

AccelBiotech



3G ESP Development Proposal

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Company Background

Overview

Accel Biotech, Inc. is a consulting firm specializing in engineering, design and development of Medical and Biotech products. The founder is an engineer with thirty years of experience in product development and manufacturing. Accel Biotech, Inc. incorporated in 2008 and operated as Richardson Consulting for 2 years prior to incorporating.

Mission

Our mission is to provide clients throughout the world with high quality product development for medical, diagnostic, biodefense and biotech products. Accel Biotech's skilled team of engineers, designers and technicians will work together to provide services from concept to development to manufacturing.

Keys to Success

- Set the highest standards for customer satisfaction.
- Provide professional quality services that are on time and on budget.
- Accelerate the development process
- Hire and retain only the best employees.

Testimonials

- Ravi Srinivasan - We have worked with Bruce Richardson and his team for over four years on medical device products. He has added enormous value from concept development through to production. He is very efficient and has delivered at costs and time that are a fraction of the competition. I enthusiastically recommend his product development group.
- Scot Weinberger - Accel Biotech Inc. has been a highly valuable contributor to our technology developments. He really understands critical elements of the product / technology development process, and reliably delivers solutions to our problems and outstanding design concepts to our program.
- Jesus Ching - Bruce Richardson is one of the best Engineers in the Valley. He delivers what he promises on time and on budget. Exceptional professional that gets it done!

Technical & Contractual Contact

- Name: Michael Robards or Bruce Richardson
- Address: 103 Cooper Ct, Los Gatos, CA 95032
- Phone: (408) 354-1700

Capabilities

Accel Biotech is experienced in the development and manufacturing of products for Medical Devices, Life Sciences, Analytical and Diagnostics markets. Our expertise in complex mechanical, optical, electronic and electro-mechanical equipment, attention to detail and an understanding of regulations allow us to offer efficient, cost-effective and high quality prototypes and products, on time.

Accel Biotech Inc. manages development and production in a dedicated, customer-focused manner. A team leader manages each project. Team leaders have hands-on experience and are intimately familiar with the demands of the customer and product requirements. They are responsible for the day-to-day direct supervision and coordination of team activities and provide a continuous point of contact with the customer. The production team leaders are also accountable to our senior management regarding cost, schedule, and quality performance issues.

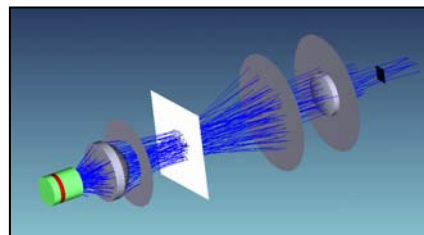
Prototype Machine Shop

- 4 Haas CNC's and 2 Bridgeport Milling machines
- Hardinge tool room lathe & engine lathe
- Welders - TIG, MIG and stick
- General fabrication tools
- Sheet metal tools - brake & shear
- High temperature oven
- MasterCAM for Solidworks



Optics Lab

- Optics table and lasers
- Optical power meters
- Positioning equipment
- Optical spectrometer
- Miscellaneous filter and optics



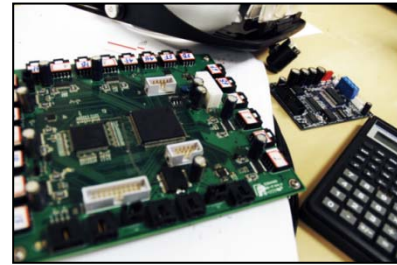
Prototype Lab

- Ovens – General and vacuum
- Ultrasonic welder
- Vacuum pumps
- Dispensing systems
- General test and measurement tools
- Force and pressure measurement equipment
- General hand tools



Electronics Lab

- Oscilloscopes
- General test equipment
- Fine pitch soldering stations
- ESD controlled environment
- Power supplies
- Function generators
- RF generators and test equipment



