Table of Contents

[1 Description 1](#_Toc54178009)

[2 Variables 1](#_Toc54178010)

[2.1 Measured 2](#_Toc54178011)

[2.2 Internal 2](#_Toc54178012)

[2.3 Input 2](#_Toc54178013)

[2.4 Constant 2](#_Toc54178014)

[2.5 Controlled 3](#_Toc54178015)

[2.6 Output 3](#_Toc54178016)

[3 Modes 4](#_Toc54178017)

[3.1 AOO 4](#_Toc54178018)

[3.1.1 Variables 4](#_Toc54178019)

[3.1.2 Requirements 4](#_Toc54178020)

[3.1.3 State Transitions 4](#_Toc54178021)

[3.1.4 Design details 4](#_Toc54178022)

[3.1.5 Testing 4](#_Toc54178023)

[3.2 VOO 4](#_Toc54178024)

[3.2.1 Variables 4](#_Toc54178025)

[3.2.2 Requirements 4](#_Toc54178026)

[3.2.3 State Transitions 4](#_Toc54178027)

[3.2.4 Design details 4](#_Toc54178028)

[3.2.5 Testing 4](#_Toc54178029)

[3.3 AAI 4](#_Toc54178030)

[3.3.1 Variables 4](#_Toc54178031)

[3.3.2 Requirements 4](#_Toc54178032)

[3.3.3 State Transitions 5](#_Toc54178033)

[3.3.4 Design details 5](#_Toc54178034)

[3.3.5 Testing 5](#_Toc54178035)

[3.4 VVI 5](#_Toc54178036)

[3.4.1 Variables 5](#_Toc54178037)

[3.4.2 Requirements 5](#_Toc54178038)

[3.4.3 State Transitions 6](#_Toc54178039)

[3.4.4 Design details 7](#_Toc54178040)

[3.4.5 Testing 7](#_Toc54178041)

# Introduction

# Variables

## Measured

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| t | ms | Time since last pulse | – |
| h\_atr\_pulse\_detected | boolean | Pulse detected in atrium | {true, false} |
| h\_vent\_pulse\_detected | boolean | Pulse detected in ventricle | {true, false} |

## Input

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| ATR\_CMP\_DETECT | boolean | Atrial signal voltage higher than threshold | {HIGH, LOW} |
| VENT\_CMP\_DETECT | boolean | Ventricular signal voltage higher than threshold | {HIGH, LOW} |

## Constant

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| p\_mode | mode | Pacemaker operational mode | {AOO,VOO,AAI,VVI} |
| p\_lower\_rate\_limit | ms | Lowest allowable heart rate | 343–2000 ± 8 ms |
| p\_upper\_rate\_limit | ms | Highest allowable heart rate | 343–1200 ± 8ms |
| p\_atr\_pulse\_amplitude | V | Desired amplitude of paced atrial pulses | 0.5–7.0 ± 12% |
| p\_vent\_pulse\_amplitude | V | Desired amplitude of paced ventricular pulses | 0.5–7.0 ± 12% |
| p\_atr\_pulse\_width | ms | Desired pulse width of paced atrial pulses | 0.05–1.9 ± 0.2 ms |
| p\_vent\_pulse\_width | ms | Desired pulse width of paced ventricular pulses | 0.05–1.9 ± 0.2 ms |
| p\_atr\_sensitivity | mV | Threshold voltage for sensing spontaneous atrial pulses | 0.25–10 ± 20% |
| p\_vent\_sensitivity | mV | Threshold voltage for sensing spontaneous ventricular pulses | 0.25–10 ± 20% |
| p\_vrp | ms | Ventricular Refractory Period | 150–500 ± 8 ms |
| p\_arp | ms | Atrial Refractory Period | 150–500 ± 8 ms |
| p\_pvarp | ms | Post-Ventricular Atrial Refractory Period | 150–500 ± 8 ms |
| p\_hysteresis\_enable | boolean | Hysteresis mode enabled | {true, false} |
| p\_hysteresis\_rate\_limit | ms | Hysteresis rate limit | 343–2000 ± 8 ms |
| p\_rate\_smoothing\_enable | boolean | Rate smoothing enabled | {true, false} |
| p\_rate\_smoothing\_down | percent | Maximum allowable pacing rate decrease | 3–25 ± 1% |
| p\_rate\_smoothing\_up | percent | Maximum allowable pacing rate increase | 3–25 ± 1% |

