

# **PACEMAKER DCM**

## **System Specifications**

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MECHTRON/SFWR ENG 3K04

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# Contents

- 1 Introduction**
- 2 System Requirements**
  - 2.1 List of Requirements
  - 2.2 Requirements Likely to Change
- 3 Design Overview**
  - 3.1 DCM GUI Design
  - 3.2 Design Decisions Likely to Change
- 4 Module Interface Specification**
  - 4.1 Table of Functions
  - 4.2 Finite State Diagram
- 5 Module Internal Design**
  - 5.1 Global Constants
  - 5.2 List Private Functions within Modules
  - 5.3 Functionality of Private Functions
- 6 Testing**
- 7 Future Additions**

# **1 Introduction**

The purpose of this documentation is to describe the functions and operational characteristics of the PACEMAKER Device Control Monitor (DCM). It will identify the functions and modules within the DCM and outline the interactions between them based on the defined requirements of the system.

## **2 Requirements**

### **2.1 List of DCM Requirements**

The purpose of the Device Control Monitor is to provide a user interface to facilitate the communication to the implanted PACEMAKER device.

The implementation of the DCM design shall be capable of carrying out the following requirements:

1. The user interface shall be capable of utilizing and managing windows for display of text and graphics.
2. The user interface shall be capable of processing user positioning and input buttons.
3. The user interface shall be capable of displaying all programmable parameters for review and modification.
4. The user interface shall be capable of visually indicating when the DCM and the device are communicating.
5. The user interface shall be capable of visually indicating when telemetry is lost due to the device being out of range.
6. The user interface shall be capable of visually indicating when telemetry is lost due to noise.
7. The user interface shall be capable of visually indicating when a different PACEMAKER device is approached than was previously interrogated.

### **2.2 Requirements Likely to Change**

Throughout the development of the PACEMAKER DCM, some requirements are likely to change as development progresses. Throughout the interactions of the DCM development certain requirements will not be necessary. The list of requirements that are likely to be changed are:

1. PACEMAKER embedded Software

## 2. PACEMAKER hardware

# 3 Design Overview

### 3.1 DCM GUI Design

The goal of the DCM design is to achieve all of the requirements stated in section 2.1. Functionality was the priority over visual appeal. The design must be initiative and straight forward to provide ease of use.



Figure 1. Design of DCM Welcome Screen

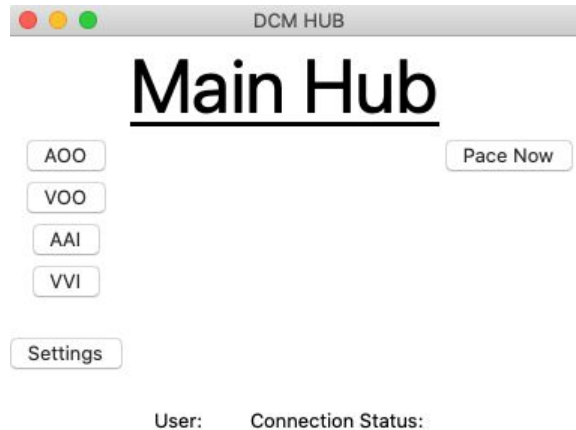


Figure 2. Design of the DCM Hub Screen

Settings

Institution: McMaster University

Application Model: Version: 1.0

DCM Serial Number: DCM Serial Number:

**McMaster University**

Figure 3. Design of the DCM Settings Screen

AOO Pacing Mode

Lower Rate Limit (ppm)	60	Enter New Value	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update
Atrial Amplitude (V)	3.5	Enter New Value	Update
Atrial Pulse Width (ms)	0.4	Enter New Value	Update

User: Connection Status:

