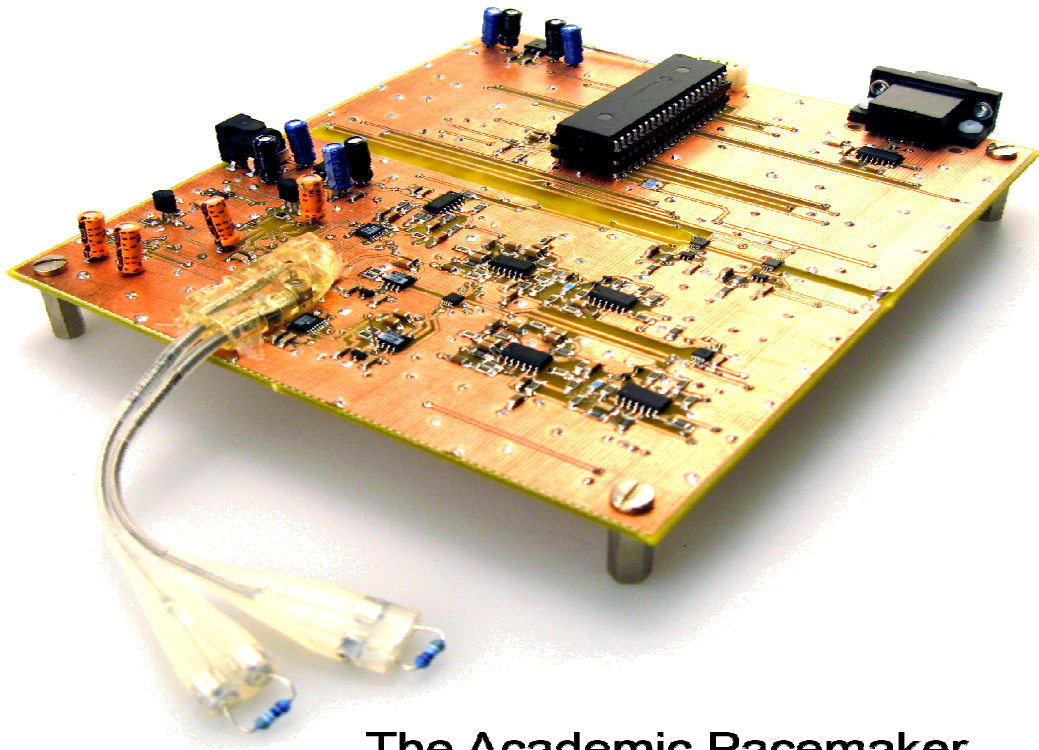# Academic Dual Chamber Pacemaker

The Academic Pacemaker

Project: 20 (Cardiac Sensing and Pacing)

Advisors: Professor Kinney and Boston Scientific (Brian Larson and Holli Pheil)

Group Members: Cliff Nixon   James Smith

Tony Ulrich   Rebecca Davis

Christopher Larson   Kua Cha

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1 Executive Summary

A challenge was presented by Boston Scientific to design and fabricate a functional DDD pacemaker adhering to strict specifications. The pacemaker's purpose was to provide a foundation for future design challenges, therefore only the basic functions were required to be implemented; sensing, pacing and lead impedance measurement. A group of 6 students from the University of Minnesota accepted this challenge as their senior design project.

After creating a system level diagram the group focused on the individual sections of the design using a divide and conquer approach. Each appropriate section was designed and verified via both simulation and prototyping. The personal goal of the group was to exceed all proposed design specifications. Proper communication between members allowed seamless execution of design implementation.

The final prototype was created; meticulous attention was given to the separation of digital and analog circuitry in order to maximize noise immunity. The pacemaker's firmware was tested and updated. Documented experiments were performed to ensure correct functionality.

The sensing circuit had high noise immunity and exceeded design specifications, sensing down to 37uV. This was achieved by providing a variable gain and reference level for the circuit, under the control of a microprocessor. The pacing circuit is able to provide nearly continuous selectable voltage amplitudes ranging from 1.2 to 7 volts, and the pulse width is only limited by the maximum frequency of the clock. The lead impedance measurement circuit has the potential to provide a consistent accurate impedance measurement of less than 1% error.

The prototype was an astounding success. All of the primary design specifications were either met or exceeded. The design group specifically implemented additional circuitry to promote product enhancement for future design challenges proposed by Boston Scientific.

This paper provides a brief description explaining the concepts and importance of pacemakers, with a concentration on DDD pacing. A detailed account of the design process, from initial concept to final results and conclusions are presented as well.

2 Introductory Material

The introductory section of this report presents the acknowledgements, pacemaker background, operating environment, intended use, and product deliverables.

2.1 Acknowledgement

The team would like to thank faculty advisor Prof. Larry Kinney, Boston Scientific's engineering advisors Brian Larson and Holli Pheil for their assistance and direction throughout the project.

2.2 Pacemaker Background

Electronic pacemakers play a vital role in today's society, providing approximately half a million people with a better quality and prolonged life. Numerous advancements have been made in pacemaker technology over the last fifty years, making current pacemakers highly sophisticated cardiac rhythm managers capable of correcting a myriad of complex heart abnormalities. The primary function of a typical pacemaker is to sense a person's heartbeat, and

pace the heart via electric stimulation when irregularities are detected. This is accomplished in many different ways due the variances found in heart conditions. One popular way a pacemaker is implemented is in a configuration commonly known as DDD, which is characterized by sensing activity in the atrium and ventricle, and is capable of pacing either or both chambers. Figure 1 is a typical example of a pacemaker (pulse generator) implanted in the heart.
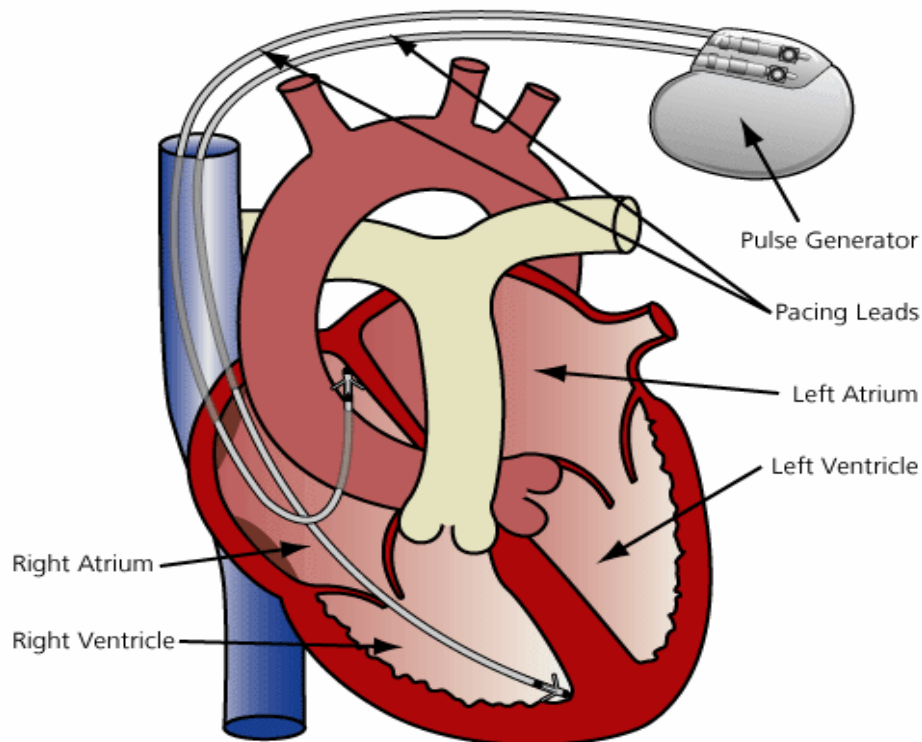
Figure 1: Pacemaker (Pulse Generator) [www.medtronic.com]

The goal of this project was to design and construct a functional DDD pacemaker intended for laboratory experimentation, which adheres to the guidelines in the Design Specifications [Appendix 3]. This project is the first phase of many projects in succeeding years which will build upon the pacemaker functions, such as telemetry and DSP, therefore special attention was given to incorporating into the project the capability of expansion and modification. Boston Scientific, a market leader in the advancement of pacemaker technology, provided guidance throughout the development of this project to ensure its success.