## Controlled

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| c\_start\_pulse | boolean | Commence paced pulse | {true, false} |

## Internal

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| i\_last\_period | ms | Last period between pulses | – |

## Output

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Units/Type** | **Description** | **Range** |
| PACE\_CHARGE\_CTRL | boolean | PWM connected to primary capacitor | {HIGH, LOW} |
| ATR\_PACE\_CTRL | boolean | Atrial ring connected to primary capacitor | {HIGH, LOW} |
| VENT\_PACE\_CTRL | boolean | Ventricular ring connected to primary capacitor | {HIGH, LOW} |
| ATR\_GND\_CTRL | boolean | Atrial ring connected to ground | {HIGH, LOW} |
| VENT\_GND\_CTRL | boolean | Ventricular ring connected to ground | {HIGH, LOW} |
| PACE\_GND\_CTRL | boolean | Atrial and Ventricular tip connected to blocking capacitor | {HIGH, LOW} |
| Z\_ATR\_CTRL | boolean | Impedance circuit connected to atrial ring | {HIGH, LOW} |
| Z\_VENT\_CTRL | boolean | Impedance circuit connected to ventricular ring | {HIGH, LOW} |
| PACING\_REF\_PWM | PWM | Reference PWM for primary capacitor | 0–100% |
| ATR\_CMP\_REF\_PWM | PWM | Reference PWM for atrial signal comparator | 0–100% |
| VENT\_CMP\_REF\_PWM | PWM | Reference PWM for ventricular signal comparator | 0–100% |

# Modes

## AOO

### Variables

#### Measured

#### Constant

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| p\_lower\_rate\_limit | LRL |  |
| p\_upper\_rate\_limit | URL |  |

#### Controlled

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| A\_pace\_start | PS |  |

### Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **Last pulse Type** | **Last period(LP)** | **t** | **Pace** |
| X | X | t<URL | False |
| Sensed (no sensing in AOO) | X | X | X |
| Paced | URL<LP<LRL | t<LRL | False |
| t=LRL | True |

### State Transitions

### State Transitions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Next State  Current State | INITIAL | PACED | UPPER RATE LIMIT | LOWER RATE LIMIT |
| INITIAL | – | t = LRL | – | – |
| PACED | – | – | – | **????** |
| UPPER RATE LIMIT | – | t = URL | – | – |
| LOWER RATE LIMIT | – | t = LRL | – | – |

### Design details

### Testing

## VOO

### Variables

#### Measured

#### Constant

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| p\_lower\_rate\_limit | LRL |  |
| p\_upper\_rate\_limit | URL |  |

#### Controlled

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| V\_pace\_start | PS |  |

### Requirements

|  |  |  |  |
| --- | --- | --- | --- |
| **Last pulse Type** | **Last period(LP)** | **t** | **Pace** |
| X | X | t<URL | False |
| Sensed (no sensing in VOO) | X | X | X |
| Paced | URL<LP<LRL | t<LRL | False |
| t=LRL | True |

### State Transitions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Next State  Current State | INITIAL | PACED | UPPER RATE LIMIT | LOWER RATE LIMIT |
| INITIAL | – | t = LRL | – | – |
| PACED | – | – | – | **????** |
| UPPER RATE LIMIT | – | t = URL | – | – |
| LOWER RATE LIMIT | – | t = LRL | – | – |

### Design details

### Testing

## AAI

### Variables

#### Measured

#### Constant

#### Controlled

### Requirements

#### With Hysteresis and Rate Smoothing enabled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Pulse Type | Last Period | t | Spontaneous pulse resets timer | Pace |
| X | X |  | false | false |
| X |  | true | false |
| Sensed |  |  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |
| Paced |  |  | false |
|  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |

### State Transitions

### Design details

### Testing

## VVI

### Variables

#### Measured

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| h\_vent\_pulse\_detected | PD |  |

#### Constant

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| p\_lower\_rate\_limit | LRL |  |
| p\_upper\_rate\_limit | URL |  |
| p\_vrp | VRP |  |
| p\_hysteresis\_enable | HE |  |
| p\_hysteresis\_limit | HL |  |
| p\_rate\_smoothing\_enable | RSE |  |
| p\_rate\_smoothing\_down | RSD |  |
| p\_rate\_smoothing\_up | RSU |  |

