P10022

Transcutaneous Signal Transmission for LVAD

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Change Log

Item	Description of Change
Agenda	New agenda.
Meeting Customer Needs	Added to address customer needs
Specifications	Accounted for op-amps change
Proposed diagram	Accounted for op-amps change
Body Diagram	New diagram
High-level Diagram	New diagram
Wire Size Picture	Moved from end of document
Pin Assignments	All tables included in full
Packaging of TETS	Deleted Silicone Mold idea, not needed
Feasibility of Design	New section to address primary component selection
Charging Circuit	Deleted, incorporated with battery
Wireless Power Transfer	Charging Circuit is now in battery
Enclosure Design	Dimensions have changed. Assembly pictures have been added to show how components fit.
Screws	Enclosure lid screws have changed to incorporate o-rings. Separate o-ring part removed.
Heat Transfer	Heat Transfer updated to be more accurate
Wire and Cable Selection	Changes made to wire gauges. Power wires split.
Bill of Materials	Updated to include all components and incorporate lead times, and identify colors
Test Plans	Updated to reflect most recent changes
Flexibility Test Plan	Significant changes to text to describe new test methods Flexibility test finalized
Risk Assessment	List updated to include only most relevant risks based on current state of project. Actions taken column added.
Project Schedule for MSDI	Shows tasks completed in MSD I
Project Schedule for MSDII	Added to show schedule for MSD II

Table of Contents

Detailed Design Review Agenda

Meeting Purpose*:*

1. Overview of the project
2. Present the design concepts
3. Confirm the design functionality
4. Confirm materials and components needed for design

Materials to be Reviewed:

1. Address meeting customer needs
2. Electronics feasibility
3. Risk Assessment
4. Design and Test Modifications

Meeting Date: 11/17/09

Meeting Location: 09-4425

Meeting time: 2:30 – 3:30 pm

Meeting Timeline		
Start time	**Topic of Review**	**Required Attendees**
2:30	Addressing customer needs	Dr. Day,Dr .Lux,Dr. Cheng
2:40	Electronics Feasibility	Dr. Day,Dr .Lux,Dr. Cheng
2:45	Wire modifications	Dr. Day,Dr .Lux,Dr. Cheng
2:40	Address use of risk assessment	Dr. Day,Dr .Lux,Dr. Cheng
2:50	Casing Modifications	Dr. Day,Dr .Lux,Dr. Cheng
3:00	Bill Of Materials	Dr. Day,Dr .Lux,Dr. Cheng
3:10	Test Plan Modifications	Dr. Day,Dr .Lux,Dr. Cheng
12:45	Questions, Concerns, Ideas, Review	Dr. Day,Dr .Lux,Dr. Cheng

High-Level Project Summary

Project Background:

A Ventricular assist device, or VAD, is a mechanical device that is used to partially replace the function of a failing heart. Some VADs are intended for short term use, typically for patients recovering from heart attacks or heart surgery, while others are intended for long term use, typically for patients suffering from congestive heart failure. Long term VADs are normally used to keep patients alive with a good quality of life while they wait for a heart transplant. The first versions of the RIT LVAD blood pump used a large cable through the skin to transmit all power and control signals. The lack of flexibility in this cable caused discomfort, limited range of motion and infection.

Problem Statement:

Eliminate as many wires as possible going through the dermis of the patient from the exterior electronics to the Left Ventricular Assist Device (LVAD) blood pump. This can be achieved using wireless technology or by other design means of eliminating unnecessary wires.

Objectives/Scope:

1. Improve flexibility of cable by eliminating redundant wires.
2. Ensure functions of the LVAD are not impaired.
3. Ensure safety of implanting the casing for internal components.

4. Wireless power transmission is optional.

Deliverables:

- Improved signal transmission that meets customer needs
- New design, sketches, mechanical and electrical drawings
- Documented signal transmission data
- A functioning prototype

Expected Project Benefits:

The current design uses 23 wires leading from the control unit to the LVAD blood pump, entering through the skin and into the body of the patient. The design is associated with many health risks to the patient because the exposure of the tissue to the cable causes many infections which often lead to death of the patient. Our project benefits the patient by eliminating all but four of the wires leading to the LVAD heart pump, therefore, reducing the size of the cable, and therefore the chance of infection.

Core Team Members:

- Carl Hoge
- Keith Lesser
- Oxana Petritchenko – Project Manager
- Robert MacGregor
- Sara Carr – Lead Engineer

Strategy & Approach

Assumptions & Constraints:

The team must obtain a well rounded understanding of the current heart pump system in order to determine which signals must be transmitted. The team must assume that certain electronics may be placed inside the body in order to eliminate larger wires passing through the skin. The ability to transmit certain signals may be a constraint on the team's ability to eliminate wires or to use smaller wires. The team will focus on design issues throughout the duration of the project in order to assist in the development of future design iterations.

Issues & Risks:

- Difficulty of signal transmission and reception.
- Obtaining parts and hardware that can be implemented with current system.
- Health risks associated with tissue damage by packaging of electronics and heat generated by them.

Customer Needs

P10022 Customer Needs

Customer Need #	Importance	Description	Comments/Status
		Signal Transmission	
CN1	4	The cable entering the body is more flexible.	
CN2	5	The cable entering the body must be smaller in diameter.	
CN3	5	Eliminate as many wires as possible from position sensors (HESA) to XPC Control Target	
CN4	5	Eliminate as many wires as possible from XPC Control Target to Active Magnetic Bearings (AMB)	
CN5	5	Eliminate as many wires as possible from from the XPC Control Target to the LVAD Motor	
CN6	3	Eliminate power wires (15V and Ground wires)	
CN7	5	The interior and exterior transceivers must have a power supply.	
		Wireless Power Transmission	
CN8	3	Power transmission through the human skin and biological tissues.	
		Safety	
CN9	5	The cable entering the body must be safe to human tissue.	
CN10	5	Packaging, materials, and connections of the inner transceiver are safe to human tissue.	
CN11	5	Heat generated by the inner transceiver does not cause tissue damage.	
CN12	5	The heat created by the body does not damage the electronics.	
CN13	5	Inner and outer transceivers must be protected from the surrounding environment of human tissue and outside forces.	
CN14	5	Protocols are comliant with IEEE and FDA standards.	
		Functionality	
CN15	5	The device must be reliable.	Heart pump functions 20 years.
CN16	5	The device must function continuously.	
CN17	5	The device must function without user intervention.	
CN18	5	The device should work with the currently established system components.	
CN19	3	The wireless technology functions in accordance with Project #10021 (miniaturization senior design team).	
		Size	
CN20	5	The interior transceiver must fit within the human body cavity.	
CN21	5	The exterior transceiver must be small enough to wear on a belt.	
CN22	5	The exterior transceiver must be light enough to wear on a belt.	
		Cost	
CN23	2	The cost should be affordable.	

Revision #5

Importance: Sample scale (5=must have, 3=nice to have, 1=preference only).

Meeting Customer Needs

The following table, based on the customer needs, gives specific aspects of the design that contribute to fulfilling each need.

Customer Need #	Importance	Description	Status
		Signal Transmission	
CN1	4	The cable entering the body is more flexible.	Flexibility will be tested using a flexiblity test outlined in the test plan. Currently, every wire ordered for use in the proposed cable is classified as a high flexibility wire by the manufacturer. Heat shrink tubing and silicone coating are also flexible materials.
CN2	5	The cable entering the body must be smaller in diameter.	The cable is designed to be less than 3 mm in diameter. If the TET system is implemented, the wire diameter will be less than 1.5 mm.
CN3	5	Eliminate as many wires as possible from position sensors (HESA) to XPC Control Target	The design calls on 3 signal wires and 4 power wires. A total of 15 wires were eliminated.
CN4	5	Eliminate as many wires as possible from XPC Control Target to Active Magnetic Bearings (AMB)	
CN5	5	Eliminate as many wires as possible from from the XPC Control Target to the LVAD Motor	
CN6	3	Eliminate power wires (15V and Ground wires)	The TET design will eliminate 4 power wires.
CN7	5	The interior and exterior transceivers must have a power supply.	The power supply of 15V will be obtained from Team P10021.
		Wireless Power Transmission	
CN8	3	Power transmission through the human skin and biological tissues.	The TET design includes coils, battery, and converters proposed in the final document.
		Safety	
CN9	5	The cable entering the body must be safe to human tissue.	The cable will be covered by a layer of silicone. LOCTITE® 5248™ has been qualified to Loctite's ISO 10993 Protocol (also, FDA) which is used for the selection of products for use in the medical device industry.
CN10	5	Packaging, materials, and connections of the inner transceiver are safe to human tissue.	The entire device will be covered by a layer of silicone. LOCTITE® 5248™ has been qualified to Loctite's ISO 10993 Protocol (also, FDA) which is used for the selection of products for use in the medical device industry.
CN11	5	Heat generated by the inner transceiver does not cause tissue damage.	Heat analysis was done to verify that the surface temperature of the case does not exceed the allowable temperature of 49.6ºC when implanted within the body. A test will be conducted in the oven to verify the performance of the design, also outlined in the test plan section.
CN12	5	The heat created by the body does not damage the electronics.	Heat analysis was done to verify that the inner temperature of electronics does not exceed the allowable temperature of 120ºC when tested in air. A test will be conducted in the oven to verify the performance of the design, also outlined in the test plan section.

Customer Need #	Importance	Description	Status
CN13	5	Inner and outer transceivers must be protected from the surrounding environment of human tissue and outside forces.	The device is shock protected by using mechanical damping grommets that were designed to absorb some energy in case of external forces acting upon the case. A drop test will be conducted to test for the shock durability of the case, outlined in the test plan section.
CN14	5	Protocols are comliant with IEEE and FDA standards.	All components are IEEE approved. The silicone coating is qualified under ISO10993 and FDA which is used for selection of products in the medical device industry.
		Functionality	
CN15	5	The device must be reliable.	The device signal output and input will be tested using wave generator and oscilloscope to ensure correct transfer of signals. Also, it will be tested for a period of 6 hours with the currently set up system in order to demonstrate reliability.
CN16	5	The device must function continuously.	The device will be tested for a period of 6 hours with the currently set up system in order to demonstrate that it will function continuously.
CN17	5	The device must function without user intervention.	The device will be tested for a period of 6 hours with the currently set up system in order to demonstrate that it will function without user intervention.
CN18	5	The device should work with the currently established system components.	The device will be tested for a period of 6 hours with the currently set up system. Dr. Cheng and Dr. Day approved feasibility of testing with the current system.
CN19	3	The wireless technology functions in accordance with Project #10021 (miniaturization senior design team).	The device will be tested for a period of 6 hours with the prototype done by the miniaturization team.
		Size	
CN20	5	The interior transceiver must fit within the human body cavity.	Within the human body cavity there is 650 cm^3 of available space. The proposed casing volume is 64 cm^3.
CN21	5	The exterior transceiver must be small enough to wear on a belt.	The dimensions of the proposed casing are 11.9 x 4.6 x 1.9 cm.
CN22	5	The exterior transceiver must be light enough to wear on a belt.	The weight of the prototype is estimated to be 70g: the casing is 46g and inner components are ~24g.
		Cost	
CN23	2	The cost should be affordable.	The device will cost approximately $2,000.

Revision #5
Importance: Sample scale (5=must have, 3=nice to have, 1=preference only).

Customer Specifications

P10022 Specifications

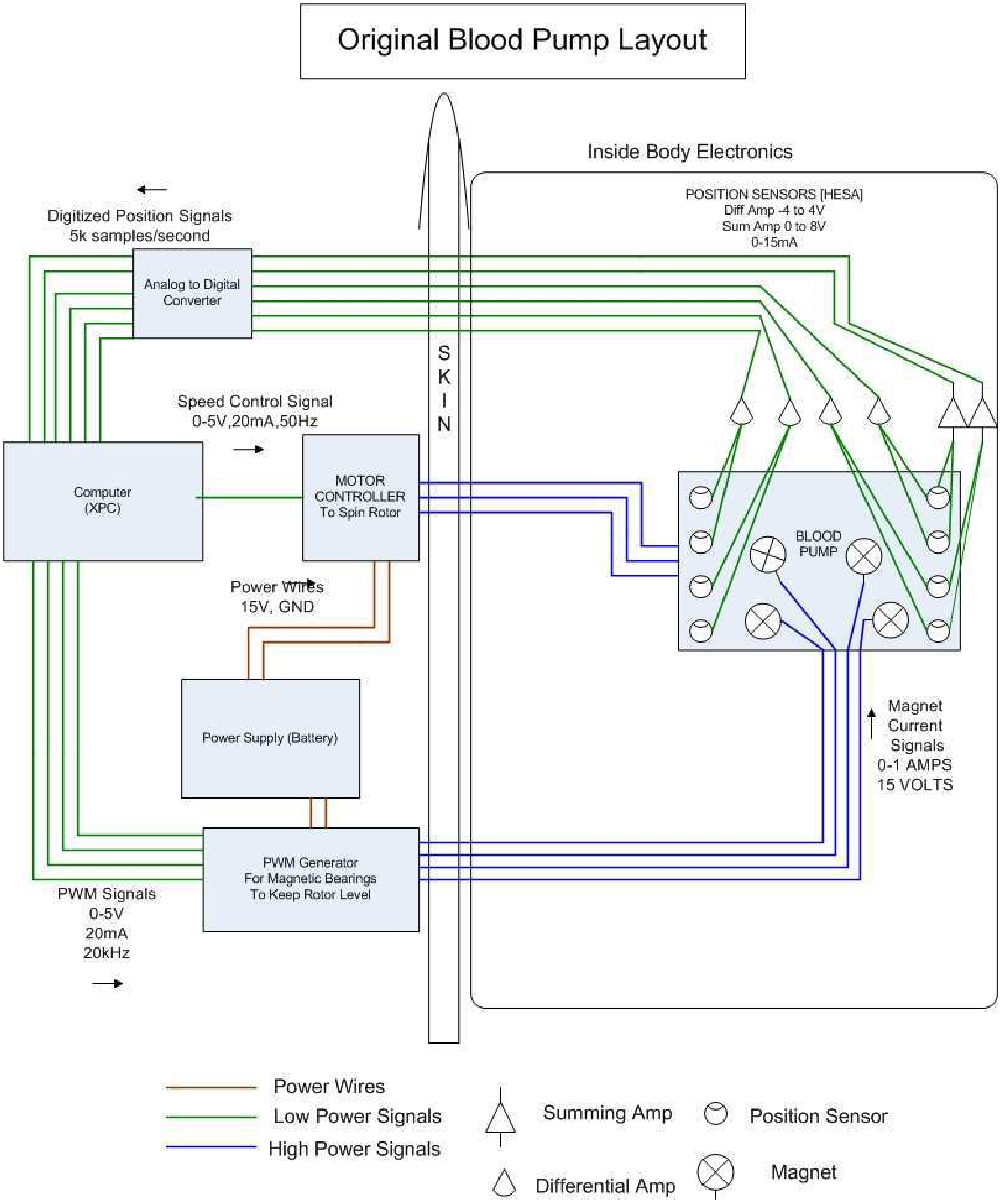
Engr. Spec. #	Import- ance	Source	Specification description	Units	Marginal Value	Ideal Value	Status
			Signal Transmission				
1	5	CN1-7	Transceiver outside the body attached to a belt or to miniaturized controller case.	Count		1	
2	5	CN1-7	Transceiver inside the body	Count		1	
3	2	CN1-7	Wire length connecting interior and exterior transceivers.	m		1.5	
4	4	CN1	Improvement in flexibility of cable	%	200	400	
5	5	CN2	Diameter of the cable entering the body.	mm	3	2	
			Signal transmission from LVAD position sensors (HESA) to XPC Control Target:				Exterior ADC
6	5	CN3	Signals from LVAD position sensors to the inner transceiver	Count		8	
7	5	CN3	Voltage	Volts		2 - 5	
8	5	CN3	Current	mA		15	
9	5	CN3	Frequency	Hz		0 - 600	
10	5	CN3	Sampling Rate	ksps/ chnl		5	
			Signals from the outer transceiver to the amplifiers	Count		8	
11	5	CN3	Voltage	Volts		2 - 5	
12	5	CN3	Current	mA	1.65	1	
13	5	CN3	Frequency	Hz		0 - 600	
14	5	CN3	Sampling Rate	ksps/ chnl		5	
			Signal transmission from XPC Control Target to Active Magnetic Bearings (AMB)				Interior PWM Generator
15	5	CN4	Signals from XPC Control Target to PWM Generator	Count		4	
16	5	CN4	Voltage	Volts		0 - 5	
17	5	CN4	Current	A		-3 - 3	
18	5	CN4	Frequency	kHz		20	
			Signal transmission of Speed Control signal from XPC Control Target to the LVAD Motor				

Engr. Spec. #	Import-ance	Source	Specification description	Units	Marginal Value	Ideal Value	Status
19	5	CN5	Signal from XPC Control Target to Motor Controller	Count		1	Interior Motor Controller
20	5	CN5	Voltage	Volts		0 - 5	
21	5	CN5	Current	mA		20	
22	5	CN5	Frequency	MHz	4	40	
23	3	CN6	Power wires eliminated (15V and Ground)	Count		2	
24	5	CN7	The interior transceiver must be grounded.	Volts		Ground	
25	5	CN7	The exterior and interior transceivers must have power supply.	W		1	
26	3	CN8	The power transmitted transcutaneously must be safe to human tissue (FDA (HDA)).	Boolean		1	
27	3	CN8	Voltage supply to internal components	V		15	
			Safety				
28	5	CN9	Cable's outer casing material must meet FDA standards for Biodevices.	Boolean		1	
29	5	CN10	Packaging materials must meet FDA Standards for Biodevices.	Boolean		1	
30	5	CN11	Safe operating increase in surface temperature above ambient tissue.	C	6.4	1	
31	5	CN12	Electronics must function at body temperatures.	C		43	
32	5	CN13	Inner and outer transceivers must be protected from the surrounding environment and outside forces.	Boolean		1	
33	5	CN13	Casing is intact after 5 drops from a specified height.	m		1.5	
34	5	CN13	Casing withstands higher pressures (no leakage under 1m water).	kPa		10	
35	5	CN14	Protocols are comliant with IEEE (802.11) and FDA standards (HDA).	Boolean		1	
			Functionality				
36	5	CN15	The device must demonstrate reliability, must function continuously for the testing period.	Hours		72	
37	5	CN16	Number of interruptions for the device's 72 hour cycle.	Count		0	
38	5	CN17	Number of user interventions for device's 72 hour cycle.	Count		0	
39	5	CN18	The device should work with the currently established system components.	Boolean		1	
40	3	CN19	The device functions in accordance with Project #10021 (Miniaturization senior design team).	Boolean		1	

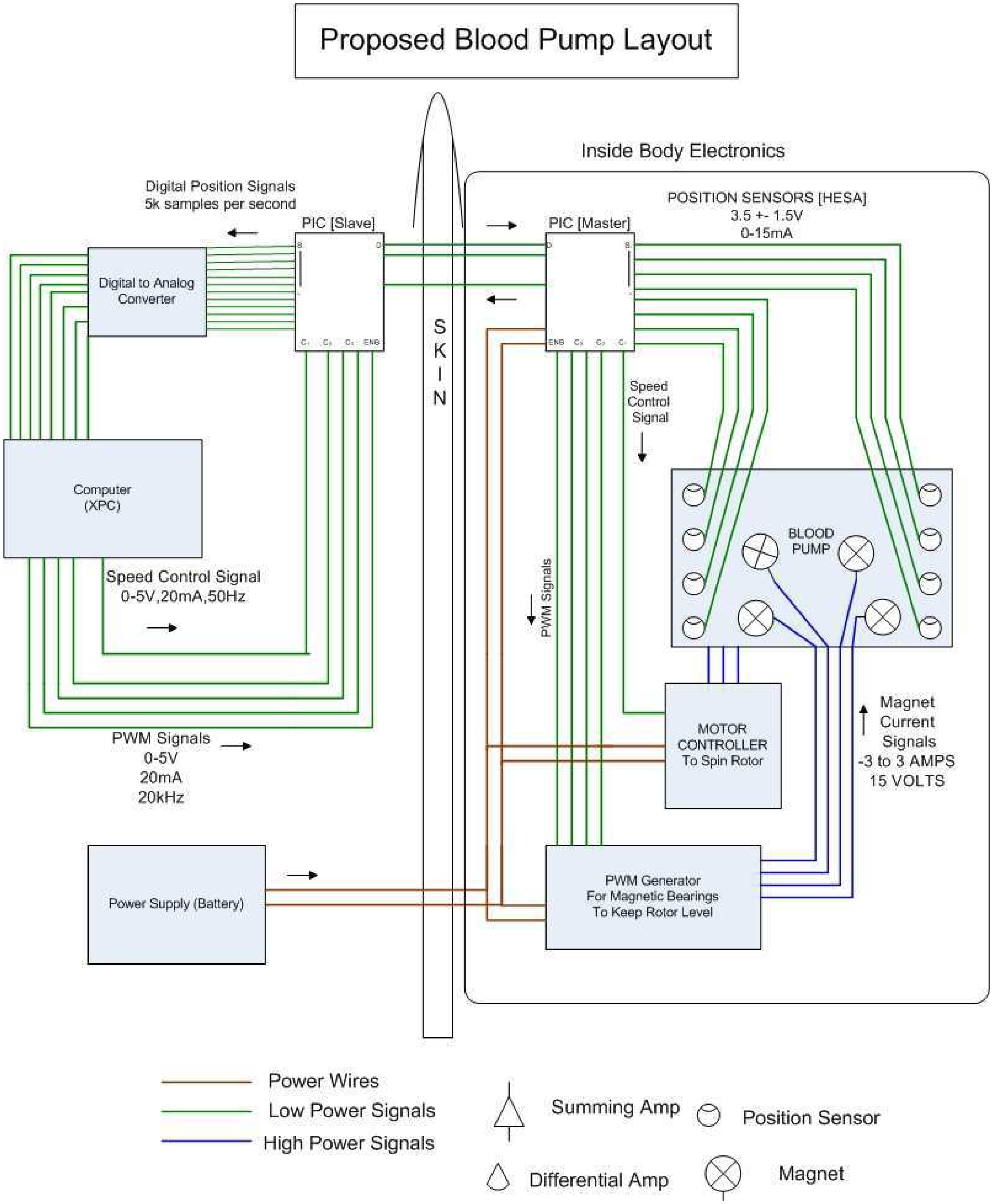
Engr. Spec. #	Import-ance	Source	Specification description	Units	Marginal Value	Ideal Value	Status
			Size				
41	5	CN20	Interior transceiver dimensions.	Cm^3	650	450	(700cm^3) Critical Anatomic Dimensions…
42	5	CN21	Exterior transceiver dimensions.	Cm^3	650	450	
43	5	CN22	Exterior transceiver weight.	kg		0.9	AbioCore weight
			Cost				
44	2	CN23	The device should not exceed allowable budget limit.	$	3746	2746	