2.3 Operating Environment

Since the pacemaker will be used for academic purposes, the primary operating environment will be in an indoor lab setting. The system could be sensitive to ESD and should be kept in a controlled environment. The system should also be relatively durable, as it could be moved around.

2.4 Intended Uses

The team anticipates that Boston Scientific will use this pacemaker to aid in the academic environment of pacemaker design and to educate students in heart failure management. The device will be designed so that it is possible to easily reprogram and provide expansion for future design teams.

2.5 Expected End Product and Deliverables

The main end product deliverables will be delivered to Boston Scientific by the end of the project, May of 2007.

The expected deliverables will include a functional prototype designed to the expected specifications set out at the beginning of the semester. This prototype will be extensively tested and will also include documentation on the hardware and software design process. Any software that has been created for the device will also be included. This includes any software created to operate device, as well as embedded software driving the pacemaker. Schematic and PCB Gerber files will also be included on a final disc with the functional prototype pacemaker.

3 Design Research

Heart disease is increasing throughout the general population. In particular, there has been a rise in the number of people developing arrhythmias. Arrhythmias (or dysrhythmias) are due to cardiac problems producing abnormal heart rhythms. In general, arrhythmias reduce heamodynamic performance including situations where the heart's natural pacemaker develops an abnormal rate or rhythm or when normal conduction pathways are interrupted and a different part of the heart takes over control of the rhythm. An arrhythmia can involve an abnormal rhythm increase (tachycardia; > 100 bpm) or decrease (bradycardia; < 60 bpm), or may be characterized by an irregular cardiac rhythm, e.g. due to asynchrony of the cardiac chambers. A "pacemaker" can restore synchrony between the atria and ventricles when a malfunction occurs in the natural pacing of the heart.

Biomedical electronic systems are increasing in both complexity and functionality due to public demand and subsequent technological improvements. It is vital to have an understanding of both the human body and electrical engineering in order to implement functional systems. The academic dual chamber pacemaker is a step in this direction, bridging the gap between electrical engineering and biology. In order to design a system, no matter what its purpose, the area of intended use must be researched in order to obtain adequate knowledge to develop system level understanding.

In order to design the pacemaker successfully, we had to research several associated areas which included: normal heart function, typical function of pacemakers, and previously implemented designs. Much of the current information on pacemaker design is privy only to companies which are involved in this area of research. Boston Scientific released the specifications used in this design to promote academic interest in pacemaker technology. The designs which we studied came from various sources and provided the system level conception for our project. At this time, pacemaker technology is well understood, but it is constantly evolving. The primary motivation for this specific project was to develop a conceptual understanding of pacemaker technology, using various electrical engineering fundamentals to

implement a successful design. The knowledge of basic pacemaker functions is necessary in order to move into more advanced stages of research and design, exploring the possibility of new architectures and applications.

4 Design Description

Figure 2 represents the basic pacemaker system which was implemented.

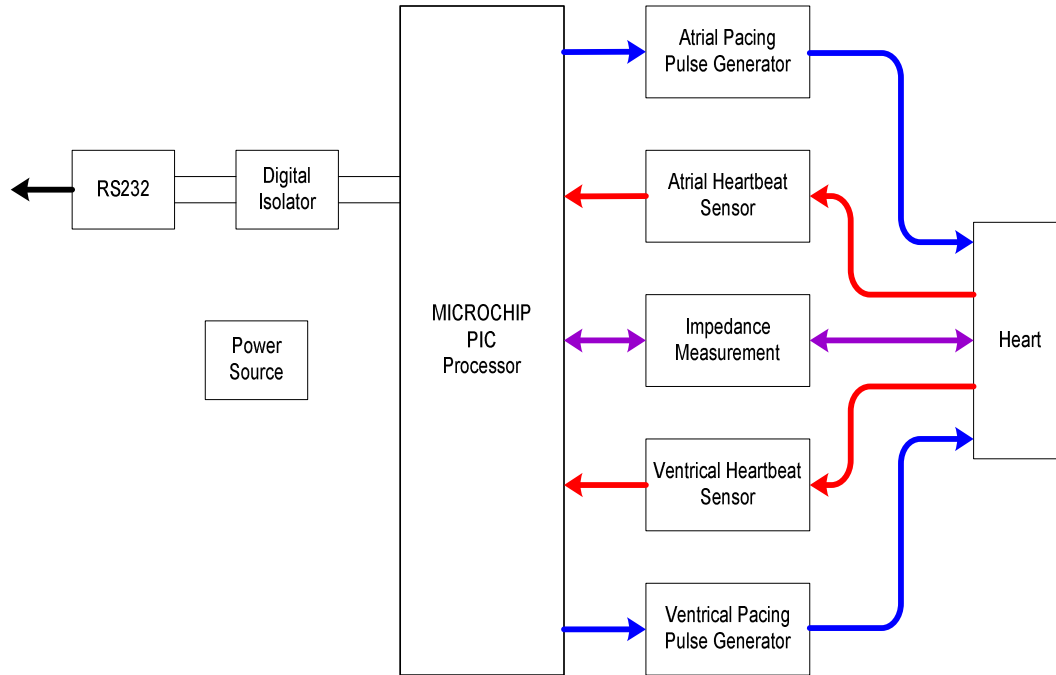**Figure 2: Pacemaker System block diagram**

4.1 Sensing

The sensing circuit was designed to amplify signals from 200uV to 30mV p-p. The following block diagram describes the sensing circuit which was implemented. Both the atrium and ventricle circuits are identical with the exception of the bandpass filter having the optimized response for each channel.
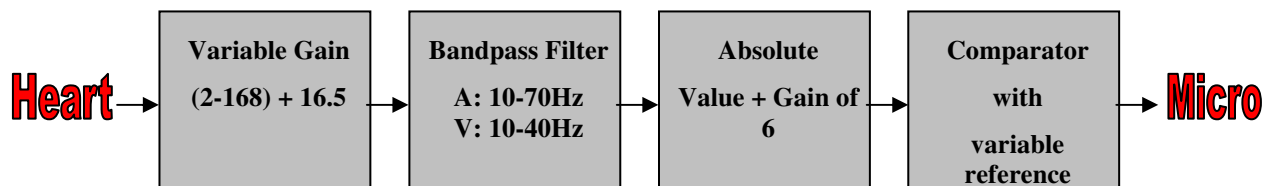

