

3K04 | Assignment 1 & 2

Simulink Report

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December 3rd, 2023

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Requirements

For Assignment 1, we considered three main requirements needed in order to both validate and verify our Simulink operation, namely: the functionality of all four modes of pacing (AOO, VOO, AAI and VVI), the physical constraints of our hardware (HeartView and FDRm-K64F) , and finally, our programmable parameters. In Assignment 2, four additional modes have been added namely AOOR, VOOR, AAIR and VVIR and we can apply our initial requirements to them as well. We can also test the functionality of the rate adaptiveness by shaking the pacemaker to simulate various speeds of activity and we expect that the pacing will increase accordingly.

Five Variables of Interest

While the pacemaker accepts both single and dual chamber types, we are considering only single-chamber modes in this assignment, and they include AOO, VOO, AAI, VVI, AOOR, AAIR, VOOR and VVIR. Consider the table below for their descriptions:

Variable	Description
A	Assume this refers to Pacing in the Atrium in all instances, and Sensing in the Atrium when 'A' is doubled
V	Assume this refers to Pacing in the Ventricles in all instances and Sensing in the Ventricles when 'V' is doubled
OO	This means that sensing and response to sensing is OFF in both Atrium and Ventricles. In this state, both perform Asynchronous Pacing, meaning they pace at a programmed rate regardless of the heart's activity.
I	This means there is an ability to INHIBIT (withhold) pacing in the Atrium and Ventricles. This is determined by the activity that is sensed in the heart and will only resume pacing when needed.
R	This is rate modulation. This means that the rate at which the heart is being pulsed is a variable number which is calculated to be close to the sensed target rate.

We must program these modes into the Simulink software and observe the resulting wavelengths formed via HeartView to determine if they align with the parameters above. For example, we expect that when AOO and VOO are activated, there will be a continuous and asynchronous pulse in the Atrium and Ventricle despite real-time change in pace of the heart. Similarly, we can expect AAI and VVI to toggle on only when heart pulses are not sensed within a certain time, and off when they are. Finally, implementing Rate Adaptive features, we expect that in AAIR or VOOR, the rate of the heart sensed by the pacemaker will directly affect the pacing sent forth. That is, we expect to see a faster pace when the pacemaker senses an increase in activity than when still.

Programmable Parameters

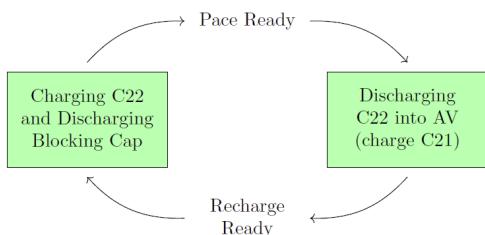
These are the parameters we must use to be able to simulate all eight modes accurately. They include variables such as Lower Rate Limit (the lowest rate that the device allows the heart to beat), the A/V Pulse Width, the A/V Pulse Amplitude, etc. Below is a table with these parameters and their values. In this assignment, we consider the values in the Nominal column our specific parameters to use in our functions (aside from the Mode Nominal, which was previously decided as AOO, VOO, AAI and VVI)

Parameter	Nominal Used	Variable in MATLAB	Description
Mode	AOO, VOO, AAI, VVI, AOOR, VOOR, AAIR, VVIR	-	Pacing Modes for the pacemaker to operate in
Lower Rate Limit	60 ppm	LOWER_RATE_LIMIT	The longest allowable pacing interval in the absence of Rate Hysteresis and Sensed intrinsic activity. Also acts as the fixed heart rate for non-adaptive modes
Upper Rate Limit	120 ppm	UPPER_RATE_LIMIT	The highest rate the pacemaker tells the heart to achieve
Maximum Sensor Rate	120 ppm	MAX_SENS_RATE	The maximum rate that the accelerometer can set the pacemaker to operate at
A or V Pulse Amplitude Regulated	3.5V	ATR_AMP, VENT_AMP	The Amplitude of the Pulse sent to the heart when pacing in either Atrium or Ventricle
A or V Pulse Width	10 ms	ATR_PW, VENT_PW	The Width of the Pulse sent to the heart when pacing in either Atrium or Ventricle

A or V Sensitivity	A- 0.75 mV V-2.5 mV	ATR_SENS, VENT_SENS	The Voltage used to determine sensitivity while pacing in Atrium or Ventricle
Ventricular Refractory Period	320 ms	VRP	The period that a pacemaker ignores sensed inputs after a pacing or sensing from Ventricle
Atrial Refractory Period	250 ms	ARP	The period that a pacemaker ignores sensed inputs after a pacing or sensing from Atrium
Recovery Time	2 mins	RECOV_TIME	Time required for the sensor rate to fall from maximum to the lower limit
Reaction Time	10 sec	REACTION_TIME	Time required to drive the active sensor rate to the maximum sensor rate
Response Factor	8	RESPOND_FACTOR	Factor that determines the increment of change in the active sensor rate
Atrial and Ventricular Heart Input Signal	-	ATR_CMP_DETECT, VENT_CMP_DETECT	Used in the sensing circuitry of the Atrium and Ventricle. Outputs ON (HIGH) when signal voltage is higher than threshold voltage and OFF (LOW) otherwise (includes 5mV hysteresis).

Parameters in Simulink

To translate the above parameters in Simulink, we must use specific verbiage within our Simulink functions and assign these variables the correct corresponding variable type. We must also specify pin arrangements for pacing to avoid unwanted pacing, false charging, etc. Reference the Appendix to view all the Pin Names, along with their Pin Numbers on the FRDM-K64F Board. Below is the mandatory process needed to pace in any mode:



Design Decisions: Initial Pacing

The design consists of 8 modes, AOO, VOO, AAI, VVI, AOOR, VOOR, AAIR and VVIR. The modes have been assigned values 1 to 8 in simulink and can be toggled through the front end control (DCM). The programmable parameters were used to determine the inputs and the rate for the “R” mode was calculated.

The first state is an initial state and the 8 pacing modes can be chosen based on the value of the mode variable.

AOO

If the mode is set as 1 then the state is AOO. Here the cycle is between a charging and discharging state where the period is determined by the expression “(60000/LOWER_RATE_LIMIT) - ATR_PW”. This expression yields the time it should take for the charging state to complete. Dividing 60000 by the LOWER_RATE_LIMIT gives the period for 1 pulse and subtracting ATR_PW subtracts the pulse width from the period, so charging should complete before the next pulse starts. The discharging occurs for the length of one pulse width so the total time for the entire cycle is 1 period of the pulse.

The appropriate pin values are assigned in the charging and discharging states. One pin of particular interest is the PACING_REF_PWM which is assigned a value using the expression “100*ATR_AMP/5”. This expression was derived as follows:

$$\begin{aligned} \text{ATR_AMP} &= 5 * \text{Duty_Cycle}/100 \\ \text{Duty_Cycle} &= 100 * \text{ATR_AMP}/5 \end{aligned}$$

So essentially the value of PACING_REF_PWM is equal to the duty cycle.

The ATR_CMP_REF_PWM pin in the discharging state is assigned a value in a similar way but ATR_SENS is used instead of ATR_AMP.

AAI

If the mode is set as 2 then the state is AAI. In addition to the charging and discharging state there is a state called proxy in this mode. In AAI pacing should only occur when no pulse from the heart is detected so when there is a pulse detected then a proxy state should be used which keeps on charging the capacitor (pacing does not occur).

Once charging is complete, if the value of ATR_CMP_DETECT is high (a pulse from the heart is detected) then the state changes from charging to proxy. The proxy state completes after ARP milliseconds. This is to account for the refractory period when no pacing should occur.

If the value of ATR_CMP_DETECT is low (pacing is required) then the state changes to discharging. The completion time for charging and discharging states is the same as discussed in AOO and VOO. But in this case the next state after discharging is the proxy state which executes for the length of time of the refractory period. Finally the state changes to charging again and the system is ready to detect a heart pulse.

VOO

If the mode is set to 3 then the state is VOO. The process in this state is the same as in AOO as discussed above but the pins have to be changed to the appropriate pins relating to the Ventricle.

VVI

If the mode is set to 4 then the mode is VVI. The process in this state is the same as in AAI as discussed above but the pins have to be changed to the appropriate pins relating to the Ventricle.

Design Decisions: Rate Adaptive Pacing

The key difference in the next 4 states is that they use “Rate Modulation”. Rate modulation occurs in the “Rate Calculator” state. The input parameters to the Rate Calculator are LOWER_RATE_LIMIT, MAX_SENS_RATE, REACTION_TIME, RECOV_TIME, RESPOND_FACTOR, ACTIVITY_THRES and ACCELEROMETER. The ACCELEROMETER parameter is of particular interest, it is the average movement calculated by measuring the movement in x,y,z directions and taking their average value:

$$\sqrt{|u|^2 + |u|^2 + |u|^2}$$

In the rate calculator the RATE is set to the LOWER_RATE_LIMIT at first, it will increase or decrease based on comparisons to the variable “target_rate”. 2 variables of interest in this state are the reduce_step_size and increase_step_size which are used to increase or decrease the RATE based on the comparisons to the target_rate. These variables were derived from the RECOV_TIME and REACTION_TIME parameters. For example increase_step_size was derived from REACTION_TIME in the following way:

$$\begin{aligned} \text{reaction time} &= (\text{MSR} - \text{LRL})/\text{step} \\ \text{increase step size} &= (\text{MSR} - \text{LRL})/\text{reaction time} \end{aligned}$$

Then the ACCELEROMETER is compared to the ACTIVITY_THRES, if its more than the threshold then the “target rate” is set to the LRL+RESPOND_FACTOR*(ACCELEROMETER - ACTIVITY_THRES). Where the RESPOND_FACTOR is the constant that amplifies the sensed data and ACTIVITY_THRES is subtracted from ACCELEROMETER to get rid of the noise from the sensed data. In this case if the calculated

target rate is more than or equal to the MSR then it is forcefully assigned the value of MSR because the pacing rate cannot exceed the Maximum Sensing Rate. If the ACCELEROMETER is less than the threshold then the target rate is set to the LRL.

The final step is to compare the existing RATE to the newly calculated target_rate. If the RATE is less than the target_rate then the value of RATE is increased by increase_step_size. If RATE is more than the target rate then the value of rate is decreased by reduce_step_size. The reason the RATE is not directly assigned the value of target_rate is because **rate smoothing** needs to be accounted for. Which means the rate of increase of RATE cannot be too high.

Finally the ACCELEROMETER is compared to the ACTIVITY_THRES after 100 msec and the cycle repeats. The RATE is then sent to the pacing modes to be used in the AOOR, AAIR, VOOR and VVIR modes.

AOOR

If the mode is set as 5 then the mode is AOOR. The process in this state is the same in AOO but the difference is that AOOR uses a modulated rate to move from charging and discharging. Instead of moving to discharging from charging after “ $(60000/\text{LOWER_RATE_LIMIT}) - \text{ATR_PW}$ ”, the time in this state would be “ $(60000/\text{RATE}) - \text{ATR_PW}$ ” where “RATE” is calculated in the rate adaptive pacing state.

AAIR

If the mode is set as 6 then the mode is AAIR. The process in this state is the same in AAI but the difference is that AAIR uses a modulated rate to move from charging and discharging. Instead of moving to discharging from charging after “ $(60000/\text{LOWER_RATE_LIMIT}) - \text{ATR_PW}$ ”, the time in this state would be “ $(60000/\text{RATE}) - \text{ATR_PW}$ ” where “RATE” is calculated in the rate-adaptive pacing state.

VOOR

If the mode is set to 7 then the state is VOOR. The process in this state is the same as in AOOR as discussed above but the pins have to be changed to the appropriate pins relating to the Ventricle.

VVIR

If the mode is set to 8 then the state is VVIR. The process in this state is the same as in AAIR as discussed above but the pins have to be changed to the appropriate pins relating to the Ventricle.

Hysteresis

All of the modes allow hysteresis pacing by detecting if the heart is naturally pacing. If a natural pacing is detected then the pacemaker does not pace for a certain amount of time. Then sensing occurs again and if no natural pacing is detected then the pacemaker will pace.

Serial Communication

For the communication between the Pacemaker and DCM, UART serial communication protocol is used for transmitting data between the two. With the serial data obtained from DCM, these values are used to assign corresponding parameter values, otherwise, initial values for said parameters are initialized before serial data is received. A function *send_params()* is declared to send current parameter values back. A Serial Recieve Block was used for receiving serial data from DCM to Simulink through USB serial communication. The Serial Recieve Block is set to receive *uint8* data with a maximum of 10 bytes to be received, and a sample time of 0.1. A Serial Transmit Block is used to transmit serial data to DCM from Simulink after all parameter values have undergone Byte Packing. Before sending Parameter values to DCM, the data of various types is sent to Byte Pack Blocks for conversion back to an array of bytes *unit8*.

Simulink

Simulink Diagrams (Assignment 1)

The Simulink diagrams produced in MATLAB consist of an input block, a middle block consisting of the stateflow logic where the input parameters will be fed into, as well as an output block, giving outputs to the simulation. (Refer to figure 1 for overall layout). The inputs consist of hardcoded values of our programmable parameters, as well as a “Heart Detect” module (refer to Figure 8) which takes in the input atrial and ventricle heart signals from the device for analysis in our stateflow schematic.

