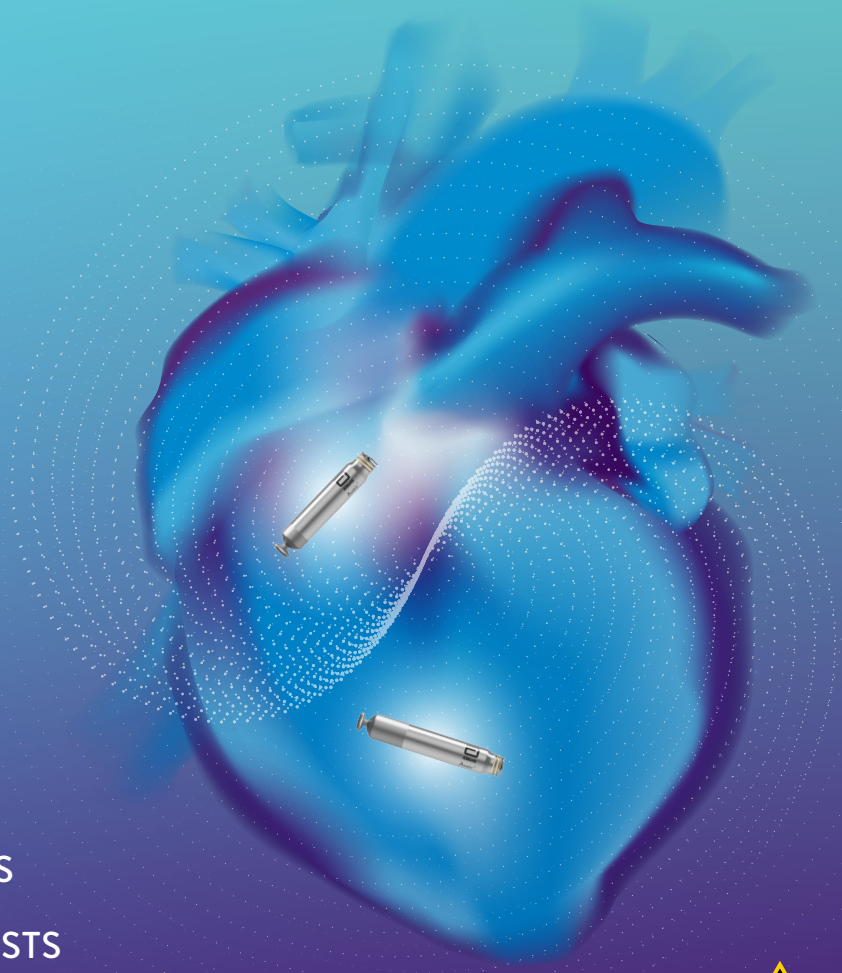
AVEIR™ LEADLESS PACEMAKER SYSTEM MRI GUIDE



GUIDE FOR CARDIAC CLINICIANS AND PHYSICIANS

GUIDE FOR RADIOLOGISTS AND MRI TECHNOLOGISTS

MR

Abbott

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FOR ASSESSMENT AND PROGRAMMING

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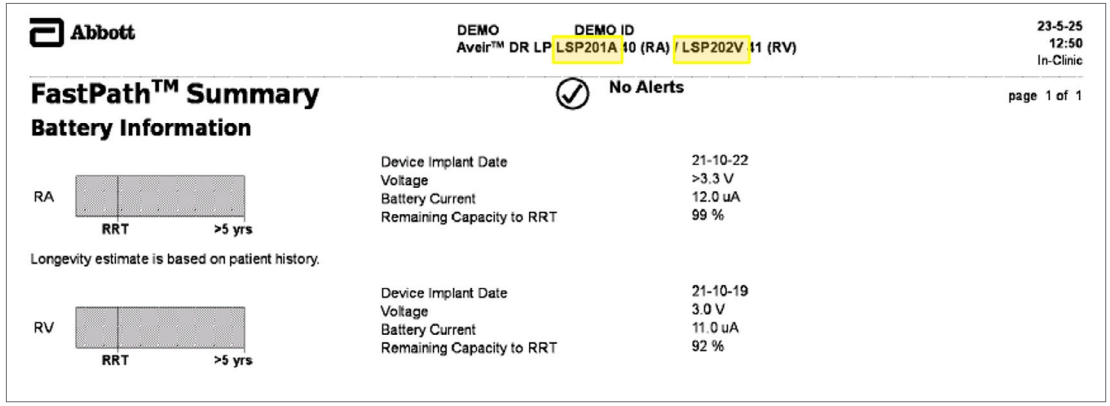
REMINDER: *It is required to program the AVEIR System to MRI Settings as part of the MRI scan workflow.*

PROCEED TO **STEP 1 >**

STEP 1

CONFIRM THAT THE PATIENT HAS AN MR CONDITIONAL SYSTEM

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



Abbott

DEMO DEMO ID
Aveir™ DR LP LSP201A 40 (RA) / LSP202V 41 (RV)

23-5-25
12:50
In-Clinic

FastPath™ Summary

No Alerts

page 1 of 1

Battery Information

RA

RRT >5 yrs

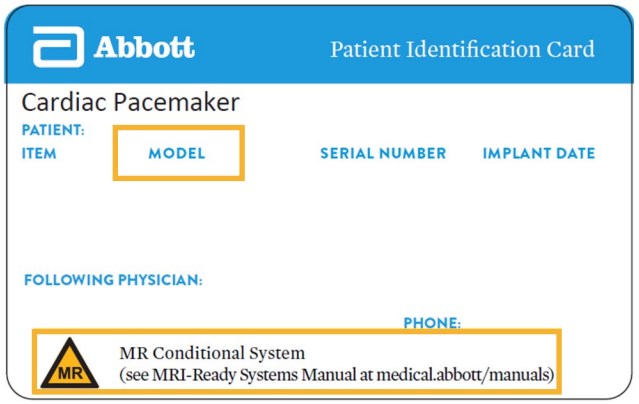
Device Implant Date	21-10-22
Voltage	>3.3 V
Battery Current	12.0 uA
Remaining Capacity to RRT	99 %

Longevity estimate is based on patient history.