Figure 3: Block Diagram of Sensing Circuit

4.1.1 Variable Gain

An AD620 instrumentation amplifier was chosen for the initial gain stage due to its low noise and frequent use in biomedical applications. LMV324 quad op amps were chosen to implement the rest of the circuit because it has rail to rail output capability. The gain of 16.5 shown above in the Variable Gain Stage was needed due to the low signals found in the atrium. The goal was to obtain a 1V p-p signal out of this stage. Two high pass filters were used for biasing the two gain stages and were both set at 10Hz. An AD5248 (256 position digital resistor) was used to control the gain of the AD620. Figure 4 shows the gain function of the AD620 with respect to the corresponding decimal number entered into the AD5248. It is important to notice the lack of control in the high gain region, since this has a strong impact on circuit performance.
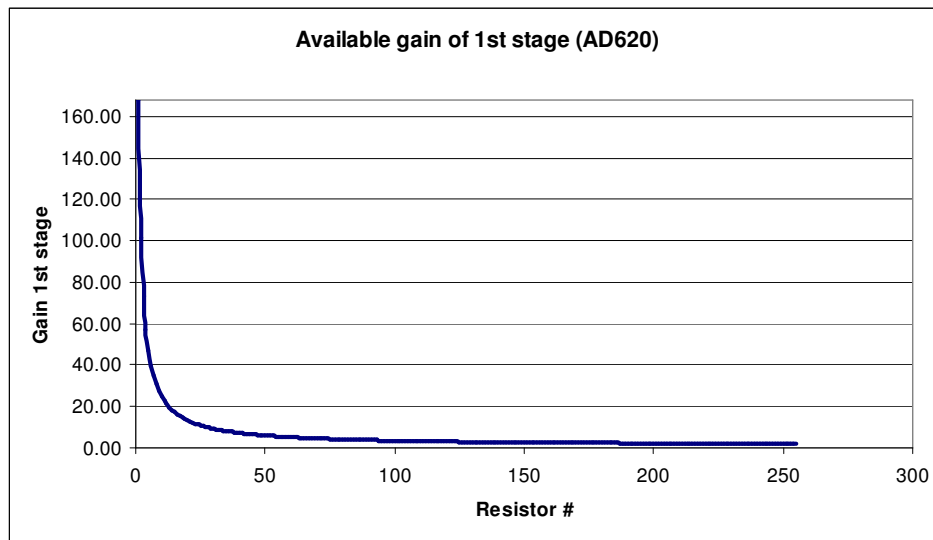
Figure 4: Gain function of AD620

4.1.2 Bandpass Filter

The filter frequencies shown in the diagram were used under the advice of Boston Scientific to achieve optimal results. Filter Pro software by Texas Instruments was used to design the Bandpass Filters which consist of two 2nd order high pass filters followed by two 2nd order low pass filters.

4.1.3 Absolute Value

Several circuits were experimented upon for the absolute value implementation. The one which produced the best results was published in EDN Magazine [4]. It is a very simple circuit that works quite well. The resistors were modified, and the diodes were substituted with Schottkys. The gain of the circuit was set to 6 in order to provide the comparator with a larger input.
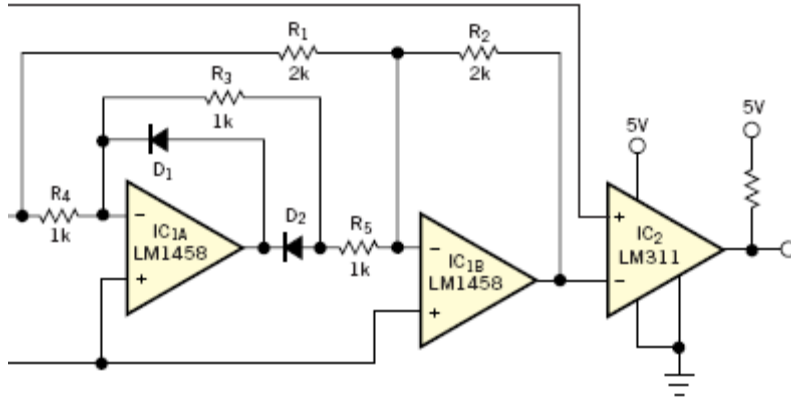
Figure 5: Absolute Value Circuit from EDN Magazine (http://www.edn.com)

4.1.4 Comparator with variable reference

The filter and gain circuits only used 7 of the 8 opamps, therefore the additional opamp was used for the comparator. An AD5248 (256 position digital resistor) is used in a voltage divider configuration in order to control the reference applied to the comparator to adjust the sensing detection amplitude. This reference was set to be variable from 1.4v to 5v, with 256 available increments. A graph showing the available reference voltage is shown below. It is important to notice that more control is achieved at lower voltage amplitudes.
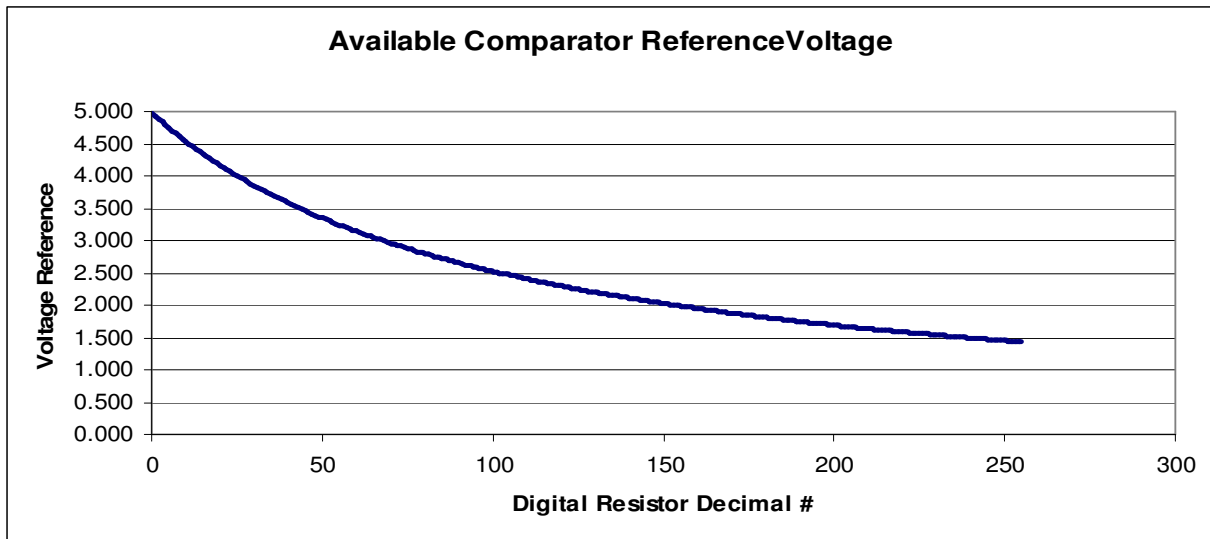
Figure 6: Comparator Reference Voltage

4.1.5 Sensing Simulation

The circuit was tested and optimized via simulation using Orcad PSPICE. By integrating the digital resistors to control gain and comparator reference, only minimal errors in sensing should occur.