High-Level Design Schematics

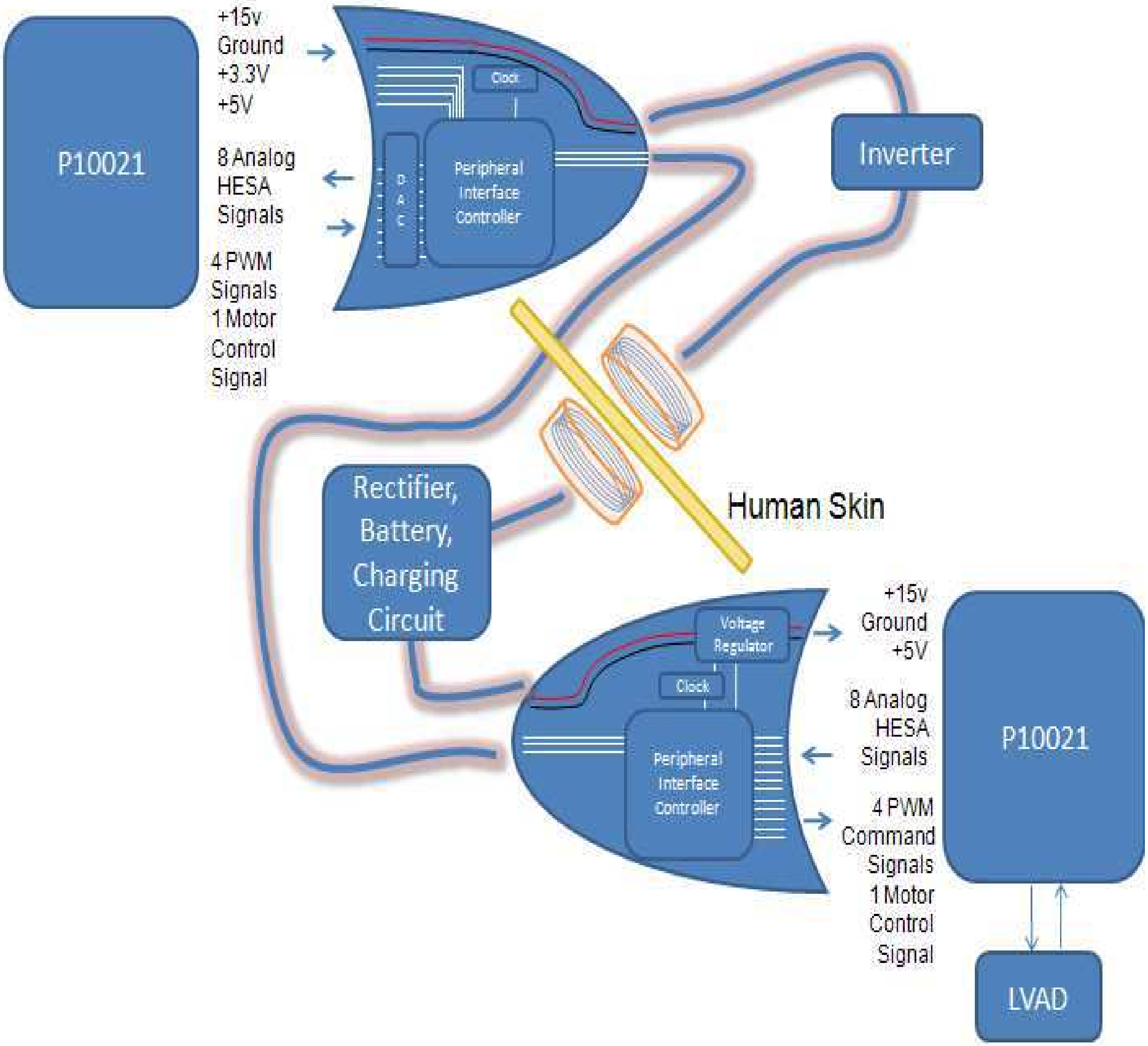
Schematic #1: Current Design



Schematic #2: Proposed Design



Schematic #3: Big Picture Design



Schematic #4: Big Picture Body Diagram

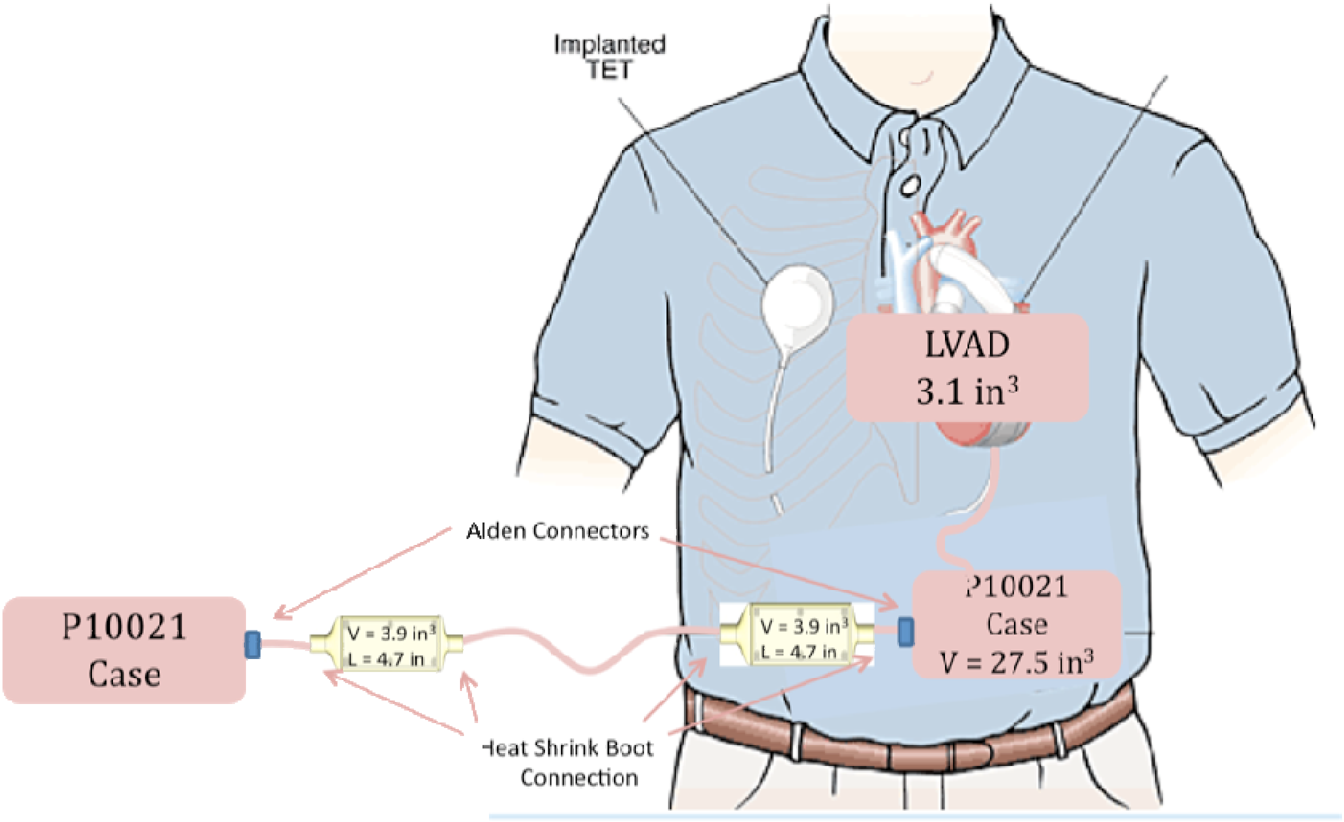
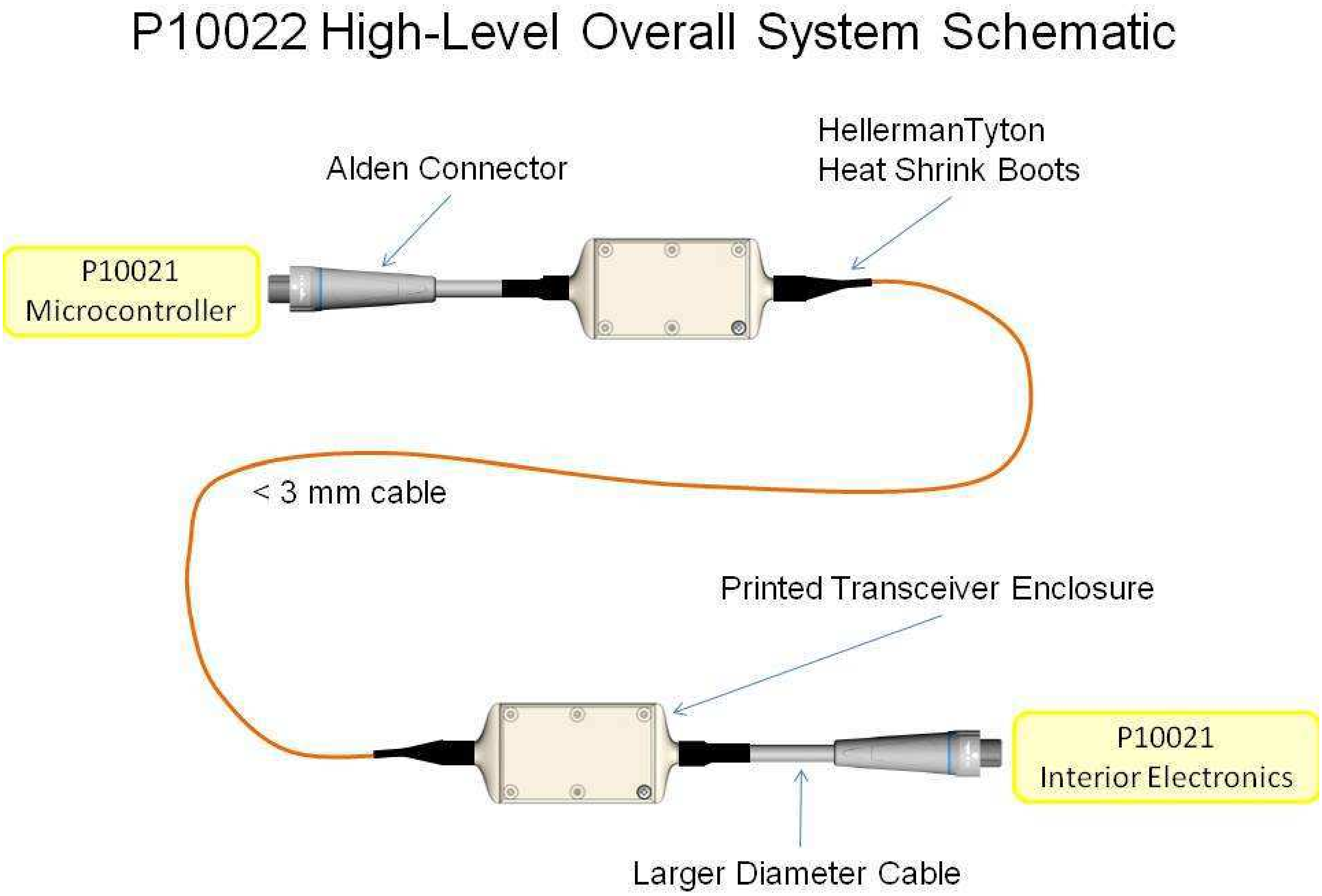


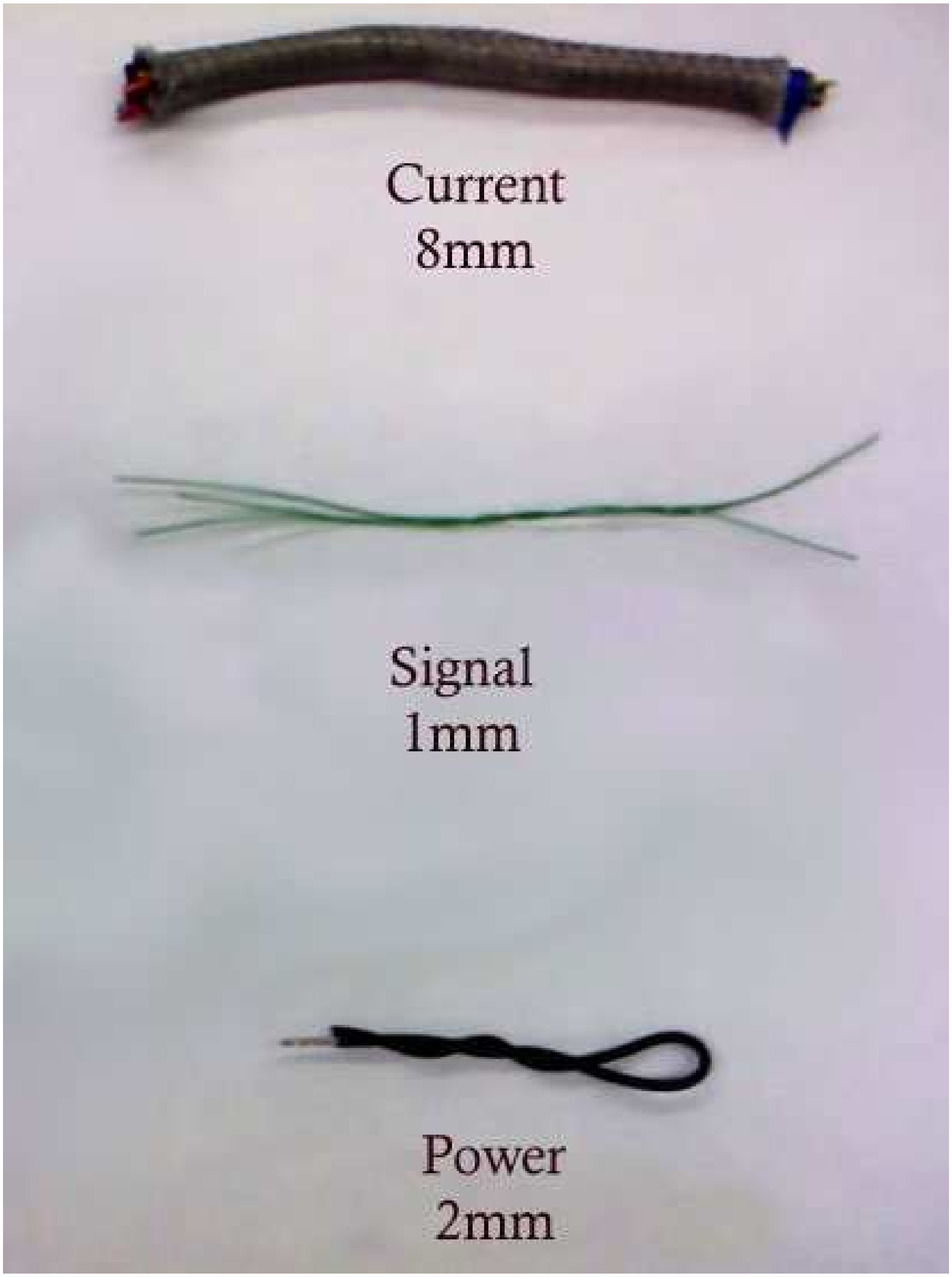
Diagram from AbioCor System

P10022 Inner Transceiver is scaled appropriately

Schematic #5: High-level Project Overview



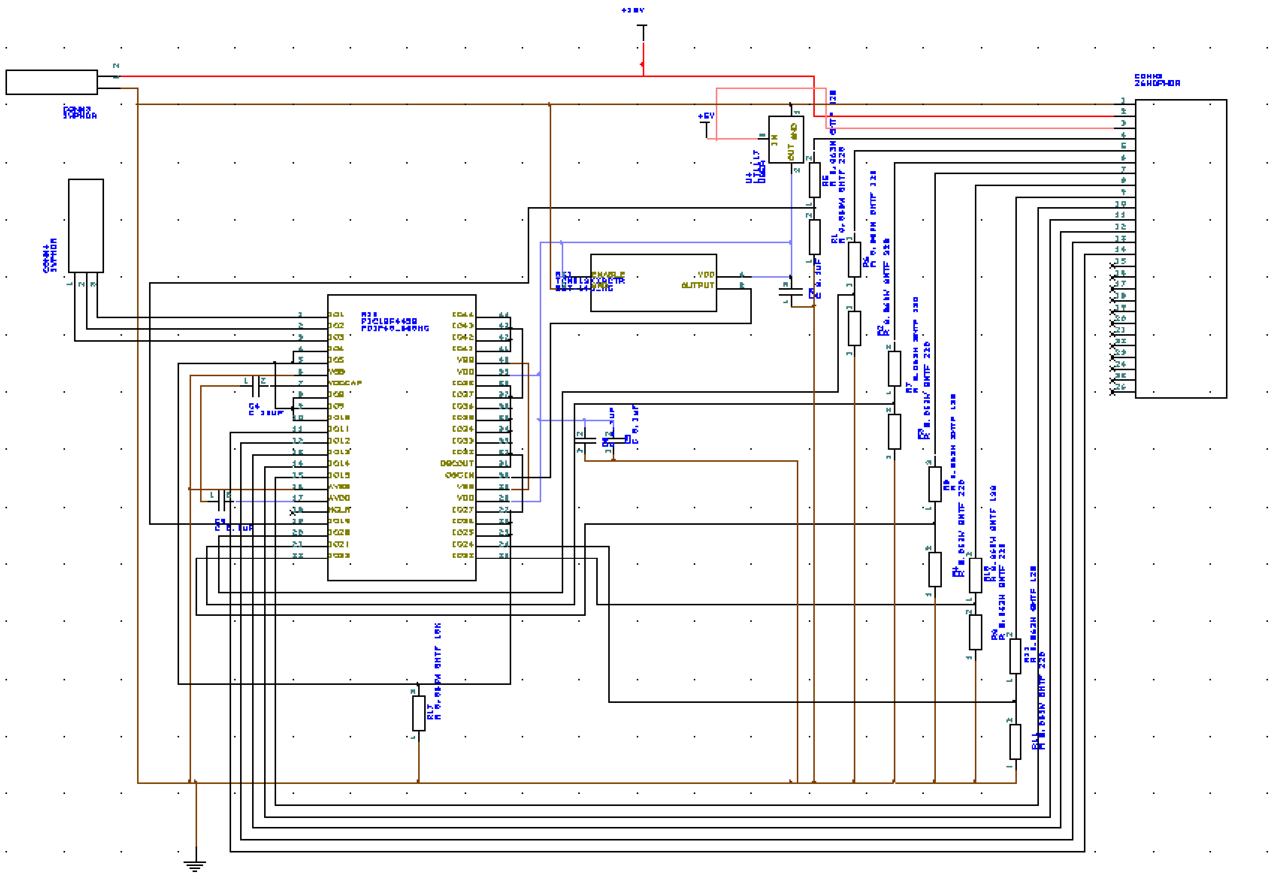
Schematic #6: Relative Wire Sizes



Electronics Design

The communication between each end of the cable is provided by two MicroChip dsPic33FJ32GP304. One transceiver is implanted inside the body and connects to the P10021 project by a 27 pin connector. Three wire Serial Peripheral Interface (SPI) is used to transmit the LVAD data to the exterior controller at frequency up to 40MHz. The voltages from HESA position monitors are shifted to the tolerance of the microcontroller using a voltage shifter. A voltage shifter is a simple circuit that uses resistors to change the potential of the signal, but is scaled in a way that can regenerate the original signals. A 5V to 3.3V voltage regulator is used to deliver a voltage source to the microprocessor; since the processor draws varying amounts of current a resistor network was not sufficient for this voltage source. These position signals are sampled by the dsPIC33F using the built in 12 bit analog to digital converter. Once digitized these signals are sent along the SPI interface. The PWM duty cycles are received on the SPI interface and sampled on the dsPIC33F and sent to the 27 pin connector to project P10021 at a rate of up to 20Mbps.

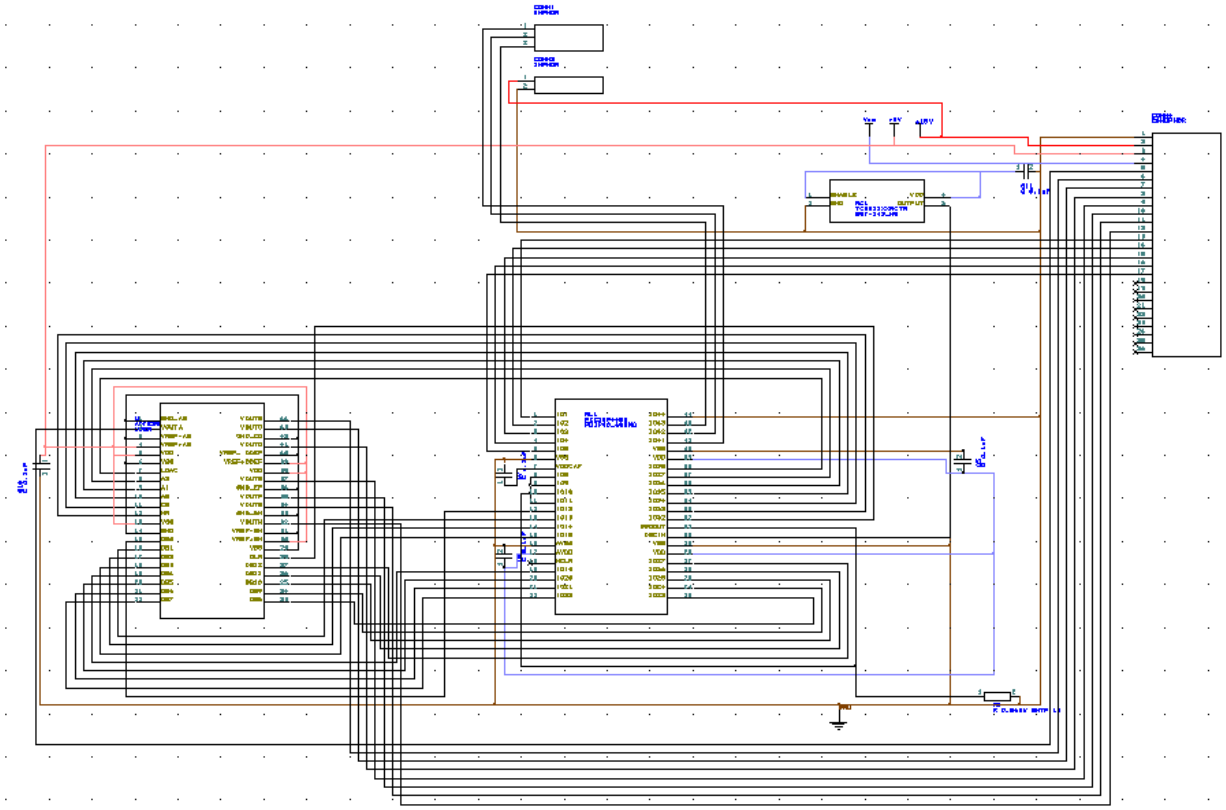
Interior Circuit Schematic



Exterior Circuit Schematic

In order to integrate fully with project P10021, the position signals must be delivered as analog signals instead of digital. Therefore, an 8-channel digital to analog converter (DAC) is utilized. The DAC takes in 12 bits at a time in a parallel interface and samples them at 125ksps. The microcontroller of project P10021 samples the position signals a 5 kHz, therefore 125ksps is a suitable speed for this application. A functional block diagram is pictured below.

In order to avoid possible errors in pin connections and to easily troubleshoot, an Excel spread sheet is kept to map each pin to each chip.