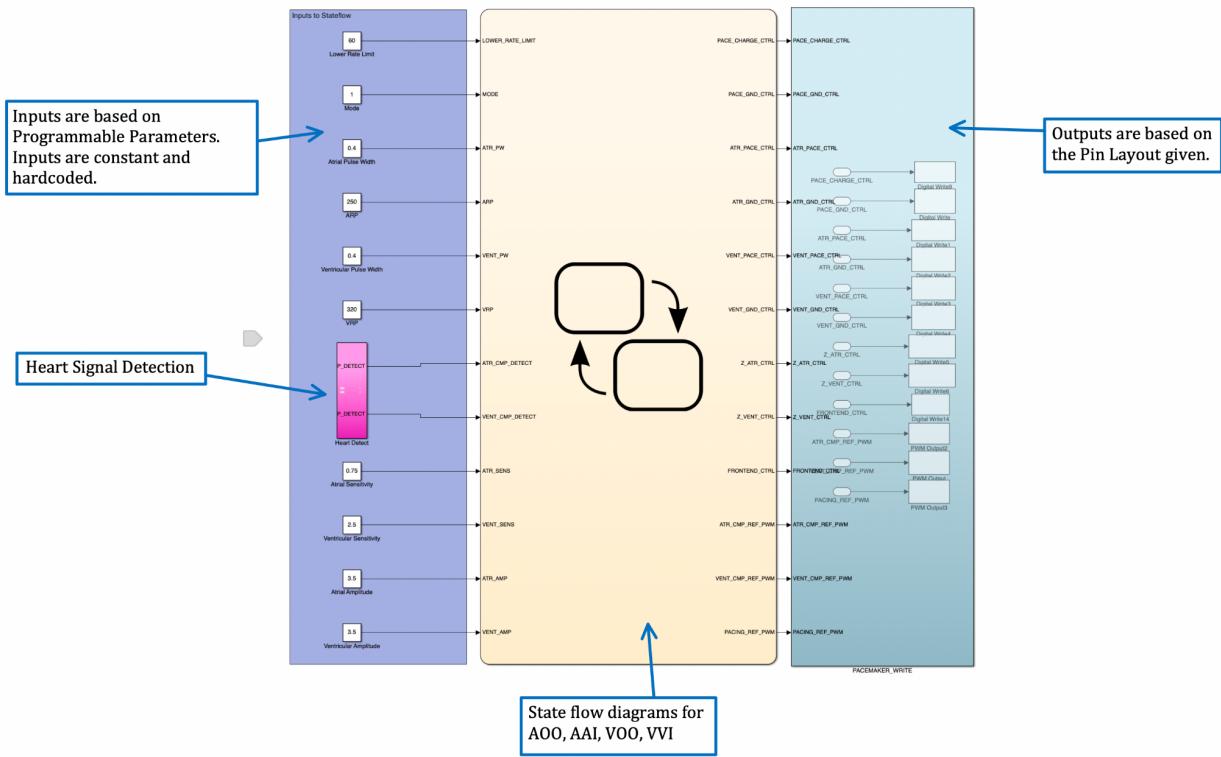


Figure 1 - Complete Simulink Model with Inputs, Modes, and Outputs

Within the middle block consists of a conditional flow schematic which takes in the MODE input, that will dictate whichever mode the pacemaker operates in. A MODE of 1 leads to AOO, 2 maps to AAI, 3 maps to VOO, and 4 leads to the VVI block.

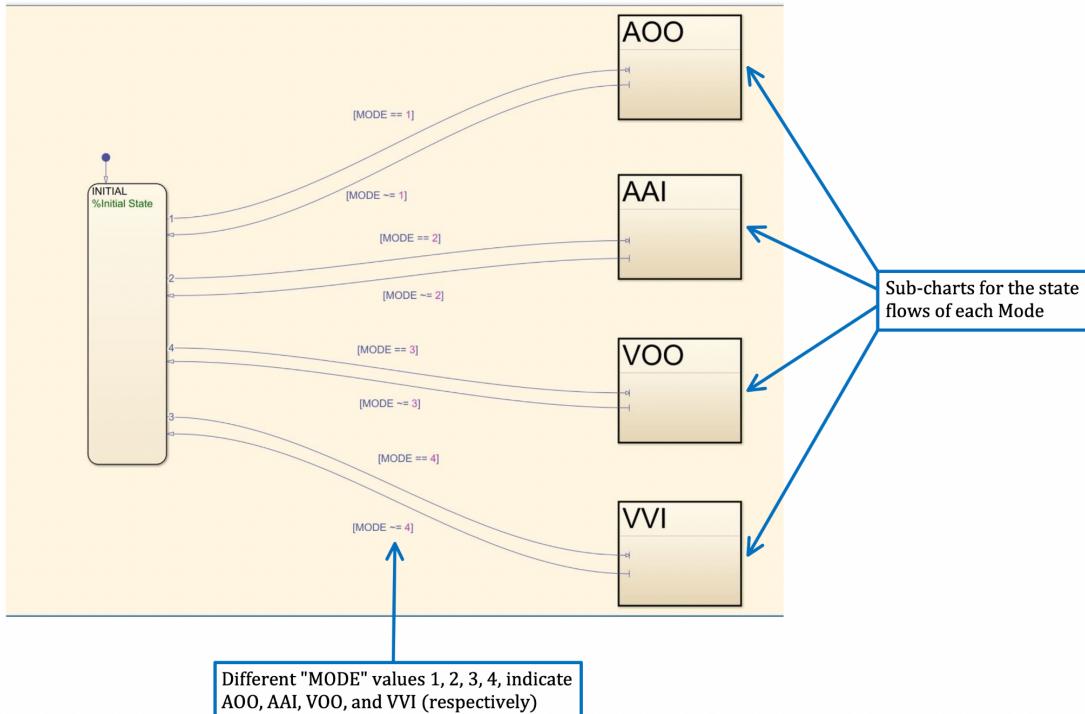


Figure 2 - Inside the main chart including the Initial state and AOO, AAI, VOO, VVI sub-states.

Within each of these blocks determined by the input MODE, leads to the stateflow schematic that will determine the behavior of the pacemaker within these state diagrams.

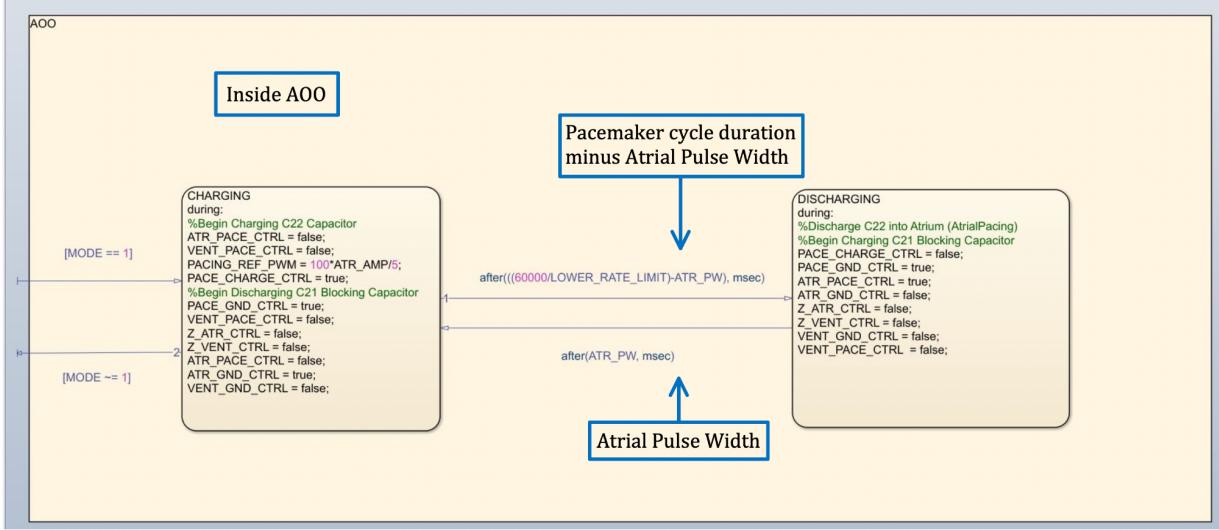


Figure 3 - Stateflow for AOO

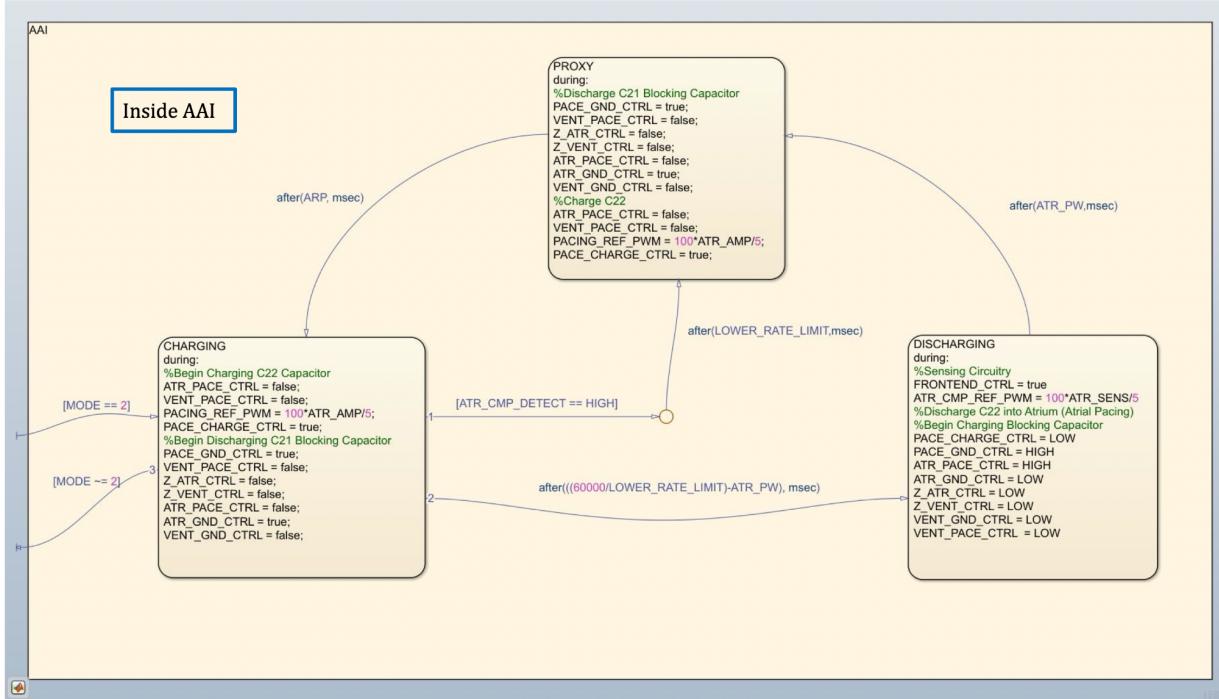


Figure 4 - Stateflow for AAI

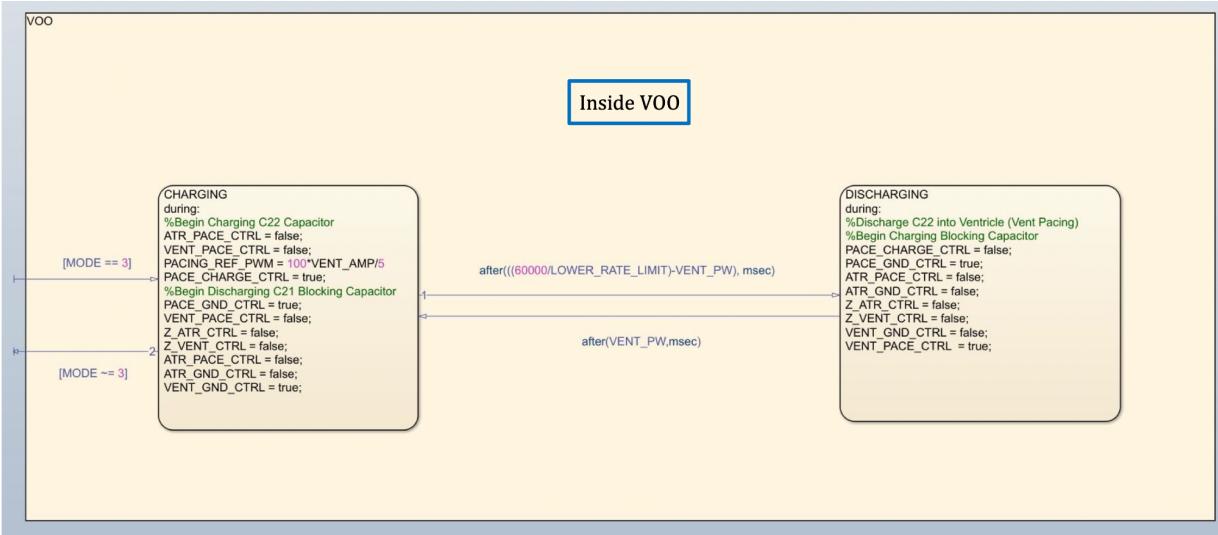


Figure 5 - State flow for VOO

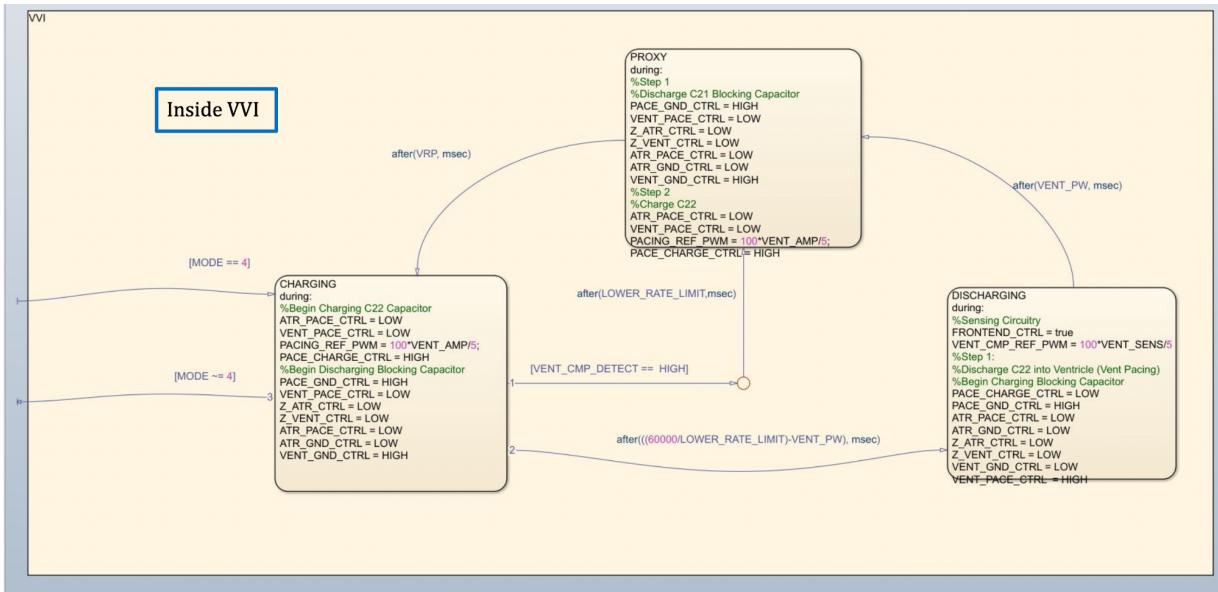


Figure 6 - State flow for VVI

Lastly, the outputs from the state flow block are listed in the output block of the simulation, with each output parameter writing to a pin of the pacemaker device.

