Understanding the Provided Documents

MT 3K04

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Requirements are highlighted in Green

# *Doc1:* Tutorial1.1

## Apparent Purpose

* To explain what an embedded system is, in relation to the Pacemaker Project
* To give a high level understanding of what you’re doing

## Key Content

**Intro to Embedded Systems**

* The pacemaker is an embedded system.
* Software: In the context of the pacemaker system, the embedded computer is the pulse generator
  + Pacemaker software implements bradycardia operating modes (unsure what this means at this point)
* User Interface: Device Controller-Monitor (DCM) includes a remote graphical user interface (GUI) that allows the user to receive data from the pacemaker device and, given that the pacemaker is programmable, transmit a new set of instructions to alter the behaviour of the pacemaker device.
* Input variables: represent physical connection between pacemaker leads and the Cardiac Conduction System (CCS) that allows the pulse generator to sense the electrical activity of the heart.
* Output Variables: represent physical connection between pacemaker leads and the Cardiac Conduction System (CCS) that allows the pulse generator to send electric stimuli to the heart.
* MCU and Peripherals: Packemaker system is based on an MCU called FRDM-K64F. see [link1](https://os.mbed.com/platforms/FRDM-K64F/) and [link2](https://inst.eecs.berkeley.edu/~ee192/sp18/files/FRDMK64FUG.pdf)
* Timers: needed to time the pacemaker lol
* Serial Comms: Used for the DCM, to be explored later
* K64F Pinout:   
  A diagram of a computer chip

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* Additional Peripherals: K64F has an accelerometer that’s supposed to measure a person’s physical activity level
* Driver Circuit:
  + Driver circuit controls other electric components, and connected to GPIO
  + Driver circuit we’re using is called pacemaker shield, see pacemaker shield doc for explanation on what it does

**Intro to the Pacemaker Project**

* Goal: Design and implement system that operates a cardiac pacemaker under the specified modes
* Scope: Design and implement the embedded pacemaker software, the driver software, and the user interface for the DCM
  + Also required to verify and document your software
* Deliverables
  + MATLAB Simulink® model implementing the pacemaker operating modes
  + DCM software
  + Technical Documentation
  + Live demonstration

# *Doc2:* Tutorial1.2

## Apparent Purpose

* Explaining required software

## Key Content

* Install stuff

**Errors**

* Firmware/Bootloader
  + May need to update board firmware if it doesn’t flash or has some bootloader error. See section 3.1 of this document for that.
* Hardware Setup Error (3.2)
* Missing Third Party Files (3.3)

# *Doc3:* Tutorial1.3

## Apparent Purpose

* How to use Simulink
  + How to implement & verify model
  + Stateflow

## Key Content

### Blocks

* Types
  + Simulink Blocks
    - Continuous: linear, continuous time system elements like transfer functions, integrators
    - Discrete: linear, discrete time system elements
    - Math operations: math stuff like gain, sum, and dot products
    - Ports & Subsystems: blocks for subsystems like Inport, Outport, Subsystem, and Model
      * Allows interfacing with inputs and outputs
    - Sinks: output/display signals
    - Sources: generate various signals like square waves
    - User defined functins: custom functions
  + K64F Blocks
    - Basic blocks for the GPIO
  + Stateflow
    - Combinational and sequential decision logic
* Variable step sizes cannot be mapped to the real time clock on the board so the model should have a fixed step size always
* Stateflow
* How to use Simulink and Stateflow
  + Junk tutorial imo

# *Doc4:* Tutorial1.4

## Apparent Purpose

* Explain System
* How to flash to K64F
* How to Debug Embedded Software

## Key Content

* LHS = pulse generator = K64F + pacemaker shield (driver board)
* RHS = heart sim = nucleo + driver circuit
* DCM = user application
  + Application layer = front end GUI
  + Communication layer = comms protocol between embedded software (i.e., the Simulink running on k64f) and DCM
* A diagram of a device hardware reference platform

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* Simulink is to implement the bradycardia operating modes
* **Pacemaker output**
* Connection between LHS/RHS
* One set of ribbon cables is to connect the pacemaker output to the heart
  + four wires representing the pacing output to the ventricle ring electrode, ventricle tip electrode, atrium ring electrode and atrium tip electrode, respectively

