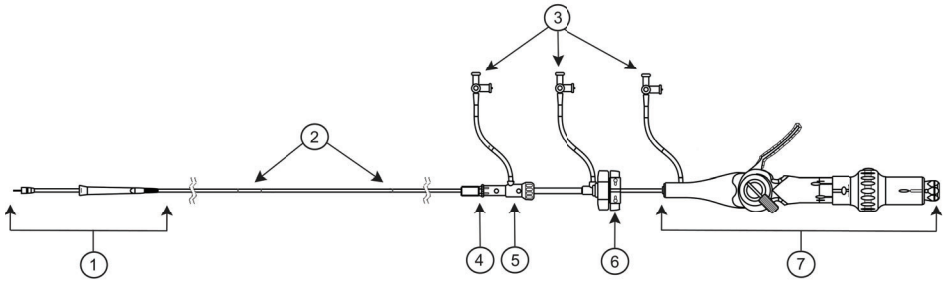
RV-implanted LP. The RV-implanted LP's activity sensor determines the target sensor-indicated rate to be used by both LPs and the rate is set (or updated) through i2i communication.

In the event of a sustained disruption in communication between the co-implanted LPs, both LPs will automatically revert to ventricular-only pacing mode until communication is restored.

## Delivery Catheter

The Aveir™ Delivery Catheter includes a steerable delivery catheter, an integrated guiding catheter with a protective sleeve designed to protect an attached LP's fixation helix and electrode, and a valve bypass tool to dilate the 25 Fr inner diameter (ID) introducer sheath hemostasis valve and advance the system into the femoral vein.

Figure 6. Delivery catheter



1. Delivery catheter tip (page 26)
2. Guide catheter with marker bands
3. Flush/irrigation ports
4. Valve bypass tool lock
5. Valve bypass tool
6. Guide catheter hub lock
7. Delivery catheter handle (page 25)

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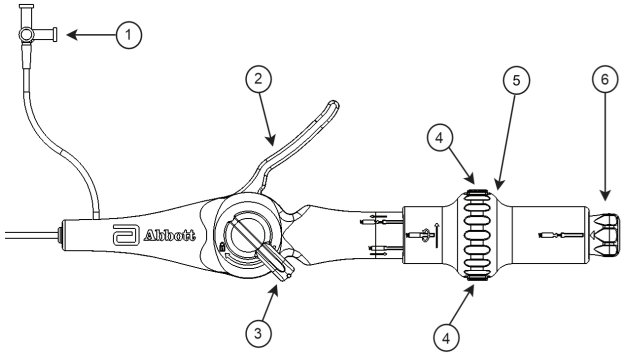
The delivery catheter provides a means to perform these actions during the implantation procedure:

- Attach and dock an individual LP to the delivery catheter, pre-loaded in a loading tool
- Position the protective sleeve over the LP's fixation helix and lock the sleeve into place
- Utilizing minimally invasive techniques, advance the LP from an access site in the groin through the femoral vein into the target heart chamber
- Hand inject contrast solution through the guide catheter flush port to its distal tip
- Adjust the protective sleeve's position to expose the flexible section of the delivery catheter
- Electrically map the endocardium with the docked LP to assess appropriateness of the implant site
- Position the LP and rotate it to affix the LP fixation helix to the endocardium
- Undock the LP from the delivery catheter leaving the LP tethered to the delivery catheter to measure thresholds with minimal force transmission from the delivery catheter
- Re-dock to the delivery catheter, unscrew and reposition the LP if necessary for acceptable thresholds
- Release the LP from the tethers of the delivery catheter, fully deploying the LP implanted in the endocardium

Apart from the docking mechanism, the delivery catheter and its control system (handle) have the same operating principle as a conventional steerable catheter and control system.

Figure 7. Delivery catheter handle




1. Flush/irrigation port
2. Deflection lever
3. Deflection brake
4. LP control knob release buttons
5. LP control knob
6. LP release knob

Figure 8. Delivery catheter tip


1. LP
2. Tethers
3. Docking cap
4. Protective sleeve

## Compatible Devices

The LP and delivery catheter are intended to be used with this compatible introducer:

Table 4. Compatible device

| Name | Model | Description |
|---|---|---|
| Aveir™ Introducer | LSN25301<br>LSN25501 | 25 Fr ID hydrophilic-coated introducer sheath<br>Refer to the Aveir™ Introducer Instructions for Use. |

**CAUTION: Do not use the LP and delivery catheter with other introducers; use with other introducers has not been tested and can damage the devices.**

The LP is intended to be used with these compatible programmer system components:

Table 5. Compatible devices

| Name | Model | Description |
|---|---|---|
| Aveir™ Link Module | LSL02 | Programmer communication unit<br>Refer to the Aveir™ Link Module Instructions for Use. |
| Merlin™ PCS | 3650 | Patient care system<br>Refer to the Merlin™ Patient Care System User's Manual. |

**CAUTION: Do not use the LP with other programmer systems because this could result in no programming or incorrect programming.**

**CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.**

If retrieval of an implanted LP becomes necessary, use this compatible retrieval catheter:

Table 6. Compatible device

| Name | Model | Description |
|---|---|---|
| Aveir™ Retrieval Catheter | LSCR111 | Retrieval catheter<br>Refer to the Aveir™ Retrieval Catheter Instructions for Use. |

**CAUTION: Retrieval of the LP with other tools has not been tested.**

### Package Contents

Each LP and delivery catheter are supplied in individual sterile packs:

- A pack that contains a tray that holds the LP inside its loading tool.
- A pack that contains a tray that holds the delivery catheter.

The trays are sterile (via ethylene oxide), for single-use only, and may not be re-sterilized.

If the sterile package has been compromised, do not use it. Contact Abbott Medical Technical Support (page 80) for return instructions.

## Instructions for Use

This section provides instructions for preparing for the implantation procedure, implanting the LP, repositioning or retrieving the LP, and patient follow-up.

Read all instructions and package labels before use because they contain essential safety information. If instructions or labels appear to be altered or illegible, do not use the devices. Contact Abbott Medical Technical Support (page 80) for return instructions.

The medical procedures described in this section are the recommended best practices for the use of the delivery catheter and implantation of the LP. Actual procedures are at the discretion of the physician.

## Room and Patient Preparation

Implantation should be performed only under these conditions:

- The staff plans for and can recognize perforation and tamponade that might occur during the implant procedure, including availability of cardiothoracic surgery facilities, an in-laboratory pericardiocentesis tray, immediate access to echocardiogram, and staff training to recognize and respond to the emergency.
- Proper emergency facilities are available for cardioversion, defibrillation and cardio-pulmonary resuscitation.
- Proper equipment is available for high resolution fluoroscopy, including the ability to record and save images, to zoom, and to obtain images in multiple projections. For adequate visualization of the dynamic movement of the devices during the procedure, a minimum frame rate of 15 FPS is recommended.
- Four heparinized saline bags and lines are required; two lines are pressurized and two are gravity dripped. Have sterile extension tubing available for use with each line, if needed.
- Patient is positioned on the table to allow multi-plane fluoroscopic visualization from the femoral vein to the heart.

  **CAUTION: During the procedure, appropriate anticoagulant therapy should be considered to reduce potential thrombus formation.**

- A Merlin™ PCS is connected to an Aveir™ Link Module. This is required for this procedure.
  - Place standard CE-marked ECG skin electrodes on the patient's cleaned and prepped chest prior to draping. Refer to the Aveir™ Link Module Instructions for Use for locations and more information.
  - Turn on the Merlin PCS, press Interrogate on the screen, and ensure the programmer is displaying surface ECG before beginning the implantation procedure. Refer to the Merlin™ Patient Care System User's Manual for programmer instructions for use and the Aveir™ Leadless Pacemaker Help Manual for LP programming information.

## Procedural Overview

This section provides an overview of the single-chamber and dual-chamber Aveir™ leadless pacemaker (LP) implantation procedures, followed by sections containing detailed instructions for each step.

### Single-Chamber Implant Procedure Overview

A single-chamber LP implant procedure consists of these main steps:

- Prepare the delivery catheter and the LP for the implantation procedure as described in Preparing the Devices for Implantation (page 33):
  - Review carefully the instructions for general handling of the LP and delivery catheter (page 33).
  - Access the entry site (page 35).
  - Remove the LP and delivery catheter from their sterile packs (page 35).
  - Load the LP onto the delivery catheter (page 36).

  - Flush the delivery catheter (page 37).
- Implant the LP into the target heart chamber following the procedures described in Implanting the Leadless Pacemaker (page 38):
  - Insert the LP and delivery catheter.
  - Confirm Communication with the Leadless Pacemaker (page 40)
  - Program the appropriate single-chamber settings. Refer to the Aveir™ Leadless Pacemaker Help Manual for LP programming information.
  - Navigate the guide catheter and position the LP in the target location (page 41).
  - Retract the protective sleeve to expose the LP, then gather electrical mapping measurements (thresholds, sensing, impedance and CEGM). (page 40)
  - Affix the LP to the cardiac tissue, enter tether mode, then perform a deflection test to verify fixation (page 48).
  - Assess the pacing and sensing thresholds, and collect commanded EGM (CEGM) to assess current of injury (COI) (page 50). Adjust the settings, as needed, to confirm acceptable performance.
  - If necessary, reposition the LP (page 54). Once repositioned, reconfirm communication with the LP, then re-affix the LP and retest fixation. Re-assess pacing and sensing thresholds, CEGM, and COI. Adjust the settings, as needed, to confirm acceptable performance.
  - Deploy the LP (page 53).

Once the single-chamber implant procedure is completed; final programming can be performed.

## Dual-Chamber Implant Procedure Overview

- A dual-chamber LP implant procedure consists of these main steps:
- **Complete the implant procedure for the first LP** described in Single-Chamber Implant Procedure Overview (page 30). Either chamber may be implanted first.
- Obtain a new delivery catheter.

  **WARNING: Dual-chamber implant procedures should use a new delivery catheter for each target chamber implantation. Using the same catheter to implant LPs within multiple chambers could lead to catheter damage and result in spontaneous release of the LP from the catheter, inability to release the LP from the catheter, or tether fracture.**
- Prepare the second delivery catheter and the second LP to be implanted for the procedure as described in Preparing the Devices for Implantation (page 33):
  - Review carefully the instructions for general handling of the LP and delivery catheter (page 33).
  - Select and access the entry site (page 35).
  - Remove the LP to be implanted from its sterile pack (page 35).
  - Load the LP onto the delivery catheter (page 36).
  - Flush the delivery catheter (page 37).
- Implant the LP into the target heart chamber following the procedures described in Implanting the Leadless Pacemaker (page 38):
  - Insert the LP and delivery catheter (page 38).
  - Retract the protective sleeve to expose the LP, then confirm communication with the LP. (page 40)
  - Navigate the guide catheter and position the LP in the target location (page 41).

- Retract the protective sleeve to expose the LP, and gather electrical mapping measurements (thresholds, sensing, impedance and CEGM).
- Affix the LP to the cardiac tissue then perform a deflection test to verify fixation (page 48).
- Assess the pacing and sensing thresholds and CEGM (page 50).
- Pair the LPs and program the appropriate dual-chamber settings. Refer to the Aveir™ Leadless Pacemaker Help Manual for LP pairing and programming information.
- Assess implant-to-implant (i2i) performance (page 50), and adjust the i2i settings, as needed, to confirm acceptable performance.
- If necessary, reposition the LP (page 54). Once repositioned, re-gather electrical mapping measurements (thresholds, sensing, impedance and CEGM), then re-affix the LP and retest fixation. Re-assess pacing and sensing thresholds, CEGM, and COI. Adjust the settings, as needed. Confirm acceptable i2i performance while in a dual chamber mode.
- Release and fully deploy the LP (page 53).

Once the dual-chamber implant procedure is completed; final programming can be performed.

## Preparing Devices for Implantation

This section provides instructions for preparing the LP and delivery catheter for the implantation procedure.

NOTE: Do not alter the system in any way.

### General Instructions for Delivery Catheter Handling

**Maintain introducer position.** Always maintain introducer position when inserting, manipulating, or withdrawing the delivery catheter through the introducer.

**Use fluoroscopy.** Use fluoroscopy to guide the delivery catheter to the desired cardiovascular location and whenever the delivery catheter is being advanced, retrieved or manipulated.

**Avoid excessive bending.** Keep the catheter handle in line with the catheter shaft because excessive bending of the catheter can affect its performance.

**Use Manipulation Controls.** Utilize the available controls and features (deflection lever, deflection brake, protective sleeve) to provide stable and accurate placement of the LP.

Do not implant an LP without assessing the structure and orientation of the respective chamber, using contrast, ICE or other means common to clinical practice.

**Monitor torque performance.** Monitor torque from the control knob to the LP and proceed slowly and with caution. Refer to "Affix Leadless Pacemaker" section for procedural details..

## General Instructions for Leadless Pacemaker Handling

**Keep loading tool closed.** Do not open the loading tool until the LP is properly attached to the tethers of the delivery catheter. After the LP is attached, keep the loading tool sterile should it be needed for reloading.

**Avoid contact with helix.** Avoid touching the LP and contact with surgical towels or drapes because deformation of the helix may result.

**Do not immerse.** Do not immerse the LP tip electrode within the helix in any fluid prior to implantation; immersion of the electrode may cause a small amount of steroid to be prematurely eluted.

**Avoid excessive handling.** Avoid touching or handling the LP tip electrode, because this could damage its low-polarization coating. Avoid handling the LP with any surgical tools such as hemostats, clamps or forceps.

**Use the introducer.** Never introduce the LP into the femoral vein without using the introducer.

**Ensure helix is covered.** Always ensure that the LP fixation helix is covered by the protective sleeve when advancing the LP through the peripheral vasculature into the target heart chamber, while advancing or withdrawing through Introducer, and during primary positioning maneuvers.

## Vein Selection and Access

1. Select the entry site. The suggested entry site is the femoral vein via a percutaneous venous puncture. Avoid implantation through femoral veins with severe angulation, tortuosity or calcification.
2. Insert and flush the introducer according to the Aveir™ Introducer Instructions for Use, then connect a gravity drip line of room temperature heparinized saline to the valve bypass irrigation port.

## Remove Devices from the Sterile Packs

To remove the delivery catheter:

1. Remove the sterile pouch containing the delivery catheter from the outer storage packaging.
2. Inspect the sterile pouch carefully to ensure that the delivery catheter is free from damage and the sterile pouch has not been opened, tampered with, punctured or in any way compromised. Contents are sterile if the sterile pouch is unopened and undamaged.
3. Open the sterile pouch and pass the tray or the delivery catheter onto the sterile field using sterile technique.
4. Remove the delivery catheter from the tray.
5. Pass the empty tray off the sterile field.

To remove the LP and loading tool:

1. Remove the LP and loading tool tray from the outer storage packaging.
2. Inspect the sterile tray carefully to ensure it has not been opened, tampered with, punctured, or in any way compromised. Contents are sterile if the sterile trays are unopened and undamaged.

   NOTE: The package's outer tray can be opened in nonsterile surroundings. However, when opening the inner tray, complete sterile technique must be observed.

3. Open the outer tray and pass the inner tray onto the sterile field using sterile technique.
4. Remove the loading tool that contains the LP from the inner tray and place onto the sterile field. Keep the loading tool closed.
5. Pass the empty tray off the sterile field.

NOTE: If the LP, while still sterile, becomes displaced from its appropriate position in the loading tool, it can be reloaded back into the loading tool. See Reloading the Leadless Pacemaker into the Loading Tool (If Necessary).

## Load the LP onto the Delivery Catheter

To load the LP onto the delivery catheter:

1. Ensure the delivery catheter's valve bypass tool is positioned toward the handle.
2. Ensure the delivery catheter's LP control knob is set in the LP loading position, commonly referred to as the short tether position, and indicated by the black marker on the handle
3. Ensure that the tethers are misaligned by extending and rotating the LP release knob counter-clockwise revealing a red indicator between the LP release knob and the LP control knob).
4. With the loading tool locked, fully insert the catheter tethers and docking cap into the loading tool (the docking cap should be retained in the loading tool). Re-align the tethers by rotating the release knob clockwise 1/2 turn until the red indicator is no longer visible. If the tethers are successfully inserted into the docking button and re-aligned, they will retain the connection between the LP and the delivery catheter.
5. If the connection was not successful, reattempt connection by repeating step 3.
6. Once the catheter is attached to the LP, slide the latch of the loading tool in the direction of the arrow, which is away from the funnel to the unlock position. After unlocking, press the curved wings together to open the loading tool and expose the LP.

7. Gently remove the LP from the loading tool by holding up the delivery catheter, taking care to protect the LP's fixation helix. Keep the loading tool in the sterile field should it be needed for reloading later in the procedure.
8. Ensure the LP is in line with the docking cap. Dock the LP to the catheter by pulling back on the LP control knob on the back end of the delivery catheter handle until an audible click is heard. Visually verify that the LP is mated to the delivery catheter.

   NOTE: The LP should be removed from the Loading Tool before the LP is docked.

9. If re-docking is necessary, undock the LP from the delivery catheter by depressing both of the LP control knob unlock buttons and sliding the LP control knob towards the black short tether line on the handle. Re-dock the LP and re-inspect the junction to ensure the LP is properly mated.
10. Advance the protective sleeve to cover the LP's fixation helix by approximately 2-4 mm. Lock the protective sleeve in place by rotating the hub lock clockwise in the directions of the arrow.
11. Manually deflect the delivery catheter and note the plane of deflection relative to the Deflection Lever on the delivery handle. Apply the Deflection Brake while deflected to confirm it is functioning properly.

## Flush the Delivery System

Flush the irrigation systems.

NOTE: The delivery catheter and guide catheter irrigation ports are flushed with pressure lines. The introducer and valve bypass irrigation ports are flushed with drip lines. Use 2,000 units of heparin per 1-liter 0.9% saline bag.

1. Flush the delivery catheter. Connect a pressurized line of room temperature heparinized saline to the delivery catheter irrigation port. Flush the delivery catheter completely until all the air is evacuated and saline is flowing freely at the distal tip.

2. Flush the guide catheter. Connect a pressurized line of room temperature heparinized saline to the 3-way stopcock. Flush the guide catheter completely until all the air is evacuated and saline is flowing freely at the end.
3. Flush the valve bypass tool. Connect a drip line of room temperature heparinized saline to the valve bypass irrigation port. Flush the catheter valve bypass tool completely until all the air is evacuated and saline is flowing freely at the end.

Once flushed, set the drip rate to 1 drop per second. Maintain continuous flush during the entire procedure.

## Implanting the Leadless Pacemaker

This section provides instructions for implanting the LP into the target heart chamber.

Use one or more of the following prior to implantation of the LP: fluoroscopy with contrast to opacify the heart chambers, Intra Cardiac Echo (ICE), or other standard means to pre-assess the cardiac structures and orientation.

### Insert the Leadless Pacemaker and Delivery Catheter

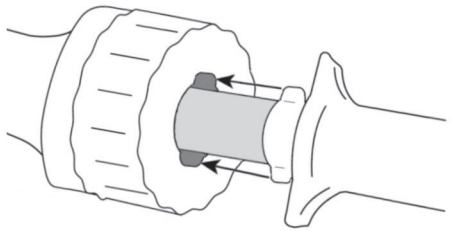
To insert the LP and delivery catheter:

1. Orient the delivery catheter so that the Deflection Lever is facing upward. This ensures that the catheter will deflect orthogonally when viewed in right anterior oblique (RAO) 30 degree fluoro view, which is the recommended primary working view.
2. Ensure the protective sleeve fully covers the LP's fixation helix and is locked into place with the hub lock.

   NOTE: To avoid compromised guide catheter irrigation, do not advance the protective sleeve by more than 1 cm beyond the helix of the LP.

3. Slide the valve bypass tool over the protective sleeve and LP until it completely covers the LP's fixation helix. Ensure all the air is evacuated and saline is flowing freely at the end.
4. Insert the valve bypass tool into the introducer sheath all the way to the hub, making sure to align the tabs of the valve bypass tool with the slots of the introducer.
5. After aligning and inserting the valve bypass tool into the introducer, lock the valve bypass tool into the introducer by rotating clockwise approximately one quarter turn.

Figure 9. Insert the valve bypass tool into the introducer and rotate clockwise 1/4 turn to lock in place



6. Under fluoroscopic guidance, slowly advance the delivery catheter and guide catheter until the LP reaches the junction of the inferior vena cava (IVC) and the right atrium.

   NOTE: Use the grey marker band on the guide catheter as an indication of when the LP is inside or outside of either the 30 or 50 cm introducers.

**CAUTION: Advancing the delivery and guide catheter through the introducer can create transient vacuum-like pressures that could lead to air aspiration or catheter damage. To prevent air aspiration, either temporarily maximize the flow rate of the heparinized saline irrigation to the valve bypass flush/irrigation port or temporarily switch to a 30cc syringe of heparinized saline connected to the flush/irrigation port. After the protective sleeve has exited the introducer, resume normal maintenance irrigation.**

**CAUTION: Do not independently advance the delivery catheter without also advancing the guide catheter as this may advance the LP outside of the protective sleeve, leaving the LP helix exposed and resulting in damage to the LP helix.**

**CAUTION: When the LP is in the heart, the delivery catheter should only be manipulated by a single operator.**

## Confirm Communication with the Leadless Pacemaker

Expose the LP by unlocking the hub lock and retracting the protective sleeve. Establish communication with the LP and program the LP as desired for the implantation procedure using the programmer system.

An LP's initial operating mode when first introduced into the bloodstream is demand pacing:

| | Right ventricle (RV) | Right atrium (RA) |
|---|---|---|
| Initial mode | VVI | AAI |

NOTE: Consider programming the LP with high pacing amplitude before entering the designated chamber. Ensure that the protective sleeve radiopaque marker is positioned distal to the LP's fixation helix, fully covering the LP so that the helix is protected. Lock the protective sleeve using the hub lock.

Refer to the Aveir™ Leadless Pacemaker Help Manual for LP programming information.

**CAUTION: Pacing output from an existing (already implanted) ventricular LP may be inhibited by detection of pacing outputs from a new LP as it is being implanted leading to possible loss of ventricular pacing. Precautions should be taken for pacemaker-dependent patients, such as programming the existing ventricular LP to VOO.**

NOTE: The LP communicates with the Aveir™ Link Module via conducted communication. As with all communication methods, this can be affected by LP orientation and electromagnetic interference. Refer to the Aveir™ Link Module Instructions for Use for more information.

## Position the Guide Catheter and Leadless Pacemaker

To position the guide catheter and LP:

**WARNING: To reduce risk of perforation when implanting an LP in the right ventricle, consider a lower- to mid-septal site for placement of the LP, especially if there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle. Situations where this may be present include, for example, the use of oral steroids, a history of right ventricular infarction, or the presence of Arrhythmogenic Right Ventricular Dysplasia (ARVD - also known as arrhythmogenic cardiomyopathy).**

NOTE: Confirm septal orientation in the right ventricle by viewing the system in the left anterior oblique (LAO) 30 degree view.

1. Ensure that the protective sleeve radiopaque marker is positioned distal to the LP's fixation helix, fully covering the LP so that the helix is protected. Lock the protective sleeve using the hub lock.
2. Slowly advance the delivery catheter with LP and guide catheter into the target chamber, actuate the deflection lever and rotate the catheter shaft as needed to provide the appropriate orientation.

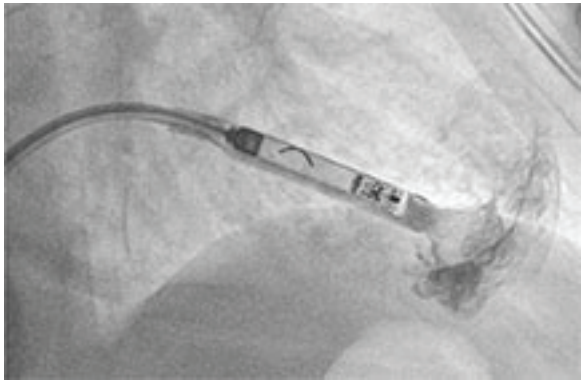
| | Right ventricle (RV) | Right atrium (RA) |
|---|---|---|
| Orientation | Orient toward the right ventricle to cross the tricuspid valve | Orient toward the right atrial appendage |

3. Visualize catheter positioning in RAO 30 fluoroscopic view.

   **WARNING: Do not apply excessive forward force to the delivery catheter, because perforation can occur.**

4. Use a combination of gentle forward force, deflection and catheter pullback to help the system enter the target heart chamber. Once in the heart chamber, stop advancement of the system.
5. Using a 20-cc syringe, flush diluted contrast through the 3-way stopcock irrigation port located on the hub lock to opacify the heart chamber.
6. **For an RV LP implant,** visualize the system in the LAO 30 view to confirm alignment with the tricuspid valve and septal orientation.
7. **For an RA LP implant**, visualize the system in RAO 30 and LAO 30
8. Continue advancing the system until the tip is approximately 1 to 2 cm from the endocardium by advancing the guide catheter shaft and applying deflection on the delivery catheter.

Figure 10. Protective sleeve covering the LP with hand injection of contrast showing the position in the RV approximately 1 to 2 cm away from the endocardium, in RAO 30 view.



9. Confirm the desired position by opacifying the heart chamber.

NOTE: Billowing of protective sleeve indicates contact with a cardiac structure and excessive forward pressure should always be avoided. Diluted contrast can be injected through the protective sleeve to confirm device location at the desired implant site.

**WARNING: Advancing the LP and protective sleeve to the endocardium could lead to perforation. The protective sleeve should be fully retracted so that the catheter has maximum flexibility before advancing the LP to the desired position in the endocardium.**

10. Check the position in the RAO 30 and LAO 30 views to confirm the desired location.

    NOTE: While choosing an implant site, consideration needs to be given to distance and angles between the two devices for i2i communications (see Brady help manual).

    The preferred implant site should be confirmed in LAO view

| | Right ventricle (RV) | Right atrium (RA) |
|---|---|---|
| Implant site | Lower- to mid-septal area | Base of right atrial appendage |

11. Unlock then retract the hub of the guide catheter all the way back allowing maximal delivery catheter flexibility and fully exposing the LP (see the following illustrations).

Figure 11. Hub of guide catheter withdrawn back to the handle

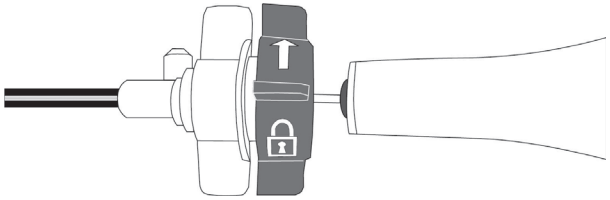
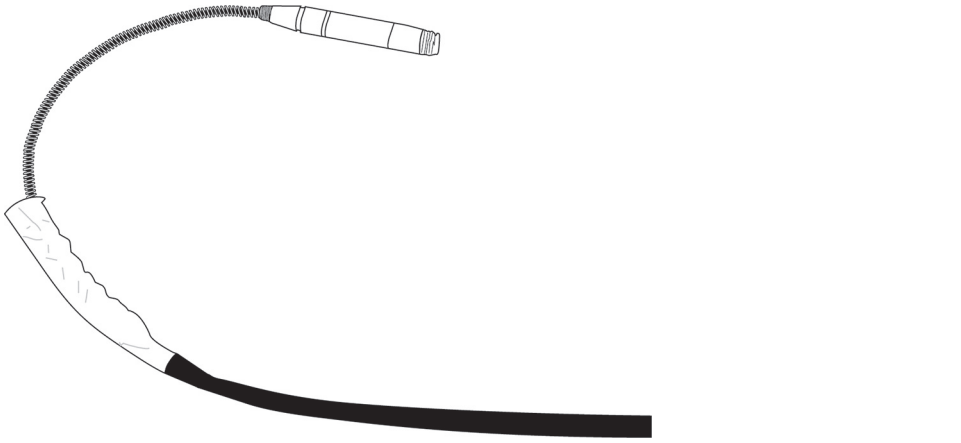


Figure 12. Deflected distal tip of delivery catheter



**WARNING: Unintended movement could lead to perforation or entanglement. Maintain the LP position by holding the delivery catheter handle against the patient table so that relative movements can be made in a controlled manner. Slowly pull back the guide catheter protective sleeve.**

**WARNING: Advancing the LP and protective sleeve to the endocardium could lead to perforation. The protective sleeve should be fully retracted so that the catheter has maximum flexibility before advancing the LP to the desired position in the endocardium.**

12. Before anchoring, carefully inspect the fixation helix while the LP is in the heart chamber to look for any helix deformation or stretching. If helix deformation or stretching is observed, take out the catheter and remove the LP, then replace it with a new LP.
13. With the LP attached to the delivery catheter and the protective sleeve completely retracted, slowly advance the LP to the desired position in the heart chamber with gentle forward pressure. Confirm contact with the endocardium by noting movement of the distal section of the delivery catheter with the cardiac cycle.

    **WARNING: Do not apply excessive forward force against the endocardium with the LP, because this could result in perforation.**
14. Confirm target implant site for LAO view.

## Perform Test

Perform electrical mapping test to confirm adequate forward contact pressure of the LP and viability of implant site:

1. After confirming movement of the LP with the cardiac cycle, use the programmer to obtain pacing, sensing, impedance and commanded EGM (CEGM) measurements per physician preference:

2. Take at least two measurements to confirm existence of clinically acceptable values:
   - If the mapping measurements are acceptable: proceed to the next step of the implant procedure, Affix the Leadless Pacemaker (page 48).
   - If the mapping measurements are unacceptable: use the control knob to rotate counterclockwise and pull back slightly on the delivery catheter until the LP is not in contact with the endocardium. Slightly deflect or un-deflect the delivery catheter and slowly advance the delivery catheter until contact can be reconfirmed by visualizing movement of the catheter with the cardiac cycle. Repeat step 1.

     **CAUTION: Confirm acceptable mapping measurements by making contact with the endocardium prior to affixing the LP to the endocardium to avoid unnecessary repositioning after LP fixation.**

     NOTE: Consider the mapping measurements in totality because the presence of current of injury in the CEGM during mapping could influence the pacing and sensing results.

## Affix the Leadless Pacemaker

To affix the LP:

1. After confirming acceptable mapping measurements, unlock the deflection lever and release catheter deflection to improve torque response and catheter flexibility.

   **CAUTION: Release all deflection just prior to and during rotation of LP control knob. Failure to release deflection could adversely affect procedural safety and catheter performance for implantation and repositioning.**
2. Visualize the curve of the catheter down to the inferior vena cava (IVC) to confirm slight movement in the catheter synchronized with the cardiac movement; excessive buckling may indicate that excessive forward force is being applied to the endocardium.

3. Under fluoroscopy with both the LP and protective sleeve visible on the fluoro screen, slowly turn the LP control knob clockwise while visualizing the radiopaque marker on the LP and counting the turns of that radiopaque marker.

   NOTE: Turns of the control knob will not necessarily match turns of the LP during implantation. An audible response of the control knob, or click, can be used as an indicator of rotational handle speed. Torque is not necessarily transmitted 1:1 from the control knob to the LP, so always proceed slowly and with caution. Do not exceed 1 $^{1}/_{2}$ turns of the LP radiopaque marker.

   NOTE: Keep the catheter shaft straight because bends in the proximal section near the handle can affect torque transmission to the LP.

   **CAUTION: Do not rotate the LP while it is still covered by the protective sleeve, as this could result in damage to the LP or protective sleeve.**

4. Immediate movement of chevron within first click may indicate inadequate forward pressure so advance the catheter no more than 1mm to ensure adequate forward pressure for helix engagement.
5. If there is no observed rotation of the radiopaque marker on the LP after one half turn of the LP control knob, do not continue to rotate. Ensure catheter deflection is off (unlocked and released) prior to turning the control knob.

   **CAUTION: Failure to rotate could result from tortuous catheter position or tissue calcification. Turn the control knob an equal number of counterclockwise rotations. Adjust the catheter and LP position, then attempt to affix the LP again.**

6. Continue to turn the control knob slowly until you have visualized a minimum of 1 $^{1}/_{4}$ turns and a maximum of 1 $^{1}/_{2}$ turns of the LP radiopaque marker. Do not exceed rotation of the LP radiopaque marker beyond 1 $^{1}/_{2}$ turns when affixing, because this may lead to perforation.

NOTE: During implantation impedance measurements may be taken and generally show an increase as helix is fixated into tissue.

7. Anchor to the target site and proceed to tether mode as soon as possible to minimize the time the LP remains docked.

   To establish tether mode, first grasp and brace the control knob, depress the 2 white unlock buttons on either side of the knob. Second, with the other hand, grasp the white handle and slowly pull back on the delivery catheter while keeping the control knob fixed. Do not advance the control knob forward on the delivery catheter.

   **CAUTION: If resistance is met, do not proceed because there may be a buildup of residual torque. Fully dock the LP and apply 2 clicks of counterclockwise rotation to the control knob, then reattempt to enter tether mode. If resistance is still encountered, ensure the LP is fully docked, apply counterclockwise rotation until the LP is un-affixed, cover the LP with the protective sleeve, then pull the LP with delivery catheter out of the patient. Obtain a new delivery catheter before continuing the procedure.**

8. It may be necessary to deflect and lock the delivery catheter either to move the docking cap away from the tricuspid valve to reduce the potential for ectopy or to maintain a coaxial orientation between the docking cap of the catheter and the docking button of the LP.