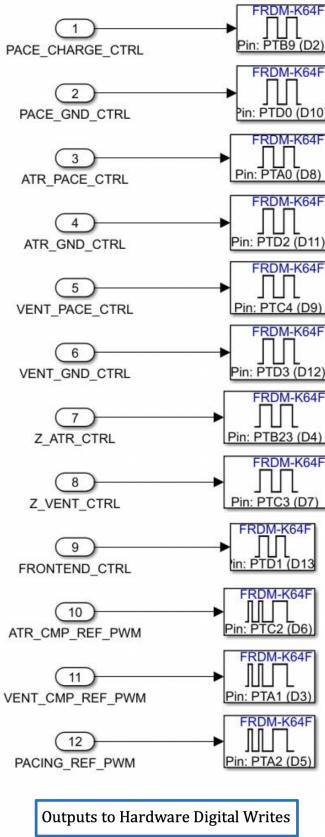


Figure 7 - Inside the output block of simulation

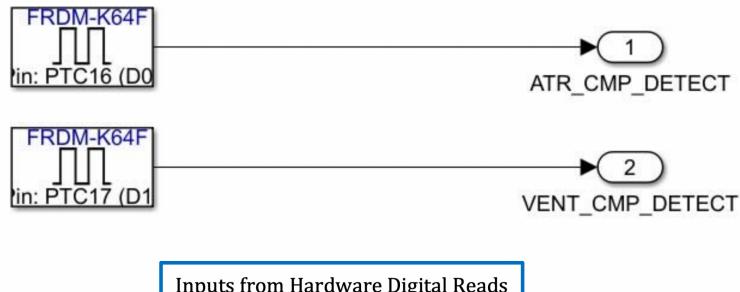
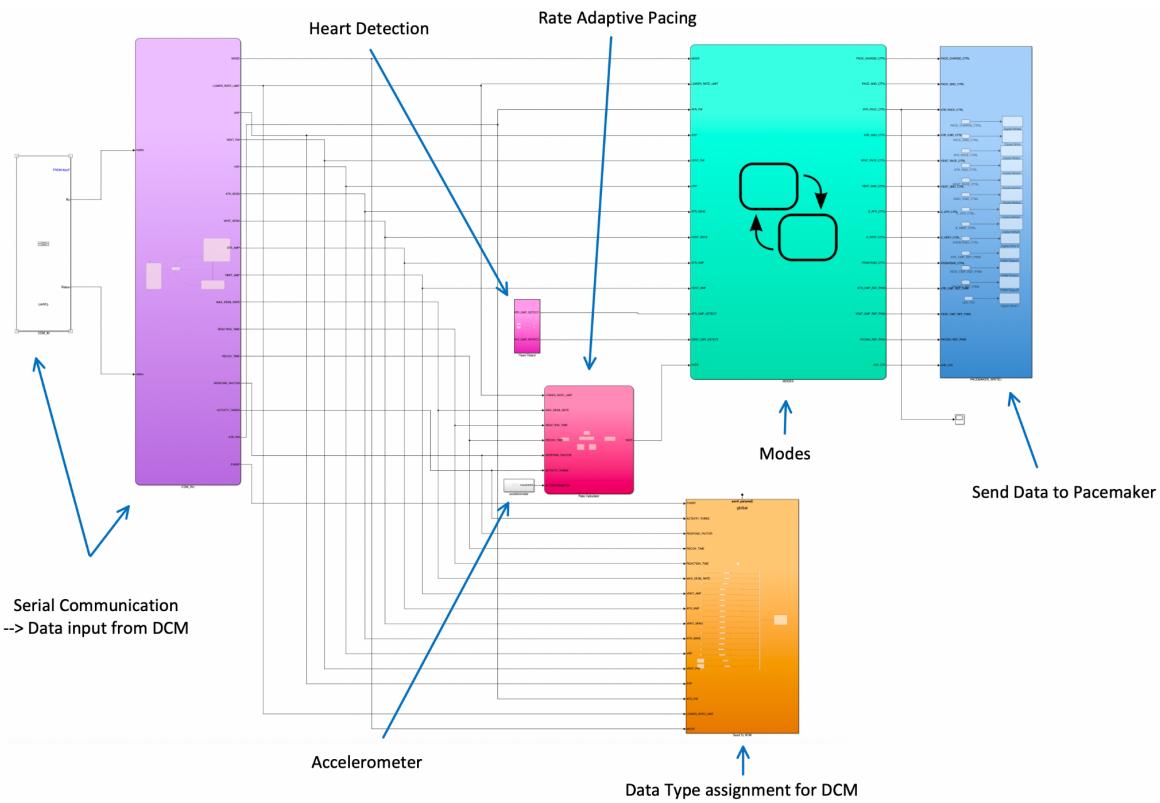


Figure 8 - Inside the Heart Detect Module within Input Parameters of Simulation

Simulink Diagrams (Assignment 2)

The diagrams provided below showcase the changes/additions made since Assignment 1. The following images display the implementation of serial communication (receiving and sending data from/to DCM), rate smoothing (done with accelerometer input), rate-adaptive pacing, byte packing for transmitting data to DCM, and four additional modes to the pacemaker (AOOR, AAIR, VOOR, VVIR).