#### Controlled

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| V\_pace\_start | PS |  |

#### Internal

|  |  |  |
| --- | --- | --- |
| **Name** | **Abbreviation** | **Reference** |
| i\_last\_period | LP |  |

### Initial Values

V\_pace\_start = false

|  |  |
| --- | --- |
| **p\_hysteresis\_enable** | **i\_last\_period** |
| true | p\_hysteresis\_limit |
| false | p\_lower\_rate\_limit |

### Requirements

#### Hysteresis and Rate Smoothing Disabled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Pulse Type | Last Period | t | Spontaneous pulse resets timer | PS |
| X | X |  | false | false |
|  | true | false |
|  | true |

#### Hysteresis Disabled and Rate Smoothing Enabled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Pulse Type | Last Period | t | Spontaneous pulse resets timer | PS |
| X | X |  | false | false |
| X |  | true | false |
|  |  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |

#### Hysteresis Enabled and Rate Smoothing Disabled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Pulse Type | Last Period | t | Spontaneous pulse resets timer | PS |
| X | X |  | false | false |
|  | true | false |
| Sensed |  | false |
|  | true |
| Paced |  | false |
|  | true |

#### Hysteresis and Rate Smoothing Enabled

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Last Pulse Type | Last Period | t | Spontaneous pulse resets timer | PS |
| X | X |  | false | false |
| X |  | true | false |
| Sensed |  |  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |
| Paced |  |  | false |
|  | true |
|  |  | false |
|  | true |
|  |  | false |
|  | true |

### State Transitions

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Next State  Current State | INITIAL | PACED | SENSED | UPPER RATE LIMIT | LOWER RATE LIMIT | HYSTERESIS LIMIT | RATE SMOOTHING DOWN | RATE SMOOTHING UP |
| INITIAL | – | HE = true  t = HL  **or**  HE = false  t = LRL | PD = true | – | – | – | – | – |
| PACED | – | – | – | – | RSE = true  LP(1+RSD) ≥ LRL  LP(1-RSU) ≤ LRL  **or**  RSE = false | – | RSE = true  LP(1+RSD) < LRL | RSE = true  LP(1-RSU) > LRL |
| SENSED | – | – | – | RSE = true  LP(1+RSD)≤URL | HE = false  RSE = false  **or**  HE = false  RSE = true  LP(1+RSD) ≥ LRL | HE = true  RSE = true  LP(1+RSD)≥HL  **or**  HE = true  RSE = false | HE = true  RSE = true  LP(1+RSD) > URL  LP(1+RSD) < HL  **or**  HE = false  RSE = true  LP(1+RSD) > URL  LP(1+RSD) < LRL | – |
| UPPER RATE LIMIT | – | t = URL | PD = true | – | – | – | – | – |
| LOWER RATE LIMIT | – | t = LRL | PD = true | – | – | – | – | – |
| HYSTERESIS LIMIT | – | t = HL | PD = true | – | – | – | – | – |
| RATE SMOOTHING DOWN | – | t=LP(1+RSD) | PD = true | – | – | – | – | – |
| RATE SMOOTHING UP | – | t=LP(1-RSD) | PD = true | – | – | – | – | – |

### State details

|  |  |
| --- | --- |
| **State** | **Description** |
| INITIAL | If hysteresis is enabled, pacemaker listens for sensed pulses until p\_hysteresis\_limit before pacing.  If hysteresis is not enabled, pacemaker listens for sensed until p\_lower\_rate\_limit before pacing. |
| PACED | Sends a 10 ms pulse on V\_pace\_start and waits for the duration of p\_vrp |
| SENSED | Waits for the duration of p\_vrp |
| UPPER RATE LIMIT | Listens for sensed pulses until p\_upper\_rate\_limit |
| LOWER RATE LIMIT | Listens for sensed pulses until p\_lower\_rate\_limit |
| HYSTERESIS LIMIT | Listens for sensed pulses until p\_hysteresis\_limit |
| RATE SMOOTHING DOWN | Listens for sensed pulses until limit defined by maximum allowable rate decrease |
| RATE SMOOTHING UP | Listens for sensed pulsed until limit defined by maximum allowable rate increase |

### Testing