Simulink-Pacemaker Documentation

Requirements

The requirements for the pacemaker involve the pacing modes it must provide, as well as configurable parameters that are changed via the DCM interface. The pacing modes required are AOO, VOO, VVI, and AAI, whose functionality shall be described in a section below. The table below displays the required parameters and relevant modes. Note that only the highlighted parameters are implemented as per the assignment specification.

Parameter	Relevant Modes	Nominal
Lower Rate Limit (unit: /min) (pos natural)	AOO, VOO, VVI, AAI	60 ppm
Upper Rate Limit (unit: /min) (pos natural)	AOO, VOO, VVI, AAI	120 ppm
Max Sensor Rate (unit /min) (pos natural)	AOOR, VOOR, VVIR, AAIR	120 ppm
Atrial Amplitude (unit: V) (pos rational)	AOO, AAI, AOOR, AAIR	3.5 V
Ventricular Amplitude (unit: V) (pos rational)	VOO, VVI, VOOR, VVIR	3.5 V
Atrial Sensitivity (unit: V) (pos rational)	AAI, AAIR	0.75 mV
Ventricular Sensitivity (unit: V) (pos rational)	VVI, VVIR	2.5 mV
VRP (unit: msec) (pos rational)	VVI, VVIR	320 ms
ARP (unit: msec) (pos rational)	AAI, AAIR	250 ms
PVARP (unit: msec) (pos rational)	AAI, AAIR	250 ms
Hysteresis	AAI, AAIR, VVI, VVIR	Off

Rate Smoothing	AAI, AAIR, VVI, VVIR	Off
Activity Threshold	AAIR, VVIR	Med
Reaction Time	AAIR, VVIR	30 sec
Response Factor	AAIR, VVIR	8
Recovery Time	AAIR, VVIR	5 min

AOO:
Regardless of how the heart would naturally beat, the AOO mode paces the atrium at a set interval. The Lower Rate Limit determines the pace at which pacing takes place. The pulse amplitude and width determine the features of the pulse. This mode does not utilize the atrial or ventricular refractive periods.

Relevant Parameters	Chambers Paced	Chambers Sensed	Response to Sensing
Lower Rate Limit, Upper Rate Limit, Atrial Amplitude	Atrium	Atrium	None

VOO:
Regardless of how the heart would naturally beat, the VOO mode paces the ventricle at a set interval. The Lower Rate Limit determines the pace at which pacing takes place. The pulse amplitude and width determine the features of the pulse. This mode does not utilize the atrial or ventricular refractive periods.

Relevant Parameters	Chambers Paced	Chambers Sensed	Response to Sensing
Lower Rate Limit, Upper Rate Limit, Ventricular Amplitude	Ventricle	Ventricle	None

AAI:
If the atrium is not already pacing itself to meet the Lower Rate Limit parameter, the AAI mode will do so.

Relevant Parameters	Chambers Paced	Chambers Sensed	Response to Sensing
Lower Rate Limit, Upper Rate Limit, Atrial Amplitude, Atrial Sensitivity, ARP,	Atrium	Atrium	Inhibited

PVARP, Hysteresis, Rate Smoothing			

VVI:
If the ventricle is not already pacing itself to meet the Lower Rate Limit parameter, the VVI mode will do so.

Relevant Parameters	Chambers Paced	Chambers Sensed	Response to Sensing
Lower Rate Limit, Upper Rate Limit, Ventricular Amplitude, Ventricular Sensitivity, VRP, Hysteresis, Rate Smoothing	Ventricle	Ventricle	Inhibited

Expected Changes to Requirements:
Pacing modes will also include AOOR, VOOR, AAIR, and VVIR modes. The additional parameters can be added for these and the overall functionality can extend from the base modes with their additional features they will provide. This aligns with the modular setup as a lot of repeated set up can be reused in an efficient and meaningful way.
The pacemaker must communicate with a DCM to implement parameter changes. It is expected that a format will need to be implemented so that data can be communicated and received. For this, serial integration via a protocol such as UART would be needed. In order to plan for this, a planned data transmission format of a bit string being sent is planned, where a bit can be set on receival for acknowledgements (ACK bit). This can be integrated via the pyserial library running on the backend of the DCM app. A class for this has already been prototyped and documented in the DCM documentation.

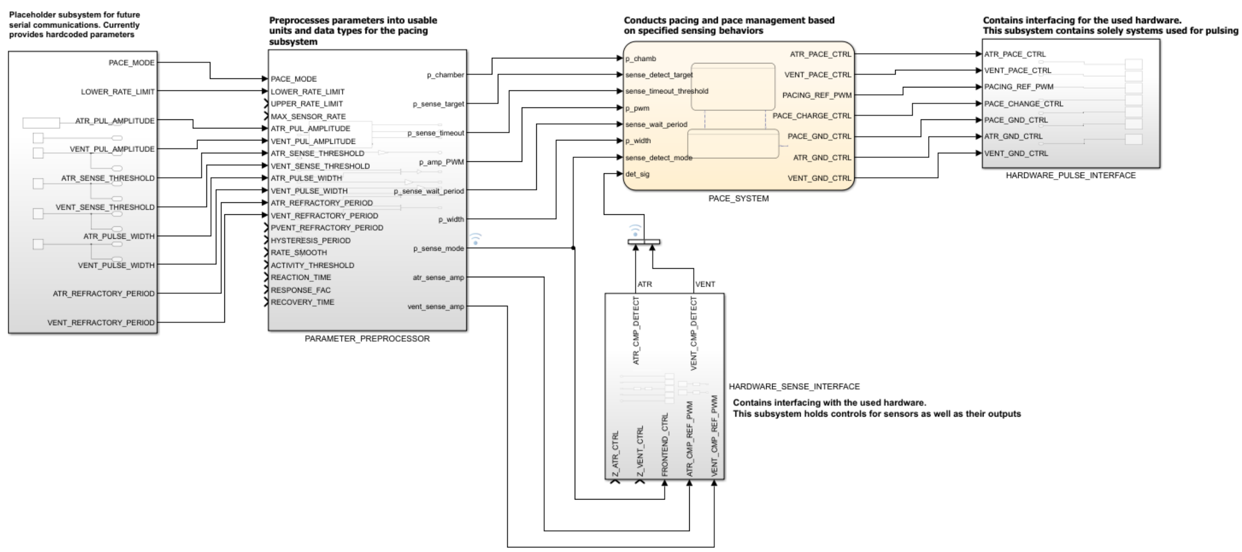
Design Decisions:

