R&D ENGINEERING INTERNSHIP WITH BYRNE MEDICAL INCORPORATED

A Record of Study

by

VIKRAM RAMAKANTH

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF ENGINEERING

December 2007

Major Subject: Engineering
College of Engineering

R&D ENGINEERING INTERNSHIP WITH BYRNE MEDICAL INCORPORATED

A Record of Study

by

VIKRAM RAMAKANTH

Submitted to the Office of Graduate Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

DOCTOR OF ENGINEERING

Approved by:

Chair of Committee,	Charles S. Lessard
Committee Members,	Bob Anderson
	Charles R. Conrad
	David Martin Hood
	Kenith E.Meissner
Head of Doctor of Engineering Programs,	Nagamangala K. Anand

December 2007

Major Subject: Engineering
College of Engineering

ABSTRACT

R&D Engineering Internship with Byrne Medical Incorporated. (December 2007)

Vikram Ramakanth, B.E., University of Madras; M.E., Texas A&M University

Chair of Advisory Committee: Dr. Charles S. Lessard

This record of study describes work done in the capacity of Research and Development (R&D) Engineer at Byrne Medical Incorporated, Conroe, TX. The company manufactures accessories used for endoscopic irrigation. The endoscopy system requires a supply of pressurized distilled water that is used by the physician for certain procedures. It becomes the responsibility of the irrigation subsystem to fulfill this need. It consists of a pressurization system, distilled water holder, tubing to convey this to the endoscope and fittings to interface the tubing to the endoscope body. Byrne Medical Inc. manufactures products from every stage of the system for many of the larger endoscope manufacturers.

As an R&D Engineer, I was placed in the operations facility to aid the engineering team in its role to develop, test, prototype and refine products. In performing this role, I had to work with managers and staff from different functional areas of the company. Projects did not stop with technical design; they called for effective communication, planning and decision making.

This document covers salient projects completed during the course of the internship. Designing an endoscopic irrigation pump to be sold in conjunction with an

instrument cart was one. An automated measurement system comprising of instrumentation interfaced with a personal computer and LabVIEW software is another.

To facilitate assembly, tools to insert plastic components into extruded tubes were designed in SolidWorks. Another project that involved mechanical design and elements of project management was designing a tubeset to be used with an Endoscopic Retrograde Cholangiopancreatography (ERCP) system. This was done by Byrne Medical Inc. for Boston Scientific Corporation, the manufacturers of the core ERCP system.

These projects not only called for engineering skills but inputs from other departments and personnel also. Inputs from regulatory affairs, technicians and clean room staff were critical to the success of all these projects.

ACKNOWLEDGEMENTS

I would like to thank my advisor, Dr. Charles S. Lessard, for his guidance and support. He gave me the freedom to explore different avenues of study and still manage to keep me on course to complete the degree. I would also like to thank Don Byrne, Alan Smith and Bob Anderson of Byrne Medical for giving me the opportunity to work as an intern at Byrne Medical Inc. I would like to thank my family for their support and encouragement.

TABLE OF CONTENTS

Page

ABSTRACT iii

ACKNOWLEDGEMENTS v

LIST OF FIGURES viii

1. INTRODUCTION 1

1.1 Endoscopic Irrigation 3
1.2 Product Line 6
1.3 Workflow 8

2. DESIGN OF IRRIGATION PUMP 11

2.1. Housing Design 12
2.2 Components 14
2.3 Prototyping 15
2.4 Setback 17
2.5 Redesign 19

3. COMPUTERIZED TEST BENCH 22

3.1 Instrument Selection 22
3.2 Software Development 24
3.3 System Features 26
3.4 Deployment 28

4. DISPOSABLE PRODUCT DEVELOPMENT 29

4.1 Clear Version 30
4.2 Product 100116 30
4.3 Product 100145 33
4.4 Product 200250 35

5. ENDOGATOR IRRIGATION UNIT 40

5.1 Stryker Version 41
5.2 Pentax Version 43

Page

6. MUSHROOM TOOL 44

7. INTERACTING WITH SUPPLIERS AND VENDORS 46

8. INSIGHTS 49

8.1 Managing a Company 49
8.2 Entrepreneurship 50

9. SUMMARY AND CONCLUSIONS 52

REFERENCES 53

VITA 54

LIST OF FIGURES

Page

Figure 1. Endoscope air and water port connected to reusable water bottle. 4

Figure 2. Tubeset hooked to irrigation line. 5

Figure 3. Peristaltic pump head on irrigation unit. 7

Figure 4. A tubeset. 8

Figure 5. Three dimensional drawing of the Bovie Cart. 12

Figure 6. Three dimensional drawing of pump enclosure. 13

Figure 7. Plastic pump exposure with cover removed to show component placement. .. 16

Figure 8. Estimating fit using three dimensional models of the pump and Bovie Cart. .. 18

Figure 9. A Bovie Cart with the irrigation unit installed. 21

Figure 10. Pressure and flow instruments connected to the data acquisition system. 23

Figure 11. Software user interface of the measurement system. 25

Figure 12. The 'Settings' panel of the measurement system. 27

Figure 13. Product 100116 made out of clear polycarbonate. 32

Figure 14. Product 100145 for use on Olympus Endoscopes. 34

Figure 15. Product 200250. 37

Figure 16. The EndoGator EGP-100 irrigation pump; shown hooked up to a tubeset. ... 40

Figure 17. The *mushroom* tool. 45

1. INTRODUCTION

An internship is an essential part of the Doctor of Engineering program at Texas A&M University. The objective of the internship is to develop the student's ability to solve broad problems that affect more than one facet of the organization. It also provides the student with the opportunity to work on these as part of an organizational team. The internship is also an opportunity for the student to apply the management training garnered during the duration of the course.

The internship was undertaken at Byrne Medical Inc, headquartered at Montgomery, Texas. The company's products are manufactured for use in the Gastrointestinal (GI) room for gastroscopy and colonoscopy procedures. The company focuses on endoscopic irrigation equipment, with a focus on disposables for endoscopes. The company also makes endoscopic irrigation pumps and pump cartridges to support the line of disposables. While the company is headquartered in Montgomery, it has a molding facility located in Montgomery and an operations facility in Conroe, Texas.

The company is privately held and employs around a hundred people including personnel for management, finance, inventory, engineering, sales, and skilled activity. The central activity is the production of disposables in the operational facility. This is done in clean rooms by trained assembly personnel.

This record of study follows the style of *American Journal of Physiology – Heart and Circulatory Physiology.*

Plastic components are procured from suppliers within the country and overseas. The molding facility supplies high volume components which are inexpensive to make in house due to economies of scale. The molding facility also houses two Computer Numerical Control (CNC) machines for precision machining operations. These machines are used to machine parts such as cap nuts and tube fittings that cannot be molded. All finished disposable products are ethylene oxide sterilized; an activity which is subcontracted.

The warehouse, which is part of the operations facility, is physically divided into non-sterile and sterile zones to house products awaiting sterilization and finished product respectively. Sales, accounting and materials management operate out of the corporate office. The company employs an internal network with common storage databases. All the key personnel in the company have access to the company's Enterprise Resource Planning (ERP) system which reduces communication complexity greatly. The company is International Organization for Standardization (ISO) certified and maintains highly traceable documentation for every activity performed. The company's products are classified as class I Food and Drug Administration (FDA) devices and hence require only a Premarket Notification (510(k)). The company is also authorized to carry the CE mark which will allow it to legally market their products in the European Union (EU).

The internship entailed being placed in the operations facility as an R&D (Research and Development) Engineer. Being a company that is employs a relatively small number of people, the role of the engineer has grown to fulfill most technical needs. The level of involvement in different tasks and projects only depends how the

engineer is able to schedule his time around them. The engineer is aided in project management by the operations manager and the Regulatory Assurance/ Quality Control (RA/QC) Manager. Broadly speaking tasks can be generated by three stimuli. One is product improvement which is a continuous process often hastened by comments and complaints from customers. The second is from external partners with whom Byrne Medical either has a marketing agreement or is an OEM (Original Equipment Manufacturer). The third is the company's internal R&D initiative. These stimuli often overlap and draw upon the engineer's project planning ability to ensure that they are completed in reasonable time frame.

1.1 Endoscopic Irrigation

The endoscope is a ‘tube’ that can be inserted through a body orifice to perform medical diagnostics and/or procedures. It is flexible along its entire length with the distal section – about a foot or less in length – capable of articulation. The endoscope contains a number of channels running along its length. There is a biopsy channel that is a multipurpose channel. There is an irrigation water line that shoots water straight out of the distal tip. The water for this line is usually supplied by an irrigation pump that is connected by a tubing system to a port on the scope body. Usually, there are two fiber optic channels; one to carry light up to the distal tip. There is also a lens at the distal tip to which the second fiber optic couples to. The scope is connected to a device known as the processor. The processor is a combination of a pneumatic pump, a light source and an image processor. There is also a dual air/water channel that opens out parallel to the distal surface, directing its flow along the lens surface. The air/water channel is

connected to a pressurized sterile water source. The sterile water source is usually a reusable water bottle that is filled with sterile water. A reusable label in the endoscopy arena implies that the component it applies to can be cleaned and reused. The process of cleaning is an extensive and thorough process. The bottle is pressurized using the processor and is designed to allow either pressurized air or water to enter the air/water channel.