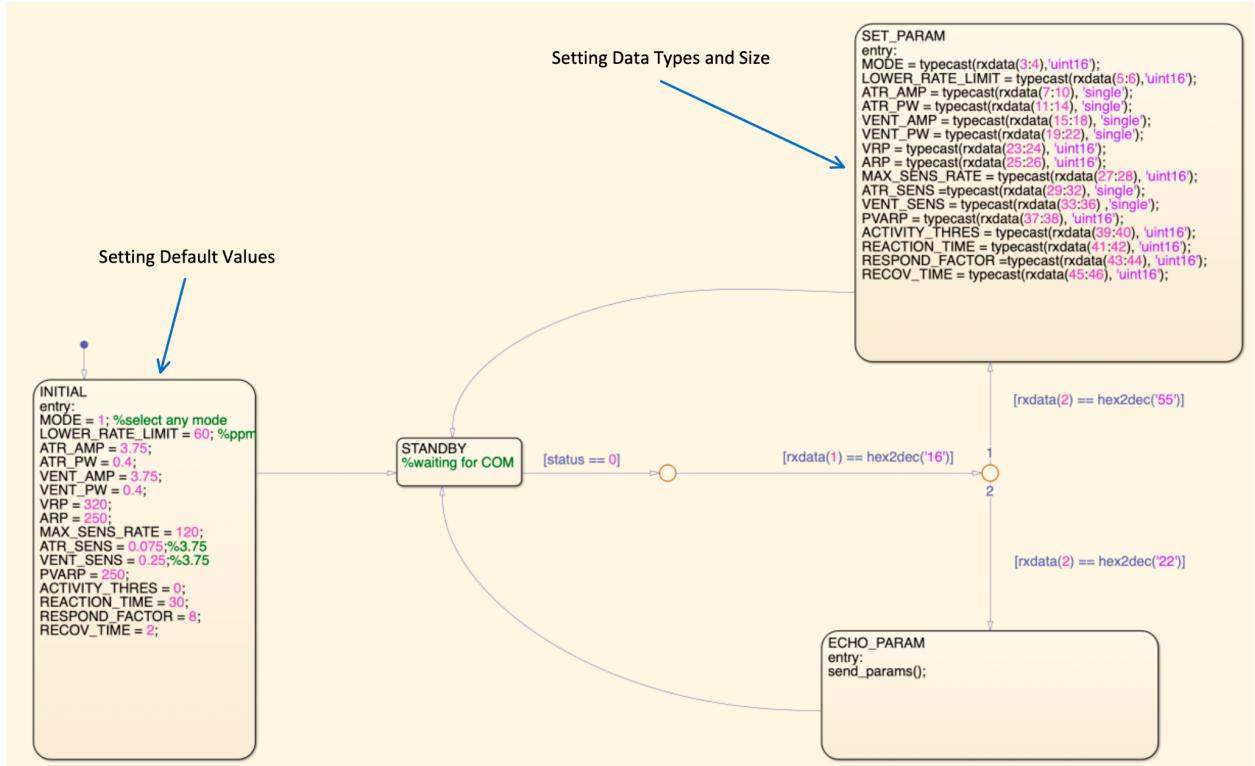


Figure 10 - Inside the Serial Communication Block

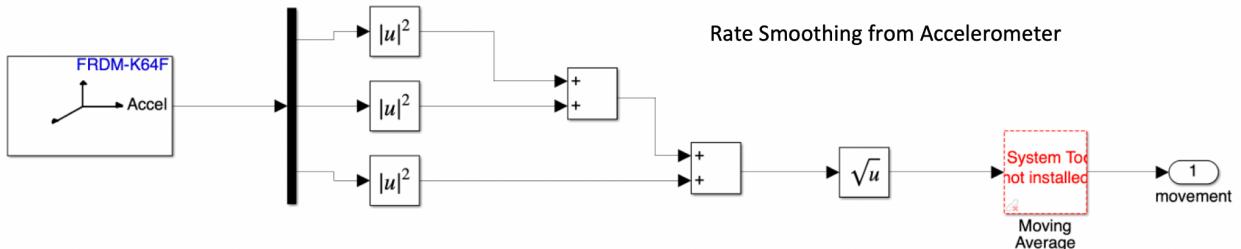


Figure 11 - Rate Smoothing is calculated from Accelerometer Data

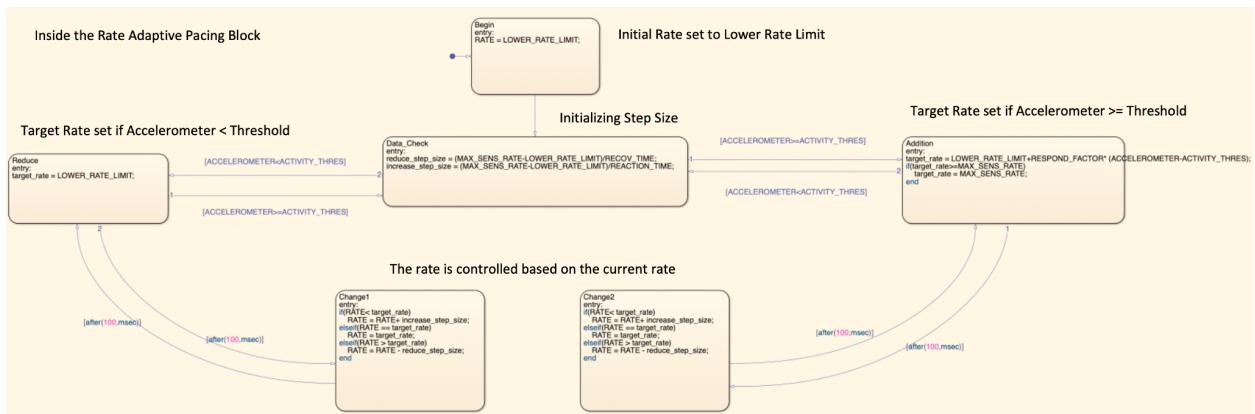


Figure 12 - Rate Adaptive Pacing based on Accelerometer movement and Rate

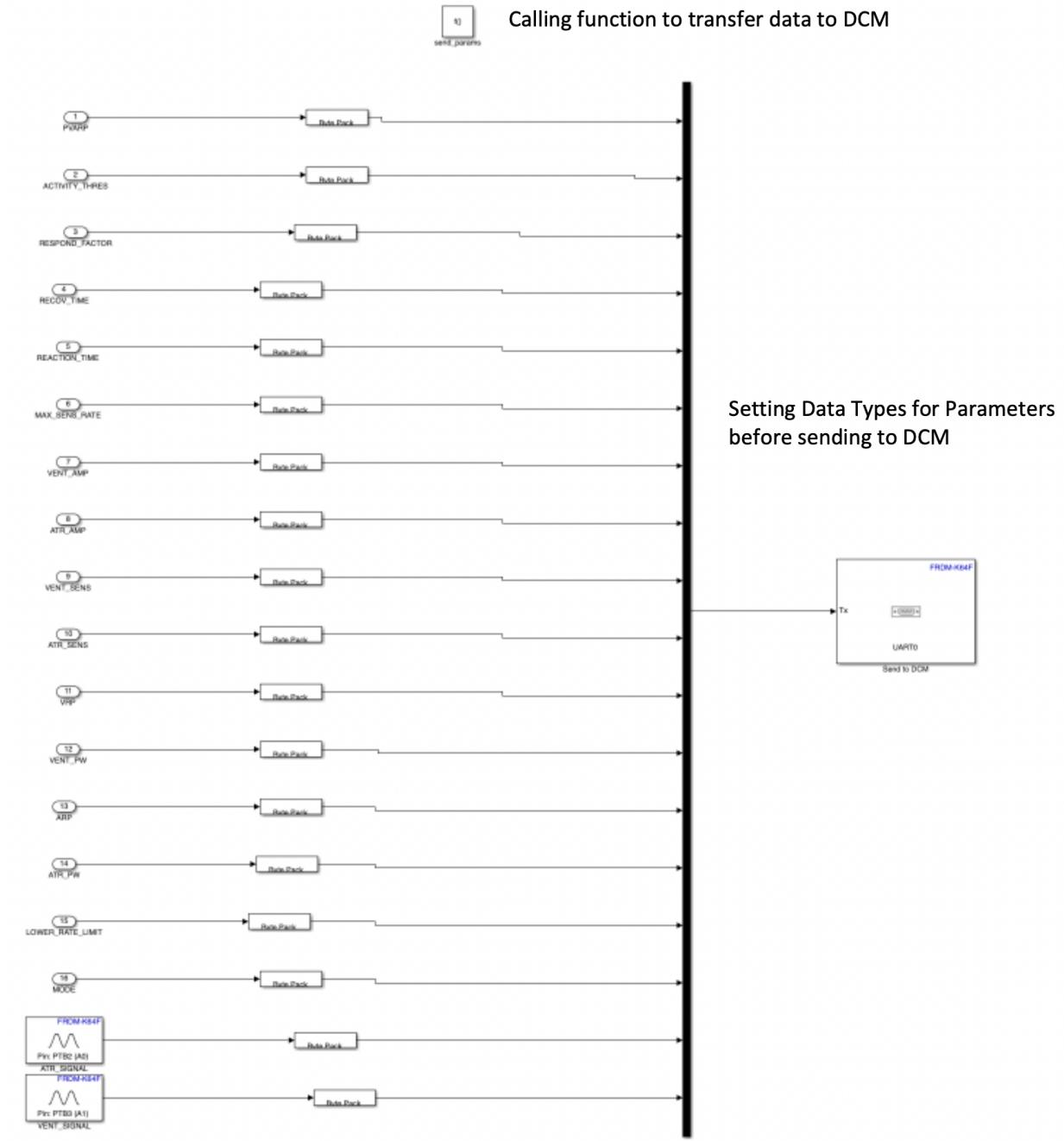


Figure 13 - Parameter Data Types change for transmitting to DCM using Embedded Coder Blocks

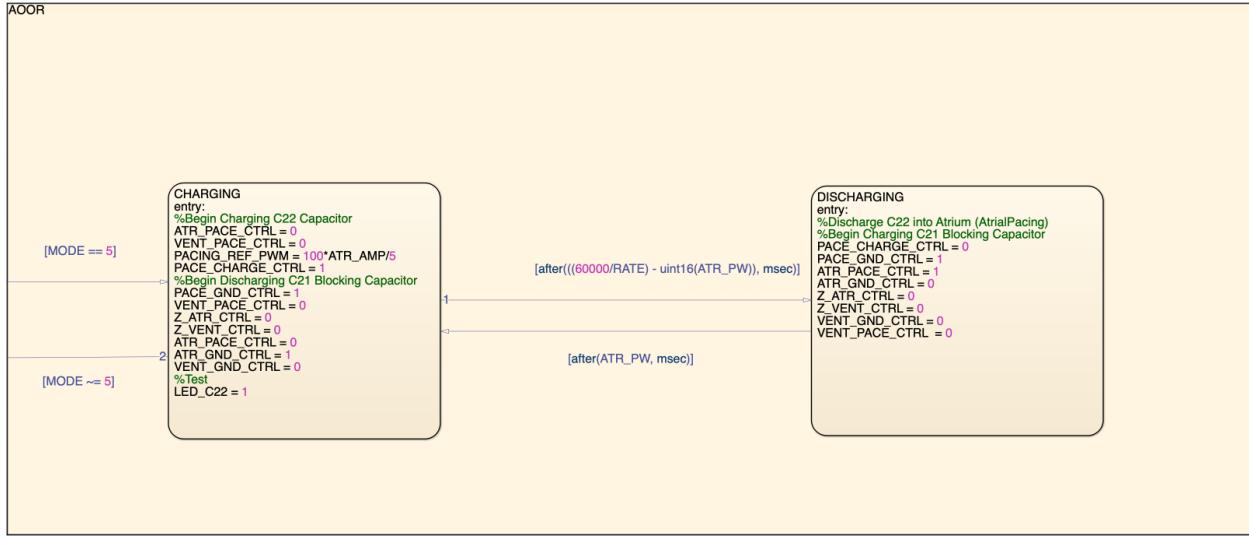


Figure 14 - Inside the AOOR block

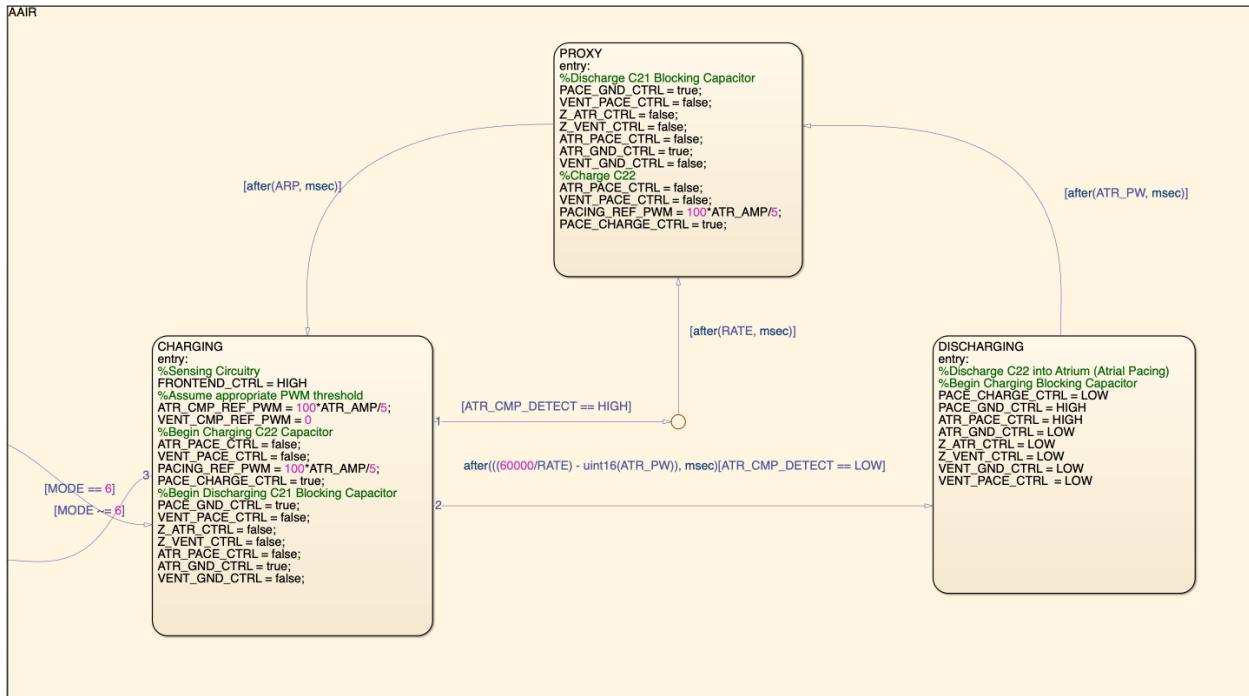


Figure 15 - Inside the AAIR block

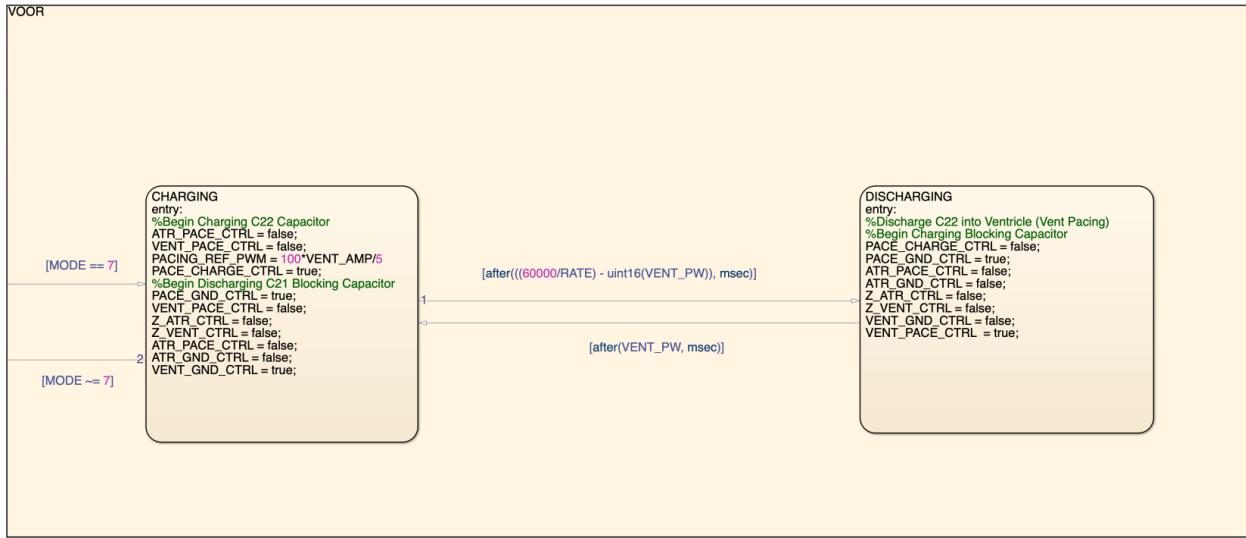


Figure 16 - Inside the VOOR block

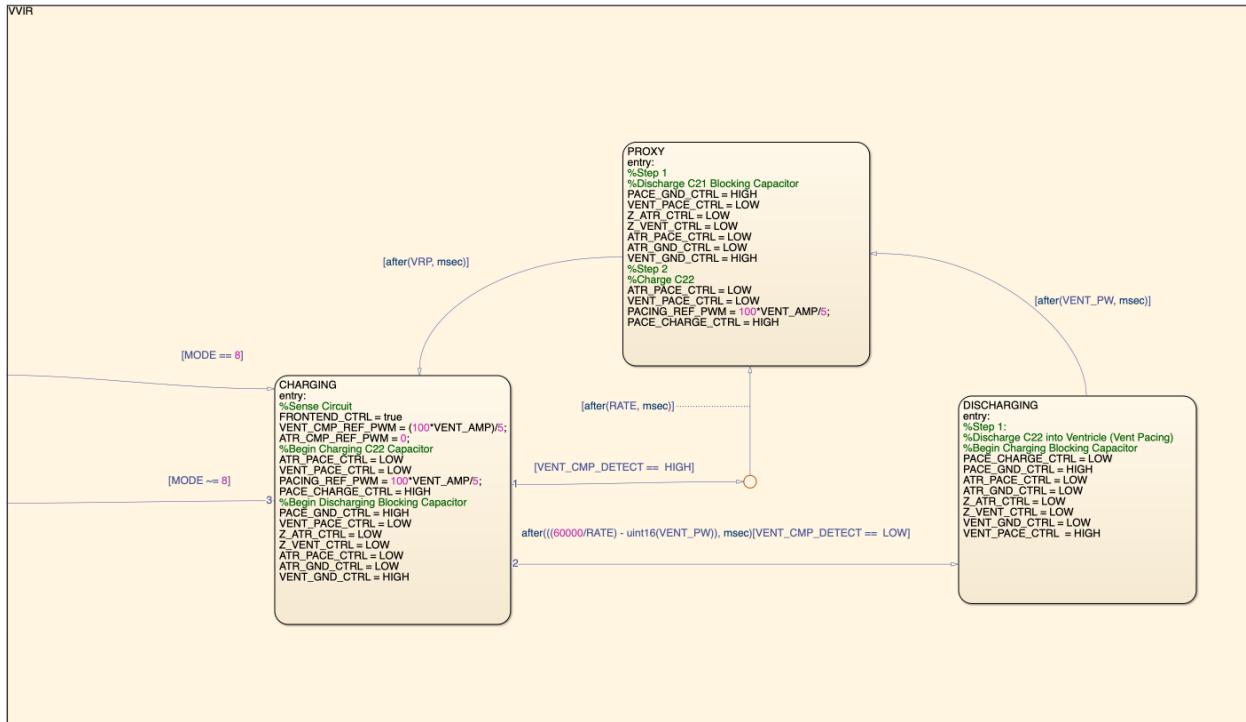


Figure 17 - Inside the VVIR block

Heartview Pacing Diagrams

The MATLAB Simulink schematic was uploaded onto the device and tested with Heartview to verify its functionality. Below are the results of testing each mode of the pacemaker.

AOO (Mode 1):

As it can be seen within AOO the pacemaker signals (i.e. in blue), they are triggered at a constant period, despite the state of the natural heart function of the atrium, because the AOO mode of the pacemaker will function independently of the heart signal.



Figure 18 - AOO output signals of pacemaker in Heartview

AAI (Mode 2):

To test the AAI functionality of the pacemaker, the ‘Beats Per Minute’ setting on Heartview was set to the lowest value to create atrial heart signals that occur much less frequently, giving the pacemaker the opportunity to be triggered. As it can be seen in the figure above, the pacemaker signals for AAI are visible under these conditions.