To implement hardware hiding, it was decided that subsystems would be used in combination with a main state flow so that the implementation of pacing modes would not rely on the correct hardware for acceptable inputs and outputs. There is a separate subsystem for hardware input, hardware output, and parameter preprocessing. A placeholder subsystem was put in place for future communication between the DCM and pacemaker, but to test the system, constants are used as input since no communication is actually taking place. In the future, the placeholder will be modified so that the inputs are not modifiable constants, but instead are values imported from the DCM. Parameters required for future modes were also included in the subsystems so they could be easily implemented and used later. The use of subsystems also allows for increased modularity, since the hardware input and output subsystems can easily be changed to work with different boards by changing what the inports and outports are mapped to.

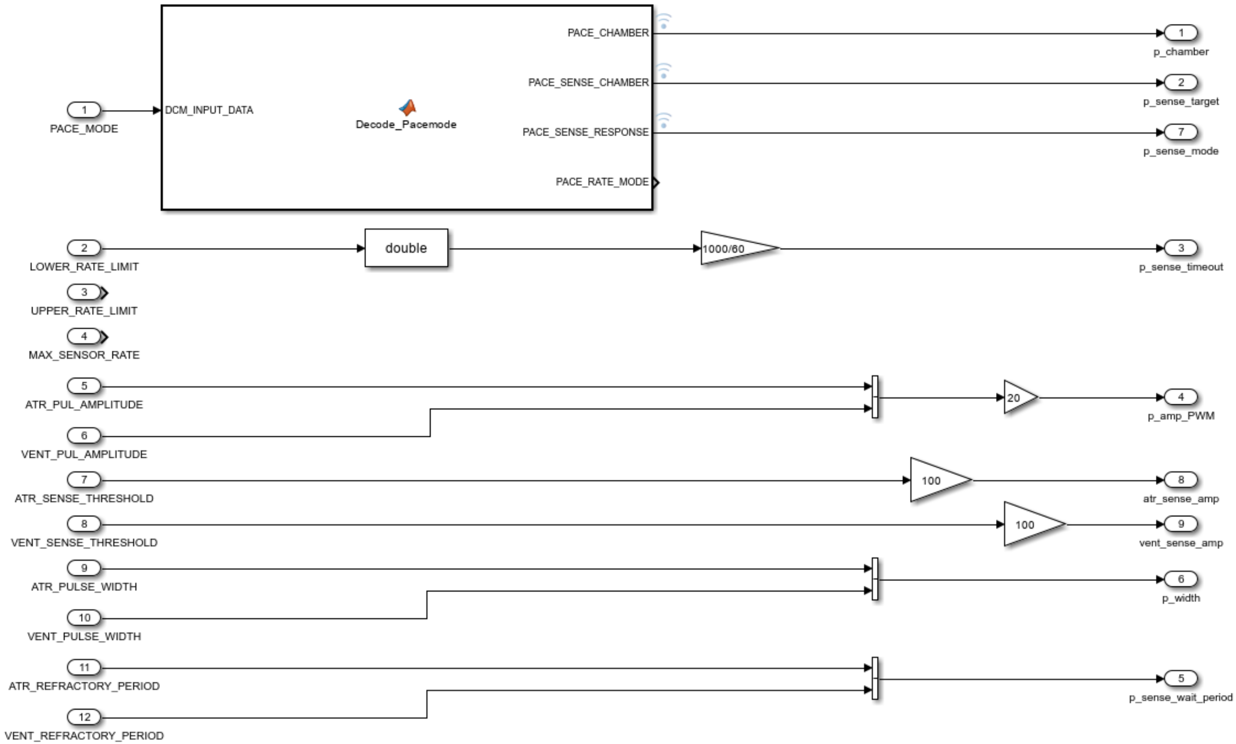
The entire design was modularized to allow for maintainability and the implementation of additional requirements in a stable manner. This will allow for any other pin mapping to be added without breaking anything preexisting. We will also be able to add assurance to the system, and all hardware hiding/abstraction will be maintained in the HAL developed.

Simulink Model

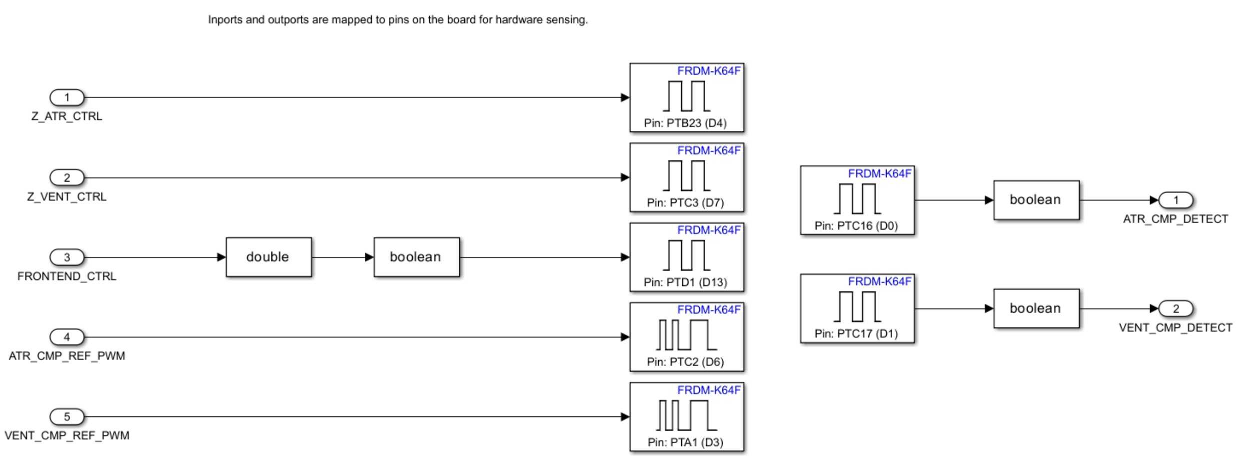
Four primary modules were used to implement the required pacing modes. Three of these modules made use of subsystems. All subsystems were linked to a main state flow to process parameters, hardware inputs, and hardware outputs.