Fig. 1. Endoscope air and water port connected to reusable water bottle.

It can be difficult to understand why the air/water system is so convoluted. The dedicated irrigation line seems to be a redundant addition to the air/water line (Fig. 1) with a pressurized water bottle that already exists. The air/water line opens out parallel to the lens surface on the distal tip. This line is supplied with water when the lens needs to be flushed of debris. This line is supplied with air, to clean the lens when the lens is in contact with a non-aqueous environment. During colonoscopy, the lens is flushed with water and then dried off with air. Air is also used in colonoscopy to insufflate the

intestines, i.e., to pump air into them. This causes them to expand and gives the doctor room to use the endoscope.

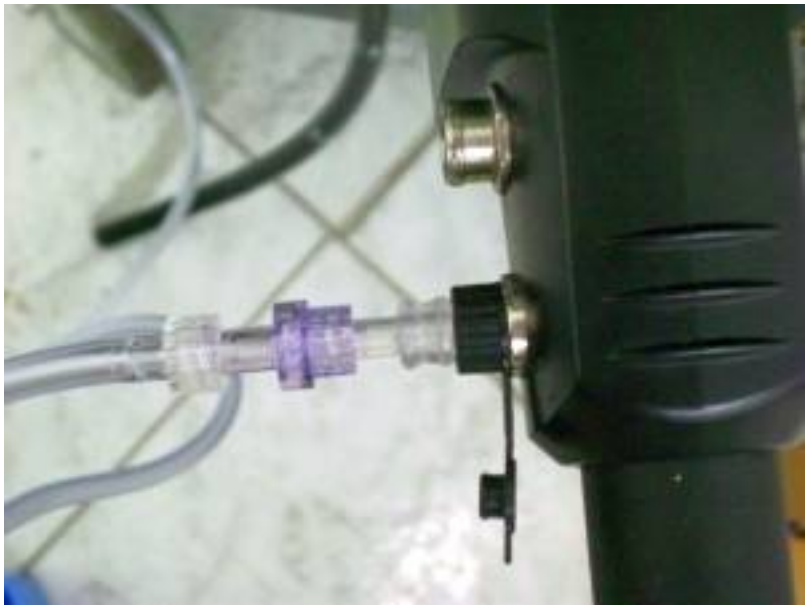

Fig. 2. Tubeset hooked to irrigation line.

The separate irrigation line (Fig. 2) is used for a different set of functions. It shoots a jet of water straight out of the distal tip. It usually delivers water at a higher flow rate when compared to water from the air/water line. This water stream is used to clean debris in regions that have to be cauterized. It is also used to navigate bowels that are not empty. The patient is required to report to a colonoscopy on an empty stomach but often times this is not the case. The water jet loosens the contents and allows the doctor to navigate.

1.2 Product Line

Byrne Medical Inc. sells its products to GI rooms as an infection risk mitigation solution to patients who undergo endoscopic procedures. The endoscope along with the sterile water bottle and custom fittings are reprocessed after each procedure. Companies such as Abbot Labs, Baxter Healthcare and McGaw Inc. market sterile water in single use plastic bottles. Byrne Medical Inc. holds a patent on the SmartCap, a bottle cap designed to fit most single use bottles. Byrne Medical also manufactures the components that allow the SmartCap to be mated with processors made by different endoscope manufacturers. This allows medical facilities to use disposable water bottles and endoscope fittings instead of the reusable ones supplied by the manufacturers. This in turn enables them to concentrate their resources on reprocessing endoscopes, which is one of the most laborious and time consuming products to reprocess in the medical industry. Being a disposable alternative, the risk of infection is greatly reduced.

Apart from its range of SmartCaps, Byrne Medical's second line is called the EndoGator or Gator in short. This consists of the EndoGator irrigation pump and a variety of tubesets that can be used with the EndoGator pump or with other pumps. The pumps used for endoscopic irrigation are of the peristaltic type (Fig. 3). These pumps use spinning rollers that pinch and drag on a tube. This produces the necessary difference in head between the ends of the tube, allowing it to pump liquid. The advantage of this type of pump is that the fluid being pumped never comes in contact with the pumping system unlike a centrifugal or a reciprocating pump. In the medical, pharmaceutical and food process industry the peristaltic pump is preferred choice. The downside to this system is

that the tubeset that comes in contact with the rollers gets worn out over a period of time and needs to be replaced regularly. *The* tubeset is sold as a 24 Hour use product with a *back flow* valve at one end of it. The valve prevents water from the endoscope from reentering the pump tubing and contaminating the water within it. The tubing is usually hooked onto the scope and after a procedure is completed the tubing is detached and reused for the next one.

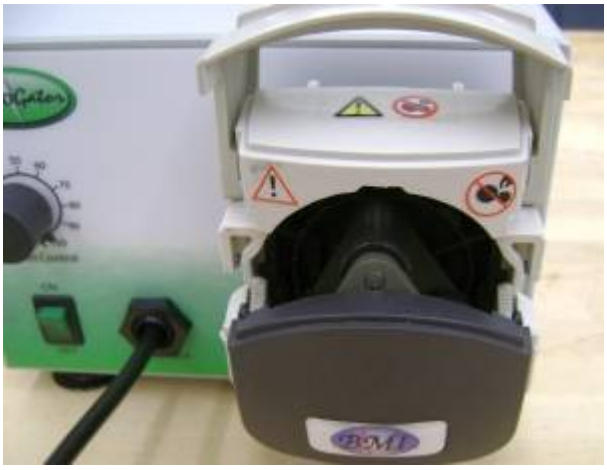

Fig. 3. Peristaltic pump head on irrigation unit.

The irrigation lines the pumps connect to have manufacturer specific connections. Byrne Medical produces an assortment of products to hook up the tubeset (Fig. 4) to these specific connections. Byrne Medical also produces pump cartridges that can be used with a different kind of peristaltic pump. These pumps usually use a plastic cartridge with a tube embedded within them. Byrne Medical manufactures reusable cartridges and disposable tubesets that can be used with these cartridges. The emphasis is again on reduced GI room maintenance and infection risk.

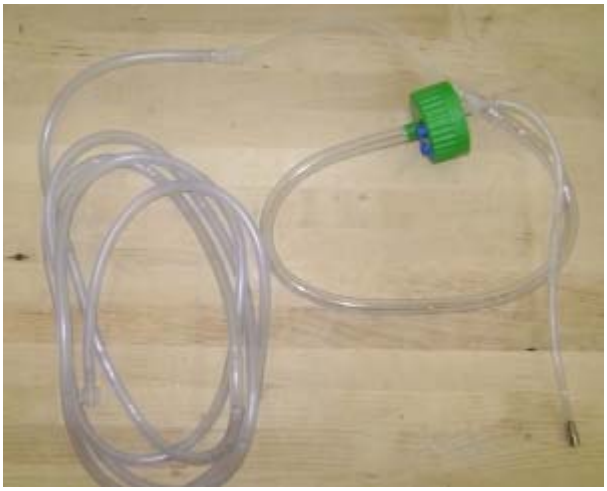

Fig. 4. A tubeset.

The risk of infection is the GI room is primarily due to cross-contamination i.e., transfer of biological matter from one patient to another. This can occur is the endoscope is not reprocessed correctly, if storage conditions are improper and if the sterile water used in the procedure is contaminated. Byrne Medical, through its disposables and the incorporation of the back flow valve in them facilitate a reduction in this risk and reprocessing complexity.

1.3 Workflow

The engineering department is part of the operations facility in Conroe, TX. The facility, headed by the operations manager, Bob Anderson, employs quality assurance personnel, technicians, warehousing and manufacturing staff. The engineer supports all these personnel in day to day activities in addition to the roles mentioned earlier. A typical day at the operations facility begins with what is called the ‘huddle meeting’. This is a meeting lead by the operations manager in the packaging area with all critical

personnel to discuss the facility's performance statistics for the previous day , delegate tasks, discuss issues briefly and schedule meeting among different groups for problems that need to be investigated. This quick meeting which lasts for fifteen minutes has a positive impact on interdepartmental communication and ensures important issues are addressed in a timely manner.

The operations manager, along with other managers, delivers a weekly performance report to the corporate office. This is a formal meeting, which focuses on strategy, human resources, production and manufacturing. Engineering issues are usually discussed among relevant personnel in specially scheduled meeting either in the operations facility or in the corporate office when needed.