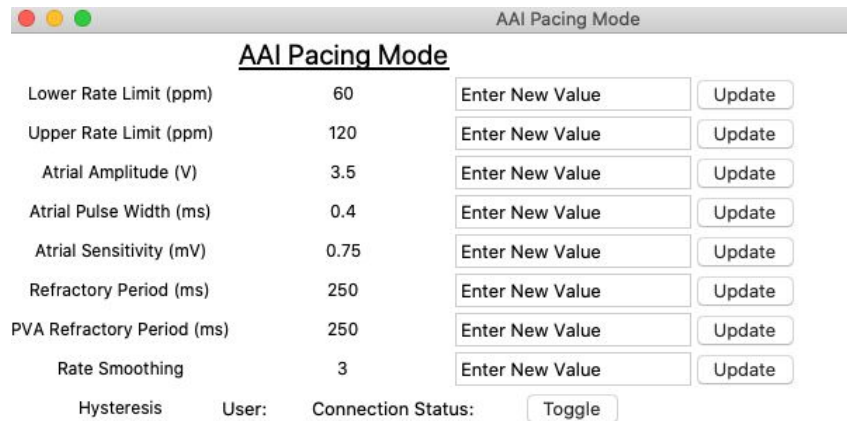
Figure 4. Design of the AOO Settings Screen

VOO Pacing Mode

Lower Rate Limit (ppm)	60	Enter New Value	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update
Ventricular Amplitude (V)	2.5	Enter New Value	Update
Ventricular Pulse Width (ms)	0.6	Enter New Value	Update

User: Connection Status:

Figure 5. Design of the VOO Settings Screen

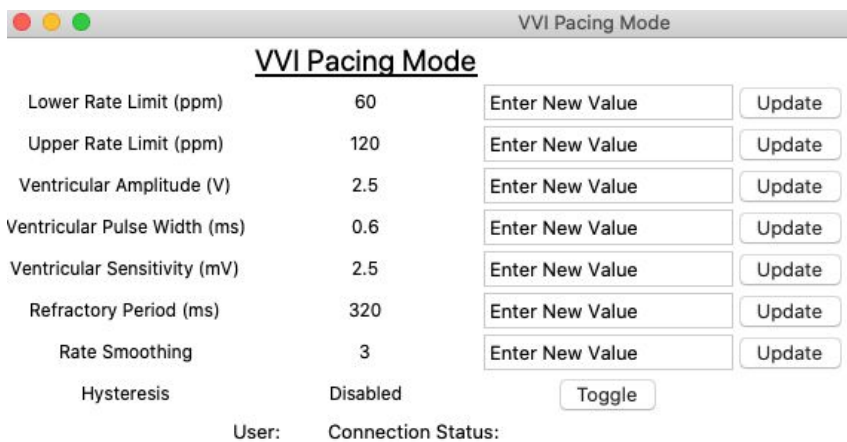


AAI Pacing Mode

Lower Rate Limit (ppm)	60	Enter New Value	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update
Atrial Amplitude (V)	3.5	Enter New Value	Update
Atrial Pulse Width (ms)	0.4	Enter New Value	Update
Atrial Sensitivity (mV)	0.75	Enter New Value	Update
Refractory Period (ms)	250	Enter New Value	Update
PVA Refractory Period (ms)	250	Enter New Value	Update
Rate Smoothing	3	Enter New Value	Update

Hysteresis      User:      Connection Status:      Toggle

Figure 6. Design of the AAI Settings Screen



VVI Pacing Mode

Lower Rate Limit (ppm)	60	Enter New Value	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update
Ventricular Amplitude (V)	2.5	Enter New Value	Update
Ventricular Pulse Width (ms)	0.6	Enter New Value	Update
Ventricular Sensitivity (mV)	2.5	Enter New Value	Update
Refractory Period (ms)	320	Enter New Value	Update
Rate Smoothing	3	Enter New Value	Update

Hysteresis      Disabled      Toggle

User:      Connection Status:

Figure 7. Design of the VVI Settings Screen

### 3.2 Design Decisions Likely to Change

Throughout the design process, some design decisions are likely to be changed.