4.1.5.1 Sensing Operation

(ADG888)

- Positive voltage applied to IN1 and IN2 of U13
- Ground applied to IN1 and IN2 of U16

(MAX4662)

- Switches on.: U5-A   U15-A
- Switches off: U5-B,C,D   U15-B,C,D

(AD5243)

- The gain of the AD620 is controlled by a 50k 256 position digital resistor
- The voltage reference for the comparators (U7-B and U12-B) is controlled by a 50k 256 position digital resistor (refer to excel chart)
- These two resistors will control the resolution for the gain and trip point for the sensing circuit
- The AD620 gain equation is shown below (Rw = 50 ohms) (D=0 – 255). Refer to the excel chart for the theoretical gains achieved at each stage with the corresponding resistance.
- Actual measurements will be taken to determine the necessary resistor values once the pacemaker is constructed.
- Once the pacemaker is constructed the fixed resistors controlling the gain of the 2nd stage and the last stage may need to be adjusted to obtain maximum gain and signal integrity.

4.2 Pacing Circuit

   Pacing is crucial when it comes to a patient with a cardiac arrhythmia. Each individual requires a different pace amplitude and duration for their particular needs. We analyzed several circuits that could potentially provide the desired output. The following circuit from the EE Evaluation Engineering website was used as a basis for the design. S1 is used to charge the Pacing Cap to the desired amplitude of the desired pulse. When a pace is need S2 connects to the pacing cap and discharges the cap through the heart. Once the desired pace width has been achieved S2 connects to ground and discharges the Blocking Cap through the heart.
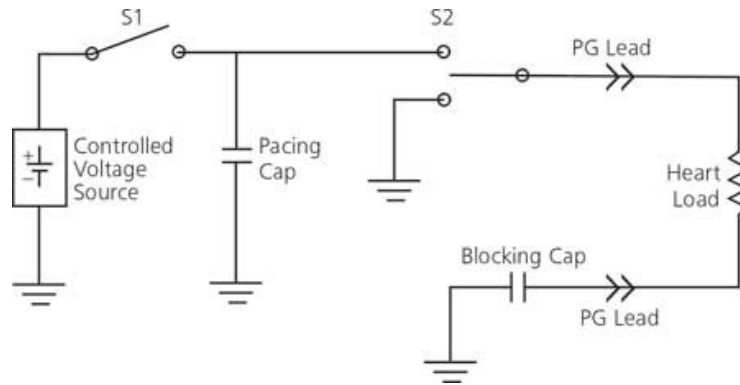
Figure 7: Basic Pacing Circuit (www.evaluationengineering.com)

4.2.1 Pacing Operation

(ADG888)

- Ground applied to either IN1 or IN2, whichever channel is being paced.
- Ground applied to IN1 and IN2 of U16 (should already be in this state)

(MAX4662) (Described for the ventricle channel)

- Turn U5-A off and turn U5-B on
- 1us later Turn U5-D on
- Turn U5-D off once the desired pulse length has been applied
- 500ns later turn on U5-C
- Keep U5-C and U5-B on for the same period of the pulse that was applied + 1us. Then turn them both off.
- 1us later turn on U5-A
- After the blanking period has expired reapply a positive to IN1 and IN2 of U13

(AD5243)

- The resistance will be previously set to provide the desired pulse amplitude.

4.3 Lead Impedance Measurement

A lead impedance measurement is taken to ensure the leads of a pacemaker are correctly inserted into the heart. When performing a lead impedance test, the resistance of the heart is measured between the tip and ring of each lead. For correctly placed leads, this resistance should be between 100 and 3000 ohms. Section 4.3.1 outlines the switch operation for the lead impedance and Section 4.3.2 outlines the procedure for measuring lead impedance.

4.3.1 Lead Impedance Operation

(ADG888)

- Ground applied to IN1 and IN2 of U13
- Positive Voltage applied to IN1 or IN2 of U16 depending on which channel is being measured

(MAX4662)

- Switches off: U5-B or U15-B depending on which channel is being measured
- Other switches will respond to a normal pace

(AD5243)

- The resistance will be set *******(to be determined)****** to provide a 2 volt pace pulse. (Allow time for the pacing cap to discharge to 1v)

(Pacing Pulse)

- The pulse shall have a period of 100us or less and 2v amplitude.
- The pulse will be sampled in the middle of the wave to avoid transients and is biased at 2.5v.

(Impedance Equation)

- Simple Voltage Divider
- RHeart = (2k * Vout) / (V(applied) – Vout)
  - ○ [Where Vout = Vout (U24A or U24D) – 2.5 and V(applied) = 2v if a 2v pulse is used]

4.3.2 Lead Impedance Measurement Procedure

- The heart is placed in series with a 2k resistor
- A normal pace is made
- The peak voltage dropped across the heart is measured by a differential amplifier and sent to an ADC on the microcontroller.
- The microcontroller samples the signal from the amplifier and outputs the peak value of the pulse.
- The following equation is used to determine lead impedance

- $Z = (2K * V) / (Vpace - V)$, where $V = Vout(diff\ amp) - 2.5$ and $Vout(diff\ amp) =$ the peak voltage dropped across the heart, 2.5 is used for biasing

4.3.3 Lead Z Simulation

The following data was taken from simulation using Orcad PSPICE. Lower percentage of errors can be achieved by using faster pulses, taking measurements close to the beginning of a pulse, and by increasing the input impedance to the differential amplifier.

RHeart	%Error
500	.026
1k	.033
2k	.95
3k	.94

4.4 Digital Control

At the core of the pacemaker is a PIC18f452 microcontroller. The PIC is responsible for directing the pacing of the heart. This particular microcontroller was chosen because of its wide academic use and flexible IO ports. The PIC18f452 is used by many instructors and publishers for teaching the basics of microcontrollers. As a result, there is a plethora of code and reference guides available to assist with programming. (one of the most useful resources is the free, academic version of Microchip's 18f compiler.) The IO ports of the PIC18f452 include several communication protocols and interrupts that streamline programming and increase response times. The comparators make use of the interrupt driven IO pins, the analog to digital converters make use of the SPI port and the computer interface uses the serial port. A third communication protocol is used for adjusting the digital resistors, but due to its relatively infrequent use, it is implemented in software.

4.4.1 Programming

The firmware for the microcontroller was written mostly using Microchip's MCC18 student edition C compiler. Several important functions have been written to assist with programming. The main functions are listed below along with where they are found and the basic function they perform.

Init.h

The routines in the init.h file are used to setup the initial conditions of the microcontroller.

initinterrupts	Sets up the timer1, INT0 and INT1
initUSART	Sets up the USART for a baud rate of 19200 and low priority interrutps
initcounter	Sets up the timer1 prescalar

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initres	Sets up the IIC communication on RD3 and RD2. Initializes the values of the digital resistors.
initspiAD	Sets up the SPI communication between the digital resistors.

Com.h

The routines in the com.h file are used for sending data between the microcontroller and the peripheral devices.