The manufacturing manager, in consultation with the operations manager and clean room supervisor, checks the company's ERP system for reorder points and schedules production of required products. This is initiated through a work order form that is prepared by the warehousing staff. The work order contains traceability information on all personnel who have worked on the product. The parts are delivered to the clean room where they are assembled. The parts are pouched, sealed, labeled, packaged, palletized and sent for sterilization. Upon sterilization, which usually takes a week, the product is final packaged and shelved in sterile zone of the warehouse. All components received from suppliers and final products are subject to quality inspection.

Though an internship, the tasks and duties assigned were the same as that for a full-time engineer. Knowledge transfer and training were not independent from day to day activities. Though not a comprehensive compilation, the following list of activities

have been identified to illustrate achievement of the Doctor of Engineering internship objectives.

2. DESIGN OF IRRIGATION PUMP

Aaron Medical manufactures and markets a medical equipment cart called the Bovie Cart. The cart is designed to be used with endoscopic systems, with room for a processor to be placed on top of it. Aaron Medical approached Byrne Medical to develop an irrigation pump that would integrate into the cart which would then allow them to market the cart as an endoscopic solution, rather than just a cart. The company supplied Byrne Medical with a cart and orthographic drawings of the cart. When the project was initiated, there was a two month development time after which a working prototype was needed. This prototype was to be displayed by Aaron Medical at the SGNA (Society of Gastroenterology Nurses and Associates) annual event held in Baltimore, MD between the 18th to the 23rd of May.

The cart is non-conventionally designed with curved faces for every wall (Fig. 5). The cart's body is divided into three shelves by two horizontal sheet metal plates. The right face of the cart has rectangular 'windows' stamped out that allows access to the three shelves. These shelves were created to allow storage of disposables, place water bottles or anything else that was needed in a GI room during the procedure. The cart has a square base that rests on four wheels.

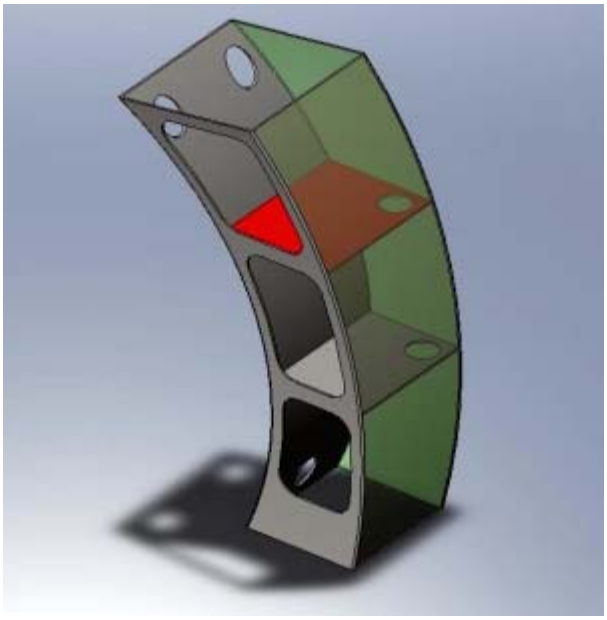

Fig. 5. Three dimensional drawing of the Bovie Cart.

2.1. Housing Design

During the initial phase of development it was decided that some sort of metal or plastic framework was required to house the pumps internal components and also support the peristaltic pump head that would stick out of the opening on the right wall. The topmost shelf, being the largest in volume, was chosen to be the location for the pump. A power supply cord would run from the base to power the pump. After a couple of meetings, it became apparent that a totally enclosed housing, made of plastic would be ideal for two reasons. One was that this design would electrically isolate the pump from rest of the cart making electrical testing and approval easier. If the pump was approved as a standalone unit, where it was placed wasn't an issue. Secondly, it would allow Byrne Medical to sell these pumps to Aaron Medical, who would then install it on

their carts at their facility. If the design called for non-enclosed housing then installation became more complicated and would require Byrne Medical to install them. This would entail shipping carts to and from Aaron Medical, an addition to both cost and logistics.

The curved surfaces of the cart proved to be challenge to design around. If all the surfaces were at right angles, a cubed housing could be easily built and accommodated into the shelf. The curved surfaces required that the pump be built to match them. This is because the pump had to cover the opening on the right wall and sit flush against it. From an aesthetic perspective, any gaps along this pump-wall interface would be undesirable. The cart was also impossible to measure owing to its irregular geometry.

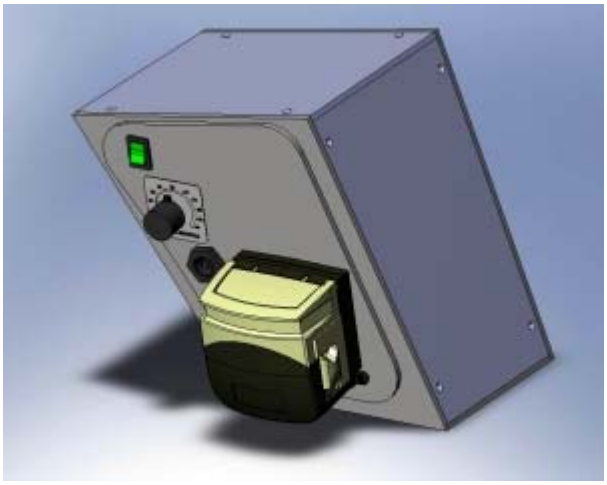

Fig. 6. Three dimensional drawing of pump enclosure.

Using the two dimensional (2D) orthographic drawings supplied by Bovie, a three dimensional (3D) model of the cart was constructed. Once completed, the 3D model of the cart was used to build the pump, virtually, within it (Fig. 6). The key

components (motor, motor controller, power supply board, pump head) used in the pump are the same ones used in the EndoGator EGP-100 pump.

2.2 Components

Key pump components used in the pump,

- Motor and Driver: Vexta Brushless DC Motor (AXHM015K-5) and Vexta Brushless DC Motor Driver (AXD15K).
- 110 V to 24 V Power Supply: Meanwell MPS-30-24.
- Pump Head Unit - Watson-Marlow Bredel 313DK Pump Head.

A brushless DC Motor is actually an AC synchronous motor. It is called a Brushless DC motor because of a similarity they share when it comes to electrically modeling them. Any electrical motor has two sets of magnetic fields that interact to produce rotary motion. One set of fields is produced by the stator, the stationary part, and the other by the rotor, the rotating part. In a Brushless DC motor, permanent magnets are embedded in the rotor eliminating the need to supply it with any electricity. The stator is supplied with an AC signal by means of an electronic controller. The controller senses the shaft position and adjusts its signal output accordingly. These motors are known to be more reliable since the do not employ commutation hardware like other DC motors.

Watson-Marlow Bredel is a popular peristaltic pump head manufacturer and is chosen as an OEM (Original Equipment Manufacturer) by most irrigation pump manufacturers. The pump head is robustly designed and requires no maintenance in the part of the end user, not even lubrication. The 313DK pump head employs two rollers

that are connected to the central shaft. The Vexta motor is coupled to this shaft through a built in speed-reduction system. The two rollers squeeze against the tube as they roll past it, generating the difference in pressure head. Due to inherent friction of operation, the tube that comes in contact with the roller degrades with time. Disposable tubing degrades faster along with a corresponding reduction in pressure when compared to reusable tubing.

Other components include a potentiometer for speed control, a power switch and a pneumatic switch that is usually connected to a foot pedal via an air hose. To use the pump, the power cord is connected to an AC power outlet and the power switch is activated. Then the desired speed is set and the tubeset is loaded into the pump head. When the user steps on the foot pedal, the motor is activated and pumping begins. Once the foot is removed from the pedal, the motor is deactivated. This allows the doctor performing the procedure to control water flow with his foot while using his hands to control the endoscope. In more sophisticated systems, buttons on the endoscope can be used to control the pump.

2.3 Prototyping

The components from the existing EGP-100 pump were used, though two of them couldn't be borrowed. Once was the Brushless DC motor mounting bracket, an aluminum sheet metal frame that supports the motor and holds it in the place within the pump. Since the Bovie irrigation unit enclosure was shaped differently, it called for a different mounting arrangement. A new design was formulated and drawn up in

SolidWorks and was manufactured by Star Precision Fabricating (Houston, Texas), who also made the mounting bracket for the EGP-100 pump.

The pump also needed a different mode of power cord attachment. The power cord needed to be permanently fixed to the unit and not be detachable since it is placed inside a cart. If the power cord detached from the irrigation unit, the Bovie Cart would have to be partially dismantled to gain access to the irrigation unit and reattach the cord. A strain relief was chosen that held the power cord to the irrigation unit.