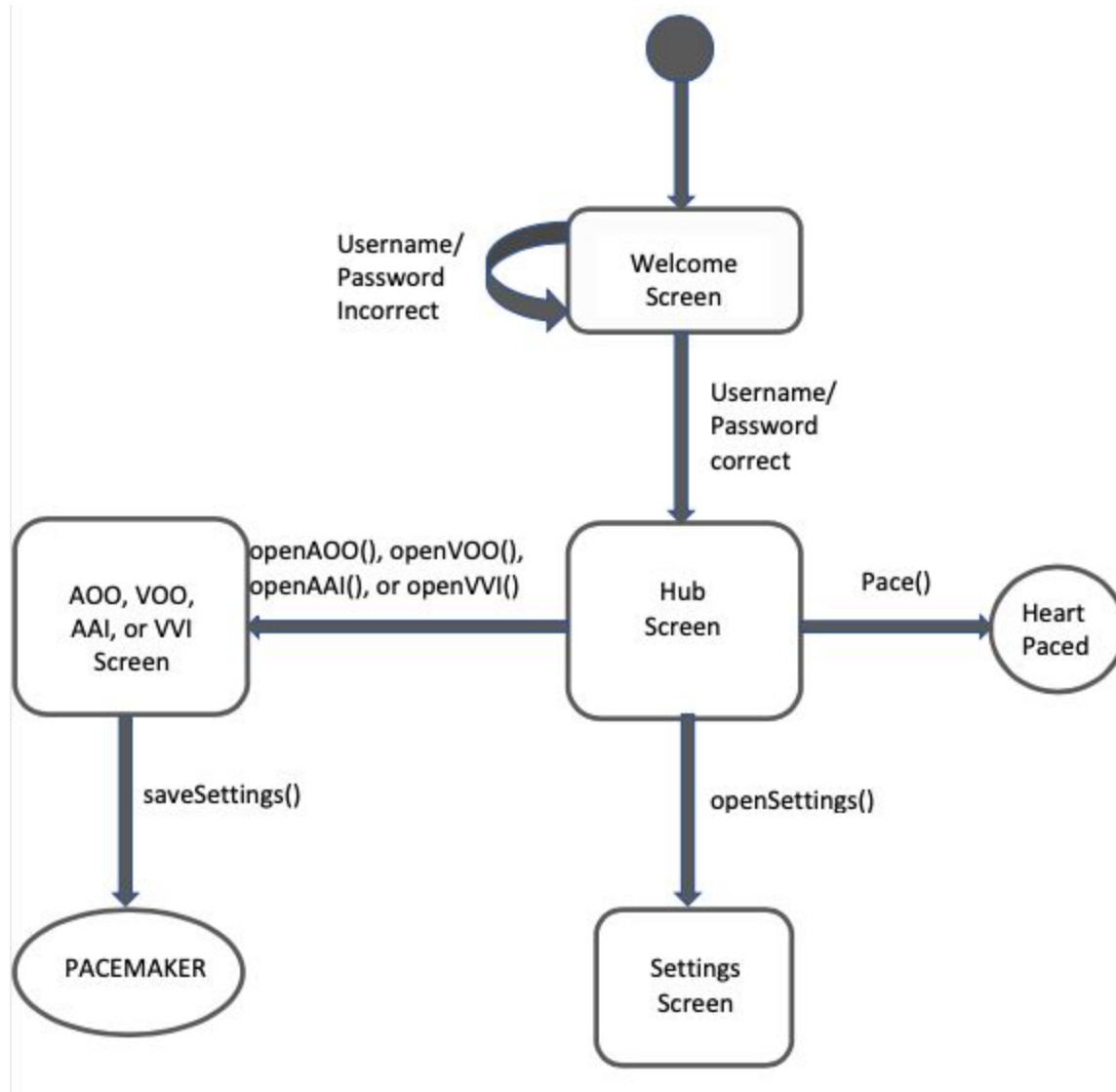
1. Addition of additional windows for more modes
2. Creation of real time Error pop up for connection lost
3. Addition of more variables as needed for additional modes

## 4 Module Interface Specification

### 4.1 Table of Modules

Name	Description
DCM_WelcomeScreen	Holds the Welcome screen for the DCM GUI
DCM_Hub	Holds the Hub screen for the DCM GUI
DCM_Setting	Holds the Settings screen for the DCM GUI
DCM_AOO, DCM_VOO, DCM_AAI, DCM_VVI	Holds the AOO, VOO, AAI, and VVI screens for the DCM GUI, respectfully