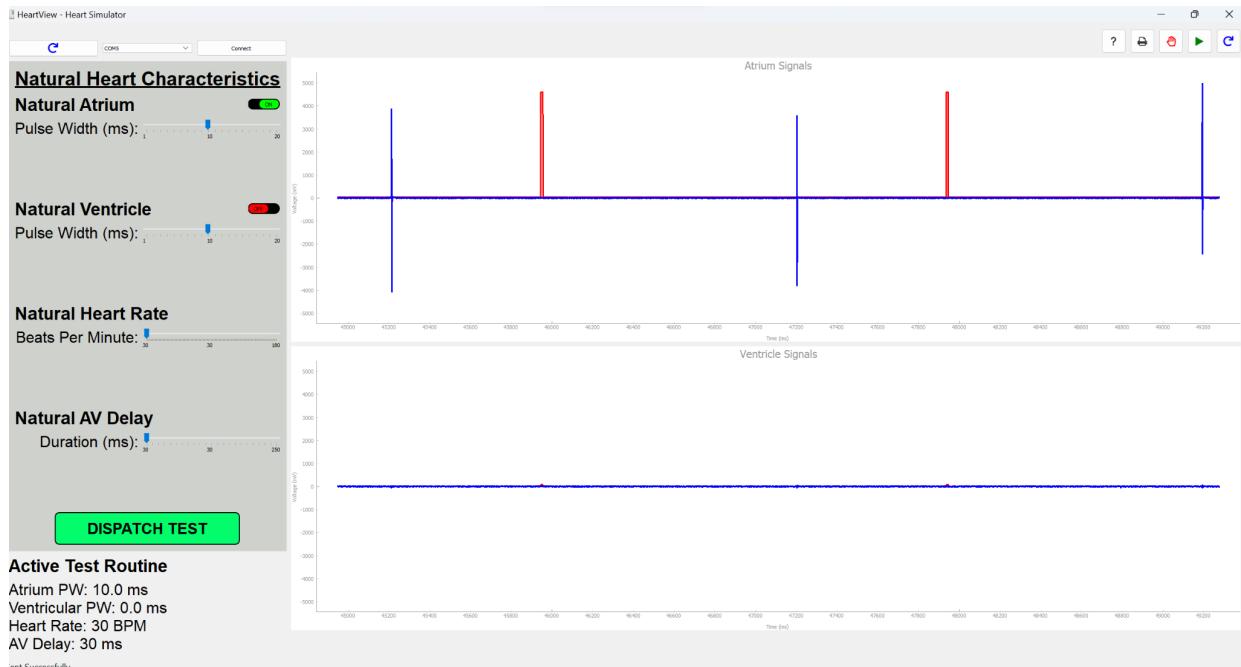


Figure 19 - AAI output signals of pacemaker in Heartview with slow BPM

The ‘Beats Per Minute’ setting on Heartview was also set to the highest setting to test if the pacemaker would still be triggered when the heart is beating very fast. The expected output was that the pacemaker would not be triggered under the detection of these signals within its detection time frame period, and the Heartview simulation displays these expected results as well.

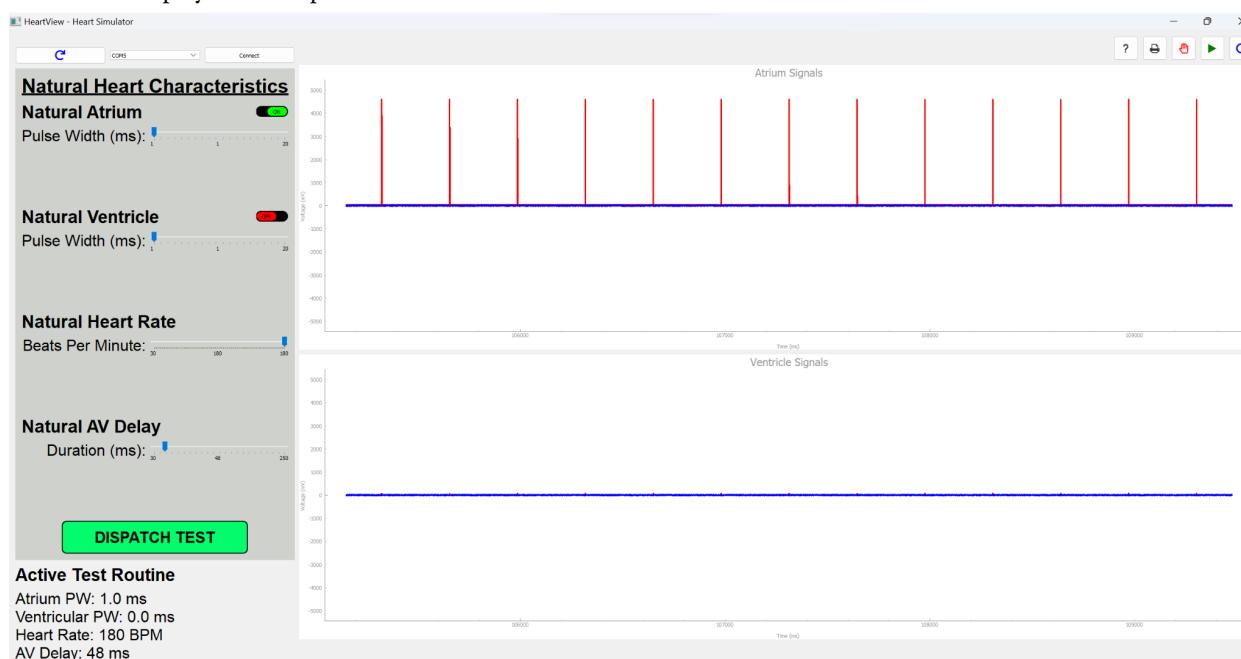


Figure 20 - AAI output signals of pacemaker in Heartview with fast BPM

VOO (Mode 3):

Similarly for VOO, the pacemaker signals are also triggered periodically (at a constant period), despite the state of the natural heart function of the ventricle, because the VOO mode of the pacemaker will function independently of the heart signal.

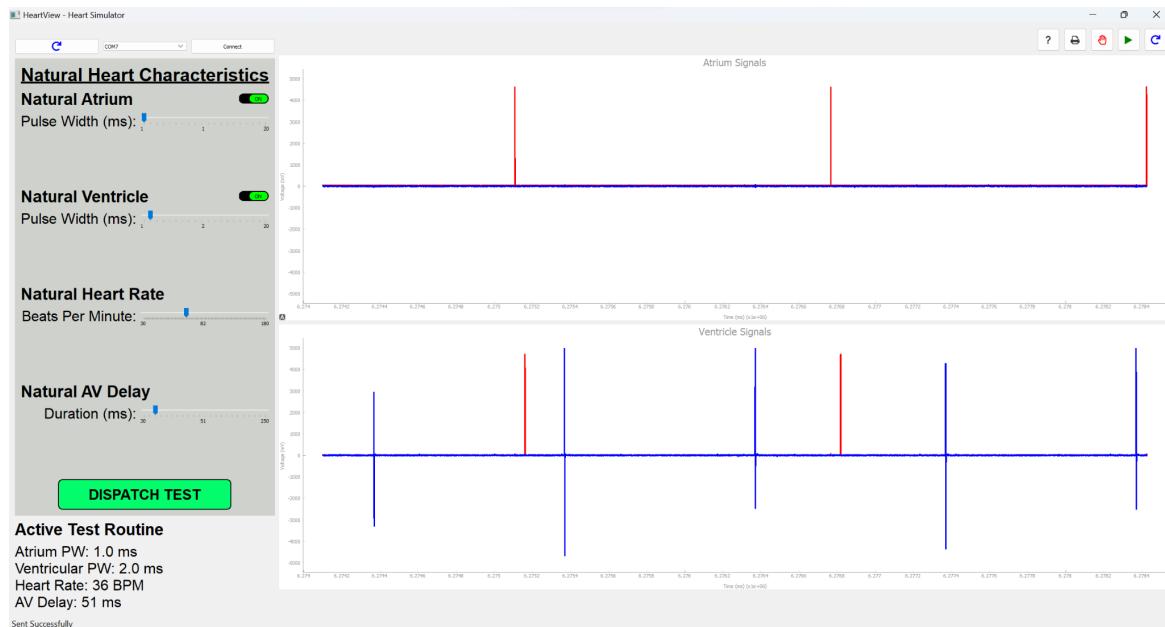


Figure 21 - VOO output signals of pacemaker in Heartview

VVI (Mode 4):

To test the VVI functionality of the pacemaker, the 'Beats Per Minute' setting on Heartview was set to the lowest value to create ventricular heart signals that occur much less frequently, giving the pacemaker the opportunity to be triggered. As it can be seen in the figure above, the pacemaker signals for VVI are visible under these conditions.



Figure 22 - VVI output signals of pacemaker in Heartview with slow BPM

The ‘Beats Per Minute’ setting on Heartview was also set to the highest setting to test if the pacemaker would still be triggered when the heart is beating very fast. The expected output was that the pacemaker would not be triggered under the detection of these signals within its detection time frame period, and the Heartview simulation displays these expected results as well.

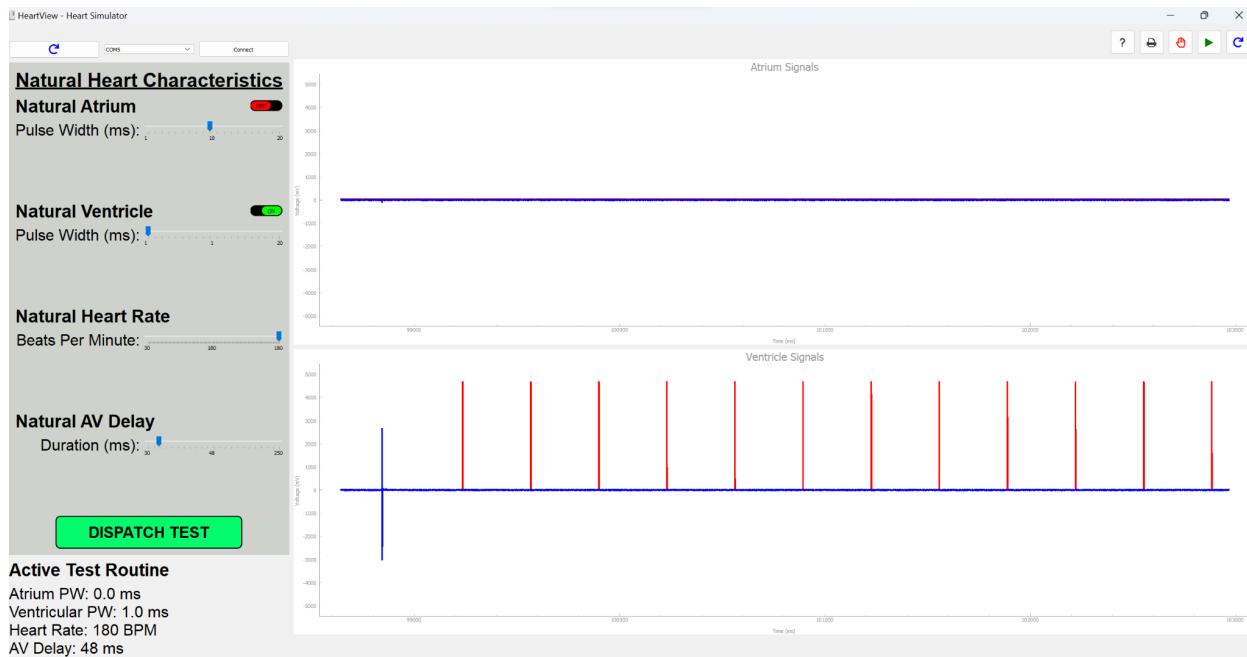


Figure 23 - VVI output signals of pacemaker in Heartview with fast BPM

Test Cases for Rate Adaptive Modes: AOOR, VOOR, AAIR, and VVIR

Purpose/Test Justification

There will be eight Test Cases conducted for the following rate adaptive modes: AOOR, VOOR, AAIR, and VVIR, with each mode containing 2 tests that verify the adaptive pacing modes of the pacemaker. The test cases for AOOR and VOOR will be done one without the natural pacing of the heart, and one with the natural pacing of the heart to verify their AOO and VOO functionality, while the AAIR and VVIR modes will have test cases where the heart rate is set higher than the Lower Rate Limit (LRL) and also set lower than the LRL to test their AAI and VVI functionality. All pacemaker modes will have test cases that will test the adaptive rate (the “R” part of each mode) from the changing rate of the accelerometer (i.e. when the device is shaken).

AOOR (Mode 5):

Test Case A - AOOR no natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	5 (AOOR)	Atrium PW (ms)	Off
Atrial Pulse Width (ms)	10	Ventricle PW (ms)	Off
Atrial Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart atrium pulse is not turned on, it can be seen that the pacemaker paces at around every 1000ms (the set time period).



Figure 24 - AOOR output signals of pacemaker in Heartview for Test Case 1 with no accelerometer change

When the natural heart atrium pulse is not turned on, but the accelerometer is shaken, it can be seen that the pacemaker paces at around every 600ms now, which is a much quicker pace due to the rate adaptive properties of the pacemaker.