   **WARNING: Repositioning of the LP after fixation may lead to perforation/perioperative pericardial effusion.**

## Test Fixation and Assess Electrical Performance

To test fixation and assess electrical performance:

1. In tether mode, perform a gentle test to verify LP fixation.

**For RV Implant:** Deflection test should be performed in short tether mode by gently depressing the deflection lever to deflect the delivery catheter 30 to 45 degrees while visualizing LP movement. Partially apply the deflection brake to dampen the movement of the delivery catheter during the deflection test. The proximal end of the LP (docking button) should move with the docking cap of the delivery catheter while the LP helix remains fixed. Return to long tether mode while performing electrical measurements.

**For RA Implant:** Pull back the delivery catheter into long tether mode, remove the slack in the tethers and apply gentle tension to the LP. Long tether mode is the preferred mode for making the electrical measurements. Once the measurements are complete slack may be returned to the tether in order to simulate a state of free LP movement.

2. Use the programmer to obtain pacing, sensing, impedance, and CEGM per physician preference for assessing viable cardiac tissue for pacing. These measurements may become sub-optimal immediately after fixation. However, they are expected to improve with time as current of injury diminishes. If pacing capture thresholds are initially elevated, testing using a longer pulse width may help identify downward trending and avoid unnecessary repositioning. Refer to the Aveir™ Leadless Pacemaker Help Manual for LP programming information.

   Abbott Medical recommends (at pulse width 0.4 ms):

| | Right ventricle (RV) | Right atrium (RA) |
|---|---|---|
| Pacing capture threshold | ≤ 1.25 V | ≤ 3.0 V |
| Sensing amplitude | R-wave amplitude ≥ 5.0 mV | P-wave amplitude ≥ 1.0 mV |

3. Assess for unintentional diaphragmatic contraction by pacing at maximum output.

   Allow enough time (up to 20 minutes) for pacing thresholds to stabilize to an acceptable range in tethered mode before considering re-positioning. Consider mapping measurements and how the current of injury in the CEGM could be influencing the electrical performance. If values worsen, in the absence of LP manipulation by catheter, do not expect them to improve over time.

   **WARNING: If the LP does not capture at maximum pulse amplitude and pulse width (6.0 V/1.5 ms) or the impedance is >2000 Ω, consider the possibility that perforation has occurred, leave the LP in place, perform an echocardiogram and prepare for possible urgent pericardiocentesis.**

4. **For a dual-chamber procedure,** use the programmer to pair the two LPs while the second LP is in tether mode, which can be done in parallel with device measurements. Once the two LPs are paired, program the appropriate dual-chamber settings and assess i2i implant-to-implant performance. Adjust i2i settings as needed to achieve acceptable i2i performance and turn off any potential sources of EMI in the room. If acceptable i2i performance cannot be obtained, repositioning of an LP may need to be considered. Refer to the Aveir™ Leadless Pacemaker Help Manual for more information on performing i2i assessments.
5. After confirming satisfactory electrical performance, proceed to Deploy the Leadless Pacemaker. If electrical performance is unsatisfactory, gently alter the position of the LP and catheter with multiple fluoroscopic views while in tether mode and repeat measurements. Reposition if unsatisfactory electrical performance persists see Reposition the Leadless Pacemaker (page 54). Before repositioning, gently alter the position of the LP and catheter with multiple fluoroscopic views while in tether mode and repeat measurements.

   NOTE: If acceptable electrical measurements cannot be obtained, carefully pull the delivery catheter with the LP out of the patient and verify that the LP electrode is not obstructed by any blood clots or tissue. If blood clots or tissue are present on the LP electrode, carefully remove them. Repeat the procedure, insert the Leadless Pacemaker and Delivery Catheter (page 38).

## Deploy the Leadless Pacemaker

To deploy the LP:

1. Once integrity of fixation, pacing, sensing and impedance values have been determined to be acceptable, position the catheter so that it is in coaxial alignment with the LP, then remove all slack in the tethers. Using one hand, grasp and brace the control knob, with the other hand, pull the white LP release knob on the end of the delivery catheter handle away from the handle revealing the red band. Rotate the release knob $^1/_2$ turn counterclockwise to a full stop. The LP is expected to release from the tethers.

   **CAUTION: While retracting the delivery catheter to release the LP, observe release fluoroscopically. Do not apply excessive tension to the LP as this may cause the LP to become unaffixed from the implant site.**

2. If necessary, to facilitate release of the LP from the tethers, assess and align the docking cap of the catheter with the docking button of the LP. Confirm there is no slack in the tethers and that there is adequate separation between the LP and the docking cap. If the tether does not yet release, slowly advance the protective sleeve until it is proximal to docking button of the LP. Next, move from long to short tether mode to facilitate release. The redocking position is also an option should tether release still not occur. These steps are most helpful for situations with acute angles.
3. Once release of the LP is confirmed, slowly retract the docking cap into the protective sleeve by first releasing the deflection from the delivery catheter and pulling the docking cap back into the inferior vena cava (IVC) while fluoroscopically visualizing the LP.
4. Pull the docking cap back into the protective sleeve and then pull the entire catheter into the valve bypass tool.
5. Unlock the valve bypass tool by turning counterclockwise approximately a quarter turn and then remove it from the introducer.

6. After LP release, re-assess electrical performance and observe helix movement on fluoroscopy to confirm mechanical stability.

## Reposition the Leadless Pacemaker (If Necessary)

To reposition the LP:

1. Verify the protective sleeve is pulled back as far as possible so that the catheter has maximum flexibility.
2. Gently advance and, if necessary, deflect the delivery catheter so it is coaxial with the docking button of the LP. Slowly pull back on the LP control knob until you hear an audible click and visualize the LP mating with the delivery catheter.
3. Advance the protective sleeve to cover the majority of the LP being careful not to be in contact with cardiac tissue.
4. Remove deflection and note the position of the LP radiopaque marker by storing a high resolution fluoroscopic still image. Slowly rotate the LP control knob counterclockwise while fluoroscopically observing the LP radiopaque marker to ensure that the LP's fixation helix has rotated between two and three turns and is fully disengaged from the endocardium.

   **CAUTION: Do not pull on the delivery catheter until the LP is fully disengaged from the endocardium. Do not apply excessive forward pressure because perforation can occur.**

   **CAUTION: Release all deflection just prior to and during rotation of LP control knob. Failure to release deflection could adversely affect procedural safety and catheter performance for implantation and repositioning.**
5. After visualizing between two and three counterclockwise turns of the LP radiopaque marker, gently pull back the delivery catheter approximately 10 mm. Avoid excessive manipulation so that the LP helix remains in the correct position and away from any valve structures or chordae.
6. Advance the protective sleeve to fully cover the LP and the helix.

7. Verify the LP helix is fully covered by the protective sleeve.
8. Repeat the procedure, Implanting the Leadless Pacemaker (page 38).

## Reloading the Leadless Pacemaker into the Loading Tool (If Necessary)

If, while still sterile, the LP becomes displaced from its appropriate position in its designated loading tool, it can be reloaded back into the loading tool.

To reload the LP into the loading tool:

1. Confirm the appropriate loading tool (page 19) to be used to reload the LP.
2. Unlock the loading tool by sliding the latch away from the funnel.
3. Press the curved wings to open the loading tool.
4. Place the LP into the loading tool, confirming that the LP is seated with the docking button in its designated position near the funnel.
5. Close the loading tool.
6. Slide the latch toward the funnel to lock the loading tool.

## Retrieving the Leadless Pacemaker (If Necessary)

After the LP is released from the delivery catheter, the LP cannot be retrieved with the delivery catheter. To retrieve an implanted LP, use an Aveir™ Retrieval Catheter. Refer to the Aveir™ Retrieval Catheter Instructions for Use.

## Leadless Pacemaker Replacement

There are several methods for LP replacement. Refer to the Aveir™ Leadless Pacemaker Help Manual for programming information for the selected replacement method.

- Retrieve an existing active LP implant and then implant a new LP in the same heart chamber.

  **WARNING: Implanting a new LP after retrieval of an existing LP in a patient who has become pacemaker dependent is not recommended unless supplemental pacing is provided.**

  **WARNING: Attempted removal of an LP that has been implanted chronically could result in patient injury.**

  **CAUTION: After retrieval, use care to implant the new LP in a different location to avoid compromising the endocardial wall.**

  NOTE: If a chronically-implanted LP is unable to be removed, it can be permanently disabled and left inside the patient.

- Implant a new LP and permanently disable an existing active LP in the same chamber by following the LP replacement (box change) workflow.

  **WARNING: When implanting an additional LP as a replacement, position the new LP and fluoroscopically confirm in multiple views that the new LP is not in physical contact with the existing implant.**

  **CAUTION: Disable the existing LP only after the new LP is enabled and verified to be working correctly.**

- Implant a traditional pacemaker or ICD and then permanently disable an existing active LP using the programmer system.

  NOTE: If not being replaced, an implanted LP can be permanently disabled through a password-protected programmer screen (accessed from Tools > Maintenance > System). Contact Abbott Medical Technical Support (page 80) for additional information on how to complete this step.

  **WARNING: When implanting a traditional pacemaker or ICD in the presence of a permanently disabled LP, fluoroscopically confirm in multiple views that the transvenous leads associated with the new implant do not come in contact with the LP.**

## Cremation of a Deceased Leadless Pacemaker Patient

It is not necessary to explant an LP from a deceased adult patient prior to cremation, although the LP should be removed if possible. Rupture of the LP during cremation is normal and is not expected to present a significant risk to surrounding life or property.

Please carefully consider the following before proceeding with cremation:

1. Cremation to be conducted only if the LP is within the intact torso.
2. Cremation in an enclosed crematorium is preferred. If open-air cremation is conducted, bystanders and inflammable materials must be kept back at least 10 meters (33 feet).
3. Following cremation, remove the LP prior to further preparation of ashes.

## Burial of a Deceased Leadless Pacemaker Patient

It is not necessary to explant an LP from a deceased adult patient prior to burial, although the LP should be removed and returned to Abbott Medical if possible. The welded titanium enclosure is expected to remain

hermetic following burial, and in the unlikely event of a breach, the volume of potentially offensive substances contained within the LP is too small to present a significant risk to the surrounding environment.

### Disposition of an Explanted Leadless Pacemaker

Do not reuse an explanted LP.

1. Clean explanted equipment with +1% sodium hypochlorite, rinse with water, dry.
2. Contact Abbott Medical Technical Support (page 80) for return instructions. All explanted and removed LPs should be returned and analyzed by Abbott Medical, including those that have undergone cremation.

## Managing and Following Patients

This section provides instructions for managing and following patients with an implanted Aveir™ Leadless Pacemaker.

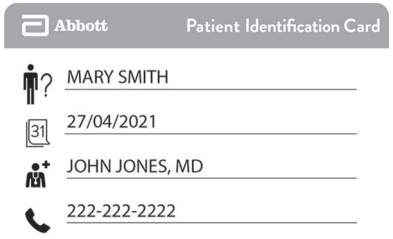
### Patient Education

Abbott Medical provides a booklet for patients to explain the LP and its operation, and to be used to supplement discussions with the patient, and spouse or other interested persons. To obtain other available patient education materials, contact Abbott Medical.

### Patient Identification Card

Complete the patient identification card provided in the outer box with the patient information, device information, implant date, and your name or healthcare facility information and contact phone number.

Figure 13. Patient Identification Card (front)




Obtain the peel-away label from the sterile package and apply it to the inner section of the card.

If the label is not available, fill out the device information (model number, serial number, and UDI number) and location of the implant in the designated inner section of the card.

Figure 14. Patient Identification Card (inner section)


Give the completed card to the patient to carry with them. This will serve as a temporary card until Abbott Medical mails a permanent card directly to the patient. To obtain a replacement card if a patient loses or damages their card, contact Abbott Medical Technical Support (page 80).

## Patient Follow-Up

Patients should be seen for follow-up per normal standard of care. If the patient experiences a spontaneous return of symptoms, it may be deemed appropriate for the patient to return for follow-up immediately.

A follow-up visit should include (at a minimum):

- Review of the FastPath™ screen.
- Review of event markers and histograms.

- Assessment of pacing, sensing, impedance and battery voltage.
- Confirmation that the final parameter settings are correct.

Progression or changes over time in the patient's underlying heart or systemic disease may necessitate a re-evaluation of the patient's clinical arrhythmias. Reprogramming of LP parameters may be required. LP settings should be re-evaluated if the patient's antiarrhythmic medication is changed.

Refer to the Aveir™ Leadless Pacemaker Help Manual for LP programming information.

If a programmer system is not available, recommended replacement time (RRT) condition can be assessed using a standard pacemaker donut magnet and the patient's ECG can be observed on a monitor. See Pacing Rates Following Magnet Detection (page 76). At a future follow-up, a programmer system can be used to customize the LP programming, if desired.

NOTE: Patients with an LP cannot be followed by trans-telephone monitoring (TTM).

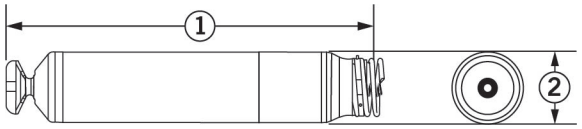
# Specifications and Characteristics

This section describes the Aveir™ Leadless Pacemaker (LP) and Aveir™ Delivery Catheter (delivery catheter) specifications and characteristics.

## Physical Specifications

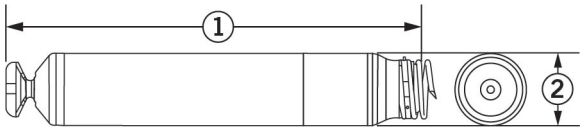
The LP has the following physical specifications:

Figure 15. LSP201A - LP dimensions




1. Length
2. Diameter

Figure 16. LP dimensions (LSP202V)




1. Length
2. Diameter

Table 7. LP physical specifications

| Specification | Model LSP201A | Model LSP202V |
|---|---|---|
| Length | 32.2 mm (1.27 in) | 38.0 mm (1.50 in) |
| Diameter | 6.5 mm (0.26 in) | 6.5 mm (0.26 in) |
| Volume | 1.0 cc | 1.1 cc |
| Mass | 2.1 grams | 2.4 grams |
| Fixation mechanism | Distal non-retractable helix | Distal non-retractable helix |
| Fixation depth | ~ 1.63 mm (0.064 in) | ~ 1.63 mm (0.064 in) |

The delivery catheter has the following physical specifications:

Table 8. Delivery catheter physical specifications

| Specification | Model LSCD201 |
|---|---|
| Effective length | 105 cm (41.3 in) |
| Tether mechanism | Extendable/retractable |
| Tether extendable length | Up to 33 mm (1.30 in) |

Compatibility has been demonstrated with a 25 Fr introducer.

## Pacemaker X-ray Identification

The LP has an X-ray absorptive marker for noninvasive identification.

Table 9. LP X-ray identification code

| Model | Code |
|---|---|
| LSP201A, LSP202V | NT |

## Pacemaker Electrodes

The LP tip electrode is a titanium-nitride coated, platinum-iridium disc located at the center of the fixation helix. The tip electrode includes a single dose of dexamethasone sodium phosphate (DSP) intended to reduce inflammation. The target dose of DSP in the monolithic controlled device (MCRD) is 301 micrograms.

The ring electrode is the uncoated part of the titanium pacemaker case.

Table 10. LP electrode physical specifications

| Specification | Model LSP201A | Model LSP202V |
|---|---|---|
| LP tip electrode | Helical | Domed |
| Tip electrode geometric surface area | ~ 5 $mm^2$ | ~ 2 $mm^2$ |
| Ring electrode geometric surface area | ~ 124 $mm^2$ | ~ 244 $mm^2$ |
| Inter-electrode distance | > 24 mm | > 24 mm |

## Non-Programmable Parameters

**Polarity:** Pacing and sensing configurations in the LP are non-programmable. The LP paces and senses from the distal electrode (tip) to the pacemaker housing (ring), similar to a bipolar lead.

**Pulse rate limit (runaway protection):** Circuitry in the LP prevents delivery of pacing pulses at rates higher than the runaway protection rate listed below.

Table 11. LP runaway protection

| Model | Runaway protection rate |
|---|---|
| LSP201A, LSP202V | 190 bpm (-7 / +20 bpm) |

Pulse rate limit is measured at 37°C ± 2°C and 500 Ω ± 1% load.

**Input Impedance:** 50 kΩ to 150 kΩ.

NOTE: See Patient Follow-Up (page 60) for recommended methods for determining that the implanted pacemaker is functioning properly.

## Detection Performance in the Presence of Electromagnetic Interference

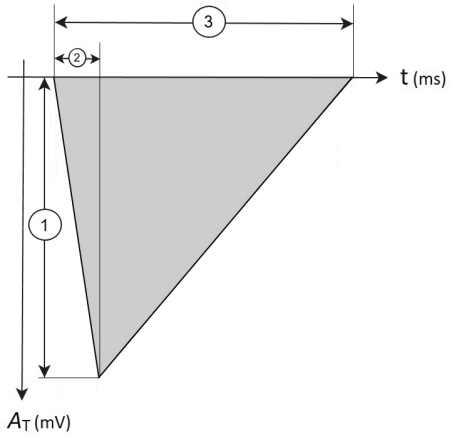
The Atrial Sensitivity setting of 0.25 mV may be more susceptible to EMI. Atrial LPs comply with the electromagnetic compatibility requirements of ISO 14117 Clause 4.5.2 at an Atrial Sensitivity setting of 0.5 mV and less sensitive settings.

The Ventricular Sensitivity setting of 0.5 mV may be more susceptible to EMI. Ventricular LPs comply with the electromagnetic compatibility requirements of ISO 14117 Clause 4.5.2 at a Ventricular Sensitivity setting of 1 mV and less sensitive settings.

## Test Pulse Sensitivity

Sensitivity was measured using the test pulse shown in the following figure.

Figure 17. Test pulse description




1. Test signal amplitude
2. 2.0 ms
3. 15.0 ms

NOTE: The signal may be either positive or negative.

## Pacemaker Power Source Information

Many factors affect LP service life, such as programmed parameters, percentage of time paced, load impedance, etc. Projected longevity does not account for such factors as sensor-driven pacing rate changes, effects of rate-limiting algorithms, the patient's medical condition, or effects of a specific pacing prescription. Furthermore, these longevity estimates are based on battery life projections, which are approximations.

**WARNING: At recommended replacement time (RRT), the nominal life of the LP is approximately 7 to 9 months. The LP should be replaced expeditiously.**

**CAUTION: High output settings or high rates can shorten the time to RRT. High output and high rate settings can reduce the duration from RRT to end of service (EOS) to less than the nominal projected value. When the programmer indicates that the LP has reached RRT, fully evaluate the LP.**

Table 12. LP power source specifications

| Specification | Model LSP201A | Model LSP202V |
|---|---|---|
| Manufacturer | Greatbatch Medical | Greatbatch Medical |
| Battery type | 1 Li-CFx | 1 Li-CFx |
| Model number | 3850 | 3851 |
| Voltage at BOS | ~ 3 V | ~ 3 V |
| Voltage at RRT | 2.75 V | 2.71 V |
| Voltage at EOS | 2.2 V | 2.2 V |

Table 12. LP power source specifications

| Specification | | Model LSP201A | Model LSP202V |
|---|---|---|---|
| Nominal Capacity | | 174 mAH | 241 mAH |
| Current consumption at beginning of service (BOS) at these parameters: | | **Model LSP201A** | **Model LSP202V** |
| Pacing mode: | Rate-modulated pacing with sensing inhibition (DDDR/AAIR/VVIR) | 0% pacing (inhibited):<br>AAIR: 1.0 µA<br>DDDR: 1.9 µA | 0% pacing (inhibited):<br>VVIR: 1.0 µA<br>DDDR: 1.9 µA |
| Basic rate: | 50 bpm | | |
| Pulse amplitude: | 2.5 V | 100% pacing: | 100% pacing: |
| Pulse duration: | 0.4 ms | AAIR: 1.9 µA | VVIR: 1.9 µA |
| Pacing load: | 500 Ω | DDDR: 3.7 µA | DDDR: 3.7 µA |

## Projected Service Life

The longevity estimate tables in this section were calculated under these conditions:

- Most comprehensive operating modes: AAIR, VVIR, DDDR
- Pulse duration: 0.4 ms

Longevity estimates are stated as nominals ± 30%.

### LSP201A Projected Service Life (Single-Chamber Mode)

Table 13. Projected service life (nominal longevity – BOS to RRT)

| **LSP201A (Single-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 11.9 | 12.8 | 13.5 |
| | | 50% | 14.5 | 15.2 | 15.8 |
| | | 0% | 18.7 | 18.9 | 19.0 |
| 50 bpm | 2.5 V | 100% | 6.3 | 7.2 | 7.9 |
| | | 50% | 9.5 | 10.5 | 11.3 |
| | | 0% | 18.7 | 18.9 | 19.0 |
| 60 bpm | 1.25 V | 100% | 10.4 | 11.2 | 11.9 |
| | 2.5 V | 100% | 5.4 | 6.1 | 6.8 |
| | 5.0 V | 100% | 1.5 | 1.8 | 2.1 |

Table 14. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP201A (Single-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 11.3 | 11.9 | 12.4 |
| | 2.5 V | 100% | 8.6 | 9.3 | 9.9 |
| 60 bpm | 1.25 V | 100% | 10.4 | 11.0 | 11.5 |
| | 2.5 V | 100% | 7.8 | 8.4 | 8.9 |

## LSP201A Projected Service Life (Dual-Chamber Mode)

Projected service life (nominal longevity – BOS to RRT)

| **LSP201A (Dual-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 7.1 | 7.9 | 8.5 |
| | | 50% | 8.1 | 8.8 | 9.4 |
| | | 0% | 9.3 | 10.0 | 10.5 |

Projected service life (nominal longevity – BOS to RRT)

| **LSP201A (Dual-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 2.5 V | 100% | 4.7 | 5.3 | 5.9 |
| | | 50% | 6.2 | 6.9 | 7.5 |
| | | 0% | 9.3 | 10.0 | 10.5 |
| 60 bpm | 1.25 V | 100% | 6.1 | 6.8 | 7.3 |
| | 2.5 V | 100% | 3.9 | 4.5 | 5.0 |
| | 5.0 V | 100% | 1.4 | 1.6 | 1.9 |

Table 15. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP201A (Dual-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 9.1 | 9.8 | 10.2 |
| | 2.5 V | 100% | 7.4 | 8.0 | 8.5 |

Table 15. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP201A (Dual-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 60 bpm | 1.25 V | 100% | 8.3 | 8.8 | 9.2 |
| | 2.5 V | 100% | 6.7 | 7.3 | 7.7 |

## LSP202V Projected Service Life (Single-Chamber Mode)

Table 16. Projected service life (nominal longevity – BOS to RRT)

| **LSP202V (Single-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 17.1 | 18.4 | 19.4 |
| | | 50% | 20.8 | 21.8 | 22.6 |
| | | 0% | 26.6 | 26.9 | 27.1 |

Table 16. Projected service life (nominal longevity – BOS to RRT)

| **LSP202V (Single-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 2.5 V | 100% | 9.2 | 10.4 | 11.5 |
| | | 50% | 13.7 | 15.0 | 16.1 |
| | | 0% | 26.6 | 26.9 | 27.1 |
| 60 bpm | 1.25 V | 100% | 15.0 | 16.1 | 17.1 |
| | 2.5 V | 100% | 7.8 | 8.9 | 9.9 |
| | 5.0 V | 100% | 2.3 | 2.7 | 3.2 |

Table 17. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP202V (Single-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 11.4 | 12.0 | 12.5 |
| | 2.5 V | 100% | 8.3 | 8.9 | 9.5 |

Table 17. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP202V (Single-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 60 bpm | 1.25 V | 100% | 10.2 | 11.0 | 11.5 |
| | 2.5 V | 100% | 7.3 | 8.1 | 8.6 |

## LSP202V Projected Service Life (Dual-Chamber Mode)

Table 18. Projected service life (nominal longevity – BOS to RRT)

| **LSP202V (Dual-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 10.3 | 11.4 | 12.2 |
| | | 50% | 11.6 | 12.7 | 13.5 |
| | | 0% | 13.3 | 14.3 | 15.0 |

Table 18. Projected service life (nominal longevity – BOS to RRT)

| **LSP202V (Dual-chamber mode)** | | | **Projected Service Life (in years)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 2.5 V | 100% | 6.8 | 7.7 | 8.5 |
| | | 50% | 9.0 | 10.0 | 10.9 |
| | | 0% | 13.3 | 14.3 | 15.0 |
| 60 bpm | 1.25 V | 100% | 8.8 | 9.8 | 10.5 |
| | 2.5 V | 100% | 5.8 | 6.6 | 7.3 |
| | 5.0 V | 100% | 2.1 | 2.5 | 2.8 |

Table 19. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP202V (Dual-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 50 bpm | 1.25 V | 100% | 9.0 | 9.6 | 10.0 |
| | 2.5 V | 100% | 7.0 | 7.6 | 8.2 |

Table 19. Prolonged service period (nominal longevity – RRT to EOS)

| **LSP202V (Dual-chamber mode)** | | | **Prolonged Service Period (in months)** | | |
|---|---|---|---|---|---|
| Pacing Rate | Pace Amplitude | % Pacing | Impedance 400 Ω | Impedance 500 Ω | Impedance 600 Ω |
| 60 bpm | 1.25 V | 100% | 8.0 | 8.6 | 9.1 |
| | 2.5 V | 100% | 6.2 | 6.8 | 7.2 |

## Pacing Rates Following Magnet Detection

When a magnet is detected by the device and magnet response is not set to Off, the LP paces asynchronously (VOO when an RV LP is present; AOO when only an RA LP is present) at 100 bpm for 5 cycles and then at a rate as a function of the LP that is pacing at the magnet rate thereafter until the magnet is no longer detected, unless any implanted LP has reached RRT in which case the subsequent pacing rate will be 65 bpm regardless of battery voltage level.

Magnet rates at various battery voltages prior to RRT are shown in the following table.

Table 20. Pacing rates following magnet detection (prior to RRT)

| **Battery Voltage** | **Magnet Rate** |
|---|---|
| $V_{batt}$ ≥3.0 V | 100 bpm |
| 3.0 > $V_{batt}$ ≥2.9 V | 97 bpm |

Table 20. Pacing rates following magnet detection (prior to RRT)

| Battery Voltage | Magnet Rate |
|---|---|
| 2.9 > $V_{batt}$ ≥2.8 V | 94 bpm |
| 2.8 > $V_{batt}$ ≥2.7 V | 91 bpm |
| 2.7 > $V_{batt}$ ≥2.6 V | 88 bpm |
| 2.6 > $V_{batt}$ | 85 bpm |

The effectiveness of magnets varies. If one magnet does not cause magnet response, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the pulse generator can also help.

## Product Materials

The following materials are intended to come into contact with blood or tissue:

Table 21. Materials in contact with blood or tissue

| Component | Material |
|---|---|
| Leadless pacemaker | ▪ 35N LT‡<br>▪ Dexamethasone sodium phosphate (DSP)<br>▪ MP35N‡<br>▪ Nylon<br>▪ Parylene<br>▪ Polyether Ether Ketone (PEEK)<br>▪ Silicone elastomer<br>▪ Silicone medical adhesive Type A<br>▪ Silicone rubber<br>▪ Titanium Grade 2<br>▪ Titanium nitride-coated platinum/iridium alloy |
| Delivery catheter | ▪ 304 and 440 stainless steel<br>▪ Barium sulfate<br>▪ Nitinol (nickel titanium)<br>▪ PEBAX‡<br>▪ Platinum-iridium |

Table 21. Materials in contact with blood or tissue

| Component | Material |
|---|---|
| | ▪ Polycarbonate<br>▪ Polyether polyurethane<br>▪ Polyethylene terephthalate (PET)<br>▪ Polytetrafluoroethylenes (PTFE)<br>▪ Silicone<br>▪ Urethane UV curable adhesives |

The following materials are not intended to come into contact with blood or tissue:

Table 22. Additional product materials

| Component | Material |
|---|---|
| Loading tool | ▪ Acetal polyoxymethylene (POM)<br>▪ Copolyester |

# Data Security

Abbott Medical takes a broad and deep approach to ensuring the safety, security and privacy of the patient information and data on our devices and systems connecting patients to healthcare providers and clinics. Patients, clinical staff, and hospital IT staff do not need to configure the pulse generator or take any special action (for example, firewall use) to safeguard patient information and device data.

To prevent unauthorized wireless data changes, all telemetry with an LP requires physical patient contact.

Safeguards for the device will be provided throughout the stated warranty period or until a replacement product is available.

The cybersecurity bill of materials (CBOM) is available upon request.

Visit the information page at abbott.com/cybersecurity to read more about Abbott's commitment to cybersecurity. Periodically, Abbott may update the website with important bulletins.

## Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

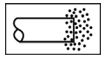
- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

## Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at medical.abbott/manuals.

| Symbol | Description |
|---|---|
| Leadless Pacemaker | Leadless Pacemaker |
| RV | Right ventricular |
| RA | Right atrial |
|  | Basic rate, Right ventricular |
|  | Basic rate, Right atrial |
| IOM | Initial operating mode |
| COM | Most comprehensive operating mode |
| AAI | Atrial pacing, atrial sensing, inhibited response |

| Symbol | Description |
|---|---|
| **AAIR** | Atrial pacing, atrial sensing, inhibited response, rate-modulated |
| **VVI** | Ventricular pacing, ventricular sensing, inhibited response |
| **VVIR** | Ventricular pacing, ventricular sensing, inhibited response, rate-modulated |
| **DDDR** | Dual-chamber pacing, dual-chamber sensing, dual-chamber response, rate-modulated |
|  | Bipolar Sensing/Bipolar Pacing |
|  | Steroid-eluting |
|  | Sensor: Core temperature |
|  | Leadless pacemaker inside loading tool |

| Symbol | Description |
|---|---|
|  | Product literature |
|  | Accessories |
|  Excursions permitted. | Excursion temperature limit. Temperature value(s) is indicated adjacent to the symbol. |
| Store at room temperature | Storage temperature. Temperature value(s) is indicated below the symbol. |
|  | Double sterile barrier |
|  | The device contains a battery and the label is affixed to this device in accordance with European Council Directive 2006/66/EC.<br><br>Return the device to Abbott Medical when explanted or dispose as |

| Symbol | Description |
|---|---|
| | potentially biohazardous material in accordance with medical practice and applicable local, state, and federal laws and regulations. |
|  | Contains hazardous substances. CAS 7440-48-4 |
|  | Patient identification card label |
|  | Location of implant |
|  | Patient identification |
|  | Implant date |
|  | Healthcare center or physician |
|  | Physician telephone |

| Symbol | Description |
|---|---|
| Delivery Catheter | Delivery Catheter |
|  | Single sterile barrier system |
|  | Open pouch from corner. |
| MD | Medical Device |
| UDI | Unique device identification number |
|  | Importer |

Abbott Medical
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

Abbott Medical
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

abbott.com

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# MRI-Ready Leadless Systems Manual

MRI Procedure Information for the MR Conditional Aveir™ Leadless Pacemaker

Model LSP112V, LSP202V, and LSP201A

Abbott

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

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

# Contents

# Introduction

This manual explains the procedures and precautions that must be followed when scanning a patient who is implanted with an MR Conditional Aveir™ Leadless Pacemaker system.

It is important to read the information in this manual before conducting an MRI scan on a patient with an implanted MR Conditional Aveir Leadless Pacemaker system. Contact Technical Support if you have any questions (page 30).

Testing has demonstrated that the MR Conditional Aveir Leadless Pacemaker system is conditionally safe for use in the MRI environment when used according to the instructions in this manual.

Enable MRI Settings to turn on a mode of operation that allows a patient with an MR Conditional system to be safely scanned by an MRI scanner when used according to the instructions in this manual.

Refer to the appropriate device user's manual for a complete listing of device-specific indications, contraindications, warnings, precautions, potential adverse events, and directions for use. Refer to the Aveir Link Module Model LSL02 manual and the Merlin™ Patient Care System (PCS) Model 3650 manual for non-MRI related information.

## Symbols

Table 1. MR Conditional symbols

| Symbol | Description |
|---|---|
|   | Device with demonstrated safety in the MR environment within defined conditions including conditions for the static magnetic field, the time-varying gradient magnetic fields and the radiofrequency fields. |

## MR Conditional Leadless Pacemaker Models

Table 2. MR Conditional Models

| Device | Model |
|---|---|
| Aveir™ leadless pacemaker | LSP112V<br>LSP202V<br>LSP201A |

NOTE: The MR Conditional Aveir Leadless Pacemaker system may be a single-chamber pacing system with one device model or a dual-chamber system consisting of a LSP112V or LSP202V in the right ventricle and a LSP201A in the right atrium.

## MRI Safety Information

A patient with this system may be safely scanned under the conditions given in this manual.
Scanning under different conditions may result in severe patient injury, death, or device malfunction.

## 3T MRI Scan Parameters for Aveir™ Leadless Pacemakers

When performing a 3T MRI scan on a patient with an MR Conditional Aveir™ Leadless Pacemaker system, the following scan parameters must be followed.