## 4.2 Finite State Diagram



## 5 Module Internal Design

## 5.1 Global Constants

Name	Type/Units	Value/Range/ Tol	Description
m_User	string	-	Holds the name of current user
m_Connection	boolean	True-False	Indications connection statues of PACEMAKER
p_pacingState	y_pacingState	True-False	Pacing State
p_pacingMode	y_pacingMode	AOO,VOO, AAI,VVI	Pacing Mode
p_hysteresis Hyst	boolean	True-False	True if hysteresis is to be used, False if not
Upper Rate Limit UpRL	ppm	120/ 50-175/ +/- 8	Maximum rate that ventricular events can be paced
Lower Rate Limit LowRL	ppm	60/ 30-175/ +/- 8	Minimum number of of generator pulses delivered per minute
Pulse Amplitude (Aor V) AtrAmp VentAmp	V	3.5/ 0.5-7.0 +/- 12%	Desired amplitude of ventricular pace
Pulse Width (A or V) AtrAmp VentAmp	mSec	0.4/ 0.05-1.9/ $\pm 0.2$	Desired width of a ventricular pace
Atrial Refractory Period ARP	mSec	250/ 150-500/ +/- 8	Duration of an Atrial refractory period
Ventricular Refractory Period VRP	mSec	320/ 150-500/ +/- 8	Duration of a ventricular refractory period
Post Ventricular Atrial Refractory Period PVARP	mSec	250/ 150-500/ +/- 8	Duration of an Atrial refractory period when using both Atrial and Ventricular pacing



Sensitivity (A or V) AtrSens VentSens	mV	A-0.75, V-2.5/ 0.25-1.0/ +/- 20%	Determines the sensitivity when using AAI or VVI modes respectively
Rate Smoothing RateSmo	unitless	3 (N/A)/ 3-21/ +/- 1%	Limits the pacing rate change

## 5.2 List Private Functions within Modules

Name	Parameters	References
checkLogin()	None	DCMWelcome()
createNewUser()	None	DCMWelcome()
openHub()	None	DCMWelcome()
openAOO()	None	DCMHub()
openVOO()	None	DCMHub()
openAAI()	None	DCMHub()
openVVI()	None	DCMHub()
openSetting()	None	DCMHub()
Pace()	None	DCMHub()
saveSettings()	None	AOOpage() VOOpage() AAIpage() VVIpage()
getModel()	None	DCMSetting()
getSerial()	None	DCMSetting()
changeLowRL()	None	AOOpage() VOOpage() AAIpage() VVIpage()

changeUpRL()	None	AOOpage() VOOpage() AAIpage() VVIpage()
changeAtrAmp()	None	AOOpage() AAIpage()
changeAtrPW()	None	AOOpage() AAIpage()
changeVentAmp( )	None	VOOpage() VVIpage()
changeVentPW()	None	VOOpage() VVIpage()
changeAtrSens()	None	AAIpage()
changeVentSens()	None	VVIpage()
changeARP()	None	AAIpage()
changeVRP()	None	VVIpage()
changePVARP()	None	AAIpage()
changeRateSmo()	None	AAIpage() VVIpage()
changeHyst()	None	AAIpage() VVIpage()

### 5.3 Functionality of Private Functions

#### DCM Welcome Screen Functions:

checkLogin()

- Gets login information from the entry fields provided. Checks to see if the given username and password are valid and contained in p\_userDatabase. Opens DCMHub() if valid

createNewUser()

- Gathers new user information from entry fields provided. Checks to see if user already exist. Raises error if it does. Creates a new username and password pair in p\_userDatabase if not.

openHub()

- Opens the Hub screen via function call.

### DCM Hub Screen Functions

openAOO()

- Opens the AOO screen via function call.

openVOO()

- Opens the VOO screen via function call.

openAAI()

- Opens the AAI screen via function call.

openVVI()

- Opens the VVI screen via function call.

openSettings()

- Opens the settings screen via function call.

Pace()

- Paces the heart via sending instructions to the PACEMAKER.