RV

RRT >5 yrs

Device Implant Date	21-10-19
Voltage	3.0 V
Battery Current	11.0 uA
Remaining Capacity to RRT	92 %



Abbott Patient Identification Card

Cardiac Pacemaker

PATIENT:

ITEM | MODEL | SERIAL NUMBER | IMPLANT DATE

FOLLOWING PHYSICIAN:

PHONE:

MR Conditional System
(see MRI-Ready Systems Manual at medical.abbott/manuals)

Patient ID card with model number highlighted.

MR Conditional Models for the AVEIR™ Leadless Pacemaker System
LSP112V
LSP202V
LSP201A

Single and Dual Chamber Aveir™ Leadless Pacemaker Systems are MR Conditional.

IF **CONFIRMED**, PROCEED TO **STEP 2 >**

STEP 2

CONFIRM THAT NO ADVERSE CONDITIONS TO MRI SCANNING ARE PRESENT

EXAMPLES OF ADVERSE CONDITIONS:

- A device is at End-of-Service
- An implanted LSP112V or LSP202V is implanted at a site other than the right ventricle
- An implanted LSP201A is implanted at a site other than the right atrium
- A device has unstable capture thresholds OR has a threshold greater than 2.5V@0.5ms
- Complaints of diaphragmatic stimulation when outputs are set to 5.0V@1.0ms, if the patient will be paced when MRI Settings are enabled
- Patients with additional cardiac hardware (ex: abandoned leads)

SEE **NEXT PAGE** FOR FURTHER CLARIFICATION RELATED TO ADDITIONAL IMPLANTED DEVICES OR ABANDONED LEADLESS PACEMAKERS.

ADDITIONAL NOTES FOR CLARIFICATION

IT IS ACCEPTABLE TO SCAN PATIENTS WITH OTHER MR CONDITIONAL IMPLANTABLE DEVICES, AS LONG AS:

1. They are not implanted in cardiac tissue*
2. MR conditions for each implanted device are met

*IT IS ACCEPTABLE TO SCAN PATIENTS WITH OTHER ABANDONED MR CONDITIONAL LEADLESS PACEMAKERS IN THE SAME CHAMBER, AS LONG AS:

1. MR conditions for each leadless pacemaker are met
2. Abandoned leadless pacemakers are deactivated

IF ANY CONDITIONS EXIST WHICH COULD MAKE MRI SCANNING UNSAFE, **DO NOT SCAN THE PATIENT.**

IF **NO ADVERSE CONDITIONS PRESENT**, PROCEED TO **STEP 3** >

STEP 3

REVIEW THE POTENTIAL ADVERSE EVENTS

THE AVEIR™ LEADLESS PACEMAKER SYSTEM HAS BEEN DESIGNED TO MINIMIZE POTENTIAL ADVERSE EVENTS THAT MAY CAUSE PATIENT HARM.

Please refer to the MRI-Ready Leadless Systems Manual for a complete list of potential adverse events that may occur in the MRI environment **here**.

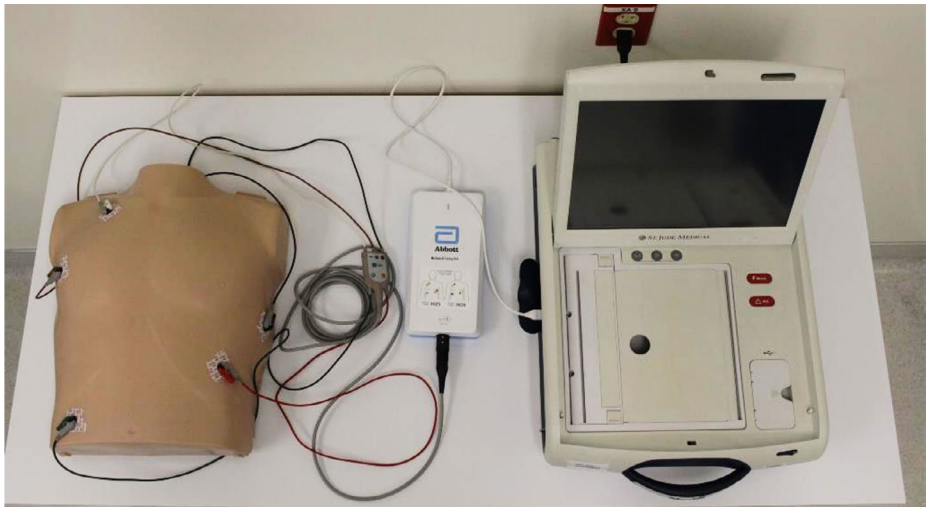
ONCE **POTENTIAL ADVERSE EVENTS ARE REVIEWED**, PROCEED TO **STEP 4 >**

STEP 4

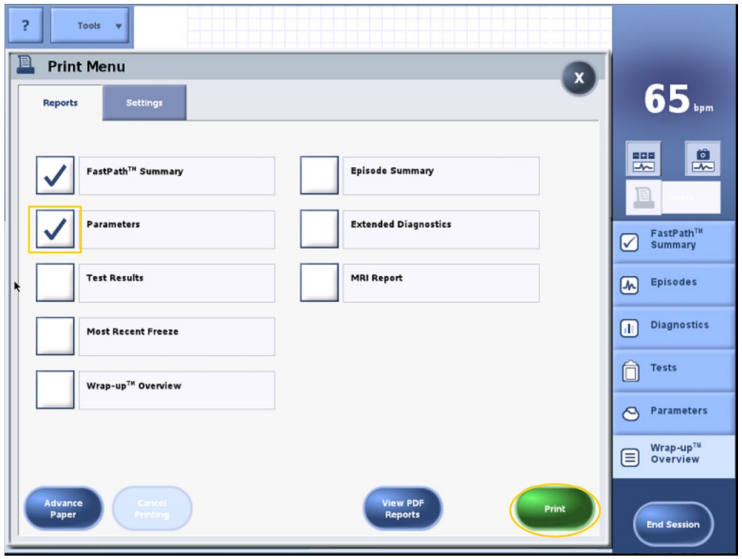
GENERATE A REPORT OF THE PATIENT'S PERMANENTLY PROGRAMMED PARAMETERS

Note: *This interrogation should be done OUTSIDE the scanner magnet room. Do not bring the programmer or accessories into the scan room. This includes patient electrodes used for programming, which must be removed prior to the MRI scan. To make note of the patient's permanent parameters, perform the following actions.*