Pin Assignments

DAC 5348

STARTS			ENDS			
PIN	VALUE	I/O	PIN	VALUE	I/O	CHIP
1	POS1	O	5	CONN	I	27 CONN
2	POS2	O	6	CONN	I	27 CONN
3	POS3	O	7	CONN	I	27 CONN
4	POS4	O	8	CONN	I	27 CONN
5	AGND	I		GND		
6	AGND	P		GND		
7	POS5	O	9	CONN	I	27 CONN
8	POS6	O	10	CONN	I	27 CONN
9	POS7	O	11	CONN	I	27 CONN
10	POS8	O	12	CONN	I	27 CONN
11	DGND	P		GND		
12	BUF	I		+5		
13	LDAC	I	35	LDAC	O	PIC33F
14	A0	I	36	A0	O	PIC33F
15	A1	I	37	A1	O	PIC33F
16	A2	I	38	A2	O	PIC33F
17	D0	I	13	D0	O	PIC33F
18	D1	I	14	D1	O	PIC33F
19	D2	I	15	D2	O	PIC33F
20	D3	I	19	D3	O	PIC33F
21	D4	I	20	D4	O	PIC33F
22	D5	I	21	D5	O	PIC33F
23	D6	I	22	D6	O	PIC33F
24	D7	I	23	D7	O	PIC33F
25	D8	I	24	D8	O	PIC33F
26	D9	I	25	D9	O	PIC33F
27	D10	I	26	D10	O	PIC33F
28	D11	I	27	D11	O	PIC33F
29	CS	I	12	CS	O	PIC33F
30	RD	I	11	RD	O	PIC33F
31	WR	I	10	WR	O	PIC33F
32	GAIN	I		GND		
33	CLR	I	9	CLR	O	PIC33F
34	PD	I	8	PD	O	PIC33F
35	VREFGH	P		+5		
36	VREFEF	P		+5		
37	VREFCD	P		+5		
38	VDD	P		+5		
39	VDD	P		+5		
40	VREFAB	P		+5		

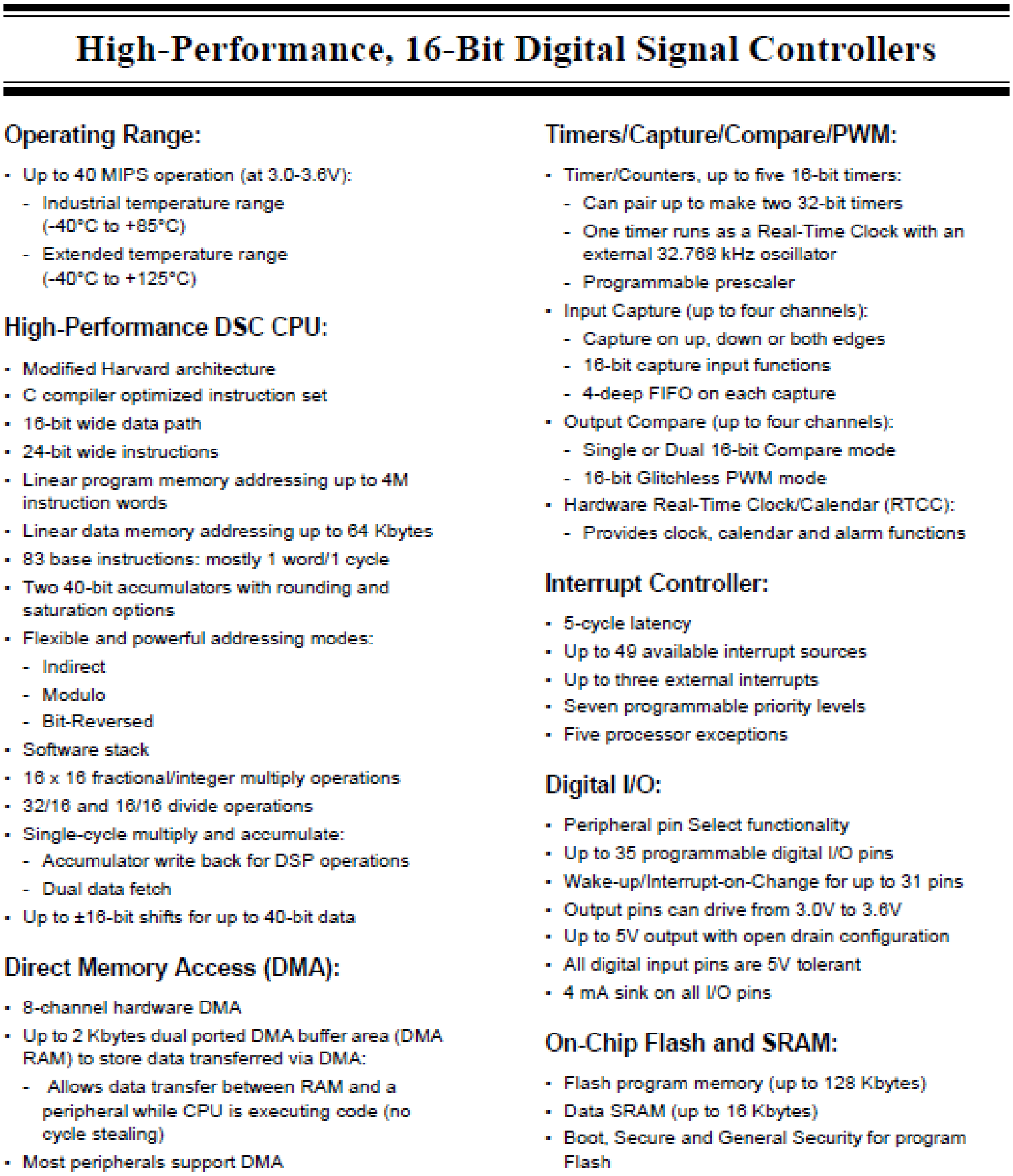
External PIC33F

STARTS			ENDS			
PIN	VALUE	I/O	PIN	VALUE	I/O	CHIP
1	PWM1	I	13	CONN	O	27 CONN
2	PWM2	I	14	CONN	O	27 CONN
3	PWM3	I	15	CONN	O	27 CONN
4	PWM4	I	16	CONN	O	27 CONN
5	MC1	I	17	CONN	O	27 CONN
6	VSS	P		GND		
7	VDDCAP	P		10uF Cap		
8	PD	O	34	PD	I	AD5348
9	CLR	O	33	CLR	I	AD5348
10	WR	O	31	WR	I	AD5348
11	RD	O	30	RD	I	AD5348
12	CS	O	29	CS	I	AD5348
13	D0	O	17	D0	I	AD5348
14	D1	O	18	D1	I	AD5348
15	D2	O	19	D2	I	AD5348
16	AVSS	P		GND		
17	AVDD	P		+3.3		
18	MCLR					
19	D3	O	20	D3	I	AD5348
20	D4	O	21	D4	I	AD5348
21	D5	O	22	D5	I	AD5348
22	D6	O	23	D6	I	AD5348
23	D7	O	24	D7	I	AD5348
24	D8	O	25	D8	I	AD5348
25	D9	O	26	D9	I	AD5348
26	D10	O	27	D10	I	AD5348
27	D11	O	28	D11	I	AD5348
28	VDD	P		+3.3		
29	VSS	P		GND		
30	OSCIN	I	3	OSC	O	632L
31	OSCOUT	O		GND		
32	NC					
33	NC					
34	NC					
35	LDAC	O	13	LDAC	I	AD5348
36	A0	O	14	A0	I	AD5348
37	A1	O	15	A1	I	AD5348
38	A2	O	16	A2	I	AD5348
39	VDD	P		+3.3		
40	VSS	P		GND		
41	SPI1	I	1	CONN		CONN3
42	SPI2	I	2	CONN		CONN3
43	SPI3	O	3	CONN		CONN3
44	SPI4	O		GND		

Internal PIC33F

STARTS			ENDS			
PIN	VALUE	I/O	PIN	VALUE	I/O	CHIP
1	SPI1	O	1	SPI1	I	CONN3
2	SPI2	O	2	SPI2	I	CONN3
3	SPI3	I	3	SPI3	O	CONN3
4	SPI4	-		GND		
5	NC	-				
6	VSS	P		GND		
7	VCAP	P		10uF		
8	NC	-				
9	NC	-				
10	NC	-				
11	PWM1	O	12	PWM1	I	CONN27
12	PWM2	O	13	PWM2	I	CONN27
13	PWM3	O	14	PWM3	I	CONN27
14	PWM4	O	15	PWM4	I	CONN27
15	MC1	O	16	MC1	I	CONN27
16	AVSS	P		+3.3		
17	AVDD	P		GND		
18	MCLR					
19	POS1	I		R1,R5	NODE	
20	POS2	I		R2,R6	NODE	
21	POS3	I		R3,R7	NODE	
22	POS4	I		R4,R8	NODE	
23	POS5	I		R9,R10	NODE	
24	POS6	I		R11,R12	NODE	
25	POS7	I		R13,R14	NODE	
26	POS8	I		R15,R16	NODE	
27	NC	-				
28	VDD	P		+3.3		
29	VSS	P		GND		
30	OSC IN	I	3	OUTPUT	O	632L
31	OSC OUT	O				
32	NC	-				
33	NC	-				
34	NC	-				
35	NC	-				
36	NC	-				
37	NC	-				
38	NC	-				
39	VDD	P		+3.3		
40	VSS	P		GND		
41	NC	-				
42	NC	-				
43	NC	-				
44	NC	-				

Micro Controller



High-Performance, 16-Bit Digital Signal Controllers

Operating Range:

- Up to 40 MIPS operation (at 3.0-3.6V):
  - Industrial temperature range (-40°C to +85°C)
  - Extended temperature range (-40°C to +125°C)

High-Performance DSC CPU:

- Modified Harvard architecture
- C compiler optimized instruction set
- 16-bit wide data path
- 24-bit wide instructions
- Linear program memory addressing up to 4M instruction words
- Linear data memory addressing up to 64 Kbytes
- 83 base instructions: mostly 1 word/1 cycle
- Two 40-bit accumulators with rounding and saturation options
- Flexible and powerful addressing modes:
  - Indirect
  - Modulo
  - Bit-Reversed
- Software stack
- 16 x 16 fractional/integer multiply operations
- 32/16 and 16/16 divide operations
- Single-cycle multiply and accumulate:
  - Accumulator write back for DSP operations
  - Dual data fetch
- Up to ±16-bit shifts for up to 40-bit data

Direct Memory Access (DMA):

- 8-channel hardware DMA
- Up to 2 Kbytes dual ported DMA buffer area (DMA RAM) to store data transferred via DMA:
  - Allows data transfer between RAM and a peripheral while CPU is executing code (no cycle stealing)
- Most peripherals support DMA

Timers/Capture/Compare/PWM:

- Timer/Counters, up to five 16-bit timers:
  - Can pair up to make two 32-bit timers
  - One timer runs as a Real-Time Clock with an external 32.768 kHz oscillator
  - Programmable prescaler
- Input Capture (up to four channels):
  - Capture on up, down or both edges
  - 16-bit capture input functions
  - 4-deep FIFO on each capture
- Output Compare (up to four channels):
  - Single or Dual 16-bit Compare mode
  - 16-bit Glitchless PWM mode
- Hardware Real-Time Clock/Calendar (RTCC):
  - Provides clock, calendar and alarm functions

Interrupt Controller:

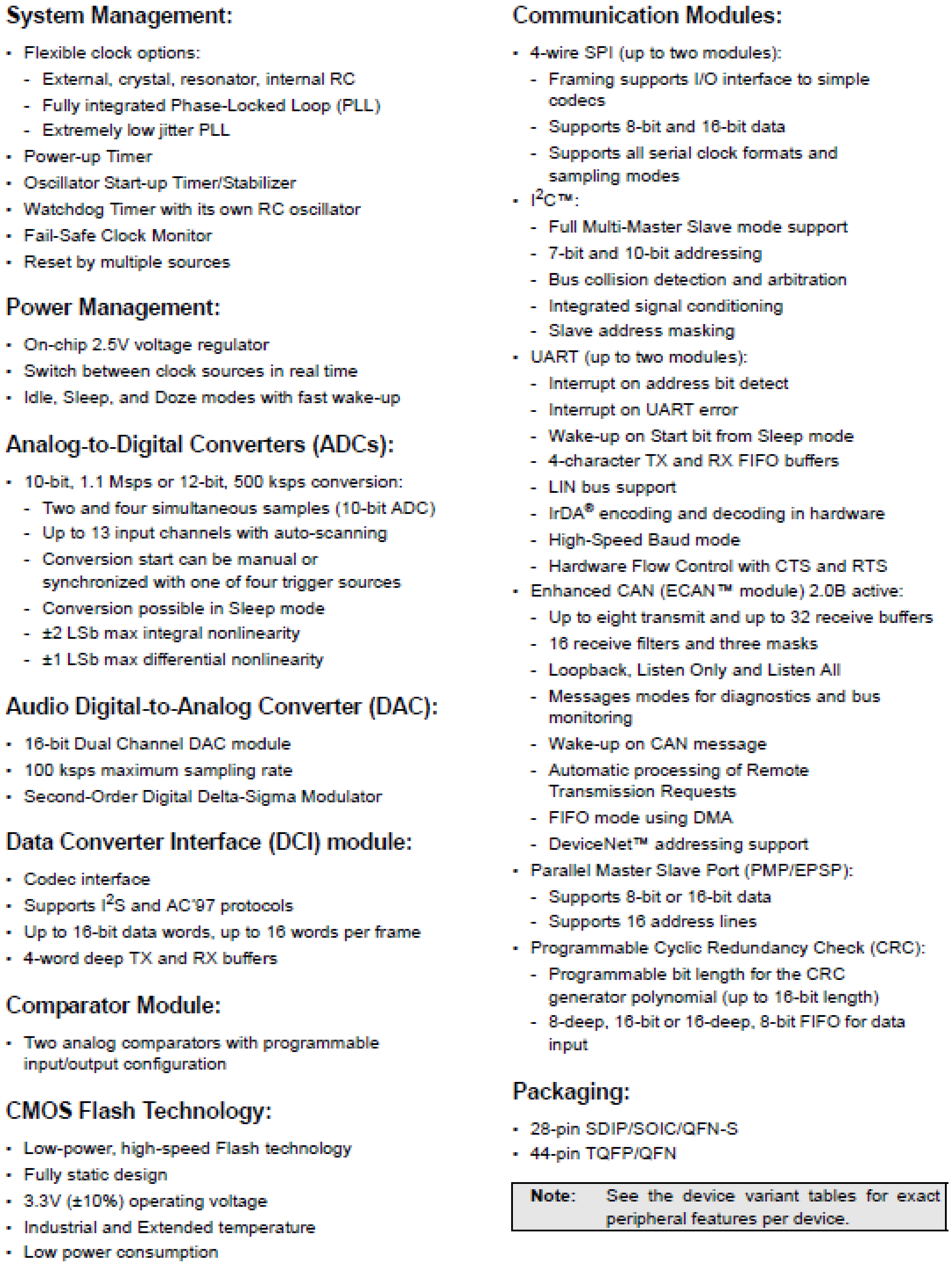
- 5-cycle latency
- Up to 49 available interrupt sources
- Up to three external interrupts
- Seven programmable priority levels
- Five processor exceptions

Digital I/O:

- Peripheral pin Select functionality
- Up to 35 programmable digital I/O pins
- Wake-up/Interrupt-on-Change for up to 31 pins
- Output pins can drive from 3.0V to 3.6V
- Up to 5V output with open drain configuration
- All digital input pins are 5V tolerant
- 4 mA sink on all I/O pins

On-Chip Flash and SRAM:

- Flash program memory (up to 128 Kbytes)
- Data SRAM (up to 16 Kbytes)
- Boot, Secure and General Security for program Flash



System Management:

- Flexible clock options:
  - External, crystal, resonator, internal RC
  - Fully integrated Phase-Locked Loop (PLL)
  - Extremely low jitter PLL
- Power-up Timer
- Oscillator Start-up Timer/Stabilizer
- Watchdog Timer with its own RC oscillator
- Fail-Safe Clock Monitor
- Reset by multiple sources

Power Management:

- On-chip 2.5V voltage regulator
- Switch between clock sources in real time
- Idle, Sleep, and Doze modes with fast wake-up

Analog-to-Digital Converters (ADCs):

- 10-bit, 1.1 Msps or 12-bit, 500 ksps conversion:
  - Two and four simultaneous samples (10-bit ADC)
  - Up to 13 input channels with auto-scanning
  - Conversion start can be manual or synchronized with one of four trigger sources
  - Conversion possible in Sleep mode
  - ±2 LSb max integral nonlinearity
  - ±1 LSb max differential nonlinearity

Audio Digital-to-Analog Converter (DAC):

- 16-bit Dual Channel DAC module
- 100 ksps maximum sampling rate
- Second-Order Digital Delta-Sigma Modulator

Data Converter Interface (DCI) module:

- Codec interface
- Supports I^2S and AC'97 protocols
- Up to 16-bit data words, up to 16 words per frame
- 4-word deep TX and RX buffers

Comparator Module:

- Two analog comparators with programmable input/output configuration

CMOS Flash Technology:

- Low-power, high-speed Flash technology
- Fully static design
- 3.3V (±10%) operating voltage
- Industrial and Extended temperature
- Low power consumption

Communication Modules:

- 4-wire SPI (up to two modules):
  - Framing supports I/O interface to simple codecs
  - Supports 8-bit and 16-bit data
  - Supports all serial clock formats and sampling modes
- I^2C™:
  - Full Multi-Master Slave mode support
  - 7-bit and 10-bit addressing
  - Bus collision detection and arbitration
  - Integrated signal conditioning
  - Slave address masking
- UART (up to two modules):
  - Interrupt on address bit detect
  - Interrupt on UART error
  - Wake-up on Start bit from Sleep mode
  - 4-character TX and RX FIFO buffers
  - LIN bus support
  - IrDA® encoding and decoding in hardware
  - High-Speed Baud mode
  - Hardware Flow Control with CTS and RTS
- Enhanced CAN (ECAN™ module) 2.0B active:
  - Up to eight transmit and up to 32 receive buffers
  - 16 receive filters and three masks
  - Loopback, Listen Only and Listen All
  - Messages modes for diagnostics and bus monitoring
  - Wake-up on CAN message
  - Automatic processing of Remote Transmission Requests
  - FIFO mode using DMA
  - DeviceNet™ addressing support
- Parallel Master Slave Port (PMP/EPSP):
  - Supports 8-bit or 16-bit data
  - Supports 16 address lines
- Programmable Cyclic Redundancy Check (CRC):
  - Programmable bit length for the CRC generator polynomial (up to 16-bit length)
  - 8-deep, 16-bit or 16-deep, 8-bit FIFO for data input

Packaging:

- 28-pin SDIP/SOIC/QFN-S
- 44-pin TQFP/QFN

Note: See the device variant tables for exact peripheral features per device.

Digital to Analog Converter

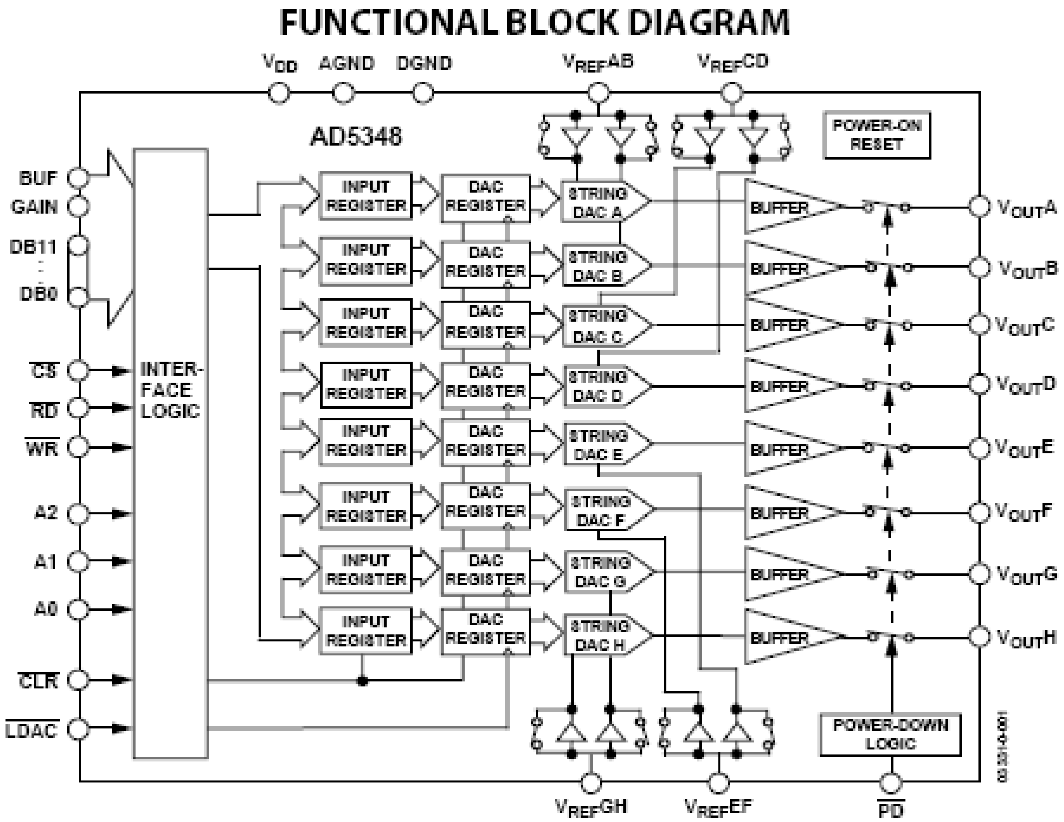
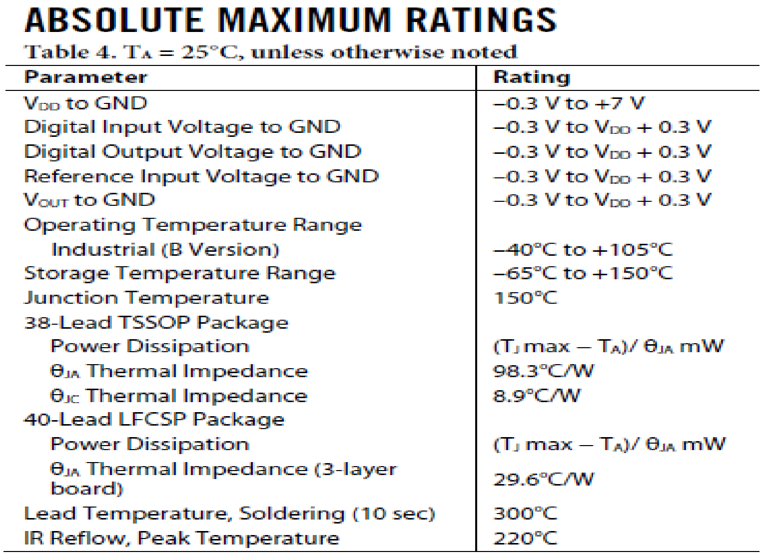


Figure X – Schematic of Digital to Analog Converter



ABSOLUTE MAXIMUM RATINGS

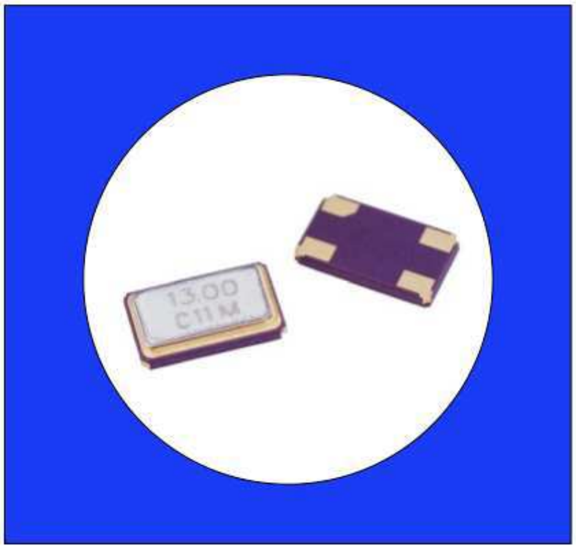
Table 4. $T_A = 25°C$, unless otherwise noted

Parameter	Rating
V_{DD} to GND	−0.3 V to +7 V
Digital Input Voltage to GND	−0.3 V to V_{DD} + 0.3 V
Digital Output Voltage to GND	−0.3 V to V_{DD} + 0.3 V
Reference Input Voltage to GND	−0.3 V to V_{DD} + 0.3 V
V_{OUT} to GND	−0.3 V to V_{DD} + 0.3 V
Operating Temperature Range	
Industrial (B Version)	−40°C to +105°C
Storage Temperature Range	−65°C to +150°C
Junction Temperature	150°C
38-Lead TSSOP Package	
Power Dissipation	$(T_J \max - T_A)/\theta_{JA}$ mW
θ_{JA} Thermal Impedance	98.3°C/W
θ_{JC} Thermal Impedance	8.9°C/W
40-Lead LFCSP Package	
Power Dissipation	$(T_J \max - T_A)/\theta_{JA}$ mW
θ_{JA} Thermal Impedance (3-layer board)	29.6°C/W
Lead Temperature, Soldering (10 sec)	300°C
IR Reflow, Peak Temperature	220°C

Clock Oscillator HCMOS/TTL CTS Model 632

FEATURES

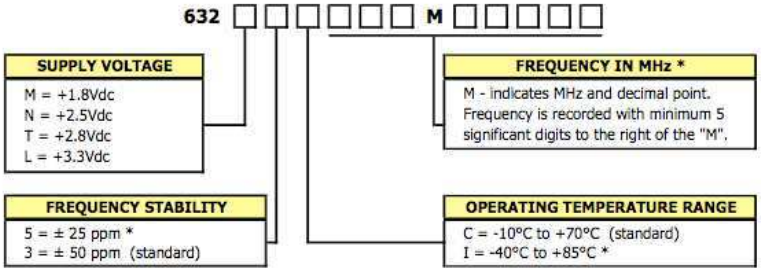
- Standard 3.2x2.5mm Surface Mount Footprint
- HCMOS/TTL Compatible
- **Fundamental and 3RD Overtone Crystals**
- Frequency Range 1.0 – 75 MHz
- Frequency Stability, ±50 ppm
- +1.8Vdc,+2.5Vdc,+2.8Vdc,+3.3Vdc Operation
- Operating Temperature to –10°C to +70°C
- Output Enable Standard
- Tape & Reel Packaging
- **RoHS/Green Compliant (6/6)**



DESCRIPTION

The Model 632 is a ceramic packaged Clock oscillator offering reduced size and enhanced stability. The small size means it is perfect for any application. The enhanced stability means it is the perfect choice for today's communications applications that require tight frequency control.