* **Pacemaker input**
  + sensing functionality of the pacemaker leads that allow it to carry electrical activity from the heart
  + separate set of ribbon cables is used to connect the heart output to the pacemaker input
  + ribbon cable has four wires representing the sensing input from: the ventricle ring electrode, ventricle tip electrode, atrium ring electrode and atrium tip electrode, respectively

* **Testing Controlling**
* A diagram of a computer hardware system

  Description automatically generated

* **Heartview**
  + Used to simulate the electrical activity in the atria and ventricles
  + Used to visualize the pacing signals produced by the pulse generator
* **Testing Controller**
  + Generates heart signals to verify the pacemaker
  + Also receives output and transmits them to you computer
  + Uses the USB interface to communicate wit Heartview on your computer
* **How to Debug Embedded Software**
  + LEDs
  + Monitor and tune
* **How to use Heartview Demo**
* Must make test cases

# *Doc5:* Tutorial2

## Apparent Purpose

* Describe pacemaker operation --> pacing, sensing
* Timing cycles/PWM

## Key Content

### Basics

* Pacemaker has 2 main functions: pacing and sensing
* Pacemaker modes determine which functions are to be performed by the pacemaker and in which chambers those functions are to be performed
* Kinds of logic:
  + timing logic 🡪 when to do which function (functions are described below)
  + Circuitry logic 🡪 read/write to GPIO pins

### Pacemaker Operating Modes

* Naming method  
  A table with black text

  Description automatically generated
* Common Modes:
  + AOO (Atrial asynchronous pacing)
  + VOO (Ventricle asynchronous pacing)
  + AAI (Atrial demand pacing)
  + VVI (Ventricle demand pacing)
  + DOO (Dual asynchronous pacing)
  + DDDR (Dual rate adaptive demand pacing)
* Permanent mode selection by changing some parameters

### Pacemaker Functionality

**Pacing Concepts**

* Read S3 of pacemaker shield for operating pacemaker hardware to generate output stimuli
* Read S3.3. of heart view to see desired waveform of pacing output

**PWM**



**Sensing Concepts**

* See pacemaker shield doc for how to control the sensing circuitry on pacemaker hardware ref plat for sense natural heart signals
* Sensitivity/sensing threshold: set it properly
* To determine reasonable level for sensing threshold:
  + pass the natural heart signals from HeartView to your pacemaker and probe the signal on a Scope in real time (using Monitor and Tune) by reading the ATR\_RECT\_SIGNAL or VENT\_RECT\_SIGNAL analog input pins
  + These signals represent the voltage seen by the comparator (Component 8 of the Sensing Flowchart) that is compared to the sensing threshold to produce the ATR\_CMP\_DETECT and VENT\_CMP\_DETECT signals respectively

**Timing Concepts**

* Choose when to sense and when to pace
* Use timing delays to track time intervals
  + Implement this in stateflow by using temporal transition labels
    - These get converted into timer stuff on the MCU

### Pacemaker Timing Cycles

* Timing cycle is shown on ECG-type schematic diagrams and are used to represent the functionality of pacemaker under a specific mode
* Useful for identifying relationships between sensed and paced cardiac events over time
* Ex: basic timing cycle for VVI
  + A diagram of an ecg

    Description automatically generated
  + Paced pulse is annotated with Vp event marker
  + First V in VVI means the pacemaker should automatically pace the ventricle once every timing cycle
  + An auto interval is the duration of a timing cycle and is referenced from the beginning of VP
  + i.e., ventricular pacing is performed at the beginning of each sensing period
  + pacemaker will release the next pacing stimulus once the automatic interval expires, which will initiate a new timing cycle
  + The automatic interval is one of the programmable parameters for VVI
  + The second “V” in “VVI” means that the pacemaker will perform sensing in the ventricle. However, to avoid sensing the artifacts of the paced QRS complex for the same heartbeat that was produced by the pacemaker, the pacemaker does not respond to sensing within the refractory period. The desired behaviour of the pacemaker is to sense the ventricle signal for a new heartbeat. As a result, the pacemaker must only respond to sensing when a sensed ventricular signal is detected outside the refractory period (V Ref above).
  + A sensed cardiac event occurs when the natural ventricular signal exceeds the ventricular sensitivity and is denoted by the Vs event marker
  + The third letter in “VVI” indicates that the pacemaker will respond to sensing by inhibiting the pace that it had planned to deliver. As a result, the pacemaker will reset its timer by commencing a new pacing period that begins at the onset of the sensed ventricular activity. The new pacing period is called the escape interval and its duration will be the same as the automatic interval.
  + For more information on timing diagrams, read the links linked at the top of Tut2 document