1. Interrogate the leadless pacemaker system using the appropriate components.



2. Print, at minimum, the Parameter Report to save a copy of original programming.

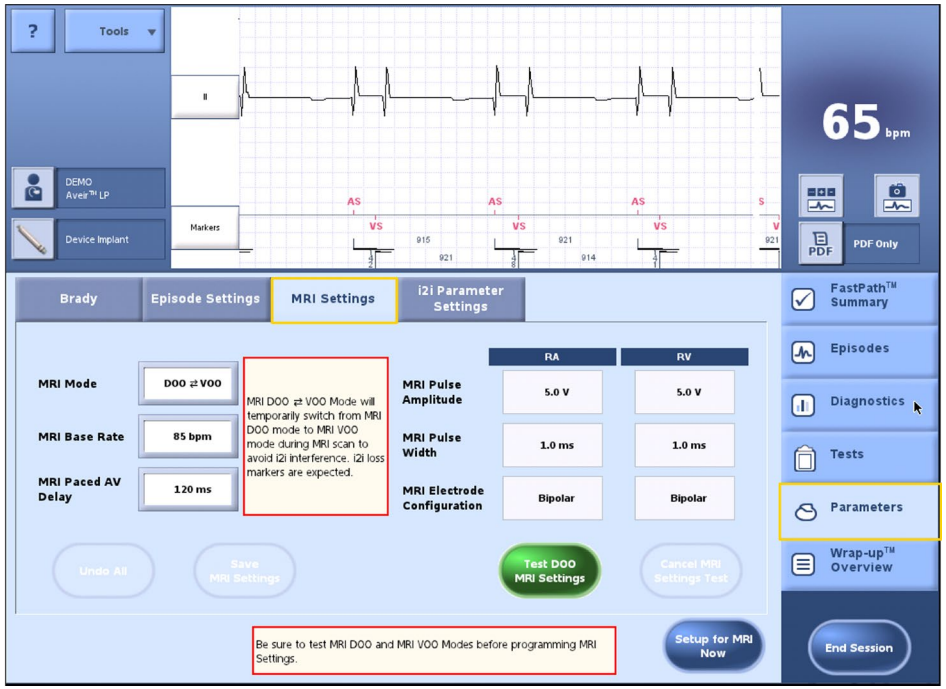


ONCE **COMPLETE**, PROCEED TO **STEP 5 >**

STEP 5

SELECT AND SAVE MRI SETTINGS

When ready, navigate to **Parameters** » **MRI Settings**



THERE ARE 3 MAIN SETTINGS YOU CAN CHANGE.

1. **MRI Mode**
   Nominal: DOO⇄VOO
   Options: DOO⇄VOO, VOO, AOO, Pacing Off

2. **MRI Base Rate**
   Nominal: 85 bpm
   Options: 30-120 bpm

3. **MRI Paced AV Delay**
   Nominal: 120 ms
   Options: 40-120 ms

Let's explore more about how to select, test, and save MRI Settings.

STEP 5

SELECT AND SAVE MRI SETTINGS

HOW TO SELECT THE MRI MODE:

Pacing Off: Do not select this mode unless you are confident the patient can be without pacing support for an extended period of time.

AOO: Do not select this mode if the patient has intermittent or complete heart block. There will not be any ventricular pacing support.

VOO: If the patient can tolerate ventricular-only pacing, this may be a good mode to select!

DOO⇄VOO: This is the nominal mode. In this mode, the device will attempt to maintain dual chamber asynchronous pacing. However, it will switch to VOO during active scanning to avoid i2i™ communication interference. If a patient is less tolerant of ventricular-only pacing, this may be the best mode to select. This mode will result in unique markers which will be explored in more detail later.

STEP 5

SELECT AND SAVE MRI SETTINGS

HOW TO SELECT THE MRI PACING RATE:

If you choose **AOO, VOO,** or **DOO⇄VOO mode**, ensure that you select a pacing rate **faster** than the patient's intrinsic heart rate. In asynchronous modes, there is no sensing of intrinsic rhythms. This means that competition with the intrinsic rhythm may occur if the device is not overdrive pacing.

HOW TO SELECT THE MRI PACED AV DELAY:

If you choose the **DOO⇄VOO mode**, ensure that you select a paced AV delay shorter than the patient's intrinsic PR interval. This avoids competing with the patient's native conduction. The nominal 120 ms will likely be shorter than most people's intrinsic conduction timing but should be adjusted if not.

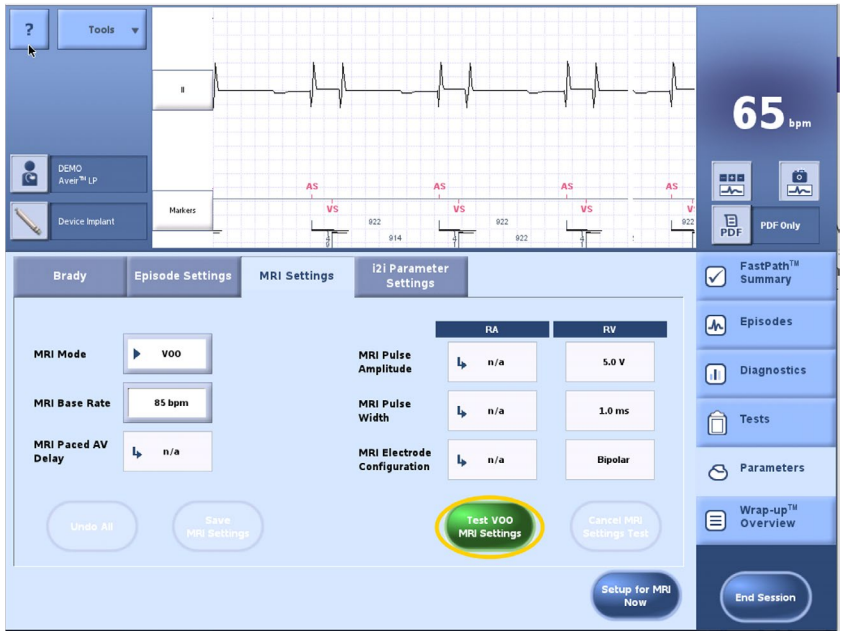
APPROPRIATE MODE, RATE, AND PACED AV DELAY **SELECTED >**

STEP 5

SELECT AND SAVE MRI SETTINGS

If you make any programming changes from the nominal settings, you will need to "Save MRI Settings" before proceeding.