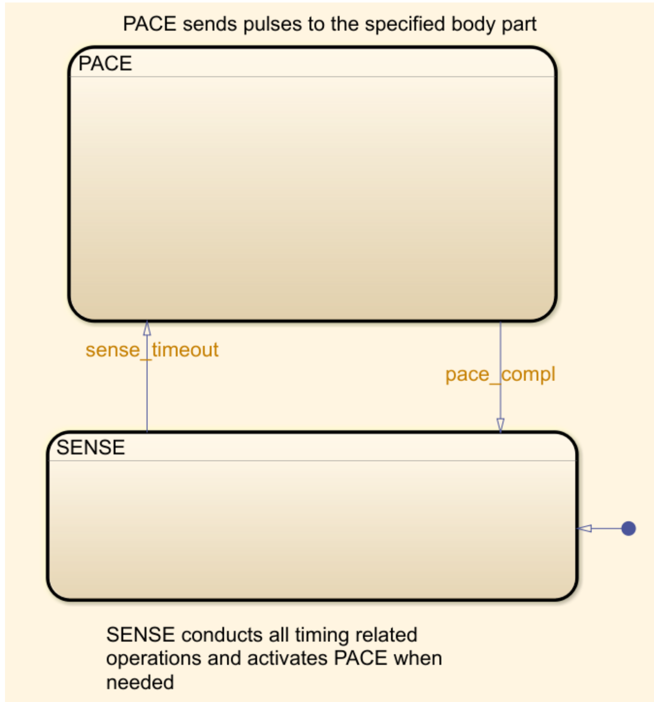
The parameter preprocessing module uses inports that use the constant parameters specified in the placeholder subsystem and processes and converts the data accordingly based on the parameter so that the outports can be used in the main state flow as well as the hardware sense interface. Some inports are not shown below as they are not being currently used for anything and are instead a placeholder for the future when they will actually be needed. It is also determined during parameter preprocessing which pacing mode is being requested, and this is done through a MATLAB function that uses the pace mode parameter and sets corresponding outports based on the requested pacing mode.



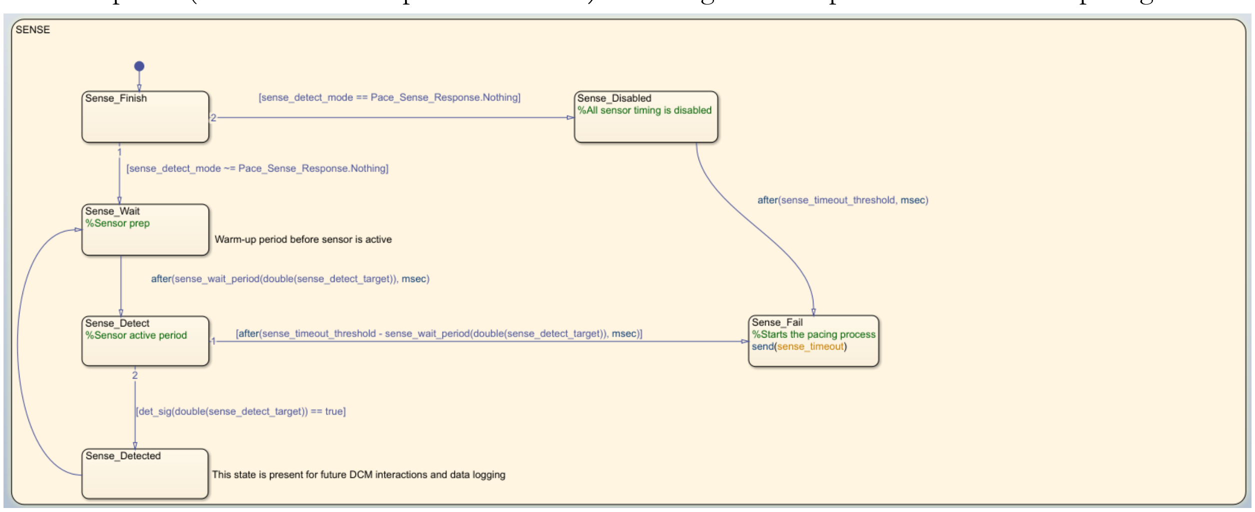
The hardware sensing interface module uses the outports from parameter preprocessing as inports, and maps those ports to pins on the FRDM-K64F board. Similarly, some pins on the board are mapped to outports which are used in the main state flow.