Table 3. 3T MRI scan parameters

| Parameter | Setting |
|---|---|
| Item Name/Identification | Refer to the MR Conditional Models table (page 2) |
| Static Magnetic Field Strength and Type of Nuclei | 3 Tesla/128 MHz excitation frequency (hydrogen atom only) |
| Magnet Type and Static Magnetic Field Orientation | Cylindrical-bore magnet, horizontal field orientation |
| Maximum Spatial Field Gradient | 30 T/m (3000 Gauss/cm) |
| Maximum Gradient Slew Rate per axis | 200 T/m/s |
| RF Transmit Conditions | First Level Controlled Operating Mode or Normal Operating Mode |

Table 3. 3T MRI scan parameters

| Parameter | Setting |
|---|---|
| | Integrated Whole Body RF Transmit Coil with RF excitation:<br>▪ Circularly polarized (CP), or<br>▪ Multichannel-2 (MC-2) |
| RF Receive Coil Type | Any receive coil may be used |
| Scan Duration | 2 W/kg or 4 W/kg of whole-body average SAR for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks). |
| Scan Region / Patient Landmarking Criteria | Full body scans allowed. Any landmark is acceptable |
| Patient Characteristics | Refer to Instructions for Cardiac Physicians and Clinicians to:<br>▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 13)<br>Refer to Instructions for Radiologists and MRI Technologists to: |

Table 3. 3T MRI scan parameters

| Parameter | Setting |
|---|---|
| | ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 27)<br>▪ Perform the Scan and Monitor the Patient (page 30) |
| Patient Position in Scanner | Supine or prone; patient's arms must be at his or her sides |
| Device Configuration | MR Conditional labeling applies to single-chamber and dual-chamber configurations.<br>If present, the LSP112V/LSP202V device must be implanted in the right ventricle.<br>If present, the LSP201A device must be implanted in the right atrium. |
| Instructions to be followed before and after the MRI exam | Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan.<br>Refer to:<br>▪ Instructions for Cardiac Physicians and Clinicians (page 12) |

Table 3. 3T MRI scan parameters

| Parameter | Setting |
|---|---|
| | ▪ Instructions for Radiologists and MRI Technologists (page 26) |
| MR Image Artifact | The presence of this system may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact. |

## 1.5T MRI Scan Parameters for Aveir™ Leadless Pacemakers

When performing a 1.5T MRI scan on a patient with an MR Conditional Aveir™ Leadless Pacemaker system, the following scan parameters must be followed.

Table 4. 1.5T MRI scan parameters

| Parameter | Setting |
|---|---|
| Item Name/Identification | Refer to the MR Conditional Models table (page 2) |
| Static Magnetic Field Strength and Type of Nuclei | 1.5 Tesla/64 MHz excitation frequency (hydrogen atom only) |
| Magnet Type and Static Magnetic Field Orientation | Cylindrical-bore magnet, horizontal field orientation |
| Maximum Spatial Field Gradient | 30 T/m (3000 Gauss/cm) |
| Maximum Gradient Slew Rate per axis | 200 T/m/s |
| RF Transmit Conditions | First Level Controlled Operating Mode or Normal Operating Mode |

Table 4. 1.5T MRI scan parameters

| Parameter | Setting |
|---|---|
| | Integrated Whole Body RF Transmit Coil<br>or<br>Detachable RF Transmit-Receive coils (Head, Lower Extremity, or Upper Extremity) with RF excitation:<br>▪ Circularly polarized (CP) |
| RF Receive Coil Type | Any receive coil may be used |
| Scan Duration | 2 W/kg or 4 W/kg of whole-body average SAR for up to 60 minutes of continuous RF (a sequence or back to back series/scan without breaks). |
| Scan Region / Patient Landmarking Criteria | Full body scans allowed. Any landmark is acceptable |
| Patient Characteristics | Refer to Instructions for Cardiac Physicians and Clinicians to:<br>▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 13) |

Table 4. 1.5T MRI scan parameters

| Parameter | Setting |
|---|---|
| | Refer to Instructions for Radiologists and MRI Technologists to:<br>▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 27)<br>▪ Perform the Scan and Monitor the Patient (page 30) |
| Patient Position in Scanner | Supine or prone; patient's arms must be at his or her sides |
| Device Configuration | MR Conditional labeling applies to single-chamber and dual-chamber configurations.<br>If implanted, the LSP112V/LSP202V device must be implanted in the right ventricle.<br>If implanted, the LSP201A device must be implanted in the right atrium. |
| Instructions to be followed before and after the MRI exam | Device programming is required for safe scanning: MRI Settings must be enabled before start of scan and disabled after completion of scan.<br>Refer to: |

Table 4. 1.5T MRI scan parameters

| Parameter | Setting |
|---|---|
| | ▪ Instructions for Cardiac Physicians and Clinicians (page 12)<br>▪ Instructions for Radiologists and MRI Technologists (page 26) |
| MR Image Artifact | The presence of this system may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact. |

## Instructions for Cardiac Physicians and Clinicians

NOTE: Radiologists and MRI technologists should see Instructions for Radiologists and MRI Technologists (page 26).

The role of cardiac physicians and clinicians in preparing a patient for an MRI scan is to:

- Confirm that the Patient has an MR Conditional Device (page 12)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 13)
- Review the Potential Adverse Events (page 14)
- Generate a Report of the Patient's Permanently Programmed Parameters (page 15)
- Select and Save MRI Settings (page 16)
- Review the MRI Checklist and Program MRI Settings (page 22)
- Disable MRI Settings (page 25)

## I. Confirm that the Patient has an MR Conditional Device

1. Review the patient's ID card or a printed report generated by the Merlin™ PCS to obtain the model number for the implanted device(s).
2. Check that each model number is MR Conditional (page 2).

## II. Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- The device is at End-of-Life
- The LSP112V or LSP202V device (if implanted) is implanted at a site other than the right ventricle
- The LSP201A device (if implanted) is implanted at a site other than the right atrium
- Patients with unstable capture thresholds
- Patients with capture threshold values of >2.5 V at a pulse width of 0.5 ms
- Complaints of diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms in patients whose device will be programmed to an asynchronous pacing mode when MRI Settings are enabled
- Patients with additional cardiac hardware (eg. abandoned leads)

  NOTE:

  - Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.
  - Scanning patients who have abandoned MR Conditional leadless pacemaker devices in the same chamber is also acceptable provided all MR Conditional requirements for each leadless pacemaker are met. Abandoned leadless pacemaker devices must be deactivated.

## III. Review the Potential Adverse Events

The Aveir™ Leadless Pacemaker system has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- Device heating resulting in tissue damage leading to loss of capture or sensing or both
- Induced currents resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Damage to the device causing it to fail to detect or treat irregular heartbeats, or to treat the patient's condition incorrectly
- Movement or vibration of the device
- Device dislodgement
- Competitive pacing and potential for VT/VF induction due to asynchronous pacing when MRI Settings are enabled
- Syncope due to loss of pacing

Potential interactions between the MRI scanner and the MR Conditional device include:

- The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in the Aveir leadless pacemaker system.

- The gradient magnetic and RF fields produced by an MRI scanner could potentially interact with the MR Conditional device and cause unintended stimulation of the heart. When all conditions outlined in this manual are met, the currents induced on the device are limited so that the potential for capturing the heart is minimized.
- If a dual-chamber system is implanted and programmed to MRI DOO⇄VOO mode, the gradient magnetic and RF fields produced by an MRI scanner will cause the pacing support to temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. Gradient magnetic and RF fields may occasionally cause individual pacing cycle variations.
- The RF fields generated by an MRI scanner could potentially interact with the device, resulting in heating. This heating could damage the surrounding tissue and compromise pacing and sensing thresholds at that site. When all conditions outlined in this manual are met, the Aveir leadless pacemaker system has been tested and shown to limit heating and to minimize thermal damage of the surrounding cardiac tissue.

## IV. Generate a Report of the Patient's Permanently Programmed Parameters

**CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.**

1. Interrogate the patient using the Aveir Link Module and the Merlin PCS.
2. If needed, perform capture and sense tests.

3. Select the Print button to print the Parameter report and any other relevant reports.
   The Merlin PCS will print to the default printer (internal printer, external printer or PDF).

   NOTE: With the exception of i2i diagnostic data, device diagnostic data will be suspended when MRI Settings are enabled. For any device, it is recommended that the clinician performs a complete follow-up prior to the MRI procedure to save all diagnostic data.

## V. Select and Save MRI Settings

The MRI parameter settings are selected at the physician's discretion.
The default MRI parameter settings are automatically stored in the MR Conditional device.

Table 5. Default MRI Settings for dual-chamber leadless pacemaker systems

| Parameter | Setting |
|---|---|
| MRI Mode | DOO⇄VOO |
| MRI Base Rate | 85 bpm |
| MRI Paced AV Delay | 120 ms |
| MRI Pulse Amplitude | 5.0 V |
| MRI Pulse Width | 1.0 ms |

Table 5. Default MRI Settings for dual-chamber leadless pacemaker systems

| Parameter | Setting |
|---|---|
| MRI Electrode Configuration | Bipolar |

NOTE: MRI DOO⇄VOO MRI Mode will temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. If selecting MRI DOO⇄VOO, be sure to test both MRI DOO and MRI VOO modes before programming MRI Settings.

Table 6. Default MRI Settings for single-chamber leadless pacemakers

| Parameter | Setting |
|---|---|
| MRI Mode | VOO or AOO |
| MRI Base Rate | 85 bpm |
| MRI Pulse Amplitude | 5.0 V |
| MRI Pulse Width | 1.0 ms |
| MRI Electrode Configuration | Bipolar |

If you change MRI Settings you must save the modified MRI Settings in the device as described below.

Refer to the Merlin™ PCS on-screen help for information on selecting, testing, and saving the MRI parameter settings.

1. After you interrogate the device with the Merlin PCS and Aveir™ Link Module, select the Parameters button on the right to open the Parameters window. Then, select the MRI Settings tab. This opens the MRI Settings window.
2. From this window, you can modify the MRI parameters that are in effect when MRI Settings are enabled.

   NOTE: For a dual chamber leadless pacemaker system that includes a leadless pacemaker with a serial number prior to 1234XXXX, you must select the Save MRI Settings button to ensure MRI Settings are updated and in effect prior to testing. To activate the Save MRI Settings button, complete the following steps:

   i. Temporarily modify MRI Mode e.g. to VOO.
   ii. Select the "Save MRI Settings" button.
   iii. You can then modify the MRI parameters to your desired settings.
   iv. Continue by Testing MRI Settings in Step 3.
3. You can temporarily test the settings by selecting the Test MRI Settings button. Use this function to evaluate the patient's hemodynamic status with the proposed MRI parameter settings.

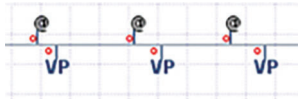
   NOTE:

- If selecting MRI DOO⇄VOO, be sure to test both MRI DOO and MRI VOO modes before programming MRI Settings.
- For MRI DOO⇄VOO mode during Test DOO MRI Settings, loss of i2i communication markers will appear during each pace cycle on the RV marker channel. See figure below, Loss of i2i communication markers on the RV marker channel during each pace cycle.

Figure 1. Loss of i2i communication markers on the RV marker channel during each pace cycle


- For MRI DOO⇄VOO mode during Test VOO MRI Settings, loss of i2i communication markers will appear during each pace cycle on both the RV and RA marker channels and atrial pacing withheld markers will appear during each pace cycle on the RA marker channel. See figure below, Loss of i2i communication markers on the RV and RA marker channels, and atrial pacing withheld event markers on the RA marker channel during each pace cycle.

Figure 2. Loss of i2i communication markers on the RV and RA marker channels, and atrial pacing withheld event markers on the RA marker channel during each pace cycle




4. Select the Cancel Test button to return to permanently programmed settings.

   **CAUTION: Failure to Cancel Test, or loss of communication with device before canceling test, can unintentionally leave the device programmed with MRI Settings.**

5. Select the Save MRI Settings button to save any changed parameters.
6. When you are satisfied with MRI Settings, select the Setup for MRI Now button to open the MRI Checklist.

   **CAUTION: Regardless of the programmed permanent pacing mode, sensed events are ignored by the device when MRI Settings are enabled. Determine whether or not pacing support is needed during the MRI scan. When pacing support is needed, set the MRI Mode to an asynchronous pacing mode (DOO⇄VOO, VOO, or AOO). When pacing support is not needed, set the MRI Mode to Pacing Off.**

   **Some patients may be susceptible to cardiac arrhythmia induced by competitive pacing when an asynchronous MRI Mode is selected. For these patients, it is important to select an appropriate MRI pacing rate to avoid competitive pacing and then minimize the duration of the asynchronous pacing operation.**

## VI. Review the MRI Checklist and Program MRI Settings

Figure 3. An example of the MRI Checklist screen for single-chamber leadless pacemakers on the Merlin ™ PCS

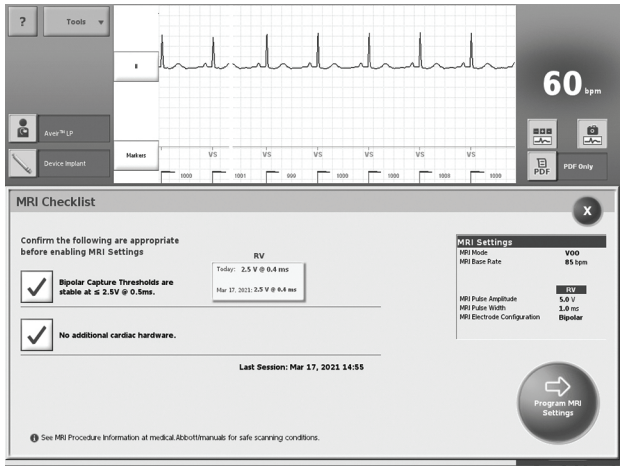
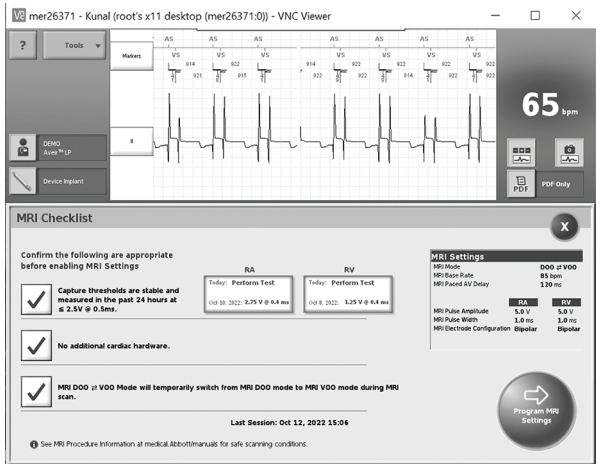


Figure 4. An example of the MRI Checklist screen for dual-chamber leadless pacemakers on the Merlin ™ PCS



1. After you have selected the appropriate MRI Settings, from the MRI Settings window on the Merlin ™ PCS, select the Setup for MRI Now button. The MRI Checklist window will open.
2. Review each condition on the checklist and check off each one that applies. You will not be able to program MRI Settings until all boxes are checked.
3. Once you have completed the checklist, select the Program MRI Settings button to enable MRI Settings. Next, MRI Settings: Active window appears. This window confirms the programmed changes.

   NOTE:

   - If the Merlin PCS emergency VVI hard button is selected when MRI Settings are enabled, the system will disable MRI Settings and display the emergency VVI dialog box. Restore MRI Settings before scanning the patient.
   - When MRI Settings are active in MRI DOO⇄VOO mode, loss of i2i communication markers will appear during each pace cycle on the RV marker channel when the device is pacing in MRI DOO or MRI VOO mode. Additionally, if the system is in i2i Noise Reversion, loss of i2i communication markers and atrial pacing withheld event markers will appear during each pace cycle on the RA marker channel.
4. Select Print MRI Report button to print the report.
5. Select End Session.
6. Remove ECG electrodes from the patient prior to entering the MRI scan.

The Patient is now ready for the MRI scan.

**CAUTION: The patient must be hemodynamically monitored and an external defibrillator must be available during the MRI scan.**

**Be sure to disable MRI Settings as soon as the MRI scan is complete.**

## VII. Disable MRI Settings

**CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone IV). These devices are considered MR Unsafe.**

Immediately following the MRI procedure, the patient's device management physician or clinician must:

1. Interrogate the device using the Aveir Link Module and the Merlin PCS.

   NOTE: When MRI Settings are active in MRI DOO⇄VOO mode, loss of i2i communication markers will appear during each pace cycle on the RV marker channel when the device is pacing in MRI DOO or MRI VOO mode. Additionally, if the system is in i2i Noise Reversion, loss of i2i communication markers and atrial pacing withheld event markers will appear during each pace cycle on the RA marker channel.

2. Disable MRI Settings by selecting the Disable MRI Settings button. This restores the permanently programmed settings.

- Confirm the permanently programmed settings are appropriate.
- Check the pacing capture thresholds after the scan is complete and ensure that the pacing parameters are programmed adequately for the patient based on the threshold.

Refer to the Merlin PCS on-screen help for information on selecting and programming parameter settings.

## Instructions for Radiologists and MRI Technologists

NOTE: Cardiac physicians and clinicians should see Instructions for Cardiac Physicians and Clinicians (page 12)

The role of the radiologist or MRI technologist is to:

- Confirm that the Patient has an MR Conditional Device (page 26)
- Confirm that No Adverse Conditions to MRI Scanning are Present (page 27)
- Review the Potential Interactions (page 27)
- Select the Correct Scan Parameters (page 28)
- Check MRI Settings Status
- Perform the Scan and Monitor the Patient (page 30)

## I. Confirm that the Patient has an MR Conditional Device

1. Review the patient's ID card or the MRI Summary Report (generated by the Merlin™ PCS) to obtain the model number of the implanted device(s).
2. Check that the model number is MR Conditional (page 2).

## II. Confirm that No Adverse Conditions to MRI Scanning are Present

If any conditions exist that could make MRI scanning unsafe, do not scan the patient. Such conditions include:

- Any patient position in the scanner other than supine or prone, with patient's arm at his or her sides
- Patients with additional cardiac hardware (eg. abandoned leads)

  NOTE:

  - Scanning patients who have other MR Conditional devices that are not implanted in cardiac tissue is acceptable provided all MR Conditional requirements for each implanted device are met.
  - Scanning patients who have abandoned MR Conditional leadless pacemaker devices in the same chamber is also acceptable provided all MR Conditional requirements for each implanted device are met. Abandoned leadless pacemaker devices must be deactivated.

## III. Review the Potential Interactions

Potential interactions between the MRI scanner and the MR Conditional device include:

- The magnetic material of an implanted device may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. These effects have been shown to be minimal in the Aveir™ Leadless Pacemaker system.

- The gradient magnetic and RF ields produced by an MRI scanner could potentially interact with the MR Conditional device and cause unintended stimulation of the heart. When all conditions outlined in this manual are met, the currents induced on the device are limited so that the potential for capturing the heart is minimized.
- If a dual-chamber system is implanted and programmed to MRI DOO⇄VOO mode, the gradient magnetic and RF ields produced by an MRI scanner will cause the pacing support to temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. Gradient magnetic and RF ields may occasionally cause individual pacing cycle variations.
- The RF ields generated by an MRI scanner could potentially interact with the device, resulting in heating. This heating could damage the surrounding tissue and compromise pacing and sensing thresholds at that site. When all conditions outlined in this manual are met, the Aveir leadless pacemaker system has been tested and shown to limit heating and to minimize thermal damage of the surrounding cardiac tissue.

## IV. Select the Correct Scan Parameters

Refer to the MRI scan parameters table (3T MRI table (page 4) or 1.5T MRI table (page 8)) for the applicable scan parameter settings.

## V. Check MRI Settings Status

**CAUTION: Do not bring any external control devices, such as a Merlin™ PCS or Aveir™ Link Module, into the scanner magnet room (Zone VI). These devices are considered MR Unsafe.**

1. Refer to the MRI Summary Report generated by the Merlin PCS.
2. Confirm these settings with the device management physician or clinician.

Table 7. MRI Settings for leadless pacemakers [1]

| Parameter | Setting |
|---|---|
| MRI Mode | DOO⇄VOO, VOO, AOO, or Pacing Off |
| MRI Base Rate | 30 - 120 bpm |
| MRI Paced AV Delay | 40-120 ms |
| MRI Pulse Amplitude | 5.0 V |
| MRI Pulse Width | 1.0 ms |
| MRI Electrode Configuration | Bipolar |

[1] This is the entire range of all possible settings for each parameter.

## VI. Perform the Scan and Monitor the Patient

**Proper patient monitoring must be provided during the MRI scan.** This includes continuous monitoring of the patient's hemodynamic function. Since the MR environment may interfere with the patient monitoring system, it is recommended that more than one of the following systems be used:

- electrocardiography
- pulse oximetry
- noninvasive blood pressure measurements

If the patient's hemodynamic function is compromised during the MRI scan, discontinue the MRI scan and take the proper measures to restore the patient's hemodynamic function.

**Verbal communication with the patient during the MRI scan is recommended.**

**Keep an external defibrillator available during the MRI scan.**

Once the MRI scan is complete, MRI Settings must be disabled by the patient's device management physician or clinician using the Merlin™ PCS and Aveir™ Link Module.

# Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)

- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.
Any serious incident should be reported to Abbott Medical and the FDA.

Abbott Medical
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

www.abbott.com

2022-10
ARTEN600283064 01

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Aveir™
Leadless Pacemaker
LSP112V, LSP201A, LSP202V

Aveir™
Link Module
LSL02

Merlin™ Patient Care System
Programmer Software
3330

# Help Manual

Abbott

# Contents

# About This Guide

This manual describes the Merlin™ Patient Care System (PCS) Programmer Software, Model 3330, and provides information on programming an Aveir™ leadless pacemaker (LP).

The Merlin PCS (Programmer, Model 3650; Programmer Software; Model 3330; with accessories) is intended to help physicians and clinicians monitor, diagnose, and record heart rhythms in patients with compatible Abbott Medical cardiac implantable devices by providing the ability to interrogate, program, display data, and test devices during implant, revision, explant, or follow-up sessions.

In this manual:

- Aveir leadless pacemaker is referred to as “LP.”
- Merlin PCS is referred to as “programmer.” Refer to the Merlin Patient Care System User's Manual for comprehensive information on programmer components, setup, maintenance, accessories, and technical data.
- Aveir™ Link Module is referred to as “Link Module.” The Link Module is used in conjunction with a Merlin PCS Model 3650 programmer to interrogate and program the LP and to monitor ECG waveforms for observing LP function. Refer to the Aveir™ Link Module Instructions for Use.
- St. Jude Medical™ Patient Cable, model 3625 or 3626, is referred to as "patient cable."
- The connected Link Module and programmer are referred to as “programmer system.”

  NOTE: The programmer system is not intended for use as an ECG monitor or general diagnostic device.

The Aveir leadless pacemaker system supports the implantation and use of an LP within the targeted chamber or chambers of the heart for monitoring a patient’s heart rate and providing rate-responsive bradycardia pacing therapy to regulate heart rate.

These are the supported clinical use configurations:

Table 1. Supported system configurations

| Most comprehensive operating mode | Clinical use | Description |
|---|---|---|
| DDDR [1] | Dual-chamber bradycardia therapy | Two functionally-paired co-implanted LPs, one in the right ventricle (RV) and one in the right atrium (RA), to provide dual-chamber pacing and sensing. |
| VVIR | Right-ventricular, single-chamber bradycardia therapy | A single LP implanted independently in the RV to provide ventricular-only pacing and sensing. |
| AAIR | Right-atrial, single-chamber bradycardia therapy | A single LP implanted independently in the RA to provide atrial-only pacing and sensing. |

[1] The Aveir™ leadless pacemaker system provides the option to upgrade a patient’s system to a dual-chamber (DDDR) configuration at a later time with the addition of a co-implanted LP that can be functionally paired with an already-implanted LP to provide dual-chamber pacing therapy.

## Tools Menu

The Tools menu provides access to these programmer tools:

- **Session Records**:
  - **Session Records.** Opens a pop-up window to export all stored (LP) session records to a location on the programmer's hard disk or an external media device.
  - **PDFs.** Opens the PDFs window to manage the reports that are stored as PDFs on the programmer's hard disk.
- **Educational Materials:**
  - **Demos.** Opens device demonstrations.
  - **Help.** Opens links for on-line Help for all supported devices.
- **Maintenance**. Opens utilities for programmer maintenance (for use by Abbott Medical personnel only).
- **Preferences.** Opens the programmer settings for language, date/time and number format, audio, printer, and patient data retention settings. See Preferences (page 3).
- **Customer Support.** Provides contact information for Technical Support representatives. See also Technical Support (page 58).
- **Print Screen**. Prints an image of the screen. See Print Screen (page 3).
- **Export Screen**. Exports an image to a supported external media device. See Export Screen (page 3).

Accessed From: Tools button

## Session Records

The Session Records option opens a pop-up window to export all stored session records for the current LP model (or for a selected model family) to a location on the programmer's hard disk or an external media device. (Session records are not viewable on the programmer screen.)

Accessed From: Tools menu > Session Records menu > Session Records button > Export button

Accessed From: Tools menu > Session Records menu > {LP device model} > Access Records button > Export button

## PDFs

When you select the Print button to create a report, the programmer saves the report as a portable document format (PDF) file. This file can exported to an external media device (such as a flash drive) connected to one of the programmer's USB ports. Adobe‡ Acrobat‡ Reader must be installed on the computer used to view an exported report (PDF) file.

The PDFs window provides these options:

- Check the number of pending reports (PDF files stored on the programmer's hard disk that have not been exported)
- Export the most recent PDF files (created in the last actual session or demo session, including the current session)
- Export all stored PDF files
- Delete all PDF files

When exporting reports, as an option, you can export a single PDF file for each session.

When you select an Export button, the Export Data screen is displayed.

NOTE: If the inserted media device is not initially detected, reinsert the media device to try to resolve the issue. If the media device is still not detected, end the session and initiate export from the Ready screen.

All PDFs are stored to this path and named according to this format:

Table 2. PDF File Storage and Naming

| | | |
|---|---|---|
| File path | **/data/PDFs/Live/<date>/<session_ID>/** | |
| | <date> | In yyyy-mm-dd format. |
| | <session-ID> | Comprised of the model and serial numbers of the LP, and sequence number of the session (in a day). |
| | Example:<br>/data/PDFs/Live/2021-04-06/113_LSP202V_113_session9/ | |
| Report name format | **Aveir(TM)-LP_<model>_<serial>_<Report_name>_<n>.pdf** | |
| | Product name, model and serial numbers of the LP, report name, and sequence number (if multiple records are generated in the same session). | |
| | Example:<br>/.../Aveir(TM)-LP_LSP202V_113_SummaryReport.pdf | |

Accessed From: Tools menu > Session Records > PDFs button

## Preferences

The Preferences window contains these tabs for setting the programmer options:

- **Date & Time**. Set the year, date, and local time on the programmer clock. It is important to set an accurate date and time because the LP's diagnostic tests and other functions are reported relative to the date and time from the programmer.

  NOTE: You cannot change date and time preferences during a programming session.

- **Language & Formats**. Set preferences for display and Help language, and for date, time, and number formats.

  ECG Notch Filter. The ECG Notch Filter (non-selectable) reduces ECG interference from the programmer's AC power line frequency. The Link Module automatically applies an ECG notch filter at both 50 Hz and 60 Hz.

- **Audio** preferences.
- **Printer** preferences.
- **Patient Data.** Set the patient data retention period (from seven days up to two years). See Patient Data (page 4).

Accessed From: Tools menu > Preferences button

### Audio Preferences

This screen contains these panels:

- **General Audio.** Select the **On** button to allow audio cues for programmer activity. You can also select a volume level. Select the **Off** button to turn all sounds off.
- **Charging Audio.** (Tachy devices only)

Accessed From: Tools menu > Preferences button > Audio tab

### Printer Preferences

When you select any Print button to create a report, the programmer saves the report as a portable document format (PDF) file. This file can be exported to an external media device (such as a flash drive) connected to one of the programmer's USB ports. You must install Adobe‡ Acrobat Reader‡ on your PC to view the file.

NOTE: To view the number of stored PDFs and to export or delete PDFs, select Tools > Session Records > PDFs.

The Printer Preferences window contains these panels:

- **Selected Printer.** Select from these printer options:
  - **Internal & PDF.** Sends the report to the programmer's internal printer and simultaneously create a PDF file on the hard disk.
  - **External & PDF.** Sends the report to an external USB printer and simultaneously create a PDF file on the hard disk. Before reports can be sent to an external printer, you must first connect the external printer to any one of the USB ports on the programmer. For more information on connecting an external printer, see the Merlin™ Patient Care System User's Manual.
  - **PDF Only (Paperless).** Sends the report to the programmer's hard disk as a PDF file (paperless printing) with no paper documents.

    NOTE: The programmer supports printing to many printer models. For a list of compatible printers, contact your Abbott Medical representative or Technical Support (page 58).

- **Number of Paper Copies.** Select how many reports are printed by the internal or external printer when the Print button is selected.

For more information on printing, see Print Settings (page 45) and Print Menu (page 44).

Accessed From: Tools menu > Preferences > Printer tab

## Print Screen

The Print Screen button prints an image of the current screen.

This function does not create a PDF.

For more information on printing, see Print Settings (page 45) and Print Menu (page 44).

Accessed From: Tools menu > Print Screen button

## Export Screen

The Export Screen button opens the Export Data window, which provides the option to save the current screen as an electronic image (in portable network graphic [PNG] format) and send the file to an external media device (such as a flash drive) connected to one of the programmer's USB ports. The programmer detects all connected devices and prompts for selection of the device to receive the data.

NOTE: If an inserted media device is not initially detected, reinsert the media device to try to resolve the issue. Alternatively, use the Print Screen (page 3) capability.

Accessed From: Tools menu > Export Screen button

# Main Programming Window

## Help

Select the Help (**?**) button during a session to open a window that provides access to the Help Manual with information on LP programming.
The main on-screen help window provides these features:

- Navigation buttons (scroll up, scroll down, return to home).
- **Print** button**.** Select the printer icon to print an entire topic.
- **Contents** tab**.** Select an entry to display the topic.
- **Search** tab**.** To search for a specific term:
  - Select the **Search** tab.
  - Select the on-screen keyboard icon on the **Enter your search** button.
  - Type the search term and select the **Done** button. The Search tab lists all topics that contain the term.
- Topic window with active hyperlinks to other topics.

## Patient Data

The Patient Data window shows LP information including the (RA/RV) LP model, serial number, firmware version, and date of implant, and allows you to save patient data to the LP memory.

Figure 1. Patient Data button


Enter the information using the on-screen keyboard, which opens when you select any of the data entry buttons on the Patient Data window.
The Patient Data window includes these data entry buttons:

- **Patient Name**. Enter the patient name. The first few characters appear on the main programming window.
- **Patient ID**. Enter a patient identification number/code.
- **Birth Date**. Select the patient's date of birth.
- **Physician Notes**. Select to enter additional information about the patient.

Select the **Program** button to save the new or updated data to the LP memory.
Accessed From: Main programming window

## Rhythm Display

The Rhythm Display on the main programming window streams real-time surface ECG [2] and can show one ECG waveform and vector. ECG lead II is available for presentation. The Rhythm Display allows freeze capture as well as printing the display in real time.

NOTE: The programmer system is not intended for use as an ECG monitor or general diagnostic device.

The ECG controls on the left side of the Rhythm Display allow changes to the ECG display:

- **Markers** button. Opens controls for configuring the markers on the Rhythm Display and provides access to Markers help. See Markers (page 6).
- **Waveform Control** button. Opens the waveform controls (page 5).

These additional controls are shown on the right side of the Rhythm Display:

- **Adjust Display** button. Opens the Adjust Display window (page 5), which allows you to select the waveform source and configuration and the ECG filter.
- **Freeze** button. Opens the Freeze Capture window (page 9).

## Waveform Control

The Waveform Control buttons on the left side of the Rhythm Display control the waveform's appearance and allow changes to the ECG display.

The first button opens the ECG Configuration window (page 5) which shows the ECG configuration, ECG lead II.

- AutoGain button. Allows the programmer to continually and automatically set the gain.
- Plus (**+**) and minus (**-**) buttons. Allows the you to set the gain manually.

Figure 2. Waveform control buttons


Accessed From: Rhythm Display > Waveform Control button

## Adjust Display

The Adjust Display button opens a window for selecting the Rhythm Display waveform source (ECG or Markers) for the waveform configuration (lead II) and adjusting the sweep speed (mm/s).

Figure 3. Adjust Display button

The **Update AutoGains** button recalculates the gain of the waveform currently displayed in the Rhythm Display that are set to Auto.

Accessed From: Rhythm Display > Adjust Display button

See also:

- ECG Configuration (page 5)
- Markers (page 6)

### ECG Configuration

The ECG Configuration window lists the electrodes and indicates the ECG vector shown on the Rhythm Display.

Table 3. ECG configurations

| Configuration | Electrodes |
|---|---|
| I * | LA(+) – RA(-) |
| II (shown on the Rhythm Display) | LL(+) – RA(-) |
| III * | LL(+) – LA(-) |
| aVR * | RA(+) – LA(-) + LL(-) |
| aVL * | LA(+) – RA(-) + LL(-) |
| aVF * | LL(+) – RA(-) + LA(-) |
| Chest * | V |

[2] Refer to the Aveir™ Link Module Instructions for Use for information on electrode placement and using the patient cable to connect to the programmer system.

Table 3. ECG configurations

| Configuration | Electrodes |
|---|---|

* Configuration not available for the Aveir™ system.

Accessed From: Adjust Display > Configuration button

## Markers

Markers are symbols that are displayed to represent paced and sensed events, intervals, refractory periods, and algorithm activity.