ReadSPI	Used to read a byte from the SPI
putsSPI	Used to write a string to the SPI
OpenSPI	Used to turn on the SPI
getsSPI	Used to read a string from the SPI
DataRdySPI	Used to check if data is present in the SPI buffer
WriteSPI	Used to write a byte to the SPI

Res.h

The routines in the res.h file are used to communicate with the digital resistors.

delay6	This is the pulse low time
delay3	This is the pulse high time
clockbit	Used to clock a bit to the resistors
setRes	Used to send a byte to the specified resistor using the IIC standard

Text.h

These routines are used to transmit data via the serial port.

linefeed	Send an ASCII line feed command
endtext	Send an ASCII end of text command
BtoC	Send a byte in ASCII hexidecimal

Main.c

This is the main program, but also contains a couple important functions that should be mentioned here.

linefeed	Send an ASCII line feed command
endtext	Send an ASCII end of text command
BtoC	Send a byte in ASCII hexidecimal

5 Circuit Design Evaluation

5.1 Sensing

It is imperative for the sensing circuit to be immune to noise. Shown in Figure's 8 and 9 are two graphs of the actual input signal which was used for testing the pacemaker. Figure 8 shows a 10mV signal with 342 mV p-p of noise, and figure 9 is a zoomed in snapshot of figure 8. This was done to test the capabilities of the filtering in order to extract the useful signal. The only part which contains useful information (simulated heart wave) is the 10mV p-p signal in the noise. Smaller signals were not distinguishable by the human eye due to the interference.

Figure 8: 342mV noise, 10mv signal

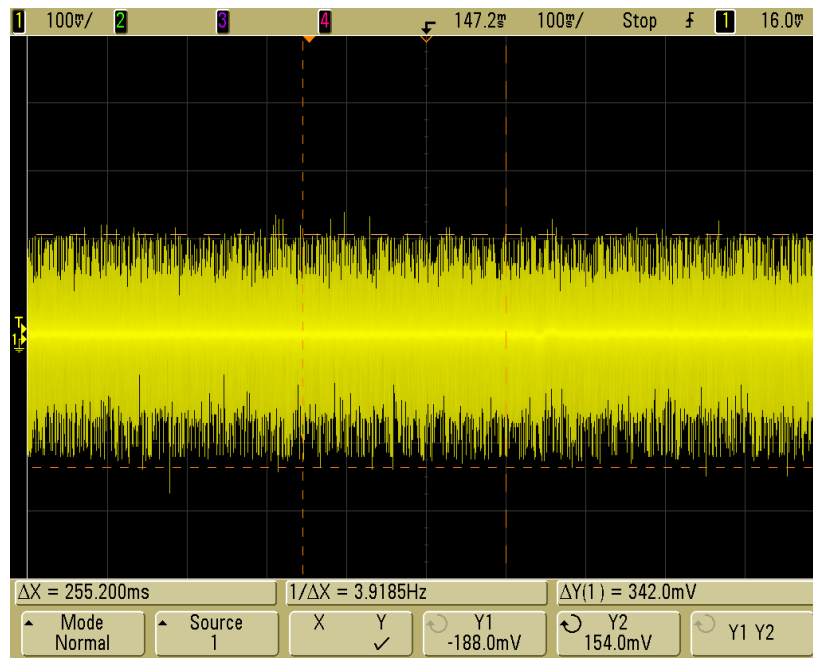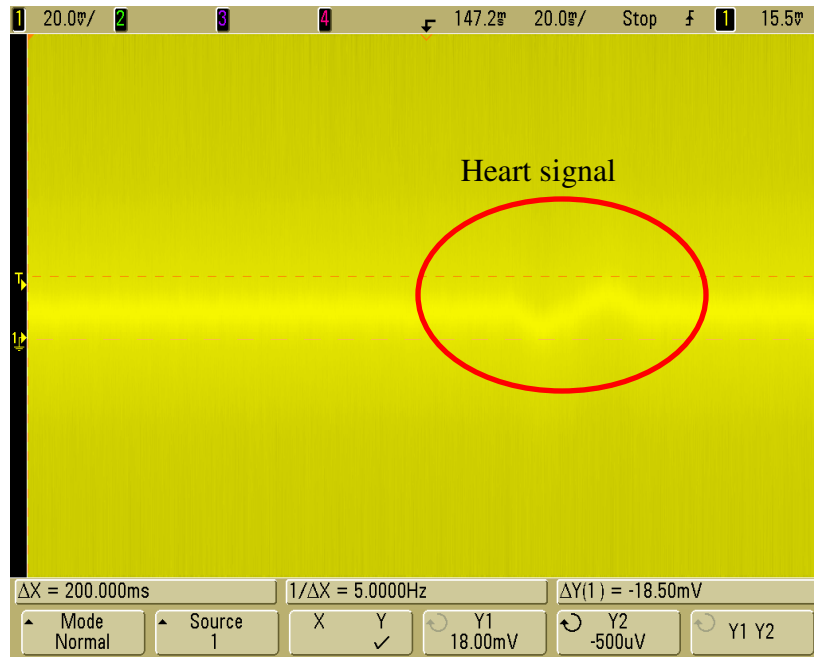**Figure 9: Magnified view**

Figure 10 shows the signal after it has passed through the bandpass filter; the input used in this case was 5mV. Figure 11 shows the signal after it passes through the absolute value circuit (green (top signal)), and the output of the comparator representing a correctly sensed heart signal (yellow (bottom) signal).
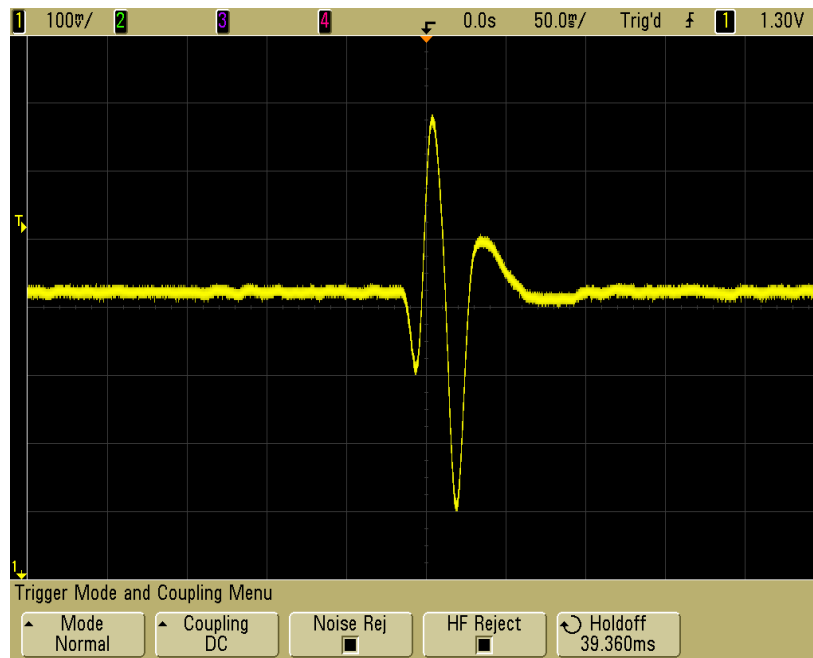
Figure 10: After filtering (5 mV input)
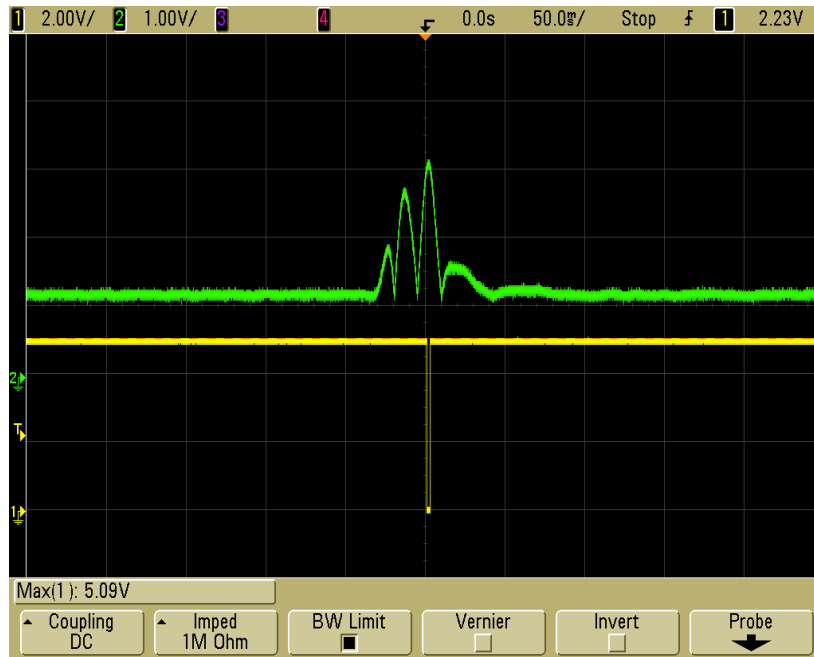
Figure 11: (Green - after absolute), Yellow (ouput of comparator)