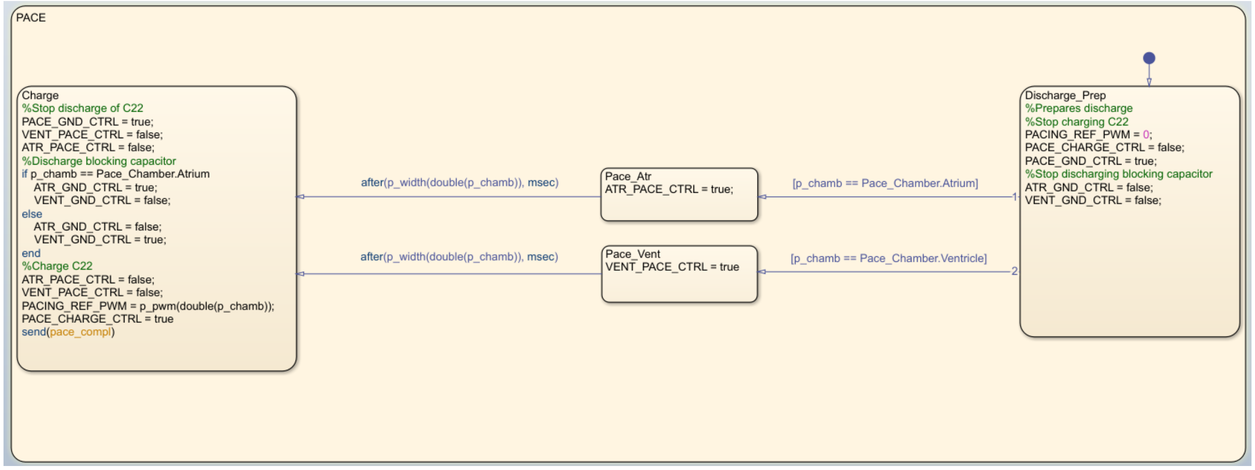
The main state flow module has two components which are sensing and pacing.



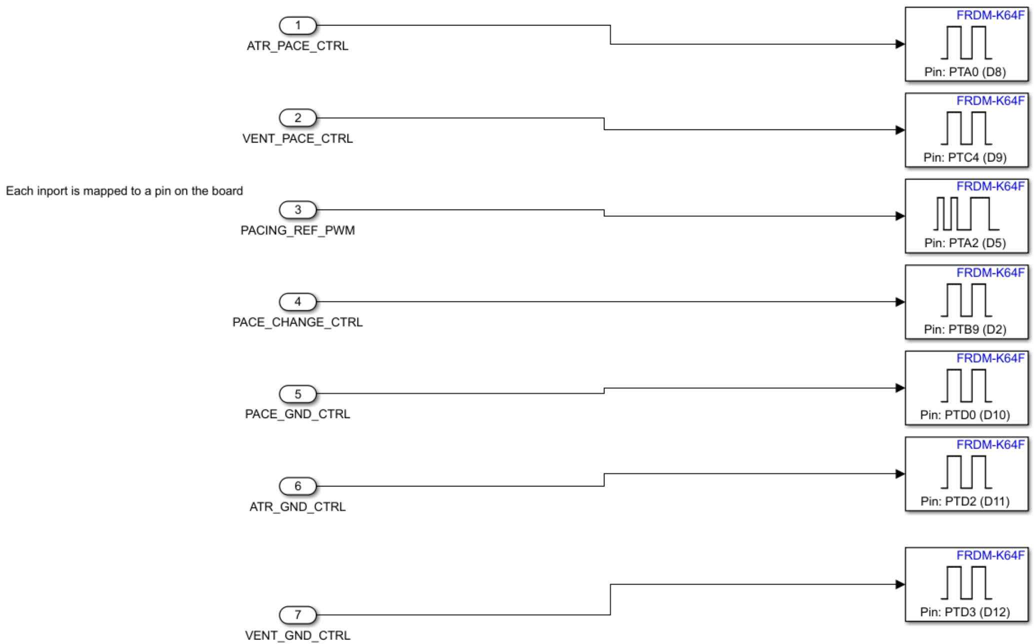
Sensing is the default state and the purpose of this state is to use sensors from the board as inputs and based on the response (whether a correct pulse is detected) send a signal to the pace state and initiate pacing.



The pacing process involves charging and discharging the primary capacitor (C22) and the blocking capacitor (C21). Depending on whether charging or discharging is taking place, control pins are set to true or false, and after charging has been completed, a signal is sent back to the sense state to determine if pacing needs to continue depending on what the sense state detects after the pace.



The hardware pulse interface module is similar to the hardware sense interface module since this module also maps inports to relevant pins on the FRDM-K64F board. The inports in this module come from outputs in the main state flow module.



Testing and Results

Testing procedures were conducted in order to ensure the functioning of the system. A series of tests were devised to ensure the implemented system satisfied the requirements:

Tested Requirement	Test name	Tested Subsystem	Measured parameters	Methodology
Implementation of specified parameters for configuration of system	Data processing test	DATA_PREPROCESSOR	Accuracy of pre-processed parameters	The program will be simulated in simulink. All outputs of DATA_PREPROCESSOR will be logged, and compared to manually calculated figures. The program will operate with the default parameters as specified in the appendix, excluding the pulse mode.
Generation of pacing pulses	Pulse test	Main stateflow; PACE	Generation of output pulse Refractory period sinking Pulse duration Pulse amplitude	The program will operate in AOO mode, no natural beats. This test is done concurrently to the AOO test. Pulses will be measured on heartview, and compared to the expected results. The program and heartview will operate with the default parameters as specified in the appendix.
Operation through specified pulse modes	AOO Test	Main stateflow; SENSE	Adherence to the specified timing behavior of AOO mode.	The program will be uploaded to the testing hardware, and attached to a heartview device. Natural pulses will be simulated at rates of 0, 30, 60, and 90 bpm. Only 0 and 30 bpm are tested for non sensing modes (AOO, VOO), with both chambers active. A singular test at 30bpm of the opposite chamber to the sensed one will be tested for both sensing modes (AAI, VVI) The program and heartview will operate with the default parameters as specified in the appendix, excluding the pulse mode for simulink, and natural heartbeat for the sensed chamber in heartview.
	VOO Test	Main stateflow; SENSE	Adherence to the specified timing behavior of VOO mode.	
	AAI Test	Main stateflow; SENSE	Adherence to the specified behavior of AAI mode.	
	VVI Test	Main stateflow; SENSE	Adherence to the specified behavior of VVI mode	

These tests are to be conducted in sequential order, from top to bottom. This is due to the dependency of some subsystems on the functioning of others, causing difficulty in error attribution in the event that dependent subsystems are at fault. The specified test order ensures that all subsystems except the one being tested are in a state of functionality. In addition, as the tested system is the software component of pre-established hardware, it was justified to constrict all pulse generation tests to the AOO pulse mode. Testing with ventricle output is redundant within the stateflow logic, and the hardware used is identical to the atrium's. Any errors incurred in such a scenario would be a hardware fault and outside the scope of this project.