NOTE: The marker channels displayed on programmer are not intended for use in the diagnosis of physiological conditions

The real-time marker channel presents markers from the LP or LPs with which the programmer is currently communicating.

NOTE: Interactions during a programming session between communication from multiple LPs operating in single-chamber mode or non-tracking dual-chamber mode may occasionally result in a dropped marker from the real-time marker channel.

Markers can be viewed as one of the five waveforms. You can configure markers from the Adjust Display window as either Basic or Full markers:

- **Basic.** Shows markers along a timeline:
  - Brady basic event markers (page 6)
  - Brady special event markers (page 8)
  - User-initiated and test markers (page 8)

Figure 4. Basic marker configuration

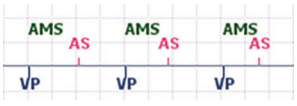
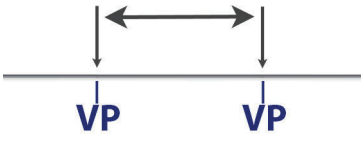



Figure 5. Programmed interval




- **Full.** Adds numeric interval and refractory periods below the basic markers:

Figure 6. Full marker configuration

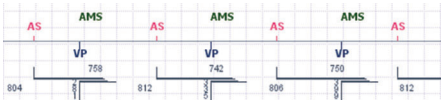
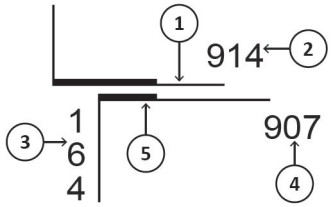



Figure 7. Interval and refractory markers (full markers)




1. Refractory period (line)
2. A-A interval
3. A-V interval
4. V-V interval
5. Absolute refractory period (thick line)

These are the available controls for changing the marker configuration:

- Select the **Adjust Display** button (page 5) on the right side of the Rhythm Display.
- Select the **Waveform Control** button (page 5) on the left side of the Rhythm Display.

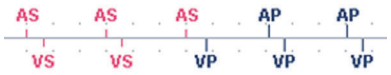
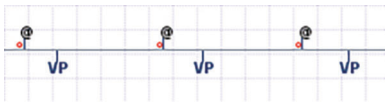
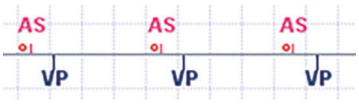
Accessed From: Rhythm Display

### Brady Basic Event Markers

Table 4. Brady basic event markers

| Marker | Description | Color |
|---|---|---|
| Mag | Magnet placement detected. | Green |

Table 4. Brady basic event markers

| Marker | Description | Color |
|---|---|---|
| AS | Atrial sensed event.* | Pink |
| AP | Atrial paced event.* | Blue |
| | * Atrial markers are displayed only for atrial events falling within the atrial alert period. | |
| VS | Ventricular sensed event. | Pink |
| VP | Ventricular paced event. | Blue |
| | Example:<br>  | |
| AR | Atrial event sensed in refractory period.<br>NOTE: This marker appears only in the marker data for a recorded event in an SEGM (page 11); this marker does not appear in the Rhythm Display.<br>Example:<br>  | Pink |
| tick mark | Implant-to-programmer (i2p) communication event.<br>An atrial communication event is indicated above the marker line.<br>A ventricular communication event is indicated below the marker line.<br>Example:<br>  | Black |
| @ | Atrial pacing withheld event.<br>In DDD(R), DDI(R) and DOO(R) modes, an atrial pacing withheld event marker may appear as a result of loss of RV LP ⟶ RA LP i2i™ communication or while the LP system is operating in safe mode during certain transitional states.<br>Example:<br>  | Black |
| o | Loss of i2i communication (page 42).<br>Loss of RA LP ⟶ RV LP communication is indicated below the marker line to the left of the RV marker.<br>Example:<br>  <br>Loss of RV LP ⟶ RA LP communication is indicated above the marker line to the left of the RA marker.<br>Example:<br>  <br>See also i2i™ Diagnostics (page 14). | Pink |

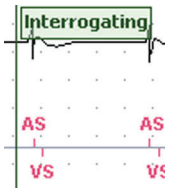
## Brady Special Event Markers

Table 5. Brady special event markers

| Marker | Description | Color |
|---|---|---|
| AMS | AMS ongoing (appears with each ventricular event).<br>Example:<br>  | Green |
| PVC | Premature ventricular contraction (PVC) detection. | |
| PMT | Pacemaker-mediated tachycardia (PMT) detection. | |
| VIP | VIP search started. | |
| VSP | Ventricular Safety Standby.<br>Example:<br>  | Blue |

## User Initiated and Test Markers

Table 6. User initiated and test markers

| Marker | Description | |
|---|---|---|
| Programmed | Completion of LP programming. | Example:<br>  |
| Interrogating | Initiation of LP interrogation, and completion of interrogation. | |
| [test value] | Test parameter setting. Test value markers appear each time a test parameter setting is changed during a test. | |
| [test type] Started | Type of test started:<br>▪ A. Capture (atrial capture test)<br>▪ A. CEGM (atrial commanded EGM)<br>▪ A. Impedance Test (atrial impedance test)<br>▪ P Wave Test (atrial sense test)<br>▪ R Wave Test (ventricular sense test)<br>▪ V. Capture (ventricular capture test)<br>▪ V. CEGM (ventricular commanded EGM)<br>▪ V. Impedance Test (ventricular impedance test) | |
| [test type] Ending | Type of test ending. | |
| [test type] Ended/ [measurement] | Type of test ended and the measurement recorded. | |
| M | For a sense test or commanded EGM, this (red) marker indicates the cardiac cycle during which the measurement was taken. | |
| Test Canceled | Test canceled | |

## Freeze Capture

The Freeze button captures the most recent 30 seconds of the waveform and shows the data in the Freeze Captures window. The Freeze Captures window also shows the presenting rhythm (first 16 seconds) freeze that is auto-captured at interrogation. The programmer saves the six most recent freezes in its memory.

Figure 8. Freeze button

The Freeze Captures window provides these controls:

- **Waveform Control** buttons, including Basic, Full, and the Hide button, which hides the selected waveform.
- **Restore Channels** button, which restores the hidden waveforms.
- **Sweep Speed** button, which selects the sweep speed (mm/s) for the freeze.
- **Show Calipers** button, which shows calipers in the Freeze Captures window that can be moved with button controls to display time measurements for a portion of the freeze. (Toggles to the Hide Calipers button.)
- **Reset Calipers** button, which, when calipers are showing, resets the caliper settings.
- **Hide Calipers** button, which hides calipers from the Freeze Captures window. (Toggles to the Show Calipers button.)
- **Scroll** buttons, which allow left and right scrolling.

Select the **Print** button to print the waveform freezes.

Accessed From: Freeze button

## FastPath™ Summary

The FastPath™ Summary button opens the FastPath™ workspace, which shows an information summary and provides quick access to details through these options:

- **Alerts** button. Opens a window that lists conditions requiring attention (page 10).
- **Battery** summary button. Shows the latest voltage measurement and longevity gauge illustrating the time left to Recommended Replacement Time (RRT) (based on current rate of usage and other data) for the active LP or LPs. Opens the Battery Details window (page 19).
- **Parameters** button. Opens the Parameters workspace to the Brady Parameters tab (page 23).
- **Episodes & Logs** button. Shows a total episode count (since last cleared). Opens the Episodes workspace to the Episode Directory tab (page 11).
- **Event counts** button. Opens the Diagnostics workspace to the Rates tab (page 12), which shows the Atrial Heart Rate Histogram and events diagnostics.
- **Test Results** buttons. Shows the status of any current tests or measurements and any available previous test results or measurements. Select the (RA/RV) **Capture, Sense**, or **Impedance** button to open the corresponding test window or the latest results of a test or impedance measurement. See Tests (page 17) and Battery & Impedance (page 19).
- **Mode Switch** button. Shows the number of AMS episodes and the mode-switch percentage. Opens the Diagnostics workspace to the Mode Switch tab (page 13), which displays the AMS Summary (page 13), and AMS Log (page 13), and V Rates During AMS (page 14) panels.
- **i2i™ Diagnostics** button. Shows the i2i throughput rates (RV $\rightarrow$ RA i2i™ communication, and RA $\rightarrow$ RV i2i communication. Opens the Diagnostics workspace to the i2i Diagnostics tab (page 14).
- **Print Summary** button. Prints a Summary Report of all information on the FastPath Summary screen. For information on the contents of the FastPath Summary Report, see Reports (page 44).
- **End Session** button. Opens a window for printing reports that have not been printed and to end the session.

Accessed From: FastPath™ Summary button

## Alerts

The Alerts panel lists conditions detected since the last follow-up. The list contains buttons that open the related workspaces. Alerts that have not been viewed are in **bold**.

These are examples of alerts that may be displayed on the Alerts panel:

- **Review Patient Data.** See Patient Data (page 4).
- **(RA/RV) LP is at RRT.** See Recommended Replacement Time (RRT) (page 45).
- **(RA/RV) LP is programmed to Emergency pacing values.** The indicated LP is operating in emergency pacing mode. See Emergency VVI (EVVI) Pacing (page 43).
- **(RA/RV) LP reset occurred.** The indicated LP has experienced a device reset. See LP Reset (page 44).

  LP resets are displayed in the Episodes > Logs window (page 11).

  Select the alert to open the Reset Alert dialog, which shows these details for the last LP reset:

  – Lifetime reset count
  – Last reset time
  – Last reset reason

Accessed From: FastPath Summary button > Alerts button

## Episodes

The Episodes button opens the Episodes workspace, which contains these tabs:

- Episode Directory (page 11) (for dual-chamber configurations)
- Logs (page 11)

Accessed From: Episodes button

## Episode Directory

The Episode Directory indicates the number of episodes recorded by the LPs since the last programming session, and provides an episode listing. Episode types listed in the Episode Directory include:

- AMS Entry
- AMS Exit

From the Episode Directory, select an episode from the list to open the Episode detail window, which displays the available EGM and marker data (page 6) for the recorded event.

Arrows allow scrolling left and right through the episodes.

The Episode Directory contains these columns:

- **Date** and **Time**. Date and time the episode was recorded.
- **Type**. Type of episode.
- **Status**. Indicates whether stored EGM (SEGM) associated with the episode is available.
- **PDF.** Episodes selected for printing (indicated by a check mark).
  You can select the directory of all episodes for printing, or open and display episodes individually and print them (or selected for printing).
  Select the **Print Selected** button to print the SEGM Summary Report.

The Status icons indicate these possible states:

Table 7. Status Icons

| State | Icon |
|---|---|
| Blue Circling Arrow. The SEGM is being retrieved. |  |
| EGM. The episode detail has been retrieved and is ready to view. |  |
| Cleared. The episode has been cleared from the LP. |  |
| No EGM. The episode is corrupted or was cleared before it was read. |  |

Accessed From: Episodes button > Episode Directory tab

See also:

- Clear Diagnostics (page 35)
- Episode Settings (page 32)

## Logs

The Logs tab lists all logged episodes for the active (RA/RV) LP or LPs and provides an episode count by type:

- **Noise Reversion.** An episode is logged each time a pace pulse is delivered during (atrial or ventricular) noise reversion.
- **Magnet Response.** An episode is logged each time a magnet is applied and magnet response is activated.
- **LP Reset**. An episode is logged each time a reset of the LP occurs. The reason for the most recent reset is also stated.

The date and time of the last occurrence of each episode type is shown.

Select the **Update Episodes** button to update the list.

Accessed From: Episodes button > Logs tab

# Diagnostics

The Diagnostics button opens the Diagnostics workspace, which contains these tabs:

- Rates (page 12)
- Conduction (page 13)
- Mode Switch (page 13)
- i2i™ Diagnostics (page 14)
- Telemetry (page 15)

The Rates, Conduction, and Mode Switch tabs display the date and time of the last session, last read data, and last cleared data. On any of tab (except Telemetry), you can select the **Read Diagnostics** button to read the current diagnostics data from the LP or LPs and update the displayed information.

Accessed From: Diagnostics button

See also Clear Diagnostics (page 35).

# Rates

The Rates tab of the Diagnostics workspace contains these panels:

- Atrial Heart Rate Histogram (page 12)
- Events diagnostics (page 12)
- Total time sampled and total time sampled in AMS
- Last session date, last read date, and last cleared date

Accessed From: Diagnostics button > Rates tab

## Atrial Heart Rate Histogram

The Atrial Heart Rate Histogram shows the distribution of all atrial paced and sensed events by rate ($min^{-1}$) recorded since the diagnostics were last cleared. Each histogram bar represents the percentage of total counts the patient's intrinsic or paced rate fell within a specific rate range. Each bar is divided into color-coded segments, which indicate the portion that was paced or sensed.

NOTE: The Atrial Heart Rate Histogram includes events that occurred during Auto Mode Switch (AMS).

The Atrial Heart Rate Histogram also displays:

- Rate parameter settings (depending on the LP operating mode): Base Rate, AMS Base Rate, Max Sensor Rate, Atrial Tachycardia Detection Rate
- Histogram legend
- Percentage of total counts sampled at Max Track Rate (page 24)

If the Sensor parameter is programmed On or Passive, a yellow dot appears in each rate range. The position of the dot on the bar graph represents the percentage of paced events that would result if the rate was determined exclusively by response to the activity sensor.

Accessed From: Diagnostics button > Rates tab

## Events

The Events panel displays a summary of the percentage of counts [3] that all events were paced for both the current time sampled and over the lifetime of the LP.

NOTE: Atrial events during Auto Mode Switch (AMS) (page 25) are included in the count.

The Events panel also displays the Events Histogram, a bar graph that shows the percentage of the total counts sampled for each event or event sequence type, not including events during AMS.

For example, an Events Histogram with an AS-VS event sequence type of 94% indicates that during the last sampling period (defined below the graph), 94% of all event sequences were of the AS-VS type. The percentage calculation is based on the count of the events for each event sequence type divided by the total counts of all event sequence types.

A summary of all paced events (described in the following table) is shown above the Events graph.

Table 8. Explanation of event summary data

| Event summary symbol | Dual-chamber modes | Single-chamber modes |
|---|---|---|
| AP | AP-VP + AP-VS | AP |
| VP | AS-VP + AP-VP | VP |
| AV Conduction | AP-VS + AS-VS | N/A |

Dual-chamber event types include:

- **AP-VP.** Atrial paced, ventricular paced
- **AP-VS.** Atrial paced, ventricular sensed
- **AS-VP.** Atrial sensed, ventricular paced
- **AS-VS.** Atrial sensed, ventricular sensed

[3] Rounding. Values >0 but <1 are designated as <1. Numbers from 1 to 99 are rounded up to the closest integer. Numbers greater than 99 and less than 100 are shown as >99.

- **PVC.** Premature ventricular contraction (a ventricular sensed event after a VS or VP event not preceded by a sensed atrial event)

Single-chamber atrial event types include:

- **AS.** Atrial sensed
- **AP.** Atrial paced

Accessed From: Diagnostics button > Rates tab

## Conduction

The Conduction tab of the Diagnostics workspace contains these panels:

- Ventricular Heart Rate Histogram (page 13)
- AV Intervals diagnostics (page 13)
- Total time sampled and total time sampled in AMS
- Last session date, last read date, and last cleared date

Accessed From: Diagnostics button > Conduction tab

### Ventricular Heart Rate Histogram

The Ventricular Heart Rate Histogram shows the distribution of all ventricular paced and sensed events by rate ($min^{-1}$) recorded since the diagnostics were last cleared. Each color-coded histogram bar represents the percentage of total counts the patient's intrinsic or paced rate fell within a specific rate range.

NOTE: The Ventricular Heart Rate Histogram does not include events that occurred during Auto Mode Switch (AMS).

If the Sensor parameter is programmed On or Passive, a yellow dot appears in each rate range. The position of the dot on the bar graph represents the percentage of paced events that would result if the rate was determined exclusively by response to the activity sensor.

The Ventricular Heart Rate Histogram also shows the settings of certain rate parameters, a histogram legend, the percentage of total counts sampled at Max Track Rate (page 24) (or the percentage of counts greater than or equal to 170 $min^{-1}$ if Max Track Rate has been programmed above 170 $min^{-1}$), and the number of PMT detections (page 30) (if the PMT Response parameter is activated).

Accessed From: Diagnostics button > Conduction tab

NOTE: When the LP system is not operating in a dual chamber mode, the Ventricular Heart Rate Histogram is displayed on the Rates tab.

Accessed From: Diagnostics button > Rates tab

### AV Intervals

The AV Intervals display is available in dual-chamber modes and includes a bar graph that shows the distribution of all recorded AV intervals by interval duration. Each histogram bar represents the percentage of counts the patient's AV interval fell within a specific interval duration range. Each bar is divided into color-coded segments, which indicate the portion that was paced or sensed.

## Mode Switch

The Mode Switch tab of the Diagnostics workspace is available in dual-chamber modes when the Auto Mode Switch (AMS) (page 25) parameter is enabled. The tab contains these panels:

- AMS Summary (page 13)
- V Rates During AMS (page 14)
- **AMS Log** button, which opens the AMS Log window (page 13)
- Total counts sampled and total time in AMS
- Last session date, last read date, and last cleared date

Accessed From: Diagnostics button > Mode Switch tab

### AMS Summary

The AMS Summary contains information on mode-switch activity, including two histograms:

- **Peak A Rate.** Each bar represents the number of mode-switch episodes that occurred with a peak filtered atrial rate within the rate range [4].
- **Duration.** Each bar represents the number of episodes that occurred in a single duration range.

Mode switch percentage is the time that the LP system spent in mode-switch divided by the total time sampled. The histogram does not show an ongoing AMS episode.

### AMS Log

The AMS Log lists all mode-switch events stored in the LP's memory.

Select the **AMS Log** button to display the AMS Log, which contains these columns:

- SEGM
- Date & Time
- Peak A Rate ($min^{-1}$) (peak atrial rate)
- Duration (D:H:M:S)

[4] The Peak A Rate is based on the shortest recorded atrial interval during AMS mode, and therefore is sensitive to the detection of any signals that may result in a transiently elevated rate.

The AMS Log may contain up to 16 events.

### V Rates During AMS

The V Rates During AMS panel contains a histogram showing ventricular activity during mode switches. Use this histogram to determine if the mode switch algorithm has successfully suppressed high ventricular pacing.

Each bar represents the percentage of the total counts that ventricular events fell inside a specific rate range. Each bar is divided into paced (VP) and sensed (VS) events.

## i2i™ Diagnostics

Bidirectional i2i™ communication (transmission/reception) is enabled when a LP is programmed to any dual-chamber mode. See i2i Communication (page 42) for more information.

Each i2i event notification is transmitted and received as a packet that comprises an encoded event marker to identify the notification as corresponding to either a sense event or a pace event, along with (if applicable) an encoded message or data (referred to as 'payload').

The LP or LPs will transmit and receive encoded i2i event notifications in VDI(R), VDD(R), DOO(R), DDI(R), and DDD(R) modes.

Table 9. i2i event notifications

| | Event Notification | Mode | | Event Notification | Mode |
|---|---|---|---|---|---|
| RA LP | Transmits a pace event notification on each delivery of an atrial pacing pulse | DOO(R), DDI(R), DDD(R) | RV LP | Transmits a pace event notification on each delivery of a ventricular pacing pulse | VDI(R), VDD(R), DOO(R), DDI(R), DDD(R) |
| | Transmits a sense event notification on each detection of an atrial sense event | VDI(R), VDD(R), DDI(R), DDD(R) | | Transmits a sense event notification on each detection of a ventricular sense event | VDI(R), VDD(R), DDI(R), DDD(R) |

The i2i™ Diagnostics tab of the Diagnostics workspace captures the following features to help in assessing the quality of the bidirectionally conducted communication between co-implanted (RA/RV) LPs:

Table 10. i2i diagnostics

| Measurement | Description |
|---|---|
| i2i Throughput | Graph summarizing the overall percentage of successful i2i communication transmissions from one LP to another. |
| Durations of i2i Loss | Graph summarizing the relative distribution (as a percentage of occurrences) of how long i2i communication was lost between LPs. |
| **Advanced i2i Diagnostic** button | Opens the Advanced i2i Diagnostics workspace (page 14). |
| **Read Diagnostics** button | Select this button to read the current diagnostics data from the LP or LPs. |

Accessed From: Diagnostics button > i2i Diagnostics tab

NOTE: Consider assessing i2i communication throughout the implant or follow-up procedure to ensure acceptable i2i throughput (transmission/reception). See also i2i Parameter Settings (page 31).

Contact Abbott Medical Technical Support (page 58) if assistance is needed in diagnosing i2i communication problems.

### Advanced i2i™ Diagnostics

The Advanced i2i™ Diagnostics workspace captures the following additional measurements for a more detailed assessment.

Table 11. Advanced i2i diagnostics

| Measurement | Description |
|---|---|
| **i2i Noise Reversion (i2iNR)** | When i2i™ communication is active, each LP initiates an i2i noise search period during each cardiac cycle.<br>When excessive noise is determined to be present during the noise search period, the LP temporarily transitions to an i2i noise reversion period during which i2i reception and transmission are disabled.<br>When a noise reversion period is completed, the LP reestablishes i2i reception and initiates a noise re-detection search period during the next cardiac cycle.<br>If excessive noise is re-detected during a noise re-detection search period, the LP temporarily transitions to another i2i noise reversion period during which i2i reception and transmission are disabled. When excessive noise is not re-detected during a noise re-detection search period, the LP reestablishes i2i reception and transmission, and returns to normal i2i function. |
| Search Max Invalid Received (count) | Maximum number of notifications of invalid bidirectional i2i events received during any individual i2i noise search period. |
| Total Occurrences (count) | Cumulative bidirectional counts that the LP initiates during an i2i noise reversion period. |

| | |
|---|---|
| Max Contiguous Duration (cycles) [5] | Maximum contiguous bidirectional duration (in cardiac cycles) of initial and all subsequent re-detection periods of an i2i noise reversion period episode. |
| Cumulative Duration (cycles) [6] | Cumulative bidirectional duration (in cardiac cycles) of all i2i noise reversion period episodes. |
| **i2i Loss Duration (min)** | Table listing the distribution of contiguous durations (in minutes) for all episodes of i2i communication loss in each direction since the diagnostics were last cleared. |
| **i2i Signal Strength** | Table listing the relative quality of i2i communication in each direction since the diagnostics were last cleared. Each LP assesses i2i signal quality 6 times per hour while not in-session with a programmer. |
| **i2i Throughput (%)** | Table listing bidirectional reception and transmission rates (event marker only, or event marker and payload). |
| Overall: Good Marker | Percentage of all i2i transmissions sent by one LP that were successfully received by its paired LP. |
| Overall: Good Marker + Good Payload | Percentage of all i2i transmissions with supplementary payload data transmitted by one LP that were successfully received by its paired LP. |
| **i2i Statistics (counts)** | Table listing bidirectional reception and transmission counts (event marker, payload). |
| Received: Good Marker + No Payload | Count of i2i messages successfully received by an LP in which the i2i messages include valid event marker information (e.g., pace or sense) and no supplementary payload data. |
| Received: Good Marker + Good Payload | Count of i2i messages successfully received by an LP in which the i2i messages include valid event marker information (e.g., pace or sense), as well as valid supplementary payload data. |
| Received: Good Marker + Bad Payload | Count of i2i messages successfully received by an LP in which the i2i messages include valid event marker information (e.g., pace or sense) but invalid supplementary payload data. |
| Received: Bad Marker | Count of i2i messages successfully received by an LP in which the i2i messages include invalid event marker information. |
| Transmitted: Marker Only | Count of i2i messages transmitted by an LP in which the i2i messages include event marker information (e.g., pace or sense) but no supplementary payload data. |
| Transmitted: Marker + Payload | Count of i2i messages transmitted by an LP in which the i2i messages include event marker information (e.g., pace or sense), as well as supplementary payload data. |
| Bridged Cycles (RA only) | Occurrences of atrial pace output that were not preceded by receipt of a valid i2i message by the atrial LP during the previous cardiac cycle. (In dual-chamber mode, atrial pacing is withheld if the atrial LP does not receive a valid i2i message within the previous two cardiac cycles.) |

For the i2i Throughput (%) and i2i Statistics measurements, these additional options are available:

- **Update**. Select this button to refresh the i2i Throughput (%) and i2i Statistics; this option does not update the LP device diagnostics or associated timestamps.
- **Save Data for Delta**. Select this button to create a snapshot of the i2i throughput (%) and i2i Statistics for comparison against the updated i2i diagnostics.
- **Show Delta**. Select this checkbox to update the display to show the differences in values between the saved snapshot and the most recently updated measurements. Clear the check box to redisplay the most recent measurements.

## Telemetry

The Telemetry tab of the Diagnostics workspace displays the following measurements to help in assessing the quality of the conducted communication (referred to as i2p communication) between each LP and the programmer. See Telemetry (i2p) Communication (page 42) for more information.

NOTE: If interrogation cannot be completed, telemetry diagnostic information is displayed on the initial screen.

Table 12. Telemetry diagnostics

| i2p measurement | Description | Target score |
|---|---|---|
| Noise Level (mV) | Indicates the filtered in-band signal present in the system. High noise scores may interact with the LP resulting in reduced telemetry performance. High noise scores also may present as data scores for other devices not present in the system. | Low score (<2 mV) |
| Threshold Level (mV) | Set by a syncword from the LP and used to distinguish between LP signal and noise. LP signal level must be above the threshold level for proper communication. | Higher than Noise Level score |
| Saturation Score (Counts) | Indicates the unfiltered signal present in the system. High saturation scores may be an indication of out-of-band noise, lead-off, or other fault in the system. | Low score (<1000) |

[5] Max Contiguous Duration diagnostics may be inaccurate if the associated follow-up period includes time in MRI DOO ⇄ VOO Mode.
[6] Cumulative Duration diagnostics may be inaccurate if the associated follow-up period includes time in MRI DOO ⇄ VOO Mode.

Table 12. Telemetry diagnostics

| i2p measurement | Description | Target score |
|---|---|---|
| LP Signal Level (mV) | Indicates the signal strength from the LP implant to the programmer. LP signal level must be above the threshold level for proper communication. Each LP will have its own score.<br>NOTE: Changes in LP signal levels (typically correlating to high noise scores) when no LP is present is evidence of in-band noise. | Higher than Threshold Level score |
| Active RV LP | Indicates the signal strength from the already implanted RV LP, if one is present. | |
| New RV LP | Indicates the signal strength from the newly implanted RV LP, if one is present. | |
| Active RA LP | Indicates the signal strength from the already implanted active RA LP, if one is present. | |
| New RA LP | Indicates the signal strength from the newly implanted RA LP, if one is present. | |
| Signal-To-Threshold Ratio | Indicates the LP Signal score divided by the Threshold Level score. | High score >2 |

Additional functions on this tab are intended to support advanced troubleshooting of telemetry problems. Contact Abbott Medical Technical Support (page 58) for assistance in diagnosing telemetry problems prior to using these options. These additional functions include:

- **Disable i2i** button. This button disables RV → RA i2i™ communication. If interrogation or programming of both devices in a dual-LP system is not possible, disabling i2i communication may allow the programmer to communicate with each LP individually to help troubleshoot scenarios, such as atrial undersensing or rapid ventricular rates that result in atrial blanking.

  NOTE: The programmer will automatically re-enable RV → RA i2i communication after you update any parameter, enter a new session, or complete an i2i Noise Reduction (i2iNR) period. If none of these conditions are met before ending the session, then remember to re-enable i2i communication manually.

- **Enable i2i** button. This button attempts to re-enable RV → RA i2i communication.

Accessed From: Diagnostics button > Telemetry tab

See also the Aveir™ Link Module Instructions for Use for guidance on troubleshooting and optimizing conducted communication.

# Tests

The Tests button opens the Tests workspace, which contains these tabs:

- Capture & Sense (page 17)
- Battery & Impedance (page 19)
- Commanded EGM (page 20)
- Rate Response Optimization (RRO) Snapshot (page 21)

# Capture & Sense

The Capture & Sense tab shows recent capture and sense test results.

NOTE: You cannot start a capture or sense test while the RRO Snapshot test is in progress.

To start a test, select from these buttons:

- **RA Capture** button. Opens the RA Capture Test window.
- **RV Capture** button. Opens the RV Capture Test window.
- **RA Sense** button. Opens the RA Sense Test window.
- **RV Sense** button. Opens the RV Sense Test window.

The **Update Sense** button automatically performs the available atrial and ventricular sense tests.

NOTE:

- A green highlighted button indicates that the test has not been performed in the current session.
- A blue highlighted button indicates that a test has been performed.
- A red highlighted button indicates that a test has been performed, but the test result does not meet the recommended safety margin:

  Pulse Amplitude or Sensitivity safety margin is less than 2:1.

  Pulse Width safety margin is less than 3:1.

Accessed From: Tests button > Capture & Sense tab

## Capture Test

The (RA/RV) Capture test measures atrial or ventricular capture thresholds to help determine appropriate Pulse Amplitude and Pulse Width settings.

The Capture Test window contains these tabs:

- **Perform Test.** Set up and run the test.
- **This Session.** Reports the results from the current session.
- **Previous Session.** Reports the last results from the previous session.

Accessed From: Tests > Capture & Sense tab > (RA/RV) Capture button

Accessed From: FastPath Summary button > Test Results > (RA/RV) Capture button

Accessed From: Device Implant button > Test Results > (New RA/RV) Capture button

### Capture Test Instructions

NOTE: You cannot start this test while the RRO Snapshot test is in progress.

To perform the capture test:

1. Select the **Tests** button.
2. Select the **Capture & Sense** tab.
3. Select the (RA/RV) **Capture** button to open the corresponding Capture Test window.
4. Select the **Perform Test** tab. The Perform Test tab provides the workspace for setting the test options for the capture test, reviewing and adjusting the temporary parameters, starting the test, and stopping the test to capture the threshold.
5. Select the **Options** button, which opens the (RA/RV) Capture Test: Test Options window to select the test parameter.
6. Select the **Test Parameter** button for the method to be used (Pulse Amplitude or Pulse Width) to determine the atrial or ventricular capture.
7. Review the Permanent parameter setting for the accompanying parameter (Pulse Amplitude or Pulse Width) to be used for the test depending on the selected test parameter. Adjust, as necessary, by selecting a Temporary setting.
8. Close the Test Options window to return to the Capture Test window.
9. Review the Permanent Parameters for the permanently programmed settings. Select the **Permanent Parameters** button to access and change any of these settings, as necessary; changing a setting from this window will permanently program the parameter to the new setting. Close the Permanent Parameters window to return to the Capture Test window.

   NOTE: Upon conclusion of testing, confirm that the permanent parameters are appropriate for the patient.

10. Review the settings for the test parameters, Pulse Amplitude, Pulse Width, Base Rate, and Sensitivity.

    In dual-chamber modes, test parameters also include Paced AV Delay and Sensed AV Delay.

    Adjust the temporary values, as necessary, for the appropriate parameters.

11. If necessary, select the **Waveform Control** button on the Rhythm Display to reset the waveform.
12. To begin the test, select the **Start Test** button.

    The panel shows a 'Test Started' flag on the waveform to indicate where the test was started.

    When the test begins running, a Stop Test button appears.

    You can adjust settings during the test:

    – To adjust the setting of the test parameter or other parameters, select the ellipsis (...) button, then select the new setting.
    – If the test parameter is Pulse Amplitude, use the plus (+) or minus (-) buttons to adjust the test parameter setting (in steps of 0.25 V).
    – If the test parameter is Pulse Width, use the plus (+) or minus (-) buttons to adjust the test parameter setting (in steps of 0.1 ms).

    NOTE:

    - If loss of telemetry (i2p communication) is detected during the test, the LP will automatically cease use of the temporary test settings and return to normal operation using the permanent parameters.
    - If marker data (page 6) indicates a loss of i2i™ communication detected during an atrial pace capture test, cancel the test. Review the i2i communication strength levels (page 31) and attempt to re-establishing i2i communication by adjusting the levels, then repeat the test.
13. To end the test, select the **Stop Test** button.

    The current test parameter value is recorded as the loss of capture level.

    The capture threshold is recorded to be one step level higher than this loss of capture level:

    – +0.25 V, for pulse amplitude
    – +0.1 ms, for pulse width

This Session panel displays the capture threshold.

A **Print** button is provided to print the test report.

### This Session

This Session panel displays the atrial or ventricular capture test waveform recorded during the current test session. You can view, change, or print the waveform like any freeze capture.

The panel shows a 'Test Ending' flag, followed by a 'Test Ended' flag on the waveform to indicate where the test was ended.

The panel displays the currently programmed test parameter and value:

- The safety margin is highlighted in orange if the programmed settings do not provide a sufficient recommended margin:
  – Pulse Amplitude or Sensitivity recommended safety margin is less than 2:1.
  – Pulse Width recommended safety margin is less than 3:1 .
- The safety margin is highlighted in blue if it is greater than or equal to these recommended margins.

The test result shows the capture threshold. From This Session panel, you can edit the capture threshold and set the test parameter value as the permanently programmed setting.

A **Print** button is provided to print the test report.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Capture button > This Session tab

### Previous Session

The Previous Session panel displays the result of the last recorded atrial or ventricular capture test from the previous session.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Capture button > Previous Session tab

## Sense Tests

The (RA/RV) Sense test measures atrial or ventricular signal amplitude (P wave or R wave) and helps determine an appropriate Sensitivity setting. The test automatically measures the signal amplitude, reports the results, and stores an appropriate Sensitivity setting for later programming.