### DCM AOO, VOO, AAI, VVI Screen Functions

changeLowRL()

- Changes the value of Lower Rate Limit in LowRL.txt and displays value

changeUpRL()

- Changes the value of Upper Rate Limit in UpRL.txt and displays value

changeAtrAmp()

- Changes the value of Atrial Amplitude in AtrialAmp.txt and displays value

changeAtrPW()

- Changes the value of Atrial Pulse Width in AtrialPW.txt and displays value

changeVentAmp()

- Changes the value of Ventricular Amplitude in VentAmp.txt and displays value

changeVentPW()

- Changes the value of Ventricular Pulse Width in VentPW.txt and displays value

changeAtrSens()

- Changes the value of Atrial Sensitivity in AtrialSens.txt and displays value

changeVentSens()

- Changes the value of Ventricular Sensitivity in VentSens.txt and displays value

changeARP()

- Changes the value of Atrial Refractory Period in ARP.txt and displays value

changeVRP()

- Changes the value of Ventricular Refractory Period in VRP.txt and displays value

changePVARP()

- Changes the value of PVARP in PVARP.txt and displays value

changeRateSmo()

- Changes the value of Rate Smoothing in RateSmo.txt and displays value

changeHyst()

- Toggles Hysteresis between enabled and disabled and records setting in Hyst.txt

### DCM Settings Screen Functions

getModel()

- Gets the current model/version number of the DCM from a software data text file. Returns a string of the version number.

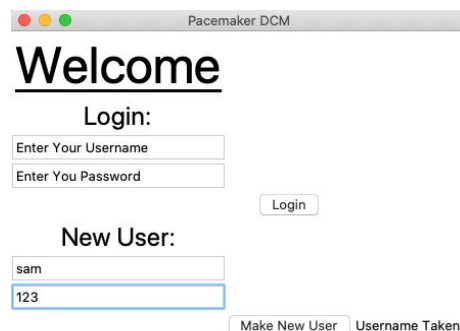
getSerial()

- Gets the serial number of the PACEMAKER from the PACEMAKER. Returns a string of the serial number.

## 6 Testing

### Testing of Welcome Screen

In order to test the create new user functionality of the DCM. We had to test that creating a new user would fail under two situations. The first situation is that a user already has the given name. To test, a user was created with the name “sam” and then the same user was attempted to be made again.

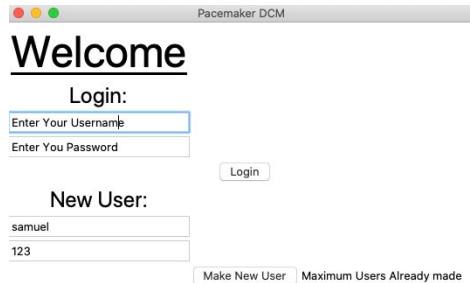


The screenshot shows a window titled "Pacemaker DCM" with a "Welcome" heading. Below the heading is a "Login:" section with two input fields: "Enter Your Username" and "Enter Your Password", followed by a "Login" button. Below that is a "New User:" section with two input fields: the first contains "sam" and the second contains "123". To the right of these fields are two buttons: "Make New User" and "Username Taken". The "Username Taken" button is highlighted, indicating the failure of the user creation attempt due to an existing username.

Figure 8. Username take test

This raised an error, and checking the file containing the usernames and passwords, a second occurrence of the user “sam” was absent. Therefore the test was passed.

In order to test the maximum number of users allowed, ten users were created and then an 11th was attempted to be made.

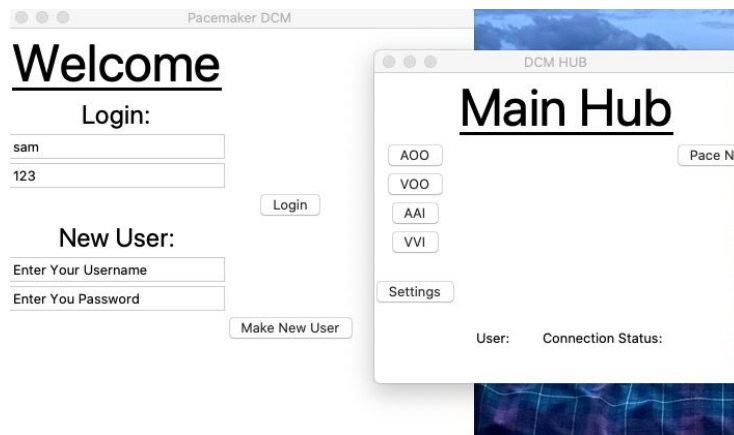


The screenshot shows the 'Welcome' interface of the Pacemaker DCM application. It features a 'Login:' section with fields for 'Enter Your Username' and 'Enter Your Password', and a 'Login' button. Below this is a 'New User:' section with fields for 'samuel' and '123', and a 'Make New User' button. A message at the bottom right of the 'New User' section reads 'Maximum Users Already made'.