Biosafety Level 2 (BSL-2) Laboratory

- Fully equipped lab for life science testing
- Biohazard flow hood
- Basic chemistry equipment



Pre-Production Testing

- Environmental testing
- In house environmental chamber
- FCC Testing – working relationships with local labs
- Shock and Vibration - relationships with local labs



Prototype Builds

- Rapid response to customer needs
- Can be done under full or limited documentation control
- Documentation to fit customer needs
- Class 100 environment if required



Production

- ISO13485:2003 production capabilities
- Flexible manufacturing



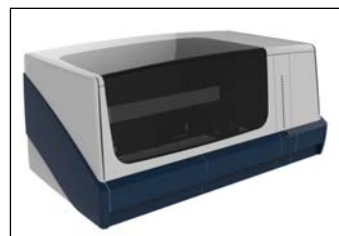
Project History

The following are products or projects to which Accel Biotech team members contributed.

Instruments

Custom Microplate Processor

- Product: Automated microplate processing system
- Scope: ID, Mechanical, Electrical, & Software design
- Status: In development – See at AMP



Chemiluminescence

- Product: Microplate reader system
- Scope: ID, electronics, Optics and Mechanical
- Status: In development



Automated Chemistry Analyzer

- Product: Automated tube handling system
- Scope: ID, Mechanical, Electronics, & Software design
- Status: In Production



Zyomyx

- Product: Field test instrument for use in Africa
- Scope: ID, Systems, Mechanical & Pilot units
- Status: In development



GenturaDx

- Product: Fully automated real time PCR system
- Scope: Instrument and Disposable development
- Status: In production ramp-up



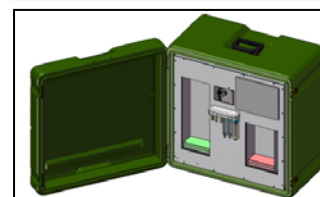
Molecular Sensing

- Product: Back-Scattering Interferometer System
- Scope: Project management, Systems, Optics, and Mechanical designs
- Status: Early access program



ICx Biosystems

- Product: Bio-threat Monitoring Systems (IBADS)
- Scope: Project management, Systems, Electronics, Fluidics, & Mechanical designs
- Status: In development



Disposables

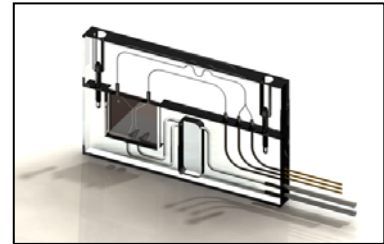
GenturaDX

- Product: DNA extraction & amplification disposable
- Scope: Micro-fluidics, Reagent storage and
- Mechanical design
- Status: In development



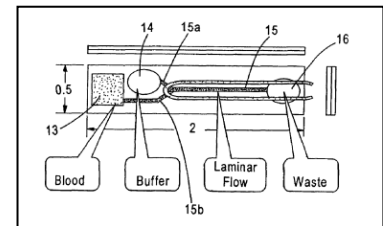
Molecular Sensing

- Product: Capillary based mixing chip
- Scope: Systems, Optics, and Mechanical designs
- Status: In development



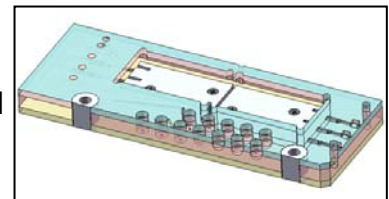
Theranos

- Product: Point of care diagnostic system
- Scope: Reagent processing lateral flow device
- Status: In development



GHC / ICx Biosystems (IBADS Project)

- Product: Instantaneous Bio-Aerosol Detector System
- Overview: Supported the development of an integrated
- fluid handling and PCR card
- Scope: Systems, Fluidics, and Mechanical
- Status: In development