The Sense Test window contains these tabs:

- **Perform Test.** Set up and run the test.
- **This Session.** Reports the results from the current session.
- **Previous Session.** Reports the last results from the previous session.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Sense button

Accessed From: FastPath Summary button > Test Results > (RA/RV) Sense button

### Sense Test Instructions

NOTE: You cannot start this test while the RRO Snapshot test is in progress.

To perform the sense test.

1. Select the **Tests** button.
2. Select the **Capture & Sense** tab.
3. Select the (RA/RV) **Sense** button to open the corresponding Sense Test window.
4. Select the **Perform Test** tab. The Perform Test shows the current permanently programmed settings for the sense test-related parameters.
5. Review the Permanent Parameters for the permanently programmed settings. Select the **Permanent Parameters** button to change any of these settings, as necessary; changing a setting from this window will permanently program the parameter to the new setting. Close the Permanent Parameters window to return to the Sense Test window.

   NOTE: Upon conclusion of testing, confirm that the permanent parameters are appropriate for the patient.

6. To begin the test, select the **Start Test** button.

The system measures (and shows in the Rhythm Display) the signal amplitude (P wave or R wave), and the test completes automatically. The M marker is shown to indicate the cardiac cycle during which the measurement was taken. This Session panel displays the Test Result as a numerical value. If no intrinsic signal is detected, the Test Result indicates 'No (P/R) wave detected'.

NOTE: In dual-chamber modes, an i2i loss marker will appear on the sensed beat for the LP not performing the sense measurement.

A **Print** button is provided to print the test report.

### This Session

This Session panel displays the (RA/RV) Sense Test Result recorded during the current test session. You can view or print the surface ECG recording like any freeze capture. A button is provided for adjusting the sweep speed, as necessary.

The panel displays the currently programmed value for the (RA/RV) Sensitivity parameter. Select the button to adjust the Sensitivity parameter setting.

- The safety margin (the ratio of the measured signal amplitude to the Sensitivity setting) is highlighted in orange if the programmed settings do not provide a sufficient recommended margin:
  - Pulse Amplitude or Sensitivity recommended safety margin is less than 2:1.
  - Pulse Width recommended safety margin is less than 3:1.
- The safety margin is highlighted in blue if it is greater than or equal to these recommended margins.

The panel includes a 52-week (P/R) Wave Trend, a graph of weekly sense threshold measurements over time.

A **Print** button is provided to print the test report.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Sense button > This Session tab

### Previous Session

The Previous Session panel displays:

- Results of the last recorded (RA/RV) Sense test from the previous session.
- 52-week (P/R) Wave Trend. The weekly sense threshold measurements over time presented as a graph.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Sense button > Previous Session tab

## Battery & Impedance

The Battery & Impedance tab displays battery information and the most recent impedance measurement:

- **Battery Profile** button, which shows the last (RA/RV) battery voltage measurement and longevity estimate, and opens the Battery Details window (page 19).
- **Impedance** buttons, which show the most recent (RA/RV) impedance measurements, and opens the corresponding Impedance windows. See Impedance Test Instructions (page 20).

Select the **Update Impedance** button to update the impedance measurement results.

Accessed From: Tests button > Battery & Impedance tab

### Battery Details

Select the Battery Profile button to open the Battery Details window, which displays the (RA/RV) Battery Information:

- Estimated Longevity (in years) and gauge showing the estimated battery longevity until recommended replacement time (RRT) (page 45) is reached (based on the current rate of usage and other data). This information is updated whenever the LP is interrogated or diagnostics are updated.
- Most recent battery voltage measurement. A battery voltage measurement first becomes available at time of implant. An LP does not perform a battery voltage measurement while in-session with a programmer, or for approximately three hours thereafter.
- Battery Current. A battery current measurement first becomes available approximately 24 hours after implant. An LP does not perform a battery current measurement while in-session with a programmer, or for approximately three hours thereafter.
- Remaining Capacity to RRT. The estimated remaining battery capacity percentage until RRT is reached.
- Battery Voltage Trend. A line graph of measurements over time including the RRT threshold level.

Select the **Print** button to print the battery profile.

Accessed From: Tests button > Battery & Impedance tab > Battery Profile button

### Magnet Rate

When magnet response is set to On and the system is programmed in any single-chamber atrial mode, the atrial LP will pace asynchronously (AOO) when it detects the sustained presence of a magnet. When magnet response is On and the system is programmed in any other single-chamber or dual-chamber mode, the ventricular LP will pace asynchronously (VOO) when it detects a magnet. Pacing output will be at 100 $min^{-1}$ for 5 cycles and then either at a rate as a function of the battery voltage of the LP that is pacing when neither LP has reached RRT (see the following table), or at a fixed rate of 65 $min^{-1}$ if either LP has reached RRT. After the system no longer detects the presence of the magnet, it will return to its programmed mode and rate.

Magnet rates at various battery voltages before reaching RRT are shown in the following table:

Table 13. Pacing rates following magnet detection (prior to RRT)

| Battery Voltage | Magnet Rate |
|---|---|
| $V_{batt} \geq 3.0$ V | 100 $min^{-1}$ |

Table 13. Pacing rates following magnet detection (prior to RRT)

| Battery Voltage | Magnet Rate |
|---|---|
| 3.0 V > $V_{batt}$ ≥ 2.9 V | 97 $min^{-1}$ |
| 2.9 V > $V_{batt}$ ≥ 2.8 V | 94 $min^{-1}$ |
| 2.8 V > $V_{batt}$ ≥ 2.7 V | 91 $min^{-1}$ |
| 2.7 V > $V_{batt}$ ≥ 2.6 V | 88 $min^{-1}$ |
| 2.6 V > $V_{batt}$ | 85 $min^{-1}$ |

The effectiveness of magnets varies. If one magnet does not cause magnet response, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the LP can also help.

### Impedance

Select an (RA/RV) Impedance button to open the corresponding Impedance window, which shows the most recent impedance measurement result from the current and previous sessions and the Impedance Trend over the most recent 52 weekly impedance measurements. The Impedance window contains these tabs:

- **Perform Test.** Run the test. If the test has been performed during the current session, the last recorded measurement is shown.
- **Previous Session.** If the test was performed during the previous session, the last recorded measurement is shown.

Accessed From: Tests button > Battery & Impedance tab > (RA/RV) Impedance button

Accessed From: FastPath Summary button > Test Results > (RA/RV) Impedance button

#### Impedance Test Instructions

To perform the Impedance test:

1. Select the Tests button.
2. Select the Battery & Impedance tab.
3. Select the (RA/RV) Impedance button to open the corresponding Impedance window.
4. Select the Perform Test tab.
5. To begin the test, select the Update Result window button. The system measures the impedance and the test completes automatically.

The Impedance window displays the Measurement Result. A **Print** button is provided to print the result.

Accessed From: Test button > Battery & Impedance tab > (RA/RV) Impedance button > Perform Test tab

Accessed From: FastPath™ Summary button > Test Results > (RA/RV) Impedance button > Perform Test tab

### Previous Session

The Previous Session panel displays:

- Results of the last recorded (RA/RV) Impedance measurement from the previous session.
- Impedance trend over the most recent 52 weekly impedance measurements.

Accessed From: Tests button > Capture & Sense tab > (RA/RV) Impedance button > Previous Session tab

## Commanded EGM

The Commanded EGM tab contains the (RA/RV) Commanded EGM button, which opens the corresponding Commanded EGM window to view or collect an intracardiac electrogram (IEGM). A commanded EGM (CEGM) or IEGM shows the heart's electrical activity as sensed by an LP. A collected CEGM shows 100 ms pre-event and 500 ms post-event durations.

NOTE: You must clear stored EGMs (SEGMs) before collecting CEGMs. To clear SEGMs, select the **Clear Diagnostics** button (page 35) from the Wrap-Up™ Overview workspace.

To collect an IEGM:

1. Select the **Tests** button.
2. Select the **Commanded EGM** tab.
3. Select the (RA/RV) **Commanded EGM** button.
4. If desired, select the **Fixed Scale All** box to standardize the Y-axis amplitude on display and print reports for all stored CEGMs. Deselect the box to allow each stored CEGM to use an independently adjusted Y-axis amplitude for display and print reports.
5. Select the **Collect CEGM at 128 Hz** button.
6. Select the **Collect CEGM at 128 Hz** button repeatedly to collect up to 12 CEGMs. Select the left and right arrows (if available) to scroll through the stored CEGMs. If you try to store more than 12 CEGMs, the earliest stored CEGM is discarded to make room for the newest CEGM.
7. To create space and protect previously collected CEGMs, delete any CEGM by scrolling to a stored CEGM and selecting the **Discard Current** button.

   NOTE:

   - Alternatively, you can select the **Collect CEGM at 512 Hz** button if you want to collect higher fidelity CEGM data.
   - You cannot collect a CEGM while an RRO Snapshot test is in progress.

Select the **Print** button to print the displayed CEGM. To print all stored CEGMs, select the **Select All for Printing** checkbox, then select the **Print** button.

Accessed From: Tests button > Commanded EGM tab

# Rate Response Optimization (RRO) Snapshot

The RRO Snapshot tab allows for the assessment and optimization of the rate response parameters.

Rate Response Optimization (RRO) Snapshot is a programmer-guided procedure to collect data on the patient's exercise response and view the effects of various Sensor parameter settings on the LP's rate response. Set the Sensor parameter to On or Passive to perform the procedure.

NOTE: Some other test functions (such as capture or sense tests or CEGM collection) are not available while the RRO Snapshot test is in progress.

You can end the test at any point; otherwise, it will automatically complete after 30 minutes.

Accessed From: Tests button > RRO Snapshot tab

## RRO Snapshot Test Instructions

The following sections describe the steps for performing the Rate Response Optimization (RRO) Snapshot test.

### Initiate the RRO Snapshot Test

To initiate the test:

1. Select the **Tests** button.
2. Select the **RRO Snapshot** tab.
3. Select the **Perform Test** button to open the Rate Response Optimization window, which displays the patient Event Log.
4. Select the **Start Test** button. This temporarily reprograms the LP's data collection parameters to enable continuous collection of activity sensor data while the patient exercises for up to 30 minutes. When the test starts, a timestamp is recorded.

   NOTE: If you select the **Cancel Test** button during the test, the test is canceled and no results are collected.

   NOTE: If you program the LP during the RRO Snapshot procedure, the test is cancelled.

### Initiate Physical Activity (Optional)

To initiate the physical activity portion of the test:

1. Optionally disconnect the patient cable either from the Link Module or from the patient.
2. Always keep the Link Module connected to the programmer via the USB cable.
3. Have the patient perform the intended exercise, such as walking the hallway for up to 30 minutes.

### Log Annotations (Optional)

Annotations can be added and modified in the patient Event Log while the test is running or after the test has completed. Annotations are displayed chronologically by timestamp. Active telemetry with the LP is not required for event annotation.

Annotations are only retained by the programmer during the active session, and are discarded when the session is ended.

1. To add an annotation to the Event Log:
   a. Select the **Add** button next to the Event Log.
   b. Select the **Select Event** button to open the Activity List, then select an event from the list.
   c. Select the **Add Event** button to add the selected activity (including the time of recording) to the Event Log.
2. An annotation in the Event Log can be edited to change the activity or recorded time. To edit an annotation:
   a. Select the **Edit** button next to the Event Log.
   b. From the Event Log, select the event to edit.
   c. Edit the event by selecting a different activity or adjusting the event's recorded time.
   d. Select the **Edit Event** button to save the changes.
3. To delete an annotation from the Event Log:
   a. Select the **Edit** button next to the Event Log.
   b. From the Event Log, select the event to be deleted.
   c. Select the **Delete Event** button.

### End Physical Activity (If Applicable)

When the patient has completed the exercise, reconnect the patient cable to the Link Module or to the patient, as applicable. The patient must be connected to the programmer through the patient cable and Link Module for the programmer to populate the test results.

### End the Test

You can end the test anytime; otherwise, it will automatically complete after 30 minutes.

To end the test:

1. Select the **End Test** button. The programmer creates the rate response model from the collected activity data.
2. Select the **View Results** button to open the Rate Response Optimization Snapshot Results window.

   NOTE: You must retrieve RRO data from the LP within two hours of the end of the test; after two hours, the RRO data is automatically cleared from the LP.

## RRO Snapshot Results

The Rate Response Optimization Snapshot Results window provides a graphical view of the effects of the modified Sensor parameter (page 23) settings on the LP's rate response to the patient's exercise. This tool is used to assess how changes in the Sensor parameter settings affect the LP's rate response.

After the RRO data are retrieved, the tested Sensor-Indicated Rate (SIR) and relative body temperature changes are shown.

The window contains these panels:

**Rate Response Model.** This graph may contain four lines:

- Green. Illustrates how the patient's pacing rate would be predicted to respond if the As Modeled parameter settings had been in effect.
- Blue. Illustrates how the patient's pacing rate changed (if Sensor is set to On) or would be predicted to change (if Sensor is set to Passive) during exercise at the currently programmed Sensor parameter settings.
- Pink. Illustrates the measured intrinsic rate during the test.
- Black. Illustrates the change in relative body temperature (this plot uses the y-axis along the right side of the graph).

**Patient event log.** This panel logs annotated events over the course of the test.

**Sensor parameters.** This panel lists the parameters Sensor Gain (page 23), Max Sensor Rate (page 24), and Base Rate (page 24) and shows the settings used during the test (As Tested). The panel provides buttons to change the modeled parameter settings to view how the response could be optimized (As Modeled). Whenever the settings in the As Modeled column differ from the As Tested column, a green line appears on the Rate Response Model to illustrate the effect on the patient's predicted sensor-indicated pacing rate.

To view how a different setting would change the exercise response, adjust the As Modeled parameters on the right. The display will be adjusted to indicate how the new settings would be predicted to change the LP's rate response.

You can print Rate Response Models from the Rate Response Optimization Snapshot Results window only. Select the **Print** button to print the test report, which contains:

- Time the test was initiated
- Parameter settings used during the test and the settings used for modeling
- Actual and modeled test results
- Annotations logged during the test

Accessed From: Tests button > Rate Response Snapshot tab > View Results button

# Brady Parameters

The Brady Parameters tab of the Parameters workspace groups and displays most of the programmable bradycardia parameters.
Select the appropriate button to change the related parameter settings:

- Basic Operation (page 23)
- Rates (page 24)
- Delays (page 26)
- Capture & Sense (page 27)
- Refractories & Blanking (page 28)
- AT/AF Detection & Response (page 25)

NOTE: The 2:1 Block Rate (page 24) is shown on all windows of the Parameters workspace except the Capture & Sense window.

Accessed From: Parameters button > Brady tab

Parameter descriptions in this section also provide the available and nominal settings.
See also Technical Data (page 53), which provides these additional tables for reference:

- Shipped and Reset/Emergency EVVI Settings (page 53)
- Programmable Parameters and Settings (page 54)

# Basic Operation

The Basic Operation window allows changes to the settings for these parameters:

- Mode (page 23)
- Magnet Response (page 23)
- Sensor (page 23)
- Sensor Gain (page 23)
- Max Sensor Rate (page 24)

Accessed From: Parameters button > Brady tab > Basic Operation button

## Mode

The Mode parameter determines the basic operation of the LP.

For timing diagrams and mode descriptions, see Operating Modes (page 35).

Accessed From: Parameters button > Brady tab > Basic Operation button

## Magnet Response

The Magnet Response parameter determines how the LP responds when a magnet is placed over it. The settings are Off (no response) and On, which causes the LP to pace asynchronously at the Magnet Rate (an indication of battery status). When the magnet is removed, the pacing rate returns to the programmed Base Rate (page 24) or Sensor-Indicated Rate (SIR).

- In a dual-chamber LP configuration, the magnet rate is 65 bpm when the battery of either active LP is at RRT.
- In a single-chamber LP configuration or a dual-chamber LP configuration operating in a single-chamber mode, the magnet rate is 65 bpm when the battery of the active LP is at RRT.

NOTE: The effectiveness of magnets varies. If one magnet does not cause a magnet response, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the LP can also help.

Settings: Off; On (Nominal: On)

Accessed From: Parameters button > Brady tab > Basic Operation button

## Sensor

The Sensor parameter turns on rate-responsive pacing, which enables the LP to increase or decrease its rate based on activity sensor data.

In the Passive setting, the LP does not activate rate-responsive pacing, but it records diagnostic data that can be read in the Rates tab (page 12) of the Diagnostics workspace.

NOTE: Interactions. When the LP reaches Recommended Replacement Time (RRT), it automatically reprograms the Sensor mode to Off, which disables rate-responsive pacing.

Settings: Off; On; Passive (Nominal: Passive)

Accessed From: Parameters button > Brady tab > Basic Operation button

## Sensor Gain

If the Sensor parameter is set to On or Passive, use the Sensor Gain parameter to increase or decrease responsiveness for a given activity:

- Increase the Sensor Gain setting to increase responsiveness for the activity.
- Decrease the Sensor Gain setting to decrease responsiveness for the activity.

Settings: 1 to 7 (Nominal: 4)

Accessed From: Parameters button > Brady tab > Basic Operation button

### Max Sensor Rate

The Max Sensor Rate (MSR) parameter sets the highest pacing rate allowed by rate-responsive pacing while the Sensor is On.

The parameter also is the highest Sensor-Indicated Rate (SIR) that can be recorded while the Sensor is Passive.

Settings: ($min^{-1}$) 90 to 130 in steps of 5; 140 to 170 in steps of 10 (Nominal: 130)

Accessed From: Parameters button > Brady tab > Basic Operation button

## Rates

The Rates window allows changes to the settings for these parameters:

- Base Rate (page 24)
- AMS Base Rate (page 25)
- Max Sensor Rate (page 24)
- Hysteresis Rate Delta (page 24)
  - Search Interval (page 25)
  - Cycle Count (page 25)

Accessed From: Parameters button > Brady tab > Rates button

### 2:1 Block Rate

The programmer displays the intrinsic atrial rate at which 2:1 AV block will occur in DDD(R) mode.

Accessed From: Parameters button > Brady tab > Delays button

### Base Rate

The Base Rate parameter sets the LP's pacing rate.

- In DDD and atrial modes, the Base Rate interval is measured from an atrial stimulus to the next atrial stimulus without an intervening atrial sensed event.
- In DDI and ventricular modes, the interval is measured from a ventricular stimulus to the next stimulus without an intervening ventricular sensed event.

Typically, pacing rates can fall lower than the Base Rate setting only if Hysteresis Rate Delta parameter (page 24) is programmed.

Settings: ($min^{-1}$) 30 to 130 in steps of 5; 140, 150 (Nominal: 50)

Accessed From: Parameters button > Brady tab > Rates button

### Max Track Rate

The Max Track Rate (MTR) parameter is the maximum ventricular pacing rate allowed by the ventricular LP in dual-chamber tracking modes VDD(R) or DDD(R). If the atrial LP senses an atrial rhythm faster than the MTR setting, the Sensed AV Delay interval (page 26) is extended to ensure that the ventricular paced rate does not exceed the MTR setting. Occasional pauses (Wenckebach behavior) may occur according to normal upper rate behavior.

As an aid to programming, when the Max Track Rate parameter is programmed, the programmer shows the intrinsic atrial rate at which 2:1 AV block occurs.

The MTR parameter is available when the LP operating mode is VDD(R) or DDD(R).

NOTE: Interactions.

- Max Sensor Rate. The Max Track Rate setting can be exceeded if the Max Sensor Rate setting (page 24) is programmed higher than the Max Track Rate setting.
- Paced AV Delay, Sensed AV Delay, and PVARP. The Max Track Rate setting is limited by the programmed Paced AV Delay (page 26), Sensed AV Delay (page 26), and PVARP (page 28) settings.
- Interactions with algorithms. The interaction of a number of algorithms may allow the LP to override the Max Track Rate and Max Sensor Rate settings. These include all ventricular-based algorithms and the Ventricular Intrinsic Preference (VIP™) Parameter (page 27) and Ventricular Safety Standby (page 29) algorithms. This interaction is more likely to occur in cases where the operational Paced AV Delay setting is significantly different than the patient’s conduction time. For more information on upper rate behavior, contact Abbott Medical Technical Support (page 58).

Settings (depending on dual-chamber configuration):

Configurations including LSP112V: ($min^{-1}$) 90 to 130 in steps of 5; 140 to 170 in steps of 10 (Nominal: 130)

Configurations including LSP202V: ($min^{-1}$) 90 to 130 in steps of 5; 140 to 180 in steps of 10 (Nominal: 130)

Accessed From: Parameters button > Brady tab > Rates button

### Hysteresis Rate Delta

The Hysteresis Rate Delta parameter is a rate below the Base Rate setting that is used when the patient’s intrinsic rhythm is preferred to pacing. When the Hysteresis Rate Delta parameter is programmed to a value other than Off, the LP decreases the pacing rate from the Base Rate setting by an amount given by the Hysteresis Rate Delta setting when it senses intrinsic activity. If the LP fails to sense intrinsic activity, the LP switches back to the Base Rate setting.

Application of the Hysteresis Rate Delta setting is triggered by the detection of a P-wave while the LP is operating in atrial-based modes DDD(R) or AAI(R), or an R-wave while the LP is operating in ventricular-based modes, DDI(R), VDD(R), or VVI(R).

These additional parameters are available when the Hysteresis Rate Delta parameter is enabled:

- Search Interval (page 25)

- Cycle Count (page 25)

Settings: ($min^{-1}$) Off; -20 to -5 in steps of 5 (Nominal: Off)

Accessed From: Parameters button > Brady tab > Rates button

### Search Interval

If the Hysteresis Rate Delta parameter is not set to Off, the Search Interval parameter tells the LP to periodically reduce the pacing rate every programmed number of minutes to search for intrinsic activity. For example, if 5 is selected, the LP reduces the pacing rate by the Hysteresis Rate Delta setting every five minutes to search for intrinsic activity.

If the LP senses an intrinsic beat between searches, the LP will start pacing using the Hysteresis Rate Delta setting.

Settings: (minutes) 1, 5, 10, 15, 30 (Nominal: 5)

Accessed From: Parameters button > Brady tab > Rates button

### Cycle Count

Used in conjunction with Search Interval, the Cycle Count parameter is the number of cycles that the LP maintains the hysteresis rate while a search period is ongoing.

If no intrinsic beat is sensed during the search period, the LP resumes pacing at the Base Rate setting. If the LP senses an intrinsic beat during the search, it maintains the rate at the reduced level until an intrinsic beat is not sensed.

Settings: (cycles) 1 to 8 (Nominal: 4)

Accessed From: Parameters button > Brady tab > Rates button

## AT/AF Detection & Response

From the AT/AF Detection & Response window, these parameters may be set:

- Auto Mode Switch (page 25)
- Atrial Tachycardia Detection Rate (page 25)
- AMS Base Rate (page 25)

The AT/AF Detection & Response functions are available when the LP operating mode is DDD(R) or VDD(R).

Accessed From: Parameters button > Brady tab > Rates button > AMS button

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

### Auto Mode Switch

The Auto Mode Switch (AMS) parameter prevents atrial-based timing modes from tracking atrial tachycardias and causing pacemaker-mediated tachycardia (PMT). The AMS algorithm switches the operating mode from VDD(R) or DDD(R) to a non-tracking ventricular-timing mode (VDI, VDIR, DDI, DDIR) when the atrial rate surpasses the Atrial Tachycardia Detection Rate (ATDR) setting (page 25). At mode-switch, the LP paces in the ventricle using the AMS Base Rate setting (page 25).

Rather than use the actual atrial rate, which cannot always distinguish between sustained tachycardia and intermittent fast cycles, AMS uses the Filtered Atrial Rate Interval (FARI), which is based on a comparison of the current atrial rate to a continually updated average rate.

When the tachyarrhythmia subsides and the FARI falls below the Max Track Rate setting (page 24) or the Sensor-Indicated Rate (SIR) (whichever is faster), the LP switches back to the original pre-AMS mode.

NOTE:

- FARI updates are suspended while the LP is in-session with the programmer and operating in a non-tracking dual-chamber mode; therefore, AMS exit will not occur intrinsically in-session. Reprogramming the LP will force an AMS exit in this in-session circumstance.
- Unless atrial pacing support during AMS is essential for the patient, consider setting the AMS Mode to VDI(R) or Off.

Diagnostic data on mode switching is displayed in the Mode Switch diagnostics panels (page 13).

Settings: Off, VDI(R), DDI(R) (Nominal: DDI)

Accessed From: Parameters button > Brady tab > Rates button > AMS button

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

### Atrial Tachycardia Detection Rate

The Atrial Tachycardia Detection Rate (ATDR) parameter sets the atrial rate at which the LP mode-switches when the Auto Mode Switch parameter (page 25) is enabled. A mode-switch occurs when the FARI rate exceeds the programmed ATDR setting. The ATDR parameter is always available because it is also used to classify events in atrial tachycardia and trigger EGM storage. Atrial events at rates greater than the ATDR setting are recorded in the Rates diagnostics (page 12).

NOTE: Interactions. During a mode switch, the PVARP parameter (page 28) is set to the Post Ventricular Atrial Blanking Period (PVAB) parameter (page 28) value plus 24 ms. When the LP exits AMS, the LP reverts to the programmed PVARP setting.

Settings: ($min^{-1}$) 110 to 200 in steps of 10; 225 to 300 in steps of 25 (Nominal: 180)

Accessed From: Parameters button > Brady tab > Rates button > AMS button

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

### AMS Base Rate

The AMS Base Rate parameter sets the ventricular pacing rate when the LP has switched from VDD(R) or DDD(R) mode to the programmed Auto Mode Switch (AMS) (page 25) pacing mode. When the LP exits AMS, the LP resumes pacing using the programmed Base Mode at the programmed Base Rate setting (page 24).

The AMS Base Rate parameter is available only when the Auto Mode Switch parameter is enabled.

Settings: ($min^{-1}$) 40 to 130 in steps of 5; 140; 150 (Nominal: 80)

Accessed From: Parameters button > Brady tab > Rates button > AMS button

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

## Delays

The Delays window allows changes to the settings for these parameters:

- Paced AV Delay (page 26)
- Sensed AV Delay (page 26)
- Rate Responsive AV Delay (page 26)
- Shortest AV Delay (page 27)
- Ventricular Intrinsic Preference (VIP™) (page 27)
- VIP™ Extension (page 27)
- VIP™ Search Interval (page 27)
- VIP™ Search Cycles (page 27)

Accessed From: Parameters button > Brady tab > Delays button

### Paced AV Delay

The Paced AV Delay parameter is the interval between an atrial paced event and a ventricular paced event.

The Paced AV Delay parameter is available when the LP operating mode is DDD(R), DDI(R), or DOO(R).

NOTE: Interactions. The longest programmable Paced AV Delay interval is determined by the Base Rate (page 24) or AMS Base Rate (page 25) settings.

The maximum Paced AV Delay settings for all programmed Base Rate and AMS Base Rate settings are shown in the following table.

Table 14. Maximum Paced AV Delay settings

| Maximum AMS Base Rate or Base Rate ($min^{-1}$) | Maximum Paced AV Delay (ms) |
|---|---|
| 30–90 | 350 |
| 95–100 | 300 |
| 105 | 250 |
| 110 | 225 |
| 115–120 | 200 |
| 125 | 180 |
| 130–150 | 170 |

Settings: (ms) 40 to 200 in steps of 10; 225 to 300 in steps of 25; 350 (Nominal: 200)

Accessed From: Parameters button > Brady tab > Delays button

### Sensed AV Delay

The Sensed AV Delay parameter is the interval between an atrial sensed event and a ventricular paced event.

The Sensed AV Delay parameter is available when the LP operating mode is DDD(R) or VDD(R).

NOTE: Interactions. The longest programmable Sensed AV Delay setting is determined by the Paced AV Delay setting (page 26). The Sensed AV Delay setting must be shorter than or equal to the Paced AV Delay setting.

Settings: (ms) 40 to 200 in steps of 10; 225 to 325 in steps of 25 (Nominal: 150)

Accessed From: Parameters button > Brady tab > Delays button

### Rate Responsive AV Delay

The Rate Responsive AV Delay parameter increases or decreases the Paced AV Delay (page 26) or Sensed AV Delay (page 26) setting in relation to changes in the Sensor-Indicated Rate (SIR) or sensed intrinsic atrial rate.

The Rate Responsive AV Delay algorithm is only applied when the rate exceeds either 60 $min^{-1}$ or a Base Rate set above 60 $min^{-1}$.

A Low/Medium/HIgh setting changes the Paced/Sensed AV Delay setting by 0.5/0.75/1.0 ms, respectively, for each one-$min^{-1}$ change in the SIR or sensed intrinsic atrial rate. As pacing rates rise, both the Paced and Sensed AV Delay settings decrease until the programmable Max Sensor Rate (page 24), Max Track Rate (page 24), or Shortest AV Delay (page 27) setting is reached.

The Rate Responsive AV Delay parameter is available when the LP operating mode is DDD(R), DDI(R), DOO(R), or VDD(R).

Settings: Off; Low, Medium; High (Nominal: Medium)

Accessed From: Parameters button > Brady tab > Delays button

### Shortest AV Delay

The Shortest AV Delay parameter is the minimum AV delay for the Rate Responsive AV Delay setting (page 26). The Shortest AV Delay must be shorter than or equal to the programmed Paced AV Delay and Sensed AV Delay settings (page 26).

The Shortest AV Delay parameter is available only when Rate Responsive AV Delay (page 26) is enabled and the LP operating mode is DDD(R), DDI(R), or VDD(R).

Settings: (ms) 40 to 120 in steps of 10 (Nominal: 100)

Accessed From: Parameters button > Brady tab > Delays button

### Ventricular Intrinsic Preference (VIP™) Parameter

The Ventricular Intrinsic Preference (VIP™) parameter enables an algorithm which allows the LP to search for intrinsic conduction that is slower than the programmed Paced AV Delay setting (page 26) or Sensed AV Delay setting (page 26). If intrinsic conduction is sensed, the Paced/Sensed AV Delay settings are extended to allow the intrinsic conduction to continue.

The VIP algorithm is available only when the LP operating mode is DDD(R) or VDD(R).

NOTE: Interactions.

- The VIP algorithm cannot be enabled when the Base Rate setting (page 24) is greater than or equal to 110 $min^{-1}$.
- VIP suspends operation under these conditions:
  - When the FARI or SIR is ³ 110 $min^{-1}$.
  - During a Capture or Sense test (page 17).
  - When mode-switching occurs. See Auto Mode Switch (page 25).

  PVCs have no effect on this feature.

Settings: Off; On (Nominal: Off)

Accessed From: Parameters button > Brady tab > Delays button

See also:

- VIP Extension (page 27)
- Search Interval (page 27)
- Search Cycles (page 27)

### VIP™ Extension

The VIP™ Extension parameter determines the incremental duration the LP extends the Paced AV Delay / (page 26)Sensed AV Delay settings (page 26) to search for intrinsic conduction.

The Paced/Sensed AV Delay intervals are periodically extended by the programmed VIP Extension. VIP will remain in effect as long as an intrinsic R-wave is sensed during the extended Paced/Sensed AV Delay. The VIP Extension is canceled and the programmed Paced/Sensed AV Delay settings are restored once a specified number of consecutive cycles (VIP search cycles) occur in which R-waves are not sensed and ventricular pacing is necessary.

The VIP algorithm is available only when the LP operating mode is DDD(R) or VDD(R).

Settings: (ms) 50 to 150 in steps of 25; 160 to 200 in steps of 10 (Nominal: 100)

Accessed From: Parameters button > Brady tab > Delays button

### VIP™ Search Interval

The Search Interval parameter determines how frequently the LP extends the Paced AV Delay / Sensed AV Delay intervals to search for intrinsic conduction.

Settings: (min) 1; 3; 5; 10; 30 (Nominal: 1)

Accessed From: Parameters button > Brady tab > Delays button

### VIP™ Search Cycles

The Search Cycles parameter determines the number of cycles the LP extends the Paced AV Delay / Sensed AV Delay intervals (page 26) to search for intrinsic conduction.

Settings: (cycles) 1 to 3; (Nominal: 2)

Accessed From: Parameters button > Brady tab > Delays button

## Capture & Sense

The Capture & Sense window allows changes to the settings for these parameters:

- Pulse Amplitude (page 28)
- Pulse Width (page 28)
- Sensitivity (page 28)

The Capture & Sense window also shows the AutoSense and Electrode Configuration (non-programmable) settings.

Accessed From: Parameters button > Brady tab > Capture & Sense button

### Pulse Amplitude

The Pulse Amplitude parameter determines how much electrical potential is applied to the myocardium during the pacing stimulus.

For a chronic, stable system, a minimum 2:1 margin between the Pulse Amplitude setting and the measured pulse amplitude capture threshold is advised for pacemaker-dependent patients.

The Pulse Amplitude setting can be evaluated with the Capture & Sense tests (page 17). Assess capture thresholds periodically to maintain an appropriate safety margin for reliable long-term capture.

Settings: (V) 0.25 to 6.0 in steps of 0.25 (Nominal: 2.5) [7]

Accessed From: Parameters button > Brady tab > Capture & Sense button

### Pulse Width

The Pulse Width parameter (pulse duration) determines how long the pace pulse output is applied to the myocardium.

For a chronic, stable system, a minimum 3:1 margin between the Pulse Width setting and the measured pulse width capture threshold is advised for pacemaker-dependent patients.

The Pulse Width setting can be evaluated with the Capture & Sense tests (page 17). Assess capture thresholds periodically to maintain an appropriate safety margin for reliable long-term capture.