# *Doc6:* What Is a Pacemaker.pdf

## Apparent Purpose

* To explain the heart
* Explain CCS disorders
* Explain why pacemakers are needed, and how they work

## Key Content

* LA RA/LV RV. A --> V. LA gets oxygenated blood, RA gets de-oxygenated. LA contracts to give oxygenated to body, RA contracts to give deoxygenated to lungs
* Cardiac cycle
  + To begin a cardiac cycle, the Sinoatrial (SA) node generates an electric stimuli that is transmitted quickly to the atria, causing the atria to contract. The signal then propagates through the Atrio-ventricular (AV) node and bundle of His.
  + The AV node is a tissue that delays and relays the cardiac impulse to the ventricles via the Purkinje fibres
  + The delay typically lasts between 120-200 milliseconds.
  + The signal spreads quickly through all the ventricular muscle via gap junctions (cell-to-cell connections) causing ventricular contraction. The muscle cells then depolarize in the opposite di- rection from polarization and the chambers relax to receive blood. During most of the time period that the chamber undergoes depolarization, its muscle cells cannot produce another action potential. This is known as a refractory period.
* Nodal cells and Purkinje cells characteristics atria and ventricles to be synchronization:
  + 1. Automaticity: the ability to initiate an electric impulse
  + 2. Excitability: the ability to respond to an electric impulse
  + 3. Conductivity: the ability to transmit an electric impulse from one cell to another
* ECG
  + most commonly used lead is Lead II and electrodes are placed on the left arm and left leg.
  + The resultant waveform is a summation of various action potentials across the heart. The letters PQRST are used to indicate the waves on the ECG recording or tracing. They are used as references when assessing a patient's ECG.
    - P wave represents atrial depolarization and contraction of atria
    - PR segment represents the AV nodal delay
    - QRS complex represents ventricular depolarization and contraction
    - T wave represents ventricular repolarization
    - TP interval represents the time in which the ventricles are relaxed and filling
* How CCS triggers mechanical events of cardiac cycle
* CCS Conduction disorders (like arrhythmia)
  + Bradycardia arrhythmia = resting heart rate too slow
  + Tachycardia = RHR too fast
* How to fix? Pacemaker!
* Parts of a pacemaker
  + Pulse generator (aka can) = battery & circuits for pacing stimuli
    - Also has lead connector
  + Leads
    - Stimuli 🡪 heart, signal 🡪 pacemaker
* Device Controller Monitor (DCM)
  + Means for reprogramming pacemaker and getting telemetery from it
  + Programmable parameters include but are not limited to:
    - Pulse rate (frequency of pacing pulse)
    - Pulse width (duration of pacing pulse)
    - Pulse amplitude
    - Sensitivity of sensing circuit
    - Mode of pacing
    - Refactory period
    - Hysteresis on/off

# *Doc7:* Pacemaker(1).pdf

## Apparent Purpose

* To explain how a pacemaker works in great detail and outline the requirements for a pacemaker in the industry

## Key Content

### System Overview

**System Overview**

* The PACEMAKER system:
  + Provides dual chamber, rate adaptive bradycardia pacing support
  + Provides historical data on device performance
  + Provides user diagnostics through brady analysis functions
* The bradycardia analysis functions permit the following pacing measurements and tests to be performed:
  + Lead impedance
  + Pacing threshold
  + P and R wave measurement
  + Battery status
  + Temporary brady pacing
  + Motion sensor trending

**Device Overview**

* The device provides programmable, single- and dual-chamber, rate-adaptive pacing, both permanent and temporary.
* In adaptive rate modes, an accelerometer is used to measure physical activity resulting in a sensor indicated rate for pacing the heart.
* The device is programmed and interrogated via bi-directional telemetry from the Device Controller-Monitor (DCM), allowing the physician to change the operating mode or parameters of the device non-invasively after implantation.
* The device provides the following history data:
  + Sensor output data
  + Atrial and ventricular rate histograms.

**DCM Features**

* The DCM has the following features:
  + 1. program and interrogate a PACEMAKER
  + 2. command delivery of “Pace-Now” pace
  + 3. acquire and show diagnostics (history) and lead signal measurement in-formation.
  + 4. acquire and show sensor history and trending information.
  + 5. show visible and audible indications of communication between the DCM and device, including beeping and LED’s for alerting the operator to error conditions.
  + 6. acquire and show multi-channel monitoring including surface electrocardiogram and telemetered signals (e.g. EGM, annotated event markers)
  + 7. print reports and strip charts.
  + 8. monitor battery status.
  + 9. output to external strip-chart recorders.
  + 10. receive cursor positioning and button inputs.
  + 11. manage windows for display of text and graphics.
  + 12. set the date and time.