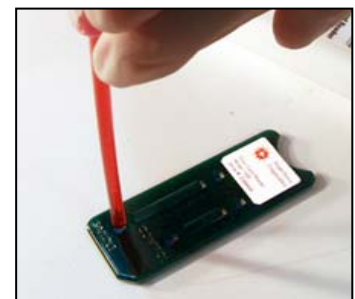
Terumo Medical – Blood Separation Disposable

- Product: Blood Separation Disposables
- Scope: Mechanical, Fluidics, Molding and Pilot units
- Status: Project was canceled



Lateral Flow Test Strip

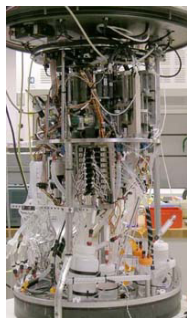
- Product: Lateral flow disposable test strip & reader
- Scope: Fluidics, Mechanical, and Optical design
- Status: In development



Overview

Summary

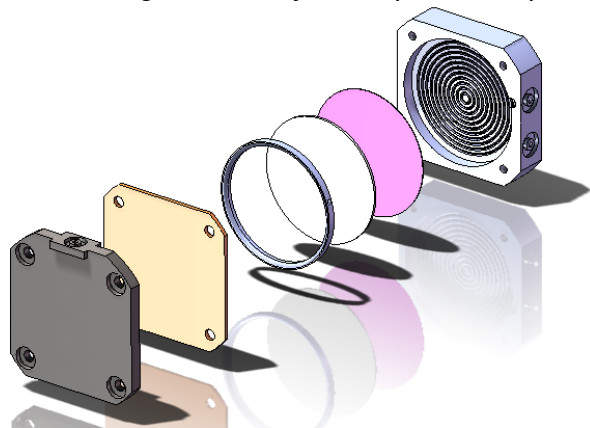
Currently MBARI is using the second generation, the 2G, ESP for open water testing. This instrument has a modular core system that can be reconfigured and modified to suit a wide variety of deployment and analysis requirements. The 2G ESP is built on the same functional concepts as the original ESP, but it is easier to service, has lower power requirements, and is more compact, robust, and user-friendly. The 2G ESP instrument is shown below.



MBARI is in the process of developing the third generation ESP or the 3G ESP. This version of the instrument would be smaller to fit within AUV's like the MBARI LRAUV shown below. The G3 version of the ESP will use a cassette based approach in contrast to the current approach that uses bulk reagents and pumps.



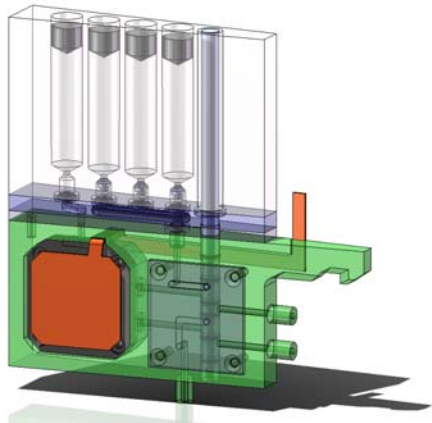
Accel Biotech completed design of the filter and cartridge designs for the archive system. The following are the key concepts developed in the first phase.