Settings: (ms) 0.1 to 1.5 in steps of 0.1 (Nominal: 0.4)

Accessed From: Parameters button > Brady tab > Capture & Sense button

### Sensitivity

The Sensitivity parameter determines the minimum amplitude of an intrinsic cardiac signal that the LP will detect. The LP detects any sensed signal equal to or greater than the programmed Sensitivity (mV) setting; the higher the setting (mV), the lower the sensitivity.

The Sensitivity level can be evaluated with the Sense Test (page 18). Assess sensing sensitivity level periodically to maintain an appropriate safety margin for reliable long-term sensing.

To avoid potential complications associated with undersensing, maintain a margin of two to four times the intrinsic cardiac amplitude (for example, for an intrinsic signal of 4 mV, program the sensitivity to 1 or 2 mV).

Low-amplitude intrinsic signals may require a high Sensitivity setting (low mV setting) to ensure that all valid signals are sensed. If the LP responds to extraneous signals or interference, a lower Sensitivity setting (higher mV setting) may help filter out those unwanted signals.

Settings (RA): (mV) 0.25 to 2.0 in steps of 0.25; 2.5 to 5.0 in steps of 0.5; 6.0 to 10.0 in steps of 1.0 (Nominal: 0.5)

Settings (RV): (mV) 0.5 to 5.0 in steps of 0.5; 6 to 10 in steps of 1.0; 12 to 18 in steps of 2 (Nominal: 2)

Accessed From: Parameters button > Brady tab > Capture & Sense button

## Refractories & Blanking

The Refractories & Blanking window allows changes to the settings for these parameters:

- PVARP (page 28)
- Post-Ventricular Atrial Blanking (PVAB) (page 28)
- (RA/RV) Base Refractory (page 29)
- Rate Responsive PVARP/VRef/ARef (page 29)
- Shortest PVARP/VRef/ARef (page 29)
- Additional Settings, PVC & PMT (page 29)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

### PVARP

The Post Ventricular Atrial Refractory Period (PVARP) parameter sets the amount of time that the atrial sensing circuit is in refractory to avoid inappropriate response to stimuli. An atrial event that is sensed during this interval is classified as a refractory event. The PVARP parameter is intended to prevent non-physiologic or retrograde P-waves from inhibiting the atrial stimulus.

The PVARP period begins after an intrinsic R-wave, PVC, or a ventricular paced pulse in VDD(R), DDI(R), or DDD(R) mode; thus, the first portion of PVARP overlaps with PVAB (page 28). Accordingly, PVARP must be at least 25 ms greater than PVAB.

Settings: (ms) 150 to 500 in steps of 25 (Nominal: 275)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

### Post-Ventricular Atrial Blanking

The Post-Ventricular Atrial Blanking (PVAB) parameter establishes an atrial absolute refractory period after ventricular paced and sensed events to prevent the atrial channel from oversensing far-field R-waves.

Atrial events during this period are blanked and do not update the FARI.

The PVAB parameter is available when the LP operating mode is VDD(R), DDI(R) or DDD(R).

NOTE: Use the Post-Ventricular Atrial Blanking parameter with caution as it may have adverse effects on atrial sensing, and indirectly, on the Auto Mode Switch function (page 25).

Settings: (ms) 60 to 200 in steps of 10; 225; 250 (Nominal: 150)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

[7] A non-programmable setting of 0 is also displayed.

### (RA/RV) Base Refractory

The Base Refractory parameter sets the portion of the pacing cycle unresponsive to signals from the (RA/RV) sensing circuit to avoid inappropriate responses to stimuli.

- The (RA) Base Refractory period begins after an atrial paced (AP) or atrial sensed (AS) event.
- The (RV) Base Refractory period begins after a ventricular paced (VP) or ventricular sensed (VS) event.

The Base Refractory setting can automatically adjust to changes in rate. See Rate Responsive PVARP/VRef/ARef (page 29).

Settings (depending on configuration):

RA, single-chamber: (ms) 160 to 400 in steps of 30; 440 to 470 in steps of 30 (Nominal: 310)

RA, dual-chamber: (ms) 160 to 400 in steps of 30; 440 to 470 in steps of 30 (Nominal: 250)

RV: (ms) 160 to 400 in steps of 30; 440 to 500 in steps of 30 (Nominal: 250)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

### Rate Responsive PVARP/VRef/ARef

When this feature is enabled, refractory periods PVARP (page 28) and (RA/RV) Base Refractory (page 29) are automatically adjusted in responses to changes in the intrinsic or paced heart rate. When the intrinsic rate or Sensor-Indicated Rate (SIR) increases, this feature will automatically shorten refractory periods. When the rate decreases, refractory periods lengthen accordingly.

- A setting of Low will preserve a 10% alert period.
- A setting of Medium will preserve a 20% alert period.
- A setting of High will preserve a 30% alert period.

This feature begins adjusting refractory periods when the intrinsic or pacing rate exceeds 60 bpm or the programmed Base Rate (page 24), whichever is higher.

Refractory periods will cease shortening when the programmed shortest refractory (Shortest PVARP/VRef/ARef (page 29)) is reached or when the maximum pacing rate is reached (Max Sensor Rate (page 24) if Sensor is On, otherwise the Max Track Rate (page 24)).

NOTE: While the LP is in-session with the programmer and operating in a non-tracking dual-chamber mode, rate responsive adjustment (expected shortening) of PVARP as the patient's heart rate increases is suspended.

**Rate Responsive PVARP/VRef.** Available in DDD(R), DDI(R), and VDD(R) modes, this parameter will adjust both PVARP and RV Base Refractory.

**Rate Responsive VRef.** Available in VVI(R) and OVO modes, this parameter will adjust RV Base Refractory.

**Rate Responsive ARef.** Available in AAI(R) and OAO modes, this parameter will adjust RA Base Refractory.

Settings: Off; Low; Medium; High (Nominal: High)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

### Shortest PVARP/VRef/ARef

The Shortest PVARP/VRef/ARef parameter sets the shortest allowable duration for PVARP/VRef/ARef (page 28) when the Rate Responsive PVARP/VRef/ARef (page 29) parameter is enabled.

- When the operating mode is DDD(R), DDI(R), or VDD(R), this parameter is named **Shortest PVARP/VRef**.
- When the operating mode is VVI(R) OVO, this parameter is named **Shortest VRef**.
- When the operating mode is AAI(R) OAO, this parameter is named **Shortest ARef**.

Settings: (ms) 150 to 450 in steps of 25 (Nominal: 175)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

## Additional Settings, PVC & PMT

### Ventricular Blanking

The Ventricular Blanking (VB) parameter determines an absolute refractory period in the ventricular channel immediately following an atrial output pulse in dual-chamber modes.

This absolute refractory period minimizes the chances of the ventricular channel sensing the atrial output and inappropriately inhibiting the ventricular output.

In DDD(R) and DDI(R) pacing modes, an atrial output pulse initiates ventricular blanking; a P-wave that inhibits the atrial pulse does not initiate ventricular blanking.

Settings: (ms) 16 to 56 in steps of 8 (Nominal: 48)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

### Ventricular Safety Standby

The Ventricular Safety Standby (VSS) parameter starts a crosstalk detection window immediately after the ventricular blanking (VB) period.

NOTE: **Crosstalk** occurs when atrial output signals are sensed by the ventricular channel and results in the inhibition of the ventricular pulse. Clinically, crosstalk usually can be identified by atrial pacing with no ventricular channel output. Crosstalk typically occurs with:

- High atrial pulse amplitude or pulse width settings
- Low ventricular sensitivity settings (greater sensitivity)
- Rapid pacing rates

To minimize crosstalk, decrease the atrial Pulse Amplitude or Pulse Width setting, or decrease the RV LP’s sensitivity.

The VSS algorithm prevents the RV LP from inappropriately sensing crosstalk that would inhibit the ventricular pulse output. If crosstalk is sensed during this crosstalk detection window, a committed ventricular pulse is delivered 120 ms after the detected crosstalk. Signals sensed outside of the crosstalk detection window inhibit the ventricular pulse.

Even if crosstalk is not sensed, the Ventricular Safety Standby parameter can prevent the inappropriate inhibition of ventricular output.

The Ventricular Safety Standby parameter is available when the LP operating mode is DDD(R) or DDI(R).

NOTE: Interactions. If the Sensed AV Delay parameter (page 26) or the Rate Responsive AV Delay parameter (page 26) is programmed shorter than 120 ms, the ventricular pulse is delivered at that shorter interval.

Settings: Off; On (Nominal: On)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

## PVC Response

The PVC Response feature detects and responds to premature ventricular contractions (PVCs). The algorithm detects a PVC if an R-wave is not preceded by an atrial event and that R-wave is also not preceded during the previous 280 ms by an atrial sense event detected within the relative refractory portion of PVARP.

The parameter has these available settings:

- **Off**. PVCs are detected only.
- **Atrial Pace**. PVCs are detected and the algorithm initiates the Atrial Pace response to a PVC confirmation.

The response consists of the initiation of a PVC PVAB (equal to the greater of 120 ms and base PVAB) and a PVC PVARP of 475 ms. If an atrial sense event is detected during this PVC PVARP, an atrial pace pulse will be delivered 330 ms later unless a normal atrial or ventricular sense event is detected or a ventricular pace pulse is delivered prior to the delivery of that atrial pace pulse. The atrial pace pulse will be delivered at the programmed atrial output.

The PVC Response parameter is available when the LP operating mode is DDI(R), DDD(R), VDI(R), or VDD(R).

The PVC Response parameter responds to PVCs when the LP operating mode is DDD(R) or VDD(R). In VDD(R) mode with PVC Response enabled, the atrial pace output is automatically set to a minimum output of 2.5V/0.6 ms. The atrial pace output cannot be adjusted while in VDD(R) mode.

NOTE: Diagnostics.

- The Rates window (page 12) of the Diagnostics workspace reports the total number of PVCs detected by the LP.
- An atrial pace response can result in the appearance of fast atrial rates in atrial diagnostics such as the Atrial Heart Rate Histogram (page 12).

Settings: Off, Atrial Pace (Nominal: Off)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

## PMT Response

The PMT Response feature detects and responds to pacemaker mediated tachycardias (PMTs). The parameter has these available settings:

- **Off.** No PMTs are detected.
- **Atrial Pace.** PMTs are detected (as described in this section) and the Atrial Pace response is started to end the PMT.

The PMT Response algorithm detects that a PMT is occurring after it has counted 10 consecutive P-V events (atrial sensed/ventricular stimulated) at a rate greater than or equal to the programmed PMT Detection Rate (page 30). After the tenth P-V event, the algorithm initiates the Atrial Pace on PMT response.

During the Atrial Pace on PMT response, the RV LP withholds ventricular output and the RA LP initiates a 330 ms alert period after the retrograde P-wave. An atrial pulse is delivered if no P-wave is detected during the alert period. This is followed by normal pacing. After PMT detection has occurred, the PMT detection algorithm is suspended for 256 cycles.

The atrial pace pulse will be delivered at the programmed atrial output. When the LP is programmed to VDD(R) mode with PMT Response enabled, the atrial pace output is automatically set to a minimum output of 2.5 V/0.6 ms. The atrial output cannot be adjusted while in VDD(R) mode.

NOTE: Interactions. The PMT algorithm is suspended during an Auto Mode Switch (page 25).

The PMT Response parameter is available when the LP operating mode is DDD(R) or VDD(R).

Settings: Off; Atrial Pace (Nominal: Off)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

## PMT Detection Rate

The PMT Detection Rate parameter determines at what rate the LP becomes alert to the presence of pacemaker-mediated tachycardia (PMT) when the PMT Response parameter (page 30) is enabled. The settings begin at 90 $min^{-1}$ (or higher if the Base Rate parameter (page 24) is programmed above 90 $min^{-1}$) and do not exceed the Max Track Rate parameter (page 24).

NOTE: Interactions.

- Base Rate. The PMT Detection Rate parameter cannot have a setting slower than the Base Rate setting. If the PMT Detection Rate is set equal to or slower than the Base Rate setting, the PMT Detection Rate parameter is automatically adjusted to 10 $min^{-1}$ faster than the Base Rate setting.
- Max Track Rate (MTR) The PMT Detection Rate parameter cannot have a setting faster than the MTR setting. If MTR parameter is set equal to or lower than than the PMT Detection Rate setting, the PMT Detection Rate parameter is automatically adjusted to a lower rate. If a lower rate is not available, then PMT detection and response will be disabled.

Settings (depending on dual-chamber configuration):

Configurations including LSP112V: ($min^{-1}$) 90 to 165 in steps of 5 (Nominal: 125)

Configurations including LSP202V: ($min^{-1}$) 90 to 175 in steps of 5 (Nominal: 125)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

# i2i™ Options

## i2i (RA/RV) Blanking Response

The i2i Blanking Response parameter adjusts the LP response in the event that an i2i™ communication signal is not received as expected.

When the i2i Blanking Response parameter is activated and an LP receives an invalid i2i event notification (one that contains a null or invalid i2i marker), the LP establishes a period in which sensed events are not detected, in order to avoid inappropriate sensing of the remote pacing pulse.

The i2i Blanking Response parameter is available for an RA LP operating in DDD(R), DDI(R), or VDD(R) mode, or for an RV LP operating in DDD(R) or DDI(R) mode. For all other modes, the parameter is set to Off.

Settings: Off; Low; Medium; High (Nominal: Off)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

## i2i Parameter Settings

The i2i Settings Management window provides options to measure the bidirectional i2i™ communication strength in-session and program the optimal strength level for LPs operating in VDD(R), DOO(R), DDI(R), or DDD(R) mode. You can set strength levels based on the results of a user-initiated i2i strength assessment, or you can set levels manually.

NOTE: Consider assessing i2i communication throughout the implant or follow-up procedure to ensure acceptable i2i throughput (transmission/reception). The i2i™ Diagnostics tab (page 14) of the Diagnostics workspace captures measurements to help in assessing the quality of the bidirectionally conducted communication between co-implanted (RA/RV) LPs.

To perform an automatic i2i strength measurement:

1. Select the **Perform Auto Assessment** button to initiate an automatic assessment based on the current i2i strength levels. (Select the **Cancel Auto Assessment** button to cancel an assessment in progress, if necessary.)

   The completed assessment provides the recommended strength level for each i2i communication direction.
2. Review the recommended strength levels.
3. Select the **Accept** button to program the recommended i2i settings to the LPs.

To adjust strength levels manually:

1. Use the plus (+) and minus (-) buttons to adjust the strength level. Changing a strength level immediately programs the i2i setting to the LPs.
2. Wait at least 15 seconds for the programmer to collect data based on the manually selected i2i strength levels.
3. Select the **Update i2i Data** button to update the i2i throughput diagnostics (transmission/reception rates).

Settings: 1 to 7 (Nominal: 4)

NOTE: Programming a high strength level (such as level 7) can substantially reduce LP battery longevity. Therefore, if using a high setting, consider monitoring the estimated longevity until RRT closely using the Battery Details window (page 19).

Accessed From: Parameters button > i2i Parameter Settings tab > i2i Parameter Settings button

## Episode Settings

The Episode Settings window of the Parameters workspace displays and allows changes to these programmable parameters. Select the appropriate button to change the parameter settings:

- Stored EGM Configuration button. Opens the Stored EGM Configuration window (page 32) to the stored EGM configuration parameters.
- Episode Triggers button. Opens the Episode Triggers window (page 32), which allows the triggers to be set for recording atrial episodes for EGM storage.

  NOTE: To ensure that all important episodes are collected, consider clearing episodes from the LP device memory at the end of each session.

Accessed From: Parameters button > Episode Settings

See also:

- Episodes (page 11)
- Clear Diagnostics (page 35)

## Stored EGM Configuration

The Stored EGM Configuration window displays and sets these SEGM configuration parameters:

- Storage Mode (page 32)
- Total Storable Episodes (page 32)
- Post-Trigger Storage Duration per Episode (page 32)
- (RA/RV) Amplitude Range (page 32)

Accessed From: Parameters button > Episode Settings > Stored EGM Configuration

### Storage Mode

The Storage Mode parameter has these available settings:

- Continuous. Stored EGMs (SEGMs) will be stored in a first-in, first-out manner; when a new episode occurs, the oldest SEGM will be overwritten to make space for a new SEGM.
- Freeze. After the maximum number of SEGMs have been collected, no additional SEGMs will be stored. See Total Storable Episodes (page 32).

Settings: Freeze, Continuous (Nominal: Continuous)

Accessed From: Parameters button > Episode Settings > Stored EGM Configuration

### Total Storable Episodes

The Total Storable Episodes parameter sets the maximum number of storable EGMs.

Settings: 1, 2, 4, (Nominal: 4)

Accessed From: Parameters button > Episode Settings > Stored EGM Configuration

### Post-Trigger Storage Duration Per Episode

The Post-Trigger Storage Duration per episode indicates the amount of EGM time recorded after an episode trigger is detected.

Settings: (seconds) auto-calculated, non-programmable

Accessed From: Parameters button > Episode Settings > Stored EGM Configuration

### Amplitude Range

(RA/RV) amplitude range (SEGM recording range).

Settings:

(RA) SEGM atrial recording range: (mV) 1.25, 3, 6, 14 (Nominal: 6)

(RV) SEGM ventricular recording range: (mV) 1.25, 3, 6, 14 (Nominal: 14)

Accessed From: Parameters button > Episode Settings > Stored EGM Configuration

## Episode Triggers

From the Episode Triggers window, these triggers can be set for recording atrial episodes for EGM storage:

- AMS Entry. Atrial episode is recorded upon AMS entry.
- AMS Exit. Atrial episode is recorded upon AMS exit.
- AMS Entry & Exit. Atrial episode is recorded upon AMS entry and exit.
- Off

Accessed From: Parameters button > Episode Settings tab > Episode Triggers button

## MRI Settings

The MRI Settings tab allows you to program basic operating parameters for an MR Conditional device that are in effect while these MRI Settings are enabled.

**WARNING: Before any attempt to scan a patient with an implanted MR Conditional device, read all the instructions in the MRI-Ready Leadless System Manual. If you have any questions, contact Technical Support (page 58) before proceeding with the MRI scan.**

The MRI Settings window contains these options:

- **Undo All** button. Restores the previously-programmed MRI Settings.
- **Save MRI Settings** button. Saves the currently selected MRI Settings to the device.
- **Test MRI Settings** button. Enables the device's MRI Settings to help you evaluate the patient's hemodynamic status with the proposed MRI parameters. When the test is complete, select the **Cancel MRI Settings Test** button.

  **CAUTION: Failure to cancel the test, or loss of communication with the device before canceling the test, can unintentionally leave the device programmed with MRI Settings.**
- **Setup for MRI Now** button. Opens the MRI Checklist (page 34) to use the programmer to enable the MRI Settings that have been saved to the device.

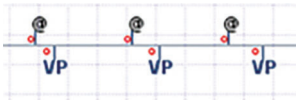
NOTE:

- During EVVI operation of the LP, MRI Settings are disabled and inaccessible.
- The name of the **Test MRI Settings** button changes depending on the selected MRI Mode. For example, if MRI DOO ⇄ VOO Mode is selected, the button is displayed as **Test DOO MRI Settings** followed by **Switch to VOO Test**.
- MRI DOO ⇄ VOO Mode will temporarily switch from MRI DOO mode to MRI VOO mode during the MRI scan to avoid i2i interference. If selecting DOO ⇄ VOO, be sure to test MRI DOO and MRI VOO modes before programming MRI Settings.
- For MRI DOO ⇄ VOO Mode during **Test DOO MRI Settings**, loss of i2i™ communication markers will appear during each pace cycle on the RV marker channel. See Brady Basic Event Markers (page 6) for additional marker information.

Figure 9. Loss of i2i communication markers on the RV marker channel during each pace cycle


- For MRI DOO ⇄ VOO Mode during **Test VOO MRI Settings**, loss of i2i communications markers will appear during each pace cycle on both the RV and RA marker channels, and atrial pacing withheld markers will appear during each pace cycle on the RA marker channel. See Brady Basic Event Markers (page 6) for additional marker information.

Figure 10. Loss of i2i communication markers on the RV and RA marker channels and atrial pacing withheld event markers on the RA marker channel during each pace cycle




Accessed From: Parameters button > MRI Settings tab

## MRI Parameters

The MRI parameter settings are stored and tested from the MRI Settings panel. These settings are only in effect when you select the **Test MRI Settings** button or when you select the **Program MRI Settings** button from the MRI Checklist (page 34) window.

NOTE: Collection of diagnostic data is suspended when MRI Settings are enabled, except when i2i diagnostic data is collected in MRI DOO ⇄ VOO Mode.

The MRI Settings provide only basic pacing functions and limit the device's interactions with the electromagnetic radiation during the MRI scan.

- MRI Mode. During an MRI scan, all sensing should be turned off, so the device does not respond to interference from the MRI environment. Mode options are either Pacing Off or an available asynchronous mode (DOO ⇄ VOO, VOO, or AOO).
- MRI Base Rate
- MRI Paced AV Delay
- MRI Pulse Amplitude (non-programmable)
- MRI Pulse Width (non-programmable)
- MRI Electrode Configuration (non-programmable)

See also MRI Settings (page 57).

## MRI Checklist

Use the MRI Checklist window to verify the current MRI Settings and to ensure that all the conditions for an MRI scan are in place before enabling the MRI Settings. Verify each condition in the checklist and check each box after each condition is verified. If a box is left unchecked, you will not be able to enable the MRI Settings.

After you have checked all the boxes, this button is enabled:

**Program MRI Settings** button. Select to enable the MRI Settings in the device in preparation for an imminent MRI scan. When you select this button, the programmer displays the MRI Settings: Active (page 34) window.

### Conditions Required for MRI

Specific conditions must be met before a patient with an MR Conditional device can have an MRI scan. Refer to the MRI-Ready Leadless System Manual for a complete list of all conditions.

These conditions must be met and confirmed on the MRI Checklist before the patient can have an MRI scan:

- **Capture thresholds are stable and measured in the past 24 hours at ≤2.5 V @ 0.5 ms.** If applicable, select the test button to perform a Capture Test (page 17) to verify that capture thresholds are stable.
- **No additional cardiac hardware.** Verify that no additional cardiac hardware (such as abandoned leads) is present by checking the patient records. You may scan patients with abandoned MR conditional LPs in the same chamber, provided that all the MR Conditional requirements for each LP are met.
- **MRI DOO ⇄ VOO Mode will temporarily switch from MRI DOO mode to MRI VOO mode during MRI scan.** This checklist item is displayed only if you select the MRI DOO ⇄ VOO Mode. Confirm that it is acceptable for the LP to switch between MRI DOO mode and MRI VOO mode when it encounters i2i interference.

Accessed From: Parameters button > MRI Settings tab > Setup for MRI Now button

## MRI Settings: Active

The MRI Settings: Active window displays the currently enabled MRI Settings, the device's permanent programmed settings, and these buttons:

- **Disable MRI Settings** button. Return to the permanent programmed settings.
- **Print MRI Report** button. Print a report containing the patient data, parameter settings, and the MRI Checklist results. This button is also accessible from the Print button > Reports tab when the MRI Settings are disabled and the device is using the permanently programmed settings.
- **End Session** button. After enabling the MRI Settings, select this button to end the programming session before proceeding to the MRI scan. Once the scan is complete, interrogate the LP and return to this window to disable MRI Settings and restore the permanently programmed settings.

  NOTE: When MRI Settings are active in MRI DOO ⇄ VOO Mode, loss of i2i™ communication markers will appear during each pace cycle on the RV marker channel when the device is pacing in MRI DOO mode or MRI VOO mode. Additionally, if the system is in i2i noise reversion, loss of i2i communication markers and atrial pacing withheld event markers will appear during each pace cycle on the RA marker channel. See Brady Basic Event Markers (page 6) for additional marker information. See MRI Settings (page 33) for example images.

Accessed From: Parameters button > MRI Settings tab > Setup for MRI Now button > MRI Checklist window > Program MRI Settings

# Wrap-up™ Overview

The Wrap-up™ Overview window allows for the review of session activities by listing battery data, test status, and session programming changes and notes. The window provides these follow-up session management controls:

- **Battery status** panel. Shows the last measured battery voltage and a gauge illustrating the battery longevity estimate (based on the battery voltage).
- **Test Status** panel. Reports the completed and uncompleted tests.
- **Session Notes** panel. Reports the status of routine follow-up tasks.
- **Programming Changes** panel. Reports changes in parameter initial and present settings.
- **Selected Reports** button. Lists the reports that have been selected to print and opens the Reports window (page 44).
- **Restore Initial Values** button (page 35). Programs the LP to the settings read at the beginning of the session.
- **Clear Diagnostics** button (page 35). Clears the episodes, diagnostics data, or both, from the LP memory.
- **Clear after Printing** check box. Select to automatically clear diagnostics from the LP memory after printing the reports from the Wrap-Up window.
- **Print Reports** button. Prints the reports listed in Selected Reports.

Accessed From: Wrap-up Overview button

## Restore Initial Values

The Restore Initial Values button reprograms the LP's settings that were read at the initial interrogation associated with the ongoing session. When you select the **Program** button on the pop-up dialog to confirm restoration of the initial values, you lose all parameter changes that you made during the current session.

Accessed From: Wrap-Up Overview button > Restore Initial Values button

## Clear Diagnostics

From the Clear Diagnostics window, diagnostics (page 12) data (except for lifetime statistics and other non-resettable data), episodes (page 11), and stored EGMs can be cleared from the LP memory. LP data collected by the programmer during the session remains available until you select the End Session button.

NOTE: Clearing diagnostics will also clear alerts.

Accessed From: Wrap-Up Overview button > Clear Diagnostics button

# Operating Modes

In shelf mode, the LP maintains a low-power state and periodically measures the impedance between the LP electrodes.

During implantation, the LP exits shelf mode and enters its initial operating mode (VVI mode for an RV LP, AAI mode for an RA LP) when the impedance is lower than the preset threshold.

On exit from shelf mode and transition to initial operating mode, the date and timestamp are recorded and stored as the LP implant date.

You can program the LP to the following therapy modes, some of which you can program to operate with rate-responsiveness (R). See Rate-Responsive Modes (page 41).

Table 15. Operating Modes

| Dual-Chamber | Atrial | Ventricular | Off Modes |
|---|---|---|---|
| DDD (page 37) | AAI (page 37) | VVI (page 36) | Pacing Off (page 41) |
| DDI (page 38) | AOO (page 37) | VOO (page 36) | |
| DOO (page 39) | OAO (page 37) | OVO (page 36) | |
| VDD (page 39) | | | |
| VDI (page 40)<br>(AMS mode only) | | | |

NOTE: i2i™ communication (page 42) (transmission/reception) is enabled when an LP is programmed to any dual-chamber mode.

## VVI

**(Ventricular Pacing, Sensing, and Inhibition)**

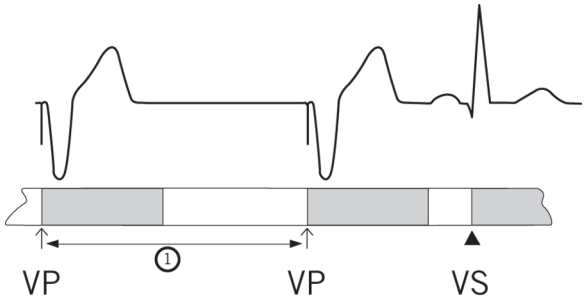
See VVI Mode timing diagram (page 36).

In VVI mode, the LP paces the ventricle at the programmed rate if it does not detect a sensed event. If the LP detects a sensed event during the alert period, it withholds the pulse and it resets the timing period to the start of the RV Base Refractory period (page 29).

**Indications.** VVI operation is indicated for symptomatic bradycardia of any etiology. This includes, but is not limited to, AV block or sinus node dysfunction and the various manifestations of sinus node dysfunction, including sinus node arrest, sinus bradycardia, and brady-tachy syndrome.

**WARNING: VVI operating mode should not be used in the presence of pacemaker syndrome.**

Figure 11. VVI Mode timing diagram




**1.** Ventricular pacing interval
Refractory Period
Alert Period
↑ Output Pulse
▲ Sensed Event

## VOO

**(Ventricular Asynchronous Pacing)**

See VOO Mode timing diagram (page 36).

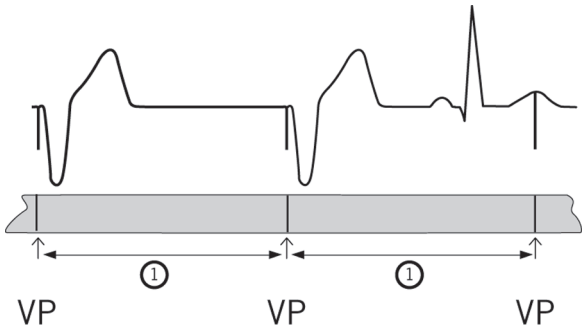
In VOO mode, the LP paces the ventricle at the programmed rate regardless of the intrinsic rhythm.

**CAUTION: VOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous ventricular tachyarrhythmias.**

**Indications.** VOO operation may be indicated for patients who are subject to electromagnetic interference or electromyogenic noise and who need continual ventricular pacing.

**WARNING: VOO mode should not be used in patients who have a competitive intrinsic cardiac rhythm and who have or are likely to experience pacemaker syndrome during single-chamber ventricular pacing.**

Figure 12. VOO Mode timing diagram




**1.** Ventricular pacing interval
Refractory Period
↑ Output Pulse

## OVO

**(Ventricular Sensing Only)**

**CAUTION: The OVO mode is not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of the device's operation.**

In OVO mode, pacing is turned off while the LP continues to detect and record ventricular sensed events. This mode is useful primarily for temporary diagnostic evaluation and recording of intrinsic activity. When this mode is programmed, the programmer shows null tick marks and displays < 30 $min^{-1}$ when no intrinsic activity is present. When intrinsic activity is present, rate and VS markers (page 6) are displayed.

## AAI

**(Atrial Pacing, Sensing, and Inhibition)**

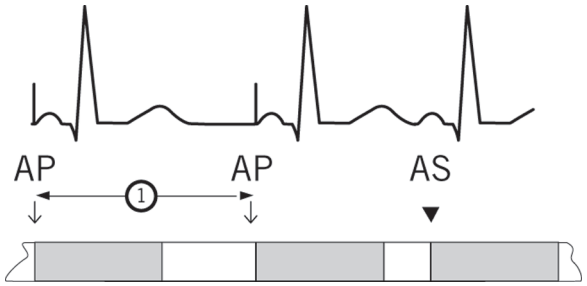
See AAI Mode timing diagram (page 37).

In AAI mode, the LP paces the atrium at the programmed rate if the atrial events are not sensed. If the LP detects a sensed event during the alert period, it withholds the pulse and resets the timing to the start of the RA Base Refractory period (page 29).

**Indications.** AAI operation is indicated for symptomatic bradycardia caused by sinus node dysfunction.

**WARNING: AAI mode should not be used in patients with AV conduction disorders, chronic atrial fibrillation, or atrial flutter.**

Figure 13. AAI Mode timing diagram




1. Programmed Rate
Refractory Period
Alert Period
↓ Output Pulse
▼▲ Sensed Event

## AOO

**(Atrial Asynchronous Pacing)**

See AOO Mode timing diagram (page 37).

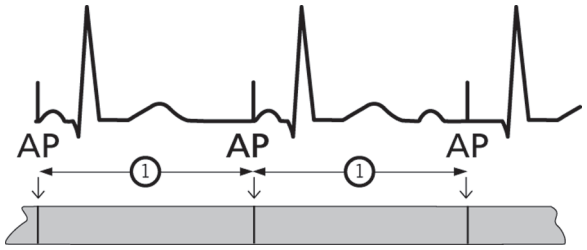
In AOO mode, the LP paces the atrium at the programmed rate regardless of intrinsic rhythm.

**CAUTION: AOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous atrial tachyarrhythmias.**

**Indications.** AOO operation may be indicated for patients who are subject to electromagnetic interference or electromyogenic noise and who need continual atrial pacing.

**WARNING: AOO mode should not be used in patients with competitive intrinsic cardiac rhythms or AV conduction disorders.**

Figure 14. AOO Mode timing diagram




1. Programmed Rate
Refractory Period
↓ Output Pulse

## OAO

**(Atrial Sensing Only)**

**CAUTION: The OAO mode is not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of the device's operation.**

In OAO mode, pacing is turned off while the LP continues to detect and record atrial sensed events. This mode is useful primarily for temporary diagnostic evaluation and recording of intrinsic activity. When this mode is programmed, the programmer shows null tick marks and displays < 30 $min^{-1}$ when no intrinsic activity is present. When intrinsic activity is present, rate and AS markers (page 6) are displayed.

## DDD

**(Dual-Chamber Pacing, Sensing, and Inhibition; Atrial Tracking)**

See DDD Mode timing diagram (page 38).

The DDD Mode is a dual-chamber, atrial-based timing mode in which increases or decreases in the sensed atrial rate are duplicated by similar changes in the ventricular rate. Sensed P-waves or R-waves inhibit output pulses, while no intrinsic activity during the alert periods result in delivered pulses. There are four pacing states:

1. **AS.** A sensed atrial event (AS) inhibits an atrial pulse and begins the Sensed AV Delay (page 26) and resets the LP timing. The RA LP becomes refractory until the end of the PVARP (page 28).
2. **AP.** During the atrial alert period, no atrial sensed event is detected, and the LP delivers an atrial pulse (AP) at the end of the alert period. This starts the Paced AV Delay (page 26) and resets the LP timing. The RA LP becomes refractory until the end of the PVARP.