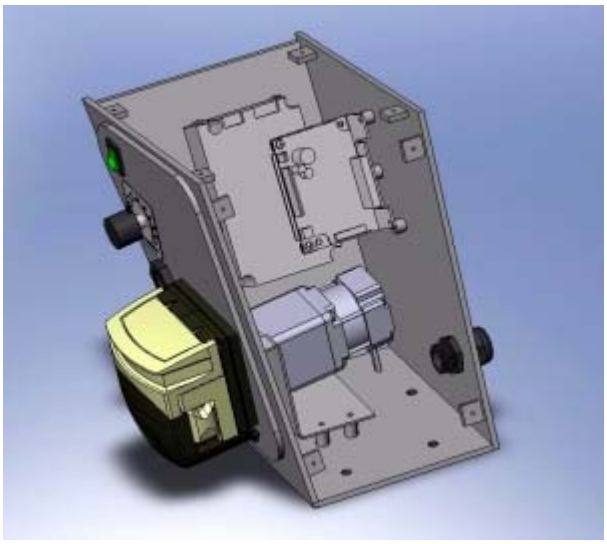

Fig. 7. Plastic pump exposure with cover removed to show component placement.

The plastic enclosure (Fig. 7) for the irrigation unit was made by Toolless Plastic Solutions Inc. They employ a process of bending plastic sheet stock to the required shape, without needing to mold them. Plastic sheets of required thickness are chosen and features are created on them using a CNC machine. The sheets are then bent to shape using heat. Features such as standoffs and screws tap points are glued as the last step.

The engineers at Toolless accepted three dimensional SolidWorks drawings and didn't need two dimensional drawings which simplified communication greatly.

2.4 Setback

The plastic pump enclosures were delivered on schedule, two weeks before the SGNA annual event at Baltimore, MD. When the box was placed in the cart, it did not fit flush with the cart surfaces. The box's faces did not parallel those of the cart and thus there were gaps between front face of the box and the window on the right wall of the cart. The design called for a close fit that made the pump look as though it were part of the cart's body. Even the color of the pump was chosen to match the cart, albeit a shade lighter, to enhance the aesthetic appeal of the product. While this flaw in fit was not a functional one, it affected the marketability of the product and its acceptability by the market. The client, Aaron Medical, was trying to sell an integrated system and the assembled product did not visually come together to support that idea.

An immediate root cause analysis was initiated. Within half a day it was apparent that the dimensions on the box were in accordance with the supplied SolidWorks drawings. The design of the box did not match requirements. This was surprising, since the box had been designed to fit to the SolidWorks drawing of the cart. Both the objects had been 3D modeled in SolidWorks; the fit was checked using software (Fig. 8). The software allows both objects to be move with respect to each other, to stop on collision and display interference volumes along with other statistics. The dimensions in the box had been fine tuned using these tools and it was perplexing as to why there was such a discrepancy in the fit.

Fig. 8. Estimating fit using three dimensional models of the pump and Bovie Cart.

The SolidWorks drawing of the cart was checked and the dimensions were cross referenced to those on the two-dimensional drawings supplied by Aaron Medical. There was no mismatch. This was expected since mistakes are easy to notice on a three dimensional drawing. If all the surfaces do not fall in place, the edges won't meet to form the solid. This led to the logical conclusion that the cart did not match its own two-dimensional drawing.

Aaron Medical was contacted and a telephonic meeting was set up with an engineer. During the meeting, it was discovered the cart was made by welding four stamped steel plates, one for each side face. The base of the cart was made separately and welded on. While the features on the faces were very precise, due to the stamping

process, the welding introduced a dimensional error in the cart. Being a manual process, the separation between corresponding faces could be off by as much as half and inch. Since the cart was sold separately, there did not exist a need for them to tolerance it more tightly. However, this made it quite difficult to custom fit it with a custom made irrigation unit.

2.5 Redesign

Despite the challenges and a two week time window, a decision was made to redesign the pump enclosure. The primary obstacle to the design was arriving at the right dimensions for the irrigation unit. The shelf in the cart was formed by the intersection of curved faces and could not be measured using the tools available – calipers, ruler, protractor and measuring tape. What would have been ideal was a CMM (Coordinate Measuring Machine) that would have measured the cart and given us a solid model of the cart.

The operations manager, Bob Anderson, suggested we chose a low tech approach; use cardboard sheets to make a mockup of box. It would indeed save us a lot of time since it decoupled the design from the cart drawing. The cart dimensions did not matter since the mockup would serve as the starting point. The mockup could be measured and the dimensions it yielded could be used to construct a new irrigation unit enclosure.

Cardboard sections from packaging boxes were cut and used to fashion the faces of the box. The base, which was rectangular in shape, was used as the starting point. Its dimensions were derived from the previous design. The face that faced the window was

added. The faces were intentionally made larger than required and the edges held together by adhesive tape. Each face was removed, reduced in area and refastened. The mockup (Fig. 9) was placed into the shelf in the cart and the process was iterated a number of times. Different combinations were tried before settling on the best possible fit. The cover of the box was not fabricated using cardboard. Since it had to fit flush with the rest of the box, it was designed in SolidWorks.

The dimensions from the mockup were extracted and used to construct a new pump enclosure. Its overall shape was very similar to the previous version. Toolless Plastic Solutions Inc. was contacted while the new drawing was being constructed. They agreed to deliver two enclosures within a week of submitting the new design. This was done and the enclosures that arrived a week later fit the cart well. The Byrne Medical technician, Wesley Phillips, who assembles the EndoGator EGP-100 pump, assembled the two prototypes.

Aaron Medical had shipped an additional cart and we now had two carts to outfit with the irrigation unit. Mounting holes had to be drilled through the quarter inch thick sheet metal base of the shelf. Wesley Phillips along with Brice Leverett, the warehouse in charge, took about two hours to mount the pumps onto the cart. The very next day the assembled carts (Fig. 9) were packaged in cardboard boxes and shipped to the SGNA event in Baltimore, MD.

Fig. 9. A Bovie Cart with the irrigation unit installed.

3. COMPUTERIZED TEST BENCH

Byrne Medical conducts extensive flow tests on their product line. This is for two main reasons,

1. New product verification and validation.

2. Failure analysis.

Pressure and flow information are routinely required for decision making, not only by engineering but also by management for strategic decisions. Pressure and flow (volume per unit time) data for air and water are required by all experiments. Before the development of this system, pressure and flow readings were manually noted and compiled into spreadsheets. Both analog and digital gauges were used in experiments. Chris Adams, a technical specialist, suggested that there should be a better way of using technology to collect data from experiments.

The engineering lab possessed a National Instruments ELVIS electrical prototyping board. This system allowed prototyping electrical circuits and more importantly was coupled to a National Instruments Data Acquisition (DAQ) card on the personal computer. The computer also had National Instruments LabVIEW version 7 installed. A decision was made to use the hardware and software to automate the data gathering process.

3.1 Instrument Selection

The engineering lab had water (McMillan S-111) and air (Omega FMA 1800) flow meters with the ability to put out an analog voltage signal. Air and pressure gauges

with electrical outputs were needed. After a search, the SUNX DP-100 air pressure gauge and the Ashcroft 2160 fluid pressure gauge were purchased. The SUNX DP-100 had analog voltage outputs like the previous gauges.

The Ashcroft 2160 pressure gauge was a loop-powered system. It did not produce a separate analog voltage reading. It varied the current in the power supply circuit corresponding to the pressure it was measuring. The gauge could accept a voltage ranging from 12 to 32 V DC and vary the current in the supply circuit to match the pressure the transducer it was seeing.

The DAQ card on the computer measured DC voltages from -10 V to 10 V. The gauges with analog voltages were directly connected to the DAQ pins on the ELVIS system (Fig. 10). The Ashcroft 2160 pressure gauge could not be connected to the DAQ since it could not sense current changes. A resistor was placed in line supplying the Ashcroft 2160 with power and the voltage drop across it was fed to the DAQ system. Instead of using a single resistor, two resistors were used in parallel to compensate for thermal variations and stray capacitances.

Fig. 10. Pressure and flow instruments connected to the data acquisition system.

3.2 Software Development

The software to control the DAQ board and present the user with an interface was development in LabVIEW. It is a graphical programming language sold by National Instruments which also makes a wide array of instrumentation hardware. LabVIEW allows the user to quickly create a program to utilize sophisticated hardware and supports real-time and multi-threaded programming. It gives a user the ability to focus on the solution rather than spend time learning and debugging software development techniques. This allows it to be used as a rapid prototyping system. LabVIEW programs cannot be executed by themselves, i.e., require LabVIEW to be installed. This makes them less portable than a C++ application. However when portability is not an issue, it proves to be an ideal development environment.

The NI-DAQ software module in LabVIEW was used to control and capture voltage signal from the DAQ board. This signal is available as a stream of numerical data that are scaled to the quantity being measured. This depends on the instrument from which the signal comes from. To maintain this relationship, all the four gauges are connected to the ELVIS system and never removed. The SUNX DP-100 and Ashcroft 2160 gauge is also powered by DC voltage from the power supply on the ELVIS board.