**Lead System Overview**

* The lead system implanted in the patient allows the device to sense intrinsic activity of the heart’s electrical signals and delivers pacing therapy to the patient’s heart.

**DCM Features During Implant**

* During implant, the DCM is used to:
  + 1. Interrogate the system
  + 2. Review battery status
  + 3. Test the PACEMAKER in the patient
  + 4. Setup the appropriate parameters
  + 5. Program the system before implantation
  + 6. Evaluate ventricular and atrial lead signal amplitudes, impedances, and pacing thresholds.

**DCM Features During Predischarge Follow Up**

* During the predischarge follow-up test, the following procedures may be performed via telemetry using the DCM:
  + 1. Interrogating the device and obtaining bradycardia sensing and pacing data
  + 2. Reprogramming to final pre-discharge value
  + 3. Printing the follow-up report for the patient’s chart

**DCM Features During Routine Follow Up**

* DCM programming is able to:
  + 1. Interrogating the device
  + 2. Checking the battery status
  + 3. Checking the brady status
  + 4. Performing P and R wave measurements
  + 5. Performing pacing threshold and lead impedance tests
  + 6. Reviewing the activity sensor history and rate histograms
  + 7. Printing a follow-up report
  + 8. If parameter values are changed during the follow-up visit, the new setting is verified by viewing the “Session Net Change” report
  + 9. Clearing the Histograms

**DCM Features During Ambulatory Care**

* The Pacing/Sensing functions will be available in the Ambulatory stage of the device life cycle.

### System Requirements

**Model Type**

* The PACEMAKER model type shall support single and dual chamber rate adaptive pacing.
* A white rectangular sign with black text

  Description automatically generated

**DCM User Languages**

* Must be available in the following languages:
  + English,
  + Danish,
  + Dutch,
  + French,
  + German,
  + Spanish,
  + Italian,
  + Swedish.

**DCM User Interface**

* The user interface is capable of the following:
  + 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.

**DCM Utility Functions**

* 1. The About function displays the following:
  + Application model number
  + Application software revision number currently in use
  + DCM serial number
  + Institution name
* 2. The Set Clock function shall set the date and time of the device.
* 3. The New Patient function shall allow a new device to be interrogated without exiting the software application.
* 4. The Quit function shall end a telemetry session.

**DCM Printed Reports**

* The following parameter and status reports are available at the user’s request:
  + 1. A Bradycardia Parameters Report shall be available.
  + 2. A Temporary Parameters Report shall be available.
  + 3. An Implant Data Report shall be available.
  + 4. A Threshold Test Results Report shall be available.
  + 5. A Measured Data Report shall be available.
  + 6. A Marker Legend Report shall be available.
  + 7. A Session Net Change Report shall be available.
  + 8. A Final Report shall be available. This will consist of the Measured Data, Threshold Test, Trending, Histograms, Implant Data, and Net Change reports.
* The following bradycardia diagnostic reports are available at the user’s request:
  + 1. A Rate Histogram Report shall be available.
  + 2. A Trending Report shall be available.
* Each report shall contain the following header information:
  + 1. Institution name
  + 2. Date and time of report printing
  + 3. Device model and serial number
  + 4. DCM serial number
  + 5. Application model and version number
  + 6. Report name

**DCM Strip Chart Recording Support**

* 1. The DCM shall be capable of displaying real time and surface ECG data, which shall be accomplished using the DCM’s internal monitor.
* 2. The system shall be capable of displaying up to three Real-Time traces (2 Telemetered, 1 Surface ECG), along with an annotation for display of event markers, in a scrollable fashion.
* 3. The DCM shall use the DCM’s internal strip chart recorder to provide a means of printing combinations of real time data.
* 4. The DCM shall be capable of printing real time telemetered data and a surface ECG.
* 5. The printer shall be capable of simultaneously printing up to three real-time traces, along with full annotation for display of event markers.

### Pacing Pulse (Simulink)

**Pacing Pulse**

* The device shall output pulses with programmable voltages and widths (atrial and ventricular) which provide electrical stimulation to the heart for pacing.