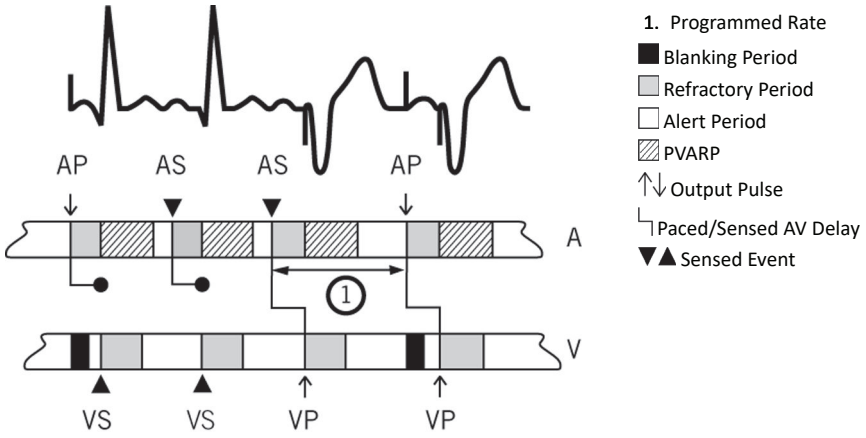
3. **VS.** The RV LP, while in an alert state, senses a ventricular sensed event (VS) and inhibits the pulse but does not reset the timing. The RV Base Refractory period (page 29) and PVARP begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out and the RV LP becomes alert to sensed events after RV Base Refractory times out.
4. **VP.** The RV LP, while in an alert state, does not sense any signals and delivers a ventricular pulse (VP) at the end of the delay. The RV Base Refractory period and PVARP begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out and the RV LP becomes alert to sensed events after RV Base Refractory times out.

**Indications.** DDD operation is indicated in the presence of AV conduction disorders with normal or abnormal sinus node function and if the patient may benefit from a high degree of ventricular pacing.

**WARNING: In DDD mode with Auto Mode Switch (AMS) (page 25), AMS should not be set to Off in the presence of chronic atrial tachyarrhythmias or silent atria; however, AMS can be set to automatically switch the LP to DDI mode in the presence of atrial tachyarrhythmias. Retrograde conduction requires the careful setting of the PVARP parameter.**

In the event of a complete or partial loss of i2i™ communication, the system maintains the most comprehensive possible functional operating mode until full i2i communication is re-established. See i2i Communication (page 42) for a table of the reversion modes.

Figure 15. DDD Mode timing diagram




## DDI

**(Dual-Chamber Pacing, Sensing, and Inhibition; No Atrial Tracking)**

See DDI Mode timing diagram (page 39).

The DDI mode is a non-tracking, dual-chamber mode in which sensed atrial activity does not cause a change in timing. Atrial tachycardias do not result in increased pacing rates. There are four pacing states:

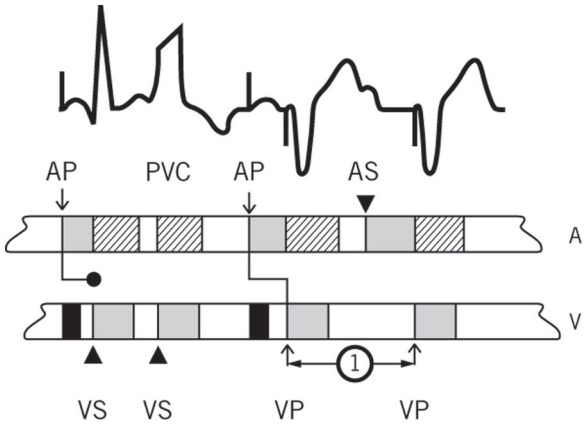
1. **AS.** A sensed atrial event (AS) inhibits the atrial pulse and begins an atrial refractory period which ends at the ventricular pulse. The RV LP remains alert to R-waves except during the RA Base Refractory period (page 29) and after an atrial pulse.
2. **AP.** During the atrial alert period, no atrial sensed event is detected, and the LP delivers an atrial pulse (AP) at the end of the alert period. This starts the Paced AV Delay (page 26) and resets the LP timing. The RA LP becomes refractory until the end of the PVARP (page 28).
3. **VS.** The RV LP, while in an alert state, senses a ventricular sensed event (VS) and inhibits the pulse but does not reset the timing. The RV Base Refractory (page 29) period and PVARP begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out and the RV LP becomes alert to sensed events after RV Base Refractory times out.
4. **VP.** The RV LP, while in an alert state, does not sense any signals and delivers a ventricular pulse (VP) at the end of the delay. The RV Base Refractory period and PVARP begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out and the RV LP becomes alert to sensed events after RV Base Refractory times out.

**Indications.** DDI operation is indicated in situations where dual-chamber pacing is required and there is a specific reason that atrial tracking is not desired.

**WARNING: DDI mode should not be used in patients with AV block with normal sinus node function and silent atria and in AV block with chronic atrial fibrillation or flutter.**

In the event of a complete or partial loss of i2i™ communication, the system maintains the most comprehensive possible functional operating mode until full i2i communication is re-established. See i2i Communication (page 42) for a table of the reversion modes.

Figure 16. DDI Mode timing diagram




1. Programmed Rate
- Blanking Period
- Refractory Period
- Alert Period
- PVARP
- Output Pulse
- Paced/Sensed AV Delay
- Sensed Event

## DOO

**(Dual-Chamber Asynchronous Pacing)**

See DOO Mode timing diagram (page 39).

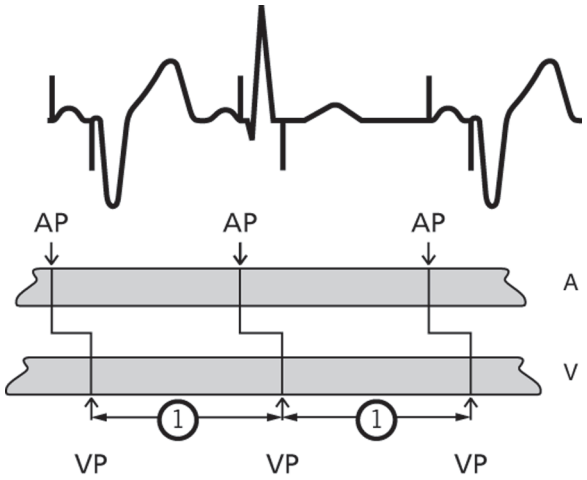
In DOO mode, the LP paces in the atrium and ventricle at the programmed Base Rate and Paced AV Delay (page 26) regardless of intrinsic activity.

**CAUTION: DOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.**

**WARNING: DOO mode should not be used in patients with competitive intrinsic cardiac rhythm.**

In the event of a complete or partial loss of i2i™ communication, the system maintains the most comprehensive possible functional operating mode until full i2i communication is re-established. See i2i Communication (page 42) for a table of the reversion modes.

Figure 17. DOO Mode timing diagram




1. Programmed Rate
- Refractory Period
- Output Pulse
- Paced/Sensed AV Delay

## VDD

**(Ventricular Pacing; Dual-Chamber Sensing and Inhibition; Atrial Tracking)**

See VDD Mode timing diagram (page 40).

The VDD mode is a dual-chamber, atrial-tracking mode with no atrial output in which ventricular pacing is synchronized to intrinsic atrial activity. The LP senses in both chambers but only paces in the ventricle.

There are three pacing states:

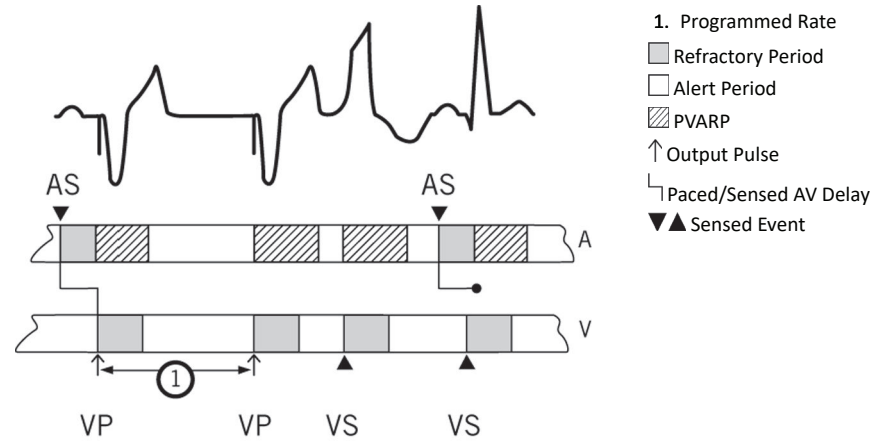
1. **AS.** A sensed atrial event during the V-V interval initiates the Sensed AV Delay (page 26) and may extend the V-V interval while AV synchrony is maintained. It is possible to track a sinus rhythm resulting in a rate lower than the programmed Base Rate (page 24).
2. **VS.** If the RA LP detects a sensed event and the RV LP detects a sensed event during the Sensed AV Delay, the V-V timing is reset.
3. **VP.** If no atrial and no ventricular events are sensed, the RV LP paces the ventricle (VVI pacing). See VVI (page 36).

**Indications.** VDD operation is indicated for AV block with normal sinus function.

**WARNING: VDD mode should not be used for patients with sinus node dysfunction, chronic atrial flutter or fibrillation, inadequate atrial sensing, or silent atria.**

In the event of a complete or partial loss of i2i™ communication, the system maintains the most comprehensive possible functional operating mode until full i2i communication is re-established. See i2i Communication (page 42) for a table of the reversion modes.

Figure 18. VDD Mode timing diagram




## VDI

**(Ventricular Pacing; Dual-Chamber Sensing and Inhibition; No Atrial Tracking)**

See VDI Mode timing diagram (page 40).

The VDI mode is a non-tracking, dual-chamber mode that is available only as a programmable Auto Mode Switch (AMS) mode (page 25). The LP system senses in both chambers but only paces in the ventricle. While VDI mode maintains atrial sensing, sensed atrial activity does not cause a change in timing. Atrial tachycardias do not result in increased pacing rates.

There are three pacing states:

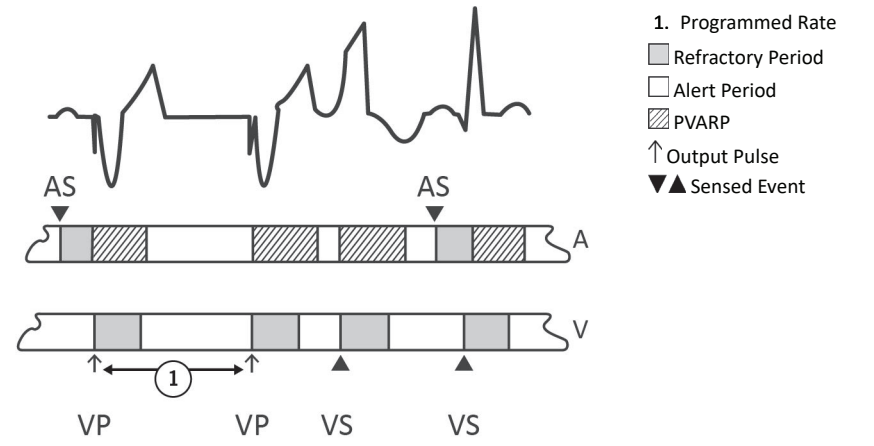
1. **AS.** An atrial sensed event (AS) begins an atrial refractory period. An AS event does not alter ventricular timing.
2. **VS.** When the RV LP, while in an alert state, senses a ventricular sensed event (VS), it inhibits a ventricular pace pulse and resets the V-V timing. The RV Base Refractory period (page 29) and RA PVARP (page 28) begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out, and the RV LP becomes alert to sensed events after RV Base Refractory times out.
3. **VP.** When the RV LP, while in an alert state, does not sense any VS event, it delivers a ventricular pulse (VP) at the end of the V-V interval defined by the programmed AMS Base Rate (page 25). The RV Base Refractory period and RA PVARP begin and continue until the periods time out. The RA LP becomes alert to sensed events after PVARP times out, and the RV LP becomes alert to sensed events after RV Base Refractory times out.

**Indications.** VDI operation is indicated in situations where ventricular pacing is required and there is a specific reason that atrial tracking and pacing is not desired.

**WARNING: VDI mode is only available for Auto Mode Switch (AMS) mode and should not be used in the presence of pacemaker syndrome.**

VDI mode is sustained during loss of i2p telemetry, or complete (bidirectional) or partial (unidirectional) loss of i2i™ communication.

Figure 19. VDI Mode timing diagram



## Pacing Off

**(Pacing and Sensing Off)**

**CAUTION: Pacing Off mode should not be used with pacemaker-dependent patients or patients who might be affected by even a short cessation of pacemaker function.**

In Pacing Off mode, atrial and ventricular pacing and sensing are disabled.

During Pacing Off mode, i2p telemetry and i2i™ communication remain enabled.

Tick marks that correspond to telemetry with the programmer (i2p communication events) continue to be displayed. See Brady Basic Event Markers (page 6).

## Rate-Responsive Modes

The function of rate-responsive modes (Sensor is On) is to alter the pacing rate to match activity changes according to programmed parameters. Rate-responsiveness can be enabled with any permanent pacing mode. For more information on Sensor programming, see Sensor (page 23).

**Indications.** Indications for rate-responsive modes are the same as those without rate-responsiveness, except that rate-responsive modes are further indicated when an increase in pacing rate with activity is desired.

**WARNING: Guidance for rate-responsive modes is the same as that for modes without rate-responsiveness, except that rate-responsive modes should not be used when pacing rates above the programmed Base Rate may not be well tolerated.**

# Additional Programming Information



## Telemetry (i2p) Communication

Each LP communicates bidirectionally with the programmer system through conducted electrical signals between the implanted LP's electrodes and skin electrodes applied to the patient's chest and connected to the programmer system with the patient cable. The LP transmits signals using circuits and electrodes already provided for pacing, with data encoded in low-current pulses delivered during the heart's refractory period. Communication between the implanted LP system and the programmer is referred to as 'i2p' communication.

NOTE:

- Refer to the Aveir™ Link Module Instructions for Use for information on electrode placement and using the patient cable to connect to the programmer system.
- Consider keeping the Aveir™ Link Module disconnected from the programmer when it is not being used to communicate with an LP.

During an active in-clinic programmer session, i2p communication occurs during the atrial and ventricular refractory periods in order to avoid inappropriate sensing of the i2p communication signal.

Additionally, during an active in-clinic programmer session for an LP system operating in a dual chamber mode, the atrial refractory period has an absolute refractory period during the AV/PV Delay instead of an absolute refractory period followed by a relative refractory period. For the refractory period outside a programmer session, see Refractories & Blanking (page 28).

NOTE: i2p communication signals may appear as artifacts on CEGMs.

In order to interrogate a dual chamber LP system, the programmer must establish i2p communication with both the RA LP and RV LP. If the programmer cannot establish i2p communication with both LPs, the Loss of Telemetry dialog (page 50) will be displayed. Contact Abbott Medical Technical Support (page 58) for assistance with diagnosing telemetry problems.

## i2i™ Communication

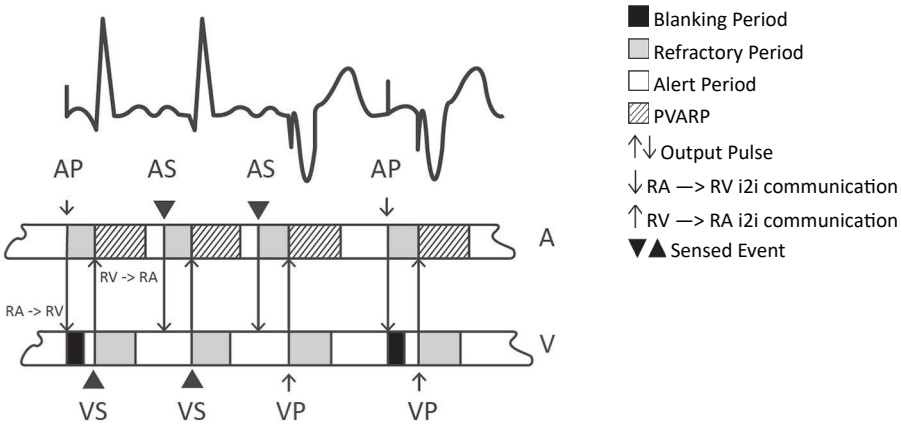
Communication between co-implanted RV and RA LPs, referred to as i2i™ communication, is achieved through conducted electrical signals.

Programming a dual-chamber mode enables bidirectional i2i communication (transmission/reception). i2i communication is disabled in all single-chamber modes in order to conserve battery life.

NOTE: Consider assessing i2i communication throughout the implant or follow-up procedure to ensure acceptable i2i throughput (transmission/reception).

Complete i2i communication consists of the RA –> RV i2i message (where the RA LP transmits an i2i signal that is received by the RV LP) and the RV –> RA i2i message (where the RV LP transmits an i2i signal that is received by the RA LP). The RA –> RV i2i message occurs with atrial pace or sense events and the RV –> RA i2i message occurs with ventricular pace or sense events (as shown in the following figure). When an expected i2i signal is not received by an LP, a loss of i2i communication marker is displayed on the marker channel. See Markers (page 6).

Figure 20. Mode timing diagram - i2i communication




Loss of i2i communication may occur as a complete loss (where both LPs are not receiving i2i communication from each other) or a partial loss (where either the RA or RV LP does not receive i2i communication from the other LP). When a complete or partial loss of i2i communication occurs, the system maintains the most comprehensive possible functional operating mode (shown in the following table) until full i2i communication is re-established.

Table 16. Functional operating mode during loss of i2i communication

| | Loss of i2i Signal | | |
|---|---|---|---|
| **Programmed Mode** | **Complete Loss RA –> RV and RV –> RA** | **Partial Loss RA –> RV** | **Partial Loss RV –> RA** |
| DDD | VDI | DDI | VDD |
| DDI | VDI | DDI | VDI |
| VDD | VDI | VDI | VDD |
| DOO | VOO | DOO | VOO |

## Device Parameters and Settings Selection

1. To change the setting for any parameter, touch the desired parameter button. A setting selection window is displayed. If all settings cannot fit on the screen, use the up and down arrows to view additional settings. The overall range of settings is usually indicated at the top and bottom of the window. The current permanently-programmed setting is marked with a small pacer icon.
2. Select the desired setting. This stores the setting in the programmer's memory (batch-stores the setting); it does not program the parameter. For the new setting to take effect, select the **Program** button.

After you select a setting, the setting selection window disappears. To leave the setting selection window before a new setting is stored, close the window.

### Batch Storing and Autoprogramming

The programmer can store several parameter settings in memory in a batch before they are permanently programmed (or canceled). When you change a parameter setting, the color of the parameter button and the buttons of all autoprogrammed parameters change to green,which means that the setting has been stored for programming later. The Program and Preview buttons are highlighted. The Preview button displays a number indicating the number of parameters that are ready for permanent programming.

Once a setting is batch-stored, these options are available:

- **Preview Changes** button. Opens the Preview Changes window to show the manually-selected and autoprogrammed settings.
- **Program** button. Permanently programs the selected parameter settings.
- **Undo All** button. From the Preview Changes window, rejects the selected parameter settings.

## Emergency VVI (EVVI) Pacing

In rare instances, it may be necessary to initiate Emergency VVI (EVVI) operation of an LP. The programmer console provides this emergency option:

**EVVI**. Press this hard button on the programmer to automatically initiate predefined high-output Emergency VVI (EVVI) pacing parameter settings in the LP. See Emergency VVI Settings (page 44).

The programmer must be actively communicating with an RV LP to initiate EVVI pacing. RA LP emergency pacing is not supported. For example, if the programmer is actively communicating with only an RA LP in the implant or generator change workflow, the RV LP would not receive the EVVI command. See Emergency VVI Unavailable (page 50).

The programmer displays a pop-up message that indicates in which LP emergency pacing is in effect. Select the **Close** button to close the message.

NOTE: The programmer cannot initiate EVVI mode under these conditions:

- During LP interrogation
- While the LP is operating in ROM mode
- During an LP reset
- While saving a copy of the LP memory
- During an LP firmware update
- During the finalization step for a new LP
- When no RV LP is present

**Revert from EVVI**. Once an LP is operating in EVVI mode, the programmer enables the **Revert from EVVI** button. Selecting this button will cause the programmer to load the most recent permanent parameter settings for batch programming. Under most conditions, the permanently programmed settings can be restored. Perform the normal follow-up tests and review the restored parameter settings.

### Emergency VVI Settings

In Emergency VVI (EVVI) mode, an LP operates at these programmed settings:

Table 17. Emergency VVI settings

| Parameter | Setting |
|---|---|
| Mode | VVI |
| Sensor | Off |
| Base Rate | 70 $min^{-1}$ |
| RV Pulse Amplitude | 6.0 V |
| RV Pulse Width | 0.6 ms |
| RV Refractory | 310 ms |
| RV Sensitivity | 2.0 mV |

NOTE: Atrial pace (AP) markers may be displayed while an LP system is operating in EVVI mode but there is no pace pulse output from the RA LP.

## LP Reset

If the LP encounters any transitory errors in the software or hardware, it operates a reset routine that attempts to overcome the error and restore normal operation. Whenever the reset function is invoked, the programmer displays a **LP reset occurred** alert at the next interrogation. See Alerts (page 10).

The reset function can usually overcome an error and restore the LP to normal operation using the permanently programmed parameters.

If the reset function is unsuccessful, the LP reverts to operating in ROM mode (page 52). If the LP cannot restore the permanently programmed settings, it reverts to the reset settings and a separate alert, **LP is programmed to Emergency pacing values**, is issued.

Because the LP stores permanently programmed parameters in non-volatile memory, permanent settings and programmability are likely to be fully restored in an error condition.

NOTE: If an LP reset occurs during or within about 3 hours of its implantation, an LP might not store the implant date data in its non-volatile memory and may therefore lose the implant date. If the implant date is incorrect, manually reprogram the LP to the correct date. Contact Technical Support for assistance (page 58).

## Print Menu

The Print Menu window contains these tabs:

- Reports (page 44)
- Settings (page 45)

Select the **View PDF Reports** button from either tab for a list of stored reports that can be viewed on the programmer screen.

Select the **Print** button from either tab to print the currently selected reports.

### Reports

The Reports window enables selection of reports in the print queue, printing selected reports, and report configuration.

The Reports panel displays all the available report types and shows any reports currently selected for printing.

To place a report in the print queue, select the checkbox next to the labeled report button. To remove a report from the print queue, de-select the checkbox.

To export stored PDF reports, select the **Export PDFs** button. See PDFs (page 2) for more information on report export.

Reports include identifying information for the implanted LP or LPs and the programmer system. Report availability and specific report data may depend on the LP system configuration.

Available reports may include these types:

- **FastPath™ Summary.** Select the checkbox to queue a summary report that contains this information:
  - Patient data
  - Battery data for the present LPs
  - Capture threshold and sense test results (current and previous session)
  - Impedance measurement (current and previous session)
  - Parameter settings summary
  - Diagnostics, logs, and episodes summaries
  - i2 Diagnostics summary (if applicable)
  - Physician notes
  - Alert summary
- **Parameters.** Select the checkbox to queue a summary report that contains patient and LP data, SEGM configuration settings, and all permanently programmed parameter settings (including i2i parameter settings, if applicable).
- **Test Results.** Select the checkbox to queue a summary report that contains Rhythm Display, LP battery information, and the results of tests performed during the current session and previous session (including trend data).
- **Most Recent Freeze.** Select the checkbox to queue a report of the last freeze capture.
- **Wrap-up™ Overview.** Select the checkbox queue the Wrap-up™ Overview summary report that contains patient and LP data, LP battery information, results of tests performed during the current and previous session, parameter settings, programming changes from the current session, and an alert summary.
- **Episodes Summary.** Select the checkbox to queue a summary report of noise reversion, magnet response, and LP reset logs, AMS log, and SEGM summary.
- **Extended Diagnostics.** Select the checkbox to queue a summary report that includes (as applicable, depending on LP system configuration):
  - Paced/sensed events histogram
  - AV interval histogram
  - Atrial Heart Rate Histogram
  - Ventricular Heart Rate Histogram
  - AMS diagnostics summary
  - i2p and i2i™ diagnostics

Accessed From: Print button > Reports tab

### Settings

The Settings window provides options for setting the print preferences and report header information.

Select the **Printer Preferences** button to change the report destination (PDF Only, Internal & PDF, or External & PDF) and the number of copies of the report.

Select the appropriate checkboxes to:

- Include the **Patient Name** and/or **Patient ID** in the printed report header. The patient information is stored in the LP memory and can be viewed or updated through the Patient Data window (page 4).
- Include the **Clinic Name** in the printed report header. Select the button to open the on-screen keyboard to enter the information into the programmer memory.
- Automatically print the FastPath™ Summary Report on initial LP interrogation. See Reports (page 44).

Accessed From: Wrap-Up Overview button > Selected Reports button > Settings tab or main programming window > Print Menu button > Settings tab

## Recommended Replacement Time (RRT)

Recommended Replacement Time (RRT) is the point at which the battery voltage can only maintain adequate operation for a nominal period of at least six months before end-of-service (EOS).

Many factors affect the longevity of the LP, such as increase in pacing output parameters or decrease in pacing impedance. In some cases, this may cause the period from RRT to EOS to decrease to less than six months.

When an LP exhibits the signs of RRT, replace it expeditiously. There are a number of indicators to this condition:

- Programmer displays an alert that the LP has reached RRT.
- Battery summary panel states **LP at RRT**.
- Magnet Rate (page 19) measures approximately 65 $min^{-1}$.
- Sensor is automatically set to Off, which disables rate-responsive pacing.

Patient follow-up visits should be scheduled at an appropriate frequency so that RRT can be detected well before EOS and should include re-reading diagnostics data and checking battery status after parameter programming.

## End-of-Service

Refer to the Aveir™ Leadless Pacemaker Instructions for Use for specific information on end-of-service (EOS) conditions.

# LP Implant and Replacement Programming

Select the **Device Implant** button on the main programming window to open the LP Implant/Replacement window to access the settings for programming a new or replacement LP implant in a single- or dual-chamber LP system.

Figure 21. Device Implant button


The LP Implant/Replacement window provides the controls for establishing communication between the programmer, any newly implanted LP, and (if applicable) any active, already implanted LP. From this window, programming tasks are performed according to the appropriate workflow for the implant procedure:

- Add and pair two newly co-implanted LPs in a dual-chamber system.
- Add a new (RA or RV) LP implant to pair with an active already implanted (RA or RV) LP to form a dual-chamber system.
- Replace an active (RA or RV) LP in a single- or dual-chamber system with a new LP.
- Replace both active LPs in a dual-chamber system with new LPs.
- Upgrade an already implanted single-chamber LP so it may be functionally paired with a newly co-implanted LP to provide dual-chamber pacing therapy.

  NOTE: You can program up to three LPs during the same session: an active, already implanted LP (RA, RV, or both), as well as a new LP being deployed either as a replacement or co-implant of an existing active LP.

The procedure for completing a new or replacement LP includes these programming steps:

- Prepare an active LP for replacement or upgrade (page 46), if applicable.
- Connect a new LP with the programmer (page 46).
- Program a new LP (page 47), which includes testing and assessing pacing and sensing thresholds before the new LP is deployed. This step may also include reprogramming an already implanted active LP, if applicable.
- Pair and program two co-implanted LPs (page 48).
- Finalize a new LP or LP system (page 49). This step also includes deactivating an already implanted LP, if replacing it with another LP.

  NOTE:

  - Refer to the Aveir™ Leadless Pacemaker Instructions for Use for procedures and safety information for implanting or replacing an LP.
  - Refer to the Aveir™ Retrieval Catheter Instructions for Use for procedures and safety information if LP replacement includes retrieval of a previously-implanted LP.
  - Refer to the Merlin™ Patient Care System User's Manual for complete instructions for use for the programmer.

Accessed From: Main programming window > Device Implant button

## Prepare an Active LP for Replacement or Upgrade

If an already-implanted LP is being replaced or upgraded, follow these steps in preparation for the procedure:

1. Ensure that the Link Module is connected to the programmer.
2. Launch the programmer software.
3. Interrogate the active LP to start a follow-up session.
4. Ensure the programmer is displaying surface ECG before beginning the new LP implantation procedure. See Rhythm Display (page 5).
5. Review the currently programmed parameters and settings for the active LP. See Brady Parameters (page 23).
6. Perform the appropriate clinical tests for the active LP including:
   - Capture threshold test to determine pulse amplitude and pulse width (page 17).
   - Sense test to determine sensitivity (page 18).
   - Impedance measurement (page 20).
7. Select the desired reports for printing, for record (page 44).

## Connect a New LP with the Programmer

Once the physician begins the implantation procedure for a new LP, the programmer should detect the new device implant and open the LP Implant/Replacement window automatically. If this does not happen, select the **Device Implant** button on the main programming window to open the LP Implant/Replacement window.

On the LP Implant/Replacement window, use the buttons on the **Communicate to** panel to control the LP implant or replacement workflow. The available options depend on the procedure:

- **Add New LP**. Select this button to detect and interrogate a new or replacement LP. (This option becomes available again for selecting a co-implanted LP in a dual-chamber configuration after the first new LP is finalized.)
- **New LP**. Select this button to enable the New LP System panel of the Summary tab, which includes options for programming and testing the new LP and for pairing the new LP with an active LP (if present) and assessing i2i™ communication.

- **LP System**. Select this button to communicate with an active LP and enable the Active LP System panel of the Summary tab, which allows for review and programming of an active LP system.

  NOTE: You can program up to three LPs during the same session: an already implanted, active LP (RA, RV, or both), as well as a new LP being deployed as a new implant, co-implant, or replacement of an already implanted LP.

After the new LP is introduced in the patient and unsheathed from the protective sleeve of the Aveir™ Delivery Catheter (as instructed in the Aveir ™ Leadless Pacemaker/Delivery Catheter Instructions for Use), follow these steps to enable the programmer to detect the new LP and establish communication:

1. Select the **Add New LP** button.
2. From the pop-up window, select the appropriate option to indicate the type of LP (single RA or RV) to be added.
3. Select the **Continue** button. Data for the added newly-implanted LP is displayed in the New LP System panel on the left side of the Summary tab:
   - Model number, serial number, and initial battery measurement.
   - Initial operating mode and parameters.

     The new LP exits shelf mode (page 35) and enters its initial operating mode:
   - VVI mode (page 36) for an RV LP
   - AAI mode (page 37) for an RA LP

     The new LP implant date is set with the current time and date stamp.
4. Perform electrical mapping to confirm clinically-acceptable sensing amplitude measurements as described in the Aveir™ Leadless Pacemaker/ Delivery Catheter Instructions for Use.
5. Select the **Read Device** button, as necessary, to read data from the LP and updated the LP System data shown on Summary tab.

If an active LP implant is already present:

- The LP Implant/Replacement window allows switching between the new LP and an already-implanted LP. Select the appropriate **Communicate to** option (New LP or LP System) for the LP to be reviewed or programmed.
  - A subset of the settings and data can continue to be reviewed and reprogrammed for the already implanted LP, as necessary; its data is displayed in the LP System panel on the right side of the Summary tab.
  - Clinical tests for the already implanted active LP are not available within the Implant/Replacement workspace.
  - In an LP replacement procedure, patient information will be transferred automatically from the already-implanted LP to new LP when the new LP is finalized.
- Markers. The programmer's real-time marker channel will only present markers from whichever LP or LPs the programmer is currently communicating.

Continue to Program the LP (page 47).

Accessed From: Main programming window > Device Implant button

## Program the LP

Once communication with the LP is confirmed, use the programmer system to assess electrical performance of the LP or LP system.

During the programming session, the **Communicate to** options are used to control selection between the LPs to be programmed.

Accessed From: Main programming window > Device Implant

### Program an Already Implanted LP

To program an already implanted active LP:

1. Select the **LP System** button.

   The Active LP System (right side) panel of the Summary tab is enabled and displays the last read information for the active (RA/RV) LP or LPs:
   - Model number, serial number, and most recent battery measurement.
   - Current programmed parameter settings. The operating mode, base rate, pulse amplitude, and pulse width parameter setting are displayed. Select the parameters button to open the Basic Operation window to view additional parameter settings, or to update the current parameter settings for the selected active LP or LPs.
   - Most recent capture, sense, and impedance test results.
   - Alerts. Select the button to view alerts (page 10).
2. Select the **Read Device** button, as necessary, to read data from the LP or LPs and update the Active LP data shown on Summary tab.
3. If the active LP is intended to operate in a dual-chamber system and the programmer is communicating with both the new and active LPs, see Pair Co-implanted LPs (page 48) for the steps for pairing the LPs.
4. Select the **Print** button to print a report.

Accessed From: Main programming window > Device Implant

### Program a New LP

For a new LP, use the programmer system to assess pacing capture, sensing amplitude, and impedance measurement. In addition, CEGMs can be collected to assess current of injury (COI).

To program a new LP:

1. If the new LP has been added and is communicating with the programmer but has not been finalized or paired with an active LP, select the **New LP** button. Or, to add a newly implanted LP, select the **Add New LP** button.