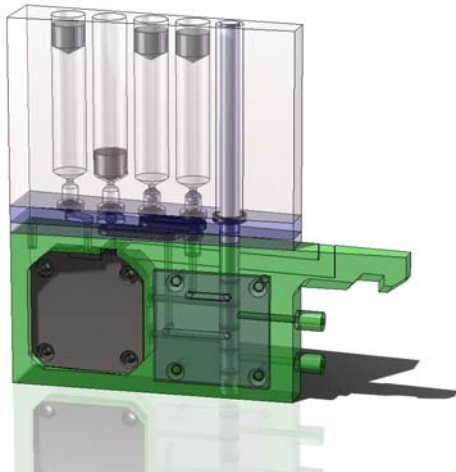
Concept of the MBARI G3 Filter Puck



Concept of the MBARI G3 Cylindrical Filter Design

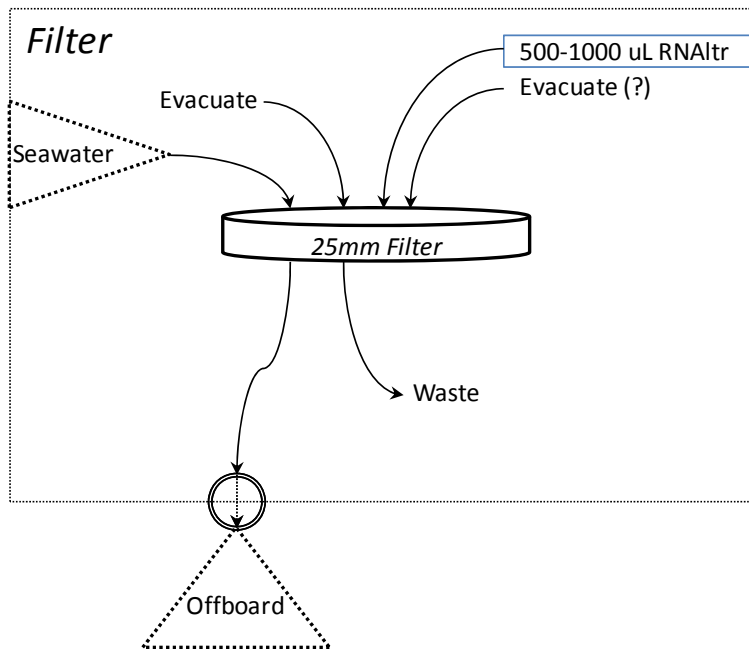


Cartridge concept with "Puck" Filter – Lysis Design

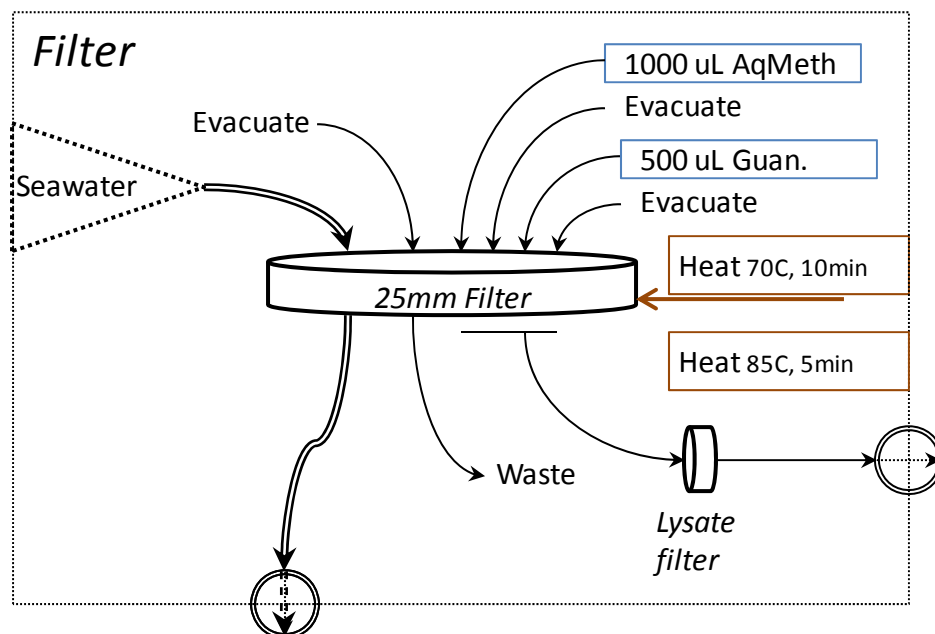


Cartridge concept with "Puck" Filter – Archive Design

Multiple cartridge designs will be required to meet the various assay protocols. The following are the two types that will be developed within the scope of this project.