**Pulse Amplitude**

* The atrial and ventricular pacing pulse amplitudes shall be independently programmable.

**Pulse Width**

* The atrial and ventricular pacing pulse width shall be independently programmable.

**Rate Sensing**

* Rate sensing shall be accomplished using bipolar electrodes and sensing circuits.
* All rate detection decisions shall be based on the measured cardiac cycle lengths of the sensed rhythm. Rate shall be evaluated on an interval-by-interval basis.

**Sensitivity Adjustment**

* A means shall be provided for the physician to manually adjust the sensing threshold of the device for both the ventricular and atrial sense channels.

### Bradycardia Operating Modes

* The following bradycardia operating modes shall be programmable:
  + Off,
  + DDDR,
  + VDDR,
  + DDIR,
  + DOOR,
  + VOOR,
  + AOOR,
  + VVIR,
  + AAIR,
  + DDD,
  + VDD,
  + DDI,
  + DOO,
  + VOO,
  + AOO,
  + VVI,
  + AAI,
  + VVT
  + AAT.
* Temporary Operation modes:
  + OVO,
  + OAO,
  + ODO,
  + OOO
* A table with text on it

  Description automatically generated
* Definitions
  + No Response To Sensing (O)
    - Pacing without sensing is asynchronous pacing. During asynchronous pacing, paces shall be delivered without regard to senses
  + Triggered Response To Sensing (T)
    - During triggered pacing, a sense in a chamber shall trigger an immediate pace in that chamber.
  + Inhibited Response To Sensing (I)
    - During Inhibited pacing, a sense in a chamber shall inhibit a pending pace in that chamber.
  + Tracked Response To Sensing (D)
    - During tracked pacing, an atrial sense shall cause a tracked ventricular pace after a programmed AV delay, unless a ventricular sense was detected beforehand.

**Bradycardia States**

* The following bradycardia states shall be available: Permanent, Temporary, Pace-Now, Magnet, and Power-On Reset (POR). Operating states shall be mutually exclusive.
* Permanent State
  + The permanent pacing state is the normal state of operation of the device. The normal pacing parameters programmed shall be used in the permanent brady state.
* Temporary Bradycardia Pacing
  + The temporary brady pacing state is independent of other pacing functions.
  + The temporary brady parameters programmed shall be used in the temporary brady state.
  + The temporary state shall be capable of being used to temporarily test various system parameters or provide patient diagnostic testing.
  + Temporary brady pacing shall be terminated by one of the following:
    - breaking the telemetry link,
    - a Pace-Now pace,
    - or a DCM command to the device to cancel temporary pacing.

* Pace-Now State
  + Commanded emergency bradycardia pacing (Pace-Now) shall be available.
  + The Pace-Now Pace parameter values are as follows:
    - 1. The mode Pace-Now pace parameter shall have a value of VVI.
    - 2. The lower rate limit Pace-Now pace parameter shall have a value of 65 ppm ±8 ms.
    - 3. The amplitude Pace-Now pace parameter shall have a value of 5.0 V ±0.5 V.
    - 4. The pulse width Pace-Now pace parameter shall have a value of 1.00 ms ±0.02 ms.
    - 5. The ventricular refractory Pace-Now pace parameter shall have a value of 320 ms ±8 ms.
    - 6. The ventricular sensitivity shall have a value of 1.5 mV.
    - 7. The first Pace-Now pacing pulse shall be issued within two cardiac cycles plus 500 ms from the time of the last user action required to activate the Pace-Now state.
    - 8. Once initiated, Pace-Now pacing shall continue until the DCM changes the device pacing mode.

### Diagnostics

* The system provides the following diagnostic tools:
  + Measured Data diagnostic tools shall be provided.
  + Threshold Test diagnostic tools shall be provided.
  + Rate Trending and Histograms diagnostic tools shall be provided.
  + Real-time data diagnostic tools shall be provided.
* Measured Data
  + Measured Data tolerances are shown in Appendix B.
* P and R Wave Measurements
  + The device shall allow for DCM-commanded measurement of P and R waves.
* Lead Impedance Measurement
  + Lead impedance measurements works as follows:
  + 1. The device shall allow for manual measurement capability.
  + 2. DCM commanded lead impedance shall be made with the device in the
  + temporary state.
  + 3. Lead impedance measurements shall be conducted at a default value of
  + 5.5 V.
* Battery Status
  + Battery status information includes the following:
  + 1. Monitoring voltage information shall be provided.
  + 2. Battery Status indicator information shall be provided.
  + 3. Last interrogation date information shall be provided.
  + 4. The battery status for the device shall be used to predict the following battery status levels:  
    A table with text and words