The program user interface (Fig. 11) allows selection of one of the four different gauges. It also allows selection of sampling interval i.e., how often the data is collected and how long the collection goes on for. A 'wait for signal' feature is implemented in software and the user can choose to enable this feature. This feature enables a module in the program that automatically chooses the first enabled gauge and samples the signal on

that line. It collects a set number of samples, calculates the RMS (Root Mean Square) value. It compares this value against a threshold value. An RMS value is chosen since yields a positive value even if the signal is an alternating; averaging such a signal will result a zero net value. The threshold is an empirical value that represents the RMS value of noise. The program triggers acquisition when it senses a signal on the line using this RMS dependent algorithm. The user interface indicates through an LED (Light Emitting Diode) indicator and also lists the gauge that is been polled.

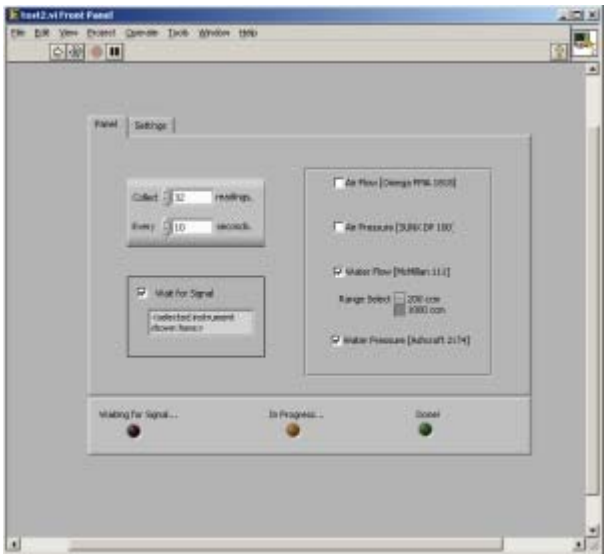

Fig. 11. Software user interface of the measurement system.

Once the collection phase is complete, the program prompts the user with a 'file save' dialog. The processed pressure and flow data is written to this file in ASCII (American Standard Code for Information Interchange) format. The data is available in columns and is suitable for use with a spreadsheet program. The number of columns and

their order in the file mirrors the gauges that at chosen for the acquisition. For example, if the air flow gauge and the air pressure gauge are chosen, then the first column will contain the data from the air flow gauge and the next one from the air pressure gauge.

There are two different McMillan flow meters used for water flow measurements. One for the 0-200 ml/min range and the other for the 200-1000 ml/min range. Since none of the devices offer a unique identification signal, it is not possible to automatically detect which one is tied to a particular DAQ channel. The program interface provides a slider switch which allows the user to select which one of the two gauges is being used. The state of this switch is polled only when the McMillan flow meter is selected and is ignored otherwise.

3.3 System Features

The user interface provides a panel called ‘Settings’ that allows users with a better understanding of the system to vary different configuration parameters. As mentioned earlier, each instrument is associated with a physical connection on the ELVIS prototyping board. This physical connection is mapped to a ‘software (virtual) channel name’ that is used by software programs to identify each channel uniquely. The software program does not require any information about the actual device connected to the channel; all it needs is the channel name and what range of voltage is expected so that it can calibrate its ADC (Analog to Digital Converter) accordingly. If the system undergoes changes and the gauges are electrically connected to different physical connect (10 connections are available for DAQ operations), then the software will have

to be updated with this information. This is option is provided for all four gauges in the settings panel.

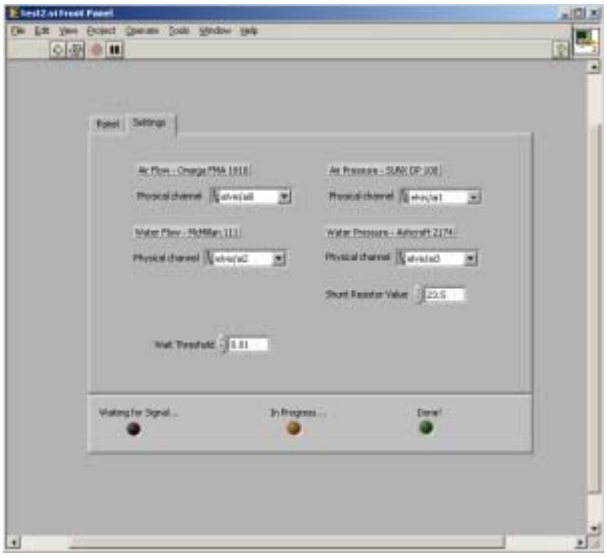

Fig. 12. The 'Settings' panel of the measurement system.

The ‘Settings’ panel also has the detection threshold level. Since this is an arbitrary value, the user might need to change it. This may not be very often and this is the reason why this control is placed here instead of the front panel. The user can lower this value if the software fails to trigger or increase it if it doesn't wait for the signal. This panel (Fig. 12) has one other feature which is the value – in ohms – of the resistor placed in the power line of the Ashcroft 2160 pressure gauge. The Ashcroft 2160 gauge doesn't produce a separate signal but varies the current in the DC supply circuit corresponding to the change in pressure. The resistor is placed in this line and the voltage across it is sensed by the DAQ hardware. To get the current in Ampere the voltage in Volt is divided

by the resistance in Ohm (Ohms law). This resistance can be varied within a certain range that is determined by the supply voltage. If any such changes are made the resistance value feature allows the user to simply enter the new resistance value.

3.4 Deployment

This system replaced manual data recording in most cases. When conducting investigations stand alone measurement devices are faster to employ. When detailed testing and statistical analysis is required the software based system proves to be more accurate and reliable. Human errors in visually observing the reading, tabulating it and reentering in a spreadsheet are eliminated. This reduces the time spent on each experiment drastically; attention is focused on analysis instead of data gathering.

The system allows readings to be captured between very short intervals of time, less than a second, something manually impossible. This enables tracking variations to a finer degree and mapping transient flow characteristics. Prior to the development of this system, only steady state analysis and averages were available. Many products are used for short bursts during endoscopic procedures and the finer level of data gathering allowed the engineering team to see how different devices behaved during such instances.

4. DISPOSABLE PRODUCT DEVELOPMENT

The core focus of the company is the development of disposable products for endoscopic irrigation. The irrigation pump, EndoGator EGP-100, was designed to boost the utilization of the company's disposable tubesets. All strategic decisions are made based on the impact they will have on this aspect of the business. The company's molding facility, sales force and customer service personnel actively support the disposable product line. Being the revenue generating part of the business, there is an emphasis on speedy complaint resolution and development.

Byrne Medical disposables are categorized into two broad product families. This categorization stems from two popular pressurization sources used in endoscopic systems. One, already introduced, is the irrigation pump. The other is a pressurized carbon dioxide (CO2) source such as a wall outlet in the GI room. An endoscopic system requires pressurized water and air – or CO2 – for regular operation; water for irrigation and air for inflating the gastrointestinal tract, otherwise known as insufflation. While air is also used, CO2 is preferred since it absorbed by the surrounding tissue faster than air. This reduces the amount of time the patient has to walk around with a ‘bloated stomach’.

The disposables that are connected to the irrigation unit are called Gator. The name, just like the EndoGator, owes its origin to the marketing phrase 'Take a bite out of back flow' that is put on tubeset packaging. This refers to the back flow valve that is put on the tubeset to prevent water in the endoscope body from reentering the tubeset

section. This allows the tubeset to be used for a 24 hour period on multiple endoscopes. The cap that screws on the bottle in colored a characteristic fern green.

The disposables that are used in pressurized air or CO2 systems are called SmartCap. The cap in this case is colored sky blue. These color combinations were chosen to develop brand visibility in the GI room.

4.1 Clear Version

Around the time the internship commenced, Byrne Medical had made a decision to go to a clear look on its product line. To achieve this look all products would be molded using clear polycarbonate instead of colored polycarbonate, polystyrene or polypropylene. This would be accompanied by a complementary shift in connectors and other fittings on the tubeset. Crystal clear polycarbonate is a hard material with a glass like clarity. The hardness creates issues in molding and manufacturing and entails redesign in many cases. Due to this, this initiative was applied in a phased manner, going from one product to the next.

4.2 Product 100116

The 100116 is a disposable adapter that uses a standard luer lock based connection to interface a tubeset to a Pentax endoscope. The 100116 connects to an auxiliary water channel on the endoscope. This channel is designed to carry water and dispense it in the form of a water jet shooting out of the distal on the instrument. Usually, this channel is connected by means of a reusable adapter to an irrigation pump that uses a reusable pumping system.