   The New LP System (left side) panel of the Summary tab is enabled and displays the last read information for the new (RA/RV) LP:

   – Model number, serial number, and most recent battery measurement.
   – Current parameter settings. The operating mode, base rate, pulse amplitude, and pulse width parameter setting are displayed. Select the parameters button to open the Basic Operation window to view additional parameter settings, or to update the current parameter settings for the new LP.
   – Alerts. Select the button to view alerts (page 10).
2. Select from the Test Results buttons to initiate the corresponding tests for the new LP.
3. Select the CEGMs button initiate collection of a commanded EGM.
4. Select the **Read Device** button, as necessary, to read data from the LP and update the New LP data shown on Summary tab.
5. Test and assess the pacing thresholds and adjust the programmed settings for the new LP, as necessary,
6. If the new LP is intended to operate in a dual-chamber system and the programmer is communicating with both the new and active LPs, the LPs may be paired. See Pair Co-implanted LPs (page 48).
7. Select the **Print** button to print a report.

Accessed From: Main programming window > Device Implant

## Pair Co-implanted LPs

In a dual-chamber configuration, two functionally-paired co-implanted LPs, one in the right ventricle (RV) and one in the right atrium (RA), provide dual-chamber pacing therapy. Communication between the co-implanted RV and RA LPs, referred to as i2i™ communication (page 42), is achieved through conducted electrical signals.

The LP Pairing panel indicates whether the new LP system may be paired or is paired already.

To pair co-implanted LPs:

1. Verify that the already implanted active LP (RA or RV) is shown on the Active LP System panel of the Summary tab.
2. Verify that the newly co-implanted LP is shown on the New LP System panel of the Summary tab.
3. Select the **New LP** button to enable the New LP System panel.
4. Select the **Pair New LP** button, which opens the Pair New LP window. The Mode and Base Rate settings for the new LP system is displayed.
5. Select the **Program** button. The new settings for the paired LP system are programmed. The already-implanted LP is unpaired from any other co-implanted LP, if applicable, and is paired to the new LP.
6. Select the **Read LP** button. The paired LPs and the initial operating parameters for the new LP system are displayed on the New LP System panel.
7. Program the appropriate dual-chamber settings. Select the **Parameters** button to open the Basic Operation window (page 23) of the Brady Parameters workspace to program the parameters for the new LP system.
8. Select from the **Test Results** buttons to perform the corresponding capture, sense, or impedance tests for the new LP as part of the new LP system.
9. Confirm acceptable implant-to-implant (i2i) performance. Select the **i2i Settings** button to open the i2i Settings Management (page 31) window to review and test the i2i settings. Accept the recommended settings or use the available controls to manually adjust the i2i signal strength between co-implanted LPs.

   NOTE: Consider assessing i2i communication throughout the implant or follow-up procedure to ensure acceptable i2i throughput (transmission/reception). The i2i™ Diagnostics tab (page 14) of the Diagnostics workspace captures measurements to help in assessing the quality of the bidirectionally conducted communication between co-implanted (RA/RV) LPs.

Accessed From: Main programming window > Device Implant button

## Unpair Co-implanted LPs (If Necessary)

To unpair a new LP system (if necessary):

1. Verify the new LP system to be unpaired is displayed in the New LP System panel of the Summary tab.
2. Select the **New LP** button.
3. Select the **Unpair New LP** button.
4. Select the **Program** button to confirm the unpairing of the LPs.

   The LP system is unpaired and i2i™ communication (page 42) between the LPs is disabled. The programmer continues to communicate with each LP individually.

   If the active LP being unpaired was originally paired with another co-implanted active LP, the original LP pairing (such as an already co-implanted LP system being replaced) is automatically restored (re-paired).

   If unpairing an already-implanted active LP system is necessary, contact Abbott Medical Technical Support (page 58) for assistance.
5. After successfully unpairing the new LP system, select the **Read LP** button to continue the session.

Accessed From: Main programming window > Device Implant button

## Finalize the New LP

After deployment (release from the delivery catheter) of a new LP implant, the LP must be finalized by the programmer.

Finalizing a new LP completes the implant procedure and sets the new LP as the active LP. If an already-implanted LP remains present in the same cardiac chamber, finalization of the new LP also simultaneously deactivates the already-implanted LP. Deactivating an already implanted LP permanently turns it off and prevents any future communications with it.

Finalize a new LP only after assessing its performance, including while paired with an active co-implanted LP, if applicable. Review the New LP System panel of the Summary tab before the new LP implant is completed and finalized.

NOTE: Print a report to retain a record of the implant test results; otherwise, a Summary report will be generated (in PDF format) after completion of the finalization step.

1. Ensure the new LP to be finalized has been deployed (released from the delivery catheter).
2. If finalizing a first-time or replacement single-chamber implant, select the **New LP** button. A pop-up dialog requests confirmation to finalize the new LP (and deactivate the already-implanted active LP, if applicable). Select the **Continue** button. Skip to the next step.

   Otherwise, select the **Continue** button to confirm and finalize the new LP, and deactivate the already-implanted LP, if applicable. (Select the **Cancel** button to cancel and return to the LP Implant/Replacement window, if necessary).

   NOTE: When an already-implanted LP is being replaced, the programmer first migrates the patient data to the new LP, then deactivates the original LP before finalizing the new LP. Finalization of the new LP also includes clearing the LP reset count.
3. Once the process is complete, select the **Close** button. The finalized new LP is now shown on the Active LP System panel (right side) of the Summary tab.
4. Select the **Return** button to return to the LP Implant/Replacement window in order to add or replace an additional LP.
5. If adding or replacing an additional LP, repeat the procedures Connect a New LP with the Programmer (page 46) through Finalize a New LP (page 49).

Once the implant process is complete, select the FastPath™ button to proceed to a follow-up session for the new LP or LP system to conduct clinical tests, set program parameters, and print reports.

NOTE: For an LP that is being replaced, the programmer will print a Deactivation Report.

Accessed From: Main programming window > Device Implant button

## Upgrade an LP

The programmer detects when a LP firmware upgrade is required and will initiate the upgrade process.

During the upgrade process:

- Diagnostic data are preserved.
- During a single RA LP upgrade, the programmed parameter settings remain in effect.
- During a single RV LP upgrade, the programmed parameter settings remain in effect. Emergency pacing is not available.
- When upgrading two LPs, the emergency pacing parameter settings will take effect.

When the programmer prompts a mandatory firmware upgrade, these are the available options:

- **End Session** button. Select the button to end the current session without completing the LP upgrade process.
- **Upgrade** button. Select the button to initiate the LP upgrade to the latest firmware version.

  Initiating the upgrade process begins downloading the latest firmware version. The programmer shows the upgrade progress and indicates when the LP has been configured and upgraded successfully. The process may take several minutes to complete.

  Select the **Continue** button. Review the patient data for accuracy.

  If a failure in the upgrade procedure occurs, select the **End Session** and contact Abbott Medical Technical Support (page 58) for assistance.

A firmware upgrade also may be user-initiated. Contact Technical Support (page 58) for assistance.

# Error and Informational Messages

## Device Not Supported

The programmer was unable to communicate with the LP device because the device is not supported or could not be identified. If this message persists after confirmation of proper setup and re-interrogation, select the **End Session** button. Contact Technical Support (page 58) for assistance.

## Different New LP Detected

During an dual-chamber implant or replacement procedure, a new (replacement) LP has been detected other than the new LP already interrogated during the current session.

Select the **End Session** button, then interrogate the new replacement LP before attempting to conduct a programming session for the LP.

## Different Device Detected

A different active LP has been detected during an ongoing session.

Select the **End Session** button, then interrogate the new LP before attempting to conduct a new programming session.

## Emergency VVI Unavailable

Emergency VVI (EVVI) pacing was requested during interrogation, and could not be started for one of the following reasons:

- Interrogation is ongoing. Retry the request after interrogation is complete.
- The programmer is communicating with an LP system that only includes an RA LP. For a single-chamber RA LP, emergency pacing is not supported. The programmer must be actively communicating with an RV LP to initiate EVVI pacing.

See Emergency VVI (EVVI) Pacing (page 43).

## Emergency VVI Was Not Started

Emergency VVI (EVVI) pacing could not be started because telemetry with the LP has been lost. See Loss of Telemetry (page 50) for additional troubleshooting information. Re-establish telemetry before re-attempting to initiate Emergency VVI (EVVI) pacing.

## EVVI Could Not Be Started

Emergency VVI (EVVI) pacing mode could not be started because telemetry with the LP has been lost during programming of the EVVI. See Loss of Telemetry (page 50) for additional troubleshooting information. Re-establish telemetry before re-attempting to initiate Emergency VVI (EVVI) pacing mode.

## Invalid Diagnostic Data

The programmer detected and cleared invalid diagnostic data upon interrogation of the LP.

Select the **Continue** button.

## Invalid Parameters Detected

The programmer detected invalid parameter setting(s).

For an RA LP, the device programmed to the reset settings.

For an RV LP, the device is reset to the emergency pacing settings.

See Shipped and Reset/Emergency Pacing Settings (page 53).

Select the **Continue** button.

## Link Compatibility

The programmer does not support the connected Link Module. Select the **End Session** button. Contact Technical Support (page 58) for assistance.

## Link Module Failure

The Link Module was not detected. The Link Module is disconnected from the programmer.

Select the **End Session** button.

Refer to the Aveir™ Link Module Instructions for Use for additional troubleshooting information.

## Loss of Telemetry

Telemetry between the device and the programmer was interrupted.

Reasons for this message include:

- The patient cable is disconnected from the Link Module.
- The electrodes are not placed accurately on the patient.
- Other electronic equipment in the area is interfering with the telemetry.

See also Telemetry (page 15).

Correct any problem, then continue the session.

Refer to the Aveir™ Link Module Instructions for Use for additional troubleshooting information.

## LP Detection Failure

In a dual-chamber configuration, an RV LP was detected, but an RA LP was not detected.

Reasons for this message include:

- The electrodes are not placed accurately on the patient.
- Other electronic equipment in the area is interfering with the telemetry.

Correct any problem, then continue the session.

Contact Technical Support (page 58) for additional troubleshooting assistance.

## Mandatory Firmware Upgrade

The programmer has detected that a firmware upgrade is required. These are the available options:

- Select the **Upgrade** button to initiate the LP upgrade to the latest firmware version. See Upgrade an LP (page 49).
- Select the **End Session** button to end the current session without completing the LP upgrade.

Contact Technical Support (page 58) if assistance is needed in upgrading an LP.

## Media Invalid or Not Present

Reasons for this error message include:

- The device connector is not fully inserted into the port.
- The media device is full. Select another device or erase enough data to allow room for the file and try again.
- The media device is write-protected or lacks proper read/write permission. Select another device or remove the write-protection or obtain permission and try again.
- The patient-tracking software or the destination PC is not operating. Reboot the PC and restart the patient-tracking software.
- The USB port is not functioning. Use another port.
- The cable for the serial connection is not functioning. Check or replace the cable.
- There is a conflict between the Link Module and the target media device. Select the **End Session** button and disconnect the Link Module.

If the issue is not resolved, end the session. Initiate the export of available data from the Ready screen.

## Modify Permanent Parameters

The parameter settings updated in this workspace will modify the permanent LP parameter settings:

- Select the **Program** button to set the permanent parameters to the updated settings.
- Select the **Cancel** button to cancel the updates and return to the previous window.

## No Media Detected

Reasons for this error message include:

- The media device is not supported by the programmer. Contact your Abbott Medical representative or Technical Support for a list of supported devices.
- The USB port is not functioning. Use another port.
- The device connector is not fully inserted into the port.
- There is a conflict between the Link Module and the target media device. Select the **End Session** button and disconnect the Link Module.

If the issue is not resolved, end the session. Initiate the export of available data from the Ready screen.

## On-Screen Keyboard

Use the On-Screen Keyboard to enter data.

- **Special Char key.** Select this key and then select the key to display the special character (labeled in green on the key).
- **Inactive Keys.** If the device memory does not support a character, the key may be displayed on the keyboard but it is not active.
- **Repeating Keys.** If you press and hold most keys on the on-screen keyboard, they are not continually typed. The exceptions are the arrow keys, the Space key, the Enter key, and the Backspace key.

- **External Keyboard.** You can use an external keyboard connected to the programmer through any of its USB ports.

## PCT with Magnet

The Pacing Capture Threshold Test could not be started because the magnet is active. Remove the magnet before performing the test.

## Problem with Media Device

The media device is not functioning properly because the device is damaged, is not recognized by the programmer, or is busy.

The programmer can communicate only with USB flash drives and serial port adapters. Contact your Abbott Medical representative or Technical Support for a list of devices that are compatible with the programmer.

## ROM Mode

The LP is operating in ROM mode. Emergency pacing is not available.

While the LP is in ROM mode, these are the available options:

- End the session.
- Upgrade the LP, if a compatible firmware version is available:
  - Save a copy of the LP device memory to the programmer.
  - Download the compatible firmware version.
  - Reset the LP.
  - Review the patient data for accuracy.

Contact Technical Support (page 58) for assistance, or if the upgrade process is unsuccessful and the LP cannot be interrogated.

## Test Ongoing

The LP is currently performing a test, and you have selected to perform a new test. The new test cannot be started until the current test is completed. Select **Close** to clear the message, and wait until the current test is completed before starting the new test.

# Technical Data

The technical data in this section include:

- Supported Devices (page 53)
- Parameter Availability and Settings
  - Shipped and Reset/Emergency EVVI Settings (page 53)
  - Programmable Parameters and Settings (page 54)
- MRI Settings (page 57)
- Physical Specifications (page 58)

## Supported Devices

Refer to the Merlin™ Patient Care System Start-Up Screen Help Manual for a list of all bradycardia devices that can be interrogated by a programmer equipped with Model 3330 software.

This manual covers the LP models listed in the following table. Traditional bradycardia devices are discussed in the Merlin™ Patient Care System Bradycardia Devices Help Manual.

NOTE: If you do not know the implanted device's model name or number, interrogate the device without the magnet.

Table 18. LPs supported by Merlin PCS

| Device | Model | Target Chamber |
|---|---|---|
| Aveir™ Leadless Pacemaker | LSP112V | Right ventricle (RV) |
| Aveir™ Leadless Pacemaker | LSP201A | Right atrium (RA) |
| Aveir™ Leadless Pacemaker | LSP202V | Right ventricle (RV) |

## Parameter Availability and Settings

### Shipped and Reset/Emergency Pacing Settings

Table 19. Shipped and reset settings: RA LP — Model LSP201A

| Parameter | Shipped Settings | Reset [8] / Emergency Pacing [9] Settings |
|---|---|---|
| **Basic Operation** | | |
| Mode | Shelf/AAI | AAI |
| Magnet Response | On | On |
| Sensor | Off | Off |
| Sensor Gain | n/a | n/a |
| Max Sensor Rate ($min^{-1}$) | n/a | n/a |
| **Rates** | | |
| Base Rate ($min^{-1}$) | 50 $min^{-1}$ | 70 $min^{-1}$ |
| **Capture & Sense** | | |
| Electrode Configuration | Bipolar (non-programmable) | Bipolar (non-programmable) |
| Pulse Amplitude (V) | 2.5 V | 0.0 V |
| Pulse Width (ms) | 0.4 ms | 0.6 ms |
| Sensitivity (mV) | 0.5 mV | 1.0 mV |
| AutoSense | Off (non-programmable) | Off (non-programmable) |
| **Refractories & Blanking** | | |
| RA Base Refractory (ARef) (ms) | 250 ms | 310 ms |
| Rate Responsive Refractory | High | Off |
| Shortest Refractory (ms) | 175 ms | n/a |

[8] RA LP reset settings may be enabled under rare device reset conditions.

[9] Emergency pacing is not available for RA LP devices. If the EVVI button is selected for a dual-chamber system, the RA LP will not receive emergency pacing.

Table 19. Shipped and reset settings: RA LP — Model LSP201A

| Parameter | Shipped Settings | Reset / Emergency Pacing Settings |
|---|---|---|
| **Hysteresis** | | |
| Hysteresis Rate Delta ($min^{-1}$) | Off | Off |
| Hysteresis Search Interval (min) | n/a | n/a |
| Hysteresis Cycle Count (cycles) | n/a | n/a |

Table 20. Shipped and reset / emergency pacing settings: RV LP — Models LSP112V, LSP202V

| Parameter | Shipped Settings | Reset / Emergency Pacing Settings |
|---|---|---|
| **Basic Operation** | | |
| Mode | Shelf/VVI | VVI |
| Magnet Response | On | On |
| Sensor | Off | Off |
| Sensor Gain | n/a | n/a |
| Maximum Sensor Rate ($min^{-1}$) | n/a | n/a |
| **Rates** | | |
| Base Rate ($min^{-1}$) | 50 $min^{-1}$ | 70 $min^{-1}$ |
| **Capture & Sense** | | |
| Electrode Configuration | Bipolar (non-programmable) | Bipolar (non-programmable) |
| Pulse Amplitude (V) | 2.5 V | 6.0 V |
| Pulse Width (ms) | 0.4 ms | 0.6 ms |
| Sensitivity (mV) | 2.0 mV | 2.0 mV |
| AutoSense | Off (non-programmable) | Off (non-programmable) |
| **Refractories & Blanking** | | |
| RV Base Refractory (VRef) (ms) | 250 ms | 310 ms |
| Rate Responsive Refractory | High | Off |
| Shortest Refractory (ms) | 175 ms | n/a |
| **Hysteresis** | | |
| Hysteresis Rate Delta ($min^{-1}$) | Off | Off |
| Hysteresis Search Interval (min) | n/a | n/a |
| Hysteresis Cycle Count (cycles) | n/a | n/a |

## Programmable Parameters and Settings

Table 21. Single-chamber programmable parameters and standard (nominal) settings: RA LP — Model LSP201A

| Parameter | Settings | Standard [10] (Nominal) Settings | Tolerance |
|---|---|---|---|
| **Basic Operation** | | | |
| Mode | AOO(R); AAI(R); OAO; Pacing Off | AAI | n/a |
| Magnet Response | Off; On | On | n/a |
| Sensor | Off; Passive; On | Passive | n/a |
| Sensor Gain | 1; 2; … 7 | 4 | n/a |
| Max Sensor Rate ($min^{-1}$) | 90; 95; … 130; 140; … 170 $min^{-1}$ | 130 $min^{-1}$ | ±3% |
| **Rates** | | | |
| Base Rate ($min^{-1}$) | 30; 35; … 130; 140; 150 $min^{-1}$ | 50 $min^{-1}$ | ±3% |
| **Capture & Sense** | | | |

[10] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Table 21. Single-chamber programmable parameters and standard (nominal) settings: RA LP — Model LSP201A

| Parameter | Settings | Standard (Nominal) Settings | Tolerance |
|---|---|---|---|
| Electrode Configuration | Bipolar (non-programmable) | Bipolar (non-programmable) | n/a |
| Pulse Amplitude (V) | 0.25 [11]; 0.5; … 6.0 V | 2.5 V | max (±15%, ±0.125 V) [12] |
| Pulse Width (ms) | 0.1; 0.2; … 1.5 ms | 0.4 ms | ±0.03 ms |
| Sensitivity (mV) | 0.25; 0.5; … 2.0; 2.5; … 5.0; 6.0; … 10.0 mV | 0.5 mV | max (±20%, ±0.25 mV) |
| AutoSense | Off (non-programmable) | Off (non-programmable) | n/a |
| **Refractories & Blanking** | | | |
| RA Base Refractory (ARef) (ms) | 160; 190; … 400; 440; 470 ms | 310 ms | max (±5%, ±12 ms) |
| Rate-Responsive Refractory | Off; Low; Medium; High | High | n/a |
| Shortest Refractory (ms) | 150; 175; … 450 ms | 175 ms | max (±5%, ±12 ms) |
| **Hysteresis** | | | |
| Hysteresis Rate Delta ($min^{-1}$) | Off; -20; -15; -10; -5 $min^{-1}$ | Off | n/a |
| Hysteresis Search Interval (min) | 1; 5; 10; 15; 30 min | 5 min | ±5% |
| Hysteresis Cycle Count (cycles) | 1; 2; … 8 cycles | 4 cycles | n/a |

Table 22. Single-chamber programmable parameters and standard (nominal) settings: RV LP — Models LSP112V, LSP202V

| Parameter | Settings | Standard [13] (Nominal) Settings | Tolerance |
|---|---|---|---|
| **Basic Operation** | | | |
| Mode | VOO(R); VVI(R); OVO; Pacing Off | VVI | n/a |
| Magnet Response | Off; On | On | n/a |
| Sensor | Off; Passive; On | Passive | n/a |
| Sensor Gain | 1; 2; … 7 | 4 | n/a |
| Max Sensor Rate ($min^{-1}$) | 90; 95; … 130; 140; … 170 $min^{-1}$ | 130 $min^{-1}$ | ±3% |
| **Rates** | | | |
| Base Rate ($min^{-1}$) | 30; 35; … 130; 140; 150 $min^{-1}$ | 50 $min^{-1}$ | ±3% |
| **Capture & Sense** | | | |
| Electrode Configuration | Bipolar (non-programmable) | Bipolar (non-programmable) | n/a |
| Pulse Amplitude (V) | 0.25; 0.5; … 6.0 V | 2.5 V | max (±15%, ±0.125 V) [14] |
| Pulse Width (ms) | 0.1; 0.2; … 1.5 ms | 0.4 ms | ±0.03 ms |
| Sensitivity (mV) | 0.5; 1.0; … 5.0; 6.0; … 10.0; 12.0 ... 18.0 mV | 2.0 mV | max (±20%, ±0.25 mV) for <15 mV; ±30% for >15 mV |
| AutoSense | Off (non-programmable) | Off (non-programmable) | n/a |
| **Refractories & Blanking** | | | |
| RV Base Refractory (VRef) (ms) | 160; 190; … 400; 440; 470; 500 ms | 250 ms | max (±5%, ±12 ms) |
| Rate-Responsive Refractory | Off; Low; Medium; High | High | n/a |
| Shortest Refractory (ms) | 150; 175; … 450 ms | 175 ms | max (±5%, ±12 ms) |
| **Hysteresis** | | | |

[11] 0 is a possible display (non-programmable) value.
[12] Tolerance is valid for a pulse amplitude measured from baseline to the absolute value of the peak of the leading edge, delivered into a load resistance of 500 Ω with the device at 37°C.
[13] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.
[14] Tolerance is valid for a pulse amplitude measured from baseline to the absolute value of the peak of the leading edge, delivered into a load resistance of 500 Ω with the device at 37°C.

Table 22. Single-chamber programmable parameters and standard (nominal) settings: RV LP — Models LSP112V, LSP202V

| Parameter | Settings | Standard (Nominal) Settings | Tolerance |
|---|---|---|---|
| Hysteresis Rate Delta ($min^{-1}$) | Off; -20; -15; -10; -5 $min^{-1}$ | Off | n/a |
| Hysteresis Search Interval (min) | 1; 5; 10; 15; 30 min | 5 min | ±5% |
| Hysteresis Cycle Count (cycles) | 1; 2; … 8 cycles | 4 cycles | n/a |

Table 23. Dual-chamber programmable parameters and standard (nominal) settings

| Parameter | Settings | Standard [15] (Nominal) Settings | Tolerance |
|---|---|---|---|
| **Basic Operation** | | | |
| Mode | AOO(R); AAI(R); OAO; VOO(R); VVI(R); OVO; VDD(R); DOO(R); DDI(R); DDD(R); Pacing Off | DDD | n/a |
| Magnet Response | Off; On | On | n/a |
| Sensor | Off; Passive; On | Passive | n/a |
| Sensor Gain | 1; 2; … 7 | 4 | n/a |
| Max Sensor Rate ($min^{-1}$) | 90; 95; … 130; 140; … 170 $min^{-1}$ | 130 $min^{-1}$ | ±3% |
| **Rates** | | | |
| Base Rate ($min^{-1}$) | 30; 35; … 130; 140; 150 $min^{-1}$ | 50 $min^{-1}$ | ±3% |
| Max Sensor Rate ($min^{-1}$) | 90; 95; … 130; 140; … 170 $min^{-1}$ | 130 $min^{-1}$ | ±3% |
| Max Track Rate ($min^{-1}$) | RA (LSP201A) + RV (LSP202V): 90; 95; … 130; 140; … 180 $min^{-1}$<br>RA (LSP201A) + RV (LSP112V): 90; 95; … 130; 140; … 170 $min^{-1}$ | 130 $min^{-1}$<br>130 $min^{-1}$ | ±3% / ±12 ms<br>±3% / ±12 ms |
| **Capture & Sense** | | | |
| Electrode Configuration | Bipolar<br>(non-programmable) | Bipolar<br>(non-programmable) | n/a |
| Pulse Amplitude (V) | 0.25; 0.5; … 6.0 V | 2.5 V | max (±15%, ±0.125 V) [16] |
| Pulse Width (ms) | 0.1; 0.2; … 1.5 ms | 0.4 ms | ±0.03 ms |
| Sensitivity (mV) | RA: 0.25; 0.5; … 2.0; 2.5; … 5.0; 6.0; … 10.0 mV<br>RV: 0.5; 1.0; … 5.0; 6.0; … 10.0; 12.0; … 18.0 mV | 0.5 mV<br>2.0 mV | max (±20%, ±0.25 mV) for <15 mV; ±30% for >15 mV |
| AutoSense | Off<br>(non-programmable) | Off<br>(non-programmable) | n/a |
| **Refractories & Blanking** | | | |
| Base Refractory (ms) | RA: 160; 190; … 400; 440; 470 ms<br>RV: 160; 190; … 400; 440; 470; 500 ms | 250 ms<br>250 ms | max (±5%, -12 ms / ±20 ms) |
| Post Ventricular Atrial Refractory Period (PVARP) | 150; 175; … 500 ms | 275 ms | max (±5%, -12 ms / ±20 ms) |
| Post-Ventricular Atrial Blanking (PVAB) | 60; 70; … 200; 225; 250 ms | 150 ms | max (±5%, -12 ms / ±20 ms) |
| Ventricular Blanking | 16; 24; … 56 ms | 48 ms | -12 ms / ±20 ms |
| Ventricular Safety Standby | Off; On | On | n/a |
| Rate-Responsive PVARP/VRef/ ARef | Off; Low; Medium; High | High | n/a |
| Shortest PVARP/VRef/ARef | 150; 175; … 450 ms | 175 ms | max (±5%, -12 ms / ±20 ms) |
| i2i Blanking Response | Off; Low; Medium; High | Off | n/a |

[15] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.
[16] Tolerance is valid for a pulse amplitude measured from baseline to the absolute value of the peak of the leading edge, delivered into a load resistance of 500 Ω with the device at 37°C.

Table 23. Dual-chamber programmable parameters and standard (nominal) settings

| Parameter | Settings | Standard (Nominal) Settings | Tolerance |
|---|---|---|---|
| **Hysteresis** | | | |
| Hysteresis Rate Delta ($min^{-1}$) | Off; -20; -15; -10; -5 $min^{-1}$ | Off | n/a |
| Hysteresis Search Interval (min) | 1; 5; 10; 15; 30 min | 5 min | ±5% |
| Hysteresis Cycle Count (cycles) | 1; 2; … 8 cycles | 4 cycles | n/a |
| **Intervals** | | | |
| Paced AV Delay (ms) | 40; 50; … 200; 225; … 300; 350 ms | 200 ms | -12 ms / ±20 ms |
| Sensed AV Delay (ms) | 40; 50; … 200; 225; … 325 ms | 150 ms | -12 ms / ±20 ms |
| Rate-Responsive AV Delay | Off; Low; Medium; High | Medium | n/a |
| Shortest AV Delay (ms) | 40; 50; … 120 ms | 100 ms | -12 ms / ±20 ms |
| Ventricular Intrinsic Preference | Off; On | Off | n/a |
| VIP Extension (ms) | 50; 75; … 150; 160; … 200 ms | 100 ms | ±12 ms |
| VIP Search Interval (min) | 1; 3; 5; 10; 30 min | 1 min | ±5% |
| VIP Search Cycles | 1; 2; 3 cycles | 2 cycles | n/a |
| **Tachycardia Responses** | | | |
| AMS Mode | VDI(R); DDI(R); Off | DDI | n/a |
| AMS Base Rate ($min^{-1}$) | 40; 45; … 130; 140; 150 $min^{-1}$ | 80 $min^{-1}$ | ±3% |
| Atrial Tachycardia Detection Rate ($min^{-1}$) | 110; 120; … 200; 225; … 300 $min^{-1}$ | 180 $min^{-1}$ | ±3% $min^{-1}$ / ±12 ms |
| PMT Response | Off; Atrial Pace | Atrial Pace | n/a |
| PMT Detection Rate ($min^{-1}$) | RA (LSP201A) + RV (LSP202V): 90; 95; … 175 $min^{-1}$<br>RA (LSP201A) + RV (LSP112V): 90; 95; … 165 $min^{-1}$ | 125 $min^{-1}$<br>125 $min^{-1}$ | ±3% |
| PVC Response | Off; Atrial Pace | Off | n/a |
| **Stored Electrograms** | | | |
| Storage Mode | Continuous; Freeze | Continuous | n/a |
| Total Storable Episodes | 1; 2; 4 | 4 | n/a |
| Amplitude Range (mV) | 1.25; 3; 6; 14 mV | RA: 6 mV<br>RV: 14 mV | ±40% |
| Episode Triggers | Off; AMS Entry; AMS Exit; AMS Entry & AMS Exit | Off | n/a |
| **i2i Parameters** | | | |
| RA -> RV i2i Setting Level | 1; 2; ... 7 | 4 | n/a |
| RV -> RA i2i Setting Level | 1; 2; ... 7 | 4 | n/a |

## MRI Settings

Table 24. MRI Settings: Models LSP112V, LSP201A, LSP202V

| Parameter | Settings | Nominal |
|---|---|---|
| MRI Mode | DOO ⇄ VOO, VOO, AOO, or Pacing Off | ▪ DOO ⇄ VOO for dual-chamber system<br>▪ VOO for single-chamber ventricular system<br>▪ AOO for single-chamber atrial system |
| MRI Base Rate | 30; 35; … 120 $min^{-1}$ in steps of 5 $min^{-1}$ | 85 $min^{-1}$ |
| MRI Paced AV Delay [17] | 40; 50; ... 120 ms in steps of 10 ms | 120 ms |
| MRI Pulse Amplitude | 5.0 V (non-programmable) | n/a |

[17] MRI Paced AV Delay setting applies only to dual-chamber systems programmed to MRI DOO ⇄ VOO Mode.

Table 24. MRI Settings: Models LSP112V, LSP201A, LSP202V

| Parameter | Settings | Nominal |
|---|---|---|
| MRI Pulse Width | 1.0 ms (non-programmable) | n/a |
| MRI Electrode Configuration | Bipolar (non-programmable) | n/a |
| Magnet Response (MRI Mode) | Off (non-programmable) | n/a |

## Physical Specifications

Table 25. LP physical specifications

| | RA LP | RV LP |
|---|---|---|
| **Model** | LSP201A | LSP112V, LSP202V |
| **Length (mm)** | 32.2 | 38.0 |
| Diameter (mm) | 6.5 | 6.5 |
| Mass (g) | 2.1 | 2.4 |
| Volume ($cm^3$) | 1.0 | 1.1 |
| Fixation mechanism | Distal, non-retractable helix | Distal, non-retractable helix |
| **Electrode configuration** | | |
| Tip | Helical | Domed |
| Ring | Cylindrical | Cylindrical |
| **Electrode surface area ($mm^2$)** | | |
| Tip | ~ 5 | ~ 2 |
| Ring | ~ 124 | ~ 244 |
| Electrode spacing ($mm^2$) | ≥ 24 | ≥ 24 |
| **Materials** | | |
| Case | Titanium Grade 2 | Titanium Grade 2 |
| Case coating | Parylene | Parylene |
| Fixation helix | MP35N‡ | MP35N‡ |
| Tip electrode | Titanium nitride-coated platinum-iridium alloy | Titanium nitride-coated platinum-iridium alloy |
| **Distal header** | Polyether Ether Ketone (PEEK), silicone rubber, nylon | Polyether Ether Ketone (PEEK), silicone rubber, nylon |
| Steroid-eluting plug | Silicone rubber with a single dose of dexamethasone sodium phosphate (DSP) | Silicone rubber with a single dose of dexamethasone sodium phosphate (DSP) |
| **Power source** | 1 lithium carbon monofluoride (Li-CFx) cell | 1 lithium carbon monofluoride (Li-CFx) cell |
| Model | 3850 | 3851 |
| Manufacturer | Greatbatch Medical | Greatbatch Medical |
| **X-ray identification code** | NT | NT |

## Data Security

Abbott Medical takes a broad and deep approach to ensuring the safety, security and privacy of the patient information and data on our devices and systems connecting patients to healthcare providers and clinics. Patients, clinical staff, and hospital IT staff do not need to configure the LP or take any special action (for example, firewall use) to safeguard patient information and device data.

Abbott Medical recommends clinics allow only authorized healthcare providers to use the programmer system (for example, by requiring badged access to the programmer system location).

Safeguards for the LP will be provided throughout the stated warranty period or until a replacement product is available.

The cybersecurity bill of materials (CBOM) is available upon request.

Visit the information page at abbott.com/cybersecurity to read more about Abbott's commitment to cybersecurity. Periodically, Abbott may update the website with important bulletins.

## Technical Support

Abbott Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- + 61 2 9936 1200 (Australia)
- medical.abbott/manuals

For additional assistance, call your local Abbott Medical representative.

Any serious incident should be reported to Abbott Medical and the FDA.

Abbott Medical
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

www.abbott.com

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