    Description automatically generated with medium confidence

### Threshold Testing

* Auto threshold tests work as follows:
  + 1. An automatic pacing threshold test in AAI, VVI, and DDD modes shall be available on command of the DCM for both pulse width and amplitude measurements.
* 2. The test starts at a user-selectable amplitude or pulse width. After approximately every fourth cardiac cycle, the DCM automatically steps down the amplitude or pulse width one setting.
* 3. The user is instructed to terminate the test by removing the telemetry wand or selecting the ”Stop” button when loss of capture is observed.
* 4. The last six test results will be displayed (each chamber) on the screen and printed report.
* 5. Programmable DDD/AAI back-up pacing with a programmable rate shall be available for atrial testing, and programmable DDD/VVI back-up pacing with programmable rate shall be available for ventricular testing.

### Bradycardia History

* To assist adjustment of pacing parameters, bradycardia history is retained in PGs for viewing with DCM.

**Rate Histograms**

* The operator interface of the system shall be able to display histograms of pacing rate and intrinsic rate distributions from a histogram recording period.
* Histogram data are recorded as follows:
  + 1. Distributions shall be recorded for all paced atrial events.
  + 2. Distributions shall be recorded for all sensed atrial events.
  + 3. Distributions shall be recorded for all paced ventricular events.
  + 4. Distributions shall be recorded for all sensed ventricular events.
  + 5. The number of premature ventricular contractions (PVCs) and atrial tachycardia response episodes shall be recorded and displayed.
  + 6. The recording period for a rate histogram shall be the time since the rate histograms were last reset to the present.
  + 7. The rate histograms shall be resettable (clearing previously recorded data) via telemetry.
  + 8. All rate histograms shall be cleared simultaneously.
  + 9. The intervals associated with the histogrammed events shall begin and end at the events specified in the following table:
    - A list of events with text

      Description automatically generated with medium confidence

**Rate Trending**

* The system shall be configurable to record and display the following data items separately or concurrently over a programmable duration and storage method:
  + 1. Pacing Rate
  + 2. Sensor Data

**Rate Duration and Time Stamp**

* The recording duration shall be programmed to one of the following options:
  + 1. Fixed: Start recording now and stop when available storage is full (time stamped at beginning).
  + 2. Continuous: Circular buÆer keeping the latest information (time stamped at end).
* The recording duration shall be time stamped as indicated above.
  + The system shall display only the programmable durations that are applicable for the current pacing mode.

**Sensor Trending**

* The system shall provide off-line prediction analysis of sensor indicated rate with or without intrinsic rate for the synchronized data collected.

### 4.7 Real-time Electrograms

* Real-time internal electrograms shall be made available from
  + 1. The atrial and ventricular sense/pace leads.
  + 2. A surface electrogram.
* The real-time electrogram transmission shall be re-initiated if the telemetry link was broken during the transmission of electrograms and then reestablished.

**4.7.1 Electrogram Viewing**

* The user shall have the option of viewing the electrograms
  + 1. On the screen
  + 2. Through a printed copy
  + The user shall have the option of selecting which electrograms are viewed and the resolution utilized.
* Internal electrogram (EGM) options provided are the following:
  + 1. An atrial internal electrogram option shall be provided.
  + 2. A ventricular internal electrogram option shall be provided.
  + 3. An atrial and ventricular internal electrogram option shall be provided.
  + For the surface electrocardiogram (ECG), the user shall have the capability to select
    - 1. The gain utilized (0.5X, 1X, or 2X)
    - 2. Whether high pass filtering is on
  + For the internal electrogram (EGM), the display gain shall
    - 1. Be selectable (0.5X, 1X, or 2X)
    - 2. Apply to all channels

### Real-time Electrogram Event Marker Annotations

The capability shall exist to print and display annotated event marker abbreviations listed below on the real-time electrogram. These markers shall be a combination of intrinsic cardiac and device-related events.

* 1. Each marker shall show time-or-occurrence, accurate to 1 ms, since the most recent, non-refractory event in that chamber.
* 2. At most one atrial marker will occur each 1 ms.
* 3. At most one ventricular marker will occur each 1 ms.
* 4. At most one augmentation marker will occur each 1 ms.