Byrne Medical introduced a number of disposable components into this system. Firstly, the reusable pumping system was replaced by a disposable one. The irrigation pump used employed a hockey puck shaped pumping cartridge with a tube placed inside it. The cartridge was secured on the pump and the pump generated a pressure head by squeezing on the tube against the cartridge. A tube was attached from a reusable water bottle to the inlet connection of this cartridge. Another tube was connected from the outlet connection of the cartridge to the adapter that linked to the Pentax endoscope. The cartridge, tubes and adapter were reusable.

Byrne Medical holds a patent on a reusable cartridge that can be used with a disposable Byrne Medical tubeset. The tubeset is placed inside this cartridge and then secured to the irrigation pump. At the end of the procedure, the tubeset in the cartridge can be changed out. A disposable version of the adapter, the 100116, can be attached to the tubeset to link with the scope. Once again, this line of disposables simplifies the cleaning process that endoscopes are subjected to.

The current version of the 100116 is machined stainless steel component attached to a length of PVC tubing. The stainless steel head attaches to the endoscope body and the PVC tube gives it the length that enables the nurse to hook it up to a tubeset.

It was observed during use that when there was residual water in the endoscope connection port, the 100116 failed to secure properly. The 100116 uses a system of two o-rings to hold it in place. When water was present, no amount of pressure enabled the nurse to secure it properly to the endoscope. As a result the fitting tended to pop out of the port when the irrigation unit was turned on.

An analysis revealed that the two o-rings created a region that trapped fluid in between them. Air trapped in between was easily compressed and did not create an attachment issue. Water, unlike air, is far less compressible and offered resistance. The Pentax predicate fitting did not use this two o-ring system and hence did not have this issue. Having identified the root cause of the problem, the next step was to design a fix. What was needed was some way to allow the fluid trapped between the o-rings to escape when it was inserted into the port. This finally resulted in an axial surface groove cut on the part; this ran under the outer o-ring. This allowed the fluid to escape the o-ring by flowing under it. This idea was incorporated into a newly designed version that was molded as a single piece out of crystalline polycarbonate (Fig. 13). This version is currently undergoing field testing.

Fig. 13. Product 100116 made out of clear polycarbonate.

4.3 Product 100145

The 100145 is a special fitting that is meant to replace reusable bottles on Olympus endoscopes. The reusable bottle is has a 500 ml water storage capacity and is connected to the endoscope by means of a two lumen tube. All endoscope are connected to a processor which contains an air compressor. When water is needed, the endoscope uses one of lumina in the tube to pressurize the bottle. The bottle pressurized thusly returns water through the other lumen. This bottle is reusable and needs to be cleaned after every procedure.

Endoscope cleaning is a labor intensive and time consuming process. After the physician has used them, all endoscopes are wiped down, removed, manually rinsed and cleaned in enzymatic solution, cleaned with a high level disinfectant, flushed with water and dried. Due to the laborious nature of this process, there is a demand for reducing the number components that actually need to be cleaned. The 100145 product provides the Olympus endoscope user just that. It is a SmartCap, a double lumen tube and a specially made fitting that connects the tube to the scope (Fig. 14). The fitting splits the two lumina into two insertion points that interface with posts on the endoscope. The SmartCap allows it to be used with any sterile water bottle from a major US manufacturer.

Fig. 14. Product 100145 for use on Olympus Endoscopes.

A complaint stated that CO2 flow was being restricted when the 100145 was being used with an external CO2 source to pressurize the bottle. The option is used when CO2 is preferred to the air supplied by the processor. The CO2 version of the SmartCap is fitted with an additional tube that allows a separate pressurized source to pump CO2 into it. The CO2 and water can leave through the double lumen tube; the flow is controlled by valves in the endoscope. This problem was not noticed in the regular non-CO2 version.

Failure mode analysis revealed that the CO2 pressurization system pumped gas at a higher pressure than the processor. At a certain point in the 100145 fitting, the increased pressure and thus flow was creating a low pressure pocket. This phenomenon is known as the *venturi effect*. In the 100145 fitting, the region of low pressure was pulling the inner tube in the double lumen tube towards a vent hole and blocking it off

completely. Since this is flow dependent, it was not observed at lower rates of flow. The solution to the issue was change in the mold that prevented the condition from recurring.

The 100145 fitting is made from two separate halves that are assembled and then welded together using an ultrasonic welder. When the 100145 was made using clear polycarbonate, the two pieces refused to slip onto each other and consequently welding quality suffered. The weld seal hermetically shuts off any air from leaking out of the part and thus it was important to prevent a loss of system pressure. A discussion with the molding facility revealed that different polymers have different shrink rates; this determines the amount of shrinkage one can expect from a component after it has been shot out of a mold and allowed to cool. Usually, molds are designed to factor in shrinkage and the mold designer is informed of the type of polymer that will be used. Since the mold was designed for a different polymer, the change to polycarbonate affected the component dimensions. In addition, polycarbonate is a very hard material when compared to polystyrene or polypropylene; the interaction between polycarbonate parts is characterized by a high level of friction and mechanical stress. This makes assembly a lot more problematic. The mold and different parts were analyzed and redesigned to eliminate leaks and manufacturing issues. Byrne Medical Inc currently sells the clear version of this product.

4.4 Product 200250

The 200250 is a specialized tubeset designed by Byrne Medical for Boston Scientific Corporation. Boston Scientific Corporation launched its SpyGlass^{TM} Direct Visualization System on May 18 2007(2). It is an ultra low diameter disposable

endoscope that can be used to examine pancreatic and bile ducts. Conventional scopes can navigate their way to the entrance of these ducts but cannot enter them owing to their comparatively larger diameter. Though procedures can be carried out by inserting catheters through the biopsy channel, visibility is greatly reduced. This new scope, owing to its diminished cross section, enables the doctor to insert it into the biopsy channel of a regular scope and navigate further. This reduces the complexity of diagnostic and treatment procedures.

The 200250 tubeset was designed to be used with the Boston Scientific SpyGlass^{TM} irrigation pump. It works perfectly well with the EGP-100 pump as well. From conception, this tubeset was designed to have a completely clear look and clean feel. To this end clear polycarbonate cap and clear tubing was used. This tubeset does not use luers to connect the pumping section to the rest of the tube but a polycarbonate molded connector. The tubes are glued to the connector using UV cured glue. This increases the time for assembling the product and Byrne Medical is currently working on procedural enhancements on acquiring new equipment to speed up the process. This includes the acquisition of a new UV glue application system which is yet to be validated. The 200250 (Fig. 15) also uses a specialized inline back flow value that is glued to one end of the tubeset. This back flow valve is sourced from Promepla of Monaco.

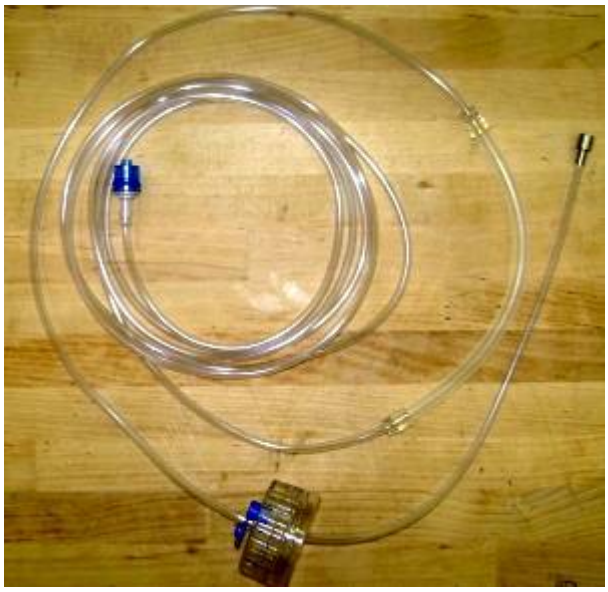

Fig. 15. Product 200250.

Different tubeset materials were tested for strength, flow rate, resistance and opacity for use in the 200250. Once the right tubing material was identified, prototype units were ready to be built. Prototyping hinged on the arrival of the mold to build the polycarbonate tube connector and the back flow from Promepla. The back flow valves, though custom built, had been validated previously. The mold for the connector however had been purchased newly and not been validated.

The mold for the connector was a six cavity mold i.e., could produce six components each and every time it was run. An initial batch of products were made and parts from each cavity were individually tested for dimensional and performance flaws. The connectors met the dimensional requirements and withstood the pressure within the tubeset without leaking.

The 200250 was built like any other product, pouched, sealed and sterilized. Sterilization was carried out using Ethylene Oxide gas. This process involves heating which affects plastic components. The products were retrieved on sterilization and tested in conjunction with a SpyGlass*TM* endoscope and irrigation unit. All the tubesets passed the validation requirements.

ISO requires that manufacturing procedures be maintained for every product being manufactured. It also makes good business sense. Since the 200250 was developed over a number of iterations, with help from staff in the clean room, they were aware, to a certain extent, of the product and what assembling it entailed.