ORDERING INFORMATION



SUPPLY VOLTAGE
M = +1.8Vdc
N = +2.5Vdc
T = +2.8Vdc
L = +3.3Vdc

FREQUENCY STABILITY
5 = ± 25 ppm *
3 = ± 50 ppm (standard)

FREQUENCY IN MHz *
M - indicates MHz and decimal point. Frequency is recorded with minimum 5 significant digits to the right of the "M".

OPERATING TEMPERATURE RANGE
C = -10°C to +70°C (standard)
I = -40°C to +85°C *

Operating Temperature	T_A	-		25		°C
Commercial			-10		70	
Industrial			-40		85	
Supply Voltage	V_{CC}	± 10 %				V
Model 632M			1.62	1.8	1.98	
Model 632N			2.25	2.5	2.75	
Model 632T			2.52	2.8	3.08	
Model 632L			2.97	3.3	3.63	
Supply Current	I_{CC}					mA
Model 632M		1.0 MHz to 20 MHz C_L=15pF	-	-	6	
		20.1 MHz to 40 MHz C_L=15pF	-	-	7	
		40.1 MHz to 75 MHz C_L=15pF	-	-	10	
Model 632N / Model 632T		1.0 MHz to 20 MHz C_L=15pF	-	-	8	
		20.1 MHz to 40 MHz C_L=15pF	-	-	10	
		40.1 MHz to 75 MHz C_L=15pF	-	-	10	
Model 632L		1.0 MHz to 20 MHz C_L=15pF	-	-	10	
		20.1 MHz to 40 MHz C_L=15pF	-	-	15	
		40.1 MHz to 75 MHz C_L=15pF	-	-	15	
Output Load	C_L				15	pF
Output Voltage Levels						V
Logic '1' Level	V_{OH}	CMOS Load	90%V_{CC}	-	-	
Logic '0' Level	V_{OL}	CMOS Load	-	-	10%V_{CC}	
Output Current						mA
Logic '1' Level	I_{OH}	V_{OH} = 90%V_{CC} (1.8V, 2.5/2.8V, 3.3V)	-	-	-2, -4, -8	
Logic '0' Level	I_{OL}	V_{OL} = 10%V_{CC} (1.8V, 2.5/2.8V, 3.3V)	-	-	+2, +4, +8	

Pseudocode

Theory of Operation

During concept selection, it was determined that one of the methods of serial communication would work best for our task. When determining the best method of transmission for this project, several factors had to be considered. The method should be fast, reliable, be able to communicate in both directions, use low power, be easy to implement, and use as few and as small of wires as possible. A comparison of some common serial communication methods have shown SPI to be the best suited to our needs.

Method	Speed	Reliability	Comm Mode	Ease of Imp.	Availability	Wires
SPI	20 Mbps	Best	Full Duplex	Simple	Widely	3
USB	480 Mbps	Good	Half Duplex	Complex	Limited	2
I2C	3 Mbps	Good	Half Duplex	Simple	Widely	2
1 Wire	<1 Mbps	Good	Half Duplex	Simple	Widely	1

A quick comparison shows SPI to be our best choice. It can communicate at speeds up to 20 Mbps. This is important, because a calculation shows the need for ~16 Mbps for optimal communication:

6*12bits*5ksps = 360kbps for Position Signal Transmission

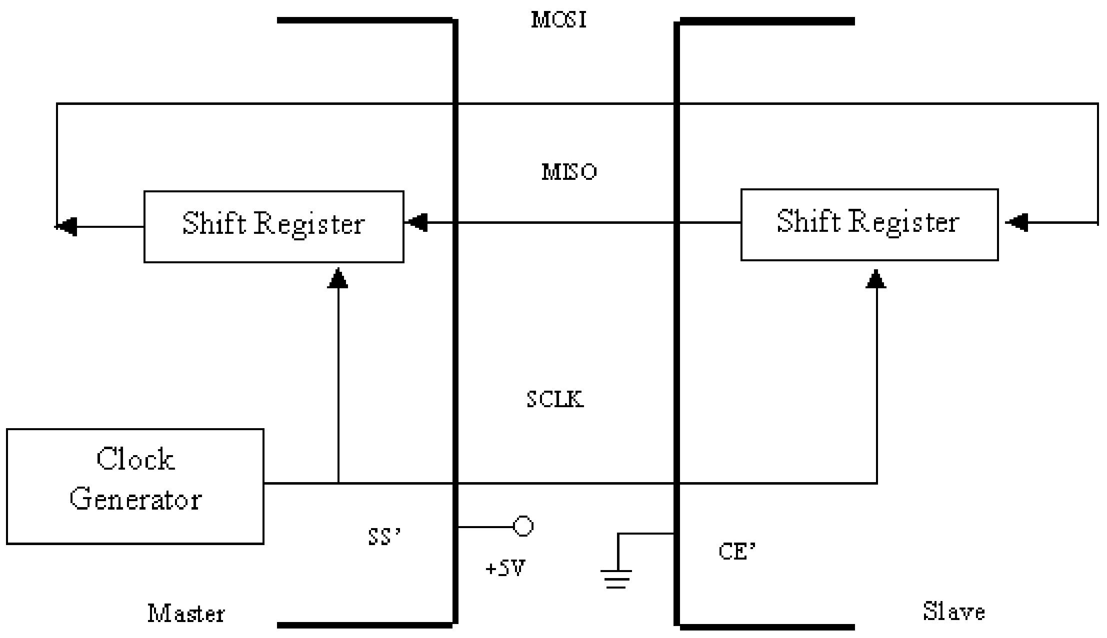
4*1bits*4MHz = 16Mbps for PWM Signal Transmission

1*1bit*5ksps = 5kbps for Motor control

Total + Overhead = ~16.5 Mbps

It has the ability to communicate in full duplex mode and should reduce communication lag. Its reliability should be very good due to the fact that it uses a clock wire, eliminating the need to have precision oscillators. It is commonly found in many microcontrollers making it easy to pick components, as opposed to USB where only certain controllers have onboard support. All methods have been around for a while and have sufficient documentation, with USB being the most complex of the four. The disadvantage of SPI is that it uses more wires, but this will hopefully be offset by the size of the wires being so small, as they will only be carrying 0-3.3V and ~5mA of current.

How the PICs will communicate will be better seen in this diagram.



Here we can see that a 3 wire system is being used to communicate between the two PICs. There is a data in, data out, and clock wire used. Data is constantly being put into the shift register, sent to the recipients shift register, where it is read into memory, and more data is put into the register to be sent out. Because there will be only two devices communicating, the slave select line can be set to high on the master and low on the slave.

In our system, the Master will be the PIC on the inside. This PIC will handle doing the A/D of the Position Signals [Hall Effect Sensor Signals], sending that information to the PIC on the outside, as well as receiving PWM information from the PIC on the outside, and sending those signals to the PWM amplifier and the motor controller.

For this project the Microchip dsPIC33FJ32GP304 was chosen for both ends. This PIC was chosen for a variety of reasons including processing power, 16-bit word size, the speed and precision of its A/D converter, wide availability, low price, and our own familiarity with the Microchip PIC line.

For each PIC separate tasks will have to be performed, and different code will be needed for each PIC. The code for these can be seen below.

Pseudocode

Master PIC (Interior)

```
#include dsPIC33f.h

Set up clock and set to external

Set I/O Pins – 7 Inputs [6 for Position Signals, 1 for SPI]

               7 Outputs [4 PWM Signals, 1 Speed Control Signal, 2 SPI]

Set 6 Positions Input Pins to be Analog Inputs

Set ADC precision to 12 bits

Set ADC to use external clock

Set SPI to use 2 Outputs / 1 Input


Main Loop

     For ADC1 -> ADC6

     Get value from ADC register

     Scale value to represent correct voltage

     Create word-sized data containing input values

     Add bits to distinguish signals from each other

     Load signal into SPI Buffer

     Wait until transfer is completed


     Read Data from SPI Buffer into Memory

     Set appropriate outputs based on received data
```

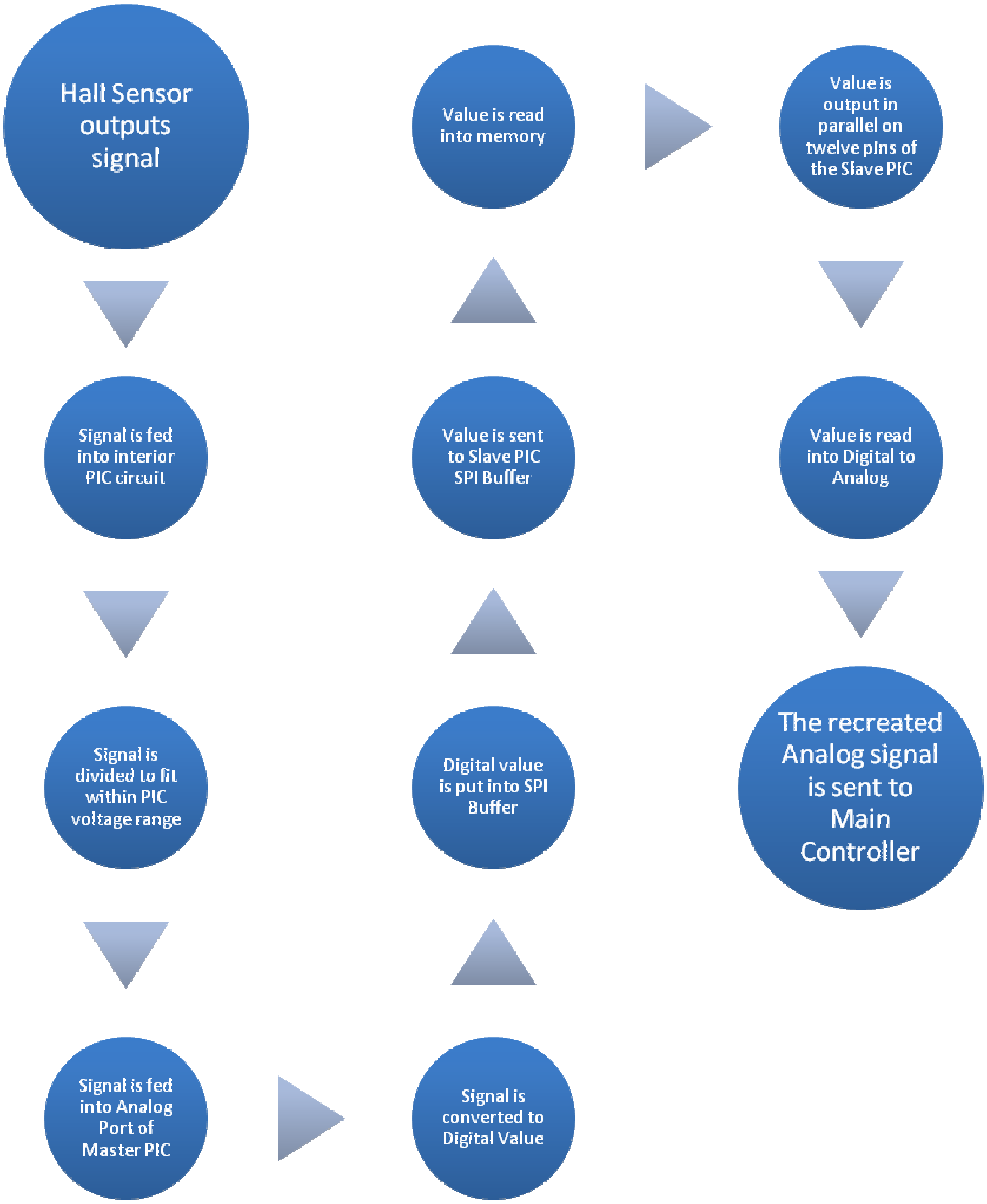
Pseudocode

Slave PIC (Exterior)

```
#include dsPIC33f.h
Set clock to external
Set I/O Pins – 7 Inputs [5 for PWM Signals, 2 for SPI]
               13 Outputs [12 Parallel Outputs for DAC, 1 SPI]
Set all I/O to digital
Set SPI to use 2 Outputs / 1 Input

Main Loop
    Sample all of the inputs
    Create a word-sized piece of data containing input information
    Load data into SPI Buffer
    Wait until transfer is completed
    Read Data from SPI Buffer into Memory
    Break data down so it can be output in parallel
    Set output pins based on data
```

Flowchart of the path of a Position Signal going from the Blood Pump → Main Controller



Feasibility of Design

For this design we have chosen to use the Microchip dsPIC33FJ32GP304. This specific chip was chosen because of its wide availability, ease of use, as well as the fact that it will meet all requirements in our design.

Interior Needs

1) ADC capable of sampling HESA signals

It needs to have an ADC capable of 5k samples per second per channel, so effectively 40k samples per second. The PIC has a capability of 500k samples per second, so it will be able to sample at over 10 times the required rate allowing for all channels to be sampled in about 8uS. The voltage of the HESA signals will be 2-5V, but a simple voltage divider will allow the voltage to fall in the PIC's allowable range of 0-3.3V

2) PWM + Digital Output

It needs to be able to output 4 20KHz PWM signals from given duty cycle information (up to 10 bit precision), as well as a digital signal for the motor speed control. This PIC has 4-channel PWM generation with up to 16-bit precision, as well as the ability to configure any of its digital I/O pins to an output, which can be used for the speed control signal.

Exterior Needs

3) Digital Output

It needs to be able to output a 12 bit digital value in parallel so that value can be read in by a DAC. The chosen PIC has up to 35 programmable I/O pins, so even after assigning pins for communication and inputs, there will be more than enough outputs available. These outputs needs to be updated at 5k times per second per channel, but the PIC can run at speeds up to 40Mhz making the update speed trivial.

4) PWM / Digital Input

It needs to be able to determine the duty cycle of the 4 PWM signal inputs with .1% accuracy. My calculation to determine the duty cycle with .1% precision was:

This is a 20kHz PWM signal

The period of the PWM signals is 1/20k seconds

The signal would need to be checked 1000 times per period to get .1% accuracy, so it would need to be checked every 1/(20k * 1000) seconds

If it needs to be checked every 1/(20k * 1000) seconds, it would be a frequency of 1/(1/(20k*1000)) = 20MHz.

Using the PIC's internal timer in gated timing mode will work for this. This timer mode keeps track of how long between an input changes state (high / low). In this mode the timer increments with the internal clock (Fcy) which is equal to Fosc / 2, so the external oscillator will need to be at 40Mhz. And the resolution of the PWM duty cycle would have to be at least 10 bits, as 2^10 = 1024 which would allow for .1% accuracy.

Common Needs

3) Communication

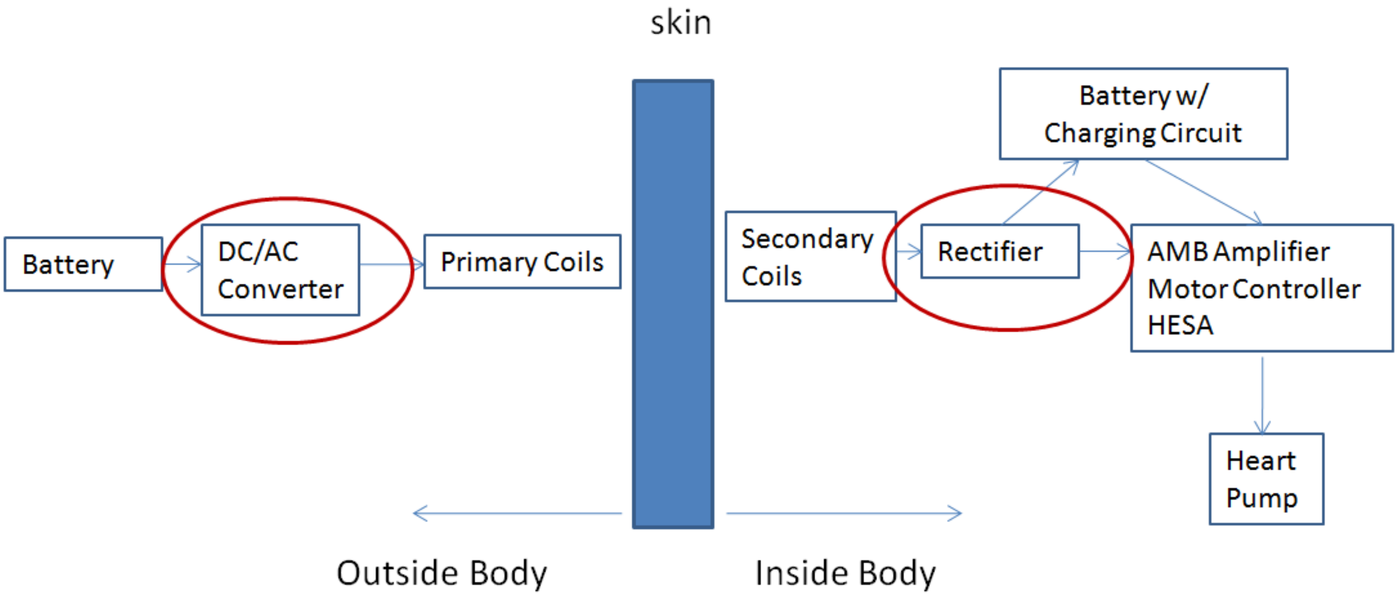
It needs to be able to send information quickly and reliably with as small of wires as possible to outside the body. The PIC given has a SSP Port, which allows for SPI to be used. This allows for data to be sent in full duplex reducing transmission delays, as well as having a throughput of up to 10Mbps, which is greater than the estimated 1Mbps needed.

4) Power

Ideally, all electronic components used for this method of transmission should use <1W. The PIC chosen should operate at full speed while only drawing ~300mA of current. So using two PIC's plus other minor components should be well under the 1W goal.

Wireless Power Transfer

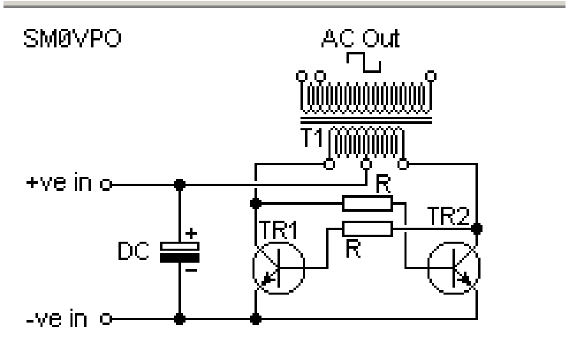
Through the use of inductive coupling, a voltage can be induced without a direct contact. Several heart pumps on the market are using this coupling such as the Abiocore and Thoratec. Using the following design, we hope to attain a wireless power transfer able to transmit 20 watts of power from an external battery to the internal system.



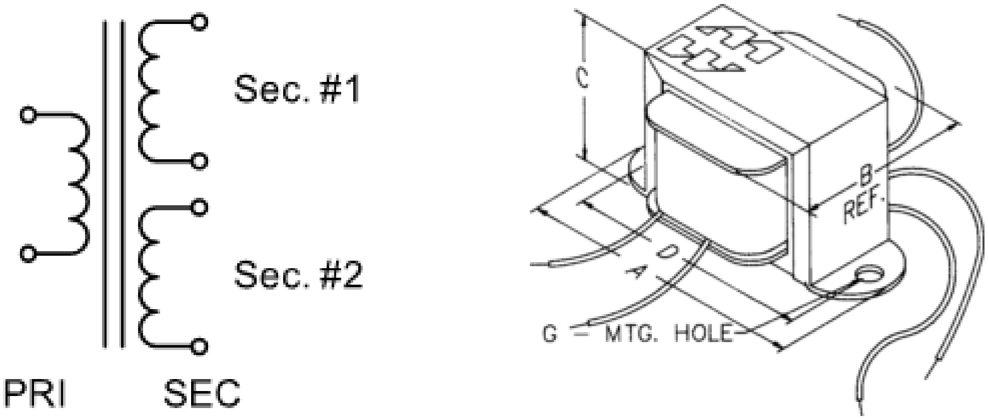
Schematic of Inductive Coupling Power Transmission System

DC/AC Inverter

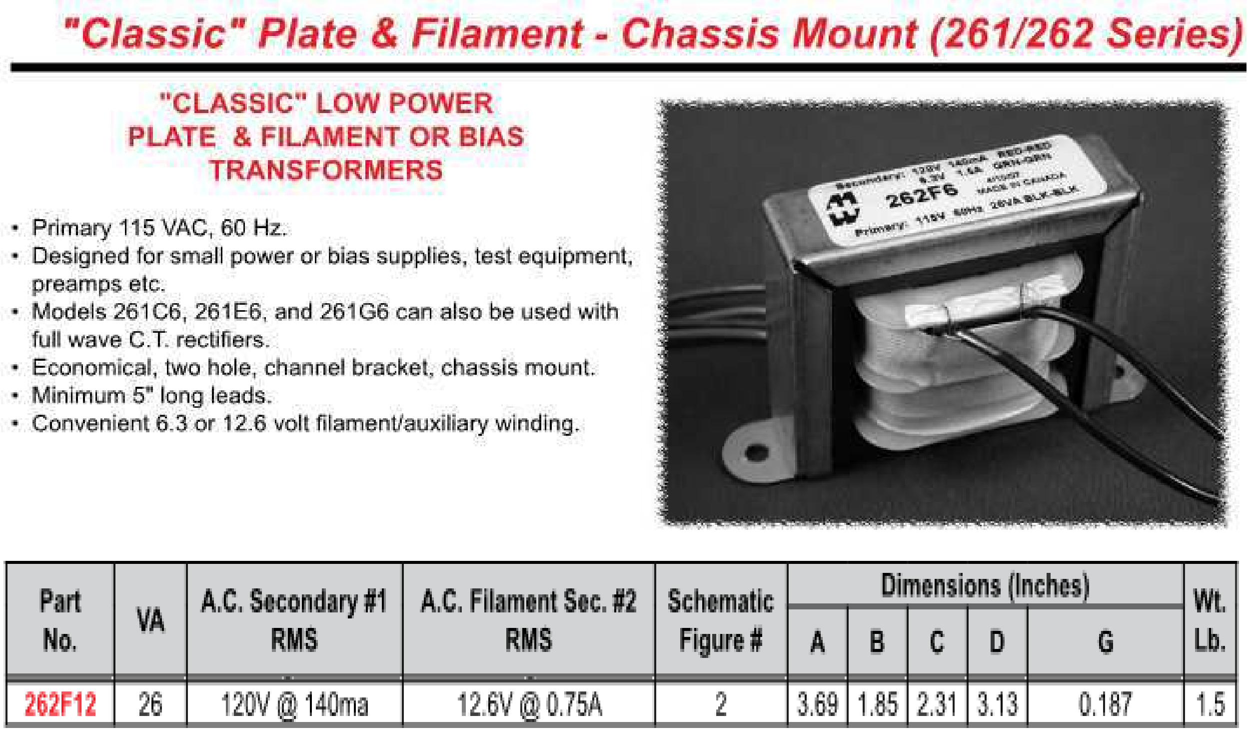
A transformer is used to convert a direct current to an alternating current using inductive coupling. A DC voltage is applied to the secondary coil (labeled SEC in diagram) and induces an AC voltage on the primary current. The DC to AC converter being used is a 60Hz monostable multi-vibrating circuit. The center lead of the primary coil has 15 volts applied to it, causing the BJT transistors to turn on and off. This oscillation will induce an AC voltage across the primary coil. The frequency of the oscillation is based on the resistor value R.