The bpm output rates in the AAI and VVI tests are designed to ensure that all boundary and nominal states are accounted for. This is also the reason that the non-sensing modes only require two output rates, as only response to natural beats needs to be assessed given their featureset.

Case type	Operating Case	Operating mode logic	Intended behavior
Corner	No natural pulsing	Sensed rate = lowest possible	Generate all pulses
Nominal	30 bpm pulsing	Sensed rate < minimum rate	Generates some but not all pulses the heart experiences
Boundary	60 bpm pulsing	Sensed rate = minimum rate	Pacemaker does not generate any pulses as natural rate is on the minimum rate
Nominal	90 bpm pulsing	Sensed rate > minimum rate	Pacemaker does not generate any pulses as rate minimum is exceeded

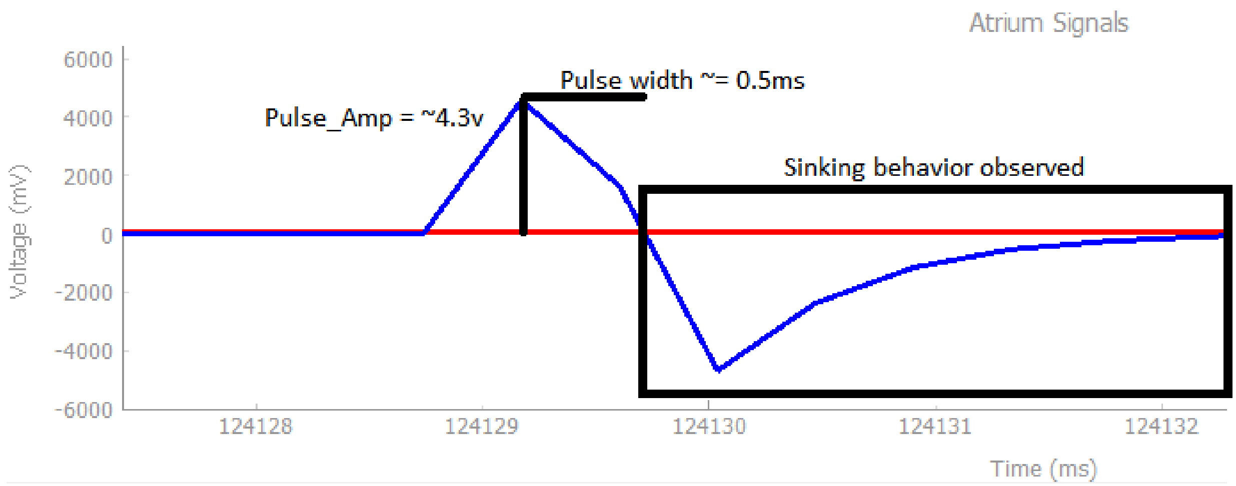
Data Processing Test

Parameter	Unit	Input Value	Output	Expected Output Value	Pass/Fail
PACE_MODE	Enum: Pace_Mode	AOO	P_chamber: Atrium P_sense_target: None_sense P_sense_mode: Nothing	P_chamber: Atrium P_sense_target: None_sense P_sense_mode: Nothing	Pass Pass Pass
LOWER_RATE_LIMIT	bpm	60	1000	1000	Pass
ATR_PUL_AMPLITUDE VENT_PUL_AMPLITUDE	V	4	80	80	Pass
ATR_SENSE_THRESHOLD VENT_SENSE_THRESHOLD	mV	0.7	70	70	Pass
ATR_PULSE_WIDTH VENT_PULSE_WIDTH	ms	0.5	0.5	0.5	Pass
ATR_REFRACTORY_PERIOD VENT_REFRACTORY_PERIOD	ms	150	150	150	Pass

Data processing went smoothly, and all parameters were able to reach the calculated results from the default parameters.

AOO/Pulse Test

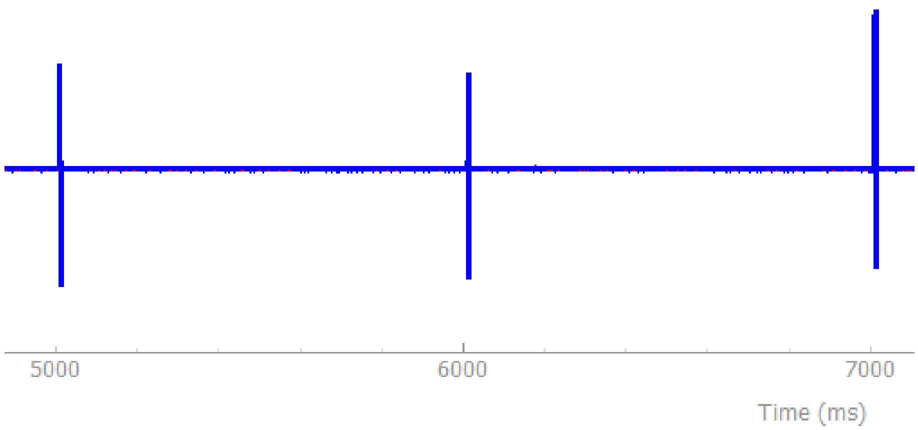
Pulse behavior test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes	Yes	Pass
Pulse width	0.5ms	~0.5ms	Pass
Pulse amplitude	4V	4.3V	Marginal
Sinking behavior	Yes	Yes	Pass