The clean room contains tools and solvents that are accessible to engineers too. To enter the clean room however, one had to wear shoe covers, hair nets and lab coats. While critical operations and investigational efforts were carried out by engineering, it was often easier to instruct the clean room supervisor to have the samples prepared.

Once the product was verified, a manufacturing procedure was required to be in place before the product could be validated. This gave both Byrne Medical and Boston Scientific Corporation traceability information. The procedure lists the process, right from pulling of required components from the warehouse to final acceptance of product load from the sterilizer. Being an intern with little knowledge on the workflow process, the procedure was developed by interviewing different members of the operations facility and tying it all together.

This project was executed in conjunction with management staff form Boston Scientific Corporation. Their management required emails and Gantt charts to track our

progress. Capital equipment was also managed since they had to loan Byrne Medical with pumps and endoscopes. The project required inputs and decisions from both companies.

The initial stage of the project was characterized by design inputs and negotiations on these inputs. Even before a prototype could be made Boston Scientific had arbitrary flow requirements. It became apparent that neither the 200250 nor any other tubeset in the market could meet their specifications. This realization resulted in scaling the flow requirements to more realistic levels.

Boston Scientific needed a large number of tests carried out- like toxicity and package validation – and supplied a long list of detailed requirements. This entailed weekly telephone conference calls with them to discuss and schedule weekly activities. This was an instructive experience in terms of how different teams collaborated to achieve common goals.

5. ENDOGATOR IRRIGATION UNIT

The EndoGator EGP-100 is Byrne Medical's irrigation pumping solution. It is into its second year of production. The company does not try to gain market share by aggressively pushing it. It is recommended to users when their outdated cartridge style pumps need to be replaced. It is also sold to smaller facilities that are moving from a syringe based pumping system to a motorized system. Being a vendor of disposable tubing they were being contacted by such institutions for an irrigation unit which led to the development of the EGP-100 unit (Fig. 16).

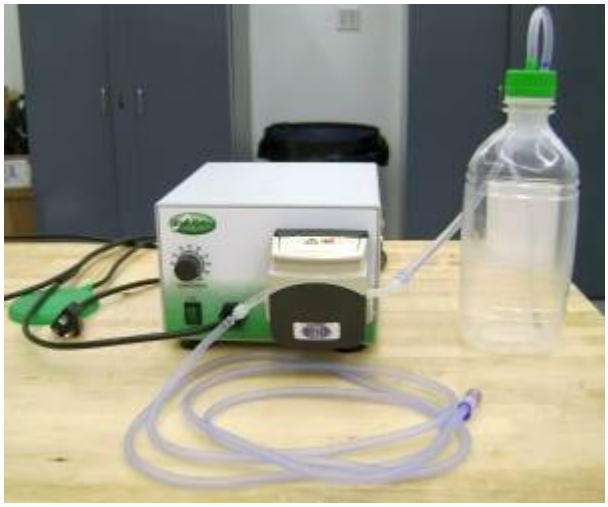

Fig. 16. The EndoGator EGP-100 irrigation unit; shown hooked up to a tubeset.

Bigger players such as Pentax, Olympus and Fujinon sell complete systems that include a processor, display, camera, light source and irrigation unit (list not comprehensive). They are designed to work together with sophisticated control

mechanisms in place. Byrne Medical tubesets can be used with existing irrigation units and the company focuses on cornering the disposable market rather than the peripherals market.

There is however a growing opportunity that Byrne Medical is strategically tapping into. The endoscopy market is dominated by Japanese companies known for their reliable and sturdy optics. There is growing trend towards single use endoscope based systems, according to Chris Adams, heralded by US medical companies. The Boston Scientific SpyGlass^{TM} endoscope is a good example. The optics is completely removable and the rest of the scope is disposable. This philosophy is in stark contrast to the ruggedness that characterizes Japanese endoscopes but is promising nonetheless; it opens up new diagnostic and treatment modalities.

Operating in this burgeoning market, new entrants are looking for proven products that they can license and distribute with their brand name on it. This saves them time and effort and allows them to concentrate on building core system components. Even established companies are looking to Byrne Medical to supply them with complete irrigation solutions that includes tubing, pump and accessories.

5.1 Stryker Version

Stryker Corporation approached Byrne Medical Inc. to supply it with tubesets and irrigation units. While tubesets were easily furnished, the irrigation units needed to be compatible with its processor, the SCU-500. An electrical connection between the processor and the irrigation unit was required that would allow it to activate the unit. The endoscope usually has programmable buttons and different functions can be assigned to

them. Stryker wanted the irrigation unit to be controllable via one of these buttons. The processor acts like a central controller hub, relaying signals to different accessories.

The processor employed a simple relay based circuit that would be used to activate the EGP-100 irrigation unit. A relay is a switching device whose contacts can be opened or closed using an electrical signal. The processor would use its internal circuitry to open or close the contacts on this relay. The EGP-100 needed a way of coupling a triggering signal to these contacts.

The internal controller board on the EGP-100 provided us with just that. It had two terminals with a potential difference of 5V DC (12 Kilo Ohm internal impedance) between them. If the two points were connected, the circuit would be completed and trigger the pump into operation. These terminals were exposed by connecting them to a subminiature phone jack type connection on the back of the pump. A stereo mini cable was used to hook up the SCU-500 processor to this jack. The relay inside the SCU-500 processor completed the circuit and activated the pump when it needed to.

Once the modification was made, the irrigation unit's electrical worthiness had to be certified. The FDA requires medical electrical products to conform to the IEC (International Technical Commission) 60601-1 standard and the UL (Underwriters Laboratories) 60601-1 deviations. This process was subcontracted to a testing and certification agency, ETL SEMKO, located in Dallas, TX. The testers in the facility were explained of the change, since they had certified the first version of the pump. They needed detailed information on how this change would affect safety. They were especially interested in short circuit hazard and fire risk.

Since Stryker Corporation planned to market the products as well, it needed the packages the products were placed in to be validated also. This concerned testing the ability of the packaging to withstand the stresses of storage and transportation. Part of this test was conducted at the operations facility. This involved drop testing and package load testing. One series of tests required vehicular vibration to be simulated. Since Byrne Medical did not posses the required equipment, this was contracted out. The products were performance tested before and after the series of the test. The packaging withstood the tests without causing damage to the products within them.

5.2 Pentax Version

This version was being designed at the time of writing this document. Pentax wanted the EGP-100 to interface with their EPK-i processor. Unlike the Stryker SCU-500, the EPK-i put out two signals to control the irrigation unit. This required adding logic circuitry to the EGP-100 irrigation unit. This would entail additional testing and certification that would delay an immediate product launch. Byrne Medical is currently talking to Pentax engineers to see if they can modify their processor to work with the existing circuitry. Failing this option a new version of the pump would have to be designed.

6. MUSHROOM TOOL

This project involved the design of a tool to be used by assemblers in the clean room. Almost every product made uses a luer taper. A luer taper is a standardized system of plumbing fittings that are used to make leak proof connections (4). There is a male fitting and a corresponding female fitting to which it attaches. The dimensions are standardized and luers are referred to by the assigned numbers, for example a number 25 male luer. There are two varieties of luer tapers; one is known as a luer lock where the two luers link together by threads and the other is a luer slip in which they hold together due to friction. Byrne Medical uses luer locks for its entire product range.

These luer locks have a barb that is inserted into a plastic tube. The luers are able to hold on to the tube due to the friction between the barb and the inner wall of the tube. A luer that is suited for use on a particular tube requires some effort to push the barb end into it. This is made easier by dipping the barb in isopropyl alcohol which as a lubricant. This process is still tedious and causes physical discomfort when repeated over the length of the working day.

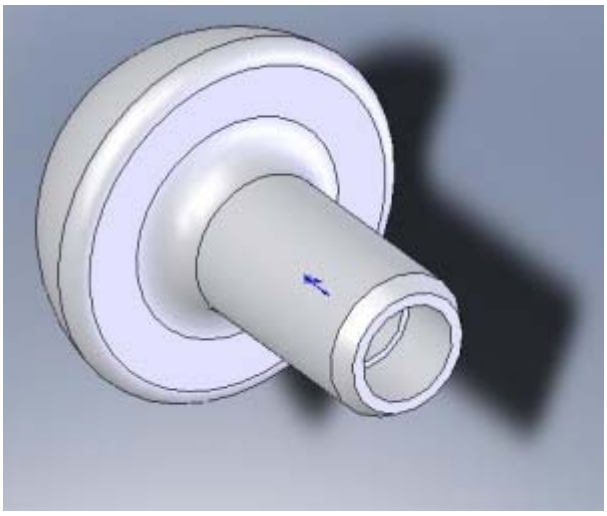

Fig. 17. The mushroom tool.