Example of a DC to AC Converter (by Harry Lythall)



Coil Diagram of Transformer (a) Example of Transformer (b)

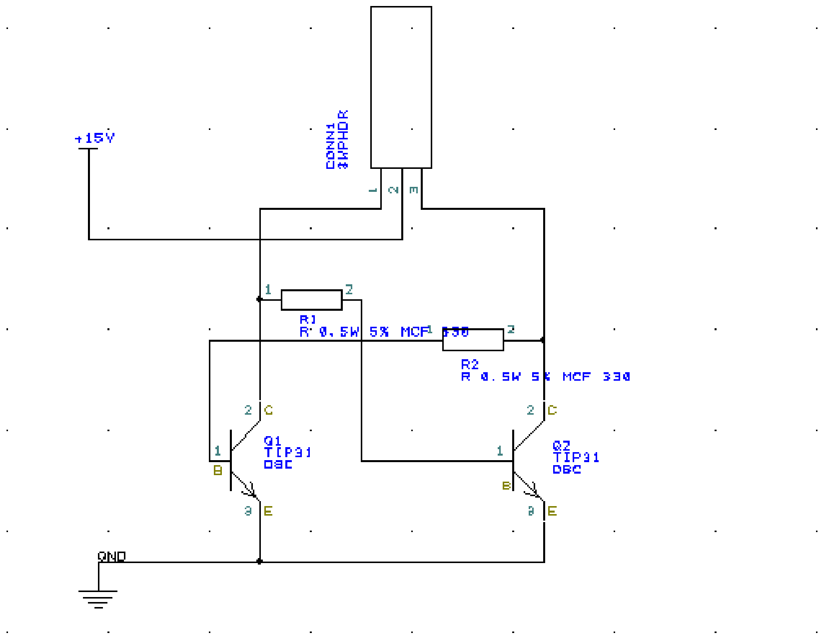


"Classic" Plate & Filament - Chassis Mount (261/262 Series)

"CLASSIC" LOW POWER PLATE & FILAMENT OR BIAS TRANSFORMERS

- Primary 115 VAC, 60 Hz.
- Designed for small power or bias supplies, test equipment, preamps etc.
- Models 261C6, 261E6, and 261G6 can also be used with full wave C.T. rectifiers.
- Economical, two hole, channel bracket, chassis mount.
- Minimum 5" long leads.
- Convenient 6.3 or 12.6 volt filament/auxiliary winding.

Part No.	VA	A.C. Secondary #1 RMS	A.C. Filament Sec. #2 RMS	Schematic Figure #	Dimensions (Inches)					Wt. Lb.
					A	B	C	D	G	
262F12	26	120V @ 140ma	12.6V @ 0.75A	2	3.69	1.85	2.31	3.13	0.187	1.5



Schematic of Inverter

AC/DC Rectifier

An AC to DC converter, also known as a rectifier is used to deliver a direct current to the heart pump. It takes the negative portion of an AC voltage and makes it positive. This is generally done using diodes. In order to eliminate ripples in the response, a capacitor can be added. In order to eliminate design and manufacturing time, an AC to DC converter will be purchased off the shelf. The GCS20 delivers 20W and 15V and comes in a small package, which is ideal for this application where there is limited space available.

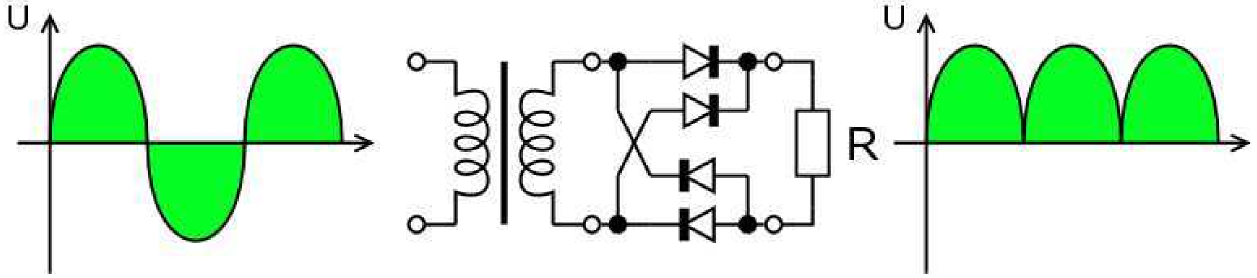
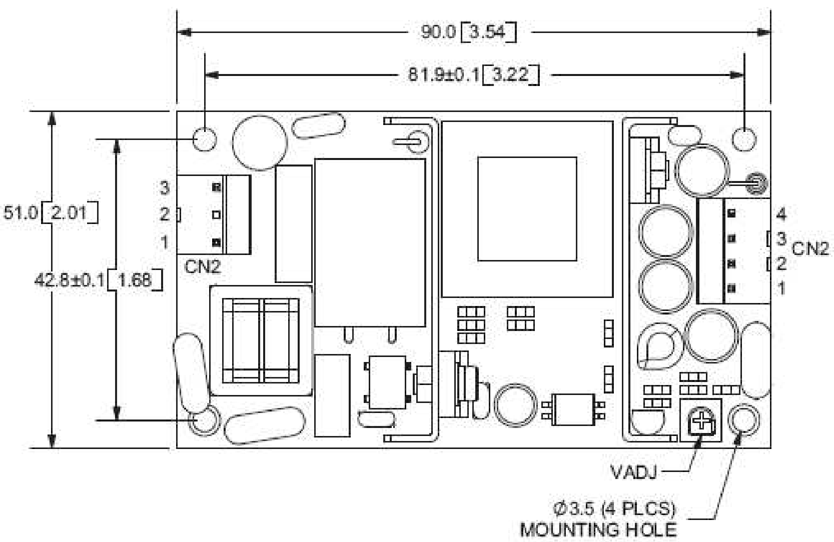


Figure – Example of a Rectifier

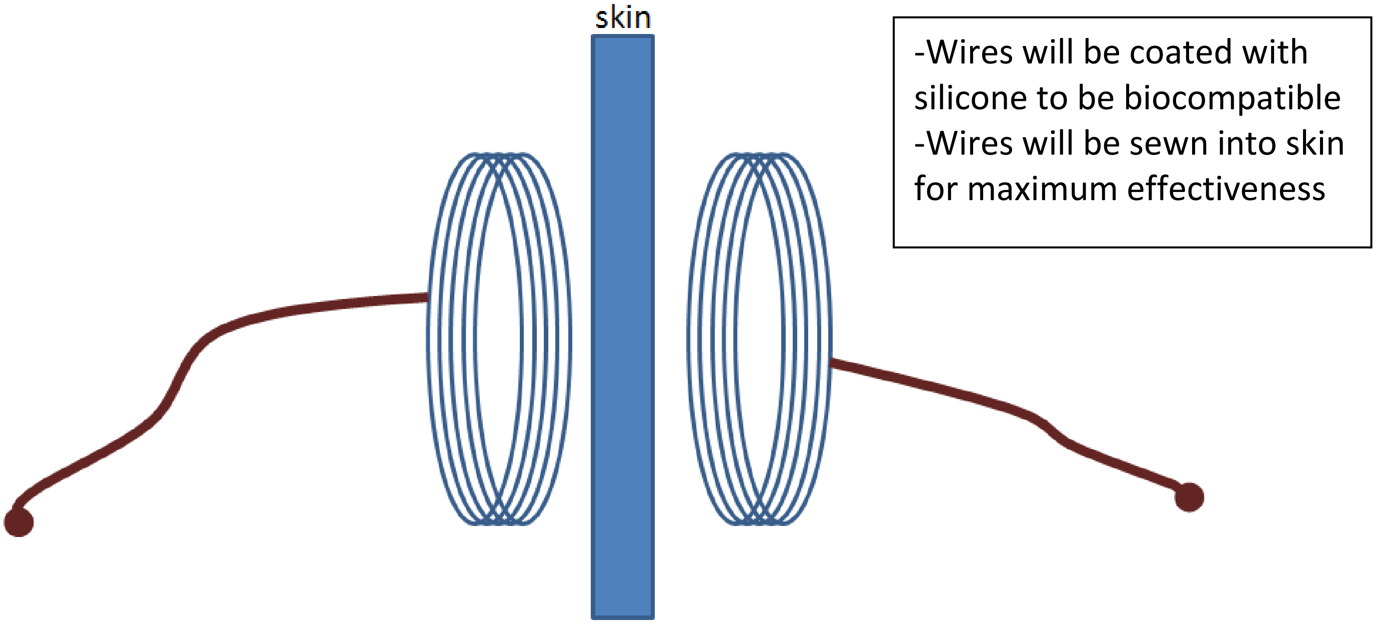
model	voltage (Vdc)	current (A)	total ^{1,2} regulation	ripple & noise^{3} (mVp-p max)	efficiency
VOF-25-15	15	1.6	±5%	150	80%



Board Layout of AC/DC Rectifier

Design of Coils

Litz wire will be used for its reduction of skin effect. As the frequency of a wire increases, the current is drawn to the edge of the conductor and away from the center. Therefore thicker gauge wire is a waste of area, since most of the current is at the surface. Litz wire contains several strands of high gauge wire that have a small cross sectional area. Although the initial design is for a low frequency system (60Hz), high frequency systems are more commonly applied (20kHz).



-Wires will be coated with silicone to be biocompatible
-Wires will be sewn into skin for maximum effectiveness

Turns of coil=16

Wire Material = 22 AWG Copper Litz wire (Approx 20 internal wires of gauge 30)

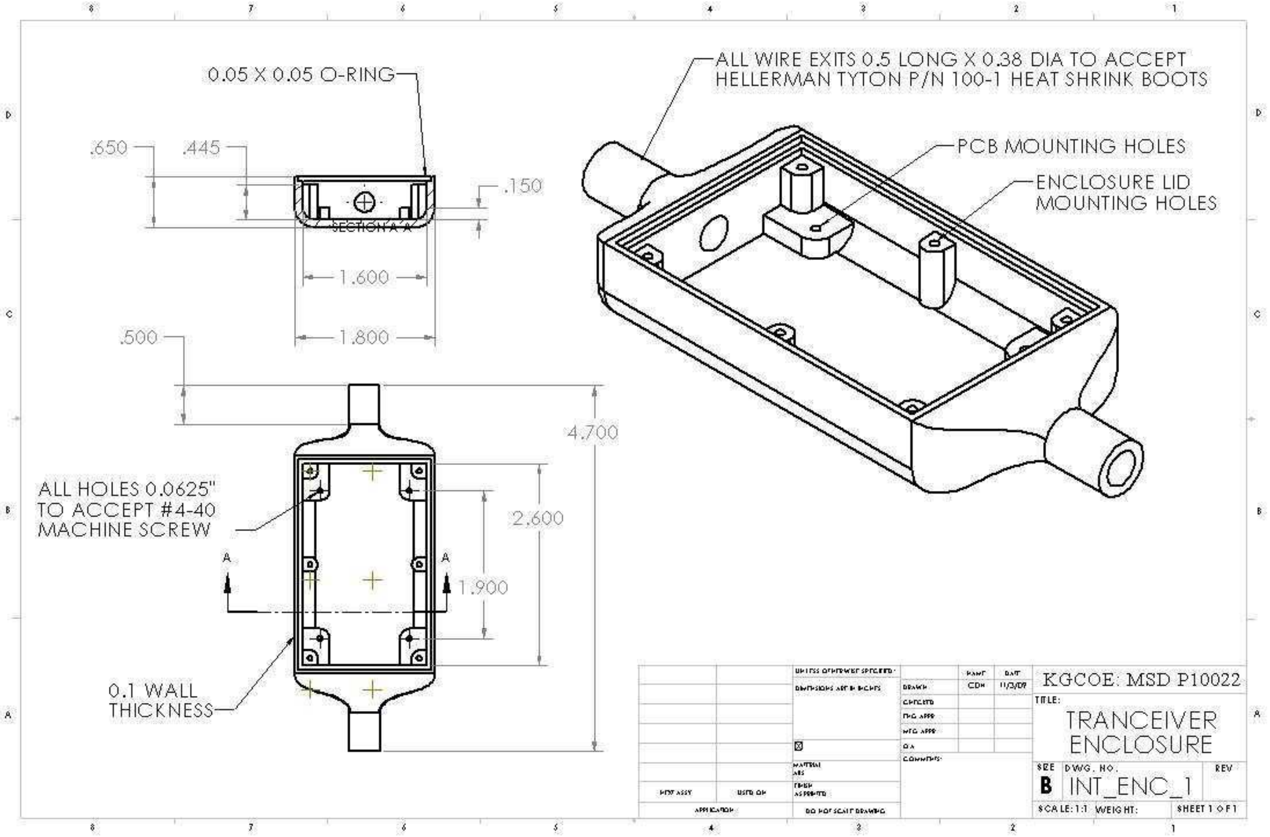
Diameter of coil = 7.1cm

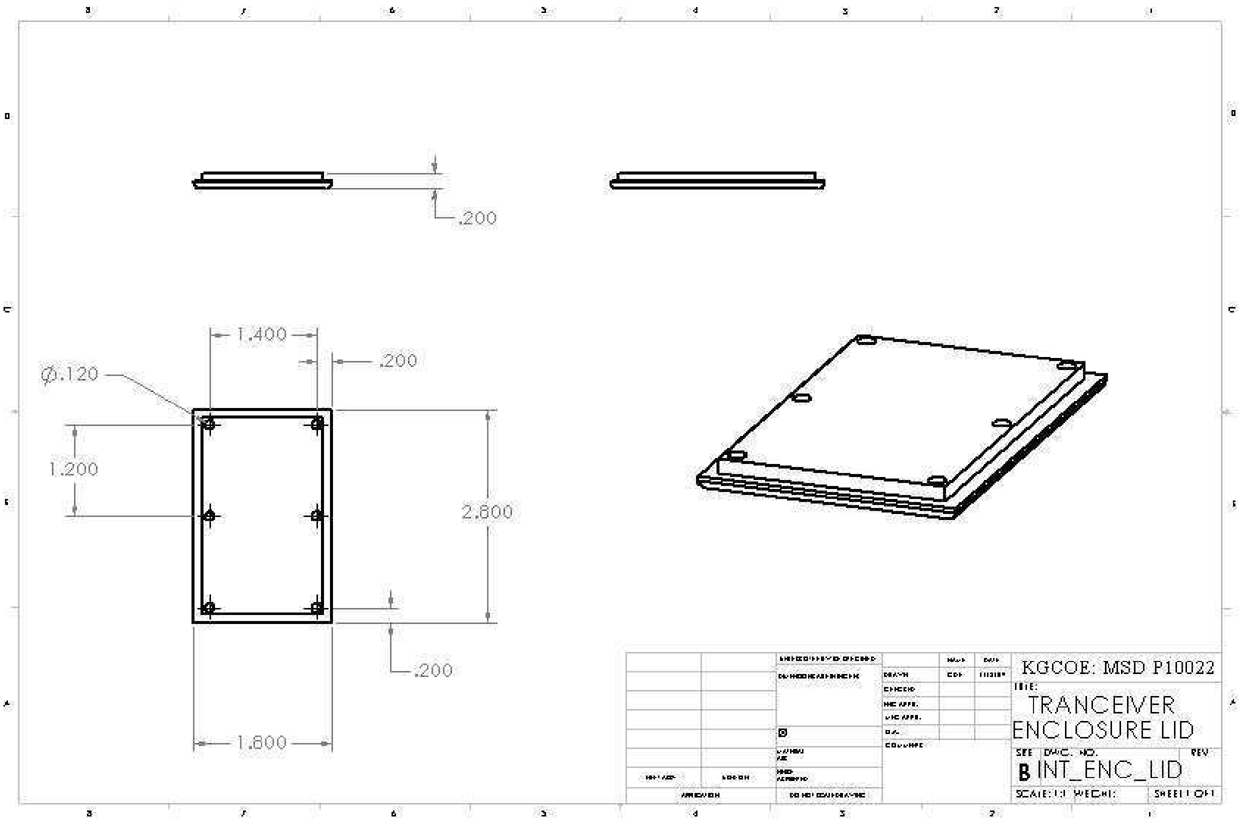
Interior and Exterior Casing Design

The following drawings represents the small enclosure that will protect the two transceivers from their surroundings and function as a part of the cable. All communication and power wires will enter though the end with one wire exit. The end with two wire exits will allow the cable to split communication and power wires in order to implement the TET subsystem.

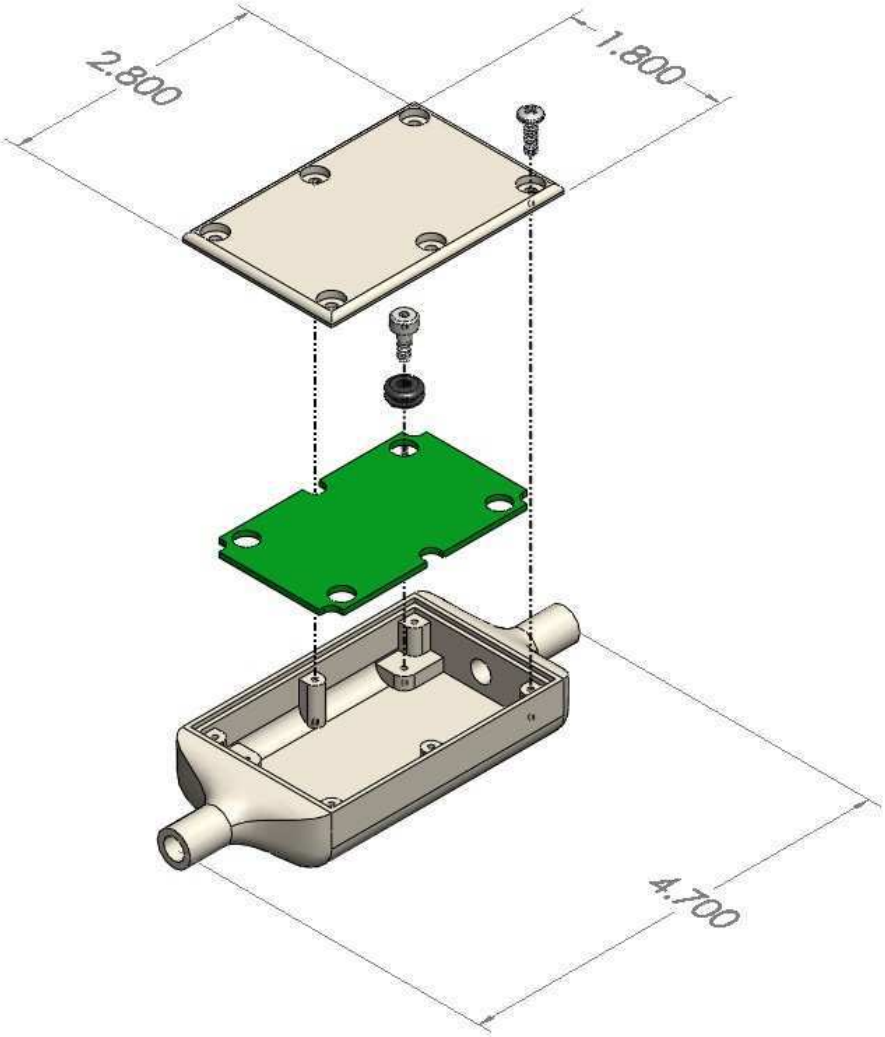
Although a silicone overcoating can ultimately provide extremely functional ingress protection, the enclosures are designed to be watertight without the overcoating. A space has been left void in-between the profiles of the enclosure and the lid in order to facilitate the use of an o-ring cord. Also, small o-rings have been selected to be installed under the exterior screw heads. These design features require testing in order to confirm their proper operation.

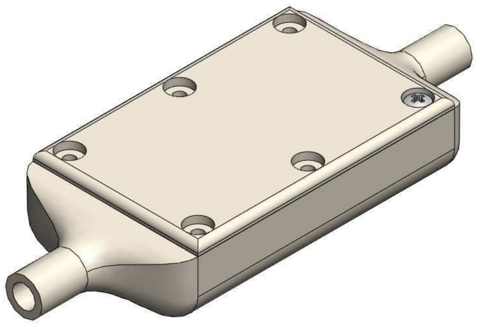
The enclosures will be produced using a Dimension Elite, rapid prototyping, 3D printer. The printer is capable of producing complex geometry that would otherwise be very expensive or nearly imposable to machine or mold.

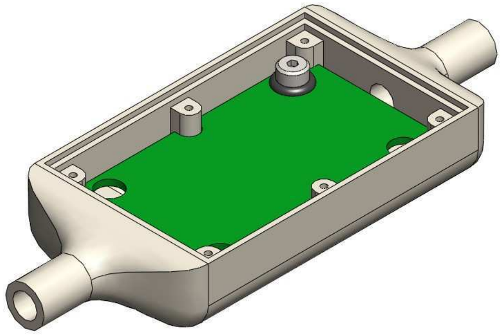


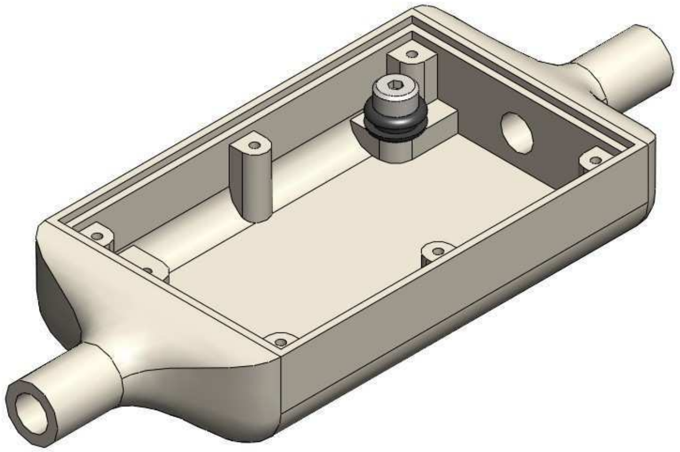

.200
1.400
.200
Ø.120
1.200
2.800
.200
1.800
KGCOE: MSD P10022
TITLE:
TRANCEIVER ENCLOSURE LID
SIZE
DWG. NO.
REV
B
INT_ENC_LID
SCALE: 1:1
WEIGHT:
SHEET 1 OF 1
DRAWN
CHECKED
ENG APPR.
MFG APPR.
Q.A.
COMMENTS:
NAME
DATE
APPLICATION
DO NOT SCALE DRAWING

The following pictures shows how the enclosure will be assembled. The PCB shown in green will have the components mounted to the bottom. The height of the components off the board has been accounted for by adjusting the level of the standoffs which the board is screwed to. The maximum PCB dimensions are 1.5” x 2.4” and it has cutouts in specific locations in order to minimize overall enclosure dimensions. As the PCB layout is completed, dimensions may need to be adjusted slightly.



