**DDD Pacemaker Specification**

1. **Introduction**

This specification document of DDD Pacemaker defines the functions and operating characteristics, identifies the system environmental performance parameters, and specifies anticipated uses of the system.

* 1. **Scope**

This specification document defines and describes necessary functions of pacemaker model design.

* 1. **Acronyms**

AP Atrial Pacing

AS Atrial Sensing

ATR Atrial Tachycardia Response

AVI Atrial Ventricular Interval

ELT Endless Loop Tachycardia

LRI Lower Rate Interval

PVARP Post-Ventricular Atrial Refractory Period

URI Upper Rate Interval

VP Ventricular Pacing

VS Ventricular Sensing

VRP Ventricular Refractory Period

1. **System Definition**
   1. **System Overview**

A pacemaker is a small electronic device that helps the heart maintain an adequate or normal heart rate. DDD Pacemaker sense and pace in both chambers, pace according to events in another chamber.

* 1. **Indications and Contraindications**

The DDD Pacemaker is indicated for patients who suffer from cardiac arrhythmia and would benefit from increasing pacing rates. The dual-chamber mode of DDD pacemaker are specifically indicated for treatment of conduction disorder between atrial and ventricular, including different degrees of AV block.

* 1. **User Persona**

Patients who suffer from cardiac arrhythmia. Professional technician should be responsible of implanting pacemaker device and perform follow-up of patiets.

1. **System Requirement**

Detailed development requirements are defined.

* 1. **No Deadlock**

The device should always be able to progress instead of stuck in some state. Whichever state the pacemaker is in, there should always be a transition to another state.

* 1. **Lower Rate Limit**

The pacemaker should fulfil its intended use, which is maintaining a minimum ventricular rate. Therefore, the maximum interval between two consecutive ventricular events should be less or equal to LRI.

* 1. **Upper Rate Limit:**

The pacemaker should not pace to increase the heart rate too high. So the minimum interval between a ventricular event and a ventricular pacing should be no less than URI.

* 1. **Persistent fast ventricular events:**

The ventricular rate should not be faster or equal to URL for more than 30 beats.

* 1. **Pacing Pulse**

Pacemaker should generate pacing pulses with programmed voltages and time length, providing electrical stimulation to the heart when pacing.

* 1. **Sensing Rate**

Rate detections are based on measured cardiac cycle length of sensed rhythm. Rate should be evaluated by five basic cycles on interval basis

* 1. **Tracked Response to sensing**

Atrial sensing should followed by a tracked ventricular pacing according to programmed AV delay during tracked pacing, unless there’s a ventricular sense within AVI time.

1. **Bradycardia Therapy**
   1. **Programmable Parameters**

Pacemaker is intended to use on patients who suffer from bradycardia, insufficient heart rate, for a DDD pacemaker, user programmable parameters that used for controlling bradycardia therapy are as follows:

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| --- | --- |
| LRI | Maximum interval between two ventricular events |
| URI | Minimum interval between two ventricular events |
| AVI | Maximum interval between an atrial event and a ventricular event |
| VRP | Interval following a ventricular event during which ventricular senses would not inhibit or trigger pacing. |
| PVARP | Interval following a ventricular event during which atrial events would not inhibit atrial pacing or trigger ventricular pacing. |

1. **Specified requirements for Simulink transitions**

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| --- | --- | --- | --- |
| **States requirements** | | | |
| Index | state | summary | description |
| 0 | DDDPM | DDD pacemaker | pacemaker state, which including all five parts. |
| 1 | URI | URI part | The pacemaker should not pace to increase the heart rate too high. So the minimum interval between a ventricular event and a ventricular pacing should be no less than URI. |
| 1.1 | IdleURI | Idle URI state | When pacemaker is currently not in a URI period |
| 1.2 | ActiveURI | Activate URI state | Indicates that less than URI time has passed after last ventricular event so no ventricular event should yet happen |
| 2 | LRI | LRI part | The pacemaker should fulfil its intended use, which is maintaining a minimum ventricular rate. Therefore, the maximum interval between two consecutive ventricular events should be less or equal to LRI. |
| 2.1 | IdleLRI | Idle LRI state | when pacemaker is in a LRI period for no more than AEI time |
| 2.2 | ActiveLRI | Activate LRI state | Indicate that an atrial event has happened in a LRI period |
| 2.3 | LRIVP | LRIVP state | Indicates that a VP happened at the end of a LRI period |
| 3 | AVI | AVI part | AVI cycle ensures interval between an atrial event and a ventricular event is no more than AVI |
| 3.1 | IdleAVI | Idle avi state | Pacemaker stay in IdleAVI state when an AVI period has not been started |
| 3.2 | ActiveAVI | Active AVI state | keep counting down in an AVI period |
| 3.3 | CAVI | CAVI state | entered after an AVI period finished and VP generated |
| 4 | VRP | VRP part | Interval following a ventricular event during which ventricular senses would not inhibit or trigger pacing. |
| 4.1 | IdleVRP | Idle VRP state | Stay in this IdleVRP when VRP period has not began |
| 4.2 | ActiveVRP | Active VRP state | indicate that pacemaker is currently in a VRP period |
| 4.3 | VRPVS | VRPVS state | temporary state after receive an Vin |
| 5 | PVARP | PVARP part | Interval following a ventricular event during which atrial events would not inhibit atrial pacing or trigger ventricular pacing. |
| 5.1 | IdlePVARP | Idle PVARP | Stay in this IdlePVARP when PVARP period has not began |
| 5.2 | AinPVARP | Ain PVARP state | When receiving an Ain signal, enter AinPVARP state, meanwhile generating an AS |
| 5.3 | ActivePVARP | Active PVARP state | indicates that pacemaker is currently in a PVARP period |
| 5.4 | PVARPAR | PVARP AR | indicates that an Ain happens in PVARP period thus should be unsensed |