- G3 Cartridge – Whole Cell Archive



- G3 Cartridge – Lyse-N-Go (HAB, Domoic Acid)

Development Plan

This collaborative development process is divided into multiple phases. The first phase focuses on developing a design direction. In the subsequent phase prototypes are developed and delivered.

Phase 1 – Filter and Cartridge Interface Concept Development (Completed)

Design Objectives

- Optimize packaging efficiency of the filter in the cartridge
- Create concepts for dual filters to support archiving, RNA, DNA, and varying pore size
- Develop interface to cartridges including valving
- Develop configurations and actuator options for emptying of the filter volume
- Develop mechanical design concepts that support motion requirements and fluid connection/volume requirements.
- Develop concepts for filter heating and temperature sensing

Key Tasks

- Review Requirements – The requirements of the filter puck will be evaluated and documented.
- Develop Concepts – Multiple concepts for the design of the filter puck will be developed.
- Preliminary Concept Review Meeting – A meeting will be held to review the filter puck concepts.
- Optimize Concepts – Optimized concepts for the filter puck will be created based on feedback from both teams.
- Preliminary FEA Analysis – Preliminary FEA analysis will be conducted for the concept(s).
- Concept Trade Study – The different concepts will be evaluated with qualitative analysis and the concepts will be evaluated with a trade study.
- Concept Review Meeting – A meeting will be held to review the optimized concepts. The goal will be to select a final design direction.
- Finalize Concepts – Feedback from the concept review meeting will be integrated into a final concept.
- Update Development Plan – The development plan will be updated.
- Phase review meeting - A phase review meeting will be held to review the final concepts, updated plan and Prototype phase requirements
- Project Management – A project manager will be assigned to the project. The manager will be responsible for conducting weekly meetings and will keep minutes and action items for all meetings.

Deliverables

- Design Concepts Documentation
- Preliminary FEA analysis
- Design Trade Study Analysis
- Final Review Meeting- A meeting will be held to review all documentation.

Duration

- Completed March 25, 2013

Phase 1 – Cartridge Concept Development (Completed)**Key Tasks**

- Review of Protocols and Requirements – The required protocols and requirements for the cartridge will be evaluated and documented.
- Develop Concepts – Multiple concepts for the design of the Archive and Lyse-No-Go cartridge will be developed. Conceptual design for valve types, reagent dispense, actuator interfaces, and preliminary plastics design will be created.
- Preliminary Concept Review Meeting – A meeting will be held to review the cartridge concepts.
- Optimize Concepts – Optimized concepts for the cartridge will be created based on feedback from the team.
- Concept Trade Study – The different concepts will be evaluated with qualitative analysis and the concepts will be evaluated with a trade study.
- Concept Review Meeting – A meeting will be held to review the optimized concepts. The goal will be to select a final design direction.
- Finalize Concepts – Feedback from the concept review meeting will be integrated into a final concept.
- Update Development Plan – The development plan will be updated.
- Phase review meeting - A phase review meeting will be held to review the final concepts and the updated plan.
- Project Management – A project manager will be assigned to the project. The manager will be responsible for conducting weekly meetings and will keep minutes and action items for all meetings.

Deliverables

- Design Concepts Documentation – For the Archive and Lyse-No-Go cartridge
- Design Trade Study Analysis
- Final Review Meeting- A meeting will be held to review all documentation.

Duration

- Completed March 25, 2013

Phase 2- Filter and Cartridge Prototype Development (Completed)

In this Phase, Accel will deliver prototype filters and cartridges for preliminary testing at MBARI.