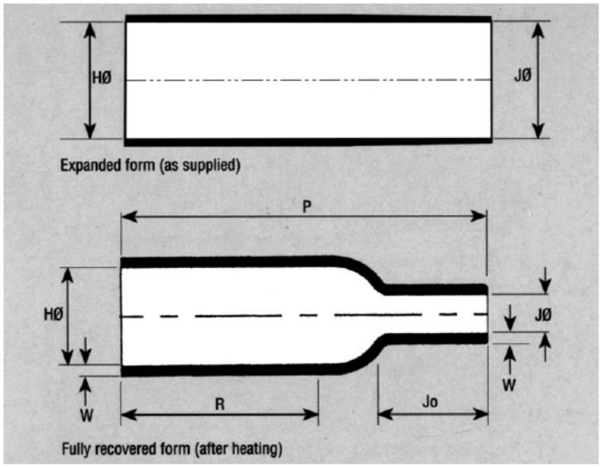


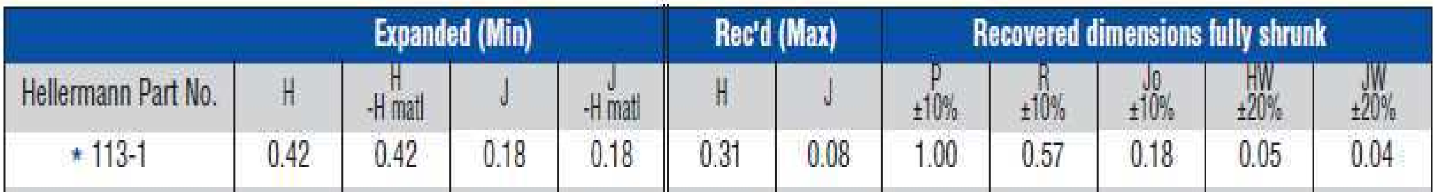




Heat Shrink Boots

Integral to the seal of both enclosures are the wire entrance/exit ports. In order to realize a seal at these points, Hellermann Tyton heat shrink boot shall be used. The boots are made of a flexible polyolefin and provide cable strain relief and mechanical protection. The large end is meant to shrink around a threaded connector end or a bare shaft. For this application, they will be assembled directly onto the transceiver enclosures which have been designed to be accommodating.





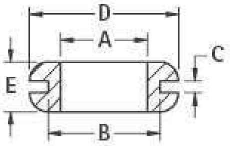
	Expanded (Min)				Rec'd (Max)		Recovered dimensions fully shrunk				
Hellermann Part No.	H	H -H matl	J	J -H matl	H	J	P ±10%	R ±10%	Jo ±10%	HW ±20%	JW ±20%
* 113-1	0.42	0.42	0.18	0.18	0.31	0.08	1.00	0.57	0.18	0.05	0.04

O-ring Cord

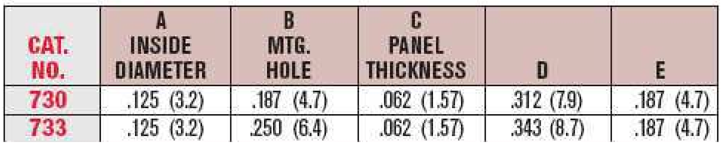
The contact surfaces between the lid and the enclosure body will incorporate a 1/16” diameter o-ring cord. The cord will be cut to the exact length required and will be compressed when tightening the screws holding the lid to the body of the enclosure.

Mechanical Damping Grommets

In order to protect the PCB and it’s components against severe mechanical shock, rubber grommets have been selected to be installed between the retaining screws and the PBC itself. These grommets will absorb some energy when the device is dropped or otherwise subject to sudden shocks.



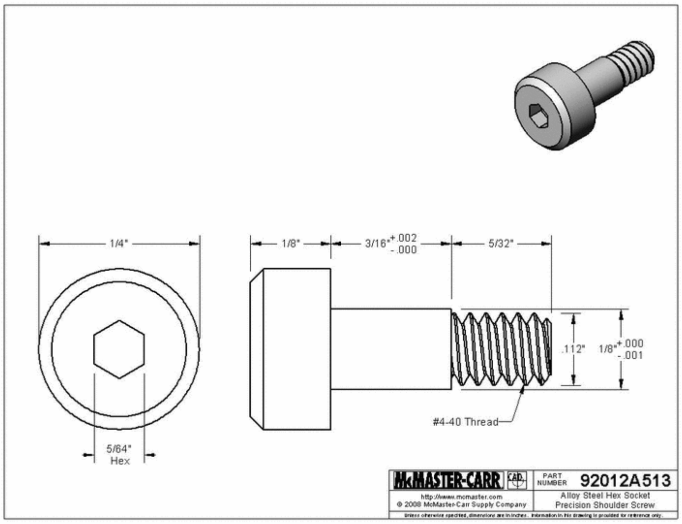
MATERIAL: Rubber, BUNA S

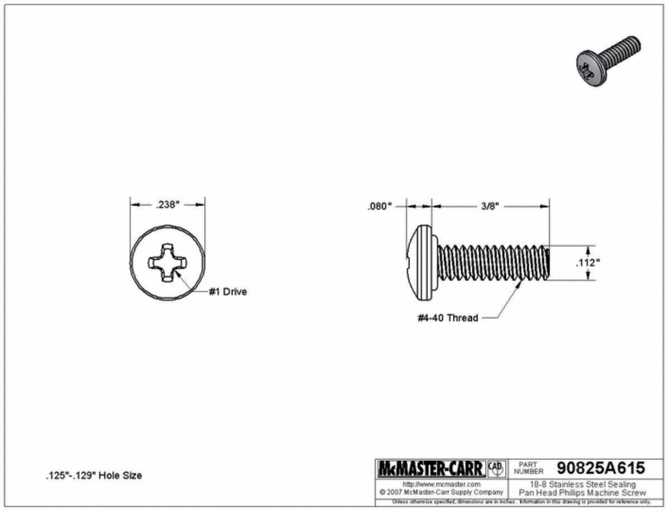


CAT. NO.	A INSIDE DIAMETER	B MTG. HOLE	C PANEL THICKNESS	D	E
730	.125 (3.2)	.187 (4.7)	.062 (1.57)	.312 (7.9)	.187 (4.7)
733	.125 (3.2)	.250 (6.4)	.062 (1.57)	.343 (8.7)	.187 (4.7)

Screws

Two screw types are needed to secure 1) the PCB to the enclosure and 2) the enclosure lid to the body. A shoulder screw has been selected for the former as it incorporates non-threaded section which will fit perfectly into the vibration damping grommets. The latter is a sealing machine screw. Both have #4-40 threads.





Alden Connector

ALDEN
CONNECT OUTSIDE THE BOX

PL-700RG-N SERIES

Plastic Shell Auto-Coupling Connectors

***27 pole** capacity disposable receptacle and support interconnects*

PL-700RG-N FEATURES

Specifically designed for electro-surgical catheter applications, the compact and cost effective PL-700 Series offers more features, contacts, and termination options than the competition.

Packaging (intuitive, compact, configurable)
- Pulse-Lok® auto-latch / quick release mechanism confirms continuity in critical surgical applications
- 14 standard color combinations
- Proprietary keying protects your single-use from being copied, or mated with the wrong connector

- Custom configurations available including passive and active devices for coding or limiting catheter usage

Performance (for harsh environments)
- Water proof
- Sterilizable
- Chemical resistant housing
- Up to 5,000 mating cycles (with std. Contacts)
- Factory terminated, overmolded cable assemblies for enhanced flex and strain relief

SPECIFICATIONS

Electrical (See Table A)
Mating Life: 5,000 cycles min.
Contact Resistance: < 10 milliohms*

Material
Connector Housing: Thermoplastic
Flex Reliefs: Thermoplastic Rubber
Contacts: Pins = Brass, Sockets = Bronze Alloy
Gold Plate per MIL-G-45204C
Reusable Socket = 30 - 45µ" Gold over 50 – 200µ" Nickel strike
Disposable Pin = 10 - 30µ" Gold over 50 – 200µ" Nickel strike

Mechanical
Mating Cycles: 20K cycles max
Retention Force (axial):
- Mated Connectors: 50 lbs. Minimum
- Cable to Connector: to 50 lbs. typical
- Backshell to Connector: 50 lbs. Minimum

Environmental
- Operating Temp: -20C to +85C
- Moisture Resistance: to IP-67
- Sterilizable: steam, gamma & EtO
- Chem. Resistance: common OR cleaning solvents
- Shelf Life: 3 years (min) Disposable Connector

* *post conditioning*

TABLE A: STANDARD CONTACT CONFIGURATIONS & SPECIFICATIONS

Up to 27 contact positions

Number of Poles	Contact Size Pin ϕ (mm)	Max Wire Gauge	Operating Voltage max	Operating Current Max	Contact Resistance
27	0.5	26	300 V RMS	2.0 A	< 10m ohms
14	0.7	22	300 V RMS	5.0 A	< 10m ohms

Other pole counts available. Consult factory.

The connector chosen was a 27 pin water proof cable designed for medical applications by Alden. The operating current of this connector is set at 2.0A which is slightly less than what is needed, but this problem can be solved by connecting current wire carrying a higher amperage to several pins to increase the maximum current through the connector. This selection was discussed and agreed upon with the P10021 Miniaturization team, who will be using the male version of the connector in their prototype.

Heat Transfer Analysis

Heat generated was approximated by the maximum power dissipated by the components on the PC Board:

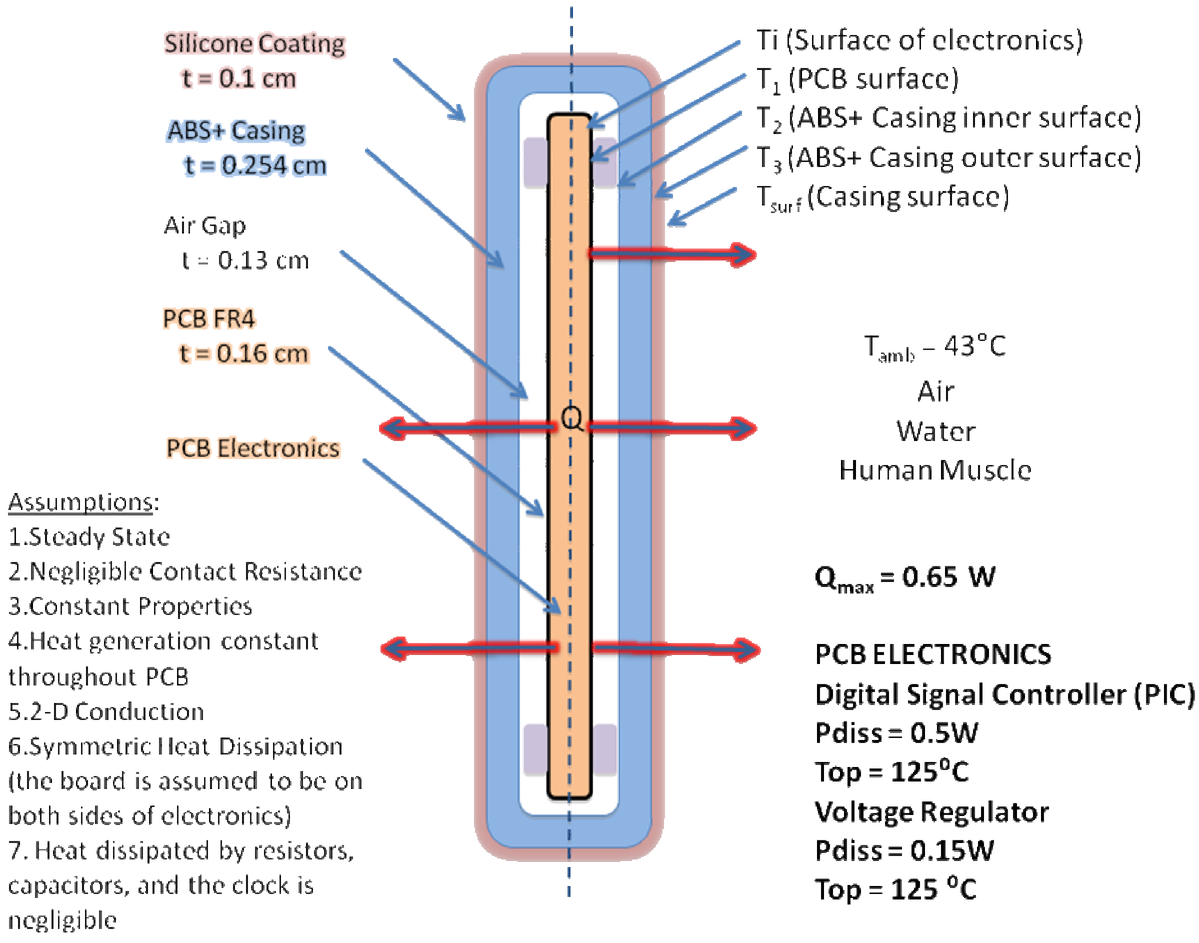
Digital Signal Controller (PIC):

$$P_{d,max} = \frac{T_j - T_a}{\theta_{ja}} = \frac{140°C - 125°C}{30°C/W} = 0.5W$$

Voltage Regulator:

$P_{diss} = (V_{in}-V_{out})*I_{out} = (5V-3.3V)*0.090A = 0.15\ W$

Resistors, capacitors, and the clock are considered to have insignificant power dissipation.



Assumptions:
1.Steady State
2.Negligible Contact Resistance
3.Constant Properties
4.Heat generation constant throughout PCB
5.2-D Conduction
6.Symmetric Heat Dissipation (the board is assumed to be on both sides of electronics)
7. Heat dissipated by resistors, capacitors, and the clock is negligible

Q_{max} = 0.65 W

PCB ELECTRONICS
Digital Signal Controller (PIC)
Pdiss = 0.5W
Top = 125°C
Voltage Regulator
Pdiss = 0.15W
Top = 125 °C

Heat Transfer Approximation with Muscle as Ambient									
Q gen (1/2)	0.33	W	Qtotal	0.65W					
Area of PCB	0.001875	m^2							
Q''	173.33	W/m^2							
Ti	58.9	C	Board, k1	0.23	W/mK	L1	0.00157	m	
T1	57.7	C	Air, k1	0.027	W/mK @ 40C	L2	0.0013	m	
T2	49.4	C	ABS, k2	0.188	W/mK	L3	0.00254	m	
T3	47.0	C	Silicone, k3	0.314	W/mK	L4	0.001	m	
T surface	**46.5**	**C**	Muscle, k4	0.5	W/mK @300K	L5	0.01	m	
T ambient	43.0	C							
Req/A=R''eq	0.09	W/K/A	Ti	58.89					

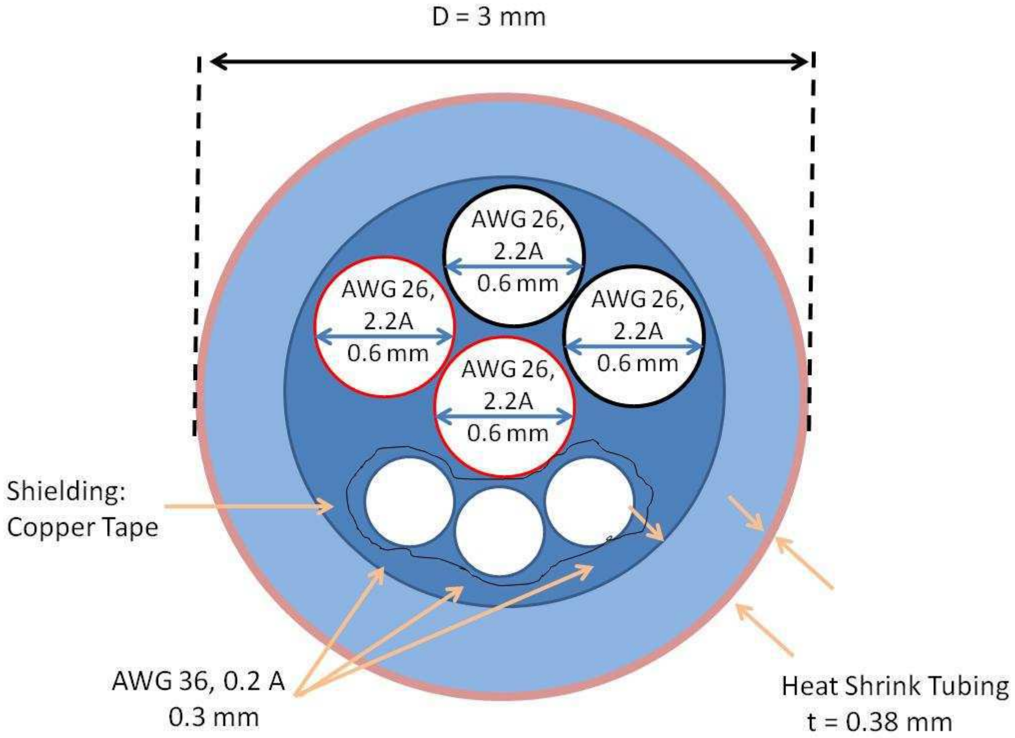
Heat Transfer Approximation with Water as Ambient								
Q generated	0.33	W						
Area of PCB	0.001875	m^2						
Q''	173.3	W/m^2						
Ti	56.3	C	Board, k1	0.23	W/mK	L1	0.00157	m
T1	55.1	C	Air, k2	0.027	W/mK @ 40C	L2	0.0013	m
T2	46.8	C	ABS, k3	0.188	W/mK	L3	0.00254	m
T3	44.4	C	Silicone, k4	0.314	W/mK	L4	0.001	m
T surface	**43.9**	**C**	Water, h5	200	W/m^2K @300K	L5	1	
T ambient	43.0	C						
Req/A=R''eq	0.08	W/K/A	Ti	56.29				

Heat Transfer Approximation with Air as Ambient								
Q generated	0.33	W						
Area of PCB	0.001875	m^2						
Q''	173.3	W/m^2						
Ti	64.1	C	Board, k1	0.23	W/mK	L1	0.00157	m
T1	62.9	C	Air, k1	0.027	W/mK @ 40C	L2	0.0013	m
T2	54.6	C	ABS, k2	0.188	W/mK	L3	0.00254	m
T3	52.2	C	Silicone, k3	0.314	W/mK	L4	0.001	m
T surface	**51.7**	**C**	Air, h4	20	W/m^2K @300K	L5	1	
T ambient	43.0	C						
Req/A=R''eq	0.12	W/K/A	Ti	64.09				

Heat Transfer Approximation with Air as Ambient								
Q generated	0.33	W						
Area of PCB	0.001875	m^2						
Q''	173.3	W/m^2						
Ti	45.1	C	Board, k1	0.23	W/mK	L1	0.00157	m
T1	43.9	C	Air, k1	0.027	W/mK @ 40C	L2	0.0013	m
T2	35.6	C	ABS, k2	0.188	W/mK	L3	0.00254	m
T3	33.2	C	Silicone, k3	0.314	W/mK	L4	0.001	m
T surface	**32.7**	**C**	Air, h4	20	W/m^2K @300K	L5	1	
T ambient	24.0	C						
Req/A=R''eq	0.12	W/K/A	Ti	45.09				

Three models are used to approximate the heat dissipation through the casing: 1. The prototype imbedded in muscle tissue; 2. Imbedded in water; 3. Imbedded in air. The ambient temperature was set at 43^{o}C regardless of the ambient picked. From the calculations it appears that the electronics will not overheat if they are used inside the human muscle or in water. Also, according to the calculations the surface of the casing of the prototype does not heat up to more than 6.4°C above ambient temperature when set in muscle tissue and/or in water, which meets Customer Need #12 and Specification #30. All the values and calculations used are conservative.

Wire and Cable Selection



The above diagram of the cross section of the proposed wire design will be used to transmit signals and power. A smaller diameter is achieved by using more, smaller wires for power rather than only two. This will also serve as redundancy.

Copper foil tape backed can be used with a copper or tin drain for electrostatic shielding. Shielding should also be electrically continuous with the signal wires. The shielding should be grounded as well at the same ground potential.