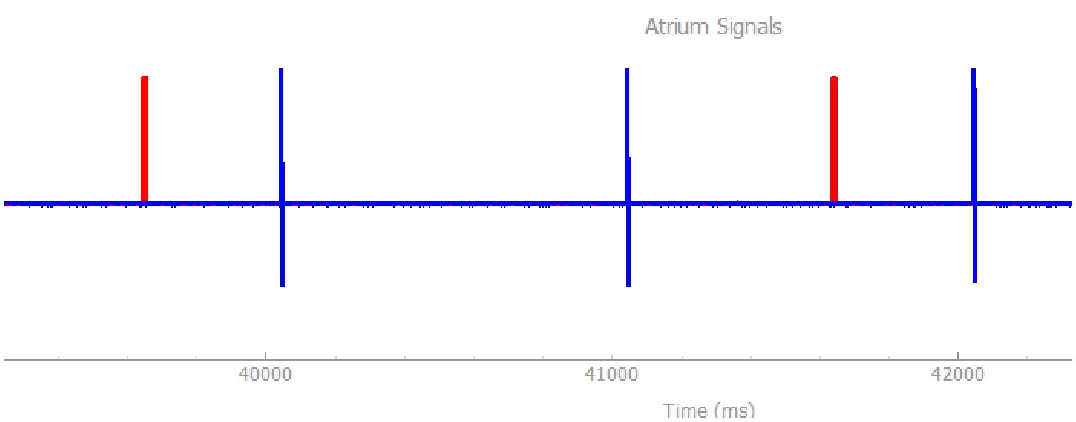
Overall, all required features of the specified pulse were generated, and most parameters had differences under the measurement limits of the heartview device. One particular feature of note was the rather substantial variance in pulse amplitude between different pulses.. The specific measured pulse had an offset of +0.3V, or approximately 7.5% deviation. A plausible solution of explicitly stopping the PWM signal during pulses was also tested, with no observable changes. After further problem assessment, we have attributed these issues to hardware limitations, possibly from the limited sample rate and accuracy of the heartview device.

0 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Atrium	Yes, Atrium	Pass
Pulse Period	1000ms	~1000ms	Pass

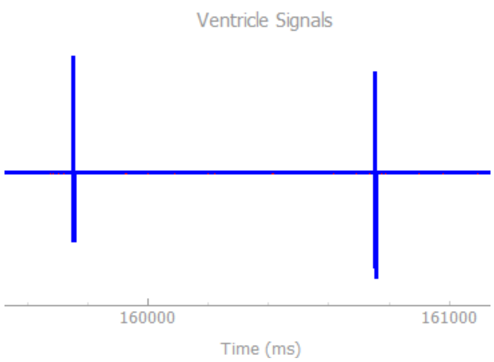
30 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Atrium	Yes, Atrium	Pass
Pulse Period	1000ms	~1000ms	Pass
Response to natural pulse	N/A	N/A	Pass

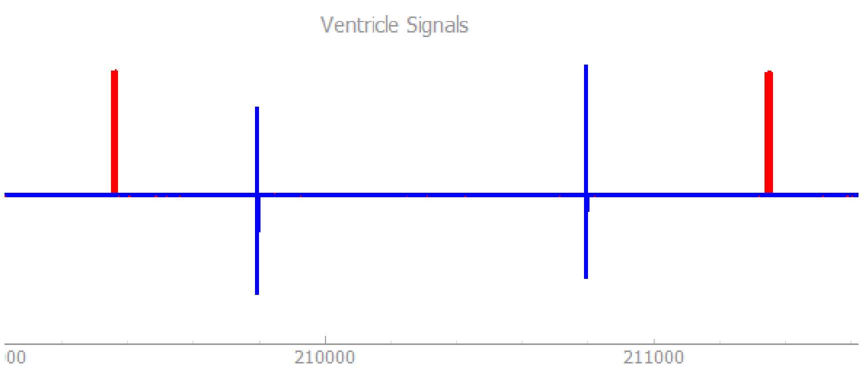
VOO test

0 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Ventricle	Yes, Ventricle	Pass
Pulse Period	1000ms	~1000ms	Pass

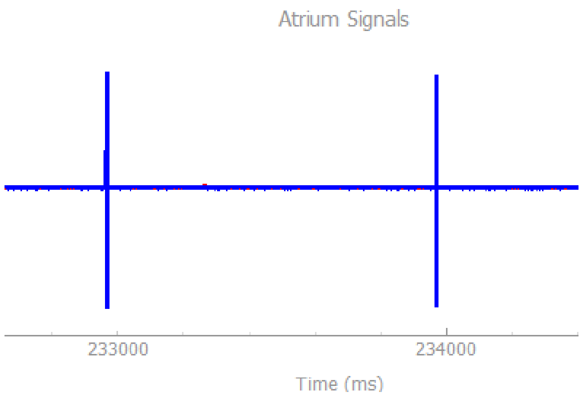
30 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Ventricle	Yes, Ventricle	Pass
Pulse Period	1000ms	~1000ms	Pass
Response to natural pulse	N/A	N/A	Pass