Further testing showed that we could detect a signal down to 37uV with 100% accuracy. Detecting down to this level far exceeded the design specification (appendix 3) of 200uV. Figure 12 show a 200uV signal after the absolute circuit prior to entering the comparator, showing that it was possible to sense down to the required level.

Figure 12: Output of Absolute Value (200uV input)

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Figure 13 shows the Comparator input verses the Signal Input. Referring back to the gain graph of the AD620 (figure 4) in the sensing Design Description section, it can be seen that the gain is based on a 1/x curve. There is very little control in the high gain region, which accounts for the lower voltage values when the signal input is in the low range. Referring b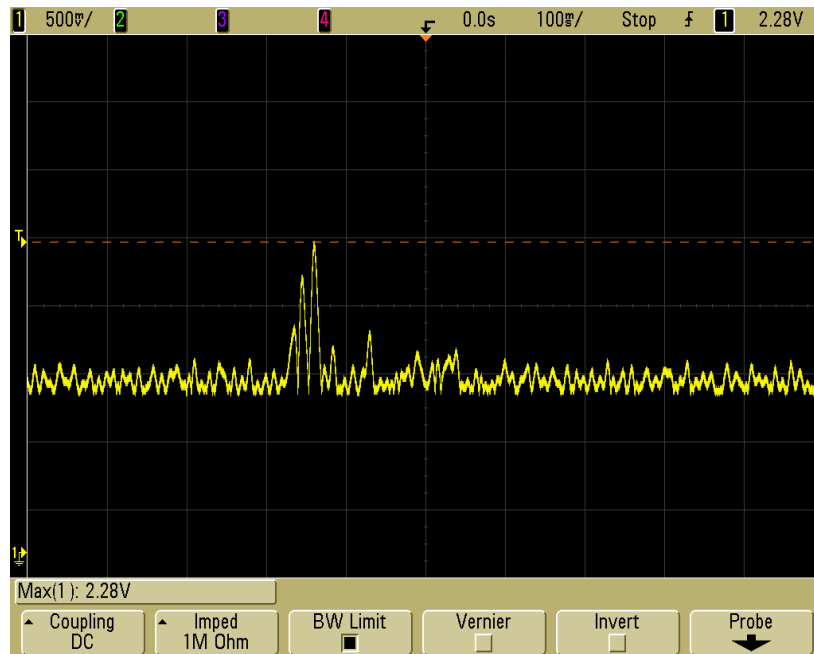ack to the voltage reference graph (figure 6), it can be seen that when the voltage is lower, there is more control over the comparator reference. This combination was intentional and was needed in order to keep the percentage of error at a minimum. For each input, the gain and reference must be adjusted accordingly, until about a 1mV signal has been reached, then the reference can be left constant, and only the gain needs to be adjusted.

Table 1 was used to test the circuit, to see how closely theory and measured results compared. The interesting thing about the results is that the measured results are almost precisely 1V different from the theoretical. We expected some attenuation but not that much. The loss was attributed to the inaccuracy of the input signal source; so this was taken into account when computing the final percentage of error, and was not seen as a problem in the circuit.
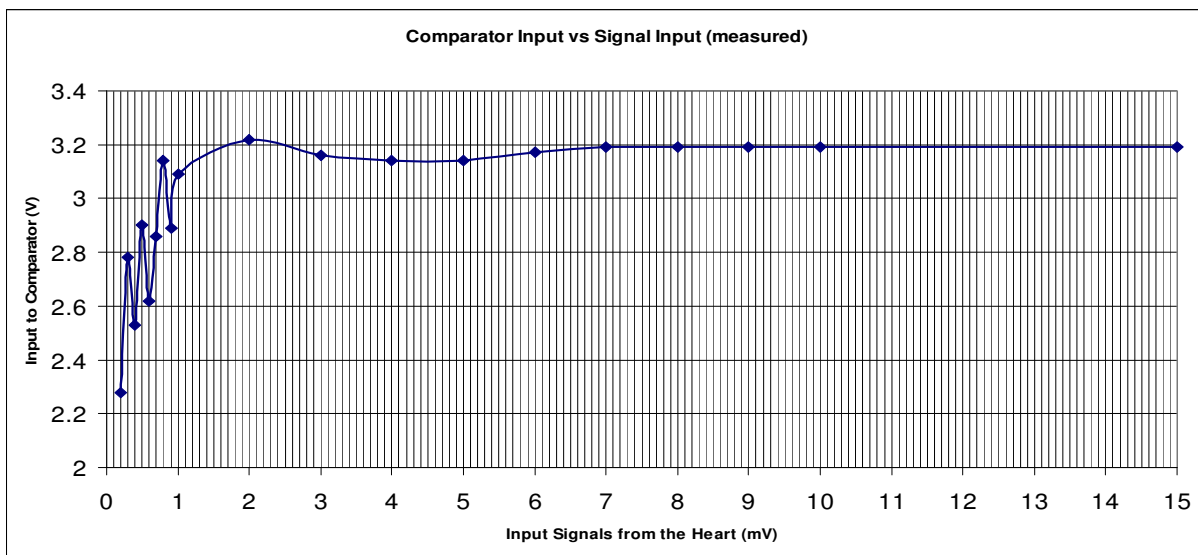
Figure 13*: Comparator Input vs Input

Table 1: Compare Theoretical vs Measured Results

Input Signals From Heart + Noise	Gain Required for 60mV AD620	Gain Achieved From Digital Resistor	Output of AD620 60mV desired	Output V Second Stage 1v p-p desired	Voltage Input to Comp	Measured Voltage Input to Comp	Difference between measured and expected	Percent of Error (add 1v)
0.00020	300.0	168.28	0.034	0.557007	2.87102	2.28	-0.59102	14.2451
0.00030	200.0	168.28	0.050	0.83551	3.706531	2.78	-0.92653	1.982161
0.00040	150.0	101.69	0.041	0.673188	3.219563	2.53	-0.68956	9.642196
0.00050	120.0	101.69	0.051	0.841485	3.724454	2.9	-0.82445	4.713328
0.00060	100.0	73.02	0.044	0.725089	3.375266	2.62	-0.75527	7.250813