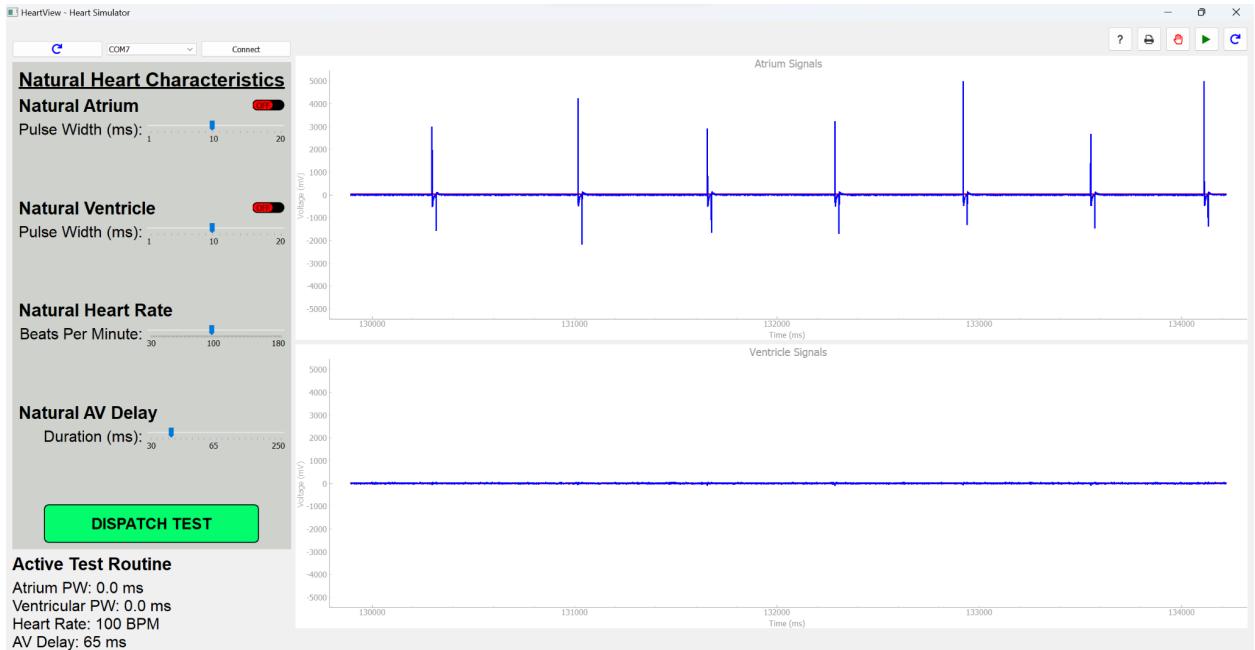


Figure 25 - AOOR output signals of pacemaker in Heartview for Test Case 1 with accelerometer changes (shaken)

Test Case B - AOOR with natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	5 (AOOR)	Atrium PW (ms)	10
Atrial Pulse Width (ms)	10	Ventricle PW (ms)	Off
Atrial Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart atrium pulse is turned on, pulsing at 100bpm, it can be seen that the pacemaker in AOOR mode still paces at around every 1000ms (the set time period), even though the heart rate is much higher than the set LRL of 60. Thereby it can be seen that the pacemaker in AOOR paces periodically regardless of what the heart pulse is at.

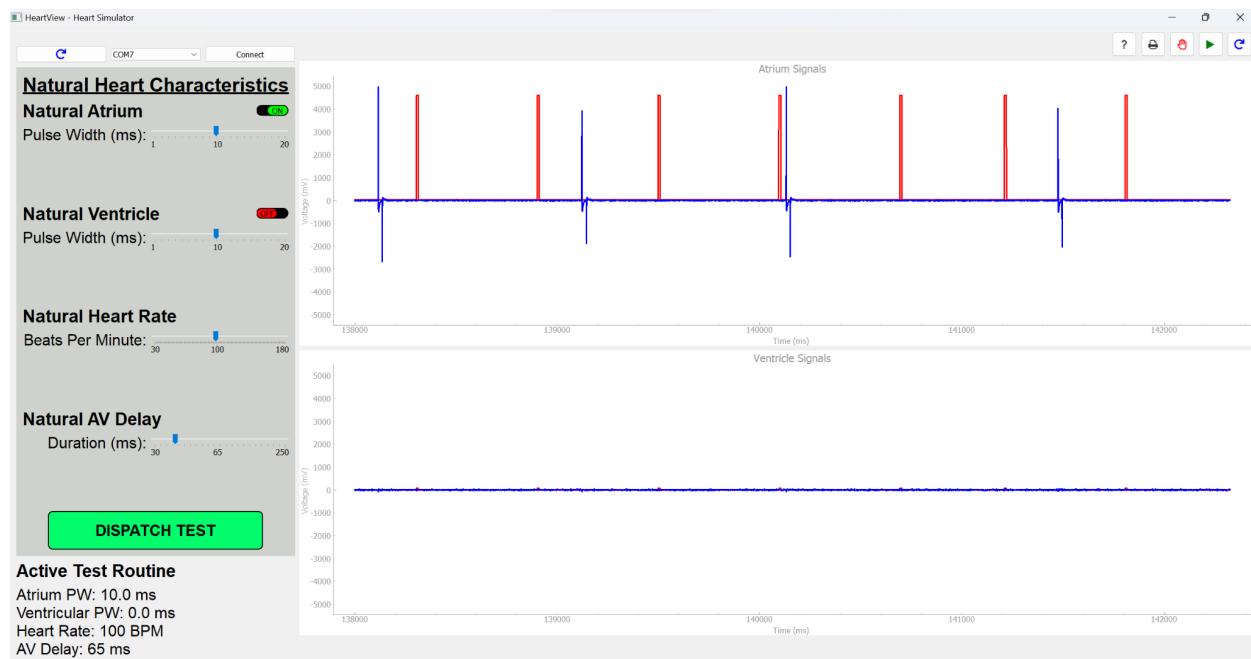


Figure 26 - AOOR output signals of pacemaker in Heartview for Test Case 2 with no accelerometer changes

When the natural heart atrium pulse is turned on pulsing at 100bpm, but the accelerometer is shaken, it can be seen that the pacemaker in AOOR mode paces faster (at around 600ms) due to the changing rate adapted from the accelerometer, but the AOOR still paces periodically at the adapted pace regardless of what the heart pulse is at (still not affected by the atrial heart pulse).

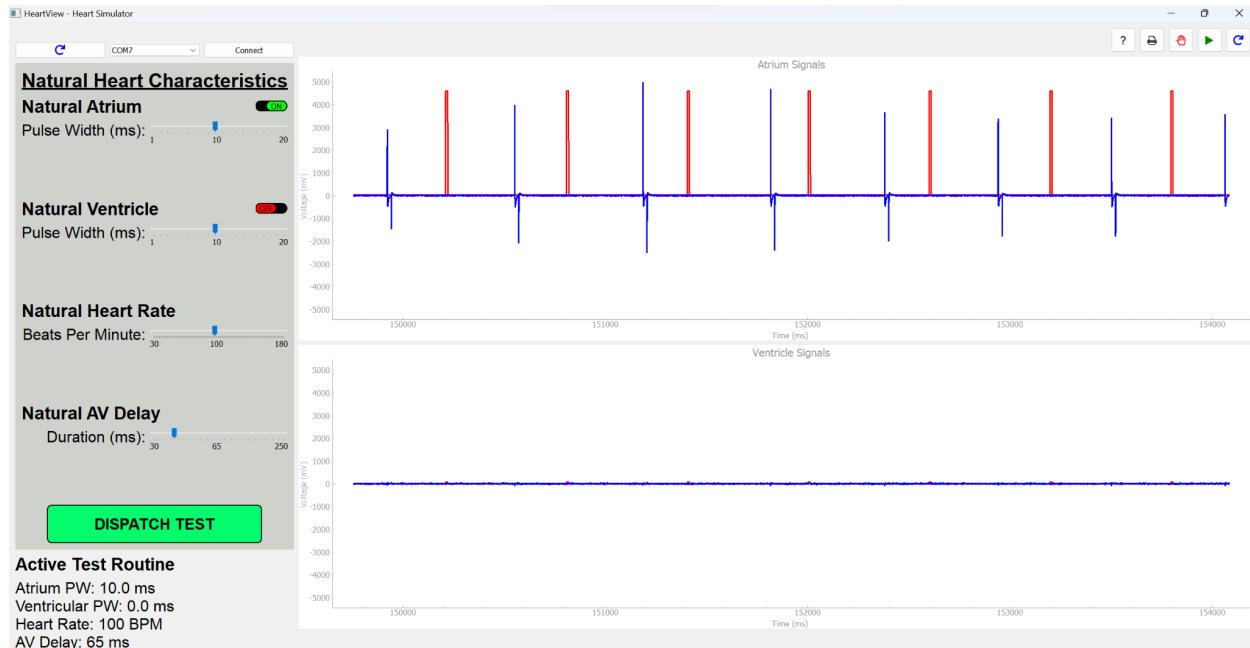


Figure 27 - AOOR output signals of pacemaker in Heartview for Test Case 2 with accelerometer changes (device shaken)

VOOR (Mode 6):

Test Case A - VOOR no natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	6 (VOOR)	Atrium PW (ms)	Off
Ventricle Pulse Width (ms)	10	Ventricle PW (ms)	Off
Ventricle Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart ventricle pulse is not turned on, it can be seen that the pacemaker paces at around every 1000ms (the set time period).

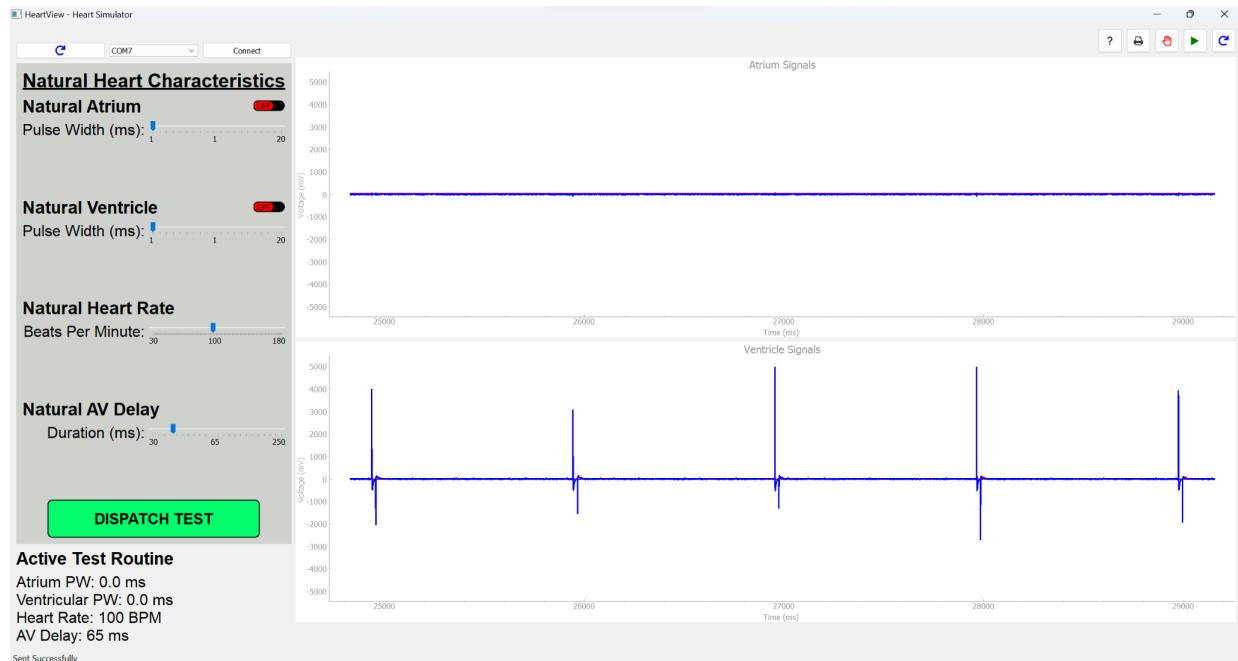


Figure 28 - VOOR output signals of pacemaker in Heartview for Test Case 3 with no accelerometer changes

When the natural heart ventricle pulse is not turned on, but the accelerometer is shaken, it can be seen that the pacemaker paces at around every 700ms now, which is a much quicker pace due to the rate adaptive properties of the pacemaker.

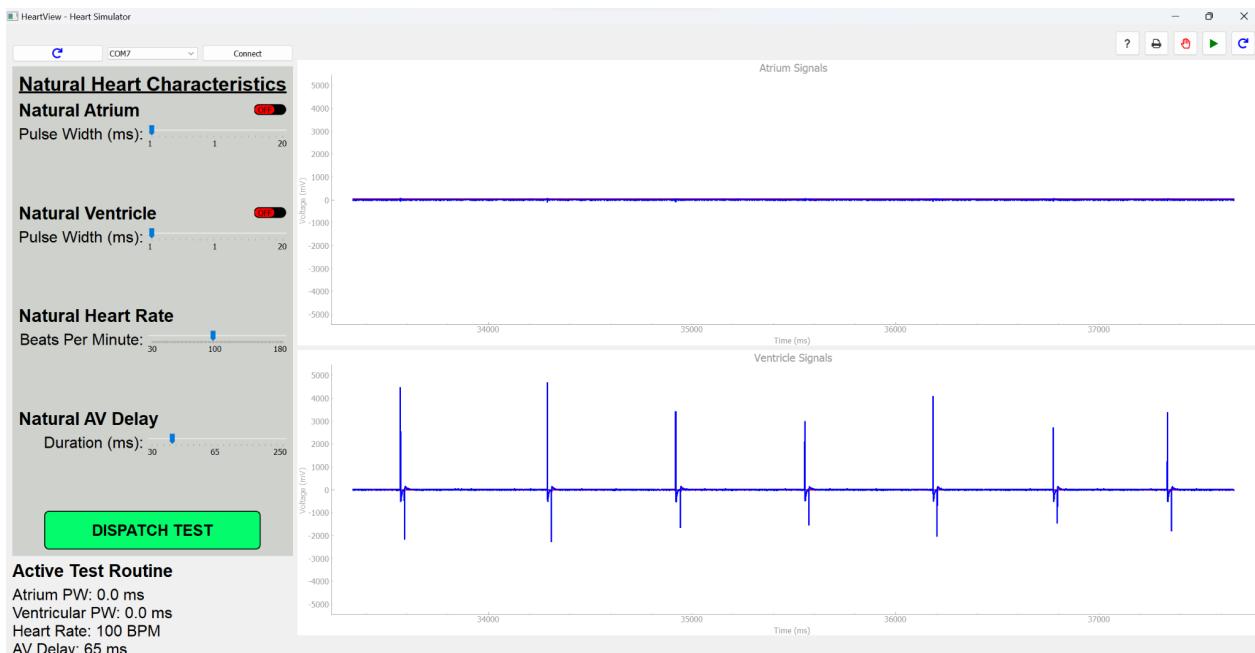


Figure 29 - VOOR output signals of pacemaker in Heartview for Test Case 3 with accelerometer changes (device shaken)

Test Case B - VOOR with natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	6 (VOOR)	Atrium PW (ms)	Off
Ventricle Pulse Width (ms)	10	Ventricle PW (ms)	1
Ventricle Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart ventricle pulse is turned on, pulsing at 100bpm, it can be seen that the pacemaker in VOOR mode still paces at around every 1000ms (the set time period), even though the heart rate is much higher than the set LRL (lower rate limit) of 60. Thereby it can be seen that the pacemaker in VOOR paces periodically regardless of what the heart pulse is at.