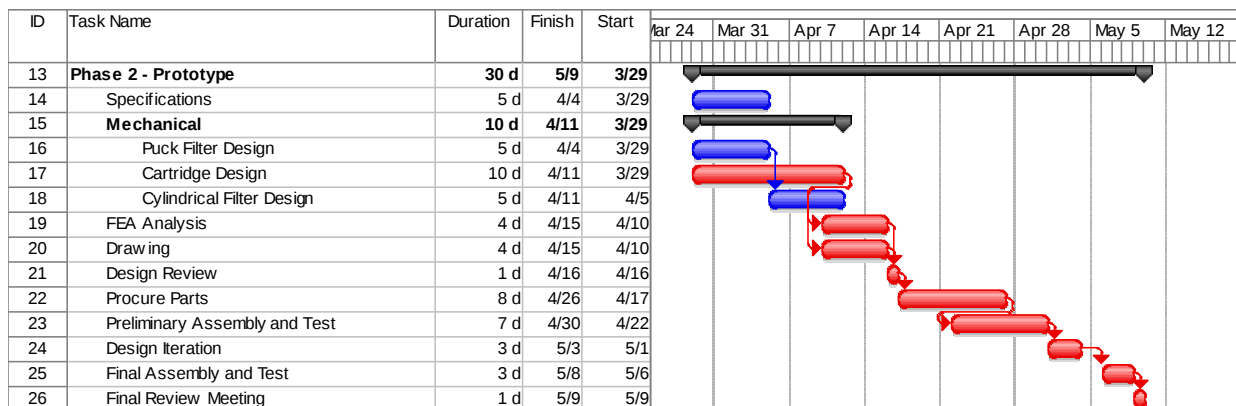
Key Tasks

- Specifications – Key specifications for the filters and cartridge will be developed with MBARI's collaboration.
- Mechanical – A complete CAD model for the new filter and cartridge interface design will be developed. The design will include;
 - Puck Filter Design – Detailed design of the puck diaphragm version of the filter module. This will include a test fixture to allow filter testing without the cartridge.
 - Cartridge Design – A design of the cartridge with the puck filter will be designed.
 - Cylindrical Filter Design – Detailed design of the bladder cylindrical the filter module will be completed. This will include a test fixture.
- FEA Analysis – A finite element analysis of the filters and cartridge will be used to validate and optimize the design.
- Drawing of the cartridge will be created. CTF drawings will be created for the complex plastic parts.
- Design Review – A formal design review will be conducted before the filters and/or cartridges are prototyped.
- Procure Parts – Prototype and purchased parts will be fabricated and/or procured.
- Preliminary Assembly and Test – The prototypes will be assembled and tested.
- Design Iteration – Issues addressed in the preliminary testing will be addressed.
- Final Assembly and Test – A final test of the prototypes will be completed at Accel Biotech before they are delivered to MBARI.
- Review Meetings – The Accel and MBARI team will conduct periodic review meetings. These will entail design and assembly updates.
- Project Management – The manager will be responsible for conducting weekly meetings and will keep minutes and action items for all meetings.

Deliverables

- Mechanical CAD Design and Drawings
 - Filter Puck Design & Test Fixture
 - Cartridge Design using the Filter Puck
 - Cylindrical Filter Design & Test Fixture
- BOM – A Bill of Materials for the filters and cartridge
- 5 Puck Prototypes w/ test fixture?
- 5 Cartridges (used with the puck)
- 5 Cylindrical Filters w/ test fixture?

Schedule Estimate



Budget Estimate

- Labor Budget Estimate

Name	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Project Manager	8	8	8	8	8	8
Manf Eng				8	16	16
Mechanical Eng #1	24	36	36	36	36	36
Mechanical Eng #2	20	20	8	4	4	4
Technician						16
Principle	4	4	4	4	4	4
Total / Week	56	68	56	60	68	84