A table with text on it

Description automatically generated

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### Faults and Error Handling

**4.9.1 Faults**

* DCM malfunctions shall be indicated.

**4.9.2 Errors**

* Errors indicated are the following:
  + 1. Parameter interactive limit errors shall be indicated.
  + 2. Printer errors shall be indicated.

### Bradycardia Therapy

A table of a patient's recovery

Description automatically generated with medium confidence

### Programmable Features

A table of electrical equipment

Description automatically generated with medium confidence

### Measured Parameters

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# *Doc8:* Pacemaker Shield Explained

## Apparent Purpose



## Key Content

### System Overview

* Pacemaker shield is designed to simulate the bioelectrical interface between the heart and a real-time microcontroller
* Total electrical signal = PQRST
* Note that a single electrical pulse can trigger the entire waveform.
* If the heart is pacing correctly without electrical assistance the pacemaker must then continue monitoring its activity until a malfunction is detected.
* Otherwise, the pacemaker will continually pace the heart to maintain proper functionality.
* For this application, a two-lead connection is utilized;
  + one to the ventricle (lower chamber of the heart),
  + and one to the atrium (higher chamber of the heart).
* These leads apply pulses at offset time instances to allow blood to flow throughout the heart and into the body.
* While sensing heart signals, data is collected through the same bipolar electrodes. The data from each chamber (atrium or ventricle) provides analog signals indicative of its electrical activity.
* This signal can be compared with a baseline voltage to detect a natural pulse. An electrode is found in each chamber and is responsible for both the sensing and the pacing.
* The shield accepts PWM input used to charge capacitors that determine voltage settings in various locations of the shield (ie. pulse voltage, comparator voltage, ...). In the case of an artificial pace (generated by the pacemaker) the shield utilizes the PWM input from the board to achieve the programmed pacing voltage. But if a natural pace preceeds it then the shield will detect the natural pace with the use of a comparator circuit and tuned PWM duty cycles.

### Pinout

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### Sensing Circuitry Flowchart

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See document for explanation

### Pacing Circuitry Flowchart

A diagram of a computer system

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See document for explanation

### Mandatory Pin Arrangement for Pacing

* This section will describe the mandatory pin settings in order to successfully pace. These are set as such in order to avoid critical errors that may occur otherwise (i.e. unwanted pacing, risking patient, false charging...).
* The pacing process is composed of three major cyclic states:
  + 1. Charging primary capacitor (C22)
  + 2. Pacing either Atrium or Ventricle
  + 3. Discharging blocking capacitor (C21)
  + Steps 1 and 3 can (and should) be done at the same time since they are not electrically dependent.

**Charging C22**

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**AV Pacing**

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**Discharging Blocking Capacitor**

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**PWM**

**A diagram of a circuit

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### Strength Duration Curve

* The heart will only fibrillate if it receives sufficient charge flow for a long enough time. The Strength-Duration Curve (SDC) displays the necessary voltages required for a corresponding pulsing period. Any combination of voltage and duration that is located below the curve will not be captured by the heart and will not properly pace either the ventricle or the atrium.
* A diagram of a normal curve

  Description automatically generated with medium confidence

### Proper Pace Capture

A pacemaker is not only responsible for providing timely paces to the heart but also to keep track of which paces were properly captured (a capture refers to the induced pacing of the heart due to an artificial stimuli). After artificial pacing is performed it is the job of the on-board controller to confirm that the proper natural behaviour is detected as a response. If the heart does not properly respond to the pulse it must record this incident and may be required to try again (with adjusted pulse characteristics, if necessary). Remember, the primary responsibility of the pacemaker is to ensure that proper pacing occurs! If an error occurs such as non-captured stimulus it defeats the purpose of the pacemaker.

### Desired Waveform

A diagram of a pulse

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### Pacemaker Impedance

A paper with text and images

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### Hysterisis Pacing

A page of a medical report

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# *Doc9:* srsVVI rev2

## Apparent Purpose



## Key Content

### Types

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### Variables – relevant to VVI

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### Constants

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### VVI Mode in Permanent Pacing

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### Pacemaker Interface with Device-Controller Monitor (DCM)

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**LOL just read the rest of the document, not useful rn coz no VVI**

# *Doc10:* Intro to Heartview

## Apparent Purpose

* Explain Heartview

### Key Content

* Signal Plots
* Serial Controls
* Test Case Builder
* Dispatcher
* Active Test Label
* Help Page
* Report Generation
* Plotter Controls
* A screenshot of a computer