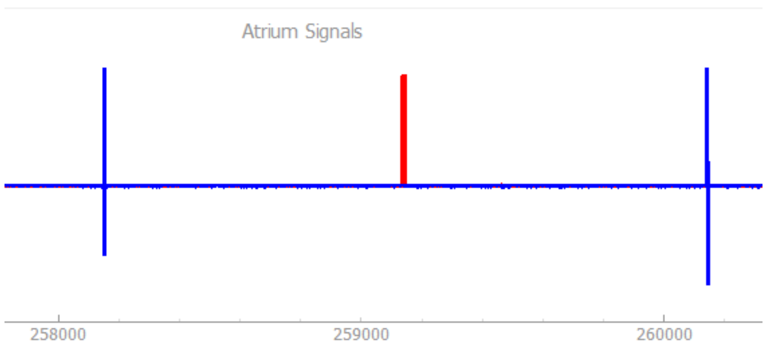
AAI test

0 bpm Natural Test



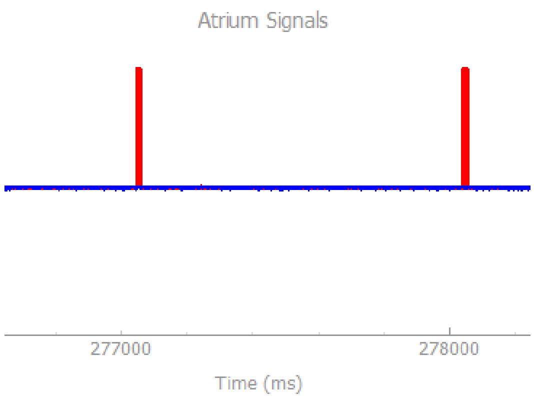
Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Atrium	Yes, Atrium	Pass
Pulse Period	1000ms	~1000ms	Pass

30 bpm Natural Test



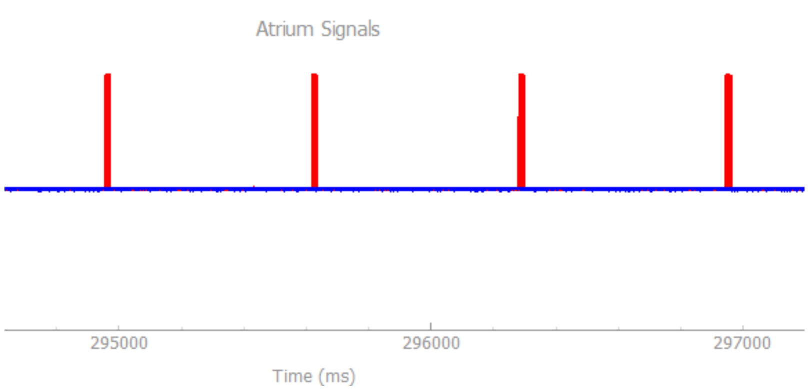
Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Atrium	Yes, Atrium	Pass
Generated pulse delay after last pulse	1000ms	~1000ms	Pass
Response to natural pulse	On Atrium pulse: Inhibits pulse, resets pulse delay	On Atrium pulse: Inhibits pulse, resets pulse delay	Pass

60 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	No	No	Pass
Generated pulse delay after last pulse	N/A	N/A	Pass
Response to natural pulse	Inhibits pulse, resets pulse delay	Inhibits pulse, resets pulse delay	Pass

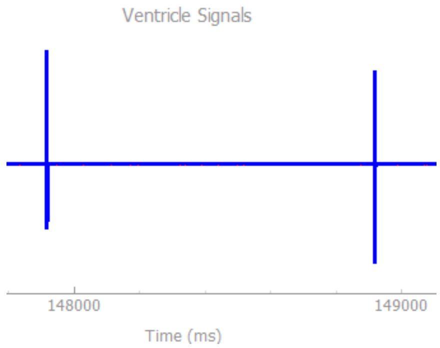
90 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	No	No	Pass
Generated pulse delay	N/A	N/A	Pass
Response to natural pulse	Inhibits pulse, resets pulse delay	Inhibits pulse, resets pulse delay	Pass

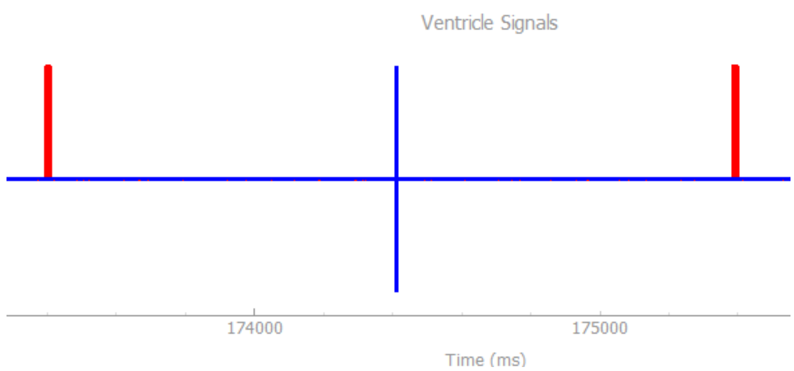
VVI test

0 bpm Natural Test



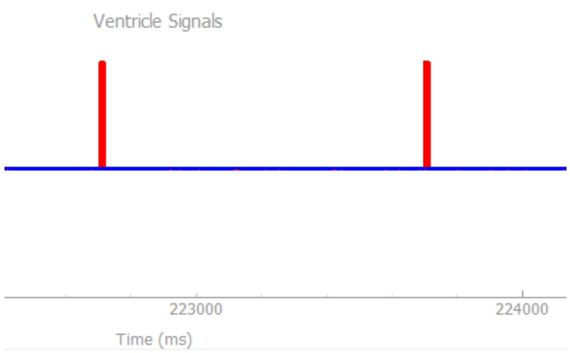
Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Ventricle	Yes, Ventricle	Pass
Pulse Period	1000ms	~1000ms	Pass

30 bpm Natural Test



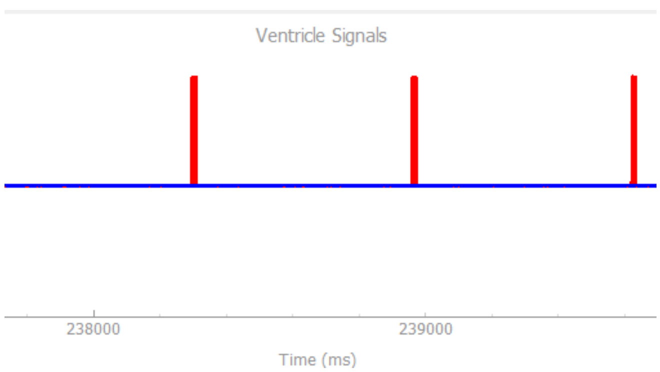
Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	Yes, Ventricle	Yes, Ventricle	Pass
Generated pulse delay after last pulse	1000ms	~1000ms	Pass
Response to natural pulse	On Ventricle pulse: Inhibits pulse, resets pulse delay	On Ventricle pulse: Inhibits pulse, resets pulse delay	Pass