- Materials Budget Estimate

Description	Quantity	Each	Cost
Raw Materials	1	\$500	\$500
Puck Parts	5	\$250	\$1,250
Cartridge Parts	5	\$500	\$2,500
Cylinder Filter Parts	5	\$250	\$1,250
Fittings & tubing	1	\$300	\$300
Test Fixture Parts	2	\$300	\$600
Other Misc	1	\$1,000	\$1,000
Sub-Total			\$8,880
Materials Markup		20%	\$1,776
Total			\$10,656

- Budget Summary Estimate

Description	Cost
Labor	\$51,520
Prototypes (Materials)	\$10,656
Total	\$62,176

Phase 3- Lyse 'N Go Development

In this Phase, Accel will deliver prototype filters and cartridges for the Lyse 'N Go G3 system for bench top testing at MBARI.

Key Tasks

- Specifications – Key specifications will be reviewed
- Mechanical – A complete CAD model for the new filter and cartridge interface design will be developed. The design will include;
 - Puck Filter Design – Detailed design of the puck utilizing the heater.
 - Cartridge Design – A design of the cartridge with the heater puck will be designed.
- Electrical – An electrical system for the heater and components will be designed. It will include:
 - Flex Circuit – A design of the cartridge flex circuit to bring power and control down to the puck filter will be designed.
 - Slip Interface – Develop an AA battery type interface between the cartridge and puck
- Drawing of the cartridge will be created. CTF drawings will be created for the complex plastic parts.
- Design Review – A formal design review will be conducted before the filters and/or cartridges are prototyped.
- Procure Parts – Prototype and purchased parts will be fabricated and/or procured.
- Preliminary Assembly and Test – The prototypes will be assembled and tested.
- Design Iteration – Issues addressed in the preliminary testing will be addressed.
- Final Assembly and Test – A final test of the prototypes will be completed at Accel Biotech before they are delivered to MBARI.
- Review Meetings – The Accel and MBARI team will conduct periodic review meetings. These will entail design and assembly updates.
- Project Management – The manager will be responsible for conducting weekly meetings and will keep minutes and action items for all meetings.

Deliverables

- Mechanical CAD Design and Drawings
- BOM – A Bill of Materials for the filters and cartridge
- 5 Puck Prototypes
- 5 Cartridges

Schedule Estimate

6 Weeks

Budget Estimate

Phase 3 - Lyse n Go

Summary

Description	Cost
Labor	\$31,410
Prototypes (Materials)	\$12,600
Total	\$44,010

Labor Hours

Name	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Project Manager	4	2	2	2	4	4
Mechanical Eng #1	20	20	4	4	4	20
Electrical Engineer	40	40	8	4	20	20
Principle	1	1	1	1	1	1
Total / Week	65	63	15	11	29	45

Labor Estimate

Name	Rate	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Project Manager	\$160	\$640	\$320	\$320	\$320	\$640	\$640
Mechanical Eng #1	\$125	\$2,500	\$2,500	\$500	\$500	\$500	\$2,500
Electrical Engineer	\$140	\$5,600	\$5,600	\$1,120	\$560	\$2,800	\$2,800
Principle	\$175	\$175	\$175	\$175	\$175	\$175	\$175
Total / Week		\$8,915	\$8,595	\$2,115	\$1,555	\$4,115	\$6,115
Phase Total							\$31,410

Materials

Description	Quantity	Each	Cost
Raw Materials	1	\$500	\$500
Puck Parts	5	\$350	\$1,750
Cartridge Parts	5	\$750	\$3,750
Heater	5	\$50	\$250
Flex Curcuit	5	\$300	\$1,500
Other Misc	1	\$1,000	\$1,000
Sub-Total			\$10,500
Materials Markup		20%	\$2,100
Total			\$12,600

Revision Summary

- R1 Revision – Initial release of plan
- R2 Revision – Reduced scope of filter conceptual design and added the Archive and Lyse-No-Go cassette conceptual design
- R3 Revision – Updated the completion of Phase 1 and updated the scope of work for Phase 2.
- R4 – Addition of Phase 3 for Lyse 'N Go detail and fab.