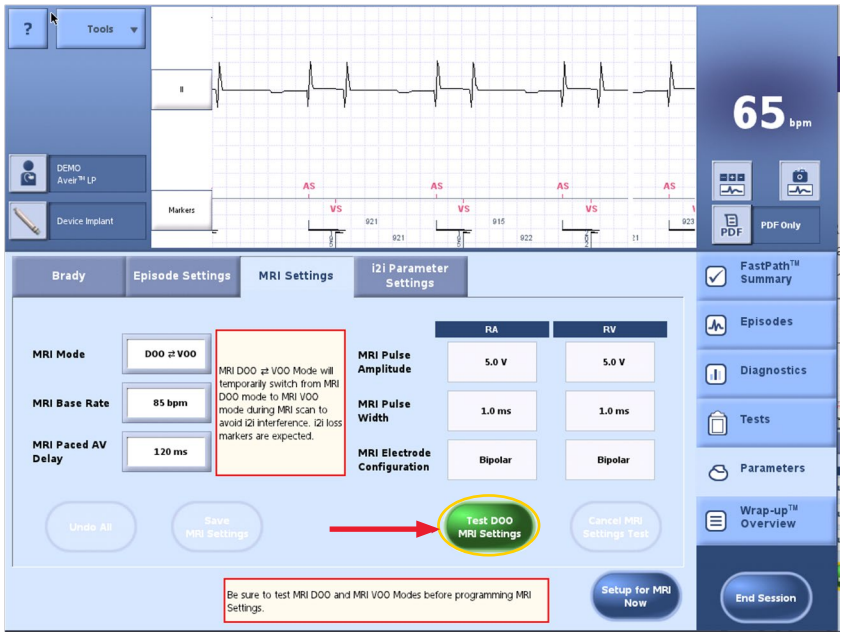
Whether you keep the nominal settings OR if you make programming changes, you will need to ensure the selected parameters provide the necessary hemodynamic support for the patient. To do this, select the "Test ____ MRI Settings" button.

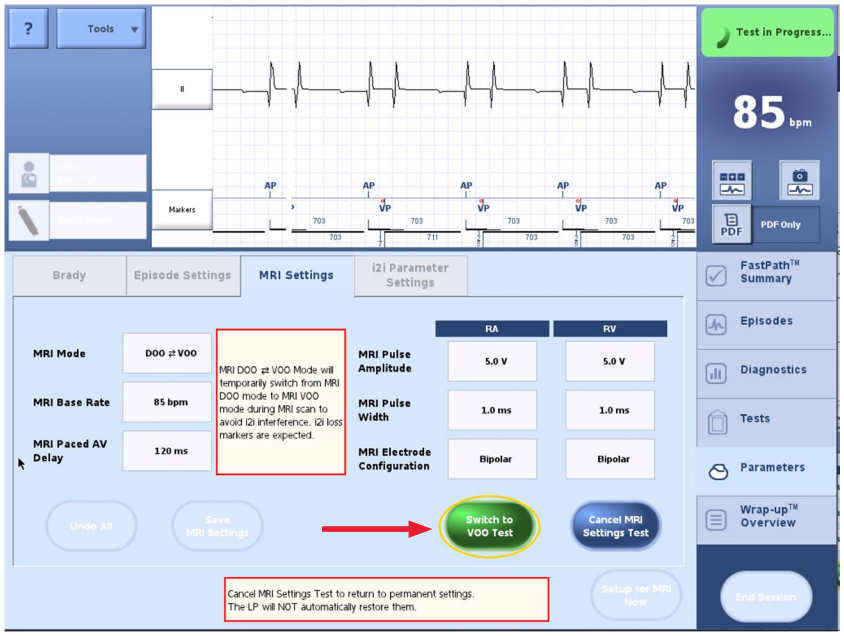


STEP 5

SELECT AND SAVE MRI SETTINGS

Note: *If you select the nominal mode DOO⇄VOO, it will ask you to subsequently test both DOO and VOO mode to ensure both are hemodynamically stable for the patient.*

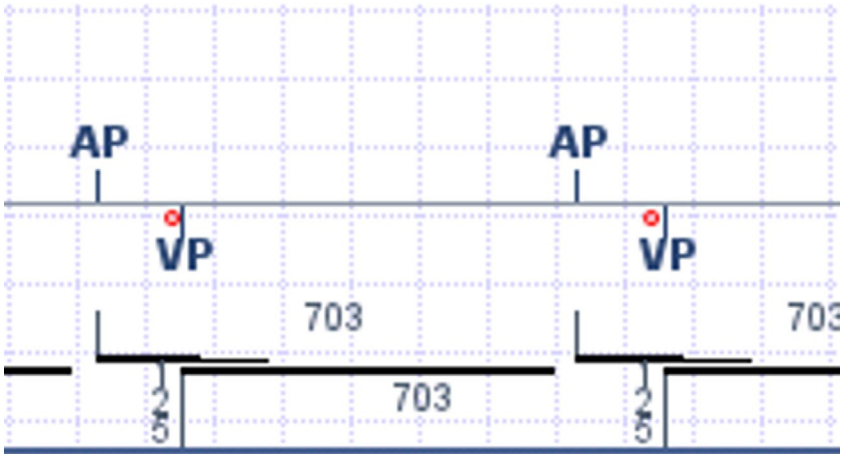




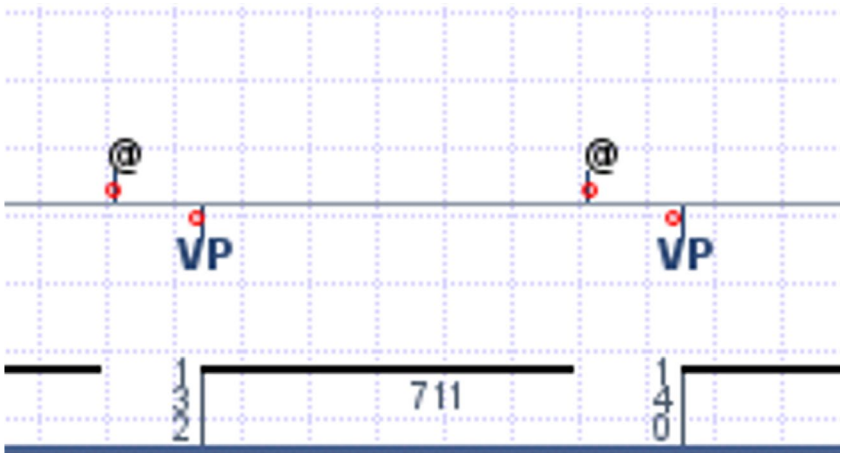
A NOTE ON MARKERS DURING MRI PROGRAMMING

IF YOU SELECT THE DOO⇄VOO MRI MODE, YOU WILL SEE UNIQUE MARKERS WHEN PROGRAMMING DEVICES FOR MRI SCANS. THIS IS EXPECTED BEHAVIOR AND SHOULD NOT BE CAUSE FOR ALARM.