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| --- | --- | --- | --- | --- |
| **Transition requirements** | | | | |
| Index | transition | | summary | description |
| from | to |
| 0 | / | DDDPM | initialize pacemaker model | set values of AS,VS,AP,VP and basic cycles. |
| In URI part | | | | |
| 0 | / | IdleURI | init URI | Initially set enterURI to be true. |
| 1 | IdleURI | ActiveURI | Activate URI period | Upon detecting a ventricular event, start a URI period until the period ends and allow VP to happen or another ventricular event happens before the period ends. |
| 2 | ActiveURI | ActiveURI | reset when VS or VP | During a URI period, another ventricular event is sensed, so the count down must be reset |
| 3 | ActiveURI | ActiveURI | count down for URI | During the URI period, this transition serves as count down function until URI period ends or another ventricular event happens |
| 4 | ActiveURI | IdleURI | go back to idle URI | after the counting down of URI period end, VP can happen |
| In LRI part | | | | |
| 0 | / | IdleLRI | init LRI | initialize count down variable tmpLRI, and initialize variables concerning AP |
| 1 | IdleLRI | IdleLRI | reset LRI period | if a ventricular event is detected in a LRI period, the count down variable should be reset |
| 2 | IdleLRI | IdleLRI | count down | keep counting down in LRI period for no more than AEI time |
| 3 | IdleLRI | ActiveLRI | AS transition | if receive an AS in Idle state, go to activate state |
| 4 | IdleLRI | ActiveLRI | remain AVI time | If AEI time passed in LRI period, pacemaker generate an AP and enter active LRI state |
| 5 | ActiveLRI | IdleLRI | reset on ventricular event | if a ventricular event is detected before LRI period ends, reset LRI cycle. |
| 6 | ActiveLRI | ActiveLRI | AP in a LRI period | If pacemaker enter active LRI state by generating an AP in a LRI period, set value of AP back to false |
| 7 | ActiveLRI | ActiveLRI | Last AVI time in LRI | Do count down when atrial event has happened in a LRI period |
| 8 | ActiveLRI | LRIVP | LRI period ends | At the end of LRI period, to keep minimum rate of ventricular events, pacemaker generate a VP |
| 9 | LRIVP | IdleLRI | back to Idle | The LRI period ends and VP generated, reset count down variable and restart from idle |
| In AVI part | | | | |
| 0 | / | IdleAVI | init avi | set VP variables to be false |
| 1 | IdleAVI | ActiveAVI | enter active AVI state | start AVI period when an atrial event happens, set value of count down variable to be AVI |
| 2 | ActiveAVI | IdleAVI | back to Idle AVI state | when AVI period has not ended, but a ventricular event has been detected |
| 3 | ActiveAVI | ActiveAVI | count down in active AVI | During an AVI period, if no VS or VP detected, keep counting down until AVI time passed |
| 4 | ActiveAVI | CAVI | end of AVI period | At the end of AVI period, give a VP to enforce maximum interval between A-V |
| 5 | CAVI | IdleAVI | reset VP | after generated VP at the end of AVI period, reset the value of VP to be false |
| In VRP part | | | | |
| 0 | / | IdleVRP | init VRP | set VS to be false |
| 1 | IdleVRP | VRPVS | enter VRPVS | when detect Vin, give VS and enter VRPVS |
| 2 | VRPVS | ActiveVRP | enter Active VRP state after VS | set VS back to false and set value of count down variable |
| 3 | IdleVRP | ActiveVRP | enter active VRP when VP | When a VP is detected, start a VRP period |
| 4 | ActiveVRP | ActiveVRP | count down in VRP | During a VRP period, keep counting down until zero |
| 5 | ActiveVRP | IdleVRP | back to Idle VRP | when a VRP period ends, go back to Idle state |
| In PVARP part | | | | |
| 0 | / | IdlePVARP | init PVARP | set AS to false |
| 1 | IdlePVARP | AinPVARP | enter Ain PVARP | generate AS when Ain |
| 2 | AinPVARP | IdlePVARP | reset AS | reset AS back to false |
| 3 | IdlePVARP | ActivePVARP | enter active state when V | when a ventricular event is detected, start PVARP period |
| 4 | ActivePVARP | IdlePVARP | back to idle PVARP state | after PVARP period has finished, back to Idle PVARP |
| 5 | ActivePVARP | ActivePVARP | count down in PVARP | During a PVARP period, count down until it ends or atrial event detected |
| 6 | ActivePVARP | PVARP\_AR | enter PVARP AR state | An atrial event happens during PVARP will be unsensed |
| 7 | PVARP\_AR | ActivePVARP | back to active PVARP | reset AR to false, continue to count down |