Bill of Materials

Item	Part Number	Company	Availability	Phone	Detailed Description	Quantity	Unit Price ($)	Extended Price ($)
1	AD5348	Digi-Key	In Stock	(781)329-4700; 1-800-344-4539	Converter; Quad, Parallel Input, Voltage Output, 12-Bit D/A Converter	10	15.56	155.60
2	CTX741TR-ND	Digi-Key	In Stock	1-800-344-4539	Clock; HCMOS/TTL Clock Oscillator Model 632; 50MHz; 3.3V; 15mA	10	1.64	16.40
3	579-DSPIC332GP304EPT	Mouser Electronics	In Stock	1-800-346-6873	Controller; Digital Signal Processors & Controllers (DSP, DSC) 16B DSC 32KB DMA 40MIPS; 44 pin	10	5.47	54.70
4	LT1117CST-3.3-ND	Digi-Key	In Stock	1-800-344-4539	Voltage Regulator, 5V to 3.3V, Single Output	5	1.95	9.75
5	587-1133-1-ND	Digi-Key	In Stock	1-800-344-4539	Capacitor, 0.1 uF Surface Mount	100	0.29	29.00
6	490-3905-1-ND	Digi-Key	In Stock	1-800-344-4539	Capacitor, 10 uF Surface Mount	100	0.31	31.00
7	P10KCBCT-ND	Digi-key	In Stock	1-800-344-4539	Resistor, 10K Surface Mount	20	0.55	11.04
8	311-4.70KCRCT-ND	Digi-Key	In Stock	1-800-344-4539	Resistor, 4.7K Surface Mount	50	0.04	2.00
9	311-2.20KCRCT-ND	Digi-Key	In Stock	1-800-344-4539	Resistor, 2.2K Surface Mount	50	0.04	2.00
10	DV164035-ND	Digi-Key	In Stock	1-800-344-4539	Programmer/Debugger; MPLAB ICD 3 In-Circuit Debugger	1	189.99	189.99
11	DM300027	Digi-Key	In Stock	480-792-7200	Demo Board Kit, Starter 16-Bit 28P	2	79.99	159.98
12	546-262F12	Mouser Electronics	In Stock	1-800-346-6873	Transformer; PLATE AND FILAMENT; 26VA; 115V	1	32.46	32.46
13	VOF-25-15	Digi-Key	In Stock	1-800-344-4539	Converter, A/D, V-Infinity VOF-25 Series, PWR SUPPLY 24W OPEN 15V 1.6A	1	20.76	20.76
14	CU-MM115	AA Portable Power Corp	In Stock	510-525-2328	Battery, Li-Ion Polymer, 14.8V, 750mAh (11.1wh) with PCB	1	95.00	95.00
15	DEV-09002	Sparkfun Electronics	2-3 Weeks	303-284-0979	Function Generator Kit	1	34.95	34.95
16	See details	MWS Wire Industries	5 days	818-991-8553	Litz wire, 26 Stands of 36 AWG Heavy poly-nylon UNSERVED litz (1lb)	1	41.86	41.86
17	296-15063-5-ND	Digi-Key	In Stock	1-800-344-4539	PWM Controller, IC FIX-FREQ HS CTRLR 16-DIP	5	3.85	19.25

18	FAN7392N-ND	Digi-Key	In Stock	1-800-344-4540	Half Bridge Driver, IC GATE DVR MONO HI/LO 14DIP	5	1.30	6.50
19	TIP31GOS-ND	Digi-Key	In Stock	1-800-344-4541	BJT NPN Transistor, TRANS NPN 3A 40V HI PWR TO220AB	16	0.57	9.12
20	TIP32-BP-ND	Digi-Key	In Stock	1-800-344-4542	BJT PNP Transistor, TRANS PNP 3A 40V TO-220	6	0.68	4.08
21	RS401LDI-ND	Digi-Key	In Stock	1-800-344-4543	H-Bridge Rectifier, RECT BRIDGE GPP 50V 4A RS-4L	5	1.58	7.90
22	LM2576HVT-15-ND	Digi-Key	In Stock	1-800-344-4544	Regulator, 15V, IC REG SIMPLE SWITCHER TO-220-5	5	5.85	29.25
23	1N5400DICT-ND	Digi-Key	In Stock	1-800-344-4545	Diode, RECTIFIER GPP 50V 3A DO-201AD	15	0.46	6.90
24	ICL7673CPAZ-ND	Digi-Key	In Stock	1-800-344-4546	Battery Switch, IC BATT BACK-UP SWITCH 8-PDIP	5	1.90	9.50
25	1010PHCT-ND	Digi-Key	In Stock	1-800-344-4547	Capacitor, 1nF, CAP 50V .001UF AXIAL CERAMIC C0G (10 items)	1	1.38	1.38
26	1103PHCT-ND	Digi-Key	In Stock	1-800-344-4548	Capacitor, 0.01uF, CAP 50V .01UF AXIAL CERAMIC X7R (10 items)	1	0.72	0.72
27	4087PHCT-ND	Digi-Key	In Stock	1-800-344-4543	Capacitor, 10uF, CAP 100V 10UF ELECT AXIAL	10	0.61	6.10
28	493-1341-ND	Digi-Key	In Stock	1-800-344-4544	Capacitor, 100uF, CAP 100UF 50V ELECT VZ RADIAL	10	0.29	2.90
29	P10278-ND	Digi-Key	In Stock	1-800-344-4545	Capacitor, 1000uF, CAP 1000UF 25V ELECT FC RADIAL	10	0.87	8.70
30	M8354-ND	Digi-Key	In Stock	1-800-344-4546	Inductor, 100uH, CHOKE RF HI CURR 100UH 10% RAD	5	4.44	22.20
31	10W-1-ND	Digi-Key	In Stock	1-800-344-4547	Resistor, 10 Ohms, RES 10 OHM 1W 5% METAL OXIDE	10	0.16	1.60
32	10KW-1-ND	Digi-Key	In Stock	1-800-344-4548	Resistor, 10 kOhms, RES 10K OHM 1W 5% METAL OXIDE	10	0.16	1.60
33	PL-700 RG-N	Amphenol Alden	In Stock	508-427-7014	Connector, 27 pin, Medical Disposable Auto-Coupling Connectors	8	30.00	240.00
34	9487T114	McMaster-Carr	In Stock	404-629-6500	Wire, 36AWG, 0.1A, 0.012'' (1.5 ft each)	14	0.52/1.5ft	7.28
35	7071K623	McMaster-Carr	In Stock	404-629-6500	Wire, 22AWG, 2.8A, 0.052"; Flexible Wire	20	1.86/ft	37.20
36	69835K81	McMaster-Carr	In Stock	404-629-6500	Wire, 26AWG, 4A, 0.039", Harsh	1	2.08	2.08

					Environment Wire (25ft)			
37	7960K31	McMaster-Carr	In Stock	404-629-6500	Heat Shrink Tubing, Di 0", thickness 0.015", L 6", Harsh Environment PTFE; 650F cure	40	3.45	138.00
38	73115K71	McMaster-Carr	In Stock	404-629-6500	Heat Shrink Tubing, Di 0.0156", thickness 0.038", L 48"; Flexible; 275F	5	4.96	24.80
39	113-1-J-WM250	Alta Electronics Inc.	4 - 5 weeks	905-819-1900	Heat Shrink Boot, Hellermann, 100 Series Bottle Shapes	6	9.33	55.98
40	76555A713	McMaster-Carr	In Stock	404-629-6500	Copper Foil Tape, ¾", 6yd	1	14.39	14.39
41	92012A513	McMaster-Carr	In Stock	404-629-6500	Screw, Hex, Alloy Steel, 4-40 Thread, 3/16" shldr L, 1/8" shldr dia.; 1/8" socket shldr screw (4 in pack)	4	3.08	12.32
42	90825A615	McMaster-Carr	In Stock	404-629-6500	Screw, Pan Head, Sealing, 4-40 Thread, 3/8" Length (10 pack)	1	6.00	6.00
43	5229T47	McMaster-Carr	In Stock	404-629-6500	Cord Stock, O-Ring, Round, 2-ft, Silicone, Black	2	0.78	1.56
44	1832A14	McMaster-Carr	In Stock	404-629-6500	Silicone, Loctite Nuva-Sil 5248, 10.1oz	1	139.79	139.79
45	P1	Brinkman Lab	1 day	--	Casing, rapid-prototyping, ABS plus	4	50.00	200.00
							Total	1,903.59
					**In stock items ship within 1 day.		Shipping (10%)	190.36
					**Note: color code signifies components for different subsystems		Total +Shipping	2,093.95

Legend

Green=Signal Transmission

Blue=Programming Tools

Purple=Transcutaneous Energy Transmission

Mauve=Wiring

Orange=Casing

Test Plans

If any of the following tests fail, there is funding for components for two extra prototypes that will be designed and re-designed according to test results.

LVAD Simulation Signal Test

Before testing the proposed prototype with the current LVAD set-up and with P10021 design, a test simulating signals entering and leaving the designed transceivers will be conducted. Agilent 33120A Function/Arbitrary Waveform Generator will be used to simulate signals entering the device, and HP54602B Oscilloscope will be used to measure the output of the transceivers. The goal is to make sure that the signals are processed correctly, and each pin of the connector corresponds to appropriate pins of the connectors inside the body.

The following signals will be generated and measured:

Signal transmission from LVAD position sensors (HESA) to XPC Control Target:	**Units**	**Input**	**Output**
Signals from LVAD position sensors to the inner transceiver	Count	8	
Voltage	Volts	2 - 5	
Current	mA	15	
Frequency	Hz	0 - 600	
Sampling Rate	ksps	5	
Signals from the outer transceiver to the amplifiers	Count	8	
Voltage	Volts	2 - 5	
Current	mA	1	
Frequency	Hz	0 - 600	
Sampling Rate	ksps	5	
Signal transmission from XPC Control Target to Active Magnetic Bearings (AMB)			
Signals from XPC Control Target to PWM Generator	Count	4	
Voltage	Volts	0 - 5	
Current	A	-3 - 3	
Frequency	kHz	20	
Signal transmission of Speed Control signal from XPC Control Target to the LVAD Motor			
Signal from XPC Control Target to Motor Controller	Count	1	
Voltage	Volts	0 - 5	
Current	mA	20	
Frequency	MHz	40	

Materials Needed:

1. HP 54602B Oscilloscope
2. Agilent 33120A Function Waveform Generator

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Comments:____

Electronics Functionality Test

Eng. Spec. #	Importance	Source	Specification Description	Unit of Measure	Ideal Value
36	5	CN15	The device must demonstrate reliability, must function continuously for the testing period.	Hours	6
37	5	CN16	Number of interruptions for the device's 6 hour cycle.	Count	0
38	5	CN17	Number of user interventions for device's 6 hour cycle.	Count	0
39	5	CN18	The device should work with the currently established system components.	Boolean	1
40	3	CN19	The device functions in accordance with Project #10021 (Miniaturization senior design team).	Boolean	1

The specifications above will be tested by plugging in the proposed device in two ways for a period of 6 hours to check the functionality of the device. One method is to test functionality of the new electronics with current system components; the second, is to test functionality with the design of the P10021 Senior Design Miniaturization team. To test functionality of the new electronics, we must have access to the current system components' signals needed to test our design. Required signals are outlined in high-level design schematics and in specifications. Upon collaboration with P10021 Senior Design team, several criteria was agreed upon to allow for testing of both designs simultaneously for a period of 15 minutes. Observations will be made at 5 minute time intervals to ensure that the electronics are working properly, without any need for adjustments.

Equipment Needed:

1. Functional LVAD (provided by Dr. Cheng and Dr. Day)
2. Motor Controller, PWM Amplifiers, Summation and Differential Amplifiers connected to the LVAD (Provided by Dr. Cheng (current system) and P10021 Miniaturization Team).
3. XPC Controller and AC-DC Converter and Power Supply (if no functional TET)

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Comments:____

Current System Test

Random Time Testing (mins)	Functioning (Yes / No)	What is malfunctioning?
0		
30		
60		

P10021 Senior Design Team Project Test

Random Time Testing (mins)	Functioning (Yes / No)	What is malfunctioning?
0		
5		
10		
15		

Wireless Power Transfer Test

The goal of this test is to demonstrate the wireless power transfer capability for the inductive power transfer. The TET should transmit 30 Watts of power through human skin and tissue, however, a demonstration of the power transmission through the coils with air as the medium in between is sufficient for the demonstration. Voltage and current can be varied to represent

Materials Needed:

1. HP 54602B Oscilloscope
2. Agilent 33120A Function Waveform Generator

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Comments:____

Trial #1:

Voltage In: __________ Voltage Out: _________

Current In: __________ Current Out: _________

Power In: ___________ Power Out: __________

Efficiency: ___________

Trial #2:

Voltage In: __________ Voltage Out: _________

Current In: __________ Current Out: _________

Power In: ___________ Power Out: __________

Efficiency: ___________

Trial #3:

Voltage In: __________ Voltage Out: _________

Current In: __________ Current Out: _________

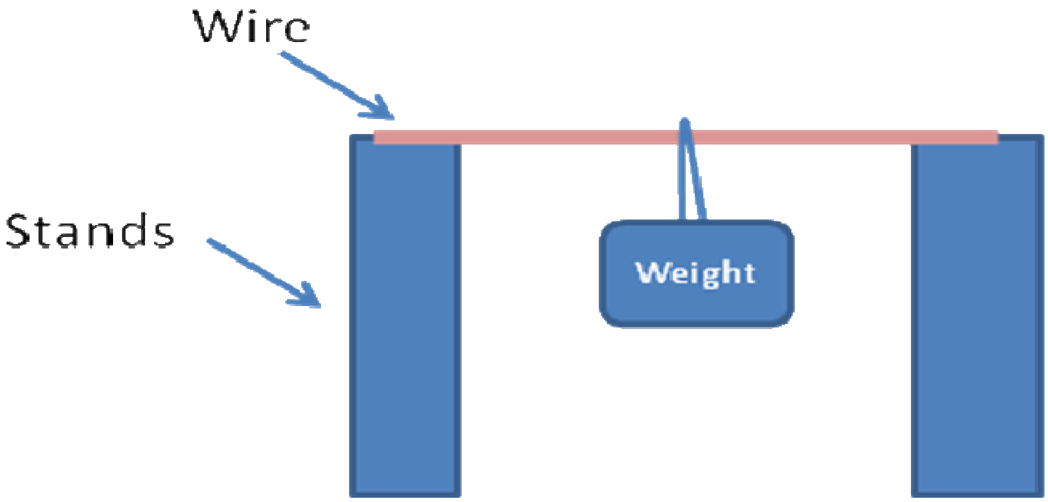
Power In: ___________ Power Out: __________

Efficiency: ___________

Flexibility Test

This test is designed to compare the flexibility of current cable used for control of the LVAD compared to the proposed new design for the cable. Currently the cable consists of 23 wires bundled into a stainless steel cable covered with Loctite 5248 Alcoxy silicone. This cable will be tested for flexibility using the technique shown below. The 4’’ cable will be placed on a steady surface of a table on small stable stands. A force will be applied by using small incremental weights of a penny or a quarter mounted on a paper clamp hanging on the wire, previously measured on a triple beam balance. The deflection will be measured with a measuring tape or a ruler for a specific weight added. The flexibility can be calculated from these values, and compared for both cables. Exactly the same conditions will be applied to both cases. The goal is for the new design cable to have flexibility 200% (150% marginally) greater than the old cable, specified in Engineering Specifications #4. An average of three measurements will be taken.

Schematic



Equipment Needed

1. Paper Clamp (Big and Small)
2. Penny/Quarter Weights
3. Triple Beam Balance
4. Two small bars/stands
5. Steady Table
6. Measuring Tape/Ruler
7. Current cable 4’’ sample
8. New cable sample 4” sample

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Are there any visual defects before or after testing? Yes / No … Yes / No

Comments:____

Average flexibility of old cable: ______________________

Average flexibility of new cable: _____________________

Heat Test

This test is designed to ensure that the casing dissipates heat produced by electronics quickly, and the electronics' surface temperature does not increase by more than 6.4°C over ambient. Also, the electronics must function properly and should not overheat if they are implanted into a body. This test covers customer needs #11 and #12, specified by engineering specifications #30 and #31. Simulating internal body fluids conditions is a tedious process, therefore, for feasibility purposes, the final product casing will be tested in air in a medium-sized oven heated to 43°C for a period of 6 hours. A thermocouple will be used to measure temperature of electronics inside the casing, on the surface of the case, and the ambient temperature of surroundings. The electronics should be functioning fully the entire time, therefore, electronics will be supplied by the appropriate voltage and current using Agilent 33120A Function Waveform Generators. If the test fails in air, the product then can be tested in water at the temperature 43°C.

Equipment Needed:

1. Medium Sized Oven – (~1 m^3 volume) heated to 43°C
2. Calibrated Thermocouples (3)
3. High Thermal Conductivity Tape
4. Agilent 33120A Function Waveform Generator (2 items)
5. HP 54602B Oscilloscope

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Are there any visual defects before or after testing? Yes / No … Yes / No

Comments:____

Time (hrs)	**Device Function (Yes / No)**	**Inside the Casing (°C)**	**Surface Temperature (°C)**	**Oven Air Ambient Temperature (°C)**

Drop Test

To fulfill engineering specifications #32 and #33, the drop test is designed to test for damage prevention due to any accidental drops of the outside casing with electronics. The inner casing and electronics will also be tested by the same method to ensure that if the package can withstand this type of impact, it can withstand other kinds of unintentional impacts by outside forces, in cases of accidents, falls or other impacts. To simulate best a random fall, a person would drop the casing with electronics at random from a height of 1.5 meters onto a standard concrete surface, and any damage to the casing will be observed and recorded. Then, the electronics will be run in simulation, to ensure that they continue to function. If the casing or electronics are damaged, the casing shall be redesigned and re-fabricated.

Equipment Needed:

1. Measuring Tape
2. HP 54602B Oscilloscope
3. Agilent 33120A Function Waveform Generator

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Are there any visual defects before or after testing? Yes / No … Yes/No

Comments:____

Trial #	Height of fall (m)	Damage to Casing Scale (1 - no damage to 5 - dysfunctional)	Damage to Electronics Scale (1 - no damage to 5 - dysfunctional)	Comments
1	1.5			
2	1.5			
3	1.5			
4	1.5			
5	1.5			

Pressure and Leak Test

This test is designed to fulfill customer need #13, corresponding to engineering specification #34, where the casing and the wire connections must withstand slightly higher pressures and be leak resistant under 1 meter of water. The casing and the cable carrying signal wires will be submerged in a tank under 1 meter of water, corresponding to pressure of 10 kPa. On one side of the casing the D Sub 15 connector will be connected, but the electronics will be removed; on the other side, the wires leaving the case should be intact. Ensure complete submersion, and keep steady under water for 15 minutes.

Equipment Needed:

1. Water
2. ~1.5m deep container
3. HP 54602B Oscilloscope
4. Agilent 33120A Function Waveform Generator

Start Date: __________ Finish Date:_______________

Engineer in charge: _________________________________

Are there any visual defects or leaks before and after testing? Yes / No … Yes / No

Comments:____

Risk Assessment

The following table has been updated to reflect the most important risks based on current project status. Additionally, a column has been added to identify those aspects of the project that are a result of the each risk item.

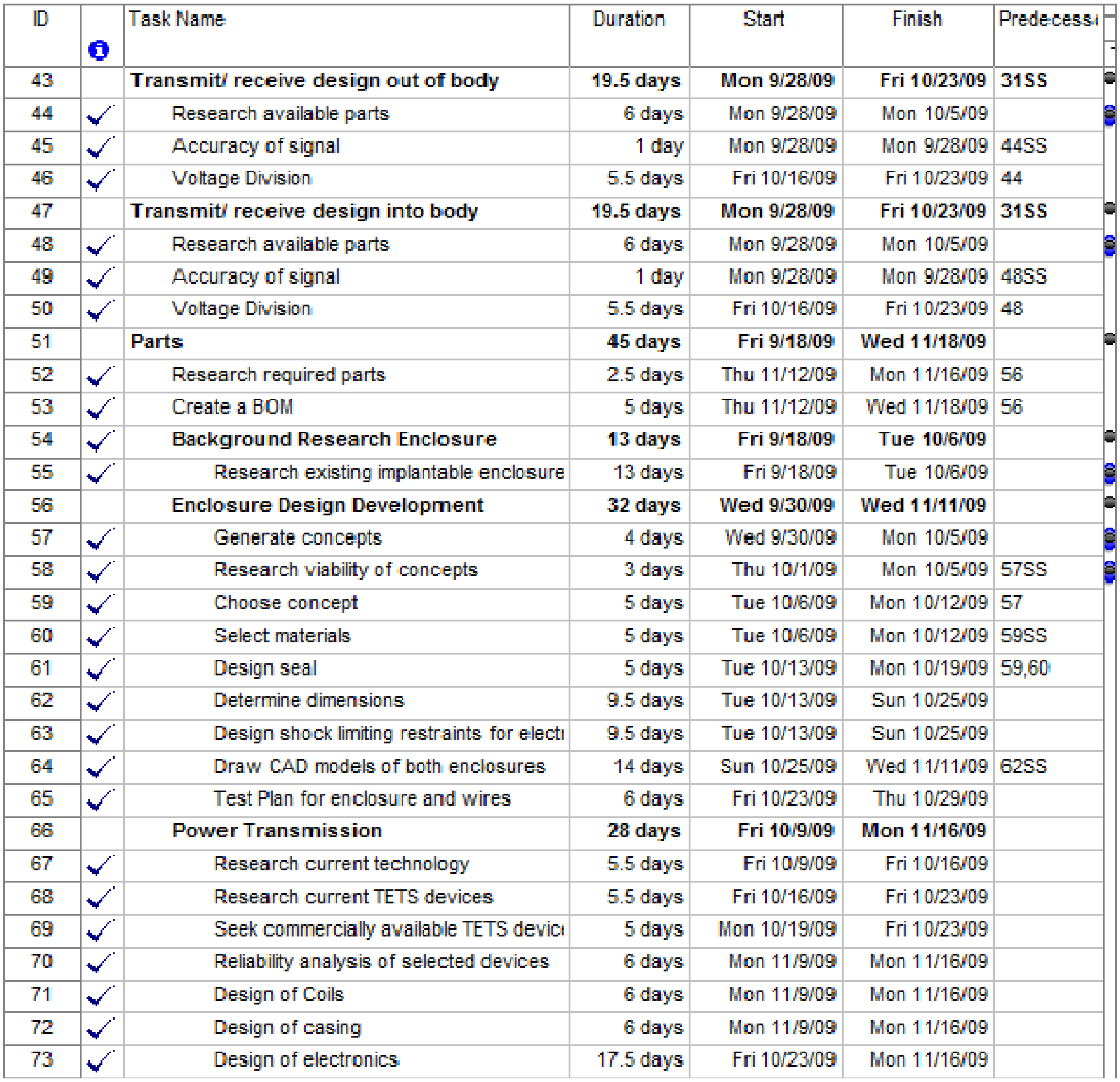
ID	Risk Item	Effect	Cause	Likelihood	Severity	Importance	Action to Minimize Risk	Owner	Actual Actions Taken By Team Members
1	Transmitted signal is not within specifications	Unacceptable signals. Project does not function with overall system.	Unknown results of controller, bad programming of controller, poor research, important considerations overlooked	3	5	15	Get advice from experts. Order evaluation board early.	Sara, Keith	Pseudo-code for signal controllers written in advance and reviewed with Professor. Signal delay time calculated.
2	Parts arrive late	Schedule is delayed	Unreliable vendor, out of stock part	3	4	12	Constant communication with vendor, use reliable vendors, have backup parts selected	Carl	For all parts, lead time is known and parts have been found to be in stock. Two alternate connectors have been identified and contacted in case free "samples" are not obtained from Alden Products. Long lead time parts have been identified to be ordered early.
3	Unacceptably long time delay is introduced by signal transmission	Poor LVAD function / project failure	Poor research, important considerations overlooked, calculations errors	1	4	4	Calculate speed and tolerance needed, analyze alternatives	Elec	Acceptable time delay has been specified by customer. Time schedule has been created to predict the actual time delay.

ID	Risk Item	Effect	Cause	Likelihood	Severity	Importance	Action to Minimize Risk	Owner	Actual Actions Taken By Team Members
4	Internal electronics are damaged by shock and leakage testing	Internal electronics need to be replaced	Case allows water to empty	2	4	8	Test the package without electronics. Order and build extra PCBs. Use common design features to seal and reduce shock.	Carl	Grommets incorporated into design to reduce shock on electronics. Silicone over coating to provide primary ingress protection. O-ring seals researched and incorporated into design to provide secondary protection.
5	Electronics fail and are destroyed during signal simulation tests	PCB is scraped	Major design flaw, i.e. short in PCB tracing, wrong signal to IC pins	2	4	8	Order extra parts with a contingency plan, perform required calculations before tests	Oxana	BOM has spare parts built into budget.
6	P10022 and P10021 are not integrated	Projects do not work together.	Poor communication, unknown behavior of signal controllers	2	2	4	Document agreements between teams	Elec	Frequent communication between MEs to specify connector part numbers and EEs to match signals.
7	TET does not provide enough power to run pump	TET section of project not effective	Not correct choice of components and parts	2	1	2	Incorporate high frequency inverter and rectifier options into design.	Sara	High frequency signal generation circuit designed. Extra time to modify TET system has been defined in MSDII plan.

ID	Risk Item	Effect	Cause	Likelihood	Severity	Importance	Action to Minimize Risk	Owner	Actual Actions Taken By Team Members
8	Internal electronics produce too much heat	Electronics and/ or biological tissue are damaged	1. High power output of electronics; 2. Poor power transfer; 3. Poor heat dissipation	1	2	2	Complete proper analyses and generate ideas of how to dissipate more heat in case electronics generate too much.	Oxana	Heat transfer analysis has been completed for transceivers for maximum power dissipation and under conservative conditions.