1. When testing DOO in DOO⇄VOO MRI Mode, you will see the below marker pattern.



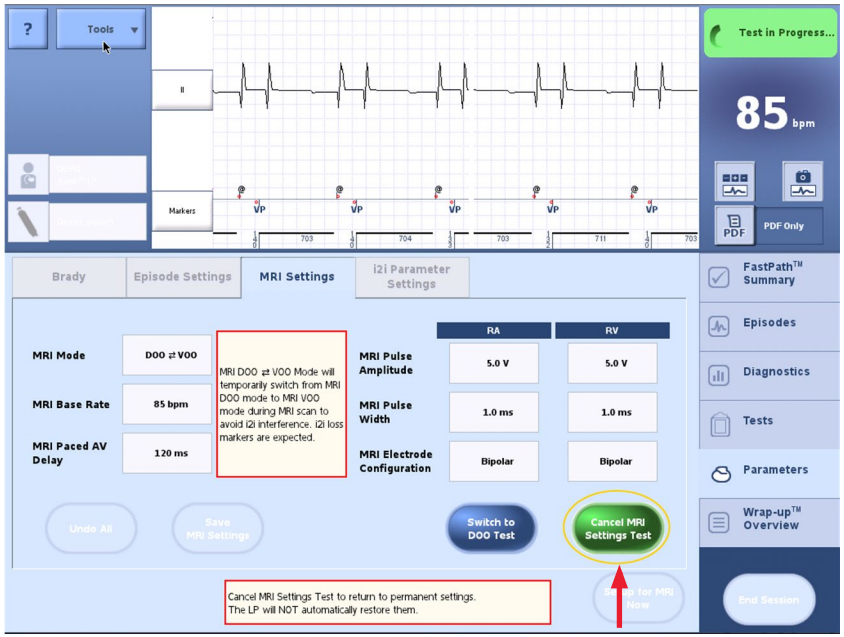
2. When testing VOO in DOO⇄VOO MRI Mode, you will see the below marker pattern.



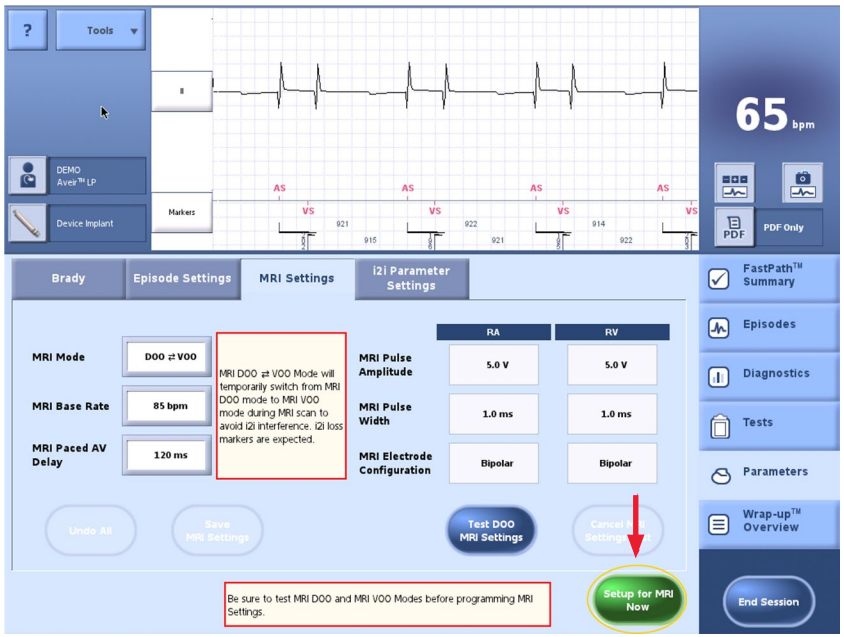
STEP 5

SELECT AND SAVE MRI SETTINGS

Once you have tested all the appropriate settings, select "**Cancel MRI Settings Test**".



Confirm and save your final preferred programming. Then select "**Setup for MRI Now**". **Step 5 is now complete.**



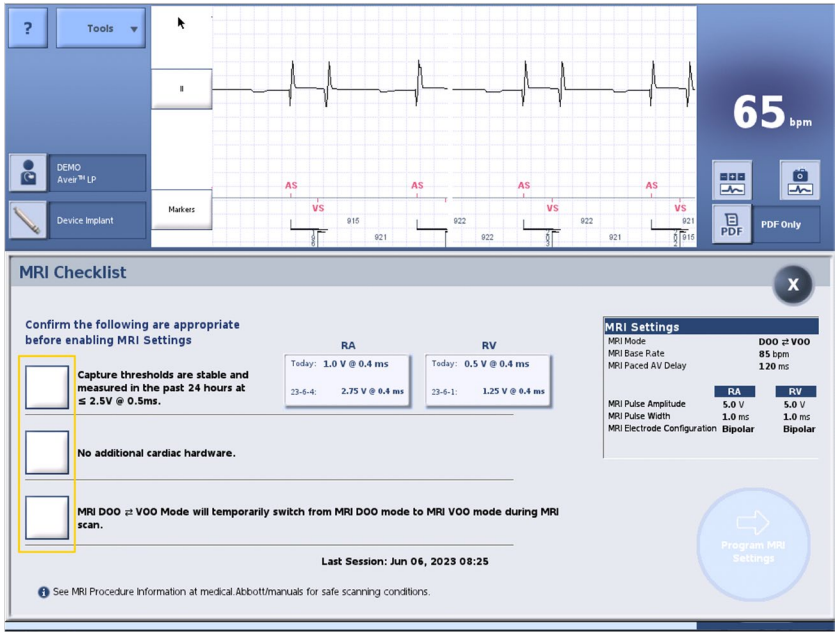
MRI SETTINGS SAVED. PROCEED TO **STEP 6 >**