Figure 9. Over creating a user test

This raised an error and after checking the file containing the usernames and passwords, no occurrence of an 11th user was found. Therefore the test passed.

In order to test the login functionality of the DCM, two tests were conducted; one where a valid username and password were given and one where an invalid username and password were given.



The screenshot shows the 'Welcome' interface of the Pacemaker DCM application. It features a 'Login:' section with fields for 'sam' and '123', and a 'Login' button. Below this is a 'New User:' section with fields for 'Enter Your Username' and 'Enter Your Password', and a 'Make New User' button. A 'Main Hub' window is overlaid on the right side of the screen, showing a 'Main Hub' title, a 'Pace No' button, and a list of buttons: 'AOO', 'VOO', 'AAI', 'VVI', and 'Settings'. At the bottom of the 'Main Hub' window, there are fields for 'User:' and 'Connection Status:'.

Figure 10. Test with valid username and password

Figure 11. Test with invalid username and password

Both of these tests passed as with a valid username and password the function `openHub()` was called and successfully executed. As with the invalid user test, it passed as an error was raised and the function `openHub()` was not called.

#### Testing AOO VOO AAI VVI Pages

In order to input new values for the variables needed in AOO, VOO, AAI, and VVI, the inputs must be in the accepted ranges outlined in section 5.1. All 4 modes follow the same logic and respond according to the variables required in each mode.

AOO Pacing Mode			
Lower Rate Limit (ppm)	60	Enter New Value	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update
Atrial Amplitude (V)	3.5	Enter New Value	Update
Atrial Pulse Width (ms)	0.4	Enter New Value	Update

Figure 12. Default Screen before user input

Default values are set when launching the program for the first time, according to the table in 5.1

AOO Pacing Mode			
Lower Rate Limit (ppm)	Invalid Value	text example	Update
Upper Rate Limit (ppm)	120	Enter New Value	Update

Figure 13. Alphabetical text test case

Alphabetical text is not accepted and informs the user of an error. The same is true with special characters or improperly formatted floating point values

AOO Pacing Mode			
Lower Rate Limit (ppm)	Invalid Value	60.5	Update
Upper Rate Limit (ppm)	Invalid Value	120.5	Update
Atrial Amplitude (V)	3.6	3.6	Update
Atrial Pulse Width (ms)	0.5	0.5	Update

Figure 14. Floating point test case

Floating point numbers are not valid for variables that require integers, and inform the user of an error. The specific type of error is not specified.

AOO Pacing Mode			
Lower Rate Limit (ppm)	Value too high	300	Update
Upper Rate Limit (ppm)	Value too low	20	Update
Atrial Amplitude (V)	Value too low	0.1	Update
Atrial Pulse Width (ms)	Value too high	7.1	Update

Figure 15. Range error test case

The program does not accept values above or below the required ranges for each variable. It informs the user if it is too high or too low.

Rate Smoothing			
Hysteresis	Disabled	Enter New Value	Toggle
Hysteresis	Enabled	Enter New Value	Toggle

Figure 16. Hysteresis Toggle test

The user can enable or disable the hysteresis mode using the toggle button. Hysteresis will be fully implemented later, but was prepared for in this version

## **7 Future Additions**

Future Additions will have to be added to the DCM in order to complete all of the requirements. Such additions are:

1. Addition of DCM and PACEMAKER communication function
2. Addition of functional Pace function
3. Addition of further PACEMAKER modes
4. Addition of Functional Connection Statue and Error raised if lost
5. Additional warnings for incorrect variable entries
6. Hysteresis full implementation