MSD I Project Schedule

ID	ℹ	Task Name	Duration	Start	Finish	Predecess
1	✓	Meet with groups and guide	1 day	Fri 9/11/09	Fri 9/11/09	
2	✓	Identify team leader	1 day	Fri 9/11/09	Fri 9/11/09	
3	✓	Decide on team norms and behaviors	5.5 days	Fri 9/11/09	Fri 9/18/09	
4	✓	Decide group structure and roles	3 days	Mon 9/14/09	Wed 9/16/09	1
5	✓	Identify project objectives	6 days	Fri 9/18/09	Fri 9/25/09	
6	✓	Meet with customer	1 day	Tue 9/15/09	Tue 9/15/09	
7	✓	Identify Customer Needs	9 days	Wed 9/16/09	Mon 9/28/09	6
8	✓	Identify known and unknowns	11 days	Fri 9/11/09	Fri 9/25/09	
9	✓	Meet with other group to discuss ideas	1 day	Fri 9/18/09	Fri 9/18/09	
10	✓	Understand full scope of joint projects	5.5 days	Fri 9/18/09	Fri 9/25/09	
11	✓	Asses risks and mitigation	5.5 days	Fri 9/18/09	Fri 9/25/09	
12	✓	Develop high level schematic	5.5 days	Thu 11/5/09	Thu 11/12/09	7SS,8SS
13	✓	Peer review for group members	1 day	Fri 9/25/09	Fri 9/25/09	
14	✓	System design schematic	5.5 days	Fri 9/25/09	Fri 10/2/09	12
15	✓	Update project plan	5.5 days	Fri 9/25/09	Fri 10/2/09	12
16	✓	Upload documents to EDGE	6 days	Fri 9/25/09	Fri 10/2/09	
17	✓	Research signal transmission technology	15 days	Fri 9/11/09	Thu 10/1/09	
18	✓	Choose signal transmission technology	1 day	Fri 10/2/09	Fri 10/2/09	17
19	✓	Design review preparation	5 days	Fri 10/2/09	Thu 10/8/09	
20	▦	Design review	0 days	Fri 10/9/09	Fri 10/9/09	19
21	✓	Meet with customer to reevaluate review if neede	1 day	Fri 10/9/09	Fri 10/9/09	20
22	✓	Meet with other teams to see level of collaboratio	1 day	Fri 10/9/09	Fri 10/9/09	20
23	✓	Reevaluate system design review	6 days	Fri 10/9/09	Fri 10/16/09	20
24	✓	Work on detailed design	11 days	Fri 10/9/09	Fri 10/23/09	
25	✓	Peer review	1 day	Fri 10/30/09	Fri 10/30/09	
26	✓	Prepare for detailed level design	12 days	Fri 10/23/09	Fri 11/6/09	24SS
27	▦	Detailed Level Design Review	0 days	Fri 11/6/09	Fri 11/6/09	26
28	✓	Prepare project management review	7 days	Fri 11/6/09	Mon 11/16/09	
29	▦	Project management review	0 days	Mon 11/16/09	Mon 11/16/09	28
30	▦	Move on to MSDII	1 day	Mon 11/16/09	Mon 11/16/09	
31		**Technology Choice**	**47 days**	**Fri 9/11/09**	**Fri 11/13/09**	
32	✓	Research possible transmission designs	11 days	Fri 9/11/09	Fri 9/25/09	
33	✓	Research data transfer	6 days	Fri 9/18/09	Fri 9/25/09	32SS
34	✓	Bill of materials (electronics)	5 days	Mon 11/9/09	Fri 11/13/09	
35	✓	Test plan for electronics	6 days	Fri 10/23/09	Thu 10/29/09	
36		**Transmission Design**	**50.5 days**	**Mon 9/28/09**	**Fri 12/4/09**	**31SS**
37	✓	Research available parts	6 days	Mon 9/28/09	Mon 10/5/09	
38	✓	Sampling Rate	5.5 days	Fri 10/9/09	Fri 10/16/09	37
39	✓	Wire length and gage	5.5 days	Fri 10/9/09	Fri 10/16/09	37
40	✓	Connectors	5 days	Fri 10/16/09	Fri 10/23/09	39
41	✓	Final Schematic/ PCB layout	5.5 days	Fri 11/27/09	Fri 12/4/09	38,40
42	✓	Outline of the code	6 days	Fri 10/30/09	Fri 11/6/09	



ID	ℹ	Task Name	Duration	Start	Finish	Predecess
43		**Transmit/ receive design out of body**	**19.5 days**	**Mon 9/28/09**	**Fri 10/23/09**	**31SS**
44	✓	Research available parts	6 days	Mon 9/28/09	Mon 10/5/09	
45	✓	Accuracy of signal	1 day	Mon 9/28/09	Mon 9/28/09	44SS
46	✓	Voltage Division	5.5 days	Fri 10/16/09	Fri 10/23/09	44
47		**Transmit/ receive design into body**	**19.5 days**	**Mon 9/28/09**	**Fri 10/23/09**	**31SS**
48	✓	Research available parts	6 days	Mon 9/28/09	Mon 10/5/09	
49	✓	Accuracy of signal	1 day	Mon 9/28/09	Mon 9/28/09	48SS
50	✓	Voltage Division	5.5 days	Fri 10/16/09	Fri 10/23/09	48
51		**Parts**	**45 days**	**Fri 9/18/09**	**Wed 11/18/09**	
52	✓	Research required parts	2.5 days	Thu 11/12/09	Mon 11/16/09	56
53	✓	Create a BOM	5 days	Thu 11/12/09	Wed 11/18/09	56
54	✓	**Background Research Enclosure**	**13 days**	**Fri 9/18/09**	**Tue 10/6/09**	
55	✓	Research existing implantable enclosure	13 days	Fri 9/18/09	Tue 10/6/09	
56		**Enclosure Design Development**	**32 days**	**Wed 9/30/09**	**Wed 11/11/09**	
57	✓	Generate concepts	4 days	Wed 9/30/09	Mon 10/5/09	
58	✓	Research viability of concepts	3 days	Thu 10/1/09	Mon 10/5/09	57SS
59	✓	Choose concept	5 days	Tue 10/6/09	Mon 10/12/09	57
60	✓	Select materials	5 days	Tue 10/6/09	Mon 10/12/09	59SS
61	✓	Design seal	5 days	Tue 10/13/09	Mon 10/19/09	59,60
62	✓	Determine dimensions	9.5 days	Tue 10/13/09	Sun 10/25/09	
63	✓	Design shock limiting restraints for electi	9.5 days	Tue 10/13/09	Sun 10/25/09	
64	✓	Draw CAD models of both enclosures	14 days	Sun 10/25/09	Wed 11/11/09	62SS
65	✓	Test Plan for enclosure and wires	6 days	Fri 10/23/09	Thu 10/29/09	
66		**Power Transmission**	**28 days**	**Fri 10/9/09**	**Mon 11/16/09**	
67	✓	Research current technology	5.5 days	Fri 10/9/09	Fri 10/16/09	
68	✓	Research current TETS devices	5.5 days	Fri 10/16/09	Fri 10/23/09	
69	✓	Seek commercially available TETS devici	5 days	Mon 10/19/09	Fri 10/23/09	
70	✓	Reliability analysis of selected devices	6 days	Mon 11/9/09	Mon 11/16/09	
71	✓	Design of Coils	6 days	Mon 11/9/09	Mon 11/16/09	
72	✓	Design of casing	6 days	Mon 11/9/09	Mon 11/16/09	
73	✓	Design of electronics	17.5 days	Fri 10/23/09	Mon 11/16/09	

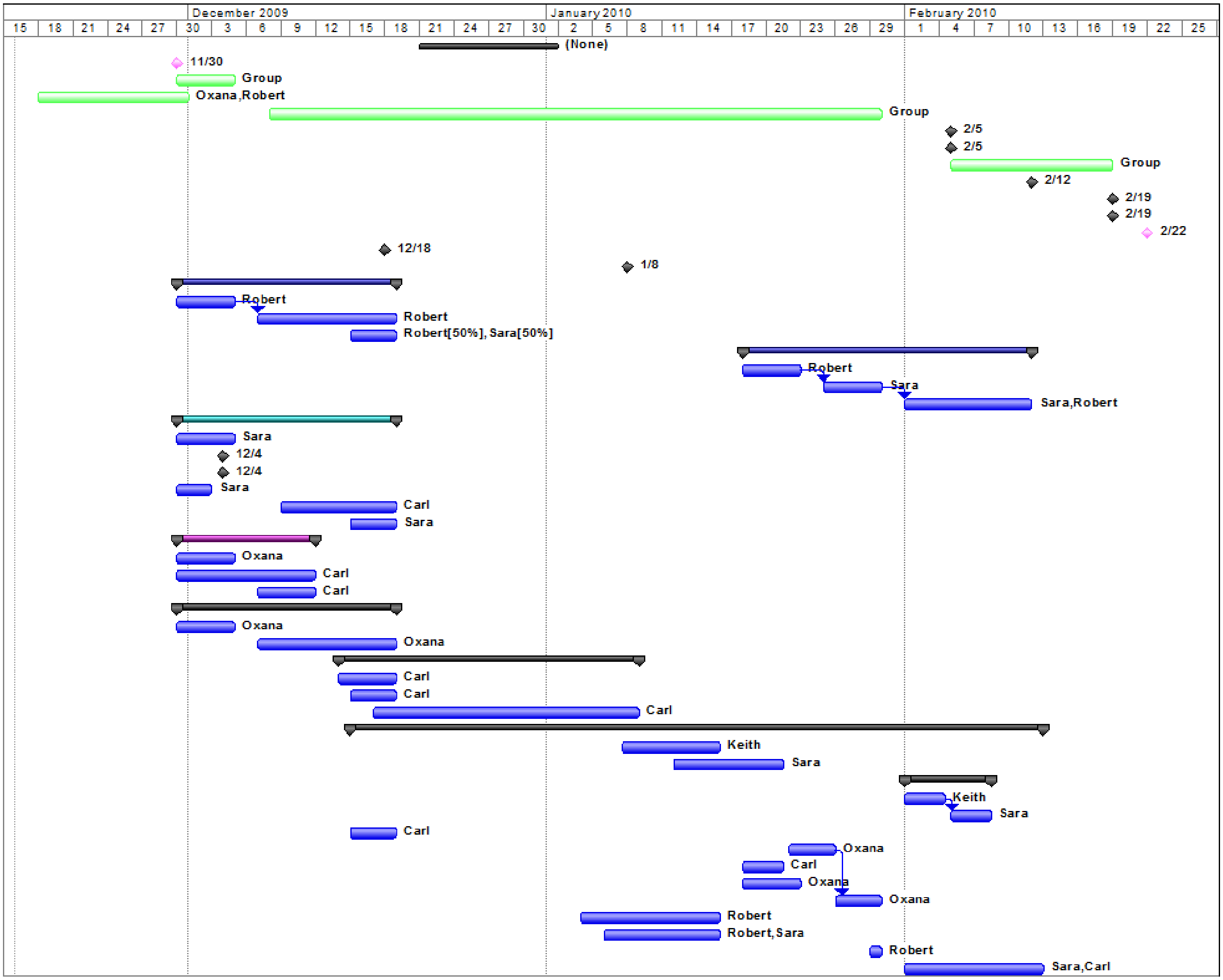
*All Tasks complete and now ready for Sr. Design II

MSD II Project Schedule

Task Num	Task Name	Duration	Start	End	Pre.	Resources
1	Winter Break	10 days	12/21/2009	1/1/2010		(None)
2	Sr Design 2 Initiation	0 days	11/30/2009	11/30/2009		
3	Close Up action Items from Design 1	5 days	11/30/2009	12/4/2009		Group
4	Order parts	9 days	11/18/2009	11/30/2009		Oxana, Robert
5	Build and Test	39 days	12/8/2009	1/29/2010		Group
6	Technical Paper Exchange (75%)	0 days	2/5/2010	2/5/2010		Group
7	Customer Demo	0 days	2/5/2010	2/5/2010		Group
8	Finish Technical Paper	10 days	2/5/2010	2/18/2010		Group
9	Function Performance Review	0 days	2/12/2010	2/12/2010		Group
10	Technical Paper Due	0 days	2/19/2010	2/19/2010		Group
11	Project Review	0 days	2/19/2010	2/19/2010		Group
12	Poster Session	0 days	2/22/2010	2/22/2010		Group
13	Order Long Lead time items	0 days	12/18/2009	12/18/2009		Robert
14	Decision to integrate TETS	0 days	1/8/2010	1/8/2010		Customer, Group
15	Build TETS system	15 days	11/30/2009	12/18/2009		
16	Receive applicable parts	5 days	11/30/2009	12/4/2009		Robert
17	Put system together	10 days	12/7/2009	12/18/2009	16	Robert
18	Diagnose problems that occur	4 days	12/15/2009	12/18/2009		Robert,Sara
19	Integrate TETS OR make TETS system work	19 days	1/18/2010	2/11/2010		
20	Collect needed components from design	5 days	1/18/2010	1/22/2010		Robert
21	Improve design and test	5 days	1/25/2010	1/29/2010	20	Sara
22	Diagnose problems	9 days	2/1/2010	2/11/2010	21	Sara,Robert
23	Electrical Components Build	15 days	11/30/2009	12/18/2009		
24	Finish PCB Layout	5 days	11/30/2009	12/4/2009		Sara
25	Send PCB design out for printing	0 days	12/4/2009	12/4/2009		Keith
26	Arrange to use surface mount lab	0 days	12/4/2009	12/4/2009		Sara
27	Order components for PCB	3 days	11/30/2009	12/2/2009		Sara
28	Surface mount components	8 days	12/9/2009	12/18/2009		Carl
29	Finalize PCB construction	4 days	12/15/2009	12/18/2009		Sara
30	Casing Build	10 days	11/30/2009	12/11/2009		
31	Order components	5 days	11/30/2009	12/4/2009		Oxana
32	Finalize 3D models	10 days	11/30/2009	12/11/2009		Carl
33	Get enclosures printed	5 days	12/7/2009	12/11/2009		Carl
34	Cable	15 days	11/30/2009	12/18/2009		
35	Order components	5 days	11/30/2009	12/4/2009		Oxana
36	Assemble	10 days	12/7/2009	12/18/2009		Oxana
37	Assembly	20 days	12/14/2009	1/8/2010		

38	Solder wires to PBC within enclosures	5 days	12/14/2009	12/18/2009		Carl
39	Apply heat shrink boots	4 days	12/15/2009	12/18/2009		Carl
40	Finalize system assembly	17 days	12/17/2009	1/8/2010		Carl
41	Testing	44 days	12/15/2009	2/12/2010		
42	LVAD Simulations Signal Test	6.5 days	1/7/2010	1/15/2010		Keith
43	Implement design corrections	7.5 days	1/12/2010	1/21/2010		Sara
44	Electronics Functionality Test	5.5 days	2/1/2010	2/8/2010		
45	With Current LVAD	3.5 days	2/1/2010	2/4/2010		Keith
46	With P10021 electronics	1.5 days	2/5/2010	2/8/2010	45	Sara
47	Flexibility Test	4 days	12/15/2009	12/18/2009		Carl
48	Heat Test	2 days	1/22/2010	1/25/2010		Oxana
49	Drop Test	3.5 days	1/18/2010	1/21/2010		Carl
50	Implement design corrections	5 days	1/18/2010	1/22/2010		Oxana
51	Pressure and Leak Test	4 days	1/26/2010	1/29/2010	48	Oxana
52	Wireless Power Test (Robert)	10 days	1/4/2010	1/15/2010		Robert
53	Implement design corrections (Robert, Sara)	8 days	1/6/2010	1/15/2010		Robert,Sara
54	Analysis of tests	1 day	1/29/2010	1/29/2010		Robert
55	Design corrections as a response to tests	10 days	2/1/2010	2/12/2010		Sara,Carl

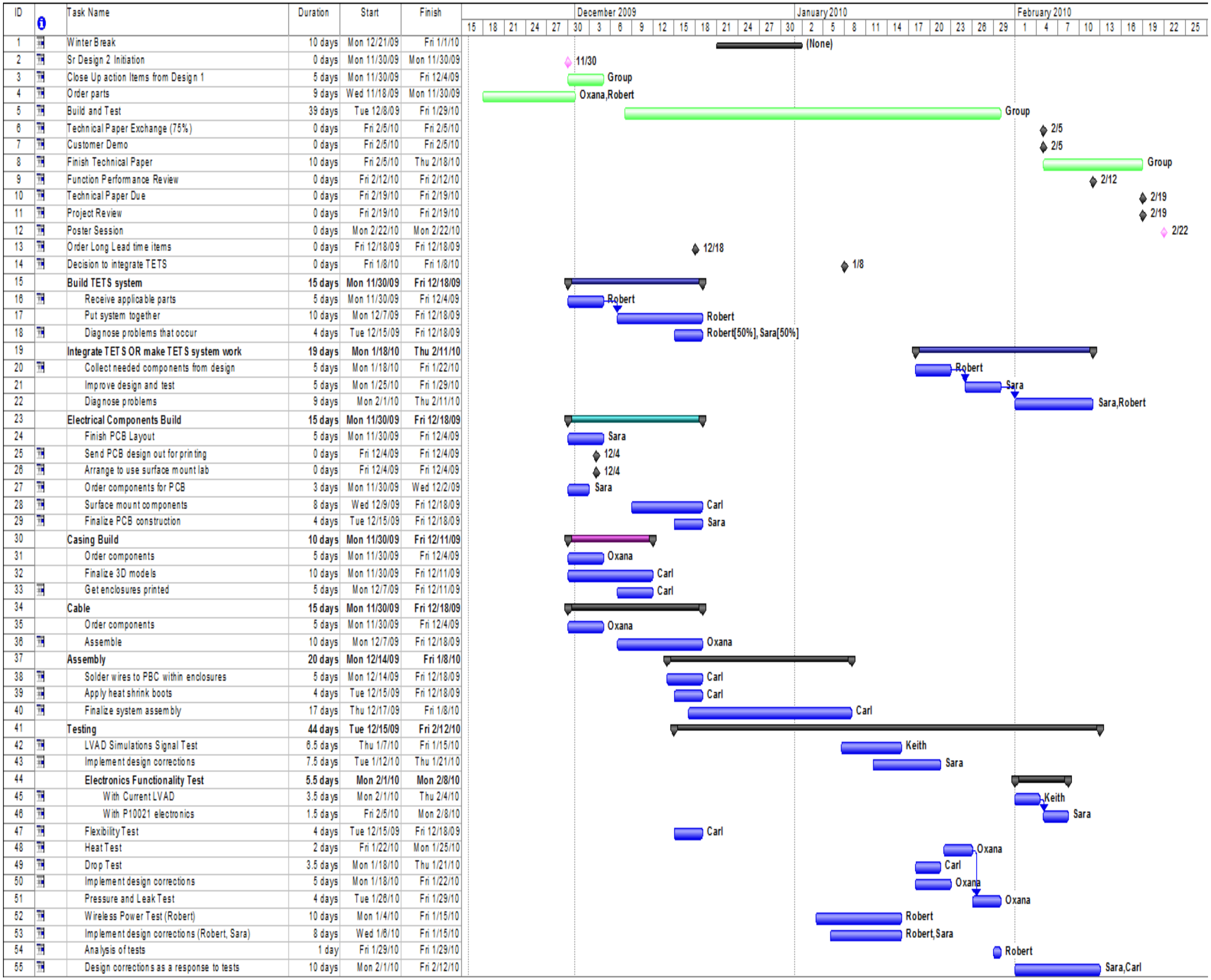
MSD II Gantt Chart



Green= Overall schedule set by Mark Smith

Blue= Actual assigned tasks to members

Black Bar=Winter Break



ID	🛈	Task Name	Duration	Start	Finish
1	▦	Winter Break	10 days	Mon 12/21/09	Fri 1/1/10
2	▦	Sr Design 2 Initiation	0 days	Mon 11/30/09	Mon 11/30/09
3	▦	Close Up action Items from Design 1	5 days	Mon 11/30/09	Fri 12/4/09
4	▦	Order parts	9 days	Wed 11/18/09	Mon 11/30/09
5	▦	Build and Test	39 days	Tue 12/8/09	Fri 1/29/10
6	▦	Technical Paper Exchange (75%)	0 days	Fri 2/5/10	Fri 2/5/10
7	▦	Customer Demo	0 days	Fri 2/5/10	Fri 2/5/10
8	▦	Finish Technical Paper	10 days	Fri 2/5/10	Thu 2/18/10
9	▦	Function Performance Review	0 days	Fri 2/12/10	Fri 2/12/10
10	▦	Technical Paper Due	0 days	Fri 2/19/10	Fri 2/19/10
11	▦	Project Review	0 days	Fri 2/19/10	Fri 2/19/10
12	▦	Poster Session	0 days	Mon 2/22/10	Mon 2/22/10
13	▦	Order Long Lead time items	0 days	Fri 12/18/09	Fri 12/18/09
14	▦	Decision to integrate TETS	0 days	Fri 1/8/10	Fri 1/8/10
15		**Build TETS system**	**15 days**	**Mon 11/30/09**	**Fri 12/18/09**
16	▦	Receive applicable parts	5 days	Mon 11/30/09	Fri 12/4/09
17		Put system together	10 days	Mon 12/7/09	Fri 12/18/09
18	▦	Diagnose problems that occur	4 days	Tue 12/15/09	Fri 12/18/09
19		**Integrate TETS OR make TETS system work**	**19 days**	**Mon 1/18/10**	**Thu 2/11/10**
20	▦	Collect needed components from design	5 days	Mon 1/18/10	Fri 1/22/10
21		Improve design and test	5 days	Mon 1/25/10	Fri 1/29/10
22		Diagnose problems	9 days	Mon 2/1/10	Thu 2/11/10
23		**Electrical Components Build**	**15 days**	**Mon 11/30/09**	**Fri 12/18/09**
24		Finish PCB Layout	5 days	Mon 11/30/09	Fri 12/4/09
25	▦	Send PCB design out for printing	0 days	Fri 12/4/09	Fri 12/4/09
26	▦	Arrange to use surface mount lab	0 days	Fri 12/4/09	Fri 12/4/09
27	▦	Order components for PCB	3 days	Mon 11/30/09	Wed 12/2/09
28	▦	Surface mount components	8 days	Wed 12/9/09	Fri 12/18/09
29	▦	Finalize PCB construction	4 days	Tue 12/15/09	Fri 12/18/09
30		**Casing Build**	**10 days**	**Mon 11/30/09**	**Fri 12/11/09**
31		Order components	5 days	Mon 11/30/09	Fri 12/4/09
32		Finalize 3D models	10 days	Mon 11/30/09	Fri 12/11/09
33	▦	Get enclosures printed	5 days	Mon 12/7/09	Fri 12/11/09
34		**Cable**	**15 days**	**Mon 11/30/09**	**Fri 12/18/09**
35		Order components	5 days	Mon 11/30/09	Fri 12/4/09
36	▦	Assemble	10 days	Mon 12/7/09	Fri 12/18/09
37		**Assembly**	**20 days**	**Mon 12/14/09**	**Fri 1/8/10**
38	▦	Solder wires to PBC within enclosures	5 days	Mon 12/14/09	Fri 12/18/09
39	▦	Apply heat shrink boots	4 days	Tue 12/15/09	Fri 12/18/09
40	▦	Finalize system assembly	17 days	Thu 12/17/09	Fri 1/8/10
41		**Testing**	**44 days**	**Tue 12/15/09**	**Fri 2/12/10**
42	▦	LVAD Simulations Signal Test	6.5 days	Thu 1/7/10	Fri 1/15/10
43	▦	Implement design corrections	7.5 days	Tue 1/12/10	Thu 1/21/10
44		**Electronics Functionality Test**	**5.5 days**	**Mon 2/1/10**	**Mon 2/8/10**
45	▦	With Current LVAD	3.5 days	Mon 2/1/10	Thu 2/4/10
46	▦	With P10021 electronics	1.5 days	Fri 2/5/10	Mon 2/8/10
47	▦	Flexibility Test	4 days	Tue 12/15/09	Fri 12/18/09
48	▦	Heat Test	2 days	Fri 1/22/10	Mon 1/25/10
49	▦	Drop Test	3.5 days	Mon 1/18/10	Thu 1/21/10
50	▦	Implement design corrections	5 days	Mon 1/18/10	Fri 1/22/10
51		Pressure and Leak Test	4 days	Tue 1/26/10	Fri 1/29/10
52	▦	Wireless Power Test (Robert)	10 days	Mon 1/4/10	Fri 1/15/10
53	▦	Implement design corrections (Robert, Sara)	8 days	Wed 1/6/10	Fri 1/15/10
54	▦	Analysis of tests	1 day	Fri 1/29/10	Fri 1/29/10
55	▦	Design corrections as a response to tests	10 days	Mon 2/1/10	Fri 2/12/10