Input Signals From Heart + Noise	Gain Required for 60mV AD620	Gain Achieved From Digital Resistor	Output of AD620 60mV desired	Output V Second Stage 1v p-p desired	Voltage Input to Comp	Measured Voltage Input to Comp	Difference between measured and expected	Percent of Error (add 1v)
0.00070	85.7	73.02	0.051	0.845937	3.73781	2.86	-0.87781	3.269024
0.00080	75.0	73.02	0.058	0.966785	4.100354	3.14	-0.96035	0.966882
0.00090	66.7	57.06	0.051	0.849909	3.749726	2.89	-0.85973	3.740911
0.00100	60.0	57.06	0.057	0.944343	4.033029	3.09	-0.94303	1.412611
0.00200	30.0	30.71	0.061	1.016501	4.249503	3.22	-1.0295	-0.69427
0.00300	20.0	19.72	0.059	0.979098	4.137294	3.16	-0.97729	0.548813
0.00400	15.0	14.66	0.059	0.970492	4.111476	3.14	-0.97148	0.693765
0.00500	12.0	11.76	0.059	0.97314	4.11942	3.14	-0.97942	0.499585
0.00600	10.0	9.87	0.059	0.980091	4.140273	3.17	-0.97027	0.717996
0.00700	8.6	8.55	0.060	0.990518	4.171553	3.19	-0.98155	0.442221
0.00800	7.5	7.57	0.061	1.002268	4.206804	3.19	-1.0168	-0.39945
0.00900	6.7	6.68	0.060	0.994986	4.184958	3.19	-0.99496	0.120479
0.01000	6.0	6.01	0.060	0.994655	4.183965	3.19	-0.99397	0.144241
0.01500	4.0	3.99	0.060	0.990518	4.171553	3.19	-0.98155	0.442221

Figure 14 shows the measured frequency response of the pacemaker. (10 – 70 Hz for the Atrial and 10 – 40 Hz for the Ventricle). There are two 2nd order high pass filters set at 10Hz used for biasing due to having a single supply which accounts far the sharper roll off on the low side, giving 6 poles total on the low side (120 dB/dec) and 4 on the high (80 dB/dec). The graph produced is an approximate representation of these cutoff frequencies, with a few anomalies located in the higher frequency range which are consistent between both channels.
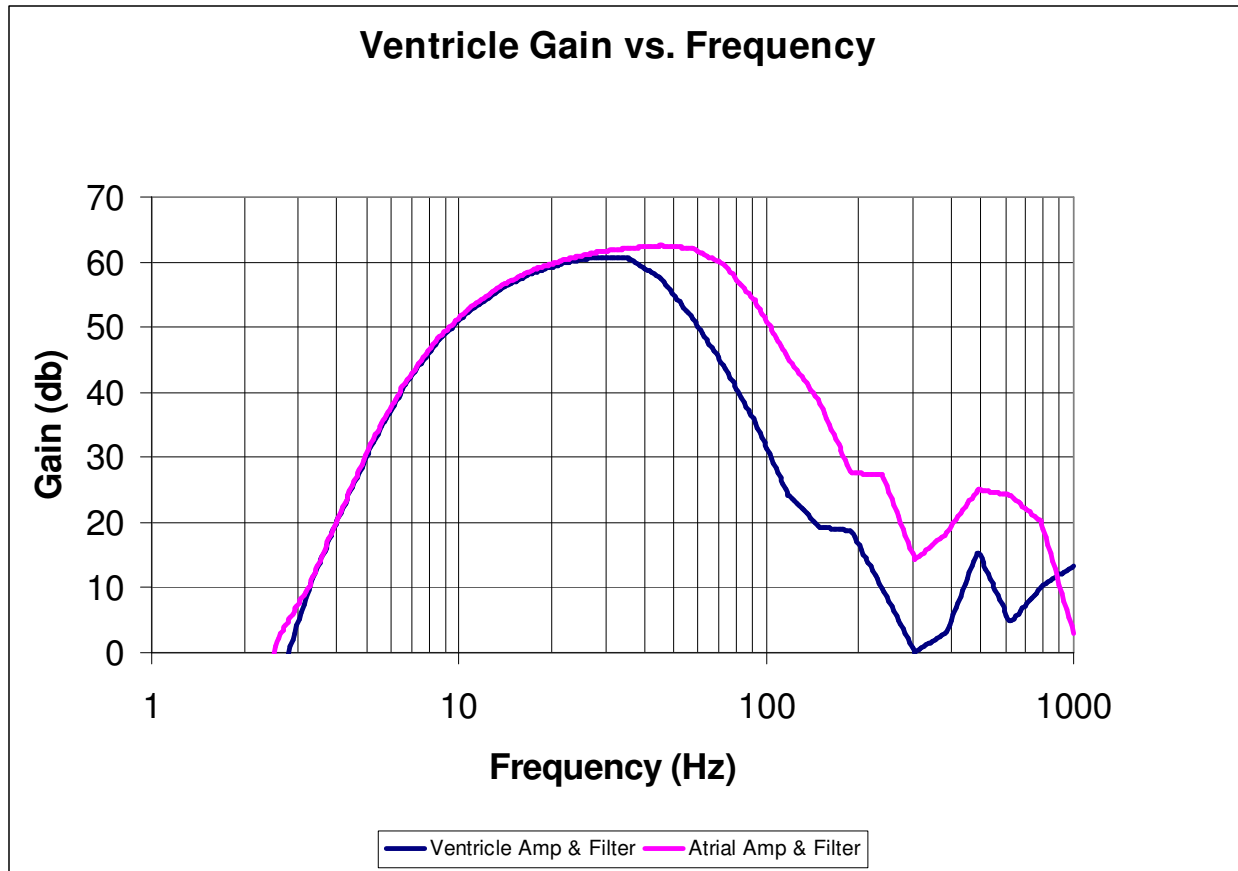
Figure 14: Sensing amplifier frequency response

5.2 Pacing

Pacing is crucial to the operation of a pacemaker. The pulse amplitude as well as the pulse width has to be variable to account for physiological differences between people. The pulse amplitude has to be variable from between 1.2V to 7V. The timing is also incredibly important in delivering a pulse. A pulse at the wrong time could cause the heart to go into ventricular fibrillation. Whether a pulse is administered as well as the timing of the pulse is controlled by the microcontroller.

The basic operation of the pacing circuit is as follows. When the sensing part of the circuit does not sense any abnormality of the normal heart rhythm no signal will be sent from the microcontroller to pace and so nothing will happen and the switch will remain open. Once the sensing circuit notices the heart beat slowing down the microcontroller will send a signal to the pacing circuit causing the switch to close and thus completing the circuit. The capacitor will then discharge and a pulse to the heart will be delivered. This pulse can be programmed to be of various amplitudes and widths. These values for any specific person are determined in tests when pacemaker is first implanted. Once the heart goes back to a normal rhythm the switch opens and the capacitor is then recharged and ready for the next pulse.