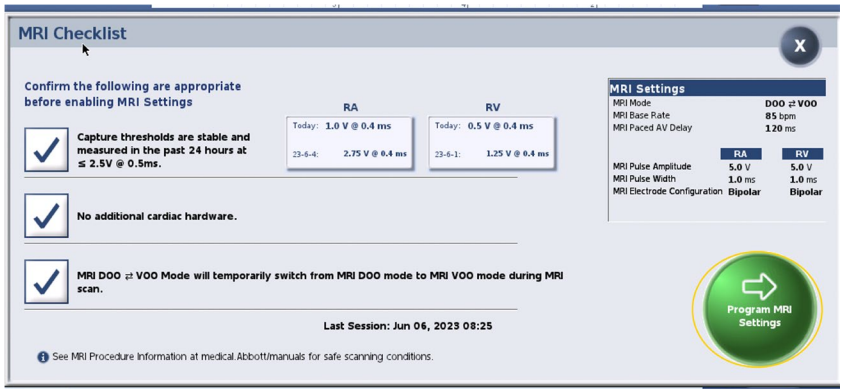
STEP 6

REVIEW THE MRI CHECKLIST AND PROGRAM MRI SETTINGS

Check each box of the MRI Checklist once you have confirmed the condition. Depending on the mode you chose in Step 5, there may be 2 or 3 boxes to check.

After all boxes are checked, you can select the green “Program MRI Settings” button.

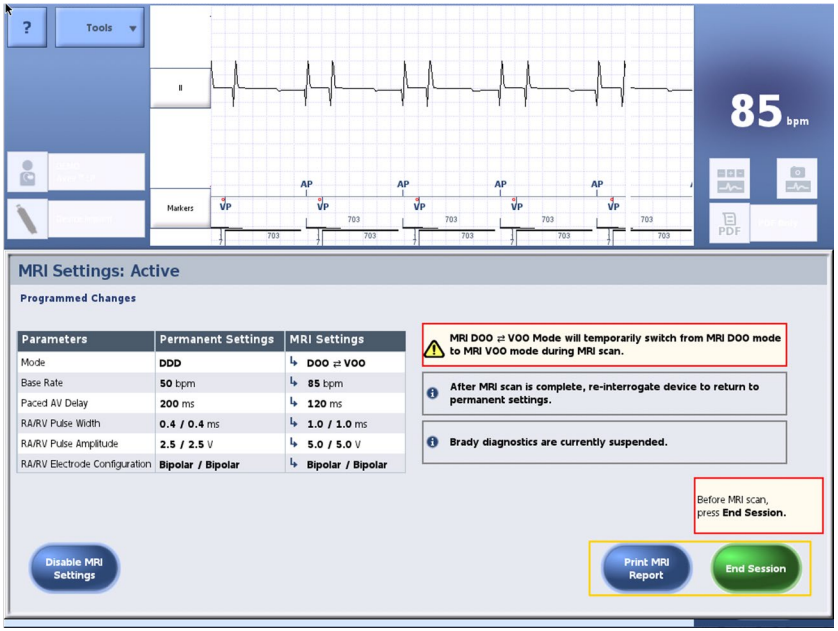




STEP 6

REVIEW THE MRI CHECKLIST AND PROGRAM MRI SETTINGS

The patient is now in MRI Settings and is ready to be scanned. You should print the MRI Report and press the green “End Session” button, prior to scanning.



PROCEED TO **MRI SCAN >**

DO NOT PROCEED PAST THIS SLIDE UNTIL THE MRI SCAN HAS BEEN COMPLETED.

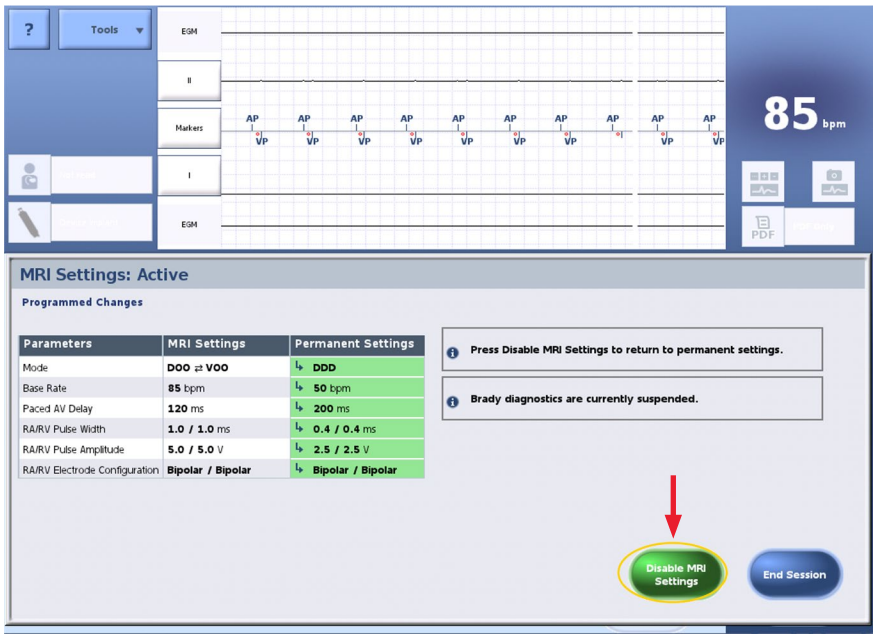
IF **COMPLETE**, PROCEED TO **STEP 7 >**

STEP 7

DISABLE MRI SETTINGS

Immediately after the MRI scan is complete, reinterrogate the patient using the Merlin Programmer, and "**Disable MRI Settings**".

Note: *This interrogation should be done OUTSIDE the scanner magnet room.*



Retest capture thresholds and confirm appropriate permanent programming.

THE MRI WORKFLOW IS NOW COMPLETE AND YOU CAN END THE SESSION.