This tool was devised to help push the barb on the luer into the tube. The name comes from the shape of the tool, which resembles that of a mushroom (Fig. 17). The assemblers hold the hemispherical portion such that its rests comfortably in the cup of their palm. They then use their other hand to load the tool with the compatible luer. Next, they push the barb end of the luer into the appropriate tube. The pressure is evenly distributed onto the palm of the hand. If the tool is not used, the assemblers would have to rely on their fingers to insert the luer.

7. INTERACTING WITH SUPPLIERS AND VENDORS

The engineering department is sought after by vendors of electrical, electronic and pneumatic equipment and accessories. They visit the operations facility, at times unannounced. Sales representatives mail out product catalogs and samples from time to time for engineers to evaluate their products.

The majority of the interaction is with suppliers with whom Byrne Medical buys products from. The representative from Oriental Motors, from where the motor for the EndoGator EGP-100 pump is sourced, is a frequent visitor. During the tenure of my internship he visited thrice. His inquiries pertain to sales levels, inventory, upcoming products and motor performance issues. He also brought in information regarding current industry events and conditions.

Plastic tubing manufacturers visit with samples of their updated product line. Though Byrne Medical Inc. has its own plastic molding facility it does not make its own tubing. Tubing is usually extrusion molded while Byrne Medical limits itself to injection molding. In Extrusion molding, as the name suggests, the melt is extruded or pulled to form linear shapes like tubes. In injection molding, the melt is injected into a mold cavity. Extrusion molding is a much more difficult process to control and since the company is not in the molding business, it does not allocate resources to that area. Thus it looks to suppliers to fill its need for tubing. The company buys PVC tubing of different hardness, depending on intended use. A tubeset is has a 'pumping section' which is the part that is placed in the peristaltic pump. This section is a usually made of

Silicone or PVC and is softer than the rest of the tubing. Its reduced hardness allows it to deform without rupturing inside a peristaltic pump head. This is a fairly standardized component that hasn't been changed across designs. The material for the rest of the tubeset can be changed, with the cost being the overriding factor.

While designing the irrigation pump for the Bovie Cart, a number of suppliers were contacted to source parts for it. Fortunately, the major ones, those who made the plastic housing and sheet metal strut for the pump were existing ones. They made similar components for the EndoGator EGP-100 irrigation pump. Since Byrne Medical already had an business relationship in place, they were readily willing to work on the prototype. Newer suppliers however were not willing to work on small orders that are typical for prototyping. In contrast, others readily supplied us with samples of their products to try out with our prototype. This experience was quite instructive in terms of what norms and expectations existed between suppliers and engineers.

Byrne Medical sources a back flow valve from Promepla, a manufacturer in Monaco, where French is the spoken language. While English is understood, French is the language of choice. Contacting their sales and engineering team by phone and email was an insightful experience, in terms of differences in communication and business values. This product is custom made for Byrne Medical and has been revised a number of times. There is a revised version that is being prototyped at the time of writing this document. Drawings and instructions were passed between Byrne Medical and Promepla's sales and engineering teams. Instructions were translated using an internet based translator, which helped to bridge the language barrier.

A team from Pentax Medical Company visited the operations facility to audit it and negotiate buying Byrne Medical products. As engineering's representative on the team meeting with them, valuable insights were garnered on issues that were relevant to top level management. Agenda setting, decision making and negotiating skill were some prominent aspects.

8. INSIGHTS

8.1 Managing a Company

The first aspect is the regulation and standards that govern the business. Byrne Medical manufactures a class I FDA device and there weren't any FDA inspections during the tenure of the internship. Byrne Medical is ISO (International Organization for Standards) certified and has also obtained the CE marking to sell its product in the European Economic Area (EEA).

Being a manufacturing unit, it is subject to OSHA (Occupational Safety and Health Administration) oversight. There are a number of issues that impact worker safety. Different solvents and adhesives are used by assemblers during the manufacturing process. UV (Ultra Violet) curing, sonic welding, winding and pouching are few of the activities that involve the use of machinery. This creates a lot of potential hazards and requires that employees are trained in their use and supervised accordingly. Byrne Medical conducts regular OSHA mandated seminars to train its staff; during the internship, seminars on handling solvents and blood borne pathogens were conducted.

The operations facility was subject to an audit by an insurance agency that was gearing to provide workers compensation for the company. The facility was also subject to a fire safety inspection. From a management perspective, the logistics of complying with regulations and standards is bewildering.

Coming from an engineering background it became apparent early on that technology was only a small part in running a successful company. While this was a fact

that was known beforehand, the actual importance of different functional groups came into prominence only during the internship. The significance of employee relationships, inventory control, scheduling, demand forecasting, supply chain, quality control, customer service, sales and leadership became apparent during the different scenarios and projects that emerged. As an engineer, one is often susceptible to the notion that a well made product will sell itself. This couldn't be farther from the truth. In many projects, fast turnaround times were called for which was in stark contrast to academic projects. Decisions required balancing competing factors such as cost, material availability, inventory levels, marketability, manufacturing ease, lead times on supplies, safety testing and regulations; the best design didn't solely depend on just scientific criteria. This makes a simple project, from a technical perspective, a challenging one nonetheless.

8.2 Entrepreneurship

Being a company that started out with just four assemblers and now with about seventy employees in three locations, the entrepreneurial drive is visible in most facets of the company. The company has two United States patents to its name. One is for a cap and tubeset that can be attached to a sterile water bottle (1). This patent allows only Byrne Medical to make devices that use a cap, tubeset and sterile water bottle arrangement for the purpose of endoscopic irrigation. Even endoscope manufacturers who make reusable tubesets and bottles cannot market versions to be used with a sterile water bottle. This offers Byrne Medical Inc. very strong market protection from large medical companies and competitors. It also forces them to work with Byrne Medical for

their requirements. Byrne Medical also holds another patent (3) on a cartridge that is used in conjunction with a tubeset on a different style of pump. This pump uses a reusable pumping cartridge which is replaced by the Byrne Medical cartridge and disposable tubeset.

The company, headed by CEO and founder, Donny M. Byrne, is in a state of constant improvement. This is not to say that all decisions made end up with positive outcomes; the company is always setting ambitious goals and ways to innovate. The company almost doubled its sales volume during the current fiscal year with only marginal increase in labor force. The company owns its own molding facility and two CNC machines. This allows prototypes and design changes to be implemented very rapidly. The company is very market savvy. At the time of writing, the company is changing the look of its entire product line. All colored plastic components are being replaced by clear plastic ones to project 'clean' glass like look. This is a marketing decision aimed to distinguish Byrne Medical products from others in the GI room.

The company trains its employees on technical and work related issues to ensure optimal work flow. During the internship two such seminars covering team work and conflict resolution were conducted. Management training classes are provided for administrative staff. The company learns from negative situations and adds to its internal lists of procedures for handling them in the future. Being an intern in a small and fast growing company provided a unique perspective on the industry and also on being successful in it.

9. SUMMARY AND CONCLUSIONS

The internship was a valuable experience in many respects. It firstly presented opportunities for engineering problem solving. This was through numerous design and troubleshooting tasks that came to the attention of the engineering department. Secondly, it was instructive in explaining the place of engineering among various other departments and competing forces within a company. This would not have been possible if Byrne Medical would have been a larger company with a lot more employees. Its size was optimal to allow different issues that would have normally not been handled by an engineer, to be bought to my notice. Such issues were novel and elucidated inner working of a typical organization.

The staff and management of Byrne Medical Inc. were very open and supportive during the course of the internship. I was able to depend on them, on a daily basis, for inputs to complete my projects. I too supported other departments to the best of my abilities. To conclude, this internship did succeed in achieving the targets that were set out at the beginning of the program.

REFERENCES

1. **Byrne, Donny M.** Adapter for the connection of a water bottle to an endoscope [Online]. United States Patent and Trademark Office (USPTO). http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F6210322 [25 September 2007]

2. Boston Scientific Announces Worldwide Launch of Spyglass(TM) Direct Visualization System [Online]. MediLexicon International Ltd. http://www.medicalnewstoday.com/articles/71348.php [25 September 2007]

3. **Byrne, Donny M.** Cartridge to be used with a peristaltic pump [Online]. United States Patent and Trademark Office (USPTO). http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F7074021 [25 September 2007]

4. Luer Taper [Online]. Wikimedia Foundation, Inc. http://en.wikipedia.org/w/index.php?title=Luer_Taper&oldid=147889503 [25 September 2007]

.

VITA

Name:	Vikram Ramakanth
Address:	No:2, Sankarapuram First Street, Annasalai, Palavakkam, Chennai, TN – 600041, India.
Email Address:	vikram_ramakanth@hotmail.com
Education:	B.E., Electrical Engineering, University of Madras, 2002 M.E., Biomedical Engineering, Texas A&M University, 2004