Shown in figure 15 is a 6v pacing pulse produced by the pacemaker. The pacing circuit was tested thoroughly and provides a full range of amplitudes ranging from 1.2 to 7v. The pulse width is fully programmable only limited by the frequency of the clock.
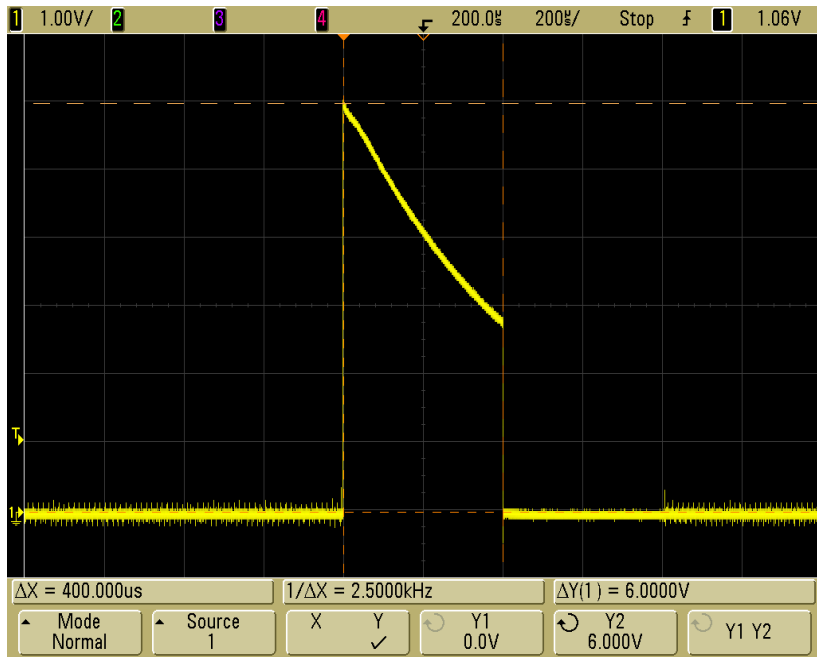
Figure 15: Pacing Pulse

6 Conclusion and Recommendations

6.1 Design Specifications Met

6.1.1 Sensing

The sensing circuit was required to have a sensitivity of + - 20%; as shown in the table in the last section this was easily achieved. It is also possible to obtain an error of less than 1% under all inputs via adjustment of the digitally controlled voltage reference at the comparator with respect to the measured results.

6.1.2 Pacing

The pacing circuit was required to provide a pulse width of .05ms to 1.9ms, with a .2ms tolerance. This was easily accomplished through digital control of the semiconductor switches involved in pacing. The pacing amplitude was required to be variable from 1.2 to 7v, with a tolerance of 12%. This was also achieved; therefore all pacing design requirements have been met.

6.1.3 Lead Impedance Measurement

The program for measuring lead impedance was not written due to time constraints. The theory for performing this operation has been verified, and simulation yielded excellent results. The requirements for this circuit are lenient, allowing 25% error. Simulation proved that an error of only 1% can be obtained. Taking into account resistor tolerances and voltage drops across switches, the error is expected to be no greater than 5%. All of the circuitry is in place, and we regret that we were unable to find the time to implement it.

6.1.4 Control

We tested the functionality of the pacemaker numerous times and had to make several updates to firmware in order to comply with the specifications. We believe the system is fully functional at this point and meets all specifications regarding control of the rate limits and blanking periods. Firmware implementation can often contain unforeseen problems which are further described in section 6.2.3.

6.2 Future Implementations / Improvements

6.2.1 Sensing

The original digital resistors chosen were 1000 position rather than 256. They were not used due to additional complexity in programming. We recommend using the 1000 position to achieve higher precision in the high gain stage of the AD620. This would allow the voltage reference at the comparator to remain constant under most all conditions. Also it is suggested to include a 2nd order passive low pass filter right at the input of the AD620 to reduce high frequency noise, so that more accurate measurements can be made. This will also clean up the total system frequency response as shown in the appropriate graphs.

6.2.2 Safety Redundant Systems

Safety Redundant Systems are widely used in current pacemakers and should be implemented at all times. This increases complexity, but is necessary in order to produce a robust system. One such implementation would be to block the pacing of the atrium while the ventricle is being paced, thereby preventing potential heart failure. The microcontroller keeps this from happening under normal conditions, which is why this is a redundant system. It is easily implemented by using the ventricle pulse as a trigger connected to a buffer amplifier with a simple timing circuit controlling a switch to disable the atrial pace circuit. There are numerous systems, such as this, which could be implemented to further enhancing the pacemaker's functionality. Basically any function of the pacemaker which could lead to heart failure needs to incorporate a safety redundant system.

6.2.3 Firmware

Programming can always be improved in virtually any system. There always exists the potential for problems due to the interpretation of compilers. Even a system which has been thoroughly tested can still have numerous problems waiting to surface under the right circumstances. Therefore it is our suggestion to investigate the code thoroughly, and perform numerous tests to verify correct functionality. One suggestion would be to use assembly language to implement the control functions. Lower level languages, although difficult to use, provide a more concrete solution.

One improvement which could be made in programming would be to make all of the parameters obtained from the specifications fully programmable by the end user. That is, a simple user interface could be created to set the upper and lower rate limit, pulse amplitudes, etc. Any system which is to be used by people other than Engineers (Doctors in this case) should provide an intuitive and simple user interface. This is the largest downfall of many systems which are produced.

6.2.4 Future Designs

The "Pacemaker System Specification" Reference [5] which was provided by Boston Scientific contains numerous specifications concerning the implementation of advanced features requiring the use of techniques such as telemetry, DSP and power management. The possibilities for improvements are endless.

6.2.5 Design Process

To implement the design, the group was divided into teams and areas which maximized talent and ability (Divide and Conquer). This process worked well for some and not so well for others. We chose no leader, and this is something which should have been done in order to allocate the work more evenly. Everything went fairly well given the short time period allotted. A lot could have went wrong, but didn't. There were many things which we would like to have accomplished, such as implementing lead impedance and extensive testing, but were unable to do so due to time constraints.

From our experience we would suggest to first designate a Project Manger. Then create a document clearly stating the requirements and expectations from each individual in the group. This document should contain specific dates pertaining to milestone completion, which should be well before due dates so that other members of the group can take action in the event that certain milestones are not met. It is imperative to have a plan of action if this occurs so that the work can be spread out evenly once again. This document should be signed by all group members, including the group advisor. Hopefully by following this method of simple project management procedure everyone will stay on track and treat the project as a job. Good Luck!

7 References

[1]   Cardiac Pacemakers Step by Step, An Illustrated Guide, Barold, Stroobandt and Sinnaeve. Blackwell Publishing Inc. 2004

[2]   *Design of Cardiac Pacemakers*, John G. Webster. IEEE PRESS, 1995

[3]   *Absolute-value comparator touts accuracy, size*, Teno Cipri, Engineering Expressions Consulting, Sunnyvale, CA -- EDN, 3/7/2002

[4]   *Testing Implantable Medical Devices*, J. Max Cortner (Guidant), EE-Evaluation Engineering, Nelson Publishing Inc., 2007

[5]   *PACEMAKER System Specification*. Boston Scientific. 2007.

8 Appendix

1. Schematic
2. Parts Placement: top and bottom layers
3. Design Specification
4. Bill of Material
5. Time Line (Gantt chart)