MRI WORKFLOW **COMPLETE >**

STEP-BY-STEP INSTRUCTIONS
FOR ASSESSMENT AND SCANNING

PRE-MRI SCAN STEPS

Step 1: Confirm that the Patient has an MR Conditional System

Step 2: Confirm that No Adverse Conditions to MRI Scanning are Present

Step 3: Review the Potential Interactions

Step 4: Select the Correct Scan Parameters

Step 5: Check MRI Settings Status

DURING-MRI SCAN STEPS

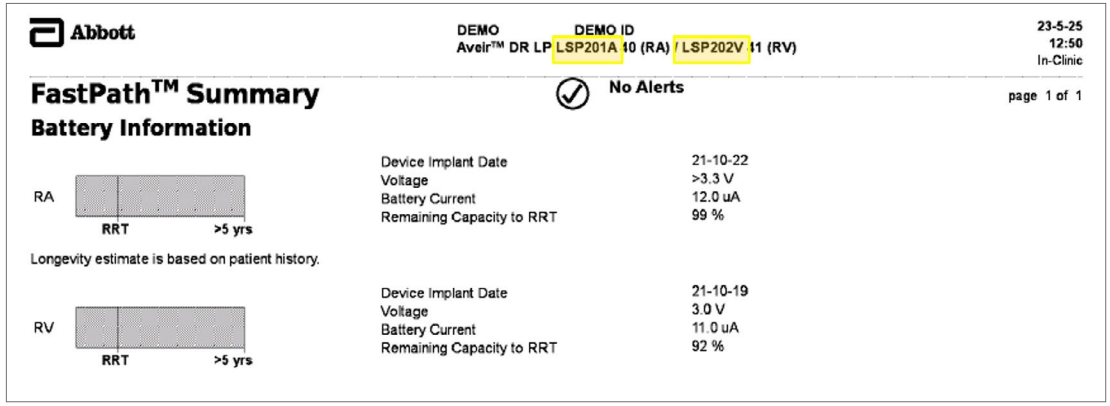
Step 6: Perform the Scan and Monitor the Patient

PROCEED TO **STEP 1 >**

STEP 1

CONFIRM THAT THE PATIENT HAS AN MR CONDITIONAL SYSTEM

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



Abbott

DEMO DEMO ID
Aveir™ DR LP LSP201A 40 (RA) / LSP202V 41 (RV)

23-5-25
12:50
In-Clinic

FastPath™ Summary

No Alerts

page 1 of 1

Battery Information

RA

RRT >5 yrs

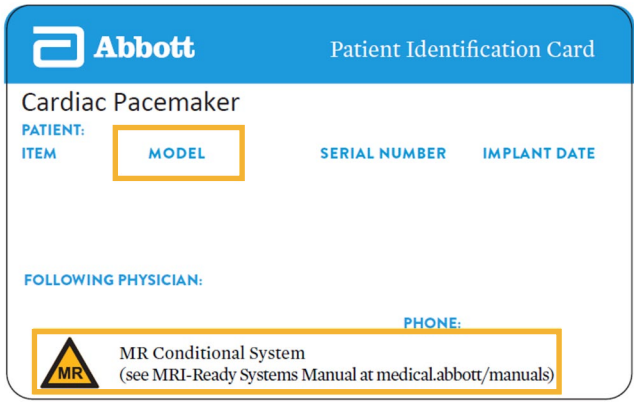
Device Implant Date	21-10-22
Voltage	>3.3 V
Battery Current	12.0 uA
Remaining Capacity to RRT	99 %

Longevity estimate is based on patient history.

RV

RRT >5 yrs

Device Implant Date	21-10-19
Voltage	3.0 V
Battery Current	11.0 uA
Remaining Capacity to RRT	92 %



Abbott Patient Identification Card

Cardiac Pacemaker

PATIENT:

ITEM | MODEL | SERIAL NUMBER | IMPLANT DATE

FOLLOWING PHYSICIAN:

PHONE:

MR Conditional System
(see MRI-Ready Systems Manual at medical.abbott/manuals)

Patient ID card with model number highlighted.

MR Conditional Models for the AVEIR™ Leadless Pacemaker System
LSP112V
LSP202V
LSP201A

Single and Dual Chamber Aveir™ Leadless Pacemaker Systems are MR Conditional.

IF **CONFIRMED**, PROCEED TO **STEP 2 >**

STEP 2

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 the patient's arms at his or her sides.
- Patients with additional cardiac hardware (ex: abandoned leads). See below for further clarification

IT IS ACCEPTABLE TO SCAN PATIENTS WITH OTHER MR CONDITIONAL IMPLANTABLE DEVICES, AS LONG AS:

1. They are not implanted in cardiac tissue*
2. MR conditions for each implanted device are met

*IT IS ACCEPTABLE TO SCAN PATIENTS WITH OTHER ABANDONED MR CONDITIONAL LEADLESS PACEMAKERS IN THE SAME CHAMBER, AS LONG AS:

1. MR conditions for each leadless pacemaker are met
2. Abandoned leadless pacemakers are deactivated

IF **NO ADVERSE CONDITIONS PRESENT**, PROCEED TO **STEP 3 >**

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STEP 3

REVIEW THE POTENTIAL INTERACTIONS

Please refer to the MRI-Ready Leadless Systems Manual for a complete list of potential interactions between the MRI scanner and the MR Conditional device **here**.

PROCEED TO **STEP 4 >**

STEP 4

SELECT THE CORRECT SCAN PARAMETERS

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 1)
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 Integrated Whole Body RF Transmit Coil with RF excitation: ▪ Circularly polarized (CP), or ▪ 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: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 4) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 8) ▪ Perform the Scan and Monitor the Patient (page 9)
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. If present, the LSP112V/LSP202V device must be implanted in the right ventricle. 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. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 8)
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 1)
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 Integrated Whole Body RF Transmit Coil or Detachable RF Transmit-Receive coils (Head, Lower Extremity, or Upper Extremity) with RF excitation: ▪ 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: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 4) Refer to Instructions for Radiologists and MRI Technologists to: ▪ Confirm that No Adverse Conditions to MRI Scanning are Present (page 8) ▪ Perform the Scan and Monitor the Patient (page 9)
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. If implanted, the LSP112V/LSP202V device must be implanted in the right ventricle. 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. Refer to: ▪ Instructions for Cardiac Physicians and Clinicians (page 4) ▪ Instructions for Radiologists and MRI Technologists (page 8)
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.