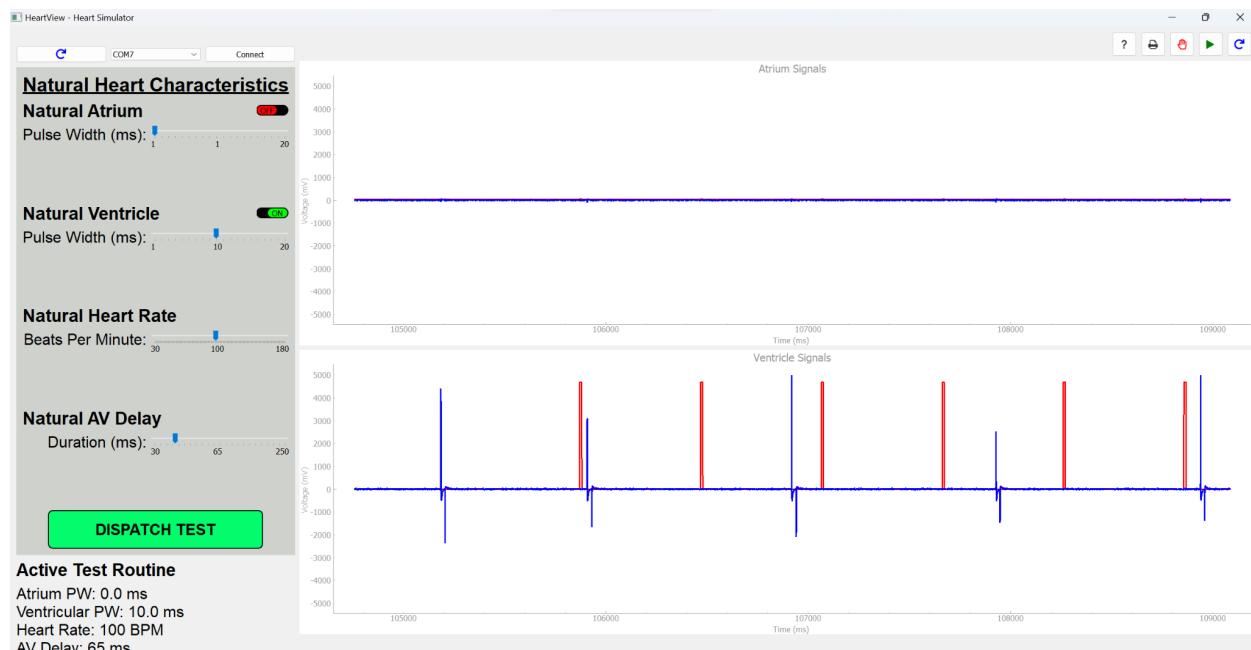


Figure 30 - VOOR output signals of pacemaker in Heartview for Test Case 4 with no accelerometer changes

When the natural heart ventricle pulse is turned on pulsing at 100bpm, but the accelerometer is shaken, it can be seen that the pacemaker in VOOR mode paces faster (at around 600-700ms) due to the changing rate adapted from the accelerometer, but the VOOR still paces periodically at the adapted pace regardless of what the heart pulse is at (still not affected by the ventricle heart pulse).

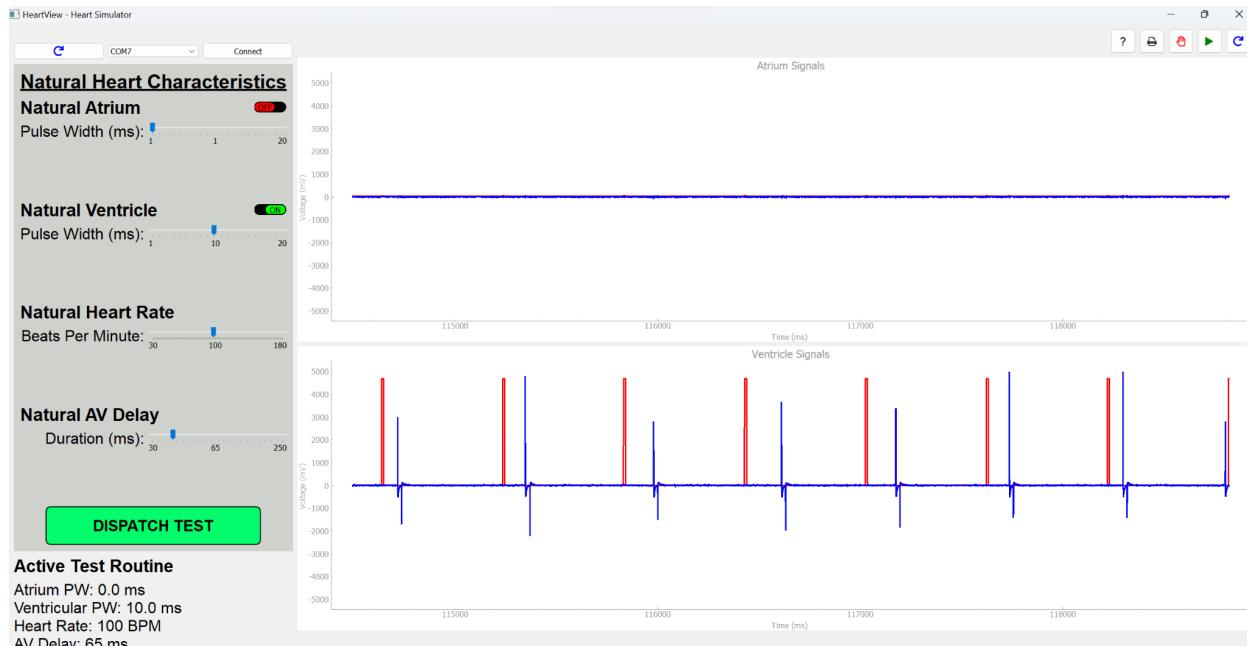


Figure 31 - VOOR output signals of pacemaker in Heartview for Test Case 4 with accelerometer changes (device shaken)

AAIR (Mode 7):

Test Case A - AAIR with quick natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	7 (AAIR)	Atrium PW (ms)	1
Atrial Pulse Width (ms)	10	Ventriicle PW (ms)	Off
Atrial Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart atrium pulse is turned on and pulsing at 100bpm, it can be seen that the pacemaker in AAIR mode does *not* pace because the heart rate exceeds the set LRL of the pacemaker which is 60. Hence, because the heart is pulsing quicker than the set LRL, the pacemaker will not trigger.

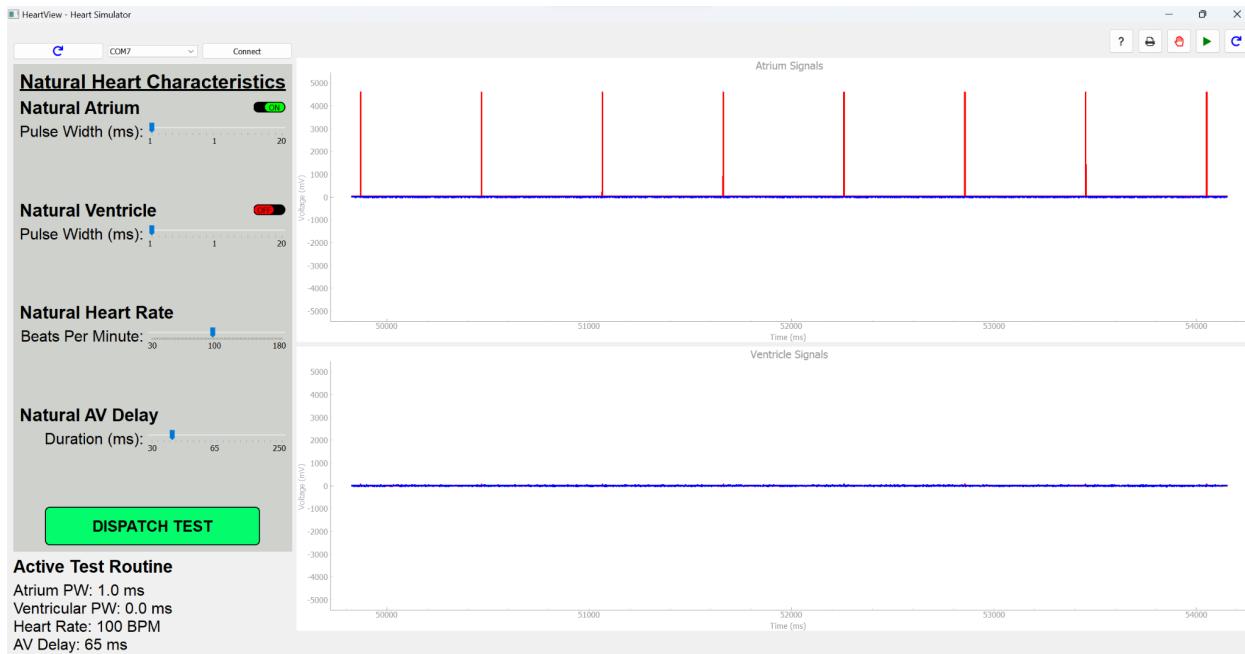


Figure 32 - AAIR output signals of pacemaker in Heartview for Test Case 5

Test Case B - AAIR with slow natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	7 (AAIR)	Atrium PW (ms)	1
Atrial Pulse Width (ms)	10	Ventricle PW (ms)	Off
Atrial Pulse Amplitude (V)	3.5	Heart Rate (bpm)	30
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart atrium pulse is turned on and pulsing at 30bpm, it can be seen that the pacemaker in AAIR mode will now pace because the heart rate is lower than the LRL of the pacemaker which is 60. Hence, because the heart is not pulsing quicker than the set LRL, the pacemaker will trigger and pulse.



Figure 33 - AAIR output signals of pacemaker in Heartview for Test Case 6 with no accelerometer changes

When the natural heart atrium pulse is turned on and pulsing at 30bpm, and the accelerometer is shaken, it can be seen that the pacemaker in AAIR mode will not only pace, but pace much quicker than before due to the rate adaptive properties of the pacemaker.

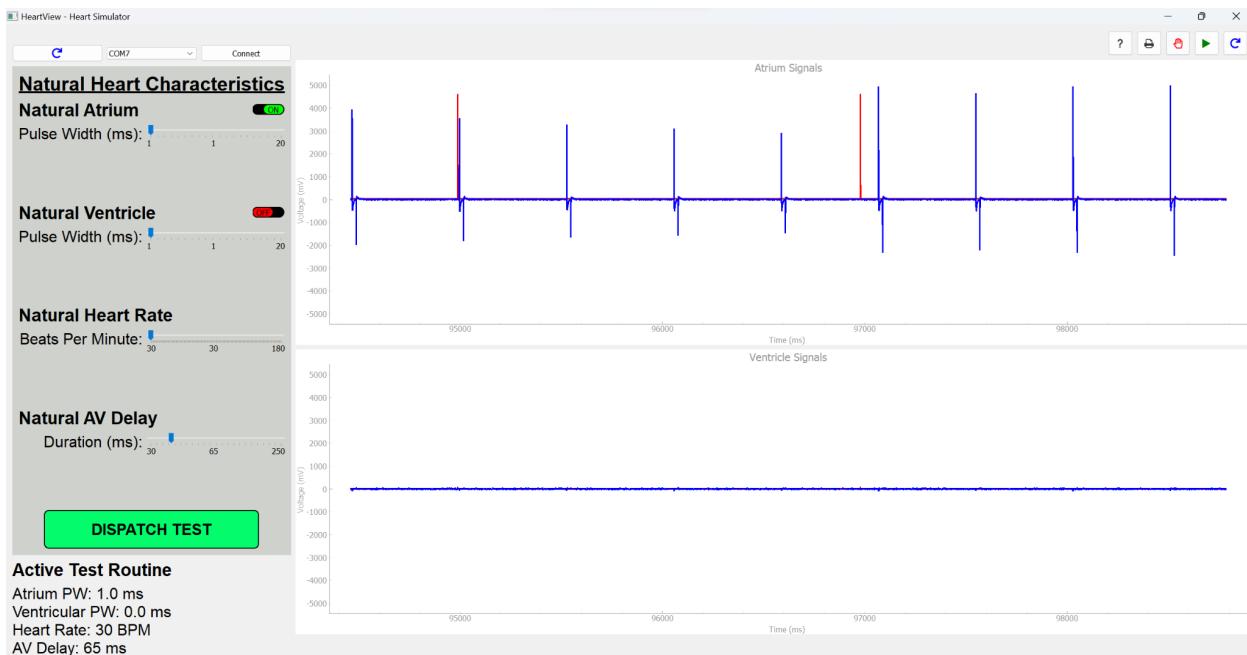


Figure 34 - AAIR output signals of pacemaker in Heartview for Test Case 6 with accelerometer changes (device shaken)

VVIR (Mode 8):

Test Case A - VVIR with quick natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	8 (VVIR)	Atrium PW (ms)	Off
Ventricle Pulse Width (ms)	10	Ventricle PW (ms)	1
Ventricle Pulse Amplitude (V)	3.5	Heart Rate (bpm)	100
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart ventricle pulse is turned on and pulsing at 100bpm, it can be seen that the pacemaker in VVIR mode does *not* pace because the heart rate exceeds the set LRL of the pacemaker which is 60. Hence, because the heart is pulsing quicker than the set LRL, the pacemaker will not trigger.