60 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	No	No	Pass
Generated pulse delay after last pulse	N/A	N/A	Pass
Response to natural pulse	Inhibits pulse, resets pulse delay	Inhibits pulse, resets pulse delay	Pass

90 bpm Natural Test



Measurement	Spec	Observed	Pass/Fail
Generation of output pulse	No	No	Pass
Generated pulse delay	N/A	N/A	Pass
Response to natural pulse	Inhibits pulse, resets pulse delay	Inhibits pulse, resets pulse delay	Pass

Testing Conclusions

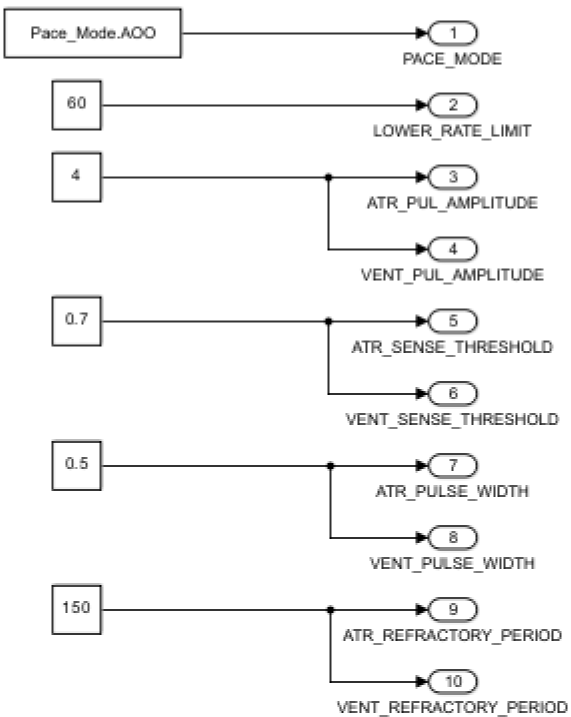
The above testing conditions provided the following conclusions for our results:

Tested Requirement	Test name	Score
Implementation of specified parameters for configuration of system	Data processing test	8/8
Generation of pacing pulses	Pulse test	2.5/3
Operation through specified pulse modes	AOO Test	5/5
	VOO Test	5/5
	AAI Test	11/11
	VVI Test	11/11

Not all tests were perfect as expected due to errors in hardware and imperfections within simulation. We received perfect scores on Implementation of specified parameters for configuration of system and Operation through specified pulse modes tests. Generation of pacing pulses was almost perfect however there was 0.5 lost due to slight imperfections observed. Overall, most tests were able to achieve the requirements of the system.

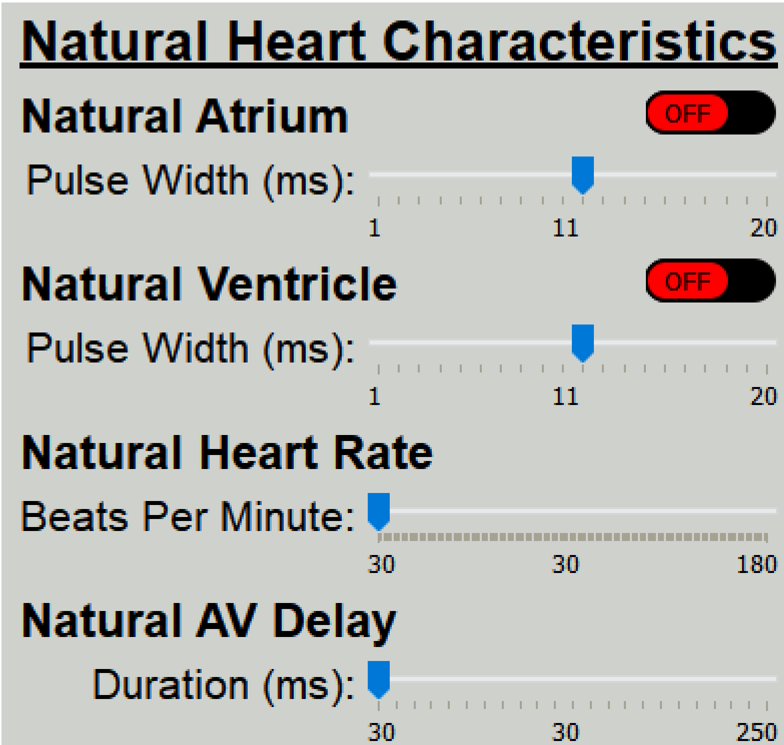
Appendix

Default parameters, Simulink



Parameter	Unit	Value
PACE_MODE	Enum: Pace_Mode	AOO (1000)
LOWER_RATE_LIMIT	bpm	60
ATR_PUL_AMPLITUDE VENT_PUL_AMPLITUDE	V	4
ATR_SENSE_THRESHOLD VENT_SENSE_THRESHOLD	V	0.7
ATR_PULSE_WIDTH VENT_PULSE_WIDTH	ms	0.5
ATR_REFRACTORY_PERIOD VENT_REFRACTORY_PERIOD	ms	150

Default parameters, heartview



Parameter	Unit	Value
Natural Atrium	boolean	off
Natural Atrium - pulse width	ms	11
Natural Ventricle	boolean	off
Natural Ventricle - pulse width	ms	11
Natural Heart Rate	bpm	30
Natural AV Delay	ms	30