**These scan parameters are tied to US regulatory approval of the AVEIR Leadless Pacemaker System.*
Please consult medical.abbott/manuals for manuals and recommendations specific to other geographies.

PROCEED TO **STEP 5 >**

STEP 5

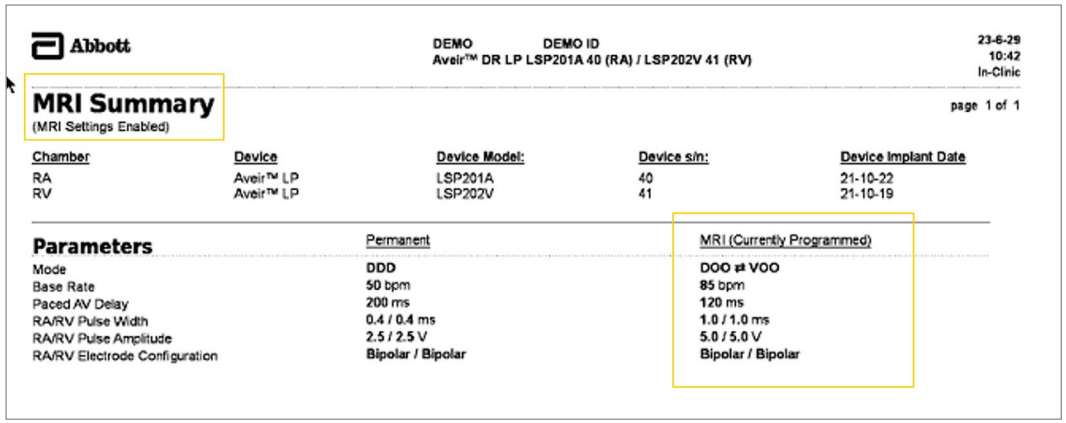
CHECK MRI SETTINGS STATUS

Confirm that a device management physician or clinician has programmed MRI Settings in anticipation of the scan before proceeding.

This can be confirmed by looking at the patient MRI Summary print-out (see image to the right).

If there is no printout, or if there is a need to re-interrogate the patient to confirm MRI Settings, do so OUTSIDE the scanner room.

Note: *No programming equipment should be brought into the scanner room, including programming electrodes.*



Abbott

DEMO DEMO ID
Aveir™ DR LP LSP201A 40 (RA) / LSP202V 41 (RV)

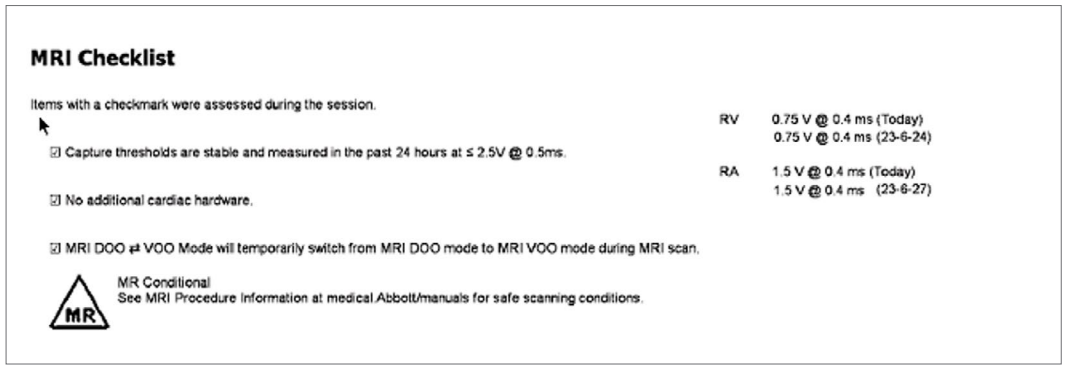
23-6-29
10:42
In-Clinic

MRI Summary
(MRI Settings Enabled)

page 1 of 1

Chamber	Device	Device Model:	Device s/n:	Device Implant Date
RA	Aveir™ LP	LSP201A	40	21-10-22
RV	Aveir™ LP	LSP202V	41	21-10-19

Parameters	Permanent	MRI (Currently Programmed)
Mode	DDD	DOO ⇄ VOO
Base Rate	50 bpm	85 bpm
Paced AV Delay	200 ms	120 ms
RA/RV Pulse Width	0.4 / 0.4 ms	1.0 / 1.0 ms
RA/RV Pulse Amplitude	2.5 / 2.5 V	5.0 / 5.0 V
RA/RV Electrode Configuration	Bipolar / Bipolar	Bipolar / Bipolar



MRI Checklist

Items with a checkmark were assessed during the session.

☑ Capture thresholds are stable and measured in the past 24 hours at ≤ 2.5V @ 0.5ms.

RV 0.75 V @ 0.4 ms (Today)
0.75 V @ 0.4 ms (23-6-24)

RA 1.5 V @ 0.4 ms (Today)
1.5 V @ 0.4 ms (23-6-27)

☑ No additional cardiac hardware.

☑ MRI DOO ⇄ VOO Mode will temporarily switch from MRI DOO mode to MRI VOO mode during MRI scan.

MR Conditional
See MRI Procedure Information at medical.Abbott/manuals for safe scanning conditions.

PROCEED TO **MRI SCAN >**

STEP 6

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 MRI 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.

MRI WORKFLOW **COMPLETE.**

ADDITIONAL RESOURCES

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)

ADDITIONAL PRODUCT AND MRI RESOURCES

For additional assistance, call your local Abbott Medical representative.

Manuals for US HCPs

MRI Resources

IMPORTANT SAFETY INFORMATION

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Abbott.com

Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: 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.

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/or 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.

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 the Product Materials section of the IFU) contained in the device and a thorough history of allergies must be discussed.

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, Valve damage and/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 pacing and/or sensing due to dislodgement or mechanical malfunction of the LP (non-battery related), Loss of capture or sensing due to embolization or fibrotic tissue response at the electrode, Increased capture threshold, Inappropriate sensor response, 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, Helix distortion), 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 hypotension, dyspnea, respiratory failure, syncope, pneumonia, hypertension, cardiac failure, reaction to sedation, renal failure, anemia, and death.

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