Figure 35 - VVIR output signals of pacemaker in Heartview for Test Case 7

Test Case B - VVIR with slow natural heart pulse

Pacemaker Initial Settings		Heartview Settings	
Mode	8 (VVIR)	Atrium PW (ms)	Off
Ventricle Pulse Width (ms)	10	Ventricle PW (ms)	1
Ventricle Pulse Amplitude (V)	3.5	Heart Rate (bpm)	30
Lower Rate Limit (ppm)	60	AV Delay (ms)	65

When the natural heart ventricle pulse is turned on and pulsing at 30 bpm, it can be seen that the pacemaker in VVIR mode will now pace because the heart rate is lower than the LRL of the pacemaker which is 60. Hence, because the heart is not pulsing quicker than the set LRL, the pacemaker will trigger and pulse.

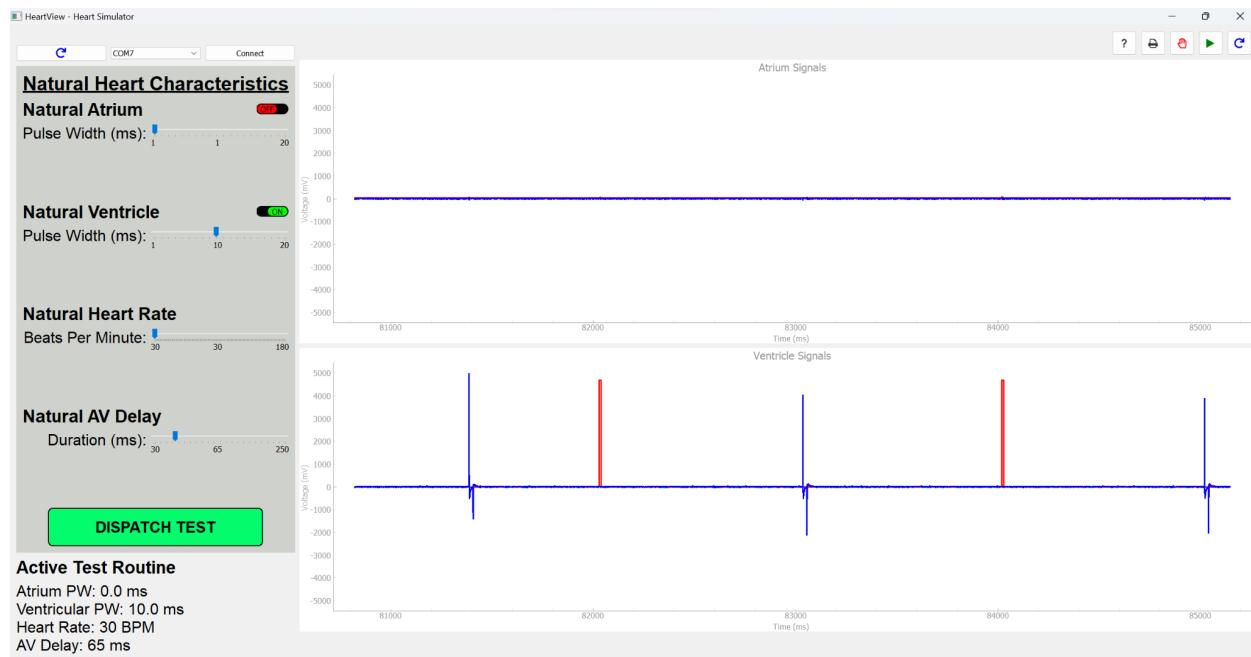


Figure 36 - VVIR output signals of pacemaker in Heartview for Test Case 7 with no accelerometer changes

When the natural heart ventricle pulse is turned on and pulsing at 30 bpm, and the accelerometer is shaken, it can be seen that the pacemaker in VVIR mode will not only pace, but pace much quicker than before due to the rate adaptive properties of the pacemaker.

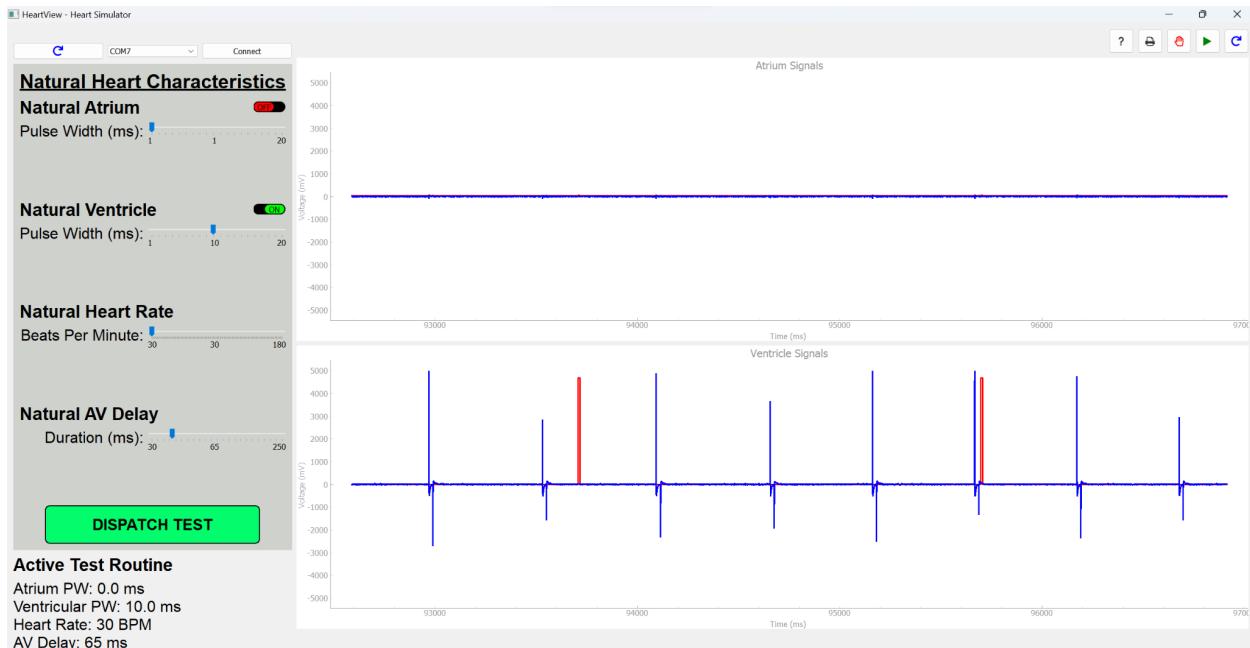


Figure 37 - VVIR output signals of pacemaker in Heartview for Test Case 7 with accelerometer changes (device shaken)

Conclusion of Expected Output and Pass/Fail Results

All modes of the pacemaker are seen to behave as expected since all actual outputs of the pacemaker align with the expected outputs and behavior of the pacemaker. Hence, for every mode and all of our test cases, the results would be classified as a Pass for each.

Appendices

Table: FRDM-K64F PINS

Mapping between Technical and Corresponding Pin Names specific for K64F microcontroller

Pin Name	Corresponding Name	Functionality
D0	ATR_CMP_DETECT	Used in the sensing circuitry of the atrium. Outputs ON (HIGH) when signal voltage is higher than threshold voltage and OFF (LOW) otherwise (includes 5mV hysteresis).
D1	VENT_CMP_DETECT	Same functionality as in ATR_CMP_DETECT but for the ventricle sensing signal (includes 5mV hysteresis).
D2	PACE_CHARGE_CTRL	<p>Used to start and stop the charging of the primary capacitor (C22).</p> <p>If ON (HIGH) → PWM charges C22 If OFF (LOW) → PWM disconnected from circuit</p> <p>NEVER allow this signal to be set to HIGH if either ATR_PACE_CTRL and/or VENT_PACE_CTRL are HIGH because then the patient may be directly connected to the PWM signal!</p>
D3	VENT_CMP_REF_PWM	<p>In order to establish a threshold for when the ventricular action potential should be sensed, this pin uses PWM to charge a capacitor that will sustain a constant voltage for comparison.</p> <p><u>Note</u> that the capacitor voltage is linearly proportional to the Duty Cycle of the PWM input. Use default PWM frequency.</p>
D4	Z_ATR_CTRL	<p>This control allows the impedance circuit to be connected to the ring electrode of the atrium. It is used to analyze the impedance of the atrial electrode and the electrical connection between the atrial electrodes and the atrium itself. The output of this circuit is found at the Z_SIGNAL pin.</p> <p>More information regarding lead impedances is mentioned in Section 4 of this document.</p>
D5	PACING_REF_PWM	<p>Used to charge the primary capacitor (C22) of the pacing circuit. The PWM voltage output by this pin saturates to 0-5V and will charge C22 if PACE_CHARGE_CTRL is HIGH.</p> <p><u>Note</u> that the capacitor voltage is linearly proportional to the Duty Cycle of the PWM input. Use default PWM frequency.</p>

D6	ATR_CMP_REF_PWM	<p>Same functionality as in VENT_CMP_REF_PWM but for the atrial action potential.</p> <p><u>Note</u> that the capacitor voltage is linearly proportional to the Duty Cycle of the PWM input. Use default PWM frequency.</p>
D7	Z_VENT_CTRL	<p>This control allows the impedance circuit to be connected to the ring electrode of the ventricle. Its use is identical to Z_ATR_CTRL but for the ventricle.</p> <p>More information regarding lead impedances is mentioned in Section 4 of this document.</p>
D8	ATR_PACE_CTRL	<p>Used to discharge the primary capacitor through the atrium. Current flows through the switch if set to HIGH. If LOW there is no current flow. Pay attention to the direction at which current flows through the electrode.</p> <p>NEVER allow this output signal to be set to HIGH if PACE_CHARGE_CTRL is HIGH because then the patient's atrium may be directly connected to the PWM signal!</p>
D9	VENT_PACE_CTRL	<p>Same functionality as in ATR_PACE_CTRL but for the ventricle.</p> <p>NEVER allow this output signal to be set to HIGH if PACE_CHARGE_CTRL is HIGH because then the patient's ventricle may be directly connected to the PWM signal!</p>
D10	PACE_GND_CTRL	<p>To allow current to flow from the ring to the tip in either the atrium or the ventricle this pin must be HIGH since it controls the switch directly following the tip.</p> <p><u>Note:</u> Once this pin is activated along with eitherPACE_CTRL pins, the charge will flow through the switch and accumulate in the blocking capacitor (C21).</p>
D11	ATR_GND_CTRL	Used to connect the ATR_RING_OUT to GND. This functionality is used when discharging the blocking capacitor through the atrium to allow no charge buildup.
D12	VENT_GND_CTRL	Same functionality as in ATR_RING_OUT but for the ventricle.
D13	FRONTEND_CTRL	<p>Used to activate the sensing circuitry.</p> <p>If ON (HIGH) → Sensing circuitry will output heart signal. If OFF (LOW) → Sensing circuitry is disconnected from patient (Green Connectors) and will output nothing.</p> <p><u>Note:</u> This switch controls both the atrial and ventricular circuits. It is up to the programmer to only record the data they desire since both will be activated.</p>
GND	GND	References electronic GND. It is good practice to test that all grounds are connected with low resistance prior to the initial startup of the device. Once the device is in use or in the body this process is no longer necessary.

AREF	-	- Disconnected by design -
SDA	-	- Disconnected by design -
SCL	-	- Disconnected by design -
A5/SCL	-	- Disconnected by design -
A4/SDA	VENT_RECT_SIGNAL	This pin connects to the sensing circuitry and is used to output the rectified analog waveform of the ventricle. This waveform is used in the comparator amplifier to detect ventricular action potentials.
A3	ATR_RECT_SIGNAL	Same output functionality as in VENT_RECT_SIGNAL but for the atrium.
A2	Z_SIGNAL	Used to analyze the impedance of either the atrium or the ventricle if necessary. More information regarding lead impedances is mentioned in Section 4 of this document.
A1	VENT_SIGNAL	This pin outputs the analog waveform of the ventricle prior to full-wave rectification. This signal best represents what is actually happening in the heart in real-time. Use this analog output as data for any electrocardiogram outputs.
A0	ATR_SIGNAL	Same functionality as in VENT_SIGNAL but for the atrium.
VIN	-	- Disconnected by design -
GND1	GND	Same functionality as GND mentioned above.
GND2	GND	Same functionality as GND mentioned above.
5V	5V	Connected to the Arduino 5V output. Used to power the electronics of the shield. It is good practice to test that this is roughly 5V prior to usage.
3V3	3V3	Arduino uses 3.3V to output an HIGH voltage from the Arduino pins. It is good practice to test that this is roughly 3.3V prior to usage.
/RESET	-	- Disconnected by design -
IOREF	-	- Disconnected by design -
RESERVED	-	- Disconnected by design -