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* How to generate reports
* Troubleshooting
* Error handling

# *Doc11:* Assignment1.pdf

## Apparent Purpose

* Explain assignment

### Key Content

### Part 1 – Pacemaker Design

* Use Simulink to implement stateflows for the following pacemaker modes for a pacemaker in permanent state:
  + AOO,
  + VOO,
  + AAI,
  + VVI (Hint: Think of the labs and the charts on Simulink).
* The stateflow should use the programmable parameters listed in the requirements document.
* You can find them using the references in the ‘Prerequisites’ section above.
  + Specifically of interest are the pulse characteristics (width, and regulated amplitude), rate characteristics (limits, and delays) and what chamber(s) are being paced.
  + Refer to Part 3 for instructions on mapping pins that are referenced by the model.
* The stateflow should not change if the pinmap is altered, but rather the correct pin should map to its corresponding component

**Hardware Hiding**

* You are required to apply hardware hiding to map the correct pins to the Simulink model (Hint: use a Simulink Subsystem to do this). Use the large table in pacemaker shield explained document to help with the mapping between hardware and design.

### Part 2 – DCM Design

* The DCM is detailed in the natural language PACEMAKER Requirements.
* There is also information in the srsVVI rev 2 document about what specific aspects of the DCM you should concentrate on.
* You are required to design and operate the DCM on your computer. Your team has the option of programming the DCM in a programming language of your 1 choice.
  + Hint: Python is a common choice to create a simple GUI (with the added bonus of a stable serial communication library, introduced in Assignment 2).
* For this assignment, you are required to:
  + 1. Develop an interface that includes a welcome screen, including the ability to register a new user (name and password), and to login as an existing user. A maximum of 10 users should be allowed to be stored locally.
  + 2. Develop essential aspects of the user interface – with respect to 3.2.2 in PACEMAKER, you should include: 1, 2 (input buttons), 3, 4, and 7.
  + 3. Develop interfaces to present all of the pacing modes mentioned in Part 1 to the user.
  + 4. Make provision for storing programmable parameter data for checking inputs – for the purposes of this assignment the parameters we want to see specifically on the DCM are: Lower Rate Limit, Upper Rate Limit, Atrial Amplitude, Atrial Pules Width, Ventricular Amplitude, and Ventricular Pulse Width, VRP, ARP. The complete set is in PACEMAKER document on page 28.
  + 5. Develop and document appropriate date structures for egram data required in future assignments.
  + 6. Implement any other requirements you elicit from the documentation that is not explicitly stated in this assignment document.
* For this assignment, you are not required to implement the communications between the DCM and Pacemaker (see Information regarding future assignments below). The scope of the DCM portion of this assignment is to implement the presentation layer (the “front-end”) of the DCM user application.

### Part 3 – Documentation

* You are required to have a full requirements document that covers your entire development process for this project. This include:
  + Part 1: For all implemented components you will need to document your design and implement the design in Simulink.
    - Document the design as follows:
    - 1. List all requirements. This should be done formally (as in not just a bunch of bullet points), but as a group you can decide what formalism you want to use (mathematical, informal, somewhere in between).
    - 2. Requirements must be concise and disjoint. They should also be traceable to the design and vice versa
    - 3. List all design decisions.
    - 4. The Simulink diagram must include necessary annotation to understand the model. There should be screenshots of the simulink model in the documentation. Provide an additional section in the document that describes testing you performed, and the results.
  + Part 2:
    - 1. List all requirements changes that are likely.
    - 2. List all design decisions that are likely to change.
    - 3. For each module:
      * (a) Describe the Purpose of the module.
      * (b) List public functions provided by the module – with their parameters.
      * (c) Describe the black-box behaviour of each function (part of the Module Interface Specification).
      * (d) Describe any global variables in the module that are within scope for all functions in the module – we call them state variables. You must describe the date structure where appropriate (part of the Module Internal Design).
      * (e) List private functions in the module, if any (part of the Module Internal Design).
      * (f) Describe the internal behaviour of each public and private function in enough detail that you can code from it with ease. Pay particular attention to how these functions maintain the state variables, or provide the values of state variables (part of the Module Internal Design).
  + Describe testing and results of those tests. This includes whether the test passes or fails. Remember, you should document every part of development, even when things don’t work the way you expect it to. There is a lot to learn from the failures that can occur during development!